Urgent Field Safety Notice: RA2023-3194049

March xx, 2023

Product Field Action # **3194049**

Product Name: **Restoris MultiCompartmental Knee (MCK) Tibial Baseplate Trial**

Identification of the Affected Products:

Table 1

Catalog Number	Product Description	Lot Number	GTIN
170615	Restoris MCK Tibial Baseplate Trial STD RM/LL Size 5	26270421	00848486003746
170616	Restoris MCK Tibial Baseplate Trial STD RM/LL Size 6	26250421	00848486003753

Dear Customer,

Stryker has initiated a voluntary, lot specific recall for the Restoris MultiCompartmental Knee (MCK) Tibial Baseplate Trials listed in Table 1. The intent of this letter is to list all known hazards and harms potentially associated with the below noted issue and list the risk mitigation factors associated with the use of the product.

Issue:

Stryker has discovered that certain lots of the Restoris MultiCompartmental Knee (MCK) Tibial Baseplate Trials contain product with incorrect size laser marking. Catalog Number 170615, Lot 26270421, Size 5 may be mismarked as Catalog Number 170616, Lot 26250421, Size 6 and vice versa.

The scope of this issue is limited to Catalog Number 170615, Lot 26270421 and Catalog Number 170616, Lot 26250421.

Potential Hazards:

In the event of the Restoris MultiCompartmental Knee (MCK) Tibial Baseplate Trial product being incorrectly laser marked (either size 5 or size 6), the following potential hazards have been identified:

- Misinformation – Part Marking
- Incorrect Bone Preparation
- Excessive Stress in Bone
- Failure to Assemble
- Excessive Stress in Soft Tissue
- Incorrect Trialing Assessment
- Mal-positioned Implant

Potential Harms:

The aforementioned potential hazards may result in the following potential harms:

- Poor fixation of the implant
- Fracture of the tibia
- Interference of soft tissue outside of the tibia

Risk Mitigation:

Risk may be mitigated in the following scenarios:

- Prior to surgical use, the user identifies during the kitting process that a nonconforming Baseplate Trial may interfere with the tray slot.
- The surgeon or surgical staff detects the difference, via an increased amount of bone exposed or an overhang over the prepared tibia, between the pre-surgical plan and a nonconforming Baseplate Trial in use during surgery.
- The surgeon or surgical staff identifies that the size-specific Insert Trial is either too loose or will not seat in the pocket of a nonconforming Baseplate Trial.

Actions Needed:

Our records indicate that you may have received the affected product(s). It is Stryker's responsibility as the manufacturer to ensure that customers who may have received these affected products also receive this important communication. We therefore request that you read this notice carefully and complete the following actions.

1. Please inform users of this Urgent Medical Device Recall and forward this notice to all individuals who need to be made aware or organizations who have consigned product.
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.
3. Quarantine and discontinue use of the recalled devices identified in the affected product list.
4. Maintain awareness of this notice internally until all required actions have been completed within your facility.
5. 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.
6. 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.
7. 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.
8. 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.

Please respond event if you do not have a record of receiving affected inventory. This will enable us to update our records and negate the need to send unnecessary reminder letters.
Your timely response will enable us to update our records and negate the need to send reminder notices.

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: email:

On behalf of Stryker, we thank you sincerely for your help and support in completing this action within the target date 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, remain on the market.

Sincerely,

Urgent Field Safety Notice: RA2023-3247448
Business Reply Form - response required

March xx, 2023

Product Field Action #: **3247448**

Product Name: **Restoris MultiCompartmental Knee (MCK) Tibial Baseplate Trial**

I have received the **Urgent Medical Device Recall** letter from Stryker dated March XX, 2023, stating that the company has initiated a voluntary recall on the above referenced affected products in *Table 1*

Catalog Number	Product Description	Lot Number	GTIN
170615	Restoris MCK Tibial Baseplate Trial STD RM/LL Size 5	26270421	00848486003746
170616	Restoris MCK Tibial Baseplate Trial STD RM/LL Size 6	26250421	00848486003753

Please complete the form even if you do not have inventory. This will preclude us to follow up.

Customer information

Customer name_____

Name of person completing this form_____

Title_____ Direct phone #_____ Email_____

Address_____ City_____ State_____ Postal code _____Country _____

If affected inventory, please provide information below. Attach additional sheet if needed.

Product code	Serial/Lot number	Qty quarantined	Qty destroyed/returned

No affected product in inventory (please check) ☐

If you have further distributed subject devices, please provide information below.

Facility Name	Facility Address	Contact person	Product code	Lot number	QTY

I have read and understand the instructions provided and acknowledge receipt of the subjected Field Safety Notice. I also agree to further distribute and communicate this important information from this letter to those whom I have distributed any of subjected devices noted in this letter.

Name (print)_____Signature_____Date _____

PLEASE COMPLETE THIS FORM WITHIN 7 CALENDAR DAYS AND RETURN IT BY USING THE EMAIL _____ OR FAX _____