Spiegelberg:
Technology for brains

IAP catheter **SND32.1.11**

Instructions for use

Content

Symbols used

REF	Reference 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
	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 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. When doing so, the air chamber must be omitted.

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	SND32.1.11
Outer diameter	3.3 mm (10 F)
Drainage lumen inner diameter	1.6 mm
Drainage total length	800 mm
Probe total length	2000 mm
Length of the double-lumen catheter	650 mm
Filling volume	< 0.15 ml
Application duration	Short term up to 30 days
Material	Polyurethane

Contents of the original packaging

1 IAP catheter
1 guide wire
1 Luer Lock Connector
1 Luer lock cap

Double packed
EO sterilised
For single use only
Latex-free

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 IAP catheter should only be used by persons who have completed medical training and have experience in dealing with nasogastric probes and intraabdominal pressure measurements (intensive care nurses).

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

Indications and intended use

The IAP catheter is used to measure intra-abdominal pressure (IAP) with an air chamber (3) attached to the proximal tip of a double-lumen catheter. One lumen (2) transmits the pressure to the ICP monitor. The second lumen (5) serves to accommodate a guide wire (6).

The air chamber system is a hollow body made of plastic (3) which is connected to a pressure transducer via a tube (2) and a connector (1). The pressure transducer is located in the ICP monitor together with the measuring electronics and a device for filling the air chamber.

For intra-abdominal measurements, the IAP catheter is placed in the stomach. The pressure is transmitted via the thin wall of the air chamber (3) to the air in the chamber and converted into electrical signals by the pressure transducer. The display on the ICP monitor then shows the average pressure and the pulse amplitude.

The IAP catheter is placed blind through the nose. The position is checked by means of an X-ray image. The guide wire (6) can then be removed. Alternatively, the position can be determined by way of auscultation.

In contrast to a measurement via a fluid column, the IAP is measured correctly even with an empty stomach.

An IAP measurement is indicated, among other things, if intra-abdominal hypertension or abdominal compartment syndrome is suspected.

Contraindications

The IAP catheter must not be used for purposes other than those specified. Its use is always contraindicated for existing diseases and injuries of the nasogastric area or the upper gastrointestinal tract. It is also contraindicated when continuous monitoring by trained personnel is not possible.

Warnings

⚠ Care and caution should be exercised when handling the IAP catheter.

⚠ Do not pull on the IAP catheter!

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

⚠ No sharp or pointed objects may be placed near the air chamber (3). These pose a risk of damage to the air chamber (3), resulting in leakage.

⚠ The guide wire (6) of the IAP catheter must be kept away from magnetic fields. It must not be used in the immediate vicinity of a magnetic resonance imaging (MRI).

⚠ The IAP catheter 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.

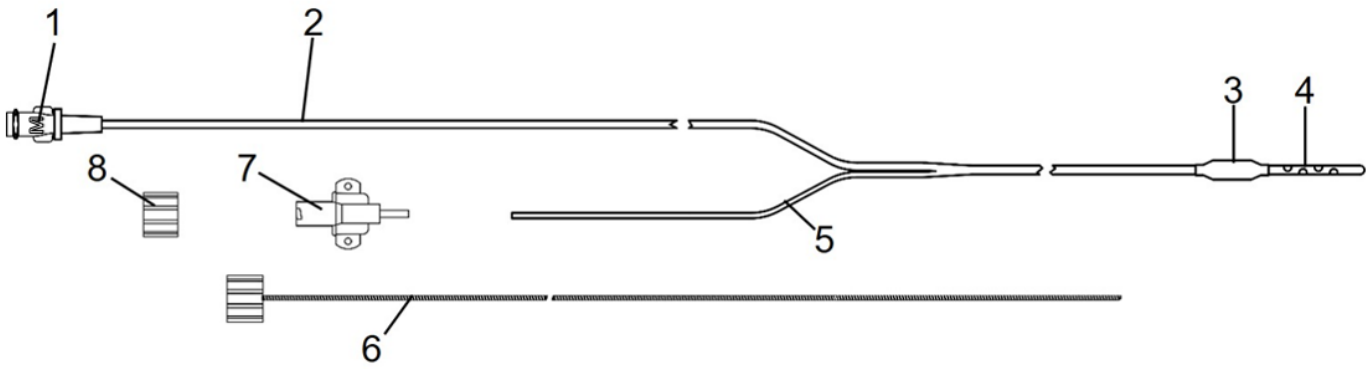
⚠ An open or damaged system must not be used further and must be replaced! Otherwise there is a risk of infection or loss of function.

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

⚠ No liquids or drugs may be administered via the IAP catheter.

⚠ The HDM connector (1) 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.



SND32.1.11

MRI safety information

Non-clinical testing has shown that the IAP catheter 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 “IAP catheter” 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 worst case of the product family[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 IAP catheter must be disconnected from the Spiegelberg ICP monitor before it is brought into rooms designated as MRI environments.

