

Urgent Field Safety Notice

Romed I.V. Catheter With Injection Port, Ref IVCATH-14G/16G/18G/20G/22G/24G, lot 190601

FSCA 25 November 2019

Date: 25 November 2019

Attention: All customers who received Romed I.V. Catheters With Injection Port, any size, lot 190601

Details on affected devices:

Affected products are the Romed I.V. Catheters With Injection Port, any size, lot 190601

REF: IVCATH-14G/16G/18G/20G/22G/24G

LOT: 190601

Description of the problem:

A number of our Romed I.V. Catheters With Injection Port from lot 190601 have been found to contain foreign particles inside the packaging, which has been linked to an increased particle count in the clean room during the manufacturing of this lot. Additionally the band between the injection port and the port cap is thicker for IVCATH-14G, and this resulted in shearing in the case of several checked samples, which gives the impression that the band may be broken.

No adverse event has been reported for this issue at this time. The products were identified during a quality control check. Van Oostveen Medical B.V. is actively working on implementing corrective and preventive actions regarding this issue.

Advise on action to be taken by the user:

Distributors and end-users who make use of the Romed I.V. Catheters With Injection Port are requested to review their inventory for the affected lot number. Affected products in stock are requested to be blocked for use immediately. Distribution of affected products has to be discontinued. All affected products can be returned to your distributor for replacement.

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.

Van Oostveen Medical B.V.

Herenweg 269

3648 CH Wilnis

The Netherlands

Contact reference person:

Silvia Hodorocea, MSc qualitycontrol@romed.nl

25 November 2019

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