Urgent Field Safety Notice: RA2023-3195918

March 14, 2023

Product Field Action # **3195918**

Product Name: **Restoris® RIO™ Reamer Handle, Straight**

Identification of the Affected Products:

Table 1

Part Number	Product Description	GTIN	Lot Number
207084	Restoris® RIO™ Reamer Handle, Straight	00848486022204	06050521
			06111021

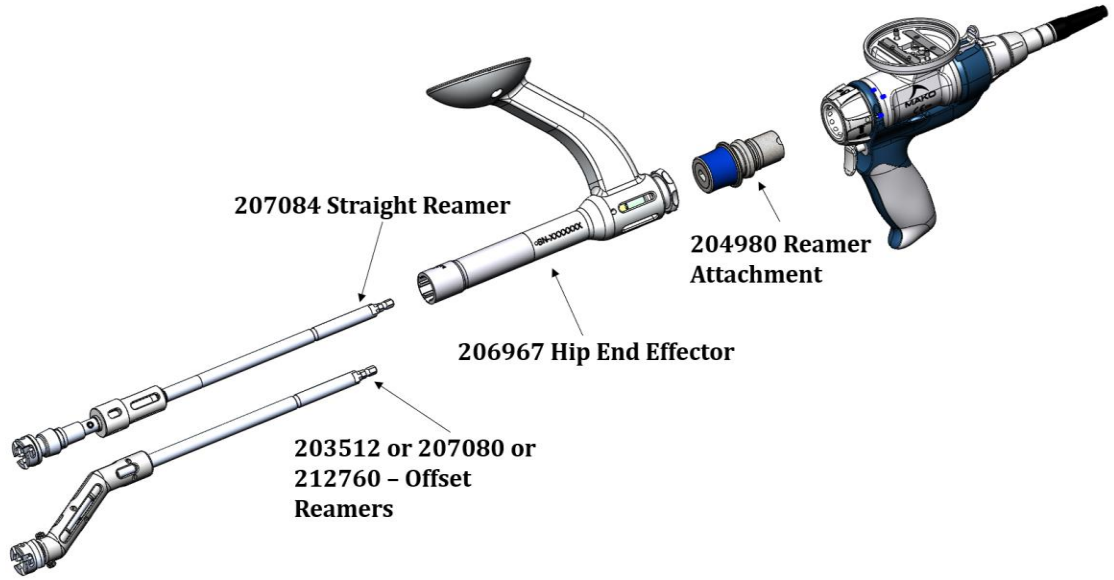
Dear Customer,

Stryker has initiated a voluntary, lot number specific recall for the Restoris® RIO™ Reamer Handle, Straight. The lot numbers impacted by this recall are included in Table 1 above.

Issue:

Stryker has discovered the potential for the Restoris® RIO™ Reamer Handle, Straight to not assemble with the Reamer Attachment (Part Number 204980). If the identified issue is present, the Reamer Handle, Straight will not fit into the Reamer Attachment as the end of the Reamer Handle, Straight is too large to insert into the inner diameter of the Reamer Attachment. The Offset Reamer Handle is not impacted by this issue. See Figure 1 below for depiction of parts.

Figure 1:



Potential Hazard:

The inability to assemble the Reamer Handle, Straight to the Reamer Attachment may lead to a potential delay in surgery of less than 15 minutes to retrieve a replacement device.

Potential Harm:

There are no identified harms associated with this issue which would lead to any known adverse health consequences.

Risk Mitigation:

The hazard may be mitigated by the following:

- The inability of the Reamer Handle, Straight to assemble to the Reamer Attachment may be identified preoperatively by hospital staff during Mako Instrument cleaning and sterilization.
- If the Reamer Attachment (P/N 204980) has an inner diameter larger than the out of specification dimension of the Reamer Handle, Straight, assembly will be successful.
- Both the Reamer Handle, Straight and Offset Reamer Handle are provided in the same instrument tray. Should the Reamer Handle, Straight not connect to the Reamer Attachment, the Offset Reamer Handle is available for immediate use.

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: RA2023-3195918
Business Reply Form - response required

March 14, 2023

Product Field Action #: **3195918**

Product Name: **Restoris® RIO™ Reamer Handle, Straight**

I have received the **Urgent Medical Device Recall** letter from Stryker dated March 13, 2023, stating that the company has initiated a voluntary recall on the above referenced affected products in *Table 1*

Part Number	Product Description	GTIN	Lot Number
207084	Restoris® RIO™ Reamer Handle, Straight	00848486022204	06050521
			06111021

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 _____