EXACTECH, INC
2320 NW 66th Court
Gainesville, FL 32653
USA
352.377.1140
352.378.2617

FSN Ref: CRC-00009
Date: 19-Dec-23

FSCA Ref: CRC-00009

Urgent Field Safety Notice
VANTAGE LP TALAR IMPACTOR INSERT

For Attention of*:

Contact details of local representative (name, e-mail, telephone, address etc.) *
David Backhuss Exactech Deutschland GmbH www.exactech.de Werftstraße 193 24143 Kiel, Germany Tel/Fax: +49-431-990293-0 / +49-431-990293-29 Email: david.backhuss@exac.com

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Urgent Field Safety Notice (FSN)
VANTAGE LP TALAR IMPACTOR INSERT
Risk addressed by FSN

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	Orthopedic Stereotaxic Instrument
1.	2. Commercial name(s)
	Vantage LP Talar Impactor Insert
1.	3. Unique Device Identifier(s) (UDI-DI)
	10885862563415
1.	4. Primary clinical purpose of device(s)*
	Per Instructions for Use (IFU) 700-096-157 Rev. - (Vantage Total Ankle System IFU): The LP Talar Impactor Insert is used to facilitate surgery using Vantage Total Ankle Implants. Operative Technique 721-00-32, Vantage Total Ankle. INDICATIONS FOR USE The Vantage Total Ankle System is indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis. It is also indicated for revision of failed previous reconstructions where sufficient bone stock and soft tissue integrity are present. The Vantage Total Ankle System is indicated for cemented use only.
1.	5. Device Model/Catalogue/part number(s)*
	351-07-04
1.	6. Software version
	Not Applicable
1.	7. Affected serial or lot number range
	Lot Numbers: 145714002 304816001 400598001 402690002 404552001
1.	8. Associated devices
	Not Applicable
	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	Exactech has received 12 complaints through the post market surveillance regarding the broken part failure of VANTAGE LP TALAR IMPACTOR INSERT at the junction between the radel impactor cover and the metal impactor frame. The reduced joint space in the mobile bearing preparation (typically 2mm shallower on the tibial resection) could result in additional stress on the part while getting the impactor handle into the proper orientation. This may be less difficult in a fixed bearing construct due to additional joint space and the T-slot in the implant.

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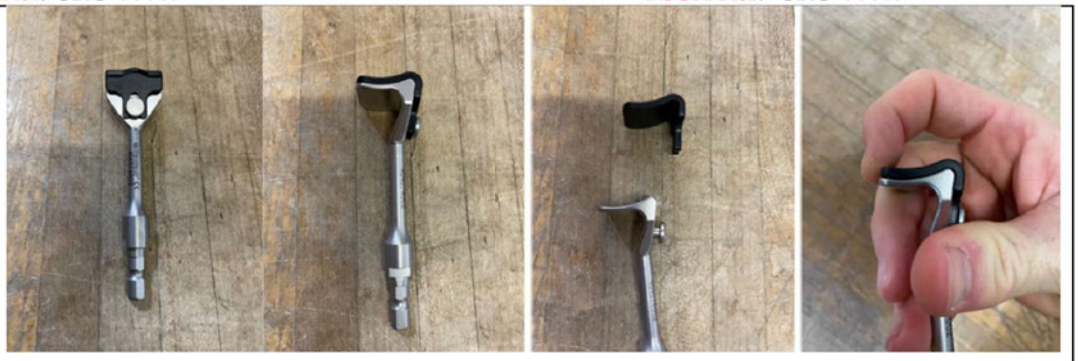

A potential misuse involves levering the Radel cover from the posterior which can weaken the junction between the Radel and stainless-steel frame (as shown in the far-right image above).

2.	2. Hazard giving rise to the FSCA*
	A number of variables including user error, implant positioning, patient factors, and implant size selection) could have all contributed to these complaints.
2.	3. Probability of problem arising
	Based upon Exactech's health hazard evaluation, the occurrence rate for the failure is very low (0.22%).
2.	4. Predicted risk to patient/users
	Based upon Exactech's health hazard evaluation, the probability of risk is negligible with no adverse health consequences.
2.	5. Further information to help characterise the problem
	No further information than the data presented above (2.3 and 2.4).
2.	6. Background on Issue
	Beginning in 2020 and as of 15 Nov 2023, Exactech has received 12 (2 US, 10 OUS) complaints associated with Part Number 351-07-04 (LP TALAR IMPACTOR INSERT), specifically the tab that connects the component to the impactor frame is fracturing intraoperatively. For the 2 complaints wherein a piece of Part Number 351-07-04 fell into the surgical wound site, the pieces were retrieved without clinical sequalae. There has been no adverse patient/user impact as a result of the aforesaid failure.
2.	7. Other information relevant to FSCA
	None
	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.

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3.	2. By when should the action be completed?	Distributors receiving this Field Safety Notice shall immediately provide the Field Safety Notice (FSN) to the affected surgeon(s) that had performed surgeries involving the affected devices noted under section I of this document. This Field Safety Notice (FSN) should be signed and returned within 15 business days.	
3.	3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? No Device is an instrument used by trained healthcare professionals. No other considerations are applicable or required as this issue does not result in any adverse patient outcomes or harm.		
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)		Yes
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☐ Other ☐ None Reference the following supplemental documents provided with the FSN: • Vantage Ankle Operative Technique 721-00-32 (see warning on page 32) • Vantage Ankle Operative Technique poster 721-00-31 (see warning on Fig 20) • Assembly/Disassembly Instructions for Vantage Talar Cover and Impactor Frame		
3	6. By when should the action be completed?	Upon notification of this Field Safety Notice (FSN) to impacted customers the FSN shall be signed and returned within 15 business days.	
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?		
	No Not appended to this FSN		

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	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Not Applicable
4.	3. For Updated FSN, key new information as follows:	
	Not Applicable	
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:	
	Not Applicable	
4	6. Anticipated timescale for follow-up FSN	Not Applicable
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Exactech, Inc.
	b. Address	2320 NW 66th Court, Gainesville, FL 32653
	c. Website address	www.exac.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	1) Vantage Ankle Operative Technique 721-00-32 (see warning on page 32) 2) Vantage Ankle Operative Technique poster 721-00-31 (see warning on Fig 20) 3) Assembly/Disassembly Instructions for Vantage Talar Cover and Impactor Frame
4.	10. Name/Signature	**Name:** **Miguel Sosa,** **Vice President, Quality Assurance**
		Signature: [redacted]

	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.

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Distributor/Importer Reply Form

1. Field Safety Notice Information	
Correction Notice Ref. no.:	CRC-00009
Correction Notice Date:	19/12/2023
Product/ Device name	Vantage LP Talar Impactor Insert
Product Code(s)	351-07-04
Batch/Serial Number (s)	Not Applicable

2. Distributor/Importer Details	
Company Name	Exactech Deutschland GmbH
Address	Werftstraße 193, Kiel, 24143 Germany
Contact Name	David Backhuss
Title or Function	General Manager
Telephone number	+49-431-990293-0
Email	david.backhuss@exac.com
1. Return acknowledgement to Sender	
Email	recalls@exac.com
Distributor/Importer Helpline	+1 800-392-2832
Postal Address	2320 NW 66th Court, Gainesville, FL 32653 USA
Web Portal	www.exac.com
Deadline for returning the Distributor/Importer reply form*	Within 15 business days of receipt of Field Safety Notice.

2. Distributors/Importers (check all that apply)		
o	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	
o	I have identified customers that received or may have received this device.	
o	I have informed the identified customers of this Field Safety Notice.	Date of communication:
Print Name		
Signature		
Date		

It is important that your organization confirms that you have received the Field Safety Notice and takes the actions detailed in this Field Safety Notice.

Your organization's reply is the evidence we need to monitor the progress of the proposed actions.