

ENTRAPMENT PREVENTION GUIDELINES

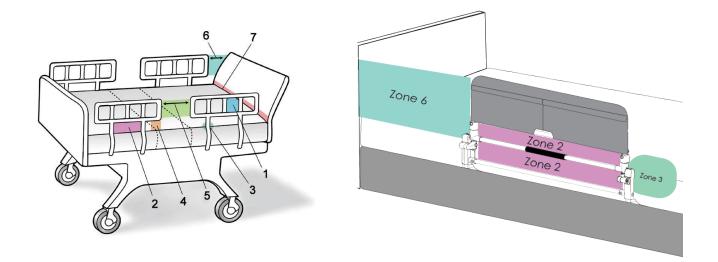
There is a risk of entrapment associated with bed rail products. NOVA is committed to informing users of potential entrapment conditions when using bed rails as well as methods to prevent entrapment.

• What is ENTRAPMENT?

* Entrapment is defined as an event in which a patient is caught, trapped or entangled in the spaces in or about the bed rail, mattress or hospital bed frame. Entrapment can result in serious injury or death

• THE SEVEN ZONES OF BED ENTRAPMENT

⁶ Entrapment is a situation where an individual can become caught by their head, neck, chest or other body parts in the tight spaces around the bed rail or bedside mobility aid.



• ZONE 1 - WITHIN THE RAIL

* Any open space between the perimeters of the rail can present a risk of head entrapment. Some NOVA products have included a nylon fabric guard material cover around part, or all, of the bed rail. The nylon fabric guard helps reduce the risk of entrapment. The product should never be used when the cover is not securely attached.

• ZONE 2 - UNDER THE RAIL, BETWEEN THE RAIL SUPPORTS OR NEXT TO A SINGLE RAIL SUPPORT

* The gap under the rail between the mattress, may allow for dangerous head entrapment. NOVA recommends zone 2 be well below the top of the mattress to reduce risk of entrapment.

• ZONE 3 - BETWEEN THE RAIL AND THE MATTRESS

* This area is the space between the inside surface of the bed rail and the mattress, and if too big it can cause a risk of head entrapment. NOVA bed rails include a safety strap that holds the bed rail against the side of the mattress. The safety strap must always be used. Do not remove the safety strap from the bed rails or user will be at risk of entrapment.

• ZONE 4 - UNDER THE RAIL AT THE ENDS OF THE RAIL

* A gap between the mattress and the lowermost portion of the rail poses a risk of neck entrapment. Also, install the bed rail such that the angle at the end of the bed rail relative to the top of a mattress is greater than 60 degrees. NOVA recommends that zone 4 be well below the top of the mattress to reduce risk of entrapment.

• ZONE 5 - BETWEEN SPLIT BED RAILS

* When partial length head and split rails are used on the same side of the bed, the space between the rails may present a risk of head, neck, or chest entrapment. The FDA has not established a distance between rails; however, NOVA recommends that users do not use bed rails in this orientation.

• ZONE 6 - BETWEEN THE END OF THE RAIL AND THE SIDE EDGE OF THE HEAD OR FOOT BOARD

* Between the end of the bed rail and the side edge of the headboard or footboard of less than 12.5" between the end of the bed rail and the side edge of the headboard or footboard can present the risk of entrapment of the head, neck, or chest.

• ZONE 7 - BETWEEN THE HEAD OR FOOT BOARD AND THE END OF THE MATTRESS

* When there is too large of a space between the inside surface of the headboard or footboard and the end of the mattress, the risk of head entrapment increases.

• BED RAILS & ENTRAPMENT: WHAT CONSIDERATIONS NEED TO BE MADE BEFORE INSTALLING OR USING BED RAILS?

- * Installation assessment Improper installation of bed rails has resulted in serious injury and even death. NOVA includes some safety device on certain bed rails to help prevent entrapment. Typical safety devices are nylon fabric guard and/or safety straps. NOVA's bed rails must never be used if the safety devices are not present or not installed properly. Failure to use the safety device will increase the risk of injury or death.
- * User assessment It is important for those who are installing the bed rail, and those who will be using the bed rail, to assess if those using the bed rails are susceptible to entrapment. Individuals who have problems with memory, sleeping, incontinence, pain, uncontrolled body movement, who get out of bed and walk unsafely without assistance, frail, weak, confused, restless, under the influence of drugs or any substance that could affect their judgment, are susceptible to entrapment. Even those individuals who can use bed rails responsibly are at risk, so it is important for those who are installing the bed rail and those using the bed rail to be aware of these risks and make the decision to accept liability for these risks.



