Healthcare

White Paper: Non-Sterile Orthopedic Implants & UDI Capture

Options, Challenges, Benefits and Next Steps

GS1 US Orthopedic Implant Workgroup

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1 Executive Summary

In 2016, GS1 US® established the *Orthopedic Implant Workgroup* ("the Workgroup") to support industry's effort to analyze challenges to making the full U.S. FDA Unique Device identifier (UDI) for non-sterile orthopedic implants available at the point-of-use. The Workgroup was comprised of device manufacturers, healthcare providers, and hardware and software solution providers. The goal of the Workgroup was to examine current processes to identify requirements and challenges to maintaining UDI Device Identifier (DI) and Production identifier (PI) information with the implant, and evaluate UDI capture options in terms of benefits and challenges from both the manufacturer and provider perspective.

The Workgroup set out to satisfy that goal through three efforts:

- Detailed analysis of data and device process flows

- Site visits to hospitals to observe a live orthopedic surgery to enhance the participants' understanding of the complexity of the operating room (OR) environment where the UDI is to be captured

- Analysis of the various options for feasibility, benefits and challenge from the perspective of manufacturer and provider based on the process flows and site visit experiences

This white paper serves to document the Workgroup's analysis, impressions, and insights in order to support the on-going industry efforts identify solutions to the challenges.

Note: GS1 US is not a representative or agent of the FDA, and the content herein has not been reviewed, approved or authorized by the FDA.

2 U.S. FDA UDI Rule

On September 24, 2013, the United States Food and Drug Administration (FDA) published a rule ("*the UDI Rule*") establishing a unique device identification system for medical devices.[1] Under the rule, the healthcare community and the public will be able to identify a device through a Unique Device Identifier (UDI) that will appear on the label and package of a device in both plain-text format and a format that can be read by automatic identification data capture (AIDC) technology (e.g., a barcode). Pursuant to Sec. 801.45 of the rule, a device must also bear a permanent marking providing the UDI on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use.

A UDI is a unique numeric or alphanumeric identification code assigned to medical devices by the labeler (e.g., manufacturer) of the device. A UDI includes two segments: a "device identifier" and a "production identifier":

- Device Identifier (DI): a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device

- Production Identifier (PI): a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device: (i) lot or batch number; (ii) serial number; (iii) expiration date; (iv) date of manufacture; and (v) for an HCT/P regulated as a device, the distinct identification code

According to the UDI Rule, a *device identifier* is always present in a UDI. However, a *production identifier* is only required if it otherwise appears on the device label. Therefore, UDIs can be comprised of either DI only, or DI+PI. Because most implants include at least one piece of production information on the label, most UDIs would include a *production identifier*.

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[1] 21 CFR § 801 (2013).

3   Non-Sterile Orthopedic Implants

The goal of the UDI Rule is to establish a system for the adequate identification of medical devices through distribution and use. To that end, the UDI provides a standardized way to identify medical devices in health-related information systems, such as electronic health records (EHR), claims, and devices registries.[2] The Office of the National Coordinator for Health IT (ONC) has noted that recording and exchanging UDIs in patient EHRs would enable clinicians to accurately identify a patient's implantable devices and prevent adverse events resulting from misidentification or non-identification of a device.[3] Non-sterile orthopedic implants (e.g., screws, plates, etc.) present unique challenges for meeting that objective.

Basic Process:

Generally, non-sterile orthopedic implants (i.e., hospital sterilized implants) are delivered unsterile from the manufacturer, intended to be sterilized by the hospital prior to the procedure. Due to the number, variety, and small size of these devices, they are usually stored in trays (or sets). These trays (holding hundreds of these small devices) may be assembled by the manufacturer or by the hospital itself. The entire tray gets sterilized prior to the procedure. During surgery, the surgeon uses what is needed. Then, the tray is disinfected and returned to storage to be replenished periodically on-site and re-sterilized for the next surgery.

