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B. Braun Melsungen AG
Division Hospital Care
Safety Officer Medical Devices

Your reference:
Our reference: RECALL 2018-04-23 LS/STK

Contact:

Fon: fon
Fax: fax
Email: mail
Internet: http://www.bbraun.de

Date: April 23, 2018

TO WHOM IT MAY CONCERN

Urgent FIELD SAFETY NOTICE

– Askina Gel

- Calgitrol Paste

To whom it may concern,

On behalf of the B. Braun Hospicare Ltd. we hereby recall the following products in the context of a FIELD SAFETY CORRECTIVE ACTION from the market:

Article Number	Article Name	Batch
14291	ASKINA® GEL 100 G	all
001419N	ASKINA GEL 15G	all
001419NRU	ASKINA GEL 15G	all
001419S	ASKINA GEL 15G	all
001419SBR	ASKINA GEL 15G	all
001419SES	ASKINA GEL 15G	all
001419SESCP	ASKINA GEL 15 GR PHARMACY	all
001419SF	ASKINA GEL 15G	all
001419SFR	ASKINA GEL 15G	all
001419SRU	ASKINA GEL 15G	all
6241001	ASKINA® CALGITROL® PASTE 100 G	all
6241505	ASKINA CALGITROL PASTE 15 G	all
6241505F	ASKINA CALGITROL PASTE 15 G	all
6241510	ASKINA CALGITROL PASTE 15 G	all
6242501	ASKINA® CALGITROL® PASTE 250 G	all

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6242501FR	ASKINA® CALGITROL® PASTE 250 G	all
6245001	ASKINA® CALGITROL® PASTE 500 G	all

Reason for the Recall

In our manufacturing site it was determined that the irradiation dose qualified for sterilization of the above mentioned products was too low. In consequence, the germ reduction through gamma irradiation may not have reached the requested sterility assurance level of 10^{-6}. The effect cannot be limited to specific batches.

Up to now we received no market feedback on any adverse patient outcome which could be associated to the above described observation. However, we have decided to recall the affected products from the market as a preventive measure.

Actions to be taken by the USER

Our records show that your facility has received one or more of the above listed products.

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

- Identify, quarantine and return affected devices.
- Do not use affected devices anymore.
- Patients with affected devices in use should be monitored carefully. If clinically uneventful, an exchange of the product is not indicated.
- Inform the responsible personnel in the affected facilities.
- Confirm the receipt of this information.

If more information is needed, please contact

Local contact 1
Name
Title
Email
telephone

Local contact 2

Kindly accept our apologies for any inconveniences.

Yours sincerely,

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