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stryker®
UK

URGENT Field Safety Notice: RA 2015-181

Description: Trident Constrained Liner Impactor Tips

Product Code: 2199-2022, 2199-2028, 2199-2032

Lot Number: All lots produced since 2012

Dear Customer,

Stryker Orthopaedics has initiated a 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

bsi.
RS11877

Risk Mitigation:

None

Actions Required

1. Immediately check your internal inventory to locate subject devices referenced in this notice.

2. Immediately quarantine any subject devices that are located to ensure that they are withdrawn from service.

3. Circulate this Field Safety Notice internally to all interested / affected parties.

4. Maintain awareness of this notice internally until all required actions have been completed within your facility.

5. Inform Stryker if any of the subject devices have been distributed to other organisations.

   a) Please provide contact details so that Stryker can inform the recipients appropriately.
   b) If you are a Distributor, note that you are responsible for notifying your affected customers.

6. Complete the attached customer response form and return to Nina Goddard by fax (01635 262 464) or by e-mail (nina.goddard@stryker.com). Once a completed form has been received, a Stryker Representative will contact you to organise the collection and replacement of any affected devices located on site.

   a) Please complete this form even if you do not have any products to return. This will preclude the need for Stryker to send any reminder notice.

7. Please inform Stryker of any adverse events concerning the use of the subject devices.

8. Comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.

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.**

If you have any further enquiries, please do not hesitate to contact the undersigned.

Yours faithfully,

Nina Goddard
Quality Assurance and Regulatory Affairs

RA 2015-181: PFA Acknowledgement Form

Description: Trident Constrained Liner Impactor Tips

Product Code: 2199-2022, 2199-2028, 2199-2032

Lot Number: All lots produced since 2012

I acknowledge receipt of the Field Safety Notice for RA 2015-181 and can confirm that:

We have not located any of these devices in our inventory: *(please delete if not applicable)*			
We have located the following devices:			
Product Description	**Product Reference**	**Lot Number**	**Qty**
We have further distributed subject devices to the following organisations:			
Facility Name			
Facility Address			

Please sign and return this form to acknowledge receipt of product notice.			
Name of Hospital / Organisation		Department	
Contact Name		Address	
Contact Title			
Contact Signature		E-mail Address	
Contact Phone No.		Date	

PLEASE COMPLETE AND FAX THIS FORM TO 01635 262 464
OR EMAIL TO NINA.GODDARD@STRYKER.COM.