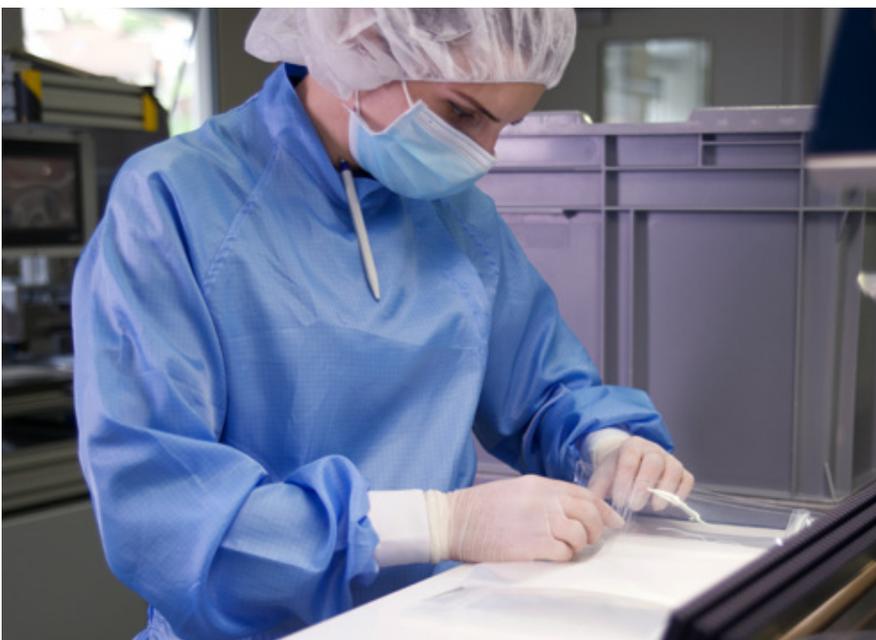


Sefar Medical Components

3-layer wound dressing with substance carrier



Sefar has developed a customer specific solution for wound dressing

In collaboration with an Italian customer, a specific problem in the field of wound healing was solved: the development of a 3-layer wound dressing for the support of cream. The 3-layer solution *fabric/knitted material/fabric* can be used to support active substances such as cream, ointment, honey and hydrogel.



The challenge

An Italian Sefar customer produces two kinds of wound and skin care products containing an aqueous extract of *Triticum vulgare*. This cream is applied to enhance wound healing. It is supported by knitted cotton materials. Wounds such as abrasions, lacerations, neuropathic ulcers, skin tears, superficial partial thickness burns, and venous leg ulcers are preferably treated with gel-impregnated dressings that accelerate the healing process and regeneration of the skin. However, these dressings currently suffer from inhomogeneous distribution of the cream over the area of the dressing. Furthermore, the actual dressing is a fibrous material which shows adherence to the skin.

Adhesion of wound dressings to the healing skin is a major problem in wound management. Expensive film or silicone dressings have to be used to circumvent this adverse effect. The Italian customer wants to improve the current cotton-based solutions and is looking for a replacement with a new 3-layer solution made of fabric. That's why Sefar has been contacted to develop customized non-adhering wound dressing solutions.

Project challenges

- The general key properties of such cream support are softness and cream release
- The material must be suitable for the production process. That includes winding, tensile strength, cutting and related parameters
- No fraying because of the cold cut processing
- Useful certification, e.g. biocompatibility certificates, are required for the medical and pharmaceutical field

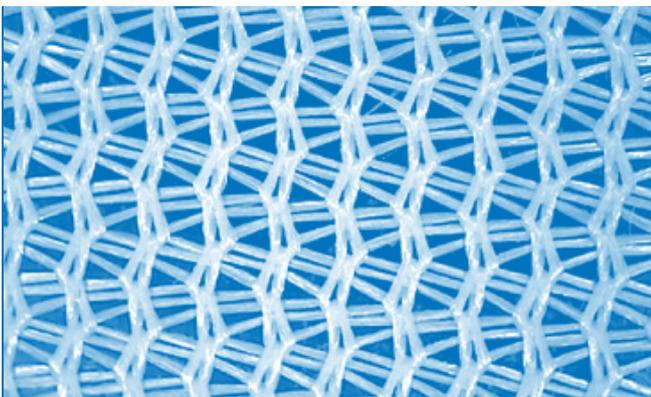
Additionally, the customer requested a number of certifications and confirmations as supporting information in order to submit the final device at the Italian authorities, as well as to obtain European Conformity (CE marking). The customer is interested in finding an improved solution for this product and has started a project with Sefar.

Sefar's solution

During the project, Sefar developed five different solutions. The workability of the materials was tested by the customer. There were some transversal slitting issues which were solved after the first trial production. The performances of softness and cream release were tested by the customer.

Sefar's invention relates to a wound dressing material with a biocompatible monofilament fabric which forms a contact face on a wound. As a result of the customer feedback, Sefar has developed a three-layer wound dressing, which has also been patented. The solution involves two layers of SEFAR MEDIFAB® 07-190/70 and one layer of knitted material. A challenge for Sefar was to develop a suitable knitted material with best overall performances, including FDA-compliance of yarns. Sefar has succeeded in this development.

Manufacturing tests have been performed by the customer, with the presence of Sefar. Accordingly, process adjustments on coating, driven roles, cross cutting, packaging, and others were done by the customer to be able to process the new material. The best pre-slitting and bonding parameters were determined in a number of trial runs.



