



Direct Supply®

ZERO OPENING ASSIST DEVICE

Owner's Manual

Please keep and refer to this Owner's Manual.

Thank you for purchasing a Direct Supply® Zero Opening Assist Device from Direct Supply Equipment & Furnishings®. Please read this entire guide carefully and keep it for future reference. This guide provides instructions, warnings, warranty information and other important information about your zero opening assist. Share this information with your housekeeping, nursing and maintenance staff to help ensure the zero opening assist device is cared for properly.

Table of Contents, Description & Intended Use, Capacity

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Description & Intended Use

This assist device is designed to fit multiple brands and models of beds. This device is only compatible with beds that are designed to accept assist devices which are mounted via holes in the bed's head deck. See the installation section of this manual for information about device setup and ensuring compatibility and safety. This device is not a bedrail and is not intended to function as a bedrail.

Capacity

The assist device has been designed and tested to meet or exceed the application of forces specified by the International Safety Standard IEC60601-2-52, "Particular requirements for the safety of electrically operated hospital beds" figure 113. Do not exceed the weight or force limitations associated with your bed and/or assist devices manufactured for use with your bed.

Warnings

Important Warnings

⚠ WARNING: Risk of serious injury or death. This product is intended only for use with beds that are capable of supporting assist devices via mounting holes in the bed's head deck. This assist device is designed for use only on beds with assist device mounting holes which align with the slots provided on the assist's mounting plate. Do not modify the assist device or your bed if the holes do not align. 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: This assist device is designed to fit multiple models of beds and can be configured to pivot to various positions. It may be possible to install this device in a manner which could result in entrapment concerns, resident injury and/or damage to your bed.

⚠ WARNING: This assist device is designed to pivot to four positions, enabling the device to be mounted to either side of a bed. Failure to use the pivot-lock system will allow the device to pivot toward the floor, potentially creating a crush hazard and/or a risk of damage to your bed.

⚠ WARNING: This manual covers the Direct Supply Zero Opening Assist Device. For warnings and instructions related to the bed itself, please see your bed's Owner's Manual. Be sure to read and follow all instructions and warnings in both manuals.

Bed System Entrapment Information

In April 1999, the U.S. Food and Drug Administration (FDA) in partnership with representatives from the hospital and Post-Acute bed industry, national healthcare organizations, resident and patient advocacy groups, and other federal agencies formed the Hospital Bed Safety Workgroup (HBSW). The workgroup's goal is to improve the safety of bed frames for residents and patients in all healthcare settings who are most vulnerable to the risk of entrapment. The efforts of the FDA and the HBSW culminated in the FDA's release of recommended guidelines intended to reduce the risk of entrapment, including dimensional limits for critical gaps and spaces between bed system components and clinical guidance for assessment and implementation of bed assist rails in various healthcare settings. Entrapment zones involve the relationship of bed components often directly assembled by the healthcare facility rather than the manufacturer. Therefore, compliance is the responsibility of the facility.

⚠ WARNING: Only use the included hardware to attach this assist device to a bed. Do not substitute hardware.

⚠ 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 or her head or neck caught in this location. Make sure 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 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 and bed system entrapment guidance, 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 worn or broken parts are identified, remove the device from service until repairs are made. Do not use substitute parts. Use only approved replacement parts. Non-approved replacement parts could cause entrapment, personal injury and damage to assist devices.

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 excessive side pressure on the assist devices. Do not use them as push handles for moving the bed. These activities could result in personal injury and damage to the assist devices and/or your bed.

This assist device is only one part of your healthcare bed system. Proper combinations of bed, mattress, head/foot panels and assist rails 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 assist devices or consider assist devices to be resident restraints in all or some instances. Always assess whether this assist device may meet the definition of a restraint on a case-by-case basis and document the need for any resident restraint. Contact your state surveyor for further guidance regarding assist devices and restraints.

