

To the ATTENTION of: Operating Room Manager

16 January 2014

URGENT MEDICAL DEVICE PRODUCT REMOVAL

Part Description / Part Number

Part Number	Part Description	Lot Numbers
QD8-2SB-C-8F	2 mm Carbide Fluted Ball, Standard, 8 Flutes. Use with QD8 Attachments.	please see list
QD8-4B-C-10F	4 mm Carbide Fluted Ball, 10 Flutes. Use with QD8 Attachments.	please see list
QD8-5B-C-10F	5 mm Carbide Fluted Ball, 10 Flutes. Use with QD8 Attachments.	please see list
QD8-7B-C-14F	7 mm Carbide Fluted Ball, 14 Flutes. Use with QD8 Attachments.	please see list
S-15DRMC	1.5 mm x 7.5 mm Cylindrical Carbide Drum. Use with SHORT Attachments.	please see list
S-15DRMC-L	1.5 mm x 7.5 mm Cylindrical Carbide Drum, Extends 25 mm. Use with SHORT Attachments.	please see list
S-1B-C	1 mm Carbide Fluted Ball, Extended Length. Use with SHORT Attachments.	please see list
S-1SB-C	1 mm Carbide Fluted Ball, Standard Length. Use with SHORT Attachments.	please see list
S-2B-C	2 mm Carbide Fluted Ball, Extended Length. Use with SHORT Attachments.	please see list
S-2SB-C	2 mm Carbide Fluted Ball, Standard Length. Use with SHORT Attachments.	please see list
S-3B-C	3 mm Carbide Fluted Ball, Extended Length. Use with SHORT Attachments.	please see list
S-3SB-C	3 mm Carbide Fluted Ball, Standard Length. Use with SHORT Attachments.	please see list
S-4B-C	4 mm Carbide Fluted Ball, Standard Length. Use with SHORT Attachments.	please see list
S-4BL-C	4 mm Carbide Fluted Ball, Extends 27 mm. Use with SHORT Attachments.	please see list
S-5B-C	5 mm Carbide Fluted Ball, Standard Length. Use with SHORT Attachments.	please see list
S-6B-C	6 mm Carbide Fluted Ball, Standard Length. Use with SHORT Attachments.	please see list
S-7B-C	7 mm Carbide Fluted Ball, Standard Length. Use with SHORT Attachments.	please see list

Dear Valued Customer,

Synthes GmbH as the authorised representative of Anspach® is initiating a voluntary recall of the above mentioned articles and lots of the Anspach® Short Carbide Cutting Burrs. Our records indicate that you may have inventory that is impacted by this removal.

Description of problem:

The laser marking location on the Anspach® Short Carbide Cutting Burrs is out of specification which causes it to align with the distal bearing of the attachment and can lead to a potential cutting burr fracture.

Potential hazard:

Potential harms identified for cutter fracture include user laceration, re-operation due to remaining fragments, soft tissue damage due to fragment retrieval, and delay in surgery.

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 to your local DePuy Synthes sales organisation in accordance with the directions on the form within 5 business days of receipt of this notification.
3. Return any affected product 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 product listed below 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 Synthes GmbH.
7. Maintain a copy of this notice.

The applicable regulatory agencies are being notified. Synthes GmbH as the authorised representative of Anspach® is voluntarily taking this action.

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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 DePuy Synthes sales representative.

Thank you for your attention and cooperation.

Synthes GmbH



Claudia Allemann
Field Action Manager



Markus Wien
Director Quality Assurance Operations

Cc:

NOTICE: MEDICAL DEVICE REMOVAL R2013803

Anspach® Short Carbide Cutting Burrs

Verification Section

Part Number	Lot number	Part Number	Lot Number
QD8-2SB-C-8F	see list	S-2SB-C	see list
QD8-4B-C-10F	see list	S-3B-C	see list
QD8-5B-C-10F	see list	S-3SB-C	see list
QD8-7B-C-14F	see list	S-4B-C	see list
S-15DRMC-L	see list	S-4BL-C	see list
S-15DRMC	see list	S-5B-C	see list
S-1B-C	see list	S-6B-C	see list
S-1SB-C	see list	S-7B-C	see list
S-2B-C	see list	-	-

- 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:

Hospital name: _____

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____

List of affected articles and lots:

Material	Material Description	Batch
S-15DRMC	1.5MM X 7.5MM CYL CARBIDE DRUM	B253007651
S-15DRMC	1.5MM X 7.5MM CYL CARBIDE DRUM	B353010823
S-15DRMC	1.5MM X 7.5MM CYL CARBIDE DRUM	D183034653
S-15DRMC	1.5MM X 7.5MM CYL CARBIDE DRUM	D373039456
S-15DRMC	1.5MM X 7.5MM CYL CARBIDE DRUM	D503042788
S-15DRMC	1.5MM X 7.5MM CYL CARBIDE DRUM	E333053785
S-15DRMC	1.5MM X 7.5MM CYL CARBIDE DRUM	E393055855
S-15DRMC	1.5MM X 7.5MM CYL CARBIDE DRUM	E333053785
S-15DRMC	1.5MM X 7.5MM CYL CARBIDE DRUM	E393055944
S-15DRMC	1.5MM X 7.5MM CYL CARBIDE DRUM	E473058131
S-15DRMC	1.5MM X 7.5MM CYL CARBIDE DRUM	B133005996
S-15DRMC	1.5MM X 7.5MM CYL CARBIDE DRUM	B353010823
S-15DRMC	1.5MM X 7.5MM CYL CARBIDE DRUM	B133005996
S-15DRMC	1.5MM X 7.5MM CYL CARBIDE DRUM	B253007651
S-15DRMC	1.5MM X 7.5MM CYL CARBIDE DRUM	F023059698
S-15DRMC	1.5MM X 7.5MM CYL CARBIDE DRUM	F046008800
S-15DRMC	1.5MM X 7.5MM CYL CARBIDE DRUM	B133005996
S-15DRMC	1.5MM X 7.5MM CYL CARBIDE DRUM	B253007651
S-15DRMC	1.5MM X 7.5MM CYL CARBIDE DRUM	B353010823
S-15DRMC	1.5MM X 7.5MM CYL CARBIDE DRUM	E393055855
S-15DRMC	1.5MM X 7.5MM CYL CARBIDE DRUM	F023059698
S-15DRMC	1.5MM X 7.5MM CYL CARBIDE DRUM	E473058131
S-15DRMC	1.5MM X 7.5MM CYL CARBIDE DRUM	E393055855
S-15DRMC	1.5MM X 7.5MM CYL CARBIDE DRUM	F476012136
S-15DRMC	1.5MM X 7.5MM CYL CARBIDE DRUM	F046008800
S-15DRMC	1.5MM X 7.5MM CYL CARBIDE DRUM	F483072095
S-15DRMC	1.5MM X 7.5MM CYL CARBIDE DRUM	G253080927
S-15DRMC	1.5MM X 7.5MM CYL CARBIDE DRUM	G046013969
S-15DRMC	1.5MM X 7.5MM CYL CARBIDE DRUM	F483072095
S-15DRMC	1.5MM X 7.5MM CYL CARBIDE DRUM	G313082440
S-15DRMC	1.5MM X 7.5MM CYL CARBIDE DRUM	G363083948
S-15DRMC-L	1.5MM X 7.5MM CYLINDRICAL CARBIDE DRUM,	E153048481
S-15DRMC-L	1.5MM X 7.5MM CYLINDRICAL CARBIDE DRUM,	G056014030
S-1B-C	1MM CARBIDE FLUTED BALL, EXTENDED	F103059333
S-1B-C	1MM CARBIDE FLUTED BALL, EXTENDED	G026013661
S-1B-C	1MM CARBIDE FLUTED BALL, EXTENDED	E103059333
S-1SB-C	1MM CARBIDE FLUTED BALL	E183049898

