Stanmore Implants

Stanmore Implants
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Field Safety Notice RA2016-159

December 20, 2016

Field Safety Notice

FSCA identifier: Product Field Corrective Action - **RA2016-159**

Type of Action: Urgent Field Safety Corrective Action: **Recall**

Description: Humeral Integral Shaft and Stem Labelling Discrepancy

Product Name:	**Catalogue Number:**
Humerus Integral Shaft and Stem implant component (80mm stem length)	mhiss/8C
Humerus Integral Shaft and Stem implant component (100mm stem length)	mhiss/10C

Batch Numbers: Please refer to attached list

These components form part of the METS Modular Proximal Humerus System.

Dear Distributor/ Healthcare Provider/ Surgeon:

On 20th December, 2016, Stanmore Implants Worldwide Limited (SIW, the manufacturer) initiated a lot-specific, product recall for the product referenced above. A customer complaint reported that the product labelling incorrectly identified the stem length size. The recall is being initiated to recall all affected lots.

Issue:

Labelling affixed on the packaging and the ordering information section (section 4.0) of the accompanying surgical procedure document (QF124/2/MAR12) incorrectly identified the stem length size as 75 mm for both mhiss/8C (80mm) and mhiss/10C (100mm) components. There is one reported complaint highlighting the aforementioned issue.

Potential Hazards:

The potential hazard associated with the incorrectly labelled Humeral Integral Shaft and Stem:

1. Surgeon uses the mislabelled Humeral Integral Shaft and Stem component

The aforementioned potential hazard may result in one or more of the following patient harm:

1. Complications associated with a delay in surgery of < 15 minutes; surgery is delayed while surgeon confirms length size of implant against trial component.

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Risk Mitigation

The instructions for use section contained within the surgical procedure document, provided with METS Modular Proximal Humerus System, references the correct stem length size (80mm or 100mm). Further, the trialing process, with accompanying trial components, would verify the reaming depth and trialing components correspond to the correct stem length size (80mm or 100mm).

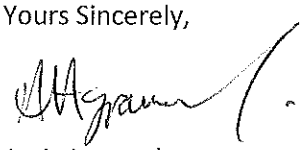
In the occurrence that any of the affected products are unused, please follow the below advice:

1. Immediately check your internal inventory and quarantine all subject devices.
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 subject devices have been distributed to other organisations. *(Please provide contact details so that SIW can inform the recipients appropriately).*
5. Complete the attached customer response form and list of affected batches form.
   (Please complete this form even if you do not have any product to return. This will preclude the need for SIW to send any reminder notice)
6. Please inform SIW of any adverse events associated with the use of the device.
7. Return the completed form and any affected devices, together with accompanying surgical procedure, to your SIW Representative.

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 the undersigned.

Yours Sincerely,



Amit Agrawal
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0044 208 238 6518
amit.agrawal@stanmoreimplants.com
Business hours: 9am – 5pm (GMT)

Attachments:
1. Acknowledgement Form
2. List of affected batch numbers

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STANMORE IMPLANTS WORLDWIDE LIMITED
FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGMENT FORM

December 20th, 2016

NAME:

ADDRESS:

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Humerus Integral Shaft and Stem implant component (100mm stem length)	mhiss/10C

Batch Numbers: Please refer to attached list

List of affected batches form appended ☐

I have received the notification from Stanmore Implants Worldwide Limited dated December 13, 2016 stating that they initiated a Field Safety Corrective Action of the above referenced product.

_____ _____

Customer (Signature) Date

_____

Customer Name (Print)

Please email this signed and dated form to Amelia.Wiltshire@stanmoreimplants.com

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LIST OF AFFECTED BATCH NUMBERS

Product Code	Batch Number	Returning Product*
MHISS/10C	B10090	
	B3697	
	B8766	
MHISS/8C	B10089	
	B11666	
	B9355	

*Please indicate the number of units