Product FSN: 694 AR

Rev 1: September 2018

FSN Ref: 2020-06-22_D200608

FSCA Ref: 2020-06-22_D200608

Date: 22.06.2020

Urgent Field Safety Notice
Device Commercial Name

For Attention of*: Customers and wholesale distributions
Notified Bodies
Competent national authorities

Contact details of local representative (name, e-mail, telephone, address etc.)*
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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)*
	Retention part of dental attachments. Non sterile device. 694 AR (Defective piece)  694 AR OL 0285 TI OL 0285 IR OL 694 R OL 694 RPR OL 724 RPR OL 0885 TI
1.	2. Commercial name(s)
	Add as Appendix if necessary. 694 AR CEKA M3 RETENTION PART SPACER 2+2 PCS OL 0285 TI REVAX M3 TI/SPACER OL 0285 IR REVAX M3 IR/SPACER OL 694 R CEKA M3 IR/SPACER OL 694 RPR CEKA M3 PR/SPACER OL 724 RPR CEKA M3 PR/SPACER OL 0885 TI REVAX M3 AXIAL TI/SPACER
1.	3. Unique Device Identifier(s) (UDI-DI)
	Not Applicable
1.	4. Primary clinical purpose of device(s)*
	How the device(s) is/are used in the clinical setting/intended use. CEKA and Preci-Line retention parts and base rings The device is to be used as a retention part to thread in males (spring pin). They form part of an attachment system and are incorporated into a dental prosthesis or a post coping by the dental technician or dentist. Long-term in-oral use is applied.

1.	5. Device Model/Catalogue/part number(s)*
	694 AR OL 0285 TI OL 0285 IR OL 694 R OL 694 RPR OL 724 RPR OL 0885 TI
1.	6. Software version
	Not Applicable
1.	7. Affected serial or lot number range
	Lot D200608
1.	8. Associated devices
	None

	2 **Reason for Field Safety Corrective Action (FSCA)***
2.	1. Description of the product problem*
	The spring pin 694 C is not screwing till the end in the retention part 694 AR , defect of retention part 694 AR thread.
2.	2. Hazard giving rise to the FSCA*
	Details of the greatest hazard to the patient/end user that the advice/action is intended to mitigate. Make clear whether risk is to user, patient or both. Should also try to indicate the residual risk if the FSN advice/action is taken. Lower device lifetime for the patient
2.	3. Probability of problem arising
	Moderate probability
2.	4. Predicted risk to patient/users
	Prothesis/device could break or split; swallowing broken components; open wound within patients mouth (product of severity 3 x probability 3) resulting in RPN 9 which is moderate risk managed to an acceptable level according to the product's risk assessment
2.	5. Further information to help characterise the problem
	Only one complaint/incidence occurred from one customer for a defect that can be easily seen when screwing the components together by the user. The manufacturer`s initial investigation advises the problem relates only to this lot of product. No injury reported for this incident.
2.	6. Background on Issue
	One customer complaint received: The spring pin 694 C is not screwing till the end in the retention part 694 AR. The manufacturer's initial investigation advised that cause of the defect was related to cutting tool used in the production for the concerned lot. Further investigations are undergoing to confirm the root cause. The Manufacturer advised no other products are affected. An additional control measure is put in place for better quality control. The Manufacturer is finalising investigation and corrective actions necessary. No other products are being produced until the investigation and corrective actions have been completed.
2.	7. Other information relevant to FSCA
	Not applicable

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? 10.07.2020	Specify where critical to patient/end user safety

3. 3. Particular considerations for: Choose an item.

Is follow-up of patients or review of patients' previous results recommended?
Choose an item.
Follow up is required
The defect should be easily identified by the users during use, if it is already fitted, it is recommended not to remove the devices due to additional infection risk. Informing the patient is up to the discretion of the dental practitioner.

3.	4. Is customer Reply Required? * YES (If yes, form attached specifying deadline for return)	Choose an item. 10.07.2020

3. 5. Action Being Taken by the Manufacturer

■ Product Removal ☐ On-site device modification/inspection
☐ Software upgrade ☐ IFU or labelling change
☐ Other ☐ None

Provide further details of the action(s) identified.

3	6. By when should the action be completed?	Specify where critical to patient/end user safety 10.07.2020
3.	7. Is the FSN required to be communicated to the patient /lay user?	Choose an item. 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. NOT Applicable

	4. General Information*	
4.	1. FSN Type*	Choose an item. Voluntary FSN
4.	2. For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant Not applicable
4.	**3.** For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken. Not Applicable	
4.	4. Further advice or information already expected in follow-up FSN? *	Choose an item. Follow up will be provided by 31.07.2020
4	5. If follow-up FSN expected, what is the further advice expected to relate to: Eg patient management, device modifications etc Follow up to update on FSN completion	
4	6. Anticipated timescale for follow-up FSN	For provision of updated advice. 31.07.2020
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Only necessary if not evident on letter-head.
	b. Address	Only necessary if not evident on letter-head.
	c. Website address	Only necessary if not evident on letter-head.
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * yes	
4.	9. List of attachments/appendices:	None
4.	10. Name/Signature	xxx

	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.