Implementation Guide

Use of ISBT 128 by North American Tissue Banks

Version 1.4.0
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1   Introduction

1.1   Purpose

The purpose of this document is to provide guidance on the implementation of the ISBT 128 Standard for North American tissues banks. Specifically it provides guidance on:

- Donation identification numbering
- Data structures that may be useful to tissue banks
- Label design options
- Software design

1.2   Scope

This document has been developed by the North American Tissue Technical Advisory Group (NATTAG) of ICCBBA. It acts as a supplement to the *ISBT 128 Standard Technical Specification* (ST-001) and the *ISBT 128 Standard Labeling of Human Tissues* (ST-003). It provides guidance for the final labeling of human tissue products in a manner that is compliant with the ISBT 128 Standard in North America.

In the US, HCT/Ps that are not regulated solely under Section 361 of the Public Health Service Act are regulated as drugs, devices and/or biological products. These products must be labeled according to the labeling requirements for drugs and/or biological products or medical devices, as applicable.

This guidance recommendation is limited to final product labeling as shown in Figure 1. Tissue banks and recovery organizations may continue to use their existing identification systems prior to final labeling or they may opt to introduce ISBT 128 identification from the point of recovery. Tissue processors will have the responsibility of ensuring traceability from the ISBT 128 final product identification back to other identifiers used earlier in the donation pathway.

Figure 1 Scope of Document

Out of the scope of this document   Use of ISBT 128 labeling
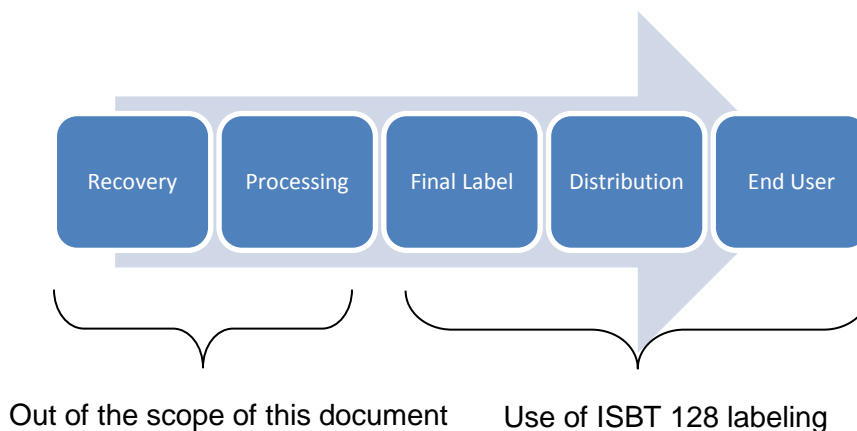
This document does not address the unique requirements of labeling of reproductive medicine products. Labeling of these products will be addressed in a future document.

This document does not address labeling of ocular tissue. Specific guidance for labeling ocular products is found in *ISBT 128 Standard Labeling of Ocular Tissue* (ST-009).

This document does not address details of labeling HCT/P regulated as medical devices in the US. Specific guidance for labeling of HCT/P regulated as medical devices is found in *ISBT 128 Standard Coding and Labeling of Medical Devices Using ISBT 128* (ST-011)

1.3   Intended Audience

The intended audience of this document is:
- Tissue bank staff (management, information technology, regulatory, technical, medical director, quality, and validation);
- Hospital or clinic staff (management, information technology, regulatory, technical, medical director, quality, and validation) who receive tissues; and
- Vendors of software, equipment, labels, and supplies used by these tissue banks and hospitals.

1.4   Normative References

All ICCBBA documents may be found on the ICCBBA Website (www.iccbba.org)

ISBT 128 Standard Technical Specification (ST-001)

ISBT 128 Standard Terminology for Medical Products of Human Origin (ST-002)

ISBT 128 Standard Labeling of Human Tissues (ST-003)

ISBT 128 Standard Labeling of Ocular Tissues (ST-009)

ISBT 128 Standard Coding and Labeling of Medical Devices Using ISBT 128 (ST-011)

1.5   Other References

Implementation Guide: Use of Data Matrix Symbols with ISBT 128 (IG-014)

Implementation Guide: Encoding Product Information [Data Structures 003, 032, 033 and 034], Tissues (IG-020)

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

Implementation Guide: Use of Flexible Date and Time [Data Structure 031] (IG-024)

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

Implementation Guide: Use of the Processing Facility Information Code [Data Structure 033] (IG-031)

Implementation Guide: Use of Donation Identification Number [Data Structure 001] (IG-033)

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

International Medical Device Regulators Form (IMDRF): UDI Guidance, Unique Device Identification (UDI) of Medical Devices, 9 December 2013.

1.6 Background

There is growing recognition at both the global level and within North America that there is a need to move towards standardization of the terminology, coding, and labeling used on tissue products in order to improve traceability and enhance patient safety. Existing US FDA regulations require a "Distinct Identification Code" and other labeling information to facilitate tracking of HCT/Ps from the donor to the recipient and vice versa.However, they do not require this uniqueness to extend outside the tissue bank. As a result, a receiving hospital may receive identically numbered tissue products from two different tissue processors. With the widespread distribution of tissue products at both a national and international level, there is increased risk of loss of traceability due to duplication of identifiers. Some hospital organizations are requiring their suppliers to use ISBT 128 identification in order to eliminate this risk, and to facilitate inventory control through the use of ISBT 128 international product description codes.

In the US some HCT/P products are regulated as medical devices by FDA CDRH. Regulation requires labeling of these products to comply with FDA's Unique Device Identification (UDI) system. ICCBBA has been approved by FDA as an Issuing Agency for UDI. The ISBT 128 device identifier and production identifiers carry the ISBT 128 donation identification number, product description code, and division number thus facilitating the traceability across all products from a single donor whether regulated as biologics or medical devices.

Beyond the US, the World Health Assembly approved resolution WHA63.22 in 2010 that urges 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 has become a non-governmental organization in official relations with WHO in order to support this strategy.

Within the European Union products regulated under the Tissues and Cells directives are required to carry a 'Single European Code (SEC)' that complies with EU regulation. Imports from outside the EU have to be labelled with an SEC prior to distribution in the EU. ICCBBA is an approved coding system for use in the SEC and products labelled with ISBT 128 can be labelled with an SEC on entering the EU with no change to identifiers or product codes.

GS1, the world's largest coding and labeling standard, has indicated their support of ISBT 128 for MPHO in a joint guidance with ICCBBA dated 17 November 2014 (see Appendix).

ISBT 128 is a well-established international standard for terminology, coding, and labeling of MPHO, which include blood, cells, tissues, human milk, and organs. It is used extensively for the coding and labeling of MPHO. AABB requires the use of ISBT 128 by their accredited blood banks and hospital transfusion services. AABB and FACT cellular

therapy accreditation standard require the use of ISBT 128 for cell therapy products, and the Eye Bank Association of America requires use of ISBT 128 for ocular tissue. Many hospitals in North America are already equipped to handle ISBT 128 labeled products through their transfusion laboratories. Some major software and labeling suppliers are already developing tissue banking modules for tissue bank and hospital use.

1.7   New in this Version

	Version 1.3.0 Chapter, Section, Table or Figure	Version 1.4.0 Chapter, Section, Table or Figure	Change	Rationale
1.	1.2	1.2	Added reference to labeling requirements for HCT/Ps.	Clarification
2.		3	New section providing additional explanations by referring to individual data elements required for traceability (e.g., product description codes and division codes) prior to describing data structures.	To clarify how traceability can be supported using various data structures.
3.	3	4	More emphasis on using the medical device traceability pathway (i.e., use of ISBT 128 Data Structures 034, 001, and 032) over the traditional biologics traceability pathway (i.e., ISBT 128 Data Structures 001, 003, and 033). However, both methods/pathways remain acceptable.	To encourage the use of a single traceability pathway regardless if the tissue is regulated as a biologic or a medical device.
4.	4.1	5.1	Updated the list of minimum labeling requirements.	To better identify the individual elements required for traceability in a way that accommodates both traceability pathway options.
5.	Throughout	Throughout	Label examples were updated.	To reflect the revised minimum labeling requirements.

2   Implementation Guidance

Implementation guidance is provided in the following sections. This guidance should be read in conjunction with the *ISBT 128 Standard Technical Specification* (ST-001)*, the ISBT 128 Standard Labeling of Human Tissues* (ST-003)*,* the *ISBT 128 Standard Terminology for Medical Products of Human Origin* (ST-002), and the *ISBT 128 Standard Coding and Labeling of Medical Devices Using ISBT 128* (ST-011).

