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Coding and Labeling of Medical Devices Using ISBT 128

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1 Introduction

1.1 Purpose

The purpose of this document is to provide requirements and guidance for the labeling of medical devices containing a human tissue or cellular component using the ISBT 128 Standard.

1.2 Scope

This document is a supplement to the *ISBT 128 Standard Technical Specification* (ST-001). It provides specific requirements and guidance for facilities labeling medical devices that contain human cells, tissues, and cellular and tissue-based products (HCT/P) that are regulated as medical devices. It focuses on Unique Device Identification (UDI) labeling.

The document addresses US regulations for medical device identification.

1.3 Intended Audience

The intended audience of this document is the staff (management, information technology, quality, validation, and laboratory) in tissue banks or cellular therapy facilities that produce HCT/P products regulated as medical devices in the US. It is also intended for software developers and label vendors that provide products for these facilities.

1.4 Normative References

ISBT 128 Standard Technical Specification (ST-001)

ISBT 128 Standard Product Description Code Database (ST-010)

Code of Federal Regulations, UDI Device Identification System, 21 CFR Parts 16, 801, 803, 806, 810, 814, 820, 821, 822, 830, 1271.3, and 1271.290 (c)

Code of Federal Regulations, 45 CFR Part 170

US, Section 201(h) of the Federal Food Drug & Cosmetic (FD&C)

ISO/IEC 15415:2011(E), Information technology — Automatic identification and data capture techniques — Bar code symbol print quality test specification — Two-dimensional symbols

ISO/IEC 15459-2:2015(E): Information technology — Unique identifiers — Part 2: Registration procedures

ISO/IEC 15459-4-2014(E): Information technology — Automatic identification and data capture techniques — Unique Identification — Part 4 Individual products and product packages

ISO/IEC 15459-3:2014(E): Information technology — Unique identifiers — Part 3: Common rules for unique identifiers

ISO/IEC 16022:2006(E), Information technology — Automatic Identification and data capture techniques — Data Matrix bar code symbology specification (and correction ISO/IEC 16022:2006/Cor 1:2008/Cor 2:2011)

1.5 Other References

ICCBBA Website (www.isbt128.org)

Implementation Guides:

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

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

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

Use of the Donation Identification Number [Data Structure 001] (IG-033)

ISBT 128 Facility Identification Number (IG-034)

ASTM F2943 - 13 Guide for Presentation of End User Labeling Information for Orthopedic Implants Used in Joint Arthroplasty

Global Unique Device Identification Database (GUDID), Guidance for Industry and Food and Drug Administration Staff, FDA, Issued June 27, 2014

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/ucm416106.htm>

UDI Formats by FDA-Accredited Issuing Agency (January 27, 2017)

<https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIIssuingAgencies/UCM489869.pdf>

Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI). Draft Guidance for Industry and Food and Drug Administration Staff, Issued July 26, 2016.

1.6 Background

In the US, human cellular and tissue products may be classified as biologics, drugs, advanced medicinal therapies, medical devices, or be placed in other regulatory categories. This classification affects how the products are labeled.

However, from a traceability standpoint, it is essential that cells and tissues, regardless of regulatory classification, be traceable from donor to recipient, and that all cells and tissues from a single donor can be readily cross-referenced to support effective recall. Effective biovigilance requires standardization of terminology and coding of products at a generic level.

This document will discuss the coding and labeling of cellular and tissue products classified as medical devices in the US, specifically in relation to CFR Part 801 regulations (referenced in Section 1.4). These regulations describe a unique device identifier (UDI) that consists of a device identifier (DI) and a production identifier (PI). This information must appear on the label in two formats:

- Automatic Identification and Data Capture (AIDC) and
- Easily readable plain-text.

The DI includes static elements related to the device. The FDA (21 CFR 801.3) defines the DI as a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device. For ISBT 128, the DI includes a manufacturer identification code and two product codes. The PI is dynamic information and may include one or more of the following: distinct identification code required by 21 CFR 1271.290 for HCT/P, lot number, serial number, manufacturing date, and expiration date.

ICCBBA has developed an ISBT 128 UDI that satisfies the regulations, and also carries the critical information required for biologics traceability and biovigilance. Using ISBT 128 identification for cells and tissues across all regulatory classifications ensures a harmonized approach to identification and a seamless traceability pathway.

The ISBT 128 UDI is based on ISBT 128 data structures that contain data identifiers. ISBT 128 data identifiers correspond to the FDA UDI data delimiters.

The ISBT 128 DI includes three elements: a Facility Identification Number, a Facility-defined Product Code, and the ISBT 128 standardized Product Description Code.

The ISBT 128 PI requires a globally unique Donation Identification Number that satisfies the distinct identification code required by 21 CFR 1271.290 and the Product Divisions Code as a serial number. Other PIs allowed by the FDA UDI regulations may also be included.

The ISBT 128 Standard is designed specifically for the labeling of medical products of human origin. Guidance developed by GS1 and ICCBBA on the selection of the most appropriate system for labeling medical devices is found in [Appendix 1](#).

1.7 Changes in this Version

The following table summarizes the major changes between Version 1.7.0 and Version 1.8.0 of this document. Actual changes or additions to requirements of the ISBT 128 Standard are in bold print; changes to formatting or organization, or additional guidance, are in regular print. When changes were a result of a formal proposal, the number of the proposal is listed in the Rationale column.

ISBT 128 Standard, Coding and Labeling of Medical Devices Using ISBT 128 (ST-011)
Version 1.7.0 vs. Version 1.8.0

	Version 1.7.0 Chapter, Section, Table, or Figure	Version 1.8.0 Chapter, Section, Table, or Figure	Change	Rationale
1.	3.1	3.1	Expanded the purpose of the DIN.	For completeness and consistency with ST-001 ISBT 128 Standard Technical Specification.
2.	3.1	3.1	Added reference to the flag characters as part of the purpose for Data Structure 001.	For completeness and consistency with ST-001 ISBT 128 Standard Technical Specification.

2 Device Identifier

Within ISBT 128, the Processor Product Identification Code [Data Structure 034] shall be used to encode the Device Identifier (UDI-DI). This data structure includes a facility identifier and two product codes: a 6-character Facility-defined Product Code (FPC) and a 5-character standardized Product Description Code (PDC).

2.1 Processor Product Identification Code (PPIC) [Data Structure 034]

Purpose: Data Structure 034 shall identify the processing or labeling facility, a Facility-defined Product Code (FPC), and a standardized Product Description Code (PDC).

Structure: =/nnnnnppppppqqqqq

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

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

nnnnn shall specify the Facility Identification Number, or the FIN(P), of the facility that assigned the PDC. For a UDI, this facility would be the labeler. The FIN(P) is issued by ICCBBA as the Issuing Agency for ISBT 128 identifiers and is encoded and interpreted by reference to the Registered Facilities Database published and maintained by ICCBBA in the password-protected area of the ICCBBA Website. The facility that assigned the PDC may, or may not, be the same facility that assigned the Donation Identification Number (DIN).

pppppp shall specify a Facility-defined Product Code (FPC) assigned by the processing or labeling facility indicating a catalog or other number that identifies the type of product within its system. If a value is not required, the default value 000000 (zeroes) shall be used. If the number is less than 6 characters, leading zeroes shall be used. The facility may choose to publish reference tables for use by the organizations receiving the product.

This code shall distinguish between two products that have the same standardized Product Description Code but require

different DIs. This may be because two product lines are slightly different or because a product changes in a way that requires a new DI but not a new Product Description Code.

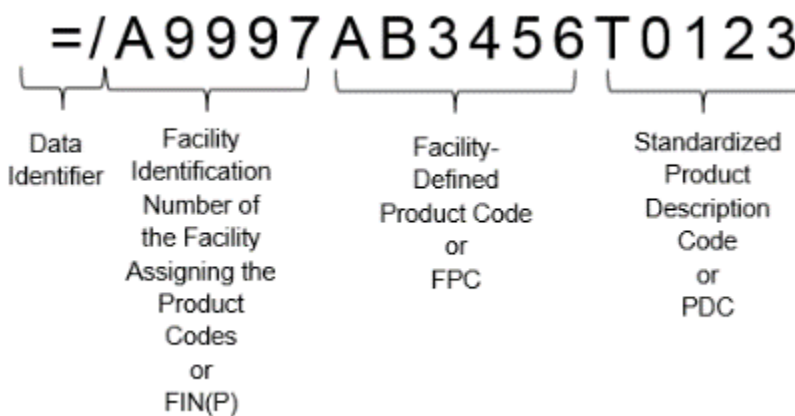
qqqqq

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

See Chapter 7 for information on selection of a standardized PDC.

Note on traceability: For all HCT/P, the combination of the ISBT 128 Donation Identification Number, PDC, and Product Divisions Code shall create global uniqueness. The FPC shall not be used as a complete or partial alternative to any of these data elements because it is not standardized.

Figure 1 Data Structure 034



3 Production Identifiers

Production Identifiers (PIs) specified in the UDI final rule may be one or more of the following:

- Distinct identification code required by 21 CFR 1271.290 for HCT/P
- Serial number
- Expiration date
- Manufacturing date
- Lot number

The data structures shown in Table 1 may be used for these identifiers.

Table 1 Production Identifiers

UDI Identifier	ISBT 128 Data Structure [Data Structure Number]
Distinct Identification Code	Donation Identification Number [001]
Serial Number	Product Divisions [032]
Expiration Date	Expiration Date [004]
Manufacturing Date	Production Date [008]
Lot Number	MPHO Lot Number [035]

To provide traceability for an HCT/P, ISBT 128 requires that the PI shall include:

- **The Donation Identification Number (DIN)**
- **The Product Divisions Code** (this code, in conjunction with the Product Description Code within the DI, is used as a serial number to uniquely identify each product from a donation event)

The expiration date, manufacturing (production) date, and lot number shall be included as part of the PI if they are used on the label.

3.1 Donation Identification Number [Data Structure 001]

Note: This is the only data structure in which the second character of the data identifier shall be part of the data content.

Purpose: Data Structure 001 shall specify:

- a thirteen (13)-character Donation Identification Number (DIN) that is a unique identification of:
 - a donation event [collection or recovery]
 - a product pool
 - for plasma derivatives, a unique identification of an aliquot from a pooled plasma derivative product
 - a fertilized oocyte/embryo formed through ART

AND

- flag character values

The 13-character DIN shall be globally unique for a one hundred year period.

Structure: =αppppyynnnnnnff

Element	Length	Type
=	1	data identifier, first character
α	1	data identifier, second character, alphanumeric {A–N; P–Z; 1–9}
pppp	4	First two characters alphanumeric {A–N, P–Z, 0–9}; second two characters numeric {0–9} Current usage is numeric for all 4 characters. Alpha characters may be introduced into positions 1 and 2 in the future (e. g., if α = A and pppp = BC12, the αpppp will be ABC12)
yy	2	numeric {0–9}
nnnnnn	6	numeric {0–9}
ff	2	alphanumeric {0–9}, {A–H, J–N, P, R–Y}

The fifteen (15)-character data content string, **αppppyynnnnnnff**, shall be encoded and interpreted as follows:

αpppp shall specify the Facility Identification Number (FIN) of the organization that assigned the DIN and shall be encoded and interpreted by reference

to the Registered Facilities Database published and maintained by ICCBBA in the password-protected area of the ICCBBA Website.

yy shall specify the last two digits of the year in which the DIN was assigned (or, in the case of a tissue processing facility assigning a DIN, this may be the year in which the first product from the donation event was processed).

