

# **URGENT FIELD SAFETY NOTICE: RA2021-2744351**

## **ACTION REQUIRED**

July, 2021

### **Identification of the Affected Product:**

Restoris® MCK Femoral Trial and Restoris® MCK Patellofemoral Trial

[Refer to Attachment: PFA 2744351 Restoris® MCK Femoral Trial and Restoris® MCK Patellofemoral Trial for affected catalog and lot numbers.](#)

Dear Customer,

Stryker has initiated a voluntary, lot number specific recall for:

- Restoris® MCK Femoral Trial, sizes 1 through 8 and 11 through 18 (LM/RL and RM/LL), of 16 catalog numbers (170501- 170508) and (170511-170518).
- Restoris® MCK Patellofemoral Trial, sizes 2 through 8 and 12 through 18 (Left and Right), of 14 catalog numbers (170402 – 170408) and (170412 – 170418).

The intent of this letter is to list hazards and harms potentially associated with the referenced products listed in Attachment: PFA 2744351 and list any risk mitigation factors.

### **Description of issue:**

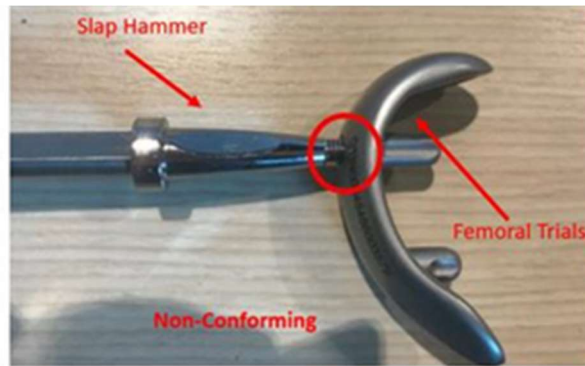
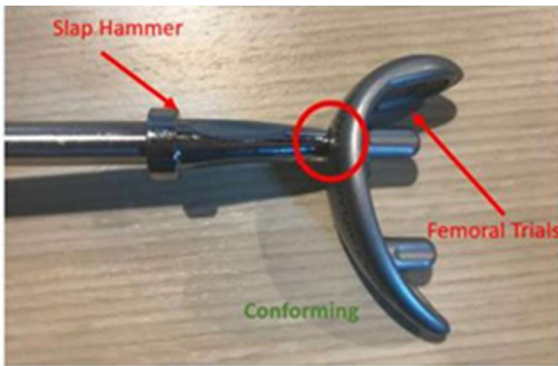
Stryker has discovered that there is a potential that the threads on the Femoral Trial Slaphammer may not engage with the threads of the Restoris® MCK Femoral Trial(s) and/or Restoris® MCK Patellofemoral Trial(s), (collectively, "Trial(s)"), preventing the extraction of such Trials using the slaphammer after use. This is due to an undersized diameter of the non-threaded portion of the Trial's extraction hole, which may prevent the Femoral Trial Slaphammer from completely engaging.

As a result of this discrepancy, customers are instructed to confirm that the threads of Restoris® MCK Femoral Trial(s) and Restoris® MCK Patellofemoral Trial(s) are able to fully engage with their Femoral Trial Slaphammer(s) at the site prior to use. Quarantine and discontinue use of the Trials identified in the affected product list that do not fully engage with the Femoral Trial Slaphammer and return the devices back to Stryker.

The Restoris® MCK Femoral Trial(s) and Restoris® MCK Patellofemoral Trial(s) continue to meet their intended use of assessing the final fit and function of the femoral and patellofemoral implant prior to implantation.

Figure 1 below displays a Femoral Trial Slaphammer engaging with a Trial (conforming extraction hole) in the image at left, and a Femoral Trial Slaphammer that does not engage with the Trial in the image at right.

Figure 1:



Stryker is aware of complaints associated with the issue. There have been no reports of serious injuries due to the failure mode associated with this recall.

