FDA, Patient Engagement Advisory Committee Meeting, Medical Device Recalls, 10-6-21

Patients should be informed when their medical device is recalled. I found the recall notice for my implant on the internet the year after the device was recalled and after the failed device had done substantial damage. The device ground out my bone like sandpaper and caused the bone in the area of the device stem to enlarge and thin.

We live in an age of unprecedented accountability. My goal is to see that procedures are put in place to inform patients of the recall of their medical device. This is a very actionable and achievable goal and the technology already exists. Informing patients has been accomplished in other countries as well as in the private sector in the United States. This needs to be a priority.

I have worked with the ethics and bioethics departments at a Chicago University. Both departments informed me that ethics is the study of the standards of right and wrong and that there are not two sides to this issue. Patients should be informed when their medical device is recalled.

- Patients have a right to know that the medical device implanted in their body has been recalled, why it has been recalled and the risks of leaving the implant in versus taking it out.
- Patients sustain serious damage because they do not know that their medical device has been recalled and that they should seek medical help.
- Patients suffer physically and emotionally when information and treatment are withheld.
- There is potential injury to the standing of the FDA and the medical profession.

My implant replaced the broken radial head in my elbow. The failed implant did too much damage to allow me to have a second implant. The radial head makes up 2 of the 3 joints in the elbow. I am now missing two thirds of my elbow.

The delay increased the likelihood of a greater number of complications, more severe complications and the faster onset of complications. The damage is painful, debilitating, permanent and degenerative and has drastically impacted my quality of life. Surgeries to manage these complications are likely.

I saw my treating surgeon two times after the recall. I presented with symptoms of a loose radial head implant during those two visits. I was not informed of the recall.

Despite my symptoms of a loose implant and the recall notice which stated that the implant could come loose, my treating surgeon informed me that he thought my recovery had run its course.

Five and a half weeks later I saw a different doctor who took X-rays. I was told that the implant had been loosening for at least a year. I still did not know about the recall.

I then saw 3 specialists who explained that my symptoms were associated with a loose implant. All recommended surgery to remove the implant. None informed me of the recall.

When I was asked what the name of my implant was so that the instructions to remove it could be obtained, I looked the implant up on the internet and was stunned to find out that it had been recalled.

My beliefs regarding the safety I expected the FDA and medical profession to provide were shattered. The damage done to my body could have been prevented.

As you will see in the information in this pdf, doctors are not required to tell patients that their medical device has been recalled.

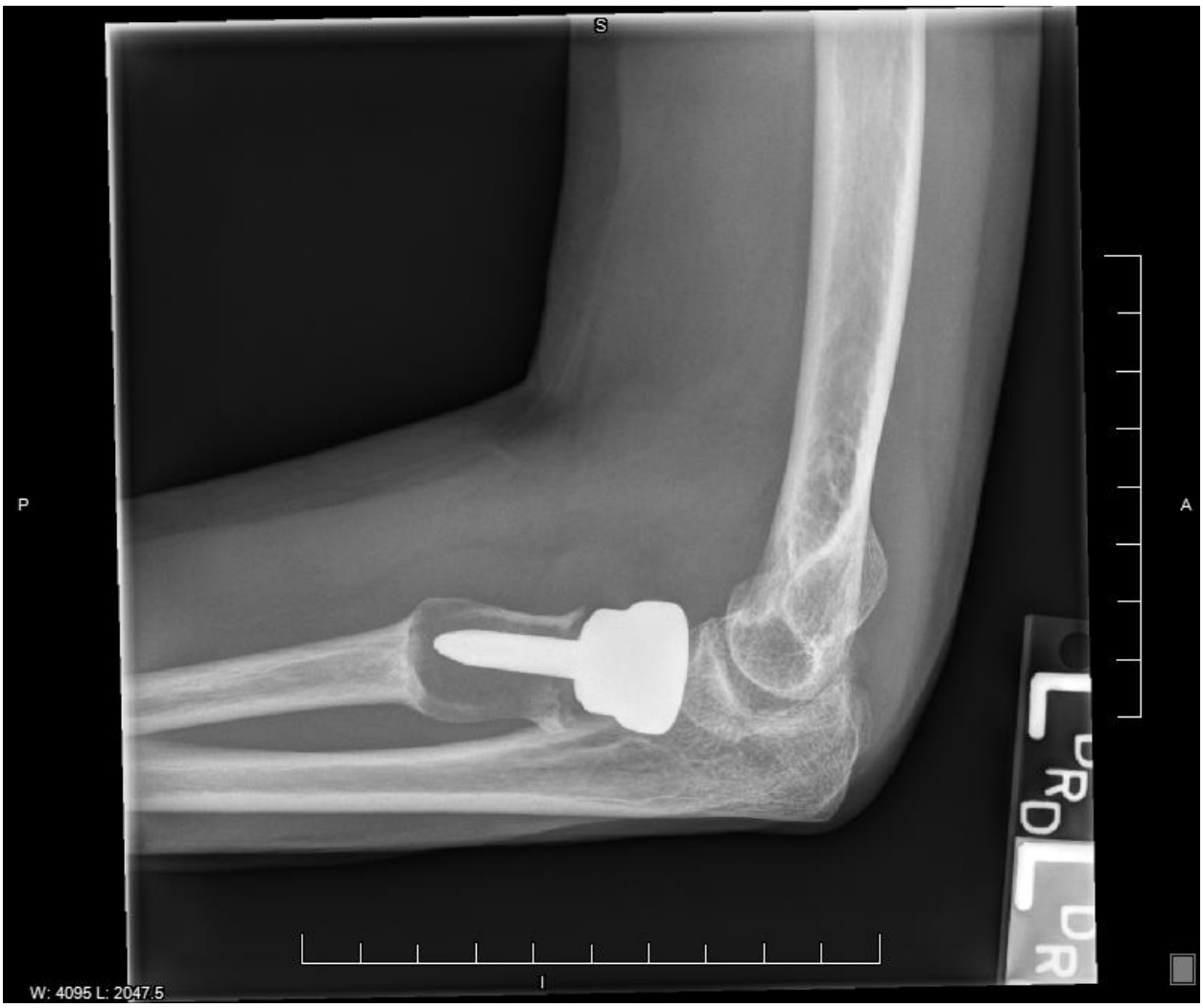
Please note: my treating surgeon acknowledged that I had not been discharged from his care when he learned of the recall. One of the 3 specialists that I saw acknowledged that he knew at the time of my visit with him that the device had been recalled.

