

June 27, 2016

To: Hospitals and Surgeons

Subject: URGENT FIELD SAFETY NOTICE - REMOVAL

FSN/FSCA: FA 2016-07

Affected Product:

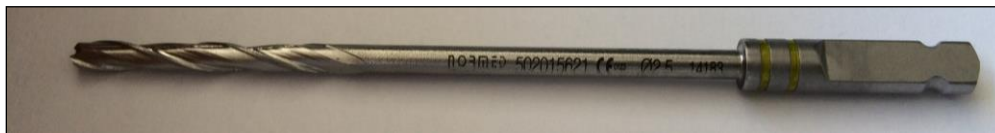
Normed - TWIST DRILL Cannulated &
Normed- V-TEK TWIST DRILL Cannulated

Material Number	Name
502015621	TWIST DR 25X95MM Cann 12MM Thd 30MM AO
502015629	TWIST D 28X150MM CBS 45 Cann 14 MM AO
502015635	V-TEK TWIST D 3.5X90MM 30MM Can 12MM Rnd
502015640	V-TEK TWIST D 40X90MM 30MM Cann 12MM Rnd
ST502015621	Drill 2,5X95 MM, Cann1,2MM 30 MM AO Ster
ST502015635	V-TEK Drill 3,5X90MM NL 30 MM 1,2MM Ster
ST502015640	V-TEK TWIST D 40X90MM 30MM Can 12MM Ster

Chart 1: List of affected Twist drills

Dear Sirs,

Zimmer GmbH is initiating a voluntary removal of several sizes of Normed Twist Drill instruments that may be in your inventories



Picture 1: Twist drill

It is identified that the tolerances from some Twist Drills (as shown in chart 1) and the tolerances from the biggest appropriate Kirschner Wires might be too tight so that the combined use of those two devices is not always performing as intended.

Our records indicate that you may have received one or more of the affected instruments.

Risks

The risk associated with the issue is a potential slight delay during the surgery due to the fact:

- 1) If the Twist Drill shouldn't match, another drill included in the system will be used (please see attachment 2).

- 2) The K-wire and the Twist Drill could become stuck together after Twist Drill insertion. The surgeon would have to remove the Twist Drill with the K-wire or to cut off the K-wire, and then obtain a new drill to proceed.
- 3) The surgeon must continue the surgery without the K-wire and check the positioning of the cannulated screw under x-ray to ensure correct positioning.

Your Responsibilities

1. Review the notification immediately and ensure affected personnel are aware of the contents without delay.
2. Assist your Zimmer Biomet sales representative with the quarantine of any affected instruments.
3. Your Zimmer Biomet sales representative will remove the affected instrument, if any, from your facility.
4. Complete the Certification of Acknowledgement from (Attachment 1) and return to fieldaction.emea@zimmerbiomet.com.
5. **If after reviewing this notification you have further questions or concerns please contact your local Zimmer Biomet representative.**

Vigilance/ Reporting Information

This voluntary notification will be reported to the local Competent Authorities.

Any adverse reactions experienced with the use of these products, and/or quality problems may also be reported according to MEDDEV 2.12-1 Rev. 8 or any relevant requirements to the local health authority in your country.

Please keep Zimmer GmbH informed of any adverse events associated with this device or any other Zimmer Biomet product. Adverse events may be reported to Zimmer Biomet at winterthur.per@zimmerbiomet.com, or to your local Zimmer Biomet representative.

Kind regards,

Anne-Catherine Morancy Meister
PMS Manager

Attachment 1 Certificate of Acknowledgement

FSN/FSCA: FA 2016-07

Affected Product:

Normed - TWIST DRILL Cannulated & Normed- V-TEK TWIST DRILL Cannulated

Material Number	Name	Quantity received	Quantity to return
502015621	TWIST DR 25X95MM Cann 12MM Thd 30MM AO		
502015629	TWIST D 28X150MM CBS 45 Cann 14 MM AO		
502015635	V-TEK TWIST D 3.5X90MM 30MM Can 12MM Rnd		
502015640	V-TEK TWIST D 40X90MM 30MM Cann 12MM Rnd		
ST502015621	Drill 2,5X95 MM, Cann1,2MM 30 MM AO Ster		
ST502015635	V-TEK Drill 3,5X90MM NL 30 MM 1,2MM Ster		
ST502015640	V-TEK TWIST D 40X90MM 30MM Can 12MM Ster		

Please email or fax the completed form to your local Zimmer Biomet contact

Fax / Email _____ / _____

By signing below, I acknowledge that I have received and understand the content of the Urgent Field Safety Notice – Removal, and that the required actions have been taken in accordance with the notice:

1. Return parts in inventory
2. Fill the list above
3. Sign the form

Printed Name: _____

Signature: _____

Hospital Name: _____

Hospital Address: _____

Phone Number: _____

Please maintain a copy of your completed form with your internal records.

ATTACHMENT 2

Replacements - correspondence table

Affected Article	Affected Article
Material Number	Name
502015621	TWIST DR 25X95MM Cann 12MM Thd 30MM AO
502015629	TWIST D 28X150MM CBS 45 Cann 14 MM AO
502015635	V-TEK TWIST D 3.5X90MM 30MM Can 12MM Rnd
502015640	V-TEK TWIST D 40X90MM 30MM Cann 12MM Rnd
ST502015621	Drill 2,5X95 MM, Cann1,2MM 30 MM AO Ster
ST502015635	V-TEK Drill 3,5X90MM NL 30 MM 1,2MM Ster
ST502015640	V-TEK TWIST D 40X90MM 30MM Can 12MM Ster

Replacement	Replacement
Material Number	Name
502015620	TWIST DRILL 25X95MM Cann 13MM STP 30MM
502015628	TWIST D 28X120MM CBS 45 Cann 14MM AO
No replacement	No replacement
No replacement	No replacement
ST502015620	TWIST D 25X95MM Cann 12MM Rnd 30MM Ster
No replacement	No replacement
No replacement	No replacement