

**URGENT
PRODUCT RECALL**

Aug 22nd, 2016

FSCA identifier: Product Field Action RA2016-107
Type of Action: Field Safety Corrective Action: **Return to Supplier**
Description: Trident Universal Impactor/Positioner
Catalog #: 2101-0200
License #: DE0004060
Lot Code: SMM7E0V (distributed in Singapore, see attached list for globally affected lots)
Product owner: Howmedica Osteonics Corp., 325 Corporate Drive, Mahwah, NJ 07430, USA
License holder: Stryker Singapore Pte Ltd, 108 Pasir Panjang Road #03-04 Golden Agri Plaza
Singapore 118535

Dear Hospital Representative,

Stryker Orthopaedics has initiated a voluntary, lot-specific recall for the Trident Universal Impactor/Positioner. The intent of this letter is to list all known hazards potentially associated with the use of this instrument and list the risk mitigation factors.

Issue:

Stryker Orthopaedics has received reports of the thread length protruding past the dome of the acetabular trial or implant. Upon investigation, it was determined that the press fit between the threaded stud and the handle shaft assembly for the Trident Universal Impactor/Positioner (P/N: 2101-0200) may lead to the gradual protrusion of the threaded stud over time.

Potential Hazards:

The potential hazards may include:

1. Protruding thread length.
2. Excessive stress on bone.

The potential harms may include:

1. Complications associated with extended hip surgery time of < 15.
2. Intraoperative fracture.
3. Loss of initial mobility during post-op recovery.
4. Periprosthetic fracture.
5. Pain associated with implant loosening.

Risk Mitigation:

Inspection of reusable devices as described in Stryker Instructions for Cleaning, Sterilization, Inspection and Maintenance of Orthopaedic Medical Devices (LSTPI-B, Rev. 2) states, "For devices that may be impacted check that the device is not damaged to the extent that it malfunctions" and "Mating

devices should be checked for proper assembly.” Performing these inspections as instructed could identify the protruding thread length prior to using the instrument in surgery, which could mitigate all of the potential harms.

In addition, the user may notice the protruding thread length when the Trident Universal Impactor/ Positioner is assembled with a trial or implant. The protruding thread may be observed when the instrument is assembled to a trial, during trialing, when the instrument is assembled to an implant, and/or during the early stages of implant impaction.

Identification of the protruding thread length by the surgeon when the Trident Universal Impactor/ Positioner is assembled to a trial or implant would mitigate potential harms 2 through 5 from occurring.

Actions Needed

- Please inform users of this Urgent Product Recall and forward this notice to all those individuals who need to be aware within your organization.
- Segregate the affected devices and return to you Stryker representative
- Complete and sign the enclosed Business Reply Form and ASEAN.PMS@stryker.com or hand to your Stryker sales representative.

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 Business Reply Form within 5 days.

Reporting of Adverse Events

Please report any adverse events or product quality problems associated with this device to Stryker. Healthcare Professionals may also report any suspected adverse events associated with these devices to the Vigilance Branch, Health Products Regulation Group, HAS at Tel: 6866 3538, Fax: 6478 9069, or report online at www.hsa.gov.sg/ae_online.

We regret any inconvenience this action may cause you and if you have any questions, feel free to contact the signatory below.

Sincerely,



Sara Jato
QA Specialist
Stryker ASEAN
sara.jato@stryker.com
ASEAN.PMS@stryker.com
Tel. +84 (0)8 3827 5399 Ext.12