I have considerable information and insights to share. You may obtain my contact information through Letise Williams, Designated Federal Officer letise.williams@fda.hhs.gov 301–796–8398.

Thank you. Mary Baude

Included in this pdf:

- X-ray showing the damage to my arm.
- Possible Procedures to Inform Patients. *(2 pages)*
- Hospital "sticker sheet" from my surgery. *(1 page)*
- Page from FDA Guidance for Industry regarding recalls and indicating that the FDA does not require industry to follow FDA recommendations. *(1 page)*
- Manufacturer Recall Strategy for my implant showing the FDA recommendation that the depth of the recall should be to the consumer/user level. The manufacturer's recommended depth of recall is shown here as the hospital level. *(3 pages)*
- Manufacturer Urgent Notice for my implant to their customers, hospitals and facilities, showing the manufacturer did not follow FDA recommendation that the depth of recall be to the consumer/user level. *(3 pages)*
- FDA recall notice for my implant showing the depth of recall is to the hospital level and not to the FDA recommended consumer/user level. Action to be taken- facilities asked to remove and return any product. *(2 pages)*
- United Kingdom recall notice for my implant - action to be taken- notify patients. The required standard of care for patients is also included. *(3 pages)*
- FDA recall notice for a Tornier implant showing that doctors were notified but that the doctors were not asked to notify patients. *(1 page)*
- FDA page regarding GUDID which states it does not contain any information about patients or anyone who uses the device. *(1 page)*
- GUDID information on my implant. Does not state the implant was recalled. *(2 pages)*
- Summary (1 page)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Possible Procedures to Notify Patients

The UDI is not needed in order to notify patients that their implant has been recalled. Hospitals have all of the information needed, even without the UDI, to notify patients of a recall.

Included in this pdf, please find:

- The sticker sheet created during my surgery. I have removed my identifying information.
- Links to current databases that could be used as templates.

The lower left of the implant sticker sheet indicates that this is the sheet that the hospital has designated to be used to mount the stickers from the implant packages. The stickers are mounted at the time of the surgery.

Included on the sticker sheet:

- The manufacturer, Synthes
- The **REF** number which is the part number of the device. It is the catalog number.
- The lot number is also shown.
- There is also a description of the device.
- My name, which I have removed, is on the sticker sheet. The sticker sheet is part of the hospital record of my surgery.

This is sufficient information for the hospital to link me with the implant. There are also other ways for the hospital to obtain the above information- package barcodes, UDI.

The manufacturer sent the URGENT NOTICE to the hospital, their customer. The hospital had purchased the medical device.

The URGENT NOTICE provides the hospital with the same information as is on the sticker sheet:

- The manufacturer, Synthes
- The **REF** number which is the part number of the device. It is the catalog number.
- The lot number, in this case, the entire system, all lots, were removed globally
- There is also a description of the device.

The hospital uses the information in the URGENT NOTICE to: **1.** determine if they have any of the product still on their shelves. **2.** If so, the hospital returns the product to the manufacturer.

In the same way, the hospital can use this information to 1. determine if there were any patients implanted with the device. 2. If so, the hospital can inform the patient of the recall.

Other databases

There are many databases that hospitals could use as a template to notify patients that their implant has been recalled.

American Academy of Orthopaedic Surgeons

Below is the link for The AAOS American Joint Replacement Registry,

https://www.aaos.org/registries/registry-program/american-joint-replacement-registry/

The second section**, AJRR Data Elements Collected**, includes patient information, hospital, surgeon and implant information. Note the UDI is not included or necessary.

The AAOS does not notify patients. Their registry is used as a research tool and resource. Their database appears to have the ability to be modified somewhat and used to notify patients.

Scrolling down near the bottom of their website, please see that there are also state registries.

Kaiser

The Kaiser Family Foundation works to improve healthcare.

