
# Operation Blueberry Castle

**Presenters**

Larry Donnelly

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# The Problem

1. Pursuant to U.S. and European Parliament law, certain medical devices must bear a permanently affixed mark known as the Unique Device Identifier (UDI). The UDI contains information about each medical device such as manufacturer, product, lot, serial and expiration date. This information from each medical device used during surgery is placed into the patient's record.

2. Previously, there has not been a single solution that was capable of capturing UDI information in an accurate, quick, easy and uniform way.

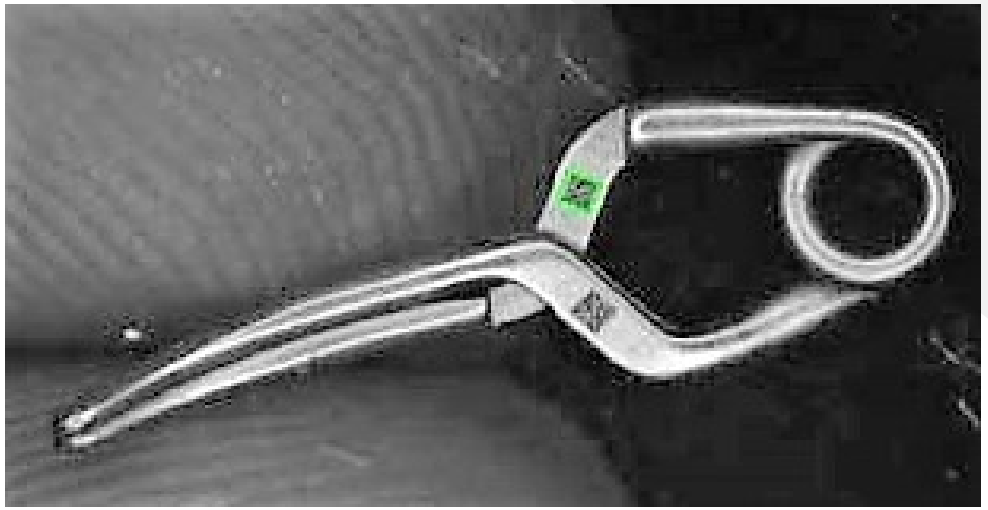
3. As healthcare change management and UDI implementation occur, there is a need for documentation hardware and software solutions that are easy to adopt with little to no training required.

4. Movement of sensitive patient information requires a secure platform to hold and transmit data (see GDPR laws).

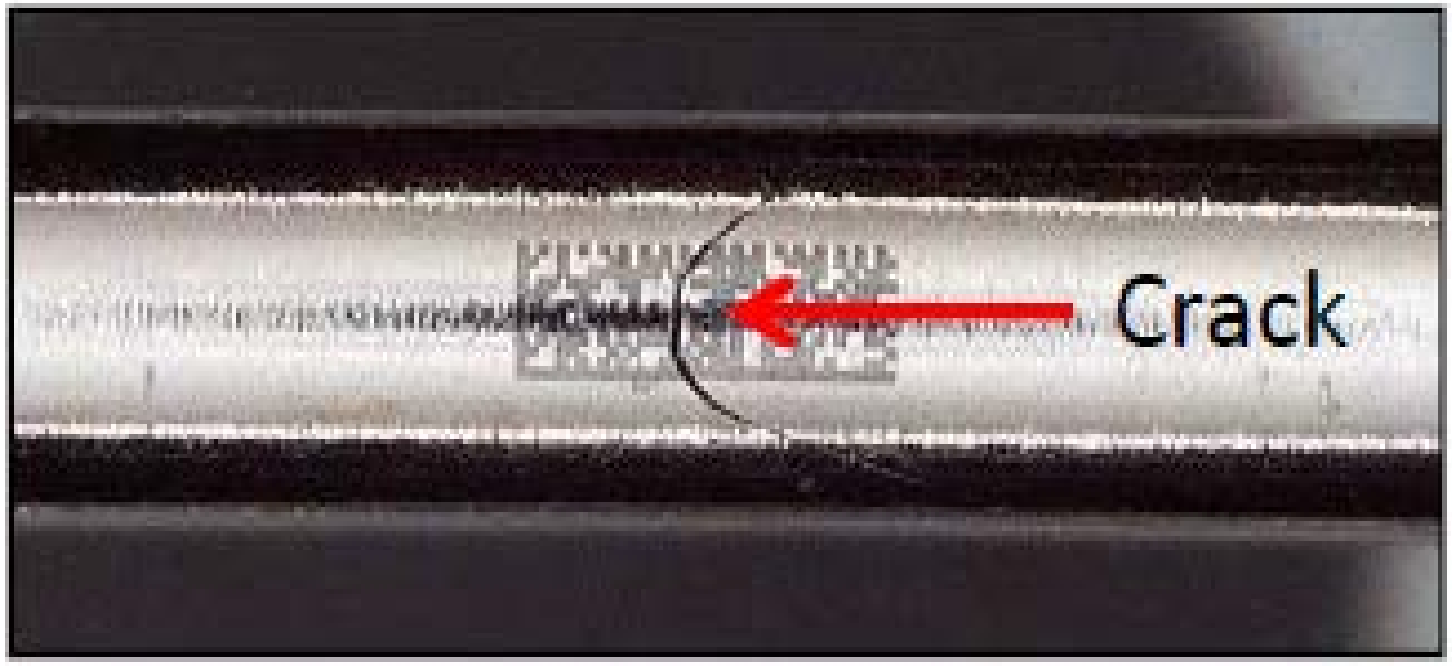
5. IT infrastructure systems that are antiquated must have a cloud based solution at an affordable cost to encourage adoption and value out of UDI compliance.

6. Until effective AIDC technology is implemented, the analog methods of recording information cost billions while providing potentially inaccurate implant and utilization data.

7. Hospitals and manufacturers need hardware and software solutions that will drive compliance.



# Direct Mark Myths



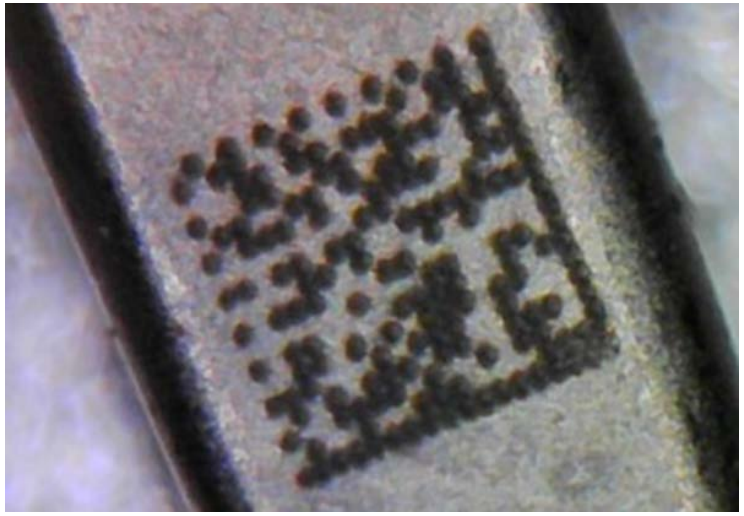

Myth: Laser etching may affect the mechanical integrity of marked implants.  (Image provided by US FDA)

