bioretec

Rev 1: September 2018
FSN Ref: VGL-103-FSN FSCA Ref: VGL-103-FSCA

Date: 13/05/2022

Urgent Field Safety Notice
Activa IM-Nail™

For Attention of*:
This version of the FSN is submitted for the attention of the Competent authorities of FI, AT, BG, CH, DK, ES, HU, IE, IT, LT, PL, and to DEKRA Certification B.V.

The local distributors in AT, BG, CH, DK, ES, HU, IE, IT, LT, PL, RU, and UAE will be notified with a version of the FSN where the contact details of local representatives are identified.
The distributors will notify the users.

Contact details of local representative (name, e-mail, telephone, address etc.)*
Will be filled in to the versions submitted to the local distributors in AT, BG, CH, DK, ES, HU, IE, IT, LT, PL, RU, and UAE.

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Urgent Field Safety Notice (FSN)
Activa IM-Nail™
For reducing risk of implant splitting during insertion

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Bioabsorbable implant for intramedullary nailing of diaphyseal forearm fractures (radius or ulna or both) in pediatric patients in the presence of appropriate immobilization. Provided as sterile.
1.	2. Commercial name(s)
	Activa IM-Nail™
1.	3. Unique Device Identifier(s) (UDI-DI)
	06438394011441, 06438394011472, 06438394008786, 06438394011489, 06438394011496, 06438394007291, 06438394011502, 06438394011519, 06438394007307
1.	4. Primary clinical purpose of device(s)*
	Activa IM-Nail™ is intended for intramedullary nailing of diaphyseal forearm fractures (radius or ulna or both) in pediatric patients in the presence of appropriate immobilization.In diaphyseal forearm fractures the Activa IM-Nail™ is indicated for the patients from 3 years to under 13 years, but the age limits depend on the biological development of the child.
1.	5. Device Model/Catalogue/part number(s)*
	B-ANIM-20200, B-ANIM-20300, B-ANIM-20400, B-ANIM-27200, B-ANIM-27300, B-ANIM-27400, B-ANIM-32200, B-ANIM-32300, B-ANIM-32400
1.	6. Affected serial or lot number range
	The updated IFU applies to all LOT numbers.

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	The sharp edge of the cortex at the entrance of the bone hole or the fracture line may split the implant during insertion if more force than light tapping is used.
2.	2. Hazard giving rise to the FSCA*
	Reoperation for removing the split implant piece is needed if there are clinically significant symptoms, per the surgeon's decision. The implant material is bioabsorbable, and therefore it is not a risk of permanent hazard, and removal is not needed if no symptoms are observed.
2.	3. Probability of problem arising
	<0,5% before implementing FSCA.
2.	4. Predicted risk to patient/users
	In the worst-case, reoperation for removing the split implant piece is needed
2.	5. Further information to help characterise the problem
	This incident is not serious: 1) If the surgeon notices it during the operation, the operation time will not be prolonged from what it typically is for this indication. The surgeon will replace the split implant with a new one. 2) If the split part of the implant causes symptoms during healing and is therefore noticed, reoperation may be needed to remove the split part of the implant via a small incision. 3) Splitting the product does not delay the healing of the fixation.
2.	6. Background on Issue

	The problem was noticed during the Post-Market Clinical Follow-up Study.
2.	7. Other information relevant to FSCA
	The attached IFU and surgical technique must be trained to users by the distributor.

	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?	Distributors shall train as soon as possible the users to whom they have delivered / will deliver Activa IM-Nail products.
3.	3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? No Based on the information received from the PMCF study, the fracture has healed without delay. If the split part does not cause symptoms, no long-term consequences are assumed, because the material is bioabsorbable: Polymer degrades in vivo by hydrolysis into alpha-hydroxy acids, and ceramic into calcium and hydrogen phosphate ions, that are metabolized by the body.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☐ Other ☐ None Revised IFU attached.	
3	6. By when should the action be completed?	unknown at present
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*	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	**Bioretec Ltd.**
	b. Address	**Yrittäjänkulma 5, FI-33710 Tampere, Finland**
	c. Website address	**www.bioretec.com**
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Fimea has been informed.	
4.	5. List of attachments/appendices:	**Activa IM-Nail IFU Rev. 2.0 04/22, Surgical technique for Pediatric Forearm Fixation Using Activa IM-Nail Rev. 2.0**
4.	6. Name/Signature	**Mari Ruotsalainen** **Director, QA & RA** **Bioretec Ltd.** **Eudamed SRN FI-MF-000001328**
		

	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.