NOVA Bed Rail Safety Guidelines

- 1. This product is intended to assist disabled persons to provide minimal to moderate weight support while standing from bed. This product is not intended to be used as a device to restrain individuals from getting into and out of bed.
 - a. INSTALLATION:

Do not use or install this product unless you read and understand these warnings and assembly instructions to ensure the product is properly installed and used. If installer/user(s) are installing this product in a nursing home, assisted living center, or a similar facility, follow these instructions and the facilities Bed Rail/Handle installation policies. If this product does not comply with the facilities installation polices, do not install this product. This product must be installed per "Entrapment Prevention Guidelines" sheet included with this product. If you have any questions regarding the installation, use, associated risks, or anything at all regarding this product by contacting a NOVA representative at (800) 557-6682 or emailing the request to info@novajoy. com.

- b. Improper installation of this product significantly increases the risk of entrapment (see section on ENTRAPMENT below). Do NOT install product without a bed frame under any circumstances. Do not install this product if you are unable to follow the instruction exactly.
- c. This product should only be used with innerspring or memory foam style mattresses. IMPORTANT: Read instructions below to make sure your mattress thickness is appropriate to use this product. This product should not be used on any bed which consists of a material that may increase the potential for gapping between the top of the mattress and the bottom of the Bed Handle. Examples of beds that will cause gapping problems include, but are not limited to waterbeds, light weight foam, air or other lightweight mattresses.
- d. Prior to use, ensure that there is no gap between the side of the product and the side of the existing bed mattress. A gap in this area means the product was installed improperly. The included components (such as clamps, safety straps, or other means) are designed to secure the product to the existing bed frame to avoid a gap in this area.
- e. This product is equipped with components to secure the product to a bed (such as nylon guard, safety straps, or other means). These components are intended to reduce the risk of entrapment (see section on ENTRAPMENT below). NEVER remove these components (such as nylon guard, safety straps, etc.) or use product without these components installed as per Assembly Instructions. Removal, modification or alteration of these components significantly increases the risk of entrapment.
- f. In the rare possibility of an adverse event with a NOVA product, contact a customer service representative at (800) 557-6682 immediately. Also report to the competent authority of your member state.
 - i. A serious event is defined as death or serious deterioration in health that results in a lifethreatening illness or injury,
 - ii. Stop using immediately if damaged or broken, or if parts are missing.
 - iii. Stop using immediately if product shifts out of its original position until it is readjusted into the correct position.
 - iv. In addition to contacting the manufacturer directly, consumers should report problems to the CPSC at this website: SaferProducts.gov or call 1-800-638-2772
 - v.For further information, see: cpsc.gov/en/Safety-Education/ Neighborhood-Safety-Network/ Posters/Adult-Bed-Rails/

2. ENTRAPMENT:

- a. There is a risk of entrapment associated with bed rails and other similar bedside mobility aids. Entrapment occurs when an individual becomes wedged between a bed rail and any other object. Entrapment has resulted in serious injury and death. Read the enclosed Entrapment Prevention Guidelines before installation or use of this product. Additional copies of the Entrapment Prevention Guidelines may be obtained by contacting a NOVA representative at (800) 557-6682 or emailing the request to info@novajoy.com
- 3. PHYSICAL AND MENTAL CONDITIONS
 - a. Individuals who have problems with physical limitations, paralysis, symptoms of dementia, Alzheimer's or memory loss, sleeping, incontinence, pain, uncontrolled body movement, getting out of bed and walk unsafely without assistance, frailty, weakness, confusion, restlessness, terminal restlessness, or are under the influence of medications, drugs, or any substance that could impair their balance or judgment, or any other unforeseeable reasons that could affect the users physical and mental ability to safely use this product, are at a higher risk of entrapment. Since these conditions are subjective and NOVA has no control who chooses to use this product, it is the installer/user(s) responsibility to consult a physician before using this product.
 - b. This product is not intended to carry the full weight of an individual. This product is only intended to provide balance and support while sitting and standing.
- 4. EXTERNAL FACTORS:
 - a. Children should not be allowed to hang on or play with this product.
 - b. Changing bed linens (bed covers, blankets, sheets, etc.) may require re-tightening of the securing strap to eliminate a gap between the Bed Handle and side of the mattress.
 - c. If product is removed and reinstalled, the securing strap and nylon guard needs to be reinstalled correctly as directed in these instructions.
- 5. WARNING SECTION:

ENTRAPMENT, STRANGULATION, SUFFOCATION AND FALL HAZARD

Gaps in and around this product can entrap and kill. People with Alzheimer's disease or dementia, or those who are sedated, confused, or frail, and are at increased risk of entrapment and strangulation. People attempting to climb over this product are at increased risk of injury or death from falls. Always make sure this product is properly secured to bed. If product can move away from bed or mattress, it can lead to entrapment and death.

a.

SUFFOCATION/STRANGULATION/ENTRAPMENT HAZARD

If product is installed incorrectly or moves from its initial position gaps can occur which can entrap and kill. People with Alzheimer's disease, dementia or other neurological conditions, or those who are sedated, confused, or frail, are at increased risk of entrapment, suffocation and strangulation.

•NEVER use unless product is tight against mattress, without gaps, and at least 12 1/2 in from headboard and foot board.

•NEVER use with children

•NEVER use on toddler, bunk, water, or inflatable beds, or on beds with mattress toppers or soft compressible pads.

b.

ENTRAPMENT HAZARD

NEVER use product without properly securing it to bed. Incorrect installation can allow product to move away from mattress, bed frame and/or head or foot boards, which can lead to entrapment and death.

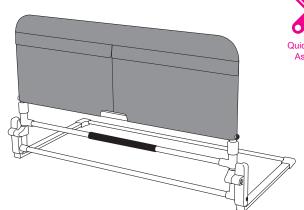
- 6. SPECIFICATIONS:
 - a. Maximum User Weight: 300 lb
 - b. Mattress Thickness Range: 8 inches to 12 inches
 - i. Ensure that the bottom crossbar is at or below the surface of the mattress. If not the bed rail needs to be needs to be adjusted to the lowest setting to achieve that
 - c.Cleaning: Clean product with warm water and a mild detergent. Dry thoroughly before using.
 - d. Recycling: Product should be recycled in accordance with national guidelines.
- 7. ENTRAPMENT WARNINGS:
 - a. Also refer to the Entrapment Prevention Guidelines sheet provided with these instructions
 - i. Product Position: Keep the product at least 12.5 inches from the head and foot end plane of the bed to help prevent entrapment issues as shown in the images below.
 - ii. Safety Strap: It is important that the Bed rail is secured to the Side of the mattress. The Safety Strap is attached and utilized during operation.



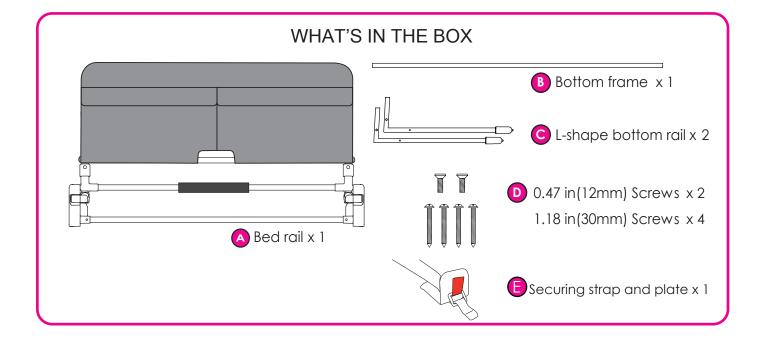
Mattress must fit Bed Frame and Assist Rail Snugly to help prevent patient entrapment. The bed rail must be securely attached to the bed frame per the instructions in the user guide. Patient entrapment with Assist Rail may cause injury or death. Please follow the manufacturer's instructions and monitor patients frequently. Please read and understand the Owners/Operator Manual prior to using this bed.