As will be seen from this guidance, ISBT 128 is a flexible standard and can accommodate different approaches to implementation. This document outlines several areas of flexibility:

- The stage at which a Donation Identification Number is assigned
- The year that is encoded within the Donation Identification Number
- Inclusion of an expiration date as part of the standardized ISBT 128 portion of the label (the electronically-readable symbol and the eye-readable text)
- Size and placement of the standardized ISBT 128 portion of the label
- Linear versus two-dimensional symbols
- The use of a biologics label format or a medical device label format for labeling human tissues

While facilities may select from among these and other options, certain aspects of an ISBT 128 label must be standardized to ensure compatibility with others using ISBT 128 for coding and labeling. This document also describes these requirements.

3 Data Elements

In order to support traceability there are a number of pieces of information (data elements) that are essential and therefore are required to appear on an ISBT 128 label. These essential data elements are:

- Donation Identification Number (DIN)
- Product Description Code (PDC)
- Division Code (DIV)

In addition, the Processing Facility Identifier (FIN(P)) is required in some circumstances, and is always required for HCT/P regulated as medical devices.

3.1 Donation Identification Number (DIN)

The DIN is a globally unique donation identification number. It contains three elements.

- The Facility Identification Number (FIN), is assigned to a facility by ICCBBA and supports global uniqueness. In order to obtain a FIN, tissue banks will need to register with ICCBBA. Tissue banks may opt to have a single FIN and manage the sequence number allocation across all of their facilities centrally, or they may request multiple FINs with each facility controlling its own sequence number allocation. ICCBBA maintains a database of code assignments and this table is available to licensed users of the ISBT 128 system. It is called "Registered Facilities" and is found in a password-protected area of the ICCBBA Website (www.iccbba.org).

- A two-digit year supports uniqueness for a 100 year period. The assigning facility has the responsibility for ensuring the uniqueness of donation identifiers that they issue across a 100-year period. To help them to achieve this, the DIN structure includes a two-digit year code. This is a nominal year identifier and should not be used as an alternative to other date structures (such as collection date, expiration date, etc.). Its purpose is solely to support the requirement for 100 year uniqueness. Individual banks may determine how they wish to use the year identifier based on the point at which the DIN is assigned. Thus for a bank choosing to assign an ISBT 128 DIN at the time of donation or recovery, the year code could be aligned with the donation or recovery date. Alternatively, for a processor assigning the DIN, it may be more appropriate to align the year code with the date processing begins. In all cases it is essential to ensure that the policy is applied consistently within the facility and that secure algorithms prevent the duplication of an identifier.

- A sequence number assigned by the facility. The facility is responsible for ensuring the sequence number is unique to each recovery event for a given year and FIN.

Together, the three elements create global uniqueness for the DIN.

3.1.1 DIN allocation options

As this guidance is focused on the use of ISBT 128 on final products, it does not directly address the point at which the ISBT 128 donation numbering is introduced. Four

possible situations are identified for informational purposes, but no recommendation is made, as the most suitable option will vary according to the needs of the tissue bank.

Assignment at Time of Recovery

Some tissue banks may wish to assign the ISBT 128 DIN at the point of donation. This could be done either by the processor allocating a DIN from their own range to the recovery organization or by the recovery organization having its own FIN and managing identifiers themselves. In all cases the assigned DIN should remain with the tissue donation and appear on all final labeled products from that donation.

Assignment at Time of Processing

If existing numbering systems are used for the earlier part of the donation pathway, then the tissue processor will assign the ISBT 128 DIN some time during processing before final labeling of the product. The tissue processor is responsible for ensuring traceability between the ISBT 128 DIN and other identifiers.

Assignment Within the Distribution Chain

When tissue products labelled with a system other than ISBT 128 move into an environment that requires ISBT 128 labeling it may be necessary for a re-labeling step to occur. Such re-labeling should be carried out under controlled conditions in an accredited tissue bank and the re-labeler is responsible for ensuring traceability between the ISBT 128 DIN and other identifiers.

Assignment by another Organization

A DIN assigned by another organization (e.g., a recovery organization) to tissue may also be used. It is a long-term goal that DINs would be assigned at the time of recovery and be used from recovery to processing and transplant.

3.2   Product Description Code (PDC)

The PDC is an international standardized product description code taken from the ICCBBA PDC Database. Products are described using terminology created by expert advisory groups such as ITTAG. They utilize a scheme of Classes (broad descriptions of product such as Skin, Split or Tendon, Achilles with Bone Block) and Attributes (more detailed information such as storage solutions or pathogen reduction methods). Each product is described minimally with a Class and may also have one or more Attributes. Detailed information on creating PDCs may be found in *Implementation Guide: Encoding Product Information [Data Structures 003, 032, 033 and 034], Tissues* (IG-020).

In some circumstances an international PDC may not be appropriate and in this situation a range of PDCs is assigned for national or local use (see Appendix B).

- A database, called the Product Description Codes Database, lists all assigned codes and the corresponding product descriptions. The database is found in a password-protected area of the ICCBBA Website (www.iccbba.org) and is accessible by licensed users.

3.3   Division Code (DIV)

A Division or Pack Code allows each product with the same DIN and PDC to be uniquely identified. For tissues (PDCs beginning with the letter "T"), a numeric division code is used. The number of available divisions depends on the data structures being utilized. If divisions are being encoded in Product Divisions (Data Structure 032) the maximum number of divisions is 999,999. If divisions are being encoded in Product Code (Data Structure 003) the maximum number of divisions is 999. For example, if there are three packs of Skin, Split, Allogeneic, Not Fenestrated, Frozen (code: T0416) from the same donor (A9999 19 123456), each will be uniquely identified using the division/pack code 1, 2, and 3 which would be represented in Data Structure 032 as 000001, 000002, and 000003 or in Data Structure 003 as 001, 002, and 003. If there are not multiple packs with the same DIN and PDC, the division code can be set to all zeros.

3.4   Processing Facility Identifier FIN(P)

The Processing Facility Identifier is used to identify the processing facility responsible for the allocation of the PDC and DIV if it is not the same as the facility that assigned the DIN. FIN(P) is a 5-character code assigned by ICCBBA and maintained in the Registered Facilities database found on the ICCBBA Website (www.iccbba.org). It is the same database as used for the FIN in the DIN.

3.5   Other Data Elements

There are other data elements that can be encoded within ISBT 128 and these include:

- Expiration Date and Time
- Collection/Recovery Date and Time
- Production Date and Time
- Product Dimensions
- Lot Number
- Supplemental Identification Number
- Facility Defined Product Code

All the above data elements are carried in ISBT 128 Data Structures.

4   Data Structures Used to Label Tissues

Data structures are the means by which information about tissues is put into computer-friendly codes. Data structures define the technical characteristics necessary for the interpretation of the information. They specify the context and structure and provide the links to the appropriate reference tables for conversion of codes into meaningful information.

Data structures comprise two elements:

- Data identifier: a two or three-character code that identifies the data structure [described in more detail in the *ISBT 128 Standard Technical Specification (ST-001)*].
- Data content: the data characters that provide the information to be conveyed (e.g., coded information that conveys the product is an Achilles tendon).

Figure 2 Data Structure
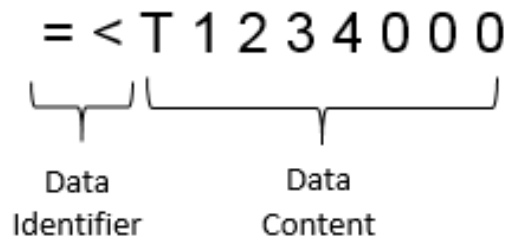
ISBT 128 data structures are used in bar codes on labels of MPHO for electronic communication. When an ISBT 128 linear bar code is printed on a label, the data content characters are printed immediately beneath the bar code, aligned with the left edge of the bar code (with the exception of the Donation Identification Number where the data content text follows different rules). See the *ISBT 128 Standard Technical Specification* (ST-001). The data identifier characters do not appear beneath the bar code since they are intended for use by a computer to properly identify the data structure rather than by a human. See Figure 3.

Figure 3 Example of ISBT 128 Linear Bar Code

T1234000

The Data structures required for traceability of tissue products include one of the following combinations:

- Processor Product Identification Code [Data Structure 034]
- Donation Identification Number [Data Structure 001]
- Product Divisions [Data Structure 032]

OR

- Donation Identification Number [Data Structure 001]
- Product Code [Data Structure 003]
- Processing Facility Information Code [Data Structure 033]

The use of the first combination of identifiers is consistent with the labeling of HCT/P medical devices as described in *ISBT 128 Standard Coding and Labeling of Medical Devices Using ISBT 128* (ST-011). Use of this combination allows tissue banks that produce products regulated as both medical devices and biologics to use this method across all products.

The use of the second set of identifiers was the original way of labeling tissue with ISBT 128 and is still in use by many facilities worldwide.

