

RENOLIT Healthcare



WHO WE ARE

RENOLIT Healthcare is an important market unit of the **RENOLIT Group**. As the market leader in medical-grade high-value polymer products, we are deeply involved in the newest ideas for advanced healthcare solutions without damaging our environment, health and economy.

WHAT YOU CAN EXPECT

For more than 50 years **RENOLIT** Healthcare has cooperated in teams with customers – leading medical device manufacturers and pharmaceutical companies – to make vital contributions to human health. In a changing global environment, we embrace our responsibility for today's and future generations. We are deeply committed to transforming creative ideas into advanced, responsible market-ready solutions.

HOW WE INNOVATE

Our three global innovation centers in Europe, the USA and China are the incubators for picking up the most current developments in order to transform them into new materials, applications and devices. Together with you, we lay the foundation for our goal:

TOGETHER TOWARDS HEALTH

SHIPPING AND QUALITY ASSURANCE

At our 4 global production sites, we offer back-up production for our key-products if required by our clients. This way, challenges at one site don't hamper agreed delivery terms. We're also at your service at your production facilities to optimise your processes.



You can watch our company

OUR HEALTHCARE PORTFOLIO

RENOLIT Healthcare is the world's leading developer and producer of medical-grade high-value polymer solutions including films, tubes and granules. Our healthcare products are spread across five application fields and two complementary product offers. Our services include EMT equipment leasing, custom-made solutions and tailor-made films.

FIELDS OF APPLICATION



BLOOD & BLOOD COMPONENTS



BIOTECHNOLOGY



IV & PHARMACOLOGICAL APPLICATIONS





COMPLEMENTARY





SERVICES



CUSTOM-MADE SOLUTIONS



EMT EQUIPMENT LEASING





BLOOD & BLOOD COMPONENTS



Injection-moulded items such as needle holders, membrane ports, break ports and various Y-connectors can be manufactured from RENOLIT MEDIGRANUUL.



The **RENOLIT**TRANSFUFOL and ES
films are used for the
manufacturing of
critical blood contact
devices. >



BLOOD & BLOOD COMPONENTS

The packaging of blood and blood components is known to be one of the most critical applications of polymer medical films. The developments are frequent, and the requirements are increasing every day.

RENOLIT is the worldwide market leader for the basic materials required for the manufacturing of blood bag systems. **RENOLIT** TRANSFUFOL and ES blood bag films are supplied to the world's leading manufacturers of blood bags and blood processing systems such as aphaeresis and therapeutic treatments. An important factor is the consistent and reliable quality of the films, often custom-made in co-development with our customers.

The features include superior embossing stability during the 121°C steam sterilisation procedure, guaranteeing the non-blocking properties on both

sides of the film. Different surface structures are available, enabling good blood separation both on automatic as well as semi-automatic fractionation machines.

The compositions of **RENOLIT** blood bag films have been carefully tested for their blood compatibility. Various formulations are available, including DEHP, TEHTM, DINCH, DEHT and citrate plasticised films. Special PVC and polyolefin compounds offer high oxygen and carbon dioxide permeability for platelet storage as well as for frozen and cryogenic storage. The thicknesses range from 0.20 to 0.75 mm and the widths from 50 to 1,350 mm, depending on the film type. The specially developed **RENOLIT** TRANSFUFOL film processing technique combines the advantages of calendering and extrusion, resulting in superior batch-to-batch consistency.

The strict clean room conditions, web cleaning technology and in-line slitting guarantee low particulate levels. Our advanced composition and production technology for **RENOLIT** MEDITUUB MAT and LIMA results in blood bag tubing with antikinking and anti-sticking properties after sterilisation.

RENOLIT TRANSFUFOL, ES films and **RENOLIT** MEDITUUB/MEDIGRANUUL are used for the manufacturing of critical blood contact devices such as:

- » blood bag systems
- » flexible leucocyte filters
- » aphaeresis systems
- » transfusion systems
- » pathogen inactivation systems
- » platelet pool bags
- » venous reservoir bags

and many more.

ALBUMIN IN FLEXIBLE PACKAGING

Plasma derivates such as albumin are traditionally packed in glass containers. **RENOLIT** Healthcare offers a range of materials for the manufacturing of flexible bags for the packaging of plasma derivates, including primary-barrier films, allowing a long shelf life of the packed product.





