URGENT MEDICAL DEVICE RECALL

June 3, 2022

Product Field Action #: **2946206**

Product Names: Triathlon® Solid CR Tibial Insert Trial

Identification of the Affected Products:

Table 1

Catalog Number	Product Description	Lot Number	GTIN
5530-T-209Y	TRIATHLON SOLID CR TIBIAL INSERT TRIAL SIZE 2 - 9MM	A234P	07613327403619
5530-T-210Y	TRIATHLON SOLID CR TIBIAL INSERT TRIAL SIZE 2 - 10MM	A234Q	07613327403541

Dear Customer,

Stryker has initiated a voluntary, lot specific recall for the Triathlon® Solid CR Tibial Insert 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 Triathlon® Solid CR Tibial Insert Trials contain product with incorrect thickness laser marking. The scope of this issue is limited to Catalog Number 5530-T-209Y, Lot A234P and Catalog Number 5530-T-210Y, Lot A234Q.

Potential Hazards:

In the event of the Triathlon® Solid CR Tibial Insert Trial product being incorrectly laser marked (either 9mm thickness or 10mm thickness), the following potential hazards have been identified:

- Misinformation - Part Marking
- Incorrect Trialing Assessment

Potential Harms:

There are no identified harms associated with this issue.

Risk Mitigation:

Risk may be mitigated prior to surgical use, during the kitting process where the insert trials would be placed in specific locations, identified by both catalog number and thickness, in instrument trays. There is an opportunity to identify that the insert trial part markings, catalog number and thickness, do not correlate with the information on the tray. If the defect is identified, the device could be replaced prior to surgery.

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.
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 affected products in Table 1.
4. Complete and sign the enclosed Urgent Medical Device Recall Business Reply Form and email to strykerortho4963@sedgwick.com/ fax (877) 243-7314.
5. **Please contact your Local Sales Office or your Stryker Sales Representative directly for product replacement and inventory questions.**
6. **Please return ALL affected product to:**

   Stryker Orthopaedics/PFA Product Returns
   Attn: Distribution Inventory Team
   325 Corporate Drive
   Dock M-East
   Mahwah, NJ 07430
   Ref. PFA 2946206

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 soprodexpreports@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 (888)-756-7846. 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

June 3, 2022

Product Field Action #: 2946206

Product Names: Triathlon® Solid CR Tibial Insert Trial

I have received the **Urgent Medical Device Recall** letter from Stryker dated June 3, 2022, stating that the company has initiated a voluntary recall on the above referenced affected products.

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

We have located and returned the following devices (Document total # returned):

Product	**Catalog Number**	**Lot Number**	**Total # Returned:**

_____ _____

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:

strykerortho4963@sedgwick.com

Fax (877) 243-7314