Below is the link for their implant registry, *The Kaiser Permanente Implant Registries*. **Under "goals", you can see that they notify the patients in their system that their implant has been recalled.**

https://national-implantregistries.kaiserpermanente.org/about

Below is a link for the Kaiser Family Foundation.

https://www.kff.org/more-about-the-kaiser-family-foundation/

Wikipedia

Wikipedia is actually a good resource in this case. Below is the Wikipedia link to Joint Replacement Registry. It gives links to 31 worldwide registries. You can use the links to get an idea, an overview of databases that are out there.

https://en.wikipedia.org/wiki/Joint_replacement_registry

9/30/15

Left ORIF elbow C

1

ArthroCare

Disposable Kit
For 1.8mm Q-Fix™ Implant

REF 25-1810
LOT 1097977
2018-02

2

ArthroCare

1.8mm Q-Fix™ Implant
Blue Co-Braid

REF 25-1800
LOT 1108006
2018-05

ET FOR IMPLANT STICKERS

3

REF 09.402.222S
22MM COCR RADIAL HEAD
2MM HT EXTENSION/14.5MM-STER
Mat Co-28Cr-6Mo

LOT 7608124
expiration
07/2019
SYNTHES

4

REF 04.402.007S
7MM TI STRAIGHT RADIAL STEM
26MM-STERILE
Mat Ti-6Al-7Nb

LOT 7654215
expiration
09/2019
SYNTHES

MOUNT SHEET FOR IMPLANT STICKERS

From ORA / Office of Enforcement Division of Compliance Management & operations

Guidance for Industry: Product Recalls, Including Removals and Corrections

This guidance document is intended to provide guidance and instructions to FDA regulated industry for obtaining information to help fulfill the Agency's plans regarding product recalls. It represents the agency's current thinking on product recalls. This guidance does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. To discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance. This guidance is available electronically to the public.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs

Office of Enforcement
Division of Compliance Management and Operations
10903 New Hampshire Avenue
WO32 - RM4367
Silver Spring, MD 20993
(301) 796-8200

Date Issued: 11/3/03

INTRODUCTION:

This guidance is intended to assist those members of industry regulated by the Food and Drug Administration (FDA) in handling all aspects of a product recall, including all corrections and removals. The guidance includes a checklist of documentation and information that FDA utilizes to evaluate, classify, monitor and audit product recalls. Various statutory provisions and regulations, described below, authorize FDA to require recalls of certain products in particular circumstances. Additionally, Subpart C of Part 7 of FDA regulations (21 CFR 7.40-59) provides general guidance for the voluntary recall of products, including those recalls initiated by a firm on its own and at FDA's request. This guidance provides more specific recommendations and applies to both mandatory and voluntary recalls of all FDA-regulated products (i.e. food, including animal feed; drugs, including animal drugs; medical and radiological devices; cosmetics; human biological products including blood; and human tissue.)

This is a level 2 guidance document published for immediate implementation in accordance with FDA's good guidance practices (21 CFR 10.115). This guidance sets forth the agency's existing practices in the handling of recalls. Interested parties may submit comments on this guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

Guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Recall Details

Event Information

Recall Event ID 76182 **EON ID**

Recall Number(s) Z-1124-2017
District Philadelphia District Office **Coordinator** Dellarese L Herbert
Firm Awareness Date 12/15/2016 **District Awareness Date** 12/29/2016
Center (Int) Center for Devices & Radiological Health **Coordinator** Sandra Segar
Recalling Firm FEI 3008812560 **Name (Int)** Synthes (USA) Products LLC
Manufacturer FEI 3008812560 **Name (Int)** Synthes (USA) Products LLC
Responsible Firm FEI 3008812560 **Name** Synthes (USA) Products LLC
Public Reason for Recall There is the possibility that the radial stem may loosen post-operatively at the stem bone interface.
Edit Mode Viewable **Recall Status (Int)** Terminated
Voluntary/Mandated (Int) Firm Initiated **Date (Int)** 12/29/2016
Firm Recommended Recall Depth Hospitals **Date Distribution Chain Notified** 12/29/2016
Recall Initiation Date (Int) 12/29/2016 **Firm Initial Notification** Letter
Determination Date **Center Coordinator Assigned Date** 02/02/2017
Classification Date 02/02/2017
FDA Sample Number N/A
Complete Reason for Recall There is a possibility that the radial stem may loosen post-operatively at the stem bone interface. The Radial Stem is subject to the recall; however, the additional products within the Synthes Radial Head Prosthesis System are being withdrawn via a Market Withdrawal.
Root Cause Under Investigation by firm
Root Cause Narrative Under Investigation. Procedures not adequately defined: It was determined that the reason the Radial Head Prosthesis stems were recalled was due to a design issue. This issue was able to get into the field at the initial launch due to inadequate design control procedures. Specifically this revision of the procedure did not specifically state that VOC should exist, nor explicitly state that Lifetime/Reliability should be considered to describe the performance requirements of the device over time, nor explicitly state that a Formative Usability Lab should be performed to assess how the device could unintentionally misused in any section.
Center Comments
Type Of Injury None.
Quantity Manufactured (b) (4)
Quantity Distributed (Int) 50,311 units
Number of Domestic Consignees (b) (4)
Number of Foreign Consignees (b)
Distributed From 02/09/2012 **To** 12/19/2016
Distribution Pattern (Int) United States Nationwide Distribution.
Manufactured From 02/14/2012 **To** 12/02/2016
Public Summary of Recall Strategy (Int) An Urgent Notice was mailed to consignees explaining the reason for the recall. Customers were asked to immediately review their inventories for the affected product and complete and return the Verification form that was included with the notification and return any of the affected product that was found.
Recall Strategy An Urgent Notice was mailed to consignees explaining the reason for the recall. Customers were asked to immediately review their inventories for the affected product and complete and return the Verification form that was included with the notification and return any of the affected product that was found.
Effectiveness Check Level A **Percent** 100
Audit Check Level D **Percent** 2
Audit/Effectiveness Check Modification
RAC Assignment Date Issued 02/03/2017
RAC Assignment Date Completed 03/15/2017
District RAC Assignment Needed? Yes
District Justification for No Audit Check
District Recommendation for No Audit Check Comments
Center Concur with District RAC Recommendation
Center RAC Assignment Needed?
Center Justification for No Audit Check
Center Recommendation Justification Comments

