URGENT FIELD SAFETY NOTICE

Commercial Name of the Product:

ICC Code	SAP Code	Product Description	Lot Number	Date of Mfg	Market Unit Qty
420673	1704596	AQUACEL™ Extra 15x15cm (1x5pk)	0C01702	24 Mar 2020	82 units

Issue Date: December 2020

X Original Notice __ Revised Notice Revision No.: Rev. 1

FSCA Ref: 2020-002

Type of action: Field Action/Product Disposal

Please note that this action only applies to product code 420673 and LOT 0C01702 of AQUACEL™ Extra 15x15cm (1x5pk).

Date: 19 January 2021

Details on affected devices:
AQUACEL® EXTRA™ is a sterile, non-woven dressing made from two layers of 70gsm sodium carboxymethylcellulose, stitched together and strengthened with regenerated cellulose fiber (Lyocell). AQUACEL® EXTRA™ was a life cycle management project from the original AQUACEL® product, to add absorbency and strength.
Intended Use: To help manage moisture in the wound which is known to interfere with the natural wound healing processes. The device is used on chronic and acute wounds.

Figure 1: AQUACEL™ Extra 15 x 15cm Carton Secondary Packaging

Figure 2: AQUACEL™ Extra 15 x 15cm Dressing

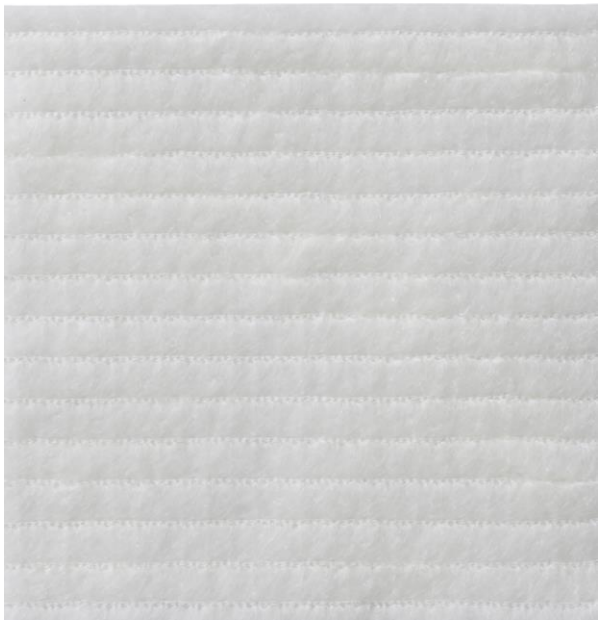


Figure 3: AQUACEL™ Extra 15 x 15cm Foil Primary Packaging

Description of the problem:
ConvaTec are voluntarily initiating a field action for the above-stated product because in some instances dressing has been found attached to the seam of the primary packaging (figure 3) therefore breaching the sterile barrier and making the product unable to be used. Using a non-sterile device on a patient may potentially expose the patient to infectious agents.

Product Identification Procedure:

- Confirmation of Specific Product Code and LOT:
  - This issue is limited to product code 420673.
  - Only the identified product code and LOT within this notice may have a potential breach in the sterile barrier packaging. Only 82 dressings from this same batch are known to be affected.
  - For this reason and to address any potential risk of harm, the affected product 420673 from LOT 0C01702 should not be used.
  - The only way to identify affected product is by comparing Product code/REF and LOT/Batch number (see Attachment 2) to the product list (see Attachment 1). There is no other discernible difference between affected and unaffected product.

DISTRIBUTOR ACTIONS:

1	Immediately stop distributing and quarantine all of the affected LOT.
2	Perform a count of affected product currently in inventory. Complete the enclosed the Corrective Action Response Form and return it to the address on the response form. **Return the attached Corrective Action Response Form even if no affected product is in inventory.**
3	You will be reimbursed for the product. Please ensure your account number is correctly identified on the attached Corrective Action Response Form.
4	If you have distributed this product to other wholesalers, then forward this letter to them and ask that they follow these Distributor Actions and return the attached Corrective Action Response Form to the address listed on the form.
5	Send a copy of this market action package to all other consignees: Retailers, if applicable, hospitals and end users. ***It is extremely important to identify the responsible individual, who is in charge of corrective action activities, at hospital locations. This will make the field action process more effective and eliminate confusion and duplicated effort.***
6	Send a complete list of all consignees to the ***ConvaTec*** Coordinator. This information is required to allow ***ConvaTec*** to perform corrective action effectiveness checks.

