DORO®

INSTRUCTION MANUAL

BLACK FOREST MEDICAL GROUP

QR3 & TEFLON HEADREST SYSTEMS AND ACCESSORIES

1001.001	DORO® QR3 Skull Clamp
3001-00	DORO® Adjustable Base Unit
3001-001	DORO® Adjustable Base Unit Takara
3001-002	DORO® Adjustable Base Unit Mizuho
3001-006	DORO® Base Unit Parkbench
3001-009	DORO® Adjustable Base Unit Teflon
3001-010	DORO® Base Unit Eschmann T-Series
3002-00	DORO® Swivel Adaptor Aluminum
3002-009	DORO® Swivel Adaptor Teflon
3003-009	DORO® QR3 Skull Clamp Teflon
3007-00	DORO® Crossbar Adaptor
3009-01	DORO® Horseshoe Base without extension arm
3009-25	DORO® Extension Bar Horseshoe
3010-00	DORO® Table Adaptor
3011-00	DORO® Side Rail Adaptor
3011-10	DORO® Side Rail Adaptor Amsco
3012-00	DORO® Cervical Spine Support
1204.001	DORO® Easy-Connect Navigation Adaptor, STRYKER
1204.002	DORO® Easy-Connect Navigation Adaptor, BRAINLAB
1204.003	DORO® Easy-Connect Navigation Adaptor, MEDTRONIC

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1. Product Description

1.1 Basic Specifications

1.1.1 DORO® QR3 Headrest System

The DORO® QR3 Headrest System is placed on the patient's skull to hold their head and neck securely in a particular position when rigid fixation is desired. The clamp is indicated for use in open and percutaneous craniotomies as well as spinal surgery when rigid skeletal fixation is necessary.

The Base Unit is designed for patient positioning in prone or supine positions. For lateral positioning we recommend using the DORO® Adjustable Base Unit Parkbench.

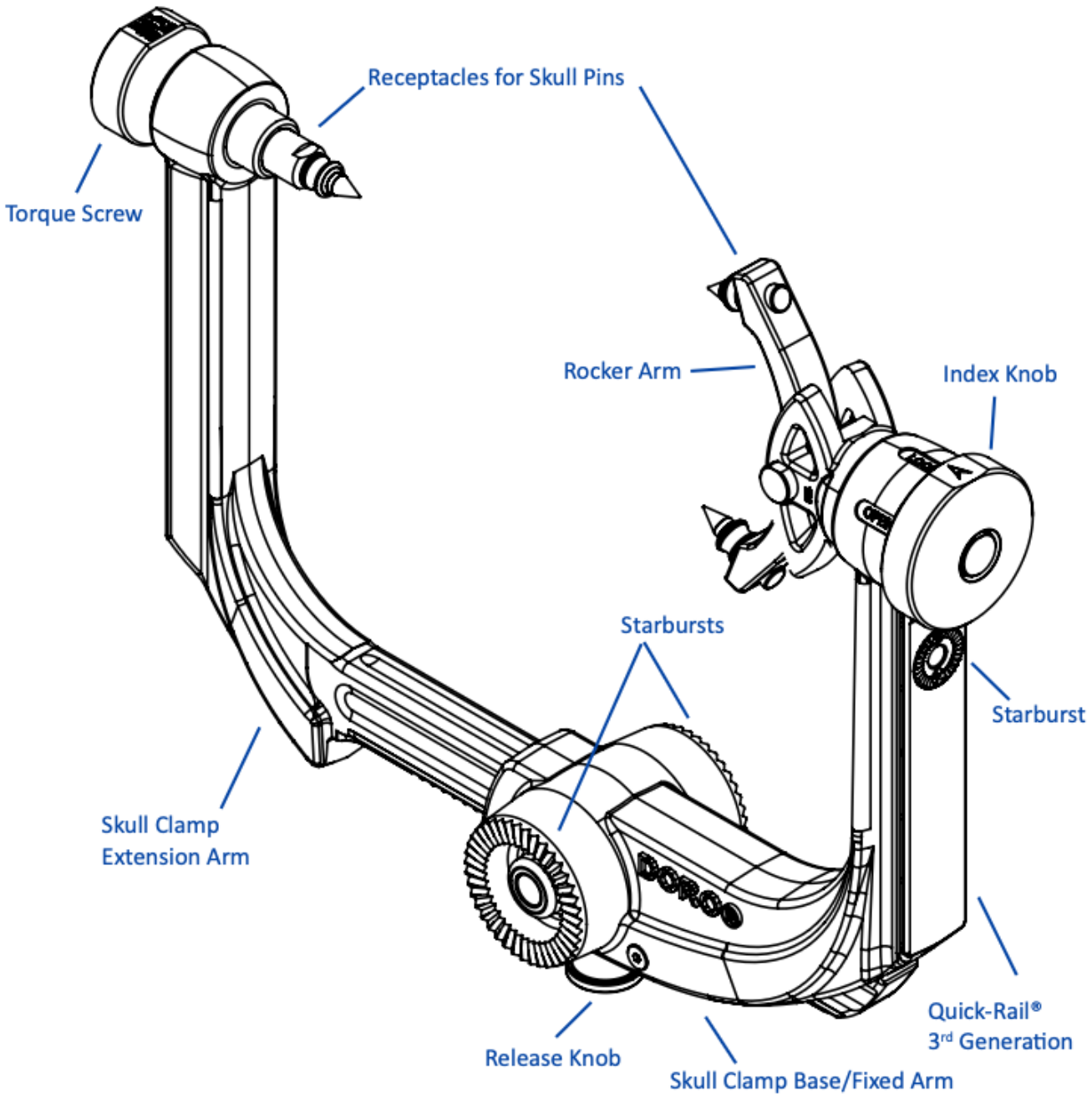
The two table rods of the DORO® Base Units are equipped with an internal insulating bush to prevent electrical stray currents when the Base Unit is connected to the OR Table.

For patients undergoing surgery in sitting positions, use the DORO® Crossbar Adaptor (item no. 3007-00) which is mounted to the side rails of the OR Table.

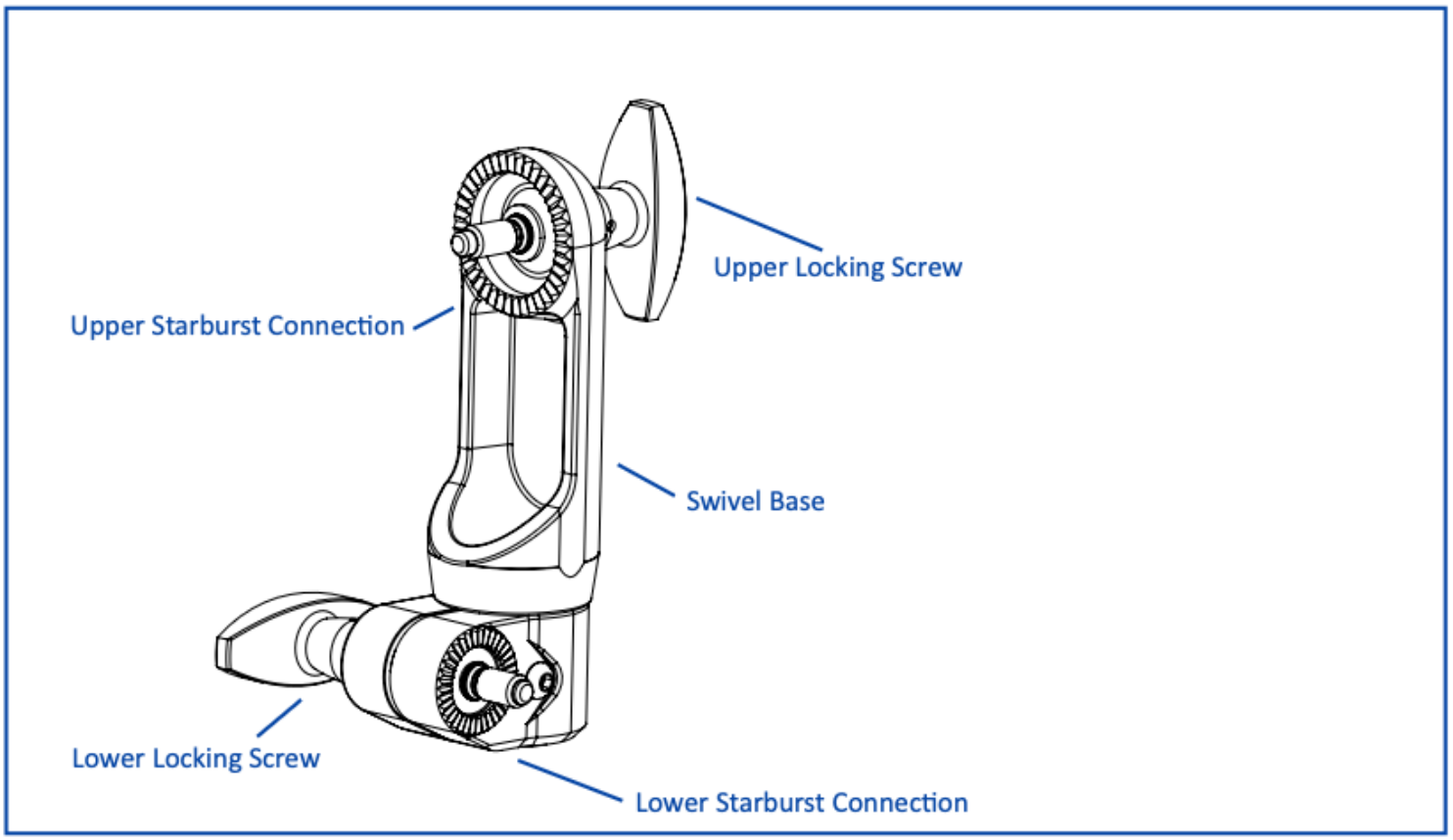
The Swivel Adaptor connects the Base Unit (by means of the Transitional Member) with the Skull Clamp. The Swivel Adaptor is rotable by 360 degrees. This allows a fully flexible adjustment of the DORO® Headrest System to the patient's position.

Item-No	Name
1001.001	DORO® **QR3 Skull Clamp** weight: 1850g, height: 284mm | adjustment range (outside width): 290 - 432mm adjustment range (head size): 57 - 195mm, depending on torque screw position
3001-00	DORO® **Adjustable Base Unit** weight: 3250g | height: 213mm | width 525mm | adjustment range rods: 117-215mm
3002-00	DORO® **Swivel Adaptor** weight: 650g | height: 175mm
3001-006	DORO® **Base Unit Parkbench** weight: 6700g | adjustment range OR table: 510 - 670mm adjustment range (outside width): 630-790mm
3001-001	DORO® **Adjustable Base Unit Takara Belmont** weight: 3000g
3001-002	DORO® **Adjustable Base Unit Mizuho** weight: 2900g
3001-010	DORO® **Base Unit Eschmann T-Series** weight: 3450g

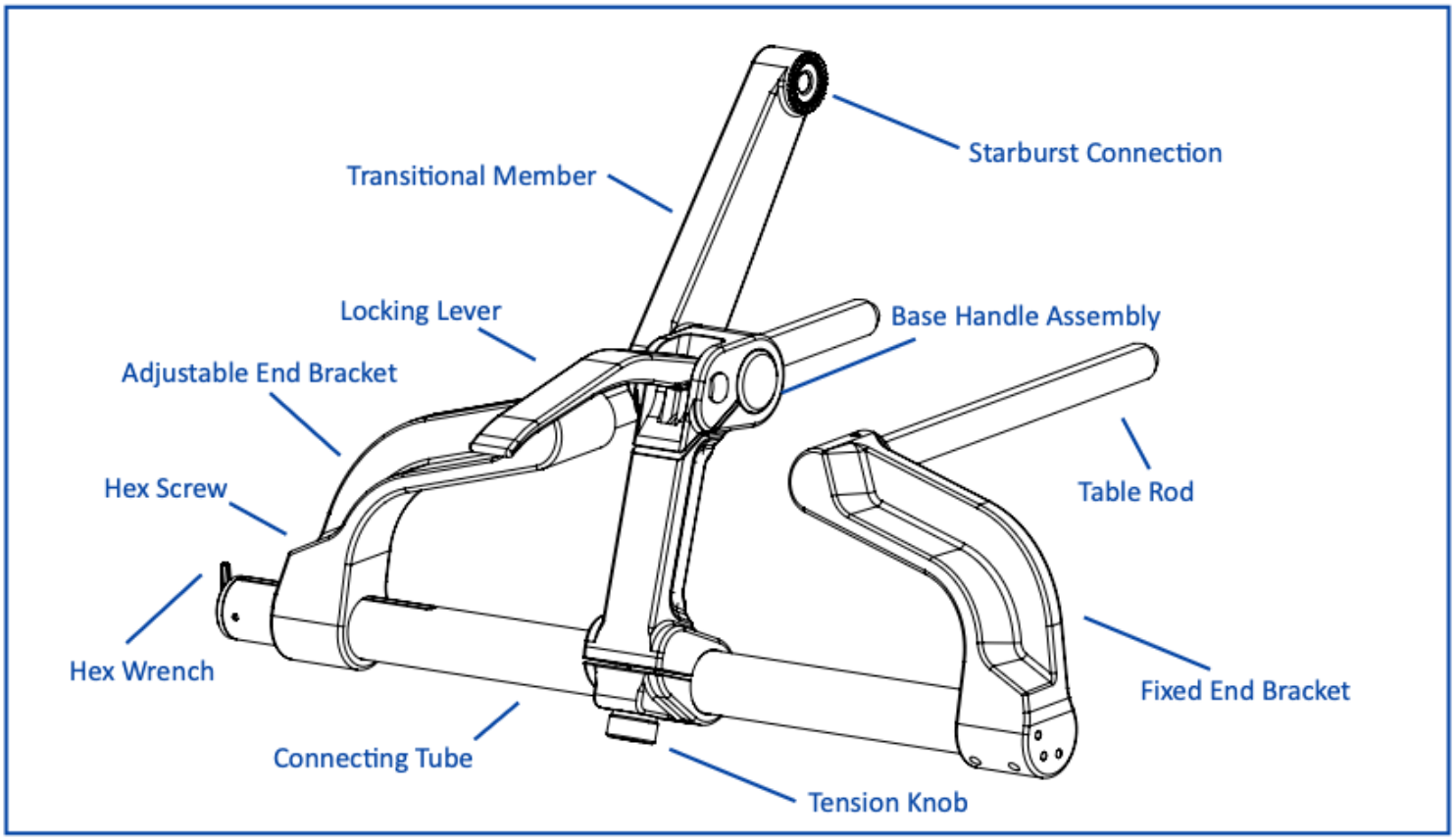
Quick Guide DORO® QR3 Headrest System, 1001.001 (3rd Generation Quick-Rail®)



