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Operating Room Implant Tracking via DPM in the Sterile Field

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What Is UDI?

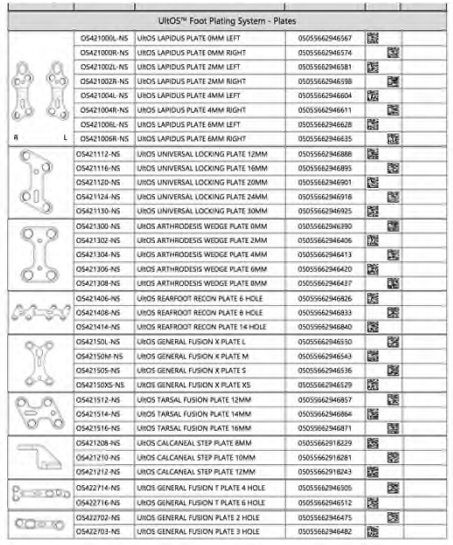
- Unique Device Identification (UDI) is an effort by global governments to create a universal identifier for medical devices.
- UDI's purpose is to increase patient safety, monitor devices, combat counterfeits, and make device movement throughout the supply chain more efficient.
- A strong component to UDI is the ability to read a universal code throughout the supply chain by utilizing a unified code that can be read via AIDC methods.
- The UDI contains all of the information of a device, include the product identifier, serial number, lot, batch, and expiry date.

Abstract

- Each year, the FDA receives several hundred thousand reports of suspected device-associated deaths, serious injuries and malfunctions.
- Federal and international laws require medical device companies to begin placing permanent Unique Device Identifier (UDI) marks onto implants, which must be electronically traced through the product's lifecycle. In the U.S., the FDA, ONC and Medicare regulate UDI compliance.
- This Case Study evaluates the effectiveness of placing a high speed, high resolution camera into the sterile field of the operating room to collect UDI information from spine implants.

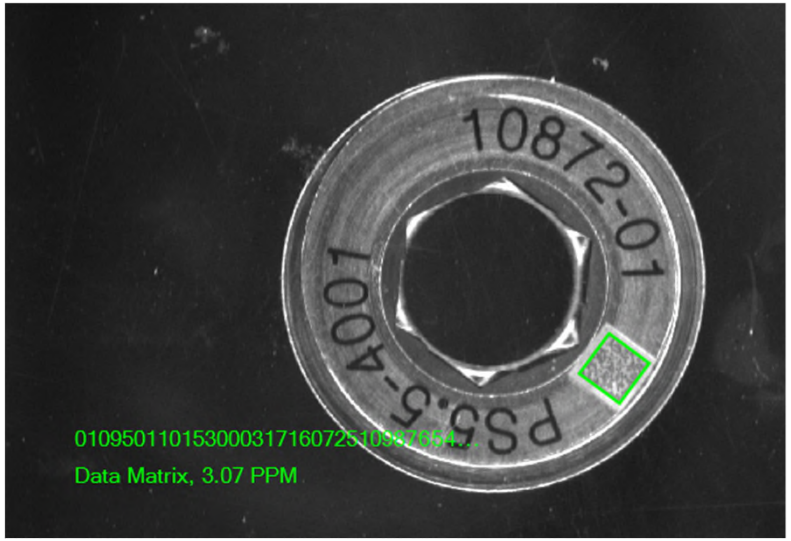
Challenges & Benefits of Direct Part Mark

- Manufacturers have to enact quality procedures to ensure the downstream readability of codes.
- If a UDI identifier is placed onto an implant or instrument, a scanner must be capable of reading it in the first place.
- Capturing implant or instrument data is the most accurate at the point of care.
- Direct part mark is consistently faster, more accurate, and easier to use rather than other data collection alternatives.



Reference Sheets

- Adds paper and a human to the process.
- Time consuming and error prone.



Sterile Scanning

- Scanned during consumption at point of use.
- 100% accurate and easy.

