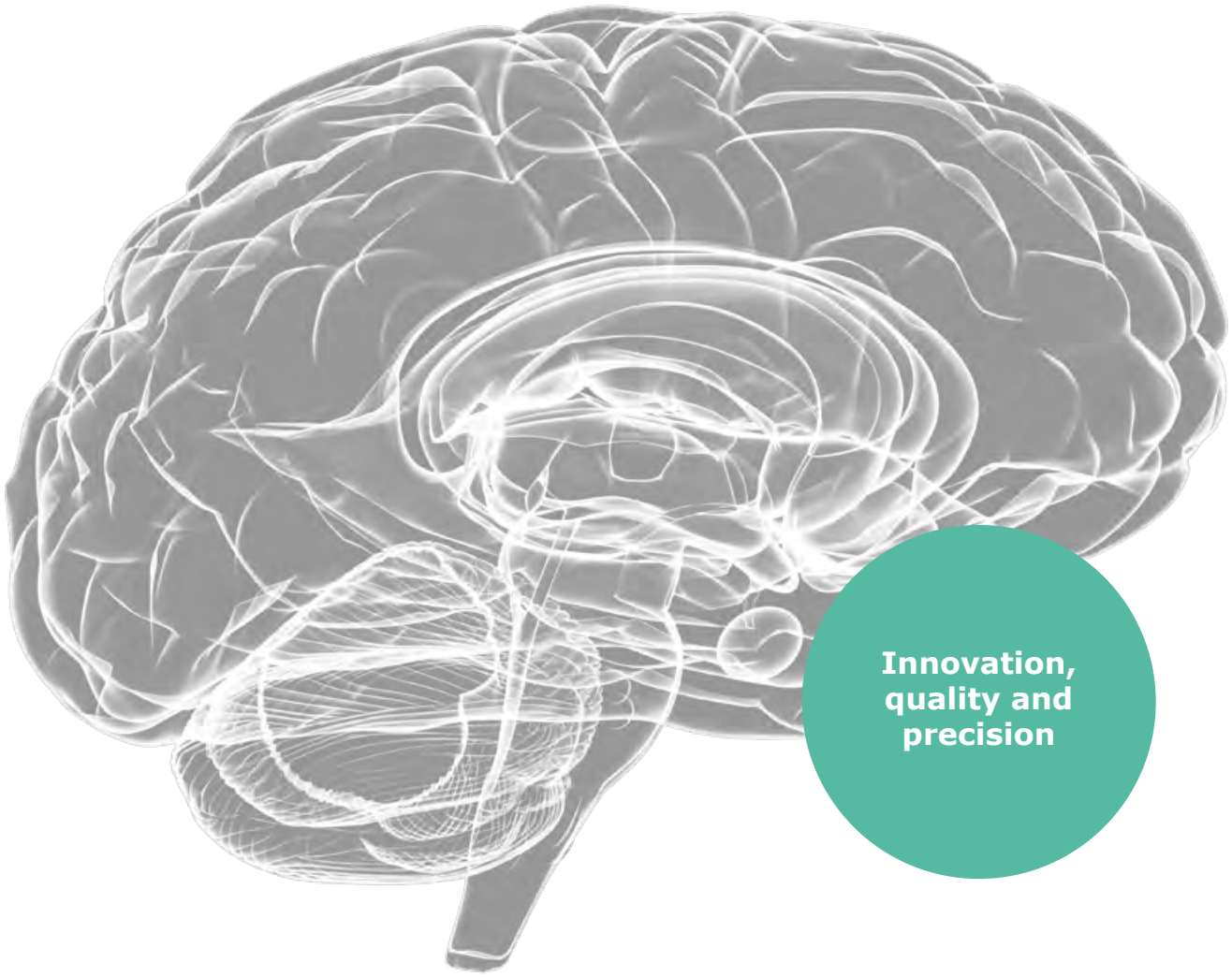
Spiegelberg:
Technology for brains

Cutting-edge development and manufacturing excellence - made in Germany

ICP- and CSF-Products



Innovation, quality and precision

Table of contents

Editorial

Stefan Paschko
Spiegelberg Managing Director

Dear customers

Spiegelberg was established in 1986 in Hamburg and today supports customers in more than 40 countries worldwide, where medical services rely on our **innovative neurosurgical devices** and the **quality of our research and manufacturing – Made in Germany.**

Spiegelberg‘s understanding of „Technology for brains“? Genuine pioneering work. Our mission is to simplify your day-to-day medical work with our enthusiasm for innovation and our passion for medical technology.