Key Challenges:

- the UDI is usually lost when the device is removed from its packaging and placed into an orthopedic tray to be sterilized

- the size, shape and substrate of the implants can complicate and/or frustrate direct marking of the UDI on the device itself

- these devices are used in a surgical setting which complicates and restricts options for UDI data capture at point of use due to heightened patient safety concerns

4   FDA & Industry Response

Recognizing these challenges, the FDA provided a 2-year extension of the UDI labeling compliance date for non-sterile orthopedic implants in order to provide additional time for effective approaches to be developed to address the challenges.[4] Since that time, the FDA and industry have continued to work together toward a solution:

In March 2016, the FDA confirmed that capture of the DI alone meets the objectives of the UDI rule for those non-sterile implantable devices where it would not be technologically feasible to capture the full UDI at point of implantation. In addition, the FDA also confirmed that using cross-reference tools (like Inventory Control Sheets) to capture the DI were acceptable methodologies until technologies to enable capture of the full UDI become available (i.e., capturing a device's DI by scanning a barcode on an Inventory Control Sheet instead of scanning a barcode on the device).[5] However, the FDA noted that it understood that industry will continue to develop technologies for making the full UDI available at the point of use that do not rely on indirect methods such as cross-reference tools, and that they look forward to receiving updates on industry's progress.

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[2] Linda Sigg, Center for Devices and Radiological Health, U.S. Food and Drug Administration. Unique Device Identification (UDI) System Regulatory Overview. January 27, 2016.

[3] Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS). *Notice of proposed rulemaking: 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications*. March 30, 2015.

[4] *FDA Letter to Implant Labelers, November 19, 2014*.

[5] *FDA Response to AdvaMed, March 22, 2016*.

5   Device and Data Process Flows

In preparation for the site visits and to promote fuller understanding of the current state, the Workgroup defined the lifecycle of orthopedic implant trays, and mapped out the data and device process flow for both manufacturers and providers.

5.1   Orthopedic Implant Trays - Lifecycle

1. **Manufacture, Mark and Verify**
   - □ Devices are manufactured and marked by manufacturers
   - □ Barcode quality is verified on devices marked with a barcode

2. **Document and Transfer for Assembly**
   - □ Device data is documented and stored in master databases by manufacturer

3. **Tray/Set Assembly and Assignment and Transport**
   - □ Ownership of Trays is assigned
   - □ Trays are consigned, loaned, purchased, or brought by manufacturer representative
   - □ Trays may be assembled by manufacturer representative or hospital Sterile Processing Department (SPD) personnel

4. **Tray/Set/Device – Healthcare Facility Entry Process**
   - □ Trays are received at hospital Central Supply or SPD
   - □ Assigned to specific physical location
   - □ SPD Department Replenishment Process for old trays
     - Verify device trays and check for replenishment
     - Configure tray
     - Sterilize
     - Wrap
     - Store
     - Reserve for surgical case
     - Transport to OR

5. **Hospital Scheduler – Reserve/Order set for Case (based upon surgeon preference)**
   - □ Based on schedule, reserve trays
   - □ Hospital owned/stocked or consignment, loaned
   - □ Assign room location, surgery, patient, date, time etc.

