

Patient Mask Set

Contact Data

Support

If you cannot find information you need in this guide, or if you have questions or problems, contact Brainlab support:

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United States, Canada, Central and South America	Tel: +1 800 597 5911 Fax: +1 708 409 1619	us.support@brainlab.com
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Spain	Tel: +34 900 649 115	
France and French-speaking regions	Tel: +33 800 676 030	
Africa, Asia, Australia, Europe	Tel: +49 89 991568 1044 Fax: +49 89 991568 5811	
Japan	Tel: +81 3 3769 6900 Fax: +81 3 3769 6901	

Feedback

Despite careful review, this user guide may contain errors. Please contact us at user.guides@brainlab.com if you have improvement suggestions.

Manufacturer

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Legal Information

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Patent Information

This product may be covered by one or more patents or pending patent applications. For details, see: www.brainlab.com/patent.

CE Label


CE	The CE label indicates that the Brainlab product complies with the General Safety and Performance Requirements of European Regulation 2017/745, the Medical Device Regulation ("MDR").
	The Patient Mask Set is a Class I product according to the rules established by the MDR. <i>NOTE: The validity of the CE label can only be confirmed for products manufactured by Brainlab.</i>

Brainlab Trademarks

- Brainlab® is a registered trademark of Brainlab AG.

Disposal Instructions

When a medical device reaches the end of its functional life, clean the device of all biomaterial/biohazards and safely dispose of the device in accordance with applicable laws and regulations.

	Only dispose of electrical and electronic equipment in accordance with statutory regulations. For information regarding the WEEE (Waste Electrical and Electronic Equipment) directive or relevant substances that could be present in the medical equipment, visit: www.brainlab.com/sustainability
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Sales in US

US federal law restricts this device to sale by or on the order of a physician.

Report Incidents Related to This Product

You are required to report any serious incident that may have occurred related to this product to Brainlab, and if within Europe, to your corresponding national competent authority for medical devices.

Symbols

Warnings



Warnings are indicated by triangular warning symbols. They contain safety-critical information regarding possible injury, death or other serious consequences associated with device use or misuse.

Cautions



















Cautions are indicated by circular caution symbols. They contain important information regarding potential device malfunctions, device failure, damage to device or damage to property.

Notes

NOTE: Notes are formatted in italic type and indicate additional useful hints.

Product Symbols

Sym bol	Explanation
	Reference (article) number <i>NOTE: Indicates the Brainlab product number.</i>
	Manufacturer's batch code
	Use by date <i>NOTE: The date is expressed as in ISO 8601 as YYYY-MM-DD.</i>
	Manufacturer
	Does not contain Latex
	Single patient - multiple use
	Refer to instruction manual or booklet
	Medical Device
	Temperature limit <i>NOTE: Indicates the temperature limits to which the medical device can be safely exposed.</i>
	Humidity limitation <i>NOTE: Indicates the range of humidity to which the medical device can be safely exposed.</i>
	Keep away from sunlight
	MR Unsafe <i>NOTE: Presents hazards in all MR environments.</i>

Sym bol	Explanation
	Keep dry
	Unique Device Identifier
	U.S. federal law restricts this device to sale by or on order of a physician
	Consult instructions for use

Using the System

Intended Use and Indications for Use/ Intended Purpose

The Patient Mask Set is used for fixation and repositioning of the patient's head during cranial stereotactic radiotherapy.

Place of Use

The **Patient Mask Set** is intended to be used in:

- Radiotherapy and Oncology department in a clinical/hospital environment
- CT or Linear accelerator environment

User Profiles

The **Patient Mask Set** is intended to be used by radiation technologists, technicians, radiographers (MTRA):

- Prepare, perform immobilization, treatment and protection devices
- Prepare and train the patient before the treatment delivery

Patient Population

The **Patient Mask Set** is intended for patients undergoing multi-fractional radiotherapy treatment as well as radiosurgery. The **Patient Mask Set** can be used for all kinds of patients, children as well as adults.

Sterile Use

The device is provided non-sterile. The mask sets required per patient treatment are also provided non-sterile and are for single patient use only.

Expected Service Life

The **Patient Mask Set** is a medical device for Single Patient, Multiple Use only. The shelf life is defined and labeled as 30 months after production of the masks.

Clinical Benefit

The **Patient Mask Set** is used for fixation and repositioning of the patient's head during cranial stereotactic radiotherapy (SRT). It is an accessory of the Brainlab **SRS Mask System**.

