



IMPLEMENTATION GUIDE

Use of the Processing Facility Information Code [Data Structure 033]

Version 1.1.0

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1 Introduction

1.1 Purpose

The purpose of this document is to provide guidance in the implementation and use of the Processing Facility Information Code [Data Structure 033].

1.2 Scope

This document is a supplement to the *ISBT 128 Standard Technical Specification* (ST-001). It provides specific guidance for cellular therapy and tissue (including ocular) facilities in the implementation and use of the Processing Facility Information Code [Data Structure 033]. This document also addresses some concerns for software developers.

The use of this data structure for tissues and cells is not currently required in most situations (but see 3.2.2). However, it is anticipated that future changes in the manner in which Donation Identification Numbers (DINs) are assigned and used may make the additional facility information essential for traceability purposes. In the meantime, some tissue and cell facilities may choose to implement this data structure for other reasons.

The use of this data structure for categories of products other than cellular therapy and tissues has not been agreed by technical advisory groups in the areas of expertise. This situation could change as users in these fields become aware of the data structure and see potential for its use.

1.3 Intended Audience

The intended audience of this document is Cellular Therapy facility staff (collection, processing, and administration facilities), Tissue (including ocular) facility staff (procurement, processing, and transplant centers), software developers, and label/software vendors.

1.4 Normative Reference

ISBT 128 Standard Technical Specification (ST-001)

ISBT 128 Standard, Standard Terminology for Medical Products of Human Origin (ST-001)

1.5 Other References

ICCBBA Website (www.iccbba.org)

Use of Data Matrix Symbols with ISBT 128 (IG-015)

Implementation Guide: ISBT 128 Facility Identification Number (IG-034)

Implementation Guide: Use of Dimensions [Data Structure 029] (IG-026)

Implementation Guide: Use of Product Divisions [Data Structure 032] (IG-023)

1.6 Background

More than one facility may be involved in the collection or recovery, processing, and labeling of a medical product of human origin. The ISBT 128 DIN includes the identity of the organization that assigned the DIN, and this is frequently the collection organization for blood and cellular therapy, and may be either the recovery organization or the processing organization for tissues, depending on when the identifier is assigned.

Traceability and biovigilance will be best served by using a single DIN issued at the time of recovery to identify all tissues grafts derived from one donor. This will require tissue banks to be able to carry the assigned DIN through their processes to final product labeling. It will mean that the facility identified in the DIN may not be the facility responsible for processing and labeling the final graft, and that grafts from different tissue processors may carry the same DIN. For this reason it will become necessary to electronically identify the facility responsible for labeling the finished graft as part of the product identification.

There may also be a desire to encode more detailed information about the product than is provided in an internationally standardized ISBT 128 Product Description Code. This additional detail can involve such variations as proprietary processes, sizes of a product, sizes of packaging, or the language on the label.

The Processing Facility Information Code [Data Structure 033] is designed to meet these needs in a flexible way. It includes a Facility Identification Number to identify the facility that assigned the Product Code and optionally a code assigned and maintained by this facility to describe characteristics of the product that go beyond the standardized ISBT 128 Product Description.

1.7 Changes in this Version

The following table summarizes the major changes between Version 1.0.0 and Version 1.1.0 of this document.

Implementation Guide: Use of the Processing Facility Information Code [Data Structure 033] Version 1.0.0 vs. Version 1.1.0

	Version 1.0.0 Chapter, Section, Table, or Figure	Version 1.1.0 Chapter, Section, Table, or Figure	Change	Rationale
1.	Throughout	Throughout	Indicated tissues included ocular tissue.	This document applies to ocular tissue.
2.	New Information	1.4	Added <i>ISBT 128 Standard, Standard Terminology for Medical Products of Human Origin (ST-001)</i> .	This document is cited.