**Potential Hazards:**

- Failure to assemble the Restoris® MCK Femoral and Restoris® MCK Patellofemoral Trial with the Femoral Trial Slaphammer.

**Potential Harms:**

- There are no harms associated with the potential hazard identified above.

**Risk Mitigations:**

If the surgeon is unable to assemble the Femoral Trial Slaphammer with a Restoris® MCK Femoral or Patellofemoral Trial(s) for extraction, the surgeon can use an alternative surgical instrument (or similar device) to remove the Trial(s).

**Recommendations for patients already treated with an affected device:**

Patients treated with an affected product should continue to be followed per the normal protocol established by his or her surgeon(s). There are no recommended changes to the frequency of the standard follow-up care protocol.

It should be noted that the failure of the insert to fully seat, may not be evident on x-ray unless the insert has dislodged.

**Required customer actions:**

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action.

We request that you read this notice carefully and complete the following actions:

1. Immediately check your internal inventory and quarantine all subject devices pending return to Stryker.
2. Circulate this Field Safety Notice internally to all interested/affected parties.

3. Maintain awareness of this notice internally until all required actions have been completed within your facility.
4. Inspect all Restoris® MCK Femoral Trial(s) and Restoris® MCK Patellofemoral Trial(s) to ensure that its threaded extraction hole(s) engages with any available Femoral Trial Slaphammers at your site.
5. **Discontinue use** of the recalled trial devices identified in Attachment PFA 268287, which do not engage with your Femoral Trial Slaphammer(s) and return the Restoris® MCK Femoral Trial(s) and Restoris® MCK Patellofemoral Trial(s) devices to Stryker.
6. **Continue to use** the Restoris® MCK Femoral Trial(s) and Restoris® MCK Patellofemoral Trial(s) if the threads fully engage with the threads on the Femoral Trial Slaphammer.
7. Inform Stryker if any of the subject devices have been distributed to other organizations.
  - a. Please provide contact details so that Stryker can inform the recipients appropriately.
  - b. If you are a Distributor, note that you are responsible for notifying your affected customers.
8. Please inform Stryker of any adverse events concerning the use of the subject devices.
  - a. Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.
9. Complete the attached customer response form. It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter. Therefore, please complete even if you no longer have any of the subject devices in your physical inventory.
10. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA
  - a. On receipt of the form, a Stryker Representative will contact you to organize any applicable ongoing actions.

We request that you respond to this notice within 7 calendar days from the date of receipt.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name:

Position:

E-mail:

Phone:

In line with the recommendations of the Meddev Vigilance Guidance document Ref.2.12-1, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.



On behalf of Stryker we thank you sincerely for your help and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards and your expectations, remain on the market.

Sincerely,

**URGENT FIELD SAFETY NOTICE: RA2021-2744351**  
**BUSINESS REPLY FORM**

July 2021

Product Name: Restoris ®MCK Femoral Trial and Restoris ®MCK Patellofemoral Trial

Catalog and Lot#: Refer to Attachment: PFA 2744351

I have received the **Urgent Medical Device Recall** letter from Stryker dated July 7, 2021 information on the voluntary recall on the above referenced affected products.

**I have inspected the Restoris ®MCK Femoral Trial and/ or the Restoris ®MCK Patellofemoral Trial product within my inventory.**

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Hospital/Agent/Risk Rep or Stryker Branch Rep Name

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Hospital or Stryker Branch Name

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Date

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Hospital or Stryker Branch Address/ City/State/ Postal Code

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Hospital/Agent/Risk Rep or Stryker Branch Rep

(Signature)

**PLEASE COMPLETE THIS FORM WITHIN 5 BUSINESS DAYS AND RETURN IT BY USING THE EMAIL OR FAX LISTED BELOW:**

Fax: [xxxx](#) or email to [xxxx](#)

