



Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

March 22, 2016

Tara M. Federici, Vice President
Zachary A. Rothstein, Associate Vice President
Technology and Regulatory Affairs
Advanced Medical Technology Association
701 Pennsylvania Ave, N.W., Suite 800
Washington, D.C. 20004-2654

Dear Tara and Zach:

This letter is in response to issues the Advanced Medical Technology Association (AdvaMed) raised to the Food and Drug Administration (FDA) regarding implementation of the Unique Device Identification final rule (UDI rule). We address each issue in the response that follows.

1. Making the UDI available at the point of implantation or use.

The objective of the UDI rule is to establish a system for the adequate identification of medical devices through distribution and use. For certain devices, FDA realizes there are unique complexities and challenges for conveying UDIs at the point of use.

[In a November 19, 2014 letter to implant manufacturers](#), FDA provided an extension of the UDI labeling compliance date to September 24, 2016, for specific listed implant devices. The additional time provided by the extension was intended to allow the affected labelers to develop and implement approaches that will help ensure that the UDI is readily available at the point of use.

On September 17, 2015, the AdvaMed Orthopedic Working Group met with FDA to present several approaches that would allow healthcare professionals to derive and record the UDI of non-sterile implant products at the point of use. We are attaching the materials you presented to FDA describing these methods and note you have made them available on your website at <http://advamed.org/res/1035/spine/trauma/cmfs-sets-and-udi>.

A. Making the UDI available at the point of implantation by using a cross reference tool with production-specific identification information on the device.

The approaches presented generally employ production-specific identification information on the device with a cross reference tool. By combining the two, the full UDI can be derived and is available at the point of use. The AdvaMed Orthopedic Working Group explained that the use of production information on the device in conjunction with cross-referencing would allow the full UDI [device identifier (DI) and production identifiers (PI)] to be derived and recorded at the point of use for most non-sterile implant products. AdvaMed asked FDA to confirm that AdvaMed's approaches meet the objectives of the UDI rule.

FDA agrees that for non-sterile implantable devices, making the UDI available by combining production-specific identification information on the device with a cross reference tool and noting in the design history file the means by which the UDI is made available at the point of implantation meets the objectives of the UDI rule given present technological limitations.

B. Using a cross-reference tool where the full UDI is not available because the production-specific information is not on the device.

For certain non-sterile implantable devices (e.g., very small bone screws), size, geometry, material specifications, and/or other markings required for patient safety make it technologically infeasible to directly mark production-specific information and therefore only the DI—not the full UDI—can be derived and recorded at the point of use. AdvaMed asked FDA to clarify that for those non-sterile implantable devices where, for the reasons stated above, it would not be technologically feasible to derive and record the full UDI at point of implantation, the availability of the DI alone meets the objectives of the UDI rule.

FDA notes that under 21 CFR 801.30(d), class I devices may exclude the production identifier (i.e., the labeling and packaging of class I devices are permitted to include the DI only). For non-sterile implantable devices not covered by the general exception in 21 CFR 801.30(d) (i.e., class II and class III devices), FDA understands with current technology there are cases in which size, geometry, material specifications, and/or other markings required for patient safety may not permit direct marking with production information, and therefore the entire UDI may not be available at point of use. In such cases, making the DI alone available at the point of use for non-sterile implantable devices meets the objectives of the UDI rule .

FDA understands industry will continue to develop technologies for making the full UDI available at the point of use that do not rely on indirect methods such as cross-reference tools. We look forward to receiving updates on industry's progress.

2. Devices consigned or loaned to health care facilities prior their applicable UDI compliance date.

FDA is aware of concern surrounding UDI labeling requirements for devices that are consigned or loaned to hospitals or other health care facilities as of their applicable UDI labeling and data submission compliance date.

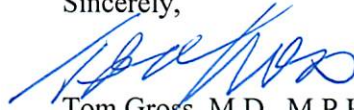
Under the UDI final rule, including the exception provided by 21 CFR 801.30(a)(1), devices labeled and consigned or loaned to hospitals or other health care facilities as of their applicable compliance date would be required to be labeled according to UDI requirements no later than three years after the labeling and data submission compliance date. However, there are consigned or loaded devices have an expected shelf and/or use life beyond the three-year period provided under 21 CFR 801.30(a)(1). AdvaMed has expressed concern that the agency will expect these devices to be UDI compliant by the end of the three-year period, which would require removal of these devices from the field before the end of their life expectancy. For such devices that would be subject to UDI direct marking requirements, but had already been directly marked with non-UDI markings, making these devices UDI compliant would also be a significant technological challenge.

We understand that certain devices consigned or loaned to hospitals or other health care facilities prior to their UDI compliance date may have life expectancies beyond the three year exception provided by 21 CFR 801.30(a)(1). We agree that, three years after the applicable labeling and data submission compliance date, having labelers locate, remove, store, and/or rework such devices that had already been

consigned or loaned to hospitals would be impractical, costly, and disruptive to clinical practice and the supply chain. We understand that it could also create shortages and have a detrimental impact on public health by interfering with healthcare delivery. As we have communicated publicly, we do not believe that the UDI program goals will be served by requiring devices already consigned or loaned to hospitals or other health care facilities before their applicable compliance date to comply with UDI requirements even after the 3-year exception expires. FDA is considering methods to formalize its policy positions on consigned and loaned devices.

Again, thank you for the work that AdvaMed and the Orthopedic Working Group has invested and continues to invest in helping to develop solutions to bring UDI to the point of use for devices in end-user sterilized surgical sets. We look forward to our continued cooperation. If you have any questions, please do not hesitate to contact me or the CDRH/OSB Informatics team.

Sincerely,

A handwritten signature in blue ink, appearing to read "Tom Gross", is written over the typed name.

Tom Gross, M.D., M.P.H.
Director, Office of Surveillance and Biometrics
Center for Devices and Radiological Health
U.S. Food and Drug Administration



AdvaMed

Advanced Medical Technology Association

Update and Demonstration to FDA: AdvaMed Ad Hoc Spine/Trauma Trays and UDI Working Group

Disclaimer: The information and perspectives represented in this document are not intended to represent a standard and do not represent legal or compliance advice.

Aug. 21, 2014 – Ad Hoc Spine/Trauma Trays and UDI Working Group presentation to FDA UDI Team

- Received verbal FDA assurance that compliance options including inventory control form with related direct part marking exceptions for DI and/or PI would be considered compliant
- Received verbal assurances in subsequent conference calls with FDA UDI team members

Nov. 19, 2014 – FDA UDI Extension Letter to Implant Labelers with link to 8/21/2014 AdvaMed presentation

Sept. 17, 2015 – Demonstration for FDA of how UDI information can be provided at point of use for devices distributed in trays and intended to be reprocessed before each use

Ad Hoc Spine/Trauma Trays and UDI Working Group continues to collaborate to respond to UDI issues and concerns

Industry is seeking methods that provide UDI information at the point of use in a way that meets:

1. The complex needs of our customers and ensures patient safety
2. The compliance requirements of the FDA
3. And is easy and straightforward to administer

1. Live demonstration of UDI compliance options at the point of use.
 - Sterile package / Implant record
 - Non-sterile implants / Inventory control sheet
 - Non-sterile instruments / Cross-referencing
 - Future considerations
2. Recommendation for UDI implementation options for non-sterile devices
3. Overview of OSEL proposals

Sterile Package Demo

1. Implants are chosen and removed from sterile packaging
2. Implants are deposited in sterile field
3. Packaging information goes to Circulating Nurse

UDI compliant labels

1. UDI label on inner package
2. UDI label on outer box



UDI compliant Chart-Stix labels

1. Chart-Stix labels are removed from sterile packaging
2. Multiple Chart-Stix labels included in packaging
3. Circulating nurse collects a Chart-Stix for each implant used during surgery for documentation in the implant record.



Implant record documentation

1. Circulating nurse collects all Chart-Stix during surgery
 2. Chart-Stix are placed in implant record after implantation
 3. From a completed implant record, the circulating nurse can:
 1. Key in GTIN/Lot#/Catalog#
 2. Scan barcode
- *Full UDI available at point of use

IMPLANT MEMO

O.R. # _____ DATE _____

R.N. Name _____

Implants/Prosthesis Sticker/ Info.

