CASE STUDY: TRACKING DIRECT-PART MARKED HOSPITAL-STERILIZED MEDICAL IMPLANTS IN THE STERILE FIELD DURING SURGERY

ABSTRACT

Each year, the FDA receives several hundred thousand medical device reports of suspected device-associated deaths, serious injuries and malfunctions. New federal laws require medical device companies to place permanent Unique Device Identifier (UDI) marks onto hospital-sterilized surgical implants, which must be electronically traced through the product's lifecycle. Further, mandated UDI adoption is required in most developed countries. This Case Study evaluates the effectiveness of placing a high speed, high resolution camera into the sterile field of the operating room. The Tractus Scanner reads UDI information that is permanently annealed onto the surfaces of hospital-sterilized implants and identifies the devices implanted anatomical locations. Each implant is identified through FDA databases to verify that no active recall exists. Tractus then transmits all Case Data to the hospital's electronic health record.

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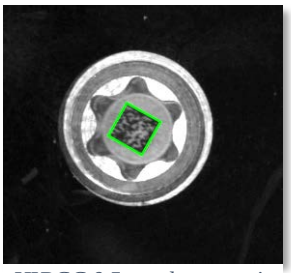
Problem

Patient Death and Injury Occur as a Result of Untraceable Defective Surgical Implants

Each year, the FDA receives several hundred thousand medical device reports of suspected device-associated deaths, serious injuries and malfunctions.

These patient deaths and injuries motivated Congress to enact federal laws **requiring medical device companies to place Unique Device Identifier (UDI) marks onto every hospital-sterilized surgical implant, which must be traced through the product's lifecycle.** Healthcare providers are expected to electronically maintain this information.

Particularly challenging to track and identify are hospital-sterilized implants, which are removed from their packaging before placement into pre-configured trays. After which, they are assigned to manufacturer representatives or are consigned to hospitals. Once separated from their packaging, all UDI device identification is permanently lost. Prior to surgery, these trays are sterilized at the hospital. During surgical procedures, sterilized implants are placed into the sterile field, near the patient. Barcode scanners normally used to read data matrix code information may not be used for these devices because they must remain outside of the sterile field, and are incapable of reading small data matrix codes. From hospital-sterilized trays containing hundreds or thousands of unidentifiable implants, numerous devices may be implanted into a patient or discarded during surgery. **The accurate match of patient to device is impossible, which is particularly concerning in the event of a recall.**



HIBCC 0.5mm data matrix

GS1 0.5mm data matrix

Simulated Surgery Testing

In an effort to determine the viability of a UDI operating room tracking solution, Matrix IT Medical Tracking System™ "Tractus™" was installed into operating rooms at a hospital and an ambulatory surgery center.

Goals

The objective of the simulated surgeries was to collect UDI information from 2D data matrix codes as small as 0.5mm^2 that are permanently marked onto surgical implants in the sterile field of the operating room. Also, labels containing the device UDI of pre-sterilized packaged devices outside of the sterile field of the operating room should be collected. Study goals included:

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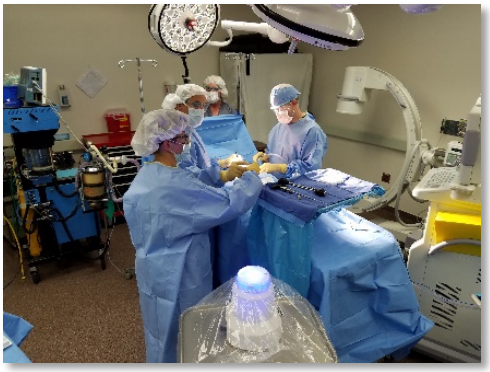
1. Demonstrate synchronization with the FDA's GUDID master device record database, MAUDE, the FDA's recalled device database, GS1's Global Data Synchronization Network (GDSN) which exchanges standardized and synchronized supply chain data.
2. Identify a comprehensive solution to collect all surgical device data, matched to patients.
3. Determine whether process speeds up, slows down or maintains neutral surgical timelines.
4. Identify UDI of scanned items via GUDID and cross reference them to the facility Master Item List.
5. Match scanned supply items to patients.
6. Identify the anatomical location of each device.
7. Quickly scan small UDI data matrix codes as small as $0.5mm^2$.
8. Verify interoperability of systems, with accurate data transfer into patient record and hospital server for other department use.
9. Reduce total case time.

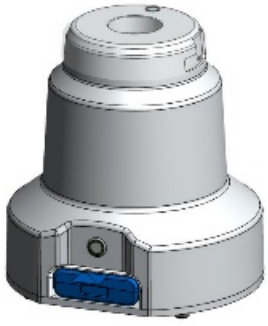
Simulated Surgery Sites and Equipment Selection

Two sites were selected to perform simulated surgeries. Wickenburg Community Hospital, which is a critical access care hospital and Wisconsin Health Center, a private ambulatory surgery center (ASC). During the month of August, 2016, the facilities initiated simulated spine surgeries designed to demonstrate data flow of the UDI for each implant and supply in the simulated surgery, as well as provide case information, including anatomical placement of each device to the hospital EHR.



Matrix IT Medical Tracking Systems (Matrix IT), is a healthcare information technology company that designed the Tractus Implant Tracking System, was selected to determine the ability to demonstrate pre and post data transfer, track both hospital-sterilized direct part marked (DPM) and pre-sterilized packaged implants labeled with GS1 data matrix codes. Tractus is comprised of the following items:

- **Tractus Sterile-Field Scanner**, which is a battery-operated, Bluetooth enabled camera and illumination system that captures hospital-sterilized medical implant UDI information at the point of care, inside of the operating room sterile field.