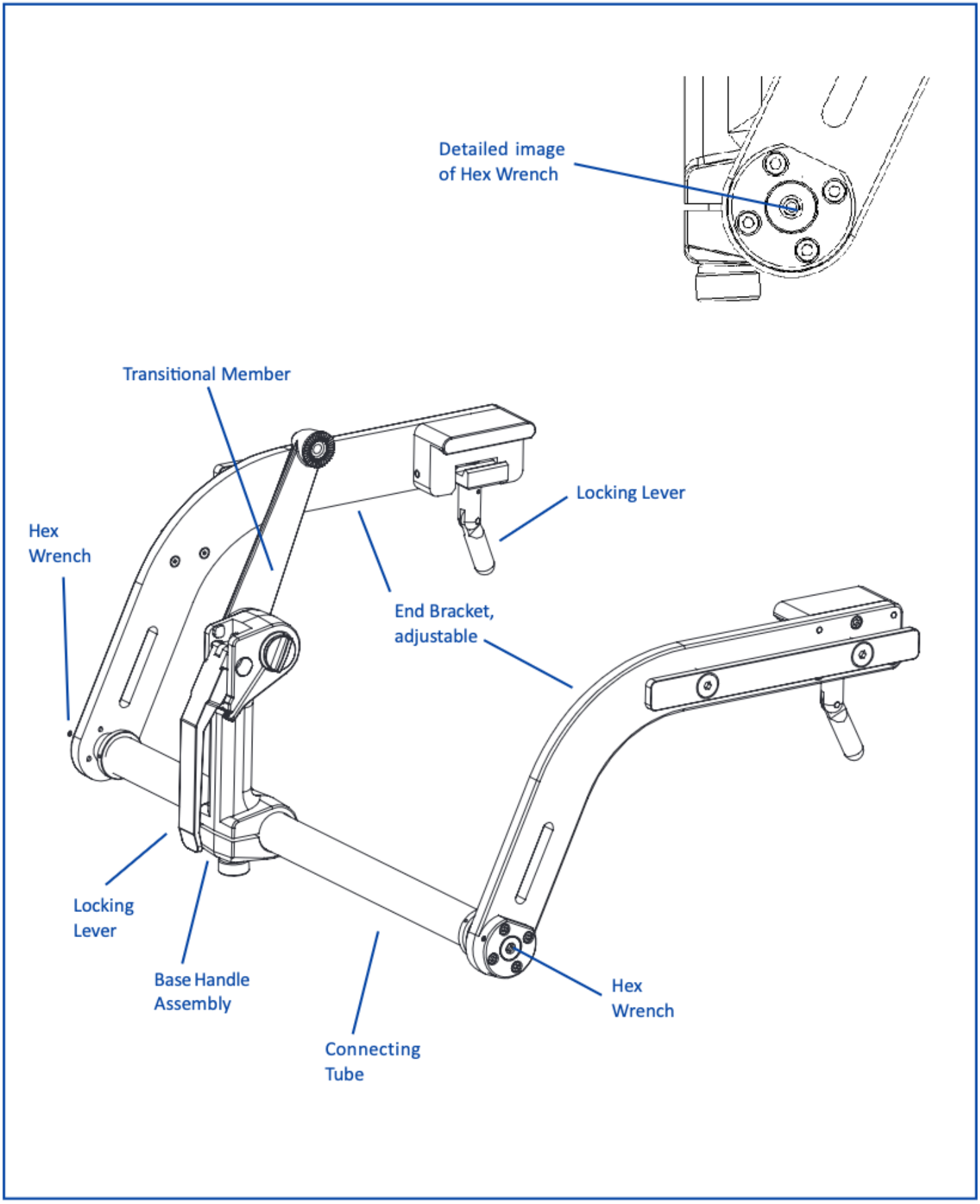
Quick Guide DORO® Swivel Adaptor Aluminum, 3002-00



Quick Guide DORO® Adjustable Base Unit, 3001-00



Quick Guide DORO® Base Unit Parkbench, 3001-006



1.1.2 DORO® Headrest System Teflon®

The DORO® Teflon® Headrest System has the same functionality as the QR3 Headrest System. Additionally, it is Teflon coated and thus can withstand regular automatic washing and steam sterilization.

Item-No	Name
3003-009	DORO® **QR3 Skull Clamp Teflon** weight: 1900g | adjustment range (head size): 57 - 195mm, depending on torque screw position adjustment range (outside width): 285 - 429mm
3001-009	DORO® **Adjustable Base Unit Teflon** weight: 3300g | width 550mm | adjustment range rods: 99 - 245mm
3002-009	DORO® **Swivel Adaptor Teflon** weight: 550g

Quick Guide DORO® Teflon® Headrest System please refer to "Quick Guide DORO® **QR3 Headrest System"**

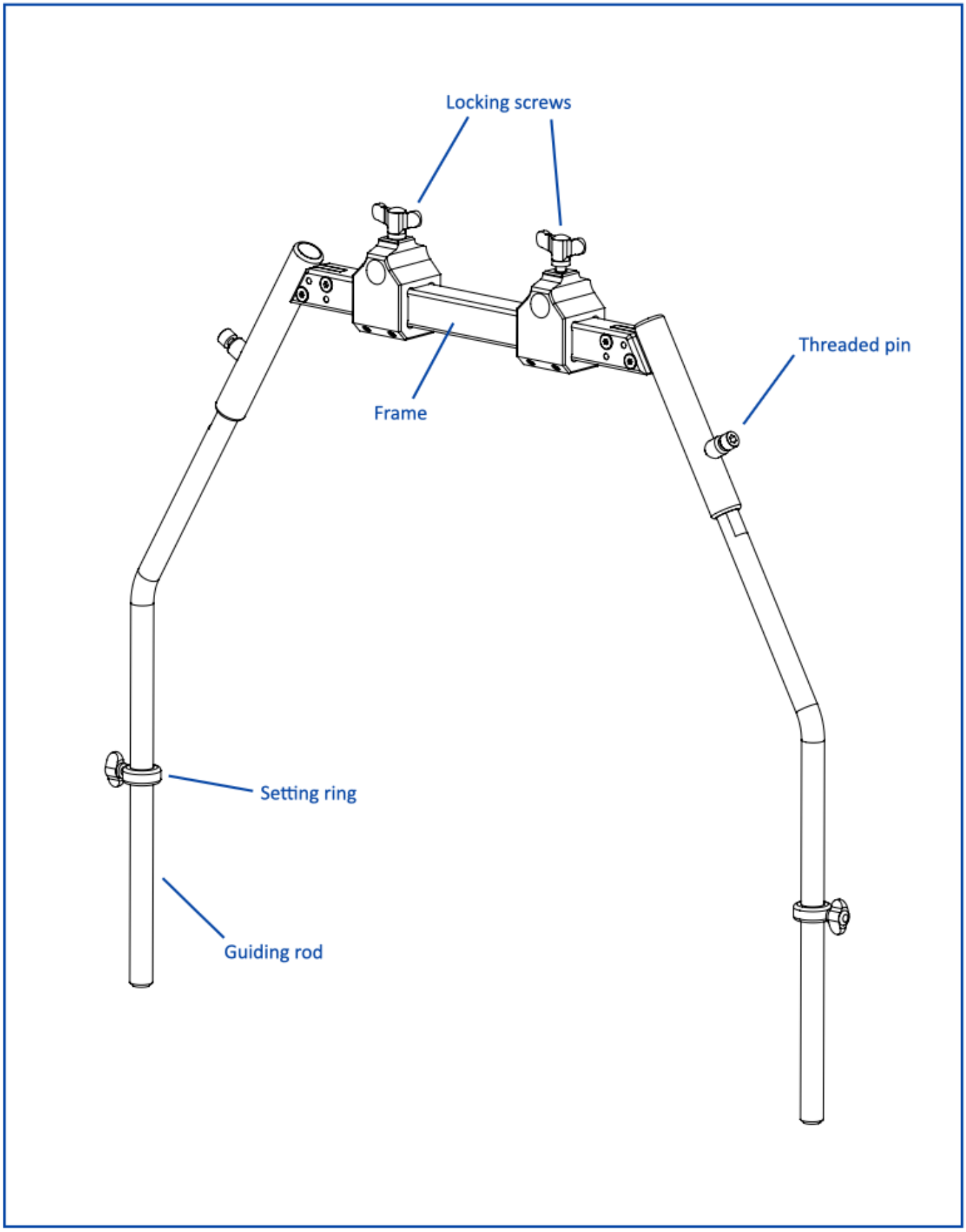
1.1.3 Accessories to DORO® Headrest Systems

The DORO® Crossbar Adaptor is connected to the side rails of operating tables. It is compatible with most standard operating table systems. The DORO® Headrest System is mounted to the top of the DORO® Crossbar Adaptor. The complete system enables surgery in a sitting position. The system is particularly suitable for surgery at the rear bottom part of the head.

The Side Rail OR Table Adaptor (item nos. 3011-00 or 3011-10) can be used with the DORO® Base Units listed in this IFU. The Side Rail OR Table Adaptor is mounted to the Side Rails of the OR Table. It was designed to mount the DORO® Aluminum Base Units to OR Tables lacking rod slots. DORO® Side Rail Adaptors can be adjusted in their width (see table below) and fit EU (25 mm x 10 mm) and US (28.6 mm x 9.5 mm) side rails.

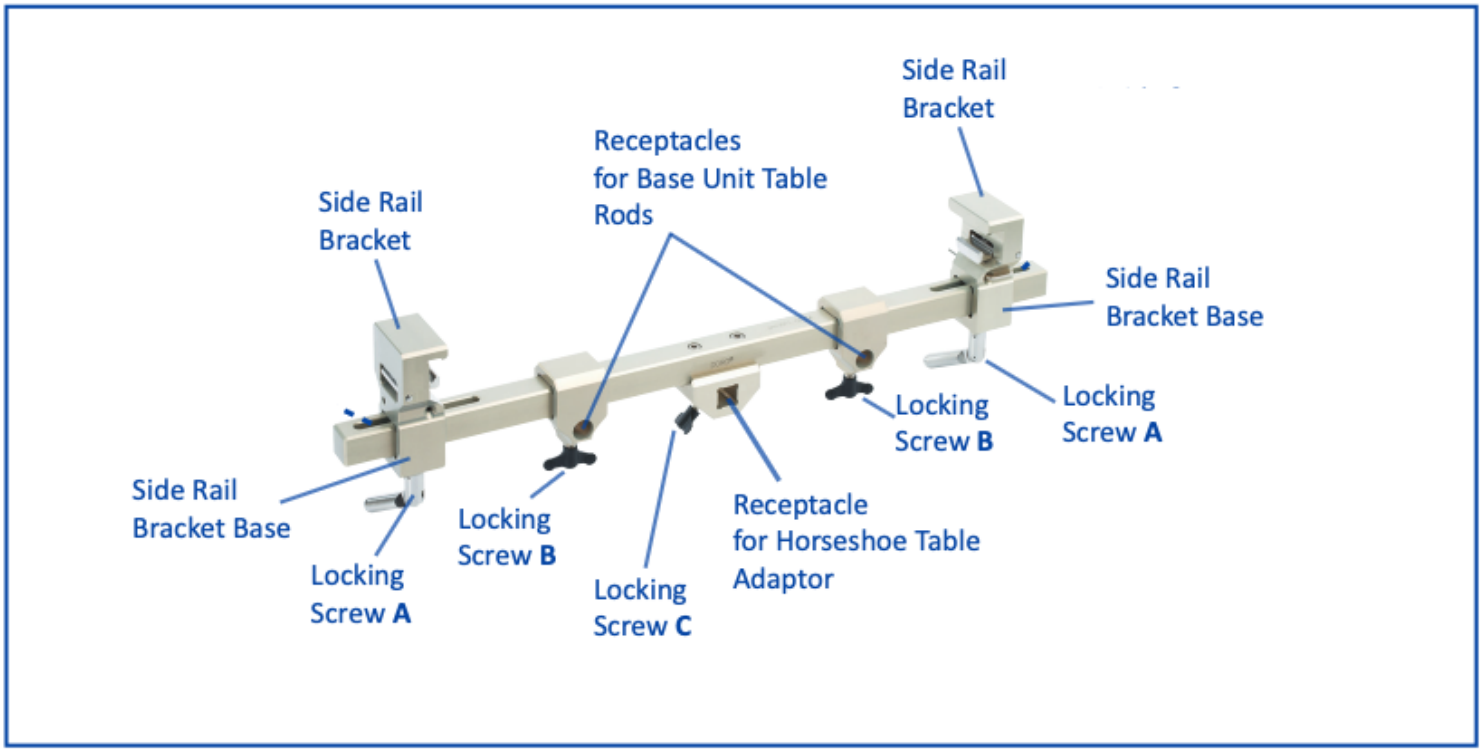
Item-No	Name
3007-00	DORO® **Crossbar Adaptor** weight: 4500g | width: 713mm, height: 673mm Adjustment range: 629 - 736mm
3010-00	DORO® **Table Adaptor** weight: 1400g
3011-00	DORO® **Side Rail Adaptor** weight: 4050g, adjustment range for side rails OR table: 512-680mm (suitable for EU/US)
3011-10	DORO® **Side Rail Adaptor Amsco** weight: 4850g, adjustment range for side rails OR table: 512-680mm (suitable for EU/US) 437-648 mm
3012-00	DORO® **Cervical Spine Support** weight: 2100g

