

**URGENT
PRODUCT RECALL**

September 11, 2018

Product Field Action Number: 1888374
Description: STERILE FLUTED HEADLESS 1/8" PIN 3.5" LONG
Affected Catalog Number(s): 7650-2038A
Affected Lot(s): SC22130X

Dear Customer,

Stryker Orthopaedics ("Stryker") has initiated a voluntary, lot-specific recall for the knee instrument referenced above. The intent of this letter is to list known hazards potentially associated with the use of the instrument and list any risk mitigation factors.

Issue:

Stryker has discovered that the outer sterile barrier of the above-referenced instrument and lot was not fully sealed. For the above-referenced instrument observed by Stryker, the inner sterile barrier seal was intact.

Potential Hazards:

Technical and medical assessments are currently underway to determine any potential hazards associated with the use of the instrument. Additional communication will be forwarded upon completion of the internal investigation on this issue.

Risk Mitigation:

According to the Instruction for Use (IFU) provided within each packaged component, the end user is instructed to inspect the package and seal for damage and, if present, to discard the device. As any damage to the packaging likely will be obvious to the end user, inspection and verification prior to transferring the device to the sterile field that both the outer and inner blister is acceptable, as per the IFU, may mitigate potential risk.

Actions Needed

1. Please inform users of this Urgent Product Recall and forward this notice to all those individuals who need to be aware within your organization.
2. Hospitals/Branches/Agencies: Complete and sign the enclosed Recall Notification Business Reply Form and fax a copy to 1-866-552-4917 or email to Strykerortho7994@stericycle.com

3. Hospitals/Branches/Agencies: Return all affected instruments available at your location to the following address.

Stryker Orthopaedics/PFA Product Returns
Attn: Distribution Inventory Team
325 Corporate Drive
Dock M-East
Mahwah, NJ 07431
Ref. PFA 1888374

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 Recall Notification Business Reply Form within 5 days.

We regret any inconvenience this action may cause you and if you have any questions, feel free to contact me at (201) 831-5000.



Stan Dube

Director, Post Market Compliance

Stryker

Joint Replacement Division

325 Corporate Drive

Mahwah, NJ 07431

stan.dube@stryker.com