ISBT 128 STANDARD

Standard Terminology for Medical Products of Human Origin

For Use with Product Description Code Database

Version 7.72
January 2024

Tracking Number ICCBBA ST-002

Published by:
ICCBBA
PO Box 11309, San Bernardino, CA 92423-1309 USA

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1 Introduction

This document provides a standard terminology for describing transfusion and transplantation products. It is designed to allow distinction between products where such is required on safety, clinical practice, or inventory management grounds. Although primarily developed to ensure standard labeling of products, the terminology has a wider application in ensuring a common international understanding of specialized terms. Other professional and accreditation bodies have adapted their terminology to be consistent with this document. All references to biologic materials in this document are of human origin unless specifically stated otherwise.

The terminology is under constant review in order to keep pace with clinical developments, and this document is regularly updated.

The underlying structure of the terminology is based on the concepts of Class, Modifiers, and Attributes:

Classes are broad descriptions of products. Examples are RED BLOOD CELLS; HPC, APHERESIS; SKIN, FULL WITH HYPODERMIS; and SOLVENT DETERGENT POOLED PLASMA.

Modifiers are applied to Classes in order to provide the next step in the categorization of the product. Examples are Washed, Thawed, and Deglycerolized. Modifiers do not apply to all product types.

Attributes provide the means to uniquely define the product. For Blood, Cellular Therapy, and Derivative products, there is a mandatory attribute group called Core Conditions which must be explicitly selected.

Core Conditions convey three types of information:

1. anticoagulant and/or additive,
2. nominal collection volume, and
3. storage temperature.

There are also attribute groups which have a default value if not explicitly assigned. These remaining attribute groups are the general categories used to describe detailed characteristics of products. Within each attribute group there are a number of possible values, referred to as variables, of which only one can be selected. For example, “intended use” is a group; “for transfusion” is a variable within that group. Where a product does not have a variable assigned for a particular group, the default variable for that group will apply.

The following sections describe the terminology for each of the families of products supported by ISBT 128: Blood, Tissues, Cellular Therapy, Ocular, Human Milk, Topical Products of Human Origin, Fecal Microbiota, Reproductive, Plasma Derivatives, In Vivo Diagnostic MPHO, Organs, and Regenerated Tissue.

1.1 Use of the Terminology in ISBT 128 Product Description Codes

The ISBT 128 Product Description Code Database, which is maintained and published by ICCBBA, uses product descriptions based on this terminology. It is the responsibility of users of ISBT 128 product codes to check the definitions before using a code to ensure that their product is correctly described within this terminology.

Where a list is specified as bounded then all the permitted values are shown. If a new value is required that is not in the list, then a request needs to be made by submitting an e-mail request to ICCBBA describing the new value required and providing a clear and concise definition.

Unbounded lists, such as those for volume or temperature ranges, are those where example values are given but additional values may exist.

> Note: Many temperature ranges are expressed using the inequalities <= or <. As these are used differently in various normative standards, this has resulted over time in requests for the inclusion of various temperature expressions in, for example, the core condition attributes. To remove the need to have separate core conditions to meet this distinction, it has been determined that for a continuous variable such as temperature the inequalities < and <= are identical for practical purposes (for example, the range <=-30C is considered indistinguishable to <-30C). Consequently, the existence of normative references distinguishing between <= and <, is not considered sufficient justification for the provision of separate core conditions

The default value for each attribute group is the value taken if no attribute value is selected for that group.

Where new characterizations of products become necessary, ICCBBA will assign new attribute groups.

In some cases there will be additional information that may be of value to the administering clinician, but does not need to be encoded. Such information can be included in eye-readable text on the label and/or in the accompanying documentation.

The values presented in this document match the values held in the Product Description Code Database with a corresponding version number. Thus version 7.72 of this document corresponds with database versions 7.72.x.

Each Product Description Code represents a unique combination of Class, Modifier (as applicable), and Attribute values (as applicable). The codes can therefore be used to map to the text descriptions required to describe the product in accordance with individual national requirements.

ICCBBA also maintains a separate database for Clinical Trials PDCs. These products might not utilize ISBT 128 internationally standardized terminology and therefore the product descriptions used for Clinical Trials PDCs are not maintained by ICCBBA. Such product descriptions would be defined by the clinical trials sponsor or manufacturer for which the PDC was assigned. Additional information regarding the Clinical Trials PDCs Database can be found here:

2 Blood

2.1 Class

2.1.1 Bounded List and Definitions

Common Name	ISBT 128 Database Name	Definition
CONVALESCENT PLASMA	CONVALESCENT PLASMA	Plasma collected from a donor who has recovered from a disease. It is collected with the intent of providing passive immunity for other patients and intended for direct transfusion. Unless otherwise specified, the product has been obtained from Whole Blood.
CRYOPRECIPITATE	CRYOPRECIPITATE	A product containing the major portion of Factor VIII and fibrinogen prepared from a unit of Fresh Frozen Plasma.
FIBRINOGEN COMPLEX	FIBRINOGEN COMPLEX	Product prepared from plasma. Contains fibrinogen and other coagulation proteins. The heat-labile coagulation factor(s) may not have been preserved.
FRESH FROZEN PLASMA	FRESH FROZEN PLASMA	Plasma that has been frozen by a process and to a temperature that will maintain the activity of labile protein fractions. Unless otherwise specified the product has been obtained from Whole Blood.
GRANULOCYTES	GRANULOCYTES	A product in which the major cellular component is granulocytes; preparation includes a sedimenting agent. Unless otherwise specified the product has been obtained from Whole Blood.
GRANULOCYTES-PLATELETS	GRANULOCYTES-PLATELETS	A product in which the major cellular components are granulocytes and platelets. Unless otherwise specified the product has been obtained from Whole Blood.
IMMUNE PLASMA	IMMUNE PLASMA	Plasma that meets requirements of, and is intended for, further manufacture into immune globulin products. Unless otherwise specified, the product has been obtained from Whole Blood and frozen.
LEUKOCYTES	LEUKOCYTES	A product in which the major cellular component is leukocytes. Unless otherwise specified the product has been obtained from Whole Blood.
PLASMA	PLASMA	Plasma. Unless otherwise specified the product has been obtained from Whole Blood and frozen.

Common Name	ISBT 128 Database Name	Definition
PLATELET-RICH BUFFY COAT	PLATELET-RICH BUFFY COAT	Buffy-coat prepared by initial hard centrifugation of whole blood for later recovery of the platelets in a second, gentle centrifugation step.
PLATELET-RICH PLASMA	PLATELET-RICH PLASMA	Plasma containing platelets removed from whole blood by a process designed to obtain maximum platelet recovery.
PLATELETS	PLATELETS	A product that contains platelets as the major cellular component. Unless otherwise specified the product has been obtained from Whole Blood.
PLATELET LYSATE	PLATELET LYSATE	A product containing lysed platelets prepared by further processing of a platelet product.
POOLED CONVALESCENT PLASMA	POOLED CONVALESCENT PLASMA	A product prepared by combining two or more single units of Convalescent Plasma into one container.
POOLED CRYOPRECIPITATE	POOLED CRYOPRECIPITATE	A product prepared by combining two or more single units of Cryoprecipitate into one container.
POOLED FIBRINOGEN COMPLEX	POOLED FIBRINOGEN COMPLEX	Product prepared from pooled plasma. Contains fibrinogen and other coagulation proteins. The heat-labile coagulation factor(s) may not have been preserved.
POOLED FRESH FROZEN PLASMA	POOLED FRESH FROZEN PLASMA	Pooled plasma that has been frozen by a process and to a temperature that will maintain the activity of labile protein fractions. Unless otherwise specified the product has been obtained from Whole Blood. When this class is associated with psoralen treatment, the plasma may have been frozen and thawed prior to the psoralen treatment.
POOLED GRANULOCYTES	POOLED GRANULOCYTES	A product prepared by combining two or more single units of Granulocytes into one container.
POOLED LEUKOCYTES	POOLED LEUKOCYTES	A product prepared by combining two or more single units of Leukocytes into one container.
POOLED PLASMA	POOLED PLASMA	A product prepared by combining two or more single units of Plasma into one container. Unless otherwise specified the product has been obtained from Whole Blood and frozen.
POOLED PLATELET-RICH BUFFY-COAT	POOLED PLATELET-RICH BUFFY-COAT	A product prepared by combining two or more single units of Platelet-Rich Buffy-Coat into one container.

Common Name	ISBT 128 Database Name	Definition
POOLED PLATELETS	POOLED PLATELETS	A product prepared by combining two or more single units of Platelets into one container.
POOLED SERUM	POOLED SERUM	A product prepared by combining two or more single units of Serum into one container.
RED BLOOD CELLS	RED BLOOD CELLS	Blood from which most of the plasma has been removed. Unless otherwise specified the product has been obtained from Whole Blood.
SERUM	SERUM	The liquid portion of blood following the completion of the clotting process.
WHOLE BLOOD	WHOLE BLOOD	A unit of blood collected into an anticoagulant and not further processed unless otherwise specified.

2.2 Modifier

2.2.1 Bounded List and Definitions

Common Name	ISBT 128 Database Name	Definition
Apheresis	Apheresis	A blood collection process in which some part of the donation is returned to the donor.
Deglycerolized	Deglycerolized	The removal of glycerol by washing.
Deglycerolized Apheresis	Deglycerolized Apheresis	The removal of glycerol by washing from an apheresis product.
Deglycerolized Rejuvenated	Deglycerolized Rejuvenated	A product in which the cells were rejuvenated (*see* below), glycerol added and then frozen, and subsequently thawed and deglycerolized.
Deglycerolized Rejuvenated Apheresis	Deglycerolized Rejuvenated Apheresis	An apheresis product in which the cells were rejuvenated (*see* below), glycerol added and then frozen, and subsequently thawed and deglycerolized.
Frozen	Frozen	A product maintained in the frozen state after preparation.
Frozen Apheresis	Frozen Apheresis	An apheresis product maintained in the frozen state after preparation.
Frozen Rejuvenated	Frozen Rejuvenated	A product in which the cells were rejuvenated (*see* below), glycerol added and then frozen.
Frozen Rejuvenated Apheresis	Frozen Rejuvenated Apheresis	An apheresis product in which the cells were rejuvenated (*see* below), glycerol added and then frozen.
Liquid	Liquid	A product that has been stored in the liquid state and has not been previously frozen.
Liquid Apheresis	Liquid Apheresis	An apheresis product that has been stored in the liquid state and has not been previously frozen.

Common Name	ISBT 128 Database Name	Definition
Lyophilized	Lyophilized	Preservation in a freeze dried state achieved by freezing followed by sublimation of water under vacuum to very low residual moisture contents.
Lyophilized Apheresis	Lyophilized Apheresis	An apheresis product that is preserved in a freeze dried state achieved by freezing followed by sublimation of water under vacuum to very low residual moisture contents.
Reconstituted	Reconstituted	Restoration of a lyophilized product by the addition of liquid.
Rejuvenated	Rejuvenated	The treatment of Red Blood Cells by a method known to restore 2,3 DPG and ATP to normal levels or above.
Rejuvenated Apheresis	Rejuvenated Apheresis	The treatment of apheresis Red Blood Cells by a method known to restore 2,3 DPG and ATP to normal levels or above.
Thawed	Thawed	A product that is currently in the liquid state but has been previously frozen.
Thawed Apheresis	Thawed Apheresis	An apheresis product that is currently in the liquid state but has been previously frozen.
Washed	Washed	The treatment of a cellular product using a compatible solution to remove most of the plasma proteins.
Washed Apheresis	Washed Apheresis	The treatment of an apheresis cellular product using a compatible solution to remove most of the plasma proteins.
Washed Thawed	Washed Thawed	A product that has been thawed and subsequently washed to remove most of the plasma proteins.
Washed Thawed Apheresis	Washed Thawed Apheresis	An apheresis product that has been thawed and subsequently washed to remove most of the plasma proteins.

2.3 Attribute

2.3.1 Core Conditions

Core Conditions is the term used to describe three pieces of information:

The anticoagulant/additive/cryoprotectant solution
The nominal volume of the original collection excluding anticoagulant
The temperature at which the product should be stored

With the exception of platelet additive solutions, abbreviated names are used in accordance with standard naming conventions for anticoagulants/additives. For the formulations for many of the Red Cell preservative solutions see: Klein, HG and Anstee, DJ: Mollison's Blood Transfusion in Clinical Medicine, 11th edition, Blackwell, 2005, pp 855 et seq.

Platelet additive solution (PAS) names and formulations are as described in the table below. See Appendix A for an explanation on the use of platelet additive solutions terminology.

Table of Platelet Additive Solutions

New Name	Citrate	Phosphate	Acetate	Magnesium	Potassium	Gluconate	Glucose	Alternative Names	Previous ISBT 128 Name
PAS	NS	NS	NS	NS	NS	NS	NS		Not named
PAS-A	X	X			X			PAS (1)	Not named
PAS-B	X		X					PAS II, PAS-2, SSP, T-Sol	PASII
PAS-C	X	X	X					PAS III, PAS-3, Intersol	PASIII
PAS-D	X		X	X	X	X		Composol PS	PAS IIIMgK (note, Composol PS should not have been called PASIIIMgK)
PAS-E	X	X	X	X	X			PAS IIIM, SSP+, *T-PAS+	Not named
PAS-F			X	X	X	X		PlasmaLyte A, Isoplate	Not named
PAS-G	X	X	X	X	X		X		Not named

Source: Ringwald, J., Zimmerman, R., and Eckstein, R: The New Generation of Platelet Additive Solution for Storage at 22°C: Development and Current Experience, Transfusion Medicine Reviews, Vol 20, No 2 (April), 2006: pp 158-164.

*Source: Terumo BCT- Platelet Additive Solution (T-PAS+) 40840, 40841, 40842, 40843 • Solutions Specification Sheet • PN: 777020-246 F

While other ingredients may also be present, the classification is based on citrate, phosphate, acetate, magnesium, potassium, gluconate, and glucose. Other ingredients that differentiate platelet additive solutions may be added as additional products are developed. Request for additional PASs should be submitted to the ICCBBA office.

Specific temperatures are not always given in the description since differing specific temperature ranges must be adhered to within a given country. For example, refg (refrigerated) is used rather than a specific range, such as 1–4 C. When a specific temperature is given it is expressed in degrees Celsius.

2.3.1.1 Core Conditions Lists and Definitions

First Position – Bounded List

Common Name	ISBT 128 Database Name	Definition
0.5 CPD	0.5 CPD	CPD Half-strength
ACD-A	ACD-A	Acid Citrate Dextrose, Formula A
ACD-A>AS1	ACD-A>AS1	Acid Citrate Dextrose, Formula A – Additive Solution 1
ACD-A>AS3	ACD-A>AS3	Acid Citrate Dextrose, Formula A – Additive Solution 3
ACD-A>PAS-B	ACD-A>PAS-B	Acid Citrate Dextrose, Formula A – Platelet Additive Solution B
ACD-A>PAS-C	ACD-A>PAS-C	Acid Citrate Dextrose, Formula A – Platelet Additive Solution C
ACD-A>PAS-D	ACD-A>PAS-D	Acid Citrate Dextrose, Formula A – Platelet Additive Solution D
ACD-A>PAS-E	ACD-A>PAS-E	Acid Citrate Dextrose, Formula A – Platelet Additive Solution E
ACD-A>PAS-F	ACD-A>PAS-F	Acid Citrate Dextrose, Formula A – Platelet Additive Solution F
ACD-A>SAGM	ACD-A>SAGM	Acid Citrate Dextrose, Formula A – Saline-Adenine-Glucose-Mannitol
ACD-A-HES	ACD-A-HES	Acid Citrate Dextrose, Formula A – Hydroxyethyl starch
ACD-B	ACD-B	Acid Citrate Dextrose, Formula B
ACD-B>MAP	ACD-B>MAP	Acid Citrate Dextrose, Formula B – Mannitol-Adenine-Phosphate
AS1	AS1	Additive Solution 1
AS2	AS2	Additive Solution 2
AS3	AS3	Additive Solution 3
AS5	AS5	Additive Solution 5
AS7	AS7	Additive Solution 7
CP2D	CP2D	Citrate Phosphate Double Dextrose
CP2D>AS3	CP2D>AS3	Citrate Phosphate Double Dextrose – Additive Solution 3
CPD-50	CPD-50	Citrate Phosphate Dextrose 50
CPD-50>SAGM	CPD-50>SAGM	Citrate Phosphate Dextrose 50 – Saline-Adenine-Glucose-Mannitol
CPD	CPD	Citrate Phosphate Dextrose
CPD>AS1	CPD>AS1	Citrate Phosphate Dextrose – Additive Solution 1
CPD>AS3	CPD>AS3	Citrate Phosphate Dextrose – Additive Solution 3
CPD>AS5	CPD>AS5	Citrate Phosphate Dextrose – Additive Solution 5
CPD>AS7	CPD>AS7	Citrate Phosphate Dextrose – Additive Solution 7
CPD>MAP	CPD>MAP	Citrate Phosphate Dextrose – Mannitol-Adenine-Phosphate
CPD>PAS-C	CPD>PAS-C	Citrate Phosphate Dextrose – Platelet Additive Solution C
CPD>PAS-D	CPD>PAS-D	Citrate Phosphate Dextrose – Platelet Additive Solution D

Common Name	ISBT 128 Database Name	Definition
CPD>PAS-E	CPD>PAS-E	Citrate Phosphate Dextrose – Platelet Additive Solution E
CPD>SAGM	CPD>SAGM	Citrate Phosphate Dextrose – Saline-Adenine-Glucose-Mannitol
CPDA-1	CPDA-1	Citrate Phosphate Dextrose Adenine, Solution 1
DMSO	DMSO	Dimethylsulfoxide
DMSO>PAS-E	DMSO>PAS-E	Dimethylsulfoxide – Platelet Additive Solution E
17% Glycerol	Gly17%	Glycerol 17%
35% Glycerol	Gly35%	Glycerol 35%
40% Glycerol	Gly40%	Glycerol 40%
Heparin	Heparin	Heparin
MAP	MAP	Mannitol-Adenine-Phosphate
NaCitrate	NaCitrate	Sodium Citrate solution
NaCitrate-Dextran	NaCitrate-Dextran	Sodium Citrate solution – Dextran
NaCitrate-HES	NaCitrate-HES	Sodium Citrate solution – Hydroxyethyl starch
NaCitrate-HES-ACD-A	NaCitrate-HES-ACD-A	Sodium Citrate solution – Hydroxyethyl starch – Acid Citrate Dextrose, Formula A
None	None	No significant amount of anticoagulant or additive is present
Not specified	NS	Not specified
PAGGS-M	PAGGS-M	Phosphate Adenine Guanosine Glucose Saline – Mannitol
SAGM	SAGM	Saline-Adenine-Glucose-Mannitol

Second Position – examples (This list is not bounded, other volumes may be defined).

Common Name	ISBT 128 Database Name	Definition
250 milliliters	250mL	The nominal volume of the original collection excluding anticoagulant is 250 milliliters.
300 milliliters	300mL	The nominal volume of the original collection excluding anticoagulant is 300 milliliters.
350 milliliters	350mL	The nominal volume of the original collection excluding anticoagulant is 350 milliliters.
450 milliliters	450mL	The nominal volume of the original collection excluding anticoagulant is 450 milliliters.
500 milliliters	500mL	The nominal volume of the original collection excluding anticoagulant is 500 milliliters.
XX	XX	“XX” specifies that the original collection volume is not encoded as part of the core conditions. Specific information may be given as additional label text.

Third Position – examples (This list is not bounded, other temperature ranges may be defined).

Common Name	ISBT 128 Database Name	Definition
< 37 C	<37C	Less than 37 degrees Celsius.
20-24 C	20-24C	Between 20 and 24 degrees Celsius; intended for the use in platelet products.
≤ -18 C	<=-18C	Less than or equal to -18 degrees Celsius.

Common Name	ISBT 128 Database Name	Definition
≤ -30 C	<=-30C	Less than or equal to -30 degrees Celsius.
≤ -65 C	<=-65C	Less than or equal to -65 degrees Celsius.
≤ -80 C	<=-80C	Less than or equal to -80 degrees Celsius.
Frozen	Frozen	Frozen (a specific range may be nationally-specified).
Refrigerated	refg	Refrigerated (between 1 to 10 degrees Celsius; narrower range may be nationally specified).
Room temperature	rt	Ambient room temperature (a specific range may be nationally-specified).

2.3.2 Groups and Variables

Any additional manipulation or change to the product from its “core” state is reflected by the addition of one or more attributes from the groups and variables detailed below. Such additional manipulations or changes are indicated by a different Product Description Code.

2.3.2.1 Groups: Bounded List and Definitions

Group Name	Description
Intended Use	Describes the expected use of the product.
System Integrity	Describes the microbiological integrity of the collection/storage system.
Irradiation	Describes any exposure of the product to irradiation to prevent graft versus host disease.
Residual Leukocyte Content	Describes the target residual leukocyte content of the product.
Altered	Describes the adding of and/or removing from a product specified elements.
Final Content	Provides supplementary information on the volume of the final product.
Preparation:Additional Info	Provides supplementary information about the preparation of a product.
Apheresis and Container:Additional Info	Provides additional information related to an apheresis procedure.
Quarantine:Additional Info	Provides information related to the time a product is stored prior to retesting a second sample subsequently collected from the donor.
Dosage:Additional Info	Provides information related to the number of platelets in a platelet product OR the number of units in a pooled product. The number of units in the latter case does not include additional units that do not contribute to the therapeutic dose (e.g., a plasma unit added to dilute a pooled platelet product).
Pathogen Reduction	Provides information about a treatment method used to reduce the possibility of the transmission of disease.
Hematocrit	Specifies the packed cell volume of a Red Blood Cells product.
Monitoring	Provides information on the on-going assessment of the product.

Group Name	Description
Donor Exposure: Additional Information	Provides information related to the number of donors whose products are present in the final product.
Antibody Specificity	Indicates the specificity of the antibody desired for further manufacture.
Infection	Provides information about specific disease history of the donor. The history information may contain information to reflect the quantity of antibody present. This attribute group is to be used with the class CONVALESCENT PLASMA.

2.3.2.2 Variables – Bounded Lists and Definitions

2.3.2.2.1 Intended Use

Common Name	ISBT 128 Database Name	Definition
Default	Default: For transfusion	The product is intended for transfusion.
For further manufacture into injectable product	For mnf: injectable	A product intended for further manufacturing (processing) into a product that is injectable.
For further manufacture into injectable product for source plasma	For mnf: injectable- source	A product collected by apheresis intended for further manufacturing (processing) into a product that is injectable. The plasma was intended for further manufacturing at the time of collection. (Note: This attribute is intended for use within the US where the US FDA requires differentiating the intended use of apheresis plasma at the time of collection.)
For further manufacture into injectable product with restricted use	For mnf: injectable restr use	A product intended for further manufacturing (processing) into a product that is injectable. The use of the product is further restricted by national regulation or guidelines.
For further manufacture into noninjectable product	For mnf: noninjectable	A product that is intended for further manufacturing into a product that is not intended for injection into humans.
For further manufacture into noninjectable product for source plasma	For mnf:noninjectable-source	A product collected by apheresis intended for further manufacturing (processing) into a product that is noninjectable. The plasma was intended for further manufacturing at the time of collection. (Note: This attribute is intended for use within the US where the US FDA requires differentiating the intended use of apheresis plasma at the time of collection.)

Common Name	ISBT 128 Database Name	Definition
For further manufacture into noninjectable product (converted)	For mnf: noninjectable-converted	A product collected by apheresis intended for further manufacturing (processing) into a product that is non-injectable. The plasma was originally intended for transfusion and subsequently the intended use of the plasma was changed. (Note: This attribute is intended for use within the US where the US FDA requires differentiating the intended use of apheresis plasma at the time of collection.)
For further manufacture into noninjectable product with restricted use	For mnf: noninjectable restr use	A product that is intended for further manufacturing into a product that is not intended for injection into humans. The use of the product is further restricted by national regulation or guidelines.
Not for transfusion or further manufacturing	Not for tx or mnf	A product that is not to be used for transfusion/transplantation or further manufacturing into products for human use.

2.3.2.2.2 System Integrity

Common Name	ISBT 128 Database Name	Definition
Default	Default: Closed	The product has been prepared in a closed system and the microbiological integrity of the system has not been compromised.
Open system	Open	The system has been opened and the microbiological integrity may have been compromised.

2.3.2.2.3 Irradiation

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not irradiated	The product has not been exposed to irradiation.
Irradiated	Irradiated	The product has been exposed to irradiation sufficient to prevent the proliferation of lymphocytes upon transfusion; the dose requirement is specified by each national regulatory organization. Information on the time interval between collection and irradiation is not encoded.
Irradiated within 5 days	Irradiated<=5d	Within 5 days of collection the product has been exposed to irradiation sufficient to prevent the proliferation of lymphocytes upon transfusion; the dose requirement is specified by each national regulatory organization.

Common Name	ISBT 128 Database Name	Definition
Irradiated within 14 days	Irradiated<=14d	Within 14 days of collection the product has been exposed to irradiation sufficient to prevent the proliferation of lymphocytes upon transfusion; the dose requirement is specified by each national regulatory organization.
RBC irradiated	RBC irradiated	The Red Blood Cells of a combined or pooled product have been exposed to irradiation sufficient to prevent the proliferation of lymphocytes upon transfusion; the dose requirement is specified by each national regulatory organization. The Plasma of the combined or pooled product may not have been irradiated. This attribute is intended to be used when local/national regulations require indicating that the Red Blood Cells, but not Plasma, have been irradiated.

