325 Corporate Drive
Mahwah, NJ 07430
t: 201 831 5000

URGENT MEDICAL DEVICE RECALL NOTIFICATION

June 3, 2016

Product Field Action #: RA 2015-181
Description: Trident Constrained Liner Impactor Tips
Catalog No.: 2199-2022, 2199-2028, 2199-2032
Lot Codes: All lots produced since 2012

Dear Branches/Hospital Risk Managers,

Stryker Orthopaedics has initiated a voluntary, lot-specific product recall for the instrument described above. The intent of this letter is to list all known hazards potentially associated with the below noted issue and the risk mitigation factors associated with the use of the instrument.

Issue:

During steam sterilization validation it was discovered that the Trident Constrained Liner Impactor Tips do not meet the required sterility assurance level (SAL) of 10^{-6}. Please note that these instruments are sterilized at the hospital prior to surgery, however, and do not come from Stryker sterile.

The Trident Constrained Liner Trial is utilized during implantation of Trident Constrained Inserts, as described in the surgical technique (Literature Number LSP44, Rev 3). Please see picture below for ease of identification of the three items.

Potential Hazards:

Due to this inability to meet the sterility assurance level, the following potential hazards and harms have been identified:

Hazardous Situation	**Harm**
Non-sterile instrument	Infection

Risk Mitigation:

None

Actions Needed:

1. Please inform users of this Medical Device Removal and forward this notice to all those individuals who need to be aware within your organization.
2. Branches/Agencies: Return all affected products available at your location to

   Stryker C/O Stericycle
   2670 Executive Dr. Suite A
   Indianapolis, IN 46241

   Attn. RA 2015-181 – Event 7995
3. Hospitals/Branches: Complete and sign the enclosed Business Reply Form and fax a copy to **888-628-0728** or email to Stericycle **strykerortho7995@stericycle.com**

Alternate or Replacement Parts:

The Trident Constrained Insert Surgical Protocol (LSP44) lists two alternate methods of locking the insert into the shell, which can be found on page 4 of the protocol. The alternate instrument part numbers are listed below. Please refer to the surgical protocol for information on how to utilize these alternate parts.

Alternate Method 1:
Cutting Edge Femoral Head Impactor (1104-1000) or Command Head Impactor (6266-0-140)

Alternate Method 2:
Threaded Trial Head (1205-0022 / 1205-0028 / 1205-0032) with appropriately sized Head Removal Key (HI-UHRK- 3638 / HI-UHRK-28 / HI-UHRK-32) and Howmedica Osteonics Threaded Impactor/Extractor Handle (2101-0004)

Our records indicate that you have received the above referenced product. It is our responsibility to ensure that customers who may have received this affected product also receive this important communication. **Please assist us in meeting our regulatory obligation by faxing back the attached 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) 831-6693.

Sincerely,

Eric Petschler
Manager, Divisional Regulatory Compliance

STRYKER ORTHOPAEDICS
URGENT MEDICAL DEVICE RECALL
NOTIFICATION BUSINESS REPLY FORM

June 3, 2016

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I have received the product recall letter from Stryker Orthopaedics dated June 3, 2016 stating that the company has initiated a voluntary, lot-specific product recall of the above referenced instrument.

_____ _____
Stryker Branch/Hospital Date

_____ _____
Stryker Branch / Agent/ Hospital (Signature)
Hospital (Signature)

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

email: **strykerortho7995@stericycle.com**
fax: **1-888-628-0728**