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 RA2016-155

11/25/2016

URGENT: Field Safety Notice

FSCA identifier: Product Field Corrective Action **RA2016-155**

Type of Action: Field Safety Corrective Action: Recall

Description: METS Modular Tumour System Product Packaging

Catalogue Numbers and Batch Numbers: See attached list of affected batches form.

Dear Distributor/Healthcare Provider/Surgeon:

On 24th November, 2016, Stanmore Implants Worldwide Limited (SIW, the manufacturer) initiated a voluntary, lot-specific product recall for the products referenced below under the heading "List of affected batch numbers".

The intent of this letter is to list all known hazards potentially associated with the use of the product covered by this Safety Notice and list the risk mitigation factors.

Issue:

Stanmore has received 5 customer inquiries reporting that at least one pouch of the double pouch packaging configuration has been punctured by the tip of the device's stem.

In some instances, the implant assemblies have punctured through both inner and outer pouches, compromising the sterile barrier.

The potential risks associated with these events are listed below.

Potential Hazards:

In the event that the packaging has been compromised, the following potential hazards may occur:

(1) Device is not utilized during surgery and replacement device is identified.
(2) Alternative sized device available in hospital stock is utilized. This could result in up to 15-minute delay to perform additional bone and soft tissue preparation to accommodate alternative size implants.
(3) Non-sterile implant.

The aforementioned potential hazards may result in one or more of the following patient harms:

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

(1) Complications associated with a delay in surgery 31- 60 minutes while new device is obtained.
(2) Intraoperative conversion surgery
(3) Infection

Risk Mitigation

There is a potential for the pouch failure to be identified, as the puncture of the pouches is easily recognizable, which would alert the surgeon to use an alternate device. It is standard surgical practice to immediately open the outer and inner pouch within minutes of use. This practice ensures a purposeful and focused inspection just prior to use. In all the reported events, the packages have been identified and the packages have been returned to Stanmore. Nonetheless, the above mentioned potential hazards and harms have been identified that may arise from damaged packaging components whether or not they are identified.

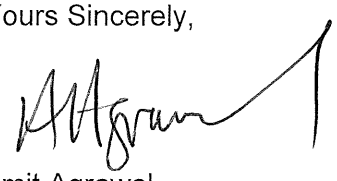
In the occurrence that any of the affected products are unused, please follow the below advice:

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.
7. Return the completed form and any affected devices 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 your local Sales Representative.

Yours Sincerely,



Amit Agrawal
Senior Manager, Regulatory Affairs & Compliance
210 Centennial Avenue,
Elstree, Hertfordshire, WD6 3SJ,
United Kingdom
0044 208 238 6518
amit.agrawal@stanmoreimplants.com
Business hours: 9am – 5pm (GMT)

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

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

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

STANMORE IMPLANTS WORLWIDE LIMITED
FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGMENT FORM

Nov 25th, 2016

NAME:

ADDRESS:

CITY, STATE ZIP, POSTCODE:

FSCA identifier: Product Field Action **RA2016-155**

Description: **METS Product Packaging**

Catalogue and Batch Numbers:

List of affected batches form appended ☐

Type of Action: Return to Supplier

I have received the notification from Stanmore Implants Worldwide Limited dated Nov 25th, 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

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

List of affected batch numbers

Product Code	Batch Number	Returning Product*
mkfh/SmLg	A10757	
	A4008	
mkfh/SmSt	A11924	
mkfh/StdLg	A12232	
mkfh/StdSt	A12047	
mkrhm/SmLg	A10625	
mkrhm/SmSt	A12136	
	A15920	
mkrhm/StdLg	A12401	
mkrhm/StdSt	A12227	
	A14239	
	A14467	
	A14987	
	A15797	
msfshft/120	B11419	
	B9611	
msfshft/135	B10445	
	B9921	
msfshft/150	B13415	
msiss/15x27C	B13677	
msiss/15x30C	B13340	
	B14216	
msiss/30x27C	B12779	
msiss/30x30C	B11437	
msiss/O15x30x38C	B11810	
	B14464	
	B14941	
msiss/O15x36x44C	B13678	
	B14590	
msiss/O30x30x38C	B11660	
	B13147	

*Please indicate the number of units