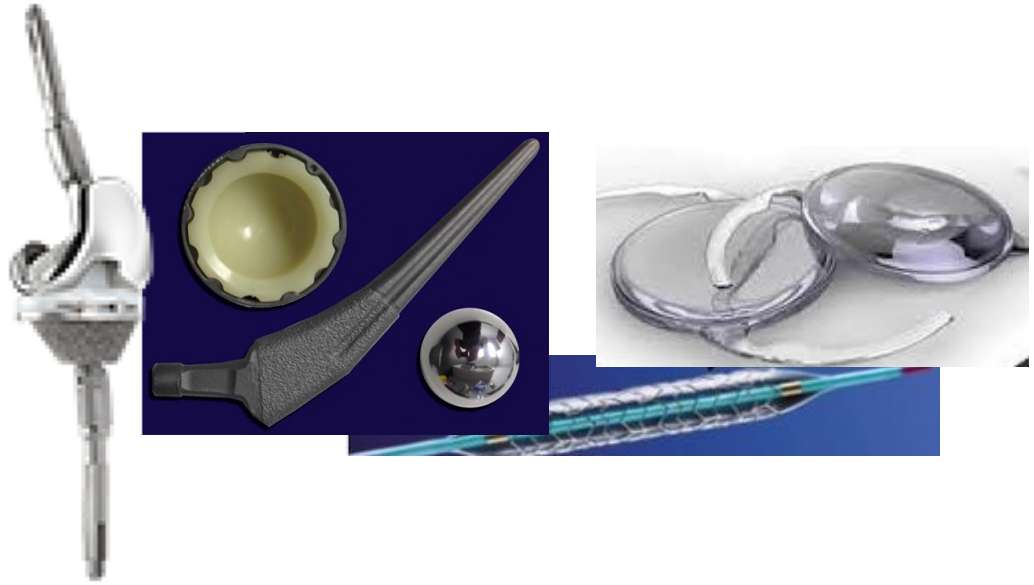
Use of RAIN RFID-based solutions for inventory management and UDI compliance for critical consumable medical devices at hospitals



March 2019

VUEMED's technologies address some of the most critical, costly, and challenging issues affecting the healthcare supply chain today

VUEMED
Cloud & SaaS & IoT

VUETRACK RF

Hands-free **RAIN RFID** solution turns distribution, storage areas, cabinets, procedure room, and hallways into a fully RFID-controlled supply chain from manufacturer to the hospital patient, and reports live all inventory transactions with 99.5% accuracy – transaction-free.

VUETRACK UDI

Software/RFID printer solution that encodes and registers in the cloud RFID tags according to FDA UDI standards, using GS1 EPC Gen2 passive RFID global standards and recording all tag events using the VueTrack-RF infrastructure.

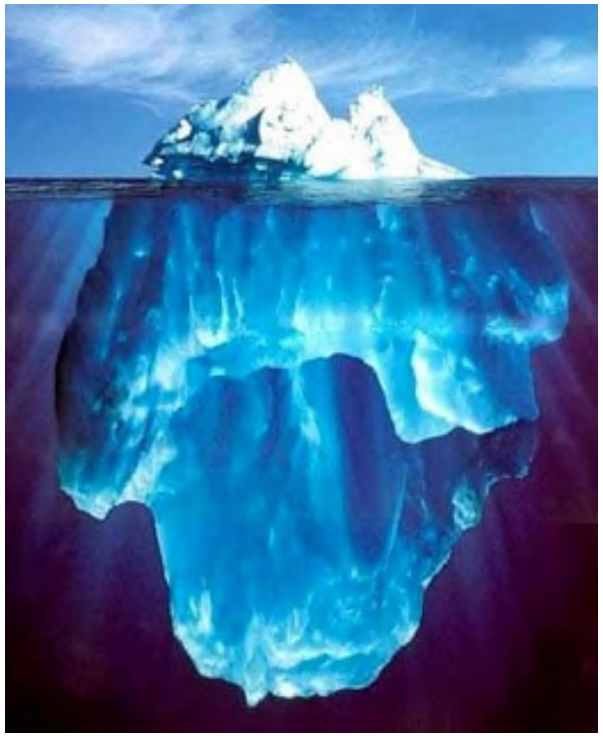
mobile VUETRACK

Hand-held **RAIN RFID** technology device powered by the VueTrack-Mobile App to manage consigned inventory, trunk stock, provide VMI services, etc. Ideal for physical inventory takes with a single scan. Provides detailed rep account data, analysis, and metrics.

VUETRACK

Comprehensive yet flexible barcode scanning solution that manages products from their delivery to the point of care, while bridging the information gap at hospitals and delivering ROI > 5x1.

The global medical device industry* is ~$390B/yr**, 40% in the U.S. alone.
U.S. hospital spending is about $1 trillion/yr***



Dollar share of products NOT tracked or accounted for by most hospitals*

Inventories are poorly managed and not tracked, costing $ billions in waste

- **Bloated inventory by >20%**
- **Excess purchases by >15%**
- **Waste levels >20%**
- **Missed revenue from inaccurate billing >18%**

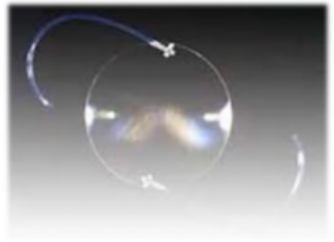
THE OPPORTUNITY

…and the entry point for more tracking technology and data applications

* Includes stents, balloons, catheters, orthopedic devices, instruments, etc.
** Visiongain, Espicom Business Intelligence, Frost & Sullivan, SelectUSA.gov
*** CMS.gov

