

**URGENT: FIELD SAFETY NOTICE**

***MEDICAL DEVICE VOLUNTARY RECALL***

27 Jan 2015

[Recipient Name]  
[Title]  
[Company Name]  
[Street Address]  
[City, ST ZIP Code]

Dear Sir / Madam,

This letter is to inform you of a voluntary product recall of specific lots of Wright Medical's SHANNON BURR XL 2.0MM X 20MM intended to be used for Minimally Invasive Surgery (MICA).

As an outcome of an investigation from our internal processes, Wright Medical UK discovered that product code WGSMI001 - SHANNON RECTA BURR XL 2.0MM X 20MM, during manufacture was assigned an incorrect product lot / batch, #4567. The product inside the pack is a SHANNON CORTA BURR XL 3.0mm x 20mm, product code WGSMI007. The difference between these products is a 1MM thickness, i.e. (actual product is 1MM thicker than described on the packaging). The difference in diameter could result in shortening of the Hallux during forefoot reconstruction surgery.

Although this issue was noted within our internal process, to date, Wright Medical UK has not been made aware of any reports of patient injury or revision surgery.

Our records show that you or your customers could have received some SHANNON BURR XL 2.0MM X 20MM manufactured with the incorrect product lot / batch number.

**Please examine your inventory for this product and check it against the attached list. Please immediately quarantine all recalled products you have found, and return all affected product to Wright Medical as soon as possible. Contact Customer Service on +44 (0) 845 833 4435 for return instructions and replacement inventory.**



Wright Medical UK  
Unit 1, Campus 5  
Letchworth Garden City  
SG6 2JF

0845 833 4435

[www.wmt.com](http://www.wmt.com)

**Also, please immediately complete the attached response form, confirming your receipt of this notice and status of product on hand, and return a copy to us by email, [customerservice-wg@wmt.emea.com](mailto:customerservice-wg@wmt.emea.com).**

Finally, we sincerely apologize for this inconvenience and want to assure you that Wright Medical is committed to providing you with the highest quality technology for your patients. Please do not hesitate to contact Tony Wilson at +44 (0) 845 833 4435 with any concerns or questions.

Sincerely,

A handwritten signature in black ink, appearing to read 'Tony Wilson', written over a horizontal line.

**Tony WILSON**  
QA/RA Manager UK



Lot Number	Ref. No	Customer Purchase Order No.	Description of product to be recalled
4567	MI001-1	4500552644	SHANNON BURR XL 2.0MM X 20MM
4567	MI001-1	4111055924	SHANNON BURR XL 2.0MM X 20MM
4567	MI001-1	050-0170787	SHANNON BURR XL 2.0MM X 20MM
4567	MI001-1	4500552640	SHANNON BURR XL 2.0MM X 20MM
4567	MI001-1	S695381	SHANNON BURR XL 2.0MM X 20MM
4567	MI001-1	FOR MEDED AUGSBURG	SHANNON BURR XL 2.0MM X 20MM
4567	MI001-1	990046529	SHANNON BURR XL 2.0MM X 20MM
4567	MI001-1	555081802	SHANNON BURR XL 2.0MM X 20MM
4567	MI001-1	4751151427	SHANNON BURR XL 2.0MM X 20MM
4567	MI001-1	2400269	SHANNON BURR XL 2.0MM X 20MM
4567	MI001-1	4751151205	SHANNON BURR XL 2.0MM X 20MM
4567	MI001-1	50849	SHANNON BURR XL 2.0MM X 20MM
4567	MI001-1	T177927	SHANNON BURR XL 2.0MM X 20MM
4567	MI001-1	93384299	SHANNON BURR XL 2.0MM X 20MM
4567	MI001-1	4500543393	SHANNON BURR XL 2.0MM X 20MM
4567	MI001-1	4841054686	SHANNON BURR XL 2.0MM X 20MM
4567	MI001-1	4751150002	SHANNON BURR XL 2.0MM X 20MM
4567	MI001-1	4500540680	SHANNON BURR XL 2.0MM X 20MM
4567	MI001-1	CDE002239	SHANNON BURR XL 2.0MM X 20MM
4567	MI001-1	T177644	SHANNON BURR XL 2.0MM X 20MM
4567	MI001-1	DRP EDT25 01/13/2015	SHANNON BURR XL 2.0MM X 20MM
4567	MI001-1	020-012452	SHANNON BURR XL 2.0MM X 20MM
4567	MI001-1	50786	SHANNON BURR XL 2.0MM X 20MM



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## SHANNON BURR VOLUNTARY RECALL

Please sign and return this form  
Email: [customerservice-wg@wmt-emea.com](mailto:customerservice-wg@wmt-emea.com)

**Status of the product:**

- No product in hand
- Product previously in inventory but none on hand at this time
- Never received product
- Product found in inventory \_\_\_\_\_
- Amount being returned \_\_\_\_\_

Signed: \_\_\_\_\_

Print Name: \_\_\_\_\_

Date: \_\_\_\_\_

Preferred Contact Information: \_\_\_\_\_