ISBT 128 Standard

Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions

For Use with Product Description Code Database

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Editor
Erwin Cabana
Lead Information Standards Specialist, ICCBBA

Standards Committee

John Armitage, Prof., BSc, PhD	United Kingdom
Paul Ashford, MSc. CEng. CSci.	ICCBBA
Wayne Bolton, B.App.Sc., M.App.Sc	Australia
Suzanne Butch, MA, MT(ASCP)SBB	United States of America
Pat Distler, MS, MT(ASCP)SBB	ICCBBA
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Diane Wilson, BSN, MSN/MHA	United States of America

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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 labelling 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.

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; CANCELLOUS BONE PEG; 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 Cryopreserved, Thawed Washed, and Mobilized.

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:

- anticoagulant and/or additive,
- nominal collection volume, and
- 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 Components, Tissues, Cellular Therapy, and Derivatives.

1.1 Use of the Terminology in ISBT 128 Product codes

The ISBT 128 Product 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.

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 database with a corresponding version number. Thus version 3.1 of this document corresponds with database versions 3.1.x.

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

2 Blood Components

2.1 Class

2.1.1 Bounded List and Definitions

Common Name	ISBT 128 Database Name	Definition
CRYOPRECIPITATE	CRYOPRECIPITATE	A product containing the major portion of Factor VIII and fibrinogen prepared from a unit of Fresh Frozen Plasma.
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.
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.
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.
POOLED CRYOPRECIPITATE	POOLED CRYOPRECIPITATE	A product prepared by combining two or more single units of Cryoprecipitate into one container.

Common Name	ISBT 128 Database Name	Definition
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 PLASMA	POOLED PLASMA	A product prepared by combining two or more single units of Plasma into one container.
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.
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 Apheresis	Deglycerolized Apheresis	The removal of glycerol by washing from an apheresis product.
Deglycerolized	Deglycerolized	The removal of glycerol by washing.
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.
Deglycerolized Rejuvenated	Deglycerolized Rejuvenated	A product in which the cells were rejuvenated (*see* below), glycerol added and then frozen, and subsequently thawed and deglycerolized.
Frozen Apheresis	Frozen Apheresis	An apheresis product maintained in the frozen state after preparation.
Frozen	Frozen	A product maintained in the frozen state after preparation.
Frozen Rejuvenated Apheresis	Frozen Rejuvenated Apheresis	An apheresis product in which the cells were rejuvenated (*see* below), glycerol added and then frozen.
Frozen Rejuvenated	Frozen Rejuvenated	A product in which the cells were rejuvenated (*see* below), glycerol added and then frozen.
Liquid Apheresis	Liquid Apheresis	An apheresis product that has been stored in the liquid state and has not been previously frozen.
Liquid	Liquid	A product that has been stored in the liquid state and has not been previously frozen.
Lyophilized	Lyophilized	Preservation 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 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.
Rejuvenated	Rejuvenated	The treatment of Red Blood Cells by a method known to restore 2,3 DPG and ATP to normal levels or above.
Thawed Apheresis	Thawed Apheresis	An apheresis product that is currently in the liquid state but has been previously frozen.
Thawed	Thawed	A product that is currently in the liquid state but has been previously frozen.
Washed Apheresis	Washed Apheresis	The treatment of an apheresis cellular product using a compatible solution to remove most of the plasma proteins.

Common Name	ISBT 128 Database Name	Definition
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.
Washed	Washed	The treatment of a cellular product using a compatible solution 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	Alternate 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+	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.

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-C	ACD-A> PAS-C	Acid Citrate Dextrose, Formula A – Platelet Additive Solution C
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
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>PAS-C	CPD>PAS-C	Citrate Phosphate Dextrose – Platelet Additive Solution C
CPD>SAGM	CPD>SAGM	Citrate Phosphate Dextrose – Saline-Adenine-Glucose-Mannitol
CPDA-1	CPDA-1	Citrate Phosphate Dextrose Adenine, Solution 1
DMSO	DMSO	Dimethylsulfoxide
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-HES	NaCitrate-HES	Sodium Citrate solution – Hydroxyethyl starch

Common Name	ISBT 128 Database Name	Definition
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.
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
< -65 C	<-65C	Less than -65 degrees Celsius.
< -30 C	<-30C	Less than -30 degrees Celsius.
≤ -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).
20-24 C	20-24C	Between 20 and 24 degrees Celsius; intended for the use in platelet products.
Room temperature	rt	Ambient room temperature (a specific range may be nationally-specified).
< 37 C	<37C	Less than 37 degrees Celsius.

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 Information	Provides supplementary information about the preparation of a product.
Apheresis Container: Additional Information	Provides additional information related to an apheresis procedure.
Quarantine: Additional Information	Provides information related to the time a product is stored prior to retesting a second sample subsequently collected from the donor.
Dosage: Additional Information	Provides information related to the number of donations or number of platelets in a pooled product.
Method of Treatment	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.

2.3.2.2 Variables – bounded lists and definitions

2.3.2.2.13 Intended Use Group

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 that is intended for injection into humans after further manufacturing (processing).
For further manufacture into injectable product with restricted use	For mnf: injectable restr use	A product that is intended for injection into humans after further manufacturing (processing). The use of the product is further restricted by national regulation or guidelines.
For further manufacture into non-injectable product	For mnf: non-injectable	A product that is intended for further manufacturing into a product that is not intended for injection into humans.
For further manufacture into non-injectable product with restricted use	For mnf: non-injectable 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 Group

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 Group

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.