Known Contraindications

There are no known contraindications for the use of this device.

Careful Handling of Hardware



System components and accessory instrumentation are comprised of precise mechanical parts. Handle them carefully.

Compatibility with Medical Devices and Software

Non-Brainlab Devices



Using medical device combinations that have not been authorized by Brainlab may adversely affect safety and/or effectiveness of the devices and endanger the safety of the patient, user and/or environment.

Compatible Brainlab Devices

The **Patient Mask Set** is compatible with the **SRS Mask System**.

Other Brainlab Instruments

Additional instrumentation may become available after release of this user guide. Contact Brainlab support if you have any questions regarding compatibility.



Only use instruments and spare parts specified by Brainlab. Using unauthorized instruments/spare parts may adversely affect safety and/or effectiveness of the medical device and endanger the safety of the patient, user and/or environment.

Training and Documentation

Brainlab Training

Before using the system, all users must participate in a mandatory training program held by a Brainlab authorized representative to ensure safe and appropriate use.

Responsibility



This system solely provides assistance to the physician and does not substitute or replace the physician's experience and/or responsibility during its use. It must always be possible for the user to proceed without the assistance of the system.

Only trained medical personnel may operate system components and accessory instrumentation.

Reading User Guides

This guide describes complex medical software or medical devices that must be used with care.

It is therefore important that all users of the system, instrument or software:

- Read this guide carefully before handling the equipment
- Have access to this guide at all times

Patient Mask Set

Overview

The **Patient Mask Set** is used for fixation and repositioning of the patient's head during cranial stereotactic radiotherapy (SRT). The mask, constructed from thermo-transformable material, is individually molded for each patient and secured to the mask ring.



The Patient Mask Set is for single patient, multiple use only.



Always use the same mask set for CT scanning, angiographic image acquisition and patient positioning.

Mask Set

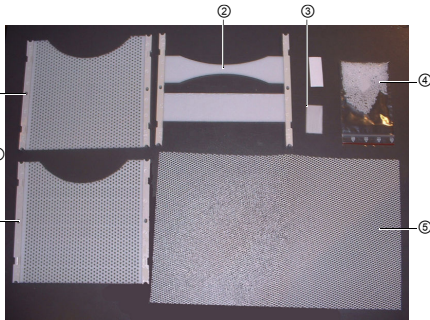


Figure 1

No.	Component
①	Top and rear masks (interchangeable)
②	Middle mask
③	Dental support strip
④	Loose pellets
⑤	Mesh

Cleaning the Mask



Do not use water with a temperature higher than 30°C (86°F), cleaning solutions, solvents or ultrasonic cleaners etc. to clean the mask set.



The masks must not be sterilized under any condition. Sterilization will destroy the device!

Storage



Always store the mask set at a temperature of min. 10°C (50°F) and max. 30°C (86°F) and relative humidity (0 - 70%).

Molding the Mask

Mask Thickness

The thickness of the material will vary depending on the size of the patient's head and the skill of the technician producing an evenly stretched mask. The density is approximately 1.15 g/mm³ at room temperature and 1.06 g/mm³ at body temperature, making it essentially tissue equivalent. Treating through 3.2 mm material with no less than 6 MeV can be done without significant loss of skin sparing. If treatment is performed with static fields rather than convergent arcs, Brainlab suggests to either window or avoid the double-layer areas of the mask for your beam path when skin-breakdown starts to occur.

Before you Begin

1. Have patients remove all items from their heads (toupee, false teeth, hearing aid, earrings, etc.).
2. Heat a water bath to 70° - 75°C (160° - 170°F).
3. As the material can stick to porous surfaces after activation, covering the patient's hair with plastic foil is recommended.
4. Line up all necessary clips and spacers.
5. Position the vertical posts at ear height.
6. Place the head of the patient into the mask ring and onto the headrest, so that the back of the head rests comfortably on the headrest.

NOTE: If the patient's head is too large or has anatomical abnormalities, the posts may be adjusted to a different level. Usually, the positions of the vertical posts do not need to be changed.



The mask material might cause slight skin irritation to patients with sensitive skin.



If lesions or open wounds are present on the patient's face, cover them (e.g., with lubricated dressings or plastic wrap.)



If the temperature of the softened mask is too high, the patient may suffer skin irritations or burns.



Do not leave the mask in the water bath for longer than 30 minutes.

How to Mold the Rear Mask

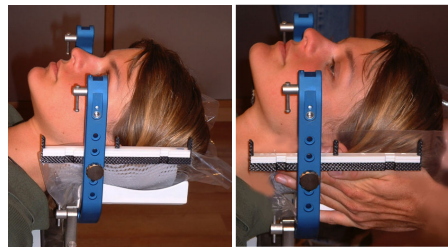
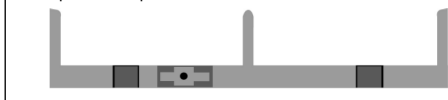


Figure 2

1. Place the rear mask in the heated water bath for two minutes.
2. Remove the mask from the bath and place it on a towel to dry.
3. Before proceeding, test the temperature of the softened mask to ensure the patient's comfort.
4. If you apply vertical posts as displayed below, lift the patient's head and snap the mask onto the upper side of the vertical posts.
3-pin vertical post:



5. If you apply vertical posts as displayed below, lift the patient's head and snap the mask onto the lower side of the vertical posts and secure the mask using the shortest clip (clip without marking).
2-pin vertical post:



6. Lower the patient's head onto the headrest.
7. Gently mold the material to the contour of the patient's head as the mask material hardens.

How to Mold the Middle Mask



Figure 3

1. Place the middle mask in the heated water bath for two minutes.
2. Place the 2 mm spacers onto the vertical posts.
3. Remove the mask from the bath and dry it.
4. Before proceeding, test the temperature of the softened mask to ensure the patient's comfort.
5. Place the mask on the center of the patient's face. The wider strip is placed just above the patient's eyebrows and the narrow strip is placed just beneath the patient's nose, but above the mouth.
6. Stretch the mask carefully and evenly towards the vertical posts.
7. Snap the mask onto the vertical posts and secure it with the S clips.

How to Mold the Nose Bridge

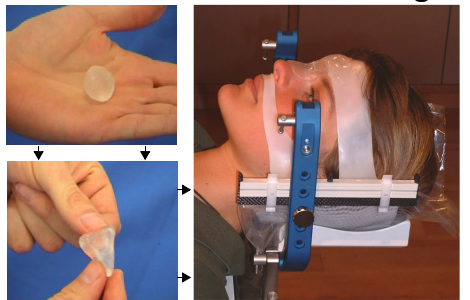


Figure 4

1. Place the loose pellets onto the mesh sheet provided with the mask set then into the water bath.
2. After the pellets have become transparent, roll them in your hand to create a T-shaped form.
3. Place the form on the bridge of the patient's nose and gently mold it towards the strip on the forehead and down towards the eyes. Do not go no closer than 3 mm to the eyes.
For the best connection, the middle mask should still be transparent when molding.

How to Mold the Top Mask



Figure 5

1. Place the top mask in the water bath for two minutes.
2. Remove the clips securing the middle mask.
3. Remove the mask from the water bath and dry it.
4. Place it centrally over the patient's face ensuring that the curve in the top mask layer is placed towards the patient's mouth.
5. Stretch the mask carefully and evenly toward the vertical posts.
6. Snap the mask onto the vertical posts and secure it with the 2 mm clips.
7. Let the mask harden at least 30 minutes.

Removing and Reattaching the Mask

Before you Proceed



To avoid confusion, note the patient name or patient ID on the provided label and stick it to the molded mask.

How to Remove the Mask

1. Make sure the mask has hardened sufficiently.
2. Remove the clips.
3. Remove the top, then middle masks.

How to Reattach the Mask

1. Mount the vertical posts to the mask ring.
2. Affix the rear mask to the vertical posts.
3. Lower the patient's head onto the rear mask.
4. Reattach the middle mask, then the top mask.
5. Secure the mask with the respective clips to the vertical posts.

How to Adjust Mask Fit

The **Patient Mask Set** can be tightened or loosened if necessary (e.g., if the patient has lost weight). To adjust the fit of the mask:

1. Remove the 2 mm clips and the top and the middle mask (the top two layers).
2. Replace the 2 mm spacer with: <ul style="list-style-type: none">- 1 mm spacer to tighten mask fit. To tighten further, remove the 1 mm spacer bar and replace the clips with the clips without marking.- 3 mm or 4 mm spacers to loosen mask fit.
3. Place the two sheets back in their former position and secure them with the appropriate clips.