Orfit®Classic

GENERAL PRODUCT INFORMATION

This product is a low-temperature thermoplastic sheet material intended for the fabrication of orthoses, external immobilization devices, and rehabilitation aids. The termoplastic sheet is directly applied to the patient after it is activated.

PRODUCT RANGE

This product is available in sheets of different stiffnesses, thicknesses, sizes, and perforation types.

Article Number	Color	Type	Thickness (mm)	Size (mm)	Perforation Type
8332.SO1	Beige	Soft	1,6	450 x 600 mm	Non Perforated
8332.SO2	Beige	Soft	1,6	450 x 600 mm	Micro Perforated
8333.SO1	Beige	Soft	2	450 x 600 mm	Non Perforated
8333.SO2	Beige	Soft	2	450 x 600 mm	Micro Perforated
8333.SO2+	Beige	Soft	2	450 x 600 mm	Micro+ Perforated
8333.SO3	Beige	Soft	2	450 x 600 mm	Maxi Perforated
8333.SO4	Beige	Soft	2	450 x 600 mm	Mini Perforated
8338.SO2	Beige	Soft	2,5	450 x 600 mm	Micro Perforated
8334.SO1	Beige	Soft	3,2	450 x 600 mm	Non Perforated
8334.SO3	Beige	Soft	3,2	450 x 600 mm	Maxi Perforated
8334.SO4	Beige	Soft	3,2	450 x 600 mm	Mini Perforated
8334.ST1	Beige	Stiff	3,2	450 x 600 mm	Non Perforated
8334.ST4	Beige	Stiff	3,2	450 x 600 mm	Mini Perforated
8354.SO1	Beige	Soft	3,2	600 x 900 mm	Non Perforated
8354.SO3	Beige	Soft	3,2	600 x 900 mm	Maxi Perforated
8354.SO4	Beige	Soft	3,2	600 x 900 mm	Mini Perforated
8354.ST1	Beige	Stiff	3,2	600 x 900 mm	Non Perforated
8354.ST4	Beige	Stiff	3,2	600 x 900 mm	Mini Perforated
8355.SO1	Beige	Soft	4,2	600 x 900 mm	Non Perforated
8355.SO4	Beige	Soft	4,2	600 x 900 mm	Mini Perforated
8355.ST1	Beige	Stiff	4,2	600 x 900 mm	Non Perforated
8355.ST4	Beige	Stiff	4,2	600 x 900 mm	Mini Perforated

Precuts are also available.

Description	Article Number	Color	Size (mm)	Thickness (mm)	Perforation Type
Complete thumb orthosis	35900	Beige	S	2	Micro Perforated
	35901	Beige	M	2	Micro Perforated
	35902	Beige	L	2	Micro Perforated
Dorsal cock-up orthosis	35818	Beige	XS	3,2	Non Perforated
	35820	Beige	S	3,2	Non Perforated
	35821	Beige	M	3,2	Non Perforated
	35822	Beige	L	3,2	Non Perforated
Gauntlet immobilization orthosis	35830	Beige	S	2	Micro Perforated
	35831	Beige	M	2	Micro Perforated
	35832	Beige	L	2	Micro Perforated
Gauntlet thumb post orthosis	35810	Beige	S	1,6	Micro Perforated
	35811	Beige	M	1,6	Micro Perforated
	35812	Beige	L	1,6	Micro Perforated
Intrinsic resting hand orthosis	35850	Beige	S	3,2	Non Perforated
	35851	Beige	M	3,2	Non Perforated
	35852	Beige	L	3,2	Non Perforated
Rheumatoid arthritis resting orthosis	35840	Beige	S	3,2	Mini Perforated
	35841	Beige	M	3,2	Mini Perforated
	35842	Beige	L	3,2	Mini Perforated
Ulnar drift orthosis	35817KL	Beige	Left	3,2	Non Perforated
	35817KR	Beige	Right	3,2	Non Perforated
Wrist + thumb orthosis	35814	Beige	S	2	Micro Perforated
	35815	Beige	M	2	Micro Perforated
	35816	Beige	L	2	Micro Perforated

PRECAUTIONS BEFORE USE

1. The workplace must be well-ventilated.
2. The necessary tools should in no way put the patient at risk.
3. Position the patient comfortably and ensure that you are in an easy working position.

WORKING TECHNIQUE

Activating

- The material is activated by heating at a temperature of 65°C (149°F).
  Possible activation sources are: Suspan water baths, dry heater, heating plate, and hot air oven.

  The activation time of the material depends on the heat source and the product thickness.

  The table below shows all activation and working information for the **water bath**. For more accurate figures, consult the technical data sheet of the product.

Type	Activation Temperature		Activation Time	Working Time	Hardening Time
Soft	65 °C	149 °F	2 - 5 minutes	1 - 2 minutes	1 - 6 minutes
Stiff	65 °C	149 °F	2 - 5 minutes	2 - 3 minutes	6 - 10 minutes

- When using a Suspan water bath, it is recommended to add a drop of liquid soap if you want to reduce the stickiness of the material.