2.3.2.2.4 Residual Leukocyte Content Group

Common Name	ISBT 128 Database Name	Definition
Default: Leukocyte content not reduced	Default: Leuk Cont not reduced	The product has not been processed to yield a target residual leukocyte content.
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 < $2x10^5$	ResLeu: <2log5	The target residual leukocyte content is less than $2x10^5$
Residual Leukocyte Content < $5x10^5$	ResLeu: <5log5	The target residual leukocyte content is less than $5x10^5$
Residual Leukocyte Content < $8.3x10^5$	ResLeu: <8.3log5	The target residual leukocyte content is less than $8.3x10^5$
Residual Leukocyte Content <$1x10^6$	ResLeu: <1log6	The target residual leukocyte content is less than $1x10^6$
Residual Leukocyte count < $1x10^6$ via whole blood filter	ResLeu: <1log6,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 count < $1x10^6$ via Red Blood Cell filter	ResLeu: <1log6,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 Content < $2.5x10^6$	ResLeu:<2.5log6	The target residual leukocyte content is less than $2.5x10^6$
Residual Leukocyte Content < $5x10^6$	ResLeu: <5log6	The target residual leukocyte content is less than $5x10^6$
Residual Leukocyte Content < $5x10^8$	ResLeu: <5log8	The target residual leukocyte content is less than $5x10^8$
Residual Leukocyte Content < $1.2x10^9$	ResLeu: <1.2log9	The target residual leukocyte content is less than $1.2x10^9$

2.3.2.2.5 Altered Group

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.
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.
Red Blood Cells reduced by sedimentation	RBC reduced by sedimentation	A blood product from which most of the red cells have been removed following separation by a sedimentation process.
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.

2.3.2.2.6 Final Content Group

Common Name	ISBT 128 Database Name	Definition
Default	Default: Usual nominal volume	The contents are consistent with the expected, usual volume.
25 milliliters	25mL	Approximately 25 milliliters; actual range of volume established by processing facility.
50 milliliters	50mL	Approximately 50 milliliters; actual range of volume established by processing facility.
< 200 milliliters	<200mL	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.
Final Content not specified	Fin Con:NS	No information is provided regarding the final content.
Low volume, anticoagulant volume adjusted	LowVol: anticoag adjusted	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 Information Group

Common Name	ISBT 128 Database Name	Definition
Default	Default: Prep: No additional info	There is no additional information about the preparation of the product.
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.

Common Name	ISBT 128 Database Name	Definition
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.
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.

2.3.2.2.8 Apheresis container— Additional Information Group

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.
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.

Common Name	ISBT 128 Database Name	Definition
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 Information Group

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	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.
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 Information Group

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 log9 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
Approximately 150 x 10^9 platelets	Approx 150 log9 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
Approximately 180 x 10^9 platelets	Approx 180 log9 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
Approximately 240 x 10^9 platelets	Approx 240 log9 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
Approximately 300 x 10^9 platelets	Approx 300 log9 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
Approximately 360 x 10^9 platelets	Approx 360 log9 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
Approximately 420 x 10^9 platelets	Approx 420 log9 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
Approximately 480 x 10^9 platelets	Approx 480 log9 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
Approximately 540 x 10^9 platelets	Approx 540 log9 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
< 3 x 10^{11} platelets	<3 log11 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 log11 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 log11 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
> 6.0 x 10^{11} platelets	>6.0 log11 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
From 2 donors	From 2 donors	Pool prepared from donations from 2 donors.
From 3 donors	From 3 donors	Pool prepared from donations from 3 donors.
From 4 donors	From 4 donors	Pool prepared from donations from 4 donors.
From 5 donors	From 5 donors	Pool prepared from donations from 5 donors.
From 6 donors	From 6 donors	Pool prepared from donations from 6 donors.
From 7 donors	From 7 donors	Pool prepared from donations from 7 donors.
From 8 donors	From 8 donors	Pool prepared from donations from 8 donors.
From 9 donors	From 9 donors	Pool prepared from donations from 9 donors.
From 10 donors	From 10 donors	Pool prepared from donations from 10 donors.

2.3.2.2.11 Method of Treatment Group

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.
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.
Solvent detergent-treated	Solvent detergent-treated	The blood product has been subjected to a validated solvent detergent treatment 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.
40% - 50%	0.4-0.5	The packed cell volume of the product is between 40 and 50 percent.
50% - 60%	0.5-0.6	The packed cell volume of the product is between 50 and 60 percent.
50% - 70%	0.5-0.7	The packed cell volume of the product is between 50 and 70 percent.
55% - 75%	0.55-0.75	The packed cell volume of the product is between 55 and 75 percent.
> 70%	>0.7	The packed cell volume of the product is greater than 70 percent.
70% - 80%	0.7-0.8	The packed cell volume of the product is between 70 and 80 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 test	Bacterial test	A one-time bacterial test performed at greater than or equal to 24 hours of incubation meeting national specifications for extension of expiry date.

3 Cellular Therapy

Important Note: The terms and definitions represented in this section were developed in 2007. Products labeled prior to the introduction of this terminology and coding system were defined using a different coding system. See Chapter 6 for definitions of these codes. The document *ISBT 128 Standard Cellular Therapy Product Coding Transition, June 2007* provides a crosswalk from previously used codes and definitions to those currently used.

3.1 Class

3.1.1 Subcategories of Classes

Cellular therapy products are divided into two class name categories.