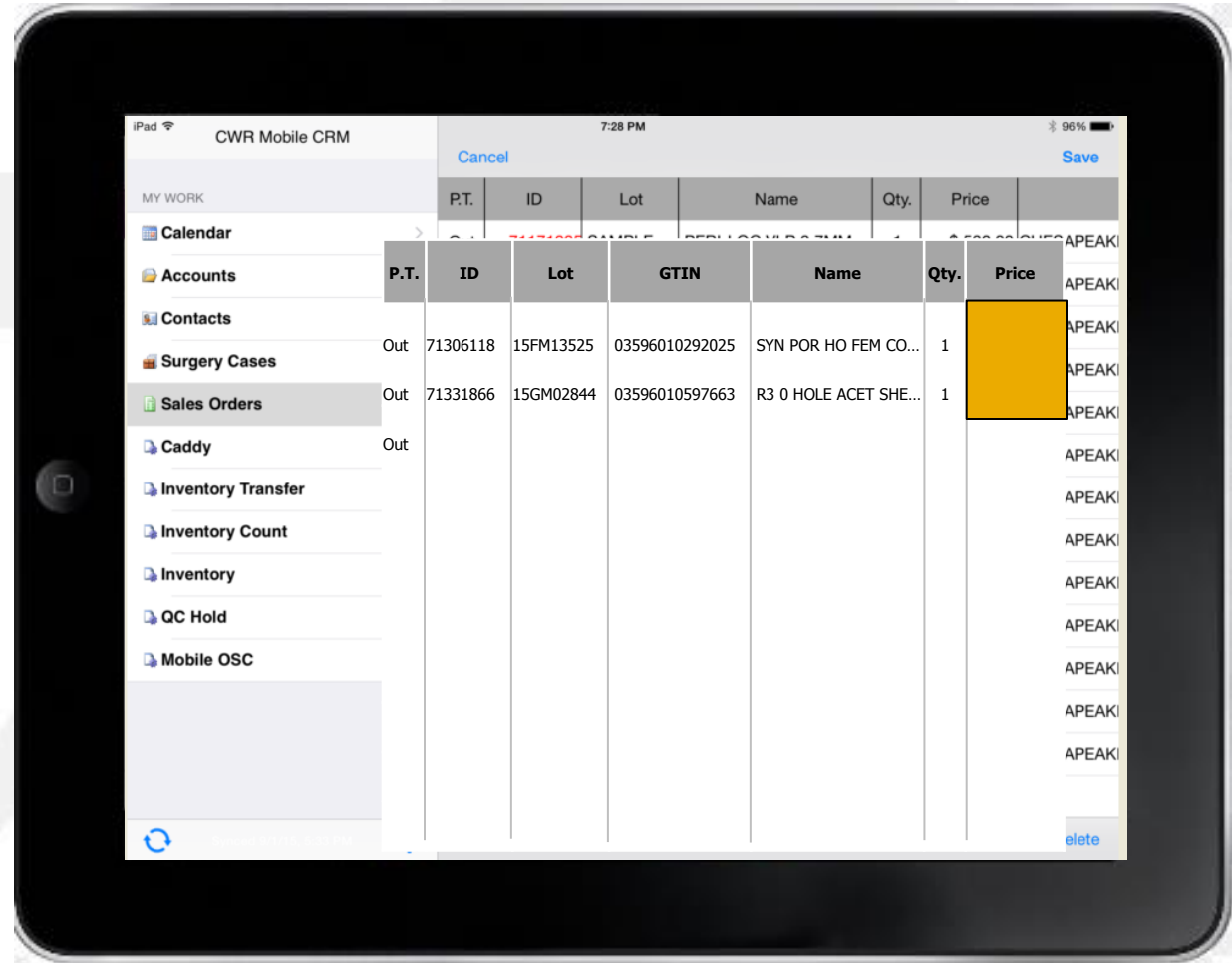
CHART-STIK® LABEL
GTIN 71306118
LOT# 15FM13525
STERILE R
EXP 2025-06-01
SMITH & NEPHEW
SIZE 18
SYNERGY PORCUS HIGH OFFSET
FEMORAL COMPONENT
TI-6AL-4V
01) 0 3596010 29202 5 (17) 250601 (10) 15FM13525
T2605TK
ATTACH TO PATIENT'S RECORD

CHART-STIK® LABEL
GTIN 71331866
LOT# 15GM02844
STERILE R
EXP 2025-07-01
SMITH & NEPHEW
68 MM OD
USE WITH SIZE 68 MM OD LINER
R3™ NO HOLE HEMISPHERICAL
STIKTITE™ COATED SHELL
TI-6AL-4V
01) 0 3596010 59788 3 (17) 250701 (10) 15GM02844
T2605TK
ATTACH TO PATIENT'S RECORD

Smart Device software:

1. GTIN
2. Lot #
3. Part #
4. Description

*Full UDI available at point of use



Order Summary




AdvaMed
Advanced Medical Technology Association

Order Summary is sent to the hospital and includes:

1. UDI information
2. Quantity
3. Price

*Full UDI sent to the hospital as part of sales order summary

ORDER SUMMARY 

Date: Sep 03, 2015 12:38 PM Sales Rep: CRM Test 1
Customer: 123456-CHESAPEAKE REGIONAL Ref #: 0ZES12681972
Bill to Account: 123456-CHESAPEAKE REGIONAL Purchase Order #:
Ship to Account: 123456-CHESAPEAKE REGIONAL Approved By:
Credit Card: Credit Card Holder:
Credit Card Expiration Date:

Surgeon: AM Surgeon: JAMES, DEVIN
Patient ID: 090315

Item # **Lot #** **GTIN**

Item #	Description	Lot #	GTIN	Qty	Unit Price	Extended Price
71306118	SYN POR HO FEM COM SZ 18	15FM13525	03596010292025	1		
71331866	R3 0 HOLE ACET SHELL 66MM	15GM02844	03596010597663	1		

Total Contract Price:

Many of Smith & Nephew's products are not listed on a government purchasing agreement such as a Federal Supply Schedule or Distribution and Pricing Agreement. Unless Smith & Nephew otherwise agrees in writing, any product not listed on a government purchasing agreement is offered for sale under Smith & Nephew's commercial terms. Smith & Nephew does not make any representations or certifications that any product not listed on a Federal Supply Schedule or other government purchasing agreement is a "domestic end product" under the Buy American Act, or a "designated country end product" or "U.S.-made end product" under the Trade Agreements Act.

I CERTIFY THAT THE ABOVE LISTED ITEMS WERE RECEIVED IN THE ORIGINAL FACTORY PACKAGING:

Signature _____ Date _____

GUDID Cross-Reference



AdvaMed

Advanced Medical Technology Association

Device Packaged as Sterile > [SYNERGY - 03596010291950](#) +
SYNERGY POROUS HIGH OFFSET FEMORAL SIZE 11
Company Name: **Smith & Nephew**, Inc. Version or Model: 71306111

Sterilization Prior To Use > [SYNERGY - 03596010291967](#) +
SYNERGY POROUS HIGH OFFSET FEMORAL SIZE 12
Company Name: **Smith & Nephew**, Inc. Version or Model: 71306112

Issuing Agency > [SYNERGY - 03596010292001](#) +
SYNERGY POROUS HIGH OFFSET FEMORAL COMPONENT SZ 16
Company Name: **Smith & Nephew**, Inc. Version or Model: 71306116

[SYNERGY - 03596010292018](#) +
SYNERGY POROUS HIGH OFFSET FEMORAL COMPONENT SZ 17
Company Name: **Smith & Nephew**, Inc. Version or Model: 71306117

[SYNERGY - 03596010292025](#) +
SYNERGY POROUS HIGH OFFSET FEMORAL COMPONENT SZ 18
Company Name: **Smith & Nephew**, Inc. Version or Model: 71306118

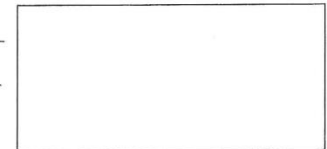
Sterile Packaging Method:

1. Labels and Chart-Stix are UDI compliant
2. The gathering of the Chart-Stix labels and placement on the implant record is standard OR protocol
3. Hospitals have multiple ways to document UDI in the EHR
 1. Scan
 2. Key in
4. Sales orders including UDI information are sent to hospitals for billing purposes

IMPLANT MEMO

O.R. # _____ DATE _____

R.N. Name _____



Implants/Prosthesis Sticker/ Info.

