

Urgent use and safety notice (03-2026-001-R)

Adhese 2 DC VivaPen Kits and DC Cannulas for VivaPen

Dear valued Ivoclar Distribution Partner,

you are receiving this urgent use and safety notice because our records indicate that you received unfortunately **Adhese 2 DC VivaPen Kits and/or DC Cannulas for VivaPen** affected by our field safety corrective action (03-2026-001-R) for distribution to professional users.

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 DC Cannulas for VivaPen and about preventive measures that should be taken by you.

The following Adhese 2 DC VivaPen Kits contain DC Cannulas for VivaPen are affected by this field safety corrective action:

Art. No.	Description	Batch No. / Serial No.	UDI Information UDI DI/UDI-PI (human readable) and Barcode/Datamatrix (machine readable)
757028	Adhese 2 DC VivaPen Kit 2ml/100	Z0BFV3	(01) 07615208464689 (11) 251030 (17) 271030 (10) Z0BFV3 (241) 757028
757028	Adhese 2 DC VivaPen Kit 2ml/100	Z0BHSV	(01) 07615208464689 (11) 251030 (17) 271030 (10) Z0BHSV (241) 757028
757028	Adhese 2 DC VivaPen Kit 2ml/100	Z0BJGV	(01) 07615208464689 (11) 251030 (17) 271030 (10) Z0BJGV (241) 757028
757028	Adhese 2 DC VivaPen Kit 2ml/100	Z0BJGW	(01) 07615208464689 (11) 251030 (17) 271030 (10) Z0BJGW (241) 757028
757028	Adhese 2 DC VivaPen Kit 2ml/100	Z0BJGX	(01) 07615208464689 (11) 251030 (17) 271030

			(10) Z0BJGX (241) 757028
757028	Adhese 2 DC VivaPen Kit 2ml/100	Z0BK4X	(01) 07615208464689 (11) 251030 (17) 271030 (10) Z0BK4X (241) 757028
757028	Adhese 2 DC VivaPen Kit 2ml/100	Z0BLZN	(01) 07615208464689 (11) 251030 (17) 271030 (10) Z0BLZN (241) 757028
757028	Adhese 2 DC VivaPen Kit 2ml/100	Z0BLZP	(01) 07615208464689 (11) 251030 (17) 271030 (10) Z0BLZP (241) 757028
757028	Adhese 2 DC VivaPen Kit 2ml/100	Z0BM67	(01) 07615208464689 (11) 251030 (17) 271030 (10) Z0BM67 (241) 757028
757028	Adhese 2 DC VivaPen Kit 2ml/100	Z0BNWP	(01) 07615208464689 (11) 251217 (17) 271217 (10) Z0BNWP (241) 757028
757028	Adhese 2 DC VivaPen Kit 2ml/100	Z0BPTZ	(01) 07615208464689 (11) 260112 (17) 280112 (10) Z0BPTZ (241) 757028
757028	Adhese 2 DC VivaPen Kit 2ml/100	Z0BR7Y	(01) 07615208464689 (11) 260112 (17) 280112 (10) Z0BR7Y (241) 757028
757028	Adhese 2 DC VivaPen Kit 2ml/100	Z0BR7Z	(01) 07615208464689 (11) 260112 (17) 280112 (10) Z0BR7Z (241) 757028
757028	Adhese 2 DC VivaPen Kit 2ml/100	Z0BRVD	(01) 07615208464689 (11) 260112 (17) 280112 (10) Z0BRVD (241) 757028

757028	Adhese 2 DC VivaPen Kit 2ml/100	Z0BSTC	(01) 07615208464689 (11) 251030 (17) 271030 (10) Z0BSTC (241) 757028
757028	Adhese 2 DC VivaPen Kit 2ml/100	Z0BSTD	(01) 07615208464689 (11) 251030 (17) 271030 (10) Z0BSTD (241) 757028
757028	Adhese 2 DC VivaPen Kit 2ml/100	Z0BSTF	(01) 07615208464689 (11) 251030 (17) 271030 (10) Z0BSTF (241) 757028
757028	Adhese 2 DC VivaPen Kit 2ml/100	Z0BSTG	(01) 07615208464689 (11) 251030 (17) 271030 (10) Z0BSTG (241) 757028
757026	Adhese 2 LC/DC VivaPen Starter Kit 0.5 ml	Z0BK52	(01) 07615208460865 (11) 250603 (17) 270603 (10) Z0BK52 (241) 757026
757026	Adhese 2 LC/DC VivaPen Starter Kit 0.5 ml	Z0BSBW	(01) 07615208460865 (11) 260112 (17) 280112 (10) Z0BSBW (241) 757026
757026	Adhese 2 LC/DC VivaPen Starter Kit 0.5 ml	Z0BSBX	(01) 07615208460865 (11) 260112 (17) 280112 (10) Z0BSBX (241) 757026
757026	Adhese 2 LC/DC VivaPen Starter Kit 0.5 ml	Z0BSBZ	(01) 07615208460865 (11) 260112 (17) 280112 (10) Z0BSBZ (241) 757026
757026	Adhese 2 LC/DC VivaPen Starter Kit 0.5 ml	Z0BSC0	(01) 07615208460865 (11) 260112 (17) 280112 (10) Z0BSC0 (241) 757026
757026	Adhese 2 LC/DC VivaPen Starter Kit 0.5 ml	Z0BSJZ	(01) 07615208460865 (11) 260112 (17) 280112