Note: In practice, this is the “nominal” year. To cut down on wastage, DIN labels may be used for up to one month in the year before, and one month in the year after, the year shown on the label.

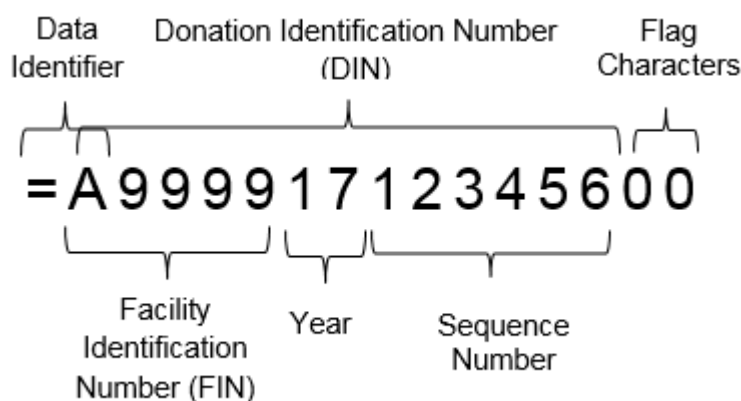
In the case of a tissue processing facility assigning a DIN, the DIN year code may be the year of the donation event OR the year in which the first product was processed. Usage shall be consistent within a facility. That is, if the DIN year code is the year the first tissue from the donation event was processed, the facility must always use the year the first tissue from a donation event was processed to determine the year code.

nnnnnn shall specify a sequence number indicating the particular collection, recovery, or product pool within the given year for the facility identified by the FIN.

ff are “flag characters.”

At the current time, flag characters shall not be used for medical devices with an HCT/P element and the value of ff shall be set to 00. Flag characters are intended for use in process control and, while are part of the DIN Data Structure, are not a part of the DIN itself.

Figure 2 Donation Identification Number Data Structure



3.2 Product Divisions [Data Structure 032]

Purpose: Data Structure 032 shall convey information about divisions and shall serve as a serial number for HCT/P regulated as medical devices.

Structure: =,dddddd

Element	Length	Type
=	1	data identifier, first character
,	1	data identifier, second character
dddddd	6	alphanumeric {A-Z, 0-9}* <i>(Note: The original image contains a typo '0-9' which has been corrected to '0-9' based on the context and the asterisk indicating a range.)</i>

*dddddd shall not be 000000 (all zeroes)

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

dddddd shall specify the division code

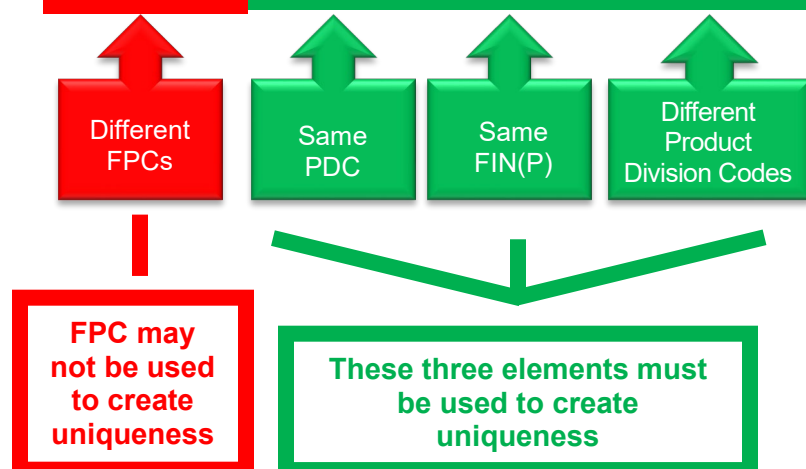
For medical device HCT/P, numeric values of 000001 to 999999 should be used to uniquely identify products.

While ISBT 128 is used for all medical products of human origin (MPHO), not all MPHO use the same set of data structures as medical devices. Certain ISBT 128 identifiers, regardless of the data structure in which they are encoded, become essential for traceability across MPHO. Within medical devices, these essential identifiers are the FIN(P) and PDC from the DI and the DIN and Product Divisions Code from the PI.

The FPC cannot be used to create uniqueness. If multiple FPCs map to one PDC, Product Division Codes must be used to uniquely identify each product. In the example in Table 2 (page 16) all products are from the same donation event (i.e., they all have the same DIN). The elements in bold font in the last column indicate how the Product Divisions Code is essential to ensure these products are uniquely identified (only the Division Codes differentiate the products). Although the FPC varies across the codes, it may not be used to create uniqueness. Therefore, the Product Divisions Code must be different for each of the four products since all have the same DIN (A9998 17 132343), FIN(P) (A9999), and PDC (T0475).

Table 2 Use of Product Division Codes to Create Uniqueness

All Products Have the DIN A9998 17 132343					
FPC	PDC	FIN(P)	Product Divisions Code	Description of Product	Data Structures 034 and 032
XYZ123	T0475	A9999	000001	BONE, PUTTY Radiation sterilization Demineralized:Yes Carrier and applicator, 2 mL	A9999 XYZ123 T0475 and 000001
XYZ124	T0475	A9999	000002	BONE, PUTTY Radiation sterilization Demineralized:Yes Carrier and applicator, 5 mL	A9999 XYZ124 T0475 and 000002
XYZ125	T0475	A9999	000003	BONE, PUTTY Radiation sterilization Demineralized:Yes Carrier and applicator, 10 mL	A9999 XYZ125 T0475 and 000003
XYZ126	T0475	A9999	000004	BONE, PUTTY Radiation sterilization Demineralized:Yes Carrier and applicator, 15 mL	A9999 XYZ126 T0475 and 000004



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.

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

3.3 Expiration Date [Data Structure 004]

Purpose: Data Structure 004 shall indicate the date at the end of which the item expires.

Structure: =>cyjjj

Element	Length	Type
=	1	data identifier, first character
>	1	data identifier, second character
c	1	numeric {0–9}
yy	2	numeric {0–9}
jjj	3	numeric {0–9}

The six (6)-character data content string, **cyjjj**, is encoded and interpreted as follows:

c shall specify the century of the year in which the item expires

yy shall specify the year within the century in which the item expires

jjj shall specify the ordinal number within the calendar year (Julian date) on which the item expires

3.4 Production Date [Data Structure 008]

Purpose: Data Structure 008 shall indicate the date on which the product was produced.

Structure: =}cyyjjj

Element	Length	Type
=	1	data identifier, first character
}	1	data identifier, second character
c	1	numeric {0–9}
yy	2	numeric {0–9}
jjj	3	numeric {0–9}

The six (6)-character data content string, **cyyjjj**, shall be encoded and interpreted as follows:

c shall specify the century of the year in which the product was produced

yy shall specify the year within the century in which the product was produced

jjj shall specify the ordinal number within the calendar year (Julian date) on which the product was produced

3.5 MPHO Lot Number [Data Structure 035]

Purpose: Data Structure 035 shall be used for the lot number of medical products of human origin

Structure: &,1xxxxxxxxxxxxxxxxxx

Element	Length	Type
&	1	data identifier, first character
,	1	data identifier, second character
1	1	data identifier, third character
xxxxxxxxxxxxxxxxxx	18	alphanumeric {A–Z; 0–9}

The data content string shall be up to 18 characters and shall be encoded and interpreted as follows:

xxxxxxxxxxxxxxxxxx Facility-defined lot number

Note: Only upper case alphas may be used in this data structure when it is used within a PI.

4 Compound Messages

In order to convey the full UDI (device identifier and production identifier information), in a single bar code, a compound message is needed. This data structure allows multiple data structures to be combined into a single message and may be used with high capacity delivery mechanisms such as 2-D symbols and radio-frequency identification (RFID) tags.

4.1 Compound Message [Data Structure 023]

Purpose: Data Structure 023 shall allow multiple data structures to be combined into a single data string to facilitate use of newer technology delivery systems.

Structure: =+aabbb

Element	Length	Type
=	1	data identifier, first character
+	1	data identifier, second character
aa	2	numeric {0-9}
bbb	3	numeric {0-9}

The 5-character data content string, **aabbb**, shall be encoded and interpreted as follows:

aa shall specify the number of ISBT 128 data structures that follow;

bbb shall be either:

- all zeroes – indicating the sequence of the data structures within the message is not specified, i.e., only the number of data structures is identified, not the sequence of those data structures or the order in which they occur.
- a three-digit number referencing an entry in an ICCBBA-maintained table that specifies the sequence of the data structures within a compound message. See Table W2, [RT017] ICCBBA-Specified Compound Messages described in the *ISBT 128 Standard Technical Specification* (ST-001). The reference table is found on the ICCBBA Website.

Rules for constructing compound messages:

1. A compound message shall comprise a string of ISBT 128 data structures (excluding nationally defined structures), beginning with the Compound Message [Data Structure 023].
2. Data structures shall be combined with no intervening characters and each data structure shall begin with its data identifier characters.
3. The string shall only contain ISBT 128 data structures (excluding nationally defined structures).

4. The number of data structures following the Compound Message Data Structure shall be indicated in element aa of the Compound Message Data Structure.
5. If the sequence of the message is unspecified, the Compound Message Data Structure shall have element bbb set to zeroes and element aa shall be set as specified in Rule 4.

Note: Because of the complexity created by multiple product categories, and the many codes that would result from permutations of order of data structures, ICCBBA now encourages the use of unspecified messages.

6. If a specified sequence is used, the reference number of the selected message from Table RT017 shall be included in element bbb of the Compound Message Data Structure. The order of the data structures shall be that shown on Table RT017 for the reference number selected.

To satisfy FDA UDI requirements, **the compound message shall always begin with the Processor Product Identification Code [Data Structure 034] (the DI)**. In addition, to meet traceability requirements, the Product Divisions [Data Structure 032] and Donation Identification Number [Data Structure 001] shall also be present. The Expiration Date [Data Structure 004] should be included. Additional PIs may also be present. The FDA UDI regulations do not specify a required sequence (order of the data structures) for the PIs. However, if non-UDI data structures are included in the compound message, they must appear after the PIs.

Reading software should be able to interpret both unspecified sequence and specified sequence compound messages. The software should always verify the integrity of the data string, including checking that the correct number of data structures appears and, when specified sequence messages are used, that the sequence of data structures is correct. Data should only be interpreted if the integrity of the relevant data structures has been confirmed.

4.2 Reference Table for Compound Messages (Specified Sequence)

A full list of specified sequence compound messages is found in Table W2, [RT017] ICCBBA-Specified Compound Messages on the ICCBBA Website. An excerpt of this table that includes some messages specific for HCT/P devices is shown as Table 3. Additional specified sequence messages may be requested by contacting tech.manager@iccbba.org.