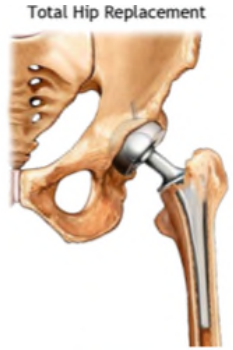
Patients' Implantable Devices List

IOL
2006

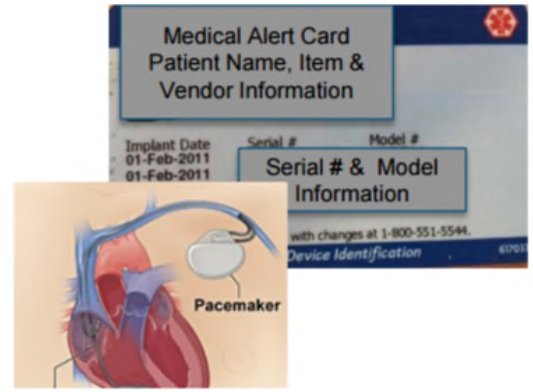


DES
2010

WALKER
2012

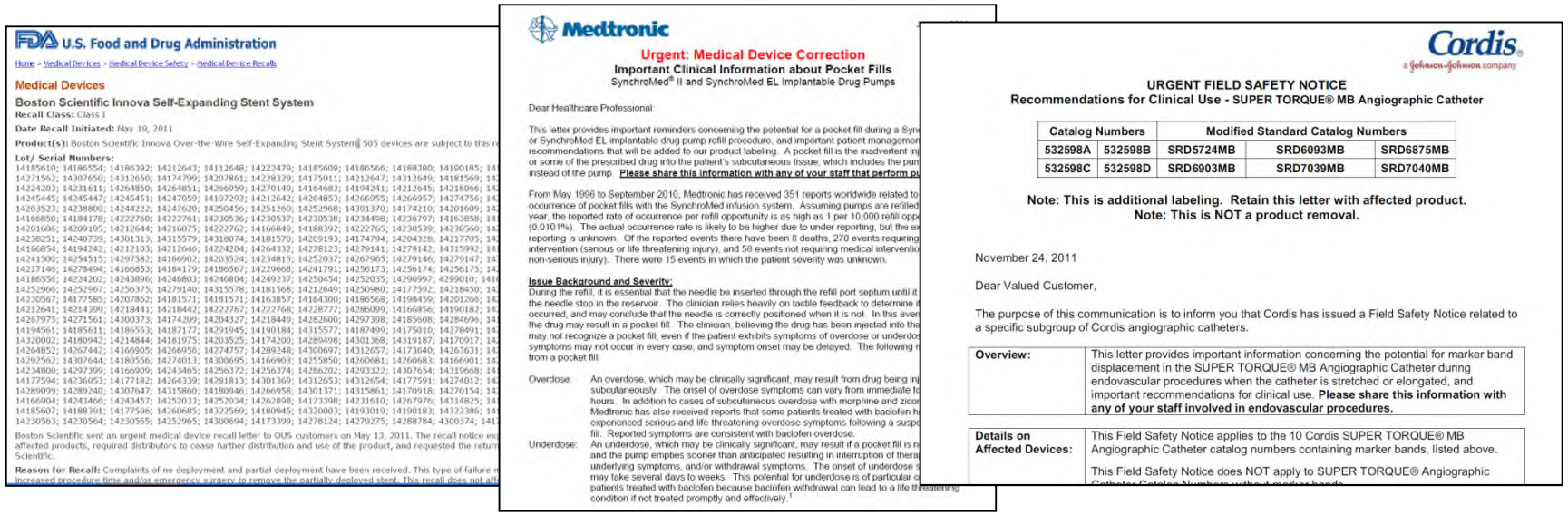


HIP
2008



PACEMAKER
2011

- 600 - 1,200 medical device recalls issued each year, affecting hundreds of millions of units
- 2-4% are Class I recalls – which pose a serious risk of injury or death* - meaning several million units need to be tracked down, removed from shelves and/or required clinical follow-up



U.S. Food and Drug Administration

Home > Medical Devices > Medical Device Safety > Medical Device Recalls

Medical Devices

Boston Scientific Innova Self-Expanding Stent System

Recall Class: Class I

Date Recall Initiated: May 19, 2011

Product(s): Boston Scientific Innova Over-the-Wire Self-Expanding Stent System 505 devices are subject to this re

Lot/ Serial Numbers:

14185610; 14186554; 14186392; 14212643; 14112648; 14222479; 14185609; 14186566; 14188380; 14190185; 14...
14271562; 14307650; 14312650; 14174799; 14207861; 14228329; 14175011; 14212647; 14312649; 14181569; 14...
14224203; 14231611; 14264850; 14264851; 14266959; 14270149; 14164683; 14194241; 14212645; 14218066; 14...
14245445; 14245447; 14245451; 14247059; 14197292; 14212642; 14264853; 14266955; 14266957; 14274756; 14...
14203523; 14238800; 14244222; 14247620; 14250456; 14251260; 14252968; 14301370; 14174210; 14201609; 14...
14166850; 14184178; 14222760; 14222761; 14230536; 14230537; 14230538; 14234498; 14236797; 14163858; 14...
14201606; 14209195; 14212644; 14216075; 14222762; 14166849; 14188392; 14222765; 14230539; 14230560; 14...
14238251; 14240739; 14301313; 14315579; 14318074; 14181570; 14209193; 14174794; 14204328; 14217705; 14...
14166854; 14194242; 14212103; 14212646; 14224204; 14264332; 14278123; 14279141; 14279142; 14315992; 14...
14241500; 14254515; 14297582; 14166902; 14203524; 14234815; 14252037; 14267965; 14279146; 14279147; 14...
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14234800; 14297399; 14166909; 14243465; 14256372; 14256374; 14286202; 14293322; 14307654; 14319668; 14...
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14185607; 14188391; 14177596; 14260685; 14322569; 14180945; 14320003; 14193019; 14190183; 14322386; 14...
14230563; 14230564; 14230565; 14252965; 14300694; 14173399; 14278124; 14279275; 14288784; 4300374; 141...

Boston Scientific sent an urgent medical device recall letter to OUS customers on May 13, 2011. The recall notice ex... affected products, required distributors to cease further distribution and use of the product, and requested the return... Scientific.

Reason for Recall: Complaints of no deployment and partial deployment have been received. This type of failure m... increased procedure time and/or emergency surgery to remove the partially deployed stent. This recall does not aff...