Our close **cooperation with well-known research institutions and leading hospitals and specialists in the field of neurosurgery** enables us to supply high-quality medical devices that are designed precisely to meet the demanding requirements of your everyday medical work.

The quality assurance of all our developments, our services and our marketing of intracranial pressure measuring devices, cerebrospinal fluid management devices and additives is based on our **DIN EN ISO 13485 certificate!**

Have a look at this brochure for an overview of our high-quality products, such as ICP-Monitors, ICP-Probes, Catheters and EVD-Kits as well as IAP-Catheters.

With kind regards,

Stefan Paschko
Spiegelberg Managing Director

ICP-Monitors to measure intracranial pressure

All Spiegelberg ICP-Monitors feature a convenient plug-and-play function. After inserting the air-pouch probe, the probe is simply connected to the monitor and starts to calibrate automatically[1] once the monitor is switched on. The latest ICP-Monitors from Spiegelberg have rechargeable batteries with a running time of up to six hours. All ICP-Monitors are compatible with most standard patient monitors.

Accurate measurement results and data analysis

Spiegelberg's ICP-Monitors provide accurate measurement results thanks to regular, automatic re-calibration[1]. In one clinical study[2], for example, a maximum drift of only +/- 2 mmHg over a period of up to 28 days could be confirmed. A digital interface allows measured values to be transferred to a PC for data analysis. The optionally available ICP-Lab software can be used for this purpose[3].

Advantages of the Spiegelberg ICP-Monitors: HDM 29.2

- Plug-and-Play Function
- Continuous measurement
- Automatic hourly re-calibration[1]
- Compatible with all standard patient monitors

[1] Integrated monitor null adjustment; no metrological calibration.
[2] Reference: Clinical Evaluation of the Intraparenchymal Spiegelberg Pressure Sensor, Congress of Neurological Surgeons, June 2003.
[3] The ICP-Lab software is not a medical device and is not approved for diagnostic purposes.

ICP-Monitor HDM 29.2

The Spiegelberg Intracranial Pressure (ICP) Monitor is used to monitor ventricular, parenchymal and epidural pressures. The ICP-Monitor can also be used in conjunction with Spiegelberg's IAP-Catheter to monitor intra-abdominal pressure.

The air-pouch system consists of a hollow synthetic core and a tube filled with < 0.15 ml of air. The pressure sensor is integrated within the ICP-Monitor alongside the measuring electronics and a provision for filling the air-pouch system.

The ICP-Monitor HDM 29.2 is fitted with a rechargeable battery and can be operated autonomously off-the-grid for up to six hours.

Note

Spiegelberg also supplies the appropriate interconnecting cables for connecting to standard patient monitors. Feel free to contact us for any further information.

Technical data for ICP-Monitors

Name	ICP-Monitor HDM 29.2
Ordering Information	HDM 29.2
Technical information	
Measurement range	0 to +100 mmHg
Operating voltage	115–230 V ~, 50/60 Hz
Display indicator	mean ICP value systolic ICP diastolic ICP mains power indicator battery charge indicator
Battery operating time	up to 6 hours
Connectivity options	Digital output Patient monitor output
Re-calibration	✓
Weight (approx.)	1.5 kg

Name	ICP-Monitor HDM 29.1	ICP-Monitor HDM 26.1
Ordering Information	HDM 29.1	HDM 26.1/FV500 (230 V) HDM 26.1/FV503 (115 V)
Technical information		
Measurement range	0 to +100 mmHg	0 to +100 mmHg
Operating voltage	230 V ~, 50/60 Hz 115 V ~, 50/60 Hz	230 V ~, 50/60 Hz 115 V ~, 50/60 Hz
Display indicator	mean ICP value systolic ICP diastolic ICP mains power indicator battery charge indicator	mean ICP value systolic ICP diastolic ICP mains power indicator battery charge indicator
Battery operating time	up to 3 hours	/
Connectivity options	Digital output Patient monitor output	Digital output Patient monitor output
Re-calibration	✓	✓
Weight (approx.)	3.4 kg	3.3 kg

To measure intracranial pressure

All Spiegelberg Ventricular Probes feature 2 distinct functionalities in one single product: measurement of ICP and drainage function. Since the technology is integrated in the monitor and not in the probe, ICP-Probes are particularly robust. All ICP-Probes can also be used directly, as they do not require a null adjustment. Spiegelberg ICP-Probes are available as tunnel or bolt versions and are MR-compatible for 1.5 and 3 Tesla under certain conditions.

