# ISBT 128 STANDARD

# Coding and Labeling of Medical Devices Using ISBT 128

Version 1.9.0

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

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

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

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

*Implementation Guide: 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 within a joint publication entitled *GS1 and ICCBBA Guidance: Identification of medical devices containing an HCT/P in the United States* (JP-002)

## 1.7 Changes in this Version

The following table summarizes the major changes between Version 1.8.0 and Version 1.9.0 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 1.8.0 vs. Version 1.9.0

| | Version 1.8.0<br>Chapter, Section, Table, or Figure | Version 1.9.0<br>Chapter, Section, Table, or Figure | Change | Rationale |
|---|---|---|---|---|
| 1. | 3.2 | 3.2 | Adjusted the definition provided for Data Structure 029 to match the definition provided within the ST-001 document. | For completeness and consistency with ST-001 ISBT 128 Standard Technical Specification. |
| 2. | 7.4.3 | 7.4.3 | Updated section to include the online version of the Product Lookup Program. | For completeness and consistency with the tools available to registered ISBT 128 users. |
| 3. | 7.5 | 7.5 | Updated to reflect submissions of PDC requests can be done using the Online Product Lookup Program on the isbt128.org site. | For completeness and consistency with the tools available to registered ISBT 128 users. |
| 4. | | Figure 22 | Added new figure to provide illustration of how the Online Lookup Program is used to submit new Product Description Code Requests | For completeness and consistency with the tools available to registered ISBT 128 users. |
| 5. | Appendix 1 | | Removed Appendix 1 and provided link to JP-002 in section 1.6. | To be consistent with the presentation of referenced documents throughout ISBT 128 publications. |

# 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:** =/nnnnnpppppppqqqqq

| 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, **nnnnnpppppppqqqqq**, 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

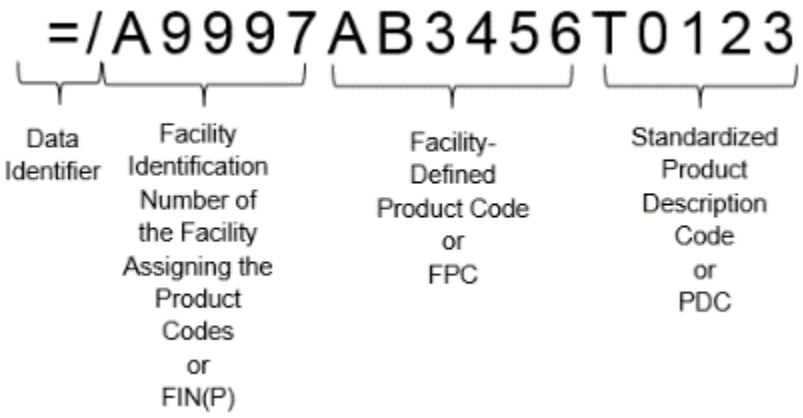
different DIs. This may be because two product lines are slightly different or because a product changes in a way that requires a new DI but not a new Product Description Code.

**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}<br><br>Current usage is numeric for all 4 characters. Alpha characters may be introduced into positions 1 and 2 in the future<br>(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).

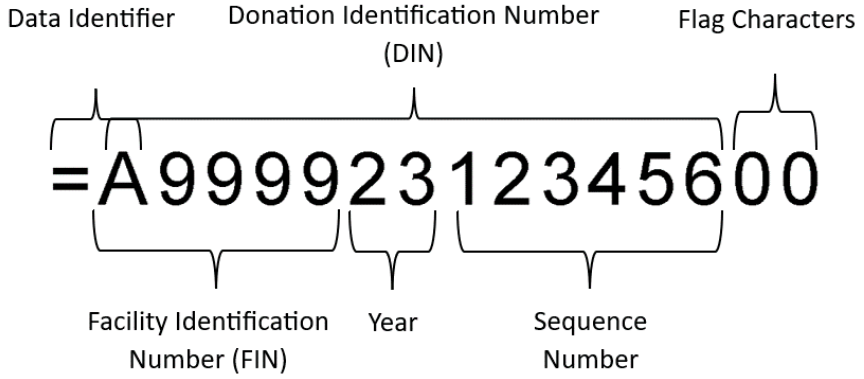
*Note: In practice, this is the "nominal" year. To cut down on wastage, DIN labels may be used for up to one month in the year before, and one month in the year after, the year shown on the label.*
*In the case of a tissue processing facility assigning a DIN, the DIN year code may be the year of the 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:

- aliquots, or
- one or more individual collections from the donor within the same donation event.

The Product Divisions Code may represent:

- one of the subunits from a single container that has been divided. This can also be referred to as an aliquot or a split.
- one of the containers from a collection, where the volume of product collected required the use of more than one container.
- a single collection into one container.

**Date of implementation depends on the data structure with which it will be used. That is:**

**When used in conjunction with Data Structure 003:** Because this data structure becomes part of the unique identification of a product, implementation of the data structure must be coordinated so that computer systems of facilities receiving the product are able to scan and interpret the codes.

This data structure may be used for Cellular Therapy or Regenerated Tissue products if:

- a product will remain within the facility that labeled it with this data structure,
  OR
- there is an agreement between the supplier and the receiver of a product to utilize this data structure sooner.

*Note: At the present time, use of the Product Divisions data structure with Data Structure 003 is restricted to Cellular Therapy and Regenerated Tissue Product Codes (where α is S and P, respectively) and for products identified using Data Structure 034. However, in the future the use of the Product Divisions Data Structure may be extended to blood products (where α is E or F).*

**When used in conjunction with Data Structure 034:** This data structure may be used at any time.

Structure: =,dddddd

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

*dddddd shall not be 000000 (all zeroes)

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

**dddddd** shall specify the Product Divisions Code.

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

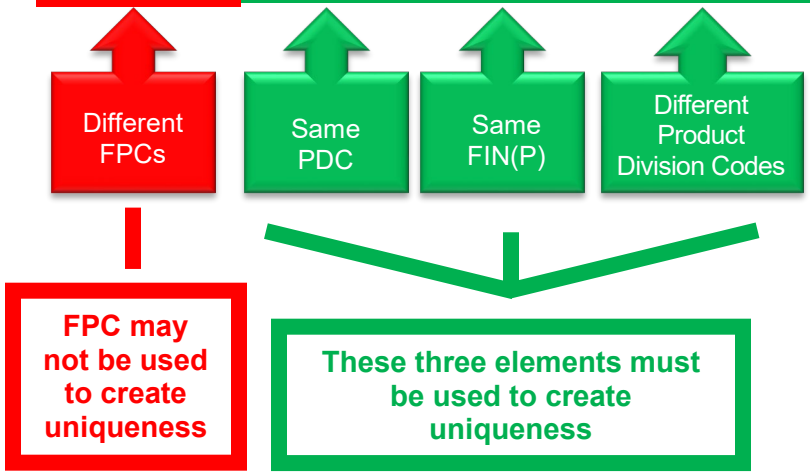
While ISBT 128 is used for all medical products of human origin (MPHO), not all MPHO use the same set of data structures as medical devices. Certain ISBT 128 identifiers, regardless of the data structure in which they are encoded, become essential for traceability across MPHO. Within medical devices, 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 17) 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 23 132343), FIN(P) (A9999), and PDC (T0475).