Note: Tractus Sterile Drape is not yet available for use in the U.S.

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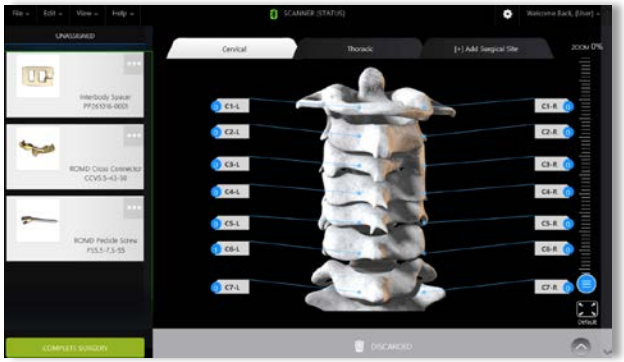
- **Tractus Drape** is a sterile equipment cover, encompassing the Tractus Scanner so that it may be used in the sterile field. The Tractus Drape contains a clear polycarbonate cap that is locked into place over the camera's view port, allowing the Tractus Scanner to capture the implant's UDI information that has been encoded into data matrix codes with a direct part mark on each device. FOBA Laser participated in the study to mark each implant with GS1 and HIBCC formatted data matrix codes.

- **Tractus Handheld Scanner**, which is a hand-held battery-operated, Bluetooth enabled camera and lighting system which collects pre-sterilized packaged medical implant and supply UDI information inside of the operating room, but outside of the sterile field.

- **Tractus Software**, which is synchronized with the FDA's GUDID master device record database, MAUDE, the FDA's recalled device database, GS1's Global Data Synchronization Network (GDSN) which exchanges standardized and synchronized supply chain data, the hospital's master inventory record and electronic health record (EHR) system, allowing for the confirmation of all FDA registered products and population of limited patient information. Post-surgery, all collected data is forwarded to the hospital's EHR system, including the anatomical location of each implanted device as well as a list of discarded supplies and implants, with the reason for discard.



Tractus Features

Tractus was designed to be a critical component in solving the FDA's UDI Final Rule and CMS' EHR Incentive Program challenge. Tractus scanners collect UDI information on all surgery utilization, including both pre-sterilized and hospital sterilized devices. Tractus easily integrated with hospital EHR systems, allowing seamless data transfer to occur.

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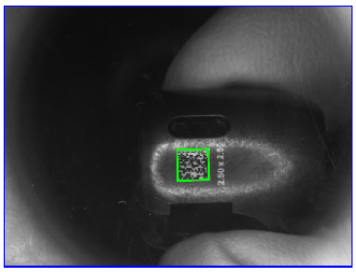
Manufacturers of hospital-sterilized implants use Tractus to identify each implant before filling trays and replenishment of sets, post-operation. This allows manufacturers to (1) create a device pedigree that guards against the $10 billion of counterfeit devices entering the global market yearly, (2) verify operating room readability, (3) keep track of field inventory, (4) validate data matrix metrics, and (5) collect case-specific utilization data.

Tractus has already integrated with major hospital Electronic Health Record systems, allowing seamless data transmission. Tractus data provides manufacturers, hospitals and payers the ability to; match recalled devices with patients, tighten inventory control, identify product performance, study significant trends, and performance. Further, it assures accurate billing; from manufacturer invoices to payer claims.

Process Control Metrics Report

Reader Name: Matrix Scanner
Timestamp: 7/1/2016 6:11:59 PM
Result Data: M824A5P60401/$XXXXXXN
Overall Result: PASS
Specification: AIM-DPM / ISO/IEC TR29158
Symbology: Data Matrix

Image:



Detailed Results:

Quality Parameter	Result (Raw)	Grade
Overall Grade [custom grade]	4.0	A
Pixels Per Module	7.95	
Cell Contrast	0.54	A

Setup

A server was placed into the operating room that provided the hospital with the ability to synchronize and maintain various data.

Before the simulated surgery events, Matrix IT integrated Tractus Software with several facility systems, including inventory management and EHR systems. Tractus automatically synchronizes with the FDA's GUDID master device record database, MAUDE, the FDA's recalled device database, GS1's Global Data Synchronization Network (GDSN) which exchanges standardized and synchronized supply chain data, providing clarity to all FDA approved and recalled medical devices and CPSI's Evident, the supply chain and EHR software system.

ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE

The following UDI collection equipment was linked to the Tractus Server and installed into the operating room:

- Tractus Sterile Field Scanner
- Tractus Drape
- Tractus Handheld Scanner
- Tractus Laptop Computer loaded with Tractus Software

Numerous orthopaedic spine implant trays and tools were brought into the operating room and placed into the operating room sterile field. The simulated "patient" was a Healthy Simulation Spine System.

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Procedure

After positioning the simulated patient, the circulating nurse logged into the Tractus Software system and prepared for a "New Case," where the following identifiers were obtained from surgery scheduling, the FDA's medical device GUDID database and the hospital's Master Item List.

1. O.R. Scheduling from dropdown menu, scan information OR key input
    a. Patient Name
    b. Patient DOB
    c. Patient MR #
    d. Physician Name
    e. Physician I.D. #
    f. Diagnosis
    g. Patient Gender
    h. Record keeper (circulating nurse)
2. Master Device Record – all devices from Supply Chain / Materials Management
3. GUDID, MAUDE, and GDSN Sync and Master Inventory were previously uploaded

A Tractus Sterile Field Scanner was placed onto a Mayo Stand and covered with a Sterile Tractus Drape attached to a clear polycarbonate cap above the camera viewing port. The cap is affixed to the scanner. Once draped, the scanner was positioned near the scrub tech for scanning of implants prior to handing to surgeon for implantation.

