

Urgent FIELD SAFETY NOTICE

To whom it may concern,
CC Chairman Medical Board and relevant Head of
Departments

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

Article Number	Article Name	Batch
6241510	ASKINA CALGITROL PASTE 15 G	all

Please note that there may be other affected identifiers that are affected globally and that recipient of this notice should check with product owner in the event the device is obtained from an overseas dealer.

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

Loo Bee Keong
General Manager (Sales)
bee_keong.loo@bbraun.com
DID:(+65)62130960
Tel:(+65)62130933
Fax:(+65)62130930
Mobile: (+65) 9668 0547

Agnes Seah
Senior Sales Manager
agnes.seah@bbraun.com
DID:(+65)62130951
Tel:(+65)62130933
Fax:(+65)62130930
Mobile: (+65) 9680 7464

Kindly accept our apologies for any inconveniences.

Yours sincerely,
Agnes Seah
Senior Sales Manager

Confirmation of Receipt of Urgent Field Safety Notice

Affected Medical Devices:

Article Number	Article Name	Batch
6241510	ASKINA CALGITROL PASTE 15 G	all

Please fill in this form and return it by fax immediately to the fax number or email to hui_min.teng@bbraun.com

+65 62130930

We hereby confirm that we are aware of the above Field Safety Notice. The Field Safety Notice was communicated within our organization.

Furthermore, we declare that:

- ☐ We do not have any remaining stock of the affected products
- ☐ We have remaining stock of _____ pcs, which are returned to supplier
Break down of returned stock batches:

Batch: _____ x _____ pcs,

Batch: _____ x _____ pcs,

Batch: _____ x _____ pcs,

Received by:

Name, date & sign

Name: _____

Phone Number: _____

Date and Signature: _____

Company Stamp:

