Field Safety Notice: RA2024-3656765

June XX, 2024

Affected product

Product Field Action #: **RA2024- 3656765**

Product Name: **UNITRAX® Endoprosthesis Head Component**

Identification of the Affected Products: See Table 1

Catalog Number	Product Description	Lot Number	GTIN
6942-5-043	UNITRAX® Endoprosthesis Head Component - 43mm	5Y1350	07613327032376
		LN815R	
		PV0H60	
6942-5-042	UNITRAX® Endoprosthesis Head Component - 42mm	4615EX	07613327032369
		HE645D	
		8A399N	
6942-5-038	UNITRAX® Endoprosthesis Head Component - 38mm	JT38AD	07613327032338

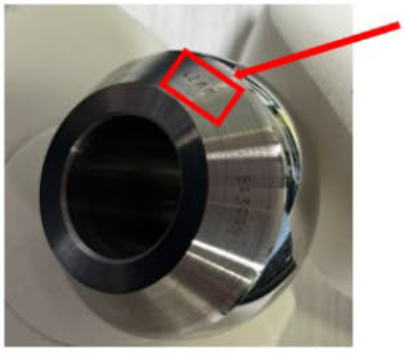
Dear Customer,

Stryker has initiated a voluntary, lot specific recall for the devices listed in Table 1 above. 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.

Product Description

The UNITRAX® Endoprosthesis Head (Unipolar) is an implantable component used in partial hip arthroplasty with the appropriate C-Taper or V40 Neck Adjustment Sleeves using the Sleeve Impactor. The Unipolar Head assembles with a compatible femoral stem within the native acetabulum.

Figure 1:



Issue

Stryker has discovered that the size on the package label of the UNITRAX® Endoprosthesis Head Component potentially may not match the device within the packaging.

This product mix only involves the three (3) sizes (43mm, 42mm, and the 38mm) listed in Table 1 above.

Potential Hazards

Misinformation on the package label may lead to a delay in surgery of ≤15 minutes to retrieve a replacement device.

Insufficient Joint Constraint

Excessive Stress in Bone

Excessive Stress in Soft Tissue

Potential Harms

- Pain
- Instability
- Joint dislocation
- Restricted motion / functional limitation / loss of mobility
- Revision surgery

Risk Mitigations

Risk may be mitigated in the following scenarios:

- The Unipolar heads have a direct part marking present on the bottom of the device that details the size of the diameter (see Figure 1). The size marking may be used as an intra-operative check before final implantation to ensure the correctly sized implant has been chosen.
- As per the surgical protocol, the surgeon must complete a trialing reduction and final joint functionality assessment to help assess and ensure proper stability, leg length, and intended range of motion is achieved. If an incorrectly sized implant is chosen, it is likely that these factors will differ from the previous trial reduction. As a result, the final assessment should alert the surgeon that a discrepancy with the final implant is present.

Recommendations for patients already implanted with an impacted device

Patients treated with an impacted product identified in Table 1 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.

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 (Table 1).
4. Complete and sign the enclosed Urgent Medical Device Recall Business Reply Form
5. Please contact your Local Sales Office or your Stryker Sales Representative directly for product replacement and inventory questions.
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 serious incidents concerning the use of the subject devices.
    a. Please comply with any local laws or regulations concerning the notification of serious incidents 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.

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:*

(In line with the recommendations of the Meddev Vigilance Guidance document Ref 2.12-1 and EU 2017/745, 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 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,

RA2024-3656765
Business Reply Form - response required

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June XX, 2024

Product Field Action #: **RA2024- 3656765**
Product Name: **UNITRAX® Endoprosthesis Head Component**

I have received the Medical Device Recall letter from Stryker dated June 19 2024, stating that the company has initiated a voluntary recall on the referenced affected products in Table 1 and I acknowledge the actions needed.

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

Customer information

Customer name: _____

Name of person completing this form: _____ Title: _____

Direct phone number: _____ Email _____

Address: _____ City: _____

Postal code: _____ Country: _____

We have not located any of these devices in our inventory *(please add check mark to box):*	

We have the following impacted devices on hand:

Product	Catalog Number	Lot number	QTY

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 subject Field Safety Notice. I also agree to further distribute and communicate this important information from this letter to those to whom I distributed any of the subject 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 ____