October, 2019

Confirmation

Dear Ladies and Gentlemen,

We hereby confirm that the Maquet product numbers 1005.50A0, 1005.51A0, 1005.52A0, 1005.56A0, 1005.53B0 and 1005.53A0 correspond to following products from PMI / DORO as listed below.

- 1005.50A0 = 3001-00 (PMI / DORO reference product number)
- 1005.51A0 = 3002-00 (PMI / DORO reference product number)
- 1005.52C0 = 1001.001 (PMI / DORO reference product number)
- 1005.56A0 = 3009-00 (PMI / DORO reference product number)
- 1005.53B0 = 3005-00 (PMI / DORO reference product number)
- 1005.53A0 = 3004-00 (PMI / DORO reference product number)

Best regards

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BLACK FOREST MEDICAL GROUP

DORO® Headrest System Aluminum
Instruction Manual

Document no.:	**EN_IFU_1001.100**
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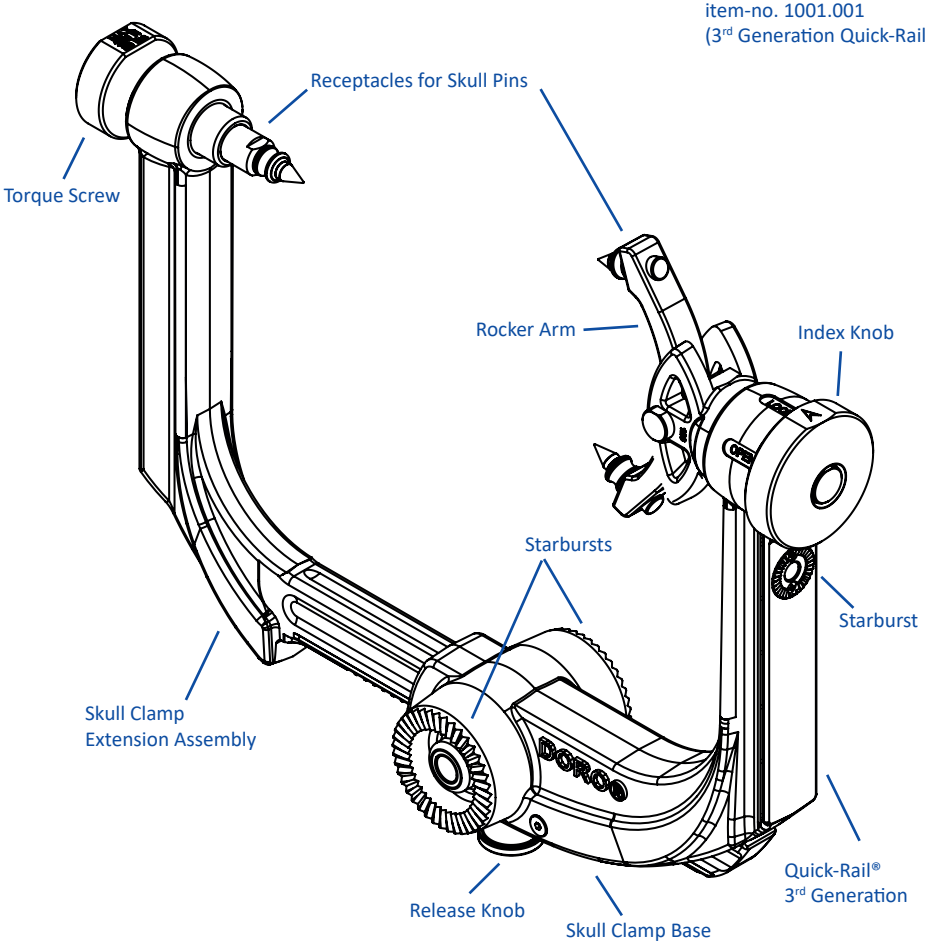
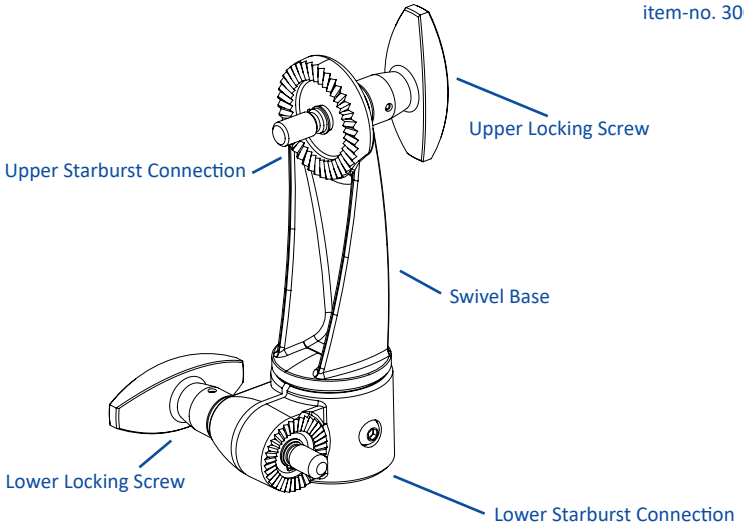
Last revision:	**2022-07-06**

1. Quick Guide

DORO® QR3 Skull Clamp,
item-no. 1001.001
(3rd Generation Quick-Rail®)



DORO® Swivel Adaptor Aluminum, item-no. 3002-00



DORO® Adjustable Base Unit, item-no. 3001-00

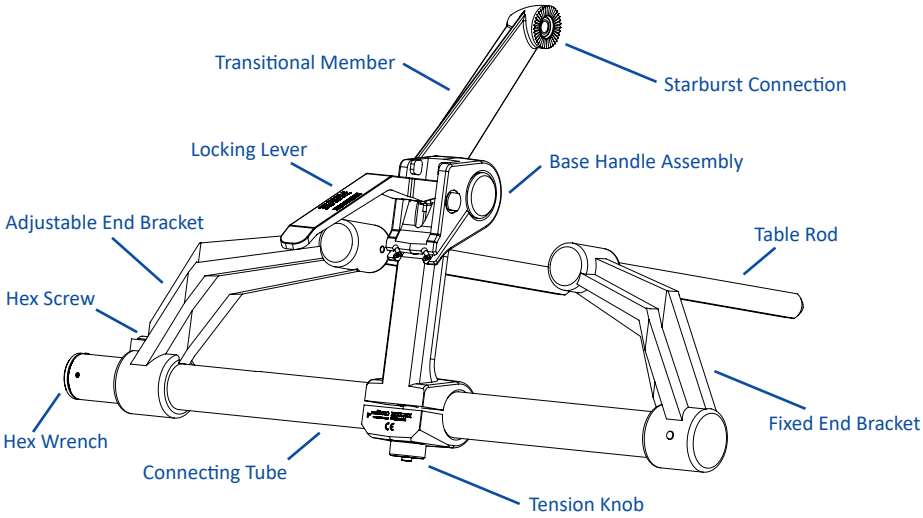


Table of contents

This instruction manual contains important information on the safe, correct and efficient use of the device. Carefully read this manual and observe all the notes and information. This instruction manual should be used in conjunction with the instruction manuals for your other equipment. Make sure to read those manuals very carefully as well. Always keep all the instruction manuals at hand.

2. Regulatory Information

2.1 CE conformity

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

2.2 FDA registration

FDA cleared.

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

3. General Safety Information

3.1 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:

Danger:
This symbol indicates a danger to the health of the patient. Failure to observe this information and to follow the appropriate instructions may result in serious injury to the patient and may even endanger the patient's life.

Warning:
This symbol indicates a danger of injury to the user of the device.

Important:
This symbol indicates important information on the proper use of the device. Failure to observe this information and to follow the appropriate instructions may cause damage to the equipment.

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!

Safe usage until:
Printed on package! Do not use after this date.

Non-Sterile:
Product provided non-sterile.

Sterile:
Sterilized with gamma radiation or ethylene oxide according to the label on the outside box.

Use only once:
Do not reuse! Destroy after usage!

MR safe:
an item that poses no known hazards in all MR environments.

MR conditional:
an item that may only be used in a MR environment with specific, defined conditions.

MR unsafe:
an item that is known to pose hazards in all MR environments.

Lot number:
Printed on package or product.

Item number:
Printed on package or product.

Medical device:
Printed on label.

Serial number:
Printed on package or product.

Keep away from sunlight:
Printed on package

Keep dry:
Printed on package

3.2 Proper handling and permitted user

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

3.3 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.

4. Basic Information

4.1 Warranty and liability

All warranty claims presuppose proper operation and treatment of the device. The manufacturer guarantees that all parts are free from defects in both materials and workmanship at the time of delivery.

4.2 Obligations of the purchaser

The purchaser must ensure that all users of the device are trained in the proper use of the device and fully understand all safety-relevant information.

- The purchaser shall be obliged to permit only trained staff, i.e. the OR team, to use the device.
- The purchaser shall also be responsible for storing this instruction manual in such a way that it is always available when the device is being used.

4.3 Use as per instructions

The device is designed and built according to the latest technical developments and to approved safety standards.

DORO® Headrest and Retractor Systems may be used

- only as a support mechanism for head and neck surgery,
- only if the device is in a proper state as far as the safety aspects are concerned.

Use as per instructions also implies

- that you follow all information furnished in this manual,
- that you clean and maintain the device as described.

4.4 Improper use

Improper use or use not conforming to the instructions contained in this manual may result in serious injuries or even death to the patient or the user and damage the device and other equipment.

5. Product description

5.1 Indication for use

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.

5.2 Contraindication

This product is not intended for use except as indicated above.

5.3 Target population

Not recommended for children under 5 years of age.

5.4 System components

The DORO® Headrest System Aluminum
consists of the following components:

Description:	**Item-no.:**
DORO® Adjustable Base Unit	3001-00
DORO® Swivel Adaptor Aluminum	3002-00
DORO® QR3 Skull Clamp	1001.001

5.5 Components description

5.5.1 DORO® Adjustable Base Unit

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 (item no. 3001-006).

Note:
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 (see instruction manual DORO® Crossbar Adaptor for mounting instructions).

5.5.2 DORO® Swivel Adaptor

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

5.5.3 DORO® Skull Clamp Aluminum

The Skull Clamp provides the receptacles for the Skull Pins which penetrate the patient's skull for rigid cranial fixation. (DORO® QR3 Skull Clamp, item no. 1001.001 and DORO® Skull Clamp (QR2), item no. 3003-00).

5.6 Additional components

5.6.1 DORO® Skull Pins

We recommend using the following skull pins with the Headrest System (please refer to instruction manual Skull Pins):

Description:	Item-no.:
DORO® Reusable Skull Pins, Stainless Steel, Adult	3005-00
DORO® Reusable Skull Pins, Stainless Steel, Pediatric	3004-00
DORO® Disposable Skull Pins, Stainless Steel, Adult	3006-00
DORO® Disposable Skull Pins, Stainless Steel, Pediatric	3006-10
DORO® Disposable Skull Pins, Titanium, Adult	3006-20
DORO® Disposable Skull Pins, Titanium, Pediatric	3006-30
DORO® Disposable Skull Pins, Stainless Steel, Adult	3006-50

5.6.2 Additional DORO® Base Units

Description:	Item-no.:
DORO® Adjustable Base Unit Takara Belmont	3001-001
DORO® Adjustable Base Unit Mizuho	3001-002
DORO® Adjustable Base Unit Mizuho, short	1001.023
DORO® Base Unit Eschmann	3001-003
DORO® Base Unit Parkbench	3001-006
DORO® Base Unit Australia	3001-008
DORO® Base Unit Eschmann T-Series	3001-010

5.6.3 Additional DORO® Swivel Adaptors

Description:	Item-no.:
DORO® Ball Pivot Adaptor	3002-50
DORO® Swivel Adaptor Navigation	3002-60

5.6.4 Additional DORO® Navigation Adaptors

(refer to instruction manual Navigation Adaptors):

Used with DORO® Skull Clamp 3003-00:

Description:	Item-no.:
DORO® Navigation Adaptor Quick-Rail®, Stryker®, Alu	3114-64
DORO® Navigation Adaptor Quick-Rail®, Medtronic, Alu	3114-65
DORO® Navigation Adaptor Quick-Rail®, Brainlab, Alu	3114-66

Used with DORO® Skull Clamp 1001.001:

Description:	Item-no.:
DORO® Easy Connect Navigation Adaptor, Stryker®, Alu	1204.001
DORO® Easy Connect Navigation Adaptor, Brainlab, Alu	1204.002
DORO® Easy Connect Navigation Adaptor, Medtronic, Alu	1204.003

5.6.5 Other additional DORO® components

Description:	Item-no.:
DORO® Quick-Clamp	1202.014
DORO® Quick-Clamp w/ Interface for Mizuho-Type Retractors	1201.045
DORO® Armrest Parkbench	3001-007
DORO® Crossbar Adaptor	3007-00
Universal Side Rail Fitting	3007-50
DORO® Table Adaptor	3010-00
DORO® Side Rail Adaptor	3011-00
DORO® Side Rail Adaptor Amsco®	3011-10
DORO® Amsco® Headrest Adaptor	3011-11
DORO® Cervical Spine Support	3012-00
DORO® Headrest Wall Storage Unit	3013-00

For more accessories and product pictures please refer to our DORO® Cranial Stabilization and Retractor Systems brochure or visit us at www.blackforestmedical.com.

