IMPLEMENTATION GUIDE
Encoding Product Information
[Data Structures 003, 032, 033, and 034] - Tissues

Version 2.0.0

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1   Introduction

1.1   Purpose

The purpose of this document is to provide detailed information about ISBT 128 product coding for tissues. Specifically, it:

- Describes the data structures used in product coding
- Compares two methods of encoding product information
- Describes the database that supports the internationally standardized Product Description Codes (PDC)
- Explains how to select an appropriate PDC
- Explains how to request new PDCs
- Explains the use of the Facility-Defined Product Code (FPC)
- Provides guidance on the coding of divisions (or packs)

1.2   Scope

This document is a supplement to the *ISBT 128 Standard Technical Specification*. It provides guidance for tissue banks in product coding. It applies only to tissue products (PDCs that begin with the letter "T").

The diagram in Figure 1 represents the information environment. The pyramid comprises a number of layers each of which is needed for standardization. This document describes the first two layers, "Terminology and Definitions" and "Reference Tables" as they pertain to product information. It will also discuss the Product Code [Data Structure 003] from the third layer. More information about other data structures, delivery mechanisms, and labeling can be found in references listed in 1.4 and 1.5.

This document does not cover labeling tissues following the medical device format. That information is contained within *ISBT 128 Standard Coding and Labeling of Medical Devices Using ISBT l28* (ST-011)

This document does not cover labeling of reproductive tissues.

Figure 1 Information Environment Layers

This document covers terminology and definitions, reference tables, and the data structures for product coding of tissue products.
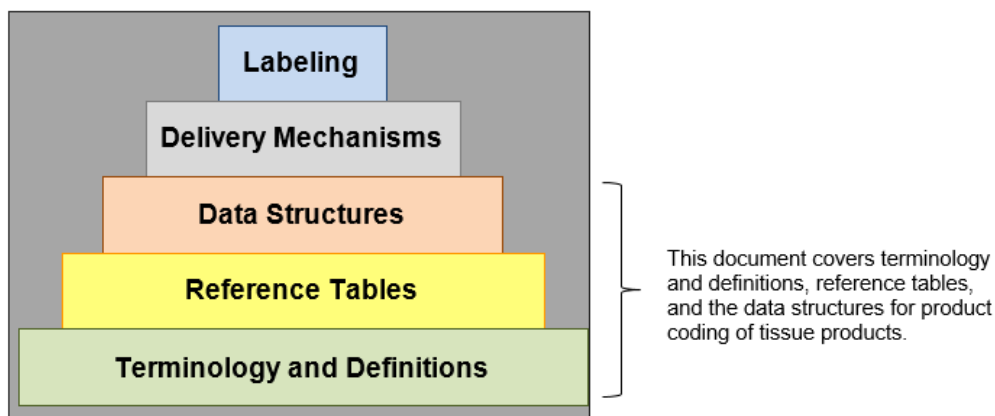
1.3   Intended Audience

The intended audience of this document is staff of tissue banks (managers, information technology, quality, validation and laboratory), software developers, and vendors of equipment used by tissue facilities. Information is also pertinent to facilities receiving products from tissue banks.

1.4   Normative Reference

ISBT 128 Standard Technical Specification (ST-001)
ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions (ST-002)
ISBT 128 Standard Labeling of Human Tissues (ST-003)
ISBT 128 Coding and Labeling of Medical Devices Using ISBT I28 (ST-011)

1.5   Other Reference

Use of Data Matrix Symbols with ISBT 128 (IG-014)
Implementation Guide: Use of Dimensions [Data Structure 029] (IG-026)
Implementation Guide: Use of the Divisions [Data Structure 032] (IG-023)
Use of the Processing Facility Information Code [Data Structure 033] (IG-031)

1.6   Background

There is wide recognition of the need to standardize the terminology, coding, and labeling of medical products of human origin (MPHO) in order to improve traceability and transparency. The 2010 World Health Assembly Resolution WHA63.22 called on member states to "encourage the implementation of globally consistent coding systems for human cells, tissues and organs as such in order to facilitate national and international traceability of materials of human origin for transplantation." ICCBBA is working with WHO in order to achieve this objective using the ISBT 128 Information Standard. On its website (http://www.who.int/transplantation/tra_isbt/en/), WHO describes ISBT 128 as the sole global standard for the identification and coding of MPHO.

Many countries around the world use ISBT 128 for blood and there is a steady global movement toward implementation of ISBT 128 for cells, tissues, and other MPHO. The use of ISBT 128 for tissues began in the United Kingdom more than a decade ago and has since expanded to a number of facilities in other countries in Europe and North America. The Eye Bank Association of America has mandated the use of ISBT 128 in its accredited eye banks by 2017 for products distributed internationally. The Cellular Therapy standards organizations [AABB, the Foundation for the Accreditation of Cellular Therapy (FACT), and the Joint Accreditation Committee for ISCT and EBMT (JACIE)] require that facilities use ISBT 128 terminology and have a plan for full implementation. The US National Marrow Donor Program (NMDP) currently has a program underway to assist facilities in their implementation of ISBT 128.

ICCBBA relies on experts in the various MPHO fields to provide advice on coding and labeling. Currently, there are four technical advisory groups that work with ICCBBA to maintain and expand the standard for use with human tissues. These groups are:

- The Eye Bank Technical Advisory Group (EBTAG)
- The European Tissue Technical Advisory Group (ETTAG)
- The North American TissueTechnical Advisory Group (NATTAG)
- The Tissue Engineered Products Technical Advisory Group (TEPTAG)

Additional groups will be established as needed in specialty areas such as reproductive medicine and organ transplant. The activities of these advisory groups are summarized on the ICCBBA Website in the Committees/Technical Advisory Groups area.

