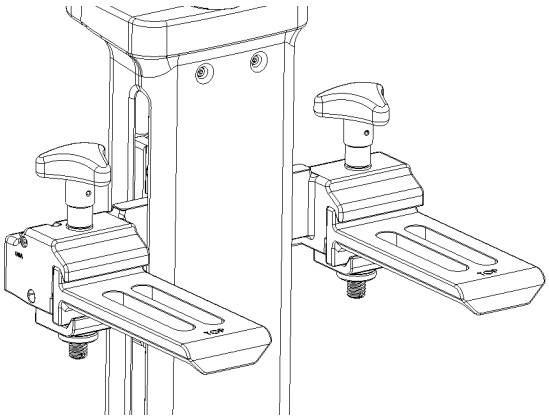
INSTRUCTIONS FOR USE

Bedrail Alignment Tool



Product No: 9119-01
Made of 6061-T6 anodized aluminum

These instructions apply to the instruments in the following brands:
VELYS™ Robotic-Assisted Solution

INDICATIONS FOR USE

The Bedrail Alignment Tool is an optional tool which attaches to the bedrail of an operating table, mates with the Holding Arm Clamps, and functions as a tool to be used with the VELYS Robotic-Assisted Solution. The Bedrail Alignment Tool is indicated for use with the VELYS Robotic-Assisted Solution perioperatively. The Bedrail Alignment Tool is provided NON-STERILE, intended to be used underneath the VELYS Device Sterile Drape.

The Bedrail Alignment Tool should be used only during robotic-assisted surgery with the VELYS Robotic-Assisted Solution. Do not use the Bedrail Alignment Tool outside of the DePuy Synthes VELYS Robotic-Assisted Solution.

INSTRUCTIONS TO SETUP BEDRAIL ALIGNMENT TOOLS WITH THE VELYS SATELLITE STATION

Assemble the Bedrail Alignment Tools to the Holding Arm Clamps

1. Ensure that the steps from Robotic-Assisted Device Initialization through Saw Blade Calibration have been completed.
2. Twist **one Holding Arm Clamp** knob counterclockwise to completely open the **Holding Arms Clamp** jaws.
3. Slide **one Bedrail Alignment Tool** into the **Holding Arm Clamp**.
    a. Align the Tool parallel to the clamp jaws as shown (*see figure 1*)
    b. The surface marked "**TOP**" should be pointed upward, away from the floor. The surface marked "**BOTTOM**" should be pointed downward, toward the floor. If not, flip the Tool over.
4. Twist **one Holding Arm Clamp** knob clockwise to close the jaws of the clamp around the **Bedrail Alignment Tool**. Do **not** use excessive force as this will make it difficult to remove the Bedrail Alignment Tool post-operatively.
5. Ensure the connection between the clamp jaws and the **Bedrail Alignment Tool** is secure.
6. Repeat steps 2-5 with the second **Bedrail Alignment Tool** and **Holding Arm Clamp**. (Ensure two **Bedrail Alignment Tools** are used to secure the Robotic-Assisted Device to the bedrail)
7. Proceed with System Draping. Apply VELYS Satellite Station Sterile Drape and VELYS Device Sterile Drape following instructions outlined in their respective IFUs

Final Positioning of the Satellite Station/Bedrail Alignment Tools with the OR Table

1. Ensure that the steps from System Draping through Robotic-Assisted Device Check have been completed, then remove the Saw from the Saw Interface as described in the Robotic-Assisted Device Transfer to the Bedrail step.
2. Ensure the following:
    - The Satellite Station Transfer is fully extended, and the **Holding Arm** is in the stacked position.
    - The OR table is level.
    - The cables coming from the Robotic- Assisted Device stay behind the clamps and will not be pinched between the Bedrail Alignment Tool (or Holding Arm) and the bedrail during the positioning of the Satellite Station.
3. Rotate the **Crank** at the back of the **Satellite Station** to raise the **Holding Arm Clamps** to a height greater than the OR table. The crank should be operated under the sterile drape by a non-sterile person. If the limits of the Satellite Station Transfer are reached, the height of the OR table can also be adjusted.
4. Roll the **Satellite Station** toward the OR table and align the ends of the **Bedrail Alignment Tools** with the space between the bedrail and the OR table. Ensure the Satellite Station is positioned such that:
    - the Satellite Station will not be in the way of the surgeon during the intra-operative workflow
    - the Holding Arm Horizontal Adjustment can align the center of the Device Array Interface with the knee center.

