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American Hospital Association

UDI Guidance Document for Medical Devices Containing HCT/P



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UDI GUIDANCE FOR DEVICES WITH HCT/P

INTRODUCTION:

Human cells, tissues, or cellular or tissue-based products (HCT/Ps) are a precious resource 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, eye banks and cellular therapy laboratories handle these 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.

Depending on the type of processing, or manipulation of the HCT/Ps, the HCT/Ps can be considered a drug, a medical device, or a biological. The intention of this document is to provide information on HCT/Ps, HCT/Ps regulation as a medical device, traceability of HCT/Ps, and the US Food and Drug Administration (FDA) Unique Device Identification (UDI) Rule and its effects on HCT/Ps regulated as a medical device.

The document has been developed by a work group of the AHRMM Learning UDI Community (LUC). It is based on the current states of an evolving area of activity. In particular, the handling of UDI data by end-users and end-users systems is still under development. The document will be updated as UDI adoption and implementations move forward and best practices are developed.

WHAT IS AN HCT/P?

Human cells, tissues, or cellular or tissue-based products (HCT/Ps) are articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient.

Examples of HCT/Ps include, but are not limited to, bone, ligament, skin, heart valve, cornea, hematopoietic stem/progenitor cells derived from peripheral and cord blood, manipulated autologous chondrocytes, epithelial cells on a synthetic matrix, and semen or other reproductive tissue. Articles that are not considered HCT/Ps include vascularized human organs for transplantation; and, whole blood or blood components or blood derivative products. Further definitions and information on HCT/Ps can be found in 21CFR 1271.3.¹ Human cells and tissues produced from one donor can be distributed to a variety of healthcare organizations. Figure 1 on page 3 displays one example of the different manufacturing processes and distribution pathways human cells and tissues procured from one donor can be issued.

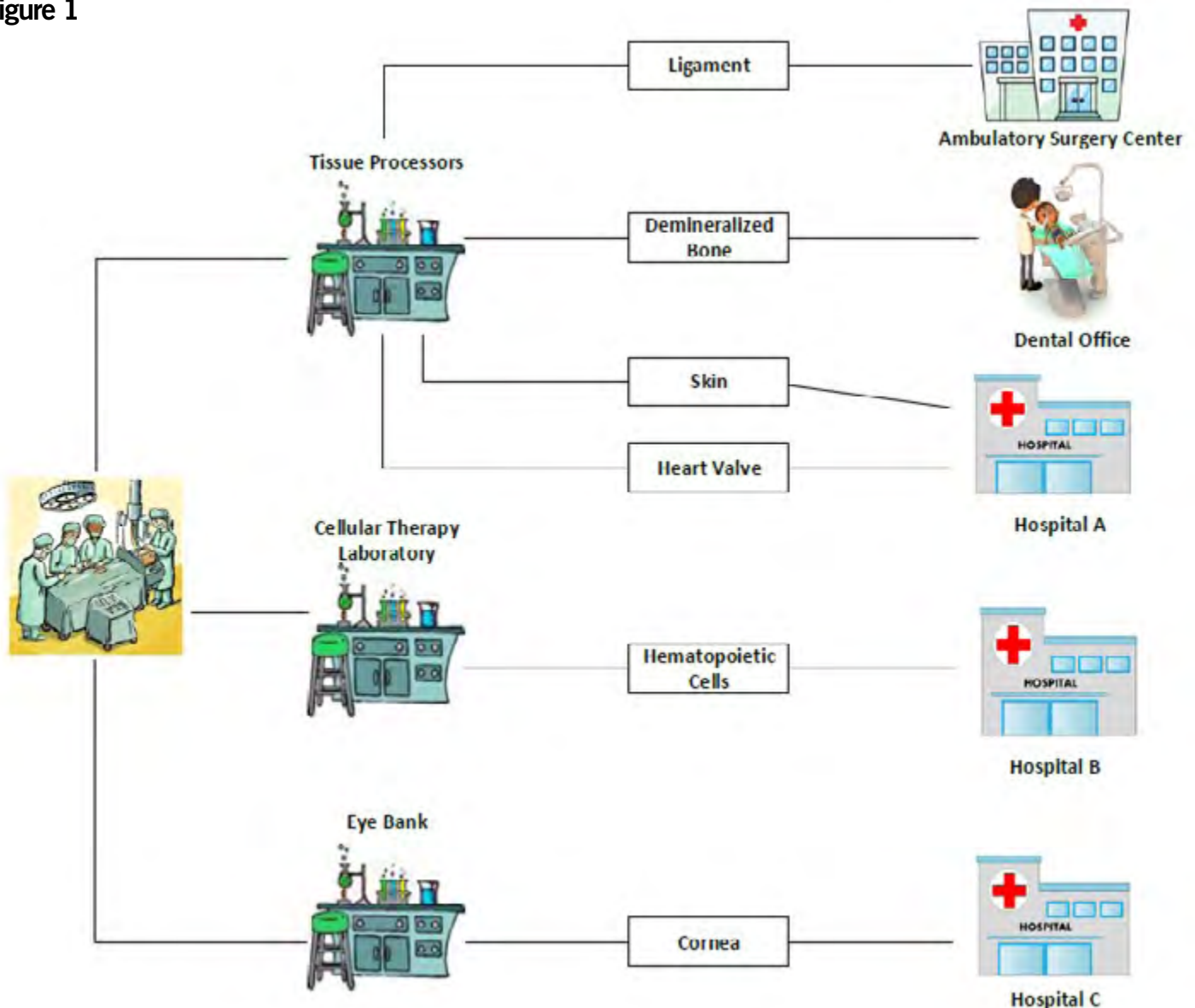
The following list provides examples of HCT/Ps that are regulated as implantable medical devices:

- Corneal lenticules
- Preserved umbilical cord vein grafts
- Human collagen
- Femoral veins intended as A-V shunts
- Demineralized bone combined with handling agents
- Bone-suture-tendon grafts

^{1,2} HCT/Ps are regulated either solely under the authority of section 361 of the Public Health Service Act or as drugs, devices and/or biological products under the authority of section 351 of the Public Health Service Act.

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Figure 1



TRACEABILITY FOR HCT/PS

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 manufacturing organization by a product number (catalogue number, identifying a product class). 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 to uniquely identify that item (product instance).

Good manufacturing practice, supported by effective regulation, controls the manufacturing process and ensures segregation between product classes and their respective batches. It also ensures the recording of traceability information for all components and processes associated with the production of a batch of product. 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.

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Traceability of this type is essential for all medical devices. However for HCT/Ps, because recall/follow-up may be associated with a specific donor, an additional traceability pathway between the donor, all products prepared from the donor, and all recipients of those products is essential and required per 21CFR 1271.290.

A single donor's tissues and cells may be recovered and sent to more than one tissue/cell processor, and this donated material can be distributed across multiple product lines. The highest element in the hierarchy in this scenario is therefore the human donor. Subsequent levels include the identification of the donation event, the tissue processor, and the product/catalogue number and the serial number of the individual products prepared.

A donor-related recall/follow-up requires identification of all the HCT/Ps associated with the single donor. This will often comprise specific items under a wide range of product lines from different organizations (eye and tissue banks). For example, one donor may donate 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 regulatory paradigms and the traceability model needs to ensure tracing/tracking of all products derived from a single donor for immediate quarantine, withdrawal or recall/follow-up with an expectation this will occur in an efficient and seamless manner.