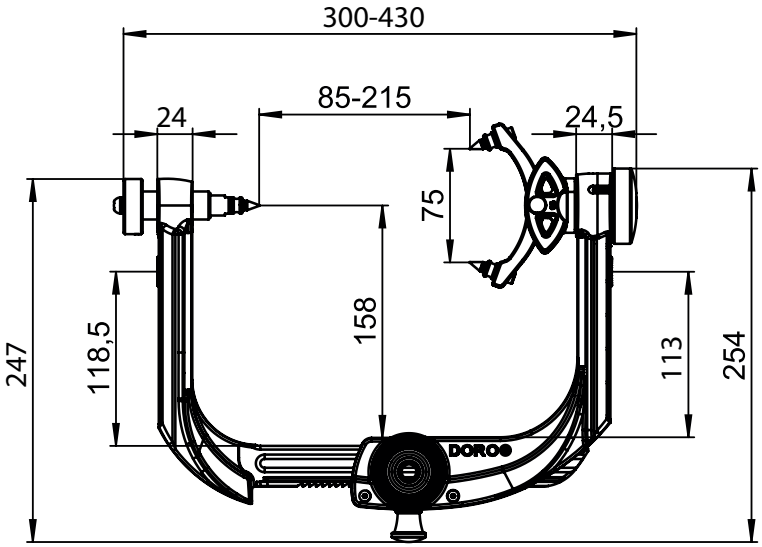
5.7 Technical specifications

Type of device:	DORO® Headrest System		
Serial number:	on each part.		
Weight:	3001-00 DORO® Adjustable Base Unit	3110 g	1.5
	3002-00 DORO® Swivel Adaptor	480 g	
	3003-00 DORO® Skull Clamp	1750 g	1.9
	1001.001 DORO® QR3 Skull Clamp	1700 g	
Material:	aluminum cast, stainless steel, high performance polymer materials		
Dimensions:	see outline drawings.		

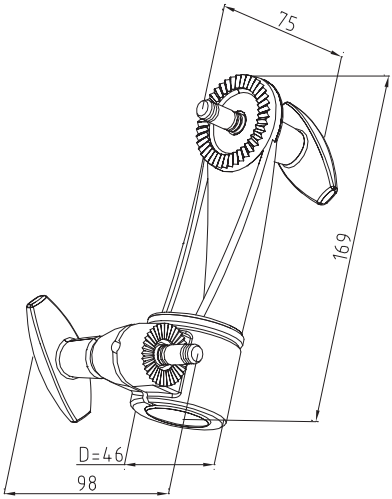
MR UNSAFE:
The DORO® QR3 Headrest System is MR Unsafe.

Important:
The DORO® QR3 Headrest System is not intended to be sterilized.

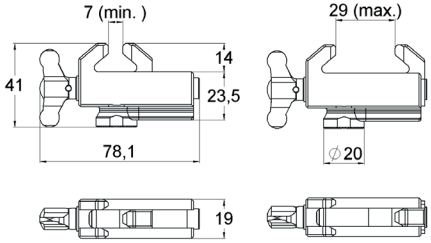
5.8 Outline drawings



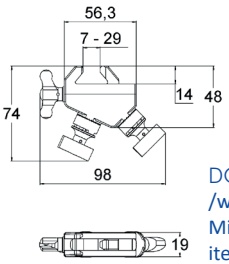
DORO® QR3 Skull Clamp, item no. 1001.001, in mm.



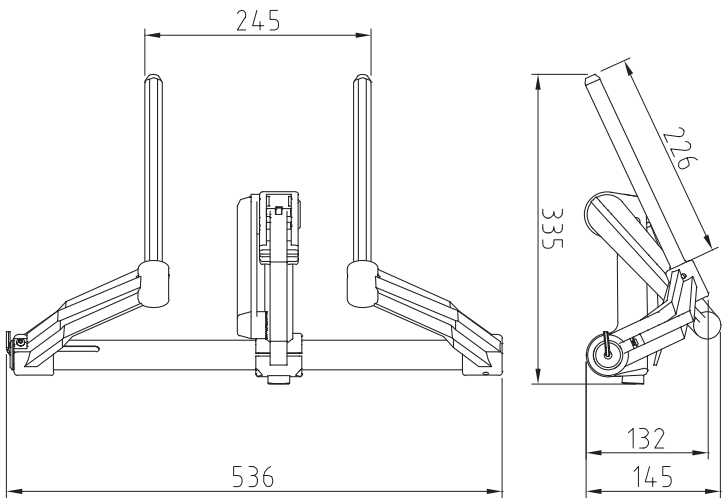
DORO® Swivel Aaptor, item no. 3002-00, in mm.



DORO® Quick-Clamp, item no. 1202.014, in mm.



DORO® Quick-Clamp /w Interface for Mizuho-Type Retractors, item no. 1201.045, in mm.



DORO® Adjustable Base Unit, item no. 3001-00, in mm.

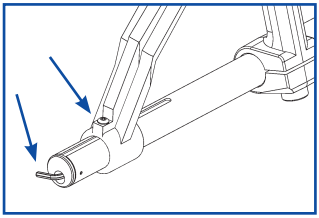
6. Mounting

6.1 Mounting of the DORO® Adjustable Base Unit

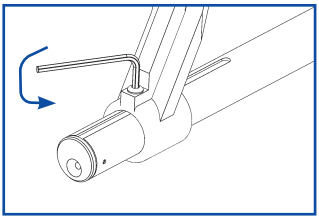
The DORO® Base Unit is mounted to the receptacles of the OR Table. Since the distance between the receptacles of OR Tables vary, the distance of the end brackets need to be adjusted. Inspect all parts prior to use for any noticeable damage i.e. cracking, surface defects etc.

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

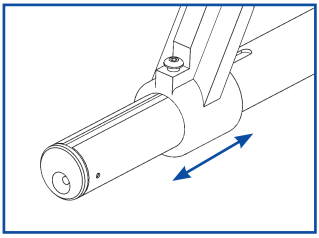
6.1.1 Adjusting the DORO Base Unit to a standard OR Table



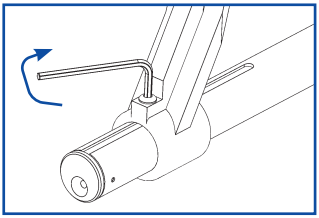
1. Remove the Hex Wrench from its storage holder on the lefthand side of the Connecting Tube.
2. Locate the Hex Screw at the adjustable End Bracket to adjust the width.



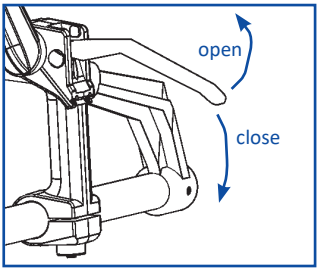
3. Using the Hex Wrench, loosen (do not remove) the Hex Screw at the left End Bracket by turning the Hex Screw counter-clockwise until the adjustable end bracket is loose.



4. 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.
5. 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.

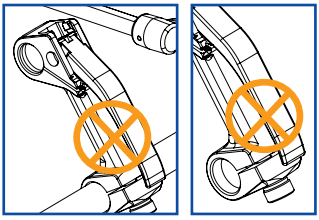


6. Make sure that the Hex Screw is seated properly in the slot of the connecting tube. Using the Hex Wrench, lock the width by turning the Hex Screw clockwise. Return the Hex Wrench to its storage holder. Once this adjustment is made for your OR Table, this step can be skipped in future use.



Open the Locking Lever to position the Base Handle Assembly at the center of the connecting tube. 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.

To adjust the Locking Lever tension see chapter 10.2.1.



Important!

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

Danger!

Danger:
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.

Note:
If disassembling of the Base Handle Assembly is required, please note the following recommendation. 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.

6.2 Mounting the DORO® Base Unit to a standard OR Table

1. Position the Base Unit at the head of the OR Table with the Base Handle Assembly centered on the connecting tube.

2. If you need to adjust the Base Unit to the width of the receptacles of the OR Table see chapter 6.1.1.

3. Insert the two table rods into the receptacles of the OR Table.

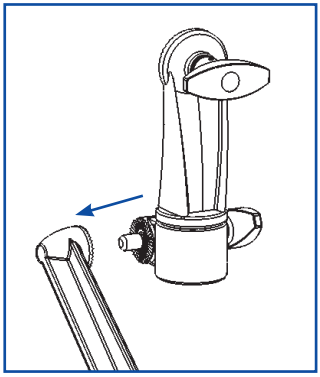
4. Turn the receptacle fastening screws at the OR Table until they are fully tightened.

5. Position the Base Handle Assembly at the desired position as described in chapter 6.1.1.

6. Ensure that all adjustable joints are tightly fastened and secured.

6.3 Mounting the DORO® Swivel Adaptor

Mount the Swivel Adaptor to the Transitional Member of the Base Unit



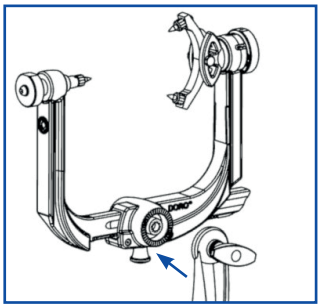
1. Position the teeth of the starburst connection of the Transitional Member and the teeth of the lower starburst connection of the Swivel Adaptor in a manner that they engage.

2. Fully tighten the lower locking screw of the Swivel Adaptor by turning it clockwise.

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

6.4 Mounting of the DORO® Skull Clamp

Mount the Skull Clamp (item no. 3003-00 or 1001.001) to the Swivel Adaptor.



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.

Danger!

Danger:
Check all fastening screws and all starburst locking mechanisms on the device and check the stability of the complete DORO® system before and after each clinical use. Make sure that the device is exactly mounted as described in this manual.

Important!

Important:
QR3 only : The main starburst of the QR3 Skull Clamp (base) is designed for connecting the QR3 Skull Clamp to DORO® Swivel Adaptors and other accessories. When connecting non-DORO® accessories with similar starburst connections, test that the connection is tight and secure and the teeth of both starbursts are fully engaged with no gap. A poor connection could be caused by a screw on the accessory which is too long. These accessories must not be used with the QR3 Skull Clamp.

6.5 Mounting of the DORO® Skull Pins

This system requires three DORO® Skull Pins of the same versions to be used. Please refer to the instruction manual of the appropriate DORO® Skull Pins.

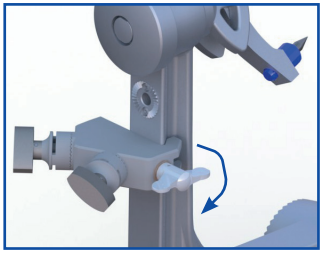
6.6 Mounting of the DORO® Easy Connect Navigation Adaptors

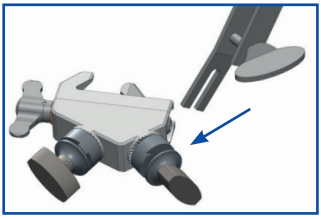
The Navigation Adaptors (item no. 1204.001, 1204.002, 1204.003) can be attached directly to the built-in starburst connections on each Quick-Rail® of the DORO® QR3 Skull Clamp (item no. 1001.001). Please refer to the instruction manual of the DORO® Easy Connect Navigation Adaptors.

6.7 Mounting Additional Accessories

6.7.1 Quick-Clamp w/ Interface for Mizuho-Type Retractors

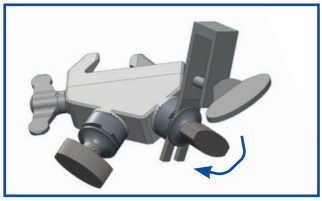
Use the Quick-Clamp w/ Interface for Mizuho-Type Retractors, item no. 1201.045, to connect Mizuho-Type Retractors to the DORO® Skull Clamp 3003-00 or 1001.001.





1. Mount the Quick-Clamp w/ Interface for Mizuho-Type Retractors (item no. 1201.045) on the Quick-Rail® of the Skull Clamp (item nos. 3003-00 or 1001.001) over the sterile drape that is covering the Skull Clamp. Fully tighten the Locking Screw of the Quick-Clamp w/ Interface for Mizuho-Type Retractors by turning it clockwise. (Picture shows Quick-Clamp w/ Interface for Mizuho-Type Retractors mounted on QR3 Skull Clamp without sterile drape).

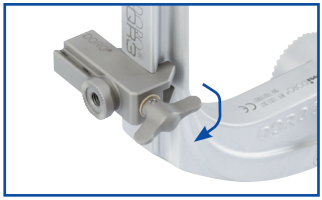
2. To mount the Mizuho-Type Retractor Arm, insert the connection piece of the Retractor Arm into the reception of the Quick-Clamp until the stop is reached and position the retractor arm as desired.



