



1 Silica gel fiber fleece  
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## NEW HOPE FOR HEALING OF CHRONICAL WOUNDS

### CLINICAL TRIAL ON THE NEW SILICA GEL WOUND DRESSING

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Time heals all wounds, or so the saying goes, but unfortunately this is not always the case. Many people have serious wounds which heal only very slowly, if at all. For chronic wounds such as these, Bayer Innovation GmbH (BIG), working in collaboration with the Fraunhofer ISC, has developed a special fleece dressing designed to accelerate the healing process. The two research scientists Walther Glaubitt and Dr. Jörn Probst were awarded the prestigious Joseph von Fraunhofer Prize 2008 by the Fraunhofer-Gesellschaft for the method they devised to process the basic material into the fiber fleece.

#### Clinical trial

Bayer Innovation, in cooperation with Fraunhofer ISC and supported by experts at Bayer HealthCare, has qualified the dress-

ing for clinical use. Colleagues from Bayer Technology Services and Currenta are also involved, for instance in the production of the dressings and on the analytical side.

At the university hospitals in Cologne and Hamburg an initial clinical trial was conducted with patients suffering from chronic venous lower leg ulcers. They were treated with the new dressing and the results were encouraging.

In the second half of 2009, the trial was expanded to include 15 hospitals in Europe and the USA and altogether 250 patients. The start of the trial was a major milestone for BIG. »It's the first project we have taken into clinical trial,« states Dr. Detlef Wollweber. And the Managing Director of BIG has something else to be pleased about: »We've achieved this after just three years of our own development time.« The purpo-



se of the trial is to show whether the new dressing from Bayer promotes the healing process in chronic wounds. »Half of the participants will be treated with our new product and the other patients will receive a conventional commercial dressing,« explains Iwer Baecker, project manager at BIG.

The healing process is evaluated at defined intervals. Hopes are high that the new development from Bayer can help to close a major treatment gap. The Professional Association of German Surgeons estimates that in Germany between two and four million patients have to cope with poorly healing, often painful wounds. These include, for example, people with a diabetic foot or with certain vascular diseases. Elderly patients in particular are afflicted by chronic wounds. Thanks to its silica gel fibers the hope is that the new wound dressing from Bayer will actively support the natural healing process. Tests have already shown that the material has what it takes to do so. The textile fibers provide healthy cells with an ideal structure on which to adhere, enabling new layers of skin to quickly form along the fibers in the dressing.

»Up to now the market has failed to provide a product which actively supports the healing process,« comments Prof. Dr. Sabine Eming from the Department of Dermatology at the University of Cologne, who heads the trial. A further advantage is that

the silica gel fibers are dissolved by the body over time. The wound dressing therefore does not have to be removed. All that remains is the newly-formed skin, which seals the wound.

The trial is scheduled for completion in 2011. »However, we hope to be able to assess the commercial prospects for this product on the basis of interim findings and to make the necessary preparations,« adds Iwer Baecker.

### ***Clinical trial on new wound dressing***

Poorly healing wounds and chronic injuries have always been a problem for physicians. A new type of wound dressing based on silica gel fiber fleece can greatly improve the healing process. This inorganic material is fully absorbed by the body in the course of the healing process. The basic technology for the synthesis and production of the new materials was developed at the Fraunhofer ISC.

Clinical trials are presently underway at the universities of Cologne and Hamburg. Patients suffering from chronic venous leg ulcers are being treated with the new wound dressing. The early results are most encouraging.

**1** *A glimpse into the spinning Fraunhofer research chamber: scientists Glaubitt and Probst.*

**2** *Changing the collection tray: The finished fleece is taken out and cut or punched to size and the unsterile dressing is packed at a slight pressure of about 800 bar.*  
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