Patented Silverline® technology

All Spiegelberg Silverline® probes incorporate a silver additive intended to reduce the possibility that the surface of the device becomes microbial compromised. This invention was awarded the innovation prize by the senate of the Free and Hanseatic City of Hamburg.

All Spiegelberg probes feature a unique silver coating

Tunnelling Silverline® Ventricular Probe

The Spiegelberg tunnelling Silverline® Ventricular Probe is supplied with a trocar with a connecting thread-link tip and is designed to tunnel past the burr hole with surgical precision. To facilitate tunnelling the probe's air tube integrates a slimline connector. The air line and the drainage tube are held together by a trocar with a connecting thread-link tip.

2 distinct functionalities in one single product

Technical data

Name	Probe 14	Probe 15
Ordering Information	SND13.1.14	SND13.1.15
Technical information		
External diameter	8 F / 2.7 mm	10 F / 3.3 mm
Internal diameter	1.5 mm	1.9 mm
Length of drainage tube	270 mm	270 mm
Implantable length	200 mm	200 mm
Overall probe length	1500 mm	1500 mm
Length of tube extension	1200 mm	1200 mm
Diameter of drainage opening	1.3 mm	1.8 mm
Number of openings	12	12
Depth markings	50–100 mm, 150 mm	50–100 mm, 150 mm
Fill volume	< 0.15 ml	< 0.15 ml
Material	silver coated, radiopaque polyurethane	
Duration of application	short-term, not more than 30 days	short-term, not more than 30 days

Silverline® Ventricular Probe with Cranial Bolt

The Spiegelberg Silverline® Ventricular Probe incorporating a cranial bolt is fixed to the calvaria to the cranial bolt. After drilling a hole and opening the dura, the probe is inserted into the ventricle with the cranial bolt drawn back. The bolt is then slid over the probe and screwed into the calvaria. The Silverline® Ventricular Probe can then be secured with the bolt lock nut. The drainage tube is connected to the provided Luer lock connector and attached to a drainage assembly. The air tube is connected to the Spiegelberg ICP-Monitor using the extension.

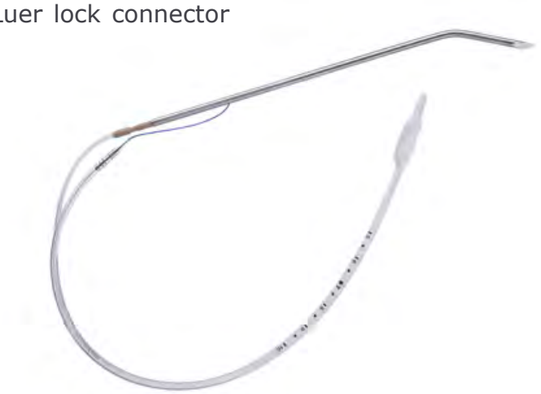
2 distinct functionalities in one single product

Technical data

Name	Probe 14S
Ordering Information	SND13.1.14S
Technical information	
External diameter	8 F / 2.7 mm
Internal diameter	1.5 mm
Length of drainage tube	270 mm
Implantable length	70 mm
Overall probe length	1500 mm
Diameter of drainage opening	1.3 mm
Number of openings	12
Depth markings	50–60–70 mm
Fill volume	< 0.15 ml
Material	silver coated, radiopaque polyurethane
Duration of application	short-term, not more than 30 days

True Tunnelling Intraventricular Probe

The True Tunnelling Intraventricular Probe from Spiegelberg is an intracranial pressure-measuring probe, with a trocar featuring a connecting thread-link tip and is designed to tunnel past the burr hole with surgical precision. The air tube of the probe is fitted with a connector to enable tunnelling. The latter is connected to a drainage tube with a trocar equipped with a connecting thread-link tip. The trocar is removed after tunnelling. The air tube is connected to the Spiegelberg ICP-Monitor via the extension. The drainage tube is connected to the Luer lock connector and attached to a drainage assembly.