BIOTECHNOLOGY



RENOLIT barrier films have been developed for 2D and 3D bag designs.

High-purity **RENOLIT** GRANUFLEX compounds can be used for various injection-moulded bag connectors. >



Special EVA and polyolefin films, exhibiting excellent cold storage behaviour, are available for stem cell storage. >



BIOTECHNOLOGY

The biotechnology sector is one of the application areas where continuous and frequent developments result in higher material requirements.

Today, flexible polymer single-use systems are replacing traditional glass and stainless steel in applications like media storage bags, bioreactors, mixing vessels, product storage and sampling containers. These disposable pre-sterilised systems are increasingly considered a safer and less costly alternative to stainless-steel equipment. This trend in the biotechnology industry is supported by exciting new developments in the polymer components of such flexible disposable systems. These components have to fulfil the strict product requirements of critical biotechnology and pharmaceutical applications.

In these fields, **RENOLIT** Healthcare is one of the leading suppliers of packaging materials for the most critical applications. After the introduction in the 1990s of the EVA-based Biotech Film range suitable for 2D and 3D bag designs we have introduced a range of biotechnology films.

The **RENOLIT** INFUFLEX barrier films comprise ultra-pure inert PE inner and outer layers and an oxygen barrier layer. The high barrier properties of these films offer significant advantages in the storage of oxygen-sensitive products. The films exhibit extremely low extractables and excellent clarity and are resistant to a wide range of chemicals. The unique film structure combined with a 1,400 mm film width offers excellent weld strength in both 2D and 3D bag designs, which are the new standard in the biotechnology industry.

The raw materials in these films have been carefully selected. Coupled with our film production sites spread across multiple continents, this builds a robust supply chain and ensures long-term availability. In addition, **RENOLIT** INFUFLEX

barrier films are produced under strict controls to minimise the risk of particulates forming.

RENOLIT MEDIPAK UVO offers excellent oxygen, carbon dioxide and UV barrier properties. Available in widths of 125 to 400 mm, this five-layer coextruded tubular film is suitable for media bags of up to 20-litre capacity.

Special EVA and polyolefin films are available for stem cell storage and cell gene therapy applications. Specially developed materials combine very high oxygen and carbon dioxide transmission rates with excellent cold storage properties down to -196°C (liquid nitrogen, cryogenic).

Compounds and clean room extruded PVC films and tubing are available for blood collection, processing and transfer sets used in cell and gene therapy applications.

RENOLIT Healthcare is known for its long history in the single-use industry, remains active in conferences and single-use bioprocessing groups such as BPSA, and follows industry guidelines as applicable.



IV & PHARMACOLOGICAL APPLICATIONS



The storage of IV solutions, drugs, active ingredients or other pharmacological solutions is supported by a wide range of our film and tubing compositions. >



RENOLIT PP ports for IV bags show excellent compatibility with the pharmaceutical solutions. >



IV & PHARMACOLOGICAL APPLICATIONS

The use of flexible bags for IV applications offers significant advantages over the traditional glass bottles and blown plastic containers. **RENOLIT** Healthcare sets the standard in aspects of quality, reliability and cost.

We offer a complete system for the manufacture of reliable and high-quality IV bags, both in polyolefin and in PVC materials:

- » RENOLIT MEDIPAK (PVC) and RENOLIT MEDIFLEX (PP) tubular film; RENOLIT INFUFLEX and MF double wound PP flat film
- » RENOLIT MEDITUUB (PVC) and RENOLIT TUBEFLEX (PP); monolayer for PP ports and multilayer PP or PP/PVC for PC ports

- » RENOLIT MEDIGRANUUL (PVC) and RENOLIT GRANUFLEX (PP) injection-moulding compounds for port manufacturing
- » RENOLIT ports and caps for IV bags and plastic bottles

The storage of drugs, active ingredients or other pharmacological solutions is supported by a wide range of film and tubing compositions. The **RENOLIT** Healthcare product range includes plasticiser-free PP-based materials and a variety of PVC materials with a range of plasticisers including DEHP, DEHT and TEHTM.

RENOLIT Healthcare films are the standard for the packaging of sterile IV and pharmacological solutions. These PVC- and polyolefin-based films are available in tubular and double wound flat films and have proven to be the most reliable and cost-effective material for IV bags.