2.3.2.2.4 Residual Leukocyte Content

Common Name	ISBT 128 Database Name	Definition
Default	Default: No information	No information regarding leukoreduction or final leukocyte concentration is provided.
Residual Leukocyte Content < $1.2x10^9$	ResLeu:<1.2E9	The target residual leukocyte content is less than $1.2x10^9$
Residual Leukocyte Content < $1x10^6$	ResLeu:<1E6	The target residual leukocyte content is less than $1x10^6$
Residual Leukocyte count < $1x10^6$ via Red Blood Cell filter	ResLeu:<1E6,RBC filtr	The target residual leukocyte content of less than $1x10^6$ is achieved by filtration of the red cells following separation from whole blood.
Residual Leukocyte count < $1x10^6$ via whole blood filter	ResLeu:<1E6,WB filtr	The target residual leukocyte content of less than $1x10^6$ is achieved by filtration of the whole blood before separation of components.
Residual Leukocyte Content < $2.5x10^6$	ResLeu:<2.5E6	The target residual leukocyte content is less than $2.5x10^6$
Residual Leukocyte Content < $2x10^5$	ResLeu:<2E5	The target residual leukocyte content is less than $2x10^5$
Residual Leukocyte Content < $3.8x10^6$	ResLeu:<3.8E6	The target residual leukocyte content is less than $3.8x10^6$
Residual Leukocyte Content < $5x10^5$	ResLeu:<5E5	The target residual leukocyte content is less than $5x10^5$

Common Name	ISBT 128 Database Name	Definition
Residual Leukocyte Content < $5x10^6$	ResLeu:<5E6	The target residual leukocyte content is less than $5x10^6$
Residual Leukocyte Content < $5x10^8$	ResLeu:<5E8	The target residual leukocyte content is less than $5x10^8$
Residual Leukocyte Content < $8.3x10^5$	ResLeu:<8.3E5	The target residual leukocyte content is less than $8.3x10^5$
Residual Leukocyte Content Not Specified	ResLeu:NS	A procedure has been used to reduce the leukocyte count of the product but the target count is not specified.
Residual Leukocyte Content Nationally Defined	ResLeu:Nationally defined	The target residual leukocyte content meets nationally defined specifications applicable to the processing facility at the time of production of clinical use products.

2.3.2.2.5 Altered

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not altered	The product has not been altered by the addition or removal of liquid or cells.
Albumin added	Albumin added	Albumin has been added to the blood product.
Buffy coat removed	Buffy coat removed	A blood product from which the buffy coat has been removed.
Complement inactivated	Complement inactivated	The product has been heat treated to inactivate complement.
Cryoprecipitate reduced	Cryo reduced	The amount of cryoprecipitate in the blood product has been reduced from the original amount.
Plasma added	Plasma added	A blood product to which plasma has been added.
Plasma reduced	Plasma reduced	A blood product from which a portion of the plasma has been removed.
Plasma reduced and albumin added	Plasma reduced/Albumin added	A blood product from which a portion of the plasma has been removed, and albumin has been added.
Plasma reduced and plasma added	Plasma reduced/Plasma added	A blood product from which most of the original plasma has been removed and, in a further step, a quantity of plasma has been added to the product.
Plasma reduced and saline added	Plasma reduced/Saline added	A blood product from which most of the original plasma has been removed and in a further step a quantity of saline has been added to the product.
Plasma removed and SAGM added	Plasma removed/SAGM added	A blood product from which, in steps performed after the initial processing of the whole blood product into components, most of the original plasma has been removed and a quantity of SAGM has been added.

Common Name	ISBT 128 Database Name	Definition
Platelets reduced	Plts reduced	The platelets have been reduced from the original amount.
Platelets and Cryoprecipitate reduced	Plts/Cryo reduced	The platelets and cryoprecipitate have been reduced from the original amount.
RBC content reduced	RBC content reduced	A blood product from which most of the red cells have been reduced.
Saline added	Saline added	A blood product to which saline has been added.
Solvent detergent plasma added	SD-Plasma added	A blood product to which solvent detergent plasma has been added.
Supernatant reduced	Supernat reduced	The supernatant additive/anticoagulant or other solution has been reduced from the original amount.
Supernatant removed	Supernat rem	A blood product from which most of the supernatant additive/anticoagulant or other solution has been removed.
Supernatant removed and albumin added	Supernat rem/ Albumin added	A blood product from which most of the supernatant additive/anticoagulant or other solution has been removed and, in a further step, albumin has been added.
Supernatant removed and plasma added	Supernat rem/ Plasma added	A blood product from which most of the supernatant additive/anticoagulant or other solution has been removed and, in a further step, a quantity of plasma has been added to the product.
Supernatant removed and quarantined plasma added	Supernat rem/Q-Plasma added	A blood product from which most of the supernatant additive/anticoagulant or other solution has been removed and, in a further step, a quantity of quarantined plasma has been added to the product.
Supernatant removed and solvent detergent plasma added	Supernat rem/SD-Plasma added	A blood product from which most of the supernatant additive/anticoagulant or other solution has been removed and, in a further step, a quantity of solvent detergent plasma has been added to the product.

2.3.2.2.6 Final Content

Common Name	ISBT 128 Database Name	Definition
Default	Default: Usual nominal volume	The contents are consistent with the expected, usual volume.
1 milliliter	1mL	Approximately 1 milliliter; actual range of volume established by processing facility.
2 milliliters	2mL	Approximately 2 milliliters; actual range of volume established by processing facility.
5 milliliters	5mL	Approximately 5 milliliters; actual range of volume established by processing facility.
25 milliliters	25mL	Approximately 25 milliliters; actual range of volume established by processing facility.

Common Name	ISBT 128 Database Name	Definition
50 milliliters	50mL	Approximately 50 milliliters; actual range of volume established by processing facility.
150 milliliters	150mL	Approximately 150 milliliters; actual range of volume established by processing facility.
< 125 milliliters	<125 mL	The volume of the blood product is less than 125 milliliters.
< 200 milliliters	<200 mL	The volume of the blood product is less than 200 milliliters.
≥ 200 milliliters and < 400 milliliters	>=200mL<400mL	The volume of the blood product is greater than or equal to 200 milliliters and is less than 400 milliliters.
≥ 400 milliliters and < 600 milliliters	>=400mL<600mL	The volume of the blood product is greater than or equal to 400 milliliters and is less than 600 milliliters.
≥ 600 milliliters	>=600mL	The volume of the blood product is greater than or equal to 600 milliliters.
≥ 800 milliliters	>=800mL	The volume of the blood product is greater than or equal to 800 milliliters.
Final Content not specified	Fin Con:NS	No information is provided regarding the final content.
Low volume, anticoagulant volume adjusted	LowVol:anticoag adj	The volume of the product is less than the expected volume and the volume of the anticoagulant into which the original collection was made was adjusted to compensate.
Low volume, anticoagulant volume not adjusted	LowVol:anticoag not adj	The volume of the product is less than the expected volume and the volume of the anticoagulant into which the original collection was made was not adjusted to compensate.

2.3.2.2.7 Preparation:Additional Info

Common Name	ISBT 128 Database Name	Definition
Default	Default: Prep: No additional info	There is no additional information about the preparation of the product.
Cryoprecipitated	Cryoprecipitated	The plasma has undergone rapid freezing followed by slow thawing to produce a cryoprecipitate.
Platelets prepared from buffy-coat	Buffy coat plts prep	The platelets were prepared from the buffy-coat following centrifugation.
Frozen in ≤ 2 hours	Frozen <=2h	The plasma was placed in the freezer within 2 hours or less from the time it was collected in a system that assured complete freezing within one hour to a temperature of <= -30 Celsius.
Frozen in ≤ 6 hours	Frozen <=6h	The plasma was placed in the freezer within 6 hours or less from the time it was collected in a system that assured complete freezing within one hour to a temperature of <= -30 Celsius.

Common Name	ISBT 128 Database Name	Definition
Frozen in ≤ 8 hours	Frozen <=8h	The plasma was placed in the freezer within 8 hours or less from the time it was collected in a system that assured complete freezing within one hour to a temperature of <= -30 Celsius.
Frozen in ≤ 15 hours	Frozen <=15h	The plasma was placed in the freezer within 15 hours or less from the time of collection.
Frozen in ≤ 18 hours	Frozen <=18h	The plasma was placed in the freezer within 18 hours or less from the time of collection in a system that assured complete freezing within one hour to a temperature of <= -30 Celsius.
Frozen in ≤ 24 hours	Frozen <=24h	The plasma was placed in the freezer within 24 hours or less from the time of collection.
Frozen in ≤ 26 hours	Frozen <=26h	The plasma was placed in the freezer within 26 hours or less from the time of collection.
Frozen in > 24 hours	Frozen >24h	The plasma was placed in the freezer more than 24 hours after the time of collection.
Frozen in ≤ 48 hours	Frozen <=48h	The plasma was placed in the freezer within 48 hours or less from the time of collection.
Frozen in ≤ 72 hours	Frozen <=72h	The plasma was placed in the freezer within 72 hours or less from the time of collection.
Frozen in ≤ 120 hours	Frozen <=120h	The plasma was placed in the freezer within 120 hours or less from the time of collection.
Granulocytes prepared using hydroxyethyl starch	Granulocytes prep: HES	Hydroxyethyl starch was used as the sedimenting agent in the laboratory preparation of the product.
Held at room temperature and Refrigerated in ≤ 24hr	RT<=24h refg	Held for up to 24 hours at room temperature prior to refrigeration.
Held at room temperature and frozen in ≤24 hours	RT<=24h frozen<=24h	Held for up to 24 hours at room temperature and subsequently placed in freezer within 24 hours from time of collection.
Oxygen and carbon dioxide reduced	O2/CO2 reduced	Product in which the levels of oxygen and carbon dioxide have been reduced to a controlled range. See accompanying documentation (or product insert) for details.
Multiple wash cycles	Multiple wash cycles	Multiple wash cycles were performed.

2.3.2.2.8 Apheresis and Container:Additional Info

Common Name	ISBT 128 Database Name	Definition
Default	Default: Aphr:No additional info	No additional information related to the apheresis procedure used or the number of containers harvested is given.

Common Name	ISBT 128 Database Name	Definition
1st container	1st container	The first of two or more containers prepared during a single apheresis procedure.
1st container: not automated	1st container: not auto	The first of two containers prepared from a single non-automated apheresis procedure.
2nd container	2nd container	The second of two or more containers prepared during a single apheresis procedure.
2nd container: not automated	2nd container: not auto	The second of two containers prepared from a single non-automated apheresis procedure.
3rd container	3rd container	The third of three or more containers prepared during a single apheresis procedure.
4th container	4th container	The fourth of four or more containers prepared during a single apheresis procedure.
5th container	5th container	The fifth of five or more containers prepared during a single apheresis procedure.
6th container	6th container	The sixth of six or more containers prepared during a single apheresis procedure.
7th container	7th container	The seventh of seven or more containers prepared during a single apheresis procedure.
8th container	8th container	The eighth of eight or more containers prepared during a single apheresis procedure.
Apheresis not automated	Aphr not automated	The apheresis procedure used was a manual method.

2.3.2.2.9 Quarantine:Additional Info

Common Name	ISBT 128 Database Name	Definition
Default	Default: Quar: No additional info	No information related to a quarantine period prior to release is given.
Nationally defined	Quar: nationally defined	The product was stored for a period (nationally determined), after which a new sample from the donor was retested.
Quarantined: ≥ 62days and retested	Quar: >=62d/retested	The product was stored for not less than 62 days, after which a new sample from the donor was retested.
Quarantined: ≥ 90 days and retested	Quar: >=90d/retested	The product was stored for not less than 90 days, after which a new sample from the donor was retested.
Quarantined: ≥ 112 days and retested	Quar: >=112d/retested	The product was stored for not less than 112 days, after which a new sample from the donor was retested.
Quarantined: ≥ 4 months and retested	Quar: >=4m/retested	The product was stored for not less than 4 months, after which a new sample from the donor was retested.

Common Name	ISBT 128 Database Name	Definition
Quarantined: ≥ 6 months and retested	Quar: >=6m/retested	The product was stored for not less than 6 months, after which a new sample from the donor was retested.

2.3.2.2.10 Dosage:Additional Info

Common Name	ISBT 128 Database Name	Definition
Default	Default: Dosage:No additional info	No information related to dosage is provided.
Approximately 120 x 10^9 platelets	Approx 120 E9 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
Approximately 150 x 10^9 platelets	Approx 150 E9 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
Approximately 180 x 10^9 platelets	Approx 180 E9 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
Approximately 240 x 10^9 platelets	Approx 240 E9 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
Approximately 300 x 10^9 platelets	Approx 300 E9 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
Approximately 360 x 10^9 platelets	Approx 360 E9 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
Approximately 420 x 10^9 platelets	Approx 420 E9 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
Approximately 480 x 10^9 platelets	Approx 480 E9 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
Approximately 540 x 10^9 platelets	Approx 540 E9 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
< 3 x 10^{11} platelets	<3 E11 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
2.0 – 4.0 x 10^{12} platelets	2.0-4.0 E12 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
3.0 – 4.7 x 10^{11} platelets	3.0-4.7 E11 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
4.8 – 5.9 x 10^{11} platelets	4.8-5.9 E11 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
> 6.0 x 10^{11} platelets	>6.0 E11 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)

Common Name	ISBT 128 Database Name	Definition
2 units	2 units	Pool prepared from 2 whole blood derived units or their apheresis equivalent.*
3 units	3 units	Pool prepared from 3 whole blood derived units or their apheresis equivalent.*
4 units	4 units	Pool prepared from 4 whole blood derived units or their apheresis equivalent.*
5 units	5 units	Pool prepared from 5 whole blood derived units or their apheresis equivalent.*
6 units	6 units	Pool prepared from 6 whole blood derived units or their apheresis equivalent.*
7 units	7 units	Pool prepared from 7 whole blood derived units or their apheresis equivalent.*
8 units	8 units	Pool prepared from 8 whole blood derived units or their apheresis equivalent.*
9 units	9 units	Pool prepared from 9 whole blood derived units or their apheresis equivalent.*
10 units	10 units	Pool prepared from 10 whole blood derived units or their apheresis equivalent.*
11 units	11 units	Pool prepared from 11 whole blood derived units or their apheresis equivalent.*
12 units	12 units	Pool prepared from 12 whole blood derived units or their apheresis equivalent.*
Pediatric dose	Pediatric dose	A pediatric dose as defined by the issuing facility, which may be based on national guidelines. Platelet count may be indicated on the label in text or in accompanying documentation.

** Prior to July 2012 this attribute was defined as 'Pool prepared from donations from X donors.' This definition may have been interpreted differently by different facilities to mean number of donor units or the number of donor exposures. The definition was changed to remove ambiguity.*

2.3.2.2.11 Pathogen Reduction

Common Name	ISBT 128 Database Name	Definition
Default	Default: No treatment	No treatment method was used.
Heat-treated	Heat-treated	The blood product has been subjected to a validated heat-treatment method known to reduce the risk of disease transmission.
Methylene blue-treated	Methylene blue-treated	The blood product has been subjected to a validated methylene blue-treatment method known to reduce the risk of disease transmission.
Pathogen reduced but method not specified	Pathogen reduced: Method NS	The blood product has been subjected to a process known to reduce the risk of disease transmission. Details of the method used are not encoded. See accompanying documentation for details.

Common Name	ISBT 128 Database Name	Definition
Psoralen-treated	Psoralen-treated	The blood product has been subjected to a validated psoralen-treatment method known to reduce the risk of disease transmission.
Riboflavin-treated	Riboflavin-treated	The blood product has been subjected to a validated riboflavin treatment process known to reduce the risk of disease transmission.
Sterile filtered	Sterile filtered	The blood product has been subjected to a validated filtration process known to reduce the risk of disease transmission.

2.3.2.2.12 Hematocrit Group

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	The packed cell volume is not specified.
Hematocrit 40% - 50%	Hct 0.4-0.5	The packed cell volume of the product is between 40 and 50 percent.
Hematocrit 50% - 55%	Hct 0.50-0.55	The packed cell volume of the product is between 50 and 55 percent.
Hematocrit 50% - 60%	Hct 0.5-0.6	The packed cell volume of the product is between 50 and 60 percent.
Hematocrit 50% - 70%	Hct 0.5-0.7	The packed cell volume of the product is between 50 and 70 percent.
Hematocrit 55% - 75%	Hct 0.55-0.75	The packed cell volume of the product is between 55 and 75 percent.
Hematocrit 60% - 85%	Hct 0.60-0.85	The packed cell volume of the product is between 60 and 85 percent.
Hematocrit > 70%	Hct >0.7	The packed cell volume of the product is greater than 70 percent.
Hematocrit 70% - 80%	Hct 0.7-0.8	The packed cell volume of the product is between 70 and 80 percent.
Hematocrit 70% - 85%	Hct 0.70-0.85	The packed cell volume of the product is between 70 and 85 percent.
Hematocrit 75% to 90%	Hct 0.75-0.9	The packed cell volume of the product is between 75 and 90 percent.

2.3.2.2.13 Monitoring

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	No monitoring is specified.
Bacterial monitoring	Bacterial monitoring	A product subjected to on-going bacterial monitoring meeting national specifications for extension of the expiry date.
Bacterial monitoring >=24 hours	Bacterial monitoring >=24h	A product subjected to on-going bacterial monitoring from a sample taken at least 24 hours after collection. Testing methodology not

Common Name	ISBT 128 Database Name	Definition
		specified in coding. See accompanying documentation for details.
Bacterial monitoring >=36 hours	Bacterial monitoring >=36h	A product subjected to on-going bacterial monitoring from a sample taken at least 36 hours after collection. Testing methodology not specified in coding. See accompanying documentation for details.
Bacterial test	Bacterial test	Tested with a point-in-time test that meets national specifications for extension of expiry date.
Bacterial test day 4	Bacterial test D4	The unit was bacterially tested on a sample taken 4 days after collection. Testing methodology not specified in coding. See accompanying documentation for details.
Bacterial test day 5	Bacterial test D5	The unit was bacterially tested on a sample taken 5 days after collection. Testing methodology not specified in coding. See accompanying documentation for details.
Bacterial test day 6	Bacterial test D6	The unit was bacterially tested on a sample taken 6 days after collection. Testing methodology not specified in coding. See accompanying documentation for details.
Bacterial test day 7	Bacterial test D7	The unit was bacterially tested on a sample taken 7 days after collection. Testing methodology not specified in coding. See accompanying documentation for details.

2.3.2.2.14 Donor Exposure: Additional Information Group

Common Name	ISBT 128 Database Name	Definition
Default	Default: No information	No information is provided.
From Multiple Donors, number not specified	From multiple donors, number not specified	Pool prepared from products from multiple donors. The number of donors is not specified. Specific information may be given as additional label text.
From 2 donors	From 2 donors	Pool prepared from products from 2 donors.
From 3 donors	From 3 donors	Pool prepared from products from 3 donors.
From 4 donors	From 4 donors	Pool prepared from products from 4 donors.
From 5 donors	From 5 donors	Pool prepared from products from 5 donors.
From 6 donors	From 6 donors	Pool prepared from products from 6 donors.
From 8 donors	From 8 donors	Pool prepared from products from 8 donors.
From 10 donors	From 10 donors	Pool prepared from products from 10 donors.

2.3.2.2.15 Antibody Specificity

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not applicable	The product is not Immune Plasma so this attribute does not apply.
Anthrax	Anthrax	Anthrax antibody is present at a concentration suitable for Anthrax hyperimmune globulin manufacture.
CMV	CMV	CMV antibody is present at a concentration suitable for CMV hyperimmune globulin manufacture.
Hepatitis A	Hepatitis A	Hepatitis A antibody is present at a concentration suitable for Hepatitis A hyperimmune globulin manufacture.
Hepatitis B	Hepatitis B	Hepatitis B antibody is present at a concentration suitable for Hepatitis B hyperimmune globulin manufacture.
Not specified	Not specified	The specificity of the antibodies is not specified in the coding.
Rabies	Rabies	Rabies antibody is present at a concentration suitable for Rabies hyperimmune globulin manufacture.
RHD	RHD	RhD antibody is present at a concentration suitable for RhD hyperimmune globulin manufacture.
SARS-CoV-2	SARS-CoV-2	SARS-CoV-2 antibody is present at a concentration suitable for SARS-CoV-2 hyperimmune globulin manufacture.
Tetanus	Tetanus	Tetanus antibody is present at a concentration suitable for Tetanus hyperimmune globulin manufacture.
Varicella zoster	Varicella zoster	Zoster antibody is present at a concentration suitable for Zoster hyperimmune globulin manufacture.

2.3.2.2.16 Infection

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not applicable	The product is not CONVALESCENT PLASMA so this attribute does not apply.
COVID-19	COVID-19	The donor has a history of COVID-19 infection.
COVID-19 high titer	COVID-19 high titer	The donor has a history of COVID-19 infection and has high titer antibodies to SARS-CoV-2, as specified by national regulation or other specification.
COVID-19 low titer	COVID-19 low titer	The donor has a history of COVID-19 infection and has low titer antibodies to SARS-CoV-2, as specified by national regulation or other specification.
Ebola	Ebola	The donor has a history of infection with Ebola virus.
Infection not specified	Infection NS	The donor has evidence of infection with an unspecified infectious agent. See accompanying documentation for details.

3 Cellular Therapy

3.1 Class

With a few exceptions, Class names are in the format type of cells, comma, source of cells.

3.1.1 Subcategories of Classes

Cellular therapy products are divided into two class name subcategories.

Subcategory 1:
At collection the product code will describe the composition of the cell therapy products. It can be HPC, NC, or MNC. These products may be collected for direct infusion without further manipulation, or may be further processed into other cellular therapy classes. If they are HPCs they would retain the class name if they are used as a source of hematopoietic progenitor cells. If these products undergo modification such as cryopreservation and thawing, the class will not change but the modification is added into the product description as an attribute.

Subcategory 2:
After enumeration or manufacture/processing of the collected products, the product is identified by the target cell population.

3.1.2 Bounded Lists and Definitions

Common Name	ISBT 128 Database Name	Definition
Subcategory 1		
CONCURRENT PLASMA, APHERESIS	CONCURRENT PLASMA, APHERESIS	Plasma collected from the donor as part of an apheresis cell collection procedure.
HPC, APHERESIS	HPC, APHERESIS	A cell product containing hematopoietic progenitor cells obtained by apheresis.
HPC, CORD BLOOD	HPC, CORD BLOOD	A cell product containing hematopoietic progenitor cells obtained from cord blood.
HPC, MARROW	HPC, MARROW	A cell product containing hematopoietic progenitor cells obtained from bone marrow.
HPC, WHOLE BLOOD	HPC, WHOLE BLOOD	A cell product containing hematopoietic progenitor cells obtained from whole blood.
MNC, APHERESIS	MNC, APHERESIS	A cell product containing mononuclear cells obtained by apheresis.

Common Name	ISBT 128 Database Name	Definition
NC, CORD BLOOD	NC, CORD BLOOD	A cell product containing nucleated cells obtained from cord blood.
NC, DECIDUA	NC, DECIDUA	A cell product containing nucleated cells obtained from the decidua.
NC, FLUID	NC, FLUID	A cell product containing nucleated cells obtained from fluid.
NC, MARROW	NC, MARROW	A cell product containing nucleated cells obtained from bone marrow.
NC, MENSTRUAL BLOOD	NC, MENSTRUAL BLOOD	A cell product containing nucleated cells obtained from menstrual blood.
NC, WHOLE BLOOD	NC, WHOLE BLOOD	A cell product containing nucleated cells obtained from whole blood.
Subcategory 2		
B CELLS, APHERESIS	B CELLS, APHERESIS	A cell product containing B cells obtained by apheresis.
CARDIAC STEM CELLS	CARDIAC STEM CELLS	A cell product containing stem cells derived from the heart.
CHONDROCYTES, CARTILAGE	CHONDROCYTES, CARTILAGE	A cell product containing chondrocytes obtained from cartilage.
DC, APHERESIS	DC, APHERESIS	A cell product containing dendritic cells obtained by apheresis.
DC, CORD BLOOD	DC, CORD BLOOD	A cell product containing dendritic cells obtained from cord blood.
DC, MARROW	DC, MARROW	A cell product containing dendritic cells obtained from bone marrow.
DC, WHOLE BLOOD	DC, WHOLE BLOOD	A cell product containing dendritic cells obtained from whole blood.
DUAL CELL FUSION	DUAL CELL FUSION	A cell product containing cell fusions formed from two cell populations. The constituent cells are identified in accompanying documentation and may be electronically identified using an ISBT 128 data structure.
EPITHELIAL CELLS, ORAL MUCOSA	EPITHELIAL CELLS, ORAL MUCOSA	A cell product containing epithelial cells obtained from the oral mucosa
EPITHELIAL CELLS, URINARY BLADDER	EPITHELIAL CELLS, URINARY BLADDER	A cell product containing epithelial cells obtained from the urinary bladder
FIBROBLASTS, SKIN	FIBROBLASTS, SKIN	A cell product containing fibroblasts obtained from skin.

Common Name	ISBT 128 Database Name	Definition
HEPATOCYTES, LIVER	HEPATOCYTES, LIVER	A cell product containing hepatocytes obtained from the liver.
INVESTIGATIONAL PRODUCT	INVESTIGATIONAL PRODUCT	A product for an investigational study that is accompanied by appropriate identifying study information. This class may be used for a specific product that may be part of a blinded comparison study. Products labeled as Investigational Product may include different doses or may include an active product or a placebo.
iPSC, CORD BLOOD	iPSC, CORD BLOOD	A cell product containing induced pluripotent stem (iPS) cells obtained from cord blood.
iPSC, SKIN	iPSC, SKIN	A cell product containing induced pluripotent stem (iPS) cells obtained from skin.
iPSC, WHOLE BLOOD	iPSC, WHOLE BLOOD	A cell product containing induced pluripotent stem (iPS) cells obtained from whole blood.
KERATINOCYTES, SKIN	KERATINOCYTES, SKIN	A cell product containing keratinocytes obtained from skin.
MALIGNANT CELLS, APHERESIS	MALIGNANT CELLS, APHERESIS	A cell product containing malignant cells obtained by apheresis.
MALIGNANT CELLS, FLUID	MALIGNANT CELLS, FLUID	A cell product containing malignant cells obtained from fluid.
MALIGNANT CELLS, MARROW	MALIGNANT CELLS, MARROW	A cell product containing malignant cells obtained from marrow.
MALIGNANT CELLS, TUMOR	MALIGNANT CELLS, TUMOR	A product containing, or derived from, malignant cells obtained from a tumor.
MALIGNANT CELLS, WHOLE BLOOD	MALIGNANT CELLS, WHOLE BLOOD	A cell product containing malignant cells obtained from whole blood.
MELANOCYTES, SKIN	MELANOCYTES, SKIN	A cell product containing melanocytes obtained from skin
MNC, CORD BLOOD	MNC, CORD BLOOD	A cell product containing mononuclear cells obtained from cord blood.

