Ivoclar Vivadent AG
Benderer Strasse 2
9494 Schaan
Liechtenstein

T +423 235 35 35
F +423 235 33 60
ivoclar.com

Ivoclar Vivadent AG | Benderer Strasse 2 | 9494 Schaan

To all users of a VivaPen Snap-On Cannula and Adhese Universal in the Vivapen

Schaan, November 15, 2022

Urgent use and safety notice (10-2022-001)
Adhese Universal VivaPen Snap-On cannulas for VivaPen

Dear VivaPen and VivaPen cannula user,

You are receiving this letter because our records indicate that you have bought VivaPen cannulas in the recent past. As the safety of your patients is of the utmost importance to us, we would like to inform you about a potential safety risk in conjunction with the VivaPen cannulas and about preventive measures that should be taken by you.

Potential safety risk: Falling off of the cannula

Due to an irregularity in the production of the cannulas some defective VivaPen cannulas have come into circulation. In rare cases, the affected cannulas may not be reliably fastened to the VivaPen after having attached them. In the worst-case, they may come off during the treatment and fall into the patient's mouth.

Important information: Due to appropriate quality assurance measures, including intensified production control, VivaPen cannulas with a manufacturing date as from September 30th 2022 are corrected for any irregularities and considered to be of impeccable quality.

Risk Minimizing Measures to be considered by Users of the Device:

1. Attach the VivaPen cannula by snapping it into place as indicated in the Instructions for Use. Make sure that you tangibly overcome a point of resistance when attaching the cannula.

Ivoclar Vivadent AG
Benderer Strasse 2
9494 Schaan
Liechtenstein

T +423 235 35 35
F +423 235 33 60
ivoclar.com

If you do not feel a "snap" when attaching the cannula, do not use it and discard it. If there are concerns regarding the fit of the cannula, please contact your distributor rep and you will be provided with a free replacement as quickly as possible.

2. Always use the VivaPen with the respective protective sleeve (see Instructions for Use, chapter 2.1.4). Correct use of the protective sleeve will prevent the cannula from coming off inside the patient's mouth and being inhaled or ingested.

3. Please sensitize your customers to consider the described risk minimizing measures for all batches of VivaPen cannulas made available on the market by Ivoclar Vivadent AG.

Please contact your dealer representative to receive the necessary information about the protective sleeves (item number #627492; 300 pcs VivaPen protective sleeves).

Contact Information

1. Regarding replacement or credit note for VivaPen cannulas affected by this field safety notice please contact the customer service of your distributor. We will arrange all refunds with your responsible distributor.

2. Queries regarding the measures laid down in this field safety notice:

Responsible Department at Manufacturer	
E-Mail	vigilance.li@ivoclar.com
Phone (German/English 8:30 am to 5 pm CET)	+49 7231 3705 355
Postal Address	Ivoclar Vivadent AG Customer Care Global Vigilance Bendererstrasse 2 FL-9494 Schaan Liechtenstein

All queries by email will be answered within one working day (24 hours)

We are very sorry for the inconvenience and thank you for your understanding. In you have any questions, please feel free to contact your customer service team at any time.

Your Ivoclar product management

Ivoclar Vivadent AG
Benderer Strasse 2
9494 Schaan
Liechtenstein

T +423 235 35 35
F +423 235 33 60
ivoclar.com

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	10-2022-001
FSN Date	2022-11-15
Product/ Device name	VivaPen Snap-On Cannulas
Product Codes	752382 752383 752384 745762 745763
Batches	all batches

2. Customer Details	
Name / Company / Practice	
Address	
Contact Name	
E-Mail	

3. Customer action undertaken on behalf of Healthcare Organisation				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.			
☐	I perform all actions requested by the FSN, e.g. mandatory use of sleeves			
☐	I have returned devices and received a replace-ment from distributor (dealer) - enter number of devices returned and date complete.	Qty:	Lot:	Date Returned (DD/MM/YY):
		Qty:	Lot:	Date Returned (DD/MM/YY):
		N/A	Comments:	
☐	No affected devices are available for return/ destruction			
☐	I do not have any affected devices.			
Print Name				
Signature				
Date				

4. Return acknowledgement to sender	
E-Mail	E-Mail address to be filled in by the dealer
Deadline for returning the customer reply form	14 days after receipt of the FSN

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.