

Certificated care solutions Gallfeet

V1.Q1.2024

INSTRUCTIONAL PROTOCOL - ORTHOPAEDIC INSOLES

Client: <NOCS> CE ID: <NOCS> Brand: <NOCS> Model: <NOCS> Article: <NOCS>

- 1. Orthopaedic insoles must be manufactured exactly according to this instructional protocol.
- 2. A modeled sole model is the milled or 3D printed material without cover material.
- 3. An orthopaedic insole is a modeled sole model including cover material.
- 4. Glue of your choice is allowed, with or without antistatic or ESD properties.
- 5. Materials of your choice are allowed for milling or 3D printing a sole model, with or without antistatic or ESD properties.
- 6. The sole model may be constructed from several different materials, for example with a hard underlayer of 70 Shore.
- 7. The average Shore value of a sole model including cover should be between 30 and 60 Shore.

The SAFETY ZONE has the following safety features:

75%



- electrical conduction
- water vapor permeability

25%[´]

3/4 sole model	4/4 sole model	Instructions
		Make the circumference of the orthopaedic insole fit for in the footwear.
→ 3/4	<i>4/4</i>	The length of the milled or 3D printed sole model, onto which the cover is glued.
		Glue the cover onto the sole model. Neskrid recommends (reactivable) PU adhesives such as Plastocoll and Plastofix. Neoprene glue and cement glue are not suitable.
	Min. space Min. space 20um	Fold over the cover material with at least 40 mm width at the center of the forefoot onto the bottom of the sole model. The flaps should be turned over behind the SAFETY ZONE. Make sure there is a maximum gap of 20 mm between the two flaps on the bottom of the sole model.

Neskrid 4Allfeet B.V.

info@neskrid.com The Netherlands

NESKRID 4ALLBRANDS

3/4 sole model	4/4 sole model	Instructions
	SAFETY ZONE	Perforate the forefoot of the orthopaedic insole with at least 6 holes with a minimum of 2 mm in diameter. The exact positions of the perforation holes in the SAFETY ZONE may be determined at your discretion. These perforation holes in the SAFETY ZONE are necessary for water vapor permeability in a 4/4 sole model.
		For the 4/4 sole model, there is no limitation on the allowable thickness in the safety zone including cover material.
SAFETY ZONE		With the 3/4 sole model, materials must never be applied under the cover material in the SAFETY ZONE, as they will then no longer meet the safety functions of the SAFETY ZONE!
		Outside the SAFETY ZONE, adjustments to the orthopaedic insoles may be made.



In order to comply with all product regulations, it is mandatory before delivery for the medical practitioner to have the orthopaedic insoles certified at **www.neskrid.com** as custom-made Medical Devices according to Regulation EU/2017/745 (MDR).



During the certification of the orthopaedic insoles, it was verified that in combination with the client's work footwear, they comply with Regulation EU/2016/425 for Personal Protective Equipment (PPE) with corresponding standard ISO 20347:2021 for work footwear without a safety toecap. In case the combination complies, the original manufacturer of the work footwear remains responsible for the complete footwear after modification, including the 4Allbrands orthopaedic insoles. The conformity of the new combination under this PPE legislation remains guaranteed.

info@neskrid.com The Netherlands