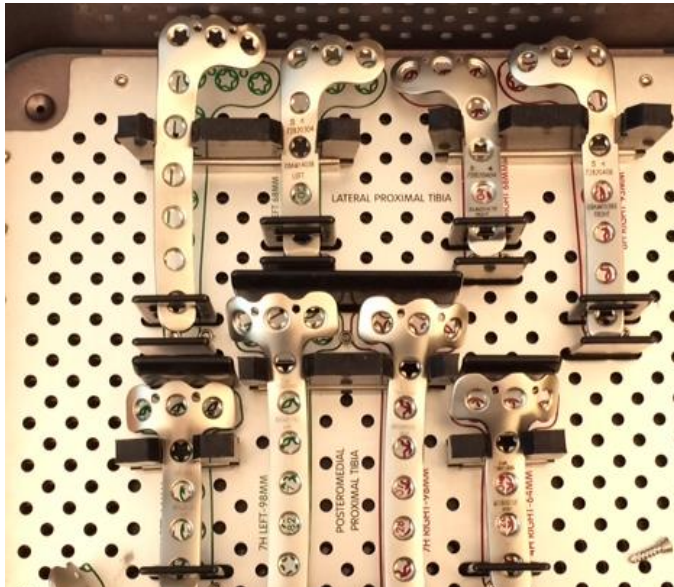


The Sterile package method meets:

1. The complex needs of our customers and ensures patient safety
2. The compliance requirements of the FDA
3. And is easy and straightforward to administer

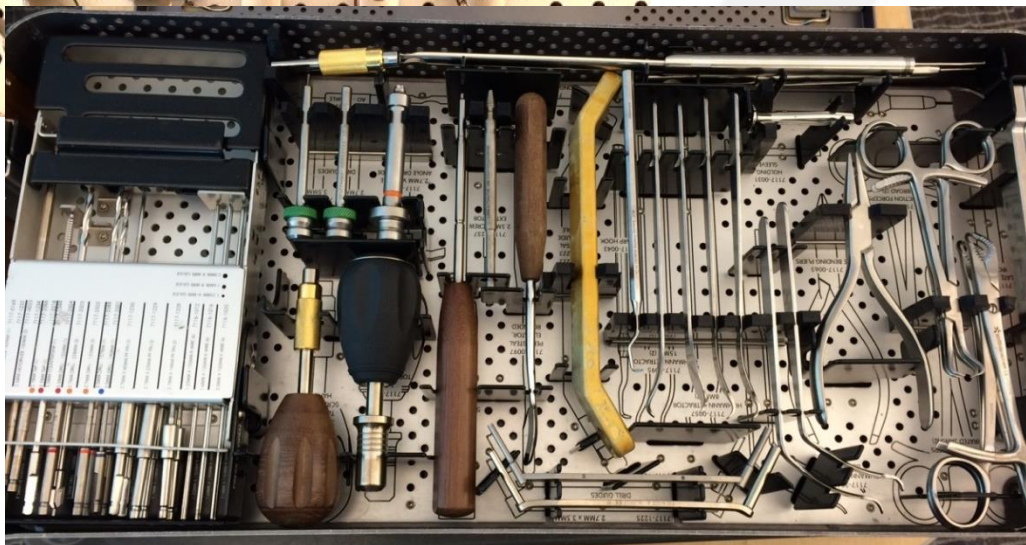
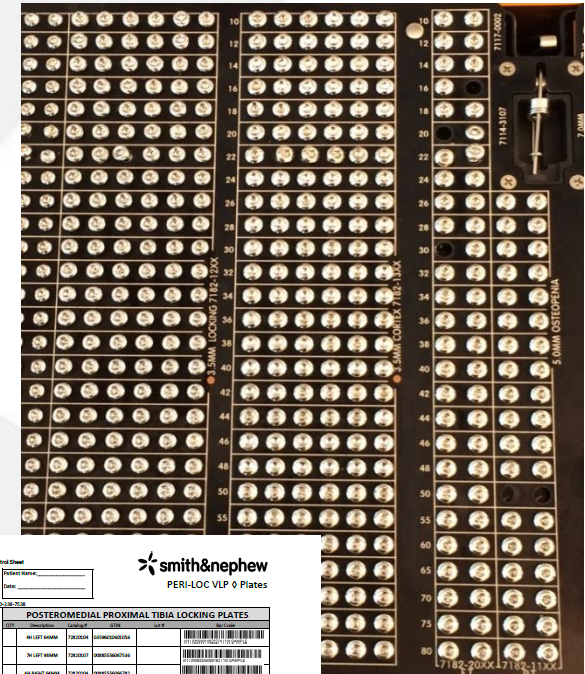


Non-Sterile Devices Demo



Proximal Tibia Fracture Demo

1. Instruments
2. Plate Tray
3. Screw Caddy
4. Inventory Sheets



Inventory Control Sheet

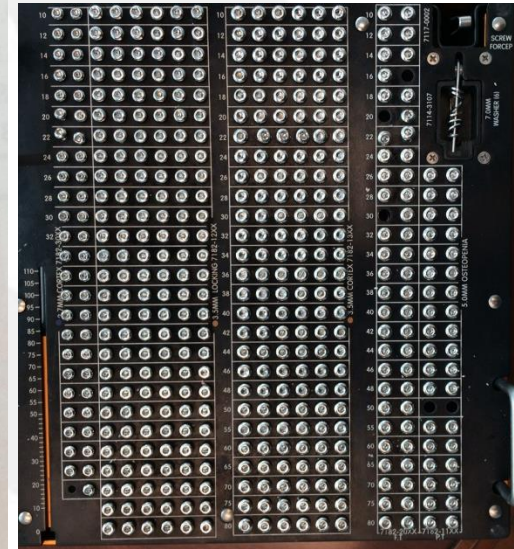
Request Name: _____
Date: _____

To order: 1-800-338-3538

PLATE	POSTEROMEDIAL PROXIMAL TIBIA LOCKING PLATES	
	SIZE	TYPE
40 LEFT 98MM	73020A	008050A0020A
36 LEFT 88MM	73020A	008050A0017A
40 RIGHT 98MM	73020A	008050A0020A
36 RIGHT 88MM	73020A	008050A0017A
40 LEFT 98MM	73020A	008050A0020A
40 RIGHT 98MM	73020A	008050A0020A
PLATE	LATERAL PROXIMAL TIBIA LOCKING PLATES	
	SIZE	TYPE
40 LEFT 98MM	73020A	008050A0020A
40 RIGHT 98MM	73020A	008050A0020A
PLATE	POSTERIOR DISTAL TIBIA LOCKING PLATES	
	SIZE	TYPE
40 LEFT 47MM	73020A	008050A0070A
36 LEFT 37MM	73020A	008050A0063A
40 RIGHT 47MM	73020A	008050A0070A
36 RIGHT 37MM	73020A	008050A0063A
PLATE	ANTERIOR DISTAL TIBIA LOCKING PLATES	
	SIZE	TYPE
40 TIBIA	73020A	008050A0070A
40 ANTERIOR	73020A	008050A0070A
PLATE	MEDIAL DISTAL TIBIA LOCKING PLATES	
	SIZE	TYPE
40 LEFT 47MM	73020A	008050A0070A
40 LEFT 37MM	73020A	008050A0063A
40 RIGHT 47MM	73020A	008050A0070A
40 RIGHT 37MM	73020A	008050A0063A

Factors that may limit DPM

1. Safety/effectiveness
2. Size/geometry of the non-sterile device
3. Material properties
4. Technological feasibility
5. Other required markings
(e.g., material type, anatomic location for use, etc.)



Surgeon calls for the implant needed

- Lateral Proximal tibia plate
- 4 hole left



Cross Reference

Circulating nurse identifies the implant on the Inventory Control sheet

Inventory Control Sheet

Patient Name: _____

Date: _____



To order: 1-800-238-7538

Inventory Control Sheet

Patient Name: _____
Date: _____

To order: 1-800-238-7538

POSTEROMEDIAL PROXIMAL TIBIA LOCKING PLATES

QTY	Description	Catalog #	GTIN	Lot #	Bar Code
	4H LEFT 64MM	72820104	03596010601056		(01) 03596010625274 (10) SAMPLE
	7H LEFT 98MM	72820107	00885556067536		(01) 00885556068182 (10) SAMPLE
	4H RIGHT 64MM	72820204	00885556066782		(01) 03596010607188 (10) SAMPLE
	7H RIGHT 98MM	72820207	00885556067062		(01) 03596010603616 (10) SAMPLE

LATERAL PROXIMAL TIBIA LOCKING PLATES

QTY	Description	Catalog #	GTIN	Lot #	Bar Code
	4H LEFT 68MM	72820304	00885556068182		(01) 00885556068182 (10) SAMPLE
	6H LEFT 93MM	72820306	03596010601049		(01) 03596010603616 (10) SAMPLE
	4H RIGHT 68MM	72820404	00885556066799		(01) 03596010607188 (10) SAMPLE
	6H RIGHT 93MM	72820406	00885556067086		(01) 03596010625267 (10) SAMPLE

POSTERIOR DISTAL TIBIA LOCKING PLATES

QTY	Description	Catalog #	GTIN	Lot #	Bar Code
	4H LEFT 64MM	72820104	03596010601056		(01) 03596010625274 (10) SAMPLE
	7H LEFT 98MM	72820107	00885556067536		(01) 00885556068182 (10) SAMPLE
	4H RIGHT 64MM	72820204	00885556066782		(01) 03596010607188 (10) SAMPLE
	7H RIGHT 98MM	72820207	00885556067062		(01) 03596010603616 (10) SAMPLE

PROXIMAL TIBIA

POSTEROMEDIAL PROXIMAL TIBIA LOCKING PLATES

QTY	Description	Catalog #	GTIN	Lot #	Bar Code
	4H LEFT 64MM	72820104	03596010601056		(01) 03596010625274 (10) SAMPLE
	7H LEFT 98MM	72820107	00885556067536		(01) 00885556068182 (10) SAMPLE
	4H RIGHT 64MM	72820204	00885556066782		(01) 03596010607188 (10) SAMPLE
	7H RIGHT 98MM	72820207	00885556067062		(01) 03596010603616 (10) SAMPLE

LATERAL PROXIMAL TIBIA LOCKING PLATES

QTY	Description	Catalog #	GTIN	Lot #	Bar Code
	4H LEFT 68MM	72820304	00885556068182		(01) 00885556068182 (10) SAMPLE
	6H LEFT 93MM	72820306	03596010601049		(01) 03596010603616 (10) SAMPLE
	4H RIGHT 68MM	72820404	00885556066799		(01) 03596010607188 (10) SAMPLE
	6H RIGHT 93MM	72820406	00885556067086		(01) 03596010625267 (10) SAMPLE

POSTERIOR DISTAL TIBIA LOCKING PLATES

QTY	Description	Catalog #	GTIN	Lot #	Bar Code
	4H LEFT 64MM	72820104	03596010601056		(01) 03596010625274 (10) SAMPLE
	7H LEFT 98MM	72820107	00885556067536		(01) 00885556068182 (10) SAMPLE
	4H RIGHT 64MM	72820204	00885556066782		(01) 03596010607188 (10) SAMPLE
	7H RIGHT 98MM	72820207	00885556067062		(01) 03596010603616 (10) SAMPLE

Implant Selection



AdvaMed
Advanced Medical Technology Association

Scrub nurse calls out the
lot #

'08AM14036'



Record Lot

Circulating nurse writes in the quantity and lot# information in the space provided.

*Full UDI available at point of use



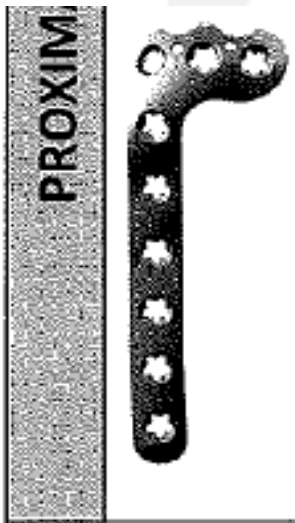
Inventory Control Sheet

Product Name: _____
Date: _____

By: _____

SMITH & NEPHEW
PERI-LOC VLP ® Plates

Tibia	Plate	POSTEROMEDIAL PROXIMAL TIBIA LOCKING PLATES	
		QTY	Lot #
PROXIMAL TIBIA	4H LEFT 68MM		
	6H LEFT 93MM		
	4H RIGHT 68MM		
	6H RIGHT 93MM		
DISTAL TIBIA	LATERAL PROXIMAL TIBIA LOCKING PLATES		
	4H LEFT 68MM		
	6H LEFT 93MM		
	4H RIGHT 68MM		
DISTAL TIBIA	POSTERIOR DISTAL TIBIA LOCKING PLATES		
	4H LEFT 68MM		
	6H LEFT 93MM		
	4H RIGHT 68MM		
DISTAL TIBIA	ANTERIOR DISTAL TIBIA LOCKING PLATES		
	4H LEFT 68MM		
	6H LEFT 93MM		
	4H RIGHT 68MM		
DISTAL TIBIA	MEDIAL DISTAL TIBIA LOCKING PLATES		
	4H LEFT 68MM		
	6H LEFT 93MM		
	4H RIGHT 68MM		



LATERAL PROXIMAL TIBIA LOCKING PLATES						
QTY	Description	Catalog #	GT/JN	Lot #	Bar Code	
1	4H LEFT 68MM	72820304	00885556068182	08AM14036	(01) 00885556068182 (10) SAMPLE	
	6H LEFT 93MM	72820306	03596010601049		(01) 03596010603616 (10) SAMPLE	
	4H RIGHT 68MM	72820404	00885556066799		(01) 03596010607168 (10) SAMPLE	
	6H RIGHT 93MM	72820406	00885556067086		(01) 03596010625267 (10) SAMPLE	

Repeat Steps for Screws

Inventory Control Sheet

Patient Name: _____
Date: _____

To order: 1-800-238-7538

































Surgeon calls for screws:

1. 3.5 cortex screw 20mm
2. 3.5 cortex screw 22mm
3. 3.5 cortex screw 24mm

Circulating nurse:

1. Locates implant on cross reference sheet
2. Documents quantity used

3.5MM CORTEX SCREWS SELF-TAPPING									
QTY	Length	Catalog #	GTIN	Bar Code	QTY	Length	Catalog #	GTIN	Bar Code
	6MM	71821306	00885556040478			36MM	71821336	03596010625533	
	8MM	71821308	00885556041031			38MM	71821338	03596010625540	
	10MM	71821310	03596010625410			40MM	71821340	03596010625557	
	12MM	71821312	03596010625427			42MM	71821342	03596010625564	
	14MM	71821314	03596010625434			44MM	71821344	03596010625571	
	16MM	71821316	03596010625441			46MM	71821346	03596010625588	
	18MM	71821318	03596010625458			48MM	71821348	03596010625595	
	20MM	71821320	03596010625465			50MM	71821350	03596010625601	
	22MM	71821322	03596010625472			55MM	71821355	03596010625618	
	24MM	71821324	03596010607188			60MM	71821360	03596010625625	
	26MM	71821326	03596010625489			65MM	71821365	00885556041406	
	28MM	71821328	03596010625496			70MM	71821370	00885556041710	
	30MM	71821330	03596010625502			75MM	71821375	00885556040263	
	32MM	71821332	03596010625519			80MM	71821380	00885556040430	
	34MM	71821334	03596010625526						

















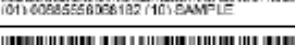




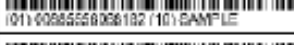








Repeat Steps

Surgeon calls for screws:

1. 3.5 locking screw 20mm
2. 3.5 locking screw 22mm
3. 3.5 locking screw 24mm

Circulating nurse:






1. Locates implant on cross reference sheet
2. Documents quantity used

3.5MM LOCKING SCREWS SELF-TAPPING										
QTY	Length	Catalog #	GTIN	Bar Code	QTY	Length	Catalog #	GTIN	Bar Code	
	6MM	71821206	00885556040850			36MM	71821236	03596010625311		
	8MM	71821208	00885556041055			38MM	71821238	03596010625328		
	10MM	71821210	03596010625229			40MM	71821240	03596010625335		
	12MM	71821212	03596010619754			42MM	71821242	03596010625342		
	14MM	71821214	03596010625236			44MM	71821244	03596010625359		
	16MM	71821216	03596010625243			46MM	71821246	03596010625366		
	18MM	71821218	03596010625250			48MM	71821248	03596010625373		
	20MM	71821220	03596010619761			50MM	71821250	03596010625380		
	22MM	71821222	03596010625267			55MM	71821255	03596010625397		
	24MM	71821224	03596010625274			60MM	71821260	03596010625403		
	26MM	71821226	03596010607164			65MM	71821265	00885556040744		
	28MM	71821228	03596010607171			70MM	71821270	00885556040935		
	30MM	71821230	03596010625281			75MM	71821275	00885556041185		
	32MM	71821232	03596010625298			80MM	71821280	00885556041345		
	34MM	71821234	03596010625304							

Implant Record Documentation

1. Circulating nurse gathers all completed inventory control sheets, and this now forms the implant record (similar to sterile packaging method)
2. From the implant record, the circulating nurse can:
 1. Key in GTIN/Lot#/Catalog#
 2. Scan barcode

*Full UDI available at point of use for the plate: Partial UDI available for the screws

