Spiegelberg:
Technology for brains

Silverline® ventricular probe with cranial bolt **SND13.1.14S**

Instructions for use

Content

Symbols used

REF	Item number		Do not use if packaging is damaged.
SN	Serial number		Upper temperature limit
STERILE EO	Sterilised with ethylene oxide		Caution!
	Do not reuse		Observe instructions for use
	Store in a dry place		Use by
	Keep away from sunlight		Date of manufacture
CE 0297	Product complies with the requirements of European Directive 93/42/EEC		Manufacturer
	Information note		MR conditional
M	HDM connector marking stands for monitor connection		

General information

The instructions for use must be read carefully before use. The product may only be used in accordance with the intended purpose. The manufacturer accepts no liability or warranty for damages caused by improper use or failure to observe the instructions for use.

The product may only be used if the sterile packaging is intact prior to first opening. The product must be transported and stored in a dry place. The following temperatures must be maintained in order to avoid influencing the product properties:

- Transport temperature: up to +50 °C
- Storage temperature: Room temperature
- Ambient temperature for application: Room temperature up to +50 °C

The product is intended for single use only and may not be reused. Reprocessing can lead to the destruction of the product or changes in the product properties. Safe use is therefore no longer guaranteed.
The product must not be cleaned. Only the tube may be moistened with isotonic NaCl solution.

The numbers in brackets refer to the illustration of the product in these instructions for use. The term “distal” means far from the patient and the term “proximal” means close to the patient.

Technical data

The stated values reflect nominal values and may differ.

REF / Order number	SND13.1.14S
Outer diameter	2.7 mm (8F)
Drainage lumen inner diameter	1.5 mm
Drainage tube total length	270 mm
Implantable length	70 mm
Probe total length	1500 mm
Drainage opening diameter	1.3 mm
Number of openings	12
Depth markings*	50-60-70 mm*
Filling volume	< 0.15 ml
Application duration	Short term up to 30 days
Material	Silver-impregnated radiopaque polyurethane

* The depth markings are printed twice. The proximal markings are used to align the ICP probe in the bolt. 70 mm alignment on the bolt means 70 mm actual depth in the brain.

Contents of the original packaging

1 ventricular probe
1 Luer lock connector with suture wing
1 cranial bolt
1 drill with depth marking (drilling diameter: 5.3 mm)
1 Allen wrench
1 dura opener
1 stylet
1 cap
1 instruction manual

Double packed
EO sterilised
For single use only

Approved accessories

HDM26.1	ICP monitor (230 V and 115 V)
HDM29.1	ICP monitor with battery (230 V and 115 V)
HDM29.2	ICP monitor
EVD30.001.01/FV800P	External ventricular drainage set (EVD set)
EVD30.004.01	External ventricular drainage set (EVD set) with plate and clamp
EVD30.106.01	External ventricular drainage bag

User group and environment

The ICP probe should only be positioned by a neurosurgeon. Further handling can be done by persons, who have completed medical training and have experience in dealing with neurological trauma (intensive care nurses).

The products are intended exclusively for use in professional healthcare facilities.

Indications and intended use

The ICP probe is used for the measurement of intracranial pressure (ICP) in adults with an air chamber (2) attached to the proximal tip of a double-lumen catheter and the drainage of cerebrospinal fluid (CSF). The air lumen (2) transmits the pressure to the ICP monitor. The drainage lumen (7) is used for the drainage of CSF.

The air chamber system is a hollow body made from plastic (2) which is connected to a pressure transducer via a tube (5) and a connector (6). The pressure transducer is located in the ICP monitor together with the measuring electronics and a device for filling the air chamber.

The ICP probe incorporate a silver additive intended to reduce the possibility that the surface of the device becomes microbially compromised.

ICP measurement and CSF drainage are indicated in the following clinical pictures, among others: severe craniocerebral trauma, subarachnoid haemorrhage, encephalopathy, hydrocephalus, intracranial haemorrhage as well as postoperative brain swelling. ICP probes are used to measure pressure when ICP must be continuously monitored and can be used for the drainage of CSF.

