

IMPORTANT – FIELD SAFETY NOTICE – PRODUCT RECALL
Celsite® Safety Access Ports 601

Our records indicate that your health care facility is involved in this Field Safety Corrective Action.
Please pay attention to the following Notice and confirm its receipt.

Note: This product recall only impacts the standard (adult) size of Celsite® Safety with the product code 601 and which have been produced from November 2017.
The small (paediatric) models with the product code 605 are not affected.

Attachment 1: list of recalled access ports batches.

Dear Sir, or Madam,

B. Braun Medical France is voluntarily recalling the batches of Celsite® Safety access ports listed in Attachment 1. This action is being taken because the listed Celsite® Safety access port body may potentially leak during use.

During internal R&D testing, we detected that liquid injected through the access port could leak from the access port body. According to the investigations we have performed, the leak, if one occurs, concerns a very small quantity of liquid.

It is worth noting that, to date, we have not received any complaints related to Celsite® Safety 601 access port leakage.

Potential hazards / patient risks:

Leakage of injected liquid in the tissues surrounding the access port body may lead to local pain and/or tissue damage, ranging from inflammatory reaction to tissue necrosis at the site of extravasation.

For patients who have already received one of the listed access ports, they should be monitored according to hospital protocol or based on clinical practice and/or guidelines with regard to the risk of drug extravasation. .

Our investigations have allowed us to identify that the Celsite® Safety access ports batches listed in Attachment 1 have been distributed to your facility. If you are still in possession of products from these batches, you should remove them from your inventory and return them to the following address with the enclosed recall confirmation form:

Local address

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

For any additional information, please contact **your local representative:**

Local contact name and telephone and/or email

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

Date : 04-12-2018

Best regards,

[Redacted signature]

[Redacted signature]