

To the ATTENTION of: Hospital Personnel

14 October 2015

URGENT NOTICE: MEDICAL DEVICE RECALL – R2015043 Spine-USS II Rod Introduction Pliers

Part Description, Part- and Lot Numbers

Part Description	Part Number	Lot Number
Spine-USS II Rod Introduction Pliers	388.508	A7XA09; A7XA51

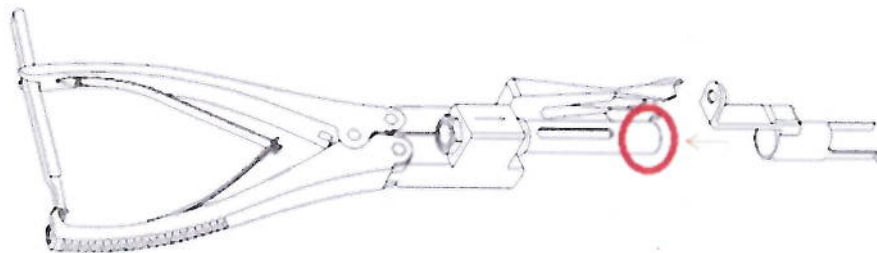
Dear Sir/Madam,

Synthes is initiating a voluntary medical device recall of two lots of Spine-USS II Rod Introduction Pliers. The USS II System is a posterior pedicle screw and hook fixation system (T1–S2) designed to provide precise and segmental stabilization of the spine in skeletally mature patients.

Our records indicate that you may have inventory that is subject to this recall.

Reason for the Field Safety Notification

Investigation revealed that 2 lots of USS II Rod Introduction Pliers manufactured with an out of specification condition have been distributed. This nonconformance may cause difficulty in assembling the Sleeve Pusher onto the Introduction Pliers resulting in an inability to use the instrument as intended.



Oversized cylinders (identified above) may cause difficulty in assembling the Sleeve Pusher onto the Introduction Pliers

Potential Patient Impact

The nonconformance noted above has the potential to result in intraoperative surgical delay, and/or challenges to properly seat the rod and secure the construct which could lead to construct failure. To date, two complaints have been reported that are related to difficulty in assembling the Sleeve Pusher onto the Introduction Pliers resulting in surgical delays of 10 and 30 minutes.

Customer actions

Please verify whether you have any of the affected products and take the following actions, as appropriate.

If you **DO HAVE** any of the identified affected product(s), please take the following steps:

- Ensure anyone in your facility impacted by this notification reads this letter carefully.
- Immediately identify and quarantine all products listed above in a manner that ensures the affected products will not be used.
- Maintain a copy of this communication with any affected product(s) identified above.
- Complete the Verification Section (page 3 of this letter) by checking the appropriate box indicating affected product has been located. Also, please indicate the number of devices found and their Lot Number. Please include your name, title, address, telephone number and signature in the spaces provided.
- Return the completed Verification Section to your local DePuy Synthes contact person.
- Contact your local DePuy Synthes contact person to arrange the return of the affected devices.

If you **DO NOT HAVE** any of the identified affected product(s), please take the following steps:

- Complete the attached Verification Section (page 3 of this letter) by checking the appropriate box indicating that no affected product has been located. Please include your name, title, address, telephone number and signature in the spaces provided. This return documentation acknowledges your receipt of medical device recall information.
- Return the completed Verification Section to your local DePuy Synthes contact person.
- 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 page 3 of the notification.

If any of the affected products has been forwarded to another facility, contact that facility to arrange return and provide them with this letter. Furthermore, keep awareness and a copy of this notice.

The applicable regulatory agencies are being notified.

We apologize for any inconvenience that this Field Safety Notification may create and appreciate your cooperation with our request. Should you have any inquiries please do not hesitate to contact your DePuy Synthes contact person.

Thank you for your attention and cooperation.


Field Action Manager

Sr. Manager, Quality Systems

Cc:

Account Name: _____

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- 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 lot number and quantity):
_____Name/Title (please print):
_____Address:

Phone Number: _____

Signature and Date: _____

RGA # (If applicable): _____

Please complete and return this page your local DePuy Synthes contact person

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.