Urgent Field Safety Notice

Field Safety Corrective Action (FSCA)

Commercial Name: AQUACEL® Foam Pro
Reference: TW-3104029
Date: 26-Aug-2026
Country: Spain
Type: New

Attention: Distributors, Healthcare Professionals, Hospitals, Procurement Departments, and End Users,

Convatec is initiating a voluntary **Field Safety Corrective Action (FSCA)** for a specific lot of **AQUACEL ® Foam Pro** following identification of the incorrect product within the primary pack.

1. Description of the Problem

Through routine **complaint handling** activities, Convatec identified that devices labelled as **AQUACEL® Foam Pro**, when opened contained a standard **AQUACEL® Foam Adhesive** device.

The primary difference between the devices is the wound contact silicone adhesive layer, with **AQUACEL® Foam Pro** incorporating a perforated silicone layer across the full wound contact surface and **AQUACEL® Foam Adhesive** incorporating a silicone border with a central wound contact window. The product packed in error does not fully conform to the approved product specification and labelling for **AQUACEL® Foam Pro.**

The difference in product design is clinically relevant and results in the delivered product being inconsistent with the approved device configuration. The issue constitutes a regulatory non-conformance under the European Medical Device Regulation (EU) 2017/745 (EU MDR), as the device supplied does not correspond to the approved device configuration and product information identified on the packaging and labelling.

2. Affected product details

Item #	Lot/Batch #	Device Description	UDI Primary Pack / Secondary Pack
423522	5J04171	AQUACEL® Foam Pro	00768455157334 / 00768455197019

Our records indicate that you may have received the affected units **distributed between Feb to Jul 2026.**

Details of the affected product codes and corresponding lot numbers are provided in **Appendix 2**.

3. Potential Risk to Patients and Users

A clinical assessment has determined that there is a potential but low risk should the discrepancy not be identified before use.

Specifically:

- AQUACEL™ Foam Pro incorporates a perforated silicone layer across the full wound contact surface.
- The incorrectly packaged product incorporates a silicone border with a central wound contact window.
- Reduced coverage may alter dressing adherence and removal characteristics compared with the intended AQUACEL™ Foam Pro design.
- In situations where the discrepancy is not recognised prior to application, there is a potential for delayed wound healing, discomfort, and minor tissue damage.
- Based on the clinical evaluation, the likelihood of serious patient harm is considered low.

Healthcare professionals remain able to identify the discrepancy through visual inspection before application.

To date, adverse events or patient harm has been reported.

4. Actions Required by Customers

Distributors, Wholesalers, & Hospitals

Please take the following actions immediately:

Important: If not Convatec please contact the supplier from whom the product was purchased to report any affected inventory and obtain instructions regarding product disposition.

- **Examine your inventory** and identify all affected product lots using the lot numbers provided in the enclosed Product Identification Table (**Appendix 2**).
- **Immediately quarantine and discontinue distribution, sale, transfer, and use** of all affected product to prevent further distribution or use.
- **Inform all appropriate personnel** within your organisation, including those responsible for inventory management, purchasing, distribution, and product use, of this FSCA.
- **If you have further distributed, transferred, or supplied any affected product, you must immediately notify all consignees and customers who may have received the affected product.** Provide them with a copy of this notification and instruct them to take the actions described in this notice.
- **Acknowledgement:** Please confirm receipt of this notice and your compliance with the required actions by completing and returning the enclosed acknowledgement form (appendix 1) **to** fsca-id@convatec.com **within 30-days.**
- If affected product is identified within your inventory, Convatec will provide a **Certificate of Destruction (COD)** for completion.
- Following destruction, please **complete and return the signed Certificate of Destruction (COD)** to Convatec as evidence to support compliance with this action.

Healthcare Professionals

Please take the following actions immediately:

Important: If not Convatec, please contact the supplier from whom the product was sourced/purchased to report any affected inventory and obtain instructions regarding product disposition.