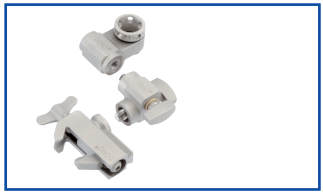
3. Securely tighten the locking screw of the Quick-Clamp w/ Interface for Mizuho-Type Retractors by turning it clockwise. The teeth of the starbust connections must be fully engaged and seated properly.

6.7.2 Quick-Clamp and Accessories

Connecting the DORO® Quick-Clamp to the Skull Clamp 3003-00 or 1001.001.



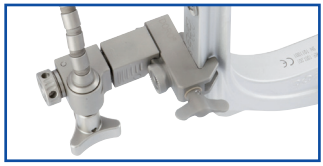
Mount the DORO® Quick-Clamp (item no. 1202.014) on the Quick-Rail® of the Skull Clamp (3003-00 or 1001.001) over the sterile drape that is covering the Skull Clamp. Fully tighten the Locking Screw of the Quick-Clamp by turning it clockwise. (Picture shows Quick-Clamp mounted on QR3 Skull Clamp without sterile drape).



Quick-Clamp shown with Quick-Clamp Coupling Universal (item no. 1202.015) and Halo Support rod Holder (item no. 1202.016).

There are two possibilities to secure additional accessories to the Quick-Clamp:

1. Use the appropriate accessories to mount the DORO® Quick-Clamp Retractor Systems like the DORO® Quick-Clamp Halo and Quick-Clamp Mc-Cue Halo Retractor System. Refer to the respective instruction manuals for further mounting and use instructions.



2. Use the built-in Quick-Rail® of the Quick-Clamp (item no. 1202.014) to connect current accessories (with interface for the Quick-Rail® of the Skull Clamp (item no. 3003-00) like the Quick-Rail® Adaptor Halo 3114-55 as well as Flexible Arms.

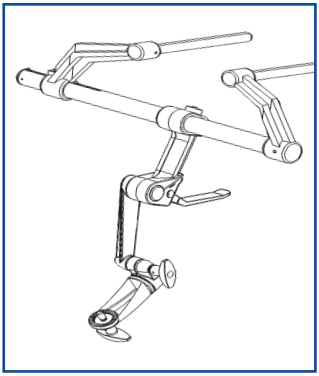
Danger:
Ensure that all adjustable joints are tightly fastened and secured.

7. Use and Handling

Note:
The user decides the best approach to secure the patient to the Skull Clamp. We recommend to secure the patient's head first to the Skull Clamp with Skull Pins and then to connect the Skull Clamp carefully by means of the Swivel Adaptor to the Base Unit and the OR Table.

The steps shown in chapter 7.1 to 7.3 are required.

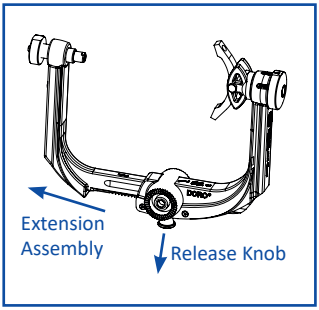
7.1 Mount the Base Unit and the Swivel Adaptor to the OR Table.



1. Mount the Base Unit to the OR Table (see Chapter 6.1).
2. Mount the Swivel Adaptor to the Transitional Member of the Base Unit (see Chapter 6.1).
3. For ease in mounting, we recommend that the Transitional Member of the Base Unit and the Swivel Adaptor are loosely connected (not fully tightened) and the Swivel Adaptor is hanging loose and pointing to the floor.

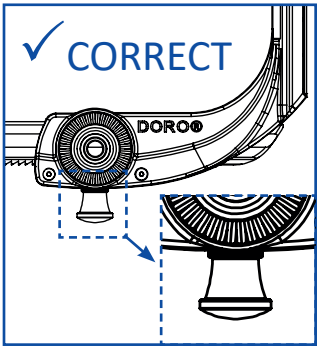
7.2 Secure the patient's head to the Skull Clamp

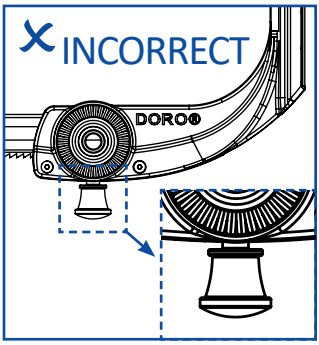
Insert the Skull Pins into the receptacles of the Skull Clamp.
(Please refer to instruction manual Skull Pins).



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.

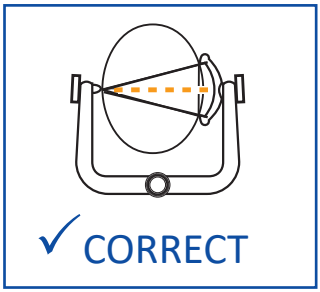




3. When you have obtained the desired width, make sure that the Quick-Release Knob is fully back against the skull clamp base.

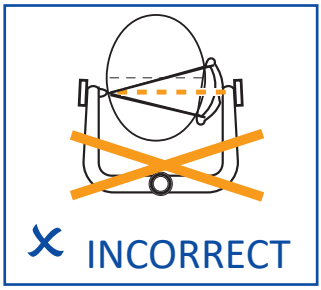
Danger!

Danger:
Avoid inadvertent opening of the Quick-Release Knob of the Skull Clamp during procedure.



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.

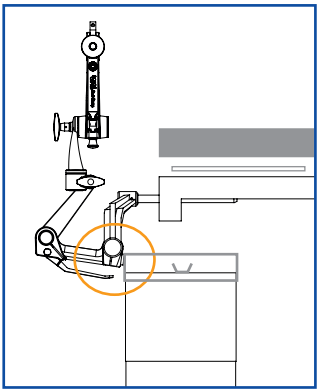


Important!

Important
Only turn the rocker arm while the Index Knob is in the "OPEN" position. Otherwise the locking mechanism will be damaged.

Danger!

Danger:
The pinning of the patient should only be performed by a licensed physician or a licensed surgeon.



Danger!

Danger:
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.

Danger!

Danger:
A patient fixated with this DORO® Headrest System and positioned on the table top of a surgical table system must not be transferred to or from the OR table column. This might cause severe injuries in case of collision.

Danger!

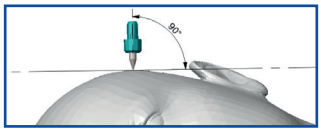
Danger:
Take extra precautions when pinning young infants, the elderly, or on restored surgical areas, including previously drilled burr holes, or any diseased bone because of the varying consistencies and thickness from that of healthy bone. It is the responsibility of the user to select the proper 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 two skull pins in the Dual-Pin Rocker Arm should be equidistant from the centerline of the head and the single skull pin in line with this centerline. The angle of the pins should be as close to 90 degrees possible to the patient skull. Use the proper clamping force.

Danger!

Danger:
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

Danger!

Danger:
Positioning the skull pin 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.

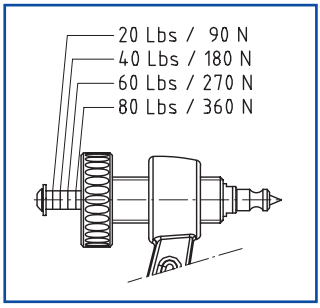


7. Turn the torque screw in order to drive the Skull Pins at an angle of 90 degrees into the patient’s head (refer to instruction manual Skull Pins, section mounting).

Danger!

Danger:
Angles other than 90 degrees may cause the system to become unstable and may result in serious injury to the patient.

8. Ensure proper position of the Skull Pins.



9. 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.

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

Note:
Before applying pressure make sure that the four pressure lines are not showing. When applying pressure the first line (20lbs/90N) becomes visible, then the second line and the third line become visible.

Danger:
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.

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

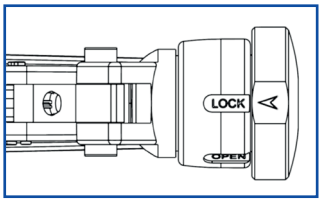
Danger:
The maximum load for the Headrest System is 12.5 kgs/27.5 lbs. Please make sure to safely position the patient's neck and shoulders to avoid excess weight.

7.3 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.

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

5. Ensure that the patient‘s head is in the required position. Tighten and check all adjustable joints starting with Skull Clamp, then Swivel Adapter, Transitional Member, Base Unit and receptacles of the OR Table.



6. Turn the Index Knob from „OPEN“ until it engages in the „LOCK“ position and make sure that the mark is in the correct position. If this cannot be done without problems, return to the „OPEN“ position, turn the rocker arm slightly and try again to engage the Index Knob in the „LOCK“ position.

Danger!

Danger:
Always make sure to stabilize the patient‘s head before adjusting the fastening screws of the Headrest System. Ensure that all adjustable joints are tightly fastened and secured. Ensure that the patient‘s head is secured while tightening joints.

8. Function and Safety Inspection

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

Danger:
Check all fastening screws and the stability of the Headrest and Retractor System before and after each clinical use.

8.1 Prior to clinical use of a DORO® device

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

Make sure that:

- the device is perfectly adjusted to the patient position required for surgery.
- all joints of the device are locked and all fastening screws are tightened.
- all components are tightly attached to each other and the star-burst connection teeth of all components are fully engaged and interlocked.
- the Index Knob of the Skull Clamp is engaged in correct position and Locking Screws of the device are properly tightened.
- the Base Handle Assembly of the Base Unit is tightly locked and that the Transitional Member is properly attached to the Base Handle Assembly.
- the Skull Clamp Base and Skull Clamp Extension Assembly are properly engaged. There must be no movement detectable in the mechanism.
- the stability of the complete system is ensured.

8.2 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.
- to check if the Base Unit Locking Lever needs to be readjusted and that the Transitional Member of the Base Unit is properly mounted.

You may only use the device if it is fully functional as described above.

Important:
Due to safety reasons, only thoroughly cleaned products must be sent back to the manufacturer. Completely reprocess the device as described in this manual.

9. Care

Before initial use, make sure to reprocess the product according to the instructions given on the following pages.

9.1 Manual Cleaning

Clean, inspect and test the device carefully. A good cleaning and maintenance procedure will extend the useful life of the device. 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.

All reusable components of the device described in Section Product Description, can be cleaned by 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 Sections Mounting and Maintenance. 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.
We recommend manual cleaning of the device. An automated cleaning procedure may be used secondary, but is not required or recommended for routine reprocessing. Repeated automated reprocessing has negative effects on the device.

Manual Cleaning as described above must be followed by a disinfection procedure.

9.2 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 the cleaning procedure using fresh detergent. Assemble all components as described in Section Mounting and Maintenance. Inspect all devices prior to cleaning or storage to ensure instruments are suitable for use. Store the device in a clean, dry, moisture free area at a temperature of 5°C/41°F to 40°C/104°F. Do not expose to direct sunlight.

Important:
Please refer to chapters Mounting and Maintenance for dismantling information. When dismantling the device for cleaning purposes and storage, make sure to restore to the original state of the system.

Important:
Do not immerse radiolucent parts longer than 12 minutes in the cleaning solution as it may cause swelling of the material.

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

9.3 Lubrication

Lubrication according to the subsequent lubrication drawing 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.

