



URGENT FIELD SAFETY NOTICE

Device: Premicath Neonatal PICC with Stylet

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

Reference: 11191

Date: December, 1st 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 PICCs which contain a Stylet.

Product Codes:

1261.153, 1261.203, 1261.205, 1261.206, 1261.207, 1261.208, 1261.306, 1261.307, 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 stylet removal. **If resistance still remains withdraw catheter and stylet simultaneously.**

Action to be taken by user:

Familiarise yourself with these revised Instructions 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 please contact your local Vygon Representative.

Your National Competent Authority has been notified in relation to the distribution of this Field Safety Notice