

**To the ATTENTION of:
Operating Room Manager**

27 May 2015

**URGENT NOTICE:
MEDICAL DEVICE RECALL – R2014161
Extraction Module for Screws Ø3.5 / 4.0 / 4.5mm**

Part Description, Part- and Lot Numbers

Part Description	Part Number	Lot Numbers
Extraction Module f/Screws Ø3.5 / 4.0 / 4.5mm	68.900.022	8584228

Dear Sir/Madam,

Synthes GmbH is initiating a voluntary medical device recall of the above mentioned Part- and Lot Numbers of the Extraction Module for Screws Ø3.5 / 4.0 / 4.5mm. The Screw extraction set contains instruments required for removing intact screws or damaged screws that are difficult to remove.

Our records indicate that you may have inventory that is impacted by this recall or have been using affected product(s) from a loan set.

Reason for the Recall:

The lid of the Extraction Module for Screws Ø3.5 / 4.0 / 4.5mm (part number 68.900.022) was incorrectly etched with part number 68.900.021, but the module contains the correct tools. This error has been isolated to product lot number 8584228.

Potential hazard:

While filling the VarioCase with the modules, the nonconformance may potentially cause a mismatch between the etching in the VarioCase Tray and on the Module which may lead to surgical delay.

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 and sign the attached reply form on page 3 of this letter and return it to your local DePuy Synthes sales organization in accordance with the directions on the form within 5 business days of receipt of this notification.
3. Return any affected product as soon as possible, but within 30 business days. A credit note will be issued for the returned items.
4. Forward this notice to anyone in your facility who may be responsible for maintaining medical instruments in service.
5. If any of the affected products 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 from your facility to DePuy Synthes.
7. Keep a copy of this notice.

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

Thank you for your attention and cooperation.

Synthes GmbH
ALBERT BECKERS ON BEHALF
OF PIERRE VAN IWAARDEN

Pierre van Iwaarden
Field Action Manager


ON BEHALF OF CHARLES GOLDBERG
Charles Goldberg
Worldwide Director Complaint Management

Cc:

Account Name: _____

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Verification Section

Part Description / Part Number:

Part Description	Part Number	Lot Numbers
Extraction Module f/Screws Ø3.5 / 4.0 / 4.5mm	68.900.022	8584228

____ We have located the identified product in stock; returned quantity is documented below.

____ We acknowledge receipt of this information, but do not have any identified product in stock; returned quantity is zero.

RETURNED DEVICES (including quantity):

Name/Title (please print): _____

Address: _____

Phone Number: _____

Signature and Date: _____

Please complete and return this page your local DePuy Synthes sales organization.

Note: If the Verification Section is answered on behalf of more than one facility and/or individual, please clearly indicate the name and address of the facility and/or individual on this page of the notification.