



Direct Supply® Panacea® Pivoting Assist Device for Panacea 1000, 1750 and 2000 Beds

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Bed System Entrapment Information

Although essential in the practice of Long Term Care, bedside rails have been the subject of regulatory review in recent years and have thusly seen evolution in their design and use.

This focus includes not only the challenge of achieving an appropriate balance between resident security and unnecessary restraint, but also the additional safety considerations of entrapment.

The U.S. Food and Drug Administration (FDA), working with our company and other industry representatives, has addressed the potential danger of entrapment with new safety guidelines for medical beds. These guidelines recommend dimensional limits for critical gaps and spaces between bed system components.

Entrapment zones involve the relationship of components often directly assembled by the healthcare facility rather than the manufacturer. Therefore, compliance is the responsibility of the facility.

Important Warnings

⚠ WARNING: Risk Of Serious Injury Or Death. This product is intended only for use with Panacea® 1000, 1750, and 2000 beds. Do not use this device with any other model or brand of bed. Use of this product on any bed it was not designed for could result in an unproven or unsafe configuration, potentially resulting in serious injury or death. For questions regarding compatibility, contact your Direct Supply account manager.

⚠ WARNING: Risk of Serious Injury or Death. Use a properly sized mattress in order to minimize the gap between the side of the mattress and the assist device. This gap must be small enough to prevent a resident from getting his/her head or neck caught in this location. Make sure that raising or lowering the bed or articulating the sleep surface does not create hazardous gaps. Failure to do so could result in serious injury or death.

⚠ WARNING: Risk Of Serious Injury Or Death. Properly locate the mounting brackets for the assist device. The gap between the head/foot panel and the assist device must be large enough to prevent a resident from getting his/her head or neck caught in this location (see the installation instructions for more information). If multiple assist devices are needed, position them such that the gap between them is large enough for the trunk and hips to easily pass through. Make sure that raising or lowering the bed or articulating the sleep surface does not create hazardous gaps. Failure to do so could result in serious injury or death.

⚠ WARNING: Risk Of Serious Injury Or Death. Do not use this assist device if any openings within the assist device body will allow a resident to get his or her head or neck lodged within these openings. Failure to do so could result in serious injury or death.

⚠ WARNING: Risk Of Serious Injury Or Death. Do not use this assist device until you have verified that it is locked in place. Injury to resident or caregiver may result if this procedure is not followed.

⚠ WARNING: An optimal bed system assessment should be conducted on each resident by a qualified clinician or medical provider to ensure maximum safety of the resident. The assessment should be conducted within the context of, and in compliance with, the state and federal guidelines related to the use of restraints, including the Clinical Guidance for the Assessment and Implementation of Side Rails published by the Hospital Bed Safety Workgroup of the U.S. Food and Drug Administration.

⚠ WARNING: In the event that worn or broken part(s) are identified, remove the device from service until repairs are made. Do NOT use substitute parts. Use only Panacea replacement parts. Non-Panacea replacement parts could cause entrapment, personal injury, and damage to bed rails.

NOTE: The assist device is intended for use as an aid in entering or exiting the bed sleep area, as well as a stable handhold during self-positioning within the bed sleep area. The devices may deform or break when subjected to excessive side pressure. DO NOT exert side pressure on the device. DO NOT use them as push handles for moving the bed. These activities could result in personal injury and damage to the device.

This assist device is only one part of your healthcare bed system. Proper combinations of bed, mattress, head/foot panels and assist devices are needed to minimize the risk of entrapment. For more information, contact your Direct Supply account manager.

⚠ WARNING: Do not permit residents to climb over the device.

⚠ WARNING: Some states may prohibit or consider assist devices to be patient restraints. Always assess whether restraints are necessary on a case-by-case basis and document the need for any patient restraint. Contact your state surveyor for further guidance regarding assist devices and restraints.

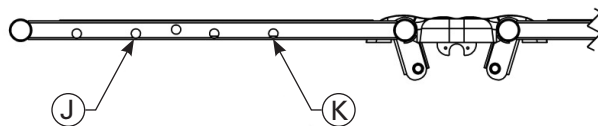
Pivoting Assist Device Installation Instructions

Suggested Tools: 1/2" Wrench, 3/8" Ratchet Wrench, 1/2" Deep Socket

Parts Required		
Item	Description	Qty
1	Assist Device	1
2	5/16"-18 Bolt	2
3	Lock Nuts 5/16"-18	2
4	Bushings	2
5	Small Washer	2
6	Large Washer	2

1. Determine where you want the assist device to be mounted (Figure 1).
2. Remove plugs from chosen mounting position holes (e.g. A & B, J & K, or C & D)
3. Orient the Assist Device (Item 1) with the bed as shown in Figure 2 on page 4.
4. When mounting to an 80" head section, line up holes A & E and holes B & F. For a 76" head section, line up holes E & J and holes F & K. The mounting bracket is attached to the foot section on either 76" or 80" beds using holes C & G and holes H & D (Figure 1). See page 4 for additional installation steps.
5. Apply small washer (Item 5) to 5/16" Bolt (Item 2). Insert bushings (Item 4) into sleep surface as identified in Step 3 above. Insert bolt through holes. Apply the large washer (Item 6) and secure with lock nut (Item 3) as shown in Figure 2 on page 4.

76" BED



80" BED

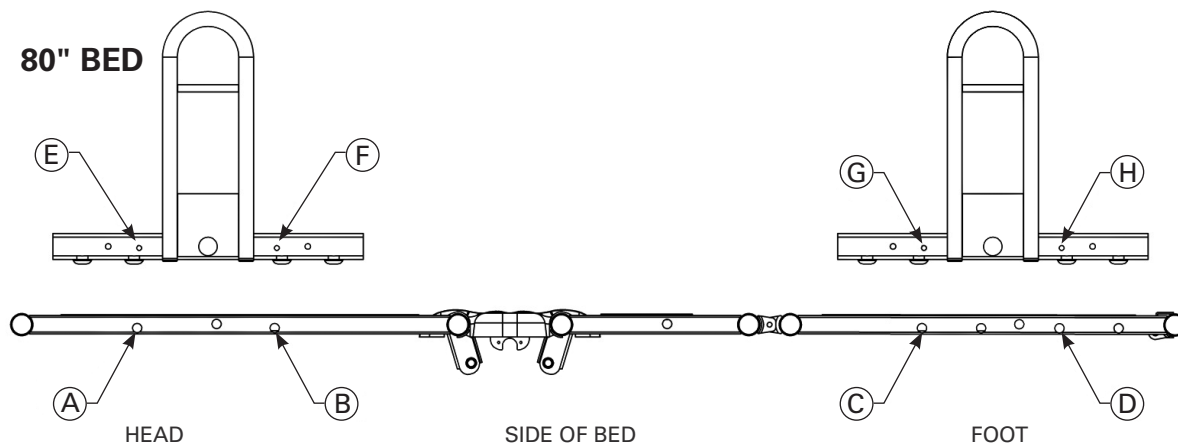


Figure 1

Pivoting Assist Device Installation Instructions (cont.)