Common Name	ISBT 128 Database Name	Definition
MNC, UMBILICAL CORD TISSUE	MNC, UMBILICAL CORD TISSUE	A cell product containing mononuclear cells derived from umbilical cord tissue.
MNC, WHOLE BLOOD	MNC, WHOLE BLOOD	A cell product containing mononuclear cells obtained from whole blood.
MSC, ADIPOSE TISSUE	MSC, ADIPOSE TISSUE	A cell product containing mesenchymal stromal cells derived from adipose tissue
MSC, AMNIOTIC MEMBRANE	MSC, AMNIOTIC MEMBRANE	A cell product containing mesenchymal stromal cells derived from amniotic membrane.
MSC, CORD BLOOD	MSC, CORD BLOOD	A cell product containing mesenchymal stromal cells derived from cord blood.
MSC, DECIDUA	MSC, DECIDUA	A cell product containing mesenchymal stromal cells derived from decidua.
MSC, DENTAL PULP	MSC, DENTAL PULP	A cell product containing mesenchymal stromal cells derived from dental pulp.
MSC, FETAL LIVER	MSC, FETAL LIVER	A cell product containing mesenchymal stromal cells derived from fetal liver.
MSC, MARROW	MSC, MARROW	A cell product containing mesenchymal stromal cells derived from bone marrow.
MSC, PLACENTA	MSC, PLACENTA	A cell product containing mesenchymal stromal cells derived from placenta.
MSC, UMBILICAL CORD	MSC, UMBILICAL CORD	A cell product containing mesenchymal stromal cells derived from umbilical cord.
MSC, WHARTON'S JELLY	MSC, WHARTON'S JELLY	A cell product containing mesenchymal stromal cells derived from Wharton's jelly.
NC, ADIPOSE TISSUE	NC, ADIPOSE TISSUE	A cell product containing nucleated cells obtained from adipose tissue.
NC, PLACENTA	NC, PLACENTA	A cell product containing nucleated cells obtained from placenta.
NC, UMBILICAL CORD	NC, UMBILICAL CORD	A cell product containing nucleated cells obtained from umbilical cord.
NC, UMBILICAL CORD VESSEL	NC, UMBILICAL CORD VESSEL	A cell product containing nucleated cells obtained from umbilical vessels.

Common Name	ISBT 128 Database Name	Definition
NK CELLS, APHERESIS	NK CELLS, APHERESIS	A cell product containing natural killer cells obtained by apheresis.
NK CELLS, CORD BLOOD	NK CELLS, CORD BLOOD	A cell product containing natural killer cells obtained from cord blood.
NK CELLS, MARROW	NK CELLS, MARROW	A cell product containing natural killer cells obtained from bone marrow.
NK CELLS, WHOLE BLOOD	NK CELLS, WHOLE BLOOD	A cell product containing natural killer cells obtained from whole blood.
OLFACTORY ENSHEATHING CELLS, OLFACTORY BULB	OLFACTORY ENSHEATHING CELLS, OLFACTORY BULB	A cell product containing olfactory ensheathing cells derived from the olfactory bulb.
PANCREATIC ISLETS	PANCREATIC ISLETS	Isolated pancreatic islets.
PANCREATIC ISLET RINSE SOLUTION	PANCREATIC ISLET RINSE SOLUTION	Solution used to flush lines and containers during Pancreatic Islet processing. May contain Islets/cells. Solution will always accompany a concurrently prepared Pancreatic Islet product.
SCHWANN CELLS, PERIPHERAL NERVE	SCHWANN CELLS, PERIPHERAL NERVE	A cell product containing Schwann cells obtained from peripheral nerve.
T CELLS, APHERESIS	T CELLS, APHERESIS	A cell product containing T cells obtained by apheresis.
T CELLS, CORD BLOOD	T CELLS, CORD BLOOD	A cell product containing T cells obtained from cord blood.
T CELLS, FLUID	T CELLS, FLUID	A cell product containing T cells obtained from fluid.
T CELLS, LYMPH NODE	T CELLS, LYMPH NODE	A cell product containing T cells obtained from a lymph node.
T CELLS, MARROW	T CELLS, MARROW	A cell product containing T cells obtained from bone marrow.
T CELLS, TUMOR	T CELLS, TUMOR	A cell product containing T cells obtained from a tumor.
T CELLS, WHOLE BLOOD	T CELLS, WHOLE BLOOD	A cell product containing T cells obtained from whole blood.

3.1.3 Abbreviations

Abbreviations are sometimes needed in documents (published papers, SOPs, etc.). The following abbreviations may be used for this purpose. In some countries, regulations may permit the use of abbreviations on partial labels when space does not permit the use of a full name. Users should consult national regulations for further information. If abbreviations are used on the label, the accompanying documentation must include the full name of the product.

No spaces should be present before the parentheses in these abbreviations. This will prevent separation of “HPC” from the parenthetical information when the abbreviation appears at the end of a printed line.

Type of Cell	Source	ISBT 128 Class Name	Abbreviation
N/A	Apheresis	CONCURRENT PLASMA, APHERESIS	CP(A)
Dendritic Cells	Apheresis	DC, APHERESIS	DC(A)
Dendritic Cells	Cord Blood	DC, CORD BLOOD	DC(CB)
Dendritic Cells	Marrow	DC, MARROW	DC(M)
Dendritic Cells	Whole Blood	DC, WHOLE BLOOD	DC(WB)
Hematopoietic Progenitor Cells	Apheresis	HPC, APHERESIS	HPC(A)
Hematopoietic Progenitor Cells	Cord Blood	HPC, CORD BLOOD	HPC(CB)
Hematopoietic Progenitor Cells	Marrow	HPC, MARROW	HPC(M)
Hematopoietic Progenitor Cells	Whole Blood	HPC, WHOLE BLOOD	HPC(WB)
N/A	N/A	INVESTIGATIONAL PRODUCT	INV PROD
Malignant Cells	Apheresis	MALIGNANT CELLS, APHERESIS	MALIG(A)
Malignant Cells	Marrow	MALIGNANT CELLS, MARROW	MALIG(M)
Malignant Cells	Tumor	MALIGNANT CELLS, TUMOR	MALIG(TM)
Malignant Cells	Whole Blood	MALIGNANT CELLS, WHOLE BLOOD	MALIG(WB)
Mononuclear Cells	Apheresis	MNC, APHERESIS	MNC(A)
Mononuclear Cells	Cord Blood	MNC, CORD BLOOD	MNC(CB)
Mononuclear Cells	Umbilical Cord Tissue	MNC, UMBILICAL CORD TISSUE	MNC(UCT)

Type of Cell	Source	ISBT 128 Class Name	Abbreviation
Mononuclear Cells	Whole Blood	MNC, WHOLE BLOOD	MNC(WB)
Mesenchymal Stromal Cells	Adipose Tissue	MSC, ADIPOSE TISSUE	MSC(AT)
Mesenchymal Stromal Cells	Cord Blood	MSC, CORD BLOOD	MSC(CB)
Mesenchymal Stromal Cells	Decidua	MSC, DECIDUA	MSC(DCD)
Mesenchymal Stromal Cells	Dental Pulp	MSC, DENTAL PULP	MSC(DP)
Mesenchymal Stromal Cells	Marrow	MSC, MARROW	MSC(M)
Mesenchymal Stromal Cells	Wharton's Jelly	MSC, WHARTON'S JELLY	MSC(WJ)
Nucleated Cells	Adipose Tissue	NC, ADIPOSE TISSUE	NC(AT)
Nucleated Cells	Cord Blood	NC, CORD BLOOD	NC(CB)
Nucleated Cells	Marrow	NC, MARROW	NC(M)
Nucleated Cells	Menstrual Blood	NC, MENSTRUAL BLOOD	NC(MB)
Nucleated Cells	Whole Blood	NC, WHOLE BLOOD	NC(WB)
Natural Killer Cells	Apheresis	NK CELLS, APHERESIS	NK(A)
Natural Killer Cells	Cord Blood	NK CELLS, CORD BLOOD	NK(CB)
Natural Killer Cells	Marrow	NK CELLS, MARROW	NK(M)
Natural Killer Cells	Whole Blood	NK CELLS, WHOLE BLOOD	NK(WB)
T Cells	Apheresis	T CELLS, APHERESIS	T CELLS(A)
T Cells	Cord Blood	T CELLS, CORD BLOOD	T CELLS(CB)
T Cells	Marrow	T CELLS, MARROW	T CELLS(M)
T Cells	Tumor	T CELLS, TUMOR	T CELLS(TM)
T Cells	Whole Blood	T CELLS, WHOLE BLOOD	T CELLS(WB)

3.2 Attribute

3.2.1 Core Conditions

Core Conditions is the term used to describe three pieces of information:

1. The anticoagulant
   "None" specifies that no significant amount of anticoagulant is present.
   "NS" indicates that the anticoagulant is not specified.

2. The nominal volume of the original product excluding anticoagulant
   "XX" specifies that the volume is variable and not provided as part of the core conditions of the product description. Other volume information may be given as additional label text.

3. The temperature at which the product should be stored.
   Specific temperatures are not always given in the description since differing specific temperature ranges must be adhered to within a given country. For example, refg (refrigerated) is used rather than a specific range, such as 1–4 C. When a specific temperature is given it is expressed in degrees Celsius.

3.2.1.1 Core Conditions – Lists and Definitions

First Position (anticoagulant/additive) – Bounded List

Common Name	ISBT 128 Database Name	Definition
Citrate and Heparin	Citrate + Heparin	Combined use of citrate and heparin at any concentration in the anticoagulant medium.
Citrate	Citrate	Any anticoagulant containing citrate used as the sole method of anticoagulation.
Heparin	Heparin	Heparin used at any concentration as the sole method of anticoagulation.
None	None	No anticoagulant. This applies to products where anticoagulant was not used at any point in the process AND to products where anticoagulant was used but further processing steps have reduced the concentration of anticoagulant to a trace amount. Further information on the residual concentration may be provided in accompanying documentation.
NS	NS	Anticoagulant not specified in coding.

Second Position (volume) – This list is not bounded, other volumes may be defined.

Common Name	ISBT 128 Database Name	Definition
XX	XX	Volume not specified in coding.

Third Position (storage temperature) – This list is not bounded, other temperature ranges may be defined.

Common Name	ISBT 128 Database Name	Definition
≤ 37 C	<=37C	Less than or equal to 37 degrees Celsius.
Refrigerated	refg	Refrigerated (between 1 – 10 degrees Celsius; narrower range may be nationally specified).
Room Temperature	rt	Ambient room temperature (range may be nationally specified).
10-20C	10-20C	Between 10 and 20 degrees Celsius.
≤ -18 C	<=-18C	Less than or equal to -18 degrees Celsius.
≤ -80 C	<=-80C	Less than or equal to -80 degrees Celsius.
≤ -120 C	<=-120C	Less than or equal to -120 degrees Celsius.
≤ -130 C	<=-130C	Less than or equal to -130 degrees Celsius.
≤ -150 C	<=-150C	Less than or equal to -150 degrees Celsius.
Liquid Nitrogen	N2 liquid	Completely immersed in the liquid phase of nitrogen.

3.2.2 Groups and Variables

Any additional manipulation or change to the product from its “core” state is reflected by the addition of one or more attributes from the groups and variables detailed below. Such additional manipulations or changes are indicated by a different Product Description Code.

3.2.2.1 Groups: Bounded Lists and Definitions

Group Name	Description
Intended Use	Describes the expected use of the product.
Manipulation	Describes processing applied to a product other than to enrich or reduce a cell population.
Cryoprotectant	Active cryoprotectant in the product.
Blood Component from 3rd Party Donor	Describes blood products from other donors used during processing, such as albumin, Fresh Frozen Plasma, AB serum, Red Blood Cells.
Other Additives	Describes additives present in the product.
Genetically Modified	Cells which have been modified by the insertion of exogenous genetic material.
Irradiation	Indicates whether or not the product has been irradiated.
Modification	Processing that changes the cellular milieu and maintains the integrity of the target cell population.
Mobilization	Indicates whether or not an agent was administered to the donor/patient to increase the yield of target cells collected.
Pooled Single Donor	Indicates whether or not the product is a combination of multiple collections of the same product type from the same donor or aliquots of the same collection.
Cultured	Indicates whether or not cells have been maintained ex vivo to activate, expand, or promote development of a specified cell population in the presence of specified additives.
Enrichment	Provides information on processing to enrich cell population. (Note: When applied to a product collected by apheresis, this attribute is used when an additional enrichment step is performed in the laboratory after the apheresis collection has been completed and often prior to additional processing or manufacturing.)
Reduction	Provides information on processing to reduce cell population or plasma. When applied to a product collected by apheresis, this attribute is used when an additional reduction step is performed in the laboratory after the apheresis collection has been completed and often prior to additional processing or manufacturing.
Fluid Source Location	Provides information on the location within the body from which the fluid was collected. This attribute group is to be used with the classes NC, FLUID; T CELLS, FLUID; MALIGNANT CELLS, FLUID.

3.2.2.2 Variables: Bounded Lists and Definitions Tables

3.2.2.2.1 Intended Use

Common Name	ISBT 128 Database Name	Definition
Default	For administration	For patient use: The product is intended for administration to patients.
For further processing	For further processing	For further processing into a product that may be administered; not intended for direct administration.
For use in further processing donor's cell product	For further processing:donor cell prod	Intended for use in further processing of cellular products from the same donor.
Not for administration	Not for admin	Not for patient use; a product that is not intended for use in patient treatment.

3.2.2.2.2 Manipulation

Common Name	ISBT 128 Database Name	Definition
Default	Not specified	No information about processing is specified in this Attribute group.
Electroporated	Electroporated	The use of an electric field to increase the permeability of the cell plasma membrane to introduce some substances (such as mRNA, drugs, etc.).
Filtered	Filtered	Product after passage through a non-leukocyte reducing filter. [Note: The bone marrow harvest procedure includes a series of filters to obtain the collected product. This is not considered a separate manipulation step. The attribute "Filtered" should not be used. Select the attribute "Filtered" if an independent filtration is performed (e.g., filtered in the laboratory using a 170 - 260 micron filter)].
Lysed	Lysed	The use of a process to disrupt the cell membranes (such as freezing cells without cryoprotectant, etc.).
Pulsed	Pulsed	The loading of antigens (such as peptides, tumor antigens, etc.) on immune cells, such as dendritic cells or T-cells, to increase the specificity of the immunotherapy.
Photodynamic treatment	Photodynamic treatment	The use of a process that involves treating cells with a photosensitizing agent followed by a light source to activate the agent.

3.2.2.2.3 Cryoprotectant

Common Name	ISBT 128 Database Name	Definition
Default	No cryoprotectant	No cryoprotectant has been added.
5% DMSO	5% DMSO	The final product contains 5% dimethylsulfoxide by volume as the cryoprotective agent.
7.5% DMSO	7.5% DMSO	The final product contains 7.5% dimethylsulfoxide by volume as the cryoprotective agent.
10% DMSO	10% DMSO	The final product contains 10% dimethylsulfoxide by volume as the cryoprotective agent.
6% HES + 5% DMSO	6% HES + 5% DMSO	The final product contains 5% dimethylsulfoxide by volume and 6% hydroxyethyl starch as the cryoprotective agents.
NS Dextran + NS DMSO	NS Dextran + NS DMSO	The final product contains dextran and dimethylsulfoxide, intended as cryoprotectants. The concentrations may be specified in text on the affixed, attached, or accompanying label.
NS DMSO + NS HES + NS Dextran	NS DMSO + NS HES + NS Dextran	The final product contains dimethylsulfoxide, hydroxyethyl starch, and dextran, intended as cryoprotectants. The concentrations may be specified in text on the affixed, attached, or accompanying label.
DMSO not specified	NS DMSO	The final product contains dimethylsulfoxide as the cryoprotective agent. The concentration may be specified in text on the affixed, attached, or accompanying label.
NS HES + NS DMSO	NS HES + NS DMSO	The final product contains hydroxyethyl starch and dimethylsulfoxide as the cryoprotective agents. The concentrations may be specified in text on the affixed, attached, or accompanying label.
NS HES + 5% DMSO	NS HES + 5% DMSO	The final product contains hydroxyethyl starch and 5% dimethylsulfoxide by volume as the cryoprotective agents. The concentration of hydroxyethyl starch may be specified in text on the affixed, attached, or accompanying label.
NS HES + 10% DMSO	NS HES + 10% DMSO	The final product contains hydroxyethyl starch and 10% dimethylsulfoxide by volume as the cryoprotective agents. The concentration of hydroxyethyl starch may be specified in text on the affixed, attached, or accompanying label.
NS Propylene glycol	NS Propylene glycol	The final product contains propylene glycol as the cryoprotective agent. The concentration may be specified in text on the affixed, attached, or accompanying label.

3.2.2.2.4 Blood Component from 3rd Party Donor*

Common Name	ISBT 128 Database Name	Definition
Default	3rd Party Comp:No	Default. No third party blood component added.

Common Name	ISBT 128 Database Name	Definition
3rd party component present	3rd Party Comp:Yes	Third party blood component added. See accompanying documentation.

**The default values of the groups Blood Component from Third Party Donor, Other Additives, and Genetically Modified have changed from those originally published. When initially published, "Not Specified" was the default value. The default value has been changed to that shown above to reflect the most common condition (that which would be expected unless otherwise noted).*

3.2.2.2.5 Other Additives*

Common Name	ISBT 128 Database Name	Definition
Default	Other Additives:No	Default. No additives other than as part of the anticoagulant solution at the time of collection.
Concurrent plasma	Concurrent plasma	Concurrently collected plasma has been added after collection to reduce cell concentration for transit, storage, processing, or cryopreservation.**
Concurrent plasma + other	Concurrent plasma + other	Concurrently collected plasma has been added after collection to reduce cell concentration for transit, storage, processing, or cryopreservation. Other additives are also present (see accompanying documentation).
Other Additives present	Other Additives:Yes	Other additives. See accompanying documentation.
Other Additives including cellular	Other Additives:Yes cellular	Other additives present including cellular material. See accompanying documentation.
Other Additives including animal source	Other Additives:Yes incl animal src	Other additives present including animal source material. See accompanying documentation.

**The default values of the groups Blood Component from Third Party Donor, Other Additives, and Genetically Modified have changed from those originally published. When initially published, "Not Specified" was the default value. The default value has been changed to that shown above to reflect the most common condition (that which would be expected unless otherwise noted).*

*** The definition for the class CONCURRENT PLASMA, APHERESIS specifies that this product only applies to apheresis collections. Therefore, even though "Concurrent plasma" is an attribute, the definition of CONCURRENT PLASMA, APHERESIS still applies. For example, Marrow collections, although the plasma in the bone marrow harvest was collected at the same time; it is not considered "Concurrent plasma".*

3.2.2.2.6 Genetically Modified*

Common Name	ISBT 128 Database Name	Definition
Default	Genetically Modified:No	Default. Not genetically modified.
Genetically modified	Genetically Modified:Yes	Genetically modified by the insertion of exogenous genetic material. See accompanying documentation.
Genetically modified, target inducible	Genetically Modified:Yes, target inducible	Genetically modified by the insertion of exogenous genetic material. Cells/(Cell function) can be altered after administration (or infusion). See accompanying documentation.

**The default values of the groups Blood Component from Third Party Donor, Other Additives, and Genetically Modified have changed from those originally published. When initially published, "Not Specified" was the default value. The default value has been changed to that shown above to reflect the most common condition (that which would be expected unless otherwise noted).*

3.2.2.2.7 Irradiation

Common Name	ISBT 128 Database Name	Definition
Default	Irradiation:No	Product was not irradiated.
Irradiation:Yes	Irradiation:Yes	Product was irradiated.

3.2.2.2.8 Modification

Common Name	ISBT 128 Database Name	Definition
Default	Not specified	Modifications are not specified in the coding.
Cryopreserved	Cryopreserved	Applies to cells in the frozen state after the addition of cryoprotectant(s).
Thawed	Thawed	Applies to cryopreserved cells that have been thawed without washing prior to final issue for administration.
Thawed Washed	Thawed Washed	Applies to cryopreserved cells that have been thawed and subsequently washed to remove cryoprotectant or other solution(s).
Washed	Washed	Applies to cells from a non-cryopreserved product that have been washed to reduce the amount of plasma, anticoagulant, and/or other solution(s).

3.2.2.2.9 Mobilization

Common Name	ISBT 128 Database Name	Definition
Default	Not specified	Mobilization is not specified in the coding.
Mobilized	Mobilized	Applies to cells that have been obtained from a donor treated with an agent increasing the concentration of cells.

3.2.2.2.10 Pooled Single Donor

Common Name	ISBT 128 Database Name	Definition
Default	Not specified	Information about product pooling is not specified in the coding.
Pooled Single Donor: Yes	Pooled Single Donor: Yes	Product is a combination of multiple collections of the same product type from the same donor or aliquots from the same collection.

3.2.2.2.11 Cultured

Common Name	ISBT 128 Database Name	Definition
Default	Cultured:No	Product was not cultured.
Cultured:Yes	Cultured:Yes	Cells that have been maintained ex vivo to activate, expand, or promote development of a specified cell population in the presence of specified additive(s).

3.2.2.2.12 Enrichment

Common Name	ISBT 128 Database Name	Definition
Default	Not specified	No information about cell enrichment is specified in the coding.
Activated T cell enriched	Activated T cell enriched	Product in which activated T cells have been enriched. The specific types of T cells can be found in accompanying documentation.
Buffy coat enriched	Buffy coat enriched	Cells remaining after reduction of mature erythrocytes and plasma.
CD3 enriched	CD3 enriched	Product in which the CD3 cells have been enriched.
CD4 enriched	CD4 enriched	Product in which the CD4 cells have been enriched.
CD4+CD8 enriched	CD4+CD8 enriched	Product in which both the CD4 and CD8 cells have been enriched.
CD14 enriched	CD14 enriched	Product in which the CD14 cells have been enriched.
CD19 enriched	CD19 enriched	Product in which the CD19 cells have been enriched.
CD34 enriched	CD34 enriched	Product in which the CD34 cells have been enriched.
CD56 enriched	CD56 enriched	Product in which the CD56 cells have been enriched.
CD133 enriched	CD133 enriched	Product in which the CD133 cells have been enriched.
CTL enriched	CTL enriched	Product in which the cytotoxic T lymphocytes have been enriched.
Gamma Delta T cell enriched	Gamma Delta T cell enriched	A product in which the Gamma Delta T cells have been enriched.
Monocyte enriched	Monocyte enriched	Product in which the monocytes have been enriched.
Mononuclear cell enriched	Mononuclear cell enriched	Product in which the mononuclear cells have been enriched.
T Reg enriched	T Reg enriched	Product in which the T regulatory lymphocytes have been enriched.

Common Name	ISBT 128 Database Name	Definition
TIL enriched	TIL enriched	A product in which autologous tumor infiltrating lymphocytes (TIL) have been enriched from the patient's tumor and cultured.
Tumor specific T cell enriched	Tumor specific T cell enriched	Product in which T cells from autologous peripheral blood have been grown to be tumor antigen specific.
Viral specific T cell enriched	Viral specific T cell enriched	A product in which viral specific T cells have been enriched.

3.2.2.2.13 Reduction

Common Name	ISBT 128 Database Name	Definition
Default	Not specified	No information about cell or plasma reduction is specified in the coding.
αβ T cell reduced	Alpha Beta T cell reduced	The cells remaining after the Alpha Beta T cells have been reduced.
αβ T/B cell reduced	Alpha Beta T+B cell reduced	The cells remaining after the Alpha Beta T cells and B cells have been reduced.
B cell reduced	B cell reduced	The cells remaining after B cells have been reduced.
CD45RA reduced	CD45RA reduced	The cells remaining after CD45RA cells have been reduced.
CD8 reduced	CD8 reduced	The cells remaining after CD8 cells have been reduced.
Plasma reduced	Plasma reduced	The cells remaining after a portion of the plasma has been depleted by sedimentation or centrifugation.
RBC reduced	RBC reduced	The cells remaining after reduction of mature erythrocytes.
T cell reduced	T cell reduced	The cells remaining after T cells have been reduced.
T Reg reduced	T Reg reduced	Product in which the T regulatory lymphocytes have been reduced.
T/B cell reduced	T+B cell reduced	The cells remaining after T cells and B cells have been reduced.
Tumor cell reduced	Tumor cell reduced	Cells remaining after tumor cells have been reduced.

3.2.2.2.14 Fluid Source Location

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not applicable	The product is not NC, FLUID; T CELLS, FLUID; MALIGNANT CELLS, FLUID so this attribute does not apply.
Peritoneal cavity	Peritoneal cavity	The space between the visceral layer and the parietal layer of the peritoneum.
Pleural space	Pleural space	The space between the visceral and parietal pleura.
Synovial joint	Synovial joint	The joint cavity within the articular capsule of a diarthrosis joint.

