NORTH AMERICA

Virtual Seminar

UDI Beyond the Basics – A Masterclass on the Evolution of UDI

Unleashing the Potential of Medical Device UDI – The Clinically Integrated Supply Chain

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Unleashing the Potential of Medical Device Unique Device Identification – The Clinically Integrated Supply Chain

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DukeHealth

I have no conflicts of interest relevant to this presentation.

Unleashing the Potential of Medical Device UDI

- Are we there yet? What do we need to solve for?
- What is the clinically integrated supply chain?
- The Duke Cardiac Catheterization Laboratory experience
- UDI implementation – roadmap for healthcare enterprises

The View from the President's Office

- 2004 - President Bush establishes a 10-year goal to develop the electronic health record (EHR)
- 2009 - President Obama signs ARRA, pushes EHR adoption through incentives, targets full implementation by 2016

Airline Safety Revolution

Andy Pasztor, Wall Street Journal, 4/16/2021

AA587, 2001

- No US plane crash fatalities since 2009 (8 billion+ passengers) – attributed to a "… sweeping safety reassessment - a virtual revolution in thinking …"
  - Unified, data-driven safety agenda
  - Voluntary reporting, no blowback on airlines or aviators for good-faith mistakes
  - Sharing of information among pilots, carriers, manufacturers, government
  - "… simple in its fundamentals but wickedly difficult to implement …"

Easier to Identify Dog Food than a …

Becton Dickinson 1/2 mL Insulin Syringe/28 G needle

Business Name	Item Number Type	Item Number
BD	Mfg Catalog Number	329461
BD	GTIN	00382903294619
Cardinal Health	PV Order Number	BF329461
Owens & Minor	PV Order Number	0722329461
American Medical Depot	Vendor Catalog Number	777127217
Government Sci Source	Vendor Catalog Number	FSC1482679CS
Alliance Joint Venture	Vendor Catalog Number	888021932
Thomas Scientific	Vendor Catalog Number	8938M25
VWR International	Vendor Catalog Number	BD329461

Why a Unique Device Identifier (UDI)?

1. Reducing medical errors
2. Simplifying device information integration in health IT systems
3. Facilitating device identification in adverse event reporting
4. Returning performance information to manufacturers
5. Improving FDA device-related safety communications
6. Expediting recall management
7. Enabling patients and consumers
8. Benefitting healthcare enterprise operations

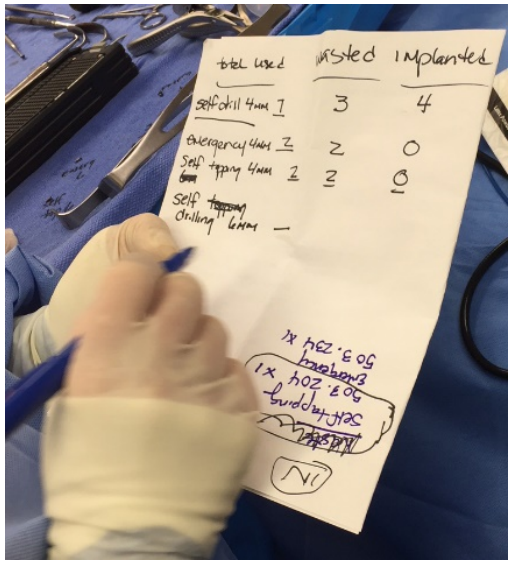
ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE

Unique Device Identification System. Federal Register 2013-23059.

https://accessgudid.nlm.nih.gov

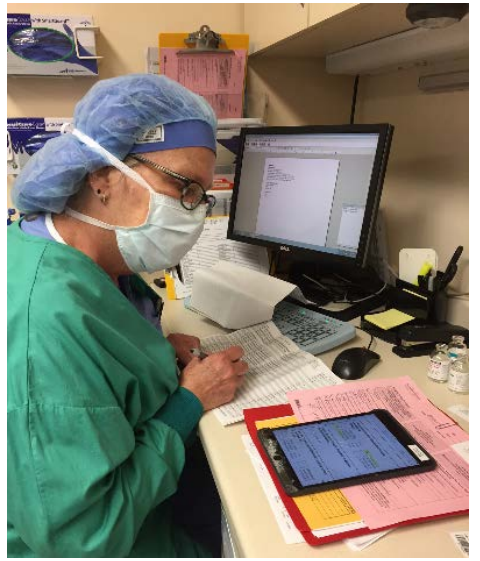
Manual Device Demand Tracking in the Operating Room (OR)