HOW TO ASSEMBLE & INSTALL YOUR

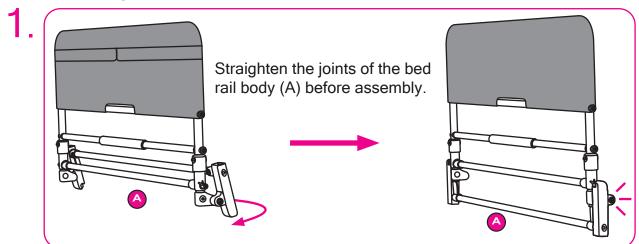




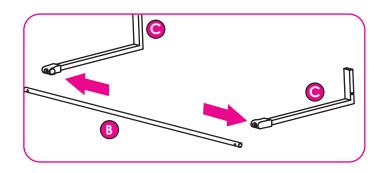




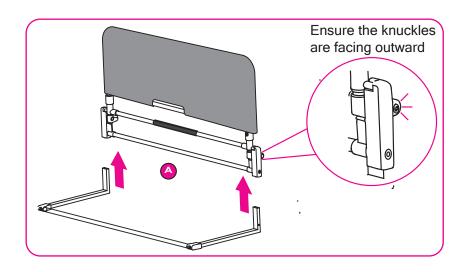
Assembly:



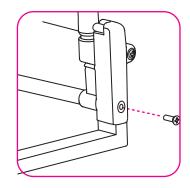
2. Connect the bottom frame (B) to the two 2x L-shaped bottom rails (C).



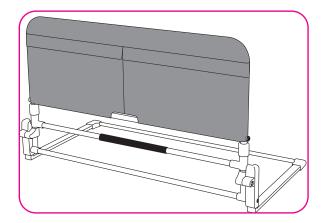
3. Take the base built in step 2 and connect it to the main body (A).



4. Use the 2x 12mm screws to secure each side of the L-shaped bottom rails to the main body.



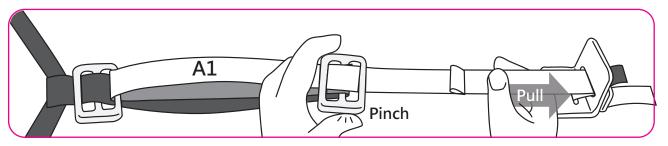
5. The bed rail has now been assembled. See the next page for installation.



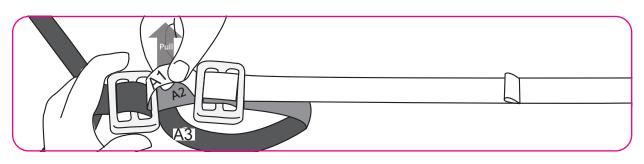
Strap Adjustment

Lengthening the strap

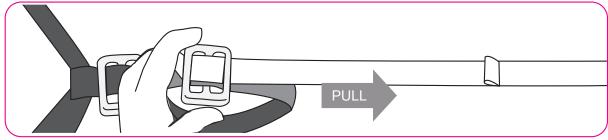
With one hand pinch the buckle in the middle, while using the other hand to pull the strap in the direction of the arrow. The buckle in the middle should be next to the buckle nearest to the bed rail.



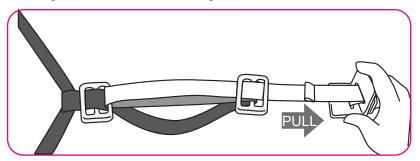
2. Pull upward on the top strap (A1).



3. Hold the buckle and pull the strap as done in step 1 until the desired length is reached..

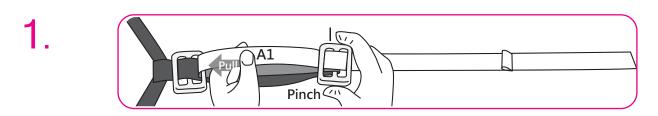


4. After all adjustments have been made, pull on the metal bracket to ensure the overall length does not change and the desired length has been reached.

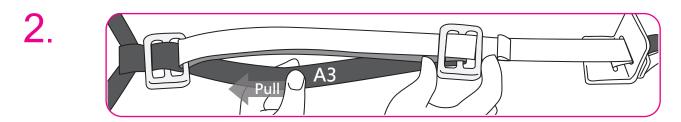


Shortening the strap

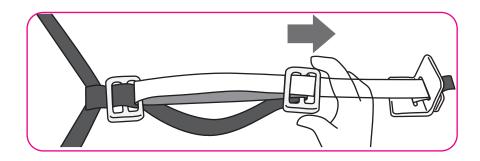
Pinch the end of the buckle and pull the strap towards the body of the bed rail..



