



NOVA ORTHO- MED, INC.

*Rec'd  
9/18/24*

8/30/2024

## **Urgent: Medical Device Correction**

### **NOVA MONARCH ROLLATOR MODEL 4329**

**Models:** 4329BL, 4329PL and 4329RD.

**Serial Number Range:**

- 4329BL: HT4329BLME0001 - HT4329BLPG0300
- 4329PL: HT4329PLME0001 - HT4329PLMM0400
- 4329RD: HT4329RDME0001 - HT4329RDMM0420

Dear Valued NOVA Customer,

The purpose of this letter is to advise you that NOVA ORTHO-MED, INC. is voluntarily correcting the NOVA MONARCH ROLLATOR for the models and serial numbers listed above. You are receiving this notification because our records indicate you may have purchased at least one of these models.

**Product Issue:**

When the end user is readjusting from the slouched seated position to an upright seated position, there is the potential for the movement to cause the backrest to lift out of the backrest holder and disengage from the unit.

We are aware of 4 product failures and 1 product injury due to the end user falling out of the unit.

**Risk to health:**

Device failure may result in potential injuries sustained from a fall, which could delay potential treatments, therapies or procedures.

**How to recognizing that the device may fail:**

The failure may occur when repositioning from the slouched and seated to a more upright seated position. This movement may cause the backrest to lift up from the backrest holder. Before leaning back on the backrest, ensure both sides of the backrest are fully connected to the backrest holder. If one side of the backrest is raised higher than the other side, that may be an indicator that the backrest is not properly connected to the holder.

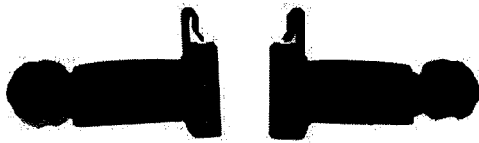
**Solution:**

To address this issue on current and future units, we have created an improved backrest holder that has a lip to prevent the backrest from disengaging from the unit.

Install the improved backrest components on the unit.

To assist in the correction, please follow the installation guide or the use the link below or the installation video

<https://youtu.be/ggPlo-nbVco>



New backrest holders will be sent to attach to your unit.  
(Replacement part #HCT-432915)



Both sides of the backrest holder

### **Actions to be taken by the Customer/User:**

Please immediately take the following steps to correct the affected units.

1. Print the NOVA MONARCH Model 4329 Product Recall Notice and post it in your store in a visible location to customers.
2. Check your inventory for 4329 model walkers (4329BL, 4329PL and 4329RD), isolate and hold the products until you contact NOVA ORTHO-MED INC for the next steps.
3. Contact all customers who purchased a 4329 model to notify them of the potential issue. Schedule a time that they can come in for repair or if the customer prefers NOVA can send the replacement components directly to their residence.
4. If you do not track serial numbers with customer purchase or do not have the customer information, please ensure that the NOVA MONARCH Model 4329 Product Recall Notice document is posted in a customer visible location.
5. Call NOVA customer service and request the replacement component to be sent to the required location. (Part# - HCT-432915)
6. Record the serial #'s of the product that have been corrected and email them to NOVA Customer Service (info@novajoy.com) so that we can have for our records. If you prefer to call, then dial 1-800-557-6682.

Contact Information: Monday through Friday, 8:30 AM to 5:00 PM, Pacific time Time.

- Toll free number: 1-800-557-6682
- Email: info@novajoy.com

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Please accept our deepest apology for this problem and the inconvenience it will cause you and your staff. It is very important that ALL proactive measures are taken to ensure our products are consistently safe and effective for our customers. We take full responsibility for the quality and safety of products you purchase from NOVA and have taken significant and effective measures to prevent future problems.

Thank you for your continued support and please do not hesitate to contact us or your NOVA contact if you have any questions or concerns.

Sincerely,

Ron Gaudiano  
Executive Vice President  
1-800-557-6682 x 106  
rong@novajoy.com

Sue Chen  
CEO  
1-800-557-6682 x 101  
suec@novajoy.com

# How to replace your

## MONARCH ROLLATOR

Item # 4329BL/4329PL/4329RD

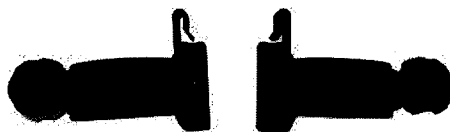
MONARCH Replacement Video  
\*PLEASE\* See URL link below or scan QR  
code to access the replacement video



<https://youtu.be/ggPlo-nbVco>

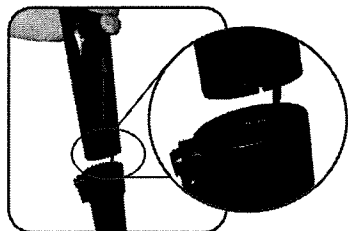
Replacement part:

- 1pr Backrest Holder



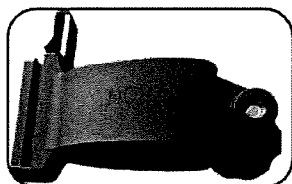
1. Remove the backrest from the unit.