Quick Guide DORO® Crossbar Adaptor, 3007-00

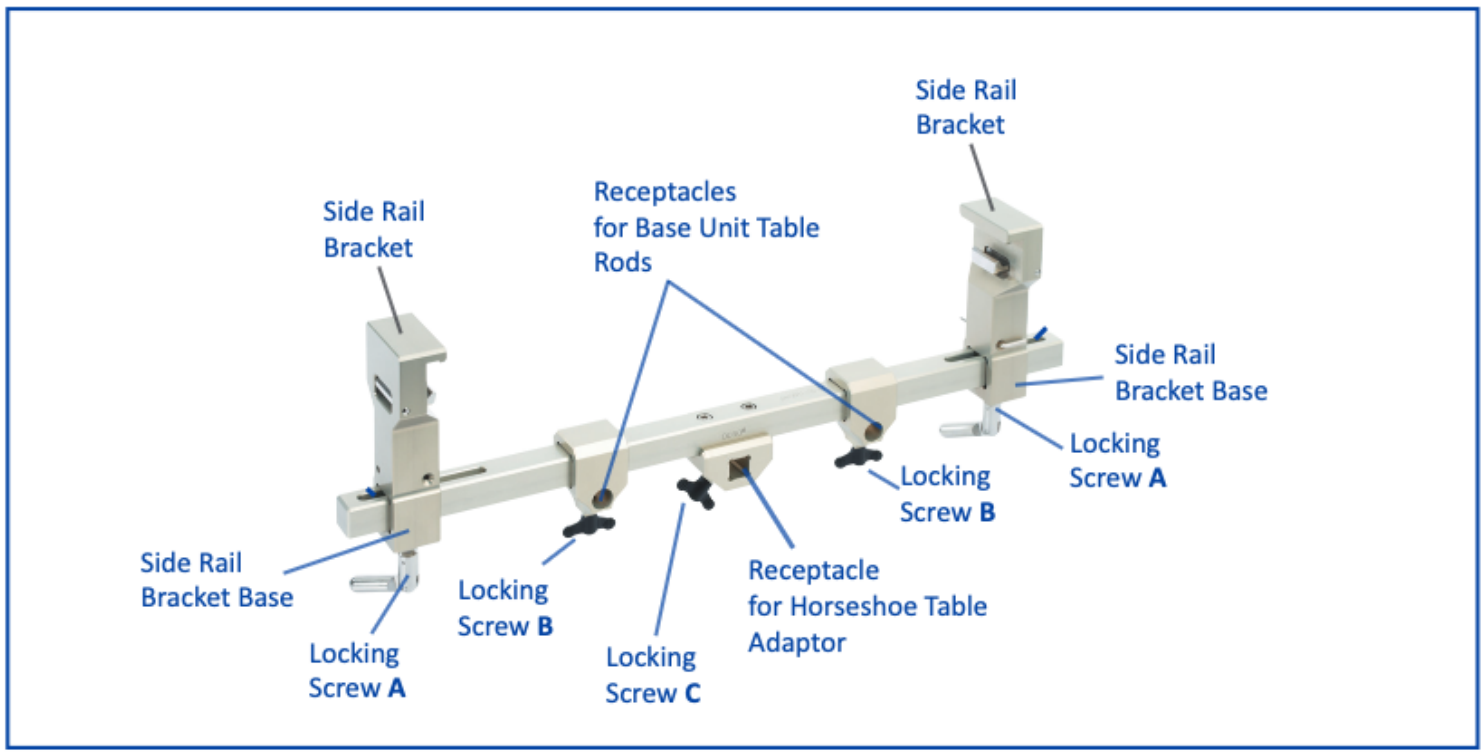


Quick Guide Side Rail Adaptors 3011-00 & 3011-10

DORO® **Side Rail OR Table Adaptor, 3011-00**



DORO® **Side Rail OR Table Adaptor AMSCO, 3011-10**



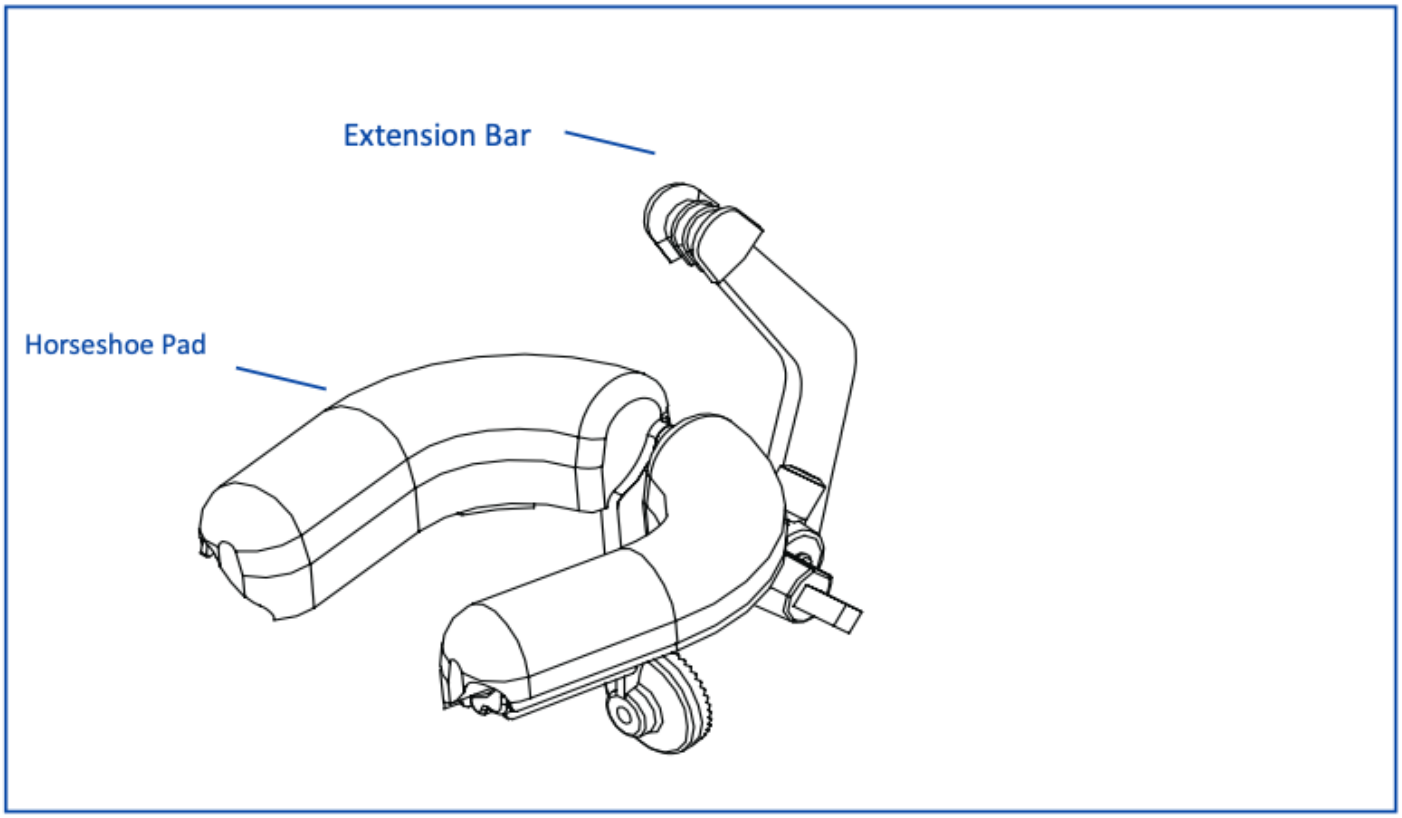
1.1.4 DORO® Swivel Horseshoe Headrest System

The DORO® Swivel Horseshoe Headrest is a component of a mechanical support system used to position the patient's head in surgery. The DORO® Horseshoe Headrest is mounted to the Swivel Adaptor which, in turn, is mounted to the operating table by means of the Base Unit.

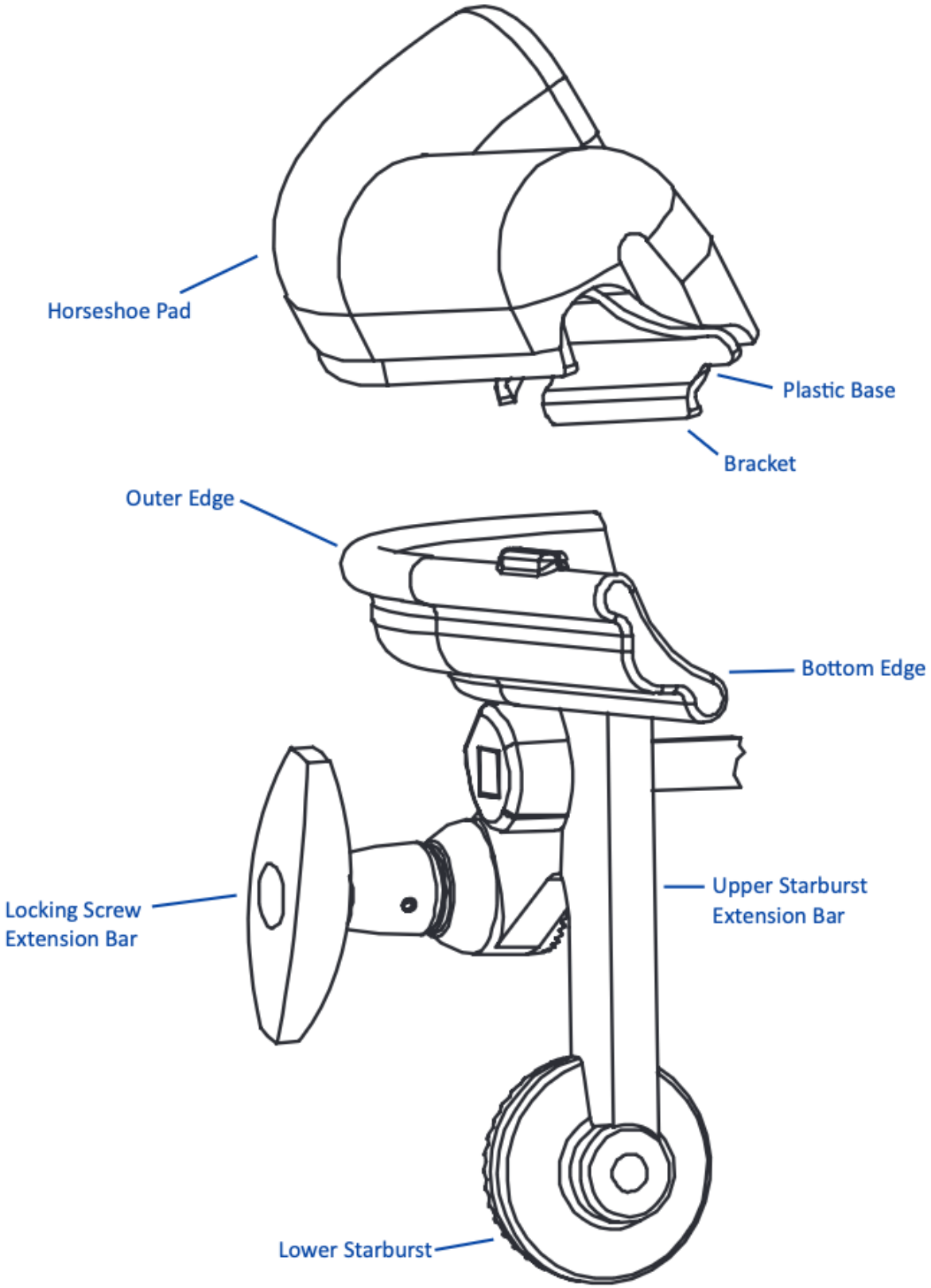
The Horseshoe Headrest is an alternative noninvasive cranial stabilization system to the rigid skull fixation with skull pins. The position of the Swivel Horseshoe Headrest can be adjusted both vertically and horizontally. The Horseshoe (Gel) Pads are reusable, but may also be replaced as needed. They are available to order as spare parts.

Item-No	Name
3009-01	DORO® **Horseshoe Base without extension arm** weight: 760g, adjustment range: 170 - 240mm
3008-10	DORO® **Horseshoe Pad, Pediatric, right** weight: 670g
3008-11	DORO® **Horseshoe Pad, Pediatric, left** weight: 670g
3009-10	DORO® **Horseshoe Pad, Adult, right** weight: 390g
3009-11	DORO® **Horseshoe Pad, Adult, left** weight: 390g
3009-25	DORO® **Extension Bar Horseshoe** weight: 270 g

Quick Guide to DORO Horseshoe Headrest System 3009-01 with Extension Bar, 3009-25



Quick Guide DORO® Swivel Horseshoe Headrest, 3009-01, shown with Horseshoe Pads (item-no 3009-00 / 3009-02 or 3008-00 / 3008-02)



1.1.5 DORO® Easy-Connect Navigation Adaptors

Easy Connect Navigation Adaptors are directly mounted to the DORO® Skull Clamp via a built-in starburst on the Quick-Rail of the DORO® QR3 Skull Clamp. The Navigation Adaptor provides a stable, secure connection of the Navigation Tracking Devices.

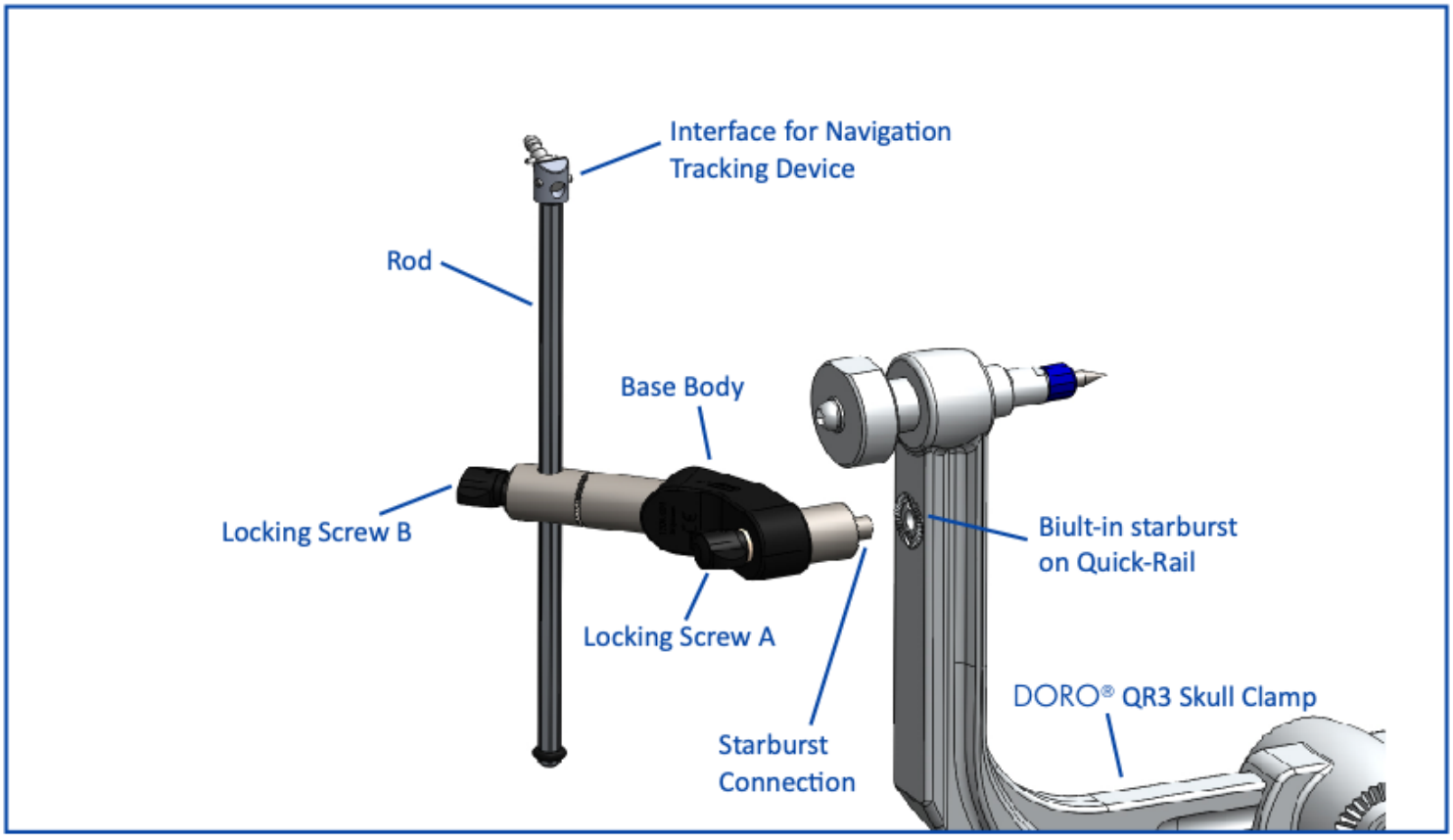
The Easy Connect Navigation Adaptor Stryker, Item-No. 1204.001, is used to connect the Stryker navigation Tracking Device.

The Easy Connect Navigation Adaptor Brainlab, Item-No. 1204.002, is used to connect the Brainlab Navigation Tracking Device.

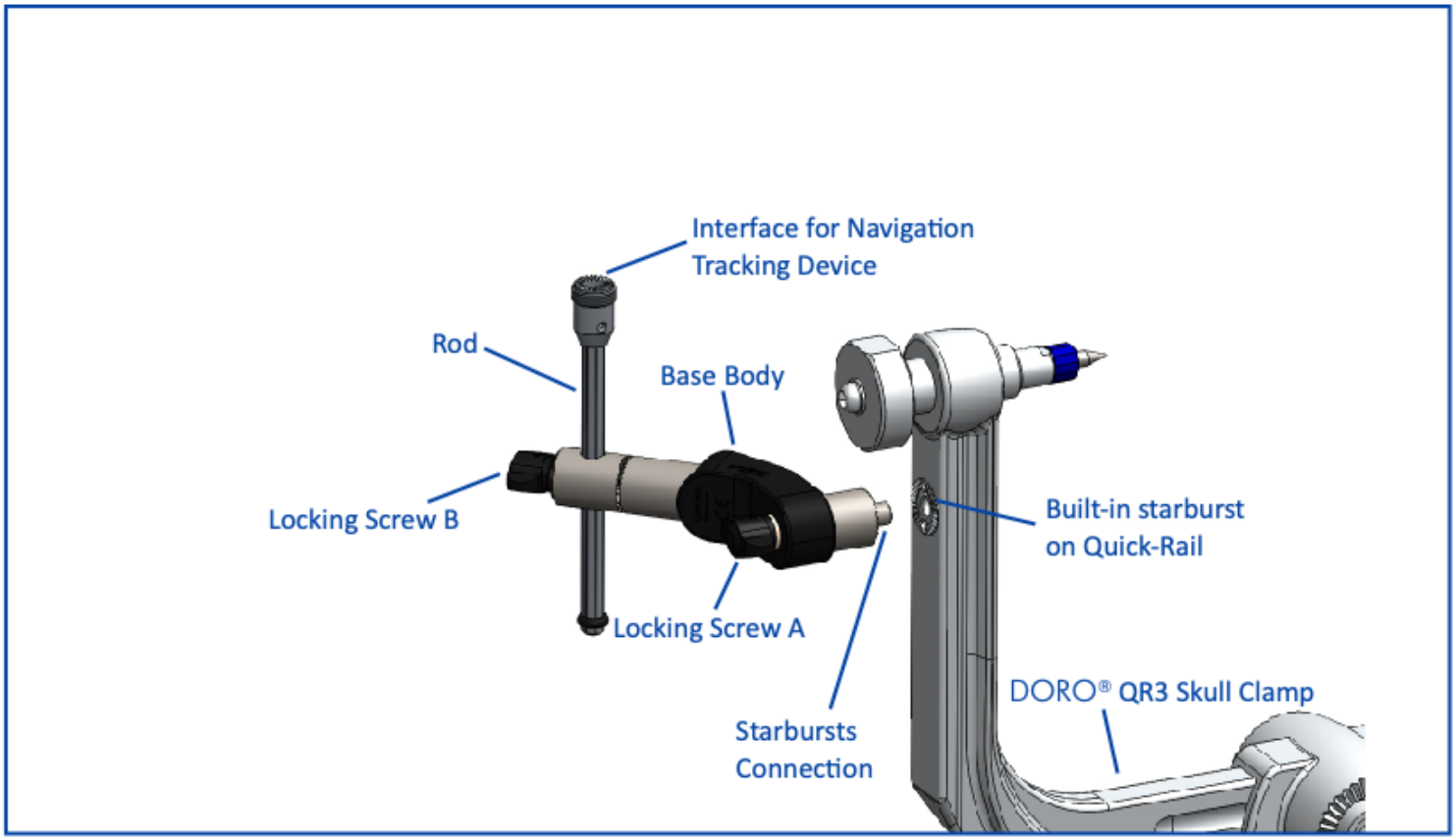
The Easy Connect Navigation Adaptor Medtronic, Item-No. 1204.003, is used to connect the Medtronic Small Passive Cranial Reference Frame.

