Unique Device Identification: Building Block for the National Evaluation System

Clearly identifying a device as part of real-world evidence

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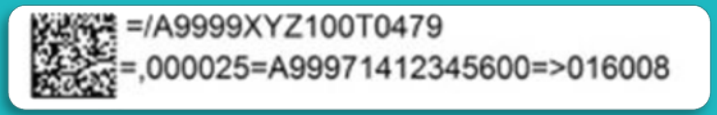
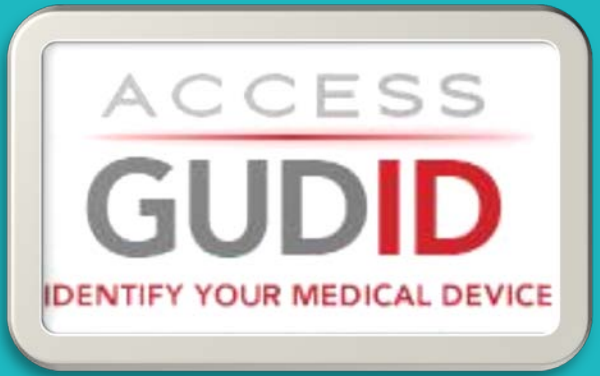
Senior Advisor for UDI Adoption

What is UDI?

- Regulation
- Requirements on Label
- Submission to Global Unique Device Identification Database (GUDID)



accessgudid.nlm.nih.gov



2010 What is UDI ?

Medical Procedures [1]		New Cars Sold [2]	
1,000,000	Cardiac Catheterizations	1,230,500	Hondas
719,000	Total Knee Arthroplasties	908,600	Nissans
332,000	Total Hip Replacements	358,500	Volkswagens

[1] Source: CDC/NCHS National Hospital Discharge Survey, 2010

[2] Source: WardsAuto - 2010 New Vehicle Sales

2007 What is UDI?

Unique Device Identification System

"The Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number."

-added to the FD&C Act by section 226 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), Public Law 110-85.

Congressional Authorization

2016 What is UDI?

WWW.FDA.GOV/UDI

UDI = Device Identifier (DI) + Production Identifiers (PI)

Unique Device Identifier (**UDI**) – *globally unique in accordance with ISO standards*

Device Identifier (**DI**) - *mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device*

Production Identifier (**PI**)—*a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:*

- lot or batch within which a device was manufactured;
- serial number of a specific device;
- expiration date of a specific device;
- manufacturing date
- distinct identification code

What is UDI?

1st requirement …*the label of every medical device shall bear a unique device identifier (UDI)…*

2nd requirement…*the labeler of a device must provide the information required … for each model or version required to bear a unique device identifier (UDI)…*

520,000+

accessgudid.nlm.nih.gov

Why is Unique Device Identification Important?

What you see and hear depends a good deal on where you are standing; it also depends on what kind of a person you are.

~C.S. Lewis

The Washington Post

By tracking device IDs, like the vehicle identification numbers on cars, regulators could spot patients across the country coming into an emergency room or developing infections after a procedure. *1/31/16*

Modern Healthcare

Experts hope the identifiers will help providers reduce costs with more efficient medical-supply management, and improve patient safety with better reporting and tracking of faulty products and adverse events. *9/25/15*

