UDI Challenge for Non-Sterile Implantable Devices

- Mary Gray, RAC
  Project Manager Regulatory Affairs | DePuy Synthes Spine
- Amy Delk
  Director, Regulatory Affairs | Stryker Corporation
- Mike Donoghue
  Vice President  Trauma Fixation Strategic Business Unit/Advanced Surgical Devices | Smith & Nephew
- Jackie Rae Elkin
Overview

• UDI implementation challenges that manufacturers of non-sterile spine, trauma, craniomaxillofacial, and extremities sets face

• Description of 4 compliance strategies companies may use to meet UDI requirement to adequately identify devices through distribution and use

• Recommendation for additional time for UDI implementation for products related to these orthopedic sets
Objectives

• Review the four UDI alternative solutions

• Allow direct marking regulations (21 CFR 801.45) for non-sterile implants

• Provide adequate time to implement alternative solutions
Impact to Public Health

• It is estimated that sets are used annually in:
  – 464,000 thoracolumbar procedures
  – 291,000 cervical procedures
  – 1,750,000 trauma procedures
  – 214,000 craniomaxillofacial procedures
  – 19,000 small joint (fingers, wrists, ankles) procedures
  – 2,738,000 total procedures

• Based on our data we estimate there are 221,130 sets currently in distribution
Why are Implants Organized in Non-sterile Sets?

• Procedures require a large number of implant options available to provide patients with customized solutions
  – Multiple sizes, lengths, and diameters needed due to anatomic variability
  – Pre-contoured implant choices to optimize outcomes
  – Many types of implant options may be used in a given procedure

• Sets are configured in an organized fashion so that OR personnel can correctly, quickly and efficiently identify the necessary implants and instruments
  – Ensures the correct choice of implant
  – Quick access to implant options minimizes OR time thus reducing anesthesia time, blood loss, and infection risk

• Sets are designed to be efficiently reprocessed and replenished for subsequent use
  – Improves surgical turnover time
  – Minimizes hospital need for storage space
Challenges

1. UDI-labeled packaging is removed prior to implants being placed in sets
2. Sets are assembled to meet specific orders
   – Hospitals, specific patients or surgeon preferences
   – This results in hundreds of potential configurations for one set
3. Sets are designed to be:
   – Sterilized prior to each use,
   – Typically consist of up to hundreds of implants, and
   – Are configured for easy identification and selection by surgeon/OR staff
4. Implants not used in surgical procedure remain in set and are reprocessed for subsequent use

5. Following cleaning and decontamination, but prior to subsequent use, set is replenished to ensure all necessary implants are available for next surgical procedure

6. Sets may be hospital owned (equity) or manufacturer owned (consignment/loaner)
   - Each set may contain 1000 implants
   - Surgeons typically use 3 to 15 sets per procedure
   - Surgeon may only use a few implants from each set
   - Hospital bills for each implant as it is used
   - Hospitals prefer consignment/loaner due to significant cost of sets
Clinical Group Perspective

• Met with AAOS, AANS, NASS, OTA and AORN via Web Conference on June 9

• We understand they have communicated directly with FDA

• Overarching concern expressed by clinicians: Do not lengthen surgical time and continue rapid access to implantable devices
UDI Solution Challenges

• UDI method should be informative, easy to use and minimize disruption in surgery flow and not increase OR time
• Sets should arrive and flow through hospital system (central sterile processing, set build, etc.) and to OR with UDI solution in place
• After surgery, unused contents should continue to be identified by a UDI
• Items within set can cycle through distribution chain repeatedly
• UDI solution should be usable when no manufacturer representative is in OR
• UDI solution should allow for data capture when item is implanted
• The solution may take a combination of several methods: DPM (with exemptions where necessary due to space or other considerations), sterile packaging, and data carrier tags or strips
• In order to meet patient needs, sets need to be rapidly replenished between procedures
Questions and Answers
Four Compliance Strategies

Companies will need the flexibility to pursue one or more strategies simultaneously or separately:

1. Data Carrier Tags – product remains UDI-tagged until use
2. Data Carrier Strips – product group remains UDI-tagged until use
3. Sterilization of Implants – product individually packaged and marked with UDI
4. Direct Part Mark – product surface bears the UDI
   - With exemption from PI marking for medium size implants and PI and DI marking for small implants
   - Accompanied by implant mapping and recording process
     - DI on caddy and inventory control sheet
Data Carrier Tags

- Tag is affixed to product by manufacturer and bears UDI information in human readable and/or AIDC technology
- OR staff removes tag and captures UDI information manually or via scanner
- Scanned information can be electronically captured and downloaded into EHR system
- Product is intended to remain tagged until point of use; once removed it cannot typically be re-attached
Data Carrier Strips

- Implants from the same LOT are attached to plastic strip where each implant has its own compartment
- Individual compartments can be snapped off strip as needed
- The plasticized paper UDI label remains with each implant on strip until point of use
- Plastic strips are loaded into trays
- OR staff break off and remove needed number of implants from plastic strip and retrieve UDI information
Individual Sterile Package

- Sterile supplied devices is common practice for a majority of implantable medical devices, including some spine and trauma sets.
- It is not common practice for large set configurations due to:
  - increased packaging waste
  - limited space in O.R.
  - increased O.R. time due to removing packaging for each implant.
Application of 21CFR 801.45
Direct Marking

- Implants are etched with a human readable and/or AIDC readable UDI
- Larger implants that have sufficient space for the UDI in human readable format will have the device identifier (DI) and production identifier (PI) marked
- Medium implants may have sufficient space for only the device identifier to be marked and will require an exemption from PI marking*
- Small implants will not have sufficient space for any human readable text and will require an exemption from PI and DI*marking

*The device identifier for small and medium implants can be documented in medical record using an inventory mapping and recording process – see next slides
Implant Mapping and Recording process

1. Surgeon calls for the desired implant which is retrieved by the scrub tech.
2. Circulating nurse will document the type and quantity of each implant used on the inventory control sheet.
3. As a secondary check, the circulating nurse can compare the implant tray map (located on back of inventory sheet) to the actual implant tray to validate the implants used.
4. Circulating nurse documents the information from the inventory sheet into the EHR.
• Inventory control sheets contain the item number, bar code, and the GTIN device identifier
• Where possible, the ‘production identifier’ will be directly marked in human readable text on the implant
• The PI can be recorded or photographed at time of usage to capture the information
• The production identifier can be recorded in the inventory control sheet and transferred to electronic medical record
Questions and Answers
• Strategies to achieve UDI compliance for non-sterile implants stored in trays will be extremely complex, costly and will require substantial time to implement

• Compliance strategies will also require significant changes in way hospitals/ OR staff currently manage orthopedic surgeries
The product development lifecycles are greatly impacted by the Design Controls necessary under the Quality System Regulation and are driving the need for additional time for implementation.

Application of Design Control to Design Process

Ref: FDA Design Control Guidance March 11, 1997
Other considerations driving the necessity of an extension or exception to comply with the UDI Rule:

• Operational impacts
  ▪ Purchasing controls for new technologies and equipment
  ▪ Supplier capacity
  ▪ Production and process change controls
  ▪ Validation (IQ, OQ, PQ) and verification
  ▪ Manufacturing Transfer

• Regulatory review and market authorization

• Training of manufacturer representatives and healthcare professionals
Time Extension Recommendation

• Regardless of solution chosen, compliance strategies will be a dynamic shift in the way companies produce, distribute and track product

• These enormous changes, coupled with the volume of Implants, Class II, and Class III medical devices that must be compliant, makes any solution a multi-year endeavor

• Without additional time for UDI implementation orthopedic sets will be unable to be shipped preventing patient access to these products thus impacting the public health
• For these reasons, on behalf of its affected members, AdvaMed recommends two additional years to implement the proposed Orthopedic Set solutions for non-sterile implants

• Individual companies will submit exception and alternative placement requests as needed
### Final Rule Compliance Timelines

<table>
<thead>
<tr>
<th>Final Rule Requirement</th>
<th>Label &amp; Date Format Compliance Date</th>
<th>Direct Marking Compliance Date</th>
<th>Unpackaged, Non-sterile Orthopedic Set Proposed Compliance Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Class III Devices</strong></td>
<td>September 24, 2014</td>
<td>September 24, 2016</td>
<td>September 24, 2016</td>
</tr>
<tr>
<td><strong>Implants, Life Supporting, Life Sustaining Devices</strong></td>
<td>September 24, 2015</td>
<td>September 24, 2015</td>
<td>September 24, 2017</td>
</tr>
<tr>
<td><strong>Class II Devices (not included above)</strong></td>
<td>September 24, 2016</td>
<td>September 24, 2018</td>
<td>September 24, 2018</td>
</tr>
<tr>
<td><strong>Class I Devices, Exempt, Not classified</strong></td>
<td>September 24, 2018</td>
<td>September 24, 2020</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Date Format for Devices Not Subject UDI</strong></td>
<td>September 24, 2018</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>
Impact to Public Health

- It is estimated that sets are used annually in:
  - 464,000 thoracolumbar procedures
  - 291,000 cervical procedures
  - 1,750,000 trauma procedures
  - 214,000 craniomaxillofacial procedures
  - 19,000 small joint (fingers, wrists, ankles) procedures
  - 2,738,000 total procedures

- Based on our data we estimate there are 221,130 sets currently in distribution
With compliance deadlines rapidly approaching, companies need to know:

- Will FDA allow direct marking regulations (21 CFR 801.45) for non-sterile implants?
- Will FDA grant, for non-sterile product in orthopedic sets:
  - Two year compliance extension, or
  - Time limited exception, or
  - Enforcement discretion