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- When activating the thermoplastic material using a dry heater, heating plate, or oven, the hot surface must be covered with a Teflon paper or rubbed with talcum powder before activation. If using the Orfit Dry Heater to activate the material follow the written instructions for Dry Heater.
  Always consult and follow the instructions for the use of the heating device that you are using.
- Only use the heat gun to heat small areas of the material to make small corrections to the shape of the orthosis, or to attach the hook and loop. The heat gun is NOT meant to be used as a heat source to activate the total length of the thermoplastic material.

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- This product becomes translucent when fully activated. This is a perfect thermo-indicator that the material is ready for use.

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Never use an open flame to activate the material.
Make sure that the temperature of the activated material will not burn the patient.
Let the material cool sufficiently before application.
Beware: temperatures of 65°C (149°F) or more can also be reached in the patient's daily life. Think of a closed car in the summer, the surface of a hot radiator, a sauna, or the proximity of an open fireplace.

Applying

1. Heat the pattern a second time until it is completely activated and moldable. Take it out of the heat source and let the surface cool for a few seconds before applying it to the patient.
   Beware: sticky materials should be kept wet during application. Use a suitable cool and smooth working surface such as metal, glass, Formica or a nylon tablet or Teflon surface.

2. Several application techniques are recommended according to the splint model and the material type:
   - Gravity technique: The material forms itself under gravity. (indicated for drape materials)
   - Manual molding: Molding by manual stretching and holding.
   - Closed technique: The material covers the entire extremity and the edges are pinched together
   - Bandaging technique: The orthosis is secured around the extremity with a bandage. Take maximum advantage of the stretch and elasticity properties of the material for a perfect fit of the orthosis.

3. Sticky materials have permanent bonding. The material easily sticks to itself and all porous surfaces. If the material accidentally bonds during activation or application, reactivate it in 65°C (149°F) water.
   To ensure that the material is well-adhered, both surfaces should be BRIEFLY DRY heated with a heat gun.

4. Do not remove the orthosis from the patient before the material has sufficiently hardened. Trim excessive material with a suitable pair of scissors before the material has completely hardened.
   If needed, slightly reactivate the material locally by dipping the material briefly back into the hot water and using a suitable pair of scissors.
   Cooling time ranges from a few minutes for small and thin orthoses to up to 10 minutes for larger orthoses. This time can be reduced by using cold air, cold water, a cold bandage, or cold spray.

Finishing

1. To attach fixation straps, hinges, outriggers, or other accessories to sticky materials, use their self-adhesive properties. First, briefly, dry heat the orthosis locally with a heat gun until it becomes sticky. Then, press the strap or accessory firmly in place to secure it.

2. There are several ways to give the edges of an orthosis a smooth and even finish:
   - Local heating and rubbing with a (wet) finger.
   - After hardening, edge finishing can be done using a deburring knife or by grinding with a light polishing wheel at a low speed (especially for most blended products)
   - Using edging strips

3. The orthoses can be given a glossy finish by heating the surface briefly with a heat gun.

MAINTENANCE

Orthoses made out of Orfit thermoplastic sheets can be cleaned with lukewarm water and liquid soap, biological detergent, or toothpaste. Rinse well and dry thoroughly. Alternatively, pre-moistened isopropyl alcohol wipes can be used.

If you are not sure about the cleaning fluid, do not use it.
Never use solvents and avoid abrasive detergents.
Do not put the entire orthosis into the hot water as this might cause the loss the shape.

Sterilization of Orfit thermoplastic sheets in an autoclave is impossible.
Disinfection is possible with alcohol, quaternary ammonium, or a solution of commercial disinfection soaps (HAC®, Sterilium®, etc.).

WASTE MANAGEMENT

After use, an orthosis can be disposed of with normal household waste without harming the environment.

INSTRUCTIONS FOR PATIENT

Provide the patient with sufficient and clear information on how to use the orthosis, wearing schedule, maintenance, and the possible constraints of the orthosis. Ensure that the patient fully understands the appropriate steps to take if adjustments are needed.

STORAGE

- It is advised to store the product in a dark, cool, dry place in the original packaging at temperatures of min. 10°C (50°F) and max. 30°C (86°F).
- Vertically stored sheets must be supported to avoid deformation. If not, they should be stored horizontally.
- Once removed from the packaging, the leftovers should be repackaged to avoid biodegradation.
- Do not lose the labels. They are crucial for product traceability.
- Our products have a limited shelf life and can only be kept for a certain period. They must be protected as much as possible from light, heat, and humidity to prevent aging.

GENERAL SAFETY ADVICE

- ***This product is not suitable for internal use. It may not be used on open wounds or in the mouth.***
- ***orthoses and rehabilitation aids made out of Orfit thermoplastics can only be made by qualified health professionals.***
- ***In the event of a serious incident that is related to the use of this product, you must report this to the distributor in your country. Please consult our website to find your distributor.***

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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