Attachment: PFA 2744351 Restoris ®MCK Femoral Trial and Restoris® MCK Patellofemoral Trial

| Catalog #     | GTIN #       | Lot # | Catalog #     | GTIN #       | Lot # | Catalog #     | GTIN #       | Lot # | Catalog #     | GTIN #       | Lot # | Catalog #     | GTIN #       | Lot # |
|---------------|--------------|-------|---------------|--------------|-------|---------------|--------------|-------|---------------|--------------|-------|---------------|--------------|-------|
| <b>170402</b> | 848486003319 | 1N3G  | <b>170415</b> | 848486003425 | 1QGP  | <b>170501</b> | 848486003463 | 18QP  | <b>170507</b> | 848486003524 | 12HN  | <b>170515</b> | 848486003586 | 16W3  |
| 170402        |              | 1BM0  | 170415        |              | 1L8N  | <b>170502</b> | 848486003470 | 11HG  | 170507        |              | 12HM  | 170515        |              | 16W4  |
| 170402        |              | 18QN  | 170415        |              | 1CYD  | 170502        |              | 11HH  | 170507        |              | 15XY  | 170515        |              | 16W1  |
| 170402        |              | 18QM  | 170415        |              | 14X9  | 170502        |              | 11HE  | 170507        |              | 15Y0  | 170515        |              | 16W2  |
| 170402        |              | 182Y  | 170415        |              | 13BJ  | 170502        |              | 1GX7  | 170507        |              | 15Y1  | 170515        |              | 1EAV  |
| 170402        |              | 1830  | <b>170416</b> | 848486003432 | 2JP4  | 170502        |              | 22PG  | 170507        |              | 1N32  | 170515        |              | 1GLM  |
| <b>170403</b> | 848486003326 | 2JNE  | 170416        |              | 1WWJ  | 170502        |              | 23L4  | 170507        |              | 1N31  | 170515        |              | 1HNW  |
| 170403        |              | 1WWG  | 170416        |              | 1WWL  | 170502        |              | 23L5  | 170507        |              | 1N30  | 170515        |              | 1HNV  |
| 170403        |              | 15XV  | 170416        |              | 1GX2  | 170502        |              | 22PE  | 170507        |              | 1NN6  | 170515        |              | 38P8  |
| 170403        |              | 11HN  | 170416        |              | 1GX3  | <b>170503</b> | 848486003487 | 14X5  | 170507        |              | 1NN5  | <b>170516</b> | 848486003593 | 14BP  |
| <b>170404</b> | 848486003333 | 2JNM  | <b>170417</b> | 848486003449 | 20V9  | 170503        |              | 16W8  | 170507        |              | 1NN8  | 170516        |              | 17CB  |
| 170404        |              | 1WWH  | 170417        |              | 1V0E  | 170503        |              | 182X  | <b>170508</b> | 848486003531 | 11AC  | 170516        |              | 1AE1  |
| <b>170405</b> | 848486003340 | 1QOV  | 170417        |              | 1M26  | 170503        |              | 1G3X  | 170508        |              | 16VN  | 170516        |              | 1B0A  |
| 170405        |              | 1BLM  | 170417        |              | 1CYB  | 170503        |              | 1G3W  | 170508        |              | 1CY9  | 170516        |              | 1AE2  |
| 170405        |              | 1BLL  | 170417        |              | 1ADJ  | 170503        |              | 2R0D  | 170508        |              | 1M21  | 170516        |              | 1B09  |
| 170405        |              | 17C3  | <b>170418</b> | 848486003456 | 32E3  | 170503        |              | 2JPV  | 170508        |              | 1QGN  | 170516        |              | 1CYA  |
| 170405        |              | 17C4  | 170418        |              | 2Q3G  | 170503        |              | 2R0E  | 170508        |              | 1WWM  | 170516        |              | 1MGD  |
| 170405        |              | 11HW  | 170418        |              | 2Q3H  | 170503        |              | 38J6  | 170508        |              | 24X3  | 170516        |              | 1MGC  |
| <b>170406</b> | 848486003357 | 17C9  | 170418        |              | 2DPG  | 170503        |              | 38J8  | 170508        |              | 288E  | 170516        |              | 1MGB  |
| <b>170407</b> | 848486003364 | 1QOQ  | 170418        |              | 1YW7  | 170503        |              | 38J7  | 170508        |              | 288G  | 170516        |              | 22PD  |
