DePuy Synthes

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DePuy Synthes
COMPANIES OF Johnson & Johnson

To the ATTENTION of:
Operating room manager

17 May 2013

URGENT: MEDICAL DEVICE PRODUCT REMOVAL

Part Description / Part Number:

Part Number	Part Description	Lot Number
359.106	Medullary Reamer Ø 6.0 mm, length 385 mm	all lots
359.107	Medullary Reamer Ø 6.5 mm, length 385 mm	all lots
359.108	Medullary Reamer Ø 7.0 mm, length 385 mm	all lots
359.109	Medullary Reamer Ø 7.5 mm, length 385 mm	all lots
359.110	Medullary Reamer Ø 8.0 mm, length 385 mm	all lots
359.111	Medullary Reamer Ø 8.5 mm, length 385 mm	all lots
359.112	Medullary Reamer Ø 9.0 mm, length 385 mm	all lots
359.113	Medullary Reamer Ø 9.5 mm, length 385 mm	all lots
359.114	Medullary Reamer Ø 10.0 mm, length 385 mm	all lots
359.115	Medullary Reamer Ø 10.5 mm, length 385 mm	all lots

Dear Sir/Madam

Synthes is initiating a medical device removal regarding all lots of the Medullary Reamers Ø 6.0 mm to 10.5 mm. Our records indicate that you have inventory that is impacted by this removal.

Description of problem:

According to the Medical Device Directive 93/42/EEC Synthes regularly updated its technical files. During such an update these products were identified as being difficult to clean due to the coiled design. In addition, evidence of corrosion was found and confirmed. Root cause of corrosion on the interior of the flexible reamer components is related to the presence of thermal oxide and heat tint from heat treating and welding operations performed in an air environment.

Patient risk:

Please note that there has not been any adverse event to patient reported regarding the two issues described above.

However, there is a minimal potential for harm to a patient to occur. This is due to the introduction of foreign material at the operative site originating from the presence of corrosion and / or the retained undefined material that could not be adequately cleaned.

Customer immediate actions:

1. Please remove and return the above mentioned articles / lots from your inventory immediately.

2. Complete the attached reply form indicating your receipt of this letter. Return the completed form by fax or email to your local Synthes sales organisation.

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

Claudia Allemann
Field Action Manager

i.V. S. Müller
Markus Wien
Director Quality Assurance Operations

Cc:

NOTICE: MEDICAL DEVICE REMOVAL

Medullary Reamers Ø 6.0 mm to 10.5 mm

359.106-359.115

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/Title (please print) _____

Phone Number: _____

Signature and Date: _____