



BARTS  
BONE  JOINT  
HEALTH



Rectopexy & the search  
for devices



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# Aims of the surgical question

**Epidemiology of  
Rectal prolapse**

**Epidemiology of  
Rectopexy**

**Rectopexy (surgical)  
coding incl  
subtypes**

**Rectopexy  
(surgical)  
complications**

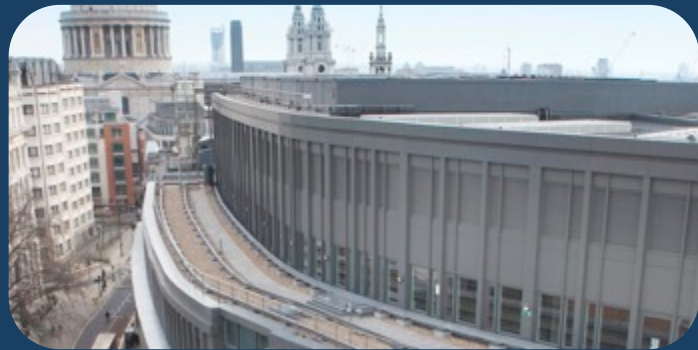
**Can we really  
identify device  
use?**

**Is the device data  
useful?**



# Studyathon as a Data Partner

5 hospitals across East London, UK = 2.6M patients, 15y horizon



## Specialist services

Cardiac/Cancer/Renal/  
Paediatrics



## Level 1 Trauma Centre

Ortho/ICU/Major trauma

Ortho:

100,000 patients per year

10,000 procedures



## QMUL University

Barts & the London  
Medical (& Dental)  
School



# Prolapse, Rectopexy & subtypes



Based upon phenotyping work pre-studyathon (props to Albert Prats Uribe & team!)

- ▣ Knowledge expert – identify prolapse, rectopexy incl those with and without device use
- ▣ Focus on OPCS -> SNOMED
- ▣ Outcome measures- complications 30d, 90d, 1y, 2y

-> CodelistGenerator; PatientProfiles; DrugUtilisation; IncidencePrevalence

-> +/- device identifier



# What happens in surgery?

From the OR to Oxford

General Comments:  
awaiting surgeons for teambrief (from trauma meeting); long combined teambrief  
operating table (traction); theatre HCA to collect patient

Implants RNJ RL Main

	Entry 1	Entry 2
Implant Description	LCP DHS PLATE 130, 4 HOLES	modular cathcart fracture head hip ball
Manufacturer	DEPUY SYNTHES	synthes
Product Number	498P700	D21091349
Serial Number	02.224.204S	1363-44-000
Quantity	1	1
Size	LCP DHS PLATE 130, 4 HOLES	44mm OD
Sterilisation Date		31/08/31
Expiry Date	01/12/31	
Surgeon has confirmed side and procedure?	Yes	Yes
Scrub nurse has read out the product information?	Yes	Yes
Scrub nurses has confirmed the size and side of implant?		Yes

Entry 4

Implant Description	c-stem AMT standard offset
Manufacturer	synthes
Product Number	D23084720
Serial Number	1570-04-070
Quantity	1
Size	size 1 12/14tape
Sterilisation Date	
Expiry Date	31/07/28
Surgeon has confirmed side and procedure?	Yes
Scrub nurse has read out the product information?	Yes
Scrub nurses has confirmed the size and side of implant?	Yes
Scrub nurses has confirmed the manufacturer of the	Yes



# ACCESS GUDID

IDENTIFY YOUR MEDICAL DEVICE



Enter Device Identifier, Name, or Company



## ABOUT AccessGUDID

The **Global Unique Device Identification Database (GUDID)** contains key device identification information submitted to the FDA about medical devices that have **Unique Device Identifiers (UDI)**.

The FDA is establishing the unique device identification system to adequately identify devices sold in the U.S.- from manufacturing through distribution to patient use. You can use AccessGUDID to search for specific medical devices or download all the GUDID data at once. AccessGUDID also offers RSS feeds and APIs to connect you directly to the data.

[MORE INFO](#)[ABOUT UDI](#)[ABOUT GUDID](#)

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Download the latest full releases and update files provided to the NLM by the FDA.

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[API Documentation](#)

Resources for application developers to get the most out of AccessGUDID.

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[RSS Documentation](#)

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ACCESS  
**GUDID**  
IDENTIFY YOUR MEDICAL DEVICE



1363-44-000

HOME ABOUT NEWS API DOWNLOAD HELP

SEARCH RESULTS FOR: **1363-44-000** (1 result)

EXPORT RESULTS


FILTERS

SORT BY

10 RESULTS PER PAGE

PAGE 1

- Company Name >
- Brand Name >
- GMDN Term Name >
- GMDN Term Status >
- FDA Product Code Name >
- FDA Product Code >
- Device Packaged As Sterile >
- Sterilization Prior To Use >
- Issuing Agency >
- Device Class >

[NA - 10603295032762](#)   
 MODULAR CATHCART FRACTURE HEAD HIP BALL 44mm OD +5mm  
**Company Name:** DEPUY ORTHOPAEDICS, **Version or Model:** 1363-44-000  
 INC.

