

URGENT FIELD SAFETY NOTICE: RA2021-2744351

ACTION REQUIRED

UPDATE

October, 2021

Identification of the Affected Product:

Restoris® MCK Femoral Trial and Restoris® MCK Patellofemoral Trials

Refer to Attachment A, “PFA 2744351 Restoris® MCK Femoral Trial and Restoris® MCK Patellofemoral Trials,” and **Attachment B, “Scope Expansion PFA 2744351 Restoris® MCK Femoral Trial and Restoris® MCK Patellofemoral Trials”** for affected catalog and lot numbers.

Dear Customer,

Stryker has expanded the scope of a voluntary, lot-specific recall that was initiated on July 7, 2021, for the Restoris® MCK Femoral Trial and Patellofemoral Trials. The specific lot numbers that are impacted by the recall are included in **Attachment A** and **Attachment B** to this letter.

The purpose of this update letter is to notify new customers that are now in scope due to the scope expansion and to notify customers that received the initial recall letter in July 2021, that this recall has been expanded to include additional lots of the Restoris® MCK Femoral and Patellofemoral Trials.

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 A**, “PFA 2682873 Restoris® MCK Femoral Trial and Restoris® MCK Patellofemoral Trials,” and **Attachment B, “Scope Expansion PFA 2682873 Restoris® MCK Femoral Trial and Restoris® MCK Patellofemoral Trials,”** 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).

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. Please inform users of this Urgent Field Safety Notice Update and forward this notice to all individuals who need to be made aware.

2. Immediately check all stock areas and/or operating room storage to determine if any devices from the affected product list are at your facility. See **Attachment B: “Scope Expansion PFA 2744351 Restoris® MCK Femoral Trial and Restoris® MCK Patellofemoral Trials.”**
3. 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.
4. **Discontinue use** of the recalled trial devices identified in **Attachment B: “Scope Expansion PFA 2744351 Restoris® MCK Femoral Trial and Restoris® MCK Patellofemoral Trials”** 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.
5. **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.
6. 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.
7. 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.
8. 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.
9. 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

October 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 Field Safety Notice** letter from Stryker dated October 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 #	Catalog #	GTIN #	Lot #	Catalog #	GTIN #	Lot #	Catalog #	GTIN #	Lot #	Catalog #	GTIN #	Lot #
170402	848486003319	1N3G	170415	848486003425	1QGP	170501	848486003463	18QP	170507	848486003524	12HN	170515	848486003586	16W3
170402		1BM0	170415		1L8N	170502	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	170416	848486003432	2JP4	170502		22PG	170507		1N32	170515		1GLM
170403	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	170503	848486003487	14X5	170507		1NN5	170516	848486003593	14BP
170404	848486003333	2JNM	170417	848486003449	20V9	170503		16W8	170507		1NN8	170516		17CB
170404		1WWH	170417		1V0E	170503		182X	170508	848486003531	11AC	170516		1AE1
170405	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	170418	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
170406	848486003357	17C9	170418		2DPG	170503		38J8	170508		288E	170516		1MGB
170407	848486003364	1Q0Q	170418		1YW7	170503		38J7	170508		288G	170516		22PD
170407		1Q0R	170418		1BLR	170504	848486003494	17BX	170508		2XP1	170517	848486003609	12HD
170408	848486003371	2Q3D	170418		1ADM	170504		1R5X	170508		2XNX	170517		15Y2
170408		2JPA	170418		17CA	170504		1QGR	170511	848486003548	1PAP	170517		15Y3
170408		2D2V				170504		1R5W	170511		1NNN	170517		19A7
170408		1VQE				170505	848486003500	11AG	170512	848486003555	11A7	170517		19A8
170408		1Q0W				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
170412	848486003395	1W74				170505		1968	170513	848486003562	1V09	170517		2A2J
170412		1CYC				170505		1AE7	170513		1V0A	170517		2JQC
170412		15XN				170505		1CCQ	170513		227B	170518	848486003616	1EAX
170412		11HX				170505		1CCN	170513		20V6	170518		1EB0
170412		11HY				170505		1CCP	170514	848486003579	11A1	170518		1EAY
170413	848486003401	1MG3				170506	848486003517	14BM	170514		1964	170518		1MG8
170413		1G40				170506		18R5	170514		1963	170518		1M20
170413		1GLN				170506		1837	170514		1L8Q	170518		1L8D
170414	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			

Attachment B: Scope Expansion PFA 2744351 Restoris® MCK Femoral Trial and Patelofemoral Trials

Catalog #	GTIN #	Lot #	Catalog #	GTIN #	Lot #	Catalog #	GTIN #	Lot #	Catalog #	GTIN #	Lot #			
170402	848486003319	1073	110415	848486003425	OVGA	170502	848486003470	OXR3	170512	848486003555	OXQY			
170403	848486003326	OYBM	110416	848486003432	OR72	170502		OXRI	170512		OXQX			
170404	848486003333	OVGN	170416		OVWN	170502		OXR2	170512		11A6			
170404		OVP6	170416		OX29	1705CB	848486003487	OR78	170513	848486003562	OXQH			
170404		OVP5	110417	848486003449	OR6Y	170503		OR7A	170513		OXQG			
170404		OYBX	170417		IONW	170503		OXR4	170513		OXQJ			
170404		OYBW	170417		IONV	170504	848486003494	OVL1	170513		IONMR			
170406	848486003357	IONY	110418	848486003456	OWC2	170504		OVL2	170513		IONMV			
170407	848486003364	IONQ				170504		OX2C	170513		IONMW			
170407		IONN				170504		OX2B	170514	848486003579	11AO			
170408	848486003371	10N5				170506	848486003517	OVIG	170515	848486003586	OPGM			
170412	848486003395	OVNI				170506		OVIE	170515		OWC7			
170412		1076				170507	848486003524	OVJ3	170517	848486003609	OBBD			
110413	848486003401	OYBQ				170507		1074	170517		OBBD			
170413		IOPE				170507		IONH	170517		1077			
110414	848486003418	OVP7				170511	848486003548	OWBW	170518	848486003616	119X			
170414		OVP8				170511		OWBX						
170414		OYCO												
170414		OYBY												
170414		OYC2												
170414		OYCI												