The Global Language of Business

IMPLEMENTATION REALITY SESSION
Unique Device Identification (UDI)

Introductory Session – AIDC

28th GS1 Healthcare Conference – Budapest

20 October 2015

UDI Implementation "Reality"…

Our Panel…

- GS1 AIDC UDI Basics
  - Chuck Biss - GS1 Global Office
  - Senior Director, AIDC Healthcare
- UDI Regulatory Considerations
  - Jackie Rae Elkin - Medtronic, Inc.
  - Global Process Owner - Standard Product Identification - Global Regulatory Operations …also our Q& A Moderator
- UDI AIDC Implementation Experiences
  - Stan Malinowski - Medtronic, Inc.
  - UDI Lead for GS1 Standards and Marking
- UDI and Direct Part Marking (DPM) Implementation
  - Akio Murata - JAMDI
  - Chairman of DPM Committee – Japan Association of Medical Device Industries

UDI Implementation

To start, UDI & AIDC…

- UDI's purpose
- GS1 standards supporting UDI requirements
  - "Translation" of GS1 AIDC to UDI

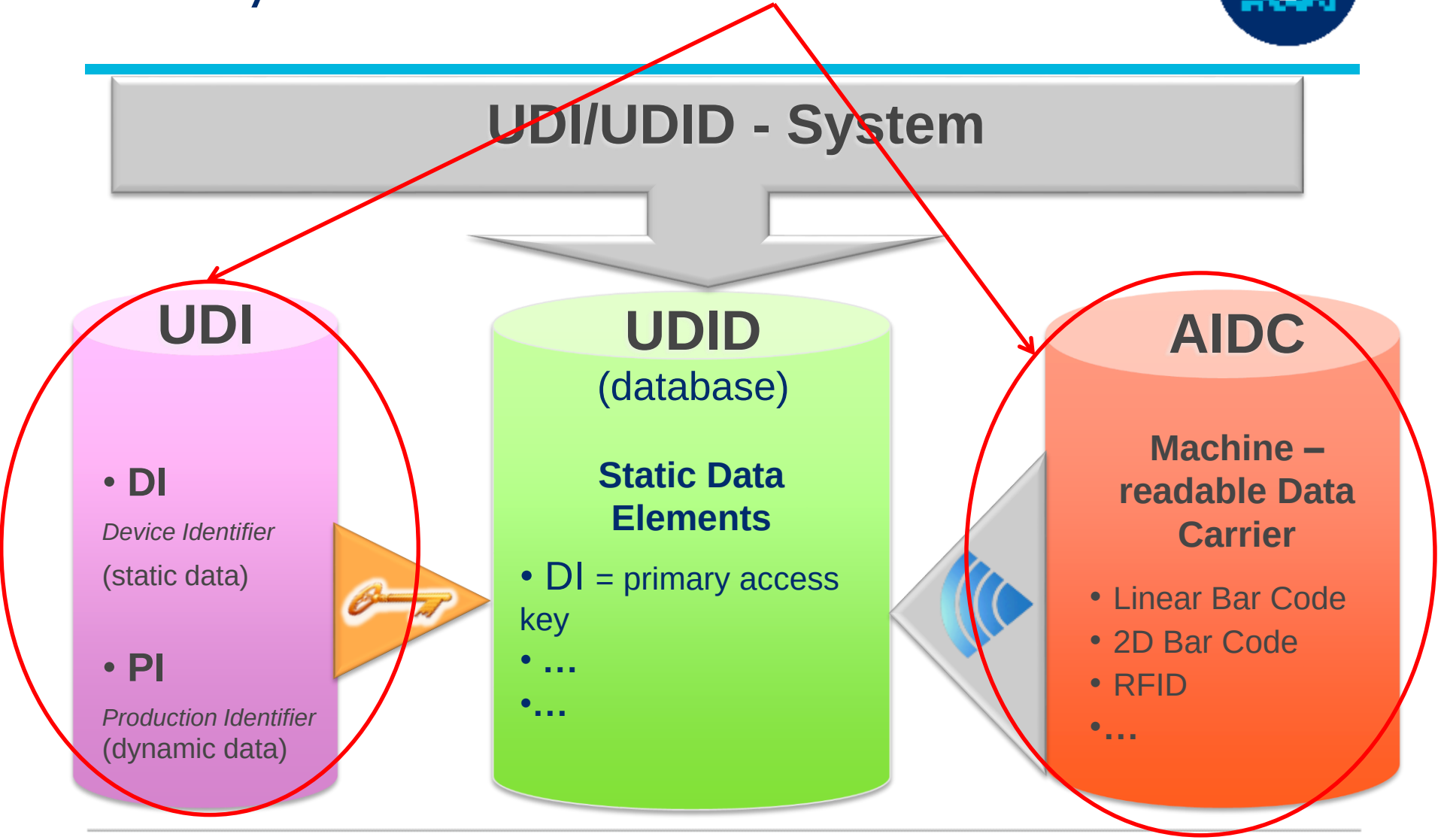
Chuck Biss
GS1 Global Office
Senior Director AIDC Healthcare
chuck.biss@gs1.org

UDI purpose…

Objective…

A common, **worldwide system for product identification** should eliminate differences between jurisdictions and offer significant benefits to manufacturers, users and/or patients, and regulatory authorities.

UDI system…The AIDC "bits"…



UDI & the GS1 system…

UDI in GS1 identification (identify) terms…

Unambiguous identification of a specific medical device… in two (2) parts:

- **Device Identifier (DI)** – ID of the "generic" medical device (GS1 **GTIN**)
- **Production Identifier (PI)** – "control" numbers or data used in a mfg. process – (GS1 **AI's** - lot/batch, serial number, expiry, etc.)

UDI Unique Device Identification	**GS1 Standards** Product Identification
DI Device Identifier (DI)	**GTIN** Global Trade Item Number
PI Production Identifier (PI) (If applicable)	**AI** Application Identifier (AI) • Expiration Date AI(17) - e.g. 141120 • Lot/Batch AI(10) - e.g. 1234AB • Serial Number AI(21) - e.g. 12345XYZ
Production Identifier data will vary by medical device type and manufacturer current practice.	
DI + PI = UDI	**GTIN or GTIN + AI(s) = UDI**

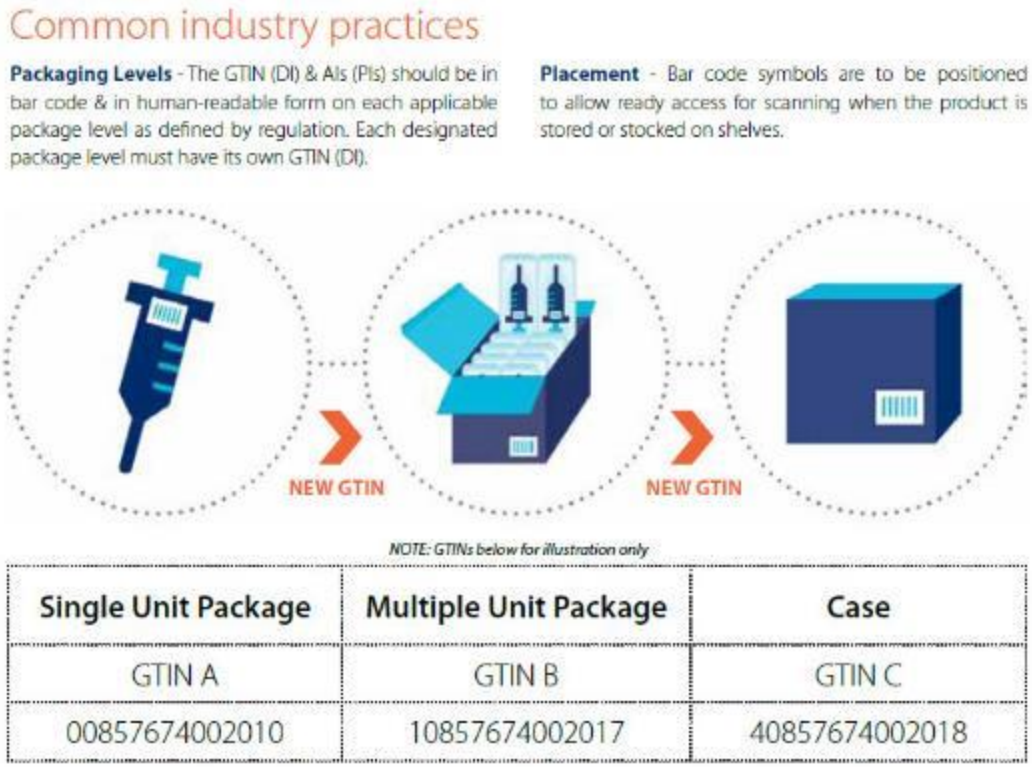
UDI & the GS1 system…

UDI in GS1 allocation (identify) terms…

Allocation - Some common reasons for a change are: Quantity, pack sterility change, re-labeling of an original device, languages, certification marks, etc.

Packaging Levels – A unique UDI s/b on each applicable packaging level as defined by regulation. Logistics items are exempt.

Always refer to local UDI regulations & GS1 GTIN Allocation Rules for details.



Placement – Bar code symbols are to be positioned to allow ready access for scanning when the product is stored or stocked on shelves.

