

URGENT: FIELD SAFETY NOTICE

Sapimed Rectoscopes and Proctoscopes

FSCA-identifier	Ref: P3/FSCA/009
Type of action (e.g. chapter 4 definition of a FSCA).	The return of the medical device to P3 Medical Ltd
Date:	28/4/21

Details on affected devices:

Sapimed Rectoscopes, Proctoscopes and related devices supplied by P3 Medical Ltd with the following lot/batch numbers:

19F027I, 18A011I, 18D007I, 19K022I, MPR 18I011I, 19D002I, 18I001I, 18K007I, 18K008I, 18K009I, 19C013I, 19G013I, 19G018I, 19K006I, 19K007I, 18D011I, 18D012I, 18D013I, 18D020I, 18G012I, 18I002I, 19A006I, 19A008I, 19A009I, 19A019I, 19A020I, 19A021I, 19A022I, 19F013I, 19F014I, 19G004I, 19J001I, 19J002I, 19J003I, 20D015I, 18I005I, 19C010I, 19I018I, 18A023I

Description of the problem:

P3 Medical Ltd is initiating a voluntary recall of the products listed above.

THERE IS A RISK THAT THESE PRODUCTS ARE NOT STERILE



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

SMA4083	The Beak - Surgical Proctoscope - box of 25
SMA4084	The Beak - Diagnostic Proctoscope - box of 25
SMA4519	Sterile MPR Multipurpose rectoscope 190mm - set box/12
SMA4520IP	Sterile 200mm Rectoscope Kit with bellows Set -box/20
SMA4522	Sterile MPR Multipurpose rectoscope 220mm -special grip: box/12
SMA4522L	MPR - Multi purpose Rectoscope. 220mm long. Sterile & Disposable. Self-LED lighting. Box of 12
SMA4525IP	Sterile 250mm Rectoscope Kit with bellows Set -box/20
SMA8200ST/50	Single-use Bellows set, Sterile box/50



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

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 email to daf@p3medical.com or post to P3 Medical Ltd, 1 Newbridge Close, Bristol, BS4 4AX, UK, or contact your usual P3 sales contact.
4. If you have products to return please advise P3 Medical Ltd using any of the methods listed above or by phone on 0117 9728888 to arrange collection.

Transmission of this Field Safety Notice:

Please pass this notice to all appropriate healthcare professionals within your organisation that need to be aware and to any third parties to whom potentially affected devices may have been transferred.

Contact reference person: Dafydd Talbot, 01179 728888

daf@p3medical.com

P3 confirms that that this notice has been provided to the MHRA



FIELD SAFETY CORRECTIVE ACTION

MEDICAL DEVICE VOLUNTARY RECALL - FIELD SAFETY NOTICE

P3 Medical Ltd – Sapimed Rectoscopes and Proctoscopes

Code	Description
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I have been informed of the P3 Medical Ltd Field Safety Corrective Action involving the P3 Medical Vented Tracheal Tube Guides (Bougies), V14750. I have reviewed my stocks for the affected products:

1	I do not have any affected products in my stock	
2	I have affected products in my stock and will quarantine it pending collection by P3 Medical Ltd	
Signature:		Date:

Name:	
Organisation:	
Address:	
Phone No.	
Email:	

Please return this notification by Fax to Dafydd Talbot, P3 Medical Ltd. +44 (0)117 9724863 or daf@p3medical.com

PLEASE RETURN THIS NOTIFICATION WHETHER OR NOT YOU HOLD ANY STOCK.
Thank you