Other data structures that may be of interest to tissue banks include:

- Expiration Date and Time [Data Structure 005]
- Collection/Recovery Date [Data Structure 006]
- Collection/Recovery Date and Time [Data Structure 007]
- Production Date [Data Structure 008]
- Production Date and Time [Data Structure 009]
- Compound Message [Data Structure 023]
- Dimensions [Data Structure 029]
- Flexible Date and Time [Data Structure 031]
- MPHO Lot Number [Data Structure 035]
- MPHO Supplemental Identification Number [Data Structure 036]

This chapter will include a high level description of the required data structures for each format as well as other data structures that users may find useful in the labeling of tissues. Specific details of coding are found in the *ISBT 128 Standard Technical Specification* (ST-001). Guidance on how and when to use these data structures appears later in this document and/or in one of the documents referenced in Section 1.5.

4.1 Donation Identification Number [Data Structure 001]

Data Structure 001 specifies:

- The Donation Identification Number (DIN)
- Flag character values.

This data structure is unique in that the second character of the data identifier also serves as the first character of the data content.

Figure 4 Donation Identification Number Data Structure
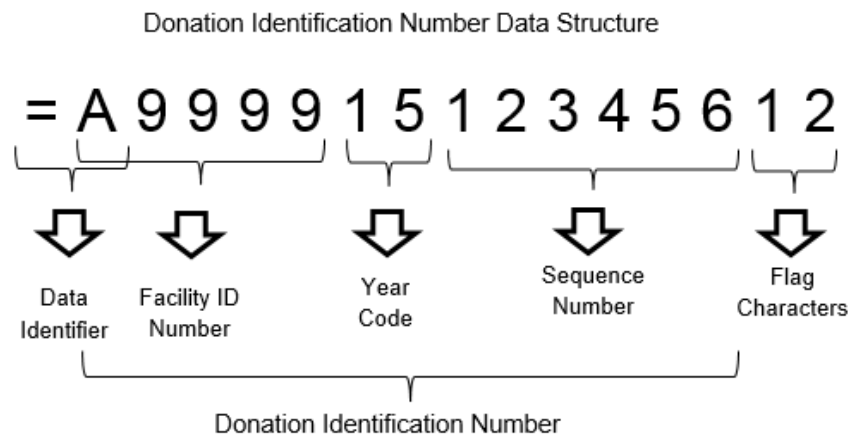
4.1.1 DIN

The DIN contains three elements as specified in Section 3.1.

4.1.2 Flag Characters

Flag characters, used for process control, are also a part of this data structure although not a part of the DIN itself. These characters allow a facility to indicate where a bar coded DIN appeared (e.g., on the product, a sample test tube, or a donor record) and can be used to facilitate automated process control. These flag characters are optional and, if not needed, the flag value of "00" should be used. Systems receiving ISBT 128 labeled tissue should accept any valid final product flag characters. In the text presentation, flag characters are rotated clockwise by 90 degrees (see Figure 5).

4.1.3 Check Character

Although not a part of the data structure (and the bar coded information), a check character is added to the end of the DIN to support verification of correct manual keyboard entry. This check character is calculated following MOD 37-2 within ISO/IEC 7064:2003(E). Whenever ISBT 128 DINs are printed in eye-readable format on a product label, the manual entry check character should appear to the right of the DIN and flag characters and enclosed in a box (see Figure 5). The check character may be any one of the thirty seven characters in the set (0-9, A-Z, asterisk). Care should therefore be taken to use a font which clearly distinguishes between similar characters

(0 and O, I and 1 etc.). Where computer systems accept manual entry of a DIN, the check character should always be a required part of the entry and software should verify the character is correct.

4.1.4   Text Presentation

The text presentation of the DIN does not include the first character of the data identifier. It includes the second character of the data identifier because it is also a part of the data content. See Figure 5.

Figure 5 Text Presentation of DIN
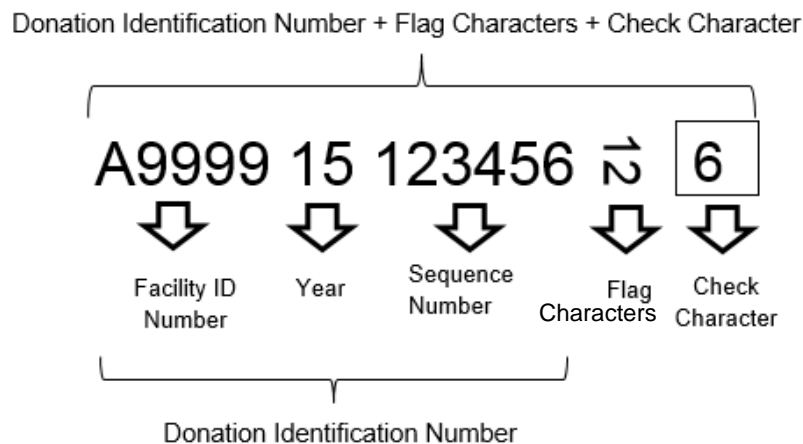
See *Implementation Guide: Use of the Donation Identification Number [Data Structure 001]* (IG-033) for further information.

4.2   Labeling Product Code [Data Structure 003]

Data Structure 003 contains two elements:

- The 5-character Product Description Code (PDC)
- For tissues (PDCs beginning with the letter "T"), a 3-character Division or Pack Code

See Figure 6.

Figure 6 Product Code Data Structure for Tissues
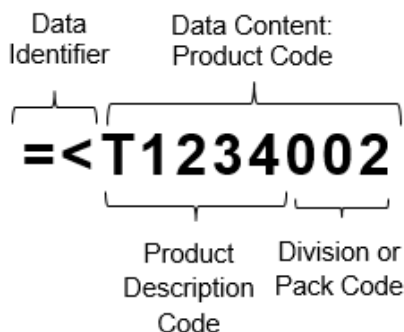
4.3   Date and Time Data Structures

4.3.1   Expiration, Recovery, and Production Dates (and Times)

There are a number of data structures designed to encode specific types of time (expiration, recovery, and production). All use the last three numbers of the year (e.g., 2014 becomes 014 in the code); the ordinal, or Julian, date (where the days of the year are numbered sequentially beginning with 001 on January 1); and, for some, the time based on a 24-hour clock. If the product expires at midnight, 2359 (23:59 or 11:59 p.m.) is encoded. See Figure 7.

Figure 7 Expiration Date and Time [Data Structure 005]
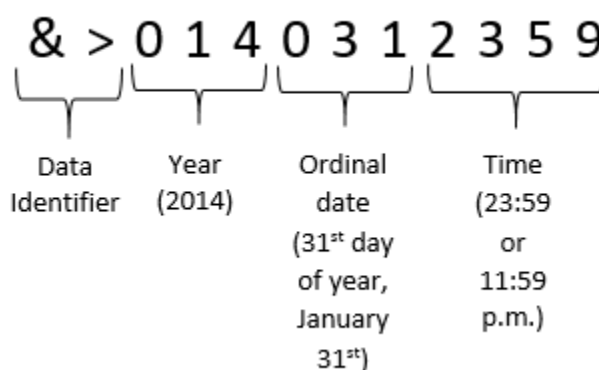
The different types of time data structures are differentiated using the data identifier (see beginning of Section 4) as shown in Table 1. Some of the data structures include only the date while others include both date and time. Where options exist, facilities may select whatever data structure works best for them.

Table 1 Data Identifiers for Date and Time Data Structures.

Type of Time	Data Identifier
Expiration Date and Time [Data Structure 005]	& >
Collection/Recovery Date [Data Structure 006]	= *
Collection/Recovery Date and Time [Data Structure 007]	& *
Production/Processing Date [Data Structure 008]	= }
Production/Processing Date and Time [Data Structure 009]	& }

4.3.2   **Flexible Date and Time [Data Structure 031]**

As the use of ISBT 128 spread from blood to other MPHO, it became clear that many more types of time (e.g., cross-clamp time, date/time of death) might be needed. Rather than create a different data structure for each type of time, a new data structure was created that supported not only multiple types of time, but also supported encoding Coordinated Universal Time (UTC).

The first character of the data content indicates if the time is local (encoded as a 1) or UTC (encoded as a 2). The second character is reserved for future use. The third and fourth characters indicate the type of date and time (Expiration is 01, Collection/Recovery is 02, Production/Processing is 03, and Cross Clamp is 04). Additional types of time may be added to this table as they are needed. See Figure 8.

Guidance for the use of this data structure is described within *Implementation Guide: Use of Flexible Date and Time [Data Structure 031]* (IG-024).

This data structure may be used in place of other date and time data structures, or may be used when a specific type of date and time data structure does not exist (e.g., cross clamp time).

