BREAS

FSN Ref: REC-901762 (rev.1) FSCA Ref: CAPA-149 / 6.6.2-2022-7340

Date: 31 January 2022

Urgent Field Safety Notice
Ventilator Trolley (REF 007384)

For Attention of*:Distributors, Customers and Clinical Users of Ventilator Trolleys (REF 007384) for Vivo 55/65, Vivo 45/45 LS, Vivo 1-2-3 and NIPPY Ventilators

Contact details of local representative (name, e-mail, telephone, address etc.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages

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1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Ventilator Trolley (Accessory)
1.	2. Commercial name(s)
	Ventilator Trolley (Trolley Stand) (Accessory) (REF 007384)
1.	3. Unique Device Identifier(s) (UDI-DI)
	(01) 07321820 073849
1.	4. Primary clinical purpose of device(s)*
	The intended use of the trolley system is to allow patient mobility while receiving ventilator treatment. The trolley shall only be used in indoor, hospital environment. The trolley system consists of a trolley base and a mounting bracket.
1.	5. Device Model/Catalogue/part number(s)*
	007384
1.	6. Software version
	Not applicable
1.	7. Affected serial or lot number range
	Ventilator trolleys (007384) distributed between 11 June 2020 and 03 December 2021
1.	8. Associated devices
	The Ventilator Trolley is an accessory to Breas Vivo 55/65, Vivo 45/45 LS, Vivo 1/2/3 and NIPPY Ventilators.

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Ventilator Trolleys (REF 007384) delivered between 11 June 2020 and 03 December 2021 have been found in some cases to be missing a metal washer which could render the mounting bracket for the ventilator unstable.
2.	2. Hazard giving rise to the FSCA*
	On 19 November 2021, Breas was notified about an incident occurring in the US involving that a Vivo 50 ventilator fell off a trolley stand onto patient's foot, causing a bruise which did not require medical intervention and which did not result in permanent impairment or damage.
2.	3. Probability of problem arising
	Occasional (observed probability 1.36×10^{-4} or 0.0136%)
2.	4. Predicted risk to patient/users
	Minor – the issue can cause temporary injury not requiring medical intervention.
2.	5. Further information to help characterise the problem
	The issue is estimated to affect not more than five percent (5%) of the trolleys in scope.
2.	6. Background on Issue
	Breas investigated the problem together with the supplier and determined the root cause to be a manufacturing problem. The washer was in some cases, omitted during manufacture of the swivel assembly which is mounted on the trolley base and is part of the Ventilator Trolley.
2.	7. Other information relevant to FSCA
	• The washer is mounted on the inside of the swivel assembly and not visible on the exterior of the delivered Ventilator Trolley.

	• The Ventilator Trolley is prepared for use by healthcare professionals and the loose mounting bracket is easily recognizable during preparation.

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User***	
	☒ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☒ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None	
3.	2. By when should the action be completed?	Initial response by 2021-02-25. On site device inspection/modification within 30 days of receipt of Inspect and Repair Kit.
3.	3. Particular considerations for: (No particular considerations.) Is follow-up of patients or review of patients' previous results recommended? No The hazardous situation is transient in nature and is resolved by the user without need for further intervention.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☒ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None 1. Communication to distributors/user of Field Safety Notice/Field Safety Corrective Action. 2. Provision of an Inspect and Repair Kit (REF 008591) for on-site inspection and, if needed, modification of affected devices. (Option 1) 3. Supply of trolley poles including the affected part for replacement. (Option 2) 4. Quarantine and inspect units in stock. 5. Supplier Corrective Action to prevent recurrence.	
3	6. By when should the action be completed?	30 June 2022
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	No Not appended to this FSN	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Breas Medical AB**
	b. Address	**Företagsvägen 1, SE-435 33 Mölnlycke, Sweden**
	c. Website address	**www.breas.com**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * YES	
4.	9. List of attachments/appendices:	Cover letter, FSN Customer Reply Form
4.	10. Name/Signature	[redacted]

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.