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# HTG Summit 2015

## August 18-19 in Danville, PA

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# Introducing UDI Labeling Strategies for Non-Sterile Implantable Products into the Surgical Setting

## Update on the SMI Initiative

SMI Strategic Marketplace Initiative

Healthcare Transformation Group

# Presentation Outline

- Initiative Background
- The Supply Chain Challenge
- Simulated Surgery
- Findings and Recommendations

# SMI Initiative Background

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- *March 2014* – Advanced Medical Technology Association (AdvaMed) created a Non-Sterile Implant Working Group to address industry concerns for UDI compliance with implantables
- *August 2014* – AdvaMed presents potential compliance strategies to FDA:
    - **Data Carrier Tags**
    - **Date Carrier Strips**
    - **Direct Marking**
    - **Individual Sterile Packaging**
    - **Inventory Sheets**

# Non-Sterile Implant Extension

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- *Nov. 2014* – FDA extends "point of use" label compliance date for many class II (FDASIA) non-sterile implants from 2015 to September of 2016
  - – GUDID submissions are still required in 2015.
  - – AdvaMed had requested 2 additional years (2017).
  - – "Most of the devices that meet these … criteria are supplied non-sterile by the manufacturer" and are "intended to be sterilized (or cleaned and sterilized) before use."

# Non-Sterile Implant Extension

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- "FDA is initiating this extension to allow time for the development and implementation of an ***alternative*** that would provide for **more accurate and precise device identification** than the requirements of 21 CFR 801 subpart B." [Labeling Requirements for Unique Device Identification – which requires the label of every medical device to bear a UDI]

# SMI Initiative Background

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*December 2014*

- FDA requests SMI organize a next step: ***obtain user feedback.***
- SMI researches potential project.


*February 2015*

- SMI commits to lead Initiative
- Major AMC commits to serve as host site
- AORN and IASHMM join effort
- SMI organizes UDI Compliance Initiative Team
- Initial site visit to academic medical center

# Supply Chain Challenge

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- Orthopaedic devices present unique challenges for UDI compliance:
  - Funky supply chain – hi touch/low control
  - Process variations in handling/management
  - No “real estate” for UDIs on many devices
  - Small devices are grouped together in “caddies” to facilitate cycling through system
  - Field replenishment system - devices are removed from their original package/label and placed in “caddies”, hampering ability to capture a full UDI at the point of use.