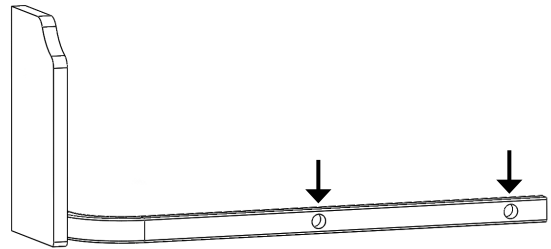
Installation

Tools Required:

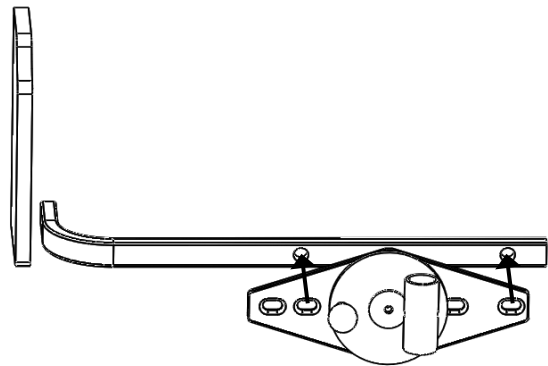
- 19 mm combination wrench or socket wrench
- 8 mm Allen wrench (hex wrench)
- 3 mm Allen wrench (hex wrench)

1. Verify your bed has $\frac{1}{2}$ " or $\frac{5}{8}$ " diameter assist device mounting holes available.

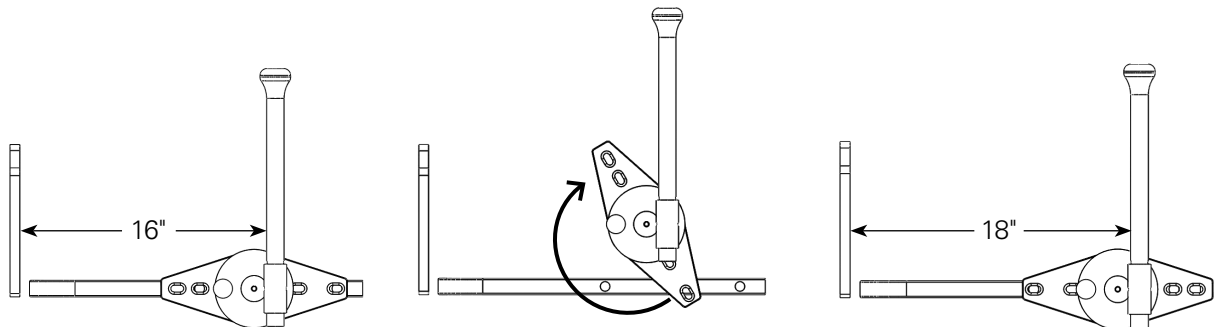
⚠ WARNING: Do not use the Direct Supply Zero Opening Assist Device if your bed is not designed to receive assist devices via the required sized holes.



2. Align the assist device mounting plate with the mounting holes in your bed deck. Ensure there are two slots in the assist device mounting plate which align with your bed's mounting holes.

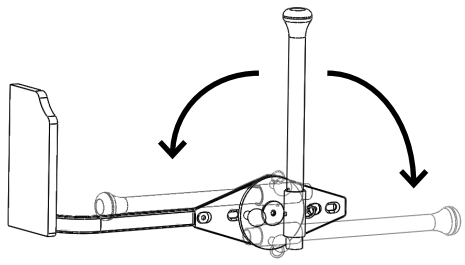


Note about hole placement: The mounting slots on your assist device are not evenly spaced, and your assist device can be mounted with either set of slots facing either direction (right or left). If setting up devices on both sides of a bed, align slots so assists on opposite sides of the bed are oriented as mirror images of each other. Additionally, check the orientation of the assist when installing the assist for the first time; the position of the assist can be adjusted 1" to 2" by rotating the mounting plate 180 degrees before installation.



⚠ WARNING: Do not use the Direct Supply Zero Opening Assist Device if the slots do not align with your bed's assist device mounting holes.