**Table 2 Use of Product Division Codes to Create Uniqueness**

| All Products Have the DIN A9998 23 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: =>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**, 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: &,1xxxxxxxxxxxxxxxxx

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

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

**xxxxxxxxxxxxxxxxx** 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<br>Facility-defined Product Code: XYZ100<br>Standardized Product Code: T0479 | =/A9997XYZ100T0479 |
| Donation Identification Number | Donation Identification Number: A999923123456 | =A99992312345600 |
| Product Divisions | 12 | =,000012 |
| Expiration Date | 31 JAN 2025 | =>025031 |

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 |
| =A99992312345600 | Donation Identification Number for the HCT/P is A999923123456. Flag characters are set to 00. |
| =,000012 | Product division is 12 |
| =>025031 | Expiration date is 31 JAN 2025 |

The data string would therefore be:

=+04000=/A9997XYZ100T0479=A99992312345600=,000012=>025031

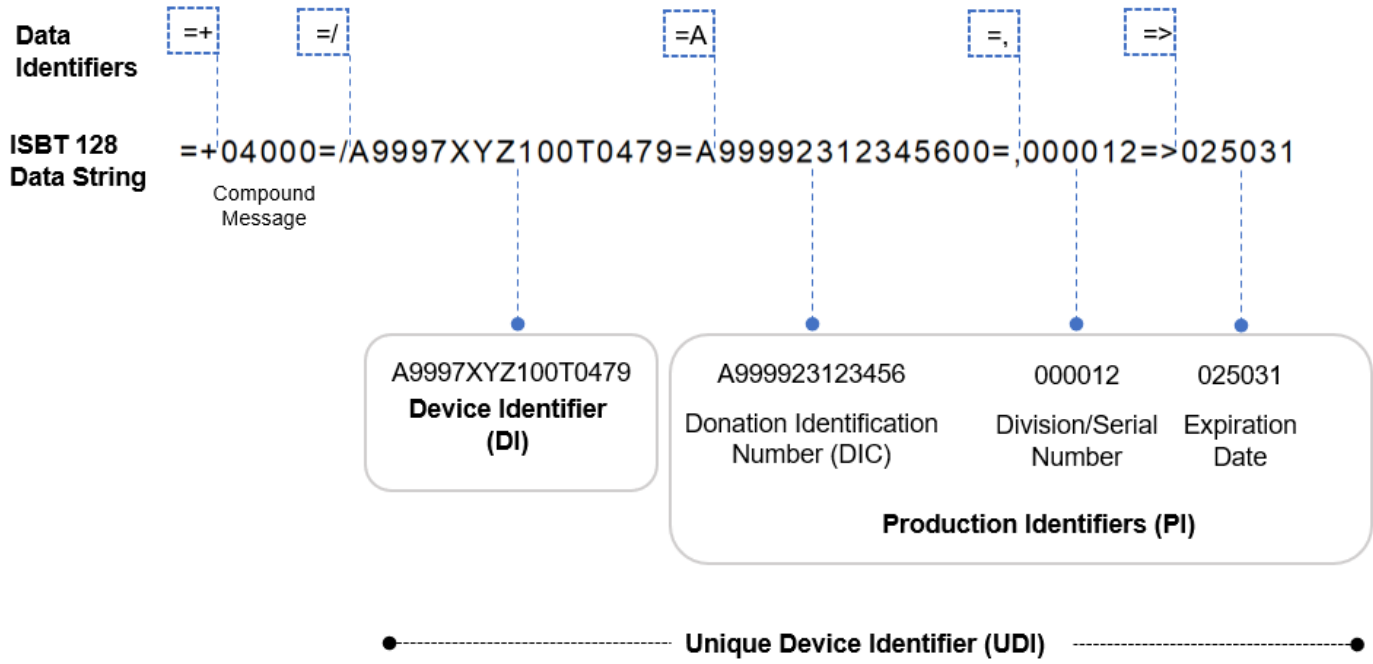
The Data Matrix symbol would be: 

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<br>Facility-defined Product Code: XYZ100<br>Standardized Product Code: T0479 | =/A9997XYZ100T0479 |
| Product Divisions | 12 | =,000012 |
| Donation Identification Number | Donation Identification Number: A999923123456 | =A99992312345600 |
| Expiration Date | 31 JAN 2025 | =>025031 |

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 |
| =A99992312345600 | Donation Identification Number for the HCT/P is A999923123456. Flag characters are set to 00. |
| =>025031 | Expiration date is 31 JAN 2025 |

The data string would therefore be:

=+04035=/A9997XYZ100T0479=,000012=A99992312345600=>025031

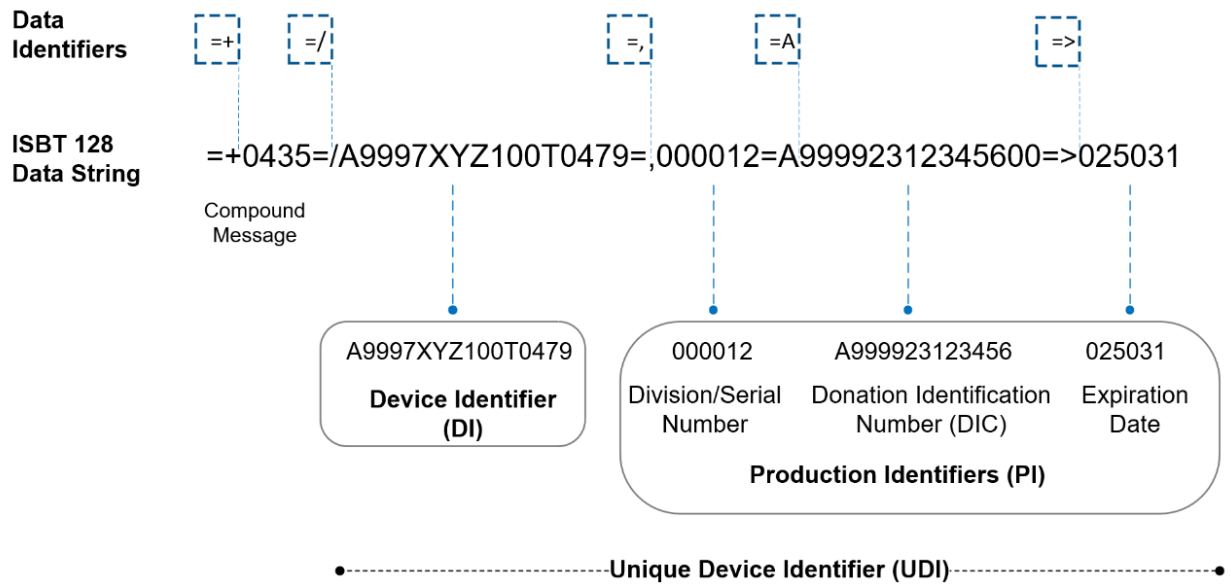
The Data Matrix symbol would be:

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.)*

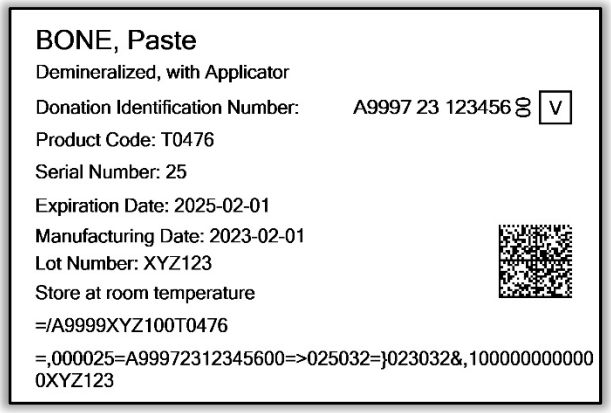
**Table 5 ISBT 128 UDI for Medical Devices Containing HCT/P**

| 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 [YYYJJJ] | 8 | 6 |
| ICCBBA | =} | Manufacturing Date | numeric [YYYJJJ] | 8 | 6 |
| ICCBBA | &,1 | MPHO Lot Number | Alphanumeric | 21 | 18 |
| ICCBBA | | *Maximum Base UDI for HCT/Ps* | *Alphanumeric* | 79 | 67 |

Example of Human Readable Bar Coded Information:

=/A9999XYZ100T0476=,000025=A99972312345600=>025032=}023032&,1000000000000XYZ123

**Figure 5 Example Label with 2-D Symbol**



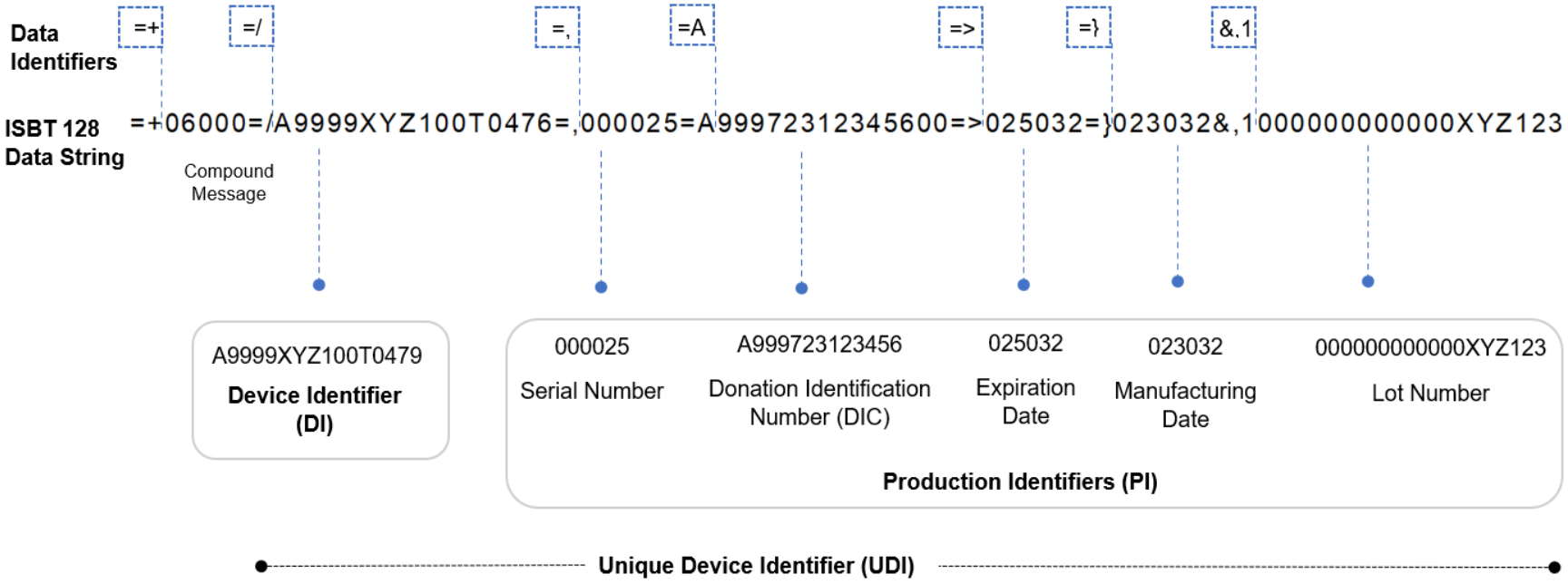

 

It is recommended that the ISBT 128 UDI be encoded within an ISBT 128 Compound Message in a 2-D Data Matrix code. However, the Standard does permit the use of Code 128 linear bar codes for compound messages.

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=A99972312345600=>025032=}023032&,1000000000000XYZ123

**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 A999723123456 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 YYYJJJ 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, 025032 refers to 1 Feb 2025.

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 YYYJJJ 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, 023032 refers to 1 Feb 2023. This is the date of manufacture as specified in 45 CFR Part 170.

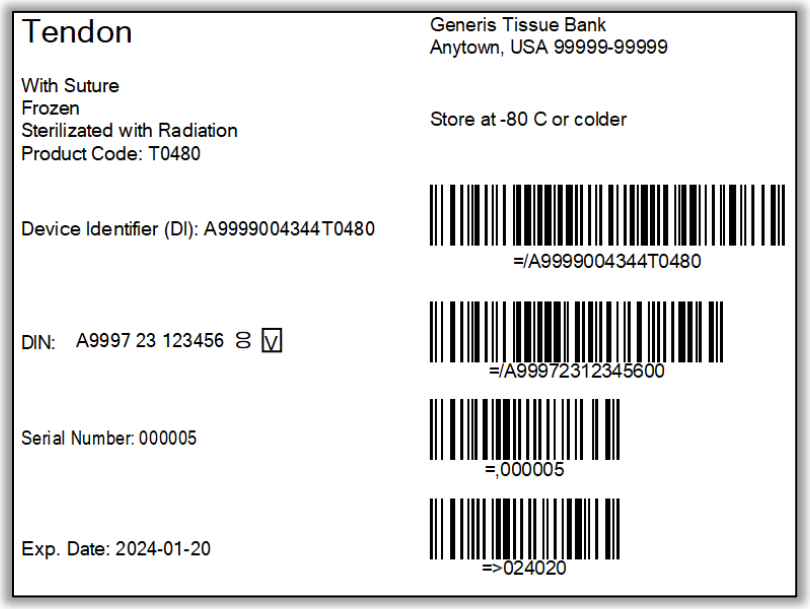
The seventh element is the Lot Number PI. This is identified by the data identifier “&,1” and the 18 data characters following this data identifier (000000000000XYZ123) are the lot or batch number as specified in 45 CFR Part 170.

*(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**



# 6 Labeling

## 6.1 Bar Code

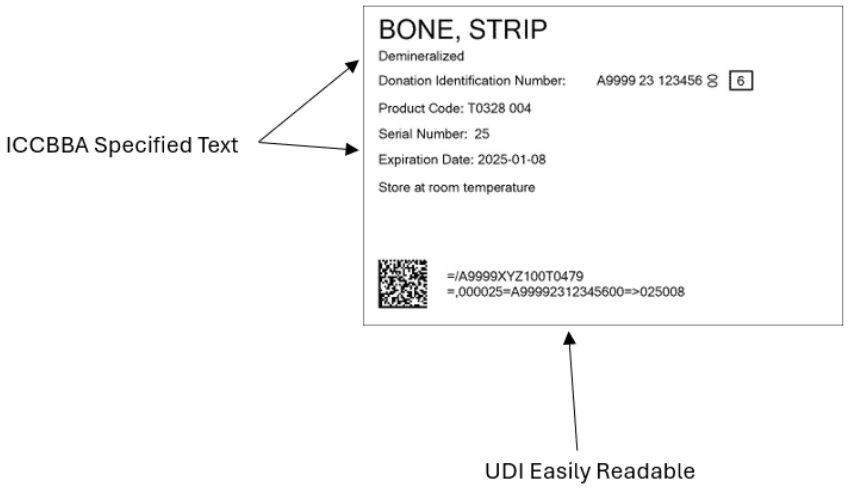
A Data Matrix (2-D) symbol may be used to convey the compound message on the product label. Printing of the symbol should follow appropriate ISO standards (listed in Section 1.4) and the *ISBT 128 Standard Technical Specification* (ST-001).