# Different Direct Part Mark Results
# The Right Equipment and Expertise are Critical to Success

## Damaged Data Matrix Code

## Damaged Human Readable Mark

## Good Data Matrix Code



# Direct Mark Myths

*“Long term resistance of UDI laser marking proved for the first time by durability test on surgical instruments.”*

9/3/2018 Long term resistance of UDI laser marking proved for the first time by durability test on surgical instruments



FOBA®

*Laser at your service*

## Long term resistance of UDI laser marking proved for the first time by durability test on surgical instruments

*27.07.2017 | In close cooperation with FOBA laser Marking + Engraving, "add'n solutions GmbH & Co. KG" of Tuttlingen/Germany, a service provider for UDI laser marking on medical devices, conducted a long term study on reusable surgical instruments. The aim was to prove that laser marks remain clearly readable in spite of multiple reprocessing procedures. The UDI must resist increased wear throughout the whole product life cycle to ensure safe traceability, which is also officially required.*

The study is comprehensively documented and has for the first time demonstrated that laser marked high contrast codes are able to resist at least 500 sterilization and cleaning cycles. FOBA's short pulse fiber marking lasers have been optimally adapted to the surface characteristics of different types of stainless steel. The appropriate laser parameters prevent the inscription from fading out or corroding. An additional passivation ensures that the complete device, including marked areas, is protected against corrosion. The American standard for the passivation of stainless steel, ASTM 967, was used for the passivation of the instruments.

"add'n solutions" utilized a precisely matched laser marking process, followed by a cleaning and passivation cycle. The surgical instruments were finally sterilized and cleaned 500 times, simulating actual wear conditions in a hospital. The steam sterilization was accompanied by an instrument cleaning with high alkaline cleaners (pH value 14), which is also equivalent to clinical cleaning procedures.

A direct mark on a medical product must not only be of high contrast and resistance, it also cannot have a negative impact on the surface quality. Until recently, it was unknown how often laser marked surgical instruments can be reprocessed without negatively impacting the quality of the mark.

Notwithstanding the type of laser used – short or ultrashort pulse laser – the recent study provided evidence that only an additional passivation, developed to exactly match the marking process, creates appropriate long term protection against corrosion and thus ensures the readability of the marks.

Data regarding the sustainability of ultra short pulse laser marks, created for example with pico or femto second lasers, is apparently still not available. The present study suggests that the assumption, that marking with ultra short pulse laser does not require passivation, is incorrect. Only accompanied by a passivation process can the complete product be reliably protected.

The latest legal regulations of the American FDA (Federal Drug Association) and the European Medical Device Regulation require that all medical products have to bear marks, with implementation deadlines that vary according to the risk class of the device. FOBA's fiber laser markers enable a reliable, efficient, fast and, due to the prevention of scrap, cost effective implementation of the valid marking standards.

"add'n solutions"' durability test confirms the company's expertise as a specialized service provider for medical device manufacturers in UDI marking. The management states to provide the best possible marking results for their customers, using FOBA's vision based marking technology. The parts marking process therefore includes an automatic optical verification of the marking results within a validated procedure.

An application case study with a detailed description of the durability test on reusable surgical instruments is available for free download on the FOBA website

www.fobalaser.com

Press release as pdf

Pictures for editorial use

https://www.fobalaser.com/news-press/article/long-term-resistance-of-udi-laser-marking-proved-for-the-first-time-by-durability-test-on-surgical-i/ 1/2

Myth: Repeated sterilization cycles will damage marked implants.

# UDI Microcodes Marked by FOBA Lasers

Myth: UDI won't fit into small codes



FOBA UDI microcode **40 times** smaller than AIM/DPM standards.

UDI datamatrix market by FOBA with up to 31 char = 1.9 mm x 0.6mm => Density = 31/(1.9x0.6) = **27 char/mm²**
Smallest current standard AIM/DPM 2D code for 31 char = 6.8mm x 6.8mm => Density = 31/(6.8x6.8)= **0.67 char/mm²**

**FOBA'S 2D CODE DENSITY SIGNIFICANTLY LARGER THAN CURRENT STANDARD**

# Email from FDA regarding data matrix code size

*"The UDI rule does not restrict the size of the AIDC technology being used to convey the UDI."*

**From:** <noreply@salesforce.com> on behalf of "gudidsupport@fda.hhs.gov" <gudidsupport@fda.hhs.gov>
**Date:** Thursday, March 30, 2017 at 7:15 AM
**To:** Pat Cairns <Pcairns@matrixmedical.co>
**Subject:** FDA UDI Help Desk Case 1116-00117887

Dear Pat Cairns,

Thank you for your interest in UDI. Your FDA UDI Help Desk case# 1116-00117887 has been reviewed by the FDA UDI Help Desk Team.

As we previously communicated in our March 14, 2017, email, the UDI rule does not restrict the size of the AIDC technology being used to convey the UDI. In fact, the preamble to the final rule explains that FDA's intent was that the AIDC requirement be 'technology neutral' and notes that "...Requiring adherence to a particular AIDC technical standard would be detrimental to innovation concerning AIDC technologies, and would, we believe, do long-term harm by slowing the adoption of new technologies... FDA agrees with comments that recommend that FDA not require the use of specific forms of AIDC or specific AIDC technologies."

If you have questions about an issuing agency's standards, please direct those questions directly to that issuing agency. Additionally, if AdvaMed has questions about the aforementioned March 14, 2017, email or other UDI issues, AdvaMed may contact us directly.

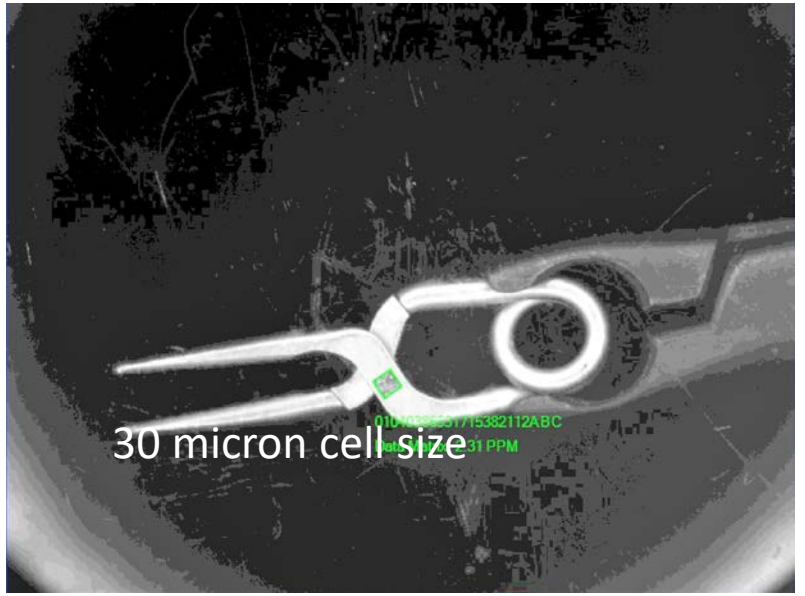
Please note, this case has been closed. If you have other questions, please contact the FDA UDI Help Desk here:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ucm368904.htm.

