URGENT MEDICAL DEVICE RECALL

March 07, 2022

Product Field Action #: 2903493

Product Names: Triathlon® Primary Tibial Baseplate
Triathlon® Tritanium Tibial Baseplate

Identification of the Affected Products:

Table 1

Catalog Number	Product Description	Lot Number	GTIN
5520-B-200	TRIATHLON PRIM CEM FXD BPLT #2	NSH9T	07613327041569
5520-B-400	TRIATHLON PRIM CEM FXD BPLT #4	JET3P	07613327050325
5520-B-500	TRIATHLON PRIM CEM FXD BPLT #5	JJ26C JAL2Y	07613327041057 07613327041057
5520-B-700	TRIATHLON PRIM CEM FXD BPLT #7	LS42C1 JA44S	07613327041064 07613327041064
5526-B-600	TRITANIUM BPLATE TRIATHLON #6	JDA9H	07613327041361
5536-B-200	TRITANIUM BPLATE TRIATHLON #2	CTD65856 CTD68500	07613327041590 07613327041590
5536-B-300	TRITANIUM BPLATE TRIATHLON #3	CTD50866 CTD61767 CTD61763 CTD64461	07613327041484 07613327041484 07613327041484 07613327041484
5536-B-400	TRITANIUM BPLATE TRIATHLON #4	CTD64718	07613327041491
5536-B-500	TRITANIUM BPLATE TRIATHLON #5	CTD46563 CTD52692	07613327041507 07613327041507
5536-B-600	TRITANIUM BPLATE TRIATHLON #6	CTD55764	07613327041514
5536-B-700	TRITANIUM BPLATE TRIATHLON #7	CTD61169	07613327041521

Dear Customer,

Stryker has initiated a voluntary, lot specific recall for the Triathlon® Primary and Tritanium Tibial Baseplates 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 any one of the following product markings on the Triathlon® Primary and Tritanium Tibial Baseplates listed in Table 1 may be incorrect: catalog number, lot number, and/or size (2 through 7). As a result, the product markings on the part may not match the catalog number, lot number, and/or size on the corresponding package and patient label.

Although the product marking on the devices may be incorrect, the device within the packaging matches the actual size that is on the corresponding package and patient labels.

Potential Hazards:

Potential delay in surgery of less than 15 minutes to retrieve a replacement device.

Potential Harms:

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

Risk Mitigation:

There are no risk mitigation factors associated with use of the devices identified in Table 1 above.

The devices identified in Table 1 above match the catalog number, lot number, and size identified on their corresponding package and patient labels. If the device is implanted, it is the correct size device and matches the package and patient labels.

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 strykerortho7614@sedgwick.com / fax (888) 714-5072.
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 2903493

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,

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