URGENT FIELD SAFETY NOTICE
END USERS

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 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 end user.

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

1. Please stop the use of all affected devices as defined in this document.
2. Ensure that all affected devices in stock are quarantined.
3. Check stock and complete the enclosed 'Recall Response Form for END USERS' which should be forwarded to your distributor **as soon as possible**.
4. Contact your distributor to arrange return of affected products, if applicable, and to arrange credit. Your Regional contact or distributor will also advise on suitable replacement stock.

PLEASE PROVIDE A COMPLETED RESPONSE AS SOON AS POSSIBLE.

Contact reference person relating to this letter: *(distributor to complete)*

Name:

Position:

Address:

Tel:

Fax:

E-mail:

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 distributor or local ConvaTec representative (see Regional contact list for details).

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

Authorisation:

Name [redacted]	Title [redacted]	Address ConvaTec Limited, First Avenue, Deeside Industrial Park, Deeside, CH5 2NU, U.K.	
Date	25th April 2018	Signature	[redacted]

Regional contact person 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

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Germany
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Switzerland

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

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Tel: +90 216 416 52 00
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Email: info@convatec.com.tr

United Kingdom
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Fax: 0800 279 9017
Email: uk.customerservice@convatec.com

ConvaTec

RECALL RESPONSE FORM for END USERS

URGENT FIELD SAFETY NOTICE

PLEASE COMPLETE AND RETURN by Fax/Email

Consignee of the device:

Consignee Name:	
Consignee Address:	

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

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

Please answer each of the following.

1. ☐ **We have NO affected product.**
2. ☐ **We have the following affected product and are following the instructions given by the distributor:**

Record quantity (pieces) for each LOT:

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

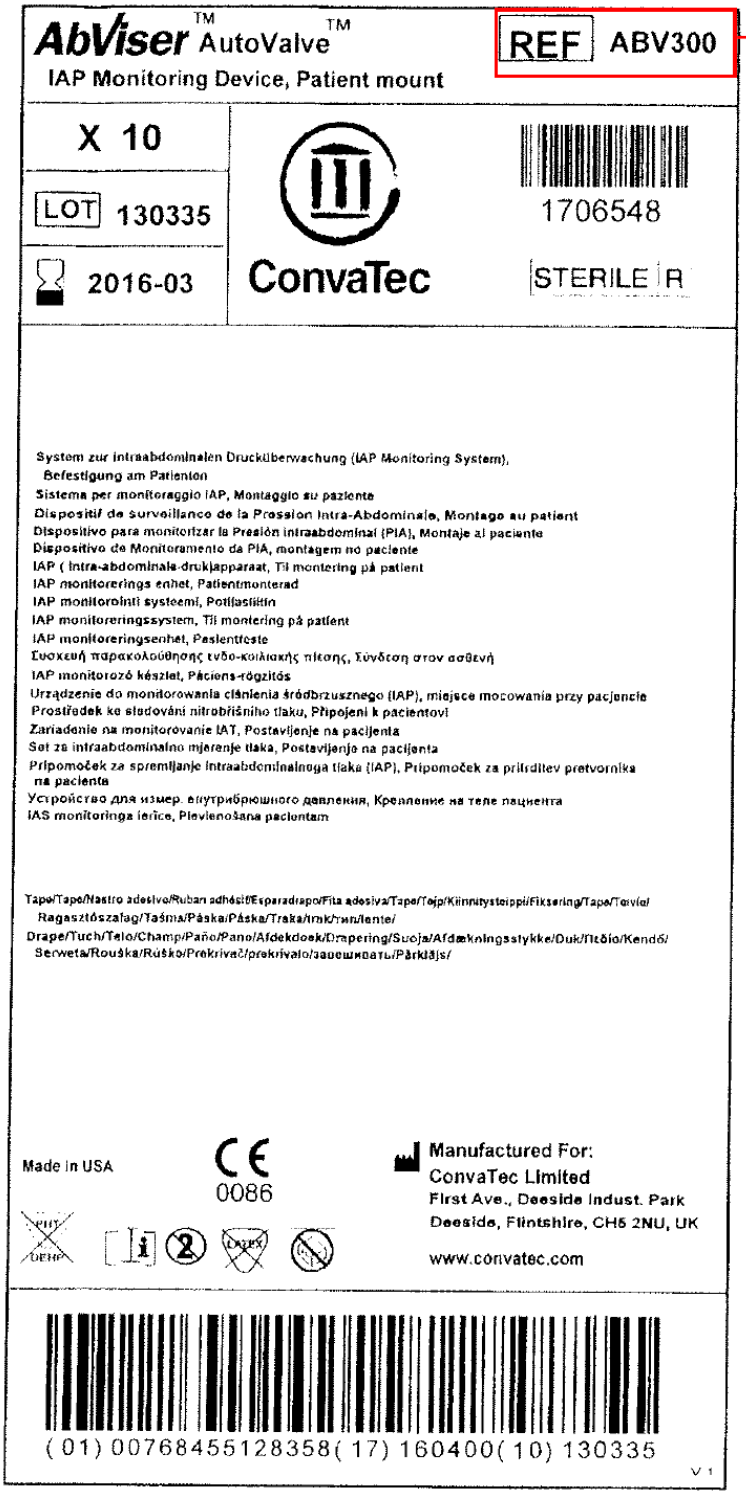
FORM Completed and Returned From:

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

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



APPRO