Also on the ICCBBA Website is information specific to each product category. Under the Subject Area tab, there are sections for Tissues, Ocular Products, and Tissue Engineered Products. Users of ISBT 128 should become familiar with the ICCBBA Website as it contains a wealth of information helpful to facilities implementing the Standard. A subscription service (accessed from the home page of the ICCBBA Website) can ensure users are notified of updates to the ISBT 128 Standard.

1.7 Changes in this Version

The following table indicates the major changes between Version 1.0.0 and Version 2.0.0. **Actual changes or additions to requirements of the ISBT 128 Standard are in bold print**; changes to formatting or organization, or additional guidance, are in regular print.

If changes were a result of a formal proposal, the number of the proposal is listed in the Rationale column.

	Version 1.0.0	Version 2.0.0	Change	Rationale
1.	Title	Title	The title of the document was changed from Implementation Guide, Use of Product Code Data Structure [003] – Tissues to Encoding Product Information [Data Structures 003, 032, 033, and 034] – Tissues.	The new title encompasses the additional data structures that may be used for encoding product information for tissues.
2.	1.1	1.1	This section was updated to reflect a broader purpose.	Several new data structures supporting the coding and labeling of tissues have been added.
3.	1.2	1.2	An explanation about how information in this document fits into the information environment was added.	This is intended as a clarification.
4.	1.4	1.4	A document on medical device coding and labeling was added.	This is a new document to support labeling of tissues as medical devices, as required by regulations in some countries.
5.	1.5	1.5	Additional references were added.	These are new documents.

	Version 1.0.0	Version 2.0.0	Change	Rationale
6.	1.6	1.6	The Background section was changed to reflect the activities of the World Health Assembly and WHO in regards to the coding and labeling of medical products of human origin (MPHO) as well as the status of ISBT 128 implementation in tissue banks.	These updates reflect increasing recognition of ISBT 128 as a global standard.
7.	2	2	New data structures (032, 033, and 034) were added.	These new data structures are used for coding information about tissue products.
8.		3	This new chapter describes the elements needed to encode information for tissues.	Additional data structures in the ISBT 128 Standard provide additional options for encoding information.
9.	3	4	**This section was updated extensively to reflect the newly restructured Product Description Code database.**	**The Product Description Code database was restructured to support expansion of the Standard. (Proposal 11-004)**
10.		4	Additional background on the development of terminology was provided.	To provide the reader with a better understanding of the process.
11.	3.1.1	**4.1 and Table 3**	**Modifiers have been phased out from tissue product descriptions. Table 3 was added.**	**This was a decision of tissue advisory groups. Information that was previously a Modifier has become an Attribute.**
12.		4.2 and 4.3	The examples were updated.	This reflects changes in the terminology.
13.	3.1.3	**4.4**	**The description of the database was changed to reflect the newly restructured database.**	**The Product Description Code database was restructured to support expansion of the Standard. (Proposal 11-004)**

	Version 1.0.0	Version 2.0.0	Change	Rationale
14.	**3.1.4.2**		**The option of using a generic PDC (T0000) has been removed.**	**The use of a generic PDC for tissues does not support the global goal of standardized coding. The T0000 PDC has been retired.**
15.	3.1.4.3		The section on use of a formula for selecting PDCs was deleted.	The use of the lookup tool has eliminated the need to use formulas to find PDCs. Also, the formulas have changed in the newly structured PDC database.
16.		4.5	This section was updated to describe the new lookup tool.	A new lookup tool that supports all product categories was developed.
17.	**3.1.5.2, Figure 4 and Figure 5**	**4.6.2, Figure 14 and Figure 15**	**Modifiers were removed.**	**This was a decision of tissue advisory groups. Information that was previously a Modifier has become an Attribute.**
18.		**5**	**This section was added to describe the FPC.**	**This is a new element for describing tissues that allows tissue banks a great deal of flexibility in incorporating facility-specific information into a product description. (Proposals 12-004 and 13-001)**
19.	**4**	**6**	**This section was expanded to include Data Structure 032.**	**This is a new data structure. (Proposal 11-003b)**
20.	4	6	Instructions for use of the Divisions code with T0000 were deleted.	Use of T0000 is no longer recommended.
21.		7	Information specific to software developers was added.	This was added to assist software developers in creating products that support the ISBT 128 Standard.

2 Product Coding Data Structures

Data structures are the means by which information is encoded into an electronically-readable format following the ISBT 128 Standard [see *ISBT 128 Standard Technical Specification* (ST-001) for further information]. Each data structure can carry multiple types of information. There are four data structures which contain specific product information and they are included in this chapter. A fifth data structure used to encode specific product information is Dimensions [Data Structure 029]. Information about the use of this data structure may be found in a separate document, Implementation Guide: Use of Dimensions [Data Structure 029] (IG-026).

2.1   Product Code [Data Structure 003]

Purpose: Data Structure 003 shall identify a product intended for human use and encode whether or not the product has been divided.

Structure: =<αooootds.