UDI is important to…

PATIENTS

Care Providers

Manufacturers

Healthcare supply chain / inventory management

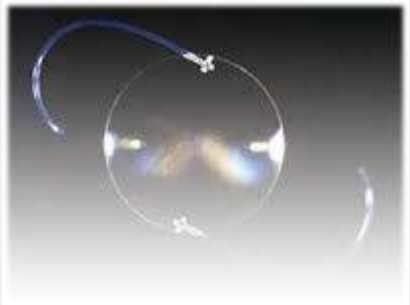
Researchers

Data Analysts

National Medical Device Evaluation System

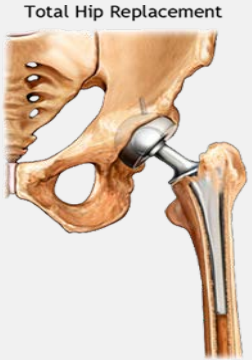
First Focus: Implants

IOL
2006

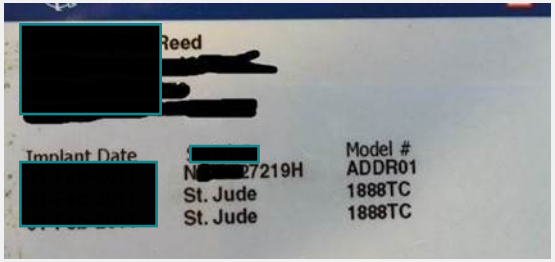


DRUG ELUTING STENT
2010

WALKER
2012



HIP
2008



PACEMAKER
2011

Patient Expectations

Adverse

I don't worry about my implants. My doctors take care of me and would let me know if e is a problem.

