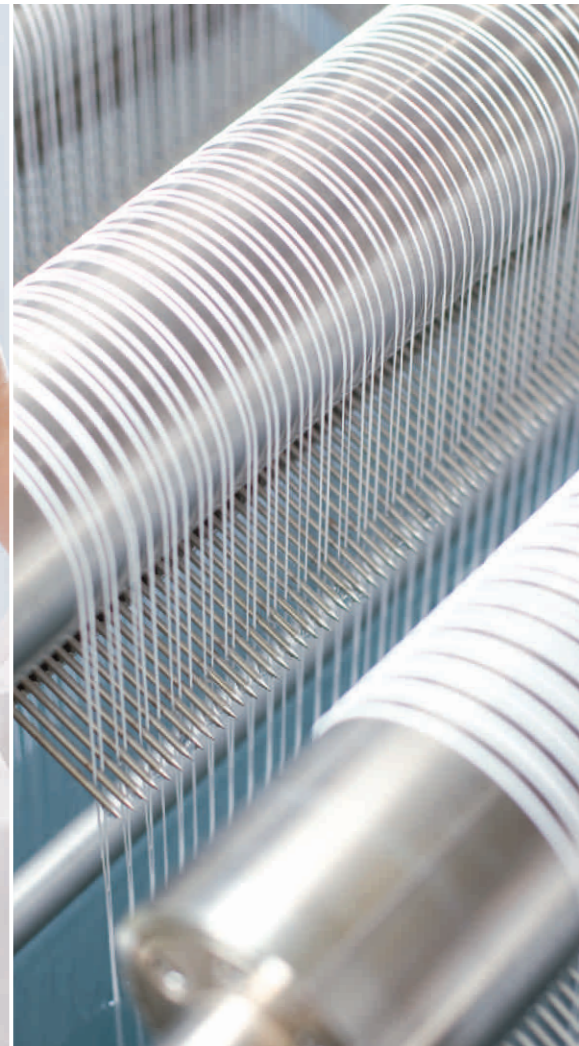


Saxonia Medical & Ascalon

Expertise in dialyser production



Dialysis

Experts in creating a better future



Company history

- 1920 Saxonia factory established in Radeberg
- 1978 Production of hollow-fibre dialysers
- 1996 Production of fully synthetic hollow-fibre dialysers begins
- 1997 Ascalon founded in Berggießhübel
- 1999 First production line for polysulphone dialysis membranes at Ascalon
- 2002 First Diacap α Polysulfone dialysers manufactured
- 2009 First xevonta dialysers manufactured

The creation of an “artificial kidney”

Like all human organs, the kidney is one of nature’s wonders. Every day, it filters toxic substances out of up to 1,700 litres of blood, which the heart pumps constantly through more than 90 kilometres of veins and capillaries. In the past, people were not expected to survive kidney failure, but things have changed today with the emergence of a kind of “artificial kidney” – the dialyser. Dialysers save the lives of thousands of people every day and there are currently 1.9 million dialysis patients all over the world. As life expectancy rises, so too does the number of people who will require medical treatment as their kidneys become less effective with age. Compared to today the world-wide demand of dialysers will be doubled by 2020.

Now, thanks to valuable innovations in medical technology, dialysis treatment has developed into a safe form of therapy that patients can tolerate well. Together with B. Braun and in close cooperation with physicians and patients, Saxonia Medical and Ascalon have had an instrumental effect on the progress made in dialysis treatment over the years. Today Saxonia, which was founded in Radeberg in 1920 and is now part of the B. Braun Group, manufactures the equipment that lies at the very heart of dialysis: the dialyser. In simple terms, dialysers remove toxic substances from the blood through physical processes. Ascalon, a further subsidiary of B. Braun, has been producing polysulphone hollow-fibre membranes, which are inserted into the dialysers, for this treatment since 1999 – a high-tech fibre for a highly effective dialysis process.

Today, B. Braun dialysers are used all over the world on a daily basis to enhance the quality of life of thousands of dialysis patients – with expertise in creating a better future.

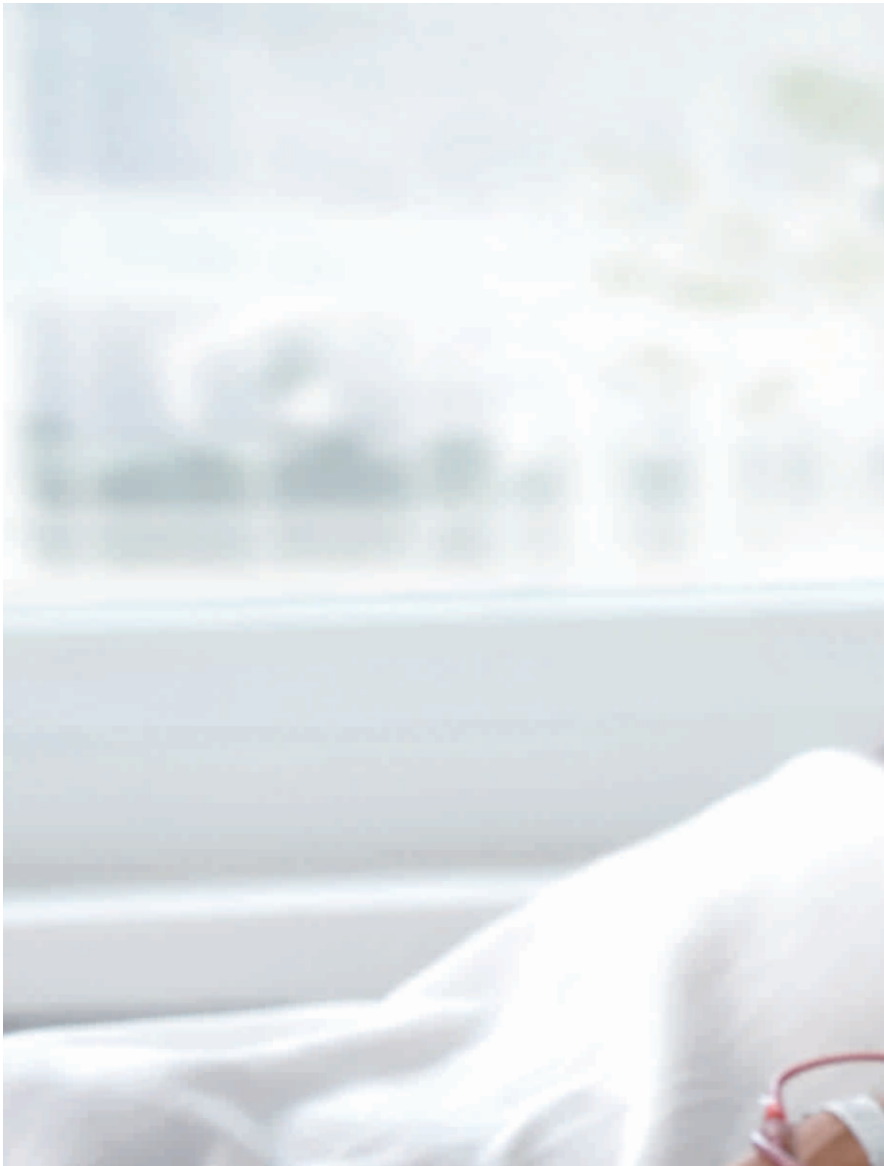


A market on the move – actively shaping the future with B. Braun

Since 2004, Saxonia Medical GmbH has been an integral part of the B. Braun Group, which Ascalon GmbH also joined in 2005. B. Braun is a global player in modern medical technology, running dialysis centres on a global scale, among other things, and supplying hospitals all over the world with dialysis products. The B. Braun product range includes dialysis machines and the dialysers, blood line systems and dialysis concentrates used with them. Our customers are physicians and hospital staff who work with dialysis products on a daily basis.

So what do physicians require from modern dialysis and, therefore, from the dialysers used during this treatment? The focus is naturally on patient comfort and the effectiveness of the dialysis treatment. In a continuous effort to improve the effectiveness of dialysis with its dialysers, B. Braun has demonstrated a keen willingness to invest since 2004. To date, the B. Braun Group has invested more than 50 million euros in research and development, as well as in constructing state-of-the-art production facilities and a comprehensive quality management system.

This commitment is essential for keeping pace with the future demands of the internationally growing dialysis market as well: worldwide, the number of dialysis patients is increasing by 5 to 7% year on year. The aim of the investments is to expand production capacity, as well as to encourage the further development of the dialysers.



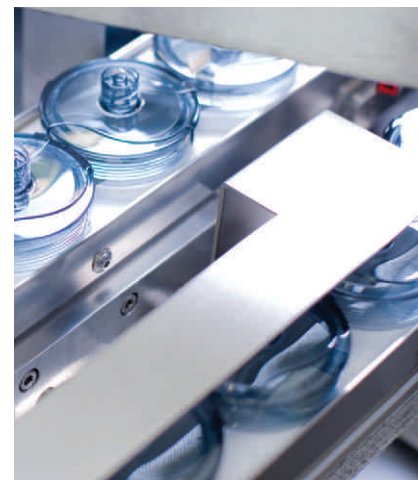
Continuous research and development – innovations are the key to future success.



The positive changes in the market and the investments B. Braun has made as a result have had a lasting impact at the Saxonia Medical and Ascalon headquarters, with the implementation of state-of-the-art technology on the one hand and employment security on the other. These two factors form the basis of a healthy corporate culture, which is reflected in the remarkable achievements of the staff. At Saxonia Medical and Ascalon, people look to the future with motivation and are ready to do their best tomorrow as well.

Having the future in our sights is also a sign of an attractive employer, and this starts with the next generation: the proportion of trainees at Saxonia Medical and Ascalon currently stands at 5%. This is also due to the successful dual-training system run in collaboration with distinguished universities.

Quality and safety – our product promises



Focus on the patient

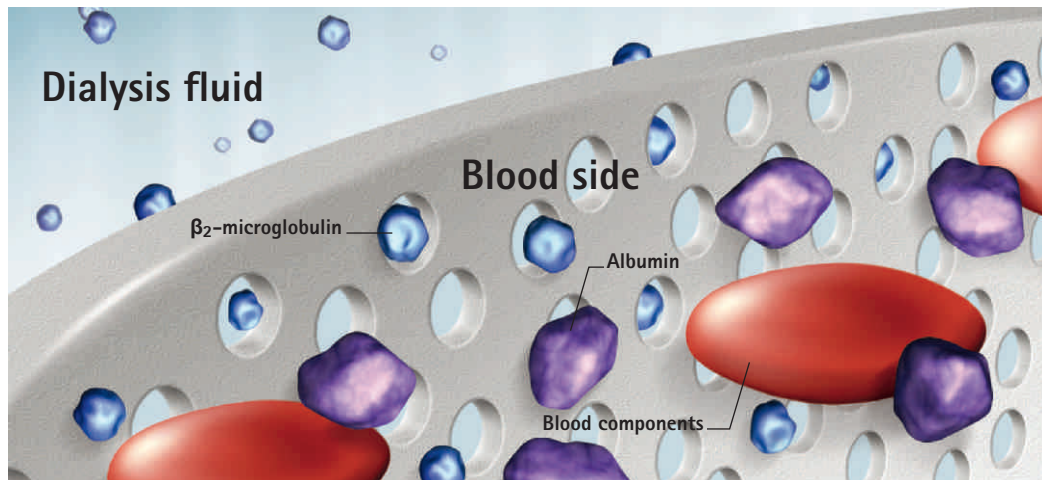
We place the greatest emphasis on making sure that our dialysers are not just technologically pioneering and high-performing, but also satisfy the highest standards of quality when they are used for treatment. Safety and quality must come into play right from the complicated manufacturing process onwards, which is why all dialysers are produced at Saxonia Medical using the very latest manufacturing equipment.

Our process-based quality management guarantees an unfailing standard of quality which far exceeds normal requirements – something we are especially proud of. Even after our products have been dispatched, ensuring the maximum degree of safety for our customers is a matter of course: each dialyser and its individual components can be returned without restrictions.



From the raw material to the end product – absolute quality assurance guarantees maximum product safety and hazard-free use.

Small pores, great impact – high technology on the nanoscale



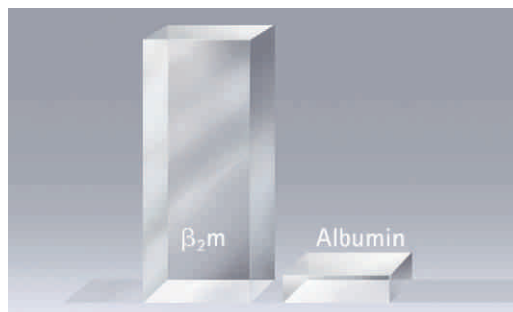
An excellent clearance range: middle molecules such as β_2 -microglobulin are eliminated as far as possible during the dialysis treatment, while important albumins in the bloodstream are retained.

The successful principle of the dialyser

What the kidneys do for healthy people, dialysers do for dialysis patients: they clean toxic substances out of the blood. Where is the challenge in this? Blood cannot be cleaned chemically, only physically: it is 'filtered' inside the dialyser with the help of a special membrane. For this purpose, the patient's blood is channelled through what are known as hollow fibres, whose walls consist of an ultra-thin membrane. Various physical processes allow important elements in the blood to be retained during this procedure, while, at the same time, harmful molecules are carried out into the dialysis fluid through pores in the membrane.

This is where the capability of the dialyser and its membrane is at its most evident: the more precisely the useful molecules are separated from the harmful ones, the more effective the treatment will be.

Based on the fibre component polysulphone, the innovative 'amembris' membrane developed by Ascalon has an optimised membrane structure and geometry which enhances the dialysis process even further. This high-tech membrane is used exclusively in the new xevonta premium dialyser generation, whose outstanding effectiveness has already been demonstrated in studies carried out across Europe.

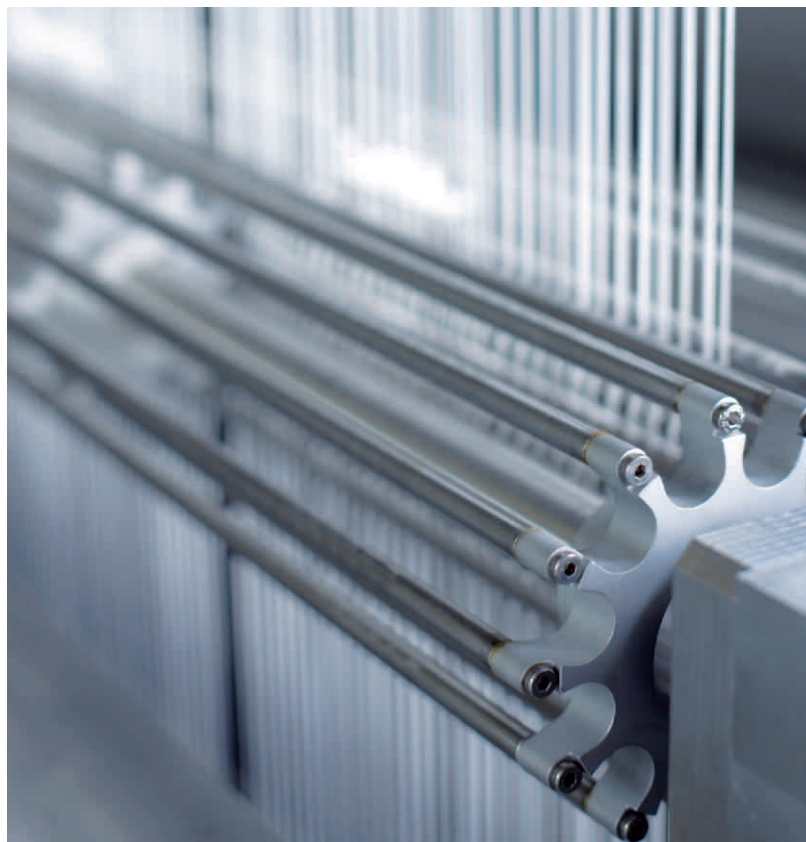


The excellent selectivity characteristic of amembris produces outstanding results for the elimination of β_2 -microglobulin and concomitantly offers an impressive retention of albumin.



The heart of the B. Braun dialyser:
its hollow-fibre membrane

The aim is perfection – the result of innovation and experience



High-performing products require the very latest production methods

The smallest pores in the hollow-fibre membrane of a B. Braun dialyser measure between just two and three millionths of a millimetre. Yet, although they are not even visible through a microscope, Saxonia Medical has successfully exploited the potential of this nanotechnology, using a state-of-the-art process chain, to produce highly effective products.

Inside the plastic housing of the dialyser, there is a bundle of hollow fibres through which the patient's blood is channelled during dialysis treatment. These hollow fibres are spun in a complicated procedure at the start of a dialyser's chain of production: this process sees two fibre components dissolved into a spinning solution.

One of these fibre components – polysulphone – forms the membrane material of the hollow fibres, while the other – PVP – acts as a pore-forming agent. By adding water during the spinning process, the polysulphone is hardened while the water-soluble PVP is partially washed out.

The real skill involved in this membrane formation process, which is crucial for the end product, lies in the formulation of the spinning solution and the management of the spinning process. One machine spins a total fibre length of around 45,000 kilometres every day – this is greater than the circumference of the earth and equates to 30 metres per minute.

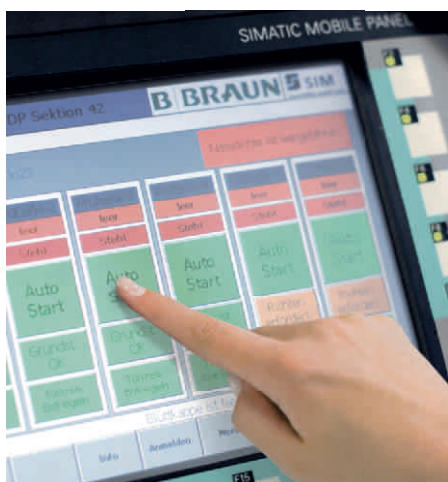


Once the hollow fibre has been spun, it is washed, dried and waved. This means that a straight fibre is formed into an undulated fibre by applying heat in a similar process to a permanent wave, in which smooth hair is transformed into long-lasting curls. The undulation of the fibres reduces the contact area between the fibres in the bundle, enabling the dialysis fluid to infiltrate the free space more quickly and thus remove the toxic substances extracted from the blood much more effectively. The undulation of the fibres also increases their surface area by making them longer – and this also increases the effectiveness of the dialysis treatment.

From l. to r.:
 Hardening the membrane fibres
 in the coagulation bath
 Undulating the membrane fibres
 Peeling the covering film off the fibre bundle

The hollow fibres are then bundled together according to the size of the dialyser, which varies depending on the model, fed into the plastic housing and sealed at the ends of the housing.

The interior of the dialyser thus contains two separate spaces that are needed for use: inside the hollow fibres flows the blood, and outside them flows the dialysis fluid, separated from the fibre interior. A two-component system, consisting of resin and a hardening agent, is used as a sealing compound. The principle behind this is simple: the two liquid synthetic components are mixed, which triggers a chemical reaction that allows the fluid substance to harden. A centrifuge is used to seal the fibre bundles at both ends of the housing at the same time. The centrifuges achieve an acceleration force that is 70 times greater than gravitational acceleration.



The high degree of automation and continuous monitoring ensure consistent quality.



Sealing the fibre bundle in the centrifuge using reactive resin and a hardening agent



Highly sophisticated technology can make a difference to health

After all the components of the dialyser have been produced and assembled, the end product is sterilised, because our customers rely on B. Braun dialysers being completely free from pathogenic germs. B. Braun advocates the use of gamma rays – an established method that is used extensively today for sterilising a wide variety of medical and pharmaceutical products.

According to standards, a product can only be labelled as 'sterile' if a viable germ is detected in no more than one out of 1,000,000 sterilised products. This is a stringent requirement, which cannot be met purely by maintaining strict clean room conditions during the production process. The effectiveness of the sterilisation procedure is checked as part of the validation of the entire production process.

High-energy radiation using Cobalt 60 is generally characterised by deep penetration and low dose rates. This is what gives it the great advantage of being able to sterilise medical products in their final packaging. Sterilisation with gamma rays is therefore a highly reliable form of sterilisation. Aside from its reliability, there are other arguments in favour of this process. Gamma rays do not leave behind any residue, nor are they high enough in energy to generate radio-activity – so this protects both the product and the environment.

The technology and production processes behind the development of B. Braun dialysers may be very extensive, but so too are the benefits, which help to reduce the suffering of dialysis patients all over the world. At Saxonia Medical, we are extremely proud of the fact that, with each individual dialyser, we make a significant contribution to improving the quality of life for these people.






Performance and diversity – B. Braun products from Saxonia Medical and Ascalon








Diversity for the best possible treatment quality

Customers all over the world appreciate the versatility of the B. Braun range of dialysers and have confidence in their effectiveness.

The latest premium dialyser is xevonta, with excellent performance that has been demonstrated in studies carried out across Europe.

High flux dialysers	Product name	Surface area (m²)	UF-coefficient (ml/h/mmHg)	Indication		
				HD	HDF	HF
	xevonta Hi 10	1.0	58	■	■	■
	Hi 12	1.2	69	■	■	■
	Hi 15	1.5	87	■	■	■
	Hi 18	1.8	99	■	■	■
	Hi 20	2.0	111	■	■	■
	Hi 23	2.3	124	■	■	■
	Hi PS 10	1.0	34	■	■	
	HI PS 12	1.2	42	■	■	
	HI PS 15	1.5	50	■	■	■
	HI PS 18	1.8	55	■	■	■
	HI PS 20	2.0	58	■	■	■
	HiFlo 18	1.8	78	■	■	
	HiFlo 23	2.3	92	■	■	

Low flux dialysers	Product name	Surface area (m ²)	UF-coefficient (ml/h/mmHg)	Indication		
				HD	HDF	HF
	Lo 10	1.0	8	■		
	Lo 12	1.2	9	■		
	Lo 15	1.5	10	■		
	Lo 18	1.8	12	■		
	Lo 20	2.0	14	■		
	Lo 23	2.3	15	■		
	LO PS 10	1.0	6.8	■		
	LO PS 12	1.2	7.9	■		
	LO PS 15	1.5	9.8	■		
	LO PS 18	1.8	12.3	■		
	LO PS 20	2.0	13.7	■		
Dialysis fluid filter and online filter	Product name	Surface area (m ²)	UF-coefficient (ml/h/mmHg)	Indication		
	Diacap Ultra	1.2	270	Dialysis fluid filter and online filter		
Haemofilter	Product name	Surface area (m ²)	UF-coefficient (ml/h/mmHg)	Indication		
	S	1.0	–	Haemofilter for acute renal replacement therapy		
	M	1.5	–			
	L	2.0	–			
Plasmafilter	Product name	Surface area (m ²)	UF-coefficient (ml/h/mmHg)	Indication		
	M	0.3	–	Apheresis		
	L	0.5	–			

Saxonia Medical and Ascalon – ideas are the staple of our innovations



It is our premises that make us proud,
it is our people who bring them to life,
it is our innovations that inspire our customers all over the world
and help them to give patients a better quality of life.
And we are resolved to do our best in the future as well.

**Saxonia Medical and Ascalon –
a successful partnership within the B. Braun Group**