Sincerely yours,
FDA UDI Help Desk Team

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?O=600&D=610&B=612&E=&S=E

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my current best judgment but does not constitute an advisory opinion, may not represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed. Staff prepared this communication in response to a specific set of facts submitted in a specific inquiry. You should not extrapolate this response to different or broader circumstances. This communication is intended for the exclusive use of the recipient. It may contain information that is protected, privileged, or confidential, and it should not be modified. If you are not the intended recipient, any dissemination, distribution, or copying is strictly prohibited. If you think you have received this communication in error, please immediately delete all copies from the saved sources and notify the FDA UDI help desk by

# Direct Mark Myths


Myth: No scanner can read small data matrix codes – especially in the sterile field.

# Blueberry Castle Project

## Observation and Simulation Analysis in Real World Environment

# Pilot Objectives

| | |
|---|---|
| Evaluate and report | Evaluate and report on the accuracy, effectiveness and cost of each method medical device manufacturers plan to present product UDI in the operating room. |
| Determine | Determine the benefits of establishing a complete operating inventory capture suite that is able to quickly and accurately capture UDI data at the point of care. |
| Provide | Provide a data architecture that overcomes antiquated or outdated systems to capture the information, while providing cost savings and data report mining. |
| Generate | Generate an exportable national framework for UDI compliance while providing value. |
| Discover | Discover benefits of UDI adoption as well as the vast data value for previously uncaptured information. |
| Develop | Develop data collection system that may be integrated with other data sources for future analysis. |
| Observe | Observe the outcomes of a unified data collection and distribution system. |
| Create | Create a public policy best practice document that can be implemented on a national level. |

# Benefits of GS1 Standards

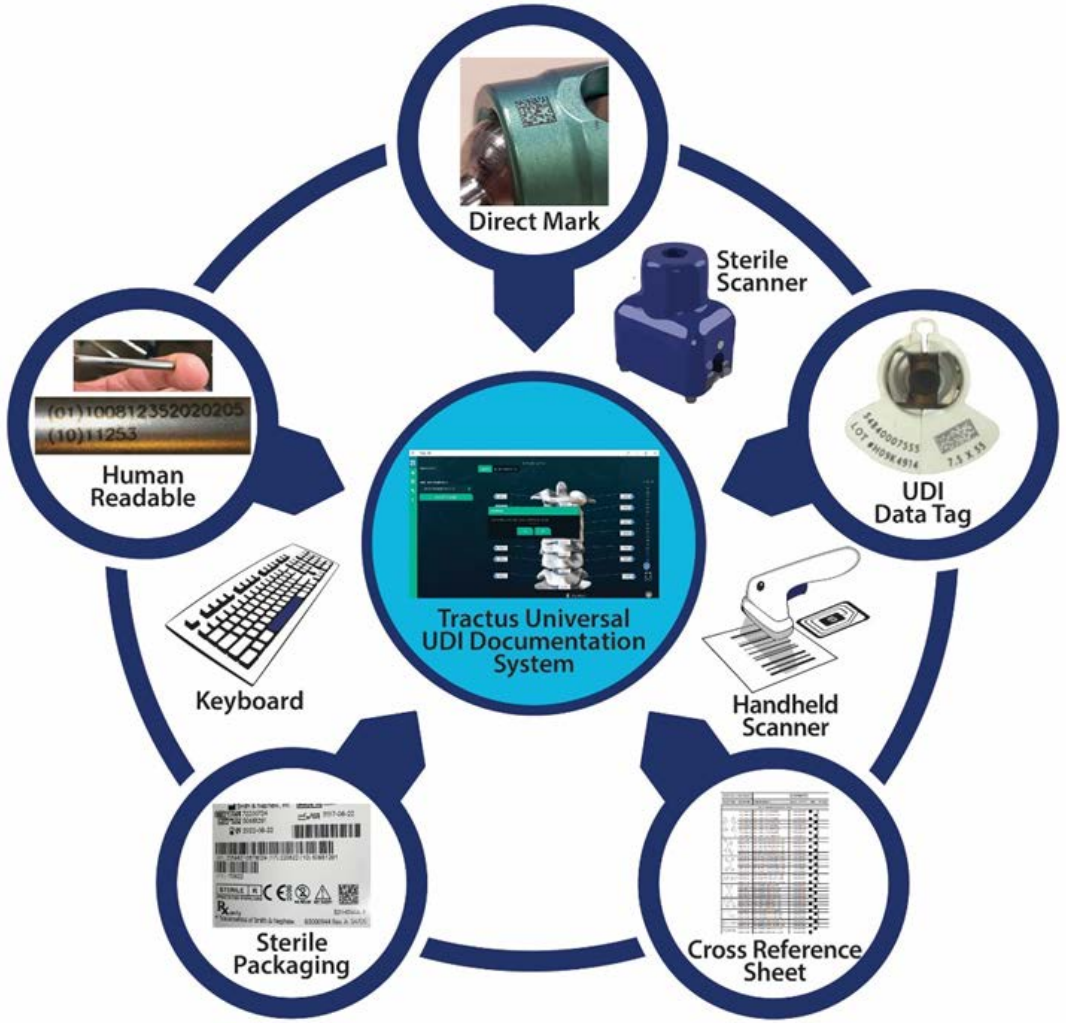
- **Interoperability**
  - Irish National Decontamination Tracking System
- **Time Savings**
  - Australian Public Healthcare
  - 50% time savings on basic tasks such as data entry
- **Product Safety Recalls**
  - NHS Derby
  - Efficiency savings of € 800,000 in 2015/16 and an estimated € 1.32m in 2016/17
- **Patient Safety**

# Problem

- The UDI must be collected at the point of care (during surgery; before implantation), and transferred to the hospital EHR system, where that information will be submitted to payers.
- Hospital sterilized devices lose all UDI information when removed from their packaging and placed into sets with identical implants.
- Other UDI collection methods may be space prohibitive, expensive, inaccurate and could increase surgical times.

# Universal Data Collection Data Sources and Input Methods

Manufacturers plan to present UDI in numerous ways, including manual methods and those that cannot identify the devices UDI.



