B. Braun Medical
Société par actions simplifiée
26 rue Armengaud
92210 Saint-Cloud

Your reference:
Our reference: FSCA 2020-07-29 MSP

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Date: July 29, 2020

TO WHOM IT MAY CONCERN

Urgent FIELD SAFETY CORRECTIVE ACTION – PRODUCT RECALL

Actreen® Lite Cath

To whom it may concern,

We, the B. Braun Medical company, have decided to proactively inform our customers in the context of a voluntary RECALL with regards to **Actreen® Lite Cath** catheters for intermittent urinary catheterization.

The **Actreen® Lite Cath** 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 regular post marketing surveillance activities, we received a complaint that the boxes of Actreen® Lite Cath catheters (secondary packaging) are printed with an incorrect expiry date. It is written 2023-05 instead of 2020-05, 2021-04 instead of 2020-04 or 2021-05 instead of 2020-05.

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

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This FSCA is an extension of the FSN 2018-10-25 MSP-CB performed in 2018-2019.

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For full list of affected products, please refer to **Attachment 1**.

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

Actions to be taken by the customer

Our records have shown that your institution has received an affected batch of **Actreen® Lite Cath** 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 organization 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 the device from your inventory
- Return the device to the following address
- Fill the enclosed recall confirmation form

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Competent Authorities is being notified that B.Braun Medical is voluntarily taking this action.

If more information is needed, please contact

Local

Local contact 1
Name
Title
Email
telephone

Local contact 2

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

Yours sincerely,

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……..
……..

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Attachment 1

Batch	Reference	Description
18D25E8SNA	**228216E**	ACTREEN LITE NELATON MALE CH16
18D26E8SNB	**228218E**	ACTREEN LITE NELATON MALE CH18
	228218J	ACTREEN LITE NELATON MALE CH18
	228218K	ACTREEN LITE NELATON MALE CH18
	228218U	ACTREEN LITE NELATON HOMME CH18
18D26E8SND	**228212A**	ACTREEN LITE NELATON MALE CH12
	228212BR	ACTREEN LITE NELATON HOMME CH12
	228212E	ACTREEN LITE NELATON MALE CH12
	228212F	ACTREEN LITE NELATON MALE CH12
	228212K	ACTREEN LITE NELATON MALE CH12
	228212N	ACTREEN LITE NELATON MALE CH12
	228212U	ACTREEN LITE NELATON HOMME CH12
18D27E8SNA	**228314DE**	ACTREEN LITE CATH NELATON 20CM CH14
	228314F	ACTREEN LITE NELATON FEMALE CH14
	228314K	ACTREEN LITE NELATON FEMALE CH14
	228314U	ACTREEN LITE NELATON FEMME CH14
18D28E8SNA	**228308A**	ACTREEN LITE NELATON FEMALE CH08
	228308DE	ACTREEN LITE CATH NELATON 20CM CH08
	228308E	ACTREEN LITE NELATON FEMALE CH08
	228308N	ACTREEN LITE NELATON FEMALE CH08
	228308RU	ACTREEN LITE NELATON FEMME CH08
18D28E8SNB	**228316DE**	ACTREEN LITE CATH NELATON 20CM CH16
	228316E	ACTREEN LITE NELATON FEMALE CH16
	228316U	ACTREEN LITE NELATON FEMME CH16
18E02E8SNB	**228212A**	ACTREEN LITE NELATON MALE CH12
	228212DE	ACTREEN LITE CATH NELATON 45CM CH12
	228212F	ACTREEN LITE NELATON MALE CH12
	228212N	ACTREEN LITE NELATON MALE CH12
	228212U	ACTREEN LITE NELATON HOMME CH12
18E03E8SNA	**228114U**	ACTREEN LITE TIEMANN CH14
18E10E8SNA	**228308RU**	ACTREEN LITE NELATON FEMME CH08