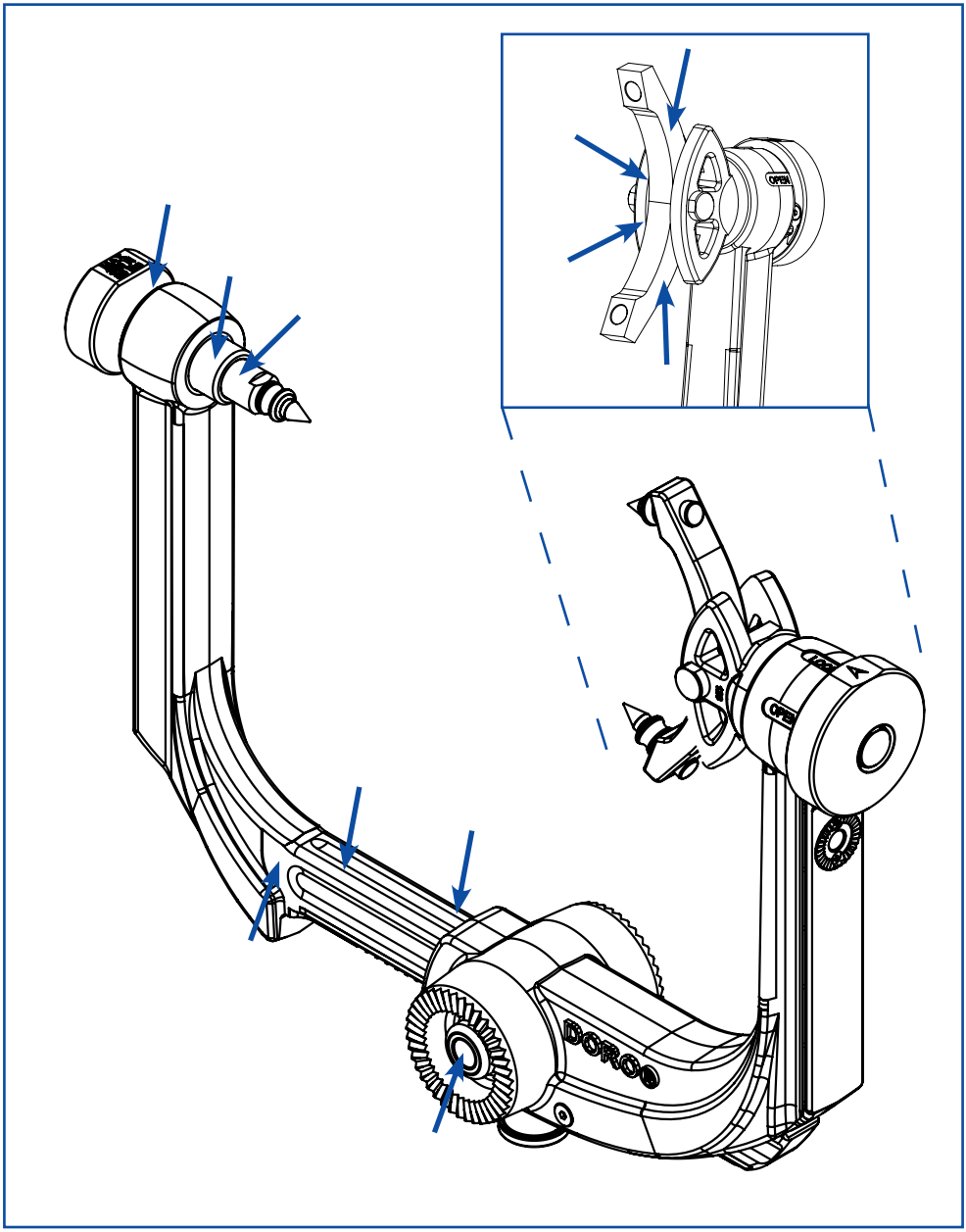
Warning:
Failure to properly lubricate as instructed will increase friction between the moving parts of the device, which may damage them. Correct lubrication increases the service life of the product and helps counteract malfunctions.

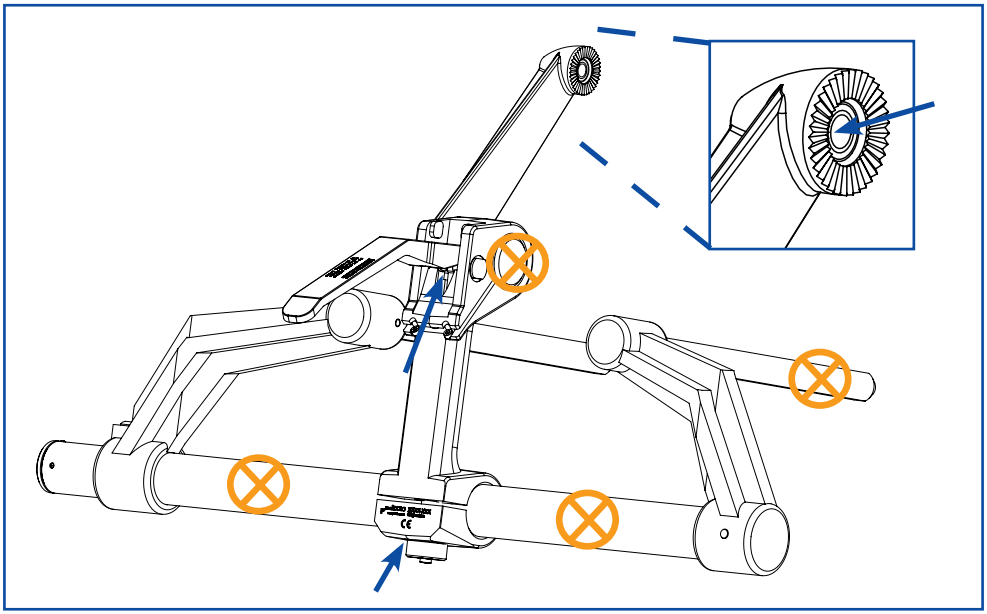
Important:
For a proper lubrication please see the subsequent lubrication drawing.

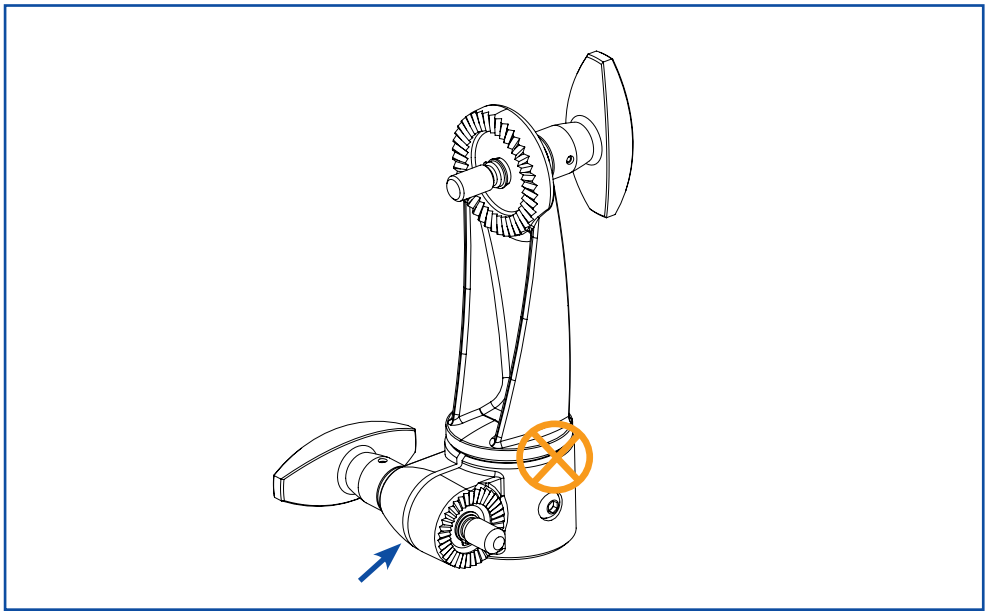
Parts that should be lubricated are indicated by an arrow.

Parts that should never be lubricated are crossed out.

9.4 Lubrication drawing







10. Preventive Maintenance and Repair

10.1 Preventive Maintenance intervals

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.

Important:
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.

10.2 Maintenance steps

1. Checking the tensioning screw: Check the tensioning screw, in particular check the tensioning pressure indicator on the tensioning screw.

2. Check all threads on the products (Helicoil thread inserts / thread inserts / threads on the tensioning screw) for possible damage, wear, and/or malfunction.

3. Check mobile components (latch clamp and ease of operation of the width adjustment). This also includes checking whether the release button reliably opens with tension in order to open the latch mechanism, and that the button reliably engages again after the latch mechanism comes together.

4. Check the open/lock mechanism (360° rotation possible, testing stability in the locked state).

5. 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 of cracks is detected in the material, regardless of the location, the product components must be replaced for safety reasons.

6. Check the toothed wheels—if wear is detected on the toothed wheels (such as broken teeth, visible deformation, points of impact on the toothed wheel), the product component must be checked by the manufacturer and, if necessary, replaced by an original component for safety reasons.

7. Check the holes for receiving 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.

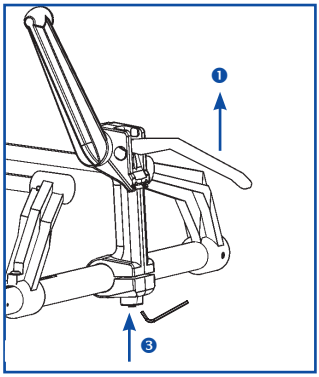
10.3 Maintenance to be performed by the purchaser

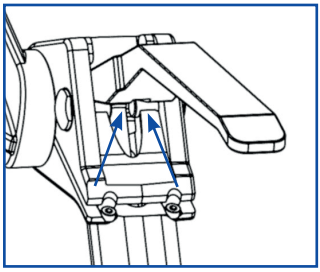
The Base Unit is adjustable in all directions. Frequent realignment of the Base Unit may cause the adjustable parts to loosen. Therefore, we strongly recommend performing the following maintenance work on a regular basis:

10.3.1 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. Frequent releasing and depressing of the lever may cause changes in the fastening tension which need to be compensated.

Check the tension of the Locking Lever at regular intervals. Proceed as described below in order to readjust the Locking Lever tension:





1. Open the Locking Lever.
2. Remove the Hex Wrench from its storage holder.
3. Hold the Tension Knob at the Base Handle Assembly and turn the lock screw inside the Tension Knob counter-clockwise using the Hex Wrench.
4. Check the Locking Lever tension by depressing and releasing the Locking Lever. Make sure that the Locking Lever with the two bolts is properly engaged in the inside of the Base Handle Assembly.
5. If necessary, turn the Tension Knob until you obtain the required tension. The lever movement should be smooth, but firm.
6. 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.

Note:
The Locking Lever must be open, while readjusting the Tension Knob.

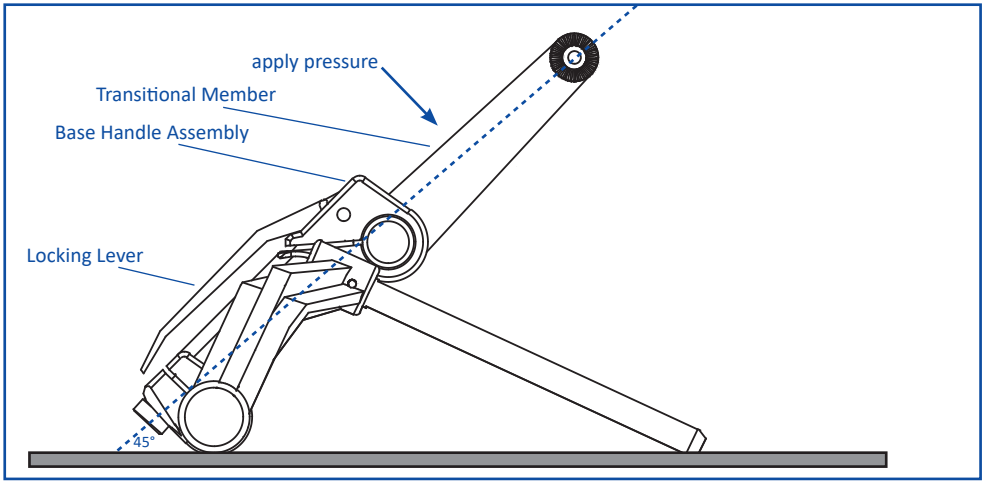
Ensure that the Locking Lever lip is properly placed under the two Stainless Steel pegs.

Warning!

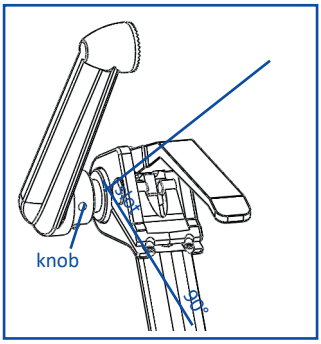
WARNING:
The Locking Lever should not be removed and should never be forced into place. Should the Locking Lever be disengaged from the internal Tension Stainless Steel Rod, carefully re-insert, ensuring that the Locking Lever lip is properly placed under the two Stainless Steel pegs (see picture) and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

10.3.2 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 it‘s stability. There must be no movement detectable. If there is movement, re-adjust as described about in 10.3.1.



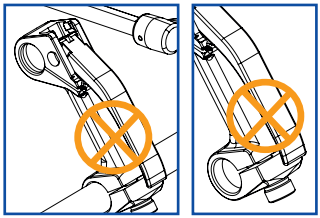
10.3.3 Replacing the Transitional Member



1. Open the Locking Lever by lifting up to release.
2. Removing: Align the Transitional Member with the slot of the base handle assembly at an angle of 90°. Remove the Transitional Member from the Base Handle Assembly by pulling it slowly to the left-hand side (or to the right-hand side). US-Version: The Transitional Member is equipped with a manual lock lever. Turn the manual lock lever clockwise to unlock the Transitional Member, then remove it as described above.
3. Replacing: Align the cleaned (or new) Transitional Member with the slot of the base handle assembly at an angle of 90° (knob should glide through slot). 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. US-Version: After replacing the Transitional Member, turn the manual lock counter-clockwise to lock the Transitional Member in place. The Transitional Member should be locked before using or transporting the base unit.

Danger!

Danger:
Push until the click can be clearly detected. US-Version: Turn the manual lock counter-clockwise completely until you have reached the end position. 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.



Important!

Important:
Never depress or close the Locking Lever without the Transitional Member and the Connecting Tube in place. This will cause damage to the Base Handle Assembly.

Danger!

Danger:
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.

Note:
If disassembling of the Base Handle Assembly is required, please note the following recommendation.
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.

11. 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.

12. Manufacturer Information

Manufacturer: **pro med instruments GmbH**
Bötzinger Str. 86
79111 Freiburg, Germany
Phone +49 761 384 222 10
Fax +49 761 384 222 80
E-Mail info@blackforestmedical.com
Website www.blackforestmedical.com

US Subsidiary: **pro med instruments, Inc.**
4529 SE 16th Place, Suite # 101
Cape Coral, FL 33904
Toll Free 877 225 4086
Fax 239 540 5790
E-Mail info.us@blackforestmedical.com
Website www.blackforestmedical.com

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

13. Free space for your notes

Notes

www.blackforestmedical.com

Quality Policy

The quality and safety of our company's products is our top priority.

- We are committed to provide products that meet our rigorous standards for safety and effectiveness, as well as applicable legal and regulatory requirements.
- We are committed to deliver high quality products and services to achieve complete customer satisfaction.
- We believe that a fair and trustful cooperation with our business partners is the foundation for continued development of the product range.
- We are committed to continuously improve the effectiveness of our quality management system, our products and our services.

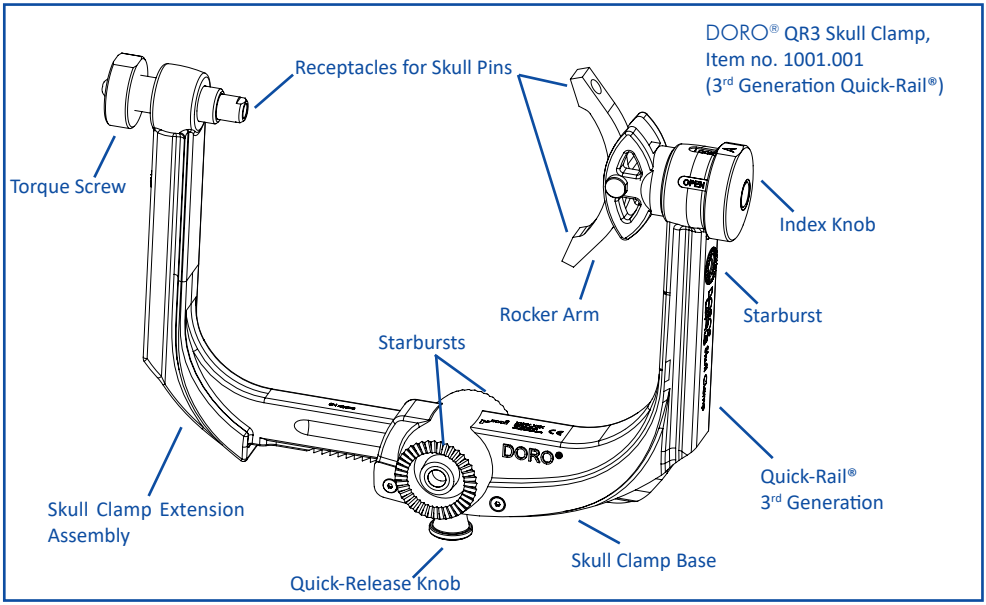
Every product we sell represents the commitment of our people to provide medical technology that improves the quality of life for the patients we serve. Motivated employees are the basis of our achievement.

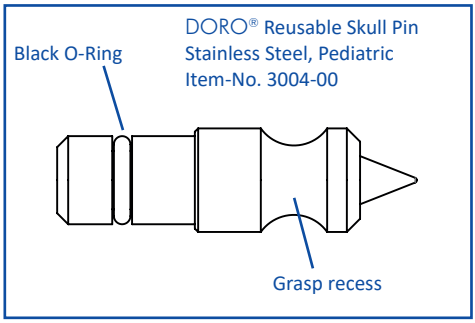
BLACK FOREST MEDICAL GROUP

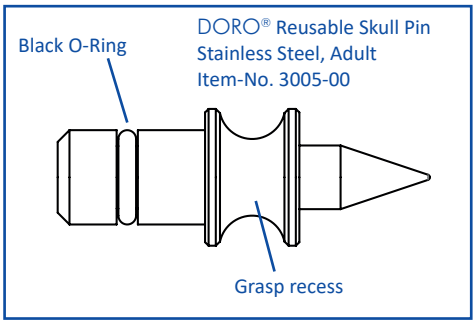
DORO® Reusable Skull Pins Stainless Steel
DORO® Reusable Skull Pins Titanium
Instruction Manual

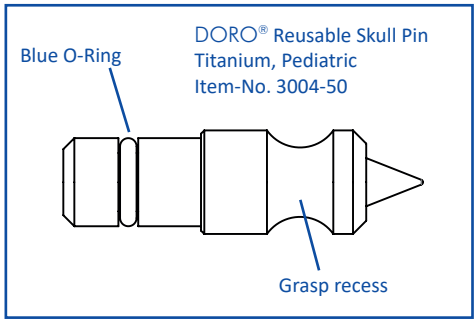
Document no.:	3005-91_EN
Version:	15
Date of creation:	1998-10-27
Last revision:	2022-12-14

1. Quick Guide









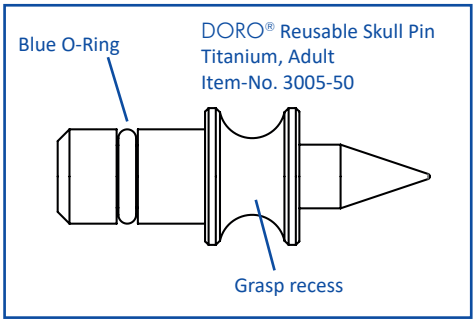


Table of contents

This instruction manual contains important information on the safe, correct and efficient use of the device. Carefully read this manual and observe all the notes and information. This instruction manual should be used in conjunction with the instruction manuals for your other equipment. Make sure to read those manuals very carefully as well. Always keep all the instruction manuals at hand.

2. Regulatory Information

2.1 CE conformity

CE 0297

CE mark:
Declaration of manufacturer with reference to the notified body that the medical device meets all the provisions of the directive 93/42/EEC which apply to it.

2.2 FDA registration

FDA cleared.

℞

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

3. General Safety Information

3.1 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:

Danger:
This symbol indicates a danger to the health of the patient. Failure to observe this information and to follow the appropriate instructions may result in serious injury to the patient and may even endanger the patient's life.

Warning:
This symbol indicates a danger of injury to the user of the device.

Important:
This symbol indicates important information on the proper use of the device. Failure to observe this information and to follow the appropriate instructions may cause damage to the equipment.

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!

Safe usage until:
Printed on package! Do not use after this date.

Sterile:
Sterilized with gamma radiation or ethylene oxide according to the label on the outside box.

Use only once:
Do not reuse! Destroy after usage!

MR safe:
an item that poses no known hazards in all MR environments.

MR conditional:
an item that may only be used in a MR environment with specific, defined conditions.

MR unsafe:
an item that is known to pose hazards in all MR environments.

Lot number:
Printed on package or product.

Item number:
Printed on package or product.

Medical device:
Printed on label.

Serial number:
Printed on package or product.

3.2 Proper handling and permitted user

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

3.3 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.

4. Basic information

4.1 Warranty and liability

All warranty claims presuppose proper operation and treatment of the device. The manufacturer guarantees that all parts are free from defects in both materials and workmanship at the time of delivery.

4.2 Obligations of the purchaser

The purchaser must ensure that all users of the device are trained in the proper use of the device and fully understand all safety-relevant information.

- The purchaser shall be obliged to permit only trained staff, i.e. the OR team, to use the device.
- The purchaser shall also be responsible for storing this instruction manual in such a way that it is always available when the device is being used.

4.3 Use as per instructions

The device is designed and built according to the latest technical developments and to approved safety standards.

DORO® Headrest and Retractor Systems may be used

- only as a support mechanism for head and neck surgery,
- only if the device is in a proper state as far as the safety aspects are concerned.

Use as per instructions also implies

- that you follow all information furnished in this manual,
- that you clean and maintain the device as described.

4.4 Improper use

Improper use or use not conforming to the instructions contained in this manual may result in serious injuries or even death to the patient or the user and damage the device and other equipment.

5. Product description

5.1 Intended use

The DORO® Headrest System is intended as a neck and head support to stabilize the patient's head during neurosurgical operative procedures.

5.2 General description

The DORO® Reusable Skull Pins are components of a mechanical support system which is used in head and neck surgery. The Reusable Skull Pins are attached to the DORO® Skull Clamp. The DORO® Skull Clamp is mounted to the operating table by means of the DORO® Swivel Adaptor and the DORO® Base Unit. This system allows the patient's head to be positioned exactly as required for surgery. The standard DORO® system requires three DORO® Skull Pins of the same version to be used. The DORO® Pins can be used with all support systems whose pin receptacles are identical to those of the DORO® Headrest System.

MR conditional
Use only those skull pins for MRI with the corresponding label and observe MR conditions. Items marked as MR conditional can be safely used under the following conditions:
Main magnetic field strength: 1.5 Tesla or 3 Tesla

Note:
The titanium pins were tested on a 1.5T and a 3T system. Therefore, the condition formulated above applies to MR scanning for these two field strength.

MR unsafe:
DORO® Reusable Skull Pins Stainless Steel are MR unsafe.

5.3 Contraindication

This product is not intended for use except as indicated above.

5.4 Components description

Description **Item-No.**

Stainless Steel (Black O-Ring)

DORO® Reusable Skull Pins Stainless Steel, Adult..... 3005-00
DORO® Reusable Skull Pins Stainless Steel, Pediatric 3004-00

Titanium (Blue O-Ring)

DORO® Reusable Skull Pins Titanium, Adult 3005-50
DORO® Reusable Skull Pins Titanium, Pediatric 3004-50

We recommend using the following components with the DORO® Reusable Skull Pins: The Reusable Skull Pins are compatible with our entire line of DORO® Skull Clamps, including the DORO® Headrest System Aluminum, the DORO® Headrest System Teflon, the DORO® Multi-Purpose Skull Clamp System and the DORO® Headrest System Radiolucent.

Additional Accessories:
For more accessories and product pictures please refer to our DORO® Cranial Stabilization and Retractor Systems brochure or visit us at www.blackforestmedical.com.

Note:
Always have the complete set of accessories and tools available.

Important - Product life-time and disposal:
Do not use the Skull Pins if their lifetime is expired. This is the case when:

- the O-Ring is broken.
- the tip is no longer sharp.

Skull Pins with an expired lifetime must only be disposed in reprocessed condition.

5.5 Recommendations for imaging procedures

Important:
The MR conditional Skull Pins might cause artifacts within a radius of 20 mm around the Skull Pin surface. Make sure to place the MR conditional Skull Pins at least 20 mm away from the Field of View.

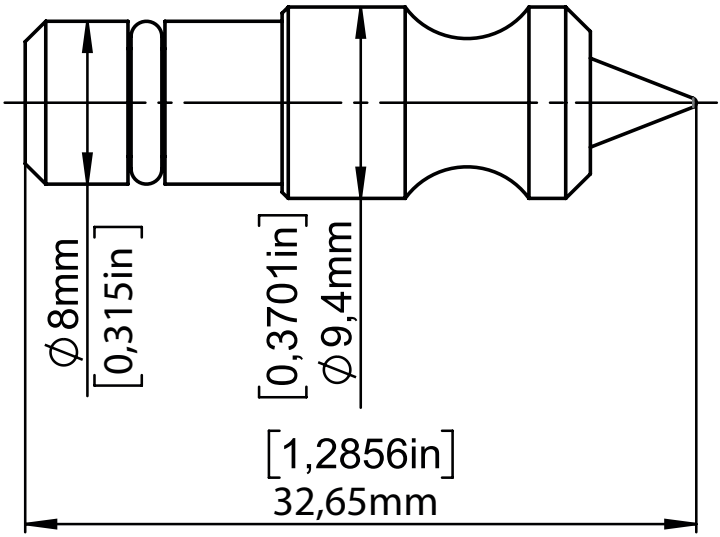
Note:
DORO LUCENT® Disposable Skull Pins (item nos. 1106.003/1106.103) have shown optimum results during imaging procedures. We recommend the usage of the DORO LUCENT® Pins in imaging procedures to avoid artifacts.