During the simulated procedure, the surgeon called out for hospital-sterilized implants. The scrub technician pulled the requested device, passing it over the camera's viewing port of the Tractus Sterile Field Scanner. The device UDI was collected and placed into the Tractus Software's "Assign" Bin. Once implanted, the surgeon identified the anatomical location of the implanted device. Using the Tractus Software, the circulating nurse transferred the implanted device from the "Assign" Bin into the correct anatomical location. Numerous devices were "implanted" using the same procedure. In addition, the circulator relocated several "unused" devices into the software system's "Discarded" Bin and provided a reason for discard, which included: Defective, Fitment, and Non-Sterile.

For supplies and implants that were sterilized inside of packages, the Tractus Handheld Scanner was used to document utilization.

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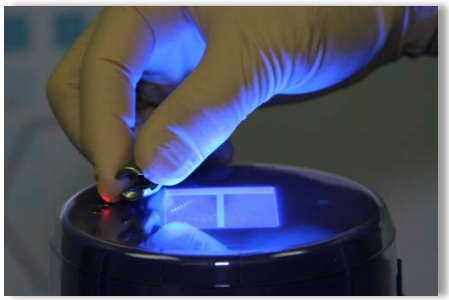
Simulated Surgery Case Flow

1. Prepare for Case
2. An anatomical representation of a male torso in the supine position was placed onto the bed. The torso's spine was revealed.
3. Prepare for Sterile Field DPM scanning
    i. Scan Tractus Sterile Drape with handheld scanner
    ii. Secure Tractus drape over the Tractus Sterile Field Scanner
    iii. Position Tractus Scanner into sterile field



4. Identify/document surgeon and patient
5. **Start Case**
6. Physician calls out for device
    iv. Scrub tech removes device from tray
    v. Scrub tech scans UDI from device or Data Carrier Tag
        i. If full UDI is not marked onto device, a cross-reference system is used to collect missing information (either DI or PI)
    vi. Scrub tech hands off device to surgeon
    vii. Surgeon implants device and calls out placement
        i. Circulator transfers device from "Assign" bin to correct anatomical placement (e.g. C3-C4 interspace or L1 pedicle left)
        ii. If device is removed from patient
            a. Surgeon calls out removal
            b. Circulator moves "Implanted Item" to "Trash Bin" and identifies reason
                i. Fitment
                ii. Defective
                iii. Non-sterile
                iv. Prior device revision or removal
    viii. All packaged products – Handheld Scanner
        i. If implant, scan package UDI and place into "Assign" Bin
        ii. Open package for scrub tech to bring into sterile field
        iii. If supply, place into "Supply" bin
        iv. Optional; write post-op notes into field
        v. **Close Case**, which transfers data to appropriate systems

Post-Operative Data Flow

1. Appropriate utilization is sent to:
    a. COMPANY (ex. Manufacturer, distributor, GPO)
    b. DEPARTMENTS (ex. medical records, EMR, EHR, central supply, SPD, revenue cycle management, surgery, etc.)
    c. INDIVIDUALS (ex. rep, agent, physician, patient)

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d. Replenishment order generated
e. Notify SPD of completed case

Findings

- Upon case completion, all surgical data was forwarded to the hospital's electronic health record, with data flowing from the Tractus Software to the facility's EHR system, including: Revenue Cycle Management, Medical Records and Supply Chain.
- The surgeon and staff reported that they believe that a reduction of case times is expected as a result of electronic data capture via Tractus vs manual systems.
- The potential for human error from manual call out of device identifiers was eliminated.
- The potential for inaccurate labeling, loss of stickers, or inaccurate identification of implanted vs discarded devices was eliminated.
- The anatomical location for each device was identified, making follow up care simplified.
- The facilities now have the capability to maintain easily indexed records matching patients to the implant and their anatomical placement.
- Once trained, staff reported the following:

i. Draping of the Tractus Sterile Field Scanner was easy, and could be performed several ways.

ii. Each Scanned device UDI was collected with no negative effects to the case flow or surgical times.

iii. The circulator easily managed the software and anatomical device placement.

iv. Tractus scanned each device within 0.33 and 0.62 second.

v. Tractus collected the full UDI from devices containing data matrix codes as small as $0.5mm^2$

vi. Compiled utilization data, with the ability to manage inventory and send device utilization reports to manufacturers.

vii. Device and case information seamlessly transferred data to the EHR

Lessons Learned

1. Manufacturers should include verification of direct part marks into their manufacturing process to ensure readability in the sterile field by the end user.
2. Manufacturers should verify that hospital has input all of their product codes into the Master Item List with corresponding UDI information.
3. FDA issuing agencies must ensure that their data matrix codes are "scalable," ensuring that full UDI capture is possible for small implants.
4. Hospitals should confirm that they allocate appropriate resources to ensure implementation success.
5. Hospital should have effective supply chain system that can cross-reference all product numbers to a specific product (ex. GTIN, Hospital generated barcode, Vendor

product code (UPC)). This information needs to be accessible to third party programs.

6. In lieu of supply chain system, Master Inventory List must cross-reference bar code(s) to products. As transition to FDA UDI standards agencies occur, cross referencing products will be crucial in accurate product identification.
7. Hospital surgery scheduling system should be accessible to provide case information (including patient and physician).
8. Hospital EHR system should be able to accept all identified case information, including anatomical location of implants.
9. EHR system should have the capability to forward appropriate case data to other systems, including medical records, inventory management, billing and collections, manufacturer, GPO, etc.
10. Hospital should assign a "project champion" to ensure that each requirement is met from each department on a timely basis.
11. Tractus eliminates data communication errors caused by verbal "call out" of UDI information.
12. Tractus may increase the speed of the case by eliminating pauses surgical team members call out hard to read numbers marked onto devices.
13. Tractus ensures utilization accuracy, including implanted vs discarded.
14. Tractus documents anatomical location in the event an implant must be removed or replaced.
15. Tractus eliminates the need for error-prone reference sheets, and reliance upon a rep to identify case utilization.
16. If available, Tractus can collect all device information, including lot and serial number, negating the need to reconcile "bill only purchase orders."

