

Accessories

User manual

DAA Top 360



for the product:

PURIST Leg Positioning System

Manufacturer**ADSM**

7b rue Lavoisier
69680 Chassieu
France
Phone: +33 428-710-310
Fax: +33 428-710-320
E-mail: office@synchronomedical.com

Distributor
(US and Canada)

Innovative Orthopedic Technologies, LLC
1115 Hwy 124
Winnie, Texas 77655
U.S.A.
Phone: +1 409-658-1017
Fax: +1 888-521-5676
Email: info@iotiot.com

Distributor
(outside the US and Canada)

Innovative Orthopedic Technologies IOT AG
Schochenmühlestrasse 4
CH-6340 Baar
Switzerland
Phone: +41 41-749-4099
Fax: +41 41-511-2248
Email: info@iotiot.com

This document may not be circulated, reproduced, used, or disclosed to third parties, neither wholly nor in part, without the prior written consent of ADSM.

Non-compliance may result in liability to indemnify.
Non-contractual pictures.

Please store this user manual carefully.

For versions of this manual in other languages, please visit www.iotiot.com.

Product DAA Top 360
Reference 6813130
BUDI-DI code 37010910DT008PURISTC6
Document number SUP_7.039
Version Rev02
Release Date 25/01/2023
Author ADSM



Table of contents

1.	Notes for users	5
1.1.	Using this user manual.....	5
1.2.	Structure of this user manual.....	5
1.3.	User manuals are part of the device.....	5
1.4.	Warning and hazard symbols	6
1.5.	Warning signs and symbols on the product and the packaging	7
1.6.	Typographical conventions and symbols	8
1.7.	Figures in this user manual.....	8
2.	Information concerning all products	9
2.1.	Conformity	9
2.2.	Check upon receipt.....	9
2.3.	Product service life	9
2.4.	Warranty and guarantee.....	9
2.5.	Original replacement parts.....	10
2.6.	Information on product liability	10
3.	DAA Top 360.....	11
3.1.	Intended use	11
3.2.	Improper use.....	12
3.3.	Hazards when used as intended	12
3.4.	Scope of delivery.....	15
3.5.	Material compatibility.....	16
3.6.	General mounting information.....	17
3.7.	Safety information for mounting.....	17
3.8.	Load bearing capacity	20
3.9.	DAA Top 360 assembly	20
3.10.	Preparation.....	22
3.10.1.	Removing the appropriate section of the operating table	23
3.11.	DAA Top 360 positioning	24
3.12.	DAA Top 360 mounting	25
3.13.	Removing the DAA Top 360	27
3.14.	Adjusting the femoral support.....	28
3.15.	Removing the femoral support and transverse support.....	29
3.16.	Technical data DAA Top 360	30
3.17.	Wear parts	31
3.18.	Accessories.....	31
4.	Maintenance/service	32
4.1.	Important information.....	32
4.2.	Checks by the operating company	33
4.3.	Maintenance plan	33
4.4.	Maintenance work	34
4.4.1.	Cleaning.....	34

4.4.2.	Disinfection.....	35
5.	Transport, storage and disposal.....	36
5.1.	Transporting while assembled	36
5.2.	Decontamination before shipping.....	36
5.3.	Storage.....	36
5.4.	Disposal	36
6.	Accessories	37
6.1.	Protective Mat	37
7.	Revision	38

1. Notes for users

1.1. Using this user manual

This user manual should make it possible for you to work safely with the device.

- ▶ Use the product only in accordance with the safety instructions and warnings in this user manual.
- ▶ If you have any questions regarding the operation of the product, please contact the distributor.

1.2. Structure of this user manual

This user manual describes the use and assembly of the product in the following chapters:

DAA Top 360	Chapt. 3
-------------	----------

Topics concerning all products are discussed in chapters 1, 2, 4 and 5:

Notes for users	Chapt. 1
Information concerning all products	Chapt. 2
Maintenance/service	Chapt. 4
Transport, storage, disposal	Chapt. 5

1.3. User manuals are part of the device

This user manual with the item number SUP_7.039 forms part of the device.

It promotes proper use of the device and contains important information to install, operate and maintain the product safely and efficiently.

- ▶ Keep this manual complete, legible and accessible to personnel at all times.
- ▶ Read these instructions - especially all safety instructions and warnings - with care before you put the product into operation for the first time.
- ▶ This manual contributes to reducing the risk of injury or illness and helps prevent the risk of damage, malfunction or inefficient operation of the devices.

- ▶ If transferring the product to third parties, include these instructions with it.
- ▶ If you lose these instructions, please order a replacement from your distributor.

1.4. Warning and hazard symbols

**DANGER****Risk of death or serious injury**

Failure to observe WILL lead to death or serious injury.

**WARNING****Risk of death or serious injury**

Failure to observe CAN lead to death or serious injury.





**CAUTION****Risk of slight injury**










A hazard which CAN lead to slight injury.





ATTENTION**Warning – property damage**

A hazard that CAN cause damage to or malfunctions of the product, equipment, other devices, etc.