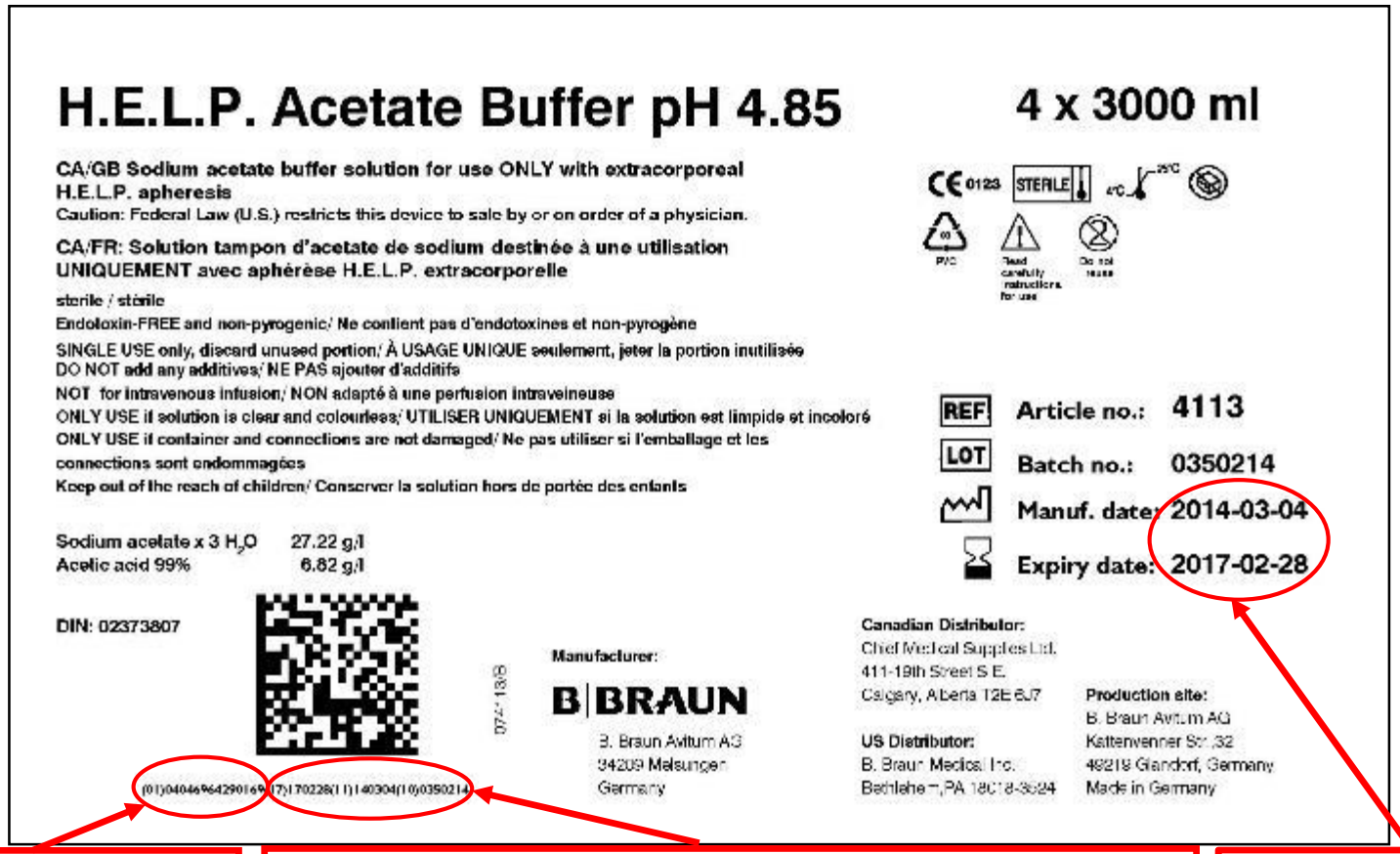
UDI & the GS1 system…

UDI in GS1 Data Carrier (capture) terms…

- Any ISO compliant machine-readable **Data Carrier** which contains the UDI is allowed, 1D/Linear & 2D/Matrix bar code symbols, RFID.
- "Direct Marking" in US FDA terms is not necessarily "direct PART marking"…

All data carriers are for illustration only, not to scale and not in proportional size to one another.
Please refer to GS1 General Specifications for detailed & up-to-date GS1 System information.
UDI requirements may vary by geography -please refer to regional UDI regulations.

UDI label – an example from B.Braun…



H.E.L.P. Acetate Buffer pH 4.85

4 x 3000 ml

CA/GB Sodium acetate buffer solution for use ONLY with extracorporeal H.E.L.P. apheresis
Caution: Federal Law (U.S.) restricts this device to sale by or on order of a physician.

CA/FR: Solution tampon d'acetate de sodium destinée à une utilisation UNIQUEMENT avec aphérèse H.E.L.P. extracorporelle

sterile / stérile
Endotoxin-FREE and non-pyrogenic/ Ne contient pas d'endotoxines et non-pyrogène
SINGLE USE only, discard unused portion/ À USAGE UNIQUE seulement, jeter la portion inutilisée
DO NOT add any additives/ NE PAS ajouter d'additifs
NOT for intravenous infusion/ NON adapté à une perfusion intraveineuse
ONLY USE if solution is clear and colourless/ UTILISER UNIQUEMENT si la solution est limpide et incolore
ONLY USE if container and connections are not damaged/ Ne pas utiliser si l'emballage et les connections sont endommagées
Keep out of the reach of children/ Conserver la solution hors de portée des enfants

Sodium acetate x 3 H_2O 27.22 g/l
Acetic acid 99% 6.82 g/l

REF Article no.: 4113
LOT Batch no.: 0350214
Manuf. date: 2014-03-04
Expiry date: 2017-02-28

DIN: 02373807

(01)04046964290169(17)170228(11)140304(10)0350214

Manufacturer:
B. Braun Avitum AG
34209 Melsungen
Germany

Canadian Distributor:
Chief Medical Supplies Ltd.
411-19th Street S.E.
Calgary, Alberta T2E 6J7

US Distributor:
B. Braun Medical Inc.
Bethlehem, PA 18018-3524

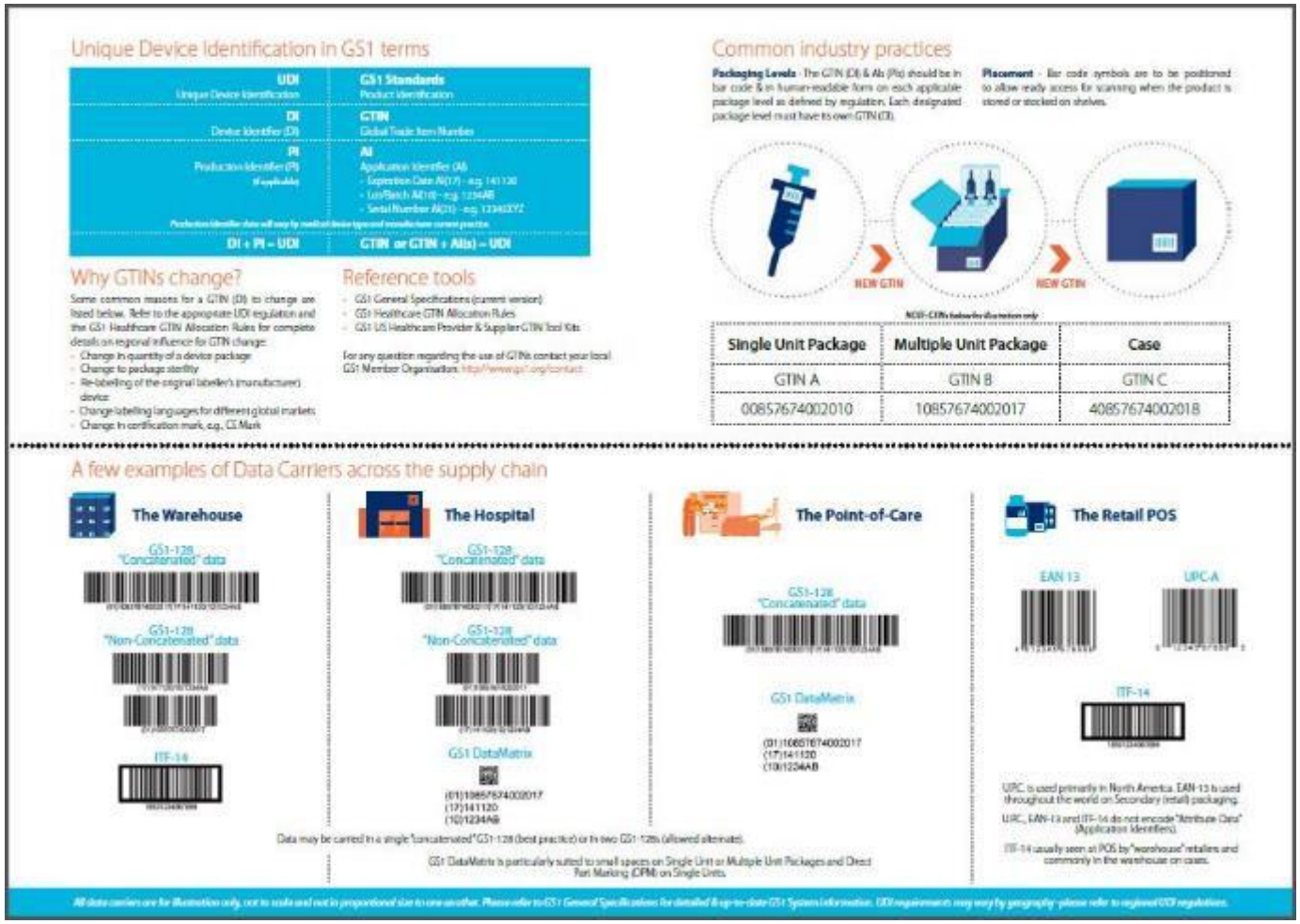
Production site:
B. Braun Avitum AG
Kattenvenner Str. 32
49219 Glandorf, Germany
Made in Germany

Device Identifier (DI)
"Static" portion
GTIN (product identifier)

Production Identifier (PI)
"Dynamic" portion
Application Identifiers (e.g. serial, lot number & expiry date)

US FDA UDI required
ISO 8601 date format

UDI / GS1 AIDC - the “snapshot”…



Available on-line at:
http://www.gs1.org/healthcare/udi
&
http://www.gs1.org/sites/default/files/docs/healthcare/UDI_Leaflet_Final.pdf

UDI Implementation

To continue, regulatory…

- UDI Regulatory Considerations
  - the FDA rule, the nuances, other pending rules…

Jackie Elkin
Medtronic, Inc.
Global Process Owner - Standard Product Identification
Global Regulatory Operations

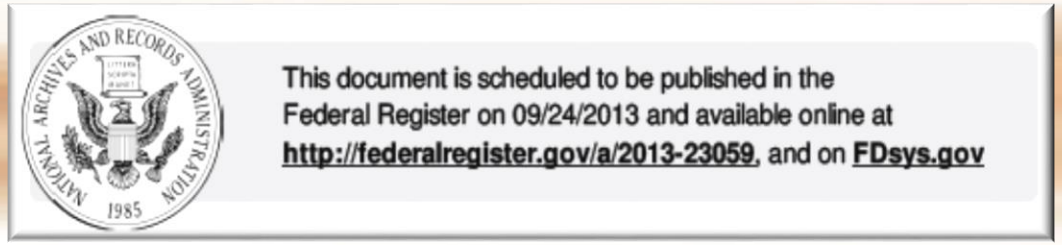
FDA Unique Device Identification (UDI) AIDC Implementation Challenges and Considerations ……. a Regulatory Perspective

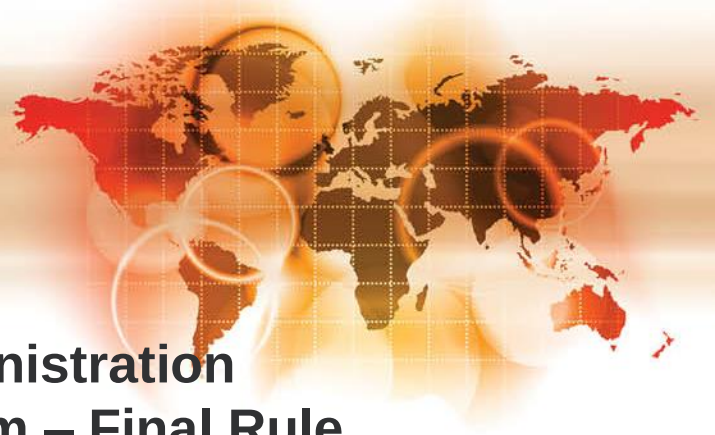
Jackie Rae Elkin
Global Regulatory Affairs
Medtronic

Unique Device Identification

Combination of 4 Distinct Ideas

1. **Development of a standardized system of Unique Device Identifiers(UDI)**
2. **Placing UDI in human readable and AutoID formats on package, label or device**
3. **GUDID – register UDI data in FDA public database**
4. **Implementation**





United States Food and Drug Administration
Unique Device Identification System – Final Rule

PENALTIES FOR FAILURE TO MEET UDI REQUIREMENTS:

Devices for which there has been a failure or refusal to furnish any material or information required by or under section 519 of the FD&C Act respecting the device are **misbranded** under section 502(t)(2) of the FD&C Act. The failure or refusal to furnish any material or information required by or under section 519 of the FD&C Act is a **prohibited act** under section 301(q)(1)(B) of the FD&C Act. Potential enforcement **actions for violations of UDI requirements include seizure, injunction, and civil and criminal penalties.**

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1 Development of a standardized system of Unique Device Identifiers(UDI)

Create a new Device Identifier when:

- A change that results in a **new Model or Version** of the device
- A change of the **Quantity** of devices within a device package
- A new Device Identifier is needed for the following changes reflected in the GUDID
  - ✓ Change in **Sterilization** indication on package label
  - ✓ Change in **Latex warning** on package label
  - ✓ Change in **Single Use** indication on package label
  - ✓ Change in **MRI safety** indication
  - ✓ Change in **Combination product** indicator field
  - ✓ Change in **Kit** indicator field

Note: Labeler may have additional assignment criteria

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Governance Considerations

- Who will be responsible for maintaining **Interchangeability** rules and **change** records?
- **Remember UDI is required in the Device History Record under 820.184 along with the labeling inspection and verification in 820.120.**
- All UDI data for a medical devices must be submitted to the GUDID **before commercialization** of the device - where is product distribution control / release trigger?

