URGENT FIELD SAFETY NOTICE
DISTRIBUTORS

Commercial name: AbViser™ AutoValve™ IAP Monitoring Device
(see Attachment 1 for full details)

Issue Date: April 25, 2018

REF No: See Attachment 1

LOT No: All Lots

FSCA ID: 2018-003

Type of action: Recall / Product Disposal

Please note that this action only applies to specific product codes and does not affect all product codes and LOTs of AbViser AutoValve IAP Monitoring Devices.

Description of the problem:

ConvaTec has voluntarily initiated a recall of specific product codes of AbViser AutoValve IAP Monitoring Device.

Internal assessment of this product's packaging has confirmed that these devices are not meeting our expectations or those of our customers. Testing conducted on AbViser AutoValve IAP Monitoring Devices confirmed the potential for a pinhole breach in the sterile barrier. Using a potentially non-sterile contaminated device on the patient may expose the patient to infectious agents increasing the patient risk of developing infection.

AbViser provides a sterile non-invasive disposable intra-abdominal pressure monitoring device containing aspiration tubing, infusion tubing, valves and optional pressure transducers for the measurement of intra-abdominal bladder pressure. The device attaches directly to the patient's existing urinary catheter/drain system providing both an enclosed fluid path for infusing fluid into the bladder catheter as well as a method for monitoring the hydrostatic pressure in the bladder.

Only the identified product codes within this notice are affected.

For this reason and to address any potential risk of harm, all of the affected products should **not be used**. If you believe any affected products remain in your inventory, please contact your Regional contact.

Product Identification Procedure:
The only way to identify affected product is by comparing product code to the recalled product list (see Attachment 1). There is no other discernable difference between affected and unaffected product.

See Attachment 2 for example package labeling that highlights the location of the product code on the device label which is located on the primary packaging and/or the shipping carton. The product code (reference number) is preceded by the word 'REF'.

Advice on action to be taken by distributor.

Our records show that you have taken delivery of affected product. Please follow the steps below:

1. Please examine both the enclosed questionnaires. Immediately stop distributing and quarantine all affected products.
2. Please forward copies of the 'Field Safety Notice END USERS' to your customers, asking them to return the affected products to you along with a completed 'Recall Response Form for END USERS'.
3. When the completed Response Form(s) have been returned to you, please complete the 'Recall Response Form for DISTRIBUTORS' and contact your ConvaTec 'Regional contact' (see page 3) for further instructions on the disposition of affected product and to arrange credit. Your Regional contact or distributor will also advise on suitable replacement stock.
4. Please also return the completed 'Recall Response Form for DISTRIBUTORS', and all 'Recall Response Form for END USERS' to your 'Regional contact' via Fax/ E-mail.

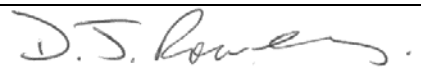
   PLEASE PROVIDE A COMPLETED RESPONSE AS SOON AS POSSIBLE.

Continue to report any adverse events involving this product to the ConvaTec Customer Care Line (see Regional contact list for details).

Transmission of this Field Safety Notice:
This notice should be sent to all others who have received the affected AbViser AutoValve IAP Monitoring Device products within your organization or to any organization where the affected devices have been transferred. ConvaTec apologizes for any inconvenience this may cause. If you have any questions, please contact your local ConvaTec representative (see Regional contact list for details).

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

Authorisation:

Name Duncan Rowley	Title Director, Regulatory Affairs and Quality Assurance, EMEA	Address ConvaTec Limited, First Avenue, Deeside Industrial Park, Deeside, CH5 2NU, U.K.	
Date	25th April 2018	Signature	

'Regional contact' for this Field Safety Corrective Action:

Belgium / Croatia / Czech Republic / Estonia / Hungary / Kuwait / Mauritius / Qatar / Romania / Saudi Arabia / Slovenia / South Africa
Tel: + 41 (0) 52 630 54 01
Fax: +41 (0) 52 630 54 99
Email: ccc.customerservice@convatec.com

Austria
Tel: 0800204034
Fax: 0800006399
Email: at.kundenservice@convatec.com

Germany
Tel: 08001624381
Fax: 08007245382
Email: de.kundenservice@convatec.com

Italy
Tel: 800500190
Email: clienti.convatec@convatec.com

Netherlands
Tel: +31 348 436 987
Fax : 0800234405
Email: nl.klantenservice@convatec.com

Norway
Tel: +47 22686095
Fax: + 47 80019602
Email: customerservicenordic@convatec.com

Portugal
Tel: +351 707201187
Fax: +351 707201189
Email: customerserviceiberia@convatec.com

Spain
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Fax: +34 936023701
Email: customerserviceiberia@convatec.com

Sweden
Tel: +46 (0)42 332010
Fax: +46 200887486
Email: customerservicenordic@convatec.com

Switzerland

Tel: 0800551110
Fax: 0800820340
Email: CustomerServiceSwitzerland@convatec.com

Turkey
Tel: +90 216 416 52 00
Fax: +90 216 416 28 30
Email: info@convatec.com.tr

United Kingdom
Tel: +44 (0) 1244 284882
Fax: 0800 279 9017
Email: uk.customerservice@convatec.com

ConvaTec

RECALL RESPONSE FORM for DISTRIBUTORS

URGENT FIELD SAFETY NOTICE

PLEASE COMPLETE AND RETURN by Fax/Email

Consignee of the device:

Consignee Account No:	
Consignee Name:	
Consignee Address:	

The following AbViser AutoValve IAP Monitoring Device have been distributed to your facility:

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

Please answer each of the following.