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 MPHO 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 |

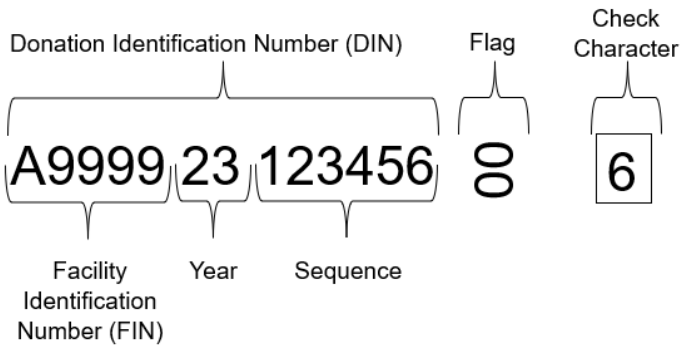
Requirements for printing specific text:

**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.

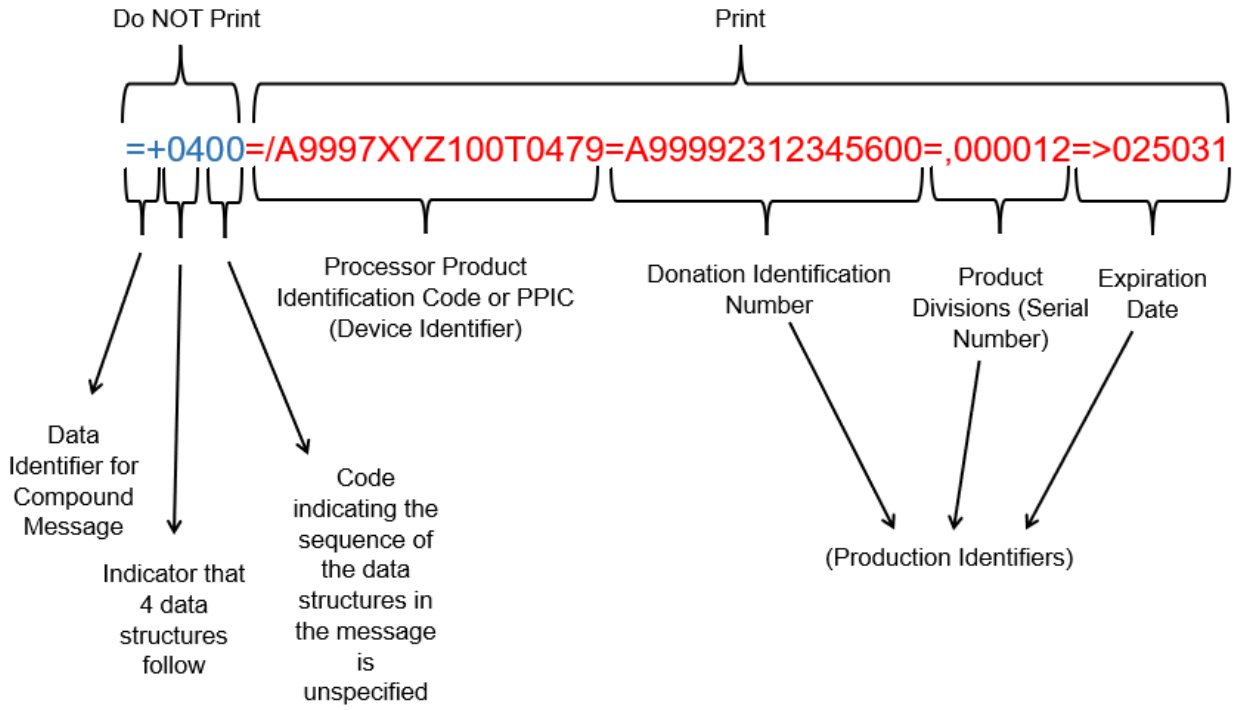
**Characters to print in eye-readable UDI text:** Eye-readable text corresponding to UDI information (easily readable plain-text referred to in the UDI regulations) shall be printed on the product label. The UDI information includes the data content and data identifiers for data structures comprising 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=A99992312345600=,000012=>025031**

It is acceptable to print the device identifier on a separate line from the production identifier (with ISBT 128 data identifiers):
**=/A9997XYZ100T0479**
**=A99992312345600=,000012=>025031**

## 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**

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

## 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: support@isbt128.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. This Product Lookup Program can be accessed by licensed users who have registered for a Member Account on the ICCBBA Website by navigating to the home page, hovering their mouse over the “Lookup Tools” drop-down menu near the top of the page, then selecting “*Find Product Information.” This will redirect users to the Online Product Lookup Tool’s webpage. Just above the Online Product Lookup Tool's interface, is the Microsoft Excel® Macro-Enabled Workbook (XLSM) Product Lookup Program file that can be downloaded onto a user’s computer so that they may use the program without requiring an online connection. This XLSM file is compatible with Microsoft Excel 2007-2013. It has

not been validated for, and cannot be used with, earlier versions of Microsoft Excel.

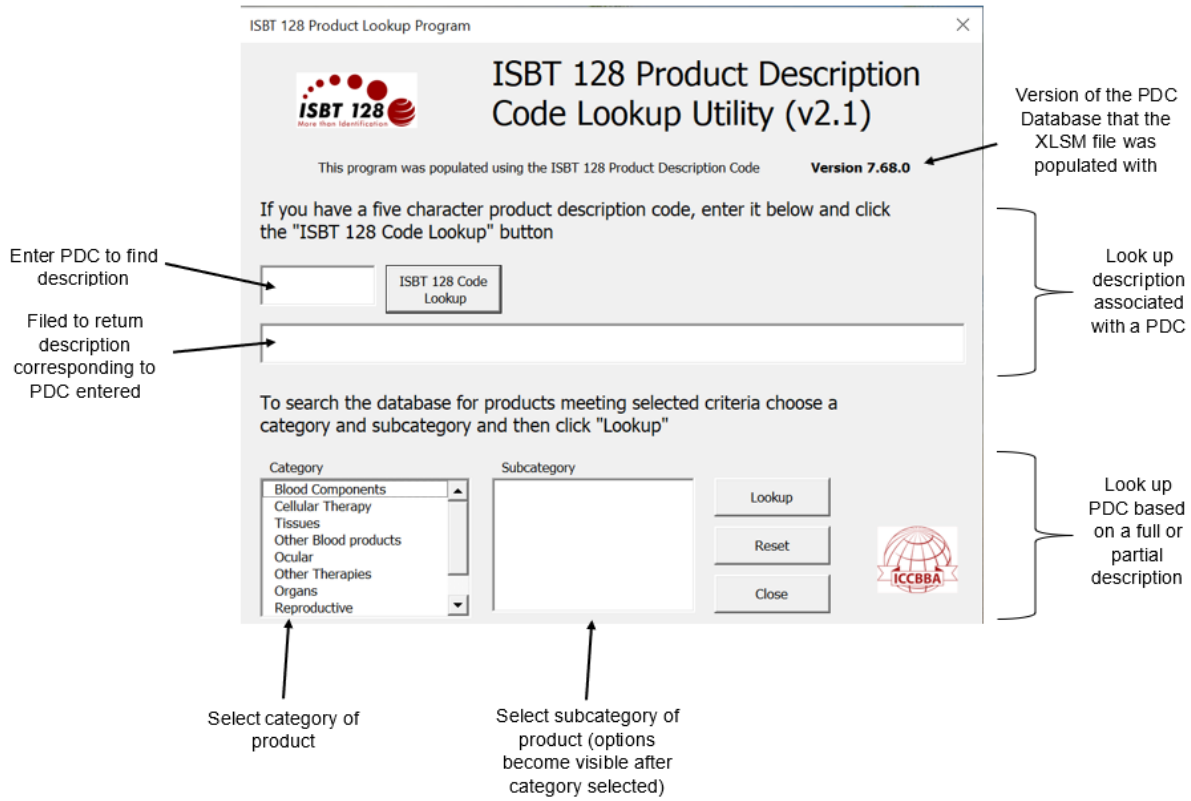
The Product Lookup Program is updated with each subsequent publication of the ISBT 128 Product Description Code Database (approximately once a month). Therefore, users who download the XLSM file must redownload this tool following these subsequent publications to ensure the tool is populated with the most up-to-date list of PDCs and terminology.

The program can be used to lookup a description for a given PDC or lookup a PDC that corresponds to a specified product's description.