	Version 1.0.0 Chapter, Section, Table, or Figure	Version 1.1.0 Chapter, Section, Table, or Figure	Change	Rationale
3.	New information	1.7	Added a version control section.	This is the first update of this document.
4.	3.2.2	3.2.2	Reworded the section discussing when a Processing Facility Identification Number [FIN(P)] is required to uniquely identify a product.	This was done to add clarity.
5.	3.2.3	3.2.3	Explained why the FPC cannot be used to create uniqueness and added a new graphic.	This was done to add clarity.
6.	5.1	Removed	Removed the sentence that recommended that ICCBBA-specified messages be used.	The complexity created by multiple product categories and the many codes that would result from permutations made the use of ICCBBA-specified messages less practical.
7.	New information	5.2	Indicated that Data Structures 032 and 034, in conjunction with the DIN, may be used in place of Data Structure 003 to create uniqueness.	This is an alternative way of identifying a product.
8.	New information	5.3	Added that Data Structure 034 also contains the FIN(P).	Both Data Structures 033 and 034 include the FIN(P).

2 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:

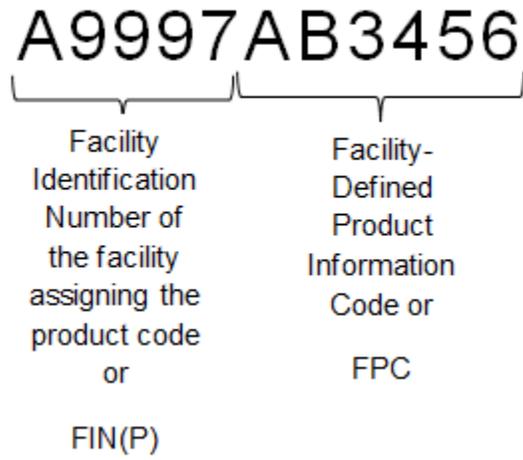
nnnnn shall specify the Facility Identification Number [FIN(P)] of the facility that assigned the Product Code and is encoded and interpreted by reference to the ICCBBA Registered Facility table published and maintained by ICCBBA in the password-protected area of the ICCBBA Website. The facility that assigned the Product Code may, or may not, be the same facility that assigned the 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, it shall be presented in a two-dimensional (2-D) bar code to ensure it is read.

pppppp shall specify a Facility-defined Product Code (FPC) assigned by the processing or labeling facility indicating a catalogue or other number that identifies the type of product within its system. 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.

Note on traceability: The ISBT 128 DIN and Product Description Code (and Product Divisions Code, when used) must create global uniqueness. The FPC must not be used as a complete or partial alternative to any of these data elements. See 3.2.3.

Figure 1 Example of Code



3 Usage

3.1 When should this data structure be used?

Currently, the use of this data structure is not generally mandatory, but it is recommended that facilities include it in future updates of their software for tissues or cells for the reasons outlined in Section 3.2.

There are two components to this data structure, (1) the Facility Identification Number [FIN(P)] for the facility that assigned the Product Code and (2) the Facility-defined Product Code (FPC).

- It is allowable to use the first portion of the data structure to encode a FIN(P) and to use the default (000000) for the FPC.
- If a facility wants to encode a FPC, it must include its FIN(P) in the first portion of the data structure. This is because a FPC must be in the context of the facility that assigned it since the same code may have entirely different meanings when used by other facilities. See Table 1 for an example.

Table 1 Example Meanings of the Same FPC at Different Facilities

	Processing Facility Information Code	Meaning of FPC 0023
Tissue Bank A	A9999 002300	10 mL container of Demineralized Freeze Dried Bone Putty
Tissue Bank B	A9997 002300	Spanish language label and product insert for all products distributed

3.1.1 Facility Identification Number

The FIN(P) should be used when:

- There is a need or desire to identify the facility that assigned the Product Code (usually a processing or labeling facility), in addition to the facility that assigned the DIN.
- The facility that assigned the Product Code wants to encode information in the FPC portion of the data structure. This includes the situation in which both DIN and Product Code are assigned by the same facility, in which case both FIN and FIN(P) will have the same value.

Examples of when the facility that assigned the Product Code should be encoded include:

- A tissue bank processes tissue that has been previously assigned a DIN by another organization.
- A hospital collecting cord blood assigns its own DIN to cord blood products. The cord blood processing facility wants to retain this DIN on the final product and associate its FIN(P) with the Product Code.

- In some countries, the name of the cellular therapy organization that made the decision to release a licensed product must be bar coded and this may be the processing facility rather than the collection facility.

