

**IMPORTANT – FIELD SAFETY NOTICE – PRODUCT RECALL**  
**Celsite Access Ports**

Product Name	Part Number	Batch Number
CELSITE ST205P	4430894	M189336T

**Note:** This product recall only impacts the above mentioned CELSITE access ports batch.

Our records indicate that your health care facility is potentially 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 n° M189336T of Celsite ST205P access ports. This action is being taken as a result of a production error during primary packaging. The wrong reference of polyurethane catheter has been packed in this particular batch.

Potential hazards / patient risks:

- If the user needs to tunnel the catheter to the port pocket:  
The tunneling is impossible because the catheter (too small diameter) cannot be mounted on the tunneling rod.  
The access port cannot be implanted. Another kit from an other batch should be used.
- If the user does not need to tunnel the catheter to the port pocket:  
The catheter can be mounted on the exit cannula of the access port. So the access port can be implanted normally.  
No additional risk than those already existing for the access port implantation are generated.  
We have performed further tests to study the connection between the access port and the catheter supplied in this particular batch. All the performed tests gave results compliant with our requirements.

For the patient already implanted with an access port of this batch, no further action or checking is required. The access port has to be removed at the end of the treatment, as usual.



If you are still in possession of products of 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.

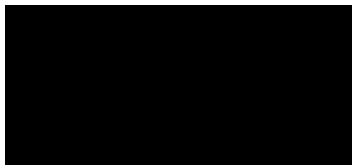
For any additional information, please contact **your local representative:**

**Local contact name and telephone and/or email**

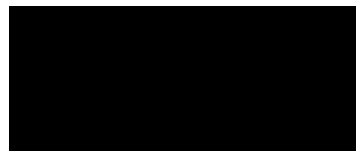
We apologize for any inconvenience this product recall may cause and we appreciate your cooperation in this matter.

Date : XX/10/2014

Best regards,



Director regulatory and scientific operations  
Pharmacien responsable  
Safety Officer  
General manager



Quality Et Regulatory Affairs Manager  
Chasseneuil CoE

## Acknowledgement Form

Of the Field Safety Notice dated of XX/10/2014

### IMPORTANT – PRODUCT RECALL Celsite ST205P Venous Access Ports

Product Name	Part Number	Batch Number
CELSITE ST205P	4430894	M189336T

Please complete this form, even if you do not have any of the concerned product and fax this form back 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:

	Quantity
Number of Celsite ST205P from batch nr M189336T still in your inventory:	

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