

Manufacturing instructions for orthopaedic (shoe) technicians

Dear Customers,

Thank you for the confidence you have shown in us by buying these orthotic blanks. In doing so you have made a good choice. We set ourselves the aim and standard of ensuring the best possible care of the foot with our orthotic blanks, in close cooperation with our partners, doctors, health insurance companies and medical services.
To find out more about our products, visit our website at: www.schein.de

These manufacturing instructions apply to the following Novaped Protect orthotic blanks:

959600000	Novaped Protect S90 pre-adhered	779600000	Novaped Protect active with loose top cover
959600550	Novaped Protect S90 with loose top cover	779600010	Novaped Protect active assembly kit Orthema/Pedcad/Swiss Comfort
979600000	Novaped Protect soft pre-adhered	779600020	Novaped Protect active assembly kit Paromed Trapez
979600011	Novaped Protect soft partially adhered	779600030	Novaped Protect active assembly kit Paromed Oval
989600000	Novaped Protect carbon pre-adhered	779600040	Novaped Protect active assembly kit GeBiom
989600550	Novaped Protect carbon with loose top cover		

Novaped Protect orthotic blanks are in line with the German Social Accident Insurance rules 112 -191 and ÖNORM Z 1259. They are also type-tested and certified in line with EN ISO 20344 and EN ISO 20345 with Protect by schein work-safety models.

An up-to-date list of certified shoe models can be requested from us or viewed on www.schein.de.

Novaped Protect orthotic blanks must only be further processed in line with these manufacturing instructions. No materials other than the listed components may be used. In the event of non-compliance, the type-testing certificate is invalid and the supplying company is liable for possible damages resulting from this.

Please read the manufacturing instructions carefully before further processing of the orthotic blanks and pay attention to the following information.

1 Determining aims / indication

Orthotic blanks are precursors to orthopaedic foot orthoses. The orthotic blank is further processed by a healthcare technician as needed according to a medical prescription into a custom-made product for a customer.

Specially made foot orthoses are functional orthotics to support, pad or correct the foot, relieve strain or redistribute pressure on the soft tissue of the feet.

2 Conditions of use

Individually processed orthotic blanks are to be handed over in suitable, usable condition.

3 Advice for use

Before the first use, the orthotic blanks must be further processed by qualified specialist personnel to suit the needs of the user.

When deciding the sizing of the orthotic blanks, the size specification is only for orientation. As with an appropriate work safety shoe, the orthotic blank should take into account the push space as well as the foot length. Due to possible differences in length, both feet must always be measured and supplied appropriately.

An orthotic blank that has already been processed is only ever intended for a single patient.

4 Safety tips

- Further processing and finishing of the orthotic blanks should only be carried out by qualified specialist personnel.
- During further processing, observe the safety precautions of the machines you use.
- The general occupational health and safety obligations of the Act on the Implementation of Measures of Occupational Safety and Health to Encourage Improvements in the Safety and Health Protection of Workers at Work (ArbSchG) must be complied with during further processing.
- Materials used for the orthotic blanks are subject to ageing

processes and their properties may change. The condition of the orthotic blanks should be checked before further processing.

- In order to protect the orthotic blanks against environmental influences during storage, we recommend a dry storage location protected against light and with a temperature of 10-30 °C.

5 Risks of use

In the case of significant foot deformities, the use of orthotic blanks is not appropriate.

6 Material specifications

lower cover:	EVA
core:	PE
top layer:	PO
top cover:	Microfibre, PES, PA, PU
supporting components:	PA, PES, carbon
padding components:	PU, PO

7 Disposal

The product and packaging must be disposed of in accordance with legal requirements.

8 Processing

Novaped Protect orthotic blanks must only be further processed in line with the following manufacturing instructions. In the event of non-compliance, the type-testing certificate is invalid and the supplying company is liable for possible damages resulting from this.

When fitting the Novaped Protect orthotic blanks into work safety shoes, care must be taken to ensure that they are fully placed on the insole. In addition, the height of the orthotic blanks in the area of the toecap must not exceed 3 mm or the height of the supplied insole of the safety shoe. A heel height of minimum 5 mm and maximum 14 mm must be maintained.

8.1 959600000 Novaped Protect S90 pre-adhered 959600550 Novaped Protect S90 with loose cover

8.1.1 Grinding and cutting

The forefoot area of the orthotic blanks can be processed through grinding and cutting to fit the shoe.

8.1.2 Finishing wedge for heel raise, inner or outer edge elevation

In the forefoot area (ball of foot and the toes), no material can be adhered in the toecap area or up to 10 mm behind it!

- Roughen the underside of the orthotic blank with a mop wheel and dust off.
- Cut the Multiforte construction material, black, 3 or 6 mm (art. no. 010774030 or 010774060) to the required size, roughen the side to be adhered on the grinding machine (24 to 40 grit) and dust off.
- Coat the underside of the orthotic blank and the roughened surface of the Multiforte evenly with Renia Ortec Spezial adhesive (art. no. 011625006) and allow to ventilate for about 20 minutes.
- With a hot-air gun, activate the adhesive film on the orthotic blank and construction material for about 20 seconds at around 120 °C and stick the materials together. In doing so, press the construction material and the orthotic blank together manually or mechanically with a suitable last.
- After the material has cooled, the construction material can be ground on the grinding machine into a heel wedge (Fig. 1) or an inner or outer edge elevation (Fig. 2). The material should taper off to 0 mm at the front at the metatarsal head (Fig. 2).

8.1.3 Bonding of the top cover

- Any adhesive can be used; the relevant processing instructions must be observed and adhered to.
- Spread adhesive on the upper side of the base.
- Spread adhesive on the underside of the cover where it is to be connected to the base. **In other words, the side of the cover that has contact with the insole must not be coated with adhesive, to avoid restricting conductivity!**

8.2 979600000 Novaped Protect soft pre-adhered 979600011 Novaped Protect soft partially adhered

8.2.1 Grinding and cutting

The orthotic blank can be ground to fit the shoe in terms of length and breadth and to adjust the corrective effect. In this context, the following construction features can be adjusted to suit the patient:

- Longitudinal arch support (Fig. 3)
- Retrocapital met pad in a teardrop shape (Fig. 4)

8.2.2 Finishing wedge for heel raise, inner or outer edge elevation

In the forefoot area (ball of foot and the toes), no material can be adhered in the toecap area or up to 10 mm behind it!

- Roughen the underside of the orthotic blank with a mop wheel and dust off.
- Cut the Multiforte construction material, black, 3 or 6 mm (art. no. 010774030 or 010774060) to the required size, roughen the side to be adhered on the grinding machine (24 to 40 grit) and dust off.
- Coat the underside of the orthotic blank and the roughened surface of the Multiforte evenly with Renia Ortec Spezial adhesive (art. no. 011625006) and allow to ventilate for about 20 minutes.
- With a hot-air gun, activate the adhesive film on the orthotic blank and construction material for about 20 seconds at around 120 °C and stick the materials together. In doing so, press the

construction material and the orthotic blank support together manually or mechanically with a suitable last.

- After the material has cooled, the construction material can be ground on the grinding machine into a heel wedge (Fig. 1) or an inner or outer edge elevation (Fig. 2). The material should taper off to 0 mm at the front at the metatarsal head (Fig. 2).

8.2.3 Bonding of the partially adhered orthotic blank

- Any adhesive can be used; the relevant processing instructions must be observed and adhered to.
- Spread adhesive on the upper side of the base.
- Spread adhesive on the underside of the cover where it is to be connected to the base. **In other words, the side of the cover that has contact with the insole must not be coated with adhesive, to avoid restricting conductivity!**

8.3 989600000 Novaped Protect carbon pre-adhered 989600550 Novaped Protect carbon with loose cover

8.3.1 Grinding and cutting

The forefoot area of the orthotic blanks can be processed through grinding and cutting to fit the shoe.