List of Globally affected lots

Product Number	Lot Number	Product Number	Lot Number	Product Number	Lot Number
2101-0200	SMM7A00	2101-0200	SMM7M00A	2101-0200	SMM8C00J
2101-0200	SMM7A00L	2101-0200	SMM7M02H	2101-0200	SMM8L05
2101-0200	SMM7A02	2101-0200	SMM7M02	2101-0200	SMM8L05A
2101-0200	SMM7A02A	2101-0200	SMM7E02M	2101-0200	SMM8L02X
2101-0200	SMM7A02E	2101-0200	SMM7E01JK	2101-0200	SMM8L04
2101-0200	SMM7A02EE	2101-0200	SMM7K03J	2101-0200	SMM6N00
2101-0200	SMM7A01T	2101-0200	SMM7K00A	2101-0200	SMM6N01
2101-0200	SMM7A01TT	2101-0200	SMM6N04	2101-0200	SMM6N01A
2101-0200	SMM7A01TD	2101-0200	SMM7N01J	2101-0200	SMM6N02
2101-0200	SMM7A01TDD	2101-0200	SMM7N01	2101-0200	SMM6N03
2101-0200	SMM7C02H	2101-0200	SMM7M06	2101-0200	SMM6N04A
2101-0200	SMM7C02	2101-0200	SMM7M09	2101-0200	SMM8L07T
2101-0200	SMM7C01	2101-0200	SMM7N03	2101-0200	SMM8L08
2101-0200	SMM7C01T	2101-0200	SMM7N03A	2101-0200	SMM8M00K
2101-0200	SMM7C01TT	2101-0200	SMM7M06A	2101-0200	SMM8M00L
2101-0200	SMM7C01W	2101-0200	SMM7M09	2101-0200	SMM8M01
2101-0200	SMM7E03	2101-0200	SMM7N00	2101-0200	SMM8M01E
2101-0200	SMM7E03A	2101-0200	SMM7M05	2101-0200	SMM8M01EE
2101-0200	SMM7E00	2101-0200	SMM7M08A	2101-0200	SMM8N02
2101-0200	SMM7A00E	2101-0200	SMM7M10	2101-0200	SMM8N02A
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2101-0200	SMM7E02A	2101-0200	SMM7N02L	2101-0200	SMM8N00
2101-0200	SMM7E01	2101-0200	SMM7M05J	2101-0200	SMM8N00A
2101-0200	SMM7E01A	2101-0200	SMM7M08	2101-0200	SMM8N00D
2101-0200	SMM7K00	2101-0200	SMM7N02	2101-0200	SMM8N01
2101-0200	SMM7K01	2101-0200	SMM7N04	2101-0200	SMM8N01A
2101-0200	SMM7K01A	2101-0200	SMM7N04J	2101-0200	SMM8N01T
2101-0200	SMM7K03	2101-0200	SMM8C00	2101-0200	SMM8S00
2101-0200	SMM7K03L	2101-0200	SMM7M01R	2101-0200	SMM8S00T
2101-0200	SMM7K02	2101-0200	SMM7M01RW	2101-0200	SMM8S00TT
2101-0200	SMM7K02T	2101-0200	SMM7M01W	2101-0200	SMM8S01
2101-0200	SMM7K03X	2101-0200	SMM7M07	2101-0200	SMM8S01A
2101-0200	SMM7K03Y	2101-0200	SMM7M07J	2101-0200	SMM8S01D
2101-0200	SMM7C02J	2101-0200	SMM6C00	2101-0200	SMM8T00
2101-0200	SMM7L00H	2101-0200	SMM7M03	2101-0200	SMM8N02T
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2101-0200	SMM7L00K	2101-0200	SMM7M03D	2101-0200	SMM8V00
2101-0200	SMM7L00	2101-0200	SMM7M03E	2101-0200	SMM8V00A
2101-0200	SMM7C01TW	2101-0200	SMM7M03L	2101-0200	SMM8V00E
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2101-0200	SMM7M00	2101-0200	SMM7M03K	2101-0200	SMM8V01A
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2101-0200	SMM8W03A	2101-0200	SMM8L03	2101-0200	SMM8V05
2101-0200	SMM8V02	2101-0200	SMM8L07	2101-0200	SMM8V06

2101-0200	SMM8W01	2101-0200	SMM8L00T	2101-0200	SMM8V04
2101-0200	SMM8W01A	2101-0200	SMM8L06	2101-0200	SMM8V03
2101-0200	SMM8W02X	2101-0200	SMM9A05	2101-0200	SMM9H00E
2101-0200	SMM8W03M	2101-0200	SMM9A06	2101-0200	SMM9H00EE
2101-0200	SMM8W03P	2101-0200	SMM9A06E	2101-0200	SMM9H00K
2101-0200	SMM8W04	2101-0200	SMM9A07	2101-0200	SMM9H00L
2101-0200	SMM8W04A	2101-0200	SMM9A08	2101-0200	SMM9H00V
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2101-0200	SMM8W05A	2101-0200	SMM9A12J	2101-0200	SMM9K01
2101-0200	SMM8W03D	2101-0200	SMM9A12T	2101-0200	SMM9K01AT
2101-0200	SMM8W03	2101-0200	SMM9A09	2101-0200	SMM9K01T
2101-0200	SMM8W05D	2101-0200	SMM9A09K	2101-0200	SMM9K01TT
2101-0200	SMM8W00A	2101-0200	SMM9A09L	2101-0200	SMM9K02A
2101-0200	SMM8W00E	2101-0200	SMM9A10	2101-0200	SMM9K03
2101-0200	SMM8W00J	2101-0200	SMM9A11	2101-0200	SMM9K02
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2101-0200	SMM8V02J	2101-0200	SMM9E01	2101-0200	SMM9L01
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2101-0200	SMM8W06H	2101-0200	SMM9E03	2101-0200	SMM9L02E
2101-0200	SMM8W05H	2101-0200	SMM9E00	2101-0200	SMM9L02M
2101-0200	SMM8W00H	2101-0200	SMM9C00A	2101-0200	SMM9L03
2101-0200	SMM8W07	2101-0200	SMM9C00D	2101-0200	SMM9L03A
2101-0200	SMM8W07K	2101-0200	SMM9C00	2101-0200	SMM9L03D
2101-0200	SMM8W07L	2101-0200	SMM9C00J	2101-0200	SMM9L03E
2101-0200	SMM8W08	2101-0200	SMM9C00K	2101-0200	SMM9L04
2101-0200	SMM8W08E	2101-0200	SMM9E05A	2101-0200	SMM9L04D
2101-0200	SMM8W07A	2101-0200	SMM9E04	2101-0200	SMM9L04E
2101-0200	SAMPLE25	2101-0200	SMM9E04A	2101-0200	SMM9L05
2101-0200	SMM8W08EE	2101-0200	SMM9E04D	2101-0200	SMM9L04A
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2101-0200	SMM9A00R	2101-0200	SMM9E05	2101-0200	SMM9L07A
2101-0200	SMM9A00T	2101-0200	SMM9E04T	2101-0200	SMM9L09
2101-0200	SMM9A01	2101-0200	SMM9E04TT	2101-0200	SMM9L09A
2101-0200	SMM9A01E	2101-0200	SMM9E06	2101-0200	SMM9L09D
2101-0200	SMM9A01EL	2101-0200	SMM9E06A	2101-0200	SMM9V00
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2101-0200	SMM9A03P	2101-0200	SMM9H01T	2101-0200	SMM9V08A
2101-0200	SMM9A04	2101-0200	SMM9H01K	2101-0200	SMM9V08
2101-0200	SMM9L09E	2101-0200	SMM9N07JK	2101-0200	SMM9V08AA
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2101-0200	SMM9L08A	2101-0200	SMM9T00	2101-0200	SMM9V04

