

IMPORTANT – FIELD SAFETY NOTICE – PRODUCT RECALL

Celsite® Access Ports

Product Name	Part Number	Batch Number°
Celsite ST205H	4436806	36896335

Note: This product recall only impacts the above mentioned Celsite® access ports batch.

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.

Dear Sir, or Madam,

B. Braun Medical France is voluntarily recalling the batch of Celsite® access ports above listed. This action is being taken because the above listed Celsite® access port kits are potentially contaminated by endotoxins.

According to the medical device regulation^[1], the endotoxin limit for devices in contact with blood is: "not more than 20 Endotoxin Units (EU) per device".

We routinely perform Bacterial Endotoxin Tests (LAL test) on our devices to ensure that they comply with the regulation for endotoxin limit. Due to a non-compliant test result on a finished product, we performed further investigations and identified that one of the components of the Celsite kit (the peelable introducer), contains a high level of endotoxins. Our investigations allow us to identify that this peelable introducer has been used in the Celsite access ports batch above mentioned and then distributed to your facility.

Potential hazards / patient risks:

High level of endotoxins in contact with patient blood could result in elevation of the patient body temperature. The peelable introducer is only used during the implantation procedure. The contact period of this component with patient blood is limited (inferior to 5minutes).

Patients who have already received an access port of this batch should be monitored within the first post-operative days. The quality of the access port system is not affected, it can be used until the end of the treatment, as usual.

[1] The United States Pharmacopoeia (USP) <161> current edition.

If you are still in possession of products from this batch, you should remove them from your inventory and return them to the following address with the enclosed recall confirmation form:

Local address

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

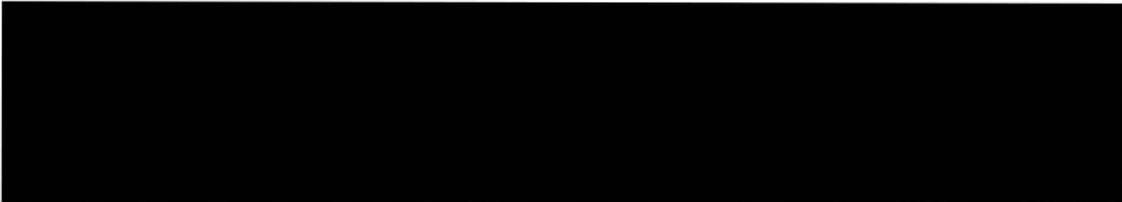
For any additional information, please contact **your local representative:**

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 : 12/06/2015

Best regards,



Director Regulatory and Scientific Operations
Pharmacien responsable
Safety Officer
General manager

Quality & Regulatory Affairs Manager
Chasseneuil CoE

Acknowledgement Form

Of the Field Safety Notice dated of 12/06/2015

IMPORTANT – PRODUCT RECALL

Celsite®

Venous Access Ports

Product Name	Part Number	Batch Number
Celsite ST205H	4436806	36896335

Please complete this form, even if you do not have any of the concerned product, and return by fax to the following Fax No. **XXXXXXXXXXXX**

1. We acknowledge receipt of the recall-notification from B. Braun Medical.

2. Please mark accordingly:

- We do not have any of the affected products in stock
- We will return the following products:

Part number	Batch	Quantity to return
4436806	36896335	

Establishment:	
Address:	
Contact Name:	
Contact Phone Number:	
Contact e-mail address:	
Date and signature <i>Establishment stamp</i>	

