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DATE: 14/09/2015

URGENT: FIELD SAFETY NOTICE

Vented Tracheal Tube Introducer with Oxygen Connector, 14ch 750mm

Armstrong Medical Brand Product Code INBV14750OX

FSCA-identifier (e.g. date)	Ref: P3/FSCA/008
Type of action (e.g. chapter 4 definition of a FSCA).	The return of the medical device
Date:	14.09.15

Details on affected devices:

Vented Tracheal Tube Introducer with Oxygen Connector, 14ch 750mm
Product Code INBV14750OX
Lot Numbers: 450087, 452136, 452830, 454029, 455024, 455025, 455817, 456711, 457153, 457964

This field safety corrective action relates only to the Introducer with angled (coude) tip, vented with O2 connector, 14ch 750mm with the lot numbers above. These products can be identified by product reference number **INBV14750OX**

Description of the problem:

P3 Medical Ltd is initiating a voluntary recall of the Armstrong Medical brand Endotracheal tube introducer 14FR 750mm Vented

THERE IS A RISK THAT THESE PRODUCTS ARE NOT STERILE

Affected devices can be identified using by the following product reference and descriptions:

Product Reference	Description
INBV14750OX	**Vented Tracheal Tube Introducer with Oxygen Connector, 14ch 750mm**

Advise on action to be taken by the user:
1. Discontinue the use of all affected product as described above with immediate effect. Where possible return all affected product to your main stores and segregate it to awaiting collection by P3 Medical Ltd.
2. Please complete and return the attached product recall response form even if you do not hold or have not held any stock.
3. After completion, please return the product recall response form to P3 Medical Ltd either by fax to +44 (0)117 9724863, email to wigleyi@p3-medical.com or post to P3 Medical Ltd, 1 Newbridge Close, Bristol, BS4 4AX, UK.
4. If you have products to return please advise P3 Medical Ltd using any of the methods listed above or by phone on +44 (0)117 9728888 to arrange collection.

Transmission of this Field Safety Notice:
Please pass this notice to all appropriate healthcare professionals within you organisation that need to be aware and to any third parties to whom potentially affected devices may have been transferred.

Contact reference person: Ioan Wigley, 01179 728888, wigleyi@p3-medical.com

P3 confirms that that this notice has been provided to the appropriate Regulatory Agency