Medtronic

Urgent: Medical Device Correction

Important Clinical Information about Pocket Fills

SynchroMed® II and SynchroMed EL Implantable Drug Pumps

Dear Healthcare Professional:

This letter provides important reminders concerning the potential for a pocket fill during a Syn... or SynchroMed EL implantable drug pump refill procedure, and important patient management... recommendations that will be added to our product labeling. A pocket fill is the inadvertent inj... or some of the prescribed drug into the patient's subcutaneous tissue, which includes the pum... instead of the pump. **Please share this information with any of your staff that perform pu...**

From May 1996 to September 2010, Medtronic has received 351 reports worldwide related to... occurrence of pocket fills with the SynchroMed infusion system. Assuming pumps are refilled... year, the reported rate of occurrence per refill opportunity is as high as 1 per 10,000 refill opp... (0.0101%). The actual occurrence rate is likely to be higher due to under reporting, but the ex... reporting is unknown. Of the reported events there have been 8 deaths, 270 events requiring... intervention (serious or life threatening injury), and 58 events not requiring medical interventio... non-serious injury). There were 15 events in which the patient severity was unknown.

Issue Background and Severity:

During the refill, it is essential that the needle be inserted through the refill port septum until it... the needle stop in the reservoir. The clinician relies heavily on tactile feedback to determine i... occurred, and may conclude that the needle is correctly positioned when it is not. In this even... the drug may result in a pocket fill. The clinician, believing the drug has been injected into the... may not recognize a pocket fill, even if the patient exhibits symptoms of overdose or underdos... symptoms may not occur in every case, and symptom onset may be delayed. The following r... from a pocket fill:

Overdose: An overdose, which may be clinically significant, may result from drug being inj... subcutaneously. The onset of overdose symptoms can vary from immediate to... hours. In addition to cases of subcutaneous overdose with morphine and zico... Medtronic has also received reports that some patients treated with baclofen h... experienced serious and life-threatening overdose symptoms following a suspe... fill. Reported symptoms are consistent with baclofen overdose.

Underdose: An underdose, which may be clinically significant, may result if a pocket fill is n... and the pump empties sooner than anticipated resulting in interruption of thera... underlying symptoms, and/or withdrawal symptoms. The onset of underdose s... may take several days to weeks. This potential for underdose is of particular c... patients treated with baclofen because baclofen withdrawal can lead to a life threatening condition if not treated promptly and effectively.[1]

Cordis
a Johnson & Johnson company

URGENT FIELD SAFETY NOTICE

Recommendations for Clinical Use - SUPER TORQUE® MB Angiographic Catheter

Catalog Numbers		Modified Standard Catalog Numbers		
532598A	532598B	SRD5724MB	SRD6093MB	SRD6875MB
532598C	532598D	SRD6903MB	SRD7039MB	SRD7040MB

Note: This is additional labeling. Retain this letter with affected product.
Note: This is NOT a product removal.

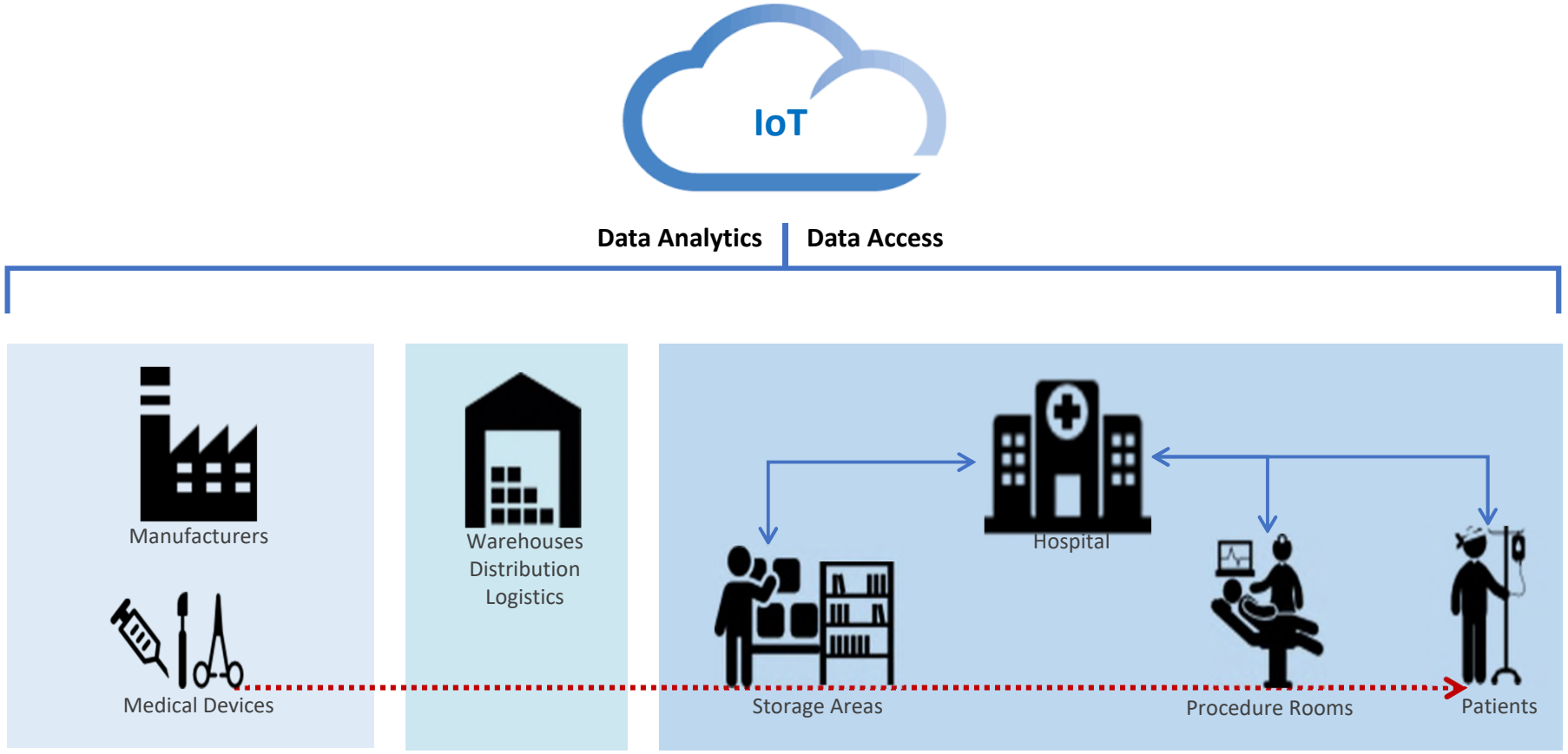
November 24, 2011

Dear Valued Customer,

The purpose of this communication is to inform you that Cordis has issued a Field Safety Notice related to a specific subgroup of Cordis angiographic catheters.