Figure 8 Example of Flexible Date and Time [Data Structure 031]
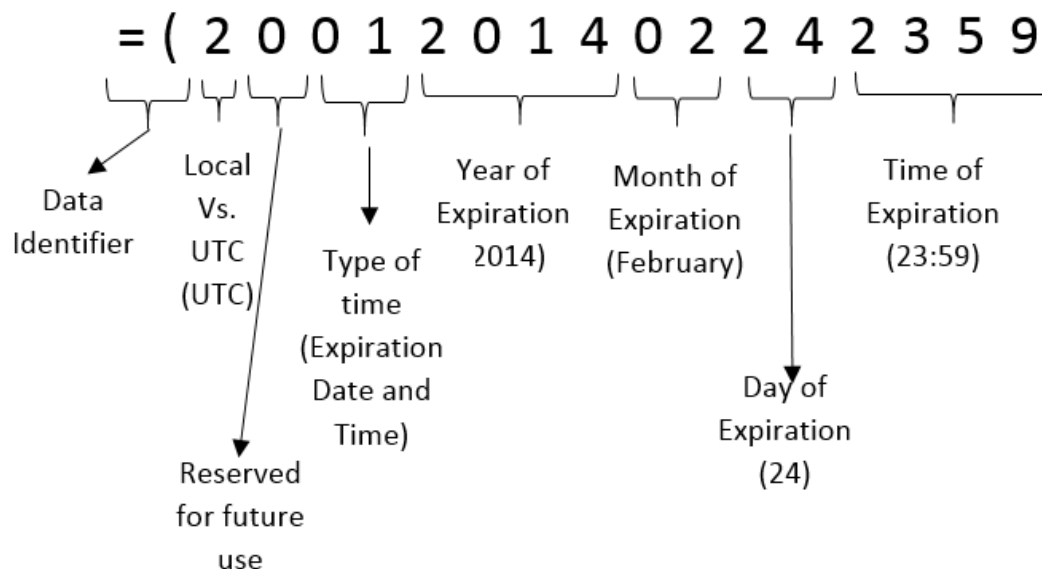
4.4   Dimensions [Data Structure 029]

This data structure was designed to convey specific measurements associated with a product. This data structure is highly flexible and can be used to convey many types of measurements. Such measurements relevant to tissue currently include volume, weight, length, width, height, area, particle size, and the number of rings on a trachea. Additional measurements can be added as they are needed. This data structure can be used to convey a specific value (e.g., the area of skin is 0.1 cm^2), a range (e.g., the size of the particles is between 0.5-1.0 mm), or a full dimension (the size of a bone block is 2.0 x 24mm x 30 mm). It permits tissue banks to differentiate between two tissue products with the same ISBT 128 standardized PDC that have characteristics requiring separate inventory management.

Given the variety of measurements that a tissue bank may want to convey, this is necessarily a complicated data structure. Readers should review *Implementation Guideline: Use of Dimensions* [Data Structure 029] (IG-026) for full details.

4.5   Product Divisions [Data Structure 032]

The Product Divisions Data Structure carries the division or pack code that uniquely identifies each product that has the same DIN and PDC. This data structure is used in conjunction with the PPIC (Data Structure 034). The division is encoded as a six-character alphanumeric value providing a high degree 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 to ZZ. This provides up to three levels of division.

4.6   Processing Facility Information Code [Data Structure 033]

Data Structure 033 identifies the facility that assigned the Product Code (generally the processing facility) as well as a facility defined product code.

There are two elements to the Processing Facility Information Code: The Facility Identification Number [FIN(P)] and the Facility Defined Product Code (FPC).

The Facility Product Code (FPC) supports the need of some facilities to be able to differentiate products that have the same ISBT 128 defined PDC, but have variations that are not covered by standardized codes. For example, a facility may need to differentiate proprietary sterilization processes, sizes of particles in a crushed bone product, or volumes of containers. The FPC may be used when the facility does not wish to encode the specific dimensions within the Dimensions data structure, but does want to differentiate products for the purpose of inventory management. The FPC is assigned by the facility and is specific to the facility. Codes cannot be interpreted out of the

context of the facility that assigned it since two facilities may well use the same code for two entirely different products. The FPC may not be used to create unique identification for the product. See Figure 9.

Figure 9 Processing Facility Information Code [Data Structure 033]

This data structure also supports the use of a single DIN for all tissue recovered from a single donor because it allows for identifying both the procurement agency (within the DIN) and the processing facility (in Data Structure 033).

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

4.7   Processor Product Identification Code [Data Structure 034]
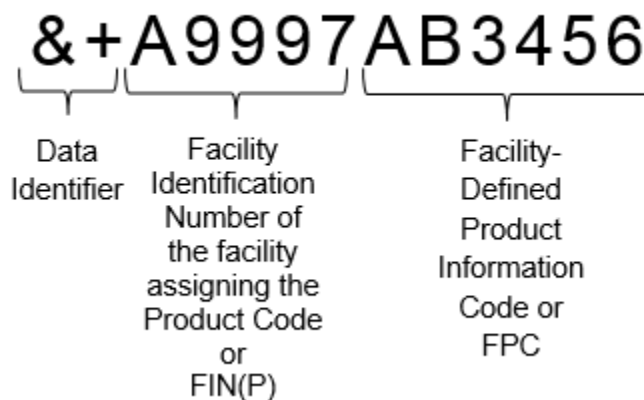
Data Structure 034 identifies the facility that assigned the Product Code (generally the processing facility), and the product both in terms of a PDC and also an additional facility assigned product code (FPC) that allows tissue banks to sub-categorize products within one PDC.

There are three elements to the Processor Product Identification Code: The Facility Identification Number [FIN(P)], the Facility-Defined Product Information Code (FPC), and the PDC.

The Facility Product Code (FPC) supports the need of some facilities to be able to differentiate products that have the same ISBT 128 defined PDC, but have variations that are not covered by standardized codes. For example, a facility may need to differentiate proprietary sterilization processes, sizes of particles in a crushed bone product, or volumes of containers. The FPC may be used when the facility does not wish to encode the specific dimensions within the Dimensions data structure, but does want to differentiate products for the purpose of inventory management. The FPC is assigned by the facility and is specific to the facility. Codes cannot be interpreted out of the context of the facility that assigned it since two facilities may well use the same code for

two entirely different products. The FPC may not be used to create unique identification for the product.

Figure 10 Processor Product Identification Code (Data Structure 034)
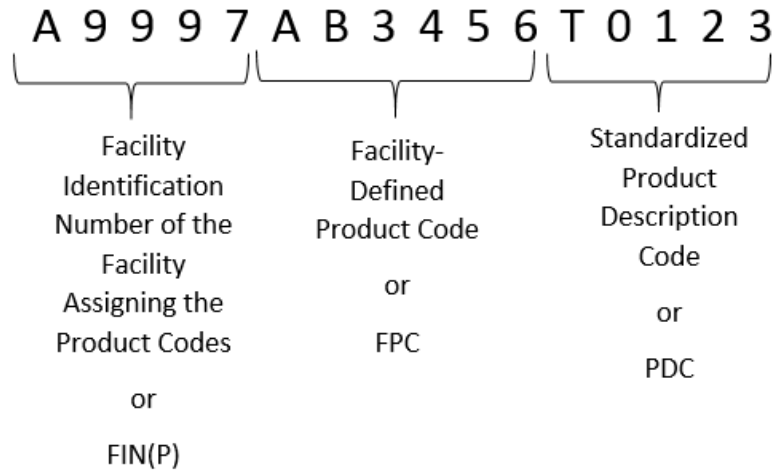
4.8 MPHO Lot Number [Data Structure 035]

This data structure supports encoding of an 18-character lot number. It is designated by the facility when a tissue has a lot number in addition to a DIN. It shall not be used to convey uniqueness for the purpose of traceability. The characters may be upper case alphas or numbers. If a lot number has fewer than 18 characters, leading zeroes should be used.

4.9 MPHO Supplemental Identification Number [Data Structure 036]

This data structure may be used for a serial or other identifying number specific to a tissue. It shall not be used to create uniqueness for the purpose of traceability. It is an 18-character identifier in which upper case alphas or numbers may be used. If the number has fewer than 18 characters, leading zeroes should be used.

5   Label Design

In order to provide a common presentation of key traceability information it is recommended that a portion of the label be standardized across all tissue processors. The location and size/orientation of this standard portion can be adjusted to suit tissue bank requirements (see examples in section 8).

The following description applies to the ISBT 128 specific label area. It does not include all of the regulatory requirements for labeling. It is the responsibility of the tissue processor to ensure regulatory and standards requirements are met elsewhere on the label, and to ensure the consistency of information across the entire label.

5.1   ISBT 128 Label Requirements

The ISBT 128 label area must have a white background.