Anticipated Beneficiaries

- Patients
- Physicians
- Device Labelers
- Manufacturers
- Supply Chain Organizations
- Surgical Facilities
- Payers, and
- Government Agencies such as the FDA, ONC, HHS, CMS and the VA

Conclusion

The use of the Tractus Implant Tracking System successfully demonstrated that hospital-sterilized implants containing data matrix codes as small as 0.5mm^2 may be easily read AT THE POINT OF USE in the operating room sterile field.

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Further reporting includes:

1. Full device UDI
2. Case Utilization
3. Anatomical placement of each device
4. Discarded items by reason for discard
5. Myriad reports, including Pricing, Time Between Implantations, and Case Time, sorted by;
    a. Device, Surgeon, Diagnosis, Patient Gender and Patient Age

Laser companies and manufacturers that use the Tractus Implant Tracking System realize the following:

1. Adjust their laser marking systems to maximize DPM location and readability.
2. Optimize the power requirements needed to maximize device integrity.
3. Verify that hospital-sterilized implant data matrix codes may be read during surgery.

In addition, Manufacturers may use the Tractus sterile Field Scanner to manage field and consigned inventory by:

1. Scanning each tray that will be configured with implant tools and devices.
2. Scanning each device's data matrix code before placing them into pre-identified trays.
3. Assigning pre-filled trays to manufacturer representatives and/or hospitals.
4. Replenishing trays after completed surgeries.

Tractus was able to synchronize with the FDA's GUDID database, identifying all FDA approved medical devices as well as hospital-specific inventory. Further, Tractus was able to provide case-specific utilization reporting that may be documented in other departments and organizations, including; Sterile Processing, Medical Records, EMR/EHR, Surgery Scheduling, Surgery Management, Revenue Cycle Management, Inventory Management, Manufacturers and Group Purchasing Organizations (containing de-identified patient information).

Based upon the above findings, we believe that widespread implementation, integration, and adoption of Tractus will (1) contribute to the ability to quickly alert patients with defective devices, thus reducing patient injury, infection and death, (2) significant financial returns in eliminating duplicative and/or inaccurate manual input, (3) accurately identifying inventory and utilization, (4) optimizing outcomes through post-market surveillance efforts and (5) accurate charge capture and billing from manufacturers and healthcare providers.

Note: Tractus Sterile Drape is not yet available for use in the U.S.

Tractus Simulated Surgery Video – Wickenburg Community Hospital

Tractus Simulated Surgery Video – Wisconsin Health Center Hospital

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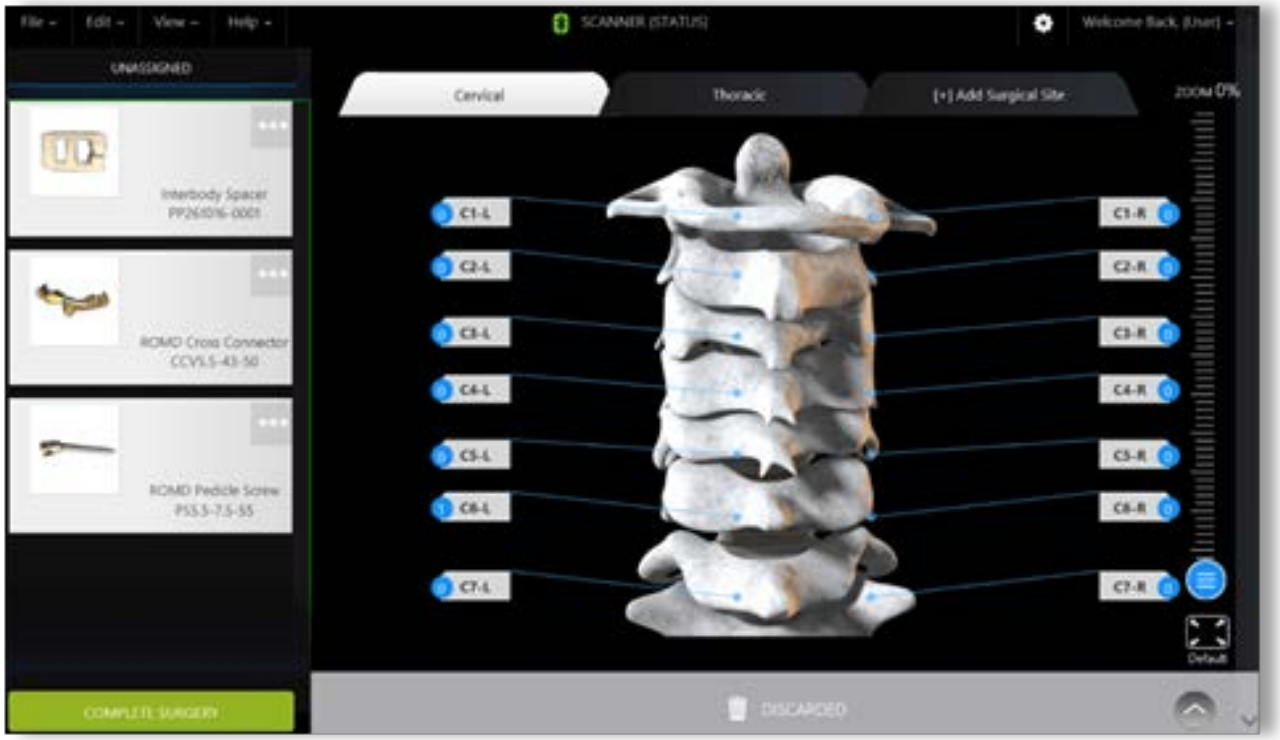
Tractus Scanner in Operating Room

Note: Tractus Sterile Drape is not yet available for use in the U.S.