4 Tissues

4.1 Class

4.1.1 Cardio/Vascular Bounded List and Definitions

Common Name	ISBT 128 Database Name	Definition
AORTIC CONDUIT		
AORTA, ARCH	AORTA, ARCH	Part of the aorta including the origin of the brachiocephalic trunk, the common carotid artery, and the left subclavian artery.
AORTA, ARCH, WITH DESCENDING THORACIC	AORTA, ARCH, W DESCENDING THORACIC	Part of the aorta including the origin of the brachiocephalic trunk and the thoracic aorta extending to the diaphragm.
AORTA, ASCENDING	AORTA, ASCENDING	Part of the aorta between the sinotubular junction and the brachiocephalic trunk.
AORTA, ASCENDING, WITH ARCH	AORTA, ASCENDING, W ARCH	Part of the aorta from the sinotubular junction and including the origin of the left subclavian artery
AORTA, DESCENDING, ABDOMINAL	AORTA, DESCENDING, ABDOMINAL	Part of the aorta between the diaphragm and the aortic bifurcation.
AORTA, DESCENDING, THORACIC	AORTA, DESCENDING, THORACIC	Part of the aorta between the left subclavian artery and the diaphragm.
AORTOILIAC, CONDUIT	AORTOILIAC, CONDUIT	Part of the aorta descending abdominal and common iliac arteries.
AORTIC VALVE		
VALVE, AORTIC	VALVE, AORTIC	The valve between the aorta and the left ventricle.
VALVE, AORTIC, WITH ASCENDING AORTA	VALVE, AORTIC, W ASC AORTA	The valve between the left ventricle and the aorta extending to the brachiocephalic trunk.
VALVE, AORTIC, WITH ASCENDING AORTA AND ARCH	VALVE, AORTIC, W ASC AORTA, ARCH	The valve between the left ventricle and the aorta extending beyond the left subclavian artery.
VALVE, AORTIC, WITH ASCENDING AORTA AND PARTIAL ARCH	VALVE, AORTIC, ASC AORTA PART ARCH	The valve between the left ventricle and the aorta extending to include part of the aortic arch with one or two head vessels.
ARTERIES		
ARTERY	ARTERY	An unspecified artery. (Note: This Class is intended to be used for products requiring further processing.)

Common Name	ISBT 128 Database Name	Definition
ARTERY, AXILLARY-BRACHIAL	ARTERY, AXILLARY-BRACHIAL	All or part of the axillary and/or brachial artery.
ARTERY, BRACHIAL	ARTERY, BRACHIAL	All or part of the brachial artery.
ARTERY, CAROTID	ARTERY, CAROTID	All or part of the carotid artery.
ARTERY, CELIAC TRUNK	ARTERY, CELIAC TRUNK	All or part of the celiac trunk artery.
ARTERY, COMMON ILIAC	ARTERY, COMMON ILIAC	All or part of the common iliac artery.
ARTERY, COMMON ILIAC WITH BRANCH	ARTERY, COMMON ILIAC WITH BRANCH	All or part of the common iliac, the bifurcation, and all or part of its branches.
ARTERY, FEMORAL, COMMON	ARTERY, FEMORAL, COMMON	All or part of the femoral artery.
ARTERY, FEMORAL-POPLITEAL	ARTERY, FEMORAL-POPLITEAL	All or part of the femoral popliteal artery.
ARTERY, FEMORAL, SUPERFICIAL	ARTERY, FEMORAL, SUPERFICIAL	All or part of the superficial femoral artery.
ARTERY, INTERNAL THORACIC	ARTERY, INTERNAL THORACIC	All or part of the internal thoracic artery. Also referred to as the internal mammary artery.
ARTERY, POPLITEAL	ARTERY, POPLITEAL	All or part of the popliteal artery.
ARTERY, RADIAL	ARTERY, RADIAL	All or part of the radial artery.
ARTERY, ULNAR	ARTERY, ULNAR	All or part of the ulnar artery.
HEART		
HEART (TISSUE)	HEART (TISSUE)	Recovered whole heart with associated vascular tissue for processing into MPHO for human application. Not suitable for organ transplantation.
HEART, PARTIAL, WITH VALVES	HEART, PARTIAL, WITH VALVES	Portion of the heart with valves.
HEART, PARTIAL, WITHOUT VALVES	HEART, PARTIAL, WITHOUT VALVES	Portion of the heart without valves.
HEART, WITH PERICARDIUM	HEART, WITH PERICARDIUM	Heart with pericardium.
MITRAL VALVE		
VALVE, MITRAL	VALVE, MITRAL	The valve between the left ventricle and left atrium.

Common Name	ISBT 128 Database Name	Definition
VALVE, MITRAL, PATCH	VALVE, MITRAL, PATCH	An entire or partial mitral leaflet with or without respective papillary muscle and chordae tendineae.
PULMONARY CONDUIT		
PULMONARY ARTERY, BRANCH PATCH	PULMONARY ARTERY, BRANCH PATCH	Patch prepared from the right or left pulmonary artery.
PULMONARY, LEFT ARTERY	PULMONARY, LEFT ARTERY	Left pulmonary artery.
PULMONARY, MAIN AND LEFT ARTERIES	PULMONARY, MAIN AND LEFT ARTERIES	Main pulmonary artery and left pulmonary artery.
PULMONARY, MAIN AND RIGHT ARTERIES	PULMONARY, MAIN AND RIGHT ARTERIES	Main pulmonary artery and right pulmonary artery.
PULMONARY, MAIN ARTERY	PULMONARY, MAIN ARTERY	Main pulmonary artery extending to the bifurcation.
PULMONARY, MAIN ARTERY PATCH	PULMONARY, MAIN ARTERY PATCH	Patch prepared from the main pulmonary artery.
PULMONARY, MAIN ARTERY WITH LEFT AND RIGHT ARTERIES	PULMONARY, MAIN ARTERY, L/R ARTERIES	Main pulmonary artery, left pulmonary artery and right pulmonary artery.
PULMONARY, RIGHT ARTERY	PULMONARY, RIGHT ARTERY	Right pulmonary artery.
PULMONARY VALVE		
VALVE, PULMONARY	VALVE, PULMONARY	The valve between the right ventricle and the main pulmonary artery.
VALVE, PULMONARY, MONOCUSP	VALVE, PULMONARY, MONOCUSP	One third of the pulmonary valve between the right ventricle and the main pulmonary artery containing one leaflet.
VALVE, PULMONARY, ONE LEAFLET	VALVE, PULMONARY, ONE LEAFLET	The valve between the right ventricle and the main pulmonary artery containing only one usable leaflet.
VALVE, PULMONARY, TWO LEAFLETS	VALVE, PULMONARY, TWO LEAFLETS	The valve between the right ventricle and the main pulmonary artery containing only two usable leaflets.
VALVE, PULMONARY, WITH MAIN ARTERY	VALVE, PULMONARY, W MAIN ARTERY	The valve between the right ventricle and the main pulmonary artery extending to the bifurcation.

Common Name	ISBT 128 Database Name	Definition
VALVE, PULMONARY, WITH MAIN, LEFT AND RIGHT ARTERIES	VALVE, PULMONARY,W MAIN,L/R ARTERIES	The valve between the right ventricle and the main pulmonary artery extending to include both the left and right pulmonary arteries.
VALVE, PULMONARY, WITH MAIN, LEFT ARTERY	VALVE, PULMONARY, W MAIN, L ARTERY	The valve between the right ventricle and the main pulmonary artery extending to include the left pulmonary artery.
VALVE, PULMONARY, WITH MAIN, RIGHT ARTERY	VALVE, PULMONARY, W MAIN, R ARTERY	The valve between the right ventricle and the main pulmonary artery extending to include the right pulmonary artery.
VEINS		
VEIN	VEIN	An unspecified vein. (Note: This Class is intended to be used for products requiring further processing.)
VEIN, FEMORAL	VEIN, FEMORAL	All or part of the femoral vein.
VEIN, GREAT SAPHENOUS	VEIN, GREAT SAPHENOUS	All or part of the great saphenous vein.
VEIN, HEPATIC	VEIN, HEPATIC	All or part of the hepatic vein.
VEIN, ILIAC	VEIN, ILIAC	All or part of the iliac vein.
VEIN, INFERIOR VENA CAVA	VEIN, INFERIOR VENA CAVA	All or part of the inferior vena cava.
VEIN, PORTAL	VEIN, PORTAL	All or part of the portal vein.
VEIN, SMALL SAPHENOUS	VEIN, SMALL SAPHENOUS	All or part of the small saphenous vein.
VEIN, SUPERIOR VENA CAVA	VEIN, SUPERIOR VENA CAVA	All or part of the superior vena cava.

4.1.2 Soft Tissue Bounded List and Definitions

Common Name	ISBT 128 Database Name	Definition
FASCIA LATA	FASCIA LATA	Recovered portion of the fascia lata.
FASCIA, RECTUS	FASCIA, RECTUS	Recovered portion of the rectus fascia.
HAMSTRING	HAMSTRING	Prominent tendons at the back of the knee.
LIGAMENT, ANTERIOR CRUCIATE, WITH BONE BLOCKS	LIGAMENT, ANTERIOR CRUCIATE BONE BLK	Anterior cruciate ligament, attached to a bone block from femur and a bone block from tibia.
LIGAMENT, MEDIAL COLLATERAL, WITH BONE BLOCKS	LIGAMENT, MEDIAL COLLATERAL BONE BLK	Medial collateral ligament, attached to a bone block from the tibia and a bone block from the femur.
LIGAMENT, POSTERIOR CRUCIATE, WITH BONE BLOCKS	LIGAMENT, POSTERIOR CRUCIATE BNE BLK	Posterior cruciate ligament, attached to a bone block from femur and a bone block from tibia.
MENISCI	MENISCI	Both the lateral and medial meniscus dissected together from the knee joint.
MENISCI WITH TIBIA PLATEAU	MENISCI WITH TIBIA PLATEAU	Lateral and medial meniscus attached to plateau from the tibia.
MENISCUS, LATERAL	MENISCUS, LATERAL	Lateral meniscus dissected from the knee joint.
MENISCUS, LATERAL, WITH TIBIA PLATEAU	MENISCUS, LATERAL, W TIBIA PLATEAU	Lateral meniscus, attached to plateau from the tibia.
MENISCUS, MEDIAL	MENISCUS, MEDIAL	Medial meniscus dissected from the knee joint.
MENISCUS, MEDIAL, WITH TIBIA PLATEAU	MENISCUS, MEDIAL, W TIBIA PLATEAU	Medial meniscus, attached to plateau from the tibia.
TENDON	TENDON	Tendon, source not specified, that has been transected from the bone.
TENDON, ACHILLES	TENDON, ACHILLES	Achilles tendon transected from the bone.
TENDON, ACHILLES BISECTED	TENDON, ACHILLES BISECTED	Achilles tendon transected from the bone, cut in half.

Common Name	ISBT 128 Database Name	Definition
TENDON, ACHILLES WITH BONE BLOCK	TENDON, ACHILLES WITH BONE BLOCK	Achilles tendon with bone block.
TENDON, ACHILLES, BISECTED, WITH SHAPED BONE BLOCK	TENDON, ACHILLES, BI, SHAPED BNE BLK	Achilles tendon, cut in half, with bone block shaped to specifications. Also referred to as Achilles Tendon – Hemi, Shaped.
TENDON, ACHILLES, WITH SHAPED BONE BLOCK	TENDON, ACHILLES, W SHAPED BONE BLK	Achilles tendon with bone block shaped to specifications.
TENDON, BICEPS FEMORIS, WITH BONE BLOCK	TENDON, BICEPS FEMORIS, W BONE BLK	Tendon of biceps femoris with bone block.
TENDON, EXTENSOR DIGITORUM LONGUS	TENDON, EXTENSOR DIGITORUM LONGUS	Tendon of extensor digitorum longus muscle transected from the bone.
TENDON, EXTENSOR HALLUCIS LONGUS	TENDON, EXTENSOR HALLUCIS LONGUS	Tendon of extensor hallucis longus muscle transected from the bone.
TENDON, FLEXOR CARPI RADIALIS	TENDON, FLEXOR CARPI RADIALIS	Tendon of flexor carpi radialis muscle transected from the bone.
TENDON, FLEXOR DIGITORUM LONGUS	TENDON, FLEXOR DIGITORUM LONGUS	Tendon of flexor digitorum longus muscle transected from the bone.
TENDON, FLEXOR HALLUCIS LONGUS	TENDON, FLEXOR HALLUCIS LONGUS	Tendon of flexor hallucis longus muscle transected from the bone.
TENDON, GRACILIS	TENDON, GRACILIS	Tendon of gracilis muscle transected from the bone.
TENDON, ILIOTIBIALIS	TENDON, ILIOTIBIALIS	Iliotibial tract (tendon of tensor fascia lata and gluteus maximus) muscle transected from the bone.
TENDON, PATELLAR WITH BONE BLOCKS	TENDON, PATELLAR W BONE BLK	Patellar tendon (sometimes called patellar ligament) with two bone blocks.

Common Name	ISBT 128 Database Name	Definition
TENDON, PATELLAR WITH BONE BLOCKS AND QUAD	TENDON, PATELLAR W BONE BLK AND QUAD	Patellar tendon (sometimes called patellar ligament) with two bone blocks and the quadriceps tendon attached.
TENDON, PATELLAR WITH SHAPED BONE BLOCKS	TENDON, PATELLAR W SHAPED BONE BLK	Patellar tendon (sometimes called patellar ligament) with two bone blocks shaped to specifications.
TENDON, PATELLAR WITH WHOLE PATELLA AND TIBIA BONE BLOCK	TENDON,PATELLAR W PATELLA, TIBIA BLK	Patellar tendon (sometimes called patellar ligament) with a whole patella and tibia bone block attached.
TENDON, PATELLAR, BISECTED WITH BONE BLOCK AND QUAD	TENDON, PATELLAR, BISECTED WITH BONE BLOCK AND QUAD	Patellar tendon (sometimes called patellar ligament) with two bone blocks and the quadriceps tendon attached, cut in half.
TENDON, PATELLAR, BISECTED WITH BONE BLOCKS	TENDON, PATELLAR, BISECTED BONE BLK	Patellar tendon (sometimes called patellar ligament) cut in half, with two bone blocks. Also referred to as Patellar Tendon – Hemi.
TENDON, PATELLAR, BISECTED WITH SHAPED BONE BLOCKS	TENDON, PATELLAR, BISECT, SHAPED BLK	Patellar tendon (sometimes called patellar ligament) cut in half, with two bone blocks shaped to specifications. Also referred to as Patellar Tendon – Hemi, Shaped.
TENDON, PERONEUS BREVIS	TENDON, PERONEUS BREVIS	Tendon of peroneus brevis muscle transected from the bone.
TENDON, PERONEUS LONGUS	TENDON, PERONEUS LONGUS	Tendon of peroneus longus muscle transected from the bone.
TENDON, PERONEUS LONGUS WITH BONE BLOCK	TENDON, PERONEUS LONGUS W BONE BLK	Tendon of peroneus longus muscle with bone block.
TENDON, PES ANSERINUS	TENDON, PES ANSERINUS	Pes anserinus tendon transected from the bone.
TENDON, PALMARIS LONGUS	TENDON, PALMARIS LONGUS	Tendon of palmaris longus muscle transected from the bone.
TENDON, PLANTARIS	TENDON, PLANTARIS	Tendon of plantaris muscle transected from the bone.

Common Name	ISBT 128 Database Name	Definition
TENDON, QUADRICEP	TENDON, QUADRICEP	Tendon of quadriceps femoris muscle transected from the bone.
TENDON, QUADRICEPS, WITH BONE BLOCK	TENDON, QUADRICEPS, W BONE BLK	Tendon of quadriceps femoris muscle with bone block.
TENDON, QUADRICEPS, WITH SHAPED BONE BLOCK	TENDON, QUAD, W SHAPED BONE BLK	Tendon of quadriceps femoris muscle with bone block shaped to specifications.
TENDON, ROTATOR CUFF	TENDON, ROTATOR CUFF	Tendons of rotator cuff transected from the bone.
TENDON, SEMITENDI-NOSUS	TENDON, SEMITENDINO -SUS	Tendon of semitendinosus muscle transected from the bone. (This may sometimes be referred to informally as hamstring.)
TENDON, SEMITEND-INOSUS/ GRACILIS	TENDON, SEMITENDINO -SUS/ GRACILIS	Tendons of semitendinosus and gracilis muscles transected from the bone and packaged together.
TENDON, TIBIALIS ANTERIOR, WITH BONE BLOCK	TENDON, TIBIALIS ANTERIOR W BONE BLK	Tendon of tibialis anterior muscle with bone block.
TENDON, TIBIALIS POSTERIOR, WITH BONE BLOCK	TENDON, TIBIALIS POSTERIOR W BNE BLK	Tendon of tibialis posterior muscle with bone block.
TENDON, TIBIALIS, ANTERIOR	TENDON, TIBIALIS, ANTERIOR	Tendon of tibialis anterior muscle transected from the bone.
TENDON, TIBIALIS, POSTERIOR	TENDON, TIBIALIS, POSTERIOR	Tendon of tibialis posterior muscle transected from the bone.

4.1.3 Bone and Cartilage Bounded List and Definitions

Common Name	ISBT 128 Database Name	Definition
ACETABULUM WITH LABRUM	ACETABULUM WITH LABRUM	Acetabular rim with labrum.
ANKLE	ANKLE	The hinge joint between the distal ends of the tibia and fibula in the lower limb and the proximal end of the talus bone in the foot; talocrural joint.

Common Name	ISBT 128 Database Name	Definition
BONE	BONE	Bone, not further specified. Porous rigid tissue making up the skeleton.
BONE, BLOCK	BONE, BLOCK	Bone cut into a rectangular cuboid; may be called a peg.
BONE, CALCANEUS	BONE, CALCANEUS	Whole or part of a calcaneus.
BONE, CHIPS	BONE, CHIPS	Bone cut into pieces of varying undefined shape.
BONE, CLAVICLE	BONE, CLAVICLE	Whole or part of a clavicle.
BONE, CRUSHED	BONE, CRUSHED	Bone fragments prepared by a crushing or pounding action.
BONE, CUBES	BONE, CUBES	Bone cut into a cube.
BONE, CUBOID	BONE, CUBOID	Whole or part of a cuboid.
BONE, DOWEL	BONE, DOWEL	Bone cut/shaped into a cylindrical piece.
BONE, FEMUR	BONE, FEMUR	Whole or part of a femur.
BONE, FIBERS	BONE, FIBERS	Thin threads or filaments of bone.
BONE, FIBERS, MOLDED	BONE, FIBERS, MOLDED	Bone fibers molded to a specific shape.
BONE, FIBERS/POWDER	BONE, FIBERS/POWDER	Bone powder combined with thin threads or filaments of bone.
BONE, FIBULA	BONE, FIBULA	Whole or part of a fibula.
BONE, GROUND	BONE, GROUND	Bone fragments prepared by a grinding or milling action.
BONE, GROUND/POWDER	BONE, GROUND/POWDER	Bone powder combined with bone fragments prepared by a grinding or milling action.
BONE, HUMERUS	BONE, HUMERUS	Whole or part of a humerus.
BONE, HUMERUS WITH ROTATOR CUFF	BONE, HUMERUS WITH ROTATOR CUFF	Whole or part of a humerus with rotator cuff.
BONE, ILIUM	BONE, ILIUM	Whole or part of an ilium.
BONE, INCUS	BONE, INCUS	Whole or part of an incus.
BONE, INTERMEDIATE CUNEIFORM	BONE, INTERMEDIATE CUNEIFORM	Whole or part of an intermediate cuneiform.
BONE, LATERAL CUNEIFORM	BONE, LATERAL CUNEIFORM	Whole or part of a lateral cuneiform.
BONE, MALLEUS	BONE, MALLEUS	Whole or part of a malleus.
BONE, MANDIBLE	BONE, MANDIBLE	Whole or part of a mandible.
BONE, MEDIAL CUNEIFORM	BONE, MEDIAL CUNEIFORM	Whole or part of a medial cuneiform.

Common Name	ISBT 128 Database Name	Definition
BONE, METACARPUS	BONE, METACARPUS	Whole or part of one metacarpal bone.
BONE, METATARSUS	BONE, METATARSUS	Whole or part of one metatarsal bone.
BONE, NAVICULAR	BONE, NAVICULAR	Whole or part of a navicular.
BONE, PASTE	BONE, PASTE	Bone powder with an agent or agents to create a smooth viscous mixture capable of slowly flowing and settling under gravity.
BONE, PATELLA	BONE, PATELLA	Whole or part of a patella.
BONE, PELVIS	BONE, PELVIS	Whole or part of a pelvis.
BONE, PHALANX	BONE, PHALANX	Whole or part of a phalanx.
BONE, PHALANX, FINGER	BONE, PHALANX, FINGER	Whole or part of a phalanx taken from a digit of the hand.
BONE, PHALANX, TOE	BONE, PHALANX, TOE	Whole or part of a phalanx taken from a digit of the foot.
BONE, POWDER	BONE, POWDER	Bone powder.
BONE, PUTTY	BONE, PUTTY	Bone reduced to a powder or other form and with the addition of an agent or agents to create a thick mixture or cement with a dough-like consistency.
BONE, RADIUS	BONE, RADIUS	Whole or part of a radius.
BONE, RIB	BONE, RIB	Whole or part of a rib.
BONE, RING	BONE, RING	Transverse portion of a bone shaft.
BONE, SCAPULA	BONE, SCAPULA	Whole or part of a scapula.
BONE, SHAPED, OTHER	BONE, SHAPED, OTHER	A shaped bone not otherwise described in ISBT 128 terminology.
BONE, SHEET	BONE, SHEET	Bone cut into a thin sheet.
BONE, SKULL	BONE, SKULL	Whole or part of a skull.
BONE, SLICE	BONE, SLICE	Transverse portion of a bone part such as an epiphysis or head.
BONE, STAPES	BONE, STAPES	Whole or part of a stapes.
BONE, STERNUM	BONE, STERNUM	Whole or part of a sternum.
BONE, STRIP	BONE, STRIP	Bone cut into a strip.
BONE, STRUT	BONE, STRUT	Longitudinal portion of a bone shaft.
BONE, TALUS	BONE, TALUS	Whole or part of a talus.
BONE, TEMPORAL	BONE, TEMPORAL	Whole or part of a temporal bone; may include inner ear bones.
BONE, TIBIA	BONE, TIBIA	Whole or part of a tibia.
BONE, ULNA	BONE, ULNA	Whole or part of an ulna.

Common Name	ISBT 128 Database Name	Definition
BONE, VERTEBRA	BONE, VERTEBRA	Whole or part of a vertebra.
BONE, WEDGE	BONE, WEDGE	Bone cut into a wedge shape.
CARTILAGE, FIBERS/POWDER	CARTILAGE, FIBERS/POWDER	Cartilage powder combined with thin threads or filaments of cartilage.
CARTILAGE, JOINT, KNEE	CARTILAGE, JOINT, KNEE	Articular cartilage obtained from the knee joint.
CARTILAGE, THYROID	CARTILAGE, THYROID	All or part of the thyroid cartilage.
COSTAL CARTILAGE	COSTAL CARTILAGE	Tough elastic tissue extensions from the ribs towards the front of the chest.
COSTAL CARTILAGE PIECES	COSTAL CARTILAGE PIECES	Costal cartilage transected from sterno-costal joint of sternum — length in cm indicated on packaging.
ELBOW	ELBOW	Joint incorporating distal humerus and the proximal ulna and proximal radius with associated tissues.
GLENOID WITH LABRUM	GLENOID WITH LABRUM	Glenoid with labrum.
HIP JOINT	HIP JOINT	Joint incorporating whole or partial hemipelvis with proximal femur attached.
KNEE JOINT	KNEE JOINT	The distal femur still attached to the proximal tibia of the leg removed by transecting the femur above the joint and the tibia below the joint.
KNEE TRIMMINGS	KNEE TRIMMINGS	Assorted pieces of cortical and cancellous bone and cartilage removed from the distal femur and proximal tibia during knee replacement surgery.
OSTEOCHON-DRAL	OSTEOCHON-DRAL	Tissue comprising bone and cartilage from an articulating joint.
WHOLE KNEE JOINT	WHOLE KNEE JOINT	The distal femur still attached to the proximal tibia (the femur transected above the joint, the tibia transected below the joint), inclusive of the patella tendon, meniscus with intact synovial fluid compartment.
WRIST	WRIST	Joint incorporating distal radius and distal ulna, carpals, and proximal metacarpal bones, with ligaments and capsule.

4.1.4 Skin Bounded List and Definitions

Common Name	ISBT 128 Database Name	Definition
DERMIS	DERMIS	Skin from which the epidermis and subcutaneous tissue have been removed leaving only the dermal layer.
SKIN, FULL	SKIN, FULL	Full thickness skin (epidermis and whole dermis).
SKIN, FULL WITH HYPODERMIS	SKIN, FULL WITH HYPODERMIS	Full thickness skin with subcutaneous tissue (epidermis, dermis, and hypodermis).
SKIN, SPLIT	SKIN, SPLIT	Split thickness skin (epidermis and upper part of dermis).

4.1.5 Other Bounded Lists and Definitions

Common Name	ISBT 128 Database Name	Definition
ADIPOSE TISSUE	ADIPOSE TISSUE	Recovered adipose tissue.
AMNIOTIC MEMBRANE	AMNIOTIC MEMBRANE	Amniotic membrane not specified as to size.
AMNIOTIC MEMBRANE, LARGE	AMNIOTIC MEMBRANE, LARGE	Amniotic membrane graft, cut in pieces larger than 3cm x 3cm – surface area indicated on packaging.
AMNIOTIC MEMBRANE SHEET	AMNIOTIC MEMBRANE SHEET	Amniotic membrane graft, cut into pieces larger than 12cm x 20cm.
AMNIOTIC MEMBRANE, SMALL	AMNIOTIC MEMBRANE, SMALL	Amniotic membrane graft, cut in squares of 3 x 3cm or less – surface area indicated on packaging.
BIRTH TISSUES	BIRTH TISSUES	A combination of all or some of the birth tissues, which may include Placenta, Umbilical Cord, Amnion, or Chorion.
CHORIONIC MEMBRANE	CHORIONIC MEMBRANE	Chorionic membrane.
DURA MATER	DURA MATER	Dura mater.
FETAL MEMBRANES	FETAL MEMBRANES	Amnion and chorion laeves.
INTERVERTEBRAL DISC TISSUE	INTERVERTEBRAL DISC TISSUE	Tissue from intervertebral disc.
LARYNX WITH TRACHEA	LARYNX WITH TRACHEA	Larynx with full trachea.
LARYNX AND TRACHEA WITH BIFURCATION	LARYNX AND TRACHEA WITH BIFURCATION	Larynx with full trachea with birfurcation including at least one ring from right and left bronchus.
LIVER (TISSUE)	LIVER (TISSUE)	Recovered portion of the liver for processing into MPHO for human application. Not suitable for organ transplantation.
LYMPH NODE (TISSUE)	LYMPH NODE (TISSUE)	Recovered lymph node for processing into MPHO for human application. Not suitable for organ transplantation.
MUSCLE TISSUE, SKELETAL	MUSCLE TISSUE, SKELETAL	Skeletal muscle tissue, specific muscle not specified.
PANCREAS (TISSUE)	PANCREAS (TISSUE)	Recovered whole or part pancreas for processing into MPHO for human application. Not suitable for organ transplantation.
PARATHY-ROID GLANDS	PARATHYROID GLANDS	Parathyroid gland(s).

Common Name	ISBT 128 Database Name	Definition
PERICARDIAL PATCH	PERICARDIAL PATCH	Pericardium, cut into a piece – surface area indicated on the packaging.
PERICARDIUM	PERICARDIUM	Conical membranous sac that normally surrounds the heart.
PERICHON-DRIUM	PERICHONDRI-UM	Perichondrium.
PERIOSTEUM	PERIOSTEUM	Periosteum.
PERIPHERAL NERVE	NERVE, PERIPHERAL	Peripheral nerve tissue including epineurium, perineurium, and endoneurial tubes.
PLACENTA	PLACENTA	Chorion frondosum (villi) & decidua basalis covered by a portion of the amnion.
PLACENTA WITH UMBILI-CAL CORD	PLACENTA WITH CORD	Placenta together with umbilical cord.
PLACENTA WITH UMBILI-CAL CORD AND FETAL MEMBRANES	PLACENTA, CORD AND MEMBRANES	Placenta together with umbilical cord and fetal membranes.
SPLEEN (TISSUE)	SPLEEN (TISSUE)	Recovered spleen for processing into MPHO for human application. Not suitable for organ transplantation.
TRACHEA	TRACHEA	Full trachea.
TRACHEA WITH BIFURCATION	TRACHEA WITH BIFURCATION	Full trachea with bifurcation including at least one ring from right and left main bronchus.
TRACHEA, PART	TRACHEA, PART	At least one ring from the trachea.
TRACHEA, PART WITH BIFURCATION	TRACHEA, PART WITH BIFURCATION	At least one ring from the trachea and at least one ring from right and left main bronchus.
TYMPANIC MEMBRANE	TYMPANIC MEMBRANE	Tympanic membrane.
TYMPANIC MEMBRANE WITH MALLEUS	TYMPANIC MEMBRANE WITH MALLEUS	Tympanic membrane with whole or part of a malleus attached.
UMBILICAL CORD TISSUE	UMBILICAL CORD TISSUE	Recovered umbilical cord tissue.

4.1.6 Bone/Soft Tissue Bounded List and Definitions

Common Name	ISBT 128 Database Name	Definition
TIBIA, PROXIMAL WITH PATELLAR TENDON	TIBIA, PROXIMAL WITH PATELLAR TENDON	Proximal portion of the tibia with patellar tendon (sometimes called patellar ligament) and patellar bone block attached.
TIBIA AND MENISCI WITH PATELLAR TENDON	TIBIA AND MENISCI WITH PATELLAR TENDON	Whole tibia and menisci with patellar tendon (sometimes called patellar ligament) and patellar bone block attached.
TIBIA WITH PATELLAR TENDON AND PATELLAR BONE BLOCK	TIBIA WITH PATELLAR TENDON AND PATELLAR BONE BLOCK	Whole tibia with patellar tendon (sometimes called patellar ligament) and patellar bone block attached.
RADIUS, WITH BICEPS TENDON	RADIUS, WITH BICEPS TENDON	Whole radius with tendon of biceps muscle attached.
ULNA, WITH TRICEPS TENDON	ULNA, WITH TRICEPS TENDON	Whole ulna with tendon of triceps muscle attached.

4.2 Modifiers

In February 2015 Tissue Product Descriptions were restructured to discontinue use of Modifiers. As a result, the terms such as Frozen, Cryopreserved, Freeze Dried, and Refrigerated, which were previously Modifiers, have become variables within the Type of Preservation Attribute group. See section 14.3.2 for the full list of retired Modifiers.

Existing product descriptions and the formulas of these Product Description Codes were restructured to change Modifiers into Attributes. Only the descriptions and formulas changed, not the actual Product Description Codes. For example:

> T0187 was previously coded as: T0187 = **Cryopreserved** PATELLA BONE BLOCK|Single and had the formula **C0162-M0022-V0065002**
>
> It has been updated as: T0187 = PATELLA BONE BLOCK|**Cryopreserved**|Single and has the formula **C0162-M0000-V0061003-V0065002**

As always, ICCBBA staff will assist users requesting new codes to select the appropriate terms.

Concerns should be addressed to the ICCBBA office at tech.manager@iccbba.org.

4.3 Attribute

4.3.1 Core Conditions

Core Conditions are not used in the definition of Tissues

4.3.2 Groups and Variables

Any additional manipulation or change to the product is reflected by the addition of one or more attributes from the groups and variables detailed below. Such additional manipulations or changes are indicated by a different Product Description Code.

4.3.2.1 Groups – Bounded List and Definition

Group Name	Description
Additives	Describes additives present in the product.
Additional Processing	Describes additional tissue processing.
Donor-Intended Recipient Relationship	Describes the relationship between the donor and the intended recipient.
Skin Fenestration	Describes the fenestration of the skin product.
Storage Solution	Describes the solution in which the tissue is stored.
Type of Preservation	Describes the technique used to preserve the tissue.
Processed to Reduce Cellular Components	Indicates whether or not the product has been decellularized.
Anatomical Position	Describes the relative position of the tissue in the donor's body prior to tissue procurement.
Processing Status	Indicates if a product is being held for further processing.
Unit of Issue	Describes the packaging of the product.
Pathogen Reduction	Describes the method of sterilization or decontamination of the product.
Nominal Granule Size	Describes the size range of the product.
Demineralization	Indicates if a product was demineralized
Associated Structures	Describes all the non-human origin items distributed with the tissue that form a component of the product.
Bone Type	Describes the type of bone.
Bone Source	Describes the bone from which the graft was prepared.
Bone Part	Describes the part of the bone.
Bone Portion	Describes the portion of the bone or of the bone part.
Cartilage Presence	Indicates the presence or absence of cartilage with the bone.
Vertebral Type	Describes the source location of the vertebra.

4.3.2.2 Variables – Bounded Lists and Definitions

4.3.2.2.1 Additives

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	Additives are not specified in the coding.
Additives present	Additives:Yes	Additives are present. Additional information may be included in accompanying documentation.
Additives present including animal source	Additives:yes incl animal src	Additives present including animal source material. See accompanying documentation.
Albumin	Albumin	Human albumin is present.
Albumin and other additives present	Albumin + other	Human albumin is present. Other additives are also present. Additional information may be included in accompanying documentation.
Autologous Plasma	Autologous plasma	Plasma from the intended recipient is present.
Autologous plasma and additives present	Autologous plasma + other	Plasma from the intended recipient is present. Other additives are also present. Additional information may be included in accompanying documentation.
Third party donor plasma	3rd party donor plasma	Plasma from a donor other than the tissue donor or the intended recipient is present.
Third party donor plasma and additives present	3rd party donor plasma + other	Plasma from a donor other than the tissue donor or the intended recipient is present. Other additives are also present. Additional information may be included in accompanying documentation.

4.3.2.2.2 Additional Processing

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	Additional processing not specified.
Marrow depleted	Marrow depleted	Processed to deplete marrow.
Cleaned	Cleaned	Processed to remove extraneous tissue.
Cryomilled	Cryomilled	Milled in the frozen state.
Milled	Milled	Product is prepared by a grinding or milling action.
Reconstituted	Reconstituted	Restoration of a lyophilized product by the addition of liquid.
Suspended	Suspended	Dispersed through a carrier medium.

4.3.2.2.3 Donor-Intended Recipient Relationship

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	No information about relationship between donor and intended recipient is provided.
Allogeneic	Allogeneic	Donor and intended recipient are different individuals.
Autologous	Autologous	Donor and intended recipient are the same individual.

4.3.2.2.4 Skin Fenestration

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	Either this attribute group does not apply (tissue class is not skin) or no information about whether the skin has been fenestrated is provided.
Fenestrated:Holes	Fenestrated:Holes	The skin has been fenestrated with holes.
Fenestrated:Slits	Fenestrated:Slits	The skin has been fenestrated with slits.
Fenestrated:Slits and holes	Fenestrated:Slits and holes	The skin has been fenestrated with slits and holes.
Meshed 1:1	Meshed 1:1	The skin has been through a mesher to facilitate stretching.
Meshed 1:1.5	Meshed 1:1.5	Surface area of the skin is increased by creating a net or web to an expansion ratio of 1:1.5.*
Meshed 1:2	Meshed 1:2	Surface area of the skin is increased by creating a net or web to an expansion ratio of 1:2.*
Meshed 1:3	Meshed 1:3	Surface area of the skin is increased by creating a net or web to an expansion ratio of 1:3.*
Not fenestrated	Not fenestrated	The skin has not been fenestrated.

** Some suppliers may present the ratio in the reverse order (final:original) – e.g. 3:1 instead of 1:3.*

4.3.2.2.5 Storage Solution

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	No information is provided about storage solution.

Common Name	ISBT 128 Database Name	Definition
Antibiotic solution	Antibiotics	Stored in a solution containing antibiotics as a decontamination step. May include antifungal agents. Further details may be available in accompanying documentation.
DMSO	DMSO	Stored in a solution containing dimethylsulfoxide as a cryoprotectant. Dimethylsulfoxide is usually in the range 5-10%. A more specific concentration may be stated in text on the label or in the accompanying documentation.
Ethanol <=35%	Ethanol <=35%	Stored in less than or equal to 35% ethanol.
Ethanol >=70%	Ethanol >=70%	Stored in greater than or equal to 70% ethanol.
Low concentration glycerol	Glycerol (low conc)	Stored in a solution containing low concentration glycerol as a cryoprotectant. Glycerol is usually in the range of 5-10%. A more specific concentration may be stated in text on the label or in the accompanying documentation.
Saline	Saline	Stored in Saline.
Sodium Hyaluronate	Sodium Hyaluronate	Sodium hyaluronate.
Vitrification solution	Vitrification	Stored in a solution used in vitrification. Details may be provided in accompanying documentation.

4.3.2.2.6 Type of Preservation

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	No coded information is provided about the type of preservation. Details about the type of preservation may appear as text on the tissue container label or in accompanying documentation.
Cryopreserved	Cryopreserved	Preserved by freezing in the presence of a cryoprotectant and using a method validated to maintain cellular viability and/or preserve tissue matrix structure. The cryoprotectant may be specified using the storage solutions attribute group or may appear in text on the label.
Dehydrated	Dehydrated	Preserved in a dehydrated state, specific methodology not specified in the coding. Additional information may be included in accompanying documentation.
Freeze dried	Freeze dried	(Lyophilized) Preserved in a dried state achieved by freezing followed by sublimation of water under vacuum to very low residual moisture contents.

Common Name	ISBT 128 Database Name	Definition
Frozen	Frozen	Preserved by freezing, but without additives specifically to protect cells/matrix and/or without the controlled freezing conditions required for cryopreservation.
High concentration glycerol	Glycerol (high conc)	Immersed in sterile glycerol with a concentration of at least 85%.
Refrigerated	Refrigerated	Preserved by refrigeration. The tissue may be immersed in a storage solution. The storage solution may be specified using the storage solutions attribute group or may appear in text on the label.This value should not be used where the type of preservation is Glycerol (high concentration).
Solvent dehydrated	Solvent dehydrated	Preserved in a dehydrated state achieved through a multistate treatment with an organic solvent. Water is removed by the solvent resulting in very low residual moisture content.

4.3.2.2.7 Processed to Reduce Cellular Components

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	No information is provided regarding a process intended to reduce cellular components.
Cell reduction process	Cell reduction process:Yes	Product has undergone a processing step intended to reduce cellular components. Details may be provided in accompanying documentation.
No cell reduction process	Cell reduction process:No	Product has not undergone a processing step intended to reduce cellular components.

4.3.2.2.8 Anatomical Position (see note below)

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not applicable or not specified	Either the anatomical position is not applicable or not specified.
Anterior	Anterior	Anterior.
Left	Left	Product derived from donated tissue from the left side of the donor’s midsagittal plane.
Left anterior	Left anterior	Left anterior.
Left lateral	Left lateral	Left lateral.
Left medial	Left medial	Left medial.
Left posterior	Left posterior	Left posterior.
Posterior	Posterior	Posterior.

Common Name	ISBT 128 Database Name	Definition
Right	Right	Product derived from donated tissue from the right side of the donor's midsagittal plane.
Right anterior	Right anterior	Right anterior.
Right lateral	Right lateral	Right lateral.
Right medial	Right medial	Right medial.
Right posterior	Right posterior	Right posterior.

Note: As of February 2015 Tissue products were restructured to manage anatomical terms as attributes. Classes with anatomical descriptors were retired and replacement classes were added.

While in general right and left are best handled as attributes, a notable exception exists. Left and right will be attributes when this is the sole difference between the two products. If this is not the case, for example the heart left and right atrium, then left and right will remain a part of the class.

4.3.2.2.9 Processing Status

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not defined	No information is provided as to the status of the product.
For further processing	For further processing	Product produced as an intermediate stage. Not suitable for clinical use without further processing.

4.3.2.2.10 Unit of Issue

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not defined	No information is provided as to the packaging of the product.
Pack	Pack	Issued as a pack of multiple items – number of items not encoded, but may be specified on packaging.
Pack of 2	Pack2	Issued as a pack containing 2 items.
Pack of 4	Pack4	Issued as a pack containing 4 items.
Single	Single	Issued as a single item.

4.3.2.2.11 Pathogen Reduction

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	No information about pathogen reduction is provided.

Common Name	ISBT 128 Database Name	Definition
Antibiotics	Antibiotics	Treated with antibiotics as a decontamination step.
Combined process	Combined process	Multiple methods of sterilization or decontamination used. Further details available in accompanying documentation.
ETO	ETO	Sterilized by exposure to ethylene oxide gas in accordance with a validated sterilization process.
No pathogen reduction	No pathogen reduction	No pathogen reduction steps have been performed.
Pathogen reduced but method not specified	Pathogen reduced: Method NS	Tissue subjected to pathogen reduction process, method not specified. Details about pathogen reduction method may appear in text on the label.
Peracetic Acid	Peracetic Acid	Exposure to peracetic acid in accordance with a validated sterilization process.
Radiation sterilization	Radiation sterilization	Exposed to ionizing radiation in accordance with a validated sterilization process.

4.3.2.2.12 Nominal Granule Size

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not defined	No information as to granule size is provided.
Coarse > 4 mm ≤ 6 mm	Coarse >4<=6 mm	Granule size is greater than 4 mm and less than or equal to 6 mm.
Fine ≤ 2 mm	Fine <=2 mm	Granule size is less than or equal to 2 mm.
Fine Powder > 0.1 mm < 1.2 mm	Fine Powder >0.1<1.2 mm	Granule size is between 0.1 mm and 1.2 mm. More information may be specified on packaging.
Medium > 2 mm ≤ 4 mm	Medium >2<=4 mm	Granule size is greater than 2 mm and less than or equal to 4 mm.
Medium Powder ≥ 1.2 mm ≤2.0 mm	Medium Powder >=1.2<=2.0 mm	Granule size is between 1.2 mm and 2 mm. More information may be specified on packaging.
Mixed ≤ 4 mm	Mixed <=4 mm	Granule size is mixed up to 4 mm.
Mixed ≤ 6 mm	Mixed <=6 mm	Granule size is mixed up to 6 mm.
Mixed ≤ 8 mm	Mixed <=8 mm	Granule size is mixed up to 8 mm.
Mixed ≤ 12 mm	Mixed <=12 mm	Granule size is mixed up to 12 mm.
Ultrafine ≤ 1 mm	Ultrafine <=1 mm	Granule size is less than or equal to 1 mm.

4.3.2.2.13 Demineralization

Common Name	ISBT 128 Database Name	Definition
Default	Default: No or not applicable	Either this product is not demineralized or this attribute group does not apply.
Demineralized and mineralized	Demin/mineralized	Graft contains both demineralized and mineralized bone.
Demineralized: Yes	Demineralized: Yes	Graft is demineralized.

4.3.2.2.14 Associated Structures

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	No associated structures are specified.
Applicator	Applicator	An applicator is included.
Carrier and Applicator	Carrier and applicator	A carrier medium and applicator are included.
Suture	Suture	Pre-sutured graft.

4.3.2.2.15 Bone Type

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not applicable	This attribute group does not apply or a bone type is not specified.
Bicortical	Bicortical	Bone graft containing 2 surfaces covered by cortical bone.
Cancellous	Cancellous	Bone graft derived from cancellous bone.
Cortical	Cortical	Bone graft derived from cortical bone.
Cortico-cancellous	Cortico-cancellous	Bone graft derived from both cancellous and cortical bone. Relative amounts of each may be stated in text on the label.
Tricortical	Tricortical	Bone graft containing 3 surfaces covered by cortical bone.
Unicortical	Unicortical	Bone graft containing 1 surface covered by cortical bone.

4.3.2.2.16 Bone Source

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not applicable or not specified	Either this attribute group does not apply or the bone source is not specified.
Calcaneal	Calcaneal	Bone derived from the calcaneus.
Femoral	Femoral	Bone derived from the femur.
Fibular	Fibular	Bone derived from the fibula.
Humeral	Humeral	Bone derived from the humerus.
Iliac	Iliac	Bone derived from ilium.
Patellar	Patellar	Bone derived from patella.
Radial	Radial	Bone derived from the radius.
Talus	Talus	Bone derived from the talus.
Tibial	Tibial	Bone derived from the tibia.
Ulnar	Ulnar	Bone derived from the ulna.
Vertebral	Vertebral	Bone derived from the vertebra.

4.3.2.2.17 Bone Part

Common Name	ISBT 128 Database Name	Definition
Default	Default: Whole or not applicable	Either all of a bone or this attribute group does not apply.
Acetabulum	Acetabulum	Acetabulum of the bone.
Ala	Ala	Ala of the bone.
Body	Body	Body of the bone.
Condyle	Condyle	Condyle.
Crest	Crest	Crest of the bone.
Epiphysis, distal	Epiphysis, distal	Distal epiphysis.
Epiphysis, distal, with shaft	Epiphysis, distal, with shaft	Distal epiphysis with the whole or part of the shaft.

Common Name	ISBT 128 Database Name	Definition
Epiphysis, proximal	Epiphysis, proximal	Proximal epiphysis.
Epiphysis, proximal, without head	Epiphysis, proximal, without head	Proximal epiphysis without the head.
Epiphysis, proximal, with shaft	Epiphysis, proximal, with shaft	Proximal epiphysis with the whole or part of the shaft.
Epiphysis, proximal with shaft, without head	Epiphysis, proximal, with shaft, without head	Proximal epiphysis with shaft and without the head.
Glenoid	Glenoid	Glenoid of the bone.
Head	Head	Head of the bone.
Plateau	Plateau	Plateau of the bone.
Shaft	Shaft	All or part of the shaft of the long bone without the epiphyses.
Trochanter major	Trochanter major	Trochanter major.
Trochanter minor	Trochanter minor	Trochanter minor.
Whole, without head	Whole, without head	Whole, without the head.

4.3.2.2.18 Bone Portion

Common Name	ISBT 128 Database Name	Definition
Default	Default: Whole or not applicable	Either the portion of the bone is whole or this attribute group does not apply.
Partial	Partial	Partial.
Half	Half	Half.
Quarter	Quarter	Quarter.
Third	Third	Third.

4.3.2.2.19 Cartilage Presence

Common Name	ISBT 128 Database Name	Definition
Default	Default: No or not applicable	Either cartilage is not present on the bone or this attribute group does not apply.
Cartilage present	Cartilage: Yes	Cartilage is present.

4.3.2.2.20 Vertebral Type

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not applicable or not specified	Either this attribute group does not apply or the vertebral type is not specified.
Cervical	Cervical	Cervical vertebrae.
Lumbar	Lumbar	Lumbar vertebrae.
Sacral	Sacral	Sacral vertebrae.
Thoracic	Thoracic	Thoracic vertebrae.

5 Ocular

5.1 Class

Common Name	ISBT 128 Database Name	Definition
CONJUNCTIVA	CONJUNCTIVA	Transparent mucous membrane passing over the inner surface of the eyelids and reflected over the front part of the sclera.
CORNEA	CORNEA	Transparent anterior part of the outer fibrous coat of the eye bounded by an outer stratified epithelium and an inner monolayer of endothelial cells. The major refractive component of the eye.
LIMBAL TISSUE	LIMBAL TISSUE	Tissue bridging the junction between the cornea and sclera.
OCULAR TISSUE, NON-CLINICAL	OCULAR TISSUE, NON-CLINICAL	Ocular tissue that is not to be used for patient treatment/transplant either directly or as a starting material for regenerative medicine.
SCLERA	SCLERA	Fibrous white outer part of the eye remaining after excision of the corneoscleral disc and removal of intraocular content and extraneous surface tissue.
WHOLE EYE	WHOLE EYE	Whole eye, including intraocular contents unless otherwise specified. May include some conjunctiva.

5.2 Attribute Groups

Group Name	Description
Corneal Graft	Specifies the type of corneal graft.
Anatomical Position	Describes the relative position of the tissue in the donor's body prior to tissue procurement.
Storage State	Specifies the storage state of the tissue in the eye bank. Delivery conditions may vary.
Storage Solution	Specifies the solution in which the tissue is stored in the eye bank.
Endothelial Cell Density	An indicator of whether the endothelial cell density is included in the labeling.
Pathogen Reduction	Describes the method of sterilization, disinfection, or decontamination of the product.

Group Name	Description
Transport Solution	Specifies the solution in which the tissue is transported from the eye bank.
Portion	Describes the portion of the ocular tissue.
Whole Eye Type	Specifies types of Whole Eye.
Lamellar Layer Preparation	Describes the method used to prepare the corneal lamellar layer(s).
Type of Non-Clinical Tissue	Describes source of tissue that is not to be used for patient treatment/transplant either directly or as a starting material for regenerative medicine.
Delivery Mechanism	Describes the non-human component(s) that are included with the ocular tissue for aid in its administration.

5.2.1 Attribute Variables

5.2.1.1 Corneal Graft

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not applicable or not specified	Either this attribute group does not apply (tissue class is not Cornea) or the corneal graft type is not specified.
Anterior and posterior layers	Anterior and posterior layers	A prepared cornea where both the anterior and posterior layers are present.
Anterior layer	Anterior layer	Corneal stroma without endothelium. May include epithelium.
Bowman Layer	Bowman Layer	An amorphous, collagenous layer beneath the epithelial basal lamina merging into the anterior stroma.
Corneal button	Corneal button	Cornea with scleral rim removed.
Corneal ring	Corneal ring	A corneal button with a central hole.
Corneoscleral disc	Corneoscleral disc	Cornea excised with scleral rim which may include some conjunctiva.
Laser shaped	Laser shaped	Full-thickness cornea shaped to a specific edge profile using laser technology.
Posterior layer	Posterior layer	Endothelium on Descemet's membrane with or without a supporting layer of posterior stroma.

Common Name	ISBT 128 Database Name	Definition
Posterior layer with stroma	Posterior layer with stroma	Endothelium on Descemet's membrane with a supporting layer of posterior stroma.
Posterior layer without stroma	Posterior layer without stroma	Endothelium on Descemet's membrane without a supporting layer of posterior stroma.
Posterior stromal layer	Posterior stromal layer	Posterior layer of stroma without Descemet/Endothelium complex. May include Dua's layer.
Split cornea	Split cornea	Split thickness, lamellar layers unspecified.
Stromal ring segment	Stromal ring segment	Stromal ring segment in which the epithelium and endothelium are removed.

5.2.1.2 Anatomical Position

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	No information is provided as to the relative position of the tissue in the donor's body prior to tissue procurement.
Left	Left	Product originated from donated tissues from the left side of the donor's midsagittal plane.
Right	Right	Product originated from donated tissues from the right side of the donor's midsagittal plane.

5.2.1.3 Storage State

Common Name	ISBT 128 Database Name	Definition
Default	Default: No information provided	No coded information about storage state is provided. Details may appear in text on the tissue container label or in accompanying documentation.
Ambient storage	Ambient storage	Stored in a solution at ambient temperature.
Cryopreserved	Cryopreserved	Preserved by freezing or vitrification in the presence of a cryoprotectant and using a method validated to maintain cellular viability and/or preserve tissue matrix structure. The information about the cryoprotectant may be specified using the storage solutions attribute group or on the tissue container label or in accompanying documentation.

Common Name	ISBT 128 Database Name	Definition
Freeze dried	Freeze dried	(Lyophilized) Preservation in the dried state achieved by freezing followed by sublimation of water under vacuum to very low residual moisture content.
Frozen	Frozen	Stored in the frozen state, but without additives specifically to protect cells/matrix and/or without the controlled freezing conditions required for cryopreservation.
Hypothermic storage	Hypothermic storage	Stored in a solution at 2 to 8°C.
Moist chamber	Moist chamber	Whole eye stored at 2 to 8°C in a humid environment.
Organ culture	Organ culture	Stored in a nutrient medium at 28 to 37°C.

5.2.1.4 Storage Solution

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	No coded information about the storage solution is provided. Details about the storage solution may appear as text on the tissue container label or in accompanying documentation.
Albumin	Albumin	Human-source albumin.
Antimicrobial solution	Antimicrobial solution	Solution containing antibiotics and may contain antimycotics.
Cryoprotectant medium	Cryoprotectant medium	Medium containing a cryoprotectant compound.
Ethanol	Ethanol	≥70% ethanol.
High Concentration Glycerol	Glycerol (high conc)	Sterile glycerol with a concentration of at least 85%.
No storage solution	No storage solution	No storage solution.
Nutrient medium	Nutrient medium	Tissue culture medium.
Recombinant albumin	Recombinant albumin	Albumin manufactured through a recombinant process.
Saline	Saline	Isotonic saline or balanced salt solution that may include antibiotics.