Overview:	This letter provides important information concerning the potential for marker band displacement in the SUPER TORQUE® MB Angiographic Catheter during endovascular procedures when the catheter is stretched or elongated, and important recommendations for clinical use. **Please share this information with any of your staff involved in endovascular procedures.**
Details on Affected Devices:	This Field Safety Notice applies to the 10 Cordis SUPER TORQUE® MB Angiographic Catheter catalog numbers containing marker bands, listed above. This Field Safety Notice does NOT apply to SUPER TORQUE® Angiographic

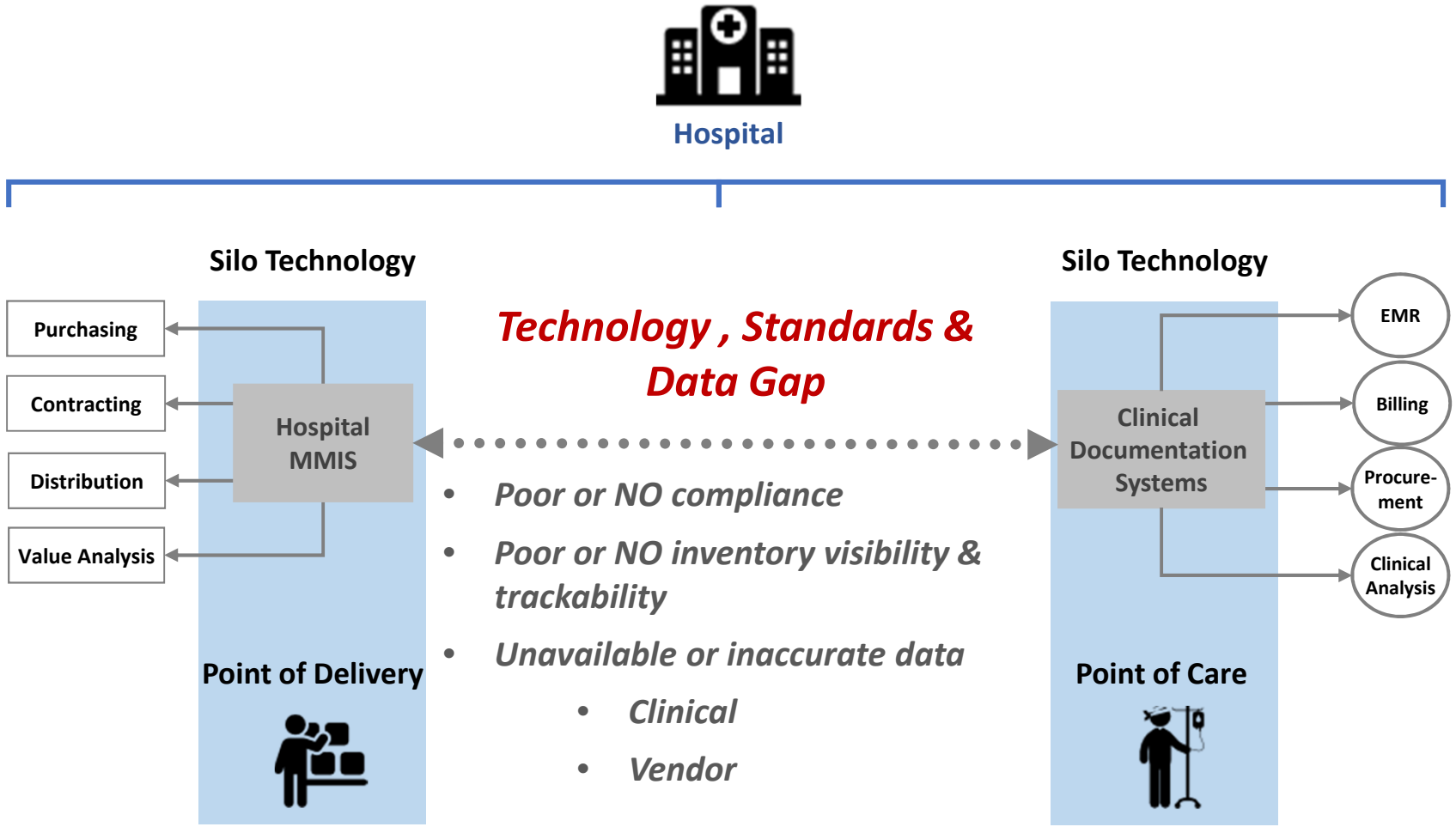
Transformation of the healthcare supply chain, from manufacturer to patient, will provide better, safer and more affordable patient care



What is driving the current sense of urgency to adopt technology to improve the healthcare supply chain?

