ANNEX 1

Urgent Field Safety Notice
RA2016-107 – UPDATE
Trident Universal Impactor/ Positioner

Product Field Action #:	RA 2016-107
Description:	Trident Universal Impactor/Positioner
Catalog No.:	2101-0200
Lot Codes:	See attached list (UPDATE)

October XX, 2016

,**UPDATE:**

Last xxxx we sent you Field Safety Notice RA 2016-107.
Now we are providing clarity regarding information about the batches affected.
The rest of the action does not change.
Please consider as affected all batches shown on the list and all batches that begin with the digits shown in the list

For a better understanding, please find an example:

In the list you have the batch: SMM7A01
If your product show *SMM7A01* is affected, if it shows: *SMM7A01*TT, it's also affected.

Dear XXX

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 and harms:

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

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. If you have issues to read the batch number, please consider it as affected

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 XXX calendar days from the date of receipt. The target date for completion of this action is XXX and your timely response will enable us to ensure that we meet this target.

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: Position: email:

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....

ANNEX I

All batches shown on the list and all batches that stars with the digits shown in the list:

SAMPLE25	SMM7N02	SMM8W05	SMM9L03
SMM6C00	SMM7N03	SMM8W06	SMM9L04
SMM6N00	SMM7N04	SMM8W07	SMM9L05
SMM6N01	SMM8C00	SMM8W08	SMM9L06
SMM6N02	SMM8L00	SMM9A00	SMM9L07
SMM6N03	SMM8L01	SMM9A01	SMM9L08
SMM6N04	SMM8L02	SMM9A02	SMM9L09
SMM7A00	SMM8L03	SMM9A03	SMM9L10
SMM7A01	SMM8L04	SMM9A04	SMM9M00
SMM7A02	SMM8L05	SMM9A05	SMM9M01
SMM7C01	SMM8L06	SMM9A06	SMM9M02
SMM7C02	SMM8L07	SMM9A07	SMM9M03
SMM7E00	SMM8L08	SMM9A08	SMM9N00
SMM7E01	SMM8M00	SMM9A09	SMM9N01
SMM7E02	SMM8M01	SMM9A10	SMM9N02
SMM7E03	SMM8N00	SMM9A11	SMM9N03
SMM7K00	SMM8N01	SMM9A12	SMM9N04
SMM7K01	SMM8N02	SMM9C00	SMM9N05
SMM7K02	SMM8S00	SMM9E00	SMM9N06
SMM7K03	SMM8S01	SMM9E01	SMM9N07
SMM7L00	SMM8S02	SMM9E02	SMM9N08
SMM7M0	SMM8T00	SMM9E03	SMM9T00
SMM7M00	SMM8V00	SMM9E04	SMM9T01
SMM7M01	SMM8V01	SMM9E05	SMM9T02
SMM7M02	SMM8V02	SMM9E06	SMM9T03
SMM7M03	SMM8V03	SMM9H00	SMM9V00
SMM7M04	SMM8V04	SMM9H01	SMM9V01
SMM7M05	SMM8V05	SMM9K00	SMM9V02
SMM7M06	SMM8V06	SMM9K01	SMM9V03
SMM7M07	SMM8V07	SMM9K02	SMM9V04
SMM7M08	SMM8W00	SMM9K03	SMM9V05
SMM7M09	SMM8W01	SMM9K04	SMM9V06
SMM7M10	SMM8W02	SMM9L00	SMM9V07
SMM7N00	SMM8W03	SMM9L01	SMM9V08
SMM7N01	SMM8W04	SMM9L02	SMM9V09

STRYKER ORTHOPAEDICS
URGENT MEDICAL DEVICE RECALL
NOTIFICATION BUSINESS REPLY FORM

August 18, 2016

Product Field Action #: RA 2016-107 **UPDATE**
Description: Trident Universal Impactor/ Positioner
Catalog No.: 2101-0200
Lot Codes: See attached list **UPDATED**

I have received the product recall letter from Stryker Orthopaedics dated August 18, 2016 stating that the company has initiated a voluntary, lot-specific recall of the above referenced instrument.

_____ _____
Stryker Branch/Hospital Name Date

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

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

email: **strykerortho6536@stericycle.com**
fax: **877-546-04444**