Element	Length	Type
=	1	data identifier, first character
<	1	data identifier, second character
α	1	alphabetic {A–Z} See below
oooo	4	numeric {0–9}
t	1	alphanumeric {A–Z; a–z; 0–9} (depends on value of α, see below)
d	1	alphanumeric {A–Z; 0–9}, (depends on value of α, see below)
s	1	alphanumeric {a–z; 0–9} (depends on value of α, see below)

The eight (8)-character data content string, **αooootds** shall be encoded and interpreted as follows.

αoooo   shall specify the Product Description Code (PDC) and shall be encoded and interpreted by reference to the Product Description Codes table within the ISBT 128 Product Description Code Database published and maintained by ICCBBA in the password-protected area of the ICCBBA Website.

α shall specify the product category. For tissues, **α** is T. A-D may be used for national or local codes (see 4.7, Page 37).

For letters used for other categories of products, consult the *ISBT 128 Standard Technical Specification* (ST-001).

oooo shall only be interpreted, when combined with **α**, through reference to the PDC database.

tds   The encoding and interpretation of **tds** shall depend upon the value of **α**. If **α** is T, **tds** shall specify a 3-digit number of divisions/packs of the product. These three characters provide a means to uniquely identify multiple occurrences of tissue products identified with the same PDC and derived from the same donation event. If multiple divisions/packs do not exist, **tds** shall be set to 000 (three zeroes).

If **α** is A-D, tds is not defined. If tds is set to something other than 000, it shall be defined in conjunction with the national/local code assignment.

Thus the full Product Code is eight characters long, with a five-character PDC and a three-character division/pack code as shown in Figure 2.

Figure 2   Example of Data Content for Data Structure 003

T0120003

Product
Description
Code

Division (or
Pack) Code
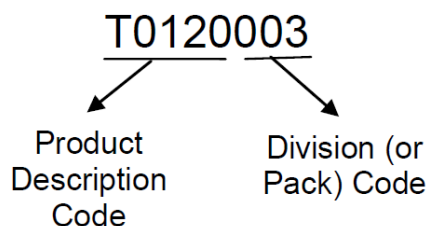
2.2   Product Divisions [Data Structure 032]

Purpose: Data Structure 032 shall convey information about divisions.

Structure: =,dddddd

Element	Length	Type
=	1	data identifier, first character
,	1	data identifier, second character
dddddd	6	alphanumeric {A–Z, 0–9}

The 6-character data string dddddd shall be encoded and interpreted as follows:

dddddd   shall specify the Division Code

The Division Code allows for a high level of flexibility.

- Digits shall be used where a single level of divisions is required (allowing up to 999,999 divisions).
- If it is desirable to show levels of divisions (to allow for divisions of divisions), alpha characters shall be used. In this situation, the six character field may be split into three pairs, each allowing AA through ZZ. This provides up to three levels of division.

Each Product Divisions code shall be unique for a given PDC and DIN.

Note: The Divisions Data Structure [033] shall not be used in conjunction with the Product Code Data Structure [003] when the value of α is T.

2.3   Processing Facility Information Code [Data Structure 033]

Purpose: Data Structure 033 shall convey information about the facility that assigned the Product Code and may include a facility-defined product code assigned by the processing or labeling facility.

Structure: &+nnnnnpppppp

| Element	Length	Type
&	1	data identifier, first character
+	1	data identifier, second character
nnnnn	5	alphanumeric {A–N, P–Z, 0–9}
pppppp	6	alphanumeric {A–Z, 0–9}

The 11-character data string nnnnnpppppp shall be encoded and interpreted as follows:

nnnnn   shall specify the Facility Identification Number of the facility that assigned the Product Code [the FIN (P)], and is encoded and interpreted by reference to the ICCBBA Registered Facility table published and maintained by ICCBBA in the password-protected area of the ICCBBA Website. The facility that assigned the Product Code may, or may not, be the same facility that assigned the Donation Identification Number (DIN).

This code, in conjunction with the DIN (Data Structure 001) and Product Code (Data Structure 003), may be required for unique identification of the product. If the FIN within Data Structure 033 is required to ensure unique identification of the product, then these data structures shall be presented in a 2D symbol to ensure all information required for traceability is read.

pppppp   shall specify a Facility-Defined Product Code (FPC) assigned by the processing or labeling facility indicating a catalog or other number that identifies the product within its system. The FPC shall not be used to create uniqueness for the product. The processing or labeling facility may choose to publish reference tables for use by the organizations receiving the product. If a value is not required, the default value 000000 (zeroes) shall be used.

Figure 3 Example of Data Content for Data Structure 033
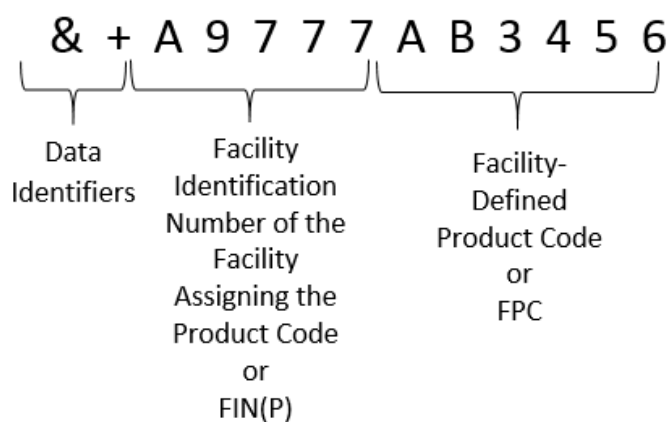
See Implementation Guide: Use of the Processing Facility Information Code [Data Structure 033] (IG-031) for more information.