Category 1:
At collection, the product code will describe the intended purpose of the collection (TC or HPC) and the source material (e.g., TC, Apheresis). These products can be collected for direct infusion without further manipulation. If these cells undergo manipulation such as cryopreservation and thawing, the class doesn't change but the modifier is added into the product code (e.g., Cryopreserved HPC, Apheresis). This category is usually identified by a comma in the full name

Category 2:
After manufacture/processing, the intention of the product can be identified by its active component. These class names are based on function followed by a further more specific delineation of the type of cells thought to predominate in the product. After processing, the class name will describe the intended active component (e.g., a donor lymphocyte infusion identified as TC-T Cells). This category is usually identified by a hyphen in the full name.

3.1.2 Meaning of "TC"

The term "TC" is used in a number of product class names. In the context of ISBT 128, TC refers to a product whose *intended* use is therapeutic. The terminology is not intended to convey actual therapeutic benefits.

3.1.3 Bounded Lists and Definitions

Common Name	ISBT 128 Database Name	Definition
CONCURRENT PLASMA, APHERESIS	CONCURRENT PLASMA, APHERESIS	Plasma collected from the donor as part of an apheresis cell collection procedure for use by the laboratory in further processing of that donor's product.
HPC, APHERESIS	HPC, APHERESIS	Peripheral blood collected by apheresis as a source of hematopoietic progenitor cells.
HPC, CORD BLOOD	HPC, CORD BLOOD	Umbilical cord blood and/or placental blood collected as a source of hematopoietic progenitor cells.
HPC, MARROW	HPC, MARROW	Bone marrow collected as a source of hematopoietic progenitor cells.
HPC, WHOLE BLOOD	HPC, WHOLE BLOOD	Whole blood collected as a source of hematopoietic progenitor cells. Mobilized unless otherwise stated in Modifier.
NC, ADIPOSE CELLS	NC, ADIPOSE CELLS	Nucleated cells collected from adipose tissue, with undefined therapeutic use at the time of collection.
NC, MENSTRUAL BLOOD	NC, MENSTRUAL BLOOD	Source of nucleated cells collected from menstrual blood, with undefined therapeutic use at the time of collection.
NC, TUMOR CELLS	NC, TUMOR CELLS	Nucleated cells collected from a tumor intended for further processing (e.g., vaccine production).
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.
TC, APHERESIS	TC, APHERESIS	Source of nucleated cells obtained by an apheresis procedure. Non-mobilized unless otherwise stated in the modifier. The product is intended for therapeutic use other than as HPCs.
TC, CORD BLOOD	TC, CORD BLOOD	Umbilical cord blood and/or placental blood collected as a source of nucleated cells. The product is intended for therapeutic use other than as HPCs.
TC, MARROW	TC, MARROW	Bone marrow collected as a source of nucleated cells. The product is intended for therapeutic use other than as HPCs.
TC, PANCREATIC ISLETS	TC, PANCREATIC ISLETS	Isolated pancreatic islets.
TC, TUMOR DERIVED	TC, TUMOR DERIVED	A product containing malignant cells or elements derived from them. The product is intended for therapeutic use.
TC, WHOLE BLOOD	TC, WHOLE BLOOD	Whole blood collected as a source of nucleated cells. The product is intended for therapeutic use other than as HPCs.

Common Name	ISBT 128 Database Name	Definition
TC-APC	TC-APC	A cell product containing antigen presenting cells other than dendritic cells. The product is intended for therapeutic use.
TC-BLINDED STUDY	TC-BLINDED STUDY	This class is reserved for use only in blinded studies of cells. The product is accompanied by appropriate identifying study information. Products labeled as TC-Blinded Study may include different doses or may include an active product and a placebo. The product is intended for therapeutic use.
TC-CTL	TC-CTL	A cell product containing cytotoxic lymphocytes. The product is intended for therapeutic use.
TC-DC	TC-DC	A cell product containing dendritic cells. The product is intended for therapeutic use.
TC-INV	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	TC-MSC	A cell product containing mesenchymal stromal cells. The product is intended for therapeutic use.
TC-MSC MD	TC-MSC MD	A cell product containing mesenchymal stromal cells derived from the bone marrow. The product is intended for therapeutic use.
TC-NK CELLS	TC-NK CELLS	A cell product containing natural killer cells. The product is intended for therapeutic use.
TC-T CELLS	TC-T CELLS	A cell product from any source containing a quantified T cell population. The product is intended for therapeutic use.
TC-TIL	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	TC-T REG CELLS	A cell product containing T regulatory lymphocytes. The product is intended for therapeutic use.

3.1.4 Abbreviations

Abbreviations are sometimes needed in documents (published papers, SOPs, etc.). The following abbreviations may be used for this purpose, but should not be used in the labeling of products.

HPC(A) for HPC, Apheresis
HPC(CB) for HPC, Cord Blood
HPC(M) for HPC, Marrow
HPC(WB) for HPC, Whole Blood

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.

3.2 Modifier

3.2.1 Bounded Lists and Definitions

Common Name	ISBT 128 Database Name	Definition
Cryopreserved	Cryopreserved	Applies to cells in the frozen state after the addition of cryoprotectant(s).
Cryopreserved Non-Mobilized	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].
Mobilized	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	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].
Pooled, Single Donor	Pooled, Single Donor	Applies to the combination of multiple collections of the same product type from the same donor.
Pooled, Single Donor Thawed Washed	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	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).
Thawed Washed Non-Mobilized	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	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).

3.3 Attribute

3.3.1 Core Conditions

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

The anticoagulant solution
"None" specifies that no significant amount of anticoagulant or additive is present.