Case Screen Shot



Inventory

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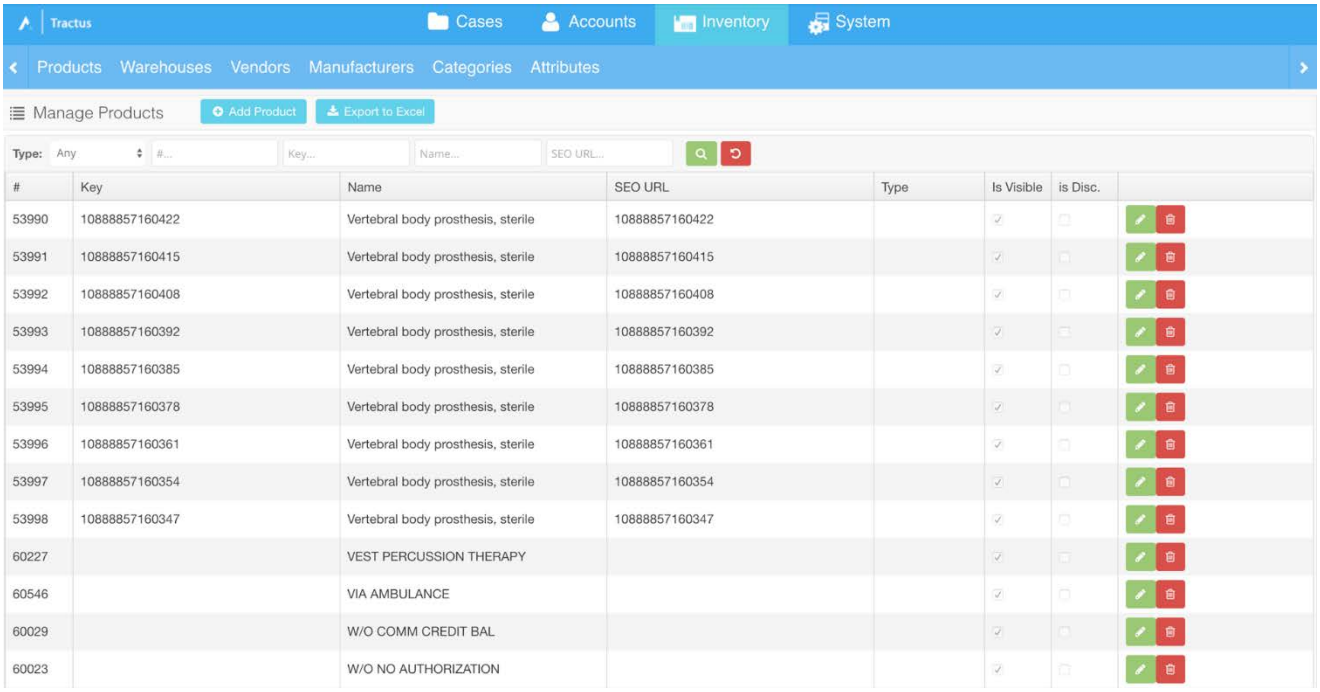