Contraindications

The ICP probe must not be used for purposes other than those specified. Components that have come into contact with infected tissue should not be used further.
Use is always contraindicated in cases of scalp infections, patients receiving anticoagulant therapy and increased bleeding tendency. It is also contraindicated when continuous monitoring by trained personnel cannot be guaranteed.

Warnings

⚠ Possible complications when using the ICP probe include dislocation, bleeding and infection.

⚠ Care and caution should be exercised when handling the ICP probe.

⚠ Do not pull on or jerk the ICP probe quickly! Quickly pulling on or jerking the probe can damage the tube.

⚠ Avoid kinks in the tube, as this will impair the measuring function and drainage.

⚠ The ICP probe must be checked for completeness prior to use. If the product is not complete, the ICP probe must not be used.

⚠ No sharp or pointed objects may be placed near the air chamber (2). These pose a risk of damage to the air chamber (2), resulting in leakage.

The air chamber (2) must be handled with care.

The air chamber (2) may only be moistened with isotonic saline solution.

The depth of the ICP probe can be checked using the marked scale (3) and the metal piece on the scale (4). The metal piece on the scale (4) is used to secure the ICP probe at a suitable depth with the cranial bolt (13+14).

The scale (3) is shown twice: the proximal scale (3) indicates the insertion depth from the cranial bone; the distal scale (3) is used to determine the depth after securing the cranial bolt (13+14).

The ICP probe must be protected from sunlight and kept away from sources of radiation. Radiation can lead to a deterioration in material properties and thus to the failure of the device functionality.

An open or damaged system must not be used further and must be replaced! Otherwise there is a risk of infection or loss of function.

Only ICP monitors from Spiegelberg may be used for ICP measurements.

The stylet (8) must not be inserted into an ICP probe which has already been positioned. This poses a risk of injury!

No liquids or drugs should be administered via the drainage lumen (7) on the ICP probe.

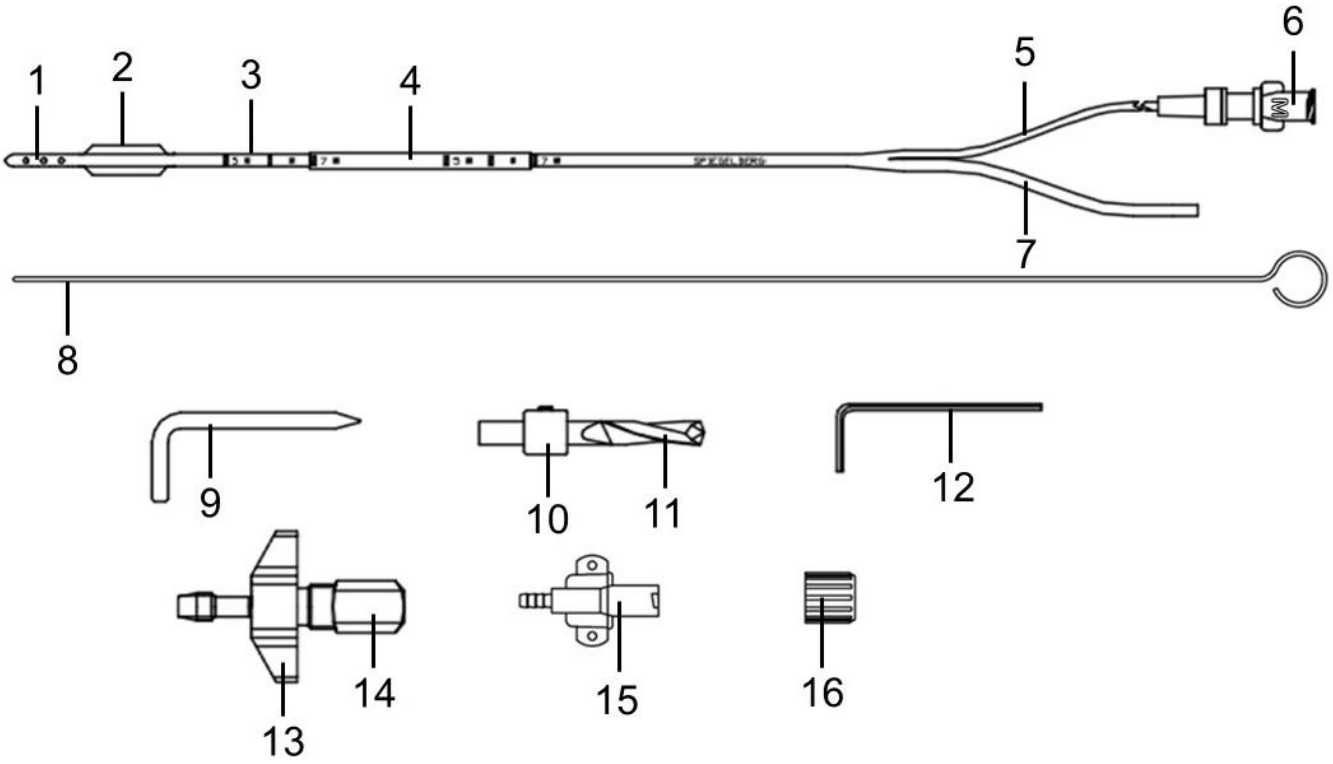
The HDM connector (6) must not be disinfected or moistened, otherwise the filter inside will clog.

