



Date: 2015-10-12

Company
Attention:
Street name XX
XX-XXXX XX City
Country

Urgent Field Safety Notice, recall of products

Hpm Roll on cuff article 3038, LOT no 12-3 xx
Hpm Roll on cuff article 3746, LOT no 10-3 xx
Hpm Roll on cuff article 4556, LOT no 11-3 xx
Hpm Roll on cuff article 5565, LOT no 12-1 xx

Hpm roll on cuffs produced during a timeframe of 20130506-20131013 with above specific LOT numbers must immediately be traced, if still in use or in stock, and sent back to Hammarplast Medical AB.

An incident occurred with leaking valve on cuff during surgical operation. This led to surgeon had to cut cuff open to release it from patient's leg with blood loss as serious result. Valve on cuffs produced during mentioned period lack an extra silicon sealing inside the valve which can lead to leakage.

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please transfer this notice to other organizations 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 information:

Ann-Charlotte Johansson, QA/RA
Hammarplast Medical AB, Kartåsgatan 8, Box 2069, 531 40 Lidköping, Sweden
+46-510-54 50 31, ac.johansson@hpm.se

The undersigned confirms that this notice has been notified the appropriate Regulatory Agency.

Ann-Charlotte Johansson

Attention! Return confirmation on page 2 to above mail address or post address.



Receipt notification

Urgent Field Safety Notice, dated 2015-10-12 from Hammarplast Medical AB regarding recall of products:

Hpm Roll on cuff article 3038, LOT no 12-3 xx
Hpm Roll on cuff article 3746, LOT no 10-3 xx
Hpm Roll on cuff article 4556, LOT no 11-3 xx
Hpm Roll on cuff article 5565, LOT no 12-1 xx

I hereby confirm that I have received and understood information in above FSN. I take responsibility to see that corrective actions described will be performed.

Signature and title

Date

Company name: _____