Rev 1: September 2018
FSN Ref: 2021-001 FSCA Ref: 2021-001

Date: 02 August 2021

Urgent Field Safety Notice
Duoderm CGF & Extra-Thin Dressings

For Attention of*: **All affected consignees in Malaysia**

Contact details of local representative (name, e-mail, telephone, address etc.)*
ConvaTec Malaysia Customer Service Tel: +603 7844 0820 Email: sasikala.sannibabu@convatec.com

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Urgent Field Safety Notice (FSN)
Duoderm CGF & Extra-Thin Dressings

	1. **Information on Affected Devices***
1.	1. Device Type(s)*
	DuoDERM CGF DuoDERM CGF Control Gel Formula Dressing is an adhesive (hydrocolloid) wound contact dressing. The hydrocolloids are contained within the dressing mass. The adhesive layer contains polymers which enhance the dressing's ability to contain wound exudate by forming a cohesive gel. The self-adherent dressing absorbs wound fluid and provides a moist environment which supports the body's healing process and aids in the removal of unnecessary material from the wound (autolytic debridement) without damaging new tissue. DuoDerm CGF Control Gel Formula Dressing may be used alone or in combination with other wound care products as directed by your healthcare professional. DuoDERM Extra Thin DuoDERM Extra Thin dressings are highly flexible, control gel formula dressings designed for use on dry to lightly exudating wounds. DuoDERM Extra Thin dressings are particularly suitable in areas subject to friction and those requiring contouring, e.g., elbows, heels.
1.	2. Commercial name(s)
	DUODERM CGF DRS 10X10CM DUODERM XTHIN DRS 10X10CM DUODERM XTHIN DRS 15X15CM
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	DuoDERM Extra Thin dressings interact with wound moisture producing a soft mass that enables removal of the dressing with little or no damage to newly formed tissues. They help isolate the wound against bacterial and other external contamination. INDICATIONS• Management of superficial, dry to lightly exudating dermal ulcers.• Post-operative wounds.• Protective dressings. DuoDerm CGF Control Gel Formula Dressing acts as a barrier to the wound against bacterial, viral and other external contamination. The dressing has been shown in laboratory experiments to block the passage of bacteria and viruses to include the Human Immunodeficiency Virus (HIV-1) while the dressing remains intact without leakage. The use of this device neither guarantees nor warrantees against AIDS transmission. INDICATIONS For Over the Counter Use: DuoDerm CGF may be used for:- minor abrasions- lacerations- minor cuts- minor scalds and burns- skin tears Under the supervision of a healthcare professional, DuoDerm CGF may be used for wounds such as:- leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed aetiology), diabetic ulcers and pressure ulcers (partial & full thickness)- surgical wounds (post-operative, donor sites, dermatological excisions)- burns (first and second degree)- traumatic wounds* minimizes the potential of exposure to nosocomial or infectious agents
1.	5. Device Model/Catalogue/part number(s)*
	See Appendix 1
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range

	See Appendix 1
1.	8. Associated devices
	N/A

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	Open seal where packaging layers are not sealed together completely, leaving partial or fully open seal after manufacturing.
2.	2. Hazard giving rise to the FSCA*
	Open seal may lead to lack of sterility. Product is sealed into the packaging layers, creating unsealed regions, packaging tears or crushed material. This may lead to an open or partial seal hazard and inconvenience to use the device as intended.
2.	3. Probability of problem arising
	The probability of the problem occurring has been rated 1 Failure unlikely: Highly unlikely that the Effect will occur.
2.	4. Predicted risk to patient/users
	As the potential hazard associated is the dressing being open or the product being sealed within the seam of the primary package, there is a possible risk of infection, delayed wound healing and increased scarring. Wound infection may result in the wound taking longer to heal than anticipated and require topical treatment or antibiotics and this could result in increased scarring. There's also the possibility of the wound requiring surgical intervention. For high risk patients who are immunocompromised such as those with diabetes, cancer or having chemotherapy the risk of developing infection greater as is the risk of them requiring surgical intervention.
2.	5. Further information to help characterise the problem
	A total of thirty (30) complaints have been generated from January 01, 2020 up to October 30, 2020, where all complaints are related to primary packaging sterile breach. No harms have been reported.
2.	6. Background on Issue
	A root cause investigation for the open seal issue on the Bodolay packaging line. Corrective actions documented in Trackwise and linked to RCI. Root cause was associated to Machine, due to worn down on the indexation wheels, cutter blades, one of the screws holding the pressure cylinder and the upper sealing plate and the red rubber used on the sealing station was not in proper conditions. This root cause investigation is closed.
	 **Image 1**  **Image 2**  **Image 3**
	7. Other information relevant to FSCA

