

Date: June 19, 2018

Subject: **URGENT RECALL FIELD CORRECTION - ACTION REQUIRED**
Instructions for Use
REPLACEMENT CUSHION SEALS for Probasics Brand Zzz-Mask SG Full Face CPAP Mask

Affected Models: PB781S, PB781M, PB781L, 781S, 781M and 781L Manufactured After May 2015.

A voluntary Field Correction is being conducted for the instructions for use that pertains to the **REPLACEMENT CUSHION SEALS for Probasics Brand Zzz-Mask SG Full Face CPAP Mask - Affected Models: PB781S, PB781M, PB781L, 781S, 781M and 781L manufactured after May 2015.**

Reason for Field Correction: Compass Health Brands Corp. has recently identified the need to clarify compatibility information for the replacement cushion seals for the Model # PB7801 Zzz-Mask SG Series Full Face CPAP Mask.

- A design change made to the cushion seal replacement part (and accompanying elbow replacement part) in May 2015 (18 months prior to Compass Health acquisition of the Probasics product line) resulted in incompatibility of the new cushion seal with the previous design of the elbow.
- ***While no complaints or injuries have been reported to-date, use of the new cushion seal with the previous design of elbow could result in unacceptable CO₂ porting.***
- Since a model number change did not accompany this design change, customers and their consumers would likely not be aware of this incompatibility.

Compass Health Brands Corp. takes patient safety seriously, and the Company wants to ensure this potential issue is avoided.

Attached is a communication that you can share with your consumers that clearly identifies the acceptable combination of cushion and elbow.

While the Model No. PB7801/7801 Probasics Brand Zzz-Mask SG Full Face CPAP Masks were discontinued in 2017, some consumers may still wish to continue use of their existing frames and obtain replacements for their existing cushions. As such, Compass Health has introduced a new replacement part kit which includes both a cushion and compatible elbow that you may offer your consumers. These replacement kits will be available for 6 months, after which time they also will be discontinued. At that time, consumers would need to purchase a new mask (Compass Health Brands Model No. 7800 is the newest design replacing the discontinued 7801).

Replacement cushion/elbow kits for mask frame 7801 are as follows:

- 781S-WE (small cushion with elbow)
- 781M-WE (medium cushion with elbow)
- 781L-WE (large cushion with elbow)



Please take the following actions:

- Ensure all affected personnel are fully informed of this notice.
- Forward this notice to your Regulatory Compliance Manager, Purchasing Manager, Customer Service Manager and Field Technicians.
- Advise your customers regarding the proper combination of cushion and elbow. The attached consumer communication letter can be used to communicate this information. As noted on the attached consumer communication letter, ***any consumers who are currently using an incompatible cushion/elbow combination should be instructed to discontinue use of the cushion and elbow and should be instructed to contact their dealer to obtain replacement kits.***
- Dispose of any current stock you may have of the affected cushion model numbers (PB781S, PB781M, PB781L, 781S, 781M and 781L manufactured after May 2015) and contact Compass Health for replacement kits (NOTE: Full mask model numbers are **NOT** affected by this recall field correction).
- Please contact Compass Health Brands Corp. Customer Support at (800) 526-8051 Monday-Friday 8:00 am EST - 5:00 pm EST to obtain replacement kits, at no charge, that you can provide to your consumers.
- **Complete and return the attached Recall Field Correction Response Form to Compass Health Brands Corp. within fifteen (15) days of receipt** of this field correction notification confirming your acknowledgement. Send completed form to Compass Health Brands Corp. via fax number 440-572-4261 or via email at recall@compasshealthbrands.com.

This voluntary Field Correction notification is being conducted with the knowledge of the United States Food and Drug Administration (FDA) in accordance with U.S. regulations. Any complaints and/or adverse events experienced with the use of this product must be reported promptly to Compass Health Brands Corp. Customer Support at (800) 526-8051 Monday-Friday 8:00 am EST - 5:00 pm EST and/or to the FDA through its MedWatch program.

Compass Health Brands Corp. appreciates your immediate attention to this urgent matter.

FIELD CORRECTION NOTICE

REPLACEMENT CUSHION SEALS

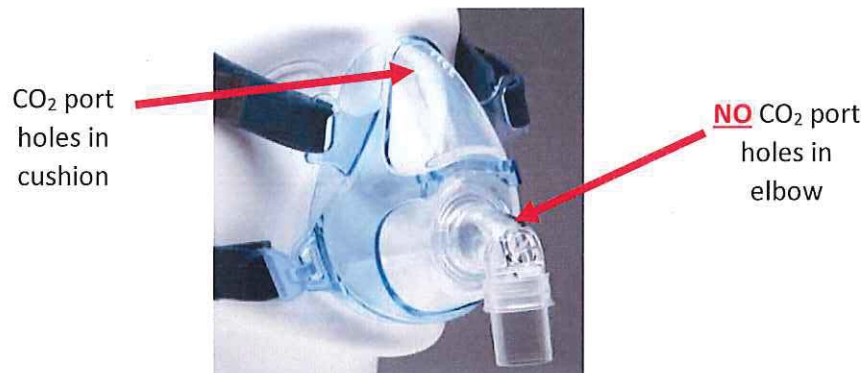
for Probasics Brand Zzz-Mask SG Full Face CPAP Mask

Affected Models: PB781S, PB781M, PB781L, 781S, 781M and 781L

Background Information: Compass Health Brands Corp. has recently identified the need to clarify compatibility information for the replacement cushion seals for the Model # PB7801 Zzz-Mask SG Series Full Face CPAP Mask. A design change made to the cushion seal replacement part (and accompanying elbow replacement part) in 2015 resulted in incompatibility of the new cushion seal with the previous design of the elbow. While no injuries have been reported to-date, use of the new cushion seal with the previous design of elbow could result in unacceptable CO₂ porting.

Remedy: Ensure that the CPAP cushion seal you are using is compatible with the CPAP elbow you are using. Ensure that you are using the correct combination of cushion seal and elbow:

PRE-2015 DESIGN – CO₂ port holes at top of cushion seal



POST-2015 DESIGN – NO CO₂ port holes at top of cushion seal



For more information or to obtain a replacement part, contact your dealer.

www.compasshealthbrands.com

ATTACHMENT A – FIELD CORRECTION REPLY FORM – RESPONSE REQUIRED

Instructions for Use - REPLACEMENT CUSHION SEALS for Probasics Brand Zzz-Mask SG Full Face CPAP Mask

**Affected Models: PB781S, PB781M, PB781L, 781S, 781M and 781L
Manufactured After May 2015**

June 19, 2018

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Please check ALL appropriate boxes:

- ☐ I have received the letter and have notified my Regulatory Compliance Team.
- ☐ I have disposed of any post-2015 design cushions in-stock and requested replacement kits.
- ☐ I have identified and notified all consumers that purchased above noted product.

Check which method of notification was used:
Mail____; E-mail____; Fax____; Phone____

CUSTOMER CONTACT PERSON INFORMATION (PLEASE PRINT CLEARLY):

Name: _____ Title: _____

Address: _____ City: _____

State: ____ Zip Code: _____ Country: _____ Telephone #: _____

Email Address: _____

Signature: _____ Date: _____