

URGENT: FIELD SAFETY NOTICE (FSN)
MODULAR CATHCART UNIPOLAR HEAD

Dear Valued Customer,

Please be advised that DePuy Orthopaedics, Inc. (Warsaw, IN) is initiating a field safety notice (FSN) for all lots of the MODULAR CATHCART UNIPOLAR HEAD (Cathcart Head). The subject products are intended for use in hemi-hip arthroplasty and the lots of the subject products covered by this notice are listed in Appendix 1.

PLEASE CAREFULLY REVIEW THIS DOCUMENT FOR THE STEPS THAT YOU SHOULD TAKE TO RESPOND TO THIS FIELD SAFETY NOTICE AND DISTRIBUTE IT TO THE APPROPRIATE PERSONNEL AT YOUR FACILITY WHO HAVE USED OR MAY USE THE SUBJECT PRODUCT.

Reason for the FSN:

During an internal review, it was determined that the Cathcart Head includes a +5mm offset, which was not specified in previous versions of the SELF-CENTERING™ Bipolar and Modular Cathcart Unipolar Endo Heads Surgical Technique Guide (STG). This +5mm offset should be taken into consideration when using a Cathcart head in a construct for hip arthroplasty procedures. The Surgical Technique Guide has been updated to reflect this clarification. Please contact your local sales consultant to receive a copy of the revised STG (reference document number DSUS/JRC/0317/2044 Rev 2).

The update includes the following table (Table 1) on Page 3:

| Cathcart Head | Tapered Spacers 12/14 ARTICUL/EZE™ | Total Head Offset |
|----------------|---------------------------------------|-------------------|
| +5 Head Offset | -3mm | +2mm |
| | +0mm | +5mm |
| | +5mm | +10mm |
| | +10mm | +15mm |

Table 1: Total Head Offset for Constructs Using Cathcart Head on Page 3 of (DSUS/JRC/0317/2044 Rev 2)

Potential Patient Impact:

Patients implanted with the Cathcart Head in a construct that exceeds the overall suggested total offset may experience the following:

- Implant (Stem) Fracture
- Pain
- Loosening
- Dislocation
- Poor Joint Mechanics
- Post-Op Bone Fracture-Major

NOTE: No adverse events have been reported for the subject product to date. Patients treated with the Cathcart Head in a construct exceeding the recommended total offset should continue to be monitored pursuant to the healthcare provider’s standard of care.

Date: 06-June-2022

Our records show that your facility may have received the Cathcart Head (Appendix 1). Please take the following actions:

1. **Product is NOT being removed from the field and does not need to be returned.**
2. Familiarize yourself with the content of this letter.
3. Review, complete **all** fields, sign, and return the attached business response form (BRF) on the last page of this letter to [Enter Affiliate Contact Information] within three (3) business days of receipt of this field safety notice. Please include "FA 2113289 Cathcart Head" in the email subject line. **IMPORTANT:** Complete the BRF even if you do not have any of the subject product in your current inventory.
4. Forward this notice to any personnel in your facility who need to be informed.
5. If any of the subject product has been forwarded to another facility, contact that facility and provide a copy of this notice to the relevant personnel.
6. Post a copy of this notice in a visible area for awareness of this field safety notice.

We recognize that this notification may require additional action on your part, and we will endeavor to alleviate any burden. If you have any questions, please contact your local DePuy Synthes Sales Consultant. For Medical Information Requests, please visit our website: <https://www.jnjmedicaldevices.com/mir>.

Thank you for your attention to this matter and your cooperation with our Requested Actions.