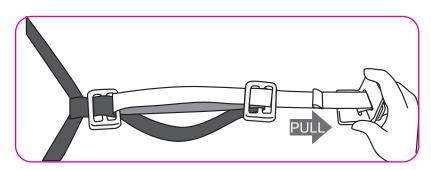
Pinch the buckle and pull the bottom strap (A3) towards the bed rail.



Pull the buckle toward the L-shaped bracket to shorten. This process may need to be done several times in order get to the desired length.



After all adjustments have been made, pull on the metal bracket to ensure the overall length does not change and the desired length has been reached.

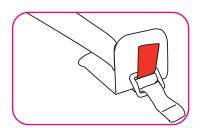


4.

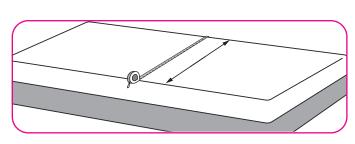
3.

Installation:

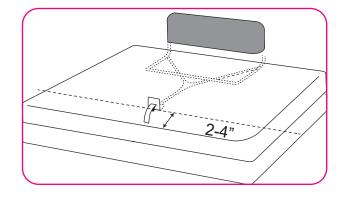
- Ensure the strap is securely
- threaded through the buckle.



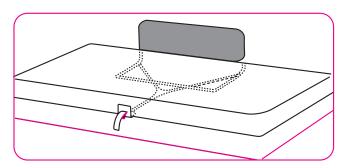
2. Measure the width of the mattress. Suitable for mattress widths of 36-80".

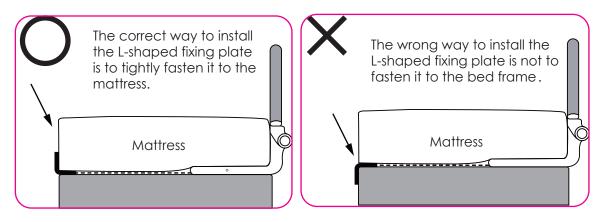


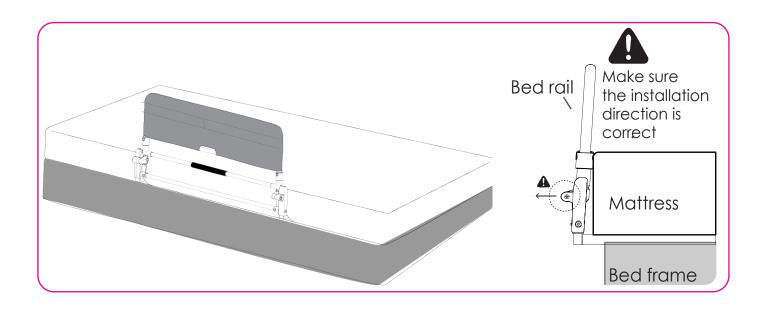
3. Place the bed rail on the edge of the bed as shown in the diagram, adjust the length of the strap and bed rail and ensure the L-shaped bracket is approximately 2-4" away from the edge of the mattress at the other end.



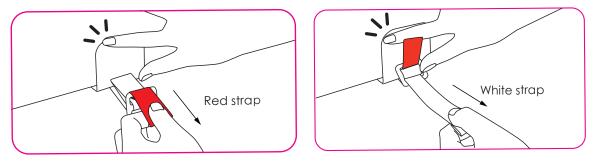
4. Position your bed rail between your mattress and bed frame Use the securing strap attached to the L-shaped tubes and feed it through until it is on the other end of the mattress.



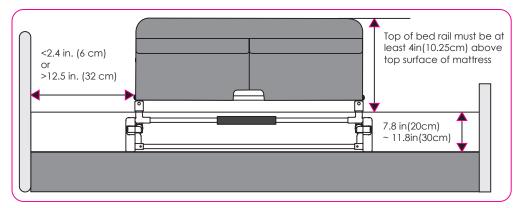




5. While the metal bracket is against the mattress first pull the red strap to ensure that it tightly fastens to the mattress. Then while holding the L-shaped bracket pull the white strap to remove all slack from the securing strap.

