Rev 1: September 2018
FSN Ref: 21/01 FSCA Ref: 21/01

Date: 08.07.2021

Urgent Field Safety Notice
Device Commercial Name

For Attention of*: Dental Laboratory (Thommen Medical Customer)

Contact details of local representative (name, e-mail, telephone, address etc.)*
Oscar Banz, regulatory@thommenmedical.com, +41 61 965 9020, Neckarsulmstrasse 28, 2540 Grenchen

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Urgent Field Safety Notice (FSN)
Device Commercial Name
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Dental implant suprastructure kit, provided non-sterile.
1.	2. Commercial name(s)
	VARIOflex abutment set for crown, PF 4.0, H 12.0
1.	3. Unique Device Identifier(s) (UDI-DI)
	7640156477900
1.	4. Primary clinical purpose of device(s)*
	Thommen Medical prosthetic components are used in combination with the Thommen Medical Dental Implant System in the upper and lower jaw for implant-borne tooth replacement.
1.	5. Device Model/Catalogue/part number(s)*
	1.04.831
1.	6. Software version
	Only where relevant.
1.	7. Affected serial or lot number range
	Lot No. 24986
1.	8. Associated devices
	Within context of the FSCA eg for IVD reagents and platforms.

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	During the packaging process of the VARIOflex set, the abutment was accidentally not packed.
2.	2. Hazard giving rise to the FSCA*
	There is no risk to user and patient, since the abutment is prepared in a dental laboratory before it will go to the dentist andpatient. Usually at the time when this abutment is being prepared in the dental laboratory, the patient has already the dentalimplant in place and is waiting for the completion of the teatment with the crown or denture. Any delays in these treatmentsbear therefore no risks.
2.	3. Probability of problem arising
	The probability of any problem arising is very unlikely.
2.	4. Predicted risk to patient/users
	Since no patients are involved at this level there is no risk to user and patient
2.	5. Further information to help characterise the problem
	None
2.	6. Background on Issue
	The missing abutment was detected in a dental laboratory, who in turn informed us immediately.
2.	7. Other information relevant to FSCA

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	This field may only contain additional information that is deemed necessary by the manufacturer to supplement information relevant to the FSCA.

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?	16.07.2021
3.	3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? No Since no patients are involved at this level there is no patient follow-up necessary.	
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

The 2 customers in Switzerland have been informed to return the faulty sets.

3	6. By when should the action be completed?	16.07.2021
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:	
	Eg patient management, device modifications etc	
4	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Thommen Medical AG**
	b. Address	**Neckarsulmstrasse 28, 2540 Grenchen**
	c. Website address	**www.thommenmedical.com**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	**Oscar Banz, RA & VIG Manager**
		O. Banz

	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.