Rev 3: 2020-03-20
FSN Ref: FSN02

FSCA Ref: FSCA01

WITTENSTEIN intens

Date: 2020-03-20

Urgent Field Safety Notice
FITBONE Receiver REF 60001780

For Attention of: Surgeons and distributors who have purchased or used the Receiver with REF 60001780

Contact details of local representative (name, e-mail, telephone, address etc.)*
WITTENSTEIN intens GmbH
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Urgent Field Safety Notice (FSN)
FITBONE Receiver REF 60001780
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Receiver REF 60001780
1.	2. Commercial name(s)
	FITBONE Receiver
1.	3. Unique Device Identifier(s) (UDI-DI)

1.	4. Primary clinical purpose of device(s)*
	FITBONE® System TAA is an intramedullary lengthening system for limb lengthening of the femur and tibia.
1.	5. Device Model/Catalogue/part number(s)*
	REF 60001780
1.	6. Software version

1.	7. Affected serial or lot number range
	REF 60001780 with production date before 2020-02-14
1.	8. Associated devices
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2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Based on two events in the field concerning the Receiver REF 60001780, the FITBONE® user have to be informed about the following: According to information from two FITBONE® user there were intermittent functional failures of the Receivers. The examination of the Receivers showed that unfavorable handling of the bipolar plug connection in the transition of the connection socket to the supply line could lead to a short circuit at this particular point.
2.	2. Hazard giving rise to the FSCA*
	Damage to the silicone insulation between the two conductors leads to a short circuit of the bipolar feedline and thus to a functional failure of the implant. This functional failure can already be detected during the intraoperative test. However, it cannot be ruled out that the failure, due to movements of the patient during the active distraction phase, will only occur after successful implantation and after successful intraoperative test. In this case, the error can be noticed by the fact that no motor noise is audible if the energy transfer is successful. Furthermore, other causes can also lead to this error pattern.
2.	3. Probability of problem arising
	Currently 2 of the 53 implanted Receivers show this error pattern. Both were detected as defective during the intraoperative test. A disadvantage for the patient due to the failure occurs only if the defect occurs during the active lengthening phase and a clinically relevant lengthening distance still has to be covered. To complete the treatment, mechanical manipulation of the subcutaneously implanted IS1 connector during distraction may be sufficient to restore temporary functionality. By manipulation, the short circuit in the bipolar feedline caused by the above described error pattern can be temporarily eliminated.
2.	4. Predicted risk to patient/users
	The error pattern is only relevant during the active distraction phase (max. approx. 100 days after successful implantation), as the function of the lengthening is no longer required after the active distraction phase. Due to the number of already implanted Receivers and the already completed

	distraction distances of these patients, we assume that less than 5 affected Receivers will fail during the active distraction phase after the successful intraoperative test. In patients where manipulation is unsuccessful, the defective Receiver must be replaced by a replacement Receiver which does not have the described deviation, by means of revision surgery. According to our estimation, about 2-3 patients can be affected.
2.	5. Further information to help characterise the problem

2.	6. Background on Issue
	For a better handling during the manufacturing process of the bipolar IS1 connector, the litz wire length for connecting the spiral coil of the bipolar feedline to the contact blocks of the IS1 socket within the socket housing was extended by 2.5 mm. If the litz wires are correctly fitted to the contact blocks (without protruding over the contact blocks), the position of the sleeves moves to the end of the socket housing or beyond. In unfavorable cases, such as excessive bending of the bipolar feedline, this might lead to damages to the silicone insulation between the two conductors at the bending point.
2.	7. Other information relevant to FSCA
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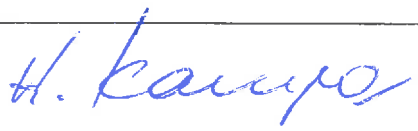
	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User***	
	☐ Identify Device ☐ Quarantine Device ☒ Return Device ☐ Destroy Device	
	☐ On-site device modification/inspection	
	☐ Follow patient management recommendations	
	☐ Take note of amendment/reinforcement of Instructions For Use (IFU)	
	☐ Other ☐ None	
	Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	2020-03-20
3.	3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? No The error pattern is only relevant during the active distraction phase (max. approx. 100 days after successful implantation), as the function of the lengthening is no longer required after the active distraction phase. The cases reported so far were detected during the intraoperative test and the defective receiver were replaced intraoperatively. Due to the already performed distractions with the implanted Receivers, it can be assumed that the probability that the error pattern only occurs during the distraction phase is low. As long as the distraction can be performed successfully, there is no need to take action.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes (Affected surgeons and distributors were already informed and sent back the Reply)

3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None Re-work of the design Specification together with the supplier	
3.	6. By when should the action be completed?	Already done
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Choose an item.	Choose an item.

	4. General Information*	
4.	1. FSN Type*	Update
4.	2. For updated FSN, reference number and date of previous FSN	DE / 0000042083 FSCA
4.	**3.** For Updated FSN, key new information as follows:	
	Template was requested by Swedish authority. Additional information is given in Chapter 2 and 3.3.	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	

4.	6. Anticipated timescale for follow-up FSN	----------
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	WITTENTEIN intens GmbH
	b. Address	Walter-Wittenstein-Straße 1, 97999 Igersheim
	c. Website address	info@wittenstein-intens.de
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes	
4.	9. List of attachments/appendices:	----------
4.	10. Name/Signature	Hartmut Kampa, Safety Officer 

	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..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.