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24 June 2015

URGENT NOTICE:
MEDICAL DEVICE RECALL – R20131567
Pull Reduction Device for Percutaneous Drill Guide Ø 4.3mm

Please distribute this information to the appropriate personnel at your facility

Part Description, Part and Lot Numbers

Part Description	Part Number	Lot Numbers					
Pull Reduction Device for Percutaneous Drill Guide ∅ 4.3mm	03.120.023	1825699	3066995	3139480	3207364	3224275	3764900
		1825946	3066996	3139483	3218030	3224581	3764900
		1959344	3066996	3139485	3218030	3224582	3775645
		1959346	3066997	3159152	3218068	3224582	3775645
		3052800	3066997	3167363	3223544	3224583	7502003
		3052800	3066997	3172147	3223544	3233445	7555756
		3052800	3092693	3201143	3223545	3233445	7555756
		3052800	3092737	3201143	3223545	3288202	7625634
		3052800	3139434	3201143	3224270	3288206	7625634
		3066995	3139434	3201143	3224271	3326906	8091016

Dear Sir/Madam,

Synthes GmbH is initiating a voluntary medical device recall of certain lots of the Pull Reduction Device listed above. The Pull Reduction Device for Percutaneous Drill Guide Ø 4.3 mm is placed through the drill guide and plate holes to pull or push bone fragments relative to the plate. This instrument can be used for: Minor Varus-valgus adjustments (approximately 2° - 4°), Translational adjustments, Stabilization of plate bone orientation during insertion of the first screws, alignment of segmental fragments and pre-drilling dense or thick cortical bone before placing a 5.0 mm locking screw.

Our records indicate that you may have inventory that is impacted by this recall.

Reason for the Recall:

The affected parts and lots of the Pull Reduction Devices may have been manufactured to an incorrect hardness specification which could result in intraoperative breakage.

Potential hazard:

In the event of an intraoperative breakage a surgical delay could occur. Breakage of the instrument into fragments during active use could lead to a significant prolongation of surgery time as the surgeon attempts to retrieve the pieces including use radiographic imaging to determine location and size of fragment. Efforts at retrieving fragments may also require

additional intraoperative maneuvers e.g. supplementary incisions that were not previously intended, leading to soft tissue damage. If the patient is sensitive to retained non-implant grade material of the broken instrument, he or she may develop an inflammatory response to the fragments that were left in the bone leading to adverse tissue reaction.

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 on page 3 of this letter to your local DePuy Synthes sales organization in accordance with the directions on the form within 5 business days of receipt of this notification.

3. Return any affected product as soon as possible, but 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 of the affected products have 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 DePuy Synthes.

7. Keep a copy of this notice.

8. As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported as a complaint to Johnson & Johnson Medical Singapore following the usual procedure.

We apologize for any inconvenience that this product recall 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.

Yours sincerely,

[redacted]

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Lee Ching Hwee
Professional Affairs Executive

Return Receipt Requested

MEDICAL DEVICE RECALL – R20131567
Pull Reduction Device for Percutaneous Drill Guide ∅4.3mm

Verification Section

Part Description / Part Number:

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		3052800	3066997	3172147	3223544	3233445	7555756
		3052800	3092693	3201143	3223545	3233445	7555756
		3052800	3092737	3201143	3223545	3288202	7625634
		3052800	3139434	3201143	3224270	3288206	7625634
		3066995	3139434	3201143	3224271	3326906	8091016

Please check (√) all that apply:

☐ Yes, I have received the Medical Device Recall Notice regarding Pull Reduction Device for Percutaneous Drill Guide Ø 4.3mm dated 23rd June 2015 from DePuy Synthes. We have passed on the Notice to all those who need to be aware within our organization, or to any organization where potentially affected devices may have been transferred.

☐ There is **NO** affected product identified in our inventory.

☐ Affected products have been segregated and the following products will be returned to DePuy Synthes

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Catalog Number	Lot Number	Quantity

Return Receipt Requested

Please sign, date and stamp below. Your signature provides confirmation that you have received and understood this notification.

_____	_____
Customer Name	Title
_____	_____
Signature & Date	Stamp *(Stamp shall bear facility name)*

Please complete and return this page your local DePuy Synthes sales organization.

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.