Center Entering Recall	
What Consumers Should Do (Int)	
Expanded Comments for What Consumers Should Do (Int)	
Firm Press Issued (Int)	URL (Int)
State Press Issued (Int)	URL (Int)
FDA Press Issued (Int)	URL (Int)
Additional Medical Product Information (Int)	URL (Int)

Consignee Details

List of Domestic and/or Foreign Consignees, addresses or commer (b) (4) (b) (4)

(b) (4)

Consignees	Approx. Number	Consignees	Approx. Number
Distributor	0	Repacker/Relabeler	0
Retailer	0	Direct Accounts	0
Institution	0	Veterans Administration	(b)(4)
Medical Facility	(b) (4)	Department of Defense	0
Internet Sales	0	Manufacturer	0
Physician	0	USDA	0
Consumer/Patient	0	Other	(b) (4)

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Summary/Termination Information

Quantity Recovered/Number of Units Corrected	A total of 1,359 was in inventory at the time of recall, 19,259 units were returned by consignees and 372 is on legal hold = 20,990 units.
Product Disposition	Returned product was destroyed in December 2017 or quarantined (372 units) as part of Johnson & Johnson's legal hold process. Certificate of Destruction, Scrap log and photographs were provided as evidence.
Number of Consignees Responding to Notification	Out of (b) (4) domestic consignees, (b) (4) have not responded to the firm's recall notice.
Effectiveness Check Information	Synthes followed up with all non-responding consignees via telephone beginning on May 3, 2017 and completing on May 25, 2017. After the third mailing notification, all non-responders were called. (b) (4) were able to be reached. A remaining (b) (4) were unable to be reached; 3 phone attempts were made to try to reach them.
Recall Audit Check Count	Audit Count Summary : Not Available
Audit Check Information	RAC assignments were issued to ATL, BLT, CIN, DAL, PHI, NOL, CHI, NWE, SEA, LOS, DEN and KAN to complete 3 audit checks each district. Completed RACs were reviewed and the firm's recall strategy was found tc be effective due to the large amount of received RACs that were found to be effective.
Section of Law Violated	501
Preventive Action Taken by Firm	Immediate recall of specified lots from the market. Procedures were updated to correct the issue.
District Follow-Up	None
District Review	Review of firm's Investigation report and root cause analysis was completed to ensure adequacy and completeness.
Legal Action	None being taken at this time.
	N/A

Class I Termination Recommendation
Recommended/Prepared By Dellarese L Herbert
District Management Approval Steven Carter **Date** 12/21/2017
Center Concurrence N/A
Recall Completed Date 12/21/2017
Termination Letter Date 02/28/2018

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CDRH Center Information

Docs Rcvd at Ctr Date 01/06/2017
HHE Sent
HHE Signed
HHE Precedent
Classifying Division DIVISION OF MANUFACTURING AND QUALITY
Classifying Branch PHYSICAL MEDICINE, ORTHOPEDIC, NEUROLOGY, AND DENTAL DEVICES BRANCH

MDR Reporting

Deaths	Injuries	Malfunctions	Other
		34	

MDR Reporting Comments
Correction and Removal Report

FEI Number	Date	Type	Number
3008812560	12/29/2016	R	018

CDRH Reason

Health Hazard Evaluation

Recall Used as Future Precedent No
Complaint Description
Hazard Description
Precedent Related Factors
User Related Factors
Population at Greater Risk
Health Consequences
Likehood of Occurence
Probability of Injury
Severity of Injury
Risk Narrative
Medical Officer Narrative