Not all recalls are donor-related and there may be other reasons why HCT/Ps are recalled (e.g., failure in a processing step may result in a recall of products prepared during the particular processing cycle). If an HCT/Ps is recalled due to the HCT/P's donor, it is important to know the distinct identification code (DIC) that the processor assigned to the product to relate back to the donor. Healthcare organizations stock several similar HCT/Ps and knowing the HCT/Ps medical device unique device identifier (UDI) and its components (DI-device identifier and PI-product identifier), which includes the DIC, can assist the healthcare organization to determine the specific HCT/P that was recalled. Identifying a medical device regulated as an HCT/P medical device and traceability is discussed later in the document.

REGULATORY AND STANDARD REQUIREMENTS FOR HCT/PS AND TRACEABILITY

To prevent the introduction, spread, and transmission of communicable diseases HCT/Ps are regulated by the U.S. Food and Drug Administration (FDA)² and the U.S. Public Health and Services Act (PHS). HCT/Ps that are regulated solely under section 361 of the PHS Act and the FDA 21 C.F.R. Part 1271, meet specific criteria (i.e., minimally manipulated, intended for homologous use, not be combined with other articles except specified types of ingredients), are referred to as "361 HCT/P". The Center for Biologicals Evaluation and Research (CBER) regulates "361 HCT/Ps".

If an HCT/P does not meet the criteria set forth in 21 C.F.R 1271, the HCT/Ps will be regulated as a drug, device, and/or biological product. An HCT/Ps regulated as a drug will be subject to regulations set-forth by the Center for Drug Evaluation and Research (CDER). If the HCT/Ps is regulated as a medical device it is regulated by the Center for Devices and Radiological Health (CDRH). HCT/Ps regulated by the FDA as a medical device require the manufacturers of the HCT/Ps to follow the Current Good Tissue Practice regulations of 21 CFR 1271 Part D. The regulation, includes the requirement for a distinct identification code (DIC) as part of the tracking system under 1271.290.

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The requirements for tracking from donor to consignee or final disposition, and from the consignee or final disposition to the donor are stated in 21 CFR 1271.290. In addition, 21 CFR 1271.290(c) requires the manufacturer to apply a distinct identification code (DIC) to facilitate tracking from donor to recipient:

“As part of your tracking system, you must ensure: That each HCT/P that you manufacture is assigned and labeled with a distinct identification code, e.g., alphanumeric, that relates the HCT/P to the donor and to all records pertaining to the HCT/P; and that labeling includes information designed to facilitate effective tracking, using the distinct identification code, from the donor to the recipient and from the recipient to the donor. Except as described in 1271.55(a)(1), you must create such a code specifically for tracking, and it may not include an individual’s name, social security number, or medical record number. You may adopt a distinct identification code assigned by another establishment engaged in the manufacturing process, or you may assign a new code. If you assign a new code to an HCT/P, you must establish and maintain procedures for relating the new code to the old code.”

The FDA has indicated that the distinct identification code may take the form of a donation identification number, serial number, lot number, or a combination of these production identifiers.

“21 CFR 1271.290(c) requires that the manufacturer of each HCT/P assign and label the HCT/P with a distinct identification code that allows the manufacturer to relate the HCT/P to the donor and to all records pertaining to the HCT/P. The distinct identification code may take the form of a donation identification number, serial number, lot number, or a combination of these production identifiers. In the GUDID, labelers of HCT/Ps regulated as medical devices should select the appropriate type of production identifier that appears on the label of the device.”

21 CFR 1271.290(f) requires labelers to inform consignees about their tracking system:

“At or before the time of distribution of an HCT/P to a consignee, you must inform the consignee in writing of the requirements in this section and of the tracking system that you have established and are maintaining to comply with these requirements.”

HCT/Ps regulated as a medical device must also comply with the U.S. FDA Unique Device Identification Rule. This rule, discussed in detail later, requires manufacturers of medical devices comply with specific medical device labeling and reporting criteria. The labeling requirements are outlined in the FDA regulation 21 CFR 801.40(b) which requires the DIC be included on the label as the corresponding production identifier that is included in the Unique Device Identifier (UDI):

“The UDI must include a device identifier segment. Whenever a device label includes a lot or batch number, a serial number, a manufacturing date, an expiration date, or for a human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device, a distinct identification code as required by §1271.290(c) of this chapter, the UDI must include a production identifier segment that conveys such information.”

Accreditation agency, organizational policy and procedure, standards of practice, applicable laws, and regulatory compliance places a number of requirements on healthcare organizations responsible for the clinical application of HCT/Ps. This includes defining the process for the documentation, completion, filing, and retention of medical records. For example, The Joint Commission 2017 Transplant Safety Standard requires healthcare organizations to retain tissue records for a minimum of ten years and the

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tissue type and its unique identifiers are documented in the patient's medical record. "For medical devices, the manufacturer may be the tissue supplier. The original numeric or alphanumeric donor and lot identification, the name(s) of the recipient(s) or the final disposition of each tissue, and the expiration dates of all tissue" are required to be kept by the healthcare organization.

THE U.S. FDA UNIQUE DEVICE IDENTIFICATION (UDI) SYSTEM

In 2013, the U.S. FDA established a Unique Device Identification (UDI) system that would identify medical devices through their distribution and use. When fully implemented, the label of most medical devices would include a UDI in human and machine readable formats. Medical device manufacturers need to comply with the FDA's implementation timeline for each medical device class.

The UDI system comprises two essential elements: the requirement that the UDI be on the device label and package; and the requirement that key characteristics of the device be submitted as a record in the Global Unique Device Identification Database (GUDID) maintained by the FDA. Effective use of the UDI system requires both these elements to be in place in order to make standard device identification data available to other systems supporting traceability and recall/follow-up requirements and electronic medical records.

The Unique Device Identifier (UDI) is composed of two parts: Device Identifier (DI) and Production Identifier (PI). The DI component of the UDI uniquely identifies the version or model of the device and the labeler of the device. The FDA has accredited three (3) issuing agencies (IA) to assign UDIs in compliance with the UDI rule. Each Issuing Agency (IA) has a specific term they use under their system that represents the DI portion of the UDI:

- GS1 - Global Trade Identification Number (GTIN)
- HIBCC - Universal Product Number (UPN)
- ICCBBA – Processor Product Identification Code (PPIC)

The UDI marking on the medical device label will follow the coding rules of the appropriate IA.

A summary of the data structures used in the UDI is available at

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

The DI provides a key to the information held in the GUDID database. FDA provides various mechanisms to access this data including an application program interface (API) to support automated lookup. Full documentation on the content of the GUDID and how to access it is provided on the AccessGUDID web at <http://accessgudid.nlm.nih.gov/>.

For effective recall/follow-up purposes, it is imperative that healthcare organization's receiving medical devices containing HCT/PS ensure that they are not only capturing the device identifier, but also the applicable production identifiers.

ELECTRONIC DOCUMENTATION REQUIREMENTS FOR HCT/PS

The ability to electronically capture an HCT/PS UDI and DIC data will depend on the end-users IT infrastructure, the version of the electronic medical record system in place, and the adoption and implementation of specific workflow processes. Today, the handling of this data by end-users and

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their electronic information systems are still under development and evolving to meet all stakeholder needs. Medical device UDIs has become part of the Centers for Medicare and Medicaid Services (CMS) Meaningful Use (MU) Stage 3 requirements. If healthcare organizations participate in the CMS MU quality reporting program, they must report on selected quality metrics, such as the UDI. The use of a certified electronic medical record assists healthcare organization with this data collection.

The Office of National Coordinator (ONC) for Health Information Technology (HIT) is the agency that certifies IT systems to ensure they have the technologic capability, functionality, and security requirements for patients and providers for interoperability. The certification is voluntary by end-user IT systems. The 2015 Office of National Coordinator (ONC) Health Information Technology (HIT) Certification Criteria Final Rule specifies that Health IT must be able to electronically perform a number of capabilities including recording and parsing the unique device identifiers associated with a patient's implantable medical device (45CFR 170.315):

“The Secretary adopts the following certification criteria for health IT.

“Health IT must be able to electronically perform the following capabilities in accordance with all applicable standards and implementation specifications adopted in this part:

(...)

“(14) Implantable device list.

(i) Record Unique Device Identifiers associated with a patient's Implantable Devices.

(ii) Parse the following identifiers from a Unique Device Identifier:

(A) Device Identifier;

(B) The following identifiers that compose the Production Identifier:

(1) The lot or batch within which a device was manufactured;

(2) The serial number of a specific device;

(3) The expiration date of a specific device;

(4) The date a specific device was manufactured; and

(5) For an HCT/P regulated as a device, the distinct identification code required by 21 CFR 1271.290(c).

(iii) Obtain and associate with each Unique Device Identifier:

(A) A description of the implantable device referenced by at least one of the following:

(1) The “GMDN PT Name” attribute associated with the Device Identifier in the Global Unique Device Identification Database.

(2) The “SNOMED CT® Description” mapped to the attribute referenced in paragraph (a)(14)(iii)(A) (1) of this section.

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(B) The following Global Unique Device Identification Database attributes:

- (1) “Brand Name”;
- (2) “Version or Model”;
- (3) “Company Name”;
- (4) “What MRI safety information does the labeling contain?”; and
- (5) “Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437).”

(iv) Display to a user an implantable device list consisting of:

(A) The active Unique Device Identifiers recorded for a patient; and

(B) For each active Unique Device Identifier recorded for a patient, the description of the implantable device specified by paragraph (a)(14)(iii)(A) of this section.

(C) A method to access all Unique Device Identifiers recorded for a patient.

(v) For each Unique Device Identifier recorded for a patient, enable a user to access:

(A) The Unique Device Identifier;

(B) The description of the implantable device specified by paragraph (a)(14)(iii)(A) of this section;

(C) The identifiers associated with the Unique Device Identifier, as specified by paragraph (a)(14)(ii) of this section;

(D) The attributes associated with the Unique Device Identifier, as specified by paragraph (a)(14)(iii)

(B) of this section.

(vi) Enable a user to change the status of a Unique Device Identifier recorded for a patient.”

Even though, certified EHRs are required to capture, parse, and display HCT/Ps medical device data, some challenges exist in practice. As noted earlier, certification of end-users IT systems is voluntary. The end-user IT system being used at the healthcare organization may not be certified. Or if it is certified it may only capture and display the HCT/Ps medical device full UDI data or only the devices DI (device identifier) portion of the UDI, not the PI data where the DIC information is grouped. The HCT/Ps DIC (distinct identification code), which is part of the UDI PI (production identifier), may be a unique DIC number or it may be the same as the HCT/Ps medical devices serial number. The HCT/Ps DIC is developed based on the HCT/Ps medical device manufacturer’s IA and their standards used for producing the UDI label. The end-user system may not populate the DIC or if the serial number is the DIC the end-user may see the same code in the serial number field and DIC field. Each HCT/Ps medical device IA complies with their own standard for developing the DIC and there is not one standard, but three to become accustomed to.

Currently, we do not know the full extent of how healthcare organizations will want to capture and use the HCT/Ps medical device data. As more healthcare organizations adopt and implement the UDI system, more will be learnt and additional best practices will be developed for HCT/Ps medical devices.

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IDENTIFYING A PRODUCT AS AN HCT/P REGULATED AS A MEDICAL DEVICE

The following sections are intended to provide guidance to end-users on how to extract essential information from the UDI and GUDID to satisfy clinical standards traceability and recall/follow-up requirements and to populate the electronic medical record in compliance with 2015 Edition Health Information Technology Certification Criteria Final Rule.

The data delimiters (application identifiers/data identifiers) used by the issuing agencies are not specific to medical devices, but are applied widely across the supply chain. It is therefore necessary to determine whether the product is (a) a medical device and (b) an HCT/P regulated as a medical device, in order to correctly parse the production identifiers.

One method to determine if a product is a medical device that is required to carry a UDI, the identifier specified by the issuing agency as the DI should be extracted and a lookup performed on the GUDID. If the DI exists in the GUDID then the product is a medical device required to carry a UDI. A medical device's DI may not always be found in the GUDID because the medical device was on the market prior to the FDA medical device class compliance date or the manufacturer has been granted an extension for complying with the GUDID requirement. The GUDID should be the most reliable source to determine if a medical device contains an HCT/Ps, but if the HCT/Ps medical device cannot be found in the GUDID, this information can always be obtained from the devices manufacturer or processor.

If the medical device is found in the GUDID, to determine if the product is an HCT/P regulated as a medical device, the GUDID data element "Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P)" should be inspected. This is a Boolean (True/False) field. If set to True the labeler has indicated that this medical device is an HCT/P regulated as a medical device.

Data Element in GUDID	Description from GUDID documentation
Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P)	Indicates that the product contains or consists of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient as defined under 21 CFR 1271.3.

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EXAMPLES FROM GUIDID:

Human Readable Format

DEVICE: **FlexiGRAFT® (00889858157155)**

[DOWNLOAD: XML](#) | [JSON](#) | [PRINT](#)

[VIEW ALL SECTIONS](#) | [CLOSE ALL SECTIONS](#)

- + DEVICE IDENTIFIER (DI) INFORMATION**
- DEVICE CHARACTERISTICS**

What MRI safety information does the labeling contain?	Labeling does not contain MRI Safety Information
Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437):	No
Device labeled as "Not made with natural rubber latex":	No
For Single-Use:	Yes
Prescription Use (Rx):	Yes
Over the Counter (OTC):	No
Kit:	No
Combination Product:	No
Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P):	Yes

- + GMDN [?]**
- + FDA PRODUCT CODE [?]**
- + STERILIZATION**
- + STORAGE AND HANDLING [?]**
- + CLINICALLY RELEVANT SIZE [?]**
- + DEVICE STATUS**

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XML version

```
▼<gudid xmlns="http://www.fda.gov/cdrh/gudid">
  ▼<device xmlns="http://www.fda.gov/cdrh/gudid" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
    <deviceRecordStatus>Published</deviceRecordStatus>
    <devicePublishDate>2015-09-24</devicePublishDate>
    <deviceCommDistributionEndDate xsi:nil="true"/>
    <deviceCommDistributionStatus>In Commercial Distribution</deviceCommDistributionStatus>
  ▼<identifiers>
    ▼<identifier>
      <deviceId>00889858157155</deviceId>
      <deviceIdType>Primary</deviceIdType>
      <deviceIdIssuingAgency>GS1</deviceIdIssuingAgency>
      <containsDINumber xsi:nil="true"/>
      <pkgQuantity xsi:nil="true"/>
      <pkgDiscontinueDate xsi:nil="true"/>
      <pkgStatus xsi:nil="true"/>
      <pkgType xsi:nil="true"/>
    </identifier>
  </identifiers>
  <brandName>FlexiGRAFT®</brandName>
  <versionModelNumber>FTBDL095108</versionModelNumber>
  <catalogNumber>FTBDL095108</catalogNumber>
  <companyName>LIFENET HEALTH</companyName>
  <deviceCount>1</deviceCount>
  <deviceDescription>Triple Bundle</deviceDescription>
  <DMEExempt>false</DMEExempt>
  <premarketExempt>false</premarketExempt>
  <deviceHCTP>true</deviceHCTP>
  <deviceKit>false</deviceKit>
  <deviceCombinationProduct>false</deviceCombinationProduct>
  <singleUse>true</singleUse>
  <lotBatch>true</lotBatch>
  <serialNumber>true</serialNumber>
  <manufacturingDate>false</manufacturingDate>
  <expirationDate>true</expirationDate>
  <donationIdNumber>true</donationIdNumber>
  <labeledContainsNRL>false</labeledContainsNRL>
  <labeledNoNRL>false</labeledNoNRL>
  <MRISafetyStatus>Labeling does not contain MRI Safety Information</MRISafetyStatus>
  <rx>true</rx>
  <otc>false</otc>
```

All manufacturers provide key data in their UDI labeling process. The package insert for all HCT/Ps will not only identify whether the product contains an HCT/P, but will also clarify how the DIC is captured within the label. The full UDI label will include all of the key elements, which must be parsed per the 2015 Health Information Technology Certification (HIT) criteria.

EXTRACTING THE DISTINCT IDENTIFICATION CODE FROM THE UDI

The HIT Final Rule requires certified electronic health record (EHR) systems to capture the UDI, and parse the device and production identifiers. The HIT Final Rule states, “Because these identifiers are part of the UDI, health IT should be able to parse these identifiers from the UDI using the issuing agency’s specifications. There is no need to query an external database or source, such as the GUDID.”

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The DIs and PIs must be stored and made accessible to end-users. This requirement applies to all medical devices carrying a UDI, but HCT/Ps require some special handling because the requirement to parse the distinct identification code is specific to HCT/P's regulated as medical devices.

The manner in which the DIC can be identified and parsed depends upon the FDA-accredited issuing agency being used for the HCT/P medical device label. ICCBBA (ISBT 128) has a specific production identifier for the DIC (donation identification number) and this is referenced within the ISBT 128 Standard. For GS1 and HIBCC, the distinct identification code may appear in one or more production identifiers and the application identifiers (AI) specifications do not address the mechanism to parse this production identifier. The following sections explain how to parse the distinct identification code for each Application Identifiers (AIs).

GS1

GS1 utilizes a system of standards which includes a Global Trade Item Number (GTIN) and AIs to appropriately identify and describe a product. GS1 recommends when applying GS1 standards to the U.S. FDA Unique Device Identification (UDI) rule for HCT/P products that the GTIN (DI) and AIs (PIs) be used together to form the UDI for HCT/P product business purposes. GS1 recommends using the Device Identifier (DI) and the Production Identifier (PI) together in describing a product and to not use only a portion of this information independently.

Within the GS1 system, the GTIN is the UDI Device Identifier (DI). The Production Identifiers (GS1 AIs) specified within the U.S. FDA UDI rule which pertain to the GS1 standard are as follows, where the AI is shown in parentheses:

- (10) Batch or lot number – a 20 character variable length alphanumeric field
- (17) Expiration date – YYMMDD
- (21) Serial number – a 20 character variable length alphanumeric field
- (11) Production date – YYMMDD


GS1 are recommending that for products identified with GS1 standards, manufacturers/processors of HCT/P products should utilize the Serial number (AI 21) field to encode the DIC. This is a variable length 20 character alphanumeric field and provides the capability to encode an alphanumeric DIC as needed and in accordance with Part 1271.290(c). However, this is not a requirement of the GS1 Standard and labellers may utilize the lot number or a combination of the serial number and lot number fields for the DIC.

FIELD EXAMPLE

Please find an example below, depicting the use of the Serial number field to accommodate the DIC code.

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Fictitious label example:

<p>DEMBONMAT DBM Paste</p> <p>Size: 1cc</p> <p>Human Tissue: Demineralized Bone Matrix</p> <p>Tissue recovered and processed under aseptic conditions. See package insert for indications, contraindications, and cautions.</p>	<p>SN 0123456789</p> <p>⌚ Use By: 2019-05-09</p> <p>QTY: 1 EA</p> <p>Generis Grafts Any Street Any Town State ZIP</p>
 (01)10304040123451(17)190509(21)0123456789	<p>Distributed By:</p> <p>Acme Tissue Distribution 9011 Orange Street City, State, ZIP Telephone 123 456 7890</p>



In the example above, the distinct identification code constitutes a serial number or unique graft identifier. The components of the GS1 DataMatrix are as follows:

- (01) Global Trade Item Number (GTIN) – unique to a single item type/ Product code/SKU
- (17) Expiration date
- (21) Serial number - distinct identification code – unique to a single donor
- (10) Batch or lot number – unique to a single graft but is not used in this example

The GTIN plus a serial number based Distinct Identification Code constitutes a unique graft identifier (recognized globally).