"NS" indicates that the anticoagulant and/or additive are not specified.

The nominal volume of the original collection excluding anticoagulant
"XX" specifies that the volume is variable and not provided as part of the core conditions of the product description (blood components). Specific information may be given as additional label text.

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.

3.3.1.1 Core Conditions—Lists and Definitions

First Position (anticoagulant/additive) – Bounded List

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

3.3.2 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.

3.3.2.1 Groups: Bounded Lists and Definitions

Group Name	Description
Intended Use	Describes the expected use of the product.
Manipulation	Describes processing applied to the collection.
Preparation — Cryoprotectant	Active cryoprotectant in the product.
Preparation – Blood Component from Third Party Donor	Describes blood products from other donors used during processing, such as albumin, Fresh Frozen Plasma, AB serum, Red Blood Cells.
Preparation – Other Additives	Describes additives introduced other than as part of the anticoagulant solution at the time of collection.
Genetically Modified	Cells which have been modified by the insertion of exogenous genetic material.

3.3.2.2 Variables: Bounded Lists and Definitions Tables

3.3.2.2.1 Intended Use Group

Common Name	ISBT 128 Database Name	Definition
Default	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.
Not for administration	Not for admin	Not for patient use; a product that is not intended for use in patient treatment.

3.3.2.2.2 Manipulation Group

Common Name	ISBT 128 Database Name	Definition
Default	Default: No manipulation	No further processing has occurred following collection.
Aβ 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	Cells remaining after B cells have been reduced.
Buffy coat enriched	buffy coat enriched	Cells remaining after reduction of mature erythrocytes and plasma.
CD4 enriched	CD4 enriched	Product in which the CD4 cell population has been enriched.
CD8 reduced	CD8 reduced	Cells remaining after the CD8 cell population has been reduced.
CD34 enriched	CD34 enriched	Product in which the CD34 cell population has been enriched.
CD133 enriched	CD133 enriched	A product in which the CD133 cell population has been enriched.
Cultured	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	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.
Filtered	Filtered	Product after passage through a non-leukocyte reducing filter.
Monocyte enriched	Monocyte enriched	Product in which the monocyte cell population has been enriched.
Mononuclear cells enriched	Mononuclear cells enriched	Cells remaining after reduction or depletion of mature erythrocytes, granulocytes and plasma.
Plasma reduced	Plasma reduced	Cells remaining after a portion of the plasma has been depleted by sedimentation or centrifugation.

Common Name	ISBT 128 Database Name	Definition
PUV treated	PUV treated	Cells treated with psoralen/ultra violet light.
RBC reduced	RBC reduced	Cells remaining after reduction of mature erythrocytes.
T/B cell reduced	T/B cell reduced	Cells remaining after T&B cells have been reduced.
T cell reduced	T cell reduced	Cells remaining after T cells have been reduced.
Tumor cells reduced	Tumor cells reduced	An identified tumor cell population has been reduced.

3.3.2.2.3 Cryoprotectant Group

Common Name	ISBT 128 Database Name	Definition
Default	Default: No cryoprotectant	No cryoprotectant has been added.
5% DMSO	5% DMSO	The concentration of the final product contains 5% dimethylsulfoxide by volume as the cryoprotective agent.
7.5% DMSO	7.5% DMSO	The concentration of the final product contains 7.5% dimethylsulfoxide by volume as the cryoprotective agent.
10% DMSO	10% DMSO	The concentration of the final product contains 10% dimethylsulfoxide by volume as the cryoprotective agent.
6% HES + 5% DMSO	6% HES + 5% DMSO	The concentration of the final product contains 6% hydroxyethyl starch and 5% dimethylsulfoxide by volume as the cryoprotective agents.
DMSO not specified	NS DMSO	The dimethylsulfoxide concentration of the final product is not specified in the coding. Additional information concerning the approximate amount of dimethylsulfoxide present will appear as text on the affixed, attached, or accompanying labeling.

3.3.2.2.4 Blood Component from Third Party Donor Group*

Common Name	ISBT 128 Database Name	Definition
Default	Default: 3rd Party Comp:No	Default. No third party blood component added.
3rd party component present	3rd Party Comp:Yes	Third party blood component added. See accompanying paperwork.

3.3.2.2.5 Preparation: Other Additives Group*

Common Name	ISBT 128 Database Name	Definition
Default	Default: Other Additives:No	Default. No additives other than as part of the anticoagulant solution at the time of collection.
Other additives present	Other Additives:Yes	Other additives. See accompanying paperwork.

3.3.2.2.6 Genetically Modified Group*

Common Name	ISBT 128 Database Name	Definition
Default	Default: Genetically Modified:No	Default. Not genetically modified.
Genetically modified	Genetically Modified:Yes	Genetically modified by the insertion of exogenous genetic material. See accompanying paperwork.

