Stanmore Implants

Stanmore Implants
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Field Safety Notice PR 2016011

17 May 2019

URGENT: Field Safety Notice UPDATE

FSCA identifier: Product Field Corrective Action – **PR 2016011**

Type of Action: Field Safety Corrective Action

Description: Femoral Head with an incorrect offset

Affected Product / Lot Number: B15652

Dear Customer

Further to our letter dated the 18th of February 2019, we informed you that for the potential hazards/harms, technical and medical assessments were underway. We now write to inform you that these have been completed and the full list of the potential hazards/harms is described below. The risk mitigation has also been updated because of the potential hazards/harms.

By way of summary, on the 15th of Feb 2019, Stanmore Implants Worldwide Ltd. (SIW) has initiated a lot specific product recall for the product referenced in the table below:

Stock Code	Batch Number
msfmh/cc28-3.5	B15652

Issue

It has been identified that a box labelled as 28mm Modular Femoral Head with a -3.5 offset (msfmh/cc28-3.5) when opened did not contain the correct head. The head was identified as 28mm Modular Femoral Head with a +3.5 offset (etched 28+3.5), resulting in a discrepancy in the offset information (+3.5 mm vs -3.5 mm).

The Potential Hazards/ Harms:

Conflicting information not identified, or alternate component unavailable. This may result in:

1. Implantation of suboptimal femoral head resulting in restricted range of motion.
2. Implantation of femoral head with suboptimal offset generating leg length discrepancy.

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Risk Mitigation:

1. Although the incorrect components were provided, the markings on the device were correct, identifying the head as size 28mm and offset as +3.5. If the product markings are reviewed, it will confirm that there is a discrepancy in the offset, and allow for mitigating actions such as additional preparation, tissue release, tissue balance or alternate component selection to be implemented.
2. If a femoral head with a different offset is selected, it may have an impact on leg length. Clinically relevant limb length discrepancies depend on the patient's height, activity and age, but a breakpoint of 20 mm is considered acceptable as a reference. The potential 7 mm impact (+3.5 and – 3.5 mm) to the length due to the offset difference is significantly smaller than the 20 mm reference, also the device is placed at an angle. Therefore, it is not expected to be noticed by the patient in terms of leg length.

Actions Needed:

1. If you haven't already done so, immediately check your internal inventory and quarantine the affected device.
   (Please note that device would be in consignment/loan kits provided by SIW).
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 SIW if any of the affected device has been distributed to other organisations.
   (Please provide contact details so that SIW can inform the recipients appropriately).
5. Complete and sign the enclosed acknowledgment Form. Email a copy to Customer Services at Stanmore.mets.requests@stryker.com
6. Return any affected device to your SIW Representative or send to
   FAO: Amelia Wiltshire
   210 Centennial Avenue,
   Elstree, Hertfordshire, WD6 3SJ,
   United Kingdom

It is our responsibility to ensure that customers who have received this affected device also receive this important communication.

Please assist us in meeting our regulatory obligation by sending back the attached Business Reply Form within 5 days.

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Stanmore Implants Worldwide Limited maintains its commitment to developing, manufacturing and marketing the highest quality products for surgeons and patients. We apologize for any inconvenience this Field Safety Corrective Action may create and appreciate your cooperation with our request.

If you have any further enquiries, please contact your local Sales Representative.

Yours Sincerely,

Dervillia Murphy

Dervillia Murphy
Director, Quality Assurance and Regulatory Compliance
210 Centennial Avenue,
Elstree, Hertfordshire, WD6 3SJ,
United Kingdom
+44 20 8238 6500
Dervillia.Murphy@stryker.com
Business hours: 9am – 5pm (GMT)

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STANMORE IMPLANTS WORLWIDE LIMITED
FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGMENT FORM

17 May 2019

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Type of Action: Field Safety Corrective Action

Description: Femoral Head with an incorrect offset

Affected Product / Lot: B15652

I, the undersigned, confirm that I have received the enclosed communication from Stanmore Implants Worldwide Limited (SIW).

Facility:

_____ _____

Customer (Signature) Date

_____

Customer Name (PRINT)

Please email this signed and dated form to Stanmore.mets.requests@stryker.com