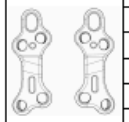
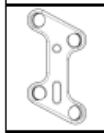
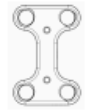
# Human readable direct mark callout

| Benefits and Challenges | |
|---|---|
| UDI Capture | • No |
| Benefits | • Based on existing O.R. practices |
| Manufacturer Challenges | • Full DI and PI on the device<br>• Space on product<br>• No standard |
| Provider Challenges | • Difficult to read; May contaminate product if sterile nurse holds device too close to face<br>• Conversion challenges<br>• Recording challenges<br>• Not UDI compliant due to manual entry<br>• Not practical<br>• Cross reference to GUDID<br>• Highly time consuming and inaccurate<br>• Human Decisions required |

# Reference Sheets

## Benefits and Challenges

| | |
|---|---|
| UDI Capture | • Capture only DI data |
| Benefits | • Based on existing OR practices<br>• Leverages AIDC technology (i.e., barcode)<br>• Easy to use and implement<br>• Manufacturer tools to support process |
| Manufacturer Challenges | • Developing and maintaining the forms and software<br>• Not possible to make PI data available |
| Provider Challenges | • Incomplete/inaccurate UDI data captured (PI data not captured)<br>• Sheets need to be prepared from each manufacturer for each procedure<br>• Technical issues (i.e., barcode readability, user experience)<br>• New technology needed (i.e., interface from scanned sheet to EHRs)<br>• Human decisions required<br>• Slows pace of surgery |

| Inventory Log | Patient Name | | Date (MM-DD-YYYY) | | |
|---|---|---|---|---|---|
| Product Image | Product Code | Product Description | FDA UDI — GTIN # | Data | Qty Used |
| UltOS™ Foot Plating System - Plates | | | | | |
|  R L | OS421000L-NS | UltOS LAPIDUS PLATE 0MM LEFT | 05055662946567 | | |
| | OS421000R-NS | UltOS LAPIDUS PLATE 0MM RIGHT | 05055662946574 | | |
| | OS421002L-NS | UltOS LAPIDUS PLATE 2MM LEFT | 05055662946581 | | |
| | OS421002R-NS | UltOS LAPIDUS PLATE 2MM RIGHT | 05055662946598 | | |
| | OS421004L-NS | UltOS LAPIDUS PLATE 4MM LEFT | 05055662946604 | | |
| | OS421004R-NS | UltOS LAPIDUS PLATE 4MM RIGHT | 05055662946611 | | |
| | OS421006L-NS | UltOS LAPIDUS PLATE 6MM LEFT | 05055662946628 | | |
| | OS421006R-NS | UltOS LAPIDUS PLATE 6MM RIGHT | 05055662946635 | | |
|  | OS421112-NS | UltOS UNIVERSAL LOCKING PLATE 12MM | 05055662946888 | | |
| | OS421116-NS | UltOS UNIVERSAL LOCKING PLATE 16MM | 05055662946895 | | |
| | OS421120-NS | UltOS UNIVERSAL LOCKING PLATE 20MM | 05055662946901 | | |
| | OS421124-NS | UltOS UNIVERSAL LOCKING PLATE 24MM | 05055662946918 | | |
| | OS421130-NS | UltOS UNIVERSAL LOCKING PLATE 30MM | 05055662946925 | | |
|  | OS421300-NS | UltOS ARTHRODESIS WEDGE PLATE 0MM | 05055662946390 | | |
| | OS421302-NS | UltOS ARTHRODESIS WEDGE PLATE 2MM | 05055662946406 | | |
| | OS421304-NS | UltOS ARTHRODESIS WEDGE PLATE 4MM | 05055662946413 | | |
| | OS421306-NS | UltOS ARTHRODESIS WEDGE PLATE 6MM | 05055662946420 | | |
| | OS421308-NS | UltOS ARTHRODESIS WEDGE PLATE 8MM | 05055662946437 | | |
|  | OS421406-NS | UltOS REARFOOT RECON PLATE 6 HOLE | 05055662946826 | | |
| | OS421408-NS | UltOS REAFROOT RECON PLATE 8 HOLE | 05055662946833 | | |
| | OS421414-NS | UltOS REAFROOT RECON PLATE 14 HOLE | 05055662946840 | | |
|  | OS42150L-NS | UltOS GENERAL FUSION X PLATE L | 05055662946550 | | |
| | OS42150M-NS | UltOS GENERAL FUSION X PLATE M | 05055662946543 | | |
| | OS42150S-NS | UltOS GENERAL FUSION X PLATE S | 05055662946536 | | |
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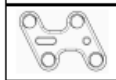
|  | OS421512-NS | UltOS TARSAL FUSION PLATE 12MM | 05055662946857 | | |
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|  | OS421208-NS | UltOS CALCANEAL STEP PLATE 8MM | 05055662918229 | | |
| | OS421210-NS | UltOS CALCANEAL STEP PLATE 10MM | 05055662918281 | | |
| | OS421212-NS | UltOS CALCANEAL STEP PLATE 12MM | 05055662918243 | | |
|  | OS422714-NS | UltOS GENERAL FUSION T PLATE 4 HOLE | 05055662946505 | | |
| | OS422716-NS | UltOS GENERAL FUSION T PLATE 6 HOLE | 05055662946512 | | |
|  | OS422702-NS | UltOS GENERAL FUSION PLATE 2 HOLE | 05055662946475 | | |
| | OS422703-NS | UltOS GENERAL FUSION PLATE 3 HOLE | 05055662946482 | | |

# Sterile Packaging

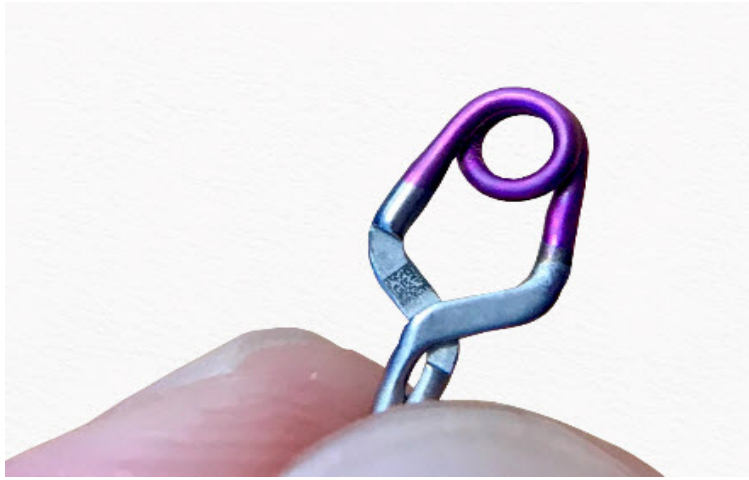
| Benefits and Challenges | |
|---|---|
| UDI Capture | • Capture both DI and PI data |
| Benefits | • Possible to place full UDI on package<br>• Leverages AIDC technology (i.e., barcode)<br>• Process already in use by manuf and providers |
| Manufacturer Challenges | • New storage and packaging strategy needed for use on implants currently placed in trays/sets<br>• Additional space needed for storage/shipping<br>• Need to implement new sterilization method |
| Provider Challenges | • Expiration of product<br>• Additional space needed for storage<br>• Increase device cost<br>• Disposal of sterile packaging materials<br>• Increase in surgical times<br>• Should visually inspect each device for potential sterile breach / contamination |

