

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

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

979616000 Novaped soft Protect BAAK bonded

The Novaped Protect BAAK insole blanks are manufactured in accordance with the German DGUV Rule 112-191 and ÖNORM Z 1259. They are specifically developed for BAAK safety shoes. The insole blanks are covered with the type-tested cover material Baak ESD Orthostep+ medic.

The Novaped Protect BAAK insole blanks are certified for BAAK safety shoes that are marked in accordance with DGUV Rule 112-191.

An up-to-date overview of the certified BAAK safety shoe models can be found at www.baak.de. The Novaped Protect BAAK insole blanks may only be further processed in accordance with these manufacturing instructions. No materials other than the listed components may be used.

Failure to comply will result in the expiration of the type examination certificate, and the supplying company will be liable for any resulting damages.

Please read these manufacturing instructions carefully before further processing of the insole blanks and observe the following information.

- | | |
|--|--|
| <p>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.</p> <p>2 Conditions of Use
Individually processed insole blanks must be dispensed in a usable and properly fitting condition.</p> <p>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.</p> <p>4 Safety Instructions</p> <ul style="list-style-type: none"> • 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. <p>5 Application Risks
In the case of significant foot deformities, the use of an insole blank is not suitable.</p> | <p>6 Material Specifications</p> <p>Base Material: EVA
Cover/Cushioning Material: BAAK ESD Orthostep+ medic cover material
Pad: EVA</p> <p>7 Disposal
The disposal of the product and packaging must be carried out in accordance with applicable legal regulations.</p> <p>8 Processing
The Novaped Protect BAAK insole blanks may only be processed in accordance with the following manufacturing instructions. Failure to comply will invalidate the type examination certificate, and the supplying company will be liable for any damages resulting from this.
When fitting the Novaped Protect BAAK insole blanks into safety shoes, ensure that they lie completely on the insole board. In the forefoot area, a height of 3 mm must not be exceeded. Since the top cover material has a thickness of 4 mm, it must be thinned out across the entire toe cap area so that the maximum height of 3 mm is not exceeded.
Additionally, it must be ensured that the cover material in the forefoot area is not covered by other materials in order to maintain ESD conductivity.</p> <p>8.1 979616000 Novaped soft Protect BAAK bonded</p> <p>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:</p> <ul style="list-style-type: none"> • Longitudinal arch support (Fig. 3) • Retrocapital pad in drop shape (Fig. 4) <p>8.1.2 Finishing Wedge for Heel Raise, Inner or Outer Edge Elevation
In the entire toe cap area, a maximum height of 3 mm must not be exceeded.
It must also be ensured that the top cover material in the forefoot area is not covered by other materials.</p> <ul style="list-style-type: none"> • Roughen and dust the underside of the insole blank with a grinding machine. • Cut the build-up material from Nora company (Lunasoft) with a Shore hardness of 40-50 Shore A to the required size, roughen the side to be glued using a grinding machine (grit 24 to 40), and remove any dust. • Coat both the underside of the insole blank and the roughened area |
|--|--|

of the built-up material evenly with adhesive (e.g., Renia Ortec Spezial, item no. 011625006) and let it air for about 20 minutes.

- Activate the adhesive film on the insole blank and build-up material using a hot air gun for about 20 seconds at approximately 120 °C, and bond the materials together. Press the build-up material onto the insole blank manually or with a suitable last.
- After the material has cooled, grind the build-up material into a heel wedge (Fig. 1) or an inner or outer edge elevation (Fig. 2) on the grinder. The material should taper to 0 mm at the metatarsal heads (Fig. 2).

9 Warranty

We provide the statutory warranty for proper use.

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

The area beneath the processed insole blank must be marked by the healthcare technician as follows:

- With the article number of the BAAK safety shoe
- With the name of the manufacturer (orthopedic company)

Please inform Schein Orthopädie Service KG if there are any abnormalities, issues, or deficiencies with the insole blanks.

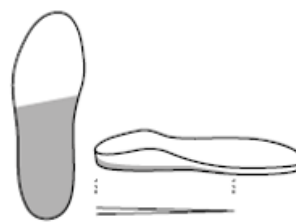


Fig. 1: Heel raise

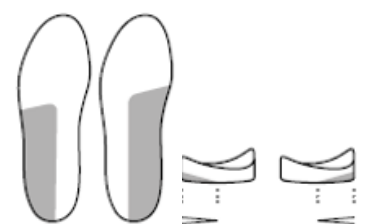


Fig. 2: Inner or outer edge elevation

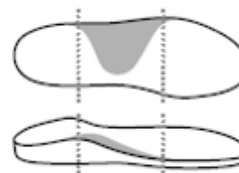


Fig. 3: Longitudinal arch support

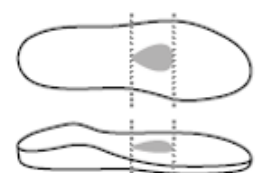


Fig. 4: Retrocapital teardrop shaped pad

Article	Size	SU	Art. no.
nora® Lunasoft SL, stone grey	approx. 1140 x 740 x 12 mm	Sheet	012650120
adhesive Renia Ortec Spezial	1 l (can)	Container	011625006

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

Schein Orthopädie Service KG
 Hildegardstr. 5
 42897 Remscheid, Germany
 Tel. +49 2191 910-0
 Fax +49 2191 910-100
 remscheid@schein.de
 www.schein.de