Check the connections for leaks on a regular basis. Should there be a leaking connection, this poses a risk of contamination or overdrainage.

The procedure for using the ICP probe must be observed and followed in the correct order.

The position of the ventricles should be checked using imaging techniques prior to application.

Contaminated components and ICP probes must not be reused.



SND13.1.14S

MRI safety information

Non-clinical testing has shown that the “Intracranial Pressure and Catheter System” is “MR conditional”. A patient with this product can be safely scanned in an MRI system meeting the following conditions:

- static magnetic field of 1.5 - 3 Tesla with
- maximum spatial field gradient of 2,300 G/cm (23 T/m)
- maximum force product of 38,000,000 G^2/cm (38 T^2/m)
- theoretically estimated whole body averaged (WBA) specific absorption rate (SAR) < 2 W/kg (Normal Operating Mode).

Under the scanning conditions defined above, the “Intracranial Pressure and Catheter System” is expected to produce a maximum temperature rise of less than

- 2.8 °C (2 W/kg, 1.5 Tesla) with an ambient temperature increase of approximately 1.1 °C (2 W/kg, 1.5 Tesla)[1]
- 2.7 °C (2 W/kg, 3 Tesla) with an ambient temperature increase of approximately 0.8 °C (2 W/kg, 3 Tesla)[2]

after 15 minutes of continuous scanning.

[1] RF-related temperature increase for probe 3PS (REF: SND13.1.63/FV535P); worst case on behalf of the whole “Intracranial Pressure and Catheter System” under the aforementioned scanning conditions

[2] RF-related temperature increase for Silverline® ventricular drainage catheter with cranial bolt (REF: EVD30.014.02); worst case on behalf of the whole “Intracranial Pressure and Catheter System” under the aforementioned scanning conditions

In non-clinical tests, the image error generated by the product is around 70.9 mm for the product family worst case[3] when the image is generated using a gradient echo pulse sequence and a 3 Tesla MRI.

WARNINGS according to the MRI safety information

- Patient injuries can occur if the conditions for safe use in rooms designated as MRI environments are not observed.
- Never exceed a maximum whole body averaged (WBA) specific absorption rate (SAR) of 2 W/kg during MRI measurement (Normal Operating Mode).
- The ICP probe must be disconnected from the Spiegelberg ICP monitor before it is brought into rooms designated as MRI environments.
- Make sure that all components of the EVD set used with the ICP probe are “MR Safe” or “MR Conditional” at 1.5 or 3 Tesla.
- Do not bring probe accessories (stylet, 8, dura opener, 9, drill, 10+11, and Allen wrench, 12) into the MRI environment.
- Spiegelberg ICP monitors must never be brought into rooms marked as MRI environments.

Application & handling

Preparing the ICP probe

The ICP probe should be checked for completeness prior to use.
The insertion depth of the ICP probe should be determined using imaging techniques prior to insertion. Please note that the air chamber (2) must be completely inside the ventricle.