2 Placing UDI in human readable and AutoID formats on package, label or device

- Updates to labels to include date format YYYY-MM-DD (does not include bar code HRI). The Date Format applies to **All** medical devices (not just those subject to UDI)
- Medical device **software version** should be captured in the Lot or Batch Production Identifier (AI 10 for GS1).
- **Manufacturing Date** on the label. Exemptions have to be granted to exclude DOM (only available if not used as control).
- Bar code quality **must be verified** with a bar code verifier. Simply scanning for readability is not verification, nor is it sufficient. Measure and verify the quality of the code to ISO/ANSI standards (ISO 15416).

UPC-A 12 Concordance with GTIN-14 on Product Package Label

When the package is going to both retail and healthcare providers supply chain, it must have an EAN/UPC barcode for Point-of-Sale application.

- The EAN/UPC cannot contain secondary information; **therefore, a second barcode to carry secondary information may be used**
- The GTIN in the secondary barcode must be same GTIN as in the EAN/UPC

Figure 1. GTIN-14 Structure Example

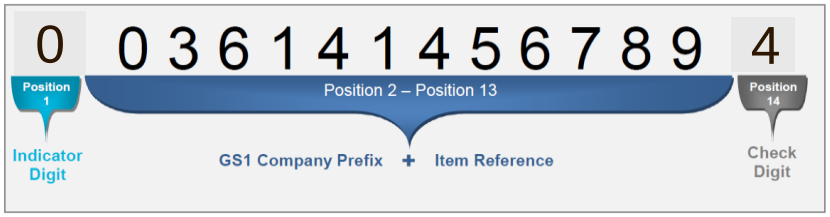
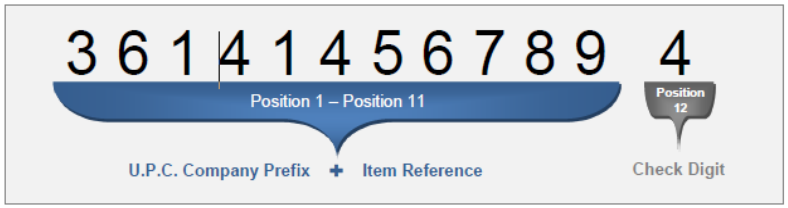


Figure 2. Segments of a GTIN-12 (based on the hypothetical GTIN "361414567894")



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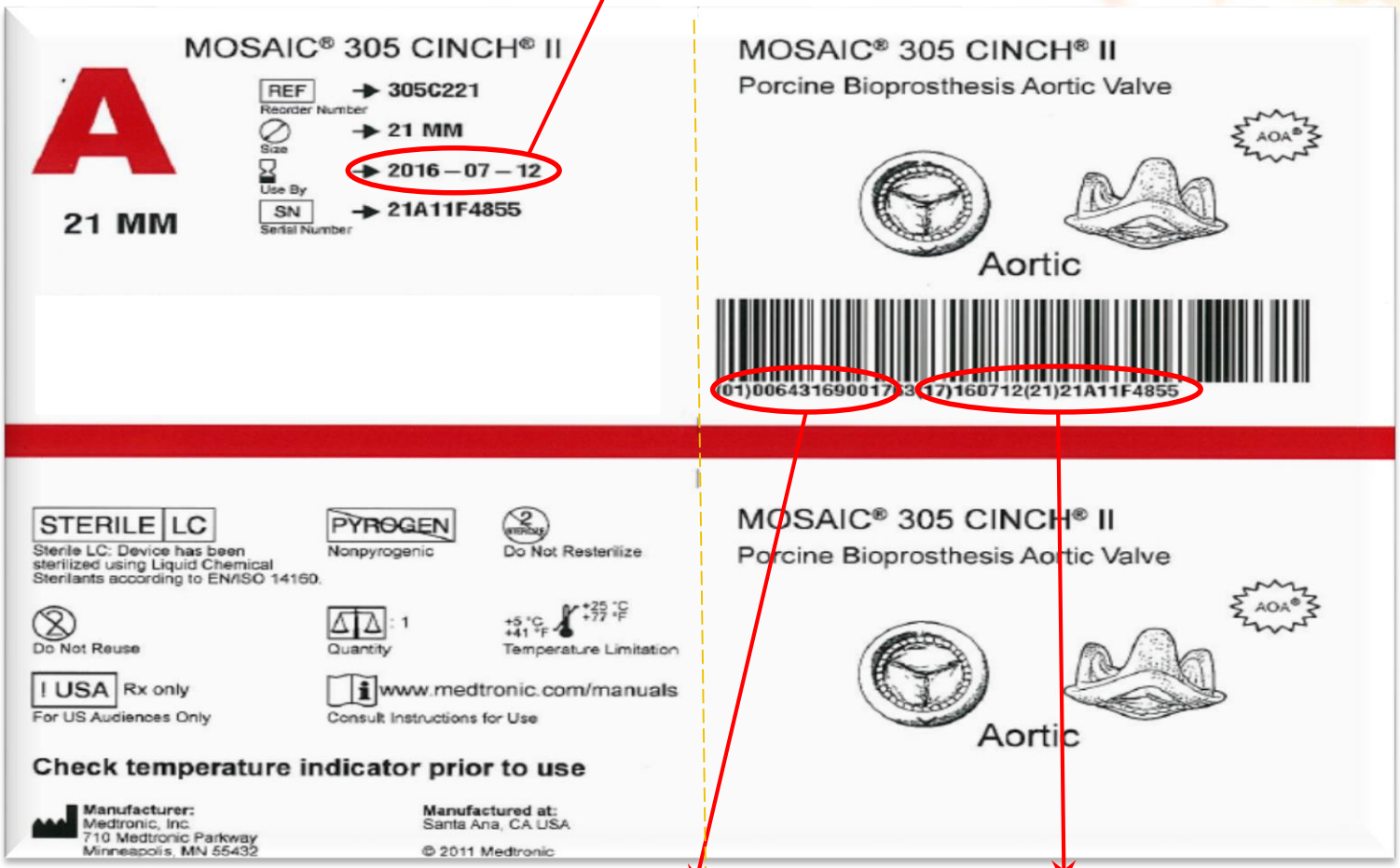
UDI Compliant Label

Date Format = YYYY-MM-DD



Device Identifier

Production Identifiers

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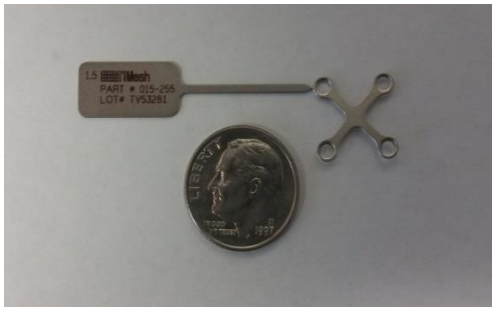
Extension Granted by FDA

FDA grants extension for UDI labeling requirements to September 24, 2016, for medical devices that meet all of the following criteria:

- *classified with product codes in the notification,*
- *implants,*
- *intended to be sterilized (or cleaned and sterilized) before use.*



What if you have a device that is not subject to Direct Marking, but you Direct Mark as a solution – do you get to use the rules and exceptions under 801.45?

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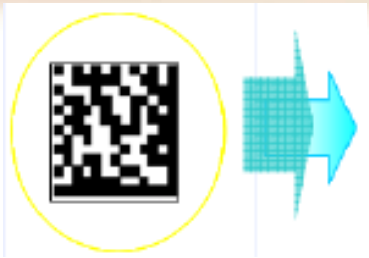
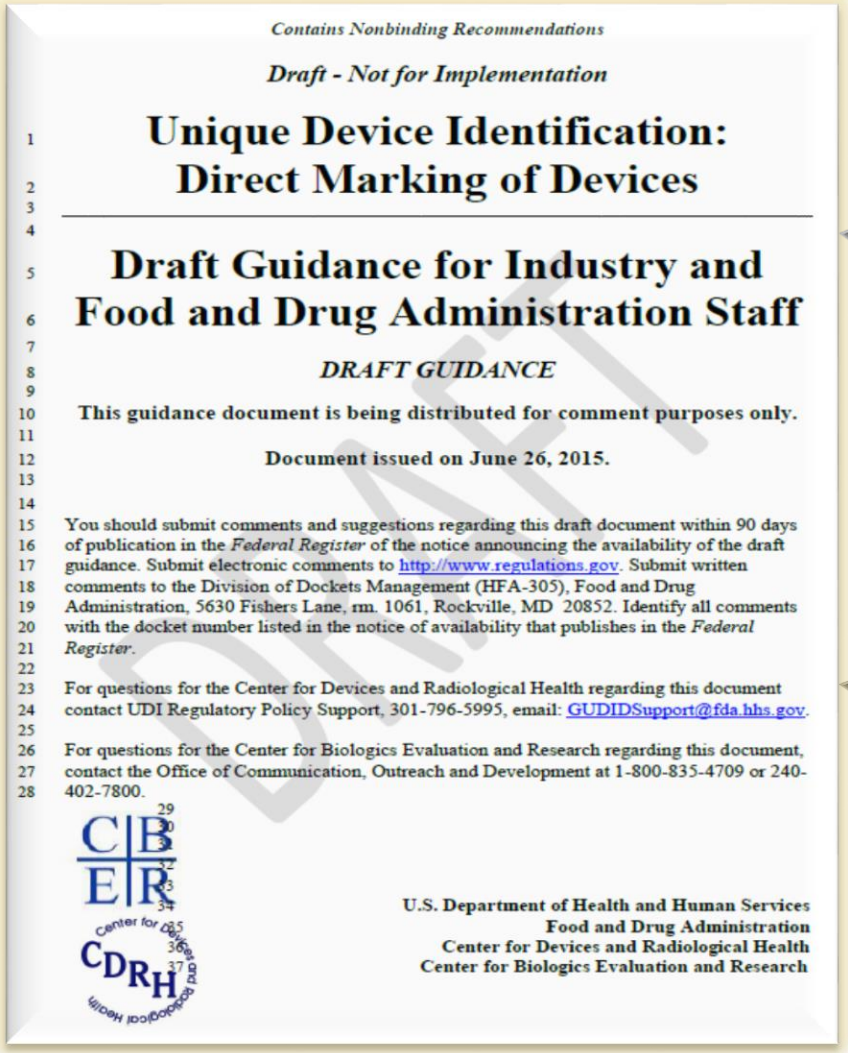
UDI Direct Marking on Device 801.45



Reusable devices that **require reprocessing** (cleaning by disinfection or sterilization) before reuse (between patient), must have the UDI directly marked on the device.