RETAILER ACTIONS:

1	Immediately stop distributing and quarantine all of the affected LOT.
2	Perform a count of affected product currently in inventory. Complete the enclosed Corrective Action Response Form and return it to the address on the response form. **Return the attached Corrective Action Response Form even if no affected product is in inventory. It is important that you send a copy of the Corrective Action Response Form to your distributor in order to receive reimbursement for the returned product.**
3	Post page one of this Field Safety Corrective Action notice in a conspicuous location in your store.

END USERS (HOSPITALS SERVICES OTHERS):

1	Immediately stop use and quarantine all the affected LOT.
2	Perform a count of affected product currently in inventory. Complete the enclosed Corrective Action Response Form and return it to the address on the response form. **Return the attached Corrective Action Response Form even if no affected product is in inventory. It is important that you send a copy of the Corrective Action Response Form to your distributor in order to receive reimbursement for the returned product.**

Transmission of this Field Safety Notice:

- This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)
- Please transfer this notice to other organisations on which this action has an impact. (As appropriate)
- 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.

ConvaTec is committed to providing quality products and services to our customers and we sincerely apologise for any inconvenience this notice may cause.

The relevant National Authorities have been advised about this Field Safety Corrective Action.

Authorisation:

Name	**Title**	**Address**	
Agnieszka M Sikorska-Brzozowska	Senior Regulatory Affairs Manager, Advanced Wound Care	ConvaTec Limited, First Avenue, Deeside Industrial Park, Deeside, CH5 2NU, U.K.	
Date 18/01/2021		**Signature**	

Regional ConvaTec Customer Service Contact:

Austria:

Tel: +43 (0) 800204034

Email: at.kundenservice@convatec.com

Finland:

Tel: +358 (0) 20 7659 600

Email: mail.fi@convatec.com

Germany:

Tel: +49 (0) 8001624381

Email: de.kundenservice@convatec.com

Israel:

Tel: 1800-800-150

Email: dafnav@philtel.co.il

Italy:

Email: Rosaria.Sessa@convatec.com

Luxembourg:

Tel: +32 (0) 23528956

Email: be.serviceclient@convatec.com

Netherlands:

Tel: +31 (0) 348436987

Email: nl.klantenservice@convatec.com

Portugal:

Tel: +351 707 201 187

Email: customerserviceiberia@convatec.com

Saudi Arabia:

Email: ccc.customerservice@convatec.com

Spain:

Tel: +34 93 6023743

Email: customerserviceiberia@convatec.com

Sweden:

Tel: +46 (0)42 332010

Email: customerservicenordic@convatec.com

Switzerland

Tel: +41 (0) 800551110

Email: ch.kundenservice@convatec.com

Tunisia:

Email: ccc.customerservice@convatec.com

UK:

Tel: + 44 (0) 1244 284882

Email: uk.customerservice@convatec.com

FIELD SAFETY NOTICE DISTRIBUTOR CORRECTIVE ACTION RESPONSE FORM

PLEASE COMPLETE AND RETURN by Email

Consignee of the device:

Consignee Account No:	
Consignee Name:	
Consignee Address:	

The following products, **:** AQUACEL™ Extra 15x15cm Dressing have been distributed to your facility:

Invoice #	Sales Order #	Product Code / REF No.	SAP Code	LOT No.	Quantity Delivered (boxes of 5)

Distributors (Tick all that apply and give details, where applicable)		
☐	I confirm the receipt, the reading and understanding of the Field Safety Notice.	
☐	I have checked my stock and quarantined inventory	Add details to Table 1
☐	I have identified customers that received or may have received this device	
☐	I have attached customer list	Add details to Table 2
☐	I have informed the identified customers of this Field Safety Notice	Date sent:

☐	I have received confirmation of reply from all identified customers	Attach responses
☐	Neither I nor any of my customers has any affected devices in inventory	

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.

Table 1. Quarantined Inventory: Record quantity (boxes of 5) for each LOT to be returned.