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

**Figure 13 Opening Screen on XLSM Lookup Tool**




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 15(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**

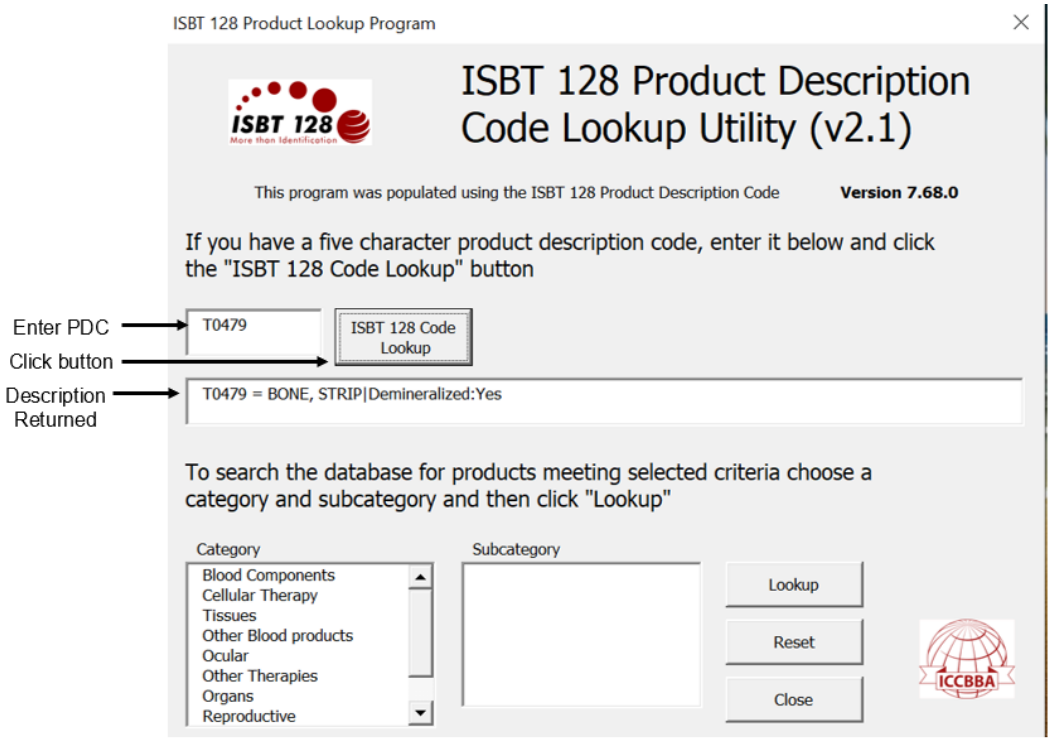



**Figure 15 Lookup a PDC for a given Product Description (Opening Screen)**

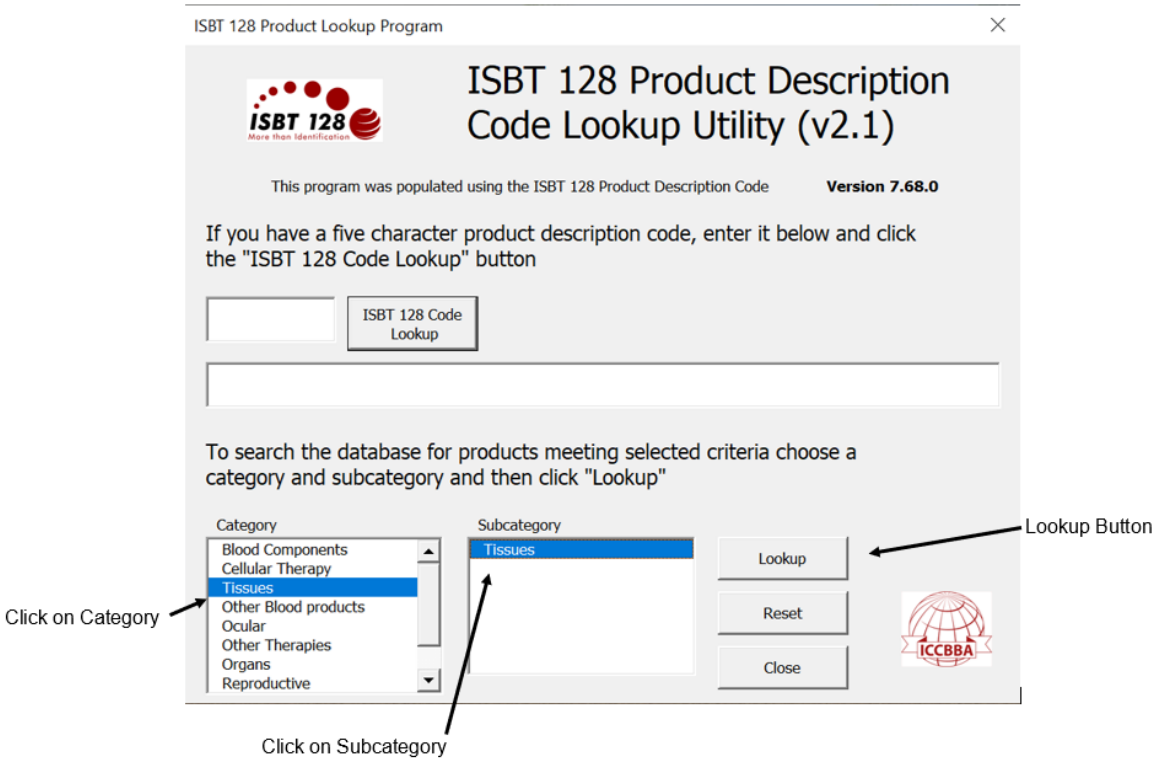


**Figure 16 Looking up a PDC from a Description Screen**

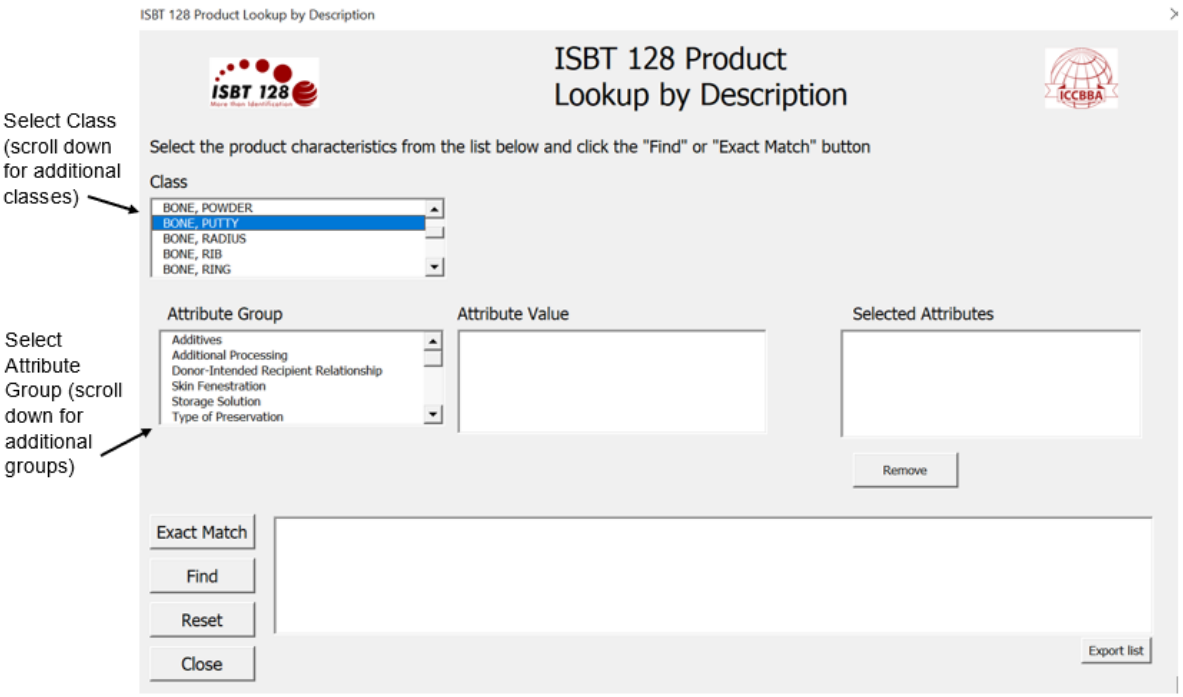


**Figure 17 Describing a Product**

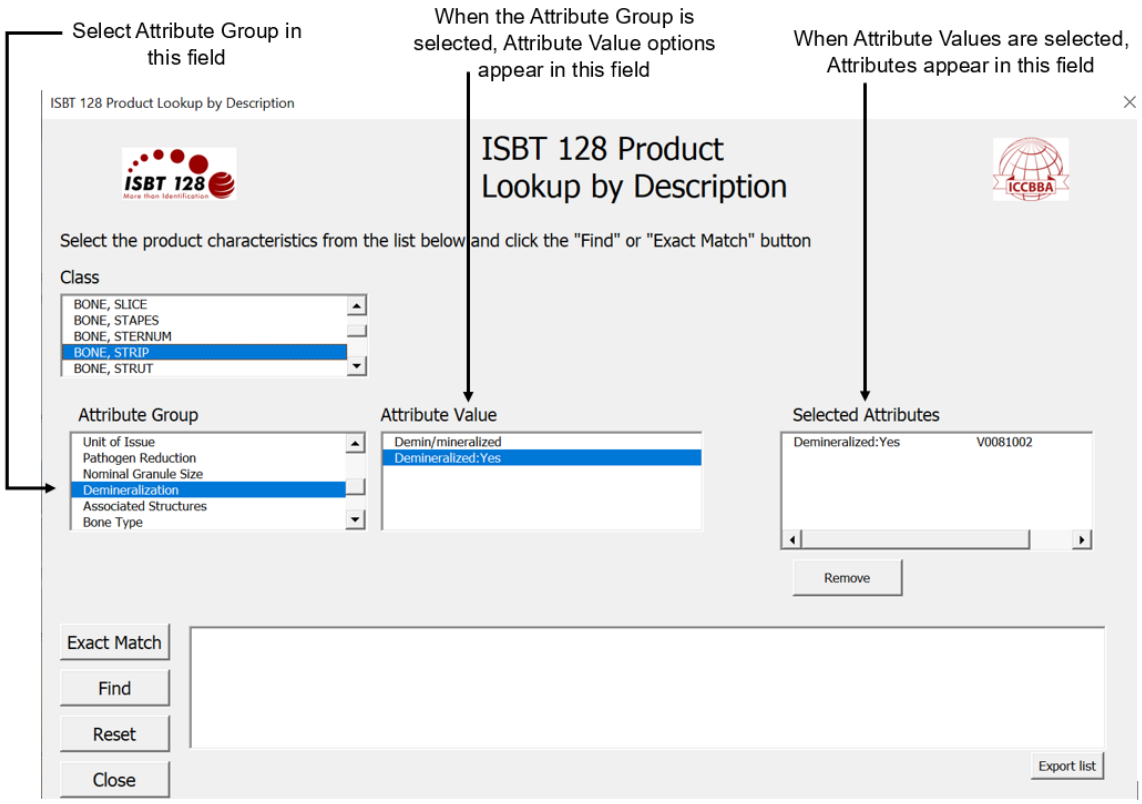


**Figure 18 Lookup PDC that Exactly Matches Criteria**

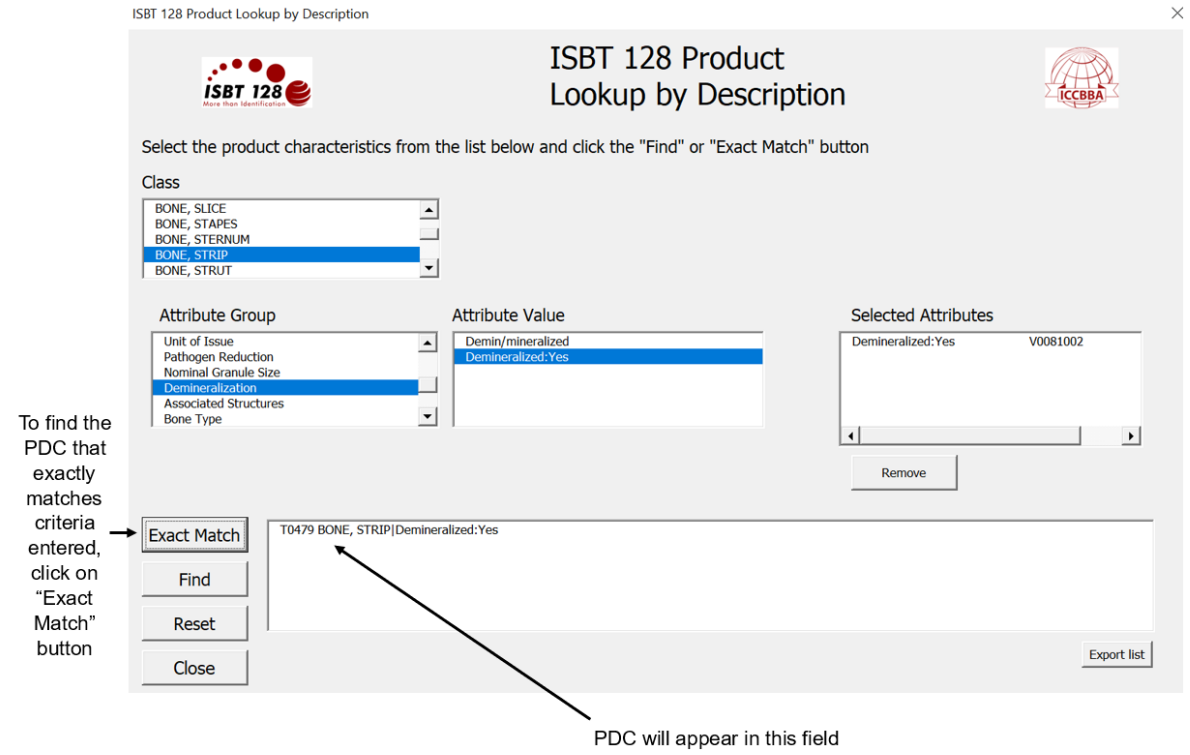



**Figure 19 Lookup All PDCs that Match Criteria**

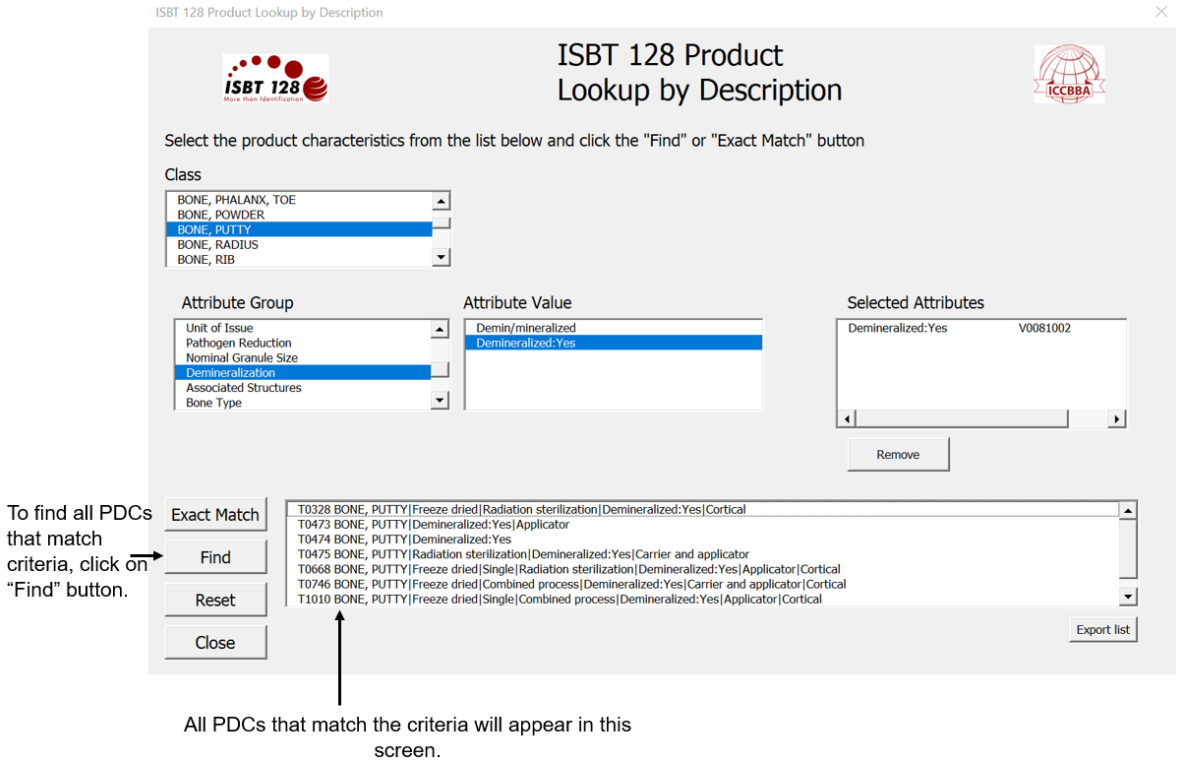


**Figure 20 Use of Export List Function**

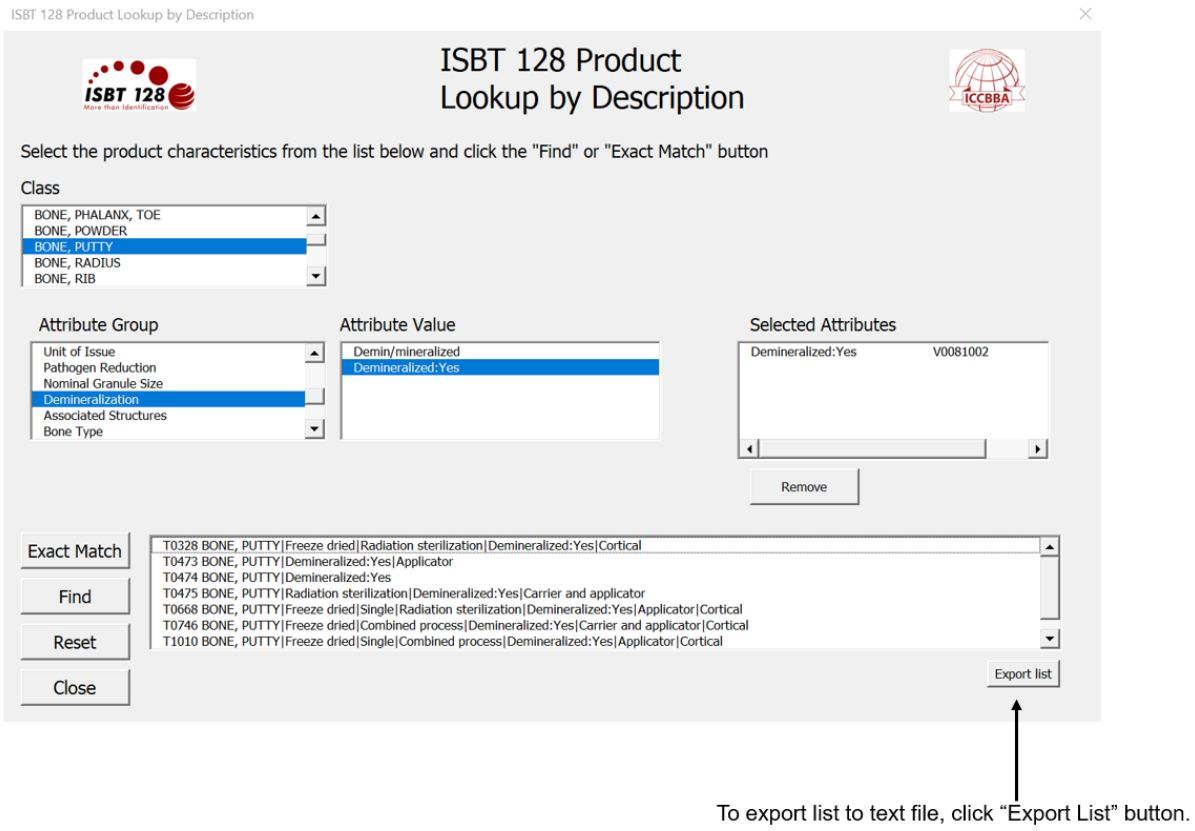
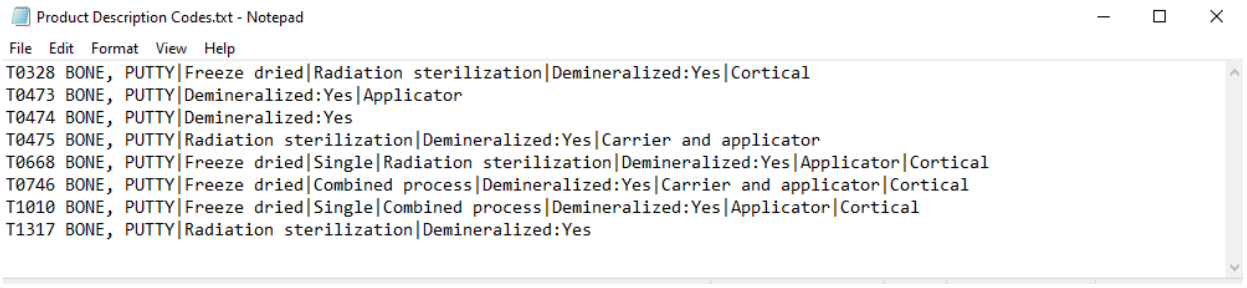



