P3 Medical Limited
1 Newbridge Close, Bristol BS4 4AX
United Kingdom

Phone +44 (0)117 972 8888
Fax +44 (0)117 972 4863
Email: info@p3-medical.com

DATE: 10/09/2015

URGENT: FIELD SAFETY NOTICE

Vented Tracheal Tube Guides (Bougies)

"PROACT" Brand Product Code PBI314750

FSCA-identifier (e.g. date)	Ref: P3/FSCA/007
Type of action (e.g. chapter 4 definition of a FSCA).	The return of the medical device
Date:	11.09.15

Details on affected devices:

"PRO-BREATH" Brand Endotracheal tube introducer 14FR 750mm Vented

Product Code PBI314750

Lot Numbers: 449807,449808,452249,452250,453321,453796

This field safety corrective action relates only to Tracheal Tube Bougie Vented, 14 ch x 750mm with the lot numbers above. These products can be identified by product reference number **PBI314750**

Description of the problem:

P3 Medical Ltd is initiating a voluntary recall of the "PRO-BREATH" 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
PBI314750	Tracheal Tube Bougie Vented, 14 ch x 750mm Sterile, Single Use

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