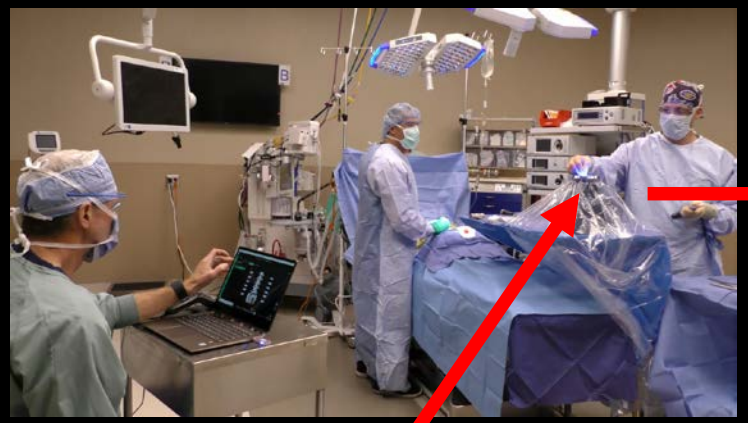
# UDI Tags

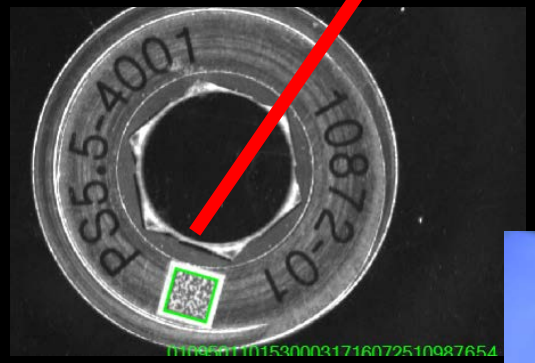
| Benefits and Challenges | |
|---|---|
| UDI Capture | • Capture both DI and PI data |
| Benefits | • Possible to place full UDI on tag<br>• Leverages AIDC technology (i.e., barcode)<br>• Easy to use |
| Manufacturer Challenges | • Proprietary solution<br>• Many products are too small to have a tag attached<br>• Difficult for use on implants placed in trays/sets<br>• Must redesign all set configurations |
| Provider Challenges | • User training<br>• Space constraints<br>• Possible increased time of device to surgeon<br>• Separation of device and tag could cause issues<br>• New processes and P&Ps (i.e., steril/disinf)<br>• Should visually inspect each device for potential bits of tag remaining before implantation<br>• Typically post-op documentation<br>• Human Decisions required outside sterile field |

# Direct Part Mark - Sterile Field Scanning

| Benefits and Challenges | |
|---|---|
| UDI Capture | • Capture both DI and PI data (depending on size of device) |
| Benefits | • Possible to place full UDI on device<br>• Leverages AIDC technology (i.e., barcode)<br>• Easy to use<br>• Data directly captured from device to pt. record<br>• Scanning technology familiar to hospital staff |
| Manufacturer Challenges | • Difficult to mark extremely small devices<br>• Efficacy of mark related to device size, shape, material, and FDA reapproval pre-market application |
| Provider Challenges | • User training and compliance<br>• Purchase new technology (i.e., interfaces with EHRs, scanners)<br>• New workflow processes and P&Ps |








File Edit View Help

UNASSIGNED

Interbody Spacer
PP261016-0001

ROMD Cross Connector
CCV5.5-43-50

ROMD Pedicle Screw
PS5.5-7.5-55

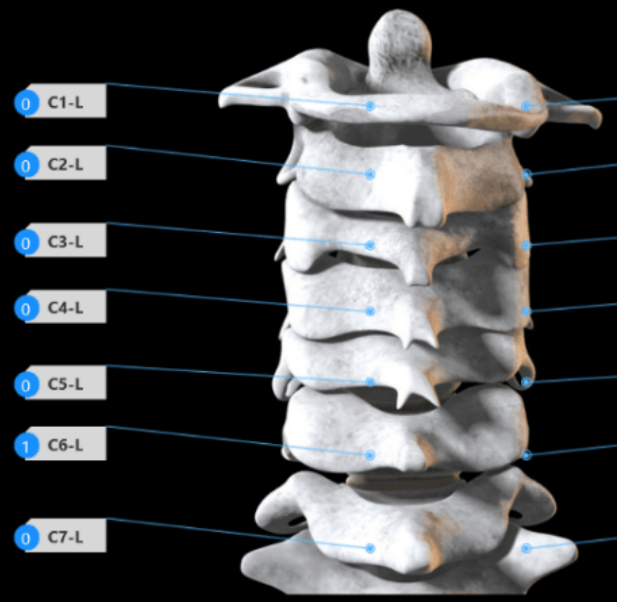
COMPLETE SURGERY

SCANNER (STATUS)

Welcome Back, (User)

Cervical | Thoracic | [+] Add Surgical Site

ZOOM 0%



C1-L 0 | C2-L 0 | C3-L 0 | C4-L 0 | C5-L 0 | C6-L 1 | C7-L 0

C1-R 0 | C2-R 0 | C3-R 0 | C4-R 0 | C5-R 0 | C6-R 0 | C7-R 0

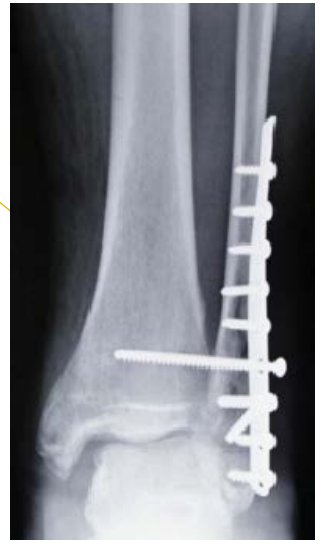
Default

DISCARDED

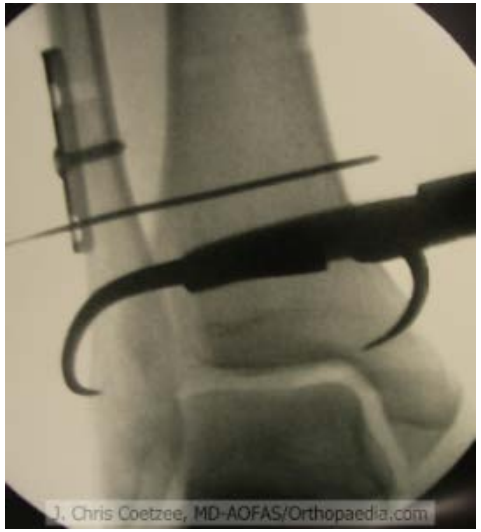
# What data can be gleaned from UDI data collection?