**Figure 21 Text File Created**



## 7.5 Requesting New PDCs

An online form can be accessed and completed by users logged in to their Member Account on the isbt128.org site, through the Online Product Lookup Tool. Users can launch the PDC request form by first building a description to describe the product that they are in search of a PDC for, and if a PDC does not currently correspond to the description specified, then a blue "Submit Product Request" button will appear at the bottom of the Lookup Tool. See Figure 22. Upon selection of the blue "Submit Product Request" button, the PDC Request form will be launched, giving the user the ability to verify the accuracy of their request prior to submission. See Figure 23.

Codes that represent new combinations of existing Classes or Attributes will generally be added within a subsequent publication of the database. The database is updated and published 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 submitted directly to 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. 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 ISBT 128 PDC Database will be regularly posted in the password-protected section of the ICCBBA Website and made apparent by a change in its Version Number. Version control sheets describing the changes are published with each update.

### 7.5.1 Completing the Request Form

The form for requesting new codes can be accessed by selecting the blue "Submit Product Request" button when it appears when utilizing the search by Product Description portion of the Online Lookup Tool. The Online Lookup Tool is found in the Lookup Tools tab, under *Find Product Information. Each PDC request submitted through the Online Lookup Tool will result in a unique request form generated. See Figure 22. If there are multiple requests that need to be made at a single time, then users may draft their list of requested descriptions and submit them directly to support@isbt128.org.