3.1.2 Facility-Defined Product Code

This portion of the data structure should be used when there is a desire to include a detailed description of the product that is not included in a standardized product description and the information is needed for inventory management or biovigilance purposes. Examples of times when a facility could use the FPC include:

- **Proprietary Processes:** A facility employs multiple proprietary pathogen reduction methods that involve the use of combined processes. Standardized ISBT 128 Product Description Codes do not differentiate the various pathogen reduction methods used by the facility. Further, the processes are proprietary and the facility does not wish to make available to ICCBBA the details necessary for appropriate coding. The facility could select a standardized Product Description Code with the attribute, "Combined processes" from the Pathogen Reduction group and then create FPCs to differentiate their processes.
- **Different languages:** A facility manufactures a product it distributes to countries speaking different languages. The labels and accompanying documentation are in the language of the receiving country. The facility may assign FPCs to differentiate products labeled in different languages.
- **Container Size:** A facility produces bone putty in 5 and 10 mL sizes. They want to be able to manage their inventory based on size, but the standardized ISBT 128 Product Description codes do not support this. The facility can select a Product Description Code for bone putty (e.g., T0328 - BONE, PUTTY|Freeze dried|Radiation sterilization|Demineralized:Yes|Cortical) and a FPC to distinguish between the 5 mL and 10 mL sizes.
- **Product Size:** A facility packages skin grafts in two sizes (small and large). It selects the Product Description Code T0326 (SKIN, FULL WITH HYPODERMIS|Frozen|Cell reduction process:Yes|Radiation sterilization), then uses a FPC to distinguish between a small skin graft of less than 10 cm² and a large skin graft of equal to, or greater than, 10 cm².

3.2 Traceability Issues

3.2.1 Current Traceability Requirements

Unique product identification (and hence traceability) in ISBT 128 is routinely based on two data structures, the DIN and the Product Code (which includes both a Product Description Code and a Division or Pack Code). The DIN uniquely identifies the donation event and the Product

Code uniquely identifies each product resulting from the donation event. See the *ISBT 128 Standard Technical Specification (ST-001)* for details about these data structures.

Figure 2 Donation Event Identification

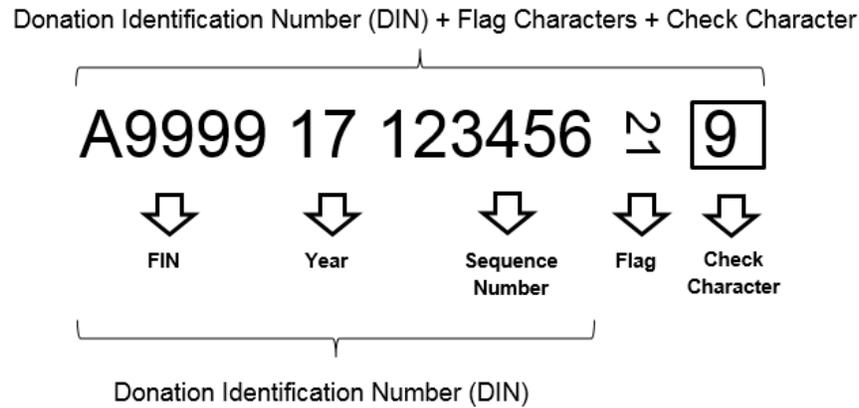


Figure 3 Tissue Product Identification

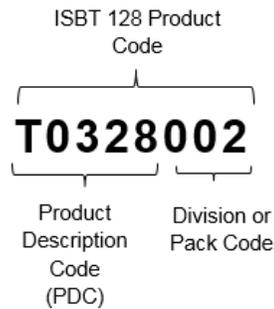
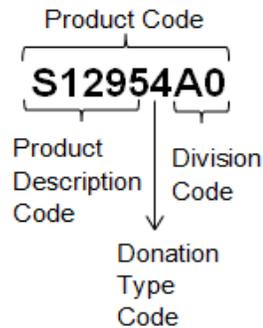


Figure 4 Cellular Therapy Product Identification



For cellular therapy products, in the future when more than the 26 first level divisions allowed by the Product Code are needed, a new data structure, Product Divisions [032], may be used. When this occurs,

