

IMPORTANT – FIELD SAFETY NOTICE – PRODUCT RECALL
Celsite® Implantofix

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 three (3) batches of Celsite® Implantofix access ports listed below. This action is being taken because the catheters do not allow the passage of the guidewire provided in the kit.

This failure has been detected after customer complaints. Our investigations allow us to determine that the internal diameter of one (1) catheter batch is not in compliance with our specifications. The internal diameter of the catheter tip is too small.

This non-compliance is due to an operator error who used tools designed for a smaller catheter for manufacturing and for self-inspection.

Article code	Product name	Lot number	Expiry date
4438604	CELSITE IMPLANTOFIX ST SET PUR 5F IV	36938641	08.10.2023
		36938038	26.09.2023
4438647	CELSITE IMPLANTOFIX SM SET PUR 5F IV	36937930	24.09.2023

Potential hazards / patient risks:

During the implantation procedure, because the internal diameter of the catheter's distal tip is too small, it will not be possible to pass the catheter over the guide wire. Then the implantation procedure of the access port will be interrupted or prolonged.

For patients having received one of the recalled Celsite Implantofix, if the implantation procedure has been possible, there is no consequence or potential risk.

Actions to be taken:

Our investigations have allowed us to identify that the Celsite® Implantofix ports batches listed above 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 : 18-01-2019

Best regards,