The minimum information content is:

- EITHER
    - Bar coded Processor Product Information Code (Data Structure 034), Donation Identification Number (Data Structure 001) and Product Divisions (Data Structure 032).
- OR
    - Donation Identification Number (Data Structure 001), Product Code (Data Structure 003). If the processing facility is not the same as the facility that assigned the DIN then the Processing Facility Information Code (Data Structure 033) is also required.
- The eye-readable Product Description Code preceded by the text "PDC:"
- The eye-readable Division Code preceded by the text "DIV:"
- The eye-readable DIN preceded by the text "DIN". Flag characters if used shall be rotated 90° clockwise. The boxed manual check character is required.
- If the processing facility is different to the facility that assigned the DIN, the eye-readable Facility Identification Number [FIN(P)] of the processing facility (labeler) preceded by the text "FIN(P):"

The minimum size for this label will depend on whether linear or 2-D bar codes are used as well as the size and shape of the package. For linear bar codes, a rectangle 50 mm by 25 mm may work. For 2-D bar codes, a rectangle 37 mm by 15 mm may be adequate. Alternative shapes may be used. Any space that accommodates the minimum information and allows the bar codes to meet nominal X dimension requirements [see *ISBT 128 Standard Technical Specification* (ST-001)] is acceptable.

The ISBT 128 information should be visually separated from other information on the label. This can be done by spatial separation as shown in Figure 14, or by having a line or box separating it from other information, as shown inFigure 15. If lines are used, they must be an adequate distance from bar codes (quiet space) to prevent interference with scanning the bar code [see *ISBT 128 Standard Technical Specification* (ST-001)]. The text "ISBT 128" can be used to help clearly indicate the ISBT 128 section of the label.

Minimum font sizes are determined by the printer used and readability. Typically, font sizes below 6 cannot be used because the printer cannot distinguish between an "o" and an "e".

Figure 11 Minimum Label Requirements
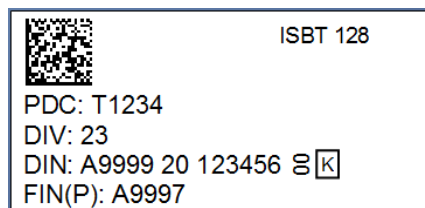
Note: 2-D symbol contains Data Structures 034, 032 and 001

In addition, the following information must appear on the label, and may or may not be in the ISBT 128 specific portion of the label:

- The text description of the product giving the product name and the division code/pack number
- The eye-readable expiration date

The expiration date may be bar coded. When using a 2-D symbol, the expiration date may be encoded in the ISBT 128 bar code even if the text appears elsewhere on the label.

Two-dimensional (Data Matrix) symbols are recommended, but linear (Code 128) bar codes may be used when the product is being labeled using the DIN, Product code and optional PPIC data structures.

See section 8 for examples of label designs that meet these criteria.

5.2   Date and Time Text

When the date and time are encoded into an ISBT 128 data structure the text may be presented in one of two ways.
- If the text is included within the standardized area of the label, it should appear as described in the *ISBT 128 Standard Technical Specification* (ST-001) (e.g., 17 MAR 2010) or in compliance with ISO 8601-2004 extended format (2010-03-17).
- If the text is elsewhere on the label, it may be presented in any appropriate format.

5.3   Electronically-Readable Symbols

Data Matrix two-dimensional (2-D) symbols are the recommended technology as these are now in widespread use in the supply chain. The information held in multiple linear bar codes can be encoded within a single 2-D bar code. The 2-D bar code takes up much less room than the corresponding linear codes leaving much more space for human-readable text and it is scanned in a single read reducing read times.

Linear bar codes are well established but increasingly being replaced with 2-D technology. The number of bar codes required, and limitations on the minimum size of each bar code, means that they take up a significant proportion of the available label space leaving little room for human-readable text. As each code has to be scanned individually, the time to scan each label is longer than for the corresponding two-dimensional label.

The choice of bar code type will depend on local circumstances.

5.3.1   Two Dimensional Symbol Option

This label design is based on a 50 mm x 50 mm template and can be placed at any position on the packaging. The label size is recommended but for special requirements, such as needing to accommodate dual language labeling or adapting the label to very small containers, the label size can be adjusted. This label design uses a single 2-D bar code to carry all the necessary data structures.

Figure 12 Two-Dimensional Symbol Label Design
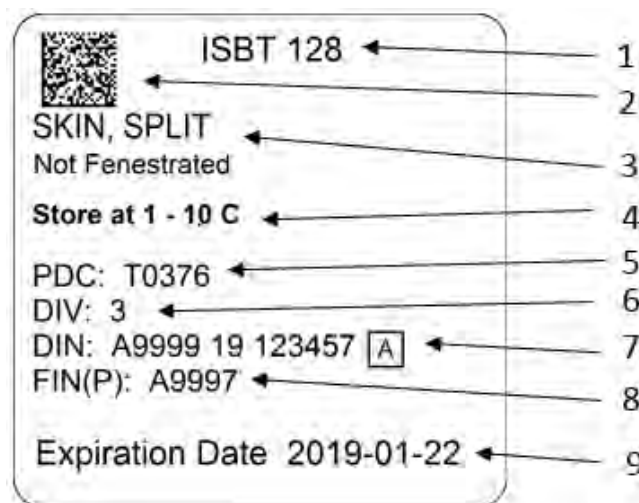
Reading from the top of the label, the content is as follows:

1) The optional text "ISBT 128" to indicate that this is the ISBT 128 compliant section of the label.
2) The 2-D symbol containing a compound message carrying the PPIC [Data Structure 034], Donation Identification Number [Data Structure 001], Product Divisions [Data Structure 032] and, optionally, the Expiration Date and Time [Data Structure 005].
3) The text description of the product giving the product name and attributes. (This is optional if this information appears elsewhere on the label).
4) The storage conditions
5) The text "PDC" and the Product Description Code in text.

6) The text "DIV:" and the Product Division in text (leading zeros may be omitted)
7) The text "DIN" and the eye-readable DIN, flag characters (if used, rotated 90° clockwise), and the boxed manual check character.
8) The text "FIN(P):" and the Processing Facility Identification Number.
9) The expiration date text using one of the two acceptable formats. This is optional if this information appears elsewhere on the label.

5.3.2   Linear Bar Code Option

This label design is based on the same format as described above but uses linear Code 128 bar codes.

Figure 13 Linear Bar Code Label Design
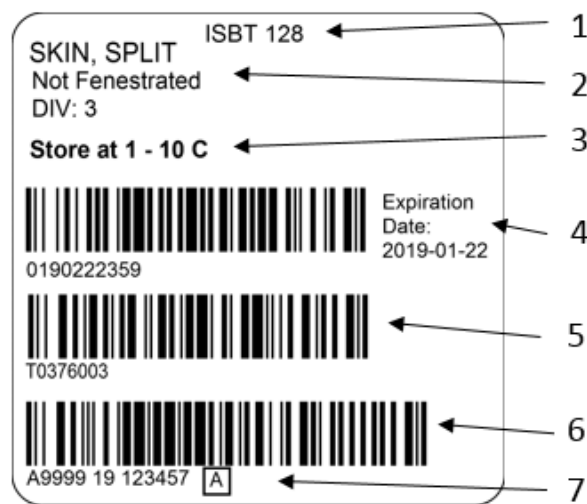
Reading from the top of the label, the content is as follows:

1) The optional text "ISBT 128" to indicate that this is the ISBT 128 compliant section of the label.
2) The text description of the product giving the product name and attributes
3) The storage conditions
4) The bar coded Expiration Date and Time [Data Structure 005], with associated text printed alongside. The printed information is optional if it appears elsewhere on the label.
5) The bar coded Product Code [Data Structure 003]
6) The bar coded DIN [Data Structure 001].
7) The eye-readable DIN, flag characters (if present, rotated 90° clockwise), and the boxed manual check character.

5.4   Label Size and Placement

The size and placement of the standard portion of the label may vary within the constraints outlined in the ISBT 128 Label Requirements section.

For some containers physical dimensions limit the available label space and the previously described designs may be too large. In such cases the amount of eye-readable information may need to be reduced to the minimum. Figure 14 shows how this can be accommodated on a tissue product carton.

Figure 14 Product Carton Label Example

In Figure 15, the ISBT 128 label portion of the label is in a strip on the left side. The PDC, DIV, DIN and FIN(P) appear in eye-readable characters. In this example the tissue processors internal identifiers are also present on other areas of the label.