Minimally, Product Requests must include a Class.

Users submitting PDC requests should also select an Attribute from each Attribute group where a non-default value is required (only one per Attribute group) to further describe the product.

### 7.5.2 Submitting the Request

Click on the “Submit” button to submit the form directly to the ICCBBA staff. You will receive an automated acknowledgement of the submission, and should there be any questions regarding the request, they should be submitted to ICCBBA at support@isbt128.org.

**Figure 22 Online Lookup Tool to Submit a New PDC Request**

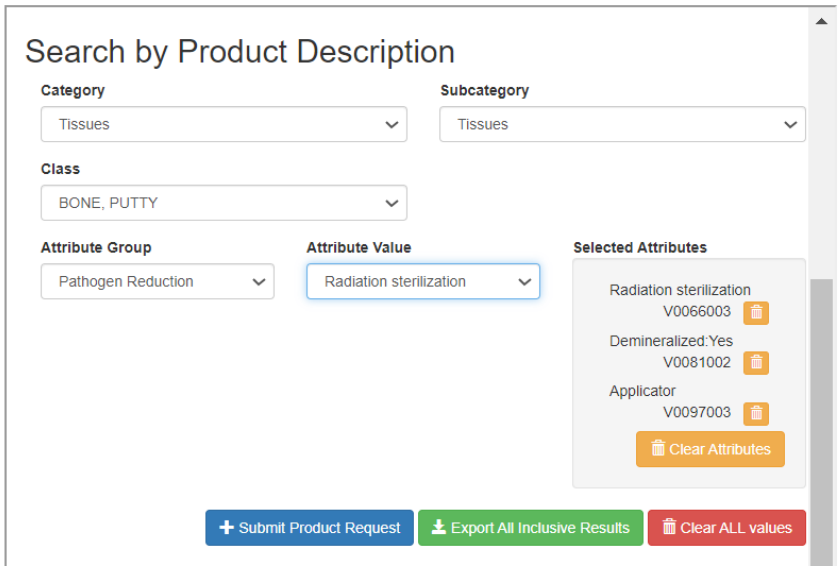
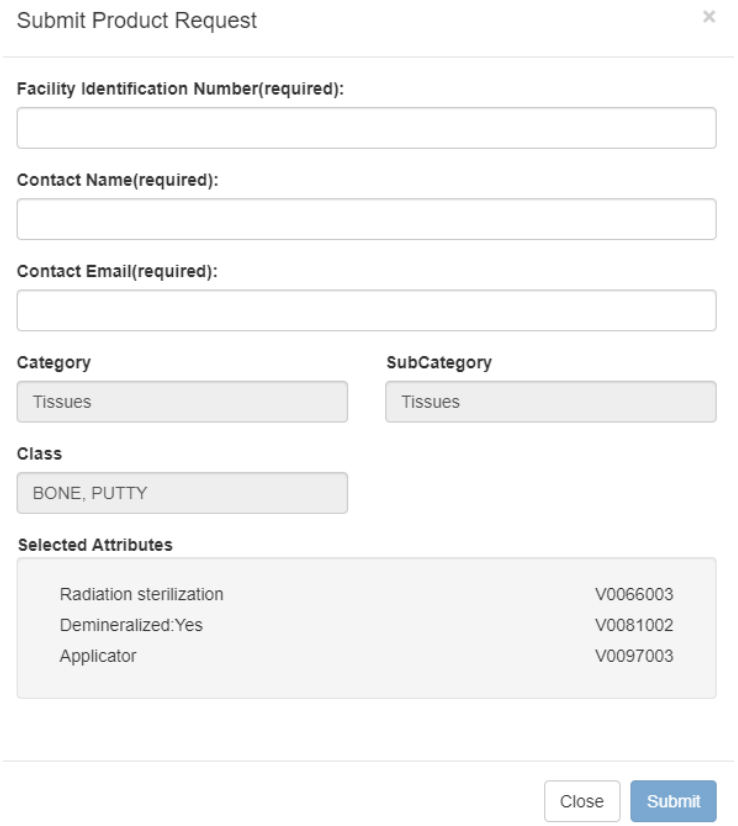



**Figure 23 Online Request Form**



# Administrative Processes

## 7.6 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.

## 7.7 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 (support@isbt128.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.

## 7.8 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.

# 8 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 |

# 9 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 | 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.)<br>ISBT 128 data identifiers correspond to the FDA UDI data delimiters. |
| 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 | An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:<br>• recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,<br>• 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<br>• 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 |
|---|---|---|
| | | animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.<br>(Section 201(h) of the Federal Food Drug & Cosmetic Act) |
| 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) | | A conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:<br>(i) The lot or batch within which a device was manufactured;<br>(ii) The serial number of a specific device;<br>(iii) The expiration date of a specific device;<br>(iv) The date a specific device was manufactured;<br>(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: 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

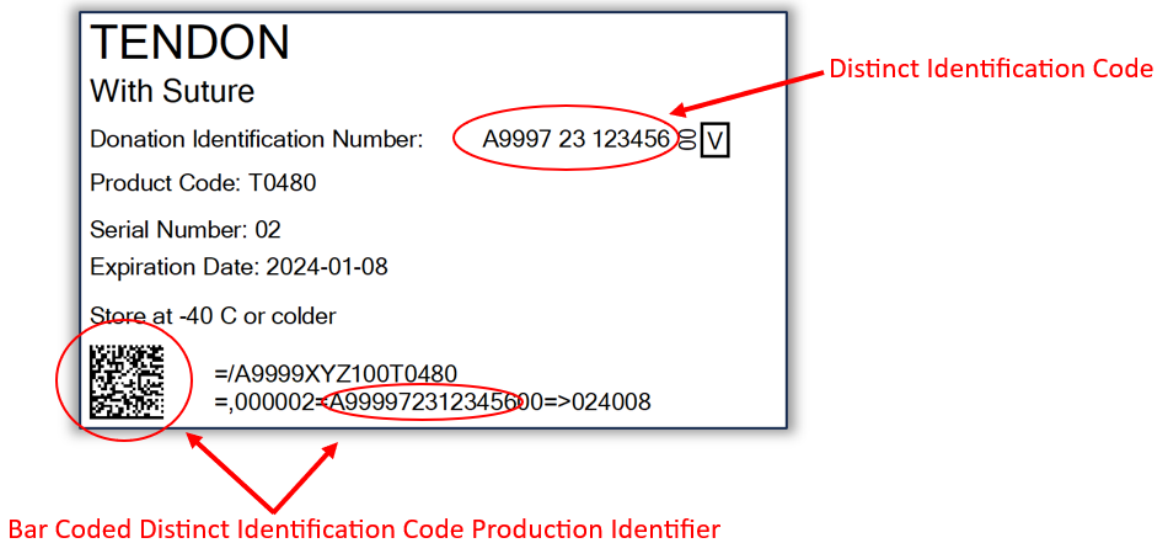
The use case illustrates what would happen when a medical device containing an HCT/P labeled with an ISBT 128 UDI is implicated in potential disease transmission.

*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 24.

**Figure 24 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.

END OF PUBLICATION

FOR ICCBBA USE ONLY

These links are for internal document control and cannot be used externally:

ST-001 ISBT 128 Standard Technical Specification
ST-010 ISBT 128 Standard Product Description Code Database
IG-014 Use of Data Matrix Symbols with ISBT 128
IG-026 Use of Dimensions [Data Structure 029]
IG-031 Use of the Processing Facility Information Code [Data Structure 033]
IG-033 Use of the Donation Identification Number [Data Structure 001]
IG-034 ISBT 128 Facility Identification Number
JP-002 GS1 and ICCBBA Guidance, Identification of medical devices containing an HCTP in the United States