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MEDDEV 2 12-1 rev. 8 Vigilance

Urgent Field Safety Notice

Commercial name of the affected device : *LEGFLOW OTW*

FSCA-identifier : *2016-03-25*

Type of FSCA : *Advice given by manufacturer regarding the use of the device*

Date: *2016-03-25*

Attention: *All distributors and hospitals using PTA balloon catheter LEGFLOW OTW*

Details on affected devices: *All LEGFLOW OTW products on stock*

Description of the problem: *The label of the Legflow OTW box shows the RATED BURST PRESSURE. In order to avoid any wrong pressure application, higher than the RBP, please disregard the additional information on the statistical average burst pressure, as application of such higher balloon dilatation pressure can result in balloon rupture due to overinflation. The Average Burst Pressure data (22 bar) placed immediately below the RBP table is NOT the Rated Burst Pressure and is not applicable during the intervention.*

Please read carefully the Compliance chart inside the unit box for proper info concerning the Rated Burst Pressure. Please do not exceed this pressure!

Advise on action to be taken by the user: *Each direct user of the product LEGFLOW OTW is asked to carefully read the information about what is the RBP for a given product before the intervention*

Transmission of this Field Safety Notice: *This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.*

Please transfer this notice to other organisations on which this action has an impact. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

CARDIONOVUM GmbH, Am Bonner Bogen 2, 53227 Bonn, Germany,
Tel. No. +49 228 90 90 590, fax no. +49 228 90 90 5920, email: info@cardionovum.eu

Reference person:

The undersigned confirms that this notice has been notified to the appropriate competent authority.

Signature.....