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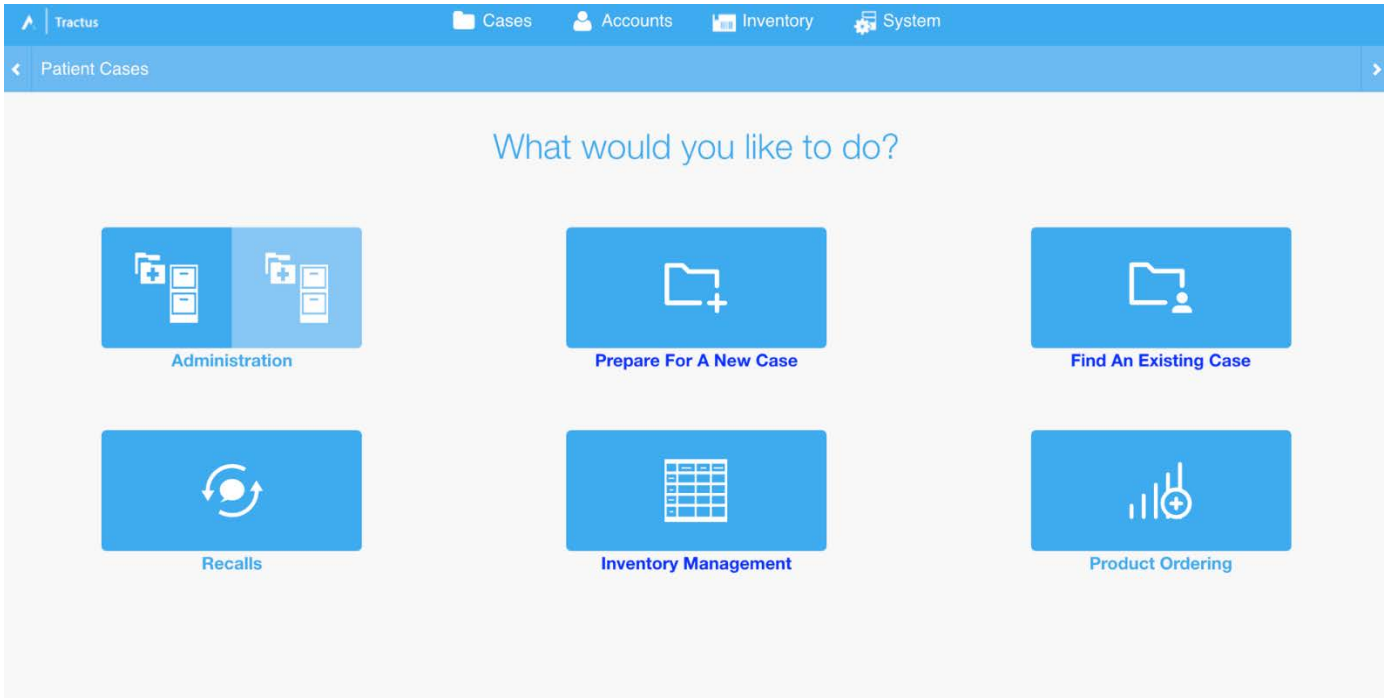
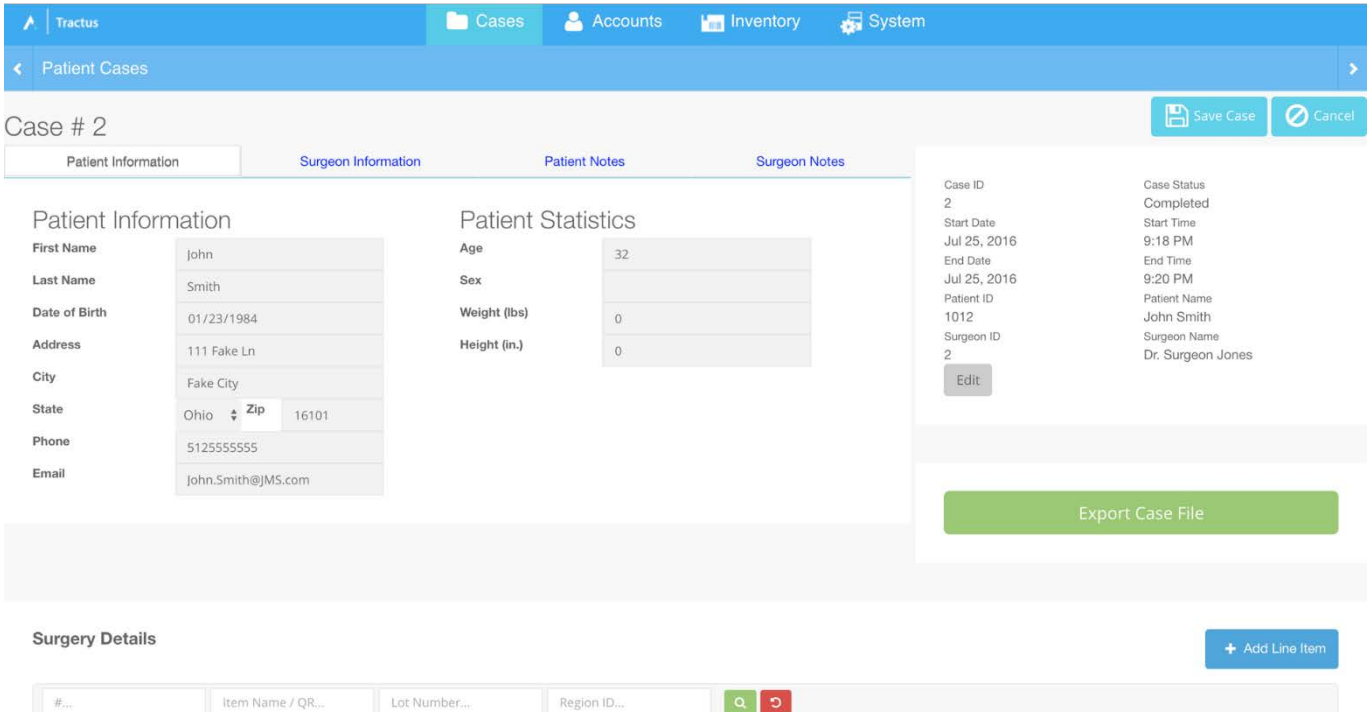
Patient Cases