Item-No	Name
1204.001	DORO® Easy-Connect Navigation Adaptor, STRYKER weight: 300g
1204.002	DORO® Easy-Connect Navigation Adaptor, BRAINLAB weight: 270g
1204.003	DORO® Easy-Connect Navigation Adaptor, MEDTRONIC weight: 380g

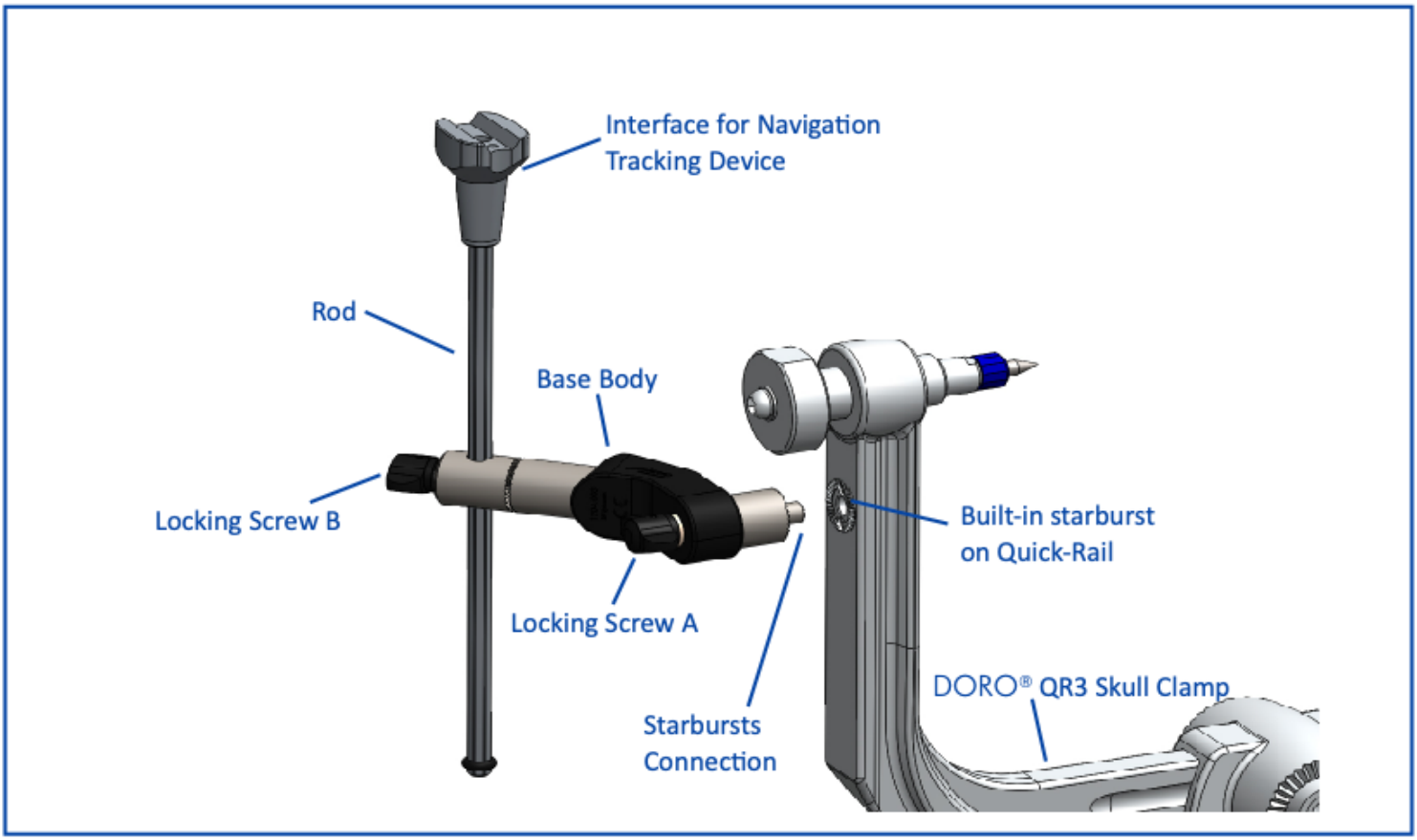
Quick Guide DORO® Easy Connect Navigation Adaptor STRYKER, 1204.001



Quick Guide DORO® **Easy Connect** Navigation Adaptor BRAINLAB, 1204.002



Quick Guide DORO® **Easy Connect** Navigation Adaptor MEDTRONIC, 1204.003



1.2 Intended Purpose/Intended Use

The DORO® Headrest System is a mechanical support system which is used in head and neck surgery when rigid cranial stabilization is desired.

It is mounted with different Base Units/Adaptors to the OR table. This system allows the patient's head to be positioned and secured for surgery. The DORO ® Headrest System provides an interface for accessories like retractor systems, navigation adaptors or other items.

The DORO® Swivel Horsehoes are components of a mechanical support system which is used in head and neck surgery when non-invasive head support is required.

1.3 Intended Population

There are currently no limitations to the targeted patient population, we don't recommend the use of invasive fixation for patients under the age of 5 years.

1.4 User

The device may only be used and applied by qualified professionals belonging to the operating team.

1.5 Contraindication

To date, there are no contraindications known. However, application of the device can be limited to certain extends, depending on the patient's condition. The risk for certain complications with the application of the device is increased in patients with a weaker than normal cranium. This includes small children as well as patients with skull or bone defects in general.

1.6 General warnings that apply to all products in this IFU

Check all locking screws at the device and the stability of the complete DORO® system before and after each clinical use.

The DORO® Headrest System is temporarily destabilized when you loosen handles and locking screws. Therefore: Ensure that all handles and locking screws at the device are properly locked prior to each clinical application of the system.

Caution when adjusting the OR table top or back plate with the side rail adaptor attached! Danger of physical injury and material damage. The side rail adaptor and attached devices hang below the table top. The risk of collision with the table top or the OR table column emerges when sliding the table top or lowering the backplate. Adjust the OR table to your needs before draping the patient and watch the attached devices during adjustment.

The maximum load for the DORO® Horseshoe Headrest and for the DORO® QR3 Headrest System is 12.5 kgs/27.5 lbs. Please make sure to safely position the patient's neck and shoulders to avoid excess weight.

The device is not MRI safe and should not be used in a MRI environment.

1.7 Safety Inspection

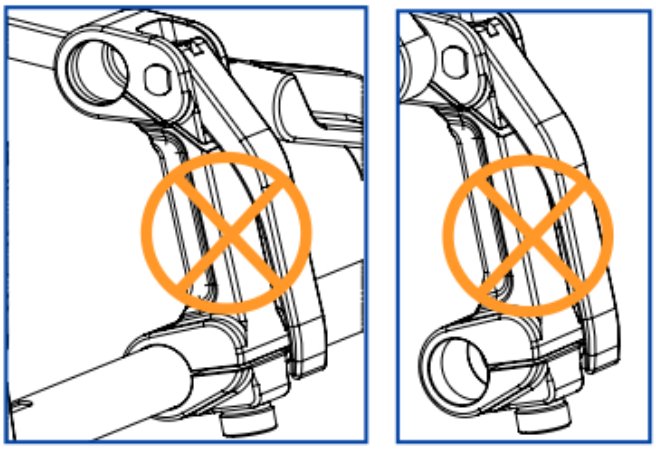
The user is responsible for function and safety inspections before and after each clinical use.

Warning! Check all locking screws and the stability of the Headrest System before and after each clinical use.

1.7.1 Prior to Clinical Use of a DORO® Device

Perform the following function and safety tests before using the device in clinical applications:

- Check if the Base Unit Locking Lever needs to be readjusted and that the Transitional Member of the Base Unit is properly mounted.
- Check if the torque screw on the scull clamp is working properly – the pressure reading is moving when applying pressure.

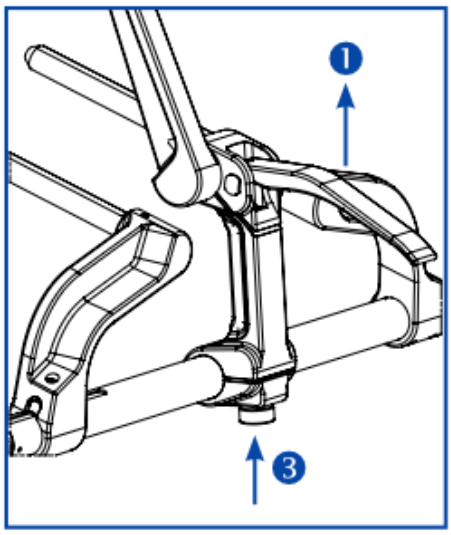


- Check all threads on the products (Helicoil thread inserts / thread inserts / threads on the torque screw) for possible damage, wear, and/or malfunction.
- Check components of skull clamp sliding mechanism (release knob and ease of width adjustment). This also includes checking whether the release knob reliably releases the tension of the sliding mechanism and engages again as the clamp is ratcheted together.
- Check the surfaces—no damage that may impair the function or could lead to a risk of injury to the patient or user. This includes a check for visible cracks in particular. If even the smallest crack is detected in the material, regardless of the location, the product components must be replaced for safety reasons.
- Check the starbursts—if wear is detected on the starburst connections (such as broken teeth, visible deformation, points of impact on the starburst connections), the product component must be checked by the manufacturer and, if necessary, replaced by an original component for safety reasons.
- Check the receptables of the skull pins: the original skull pins must be able to be inserted and removed completely. They must not fall out by themselves when the tip of the skull pin is facing vertically downward.

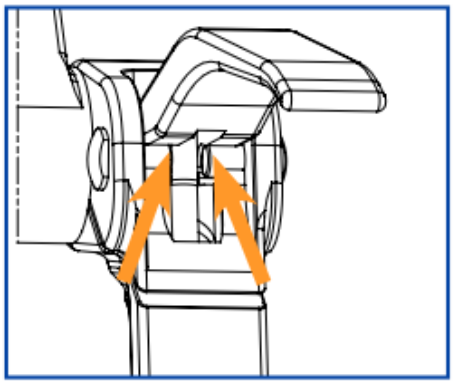
The Base Unit is adjustable in all directions. Frequent realignment of the Base Unit may cause the adjustable parts to loosen. Therefore, we strongly recommend performing the following funtionality check before each use.

Adjusting the Locking Lever

The Locking Lever of the Base handle assembly arrests both the Base Handle Assembly to the connecting tube and the Transitional Member to the Base handle assembly. Check the adjustment:



1. Open the Locking Lever.
2. Hold the Tension Knob at the Base Handle Assembly and turn the lock screw inside the Tension Knob counter-clockwise using the Hex Wrench.
3. Check the Locking Lever tension by depressing and releasing the Locking Lever. Make sure that the two Locking Lever hooks are properly placed under the two stainless steel pegs of the Base Handle Assembly.

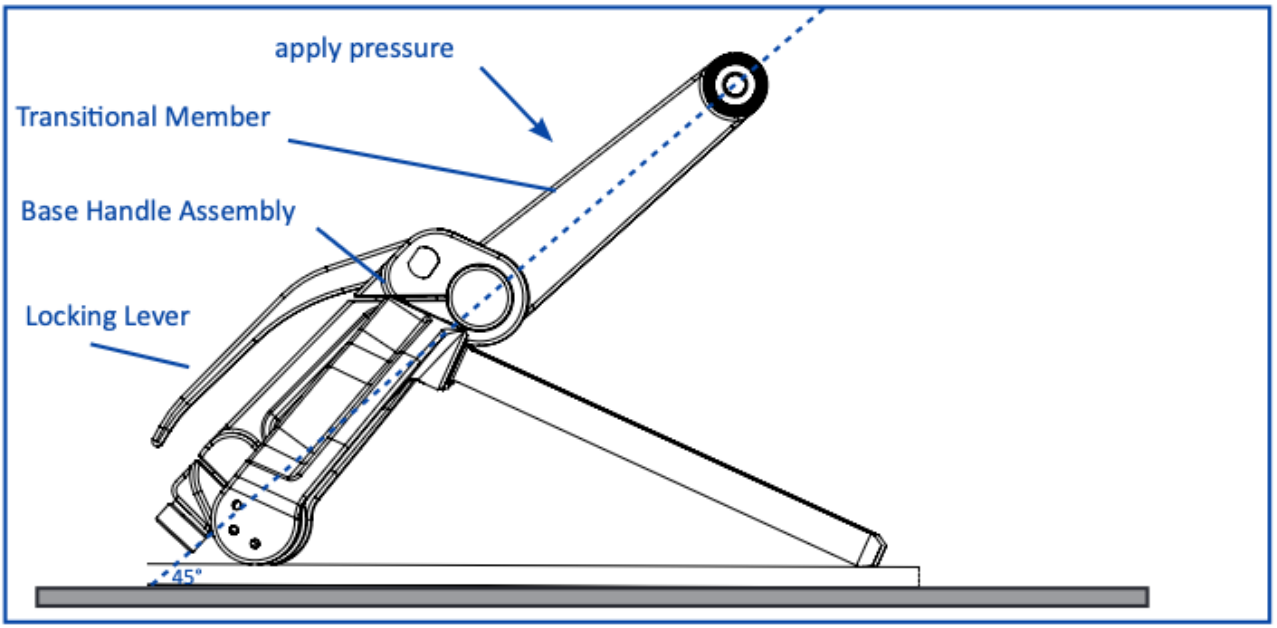


4. If necessary, turn the Tension Knob until you obtain the required tension. The lever movement should be smooth, but firm.
5. Holding the Tension Knob, close the lock screw inside the Tension Knob by turning it clockwise using the Hex Wrench. Ensure that the Locking Lever lip is properly placed under the two Stainless Steel pegs.

Warning!

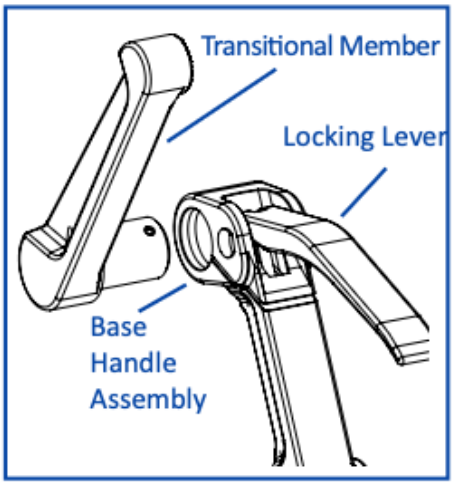
The Locking Lever should not be removed and should never be forced into place. Should the Locking Lever be disengaged from the internal Tension Stainless Steel Rod, carefully re-insert, ensuring that the Locking Lever hooks are properly placed under the two Stainless Steel pegs and that it is squarely positioned before lowering the Locking Lever. If the Locking Lever is on an angle, it may damage the internal mechanism.

Checking the stability of the Transitional Member



Place the Base Unit on a straight surface e.g. a clean table. Align the Base Handle Assembly with the Transitional Member at an angle of 45° to this surface. Close the Locking Lever and apply pressure to the Transitional Member in order to check its stability. There must be no movement detectable. If there is movement, re-adjust as described above.

Replacing the Transitional Member



1. Open the Locking Lever by lifting up to release.
2. Removing: Remove the Transitional Member from the Base Handle Assembly by pulling it slowly to the lefthand side (or to the right-hand side).
3. Replacing: Insert the cleaned (or new) Transitional Member into the receptacle of the Base Handle Assembly until a click indicates that you have fully engaged the Transitional Member. The Transitional Member should be locked before using or transporting the base unit.

If disassembling of the Base Handle Assembly is required, completely open the tension knob before disassembling the Base Handle Assembly. This will decrease the risk of major damages when accidently closing the Locking Lever without Transitional Member or Connecting Tube in place.

Warning!

Push until the click can be clearly detected. Ensure that the Transitional Member is safely locked in the Base handle assembly. Otherwise, the system stability is not ensured.

Do not use Transitional Members provided by other manufacturers.

Warning!