5.2.1.5 Endothelial Cell Density

Common Name	ISBT 128 Database Name	Definition
Default	Default: No information provided	No information about the endothelial cell density is provided.
Cell density information provided	Cell density info provided	Information about endothelial cell density is included in the labeling.

5.2.1.6 Pathogen Reduction

Common Name	ISBT 128 Database Name	Definition
Default	Default: No information	No information about pathogen reduction is provided.
No pathogen reduction	No pathogen reduction	No pathogen reduction steps have been performed.
Pathogen reduced but method not specified	Pathogen reduced: Method NS	Tissue subjected to pathogen reduction process, method not specified. Details about pathogen reduction method may appear in text on the label.
Radiation sterilization	Radiation sterilization	Exposed to ionizing radiation in accordance with a validated sterilization process.

5.2.1.7 Transport Solution

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	No transport solution is specified in the coding.
Dextran	Dextran	Dextran. Concentration may be specified in the accompanying documentation.

5.2.1.8 Portion

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	Information not specified in the coding. May be specified in accompanying documentation.
Eighth	Eighth	Eighth.
Half	Half	Half.

Common Name	ISBT 128 Database Name	Definition
Part, NS	Part, NS	Part but portion not specified.
Quarter	Quarter	Quarter.
Sixth	Sixth	Sixth.
Third	Third	Third.
Whole	Whole	Whole.

5.2.1.9 Whole Eye Type

Common Name	ISBT 128 Database Name	Definition
Default	Default: not applicable or not specified	Either this attribute group does not apply (tissue class is not Whole Eye) or the type of whole eye is not specified.
Contents removed	Contents removed	Whole eye with intraocular contents removed and an opening at the previous site of insertion of the optic nerve, or elsewhere, used for the removal of the intraocular contents.

5.2.1.10 Lamellar Layer Preparation

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not applicable or not specified	The method of preparation of lamellar layer(s) is not specified or this Attribute group does not apply. The Attribute group would not apply either because the tissue is not cornea or because the cornea is a full-thickness cornea that has not been divided into lamellar layers.
Laser	Laser	A laser was used to prepare the lamellar layer(s).
Manual dissection	Manual dissection	Manual dissection (separation by cutting, peeling, or stripping) was used to prepare the lamellar layer(s).
Microkeratome	Microkeratome	A microkeratome was used to prepare the lamellar layer(s).

5.2.1.11 Type of Non-Clinical Tissue

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not applicable or not specified	Tissue is for clinical use or, if for non-clinical use, type of non-clinical tissue is not encoded.
Aqueous humor	Aqueous humor	Transparent fluid located in the anterior and posterior chambers of the eye (i.e., the space between the lens and the cornea).
Cornea	Cornea	Tissue from all or part of the cornea.
Iris	Iris	Tissue from all or part of the iris, the diaphragm of pigmented tissue between the cornea and the lens that controls the amount of light entering the eye by adjusting the diameter of the pupil, its central orifice.
Lens	Lens	Tissue from all or part of the lens, the transparent, biconvex body located between the iris and the vitreous body and connected to the ciliary body by suspensory ligament. Contraction of ciliary muscles changes lens shape and thus refractive power of the eye (accommodation).
Optic nerve	Optic nerve	Retinal ganglion cell axons converge towards the optic disc and pass through the sclera and out of the eye at the lamina cribrosa to form the optic nerve with a diameter of 3-4 mm. Passes out of the orbit through the optic canal.
Meibum	Meibum	Oil produced by the meibomian glands.
Posterior part	Posterior part	Whole eye with the corneoscleral disc removed.
Retina	Retina	Tissue from all or part of the retina, the neural light-sensitive layer lining the inner surface of the eye from the optic disc to the ora serrata and whose external surface is in contact with the choroid.
Vitreous humor	Vitreous humor	Transparent gel located in the posterior segment (vitreous cavity) of the eye (i.e., large space between the lens and the retina).

5.2.1.12 Delivery Mechanism

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not applicable or not specified	Either this attribute group does not apply, or no non-human components are specified for aid in the administration of the ocular tissue.
Preloaded	Preloaded	Tissue preloaded in a delivery apparatus.

6 Plasma Derivatives

Plasma derivatives are defined as “A product that contains concentrated fractions of plasma proteins that have been separated using physico-chemical or other fractionation processes. It is made from pooling plasma from large numbers of donors and is traced based on the lot or batch number of the pooled product.”

It is recommended that those products for which ABO blood group is not relevant (e.g., Rh Immune Globulin or Gamma Globulin) be labeled with GS1 bar codes. Conversely, plasma derivatives for which the ABO blood group is relevant should be labeled with ISBT 128. See Bar Coding Plasma Derivatives, Implementation Guide, Issue #1.0 (http://www.gs1.org/sites/default/files/docs/barcodes/BD_Implementation_Guide_v1_0_24_aug_2010.pdf) for further information.

6.1 Class

6.1.1 Bounded Lists and Definitions

Common Name	ISBT 128 Database Name	Definition
SOLVENT DETERGENT POOLED PLASMA	SOLVENT DETERGENT POOLED PLASMA	Plasma that has been prepared by combining multiple units from single donors; pathogen-inactivating using a solvent detergent (SD) process with subsequent removal of the SD reagents; aliquotting into individual dose containers; and freezing by a process and to a temperature that will maintain the activity of labile protein fractions.

6.2 Modifier

6.2.1 Bounded Lists and Definitions

Common Name	ISBT 128 Database Name	Definition
Thawed	Thawed	A product that is currently in the liquid state but has been previously frozen.

6.3 Attribute

Note: Both Plasma Derivatives and In Vivo Diagnostic MPHO (Medical Products of Human Origin) are in the Other Blood Products category. They therefore share attribute groups and variables; not all variables are applicable for Plasma Derivatives. Attribute Groups and Variables that are not applicable are shaded in gray.

6.3.1 Core Conditions

Please see Section 2.3.1. for an explanation of Core Conditions.

6.3.1.1 Core Conditions Lists and Definitions

First Position (anticoagulant/additive) – Bounded List

Common Name	ISBT 128 Database Name	Definition
Not specified	NS	Not specified.
ACD-A	ACD-A	Acid Citrate Dextrose, Formula A.
ACD-A-HES	ACD-A-HES	Acid Citrate Dextrose, Formula A – Hydroxyethyl starch.
Heparin-HES	Heparin-HES	Heparin – Hydroxyethyl starch.

Note: ACD-A, ACD-A-HES, Heparin-HES are not valid anticoagulant/additives for Plasma Derivatives.

Second Position (volume) – This list is not bounded, other volumes may be defined.

Common Name	ISBT 128 Database Name	Definition
Not specified	NS	Not specified.

Third Position (storage temperature) – This list is not bounded, other temperature ranges may be defined.

Common Name	ISBT 128 Database Name	Definition
≤ -18 C	<=-18C	Less than or equal to -18 degrees Celsius.
Refrigerated	refg	Refrigerated (between 1 to 10 degrees Celsius; narrower range may be nationally specified).
Room temperature	rt	Ambient room temperature (a specific range may be nationally-specified).

6.3.2 Groups and Variables

Additional information about a product is supplied as attributes. Such attributes are indicated by a different Product Description Code.

6.3.2.1 Groups: Bounded List and Definitions

Group Name	Description
Blood Group	Specifies ABO Blood Group and/or RhD type.
Altered	Describes the physical or chemical means for changing the composition or structure of the product.
Donor-Intended Recipient Relationship	Describes the relationship between the donor and the intended recipient.

Note: Altered and Donor-Intended Recipient Relationship are not applicable Attribute Groups for Plasma Derivatives.

6.3.2.2 Variables – Bounded Lists and Definitions

6.3.2.2.1 Blood Group

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	The blood group is not specified.
O	O	The product is prepared from Group O donations.
A	A	The product is prepared from Group A donations.
B	B	The product is prepared from Group B donations.
AB	AB	The product is prepared from Group AB donations.
ABO independent	ABO independent	A product prepared from a pool of plasma of different ABO groups in which the anti-A and anti-B antibodies have been neutralized.

6.3.2.2.2 Altered

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	Information about the physical or chemical means for changing the composition or structure of the product is not specified.
Heat-Denatured	Heat denatured	The product has been heat-denatured for an unspecified amount of time.

Note: Altered is not an applicable Attribute Group for Plasma Derivatives, table included for completeness.

6.3.2.2.3 Donor-Intended Recipient Relationship

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	No information about relationship between donor and intended recipient is provided.
Autologous	Autologous	Donor and intended recipient are the same individual.

Note: Donor-Intended Recipient Relationship is not an applicable Attribute Group for Plasma Derivatives, table included for completeness.

7 In Vivo Diagnostic MPHO

7.1 Class

7.1.1 Bounded Lists and Definitions

Common Name	ISBT 128 Database Name	Definition
RADIOLABELED DIAGNOSTICS, LEUKOCYTES	RADIOLABELED DIAGNOSTICS, LEUKOCYTES	A radiolabeled product for diagnostic purposes in which the major cellular component is leukocytes.
RADIOLABELED DIAGNOSTICS, PLATELETS	RADIOLABELED DIAGNOSTICS, PLATELETS	A radiolabeled product for diagnostic purposes in which the major cellular component is platelets.
RADIOLABELED DIAGNOSTICS, RED BLOOD CELLS	RADIOLABELED DIAGNOSTICS, RBC	A radiolabeled product for diagnostic purposes in which most of the plasma has been removed from blood.

7.2 Modifier

7.2.1 Bounded Lists and Definitions

Common Name	ISBT 128 Database Name	Definition
Thawed	Thawed	A product that is currently in the liquid state but has been previously frozen.

Note: Thawed is not an applicable Modifier for In Vivo Diagnostic MPHO.

7.3 Attribute

Note: Both Plasma Derivatives and In Vivo Diagnostic MPHO (Medical Products of Human Origin) are in the Other Blood Products category. They therefore share attribute groups and variables; not all variables are applicable for Plasma Derivatives. Attribute Groups and Variables that are not applicable are shaded in gray.

7.3.1 Core Conditions

Please see Section 2.3.1 for an explanation of Core Conditions.

7.3.1.1 Core Conditions lists and definitions

First Position (anticoagulant/additive) – Bounded List

Common Name	ISBT 128 Database Name	Definition
Not specified	NS	Not specified.
ACD-A	ACD-A	Acid Citrate Dextrose, Formula A.
ACD-A-HES	ACD-A-HES	Acid Citrate Dextrose, Formula A – Hydroxyethyl starch.
Heparin-HES	Heparin-HES	Heparin – Hydroxyethyl starch.

Second Position (volume) – This list is not bounded, other volumes may be defined.

Common Name	ISBT 128 Database Name	Definition
Not specified	NS	Not specified

Third Position (storage temperature) – This list is not bounded, other temperature ranges may be defined.

Common Name	ISBT 128 Database Name	Definition
≤ -18 C	<=-18C	Less than or equal to -18 degrees Celsius.
Refrigerated	refg	Refrigerated (between 1 to 10 degrees Celsius; narrower range may be nationally specified).
Room temperature	rt	Ambient room temperature (a specific range may be nationally-specified).

7.3.2 Groups and Variables

Additional information about a product is supplied as attributes. Such attributes are indicated by a different Product Description Code.

7.3.2.1 Groups: Bounded List and Definitions

Group Name	Description
Blood Group	Specifies ABO Blood Group and/or RhD type.
Altered	Describes the physical or chemical means for changing the composition or structure of the product.
Donor-Intended Recipient Relationship	Describes the relationship between the donor and the intended recipient.

7.3.2.2 Variables – Bounded Lists and Definitions

7.3.2.2.1 Blood Group

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	The blood group is not specified.
O	O	The product is prepared from Group O donations.
A	A	The product is prepared from Group A donations.
B	B	The product is prepared from Group B donations.
AB	AB	The product is prepared from Group AB donations.
ABO independent	ABO independent	A product prepared from a pool of plasma of different ABO groups in which the anti-A and anti-B antibodies have been neutralized.

7.3.2.2.2 Altered

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	Information about the physical or chemical means for changing the composition or structure of the product is not specified.
Heat-Denatured	Heat denatured	The product has been heat-denatured for an unspecified amount of time.

7.3.2.2.3 Donor-Intended Recipient Relationship

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	No information about relationship between donor and intended recipient is provided.
Autologous	Autologous	Donor and intended recipient are the same individual.

8 Human Milk

8.1 Class

8.1.1 Human Milk

Common Name	ISBT 128 Database Name	Definition
HUMAN MILK	HUMAN MILK	Milk from a human donor.

8.2 Attribute Groups

Note: Both Human Milk and Topical Products of Human Origin are in the Other Therapies category. They therefore share attribute groups and variables; not all variables are valid for Human Milk. Invalid Attribute Groups and Variables are shaded in gray.

Group Name	Description
Storage Conditions	Describes the temperature at which the product should be stored.
Pathogen Reduction Status	Describes the status of sterilization or decontamination of the product.
Processing Status	Describes the status of the product in regard to its acceptability for use.
Additives	Describes additives introduced during the processing of the product.
Donor-Intended Recipient Relationship	Describes the relationship between the donor and the intended recipient.
Milk Type	Describes the type of milk in the product.
Pooling Status	Describes whether or not the product is a combination of multiple collections from the same donor or multiple donors.
Preparation	Describes additional processing steps.
Nutritional Additives	Indicates nutrients have been introduced during the processing of the product. More information is provided in the packaging.
Dietary Characteristics	Indicates if the dietary characteristics of the donor are provided in the packaging.
Calorie Count	Indicates if a calorie count of the product is provided in the packaging.
Nutritional Analysis	Indicates if the nutrient content of the product is provided in the packaging.

Group Name	Description
Donor Classification	Describes the classification of the donor.
Eye Drops Source	Describes the MPHO product from which the eye drops were prepared.

Note: Gray values are not valid attribute groups for Human Milk.

8.2.1 Attribute Variables

8.2.1.1 Storage Conditions

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	Storage conditions not encoded. May be present in text on the label.
0 to 4C	0-4C	Stored between 0 degrees Celsius and 4 degrees Celsius.
≤-18 C	<=-18C	Product stored at <=-18 degrees Celsius.
≤-20 C	<=-20C	Product stored at <=-20 degrees Celsius.
≤-25 C	<=-25C	Product stored at <=-25 degrees Celsius.
≤-30 C	<=-30C	Product stored at <=-30 degrees Celsius.
≤-70 C	<=-70C	Product stored at <=-70 degrees Celsius.
20-24 C	20-24C	Stored between 20-24 degrees Celsius.
Freeze dried	Freeze dried	Preservation in a freeze dried state achieved by freezing follwed by sublimation of water under vacuum to very low residual moisture contents.
Frozen	Frozen	Product stored in the frozen state.
Refrigerated	Refg	Stored between 1 and 10 degrees Celsius; range may be less depending on national requirements.
Thawed	Thawed	A product that is currently in a liquid state but that has been previously frozen. Post thaw storage shall be in compliance with supplier facility's policy.

8.2.1.2 Pathogen Reduction Status

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	The pathogen reduction status of the product is not specified.
Pasteurized	Pasteurized	The product has been pasteurized in accordance with national guidelines.
Raw	Raw	No pathogen reduction process has been performed.

8.2.1.3 Processing Status

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	No information is provided as to the processing status of the product.
For further processing	For further processing	The product is in an intermediate stage. Not suitable for use without further processing.
For nutritional use	For nutritional use	The product is acceptable for nutritional use.
Not for clinical use	Not for clinical use	The product is not intended for patient use.

8.2.1.4 Additives

Common Name	ISBT 128 Database Name	Definition
Default	Default: Additive Not Present	Additives are not present.
PAS-F	PAS-F	Platelet additive solution F. See Table of Platelet Additive Solutions in section 2.3.1.
Saline	Saline	0.9% NaCl added.

Note: Gray values are not valid attributes for Human Milk.

8.2.1.5 Donor-Intended Recipient Relationship

Common Name	ISBT 128 Database Name	Definition
Default	Default: Allogeneic	Donor and intended recipient are different individuals.
Autologous	Autologous	Donor and intended recipient are the same individual.

Common Name	ISBT 128 Database Name	Definition
Maternal	Maternal	The donor is the mother of the intended recipient.
Specified recipient	Specified recipient	The donor has provided milk for a specific recipient.

Note: Gray values are not valid attributes for Human Milk.

8.2.1.6 Milk Type

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	No additional information on the type of milk or not applicable because product is not human milk.
Colostrum	Colostrum	Expressed ante-natally and during the first few days post-partum prior to the onset of Lactogenesis II. May be more specifically defined by the supplying milk bank.
Pre-term	Pre-term	Expressed within the first 4 weeks post-partum by a mother delivered at or before 36 weeks gestation.
Term	Term	Expressed after 36 weeks gestation or before 36 weeks but after 4 weeks post-partum.

8.2.1.7 Pooling Status

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	No information is provided on the pooling status.
Pooled, <7 donors	Pooled, <7 donors	Sourced from a pool of no more than six donors.
Pooled, donors ≥7	Pooled, donors >=7	Sourced from a pool of greater than or equal to 7 donors.
Pooled, single donor	Pooled, single donor	Sourced from multiple expressions from a single donor.
Single donor expression	Single donor expression	Sourced from a single expression from a single donor.

8.2.1.8 Preparation

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	No additional preparation is specified.
Fat reduced	Fat reduced	Product has been centrifuged and the cream layer has been removed.

8.2.1.9 Nutritional Additives

Common Name	ISBT 128 Database Name	Definition
Default	Default: Nutrients not added	Nutrient additives are not present in the product.
Nutrients added	Nutrients added	Nutrients have been added to the product. Additional information may appear in text on label or in accompanying documentation.

8.2.1.10 Dietary Characteristics

Common Name	ISBT 128 Database Name	Definition
Default	Default: Dietary characteristics NS	No special dietary characteristics are specified.
Special dietary characteristics	Special dietary characteristics: Yes	Product expressed by a mother who has declared special dietary characteristics. Additional information may appear in text on label or in accompanying documentation.

8.2.1.11 Calorie Count

Common Name	ISBT 128 Database Name	Definition
Default	Default: Specified calorie value NS	A calorie value is not specified.
Calorie value specifed	Specified calorie value: Yes	A calorie value has been determined. Additional information may appear in text on label or in accompanying documentation.

8.2.1.12 Nutritional Analysis

Common Name	ISBT 128 Database Name	Definition
Default	Default: Nutritional analysis NS	Nutrient content of the product is not specified.
Nutritional analysis specified	Specified nutritional analysis: Yes	The nutrient content of the product has been analyzed. Additional information may appear in text on label or in accompanying documentation.

8.2.1.13 Donor Classification

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	Donor classification is not specified in the coding.
Volunteer donor	Volunteer donor	Donor provided milk without monetary compensation beyond the reimbursement of reasonable expenses.
Paid donor	Paid donor	Donor received payment for providing milk greater than the reimbursement of reasonable expenses.

8.2.1.14 Eye Drops Source

Common Name	ISBT 128 Database Name	Definition
Default	Default: No information or not applicable	Either no information is provided as to the source of the eye drops or this attribute group does not apply (the class is not Eye Drops).
Cord Blood Platelet Lysate	Cord blood platelet lysate	Eye drops prepared from cord blood platelet lysate.
Plasma	Plasma	Eye drops prepared from plasma. See accompanying documentation for anticoagulant and other details.
Platelet Lysate	Platelet lysate	Eye drops prepared from platelet lysate.
Serum	Serum	Eye drops prepared from serum.

Note: Gray values are not valid attributes for Human Milk.

9 Topical Products of Human Origin

9.1 Class

Common Name	ISBT 128 Database Name	Definition
EYE DROPS	EYE DROPS	A liquid product intended for application onto the ocular surface.
FIBRIN SEALANT	FIBRIN SEALANT	A product comprising separate containers of thrombin and a source of fibrinogen that are intended for simultaneous application. The product may also include a delivery device. (Note: This product may also be used as a matrix in cellular therapy/regenerated tissue procedures. In this situation, it would be coded as an Attribute, not as a Class.)
SERUM, DILUTED	SERUM, DILUTED	The liquid portion of blood following the completion of the clotting process intended to be processed into a product for topical application.

9.2 Attribute Groups

Note: Both Human Milk and Topical Products of Human Origin are in the Other Therapies category. They therefore share attribute groups and variables; not all variables are valid for Topical products. Invalid Attribute Groups and Variables are shaded in gray.

Group Name	Description
Storage Conditions	Describes the temperature at which the product should be stored.
Pathogen Reduction Status	Describes the status of sterilization or decontamination of the product.
Processing Status	Describes the status of the product in regard to its acceptability for use.
Additives	Describes additives introduced during the processing of the product.
Donor-Intended Recipient Relationship	Describes the relationship between the donor and the intended recipient.
Milk Type	Describes the type of milk in the product.
Pooling Status	Describes whether or not the product is a combination of multiple collections from the same donor or multiple donors.

Group Name	Description
Preparation	Describes additional processing steps.
Nutritional Additives	Indicates nutrients have been introduced during the processing of the product. More information is provided in the packaging.
Dietary characteristics	Indicates if the dietary characteristics of the donor are provided in the packaging.
Calorie Count	Indicates if a calorie count of the product is provided in the packaging.
Nutritional Analysis	Indicates if the nutrient content of the product is provided in the packaging.
Donor Classification	Describes the classification of the donor.
Eye Drops Source	Describes the MPHO product from which the eye drops were prepared.

9.2.1 Attribute Variables

9.2.1.1 Storage Conditions

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	Storage conditions not encoded. May be present in text on the label.
0 to 4C	0-4C	Stored between 0 degrees Celsius and 4 degrees Celsius.
≤-18 C	<=-18C	Product stored at <=-18 degrees Celsius.
≤-20 C	<=-20C	Product stored at <=-20 degrees Celsius.
≤-25 C	<=-25C	Product stored at <=-25 degrees Celsius.
≤-30 C	<=-30C	Product stored at <=-30 degrees Celsius.
≤-70 C	<=-70 C	Product stored at <=-70 degrees Celsius.
20-24 C	20-24C	Stored between 20-24 degrees Celsius.
Freeze dried	Freeze dried	Preservation in a freeze dried state achieved by freezing follwed by sublimation of water under vacuum to very low residual moisture contents.
Frozen	Frozen	Product stored in the frozen state.
Refrigerated	Refg	Stored between 1 and 10 degrees Celsius; range may be less depending on national requirements.
Thawed	Thawed	A product that is currently in a liquid state but that has been previously frozen. Post thaw storage shall be in compliance with supplier facility's policy.

Note: Gray values are not valid attributes for Topical Products of Human Origin.

9.2.1.2 Pathogen Reduction Status

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	The pathogen reduction status of the product is not specified.
Pasteurized	Pasteurized	The product has been pasteurized in accordance with national guidelines.
Raw	Raw	No pathogen reduction process has been performed.

Note: Gray values are not valid attributes for Topical Products of Human Origin.

9.2.1.3 Processing Status

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	No information is provided as to the processing status of the product.
For further processing	For further processing	The product is in an intermediate stage. Not suitable for use without further processing.
For nutritional use	For nutritional use	The product is acceptable for nutritional use.
Not for clinical use	Not for clinical use	Not for clinical use.

Note: Gray values are not valid attributes for Topical Products of Human Origin.

9.2.1.4 Additives

Common Name	ISBT 128 Database Name	Definition
Default	Default: Additive Not Present	Additives are not present.
PAS-F	PAS-F	Platelet additive solution F. See Table of Platelet Additive Solutions in section 2.3.1.
Saline	Saline	0.9% NaCl added.

9.2.1.5 Donor-Intended Recipient Relationship

Common Name	ISBT 128 Database Name	Definition
Default	Default: Allogeneic	Donor and intended recipient are different individuals.
Autologous	Autologous	Donor and intended recipient are the same individual.
Maternal	Maternal	The donor is the mother of the intended recipient.
Specified recipient	Specified recipient	The donor has provided milk for a specific recipient.

Note: Gray values are not valid attributes for Topical Products of Human Origin.

9.2.1.6 Milk Type

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	No additional information on the type of milk or not applicable because product is not human milk.
Colostrum	Colostrum	Expressed ante-natally and during the first few days post-partum prior to the onset of Lactogenesis II. May be more specifically defined by the supplying milk bank.
Pre-term	Pre-term	expressed within the first 4 weeks post-partum by a mother delivered at or before 36 weeks gestation.
Term	Term	expressed after 36 weeks gestation or before 36 weeks but after 4 weeks post-partum.

Note: Gray values are not valid attributes for Topical Products of Human Origin.

9.2.1.7 Pooling Status

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	No information is provided on the pooling status.
Pooled, <7 donors	Pooled, <7 donors	Sourced from a pool of no more than six donors.
Pooled, donors ≥7	Pooled, donors >=7	Sourced from a pool of greater than or equal to 7 donors.
Pooled, Single donor	Pooled, Single donor	Sourced from multiple expressions from a single donor.
Single donor expression	Single donor expression	Sourced from a single expression from a single donor.

Note: Gray values are not valid attributes for Topical Products of Human Origin.

9.2.1.8 Preparation

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not Specified	No additional preparation is specified.
Fat Reduced	Fat Reduced	Product has been centrifuged and the cream layer has been removed.

Note: Gray values are not valid attributes for Topical Products of Human Origin.

9.2.1.9 Nutritional Additives

Common Name	ISBT 128 Database Name	Definition
Default	Default: Nutrients not added	Nutrient additives are not present in the product.
Nutrients added	Nutrients added	Nutrients have been added to the product. Additional information may appear in text on label or in accompanying documentation.

Note: Gray values are not valid attributes for Topical Products of Human Origin.

9.2.1.10 Dietary Characteristics

Common Name	ISBT 128 Database Name	Definition
Default	Default: Dietary characteristics not specified	No special dietary characteristics are specified.
Special dietary characteristics	Special dietary characteristics: Yes	Product expressed by a mother who has declared special dietary characteristics. Additional information may appear in text on label or in accompanying documentation.