6. **Start Case and Document UDI for any implemented device**
   - □ Multiple Options for UDI Capture
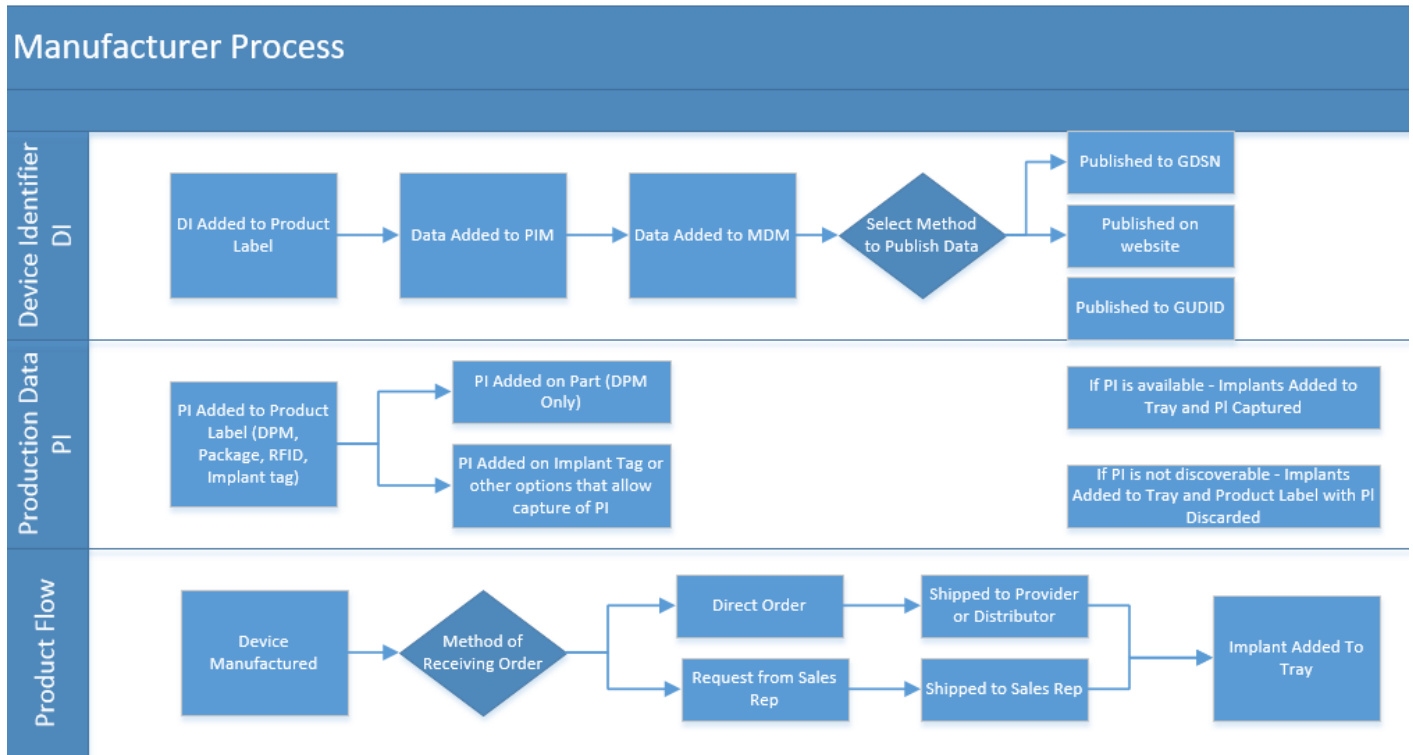
7. **Complete Case**
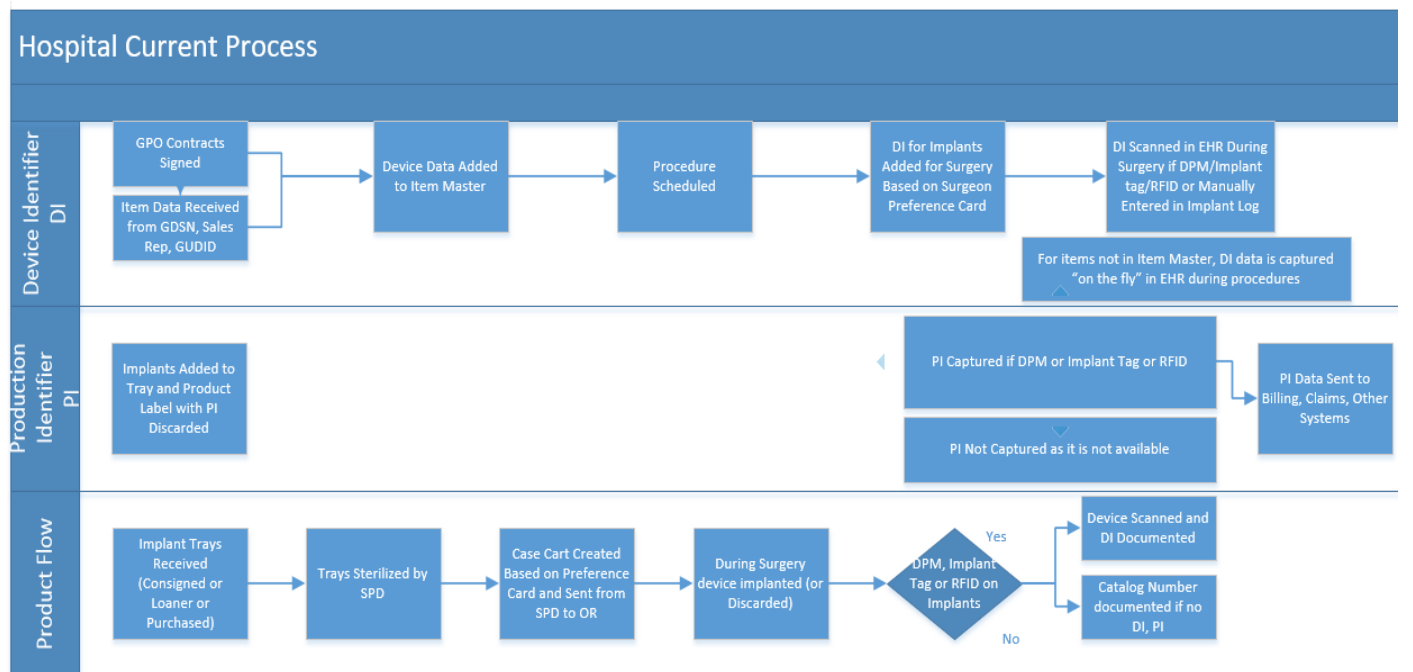   - □ Device usage is documented and stored in EHR