LOT No.	Units on Hand

Table 2. Customer List: Please provide details of affected**:** AQUACEL™ Extra 15x15cm Dressing product that were distributed to your customers.

Customer Name	Product Code / REF No.	SAP Code	LOT No.	Quantity (boxes of 5)

FORM Completed and Returned From:	
Name (CAPITAL LETTERS):	
Position:	
Company Name:	
Address:	
Phone No:	
Signature:	
Date (dd/mmm/yyyy):	

FIELD SAFETY NOTICE CUSTOMER CORRECTIVE ACTION RESPONSE FORM

PLEASE COMPLETE AND RETURN by Email

Consignee of the device:

Consignee Account No:	
Consignee Name:	
Consignee Address:	

The following products, **:** AQUACEL™ Extra 15x15cm Dressing have been distributed to your facility:

Invoice #	Sales Order #	Product Code / REF No.	SAP Code	LOT No.	Quantity Delivered (boxes of 5)

Customer action undertaken on behalf of Healthcare Organisation (Tick all that apply)		
☐	I confirm receipt of the Field Safety Notice and that I read and understand its content.	
☐	I performed all actions requested by the FSN.	
☐	The information and required actions have been brought to the attention of all relevant users and executed.	
☐	I have checked my stock and quarantined inventory	Add details to Table 1
☐	No affected devices are available for return	

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.

Table 1. Quarantined Inventory: Record quantity (boxes of 5) for each LOT to be returned.

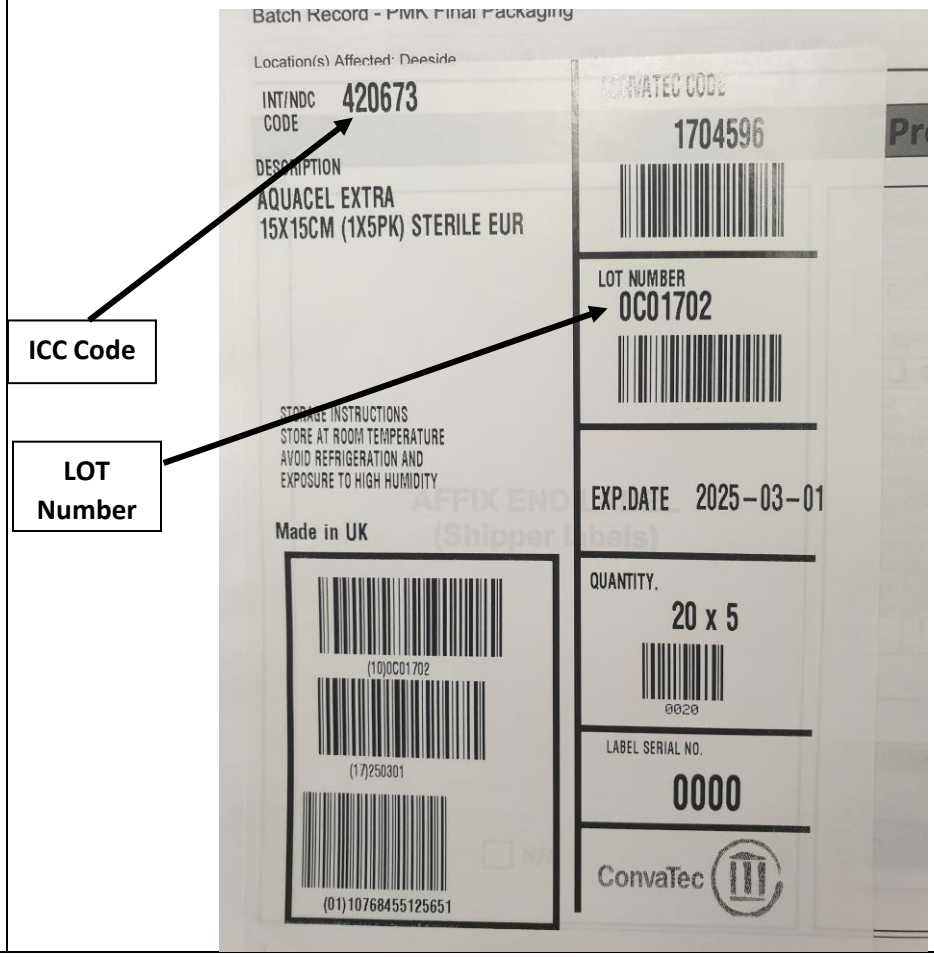
LOT No.	Units on Hand

FORM Completed and Returned From:	
Name (CAPITAL LETTERS):	
Position:	
Company Name:	
Address:	
Phone No:	
Signature:	
Date (dd/mmm/yyyy):	