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HIBCC

The HIBCC Standard does not provide a specific production identifier for the distinct identification code. Labelers are permitted by FDA to use a serial number, lot number, or combination of serial and lot number as a distinct identification code. Which of these identifiers is fulfilling the role of the distinct identification code will vary between labelers, and could vary between products from a single labeler. Currently, in order to parse the distinct identification code from the UDI, it will be necessary to maintain a reference table on end-user systems that identifies for each DI the appropriate production identifiers to be parsed to obtain the distinct identification code. This information will need to be obtained direct from the labeler in each case. It should be noted that the distinct identification code will be unique to the labeler, but may not be unique to the end-user (i.e. the same distinct identification code may be used by two labelers to identify different donors). To ensure uniqueness the distinct identification code will need to be associated with the labeler identity.

ICCBBA/ISBT 128

Within the ISBT 128 system the Processor Product Identification Code (data identifier “=”) is the DI. The Production Identifiers (ISBT 128 Data Identifiers) specified within the U.S. FDA UDI rule, which pertain to the ICCBBA ISBT 128 standard are as follows, where the data identifier is shown in parentheses:

(&,1) MPHO Lot Number – an 18 character alphanumeric field

(=>) Expiration date – YYYYJJJ

(=,) Serial number – a 6 character alphanumeric field

(=}) Manufacturing date – YYYYJJJ

(=) Donation Identification Number (Distinct Identification Code required by 21 CFR 1271.290(c)) – a 13-character alphanumeric field

In ISBT 128 the distinct identification code is the donation identification number and this can be parsed directly from the corresponding production identifier. The donation identification number is a mandatory data item in ISBT 128 so will always be present. The ISBT 128 donation identification number is a globally unique identifier compliant with ISO/IEC 15459-3 and maps to a unique donor worldwide.

**Bone, Filler, Strip
Demineralized**

Donation Identification Number: A9997 14 123456 8 8

Product Code: T0479

Serial Number: 25

Expiration Date: 2016-01-08

Store at room temperature



=/A9999XYZ100T0479

=,000025=A99971412345600=>016008

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DISPLAYING AND ACCESSING THE UDI

End-user systems are required to display to a user the UDIs recorded for a patient, and for each, enable a user to access all the production identifiers associated with the UDI specified information from the GUDID. How the HCT/Ps medical device data is electronically displayed to the end-user depends on several factors, such as, but not limited to the following:

- the electronic information system the end-user has implemented;
- the technology (manual or AIDC) used to capture the HCT/Ps medical device UDI data;
- the format of the HCT/Ps medical device data included on the package label;
- the interface between the technology used to capture the HCT/P medical device data and the end-users electronic information system; and
- the interoperability between the end-users supply chain system and the electronic health record (EHR) system.

How HCT/Ps medical device data is captured by the end-user may not only affect how the HCT/P medical device data is electronically displayed, but also how the data can be used for secondary uses. Also, where HCT/Ps medical device data will be stored will depend on the capabilities of the healthcare organizations information system, the organization's IT infrastructure, and the organization's business processes. Whether this data is segregated in disparate systems throughout the various departments within a healthcare organization that use HCT/Ps medical devices for invasive or surgical procedures, or in an application that can be accessed by all stakeholders, having access to all the HCT/Ps medical device UDI data, including the DIC data, adds an additional layer of information for patient safety.