Multiple, error-prone manual steps to get usage information recorded



Surgery Tech: Records in (sterile) field

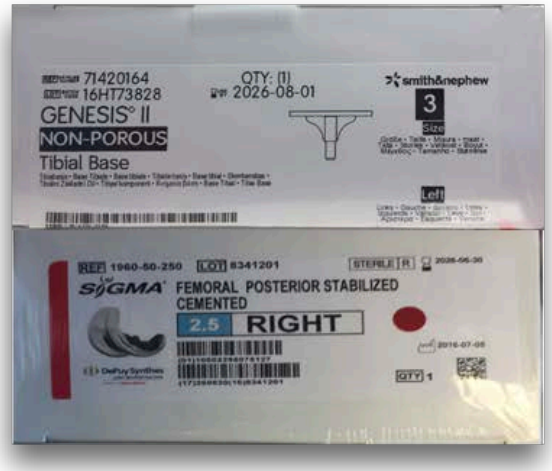
Circulating Nurse: Transcribes onto supplies form



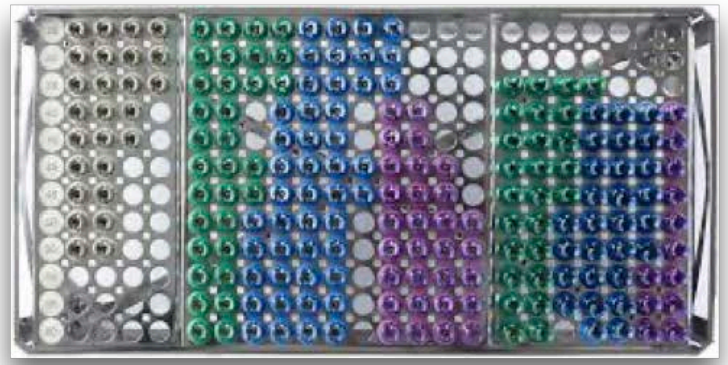
Data Manager: Manually enters into IT system

Physician: Recalls from memory!

Two Classifications of O.R. Supplies



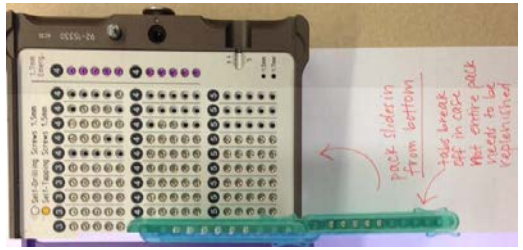
- Joints: hips, knees
- "Consumables": suture, etc.
- Sterile in labeled/bar-coded package
- Removed from package/POU at "edge of field"



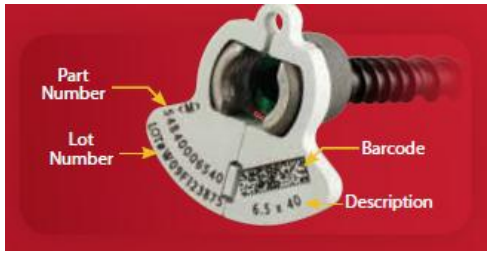
- Arrive at hospital non-sterile in package with label
- Removed from package, and sterilized at hospital
- POU inside sterile field
- Can't be (easily) scanned

Potential Approaches – In-Field Tracking

- Inventory sheets – “yesterday’s technology tomorrow”
- Individual sterile packaging – logistical, operational, workflow issues
- Direct part marking – not a viable solution for small parts
- Data carrier strips (devices from same lot attached to plastic strip)
- Data carrier tags (affixed to product, removed at point of use)
- Alternatives ???