Recalls

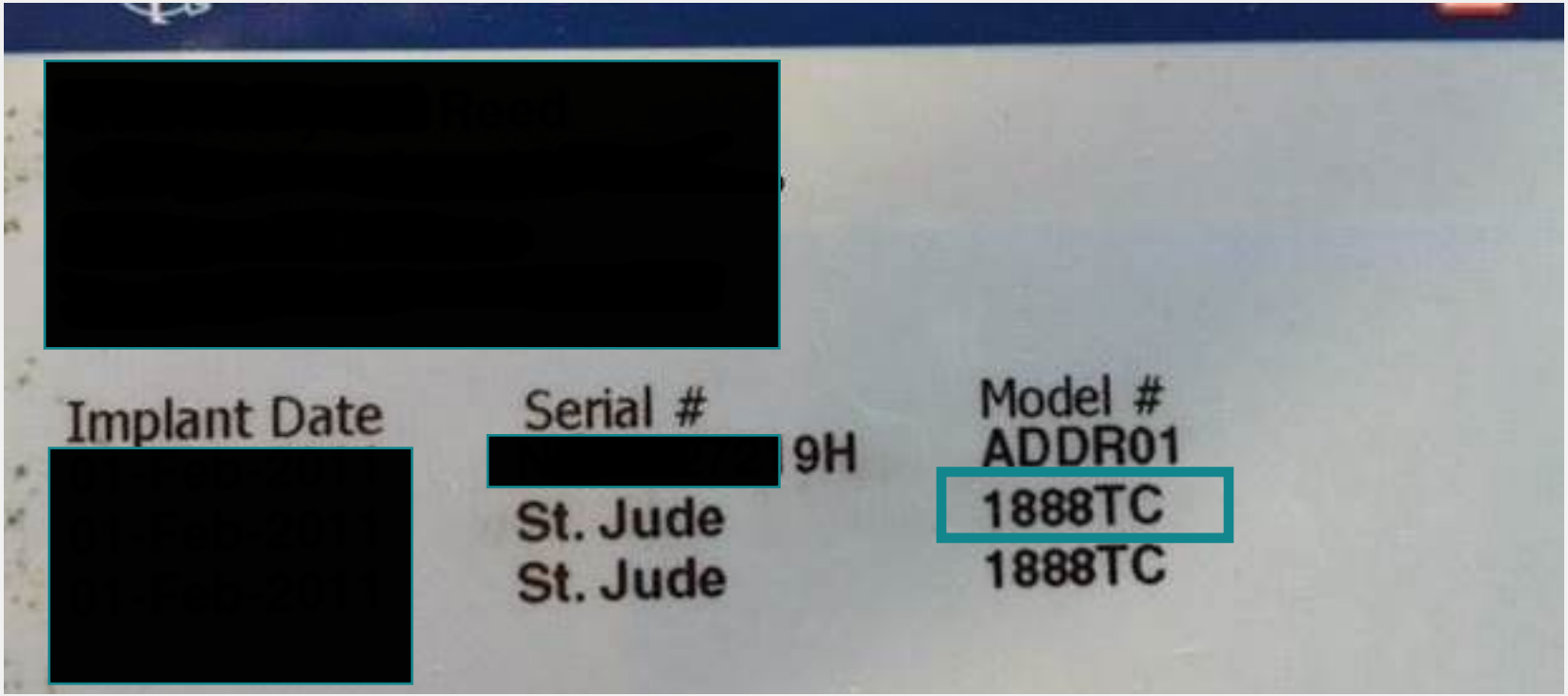
De

Evaluation Gap

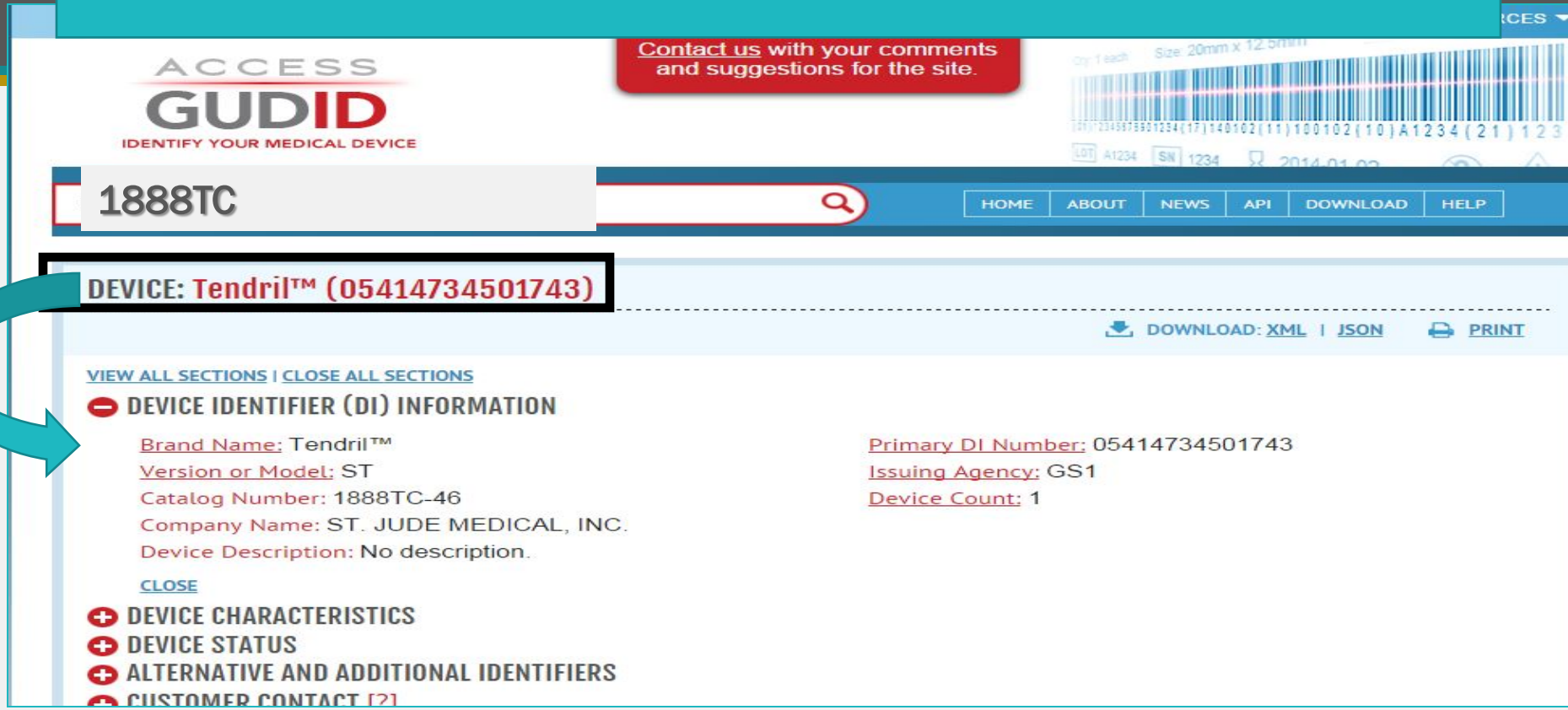
Registries

ns

Current Implant Information



Device Identifier =>Standard Data



Link Patient to Device Identifier

MR # 00000000000

Active Implantable Device List

DI Lot Serial Expiration Mfr Date DIC	Description (GMDN or SNOMED)	Company Name	Brand Name	Model	MRI Safe	Labeled as containing latex
05414734501743 Lot: 123456 Exp:12/31/2025	Endocardial pacing lead	St. Jude Medical Inc.	Tendril™	ST	Labeling does not contain MRI Safety Information	No

UDI is important to the….

National Medical Device Evaluation System

UDI is the Link between patient and device that can improve:

- Ability to detect and respond to safety issues – active and reported
- Efficiency to manage device recalls and remove harmful product