Creating Unity

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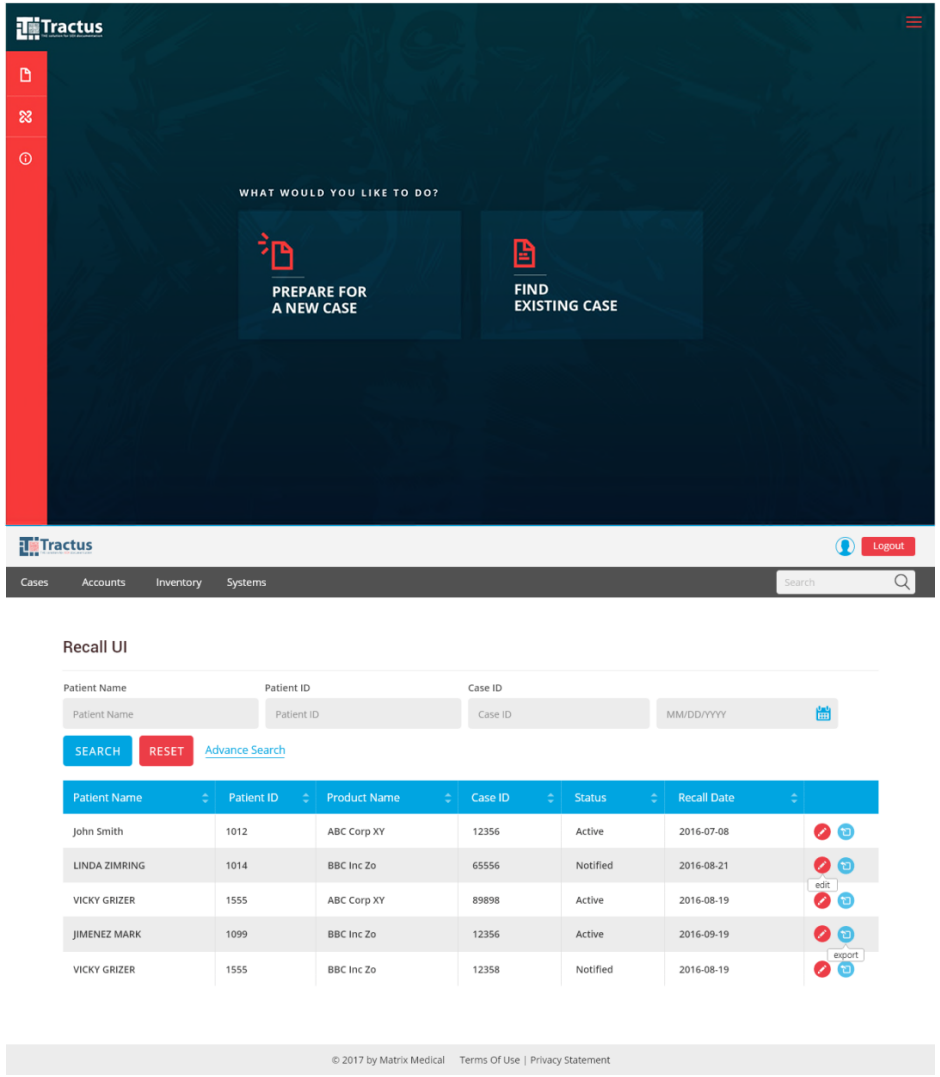
- Within the operating room, there should be a single system that can drive point of capture throughout the entire supply chain.
- A single software system must be designed with the goal of decoding the UDI through AIDC methods, regardless of the format.
- The system should be fast, easy, and adapt to the environment by being able to capture RFID, 1D, 2D, and DPM codes.
- Operator performance should not be slowed, regardless of the code size or reader (testing performed down to 0.3mm^2 @ 20 micron x-dimension).

Study Goals



- Capture 100% of all devices without slowing down the operative procedure.
- Upload the data to the patient record and document the inventory being utilized.
- Read UDI information that is permanently annealed onto the surfaces of hospital-sterilized implants, and record the patient's implanted anatomical locations.
- Capture other implant and supply information through the handheld scanner.
- Ensure that a device or instrument is not under an active FDA recall notice.