			(10) Z0BSJZ (241) 757026
757026	Adhese 2 LC/DC VivaPen Starter Kit 0.5 ml	Z0BSK0	(01) 07615208460865 (11) 260112 (17) 280112 (10) Z0BSK0 (241) 757026
757026	Adhese 2 LC/DC VivaPen Starter Kit 0.5 ml	Z0BSK1	(01) 07615208460865 (11) 260114 (17) 280114 (10) Z0BSK1 (241) 757026
757026	Adhese 2 LC/DC VivaPen Starter Kit 0.5 ml	Z0BSK2	(01) 07615208460865 (11) 260114 (17) 280114 (10) Z0BSK2 (241) 757026
757026	Adhese 2 LC/DC VivaPen Starter Kit 0.5 ml	Z0BSK3	(01) 07615208460865 (11) 260114 (17) 280114 (10) Z0BSK3 (241) 757026

The following blue DC Cannulas for VivaPen are affected by this field safety corrective action:

Art. No.	Description	Batch No. / Serial No.	UDI Information UDI DI/UDI-PI (human readable) and Barcode/Datamatrix (machine readable)
	DC Cannulas for VivaPen/25 (Part of affected kits)	Z0BP65 Z0BR10 Z0BRVH Z0BSWY Z0BRCP Z0BNNS Z0BSWX Z0BP0S Z0BNNT Z0BH1P Z0BHH6 Z0BJS2 Z0BJVR Z095FM Z09JXT Z09LOX Z095FM Z0BBPY	N/A

	DC Cannulas for VivaPen/10 (Part of affected kits)	Z0BR5Z Z0BP0S Z09JXS Z095JG Z095JH	N/A
757036	DC Cannulas for VivaPen /100	Z0BKPJ	(01) 07615208464757 (11) 260107 (17) 280107 (10) Z0BKPJ (241) 757036
757036	DC Cannulas for VivaPen /100	Z0BKPK	(01) 07615208464757 (11) 260107 (17) 280107 (10) Z0BKPK (241) 757036
757036	DC Cannulas for VivaPen /100	Z0BNFX	(01) 07615208464757 (11) 260123 (17) 280123 (10) Z0BNFX (241) 757036
757036	DC Cannulas for VivaPen /100	Z0BP64	(01) 07615208464757 (11) 260129 (17) 280129 (10) Z0BP64 (241) 757036
757036	DC Cannulas for VivaPen /100	Z0BR11	(01) 07615208464757 (11) 260204 (17) 280204 (10) Z0BR11 (241) 757036
757036	DC Cannulas for VivaPen /100	Z0BRCL	(01) 07615208464757 (11) 260206 (17) 280206 (10) Z0BRCL (241) 757036
757036	DC Cannulas for VivaPen /100	Z0BS9K	(01) 07615208464757 (11) 260212 (17) 280212 (10) Z0BS9K (241) 757036
757036	DC Cannulas for VivaPen /100	Z0BS9L	(01) 07615208464757 (11) 260212 (17) 280212 (10) Z0BS9L (241) 757036
757036	DC Cannulas for VivaPen /100	Z0BSKV	(01) 07615208464757 (11) 260216 (17) 280216

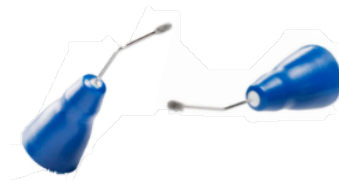
			(10) Z0BSKV (241) 757036
757036	DC Cannulas for VivaPen /100	Z0BSKX	(01) 07615208464757 (11) 260216 (17) 280216 (10) Z0BSKX (241) 757036

Potential safety risk: Reduced bonding of the restauration to the tooth structure and a potential loss of the restauration.

The Adhese 2 DC product in VivaPen contains blue cannulas that enable a dual curing functionality of the adhesive. To achieve this function, the blue cannulas are coated with a defined amount of activator.

During additional quality testing, an unexpected variation in the amount of activator on some cannulas was observed. Depending on the individual clinical situation, this amount potentially results in a reduced bonding of the restauration to the tooth structure and a potential loss of the restauration.

