

To the ATTENTION of: Operating Room Manager

10 January 2014

URGENT MEDICAL DEVICE PRODUCT RECALL

Part Description / Part Number

Part Number	Part Description	Lot Numbers
487.982	Midface Distractor, complete, distraction length 40 mm, Titanium Alloy (TAN)	Lots prior to 6913910 Please see list on page 4 for more details

Dear Valued Customer,

Synthes GmbH is initiating a voluntary recall of the above mentioned articles and lots of the Midface Distractor, complete, distraction length 40 mm, Titanium Alloy (TAN). Our records indicate that you may have inventory that is impacted by this recall.

Description of the problem:

There is the potential for the anterior footplates to not fit onto the Midface Distractor assembly (part number 487.982) as the tab of some distractors may be oversized. There have been no adverse events associated with this issue.

Potential hazard:

Reasonable probability exists that there may be more than one affected distractor body in a surgical set at a hospital. Because recognition of the defined defect may not be detected until the intraoperative patient treatment period there is the potential that the index surgical goals will not be achieved and a second unanticipated surgical intervention would be required.

Customer immediate actions:

1. Immediately identify and quarantine all unused products listed above in a manner that ensures the affected products will not be used.
2. Review, complete, sign and return the attached reply form to your local DePuy 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. A credit note will be issued for the returned items.
4. Forward this notice to anyone in your facility that needs to be informed.
5. If any product listed below has been forwarded to another facility, contact that facility to arrange return.
6. Maintain awareness of this notice until all products listed below have been returned to DePuy Synthes.
7. Maintain a copy of this notice.

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

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

Thank you for your attention and cooperation.

Synthes GmbH



Claudia Allemann
Field Action Manager



Markus Wien
Director Quality Assurance Operations

NOTICE: MEDICAL DEVICE RECALL R2013799

**Midface Distractor, complete, distraction length 40 mm,
Titanium Alloy (TAN)**

Verification Section

Part Number	Part Description	Lot Numbers
487.982	Midface Distractor, complete, distraction length 40 mm, Titanium Alloy (TAN)	Lots prior to 6913910

- 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:

Hospital name: _____

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____

List of recalled lot numbers R2013799:

Material	Lot number
487.982	1184725
487.982	4695752
487.982	4762480
487.982	4762482
487.982	4762484
487.982	4762485
487.982	4987627
487.982	4987629
487.982	4987630
487.982	4987631
487.982	5202210
487.982	5202218
487.982	5206663
487.982	5206665
487.982	5206666
487.982	5206675
487.982	5298124
487.982	5298125
487.982	5359785
487.982	5359791
487.982	5682058
487.982	5810034
487.982	5837111
487.982	5866840
487.982	6107481
487.982	6123840
487.982	6142716
487.982	6142720
487.982	6240420
487.982	6279876
487.982	6279877
487.982	6504698
487.982	6646270
487.982	6646338
487.982	6707596
487.982	6818435
487.982	6818436
487.982	6818437
487.982	6862526
487.982	6862531
487.982	6913910