< 1 >



ACCESS  
**GUDID**  
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1570-04-070

SEARCH RESULTS FOR: **1570-04-070** (1 result)

[EXPORT RESULTS](#)

Company Name	>	<a href="#">C-STEM - 10603295059592</a>
Brand Name	>	C-STEM AMT Cemented Stem Standard Offset SIZE 1 12/14 TAPER
GMDN Term Name	>	<b>Company Name:</b> DEPUY (IRELAND) <b>Version or Model:</b> 1570-04-070
GMDN Term Status	>	<input type="button" value="1"/>
FDA Product Code Name	>	
FDA Product Code	>	
Device Packaged As Sterile	>	
Sterilization Prior To Use	>	
Issuing Agency	>	
Device Class	>	





# Studyathon – Rectopexy - Devices

Finding the associated device



Equipment serial number	Equipment serial number	80511303	4594507	4231843	08/05/2018	NULL	32817	NULL	UPA31015
Equipment serial number	Equipment serial number	80572832	4604634	4231843	31/01/2018	NULL	32817	NULL	UPA31015
Equipment serial number	Equipment serial number	87243359	49306379	4231843	01/02/2018	NULL	32817	NULL	UPA31015
Equipment serial number	Equipment serial number	88835959	50655593	4231843	16/01/2019	NULL	32817	NULL	UPA31015
Equipment serial number	Equipment serial number	89117294	50890772	4231843	31/07/2019	NULL	32817	NULL	UPA31015



ACCESS  
**GUDID**  
IDENTIFY YOUR MEDICAL DEVICE



UPA31015

HOME ABOUT NEWS API DOWNLOAD HELP

SEARCH RESULTS FOR: **UPA31015** (1 result)

EXPORT RESULTS

FILTERS

SORT BY

10 RESULTS PER PAGE

PAGE 1

- Company Name >
- Brand Name >
- GMDN Term Name >
- GMDN Term Status >
- FDA Product Code Name >
- FDA Product Code >
- Device Packaged As >
- Sterile >

**ULTRAPRO ADVANCED - 10705031236998**



Macroporous Partially Absorbable Mesh

**Company Name:** Johnson & Johnson

**Version or Model:** UPA31015

International Inc.

< 1 >



# Device Progress

What did we achieve?

- ✧ Discovered specific implants in our cohorts
- ✧ Generated device specific cohort – future use
- ✧ 1,200,000 implantable device serial numbers found in Barts Data during Studyathon
- ✧ Identification of devices in other UK Node partners



# Learning Points

- ▣ Consistency of data entry
- ▣ Formats of UDI vary internationally (but predictable)
- ▣ Understanding UDI format in our data
- ▣ Developing infrastructure to analyse data related to these devices



# What's next?

Taking the work forward

01

Identify approved devices

02

Re-format data within our CDM for devices

03

Check consistency of data entry

04

Generate device specific cohorts

05

Develop longitudinal surveillance of specific devices

06

Build infrastructure and capacity + local community



# Big Thanks to Collaborators

- ▣ Lancashire Teaching Hospitals NHS trust
- ▣ CPRD
- ▣ University of Dundee
- ▣ University of Oxford





Thank you

@jennifercelane  
@usamarahman  
@xlgriffin





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E [boneandjointhealth@qmul.ac.uk](mailto:boneandjointhealth@qmul.ac.uk)



@bartsbonejoint



@boneandjointhealth



@...





Issuing Agency/Entity	Qualifier	Identifier	Data type	Human Readable Field Size	Database Field Size
GS1	(01)	DI (GTIN)	Numeric	18 (incl. identifier + data delimiter)	. 14 digits . digit characters '0' to '9'
GS1	(11)	Manufacturing/ Production Date	numeric [YYMMDD]	10 (incl. identifier + data delimiter)	. 6 digits . digit characters '0' to '9'
GS1	(17)	Expiration Date	numeric [YYMMDD]	10 (incl. identifier + data delimiter)	. 6 digits . digit characters '0' to '9'
GS1	(10)	Batch/Lot Number	alphanumeric	24 (max) (incl. identifier + data delimiter)	. 20 (max) . GS1 AI encodable character set 82*
GS1	(21)	Serial Number	alphanumeric	24 (max) (incl. identifier + data delimiter)	. 20 (max) . GS1 AI encodable character set 82*
<i>GS1</i>		<i>Maximum Base UDI</i>	<i>alphanumeric</i>	86	<b>66</b>
<b>ex: (01)09506000117843(11)141231(17)201231(10)1234AB(21)5678CD</b>					

\* See Table 7.11.1 of the GS1 General Specifications:  
[https://www.gs1.org/docs/barcodes/GS1\\_General\\_Specifications.pdf](https://www.gs1.org/docs/barcodes/GS1_General_Specifications.pdf)