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

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

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

- Please ensure that all components of the drainage bag used with the catheter are “MR Safe” or “MR Conditional” at 1.5 or 3 Tesla.
- Do not bring catheter accessories (guide wire 6) into the MRI environment.
- Spiegelberg ICP monitors must never be brought into rooms marked as MRI environments.

Application & handling

Preparation of the IAP catheter

The IAP catheter should be checked for completeness prior to use. The guide wire (6) is already located in the drainage lumen (5).

NOTE! The guide wire (6) remains in the drainage lumen (5) before inserting the IAP catheter and should not be removed. If it has been removed before using the IAP catheter, it must be carefully reinserted.

The insertion depth of the IAP catheter must be measured before insertion and marked on the tube (e.g. with a plaster). Please note that the air chamber (3) must be completely inside the stomach.

WARNING! If the IAP catheter is inserted too far, there is a risk that it will enter the bowel. This would mean that an IAP measurement as per the intended purpose would no longer be possible.

WARNING! When marking the insertion depth, the tube must not become disconnected or damaged.

Insertion of the IAP catheter

NOTE! The guide wire (3) must be used to insert the IAP catheter. Otherwise there is a risk of the tube being misplaced, kinked or rolled up.

The IAP catheter should be placed like a nasogastric tube. It is inserted into the stomach through the patient's nose with the aid of the guide wire (6). If necessary, it can be moistened with isotonic NaCl solution to reduce possible friction.

WARNING! In the event that the air chamber (3) becomes partially or completely detached from the tube during use, the IAP catheter must be replaced and the detached parts removed.

Location of the IAP catheter

The position of the IAP catheter can be determined radiologically or by auscultation.
The guide wire (6) must remain in the IAP catheter for radiological positioning.
When determining the position via auscultation, the drainage lumen (5) without guide wire (6) with attached Luer Lock Connector (7) is used.

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

Securing the IAP catheter

The IAP catheter can be attached to the patient's skin with a plaster.

WARNING! Make sure that neither the air lumen (2) nor the drainage lumen (5) of the IAP catheter are constricted.

Removal of the guide wire

1. Slowly and carefully pull out the guide wire (6) from the drainage lumen (5).
2. Screw the cap (8) onto the Luer Lock Connector (7).
3. Push the distal end of the drainage lumen (5) over the entire length of the metal part of the Luer Lock Connector (7).

WARNING! Jerky or rapid withdrawal can damage the drainage lumen (5) or the guide wire (6).

NOTE! If the guide wire cannot be removed, the IAP catheter must be replaced with a new product.

Connection with a drainage bag

1. Remove the cap (8) from the Luer Lock Connector (7).
2. Connect the Luer Lock Connector (7) to the connector on the drainage bag.
3. Turn the Luer Lock Connector (7) 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 (1, 7) on the IAP catheter leads to a leaky connection with the drainage bag.

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

Connection to the ICP monitor

WARNING! The HDM connector (1) must not be disinfected or moistened, otherwise the filter inside the connector will clog.

WARNING! The HDM connector (1) must be kept dry. Otherwise the IAP catheter may lose function or the ICP monitor may be damaged.

1. Connect the HDM connector (1) of the IAP catheter to the probe connector on the ICP monitor.
2. Turn the HDM connector (1) clockwise until a clear resistance is felt and the IAP catheter is firmly connected to the ICP monitor.
3. Check the display on the ICP monitor and the values for plausibility.

NOTE! Mixing up the connectors (1, 7) on the IAP catheter will result in a leaking connection with the EVD set.

NOTE! The monitor connection, HDM connector (1), is marked with an "M".

Drainage of fluids

Liquids in the stomach are drained through the drainage holes (4) via the drainage lumen (5) and into the drainage bag. If there is no flow, the tube system must be checked for kinks or constrictions.

NOTE! Kinks and constrictions in the drainage tube (5) must be avoided, otherwise drainage is only possible to a limited extent.

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

Loosen the connection to the drainage bag

1. Turn the Luer Lock Connector (7) counter clockwise.
2. Quickly cap the Luer Lock Connector (7) with the cap (8).

Replacing the drainage bag

1. Disconnect the Luer Lock Connector (7) and the drainage bag.
2. Quickly cap the Luer Lock Connector (7) with the cap (8).
3. Replace the drainage bag according to the manufacturer’s instructions.
4. Remove the cap (8) from the Luer Lock Connector (7).
5. Connect the Luer Lock Connector (7) to the drainage bag.

Removal of the IAP catheter

NOTE! Proceed slowly and carefully when removing the IAP catheter. It must be ensured that no tissue is damaged.

NOTE! The IAP catheter must not be removed with quick jerks so as to avoid injuries and the splashing of blood, gastric acid and other stomach contents.

1. Disconnect the IAP catheter from the ICP monitor and from the drainage bag.
2. Loosen the fixings attaching the IAP catheter to the patient.
3. Pull out the IAP catheter.
4. Check that the IAP catheter has been completely removed.
5. Observe the condition of the patient.

NOTE! No components of the IAP catheter (e.g. the air chamber, 3) may be left in the patient.

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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