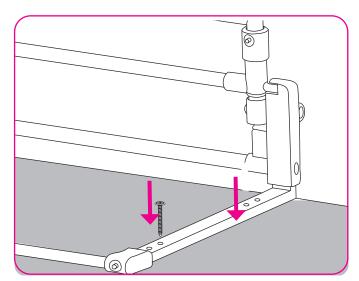


Product Positioning: Keep the product at least 12.5" from the headboard and footboard and the top of the bed rail must be at least 4" above the surface of the mattress to prevent any potential entrapment issues



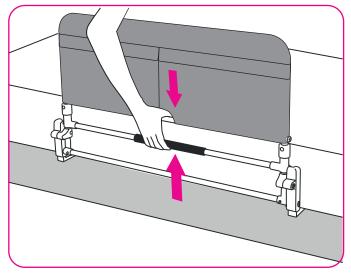
Bed Rail Reinforcement:

- 1 It is highly recommended to use the 4x
- 30mm screws to secure the L-shaped bottom rail onto the bed frame for more security.

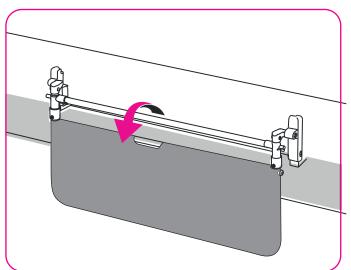


Operation:

- To unlock the folding mechanism,
- squeeze the tube with the cutout and the tube with the foam padding together.



2. Once unlocked the bed rail can be folded down to facilitate getting in and out of bed.



\Lambda WARNING

Read all instructions carefully before use. Failure to do so may result in serious injury. NOVA Medical Products shall have no liability for any damage or injury resulting from improper assembly, installation, and/or use of this product.

- ALWAYS ensure push buttons are fully engaged and protruding from each corresponding hole before using.
- ALWAYS ensure handle bar is level and secure before using.
- Assistance and supervision is required for users who are too weak or uncoordinated. ONLY use as a • stability aid.
- DO NOT exceed the weight capacity of 300 lb.

CARE AND MAINTENANCE

Use a non-abrasive, mild cleaning agent and soft cloth to wipe down surface of the Folding Bed Rail. Dry completely before using. DO NOT use harsh solvents included lacquer thinner, turpentine, and acetone.

WARRANTY INFORMATION

NOVA stands firm on our commitment to providing the highest quality products, as well as exceptional service. This product was built to precise standards and thoroughly inspected prior to shipment. This warranty represents our confidence in the materials and workmanship of our product.

NOVA extends this warranty only to the original purchaser of this product. The warranty does not extend to any subsequent purchaser or owner. The warranty is void upon any sale or transfer of ownership or use by other person. NOVA warrants its products are free from defects in material and workmanship under NORMAL use for the period commencing upon the date of purchase and continuing for the following specified period of time after that date:

Metal Frame Non-Metal/Metal parts

1800 557 6682

novajoy.com

Limited Lifetime Warranty One Year Limited Warranty (rubber tips, plastic or metal hardware)

This warranty does not cover problems due to user negligence, misuse of the product, failure to adhere to product instructions, or normal wear and tear. Items that have been subject to negligent abuse, modified without prior written authorization are not covered within this warranty.

For warranty service, please contact the dealer from whom you purchased your NOVA product. In the event that you do not receive satisfactory service, please call us directly at the number on the bottom front of this sheet. Be prepared to indicate, the nature of the defect, the product serial number, and the name and location of where you purchased the product. You will also be required to provide a receipt of your purchase. Do not return any products to our office without prior consent.

Repair or replacement is the only remedy under this limited warranty. This warranty does not include any labor or shipping charges incurred in replacement part installation or repair of product.

THIS WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER EXPRESS WARRANTIES, IMPLIED WARRANTIES, IF ANY, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. NOVA SHALL NOT BE LIABLE FOR ANY SEQUENTIAL OR INCIDENTAL DAMAGES WHATSOEVER.

IMPORTANT WARNING FOLLOW ALL DIRECTIONS CAREFULLY BEFORE USE. FAILURE TO DO SO MAY RESULT IN SERIOUS INJURY. CONTACT US! **CARE • QUALITY • INNOVATION** Connect with us! We're here to help novajoy.com f novamedicalprod info@novajoy.com novamedicalprod

novawalkerstalk

y

Γ



THE NOVA PROMISE

NOVA Medical Products