2101-0200	SMM9A09P	2101-0200	SMM9T00A	2101-0200	SMM9V09
2101-0200	SMM9K01L	2101-0200	SMM9T02	2101-0200	SMM9V09A
2101-0200	SMM9L06	2101-0200	SMM8V07A	2101-0200	SMM9V09K
2101-0200	SMM9M01L	2101-0200	SMM7E01T	2101-0200	SMM9V03
2101-0200	SMM9M01	2101-0200	SMM7K01AA	2101-0200	SMM9V02E
2101-0200	SMM9M01A	2101-0200	SMM9T00K	2101-0200	SMM9V02H
2101-0200	SMM9M03	2101-0200	SMM9T00J	2101-0200	SMM9V02K
2101-0200	SMM9M03A	2101-0200	SMM9T03	2101-0200	SMM9V09E
2101-0200	SMM9M03D	2101-0200	SMM9T03A	2101-0200	SMM9V09L
2101-0200	SMM9M03E	2101-0200	SMM9T03D	2101-0200	SMM9V09LE
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2101-0200	SMM9M02A	2101-0200	SMM9T03N	2101-0200	SMM9V00HJ
2101-0200	SMM9M02L	2101-0200	SMM9T03L	2101-0200	SMM9V00JH
2101-0200	SMM9M00	2101-0200	SMM9T03M	2101-0200	SMM9V00H
2101-0200	SMM9L10A	2101-0200	SMM8W00M	2101-0200	SMM9N03
2101-0200	SMM9N02M	2101-0200	SMM8V01T	2101-0200	SMM9N04
2101-0200	SMM9N02	2101-0200	SMM8V07T	2101-0200	SMM9N06
2101-0200	SMM9N00	2101-0200	SMM8W00T	2101-0200	SMM9N06A
2101-0200	SMM9N00X	2101-0200	SMM8V03T	2101-0200	SMM9N07
2101-0200	SMM9N00Y	2101-0200	SMM8V05T	2101-0200	SMM9N08
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2101-0200	SMM9N02J	2101-0200	SMM9V01	2101-0200	SMM9N07A
2101-0200	SMM9N01	2101-0200	SMM9V01A	2101-0200	SMM9N07AA
2101-0200	SMM9N01A	2101-0200	SMM9V01T	2101-0200	SMM9N08A
2101-0200	SMM9N01J	2101-0200	SMM9V01D	2101-0200	SMM9N08D
2101-0200	SMM9N05A	2101-0200	SMM9V01J	2101-0200	SMM9N06T
2101-0200	SMM9N05	2101-0200	SMM9V01X	2101-0200	SMM9N06TA
2101-0200	SMM9N05D	2101-0200	SMM9V00A	2101-0200	SMM9N07M
2101-0200	SMM9N07J				

**STRYKER ORTHOPAEDICS
URGENT MEDICAL DEVICE RECALL
NOTIFICATION BUSINESS REPLY FORM**

Aug 22nd, 2016

FSCA identifier: Product Field Action RA2016-107
Type of Action: Field Safety Corrective Action: **Return to Supplier**
Description: Trident Universal Impactor/Positioner
Catalog #: 2101-0200
License #: DE0004060
Lot Code: XXXXXXXXXX
Product owner: Howmedica Osteonics Corp., 325 Corporate Drive, Mahwah, NJ 07430, USA
License holder: Stryker Singapore Pte Ltd, 108 Pasir Panjang Road #03-04 Golden Agri Plaza
Singapore 118535

I have received the product recall letter from Stryker Orthopaedics dated Aug 22nd, 2016 stating that the company has initiated a voluntary lot-specific recall of the above referenced instrument.

Hospital Name

Date

Hospital Representative
(Name and signature)

Hospital stamp

**PLEASE COMPLETE THIS FORM WITHIN 5 BUSINESS DAYS AND RETURN IT VIA EMAIL
(ASEAN.PMS@stryker.com) OR HAND TO YOUR STRYKER SALES REPRESENTATIVE**