VALOC

FSN Ref: FSN1 FSCA Ref: FSCA1

Date 16-April-2020

Urgent Field Safety Notice
Adapter Optiloc® for handpiece length, 26 mm

For Attention of*:[Person responsible at Distributor and Dentist]

Contact details of local representative
Straumann Group Adriatic d.o.o., Lidija Marić Mačefat, Stefanovecka cesta 10, 10000 Zagreb, Croatia, lmaricmacefat@sanitaria.hr, +38 5161 811 78

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Urgent Field Safety Notice (FSN)
Adapter Optiloc® for handpiece length, 26 mm
Lack of retention between Adapter Optiloc® and handpiece

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	Adapter Optiloc® for handpiece, length 26mm Ref. 170.1 
1.	2. Commercial name(s)
	Adapter Optiloc® for handpiece, length 26 mm
1.	3. Unique Device Identifier(s) (UDI-DI)
	07640181451470
1.	4. Primary clinical purpose of device(s)*
	The Adapter Optiloc® for handpiece is intended to facilitate the proper insertion of single-piece Mini Implants. The Mini Implant is inserted by hand into the drill hole. The Mini Implant is moved into the final position by applying torque with the handpiece using the Adapter Optiloc® (Ref. 170.1).
1.	5. Device Model/Catalogue/part number(s)*
	170.1
	Batch codes: 17.93403, CH103888, CH103889, CH109608, CH111240, CH112666, CH112735, CH114073, CH115834, CH118133, CH121025, CH127520

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	The Adapter Optiloc® (Ref. 170.1) might not engage properly with the locking mechanism of the handpiece. This could result in a lack of retention between the Adapter Optiloc® (Ref. 170.1) and the handpiece.
2.	2. Hazard giving rise to the FSCA*
	If there is a lack of retention between the Adapter Optiloc® (Ref. 170.1) and the handpiece, the device might fall off the handpiece after the procedure of Mini Implant insertion and it might be ingested or aspirated, which could necessitate additional intervention or immediate treatment. No such case has been reported to Valoc AG.
2.	3. Probability of problem arising
	Based on complaint investigation, testing has shown that not all parts are affected. According to the total cumulative complaint data, the occurrence rate of the issue arising is 0.65% which corresponds to a probability of "probable" (6.5 x 10-3). Out of the 0.65% of potentially problematic parts, based on scientific literature, the probability of a clinical complication arising as a result of ingestion or aspiration is 1%, translating to a probability of 1x10-2. The combined probability is "remote" (6.5 x 10-5) . No such case has been reported to Valoc AG.
2.	4. Predicted risk to patient/users

	CAPA 9 Risk Assessment has determined a probability "occasional" (3) and severity "serious" (3, short-term injury or impairment requiring additional medical intervention to correct). No such case has been reported to Valoc AG.
2.	5. Background on Issue
	Valoc AG has received a small number of complaints reporting lack of retention of the Adapter Optiloc® (Ref. 170.1) in the handpiece. The investigation of these complaints has shown that in some cases the Adapter Optiloc® (Ref. 170.1) does not engage with the locking mechanisms of the handpiece. The root cause is the wrong position of the step in the shaft which engages with the locking mechanism of the handpiece. In some cases, the interaction of the production tolerances of both the product and the handpiece used can lead to the problem. In the majority of cases, the locking mechanism engages as intended without a problem occurring.

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

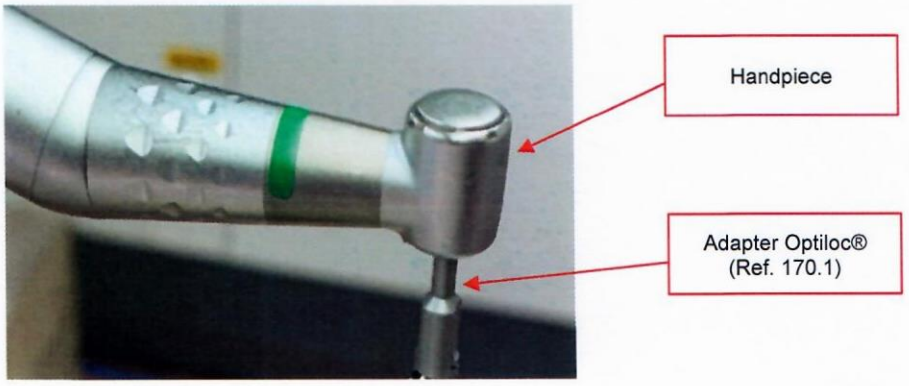
☒ On-site device modification/inspection

☐ Follow patient management recommendations

☒ Take note of amendment/reinforcement of Instructions For Use (IFU)

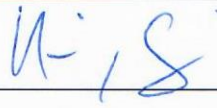
☐ Other ☐ None

Conduct a check of the retention mechanism with the handpiece as part of the inspection. Insert the Adapter Optiloc® (Ref. 170.1) into the handpieces used and check the engagement of the locking mechanisms by pulling on the Adapter Optiloc® (Ref. 170.1). Proper engagement of the locking mechanism is indicated by a clicking sound. Make sure that the Adapter Optiloc® (Ref. 170.1) cannot be pulled out of the handpiece.
Return the device if the locking mechanism does not work properly.
Complete and return the Distributor/Customer Response Form.



3.	2. By when should the action be completed?	15.05.2020
3.	3. Is customer Reply Required? *	Yes

	(If yes, form attached specifying deadline for return)	
3.	**4. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☒ Other ☐ None - Design change of product (corrected positioning of the step in the shaft). - Addition of warning in IFU regarding ensuring proper connection to handpiece before every use.	
3	5. By when should the action be completed?	03.04.2020
3.	6. Is the FSN required to be communicated to the patient /lay user?	No

	4. General Information*	
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN? *	No
4.	3. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	4. List of attachments/appendices:	IFU 118 Rev. 1, Distributor Reply Form, Customer Reply Form
4.	5. Name/Signature	Yanis Guesmia Management Representative Valoc AG
		

	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.