

To the ATTENTION of: Operating room manager

14 June 2013

URGENT: MEDICAL DEVICE PRODUCT REMOVAL

Part Description / Part Number:

Part Number	Part Description	Lot Number
03.632.008	Reduction Instrument for Spondylolisthesis, standard, for Matrix 5.5	all lots

Dear Sir/Madam

Synthes is initiating a medical device removal of all lots of the Reduction Instrument for Spondylolisthesis, standard, for Matrix 5.5. Our records indicate that you have inventory that is impacted by this removal.

Description of problem:

Synthes received several complaints that during spine surgery using the Reduction Instrument for Spondylolisthesis, standard, for Matrix 5.5 (03.632.008), the reduction insert broke and pieces broke off. Once the reduction insert breaks, the instrument does not function as required. Investigation showed that misassembly of the instrument in the operating room is a probable root cause. Out of precaution Synthes has decided to remove the product from the market.

Patient risk:

In a hypothetical worst case scenario, the breakage of the insert represents the potential for an unretrieved device fragment. If the insert breaks and fragment(s) are retained there is the potential that they will not be retrieved. Additional operative time may be required to attempt retrieval and X-ray may not be effective to confirm that all fragments have been retrieved because the fragments are radiolucent. If fragments are retained there is the potential for an unfavorable response to the foreign material (chemical, biological or physical) within the body (including implant-related metal debris, wear particles, non-biocompatible materials) to occur

which may trigger a localised reaction. The patient may be symptomatic requiring treatment and non-surgical treatment will not be effective as the disease progresses requiring revision surgery or reoperation. If treated on time, no permanent impairment is expected.

Customer immediate actions:

1. Immediately identify and quarantine all products listed above in a manner that ensures the affected product will not be used anymore.
2. Review, complete, sign and return the attached reply form to your local Synthes sales organisation in accordance with the directions on the form within 5 business days of receipt of this notification.
3. Return any affected product within 30 business days.
4. Forward this notice to anyone in your facility that needs to be informed.
5. If any product listed above has been forwarded to another facility, contact that facility to arrange return.
6. Maintain awareness of this notice until all products listed above have been returned to Synthes GmbH.
7. Maintain a copy of this notice for your records

The applicable regulatory agencies are being notified. Synthes GmbH is voluntarily taking this action.

We apologise for any inconvenience that this product removal may create and appreciate your cooperation with our request. Should you have any queries please do not hesitate to contact your Synthes sales representative.

Thank you for your attention and cooperation.

Synthes GmbH



Field Action Manager



Director Quality Assurance Operations

Cc:

NOTICE: MEDICAL DEVICE REMOVAL**Reduction Instrument for Spondylolisthesis,
standard, for Matrix 5.5****03.632.008, all lots****Verification Section**

- We have located the identified product in stock; returned quantity is documented below, and a copy of this letter is being retained for our records.
- We do not have any identified product in stock; returned quantity is zero. We have retained a copy of this letter for our records.

RETURNED DEVICES (including quantity) and/or COMMENTS:

Name of hospital: _____

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____