** Note: 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).*

4 Tissues

4.1 Class

4.1.1 Cardio/Vascular Bounded List and Definitions

Common Name	ISBT 128 Database Name	Definition
ABDOMINAL BIFURCATION	ABDOMINAL BIFURCATION	The lower section of the abdominal aorta and up to 5cm of each iliac artery.
AORTIC ARCH	AORTIC ARCH	A section of the aorta, including branches of the brachiocephalic, left common carotid and left subclavian arteries.
AORTIC NON-VALVED CONDUIT	AORTIC NON-VALVED CONDUIT	A section of aortic conduit, not containing a valve.
AORTIC PATCH	AORTIC PATCH	A piece of the aorta.
BLOOD VESSEL	BLOOD VESSEL	A tube in the body carrying blood to (vein) or from (artery) the heart.
HEART	HEART	Whole heart or block from the heart including the aortic and/or pulmonary valves (start product).
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.
PULMONARY PATCH	PULMONARY PATCH	A section of the pulmonary trunk.
SAPHENOUS VEIN	SAPHENOUS VEIN	A segment of a saphenous vein.
SUPERFICIAL FEMORAL ARTERY	SUPERFICIAL FEMORAL ARTERY	A section of the femoral artery from the bifurcation of the common femoral artery with the profunda femoris artery to the popliteral artery.
THORACIC AORTA	THORACIC AORTA	A section of the aorta from the second sternocostal articulation to the forth thoracic vertebra, including branches of the brachiocephalic, left common carotid and left subclavian arteries.
VALVE, AORTIC	VALVE, AORTIC	An aortic cardiac valve, comprising the valve leaflets with a specified annular diameter.
VALVE, MITRAL	VALVE, MITRAL	A mitral cardiac valve, comprising the valve leaflets with a specified annular diameter.
VALVE, PULMONARY	VALVE, PULMONARY	A pulmonary cardiac valve, comprising the valve leaflets with a specified length of pulmonary artery, including lengths and diameters of bifurcations where appropriate and muscle skirt below and of specified diameter.

4.1.2 Musculo/Skeletal Bounded List and Definitions

Common Name	ISBT 128 Database Name	Definition
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.
BONE	BONE	Bone, not further specified. Porous rigid tissue making up the skeleton.
CADAVERIC CANCELLOUS BONE	CADAVERIC CANCELLOUS BONE	Cancellous bone from a cadaveric donor.
CADAVERIC CORTICAL BONE	CADAVERIC CORTICAL BONE	Cortical bone from a cadaveric donor.
CALCAR FEMORALE	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 CHIPS	Cancellous bone, cut in pieces of nominally 6mm x 6mm x 30mm.
CANCELLOUS BONE CUBES	CANCELLOUS BONE CUBES	Cancellous bone, cut in cubes of nominally 1cm.
CANCELLOUS BONE DOWEL	CANCELLOUS BONE DOWEL	A cancellous bone cylinder of 9–11mm length and 14–16mm diameter.
CANCELLOUS BONE PEG	CANCELLOUS BONE PEG	Cancellous bone, cut as a single piece of nominally 15 x 15 x 30mm.
CANCELLOUS FEMORAL KNEE SLICE	CANCELLOUS FEMORAL KNEE SLICE	Slice taken across the distal femur in the medial, lateral plane: depth nominally 1cm.
CANCELLOUS TIBIAL KNEE SLICE	CANCELLOUS TIBIAL KNEE SLICE	Slice taken across the proximal tibia in the medial, lateral plane: depth nominally 1cm.
CORTICAL BONE, GROUND, PASTE	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	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	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.
CORTICAL FEMORAL BONE STRIP	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.

Common Name	ISBT 128 Database Name	Definition
CORTICAL SHEET	CORTICAL SHEET	Cortical bone, cut in sheets of 100–300µm thickness.
CORTICO-CANCELLOUS BONE, CRUSHED	CORTICO-CANCELLOUS BONE, CRUSHED	Corticocancellous bone subjected to crushing action (force) to yield varying sizes of bone fragments.
CORTICO-CANCELLOUS BONE, GROUND	CORTICO-CANCELLOUS BONE, GROUND	Corticocancellous bone ground to varying sizes through mill action.
CORTICO-CANCELLOUS FEMORAL BONE RING	CORTICO-CANCELLOUS 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.
CORTICO-CANCELLOUS FEMORAL BONE STRIP	CORTICO-CANCELLOUS 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.
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.
CRANIAL PLATE	CRANIAL PLATE	Piece of bone from the cranium component of the skull.
FEMORAL CONDYLE, LATERAL, LEFT	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	FEMORAL CONDYLE, LATERAL, RIGHT	Lateral lower extremity of the right femur inclusive of cartilaginous surface transected with 1-2cm cancellous bone.
FEMORAL CONDYLE, MEDIAL, LEFT	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	FEMORAL CONDYLE, MEDIAL, RIGHT	Medial lower extremity of the right femur inclusive of cartilaginous surface transected with 1-2cm cancellous bone.
FEMORAL HEAD	FEMORAL HEAD	Proximal head of the femur.
FEMORAL HEAD, HALF	FEMORAL HEAD, HALF	Either half of a femoral head bisected in the distal proximal plane.
FEMORAL HEAD, LEFT	FEMORAL HEAD, LEFT	Proximal head of the femur removed from the left femur by transecting the femoral neck.
FEMORAL HEAD, QUARTER	FEMORAL HEAD, QUARTER	A quartered proximal head of the femur.
FEMORAL HEAD, RIGHT	FEMORAL HEAD, RIGHT	Proximal head of the femur removed from the right femur by transecting the femoral neck.
FEMORAL HEAD SLICE	FEMORAL HEAD SLICE	A slice of the femoral head, taken in the distal proximal plane 4–8mm deep.