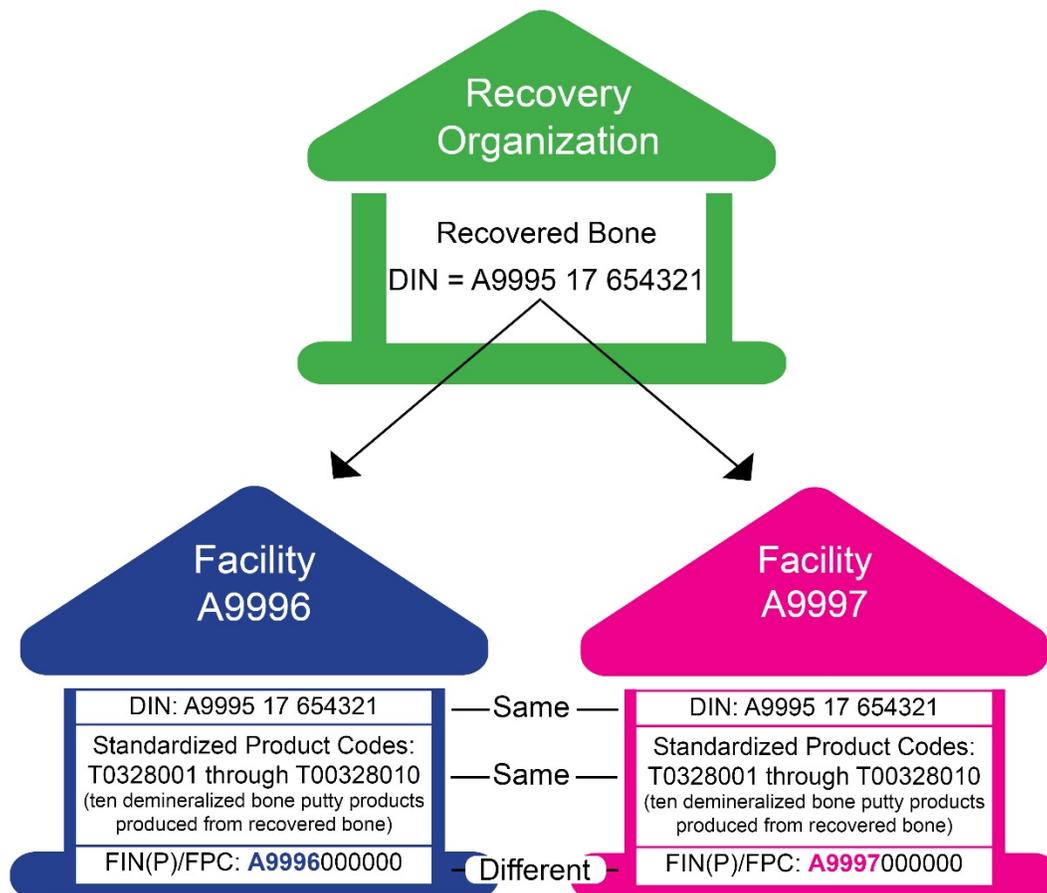
information from this data structure is also needed to create unique product identification. See *Implementation Guide, Use of Product Divisions [Data Structure 032] (IG-023)* and *ISBT 128 Standard Technical Specification (ST-001)* for details about this data structure and when it may be used.

3.2.2 Potential Requirement for FIN(P) of Facility Assigning the Product Code

The FIN(P) may be needed to ensure traceability. This would occur when a recovery agency assigns a DIN to a donation event and distributes similar tissue from that event to two different processors, who process it into the same product.

For example, a recovery agency with the FIN A9995 recovers bone from a donor and identifies it with the DIN A9995 17 654321. They ship a portion of the bone to facility A9996 and another portion to facility A9997. Both A9996 and A9997 produce 10 demineralized bone putty products. It can be seen from Figure 5 that in this case uniqueness requires the FIN(P) as part of the unique identifier.

Figure 5 Use of Facility Identification Number FIN(P) to Create Uniqueness



This situation would occur when:

- The organization that assigns the Product Code is not the same as the organization that assigns the DIN **and**
- More than one organization receives the same type of tissue from the same recovery organization **and**
- The two processing facilities make the same products from the tissue

While a recovery organization sending portions of the same type of tissue to two different processors, and the processors making the exact same product, is not a likely scenario today, it could become more likely.

Because the potential for such a scenario exists, it is recommended that future versions of software for tissue and cellular therapy product management be developed to include the coding and decoding of this data structure.