Data Carrier Strip

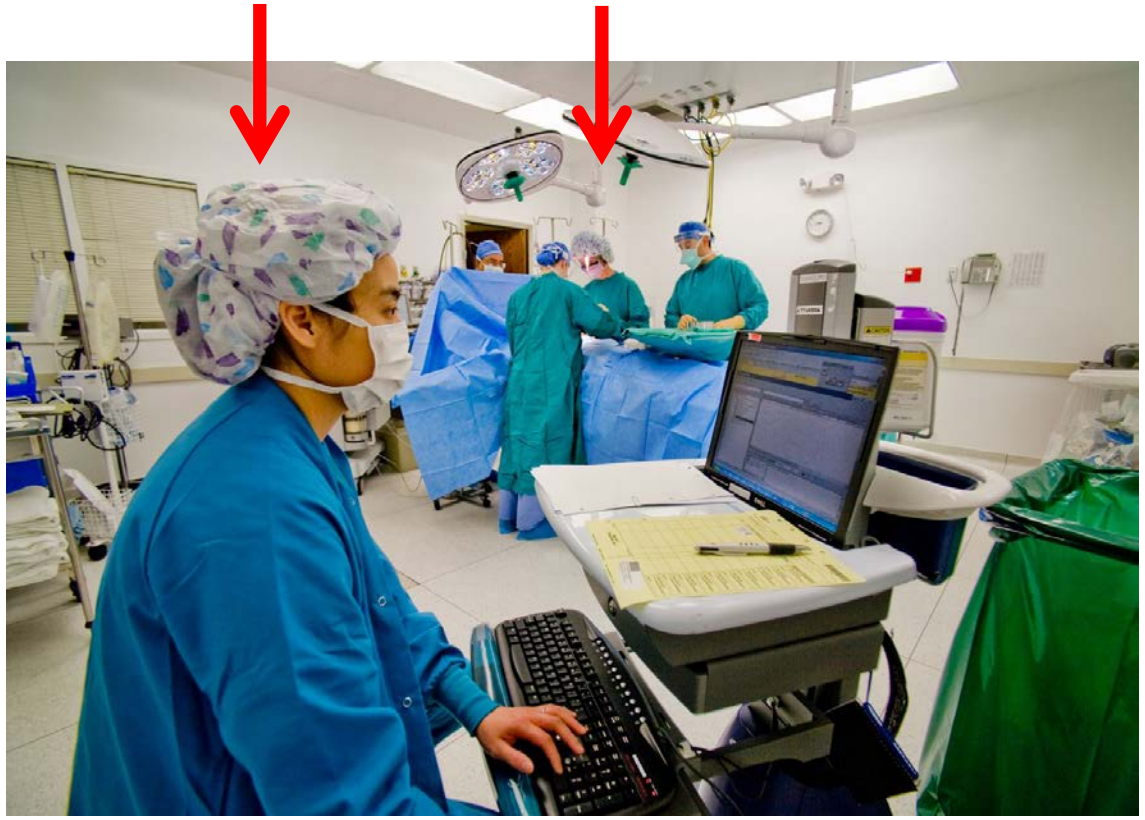


Data Carrier Tag

SMI UDI Compliance Initiative Report - Pleasants J. et al, 2015

Not point of use **Point of Use**

- Inconsistent labeling of sterile, “edge of field” packaged products
- “Non-steriles” cannot be directly scanned
- Point of recording is not the POU
- Need for single process for all supplies and devices integrated into OR workflow



Current State: Multitude of Issues

Hospitals / Clinicians / Healthcare

- Disconnected, manual supply chain, inventory control, clinical documentation, device recall processes
- Wasted supplies, lost revenue, higher costs
- Repetitive & inaccurate documentation, unnecessary clinician burden
- Inefficient/ineffective device assessment, compromised public health

Health IT Systems

- Lack of integrated, single source of truth based on electronically managed data at point of use
- Incomplete / inaccurate data → lack of confidence
- Deprecated analytics

Clinically Integrated Supply Chain

"… the collaboration of supply chain professionals, clinicians and senior leadership to make more informed product choices that support quality outcomes while reducing waste and lowering costs …"

3 steps to create a clinically integrated supply chain:

1. Commit to culture change
2. Use data analytics to support decision making
3. Educate clinicians

Becker's Hospital Review, 12/3/2018

HIMSS Clinically Integrated Supply Outcomes Model (CISOM Maturity Model)

Stage 0: manual inventory & supply, no supply chain strategy
Stage 1: basic supply chain processes as organization business function
Stage 2: tracking & automation focused on supply costs, inventory management
Stage 3: supply chain strategy creates visibility of inventory across organization
→ automates financial processes, informs product standardization
Stage 4: integration and linkage with clinicians and patient care
Stage 5: automated / integrated at POC to enable tracking, traceability, recalls
Stage 6: integration into care processes, with tracking at the point of care, enabling of analytics, linkage with adverse events / outcomes
Stage 7: precision and personalized healthcare, predictive analytics at POC, patient-enabled literacy

https://www.himss.org/what-we-do-solutions/digital-health-transformation/maturity-models/clinically-integrated-supply-outcomes-model-cisom