Common Name	ISBT 128 Database Name	Definition
FEMORAL SHAFT, LEFT	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	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, LEFT	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	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, LEFT	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	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.
FIBULA	FIBULA	The lateral and narrower of two bones of the lower limb.
GROUND BONE	GROUND BONE	Predominantly cancellous bone morcellized and free of cartilage.
HAMSTRING	HAMSTRING	The prominent tendons at the back of the knee.
HUMERUS	HUMERUS	The bone of the upper limb between the shoulder and the elbow.
HUMERUS, DISTAL	HUMERUS, DISTAL	The distal portion of the humerus including a portion of the shaft and the distal epiphysis.
HUMERUS, PROXIMAL	HUMERUS, PROXIMAL	The proximal portion of the humerus including a portion of the shaft and the proximal epiphysis.
ILIAC CREST	ILIAC CREST	Pieces of iliac crest (start product).
KNEE JOINT, LEFT	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	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.

Common Name	ISBT 128 Database Name	Definition
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.
LIGAMENT, ANTERIOR CRUCIATE, WITH BONE BLOCKS	LIGAMENT, ANTERIOR CRUCIATE, WITH BONE BLOCKS	An 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, WITH BONE BLOCKS	A 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, WITH BONE BLOCKS	A posterior cruciate ligament, attached to a bone block from femur and a bone block from tibia.
MENISCI	MENISCI	A single graft consisting of both the lateral and medial meniscus dissected from the knee joint. Anatomically identified as left or right.
MENISCI, LEFT	MENISCI, LEFT	A single graft consisting of both the lateral and medial meniscus dissected from the left knee joint.
MENISCI, RIGHT	MENISCI, RIGHT	A single graft consisting of both the lateral and medial meniscus dissected from the right knee joint.
MENISCUS	MENISCUS	A meniscus.
MENISCUS LATERAL	MENISCUS LATERAL	A lateral meniscus dissected from the knee joint.
MENISCUS, LATERAL, LEFT	MENISCUS, LATERAL, LEFT	A lateral meniscus dissected from the left knee joint.
MENISCUS, LATERAL, RIGHT	MENISCUS, LATERAL, RIGHT	A lateral meniscus dissected from the right knee joint.
MENISCUS, LATERAL, WITH TIBIA PLATEAU	MENISCUS, LATERAL, WITH TIBIA PLATEAU	A lateral meniscus, attached to an approximately 2 cm high plateau from the tibia.
MENISCUS MEDIAL	MENISCUS MEDIAL	A medial meniscus dissected from the knee joint.
MENISCUS, MEDIAL, LEFT	MENISCUS, MEDIAL, LEFT	A medial meniscus dissected from the left knee joint.
MENISCUS, MEDIAL, RIGHT	MENISCUS, MEDIAL, RIGHT	A medial meniscus dissected from the right knee joint.
MENISCUS, MEDIAL, WITH TIBIA PLATEAU	MENISCUS, MEDIAL, WITH TIBIA PLATEAU	A medial meniscus, attached to an approximately 2 cm high plateau from the tibia.
OSTEOCHONDRAL	OSTEOCHONDRAL	Tissue comprising bone and cartilage from an articulating joint.

Common Name	ISBT 128 Database Name	Definition
PATELLA BONE BLOCK	PATELLA BONE BLOCK	An entire patella inclusive of cartilaginous posterior surface, tendon removed from points of insertion.
PELVIS, MASSIVE ALLOGRAFT, LEFT	PELVIS, MASSIVE ALLOGRAFT, LEFT	Massive allograft of left pelvis comprising the majority of the Os Innominatum (nameless bone).
PELVIS, MASSIVE ALLOGRAFT, RIGHT	PELVIS, MASSIVE ALLOGRAFT, RIGHT	Massive allograft of right pelvis comprising the majority of the Os Innominatum (nameless bone).
RIB	RIB	A long curved bone extending from the vertebral column to or toward the sternum.
STRUT, NARROW	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	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	TENDON	A cord or band of tough tissue normally found attaching muscle to bone.
TENDON, ACHILLES	TENDON, ACHILLES	An Achilles tendon, attached to a bone block from the calcaneus: at least 15cm in length, including bone block.
TENDON, ACHILLES, LEFT	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	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 FEMORIS, WITH BONE BLOCK	TENDON, BICEPS FEMORIS, WITH BONE BLOCK	A biceps femoris tendon, attached to a bone block from fibula.
TENDON, FLEXOR DIGITORUM LONGUS	TENDON, FLEXOR DIGITORUM LONGUS	A flexor digitorum longus tendon.
TENDON, FLEXOR HALLUCIS LONGUS	TENDON, FLEXOR HALLUCIS LONGUS	A flexor hallucis longus tendon.
TENDON, GRACILIS	TENDON, GRACILIS	A gracilis tendon.
TENDON, ILIOTIBIALIS	TENDON, ILIOTIBIALIS	An iliotibial tract (tendon of tensor fascia lata and gluteus maximus).
TENDON, PATELLA, HALF	TENDON, PATELLA, HALF	A patella tendon, attached to a bone block from the patella bone and a bone block from the tibia, bisected in the distal proximal plane.