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Product Information

Product : 1
Industry-Product Code 87-KWI
Precedent Recall Z-1238-2013
Precedent Policy
Precedent Policy Comment
Product Description (Int) (Label/Packaging) Synthes Radial Head Prosthesis System, Surgical instrument motors and accessories Product Usage: Intended for primary and revision joint replacement of the radial head.
Trade Name (Int) Synthes Radial Head Prosthesis System
Generic Name (Int) Prosthesis, elbow, hemi-, radial, polymer
Product Usage Intended for primary and revision joint replacement of the radial head.
Product Quantity Distributed (Int) 50,311 units
Recall Number (Int) Z-1124-2017
Product Public Reason for Recall (Int) There is the possibility that the radial stem may loosen post-operatively at the stem bone interface.
Field Recommended Classification Class II
Center Determination/Classification (Int) Class II
Center Recommended Depth Consumers/User
Product Effectiveness Check Level A **Percent** 100
Product Audit Check Level D **Percent** 2
Code Information (Int) Part Numbers: 03.402.006 03.402.007 03.402.008 03.402.009 03.402.010 03.402.018 03.402.020 03.402.022 03.402.024 03.402.026 03.402.028 03.402.106 03.402.107 03.402.108 03.402.109 03.402.110 03.402.218 03.402.220 03.402.222 03.402.224 03.402.226 03.402.228 03.402.418 03.402.420 03.402.422 03.402.424 03.402.426 03.402.428 03.402.618 03.402.620 03.402.622 03.402.624 03.402.626 03.402.628 03.402.701 03.402.710 03.402.711 03.402.712 03.402.716 03.402.717 03.402.718 03.402.719 03.402.720 03.402.721 03.402.722 03.402.723 03.402.724 03.402.725 03.402.726 03.402.727 03.402.728 03.402.729 03.402.730 03.402.731 03.402.732 03.402.733 03.402.734 03.402.735 03.402.740 03.402.741 03.402.744 04.402.006S 04.402.007S 04.402.008S 04.402.009S 04.402.010S 04.402.026S 04.402.027S 04.402.028S 04.402.029S 04.402.030S 09.402.018S 09.402.020S 09.402.022S 09.402.024S 09.402.026S 09.402.028S 09.402.218S 09.402.220S 09.402.222S 09.402.224S 09.402.226S 09.402.228S 09.402.418S 09.402.420S 09.402.422S 09.402.424S 09.402.426S 09.402.428S 09.402.618S 09.402.620S 09.402.622S 09.402.624S 09.402.626S 09.402.628S 60.402.001 60.402.002 61.402.001 01.402.001E
Expected Life
Shelf Life

04 Jan 2017

URGENT NOTICE:
MEDICAL DEVICE FIELD SAFETY NOTIFICATION-
Product Recall 555531- Radial Head Prosthesis System

Please distribute this information to appropriate personnel at your facility.

Dear Sir/Madam,

Part Description, Part and Lot Numbers

Part Number	Part Description	Lot Number
See Attachment 1	See Attachment 1	All lots

Synthes GmbH is initiating a product removal of the DePuy Synthes Radial Head Prosthesis System. The DePuy Synthes Radial Head Prosthesis System is intended for primary and revision joint replacement of the radial head.

Our records indicate that you may have inventory that is impacted or have been using affected product(s).

Reason for the Recall

The entire DePuy Synthes Radial Head Prosthesis System is affected by this removal, however it is the radial stem that has the possibility of loosening post-operatively at the stem bone interface. Based on the currently available data, we believe the cause to be multifactorial (including possible product characteristics, operative and patient factors), but we have not been able to fully characterize these factors. Consequently, we have not been able at this time to issue further instructions to surgeons that might lead to a reduction in issue rate and have decided to remove the DePuy Synthes Radial Head Prosthesis Stem from the global market.

Health care practitioners that have treated patients using the DePuy Synthes Radial Head Prosthesis System should continue to follow those patients in the usual manner.

The DePuy Synthes Radial Head Prosthesis System, except for the stem, will be available upon request for revision surgeries in which only the head would be replaced using the evaluation or loaner set programs only.

Potential Patient Impact:

If the radial stem becomes loose post-operatively, the following may occur; Device Loosening, Osteolysis, Poor Joint Mechanics, Pain, Bone Fracture – Post-operatively, and Soft tissue Damage (Soft Tissue Irritation).

Johnson & Johnson Medical Singapore
a division of Johnson & Johnson Pte Ltd.
No. 2 International Business Park, #07-01, Tower One, The Strategy, Singapore 609930
Tel: +65 6827 6000 Fax: +65 6720 0750
Business Reg No. 52836279L Company Reg No. 197402104W

Customer immediate actions:

1. Immediately review your inventory to identify and quarantine all affected products listed above in a manner that ensures the affected products will not be used.
2. Review, complete, sign and return the attached reply form on page 3 of this letter to your local DePuy Synthes sales organization in accordance with the directions on the form within 5 business days of receipt of this notification.
3. Return any affected product as soon as possible, but within 30 business days. A credit note will be issued for the returned items.
4. Forward this notice to anyone in your facility that needs to be informed.
5. If any of the affected products has been forwarded to another facility, contact that facility to arrange return.
6. Maintain awareness of this notice until all products listed below have been returned to DePuy Synthes.
7. Keep a copy of this notice.

We apologize for any inconvenience that this product recall may create and appreciate your cooperation with our request. Should you have any inquiries please do not hesitate to contact your DePuy Synthes sales consultant.

Thank you for your attention and cooperation.

[redacted]

Johnson & Johnson Medical Singapore
a division of Johnson & Johnson Pte Ltd.
No. 2 International Business Park, #07-01, Tower One, The Strategy, Singapore 609930
Tel: +65 6827 6000 Fax: +65 6720 0750
Business Reg No. 52836279L Company Reg No. 197402104W

Johnson & Johnson MEDICAL

URGENT NOTICE:
MEDICAL DEVICE FIELD SAFETY NOTIFICATION-
Product Recall 555531- Radial Head Prosthesis System

Please distribute this information to appropriate personnel at your facility.