S-1SB-C	1MM CARBIDE FLUTED BALL	E163049213
S-1SB-C	1MM CARBIDE FLUTED BALL	E263052407
S-1SB-C	1MM CARBIDE FLUTED BALL	E183049898
S-1SB-C	1MM CARBIDE FLUTED BALL	E163049213
S-1SB-C	1MM CARBIDE FLUTED BALL	E183049898
S-1SB-C	1MM CARBIDE FLUTED BALL	E263052407
S-2B-C	2MM CARBIDE FLUTED BALL, EXTENDED	B403012550
S-2B-C	2MM CARBIDE FLUTED BALL, EXTENDED	B453013945
S-2B-C	2MM CARBIDE FLUTED BALL, EXTENDED	C053014937
S-2B-C	2MM CARBIDE FLUTED BALL, EXTENDED	C273023094
S-2B-C	2MM CARBIDE FLUTED BALL, EXTENDED	C303024324
S-2B-C	2MM CARBIDE FLUTED BALL, EXTENDED	C443026232
S-2B-C	2MM CARBIDE FLUTED BALL, EXTENDED	C513029760
S-2B-C	2MM CARBIDE FLUTED BALL, EXTENDED	D063031943
S-2B-C	2MM CARBIDE FLUTED BALL, EXTENDED	D213035485
S-2B-C	2MM CARBIDE FLUTED BALL, EXTENDED	D193034890
S-2B-C	2MM CARBIDE FLUTED BALL, EXTENDED	D383039657
S-2B-C	2MM CARBIDE FLUTED BALL, EXTENDED	D213035485
S-2B-C	2MM CARBIDE FLUTED BALL, EXTENDED	E023043412
S-2B-C	2MM CARBIDE FLUTED BALL, EXTENDED	E293053152
S-2B-C	2MM CARBIDE FLUTED BALL, EXTENDED	E023043412
S-2B-C	2MM CARBIDE FLUTED BALL, EXTENDED	E293053152
S-2B-C	2MM CARBIDE FLUTED BALL, EXTENDED	G223078543
S-2B-C	2MM CARBIDE FLUTED BALL, EXTENDED	E023043412
S-2SB-C	2MM CARBIDE FLUTED BALL	E293052911
S-2SB-C	2MM CARBIDE FLUTED BALL	E403056210
S-2SB-C	2MM CARBIDE FLUTED BALL	335859
S-2SB-C	2MM CARBIDE FLUTED BALL	F083061993
S-2SB-C	2MM CARBIDE FLUTED BALL	E293052911
S-2SB-C	2MM CARBIDE FLUTED BALL	E403056210

S-2SB-C	2MM CARBIDE FLUTED BALL	G043074760
S-2SB-C	2MM CARBIDE FLUTED BALL	F083061993
S-3B-C	3MM CARBIDE FLUTED BALL, EXTENDED	B383012010
S-3B-C	3MM CARBIDE FLUTED BALL, EXTENDED	B463014362
S-3B-C	3MM CARBIDE FLUTED BALL, EXTENDED	B453013962
S-3B-C	3MM CARBIDE FLUTED BALL, EXTENDED	B463014362
S-3B-C	3MM CARBIDE FLUTED BALL, EXTENDED	C313017460
S-3B-C	3MM CARBIDE FLUTED BALL, EXTENDED	C383026166
S-3B-C	3MM CARBIDE FLUTED BALL, EXTENDED	D053031196
S-3B-C	3MM CARBIDE FLUTED BALL, EXTENDED	D153033593
S-3B-C	3MM CARBIDE FLUTED BALL, EXTENDED	D053031196
S-3B-C	3MM CARBIDE FLUTED BALL, EXTENDED	D213034980
S-3B-C	3MM CARBIDE FLUTED BALL, EXTENDED	D233035926
S-3B-C	3MM CARBIDE FLUTED BALL, EXTENDED	E043045226
S-3B-C	3MM CARBIDE FLUTED BALL, EXTENDED	E093046859
S-3B-C	3MM CARBIDE FLUTED BALL, EXTENDED	E223051311
S-3B-C	3MM CARBIDE FLUTED BALL, EXTENDED	G083075741
S-3B-C	3MM CARBIDE FLUTED BALL, EXTENDED	G243080666
S-3B-C	3MM CARBIDE FLUTED BALL, EXTENDED	E223051311
S-3SB-C	3MM CARBIDE FLUTED BALL	C073015750
S-3SB-C	3MM CARBIDE FLUTED BALL	C163019559
S-3SB-C	3MM CARBIDE FLUTED BALL	C293023851
S-3SB-C	3MM CARBIDE FLUTED BALL	C433027411
S-3SB-C	3MM CARBIDE FLUTED BALL	E193049913
S-3SB-C	3MM CARBIDE FLUTED BALL	E353055022
S-3SB-C	3MM CARBIDE FLUTED BALL	E193049913
S-3SB-C	3MM CARBIDE FLUTED BALL	F456011604
S-3SB-C	3MM CARBIDE FLUTED BALL	E193049913
S-4B-C	4MM CARBIDE FLUTED BALL	C123014361
S-4B-C	4MM CARBIDE FLUTED BALL	C263021273