1. **Have You Distributed the Product Further?** **NO** ☐ **YES*** ☐
   If YES, have you notified down to your customer?** **NO ☐ **YES** ☐
   ***If NO explain why not:**

2. ☐ **We have NO affected product.**
3. ☐ **We have the following affected product:**

Record quantity (pieces) for each LOT to be disposed:

LOT No.	Units on Hand	LOT No.	Units on Hand	LOT No.	Units on Hand	LOT No.	Units on Hand	LOT No.	Units on Hand

Provide details of affected AbViser AutoValve IAP Monitoring Device that were distributed to your customers:

Customer Name	Product Code / REF No.	SAP Code	LOT No.	Quantity (pieces)

FORM Completed and Returned From:

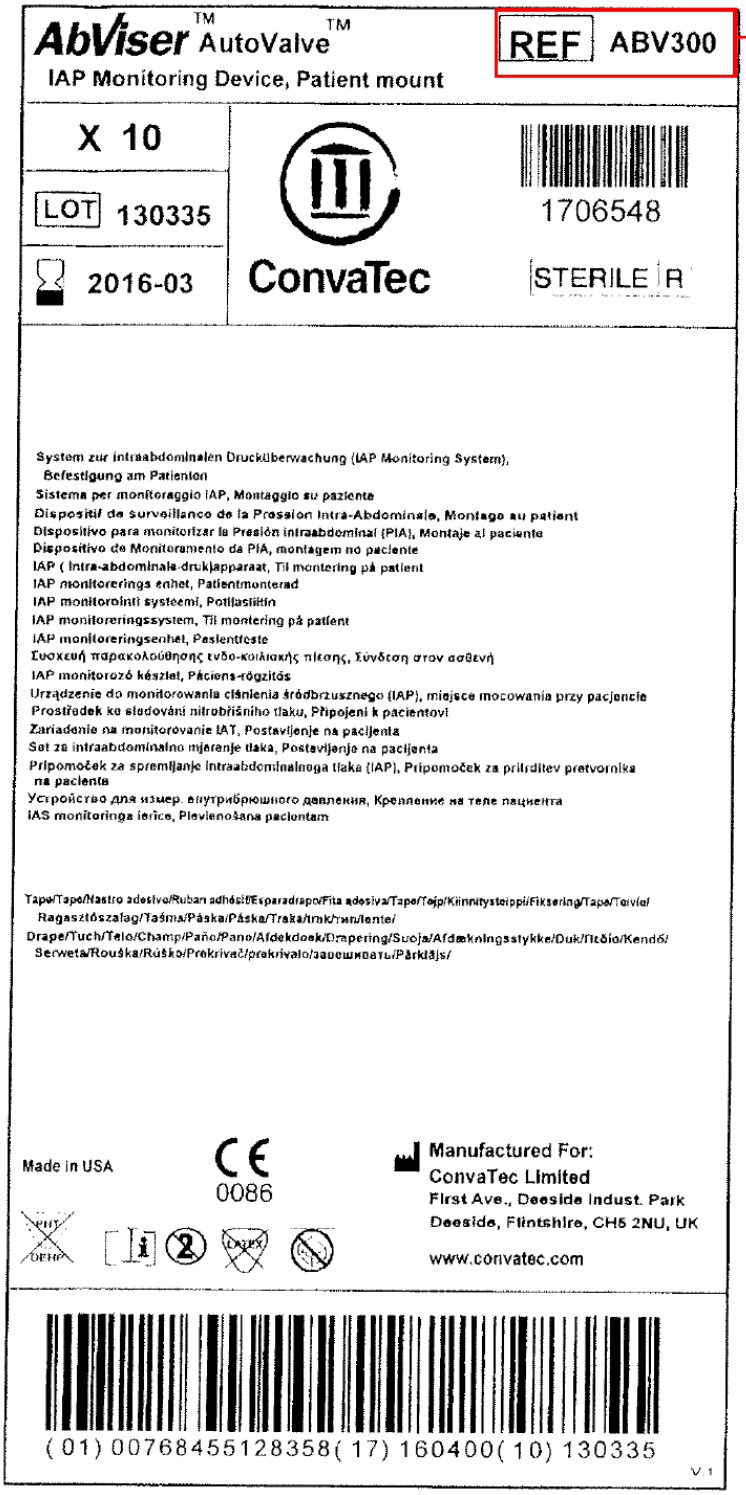
Name (CAPITAL LETTERS):	
Position:	
Company Name:	
Address:	
Phone No:	
Signature:	
Date (dd/mm/yyyy):	

☐ As requested, I have also provided a copy of all 'Recall Response Forms for END USERS' returned from customers who received affected product (please tick to confirm).

Attachment 1: Product Codes Affected

Product Code / REF No.	Description
ABV300	AbViser AutoValve IAP Monitoring Device, Patient Mount
ABV301	AbViser AutoValve IAP Monitoring Device, Pole Mount
ABV601	AbViser AutoValve IAP Monitoring Device, without Transducer

Attachment 2: Example Package Labeling



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