The **RENOLIT** Healthcare film compositions have been tested according to the relevant ISO 10993

standards and fulfil the test requirements of the various pharmacopoeias.

The storage of ready-to-use active ingredient solutions often requires special materials exhibiting low absorption of the drug components. For this application we offer low-absorption film and tubing based on cyclic olefin copolymers.

For polyolefin IV systems the unique **RENOLIT** TUBEFLEX monolayer types, combined with PP-based **RENOLIT** GRANUFLEX injection-moulded ports, offer a significant economic advantage compared with the multilayer **RENOLIT** TUBEFLEX used for polycarbonate ports. A combination of co-extruded PP/PVC tubing is possible as well.

For IV administration sets, **RENOLIT** MEDITUUB is the material of choice. The main features are the superior non-kinking properties, excellent transparency, and suitability for steam, ETO and gamma sterilisation.



DIALYSIS



Reliable sealing and high filling efficiency can be achieved with RENOLIT MEDIPAK-S. >



DIALYSIS

One of the largest application areas for **RENOLIT** Healthcare products is dialysis. Our materials play an important role here and together with partners we are working on the development of the next generation of dialysis systems.

For renal intensive care treatments, multi-compartment polypropylene bags with peelable seal or special high-pH-resistant PVC bags are used to store sterile solutions based on sodium bicarbonate. Such bags are also used for highly concentrated dialysis solutions.

All these speciality bags can be manufactured from a range of **RENOLIT** Healthcare films, depending on the customer's choice:

- » RENOLIT INFUFLEX: polyolefin film, flexible and transparent. Suitable for multi-chamber bags with peelable seal technology. Compatible with high-pH solutions such as sodium bicarbonate.
- » RENOLIT TUBEFLEX: polyolefin tubing for use with RENOLIT MEDIFLEX and RENOLIT INFUFLEX
- » RENOLIT MEDIPAK: tubular PVC film for sterile solution packaging, available with a variety of plasticisers including DEHP and DEHT
- » RENOLIT MEDIPAK ALKA: tubular PVC film for the packaging of sterile sodium bicarbonate solutions and other solutions with a pH > 7

The applications of **RENOLIT** Healthcare products in peritoneal dialysis are highly diverse. In peritoneal

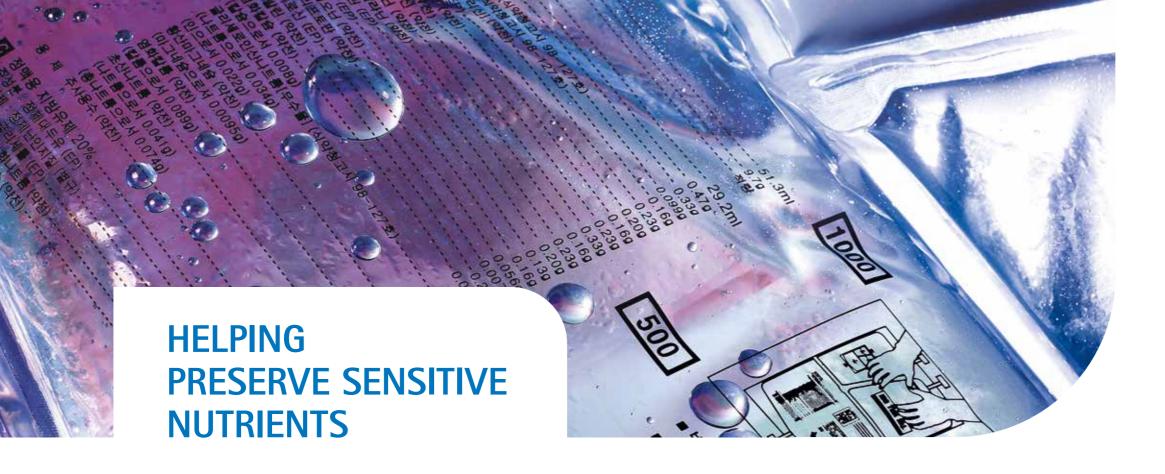
dialysis treatments, the peritoneal cavity of the patient acts as dialysing membrane. Usually applied as a home therapy, the patient can enjoy a relatively high freedom of movement without the need for frequent visits to the clinic or hospital.

RENOLIT Healthcare provides the double-bag CAPD system ready to fill using PVC or PP material and the individual components.

RENOLIT Healthcare materials are suitable for the traditional lactate-based CAPD solutions and also for the next-generation sodium bicarbonate solutions with pH > 7 and speciality glucose or amino acid solutions. Special drainage bags are available in PVC and polyolefin material suitable for CAPD systems as well as for automated peritoneal dialysis applications. The high quality of **RENOLIT** Healthcare products helps ensure reliable dialysis systems.



NUTRITION



RENOLIT materials are used for life-saving enteral and parenteral nutrition devices. >



NUTRITION

Total Parental Nutrition (TPN) is required when a patient's demand for macro- and micronutrients cannot be covered by regular oral or enteral nutrition. Let's collaborate to innovate TPN systems with advanced features in many terms.

RENOLIT Healthcare PP and EVA films are used for the storage of lipophilic solutions, an application where PVC with TEHTM, DEHT or DINCH plasticisers are also used.

RENOLIT MEDIPAK EVA tubular film is available in a transparent or frosted surface and a ribbed version. A special surface embossing on the outside of the tubular film reduces the sticking and blocking effect and facilitates its use on automated welding machines. **RENOLIT** EVA flat film is available in a combination of transparent and frosted surfaces.

Several multilayer **RENOLIT** Healthcare films offer barrier functions to oxygen and UV light and excellent cold temperature resistance. The coextruded **RENOLIT** MEDIPAK UVO tubular film contains an EVA fluid contact layer, is weldable at high frequencies and is suitable for ETO and gamma sterilisation.

Special **RENOLIT** MEDITUUB EVA and co-extruded **RENOLIT** MEDITUUB PVC/EVA are available to ensure a proper connection with the bag ports.

Many parenteral nutrition solutions require steam-sterilisable multi-compartment bags with peelable seal, which can be manufactured from the **RENOLIT** INFUFLEX polyolefin films. In combination with **RENOLIT** TUBEFLEX tubing and **RENOLIT** GRANUFLEX based ports, a complete polyolefin system can be realised.

The **RENOLIT** Healthcare product range also offers a unique high oxygen barrier film suitable for multicompartment bags with peelable seal. This innovative barrier film keeps its high clarity and flexibility after steam sterilisation at 121°C.

The high barrier properties of this film offer significant advantages in the storage of oxygensensitive products, reducing or eliminating the need for a barrier overwrap package and oxygen scavengers.

Enteral nutrition applications require reliable and cost-effective packaging materials. Various **RENOLIT** Healthcare materials are available for the large diversity in enteral feeding products:

- » **RENOLIT** TRANSFUFOL extruded film
- » RENOLIT SOLCARE calendered films, costeffective and available in transparent and white
- » RENOLIT EVA flat film and RENOLIT MEDIPAK EVA tubular film, often used for longer shelf-life storage of fatty solutions

The well-known **RENOLIT** MEDIPAK 9002 UVO is a multilayer co-extruded tubular film with high barrier properties to oxygen, carbon dioxide and UV light. Together with two new **RENOLIT** tubular films, it is the basis for safe and protective packaging for the compounding, administration and storage of TPN solutions with a longer shelf life. The new **RENOLIT** MEDIPAK 9002 UVO micro rib is designed for the manufacturing of double- or multi-chamber compounding bags with an O_2 and UV barrier. The bag chambers are separated by an external clamp. The new **RENOLIT** MEDIPAK 9020 UVO yellow is a film suitable for single-chamber compounding bags with barrier O_2 and extended UV range according to USP <671>.





PORTS & CAPS



PP ports for flexible bag manufacturing are available in an exclusive double-port design, assuring reliability and cost-effectiveness. >





PORTS & CAPS

The production of flexible bags or plastic bottles for intravenous solutions requires specially designed ports and caps. We offer a large variety of high-quality components for automated form-fill-seal and blow-fill-seal machines.

For flexible bags for intravenous solutions we propose polypropylene port and cap systems that can be sealed directly to the film. Bags with flexible tubing can be fitted with polycarbonate spike ports and injection ports as well as with polypropylene twist-off ports.

The design and rubber composition of the polycarbonate spike ports and injection ports offer excellent spike retention and assure minimum fragmentation upon piercing. Various compositions of the rubber components are available. Compositions can be developed to meet customer requirements.

RENOLIT Healthcare unique port and cap designs support highly cost-effective and automated flexible bag manufacturing.

A range of high-quality caps is available for the manufacturing of blow-moulded plastic bottles for IV solutions, including Eurocap, foil caps and more.

These caps can be supplied in polypropylene and polyethylene compositions to ensure compatibility with the bottle material and with the sterilisation temperature – up to 121°C for polypropylene caps.

The **RENOLIT** Healthcare ports and caps are manufactured on automated injection-moulding machines and assembled under ISO clean room conditions.

General note:

Certain ports and caps may not be available for sale in all countries.



SECONDARY PACKAGING



Blood bag sets can be packed and steamsterilised in **RENOLIT** WRAPFLEX films. >



SECONDARY PACKAGING

To ensure the best protection and quality, **RENOLIT** Healthcare offers co-extruded multilayer polyolefin films for the overwrapping of sterile solution bags and blood bag systems. Safe and reliable easy opening by a peelable seal.

SECONDARY PACKAGING

RENOLIT WRAPFLEX films are PP-based films designed for the overwrapping/outer packaging of sterile solution bags and blood bag systems.

Typically, these bags and blood bag systems are steam-sterilised in the overwrap at 121°C in a one-step final sterilisation. The **RENOLIT** WRAPFLEX multilayer films with full PP composition offer significant advantages over traditional polyamide-or polyester-based films. The benefits include higher flexibility, greater transparency, very good puncture resistance after steam sterilisation, and recycling options achieved by the full PP compatible composition.

RENOLIT WRAPFLEX films are manufactured from medical-grade raw materials in a clean room. The system is based on a reliable peelable seal opening of the overwrap package with proven functionality for IV bags and blood bag systems.

The films can easily be processed on all modern overwrapping machines. The bottom film can be thermoformed to offer a perfect fit around the product.

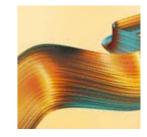




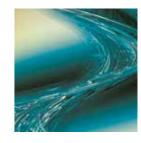
Together with our customers and partners we work on innovative and custom-made solutions. >



Tailor-made films take the individual wishes of our customers into account. >



With **EMT equipment leasing** costs can be optimised enormously. >



SERVICES

With a wide range of new customer services, you will find in **RENOLIT** Healthcare a strong partner with innovative and customised full-service solutions to meet your specific challenges.

Whether as part of a joint venture or in the form of a partnership – as a service partner **RENOLIT** Healthcare provides our customers with comprehensive advice in different matters. This includes:

- » consultancy in suitable packaging methods
- » design of new recipes
- » qualified advice on regulatory issues
- » research
- » root cause analysis
- » support in new product development
- design of healthcare-related devices
- consultancy on validation and registration of new products for healthcare applications

- » raw material change procedure of already registered and certified products
- » polymer processing problems

CUSTOM-MADE SOLUTIONS

Drawing on our experience with high-value polymer films, we have evolved towards an innovative solutions provider. In order to reach new standards, we combine innovation with partnership. Our custom-made solutions offer an even broader range and focus on more than just our products. By providing this, we cover solutions from supply chain, packaging and consulting to quality, support and a lot more. Together with our customers we take healthcare to the next level.

TAILOR-MADE FILMS

Many of our films are developed and produced according to special specifications of our customers. During production we place the utmost importance on quality assurance and control. Depending on the multiple needs of our clients,

RENOLIT Healthcare offers tailor-made solutions for different specific film qualities like specific barriers, puncture resistance, gas and liquid barriers, specific mechanical properties, optical properties and transparency.

EMT EQUIPMENT LEASING

Our new Extrusion Modeling Technology (EMT) allows the development of the next generation of multilayer films with exceptional properties. In addition to an improvement in product properties, our technology can significantly reduce the use of raw materials. This can drive our industry towards greener and more sustainable solutions. Our leasing concept not only includes EMT die leasing itself but also the configuration and cleaning of EMT dies. Furthermore, the service concept also covers the optimisation of existing recipes for using with EMT die technology as well as the design and development of new films with previously unseen combinations of properties. Last but not least, aftersales service and consultancy will be offered by **RENOLIT** Healthcare.





RENOLIT Healthcare WORLDWIDE



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