**An example of the use of UDI data from the products you order is the ability to analyze which types of ankle surgery (syndesmosis  surgery) produce best outcomes and are most cost effective for a young healthy male vs a senior female with osteoporosis.**

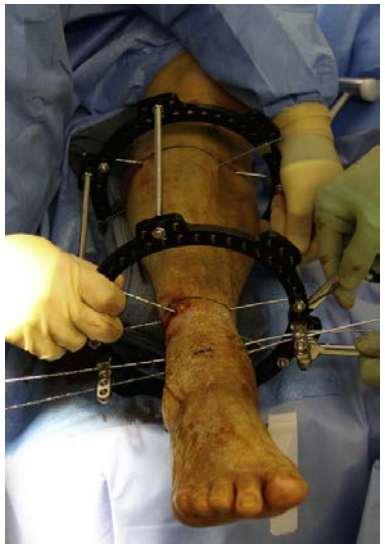
*Fixation Screws and Plate*



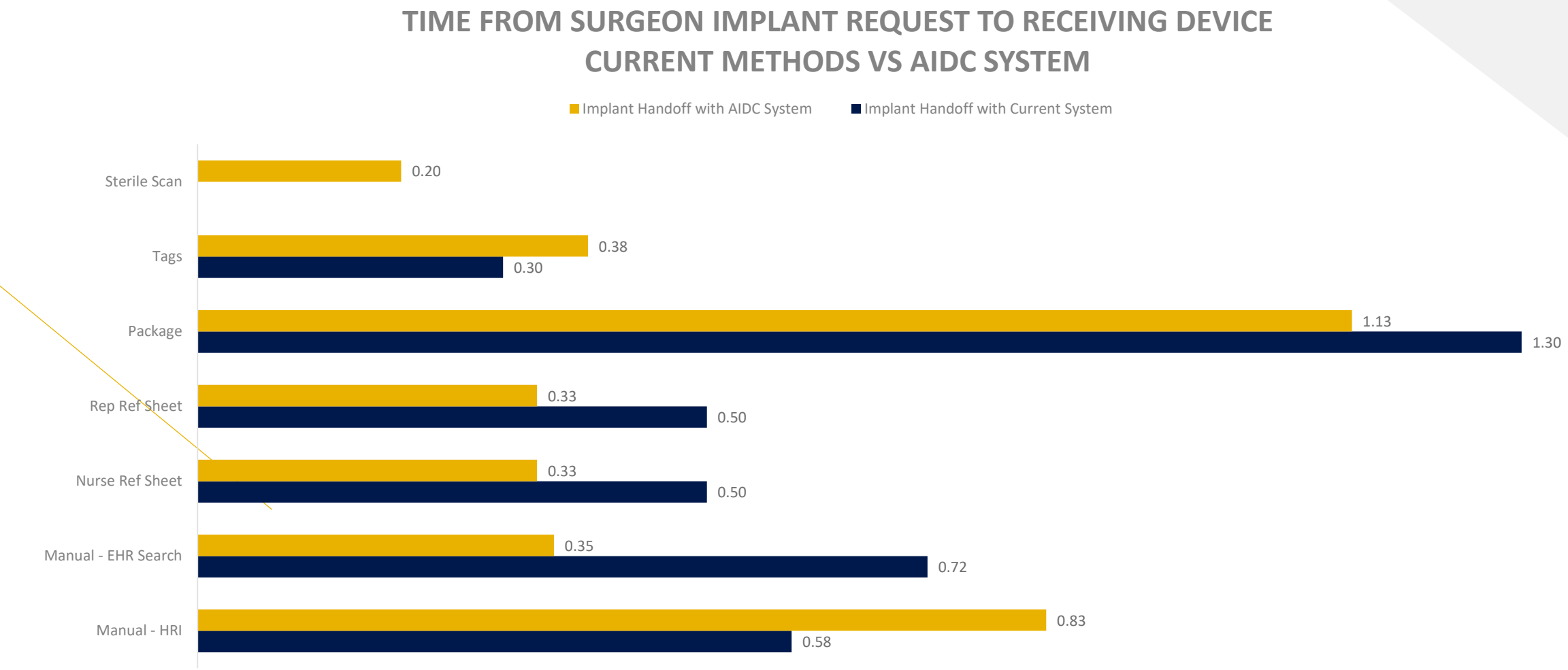
*Tightrope Fiber*



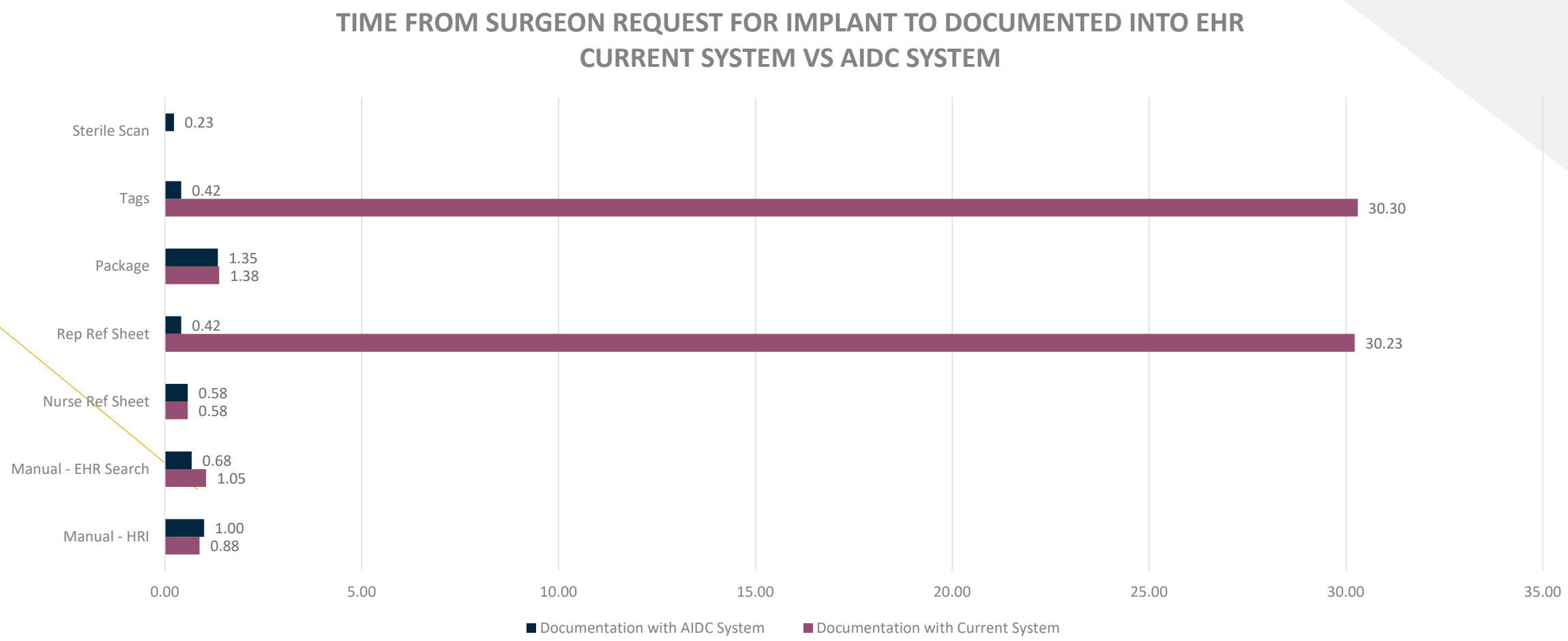

*K-Wire*



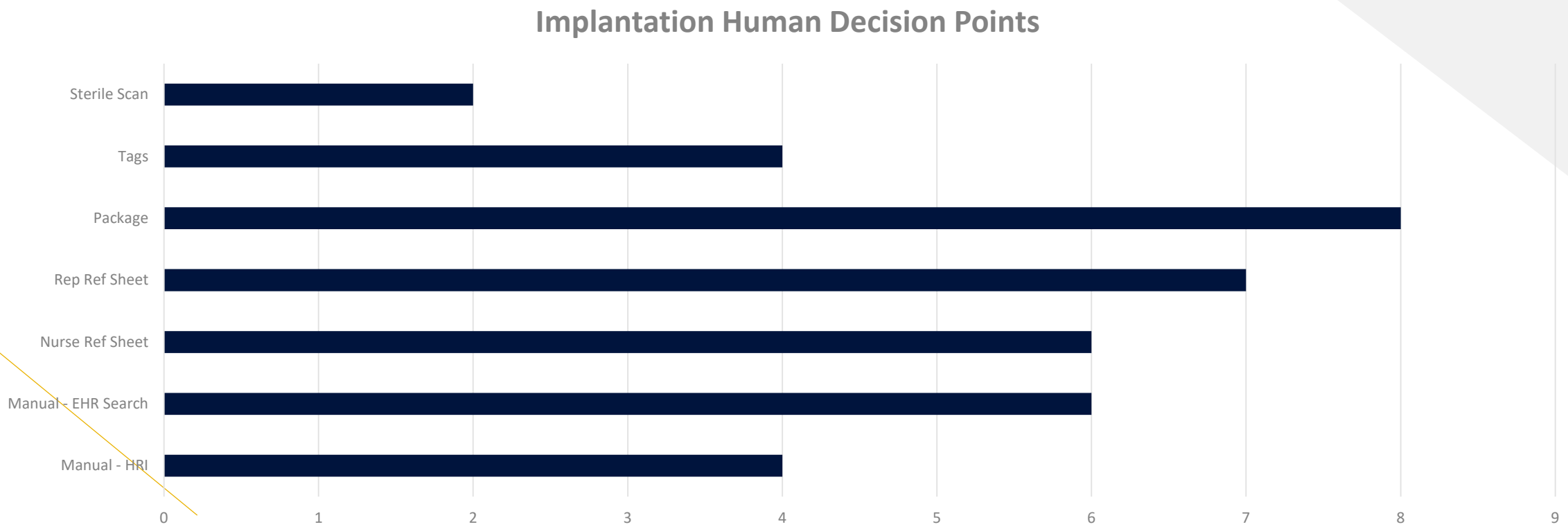
# Blueberry Castle Observation



# Blueberry Castle Observations

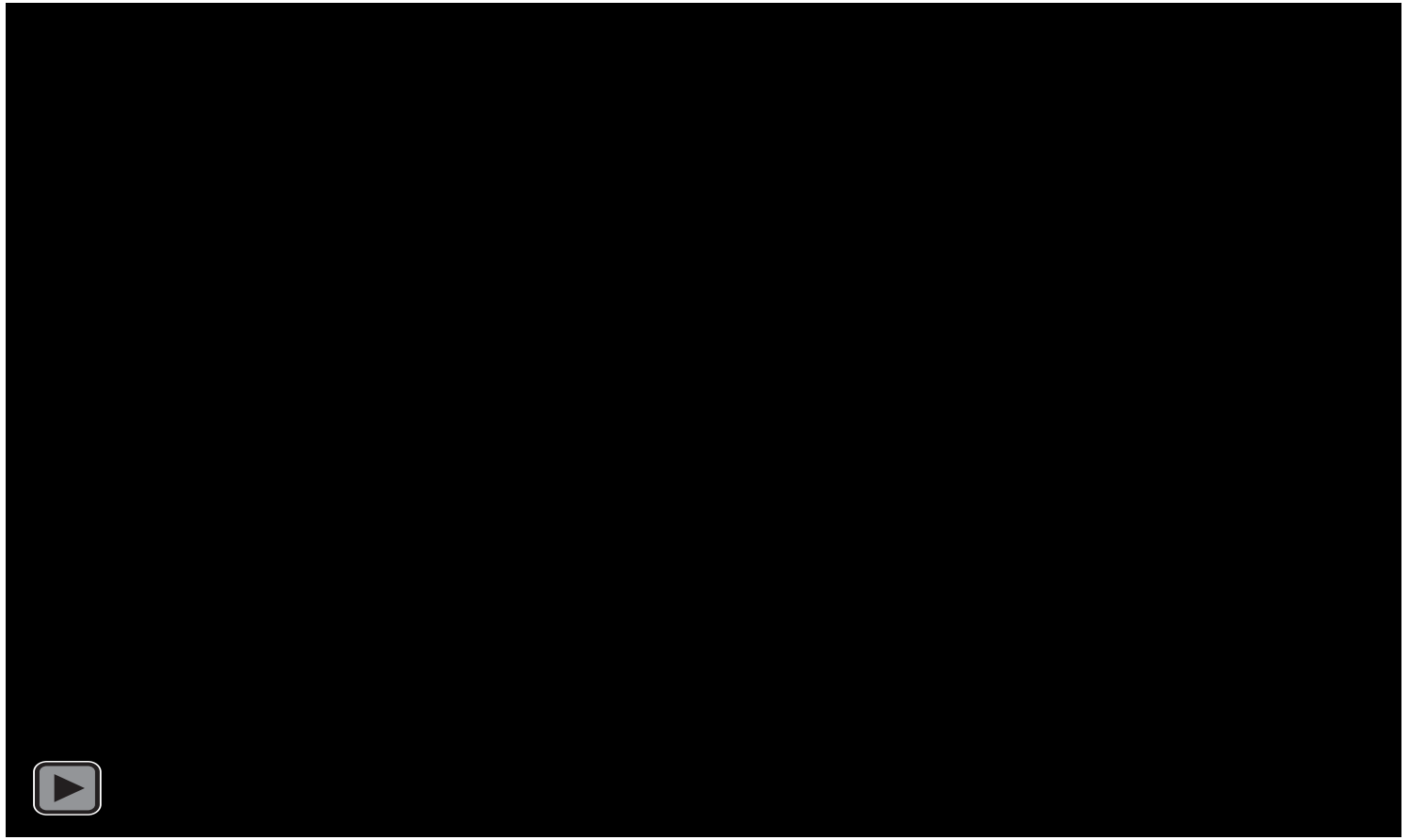


# Blueberry Castle Observations




| STERILE FIELD | | | | | | | OUTSIDE STERILE FIELD | | | | | | | | OUTSIDE O.R. |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Surgeon Callout | Tech Device Search | Select and Load Device | Tech Safety Check | Tech Scans Device/Tag | Read Device Info | Surgeon Handoff | Circulator Package Search | Circulator Selects Package | Circulator Safety Check | Circulator Scans Pkg & Exp. Check | Device/UDI Callback | Search for Device Info | Circulator Documents in EHR | Rep Documents | Circulator Opens Pkg and Drops onto Table | Post Op Data Input |

