URGENT MEDICAL DEVICE
RECALL NOTIFICATION
Scorpio Patella Assembly Instrument

August xx, 2016

Product Field Action #: RA 2016-098
Description: Scorpio Patella Assembly Instrument
Catalog No.: 3182-1000
Lot Codes: See attached list

Dear XXX,

Stryker Orthopaedics has initiated a voluntary, lot-specific recall for the Scorpio Patella Assembly Instrument. 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 four (4) reports of disassociated components of the Scorpio Patella Assembly Instrument. An investigation revealed that the press-fit specifications between the pin(s) and either one or both clamping subcomponents were not met. No adverse patient consequences were reported.

Potential Hazards:

The instrument components, including pins and clamping subcomponents may potentially disassociate and fall into the wound intraoperatively, necessitating retrieval. As such, the potential harms may include:

- Complications associated with extended surgery time of less than 15 minutes.
- Complications associated with extended surgery time of 31-60 minutes.
- Local inflammatory response.
- Tissue Damage
- Revision surgery to retrieve loose components.
- Inflammatory response.

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) indicates that "instruments with moving parts should be operated to check correct operation". Additionally, the Instructions for Use (QIN 4382, Rev. D) states that "instruments with articulating surfaces must be tested for movement." Performing these inspections as instructed may result in the device disassociating prior to reaching the operating room, which could mitigate all of the potential hazards.

If a pin disassociates, the Scorpio Patella Assembly Instrument cannot be used, thereby increasing awareness of the disassociation.
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.

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 to 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 organizations.

    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.
    Please comply with any local regulations concerning the notification of adverse events to your National or local Competent Authorities.

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 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.
    On receipt of the form, a Stryker Representative will contact you to organize 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:
Position:
Email
Telephone

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 cause. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remaining on the market.

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STRYKER ORTHOPAEDICS
URGENT MEDICAL DEVICE RECALL
NOTIFICATION BUSINESS REPLY FORM

August 1, 2016

Product Field Action #: RA 2016-098
Description: Scorpio Patella Assembly Instrument
Catalog No.: 3182-1000
Lot Codes: See attached list

I have received the product recall letter from Stryker Orthopaedics dated July XX, 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:

Affected lots for Patella Assembly Instrument (RA2016-098)

RD8E100	RD6W102M	RD5H286A	RD2V022	RD2K049
RD8A054TT	RD6W103	RD5H286J	RD2T037A	RD7A076M
RD8A054T	RD6S136A	RD5H286	RD2V031C	RD5N361T
RD8E099M	RD6V112A	RD4M068J	RD2V021C	RD7A076
RD8E099A	RD6V112	RD4E226W	RD2V021	RD7A074H
RD8E099	RD6W102	RD4S220W	RD2V023X2	RD6W103A
RD8A054A	RD6S136M	RD4M069D	RD2V023X3	RD6V108
RD8E099D	RD5W148M	RD4S220	RD2V023	RD7A074
RD8A053A	RD5M237K	RD4S220A	RD2V031A	RD7A074A
RD8A054	RD5T290X	RD4S220A1	RD2V023X1	RD6W103M
RD8A053T	RD5T290A	RD4M069	RD2V031	RD5K116A
RD7K062L	RD6S137A	RD4L128X1	RD2V031X2	RD5M236T
RD8A052A	RD5W148A	RD4L128V	RD2V031X1	RD5K116T
RD8A052E	RD6S137	RD4E226J	RD2N030K	RD3V002A
RD8A052	RD6S136	RD4M068	RD2T037	RD5M237
RD8A053	RD5W148X	RD4L128	RD2T037X	RD5K116N
RD7E128D	RD5W148	RD4E226M	RD2N030E	RD5K116
RD5T290H	RD5T290M	RD4E226L1	RD2N030S	RD5M236
RD7E128T	RD5T290E	RD4C230L	RD2N030X	RD5H286L
RD5S262D	RD5T290	RD4E226L	RD2N030XX	RD3T155L
RD5T290W	RD5T290D	RD4E226	RD2N030	RD2V021E
RD7K062E	RD5N361A	RD4C162L	RD2K068W	RD2V022W
RD5S262X	RD5S305J	RD4C162	RD2N030X1	RD2V021S
RD7E128Y	RD5S305M	RD4C230	RD2M019E	RD2V022K
RD7A076MA	RD5N361M	RD4C230X	RD2M039	RD2V022E
RD6W102MA	RD5S305	RD3V002P	RD2M019H	RD2V021H
RD7K062A	RD5S262A	RD3V002X1	RD2K049H	RD2V023E
RD7K062	RD5S262M1	RD3V002X2	RD2M003H	RD2T037W
RD7E128H	RD5S262M	RD3V002D1	RD2M038H	RD2K068X1
RD7A076A	RD5S262J	RD3V002	RD2K068B	RD2K068
RD7E128A	RD5S262	RD3V002D	RD2M003	RD2K049R
RD7E128	RD5N361H	RD3V206D	RD2M038	RD2K049E
RD6W103D	RD5M259M	RD3T160L1	RD2M019	RD2K017E
RD6V108J	RD5N361	RD3V206X1	RD2K068S	RD2H056
RD6V108K	RD5H286D	RD3T155L1	RD2K056S	RD2K056
RD6V108H	RD5M259T	RD3T160L3	RD2K065S	RD2K065
RD7A076H	RD5M236H	RD3T160	RD2K049S	RD2K017
RD6V112M	RD5M259	RD3T160L2	RD2K068E	
RD7A074D	RD5M237L	RD3T160L	RD2H056E	
RD7A076J	RD5K116J	RD3V206	RD2K065E	

RD6V112H	RD4S220D	RD3T155	RD2K056E	