

Cover letter to customers, homecare providers and distributors

31 January 2022

Subject: Field Safety Corrective Action for Breas Ventilator Trolley (REF 007384)

Reference: CAPA-149 / 6.6.2-2022-7340

Dear Valued Partner

Breas Medical has received market feedback that there may be a possibility that the ventilator mounting brackets for the Vivo 55/65, Vivo 45/45 LS, Vivo 1-2-3 and NIPPY models can become detached from the Breas Ventilator Trolley (see Figure 1 below) whilst in use.

Breas Medical urgently investigated this feedback and concluded that there is a possibility, that the swivel assembly may not have been manufactured according to Breas Medical's specification and it may not contain the metal washer as shown in Figure 2. The issue may affect Ventilator Trolleys delivered between 11 June 2020 and 3 December 2021.



Figure 1 Breas Ventilator Trolley (REF 007384)



Figure 2 Swivel assembly with metal washer

The Solution

Breas Medical's recommended solution (Option 1) is to provide Inspect and Repair Kits (REF 008591) to all those potentially affected by this notice. The Inspect and Repair Kits are used to inspect the Trolley to determine if remedial action is required, and to replace the defective part if needed.

To obtain Inspect and Repair Kits, we are asking customers to identify Trolleys delivered from Breas between 11 June 2020 and 3 December 2021.

For customers who do not wish to inspect the Trolley swivel assembly, Breas Medical can arrange replacement of the trolley pole including the swivel assembly (Option 2). Breas Medical advises that this option will likely involve more effort than Option 1.

Option 1

- We (the Customer) will identify Breas Ventilator Trolleys (REF 007384) delivered between 11 June 2020 and 3 December 2021.
- Breas will provide us with the corresponding number of Inspect and Repair Kits (REF 008591).
- We will inspect the swivel assembly and complete the enclosed form to indicate whether the trolley contained the necessary washer and no further action is needed, or if the washer was missing and the swivel assembly was replaced by the new one.
- We will scrap the replaced swivel assembly.

Option 2

- We (the Customer) will identify Breas Ventilator Trolleys (REF 007384) delivered between 11 June 2020 and 3 December 2021.
- We wish to be contacted by Breas to arrange replacement of the trolley pole, which includes a new pivot and swivel assembly.
- We will transfer this pole onto the existing Trolley base, and then transfer the basket, rail and trolley mount.
- We will scrap the replaced trolley pole.

Confirmation of receipt

We kindly ask you to acknowledge receipt of this Field Safety Notice together with your choice to remedy the issue using attached reply form "Trolley Field Safety Notice Distributor/Customer Reply Form with Option Selection".

Sincerely,

Ivan Liljegren
Senior Vice President, Global Quality Assurance and Regulatory Affairs