3. Determine which direction(s) you want the assist device to pivot (up, right, left).



4. Set the pivot lock by inserting one or two set screws into the pivot lock holes in the back of the assist device mounting plate. See chart below for placement instructions:

To pivot to three positions:	To pivot to two positions:	To use as non-pivoting assist:
Insert one set screw into hole A (right hole with handle pointing up) using a 3 mm Allen (hex) wrench. Fully insert but do not tighten.	Insert one set screw into hole A and one set screw into either hole D or hole B (will prevent pivoting in the opposite direction of screw placement). Fully insert but do not tighten.	Insert one set screw into hole B and one set screw into hole D using a 3 mm Allen (hex) wrench. Fully insert but do not tighten.
*NOTE – hole placement on BACK of assist device	*NOTE – hole placement on BACK of assist device	*NOTE – hole placement on BACK of assist device

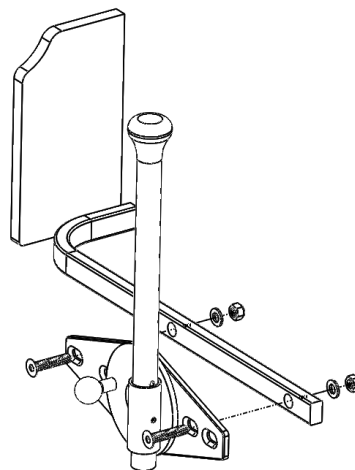
⚠ WARNING: Do not allow the assist device to pivot in all four directions. Allowing the device to pivot toward the floor may potentially create a crush hazard and/or damage to your bed.

Installation *(cont.)*

5. Mount the assist device mounting plate to your bed using the provided bolts, nuts and washers.

- Correct order of hardware: Bolt → Assist Device → Bed Deck → Flat Washer → Nut
- Using a 19 mm combination wrench or socket wrench and an 8 mm Allen wrench, securely tighten both sets of hardware

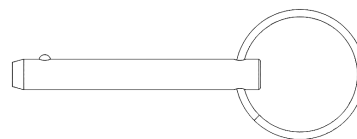
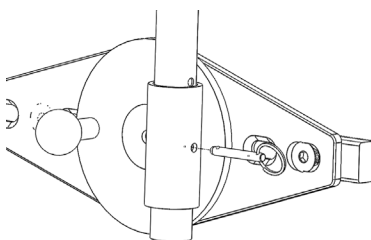
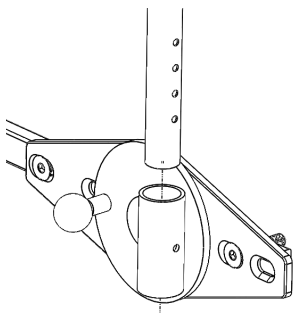
⚠ WARNING: Only use the included hardware to attach this assist device to a bed. Do not substitute hardware. Safe installation requires use of all provided attachment hardware.



6. Insert the assist handle into the support tube on the assist device mounting plate.

Position the assist at the desired height setting and then secure the assist with the included retention hardware.

For quick-release adjustment of handle height and quick removal of the assist handle, use the included retention pin.



To prevent rapid height adjustment or removal of the assist, use the included nut and bolt to secure the assist handle to the support tube.

7. Before putting the assist device into use, review the installation and overall bed system for functionality and safety:
 - a. Assist device should feel solid and stable. Ensure 50 lbs. of force can be exerted on the assist in any direction without damage or permanent deflection.
 - b. Verify the device can be pivoted to the desired directions and that the pivot-lock system is preventing pivoting in other directions.

NOTE – In some configurations, this assist may contact the bed’s headboard when pivoted toward the head of the bed. If this occurs on your installation, you may be able to prevent the contact by lowering the height of the assist handle. Alternatively, adjust the pivot-lock system to prevent pivoting toward the head of the bed (see step #4 for guidance on how to set up your pivot-lock system)

- c. Review the overall bed system for compliance to FDA entrapment guidelines, state and local regulations, and your company’s policies. Do not use the bed system until all entrapment concerns have been addressed and resolved.