If you encounter one of the following malfunctions:

- Transitional Member and/or Connecting Tube does not fit into the respective receptacle of the Base Handle Assembly.
- Transitional Member and/or Connecting Tube moves roughly within their respective receptacle of the Base Handle Assembly.

Do not attempt to repair the device or its components. Do no longer use the device. Send it in for inspection immediately.

You may only use the device if it is fully functional and undamaged as described above. Please contact your authorized distributor or the manufacturer if this is not the case.

1.7.2 After Clinical Use of a DORO® Device

Perform the following function and safety tests after having used the device in clinical applications:

Make sure:

- that the device is complete and is not damaged. If the device appears to be damaged or does not seem to function properly, immediately send the device to the manufacturer or to your authorized distributor for repair.

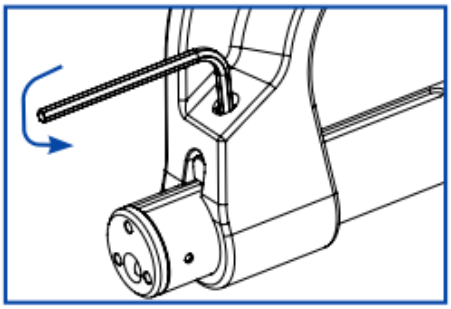
You may only use the device if it is fully functional as described above. Please contact your distributor or the manufacturer if this is not the case. For more information, please see chapter 3, Reprocessing and Maintenance.

2. Function

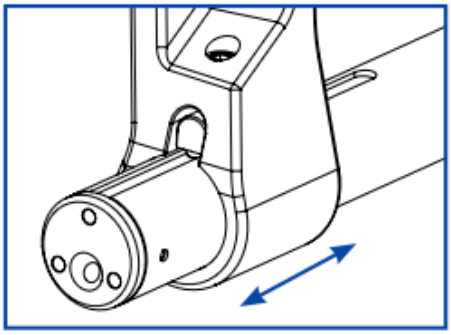
2.1 Function DORO® QR3 Headrest System

2.1.1 Attaching (mounting) the 3001-00 DORO® Adjustable Base Unit to the OR table

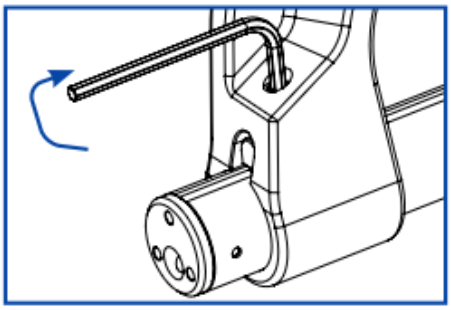
The QR3 Headrest System may be mounted / assembled with either
3001-00 / 3001-002 / 3001-001 / 3001-010 Base Units



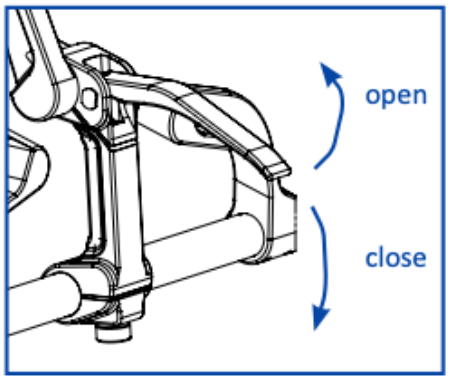
1. Position the Base Unit at the head of the OR Table with the Base Handle Assembly centered on the connecting tube.
2. Adjust the DORO Base Unit to a standard OR Table by using the Hex Wrench, loosen (do not remove) the Hex Screw at the Adjustable End Bracket by turning the Hex Screw counter-clockwise until the Adjustable End Bracket is loose.



3. Carefully slide the Adjustable End Bracket over the connecting tube to adjust the width of the table rods to the width of the receptacles of the OR Table.
4. Insert the two table rods into the receptacles of the OR Table to verify that the width match and the Base Unit is seated properly.



5. Using the Hex Wrench, lock the width by turning the Hex Screw clockwise. Once this adjustment is made for your OR Table, this step can be skipped in future use.

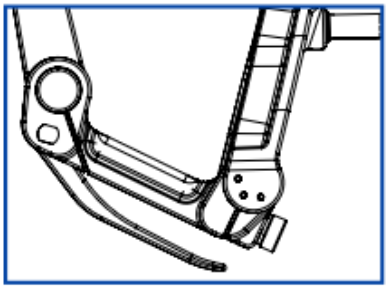


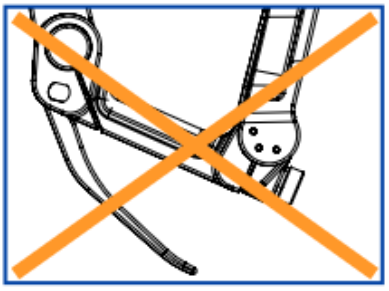
6. Position the Base Handle Assembly at the center of the connecting tube by opening the Locking lever. Make sure that the Transitional Member is connected to the Base Handle Assembly, otherwise connect the Transitional Member before closing. Close the Locking Lever to lock the position.
7. Ensure that all adjustable joints are tightly fastened and secured.

If you do not use the DORO Base Unit Parkbench, continue please chapter 2.1.4

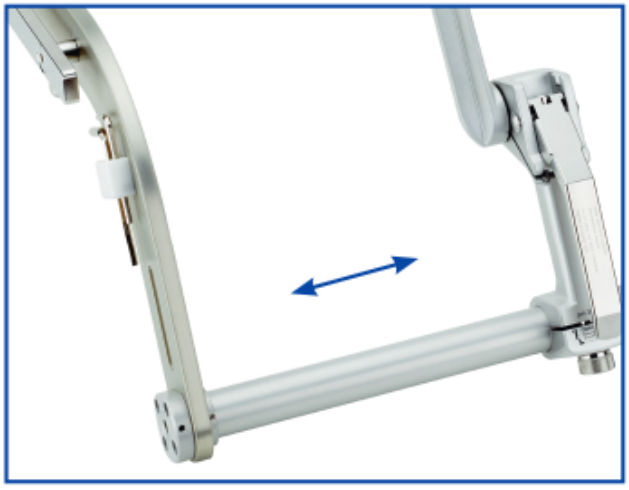
Please make sure that:

- the locking lever on the base handle assembly of the base unit is firmly locked as shown in the following figure, i.e., parallel with the base handle assembly,
- the transitional member is properly attached to the base handle assembly.



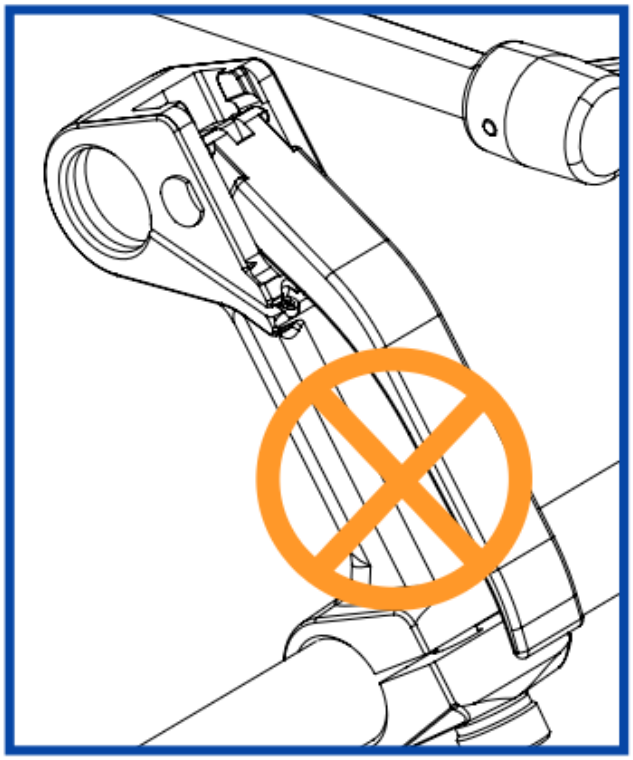


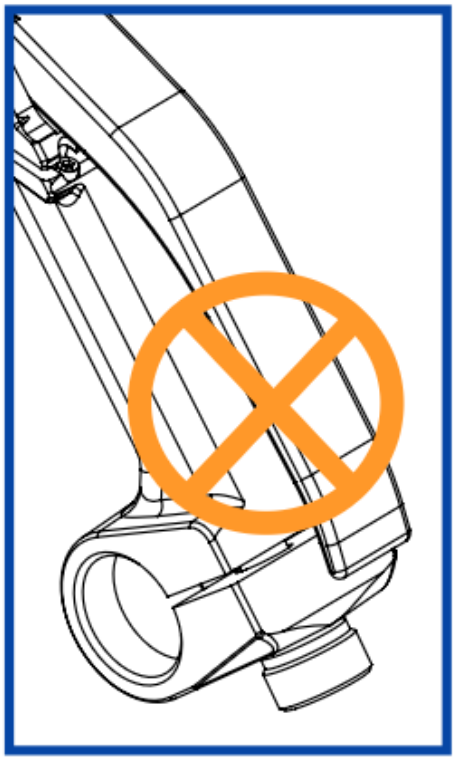
2.1.2 Alternative DORO® Base Unit Parkbench (3001-006): Attaching



1. Using the Hex Wrench, loosen (do not remove) all Hex Socket Screws by turning the Hex Screw counter-clockwise until the adjustable end bracket is loose.
2. Slip the two arms of the Base Unit onto the side rails of the OR table. Move the arms sideways (max. 80 mm) to adjust the widths of the Base Unit to the dimensions of the OR table.
3. Lock the Base Unit width by closing tight all Hex Screws.
4. Position the Base Handle Assembly at the center of the connecting tube by opening the Locking lever. Make sure that the Transitional Member is connected to the Base Handle Assembly, otherwise connect the Transitional Member before closing. Close the Locking Lever to lock the position.

Warning! Never close the Locking Lever without the Transitional Member and the Connecting Tube in place. This will damage the Base Handle Assembly.



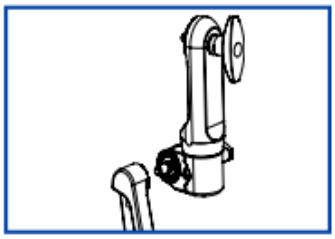


2.1.3 AlternativeDORO® Base Unit Parkbench (3001-006): Positioning

The Base Unit Parkbench is designed for patient positioning in prone, supine and lateral positions. For lateral patient positioning, we recommend the Parkbench Armrest (item no. 3001-007) connected to the side rail with the Universal Side Rail Fitting (item no. 3007-50).

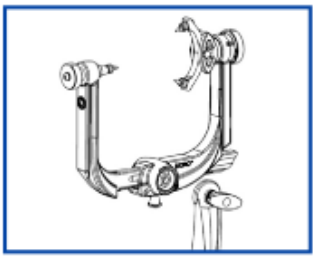
The DORO® Base Unit Parkbench set up for lateral positioning.

2.1.4 Mounting the DORO® Swivel Adaptor (3002-00)



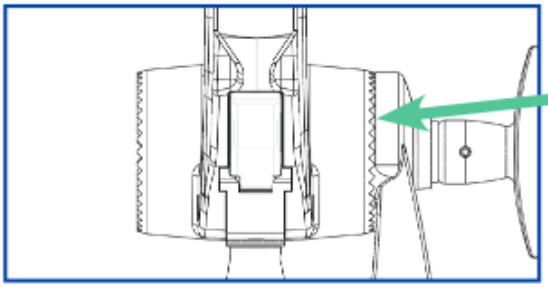
1. Position the teeth of the starburst connection of the Transitional Member and the teeth of the lower starburst connection of the Swivel Adaptor in a manner that they engage.
2. Fully tighten the lower locking screw of the Swivel Adaptor by turning it clockwise. The teeth of the starburst connections must be fully engaged and seated properly.

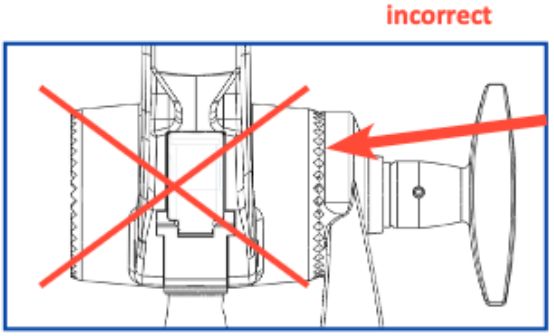
2.1.5 Mounting the DORO® Skull Clamp (1001.001)



1. Position the teeth of the upper starburst connection of the Swivel Adaptor and the teeth of the starburst connection of the Skull Clamp in a manner that they engage.
2. Position the Skull Clamp as desired.
3. Fully tighten the upper locking screw of the Swivel Adaptor by turning it clockwise.

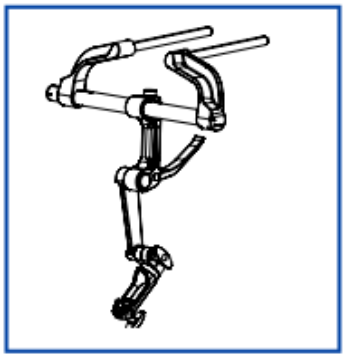
Note: The teeth of the starburst connections must be fully engaged and seated properly.





2.1.6 Workflow for positioning the patient in the DORO® QR3 Headrest System

2.1.6.1 Preparing the Base Unit and the Swivel Adaptor for application



For easy application, we recommend that the Transitional Members and the Swivel Adaptor are loosely connected (not fully tightened) and the Swivel Adaptor is hanging loose and pointing to the floor. Make sure to leave enough space between the teeth of the starburst to prevent them from grinding against each other when hanging loose.

2.1.6.2 Secure the patient's head to the Skull Clamp - Pinning

Warning!

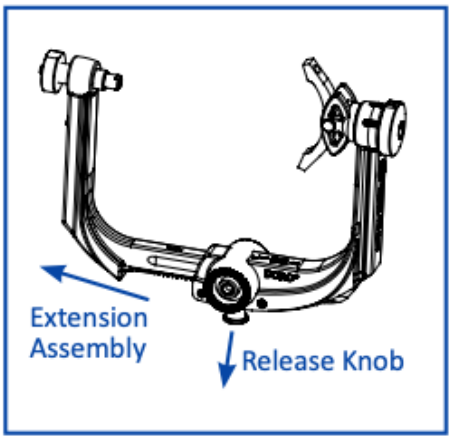
Only DORO® Skull Pins are validated for use with DORO® Skull Clamps.

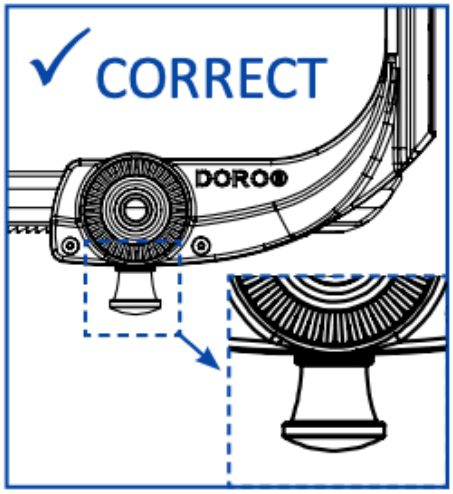
Insert the Skull Pins into the receptacles of the Skull Clamp. (Please refer to instruction manual Skull Pins).

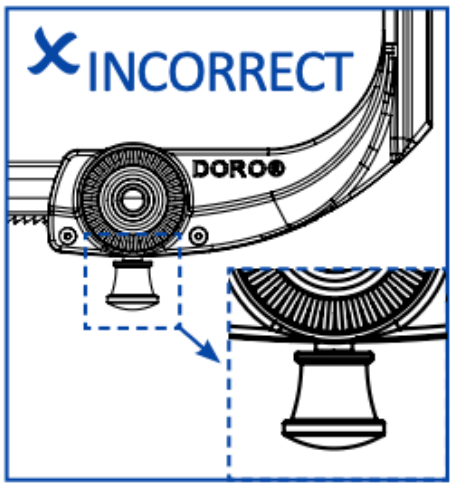
Adjusting the required Skull Clamp width:

1. Pull down the Release Knob at the Skull Clamp base and pull the Extension Assembly away from the Skull Clamp base to widen the Skull Clamp.