Technical data

Name	True Tunneling Intraventricular Probe 7F	True Tunneling Intraventricular Probe 9F
Ordering Information	SND13.1.13TT	SND13.1.13XLTT
Technical information		
External diameter	7 F / 2.3 mm	9 F / 3.0 mm
Internal diameter	1.0 mm	1.6 mm
Length of drainage tube	270 mm	270 mm
Implantable length	200 mm	200 mm
Overall probe length	1500 mm	1500 mm
Length of extension tube	1200 mm	1200 mm
Diameter of drainage opening	1.0 mm	1.6 mm
Number of openings	4	4
Depth markings	50–100 mm, 150 mm	50–100 mm, 150 mm
Fill volume	< 0.15 ml	< 0.15 ml
Material	Polyurethane	Polyurethane
Duration of application	short-term, not more than 30 days	short-term, not more than 30 days

Ventricular Probe

The Spiegelberg Ventricular Probe measures the intraventricular pressure using an air-pouch mounted on the distal end of the dual lumen probe. One lumen transmits pressure to the ICP-Monitor, and the other is used for draining cerebrospinal fluid (CSF).

2 distinct functionalities in one single product

Technical data

Name	Probe 3	Probe 3XL
Ordering Information	SND13.1.13/FV532P	SND13.1.13XL/FV533P
Technical information		
External diameter	7 F / 2.3 mm	9 F / 3.0 mm
Internal diameter	1.0 mm	1.6 mm
Length of drainage tube	270 mm	270 mm
Implantable length	130 mm	130 mm
Overall probe length	1500 mm	1500 mm
Diameter of drainage opening	1.0 mm	1.6 mm
Number of openings	4	4
Depth markings	50–100 mm	50–100 mm
Fill volume	< 0.15 ml	< 0.15 ml
Material	Polyurethane	Polyurethane
Duration of application	short-term, not more than 30 days	short-term, not more than 30 days

Tunnelling Parenchymal Probe

The Spiegelberg Tunnelling Parenchymal Probe is a probe with a trocar designed to measure parenchymal intracranial pressure. The probe is inserted into the parenchyma through a burr hole and is used to tunnel past the burr hole with surgical precision. The air tube is fitted with a connector that attaches to the trocar in order to facilitate tunnelling. The trocar is removed after tunnelling and the air tube is connected to the Spiegelberg ICP-Monitor using the extension.The tunnelling parenchymal probe is fixed to the skin with a suturing flap.

Parenchymal Probe

The Spiegelberg Parenchymal Probe is used to measure parenchymal intracranial pressure. The probe is inserted into the parenchyma through a burr hole. The Spiegelberg Parenchymal Probe is fixed to the skin with a suturing flap.

Technical data

Name	3PN Probe with Trocar	Probe 3PN
Ordering Information	SND13.1.54	SND13.1.53/FV534P
Technical information		
External diameter	4 F / 1.3 mm	4 F / 1.3 mm
Implantable length	160 mm	120 mm
Overall probe length	1500 mm	1500 mm
Length of extension tube	1300 mm	/
Fill volume	< 0.15 ml	< 0.15 ml
Material	Polyurethane	Polyurethane
Duration of application	short-term, not more than 30 days	short-term, not more than 30 days

Parenchymal Probe with Cranial Bolt (Probe 3PS)

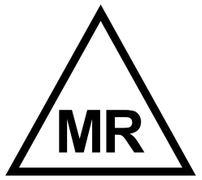
The Spiegelberg Parenchymal Probe with Cranial Bolt measures the parenchymal intracranial pressure. The probe is fixed in the parenchyma with a bolt that is screwed into the calvaria.

Epidural Probe (Probe 2)

The Spiegelberg Epidural Probe is used postoperatively after larger trepanations. The probe is positioned directly under the bone flap. After mobilisation of a sufficiently large area of the dura, the Spiegelberg Epidural Probe can be inserted through the burr hole between the dura and the cranial bone.

