

URGENT Field Safety Notice

Product Name: Femoral Stem Curved msstm/13x150

FSCA-identifier FSCA 796

Type of action: Field Safety Corrective action

Date: 28th February 2014

Details on affected devices:

Description: - Femoral Stem Curved

Part Reference Number:- msstm/13x150

Batch Number and expiry date:- B10800 expiry date 2017-11

Description of the problem:

Stanmore Implants Worldwide is issuing this communication to inform all users of the above device and the specific batch referenced that an issue has been identified.

We have identified that the stems in this batch have not been set in accordance with the device specifications, resulting in the stems being straight and not curved over the length of the stem.

This could result in a range of possible issues which include an insufficient cement mantle, pain, loosening, bone erosion, and early failure.

Stanmore Implants Worldwide can confirm that it has not had any reported incidents as a result of this issue.

Advise on action to be taken by the user:

- Can you please identify and quarantine any devices that you might have from the affected batch specified. Do not use any affected devices.
- For any devices that have been implanted we recommend that lateral x-rays are taken to determine the fit of the stem within the bone canal. These patients should receive regular follow ups and close monitoring.
- Can you please complete and return the form attached to Stanmore Implants Worldwide Limited.

Transmission of this Field Safety Notice:



**STANMORE IMPLANTS WORLDWIDE
FIELD SAFETY NOTICE**
210 Centennial Avenue, Centennial Park, Elstree, WD6 3SJ

Please ensure this notice is passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred

Please transfer this notice to other organisations on which this action has an impact

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action

No other devices produced by Stanmore Implants Worldwide Ltd are affected by this notice.

We apologise for any confusion or inconvenience this issue may cause you. If you have any additional questions, please contact us directly.

Contact details Mr Sudha Shunmugam
 METS Product Manager
 sudha.shunmugam@stanmoreimplants.com

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Thank you for your continued support of Stanmore Implants Worldwide Limited

Signature:

A handwritten signature in black ink that reads 'Jon Charters'.

Jon Charters

Director of Regulatory Affairs

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