Cardiac Cath Lab – An Optimal Test Environment

Rationale

- High volume of cases
- Supplies, devices are UDI marked
- High-cost devices, implants
- Semi-sterile environment – fewer logistical barriers than the OR

Pre-Conditions

- CISOM Stage 2+: robust supply chain, item master
- Agile procedure documentation system

Project Goals: *The High Reliability Organization*

1. Single source of truth for disposables, devices, supplies
2. Point of use UDI scanning, including usage (differentiation of supplies from implanted devices, wastage, etc.)
3. Liquid, real-time data exchange across requisite IT systems (inventory management, supply chain, procedure documentation and reporting, and electronic health record HIT systems
4. Global use of UDI, associated data across inventory management (stocking and usage), supply chain (contracts, replenishment), clinical documentation (procedure reporting), billing and charge capture (financials)

Source: Google.com

Project Stages

1. Strategy setting – high-level goals: framework, scope, overall project plan
2. Planning – specifying dataflows, workflows, cost, deliverables, timelines
3. Technical build – new inventory management system, user interfaces, source of truth assignments, multiple IT interfaces, testing
4. Deployment (Big Bang)

G2 Planning

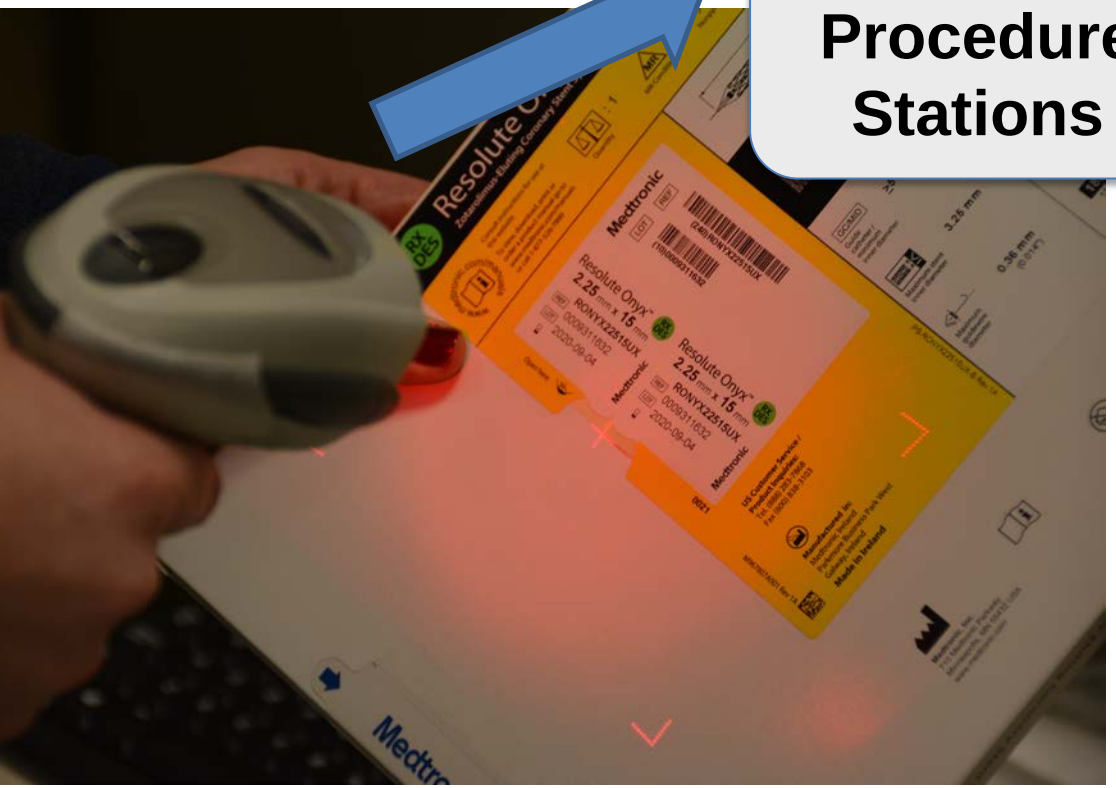
Work Completed For G2 Review / Approval	Date Completed	Owner	Resource	Status
Pass G1 (Gate 1)	4/22/2016	Dustin Williams	Tim Small	Complete
G2 Planned and Resource	6/10/2016	Dustin Williams	Tim Small	Complete
V10 Upgrade/ SAP Pyxis Interface complete	8/23/2016	Dustin Williams	Tim Small	Complete
Functional Orders Interface Specifcations	12/12/2016	Dustin Williams	Tim Small	Complete

