

URGENT MEDICAL DEVICE RECALL

Voyager Rollator

Model Number: RLEU10xx (RLEU10BL, RLEU10PK, RLEU10WT)

Lot/Serial Nos: RM2005000001 - RM21004005000



January 2022

Dear Valued Customer:

Our records show that you may have purchased Voyager Rollator. 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.

REQUIRED ACTION:

1. The Voyager Rollator casters and axles require replacement.
2. Contact Compass Health Brands at (800) 947-1728 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.
3. 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.
4. Complete and return the attached Consumer 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.
5. **Field correction repairs must be completed on affected units before further use of the unit.**

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.

Sincerely,
Compass Health Brands

ATTACHMENT A – CONSUMER FIELD CORRECTION REPLY FORM – RESPONSE REQUIRED

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Complete and return this Consumer 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.

Number of Voyager Rollators you own _____

Model Number of the Voyager Rollator(s) you own _____

Serial Number of the Voyager Rollator(s) you own _____

CUSTOMER CONTACT PERSON INFORMATION (PLEASE PRINT CLEARLY):

Name: _____

Address: _____ City: _____

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

Email Address: _____

Signature: _____ Date: _____