Rev 1: September 2018
FSN Ref: 2021-010
FSCA Ref: 2021-010

Date: 16/11/2021

Urgent Field Safety Notice
Avelle™ Negative Pressure Wound Therapy (NPWT) Pump

For Attention of*: NHS DISTRIBUTION CENTRE

Contact details of local representative Regional ConvaTec Customer Service Contact Tel: **Convatec office tel – 01244 284882** **Email: uk.customerservice@convatec.com**

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Avelle™ Negative Pressure Wound Therapy (NPWT) Pump

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	The Avelle™ Pump is a battery powered unit which can be attached directly to the dressing or via supplied tubing to the luer lock system. The pump unit is a moulded thermoplastic casing which houses a printed circuit board with built in software. The pump unit is powered by 3xAAA batteries. The software controls the pressure generated by the pump to a nominal 80mmHg (+/- 20mmHg) of negative pressure, and the pressure relief valve limits the maximum negative pressure should the software fail to keep the pressure within its predetermined limits. The software controls the unit's maximum 30-day life span.
1.	2. Commercial name(s)
	Avelle™ Negative Pressure Wound Therapy (NPWT) Pump
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	The Avelle™ NPWT system is indicated for use on patients that would benefit from a NPWT device and with a low to moderately exuding wound, such as: Chronic wounds e.g. leg ulcers · Acute wounds · Dehisced wounds · Flaps and grafts · Surgically closed incision sites - and is intended to be used by clinicians and their associated patients. The Avelle™ NPWT system combines a sterile dressing comprising gelling fibre technology to absorb wound exudate with negative pressure applied to the wound via a vacuum pump. As with other modern wound dressings such as AQUACEL®, a single Avelle™ dressing may be worn up to 7 days but may be changed sooner dependent on the level of exudate and clinical need.
1.	5. Affected serial or lot number range
	Please see Appendix 1

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	The Avelle™ pump kit contains an unapproved luer lock connector located on the male end of the Avelle™ tube.
2.	2. Hazard giving rise to the FSCA*
	The following hazards have been identified are: 1) Tissue Damage, Non-penetrating wounds. (maceration) 2) Inconvenience 3) Infection (Requires Prescriptive Treatment e.g. Oral, I.V. Antibiotics, Surgical, Debridement or Excision

	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 Please see Attachment 2 for action to be taken	
3.	2. By when should the action be completed?	Within 21 days.
3.	3. Particular considerations for: Choose an item. 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 Product that has been shipped will be destroyed. Product that has remained within ConvaTec will be reworked with the incorrect luer removed and replaced with the correct luer.	
3	6. By when should the action be completed?	Rework to be performed in accordance with timelines defined in the CAPA
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. Further advice or information already expected in follow-up FSN? *	No
4.	3. Manufacturer information	
	(For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	ConvaTec Limited
	b. Address	Site of manufacture: Brightwake Limited, Lowmoor Business Park, Kirkby in Ashfield, Notts, NG17 7JZ, UK Legal manufacturer – ConvaTec Limited, First Avenue, Deeside Industrial Park, Deeside, Flintshire, CH5 2NU
	c. Website address	https://www.convatec.co.uk
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	5. List of attachments/appendices:	Attachment 1: Serial and Lot numbers of affected devices Attachment 2: Distributor and customer actions Attachment 3: Example of Product packaging
4.	6. Name/Signature	Agnieszka Sikorska-Brzozowska Regulatory Affairs Manager DocuSigned by: Agnieszka Sikorska-Brzozowska Signer Name: Agnieszka Sikorska-Brzozowska Signing Reason: I approve this document Signing Time: Nov 8, 2021	1:13:59 PM GMT A2763E90ABDE41E08D813BBDB87791C7
		Lars Bresler Vice President Quality, Infusion Care (Authorised Representative) DocuSigned by: Lars Bresler Signer Name: Lars Bresler Signing Reason: I approve this document Signing Time: Nov 8, 2021	1:07 PM GMT

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.*

ATTACHMENT 1

Material	Batch	Description
1724310	WO027648	AVELLE NPWT PUMP 6 BATTERY (1X1PK) EUR
1724310	WO027645	AVELLE NPWT PUMP 6 BATTERY (1X1PK)
1724310	WO028197	BOMBA AVELLE 6PILAS (1 UD)
1724311	WO026332	AVELLE NPWT PUMP 6 BATTERY (1X1PK) CEE
1724310	WO027732	AVELLE NPWT PUMP 6 BATTERY (1X1PK) EUR
1724310	WO028195	AVELLE NPWT PUMP 6 BATTERY (1X1PK) EUR
1724310	WO027647	AVELLE NPWT PUMP 6 BATTERY (1X1PK) EUR
1724310	WO027734	AVELLE NPWT PUMP 6 BATTERY (1X1PK) EUR
1724310	WO027730	AVELLE NPWT PUMP 6 BATTERY (1X1PK) EUR
1724310	WO027731	AVELLE NPWT PUMP 6 BATTERY (1X1PK) EUR
1724311	WO026333	AVELLE NPWT PUMP 6 BATTERY (1X1PK) CEE
1722512	WO023517	AVELLE NPWT PUMP 6 BATTERY (1X1PK) NAI
1718824	WO028552	AVELLE TUBULADURA ADICIONAL SET (5 UD)
1718824	WO027992	AVELLE NPWT PUMP SPARE TUBE SET 1X5 INT

ATTACHMENT 2

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 in accordance with official regulations: **Dressing:** Used dressings should be disposed of as clinical waste in accordance with local clinical protocols. **Batteries:** Batteries should be recycled **Pump:** After use pump units should be decontaminated and recycled in accordance with local recycling regulations and directives. Unused pumps should be recycled in accordance with local recycling regulations and directives. **Complete the Certificate of Destruction and return to ConvaTec to obtain credit for the affected product.** Complete the enclosed the Corrective Action Response Form and return it with the Certificate of Destruction to the address on the response form. **Return the attached Corrective Action Response Form even if no affected product is in inventory.**
3	Submit the Corrective Action Response Form and Certificate of Destruction to Customer Services for reimbursement for the destroyed 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.