Implant Recording

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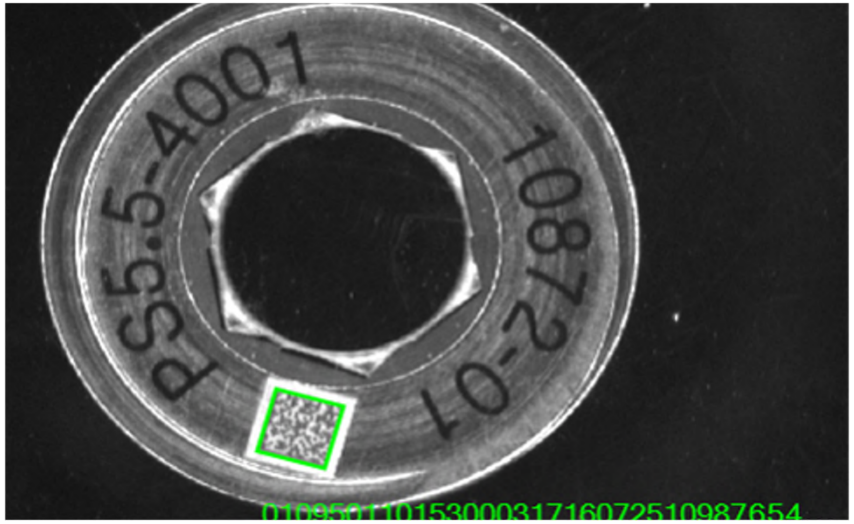
- Surgeon calls for an implant.
- If hospital sterilized, the scrub tech selects a UDI direct marked implant from a sterile set, and scans the data matrix code containing the UDI with the TRACTUS scanner.
- If packaged, the “non-sterile nurse” opens the package and drops the device onto the sterile table, where the scrub tech collects it and hands it off to the surgeon.
- Device data is transmitted to the circulating nurse’s computer software system.
- Circulator correlates the device to the implanted anatomical location.
- Wasted and explanted devices are moved into the software’s “Discarded Bin.”
- After completion, case data is transferred to the hospital EHR system.

