

ESSITY/BSN-Letterhead

BSN ADDRESS

NAME OF RESPONSIBLE (The responsible for the recall in this country)

DATE

Customer's address

Urgent Field Safety Notice

Recall
concerning

JOBST COMPRI2 / JOBST COMPRI2 LITE

Concering users of Jobst Compri2

Identification of Affected Devices:

Jost Compri2

REF No.: 76271-01 shipper boxes
76271-02 folding boxes

LOT-Code(s): 127384

Description of the problem:

We would like to inform you about a possible problem with the above listed LOT 127384 of Jobst Compri2 respectively Jobst Compri2 lite two-layer compression bandage kit.

We were informed that the labelling of the above listed lot may be misleading. The shipper of the affected lot is correctly labelled **Jobst Compri2**, whereas the folding boxes inside the shipper do not contain **Jobst Compri2 Lite** as labelled on the folding box.

Jobst Compri2 Lite delivers a pressure of 20-30 mmHg which is indicated for patients with an Ankle Blood Pressure Index (ABPI) of 0.5-0.8.

Jobst Compri2 inside the folding box delivers a higher pressure of 40 mmHg which is indicated for patients with an ABPI higher than 0.8 and which is **contraindicated for patient with an ABPI lower than 0.8.**

The compression bandage inside the folding box is correctly labelled as Jobst Compri2 for ABPI > 0.8, but this might be overseen during routine use. Therefore, we would like to voluntarily recall the above lot of Jobst Compri2 Lite as a precaution and protective safety measure.

Potential hazards:

In patient with mixed leg ulcers and an ABPI lower than 0.8., an application of a too high pressure may result in a suppression of peripheral blood circulation, and in a worst-case in damage of superficial and/or deep tissue.

What measures should be taken from you?

Please check your stock of Jobst Compri2 and Jobst Compri2 Lite

Send back all **shipper boxes** of **REF** number **76271-01**, **LOT** number **127384**
and all folding boxes of **REF** number **76271-02**, **LOT** number **127384**

you hold on stock.

To simplify processing for you, please find attached a fax response form and prepared labels for the return.

Please indicate on the fax response form:

- _ the number of goods to be taken back,
- _ the date of when we may collect the goods, and
- _ the place where we can pick up the items.

Please also use the fax form to inform us in case you have already used up all the products from the above-mentioned lots in full.

After having received your fax response we will arrange for collection of the affected goods by **NAME OF COURIER TO BE FILLED IN**.

We apologize for any inconvenience that might be associated with this recall.

Please be assured that the quality of our products and their reliability in daily use are our highest priority.

Disclosure of the information described here

Please ensure that all users and individuals to be informed in your organization receive informational aware of this Urgent Field Safety Notice.

If you supply products to third parties, please forward a copy of this information or inform the contact person listed below.

Please keep this information at least as long, until the recall action has been completed.

The health authority of your country has been provided with a copy of this Urgent Field Safety Notice.

Contact Person

Our colleague, **NAME; PHONE NUMBER OF CONTACT PERSON TO BE FILLED IN** is at your disposal for any questions.

Yours sincerely,

Essity/BSN medical GmbH

Attachment: Fax response form

Field Safety Notice Customer Reply Form Recall Jobst Compri2

1. Field Safety Notice (FSN) information	
FSN Reference number*	QIM 500077717 and QIM 500077719
FSN Date*	26/01/2022
Product/ Device name*	Jobst Compri2
Product Code(s)	76271-01
Batch/Serial Number (s)	127384

2. Customer Details	
Account Number	To be filled in if applicable!
Healthcare Organisation Name*	To be filled in!
Organisation Address*	To be filled in!
Department/Unit	To be filled in if applicable!
Shipping address if different to above	To be filled in!
Contact Name*	To be filled in!
Title or Function	To be filled in!
Telephone number*	To be filled in!
Email*	To be filled in!

Table to be filled in by customer!

3. Customer action undertaken on behalf of Healthcare Organisation			
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A	
<input type="checkbox"/>	I performed all actions requested by the FSN.	Customer to complete or enter N/A	
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A	
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:
		Qty:	Date Returned (DD/MM/YY):
		N/A	Comments:
<input type="checkbox"/>	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:
		Qty	Lot/Serial Number:
		N/A	Comments:
<input type="checkbox"/>	No affected devices are available for return/ destruction	Customer to complete or enter N/A	
<input type="checkbox"/>	Other Action (Define):		
<input type="checkbox"/>	I do not have any affected devices.	Customer to complete or enter N/A	
<input type="checkbox"/>	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query	
Print Name*			

BSN medical GmbH
Schützenstraße 1
22761 Hamburg – Germany



Signature*	
Date*	

4. Return acknowledgement to sender	
Email	To be filled in!
Customer Helpline	To be filled in!
Postal Address	To be filled in!
Deadline for returning the customer reply form*	28 Feb. 2022

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.