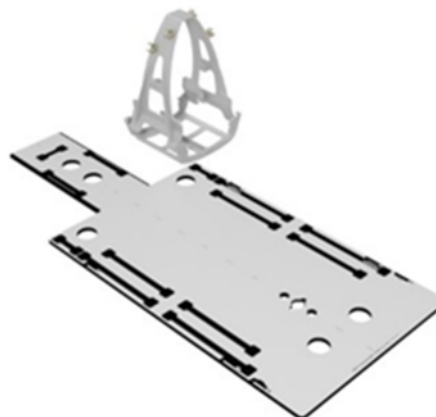


ORFIT® MRI-S SOLUTION HEAD, NECK AND SHOULDERS



Article No. : 29102

A. GENERAL PRODUCT INFORMATION

The products referred to in these instructions are medical devices, used for patient positioning and immobilisation (head & neck) in radiation therapy. This product can only be used during simulation.

This product may only be used in combination with immobilisation masks produced by Orfit. Orfit prohibits the use of unauthorized third-party products in conjunction with its own products.

B. PRODUCT DESCRIPTION

This HPL (high pressure laminate) base plate can be used on various Siemens MAGNETOM® family MRI scanners. The base plate has a support structure to mount two flexible coils (2) around the head of a patient and still be able to use a thermoplastic mask. Specific fixation devices are used to attach the base plate to the different kinds of couches of the MAGNETOM® family (1).

EFFICAST® pre-cuts can be secured on the base plate via the HP (High Precision) slots (3). HP head rests, blocks and wedges and other cushions fit in the knob holes provided (4).

Information on these other parts and instructions on how to make masks can be found in the respective 'Instructions for Use' and on www.orfit.com.



Note: This picture does not show the pelvic slots and leg separator hole in the base plate.

C. PART LIST

Art. No.	Description	#
29102/1	HPL base plate	1
29102/2	Head Bridge for Flex Coils Large	1
29102/3	Head Levers for Flex Coils Large (2 pcs.)	1
29102/4	Base Plate Indexing Support Type 1	4
29102/5	Base Plate Indexing Support Type 2	1
29102/6	Base Plate Indexing Support Type 3	3
29102/8	Base Plate Indexing Support Type 4	1
29102/9	Base Plate Indexing Support Type 5	3
32702-MD	Set of 6 HP Head Supports - Regular Density	1
32110/8	EVA Handle Set - Small	2
32110/9	EVA Handle Set - Medium	1
32110/7	EVA Handle Set - Large	1

D. FIXATION OF THE BASE PLATE TO THE MRI SYSTEM

Depending on the type of MRI system, different fixation devices are needed for installing the base plate. The following table explains for which kind of MRI system, which kind of fixation device should be used. The positions are marked on the base plate as an A and B side in combination with numbers 1 to 3 from head to foot side respectively.

Tim systems	Indexing support	Base Plate Position
Avanto, Trio, Espree, Symphony	4 x 29102/4	1A, 2A, 1B, 2B
Verio	4 x 29102/4	1A, 3A, 1B, 3B
Tim 4G systems	Indexing support	Base Plate Position
Skyra, Spectra, Aera with narrow T groove (see below for serial number)	3 x 29102/6 1 x 29102/5	2A, 1B, 2B 1A
Skyra, Spectra, Aera with wide T groove (see below for serial number), Vida, Sola	3 x 29102/9 1 x 29102/8	2A, 1B, 2B 1A

Note: The MAGNETOM Systems including the tables with the narrow T groove have a serial number lower than:

- Aera: 42466,
- Skyra fixed table: 46160
- Skyra mobile table: 46165
- Skyra fit: 70025
- Spectra: 72047

The MAGNETOM Systems including the tables with the wide T groove have a serial number higher than or equal to:

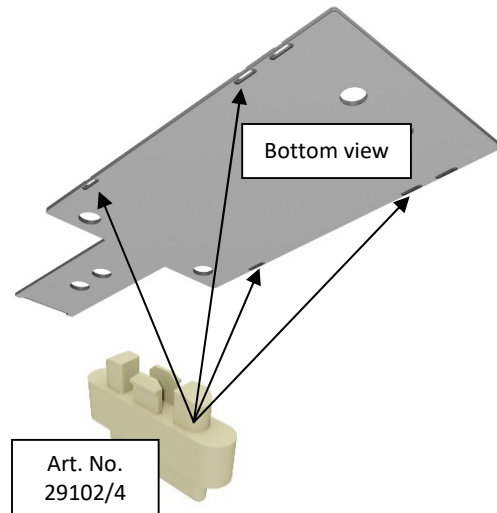
- Aera: 42466,
- Skyra fixed table: 46160
- Skyra mobile table: 46165
- Skyra fit: 70025
- Spectra: 72047

There are 5 different indexing supports available. They are shown in the picture below and from left to right the article numbers are 29102/4, 29102/5, 29102/6, 29102/8 and 29102/9

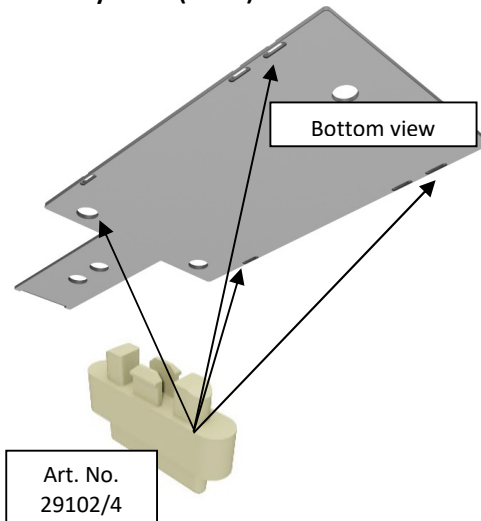


Fixation block 29102/4 is a symmetrical block so it doesn't matter how it is inserted in the baseplate. The other indexing blocks are not symmetrical and have to be inserted as shown on the photos below.

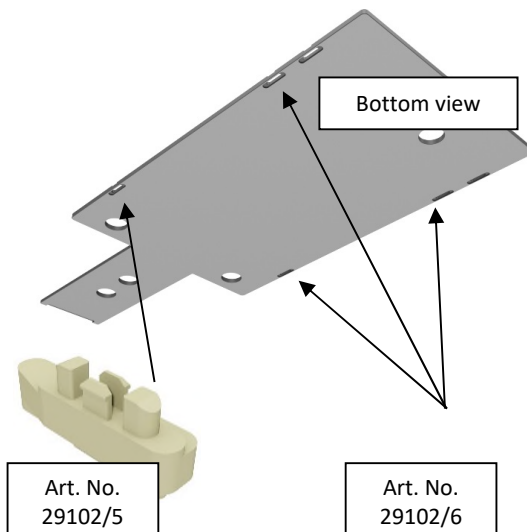
D.1 TIM Systems (Avanto, Trio a Tim System, Espree)



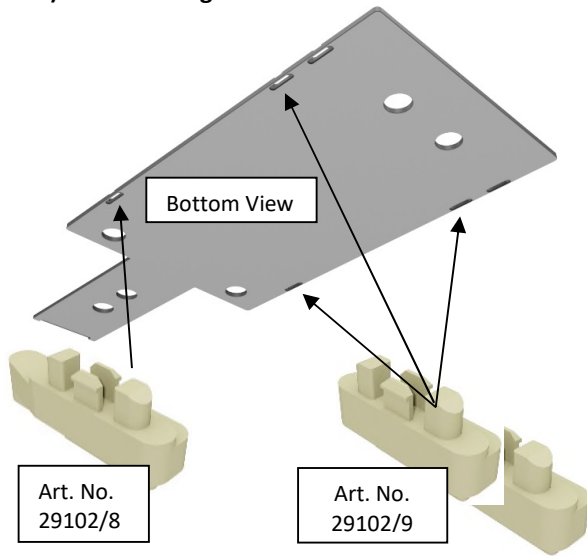
D.2 TIM Systems (Verio)



D.3 TIM 4G Systems (Skyra, Spectra, Aera) with narrow T groove



D.4 TIM 4G Systems (Skyra, Spectra, Aera, Vida, Sola) with wide T groove



How to attach 29102/5

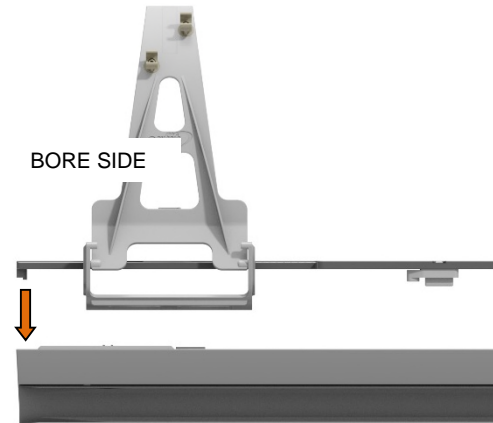


How to attach 29102/6

The indexing supports simply slide into the fixation slot of the MRI table.



For easy reference, look at the cranial end of the base plate to be supported on the head end of the MR table.

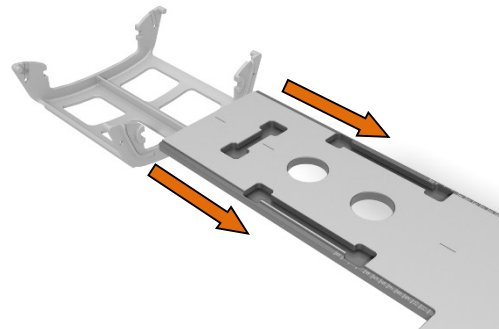


When installing the base plate the spine coil and spine coil cushion do not have to be removed.

E. INSTALLATION COILS

The following actions will need to be taken to assemble the components of this package.

1. Slide the head bridge (Ref. 29102/2) of the support structure over the cranial end of the base plate to the desired position.



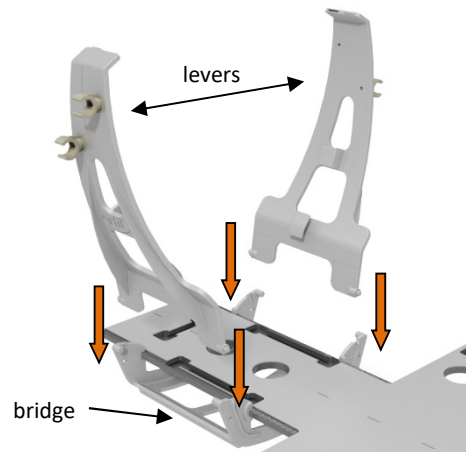
2. Install the base plate on the MRI system. Depending on the type of MRI system, different fixation devices are needed for installing the base plate. Refer to section D to determine the correct fixation device for your MRI system.
3. Step 1: Place the 4-channel Flex Large coil on the head lever as shown on below picture. Use the centre cross of the antenna and the head lever clamps (A) as reference points. The cable

adapter of both antennas should point towards the MRI tunnel.

Step 2: Rotate the antenna into the lever clamps until fully aligned.

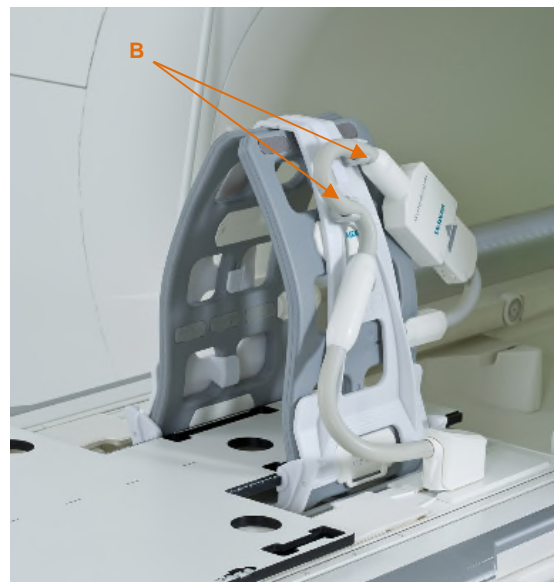


4. Click the levers into the bridge of the support structure. The antenna's must slide underneath the base plate.



Note: Antennas are not shown in this picture

5. Attach the coil cables to the two small clamps (B) on the side of the levers.



Location of cable clamps (B) can vary

6. Rotate the antenna supports in 'open' position and position the patient on the baseplate. Be aware to use the correct head support and blocks and wedges.
7. Attach the thermoplastic mask to the base plate by securing it with the blue EVA blocks.

8. Close the two levers and lock them with the Velcro strap.



When scanning the pelvic area of the patient, use a pelvic mask and attach it to the base plate. Place a body coil over the pelvis of the patient.

F. PRECAUTIONS FOR USE

- Always fix the base plate securely to the MRI system before positioning a patient.
- CAUTION! Collision on MAGNETOM® systems with 60cm bore (MAGNETOM® Spectra, Avanto, Symphony a Tim System, Trio a Tim System): After light marking use manual table movement only to shuttle the patient into the bore and visually check the motion as the levers including clamps or the clamped coil cables may collide with the bore tube. Do not use the 'Centre button' functionality.

- The installation of the MRI-S base plate on the table of the Magnetom scanner leads to an offset head position towards the feet end. An offset of the head from the defined position (without fixed head coil) could possibly lead to a potential incorrect SAR estimation if an overlay is used. Therefore following should be taken into account:
 - A scan in first level mode should be avoided.
 - Scanning of sedated patients should be avoided.
 - Patients should be made aware of using the squeeze ball in case of heating sensations.
- When matching the CT images with the MRI image, beware of discrepancies between the two images due to different positioning of the patient.
- Always attach the base plate to the table as described above.
- Always include the thermoplastic mask and the mask profiles in the Field-Of-View to avoid fold over artefacts.
- Beware of fold over artefacts from items that are placed outside of the Field-Of-View.
- Scan the device before the first clinical use to insure that there are no artefacts.
- Maximum distributed patient load = 180kg

G. STORAGE

Always store the product in a safe place to prevent it from getting damaged or falling onto other objects. Prevent hard objects from falling onto the plate. Store the base plate between +10°C (50°F) and 40°C (122°F).

H. PHYSICAL PROPERTIES

This plate is made of a high pressure wood laminate with a PVC support structure. No ferromagnetic materials are used.

Dimensions: L 1310mm x W 540mm x H 12mm

Weight : +/- 9kg

Density HPL: 1,4 gr/m³



I. MAINTENANCE AND WASTE MANAGEMENT

This product can be cleaned and disinfected by means of an isopropanol based disinfectant, applied with a soft cloth. If unsure about the cleaning fluid, do not use. **Never use aerosol sprays, corrosive cleaning agents, solvents or abrasive detergents.**

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 if there are any questions or concerns.

The product can be disposed of with household waste.

J. 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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