3.2.3 Facility-Defined Product Code (FPC)

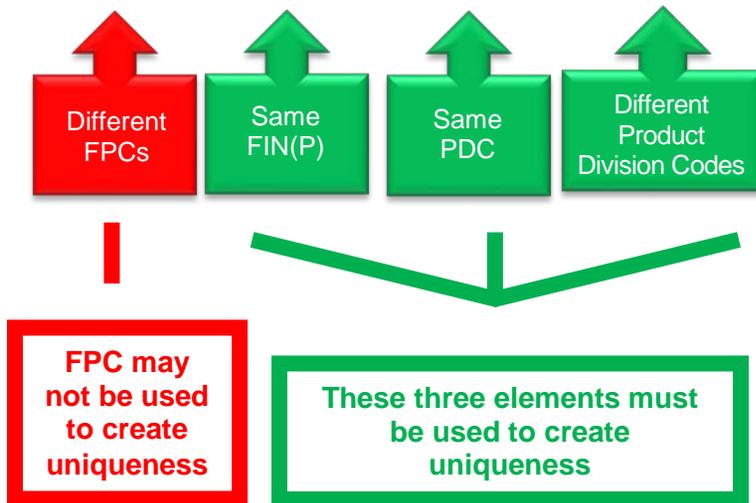
The FPC may NOT be used for establishing uniqueness (traceability) because the FPC is not a standardized code and its capture is not required by all computer systems. Every product carrying the same DIN and ISBT 128 Product Description Code shall be differentiated using the ISBT 128 Division Code, even if these products carry different FPCs.

Example: A facility (A9998) produces different sized containers of demineralized bone putty. It assigns the different sizes of products different FPCs because volume is not encoded in ISBT 128 standardized PDCs. It must also assign each product a different Division Code since the FPC cannot be used to create uniqueness. See Table 2.

It can be seen from Table 2 that uniqueness of product identification is created using the Division Code within the Product Code because the DIN and the Product Description Code are the same for all products, although the FPCs are different.

Table 2 Example Labeling for Demineralized Bone Putty

FPC	FIN(P)	PDC	Division Code	Description of Product	Data Structures 033 and 003
XYZ123	A9999	T0475	001	BONE, PUTTY Radiation sterilization Demineralized:Yes Carrier and applicator, 2 mL	A9999XYZ123 and T0475001
XYZ124	A9999	T0475	002	BONE, PUTTY Radiation sterilization Demineralized:Yes Carrier and applicator, 5 mL	A9999XYZ124 and T0475002
XYZ125	A9999	T0475	003	BONE, PUTTY Radiation sterilization Demineralized:Yes Carrier and applicator, 10 mL	A9999XYZ125 and T0475003
XYZ126	A9999	T0475	004	BONE, PUTTY Radiation sterilization Demineralized:Yes Carrier and applicator, 15 mL	A9999XYZ126 and T0475004



For products with the same DIN: If the PDC and the FIN(P) are the same, the Product Divisions Code must be used to create uniqueness. *The FPC cannot be used for this purpose.*

The FPC was used to encode volume, which is not included in the ISBT 128 PDC.

3.3 Standardized ISBT 128 Product Description Code Versus Facility-Defined Product Code

Standardized ISBT 128 Product Description Codes are managed by ICCBBA and appropriate Technical Advisory Groups (TAGs). The level of detail that is supported by standardized codes is determined by the TAGs based on what is thought to be needed for communication of key characteristics to end users, traceability, biovigilance, routine inventory management, and other factors.

