Rev 1: September 2018
FSN Ref: FSN-Recall-012 FSCA Ref: Recall 012

Date: 22.04.2026

Urgent Field Safety Notice
siliconeglue

For Attention of: Person responsible of Medical Devices Safety / vigilance – Passed on to all user departments and users

Contact details of local representative
VYGON Confidential business information email: Confidential business information

Urgent Field Safety Notice (FSN)
siliconeglue
incorrect expiry date

1. Information on Affected Devices	
1.	1. Device Type
	Adhesives, Liquid
	  affected batches: 060226GD & 110326GD 
1.	2. Commercial name
	siliconeglue
1.	3. Unique Device Identifiers
	(01)03660812124515(17)310209(30)1(10)060226GD (01)03660812124515(17)310209(30)1(10)110326GD
1.	4. Primary clinical purpose of device(s)
	siliconeglue (product code 2197.000) is a part of different “repairset lifecath” manufactured by VYGON Germany GmbH.
1.	5. Device Model/Catalogue/part number
	2197.000
1.	6. Software version
	n/a
1.	7. Affected lot numbers
	060226GD & 110326GD
1.	8. Associated devices
	n/a

2. Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem
	An incorrect expiry date of 5 years (2031-02-09) was applied to the purchased product, while the manufacturer's validated shelf life is limited to 720 days from manufacture. The correct expire date is: 2027-01-07
2.	2. Hazard giving rise to the FSCA
	Use of the sterile product beyond the validated shelf life of 720 days may lead to reduced product performance and uncertainty regarding its safe and effective use.
2.	3. Probability of problem arising
	Based on available complaint data and review of additional batches, the probability of the problem arising is assessed as low and limited to the identified affected lots only.
2.	4. Predicted risk to patient/users
	The anticipated risk to patients and users is considered low, as no harm is expected until 2027-01-07 (corrected expiry date); potential harm could only occur if the product were used beyond this period, where reduced performance may arise.
2.	5. Further information to help characterise the problem
	n/a
2.	6. Background on Issue
	The issue was identified following the receipt of two complaints from company subsidiaries, which questioned the correctness of the expiry date indicated on the product label. As part of the subsequent investigation, a review of the labelling and incoming documentation was performed. The investigation revealed that the expiry date applied on the product label was based on expiry date information stated on the manufacturer's delivery note. The delivery note indicated a shelf life of 5 years, whereas the manufacturer's product data sheet specifies a validated shelf life of 720 days from the date of manufacture. The incorrect expiry date from the delivery documentation was taken over during label creation without detection. The two complaints were limited to the correctness of the labelling information; no adverse events, product malfunctions, or patient harm were reported.
2.	7. Other information relevant to FSCA
	Correct expiry date of affected batches: 2027-01-07 The products of the affected batches (see point 1.5 and 1.7) are being recalled (reference number: Recall 012). The users are advised to destroy the affected products as stated in the following section 3.

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	
3.	2. By when should the action be completed?	The action must be implemented until 2026-05-30 upon receipt of this Field Safety Notice.
3.	3. Particular considerations for: n/a Is follow-up of patients or review of patients' previous results recommended? No	
3.	4. Is customer Reply Required?	Yes Please see document "FSN-Recall-012_2197-000_VYGON-Germany-GmbH_Customer-reply" or "FSN-Recall-012_2197-000_VYGON-Germany-GmbH_Distributor-reply"
3.	5. **Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Recall of affected batches.	
3	6. By when should the action be completed?	unknown at present
3.	7. Is the FSN required to be communicated to the patient /lay user?	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?	
	n/a	

4. General Information		
4.	1. FSN Type	New
4.	2. For updated FSN, reference number and date of previous FSN	n/a

4.	3. For Updated FSN, key new information as follows:	
	n/a	
4.	4. Further advice or information already expected in follow-up FSN?	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	n/a	
4	6. Anticipated timescale for follow-up FSN	n/a
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	VYGON Germany GmbH
	b. Address	Confidential business information
	c. Website address	https://www.vygon.de/ Confidential business information
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	9. List of attachments/appendices:	n/a
4.	10. Name/Signature	Personal data Personal data

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 affected devices have been transferred. Please transfer this notice to other organisations on which this action has an impact. 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.