

Secu-Pack®

**SENGEWALD** 

Medical Packaging  
Higher quality, more safety.



Secu-Pack®



Sengewald is the largest OR drape manufacturer in Germany and, together with their subsidiary, MSP Schmeiser (Horb, Baden Wuerttemberg) is technologically amongst the worldwide leading makers of disposable drapes as well as standard, custom and complete packs. At the same time we have been developing and producing custom sterilisation packaging for nearly three decades for individual customers and are a competent and highly efficient partner for the medical device industry, clinics and practices.

## Secu-Pack® Sterility Assurance

Proven in clinics, practices and industry.

### Experience since 1979

As one of the first companies in Europe Sengewald advanced the production of modern sterilisation packaging for the medical device industry and for use in hospitals. Sengewald can therefore look back on over 25 years of experience in the making of medical packaging. The continuous further development of these packaging systems has resulted in an extensive and comprehensive product portfolio which is designed to fully meet the special requirements on the packaging of the individual medical devices. The constant stream of new customer wishes, an innovative and powerful in-house development department and reliable raw materials partners lead to new, high-performance and individual packaging solutions for our customers. A trained team of sales representatives is always available to support our customers on site and conceive, together with your experts, the optimum packaging solution for your medical devices.







## Production in a Cleanroom Environment

Optimum safety for flexible solutions.

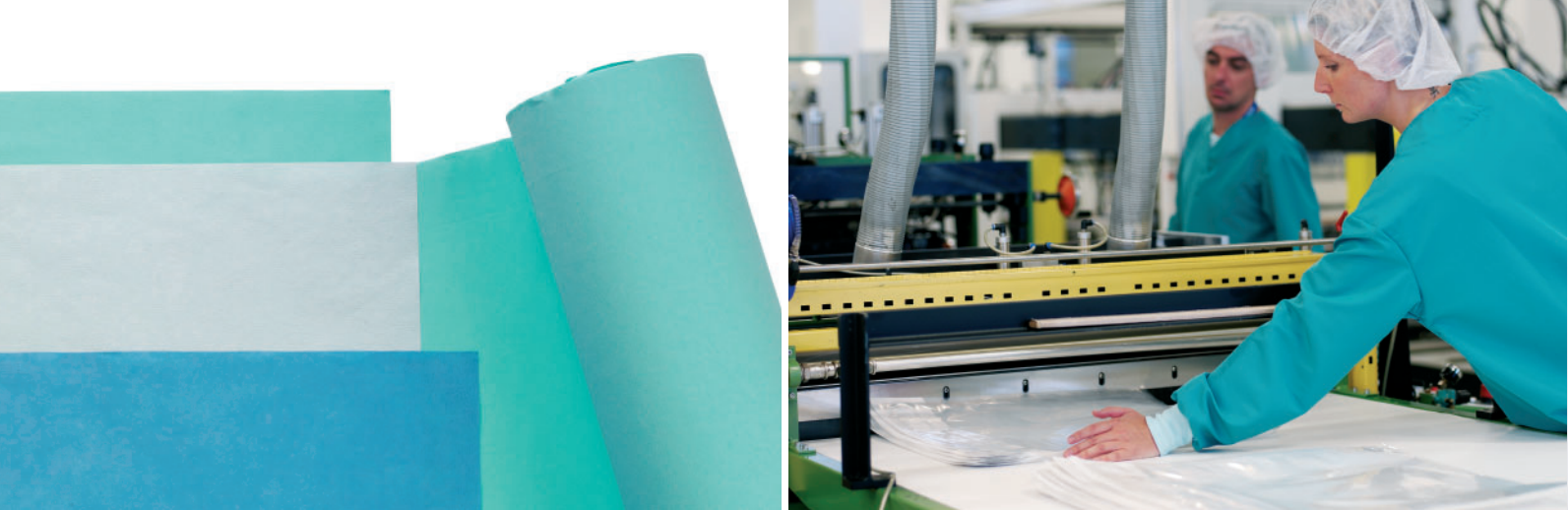
### Technically up to date

The packaging products are all manufactured in a class 8 cleanroom at Sengewald in accordance with the ISO 14644 standard. A modern and automated production plant guarantees the greatest safety for the products that they contain and offer a wide range of individual production options in order to ensure that the special requirements on the packaging are optimally met.

