Rev 2: February 2020
FSN Ref: CAPA-2025-05 FSCA Ref: CAPA-2025-05

Date: 2025-03-04

Field Safety Notice
MICROCONE NI implant

For Attention of*: FSCA responsible person in your organization

Contact details of local representative (name, e-mail, telephone, address etc.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages.

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Field Safety Notice (FSN)
MICROCONE NI implant
Risk addressed by FSN

1. Information on Affected Devices*

1. 1. Device Type(s)*

MICROCONE implants are screw-shaped dental implants which serve as tooth root replacements.

1. 2. Commercial name(s)*

MICROCONE implant

1. 3. Unique Device Identifier(s) (UDI-DI)

04251574831859
04251574831866
04251574831873

1. 4. Primary clinical purpose of device(s)*

Restoration of the esthetics and functionality of the teeth in partially or fully edentulous patients. The MICROCONE NI Implants D 3.0 may only be used to replace the upper, lateral incisors (region 12/22) and the lower, middle and lateral incisors (region 31/32/41/42).

1. 5. Device Model/Catalogue/part number(s)*

1-01-06
1-01-07
1-01-08

1. 6. Software version

n/a

1. 7. Affected serial or lot number range

1-01-06	1-01-07	1-01-08
L0063582	L0063593	L0063596
L0065343	L0064678	L0065345
L0072370	L0065406	L0076434
L0073077	L0065408	L0090086
L0073078	L0075120	L0090087
L0074465	L0076079	L0116201
L0075119	L0077622	
L0075357	L0085095	
L0076433	L0085096	
L0077621	L0090005	
L0078616	L0090998	
L0082746	L0116199	
L0082747	L0116200	
L0083949	L0117450	
L0083951	L0124710	
L0090543		
L0093926		
L0098542		
L0103386		

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	L0110966 L0110968 L0114579 L0116197 L0119513 L0123340 L0123341
1.	8. Associated devices
	n/a

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	It has been detected that the above listed batches are manufactured from titanium grade 4 instead of Ti-6Al-4V ELI.
2.	2. Hazard giving rise to the FSCA*
	MICROCONE NI implants with diameter D 3.0 are used to replace the upper, lateral incisors (region 12/22) and the lower, middle and lateral incisors (region 31/32/41/42). In comparison to MICROCONE RI implants with diameter D 3.5-5.0 which are manufactured from titanium grade 4, MICROCONE NI implants with diameter D 3.0 are manufactured from the material Ti-6Al-4V ELI, whereas both materials are SOTA dental implant materials. Complaint data available to date do not indicate a significant difference between the conforming and nonconforming products. Our investigation including biocompatibility assessment or stability testing shows that there is no elevated risk for the patient in comparison to the conforming product. However, to prevent further implantation of nonconforming products, the affected batches are recalled. Already successfully implanted nonconforming products should be monitored at regular intervals in the dental practice and do not need to be removed or replaced.
2.	3. Probability of problem arising
	-
2.	4. Predicted risk to patient/users
	-
2.	5. Further information to help characterise the problem
	-
2.	6. Background on Issue
	-
2.	7. Other information relevant to FSCA
	-

3. Type of Action to mitigate the risk*		
3.	**1. Action To Be Taken by the User*** ☒ Identify Device ☒ Quarantine Device ☒ Return Device	
3.	2. By when should the action be completed?	24 MAR 2025

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3.	3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? No Already successfully implanted nonconforming products should be monitored at regular intervals in the dental practice and do not need to be removed or replaced.	
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 Affected products on the market will be recalled.	
3.	6. By when should the action be completed?	04 SEP 2025
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. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	MEDENTiKA GmbH
	b. Address	Hammweg 8-10, 76549 Hügelsheim, Germany
	c. Website address	www.medentika.de
4.	3. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	4. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	5. Name/Signature	Insert Name and Title here and signature below.

	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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