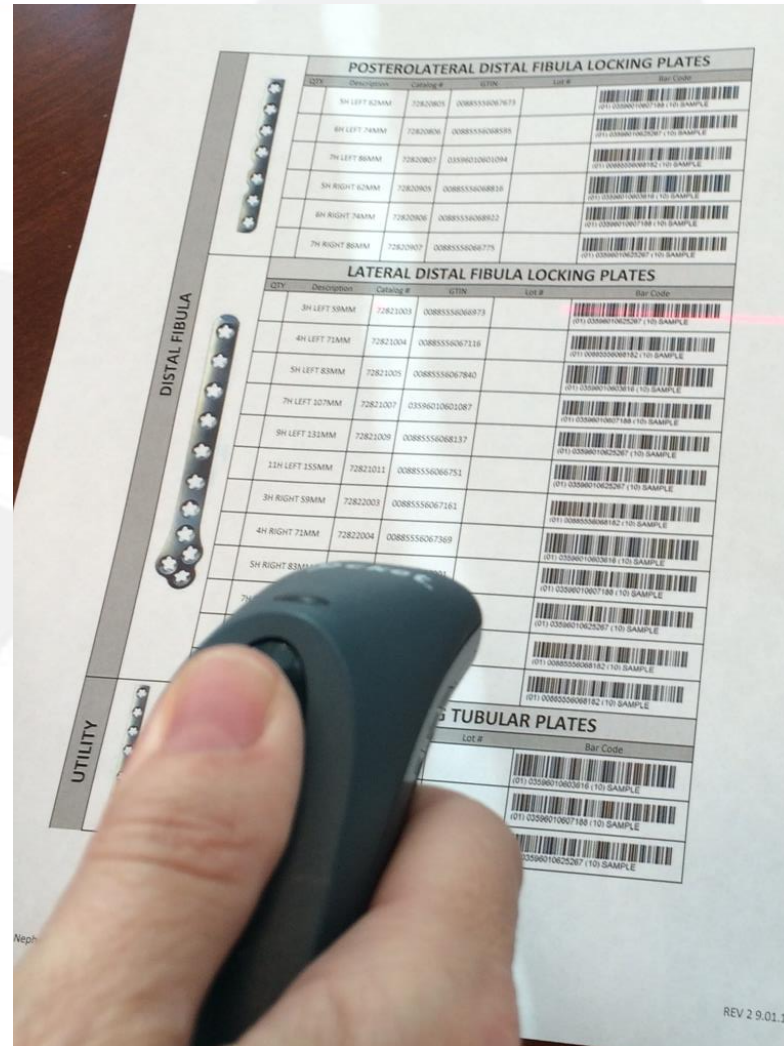
PROXIMAL	LATERAL PROXIMAL TIBIA LOCKING PLATES					
	Qty	Description	Catalog #	GTIN	Lot #	Bar Code
	1	4H LEFT 68MM	72820304	00885556068182	08AM14036	 (01) 00885556068182 (10) SAMPLE
		6H LEFT 93MM	72820306	03596010601049		 (01) 03596010601049 (10) SAMPLE
		4H RIGHT 68MM	72820404	00885556066799		 (01) 03596010607188 (10) SAMPLE
		6H RIGHT 93MM	72820406	00885556067086		 (01) 03596010625287 (10) SAMPLE

20MM	71821320	03596010625465		50MM	71821350	03596010625601	
22MM	71821322	03596010625472		55MM	71821355	03596010625618	
24MM	71821324	03596010607188		60MM	71821360	03596010625625	

20MM	71821220	03596010619761		50MM	71821250	03596010625380	
22MM	71821222	03596010625267		55MM	71821255	03596010625397	
24MM	71821224	03596010625274		60MM	71821260	03596010625403	

Barcode Scanner

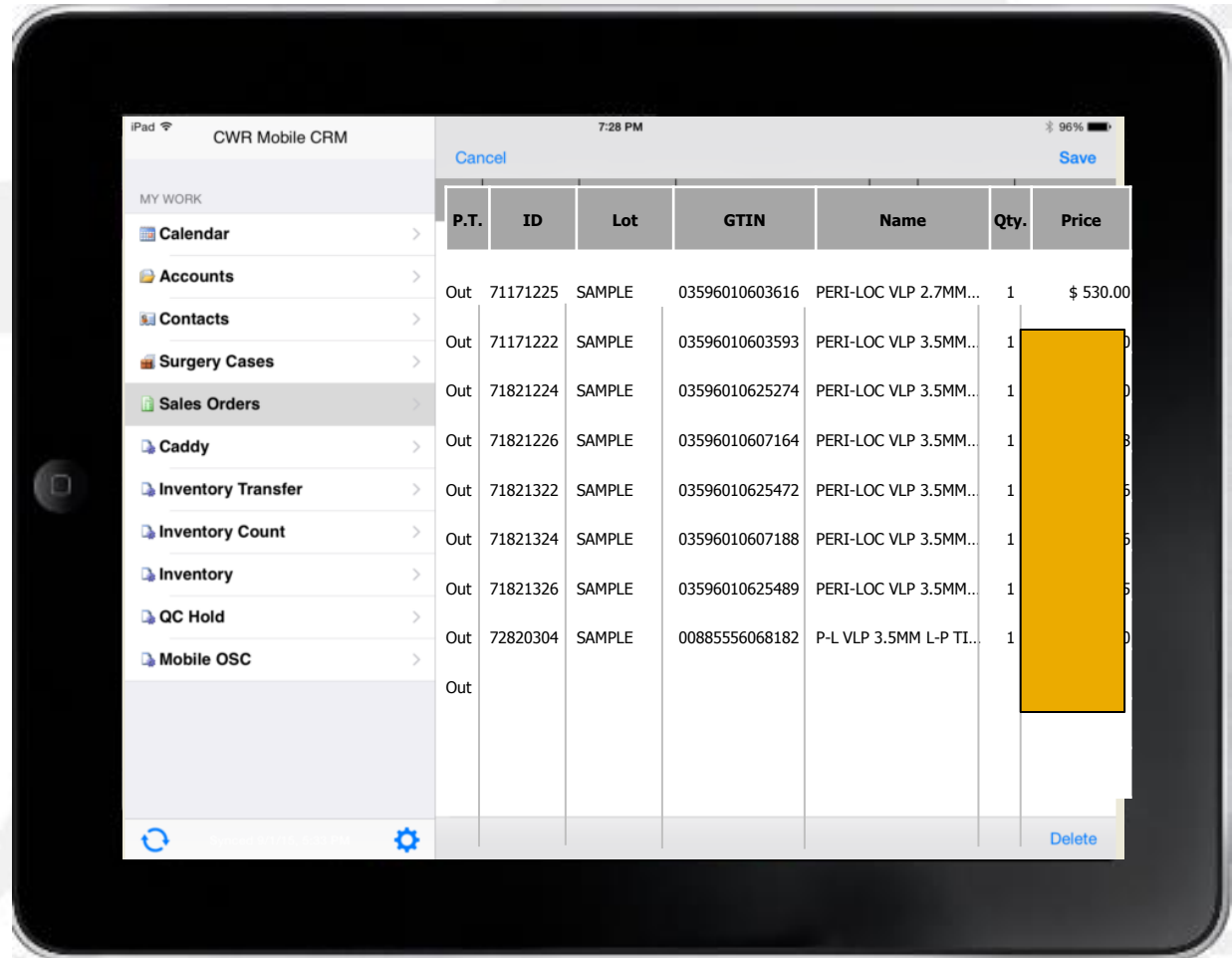
Inventory control sheets have a simple method to cross reference to the GTIN and this information can be scanned into EHR



Smart Device software:

1. GTIN
2. Lot # if available
3. Part #
4. Description

*Full or partial UDI available at point of use



CWR Mobile CRM

7:28 PM 96%

Cancel Save

P.T.	ID	Lot	GTIN	Name	Qty.	Price
Out	71171225	SAMPLE	03596010603616	PERI-LOC VLP 2.7MM...	1	\$ 530.00
Out	71171222	SAMPLE	03596010603593	PERI-LOC VLP 3.5MM...	1	
Out	71821224	SAMPLE	03596010625274	PERI-LOC VLP 3.5MM...	1	
Out	71821226	SAMPLE	03596010607164	PERI-LOC VLP 3.5MM...	1	
Out	71821322	SAMPLE	03596010625472	PERI-LOC VLP 3.5MM...	1	
Out	71821324	SAMPLE	03596010607188	PERI-LOC VLP 3.5MM...	1	
Out	71821326	SAMPLE	03596010625489	PERI-LOC VLP 3.5MM...	1	
Out	72820304	SAMPLE	00885556068182	P-L VLP 3.5MM L-P TI...	1	
Out						

MY WORK

- Calendar
- Accounts
- Contacts
- Surgery Cases
- Sales Orders
- Caddy
- Inventory Transfer
- Inventory Count
- Inventory
- QC Hold
- Mobile OSC

Refresh Settings Delete

Order Summary

Order Summary is sent to the hospital and includes:

1. UDI information
2. Quantity
3. Price

*Full or partial UDI sent to the hospital as part of sales order summary

ORDER SUMMARY

Date: Sep 01, 2015 05:04 PM
 Customer: 123456- CHESAPEAKE REGIONAL
 Bill to Account: 123456- CHESAPEAKE REGIONAL
 Ship to Account: 123456- CHESAPEAKE REGIONAL
 Credit Card:
 Credit Card #:

smith&nephew

Sales Rep: CRM Test 1
 Ref #: 0ZE512675964
 Purchase Order #:
 Approved By:
 Credit Card Holder:
 Credit Card Expiration Date:

Surgery: _____ Surgeon: | JAMES, DEVI
 Patient: _____ 90115

Item #

Lot #

GTIN

Item #	Description	Lot #	GTIN	Qty	Unit Price	Extended Price
71171225	PERI-LOC VLP 2.7MM X 3.5MM DRILL GUIDE	SAMPLE	03596010603616	1		
71171222	PERI-LOC VLP UNIV DRILL GUIDE HANDLE	SAMPLE	03596010603593	1		
71821224	PERI-LOC VLP 3.5MM X 24MM LCK SCRW S-T	SAMPLE	03596010625274	1		
71821226	PERI-LOC VLP 3.5MM X 26MM LCK SCRW S-T	SAMPLE	03596010607164	1		
71821322	PERI-LOC VLP 3.5MM X 22MM CRTX SCRW S-T	SAMPLE	03596010625472	1		
71821324	PERI-LOC VLP 3.5MM X 24MM CRTX SCRW S-T	SAMPLE	03596010607188	1		
71821326	PERI-LOC VLP 3.5MM X 26MM CRTX SCRW S-T	SAMPLE	03596010625489	1		
72820304	P-L VLP 3.5MM L-P TIBIA LK PL 4H L 68MM	SAMPLE	00885556068182	1		

Total Contract Price:

Many of Smith & Nephew's products are not listed on a government purchasing agreement such as a Federal Supply Schedule or Distribution and Pricing Agreement. Unless Smith & Nephew otherwise agrees in writing, any product not listed on a government purchasing agreement is offered for sale under Smith & Nephew's commercial terms. Smith & Nephew does not make any representations or certifications that any product not listed on a Federal Supply Schedule or other government purchasing agreement is a "domestic end product" under the Buy American Act, or a "designated country end product" or "U.S.-made end product" under the Trade Agreements Act.

I CERTIFY THAT THE ABOVE LISTED ITEMS WERE RECEIVED IN THE ORIGINAL FACTORY PACKAGING:

Signature _____ Date _____

Additional Cross Reference Approach

Review Case Information (Optional)

In the UDI site's interactive areas, all information you provide is optional and the information will be governed by our Privacy Policy

Hospital Name:

Operating Room:

Surgery Date and Time:

Surgeon Name:

Case ID:

clear case information

Search Products:

- Trauma
- All Operating Companies
- CMF
- Codman
- Mitek
- Orthopaedics
- Spine
- Trauma

Starts With

Match: SKU GTIN Description

Search

Search Results

Add products to your case

Product No.	UOM	UOM
02.112.006	Trauma	10886982032553
3.5MM LCP SUP ANT CLAVICLE PLW/LAT EXTN 3H/RT/69MM		
02.112.065	Trauma	10886982032560

Click "Done!" when finished.

Your Case (0)

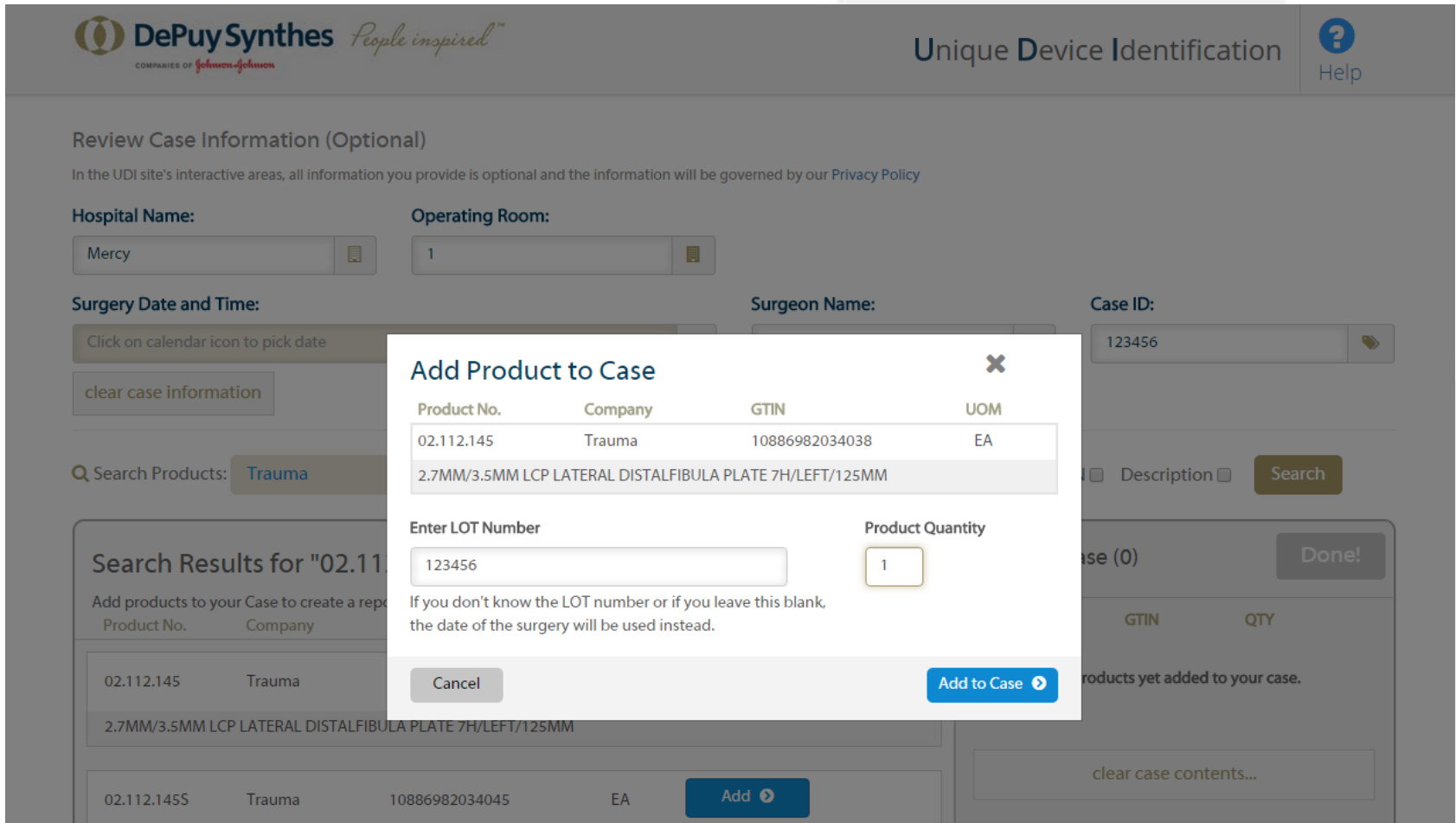
Done!

Product No. GTIN QTY

No products yet added to your case.

clear case contents...

Additional Cross Reference Approach



DePuySynthes *People inspired™*
COMPANIES OF Johnson & Johnson

Unique Device Identification Help

Review Case Information (Optional)

In the UDI site's interactive areas, all information you provide is optional and the information will be governed by our Privacy Policy

Hospital Name: Mercy **Operating Room:** 1

Surgery Date and Time: **Surgeon Name:** **Case ID:** 123456

Search Products: **Trauma**

Search Results for "02.11

Add products to your Case to create a report

Product No.	Company	GTIN	QTY
02.112.145	Trauma	10886982034038	EA
2.7MM/3.5MM LCP LATERAL DISTALFIBULA PLATE 7H/LEFT/125MM			
02.112.145S	Trauma	10886982034045	EA

Add Product to Case

Product No.	Company	GTIN	UOM
02.112.145	Trauma	10886982034038	EA
2.7MM/3.5MM LCP LATERAL DISTALFIBULA PLATE 7H/LEFT/125MM			

Enter LOT Number: Product Quantity:

If you don't know the LOT number or if you leave this blank, the date of the surgery will be used instead.

Additional Cross Reference Approach

Search Products: SKU GTIN Description

Search Results for "204." (109)

Add products to your Case to create a report of all Items. Click "Done!" when finished.