1.5. Warning signs and symbols on the product and the packaging






Symbol	Meaning
 <p>Read the user manual!</p>	<ul style="list-style-type: none"> ▶ Read the user manual. ▶ Observe important notice in the user manual. ▶ Read the user manual before installing and using the device.
 <p>WARNING!</p>	<p style="text-align: center;">WARNING</p> <p style="text-align: center;">Prohibition sign, Do not sit!</p>
 <p>WARNING!</p>	<p style="text-align: center;">WARNING</p> <p style="text-align: center;">Hazard symbols indicating possible injuries at the location of the symbol.</p>
 <p>Caution: Keep Hands Clear</p>	<p style="text-align: center;">Crushing hazard for hands</p> <p style="text-align: center;">Warning sign indicating a crushing hazard for hands at the location of the symbol.</p>

Symbol	Meaning
	<p>CAUTION: SEE INSTRUCTION MANUAL</p>
	<p>CE-mark</p>
	<p>Batch number</p>
	<p>Reference</p>
	<p>Manufacturer</p>
	<p>Unique Device Identifier</p>
	<p>Prescription-only</p>
	<p>READ THE INSTRUCTIONS</p>
	<p>Medical Device</p>

	Body weight
	Non Sterile Device
	Authorized representative in Switzerland
	Date of manufacturing and country of origin

Symbols on the packaging	
	This side up
	Fragile; treat with the required care
	Keep dry

1.6. Typographical conventions and symbols

Symbol	Meaning
	Notice with especially useful information and tips
	Request for action
	Result of a request for action
	List point 1
	List point 2

1.7. Figures in this user manual

Some of the figures in this user manual are schematics where the colors do not necessarily correspond to the final product.

2. Information concerning all products

2.1. Conformity



This medical product complies with the provisions of the Medical Device REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Medical Device Class

This accessory is classified according to annex VIII, chapter III, rule 1 of the MDR:

Class I general, non-sterile, no measuring function.

2.2. Check upon receipt

Immediately on receipt, check that the components are complete and undamaged. Report any transport damage to the distributor immediately.



WARNING

Risk of contamination

These devices are not shipped in sterile condition.

- ▶ Please clean and disinfect the devices according to the procedures approved by your organization.
-

2.3. Product service life

The device was developed for an expected service life of 10 years.

This does not apply to wear parts such as pads on the tabletop, POP, and femoral support.

2.4. Warranty and guarantee

The warranty provisions form part of the manufacturer's General Terms and Conditions.

Using unauthorized replacement parts voids the manufacturer's warranty.

2.5. Original replacement parts

The manufacturer shall only be liable for the safety of the products if the products are maintained by authorized maintenance personnel and if original replacement parts are used. This applies to maintenance, repairs and modifications.

2.6. Information on product liability

Manufacturer's liability

ADSM shall only be liable for safe operation, reliability and performance of the product if:

- assembly and maintenance are carried out solely by persons authorized to do this by ADSM
- the device is operated according to this user manual
- the product is used within the scope of application described here
- no unauthorized modifications are made to the product

3. DAA Top 360



Fig. 3-1: DAA Top 360

3.1. Intended use

The device is designed exclusively for the described intended use.

The DAA Top 360 is intended solely for use in combination with the following medical products:

- PURIST Leg Positioning System

The product consists of a tabletop surface, a perineal post and a femoral support.

The product is an extension of the operating table used in hip joint surgeries for resting the patient's pelvis in a supine position.

The patient is positioned with their perineum close to the padded perineal post. The perineal post is a retaining device protecting against horizontal movement of the patient during hip joint operations involving tensile forces.

The product also allows the femur to be supported by a variable-height femoral support. The femoral support can be moved to the side during the operation for good C-arm radiography in order to prevent shadows from being cast on the X-ray image.

The product may only be used as an accessory for operating tables where the lateral accessory rails are compatible with the product with regard to geometry and load capacity, see chapter "Technical data".

The product may only be mounted/operated by qualified surgical staff who are familiar with patient positioning.

3.2. Improper use

The product must not be used for any other purpose than that indicated in chapter 3.1.



CAUTION

Hazards when used improperly

If the DAA Top 360 slides because it was not fixed firmly enough to the operating table, the patient may be moved.

- ▶ Make sure that the DAA Top 360 is positioned and mounted correctly.
- ▶ Check that the retaining straps are properly tightened and secured.



CAUTION

Hazards when used improperly

Injuries can be sustained if the DAA Top 360 is not used as intended.

- ▶ Use the DAA Top 360 only for tasks stated in chapter 3.1 Intended use.

3.3. Hazards when used as intended



WARNING

Risk of injury through radiation

When using a DAA Top 360 in conjunction with an X-ray system, the high-frequency electromagnetic radiation may cause radiation hazards.

- ▶ Observe the operating instructions for the X-ray system.
- ▶ Only to be operated by trained personnel.

**CAUTION****Risk of injury from improper mounting of the DAA Top 360**

If the DAA Top 360 slides because it was not fixed firmly enough to the operating table, the patient may be moved.