The production areas are subject to the stringent surveillance required in connection with cleanroom manufacturing and are continuously monitored to ensure the lowest possible particle count. Regular bioburden tests conducted by external agencies enable us to monitor microorganisms in the manufacturing environment and on the products themselves. In the course of our hygiene management system all of the possible avenues by which bacteria or particles can enter the cleanrooms are investigated in order to eliminate contamination as far as possible.

The implementation and maintenance of a risk management system also forms part of our extensive safety precautions.





## Medical Packaging Product Range

High performance packaging for individual customer requirements.

### Our Service

- Full service from advice on the packaging to punctual delivery with comprehensive on-site support by our sales representatives.
- Well-founded technical know-how.
- High-grade flexographic printing in up to four colours.

**Customer-specific packaging solutions in individual sizes with print as desired.**  
**Please ask your sales representatives!**

Detailed technical data sheets can be gladly provided upon request.





## Our Range

### MEDIPEEL® Pouches, Tubes, Self-Adhesive Pouches:

- Made of medical paper and PET-O/PP film (MEDIPEEL®D) or PET-O/PE film (MEDIPEEL®R)
- For lightweight products without sharp edges
- Suitable for sterilisation by steam, formalene and ethylene oxide (MEDIPEEL®D) or ethylene oxide and irradiation (MEDIPEEL®R)

### FLEXOPEEL® Pouches, Tubes:

- A combination of Tyvek® and various grades of film (e.g. PET-O/PE or PA/PE film)
- Specially for products with sharp edges
- High puncture resistance
- Suitable for sterilisation by ethylene oxide and irradiation

### FLEXOPEEL® Header Pouches:

- Made of various grades of medical film with a peelable coated Tyvek® header
- For high volume or heavy products
- Suitable for sterilisation by ethylene oxide and irradiation

### CLEERPEEL® Pouches:

- Made using a wide range of different film grades depending upon the requirements and field of application
- Highly transparent or coloured films
- When peeled open, a white area demonstrates the integrity of the seals
- The sterile products are hermetically sealed, permitting vacuum packaging.
- Also available as header pouches with peelable film header
- Suitable for sterilisation by irradiation

### FLEXOTEAR® Pouches:

- Made of coextruded PE film
- Optionally with additional Tyvek® valve (up to two valves are possible) with tear aid and special LINEARTEAR® effect (i.e. easy linear tearing at a freely defined tear notch position)
- Suitable for sterilisation by irradiation
- With Tyvek® valve(s) also suitable for sterilisation by ethylene oxide

### FLEXOPOR® Pouches:

- Made of Tyvek® and PET-O/HDPE film
- Bacteriological barrier effect
- High puncture resistance
- Suitable for sterilisation by steam up to 121°C, ethylene oxide and irradiation

### STERIFLEX® Sterilisation Accessories:

- Wrapping paper and sterilisation nonwovens
- Adhesive tapes with and without indicator
- Test cards for sterilisation

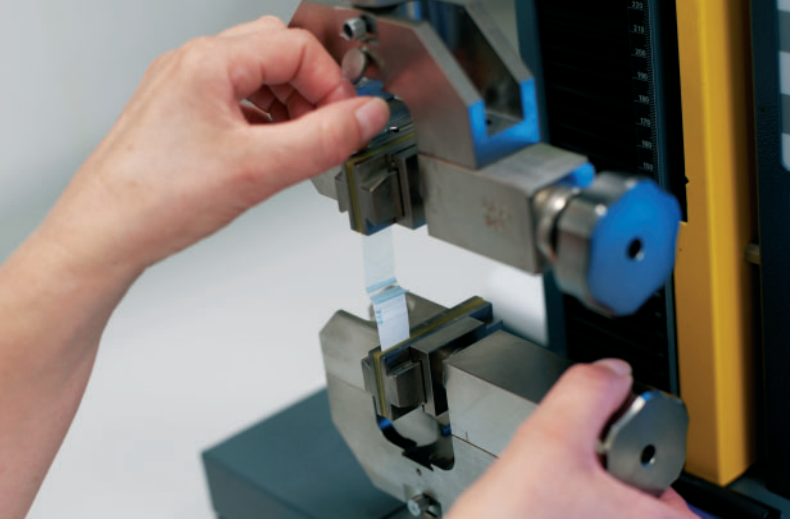
### Lids and Machine Rolls:

- Printed and unprinted lids made of various raw materials (paper, Tyvek®, film etc.) in individual forms as closures for blister packaging
- Packaging materials, such as paper or Tyvek® as machine rolls (printed or unprinted) for conversion on packing machines

Tyvek® is a DuPont registered trademark.