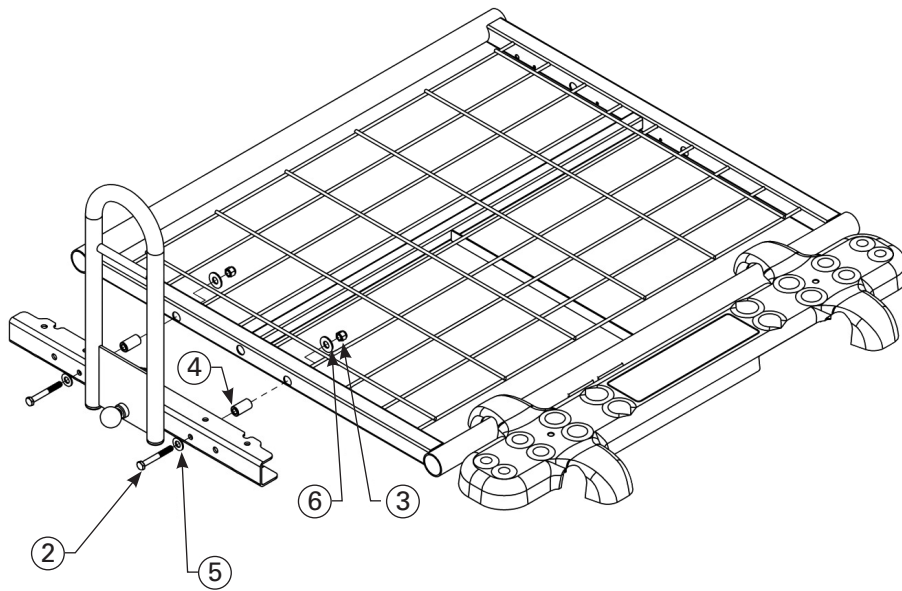


Figure 2

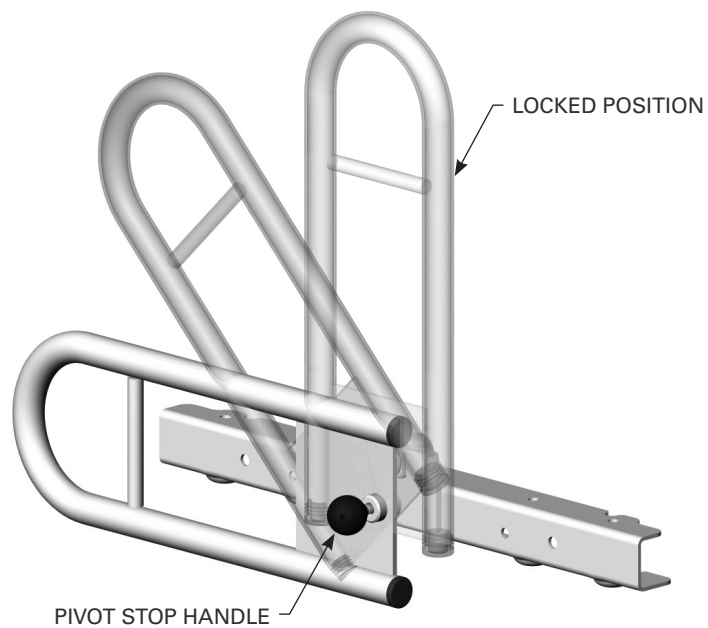


Figure 3

Operation Instructions

1. From the "Locked" position, hold onto the assist device and pull the Pivot Stop Handle to release the lock. Rotate assist device in the desired direction, counterclockwise (Figure 3 on page 4) or clockwise (Figure 4), until it rests on the rotational stop. Assist device should be parallel with the sleep deck when "Unlocked".
2. To lock assist device, hold onto the assist device and rotate it into the "Locked" position. Make sure the Pivot Stop Handle is depressed (Figure 4); there should be an audible "click" when the assist device lock is engaged.

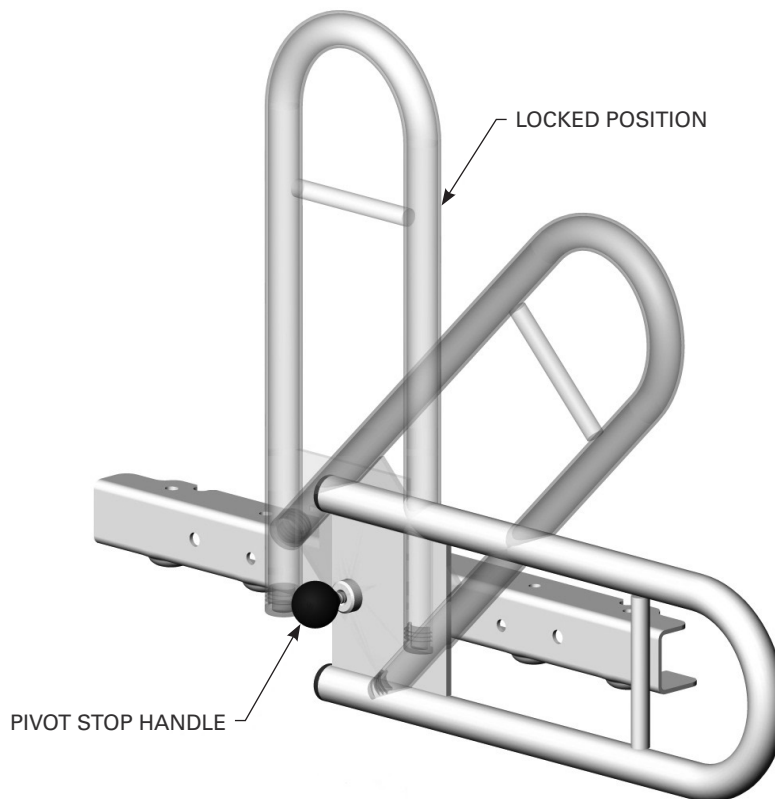


Figure 4

Limited Warranty

We offer to you, as the original purchaser, a warranty for the Direct Supply Panacea Pivoting Assist Device. Our warranty applies for the limited warranty period stated below. If any device or device part listed below is defective in material or workmanship during the applicable limited warranty period, we will repair or replace it at our cost. Please note that the decision to repair or replace a device or device part will be at our discretion. Our warranty applies only if the device is properly maintained by the original purchaser for normal, indoor use and does not cover normal wear and tear, modification of the device or damage caused by abuse, improper use, failure to maintain, use which exceeds the published device limitations or the combination of any device with another product. In addition, our warranty does not cover fading, colorfastness, stains, spills or exposure to chemicals, odors, heat or light. In certain cases, we may provide you repair or adjustment instructions and/or replacement parts, and ask you to perform a repair or adjustment or replace a defective part.

Our warranty gives you specific legal rights, and you may also have other rights, which vary, from state to state. Please note that our limited warranty period begins when we ship the device to you. The limited warranty period and our obligations under the warranty end once you transfer the device to someone else, or at the end of the applicable limited warranty period identified below, whichever is earlier.

	Warranty Period (Parts Only)	Anticipated Usable Device Life
Direct Supply Panacea Pivoting Assist Device	1 year	1 year

Anticipated Usable Device Life is based on normal use with proper maintenance, cleaning and storage. You should still inspect, monitor and care for the device as described in this guide, as the device may need to be replaced sooner than anticipated in particular situations.

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Customer Service

Our promise to you is that you will have a convenient and easy ordering experience, receive a quality Direct Supply Panacea Pivoting Assist Device and enjoy outrageous customer service. If you have any questions about the Pivoting Assist Device you have purchased or would like to request warranty service, please contact: **Direct Supply Equipment & Furnishings** at 1-800-634-7328, 6767 North Industrial Road, Milwaukee, WI 53223, or at DearDirect@DirectSupply.net.