- ▶ Make sure that the DAA Top 360 is positioned and mounted correctly.
- ▶ Check that the retaining straps are properly tightened and secured.

**WARNING****Risk of injury from tilting of the operating table**

Use of the DAA Top 360 tabletop will cause the patient to be shifted farther away (~25 cm) from the central column of the OR table. This can affect the stability of the OR table, can reduce the patient weight limit of the OR table, and could cause the operating table to tilt and cause injuries.

- ▶ Only mount the product on the middle section of an operating table.
- ▶ Ensure to follow user instructions of the OR table used. Orientation (normal vs. reverse) and use of different OR table functions (i.e. slide) may also influence patient weight capacity. Check with the OR table manufacturer to ensure you are safely operating the DAA Top 360 with the specific OR table used.

**CAUTION****Risk of injury from breaking DAA Top 360**

The tabletop of the DAA Top 360 will break under heavy patients over 227 kg (500 lb.)

- ▶ Maximum permitted patient weight is 227 kg (500 lb.)
- ▶ Do not sit on the product, only position patient while laying down.

**CAUTION****Chemical hazard from cleaning agents**

Injuries may occur if the pads are not completely free from cleaning agents after cleaning.

- ▶ Cover the pads with a disposable protective cover before each surgery.
- ▶ Replace POP and femoral support pads after approx. ten surgeries.
- ▶ Replace the tabletop pad after 1 year.

**WARNING****Risk of contamination**

Dirty materials on the product can cause infection.

- ▶ Avoid direct skin contact with contaminated material.
 - ▶ Cover surfaces with disposable protective covers before every surgery.
 - ▶ Replace POP and femoral support pads after approx. ten surgeries.
 - ▶ Replace the tabletop pad after 1 year.
-

**CAUTION****Risk of skin irritation**

Dirty materials on the product can cause skin irritation.

- ▶ Avoid direct skin contact with contaminated material.
 - ▶ Cover surfaces with disposable protective covers before every surgery.
 - ▶ Replace POP and femoral support pads after approx. ten surgeries.
 - ▶ Replace the tabletop pad after 1 year.
-

**CAUTION****Risk of injury to patients weighing over 150 kg (330 lb.)**

During surgery, the patient may lie for more than 1 hour on their back on the DAA Top 360 tabletop.

This can result in injuries to the back caused by the tabletop (nerve compression or skin lesions).

- ▶ If the patient weighs more than 150 kg (330 lb.), use an additional mattress or gel mat.
-

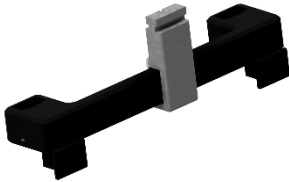
3.4. Scope of delivery

When delivered, the DAA Top 360 consists of the following components and includes a M5 Allen wrench:



DAA Top 360 tabletop

Fig. 3-2: DAA Top 360 tabletop



Transverse support

Fig. 3-3: Transverse support



Femoral support

Fig. 3-4: Femoral support



Perineal post

Fig. 3-5: Perineal post



Retaining straps (qty 4)

Fig. 3-6: Retaining strap

3.5. Material compatibility

ATTENTION

Corrosive substances can damage the product

Use of corrosive substances for cleaning can damage the product.

- ▶ Only use substances for cleaning which do not corrode the following materials.
- ▶ Pay attention to the cleaning instructions (see chapter 4.4.1).

DAA Top 360	
Component	Materials
CFK tabletop	Carbon fiber
Tabletop pad	PU core encased in conductive material
Tabletop side guides	Plastic
Attachment holders	Metal
Rubber feet	Rubber
Perineal post	Plastic
POP pad	Elastomer
Transverse support	Plastic with metal cross element
Femoral support pad	Elastomer
Retaining straps	Nylon with metal buckle

3.6. General mounting information

The device is an extension of the operating table, mounted on the operating table for hip joint surgeries.

- ▶ Remove the product again after the surgery, clean and disinfect it and put it into storage.

3.7. Safety information for mounting



WARNING

Risk of injury through radiation

When using a DAA Top 360 in conjunction with an X-ray system, the high-frequency electromagnetic radiation may cause radiation hazards.

- ▶ Observe the operating instructions for the X-ray system.
 - ▶ Only to be operated by trained personnel.
-



CAUTION

Risk of injury from improper mounting of the DAA Top 360

If the DAA Top 360 slides because it was not fixed firmly enough to the operating table, the patient may be moved.

- ▶ Make sure that the DAA Top 360 is positioned and mounted correctly.
 - ▶ Check that the retaining straps are properly tightened and secured on the attachments.
-



CAUTION

Risk of injury from breaking DAA Top 360

The plate of the DAA Top 360 will break in case of heavy patients over 227 kg (500 lb.).

- ▶ The maximum permitted patient weight is 227 kg (500 lb.)
 - ▶ Do not sit on the product, only position patient while laying down.
-

**CAUTION****Risk of injury from mounting on defective operating table accessory rails**

If the product is mounted on incompatible operating table accessory rails, this can lead to falling and consequently to injuries.

- ▶ Before mounting, always ensure that there is no damage on the accessory rails of the operating table.
-

**CAUTION****Risk of injury from loose screws**

If the screws on the product are not tightened properly, injuries may occur during surgery.

- ▶ Before mounting the product, always check tight seating of all screws and have the screws tightened by maintenance personnel if required.
-

**WARNING****Risk of contamination during mounting**

The product may contain bacteria and germs from previous surgeries which pose a risk to installers, patients and operating personnel.

- ▶ Clean and disinfect the product according to instructions after each surgery.
 - ▶ Disinfect the product according to instructions before each surgery.
-

**WARNING****Risk of injury from tilting of the operating table**

Use of the DAA Top 360 tabletop will cause the patient to be shifted farther away (~25 cm) from the central column of the OR table. This can affect the stability of the OR table, can reduce the patient weight limit of the OR table, and could cause the operating table to tilt and cause injuries.

- ▶ Only mount the product on the middle section of an operating table.
 - ▶ Ensure to follow user instructions of the OR table used. Orientation (normal vs. reverse) and use of different OR table functions (i.e. slide) may also influence patient weight capacity. Check with the OR table manufacturer to ensure you are safely operating the DAA Top 360 with the specific OR table used.
-

*Note: The figure below shows an OR table in normal orientation. If you are using an OR table in reverse orientation, the leg section (1) indicated below is the head section, and the head section (4) indicated below is the leg section.

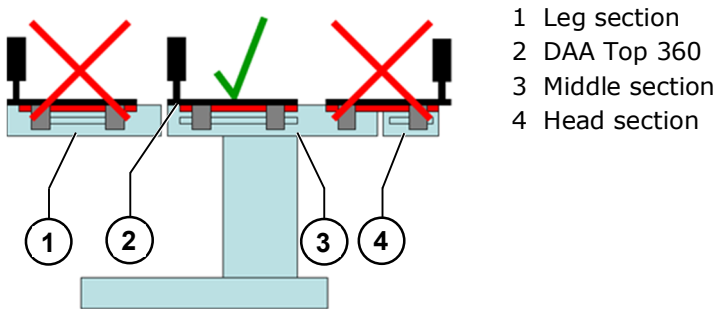


Fig. 3-7: Correct position on the middle section of the operating table



CAUTION

Risk of injury during mounting

When clamping the DAA Top 360 onto the operating table accessory rail, there is a risk of injury in the form of trapped fingers.

- ▶ Tighten the retaining straps carefully.

3.8. Load bearing capacity

ATTENTION

Risk of breaking

- ▶ Check the manufacturer's recommendation for the maximum load on the operating table accessory rail before attaching the DAA Top 360 to an accessory rail.
-

3.9. DAA Top 360 assembly

When delivered, the product is preassembled apart from the perineal post, transverse support, and femoral support.



Fig. 3-8: DAA Top 360 as delivered

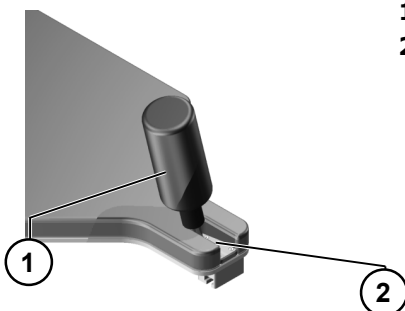


Fig. 3-9: Mounting the perineal post

- 1 Perineal Post
- 2 POP flange

- ▶ Insert the perineal post (1) into the POP flange (2) as far as possible.

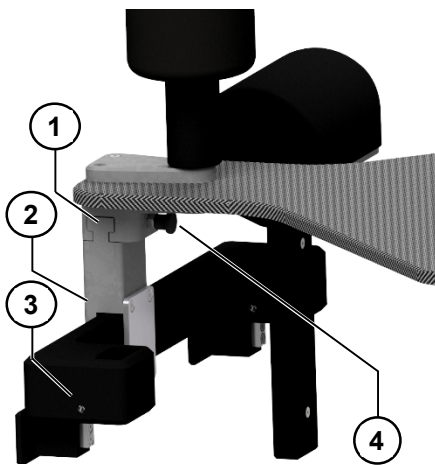


Fig. 3-10: *Mounting the transverse support*

- 1 T-slot guide
- 2 Cross element
- 3 Transverse support
- 4 Locking pin

▶ Pull the locking pin (4) and push the cross element (2) with the transverse support (3) into the T-slot guide (1).

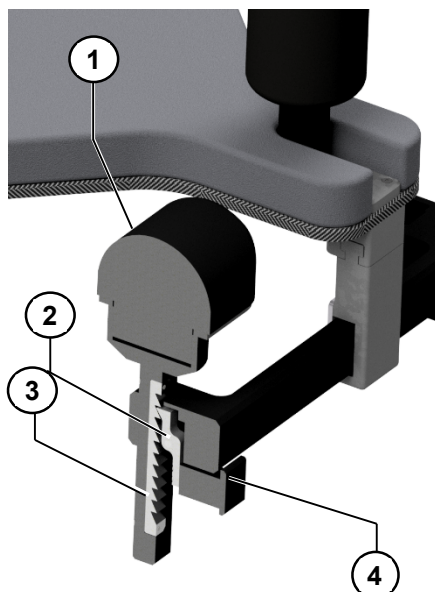


Fig. 3-11: *Mounting the femoral support*

- 1 Femoral support
- 2 Latch
- 3 Toothed rack
- 4 Push knob

▶ Press the push knob (4) and push the femoral support (1) with pad into the transverse support from above.

In the femoral support there is a toothed rack (3) that is fixed vertically by a latch (2).



The femoral support can be mounted on either the left or right side in the transverse support.

3.10. Preparation

- ▶ Ensure the four retaining straps required for mounting the product are available.



WARNING

Risk of injury from tilting of the operating table

Use of the DAA Top 360 tabletop will cause the patient to be shifted farther away (~25 cm) from the central column of the OR table. This can affect the stability of the OR table, can reduce the patient weight limit of the OR table, and could cause the operating table to tilt and cause injuries.

- ▶ Only mount the product on the middle section of an operating table.
 - ▶ Ensure to follow user instructions of the OR table used. Orientation (normal vs. reverse) and use of different OR table functions (i.e. slide) may also influence patient weight capacity. Check with the OR table manufacturer to ensure you are safely operating the DAA Top 360 with the specific OR table used.
-

3.10.1. Removing the appropriate section of the operating table

*Note: The figures below show an OR table in normal orientation. If you are using an OR table in reverse orientation, the leg section (1) indicated below is the head section, and the head section (4) indicated below is the leg section.

► Remove the leg section (1) of the operating table.

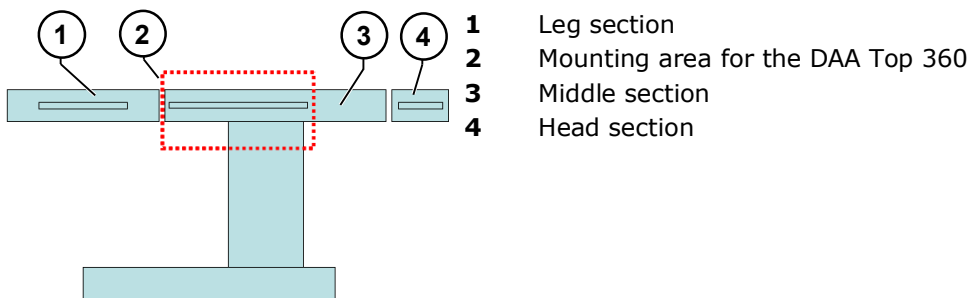


Fig. 3-12: Operating table with leg section

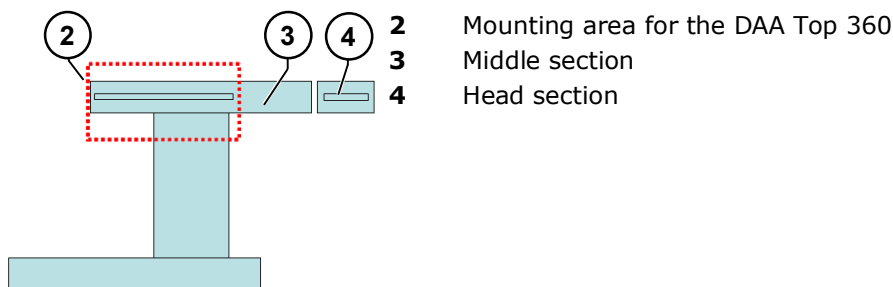


Fig. 3-13: Operating table without leg section

3.11. DAA Top 360 positioning

This product can be used with many commercial standard operating tables.

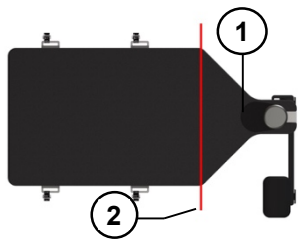


Fig. 3-14: DAA Top 360 positioning

- 1 Distal portion of DAA Top 360
- 2 Distal edge of OR table

- ▶ Remove OR table pads.
- ▶ Place the DAA Top 360 onto the operating table. The distal portion of the DAA Top 360 (1) should extend past the distal edge of the OR table (2).

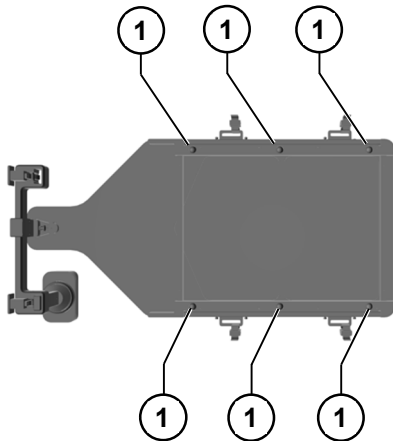


Fig. 3-15: DAA Top 360 rubber feet - view from below

- 1 Rubber Feet

- ▶ Ensure the OR table is level.
- ▶ All six rubber feet (1) should contact the OR table surface if possible for maximum stability.

3.12. DAA Top 360 mounting

This product can be attached to many commercial standard operating tables.

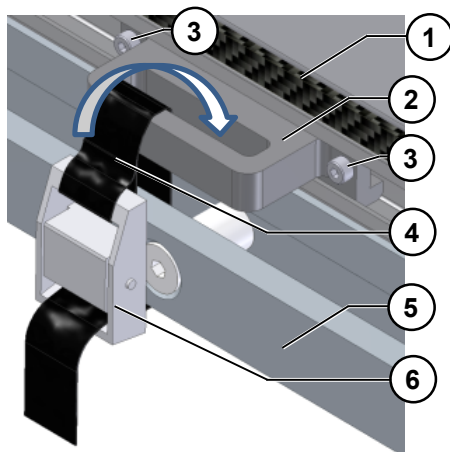


Fig. 3-16: DAA 360 mounting

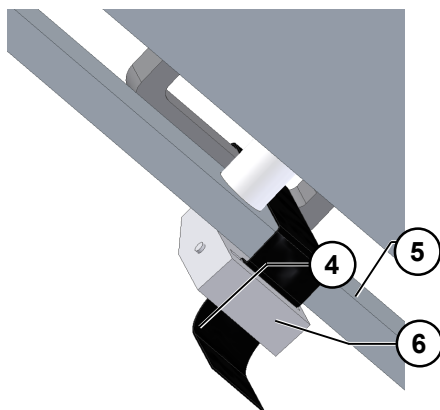


Fig. 3-17: Attachment view from below

- 1 DAA Top 360
- 2 Attachment
- 3 Screw on the attachment
- 4 Retaining strap
- 5 Operating table accessory rail
- 6 Buckle

- ▶ Choose the position of the retaining strap (4) on the attachment (2) and OR table accessory rail (5) so that the DAA Top 360 (1) cannot slide if the perineal post is pulled distally.
- ▶ Move the attachment (2) in the fixing rail accordingly and tighten the screws (3).
- ▶ Insert the retaining strap (4) through the attachment (2) from above.
- ▶ Insert the retaining strap (4) downwards around the operating table accessory rail (5) and from the back through the buckle (6) and secure the DAA Top 360 on the operating table by pulling down on the retaining strap (4) firmly. Repeat this process for all four straps.
- ▶ Make sure that the Velcro fastener securely holds the tabletop pad on the CFK tabletop.

**CAUTION****Risk of injury from improper mounting of the DAA Top 360**

If the DAA Top 360 slides because it was not fixed firmly enough to the operating table, the patient may be moved.

- ▶ Make sure that the DAA Top 360 is positioned and mounted correctly.
 - ▶ Check that the straps are properly tightened and secured on the attachments.
-

**CAUTION****Risk of injury from loose attachments**

A loose DAA Top 360 can cause injuries during surgery.

- ▶ Make sure that the DAA Top 360 is positioned and mounted correctly.
 - ▶ Before using the DAA Top 360, make sure that the straps have been firmly tightened on the attachments.
-

**WARNING****Risk of contamination**

The DAA Top 360 can contain hazardous germs.

- ▶ Properly disinfect the DAA Top 360 before use.
 - ▶ Use a new disposable protective cover before each surgery.
-

**Note**

Replace POP and femoral pads after approx. ten operations.
Replace tabletop pad after 1 year.

**CAUTION****Chemical hazard from cleaning agents**

Injuries may occur if the DAA Top 360 is not completely free from cleaning agents after cleaning.

- ▶ The DAA Top 360 must be covered with disposable protective covers before each surgery.
 - ▶ Replace the DAA Top 360 tabletop pad after 1 year.
 - ▶ Replace the DAA Top 360 femoral support pad after approx. ten surgeries.
 - ▶ Replace the DAA Top 360 POP pad after approx. ten surgeries.
-

**CAUTION****Risk of injury from breaking femoral support**

If traction is applied to the leg while it is resting on the femoral support, breakage of the boom can cause leg injuries because the combination of the leg's weight and tensile load exceeds the load-bearing capacity of the femoral support's boom.

- ▶ Do not apply traction to the leg when it is resting on the femoral support.
-

**CAUTION****Risk of injury to the thigh caused by the femoral support**

During surgery, the thigh is resting on the femoral support for a long time. The thigh tissue is very sensitive. Nerve compressions and skin lesions can occur.

- ▶ The surgeon is responsible for ensuring that the leg is properly held and cushioned on the femoral support.
-

3.13. Removing the DAA Top 360

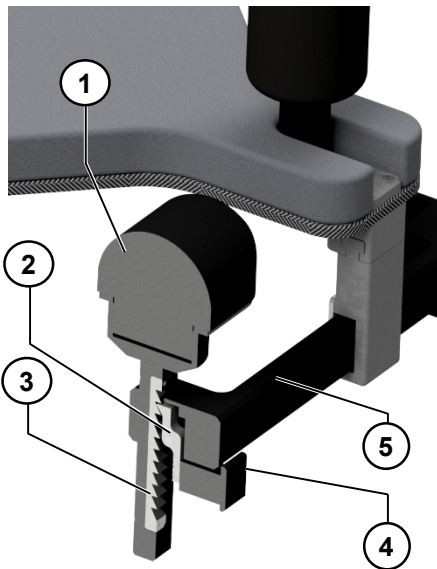
After use, the product must be removed from the operating table.

Disassembly is carried out in the following steps:

- ▶ Remove the DAA Top 360 tabletop pad.
- ▶ Pull the perineal post out of the holder.
- ▶ Remove the femoral support.
- ▶ Release and remove the straps on the attachments.
- ▶ Clean and disinfect all parts and package for storage.

3.14. Adjusting the femoral support

The height of the femoral pad can be changed in 10 mm increments.



- 1 Pad holder with pad
- 2 Latch
- 3 Toothed rack
- 4 Push knob
- 5 Transverse support

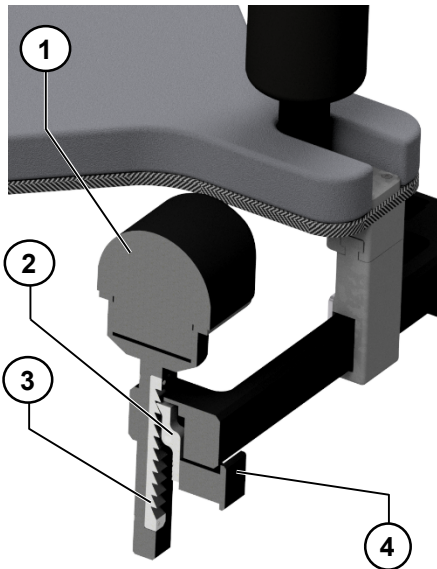
► Press the push knob (4) and adjust the pad holder (1) to the required height in 10 mm increments.

In the pad holder there is a toothed rack (3) that is fixed vertically by a latch (2).

The transverse support (5) can be moved to the side and can be pushed out of the exposure field when an X-ray image is taken.

Fig. 3-18: Adjusting the femoral support height

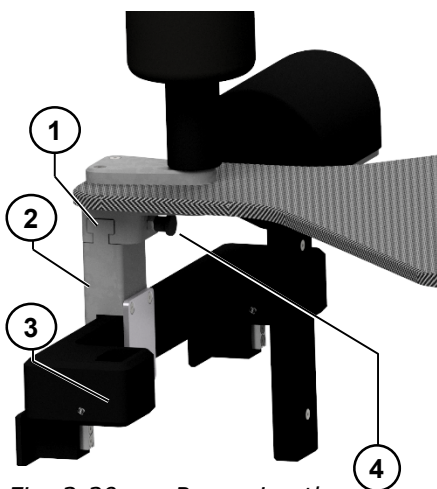
3.15. Removing the femoral support and transverse support



- 1 Femoral support
- 2 Latch
- 3 Toothed rack
- 4 Push knob

► Press the push knob (4) and pull the femoral support (1) with the pad upwards and out of the transverse support.

Fig. 3-19: Removing the femoral support




- 1 T-slot guide
- 2 Cross element
- 3 Transverse support
- 4 Locking pin

► Pull the locking pin (4) and pull the cross element (2) with the transverse support (3) out of the T-slot guide (1).

Fig. 3-20: Removing the transverse support

3.16. Technical data DAA Top 360

	The following details refer to the product without the pads.
---	--

	Designation/ Description	DAA Top 360
General information		
	Weight [kg]	13
	Service life [a]	10
	Length [mm]	1045
	Width [mm]	500
	Height [mm]	430
	Max. permitted patient weight [kg]	227
Operating conditions		
	Temperature range [°C]	+10...+40
	Relative humidity [%]	10...80
	Air pressure [kPa]	70...106
Storage conditions		
	Temperature range [°C]	+5...+40
	Relative humidity [%]	5...85
	Air pressure [kPa]	70...106
Transport conditions		
	Temperature range [°C]	-25...+60
	Relative humidity [%]	+5...+85
	Air pressure [kPa]	70...106
Medical device class	Class	I

3.17. Wear parts

Order number	Description	Category ¹
681 3137	Tabletop Pad – DAA Top 360	1
681 3136	Pad for the POP / Tabletop	1
681 3135	Femoral support pad – DAA Top 360	1

1) Explanation for the spare part categories

- | | |
|-------------------------|---|
| 1 Wear part | Part which is destroyed by mechanical stress in the surface |
| 2 Spare part /accessory | Identically constructed part to replace the defective part or to be installed as an accessory |

3.18. Accessories

Order number	Description	Category ¹
981 2001	Protective Mat	2

4. Maintenance/service

A list of the available replacement parts and consumables can be obtained from the distributor.

4.1. Important information

As with every technical device, these products also require

- proper operation in accordance with this user manual
- regular checks by the user
- regular maintenance and repair

These precautionary measures will allow you to keep the device in a functioning and safe operating condition. The operating company of a surgical facility is obligated to comply with this based on the accident prevention regulations, the Medical Devices Regulation and other regulations.

Maintenance consists of

- inspection work which can be carried out by the operating company
- maintenance tasks that are carried out by persons expressly authorized within the framework of service agreements or through service contracts
- cleaning work carried out by personnel instructed by the operating company
- disinfection tasks carried out by personnel instructed by the operating company

Maintenance work may only be carried out by specially trained or authorized personnel.

4.2. Checks by the operating company

The operating company has to check the device for obvious defects. If functional defects or other deviations from normal operating behavior occur, the operating company may no longer operate the device and has to inform customer service. Put the device back into operation only after repair is complete. Operation using defective components can result in increased safety risks.



CAUTION

Risk of injury from defective components

Defective components pose a risk of injury.

- ▶ Replace defective components only with original spare parts.

4.3. Maintenance plan

The following sections describe tasks which are required for optimum operation of the device without malfunctions.

If regular checks reveal increased wear, shorten the required maintenance intervals according to the actual signs of wear. If you have any questions about maintenance tasks and intervals, please contact the manufacturer; see contact data on page 2.

Interval	Maintenance task	Personnel
annually	Technical check of the device	Medical technician of the operating company
as needed	Tighten bolts	Medical technician of the operating company
before each use	Check accessory rails on the operating table for defects	Qualified medical personnel
before each use	Check tight seating of the screws on the rails of the operating table	Qualified medical personnel
before each use	Clean and disinfect the device	Qualified medical personnel

4.4. Maintenance work



WARNING

Risk of contamination

These devices are not shipped in sterile condition.

- ▶ Please clean and disinfect the devices according to the procedures approved by your organization.
-

4.4.1. Cleaning

Please take care in your selection of a cleaning agent:

ATTENTION

Surface damage due to wrong cleaning agent

- ▶ Do not use corrosives, solvents or grinding agents for cleaning or polishing.

 - ▶ Clean **plastic surfaces** only with a soap solution. The use of any other agents, such as those with high alcohol content, will cause the material to become dull or brittle.
 - ▶ Wipe **pads** with a moist cloth and a neutral cleaning agent.
 - ▶ Use only a moist cloth and mild cleaning agents to wipe off **painted parts and aluminum surfaces** and wipe dry with a dry, fluff-free cloth.

 - ▶ After cleaning, make sure that all moistened surfaces are properly dried.
-

4.4.2. Disinfection

Please take care in your selection of a disinfectant:

ATTENTION

Surface damage caused by wrong disinfectant

- ▶ Do not use any corrosive, solvent or gaseous disinfectants.
-

Surface disinfectants containing a range of additives such as aldehyde, quaternary compounds, guanidine derivatives and active oxygen have proved successful.

ATTENTION

Surface damage caused by skin disinfectant during surgery

- ▶ Avoid accumulations of skin disinfectant under the patient.
-

The methods used for disinfecting have to comply with the valid legal provisions and guidelines for disinfecting and for explosion protection.

- ▶ After disinfecting, make sure that all moistened surfaces are properly dried.

5. Transport, storage and disposal

5.1. Transporting while assembled

ATTENTION

Risk of damage from loose screws

If the product is transported while assembled, screws may become loosened which can result in damage.

- ▶ Do not transport the product while assembled.
 - ▶ Always check tight seating of screws.
-

5.2. Decontamination before shipping



WARNING

Health risk from contaminated device

Dangerous pathogens may be present on the device.

- ▶ Clean and disinfect the device according to the procedures approved by your organization before shipping.
-

5.3. Storage

ATTENTION

Risk of damage from incorrect storage

Incorrect storage of the product may result in damage.

- ▶ Store the product as per the storage conditions (see chapter 3.16. Technical data)
-

5.4. Disposal

Please ensure to properly dispose of or recycle the device and ensure that the pertinent legal requirements are observed. For this reason, this product must not be disposed of in ordinary industrial or household waste. Dispose of the individual component parts separately.

ADSM can provide support for proper disposal if necessary.

6. Accessories

6.1. Protective Mat

The protective mat can be used to protect the OR table surface and protect the bottom side of the DAA Top 360.

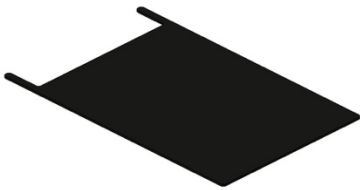


Fig. 6-1: Protective mat

- ▶ Place the protective mat so it lies between the OR table surface and the DAA Top 360.

7. Revision

Version	Release Date	Company	Reason for Change
Rev01	15/10/2020	ADSM	Creation
Rev02	25/01/2023	ADSM	<ul style="list-style-type: none"> -Update logo on labels -Clarified language regarding warning label for OR table tilting -Added note clarifying that the OR table sections may vary based on OR table orientation. -Added accessories section including protective mat. -updated IOT logos