8.3.2 Finishing wedge for heel raise, inner or outer edge elevation

In the forefoot area (ball of foot and the toes), no material can be adhered in the toecap area or up to 10 mm behind it!

- Roughen the underside of the orthotic blank with a mop wheel and dust off.
- Cut the Multiforte construction material, black, 3 or 6 mm (art. no. 010774030 or 010774060) to the required size, roughen the side to be adhered on the grinding machine (24 to 40 grit) and dust off.
- Coat the underside of the orthotic blank and the roughened surface of the Multiforte evenly with Renia Ortec Spezial adhesive (art. no. 011625006) and allow to ventilate for about 20 minutes.
- With a hot-air gun, activate the adhesive film on the orthotic blank and construction material for about 20 seconds at around 120 °C and stick the materials together. In doing so, press the construction material and the orthotic blank together manually or mechanically with a suitable last.
- After the material has cooled, the construction material can be ground on the grinding machine into a heel wedge (Fig. 1) or an inner or outer edge elevation (Fig. 2). The material should taper off to 0 mm at the front at the metatarsal head (Fig. 2).

8.3.3 Bonding of the top cover

- Any adhesive can be used; the relevant processing instructions must be observed and adhered to.
- Spread adhesive on the upper side of the base.
- Spread adhesive on the underside of the cover where it is to be connected to the base. **In other words, the side of the cover that has contact with the insole must not be coated with adhesive, to avoid restricting conductivity!**

- 8.4 779600000 Novaped Protect active with loose cover**
779600010 Novaped Protect active assembly kit Orthema/
Pedcad/Swiss Comfort
779600020 Novaped Protect active assembly kit Paromed Trapez
779600030 Novaped Protect active assembly kit Paromed Oval
779600040 Novaped Protect active assembly kit GeBiom

8.4.1 Grinding and cutting

The orthotic blank can be ground to fit the shoe in terms of length and breadth and to adjust the corrective effect. In this context, the following construction features can be adjusted to suit the patient:

- Longitudinal arch support (Fig. 3)
- Retrocapital met pad in a teardrop shape (Fig. 4)

8.4.2 Finishing wedge for heel raise, inner or outer edge elevation

In the forefoot area (ball of foot and the toes), no material can be adhered in the toecap area or up to 10 mm behind it!

- Roughen the underside of the orthotic blank with a mop wheel and dust off.
- Cut the Multiform ESD construction material, black, 5 mm (art. no. 010689050) to the required size, roughen the side to be adhered on the grinding machine (24 to 40 grit) and dust off.
- Coat the underside of the orthotic blank and the roughened surface of the Multiform evenly with Renia Renol =RS=, anti-static adhesive (e.g. art. no. 011628090 or art. no. 011628850) and allow to ventilate for about 20 minutes.
- With a hot-air gun, activate the adhesive film on the orthotic blank and construction material for about 20 seconds at around 120 °C and stick the materials together. In doing so, press the construction material and the orthotic blank together manually or mechanically with a suitable last.
- After the material has cooled, the construction material can be ground on the grinding machine into a heel wedge (Fig. 1) or an inner or outer edge elevation (Fig. 2). The material should taper off to 0 mm at the front at the metatarsal head (Fig. 2).

8.4.3 Integration of additional heel padding

- For the integration of a heel spur cut-out, remove the corresponding material from the upper side of the orthotic blank with a grinding machine and replace it with padding material made of p², 6 mm (art. no. 964120320 or art. no. 011072060).
- The padding material must only be bonded with Renia Renol =RS=, anti-static adhesive (art. no. 011628090 or art. no. 011628850).
- Dust off the orthotic blank and padding.
- Use a clean brush to coat the padding and orthotic blank with Renia Renol =RS=, anti-static adhesive (art. no. 011628090 or 011628850) so that an adhesive film can form.
- Allow the adhesive layer to dry.
- Insert the padding and press firmly. Then smooth the edges with a pumice or similar (Fig. 5).

