



PARTNERS FOR ENDOSCOPY

8th February 2021

Urgent Field Safety Notice – MHRA Alerted

ScopeFlow Water Bottle Tubing Product
Withdrawal of product from market

Details on affected Devices:

Product code: PFE145, PFE145CO2, PFE165, PFE165CO2

All Non Pure types of disposable water bottle adapters – ScopeFlow
(note, this does not affect the ScopeFlow Pure range)

Description of the Problem:

If you are using the semi disposable water bottle that does not have a built-in filter, the air in the water bottle is from the room air and, if a previous patient has had Covid 19, the water may be carrying the virus.

Advice on Action to be taken by the User:

We are contacting you urgently to replace any of the unfiltered water bottle caps that you may have with the filtered range. This will be done free of charge. If you are in any doubt, just look at the inside of the water bottle top to see if a filter is present. The below image shows what the filtered cap should look like.



Fig 1 – Image of filter within the cap

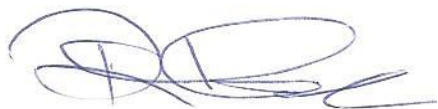
Transmission of this Field Safety Notice:

This notice needs to be passed on to all those units that need to be aware within your Organisation, or to any organisation where the potentially affected devices have been transferred (if appropriate). This will predominately be endoscopy units.

Contact Reference Person:

Rob Hartley, Director
Partners for Endoscopy Limited
Hartley House
Galveston Grove
Fenton
Stoke on Trent, ST4 3PE
Tel: 01782 594164

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency (MHRA)



Acknowledgement:

Please could affected customers acknowledge that they have received, read and understood this Field Safety Notice and have taken any further actions by completing the form overleaf and returning to Partners for Endoscopy Limited. Please complete the form and return even if you do not currently use the Scopeflow product to ensure that we have this on record.

Acknowledgement of this Field Safety Notice:

I acknowledge that I have received, read and understood the attached Field Safety Notice regarding the ScopeFlow product, have passed it on to other persons or organisations affected by this notice and have taken further actions where appropriate as below:

Signature:

Name:

Date:

Hospital/Unit/:
Organisation

I confirm that I have taken the following action:-

- I have no stock remaining of the ScopeFlow product covered by this FSN.
- I have quarantined our current stock of ScopeFlow and arranged an exchange for the ScopeFlow Pure product.

Please return to:

Post: Andrea Goodier, Quality manager
Partners for Endoscopy Limited
Hartley House
Galveston Grove
Fenton
Stoke on Trent
ST4 3PE

e.mail: andrea@pfemedical.co.uk

fax: 01782 323148