B. Braun Medical
Société par actions simplifiée
26 rue Armengaud
92210 Saint-Cloud

July 21, 2025

URGENT – FIELD SAFETY NOTICE – PRODUCT RECALL

Celsite® Babyport

FSCA 2025-07

B. Braun Organisation

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 is voluntarily recalling the batches of Celsite® Babyport access ports below listed.

Article Code	UDI code	Article Description	Batch *(please adapt to customer)*
4433742	(0)4038653917587	CELSITE BABYPORT SET PUR 4,5F IV	37037609
			37037610
			37037611
			37037616
			37037759
			37037816
			37037817
			37037818
			37038581
			37038914
			37039625
			37039788
			37039789
			37040613
			37040947
			37041041
			37042035
			37042433
			37043552
			37043629
			37043842
			37044066
			37044740
			37044818
			37045170
			37046301
			37046521

Description of the medical device deficiency:

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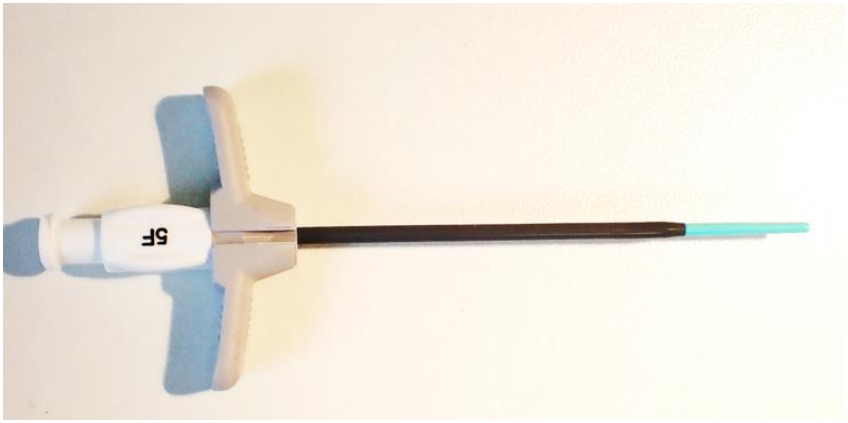
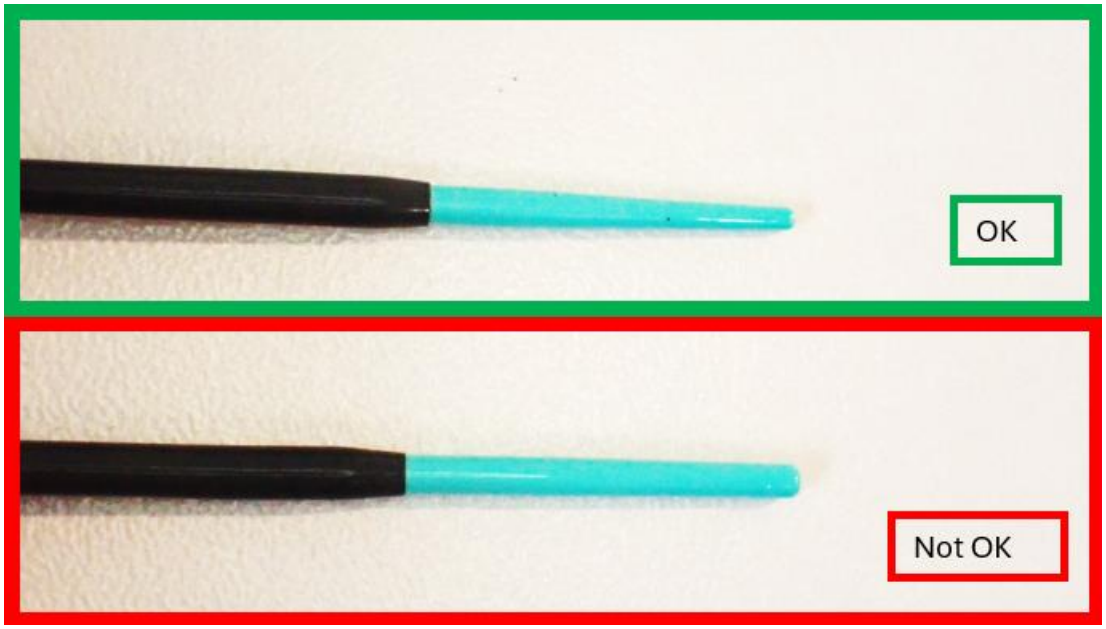
During the course of Post-Market surveillance activities, B.Braun Medical identified that the tear-away introducer supplied in the kits of the above listed batches of Celsite® Babyport access port may potentially present a defect at the level of the distal tip.



Picture of a tear-away introducer supplied in Celsite® Babyport kits

Investigations revealed that the distal end of the tear-away dilator is not tapered as expected. When conform, the tapered tip of the introducer gradually dilates the puncture to a vessel and opens up a passageway sufficient for the subsequent steps of the procedure.

With a non-tapered introducer, the end that opens the passage has a larger diameter, so much so that dilation of the puncture is less progressive.



Potential hazards / patient risks:

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This defect may occasionally result in minor injury such as damage to the vessel, wall tearing of the vessel.

For patients who have already been implanted with an access port from the above-mentioned batches of Celsite® Babyport access ports, there are no safety concerns, no specific monitoring is needed because the quality of the access port system is not affected: It can be used until the end of the treatment, as usual.

Due to this field safety notice, we kindly ask you to take the following measures:

1. Check whether you have the above-mentioned product in stock, and quarantine it.
2. Confirm the receipt of this Field Safety Notice on the enclosed confirmation form.
3. Additionally record on the enclosed confirmation form the received amount of potentially affected products with the above-mentioned batch number(s) as well as the amount used and the amount to be returned.
4. Even if you don't have any inventory, please return the completed and signed confirmation form in a timely manner to the fax number or e-mail address given on the form.
5. Return the quarantined product to the following address with a copy of the enclosed confirmation form.LOCAL ADDRESS
6. Please retain this Field Safety Notice until you have completed all the above measures.

Distribution of Information:
Please make sure that all users of the above-mentioned products in your organization and other concerned persons are informed about this Field Safety Corrective Action. If you have forwarded the products to a third party, please forward a copy of the Field Safety Notice to them or inform the contact person mentioned below.

Compensation and Assistance:

We sincerely apologize for any inconvenience this recall may cause. To compensate for the recalled product(s), a replacement or a credit note. Please contact our dedicated customer service team to arrange for compensation.

Contact Information: If you have any questions or concerns, please reach out to us via: LOCAL CONTACT

The National Competent Authority has been notified of this Field Safety Corrective Action.

Thank you for your prompt attention to this matter and your continued trust in our products. We value your cooperation and sincerely regret any disruption caused.

Best regards,

Charlotte BOULANGER
Headquarters France, St Cloud

Patrick RAUGEL
Competence Center Chasseneuil,

B. Braun Medical
Société par actions simplifiée
26 rue Armengaud
92210 Saint-Cloud

Regulatory Affairs and Vigilance Manager
Safety Officer

Deputy Director in charge of Quality and
delegated Regulatory Affairs

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Confirmation of Receipt of the Field Safety Notice
Celsite® Babyport - FSCA 2025-07

You received **Celsite® Babyport access ports** listed in the table below.

Please fill out this form including the table completely.

Please return the form immediately to the following fax number or e-mail address.

Please enter the fax number and/or e-mail address of the local contact person

1. **We acknowledge receipt of the recall-notification from B.Braun Medical.**
2. **The result of the inventory check due to this Urgent Field Safety Notice is as follows:**

Article Description	Article Code	Batch	Amount Received	Amount Used	Amount to be Returned
(please customize)	*(please customize)*	*(please customize)*			

☐ We do not have any of the affected products in stock.

☐ We will return ……(quantity) products to the following address: LOCAL CONTACT

Herewith, we confirm that we received and noticed the Field Safety Notice from 2025-07-xx concerning the above mentioned medical devices. The Field Safety Notice was distributed and communicated within our organization.

Name: _____

Address: _____

Phone number: _____

Email address: _____

Date and Signature: _____

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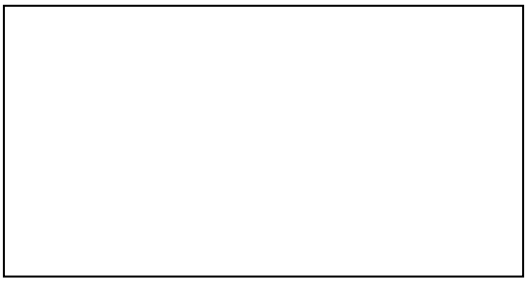
Stamp:



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53 99

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