INNOMED, INC.
103 Estus Drive
Savannah, GA 31404

FSN Ref: 520054FSN24 FSCA Ref: 520054REC24

Date: 2024/03/08

Field Safety Notice
Cup Removal Starter Instrument-54MM

For Attention of: **Lene Fischer**

Contact details of local representative (name, e-mail, telephone, address etc.)
Lene Fischer **Fischer Medical ApS** **Ellekær 9, Varemodtagelsen** **DK-2730 Herlev**

PHONE: 912-236-0000 / 800-548-2362 FAX: 912-236-7766
E-MAIL: info@innomed.net www.innomed.net

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Field Safety Notice (FSN)
Cup Removal Instrumental
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Extractor
1.	2. Commercial name(s)*
	Add as Appendix if necessary.
1.	3. Unique Device Identifier(s) (UDI-DI)
	00840277104007
1.	4. Primary clinical purpose of device(s)*
	Helps to quickly and precisely remove an acetabular cup with minimal bone loss.
1.	5. Device Model/Catalogue/part number(s)*
	5400-54
1.	6. Software version
	NA
1.	7. Affected serial or lot number range
	1223K
1.	8. Associated devices
	NA

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	54 mm finisher blade was inadvertently affixed to the shaft of the CupX handle in lieu of the 54 mm starter blade.
2.	2. Hazard giving rise to the FSCA*
	There are no health hazards associated with the FSCA
2.	3. Probability of problem arising
	There is zero probability that a problem will arise.
2.	4. Predicted risk to patient/users
	The risk is minimal. The blade stays in contact with the cup longer making it minutely challenging to engage the angle of the shaft.
2.	5. Further information to help characterise the problem
	NA
2.	6. Background on Issue
	During inventory survey, the contract manufacturer noted the described issue, and alerted legal manufacturer, Innomed, Inc. of the issue.
2.	7. Other information relevant to FSCA
	This field may only contain additional information that is deemed necessary by the manufacturer to supplement information relevant to the 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?	May 15, 2024
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No No patient follow up is required because the risk is minimal	
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 Innomed, Inc. provided US domestic customers call tags to return the affected devices. International customers were asked to destroy the affected devices	
3.	6. By when should the action be completed?	May 15, 2024
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.	

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	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant.
4.	3. For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
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:	
	Status on returned and disposed devices.	
4.	6. Anticipated timescale for follow-up FSN	May 20, 2024
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Innomed, Inc.
	b. Address	103 Estus Drive, Savannah, GA 31404
	c. Website address	Only necessary if not evident on letter-head.
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. Yes	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	Irene Davis VP Quality Assurance *Irene Davis*

	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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