Patient Statistics



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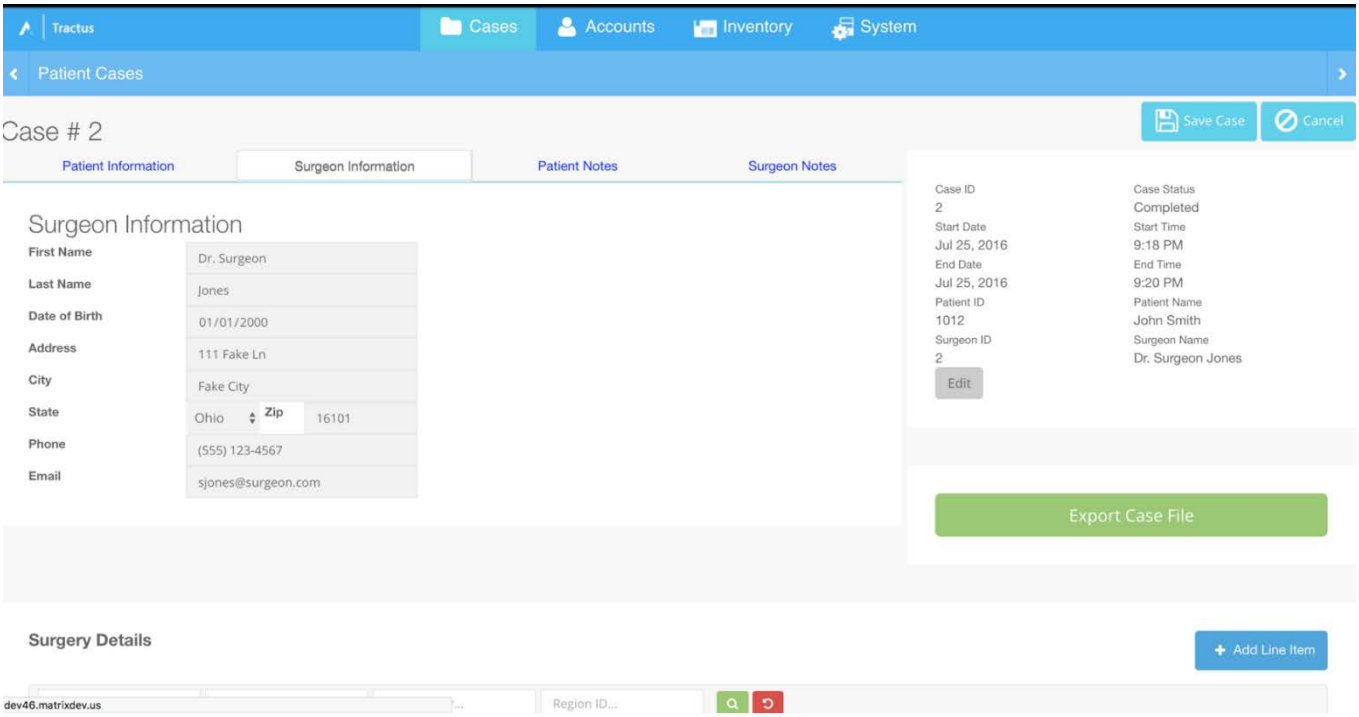
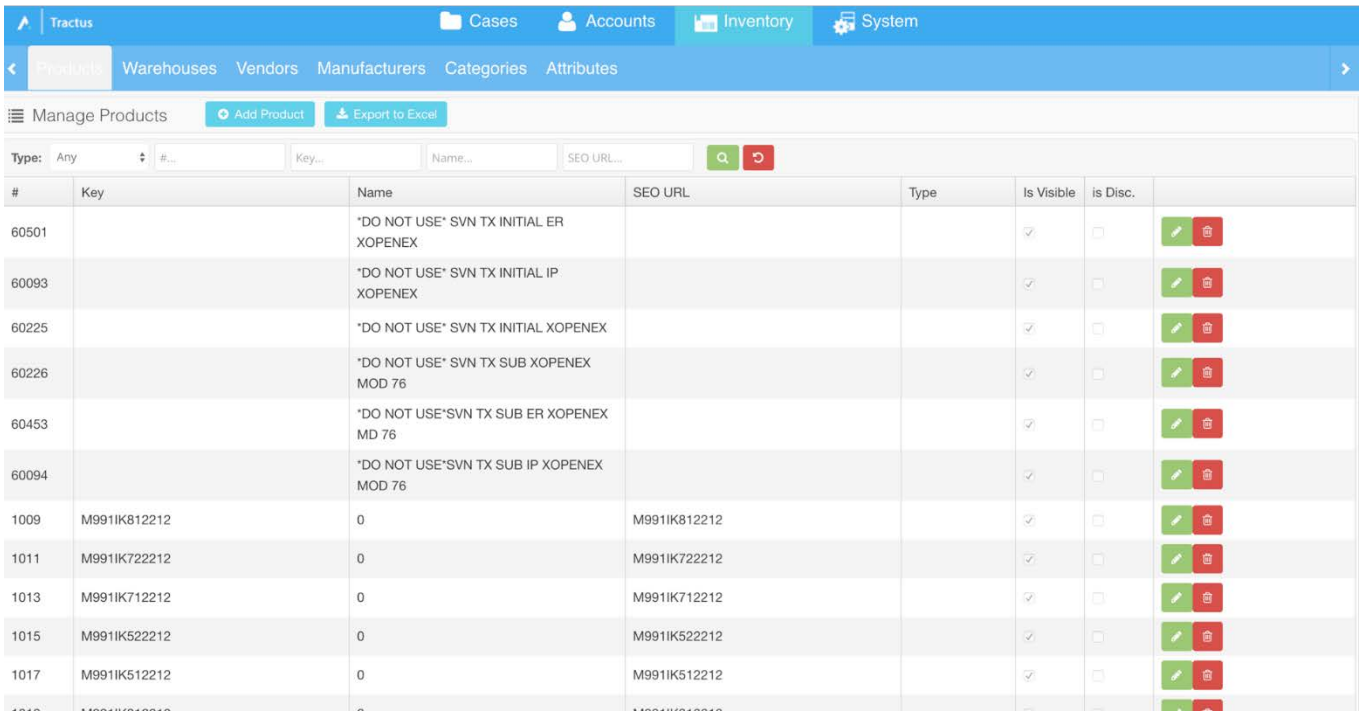
Surgeon Information