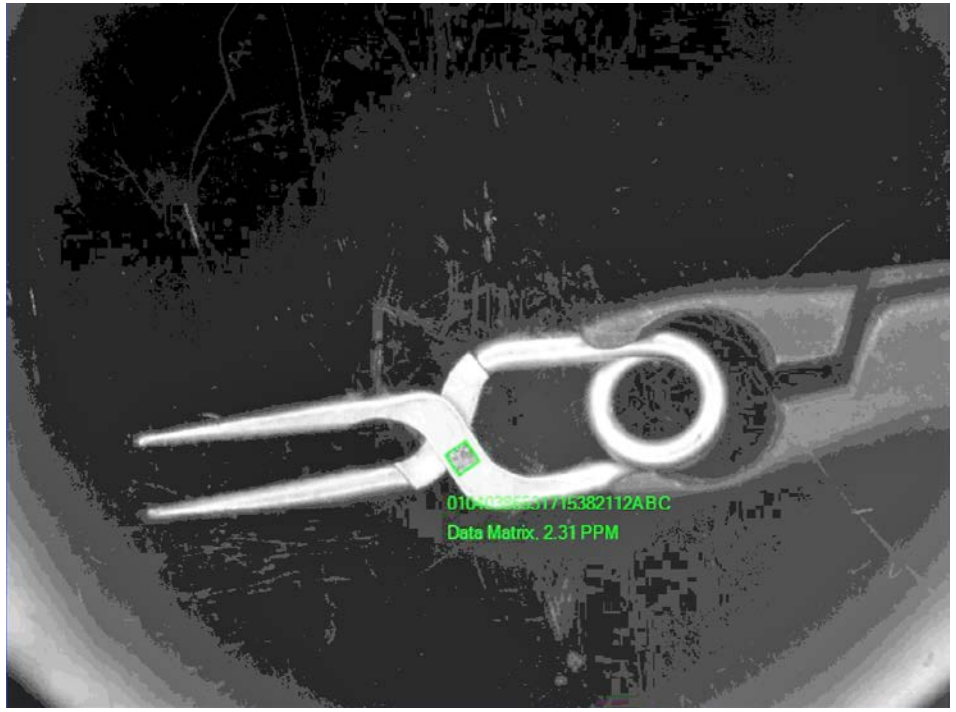
# Demonstration of Sterile Field Scanning



# Demonstration of Reference Sheet Documentation via Callout

# How GS1 can help facilitate UDI adoption in healthcare

1. Change GS1 recommendations to represent current technology
2. Adopt new micro data matrix code standards
3. Educate manufacturers on both benefits and how to mark product
4. Do not recommend manual methods to collect UDI (i.e. ref sheets).
5. Publish recommendations

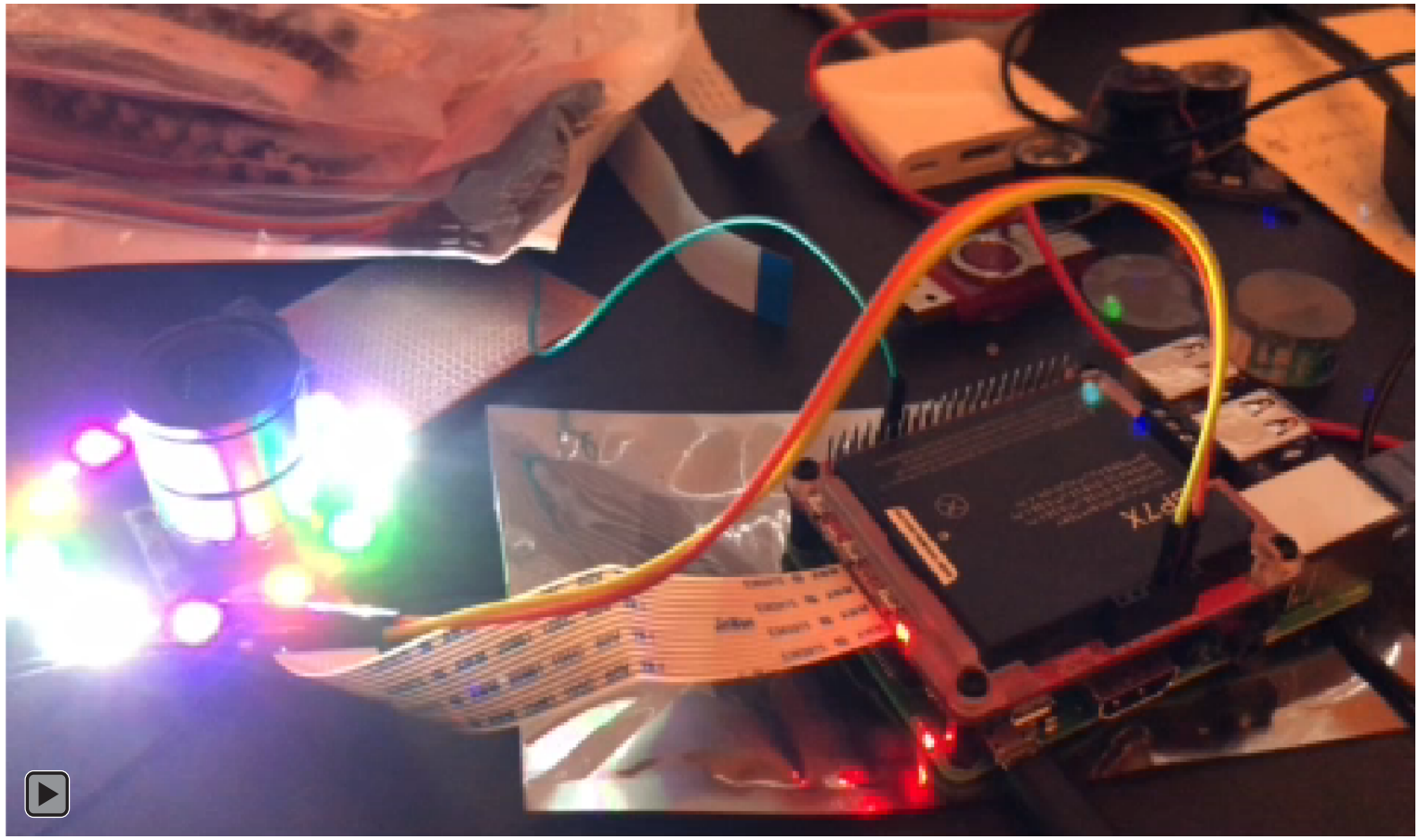


# Example of how technology can be leveraged to improve data matrix code readability

HDR technology to enhance image

Standard camera configuration

# Using light to improve decode capabilities




**Thank You**

**Any Questions?**

# Reference: UCD Consulting Project