Spiegelberg

Technology for brains

Probe 3PS **SND13.1.63/FV535P**

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	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	SND13.1.63/FV535P
Outer diameter	1.3 mm (4 F)
Implantable length	40 mm
Probe total length	1500 mm
Filling volume	< 0.15 ml
Application duration	Short term up to 30 days
Material	Polyurethane

Contents of the original packaging

1 probe 3PS
1 cranial bolt
1 drill with depth mark (drilling diameter: 3.8 mm)
1 Allen wrench
1 dura opener
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

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 parenchymal measurement of intracranial pressure (ICP) in adults with an air chamber (1) attached to the proximal tip of a double-lumen catheter. The air lumen (1) transmits the pressure to the ICP monitor.

The air chamber system is a hollow body made of plastic (1) which is connected to a pressure transducer via a tube and a connector (3). The pressure transducer is located in the ICP monitor together with the measuring electronics and a device for filling the air chamber (1).

ICP measurement is 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.

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.


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 (1). These pose a risk of damage to the air chamber (1), resulting in leakage.


The air chamber (1) must be handled with care.


The air chamber (1) may only be moistened with isotonic saline solution.


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.

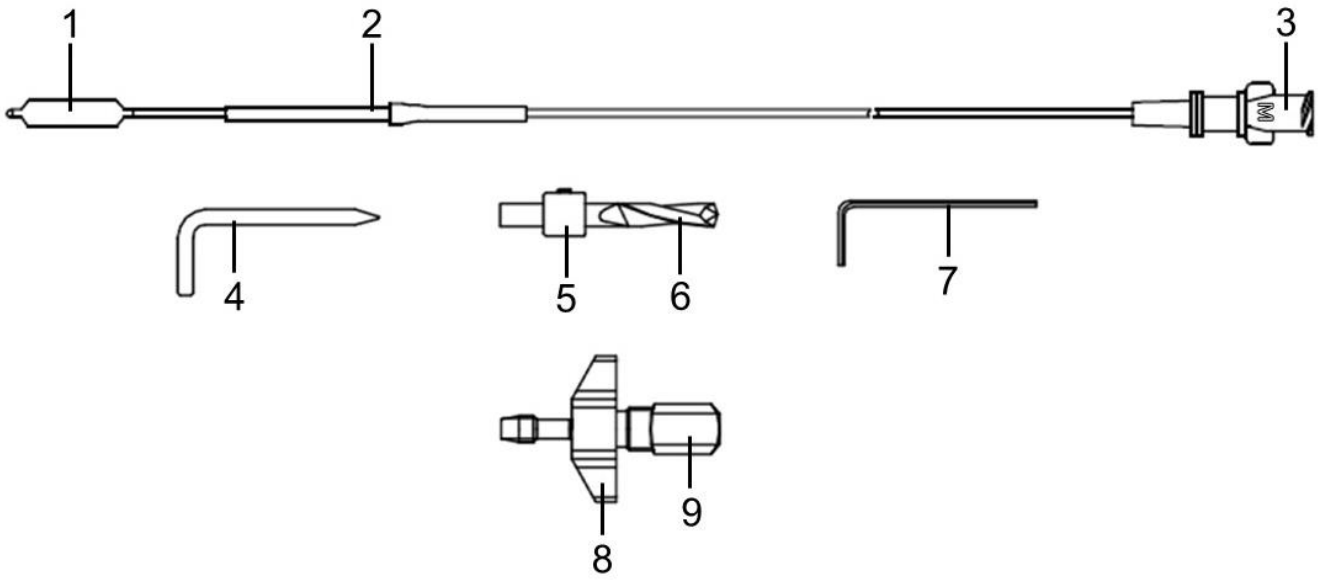

Only ICP monitors from Spiegelberg may be used for ICP measurements.


Contaminated components and ICP probes must not be reused.


It is essential that the supplied components are used as compatibility with the ICP probe is guaranteed.


The HDM connector (3) must not be disinfected or moistened, otherwise the filter inside will clog.


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



SND13.1.63/FV535P

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.

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.

[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

[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”.

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 (dura opener, 4, drill, 5+6, and Allen wrench, 7) 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.

Preparation of the application area

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

NOTE! The supplied drill (6) with depth mark (5) 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 (6).
4. Loosen the depth mark (5) with the Allen wrench (7).
5. Adjust the depth mark (5) on the drill (6).
6. Tighten the depth mark (5) firmly with the Allen wrench (7) to prevent slipping.
7. Insert the drill (6) into a hand brace.
8. Place the drill hole.
9. Clean the drill hole completely to remove any chips, splinters and bone fragments.

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

NOTE! If the drill hole is too small, it will not be possible to insert the cranial bolt (8+9) 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 (1) may be damaged when inserting the ICP probe.

Inserting the cranial bolt

1. Loosen the clamping nut on the cranial bolt (9) by turning it counter clockwise until the clamping nut (9) can be removed.
2. Insert the cranial bolt (8+9) into the drill hole by turning it clockwise. To do this, turn the bolt using the bolt wings (8).

3. Remove the protective tube from the dura opener (4).
4. Use the dura opener (4) to incise the dura through the cranial bolt (8+9).
5. Bolt the clamping nut (9) on slightly by turning it clockwise.

Inserting the ICP probe

NOTE! The air chamber (1) should be moistened with isotonic saline solution prior to use in order to reduce possible friction and thus prevent damage to the probe.

1. Insert the ICP probe through the clamping nut on the cranial bolt (9) until the reinforcing tube (2) is completely inside the bolt.
2. Tighten the clamping nut (9) by turning it clockwise until the probe is secure.

WARNING! In the event that the air chamber (1) becomes partially or completely detached from the tube during use, the ICP probe must be replaced and the detached parts removed.

NOTE! The ICP probe must be inserted until the reinforcing tube (2) has completely disappeared into the cranial bolt (8+9), otherwise the air chamber (1) may be constricted and incorrect measured values may then be obtained. This corresponds to a depth of 40 mm.

Connection to the ICP monitor

WARNING! The HDM connector (3) must not be disinfected or moistened, otherwise the filter inside the connector will clog.

WARNING! The HDM connector (3) 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 (3), do not connect it to the ICP monitor.

1. Connect the HDM connector (3) on the ICP probe to the probe connector on the ICP monitor.
2. Turn the HDM connector (3) 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 (3), is marked with an "M".

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 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.

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.

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 and possibly tearing the ICP probe.

1. Disconnect the ICP probe from the ICP monitor.
2. Fully loosen the clamping nut on the cranial bolt (9).
3. Pull out the ICP probe.
4. Check that the ICP probe has been removed completely and that the tissue has not been damaged.
5. Remove the cranial bolt (8+9).
6. Observe the condition of the patient.

NOTE! No components of the ICP probe (e.g. the air chamber, 1) may be left in the patient.

NOTE! If the cranial bolt (8+9) 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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