Common Name	ISBT 128 Database Name	Definition
TENDON, PATELLA, HALF, SHAPED	TENDON, PATELLA, HALF, SHAPED	A patella tendon, attached to a bone block from the patella bone and a bone block from the tibia, bisected in the distal proximal plane. Bone blocks shaped to form cylinders which pass through spacers of specified diameter indicated on packaging.
TENDON, PATELLA, LEFT	TENDON, PATELLA, LEFT	A patella tendon attached to the whole left patella bone and a bone block from the left tibia.
TENDON, PATELLA, RIGHT	TENDON, PATELLA, RIGHT	A patella tendon attached to the whole right patella bone and a bone block from the right tibia.
TENDON, PATELLA, WHOLE	TENDON, PATELLA, WHOLE	A patella tendon, attached to a bone block from the patella bone and a bone block from the tibia.
TENDON, PATELLA, WHOLE, SHAPED	TENDON, PATELLA, WHOLE, SHAPED	A patella tendon, attached to a bone block from the patella bone and a bone block from the tibia. Bone blocks shaped to form cuboids which pass through spacers of specified diameter-diameter indicated on the packaging.
TENDON, PATELLA, WHOLE, WITH EXTENSOR	TENDON, PATELLA, WHOLE, WITH EXTENSOR	A patella tendon, attached to a bone block from the patella bone and a bone block from the tibia, and extensions of the quadriceps tendon.
TENDON, PERONEUS LONGUS WITH BONE BLOCK	TENDON, PERONEUS LONGUS WITH BONE BLOCK	A peroneus longus tendon, attached to a bone block from the 1st metatarsal bone.
TENDON, PLANTARIS	TENDON, PLANTARIS	The thin long tendon of plantaris embedded medially into the Achilles tendon.
TENDON, QUADRICEPS, WITH BONE BLOCK	TENDON, QUADRICEPS, WITH BONE BLOCK	A quadriceps tendon, attached to a bone block from the patella.
TENDON, SEMITENDINOSUS	TENDON, SEMITENDINOSUS	A semitendinosus tendon.
TENDON, SEMITENDINOSUS, LEFT	TENDON, SEMITENDINOSUS, LEFT	A semitendinosus tendon at least 20cm length, obtained from the left leg.
TENDON, SEMITENDINOSUS, RIGHT	TENDON, SEMITENDINOSUS, RIGHT	A semitendinosus tendon at least 20cm length, obtained from the right leg.
TENDON, TIBIALIS, ANTERIOR	TENDON, TIBIALIS, ANTERIOR	The tendon connecting the medial cuneiform and first metatarsal bones of the foot to the anterior tibialis muscle.

Common Name	ISBT 128 Database Name	Definition
TENDON, TIBIALIS ANTERIOR, WITH BONE BLOCK	TENDON, TIBIALIS ANTERIOR, WITH BONE BLOCK	A tibialis anterior tendon, attached to a bone block from the medial cuneiform bone.
TENDON, TIBIALIS, POSTERIOR	TENDON, TIBIALIS, POSTERIOR	The tendon connecting the tarsal (i.e., navicular bone) and metatarsal bones to the posterior tibialis muscle. The tendon descends posterior to the medial malleolus.
TENDON, TIBIALIS POSTERIOR, WITH BONE BLOCK	TENDON, TIBIALIS POSTERIOR, WITH BONE BLOCK	A tibialis posterior tendon, attached to a bone block from the navicular bone.
TENDON, TOE EXTENSOR	TENDON, TOE EXTENSOR	A toe extensor tendon at least 9cm length.
TIBIA	TIBIA	The medial and larger of the two bones of the lower limb, between the knee and ankle.
TIBIA, PROXIMAL, LATERAL, LEFT	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	TIBIA, PROXIMAL, LATERAL, RIGHT	Lateral upper extremity of the right tibia inclusive of cartilaginous surface transected with 1-2cm cancellous bone.
TIBIA, PROXIMAL, LEFT	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	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	TIBIA, PROXIMAL, MEDIAL, RIGHT	Medial upper extremity of the right tibia inclusive of cartilaginous surface transected with 1-2cm cancellous bone.
TIBIA, PROXIMAL, RIGHT	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.
TIBIA SHAFT	TIBIA SHAFT	A section of the mid shaft of the tibia, removed by transecting.
TRI-CORTICAL WEDGE	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.

Common Name	ISBT 128 Database Name	Definition
WHOLE KNEE JOINT, LEFT	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	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.

4.1.3 Ocular Bounded List and Definitions

Common Name	ISBT 128 Database Name	Definition
EYE, LEFT	EYE, LEFT	A left eye removed from its socket.
EYE, RIGHT	EYE, RIGHT	A right eye removed from its socket.

4.1.4 Skin Bounded List and Definitions

Common Name	ISBT 128 Database Name	Definition
SKIN	SKIN	Skin, not specified as to size.
SKIN, FULL WITH HYPODERMIS	SKIN, FULL WITH HYPODERMIS	Full thickness skin with subcutaneous tissue (epidermis, dermis, and hypodermis).
SKIN, LARGE	SKIN, LARGE	Split thickness skin graft of greater than $10cm^2$ - surface area indicated on packaging.
SKIN, SMALL	SKIN, SMALL	Split thickness skin graft of $10cm^2$ or smaller - surface area indicated on packaging.

4.1.5 Other Bounded List and Definitions

Common Name	ISBT 128 Database Name	Definition
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.
TISSUE	TISSUE	Human tissue not otherwise specified.

