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).

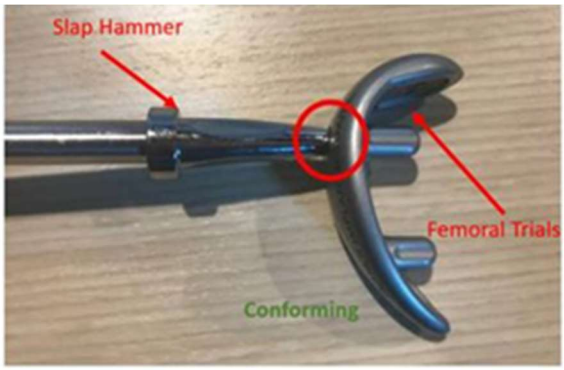
The intent of this letter is to list hazards and harms potentially associated with the referenced products listed in Attachment: PFA 2744351 and list any risk mitigation factors.

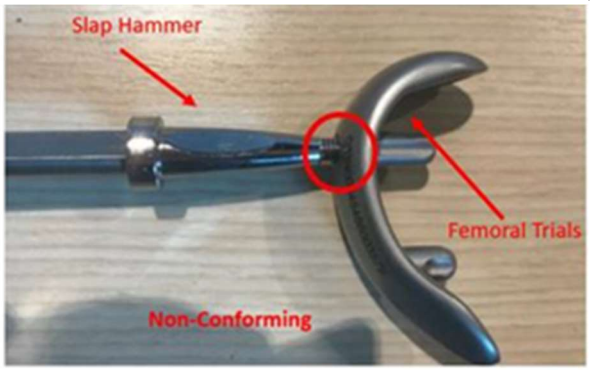
Description of issue:

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.

_____

Hospital/Agent/Risk Rep or Stryker Branch Rep Name

_____ _____

Hospital or Stryker Branch Name Date

_____

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

_____

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 #
170402	848486003319	1N3G
170402		1BM0
170402		18QN
170402		18QM
170402		182Y
170402		1830
170403	848486003326	2JNE
170403		1WWG
170403		15XV
170403		11HN
170404	848486003333	2JNM
170404		1WWH
170405	848486003340	1Q0V
170405		1BLM
170405		1BLL
170405		17C3
170405		17C4
170405		11HW
170406	848486003357	17C9
170407	848486003364	1Q0Q
170407		1Q0R
170408	848486003371	2Q3D
170408		2JPA
170408		2D2V
170408		1VQE
170408		1Q0W
170408		1HNG
170408		199M
170408		1B07
170412	848486003395	1W74
170412		1CYC
170412		15XN
170412		11HX
170412		11HY
170413	848486003401	1MG3
170413		1G40
170413		1GLN
170414	848486003418	246P

Catalog #	GTIN #	Lot #
170415	848486003425	1QGP
170415		1L8N
170415		1CYD
170415		14X9
170415		13BJ
170416	848486003432	2JP4
170416		1WWJ
170416		1WWL
170416		1GX2
170416		1GX3
170417	848486003449	20V9
170417		1V0E
170417		1M26
170417		1CYB
170417		1ADJ
170418	848486003456	32E3
170418		2Q3G
170418		2Q3H
170418		2DPG
170418		1YW7
170418		1BLR
170418		1ADM
170418		17CA

Catalog #	GTIN #	Lot #
170501	848486003463	18QP
170502	848486003470	11HG
170502		11HH
170502		11HE
170502		1GX7
170502		22PG
170502		23L4
170502		23L5
170502		22PE
170503	848486003487	14X5
170503		16W8
170503		182X
170503		1G3X
170503		1G3W
170503		2R0D
170503		2JPV
170503		2R0E
170503		38J6
170503		38J8
170503		38J7
170504	848486003494	17BX
170504		1R5X
170504		1QGR
170504		1R5W
170505	848486003500	11AG
170505		11AE
170505		11AD
170505		1835
170505		19A0
170505		1968
170505		1AE7
170505		1CCQ
170505		1CCN
170505		1CCP
170506	848486003517	14BM
170506		18R5
170506		1837
170506		18R4
170506		1GXJ
170506		1GXL
170506		1JRL

Catalog #	GTIN #	Lot #
170507	848486003524	12HN
170507		12HM
170507		15XY
170507		15Y0
170507		15Y1
170507		1N32
170507		1N31
170507		1N30
170507		1NN6
170507		1NN5
170507		1NN8
170508	848486003531	11AC
170508		16VN
170508		1CY9
170508		1M21
170508		1QGN
170508		1WWM
170508		24X3
170508		288E
170508		288G
170508		2XP1
170508		2XNX
170511	848486003548	1PAP
170511		1NNN
170512	848486003555	11A7
170512		11J3
170512		11J2
170512		20RV
170512		20RR
170513	848486003562	1V09
170513		1V0A
170513		227B
170513		20V6
170514	848486003579	11A1
170514		1964
170514		1963
170514		1L8Q
170514		1L8P
170514		21H2
170514		21H3
170514		23L3
170514		23L2

Catalog #	GTIN #	Lot #
170515	848486003586	16W3
170515		16W4
170515		16W1
170515		16W2
170515		1EAV
170515		1GLM
170515		1HNW
170515		1HNV
170515		38P8
170516	848486003593	14BP
170516		17CB
170516		1AE1
170516		1B0A
170516		1AE2
170516		1B09
170516		1CYA
170516		1MGD
170516		1MGC
170516		1MGB
170516		22PD
170517	848486003609	12HD
170517		15Y2
170517		15Y3
170517		19A7
170517		19A8
170517		1C1Q
170517		1GLB
170517		1GLC
170517		2A2H
170517		2A2J
170517		2JQC
170518	848486003616	1EAX
170518		1EB0
170518		1EAY
170518		1MG8
170518		1M20
170518		1L8D
170518		1MG7
170518		1MG6
170518		1M1Y