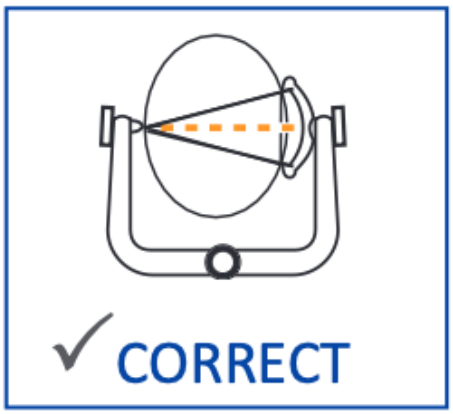
2. Place the patient's head in the desired position within the Skull Clamp. Push the Extension Assembly carefully into the Skull Clamp Base to reduce the Skull Clamp width.

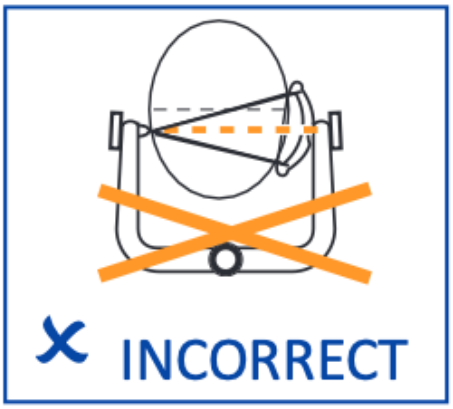






3. When you have obtained the desired width, make sure that the Release Knob is fully back against the skull clamp base.

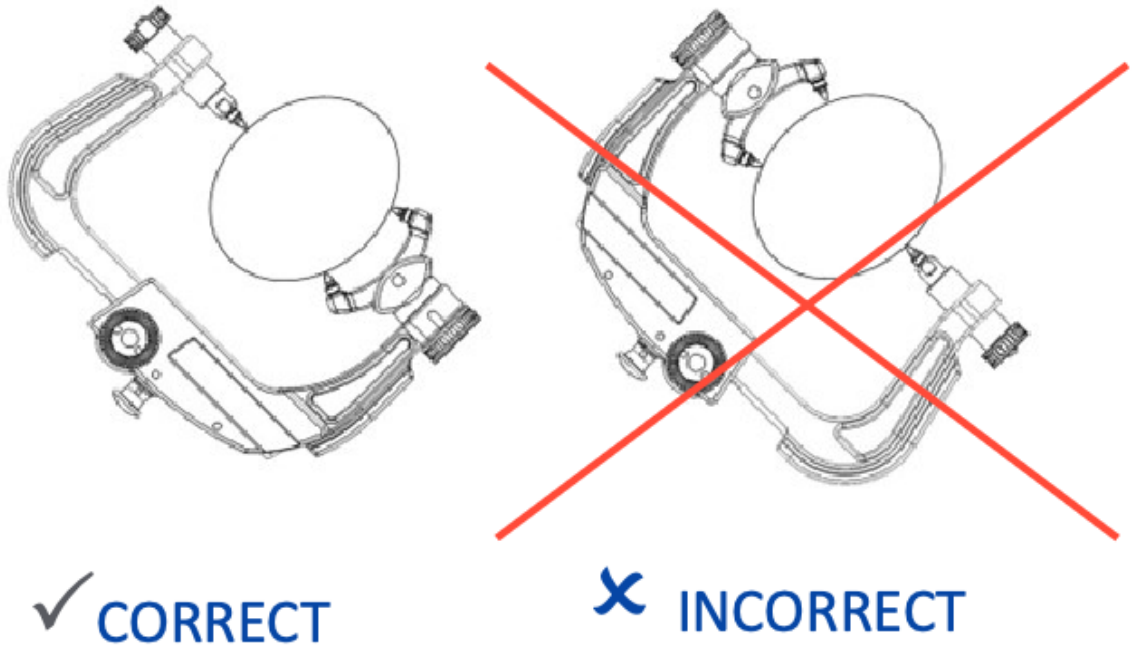


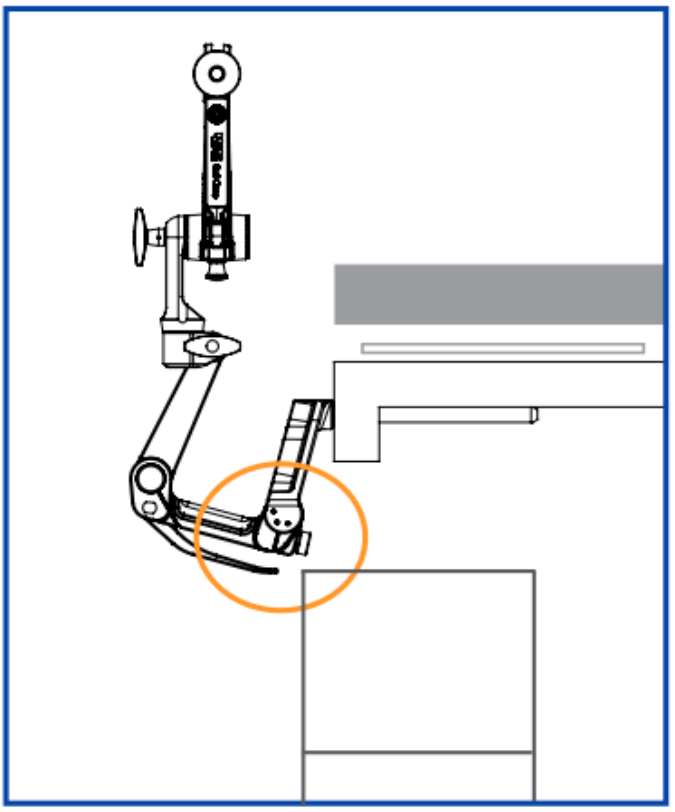


4. Adjust the Skull Clamp to the width of the patient's head in the manner that the two Skull Pins in the rocker arm are equidistant from the centerline of the head and the single Skull Pin at the Extension Assembly is in line with this centerline.

5. Adjust the Rocker Arm to the desired position.

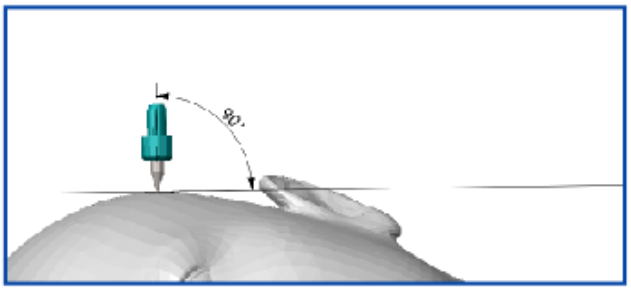
Warning! Make sure that the fixed extension arm with the **two pin holder** supports the weight of the patient's head if a repositioning of the skull clamp in a vertical orientation is necessary. Otherwise, the risk of slippage will be increased.





Warning!

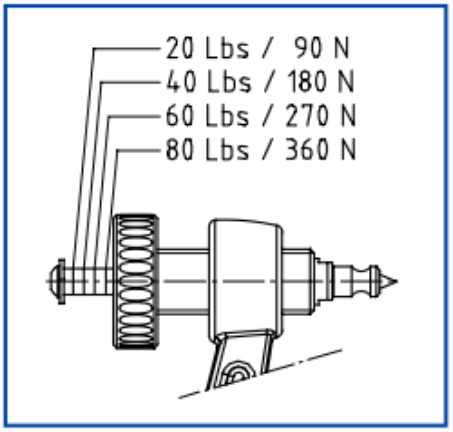
Take particular care when utilizing a DORO Headrest System on a surgical table system with a stationary column and removable table top. A patient fixated in a DORO system on such a table top must not be transferred to or from the column. This might cause severe injuries in case of collision.



6. Turn the torque screw in order to drive the Skull Pins at an angle of 90 degrees into the patient's head (please also refer to the instruction manual Skull Pins).
7. Ensure proper position of the Skull Pins.

Warning!

Angles other than around 90° may cause the system to become unstable and may result in serious injury to the patient.



8. Adjust the clamping force by means of the torque-screw. The adjusted clamping force is readable at the scale in stages up to 360 N/80 lbs (maximum setting). The visible scale stages are 90/180/270/360 N or 20/40/60/80 lbs.
9. If necessary, readjust the clamping force. Turn the torque screw clockwise to increase the clamping force.

The pinning of the patient should only be performed by a licensed clinical professional.

The risk of unintentional head movement (slippage) is increased with lateral forces on the skull pins. Take extra care when putting traction on the head by means of the skull clamp, as it frequently occurs in, but is not limited to, posterior cervical fusion surgery.

Take extra precautions when pinning young infants, the elderly, or on restored surgical areas, including previously drilled burr holes, or any diseased bone because of the varying consistencies and thickness from that of healthy bone. It is the responsibility of the user to select the proper type of fixation and the correct clamping pressure in view of the skull thickness and bone structure of the patient's head. For rigid fixation, ensure the proper position of the patient's head.

The distance of the skull pin from the Rocker Arm below to the centerline of the head should be equal to or greater than the distance of the upper pin to the centerline of the head. The angle of the pins should be as close to 90 degrees possible to the patient skull. Use the proper clamping force.

The user decides which type of fixation and what clamping force are required, based on the thickness of the skull and the bone structure. Therefore: refer to the instruction manual Skull Pins. For pediatric cases we recommend the DORO® Multi-Purpose Skull Clamp with 4-point fixation or non-invasive gel pads.

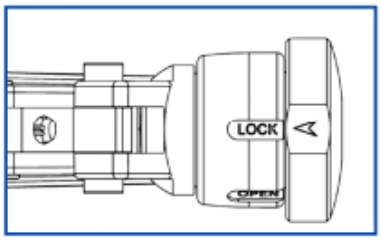
Positioning the skull pins incorrectly can lead to serious injuries to the patient. Therefore: Avoid sensitive areas like the frontal sinus, temporal fossa, blood vessels or nerves. Amongst other things, when positioning patients with skull pins, a venous blood vessel can be damaged by a skull pin. This damage causes the risk of a venous air embolism. Researches of literature show that the risk of a venous air embolism is increased by a difference in level between the patient's heart and head (head level higher than the heart). If the skull pins are removed in such a patient position, air can enter through a vessel damaged by a skull pin. Measures for avoiding a venous air embolism are very situation dependent. The decision about whether and which measures are sensible and to be implemented are the responsibility of the user.

The DORO® Skull Clamp may cause damage to the patient's skull. The head may fall out of the Skull Clamp or the Skull Pins may break through into the brain if using an incorrect clamping force. It is absolutely necessary to follow the instruction of the surgeon, when defining the clamping force to be applied.

Avoid inadvertent opening of the Release Knob of the Skull Clamp during procedure.

2.1.6.3 Connecting the Skull Clamp to the Swivel Adaptor

1. After securing the patient's head to the Skull Clamp, position the patient's head exactly as required for surgery and stabilize the head. Carefully hold the patient's head and Skull Clamp while proceeding.
2. Connect the Skull Clamp to the Base Unit by means of the Swivel Adaptor: Position the teeth of the upper starburst connection of the Swivel Adaptor and the teeth of the starburst connection of the Skull Clamp in a manner that they engage.
3. Carefully hold Skull Clamp and Swivel Adaptor to prevent the system from losing its stability.
4. Fully tighten the upper locking screw of the Swivel Adaptor by turning it clockwise.
5. Ensure that the patient's head is in the required position. Tighten all adjustable joints starting with Skull Clamp then Swivel Adapter, Transitional Members and Base Unit and receptacles of the OR Table.



6. Turn the Index Knob from "OPEN" until it fully engages in the "LOCK" position". Ensure that the Index Knob arrow is perfectly aligned with the "LOCK" marking. If there is significant resistance preventing the Knob from turning, return to the "OPEN" position, rotate the rocker arm slightly, and try again to engage the it in the "LOCK" position.

7. Check all adjustable joints starting with Skull Clamp, then Swivel Adapter, Transitional Members and Base Unit and receptacles of the OR Table.

8. If necessary, readjust the clamping force. Turn the torque screw clockwise to increase the clamping force.

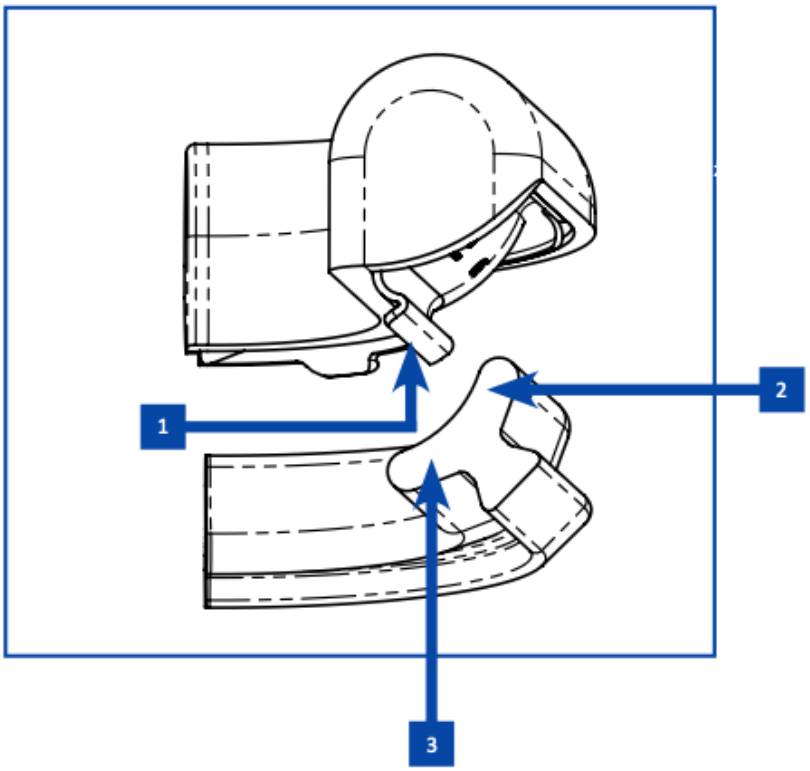
Warning!

Always stabilize the patient's head before adjusting the joints of the Headrest System in order to reposition the patient. Ensure that all connections are then tightly fastened and secured before proceeding. The teeth of the starburst connections must be fully engaged and seated properly.

2.2 Function and Workflow for Positioning the DORO® Swivel Horseshoe System

2.2.1 Mounting the 3008-10/-11 or 3009-10/-11 Horseshoe Pads

1. Pull the Horseshoe Pad over the outer edge 2 of the base and press it down until the long bracket 1 engages at the bottom edge 3 at the inside of the base.
2. Place the Horseshoe Pad over the outer edge of the base first and then push the Horseshoe Pad downwards on the inner side. If you do this procedure in the opposite way, you may be damaging the plastic base which is glued to the Horseshoe Pad on the outer side and this may cause the Horseshoe Pad to break.



2.2.2 Adjust and fix the Horseshoe (3009-01)

1. Position the teeth of the upper starburst connection of the swivel adaptor/table adaptor and the teeth of the lower starburst connection of the horseshoe headrest in a manner that they engage. Turn the upper locking screw of the swivel adaptor/table adaptor clockwise and position the horseshoe headrest as desired.

2. Tightly close the upper locking screw of the swivel adaptor/table adaptor.

3. Open the locking screw at the bottom part and position the moving part of the horseshoe headrest as required by the size of the patient's head as follows: Turn the locking screw counter-clockwise in order to loosen the moving half of the bottom part of the horseshoe headrest. Move this part of the base rod until the horseshoe obtains the desired width.

4. Make sure the horseshoe pads are properly attached to the bottom part. Tightly close the locking screw in order to lock the moving half of the horseshoe.
5. Close the starburst screw to attach the Horseshoe to the Swivel Adaptor.

2.2.3 Adjust the Swivel Adaptor/Base Unit

1. Move the patient to the position required for surgery.
2. Stabilize the patient's head.
3. Hold the Horseshoe Base in order to prevent the system from collapsing.
4. Open all the locking screws of all the adjustable joints of the DORO® system.
5. Adjust the Base Unit and the Swivel Adaptor as required.
6. Lock the joints of the Base Unit and the Swivel Adaptor.

