

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

8 May 2015

**URGENT NOTICE:
MEDICAL DEVICE RECALL – R2014185
CHISEL BLADES**

Part Description, Part- and Lot Numbers

Part Description	Part Numbers	Lot Numbers
Chisel Blade, long, width 10 mm	399.555	A7OA30, T921923, T933948, T935423
Chisel Blade, long, width 16 mm	399.565	A7QA37, T936951
Chisel Blade, long, width 25 mm	399.575	A7OA36, T937762, T966630
Chisel Blade, long, width 5.0 mm	399.585	A7OA30, T939691

Dear Sir/Madam,

Synthes GmbH is initiating a voluntary medical device recall of the above mentioned Part- and Lot Numbers of the Chisel Blade. The Chisel Blades are used in conjunction with the conventional chisel handle (part 399.540) to cut and shape bone during orthopedic surgery.

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

Reason for the Recall:

The incorrect label was applied to the product that is the subject of this action. Certain lots of the Chisel Blades that were shipped to your facility may be labeled as "NOT FOR HUMAN USE; FOR VETERINARY USE ONLY" as displayed in Figure 1.



Figure 1 - Incorrect Label for Part Number 399.565

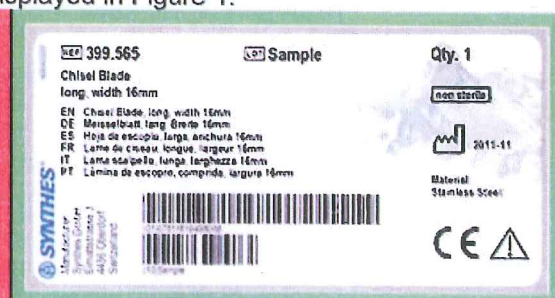


Figure 2 - Correct Label for Part Number 399.565

Potential hazard:

The device is identical to the one used in humans. The incorrect label will not cause or expose the patient and/or user to an increased harm. This wrong information is not relevant to the function of the device.


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 on page 3 of this letter 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 that needs to be informed.
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 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


Pierre van Iwaarden
Field Action Manager FOR CHARLES GOLDBERG

Charles Goldberg
Worldwide Director Complaint Management

Cc:

Account Name: _____

**URGENT NOTICE:
MEDICAL DEVICE RECALL – R2014185
CHISEL BLADES**

Verification Section

Part Description / Part Number:

Part Description	Part Numbers	Lot Numbers
Chisel Blade, long, width 10 mm	399.555	A7OA30, T921923, T933948, T935423
Chisel Blade, long, width 16 mm	399.565	A7QA37, T936951
Chisel Blade, long, width 25 mm	399.575	A7OA36, T937762, T966630
Chisel Blade, long, width 5.0 mm	399.585	A7OA30, T939691

Please verify:

 We have located the identified product in stock; returned quantity is as per 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 to 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.