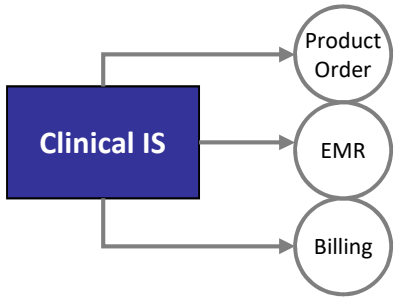
- **Imperative cost reduction**:
  - Waste of time locating products and assets; waste through expirations
  - Risk to the patient: stock-out, expired or recalled items, inaccurate medical records
  - Efficiency: leaner, consolidated supplies; less time delivering better care
- **Market enthusiasm for SaaS, Cloud-based, high ROI solutions**
- Market seeking to achieve **100% compliance**, visibility, and trackability in supplies management, and scalability to assets/equipment and people
- FDA's Unique Device Identifier (**UDI**) by 2020
  - Global impact: barcodes or RFID, EPC and GS1, HIBCC
- **Reimbursement environment changing**:
  - Shrinking reimbursement – do more for less
  - Higher level procedural details becoming required by payors, including UDI data by CMS

This gap of technology, standards, and data reinforces existing silos inside hospitals and prevents the supply chain from being transformed into a value chain both inside and outside hospitals

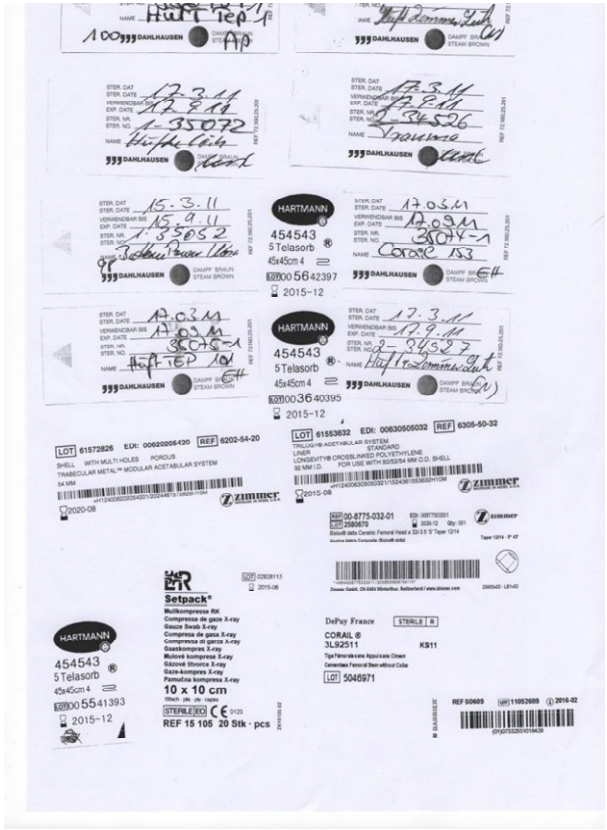


Supply documentation at the point of care is **still** highly manual, duplicative, and error-ridden

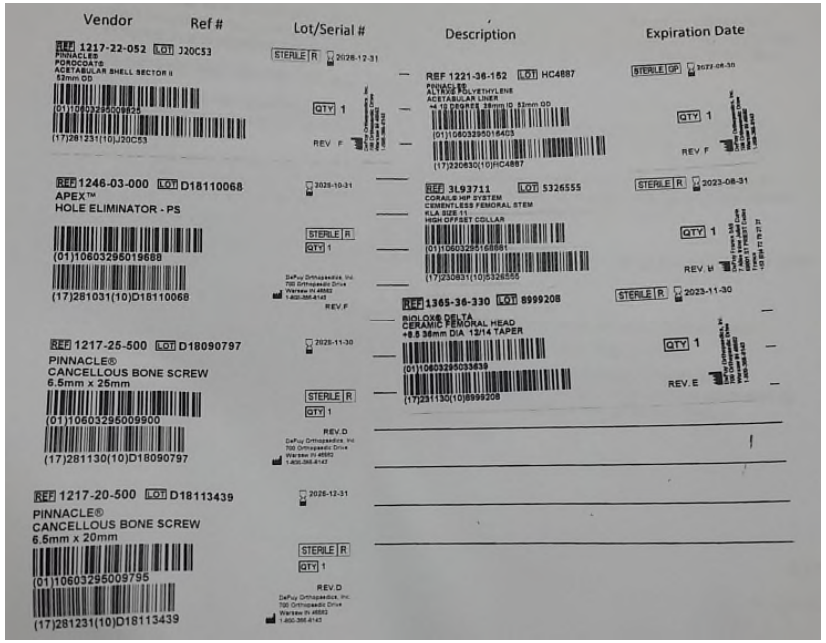
Clinical Departments



Implant Record – 2013

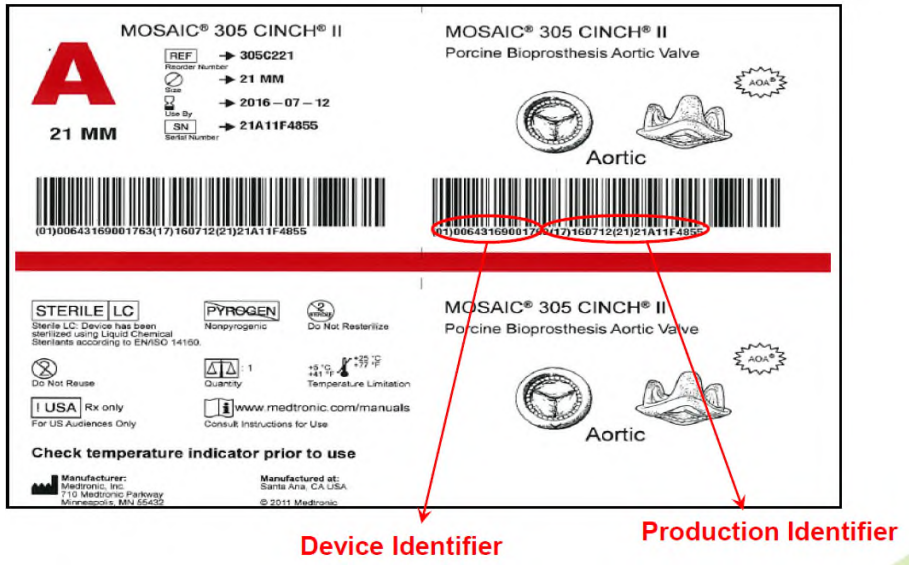


Implant Record – 2019



What is UDI?