Product No.	Company	GTIN ↑	UOM	
204.010	Trauma	10886982145338	EA	<input type="button" value="Add"/>
3.5MM CORTEX SCREW 10MM				
204.012	Trauma	10886982145345	EA	<input type="button" value="Add"/>
3.5MM CORTEX SCREW 12MM				
204.014	Trauma	10886982145352	EA	<input type="button" value="Add"/>
3.5MM CORTEX SCREW 14MM				
204.016	Trauma	10886982145369	EA	<input type="button" value="Add"/>
3.5MM CORTEX SCREW 16MM				
204.018	Trauma	10886982145376	EA	<input type="button" value="Add"/>
3.5MM CORTEX SCREW 18MM				
204.020	Trauma	10886982145383	EA	<input type="button" value="Add"/>

Your Case (6)

Product No.	GTIN	QTY		
02.112.145	10886982034038	1	<input type="button" value="Edit"/>	<input type="button" value="Delete"/>
2.7MM/3.5MM LCP LATERAL DISTALFIBULA PLATE 7H/LEFT/125MM				
202.212	10886982143969	2	<input type="button" value="Edit"/>	<input type="button" value="Delete"/>
2.7MM LOCKING SCREW SLF-TPNGWITH T8 STARDRIVE RECESS 12MM				
202.232	10886982144072	1	<input type="button" value="Edit"/>	<input type="button" value="Delete"/>
2.7MM LOCKING SCREW SLF-TPNGWITH T8 STARDRIVE RECESS 32MM				
204.020	10886982145383	1	<input type="button" value="Edit"/>	<input type="button" value="Delete"/>
3.5MM CORTEX SCREW 20MM				
213.032	10886982153135	1	<input type="button" value="Edit"/>	<input type="button" value="Delete"/>
3.5MM LOCKING SCREWS-SELF-TAPPING 32MM				

Additional Cross Reference Approach

Review Case Information (Optional)

In the UDI site's interactive areas, all information you provide is optional and the information will be governed by our [Privacy Policy](#)

Hospital Name:

Mercy

Operating Room:

1

Surgery Date and Time:

Click on calendar icon to pick date



Surgeon Name:

Smith



Case ID:


123456



clear case information

 Your Case (6)

Download:

Excel 

PDF 

		UDI				
Product No.	Company	GTIN	LOT Number	Date Lot	UOM	Quantity
1	02.112.145	Trauma	10886982034038	123456	EA	1
2.7MM/3.5MM LCP LATERAL DISTALFIBULA PLATE 7H/LEFT/125MM						
2	202.212	Trauma	10886982143969	456789	EA	2
2.7MM LOCKING SCREW SLF-TPNGWITH T8 STARDRIVE RECESS 12MM						
3	202.232	Trauma	10886982144072	78965	EA	1
2.7MM LOCKING SCREW SLF-TPNGWITH T8 STARDRIVE RECESS 32MM						
4	204.020	Trauma	10886982145383	56421	EA	1
3.5MM CORTEX SCREW 20MM						

Download PDF with:

1D Barcodes

UDI 1D Barcode

2D Barcodes

Additional Cross Reference Approach



AdvaMed
Advanced Medical Technology Association



Unique Device Identification

Case Report (ID: 123456)

Surgery Date and Time:
Surgeon Name: Smith
Hospital Name: Mercy
Operating Room: 1
Case ID: 123456

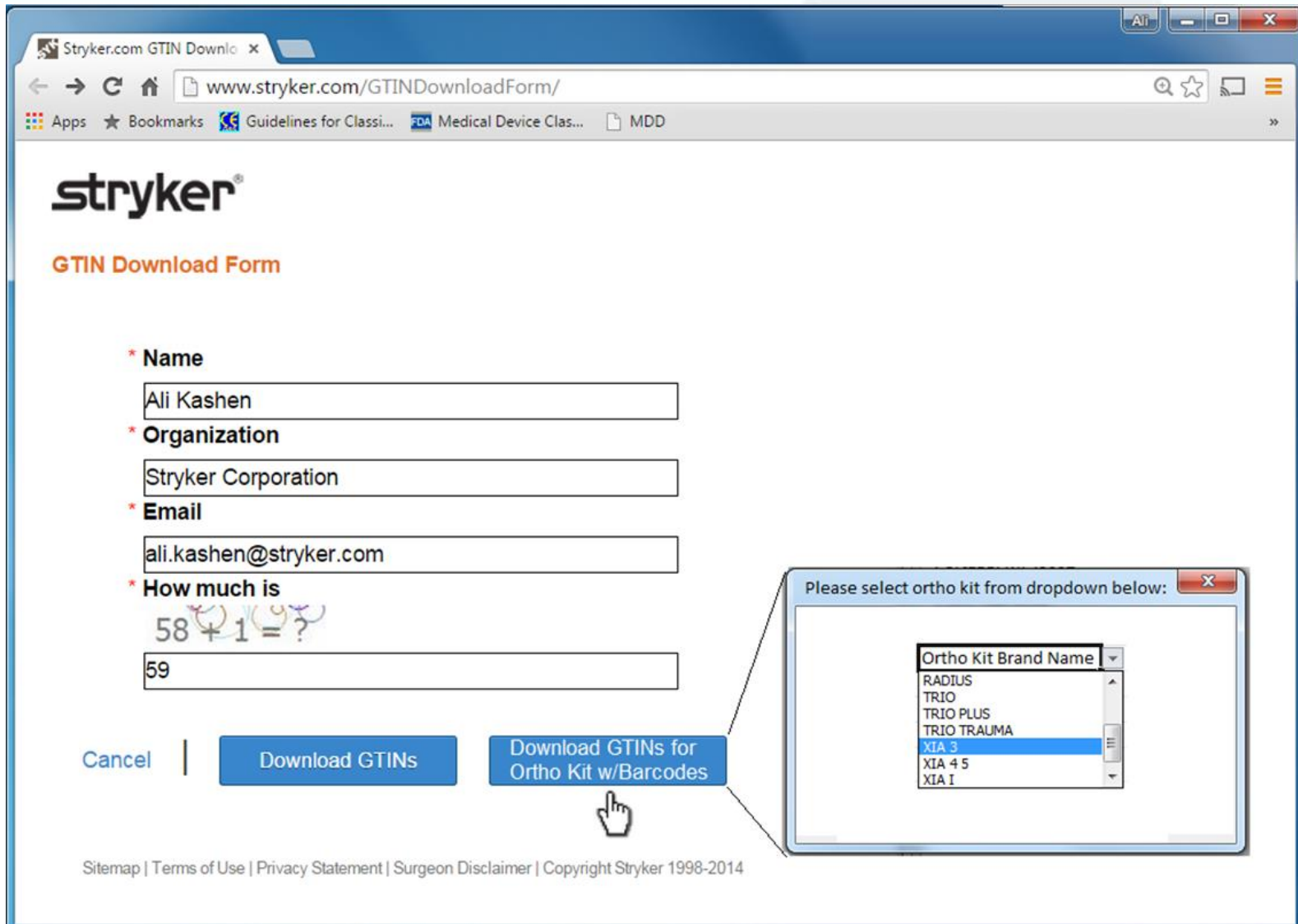
Products

Product No.	Company	UDI		Date Lot	UOM	QTY	Barcode
		GTIN	LOT No.				
1. 02.112.145	Trauma	10886982034038	123456		EA	1	 (01)10886982034038(10)123456
2.7MM/3.5MM LCP LATERAL DISTALFIBULA PLATE 7H/LEFT/125MM							
2. 202.212	Trauma	10886982143969	456789		EA	2	 (01)10886982143969(10)456789
2.7MM LOCKING SCREW SLF-TPNGWITH T8 STARDRIVE RECESS 12MM							
3. 202.232	Trauma	10886982144072	78965		EA	1	 (01)10886982144072(10)78965
2.7MM LOCKING SCREW SLF-TPNGWITH T8 STARDRIVE RECESS 32MM							
4. 204.020	Trauma	10886982145383	56421		EA	1	 (01)10886982145383(10)56421
3.5MM CORTEX SCREW 20MM							
5. 213.032	Trauma	10886982153135	332145		EA	1	 (01)10886982153135(10)332145
3.5MM LOCKING SCREWSLSELF-TAPPING 32MM							
6. 213.034	Trauma	10886982153142	542134		EA	1	 (01)10886982153142(10)542134
3.5MM LOCKING SCREWSLSELF-TAPPING 34MM							

Additional Cross Reference Approach

	A1	f_x	Product No.
	A	B	C
1	Product No.	Company	GTIN
2	02.112.145	Trauma	10886982034038
3	202.212	Trauma	10886982143969
4	202.232	Trauma	10886982144072
5	204.020	Trauma	10886982145383
6	213.032	Trauma	10886982153135
7	213.034	Trauma	10886982153142
8			
9	This document contains sensitive data that is highly restricted		
10			
11			
12			
13			
14			
15			

Additional Cross Reference Approach



The screenshot shows a web browser window at www.stryker.com/GTINDownloadForm/. The page features the Stryker logo and the title "GTIN Download Form". The form includes the following fields:

