

SAGITTILT™ PRONE BREAST SOLUTION



Article No. : 32070

A. GENERAL PRODUCT INFORMATION

The products referred to in these instructions are medical devices, used for patient positioning and immobilization in radiation therapy.

B. PRODUCT DESCRIPTION

The SAGITTILT Prone Breast Solution is a positioning and immobilization system that accurately sets up and reproduces the prone position of a breast patient during both simulation and treatment. A cut-out is provided for the ipsi-lateral breast to drop into. Additionally the patient can be tilted to let the ipsi-lateral breast fall deeper into the cut-out and further away from the organs at risk, such as heart and lung.

Several parts of the SAGITTILT Prone Breast Solution are adjustable in position to better suit the patient's anatomy. For increased precision the set-up can be combined with an Orfit thermoplastic EFFICAST mask. The mask also secures the position of the patient when tilting the system. Information regarding the moulding of EFFICAST masks can be found in the respective 'Instructions for Use'.

C. SET-UP OF THE PATIENT

A patient set-up starts with positioning the chin in the chin support. This is a fixed support and is a reference to position the other parts of the system. There are 2 possible positions for the chin. It can be placed in the curvature of the cushion or it can rest against the cushion (Figure 1).



Figure 1

Warning: Do not apply point loads on the breast bridge when positioning a patient.

The following parts of the SAGITTILT Prone Breast Solution can be adjusted to the patient's anatomy:

1. The position of the arms can be adjusted longitudinally by using the most cranial pin (A, Figure 2) of the system. When pulling the pin the whole cranial system, from the hand supports up to the elbow supports, will move. Be aware that the system automatically slides caudally when you lift the pin.
A tool is provided as an aid to move the system when patient load is applied (Figure 3). To move the system cranially, insert the pin of the tool in the second hole before the support plate and swivel the tool a quarter turn forwards (cranially) while pulling the pin upwards (Figure 4). To move the system caudally, insert the pin of the tool in the first hole before the support plate and swivel the tool a quarter turn backwards (caudally) while pulling the pin upwards (Figure 5).
2. The position of the elbows can be adjusted laterally. Each elbow support has a pin on the side (B, Figure 2). Once the pin is lifted the elbow support can slide in the lateral direction.
3. The position of the hand grips can be moved longitudinally so both hands can grab the hand supports. The movement of the support structure is enabled by using pin C (Figure 2). The hand grips can be turned 180° to increase the available positions.
4. The forehead support can be moved in 2 directions. The first movement is in the longitudinal direction, by pulling pin D (Figure 2).

5. The second movement of the forehead support is in the vertical direction, by pulling pin E (Figure 6).
6. The foot support is adjusted by moving it in the cranial-caudal direction (Figure 7).



Figure 2



Figure 3



Figure 4

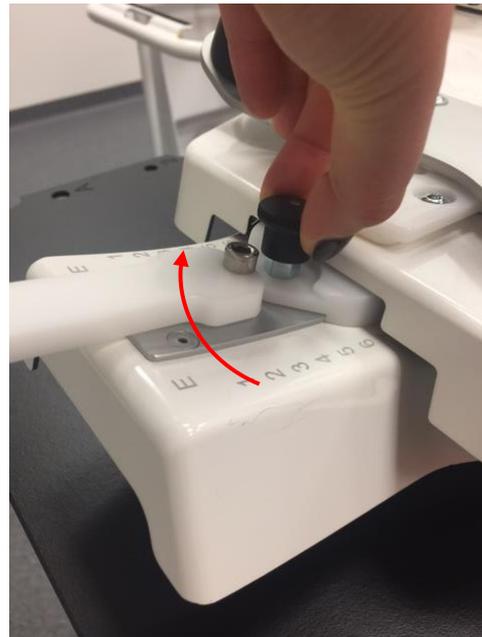


Figure 5



Figure 6



Figure 7

A small mirror is an accessory of the SAGITTILT Prone Breast Solution. This mirror is used to visualize the sternum and the contra-lateral breast of the patient (Figure 8). The contra-lateral breast should be pulled to the side so it doesn't drop into the cut-out.



Figure 8

D. THERMOPLASTIC IMMOBILIZATION MASK

A 2-points thermoplastic mask can be moulded over the pelvis of the patient. Three positions are available to attach the mask to the SAGITTILT Prone Breast Solution: a caudal, middle and cranial position (Figure 9).

Each slot contains 2 blocks, when sliding these blocks from left to right the three different positions can be obtained (Figure 10).

Choose the position that is the most suitable for the anatomy of your patient.



Caudal Middle Cranial
Figure 9



Figure 10

E. TILTING OF THE SYSTEM

The SAGITTILT Prone Breast Solution can be tilted by 10 degrees on each side. To enable the tilting mechanism, the shaft, that connects the cranial and caudal part of the system, needs to be in place.

The tilting can be performed by one person only and can be executed on either side of the patient. To tilt, grab the black handgrips with both hands and pull the two metal handles, marked in Figure 11, towards you. Then push the system in the desired position (Figure 12). Never force the system to tilt. A read-out for the tilting degrees is available on both sides of the system on the cranial end (Figure 13).



Figure 11



Figure 12



Figure 13

F. MOVEMENT OF THE SHAFT

In order to tilt the system, the shaft needs to be in place. This is a security measure. Because the shaft might be in the beam trajectory, it has to be removed before starting the treatment.

Note: Do not insert anything else in the hole of the locking mechanism except for the shaft.

