



## INSTRUCTIONAL PROTOCOL - ORTHOPAEDIC INSOLES

in SAFETY FOOTWEAR

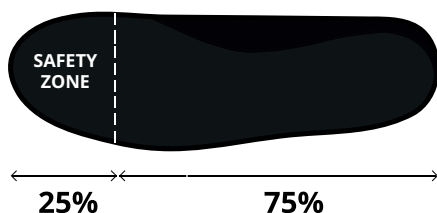
Client: <NOCS>  
CE ID: <NOCS>

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.






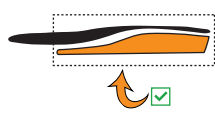
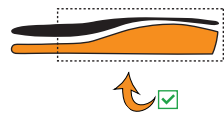
The SAFETY ZONE has the following safety features:



- electrical conduction
- residual height under the safety toe cap
- water vapor permeability

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



3/4 sole model	4/4 sole model	Instructions
		<b>Perforate the forefoot of the orthopaedic insole with at least 6 holes with a minimum of 2 mm in diameter.</b> The exact positions of the perforation holes in the <b>SAFETY ZONE</b> may be determined at your discretion. These perforation holes in the <b>SAFETY ZONE</b> are necessary for water vapor permeability in a 4/4 sole model.
		<b>For the 4/4 sole model, the permissible thickness in the safety zone is a maximum of &lt;NOCS&gt; mm including cover material.</b> When modeling and manufacturing, always consider this permissible thickness of orthopaedic insoles under the <b>SAFETY ZONE</b> .
		<b>With the 3/4 sole model, materials must never be applied under the cover material in the SAFETY ZONE,</b> as they will then no longer meet the safety functions of the SAFETY ZONE!
		<b>Outside the SAFETY ZONE,</b> 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](http://www.neskrid.com) as custom-made Medical Devices according to Regulation EU/2017/745 (MDR).



During the certification of the orthopaedic insoles it was checked whether they in combination with the client's safety footwear comply with Regulation EU/2016/425 for Personal Protective Equipment (PPE) with corresponding standard ISO 20345:2021 for safety footwear. In case the combination complies, the original manufacturer of the safety footwear remains responsible for the complete footwear after modification, including the 4Allbrands orthopaedic insoles. The compliance of the new combination under this PPE legislation remains guaranteed.



During the certification of the orthopaedic insoles, the maximum thickness including cover material in the respective work or safety footwear is specified. The medical practitioner should always check whether the orthopaedic insoles meet this maximum thickness in the **SAFETY ZONE**. The client's medical practitioner should always be aware of this.