8. **Post Case Process – Return, replenish, prepare**
   - □ Unused trays are sent to SPD
   - □ Replenishment process is completed for used devices

5.2 Manufacturer Process

5.3 Current Hospital Process

6   Site Visits: Observations & Insights

The Workgroup conducted site visits to observe live orthopedic surgeries in order to enhance the participants' understanding of the complexity of the OR environment where the UDI is to be captured. The Workgroup visited two hospitals, including multi-day visits to two large hospital systems.

The goals of the site visits were to:

- Observe cases being performed

- Document the current processes for capturing UDI

- Document technology requirements needed to capture UDI without impeding the flow of the procedure

Workgroup participants found the site visits to be invaluable. The experience enabled participants to observe and learn about the challenges providers undergo on a daily basis, and to realize and remember that the most important thing in the OR is the patient- not how to capture the UDI. Even manufacturers who are accustomed to being in ORs to assist with their devices found the experience to be extremely valuable. These manufacturers noted they are usually focused only on the patient and the devices. The site visits were the first time many of them had focused on OR systems and processes, which they felt provided tremendous insights to help them support their provider customers. In addition, the site visits provided concrete experiences that helped context other experiences that Workgroup participants have had in their own work, and triggering additional insights about the challenges and issues. Key observations and insights are discussed below.[6]

6.1   OR Environment

- The sheer volume of work and responsibility on the OR nurses was eye-opening to participants, and reinforced that whatever solution is used must be easy and fast without increasing staff.

- There are numerous devices and supplies used in a surgery. Markings need to be predictable in order to support the nurse in locating and scanning barcodes (i.e., there should be no variations between what is marked and what is not; where marks are located; etc.).

- The primary focus in the OR is and must be on the patient. Therefore, the *timing* and *location* of data capture should be fully considered when evaluating data capture options in order to not distract from or undermine focus on patient safety and the success of the procedure.

- Barcodes are being read at the same time as the surgical procedure. There is a tremendous amount of work for the circulating nurse to manage. As a result, the first time a barcode does not scan, they tend to stop scanning and go back to manual recording or not recording at all.

  - Unsuccessful experiences scanning barcodes runs the risk of nurses abandoning barcode scanning all together and opting instead to simply write the information to avoid the confusion. Because manual data entry is error-prone and slow, promoting barcode readability in the OR is essential.

6.2   Causes of Barcode Readability Issues

Some providers report issues that barcodes do not scan properly, assuming the issue was barcode quality. However, readability issues may not be related to barcode quality – but to issues in provider IT systems related to data, systems integration, and item masters. Four key types of problems were identified:

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[6] Survey performed and resulting data was limited in scope and is not intended to be an exhaustive review of the issues discussed and should not be relied on as such. The information provided is for informational purposes only and is not intended to disparage or otherwise reflect negatively on any individual company. Your reliance on the information presented is at your own risk and GS1 US, Inc. will not be responsible for any liability arising from or related to your use thereof.