To remove the shaft pull it in the caudal direction (Figure 14) and slide it backwards until it hits a stop (Figure 15).



Figure 14



Figure 15

To put the shaft back in place, pull it again to the front and click it into the cranial end of the system.

Make sure that both the cranial and caudal part of the system are placed in the same angle when connecting the parts with the metal shaft.

G. DISMANTLING OF THE SYSTEM

The SAGITTILT Prone Breast Solution consists of 3 pieces that can be dismantled for easy storage. To assemble the system, follow the steps in the reverse order.

1. Verify if the tilting mechanism is placed in the 0° position and if the shaft is in place in the cranial end of the system.
2. Pull pin F (Figure 16) to enable the movement of the forehead support structure as demonstrated by the green arrow. Move the forehead support

completely backwards until the middle section of the system can be detached.

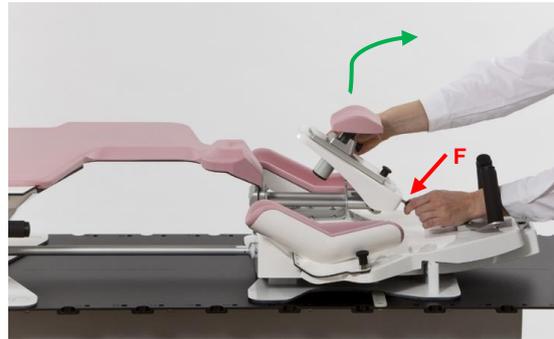


Figure 16

3. Remove the middle section of the system as demonstrated in Figure 17 and 18.



Figure 17



Figure 18

4. Remove the shaft as explained in paragraph F.
5. Now the cranial and caudal end of the system are detached and can be removed and stored on the trolley.

Warning: Do not use the shaft as a handle to lift the system.

Warning: When assembling verify if pin F is properly closed. This locks the breast bridge to the cranial end of the system.

The elbow support can be detached for easy cleaning. When the SAGITTILT arrives in the packaging the elbow supports still need to be mounted. This is done by following the steps below.

1. Pull the knob upwards and turn it so it stays in an open position.



Figure 19

- Slide the elbow support onto the cranial end by locking the 2 white sliders in each other.



Figure 20

- When you reach half way the support will be blocked by the metal pin at the bottom of the support. Then lift up the support slightly to insert the pin in the hole.



Figure 21



Figure 22

- Now turn the knob downwards again to lock the elbow support in place.



Figure 23

H. PRECAUTIONS FOR USE

- Always place the SAGITTILT Prone Breast Solution on a flat surface. Always fix the system securely to the treatment couch by means of two 2-pin bars before positioning a patient. Cut-outs for a 2-pin bar are provided both on the cranial and caudal end of the system. They are marked with red lines on the side for easy positioning. If the SAGITTILT Prone Breast Solution is not attached correctly to the couch, it might come loose.
- The minimum length of the treatment couch should be 2440 mm or 96.1". The whole system needs to be supported by the couch.

3. **Verify the rotation mechanism of the system before positioning a patient. Simply rotate the system 10° to one side and 10° to the other. This makes sure that the cranial part of the system is flush with the table.**
4. **When positioning a patient that weighs more than 90kg/198lbs, make sure to make them step on the system from the right side.** The left side of the system will not resist more than 90kg/198lbs and will go in an automatic tilt.
5. Always use a thermoplastic mask when positioning the patient. This will prevent the patient from sliding down the device.
6. Pull the shaft backwards before helping the patient getting on and off the SAGITTILT. This will make sure the system stays in place.
7. The diameter of the CT bore should be minimum 80cm so the SAGITTILT with a patient on top will fit.
8. When assembling the SAGITTILT prone breast solution and attaching the middle section, make sure that the chin part of the breast bridge is pushed completely downwards before fastening it by closing the forehead support.
9. When moving the adjustable parts for the head and arms, beware not to pinch the fingers by putting them in between the movable plates and the support structure.

I. 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 system. Store the system between +10°C (50°F) and 40°C (122°F).

J. PROPERTIES

Physical Properties

The support structure is constructed out of carbon fibre.

The patient support cushions are made from a viscoelastic PU foam core with a PU coating.

The tilting mechanism contains metal parts.

Total Dimensions:

L 2440 mm x W 622 mm x H 235 mm

L 96.1" x W 24.5" x H 9.3"

Caudal Part:

L 1540 mm x W 622 mm x H 215 mm

L 60.6" x W 24.5" x H 8.5"

Cranial Part:

L 570 mm x W 510 mm x H 235 mm

L 22.4" x W 20.1" x H 9.3"

Breast Bridge:

L 650 mm x W 480 mm x H 25 mm

L 25.6" x W 18.9" x H 1.0"

Total Weight : 25 kg / 55 lbs

Caudal Part: 14.50 kg / 31.9 lbs

Cranial Part: 8.36 kg / 18.4 lbs

Breast Bridge: 2.30 kg / 5.1 lbs

Maximum distributed patient load: 180 kg / 396 lbs

Warning: do not apply this force in point loads on the breast bridge.

K. 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. Do not soak the cushions.** Further cleaning instructions can be found in the [Orfit Cleaning Guidelines](#).

The elbow supports can be detached for easy cleaning. Simply pull pin B (Figure 1) upwards and turn it till it locks. Then slide the elbow support laterally until it slides out of the frame. To assemble the support again, slide it back in the frame and lock it by turning the pin downwards. 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.

L. 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.

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