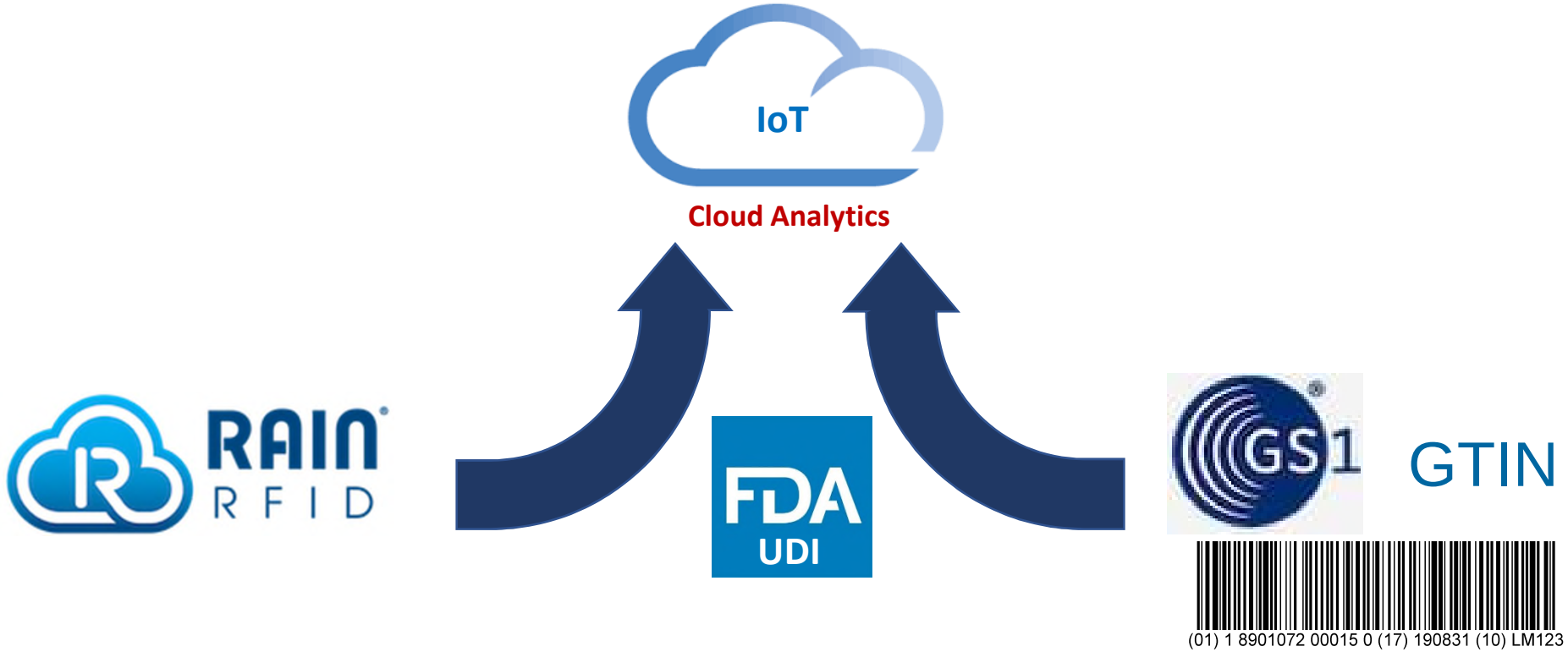
- ✓ FDA-mandated
- ✓ Standard encoding system for all medical devices
- ✓ Enables track & trace from point of origin to the patient
- ✓ Designed to prevent errors and support recalls
- ✓ Human AND machine-readable label can use barcodes and RFID
- ✓ Fully implemented by 2020



RAIN RFID solutions offer incomparable benefits to address these problems

- **Traceability Throughout the Hospital**
- **Extensive Risk and Waste Mitigation**
- **User Compliance**
- **IoT for the Healthcare Supply Chain**
- **UDI and Global Standards Compliance**
- **Data Accuracy**
- **Scalability to Track Assets & People too**
- **High ROI**

Rain RFID and GTIN Barcodes bring the highest level of trackability, visibility and accuracy to inventory management and POC documentation



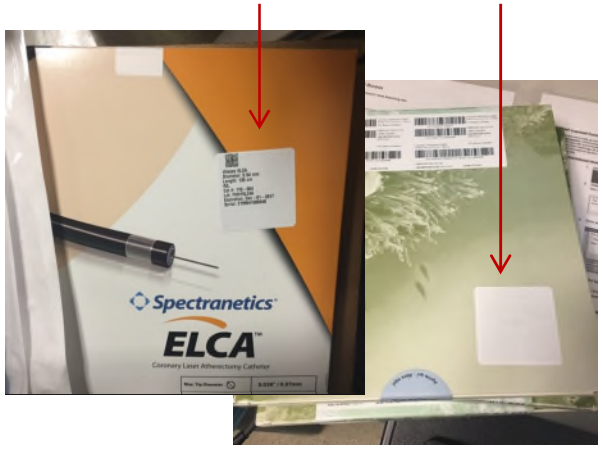
VUETRACK UDI

FDA-mandated Unique Device Identifier (UDI) data is resident on the tag itself using GS1 EPC GEN2 UHF encoding standards

