COMPASSHEALTH

Date: April 1, 2019

Subject: URGENT: RECALL - **ACTION REQUIRED**

**MediPress Segmental Garments (Lymphedema Sleeves) (accessory for MediPress Pneumatic Compression Lymphedema Pump)**

**Affected Models: #6102-S, #6103L-S, #6103M-S, #6103S-S, #6104M-S #6104S-S**

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A voluntary Recall is being conducted for the above noted sleeves - **Affected Models: #6102-S, #6103L-S, #6103M-S, #6103S-S, #6104M-S #6104S-S**

> **NOTE: The MediPress Pneumatic Compression Lymphedema Pump (Model 6101) IS NOT impacted and IS NOT being recalled.**

**Reason for Recall/Field Correction**: Compass Health Brands Corp. has recently identified that a design change to the above noted sleeves did not receive proper premarket clearance as required by Section 510(k) of the Food, Drug and Cosmetic Act.

- A design change was made to the sleeves in 2012 (while under ownership of Pyramid Industries, LLC - 5 years prior to Compass Health acquisition of the MediPress product line); *the design change was from single-chamber to segmented-chamber sleeves.*

- ***While no complaints, injuries or adverse events have been reported regarding these sleeves, substantial equivalence to currently cleared devices cannot be assured.*** Compass Health Brands Corp. places patient health and safety first and foremost, and wants to ensure the safety and effectiveness of all of our products.

***Attached is a communication that summarizes this information for you to share with your customers/consumers.***

**REQUIRED ACTION: Please take the following actions IMMEDIATELY:**

1. 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.

2. Advise your customers regarding this recall (see attached communication developed for this purpose).

3. Immediately check your stock for the model numbers above and quarantine all affected product.

4. ***Complete and return the attached Recall Response Form to Compass Health Brands Corp. within fifteen (15) days of receipt of this notification. RESPONSE FORM MUST BE RETURNED***

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***EVEN IF YOU HAVE NO STOCK OR HAVE NO RECORD OF PURCHASING THESE SLEEVES*** ***(FDA requires documentation of our notification to you).***

**Indicate on the Response Form the quantity of each model number you have in stock.**

- When we receive your completed Response Form, you will be sent return labels (if applicable) to allow you to return any recalled product you have on-hand.

- Once the returned product is received, replacement sleeves will be sent out to you. (NOTE: the replacement sleeves are single chamber, vs. the segmented chamber sleeves that are the subject of this recall. The single chamber sleeves are the design that received the original premarket clearance from FDA).

  If your customers/consumers have any of the recalled sleeves to return (following your communication to them), have them return the items to you for collection. Complete the Consumer Returns Form with quantities and return the form to Compass Health Brands. Once we receive your completed Consumer Returns Form, you will be sent return labels. Once the recalled sleeves are returned, replacements will be sent to you to provide to your customers.

***Return completed Response Form and Consumer Returns Form to Compass Health Brands Corp. via email at recall@compasshealthbrands.com or via fax: 440-268-2116.***

This voluntary Recall/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) 376-7263 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. If you have any questions, please contact 440-238-2609.

Sincerely,

Elizabeth Proctor

**Elizabeth Proctor**
**Regulatory Affairs Manager**
6753 Engle Rd., Middleburg Heights, OH 44130
**Phone:** 440-238-2609 **Fax:** 440-268-2116
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April 1, 2019

# RECALL RESPONSE FORM

## RESPONSE REQUIRED

**MediPress Segmental Garments (Lymphedema Sleeves)**
**(accessory for MediPress Pneumatic Compression Lymphedema Pump)**

**Affected Models: #6102-S, #6103L-S, #6103M-S, #6103S-S, #6104M-S #6104S-S**

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**Complete and return this Response Form to Compass Health Brands Corp. within fifteen (15) days of receipt of this notification, via email at recall@compasshealthbrands.com or via fax number 440-268-2116.**

**Please check ALL appropriate boxes:**

☐ I have received the letter and have notified my Regulatory Compliance Team.

☐ I have recalled sleeves in-stock as follows:

| MODEL NO.: | QUANTITY TO BE RETURNED*: |
|---|---|
| #6102-S | |
| #6103L-S | |
| #6103M-S | |
| #6103S-S | |
| #6104M-S | |
| #6104S-S | |

**Indicate "0" if you do not have any of a model no. to return.*

☐ I have identified and notified all customers/consumers that purchased above noted product.

Check method of notification used: Mail_____ E-mail_____ Fax_____ Phone_____

☐ Other:_____

**CUSTOMER CONTACT INFORMATION (PLEASE PRINT CLEARLY):**

Company Name:_____ Customer Acct. #:_____

Name: _____ Title: _____

Address: _____ City: _____

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

Email Address: _____

Signature: _____ Date: _____

# RECALL NOTICE

## MediPress Segmental Garments (Lymphedema Sleeves)

(accessory for MediPress Pneumatic Compression Lymphedema Pump)

**Affected Models: #6102-S, #6103L-S, #6103M-S, #6103S-S, #6104M-S #6104S-S**

**Background Information:** Compass Health Brands Corp. has recently identified that a design change to the above noted sleeves did not receive proper premarket clearance as required by Section 510(k) of the Food, Drug and Cosmetic Act.

- *A design change was made to the sleeves in 2012 (while under ownership of Pyramid Industries, LLC - 5 years prior to Compass Health acquisition of the MediPress product line); the design change was from single-chamber to segmented-chamber sleeves.*

- ***While no complaints or adverse events have been reported regarding these sleeves, substantial equivalence to currently cleared devices cannot be assured.*** Compass Health Brands Corp. places patient health and safety first and foremost and wants to ensure the safety and effectiveness of all of our products.

**Remedy: Discontinue use of the above noted sleeves. Model Numbers are located on the sleeves as noted below:**



**To obtain a replacement, contact the dealer that sent you this notice.**
**For more information about the recall, visit:** www.compasshealthbrands.com

In cooperation with the US Food & Drug Administration.

Published 4/1/2019

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April 1, 2019

# ***CONSUMER RETURNS FORM***

**MediPress Segmental Garments (Lymphedema Sleeves)**
**(accessory for MediPress Pneumatic Compression Lymphedema Pump)**

**Affected Models: #6102-S, #6103L-S, #6103M-S, #6103S-S, #6104M-S #6104S-S**

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**Complete and return this Consumer Returns Form *if you have product that your customers returned to you for replacement.***

Return to Compass Health Brands via email at recall@compasshealthbrands.com or via fax number 440-268-2116. Once we receive this completed form, you will be sent return labels to return the devices. Upon receipt of the returned devices, your replacements will be sent to you.

| MODEL NO.: | QUANTITY TO BE RETURNED*: |
|---|---|
| #6102-S | |
| #6103L-S | |
| #6103M-S | |
| #6103S-S | |
| #6104M-S | |
| #6104S-S | |

**Indicate "0" if you do not have any of a model no. to return.*

**CUSTOMER CONTACT INFORMATION (PLEASE PRINT CLEARLY):**

Company Name:_____ Customer Acct. #:_____

Name: _____ Title: _____

Address: _____ City: _____

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

Email Address: _____

Signature: _____ Date: _____