Technical data

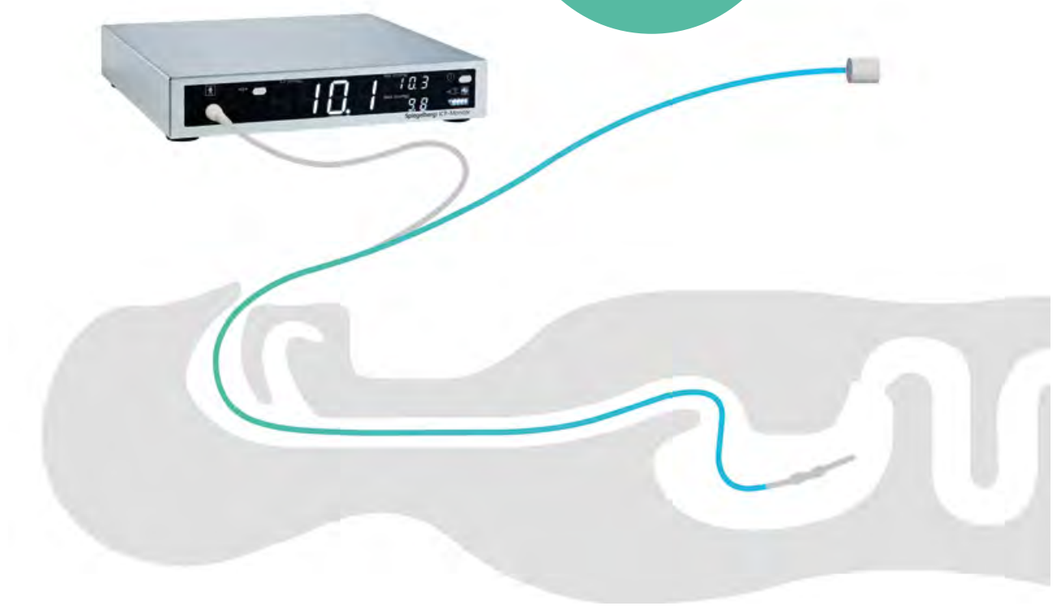
Name	Probe 3PS	Probe 2
Ordering Information	SND13.1.63/FV535P	SND13.1.12/FV531P
Technical information		
External diameter	4 F / 1.3 mm	2.0 mm
Implantable length	40 mm	200 mm
Overall probe length	1500 mm	1500 mm
Air-pouch width	/	11 mm
Air-pouch length	/	25 mm
Fill volume	< 0.15 ml	< 0.15 ml
Material	Polyurethane	Polyurethane
Duration of application	short-term, not more than 30 days	short-term, not more than 30 days



MR Safety Information

Non-clinical tests have shown that Spiegelberg probes at 1.5 T and 3 T are conditionally MR-compatible (MR Conditional). Patients fitted with these products can be safely scanned in an MR system as long as the MR safety instructions included with the product are observed.

Only available at Spiegelberg!



For measuring intra-abdominal pressure

The Spiegelberg IAP-Catheter continuously measures intra-abdominal pressure through the air pouch located at the tip of the catheter and is compatible with all Spiegelberg ICP-Monitors.

When using the Spiegelberg IAP measuring system, the catheter is inserted into the gastric cavity through the patient's nose or mouth like a gastric tube.

Measurements are taken by the patented Spiegelberg air pouch system. The intra-abdominal pressure is transmitted through the thin wall of the Spiegelberg air pouch system into the IAP-Catheter and to the connected ICP-Monitor, where the pressure transducer converts the information into an electrical signal.

A mean pressure level is displayed on the Spiegelberg Monitor. The pressure sensor self-calibrates hourly and adjusts the null value. The catheter has two lumens: one lumen, which contains the air pouch and is connected to the monitor, and the second lumen, which contains a spiral guide wire for determining the position by auscultation after removal of the wire or, if necessary, for drainage.

Advantages of the Spiegelberg IAP-Monitors

- Continuous IAP measurement - any changes are detected as soon as they occur
- Integrated null adjustment
- Applicable for up to 30 days
- Conditionally MR-compatible

Technical data

Name	IAP-Catheter
Ordering Information	SND32.1.11
Technical information	
External diameter	10 F / 3.3 mm
Internal diameter	1.6 mm
Length of drainage tube	800 mm
Implantable length	650 mm
Overall probe length	2000 mm
Diameter of drainage opening	2 mm
Number of openings	4
Fill volume	< 0.15 ml
Material	Polyurethane
Duration of application	short-term, not more than 30 days

Catheters reference list

		Length	External diameter			
			1.6 mm	2.0 mm (6 F)	2.7 mm (8 F)	3.3 mm (10 F)
EVD	**Standard-Polyurethane**					
	Ventricular Catheter	270 mm			EVD30.010.01	EVD30.030.01
	Ventricular Probe with Cranial Bolt	270 mm			EVD30.014.01	EVD30.034.01
	Silver coated polyurethane					
	Ventricular Catheter	270 mm		EVD30.020.02	EVD30.010.02	EVD30.030.02
	Ventricular Probe with Cranial Bolt	270 mm			EVD30.014.02	EVD30.034.02
ESD	Subdural Drainage Catheter	270 mm			EVD30.015.02	EVD30.035.02
ELD	Lumbar Drainage Catheter	800 mm	ELD33.010.02			

