

**To the ATTENTION of:
Operating room manager**

06 November 2012

URGENT: MEDICAL DEVICE PRODUCT REMOVAL

Part Description / Part Number: See attached list

MCA	MICRO CURVED ATTACHMENT
MCA5-05SD	0.5MM DIAMOND BALL, 5.6CM
MCA5-06SD	0.6MM DIAMOND BALL, 5.6CM
MCA5-07SD	0.7MM DIAMOND BALL, 5.6CM
MCA5-08SD	0.8MM DIAMOND BALL, 5.6CM
MCA5-15SB	1.5MM FLUTED BALL, 5.6CM
MCA5-15SD	1.5MM DIAMOND BALL, 5.6CM
MCA5-1SB	1MM FLUTED BALL, 5.6CM
MCA5-1SD	1MM DIAMOND BALL, 5.6CM
MCA5-2SB	2MM FLUTED BALL, 5.6CM
MCA5-2SD	2MM DIAMOND BALL, 5.6CM
MCA7-05SD	0.5MM DIAMOND BALL, 7.3CM
MCA7-06SD	0.6MM DIAMOND BALL, 7.3CM
MCA7-07SD	0.7MM DIAMOND BALL, 7.3CM
MCA7-08SD	0.8MM DIAMOND BALL, 7.3CM
MCA7-15SB	1.5MM FLUTED BALL, 7.3CM
MCA7-15SD	1.5MM DIAMOND BALL, 7.3CM
MCA7-1SB	1MM FLUTED BALL, 7.3CM
MCA7-1SD	1MM DIAMOND BALL, 7.3CM
MCA7-2SB	2MM FLUTED BALL, 7.3CM
MCA7-2SD	2MM DIAMOND BALL, 7.3CM

Dear Sir/Madam

Synthes is initiating a Medical Device removal regarding the MCA Cutting Burrs. Our records indicate that you have inventory that is impacted by this removal.

Description of Problem:

During a recent review of documentation we determined that the current directions for use for the MCA cutting burrs (item 18-0079) and MCA Micro Curved Attachment (item 18-0060) do not provide clear details regarding the intended use specifically for the MCA burrs. The MCA burrs are intended for use in delicate bone in otologic procedures such as cochleostomy. The use of the device in dense bone removal may result in cutter/ burr fracture. If a fracture occurs, contact your local Synthes Sales organization by reporting this as a complaint. If the procedure was done successfully, no additional patient follow up is necessary.

Customer Immediate Actions:

1. Please remove and return any MCA items 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 organization

We apologize 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



Heinz Gribi
Manager Complaint Handling Unit

Cc:

NOTICE: MEDICAL DEVICE REMOVAL

MCA Attachments and Cutting Burrs

Verification Section

- We have located the identified product in stock; returned quantity is documented below, and has retained a copy of this letter for our records.
- We do not have any identified product in stock; returned quantity is zero, and has retained a copy of this letter for our records.

RETURNED DEVICES (including quantity):

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____

URGENT DEVICE CORRECTION DETAILS			
Part Number	Description	Qty	Batch
MCA	MICRO CURVED ATTACHMENT		
MCA5-05SD	0.5MM DIAMOND BALL, 5.6CM		
MCA5-06SD	0.6MM DIAMOND BALL, 5.6CM		
MCA5-07SD	0.7MM DIAMOND BALL, 5.6CM		
MCA5-08SD	0.8MM DIAMOND BALL, 5.6CM		
MCA5-15SB	1.5MM FLUTED BALL, 5.6CM		
MCA5-15SD	1.5MM DIAMOND BALL, 5.6CM		
MCA5-1SB	1MM FLUTED BALL, 5.6CM		
MCA5-1SD	1MM DIAMOND BALL, 5.6CM		
MCA5-2SB	2MM FLUTED BALL, 5.6CM		
MCA5-2SD	2MM DIAMOND BALL, 5.6CM		
MCA7-05SD	0.5MM DIAMOND BALL, 7.3CM		
MCA7-06SD	0.6MM DIAMOND BALL, 7.3CM		
MCA7-07SD	0.7MM DIAMOND BALL, 7.3CM		
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