Stanmore Implants

Stanmore Implants
210 Centennial Avenue
Centennial Park
Elstree
WD6 3SJ
United Kingdom

T +44 (0) 20 8238 6500
F +44 (0) 20 8953 7443
www.stanmoreimplants.com

Field Safety Notice PR 2016011

18 Feb 2019

URGENT: Field Safety Notice

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,

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 with msfmh/cc28+3.5), resulting in a discrepancy in the offset information (+3.5 mm vs -3.5 mm).

Potential Hazards:

Technical and medical assessments are currently underway to determine any potential hazards associated with the use of the product. An additional communication will be forwarded upon completion of the internal investigation on this issue.

Risk Mitigation:

The femoral heads are etched with size and offset information. Although the product packaging for this batch may not match the product contained within, the etched details on the device would increase the likelihood that the surgeon or surgical staff would recognise that the incorrect device was contained in the package.

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Actions Needed:

1. 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

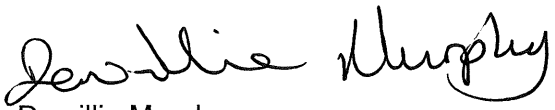
It is our responsibility to ensure that customers who have received this affected device also receive this important communication.

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

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
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

18 Feb 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