Table 3 Specified Sequence Compound Messages for HCT/P Devices

ICCBBA-Specified Message Number	Data Structures
034	Processor Product Identification Code [034], Product Divisions [032], Donation Identification Number [001]
035	Processor Product Identification Code [034], Product Divisions [032], Donation Identification Number [001], Expiration Date [004]
036	Processor Product Identification Code [034], Product Divisions [032], Donation Identification Number [001], Production Date [008]
037	Processor Product Identification Code [034], Product Divisions [032], Donation Identification Number [001], Expiration Date [004], Production Date [008]

4.3 Creating Compound Messages

Compound Messages can be created using either an unspecified or a specified sequence of data structures. Facilities may select whichever type of message works best for them.

4.3.1 Creating a Compound Message (Unspecified Sequence)

The data structures and their sequence desired in the example compound message are:

- Processor Product Identification Code [034]
- Donation Identification Number [001]
- Product Divisions [032]
- Expiration Date [004]

The message desired is:

Data Structure	Information to transfer	Data Identifier and Code
Processor Product Identification Code or PPIC (DI)	Facility: A9997 Facility-defined Product Code: XYZ100 Standardized Product Code: T0479	=/A9997XYZ100T0479
Donation Identification Number	Donation Identification Number: A999917123456	=A99991712345600
Product Divisions	12	=,000012
Expiration Date	31 JAN 2019	=>019031

A compound message with this data is:

Data Characters	Meaning of Data Characters
=+	Data identifier
04	There are four data structures in the message
000	This is a message with an unspecified sequence of data structures
=/A9997XYZ100T0479	Processor Product Identification Code is A9997XYZ100T0479
=A99991712345600	Donation Identification Number for the HCT/P is A999917123456. Flag characters are set to 00.
=,000012	Product division is 12
=>019031	Expiration date is 31 JAN 2019

The data string would therefore be:

=+04000=/A9997XYZ100T0479=A99991712345600=,000012=>019031

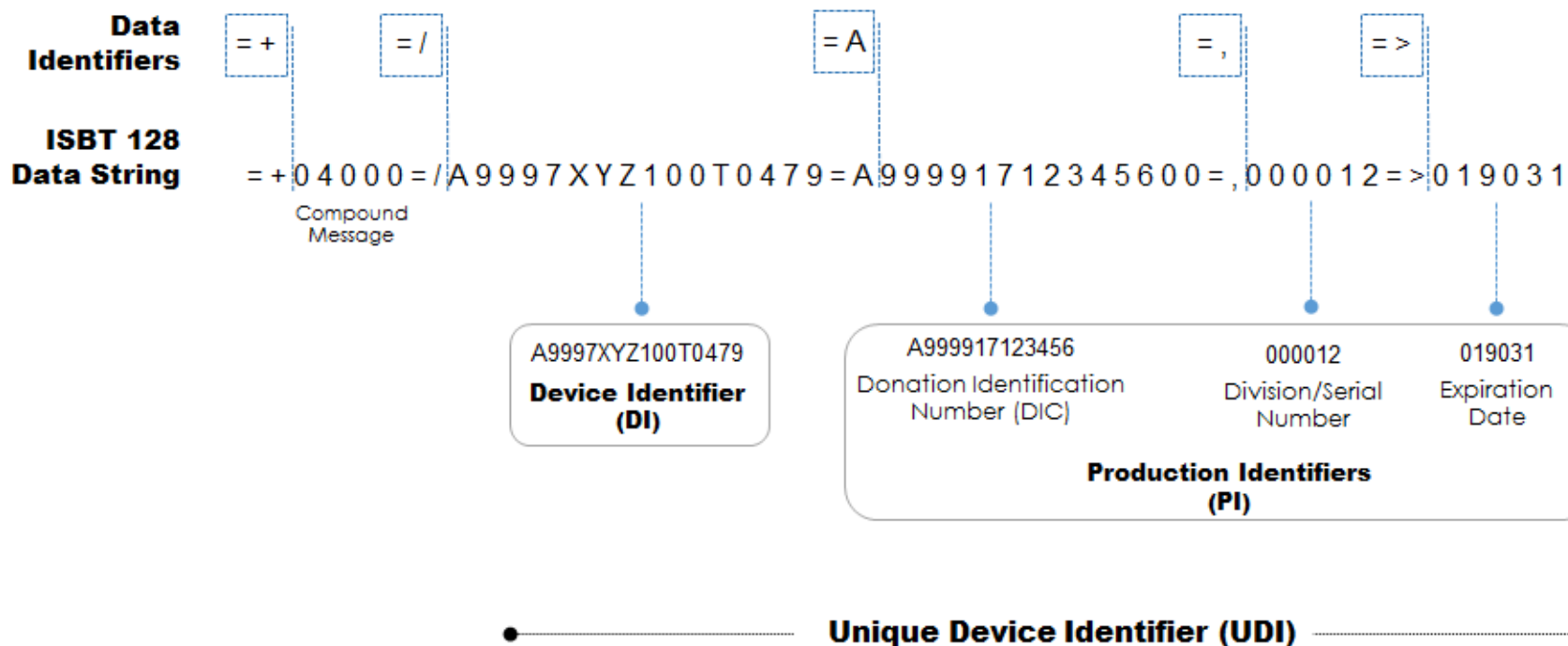
The Data Matrix symbol would be:



This symbol, created with an X dimension of 0.36 mm has a size of approximately 9 mm by 9 mm.

Figure 3 shows how this message is parsed.

Figure 3 Compound Message (Unspecified Sequence)



4.3.2 Creating a Compound Message (Specified Sequence)

The data structures desired in the example compound message are:

- Processor Product Identification Code [034]
- Product Divisions [032]
- Donation Identification Number [001]
- Expiration Date [004]

Per Table W2 [RT017] - ICCBBA-Specified Compound Messages, these data structures are in the specified compound message #035.

Table 4 Excerpt from RT017

ID	Number of Data Structures	Data Structure Numbers	Data Structures
035	04	[034];[032];[001];[004]	Processor Product Identification Code;Product Divisions;Donation Identification Number;Expiration Date

The message desired in the example is:

Data Structure	Information to transfer	Data Identifier and Code
Processor Product Identification Code or PPIC (DI)	Facility: A9997 Facility-defined Product Code: XYZ100 Standardized Product Code: T0479	=/A9997XYZ100T0479
Product Divisions	12	=,000012
Donation Identification Number	Donation Identification Number: A999917123456	=A99991712345600
Expiration Date	31 JAN 2019	=>019031

A compound message with this data is:

Data Characters	Meaning of Data Characters
=+	Data identifier
04	There are four data structures in the message
035	This message has a sequence of data structures that is specified in line 035 from Table RT017
=/A9997XYZ100T0479	Processor Product Identification Code is A9997XYZ100T0479
=,000012	Product division is 12
=A99991712345600	Donation Identification Number for the HCT/P is A999917123456. Flag characters are set to 00.
=>019031	Expiration date is 31 JAN 2019

The data string would therefore be:

=+04035=/A9997XYZ100T0479=,000012=A99991712345600=>019031

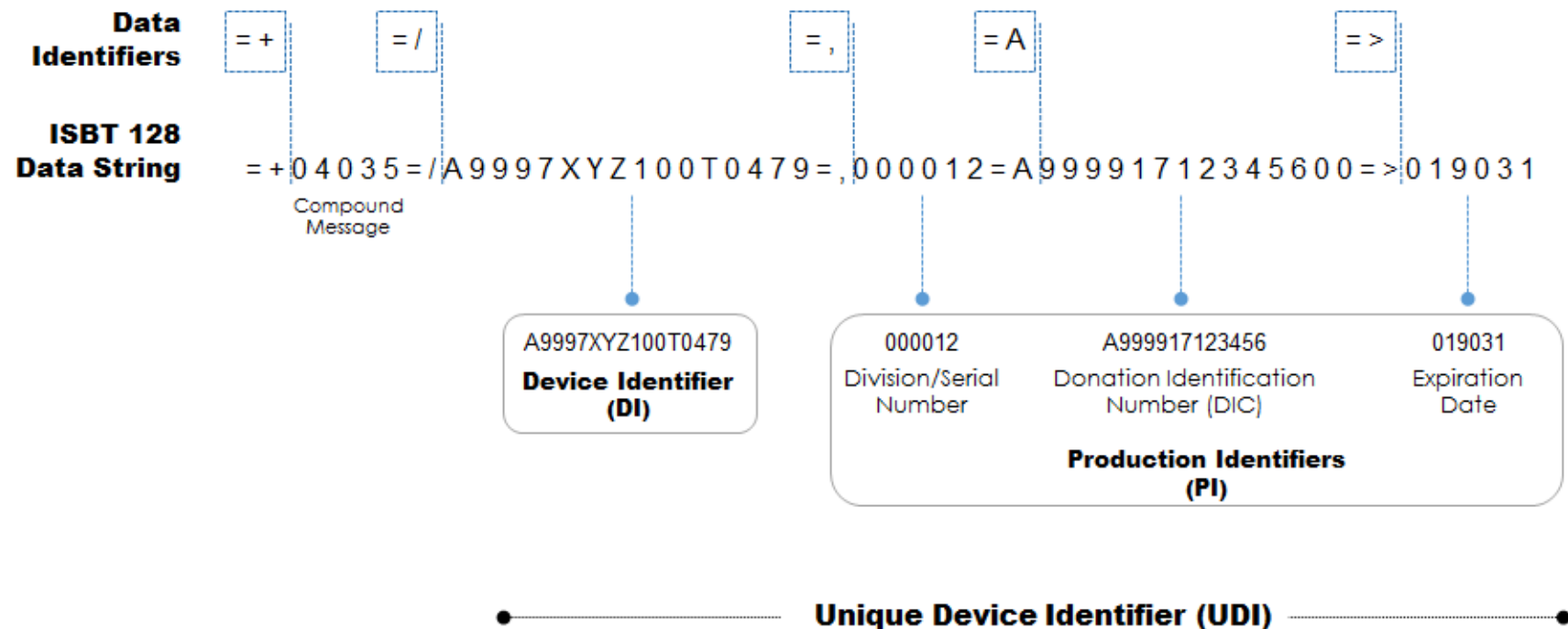
The Data Matrix symbol would be:



This symbol, created with an X dimension of 0.36 mm has a size of approximately 9 mm by 9 mm.

Figure 4 shows how this message is parsed.

Figure 4 Compound Message (Specified Sequence)



5 Parsing the ISBT 128 UDI to Extract the Data Items Required by 45 CFR Part 170

The approved formats for an ISBT 128 UDI are specified in the FDA document “UDI formats by FDA-Accredited Issuing Agency.” The relevant table is reproduced below. The ISBT 128 UDI is based on ISBT 128 data structures that contain data identifiers. ISBT 128 data identifiers correspond to the FDA UDI data delimiters. (Note: The example human readable bar coded information was updated to utilize current dates and a more relevant Product Description Code.)

