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 Holik orthotic blanks:

979611000 Novaped Protect soft Holik pre-adhered
979611011 Novaped Protect soft Holik partially adhered

Novaped Protect Holik orthotic blanks are in line with the German Social Accident Insurance rules 112–191 and ÖNORM Z 1259. They are specially developed for Holik firefighter boots and type-tested in line with EN ISO 20344 and EN ISO 20345. An up-to-date list of certified shoe models can be requested from Holik International. Novaped Protect Holik 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.

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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 Holik 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 Holik 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.

A heel height of minimum 5 mm and maximum 9.5 mm must be maintained.

8.1 979610000 Novaped Protect soft Holik pre-adhered
979600011 Novaped Protect soft Holik partially adhered

8.1.1 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)

8.1.2 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! In the forefoot area, the foot orthosis must not exceed a material thickness of 3 mm.

- 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).

8.2.3 Bonding of 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!**

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.

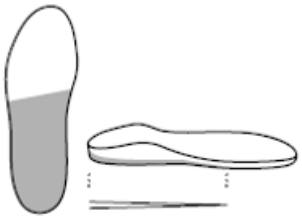

Fig. 1: Heel raise up to 5 mm

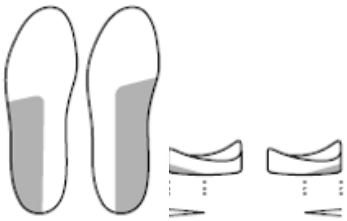

Fig. 2: Inner or outer edge elevation

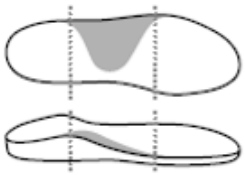

Fig. 3: Longitudinal arch support

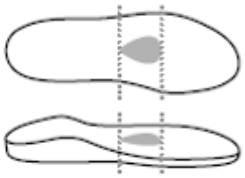

Fig. 4: Retrocapital teardrop shaped met pad

Fig. 5: Plantar fasciitis padding

Article	Size	SU	Art. no.
Multiforte, black	Approx 1.000 x 1.000 x 3 mm	Sheet	010774030
Multiforte, black	Approx 1.000 x 1.000 x 6 mm	Sheet	010774060
Renia Ortec Spezial adhesive	1 l (tin)	Container	011625006

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

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