

URGENT MEDICAL DEVICE RECALL

March 30, 2022

Product Field Action #: **2965398**

Product Name: Triathlon® Tritanium® Tibial Component

Identification of the Affected Products:

Table 1

Catalog Number	Product Description	GTIN	Lot Number
5536-B-600	Triathlon® Tritanium® Tibial Component (Size 6)	07613327041514	CTD69463
5536-B-500	Triathlon® Tritanium® Tibial Component (Size 5)	07613327041507	CTD69106

Dear Customer,

Stryker has initiated a voluntary, lot number specific recall for the Triathlon® Tritanium® Tibial Component. The lot numbers impacted by this recall are included in Table 1 above.

Issue:

Stryker has discovered a potential product mix where the size of the Triathlon® Tritanium® Tibial Component inside the package does not match the package labeling.

Potential Hazards/Harms:

Technical and medical assessments are currently underway to determine any potential hazards and harms associated with the use of an impacted Triathlon® Tritanium® Tibial Component.

An updated communication will be forwarded upon completion of the internal investigation on this issue.

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. **Complete and sign the enclosed Urgent Medical Device Recall Business Reply Form** and email to strykerortho6561@sedgwick.com. / Fax: (866) 654-0894.
5. **Please contact your Local Sales Office or your Stryker Sales Representative directly for product replacement and inventory questions.**
6. **Please return the devices back to Stryker using the following address:**

**Stryker Orthopaedics/PFA Product Returns
Attn: Distribution Inventory Team
325 Corporate Drive
Dock M-East
Mahwah, NJ 07430
Ref. PFA 2965398**

Please assist us in meeting our regulatory obligation by emailing back the attached Urgent Medical Device Recall Business Reply Form within 5 days. A response is required, even though you may not have any physical inventory on site.

Under 21 CFR 803, manufacturers are also required to report any serious injuries where a product has contributed or may have contributed to the event. Please keep Stryker informed of any adverse events associated with this product by emailing sprodexpreports@stryker.com.

We regret any inconvenience this action may cause. If you have any questions or concerns after reviewing this letter, please contact Customer Service at (201) 831-5000. For questions pertaining to the recall, email SO_M_PRODUCT_FIELD_ACTION_RESPONSE@stryker.com

Sincerely,

Dervillia Murphy
Vice President, Regulatory Interactions
Stryker

Joint Replacement Division
210 Centennial Park
Elstree, WD6 3SJ, United Kingdom



URGENT MEDICAL DEVICE RECALL BUSINESS REPLY FORM

March 30, 2022

Product Field Action #: **2965398**

Product Name: Triathlon® Tritanium® Tibial Component

I have received the **Urgent Medical Device Recall** letter from Stryker dated March 30, 2022, stating that the company has initiated a voluntary recall on the above referenced affected products in Table 1.

We have not located any of these devices in our inventory <i>(please add check mark to box):</i>		
We have the following impacted devices on hand:		
Product	Catalog Number	Lot Number

Hospital Name

Date

Hospital Address

Hospital Rep
(Signature)

PLEASE COMPLETE THIS FORM WITHIN 5 BUSINESS DAYS AND RETURN IT BY USING THE EMAIL LISTED BELOW:

strykerortho6561@sedgwick.com
(866) 654-0894