Client

Address

SAFETY NOTIFICATION

FSN – SAFETY INFORMATION

FSN no.: *CAPA83*	**Date:** *24/10/2019*
Recipient:	For the attention of the Facility Director, Local Medical Device Vigilance Correspondent, and healthcare professionals and departments concerned,
Type of action: *Field Safety Corrective Action – Safety information*	

Dear Sir or Madam,

We are writing to inform you that FH ORTHOPEDICS, having notified the competent authorities, is voluntarily initiating the release of this safety information about the references(s) listed below.

- Information about the products concerned:

Product(s): *Cannulated TLS DRILL BIT Ø 2.5*	
Reference(s): *254 537 – Cannulated Ø 2.5 DRILL BIT Ø 6* *253 165 – Cannulated Ø 2.5 DRILL BIT Ø 7* *251 830 – Cannulated Ø 2.5 DRILL BIT Ø 8* *250 102 – Cannulated Ø 2.5 DRILL BIT Ø 9* *250 101 – Cannulated Ø 2.5 DRILL BIT Ø 10* *251 831 – Cannulated Ø 2.5 DRILL BIT Ø 11*	**Lot(s):** *All lots*

- Description of the incident giving rise to the action:

This action is being undertaken following the analysis of data from the post-market surveillance program.

It was shown that preventive maintenance by visual inspection of TLS drill bits is recommended in order to avoid any risk of not detecting wear of the instrument.

- Potential associated risks:

The risk is that a piece of metal, such as a wing of the drill bit, will become deformed and/or break and have to be recovered, increasing the length of the surgery.

- Recommendations:

Surveillance of these instruments by visual inspection is recommended to check that they do not show any signs of fragility, after their use at the end of the surgery, in order to avoid any risk of not detecting wear of the instrument:

- No deformation of the wings
- No wear (fissure, integrity of the wings)
- Sharpness of the wings

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If necessary, we recommend a preventive exchange of the instrument.

Furthermore, it is important to spin the drill bit 360° as recommended in the surgical technique in order to avoid weakening the wings with stresses that are too great by not following the operating technique.

As recommended in the FH instruments operating, cleaning and sterilisation instructions:

*"**Warning***

[…] Note: Drill bits, pins, rasps and sharp instruments may be treated with alkaline detergents. They should be inspected thoroughly after treating to ensure that the sharp edges are not damaged."

*"**Inspection before sterilisation***

[…] Check that there is no instrument deformation"

- Immediate actions to implement:

Our records indicate that we delivered products affected by this safety information to your Healthcare Facility. We ask that you locate and cease to use all products. Please proceed as follows:

1- **Circulate this information to all persons who use or order these products within your Facility.**
2- **Fill in the enclosed Acknowledgement of Receipt form and fax it to +33 3 89 81 84 26 or email it to vigilancedepartment@groupe-fh.fr, even if you have no products in stock.**
3- **Please contact the sales assistant for your sector if you would like to have one of your instruments replaced.**

- Contact persons for any information:

Our Medical Device Vigilance Correspondent, Mrs. Cécilia Hernoux, and our Quality Assurance Manager, Mrs. Elodie Gaumez, remain at your disposal for any further information by email at vigilancedepartment@groupe-fh.fr.

Please accept our apologies for the inconvenience caused by this action and thank you for your understanding and cooperation.

With our sincere regards,

FH Orthopedics

Mrs. Cécilia Hernoux

FH Medical Device Vigilance Correspondent

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GROUPE FH ORTHO

CUSTOMER RESPONSE FORM - CAPA83

Please fill in this response form within 7 days and fax it back to us +33 3 89 81 84 26 or email it to us at vigilancedepartment@groupe-fh.fr .

I attest that:

- **I have received the safety notification from Fournitures Hospitalières concerning the safety information regarding the Cannulated TLS DRILL BIT Ø 2.5, and have circulated it to all those concerned within our Facility.**

Facility:	**Name and position of the signer:**
Date:	**Signature:**

- For the purpose of updating our database, would you please confirm:

Last and First name of your Local Medical Device Vigilance Correspondent:	**Email address:**
Telephone:	**Fax (if applicable):**

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