Silverline® Ventricular Drainage Catheter

The Spiegelber Silverline® Ventricular Drainage Catheter is used for draining CSF to reduce elevated intracranial pressure. Indications may include sub arachnoid haemorrhage, traumatic brain injury and acute hydrocephalus. The Silverline® Ventricular Drainage Catheter is manufactured from radiopaque polyurethane. It compromises a closed round tip with labelled depth graduations. All Silverline® Ventricular Drainage Catheters incorporate a silver additive intended to reduce the possibility that the surface of the device becomes microbial compromised. It is supplied with a mandrin, a trocar, a Luer lock connector, a slotted suture attachment and a sealing cap.

Awarded the innovation prize

Technical data

Name	Silverline® Ventricular Drainage Catheter		
Ordering Information	EVD30.020.02	EVD30.010.02	EVD30.030.02
Technical information			
Length	270 mm	270 mm	270 mm
External diameter	6 F / 2.0 mm	8 F / 2.7 mm	10 F / 3.3 mm
Internal diameter	1.0 mm	1.5 mm	1.9 mm
Diameter of drainage opening	0.9 mm	1.2 mm	1.7 mm
Number of openings	16	16	16
Depth markings	50–100 mm, 150 mm, 200 mm		
Material	silver coated, radiopaque polyurethane		
Duration of application	short-term, up to 30 days	short-term, up to 30 days	short-term, up to 30 days

Silverline® Ventricular Drainage Catheter with Cranial bolt

The Ventricular Drainage Catheter is fixed to the calvaria with a cranial bolt. After drilling a hole and opening the dura, the catheter is inserted into the ventricle. The bolt is then slid over the catheter and screwed into the calvaria. The catheter is then secured with the blot lock nut. All Silverline® Ventricular Drainage Catheters incorporate a silver additive intended to reduce the possibility that the surface of the device becomes microbial compromised.

Technical data

Name	Silverline® Ventricular Probe with Cranial Bolt	
Ordering Information	EVD30.014.02	EVD30.034.02
Technical information		
Length	270 mm	270 mm
External diameter	8 F / 2.7 mm	10 F / 3.3 mm
Internal diameter	1.5 mm	1.9 mm
Diameter of drainage opening	1.2 mm	1.7 mm
Number of openings	16	16
Depth markings*	50–70 mm	50–70 mm
Material	silver coated, radiopaque polyurethane	
Duration of application	short-term, not more than 30 days	short-term, not more than 30 days

* Two depth markings; the proximal mark denotes the orientation of the bolt. The 70-mm mark on the bolt corresponds to the actual brain depth.

Silverline® Subdural Drainage Catheter

The Silverline® Subdural Drainage Catheter is specifically indicated for drainage following evacuation of chronic subdural haematomas (CSH) and includes a 6 cm long perforation zone near the tip. It is supplied with a mandrin, a trocar, a Luer lock connector and a slotted suture attachment.

Technical data

Name	Silverline® Subdural Drainage Catheter	
Ordering Information	EVD30.015.02	EVD30.035.02
Technical information		
Length	270 mm	270 mm
External diameter	8 F / 2.7 mm	10 F / 3.3 mm
Internal diameter	1.5 mm	1.9 mm
Diameter of drainage opening	1.2 mm	1.7 mm
Number of openings	48	48
Depth markings	70–100 mm, 150 mm, 200 mm	70–100 mm, 150 mm, 200 mm
Material	silver coated, radiopaque polyurethane	
Duration of application	short-term, not more than 30 days	short-term, not more than 30 days

Ventricular Drainage Catheter

The Spiegelber Silverline® Ventricular Drainage Catheter is used for draining CSF to reduce elevated intracranial pressure – for example in the case of subarachnoid haemorrhage, traumatic brain injury and acute hydrocephalus. The Spiegelberg Ventricular Drainage Catheter is manufactured from radiopaque polyurethane. It features a closed round tip and the tube is graduated. It is supplied with a mandrin, a trocar, a Luer lock connector and a slotted suture attachment.

Technical data

Name	Ventricular Drainage Catheter	
Ordering Information	EVD30.010.01	EVD30.030.01
Technical information		
Length	270 mm	270 mm
External diameter	8 F / 2.7 mm	10 F / 3.3 mm
Internal diameter	1.5 mm	1.9 mm
Diameter of drainage opening	1.2 mm	1.7 mm
Number of openings	16	16
Depth markings	50–100 mm, 150 mm, 200 mm	50–100 mm, 150 mm, 200 mm
Material	radiopaque polyurethane	radiopaque polyurethane
Duration of application	short-term, not more than 30 days	short-term, not more than 30 days

External Silverline® Lumbar Drainage Catheter

The External Silverline® Lumbar Drainage Catheter is used to drain CSF during a therapy. External lumbar drainage is used to treat cerebrospinal fluid fistulas for the invasive diagnosis of normal pressure hydrocephalus (NPH). The Silverline® Lumbar Drainage Catheter incorporate a silver additive intended to reduce the possibility that the surface of the device becomes microbial compromised. It is supplied with a Tuohy needle, a Luer lock connector and a slotted suture attachment as well as other accessories.

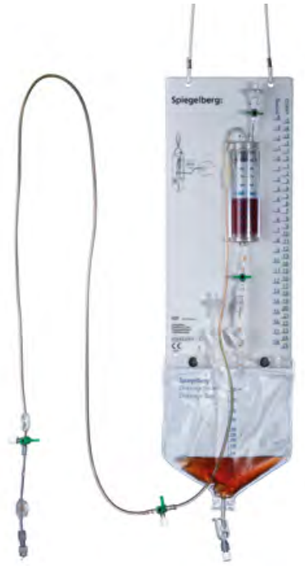
Technical data

Name	External Silverline® Lumbar Drainage Catheter
Ordering Information	ELD33.010.02
Technical information	
Length	800 mm
External diameter	1.6 mm
Internal diameter	0.8 mm
Diameter of drainage opening	0.7 mm
Number of openings	20
Depth markings	50–295 mm
Material	silver coated, radiopaque polyurethane
Duration of application	short-term, not more than 30 days

External Ventricular Drainage Kit

The Spiegelberg External Ventricular Drainage Kit is used to drain and collect cerebrospinal fluid during external ventricular drainage. The kit contains a Luer lock connector to attach a ventricular catheter, a probe with drainage function, as well as a drip chamber and a replaceable collection bag. The tube connection includes an injection port.

The system also comprises two four-way valves for connecting proximal and distal pressure transducers, as well as a pump chamber and a non-return valve. The drip chamber is vented through a replaceable filter. With the exception of the filter and the collection bag, all tube connections are permanently bonded.



External Ventricular Drainage Kit with Plate and Clamp

The Spiegelberg External Ventricular Drainage Kit with Plate and Clamp is used for the drainage and collection of cerebrospinal fluid during external ventricular drainage. The kit contains a Luer lock connector to attach a ventricular catheter, a probe with drainage function, as well as a drip chamber and a replaceable collection bag. The tube connection includes an injection port. The Spielgelberg EVD-Kit also comprises two three-way valves for connecting proximal and distal pressure transducers, as well as a pump chamber and a non-return valve. The drip chamber is vented through a replaceable filter.

The drip chamber is mounted on a plate with mmHg and cmH_2O graduations, which facilitates positioning of the patient to localise the foramen Monroi. With the exception of the filter and the collection bag, all tube connections are permanently bonded.

Technical data

Name	External Ventricular Drainage Kit	External Ventricular Drainage Kit with Plate and Clamp
Ordering Information	EVD30.001.01/FV800	EVD30.004.01
Technical information		
Length	1900 mm	1900 mm
Drip chamber volume	100 ml	100 ml
Drainage bag volume	700 ml	700 ml
Duration of application	short-term, up to 30 days	short-term, up to 30 days

Accessories for the External Ventricular Drainage Kit

Replacement collection bags and filters are available for both Spiegelberg External Ventricle Drainage Sets.

Name	Bag for the External Ventricular Drainage Kit	Filter for the External Ventricular Drainage Kit
Ordering Information	EVD30.101.02	EVD30.102.01/FV803

Spiegelberg
Technology for brains

Manufacturer

Spiegelberg GmbH & Co. KG
Tempowerkring 4
21079 Hamburg
Germany

Phone: +49 40 790178-0
Fax: +49 40 790178-10

info@spiegelberg.de
www.spiegelberg.de

DIN EN ISO 13485 certified