MEDICAL DEVICE RECALL

October 16, 2019

Product Field Action #: 2162903

Product name: 1 ½" Headed Nail Triathlon®Instruments

Affected Product(s):

Product Description	Catalog #	Lot #
1 ½" Headed Nail Triathlon Instruments	6541-4-515	SS18716A

Dear Customer,

Stryker has initiated a voluntary, lot-specific recall for the above referenced product. The intent of this letter is to list known hazards or harms potentially associated with the aforementioned product and list any risk mitigation factors.

Issue:

Stryker has discovered that a specific lot of the 1 ½" Headed Nail Triathlon Instrument was incorrectly packaged with a ¾" Headed Nail Triathlon Instrument. The Headed Nail Triathlon Instruments are used to temporarily secure the Triathlon Universal Tibial Template to the resected tibia during surgery. Additionally, the Triathlon Headed Nails may be used to temporarily secure the MIS A/P Sizer Adjustment Housing component of the MIS Femoral Sizer Assembly to the resected femur during surgery.

Potential Hazards:

In the event of a product mix between the 1 ½" and the ¾" Headed Nail Triathlon Instruments, the following potential hazard has been identified:

- Prior to surgery, during the kitting process, the instrumentation tray was intended to be kitted with a 1 ½" Headed Nail Triathlon Instrument instead it was incorrectly kitted with a ¾" Headed Nail Triathlon Instrument. This may result in a delay of surgery of ≤ 15 minutes to obtain and use an alternate pin or nail to complete the surgery.

Potential Harms:

- Complications associated with an extended surgery time of approximately 15 minutes or less.

Risk Mitigation:

The ¾" and 1 ½" Headed Nail Triathlon Instruments are sold as non-sterile instruments that are placed into an instrumentation tray and queued for sterilization. Prior to surgery, during the kitting process, the end user would notice the obvious difference in the length of the ¾" Headed Nail Triathlon Instrument and the lack of writing on the ¾" Headed Nail Triathlon Instrument that appears on the 1 ½" Headed Nail Triathlon Instrument. In light of the obvious nature of the size discrepancy, it is unlikely that this discrepancy would go unnoticed and that the ¾" Headed Nail Triathlon Instrument would be used during surgery. Further, the Headed Nail Triathlon Instruments are only used to temporarily secure the Triathlon Universal Tibial Template to the resected tibia or to temporarily secure the MIS A/P Sizer Adjustment Housing component of the MIS Femoral Sizer Assembly to the resected femur during surgery. Therefore, the product would not be implanted.

Unaffected Instruments:

There are unaffected lots available for the 1 ½" Headed Nail Triathlon Instruments, P/N# 6541-4-515.

Actions Needed:

1. Please inform users of this Medical Device Recall and forward this notice to all those individuals who need to be aware within your organization.
2. Immediately check all stock areas and/or operating room storage to determine if the devices from the affected product list are at your facility.
3. Quarantine and discontinue use of the recalled devices.
4. Hospitals/Branches/Agencies: Complete and sign the enclosed Medical Device Recall Business Reply Form and fax a copy to 1-877-857-4143 or email to Strykerortho4467@stericycle.com. **A response is required, even though you may not have any physical inventory on site at this time.**
5. Hospitals Only: Please contact your Local Sales Office or your Stryker Sales Representative directly for product returns and inventory questions.
6. Branches/Agencies Only: Return all affected instruments available at your location to the following address.

Stryker Orthopaedics/PFA Product Returns
Ref. PFA 2162903
Attn: Distribution Inventory Team
325 Corporate Drive
Dock M-East
Mahwah, NJ 07430

Our records indicate that you have received the above referenced instrument. It is our responsibility to ensure that customers who may have received this affected instrument also receive this important communication.

Please assist us in meeting our regulatory obligation by faxing back the attached Urgent Medical Device Recall Business Reply Form within 5 days.

If you have any questions, please contact your local Sales Office or the Stryker Sales Representative for assistance.

We regret any inconvenience this action may cause you and if you have any questions, please contact Customer Service at (201) 831-5000.

Sincerely,

Elizabeth Beato
Sr. Staff Regulatory Compliance Specialist
Regulatory Compliance
Stryker
Joint Replacement Division
325 Corporate Drive
Mahwah, NJ 07430
[redacted]