2.4 Processor Product Identification Code [Data Structure 034]

Purpose: Data Structure 034, the Processor Product Identification Code (PPIC), shall identify the processing or labeling facility, a facility-assigned facility product code, and a standardized PDC. This data structure may be used for medical device identification.

Structure: =/nnnnnppppppqqqqq

Element	Length	Type
=	1	data identifier, first character
/	1	data identifier, second character
nnnnn	5	alphanumeric {A–N, P–Z, 0–9}
pppppp	6	alphanumeric {A–Z, 0–9}
qqqqq	5	alphanumeric {A–Z, 0–9}

The 16-character data string nnnnnppppppqqqqq shall be encoded and interpreted as follows:

nnnnn   shall specify the Facility Identification Number of the facility that assigned the Product Code [the FIN(P)],and shall be encoded and interpreted by reference to the ICCBBA Registered Facility table published and maintained by ICCBBA in the password-protected area of the ICCBBA Website. The facility that assigned the Product Code may, or may not, be the same facility that assigned the DIN.

pppppp   shall specify a Facility-Defined Product Code (FPC) assigned by the processing or labeling facility indicating a catalog or other number that identifies the product within its system. This code shall not be used to create uniqueness for the product. If a value is not required, the default value 000000 (zeroes) shall be used. This facility may choose to publish reference tables for use by the organizations receiving the product.

qqqqq   shall be encoded and interpreted by reference to the Product Description Codes table within the ISBT 128 Product Description Code Database published and maintained by ICCBBA in the password-protected area of the ICCBBA Website.

Figure 4 Example of Data Content for Data Structure 034
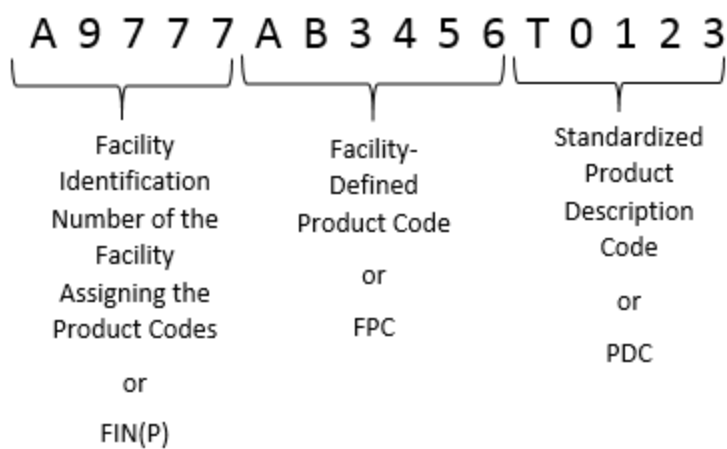
3   Product Coding Elements

There are two mandatory elements involved in product coding. They are:

Product Description Code (PDC)	These are internationally standardized codes, although an option for nationally- or locally-defined codes exists. The code differentiates products produced from a given recovery event. It shall be encoded either in Data Structure 003 or 034.
Divisions (or packs)	These codes shall be used to differentiate multiple products with the same DIN and PDC (e.g., multiple vials of bone powder from the same recovery event). It shall be encoded either in Data Structure 003 or 032.

Additionally, there is an optional element in product coding. It is:

Facility-Defined Product Codes (FPC)	These are product codes assigned by the processing facility and must be used in conjunction with the Processing Facility Identification Number [FIN(P)]. FPC shall be encoded either in Data Structure 033 or 034. An FPC shall not be used to create uniqueness for the purpose of traceability.

Because of how information is encoded into the various data structures, specific combinations of data structures shall be used together to provide data needed for traceability.

One of these combinations of data structures is called "traditional coding" throughout this document because it is based on the use of a data structure for product coding that has been in use for a long time. In this option, Data Structures 003 and 033 are used for product coding.

The other combination of data structures, called "medical device coding" throughout this document, was created specifically for tissue products regulated as medical devices in the US, but may be used for all tissues anywhere in the world. In this option, Data Structures 032 and 034 are used for product coding.

The three elements of product coding and valid combinations of data structures are listed in Table 1. It can be seen that the same information is encoded by the two methods; it is simply arranged differently.

Table 1 Valid Combinations of Data Structures

Information Element	Traditional Coding Data Structures	Medical Device Coding Data Structures
PDC	Product Code [Data Structure 003]	Processor Product Identification Code [Data Structure 034]
Divisions (or packs)	Product Code [Data Structure 003]	Product Divisions [Data Structure 032]
FPC	Processing Facility Information Code [Data Structure 033] *Note: If an FPC is not used, and the processing facility identification is not required for other reasons, the use of Data Structure 033 is optional.*	Processor Product Identification Code [Data Structure 034]

Facilities may select the combination of data structures that works best for them, or they may use both depending on the product (e.g., use traditional for tissues regulated as biologics and medical device for tissues regulated as devices). Receiving facilities must be able to read and interpret either set of data structures. Table 2 compares the two methods of coding product information.