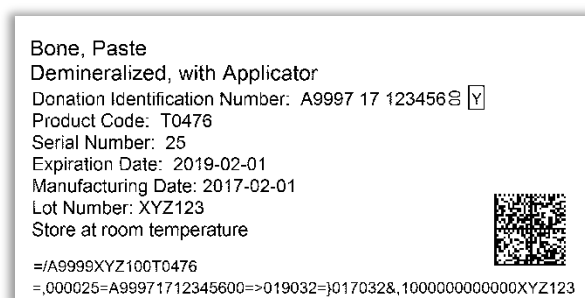
Table 5 ISBT 128 UDI for Medical Devices Containing HCT/P

Issuing Agency	Data Delimiters	Identifier	Data type	Human Readable Barcode Field Size	Database Field Size
ICCBBA	=/	DI (Device Identifier)	Alphanumeric	18	16
ICCBBA	=,	Serial Number	Alphanumeric	8	6
ICCBBA	=	Distinct Identification Code (Donation Identification Number)	Alphanumeric	16	15
ICCBBA	=>	Expiration Date	numeric [YYYYJJJ]	8	6
ICCBBA	=}	Manufacturing Date	numeric [YYYYJJJ]	8	6
ICCBBA	&,1	MPHO Lot Number	Alphanumeric	21	18
ICCBBA		<i>Maximum Base UDI for HCT/Ps</i>	<i>Alphanumeric</i>	79	67

Example of Human Readable Bar Coded Information:

=/A9999XYZ100T0476=,000025=A99971712345600=>019032=}017032&,1000000000000XYZ123

Figure 5 Example Label with 2-D Symbol

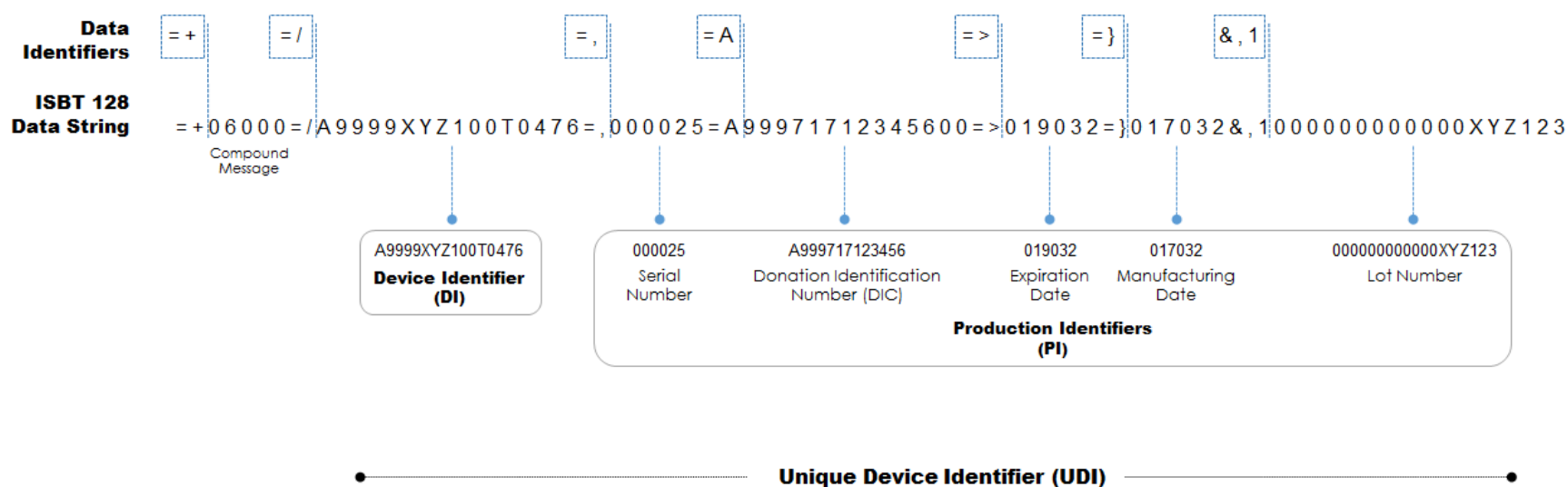


It is recommended that the ISBT 128 UDI be encoded within an ISBT 128 Compound Message in a 2-D Data Matrix code. However, the Standard does permit the use of Code 128 linear bar codes for compound messages.

When the UDI is encoded in a Data Matrix code the full UDI will be received as a single input string. An example is:

=+06000=/A9999XYZ100T0476=,000025=A99971712345600=>019032=}017032&,10000000000000XYZ123

Figure 6 Parsing of an ISBT 128 UDI



The initial “=” character indicates that this is an ISBT 128 data string. Elements of the message are divided either by the “=” or the “&” character.

The first element (=+06000) indicates that this is a compound message and the content can be interpreted in accordance with Section 4.1.

The second element is the Device Identifier (DI). This is identified by the data identifier “=” and the 16 data characters following this data identifier comprise the device identifier (A9999XYZ100T0476) as specified in 45 CFR Part 170.

The remaining elements are the production identifiers and may appear in any order. They are each identified by a data identifier. The Donation Identification Number [referred to as the distinct identification code required by 21 CFR 1271.290(c)] and the serial number are mandatory PIs. The other PIs are optional within the ISBT 128 Standard.

In the above example the third element is the Product Divisions Code (Serial Number PI). It is identified by the data identifier “=,” and has six data characters (000025). This is the “serial number of a specific device” as specified in 45 CFR Part 170.

The fourth element is the Donation Identification Number (Distinct Identification Code PI). It is identified by the data identifier “=” followed by any alpha/numeric character. The “=” character is followed by 15 data characters, but only the first 13 of these are the Donation Identification Number. The last two characters are flag characters and should be ignored. Thus, in the example, the data characters A999717123456 form the Donation Identification Number. This is the distinct identification code required by 21 CFR 1271.290(c) as specified in 45 CFR Part 170.

The fifth element is the Expiration Date PI. This is identified by the data identifier “=>” and has six data characters. These are presented in an YYYYJJJ format where the first three characters form a three-digit year and the next three characters are the ordinal number within the calendar year (Julian date). Thus, 019032 refers to 1 Feb 2019.







The sixth element is the Manufacturing Date PI. This is identified by the data identifier “=)” and has six data characters. These are presented in an YYYYJJJ format where the first three characters form a three-digit year and the next three characters are the ordinal number within the calendar year (Julian date). Thus, 017032 refers to 1 Feb 2017. This is the date of manufacture as specified in 45 CFR Part 170.

The seventh element is the Lot Number PI. This is identified by the data identifier “&,1” and the 18 data characters following this data identifier (000000000000XYZ123) are the lot or batch number as specified in 45 CFR Part 170.

(Note: If non-UDI data structures are included in the message, they appear after the PIs.)

If the UDI is presented as linear barcodes, each element shall be carried in an individual Code 128 linear code and will be identified by its data identifiers. The compound message data structure is not used in this situation. See Figure 7.

Figure 7 Example Label with Multiple Linear Bar Codes

Tendon	Generis Tissue Bank Anytown, USA 99999-9999
With Suture	
Frozen	Store at -80 C or colder
Sterilized with Radiation	
Product Code: T0480	
Device Identifier (DI): A9999004344T0480	 =/A9999004344T0480
DIN: A9997 17 123456  	 =A99971712345600
Serial Number: 000005	 =.000005
Exp. Date: 2018-01-20	 =>018020

6 Labeling

6.1 Bar Code

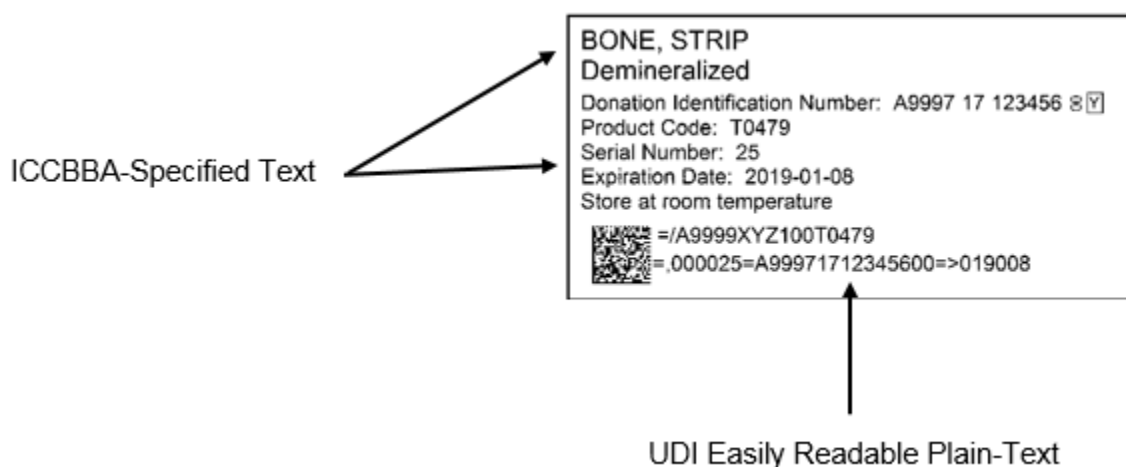
A Data Matrix (2-D) symbol may be used to convey the compound message on the product label. Printing of the symbol should follow appropriate ISO standards (listed in Section 1.4) and the *ISBT 128 Standard Technical Specification* (ST-001).

Linear bar codes may be used if space on the label permits. Because of the length of the bar codes, separate bar codes would be needed for the DI and the PI. Separate bar codes would also be needed for the various data structures within the PI.

6.2 Text

Both the easily readable plain-text that corresponds to the data characters encoded in the AIDC UDI and ICCBBA-specified text should be printed as shown in Figure 8.

Figure 8 Label Example



6.2.1 ICCBBA-Specified Text

ICCBBA-specified text corresponding to the UDI identifiers should be displayed in a way easily interpreted by humans. This text may be printed in any order and may omit leading zeroes. Font selected must allow differentiation between similar characters (e.g., 0/O and 1/I).

Information corresponding to identifiers essential for traceability in ISBT 128 should be near the electronically-readable symbol. At a minimum, this should include:

- The Donation Identification Number (Distinct Identification Code)
- The Product Description Code
- The Product Divisions Code (serial number)

The identification of the processor (name of processor), also needed for traceability, should be present on the label, but the specific location is not mandated. This flexible placement is also true for the expiration date and the MPOH lot number.

The codes should be identified with a label (e.g., “Donation Identification Number” and “Product Code”), but this label may be abbreviated if space is limited. See Table 6 for recommended abbreviations.

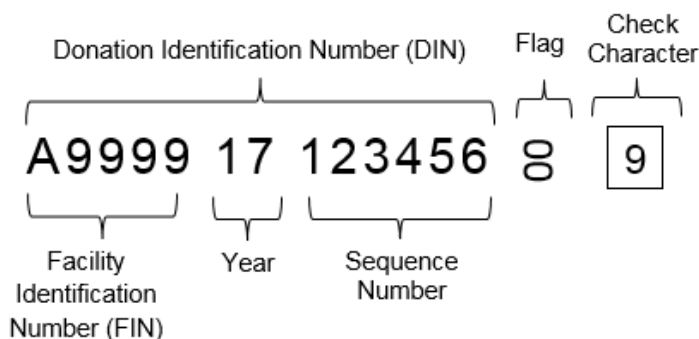
Table 6 Abbreviations Found on Labels

Information	Recommended Abbreviation(s)
Donation Identification Number	DIN
Product Description Code	Prod Code or PC
Product Divisions Code	Pack, Serial Number, or SN
Expiration Date	Exp or Exp Date
Manufacturing or Production Date	Mnf Date or Prod Date
Lot Number	Lot No. or LN

Requirements for printing specific text:

Expiration Date: The expiration date, if applicable, must be printed in the format required by 21 CFR 801.18: YYYY-MM-DD (four-digit year, hyphen, two-digit month, hyphen, two-digit day).