The problem relates exclusively to the blue DC cannulas. The adhesive Adhese® 2 can be used without any problems with the black cannulas in light-curing mode or with the single dose brushes in the self-curing mode.



Picture of affected "Blue DC Cannula for the VivaPen "

What are you as distributor expected to do in order to support a compliant execution of the FSCA?

1. Identify the affected batch number of Adhese 2 DC VivaPen Kits and DC Cannulas for VivaPen:

<p>Adhese 2 DC VivaPen Kit</p> <p>Adhese® 2 DC VivaPen® 2ml/100 Kit</p> <p>REF 757028 LOT Z0BLZP</p> <p>Mfg. Date 2025-10-30 Exp. 2027-10-30</p> <p>Contents: 1 x 2 ml Adhese® 2 VivaPen® 4 x 25 DC Cannulas for VivaPen® 5 x 20 VivaPen® Sleeves 1 x Storage Tin</p>	<p>DC Cannulas for VivaPen</p> <p>DC Cannulas for VivaPen® 25 pcs</p> <p>REF 757025 LOT Z095FM</p> <p>Mfg. Date 2025-03-21 Exp. 2027-03-21</p> <p>Made in Liechtenstein</p>
<p>DC Cannulas for VivaPen /BAG (Part of the affected kit)</p>	

2. Separate and block the devices affected in your warehouse so that they can no longer be sold to professional users.
3. Please inform the user you have provided the affected products with the Field Safety Notice (Customer Centric) provided as an attachment to this notification.
4. Please contact Ivoclar Global Partner Support immediately via email at dlliglobalpartnersupport@ivoclar.com to arrange for the pick-up of the devices affected by this FSCA.
5. Confirm receipt of this Field Safety Notice and the implementation of the measures mentioned using the attached Customer Reply Form and return the completed form to vigilance.li@ivoclar.com

Contact Information

Queries regarding the safety measures described in this Field Safety Notice should be addressed to vigilance.li@ivoclar.com

Document ID: TEFO-04821-EN
Document title: FSN (Distributor/Importer)
Module: Global Vigilance (Corp)
Module owner: Expert Global Vigilance



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

Important: If you have given the products to a third party, e.g. other distributor please forward a copy of this information or inform Global Vigilance via vigilance.li@ivoclar.com

Ivoclar Vivadent AG has granted a credit note/replacement delivery for affected goods to the professional users who have purchased the affected devices from you. The affected professional users will contact you, valued partner, regarding the credit/replacement delivery, which they can settle with the responsible Sales Representative.

Ivoclar will check the availability of required replacement material and let you know when the replacement material will be shipped to you.

We are very sorry for the inconvenience and thank you for your understanding.

In case you have any questions, please feel free to contact Global Partner Support.

Schaan, 2026-03-16

Dr. Falk Brustmann
Expert Global Vigilance
Ivoclar Vivadent AG

Customer Reply Form

1. Field Safety Notice (FSN) Information	
Reference number	03-2026-001
Date	2026-03-16
Product/ Device name	Adhese 2 DC VivaPen Kit DC Cannulas for VivaPen
Product Codes (Article No.)	757026 757028 758706 757036
Lot/Batch or SerialNo.	Z0BK52, Z0BSBW, Z0BSBX, Z0BSBY, Z0BSBZ, Z0BSC0, Z0BSJZ, Z0BSK0, Z0BSK1, Z0BSK2, Z0BSK3, Z0BFV3, Z0BHSV, Z0BJGV, Z0BJGW, Z0BJGX, Z0BK4X, Z0BLZN, Z0BLZP, Z0BM67, Z0BNWP, Z0BPTZ, Z0BRVD, Z0BSTC, Z0BSTD, Z0BSTF, Z0BSTG, Z0BKPJ, Z0BKPK, Z0BNFX, Z0BP64, Z0BP65, Z0BR11, Z0BRCL, Z0BS9K, Z0BS9L, Z0BSKV, Z0BSKX, Z0BR7Y, Z0BR7Z

2. Distributor Details (to be completed by the distributor of the affected devices)	
Distributor	
Address	
Contact Name	
E-Mail	

3. Actions to be taken by the distributor				
<input checked="" type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.			
<input type="checkbox"/>	I perform all actions requested by the Field Safety Notice			
<input type="checkbox"/>	I have separated and blocked the affected devices	Qty(box):	Lot:	Date (DD/MM/YY):
<input type="checkbox"/>		Qty(box):	Lot:	
<input type="checkbox"/>		Qty(box):	Lot:	
<input type="checkbox"/>	N/A	N/A	Comments:	
<input type="checkbox"/>	No affected devices are available for pick-up by Ivoclar/ Affected devices already			

	sold / made available to professional users	
<input type="checkbox"/>	I do not have any affected devices.	
Print Name		
Signature		
Date		

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.