- Understanding of device characteristics to reduce medical errors
- Precision in studying devices in diverse populations and better understand how devices behave in the real world

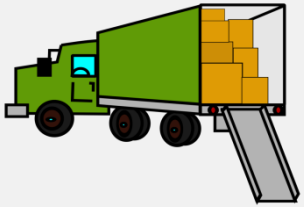
Developing a Learning UDI Community

How wonderful it is that nobody need wait a single moment before starting to improve the world. ***~Anne Frank***

Building a Community to Ensure UDI Adoption

FDA ⟷ Device Labelers

Data Analysts



Health Supply Chain

Patients Consumers

Care Providers

Healthcare Organizations

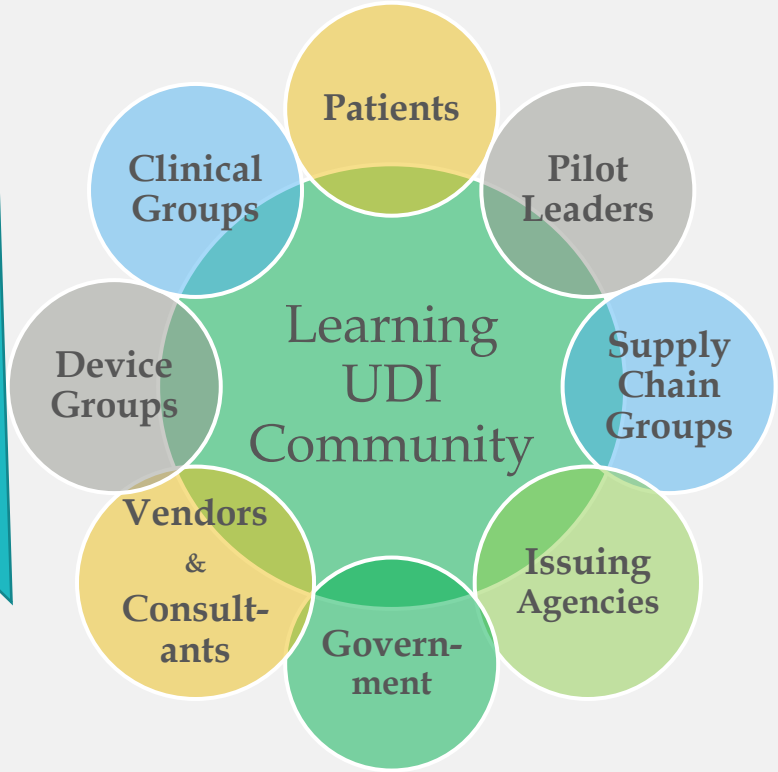
Researchers

Learn More at the UDI Roundtable

Implant ?
- Clinicians
- Manufacturers
- FDA

Device Type?
- GMDN
- UNSPSC

Unit of Use?
- Distributors
- Manufacturers
- Hospital Supply Chain



Thank you!