Compass Health Brands Recalls CPAP Mask Cushion Devices Due to Possible Air Leaks

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

- Recalled Product(s): Replacement Cushion Seals for Probasics Brand Zzz-Mask SG Full Face CPAP Mask
- Product Codes: PB781S, PB781M, PB781L, 781S, 781M and 781L
- Manufacturing Dates: May 1, 2015 to unknown
- Distribution Dates: May 4, 2015 to October 10, 2017
- Devices Recalled in the U.S.: 742 nationwide

Device Use:

The Probasics Brand Zzz-Mask SG Full Face CPAP Mask is designed for patients requiring **Continuous Positive Airway Pressure (https://medlineplus.gov/ency/article/001916.htm)** (CPAP) for the treatment of **obstructive sleep apnea (https://vsearch.nlm.nih.gov/vivisimo/cgi-bin/query-meta?v%3aproject=medlineplus&v%3asources=medlineplus-bundle&query=sleep%20apnea&)** in the home, hospital, or other clinical setting. CPAP machines use mild air pressure to keep airways open during sleep. The air is delivered through a mask that fits over the nose and mouth. The mask contains an elbow adapter which allows the user to connect the mask to the CPAP machine. The mask cushion is used for both comfort and to provide a seal between the face and the mask.

Reason for Recall

Compass Health is recalling the replacement cushion seals for the Probasics Brand Zzz-Mask SG Full Face CPAP Mask due a design change made to the cushion seal replacement part and accompanying elbow replacement part that causes the seal to be incompatible with the mask. While no complaints or injuries have been reported, the use of the new cushion with the previous design of the mask could result in an air leak that interrupts therapy. The use of the affected mask seal may cause serious adverse health consequences, including increased risk of bronchitis or pneumonia, apnea, high blood pressure, heart attack, or death.

Who is affected?

- Patients who use the Probasics Brand Zzz-Mask SG Full Face CPAP Mask.
- Health care providers who prescribe the Probasics Brand Zzz-Mask SG Full Face CPAP Mask.

What to Do:

On June 19, 2018, Compass Health sent an **Urgent Recall Field Correction Notice (http://www.compasshealthbrands.com/pdf/Recall-CPAP-Masks-June2018.pdf)** (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm) to affected customers. The notice asked customers to:

- Review the recall notice and ensure appropriate staff and customers are aware of the issue.
- Advise customers of the proper cushion and elbow combination.
  - Any consumer using an incompatible cushion/elbow combination should be instructed to discontinue use of the mask and contact their dealer for a replacement kit.
- Dispose of all affected product(s) in-stock in accordance with the facility's destruction protocol.
  - Affected product does not need to be returned to Compass Health.
- Contact Compass Health for replacement kits.
- Complete and return the Recall Field Response Form to Compass Health Brands Corporation within 15 days of receipt by fax at 440-572-4261 or email at **recall@compasshealthbrands.com (mailto:recall@compasshealthbrands.com)**.

Contact Information

Customers who have questions or need additional information or support related to this recall should contact Compass Health Brands Corporation Customer Support at (800) 526-8051 Monday - Friday 8:00 am Eastern Standard Time – 5:00 pm Eastern Standard Time.

Date Recall Initiated

May 22, 2018

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experience using these devices to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home)** either online, by regular mail or by FAX to 1-800-FDA-0178.

More in Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/default.htm)

2018 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm590900.htm)

2017 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm535289.htm)

2016 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm480134.htm)