

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.

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* <i>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.</i>
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*	
	<input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> 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*	
	<input checked="" type="checkbox"/> Product Removal <input checked="" type="checkbox"/> 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.	

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	
	<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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.*</p>

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

Template for a Field Safety Notice Customer Reply Form

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	446_1000788906
FSN Date*	14.12.2022
Product/ Device name*	QUATTROCONE30 Implant
Product Code(s)	4-01-01 4-01-02 4-01-03
Batch/Serial Number (s)	L0027060 L0027061 L0065893 L0067687 L0074580 L0088587 L0071168 L0088586

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			
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A	
<input type="checkbox"/>	I performed all actions requested by the FSN.	Customer to complete or enter N/A	
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A	
<input type="checkbox"/>	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:

<input type="checkbox"/>	No affected devices are available for return/ destruction	Customer to complete or enter N/A
<input type="checkbox"/>	Other Action (Define):	
<input type="checkbox"/>	I do not have any affected devices.	Customer to complete or enter N/A
<input type="checkbox"/>	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.