Dear Sir/Madam,

Part Description, Part and Lot Numbers

Affected Product:

Part Description	Part Number(s)	Lot Numbers
See Attachment 1	See Attachment 1	All Lots

Please check (√) accordingly:

☐ We acknowledge receipt of this information, but do not have any identified product in stock; returned quantity is zero.

☐ We located the identified product in stock; returned quantity is documented below:

Product Code	(Serial/Lot Number)	Quantity (Number in "Eaches")

Please sign, date and stamp below. Your signature provides confirmation that you have received and understood this notification.

Customer Name _____ Title _____

Signature & Date _____ Stamp ***(Stamp shall bear facility name)*** _____

Please complete this Verification Section and return to your Depuy Synthes representative or fax it to +65 6720 0750 within **(5) five business days** of receipt of the Field Safety Notice.

Johnson & Johnson MEDICAL

Johnson & Johnson Medical Singapore
a division of Johnson & Johnson Pte Ltd.
No. 2 International Business Park, #07-01, Tower One, The Strategy, Singapore 609930
Tel: +65 6827 6000 Fax: +65 6720 0750
Business Reg No. 52836279L Company Reg No. 197402104W

FDA

Class 2 Device Recall Synthes Radial Head Prosthesis System

See Related Information[22]

Class 2 Device Recall Synthes Radial Head Prosthesis System

Date Initiated by Firm	December 29, 2016
Create Date	February 02, 2017
Recall Status[1]	Terminated [3] on February 06, 2018
Recall Number	Z-1124-2017
Recall Event ID	76182[23]
510(K)Number	K112030[24]
Product Classification	Prosthesis, elbow, hemi-, radial, polymer[25] - **Product Code** KWI[26]
Product	Synthes Radial Head Prosthesis System, Surgical instrument motors and accessories Product Usage: Intended for primary and revision joint replacement of the radial head.
Code Information	Part Numbers:, 03.402.006, 03.402.007, 03.402.008, 03.402.009, 03.402.010, 03.402.018, 03.402.020, 03.402.022, 03.402.024, 03.402.026, 03.402.028, 03.402.106, 03.402.107, 03.402.108, 03.402.109, 03.402.110, 03.402.218, 03.402.220, 03.402.222, 03.402.224, 03.402.226, 03.402.228, 03.402.418, 03.402.420, 03.402.422, 03.402.424, 03.402.426, 03.402.428, 03.402.618, 03.402.620, 03.402.622, 03.402.624, 03.402.626, 03.402.628, 03.402.701, 03.402.710, 03.402.711, 03.402.712, 03.402.716, 03.402.717, 03.402.718, 03.402.719, 03.402.720, 03.402.721, 03.402.722, 03.402.723, 03.402.724, 03.402.725, 03.402.726, 03.402.727, 03.402.728, 03.402.729, 03.402.730, 03.402.731, 03.402.732, 03.402.733, 03.402.734, 03.402.735, 03.402.740, 03.402.741, 03.402.744, 04.402.006S, 04.402.007S, 04.402.008S, 04.402.009S, 04.402.010S, 04.402.026S, 04.402.027S, 04.402.028S, 04.402.029S, 04.402.030S, 09.402.018S, 09.402.020S, 09.402.022S, 09.402.024S, 09.402.026S, 09.402.028S, 09.402.218S, 09.402.220S, 09.402.222S, 09.402.224S, 09.402.226S, 09.402.228S, 09.402.418S, 09.402.420S, 09.402.422S, 09.402.424S, 09.402.426S, 09.402.428S, 09.402.618S, 09.402.620S, 09.402.622S, 09.402.624S, 09.402.626S, 09.402.628S, 60.402.001, 60.402.002, 61.402.001, 01.402.001E.

Recalling Firm/ Manufacturer	Synthes (USA) Products LLC 1301 Goshen Pkwy West Chester PA 19380-5986
Manufacturer Reason for Recall	There is the possibility that the radial stem may loosen post-operatively at the stem bone interface.
FDA Determined Cause [2]	Under Investigation by firm
Action	An Urgent Notice was mailed to consignees explaining the reason for the recall. Customers were asked to immediately review their inventories for the affected product and complete and return the Verification form that was included with the notification and return any of the affected product that was found.
Quantity in Commerce	50,311 units
Distribution	United States Nationwide Distribution.
Total Product Life Cycle	TPLC Device Report[27]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

[3] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[29].

510(K) Database	510(K)s with Product Code = KWI and Original Applicant = SYNTHES USA, LLC[30]

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm

GOV.UK

1. Home (https://www.gov.uk/)
2. Alerts and recalls for drugs and medical devices (https://www.gov.uk/drug-device-alerts)

DePuy Synthes Radial Head elbow prosthesis system: risk of post-operative loosening of the radial stem

From: Medicines and Healthcare products Regulatory Agency (https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency)
Published: 12 June 2017
Issued: 12 June 2017
Alert type: Medical device alert (https://www.gov.uk/drug-device-alerts?alert_type%5B%5D=devices)
Medical specialty: Orthopaedics (https://www.gov.uk/drug-device-alerts?medical_specialism%5B%5D=orthopaedics)

Manufactured by Synthes GmbH - Recall of Radial Head Prosthesis System. Associated Radial Head Prosthesis system parts also need to be returned to DePuy Synthes but will be available for revision surgeries of the radial head component.