2. Remove the knob from one of the replacement parts. On the unit, use the orange button lift the handle from the frame to expose the brake cover.

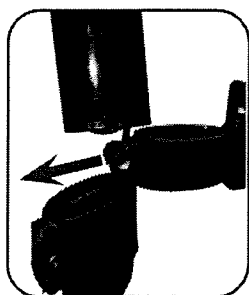


### \*PLEASE NOTE\*

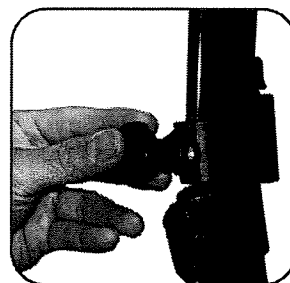
For the next step ensure the side with the "NOVA" logo and metal threading is facing the inside of the unit so when the knob is reattached the knob is facing the outside.



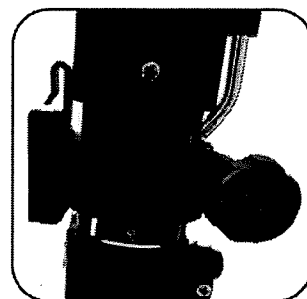
3. Tuck the handle under your arm then use both hands to pull the sides of the replacement part to create an opening for the cable cover to slide through.



4. Slide the backrest holder up the handle to the desired height and then turn the knob to secure into place.



5. Ensure the knob is facing the outside of the unit.



6. Repeat for the other side and set the backrest holders to the same desired height. Lastly reattach the backrest to the new backrest holders.





1470 Beachey Place  
Carson, CA 90746  
Tel: 1-800-557-6682

## NOVA ORTHO- MED, INC.

**Models:** 4329BL, 4329PL and 4329RD.

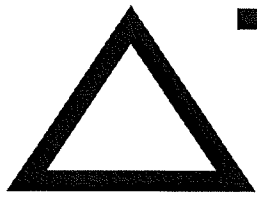
**Serial Number Range:**

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- 4329PL: HT4329PLME0001 - HT4329PLMM0400
- 4329RD: HT4329RDME0001 - HT4329RDMM0420

<input type="checkbox"/>	I have read and understand the recall instructions provided in the letter.	
<input type="checkbox"/>	I have checked my stock and have quarantined inventory consisting of <units or cases>.	
Indicate disposition of recalled product:		
<input type="checkbox"/>	Returned (specify quantity, date and method)/held for return:	
	Returned:	
<input type="checkbox"/>	Corrected (specify quantity and date):	
	Corrected:	
<input type="checkbox"/>	Quarantined pending correction (specify quantity):	
	Quarantined:	
<input type="checkbox"/>	I have identified and notified my customers that were shipped or may have been shipped this product by (specify date and method of notification); <or> Attached is a list of customers who received/may have received this product. Please notify my customers	
Any adverse events associated with recalled product?		<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, please explain:		
Please check the appropriate box(es) to describe your business		



[illegible]



# Product Safety Recall



## NOVA MONARCH ROLLATOR MODEL #4329

Colors: Blue, Purple and Red

**Purchased from 8/11/2021 to Current**

**Defect:** When the end user is readjusting from the slouched seated position to an upright seated position, there is the potential for the movement to cause the backrest to lift out of the backrest holder and disengage from the unit.

**Hazard:** Potential risk for the backrest to lift up and disengage from the unit which may lead to a fall hazard.

**What to do:** Immediately contact NOVA Medical Products and provide us with the serial number of your walker. We will assist in the next step to repair your rollator.

### Contact Details:

NOVA MEDICAL PRODUCTS  
1470 BEACHEY PLACE  
CARSON CA 90746  
PHONE: 1-800-557-6682  
EMAIL: [info@novajoy.com](mailto:info@novajoy.com)

**EFFECTIVE DATE:**

8/27/2024