- Direct Mark UDI can be the **same or different** than UDI on package label
- UDI can be in **Human Readable** or **AIDC** or **Both**
- Remember the **exceptions** in the rule:
  - ✓ Interfere with safety and efficacy
  - ✓ Not technically feasible
  - ✓ SUD
  - ✓ Previously marked
- **Self exempt** and document in **Design History File.**

FDA Draft Guidance
UDI Direct Marking of Devices



Contains Nonbinding Recommendations

Draft - Not for Implementation

Unique Device Identification: Direct Marking of Devices

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Document issued on June 26, 2015.

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions for the Center for Devices and Radiological Health regarding this document contact UDI Regulatory Policy Support, 301-796-5995, email: GUDIDSupport@fda.hhs.gov.

For questions for the Center for Biologics Evaluation and Research regarding this document, contact the Office of Communication, Outreach and Development at 1-800-835-4709 or 240-402-7800.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

A. Direct Marking

Does FDA specify a method to directly mark a device?

No……

The labeler should determine the appropriate method to provide such a marking on the device itself**.**

May a labeler voluntarily comply with direct marking requirements?

Yes……..

We encourage affixing a UDI permanently on devices even when not required.

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FDA Draft Guidance
UDI Direct Marking of Devices

UDI formats by FDA-Accredited Issuing Agency

This docum… identifier (U… has a unique process. An… before impl… additional q…

Please note… adoption of… for UDI repr… available at…

Each FDA-accredited issuing agency has a unique UDI format that has been approved by FDA during the initial accreditation process. Any changes to the format of the UDI by an issuing agency must be approved by FDA before implementation……..

…ce …gency …n …l by FDA …l for any …ndard …dations …ll be

GS1® Issuing Agency²

Issuing Agency	Data Delimiters	Identifier	Data type	Human Readable Field Size	Database Field Size
GS1	(01)	DI	Numeric	16	14
GS1	(11)	Manufacturing/ Production Date	numeric [YYMMDD]	8	6
GS1	(17)	Expiration Date	numeric [YYMMDD]	8	6
GS1	(10)	Batch/Lot Number	alphanumeric	22	20
GS1	(21)	Serial Number	alphanumeric	22	20
GS1		***Maximum Base UDI***	***alphanumeric***	***76***	***66***
ex: (01) 51022222233336(11)141231(17)150707(10)A213B1(21)1234					

B. UDI Format

For a UDI direct marking, are both the plain text and AIDC forms required? No……..

Both the plain text and the AIDC forms of the directly marked UDI should adhere to the UDI format specified by the FDA-Accredited Issuing Agency.

See 21 CFR 830.20 and "UDI Formats by FDA-Accredited Issuing Agency (May 7, 2014)."

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FDA Draft Guidance
UDI Direct Marking of Devices

B. UDI Format

If the UDI that appears on the device label changes, must the directly marked UDI be replaced?

No. Under 21 CFR 801.45(d)(4), once a device has been marked in compliance with the UDI direct marking requirements, there is no requirement to replace the UDI direct marking even if the UDI that appears on the label changes.

FDA Draft Guidance
UDI Direct Marking of Devices

C. Reprocessing

2. What does FDA consider "reprocessed" for the purpose of direct marking?

Reprocessing is defined as validated processes used to render a medical device, which has been previously used or contaminated, fit for a subsequent use. See "Reprocessing Med... for Indu... (Rep..., biolo... devices are safe for the next p... purposes of UDI direct marking requirements, we consider a device that is intended to be cleaned and either sterilized or disinfected before each use to be re...processed. If a device is intended only to be cleaned betw... purp... more... ce does...

If a device is intended **only to be cleaned** between uses by different patients, this **would not** be considered reprocessing for the purposes of the UDI direct marking requirements.

If the device is intended to be used more than once on or **by the same patient**, and not on or by different patients, the device **does not** need to be directly marked with a UDI.

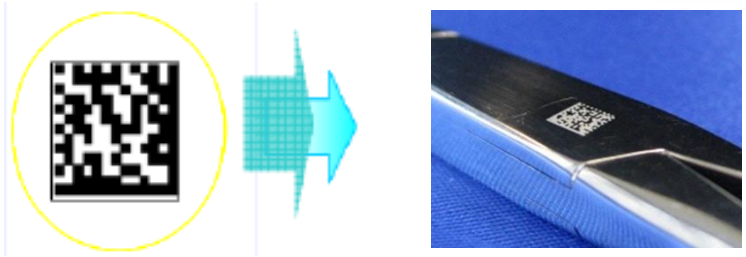
FDA Draft Guidance
UDI Direct Marking of Devices

D. Exceptions to Direct Marking

2. Does a non-UDI direct marking (such as the name of the company or part or catalog number) on a device itself meet the UDI direct marking requirements?

No. The name of the company or part/catalog number only does not meet the UDI direct marking requirements under 21 CR 801.45. If your device design with a non-UDI direct marking has been cleared or approved, we are unlikely to find merit in a justification for an exception under 21 CFR 801.45(d)(1) that direct marking would interfere with the safety or effectiveness of the device. **In addition, lack of space because non-UDI direct marking has taken up the otherwise available space for a UDI direct marking will typically not be sufficient justification for an exception under 21 CFR 801.45(d)(2)** that the device cannot be directly marked because it is not technologically feasible.

UDI Direct Marking on Device Challenges



- Significant impact to develop new methods for direct marking of various device materials, create testing methods to prove continued safety and efficacy.
- May require **re-approval** of the device in markets around the world
- Feasibility of direct marking is an issue with many devices due to device surface size and/or material (may also compromise integrity of material).
- Consider legacy products placed on market in consignment and remember the 3 years to deplete inventory begins to toll with the compliance timelines. How will FDA treat consignment product ?

Reminder: The UDI Rule requires **a lot** of interpretation and a bit of deductive reasoning

The **objective** of UDI is to **establish a system to adequately identify devices through distribution and use.** The **purpose** is to **rapidly and definitively identify a device** and it is intended to lead to more **accurate reporting** of adverse events by **making it easier to identify the device** prior to submitting a report.

in·ter·pret
\in-ˈtər-prət, -pət
: to explain the meaning of (something)
: to understand (something) in a specified way

Medtronic

Thank You!

Jackie Rae Elkin
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Medtronic - Global Regulatory Affairs
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Office: 1.763.505.2575 Mobile: 1.612.801.6615
jackie.elkin@medtronic.com

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UDI Implementation

To continue, implementation experiences…

- UDI AIDC Implementation
  - one company's implementation view to date, good and bad…

Stan Malinowski
Medtronic, Inc.
UDI Lead for GS1 Standards and Marking

The Global Language of Business

UDI AIDC Implementation Experiences

28th Global GS1 Healthcare Conference

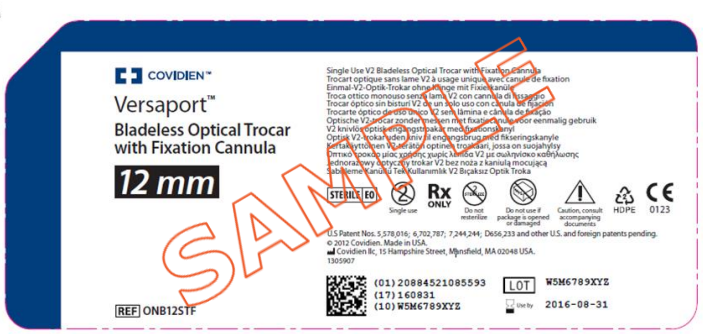
October 20, 2015

Stan Malinowski

Agenda

UDI Approach

- Where to Begin?
- Critical Success Factors
- Program/Project Management
- AIDC in Healthcare
- Data Quality and Management
- Information Publication



Where to Begin?

Get Educated

- UDI Final Rule
- GS1, HIBCC and ICCBBA standards
- IMDRF UDI Guidance
- EU Recommendations and others

Get Engaged

- Medical device industry groups
- Talk to your peers
- Standards organizations
- Implementation workgroups
- Industry projects
- Talk to the agency

Critical Success Factors

Organizational Awareness

- Understand UDI
- Identify beneficial business impact
- Recognize consequence of non-compliance

Organizational Support

- Engage senior leadership
- Secure resources to implement UDI changes
- Prioritize within the business

Establishing the Project

Scope
- Define what is in and out of scope
- Minimize scope creep
- Include label and data updates, data management, and equipment

Schedule
- Develop schedule based on availability of resources and compliance dates
- Priority by product risk class and impacts

Resource
- Establish consistent project management
- Build cross-functional team with company and industry knowledge
- Consider extended team of employees, temporary staff, and consultants

Budget
- Secure consensus that UDI compliance requires investment
- Determine available expense and capital budgets to support the project

Understanding the Initiative

US Regulations

- UDI
- Labeling
- Conforming amendments

Global Regulations

- Regional variation will be challenging
- Define strategy for regional compliance

Device Labeling

- Labeling artwork may need new AIDC (Automatic Information and Data Capture) marking
- Space may be an issue due to other regulatory requirements
- Consider options when developing an AIDC policy

Direct Marking

- Direct part marking may be required
- Understand the regulation
- Understand your capabilities
- Understand the exemption process when available

Understanding the Initiative

Data Quality

- Information may be unstructured
- Data that may have been for internal use now will reside in an FDA database
- Analyze the current state vs. future state and develop a plan

Data Management

- Creation, processing, storage and publication of data
- New platforms may be required
- Modification to existing data management systems may cause disruption in the business

Data Governance

- Data governance will be needed to control enterprise data
- Keeping the data quality level

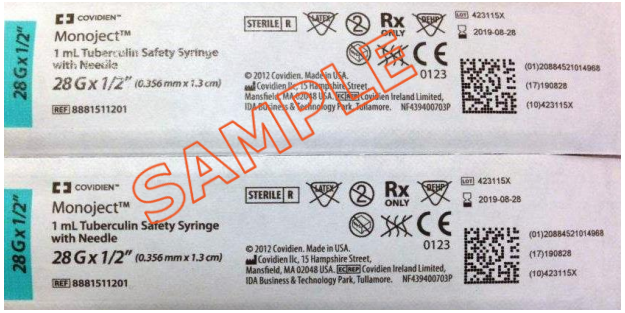
Business Process

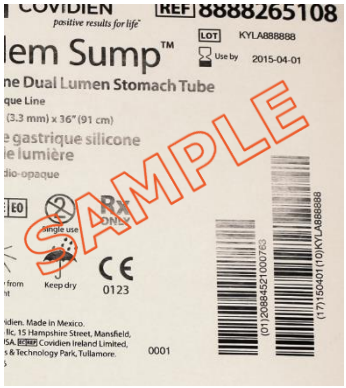
- Sustainable business processes will enable compliance
- Keeps focus after the project is over

AIDC in Healthcare

Application of UDI

- Multiple device package levels
- Preferred formats for distribution vs. point of use, or by customer
- Content requirements create space challenges
- Label application for inner and outer boxes

