



Value Life

## **Urgent Field Safety Notice**

**Device:** Premicath Neonatal PICC with Stylet

**Issue:** Revision of Instructions for Use (IFU /DFU)

**Reference:** 11191

**Date:** September 21<sup>st</sup> 2017

**Action:** Device modification' in accordance with MEDDEV 2.12

**Attention:** All clinicians involved in the placing of Neonatal PICC's

### **Details of affected Device**

**Product Brand Name:** Premicath Neonatal PICC which contain a Stylet.

### **Product Codes:**

1261.153, 1261.203, 1261.206, 1261.207, 1261.208, 1261.306, 6261.203, 6261.206, 6261.306

### **Description**

We wish to highlight to users the revised Instructions for Use (IFU) concerning the removal of the Stylet. Below is the relevant segment with the revised text highlighted.

In order to remove the stylet, disconnect between the T-Piece and catheter hub. If difficulty is experienced stop, let vein rest for a minute and try removal again very slowly.

Gentle flushing of the catheter **with saline or diluted lipid solution may assist in guidewire removal. If resistance still remains withdraw catheter and stylet simultaneously.**

### **Action to be taken by user:**

Familiarise yourself with these revised Instruction for Use.

Please share this notice with all other users so they are aware of these revised Instructions for Use.

**Contact Information:** For any further information in Ireland contact Denis Coakley at [dcoakley@vygon.ie](mailto:dcoakley@vygon.ie). For other countries please contact your local Vygon Representative.

The Health Products Regulatory Authority (HPRA) Ireland has been notified in relation to the distribution of this Field Safety Notice.



Value Life

## **ACKNOWLEDGEMENT AND CUSTOMER RESPONSE FORM**

**URGENT: FSN – Vygon PREMICALH**

**PLEASE COMPLETE AND RETURN THIS FORM BY FAX TO: 01-4105721 or E-Mail to [info@vygon.ie](mailto:info@vygon.ie)**

<b>Hospital</b>	
<b>Contact Name</b>	
<b>Function</b>	
<b>Tel Number</b>	
<b>E-Mail</b>	

We acknowledge receipt of the above FSN and that the information contained in this Field Safety Notice has been shared with all recipients / end users of the Products listed below within our organisation.

Signature and Date:

---