Contents

Action

- Do not implant these devices (see details below).
- Locate and return all affected products to DePuy Synthes as detailed in their Field Safety Notice (https://mhra.filecamp.com/public/file/2jrp-e7r0of1g).
- Identify and advise all patients implanted with affected devices to contact their orthopaedic surgeon if they develop symptoms such as pain, loss of function or instability.

- Consider monitoring patients at 6 monthly intervals for up to 2 years post-implantation, with both clinical and radiographic assessments (i.e. X-rays[1]) to identify possible loosening of the radial stem.
- Any asymptomatic patients identified with loosening of their implants should continue to be monitored at 6-monthly intervals for progressive osteolysis (including potential risk of fracture), or the development of symptoms needing revision surgery.
- Report all adverse events involving this device to DePuy Synthes and to MHRA or the appropriate Devolved Administration.

Action by

- Medical directors
- Orthopaedic departments
- Orthopaedic surgeons
- Staff involved in the management of patients with joint related implants

Deadlines for actions

Actions underway: 19 June 2017

Actions complete: 3 July 2017

NOTE: These deadlines are for systems to be in place to take actions and not for the completion of patient follow up and imaging.

Device details

All lots of the DePuy-Synthes Radial Head prosthesis system are affected.

For part number and description information for the device and associated parts refer to Attachment 1 of the manufacturer's Field Safety Notice (https://mhra.filecamp.com/public/file/2jrp-e7r0of1g) and the spreadsheet attached to this alert, which includes both catalogue numbers and relevant UDI Device Identifier codes (GS1 GTINs).

Problem / background

In December 2016, DePuy-Synthes issued a Field Safety Notice (https://mhra.filecamp.com/public/file/2jrp-e7r0of1g) informing clinicians of the recall of the Radial Head prosthesis due to the possibility of post-operative loosening of the stem at the stem-bone interface. Implant loosening may lead to osteolysis, poor joint mechanics, bone fracture or soft tissue damage.

The radial stem was introduced into the UK market in 2015 and up to the publication date of this medical device alert, MHRA has received no reports of stem loosening.

Manufacturer contacts

Martyn Kedie
Johnson & Johnson Medical Ltd
DePuy Synthes
Leeds One
St Anthony's Road
Leeds, LS11 8DT

Telephone: 0113 387 6261

Email: MDFieldActionsUKIrl@its.jnj.com

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Fracture clinics
- Orthopaedic surgeons
- Outpatient clinics
- Physiotherapists
- Purchasing managers
- Radiology departments
- Radiology directors
- Risk managers
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres

Public Health England

Directors for onward distribution to:

- Collaborating centres
- Consultants in communicable disease control
- Divisional directors
- Heads of department
- Heads of health, safety and quality
- Health protection nurses

NHS England area teams

CAS liaison officers for onward distribution to all relevant staff including:

- General practice managers
- General practice nurses
- General practitioners

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

- Adult placement
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Class 2 Device Recall Tornier Latitude Elbow Prosthesis

See Related Information

Date Initiated by Firm	June 23, 2011
Date Posted	August 29, 2011
Recall Status[1]	Terminated [3] on July 17, 2012
Recall Number	Z-3082-2011
Recall Event ID	59399
510(K)Number	K100562
Product Classification	Prosthesis, elbow, semi-constrained, cemented - **Product Code** JDB
Product	Latitude", Tige Humerale, Humeral Stem, Medium 77 mm, Humeral Stem Right, For Cemented use only, Sterile R, REF 0030402, Tornier In. Edina, MN 55435 USA. The Tornier In. Latitude Elbow Prosthesis is intended for total elbow arthroplasty. Prosthetic replacement with this device may be indicated to relieve severe pain or significant disability following the effects of primary or secondary osteoarthritis and rheumatoid arthritis; correction of functional deformities; revision procedures where other treatments or devices have failed; treatment of fractures that are unmanageable using others techniques. The Tornier In. Latitude Elbow Prosthesis is intended for cemented use only.
Code Information	CC0810047
Recalling Firm/ Manufacturer	Tornier, Inc 7701 France Ave S Ste 600 Edina MN 55435-3202
For Additional Information Contact	952-426-7600
Manufacturer Reason for Recall	Tornier has discovered that some models of the Tornier latitude Elbow Prosthesis (Small and Medium Humeral stems) were manufactured with a humeral screw that may not function as designed.
FDA Determined Cause [2]	Process change control
Action	Tornier, Inc. sent an "Urgent Product Correction" letter dated June 23, 2011. The letter was addressed to the doctors. The letter described the product and the problem. Doctors were insructed to monitor patients that have received the units for evidence of humeral screw loosening. For questions customers were instructed to contact the Customer Service Department at 1-888-494-7950.
Quantity in Commerce	3
Distribution	Nationwide Distribution including FL and MO
Total Product Life Cycle	TPLC Device Report

ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE

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. We anticipate the release of additional web services for testing by the end of 2015. Please see the API Documentation for more information.

Medical devices cover a wide range of products - implants, CT scanners, surgical instruments, contact lenses, wheelchairs, and blood glucose tests, to name a few. Unlike drugs, many medical devices currently do not have a unique identifier that clearly distinguishes one product from another. But this is changing. The UDI system will provide a consistent and standard way to identify medical devices throughout their distribution and use by health care providers and patients.

