stryker

URGENT:
Field Safety Notice

LATITUDE EV HUMERAL STEM TRIAL

Attn: Health Care Professionals, Operators of Medical Devices, Distributors

Recall Number: RA2025-3909276

XX-March-2025

Product Affected

Catalog number	GTIN	Product description	Batch Lot #	Distribution Dates
9030103	00846832015054	Latitude EV Humeral Stem Trial, Size Large 150mm Right	CC0421265	19-Oct-2022 to 16-Dec-2024

The purpose of this notification is to advise that Stryker is conducting a field action for one batch lot of Latitude EV Humeral Stem Trials. Please refer to the table above for catalog and lot number within the scope of this field action that was identified as shipped to distributors and end users.

Product description

The Latitude Humeral Trial Stem is used with the Latitude EV Total Elbow arthroplasty system. The system consists of a Humeral Stem, a Humeral or anatomical spool, and a humeral screw. The Latitude Elbow prostheses and Latitude EV total Elbow Arthroplasty systems are intended for hemi and total elbow arthroplasty. These systems are designed to facilitate the reproduction of the natural flexion/extension axis and kinematics of the elbow through their anatomical designs.

Product issue

Subsequent to a product complaint, Stryker confirmed that a specific lot of Latitude Humeral Trial Stems has the incorrect direct part marking.

- Laser Marked: 9030103, Humeral Stem Trial 150mm Large / Right, Yellow color indicator (incorrect)
- Device Actually: 9030092, Humeral Stem Trial 150mm Medium / Left, Red color indicator (correct)

Potential risks

The hazards associated with this issue are compromised traceability and the device being not fully functional. This nonconformance may be detected pre-operatively. However, if the nonconformance is not identified prior to surgery, the potential harms could be elongation of surgery and/or intraoperative bone fracture.

Actions needed

Our records indicate that you may have received one or more of the subject devices. 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. Immediately check your internal inventory to locate the product listed on the attached business reply form, remove them from their point of use, and isolate/quarantine the unit(s) to prevent accidental use.
2. Return the enclosed business reply form by email to confirm receipt of this notification/document product segregation.
    a. **Response is required, even if you may not have any physical inventory on site anymore.** 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.
3. Upon receipt of the completed business reply form, Stryker will contact you to arrange for the return of your product(s).
4. Maintain awareness of this communication internally until all required actions have been completed within your facility.
5. If you have further distributed the affected product, please notify the applicable parties at once about this recall. You may copy and distribute this notification letter.
    a. If possible, inform us if any of the subject devices have been distributed to other organizations, including contact details so that we can inform the recipients appropriately.
    b. If you are a distributor, note that you are responsible for notifying your affected customers.
6. Please inform us of any adverse events and/or report them to the Health/Competent Authorities in accordance with current regulations.

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 Medical Device Coordination Group Guidance document Ref MDCG 2023-3 and EU MDR 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 and regret any inconvenience 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,

stryker

Business Reply Form

Account name:
Account Address:

LATITUDE® EV HUMERAL STEM TRIAL

Recall Number: RA2025-3909276

XX-March-2025

Please complete and sign this form. Email the completed form to XXXX@stryker.com by XX-Mar-2025.

Note: Your signature indicates that you have received and understand the enclosed notification and that you have performed all actions requested.

Catalog number	Product description	Batch Lot number	Quantity on Hand
9030103	Latitude® EV Humeral Stem Trial, Size Large Right 150mm	CC0421265	

*If all devices have been used and no affected devices are available for return please enter 0 (zero).

Form completed by:

Printed Name		**Title**	
Signature		**Phone**	
Date		**Email**	

If you have further distributed any affected product, please indicate to whom, if possible:

Product(s) Distributed		**Quantity** Distributed	
Facility Name		**Contact Person**	
Full Address			