Figure 15 Vial Label Example
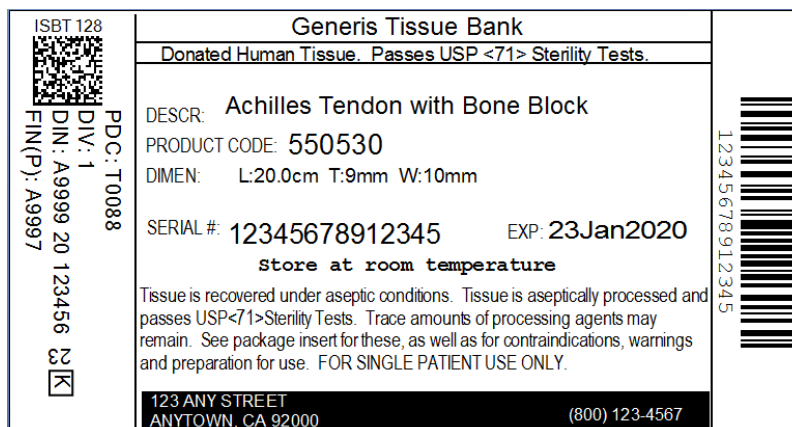
6 Label Locations

The ISBT 128 label should be available at the time of transplantation so that information can be directly scanned into patient records. This is essential to eliminate the risk of manual transcription errors at this critical point of information transfer. However, for tracking purposes the label will need to be scanned at various other points in the production and supply chain. To ensure this visibility of the label throughout the pathway from product release to transplantation, it may be necessary to have multiple copies of the label on different levels of packaging, or to make use of transparent outer packaging through which the underlying label can be scanned.

7   Guidance for Software Developers

Software written to print and read these labels should be compliant with the requirements of the *ISBT 128 Standard Technical Specification* (ST-001). Additional information is available from ISBT 128 Implementation Guides.

When assigning and reading ISBT 128 identification, it should be understood that the DIN provides uniqueness of the donation (i.e., all tissue products identified with this DIN were derived from the same donation). Uniqueness of the individual tissue product is provided by a combination of the DIN, PDC, DIV, and the FIN(P).

Where the ISBT 128 identification is being assigned to a final product, systems must ensure that there is mapping between the assigned ISBT 128 number and other identifiers used earlier in the donation pathway.

When printing ISBT 128 labels the requirements of the *ISBT 128 Standard Technical Specification* (ST-001) and the *ISBT 128 Standard Labeling of Human Tissues* (ST-003) must be applied. In particular, bar code size and density requirements and the need for sufficient quiet space around code symbols must be observed.

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 2-D bar codes carrying multiple ISBT 128 data structures in a compound message and multiple linear bar codes each containing a single ISBT 128 data structure. Finally the software should support both the labeling strategies described in this document.

Software should support electronic input of expiration date bar code if present using either Data Structure 005 or Data Structure 031, or manual entry if not available.

The following sample labels are provided to assist in software design and testing.

8 Label Examples

Note: It is not intended that the following examples represent the entire tissue label. They are intended only as a portion of the total label.

Figure 16 Ground Bone with Linear Bar Codes
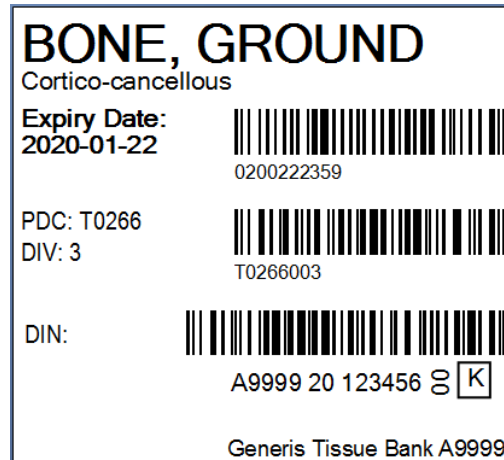
Figure 17 Bone Putty Label with 2-D Symbol
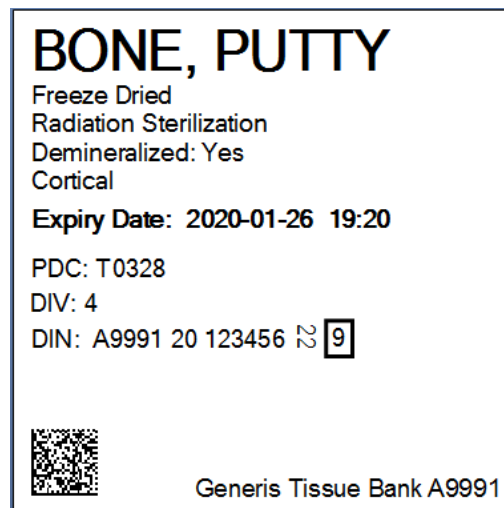
Figure 18 Skin Label with 2-D Symbol

SKIN, FULL
WITH HYPODERMIS
Frozen, Decellularized
Radiation Sterilization

Store at <-20 C
Expiration Date: 2020-01-10
PDC: T0326
DIV: 3
DIN: A9999 20 123456 ⧖ K

Generis Tissue Bank A9999
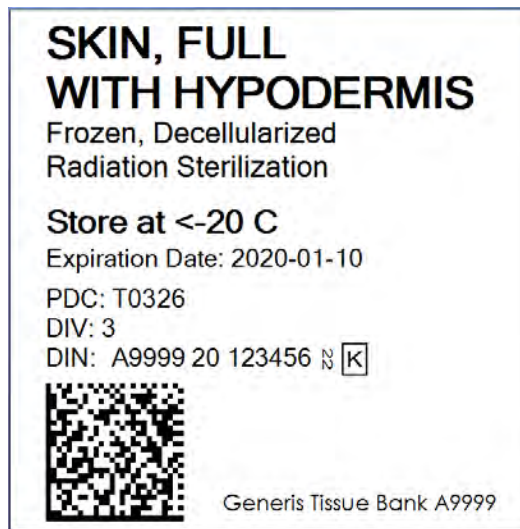
Figure 19 Linear Bar Codes on 4" x 4" Label

A9999 17 123654 ⧖ Y

Reliable Tissue Center
Anywhere Worldwide

T300

FIT FOR CLINICAL USE

T0027003

BONE, GROUND
Freeze Dried
Radiation Sterilization

CONTAINER 3
Nominal Volume 35 ml

0190302359

Expiry Date:

2019-01-30

If stored at -20 C or lower

See package insert for more information

Abbreviations

Abbreviation	Definition
AABB	American Association of Blood Banks
AATB	American Association of Tissue Banks
CDRH	Center for Devices and Radiological Health
DIN	Donation Identification Number
DIV	Division Number
FACT	Foundation for the Accreditation of Cellular Therapy
FDA	Food and Drug Administration
FIN	Facility Identification Number
FIN(P)	Facility Identification Number, Processing Facility
FPC	Facility-defined Product Code
HCT/P	Human Cells, Tissues, and Cell and Tissue Based Products
ICCBBA	International Council for Commonality in Blood Banking Automation
IEC	International Electrotechncial Commission
ISO	International Standards Organization
ITTAG	International Tissue Technical Advisory Group
MPHO	Medical Products of Human Origin
NATTAG	North America Tissue Technical Advisory Group
NGO	Non-governmental Organization
PDC	Product Description Code
SEC	Single European Code
UDI	Unique Device Identifier
WHO	World Health Organization

Glossary

General Terminology Used in ISBT 128 Coding	
Data Structure	Defined format for information transfer within ISBT 128. The data structure defines the data identifiers, the data content, and the means to encode specific information within the data content. It specifies the context and structure and provides the links to the appropriate reference tables for conversion of codes to meaningful information.
Data Content	The characters in a data structure that encode the desired message (a Product Code, for example)
Terminology Used in Donation Coding	
Donation Event	Recovery of donated tissues from a donor during a single recovery process.
Donation Identification Number (DIN)	A thirteen-character code that identifies tissues from a single donation event. This identifier allows each donation event to be uniquely identified globally for a period of 100 years. The DIN comprises three elements: the Facility Identification Number (FIN), DIN year code, and DIN sequence number.
Facility Identification Number (FIN)	A five-character alphanumeric code assigned to facilities licensed to use ISBT 128 by ICCBBA. The code provides a globally unique identifier that is an essential element of a Donation Identification Number.
DIN Year Code	A two-character numeric code assigned by the facility that is used to ensure uniqueness of a Donation Identification Number for a period of 100 years.
DIN Sequence Number	A six-character numeric code assigned by a tissue facility as part of the Donation Identification Number to ensure unique identification of each donation event.
Flag Characters	A two-character code that is an element of the Donation Identification Number data structure. Flag characters can be used to identify the specific instance of a DIN label (e.g. distinguish between the DIN label read from a sample tube and the DIN label read from the product packaging) and may be used to facilitate process control.
Check Character	A character used to ensure the accuracy of the data in a data structure when such data is entered manually via a keyboard. The value is calculated by applying an algorithm to the appropriate data [see *ISBT 128 Standard Technical Specification* (ST-001) for details]. The check character is most often used in association with the Donation

