

## Manufacturing Instructions for Orthopaedic (Shoe) Technicians

Dear Customers,

Thank you for the confidence you have shown in us by purchasing these insole blanks. You've made a good decision. Our goal and commitment are to ensure the best possible support for the foot using our insole blanks—in close cooperation with our partners, physicians, health insurance providers, and medical services. Learn more about our products by visiting our website: [www.schein.de](http://www.schein.de)

These manufacturing instructions apply to the following Novaped Protect Holik insole blanks:

979611000 Novaped soft Protect Holik bonded  
979611011 Novaped soft Protect Holik partially bonded

**Novaped Protect Holik insole 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 insole 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 insole blanks and pay attention to the following information.**

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### 1 Purpose / Indication

Insole blanks are preliminary products used to manufacture orthopedic insoles. Based on a medical prescription, an insole blank is individually customized and processed by a healthcare technician to create a bespoke orthopedic insole for a specific customer. Custom-made insoles are functional orthoses designed to support, cushion, or correct the foot, as well as to relieve pressure or redistribute load on the soft tissues of the foot.

### 2 Conditions of Use

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

### 3 Instructions for Use

Before initial use, the insole blanks must be processed by qualified specialists according to the user's individual needs and in accordance with these manufacturing instructions.

The size marking on the insole blanks serves only as a guide. Like a well-fitting safety shoe, the insole blank should consider not only foot length but also the toe box (shoe interior space).

Because foot lengths may differ, both feet must always be measured and individually fitted.

A processed insole blank is intended for use by one patient only.

### 4 Safety Instructions

- Insole blanks must be processed and customized only by qualified specialist personnel.
- Observe all safety instructions of any machines used during processing.
- General occupational health and safety regulations (according to the German Occupational Safety and Health Act – ArbSchG) must be followed during processing.
- The materials used in insole blanks are subject to aging and may change their properties over time. The condition of the insole

blanks should always be checked before processing.

- To protect insole blanks from environmental influences during storage, we recommend storing them in a dry, light-protected location at temperatures between 10–30 °C.

### 5 Application Risks

In the case of significant foot deformities, the use of an insole blank is not suitable.

### 6 Material Specifications

Base Material: EVA  
Reinforcement: PES  
Cover/Cushioning Material: Protect by schein ESD cover material  
Pad: SBR  
Cushioning Components: PU

### 7 Disposal

The disposal of the product and packaging must be carried out in accordance with applicable legal regulations.

### 8 Processing

**Novaped Protect Holik insole 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 insole 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 insole 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 soft Protect Holik bonded 979600011 Novaped soft Protect Holik partially bonded

### 8.1.1 Grinding and cutting

The outline of the insole blank may be ground in length and width, as well as adjusted for correction. The following features can be adapted to 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 insole 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 insole 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 insole 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 insole 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 the Partially Bonded Insole 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 board must not be coated with adhesive, to avoid restricting conductivity!**

## 9 Warranty

We grant the statutory warranty for use as intended.

## 10 Labeling

The processed insole blank must be labeled on the underside by the healthcare technician as follows:

- Company name
- Unique identifier (e.g. patient code)
- Manufacturer's name and address (orthopedic business)
- Manufacturing date
- Medical product
- Product description
- Custom-made product

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

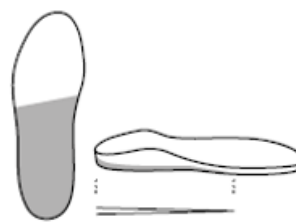


Fig. 1: Heel raise up

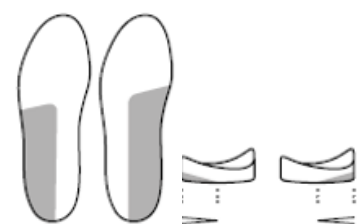


Fig. 2: Inner or outer edge elevation

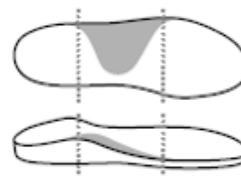


Fig. 3: Longitudinal arch support

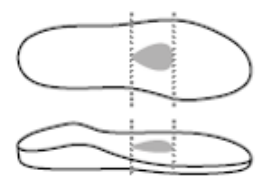


Fig. 4: Retrocapital teardrop shaped met pad



Fig. 5: Plantar fasciitis padding

Article	Size	SU	Art. no.
Multiforte, black	approx. 1000 x 1000 x 3 mm	Sheet	010774030
Multiforte, black	approx. 1000 x 1000 x 6 mm	Sheet	010774060
Renia Ortec Spezial adhesive	1 l (can)	Container	011625006

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

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