

THERMOFIT



Article Nos. : **32390**
32391
32392

A. GENERAL PRODUCT INFORMATION

The product referred to in these instructions is a medical device used for patient positioning and immobilisation in radiation therapy.

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

Art. No.	Size
32390	13.5 cm x 30 cm
32391	23 cm x 30 cm
32392	35 cm x 30 cm

Thermofit comes in three different sizes:

- **# 32390: 13.5 cm x 30 cm**
 Designed for patients with a standard anatomy to fill up gaps between the head support and the head/neck of the patient.
- **# 32391: 23 cm x 30 cm**
 Designed for patients with a larger head to fill up gaps between the head support and the head/neck of the patient.
- **# 32392: 35 cm x 30 cm**
 Designed for offering the highest stability for any type of patient.

C. HEATING

C.1 Digital Dry-Heat Convection Oven

Refer to the instructions for use of the Digital Dry-Heat Convection Oven (art. No. 35118) for more detailed operating instructions of this device.

1. Switch on the Digital Dry-Heat Convection Oven and set the right temperature and timing according to the chart below.

Size	Temperature		Time
	75°C	167°F	
Small (# 32390)	75°C	167°F	7 min.
Small (# 32390)	80°C	176°F	6 min.
Medium (# 32391)	75°C	167°F	7 min.
Medium (# 32391)	80°C	176°F	6 min.
Large (# 32392)	75°C	167°F	7 min.
Large (# 32392)	80°C	176°F	6 min.

2. Put the Thermofit either on the lower or upper rack of the oven and close the appliance.
3. Wait for the appropriate time (see chart above) until the material is softened, flexible and mouldable. Then carefully remove it from the oven.
Wait 10-15 sec. until the material is cooled a bit. This way the surface temperature will be more comfortable for the patient's skin.
 Check the temperature of the Thermofit with your hand.
4. When the material has cooled sufficiently, the Thermofit can be placed in the head support. Refer to the moulding instructions in the next paragraph.

C.2 Water Bath

Refer to the instructions for use of the water bath (art. No. 35097) for more detailed operating instructions of this device.

1. Switch on the water bath and set the right temperature and timing according to the chart below. Do not heat Thermofit in the water bath at a temperature higher than 70°C.

Size	Temperature		Time
	70°C	158°F	
Small (# 32390)	70°C	158°F	6 min.
Medium (# 32391)	70°C	158°F	6 min.
Large (# 32392)	70°C	158°F	10 min.

2. Make sure to put the Thermofit in the appropriate waterproof plastic bag before putting it in the water. Thermofit small can be heated in waterproof bags 32405/10 and Thermofit medium and large can be heated in waterproof bags 32406/10. Make sure to seal the bag properly before putting it in the water bath. Put the bag with the Thermofit below the grid of the water bath or put a weight on top of the bag to prevent it from floating. This will ensure the Thermofit is sufficiently heated.
3. Wait for the appropriate time (see chart above) until the material is softened, flexible and mouldable. Then carefully remove it from the oven or water bath.
Wait 10-15 sec. until the material is cooled a bit. This way the surface temperature will be more comfortable for the patient's skin.
 Check the temperature of the Thermofit with your hand.
4. When the material has cooled sufficiently, the Thermofit can be placed in the head support. Refer to the moulding instructions in the next paragraph.

D. MOULDING

Depending on the size of the Thermofit, another moulding technique might need to be used.

1. # 32390

- Once the Thermofit has cooled slightly, place it in the head support and pre-mould it slightly.



- Position the patient in the head support on top of the Thermofit.
- Mould the Thermofit there where you see gaps between the sheet and the head and neck of the patient.



- The Thermofit should harden for minimum 10 minutes. before lifting the head of the patient.

2. # 32391

- Once the Thermofit has cooled slightly, place it in the head support and pre-mould it slightly.



- Position the patient in the head support on top of the Thermofit.
- Mould the Thermofit there where you see gaps between the sheet and the head and neck of the patient.





- In total the Thermofit should harden for minimum 10 minutes. before lifting the head of the patient.

3. # 32392

- Once the Thermofit has cooled slightly, place it in the head support and pre-mould it slightly.



- Verify that the Velcro is facing outwards and that the ear holes are facing caudally.
- Now fold the Thermofit around the head and attach it with 3 Velcro straps.



- One strap is attached over the chin, one over the forehead and one over the crown of the head.



- Make sure to fold the Thermofit over the cranial stop of the Head Support. This can be used as a reference when repositioning the Thermofit.



- Mould in the neck area to make sure that the Thermofit contours the neck nicely.



- Leave the Thermofit to harden for minimum 5 minutes. before releasing the Velcro and moulding a thermoplastic mask over it. For instructions on how to mould the mask, please refer to the instructions for use of the applicable mask.



- In total the Thermofit should harden for minimum 10 minutes. before lifting the head of the patient.
- It is possible to cut out the ear holes to provide more comfort for the patient. Do this with a strong pair of scissors. It should be done when the Thermofit has hardened completely and the patient is no longer lying in the Thermofit. Once the holes are cut, the inner layer is exposed. For hygienic reasons cover this with tape to create a closed surface again.



E. DOSIMETRIC PROPERTIES

Attenuation (at 6 MV and 15 MV) and skin build up (SBU) values:

Attenuation (± 0.15%)		Skin build-up (± 0.1 mm)
6 MV	15MV	mm H ₂ O equiv.
1.4 %	0.9 %	3.6

Note: Use these numbers as a guidance only. Perform the measurements again in your department to verify the results.

F. PRECAUTIONS FOR USE

- Verify that the Thermofit is repositioned correctly in the head support before positioning the patient.
- Always make sure that the product is not too hot before moulding it on the patient.
- This is a one-patient-only product.
- Write down the identification of the patient with a marker on the Thermofit.
- The stockinet covering the inner layer contains Nylon.

G. 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.**

The product can be disposed of with household waste.

A. PACKAGES

Articles 32392 & 32406/10 are part of following SRS-Fix packages:

- 36404: SRS-Fix Consumable Package 2 – HP Profiles
- 36406: SRS-Fix Consumable Package 4 – Push-pin Profiles

B. 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:

It is prohibited to make alterations to this text without prior approval from Orfit Industries.



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Ref. No. 50093
 VERSION 8
 LAST UPDATE: 07/01/2022
 REVISION DATE: 07/01/2024