

Date: 12 Feb 2020

Urgent Field Safety Notice
Nextra® Hammertoe Correction System

For Attention of*: Risk Managers

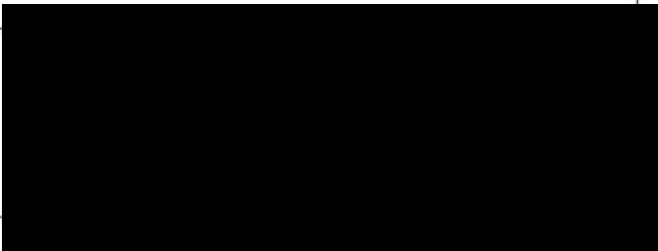
Contact details of local representative (name, e-mail, telephone, address etc.)*


Urgent Field Safety Notice (FSN)
Nextra® Hammertoe Correction System
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)* Orthopedic Implant
1.	2. Commercial name(s) Nextra Hammertoe Correction System
1.	3. Unique Device Identifier(s) (UDI-DI) 00817701020011
1.	4. Primary clinical purpose of device(s)* The Nextra Hammertoe Correction System is a system of implants and associated instruments which is indicated for small bone reconstruction limited to inter-digital repair and fusion of the lesser toes.
1.	5. Device Model/Catalogue/part number(s)* NX-4532K 4.5 Middle and 3.2 Proximal Kit
1.	6. Affected serial or lot number range 168117318B

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem* The product listed in Table 1 above contains a reversible driver designed to engage with both pieces of the two-part Nextra implant construct. The proximal end of the driver in the affected product may be oversized in varying degrees, potentially making it difficult to connect with and remove from the proximal Nextra implant.
2.	2. Hazard giving rise to the FSCA* The problem can result in surgical delay, in-situ removal of the implant, and use of alternative surgical approach.
2.	3. Probability of problem arising It is probable that lot 168117318B exhibits the oversized driver condition.
2.	4. Predicted risk to patient/users Low (outcome in which the probability of serious adverse health consequences is remote).
2.	5. Further information to help characterise the problem Nextremity Solutions is aware of 6 incidents in which the issue of oversized driver was reported or confirmed through product review. 4 instances resulted in surgical delay of greater than 30 minutes. 2 instances resulted in in-situ removal of 4 total implants. 2 instances resulted the surgeon switching to an alternate surgical approach.

3. Type of Action to mitigate the risk*		
3.	1. Action To Be Taken by the User* <input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Follow patient management recommendations <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input type="checkbox"/> Other <input type="checkbox"/> None	
3.	2. By when should the action be completed?	Action should be completed within 3 days of receiving the FSN.
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	4. Action Being Taken by the Manufacturer <input checked="" type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input type="checkbox"/> Other <input type="checkbox"/> None	
3	5. By when should the action be completed?	Action will be completed as soon as practical without undue delay.
3.	6. Is the FSN required to be communicated to the patient /lay user?	No

4. General Information*	
4.	1. FSN Type* New
4.	2. Further advice or information already expected in follow-up FSN? * No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)
	a. Company Name Nextremity Solutions
	b. Address 210 North Buffalo Street Warsaw, IN USA 46550
	c. Website address https://www.nextremity.com/
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *
4.	5. Name/Signature 

Template for a Field Safety Notice Customer Reply Form

Customer Reply Form

1. Field Safety Notice (FSN) information				
FSN Reference number*		FSN-001		
FSN Date*		12 Feb 2020		
Product/ Device name*		Nextra Hammertoe Correction System		
Product Code(s)		NX-4532K		
Batch/Serial Number (s)		168117318B		
2. Customer Details				
Account Number				
Healthcare Organisation Name*				
Organisation Address*				
Department/Unit				
Contact Name*				
Title or Function				
Telephone number*				
Email*				
3. Customer action undertaken on behalf of Healthcare Organisation				
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A		
<input type="checkbox"/>	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned(DD/MM/YY):
		N/A	Comments:	
<input type="checkbox"/>	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:	
		Qty	Lot/Serial Number:	
		N/A	Comments:	
<input type="checkbox"/>	No affected devices are available for return/ destruction	Customer to complete or enter N/A		
<input type="checkbox"/>	Other Action (Define):			
<input type="checkbox"/>	I do not have any affected devices.	Customer to complete or enter N/A		
<input type="checkbox"/>	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query		
Print Name*		Customer print name here		
Signature*		Customer sign here		
Date*				

4. Return acknowledgement to sender	
Email	
Customer Helpline	
Postal Address	
Web Portal	
Fax	
Deadline for returning the customer reply form*	Within 3 days of receiving the FSN.

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.