    This can be achieved, for example, by positioning the Satellite Station at the level of the patient's hip.
5. Use the **Satellite Station Crank** to slowly lower the **Holding Arm** and **Bedrail Alignment Tools** into their intended position between the bedrail and the OR table. Crank until light contact is achieved between the Bedrail Alignment Tool and the bedrail.
    a. The crank should be operated under the sterile drape by a non-sterile person.
6. Lock all four **Satellite Station Casters**.
7. Break the blue "tear here" labels on the Device Sterile Drape to allow Robotic-Assisted Device's full range of motion.

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8. If adjustments to the OR table are desired, the **Holding Arm** and **Bedrail Alignment Tool** must be raised off of the bedrail.
9. Proceed with mounting the Saw on the Saw Interface as described in the Setup Completion Step.

Remove the of Satellite Station/Bedrail Alignment Tools from the OR Table and Disassembly of Bedrail Alignment Tools from Holding Arm Clamps

1. Ensure that the System Tear-Down Instructions are completed though locking the Horizontal Adjustment Locking Mechanism with the Robotic-Assisted Device over the stacked Holding Arm Horizontal Adjustment. This should include ensuring the Robotic-Assisted Device is in the home position and the Saw is removed.
2. Rotate the **Crank** at the back of the **Satellite Station** to raise the **Bedrail Alignment Tools** above the bedrail, so that the **Bedrail Alignment Tools** no longer contacts the Bedrail.
3. Unlock all four **Satellite Station Casters**.
4. Pull the Satellite Station to move the Robotic-Assisted Device away from the surgical field.
5. Continue with Single-Use Instrument Disposal and Drape Disposal (do not remove drapes before the above steps are completed).
6. After the Drapes have been removed and disposed of, twist **one Holding Arm Clamp** knob counterclockwise to completely open the **Holding Arms Clamp** jaws.
7. Slide the Bedrail Alignment Tool out of the Holding Arm Clamp.
8. Repeat steps 6-7 with the second Bedrail Alignment Tool and Holding Arm Clamp.

MATERIALS AND RESTRICTED SUBSTANCES

The Bedrail Alignment Tool is manufactured from 6061-T6 aluminum which is clear anodized.

WARNINGS AND CAUTIONS

The Bedrail Alignment Tool is reusable, NON-STERILE and is intended for multiple uses. It **must be cleaned per the cleaning instructions provided** before each subsequent use. It must be used **under** the VELYS Device Sterile Drape. Appropriate cleaning methods must be used to avoid damage and deterioration to the Tool. Do not use the Bedrail Alignment Tool if you are unable to clean according to these methods.

The Bedrail Alignment Tool is compatible with the following variants of the VELYS Robotic-Assisted Solution and no other DePuy Synthes products or VELYS Capital Equipment.

Holding Arm Variant Finished Good Number	Holding Arm Description
451570103	VELYS Robotic System Holding Arm Assembly - USA
451570228	VELYS Robotic System Holding Arm Assembly - JPN
451570229	VELYS Robotic System Holding Arm Assembly - EU
451570227	VELYS Robotic System Holding Arm Assembly - CHE

- Ensure the interfaces of the Bedrail Alignment Tools and the bedrail are over the reinforcement patch to prevent the drape from tearing. Ensure no remaining folds in the Device Drape are located between the Bedrail Alignment Tool and the reinforcement patch. Attaching over the folds in the drape may limit the Robotic-Assisted Device range of motion.
- Care should be taken not to deform the Bedrail Alignment Tool by using excessive compression, torsional forces, or drops, especially while lowering the Tool onto the bedrail
- Visually inspect for damage such as corrosion, discoloration, excessive scratches, flaking, wear, distortion, and cracks before reprocessing.
- Significant deformities render the Tool ineffective and will no longer function as Tool for the VELYS Robotic-Assisted Solution.
- Once the Bedrail Alignment Tool has reached end of life, user should destroy the Tool so it is no longer useable as intended by its original design requirements. Then the Tool can be recycled by a third-party metal recycler. This product is 100% aluminum.