| 170407        |              | 1QOR  | 170418        |              | 1BLR  | <b>170504</b> | 848486003494 | 17BX  | 170508        |              | 2XP1  | <b>170517</b> | 848486003609 | 12HD  |
| <b>170408</b> | 848486003371 | 2Q3D  | 170418        |              | 1ADM  | 170504        |              | 1R5X  | 170508        |              | 2XNX  | 170517        |              | 15Y2  |
| 170408        |              | 2JPA  | 170418        |              | 17CA  | 170504        |              | 1QGR  | <b>170511</b> | 848486003548 | 1PAP  | 170517        |              | 15Y3  |
| 170408        |              | 2D2V  |               |              |       | 170504        |              | 1R5W  | 170511        |              | 1NNN  | 170517        |              | 19A7  |
| 170408        |              | 1VQE  |               |              |       | <b>170505</b> | 848486003500 | 11AG  | <b>170512</b> | 848486003555 | 11A7  | 170517        |              | 19A8  |
| 170408        |              | 1QOW  |               |              |       | 170505        |              | 11AE  | 170512        |              | 11J3  | 170517        |              | 1C1Q  |
| 170408        |              | 1HNG  |               |              |       | 170505        |              | 11AD  | 170512        |              | 11J2  | 170517        |              | 1GLB  |
| 170408        |              | 199M  |               |              |       | 170505        |              | 1835  | 170512        |              | 20RV  | 170517        |              | 1GLC  |
| 170408        |              | 1B07  |               |              |       | 170505        |              | 19A0  | 170512        |              | 20RR  | 170517        |              | 2A2H  |
| <b>170412</b> | 848486003395 | 1W74  |               |              |       | 170505        |              | 1968  | <b>170513</b> | 848486003562 | 1V09  | 170517        |              | 2A2J  |
| 170412        |              | 1CYC  |               |              |       | 170505        |              | 1AE7  | 170513        |              | 1V0A  | 170517        |              | 2JQC  |
| 170412        |              | 15XN  |               |              |       | 170505        |              | 1CCQ  | 170513        |              | 227B  | <b>170518</b> | 848486003616 | 1EAX  |
| 170412        |              | 11HX  |               |              |       | 170505        |              | 1CCN  | 170513        |              | 20V6  | 170518        |              | 1EB0  |
| 170412        |              | 11HY  |               |              |       | 170505        |              | 1CCP  | <b>170514</b> | 848486003579 | 11A1  | 170518        |              | 1EAY  |
| <b>170413</b> | 848486003401 | 1MG3  |               |              |       | <b>170506</b> | 848486003517 | 14BM  | 170514        |              | 1964  | 170518        |              | 1MG8  |
| 170413        |              | 1G40  |               |              |       | 170506        |              | 18R5  | 170514        |              | 1963  | 170518        |              | 1M20  |
| 170413        |              | 1GLN  |               |              |       | 170506        |              | 1837  | 170514        |              | 1L8Q  | 170518        |              | 1L8D  |
| <b>170414</b> | 848486003418 | 246P  |               |              |       | 170506        |              | 18R4  | 170514        |              | 1L8P  | 170518        |              | 1MG7  |
|               |              |       |               |              |       | 170506        |              | 1GXJ  | 170514        |              | 21H2  | 170518        |              | 1MG6  |
|               |              |       |               |              |       | 170506        |              | 1GXL  | 170514        |              | 21H3  | 170518        |              | 1M1Y  |
|               |              |       |               |              |       | 170506        |              | 1JRL  | 170514        |              | 23L3  |               |              |       |
|               |              |       |               |              |       |               |              |       | 170514        |              | 23L2  |               |              |       |