Data Synchronization



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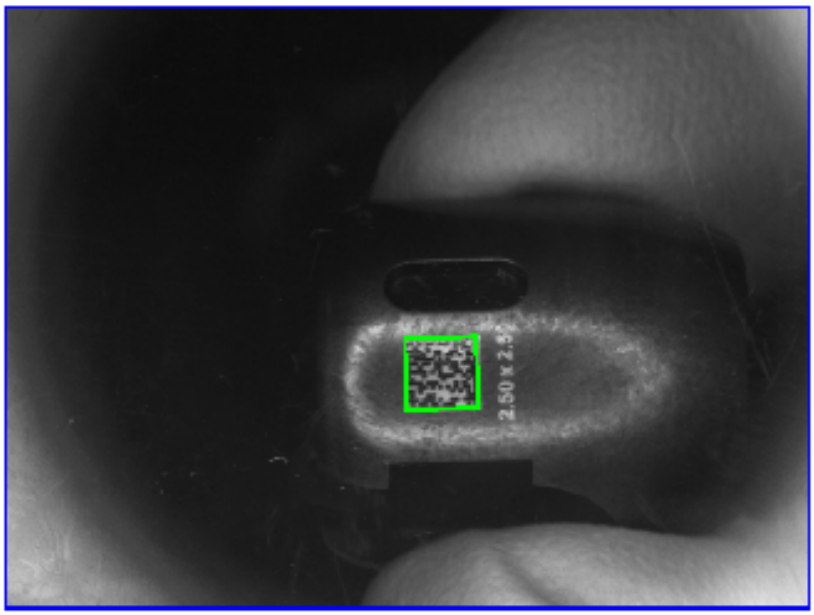
Process Control Metrics Report (HIBCC)

Process Control Metrics Report

Reader Name: Matrix Scanner
Timestamp: 7/1/2016 6:11:59 PM
Result Data: M824A5P60401/$XXXXXXN
Overall Result: PASS
Specification: AIM-DPM / ISO/IEC TR29158
Symbology: Data Matrix

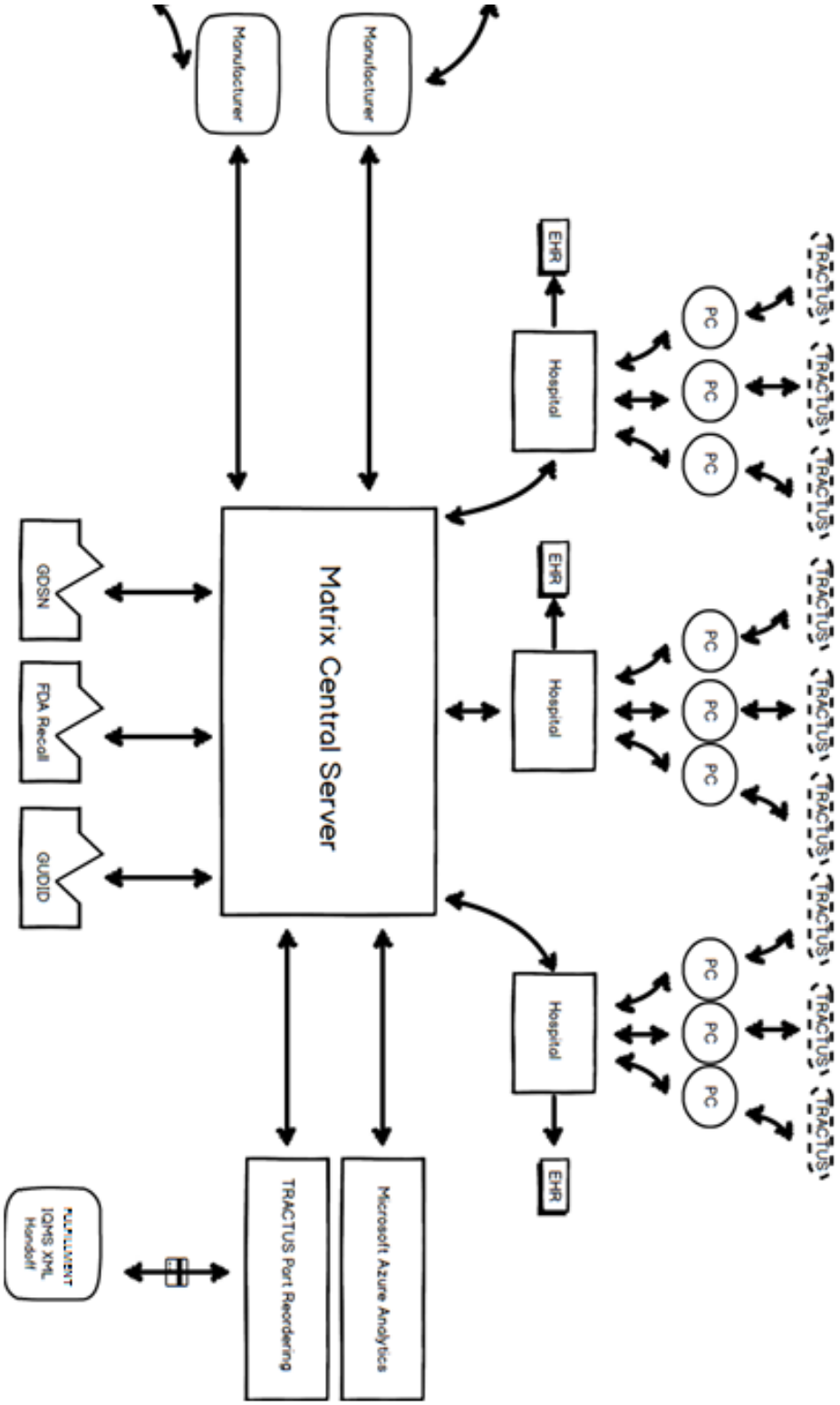
Image:



Detailed Results:

Quality Parameter	Result (Raw)	Grade
Overall Grade [custom grade]	4.0	A
Pixels Per Module	7.95	
Cell Contrast	0.54	A

Tractus System Configuration



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Hospital Data Flow