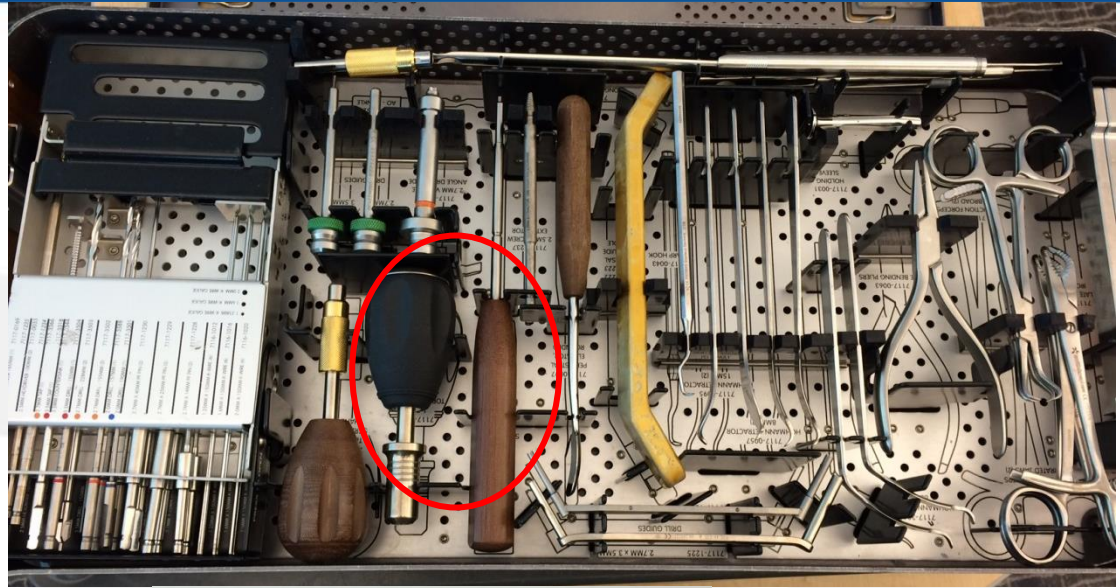
- Name:** Ali Kashen
- Organization:** Stryker Corporation
- Email:** ali.kashen@stryker.com
- How much is:** 58 + 1 = ? (with a CAPTCHA image) and 59

At the bottom, there are three buttons: "Cancel", "Download GTINs", and "Download GTINs for Ortho Kit w/Barcodes". A callout box points to the "Download GTINs for Ortho Kit w/Barcodes" button, displaying a dropdown menu titled "Ortho Kit Brand Name" with the following options:

- RADIUS
- TRIO
- TRIO PLUS
- TRIO TRAUMA
- XIA 3
- XIA 4 5
- XIA I

At the bottom of the page, there is a footer with the text: "Sitemap | Terms of Use | Privacy Statement | Surgeon Disclaimer | Copyright Stryker 1998-2014".

How can hospitals easily determine the UDI of instruments already in commercial distribution?



Instrument Cross Reference



AdvaMed
Advanced Medical Technology Association

1. Identify the instrument to cross reference
 2. Match item number to inventory control sheet
 3. Write in lot# in space provided
- *Full UDI available at point of use



Inventory Control Sheet

Patient Name: _____
Date: _____

To order: 1-800-238-7538

INSTRUMENTS					
QTY	Description	Catalog #	GTIN	Lot #	Bar Code
	BALL SPIKE PUSHER	71171210	03596010603494		 (01) 03596010625274 (10) SAMPLE
	FIBULA CLAMP	71171211	03596010603500		 (01) 03596010607188 (10) SAMPLE
	BALL SPIKE REDUCTION CLAMP MEDIUM	71171212	03596010603517		 (01) 03596010607188 (10) SAMPLE
	BALL SPIKE REDUCTION CLAMP LARGE	71171213	03596010603524		 (01) 03596010603616 (10) SAMPLE
	LATERAL PROXIMAL TIBIA POSITIONING GUIDE RIGHT	71171216	03596010603531		 (01) 03596010625287 (10) SAMPLE
	LATERAL PROXIMAL TIBIA POSITIONING GUIDE LEFT	71171217	03596010603548		 (01) 03596010625274 (10) SAMPLE
	ANTERIOR DISTAL TIBIA POSITIONING GUIDE	71171218	03596010603555		 (01) 03596010607188 (10) SAMPLE
	2.7MM VARIABLE ANGLE DRILL GUIDE	71171219	03596010603562		 (01) 03596010607188 (10) SAMPLE
	15MM SPIKED WASHER	71171220	03596010603579		 (01) 03596010603616 (10) SAMPLE
	25MM SPIKED WASHER	71171221	03596010603586		 (01) 03596010625287 (10) SAMPLE

	PLATE BENDING IRON	71171233	03596010603692		 (01) 00885556068182 (10) SAMPLE
	2.5MM HEX SCREW EXTRACTOR WITH QUICK CONNECT	71171237	03596010603708		 (01) 03596010607188 (10) SAMPLE
1	1.7Nm TORQUE LIMITING SCREWDRIVER	71171238	03596010603715	07LSY0043	 (01) 03596010603616 (10) SAMPLE

www.smith-nephew.com Orders and Inquiries: 1-800-238-7538

REV2 09.01.1

GUDID Cross Reference



AdvaMed

Advanced Medical Technology Association

http://accessgudid.nlm.nih.gov/devices/search?page=5&query=§

AccessGUDID - Smith &am...

File Edit View Favorites Tools Help

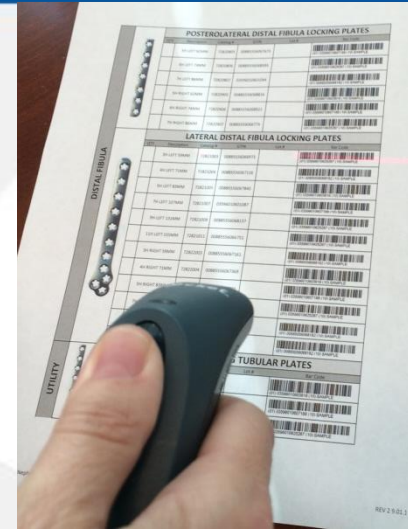
Suggested Sites Free Hotmail Web Slice Gallery

Device Packaged as	>	REFLECTION - 00885556020494	+
Sterile		ALUMINA CERAMIC LINER 28ID 46-48OD	
Sterilization Prior To Use	>	Company Name: Smith & Nephew , Inc. <u>Version or Model:</u> 71338346	
Issuing Agency	>	REFLECTION - 00885556021316	+
		REFLECTION FSO5 CERAMIC ACETABULAR COMPONENT 56MM	
		Company Name: Smith & Nephew , Inc. <u>Version or Model:</u> 71332056	
		REFLECTION - 03596010385635	+
		CERAMIC ACETABULAR LINER REMOVAL TOOL 28ID 50-54OD	
		Company Name: Smith & Nephew , Inc. <u>Version or Model:</u> 71369050	
		REFLECTION - 03596010385628	+
		CERAMIC ACETABULAR LINER REMOVAL TOOL 28ID 46-48OD	
		Company Name: Smith & Nephew , Inc. <u>Version or Model:</u> 71369046	
		REFLECTION - 03596010385642	+
		CERAMIC ACETABULAR LINER REMOVAL TOOL 28ID 56-66OD	
		Company Name: Smith & Nephew , Inc. <u>Version or Model:</u> 71369056	
		REFLECTION - 03596010419774	+
		TRIAL ACETABULAR LINER 28MM ID 46-48MM TAPERED OD	
		Company Name: Smith & Nephew , Inc. <u>Version or Model:</u> 71368046	

Non-sterile device method:

1. The UDI can be easily derived and made available at the point of use with a cross reference method such as an inventory control sheet.
2. The use of inventory control sheets / implant records represent standard OR protocol for implant documentation
3. The UDI information can be easily documented in the EHR
4. Sales orders including UDI information are sent to hospitals for billing purposes*

*This is not intended to reflect a UDI requirement.



The non-sterile device method meets:

1. The complex needs of our customers and ensures patient safety
2. The compliance requirements of the FDA*
3. And is easy and straightforward to administer



*Exceptions or alternate technologies required for some devices (implants and instruments)

- Industry has demonstrated that utilization of cross referencing tools are easy to administer and are an effective method for deriving the UDI at the point of use
- These methods can be used for finished devices that are shipped either before or after their respective compliance date
- Familiarity with the approach will improve the uptake and adoption of UDI at point of use and inclusion in EHRs by healthcare providers

Because the UDI can be easily derived at the point of use, AdvaMed is asking for:

- Clear written FDA confirmation that the method of direct part marking, combined with the use of a cross reference tool such as an inventory control sheet, is an acceptable means to comply with the UDI rule, and
- Grant an exception or alternate for non-sterile single use reprocessed devices where it is not technologically feasible to provide the DI and/or PI

The methods demonstrated today can be used for finished devices that are shipped either before or after their respective compliance date. Accordingly, AdvaMed continues to request a response to its legal opinion submitted 2/2/2015 concerning excluded transactions from the UDI rule.



AdvaMed

Advanced Medical Technology Association

BRINGING INNOVATION TO PATIENT CARE WORLDWIDE

September 17, 2015