- **Absence of data**: The prevailing theory for item master management at healthcare providers has been to limit the product data stored in the item master to only those products that are routinely used (instead of storing data for all products).[7] As a result, there are many products used in hospitals that are not in the item master. This can cause barcodes to fail because if the GTIN encoded in a barcode is not in the system, the scan will fail.

- **Lack of systems integration**: EHR system modules used in the OR are not often integrated with Enterprise Resource Planning (ERP) or supply chain systems. The absence of systems integration in this area and/or incompatibility of systems can undermine data availability and data quality.

- **Lack of data governance processes**: OR systems often do not have a data governance process in place to help them resolve data quality issues once they are discovered.

    - For example, a typical pharmacy system has a reconciliation process. When an issue occurs, the data is recorded and held in a reconciliation page so the provider can address and resolve the issue (e.g., add to the item master; edit in the item master; mark as an exception; etc.). This type of mechanism provides a vehicle for working to resolve data quality issues.

    - However, OR systems typically do not have this mechanism, making it harder to fix a data quality issue so that the scanning problem does not occur again in the next surgery.

6.3   Lack of a Standard Definition of Implants versus Supplies

- Providers have their own definition scheme for what constitutes an "implant" (which are recorded in patient records) versus what is considered "supplies" (which are not recorded in patient records).

- This definition does not always align with the definition of implantable devices as defined in UDI Rule.

- As a result, there are many devices categorized as implantable devices under the UDI Rule for which the UDI will not be captured in the OR because they are considered "supplies" under the provider definition.

7   Evolving UDI Capture Technologies

Using the process flows as well as the observations and insights gleaned from the site visits, the Workgroup examined current UDI data capture options for feasibility, benefits and challenges. In addition, brainstorming by the Workgroup identified two additional options that could be considered. The UDI capture technologies examined in this section are:

- Inventory Control Sheet

- Data Carrier Tags

- Data Carrier Strips

- Sterile Packaged Items

- Direct Part Mark

- Sterile Field Scanners

- Radio Frequency Identification (RFID) Tags

- Software Solutions for Tray Mapping

The feasibility, benefits and challenges identified below represent both the manufacturer's perspective as well as the provider's perspective in order to promote a holistic view of each option. They represent

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[7] Karen Conway. *Item data: It's not just for supply chain anymore*. Healthcare Purchasing News. August 24, 2016.

the current thinking of the Workgroup based on the process flow analysis, site visit observations and learnings, as well as participants' own experiences.

7.1 Current Approach

7.1.1 Inventory Control Sheets

General Description: In preparing for a case, the OR nurse sets up Inventory Control Sheets for all of the devices to be brought into the OR. An Inventory Control Sheets is set up for each manufacturer listing devices with vendor part number and description along with the corresponding DI (e.g., GTIN) and GTIN barcode for each device. Space is also provided for quantity and lot number. Manufacturers have on-line tools providers can use for to set up the Inventory Control Sheet for their products (i.e., select products and the tool automatically populates the form with the information). Each manufacturer has their own tool listing only their devices. Either a nurse, manufacturer representative, or hospital material management staff member visits each site to set up all of the necessary Inventory Control Sheets for the case. During the procedure, when the surgeon calls for a device, the circulating nurse locates the device in the Inventory Control Sheet and enters the quantity in the space provided. After the surgery, the nurse gathers all of the Inventory Control Sheets and enters the information for the devices used into the patient record by either scanning the barcode on the Inventory Control Sheet or manual data entry.

Note: Examples of Inventory Control Sheet tools: *Depuy Synthes*, *Stryker*.