Note: Gray values are not valid attributes for Topical Products of Human Origin.

9.2.1.11 Calorie Count

Common Name	ISBT 128 Database Name	Definition
Default	Default: Specified calorie value NS	A calorie value is not specified.
Calorie value specifed	Specified calorie value: Yes	A calorie value has been determined. Additional information may appear in text on label or in accompanying documentation.

Note: Gray values are not valid attributes for Topical Products of Human Origin.

9.2.1.12 Nutritional Analysis

Common Name	ISBT 128 Database Name	Definition
Default	Default: Nutritional analysis NS	Nutrient content of the product is not specified.
Specified nutritional analysis	Specified Nutritional analysis: Yes	The nutrient content of the product has been analyzed. Additional information may appear in text on label or in accompanying documentation.

Note: Gray values are not valid attributes for Topical Products of Human Origin.

9.2.1.13 Donor Classification

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	Donor classification is not specified in the coding.
Volunteer donor	Volunteer donor	Donor provided milk without monetary compensation beyond the reimbursement of reasonable expenses.
Paid donor	Paid donor	Donor received payment for providing milk greater than the reimbursement of reasonable expenses.

Note: Gray values are not valid attributes for Topical Products of Human Origin.

9.2.1.14 Eye Drops Source

Common Name	ISBT 128 Database Name	Definition
Default	Default: No information or not applicable	Either no information is provided as to the source of the eye drops or this attribute group does not apply (the class is not Eye Drops).
Cord Blood Platelet Lysate	Cord blood platelet lysate	Eye drops prepared from cord blood platelet lysate.
Plasma	Plasma	Eye drops prepared from plasma. See accompanying documentation for anticoagulant and other details.
Platelet Lysate	Platelet lysate	Eye drops prepared from platelet lysate.
Serum	Serum	Eye drops prepared from serum.

10 Fecal Microbiota

10.1 Class

Common Name	ISBT 128 Database Name	Definition
FECAL MICROBIOTA	FECAL MICROBIOTA	A product containing fecal microorganisms from a human donor.

10.2 Attribute Groups

Group Name	Description
Storage State	Describes the storage state in which the product is maintained.
Cryoprotectant	Describes the cryoprotectant in the product.
Additional Information	Provides supplementary information about the preparation of a product.

10.2.1 Attribute Variables

10.2.1.1 Storage State

Common Name	ISBT 128 Database Name	Definition
Default	Default: No information provided	No coded information about the storage state is provided. Details may appear in text on the container label or in accompanying documentation.
Cryopreserved	Cryopreserved	Preserved by freezing in the presence of a cryoprotectant and using a method validated to maintain cellular viability.
Thawed	Thawed	A product that is currently in the liquid state but has been previously cryopreserved.

10.2.1.2 Cyoprotectant

Common Name	ISBT 128 Database Name	Definition
Default	Default: None or not specified	Either there is no cryoprotectant present or the cryoprotectant is not specified in the coding.
Glycerol	Glycerol	Glycerol has been added to the product as a cryoprotectant. The concentration of glycerol is not specified in the coding. A specific concentration may be stated in text on the label or in the accompanying documentation.

10.2.1.3 Additional Information

Common Name	ISBT 128 Database Name	Definition
Default	Default: No additional info	There is no additional information about the preparation of the product.
Oral preparation	Oral prep	Product processed to make it suitable for ingestion.
Syringe preparation	Syringe prep	Product processed to make it suitable for syringe delivery.

11 Reproductive

11.1 Class

Common Name	ISBT 128 Database Name	Definition
EMBRYO	EMBRYO	The biological organism resulting from the development of the zygote, until eight completed weeks after fertilization, equivalent to 10 weeks of gestational age.
OOCYTE	OOCYTE	The female gamete .
OVARIAN TISSUE	OVARIAN TISSUE	Fragment of the ovary.
SPERM	SPERM	The male gamete.
TESTICULAR TISSUE	TESTICULAR TISSUE	Fragment of testicular tissue.
ZYGOTE	ZYGOTE	A single cell resulting from fertilization of a mature oocyte by a spermatozoon and before completion of the first mitotic division.

11.2 Attribute Groups

Group Name	Description
Type of Preservation	Describes the technique used to preserve the tissue or cells.
Sperm Procurement Method	Describes the method used to procure sperm.
Oocyte Maturation Stage	Describes the stage of maturation of the oocyte.
Embryo Development Stage	Describes the stage of development of the embryo.
Embryo Preservation Day	Indicates the number of days following insemination on which the embryo was preserved (calendar days).
Sperm Preparation	Provides information about the preparation of sperm.
Unit of Issue	Describes the packaging of the product.

11.2.1 Attribute Variables

11.2.1.1 Type of Preservation

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	No coded information is provided about the type of preservation. Details about the type of preservation may appear as text on the tissue or cells container label or in accompanying documentation.
Cryopreserved by slow active freezing	Cryopreserved by slow active freezing	Product cryopreserved using a computerized controlled-rate freezer.
Cryopreserved by slow passive freezing	Cryopreserved by slow passive freezing	Product cryopreserved without using a computerized controlled-rate freezer.
Cryopreserved by vitrification	Cryopreserved by vitrification	Product cryopreserved using a technique that leads to a glass-like solidification.
Not cryopreserved	Not cryopreserved	Fresh or refrigerated product.

11.2.1.2 Sperm Procurement Method

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	Collection or recovery method is not specified, or not applicable (i.e., product is not sperm).
Aspirated epididymal	Aspirated epididymal	Sperm procured by aspiration from epididymis.
Aspirated testicular	Aspirated testicular	Sperm procured by percutaneous aspiration from testis.
Biopsy testicular	Biopsy testicular	Sperm procured by biopsy of testis.
Ejaculated	Ejaculated	Sperm procured from ejaculate.

11.2.1.3 Oocyte Maturation Stage

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	No information about the oocyte maturation stage is provided OR not applicable (i.e., product is not an oocyte).
Immature	Immature	An oocyte at prophase of meiosis I (i.e. an oocyte at the germinal vesicle (GV) stage).

Common Name	ISBT 128 Database Name	Definition
Mature	Mature	An oocyte at metaphase of meiosis II, exhibiting the first polar body and with the ability to become fertilized.
Maturing	Maturing	An oocyte that has progressed from prophase I but has not completed telophase I, thus does not exhibit the first polar body.

11.2.1.4 Embryo Development Stage

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	No information about the embryo development stage is provided OR not applicable (i.e., product is not an embryo).
Blastocyst	Blastocyst	Embryo at the blastocyst stage, containing a fluid filled central cavity, an outer layer of cells and an inner group of cells. Typically occurs at day 5–6 after insemination.
Cleavage stage	Cleavage stage	Embryo beginning at the two cell stage and up to, but not including, the morula stage.
Morula	Morula	Embryo after completion of compaction, typically 4 days after insemination or ICSI.

11.2.1.5 Embryo Preservation Day

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	No information about the embryo preservation day is provided OR not applicable (i.e., product is not an embryo).
Day 1	Day 1	Embryo preserved on day 1 after insemination.
Day 2	Day 2	Embryo preserved on day 2 after insemination.
Day 3	Day 3	Embryo preserved on day 3 after insemination.
Day 4	Day 4	Embryo preserved on day 4 after insemination.
Day 5	Day 5	Embryo preserved on day 5 after insemination.
Day 6	Day 6	Embryo preserved on day 6 after insemination.
Day 7	Day 7	Embryo preserved on day 7 after insemination.

11.2.1.6 Sperm Preparation

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	No information about the preparation of sperm is provided, or not applicable (i.e., product is not sperm).
Prepared	Prepared	Viable sperm cells have been isolated from other contents of the seminal fluid.
Unwashed	Unwashed	Raw ejaculate.
Washed	Washed	The ejaculate has been washed by centrifugation in a buffer solution.

11.2.1.7 Unit of Issue

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not defined	No information is provided as to the packaging of the product.
Pack of 2	Pack2	Issued as a pack containing 2 items.
Pack of 3	Pack3	Issued as a pack containing 3 items.
Pack of 4	Pack4	Issued as a pack containing 4 items.

12 Organ

12.1 Class

Common Name	ISBT 128 Database Name	Definition
HEART	HEART	Heart.
HEART LUNG	HEART LUNG	Heart with both lungs including bronchi and trachea.
INTESTINE	INTESTINE	Intestine, any portion, without liver.
KIDNEY, DOUBLE	KIDNEY, DOUBLE	Two separated kidneys from the same donor intended for a single recipient.
KIDNEY, EN BLOC	KIDNEY, EN BLOC	Two kidneys connected by a common blood supply.
KIDNEY, SINGLE	KIDNEY, SINGLE	A single kidney.
LIVER, EXTENDED RIGHT LOBE	LIVER, EXTENDED RIGHT LOBE	Extended right lobe of liver (Segments 4, 5, 6, 7, 8).
LIVER, LEFT LATERAL SEGMENT	LIVER, LEFT LATERAL SEGMENT	Left lateral segment of liver (Segments 2, 3).
LIVER, LEFT LOBE	LIVER, LEFT LOBE	Left lobe of liver (Segments 2, 3, 4).
LIVER, MONO-SEGMENT 2	LIVER, MONO-SEGMENT 2	Segment 2 of liver.
LIVER, MONO-SEGMENT 3	LIVER, MONO-SEGMENT 3	Segment 3 of liver.
LIVER, RIGHT LOBE	LIVER, RIGHT LOBE	Right lobe of liver (Segments 5, 6, 7, 8).
LIVER, SPLIT	LIVER, SPLIT	Part of a liver. Segments not specified.
LUNG, DOUBLE	LUNG, DOUBLE	Right and left lungs including contiguous pulmonary artery, bronchi, trachea, and left atrial cuff.
LUNG, LEFT	LUNG, LEFT	Left lung including contiguous pulmonary artery, left bronchus, and left atrial cuff.
LUNG, LEFT LOBE	LUNG, LEFT LOBE	Lower lobe of left lung including a short length of the inferior pulmonary artery, the inferior pulmonary vein, and the inferior lobe bronchus.
LUNG, RIGHT	LUNG, RIGHT	Right lung including contiguous pulmonary artery, right bronchus, and left atrial cuff.
LUNG, RIGHT LOBE	LUNG, RIGHT LOBE	Lower lobe of right lung including a short length of the inferior pulmonary artery, the inferior pulmonary vein, and the inferior lobe bronchus.
MULTIVISCERAL	MULTIVISCERAL	Liver with intestine (or portion). May include stomach, pancreas, and/or spleen.
PANCREAS	PANCREAS	Pancreas with duodenum, may include spleen and splenic artery.
RECONSTRUCTION TISSUE	RECONSTRUCTION TISSUE	Other tissue recovered for reconstruction purposes.

Common Name	ISBT 128 Database Name	Definition
VESSELS FOR RECONSTRUCTION	VESSELS FOR RECONSTRUCTION	Vessels recovered for reconstruction purposes.
WHOLE LIVER	WHOLE LIVER	Whole Liver graft (Segments 1, 2, 3, 4, 5, 6, 7, 8).

12.2 Attribute Groups

Group Name	Description
Anatomical Position	Describes the relative position of the organ in the donor's body prior to organ procurement.
Donor Type	Describes if the organ was procured from a living or deceased donor.
Intended Use	Describes the intended use of the organ.
Vessels	Describes vessels recovered with an organ.

12.2.1 Attribute Variables

12.2.1.1 Anatomical Position

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	The anatomical position of the organ is not specified in the coding.
Left	Left	The organ originated from donated tissues from the left side of the donor's midsagittal plane.*
Right	Right	The organ originated from donated tissues from the right side of the donor's midsagittal plane.*

Note: This group applies to kidney only.
**While in general right and left are best handled as attributes, a notable exception exists. Left and right will be attributes when this is the sole difference between the two products. If this is not the case, for example the left and right lung lobes, then left and right will remain a part of the class.*

12.2.1.2 Donor Type

Common Name	ISBT 128 Database Name	Definition
Default	Default: Deceased	The organ was obtained from a deceased donor.
Living	Living	The organ was obtained from a living donor.

Note: This group applies to kidney, liver, and lung.

12.2.1.3 Intended Use

Common Name	ISBT 128 Database Name	Definition
Default	Default: For transplant	This organ is intended for transplant to a patient.
For research only	For research only	The organ is not for transplant into a patient. For research, investigation or repository use only.
For cell isolation	For cell isolation	The organ is not for direct transplant into a patient. For isolation of cells that may be used for treatment of patients.

12.2.1.4 Vessels

Common Name	ISBT 128 Database Name	Definition
Default	Default: NA or NS	Not applicable (class is not Vessels for Reconstruction) or not specified.
Artery, Iliac	Artery, Iliac	An iliac artery recovered with an organ for the purposes of reconstruction.
Artery, Pulmonary	Artery, Pulmonary	A pulmonary artery recovered with an organ for the purposes of reconstruction.
Vein, Iliac	Vein, Iliac	An iliac vein recovered with an organ for the purposes of reconstruction.

13 Regenerated Tissues

13.1 Class

Common Name	ISBT 128 Database Name	Definition
REGENERATED CARTILAGE	REGENERATED CARTILAGE	Viable chondrocytes constructed into tissue
REGENERATED CORNEAL EPITHELIUM	REGENERATED CORNEAL EPITHELIUM	Viable corneal epithelial cells constructed into tissue.
REGENERATED DERMIS	REGENERATED DERMIS	Viable dermis cells constructed into tissue
REGENERATED ELASTIC CARTILAGE	REGENERATED ELASTIC CARTILAGE	Viable elastic cartilage chondrocytes constructed into tissue
REGENERATED EPIDERMIS	REGENERATED EPIDERMIS	Viable cells constructed into epidermis.
REGENERATED FIBROCARTILAGE	REGENERATED FIBROCARTILAGE	Viable fibrocartilage chondrocytes constructed into tissue
REGENERATED HYALINE CARTILAGE	REGENERATED HYALINE CARTILAGE	Viable hyaline cartilage chondrocytes constructed into tissue
REGENERATED LIVER TISSUE	REGENERATED LIVER TISSUE	Viable liver cells constructed into tissue
REGENERATED ORAL MUCOSA	REGENERATED ORAL MUCOSA	Viable oral mucosa cells constructed into tissue
REGENERATED SKIN	REGENERATED SKIN	Viable skin cells constructed into tissue
REGENERATED TRACHEA	REGENERATED TRACHEA	Viable cells seeded onto a trachea or trachea segment scaffold.
REGENERATED TISSUE	REGENERATED TISSUE	Viable cells in a scaffold without a named tissue structure.

13.2 Attribute Groups

Group Name	Description
Type of Cells	Describes the primary type of cells used to create the product.
Storage Temperature	Describes the storage temperature range.
Delivery Method	Describes the form of the product for implantation.
Ancillary Substances	Indicates the presence of substances used during the manufacturing of products that may not be entirely removed.
Excipients	Indicates the presence of inactive ingredients that were added during product formulation.
Source of Cells	Specifies the source of the cells.

Group Name	Description
Origin of Scaffold	Specifies the origin of the scaffold. (The scaffold is the support for cells enabling a 2-D or 3-D structure.)
Scaffold Degradability	Specifies whether the scaffold will stay in place or be degraded.

13.2.1 Attribute Variables

13.2.1.1 Type of Cells

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	The type of cells within the product is not specified in the coding. Details may be stated in text on the label or in the accompanying documentation.
Chondrocytes	Chondrocytes	Chondrocytes are the primary cell type present in the product.
Epithelial cells	Epithelial cells	Epithelial Cells are the primary cell type present in the product.
Fibroblasts	Fibroblasts	Fibroblasts are the primary cell type present in the product.
Hepatocytes	Hepatocytes	Hepatocytes are the primary cell type present in the product.
Keratinocytes	Keratinocytes	Keratinocytes are the primary cell type present in the product.
Melanocytes	Melanocytes	Melanocytes are the primary cell type present in the product.
Multiple cell types	Multiple cell types	Multiple cell types are present in the product
MSC	MSC	Mesenchymal stromal cells are the primary cell type present in the product.
Urothelial cells	Urothelial cells	Urothelial Cells are the primary cell type present in the product.

13.2.1.2 Storage Temperature

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	The storage temperature is not specified in the coding. Details may be stated in text on the label or in the accompanying documentation.
RT	RT	Room temperature --The product is to be stored at room temperature. Specific ranges may be specified by national authorities.

Common Name	ISBT 128 Database Name	Definition
Refg	Refg	Refrigerated – The product is to be stored at refrigerated temperatures. Specific ranges may be specified by national authorities.
Cryopreserved	Cryopreserved	Cryopreserved – The product contains cryoprotectant(s) and is to be stored in the frozen state. Further details may be stated in text on the label or in the accompanying documentation.

13.2.1.3 Delivery Method

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	The method of delivering the implanted cells is not specified in the coding. Details may be stated in text on the label or in the accompanying documentation.
Sheet	Sheet	The product is presented as a sheet.

13.2.1.4 Ancillary Substances

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	The presence of ancillary substances is not specified in the coding. Details may be stated in text on the label or in the accompanying documentation.
Ancillary substances present	Ancillary substances:Yes	Ancillary substances are present in the product. Further details may be stated in text on the label or in the accompanying documentation.

13.2.1.5 Excipients

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	The presence of excipients is not specified in the coding. Details may be stated in text on the label or in the accompanying documentation.
Excipients present including animal origin	Excipients:Yes, including animal origin	Excipients, including excipients of animal origin, are present in the product. Further details may be stated in text on the label or in the accompanying documentation.
Excipients: Yes	Excipients:Yes	Excipients are present in the product. Further details may be may be stated in text on the label or in the accompanying documentation.

13.2.1.6 Source of Cells

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	The source of cells is not specified in the coding.
Adipose tissue	Adipose tissue	Adipose tissue is the source of the primary cells in the product.
Bone marrow	Bone marrow	Bone marrow is the source of the primary cells in the product.
Cord blood	Cord blood	Cord blood is the source of the primary cells in the product.
Umbilical cord	Umbilical cord	Umbilical cord blood is the source of the primary cells in the product.

13.2.1.7 Origin of Scaffold

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	Scaffold type is not specified in the coding. Details may be stated in text on the label or in the accompanying documentation.
Allogeneic scaffold	Allogeneic scaffold	The scaffold is formed from decellularized human tissue not from the intended recipient.
Autologous scaffold	Autologous scaffold	The scaffold is formed from decellularized tissue from the intended recipient.
Synthetic scaffold	Synthetic scaffold	The scaffold has been formed by chemical synthesis and does not contain human or animal materials.
Xeno scaffold	Xeno scaffold	The scaffold is formed from decellularized non-human animal tissue.

13.2.1.8 Scaffold Degradability

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not applicable or not specified	Not applicable because the regenerated tissue product does not contain a scaffold, or information about the composition of the scaffold is not encoded.
Degradable	Degradable scaffold	Scaffold intended to be degraded or metabolized.
Non-degradable scaffold	Non-degradable scaffold	Scaffold intended to remain as a permanent or semi-permanent structure.

14 Retired Terminology

Over time, product descriptions codes and the associated terminology may become inappropriate, redundant, or errors may be discovered. As a result, a mechanism must exist to discontinue future use of these codes and terms. However, because products may exist in inventories across the world, the product description codes must be retained in the database for backward compatibility.

To accomplish this goal, a column exists in the Product Description Code database. This "Retired Date" column indicates the date on which ICCBBA recommended the codes no longer be used for new products. Software should be written to recognize these codes, but not assign them to newly created products. It is understood that facilities must be given time to retire product description codes after ICCBBA has made its recommendation.

Below are terms and their definitions that have been retired.

14.1 Blood

14.1.1 Class

Term	Definition
LYMPHOCYTES	A product in which the major cellular component is lymphocytes. Unless otherwise specified the product has been obtained from Whole Blood.
MONOCYTES	A product in which the major cellular component is monocytes. Unless otherwise specified the product has been obtained from Whole Blood.

14.1.2 Attribute

14.1.2.1 Core Conditions

Term	Definition
CP2D–AS3/XX/refg	E@B0
CP2DA/450mL/refg	E@14
DMSO/NS/<=-80C	E@CK
None/NS/<=-18C	E@BD
None/NS/rt	E@BF

14.1.2.2 Attributes: Groups

Term	Definition
Platelet Count	Specifies whether additional platelet count information is provided.

14.1.3 Attributes: Variables

14.1.3.1 Platelet Count Group

Term	Definition
Default: no information	Platelet Count may or may not be specified
Count not encoded	Platelet count is provided in eye-readable form only.

14.1.3.2 Pathogen Reduction

Term	Definition
Solvent detergent-treated	The blood product has been subjected to a validated solvent detergent treatment process known to reduce the risk of disease transmission.

14.2 Cellular Therapy

14.2.1 Class

Term	Definition
LYMPHOCYTES, Apheresis	Lymphocytes obtained by appropriate manipulation of an apheresis collection.
MNC, Apheresis (from terminology prior to 2007); changed to Mononuclear Cells, Apheresis in 2013	Mononuclear cells obtained by apheresis.
NC, SYNOVIAL FLUID	A cell product containing nucleated cells obtained from synovial fluid.
POOLED HPC, Apheresis	Pool of multiple HPC Apheresis collections from the same donor.
TC-CTL, Apheresis	(Not defined).
TC-DC, Apheresis	(Not defined).
TC-DC, CORD	(Not defined).
TC-DC, MARROW	(Not defined).
T CELLS	T cells obtained by appropriate manipulation of a Whole Blood collection.
TC-CTL, WHOLE BLOOD	(Not defined).
TC-T, Apheresis	(Not defined).
TC-T, WHOLE BLOOD	(Not defined).
TC-APC	A cell product containing antigen presenting cells other than dendritic cells. The product is intended for therapeutic use.
TC-CTL	A cell product containing cytotoxic lymphocytes. The product is intended for therapeutic use.
TC-DC	A cell product containing dendritic cells. The product is intended for therapeutic use.

Term	Definition
TC-INV	A cell product for an investigational study that is accompanied by appropriate identifying study information. The product is intended for therapeutic use. This class is used for a specific product, not a product that is part of a blinded comparison study. Throughout the study, products labeled as TC-INV will be the same product, although the dose may vary within a specified range defined by the study.
TC-MSC	A cell product containing mesenchymal stromal cells. The product is intended for therapeutic use.
TC-NK CELLS	A cell product containing natural killer cells. The product is intended for therapeutic use.
TC-T CELLS	A cell product from any source containing a quantified T cell population. The product is intended for therapeutic use.
TC, TUMOR DERIVED	A product containing malignant cells or elements derived from them. The product is intended for therapeutic use.
TC-TIL	A cell product containing autologous tumor infiltrating lymphocytes (TIL) which have been isolated from the patient's tumor and cultured with lymphokines. The product is intended for therapeutic use.
TC-T REG CELLS	A cell product containing T regulatory lymphocytes. The product is intended for therapeutic use.

14.2.2 Modifiers

14.2.2.1 Bounded Lists and Definitions

Term	Definition
Cryopreserved	Applies to cells in the frozen state after the addition of cryoprotectant(s).
Cryopreserved Non-Mobilized	Applies to cells that have been obtained from a donor not treated with an agent to increase the concentration of the target cell population(s) and then frozen after the addition of cryoprotectant. [To be used only for HPC, Apheresis or HPC, Whole Blood].
Frozen	Describes a product in the cryopreserved state at a designated temperature.
Heparinized	Describes a product prepared by adding a variable amount of heparin to the anticoagulant before beginning the collection procedure, or in which heparin is the sole anticoagulant. Processing records should provide a record of the amount of heparin used; the label text should specify the amount of heparin in the final product.
Mobilized	Applies to cells that have been obtained from a donor treated with an agent to increase the concentration of the target cell population(s) [to be used only for TC, Apheresis or bone marrow].
Non-Mobilized	Applies to cells that have been obtained from a donor not treated with an agent to increase the concentration of the target cell population(s) [To be used only for HPC, Apheresis or HPC, Whole Blood].

Term	Definition
Pooled, Single Donor	Applies to the combination of multiple collections of the same product type from the same donor.
Pooled, Single Donor Cryopreserved	Applies to the combination of multiple collections of the same product type from the same donor and then frozen after the addition of cryoprotectant.
Pooled, Single Donor Thawed Washed	Applies to the combination of multiple collections of cryopreserved cells from the same donor of the same product type that have been thawed and washed to remove cryoprotectant or other solution(s).
Thawed	Applies to cryopreserved cells that have been thawed without washing prior to final issue for administration.
Thawed Washed	Applies to cryopreserved cells that have been thawed and subsequently washed to remove cryoprotectant or other solution(s).
Thawed Washed Non-Mobilized	Applies to cells that have been obtained from a donor not treated with an agent to increase the concentration of the target cell population(s) then thawed and subsequently washed to remove cryoprotectant or other solution(s). [To be used only for HPC, Apheresis or HPC, Whole Blood].
Washed	Applies to cells from a non-cryopreserved product that have been washed to reduce the amount of plasma, anticoagulant, and/or other solution(s).

14.2.3 Attributes

14.2.3.1 Core Conditions, First Position

Term	Definition
ACD-A	Acid Citrate Dextrose, Formula A.
ACD-A+10% DMSO	Acid Citrate Dextrose, Formula A – 10% Dimethylsulfoxide.
ACD-A + Heparin	Acid Citrate Dextrose, Formula A – heparin.
ACD-A + Heparin+6% HES	Acid Citrate Dextrose, Formula A – heparin – 6% Hydroxyethyl starch.
ACD-A + Heparin+6% HES + 10% DMSO	Acid Citrate Dextrose, Formula A– Heparin – 6% Hydroxyethyl starch – 10% Dimethylsulfoxide
CPDA-1	Citrate Phosphate Dextrose Adenine.
CPDA-1+DMSO	Citrate Phosphate Dextrose Adenine – Dimethylsulfoxide.
CPDA-1+10% DMSO+30% SSPP+10% plasma	Citrate Phosphate Dextrose Adenine – 10% Dimethylsulfoxide + 30% Isotonic Albumin + 10% plasma.
CPDA-1+10% DMSO+0.8% HES+1% dextran	Citrate Phosphate Dextrose Adenine – 10% Dimethylsulfoxide – 8% Hydroxyethyl starch + 1% Dextran.
CPD	Citrate Phosphate Dextrose.
CPD+Heparin	Citrate Phosphate Dextrose – heparin.
DMSO	Dimethylsulfoxide.
HES-DMSO	Hydroxyethyl starch – Dimethylsulfoxide.
PBS	Phosphate Buffered Saline.
PBS+alb+4% NaCitrate	Phosphate Buffered Saline – albumin – 4% Sodium Citrate.