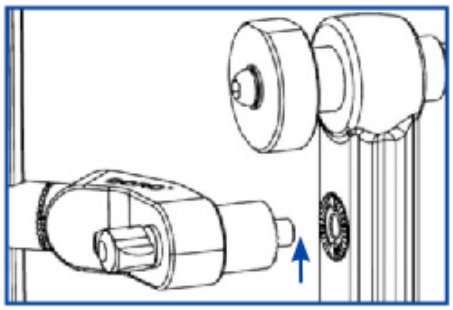
2.2.4 Placing the Patient's Head on the Horseshoe Headrest

Make sure that the pressure of the patient's head is evenly distributed on the Horseshoe Pads and that there is no lateral movement of the patient's head.

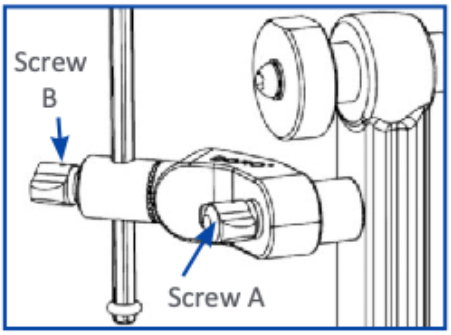
2.2.5 Optional: Mount the extension bar (3009-25)

1. The extension bar is used for spine traction. It can be mounted in various positions.
2. Mount the extension bar to the bottom part of the horseshoe base by means of the adjustment screw. Position the extension bar as required and then fully lock the adjustment screw by turning it clockwise.

2.3 Function DORO® Easy Connect Navigation Adaptors (1204.001/1204.002/1204.003)

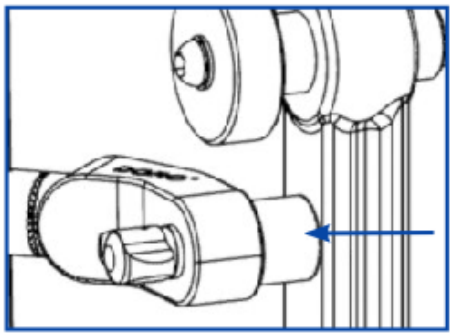


1. Connect the starburst of the appropriate Navigation Adaptor with the starburst on the Quick-Rail. Slightly tighten the Locking Screw A.



2. Position the Navigation Adaptor as required for surgery.

3. Securely tighten both Locking Screws (Screw A and B).



4. Make sure that the built-in starburst on the Quick- Rail engages properly with the starburst of the Easy Connect Navigation Adaptor.

The DORO® Navigation Adaptor serves as a holder for Navigation Tracking Devices and is directly mounted onto the starburst on the Quick-Rail of the DORO® QR3 Skull Clamp. Attach the appropriate Navigation Tracking Device directly to the rod of the appropriate DORO® Easy Connect Navigation Adaptor. If necessary re-position as required for surgery.

Item no. 1204.001 for Stryker

Item no. 1204.002 for Brainlab

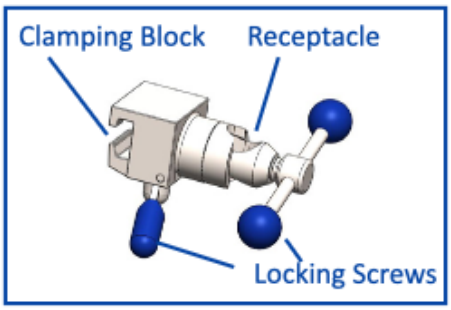
Item no. 1204.003 for Medtronic

2.4 Function Accessories

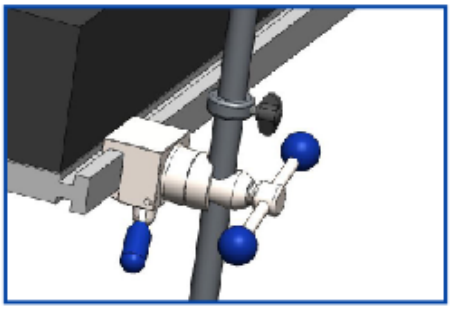
2.4.1 Function DORO® Crossbar Adaptor (3007-00)

The Crossbar Adaptor serves as a holder for the DORO® Headrest System. The DORO® Headrest System allows an extremely flexible positioning of the patient's head as required by the surgical application, e.g. sitting position.

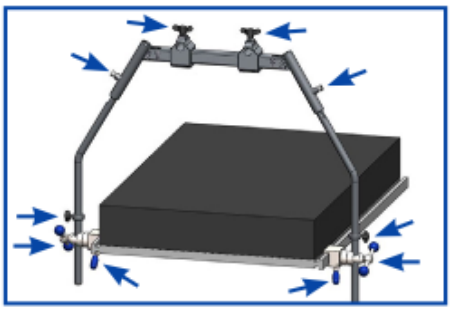
2.4.1.1 Mounting the DORO® Crossbar Adaptor



Connect two Universal Side Rail Fittings (item no. 3007-50) to the both side rails of the OR table. For a secure and stable fit make sure that the clamping blocks fully enclose the side rails and that the locking screw is under the OR table.



Insert the guiding rods of the Crossbar Adaptor into the receptacles of the two Universal Side Rail Fittings.



Open all the screws to adjust the Crossbar Adaptor in a suitable position for the patient and surgical approach. Close all locking screws tightly. Utilize the large Hex Wrench for Crossbar Adaptor (Item no. 7010-03-021) to lock the Threaded Pin at the top of each guiding rod. Then, close all locking screws tightly by hand and the one in the middle with the large hex wrench.

Setup with attached Crossbar Adaptor.

Warning!

Do not touch the operating table support areas or moving parts when adjusting the unit.
Parts which point downward (such as leg plates, accessories) may collide with other objects when you adjust the system. Ensure that hoses, OP tissues, etc. cannot be caught between moving parts of the unit.

2.4.2 Function DORO® Side Rail OR Table Adaptors (3011-00 + 3011-10)

The Side Rail OR Table Adaptor can be used with the DORO® Base Units and Adaptors listed in this IFU. It is part of a mechanical support system used for head surgery. The Side Rail OR Table Adaptor is mounted to the Side Rails of the OR Table. It was designed to mount the DORO® Base Units and Adaptors to OR Tables lacking rod slots.
The Side Rail OR Table Adaptors can be used with the following Base Units:

- 3001-00 DORO® Adjustable Base Unit
- 3001-009 DORO® Adjustable Base Unit Teflon®

2.4.2.1 Adjusting the width of the Side Rail OR Table Adaptors

1. Using the Hex Wrench, loosen (do not remove) the Hex Screws by turning them counter-clockwise until each Side Rail Bracket Base can be moved along the guide.
2. Carefully slide the Side Rail Brackets onto the Side Rails of the OR Table to adjust the width of the Adaptor to the OR Table.
3. Make sure that the Adaptor fits properly.
4. Using the Hex Wrench, lock the width by fully tightening all Hex Screws. Once this adjustment is made for your OR Table, this step can be skipped in future use.

2.4.2.2 Mounting the Side Rail OR Table Adaptor to a standard OR Table

Slide the Side Rail Brackets onto the Side Rails on the head end of the OR Table as required for surgery. Securely lock by turning both Locking Screws A clockwise.

2.4.2.3 Mounting the recommended Base Units

Fully insert the Table Rods of the Base Unit into the Receptacles for Base Unit Table Rods. Securely lock by turning both Locking Screws B clockwise.

3. Reprocessing and Maintenance

Before initial and each use, make sure to reprocess the product according to the instructions given on the following pages. The products in this IFU can be divided into the following groups, which have each a different reprocessing process.

3.1 Manual Cleaning/Disinfection

Reference	Name
1001.001	DORO® QR3 Skull Clamp
3001-00	DORO® Adjustable Base Unit
3002-00	DORO® Swivel Adaptor
3001-001	DORO® Adjustable Base Unit Takara Belmont
3001-002	DORO® Adjustable Base Unit Mizuho
3001-006	DORO® Base Unit Parkbench
3001-010	DORO® Base Uit Eschmann T-Series
3007-00	DORO® Crossbar Adaptor
3008-10/-11 3009-10/-11	DORO® Horseshoe Pads *For more information see Instructions for Use "RDL Headrest Systems and Accessories"*
3009-01	DORO® Horseshoe Base without extension arm
3009-25	DORO® Extension Bar Horseshoe
3010-00	DORO® Table Adaptor
3011-00	DORO® Side Rail Adaptor
3011-10	DORO® Side Rail Adaptor Amsco

Manual Cleaning

- Cleaning and rinsing must take place immediately after each use for best effect. Failure to clean promptly may result in adherent particles or dried secretions that may resist cleaning and complicate or resist future cleaning.
- Do not use a fixating detergent or hot water (>40°C/104°F) as this can cause the fixation of residual which may influence the result of the reprocessing process. Devices must be completely cleaned and rinsed of all foreign matter.
- Storage and transport of the device to the reprocessing location must be ensured in a sealed container to avoid any damage to the device and any contamination of the environment.
- Cleaning detergent: mildly alkaline cleaner safe for all types of surgical grade stainless steel, aluminum, Teflon (Polytetrafluoroethylene) and high performance polymer materials or with a manufacturer's approved detergent designed for use with stainless steel, aluminum, Teflon and high performance polymer materials (like 0,5% neodisher MediClean, Dr. Weigert).
- Disassemble all components as described in chapter 2, Function. Remove gross soil by using paper wipes.
- Prepare the cleaning solution (like 0,5% neodisher MediClean, Dr. Weigert) per the cleaning solution manufacturer's instructions.
- Soak soiled instruments for 5 minutes.
- Use a soft nylon bristle brush to scrub all exposed surfaces thoroughly under running tap water until all traces of blood and debris are visually removed. Take extra care around threads, lumens, crevices, seams and any hard to reach areas.
- If the device has sliding mechanisms or hinged joints, actuate the area to free any trapped blood and debris. Brush delicate features of the instruments with care to avoid bending or breaking of such features.
- Using a syringe filled with cold tap water, flush internal areas that cannot be accessed with a brush for at least 20 seconds with a static water pressure of at least 4.2 bar.

- Rinse each component thoroughly under warm running tap water until all visible traces of detergent are removed. Rinse all lumens, internal areas, sliding mechanisms, and hinged joints, actuating sliding mechanisms and hinged joints while rinsing.
- Manual Cleaning as described above must be followed by a disinfection procedure.

Never use an automated washer/disinfector or steam sterilize these devices. If you autoclave the device, the heat will damage the internal components and may damage the exterior finish.

Following these steps, go on to chapter 3.4 Lubrication.

3.2 Manual Pre Cleaning + Automated Cleaning in a washer/disinfector

Reference	Name
1001.001	DORO® QR3 Skull Clamp
3001-00	DORO® Adjustable Base Unit
3001-001	DORO® Adjustable Base Unit Takara Belmont
3001-002	DORO® Adjustable Base Unit Mizuho
3001-006	DORO® Base Unit Parkbench
3001-010	DORO® Base Uit Eschmann T-Series
3002-00	DORO® Swivel Adaptor
3007-00	DORO® Crossbar Adaptor
3009-01	DORO® Horseshoe Base without extension arm
3009-25	DORO® Extension Bar Horseshoe

We recommend manual cleaning of the device. An automated cleaning procedure may be used secondary, but is not required or recommennded for routine reprocessing. Repeated automated reporcessing has negative effects on the device.

Automated Cleaning

Place the precleaned and dismantled products in an OR rack and start the automated cleaning and disinfection procedure:

1. 2 min pre-washing with cold water.
2. Drain.
3. 5 min cleaning with mildly alkaline cleaner (like 0,5% neodisher MediClean, Dr. Weigert) at 55°C/131°F.
4. Drain.
5. 3 min neutralizing with cold water.
6. Drain.
7. 2 min intermediate rinsing with cold water.
8. Drain.

Thermal Disinfection has to be processed according national requirements and to the A0 value according to ISO 15883. Dry immediately after final rinse. Use the drying cycle of the washer/ disinfector and – if required – a clean lint-free cloth for drying. Dry internal areas with filtered compressed air, if available. Inspect each component for remaining debris; if any are present, repeat cleaning procedure using fresh detergent.

Never steam sterilize these devices. If you autoclave the device, the heat will damage the internal components and may damage the exterior finish.

Following these steps, go on to chapter 3.4 Lubrication.

3.3 Manual Pre Cleaning and Automated Cleaning in a washer/disinfector and Sterilization

Reference	Name
3003-009	DORO® QR3 Skull Clamp Teflon
3001-009	DORO® Adjustable Base Unit Teflon
3002-009	DORO® Swivel Adaptor Teflon
1204.001	DORO® Easy-Connect Navigation Adaptor, STRYKER
1204.002	DORO® Easy-Connect Navigation Adaptor, BRAINLAB
1204.003	DORO® BEasy-Connect Navigation Adaptor, MEDTRONIC

These devices must first be manual pre-cleaned, automated cleaned and disinfected as described above. **Following these steps, go on to chapter 3.4 Lubrication.** After that, these items may be steam sterilized:

Steam Sterilization

Follow the sterilizer manufacturer's instructions for operation and loading of steam autoclaves. There must be direct steam exposure to all surfaces of the device being sterilized including the internal surface and tubes channels. Allow devices to air cool to room temperature before use.

This product was validated by steam sterilization

- with sterilization case
- double wrapped
- prevacuum (3 vacuum pulses at a pressure of at least 60 mbar)
- minimum 132°C / 269.6°F
- minimum 4 minutes hold time (complete cycle)
- drying time at least 10 min

Medical Facilities should follow the Standard guidelines that are appropriate for their country in accordance with ISO 13060/ ISO 17665 and follow the sterilizer manufacturer's instruction for loading and operating the sterilizer with the appropriate temperatures and sterilization times. Other sterilization methods and cycles may be used. The product components are guaranteed to withstand a sterilization temperature up to 137°C/278.6°F. However, it is advisable that facilities validate the alternative method using appropriate standards.

Important: Autoclave temperatures should not exceed 137°C/278.6°F; handles, insulation or other parts may be damaged. Do not sterilize with hot air.

3.4 Lubrication

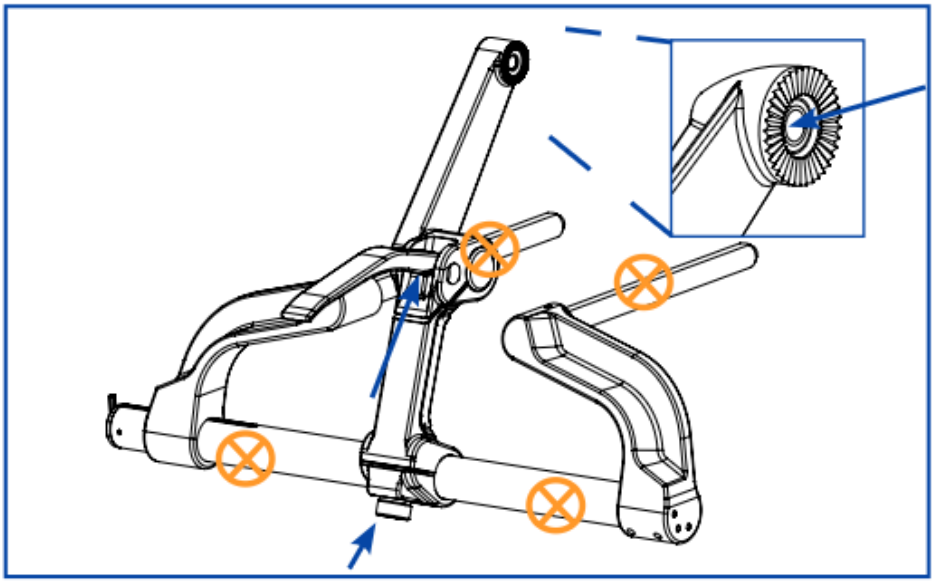
Devices without subsequent lubrication drawings do not have to be lubricated.

Lubrication according to the subsequent lubrication drawings should be done after every wash. Failure to lubricate the headrest and retractor system as recommended will significantly reduce the life of the equipment and may affect its function. You can lubricate with any medical grade lubricant.

