Rev 2: February 2020
FSN Ref: 446_1000788906 FSCA Ref: 446_1000788906

Date: 2022-12-14

Field Safety Notice
Device Commercial Name

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)
Device Commercial Name
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	QUATTROCONE30 are dental implant systems consisting of screw-shaped dental implants and the associated prosthetic components. The endosseous implants serve as tooth root replacements.
1.	2. Commercial name(s)*
	QUATTROCONE30 Implant
1.	3. Unique Device Identifier(s) (UDI-DI)
	04251574832597, 04251574832603, 04251574832610
1.	4. Primary clinical purpose of device(s)*
	QUATTROCONE implants are used to anchor dentures in the jawbone. The angled QUATTROCONE30 implants are used as terminal implants within the framework of the so-called "Quattrofix concept".
1.	5. Device Model/Catalogue/part number(s)*
	4-01-01, 4-01-02, 4-01-03
1.	6. Software version
	n/a
1.	7. Affected serial or lot number range
	L0027060, L0027061, L0065893, L0067687, L0074580, L0088587, L0071168, L0088586
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 labelling falsely indicates a closure screw to be included.
2.	2. Hazard giving rise to the FSCA*
	The QUATTROCONE30 implant is for use in an angulated drilling hole of 30°. The product is indicated for immediate loading and therefore a closure screw is not required. In the rare cases when the prosthetic restoration is not immediately after implantation, this could lead to follow-up treatment. This Field Safety Corrective Action does not affect already successfully implanted products. No special follow up is required for those patients.
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
	-

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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	
3.	2. By when should the action be completed?	28 FEB 2023
3.	3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? No Successfully implanted products are not concerned as the practitioner used it without a closure screw. There is no risk for patients with already implanted products, therefore there is no need for a follow-up.	
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 ☒ IFU or labelling change Products on the market will be recalled. Correction of labels for future lots.	
3.	6. By when should the action be completed?	28 FEB 2023
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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