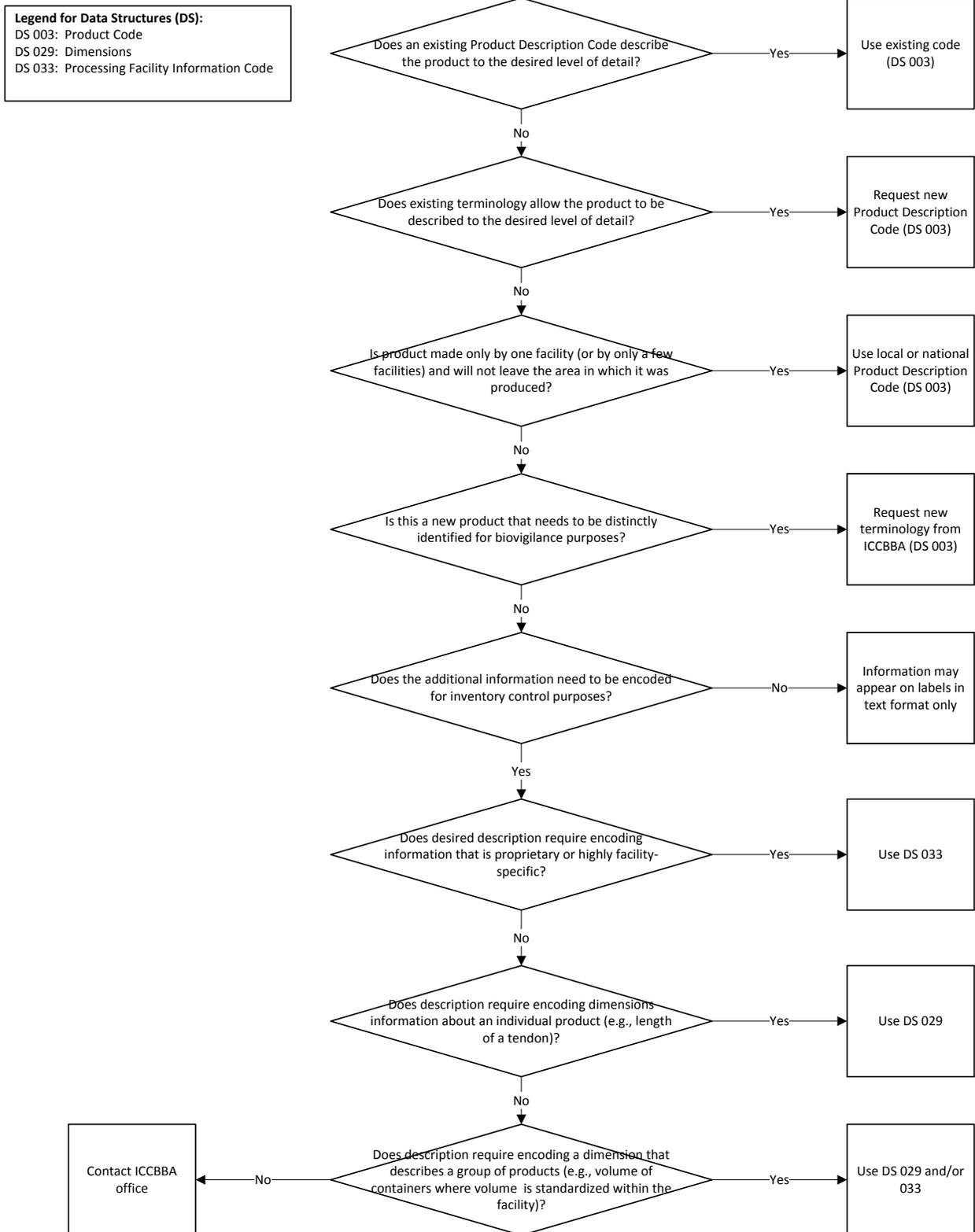
Other data structures (e.g., Dimensions [Data Structure 029] and the Processing Facility Information Code [Data Structure 033]) can supplement the Product Description Code to provide further detail about products. Additionally, product information may appear only as text if it is present primarily to convey information important only to human decision making, rather than for inventory management or biovigilance reasons.

When a facility has determined that an existing Product Description Code does not adequately describe its product, it should begin by reviewing the *ISBT 128 Standard Terminology for Medical Products of Human Origin* (ST-002) to determine if existing terminology can be used to create a code for their product. If existing terminology does not describe the product, then either new terminology must be added or the Processing Facility Information Code [Data Structure 033] and/or the Dimensions [Data Structure 029] may be used. [More information on the Dimensions Data Structure may be found in the *ISBT 128 Standard Technical Specification* (ST-001) and *Implementation Guide: Use of Dimensions [Data Structure 029]* (IG-026).]

Figure 6 provides an algorithm for determining which data structure(s) should be used to convey product information.

Users are encouraged to contact the ICCBBA office if they have any questions about whether a standardized Product Description Code should be created or they should use a Facility-defined Product Code (FPC).