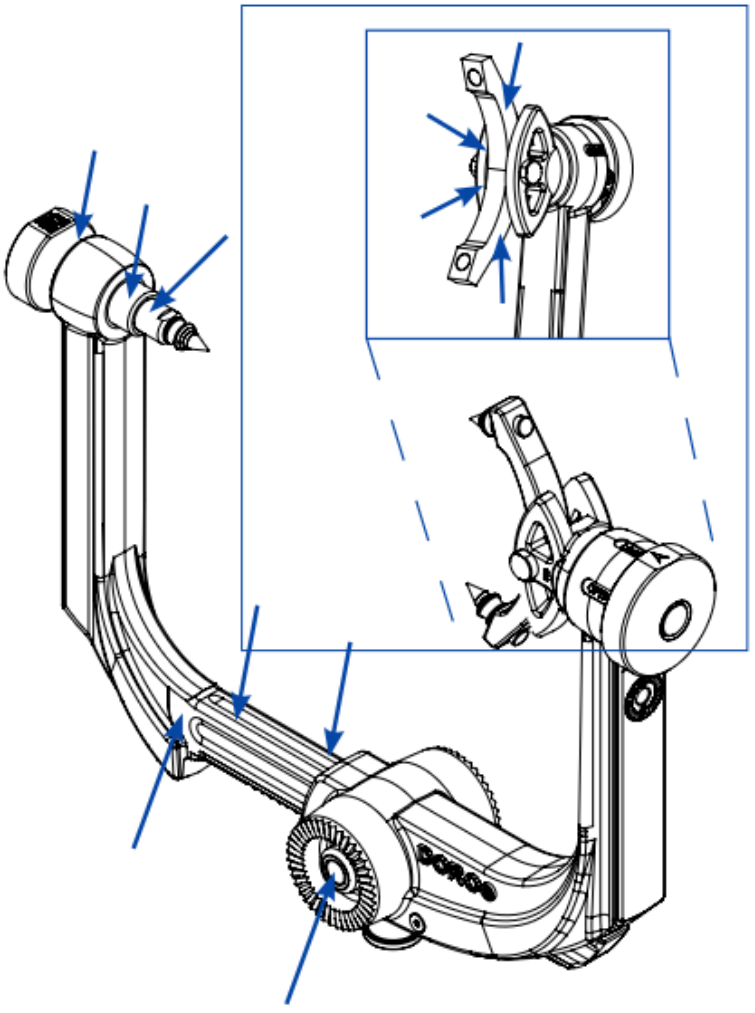
Parts that should be lubricated are marked with a blue arrow

Parts that should never be lubricated are crossed out.

3.4.1 Lubrication Base Unit

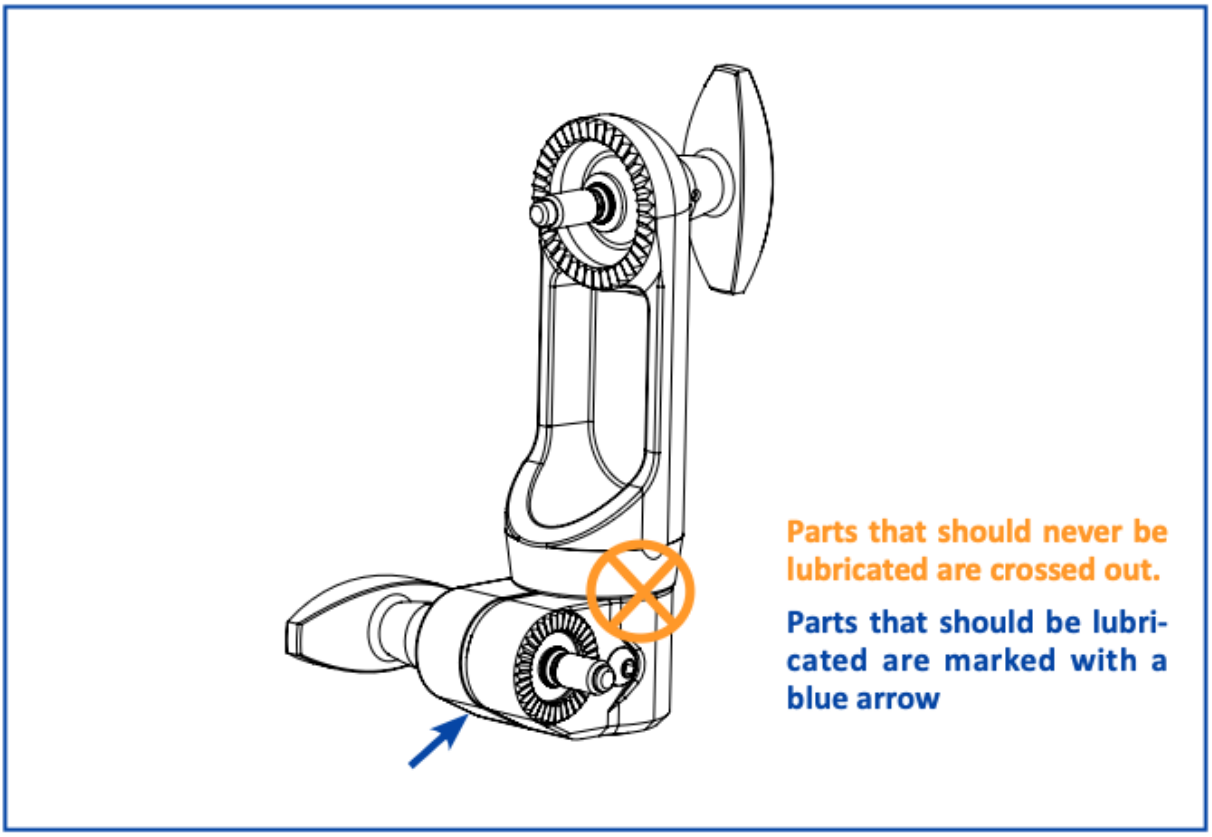


3.4.2 Lubrication Skull Clamp

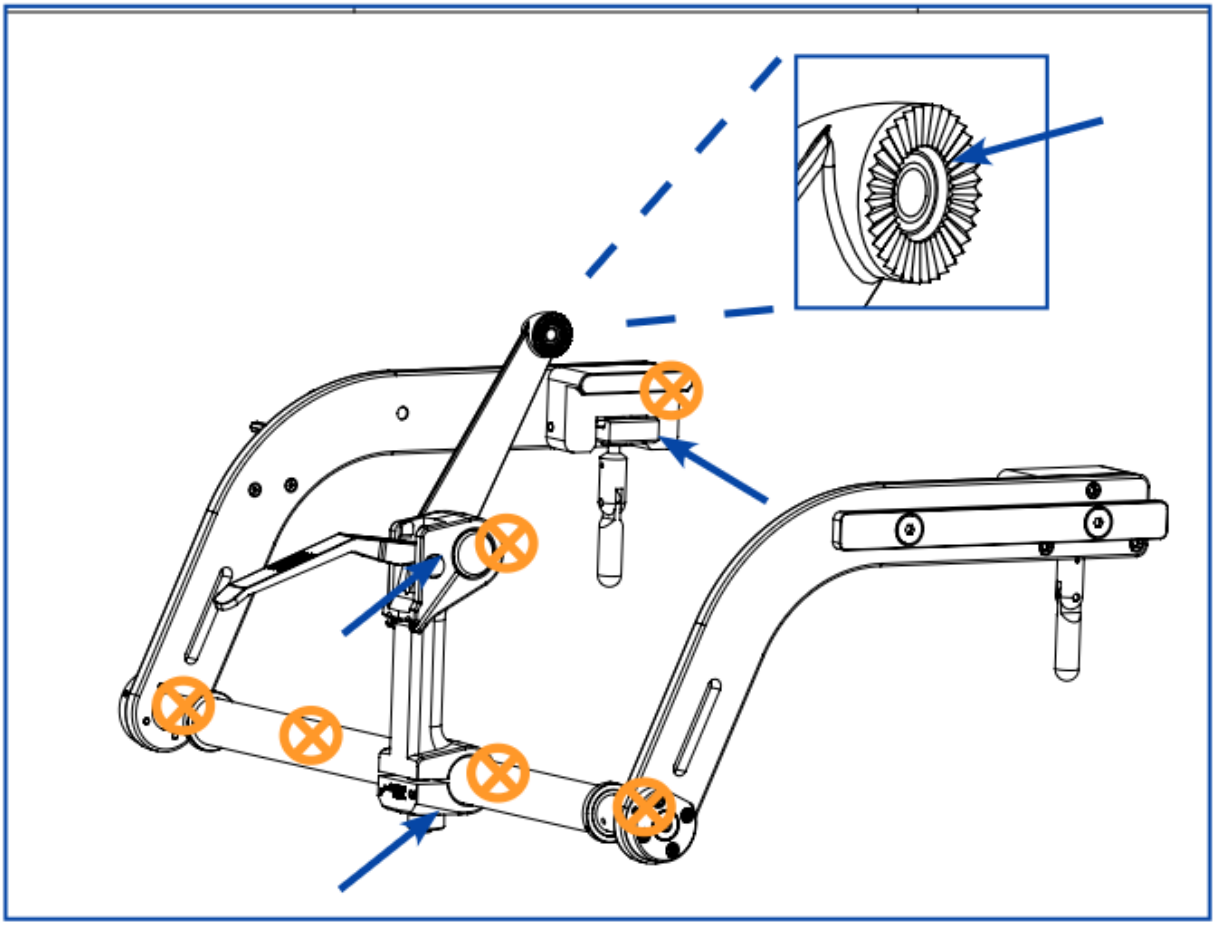


Parts that should be lubricated are marked with a blue arrow

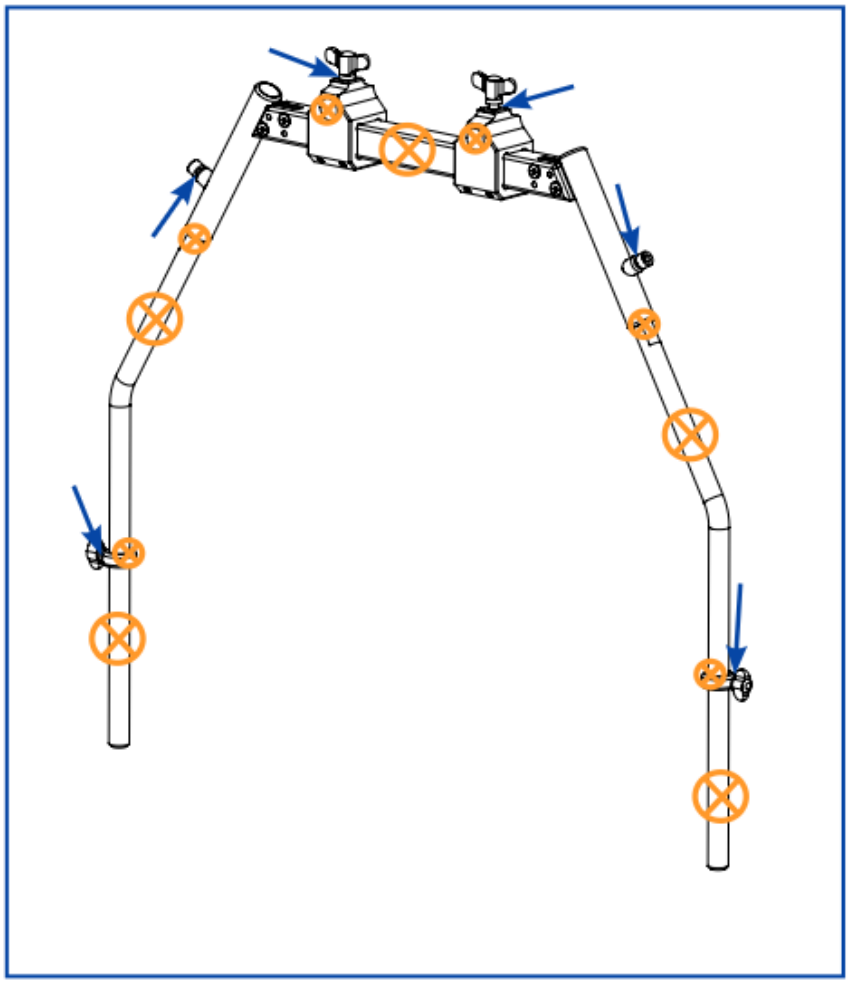
3.4.3 Lubrication Swivel Adaptor



3.4.4 Lubrication Base Unit Parkbench



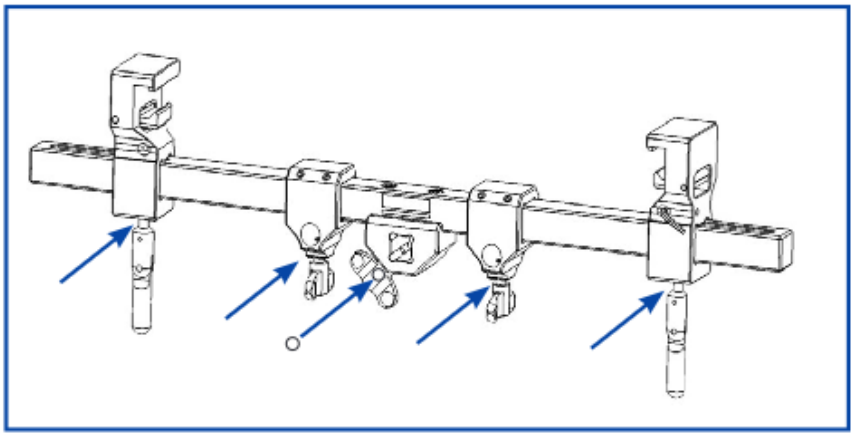
3.4.5 Lubrication Crossbar Adaptor



Parts that should be lubricated are marked with a blue arrow

Parts that should never be lubricated are crossed out.

3.4.6 Lubrication 3011-XX Side Rail Adaptors



3.5 Storage

Store the device in a clean, dry, moisture free area.

3.6 Maintenance

The purchaser shall be obliged to send the device to the manufacturer or to the authorized distributor once a year for preventive maintenance. The manufacturer will perform all required work.

Due to safety reasons, only thoroughly cleaned products must be sent back to the manufacturer. Completely reprocess the device as described in this manual. Please refer to the appendix to this instruction manual for the address of the manufacturer or the authorized distributor. Non-compliance to annual maintenance may lead to serious injury of the patient or user.

4. Environmentally Compatible Disposal

The purchaser or user is responsible for rendering the device unusable if it is no longer to be applied (prevention of misuse).

Disposal:
Segregate the components of the device according to material (e.g. aluminum, high performance polymer materials, etc.) for recycling. You can return old devices to the manufacturer or authorized distributor.

5. General Information

5.1 Damaged Packaging

Please contact your distributor or the manufacturer if packaging is damaged.

5.2 Creutzfeldt Jakob Disease

Warning!

If the patient is suspected of having the Creutzfeldt Jakob Disease, adequate measures must be taken to prevent possible transmission to other patients, users, and third parties. The device also should not be reused with any other patient. Please consult individual national infection control/prevention protocols for specific guidance regarding processing medical devices with suspected exposure to Creutzfeldt Jakob Disease.

5.3 Regulatory Information

5.3.1 CE Conformity

CE mark:
Declaration of manufacturer under sole responsibility that the medical device meets all the provisions of the Regulation (EU) 2017/745.

5.3.2 FDA registration

FDA cleared.

Note:
Caution: Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician.

5.4 Manufacturer Information

Manufacturer: **Black Forest Medical GmbH (registered as pro med instruments GmbH – duration of transition period is country specific)**

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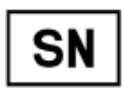
DORO® devices are protected by one or multiple patents. Patents related to DORO® products are listed at www.blackforestmedical.com

We do not accept liability for combinations of products other than those listed in these instructions for use.

5.5 Symbols used for Safety Information

This instruction manual contains the basic information required for the safe use of the device. The symbols explained below might be used in this instruction manual and/or on the product labels to point out safety-relevant information:

	**Warning:** This symbol indicates a warning for the potential danger to patient and user as well as important information on the proper use of the device.
	**Note:** This symbol provides tips concerning the use of the device. Such information will help you use the device to its full potential.
	**Consult instructions for use:** Read operating instructions!
	**Manufacturer:** Manufacturer's name and address.
	**Date of manufacture:** Printed on package!
	**Non-Sterile:** Product provided non-sterile.
	**MR unsafe:** an item that is known to pose hazards in all MR environments.
	**Item number:** Printed on package or product.
	**Medical device:** Printed on label.
	**Serial number:** Printed on package or product.

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