5.6 Technical specifications

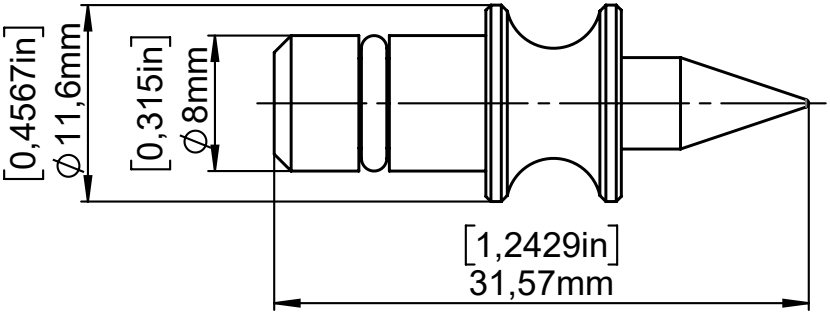
Type of device:	DORO® Reusable Skull Pins Stainless Steel
Item number:	3004-00 and 3005-00
Lot number:	on Skull Pin body
Weight:	9g
Material:	stainless steel, Ethylen-Propylen-Dien-Rubber
Dimensions:	see outline drawings

Type of device:	DORO® Reusable Skull Pins Titanium
Item number:	3004-50 and 3005-50
Lot number:	on Skull Pin body
Weight:	7g
Material:	titanium, Silicone-Rubber
Dimensions:	see outline drawings

5.7 Outline drawing



Items nos. 3004-00 / 3004-50 in mm.



Items nos. 3005-00 / 3005-50 in mm.

6. Mounting

6.1 Preparations for mounting/use

Within the preparation phase, the surgical trajectory at the patient's head is determined by means of imaging technologies. During this process, the skull thickness at the planned positions of the Skull Pins is measured.

The following options are possible:

1. Fixation by means of Skull Pins for children (MR conditional or MR unsafe)
2. Fixation by means of Skull Pins for adults (MR conditional or MR unsafe)

Please refer to the instruction manual of the skull clamp for the penetration depth of the Skull Pins.

For pediatric cases, we recommend the Multi-Purpose Skull Clamp with a variety of pin (3-and 4-point fixation) and non-invasive gel pad fixation options.


Important!

Important:
Skull Pins are designed for rigid fixation in healthy mature skull bone. It is the responsibility of the user to select the proper type of fixation (rigid or noninvasive fixation), the correct skull pin type according the planned application and the correct clamping pressure in view of the skull thickness, skull size, bone structure and in view of the patient's age. For young infants and patients with weak bone structure, small skull thickness or size, it is recommended to use non-invasive headrests. 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.

6.2 Mounting

Danger!

Danger:
The Reusable Skull Pins are not factory-sterilized. Therefore: sterilize the Skull Pins prior to clinical use (refer to section Care).

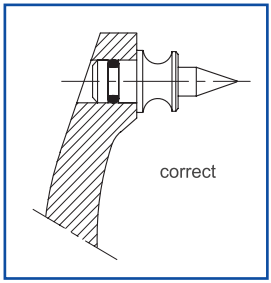
Warning!

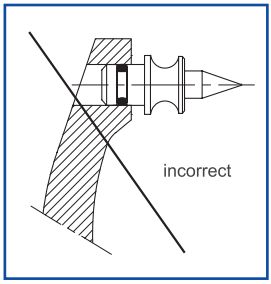
Warning:
Carefully handle the skull pins in order to prevent injuries caused by the pin points. Only touch the skull pins at the grasp recess.

Note:
Different Skull Pins are available for adult and for children and in MR unsafe or MR conditional conditions.

1. Carefully remove the Skull Pins from the package; use the grasp recess to handle the pins.

2. Make sure that the skull pins are not damaged . Immediately replace damaged skull pins with undamaged skull pins.





3. Insert the skull pin into the skull pin receptacles on the skull lamp, push each pin in until they are all seated firmly and cannot be inserted any farther in the receptacle. Ensure tight fit of the skull pin in the receptacle.

Danger:
Failure to properly insert the skull pins into the receptacles of the skull clamp may cause serious injuries or death of the patient. Therefore: Fully insert the skull pins until the stop is reached. The skull pins must be fully and tightly seated in the receptacles.

Danger:
Using damaged skull pins may cause serious injuries or death of the patient. Therefore: always perform a visual inspection of the Skull Pins prior to inserting them.Therefore: Make sure that the Skull Pins are not damaged. Never use the Skull Pins even if the slightest imperfections or surface damages are noted. Make sure that all three or four pins to be used are of the same length. Never use Skull Pins with broken tips.

Danger:
Do not use MR unsafe items in MR environment.

4. To remove a used skull pin from the skull clamp, grasp the Grasp recess and rotate in a clockwise direction to remove. Disassemble the Skull Clamp before removing a Skull Pin by pulling the release knob and removing the Extension Assembly from the Skull Clamp Base in order to prevent injuries caused by the pin tips.

7. Use and Handling

Insert the skull pins into the receptacles of the skull clamp as described in chapter Mounting.


Danger!

Danger:
This instruction manual should be used in conjunction with the instruction manual of your headrest system. The pinning of the patient should only be performed by a licensed physician or a licensed surgeon. Carefully read and follow the pinning instructions in the instruction manual of the headrest system.


Danger!

Danger:
Positioning the skull pin incorrectly can lead to serious injuries to the patient. Therefore: Avoid sensitive areas like the frontal sinus, temporal fossa, blood vessels or nerves. Take extra care to avoid puncture of the superficial temporal artery. 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.


Danger!

Danger:
Literature suggests that, because of the soft bone and unfused sutures, invasive cranial fixation using skull pins involves a higher risk of complications in pediatric patients. Such Complications can be among others: depressed cranial fracture, intracranial hemorrhage, spinal fluid leakage and shunt perforation. Non-invasive stabilization methods might be preferred or an additional head support considered. The operating surgeon decides which type of fixation and what clamping force are required, based on the thickness of the skull and the bone structure. To reduce the risks mentioned above, for pediatric cases the DORO® Multi-Purpose Skull Clamp with 4-point fixation and pediatric skull pins or non-invasive gel pads can be used.

Danger:
There are different types of Skull Pins available. Make sure to use the correct type of Skull Pin according to the application requirements.

8. Function and safety inspection

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

Danger:
Check all fastening screws and the stability of the complete headrest and retractor system before and after each clinical use.

8.1 Prior to clinical use of DORO® Reusable Skull Pins

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

Make sure that:
- the tip is still sharp
- the O-Ring is not broken

9. Care

9.1 Pre-treatment and transport

After each use prevent the products from drying and remove coarse dirt (like visible blood, tissue, protein) from the Skull Pins immediately, but within one hour. Use running cold water (<40 °C) or submerge it in tap water/disinfection solution (recommended: Mediclean Forte, Dr. Weigert, Hamburg, Germany at an appropriate concentration 1 %. Follow instructions and warnings by manufacturer. Avoid contact with eyes). Do not use fixation agents or hot water (>40 °C) as this may result in the fixation of residues and could reduce the cleaning success. Storage and transport of the instruments to the reprocessing location must be ensured in an adequate standard container to avoid damage to the instruments and any contamination of the environment.

9.2 Manual reprocessing

- Remove all visible accumulations of dirt (like visible blood, tissue, protein) by using a soft brush (preferably single-use). Lightly brush all surfaces several times to loosen any bulk solid residuals.
- Prepare an ultrasonic bath (35 °C to max. 40 °C) using an alkaline cleaning agent (recommended: Mediclean Forte, Dr. Weigert, Hamburg, Germany at an appropriate concentration 1 %).
- Rinse the product in the bath so that they are completely submersed.
- Sonicate the product for 10 min (35 °C to max. 40 °C)
- Rinse the entire product thoroughly with deionized water to remove all traces of cleaning solution.

9.3 Manual disinfection process description (European rules)

According to European rules and regulations the manually cleaned instrument has to be disinfected before sterilization. For disinfection use a 70 % ethanol solution (see VAH/DGHM). The disinfectant shall be applied on the instrument twice with a residence time of at least 5 minutes.

9.4 Automated reprocessing

9.4.1 Manual precleaning

See chapter “Manual Reprocessing”.

9.4.2 Automated cleaning and thermal disinfection

- Place the product in a basket of a medical washer-disinfector with a controlled dosage of an alkaline cleaning agent at an appropriate concentration of 1 %.
- Clean the device by using a cleaning program normally used for surgical equipment, i.e. 55 °C (± 3 °C) for 5 min, (washer-disinfector according to ISO 15883-1).

  [Validation conditions:
  a) cleaning agent: Mediclean Forte, Dr. Weigert, Hamburg, Germany with a concentration of 1 %,
  b) washer-disinfector: Miele G7882 with DOSK90 module, program: B].
- Rinse twice with cold tap water (5-20 °C).
- Finale rinsing and disinfection step with deionized water at 93 °C (+2 °C, A0 ≥ 600) for at least 5 min.
- Dry it with a validated and appropriate drying process according to ISO 15883-1.

9.5 Functional test, storage and packaging

Perform visual inspection for cleanliness. If necessary, repeat the cleaning process until the instrument is optically clean. Inspect devices as described in section “Inspection and functional check before use”. For sterilization of the Skull Pins, an appropriate tray is recommended, which is packaged in heat-sealable paper/foil pouches. Packaging for sterilization has to comply with ISO 11607 and EN 868 standards for packaging for sterilized instruments.

9.6 Sterilization

The items shall be steam sterilized at 135 °C for 3 min or alternatively at 134 °C for 5 min preferably using an autoclave that provides a pre-vacuum option (depending on the national requirements). Follow the sterilizer manufacturer's instructions for operation and loading of steam autoclaves. There must be direct steam exposure to all surfaces of the instruments. Allow instrument to air cool to room temperature before use.

- Steam sterilizer according to EN 13060 or EN 285
  [Validation conditions: Tuttnauer Systec V90.]
- Validation according to EN ISO 17665 (previously EN 554/ANSI AAMI ISO 11134), valid IQ/OQ (commissioning) and product specific performance qualification [PQ]).
- However, national regulations in some countries may require sterilization at higher temperatures as well as longer exposure times. In this case, make sure not to exceed a sterilization temperature of 137 °C (280 °F) plus tolerance according to EN ISO 17665.

9.7 Storage

Sterilized instruments must be stored in a clean, dry, moisture free area at moderate temperature of 5 °C to 40 °C. Perform visual inspection after storage for undamaged packaging before use.

Note:
Contact the manufacturer of your steam autoclave to confirm appropriate temperatures and sterilization times. For further information, please visit www.who.int to download the World Health Organization's Guidelines for Infection Control.

11. 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.

12. Manufacturer Information

Manufacturer: **pro med instruments GmbH**
Bötzinger Str. 86
79111 Freiburg, Germany
Phone +49 761 384 222 10
Fax +49 761 384 222 80
E-Mail info@blackforestmedical.com
Website www.blackforestmedical.com

US Subsidiary: **pro med instruments, Inc.**
4529 SE 16th Place, Suite # 101
Cape Coral, FL 33904
Toll Free 877 225 4086
Fax 239 540 5790
E-Mail info.us@blackforestmedical.com
Website www.blackforestmedical.com

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

www.blackforestmedical.com

Quality Policy

The quality and safety of our company's products is our top priority.

- We are committed to provide products that meet our rigorous standards for safety and effectiveness, as well as applicable legal and regulatory requirements.
- We are committed to deliver high quality products and services to achieve complete customer satisfaction.
- We believe that a fair and trustful cooperation with our business partners is the foundation for continued development of the product range.
- We are committed to continuously improve the effectiveness of our quality management system, our products and our services.

Every product we sell represents the commitment of our people to provide medical technology that improves the quality of life for the patients we serve. Motivated employees are the basis of our achievement.

