ZIMMER BIOMET

March 27, 2019

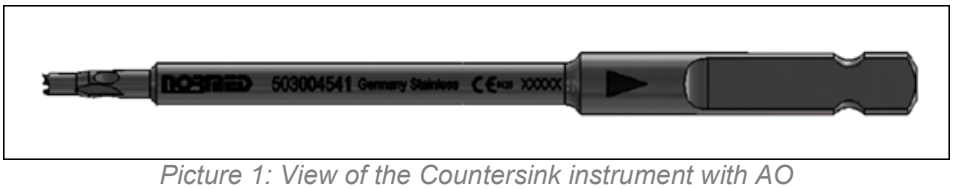
To: Hospital

Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE-REMOVAL**

Reference: **ZFA 2018-00611**

Affected Product: **Foot and Ankle Instruments (Drill / Tap and Countersink)**

Manufactured by Normed Medizin Technik GmbH (as indicated in Annex 2)



Picture 1: View of the Countersink instrument with AO

Picture 2: View of Drills

Picture 3: View of a Tap

Zimmer GmbH is conducting a medical device Field Safety Notice (Removal) for specific instruments formerly manufactured and marked by Normed Medizin Technik GmbH as specified in annex 2. All lots manufactured by this company are within the scope of this field action. Only instruments marked with the name/ logo “Normed” are subject to this removal action. Potentially affected products can be recognized as indicated in annex 1 (either directly with the marking on unsterile instruments or on the labels for sterile instruments). If you encounter any issue for the adequate identification of the potentially affected instruments, please contact your Zimmer Biomet representative for support.

The instruments are used for different Foot and Ankle implant systems.

Zimmer Biomet received a certain number of complaints reporting tip breakages. An investigation identifies that Normed Medizin Technik GmbH possibly manufactured certain lots from a different material than defined in the applicable

specifications. As a precautionary measure Zimmer Biomet has decided to remove the complete family of instruments that were manufactured by Normed Medizin Technik GmbH prior to its manufacturing transfer to Zimmer Biomet in 2014.

Please note that instruments labelled under Zimmer GmbH as manufacturer are not affected by this removal action and can continue to be used. Only instruments marked with the name/ logo "Normed" are subject to this removal action. Please review annex 1 for identification of the specific affected instruments.

Please ensure the removal of all instruments in your ownership marked with the name/ logo Normed.

If your clinic needs replacements for a surgery it is recommended you contact your Zimmer Biomet representative to obtain replacements or a loaner kit to ensure that the surgery is conducted with the instrumentation labelled under Zimmer GmbH.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	None	*Instrument breaks and no replacement instrument is available. Planned procedure cannot be fully finalized which might lead to change of the therapeutical approach (>30min).*
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	None	*Foreign body (from the instrument) remains as encapsulated foreign body or in the plate which could lead to (inflammatory) tissue reaction. Early revision surgery might be needed at a later stage*

Our records indicate that you may have received one or more of the possible affected instruments. The pieces were distributed by the company Normed Medizin Technik GmbH between from approx. 2000 to 2019 (local deployments might differ).

Hospital Responsibilities:

1. Review this notice and ensure that affected personnel are aware of the contents.
2. If you have affected product at your facility, assist your Zimmer Biomet sales representative and quarantine all affected product. Your Zimmer Biomet sales representative will remove the affected product from your facility.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.emea@zimmerbiomet.com. This form must be returned even if you do not have affected products at your facility.
4. Retain a copy of the acknowledgement form with your field action records in the event of a compliance audit of your facility's documentation.

5. If you have further questions or concerns after reviewing this notice, please contact your Zimmer Biomet representative.

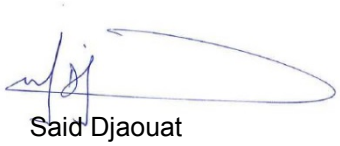
Other Information
This medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices as per MEDDEV 2.12-1 in Europe.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing winterthur.per@zimmerbiomet.com or to your local Zimmer Biomet contact.

Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes.
The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies.

We would like to thank you for your co-operation in advance and regret any inconveniences caused by this field action.

Sincerely,



Said Djaouat
VP EMEA QARC

ANNEX 1
Identification of the potentially affected products

Please check the name of manufacturer, the CE mark reference or the manufacturing information on the labels or directly the manufacturer name on the instrument.

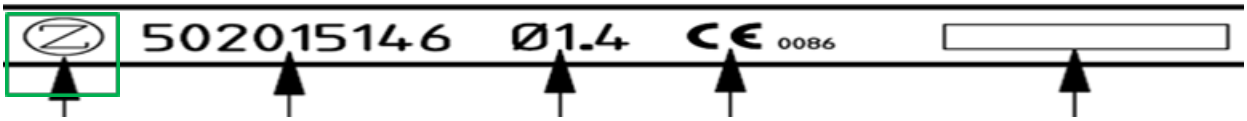
NORMED Medizin-Technik GmbH: Packaging Information- **Affected by the Removal**

NORMED Medizin-Technik GmbH: Product Marking- **Affected by the Removal**

Normed Instruments- **Affected by the Removal**

Zimmer Biomet Product: Packaging Information- **Not affected by the Removal**

Zimmer Biomet Instrument- **Not affected by the Removal**



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ANNEX 2- List of potentially affected products