Figure 6 Considerations in Determining How to Present Product Information

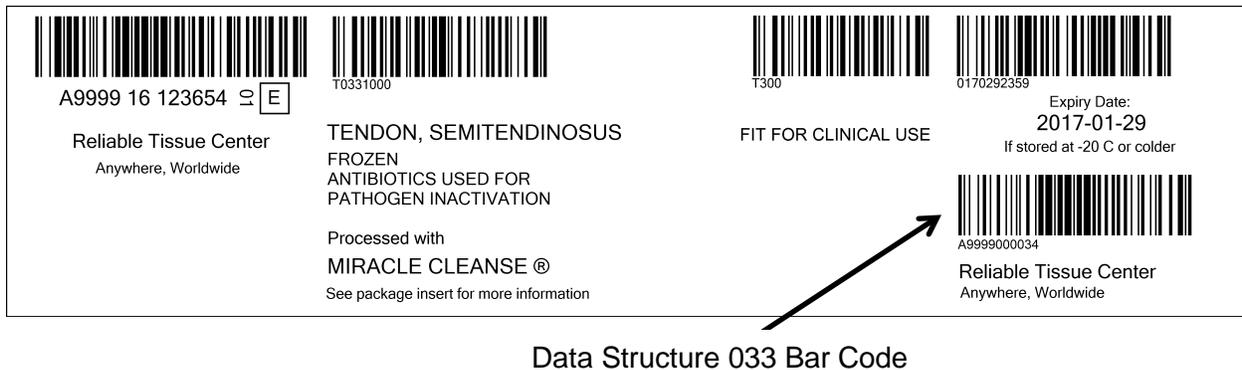


4 Product Labels

It is recommended that 2-D symbols be used when the Processing Facility Information Code is used for labeling products. This would ensure that all data structures, including Data Structure 033, are scanned. If Data Structure 033 is required to ensure uniqueness then it shall be presented in a 2-D barcode to ensure it is read.

Example 1:

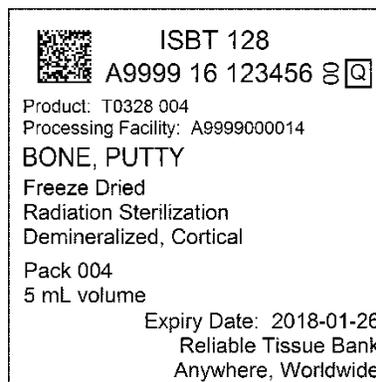
Figure 7 Proprietary Information Conveyed



Reliable Tissue Center (A9999) is both the recovery organization and the processing facility for the tissue in this example label. They have a proprietary process (“Miracle Cleanse”) that has been encoded using Data Structure 033. The bar code appears on the far right side of the label on the bottom. “Miracle Cleanse” utilizes antibiotics so the Product Description Code T0331 (TENDON, SEMITENDINOSUS|Frozen|Antibiotics) was used in the Product Code.

Example 2:

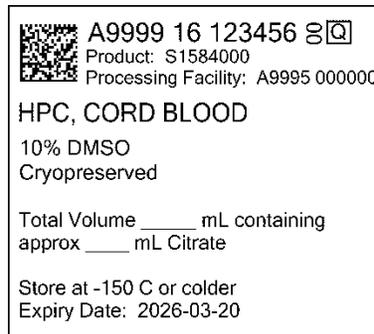
Figure 8 Package Size Conveyed



In this example, Reliable Tissue Bank (A9999) has used the FPC (000014) within the Data Structure 033 (full data content is A9999000014) to convey that the cortical bone putty is in a 5 mL size container. A 2-D bar code was used that encoded the following data structures: DIN [001], Product Code [003], Expiry Date [005], and the Processing Facility Information Code [033].

Example 3:

Figure 9 Cellular Therapy Label



In the example in Figure 9, a cellular therapy processing facility has encoded four data structures into the 2-D bar code: (DIN [001], Product Code [003], Expiry Date [005], and the Processing Facility Information Code [033] with the FPC set to the default 000000. Text information includes everything required for traceability: the DIN, Product Code, and FIN(P). The FPC (set to the default value 000000) is included for completeness in the text information in the event the information would need to be entered via a keyboard. This facility chose to put a space between the FIN(P) and the FPC, but this is a matter of choice, not a requirement or recommendation.

