

To the attention of Hospital Personnel

Return Receipt Requested

30 July 2015

URGENT NOTICE:
MEDICAL DEVICE FIELD SAFETY NOTIFICATION – FSN930200
Anspach G1 Dissection Tools

PLEASE DISTRIBUTE THIS INFORMATION TO APPROPRIATE PERSONNEL AT YOUR FACILITY WHO MAY USE THE PRODUCT WHICH IS THE SUBJECT OF THIS NOTICE

Synthes GmbH, as the EU Authorized representative for Anspach, is initiating a voluntary medical device Field Safety Notification for all lots of the Anspach G1 Dissection Tools (Cutting Tools/Cutters) products listed below.

Affected Products/Lots

Part Description	Part Numbers	Lot Numbers	Label Error
10 mm x 14 mm Fluted Drum, Side Cut Only.	L-10DRC-G1	All	Compatibility with Multiple Attachments
5 mm x 14 mm Fluted Drum, Side Cut Only.	L-5DRC-G1	All	Compatibility with Multiple Attachments
6.8 mm x 10.6 mm Extra Coarse Diamond Drum.	L-68DRMDX-G1	All	Compatibility with Multiple Attachments
6 mm x 14 mm Fluted Drum, Side Cut Only.	L-6DRC-G1	All	Compatibility with Multiple Attachments
7 mm Fluted Acorn.	L-7AC-G1	All	Compatibility with Multiple Attachments
7 mm Fluted Ball.	L-7B-G1	All	Compatibility with Multiple Attachments
7 mm x 14 mm Fluted Drum, Side Cut Only.	L-7DRC-G1	All	Compatibility with Multiple Attachments
8 mm x 12.5 mm Fluted Barrel.	L-8BA-G1	All	Compatibility with Multiple Attachments
8 mm x 14 mm Fluted Drum, Side Cut Only.	L-8DRC-G1	All	Compatibility with Multiple Attachments
8 mm Extra Coarse Diamond Ball.	L-8DX-G1	All	Compatibility with Multiple Attachments
9 mm Fluted Ball.	L-9B-G1	All	Compatibility with Multiple Attachments
9 mm x 14 mm Fluted Drum, Side Cut Only.	L-9DRC-G1	All	Compatibility with Multiple Attachments
3 mm Coarse Diamond Ball, 2 mm Shaft Exposure.	M-3DC-2-G1	All	Compatibility with Multiple Attachments; Specified Shaft Exposure May Not be Accurate
3 mm Fluted Ball, 2 mm Shaft Exposure.	M-3SB-2-G1	All	Compatibility with Multiple Attachments; Specified Shaft Exposure May Not be Accurate
4 mm x 11 mm Fluted Barrel, 14 Flutes.	M-4BA-A-G1	All	Compatibility with Multiple Attachments
5 mm Fluted Ball, 2 mm Shaft Exposure.	M-5B-2-G1	All	Compatibility with Multiple Attachments; Specified Shaft Exposure May Not be Accurate
5 mm x 11.3 mm Fluted Barrel.	M-5BA-A-G1	All	Compatibility with Multiple Attachments