# The Field Replenishment Challenge

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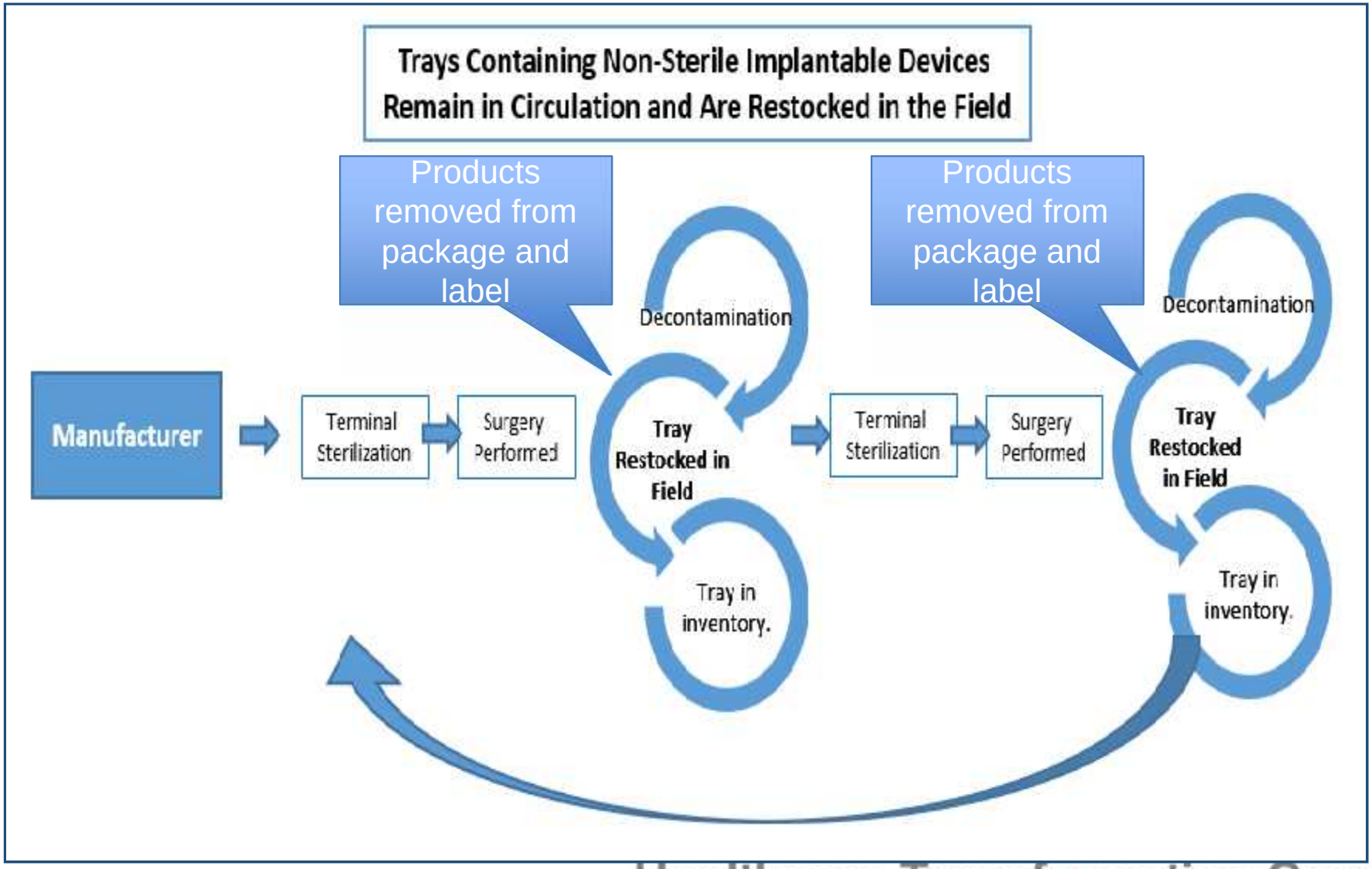

# Labeling Strategy: **Data Carrier Tags**

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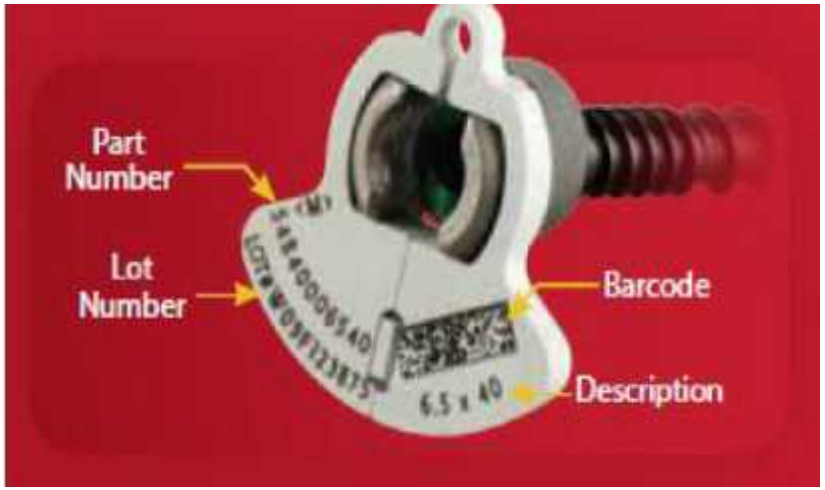
- Tag is affixed to product by manufacturer and bears UDI information in human readable and/or AIDC technology
- OR staff removes tag and captures UDI information manually or via scanner
- Scanned information can be electronically captured and downloaded into EHR system
- Product is intended to remain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

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# Labeling Strategy: **Data Carrier Strips**