Face of a polyester multifilament knitted Sefar fabric

Customer value with Sefar's solution

Due to the customer requirements, the SEFAR MEDITEX® ACC bonding technology that physically connects any man-made media has been developed. The technology relies on point bonding which eliminates the need of adhesives and avoids polymer decomposition as in thermal bonding process.

Treatments of certain wounds and chronic wounds require dressings that combine a non-adherent contact layer with a liquid or odor-absorbing media. Other injuries need a non-adherent contact layer along with a padding cushion. In either case, the liquid and gas flow need to be within sharp limits and must not vary due to obstructing, irregular adhesives. Also, adverse effects from adhesives or decomposed polymers must be avoided. In addition, the nature and capacity of the absorbent need to be customized for specific therapies. For large areas, oozing wounds, often the wet stability of non-woven dressings, poses problems upon removal. Therefore, the combination of a two dimensionally stable, woven structure with a freely selectable non-woven or foam layer offers unlimited opportunities. The SEFAR MEDITEX® ACC technology perfectly meets these needs and gives the customer an infinite choice of media combinations.

With SEFAR MEDITEX® ACC technology a non-adherent contact layer, the monofilament fabric, can be combined with a cream-holding, high surface non-woven. This combination results in a perfectly homogenous, smooth and non-adherent material to be coated with the healing supporting cream.

Important advantages include

- Faster healing process
- Homogeneous cream release
- Homogeneous cream distribution
- 72 hours life
- Easier release from wound



Overview of a point-bonded media shows the smooth and regular surface of the material

Why did the customer choose the Sefar solution?

Sefar created SEFAR MEDITEX® label, a single brand to unify specific medical grade fabric lines. All SEFAR MEDITEX® fabrics are carefully produced to ensure they are suitable for use in medical applications. The unique multi-layer products of the SEFAR MEDITEX® ACC product line are manufactured by bonding different media. This bonding of complementary media permits different media properties to be combined in one material.

Customer's advantages in this project

- Converting processed in a cleanroom ISO class 7 according to ISO 14644-1
- Well-trained staff and high-level equipment for flawless testing
- Global team of experts to support R&D departments
- Cooperation in development of innovative and sustainable solutions
- Sefar's experience and know-how in processing



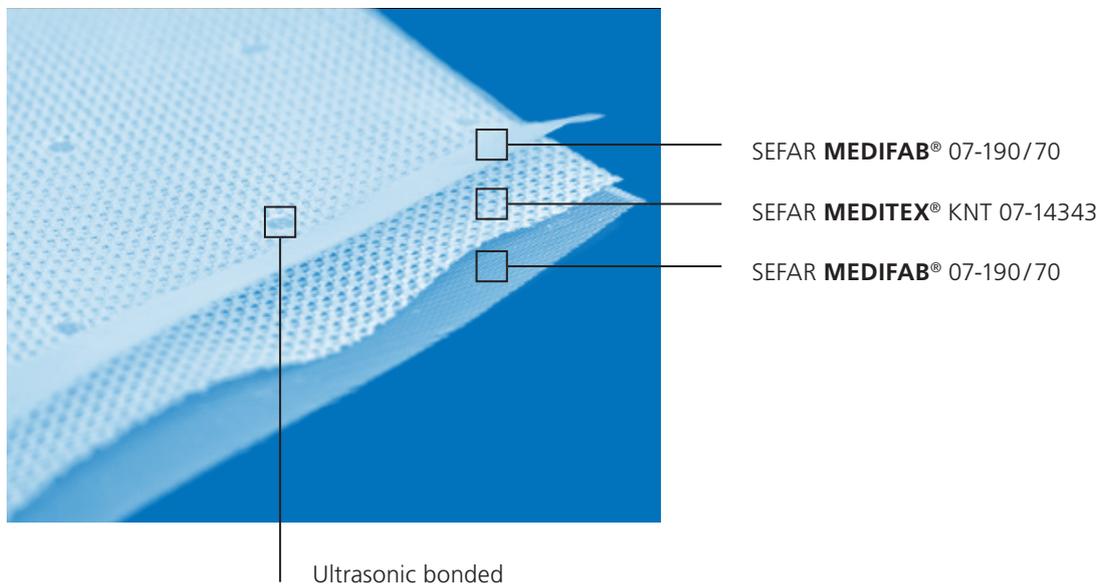
Single layers of a bonded fabric

Multiplication potential

Bonded multi-layer solutions based on man-made fibers offer potential in various wound dressing applications. The concept can replace knitted cotton structures or serve as a support for a number of healing supporting compounds.

The 3-layer solution fabric / knitted material / fabric can be used to support active substances such as cream, ointment, honey, hydrogel. Another possible field of application could be, for example, in alternative medicine.

Structure of 3-layer wound dressing solution



For further information or technical advice please contact your local Sefar representative.

All technical information given here are based on Sefar's previous experiences or test results. The information should be understood merely for guidance purposes and must be regarded as non binding. Sefar provides this information to the best of its knowledge but accuracy and completeness is not guaranteed and Sefar assumes no liability. Many factors beyond Sefar's control can affect the performance of a Sefar product. It is the sole responsibility of the user to determine the fitness of use for their application, and in doing so ensure that all applicable laws and regulations are observed. We expressly point out that the SEFAR MEDIFAB® and SEFAR MEDITEX® products offered are not explicitly developed for medical implants and/or implants components. In the event of your company and/or any of your end customers using our products for such applications or supplying them to third parties please contact us immediately.

