B|BRAUN
SHARING EXPERTISE

IMPORTANT – FIELD SAFETY NOTICE – PRODUCT RECALL

Celsite® PICC-Cel
Peripherally Inserted Central venous Catheters

Product Name	Part Number	Batch Number°
CELSITE PICC-CEL 4F SL 51CM, NIT, 45 CM	4434082	36930404

Note: This product recall only impacts the above mentioned ® 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® PICC-Cel above listed under request of one of our supplier.
This action is being taken because our supplier inform us that the tear away (also called peelable sheath) they supply, might contain unsafe levels of bacterial endotoxins (Pyrogens) that were introduced during a manufacturing step.

Potential hazards / patient risks:
Bacterial Endotoxins can activate the inflammatory process and produce fever, chills, and hypotension in a patient. It is worth noting that no case has been reported.

Patients who have already received a Celsite® PICC-Cel of this batch should be monitored within the first post-operative days. The quality of the catheter is not affected, it can be used until the end of the treatment, as usual.

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 : 15/05/2018

Best regards,

Didier Gerbaud
Director Regulatory and Scientific Operations
Pharmacien responsable
Safety Officer
General manager

Catherine Boismenu
Quality & Regulatory Affairs Manager
Chasseneuil CoE

Acknowledgement Form
Of the Field Safety Notice dated on 15/05/2018

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

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
4434082	36930404	

Establishment:	
Address:	
Contact Name:	
Contact Phone Number:	
Contact e-mail address:	
Date and signature *Establishment stamp*	