	Identification Number data structure but may be used with some other ISBT 128 data structures.
	Example of Donation Numbering: Donation Identification Number + Flag Characters + Check Character W0000 10 123456 12 O FIN Year Sequence Number Flag Check Character Donation Identification Number
Terminology Used in Product Coding	
Product Code	An eight-character ISBT 128 code that comprises the Product Description Code and a division code/pack number. This code makes each product from a collection unique. This is the data content for the Product Code Data Structure.
Product Description Code	A five-character ISBT 128 alphanumeric code assigned to each unique product type listed in the ISBT 128 Product Description Codes database.
Division Code	A number that uniquely identifies multiple products with the same Product Description Code and Donation Identification Number. This code is generally sequentially assigned to products from the same donation event. May also be referred to as pack number. Is either a three digit or six digit number depending on the data structure used.
Pack Number	See Division Code

Example of Product Coding:
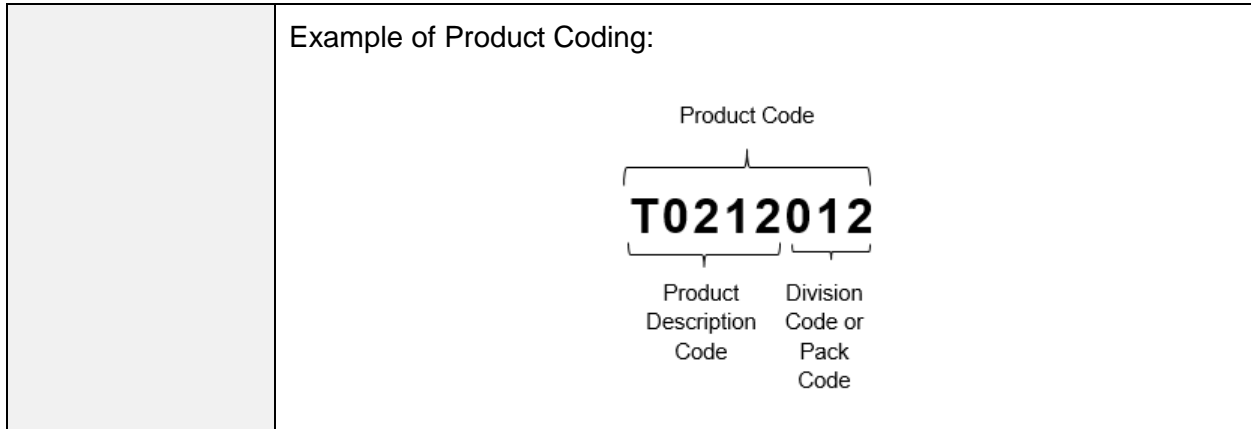
Appendix A: GS1/ICCBBA Guidance

Identification of medical devices containing an HCT/P in the United States.
Recommendation for labelling Issued by ICCBBA and GS1 on 17 November 2014

Introduction

This recommendation applies specifically to the identification of human cells, tissues and cellular and tissue-based products (HCT/Ps) that are regulated as medical devices using a Unique Device Identifier (UDI) as required under the US Food and Drug Administration's (FDA's) Unique Device Identification System Final Rule (78 FR 58785; September 24, 2013).

GS1 and ICCBBA, working within the terms of an existing Memorandum of Understanding, have developed this recommendation to clarify the appropriate use of the GS1 and ISBT 128 unique device identifiers, and the interfaces between the standards.

The GS1 – ICCBBA collaboration

GS1 and ICCBBA established a Memorandum of Understanding in Aug 2007 to set out a framework of cooperation between the two organizations in areas of mutual interest. In particular it was recognized both standards play an important role in their respective spheres, there would be areas of interface between the two standards, and these should be well defined with logical transition. By developing this collaboration, the two organizations intend to provide their coordinated contribution to patient safety.

Collaborative actions have resulted in:
1. A guidance document on labeling of plasma derivatives;
2. A harmonized approach to the use of both GS1 and ISBT 128 in the identification of blood collection sets; and,
3. The development of an ISO Standard on patient identification.

In each case the organizations have worked together to ensure the solution presented is based on the standard best suited to the business process.

Understanding traceability

Traceability by unit / by lot (batch)

The hierarchy model for traditional supply chain goods can be represented as a sequence of one to many relationships with the product manufacturer as the highest element in the chain. Thus, a manufacturer will make multiple products, each uniquely identified within the organization by a product number (catalogue number, identifying a product class) and Global Trade Item Number (GS1 GTIN). Each product will typically be produced in batches identified by a batch or lot number. In situations where serialization is required, each item will carry its own serial number, which together with the GTIN identifies that item uniquely (product instance).

Identification of medical devices containing an HCT/P in the United States.

Recommendation for labelling Issued by ICCBBA and GS1 on 17 November 2014
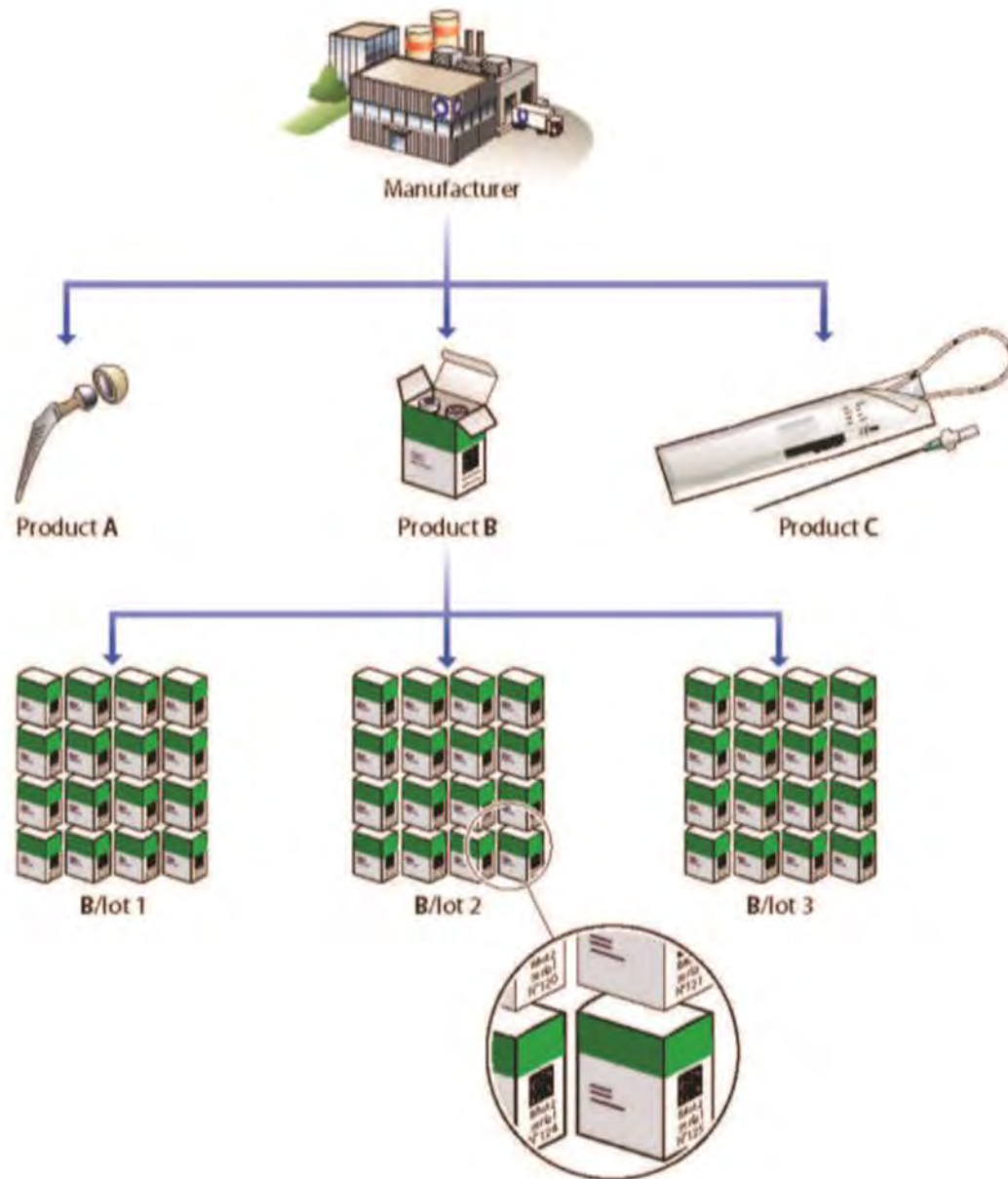
Identification of medical devices containing an HCT/P in the United States.
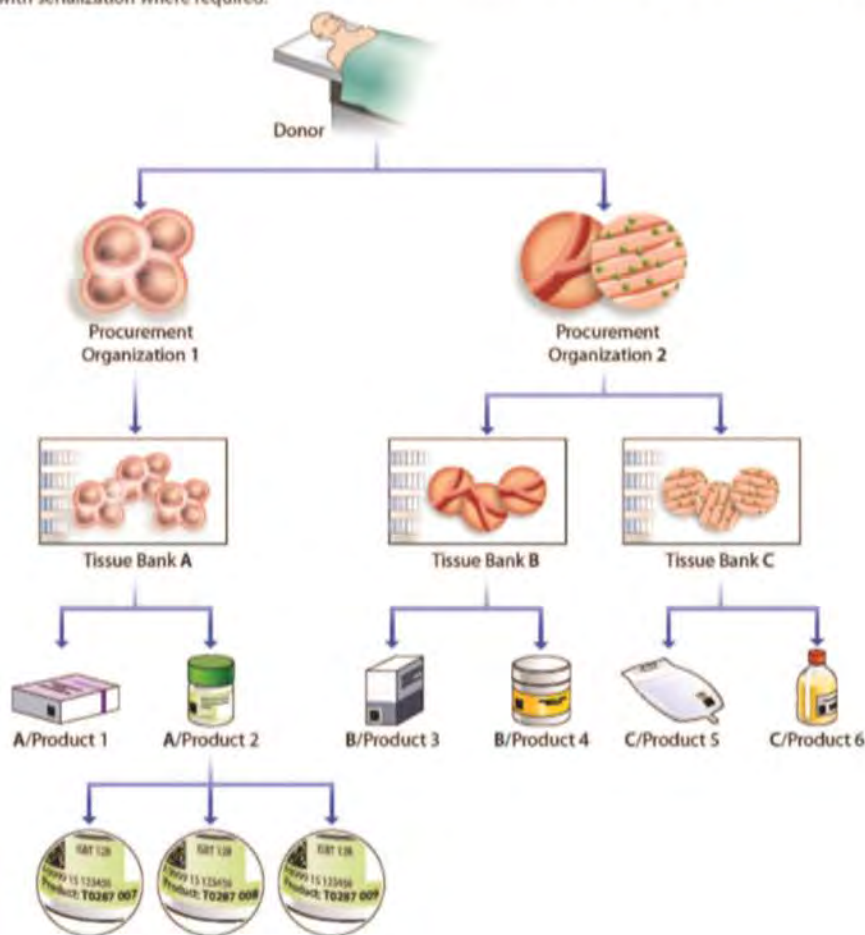## Recommendation for labelling Issued by ICCBBA and GS1 on 17 November 2014

