Customer

Address

DISTRIBUTOR SAFETY NOTIFICATION

FSN – SAFETY INFORMATION

FSN no.: *GLB100563*	**Date:** *11/12/2020*
Recipient:	To distributors
Type of action: *Field Safety Corrective Action – Safety information*	

Dear Sir or Madam,

We hereby inform you that FH ORTHO is releasing a voluntary safety information concerning the references listed below.

- Information about the products concerned:

Product(s): *BePod percutaneous screw*	
Reference(s): 270681, 270682, 270683, 270684, 270685, 270686, 270687, 270688, 267823, 267824, 267825, 267826, 267827, 267828, 267829, 267830, 267831, 267832, 270689, 270690, 270691, 270692, 270693, 256454, 256455, 256456, 256457, 256458, 256459, 256460, 256461, 256462, 256463, 256464, 256465, 264241, 264242, 264243, 264244, 264245, 264246, 264247, 264248, 264249, 264250, 264251, 268413, 268414, 268415, 268416, 268417, 268418, 268419, 268420, 268421, 268422, 268423	**Lot(s):** *All lots*

- Description of the incident giving rise to the action:

This action is in response to a translation mistake in the English and Spanish instruction documents. In the "Indications for use" part, the term "non compressive" in the French version was translated as "compressive" in these languages. The term is used just once in the instructions.

INDICATIONS D'UTILISATION :

Les vis canulées 3A et les vis sécables autocompressives sont conçues pour répondre aux indications suivantes :
- Traitement des Hallux Valgus du 1er rayon (gros orteil) par ostéosynthèse compressive, suite à des ostéotomies métatarsiennes et phalangiennes, distales et proximales.
- Ostéosynthèse compressive de fractures de plusieurs os de l'avant-pied.

Les vis canulées percutanées, les vis canulées biseautées 45B sont conçues pour répondre aux indications suivantes :
- Traitement des Hallux Valgus du 1er rayon (gros orteil) par ostéosynthèse non compressive, suite à des ostéotomies métatarsiennes et phalangiennes, distales et proximales.
- Ostéosynthèse non compressive de fractures de plusieurs os de l'avant-pied.

FH ORTHO SAS, 3 rue de la Forêt 68990 Heimsbrunn, France - Tel.: +33 (0)3 89 81 90 92- Fax: +33 (0)3 89 81 80 11 - www.fhortho.com

INDICATIONS FOR USE:

3A cannulated screws and scored self-compressive screws are designed for the following indications:
- Treatment of Hallux Valgus of the first metatarsal shaft (big toe) by compressive osteosynthesis, following distal and proximal metatarsal and phalangeal osteotomy.
- Compressive osteosynthsis of fractures of several bones in the forefoot.

Percutaneous cannulated screws, 45B bevelled cannulated screws are designed for the following indications:
- Treatment of Hallux Valgus of the first metatarsal shaft (big toe) by compressive osteosynthesis, following distal and proximal metatarsal and phalangeal osteotomy.
- Compressive osteosynthesis of fractures of several bones in the forefoot.

INDICACIONES DE UTILIZACIÓN:

Los tornillos canulados 3A y los tornillos divisibles autocompresivos están diseñados para responder a las indicaciones siguientes:
- Tratamiento de Hallux Valgus del primer radio (dedo pulgar) por osteosíntesis compresiva, después de osteotomías metatarsianas y falangianas, distales y proximales.
- Osteosíntesis compresiva de fracturas de varios huesos del antepié.

Los tornillos percutáneos , los tornillos canulados biselados 45B están diseñados para responder a las indicaciones siguientes:
- Tratamiento de Hallux Valgus del primer radio (dedo pulgar) por osteosíntesis compresiva, después de osteotomías metatarsianas y falangianas, distales y proximales.
- Osteosíntesis no compresiva de fracturas de varios huesos del antepié.

- Potential associated risks:

A risk assessment has been carried out and has determined that the risk for patients is minor.

- Recommendations:

We recommend consulting the diagram on the implant box and the surgical technique for “Indications for use” because these are compliant and clearly indicate that the screws are non compressive.

The enclosed flyer must be distributed to all customers using BEPOD forefoot percutaneous screws:

- Percutaneous screws diameter 3 and 2.5mm
- 45B screws

- Immediate actions to implement:

Our records indicate that we have supplied you with products affected by this safety information. We ask that you locate and cease to use all products. Please proceed as follows:

1- **Identify all the products concerned, both in your own stock and at your customers’.**
2- **Communicate this information to all your personnel and any customers using these products, along with the flyer enclosed with this safety information.**
3- **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 neither you nor your customers have any products in stock.**
4- **After implementation of the action, the screws can be used.**

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- Contact persons for any information:

Our Medical Device Vigilance Correspondent, ..., and our Quality Assurance Manager, ..., 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,

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FH ORTHO group Medical Device Vigilance Correspondent

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GROUPE FH ORTHO

DISTRIBUTOR RESPONSE FORM – No. GLB100563 - 11/2020

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 FH ORTHO regarding the safety information concerning the instructions for BePOD percutaneous screws, and I have communicated it to the people concerned within my company and have implemented the immediate measures required,**
- **I have identified and informed the customers that had received the products concerned by this notification,**
- **I have received confirmation of receipt of this notification from these customers,**
- **I have submitted this declaration to the competent authority in my country, in application of current regulations.**

Customer name:	Date of customer notification by the distributor	Date of implementation confirmation by the customer

Distributor:	Name and position of the signer:
Date:	Signature:

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