COMPASSHEALTH

URGENT MEDICAL DEVICE RECALL

Timely Response Required

Voyager Rollator

Model Number: RLEU10xx (RLEU10BL, RLEU10PK, RLEU10WT)

Lot/Serial Nos: RM2005000001 - RM21004005000

January 2022

Dear Valued Customer:

A voluntary Field Correction is being initiated by Compass Health Brands for the Voyager Rollator (cobalt blue, rose gold and ice palace).

Reason for Field Correction: Compass Health Brands has recently identified a manufacturer quality issue with product manufactured between May 2020 and April 2021. The wheel spoke could crack causing the wheel to separate from the axle. To date, Compass Health Brands has received 47 customer complaints over the last 18 months for wheels breaking, including four (4) complaints which involved user injury.

RISK TO HEALTH:
If the defective device is used and the wheel spoke fails, the patient may suffer minor injuries, including bruising and lacerations requiring stitches.

ACTIONS TO BE TAKEN BY THE CUSTOMER:
Users should stop using the subject products and contact Compass Health Brands. The manufacturer has changed the wheel spoke design to increase the spoke thickness and strength. The manufacturer will supply replacement wheels with the improvement. The improved wheels will be made available to users to replace the existing wheels on the product.

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REQUIRED ACTION:

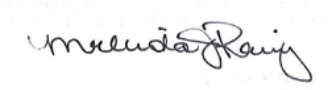
1. Ensure all affected personnel are fully informed of this notice.
2. Forward this notice to your Regulatory Compliance Manager, Purchasing Manager, Customer Service Manager and Field Technicians.
3. The Voyager Rollator casters and axles require replacement.
4. Dealers/distributors or end users should contact Compass Health Brands at (800) 947-1728 and to order replacement kits, P/N ***Voyager-Kit***. This kit contains all the parts necessary to complete replacement of the Voyager Rollator casters and axles.
5. The replacement can be performed by the dealer/distributor or the end user. A Voyager Caster Installment Guide will be sent as part of the Field Action Kit P/N Voyager-Kit and are posted on the Compass Health Brands website. No special certification is required.
6. Complete and return the attached Field Correction Response Form to Compass Health Brands within fifteen (15) days of receipt of this field correction notification confirming your acknowledgement. Send completed form to Compass Health Brands via email at recall@compasshealthbrands.com. Complete and return this form even if you do not have affected product on hand.
7. **Field correction repairs must be completed on affected units before further use or sale of the product.**

If you have transferred possession of this product to another individual/department/location, please notify your consignee of this recall communication.

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 Customer Support at (800) 947-1728 Monday-Friday 8:00 am EST - 5:00 pm EST and/or to the FDA through its MedWatch program.

Compass Health Brands appreciates your immediate attention to this urgent matter and recognizes the inconvenience this may cause.

Thank you,



Melinda J. Rainey – Sr. Compliance Specialist

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ATTACHMENT A – FIELD CORRECTION REPLY FORM – RESPONSE REQUIRED

Voyager Rollator
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Complete and return the attached Field Correction Response Form to Compass Health Brands within fifteen (15) days of receipt of this field correction notification confirming your acknowledgement. Send completed form to Compass Health Brands via email at recall@compasshealthbrands.com.

Please check ALL appropriate boxes (print clearly).

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

☐ Wholesaler/Distributor only: I have identified and notified all customers that purchased product.

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

☐ Have you distributed the product further to the retail level? Yes____ No ____

If yes, have you notified your retail customers? Yes____ No ____

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

How many repair kits do you require for your customers/stock? _____

How many repair kits do you require for your retail customers? _____

CUSTOMER CONTACT PERSON INFORMATION (PLEASE PRINT CLEARLY):

Name: _____ Title: _____

Address: _____ City: _____

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

Email Address: _____

Signature: _____ Date: _____