Attachment 1 Product Details:

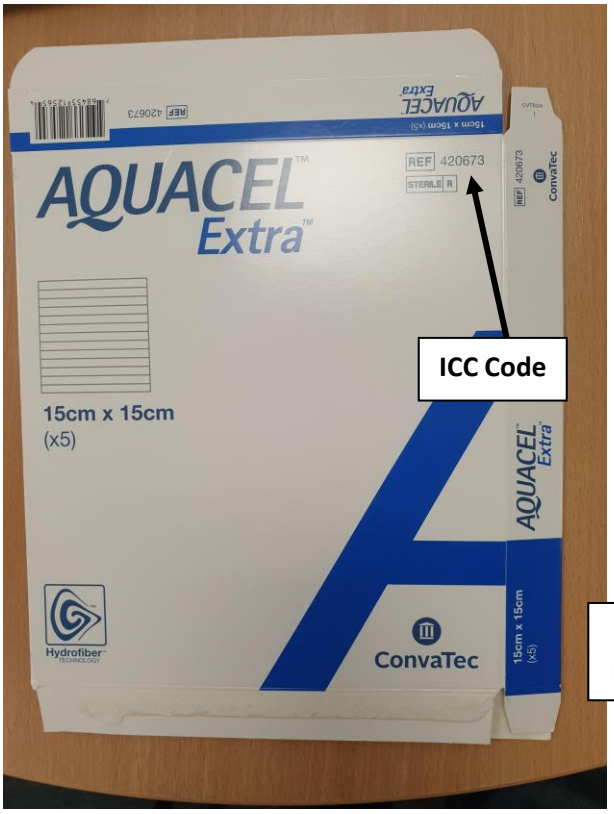
ICC Code	SAP Code	Product Description	Lot Number	Date of Mfg	Market Unit Qty
420673	1704596	AQUACEL™ Extra Dressing 15 x 15cm	0C01702	24 Mar 2020	82 units

Attachment 2 Examples of Labelling and Affected Product:

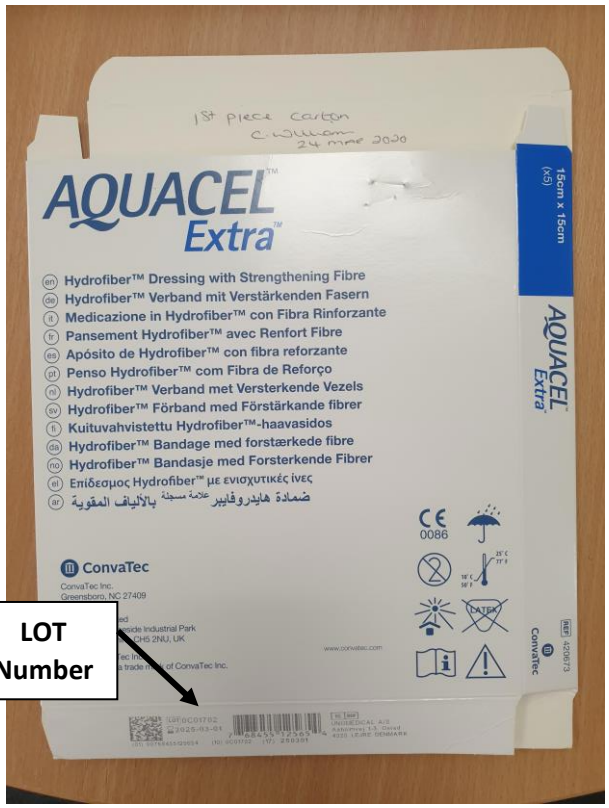
The shipper labelling will include the product REF/ICC code and the product LOT number (see example to the right).	**Shipper Label:** 

The market unit labelling will include the product REF/ICC code and the product LOT number (see example to the right).

Front of Carton:



Back of Carton:



Foil Packaging: