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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Template for a Field Safety Notice Customer Reply Form

Customer Reply Form

1. Field Safety Notice (FSN) information			
FSN Reference number*	CAPA-2025-05		
FSN Date*	04-Mar-2025		
Product/ Device name*	MICROCONE NI implant		
Product Code(s)	1-01-06 1-01-07 1-01-08		
Batch/Serial Number (s)	**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		
	L0110966		
	L0110968		
	L0114579		
	L0116197		
	L0119513		
	L0123340		
	L0123341		

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A		
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
☐	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:	
☐	No affected devices are available for return/ destruction	Customer to complete or enter N/A		
☐	Other Action (Define):			
☐	I do not have any affected devices.	Customer to complete or enter N/A		
☐	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	Pre-filled by manufacturer/sender/requester
Customer Helpline	Pre-filled by manufacturer/sender/requester
Postal Address	Pre-filled by manufacturer/sender/requester
Web Portal	Pre-filled by manufacturer/sender/requester
Fax	Pre-filled by manufacturer/sender/requester
Deadline for returning the customer reply form*	Pre-filled by manufacturer/sender/requester

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.

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Template for a Field Safety Notice Distributor/Importer Reply Form

Distributor/Importer Reply Form

1. Field Safety Notice (FSN) information			
FSN Reference number*	CAPA-2025-05		
FSN Date*	04-Mar-2025		
Product/ Device name*	MICROCONE NI implant		
Product Code(s)	1-01-06 1-01-07 1-01-08		
Batch/Serial Number (s)	**1-01-06**	**1-01-07**	**1-01-08**
	L0063582	L0063593	L0063596
	L0065343	L0064678	L0065345
	L0072370	L0065406	L0076434
	L0073077	L0065408	L0090086
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	L0082747	L0116200	
	L0083949	L0117450	
	L0083951	L0124710	
	L0090543		
	L0093926		
	L0098542		
	L0103386		
	L0110966		
	L0110968		
	L0114579		
	L0116197		
	L0119513		
	L0123340		
	L0123341		

2. Distributor/Importer Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Return acknowledgement to Sender	
Email	regulatory@medentika.de
Distributor/Importer Helpline	Not applicable
Postal Address	Hammweg 8-10. D-76549 Hügelsheim
Web Portal	www.medentika.de
Deadline for returning the Distributor/Importer reply form*	24-Mar-2025

4. Distributors/Importers (Tick all that apply)		
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A
☐	I have checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date
☐	I have identified customers that received or may have received this device	
☐	I have attached customer list	
☐	I have informed the identified customers of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified customers	
☐	I have returned affected devices - enter number of devices returned and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
☐	I have destroyed affected devices – enter number destroyed and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
☐	Neither I nor any of my customers has any affected devices in inventory	
Print Name*		Distributor/Importer print name here
Signature*		Distributor/Importer sign Here
Date *		

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.