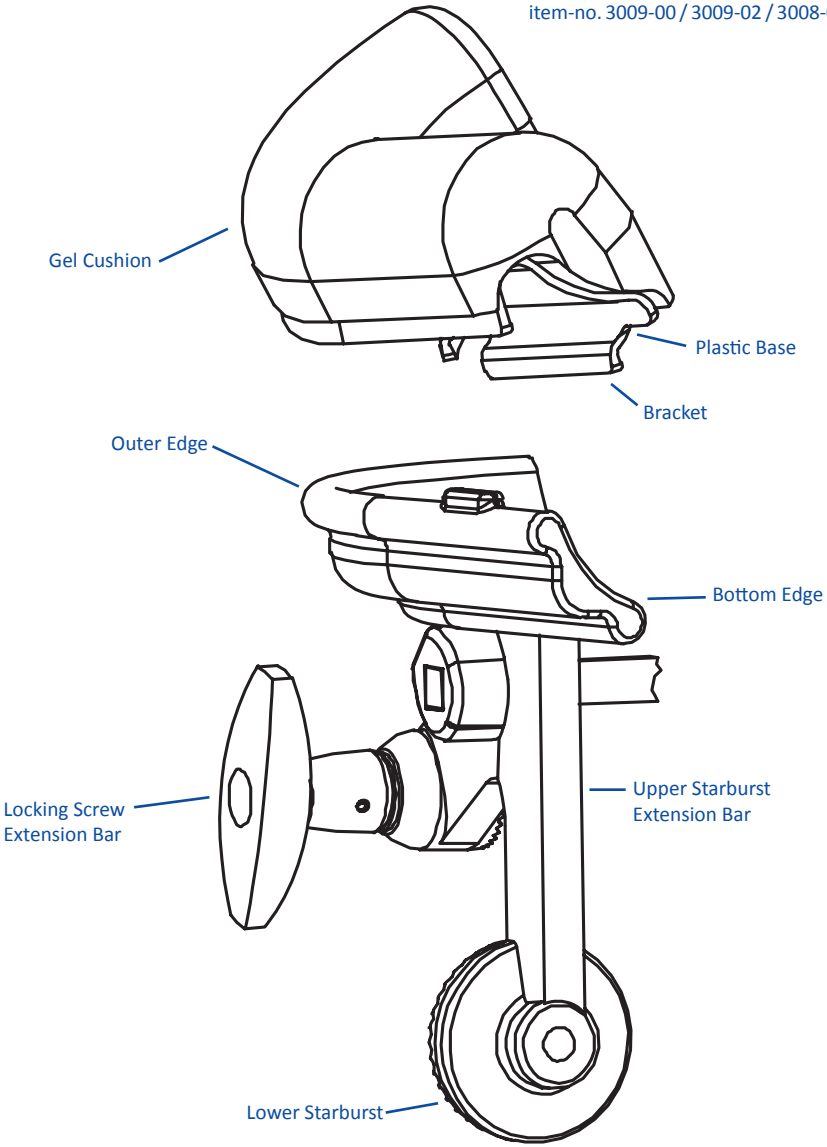
DORO® Swivel Horseshoe Headrest

Instruction Manual

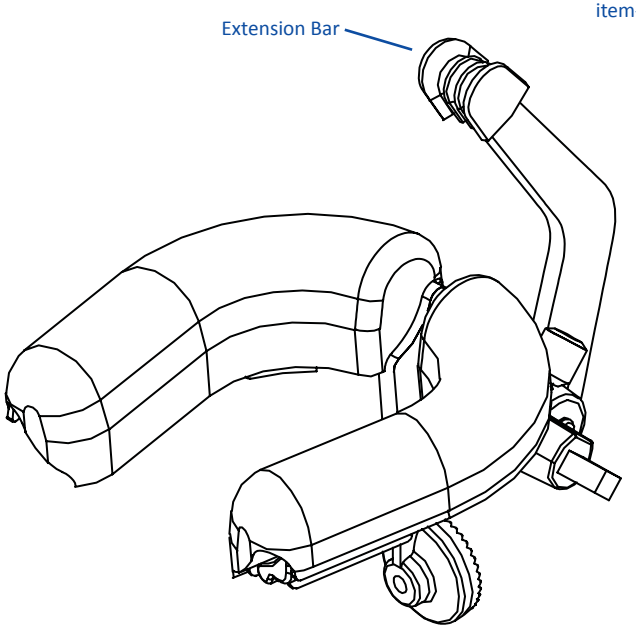
Document no.:	3010-90_EN
Version:	12
Date of creation:	1999-08-19
Last revision:	2017-06-29

1. Quick Guide

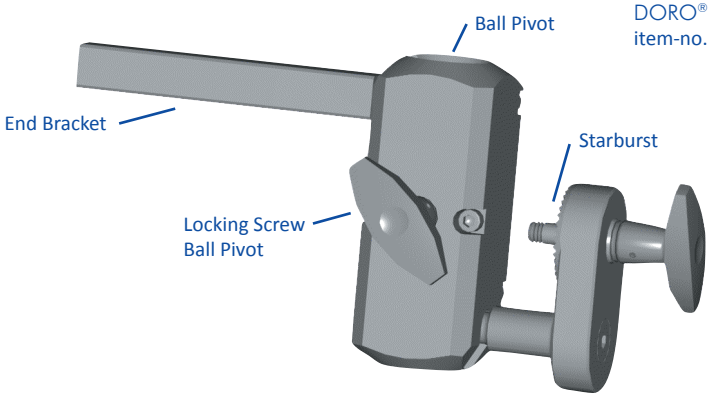
DORO® Swivel Horseshoe Headrest
item-no. 3009-00 / 3009-02 / 3008-00 / 3008-02



DORO® Swivel Horseshoe Headrest
with Extension Bar
item-no. 3009-00 / 3008-00



DORO® Horseshoe Table Adaptor
item-no. 3009-16



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2. Regulatory Information

2.1 CE conformity

CE mark:
Declaration of manufacturer under sole responsibility, that the medical device meets all the provisions of the directive 93/42/EEC which apply to it.

2.2 FDA registration

The DORO® Headrest and Retractor Systems are registered with the 510(k) Numbers K001808, K032331, K063494.

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

3. General Safety Information

3.1 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:

Danger:
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Warning:
This symbol indicates a danger of injury to the user of the device.

Important:
This symbol indicates important information on the proper use of the device. Failure to observe this information and to follow the appropriate instructions may cause damage to the equipment.

Note:
This symbol provides tips concerning the use of the device.
Such information will help you use the device to its full potential.

Exclusion of liability:
This symbol points out exclusions of liability of the manufacturer.
Such disclaimers result if the purchaser or user does not employ the device properly or fails to follow the instructions.

Consult instructions for use:
Read operating instructions!

Manufacturer:
Manufacturer's name and address.

Date of manufacture:
Printed on package!

Safe usage until:
Printed on package! Do not use after this date.

Sterile:
Sterilized with gamma radiation or ethylene oxide according to the label on the outside box.

Use only once:
Do not reuse! Destroy after usage!

MR safe:
an item that poses no known hazards in all MR environments.

MR conditional:
an item that may only be used in a MR environment with specific defined conditions.

MR unsafe:
an item that is known to pose hazards in all MR environments.

Lot number:
Printed on package or product.

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

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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.

4. Basic information

4.1 Warranty and liability

All warranty claims presuppose proper operation and treatment of the device. The manufacturer guarantees that all parts are free from defects in both materials and workmanship at the time of delivery.

Exclusion of liability:
The manufacturer shall not be liable for damages resulting from incorrect use of the device, failure to follow the instructions furnished in this manual or improper or insufficient maintenance.

4.2 Obligations of the purchaser

The purchaser must ensure that all users of the device are trained in the proper use of the device and fully understand all safety-relevant information.

- The purchaser shall be obliged to permit only trained staff, i.e. the OR team, to use the device.
- The purchaser shall also be responsible for storing this instruction manual in such a way that it is always available when the device is being used.

Exclusion of liability:
The manufacturer shall not be liable for damages resulting from the failure of the purchaser to train the users of the device.

4.3 Use as per instructions

The device is designed and built according to the latest technical developments and to approved safety standards.

DORO® Headrest and Retractor Systems may be used
- only as a support mechanism for head and neck surgery,
- only if the device is in a proper state as far as the safety aspects are concerned.

Use as per instructions also implies
- that you follow all information furnished in this manual,
- that you clean and maintain the device as described.

4.4 Improper use

Improper use or use not conforming to the instructions contained in this manual may result in serious injuries or even death to the patient or the user and damage the device and other equipment.

Exclusion of liability:
The manufacturer shall not be liable for damages resulting from improper use.

Exclusion of liability:
DORO® Headrest and Retractor Systems can be mounted to all standard OR Tables. The manufacturer shall not be liable for damages resulting from the use of the device in conjunction with non-standardized OR Tables.

5. Product description

5.1 General description/Intended use

The DORO® Swivel Horseshoe Headrest is a component of a mechanical support system used to support 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 can also be mounted directly to the operating table with the DORO® Table Adaptor Horseshoe (instead of Swivel Adaptor/Base Unit). The Horseshoe Headrest is an alternative non-invasive 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 Gel Pads may be replaced. They are available as spare parts.

5.2 Components

5.2.1 The DORO® Swivel Horseshoe Headrest, Adult, /w Extension Bar, item no. 3009-00 consists of:

DORO® Horseshoe Base 3009-01
DORO® Extension Bar Horseshoe 3009-25
DORO® Horseshoe Pad, Adult, right 3009-10
DORO® Horseshoe Pad, Adult, left 3009-11

5.2.2 The DORO® Swivel Horseshoe Headrest, Pediatric, /w Extension Bar, item no. 3008-00 consists of:

DORO® Horseshoe Base 3009-01
DORO® Extension Bar Horseshoe 3009-25
DORO® Horseshoe Pad, Pediatric, right 3008-10
DORO® Horseshoe Pad, Pediatric, left 3008-11

5.2.3 The DORO® Swivel Horseshoe Headrest, Adult, w/o Extension Bar, item no. 3009-02 consists of:

DORO® Horseshoe Base 3009-01
DORO® Horseshoe Pad, Adult, right 3009-10
DORO® Horseshoe Pad, Adult, left 3009-11

5.2.4 The DORO® Swivel Horseshoe Headrest, Pediatric, w/o Extension Bar, item no. 3008-02 consists of:

DORO® Horseshoe Base 3009-01
DORO® Horseshoe Pad, Pediatric, right 3008-10
DORO® Horseshoe Pad, Pediatric, left 3008-11

5.3 Accessories

We recommend to use the following DORO® equipment to complete the DORO® Swivel Horseshoe Headrest Aluminum.

5.3.1 Base Units

DORO® Adjustable Base Unit 3001-00
DORO® Adjustable Base Unit Takara Belmont 3001-001
DORO® Adjustable Base Unit Mizuho 3001-002
DORO® Adjustable Base Unit Eschmann 3001-003
DORO® Adjustable Base Unit Parkbench 3001-006
DORO® Adjustable Base Unit Australia 3001-008
DORO® Adjustable Base Unit Eschmann T-Series 3001-010

5.3.2 Swivel Adaptors

DORO® Swivel Adaptor 3002-00
DORO® Ball Pivot Adaptor 3002-50
DORO® Swivel Adaptor Navigation 3002-60

5.3.3 Table Adaptors

DORO® Table Adaptor Horseshoe 3009-16
DORO® Table Adaptor Horseshoe Hexagon 3009-17

Alternative set ups	Components
Alternative 1	DORO® Base Unit and DORO® Swivel Adaptor
Alternative 2	DORO® Table Adaptor Horseshoe
Alternative 3	DORO Table Adaptor Horseshoe Hexagon (for hexagonal OR table receptacles)

For more accessories and product pictures please refer to our DORO® Cranial Stabilization and Retractor Systems brochure or visit us at www.pmisurgical.com.

Exclusion of liability:
The manufacturer shall not be liable for third-party components which are used in conjunction with the DORO® Swivel Horseshoe Headrests.

5.4 Technical specifications

Type of device: DORO® Swivel Horseshoe Headrest, Adult.
DORO® Swivel Horseshoe Headrest, Pediatric.
Serial number: on bottom part.
Weight: DORO® Swivel Horseshoe Headrest,
w/o Gel Pads.....990g
Material: aluminum cast, stainless steel,
high performance polymer materials, silicone gel.

6. Mounting

Important:
The DORO® Horseshoe Pad consists of a gel cushion and a plastic base. Always hold the plastic base to remove the Horseshoe Pad. Never pull on the gel cushion, otherwise the Horseshoe Pad will be damaged.

6.1 Mounting the DORO® Horseshoe Pad

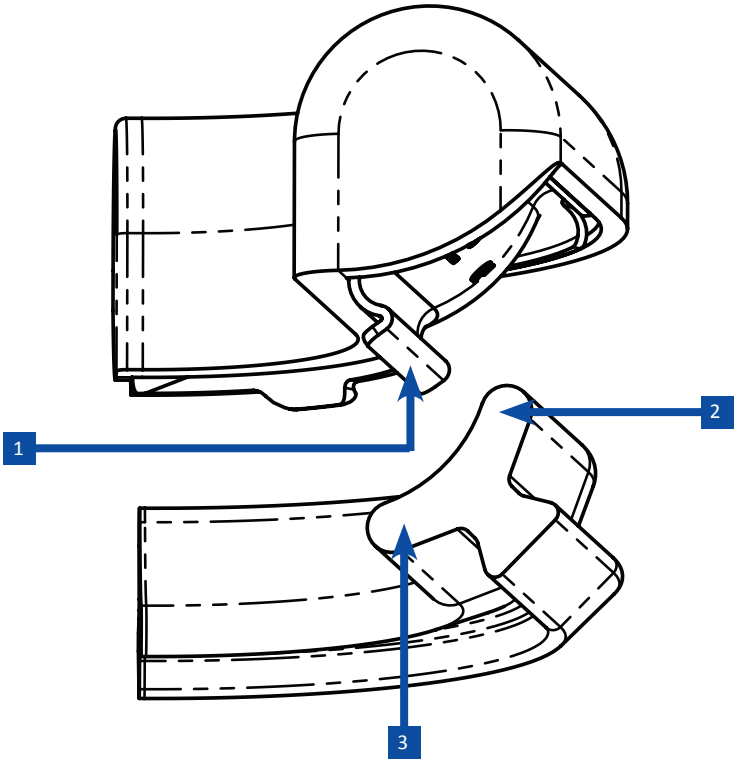
Pull the Horseshoe Pad over the outer edge 2 of the bottom part of the Horseshoe Base and press it down until the long bracket 1 engages at the bottom edge 3 at the inside of the bottom part.