S-4B-C	4MM CARBIDE FLUTED BALL	E303052507
S-4B-C	4MM CARBIDE FLUTED BALL	F133061458
S-4B-C	4MM CARBIDE FLUTED BALL	E303052507
S-4B-C	4MM CARBIDE FLUTED BALL	G023074168
S-4B-C	4MM CARBIDE FLUTED BALL	F133061458
S-4B-C	4MM CARBIDE FLUTED BALL	G213080022
S-4B-C	4MM CARBIDE FLUTED BALL	G213080023
S-4B-C	4MM CARBIDE FLUTED BALL	G293082309
S-4B-C	4MM CARBIDE FLUTED BALL	G323082926
S-4B-C	4MM CARBIDE FLUTED BALL	E303052507
S-4B-C	4MM CARBIDE FLUTED BALL	G383084288
S-4BL-C	4MM CARBIDE FLUTED BALL, EXT 27MM	C023014787
S-4BL-C	4MM CARBIDE FLUTED BALL, EXT 27MM	D163034199
S-4BL-C	4MM CARBIDE FLUTED BALL, EXT 27MM	D423040825
S-4BL-C	4MM CARBIDE FLUTED BALL, EXT 27MM	E083046345
S-4BL-C	4MM CARBIDE FLUTED BALL, EXT 27MM	E333054375
S-4BL-C	4MM CARBIDE FLUTED BALL, EXT 27MM	B283009811
S-4BL-C	4MM CARBIDE FLUTED BALL, EXT 27MM	E083046345
S-4BL-C	4MM CARBIDE FLUTED BALL, EXT 27MM	D423040825
S-4BL-C	4MM CARBIDE FLUTED BALL, EXT 27MM	E333054375
S-4BL-C	4MM CARBIDE FLUTED BALL, EXT 27MM	D423040825
S-4BL-C	4MM CARBIDE FLUTED BALL, EXT 27MM	G253080939
S-4BL-C	4MM CARBIDE FLUTED BALL, EXT 27MM	D423040825
S-5B-C	5MM CARBIDE FLUTED BALL	B463014365
S-5B-C	5MM CARBIDE FLUTED BALL	B053003293
S-5B-C	5MM CARBIDE FLUTED BALL	B463014365
S-5B-C	5MM CARBIDE FLUTED BALL	B453014364
S-5B-C	5MM CARBIDE FLUTED BALL	C123014613
S-5B-C	5MM CARBIDE FLUTED BALL	C143019328
S-5B-C	5MM CARBIDE FLUTED BALL	E243051463
S-5B-C	5MM CARBIDE FLUTED BALL	E233051108
S-5B-C	5MM CARBIDE FLUTED BALL	E243051463
S-5B-C	5MM CARBIDE FLUTED BALL	E233051108
S-5B-C	5MM CARBIDE FLUTED BALL	F466011696
S-5B-C	5MM CARBIDE FLUTED BALL	G016013492

S-5B-C	5MM CARBIDE FLUTED BALL	E233051108
S-5B-C	5MM CARBIDE FLUTED BALL	G293081320
S-6B-C	6MM CARBIDE FLUTED BALL	C033016270
S-6B-C	6MM CARBIDE FLUTED BALL	C503029501
S-6B-C	6MM CARBIDE FLUTED BALL	D463041744
S-6B-C	6MM CARBIDE FLUTED BALL	D513043069
S-6B-C	6MM CARBIDE FLUTED BALL	E093046617
S-6B-C	6MM CARBIDE FLUTED BALL	335962
S-6B-C	6MM CARBIDE FLUTED BALL	F043061133
S-6B-C	6MM CARBIDE FLUTED BALL	F456011474
S-6B-C	6MM CARBIDE FLUTED BALL	F043061133
S-6B-C	6MM CARBIDE FLUTED BALL	D463041744
S-6B-C	6MM CARBIDE FLUTED BALL	D513043069
S-6B-C	6MM CARBIDE FLUTED BALL	E093046617
S-6B-C	6MM CARBIDE FLUTED BALL	D463041744
S-7B-C	7MM CARBIDE FLUTED BALL	E123047800
S-7B-C	7MM CARBIDE FLUTED BALL	E283052824
S-7B-C	7MM CARBIDE FLUTED BALL	E393055260
S-7B-C	7MM CARBIDE FLUTED BALL	E123047800
S-7B-C	7MM CARBIDE FLUTED BALL	F456011651
S-7B-C	7MM CARBIDE FLUTED BALL	E393055260
S-7B-C	7MM CARBIDE FLUTED BALL	E283052824
S-7B-C	7MM CARBIDE FLUTED BALL	E123047800