Table 7-1 Inventory Control Sheets

Benefits and Challenges	
UDI Capture	▪ DI always, PI if available from the product (PI is captured not from the control sheets but from the product)
Benefits	▪ Based on existing OR practices ▪ Currently in use ▪ Ease of implementation ▪ Supported by manufacturer tools ▪ Leverages AIDC
Manufacturer Challenges	▪ Often not feasible to also make PI available on certain implants because of size, material or other constraints
Hospital Provider Challenges	▪ Incomplete and/or inaccurate data in item master and supporting databases can cause barcode readability issues ▪ OR nurse needs to prepare Inventory Control Sheets for each manufacturer individually (i.e., no one tool where all devices listed together) ▪ Multiple step process for OR nurse: record usage during procedure then enter the information from the sheets into patient records after procedure ▪ UDI Rule definition of "implantable device" not aligned with provider definition of what constitutes an implantable device to be captured and recorded in the patient record ▪ Technical issues at providers undermining barcode readability and customer experience/satisfaction ▪ PI will have to be captured in conjunction with another solution

7.2   Other Options (previously identified)

7.2.1   Data Carrier Tags

General Description: A tag marked with the UDI in human readable text and a barcode is affixed to the product by the manufacturer. When the device is selected in the OR, the nurse removes the tag and captures the UDI either electronically (scanner) or manually to be recorded in the patient's EHR.

Table 7-2 Data Carrier Tags

Benefits and Challenges	
UDI Capture	▪ DI and PI
Benefits	▪ Possible to mark and document the full UDI on tag ▪ Leverages AIDC
Manufacturer Challenges	▪ Proprietary solution of one device manufacturer who uses it for devices they manufacture ▪ Large percentage of products are too small to have a tag attached ▪ Not feasible for devices that need to be held in tray holes
Hospital Provider Challenges	▪ User training ▪ Tag getting separated from device could cause issues

7.2.2   Data Carrier Strips

General Description: Devices from the same lot are affixed to plastic strips loaded in surgical trays. Each individual device has its own plastic UDI label. When the device is selected in the OR, the nurse snaps the device off the strip and captures the UDI either electronically (scanner) or manually to be recorded in the patient's EHR.

This approach is not currently in use and therefore was not reviewed by the Workgroup.

7.2.3   Sterile Packaged Items

General Description: Devices are supplied in sterile packaging marked with the UDI in human readable text and a barcode. When the device is selected in the OR, the nurse removes the device from its package and captures the UDI electronically (scanner) or manually to be recorded in the patient's EHR.

Table 7-3 Sterile Packaged Items

Benefits and Challenges	
UDI Capture	▪ DI and PI
Benefits	▪ Possible to mark and document the full UDI ▪ Leverages AIDC
Manufacturer Challenges	▪ Not feasible for devices that need to be stored in tray holes ▪ Additional space to store sterile products ▪ Need new storage strategy for individual packages since sterile packaged products would not fit in existing tray slots ▪ Timeline to implement new sterilization method
Hospital Provider Challenges	▪ Sterility expiration ▪ Additional space to store products ▪ Nursing staff additional processes ▪ Operational impact ▪ Increased cost for sterile products ▪ Disposal of sterile packaging material

7.2.4 Direct Park Mark (DPM)

General Description: Devices are directly marked with their UDI in human readable text and/or a barcode using a permanent marking method like etching, engraving, etc. When the device is selected in the OR, the nurse captures the UDI either electronically (scanner) or manually to be recorded in the patient's EHR.

✅ **Note**: Implant size, substrate material and other constraints impact what parts of the UDI can be imprinted on implantable orthopedic devices (i.e., larger devices may be able to accommodate human readable and barcoded DI and PI; some medium sized devices may only have space for a barcoded DI and PI (no human readable); small devices may not be able to accommodate any marking; etc.).

There is an on-going effort to evolve current data matrix standards to include a smaller symbol size to accommodate DPM on small orthopedic implants like screws. Although the ISO standards for data matrix symbols do not impose size limitations, the commercial standards used to implement the ISO data matrix standards, including GS1 Standards, do impose size restrictions (as discussed by the _Association for Automatic Identification & Mobility (AIM) in their letter to the FDA dated December 6, 2016_). Key developments:

■ Existing scanners at providers might not be able to capture the new small barcode. However, scanner solutions are being developed around the smaller symbol size.[8]

■ Some manufacturers have begun examining use of the smaller symbol size for DPM.[9]

■ As data matrix evolves, GS1 Standards to accommodate the smaller symbol size can be developed pursuant to the GS1 Global Standards Management Process (GSMP).