Term	Definition
PBS+alb+4% NaCitrate+10% DMSO	Phosphate Buffered Saline – albumin – 4% Sodium Citrate – 10% Dimethylsulfoxide.

14.2.4 Attributes: Groups

Term	Definition
System Integrity	Describes the microbiological integrity of the collection/storage system.
Preparation — Additional Information	Provides supplementary information about the preparation of a product.
Final Product — Additional Information	Provides additional information regarding the number of containers of final product prepared from a collection.
Further Processing	Describes additional processing steps.

14.2.4.1 Attributes: Variables

14.2.4.1.1 System Integrity Group

Term	Definition
Default: Closed	**The product has been prepared in a closed system and the microbiological integrity of the system has not been compromised.**
Open	Open System: the system has been opened and the microbiological integrity may have been compromised.

14.2.4.1.2 Preparation: Additional Information Group

Term	Definition
Default: no preparation information	**There is no information about the preparation of the product.**
1.25% Albumin in saline added	A product to which 1.25% albumin in saline has been added.
6% HES + 5% DMSO	Moved to Cryoprotectant Attribute group.
6% HES+5% DMSO-Plasma added	A product to which hydroxyethyl starch, dimethylsulfoxide and plasma have been added.
10% DMSO	Moved to Cryoprotectant Attribute group.
Dextran+Albumin added	A product to which dextran and albumin have been added.
Donor erythrocytes added	A product to which donor erythrocytes have been added.
Heparin added	A product to which heparin has been added.
Plasma added	A product to which plasma has been added.
Plasma reduced	A product from which some of the plasma has been removed.
Plasma removed	A product from which most of the plasma has been removed.

14.2.4.1.3 Final Product: Additional Information Group

Term	Definition
Default	**A single container of final product was prepared from the collection.**
1st container	The first of two or more containers holding a product prepared from one collection.

Term	Definition
2nd container	The second of two or more containers holding a product prepared from one collection.
3rd container	The third of three or more containers holding a product prepared from collection.
4th container	The fourth of four or more containers holding a product prepared from one collection.
5th container	The fifth of five or more containers holding a product prepared from one collection.
6th container	The sixth of six or more containers holding a product prepared from one collection.
7th container	The seventh of seven or more containers holding a product prepared from one collection.
8th container	The eighth of eight or more containers holding a product prepared from one collection.
9th container	The ninth of nine or more containers holding a product prepared from one collection.
10th container	The tenth of ten or more containers holding a product prepared from one collection.
11th container	The eleventh of eleven or more containers holding a product prepared from one collection.
12th container	The twelfth of twelve or more containers holding a product prepared from one collection.
13th container	The thirteenth of thirteen or more containers holding a product prepared from one collection.
14th container	The fourteenth of fourteen or more containers holding a product prepared from one collection.
15th container	The fifteenth of fifteen or more containers holding a product prepared from one collection.
16th container	The sixteenth of sixteen or more containers holding a product prepared from one collection.

14.2.4.1.4 Manipulation Group

Term	Definition
AC133-selected	The AC133 cell population has been selected for by appropriate manipulation.
CD8-depleted	The CD8 cell population has been reduced by appropriate manipulation.
CD34-removed	The CD34 cell population has been reduced by appropriate manipulation.
Density enriched	Not defined.
Extensive	Extensively Manipulated: further positive or negative selection of specific fractions from a minimally manipulated product.
From buffy coat	Not defined.
Minimal	Minimally Manipulated: processed by centrifugation and/or density gradient fractionation to concentrate the mononuclear cell fraction [includes depletion of red blood cells and plasma].
T-cells depleted	T-cells have been removed from the product.
Alpha Beta T cell reduced*	The cells remaining after the Alpha Beta T cells have been reduced.

Term	Definition
Alpha Beta T/B cell reduced*	The cells remaining after the Alpha Beta T cells and B cells have been reduced.
B cell reduced*	Cells remaining after B cells have been reduced.
Buffy coat enriched**	Cells remaining after reduction of mature erythrocytes and plasma.
CD4 enriched**	Product in which the CD4 cell population has been enriched.
CD8 reduced*	Cells remaining after the CD8 cell population has been reduced.
CD34 enriched**	Product in which the CD34 cell population has been enriched.
CD56 enriched**	Product in which the CD56 cell population has been enriched.
CD133 enriched**	A product in which the CD133 cell population has been enriched.
Cultured***	Cells that have been maintained ex vivo to activate, expand, or promote development of a specified cell population in the presence of specified additive(s).
Diluted	A product to which an additional diluent (e.g. Concurrent Plasma) has been added after collection to reduce cell concentration for transit, storage, processing, or cryopreservation.
Monocyte enriched**	Product in which the monocyte cell population has been enriched.
Mono-nuclear cells enriched**	Cells remaining after reduction or depletion of mature erythrocytes, granulocytes and plasma.
Plasma reduced*	Cells remaining after a portion of the plasma has been depleted by sedimentation or centrifugation.
RBC reduced*	Cells remaining after reduction of mature erythrocytes.
T/B cell reduced*	Cells remaining after T&B cells have been reduced.
T cell reduced*	Cells remaining after T cells have been reduced.
Tumor cells reduced*	An identified tumor cell population has been reduced.

** These terms were retired from the Manipulation Group and moved into the Reduction Group.*
***These terms were retired from the Manipulation Group and moved into the Enrichment Group.*
****This term was retired from the Manipulation Group and moved into the Cultured Group.*

14.2.4.1.5 Further Processing Group

Term	Definition
Default: no further processing	**(Not defined).**
Volume DMSO reduced	(Not defined).

14.2.4.1.6 Cryoprotectant Group

Term	Definition
DMSO reduced	The cells were frozen using DMSO as a cryoprotective agent that has subsequently been partially removed using a wash procedure after thawing.

14.2.4.1.7 Mobilization

Term	Definition
Non-mobilized	Applies to cells that have been obtained from a donor not treated with an agent to increase the concentration of the target cell population(s).

14.3 Tissue Terminology

14.3.1 Class

Term	Definition
AORTIC NON-VALVED CONDUIT	A section of aortic conduit, not containing a valve.
AORTIC PATCH	A piece of the aorta.
BLOOD VESSEL	A tube in the body carrying blood to (vein) or from (artery) the heart.
CADAVERIC CANCELLOUS BONE	Cancellous bone from a cadaveric donor.
CADAVERIC CORTICAL BONE	Cortical bone from a cadaveric donor.
CALCAR FEMORALE	Vertically oriented bone that originates in posteromedial portion of femoral shaft under lesser trochanter which radiates laterally toward posterior aspect of greater trochanter.
CANCELLOUS BONE CHIPS	Cancellous bone, cut in pieces of nominally 6mm x 6mm x 30mm.
CANCELLOUS BONE CUBES	Cancellous bone, cut in cubes of nominally 1cm.
CANCELLOUS BONE DOWEL	A cancellous bone cylinder of 9–11mm length and 14–16mm diameter.
CANCELLOUS BONE PEG	Cancellous bone, cut as a single piece of nominally 15 x 15 x 30mm.
CANCELLOUS FEMORAL KNEE SLICE	Slice taken across the distal femur in the medial, lateral plane: depth nominally 1cm.
CANCELLOUS TIBIAL KNEE SLICE	Slice taken across the proximal tibia in the medial, lateral plane: depth nominally 1cm.
CORTICAL BONE BLOCKS	Pieces of cortical bone that have been machined into a cube shaped block.
CORTICAL BONE, GROUND, PASTE	Predominantly cortical bone reduced to a powder and with the addition of an agent or agents to create a smooth viscous mixture.
CORTICAL BONE, GROUND, PUTTY	Predominantly cortical bone reduced to a powder and with the addition of an agent or agents to create a thick mixture or cement with a dough-like consistency.
CORTICAL FEMORAL BONE RING	A hollow cylinder of cortical bone, cut from the central portion of the shaft of a femur — depth in mm indicated on packaging.

Term	Definition
CORTICAL FEMORAL BONE STRIP	A length of the central part of the femur, cut in narrow strips of varying width, usually 5–20mm in the proximal distal plane — length in cm indicated on packaging.
CORTICAL SHEET	Cortical bone, cut in sheets of 100–300µm thickness.
CORTICOCANCELLOUS BONE, CRUSHED	Corticocancellous bone subjected to crushing action (force) to yield varying sizes of bone fragments.
CORTICOCANCELLOUS BONE, GROUND	Corticocancellous bone ground to varying sizes through mill action.
CORTICOCANCELLOUS FEMORAL BONE RING	A cylinder of cortical bone, enclosing a cylinder of cancellous bone, cut from the distal or proximal part of the femur — depth in mm indicated on packaging.
CORTICOCANCELLOUS FEMORAL BONE STRIP	Distal or proximal part of femoral shaft, including cortical and cancellous bone, cut in the proximal, distal plane in narrow strips of varying width, usually 5–20mm — length in cm indicated on packaging.
CRANIAL PLATE	Piece of bone from the cranium component of the skull. (Replaced in the database with new class BONE, SKULL).
EYE, LEFT	A left eye removed from its socket.
EYE, RIGHT	A right eye removed from its socket.
FEMORAL CONDYLE, LATERAL	Lateral lower extremity of the femur inclusive of cartilaginous surface transected with 1-2cm cancellous bone.
FEMORAL CONDYLE, LATERAL, LEFT	Lateral lower extremity of the left femur inclusive of cartilaginous surface transected with 1-2cm cancellous bone.
FEMORAL CONDYLE, LATERAL, RIGHT	Lateral lower extremity of the right femur inclusive of cartilaginous surface transected with 1-2cm cancellous bone.
FEMORAL CONDYLE, MEDIAL	Medial lower extremity of the femur inclusive of cartilaginous surface transected with 1-2cm cancellous bone.
FEMORAL CONDYLE, MEDIAL, LEFT	Medial lower extremity of the left femur inclusive of cartilaginous surface transected with 1-2cm cancellous bone.
FEMORAL CONDYLE, MEDIAL, RIGHT	Medial lower extremity of the right femur inclusive of cartilaginous surface transected with 1-2cm cancellous bone.
FEMORAL HEAD	Proximal head of the femur.
FEMORAL HEAD SLICE	A slice of the femoral head, taken in the distal proximal plane 4–8mm deep.
FEMORAL HEAD, HALF	Either half of a femoral head bisected in the distal proximal plane.
FEMORAL HEAD, LEFT	Proximal head of the femur removed from the left femur by transecting the femoral neck.
FEMORAL HEAD, RIGHT	Proximal head of the femur removed from the right femur by transecting the femoral neck.
FEMORAL HEAD, QUARTER	A quartered proximal head of the femur.

Term	Definition
FEMORAL SHAFT	The mid-portion of the femur removed by transecting the femur just below the tuberosities and just above the distal joint.
FEMORAL SHAFT, LEFT	The mid-portion of the left femur removed by transecting the femur just below the tuberosities and just above the distal joint.
FEMORAL SHAFT, RIGHT	The mid-portion of the right femur removed by transecting the femur just below the tuberosities and just above the distal joint.
FEMUR, DISTAL	Distal portion of the femur, including the femoral condyles and part of the femoral shaft, removed by transecting the shaft in the mid-portion.
FEMUR, DISTAL, LEFT	Distal portion of the left femur, including the femoral condyles and part of the femoral shaft, removed by transecting the shaft in the mid-portion.
FEMUR, DISTAL, RIGHT	Distal portion of the right femur, including the femoral condyles and part of the femoral shaft, removed by transecting the shaft in the mid-portion.
FEMUR, PROXIMAL	Proximal part of the femur, including the head,.tuberosities and part of the shaft removed by transecting the femoral shaft in the mid-portion.
FEMUR, PROXIMAL, LEFT	Proximal part of the femur, including the head, tuberosities and part of the shaft removed by transecting the left femoral shaft in the mid-portion.
FEMUR, PROXIMAL, RIGHT	Proximal part of the femur, including the head, tuberosities and part of the shaft removed by transecting the right femoral shaft in the mid-portion.
HUMERUS, DISTAL	The distal portion of the humerus including a portion of the shaft and the distal epiphysis.
HUMERUS, PROXIMAL	The proximal portion of the humerus including a portion of the shaft and the proximal epiphysis.
ILIAC CREST	Pieces of iliac crest (start product).
KNEE JOINT, LEFT	The distal femur still attached to the proximal tibia of the left leg removed by transecting the femur above the joint and the tibia below the joint.
KNEE JOINT, RIGHT	The distal femur still attached to the proximal tibia of the right leg removed by transecting the femur above the joint and the tibia below the joint.
MENISCI, LEFT	A single graft consisting of both the lateral and medial meniscus dissected from the left knee joint.
MENISCI, RIGHT	A single graft consisting of both the lateral and medial meniscus dissected from the right knee joint.
MENISCUS	A meniscus.
MENISCUS, LATERAL, LEFT	A lateral meniscus dissected from the left knee joint.
MENISCUS, LATERAL, RIGHT	A lateral meniscus dissected from the right knee joint.
MENISCUS, MEDIAL, LEFT	A medial meniscus dissected from the left knee joint.

Term	Definition
MENISCUS, MEDIAL, RIGHT	A medial meniscus dissected from the right knee joint.
OVARIAN TISSUE	Fragment of the ovary.
PATELLA BONE BLOCK	An entire patella inclusive of cartilaginous posterior surface, tendon removed from points of insertion.
PELVIS, MASSIVE ALLOGRAFT	Massive allograft of pelvis comprising the majority of the Os Innominatum (nameless bone). (Replaced in the database with new class BONE, PELVIS)
PELVIS, MASSIVE ALLOGRAFT, LEFT	Massive allograft of left pelvis comprising the majority of the Os Innominatum (nameless bone).
PELVIS, MASSIVE ALLOGRAFT, RIGHT	Massive allograft of right pelvis comprising the majority of the Os Innominatum (nameless bone).
RADIUS, DISTAL	The distal portion of the radius including a portion of the shaft and the distal epiphysis.
RADIUS, PROXIMAL	The proximal portion of the radius including a portion of the shaft and the proximal epiphysis.
SAPHENOUS VEIN	A segment of a saphenous vein.
SKIN	Skin, not specified as to size.
SKIN, LARGE	Split thickness skin graft of greater than $10cm^2$ - surface area indicated on packaging.
SKIN, SMALL	Split thickness skin graft of $10cm^2$ or smaller - surface area indicated on packaging.
STRUT, NARROW	A length of the central part of the femur, cut in quarters in the proximal distal plane — length in cm indicated on packaging.
STRUT, WIDE	A length of the central part of the femur, cut in halves in the proximal distal plane — length in cm indicated on packaging.
TENDON, ACHILLES, LEFT	An Achilles tendon, attached to the bone block from the left calcaneus: at least 15 cm in length, including bone block.
TENDON, ACHILLES, RIGHT	An Achilles tendon, attached to the bone block from the right calcaneus: at least 15 cm in length, including bone block.
TENDON, BICEPS WITH RADIUS	Tendon of biceps muscle with whole or part of a radius.
TENDON, PATELLA, LEFT	A patella tendon attached to the whole left patella bone and a bone block from the left tibia.
TENDON, PATELLA, RIGHT	A patella tendon attached to the whole right patella bone and a bone block from the right tibia.
TENDON, SEMITENDINOSUS, LEFT	A semitendinosus tendon at least 20cm length, obtained from the left leg.
TENDON, SEMITENDINOSUS, RIGHT	A semitendinosus tendon at least 20cm length, obtained from the right leg.
TENDON, TRICEPS WITH ULNA	Tendon of triceps muscle with whole or part of an ulna.
TENDON, TOE EXTENSOR	A toe extensor tendon at least 9cm length.
TIBIA SHAFT	A section of the mid shaft of the tibia, removed by transecting.
TIBIA, PROXIMAL	Upper extremity of the tibia inclusive of cartilaginous surface transected with 1-2cm cancellous bone.
TIBIA, PROXIMAL, LATERAL	Lateral upper extremity of the tibia inclusive of cartilaginous surface transected with 1-2cm cancellous bone.

Term	Definition
TIBIA, PROXIMAL, MEDIAL	Medial upper extremity of the tibia inclusive of cartilaginous surface transected with 1-2cm cancellous bone.
TIBIA, PROXIMAL, LATERAL, LEFT	Lateral upper extremity of the left tibia inclusive of cartilaginous surface transected with 1-2cm cancellous bone.
TIBIA, PROXIMAL, LATERAL, RIGHT	Lateral upper extremity of the right tibia inclusive of cartilaginous surface transected with 1-2cm cancellous bone.
TIBIA, PROXIMAL, LEFT	Proximal part of the left tibia, including the tibial plateau and part of the tibial shaft, without cartilage, removed by transecting the tibial shaft in the mid-portion.
TIBIA, PROXIMAL, MEDIAL, LEFT	Medial upper extremity of the left tibia inclusive of cartilaginous surface transected with 1-2cm cancellous bone.
TIBIA, PROXIMAL, MEDIAL, RIGHT	Medial upper extremity of the right tibia inclusive of cartilaginous surface transected with 1-2cm cancellous bone.
TIBIA, PROXIMAL, RIGHT	Proximal part of the right tibia, including the tibial plateau and part of the tibial shaft, without cartilage, removed by transecting the tibial shaft in the mid-portion.
TISSUE	Human tissue not otherwise specified.
TRI-CORTICAL WEDGE	Section of iliac crest, with three facets covered by cortex, cut 30mm in length perpendicular to and 15mm along superior iliac spine.
ULNA, DISTAL	The distal portion of the ulna including a portion of the shaft and the distal epiphysis.
ULNA, PROXIMAL	The proximal portion of the ulna including a portion of the shaft and the proximal epiphysis.
WHOLE KNEE JOINT, LEFT	The distal femur still attached to the proximal tibia of the left leg (the femur transected above the joint, the tibia transected below the joint), inclusive of the patella tendon, meniscus with intact synovial fluid compartment.
WHOLE KNEE JOINT, RIGHT	The distal femur still attached to the proximal tibia of the right leg (the femur transected above the joint, the tibia transected below the joint), inclusive of the patella tendon, meniscus with intact synovial fluid compartment.

14.3.2 Modifiers

14.3.2.1 Bounded Lists and Definitions

Term	Definition
Cleaned Frozen Acellular	Processed to remove extraneous tissue and treated to deplete cell, cell remnant and nucleic acid content.
Cleaned Frozen	Processed to remove extraneous tissue and, in the case of bone, to deplete blood and bone marrow. Frozen to, and stored at or below –20°C.
Cryopreserved	Processed to remove extraneous tissue and bacterial and fungal contaminants. Cryopreserved using a cryoprotective agent and stored below -135°C.
Decontaminated Frozen	Chemically decontaminated and free of viable bacteria and fungi by culture. Frozen to, and stored at, below -40°C.
Demineralized	Bone that has been acid-treated.

Term	Definition
Demineralized Freeze Dried	Bone that has been acid-treated and then freeze-dried to less than 5% residual moisture.
Demineralized Pooled Single Donor	Tissue from a single donor processed as a single batch that has been acid-treated.
Freeze Dried	Processed to remove extraneous tissue and, in the case of bone, to deplete trabecular bone marrow. Freeze-dried to less than 5% residual moisture.
Frozen	Frozen to, and stored at, below -40°C.
Glycerolized	Disinfected and preserved using high concentration (>90%) glycerol. Free of viable bacteria and fungi by culture. Stored at 2-8°C.
Pooled Multiple Donor	Tissue from more than one donor to be processed, or in process, as a single batch.
Pooled Single Donor	Tissue from a single donor to be processed, or in process, as a single batch.
Refrigerated	Refrigerated (between 1 to 10°C; narrower range may be nationally-specified).

14.3.3 Attributes: Groups

Term	Definition
Pooled Processing of Products	Describes how products were pooled during processing. (Will be retired as soon as it is created).

14.3.4 Attributes: Variables

14.3.4.1.1 Pooled Processing of Products

Term	Definition
Default: Not pooled	**The tissue was not processed as a pool.**
Pooled single donor	Tissue products from a single donor were processed as a single batch.
Pooled multiple donors	Tissue products from more than one donor were processed as a single batch.

14.4 Ocular Terminology

14.4.1 Classes

Term	Definition
IRIS	The diaphragm of pigmented tissue between the cornea and the lens that controls the amount of light entering the eye by adjusting the diameter of the pupil, its central orifice.
LENS	Transparent, biconvex body located between the iris and the vitreous body and connected to the ciliary body by suspensory ligament. Contraction of ciliary muscles changes lens shape and thus refractive power of the eye (accommodation).

Term	Definition
OPTIC NERVE	Retinal ganglion cell axons converge towards the optic disc and pass through the sclera and out of the eye at the lamina cribrosa to form the optic nerve with a diameter of 3-4 mm. Passes out of the orbit through the optic canal.
POSTERIOR PART	Whole eye with the corneoscleral disc removed.
RETINA	Neural light-sensitive layer lining the inner surface of the eye from the optic disc to the ora serrata and whose external surface is in contact with the choroid.

14.4.2 Attribute Groups

Term	Definition
Scleral Graft	Specifies the type of scleral graft.

14.4.3 Attribute Variables

14.4.3.1 Scleral Graft

Term	Definition
Default: Not applicable or not specified	**Either this attribute group does not apply (tissue class is not Sclera) or the scleral graft type is not specified.**
Part sclera	A portion of the sclera from one eye.
Whole sclera	Complete sclera from one eye remaining after excision of corneoscleral disc.

14.5 Topical Products of Human Origin

14.5.1 Classes

Term	Definition
SERUM EYE DROPS	A product containing serum intended for treatment of the ocular surface.

14.6 Fecal Microbiota

14.6.1 Attribute Variables

14.6.1.1 Storage State

Term	Definition
Frozen	A product maintained in the frozen state after preparation.

14.7 Reproductive Terminology

14.7.1 Attribute Groups

Group Name	Definition
Donor-Intended Recipient Relationship	Describes the relationship between the donor and the intended recipient.
Processing Status	Indicates is a product is being held for further processing.

14.7.2 Attribute Variables

14.7.2.1 Donor-Intended Recipient Relationship

Term	Definition
Default: Not specified	**No information about relationship between donor and intended recipient is provided.**
Allogeneic	Donor and intended recipient are different individuals.
Autologous	Donor and intended recipient are the same individual.

14.7.2.2 Processing Status

Term	Definition
Default: Not defined	**No information is provided as to the status of the product.**
For further processing	Product produced as an intermediate stage. Not suitable for clinical use without further processing.

14.7.2.3 Type of Preservation

Term	Definition
Cryopreserved	Preserved by freezing in the presence of a cryoprotectant and using a method validated to maintain cellular viability and/or preserve tissue matrix structure.

14.7.2.4 Sperm Procurement Method

Term	Definition
Extracted	Product procured by aspiration or biopsy.

14.7.2.5 Oocyte Maturation Stage

Term	Definition
MI	Metaphase I.

14.7.2.6 Embryo Development Stage

Term	Definition
Fertilized oocyte	A fertilized oocyte that has not undergone cell division.

14.8 Regenerated Tissue

14.8.1 Attribute Variables

14.8.1.1 Ancillary Substances

Term	Definition
Ancillary substances:Yes including animal origin	Ancillary substance(s) including of animal origin are present in the product. Further details may be stated in the text on the label or in the accompanying documentation.

15 Appendix A

Terminology for Platelet Additive Solutions

Introduction

Platelet additive solutions (PASs) have been utilized for many years. However, the variety and frequency of use of PASs continues to grow as research reveals formulations that yield improved platelet survival, decrease the amount of plasma transfused, and in some cases, allow for pathogen inactivation.

There has been no consistent approach to terminology for these additive solutions. The same formulation can have multiple commercial names, and, in some cases, a term may have more than one meaning.

Terminology

To ensure unambiguous labeling of products containing platelet additive solutions, ICCBBA has adopted a generic nomenclature (Ashford, et al). The nomenclature has the format PAS-X, where X is an alpha character. PASs will be defined in terms of their active ingredients. Therefore, ingredients common to all, such as Sodium Chloride, are not listed. Similarly, Bicarbonate, that is added to some and is a metabolic end product of others, is not listed. The percentage of plasma utilized and the exact amounts of each ingredient in the PAS are also not incorporated into the coding, but may be included as text on the label.

By defining PASs in this generic manner, the system allows

- Solutions with the same active ingredients from different commercial sources to be coded in the same manner
- Ready expansion as new PASs are developed
- Standardized, non-proprietary terminology for PASs
- A common understanding of the ingredients present in a given PAS

Label Text

Because of different languages and regulations around the world, ISBT 128 does not define what text must appear on a blood product label. Conventions for text terminology on the label are best determined at a national level. The Standard, therefore, does not specify that the text used in the database for PASs appear on the label. For example, if a country has been labeling products with “PASIII” or “Intersol,” it may continue to do so. However, it would be equally acceptable to use PAS-C as text on the label, and we would encourage this to achieve international consistency.

As mentioned above, the percentage of plasma and quantities of each ingredient, as well as other information required by regulations, may be included in text on the label.

New PAS Codes and Further Information

Requests for further information or requests to add additional PAS solutions to the table should be sent to the ICCBBA technical director at tech.manager@iccbba.org.

Reference Ashford, P. , Gulliksson, H, et al.. Standard Terminology for Platelet Additive Solutions. *Vox Sanguinis* (2010) 98, 577-578.

16 Other References

ICCBBA:
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