Most devices will be required to have a UDI on their label and packaging, and for certain devices, on the product itself. Device companies must also submit certain information about these devices to the GUDID (pronounced "Good ID"). Please note: **The GUDID does not collect or contain any information about patients or anyone who uses a device.**

UDIs will be phased in over several years, starting with the highest risk devices, such as heart valves and pacemakers. Because of this, records for only a fraction of devices currently in use have been submitted to GUDID. For more information about UDI and GUDID, see below.

The National Library of Medicine (NLM), in collaboration with the FDA, has created the AccessGUDID portal to make device identification information in the GUDID available for everyone, including patients, caregivers, health care providers, hospitals, and industry. In our beta release of AccessGUDID, basic search and download functions are available. We plan to develop advanced search and web service capability in the future. The device information available on AccessGUDID is the most recent data submitted to the FDA that has completed the "grace period" after initial publication. (The grace period is the time during which device companies may make significant edits to their information; once the grace period is completed, only limited editing of device information is possible.) GUDID data is updated every business day, so the most up to date information can be searched or downloaded from this site.

ABOUT A UNIQUE DEVICE IDENTIFIER

A UDI is composed of two parts:

Device Identifier (DI) - A unique numeric or alphanumeric code specific to a device version or model.

Production Identifier(s) (PI) - Numeric or alphanumeric codes that identify production information for a device and can include the following:

- The lot or batch number;
- The serial number;
- The expiration date;
- The date the device was manufactured;
- For a Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P) regulated as a device, the distinct identification code that allows the manufacturer to associate the HCT/P to the donor.

ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE

printed w/ expanded info
says "in commercial distribution"

SEARCH RESULTS FOR: synthes (88 results)

Company Name
Brand Name
GMDN Term

Elbow radius prosthesis (88)

FDA Product Code Name
FDA Product Code
Device Packaged As Sterile
Sterilization Prior To Use
Issuing Agency
Device Class

Class II (88)

Implantable

NA - 10886982079985
7MM CURVED TRIAL RADIAL STEM 42MM
Company Name: SYNTHES (U.S.A.) LP **Version or Model:** 03.402.107

NA - 10886982079954
26MM TRIAL RADIAL HEAD STANDARD HEIGHT/13.5MM
Company Name: SYNTHES (U.S.A.) LP **Version or Model:** 03.402.026

NA - 10886982079862
6MM STRAIGHT TRIAL RADIAL STEM 24MM
Company Name: SYNTHES (U.S.A.) LP **Version or Model:** 03.402.006

NA - 10886982132772
22MM COCR RADIAL HEAD 6MM HT EXTENSION/18.5MM-STER
Company Name: SYNTHES (U.S.A.) LP **Version or Model:** 09.402.622S

NA - 10886982132673
26MM COCR RADIAL HEAD 2MM HT EXTENSION/15.5MM-STER
Company Name: SYNTHES (U.S.A.) LP **Version or Model:** 09.402.226S

NA - 10886982132659
22MM COCR RADIAL HEAD 2MM HT EXTENSION/14.5MM-STER
Company Name: SYNTHES (U.S.A.) LP **Version or Model:** 09.402.222S
Commercial Distribution Status: In Commercial Distribution **Catalog Number:** 09402222S
Device IDs: **GMDN Terms:**
H67909402222S0 (**Secondary**) Elbow radius prosthesis
10886982132659 (**Primary**)

← radial head

NA - 10886982132581
20MM COCR RADIAL HEAD STANDARD HEIGHT/12.0MM-STERILE
Company Name: SYNTHES (U.S.A.) LP **Version or Model:** 09.402.020S

NA - 10886982128089
6MM TI CURVED RADIAL STEM 40MM-STERILE
Company Name: SYNTHES (U.S.A.) LP **Version or Model:** 04.402.026S

NA - 10886982128065

9MM TI STRAIGHT RADIAL STEM 30MM-STERILE

Company Name: SYNTHES (U.S.A.) LP

Version or Model: 04.402.009S

NA - 10886982128041

7MM TI STRAIGHT RADIAL STEM 26MM-STERILE

stem

Company Name: SYNTHES (U.S.A.) LP

Commercial Distribution Status: In Commercial Distribution

Device IDs:

H67904402007S0 (**Secondary**)

10886982128041 (**Primary**)

Version or Model: 04.402.007S

Catalog Number: 04402007S

GMDN Terms:

Elbow radius prosthesis

< 1 ... 4 5 6 7 8 9 >

Summary

- The manufacturer does not have a record of who has an implant and does not inform the patient.
- The FDA does not have a record of who has an implant and does not inform the patient.
- Hospitals and doctors do have a record but are not required to inform the patient of a recall.
- **The FDA did *recommend* that the manufacturer notify patients of the recall of my device.**
- The manufacturer only notified the hospital of my recall and asked only that any product be returned.
- **Patients are the first to experience the health problems caused by the new medical device.**
- **When the device is recalled, the patient is not informed.**
- Medical devices do have a Unique Device Identifier.
- The Global Unique Device Identification Database (GUDID) contains device identification information.
- This information is submitted to the FDA by the manufacturer.
- The GUDID states it does not contain any information about patients or anyone who uses the device.
- **The GUDID does not state that *my* implant was recalled- only that it is in commercial distribution.**
- We have the technology in place to notify patients.