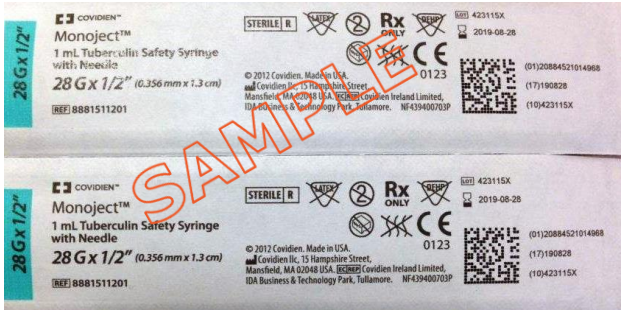


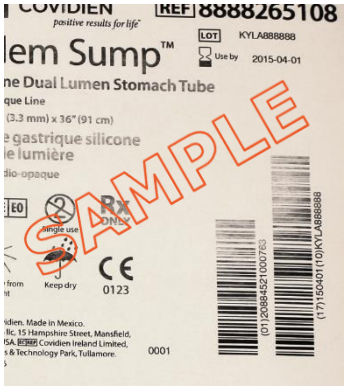


AIDC in Healthcare

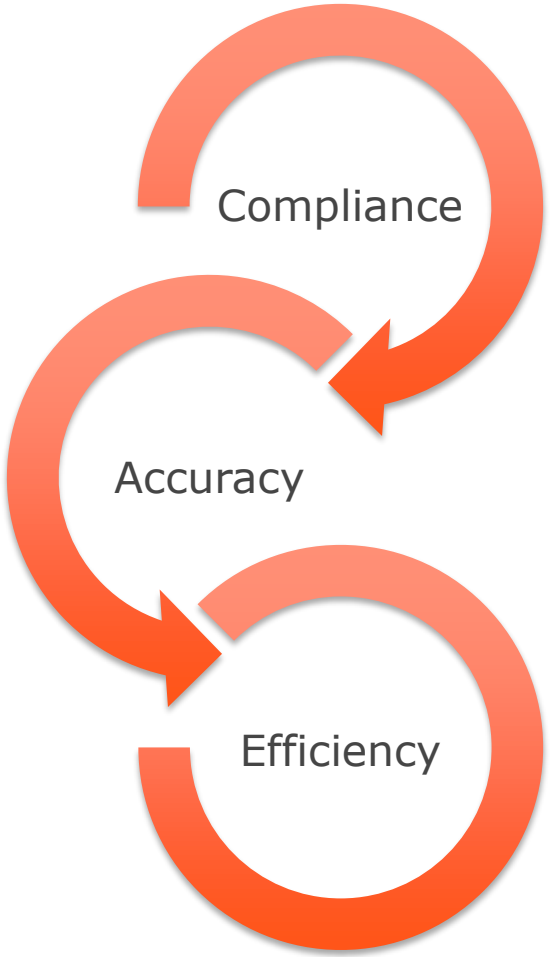
Application of UDI (Details)

- Printing on primary packaging substrates: inkjet, thermal transfer
- Printing software inconsistencies
- Barcode verification for AIDC quality
  - Process Controls Variables & Process Capability
- Documentation in Device History Record





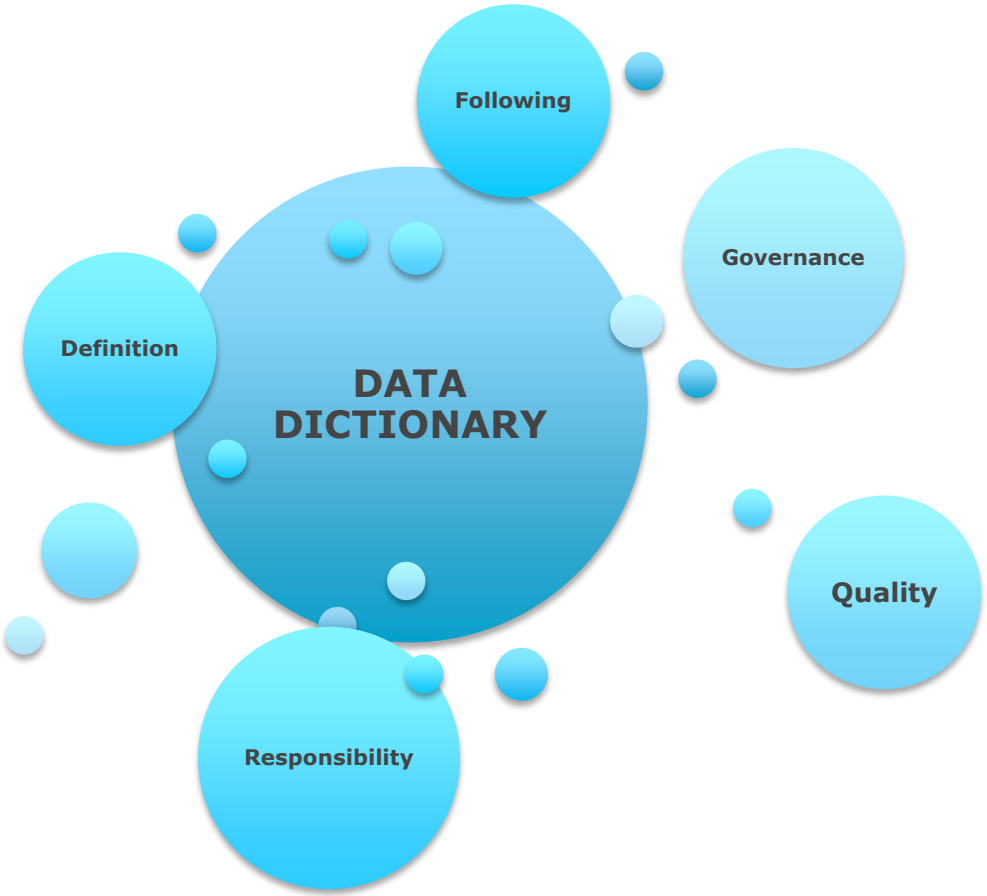
Why Data Quality?



Definition of Data

What is Product Data?

- Attributes
- Item Level
- Packaging Level
- Compliance and Standards
- “Data Dictionary”



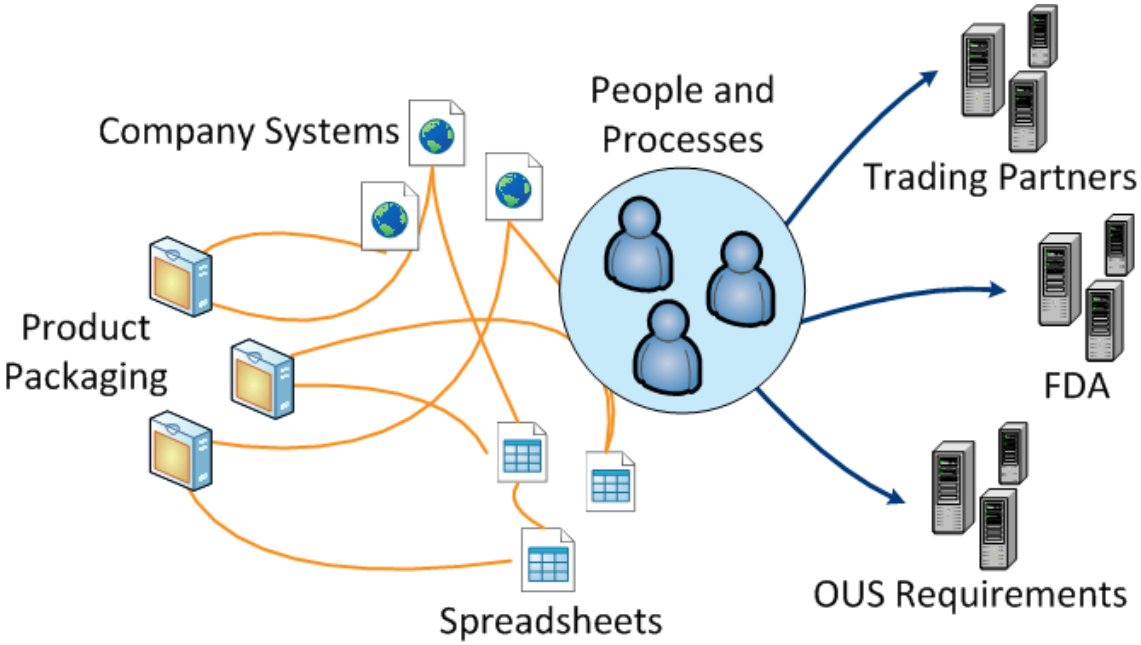
GTIN Hierarchy

Company	Reorder Code	UOM	QOM	GTIN
Covidien	9255	EA	1	10884521021914
Covidien	9255	CT	25	20884521021911
Covidien	9255	CA	100	30884521021918

Infrastructure and Systems

Starting Out…

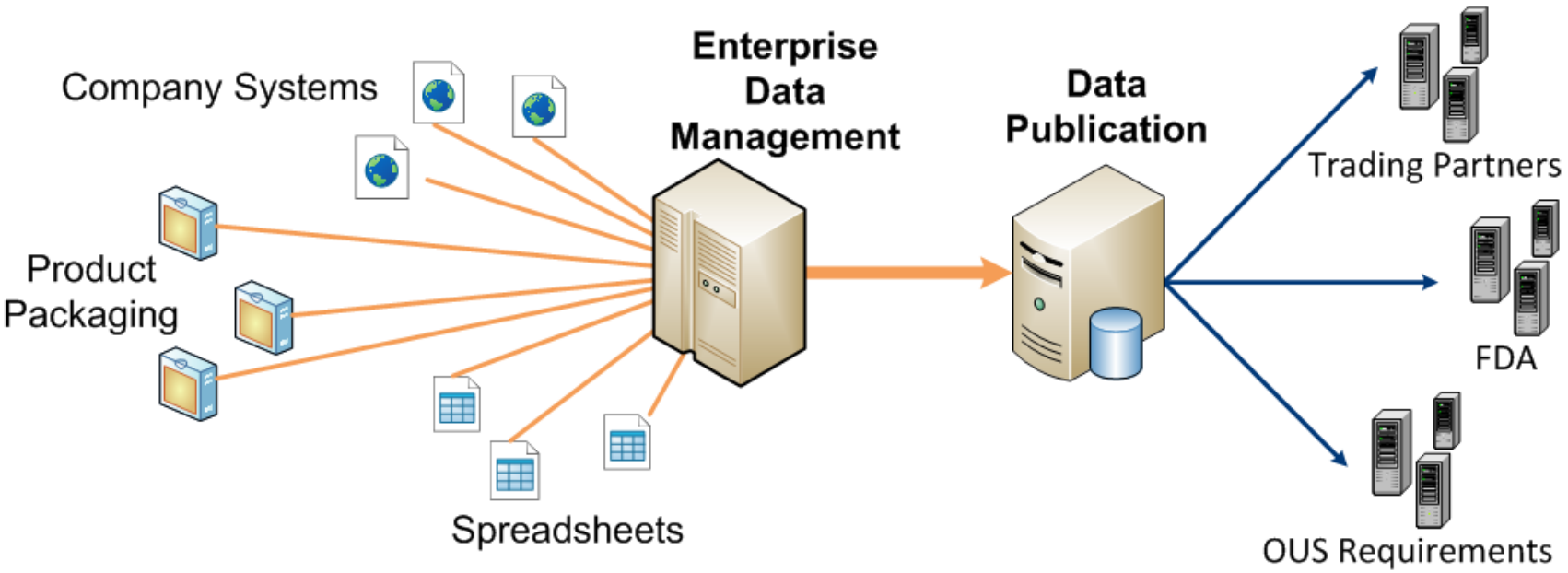
- Manual interactions
- Un-validated
- Lack of definition
- Disconnections
- Data degradation
- Multiple requirements



Future State

Strategic Approach…

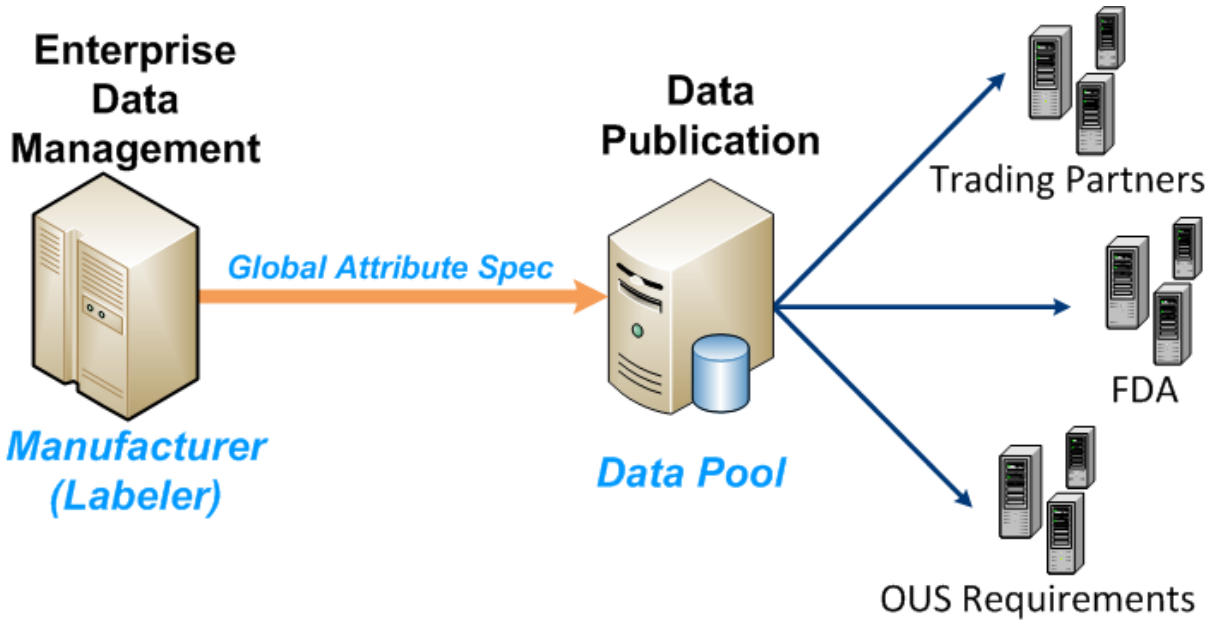
- Defined processes
- Data quality
- Validated interactions
- Model of publication and consumption



Data Publication

Best Practices…

- Global Attribute Spec for all UDI Data
- Scalable for UDI and GDSN publications
- Future applicability OUS
- Other Data Pool applications



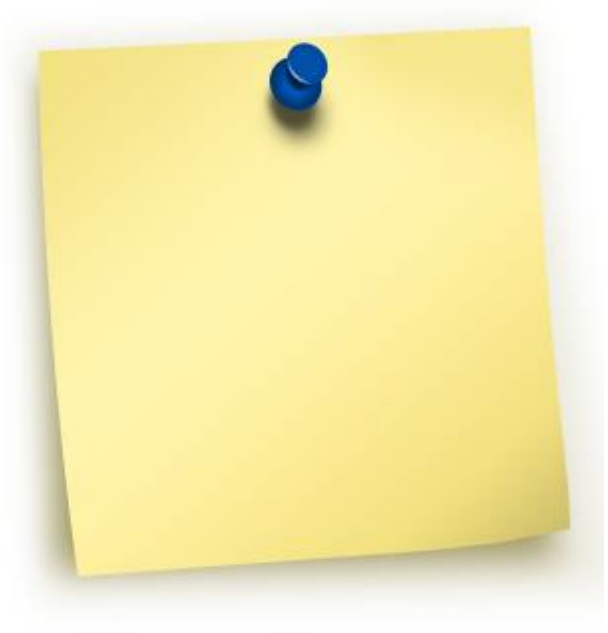
Why Data Pool / GDSN for UDI?

Service	Compliance	Advantage
• Competency for transmitting data • Attribute definition • Existing supplier	• Compliance Reports • Traceability of submission • Validation of software	• One feed to your data pool may serve multiple recipients – take advantage of scale! • Investigate overlap with other 'product catalogs'

Take-aways

Key Points to Remember

- Understand the initiative – establish project
- UDI value is in the data
- AIDC implementation is different in Healthcare
- Data Pool / GDSN for UDI has advantages
- **Start early!**



UDI Implementation

To continue, implementation experiences…

- UDI and Direct Part Marking (DPM) Implementation
  - a technical guideline developed in Japan

Akio Murata
Japan Association of Medical Device Industries
Chairman of DPM Committee

Technical Guideline on Direct Marking for Two-Dimensional Symbol on Steel Instruments

一般社団法人
日本医療機器工業会
Japan Association of Medical Devices Industries

Chairman of D.P.M. Committee Jamdi

Akio Murata

1. What is about The Technical Guideline

- This Technical Guideline shows a recommended method for suppliers to make direct marking on steel instruments jointly developed by the Japan Association of Medical Devices Industries (JAMDI) and the Japanese Society of Medical Instrumentation (JSMI)

- It helps medical institutions to make marking inside the hospital (in-hospital marking).

2. Efforts toward The Technical Guideline

Empirical Research to Improve Marking and Reading Accuracy since DPM General Guideline published in 2006

- Comparative study on improving accuracy in reading display patterns of two-dimensional symbols, Operative Medicine, 29(3), 2008.
- Empirical research on practical marking specifications and reading technology for two-dimensional symbols on steel instruments, Operative Medicine, No. 126, pp. 144, 2008.
- Research on how to indicate two-dimensional symbols on surgical steel instruments with abrasive resistance considered, Medical Instrumentation, 80(2), 2010.
- Technical investigation on marking depth for two-dimensional symbols on surgical steel instruments, Operative Medicine, 32(2), 2010.
- Comparative study on shipment responsibility and traceability associated with identification of surgical steel instruments, Medical Instrumentation, 81(2), 2011.
- Research on abrasion evaluation of dot pin method for marking two-dimensional symbol on surgical steel instruments, Medical Instrumentation, 82(2), 2012.
- Research on corrosion evaluation of dot pin method for marking two-dimensional symbol on surgical steel instruments, Medical Instrumentation, 82(2), 2012.

3. FDA Guidance for Direct Marking of Device

Contains Nonbinding Recommendations

Draft - Not for Implementation

Unique Device Identification: Direct Marking of Devices

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Document issued on June 26, 2015.

3. FDA Guidance for Direct Marking of Device

Does FDA specify a method to directly mark a device?

NO !

The labeler should determine the appropriate method to provide such a marking on the device itself.

4. ISO Guideline for DPM

TECHNICAL REPORT

ISO/IEC TR 24720

First edition
2008-06-01

Information technology — Automatic identification and data capture techniques — Guidelines for direct part marking (DPM)

Technologies de l'information — Techniques automatiques d'identification et de capture des données — Lignes directrices pour DPM («direct part marking»)

4. ISO Guideline for DPM

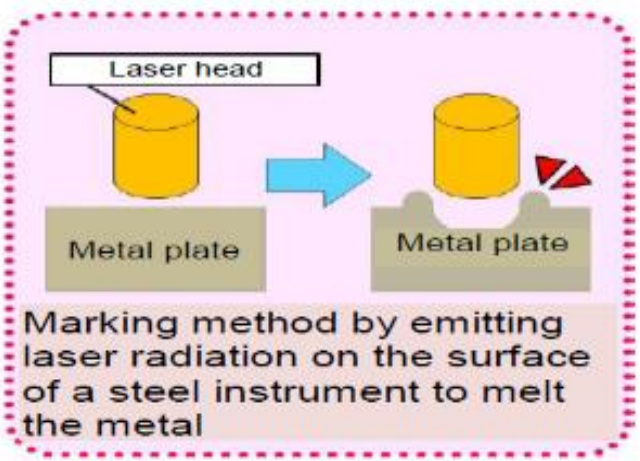
Table 1 — Marking Method Selection

MARKING PROCESS \ MATERIAL TO BE MARKED	METALLICS								NON-METALLICS								
	Aluminum	Anodized	Beryllium	Carbon Steel	Copper	Brass	Magnesium	Titanium	Ceramics	Glass	Cloth	Painted	Plastics	Rubber	Teflon	Wood	Epoxy-glass
Abrasive Blast	•	•		•	•	•	•	•	•			•	•		•		
Adhesive Dispensing	•	•	•	•	•	•	•	•	•	•	1	•	•	•		•	
Cast, Forge Or Mold	•	•	•	•	•	•	•	•	•				•	•			
Dot Peen	•			1	•	•		•				1	1				
Electro-Chemical Coloring	•	•	•	•	•	•	•	•									
Electro-Chemical Etching	•	•	•	•	•	•	•	•									
Embroidery											•						
Ink Jet	•	•	•	•	•	•	•	•	•	•	1	•	•	•			•
Laser Bonding	•		•	•		•	•	•	•	•			•				
Laser - Short Wave Lengths	•	1	•	•	•		•	•	•	•		1	•	•	•	•	•
Laser Visible Wave Lengths	1	1		•	1	•						1	•				•
Laser – Long Wave Lengths		1							•	•		1				•	•
LENS	•	1	•	•	•	•	•	•									
LISI	•	2		•	•		2	2									
Silk Screen	•	•	•	•	•	•	•	•	•	•		•	•	•		•	•
Stencil	•	•	•	•	•	•	•	•	•	•		•	•	•		•	
Thin Film Deposition	•	•	•	•	•	•	•	•	•	•			•	•			

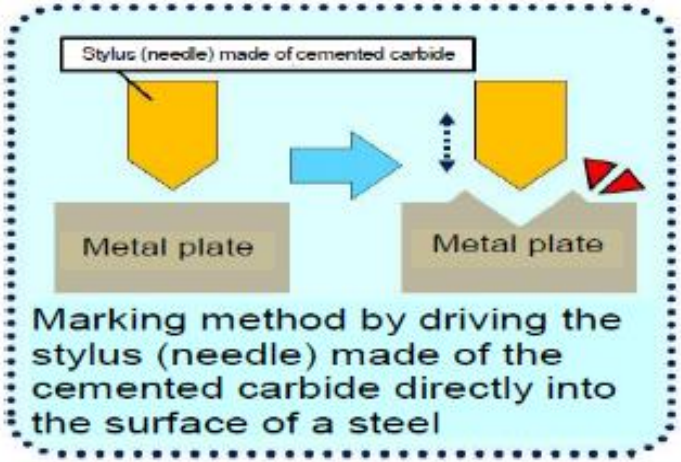
It is not supposed reprocessing use

4. ISO Guideline for DPM

Comparison of Marking Mechanisms between Laser and Dot Pin Methods



Marking Mechanism of Laser Method

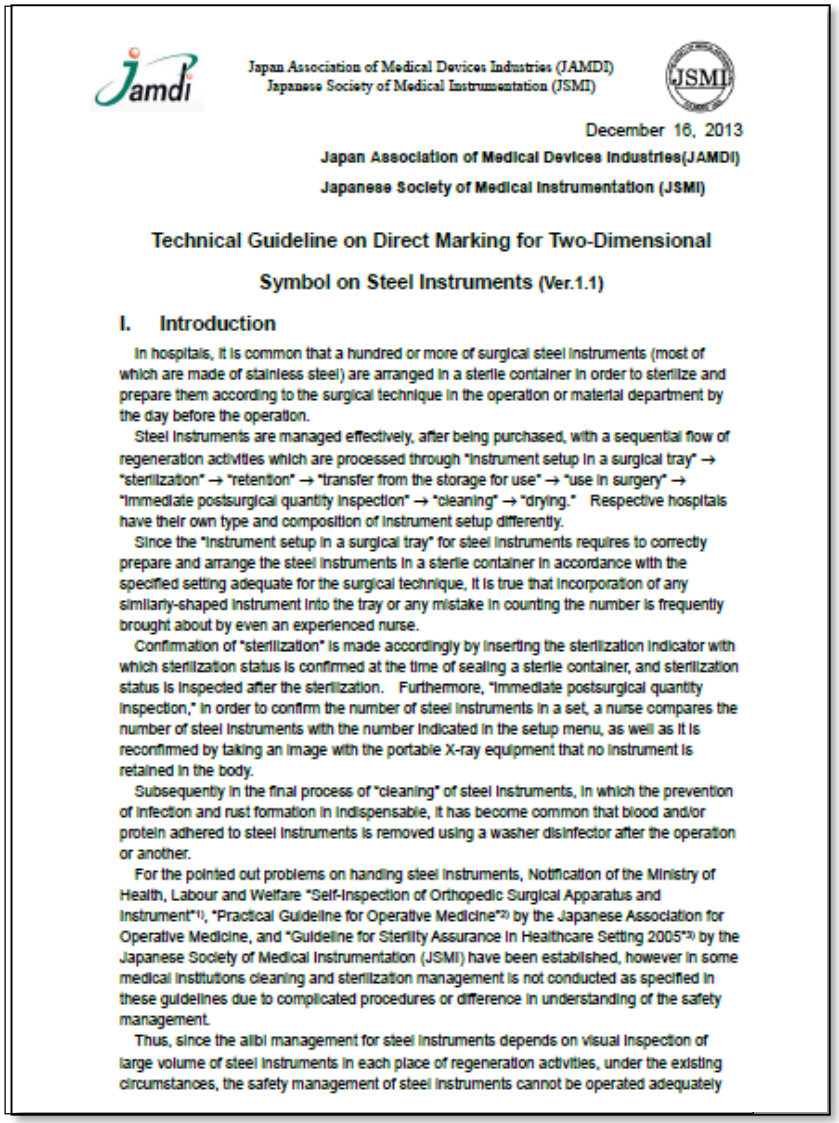


Marking Mechanism of Dot Pin Method

ML-7111A
LD-excitation YVO4
by MT corp.

METAZA
MPX-90M
by R corp.

5. Contents of The Technical Guideline



Japan Association of Medical Devices Industries (JAMDI)
Japanese Society of Medical Instrumentation (JSMI)

December 16, 2013

Japan Association of Medical Devices Industries(JAMDI)

Japanese Society of Medical Instrumentation (JSMI)

Technical Guideline on Direct Marking for Two-Dimensional Symbol on Steel Instruments (Ver.1.1)

I. Introduction

In hospitals, it is common that a hundred or more of surgical steel instruments (most of which are made of stainless steel) are arranged in a sterile container in order to sterilize and prepare them according to the surgical technique in the operation or material department by the day before the operation.

Steel instruments are managed effectively, after being purchased, with a sequential flow of regeneration activities which are processed through "instrument setup in a surgical tray" → "sterilization" → "retention" → "transfer from the storage for use" → "use in surgery" → "immediate postsurgical quantity inspection" → "cleaning" → "drying." Respective hospitals have their own type and composition of instrument setup differently.

Since the "instrument setup in a surgical tray" for steel instruments requires to correctly prepare and arrange the steel instruments in a sterile container in accordance with the specified setting adequate for the surgical technique, it is true that incorporation of any similarly-shaped instrument into the tray or any mistake in counting the number is frequently brought about by even an experienced nurse.

Confirmation of "sterilization" is made accordingly by inserting the sterilization indicator with which sterilization status is confirmed at the time of sealing a sterile container, and sterilization status is inspected after the sterilization. Furthermore, "immediate postsurgical quantity inspection," in order to confirm the number of steel instruments in a set, a nurse compares the number of steel instruments with the number indicated in the setup menu, as well as it is reconfirmed by taking an image with the portable X-ray equipment that no instrument is retained in the body.

Subsequently in the final process of "cleaning" of steel instruments, in which the prevention of infection and rust formation in indispensable, it has become common that blood and/or protein adhered to steel instruments is removed using a washer disinfector after the operation or another.

For the pointed out problems on handing steel instruments, Notification of the Ministry of Health, Labour and Welfare "Self-Inspection of Orthopedic Surgical Apparatus and Instrument"[1], "Practical Guideline for Operative Medicine"[2] by the Japanese Association for Operative Medicine, and "Guideline for Sterility Assurance in Healthcare Setting 2005"[3] by the Japanese Society of Medical Instrumentation (JSMI) have been established, however in some medical institutions cleaning and sterilization management is not conducted as specified in these guidelines due to complicated procedures or difference in understanding of the safety management.

Thus, since the alibi management for steel instruments depends on visual inspection of large volume of steel instruments in each place of regeneration activities, under the existing circumstances, the safety management of steel instruments cannot be operated adequately

CONTENTS

6. Remarkable points of The Technical Guideline

- Describe the guideline based on GS1 standard.

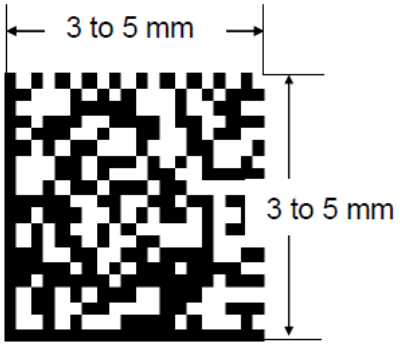
- Describe the Direct marking method for many years use of the surgical instruments.

- Define the minimum depth of the marking
- Recommend optimized shape and size of GS1 DataMatrix
- Define the marking method to withstand sterilization to be repeated for multiple use

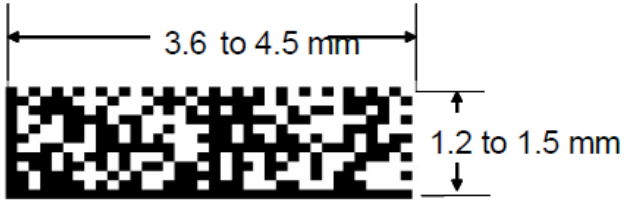
6. Remarkable points of The Technical Guideline

An Example of the technical recommendation
Size Specifications for Two-dimensional Symbol

- Recommend the two-dimensional symbols in 3 to 5 mm square for GS1 DataMatrix 18X18 cells, consisting of a total of 26 digits: AI (01), 2 digits + GTIN, 14 digits; AI (21), 2



a) When 3 mm or more square of marking area is assured on the steel instrument

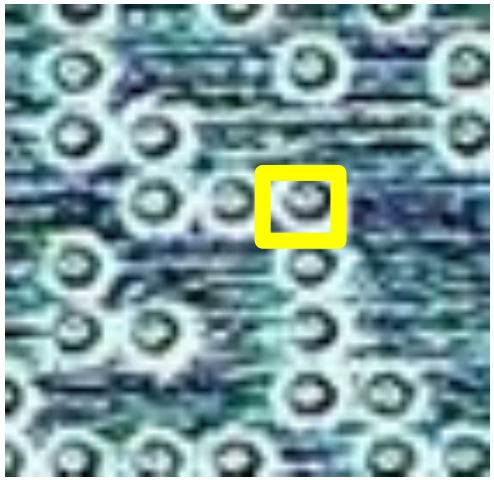


b) When approx. 3 mm square of marking area cannot be assured on the steel instrument due to its rod

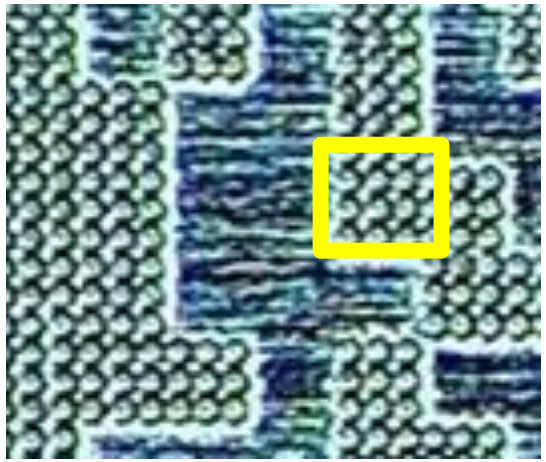
6. Remarkable points of The Technical Guideline

An Example of the technical recommendation
One Dot Per Cell to n-by-n Dots

- In the conventional two-dimensional symbol indication, one cell consists of one dot.
- This guideline, however, recommends printing with n-by-n dots per one cell, because a precise marking technique has been established.



a) One dot per cell



b) n-by-n dots per cell

7. DPM Implementation in Hospital

Five hospitals implemented DPM utilized the Technical Guideline

NTT Medical Center Tokyo

Tokyo Medical and Dental University Hospital

Saitama Prefectural Cancer Center

University of Fukui Hospital

Fukushima Medical University Hospital

7. DPM Implementation in Hospital

NTT Medical Center Tokyo: Overview

Figures	
Beds	665
Outpatients per day	Approx. 2,117
Operating rooms	10
Operations per year	Approx. 5,518
Nurses in Ope. Dept.	21
Staff in supply room	10
Washers	3
Sterilizers	6
Surgical containers	Approx. 189
Steel instruments (DPM)	**Approx. 20,000**

7. DPM Implementation in Hospital

Tokyo Medical and Dental University Hospital: Overview

Figures	
Beds	763
Outpatients per day	Approx. 2,300
Operating rooms	15
Operations per year	Approx. 7,700
Nurses in Ope. Dept.	65
Staff in supply room	16
Washers	6
Sterilizers	8
Surgical containers	Approx. 550
Steel instruments (DPM)	**Approx. 31,000**

7. DPM Implementation in Hospital

Saitama Prefectural Cancer Center: Overview

Figures	
Beds	503
Outpatients per day	Approx. 2,300
Operating rooms	12
Operations per year	Approx. 3,000
Nurses in Ope. Dept.	20
Staff in supply room	10
Washers	4
Sterilizers	5
Surgical containers and packs	Approx. 120
Steel instruments (DPM)	**Approx. 20,000**

7. DPM Implementation in Hospital

University of Fukui Hospital: Overview

Figures	
Beds	600
Outpatients per day	Approx. 1,199
Operating rooms	12
Operations per year	Approx. 5,400
Steel instruments (DPM)	**Approx. 1,500**

7. DPM Implementation in Hospital

Fukushima Medical University Hospital: Overview

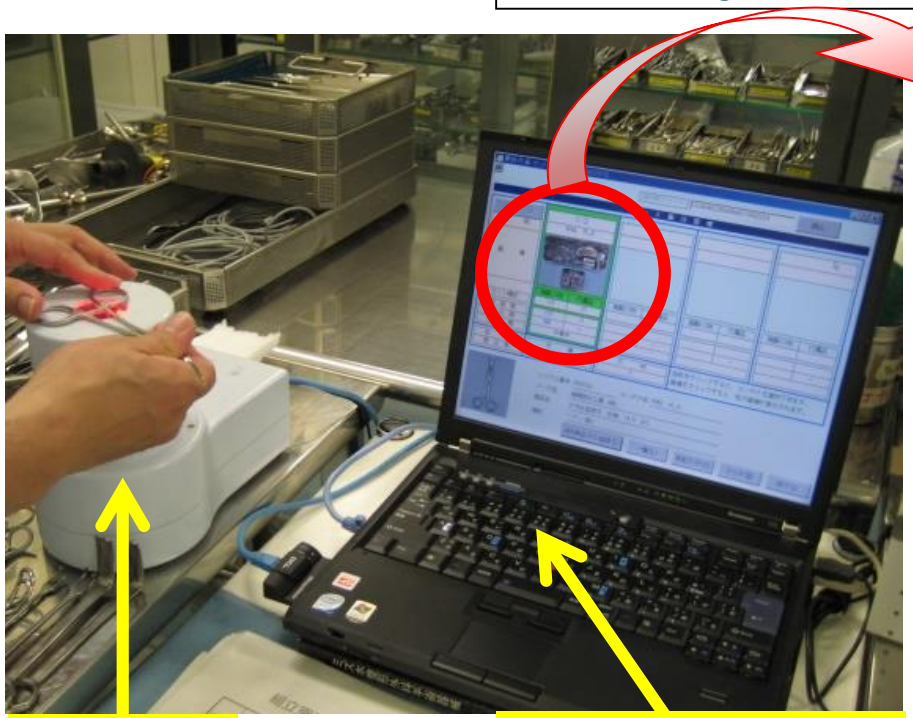
Figures	
Beds	778
Outpatients per day	Approx. 1,500
Operating rooms	12
Operations per year	Approx. 6,000
Nurses in Ope. Dept.	40
Staff in supply room	16
Washers	7
Sterilizers	11
Surgical containers and packs	Approx. 1,400
Steel instruments (DPM)	**Approx. 35,000**

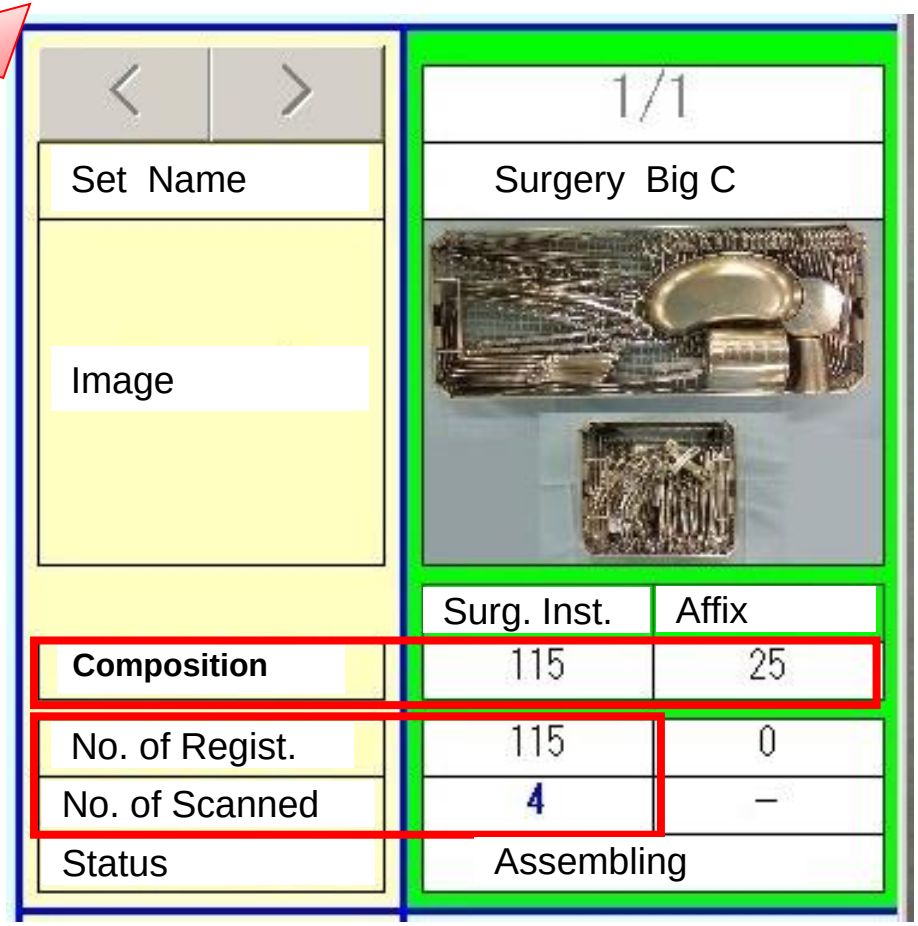
7. DPM Implementation in Hospital

Application Example in NTT Medical Center Tokyo

for preventing assembly error

Showing the set to be assembled





7. DPM Implementation in Hospital

Data structure of GIAI

- **Global Individual Asset Identifier(GIAI) : AI 8004**

Format of the Element String					
Application Identifier	Global Individual Asset Identifier (GIAI)				
	GS1 Company Prefix		Individual Asset Reference		
8 0 0 4	N_1 ...	N_j	X_{j+1} ...	variable length	$X_{j\ (j<=30)}$

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- **AI 8004 GS1 Company Prefix + Individual Asset Reference Number**

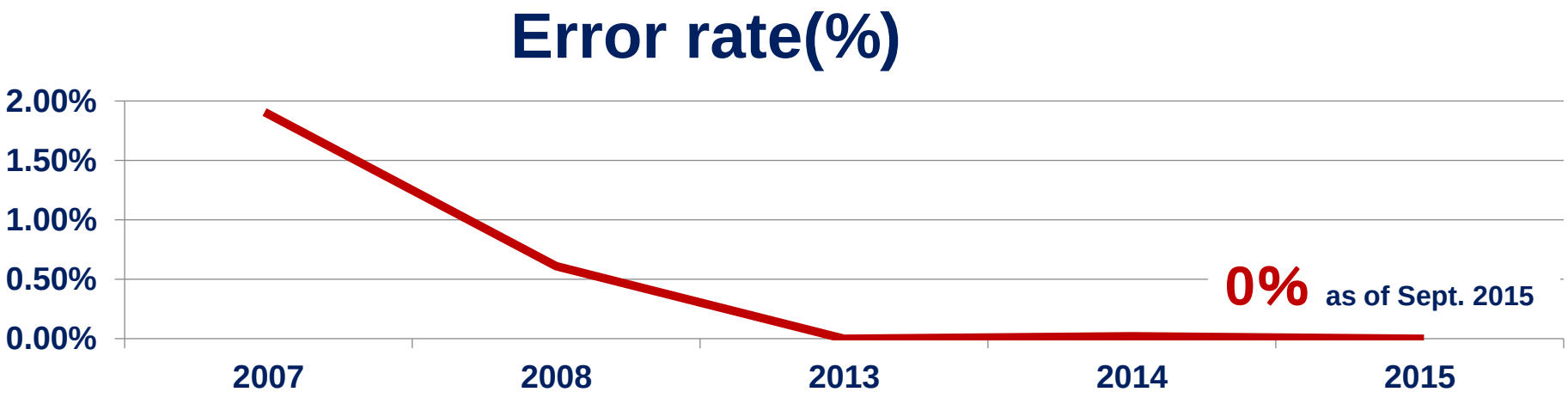
- **The GIAI format of NTT Medical Center Tokyo:**
  - **AI : 8004 (4 digits)**
  - **GS1 Company Prefix : 456238706 (9 digits)**
  - **Individual Asset Reference Number : use 13 digits**

7. DPM Implementation in Hospital

Benefit 1

Operational Errors in the CSSD

Data Sauce : NTT Medical Center Tokyo



Data on reduction of operational errors by using GS1 DataMatrix for identifying surgical instruments

	Apr. 07 - Mar. 08	Apr. 08 –Mar. 09	Apr. 13 – Mar. 14	Apr. 14 – Mar. 15	Apr. 15 – Sept. 15
Number of Errors	108	34	0	1	0
Number of surgeries	5, 712	5, 585	5, 539	5, 478	2, 677
Incidence of errors	1.89%	0.61%	0	0.02%	0

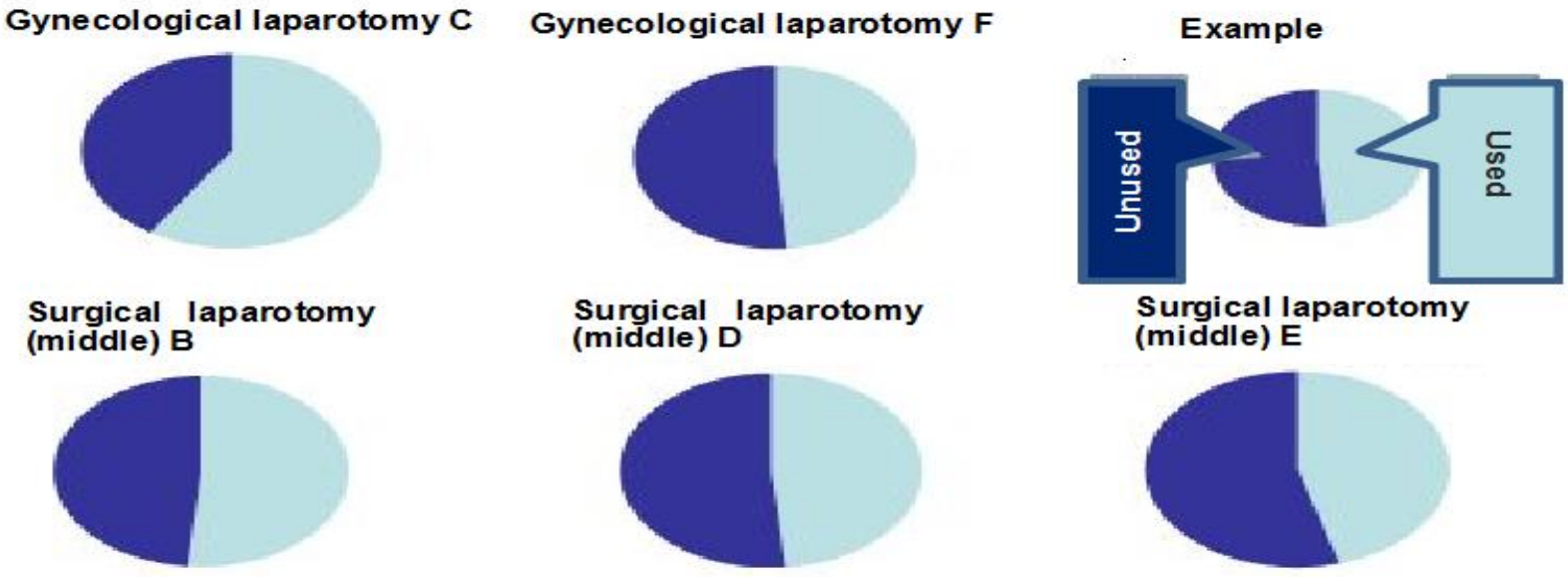
7. DPM Implementation in Hospital

Benefit 2

Easy to find used/unused surgical instruments

Data Sauce : NTT Medical Center Tokyo

- About 40-55% of surgical instruments in a container remained unused.
- These data revealed that hospital assets had become **dead storage**.



8. Conclusion

- **We developed a Technical Guideline on Direct Marking for Two-Dimensional Symbol on Steel Instruments**

- **Benefits of the direct marking utilized this technical guideline are confirmed by hospital implementation**

- **We are convinced that the technical specifications in this “technical guideline” will help Direct Marking indication required by other regulations such as IMDRF UDI rules, FDA UDI rules.**

Thank you

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The Global Language of Business

UDI and Direct Part Marking Implementation

28th Global GS1 Healthcare Conference

October 20, 2015

Akio Murata

To conclude… audience questions…