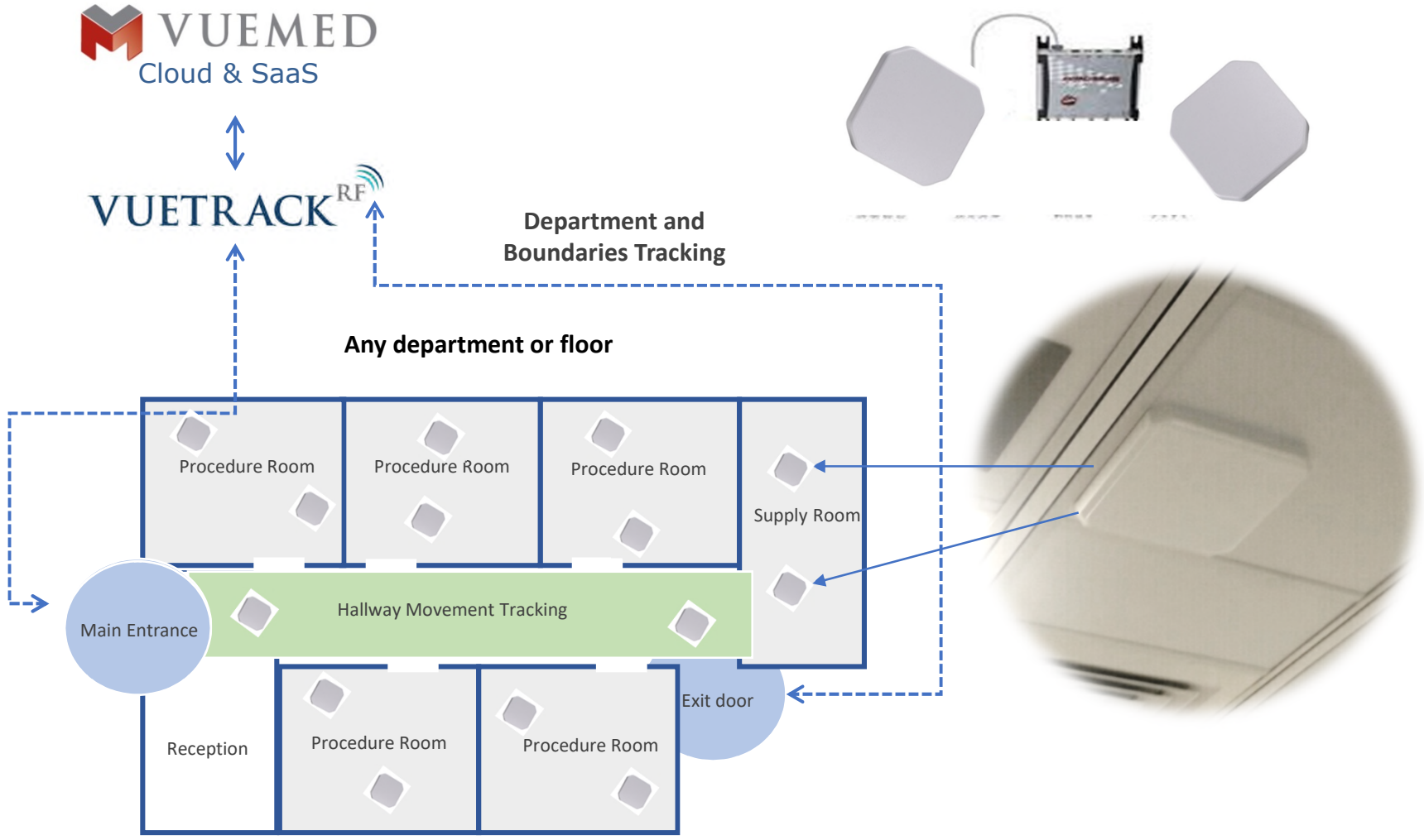
Tagging Station

Tag encoding

- Device Identifier
- Production Identifier Data as applicable:
  - Lot Number
  - Batch Number
  - Serial Number
  - Expiration Date
  - Manufacture Date
  - HCT/P ID
- The UDI-encoded RFID tag may be printed with human readable text and a 2D barcode or blank



Tracks inventory in supply and procedure rooms, as well as movement throughout, and entry & exit from the department



