

AERIAL® COUCH TOP FOR PROTON THERAPY

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Caution: Federal law restricts this device to sale by or on the order of a physician

1. General Product Information

The Aerial Couch Top for Proton Therapy is a medical device used for patient positioning and immobilisation in proton therapy. Its homogenous and streamlined design meets the specific standards proton therapy demands. The free-hanging design of all extensions ensures excellent homogeneity and dosimetric properties. The Aerial Couch Top is engineered to create a high level of accuracy, resulting in an excellent reproducibility.

Different versions of the Aerial Couch Top for Proton Therapy are available for use with machines from different vendors such as IBA and Mevion Proton Therapy systems.

This product may only be used in combination with immobilisation products from Orfit. Orfit prohibits the use of unauthorised third-party products in conjunction with its own products.

2. Product Description

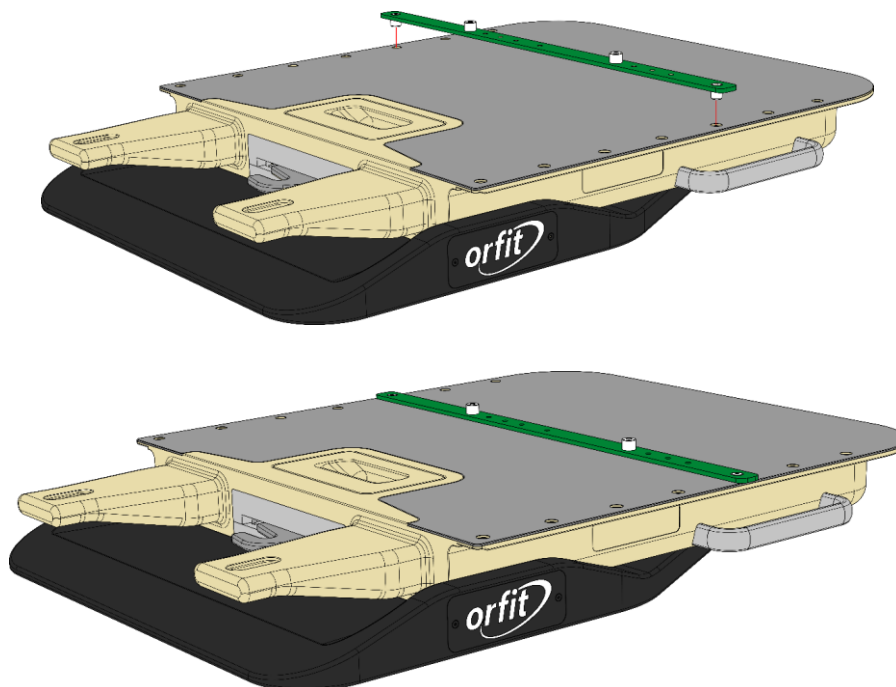
Intended Use

The Aerial Couch Top for Proton Therapy is intended to support, position and immobilise patients during proton therapy treatments. The base part is the basic element of the Orfit Aerial Couch Top. It is used in combination with different extensions to form a reproducible patient positioning and immobilisation system. An HP PRO extension for head & neck treatments and a rectangular extension onto which several other immobilisation products can be indexed are available. Information on these other parts can be found in the respective 'instructions for use' and on www.orfit.com.

Features

The base part is attached to the robot of the proton therapy machine by an interface plate. The type of interface plate depends on the type of robot delivered with the treatment machine. The base part can be installed on IBA Proteus ONE and Proteus PLUS machines with Leoni and Forte robots and on Mevion S250 Machines with a Mevion Robot.

According to the type of treatment, different extension base plates are available that can be attached to the base part by means of a user-friendly locking mechanism located outside of the treatment zone. This locking mechanism has a dual safety to prevent the extension from unlocking during set-up or treatment. All extensions are hanging freely and they don't require a support mechanism that needs to be moved or to be taken into account during planning and treatment. All extensions are made of carbon fibre for excellent homogeneity and dosimetric properties. The base part as well as the different extensions make use of the same indexing mechanism. The indexing holes are spaced every 70 mm along the length of the couch. The Orfit 2-pin indexing bars 32191 can be used to index any patient positioning and immobilisation system to the Aerial Couch Top.



3. Installation

General Installation Information

All fasteners used to mount the couch base to the robot interface and robot itself, should be tightened to a torque value as indicated. Refer to the table below, containing recommended values based on engineering standards.

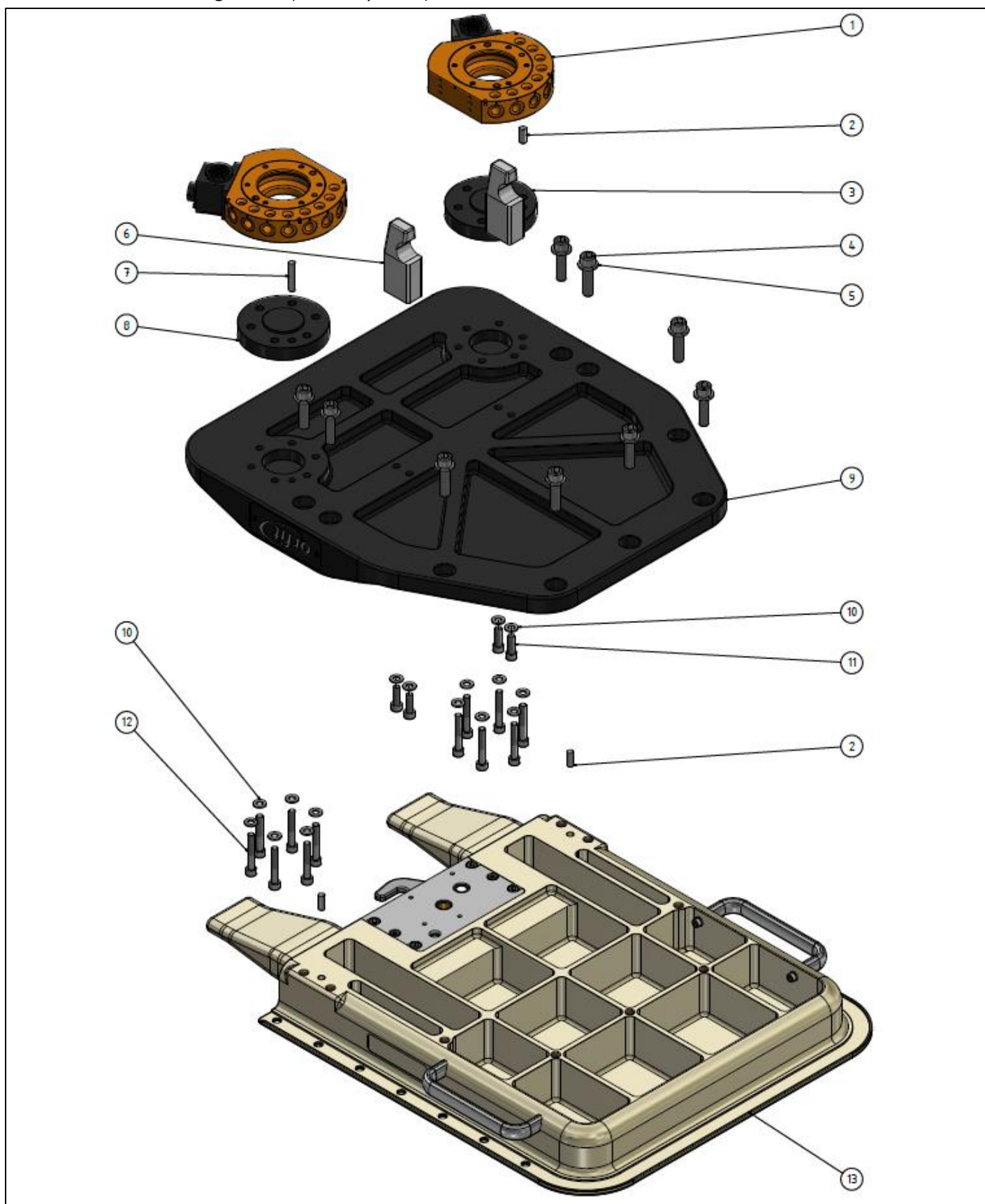
Furthermore, removable (blue) – medium strength - Loctite 243 must be used on most fasteners (see table).

Failing to do so may cause vibration to loosen bolts over time. Apply a few drops of Threadlocker on the threads before fastening the bolts. To assure a good bonding, pre-treat the threads with a general purpose cleaner - like Loctite 7063 – to remove greases, oils, lubrication fluids etc.



Part Lists

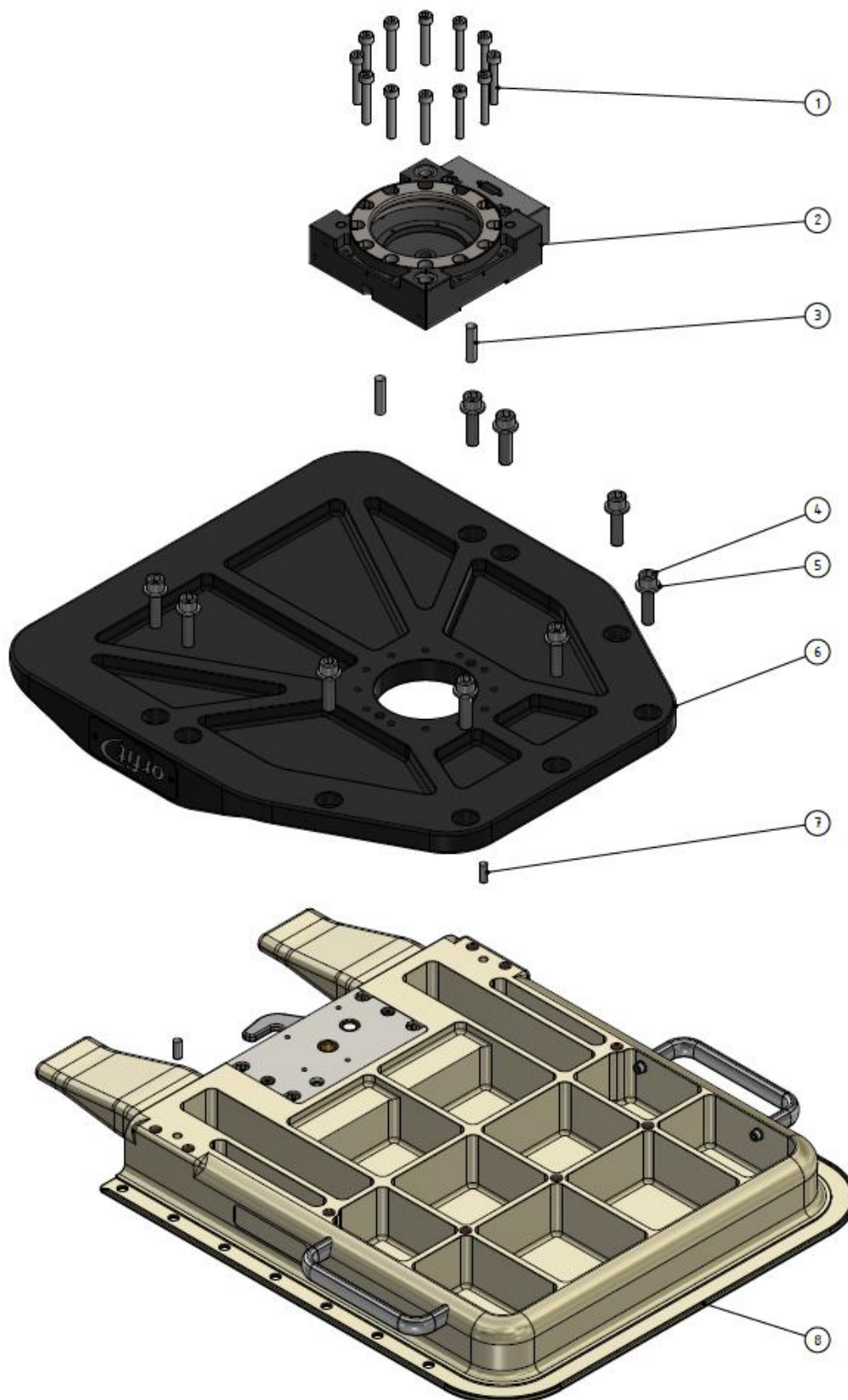
1. Forte robot configuration (for IBA systems) – Ref. 32827



Part List 32827			
Item Number	Part Number	Description	QTY
1	N/A	SWA-071-G19-000-US (Schunk/ATI ref.) Tool Changer – NOT PROVIDED BY ORFIT	2
2	32825/2/8	Dowel Pin 8 (m6) x 20	3
3	32825/13	Cylindrical Positioning Plate 1	1
4	32825/2/6	DIN 912 - M12 -1.75 x 45 mm, Class 12.9	9
5	32825/2/7	M12 Washer	9
6	32825/15	Mount for Safety Bar	2
7	32825/14	Dowel Pin 8 (h6) x 40 mm	1
8	32825/17	Cylindrical Positioning Plate 2	1
9	32827/2	Forte Adapter Assy	1
10	32825/20	Washer M8	16
11	32825/19	DIN 912 – M8 -1.5 x 25 mm, Class 12.9	4
12	32825/18	DIN 912 – M8 -1.5 x 50 mm, Class 12.9	12
13	32825/1	Base Part Assembly	1

Fastener Size, Class and Torque Specifications				
Mounting conditions	Fastener Size and Property Class	Recommended Torque	Threadlocker	Bolt Marking
Base Part Assembly (ref. 32825/1) to Forte Adapter Assy (ref. 32827/2)	DIN 912 - M12 -1.75 x 45 mm Class 12.9	49 Nm (36 ft-lbs)	Yes	Yes
Forte Adapter Assy (ref. 32827/2) to Robot Tool Side Couplers (not provided by Orfit). <i>Confirm torque with Robot Manufacturer.</i>	DIN 912 – M8 -1.5 x 50 mm Class 12.9	16 Nm (12 ft-lbs)	Yes	Yes (marking only within counterbore holes!)
Forte Adapter Assy (ref. 32827/2) to Mount for Safety Bar (ref. 32825/15).	DIN 912 – M8 -1.5 x 25 mm Class 12.9	16 Nm (12 ft-lbs)	Yes	No

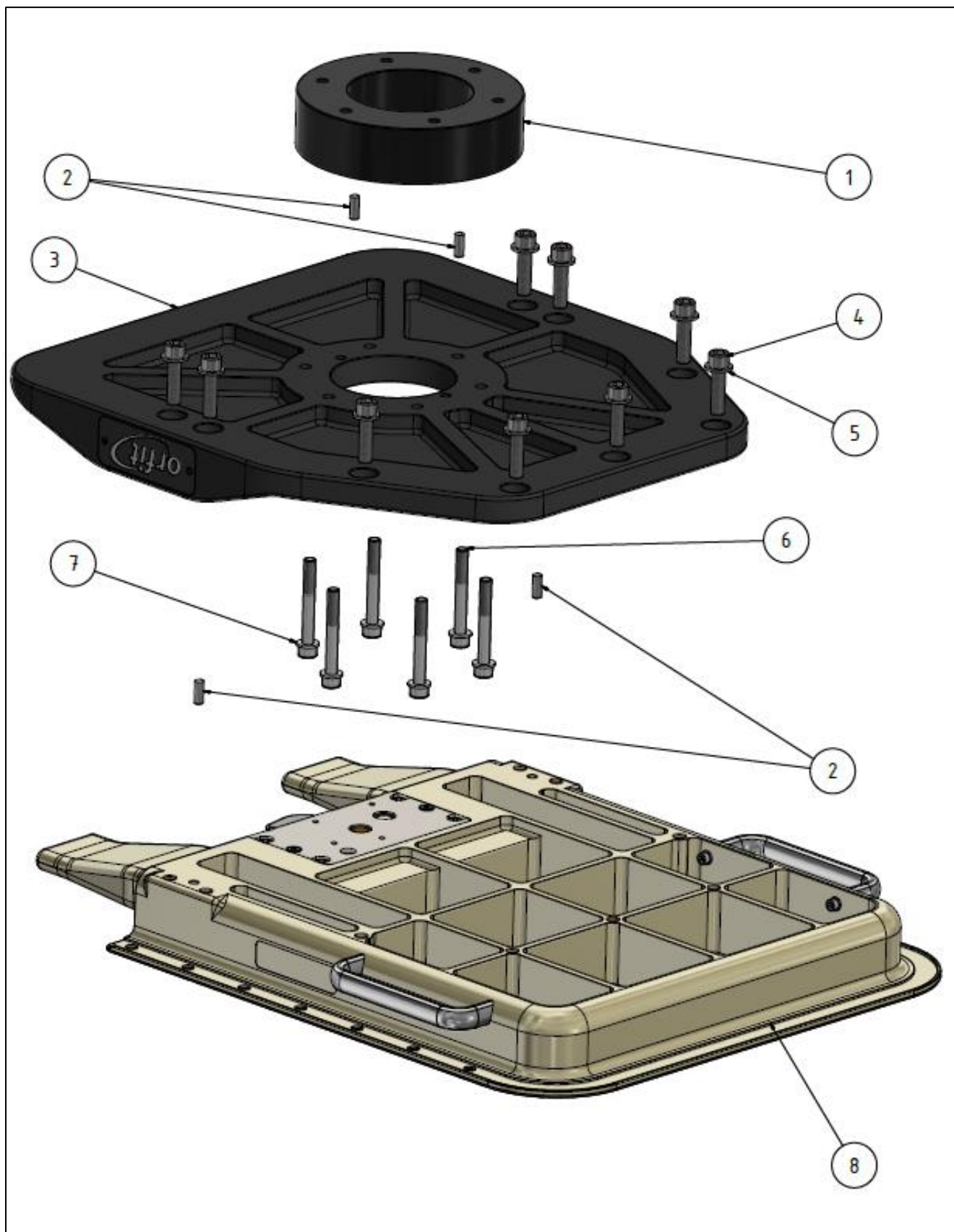
2. Leoni/Bizlink Orion robot configuration (for IBA systems) – Ref. 32826



Part List 32826			
Item Number	Part Number	Description	QTY
1	32825/4/4	DIN 912 – M8 -1.25 x 60 mm, Class 12.9	12
2	N/A	QC-210 Base Tool Changer (Schunk/ATI) – NOT PROVIDED BY ORFIT	1
3	32825/4/3	Dowel Pin 10 x 32 (h6)	2
4	32825/2/6	DIN 912 - M12 -1.75 x 45 mm, Class 12.9	9
5	32825/2/7	M12 Washer	9
6	32826/2	Leoni Adapter Assy	1
7	32825/2/8	Dowel Pin 8 (m6) x 20	2
8	32825/1	Base Part Assembly	1

Fastener Size, Class and Torque Specifications				
Mounting conditions	Fastener Size and Property Class	Recommended Torque	Threadlocker	Bolt Marking
Base Part Assembly (ref. 32825/1) to Leoni Adapter Assy (ref. 32826/2).	DIN 912 - M12 -1.75 x 45 mm Class 12.9	49Nm (36 ft-lbs)	Yes	Yes
Robot Tool Side Coupler (not provided by Orfit) to Leoni Adapter Assy (ref. 32826/2). <i>Confirm torque with Robot Manufacturer.</i>	DIN 912 – M8 -1.25 x 60 mm Class 12.9	27 Nm (20 ft-lbs)	Yes	Check mounting conditions in tool changer / robot manual

3. Mevion Robot configuration (for Mevion systems) – Ref. 32838



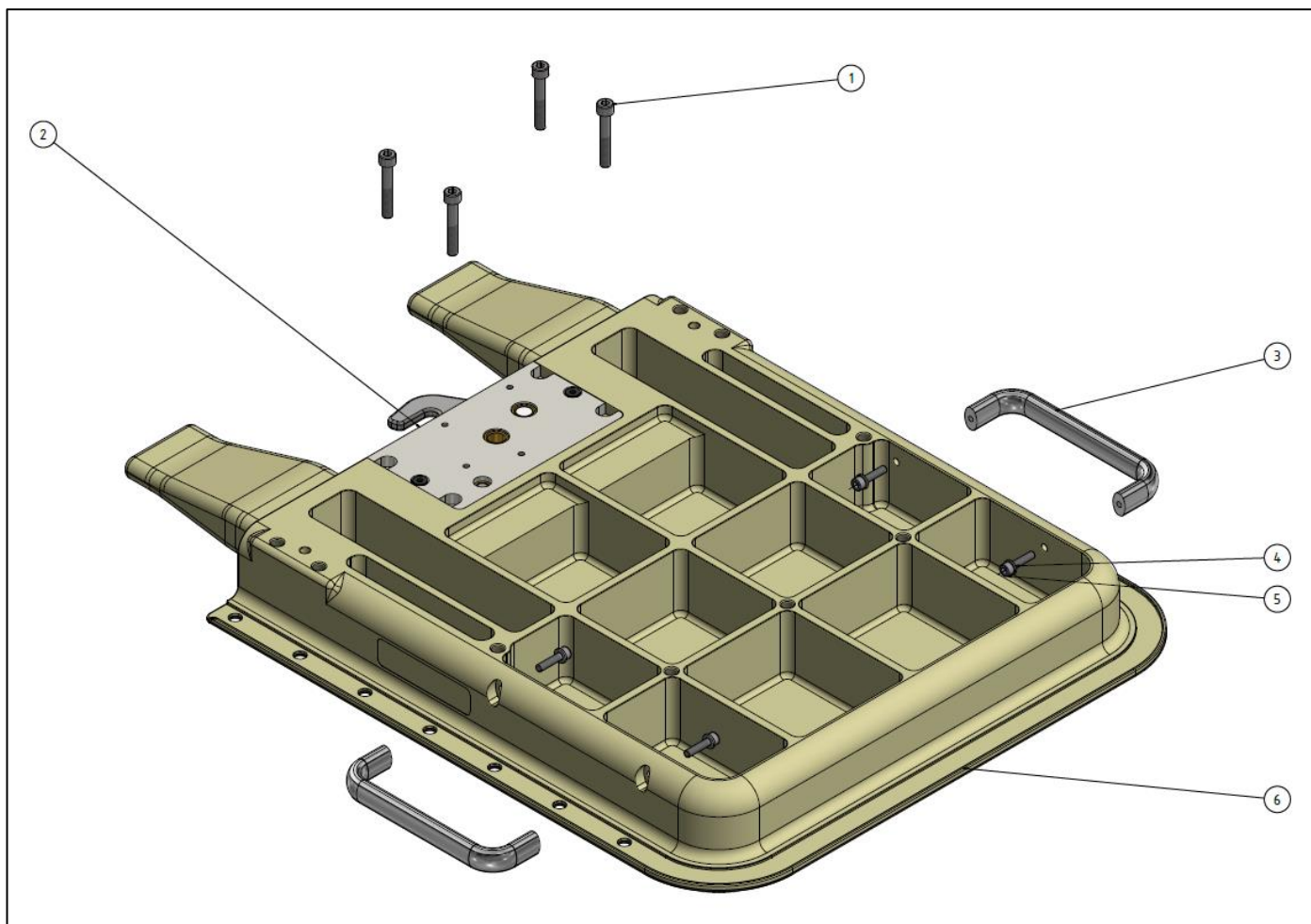
Part List 32838			
Item Number	Part Number	Description	QTY
1	32825/11/1	Spacer Ring	1
2	32825/2/8	Dowel Pin 8 (m6) x 20	4
3	32838/2	Mevion Robot Adapter Assy	1
4	32825/2/6	DIN 912 - M12 -1.75 x 45 mm, Class 12.9	9
5	32825/2/7	M12 Washer	9
6	32825/21	DIN 912 - M10 -1.5 x 80 mm, Class 12.9	6
7	32825/22	M10 Washer	6
8	32825/1	Base Part Assembly	1

Fastener Size, Class and Torque Specifications				
Mounting conditions	Fastener Size and Property Class	Recommended Torque	Threadlocker	Bolt Marking
Base Part Assembly (ref. 32825/1) to Mevion Robot Adapter Assy (ref. 32838/2).	DIN 912 - M12 -1.75 x 45 mm Class 12.9	49Nm (36 ft-lbs)	Yes	Yes
Mevion Robot Adapter Assy (ref. 32838/2) to Mevion Robot. <i>Confirm torque with Robot Manufacturer.</i>	DIN 912 - M10 -1.5 x 80 mm Class 12.9	42 Nm (31 ft-lbs)	Yes	Yes (marking only within counterbore holes!)

WARNING!

Since the Mevion robot has a sensitive calibration, installations of the couch should only be done by trained service personnel.

4. Base Part Assembly (Fastener Information) – Ref. 32825/1



Part List 32825/1			
Item Number	Part Number	Description	QTY
1	32825/3/35	DIN 912 - M8 – 1.25 x 45 mm, Class 12.9	4
2	32825/3	Locking Module Assembly	1
3	32825/2/3	Aluminum Handle	2
4	32825/2/5	M6 Washer – A4	4
5	32825/2/4	DIN 912 – M6 - 1 x 25 mm, A4	4
6	32825/2	Couch Base Assembly	1

Fastener Size, Class and Torque Specifications				
Mounting conditions	Fastener Size and Property Class	Recommended Torque	Threadlocker	Bolt Marking
Locking Module Assembly (ref. 32825/3) to Couch Base Assembly (ref. 32825/2)	DIN 912 - M8 – 1.25 x 45 mm, Class 12.9	16 Nm (12 ft-lbs)	Yes	No
Aluminum Handles (ref. 32825/2/3) to Couch base Assembly (ref. 32825/2)	DIN 912 – M6 - 1 x 25 mm, A4	TBC	Yes	No

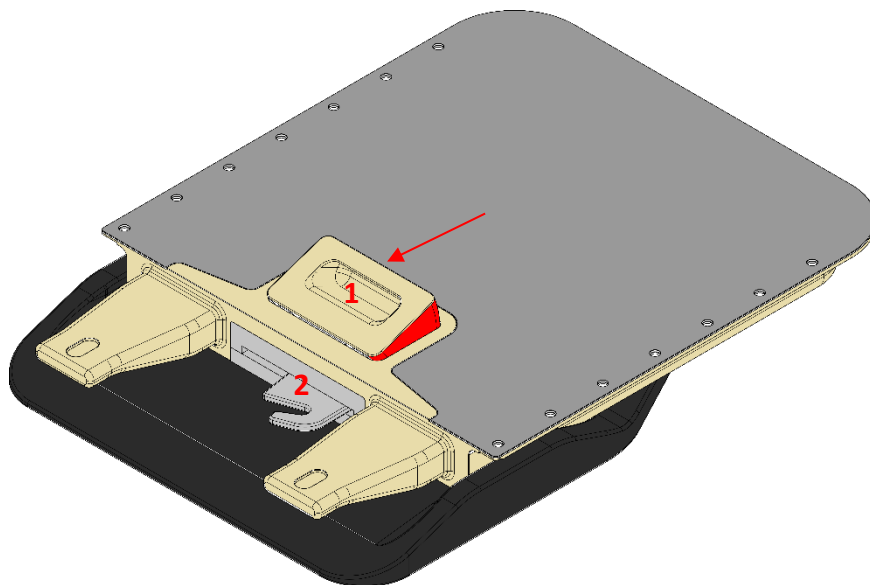
4. Operating Instructions

Locking Mechanism

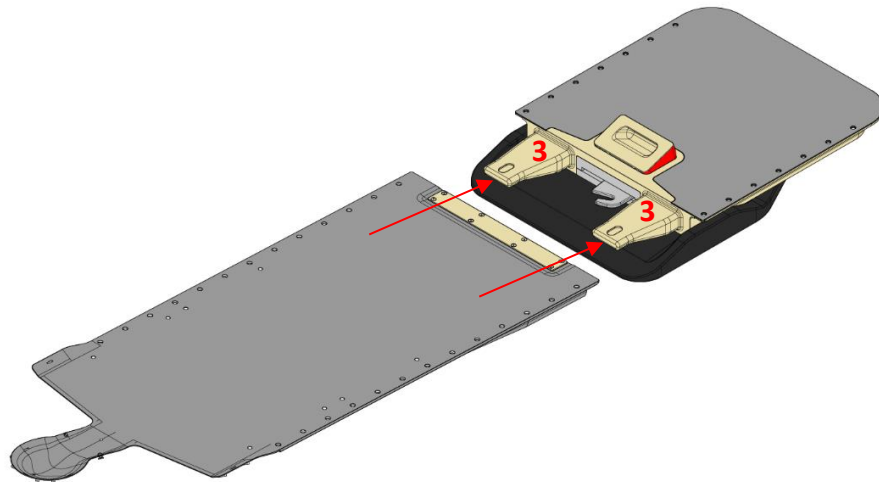
The couch base part is equipped with a locking mechanism to assure a tight and secure connection between the base part and the couch extension. The locking module is integrated in the couch and is operated with the lever handle. It is designed for ease-of-use and only requires a minimal operating action without compromising on user safety. Follow the procedures below to connect or disconnect the extension part from the couch base.

Procedure to mount an extension:

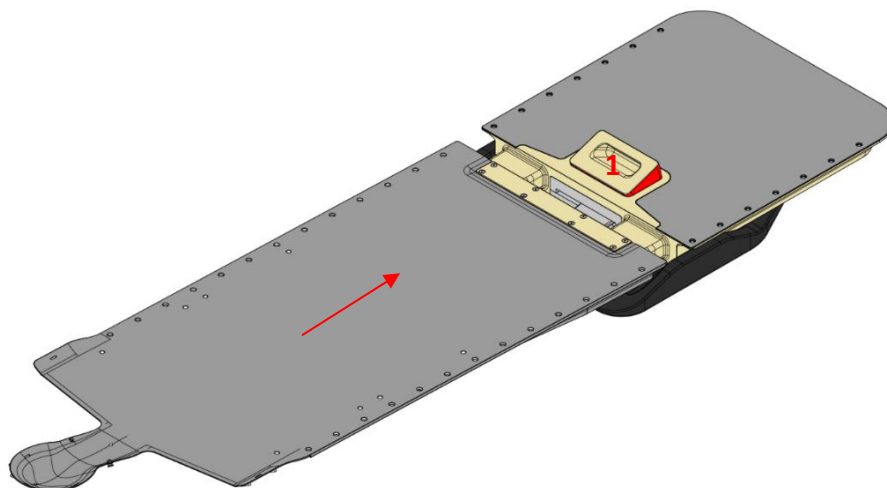
1. Pull the release lever (1) upwards. By lifting the release handle, the latch plate (2) will turn in the open position. The handle will stay in the upright position, showing an 'unlocked' sign at the sides.



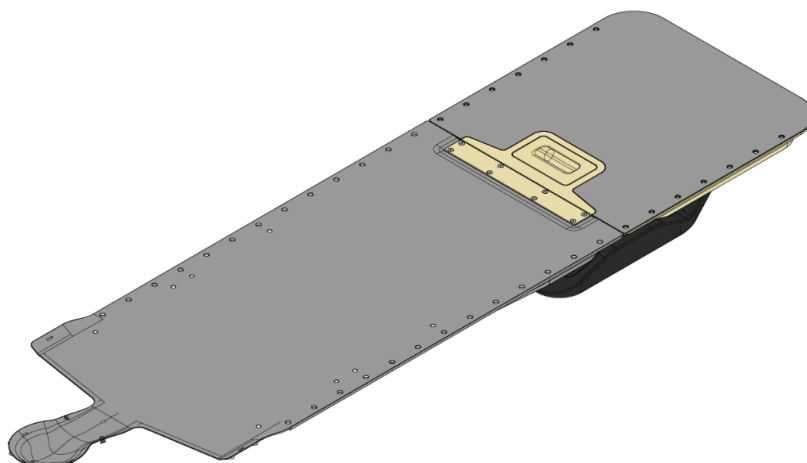
2. Grab the extension at the sides and hold the extension in front of the tabs and make sure the tabs (3) are positioned within the opposite cavities.



3. Slide the extension towards the base. By sliding the extension towards the base, the latch plate will turn into the locked position. The release handle – which is connected with the locking pin – will fall down into the locking position.

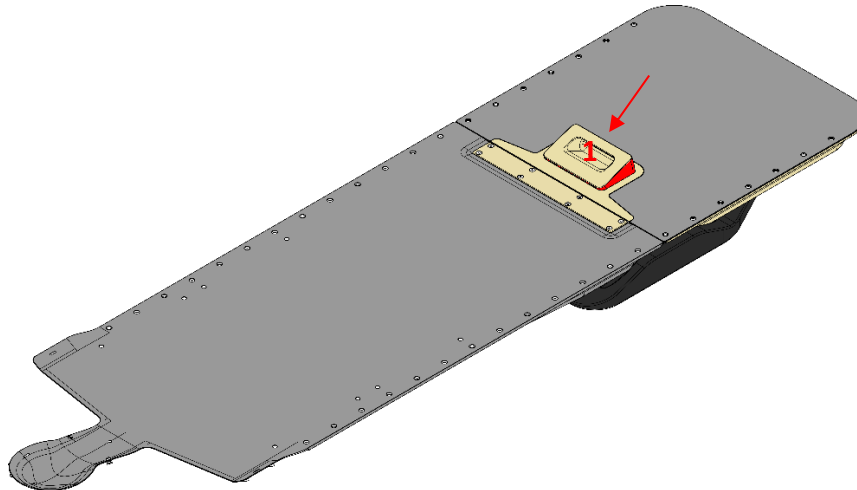


4. When the handle surface is flush with the top surface of the couch (the red unlocked sign is not visible), and when there is a small seam of +/- 1 mm between the couch base and the extension, then the couch extension is correctly secured to the couch base.

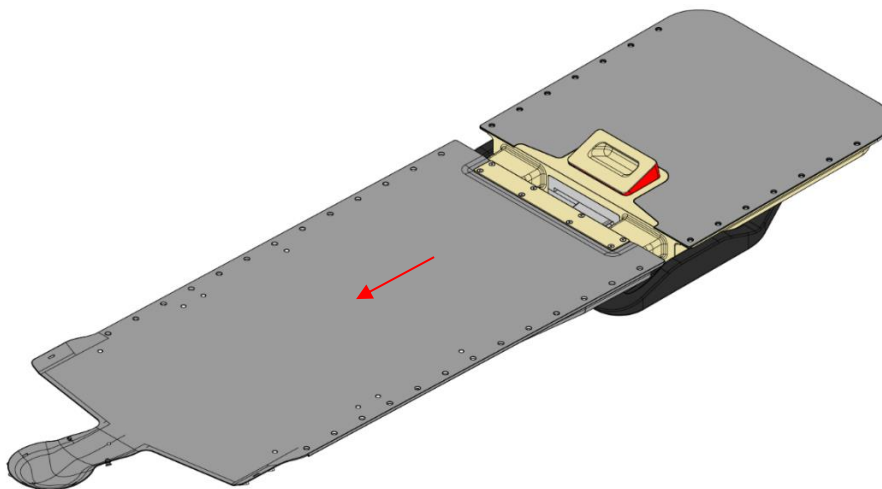


Procedure to dismount an extension:

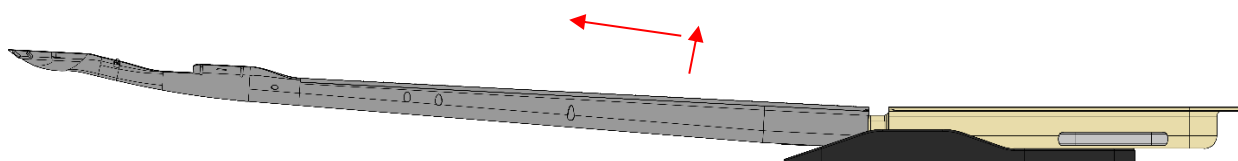
1. Pull the release lever. By pulling the release handle (1), the latch plate will be actuated and unlocked. The handle will stay in the upright position, showing an 'unlocked' sign at the sides.



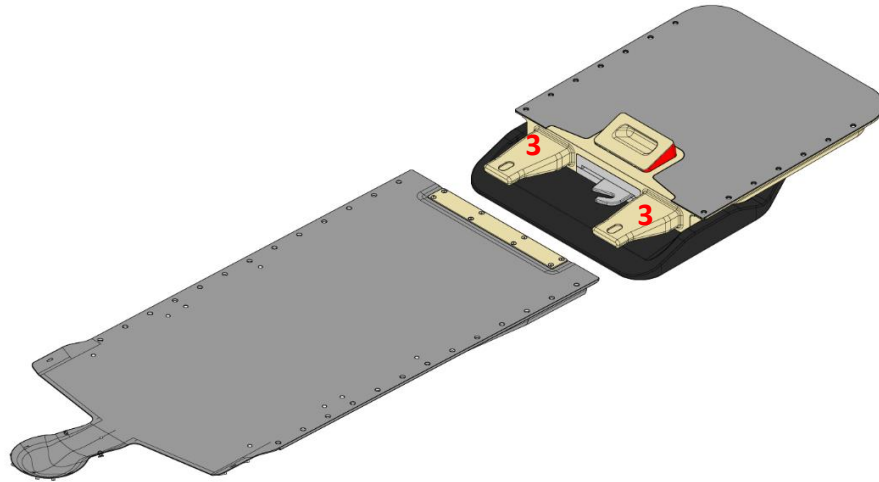
2. Grab the extension slide the extension outwards - in longitudinal direction – away from the couch base part.



3. When reaching the stop (second safety mechanism), lift the extension slightly. **Make sure you hold the extension around the 'hand' pictogram stickers with two hands because the extension is heavier towards the bottom!** The weight of the extension is not evenly distributed.



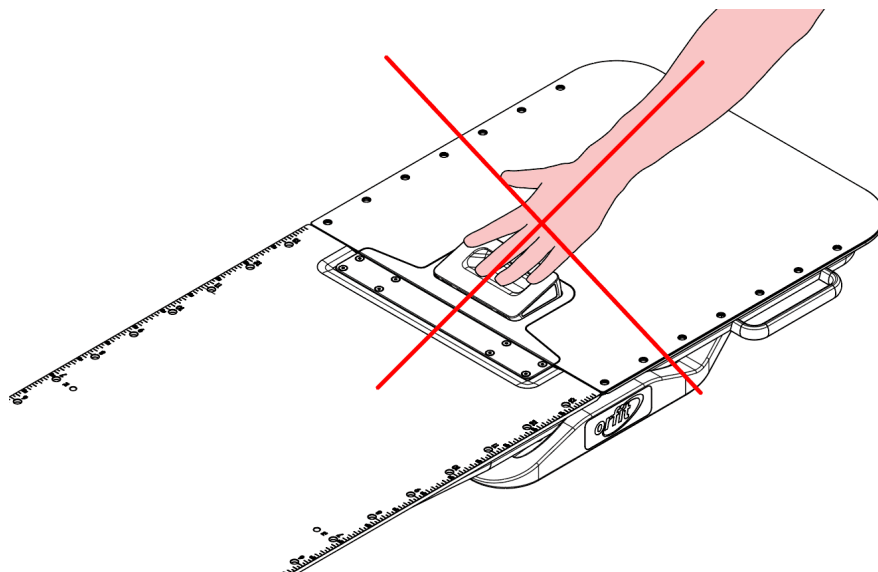
4. Remove the extension from the tabs (3).



5. Store the extension safely in a storage cart or against the wall to make sure it will not get damaged.

Caution!

- Never try to force the handle downwards because it might be blocked by the safety mechanism. It should lock by itself when moving the extension towards the end position.



- Once the release lever is pulled upwards, you have to remove of the extension completely (!) from the tabs before you can lock it again.

Patient Set-up form Available

A patient set-up form is available at the Orfit website. Please consult: www.orfit.be

5. Precautions for Use

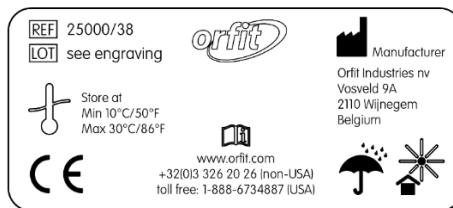
Warning labels and descriptions



An item marked 'MR Unsafe' is known to pose hazards in all MR environments.



Unbalanced (top heavy) parts of which the weight is not distributed evenly over the part are equipped with the 'Hands Here' pictogram. To easily handle the part, hands should be placed in the center of gravity. This blue label indicates the location where to place your hands when holding, installing or removing the part.



In this type of label you will find the general information including: manufacturer, information on the article and lot number, temperature (and other environmental information), CE marking and where to find information of the device.



Do not use if package is damaged. This label is used on devices that must not be used if the packaging holding the device is damaged. Damages on the packaging should be reported immediately to Orfit, because it may have influence on the structural integrity of the part.



The line represents the end of the sitting / patient's installation zone.

The area beyond this line, in the direction of the arrows, was designed to support the patient's upper torso only, not exceeding the load rating.

Standing or sitting on the couch insert/extension beyond the 'No Sitting Line' indication, may damage the device and cause injury.

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TREATMENT ZONE

The line marks the beginning of the treatment zone: the low density, homogenous area.



Use caution when moving the extension part towards the base part to avoid injury to the clinical staff or to the patient. Be careful for pinch points in the area of the seam. This area is marked with warning labels.



Use caution, read and understand the specific warning information before using the device.



Read and fully understand the operator manual before using the device. Failure to follow the operating instructions could result in serious injury.



MAXIMUM SAFE WORKING LOAD

235 kg (518 lbs) uniformly distributed load
Refer to insert and robotic system for specific load capacity which may be less.

Do not exceed 235 kg (518 lbs) uniformly distributed load or maximum safe working load of the (entire!) couch top. The specific load rating of the extension or robotic system may be less. In that case, refer to their specific load capacity information.



This sign marks that the release lever is in the 'unlocked' position. When the lever is in this position, don't put patients on the treatment couch. Always make sure the couch extension is locked to the base part before installing a patient on the couch. In a locked position, the red sign should not be visible.

Collision hazards

Use caution when moving the couch or gantry to avoid equipment damage or patient injury. The wide variety of motions obtainable with couch bases and gantry heads may present situations where the Aerial couch base or extension collides with other items. Equipment damage may occur.

General Precautions

Intended for hospitals -> Radiotherapy (proton therapy) departments. The product may only be used with the scope of its technical data (see chapter 6)

The product is intended for installation on IBA Proteus ONE and Proteus PLUS machines with Leoni and Forte robots and Mevion S250 Series with Mevion Robot. The application guidelines must be observed and complied with.

The product can only be used for the intended use (unless obtained written approval by ORFIT). Any utilization that exceeds or differs from the appropriate use is regarded as misuse.

Make no changes to the product

Conversions, changes and reworking, e.g. additional threads/ mounting parts or safety devices can impair the functioning and safety of the product or damage it.

- ➔ Structural changes should only be made with the written approval of ORFIT.
-

Spare parts

Using unauthorized spare parts can endanger personnel and damage the product or cause it to malfunction.

- ➔ Use only original spare parts authorized or approved by ORFIT.
-

Personnel qualification

If the personnel working with the product is not sufficiently qualified, the result may be serious injury and significant property damage.

- ➔ All work may only be performed by qualified personnel.
 - ➔ Before working with the product, the personnel must have read and understood the complete assembly and operating manual.
 - ➔ Observe the national safety regulations and rules and general safety instructions.
-

Notes on safe operation

Incorrect handling and assembly may impair the product's safety and cause serious injuries and considerable material damage.

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- ➔ Be careful not to drop or bump the couch base or couch extensions: hard impacts can (sometimes invisibly/internally) result in a loss of mechanical properties!
 - ➔ Avoid any manner of working that may interfere with the function and operational safety of the product.
 - ➔ Use the product as intended.
 - ➔ Read and understand the safety notes and assembly instructions.
 - ➔ Do not expose the product to any aggressive agents.
 - ➔ Eliminate any malfunctioning immediately.
 - ➔ Stop using the product in case a collision of the couch with the room or robot happened.
 - ➔ Observe the care and maintenance instructions.
 - ➔ Consult the local safety, accident prevention and environmental protection regulations regarding the product's application field.
 - ➔ Don't place sharp objects on the couch as this may damage the carbon fibre top layer.
-

6. Properties

Physical properties of the couch base part

Dimensions:

721 x 540 x 90 mm (28.385 x 21.260 x 3.543 inches) – excluding robot spacers etc.

Weight:

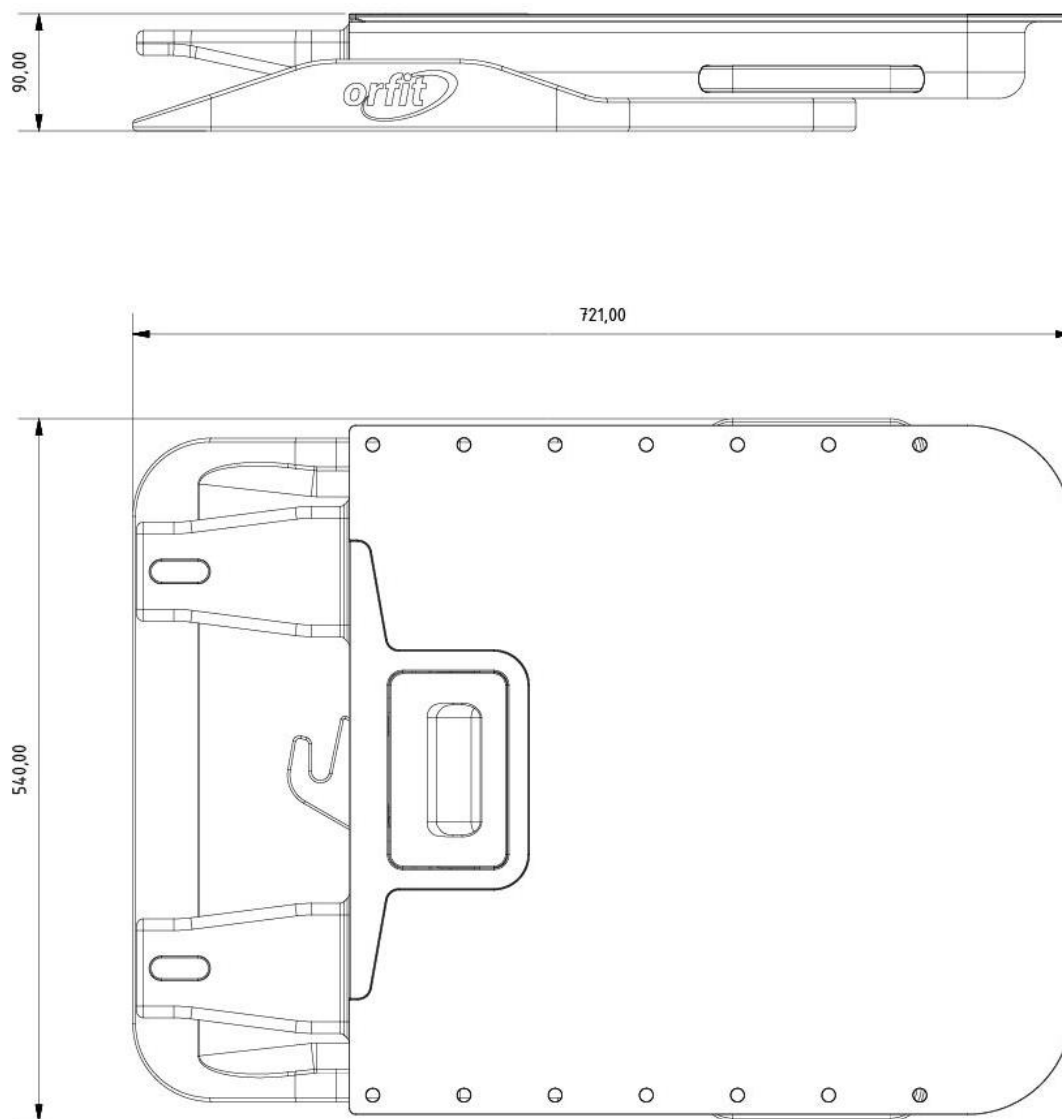
Ref. 32826 (IBA + Leoni Orion robot) : 35 kg (77.2 lbs)

Note: excluding tool changer of robot.

Ref. 32827 (IBA + Forte robot) : 36.5 (80.5 lbs) – including coupler spacers + safety handle hooks.

Note: excluding tool changer of robot

Ref. 32838 (Mevion + Mevion Robot) : 38 kg (83.8 lbs) – including spacer ring.



Mechanical properties

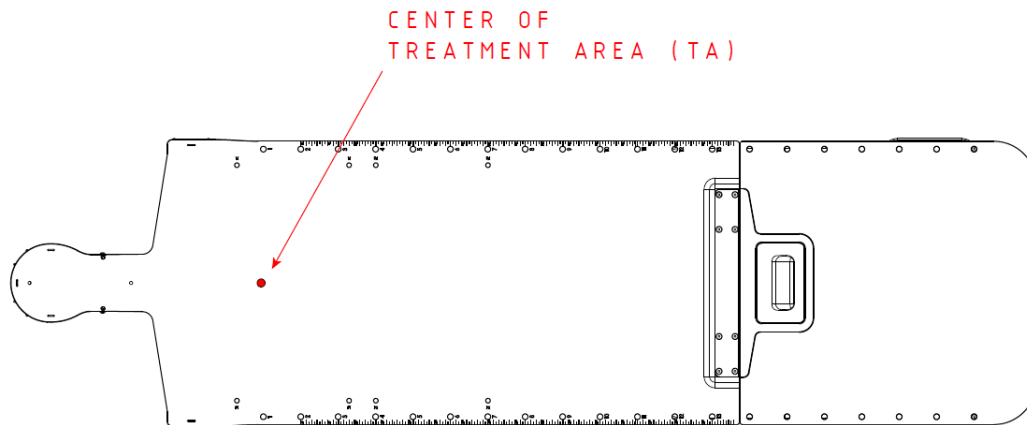
Deflection:

As deflection information is 'Couch Extension'-specific, consult the Instruction For Use of the couch extension for more information.

The Aerial Couch Extensions meet the deflection standards and requirements of IEC 60976 norm.

The IEC 60976 deflection requirements consist of two tests. The first test requires a 150 kg mass, distributed over 2 meters measured from the top end of the couch. The second test requires a 30 kg mass, distributed over 1 meter measured from the top end of the couch. The difference in deflection at the centre of the Treatment Area shall be lower than 5 mm.

When the Aerial Couch (Couch Base + 25000/34 extension) is mounted to a rigid base, the difference in deflection in the Center of the TA (850 mm from robot rotation axis) is about 1.10 mm.

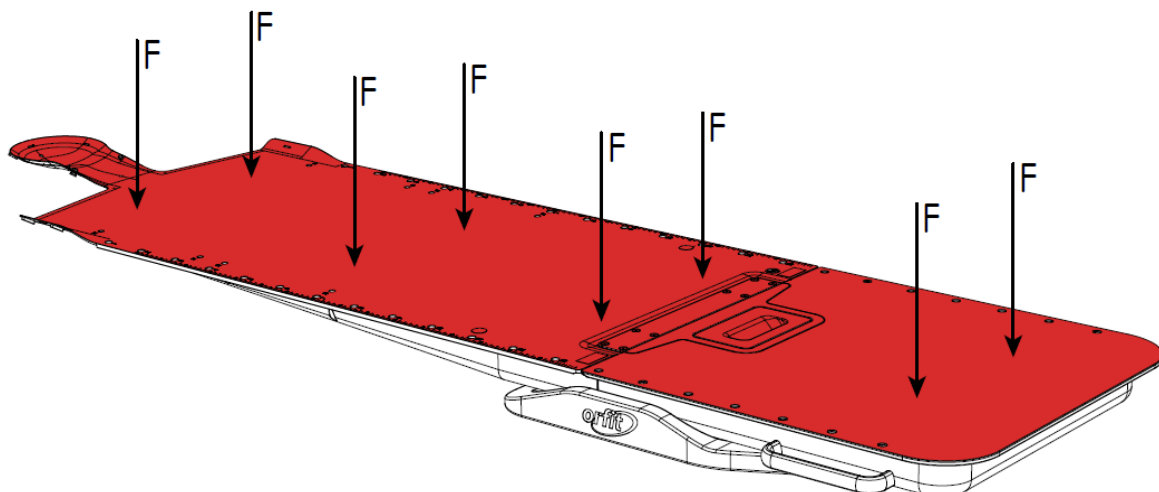


Load Rating and Capacity:

1. Load rating of couch: Max Safe Working Load: 235 kg (518 lbs)

Note:

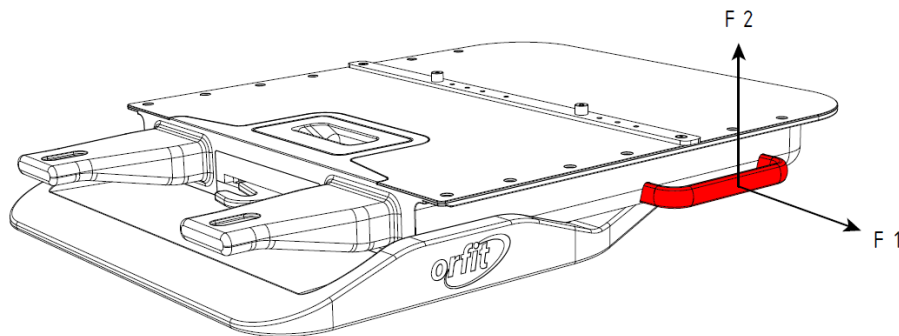
- The maximum load is distributed over the entire couch; extension + base part(see image)
- The specific load capacity of the robotic system may be less. Please respect the specific safety requirements of the robotic positioning system!



2. Load rating of side handles:

F1: 2750 Newton / 275 kg

F2: 1500 Newton / 150 kg



Material properties

The base part of the couch is made from the following materials;

- Aluminium
- Carbon fibre
- Stainless Steel
- Steel
- Bronze
- Rubber

Dosimetric properties

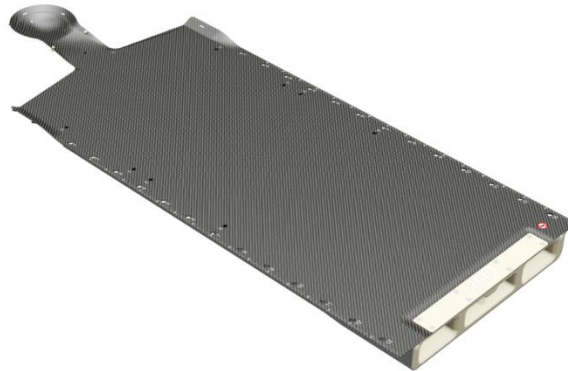
The base part of the Aerial couch is made of metallic parts and is therefore not intended for beam passage. Please consult the Instructions For Use of the different couch extensions for their specific dosimetric properties.

The cantilevered couch extensions are radiolucent and meet IEC and FDA requirements for attenuation. Thanks to the stiff & light composite structure, the boards provide high-quality images for kilovoltage imaging using standard X-ray and Cone Beam CT (CBCT), as well as portal imaging using Megavoltage energies.

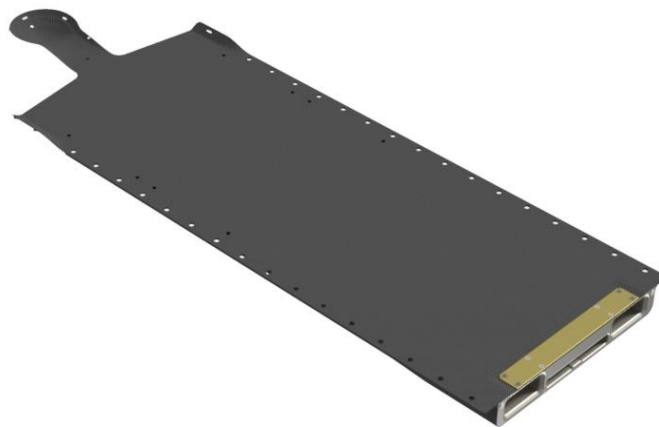
7. Compatible products

A wide range couch extensions are available for the Aerial Couch. More information about these extensions can be found in the respective instructions for use. Information on accessories and thermoplastic masks that can be used with the extensions can also be found in the respective instructions for use and on www.orfit.com.

25000/34 – HP PRO Extension for Adult (Intracranial)



25000/40 – HP PRO Extension for Adult – Long Version (Cranio-spinal)



25000/38 & 25000/53 – Rectangular Couch Extensions (Long version & Short version)



25000/67 – HP PRO Extension for Adult – Short Version



25000/62 – HP PRO Extension – Paediatric 0-7 years



8. Storage

Environmental conditions

When not connected to the robot, always store the product in a safe place to prevent it from getting damaged. Always store the couch base part flat, and never store in an upright position as this might damage the thin edges. Prevent hard objects from falling onto the plate. Do not place any heavy items on top of the extension while stored. Respect the following environmental conditions:

Operating Temperature Range:
10° C to 40° C (50° F to 104° F)

Operating Relative Humidity:
10% to 90% Non-Condensing

Storage Temperature Range:
0° C to 50° C (32° F to 122° F)

Storage Relative Humidity:
0% to 95%

Incorrect ambient and operating conditions can make the product unsafe, leading to the risk of serious injuries, considerable material damage and/or a significant reduction to the product's life span.

9. Maintenance and waste management

Contact information regarding service

welcome@orfit.com

Preventive maintenance

Periodic checks of the product should be done to insure the parts are not worn and require repair or replacement. Do not attempt to make repairs yourself. Contact your distributor or local sales representative if there are any questions or concerns.

Periodic checks of the following parts is extremely important in order to safeguard a good and secure operation:

- Lever handle locks correctly.
- Tabs of the couch show no considerable damage (apart from normal wear).
- Tabs and locking mechanism need periodic lubrication to facilitate an easy sliding fit. (refer to specific instructions on how to properly lubricate and clean the parts).
- Periodically check all fasteners for tightness:
 - Robot coupler connected with all bolts snug-tightened with prescribed torque. – See chapter 3.
 - Robot interface plate and base part connected with all bolts snug-tightened with prescribed torque. – See chapter 3.
- No damage of latch plate



Cleaning

This product can be cleaned and disinfected by means of soapy water, ethanol or an isopropanol based disinfectant, applied with a soft cloth. Do not pour or spray liquids directly onto the couch as they may flow into the seams of the locking mechanism. Always apply the solution on a clean cloth before wiping the surface.

If unsure about the cleaning fluid, do not use. Never use aerosol sprays, corrosive cleaning agents, solvents or abrasive detergents.

Protect the locking mechanism from the following contaminations: chips, liquids, dust and dirt.

Accumulation of dust and dirt may influence smooth functioning of the connective mechanism.

Proper maintenance will positively influence longevity and ease of use of the product.

Since the connection between the extension and the base part is assured by a very tight fit (for accuracy and strength), it is important to keep the tabs (of the base part) and the cavities (in the extension) clean. In case of excessive contamination, there will be a risk that the extension will not completely move into its final position. To avoid this from happening, make sure the product is kept clean.

Lubrication

Make sure to clean the interface of dirt and dust before lubricating.

Orfit advises to clean and lubricate the interface with an interval of 3 weeks. This interval can be shorter or longer, depending on intensity of use.

Note:

For lubrication we recommend using a teflon / PTFE based lubricant with a low viscosity to make sure the lubrication film is thin (kinematic viscosity of +/- 22 CsT) and not sticky. Make sure the lubricant doesn't pose any threat to its operational environment: medical grade / food grade.

- Lubrication of tabs (base part)
 - Make sure the part is thoroughly cleaned and free of dust/dirt(see instruction above).
 - Apply lubricant on both tabs
 - Disperse the lubricant on the top, bottom and sides of the tabs by using a paper tissue or a clean rag.



- Lubrication of cavities (couch extensions)
 - Make sure the part is thoroughly cleaned and free of dust/dirt(see instruction above).
 - Apply lubricant in both cavities
 - Disperse the lubricant on the top, bottom and sides of the cavities by using a paper tissue or a clean rag.



Recycling and disposal

All parts of the product can be disposed of with general household waste. But please note that the **aluminium parts can be recycled** (without loss of quality). Please take into account the ecological aspect and try to get these parts recycled as they contain high quality metals.



10. Trouble shooting

Locking mechanism doesn't work

- Take off the extension (fully!) from the tabs and insert it again
- The lever should be upright (see 'unlocked' sign at the side of the handle) when inserting the extension.

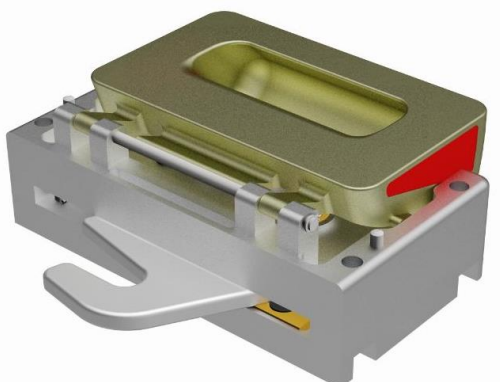
Extension doesn't slide towards the end

- Dirt on the tabs: clean the tabs, see chapter 'lubrication'
- Dirt in cavities of extensions: clean the connection, see chapter 'lubrication'
- Check if secondary locking pins are fully fastened and don't stick out.

In case of loss of power

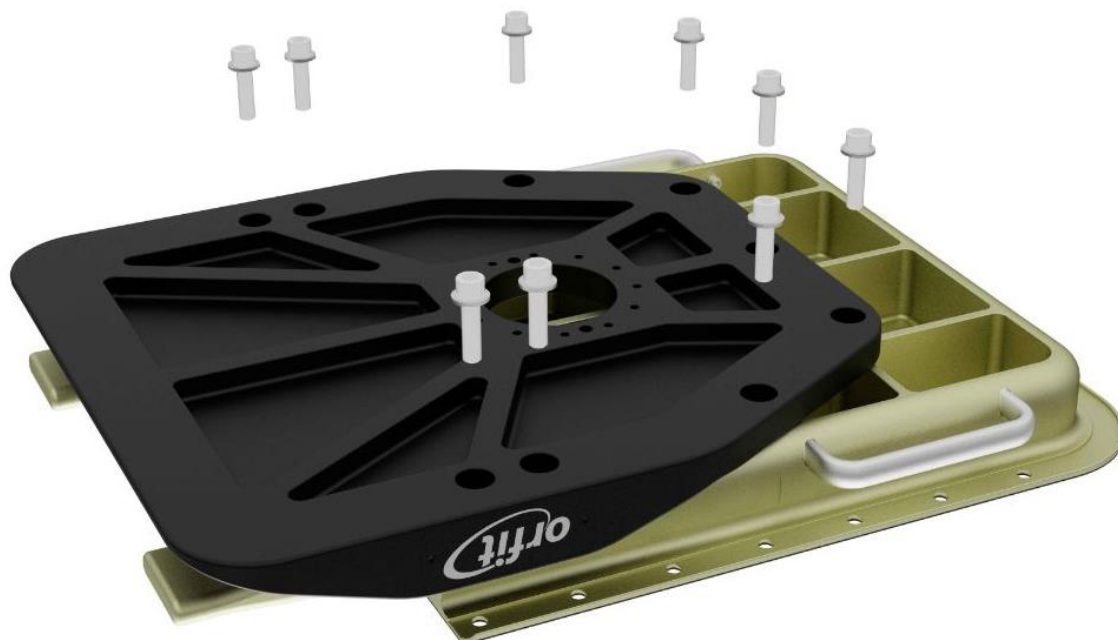
- Dismount couch to get access to coupler/tool changer. (see Schunk IFU)

11. Assembly / disassembly of locking module



The locking module (ref. 32825/3) can be assembled/disassembled for maintenance purposes. In order to have access to the Locking Module (ref. 32825/3), you first have to disassemble the robot interface plate. Follow the steps below to dismount the robot interface plate and locking module. If you want to install the part again, follow the steps in reverse order. Make sure the bolts are fastened with the prescribed torque and threadlocker. (see chapter 3).

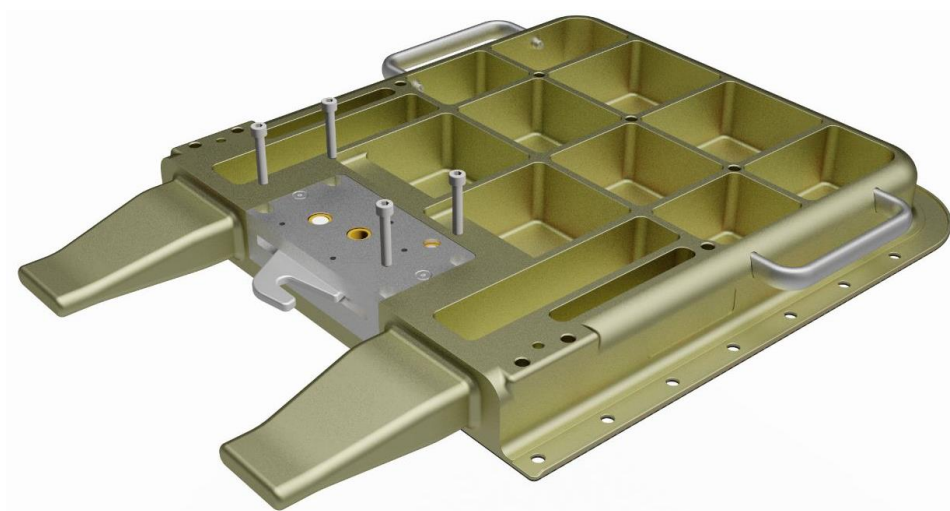
Step 1: unscrew the 9 x M12 bolts and washers.



Step 2: take off robot interface plate and two dowel pins.



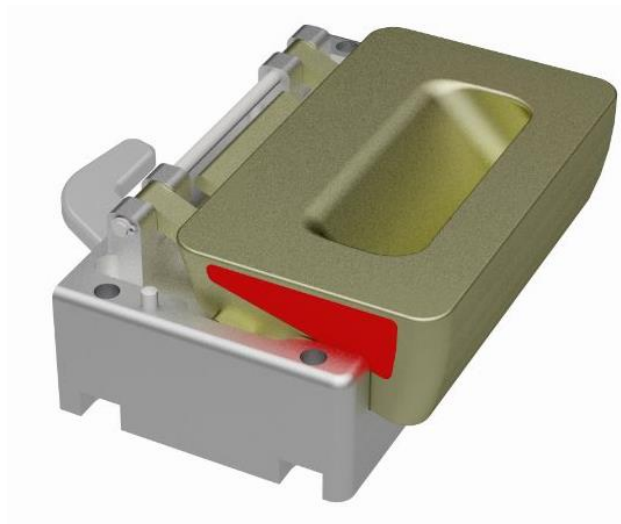
Step 3: unscrew the 4 x M8 bolts.



Step 4: the locking module can now be taken out. As the module is positioned with two dowel pins, you first have to move it out straight, before turning it out of the cavity as shown below. If it doesn't come out easily, you can (!) 'softly' knock or push on the release handle from the other side.



Step 5: the locking module is now disassembled.



12. Warranty

Orfit warrants that its products, if used as intended, are free from defects in materials and workmanship for a period of two (2) years from date of purchase. Please note that failure or damage arising from ordinary wear and tear or overloading are not included in the warranty.

When a product fails during the limited warranty period for reasons covered by the limited warranty (excluding misuse or unintended use), Orfit will decide to:

- Repair the device, or
- Replace the device with another device.

Orfit maintains the option to either repair or replace any item that falls under said warranty.

If the device is altered in any (without prior written permission from Orfit), Orfit has the right to refuse any warranty on the product. This warranty excludes any products that are not manufactured by Orfit.

To request warranty service, please contact your local distributor or sales representative. Adding the information below will help Orfit in processing the complaint and in finding a solution to the problem:

- The facility name, address and telephone number.
 - Your name
 - Date of purchase
 - Billing/Account name and address with zip code
 - Product description, including lot and serial numbers. (written or with pictures)
 - Information on the failure
 - Visual information (pictures / movie)
-

13. Intellectual property

Trademarks

Aerial Couch® is a registered trademark of Orfit Industries.

Patents

BE2018/5513

EP2019/069037

14. Additional information

For additional information such as distributor contact information, product brochures, Safety Data Sheets and regulatory information, please visit our website www.orfit.com.

Note:

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ORFIT INDUSTRIES
Vosveld 9A | B-2110 Wijnegem | Belgium
T (+32) (0)3 326 20 26
welcome@orfit.com

www.orfit.com



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