- **Review your supplies:** Examine your personal supplies and determine whether you have any affected product identified in the Product Identification Table (**Appendix 2**).
- **Discontinue use and obtain replacement product:** If you identify affected product, discontinue use of the affected device and contact your supplier, healthcare provider, or Convatec representative to obtain replacement product as soon as possible.
  Acknowledgement: Please confirm receipt of this notice and your compliance with the required actions by completing and returning the enclosed acknowledgement form (appendix 1) **to** fsca-id@convatec.com **within 30-days.**
- Our customer care teams are available to assist you with any questions you may have regarding this communication and provide product alternatives if needed. Please contact

End Users

Please take the following actions immediately:

Patients currently using **AQUACEL® Foam Pro** should contact their healthcare professional if they have concerns regarding their dressing.

Healthcare professionals should monitor patients according to normal clinical practice and replace affected product where appropriate.

4. Corrective Action Being Taken by Convatec

Convatec has initiated this voluntary Field Safety Corrective Action to remove affected product from the market and ensure continued compliance with applicable regulatory requirements.

Additional measures have been implemented to strengthen product verification and packaging controls and to prevent recurrence of this issue.

Replacement product or a suitable alternative will be made available where appropriate.

5. Transmission of this Field Safety Notice

- This notice should be brought to the attention of all personnel within your organisation who need to be aware of this action.
- If any affected devices have been transferred to another organisation, please provide a copy of this notice to those organisations.
- Please maintain awareness of this notice until all required actions have been completed.
- Any adverse events or complaints associated with the affected product should be reported to Convatec through normal reporting channels.

Reporting to Authorities

Convatec has notified the relevant Competent Authorities, including the Spanish Agency of Medicines and Medical Devices (AEMPS), as required under applicable EU MDR requirements.

6. Contact Information

Customer Services (Replacement/Credits): CustomerServiceIberia@convatec.com
FSCA/FSN/Response Form Questions: fsca-id@convatec.com

Convatec remains committed to transparency, regulatory compliance, and delivering high-quality products Thank you for your understanding and we apologise for any inconvenience this action may cause.

Sincerely,
Tara Turney

Senior Director - Regulatory Affairs

APPENDIX 1

RESPONSE FORM

- *Immediately complete*
- *If you have no affected product a completed response form is still required*
- *Please return the completed form via email* fsca-id@convatec.com

Issue Date: August 2026 **CVT FSCA Ref:** TW-3104029

Original Notice: X **Revised Notice:** N/A **Revision Number:** 1

Invoice #	Sales Order #	Product Code	SAP Code	LOT#	Quantity Delivered

Account No:	
Business Name:	
Address:	

Yes	No		
		I confirm receipt, understanding and acknowledgement of this notification	
		I have checked my inventory, and I have **no product on hand**	
		I have checked my inventory, and **I have product on hand**	QTY
		I have checked my inventory, quarantined, and disposed of affected inventory	
		I have attached a Certificate of Destruction (COD) as requested evidence	
		I have identified customers that received or may have received affected product	
		I have informed the identified customers of this notification	Date Sent

NOTE: If the statements listed within the table are not applicable, please mark as N/A

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ACTION ACKNOWLEDGEMENT

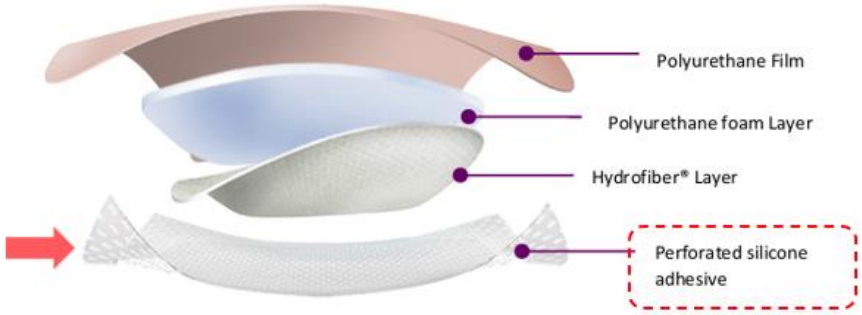
NAME	
POSITION	
SIGNATURE	
DATE	

APPENDIX 2

Product Identification Table

Country	Product SAP Code	Product ICC Code	Lot Number	Device Description	Date of Manufacture	Expiry Date
Spain	1735228	423522	5J04171	AQUACEL FOAM PRO 15X15CM 3U	24-Sep-2025	01-Sep-2030

Schematic of AQUACEL® Foam Pro:



Schematic of Aquacel Foam Adhesive: