

# Innovative Composite Inner Lining System for Diabetic Footwear

*The alarming increase in the number of diabetes patients means that there is a steadily growing demand for medical aids, not only in Germany but world wide. The provision of footwear and footwear components for diabetics generally requires consideration of physical and design aspects. In contrast, aspects of hygiene hardly play a role in spite of their enormous relevance for health. This gap had to be filled, and that was accomplished by PFI in two joint projects undertaken with the Pirmasens-based company Colortex GmbH. A composite system for insoles developed in the first project is already commercially available. The result of the second project is an innovative, removable three-dimensional inner lining system for diabetic footwear.*



Diabetics are more susceptible to infection and frequently also suffer from severely impaired wound healing. Objects worn close to the skin therefore have to be cleaned after wearing and, where appropriate, also disinfected. That raises the hygiene demands on prescribed aids.

## Project Goal

The goal of the first project was the market-oriented development of inner lining systems for diabetic shoes. Here Colortex GmbH was responsible for the design aspects, whereas aspects of hygienic relevance were handled by the PFI Microbiology Laboratory.

Accompanying studies on test persons with skin-sensory monitoring and pressure measurements on selected inner lining systems and correspondingly equipped shoes were conducted under supervision by specialists from the fields of medicine and orthopaedic-shoe technology. The results obtained supported the development and optimisation of the product and its hygienic cleaning procedure.

## Shoe-orthopaedic Properties and Hygiene Aspects

Demands placed on an upper and its inner lining differ from those placed on a shoe insole, meaning that different materials with different properties had to be used. As a further challenge, it was necessary to develop a stable three-dimensional structure which can be reliably inserted into shoes.

Suitable materials were selected in a targeted manner, paying due attention to physical, chemical, haptic, optical, processing-relevant, and hygienic aspects as well as shoe technical requirements, on the basis of results from previous studies. Different designs and laminations could be developed thanks to innovative advances in textiles, films, and thermoplastic reinforcing materials. Nubs are applied by 3D printing.

Microbiological laboratory studies with simulation of diabetic skin flora (bacteria, yeasts, and dermatophytes) were performed to evaluate the hygienic properties of individual materials, partly with antimicrobial finishes, and newly developed composite systems, and an appropriate selection was made. These results were of decisive importance for the design of the new composite system.

## Hygienic Cleaning Procedure

Efficient hygienic cleaning procedures were then examined, evaluated, and refined, with due attention to material durability – especially retention of shape and function. Sufficient reduction of all relevant groups of microorganisms on the newly developed product was accomplished by dry heat and wet-chemical disinfection. This makes it possible to ensure improved hygienic properties and reduced danger of microbial contamination and thus to minimise the risk of re-infection with attendant possible complications.

## Studies on Test Persons

To conduct the studies on test persons, several uniform three-dimensional inner lining systems were produced by shoe manufacturer Elten GmbH from suitable composite materials, integrated into a corresponding number of commercially available work shoes of different sizes, and made available for the tests.

Skin-sensory studies by means of patch tests prior to and during the test phase were all negative and gave no indication of intolerance or epidermal sensitisation towards the newly developed product tested.

Pressure measurements performed by the company Fuß-Orthopädie-Technik Roman Eggs GmbH on selected inner lining systems or correspondingly fitted shoes contributed to the development and optimisation of the systems.

Dr. med. Matthias Frank, Head Physician at the Internal Medicine Department, Diakonie Klinikum Neunkirchen, also supervised the studies on test persons.

## Conclusion

The inner lining system developed and optimised in the course of this project exhibits excellent footwear-relevant and hygienic properties. Among other features, it also includes a special membrane serving as a “secretion barrier” protecting deeper layers and the shoe interior against the entry of secretions and germs. Nubs attached to the textile upper material stabilise the three-dimensional system and serve to ensure reliable insertion into the shoe for which it is intended.

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## Further information

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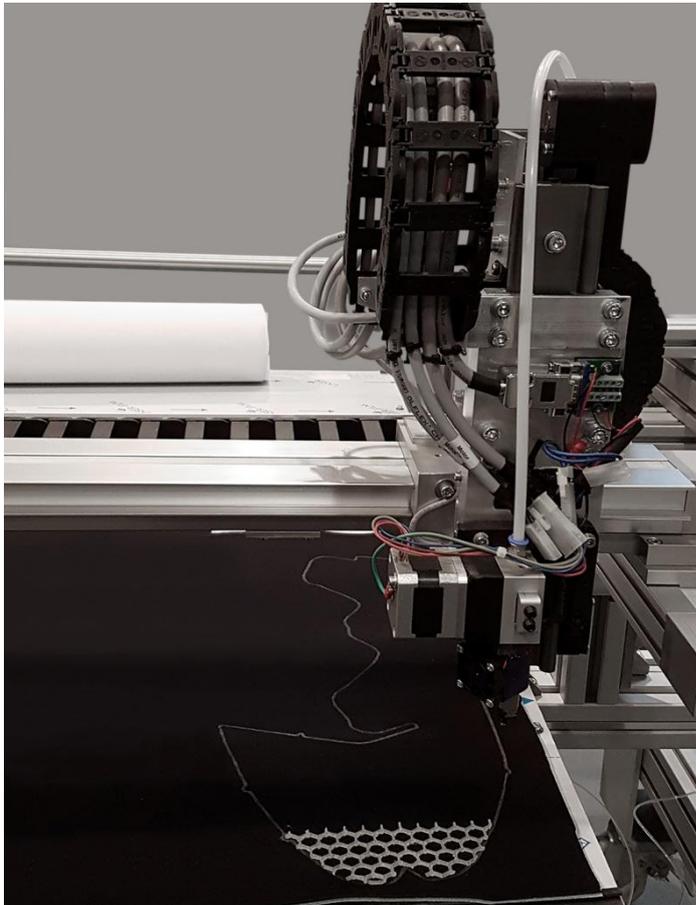
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aufgrund eines Beschlusses  
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**Figure 1: Innovative inner lining system for diabetic footwear**



**Figure 2: Printed-on nubs**