

## Vygon (UK) Ltd

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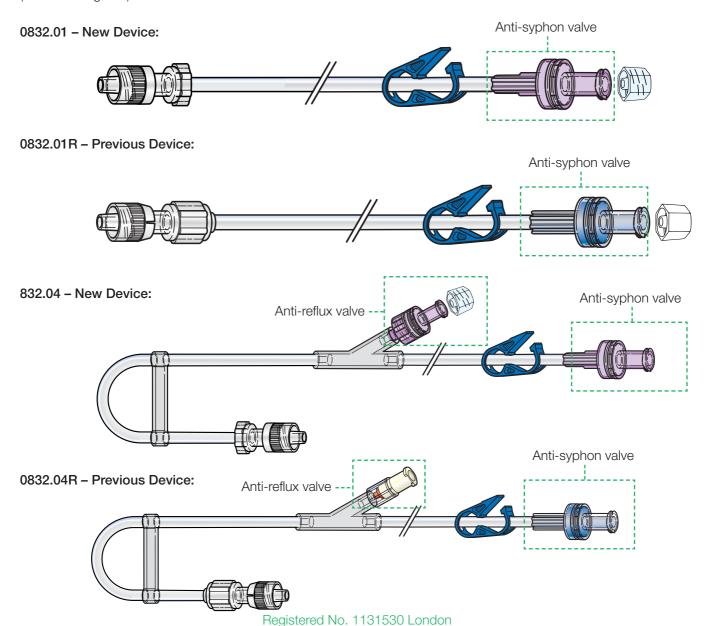
Tel: +44 (0) 1793 748800 Fax: +44 (0) 1793 748899

Our Ref: 1302/29422/16 Dear Sir/Madam,

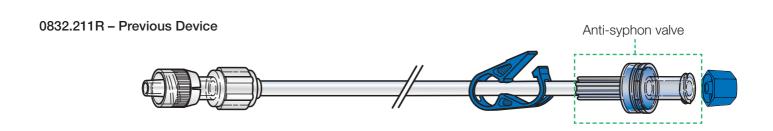
## PRODUCT MODIFICATION UPDATE - PROTECT-A-LINE ANTI-SYPHON

We are writing to inform you that, following a recent change of manufacturer, a new anti-syphon valve has been supplied with product codes 0832.01, 0832.04 and 0832.211.

The new anti-syphon valve has a higher opening pressure than the anti-syphon valve supplied with the previous devices (codes ending in R):







We can advise that the opening pressure of the new anti-syphon valve ranges from 210 millibar (approximately 157.51 mmHg) to 290 millibar (approximately 217.51 mmHg).

Due to the higher opening pressure, infusion pump levels may need to be adjusted to prevent occlusion alarms. Whilst we appreciate that this may not be ideal, we can confirm that the manufacturer is currently validating a new anti-syphon valve with a lower opening pressure. If the new anti-syphon valve passes testing and is successfully validated, we hope to be able to begin supplying product codes: 0832.01, 0832.04 and 0832.211 with an improved anti-syphon valve within approximately 4-5 months.

## 0832.04 Update

As mentioned in our previous product modification notice (ref: 1212/29139/00), devices of product code: 0832.04 with a batch number ending in BA have been supplied with a vented cap on the female ports. It is vital that these caps are removed and replaced with non-vented caps (or a needle-free access device) if the port is to remain unused when connected to a patient. If these vented caps are left on unused ports when the line is connected, air can enter the line and pose a risk of air embolism.

We can confirm that we have reviewed the use of vented caps with the manufacturer of these extension lines and hope to begin supplying product code: 0832.04 with non-vented caps in approximately 5-6 weeks.

Please do not hesitate to contact us if you have any further questions, as we are always happy to help wherever we can.

Yours Sincerely,

Kate O'Connell
Laboratory Supervisor

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