WARNING! There is a risk of tissue damage if the ICP probe is inserted too far. In addition, incorrect measured values may be obtained.

NOTE! If the printed image on the scale (3) is not clearly legible, another ICP probe must be used.

Preparation of the application area

NOTE! The appropriate insertion site and technique must be selected by the surgeon.

NOTE! The supplied drill (11) with depth marking (10) must be used to place the drill hole.

1. Perform aseptic preparation of the surgical area and put up surgical drapes.
2. Open up the scalp.
3. Remove the protective tube from the drill (11).
4. Loosen the depth marking (10) with the Allen wrench (12).
5. Adjust the depth marking (10) on the drill (11).
6. Tighten the depth marking (10) firmly with the Allen wrench (12) to prevent slipping.
7. Insert the drill (11) into a hand brace.
8. Place the drill hole.

[3] Determined using the Silverline® ventricular drainage catheter with cranial bolt (REF: EVD30.014.02); worst case on behalf of the whole “Intracranial Pressure and Catheter System”.

9. Clean the drill hole completely to remove any chips, splinters and bone fragments.
10. Remove the protective tube from the dura opener (9). Incise the dura using the dura opener (9).
11. Place the cap (16) on the plastic end of the Luer lock connector (15).

WARNING! Care should be taken during drilling and when opening the dura to avoid drilling too deep and damaging the dura.

WARNING! The stylet (8) may not be used to open the dura. This may cause damage to the tissue or to the stylet (8).

NOTE! If the drill hole is too small, it will not be possible to insert the cranial bolt (13+14) or insertion will not be possible without causing damage.

NOTE! If the drill hole is not cleaned completely to remove any chips, splinters and bone fragments, the air chamber (2) may be damaged when inserting the ICP probe.

Inserting the ICP probe

NOTE! The stylet (8) must be used for insertion of the ICP probe. Otherwise there is a risk of the tube kinking or rolling up.

NOTE! The stylet (8) may only be inserted into the drainage lumen (7), otherwise the filter on the HDM connector (6) will be damaged. This may result in incorrect measured values or the loss of function of the ICP probe.

NOTE! The air chamber (2) should be moistened with isotonic saline solution prior to use in order to reduce possible friction.

1. Loosen the clamping nut on the cranial bolt (14) by turning it counter clockwise until the clamping nut (14) is loose. Ensure that the clamping nut (14) is not removed entirely.
2. Insert the stylet (8) into the drainage lumen (7).
3. Push the ICP probe through the clamping nut on the cranial bolt (14) until the reinforcing tube (4) emerges completely from the bolt.
4. Position the ICP probe in the ventricle.
5. Check the correct positioning based on the flow of cerebrospinal fluid.
6. Insert the cranial bolt (13+14) into the drill hole by turning it clockwise. To do this, turn the bolt using the bolt wings (13).
7. Determine the correct depth using the printed scale (3).
8. Remove the stylet (8).
9. Tighten the clamping nut (14) by turning it clockwise until the probe is secure.
10. Push the distal end of the drainage lumen (7) over the entire length of the metal part of the Luer lock connector (15).
11. Secure the ICP probe onto the Luer lock connector (15) using the suture wing.

WARNING! In the event that the air chamber (2) or another component becomes partially or completely detached from the tube during use, the ICP probe must be replaced and the detached parts removed, e.g. to avoid a rejection reaction.

WARNING! The stylet (8) must not be inserted into an ICP probe which has already been positioned. This poses a risk of injury! If the stylet (8) is to be reinserted, the ICP probe must be pulled out and then reinserted.

NOTE! The ICP probe must be inserted at a minimum depth of 50 mm and a maximum depth of 70 mm. Otherwise, there is a risk that the lumens will be pinched when tightening the clamping nut (14).

Connection to an EVD set

1. Remove the cap (16) from the Luer lock connector (15).
2. Connect the Luer lock connector (15) to the connector on the EVD set.
3. Turn the Luer lock connector (15) until significant resistance can be felt and the connection is secure.
4. Perform a visual check for leaks and function.

NOTE! Mixing up the connectors (6, 15) on the ICP probe will result in a leaking connection with the EVD set.