Good manufacturing practice, supported by effective regulation, controls the manufacturing process and ensures segregation between product classes and their respective batches. Therefore when product recall or follow up is required, it is almost exclusively contained within one of the grouping levels of the model. Most commonly this occurs at the batch/lot level or the product level.

Traceability to the donation

In the case of human tissue, the hierarchy model is different because most recall/follow up events have been associated with a specific donor. A single donor's tissues may be recovered and sent to more than one tissue bank processor, and this tissue can be distributed across multiple product lines.

The highest element in the hierarchy in this scenario is therefore the tissue donor. Subsequent levels include the identification of the donation event, the tissue processor, and the product/catalogue number of the individual products prepared together with serialization where required.

Identification of medical devices containing an HCT/P in the United States.
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Recall and follow up activities are generally associated with a specific tissue donor. A donor-related recall requires identification of all the tissue and organs associated with the single donor. This will often comprise specific items under a wide range of product lines from different organizations (an organ procurement organization, an eye bank and tissue processors). For example, one donor may donate solid organs (kidney, liver), corneas, skin, heart valves and vessels, bone (further processed to a range of products including shaped grafts and demineralized bone matrix), and soft tissue such as tendons, ligaments, amniotic membrane, pericardium, fascia, and nerves. This range of products spans multiple regulatory paradigms (organs, medical devices, biologics) and there can be a need for product tracing/tracking for immediate quarantine, withdrawal or recall with an expectation this will occur in an efficient and seamless manner.

A second scenario in tissue banking occurs when a problem has been identified by a single processor and involvement included a particular product line or many product lines. The latter scenario can include many lots, multiple products, and several donors.

The special nature of HCT/Ps

HCT/Ps are a precious resource most often provided by deceased donors and/or acutely grieving family members. Living donors also provide HCT/Ps that can improve and save lives of recipients in need. Tissue banks handle these medical products of human origin with care and respect, understanding the special gift of donation. It is important this care and respect is followed from the time of donation and recovery to the moment of implant, transplant, infusion, or transfer to a human recipient.

HCT/Ps have unique characteristics that impact their handling through the supply chain. In particular:
- HCT/Ps are regulated under 21 CFR Parts 1270 and 1271 by the FDA's Center for Biologics Evaluation and Research (CBER);
- HCT/Ps must carry a distinct identification code that relates each HCT/P to the donor and all records pertaining to the donor, and that labeling include information to facilitate effective tracking (using the distinct identification code) from the donor to the recipient and from the recipient to the donor;
- The ability to track all HCT/Ps from the donor to the consignee or final disposition, and from the consignee or final disposition to the donor, is expected;
- HCT/P management in healthcare facilities is subject to stringent standards (e.g., standards and elements of performance in The Joint Commission's Transplant Safety Chapter; AABB's Standards for Blood Banks and Transfusion Services);
- HCT/Ps can transmit disease. Enhanced traceability, with specific reference to traceability to the donor (or donors), is essential in the investigation and prevention of disease transmission; and
- There is a recognized need for standard product terminology and coding to support biovigilance as identified by World Health Assembly resolution WHA63.22.

The standard employed for medical devices containing an HCT/P, and supply chain procedures, should explicitly support these characteristics.

GS1 labeling: for the general supply chain

The FDA requirement for UDI applies to all medical devices distributed in the USA. The vast majority of these devices follow a standard manufacturing process model and can be effectively traced using traceability by lot/batch number. These should be labeled using the GS1 UDI that meets users' requirements in North America and across the world.

Through its normal standards management process GS1 and its users ensure that the GS1 system of standards continuously accommodates regulatory requirements.

ICCBBA labeling: for medical products of human origin

ISBT 128 is designed specifically to meet the special needs of HCT/P traceability. The use of a globally unique donation identification number, and the maintenance of international standard terminology and coding, ensures effective traceability to the donor and supports biovigilance activity.

Identification of medical devices containing an HCT/P in the United States.
Recommendation for labelling Issued by ICCBBA and GS1 on 17 November 2014

ICCBBA was established, and continues to operate, specifically to address the identification and traceability needs of medical products derived from human donors. To this end the organization has established links with over 300 professional experts in the field of transfusion and transplantation who participate in technical advisory groups responsible for ensuring the ongoing suitability of the standard.

At the international level, ICCBBA is a nongovernmental organization in official relations with the World Health Organization and ISBT 128 is recognized by WHO as the sole global standard for the identification and coding of Medical Products of Human Origin (which includes HCT/Ps)

ISBT 128 product terminology is incorporated into the European Union (EU) Product Compendium making it fully compatible with the Single European Code (SEC). The SEC will be required on tissues and cells distributed in the EU, including imports from third countries, in accordance with forthcoming EU legislation.

Characteristics Specific to ISBT 128

The following characteristics are specific to ISBT 128 and address the special supply chain needs for HCT/Ps as described above:

1. The ISBT 128 Standard Terminology and associated Product Code Database meet the need for standardized product coding across multiple providers in order to support biovigilance activity as recognized in World Health Assembly Resolution WHA63.22;

2. The device identifier combines a standard product description code with a tissue bank specified code element allowing tissue banks to assign distinct product type identifiers within a structured framework;

3. The standardized globally unique donation identification number (distinct identification code) is presented in a consistent, electronically readable format that supports rapid recall;

4. The scope and focus of ISBT 128 provides a specific and consistent identification system that spans all medical products derived from a human donor (including blood, cells, tissues, organs, milk); and is

5. Accepted by the European Commission for use in the Single European Code being introduced for use on all tissues and cells distributed in the European Union.

Summary

GS1 & ICCBBA collaborate to enhance patient safety, by recommending the use of the standard meeting specific business requirements.

Following a review of the business requirements of various supply chain parties, GS1 and ICCBBA recommend that medical devices that contain an HCT/P should be identified using the ISBT 128 Standard. Other medical devices should be identified using the GS1 system of standards.

Appendix B: National and Local Codes

The block of PDCs A0000-D9999 has been reserved for use as nationally or facility defined PDCs. There shall 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. For example, 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/regional/national, the user should contact the ICCBBA office.

National agencies may reserve a range of these values for national assignment. **In the US, B7000 through B9999 have been reserved for national use**. **There are no nationally defined codes for Canada at this time.**

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, the facility shall 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 shall 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 shall be retained permanently for traceability purposes. Once assigned, codes shall not be reassigned.