

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

Adhese 2 DC VivaPen Kits and DC Cannulas for VivaPen

Dear valued Adhese 2 user,

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 Z09L0X 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

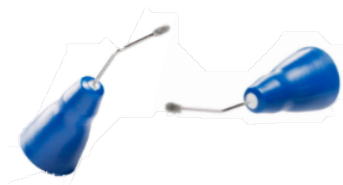
			(10) Z0BSKV (241) 757036
757036	DC Cannulas for VivaPen /100	Z0BSKX	(01) 07615208464757 (11) 260216 (17) 280216 (10) Z0BSKX (241) 757036

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

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 restoration to the tooth structure and a potential loss of the restoration.

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 "

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

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>UDI (01)07615208464689 (11)251030 (17)271030 (10)Z0BLZP (241)757028</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> (01)07615208464672 (11)250321 (17)270321 (10)Z095FM (241)757025</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 practice so that they can no longer be used for dental restorations.

3 (a). Please contact your Ivoclar Sales Representative immediately to arrange for the pick-up of the sealed/unopened Adhese 2 DC VivaPen kit .

(or) use the Adhese 2 VivaPen in light-curing option in combination with black VivaPen Cannulas

3 (b) Please dispose of the blue DC cannulas for VivaPen in the clinical waste bin and confirm disposal using the attached Customer Reply Form.

4. 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

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 dentist 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 devices to the professional users which they can settle with your Ivoclar 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 your Ivoclar Sales Representative at any time.

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, Z0BR7Y, Z0BR7Z, Z0BRVD, Z0BSTC, Z0BSTD, Z0BSTF, Z0BSTG, Z0BKPJ, Z0BKPK, Z0BNFX, Z0BP64, Z0BP65, Z0BR11, Z0BRCL, Z0BS9K, Z0BS9L, Z0BSKV, Z0BSKX, Z0BR7Y, Z0BR7Z

2. User Details (to be completed by the user of the affected medical devices)	
Name / Company / Dental Lab / Dentists Office	
Address	
Contact Name	
E-Mail	
Distributor (Please name the distributor from whom you have purchased the affected medical devices)	

3. Customer action undertaken on behalf of Healthcare Organisation				
<input 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 returned devices and received a replacement	Qty:	Lot:	Date Returned (DD/MM/YY):
		Qty:	Lot:	Date Returned (DD/MM/YY):
		Qty:	Lot:	Date Returned (DD/MM/YY):

from distributor- 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:	
<input type="checkbox"/>	No affected devices are available for return/ disposal		
<input type="checkbox"/>	I disposed the affected DC Cannulas for VivaPen		
<input type="checkbox"/>	I have already used up all of the affected devices		
	Comment:		
Print Name			
Signature			
Date			

4. Return acknowledgement to sender	
E-Mail	E-Mail address to be filled in by the distributor or vigilance.li@ivoclar.com
Deadline for returning the customer reply form	14 days after receipt of the FSN

5. Replacement Delivery/ Credit Note (this table can be removed if not needed)	
<input type="checkbox"/>	I requested a replacement delivery from distributor mentioned under section 2
<input type="checkbox"/>	I requested a credit note from distributor mentioned under section 2

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.