Valkenswaard, 22/03/2024

URGENT - FIELD SAFETY NOTICE – RECALL ALGAFLEX & OCTOFLUX – FSN CAPA24-010

Dear Customer,

As the legal distributor of the article in question, we would like to inform you that our manufacturer PEROUSE MEDICAL has identified a manufacturing defect for the Algaflex® and Octoflux® range. Several references and batch numbers are involved in this defect.

PEROUSE MEDICAL became aware of a problem related to the blister packs of some of its products. There could be a rupture of the sterile barrier system (pierced blister) of the products. Indeed, the blister packs may have microholes visible to the naked eye only with a special lighting at a close distance from the blister. These microholes are not visible with naked eye under normal lighting.

More detailed information can be found in the document "Detailed information on recall". If you would like to receive this information in Dutch, please do not hesitate to contact us.

We have verified your purchase history and, according to our records, you have received the following products:

Reference	Description	Batch Number	Quantity
VPE0163PQ	Algaflex low pressure lines 50cm (spinlock MLL)	23122602	1900
VPE0163PS	Algaflex low pressure lines 150cm (spinlock MLL)	23112551	200
VPE0170PS	Octoflux filling and injection set + saline line (300 PSI)	23092554	3775

We kindly ask you to acknowledge receipt of this FSN and complete the attached "Customer Reply Form" and return it as soon as possible (by March 29th the latest) so that we can proceed with the withdrawal of the products concerned.

The IGJ has been informed of this safety notification.

If you would like to receive more information regarding this recall or any other matter, please contact our Sales Support, reachable on +31 (0)40 208 93 80 or via email salessupportnl@vygon.com.

We apologise for any inconvenience this FSN may cause.