Table 7-4 Direct Part Marking

Benefits and Challenges	
UDI Capture	▪ DI and PI (depending on size)
Benefits	▪ Possible to mark and document the full UDI ▪ May leverage AIDC ▪ Ease of use ▪ Direct capture from the device
Manufacturer Challenges	▪ Marking extremely small devices ▪ Ensuring efficacy of direct marking related to specific device shapes and materials
Hospital Provider Challenges	▪ Introduction of new technology ▪ New equipment may be needed ▪ Compliance and user training ▪ Process changes and additional cost to implement scanners

7.2.5 Sterile Field Scanner Systems

General Description: Devices are marked with their UDI using either a direct mark on the device (e.g., etching, engraving, etc.), a tag, or a sterile packaged device. When a device is selected in the OR, the nurse uses a wireless sterile field scanner to electronically capture the full UDI (DI+PI) at the point of selection in the OR.

✅ **Note**: Sterile field scanners are being presented here as an example of emerging technology and the thought leadership that is on-going with regard to orthopedic implant UDI capture issues. Key developments:

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[8] Link to Matrix IT Video showing scanner for DPM Capture: _https://www.youtube.com/watch?v=tEY_lXw9pTo_
[9] _Current Landscape of UDI Implementation_. Ad Hoc Spine/Trauma Trays and UDI Working Group. AdvaMed. June 05, 2017.

- Sterile field solutions have been developed to accommodate the smaller symbol size in addition to existing symbols and sizes.
- Sterile field scanner systems have been developed to enable the OR nurse to enter a UDI from any/all marking methods (e.g., sterile packaging, direct marking, data carrier tag/strip, etc.) and collection methods (e.g., scanning, manual data entry from an HRI, cross-reference sheet, etc.).
- Within milliseconds, sterile field scanning allows hospitals to collect UDI data without relying upon additional staff to "count" and report utilization.
- Permits devices to remain configured in sets in the field without expiration.
- Example of a sterile field scanner system: *Matrix IT Video of scanner for DPM Capture*.

Table 7-5 Sterile Field Scanner Systems

Benefits and Challenges	
UDI Capture	▪ DI and PI
Benefits	▪ Possible to capture the full UDI ▪ Direct capture from the device at point of use ▪ Leverages AIDC ▪ Ease of use
Hospital Provider Challenges	▪ Introduction of new technology ▪ New equipment may be needed ▪ Compliance and user training ▪ Process changes and additional cost to implement scanners

7.3 Additional Options (identified by Workgroup)

7.3.1 RFID Tags

General Description: An RFID tag encoding the UDI in human readable text is affixed to the product by the manufacturer. When the device is selected in the OR, the nurse removes the tag and captures the UDI electronically (scanner) or manually to be recorded in the patient's EHR.

✅ **Note**: Workgroup participants identified this option for consideration in this effort, but was not aware of any studies on this.

Table 7-6 RFID Tags

Benefits and Challenges	
UDI Capture	▪ DI and PI (dependent on size)
Benefits	▪ Possible to mark and document the full UDI ▪ Leverages AIDC ▪ Ease of use ▪ Direct capture from the device
Manufacturer Challenges	▪ Not typically feasible to implement on existing device designs ▪ Not feasible for smaller devices ▪ Cost ▪ Technology not proven for autoclave (sterilization) life cycles
Hospital Provider Challenges	▪ Introduction of new technology ▪ Cost of solution ▪ New equipment may be needed ▪ Patient privacy issues for implantable items

7.3.2 Tray Mapping Software

General Description: Workgroup participants identified this concept of browser-based maps of a surgical implant tray. As devices are taken from the tray, system will capture removal as usage. This approach is being presented here as an example of the brain-storming and thought leadership that is on-going with regard to these challenges.

✅ **Note**: This potential approach is not currently developed or available. The Workgroup is not aware of any studies on this.