ADVERSE EVENTS AND COMPLICATIONS

Possible Adverse Events

1. Hand or finger of the user is pinched between the clamp jaws during installation.
2. Glove tear during installation causing contamination.
3. Perforation of VELYS Device Drape causing contamination.
4. Contact with patient.
5. Bending, fracture, or surface damage of the Tool.
6. Loosening of the Tool/clamp interface or improper loading of the Tool.
    a. Tool falls onto the ground and becomes contaminated.
    b. Tool falls onto the user and injury occurs.
    c. Insufficient contact with the bedrail.
7. Satellite Cart tilts backward if table is raised without first raising the Clamp-Bedrail Alignment Tool assembly.
8. Horizontal translation along bedrail when casters are not locked.

Reporting of Serious Incidents

Any serious incident that has occurred in relation to the Bedrail Alignment Tool should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. Serious incident means any incident that directly or indirectly led, might have led, or might lead to any of the following:

a) The death of a patient, user or other person
b) The temporary or permanent serious deterioration of a patient's, user's, or other person's state of health.
c) A serious public health threat.

CLEANING AND STERILIZATION

Bedrail Alignment Tool

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Please use the following guidelines when sterilizing this product:

Sterilizer Type:	Pre-vacuum Steam Sterilizer
Minimum Temperature:	132 degrees C / 270 degrees F
Minimum Cycle Time:	**4 minutes**
Minimum Dry Time:	30 minutes

Innomed recommends that the cleaning and decontamination of instruments follow the guidelines set forth by AORN/HIMA and AAMI. Both physical and chemical (detergent) processes are necessary to minimize the bioburden on all soiled items. Chemical (detergent) cleaners alone cannot remove all soil and debris, therefore a careful manual cleaning of each item with a soft sponge or cloth is essential for maximum decontamination. Carefully inspect hidden areas such as cannulations and recesses to assure any residual materials are removed. Once the items have been cleaned and decontaminated, they should be thoroughly rinsed with clean water to remove any detergent or chemical residue before sterilization. Innomed recommends the use of a mild enzymatic detergent with a low pH. Do not use multipurpose detergents to wash or soak your instruments. Use a specifically compounded low-suds detergent for all instruments. Detergents designed for surgical instruments, pads and straps are specifically formulated to remove protein, organic debris and blood. The neutral pH balance will not damage aluminum. The solution is gentle enough for manual (hand) as well as ultrasonic cleaning.

INSTRUMENT CARE PROCEDURE

1. Visually inspect instruments before cleaning for corrosion, discoloration, cracks, tears, excessive scratches, distortion, flaking, and chipping
   a. If one or more of these are identified, Bedrail Alignment Tool must be removed from use and discarded.
2. Clean instruments thoroughly after use.
   a. If you use a pre-soak solution; be certain that it has a neutral pH balance.
   b. Clean instruments in an open position by either hand or ultrasonic cleaner.
   c. Use a non-metallic brush (toothbrush) to remove stubborn debris. DO NOT use abrasive cleaning solutions or scouring pads.
   d. DO NOT expose instruments to bleach.

Post-operative processing for subsequent operations does not require re-sterilization and shall follow the cleaning instructions below:

CLEANING

1. Twist the Holding Arm Clamp knob counterclockwise to open the clamp jaws.
2. Remove the Bedrail Alignment Tool from Holding Arms Clamps.
3. Clean and disinfect surface using the surface disinfectant and lint-free cloth.
4. Dry thoroughly with non-abrasive cloth.
5. See Instructions to Assemble the Bedrail Alignment Tools to the Holding Arm Clamps.

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