Planning for G3

Work Proposal For Next Stage	Target Start	Target Finish	Owner	Resources	J	F	M	A	M	J	J	A	S	O	N	D	Status
DESIGN/CODE/BUILD/SETUP	**1/1/2017**	**6/9/2017**	**Dustin Williams**	Tim Small													On Track
CareFusion Orders Interface Detailed Specifications	1/1/2017	4/7/2017	Dustin Williams	CareFusion													On Track
Suppy Usage Interface (Lumedx)	2/20/2017	4/7/2017	Joe Kelly	Joe Kelly													On Track
Outgoing Radiant Interface	4/3/2017	4/24/2017	Dustin Williams	Melanie McIndoo													On Track
Item Master Load	4/24/2017	5/12/2017	Kirk Wiedmeier	Helen Brann													On Track
Duke University Supply Stations Install	4/17/2017	4/21/2017	Kirk Wiedmeier	Helen Brann													On Track
Duke Regional Supply Stations Install	4/24/2017	4/28/2017	Kirk Wiedmeier	Robin Butler													On Track
Duke Raleigh Supply Station Install	6/5/2017	6/9/2017	Kirk Wiedmeier	Abbie Dickersheid													On Track
Test Environment	4/3/2017	4/14/2017	Dustin Williams	CareFusion													On Track
Station Inventory Scan/Load	4/24/2017	5/12/2017	Helen Brann	Duke, LumedX													On Track
CareFusion Security Server	3/3/2017	4/13/2017	Dustin Williams	Tim Small													On Track
TESTING	**4/24/2017**	**4/28/2017**	**Dustin Williams**	Kirk Wiedmeier													
CareFusion Orders Interface/Outgoing Radiant	4/24/2017	4/28/2017	Dustin Williams	CareFusion, Duke													On Track
Suppy Usage Interface (Lumedx)	4/24/2017	4/28/2017	Dustin Williams	CareFusion, Duke													On Track
Cath & EP Procedural Stations integration	4/24/2017	4/28/2017	Dustin Williams	CareFusion, Duke													On Track
TRAINING	**2/1/2017**	**5/26/2017**	**Dustin Williams**	Tim Small													On Track
Identify/Load LMS Content	2/1/2017	3/3/2017	Helen Brann	Brian Aucoin													On Track
Super User training (about 5)	5/22/2017	5/26/2017	Dustin Williams	CareFusion, Duke													On Track
User training (about 20)	5/22/2017	5/26/2017	Dustin Williams	CareFusion, Duke													On Track
STRA	**4/3/2017**	**5/23/2017**	**Dustin Williams**	Tim Small													On Track
G3	**5/26/2017**	**5/26/2017**	**Dustin Williams**	Tim Small													On Track
RELEASE TO PRODUCTION	**6/12/2017**	**7/24/2017**	**Dustin Williams**	Tim Small													On Track
Go Live Duke University Ep/Cath	6/12/2017	6/12/2017	Kirk Wiedmeier	CareFusion, Duke													On Track
Go Live Duke Regional EpCath Lab	6/12/2017	6/12/2017	Kirk Wiedmeier	CareFusion, Duke													On Track
Go Live Duke Raleigh Ep/Cath Labs	7/12/2016	7/12/2017	Kirk Wiedmeier	CareFusion, Duke													On Track
Post Implementation	**7/18/2017**	**7/24/2017**	**Dustin Williams**	Process Owners													On Track
Production monitoring	7/18/2017	7/24/2017	Kirk Wiedmeier	CareFusion, Duke													On Track
Resolve outstanding issues	7/18/2017	7/24/2017	Kirk Wiedmeier	Duke, PMO													On Track
PROJECT CLOSE	7/28/2017	7/28/2017	**PMO**	Tim Small													On Track
Release Project Manager	7/28/2017	7/28/2017	PMO	Tim Small													On Track