DIN: When the DIN is printed within the ICCBBA-defined text, it should be printed in a standardized format and should include a check character (see Figure 9). In the US, the Facility Identification Number (FIN) is printed, followed by a space, the year code, a space, the sequence number, a space, the flag characters rotated 90 degrees clockwise, and the check character printed within a box. The first character of the data identifier is not printed; the second character of the data identifier is printed only because it is also the first character of the FIN. For calculating the check character, see *Use of the Donation Identification Number [Data Structure 001]* (IG-033).

Figure 9 Printing of DIN in ICCBBA-Specified Text

The ISBT 128 Class name and Attributes may be printed, but this is not required.

6.2.2 UDI Easily Readable Plain-Text

The format of easily readable plain-text shall follow the ISBT 128-specified format.

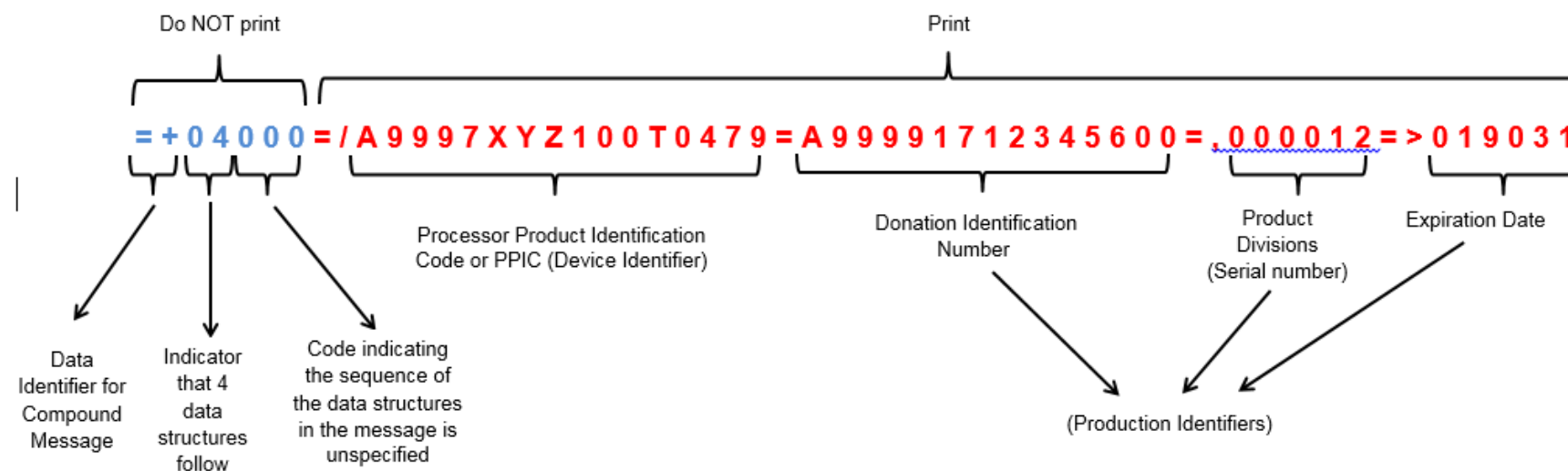
Data structures within the UDI easily readable plain-text shall be in the order they appear within the electronically-readable symbol. The easily readable plain-text UDI should be displayed below or near the corresponding electronically-readable symbol or the AIDC form.

Characters to print in eye-readable UDI text: Eye-readable text corresponding to UDI information (easily readable plain-text referred to in the UDI regulations) shall be printed on the product label. The UDI information includes the data content and data identifiers for data structures comprising the DI and PI. See Figure 10.

Characters NOT to print in eye-readable UDI text: The characters corresponding to the compound message data identifier and message code. See Figure 10.

Figure 10 Eye-Readable Text for UDI

Bar coded message:



Eye-readable text for the code above should be as shown below (and as shown in red above):

=/A9997XYZ100T0479=A99991712345600=,000012=>019031

It is acceptable to print the device identifier on a separate line from the production identifier (with ISBT 128 data identifiers):

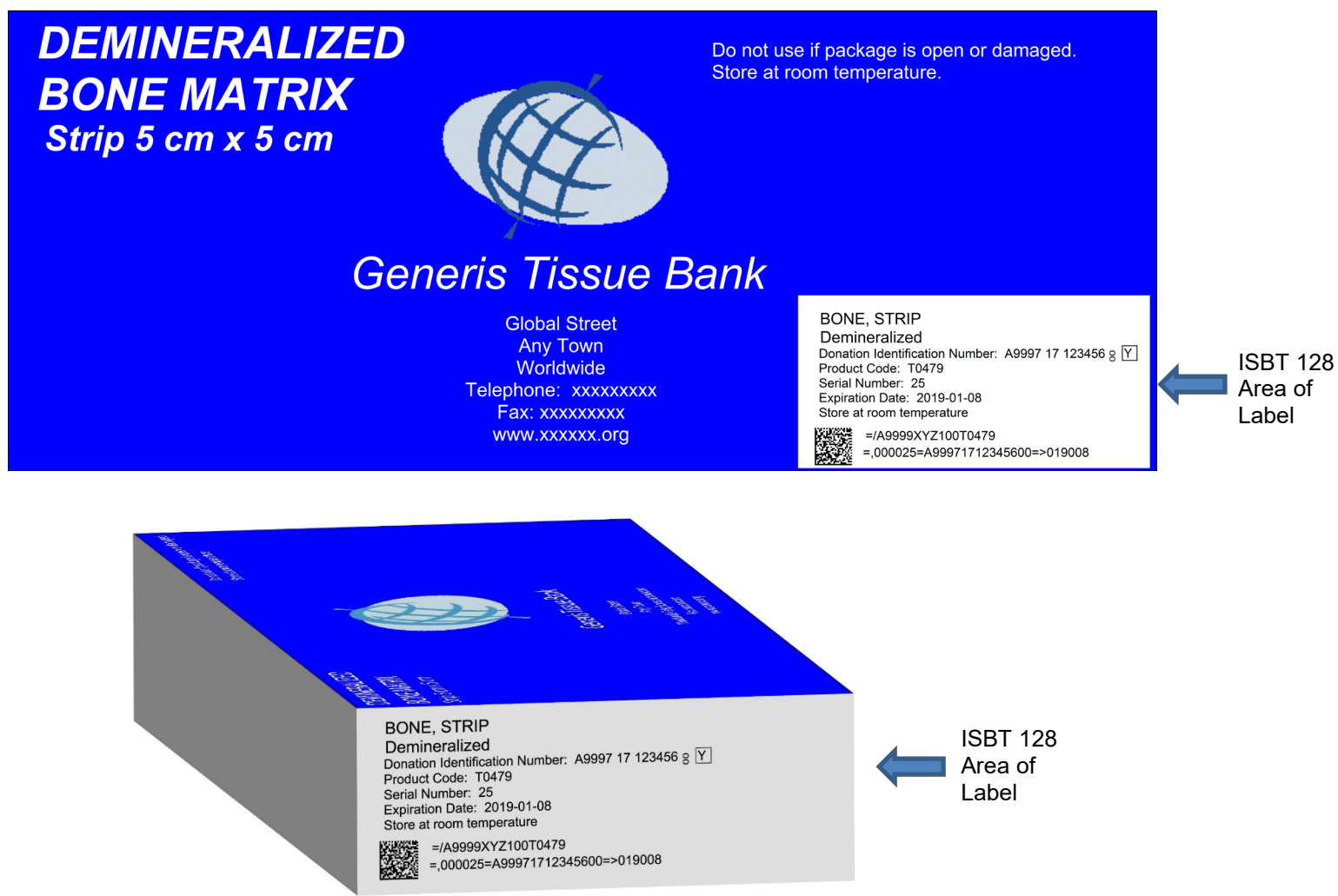
=/A9997XYZ100T0479

=A99991712345600=,000012=>019031

6.3 Position on Package

Positioning of the UDI on the label is not standardized at this time. Below are two options, but other placement is acceptable.

Figure 11 Example Labels – Device with HCT/P Component



ASTM guidance (see Section 1.5) exists for standardizing the presentation on the label of the information for orthopedic implants used in arthroplasty and includes the location the information should appear on the box. This scheme, shown in Figure 12, could be adapted for other implants. Facilities may want to take this information into consideration for label design.

Figure 12 ASTM Format for Orthopedic Implants Used in Arthroplasty

Zone A	Zone B	Zone C
1) Company name/logo 2) Material, including coatings 3) Implant schematic	1) Brand name 2) Implant description 3) Implant selection considerations	1) Primary size 2) Secondary size/features 3) Body side
Zone D 1) Expiration date 2) Part/reference number 3) Lot/Batch code 4) UDI/Bar code 5) Quantity 6) Sterilization method		

6.4 UDI on Higher Levels of Packaging

Most HCT/P are shipped as individual devices (packages of one device). Organizations that package multiple devices as a routine packaging configuration should consult ICCBBA (email: iccbba@iccbba.org) for guidance on assigning a UDI for both the individual devices and the multi-device package.

7 Internationally Standardized Product Description Codes (PDCs)

Standardized PDCs are the last 5 characters in the Processor Product Identification Code [Data Structure 034], which is the device identifier (DI), and correspond to a standardized description of the HCT/P product through a reference table. Products are described through the use of Class and Attributes. Each of the characteristics that make up the product description is defined in the document: *ISBT 128 Standard Terminology for Medical Products of Human Origin* (ST-002).

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

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

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

7.1 Terminology

PDCs uniquely define HCT/P in terms of their characteristics. All products have a Class and may have one or more Attributes.

7.1.1 Class

Class is a general description of products (such as Bone, Paste or Tendon, Achilles).

7.1.2 Attributes

Attributes provide additional information about HCT/P. HCT/P thus may be further described through the addition of one Attribute variable from one or more Attribute groups.

Attributes are organized into groups of mutually exclusive terms. Each group has a default value that applies if no Attribute variables are selected.

The document *ISBT 128 Standard Terminology for Medical Products of Human Origin* (ST-002) provides complete descriptions of currently defined Classes and Attributes.

7.2 Structure of Product Descriptions within the Database

Once defined, product descriptions are placed into a reference table database. Each description is assigned a unique five-character ISBT 128 Product Description Code (PDC) for electronic communication. Although there is no structure to the five-character PDC, the description of the product within the database is rigidly structured. Each product is defined in the ICCBBA database minimally in terms of its Class.