Table 2 Comparison of Traditional versus Medical Device Coding Methods

Characteristic	Traditional (Data Structures 003 and 033)	Medical Device (Data Structures 032 and 034)
Bar code symbology	Linear (Code 128) or 2D (Data Matrix)	2D (Data Matrix)
Backward compatibility	Adds only one new data structure [033] compared to blood or cellular therapy coding, thus requiring minimal change to software. If linear bar codes are used, software does not need to interpret compound messages. This allows more rapid adoption by receiving facilities.	Requires two new data structures and the capability of interpreting compound messages encoded in 2D symbols
Number of divisions that can be encoded	999	999,999
Readily compatible with the Single European Coding (SEC) system	Yes	No (SEC supports only a 3-character division code)
Formatted for unique device identifier (UDI)	No	Yes

4　Product Description Codes (PDC)

The PDC is an internationally standardized product identification. The first five characters of the Product Code, and the last 5 characters of the Processor Product Identification Code, comprise a code that maps to a product description through a reference table. The products are described through the use of tissue Class and Attributes. Each of the Class and Attribute terms that are used to create tissue product descriptions are defined in the document*: Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions.*

In general, the product descriptions included in the ISBT 128 PDC database are intended for use in final product labeling. A "final product" is defined as a product appropriate for transfer from the recovery and/or processing facility inventory to some other inventory. However, with the use of the "For Further Processing" Attribute, facilities may optionally use ISBT 128 product codes internally from the time of the recovery of tissue.

An outdate period is not defined in the description since each country determines the permissible period after recovery or further processing during which the tissue product may be used.

The PDC contains information about manufacturing, but is not intended to be a complete record of all processing steps; that is, it is not a portable data file of the manufacturing process.

4.1　Terminology and Definitions

The foundation of ISBT 128 product coding is standardized terminology. The process begins by having international groups of experts on Technical Advisory Groups (TAGs) select and define terms for different types of biological products through consensus processes. For tissue products, these groups are the Eye Bank Technical Advisory Group (EBTAG), the European Tissue Technical Advisory Group (ETTAG), the North American Technical Advisory Group (NATTAG), and the Tissue Engineered Product Technical Advisory Group (TEPTAG).

It is critical that the words used to identify and define each product are precise and unambiguous. Terminology is based on the concepts of Classes and Attributes, a hierarchy of terms which are used as building blocks to describe blood products.

Class is a general description of tissue products (such as Tendon, Achilles with Bone Block or Valve, Pulmonary).

Attributes provide additional information about the tissue product. Tissues thus may be further described through the addition of one Attribute variable from one or more Attribute groups.

Tissue Attributes are organized into groups as shown in Table 3.

Table 3 Tissue Attribute Groups

Group Name	Description
Additives	Describes additives present in the product.
Additional Processing	Describes additional tissue processing.
Donor-Intended Recipient Relationship	Describes the relationship between the donor and the intended recipient.
Meshed	Describes the degree to which the surface area of the skin has been increased by creating a net or web.
Storage Solution	Describes the solution in which the tissue is stored.
Type of Preservation	Describes the technique used to preserve the tissue.
Processed to Reduce Cellular Components	Indicates whether or not the product has been decellularized.
Anatomical Position	Describes the relative position of the tissue in the donor's body prior to tissue procurement.
Processing Status	Indicates if a product is being held for further processing.
Unit of Issue	Describes the packaging of the product.
Pathogen Reduction	Describes the method of sterilization or decontamination of the product.
Nominal Granule Size	Describes the size range of the product.
Demineralization	Indicates if a product was demineralized

For each group, there is a default value and multiple other mutually exclusive options (variables). For example, for the Meshed group, the default and other variables are listed in Table 4. Unless otherwise stated, it is assumed that the "default" state applies.

Table 4 Meshed Group Variables

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

The document *Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions* (ST-002) provides complete lists and definitions of all tissue Classes and Attributes.

4.2 Product Descriptions

Using the nomenclature provided in *Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions,* tissue products may be described in various levels of detail. The terms may be used as building blocks by selecting those terms that best describe a product. The terms are then strung together to form the description of a given tissue product.

- First a Class must be selected.
- Then a variable from one or more Attribute groups may be selected. A selection from Attribute groups/variables is not required.

An example tissue product description is:

   Class: TENDON, PATELLAR WITH SHAPED BONE BLOCK
   Attribute Variables: Frozen, Radiation sterilization

Because variables from only two groups (Type of Preservation and Pathogen Reduction) were selected, the default values from all other Attribute groups apply to this product. This means the following additional information applies:

Additives	Additives are not specified in the coding
Additional Processing	Additional processing not specified
Donor-Intended Recipient Relationship	No information about the relationship between donor and intended recipient is provided.
Meshed	Either this attribute group does not apply (tissue is not skin) or no information about whether the skin has been meshed is provided.
Storage Solution	No information is provided about storage solution.
Processed to Reduce Cellular Components	No information is provided regarding a process intended to reduce cellular components.
Anatomical Position	No information is provided as to the relative position of the tissue in the donor's body prior to tissue procurement.
Processing Status	No information is provided as to the status of the product.
Unit of Issue	No information is provided as to the packaging of the product.
Nominal Granule Size	No information as to granule size is provided.
Demineralized	Not applicable or not demineralized.

4.3   Structure of Product Descriptions within the Database

Once defined, product descriptions are placed into a reference table database. Each description is assigned a unique five-character PDC for electronic communication. Although there is no structure to the five-character PDC, the description of the product within the database is rigidly structured. Each product is defined in the ICCBBA database minimally in terms of its Class.

The Class and Attributes are separated in the product description by the "|" delimiter: CLASS|Attribute|Attribute. Only one variable from each Attribute group may be used.

For example:

PDC	Description
T0446	ARTERY, FEMORAL, SUPERFICIAL|Left|For further processing
T0447	TENDON, SEMITENDINOSUS|Frozen|Radiation sterilization
T0448	TENDON, TIBIALIS, POSTERIOR|Frozen|Radiation sterilization

The order in which the Attributes appear in the description field of the database is in the order of the Attribute groups shown on Table 3.