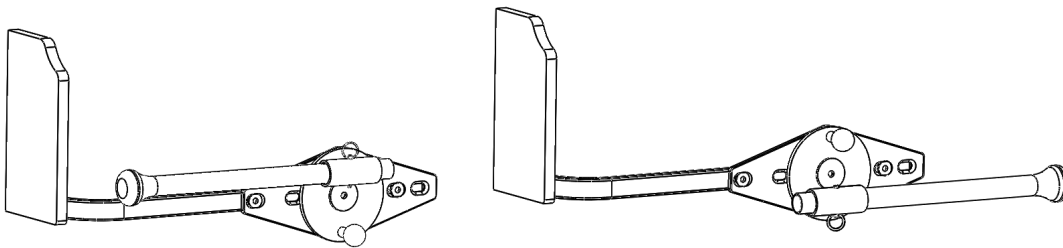
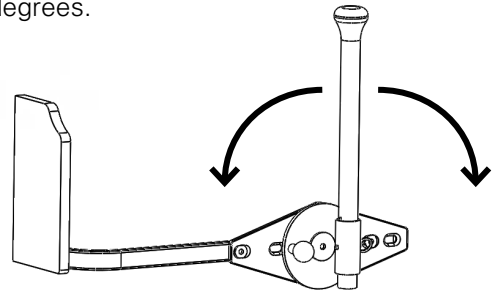
⚠ WARNING: Prior to use, an optimal bed system assessment must be conducted for each resident by a qualified clinician or medical provider to ensure maximum safety of the resident. The assessment should be conducted within the context of, and in compliance with, the state and federal guidelines related to the use of restraints and bed system entrapment guidance, 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.

Operation

1. While pulling handle out, rotate assist device left or right 90 degrees.

NOTE: Do not rotate assist device more than 90 degrees.

2. Rotate handle to lock into position.



3. Adjust handle height by removing the release pin or bolt, moving the handle to the desired position, and then reinserting pin or bolt.

Maintenance

Routine Inspection

1. Review the "WARNINGS" listed in this manual and inspect for compliance.
2. Inspect all components for damage or excessive wear.
3. Visually examine all welds for cracks.
4. Tighten attachment bolts and center pivot screw.
5. Inspect all bolts and fasteners. (Do not overtighten bolts at pivot points.)

Cleaning

Clean with a mild solution of antiseptic cleaner and warm water. Read and follow all label instructions on the cleaning products. DO NOT STEAM OR PRESSURE WASH.

Limited Warranty

We offer to you, as the original purchaser, a warranty for the Direct Supply Zero Opening Assist. 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® Zero Opening Assist Device	3 years	3 years

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.

DIRECT SUPPLY MANUFACTURING, INC. MAKES NO IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE; THESE AND ALL OTHER IMPLIED WARRANTIES ARE SPECIFICALLY DISCLAIMED. TO THE FULLEST EXTENT ALLOWED BY LAW, DIRECT SUPPLY MANUFACTURING, INC. WILL NOT BE LIABLE FOR ANY INCIDENTAL, SPECIAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, OR LOST PROFITS THAT MAY RESULT FROM THE DEVICE OR YOUR USE OF OR INABILITY TO USE THE DEVICE EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. OUR TOTAL LIABILITY TO YOU, IF ANY, IS LIMITED TO THE PRICE OF THE DEVICE OR SERVICE GIVING RISE TO YOUR CLAIM. Some states do not allow an exclusion or limitation of incidental or consequential damages, or how long an implied warranty lasts, so the above limitations or exclusions may not apply to you. If implied warranties are not excluded, and to the extent allowed by law, we limit any and all implied warranties to the applicable warranty period identified above. Except for rights under any applicable state law, the remedies provided under this warranty are your sole and exclusive remedy for any breach of our warranty and state the entire limit of our responsibilities.

Customer Service

Our promise to you is that you will have a convenient and easy ordering experience, receive a quality Zero Opening Assist and enjoy outrageous customer service. If you have any questions about the zero opening assist you have purchased or would like to request warranty service, please contact: **Direct Supply Equipment & Furnishings** at 1-800-634-7328, 7301 West Champions Way, Milwaukee, WI 53223, SalesSupport@DirectSupply.com.



DirectSupply.com

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