### Tailor-Made Solutions to Meet Your Goal

Our medical packaging guarantees that sterile products stay that way. For a long time our special pouches and tubes have proven the necessary safety during transport and storage. The multitude of manufacturing options, know-how accumulated over many years and a professional development team guarantee the optimum packaging solution for your products.

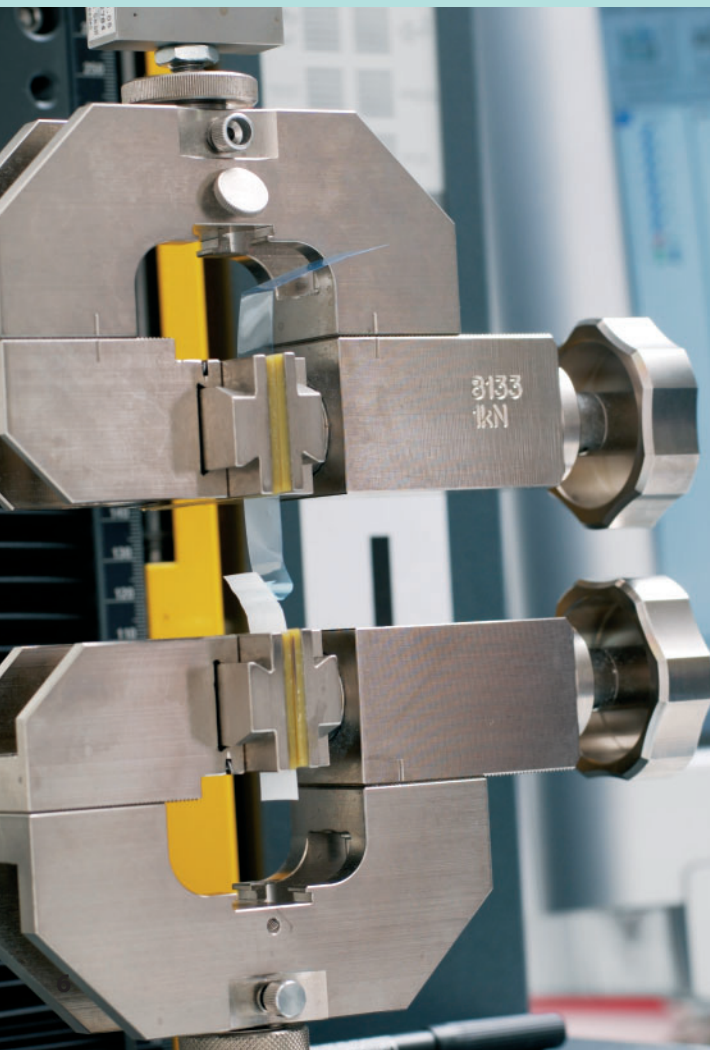


### **Consistent Quality Management**

To be able to guarantee maximum safety, Sengewald manufactures all of the products for the medical industry in accordance with the requirements of the EN ISO 13485 quality management system and has the corresponding certification to this standard. Furthermore the products all comply with the national and international standards applicable to each product group. Sengewald's medical packaging range therefore conforms to DIN 58953, DIN EN 868 and DIN EN ISO 11607 standards.

## **Sterilisation Packaging in Focus**

Inspected quality for maximum safety.



We maintain a comprehensive quality assurance system with continuous in-process and quality inspections. The results of these inspections are documented and archived to ensure that any production run can be completely traced in every regard at any time. In addition with the aid of an external specialist institution Sengewald operates an effective insect prevention system, which includes not only insect combat but also surveillance and statistical evaluation, throughout the entire manufacturing area.

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- Well-founded technical know-how.
- High-grade flexographic printing in up to four colours.

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Please ask your sales representatives!**



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