Images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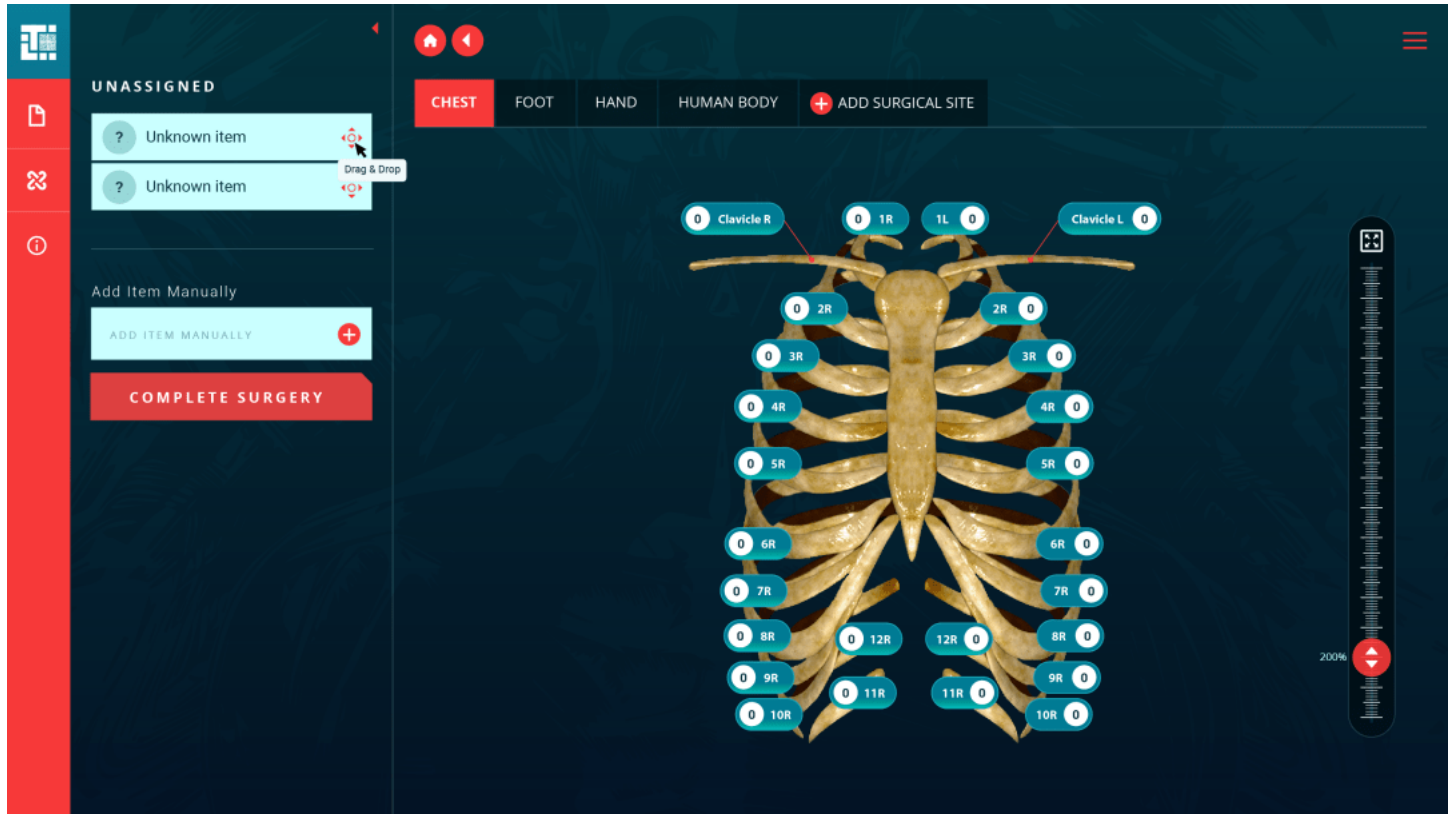
UNASSIGNED
Unknown item
Unknown item
Drag & Drop
Add Item Manually
ADD ITEM MANUALLY
COMPLETE SURGERY
CHEST
FOOT
HAND
HUMAN BODY
ADD SURGICAL SITE
Clavicle R
1R
1L
Clavicle L
2R
3R
4R
5R
6R
7R
8R
12R
9R
11R
10R
200%

Observations

- 100% accurate UDI data collection, in real time during surgery.
- Average scan decode time of a 56 character UDI was about 0.029 seconds.
- Integrated into existing processes, without surgical flow disruption.
- Staff documentation time decreased.
- Information seamlessly transferred to the hospital EHR system.
- Reduction of case times via electronic data capture.
- Potential for human error eliminated.
- Draping of the scanner was easy, and could be performed several ways.
- Scanned device UDIs were collected, with no negative effects to the case flow or surgical times.
- Easy scanning, software management, and anatomical device assignment.

Summary

- Device manufacturers must provide UDI compliant products. However, the methods that they plan to deliver UDIs to hospitals vary widely, including manual call out, reference sheets and sterile packaging.
- These methods will have an impact on surgeon performance; as well as hospital staffing and quality.
  Sterile field scanning is the only method that fully complies with U.S. and international laws, and does not introduce human error, increase hospital staffing, slow down surgical pace, require expiration data tracking or increase storage requirements.
- A universal system must incorporate all forms of scanning technology in order to reduce confusion in the operating room and create a tangible time and accuracy benefit for the patient.

Tractus
THE solution for UDI documentation

The Future

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Project Blueberry Castle is a three phase study driven by Matrix IT with top industry partners in the hospital, technology and medical device sectors. The study's goal is to create a best practice that may be adopted by countries for easy operating room UDI capture and compliance.

Today, six countries and 40 hospitals are slated for the study. Further, practical data learning models will be built around operative performance, device performance, and methods to enhance theater efficiency.

Questions?

- To learn more about the study or the technology driving the change, go to:

www.matrixthis.com (US)

www.steritrack.com (EU)