NOTE! Visual checks of the connection to the EVD set must be carried out on a regular basis.

Connection to the ICP monitor

WARNING! The HDM connector (6) must not be disinfected or moistened, otherwise the filter inside the connector will clog.

WARNING! The HDM connector (6) must be kept dry. Otherwise the ICP probe may lose function or the ICP monitor may be damaged.

NOTE! If any liquid gets into the HDM connector (6), do not connect it to the ICP monitor.

1. Connect the HDM connector (6) on the ICP probe to the probe connector on the ICP monitor.
2. Turn the HDM connector (6) clockwise until significant resistance can be felt and the ICP probe is firmly connected to the ICP monitor.
3. Check the display on the ICP monitor and the values for plausibility.

NOTE! The monitor connection, HDM connector (6), is marked with an "M".

NOTE! Mixing up the connectors (6, 15) on the ICP probe will result in a leaking connection with the ICP monitor and may lead to damage to the ICP monitor.

NOTE! The function of the ICP probe can be confirmed by the pulsatile signal on the ICP monitor.

Checking the function of the ICP probe

1. Use the measured values and the flow of CSF to check the function of the ICP probe.
2. Check the plausibility of the measured values using the pulsatile signal or the amplitude between the systolic and diastolic measured value.

Drainage of CSF

CSF in the ventricle passes through the drainage holes (1) via the drainage lumen (7) into the EVD set. If there is no flow of CSF, the tube system must be checked for kinks or constriction.

NOTE! Kinks and constriction in the drainage lumen (7) must be avoided, as otherwise drainage will be restricted.

NOTE! Where there is no flow of CSF, this indicates a blockage, kink or constriction. In the event of a blockage, the ICP probe must be replaced.

Disconnecting the EVD set

1. Turn the Luer lock connector (15) counter clockwise.
2. Quickly cap the Luer lock connector (15) with the cap (16).

Replacing the EVD set

1. Disconnect the Luer lock connector (15) and the EVD set.
2. Quickly cap the Luer lock connector (15) with the cap (16).
3. Replace the EVD set according to the manufacturer’s instructions.
4. Remove the cap (16) from the Luer lock connector (15).
5. Connect the Luer lock connector (15) to the EVD set.

Closing the wound

After the proper function of the ICP probe has been confirmed, the wound on the scalp can be closed. The technique and material used for this are to be determined by the surgeon.

NOTE! When closing the wound, care must be taken not to damage the ICP probe.

Determining the position of the ICP probe

The position of the ICP probe can be checked using imaging techniques.

NOTE! The correct positioning of the ICP probe and the condition of the patient must be checked at regular intervals.

Removing the ICP probe

NOTE! Proceed slowly and carefully when removing the ICP probe. It must be ensured that no tissue is damaged and that the suture wing on the Luer lock connector (15) has been detached.

NOTE! The ICP probe must not be removed in a fast and jerky manner in order to avoid injuries and prevent blood, CSF and possibly tissue from being sprayed around.

NOTE! The ICP probe must not be pulled over sharp or uneven edges during removal to avoid damaging the tube (3) and thus tearing the ICP probe.

1. Disconnect the ICP probe from the ICP monitor and from the EVD set.
2. Loosen the fixings attaching the ICP probe to the patient.
3. Fully loosen the clamping nut on the cranial bolt (14).

4. Pull out the ICP probe.
5. Check that the ICP probe has been removed completely and that the tissue has not been damaged.
6. Remove the cranial bolt (13, 14).
7. Observe the condition of the patient.

NOTE! No components of the ICP probe (e.g. the air chamber, 2) may be left in the patient.

NOTE! If the cranial bolt (13, 14) cannot be loosened, it must not be loosened by force; instead, loosen the bolt by moving it back and forth gently.

Disposal

After use, the product should be disposed of in accordance with the regulations for infectious waste and/or in accordance with national or regional regulations.

Returns policy

Before returning a product, approval must be obtained from the customer service department. Returns will not be accepted unless the return has been approved in advance by Spiegelberg in the context of a complaint or a return has specifically been requested.

Contaminated/used products must be packaged in a bag for biological hazardous substances for return shipment.

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Subject to technical changes.

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