B. Braun Medical Ltd.
3 Naas Road Industrial Park
Dublin 12
e-mail: productcomplaints.ie@bbraun.com
http://www.bbraun.com

Date:
October 13, 2020

Urgent FIELD SAFETY CORRECTIVE ACTION – PRODUCT RECALL

Actreen®

Batch	Reference	Description
18G12E7SDC	239012E	ACTREEN® MINI SET CH12

To whom it may concern,

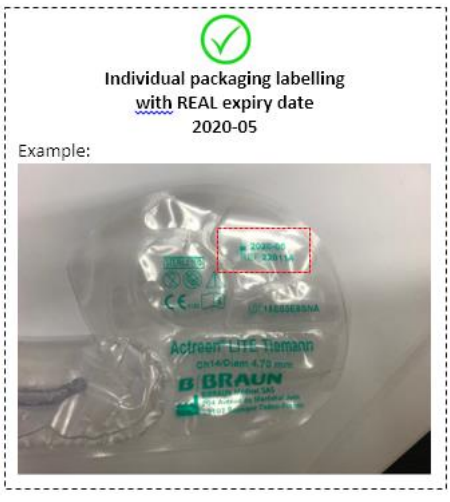
The B. Braun Medical company has decided to proactively inform our customers in the context of a voluntary RECALL with regard to the above mentioned **Actreen®** catheters for intermittent urinary catheterization.

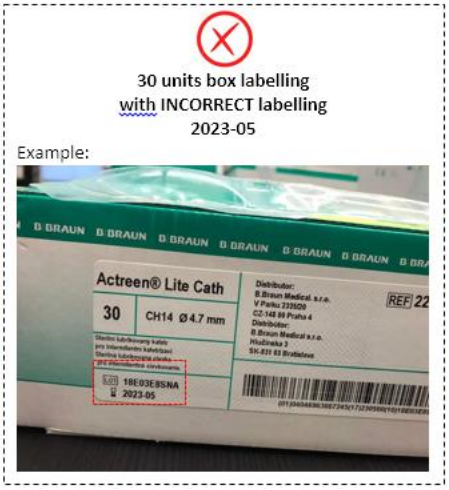
The **Actreen®** catheters are distributed in boxes of 30 individually packaged units.
The expiry date is printed on the box (secondary packaging) and on individual packaging (primary packaging).

Reason for the voluntary Recall (Field Safety Corrective Action)

In the course of our internal quality control processes, we realised that the boxes of Actreen® catheters (secondary packaging) are printed with an incorrect expiry date.

Our investigations allow us to determine that only the boxes are affected. The individual packaging is correctly printed with the real expiry date.





As the individual packaging (primary packaging) is correctly printed with the real expiry date, the risk is limited for the patients or users.

B BRAUN
SHARING EXPERTISE

Actions to be taken by the customer

Our records have shown that your institution has received an affected batch of **Actreen®** as specified in the table above.

We kindly ask you to initiate the following activities immediately and with priority:

- Review this Field Safety Notice in its entirety and ensure that all users of the above-mentioned products in your organisation and other concerned persons are informed about this Field Safety Notice. If you are a distributor, please forward this correction notification to your customers.
- Remove affected devices from your inventory
- Return affected devices to your distributor
- Complete the enclosed Customer Acknowledgement Form and return this to B. Braun (email: productcomplaints.ie@bbraun.com)

Competent Authorities, including the HPRA, are being notified that B. Braun Medical is voluntarily taking this action.

If more information is needed, please contact

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We apologise for any inconvenience this product recall may cause and we appreciate your cooperation in this matter.

Yours sincerely,

Susan O'Connor

Susan O'Connor
Commercial Manager OPM

Roberta Egan

Roberta Egan
Regulatory Affairs Manager