Clinically Integrated Supply Chain:
UDI as the Single Source of Truth

- Manufacturer
- Supply chain (item master, procurement)
- (Local) inventory management
- Point of use scanning and usage (e.g., wastage)
- Clinical documentation (e.g., procedure notes, EHR implant log)
- Charge capture / billing
- Inventory JIT replenishment



Epic Radiant EHR

Orders ORM
Pt data
Accession, case #
Procedure data

SAP Item Master

Items data (ASCII)

EDW

Pyxis Procedure Stations

BD CCE Care Coordination Engine

Usage DFT
Pt data
Accession #
UDI (DI + PI)
Serial, lot #
Expiration
Procedure data

Inventory replenishment data

Lumedx Procedure Documentation

SAP Replenishment JIT Ordering

What Does UDI "Single Source of Truth" Enable?

- Standardized device description in clinical documentation
  - no more MD recall, transcription errors in procedure reports
- Tight inventory management (e.g., lower PAR levels, JIT supply chain)
- Device use attribution (e.g., implants, wastage)
- Consignment device management
- UDI to the EHR (exported to the UDI device implant table)
- Device explants (e.g., CIED) – closing the loop
- Administrative reporting (e.g., device usage reports)
- Adverse event reporting (e.g., FDA MedWatch)
- Analytics (e.g., recall management)

Our Results

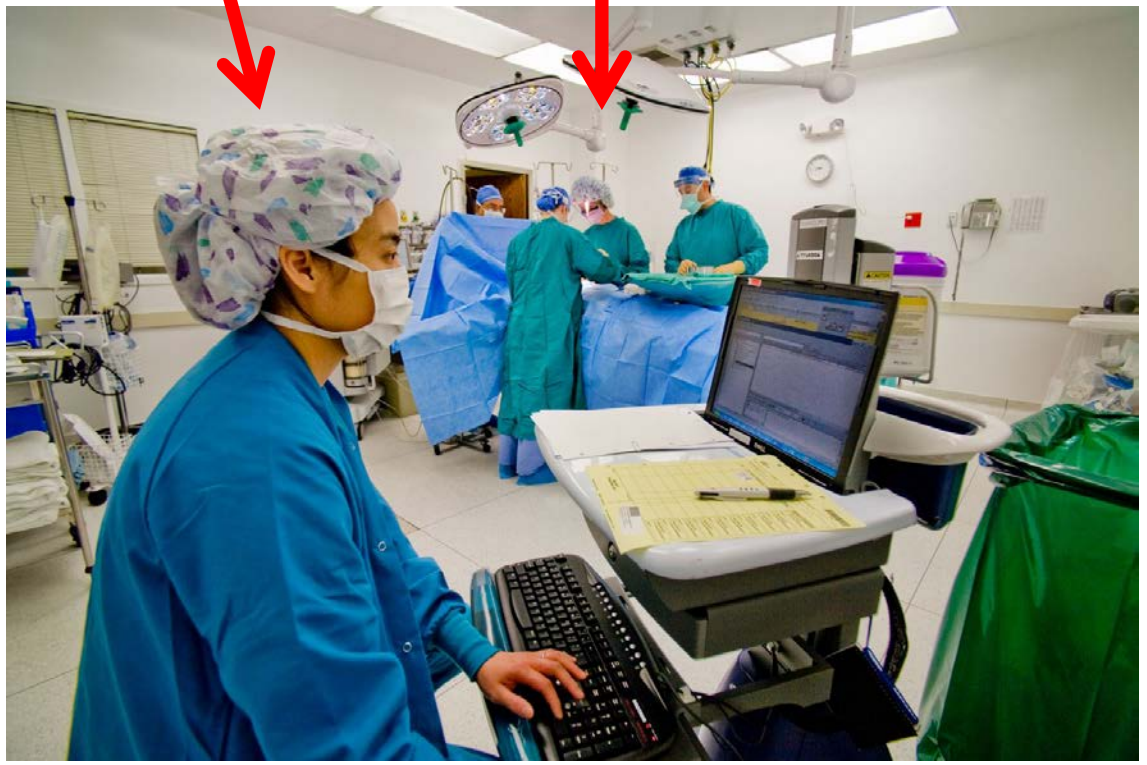
1. Successful go-live, no glitches
2. Elimination of manual clinical, inventory management documentation
3. Reduction of clinical documentation errors to negligible levels
4. Time savings of 20 minutes per case (CIED device implants / explants)
5. Automated listing of implant information in EHR device implant table
6. Tightly managed inventory, supply chain replenishment processes
7. Query-based device recalls
8. >$500,000 / year net positive (cardiac cath and electrophysiology labs)

