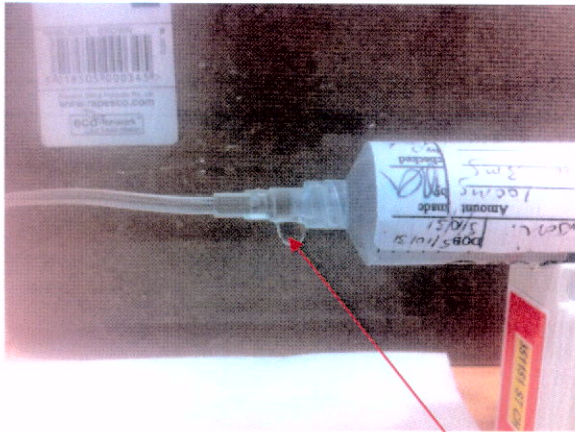

Urgent Field Safety Notice

Ref: FSN2016-001

Product name: Product Code - 100-172S, 100-172SLL
Batch Numbers: All batches manufactured 2014 and 2015
Date: 4th January 2016
Type of Action: **Recall Notice**

**Attention: All customers using CME Syringe Extension sets 100-172S & 100-172SLL
(For use with the CME T34/T60 pumps used for pain management and symptom relief in palliative care)**



Leaking between the set luer connector and syringe

Description of the problem:

CME has received a number of reports from customers involving leakage from the connection between the CME extension set female luer connector and the syringe for Product Code - 100-172S, 100-172SLL. T34 syringe pumps and sets are not designed for use with life sustaining therapy. The risk of the leak is therefore limited to a slight under-infusion in pain management which could affect patient's pain control if undetected. Although the failure rate is considered to be low (0.1%), CME have now taken the decision to recall all sets.

Advise on action to be taken by the user:

- Quarantine all affected sets and contact CME Medical Customer Support team on 01253 206700 to arrange collection and credit.
- CME Medical can supply an alternative interim set as described in Customer Information Bulletin CB-006 until a newly designed direct replacement of products 100-172S/100-172SLL is available.



Caesarea Medical Electronics

Transmission of this Field Safety Notice:

This notice must be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (If appropriate)

Please transfer this notice to other organisations on which this action has an impact. (If appropriate)

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

Clare Unsworth – QA Manager, CME Medical UK Limited

E-mail: QA@cmemedical.co.uk

Customer Support: 01253 206700

Please complete the acknowledgement form accompanying this FSN and return it to the address provided. Alternately, please scan and email back to the QA email - qa@cmemedical.co.uk

THE COMPETENT AUTHORITIES IN ALL COUNTRIES AFFECTED BY THIS ACTION HAVE BEEN INFORMED OF THIS FIELD SAFETY NOTICE.

Yours Sincerely

Swi Barak
CEO
Caesarea Medical Electronics Ltd.

A handwritten signature in blue ink, appearing to read 'Swi Barak', is written over the printed name and title.