Kindest regards,

Kimberly Long, Staff QS Action Coordinator

Email: OneMD-Field-Actions@its.jnj.com | Telephone: + 1 574-221-8156

Appendix 1: MODULAR CATHCART UNIPOLAR HEAD (Cathcart Head) Subject Parts and Lots

| Part Number | Variant Part Number | Material Description | GTIN | Lots |
|-------------|--|--|----------------|------|
| 136341000 | 136341000-11 136341000-12 136341000-13 136341000-14 | MODULAR CATHCART FRACTURE HEAD HIP BALL 41MM | 10603295032371 | All |
| 136342000 | 136342000-11 136342000-12 136342000-13 136342000-14 | MODULAR CATHCART FRACTURE HEAD HIP BALL 42MM | 10603295032748 | All |
| 136343000 | 136343000-11 136343000-12 136343000-13 136343000-14 | MODULAR CATHCART FRACTURE HEAD HIP BALL 43MM | 10603295032755 | All |
| 136344000 | 136344000-11 136344000-12 136344000-13 136344000-14 | MODULAR CATHCART FRACTURE HEAD HIP BALL 44MM | 10603295032762 | All |
| 136345000 | 136345000-11 136345000-12 136345000-13 136345000-14 | MODULAR CATHCART FRACTURE HEAD HIP BALL 45MM | 10603295032779 | All |
| 136346000 | 136346000-11 136346000-12 136346000-13 136346000-14 | MODULAR CATHCART FRACTURE HEAD HIP BALL 46MM | 10603295032786 | All |
| 136347000 | 136347000-11 136347000-12 136347000-13 136347000-14 | MODULAR CATHCART FRACTURE HEAD HIP BALL 47MM | 10603295032793 | All |
| 136348000 | 136348000-11 136348000-12 136348000-13 136348000-14 | MODULAR CATHCART FRACTURE HEAD HIP BALL 48MM | 10603295032809 | All |
| 136349000 | 136349000-11 136349000-12 136349000-13 136349000-14 | MODULAR CATHCART FRACTURE HEAD HIP BALL 49MM | 10603295032816 | All |
| 136350000 | 136350000-11 136350000-12 136350000-13 136350000-14 | MODULAR CATHCART FRACTURE HEAD HIP BALL 50MM | 10603295032823 | All |

| Part Number | Variant Part Number | Material Description | GTIN | Lots |
|-------------|--|--|----------------|------|
| 136351000 | 136351000-11 136351000-12 136351000-13 136351000-14 | MODULAR CATHCART FRACTURE HEAD HIP BALL 51MM | 10603295032830 | All |
| 136352000 | 136352000-11 136352000-12 136352000-13 136352000-14 | MODULAR CATHCART FRACTURE HEAD HIP BALL 52MM | 10603295032847 | All |
| 136353000 | 136353000-11 136353000-12 136353000-13 136353000-14 | MODULAR CATHCART FRACTURE HEAD HIP BALL 53MM | 10603295032854 | All |
| 136354000 | 136354000-11 136354000-12 136354000-13 136354000-14 | MODULAR CATHCART FRACTURE HEAD HIP BALL 54MM | 10603295032861 | All |
| 136356000 | 136356000-11 136356000-12 136356000-13 136356000-14 | MODULAR CATHCART FRACTURE HEAD HIP BALL 56MM | 10603295032878 | All |
| 136358000 | 136358000-11 136358000-12 136358000-13 136358000-14 | MODULAR CATHCART FRACTURE HEAD HIP BALL 58MM | 10603295032885 | All |
| 136360000 | 136360000-11 136360000-12 136360000-13 136360000-14 | MODULAR CATHCART FRACTURE HEAD HIP BALL 60MM | 10603295032892 | All |

URGENT: FIELD SAFETY NOTICE (FSN)
MODULAR CATHCART UNIPOLAR HEAD
Business Reply Form (BRF)

Product Subject to this FSN: Our records show that your facility may have received a Cathcart Head.

Please complete this BRF **within three (3) business days upon receipt of this Notice** and email this form to [Enter Affiliate Contact Information]. **IMPORTANT:** Complete the BRF even if you currently do not have any product in your inventory.

Note: Product is NOT being removed from the field and does not need to be returned

By signing this form, I am confirming that I have read and understand the notification.

| | |
|---|-------------------------|
| Your Name: | Facility/Business Name: |
| Signed*: | Date: |
| Facility/Business Address, City: | |
| Account Number: | |
| J&J Sales Rep (as applicable): | |
| Date the notification was received: | |
| Email Address: | Telephone Number: |
| <i>*Your signature provides confirmation that you have received and understood this notification.</i> | |
| Your comments are always welcome: | |

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