The Class and Attributes are separated in the product name by the “|” delimiter:
CLASS|Attribute

For example:

Product Description Code	Description
T0474	BONE, PUTTY Demineralized:Yes

Attributes may be used to further describe the product. Only one variable from each Attribute group may be used. Attributes are also separated by the “|” delimiter:
CLASS|Attribute|Attribute

For example:

Product Description Code	Description
T0475	BONE, PUTTY Radiation sterilization Demineralized:Yes Carrier and applicator
T0476	BONE, PASTE Demineralized:Yes Applicator

The order in which the Attributes appear in the description field of the database is the order in which they appear in the Attribute table of the database.

The order in which text appears in the description field of the database does not specify the order in which Attributes will appear as label text. Since this can be country-specific, national guidelines as to the placement of label text should be consulted.

7.3 PDC Database

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

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

ISBT 128 Product Description Code Database

7.4 Selecting PDCs

Tissue PDCs begin with the letter “T”. The codes are listed in alphabetical order in the full database so tissue codes are found near the end. To appropriately select product descriptions, it is important to understand the definitions of each term. These definitions are found in *ISBT 128 Standard Terminology for Medical Products of Human Origin* (ST-002).

7.4.1 “Retired” Codes

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

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

7.4.2 Level of Detail

Following national guidelines, facilities can determine the level of detail that must be encoded into an electronically-readable format according to the needs of its customers.

Note: For more detail about the dimensions of a product (volume, length, height, depth, etc.), another data structure, Dimensions [Data Structure 029] may be used. For more information on the use of this data structure, see the ISBT 128 Standard Technical Specification (ST-001) and Implementation Guide: Use of Dimensions [Data Structure 029] (IG-026). If dimension information is encoded, it should be entered into the Clinically Relevant Size field of the GUDID.

7.4.3 Using the Product Code Lookup Tool to Locate PDCs

Searching for the correct PDC can be simplified by the use of the ISBT 128 Product Lookup Program available on the ICCBBA Website. (From home page, select “Lookup Tools” from the menu at the top of the page. Then select “Find Product Information.”) This is a Microsoft Excel® Macro-Enabled Workbook file (XLSM) that can be downloaded onto your computer. It is compatible with Microsoft Excel 2007-2013. It has not been validated for, and cannot be used with, earlier versions of Microsoft Excel.

It is updated with each new version of the ISBT 128 Product Description Code Database (approximately once a month). Therefore, users must download this tool frequently to ensure the most recent PDCs are available.

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

When the program is opened, the ISBT 128 Product Description Code Lookup Utility screen will appear. See Figure 13.

Figure 13 Opening Screen on Lookup Tool

The screenshot shows the 'ISBT 128 Product Description Code Lookup Utility' window. It features the ISBT 128 logo with the tagline 'More than Identification'. The main heading is 'ISBT 128 Product Description Code Lookup Utility'. Below this, a text box instructs: 'If you have a five character product description code, enter it below and click the "ISBT 128 Code Lookup" button'. This section is annotated with 'Enter PDC to find description' pointing to a text input field and 'Look up description associated with a PDC' pointing to the 'ISBT 128 Code Lookup' button. Below the text box is a large empty field annotated with 'Field to return description corresponding to PDC entered'. The lower section is titled 'To search the database for products meeting selected criteria choose a category and subcategory and then click "Lookup"'. It contains a 'Category' dropdown menu with options: Blood Components, Cellular Therapy, Tissues, Other Blood products, Ocular, Other Therapies, Organs, and Reproductive. This is annotated with 'Select category of product'. Next to it is a 'Subcategory' text box, annotated with 'Select subcategory of product (options become visible after category selected)'. To the right of these are three buttons: 'Lookup', 'Reset', and 'Close'. This entire lower section is annotated with 'Look up PDC based on a full or partial description'. The ICCBBA logo is visible in the bottom right corner of the window.

To find the description when you know the PDC (see Figure 14):

- Enter the PDC in the first field.
- Click on the ISBT 128 Code Lookup button.
- The description will appear in the field below the ISBT 128 Code Lookup button.
- To lookup another description, click the Reset button and repeat the first 2 steps.
- To close the tool, click the Close button.

To find a PDC for a given product description:

- Click on Tissues in the Category field and Tissues in the Subcategory field. See Figure 16. (Currently, category and subcategory are the same, but this will not always be the case.)
- Click the Lookup button to the right of the Subcategory field.
- The ISBT 128 Product Lookup by Description screen will appear. See Figure 16.
- Click on the Class desired. See Figure 16.
- Select Attributes, if desired. See Figure 17.
 - Click on the Attribute group desired. Attribute values corresponding to the Attribute group selected will appear in the Attribute Value field.
 - Click on the Attribute desired. This value will appear in the Selected Attributes field.
- Select additional Attributes following these same steps.
- At this point, there are two options, “Exact Match” and “Find.”
 - Clicking “Exact Match” will bring up the PDC that exactly meets the selection criteria. See Figure 18.
 - Clicking “Find” will result in a list of products that include these criteria. See Figure 19.
- If desired, click the Export List button to export the list of products in a text file to a selected location. See Figure 20 and Figure 21. The text file will be named Product Description Codes. (Note: If you export a second list to the same location, it will overwrite the first list unless you change the name of the file.)
- Use the Reset button to clear the screen and allow a new query to be performed.
- Use the Close button to close the ISBT 128 Product Lookup by Description screen.

Figure 14 Lookup a Description from a PDC

ISBT 128 Product Lookup Program

ISBT 128
More than Identification

ISBT 128 Product Description Code Lookup Utility

If you have a five character product description code, enter it below and click the "ISBT 128 Code Lookup" button

Enter PDC → T0479
Click button → ISBT 128 Code Lookup
Description returned → T0479 = BONE, STRIP|Deminerlized:Yes

To search the database for products meeting selected criteria choose a category and subcategory and then click "Lookup"

Category	Subcategory	
Blood Components		Lookup Reset Close
Cellular Therapy		
Tissues		
Other Blood products		
Ocular		
Other Therapies		
Organs		
Reproductive		

Figure 15 Lookup a PDC for a given Product Description (Opening Screen)

ISBT 128 Product Lookup Program

ISBT 128
More than Identification

ISBT 128 Product Description Code Lookup Utility

If you have a five character product description code, enter it below and click the "ISBT 128 Code Lookup" button

Click on Category → Tissues
Click on Subcategory → Tissues

Lookup button → Lookup

To search the database for products meeting selected criteria choose a category and subcategory and then click "Lookup"

Category	Subcategory	
Blood Components		Lookup Reset Close
Cellular Therapy		
Tissues	Tissues	
Other Blood products		
Ocular		
Other Therapies		
Organs		
Reproductive		

Figure 16 Looking up a PDC from a Description Screen

ISBT 128 Product Lookup by Description

Select the product characteristics from the list below and click the "Find" or "Exact Match" button

Class

ISBT 128
More than Identification

ICCBBBA

Class

BOLE, POWDER
BOLE, RADIUS
BOLE, RIB
BOLE, RING
BOLE, SCAPULA

Attribute Group

Nominal Granule Size
Demineralization
Associated Structures
Bone Type
Bone Source
Bone Part
Bone Portion

Attribute Value

Selected Attributes

Remove

Exact Match

Find

Reset

Close

Export list

Select Class
(scroll down
for additional
classes)

Select Attribute
Group (scroll
down for
additional
groups)

Figure 17 Describing a Product

Select Attribute Group in this field

When Attribute Group is selected, Attribute Value options appear in this field

When Attribute Values are selected, Attributes appear in this field

ISBT 128 Product Lookup by Description

Select the product characteristics from the list below and click the "Find" or "Exact Match" button

Class

BONE, SHEET
BONE, SKULL
BONE, SLICE
BONE, STEINUM
BONE, STRIP
BONE, STRUT

Attribute Group

Processing Status
Unit of Issue
Pathogen Reduction
Nominal Granule Size
Deminerlization
Associated Structures
Bone Type

Attribute Value

Deminerlized:Yes

Selected Attributes

Deminerlized:Yes V0081002

Remove

Exact Match

Find

Reset

Close

Export list

Figure 18 Lookup PDC that Exactly Matches Criteria

ISBT 128 Product Lookup by Description

Select the product characteristics from the list below and click the "Find" or "Exact Match" button

Class

BONE, SHAPED, OTHER
BONE, SHEET
BONE, SKULL
BONE, SLICE
BONE, STERNUM
BONE, STRIP

Attribute Group

Processed to Reduce Cellular Components
Anatomical Position
Processing Status
Unit of Issue
Pathogen Reduction
Nominal Granule Size
Demerization

Attribute Value

Demerized:Yes

Selected Attributes

Demerized:Yes V0081002

Remove

Exact Match Find Reset Close

T0479 BONE, STRIP(Demerized:Yes)

Export list

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

PDC will appear in this field

Figure 19 Lookup All PDCs that Match Criteria

ISBT 128 Product Lookup by Description

Select the product characteristics from the list below and click the "Find" or "Exact Match" button

Class

BONE, PELVIS
BONE, PHALANX
BONE, POWDER
BONE, PUTTY
BONE, RADIUS
BONE, RIB

Attribute Group

Processed to Reduce Cellular Components
Anatomical Position
Processing Status
Unit of Issue
Pathogen Reduction
Nominal Granule Size
Demerization

Attribute Value

Demerized:Yes

Selected Attributes

Demerized:Yes V0081002

Remove

Exact Match Find Reset Close

T0128 BONE, PUTTY(Freeze dried/Radiation sterilization/Demerized:Yes/Cortical)
T0473 BONE, PUTTY(Demerized:Yes/Applicator)
T0474 BONE, PUTTY(Demerized:Yes)
T0475 BONE, PUTTY(Radiation sterilization/Demerized:Yes/Carrier and applicator)

Export list

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

All PDCs that match criteria appear in this screen.

Figure 20 Use of Export List Function

ISBT 128 Product Lookup by Description

Select the product characteristics from the list below and click the "Find" or "Exact Match" button

Class

BONE, PELVIS
BONE, PHALANX
BONE, POWDER
BONE, PUTTY
BONE, RADIUS
BONE, RIB

Attribute Group

Processed to Reduce Cellular Components
Anatomical Position
Processing Status
Unit of Issue
Pathogen Reduction
Nominal Granule Size
Demineralization

Attribute Value

Demineralized:Yes

Selected Attributes

Demineralized:Yes V0081002

Remove

Exact Match

Find
Reset
Close

T0328 BONE, PUTTY Freeze dried|Radiation sterilization|Demineralized:Yes|Cortical
T0473 BONE, PUTTY Demineralized:Yes|Applicator
T0474 BONE, PUTTY Demineralized:Yes
T0475 BONE, PUTTY Radiation sterilization|Demineralized:Yes|Carrier and applicator

Export list

To export list to a text file, click "Export list" button.

Figure 21 Text File Created

Product Description Codes.txt - Notepad

File Edit Format View Help

T0328 BONE, PUTTY|Freeze dried|Radiation sterilization|Demineralized:Yes|Cortical
T0473 BONE, PUTTY|Demineralized:Yes|Applicator
T0474 BONE, PUTTY|Demineralized:Yes
T0475 BONE, PUTTY|Radiation sterilization|Demineralized:Yes|Carrier and applicator

7.5 Requesting New PDCs

An online form for requesting new PDCs is available on the ICCBBA Website. See Figure 22.

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

If a new Class, a new Attribute group, or a new variable within an existing Attribute group is included in the requested Product Description Code, the request must be accompanied by appropriate definitions of the new characteristic. Requests for new characteristics will be reviewed by appropriate technical advisory groups to ensure international consensus with the terminology chosen.

New PDCs must be compatible with the existing system. If there is a question of compatibility, the request may be referred to the Standards Committee of ICCBBA.

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

7.5.1 Completing the Request Form

The form for requesting new codes is found on the ICCBBA Website. It is found in the Subject Area tab, under Tissues or Cellular Therapy (as appropriate for the product being requested) and is called Request a Code. One completed form is required for each new PDC requested. See Figure 22.

Minimally, the request must include a Class.

Select one Class from the dropdown list.

Select an Attribute from each Attribute group where a non-default value is required (only one per Attribute group) from the dropdown lists.

Click on “Submit to ICCBBA.”

If a new Class, Attribute group, or variable within an Attribute group is needed, please contact the ICCBBA Technical Manager (tech.manager@iccbba.org). A definition compatible with the format of those in the *ISBT 128 Standard Terminology for Medical Products of Human Origin* (ST-002) must accompany such a request.

7.5.2 Submitting the Request

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

Figure 22 Online Request Form

Home > Subject Area > Tissues > Request a Code

CONTACT US

in Follow 163

Inside this section:

Tissues

Technical Specification

Standard Terminology

Tissues - Documents

Request a Code

Presentations

Discussion Forum

Tissues Vendor Information

Published Papers

Tissues Endorsements


ISBT 128 Supported Logo

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ICCBBA enhances safety for patients by managing and promoting the ISBT 128 international information standard for use in transfusion and transplantation.

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Product Description Code Request Form - Tissues

You must be logged in to view the form.

- If your facility's licensing fees are up to date, and you wish to request a password, please complete the [Password Request Form](#).

Requestors can expect a turnaround time of 4-7 weeks for routine requests. Requests that require new terminology or in-depth review, may take longer to process.

Form for use by facilities making requests for "Tissue" Product Description Codes. For further instructions on how to fill out this form, click [here](#).

Facility Identification Number

Contact Name

Contact Email

Address

---SELECT ONE CLASS ONLY---

Class (Cardio/Vascular)

Class (Soft Tissue)

Class (Bone)

Class (Skin)

Class (Other)

Additive

Additional Processing

Donor-Intended Recipient Relationship

Meshed

Storage Solution

Type of Preservation

Processed to Reduce Cellular Components

Anatomical Position

Processing Status

Unit of Issue

Pathogen Reduction

Nominal Granule Size

Demineralization

Associated Structures

Bone Type

Bone Source

Bone Part

Bone Portion

Cartilage Presence

Veterbral Type

8 Administrative Processes

8.1 Registration and Licensing

With the exception of empty blood containers, the scope of ICCBBA is limited to coding MPHO. In the United States, this means that only those medical devices with an HCT/P component will be addressed in ISBT 128 coding. Labelers that distribute devices without an HCT/P component should contact one of the other issuing agencies.

Each facility that implements ISBT 128, or plans to implement ISBT 128 and needs access to password-protected information from the ICCBBA Website, must register with ICCBBA. Specific requirements for registration and a form for this purpose may be found on the ICCBBA Website.

Before implementing ISBT 128, each registered facility shall pay the annual license fee. The annual license fee is set by the ICCBBA Board of Directors to cover the anticipated expenses for the fiscal year for which the fee is assessed. It is invoiced to every registered facility at its last known address early in each calendar year. The terms under which ISBT 128 is licensed for use are provided in the ICCBBA License Agreement, a copy of which can be found on the ICCBBA Website.

ICCBBA assigns Facility Identification Numbers (FINs) that are used in a number of data structures, including the one used for the DI (Data Structure 34), to identify the assigning organization. FINs are published in the password-protected area of the ICCBBA Website. An organization may have more than one FIN if it is useful for its operational needs. See Implementation Guide: ISBT 128 Facility Identification Number (IG-034) for further information about assignment of FINs, inactivation of FINs, the process to follow when an organization changes its name, etc.

8.2 Nonconformities with the ISBT 128 Standard

The use of an approved coding and labeling system is required for medical devices in the US by federal regulation. It is essential that facilities using ISBT 128 comply with the standard to meet these requirements and to ensure traceability. When requested, ICCBBA technical staff will provide technical support, including label review, through its help desk (iccbba@iccbba.org) to facilities implementing ISBT 128.

Should ICCBBA become aware of a facility utilizing ISBT 128 for UDI that is not in compliance with the Standard, it will work with the facilities to bring it into compliance. It will follow-up with the facility by discussing the deficiency(ies) in their use of the standard and provide educational materials as needed. If appropriate, an agreed Corrective Action Plan will be developed.

8.3 Suspension and Revocation of License

A facility's license to use ISBT 128 will be suspended if it is unable to substantially comply with the standard in a reasonable period of time following notification of a problem. ICCBBA staff will work with facilities to resolve issues prior to suspending a license. If a facility has a suspended license for more than 12 months and no attempt is

made to come into compliance, the license to use ISBT 128 will be revoked. ICCBBA will notify a facility in writing via email or standard mail if its license to use ISBT 128 will be, or has been, suspended or revoked.

ICCBBA will notify appropriate regulatory authorities that a facility's license to use ISBT 128 will be, or has been, suspended or revoked.

9 Abbreviations

AIDC	Automatic Identification and Data Capture
ASTM	Formerly known as American Society for Testing and Materials. Now is called ASTM International.
CFR	Code of Federal Regulations
DI	Device Identifier
DIN	Donation Identification Number
FDA	US Food and Drug Administration
FIN	Facility Identification Number
FIN(P)	Facility Identification Number of the Processing Facility
FPC	Facility-Defined Product Code
GUDID	Global Unique Device Identification Database
HCT/P	Human Cells, Tissues, and Cellular and Tissue-Based Products
IEC	International Electrotechnical Commission
ISO	International Standards Organization
MPHO	Medical Products of Human Origin
PDC	Product Description Code
PI	Production Identifier(s)
PPIC	Processor Product Identification Code
UDI	Unique Device Identifier

10 Glossary

Term	Definition
Data Content	The characters in a data structure that encode the information for which the data structure is named. The data content does not include the data identifier. (The Donation Identification Number is an exception to this rule. See Section 3.1, page 13.)
Data Delimiter	Term used by the FDA which corresponds to ISBT 128 data identifier.
Data Identifier	<p>The first two or three characters in a data structure that identify the data structure. These will always be present when the data structure is used as a bar code, but may be omitted when the data structure is used in situations in which the data structure identity is unambiguously and explicitly defined (e.g., electronic messaging). The Donation Identification Number is an exception to this rule. The second character of the data identifier can never be dropped because it is also part of the data content.)</p> <p>ISBT 128 data identifiers correspond to the FDA UDI data delimiters.</p>
Data Structure	Information content comprising the data identifier and data content. When a data structure is represented as a bar code, the term data structure does not include the symbology-specific start and stop codes that are always present, the symbology-specific check characters, or any specified control characters.
Device Identifier (DI)	A mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device (21 CFR 801. 3).
Medical Device	<p>An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:</p> <ul style="list-style-type: none"> • recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, • intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or • intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other

Term		Definition
		<p>animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.</p> <p>(Section 201(h) of the Federal Food Drug & Cosmetic Act)</p>
Ordinal Date		A system for maintaining dates that numbers the first day of the year (January 1) as 1 and the last (December 31) as 365 or 366 (in a leap year). Also known as Julian Date.
Production Identifier (PI)		<p>A conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:</p> <ul style="list-style-type: none"> (i) The lot or batch within which a device was manufactured; (ii) The serial number of a specific device; (iii) The expiration date of a specific device; (iv) The date a specific device was manufactured; (v) For HCT/P regulated as a device, the distinct identification code required by § 1271. 290(c) (CFR 801. 3).
Text		The human-readable representation of information.
	Easily readable plain-text	The legible interpretation of the data characters encoded in the UDI as presented in AIDC form. The easily readable plain-text UDI must include the device identifier (DI), production identifiers (PIs), and data delimiters contained in the UDI.
	ICCBBA-specified text	Text corresponding to information required for traceability along with a label indicating the type of information (e. g., "Donation Identification Number"). Information required for traceability includes the FIN(P), the DIN, the Product Code, and the Product Divisions Code.
Unique Device Identifier (UDI)		An identifier that adequately identifies a device through its distribution and use by meeting the requirements of 21 CFR 830. 20. A unique device identifier is composed of a device identifier and a production identifier (21 CFR 801. 3).

Appendix 1: 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.

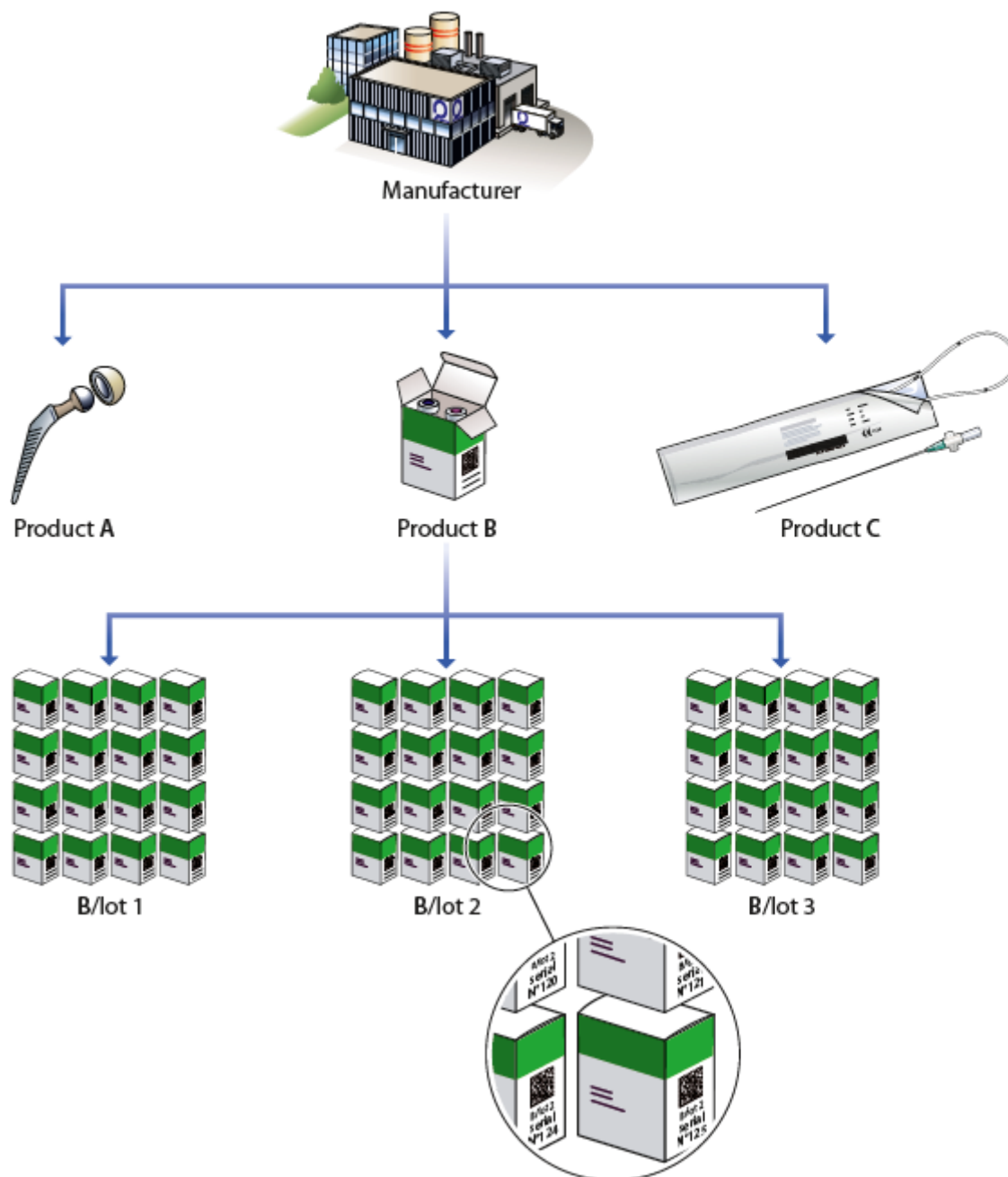
Understanding traceability Traceability by unit / by lot (batch)