4.2 Modifier

4.2.1 Bounded List and Definitions

Common Name	ISBT 128 Database Name	Definition
Cleaned Frozen Acellular	Cleaned Frozen Acellular	Processed to remove extraneous tissue and treated to deplete cell, cell remnant and nucleic acid content.
Cleaned Frozen	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	Cryopreserved	Processed to remove extraneous tissue and bacterial and fungal contaminants. Cryopreserved using a cryoprotective agent and stored below -135°C.
Decontaminated Frozen	Decontaminated Frozen	Chemically decontaminated and free of viable bacteria and fungi by culture. Frozen to, and stored at, below -40°C.
Demineralized	Demineralized	Bone that has been acid-treated.
Demineralized Freeze Dried	Demineralized Freeze Dried	Bone that has been acid-treated and then freeze-dried to less than 5% residual moisture.
Demineralized Pooled Single Donor	Demineralized Pooled Single Donor	Tissue from a single donor processed as a single batch that has been acid-treated.
Freeze Dried	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	Frozen to, and stored at, below -40°C.
Glycerolized	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	Pooled Multiple Donor	Tissue from more than one donor to be processed, or in process, as a single batch.
Pooled Single Donor	Pooled Single Donor	Tissue from a single donor to be processed, or in process, as a single batch.
Refrigerated	Refrigerated	Refrigerated (between 1 to 10°C; narrower range may be nationally-specified).

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 definitions

Group Name	Description
Nominal Granule Size	Describes the size range of the product
Pathogen Reduction	Describes the method of sterilization or decontamination of the product.
Unit of Issue	Describes the packaging of the product
Usage	Describes the intended use of the product
Anatomical Position	Describes the relative position of the product
Processed to Reduce Cellular Components	Indicates whether or not the product has been decellularized
Type of Preservation	Describes the technique used to preserve the tissue

4.3.2.2 Variables – bounded lists and definitions

4.3.2.2.1 Nominal Granule Size

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not defined	No information as to granule size is provided.
Coarse > 4mm ≤ 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<1.2mm	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 ≤2.0mm	Medium Powder >=1.2<=2.0mm	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.
Ultrafine ≤ 1 mm	Ultrafine <=1 mm	Granule size is less than or equal to 1 mm.

4.3.2.2.2 Pathogen Reduction

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	No information about pathogen reduction is provided.
ETO	ETO	Sterilized by exposure to ethylene oxide gas in the final container.
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 used as a sterilant in the processing procedure.
Radiation sterilization	Radiation sterilization	Exposed to ionizing radiation in accordance with a validated sterilization process.

4.3.2.2.3 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.

4.3.2.2.4 Usage

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.

4.3.2.2.5 Anatomical Position (see note below)

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

4.3.2.2.6 Processed to Reduce Cellular Components

Common Name	ISBT 128 Database Name	Definition
Default	Default: Not specified	No information is provided regarding a process to reduce cellular components.
Cell reduction process	Cell reduction process:Yes	Product has undergone a processing step 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 to reduce cellular components.

4.3.2.2.7 Type of Preservation (Currently this group only applies to new skin terminology and may be expanded in the future.)

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.
Frozen	Frozen	Preserved by freezing, but without additives specifically to protect cells/matrix and/or without the controlled freezing conditions required for cryopreservation.

Note: Prior to the introduction of the Anatomical Position attribute group, the Left and Right descriptors only existed as part of the Class name. It was recently determined that in general (see below for an exception*****) such descriptors would be better managed as attributes rather than part of the Class name.

Initially, the use of these Left and Right attributes will be restricted to new product description codes that require left/right designations.

The existing product description codes with Left and Right in the Class names would not change; however, eventually the Product Description formula for these codes would change. That is, Cryopreserved Menisci, Left would continue to have T0185 as its product description code; however, it's formula would eventually change so that "left" was coded as an attribute instead of being part of the class name.

The retirement and issue of replacement classes and the re-coding of the class and attributes in existing product codes (changing product description formulas) is scheduled in the future to allow time for vendors to update their software to accommodate this change.

There will be a transition period in which some product codes will have the Left and Right descriptors as part of the class name, and some product codes will have these descriptors as an attribute.

- 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.

5 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.

5.1 Class

5.1.1 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.

5.2 Modifier

5.2.1 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.

5.3 Attribute

5.3.1 Core Conditions

Please see Section 2.3.1 for an explanation of Core Conditions.

5.3.1.1 Core Conditions lists and definitions

First Position (anticoagulant/additive) – bounded list

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

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 Celsius.
Refrigerated	refg	Refrigerated (between 1 to 10 Celsius; narrower range may be nationally specified).

5.3.2 Groups and Variables

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

5.3.2.1 Groups: Bounded list and definitions

Group Name	Description
Blood Group	Specifies ABO Blood Group and/or RhD type.

Variables – bounded lists and definitions

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.

6 Retired Codes

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

To accomplish this goal, a new column has been added to ICCBBA databases. 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 codes after ICCBBA has made its recommendation.

Below are codes and their definitions that have been retired.

6.1 Blood Codes

6.1.1 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.

6.1.2 Attribute

6.1.2.1 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

6.1.2.2 Attributes: Groups

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

6.1.2.3 Attributes: Variables

Platelet Count Group

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

6.2 Cellular Therapy Codes

6.2.1 Class

Term	Definition
LYMPHOCYTES, Apheresis	Lymphocytes obtained by appropriate manipulation of an apheresis collection
MNC, Apheresis	Mononuclear cells obtained by apheresis
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, Apheresis	T cells obtained by appropriate manipulation of an apheresis collection
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)

6.2.2 Modifiers

Term	Definition
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.

6.2.3 Attributes

6.2.3.1 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

6.2.4 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

6.2.4.1 Attributes: Variables

6.2.4.1.1 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.

6.2.4.1.2 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

6.2.4.1.3 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
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

6.2.4.1.4 Manipulation Group

Term	Definition
AC133-selected	The ACC133 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.
CD56 enriched	Not defined
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

6.2.4.1.5 Further Processing Group

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

6.2.4.6 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.

6.3 Tissue Codes

No tissue codes have been retired.

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.director@iccbba.org.

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