Important:
Place the Horseshoe Pad over the outer edge of the bottom part 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 adhered to the Horseshoe Pad on the outer side and this may cause the Horseshoe Pad to split.

6.2 Removing the DORO® Horseshoe Pad

The Horseshoe Pad is removed from the bottom part by means of lifting the long bracket 1 at the inside edge of the plastic base.

Danger:
Incorrect disassembly, for example pulling at the part filled with gel, can damage the Horseshoe Pad and injure the patient.



Mouting the DORO® Horseshoe Pad

6.3 Mounting the DORO® Horseshoe Headrest

6.3.1 Mounting the Swivel Adaptor/Base Unit

1. Mount the base unit to the receptacles or side rails of the operating table (refer to the instruction manual of the headrest system).

2. Mount the swivel adaptor to the transitional member of the base unit (refer to the instruction manual of the headrest system).

6.3.2 Mounting the Table Adaptor Horseshoe

1. To mount the DORO® Table Adaptor Horseshoe, item-no. 3009-16 to the operating table, push the square end bracket into the appropriate receptacle of the operating table. If your operating table has a hexagonal receptacle, use the DORO® Table Adaptor Horseshoe Hexagon, item no. 3009-17.

2. Turn the receptacle fastening screws at the operating table until fully tightened.

6.3.3 Mounting the Horseshoe to the Swivel Adaptor/Table Adaptor

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 of the Extension Bar in order to position the extension bar as required. You may also remove it.

4. Make sure the horseshoe pads are properly attached to the bottom part.

Danger:
Check all fastening screws and all starburst locking mechanisms on the device and check the stability of the complete DORO® system before and after each clinical use. Make sure that the device is exactly mounted as described in this manual.

7. Use and Handling

7.1 Using the DORO® Horseshoe Headrest

The DORO® Horseshoe Headrest is part of a headrest system. It serves as a convenient headrest for the patient during surgery in prone or supine positions when non-invasive fixation is required.

The patient‘s head is positioned in several steps:

1. Adjust the base unit / table adaptor and the DORO® Horseshoe Headrest to the patient‘s position.

2. Adjust the DORO® Horseshoe Headrest to the size of the patient‘s head.

3. Carefully place the patient‘s head on the horseshoe headrest.

4. Mount the extension bar (optional).

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

Consult instructions for use:
Please consult the instructions for use of the base unit, transitional members and/or table adaptors used to set up a cranial stabilization system.

Exclusion of liability:
The manufacturer shall not be liable for damages resulting from improper mounting or improper positioning of the patients head on the device.

7.2 Detailed description

7.2.1 Adjust the Base Unit and the Swivel Adaptor / the Table Adaptor

1. Move the patient to the position required for surgery.

2. Stabilize the patient's head.

3. Hold the base unit, the swivel adaptor / table adaptor horseshoe and the horseshoe headrest 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 / table adaptor horseshoe as required.

6. Lock the joints of the base unit and the swivel adaptor / table adaptor horseshoe (also refer to the instruction manuals base unit and swivel adaptor).

7.2.2 Adjust the DORO® Horseshoe Headrest

1. 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.

2. Make sure the horseshoe pads are properly attached to the bottom part.

3. Make sure the patient's head fits onto the horseshoe pad.

4. Tightly close the locking screw in order to lock the moving half of the horseshoe.

7.2.3 Place 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.

7.2.4 Mount the extension bar

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.

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

Danger:
Make sure that the patients head is safely positioned on the horseshoe pads and can not move during surgery. Pressure of the head must be evenly distributed on the horseshoe pads.

Exclusion of liability:
The manufacturer shall not be liable for damages resulting from improper mounting or improper positioning of the patients head on the device.

8. Function and safety inspection

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

Exclusion of liability:
The manufacturer shall not be liable for damages resulting from improper function and safety inspections or failure of the user to perform such inspections.

Danger:
Check all fastening screws and the stability of the Headrest and Retractor System before and after each clinical use.

8.1 Prior to clinical use of a DORO® device

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

Make sure that:

- the device is perfectly adjusted to the patient position required for surgery.
- all joints of the device are locked and all fastening screws are tightened.
- all components are tightly attached to each other and the starburst connection teeth of all components are fully engaged and interlocked.
- the Index Knob is engaged in correct position and Locking Screws of the device are properly tightened.
- the Base Handle Assembly of the Base Unit is tightly locked and that the Transitional Member is properly attached to the Base Handle Assembly.
- the Skull Clamp Base and Skull Clamp Extension Assembly are properly engaged. There must be no movement detectable in the mechanism.
- the stability of the complete system is ensured.

8.2 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.
- to check if the Base Unit Locking Lever needs to be readjusted and that the Transitional Member of the Base Unit is properly mounted.

You may only use the device if it is fully functional as described above.

Important:
Due to safety reasons, only thoroughly cleaned products must be sent back to the manufacturer. Completely reprocess the device as described in this manual.

9. Care

Before initial use, make sure to reprocess the product according to the instructions given in the following pages.

9.1 Manual Cleaning

Clean, inspect and test the device carefully. A good cleaning and maintenance procedure will extend the useful life of the device. 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.

All reusable components of the device described in Section Product Description, can be cleaned by 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 Sections Mounting and Maintenance. 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.
We recommend manual cleaning of the device. An automated cleaning procedure may be used secondary, but is not required or recommended for routine reprocessing. Repeated automated reprocessing has negative effects on the device.

Manual Cleaning as described above must be followed by a disinfection procedure.

9.2 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 the cleaning procedure using fresh detergent. Assemble all components as described in Section Mounting and Maintenance. Inspect all devices prior to cleaning or storage to ensure instruments are suitable for use. Store the device in a clean, dry, moisture free area at a temperature of 5°C/41°F to 40°C/104°F.

Important:
Please refer to chapters Mounting and Maintenance for dismantling information. When dismantling the device for cleaning purposes and storage, make sure to restore to the original state of the system.

Important:
Do not immerse radiolucent parts longer than 12 minutes in the cleaning solution as it may cause swelling of the material.

Exclusion of liability:
The manufacturer shall not be liable for damages resulting from improper cleaning and handling of the product and its parts.

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

9.3 Manual Cleaning of Horseshoe Pads

Remove the horseshoe pads from the bottom part after each clinical use and clean them. They can be easily cleaned using standard operating room cleaning agents. Avoid soaking the horseshoe pads for long periods in cleaning fluid.

Important:
The Pads must never be mashine-washed or autoclaved.

Spray or wipe (do not immerse) the device with a disinfectant (like Incidur Spray, Henkel Hygiene GmbH), as directed by the germicide manufacturer.
Damaged pads must be removed and replaced with spare horseshoe pads.

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

9.3.1 Lubrication

Do NOT lubricate the horseshoe pads.

9.3.2 Storage

Important:
Store the horseshoe pads at room temperature in a dry environment. Avoid exposing the horseshoe pads to direct sunlight.

9.4 Lubrication

Lubrication according to the subsequent lubrication drawing should be done after every wash. Failure to lubricate the Headrest System and Retractor System as recommended will result in a greatly reduced lifetime of the equipment. You can lubricate with any medical grade lubricant.

Warning:
Failure to proper lubricate as instructed will increase friction between the moving parts of the device, which may damage them. Proper lubrication will increase the lifetime of the product.

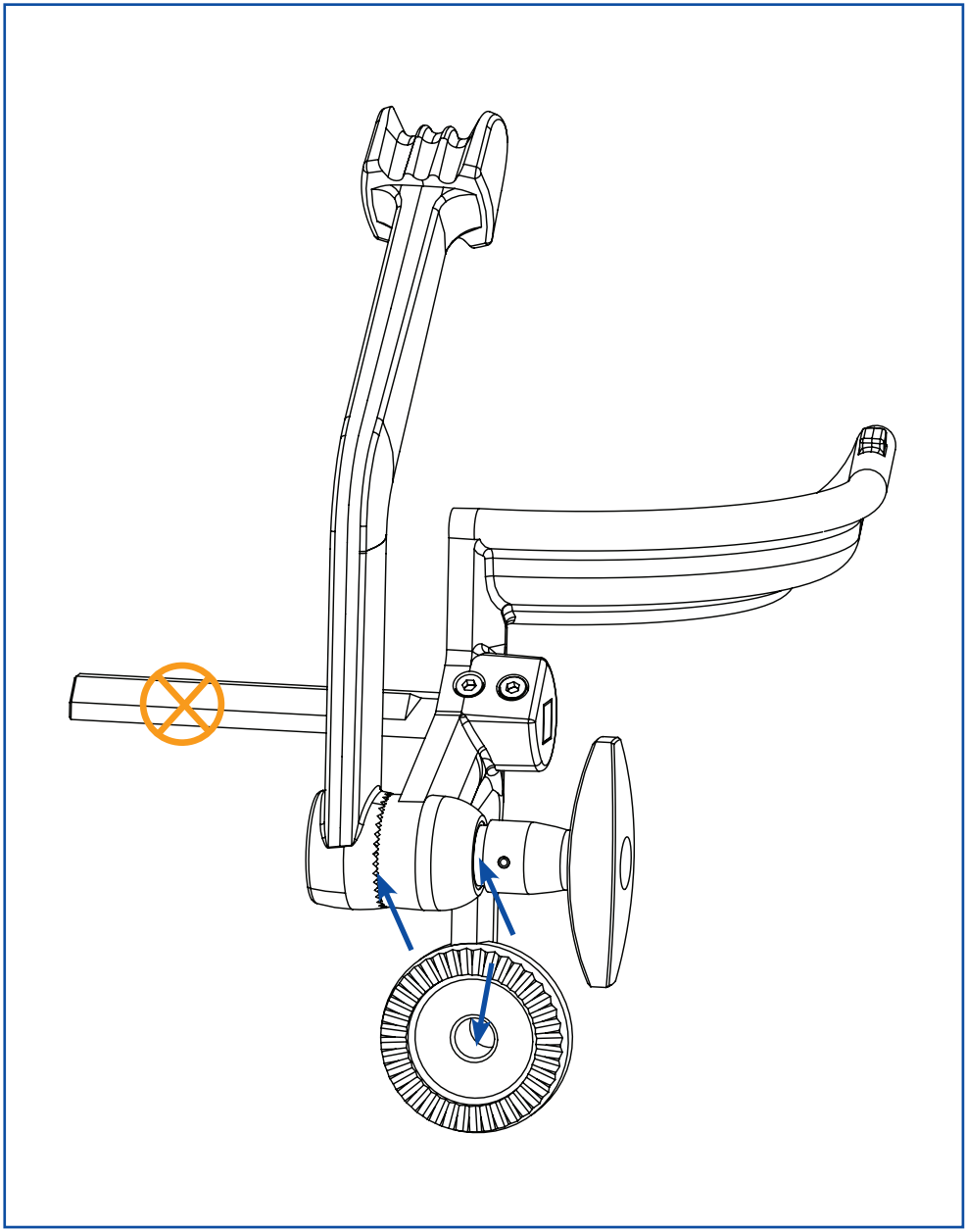
Important:
For a proper lubrication please see the subsequent lubrication drawing.

Important:
A sterilizable product has to be lubricated before sterilization. Ensure to use a lubricant suitable for sterilization.

Parts that should be lubricated are indicated by an arrow.

Parts that should never be lubricated are crossed out.

9.5 Lubrication drawing



10. Maintenance and repair

10.1 Maintenance intervals

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

Important:
Due to safety reasons, only thoroughly cleaned products must be sent back to the manufacturer. Completely reprocess the device as described in this manual.

Exclusion of liability:
The manufacturer shall not be liable for damages resulting from the failure of the purchaser or user to submit the device for maintenance.

Please refer to the appendix to this instruction manual for the address of the manufacturer or the authorized distributor.

11. 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 (aluminum, high performance polymer materials, etc.) for recycling.

You can return old devices to the manufacturer or authorized distributor.

12. Manufacturer information

Manufacturer: **pro med instruments GmbH**
Bötzinger Str. 38
79111 Freiburg, Germany
Phone +49 761 384 222 10
Fax +49 761 384 222 80
E-Mail pmi@pmisurgical.com
Website http://www.pmisurgical.com

US Subsidiary: **pro med instruments, Inc.**
4529 SE 16th Place, Suite # 101
Cape Coral, FL 33904
Toll Free 877 225 4086
Fax 239 369 2370
E-Mail pmi.us@pmisurgical.com
Website http://www.pmisurgical.com

13. Free space for your notes

www.pmisurgical.com

PMI Quality Policy

At pro med instruments the quality and safety of our company's products is our top priority.

- We are committed to provide products that meet our rigorous standards for safety and effectiveness, as well as applicable legal and regulatory requirements.
- We are committed to deliver high quality products and services to achieve complete customer satisfaction.
- We believe that a fair and trustful cooperation with our business partners is the foundation for continued development of the product range.
- We are committed to continuously improve the effectiveness of our quality management system, our products and our services.

Every product we sell represents the commitment of our people to provide medical technology that improves the quality of life for the patients we serve. Motivated employees are the basis of our achievement.