5 Software Developers

5.1 Ensuring Traceability when Data Structure 033 Becomes Required for Traceability

The current traceability model on which ISBT 128 is based assumes that the FIN in the DIN identifies the facility responsible for assigning the DIN and for assigning, or having traceability records to the organization that assigned, the final Product Code.

Tissue banking provides a new challenge in that tissue from a single donation may be sent to more than one facility for processing. For example, in some countries ocular tissue may be sent to an eye bank facility, cardio-vascular tissue to a specialist cardiovascular processing facility, and musculo-skeletal tissue to a third tissue facility. Currently each of these facilities may identify the tissue using their own identification numbers, resulting in tissue from a single donor carrying more than one DIN.

However, traceability and biovigilance will be best served by using a single DIN issued at the time of recovery to identify all tissues grafts derived from one donor. This model is used in some countries (for example, the Italian system of a nationally-assigned identifier) and should be encouraged on a global basis.

ICCBBA strongly supports the adoption of this approach and is developing the ISBT 128 Standard to be compatible with the required changes to the traceability model through the introduction of this new data structure.

Use of a single DIN assigned at the point of recovery will require tissue banks to be able to carry the assigned DIN through their process to final product labeling. It will mean that the facility identified in the DIN may not be the facility responsible for processing and labeling the final graft, and that grafts from different tissue processors may carry the same DIN. For this reason it becomes necessary to electronically identify the organization responsible for assigning the Product Code to the finished graft, and this information will become an essential element of the traceability key data.

Software developers should recognize that the scenario described above is likely to occur over a long period of time, and that a hybrid situation will exist where some tissue grafts carry the additional facility identifier and others do not. When the additional facility information is not present, it should be assumed that the FIN in the Donation Identification Number is also the FIN of the organization assigning, or having traceability records to the organization that assigned, the Product Code.

If linear bar codes are used, it would become essential that users scan Data Structure 033 whenever it is present. Software should be written to encourage the user to scan this bar code. For example, the software might prompt the user to either scan the Data Structure 033 bar code or to actively respond that the bar code is not present.

If 2-D symbols are used, such prompting would not be needed since a single scan would include all data structures. The software must be written to ensure the bar code is internally consistent; i.e., if an ICCBBA-specified compound message that includes Data Structure 033 is used, then the software must ensure Data Structure 033 is read.) See

the *ISBT 128 Standard Technical Specification and Implementation Guide, Use of Data Matrix Symbols with ISBT 128 (IG-015)* for more information about the use of Compound Messages within a 2-D symbol.

5.2 Facility-Defined Product Code

The FPC is assigned by the facility identified in the first part of the data structure and has specific meaning to that organization. It is not a unique code in that different facilities may use the same value for different purposes and so must always be associated with the accompanying FIN. Organizations assigning these codes may, or may not, publish reference tables to allow users to interpret the meaning of the code.

The FPC is NOT to be used as part of the unique identification of the product. Uniqueness must be provided by the combination of DIN and the ISBT 128 Product Code (Product Description Code and Division Code). *Note: A combination of Data Structure 032 and Data Structure 034 may be used in place of the Product Code [Data Structure 003] for some product categories.*

5.3 Global Requirements

This enhanced traceability model where a single identifier is assigned to all products from a recovery event is a new concept and it is not yet clear how rapidly it will be adopted. It is likely that there will be a long period in which some countries have moved to using a single DIN and others have not. This will create a mixed labeling situation in which some products carry this new data structure and others do not.

Both cell therapy and tissue products are distributed globally. Therefore, even if only a small number of countries adopt the use of this data structure, products so labeled are likely to be shipped globally.

Therefore, it is recommended that software in all countries be developed to support the use of this data structure [and/or Data Structure 034, which also contains the FIN(P)] for medical products of human origin.

5.4 Other Categories of Products

As noted in Section 1.2, the use of this data structure for categories of products other than cellular therapy and tissues has not been agreed by technical advisory groups in the areas of expertise. This situation could change as users in these fields become aware of the data structure and see potential for its use. Software developers in these areas (blood, organs, reproductive tissue, human milk, and derivatives) should keep the potential use of this data structure in mind when developing software.