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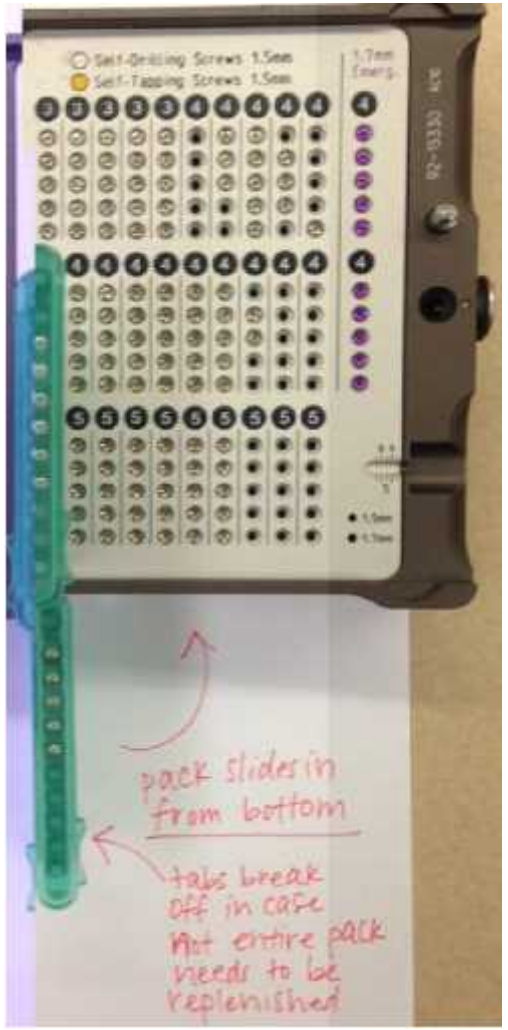
- Implants from the same LOT are attached to plastic strip where each implant has its own compartment
- Individual compartments can be snapped off strip as needed
- The plasticized paper UDI label remains with each implant on strip until point of use.
- Plastic strips are loaded into trays
- Staff break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



# Labeling Strategy: **Individual Sterile Packs**

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- Sterile supplied devices are common practice for many implantable medical devices, including some spine and trauma products.
- 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 information

# Labeling Strategy: Direct Part 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 sized implants may have sufficient space for only the device identifier to be marked
- Small implants will not have sufficient space for any human readable text. Exemption?

# Labeling Strategy: **Inventory Sheets**

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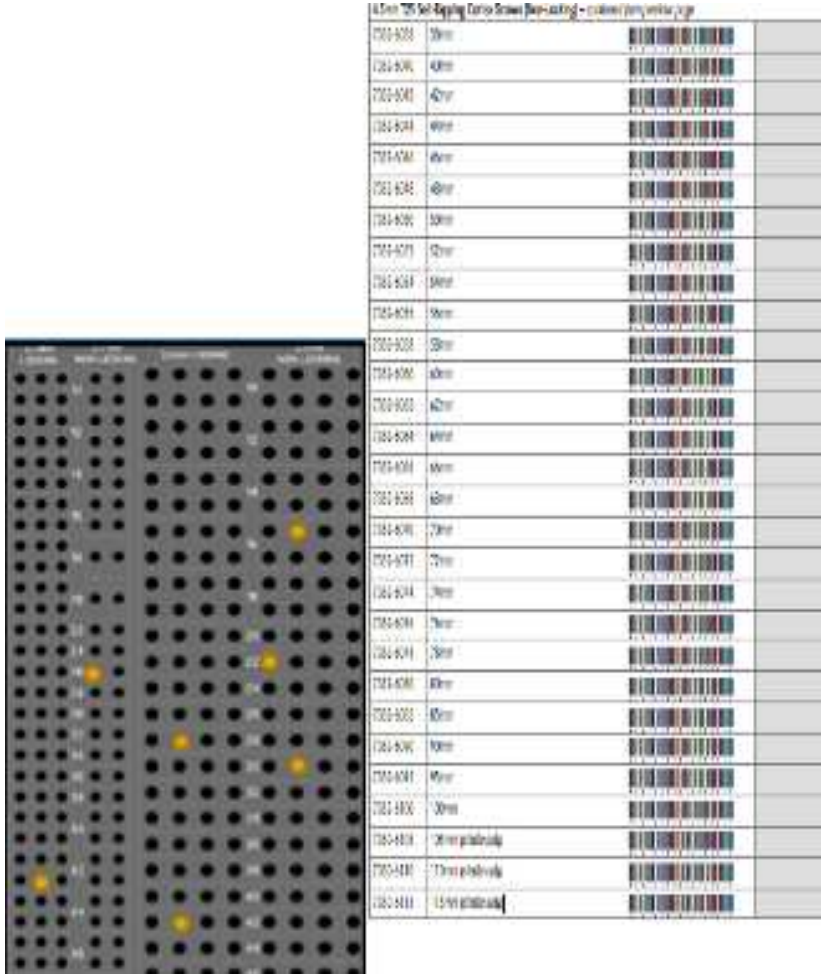
- Sheet is a map of the items in the implant tray
- Circulating nurse will document implants used and quantities on the inventory sheet.
- Inventory sheet could have UDI and a bar code for scanning or keying into electronic health record