2.	N/A

	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 Complete actions detailed in Appendix 2	
3.	2. By when should the action be completed?	As soon as possible.
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? * (If yes, form attached specifying deadline for return)	Yes within 30 days
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Please see appendix 2 with full details on the product removal process.	
3	6. By when should the action be completed?	N/A
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	**Convatec Limited**
	b. Address	Legal manufacturer - First Avenue, Deeside Industrial Park, Deeside, Flintshire, CH5 2NU Site of manufacture - ConvaTec Dominican Republic Inc. Carretera Sanchez K.M. 18,5Parque Industrial Itabo,S.A. Haina, DO33102 Dominican Republic
	c. Website address	**www.Convatec.com**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes	
4.	9. List of attachments/appendices:	**Appendix 1: Product List** **Appendix 2: Distributor, Retailer and Customer Actions**
4.	10. Name/Signature	**Agnieszka M Sikorska-Brzozowska** **Senior Regulatory Affairs Manager**
		DocuSigned by: Agnieszka Sikorska-Brzozowska Signer Name: Agnieszka Sikorska-Brzozowska Signing Reason: I approve this document Signing Time: Jul 27, 2021 12:32:07 PM BST A2758F90ABDE41E08D8A1BBDB87781C7

	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 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..*

Appendix 1: Product Codes & LOT Numbers Affected

Product Name	Product Identifier (ICC#)	Product SAP#	Lot Number	Date of Mfg.	Market Unit Qty.	Devices Qty.
DUODERM EXTRA THIN CGF DRESSING	187955	1704768	9H00183	06-Aug-19	3454	34540
	187955	1704768	9H01234	14-Aug-19	1898	18980
	187955	1704768	9K02656	23-Oct-19	632	6320
	187955	1704768	9L01731	13-Nov-19	5560	55600
	187955	1704768	9M01779	20-Dec-19	38	380
DUODERM™ CGF™ CONTROL GEL FORMULA DRESSING	187660	1704761	0A03460	21-Jan-20	354	1770
	187660	1704761	9A04124Y	23-Jan-19	1120	5600
	187660	1704761	9B02984Y	22-Feb-19	2661	13305

Note: This is the list of affected products lots imported and distributed in Malaysia. There is other product models and product lots affected globally. If in doubt, please check with ConvaTec Malaysia Customer Service.

Appendix 2: Distributor, Retailer and Customer Actions

DISTRIBUTOR ACTIONS:

1	Immediately stop distributing and quarantine all of the affected LOT.
2	Perform a count of affected product currently in inventory. Dispose of all affected product. 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.**
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
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***
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 following region-specific action: Canada – Return all affected product to ConvaTec. All other regions - Dispose of all affected product. 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	For Retailers with a physical location, please post a copy of the Retailer Notice in a conspicuous area of your store. For Retailers with a digital location, please e-mail or post a copy of the Retailer Notice to all to customers.

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 following region-specific action: Canada – Return all affected product to ConvaTec. All other regions - Dispose of all affected product. 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.

Rev 1: September 2018
FSN Ref: 2021-001 FSCA Ref: 2021-001

RETAILER NOTICE - URGENT - MEDICAL DEVICE FIELD SAFETY NOTICE

DUODERM CGF DRS 10X10CM (1X5PK) NAI
DUODERM XTHIN DRS 10X10CM (1X10PK) NAI

Dear Product User,

We are writing to inform you of a potential product packaging issue affecting batches of the above listed products. An increasing trend of in complaints related to open seals, tears and rips in the primary packaging was reported in 2020 for DuoDERM Extra Thin and DuoDERM CGF products families. As the potential hazard is the dressing being open or the product being sealed within the seam of the primary package, there is potential for a breach in the sterile barrier resulting in a possible risk of infection, delayed wound healing and increased scarring. For this reason, ConvaTec are initiating a voluntary recall of product potentially affected by this issue. The following batches of products are being recalled:

Product Identifier (ICC#)	Lot Number
187955	9H00183
187955	9H01234
187955	9K02656
187955	9L01731
187955	9M01779
187660	0A03460
187660	9A04124Y
187660	9B02984Y

NOTE: Only the product codes and lot numbers identified within this notice are affected.
We are providing you with this communication to make you aware of the issue and outline the steps that you can take if you have product affected by this issue.
1) Check all DuoDERM products in your possession against the Product Codes and Lot Numbers listed above.
2) Please return all affected stock to your original supplier for reimbursement.

ConvaTec strives to provide the highest quality products and services to every customer. We want to reassure you that we have addressed the issue on the manufacturing line and corrected product has been distributed into the market.

Rev 1: September 2018
FSN Ref: 2021-001 FSCA Ref: 2021-001

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 have been distributed to your facility: Duoderm CGF & EXTRA THIN Dressings

Invoice #	Sales Order #	Product Code / REF No.	SAP Code	LOT No.	Quantity Delivered

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, quarantined and disposed of affected 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 hav 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 for each LOT.*

LOT No.	Units on Hand

Table 2. Customer List: Please provide details of affected Duoderm CGF & EXTRA THIN Dressings that were distributed to your customers.

Customer Name	Product Code / REF No.	SAP Code	LOT No.	Quantity

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

Rev 1: September 2018

FSN Ref: 2021-001 FSCA Ref: 2021-001

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, **:** Duoderm CGF & EXTRA THIN Dressings have been distributed to your facility:

Invoice #	Sales Order #	Product Code / REF No.	SAP Code	LOT No.	Quantity Delivered

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.	
☐	Canada - I have checked my stock, quarantined and returned all affected product to ConvaTec. All other regions - I have checked my stock, quarantined and disposed of affected 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 progres of the corrective actions.

Table 1. Quarantined Inventory: *Record quantity for each LOT.*

LOT No.	Units on Hand

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