

Business partners of Ivoclar Vivadent AG

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Schaan, November 15, 2022

Urgent Use and Safety Notice (10-2022-001) VivaPen Snap-On Cannulas for VivaPen

Dear Sir or Madam

The purpose of this letter is to inform you about an **urgent Use and Safety Notice that has been issued for our products VivaPen and VivaPen Snap-On Cannulas**.

During the past few months, individual users have informed us about the fact that in rare cases the Viva-Pen Cannula became detached from the VivaPen during use. As the cannulas may come off during the treatment, there is a potential risk for patients, as they could ingest or inhale them. In this context we would like to point out that the mentioned risk can be avoided if the VivaPen is used with a protective sleeve as described in the Instructions for Use.

Based on the number of complaints we received, it can be assumed that only a small number of the cannulas sold has been affected. The number of reported cases amounts to < 0.001% of the sales volume worldwide.

Ivoclar Vivadent AG has carried out a risk assessment and, as a preventive measure (FSN - Field Safety Notice), has decided to actively inform VivaPen users about the risk. **Please forward the attached Use and Safety Notice to all your VivaPen customers immediately and ask them to confirm the receipt of the Notice.**

The Use and Safety Notice explains how users can make sure that the cannula is reliably fastened to the VivaPen. Moreover, we advise users to use the protective sleeve as described in the Instructions for Use, as this will eliminate the risk. In the Notice, we point out that defective cannulas must not be used and should either be discarded or returned to the respective Customer Service team.

The problem responsible for the cannula coming off has been resolved since 30 September 2022. Moreover, stricter quality assurance measures have been put in place by the manufacturer. Therefore, all current deliveries involve products that are of impeccable quality. Should you still have cannulas in stock that were supplied before 1 November 2022, you can get in touch with our sales organization to arrange the replacement of the cannulas.

How to inform your customers

Please immediately send the attached customer letter to all your VivaPen and VivaPen Cannula clients in 2022. We are very sorry for the inconvenience and thank you in advance for supporting us in informing the VivaPen users.

Please instruct your customer to acknowledge receipt of this field safety notice issued by Ivoclar Vivadent AG and to confirm that the risk minimizing measures defined by Ivoclar Vivadent AG are implemented. Please collect the feedback from your customers and submit this compiled feedback to vigilance.li@ivoclar.com

Please find attached the FSN and the template for customer reply to be used.

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.



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.

Contact Details for this Field Safety Notice:

Name and Function: Dr. Falk Brustmann (Global Vigilance Manager)

Email: vigilance.li@ivoclar.com

Phone: +49 7231 3705355 (German/English- Available 08:30 am to 05:00 pm CET)

All email requests are answered within one business day!

Sincerely

Your Ivoclar Product Management

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