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UDI Challenge for Non-Sterile Implantable Devices

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Overview

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- 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

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- 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

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- 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?

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- 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

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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

Challenges

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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

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- 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

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- 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

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Questions and Answers

Four Compliance Strategies

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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

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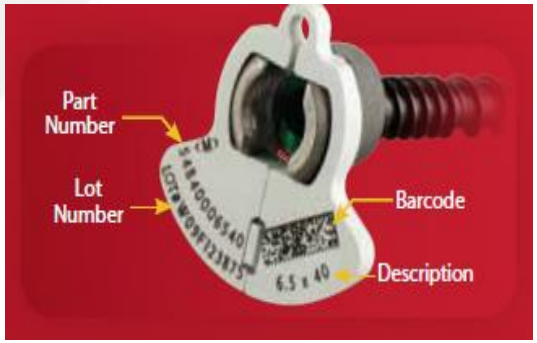
- Tag is affixed to product by manufacturer and bears UDI information in human readable and/or AIDC technology
- OR staff removes tag and captures UDI information manually or via scanner
- Scanned information can be electronically captured and downloaded into EHR system
- Product is intended to remain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



Data Carrier Strips

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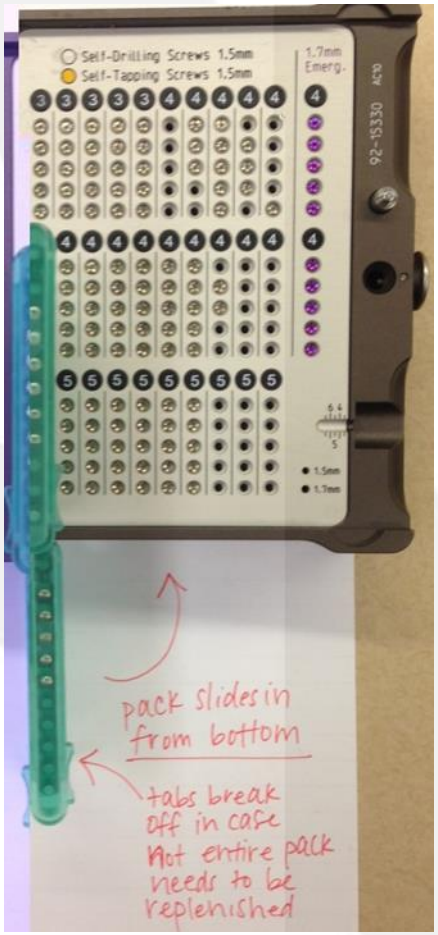
- Implants from the same LOT are attached to plastic strip where each implant has its own compartment
- Individual compartments can be snapped off strip as needed
- The plasticized paper UDI label remains with each implant on strip until point of use
- Plastic strips are loaded into trays
- OR staff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



Individual Sterile Package

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- 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

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- 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

Figure A: Large Implant with DI and PI

Figure B: Medium Implant with only DI

*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

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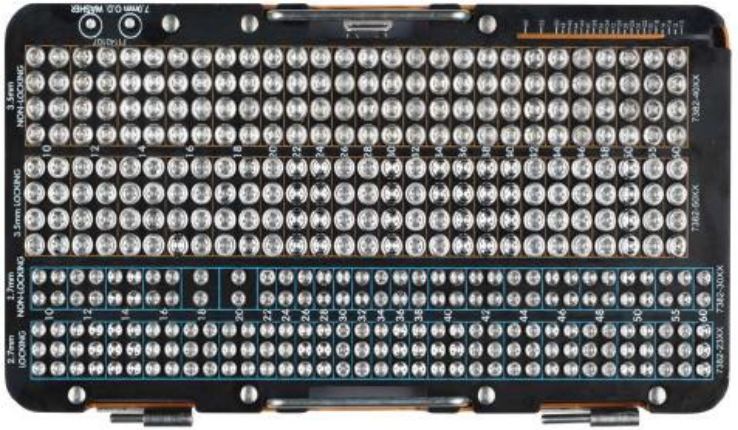
PERI-LOC* Small Fragment Screw Caddy

2.7mm Locking Screws 7382-23XX			
L	QTY	BC	GTIN
10			12345678912345
12			45698745301248
14			18952401435687
16			35982406580014
18			92014568446852
20			22547789632155
22			99568744123651
24			32459986521474
26			35871699582245
28			16891335846085
30			95666654225847
32			32589655412588
34			15986544856325
36			75698852100365
38			93256678745214
40			88622215885477

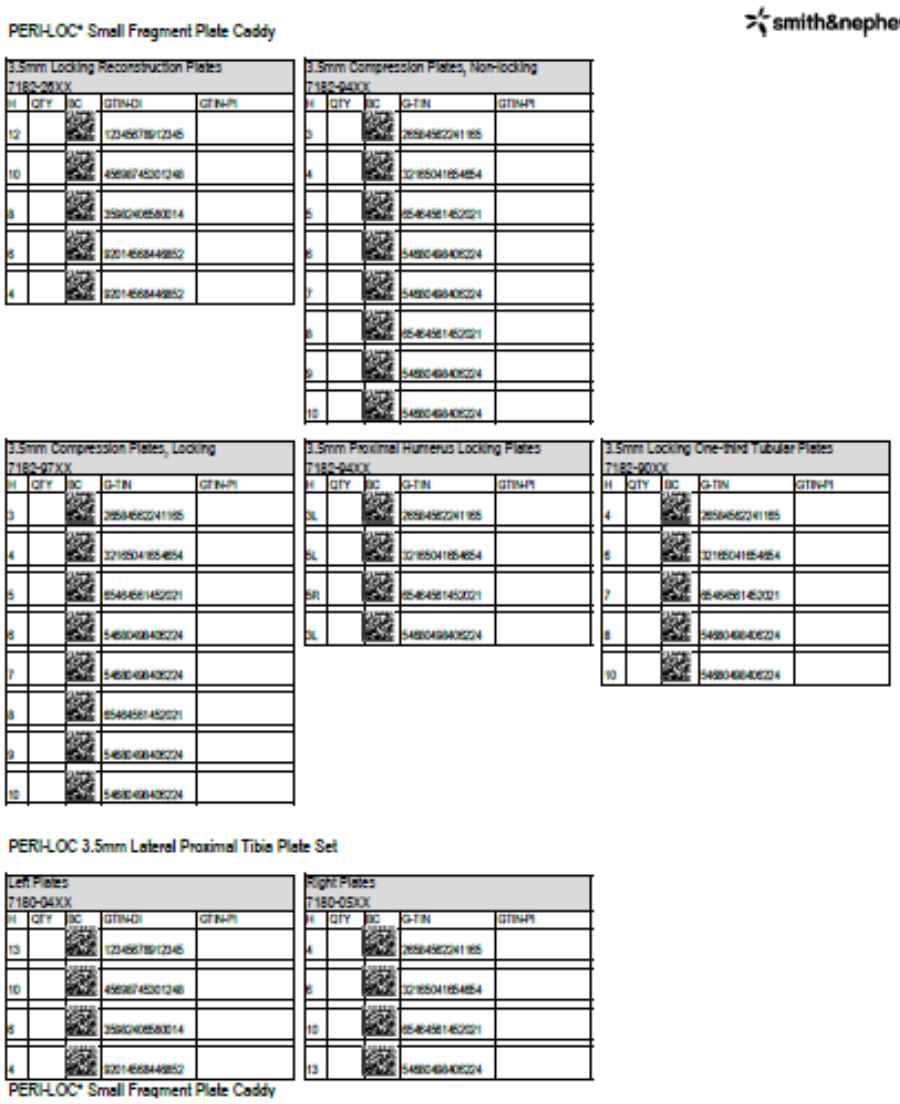
2.7mm Non-locking Screws 7382-30XX			
L	QTY	BC	GTIN
10			26584562241165
12			32165041654654
14			44565460146541
16			65464561452021
18			54560498406224
20			56478974031215
22			54878960315341
24			69401604894103
26			34857406131065
28			15649804651564
30			46060644654655
32			49654654046548
34			24894054164804
36			87414089401605
38			76540541061216
40			65105410651561

3.5mm Locking Screws 7382-50XX			
L	QTY	BC	GTIN
10			66654645564060
12			49946846510615
14			98791465106548
16			56874892465464
18			87987489489498
20			21549794126655
22			89789809419541
24			54654650549616
26			34874648948848
28			98798744165416
30			77489109889048
32			18499646545646
34			21654654165146
36			22415456558444
38			87984564564655
40			33154151313999

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.



Implant Mapping and Recording process



PERI-LOC* Small Fragment Plate Caddy

smith&nephew

3.5mm Locking Reconstruction Plates 7180-06XX

H	QTY	BC	GTIN-DI	GTIN-PI
12			12345678912345	
10			4569874530124B	
8			3592406580014	
6			9201456844852	
4			9201456844852	

3.5mm Compression Plates, Non-locking 7180-04XX

H	QTY	BC	G-TIN	GTIN-PI
3			26584562241165	
4			32165041654654	
5			65464561452021	
6			54804984840224	
7			54804984840224	
8			65464561452021	
9			54804984840224	
10			54804984840224	

3.5mm Compression Plates, Locking 7180-97XX

H	QTY	BC	G-TIN	GTIN-PI
3			26584562241165	
4			32165041654654	
5			65464561452021	
6			54804984840224	
7			54804984840224	
8			65464561452021	
9			54804984840224	
10			54804984840224	

3.5mm Proximal Humerus Locking Plates 7180-94XX

H	QTY	BC	G-TIN	GTIN-PI
3L			26584562241165	
5L			32165041654654	
5R			65464561452021	
3L			54804984840224	

3.5mm Locking One-third Tubular Plates 7180-90XX

H	QTY	BC	G-TIN	GTIN-PI
4			26584562241165	
6			32165041654654	
7			65464561452021	
8			54804984840224	
10			54804984840224	

PERI-LOC 3.5mm Lateral Proximal Tibia Plate Set

Left Plates 7180-04XX

H	QTY	BC	GTIN-DI	GTIN-PI
13			12345678912345	
10			4569874530124B	
8			3592406580014	
4			9201456844852	

Right Plates 7180-05XX

H	QTY	BC	G-TIN	GTIN-PI
4			26584562241165	
6			32165041654654	
10			65464561452021	
13			54804984840224	

PERI-LOC* Small Fragment Plate Caddy

- 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

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Questions and Answers

Time Extension Recommendation

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- 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

Time Extension Recommendation

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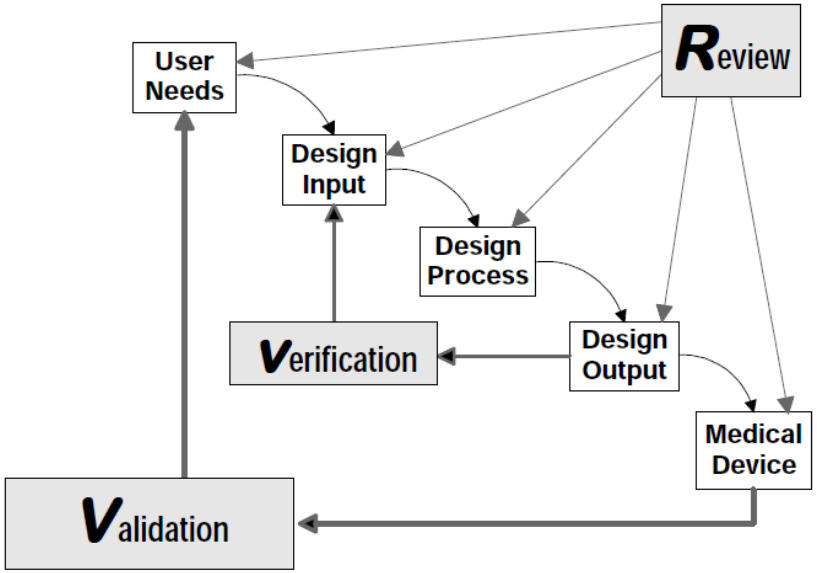
The product development lifecycles are greatly impacted by the Design Controls necessary under the Quality System Regulation and are driving the need for additional time for implementation

Application of Design Control to Design Process



Ref: FDA Design Control Guidance March 11, 1997

Time Extension Recommendation

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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

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- 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

Time Extension Recommendation

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- 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

Time Extension Recommendation

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Final Rule Compliance Timelines			
Final Rule Requirement	**Label & Date Format Compliance Date**	**Direct Marking Compliance Date**	**Unpackaged, Non-sterile Orthopedic Set Proposed Compliance Date**
Class III Devices	September 24, 2014	September 24, 2016	September 24, 2016
Implants, Life Supporting, Life Sustaining Devices	September 24, 2015	September 24, 2015	September 24, 2017
Class II Devices (not included above)	September 24, 2016	September 24, 2018	September 24, 2018
Class I Devices, Exempt, Not classified	September 24, 2018	September 24, 2020	N/A
Date Format for Devices Not Subject UDI	September 24, 2018	N/A	N/A

Impact to Public Health

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  - 214,000 craniomaxillofacial procedures
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- Based on our data we estimate there are 221,130 sets currently in distribution

Questions For FDA

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- 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

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