The order in which text appears in the description field of the database does not specify the order in which Attributes will appear as label text. Since this can be country-specific, national guidelines as to the order of label text should be consulted. Additionally precise wording used on labels may be nationally-defined rather than using the exact words found in the database description as long as the same meaning is retained.

4.4   PDC Database

Starting with Version 6.0.0, the ISBT 128 Product Description Code database has been restructured to accommodate future growth. Tables following the previous format will temporarily continue to be provided. As the use of ISBT 128 continues to grow (more than 11,000 Product Description Codes and 11 types of products now exist), it is expected that the original database structure will become inadequate. While the limitations of the database have not been reached, it is deemed necessary to redesign the database now to support the anticipated growth. While it cannot be foreseen just how long the old database design will continue to meet the needs, ICCBBA strongly recommends that software that utilizes more than just the Product Description Codes (e.g., uses product formulas) be updated as soon as possible. ICCBBA will continue to support the current tables until the end of 2016, unless the original table structures can no longer support new products.

Details of the new database structure may be found in *ISBT 128 Standard Product Description Code Database* (ST-010).

The structure of the new database may not affect all existing ISBT 128 software. Existing software that only utilizes the ISBT 128 PDCs should not be affected. The PDCs themselves have not been redefined or restructured.

All ISBT 128 database tables shall be published in the password-protected area of the ICCBBA Website. This file is a Microsoft Access® file and listed on the Website as:

ISBT 128 Product Description Code Database

4.5   Selecting PDCs

Tissue PDCs begin with the letter "T". The codes are listed in alphabetical order in the full database so tissue codes are found toward the end of the full database tables.

To appropriately select product descriptions, it is important to understand the definitions of each term. These definitions are found in *Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions*. This document must be consulted in order to select the appropriate descriptions and codes for tissue products.

4.5.1   "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 column exists in the ICCBBA database to indicate such codes. 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.

4.5.2   Level of Detail

Facilities can determine the level of detail that must be encoded into an electronically-readable format according to the needs of its customers. For example, a facility may choose to use a code that includes anatomical position, such as:

T0443: ARTERY, FEMORAL, SUPERFICIAL | Allogeneic | DMSO | Cryopreserved | Right | Antibiotics

Or they may choose a less detailed code, such as:

T0350: ARTERY, FEMORAL, SUPERFICIAL | DMSO | Cryopreserved | Single | Antibiotics

4.5.3   Using the Product Code Look-up Tool to Find PDCs

Searching for the correct PDC can be simplified by the use of the PDC lookup program available on the ICCBBA Website. (From home page, select "Lookup Tools" from the menu at the top of the page. Then select "Find Product Information.") This is a Microsoft Excel file that can be downloaded onto your computer. It is compatible with Microsoft Excel 2007-2013. It has not been validated, and should not be used, with earlier versions of Microsoft Excel.

It is updated with each new version of the PDC database (approximately once a month). Therefore, users must download this tool frequently to ensure the most recent PDCs are available.

The program can be used to lookup a description for a given PDC or to look up a PDC based on a description.

When the program is opened, the ISBT 128 Product Description Code Lookup Utility screen will appear. See Figure 5.

Figure 5 Opening Screen of Lookup Tool

To find the description when you know the PDC (See Figure 6):
- Enter the PDC in the first field.
- Click on the ISBT 128 Code Lookup button.
- The description will appear in the field below the ISBT 128 Code Lookup button.
- To lookup another description, click the Reset button and repeat the first 3 steps.
- To close tool, click the Close button.

To find a PDC for a given product description:
- Click on Tissues in the Category Field and Tissues in the Subcategory field. See Figure 7. (Currently, category and subcategory are the same, but this will not always be the case.)
- Click the "Lookup" button to the right of the Subcategory field. The ISBT 128 Product Lookup screen will appear. See Figure 8.
- Click on the Class desired. See Figure 8.
- Select Attributes, if desired. See Figure 9.
    - Click on the Attribute Group desired. Attribute values corresponding to the class selected will appear in the Attribute Value field.
    - Click on the value desired. This value will appear in the Selected Attributes window.
    - Select additional Attributes following these same steps.
- At this point there are two options, "Exact Match" and "Find."
    - Clicking "Exact Match" will bring up the PDC that exactly meets the selection criteria. See Figure 10.
    - Clicking "Find" will result in a list of products that include these criteria. See Figure 11.
- If desired, click the Export List button to export the list of products in a text file to a selected location. See Figure 12 and Figure 13. The text file will be named Product Description Codes. (Note: If you export a second list to the same location, it will overwrite the first list unless you change the name of the first file.)
- Use the Reset button to clear the screen and allow a new query to be performed.
- Use the Close button to close the tool.

Figure 6   Lookup a Description from a PDC

Figure 7   Lookup a PDC from a Description   (Opening Screen)

Figure 8 ISBT 128 Product Lookup by Description Screen

Figure 9 Describing Product

Figure 10 Lookup PDC that Exactly Matches Criteria

To find the PDC that exactly matches criteria entered, click on "Exact Match".

PDC will appear in this field.

Figure 11 Lookup All PDCs that Meet Criteria

To find all PDCs that meet criteria, click on "Find" button.

All PDCs that meet criteria appear in this screen.

