

Urgent Field Safety Notice
 Wright Medical EMEA
 FSCA – Identifier : WMT19032012
 FIELD SAFETY CORRECTIVE ACTION: Return to Supplier

Date:

Dear Distributor/Surgeon,

Wright Medical Technology initiated a voluntary Field Safety Corrective Action for the VALOR® Targeting Guide

The intent of this letter is to inform you of all know risks potentially associated with the use of the products affected by this voluntary Field Safety Corrective Action and list any action to be taken by you.

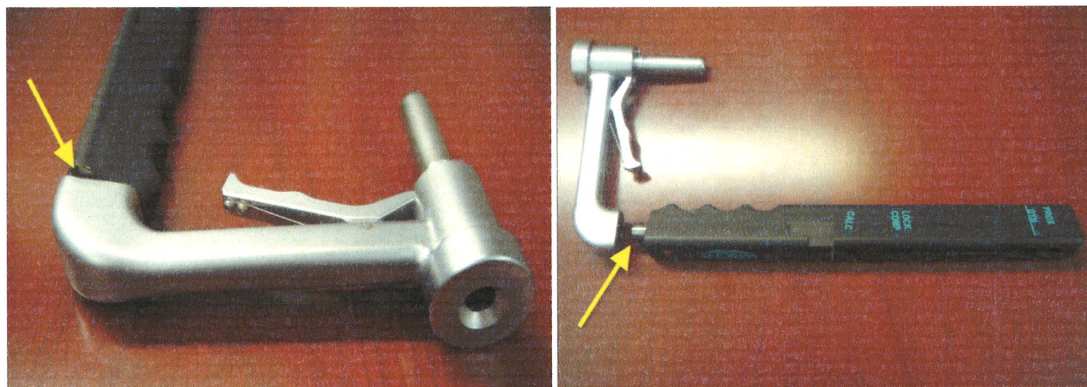
DETAILS OF AFFECTED DEVICES

Description	Part Number	Lot Number
VALOR® Targeting Guide	4150011000	all
VALOR® TTC FUSION INSTRUMENT SET (only item 4150011000 of the kit)	4150KIT1	all

DESCRIPTION OF THE PROBLEM

The VALOR® Targeting guide is designed to guide the calcaneal screw trough the pre-set VALOR® Nail. As a result of field complaints, investigation shows the rotation and/or breakage of the VALOR® Targeting Guide handle. This condition in turn will move the compression guide slot and causes mal-alignment with the VALOR® screw (s) and VALOR® nail.

Visual representations of the rotation and/or breakage of the Guide handle are provided below:

*POTENTIAL RISK*

The possibility exist that if the targeting guide handle is loose, broken or rotated during surgery, This condition in turn will move the compression guide slot and causes mal-alignment with the VALOR® screw (s) and VALOR® nail.

ACTIONS TO BE TAKE BY THE USER

Our records indicate that you have received the above referenced product and we are requesting your assistance in this voluntary Field Safety Corrective Action (FSCA):

Wright Medical EMEA B.V.

Atlas Arena, Asia Building Hoogoorddreef 5 1101 BA Amsterdam The Netherlands

Head Office Phone +31 (0)20 545 01 00 Fax +31 (0)20 545 01 09

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VAT ID NL817520120B01 Chamber of Commerce 342 65 167

- Immediately check the internal inventory and quarantine all subject products
- **COMPLETE AND RETURN** the attached FSCA Acknowledgement
- Circulate this Field Safety Notice internally to all affected parties
- Inform Wright Medical Technology of any adverse event immediately
- Return any unused product to the local Wright Medical representative for destruction.
- This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

CONTACT REFERENCE PERSON

For questions or additional information please contact:

Stephanie Valk, Authorized Rep. Quality Manager, EMEA	Cathy A.M. Park, Manufacturer Recall Coordinator, Product Compliance
Wright Medical EMEA Hoogoorddreef 5 1101 BA Amsterdam The Netherlands	Wright Medical Technology, Inc 5677 Airline Road U.S.A.
Phone: +31 (0) 20545 01 13	Phone: 01-901-867-9971
Email: svalk@wmt-emea.com	Email: cathy.Park@wmt.com

The undersigned confirms that this notice has been sent to the appropriate Regulatory Agency.

Wright Medical Technology maintains its commitment to developing, manufacturing and marketing the highest quality products for surgeons and patients. We apologize for any inconvenience this Field Safety corrective Action may create and appreciate your cooperation with our request.

Stephanie Valk
Quality Assurance Manager EMEA

Wright Medical EMEA B.V.

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Wright Medical Technology, Inc.

Field Safety Corrective Action Acknowledgement Form

FSCA Identifier: WMT

Description	Part Number	Lot Number
VALOR ® Targeting Guide	4150011000	all
VALOR® TTC FUSION INSTRUMENT SET (only item 4150011000 of the kit)	4150KIT1	all

Name	
Hospital / Company Name	
Address	
Country	
Phone Number	

I have received the notification from Wright Medical Technology stating that they initiated a voluntary Field Safety Corrective Action of the above referenced products.

Signature

Date

Printed Name