6 mm x 11.3 mm Fluted Barrel.	M-6BA-A-G1	All	Compatibility with Multiple Attachments
6 mm Coarse Diamond Ball, 2 mm Shaft Exposure.	M-6DC-2-G1	All	Compatibility with Multiple Attachments: Specified Shaft Exposure May Not be Accurate
7 mm Fluted Acorn	M-7AC-G1	All	Compatibility with Multiple Attachments
7 mm Extra Coarse Diamond Ball.	M-7DX-G1	All	Compatibility with Multiple Attachments
8 mm x 12.5 mm Fluted Barrel	M-8BA-G1	All	Compatibility with Multiple Attachments
4 mm Fluted Ball, Extends 27 mm.	M-4B-27-G1	All	Specified Shaft Exposure May Not be Accurate
5 mm Fluted Ball, Extends 27 mm.	M-5B-27-G1	All	Specified Shaft Exposure May Not be Accurate
1.5 mm x 7.5 mm Cylindrical Carbide Drum, Extends 25 mm.	S-15DRMC-L-G1	All	Specified Shaft Exposure May Not be Accurate
3 mm Coarse Diamond Ball, 22 mm Shaft Exposure.	S-3SDC-22-G1	All	Specified Shaft Exposure May Not be Accurate
4 mm Carbide Fluted Ball, Extends 27 mm.	S-4BL-C-G1	All	Specified Shaft Exposure May Not be Accurate
4 mm Coarse Diamond Ball, 22 mm Shaft Exposure.	S-4DC-22-G1	All	Specified Shaft Exposure May Not be Accurate
4 mm Diamond Ball, Extends 27 mm.	S-4D-L-G1	All	Specified Shaft Exposure May Not be Accurate
5 mm Fluted Ball, 2 mm Shaft Exposure.	S-5B-2-G1	All	Specified Shaft Exposure May Not be Accurate
5 mm Diamond Ball, 2 mm Shaft Exposure.	S-5D-2-G1	All	Specified Shaft Exposure May Not be Accurate
5 mm Coarse Diamond Ball, 22 mm Shaft Exposure.	S-5DC-22-G1	All	Specified Shaft Exposure May Not be Accurate
2.3 mm Fluted Matchstick, Extends 22 mm.	S-8N-L-G1	All	Specified Shaft Exposure May Not be Accurate
3 mm Fluted Matchstick, Extends 8.9 mm, Less Aggressive.	S-8NS-M-G1	All	Specified Shaft Exposure May Not be Accurate

Synthes GmbH asks that you review the information contained in this Field Safety Notification and complete the Verification Section located on page 5 and 6 of this notification. Please note that this is a Medical Device Field Safety Notification only, and it is not required to return your inventory of G1 Dissection Tools.

Reason for the Field Safety Notification:

- 1) **LACK OF COMPATIBILITY WITH MULTIPLE ATTACHMENTS:** The G1 Cutting Tools listed are not compatible with all attachments listed on the labeling.
- 2) **SPECIFIED SHAFT EXPOSURE MAY NOT BE ACCURATE:** The G1 Cutting Tools listed are labeled with a specified shaft exposure; e.g. "2 mm Shaft Exposure". This shaft exposure may not be consistent when used with each listed attachment on the product label.

The specific reason per affected part is indicated in the table of Affected Products/Lots above.

Potential hazard:

1) **COMPATIBILITY WITH MULTIPLE ATTACHMENTS:** There are multiple Attachments listed on the labels of the affected G1 Cutting Tools, however, not all Cutting Tool/Attachment combinations can be secured successfully. If the Cutting Tool is not secured successfully, an alternate Attachment that is currently identified on the label should be readily available. There is negligible risk to the patient.

2) **SPECIFIED SHAFT EXPOSURE MAY NOT BE ACCURATE:** The G1 Cutting Tools listed are labeled with a "2mm Shaft Exposure", however, depending on the Attachment used

in conjunction with the Cutting Tool, the Shaft Exposure may be greater. The cutting burr will still function as intended. There is no risk to the patient because the surgeon should be able to visually identify the shaft exposure length for the procedure prior to surgery.

To date, there have been no complaints or reports of adverse events associated with the affected product.

ACTION REQUIRED:

Our records show that your facility has received one or more of the affected product(s) subject to this Field Safety Notification.

Please note that it is not required to return your inventory of G1 Dissection Tools.

- 1) Please review Table 1 to ensure G1 Cutting Tool & Attachment compatibility. The Cutting Tool/Attachment combination noted with a checkmark (✓) in Table 1 will function as intended. The Cutting Tool/Attachment combinations noted with an "X" in Table 1 will not secure effectively and should not be used.

The G1 Dissection Tools are intended for surgical bone cutting and shaping procedures by trained medical/surgical personnel.

