ORFIT® CLASSIC

A.	GENERAL PRODUCT INFORMATION

ORFIT CLASSIC is a low temperature thermoplastic sheet material for the fabrication of orthoses, external immobilisation devices and rehabilitation aids.

ORFIT CLASSIC is applied directly to the patient after it is activated.

! *ORFTI CLASSIC is not suitable for internal use. It may not be used on open wounds or in the mouth.*

B.	PRODUCT RANGE

ORFIT CLASSIC is available in sheets of different thicknesses, sizes and types of perforation.

Art. no.	Type	Thickness (mm)	Sizes (mm)	Perforation type
8332.SO1 8332.SO2	soft	1.6	450 x 600	non-perforated micro
8333.SO1 8333.SO2 8333.SO2+ 8333.SO3 8333.SO4	soft	2.0	450 x 600	non perforated micro micro plus maxi mini
8338.SO2	soft	2.5	450 x 600	micro
8334.SO1 8334.SO3 8334.SO4 8354.SO1 8354.SO3 8354.SO4 8334.ST1 8334.ST4 8354.ST1 8354.ST4	soft stiff	3.2	450 x 600 600 x 900 450 x 600	non-perforated maxi mini non perforated maxi mini non-perforated mini non-perforated mini
8355.SO1 8355.SO4 8355.ST1 8355.ST4	soft stiff	4.2	600 x 900	non-perforated mini non-perforated mini

C.	PRECAUTIONS BEFORE USE

1. The workplace must be well-ventilated to avoid overheating.
2. The necessary tools should in no way put the patient at risk.
3. Encourage the patient to assume a comfortable position and make sure that you yourself are in an easy working position.
4. Rub the orthosis with talcum powder before applying to the patient.

! 5. *Make sure that the temperature of the activated material will not burn the patient.*

D.	ACTIVATION TECHNIQUE

1. ORFIT CLASSIC is softened by heating at a minimum temperature of 65°C (149°F). Possible activation sources are: Suspan water baths, heat gun, heating plate, hot air oven. The activation time depends on the heat source and varies from 2 to 5 minutes.

2. When using a Suspan water bath, it is recommended to use distilled water and to add a teaspoon of liquid soap to facilitate the moulding.
   Do not towel ORFIT CLASSIC but let it cool on a non-porous surface (Formica, glass, steel, etc.).
   When dry heating ORFIT CLASSIC, both sides of the material must be rubbed with talcum powder before activation.
   When using a heating plate or an oven, the hot surface must be covered with a Teflon film.
   When using a heat gun, do not exceed the temperature of 250°C (482°F) to avoid breakdown of the material.

3. ORFIT CLASSIC becomes transparent at the softening temperature. This is a perfect indicator that the right temperature has been reached in the material.

! 4. *Be careful: 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.*

5. High temperatures up to a maximum of 120°C (248°F) do not damage Orfit Classic, but are not user-friendly. Higher temperatures are allowed on the condition that the activation time is reduced accordingly and that the product is sufficiently rubbed with talcum powder. Wear Latex gloves and do not apply ORFIT CLASSIC directly to the patient's skin at these high activation temperatures.

6. Note that when an orthosis is left unattended in hot water for an extended period of time, the ORFIT CLASSIC will gradually lose its transparency without being damaged. When left in a water bath that has been switched off, a white film will form on the surface of the splinting material and a residue may stick to the grill. These phenomena only affect the cosmetic appearance of the orthosis.

! 7. *Never use an open flame to activate ORFIT CLASSIC.*

E.   WORKING PROPERTIES

Cutting

1. Draw the orthotic pattern on the ORFIT CLASSIC sheet by means of a marker.

2. Cut the pattern roughly with a suitable pair of scissors or use a cutter. When using a cutter, carve a straight line and break the sheet in two.

!   *Be careful of possible cuts when using a cutter; always keep the assisting hand away from the cutting line.*

3. Heat the ORFIT CLASSIC sheet until it is formable but not yet stretchable and cut the precise orthotic pattern with a pair of scissors.

Applying

1. Activate the ORFIT CLASSIC pattern until it is completely transparent. Take it out of the water and let its surface cool for a few seconds, WITHOUT DRYING. If necessary, put the wet pattern on a suitable working surface with a Formica or nylon top or on a surface that is covered with Teflon film.

2. Several application techniques are possible:
   - gravity technique: the material forms itself under gravity.
   - closed technique: form the material around the extremity and stick the edges together.
   - bandaging technique: secure the orthosis by means of a Latex bandage.

   Utilise the stretch and elastic properties of ORFIT CLASSIC to a maximum.

3. ORFIT CLASSIC easily sticks to itself and to all porous surfaces. In case of accidental bonding, the 2 parts that are stuck can be taken apart when completely reactivated.
   Permanent adhesion to attach fixation straps and orthosis accessories is possible with dry heat.

!   *In order to ensure that the material is well-adhered, both surfaces should be BRIEFLY DRY heated at high temperature (max. 250°C – 482°F).*

4. Do not remove the orthosis from the patient before ORFIT CLASSIC has completely hardened.
   You may cut the excessive material away before complete hardening. To do so, use a suitable pair of bandage scissors.
   The cooling time can be shortened by means of cold air, using a cold bandage or a cold spray.

F.   FINISHING

1. There are several ways to give the edges of an ORFIT CLASSIC orthosis a smooth and even finish:
   - local reheating and rubbing with a wet finger,
   - after hardening, edge finishing can be done by means of a deburring knife,
   - grinding by using a suitable grinding tool at a low turning speed.

2. The ORFIT CLASSIC orthosis can be given a glossy surface finish by heating it with a heat gun for a few seconds.

G.   MAINTENANCE AND WASTE MANAGEMENT

Orthoses made of ORFIT CLASSIC should be cleaned daily. Use lukewarm water and disinfecting soap or pre-moistened isopropanol wipes. Rinse well.

! *Never use solvents. Avoid acid detergents.*

Sterilization of ORFIT CLASSIC orthoses in an autoclave is impossible.
Disinfection is possible with alcohol, quaternary ammonium or a solution of commercial disinfecting soaps (HAC®, Sterilium®, etc.).
After use, an orthosis can be disposed of with normal household waste without harming the environment. ORFIT CLASSIC is biodegradable.

H.   ADVICE FOR THE PATIENT

! *Give the patient sufficient information about the exact use of the orthosis and about the possible constraints of the orthosis.*

I.   STORAGE

- ORFIT CLASSIC can be stored vertically, if supported, or horizontally.
- It must be stored in a dark, cool, dry place at a temperature of min. 10°C (50°F) and max. 30°C (86°F) and in the original packaging.
- Once removed from the packaging, the left-overs should be stored back in the packaging to avoid biodegradation.

Low temperature thermoplastics can only be kept for a limited period of time and must be protected as much as possible from light, heat and humidity. The material ages in direct relation to storage circumstances. When too old, it becomes brittle and too soft when activated.

J.   GENERAL SAFETY ADVICE

! * *ORFIT CLASSIC is not suitable for internal use. It may not be used on open wounds or in the mouth.*
! * *Never use an open flame to activate ORFIT CLASSIC.*
! * *To make orthoses and rehabilitation aids, ORFIT CLASSIC may only be used by qualified health professionals.*

K.   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