Table 7-7 Tray Mapping Software

Benefits and Challenges	
UDI Capture	▪ DI and PI
Benefits	▪ Ease of use
Manufacturer Challenges	▪ Solution is dependent on user compliance ▪ Devices cannot be moved from original spots in programmed tray locations ▪ Could result in incorrect information being recorded if devices are moved from one location to other
Hospital Provider Challenges	▪ Surgeon preference tray configuration would be challenging ▪ Compliance and user training ▪ Cost of solution

8   Conclusion & Recommendations

The Workgroup set out to conduct a detailed analysis of data and device process flows, observe live surgeries, and analyze the various options. Their work highlighted and reinforced the complexity of the OR, and the challenges associated with managing these devices efficiently and effectively to support the safety of the procedure. The insights gained enabled the Workgroup to identify positive next steps.

8.1   Improve DI Capture and Minimize Manual Data Entry

The current method of using Inventory Control Sheets (as described above) has proven an effective approach for capturing the DI. As efforts to find a solution for capturing the full UDI continue, there is a clear opportunity to improve and enhance this process.

Nurses enter the information for the devices used into the patient record by either scanning the barcode on the Inventory Control Sheet or manual data entry (which is an error-prone, inefficient process to be avoided). Barcodes are made available to help nurses avoid manual data entry, but providers have had serious issues with barcodes not scanning -- which has only increased and promoted the use of manual data entry in the OR.

The Workgroup believes that minimizing manual data entry is extremely important. During the study, it became apparent that a major cause of barcode scan failures were caused by technical issues at the provider related to data quality, systems integration, and item masters. These issues can cause barcode scanning problems because if the GTIN encoded in a barcode is not in the system, the scan will fail. Therefore, the Workgroup recommends that a positive and valuable next step is to help providers resolve their system issues in order to promote the use of the barcodes, discourage manual data entry, and improve DI recording and accuracy:

▪ Providers have started working on projects to comply with Meaningful Use Stage 3 requirements for capturing/recording UDIs for implantable devices. Supporting and expanding such efforts to help providers improve their data issues is a valuable and achievable goal.

- As part of this effort, providers should be working to obtain GTIN data from authoritative sources, and store this data in their item master files.

  - Authoritative sources include the FDA Global Unique Device Identification Database (GUDID) and the manufacturers themselves.

  - Some manufacturers have been working to provide downloadable data to their provider customers to support Meaningful Use 2018 requirements.

  - Alternatively, providers can obtain data from some suppliers using the GS1 Global Data Synchronization Network™ (GDSN®).

- Another integral part of this effort is to address system integration issues so that OR systems have access to accurate, up-to-date GTIN data, and are connected with other providers systems to promote data quality and enhance data governance.

8.2 Implement Technology and Re-evaluate Other Considerations

One of the key take-aways from this effort was the universal opinion that a "one size fits all" solution is not only not available at this time, but likely not desirable. The category of "non-sterile orthopedic implantable devices" encompasses such significant variety that it seems very likely that there are devices for which capture of the full UDI is justified, and devices for which it is not.

- As industry continues to work toward new solutions, it is essential that providers start small. Placing initial focus on just capturing DIs using options like Inventory Control Sheets (where feasible) would be a valuable start.

- Once providers have the DI (GTIN) data available for most of the implantable devices in their item master files, they can expand to other options as they become available and feasible.

In addition, as industry continues to seek technical solutions for devices where it is justified, there is an opportunity the FDA and industry to work together to evaluate other factors beyond technology that provide insight about devices for which it might not be justified. Several findings from this project signal the need for such efforts.

- For example, there are many devices categorized as implantable devices under the UDI Rule for which the UDI will not be captured in the OR simply because providers do not consider them implantable devices to be recorded under their policies. If the primary reason for marking and capturing the full UDI is to support providers in recording that information, the fact that providers do not record that information for certain types of devices needs to be seriously considered.

- The need for/value of the information and the goals being served also need to be considered. For example, if recall is an important goal, then it might be valuable to assess the probability of recall of various device types, and especially the likelihood of surgical revision/removal (which is often decided based on the risks and benefits associated with having the patient undergo another surgery, as opposed to simply the existence of a defect).

As industry continues to seek technical solutions, a collaborative effort between FDA and industry to evaluate different types of devices and define a more detailed cost/benefit analysis that considers the need for, value and actual use of the information for each group would be a valuable effort.

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IAPMO

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*If applicable

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