Table 1:

COMPATIBILITY WITH MULTIPLE ATTACHMENTS					
CUTTER	ATTACHMENT				
	QD11-G1	QD-11	MEDIUM	MEDIUM-G1	QD11-S
M-4BA-A-G1	X	X	✓	✓	✓
M-5BA-A-G1	X	X	✓	✓	✓
M-6BA-A-G1	X	X	✓	✓	✓
M-7AC-G1	X	X	✓	✓	✓
M-7DX-G1	X	X	✓	✓	✓
M-8BA-G1	X	X	✓	✓	✓
	QD14-G1	QD-14	LONG	LONG-G1	QD14-S
L-5DRC-G1	X	X	✓	✓	✓
L-6DRMDX-G1	X	X	✓	✓	✓
L-6DRC-G1	X	X	✓	✓	✓
L-7AC-G1	X	X	✓	✓	✓
L-7B-G1	X	X	✓	✓	✓
L-7DRC-G1	X	X	✓	✓	✓
L-8BA-G1	X	X	✓	✓	✓
L-8DRC-G1	X	X	✓	✓	✓
L-8DX-G1	X	X	✓	✓	✓
L-9B-G1	X	X	✓	✓	✓
L-9DRC-G1	X	X	✓	✓	✓
L-10DRC-G1	X	X	✓	✓	✓
	QD11-G1	QD-11	MEDIUM	MEDIUM-G1	QD11-S
M-3DC-2-G1	X	✓	✓	✓	✓
M-3SB-2-G1	X	✓	✓	✓	✓
M-5B-2-G1	X	✓	✓	✓	✓
M-6DC-2-G1	X	✓	✓	✓	✓

- 2) Please review Table 2 to identify which Cutting Tool/Attachment combinations provide the stated 2 mm Shaft Exposure. The Cutting Tool/Attachment combination noted with a checkmark (✓) in Table 2 will provide 2 mm Shaft Exposure. The Cutting Tool/Attachment combinations noted with an "X" in Table 2 will not provide 2 mm Shaft Exposure and should not be used.

Table 2:

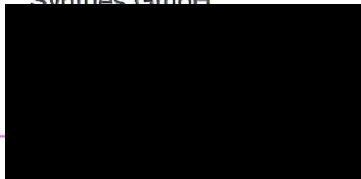
SPECIFIED SHAFT EXPOSURE MAY NOT BE ACCURATE					
CUTTER	ATTACHMENT				
	MEDIUM	MEDIUM-G1	QD11-G1	QD11	QD11-S
M-3DC-2-G1	✓	✓	X	X	X
M-3SB-2-G1	✓	✓	X	X	X
M-4B-27-G1	✓	✓	X	X	X
M-5B-27-G1	✓	✓	X	X	X
M-5B-2-G1	✓	✓	X	X	X
M-6DC-2-G1	✓	✓	X	X	X
	SHORT	SHORT-G1	QD8-G1	QD8	QD8-S
S-3SDC-22-G1	✓	✓	X	X	X
S-4BL-C-G1	✓	✓	X	X	X
S-4DC-22-G1	✓	✓	X	X	X
S-4D-L-G1	✓	✓	X	X	X
S-5B-2-G1	✓	✓	X	X	X
S-5D-2-G1	✓	✓	X	X	X
S-5DC-22-G1	✓	✓	X	X	X
S-8N-L-G1	✓	✓	X	X	X
S-8NS-M-G1	✓	✓	X	X	X
S-15DRMC-L-G1	✓	✓	X	X	X

- 3) Review, complete, sign and return the attached reply form to your local DePuy Synthes contact person. Returning the form will prevent you from receiving repeat notices.
1. Share this letter with others in your facility that need to be made aware of this Field Safety Notification.
 2. If you distribute any of the affected products to other services or facilities, please forward this letter as appropriate immediately.
 3. Keep a copy of this notice with the affected product.

We apologize for any inconvenience that this product 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 Sales Consultant.

Thank you for your attention and cooperation.

Synthes GmbH



Field Action Manager



Senior QA Manager Product Safety

Cc:

Account Name: _____

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Verification Section

Affected Product/Lot

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3 mm Fluted Matchstick, Extends 8.9 mm, Less Aggressive.	S-8NS-M-G1	All	Specified Shaft Exposure May Not be Accurate

The undersigned acknowledges receipt of the subject Field Safety Notification in reference to the G1 Cutting Tool label issues.

CUSTOMER DETAILS	
Facility Name:	
Facility Address:	
Account Number:	
Reply Confirmation Completed by: (Please Print Name)	
Signature and Date: (REQUIRED FIELD)	
Title: (Please Print)	
Telephone Number: (Include Area Code and Extension)	
Email address:	

Please complete and return this page 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 this page of the notification.