# URGENT Field Safety Notice: RA 2016-107
## Trident Universal Impactor/Positioner

**Description:** Trident Universal Impactor / Positioner

**Product Code:** 2101-0200

**Lot Number:** See attached list

Dear Customer,

Stryker Orthopaedics has initiated a 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 and harms

The potential hazards may include:
- Protruding thread length.
- Excessive stress on bone.

The potential harms may include:
- Complications associated with extended hip surgery time of < 15.
- Intraoperative fracture.
- Loss of initial mobility during post-op recovery.
- Periprosthetic fracture.
- 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.

**Stryker UK**
Stryker House, Hambridge Road, Newbury, Berks. RG14 5AW | P +44 1635 262400 | F +44 1635 580300| stryker.com

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

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action.

We request that you read this notice carefully and complete the following actions:

1. Immediately check your internal inventory and quarantine all subject devices pending return to Stryker.

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

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

4. 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.

5. Please inform Stryker of any adverse events concerning the use of the subject devices.
    a) Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.

6. Complete the attached customer response form. It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter. Therefore please complete even if you no longer have any of the subject devices in your physical inventory.

7. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA
    a) On receipt of the form, a Stryker Representative will contact you to organise any applicable ongoing actions.

We request that you respond to this notice within 7 calendar days from the date of receipt.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name: Nina Goddard
Position: RAQA Specialist
Telephone: 01635 262 476
Fax: 01635 262 464
E-mail: nina.goddard@stryker.com

In line with the recommendations of the Meddev Vigilance Guidance document Ref 2.12-1, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker we thank you sincerely for your help and support in completing this action within the target date and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Yours faithfully,

Nina Goddard
Regulatory Affairs and Quality Assurance

stryker

## List of Affected Lot Numbers

| 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 |
| 2101-0200 | SMM7E02 | 2101-0200 | SMM7N00A | 2101-0200 | SMM8M01A |
| 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 |
| 2101-0200 | SMM7L00J | 2101-0200 | SMM7M03A | 2101-0200 | SMM8S02 |
| 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 |
| 2101-0200 | SMM7M01 | 2101-0200 | SMM7M04 | 2101-0200 | SMM8T00A |

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|---|---|---|---|---|---|
| 2101-0200 | SMM7A02T | 2101-0200 | SMM7M04L | 2101-0200 | SMM8V01 |
| 2101-0200 | SMM7M00 | 2101-0200 | SMM7M03K | 2101-0200 | SMM8V01A |
| 2101-0200 | SMM8W02 | 2101-0200 | SMM8L01 | 2101-0200 | SMM8V01D |
| 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 |
| 2101-0200 | SMM8W05 | 2101-0200 | SMM9A12 | 2101-0200 | SMM9K00 |
| 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 |
| 2101-0200 | SMM8W00K | 2101-0200 | SMM9A11D | 2101-0200 | SMM9K04 |
| 2101-0200 | SMM8W00 | 2101-0200 | SMM9A07L | 2101-0200 | SMM9L00 |
| 2101-0200 | SMM8V02J | 2101-0200 | SMM9E01 | 2101-0200 | SMM9L01 |
| 2101-0200 | SMM8W00D | 2101-0200 | SMM9E02 | 2101-0200 | SMM9L02 |
| 2101-0200 | SMM8V07 | 2101-0200 | SMM9E02A | 2101-0200 | SMM9L02A |
| 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 |
| 2101-0200 | SMM9A00 | 2101-0200 | SMM9E04E | 2101-0200 | SMM9L07 |
| 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 |
| 2101-0200 | SMM9A02 | 2101-0200 | SMM9E06D | 2101-0200 | SMM9V02 |

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|---|---|---|---|---|---|
| 2101-0200 | SMM9A02E | 2101-0200 | SMM9A03HD | 2101-0200 | SMM9V02A |
| 2101-0200 | SMM9A03 | 2101-0200 | SMM9A12X | 2101-0200 | SMM9V02D |
| 2101-0200 | SMM9A03K | 2101-0200 | SMM9H01 | 2101-0200 | SMM9V05 |
| 2101-0200 | SMM9A03L | 2101-0200 | SMM9H01A | 2101-0200 | SMM9V07 |
| 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 |
| 2101-0200 | SMM9L10 | 2101-0200 | SMM9N07N | 2101-0200 | SMM9V06 |
| 2101-0200 | SMM9L08 | 2101-0200 | SMM9T01 | 2101-0200 | SMM9V09J |
| 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 |
| 2101-0200 | SMM9M02 | 2101-0200 | SMM8W01AA | 2101-0200 | SMM9V09LL |
| 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 |
| 2101-0200 | SMM9N02K | 2101-0200 | SMM8V07TT | 2101-0200 | SMM9N08E |
| 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 | | | | |

# RA 2016-107: PFA Acknowledgement Form

I acknowledge receipt of the Field Safety Notice for RA 2016-107 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 |
|---|---|---|---|
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**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**