Figure 12 Use of Export List Function

Figure 13 Text File Created by Lookup Tool

4.6 Requesting New PDCs

An on-line form for requesting a new PDC for tissues is available on the ICCBBA Website. See Figure 14.

Countries are encouraged to appoint an individual or committee to manage code requests on a national basis in order to retain consistency within the country.

Codes that represent new combinations of existing Classes and Attributes will generally be added on the next database update. The database is updated approximately 10 times each year.

If a new Class, Attribute Group, or variable within an Attribute Group is needed, please contact the ICCBBA Technical Director (tech.director@iccbba.org). A definition compatible with the format of those in the *Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions* should accompany such a request. Requests for new terms will be reviewed by the appropriate technical experts to ensure international consensus with the terminology chosen.

Updates to the PDCs will be regularly posted in the password protected section of the ICCBBA Website and made apparent by a change in the Version Number of the ISBT 128 Product Description Code Database. Version control sheets describing the changes are published with each update.

4.6.1 Completing the Request Form

The form for requesting new tissue codes is found on the ICCBBA Website. It is found in the Subject Area tab, under Tissues and is called Request a Code. One completed form is required for each new PDC requested.

Minimally, the request must include a Class.

Select one Class from the dropdown list.

If needed, select Attributes from each Attribute Group where a non-default value is required (only one per Attribute Group) from the dropdown lists.

Click on "Submit to ICCBBA".

4.6.2 Submitting the Request

Click on the "Submit to ICCBBA" button to submit the form to the appropriate individual at ICCBBA. You will receive an automated acknowledgement of the submission. Questions should be submitted to ICCBBA at iccbba@iccbba.org.

Figure 14 On-Line Request Form

Figure 15 Examples of Drop-Down Menus: Classes

CLASS

(Scroll down on Website dropdown menu for
more options)

```
--Select Class--
ADIPOSE TISSUE
AMNIOTIC MEMBRANE
AMNIOTIC MEMBRANE, LARGE
AMNIOTIC MEMBRANE SHEET
AMNIOTIC MEMBRANE, SMALL
ANKLE
AORTA, ARCH
AORTA, ARCH, WITH DESCENDING THORACIC
AORTA, ASCENDING
AORTA, ASCENDING, WITH ARCH
AORTA, DESCENDING, ABDOMINAL
AORTA, DESCENDING, THORACIC
AORTOILIAC, CONDUIT
ARTERY, BRACHIAL
ARTERY, COMMON ILIAC
ARTERY, FEMORAL, COMMON
ARTERY, FEMORAL, SUPERFICIAL
ARTERY, INTERNAL THORACIC
ARTERY, RADIAL
ARTERY, ULNAR
BONE
CADAVERIC CANCELLOUS BONE
CADAVERIC CORTICAL BONE
CALCAR FEMORALE
CANCELLOUS BONE CHIPS
CANCELLOUS BONE CUBES
CANCELLOUS BONE DOWEL
CANCELLOUS BONE PEG
CANCELLOUS FEMORAL KNEE SLICE
```

Figure 16 Examples of Attribute Drop-Down Menus

Additive

```
Default: Not specified
Additives:Yes
Additives:yes incl animal src
Albumin
Albumin + other
Autologous plasma
Autologous plasma + other
3rd party donor plasma
3rd party donor plasma + other
```

Additional Processing

```
Default: Not specified
Marrow depleted
Cleaned
```

Donor-Intended Recipient Relationship

```
Default: Not specified
Allogeneic
Autologous
```

Meshed

```
Default: Not specified
Meshed 1:1
Meshed 1:1.5
Meshed 1:2
Meshed 1:3
Not meshed
```

Storage Solution

```
Default: Not specified
Cryopreserved
Freeze dried
Frozen
Glycerol (high conc)
Refrigerated
Solvent dehydrated
```

Type of Preservation

```
Default: Not specified
Antibiotic
DMSO
Glycerol (low conc)
Vitrification
```

Processed to Reduce Cellular Components

```
Default: Not specified
Cell reduction process:Yes
Cell reduction process:No
```

Anatomical Position

```
Default: Not specified
Left
Right
```

Processing Status

```
Default: Not defined
For further processing
```

Unit of Issue

```
Default: Not defined
Single
Pack
Pack2
Pack4
```

Pathogen Reduction

```
Default: Not specified
Antibiotics
Combined process
ETO
No pathogen reduction
Pathogen reduced: method NS
Peracetic acid
Radiation sterilization
```

Nominal Granule Size

```
Default: Not defined
Coarse >4<=6 mm
Medium >2<=4 mm
Fine <=2 mm
Ultrafine <=1 mm
Mixed <=6 mm
Mixed <=4 mm
Medium Powder >=1.2<=2.0 mm
Fine Powder >0.1<1.2 mm
```

Demineralization

```
Default: No or not applicable
Demineralized:Yes
```

4.7   Product Codes Designated for Local or National Use

Because the use of a PDC within Data Structure 003 or 034 is mandatory, and because not all products may be defined within the list of internationally standardized product codes, a means to create a local or national code within these data structures is needed. The block of PDCs, A0000-D9999, has been reserved for use as nationally- or facility-defined product codes. There will be no international interpretation associated with these values.

These codes should ONLY be used where there is not an appropriate international code and there is good reason why an international code should not be allocated. Local codes should be used when a product is only produced in one or a very small number of facilities. If there is any uncertainty whether the code assigned to a product should be international or local/national, the user should contact the ICCBBA office.

