LEARNING UDI COMMUNITY

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Association for Healthcare Resource & Materials Management
Advancing the Healthcare Supply Chain
A professional membership group of the American Hospital Association

Franciscan Missionaries of Our Lady Health System (FMOLHS) UDI Capture Case Study:

Automation of Product Data Capture in the Electronic Health Record

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LEARNING UDI COMMUNITY CASE STUDY

WORK GROUP TITLE:

UDI Capture Work Group

CASE STUDY PARTICIPANTS

Sandi Michel, MPMP, ITIL, CLSSBB, Director of Supply Chain Systems and Quality, the Office of Data Standards & Interoperability for Franciscan Missionaries of Our Lady Health System (FMOLHS)

CASE STUDY ORGANIZATION

Franciscan Missionaries of Our Lady Health System (FMOLHS) is the leading healthcare innovator in Louisiana. FMOLHS brings together outstanding clinicians, the most advanced technology and leading research to ensure that its patients receive the highest quality and safest care possible. With hospitals, clinics, and physicians located throughout our state, FMOLHS is the largest in Louisiana. As a nonprofit, mission-focused Catholic healthcare ministry, FMOLHS gives special attention to its citizens who are most in need. During the most recent fiscal year, the health system provided more than $39 million in unreimbursed care and community support to the underprivileged.

OPENING STATEMENT

FMOLHS is a pioneer in healthcare data standards implementation. Previous case studies have documented the organization's journey over the past seven years. The health system's first work with standards was a pilot program with seven suppliers to use GS1[1] Global Location Numbers (GLNs) and GS1 Global Trade Item Numbers (GTINs) in electronic data transactions (EDI) to improve the efficiency and accuracy of the procure-to-pay process. The work that FMOLHS did with its supplier Cook Medical is documented in an AHRMM Cost, Quality, and Outcomes Movement (CQO) case study.

An AHRMM UDI Capture Work Group case study documented how FMOLHS first aligned with the U.S. Food and Drug Administration's (FDA) unique device identification (UDI) rule by capturing the device identifier (DI[2]) portion of the UDI for tissue and biologics products in a third party UDI tracking solution equipped with barcode scanning technology.

Now FMOLHS has taken its work one giant leap further. Sandi Michel, MPMP, ITIL, CLSSBB, Director of Supply Chain Systems and Quality, the Office of Data Standards & Interoperability for FMOLHS and her team have been working to leverage UDI barcodes and system integration for the automation of product data capture in the electronic health record (EHR). Through this work, they hope to increase the accuracy and completeness of product data in patients' medical records, and improve workflow efficiency so that clinicians can spend less time on product documentation and more time on patient care.

In early 2016, FMOLHS began implementation of its new Epic electronic health record (EHR) system throughout its hospitals and surgery center. The health system took this opportunity to establish system integration and barcode scanning capabilities that would facilitate automated capture and sharing of DI data across multiple systems and functions.

[1] An FDA-accredited issuing agency (IA) is an organization that operates a system for assignment of UDIs according to the UDI Rule. FDA has accredited three issuing agencies – GS1, HIBCC, and ICCBBA.

[2] A device identifier (DI) is a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device.

Barcode scanning and scanning integration

Throughout 2017, the FMOLHS supply chain team has been going to each of the health system's hospitals and its surgery center to scan barcodes on every medical-surgical product they can find. In Michel's words they are scanning "anything and everything that is ordered and stored for any of our departments." To date they have scanned product barcodes for Our Lady of the Lake Regional Medical Center, St. Elizabeth Hospital, Louisiana State University (LSU) Surgery Center, Our Lady of Lourdes Regional Medical Center, and St. Francis Medical Center.

The FMOLHS team sends the scanned product data to their supply chain solutions provider GHX, which in turn compares the data to data they have sourced from the FDA's Global Unique Device Identification Database (GUDID) and GS1's Global Data Synchronisation Network (GDSN). The correlated data is then loaded to their Clinical ConneXion solution. This platform leverages FMOLHS' virtual item master, purchase order (PO) history and contract data to feed cleansed and enriched product data, including the DIs, to the FMOLHS EHR system for clinical processes, including patient medical record documentation and billing. This platform leverages FMOLHS' virtual item master.

As a clinician uses a product on a patient in a procedural area (e.g. OR, Cath Lab), he/she scans the product's barcode into the EHR to auto-populate the DI information within the patient's medical record. If the barcode also contains the production identifier (PI[3]) portion of the UDI, this too will populate into the medical record. If the barcode does not contain the PI, then the clinician manually enters this information (e.g. lot/batch number, serial number, expiration date, etc.) into the EHR. For medical devices, the DI and PI data is automatically transmitted from the EHR to FMOLHS' third party UDI tracking solution. During a procedure or operation, the DI information is scanned if shown in a barcode, and the PI information is scanned if in a barcode or typed into the EHR if just human readable. Then, the DI and PI is automatically transmitted from the EHR to Champion UDI Tracker, FMOLHS' third party UDI tracking solution.

A green indicator light on the scanner and an audible beep tell the clinician that the product barcode has successfully scanned. When a clinician comes across a product with a barcode that does not scan correctly, he/she can still use the product on the patient but places the empty package into a designated tote. The FMOLHS supply chain team collects these totes every couple of days, researches the problem, resolves the issues and alerts GHX to make the necessary updates to FMOLHS virtual item master.

The FMOLHS team has captured product data from multiple barcode modalities, including the GS1 GTIN, HIBCC Labeler Identification Code (LIC), and the Universal Product Code (UPC) within its systems so that a clinician captures the required data regardless of which barcode he/she scans at the point of use.

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[3] A production identifier (PI) is a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device:

- the lot or batch number within which a device was manufactured;
- the serial number of a specific device;
- the expiration date of a specific device;
- the date a specific device was manufactured;
- the distinct identification code required by §1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device.

DATE INITIATIVE WAS IMPLEMENTED

March 2017

CHALLENGES TO IMPLEMENTING A UDI CAPTURE SOLUTION

According to Michel, they have encountered products that do not contain PI information on the unit of use packaging. If the product's higher levels of packaging contain the DI information, the supply chain team can capture that information in the integrated systems. But if the individual item's package contains no PI information, the clinician cannot record it at the point of use.

"Let's say the product comes in a case or a box, and the clinician is only using one in that box, if that information isn't on the unit of use they can't enter it into the EHR," said Michel. "They can later backtrack and do a lot of research to see if they can get the information - sometimes they can get it and sometimes they can't."

Michel also reports that there have been instances where a product will have barcodes on its packaging in one shipment, but then in the next shipment there are no barcodes. She has determined that this is the case when the health system receives older stock where the manufacturer has not yet applied barcodes to the labeling.

Another issue is barcode standardization. Michel says some product packaging contains multiple barcode modalities – with some having a GS1 GTIN, HIBCC LIC and/or UPC barcode. Each of these barcodes can contain different information. She also notes how sometimes a product will have a barcode containing the DI information but not the PI information.

"If there are many barcodes on the package then the nurse doesn't know which one to scan," said Michel. "If the barcodes are too close together on the package the nurse will literally have to put a finger over one of them so that he/she can scan one at a time. If we could get everything in one 2D barcode that would be so much easier because a nurse would just scan that one little box and the data would populate all of the required fields."

STAKEHOLDERS INVOLVED

- FMOLHS executive team
- VP of materials management
- Purchasing team
- Project manager
- IT team
- MMIS team
- Clinicians
- Facility leaders
- Nurses
- Physicians

- Accounts payable (AP) team
- Logistics team
- ERP system vendor (Lawson)
- EHR system vendor (EPIC)
- Supply chain solutions vendor (GHX)

SOLUTION

The FMOLHS team has scanned barcodes on products used within the health system and this product DI data is contained within their virtual item master. The virtual item master feeds this data to FMOLHS' EHR system. When a clinician scans a product's barcode at the point of use, the EHR populates the product's DI data into the patient's record by referencing the virtual item master. If the product barcode contains PI information, the scan populates this data into the patient's record as well. If the PI data is not contained within the barcode, the clinician can manually enter it into the EHR. If the product is a medical device, the DI and PI data is also automatically transmitted to FMOLHS' UDI tracking solution.

SOLUTION PROCESS:

The graphics in the Appendix represent FMOLHS' processes and workflows as of October 2017, they will continue to evolve as the health system implements its UDI capture solution throughout its facilities.

TECHNOLOGY USED OR IMPLEMENTED AS A RESULT OF THIS INITIATIVE

- Lawson enterprise resource planning (ERP) system
- GHX Clinical ConneXion solution
- Champion UDITracker solution
- Honeywell barcode scanners
- Epic electronic health record (EHR) system

SUCCESS FACTORS

Michel notes that close collaboration with the clinical team is a key factor to success. She and her team diligently communicate with the nursing staff to provide them with all of the information they need and to answer their questions. She adds that her team is visibly present in the clinical areas to provide support and frequently follows up to ensure things are going well as the solution rolls out.

Other success factors include:

- Bringing the right stakeholders to the table.
- Constant communication and personal interactions.
- Thorough training for everyone involved, including follow up to ensure they are comfortable with the new processes/solutions.

- Doing what you say you are going to do – following through on your commitments.

LESSONS LEARNED

"Originally I was told the nurses would reject these new processes but it has been the total opposite," said Michel. "They love scanning versus typing in all the numbers because it saves them so much time."

NEXT STEPS

Michel and her team want to take the information they are capturing in the EHR and move it beyond to:

- Claims: Transmitting the data captured in the EHR system to payers, including the Centers for Medicare and Medicaid Services (CMS) to facilitate claims processing.
- Registries: Transmitting the data captured in the EHR system to clinical registries, such as the National Cardiovascular Data Registry (NCDR).

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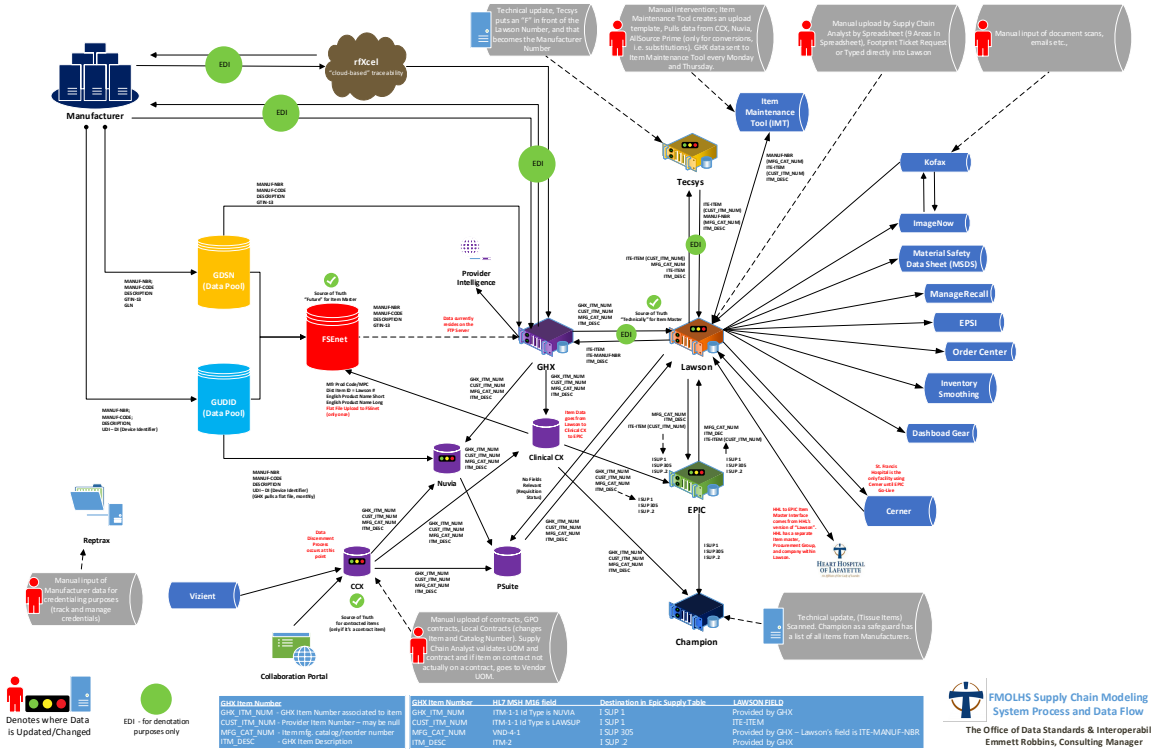
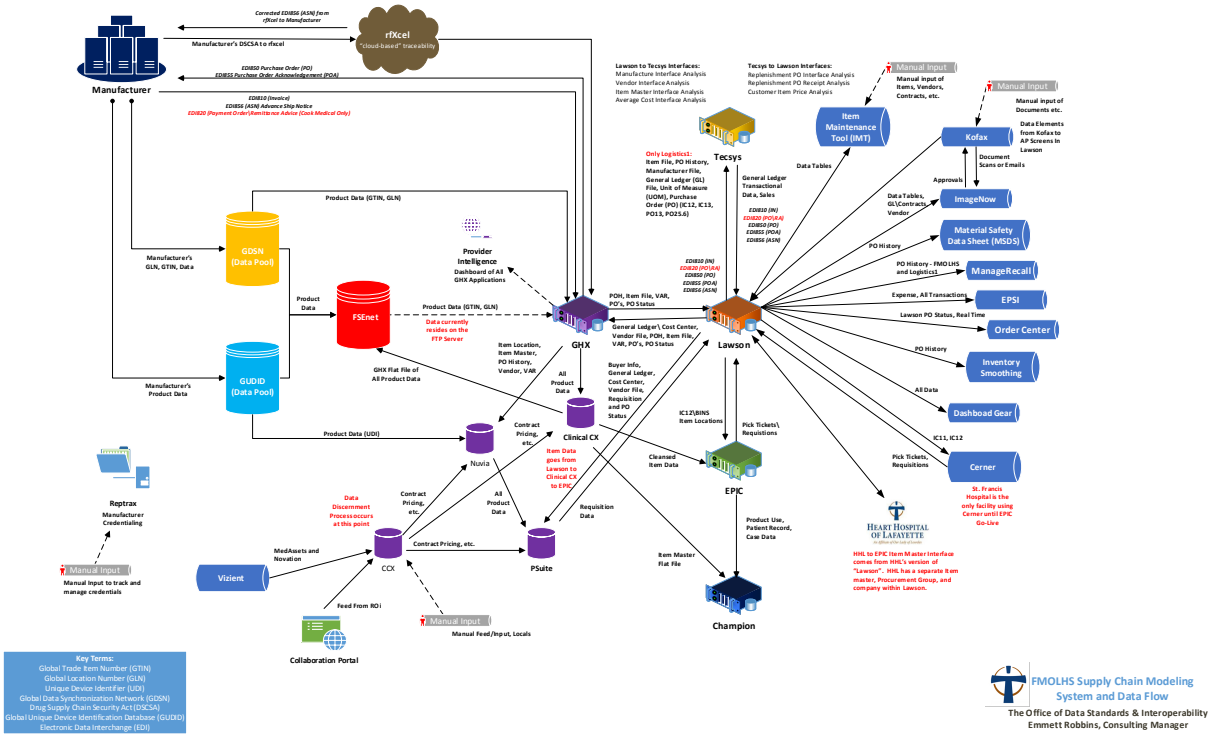
APPENDIX:

Graphic 1: Supply Chain Processing Mapping: Source of Key Attributes



Graphic 2: Supply Chain Data and Process Analysis: System to System Interoperability



APPENDIX 1: GS1 UDI Label Example

UDI Components

UDI = Device Identifier (DI) + Production Identifiers (PI)

GTIN® + Application Identifiers (AI)

*Another Production Identifier is Manufacture Date

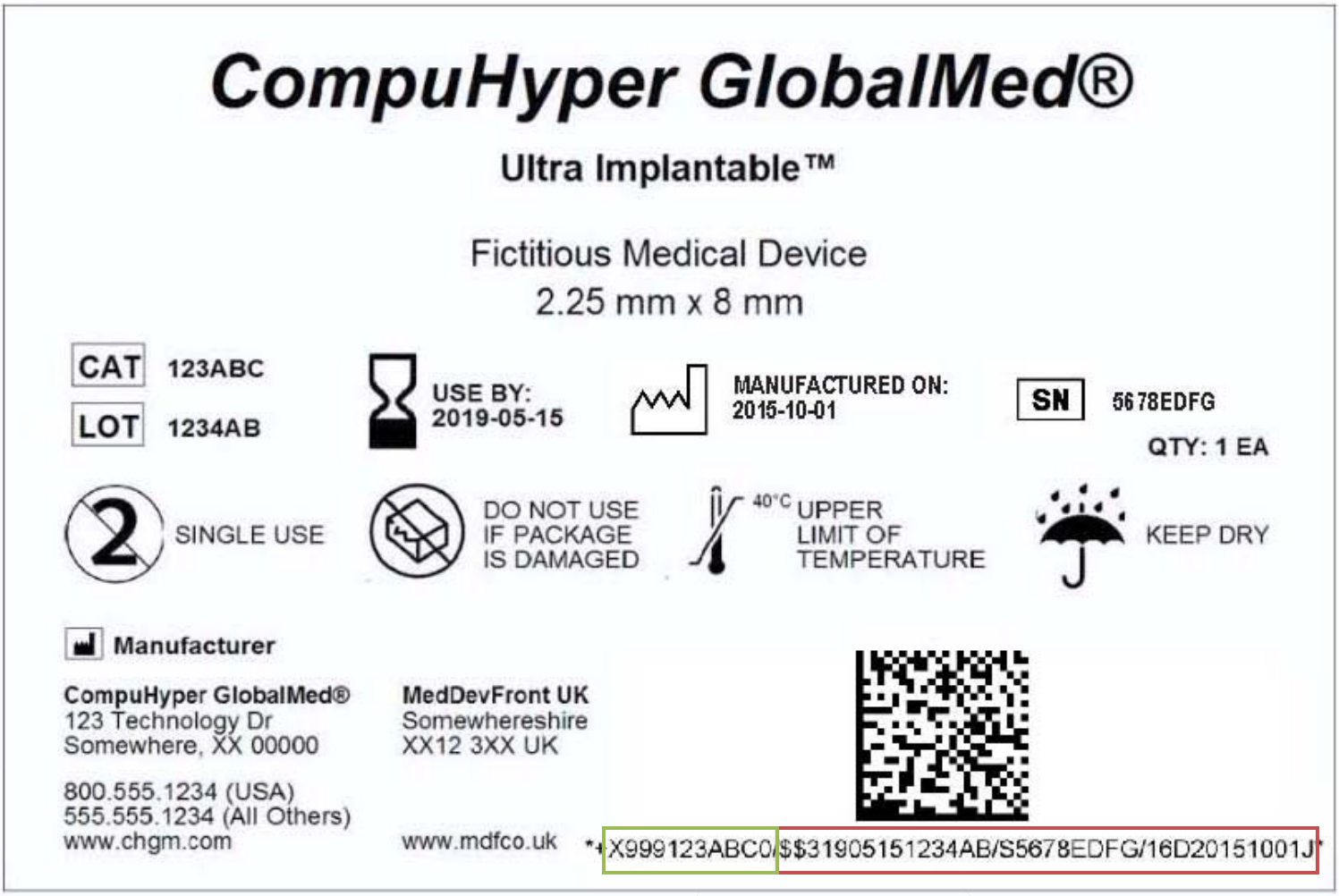
APPENDIX 2: HIBCC UDI Label Example

Health Industry Business
Communications Council

2525 E. Arizona Biltmore Cir.
Suite 127
Phoenix, AZ 85016
602-381-1091
FAX 602-381-1093
www.hibcc.org

HIBCC UDI Label Example

DataMatrix

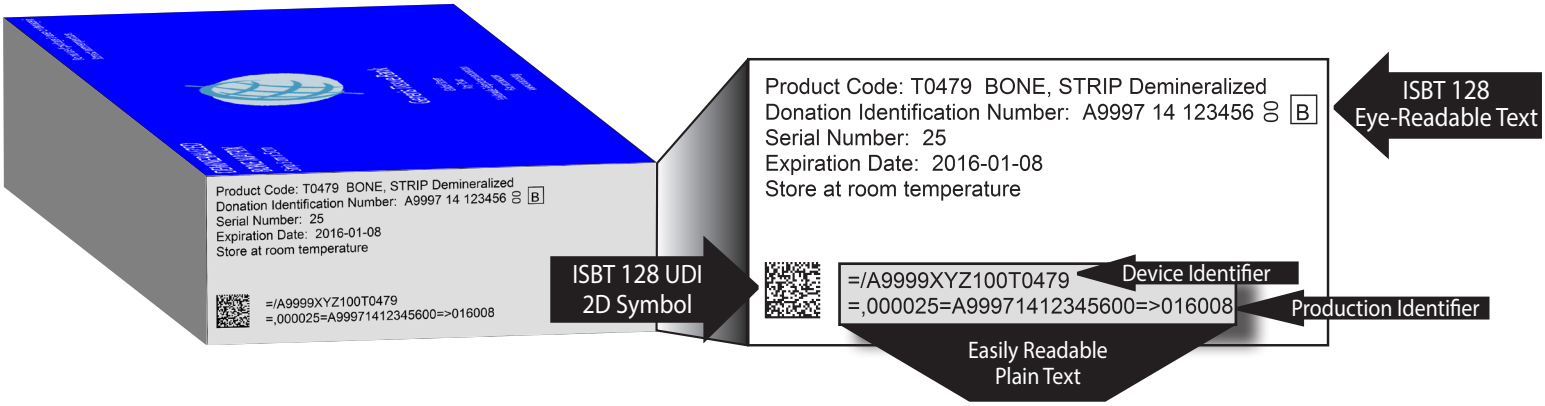


APPENDIX 3: ICCBBA UDI Label Example

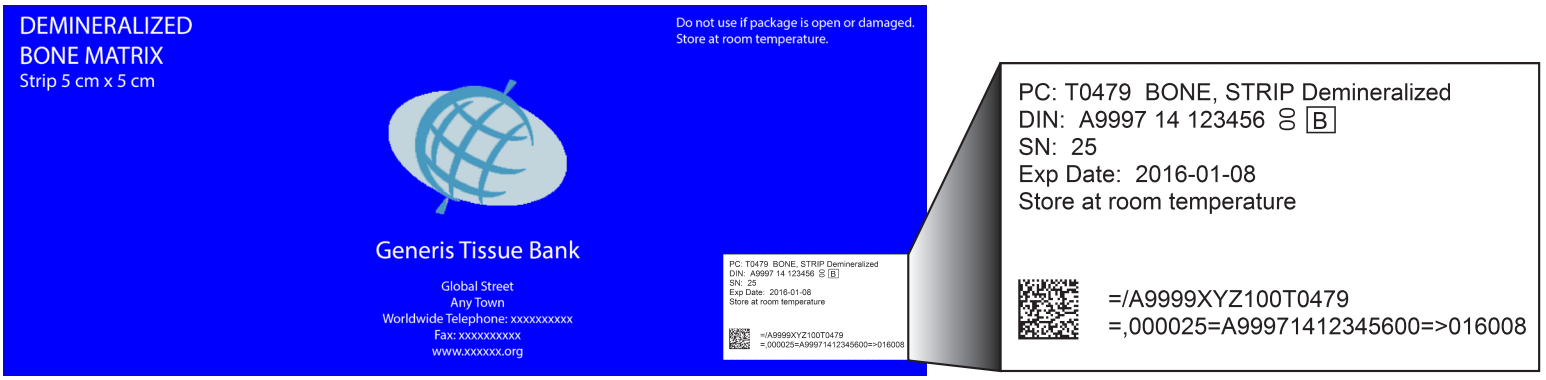
USING ISBT 128 UNIQUE DEVICE IDENTIFIER ON MEDICAL DEVICES THAT CONTAIN HUMAN TISSUE

ISBT 128
More than Identification

Medical devices containing Human Cells, Tissues, or Cellular and Tissue-Based Products (HCT/P) labeled using ISBT 128 will provide UDI information, including the Donation Identification Number, in a standardized electronically-readable format and in eye-readable text. These illustrations show examples of how the information may be presented. The two-dimensional symbol contains the critical tracking information. Receiving systems should be programmed to scan and interpret this symbol to provide optimal efficiency and accuracy.



Item	Recommended Abbreviation(s)	What it Identifies
Donation Identification Number	DIN	This identifier links the product to its donor (the Distinct Identification Code as required by 21 CFR 1271.290(c)).
Product Code	Prod Code or PC	This code identifies the type of product (e.g., bone powder or a pre-sutured tendon).
Pack Number or Serial Number	Pack or SN	This code uniquely identifies a specific product for a given DIN and Product Code.
Expiration Date	Exp or Exp Date	The date on which the product should no longer be used.
Manufacturing or Production Date	Mnf Date or Prod Date	The date on which the product was made.
Lot Number	Lot No. or LN	This identifier links to a production record of the process or the tissue.
Device Identifier	DI	The FDA UDI Device Identifier (identifies the specific version or model of a device and the labeler of the device).
Production Identifier	PI	The FDA UDI Production Identifier (information that more precisely identifies the device).



GS1 and ICCBBA Joint Guidance recommends use of ISBT 128 on medical devices containing HCT/P.