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.

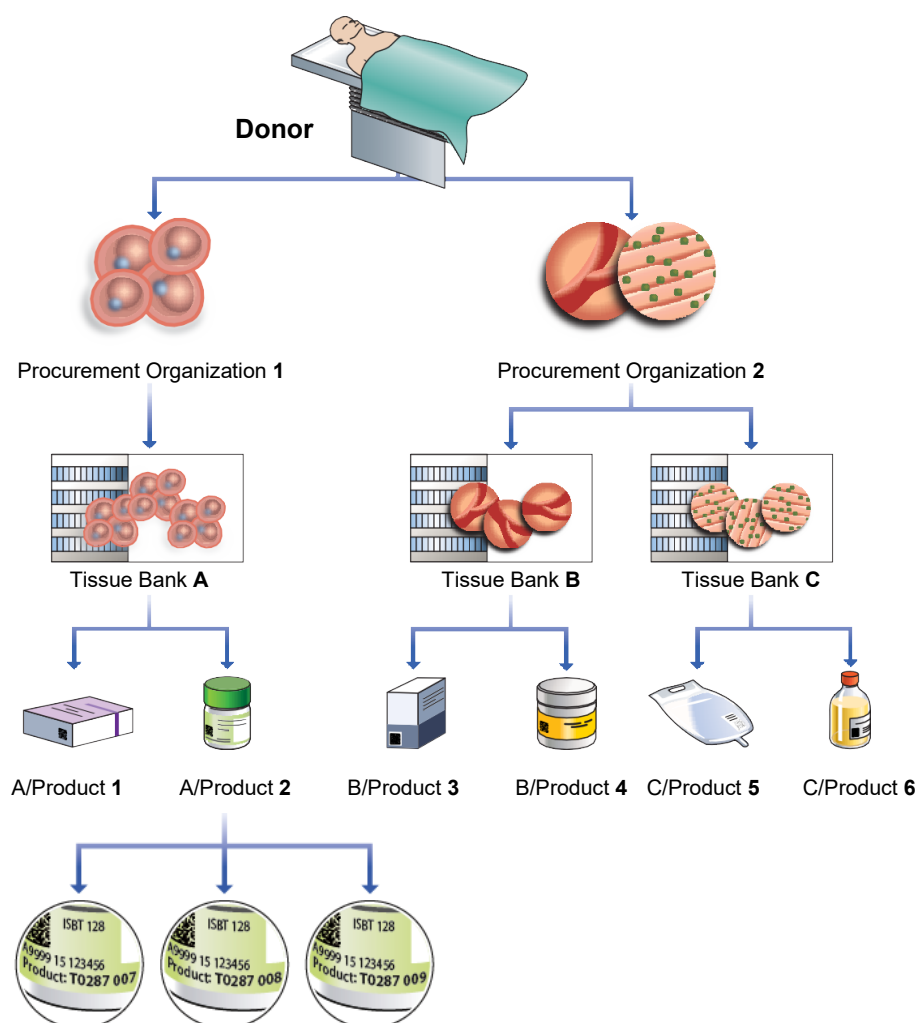
Recommendation for labelling Issued by ICCBBA and GS1 on 17 November 2014

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.

Recommendation for labelling Issued by ICCBBA and GS1 on 17 November 2014

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.

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 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.

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.

Note: See Section 6.4 for the use of GS1 and ISBT 128 together for different levels of packaging.

Appendix 2: Use Case for Medical Device Containing HCT/P

Background

HCT/P products are derived from human donors. As such, they have unique characteristics that have implications throughout the supply chain. In particular, it is important to recognize that:

- A single donor can be the source of many different products. For example, one donor may donate skin, tendons, heart valves, and a wide range of bone products. All of these different products share a common history.
- HCT/P carry a risk of disease transmission. While this risk is minimized by testing and processing, it can never be entirely eliminated.
- It is therefore imperative that following detection of disease transmission by an HCT/P, all other products derived from the same donor can be rapidly removed from the supply chain and all patients who have received products from the donor can be followed up.
- Therefore, the traceability model for HCT/P has unique characteristics that are not present for other healthcare products. In particular, an identifier is required to allow tracking from recipient to donor and from donor to recipient. (FDA regulation uses the term “distinct identification code” – see 21CFR 1271.290(c)).
- This identifier needs to be captured at all point in the supply chain in order to allow rapid tracking and recall of products.

Effective traceability of HCT/P requires that the distinct identification code for the donor can be tracked throughout the supply chain from donor to recipient, and that other products from that donor, whether regulated as devices or biologics, can be identified and recalled.

Past experience has demonstrated that current traceability is sub-optimal with tracing being slow and sometimes incomplete. Reasons include a lack of standardization in the structure and presentation of the distinct identification code; lack of uniqueness of the distinct identification code throughout the supply chain; and lack of a standardized electronic format for the distinct identification code.

Within the ISBT 128 system the Donation Identification Number (DIN) fulfils the role of the distinct identification code. This identifier is standardized, globally unique, and identified in coding with its own PI to facilitate parsing from the UDI.

This use case identifies how traceability can be significantly improved using the distinct identification code PI.

Use Case

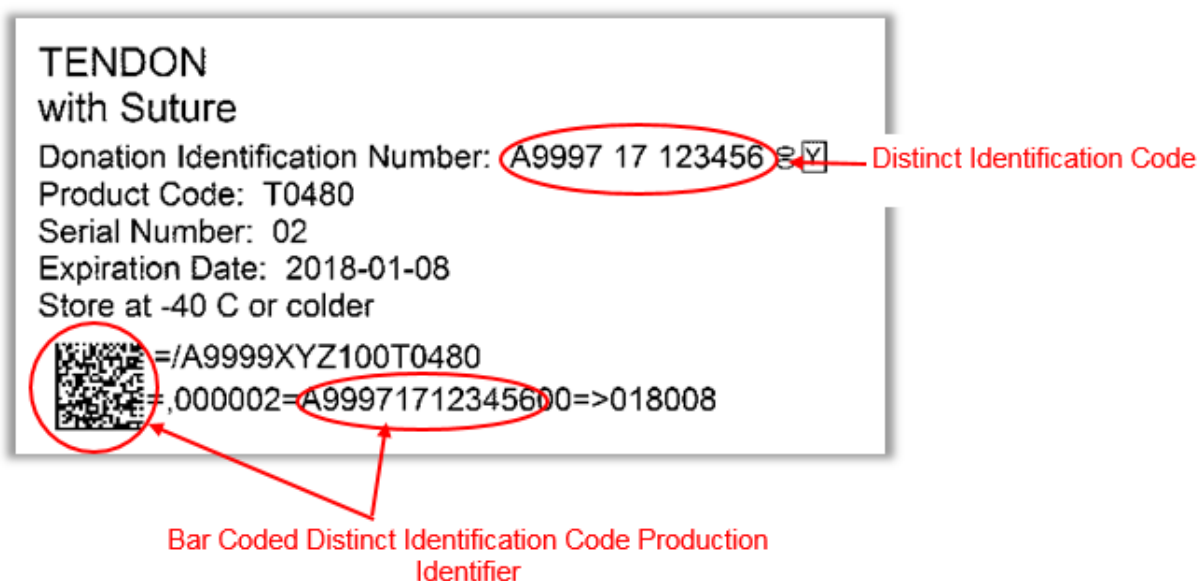
The use case illustrates what would happen when a medical device containing an HCT/P labeled with an ISBT 128 UDI is implicated in potential disease transmission.

Note: The ISBT 128 Standard requires that the same distinct identification code (ISBT 128 Donation Identification Number) is used on all tissue products prepared from a particular donor by a specified tissue processor.

Mr. Smith requires transplantation of a tendon with suture (a medical device containing an HCT/P) during an anterior cruciate ligament repair.

The product is received from a tissue bank, via a distributor and is entered into hospital materials management system by scanning of the ISBT 128 UDI barcodes [DI and PIs for distinct identification code (ISBT 128 Donation Identification Number), serial number, and expiration date]. See Figure 23.

Figure 23 Example HCT/P Label



When the product is to be transplanted, the UDI label is scanned and the product is removed from materials inventory. The record of the implant is recorded in Mr. Smith's electronic medical record using the UDI DI and PIs.

Some months following surgery Mr. Smith is found to be positive for Hepatitis C virus (HCV). The hospital informs the tissue processor and CDRH. CDRH, recognizing the infectious disease implications, pass the information on to CDC. The tissue processor performs additional testing on stored samples from the donor and detects very low levels of HCV. CDC conducts an epidemiologic and laboratory investigation and determines that there is a significant probability that the disease was transmitted by the implant. It alerts the public health and clinical and laboratory communities by issuing a Health Alert Network advisory for healthcare facilities to withdraw all HCT/P that carry the implicated distinct identification code. The manufacturer issues a voluntary recall. CDC works with the manufacturer to identify other hospitals which may

have received product from the same donor. Once these hospitals have been identified, CDC works with the state/local health departments who contact healthcare facilities to determine if the products have been used or are still in inventory.

Healthcare facilities enter the distinct identification code into their tissue/materials management systems and these systems search inventory and identify products to be withdrawn pending return to the supplier. The systems also add the distinct identification code onto a reference list which is checked each time new inventory is added, thus allowing the system to alert the user if an attempt is made to receive products that have been recalled.

Healthcare facilities also enter the distinct identification code into their electronic patient record systems. These systems search for patient records containing a UDI with this distinct identification code PI. Patients who have received these products are identified for follow up.