National agencies may elect to reserve a range of these values for national assignment. Where this is done it is the responsibility of the national agency to ensure that definitions are provided for use within the country and that products bearing such codes are not transferred outside the national boundary.

Individual facilities may also assign codes for their own use provided that these do not conflict with codes assigned at the national level. Where such codes are used, it is the responsibility of the facility to ensure that definitions are provided for use within their service region, and that products bearing such codes are not transferred outside their normal distribution network. Care should be taken in interpreting the product description from a local code as this will be specific to the supplier.

In all cases, the product definition for nationally or facility assigned codes must be retained permanently for traceability purposes. Once assigned, codes should not be reassigned.

5   Facility-Defined Product Codes (FPC)

The use of a Facility-Defined Product Code (FPC) is optional. These codes were designed to allow facilities to describe their products in whatever way they felt appropriate. Information not encoded in the internationally standardized codes (e.g., the volume of a product or the size of the bone cube) may be encoded using the FPC. The codes may also be used to indicate packaging characteristics, such as labeling for a given distributor or in a given language.

Note: Measurements of tissue products may also be encoded using Dimensions [Data Structure 029]. See *Implementation Guide: Use of Dimensions [Data Structure 029]* (IG-026).

These codes are assigned by the facility and are specific to that facility. The facility may provide reference tables to its customers for use in interpretation of these codes.

These codes shall not be used to create uniqueness required for traceability of products. They should be used as additional information.

6   Division or Pack Codes

Product divisions or packs may be identified within the Product Code [Data Structure 003] or in the Product Divisions [Data Structure 032]. As noted in Table 1, page 19, either of these data structures may be used, but must be used in a valid combination with other data structures.

6.1   Coding within Data Structure 003

The purpose of the product division or pack characters is to provide a means to uniquely identify multiple occurrences of tissue products identified with the same PDC and derived from the same donation event. It is encoded using the last 3 characters of the Product Code [Data Structure 003] as shown in Figure 2.

Figure 17   Product Code
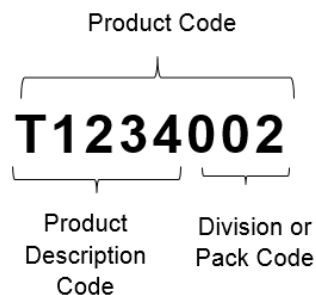
When multiple identical products result from a single donation, individual divisions are distinguished by these characters. For example:

T0416001 Container 001 of SKIN, SPLIT|Allogeneic|Not meshed|Frozen
T0416002 Container 002 of SKIN, SPLIT|Allogeneic|Not meshed|Frozen
T0416003 Container 003 of SKIN, SPLIT|Allogeneic|Not meshed|Frozen

Only numeric values are valid for tissues. If a product is not divided, or if the division number does not need to be specifically identified, the product division characters shall be set to "000" (three zeroes).

6.2   Coding within Product Divisions [Data Structure 032]

This data structure allows a 6-character division or pack code. Values can be numeric or alpha. See *Implementation Guide: Use of Product Divisions [Data Structure 032]* (IG-023) for more information on the use of this data structure.

7 Software Developers

Software for facilities receiving tissue should be able to accommodate either the traditional or the medical device method of coding if there is a possibility that products labeled in both of these ways will be received. The information and the codes used are the same, but the data structures used to encode it are different.

The Processing Facility Identification Number, or FIN(P), is required if the FPC is used or if the tissue processor obtains tissue from a tissue procurement organization that provides product to more than one tissue processor. When the FIN(P) is present, it shall be recorded in records for the tissue.

The FPC may not be used for uniquely identifying a product for traceability purposes. If an FPC maps to multiple PDCs, division (or pack) codes must be used to uniquely identify each product. For example:

FPC	Description of Product	PDC	Data Structure 003 (Traditional Coding method)	Data Structure 032 and 034 (Medical Device Coding method)
XYZ123	CORTICOCANCELLOUS BONE, CRUSHED, 5 mL, first vial	T0265	T0265001	000001 and A9999XYZ123T0265
XYZ123	CORTICOCANCELLOUS BONE, CRUSHED, 5 mL, second vial	T0265	T0265002	000002 and A9999XYZ123T0265
XYZ157	CORTICOCANCELLOUS BONE, CRUSHED, 10 mL, first vial	T0265	T0265003	000003 and A9999XYZ157T0265
XYZ157	CORTICOCANCELLOUS BONE, CRUSHED, 10 mL, second vial	T0265	T0265004	000004 and A9999XYZ157T0265

Retired PDCs (those with a date in the "Retired Date" field in the Product Description Code database) should be recognized by the software. However, as soon as possible after the retirement date, they should not be used to label new products.

When writing software to read ISBT 128 labels, it should be recognized that tissue products can be received from multiple sources and each source may use different options available within the ISBT 128 Standard. Software should accommodate all valid scenarios. As an example, one tissue bank may opt not to use the flag characters in the DIN data structure, and thus always provide donations with flag characters of "00". Another bank may choose to use the process control flags and thus have other values in the flag characters. Both options are valid, and so any valid flag character value should be accepted by the reading software. For similar reasons, software should be able to support the use of both multiple linear bar codes each containing a single ISBT 128 data structure and 2-D bar codes carrying multiple ISBT 128 data structures in a compound message.

Acronyms Used

DIN   Donation Identification Number

FIN(P)   FIN of the facility assigning the Product Code

FPC   Facility-Defined Product Code

MPHO   Medical Products of Human Origin

PDC   Product Description Code

WHO   World Health Organization