CUSTOMER 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 in accordance with official regulations: **Dressing:** Used dressings should be disposed of as clinical waste in accordance with local clinical protocols. **Batteries:** Batteries should be recycled **Pump:** After use pump units should be decontaminated and recycled in accordance with local recycling regulations and applicable directives. Unused pumps should be recycled in accordance with local recycling regulations and directives. **Complete the Certificate of Destruction for disposal of the product and return to ConvaTec to obtain credit for the affected product.** Complete the enclosed Corrective Action Response Form and return it with the Certificate of Destruction 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 and Certificate of Destruction 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.

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FIELD SAFETY NOTICE DISTRIBUTOR CORRECTIVE ACTION RESPONSE FORM

PLEASE COMPLETE AND RETURN by Email

Consignee of the device:

Consignee Account No:	10315172
Consignee Name:	NHS distribution centre
Consignee Address:	VALLEY DRIVE, RUGBY,WARWICK,CV21 1TN

The following products have been distributed to your facility -Avelle™ Negative Pressure Wound Therapy (NPWT) Pump :
:

Invoice #	Sales Order #	Product Code / REF No.	SAP Code	LOT No.	Quantity Delivered
3001435288	C24085879/3486	421551	1724310	WO027648	60

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 attached the Certificate of Destruction	
☐	I have identified customers that received or may have received this device	
☐	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 for each LOT disposed of.*

LOT No.	Units on Hand

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

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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 have been distributed to your facility (Avelle™ Negative Pressure Wound Therapy (NPWT) Pump):
:

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.	
☐	I have checked my stock, quarantined and disposed of affected inventory	Add details to Table 1
☐	I have attached the Certificate of Destruction	
☐	No affected devices are available for return	

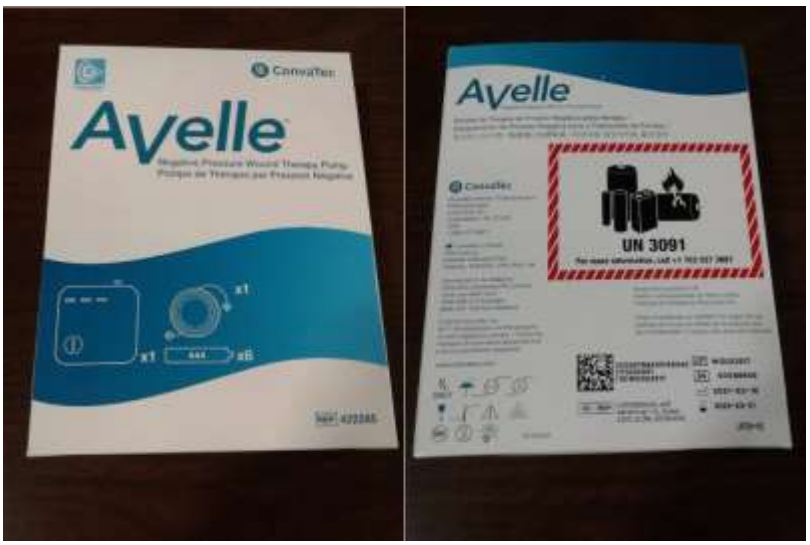
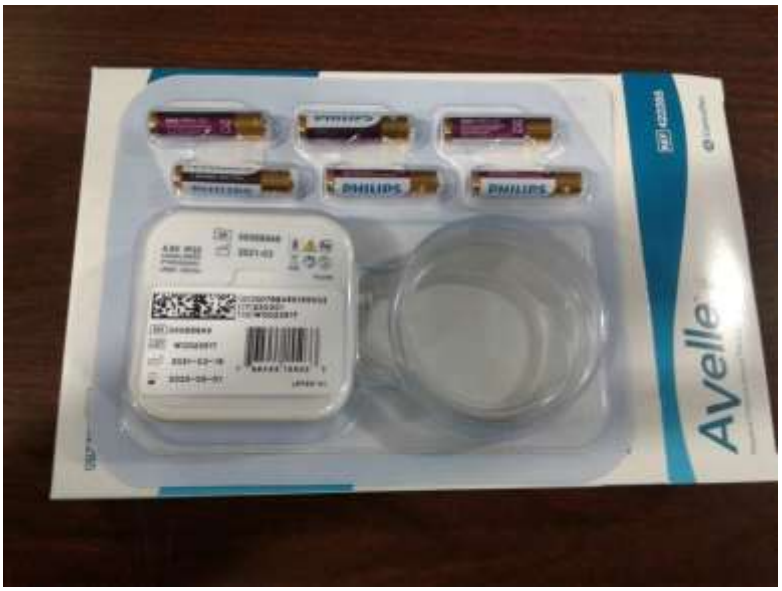
It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN. Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

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

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 3 – Representative product label
Please note this image is an example to show the position of the Product Code and Lot Number, the Product Codes and Lot Numbers of the affected batches can be found in Appendix 1.

Carton (market unit) / secondary pack Front Back 	Front and back of the market unit. The Ref number is at the bottom right of the front panel (see image on the left) The lot number is at the bottom right of the back panel (see image on the right)
Primary pack 	The lot number is on the label affixed on the back panel of the primary pack.