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# SMI Team Charter

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## Initiative Objectives

- To simulate the compliance strategies in a near-real environment, focusing on:

  a) The operational impact of each labeling strategy on the full surgical process (pre, intra, and post op)

  b) Each strategy's ability to support the accurate capture by providers of device UDI data into applicable systems, such as an electronic medical record

# Initiative Process

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- ✓Host site secured, visit conducted
- ✓Team charter, education, & background
- ✓Simulation lab secured and scheduled
- ✓Surgical teams recruited, briefed
- ✓Logistics coordinated
- ✓Current process documented
- ✓Focus on Inventory Sheet, DPM, and Sterile Package labeling strategies
- ✓Simulations conducted

# Simulated Surgeries

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## Duke Simulation Laboratory

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# Simulated Surgeries

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## Duke Simulation Laboratory


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# Simulated Surgeries

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- Open reduction internal fixation of an ankle fracture
- Transforminal lumbar interbody fusion


on Group

# Key Findings

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- **The incorporation and integration of UDI's into healthcare provider information systems (ERP, EMR, SIS, etc.) is required in order to enable the capture – manual or automatic - of UDI at the point of use.**
  - **Significant investment & time are required.**
  - **Providers are not ready.**

# Key Findings

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- **The primary personnel impact of introducing UDI into the surgical setting is on the circulator, who fulfills multiple responsibilities including direct patient care and accounting for products used.**

# Key Findings

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- Across the industry, variations in processes and management systems exist for non-sterile implantables.
- Multiple factors drive variations – surgical preference, techniques, finances, products, hospital staff, sales staff, OR design, nurses, information systems, barcode scanners, etc.

# Key Findings

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- **Any labeling strategy that ultimately slows the total surgical time or interrupts a surgeon's tempo is not acceptable.**

# Key Findings

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- **UDI information on sterile packaged devices can be captured manually or with a bar code scanner (if the data capture information system and equipment are in place).**

# Key Findings

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- **UDI information on direct part marked devices can be captured manually or with a bar code scanner (if the data capture information system and equipment are in place).**

# Key Findings

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- **UDI information on most devices supplied in implant trays (inventory sheet) cannot currently be captured manually or with a bar code scanner**
  - **There was no UDI information on the devices or the "caddies".**
  - **Devices were removed from their package/labels during the field replenishment process.**
  - **Computerized crosswalks can yield DI information only.**

# Recommendations

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- **Expand this collaborative effort to gather broader user input and insights.**
  - The Healthcare Transformation Group (HTG) is an action oriented collaboration focused on driving positive change in the healthcare industry. Working with this group to expand the perspective and gain further insights is recommended. In addition, involving national organizations such as the American Academy of Orthopedic Surgeons and the Orthopaedic Trauma Association will further expand the perspectives and insights.

# Recommendations



- **Work with national nursing leadership organizations, such as AORN, to investigate in more detail the impact on the role of the circulator.**
  - This role includes responsibility for data collection and documentation. The introduction of the UDI number and scanning technology presents additional challenges for the circulator.
  - Industry awareness of UDI in the perioperative setting needs to be increased.

# THANK YOU.