8.4.4 Bonding of the top cover

The foot orthosis is only to be handed over bonded with the enclosed cover.

- The padding material must only be bonded with Renia Renol =RS=, anti-static adhesive (art. no. 011628090 or 011628850).
- Dust off the orthotic blank.
- Use a brush to coat the cover and orthotic blank with Renia Renol =RS=, anti-static adhesive (art. no. 011628090 or 011628850) so that an adhesive film can form.
- Allow the adhesive layer to dry.
- With a hot-air gun, activate the adhesive film on the orthotic blank and top cover material for about 20 seconds at around 120°C and stick the materials together. In doing so, press the cover material and the orthotic blank together manually or mechanically with a

suitable last.

- Leave the adhesive bond to dry for at least 24 hours.
- Add holes to the forefoot perforation (e.g. with a punch, art. no. 062220230, or a piercing die (purchase from Ruckgaber-Brüggemann, tel. +49 (0)7457 949 70, rottenburg@schein.de), art. no. 10980035).

8.4.5 Milling your own orthotic blank from a Novaped Protect active assembly kit

In the forefoot area, the material thickness must not exceed 3 mm or the height of the supplied insole of the safety shoe. The midpoint of the heel must be at least 5 mm and not thicker than 14 mm. These details are based on use of the provided cover combination.

A forefoot perforation is absolutely necessary (e.g. with a punch, art. no. 062220230, or a piercing die (purchase from Ruckgaber-Brüggemann, tel. +49 (0)7457 949 70, rottenburg@schein.de), art. no. 10980035). The information above on preparing the Novaped Protect active foot orthosis also applies.



Fig. 1: Heel raise up to 5 mm



Fig. 2: Inner or outer edge elevation

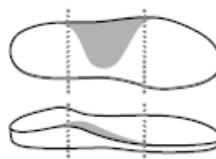


Fig. 3: Longitudinal arch support

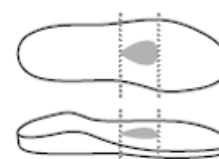


Fig. 4: Retrocapital teardrop shaped met pad



Fig. 5: Plantar fasciitis padding

Article	Size	SU	Art. no.	Usable for art. no.			
				779600***	959600***	979600***	989600***
Multiforte, black	Approx 1.000 x 1.000 x 3 mm	Sheet	010774030		X	X	X
Multiforte, black	Approx 1.000 x 1.000 x 6 mm	Sheet	010774060		X	X	X
Multiform ESD, ESD-capable, black	Approx 1.050 x 1.050 x 5 mm	Sheet	010689050	X			
p ² , rough on one side, nude	Approx 363 x 269 x 6 mm	Sheet	964120320	X			
p ² , rough on one side, nude	Approx 1.370 x 1.000 x 6 mm	Sheet	011072060	X			
Renia Ortec Spezial adhesive	1 l (tin)	Container	011625006		X	X	X
Renia Renol =RS= adhesive	90 g (tube)	Container	011628090	X			
Renia Renol =RS= adhesive	640 g (tin)	Container	011628850	X			

Tab.: Permitted materials for further processing of Novaped Protect orthotic blanks

9 Warranty

We grant the statutory warranty for use as intended.

10 Labelling

The processed orthotic blank is to be labelled on the underside by the healthcare technician as follows:

- Company name
- Unique identifier (e.g. patient code)
- Manufacturer name and address
- Date of manufacture
- Medical product
- Product description
- Custom-made product

Please inform the company Schein Orthopädie Service KG in case of anomalies, problems or defects with the orthotic blanks.

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