Reference	Description
502015106	Drill Sys2.7, 2x105mm
502015107	Drill Sys2.7, 2x103mm, AO
502015114	Drill, 15mm stop, 1x83mm
502015115	Drill, 15mm stop, 1x76mm, AO
502015120	Drill, 26mm stop, 1.4x94mm
502015124	Drill, 26mm stop, 1.4x81mm, AO
502015130	Drill, 26mm stop, 1.9x94mm
502015131	Drill, 19mm stop, 1.9x87mm, AO
502015136	Drill, 2.5x94mm
502015137	Drill, 2.5x87mm, AO
502015142	Drill, 2.5x135mm, AO
502015145	Drill, 26mm stop, 1.4x94mm
502015146	Drill, 26mm stop, 1.4x81mm, AO
502015206	Drill for 2.7mm screw, 20mm stop, 2x105mm
ST502015206	Drill for 2.7mm screw, 20mm stop, 2x105mm
502015207	Drill for 2.7mm screw, 23mm stop, 2x103mm, AO
ST502015207	Drill for 2.7mm screw, 23mm stop, 2x103mm, AO
502015208	Drill for 2.7mm screw, 2x100mm, AO
ST502015208	Drill for 2.7mm screw, 2x100mm, AO
502015211	Drill for 2.7mm screw, 2x125mm
502015212	Drill for 2.7mm screw, 2x120mm, AO
ST502015212	Drill for 2.7mm screw, 2x120mm, AO
502015213	Osteofresh arthrodesis drill, 2x70mm, center tip, AO, 10mm stop
502015216	Drill for 3.5mm screw, 2.5x120mm, AO
ST502015216	Drill for 3.5mm screw, 2.5x120mm, AO
502015217	Drill, 2.7x125mm, AO
ST502015217	Drill, 2.7x125mm, AO
502015218	Drill for 3.5mm screw, 2.5x125mm
502015402	Drill, cannulated, 4x120mm, AO
ST502015402	Drill, cannulated, 4x120mm, AO
502015403	Drill, cannulated, 4x150mm, AO
ST502015403	Drill, cannulated, 4x150mm, AO
502015619	Drill, cannulated, 2x95mm, round shaft
ST502015619	Drill, cannulated, 2x95mm, round shaft
502015620	Drill, cannulated, 2.5x95mm, round shaft
ST502015620	Drill, cannulated, 2.5x95mm, round shaft
502015621	Drill, cannulated, 2.5x95mm, AO

Reference	Description
ST502015621	Drill, cannulated, 2.5x95mm, AO
502015623	Drill, cannulated, 2x95mm, AO
ST502015623	Drill, cannulated, 2x95mm, AO
502015628	Drill, cannulated, 2.8x120mm, AO
ST502015628	Drill, cannulated, 2.8x120mm, AO
502015629	Drill, cannulated, 2.8x150mm, AO
502015630	Drill, cannulated, 3x90mm, round shaft
ST502015630	Drill, cannulated, 3x90mm, round shaft
502015631	Drill, cannulated, 3x90mm, AO
ST502015631	Drill, cannulated, 3x90mm, AO
502015634	V-TEK™, IVP step drill 2-3.4x124mm, 16mm stop, contra-angle
502015635	Drill, cannulated, 3.5x90mm, round shaft
ST502015635	Drill, cannulated, 3.5x90mm, round shaft
502015636	V-TEK™, IVP step drill 2-3.4x124mm, 16mm stop, AO
502015637	V-TEK™, IVP step drill 2.5-3.9x124mm, 16mm stop, contra-angle
502015638	V-TEK™, IVP step drill 2.5-3.9x124mm, 16mm stop, AO
502015640	Drill, cannulated, 4x90mm, round shaft
ST502015640	Drill, cannulated, 4x90mm, round shaft
502015650	Drill, 3.2x145mm, AO
ST502015650	Drill, 3.2x145mm, AO
502015706	Drill, contra-angle, 1.5x85mm
ST502015706	Drill, contra-angle, 1.5x85mm
503002041	CBS 7.5 tap, cannulated, AO
503004177	MaxiCan 4.5 countersink, cannulated, AO
503004341	CBS micro, countersink, cannulated, round-shaft
503004342	CBS high, countersink, cannulated, round-shaft
503004351	CBS 4.5 countersink, cannulated, 18mm stop, round-shaft
503004352	CBS 4.0 countersink, cannulated, 15mm stop, AO
503004353	CBS 4.0 countersink, cannulated, 30mm stop, AO
503004541	CBS micro, countersink, cannulated, AO
ST503004541	CBS micro, countersink, cannulated, AO
503004542	CBS high, countersink, cannulated, AO
ST503004542	CBS high, countersink, cannulated, AO
28.66.110	V-TEK™, standard-countersink, cannulated, round shaft
28.66.111	V-TEK™, standard-countersink, cannulated, AO
ST28.66.111	V-TEK™, standard-countersink, cannulated, AO
28.66.112	V-TEK™, micro-countersink, round shaft
28.66.113	V-TEK™, Micro-countersink, AO
ST28.66.113	V-TEK™, Micro-countersink, AO

ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: **Foot and Ankle Instruments (Drill / Tap and Countersink)**

Manufactured by Normed Medizin Technik GmbH

Field Action Reference: **ZFA 2018-00611**

Please return the completed form to your Zimmer Biomet contact person or by e-mail
fieldaction.emea@zimmerbiomet.com

☐ I received and understood the Field Safety Notice.

Regarding the parts:

☐ All inventories for the affected parts have been checked and following parts are to be returned:

Reference	Number of parts returned

OR

☐ The affected products which are unavailable for return have been discarded

By signing below, I acknowledge that the required actions have been taken in accordance with the Field Safety Notice.

Hospital Facility

Printed Name: _____ **Signature:** _____ **Date:**____/____/____

Title: _____ **Telephone:** ( ) ____-_____

Facility Name: _____ **Facility Address:** _____

City:_____ **ZIP:**_____ **Country:**_____