Supply Rooms

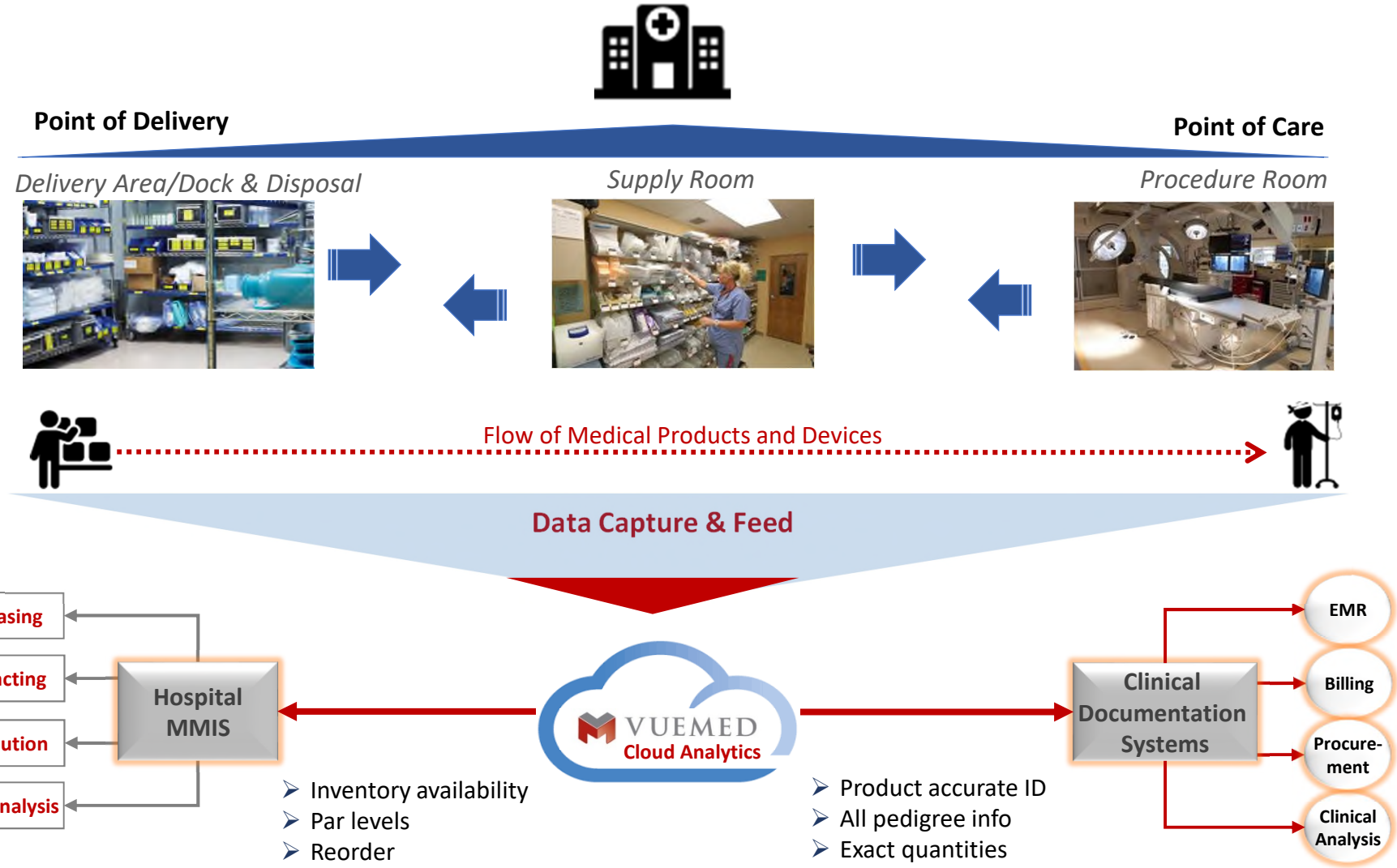
Hallways / Cabinets

Procedure Rooms

mobile VUETRACK

- Several hand-held RAIN RFID readers available
- Android-based mobile apps for inventory counts on the go.
- Simple to use, and cost-effective.
- Users can capture RFID tags or barcodes with unparalleled performance and report all captured data to the Cloud.
- An audit of a whole room of RFID-tagged inventory takes only seconds.
- Identifies and locates products in real-time.

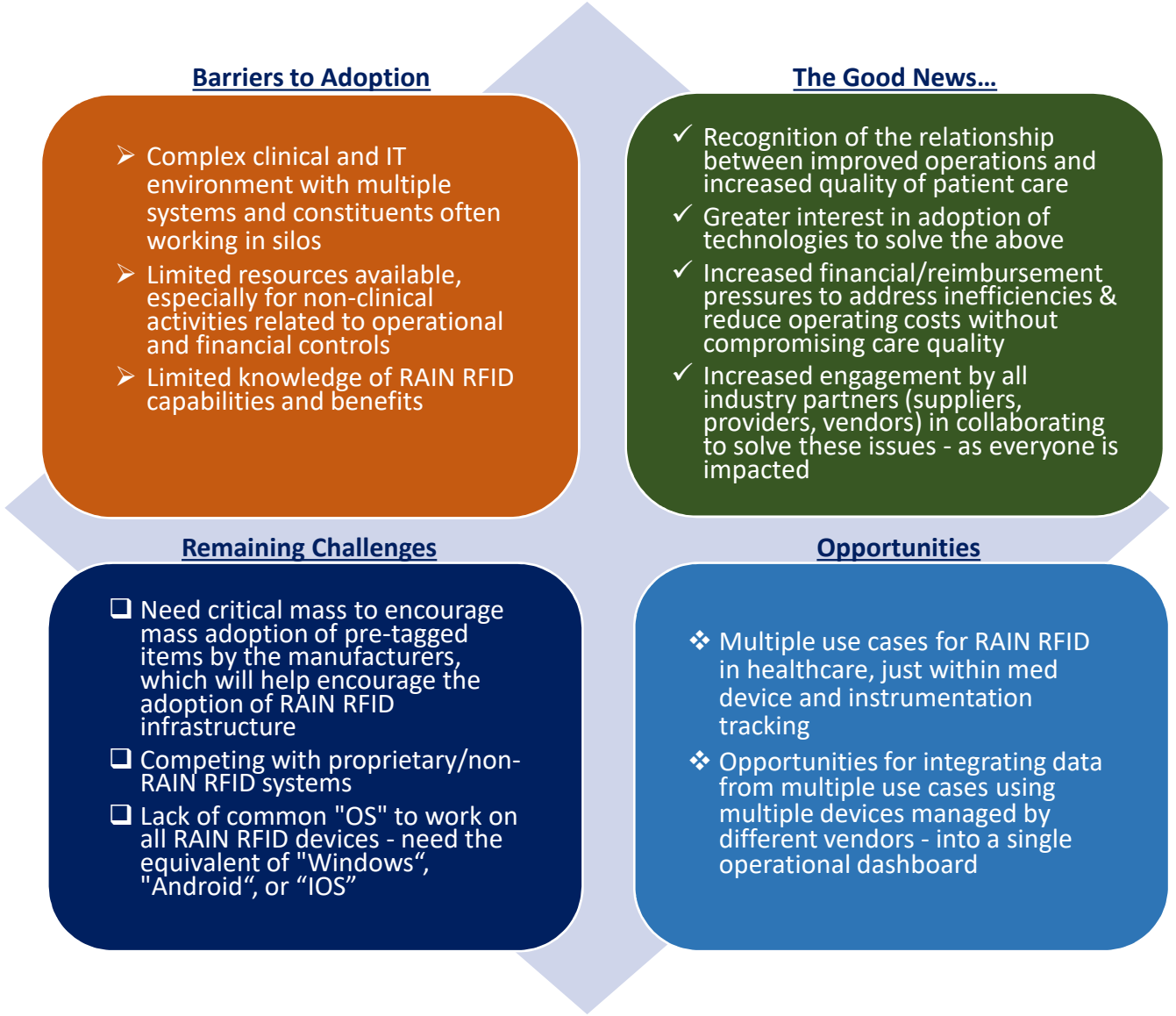
All data about products and their movements from delivery to point of care are recorded and fed into other hospital systems as well as the VUEMED Cloud for analyses and guidance



High performing, versatile and cost effective RAIN RFID solutions help generate significant ROI for hospitals, and their suppliers

Typical Sources of Savings:	Typical Magnitude of Savings
Eliminate expirations *Ongoing waste reduction*	8% to 12% of total inventory value
Inventory size reduction *One-time and continuous lean levels*	5% to 15% of total inventory value
Reduction in product purchases *Opportunity to buy less and borrow instead of buy*	10% of total new orders' value
Increase billed revenue capture *Capture missed revenue, avoid fraud risks (insurance fines)*	10% of total billed revenue

RAIN RFID can become a ubiquitous part of any hospital infrastructure as a foundational sensing technology and deliver the full benefits of IoT - from manufacturer to the patient



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