|  |  |
| --- | --- |
| B|BRAUN | B. Braun Melsungen AGDivision Hospital CareSafety Officer Medical Devices34209 MelsungenGermany |
|  |  |  |
|  |  | Your reference: |  |
| Our reference: | RECALL 2018-04-23 LS/STK |
|  |  |
| TO WHOM IT MAY CONCERN |  | Contact: |  |
|  |
| Fon: | fon |
| Fax: | fax |
| Email: | mail |
| Internet: | http://www.bbraun.de |
|  |  |  |  |
|  |  | Date: | April 23, 2018 |

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 |
| 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 1NameTitleEmailtelephone | Local contact 2 |

Kindly accept our apologies for any inconveniences.

Yours sincerely,