FSN Ref: FSN_CP22002_CP21002 FSCA Ref: FSCA_CP22002, FSCA_CP21002

Date: 2022-08-19

Field Safety Notice
TAMINA 3.5mm Proximal Humerus System

For attention of: Operating surgeons

We would like to inform you with this notification letter that the company Bonebridge AG is performing a Field Safety Corrective Action (FSCA) for the following product:

LOT	REF	Name
n/a	n/a	TAMINA 3.5mm Proximal Humerus System

The Instruction For Use (IFU) and the Surgical Technique have been revised by the manufacturer. The list of potential risk factors has been expanded in the IFU and the instructions for postoperative care reinforced. In the Surgical Technique, a note regarding correct screw placement has been added. The Instruction For Use as well as the Surgical Technique are subject to continuous revision. It is imperative to verify that the current electronic or printed versions are at all times identical to the latest versions provided at www.bonebridge.ch/ifu.

PLEASE READ THIS DOCUMENT CAREFULLY. PLEASE MAKE THIS DOCUMENT AVAILABLE TO ALL PERSONNEL IN YOUR FACILITY WHO HAVE WORKED WITH OR ARE WORKING WITH THE ABOVE-MENTIONED PRODUCT.

Contact details of local representative
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Field Safety Notice
Reinforcement of Instruction for Use (IFU) and Surgical Technique
TAMINA 3.5mm Proximal Humerus System

1. Information on Affected Devices	
1.	1. Device Type
	The TAMINA 3.5mm Proximal Humerus System is an implantable device used for osteosynthesis in the treatment of proximal humerus fractures.
1.	2. Commercial name
	TAMINA 3.5mm Proximal Humerus System
1.	3. Primary clinical purpose of device
	The TAMINA 3.5mm Proximal Humerus System is intended for use in internal fixation of the proximal humerus/humeral shaft in skeletally mature patients
1.	4. Device Model/Catalogue/part number
	TAMINA 3.5mm Proximal Humerus System

2. Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem
	None
2.	2. Hazard giving rise to the FSCA
	Bonebridge was made aware of two complications (screw loosening) involving the TAMINA 3.5mm Proximal Humerus System. In the first case the medial calcar screw backed out. Revision surgery had to be performed. This incident took place in a morbidly obese patient (obesity class III, BMI >40). Due to the increased risk of exceptionally high implant load due to their body weight, these patients carry a higher risk of implant failure, especially when instructions for postoperative care are not strictly followed. Patients that are considered overweight (morbidly obese) should be instructed to strictly adhere to the instructions of their physician. In particular, these patients should avoid active movements of the affected extremities within the first 6 weeks after surgery. The patients must strictly adhere to the instruction given by their physician and/or physiotherapist. In the second case screw loosening was detected at six weeks requiring revision surgery. An insufficient number of screws was placed in the humeral head which resulted in insufficient protection of the humeral head against varus displacement. In cases where the calcar region is comminuted and cannot be solidly impacted intraoperatively, the humeral head must be protected against varus displacement using all three proximal screws with adequate length in addition to the two calcar screws.
2.	3. Probability of problem arising
	In scientific literature, the screw loosening rate is reported to be ~4%. If the surgical procedure as well as postoperative treatment is performed according to the surgical technique, the occurrence of screw loosening is therefore unlikely. Patients with one or several risk factors such as morbid obesity might carry a higher risk for complications.
2.	4. Predicted risk to patient/users
	The health hazard evaluation indicated that the predicted risk for the patient is considered acceptable as screw loosening is a well known but rather rare complication of ORIF. It should also be noted that despite screw loosening proper fracture healing may still occur.

2.	5. Background on Issue
	The investigation of the first incident has shown that the patient suffers from obesity class III and poor body sensation/insensitivity to pain. A high mechanical load due to the very high body weight favors screw loosening. Therefore, non-compliance of the patient (patient applying premature load on the upper arm) is highly probable in this case. The investigation of the second incident revealed that screw loosening was most likely attributed to an insufficient number of screws placed in the humeral head. The fact that the surgery was performed in osteopenic bone contributed to the complication.

3. Type of Action to mitigate the risk		
3.	**1. Action To Be Taken by the User** ☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification / inspection ☐ Follow patient management recommendations ☒ Take note of reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Please make this document available to all personnel in your facility who have worked with or are working with the product.	
3.	2. By when should the action be completed?	Immediately
3.	3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? No The reinforcement of the Instruction For Use (IFU) and the Surgical Technique is not attributed to an issue with the device. There is no specific patient monitoring recommended related to this notification letter beyond the existing follow-up plan.	
3.	4. Is customer Reply Required?	No
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☐ Other ☐ None The IFU and the Surgical Technique have been revised. • In the IFU the section "Potential risk factors" has been expanded with "Obese patients with an increased risk of exceptionally high implant load" (BMI > 40 / class III obesity). Furthermore the section "Postoperative Care" has been reinforced in the IFU and the Surgical Technique.	

	• In the Surgical Technique, the following note has been added: “In osteopenic bone as well as when the calcar region is comminuted and can't be solidly impacted during surgery, the humeral head should be protected against varus displacement using, in addition to the two calcar screws, all three proximal screws with adequate length.”	
3.	6. By when should the action be completed?	Revised IFU (Version 11, released 08/22) is in effect and available at www.bonebridge.ch/ifu Revised Surgical Technique (Version 10, released 08/22) is in effect and available at www.bonebridge.ch/ifu
3.	7. Is the FSN required to be communicated to the patient /lay user?	No

4. General Information		
4.	1. FSN Type	New
4.	2. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Bonebridge AG
	b. Address	Bahnhofstrasse 11, 6300 Zug, Switzerland
	c. Website address	bonebridge.ch
4.	3. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	Name/Signature	Christof Gerber MD, CEO Bonebridge AG

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.