4 Problems to Solve

1. Inefficient, error-prone manual processes (and culture!)
2. Separate workflows for pre-packaged sterile devices vs. “non-steriles” supplied in trays
3. Inability to (easily) associate UDI to non-steriles
4. Documentation not at point of use

Not point of use

Point of Use



Set Mapping

- Tray locations marked with durable microchip technology
- Tray information mapped via software
- Laser wand reader that sterilizes
- Scan at POU inside sterile field
- Works with ANY vendor, any tray
- “Roll in” solution, **no** disruption to surgical workflows

1. Sterile Field POU scanning of implant usage (Scan Ready Trays)

2.

Edge of Field POU **label** scanning via OCR (Symmetric)

3.

UDI data output with barcodes (on 4x6 labels)

Booking Number:	UVMS789653259
Surgeon Name:	Smith, Edward (Orthopedics)
Case Type:	Distal Radius ORIF
Case Date:	Fri, Jan 29, 2021 1:00:00 PM
Circulating Nurse:	Jenn Crowley
Patient Initials:	PS

IMPLANTS

Id	Name	Par	Used	Wasted	Tota
137-14305	DRLP, Intra Articular, Small-R	1	1	0	1
08809438365796					
901-31120	Drill Bit, AO Chuck-2.0 X 130m	1	1	0	1
225-24114	2.5mm Locking Screw, Small Hea	9	1	0	1
08809517537519					
225-24116	2.5mm Locking Screw, Small Hea	9	1	0	1
08809517537526					
225-24118	2.5mm Locking Screw, Small Hea	9	1	0	1
08809517537533					
225-25114	2.5mm Locking Screw, Blunt Tip	9	0	1	1
08809517537625					
225-25116	2.5mm Locking Screw, Blunt Tip	9	3	0	3
08809517537632					

CONSUMABLES

Id	Name	Part	Lot	Exp
	Clip Applier with Clip Logic	176630	Hj65984	Dec 15 2021
10884521057852				
	Paddle Retractor	173046	DS95562	Mar 03 2022
10884523000771				

Thank You!

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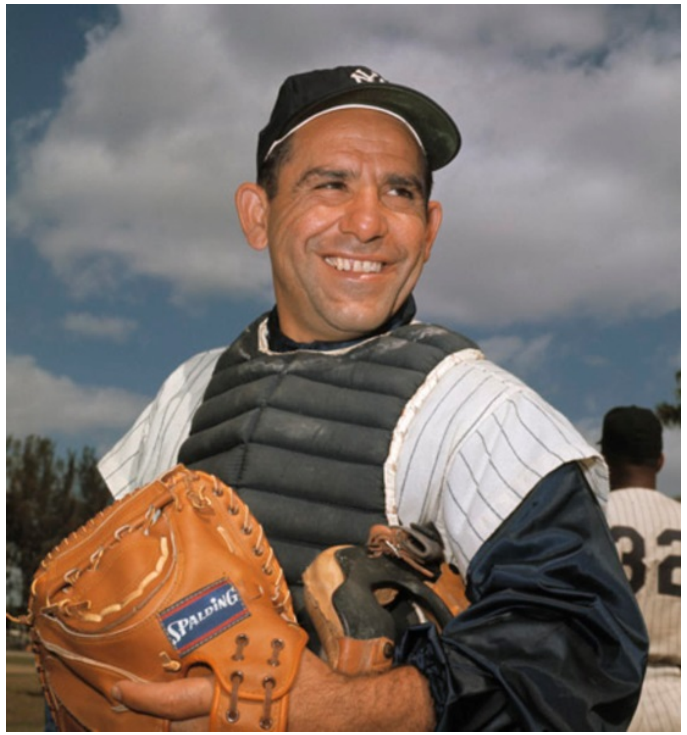

If you don't know where you are going, chances are you will end up somewhere else.

-- Yogi Berra (1925-2015)