Spiegelberg:
Technology for brains

Silverline® lumbar drainage catheter **ELD33.010.02**

Instructions for use

Content

Symbols used

REF	Item number		Do not use if packaging is damaged.
LOT	Batch 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

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 hose 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. The product is described as a “lumbar catheter” in the following.

Technical data

The stated values reflect nominal values and may differ.

REF / Order number	ELD33.010.02
Outer diameter	1.6 mm
Drainage lumen inner diameter	0.8 mm
Drainage hose total length	800 mm
Drainage opening diameter	0.7 mm
Number of openings	20
Depth markings	50 – 295 mm (in 5 mm intervals)
Application duration	Short term up to 30 days
Material	Silver-impregnated radiopaque polyurethane

Contents of the original packaging

1 lumbar catheter
1 Tuohy needle
1 Luer lock connector
1 slotted suture attachment
1 end cap
1 instruction manual

Double packed
EO sterilised
For single use only

Approved accessories

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 lumbar catheter may 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 lumbar catheter drains cerebrospinal fluid (CSF) for diagnostic and therapeutic purposes in adults. The proximal end is inserted into the lumbar subarachnoid space for this purpose. The distal end is connected to a droplet chamber system (EVD set) or a drainage bag.

The lumbar catheter is impregnated with a silver additive to reduce the probability of microbial colonisation of its surface.

Application of the lumbar catheter is indicated for the invasive diagnostic evaluation of normal pressure hydrocephalus (NPH), risk mitigation for spinal cord ischemia in the event of thoracoabdominal aortic procedures and prevention of delayed neurological deficits after subarachnoid haemorrhages.

Contraindications

The lumbar catheter 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 infections in the relevant area of the skin, 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 lumbar catheter include dislocations, bleeding and infections.


Care and caution should be exercised when handling the lumbar catheter.


Do not pull on or jerk the lumbar catheter quickly! Quickly pulling on or jerking the probe can damage the hose.


Avoid kinks in the hose, as this will impair the drainage.


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


The Luer lock connector (6+7) must not be disinfected or moistened, as the material may become brittle. This may result in a loss of function of the lumbar catheter.


The depth of the lumbar catheter can be checked using the marked scale (2).


The lumbar 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.


It is essential that the supplied components are used in order to guarantee compatibility with the lumbar catheter.


No liquids or drugs may be administered via the lumbar catheter.


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

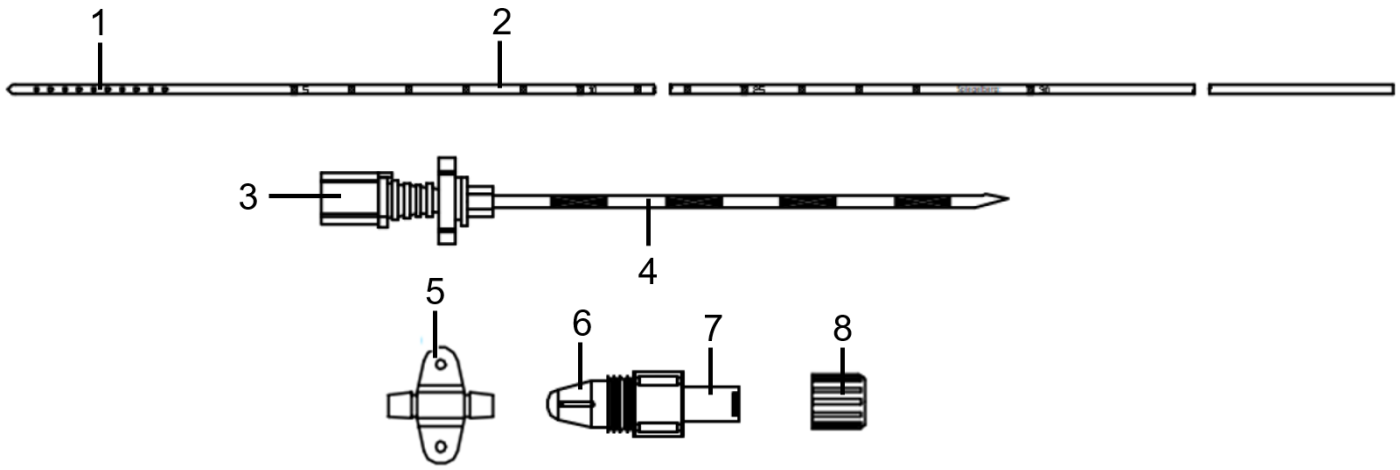
The procedure for using the lumbar catheter must be observed and followed in the correct order.

The position of the lumbar subarachnoid space should be checked using imaging techniques prior to application.

A successful treatment of CSF fistulas with the lumbar catheter cannot be guaranteed.

Contaminated components and lumbar catheters must not be reused.

If problems occur during application or components become detached, a new lumbar catheter should be used.



ELD33.010.02

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 screw (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).
- Make sure that all components of the EVD set used with the lumbar catheter are “MR Safe” or “MR Conditional” at 1.5 or 3 tesla.
- Do not bring catheter accessories (Tuohy needle with core, 3+4) into the MRI environment.

Application & handling

Preparation of the lumbar catheter

The lumbar catheter should be checked for completeness prior to use.
The insertion depth of the lumbar catheter should be determined using imaging techniques prior to insertion.

WARNING! There is a risk of tissue damage if the lumbar catheter is inserted too far.

NOTE! If the printed image on the scale (2) is not clearly legible, another lumbar catheter must be used.

Preparation of the application area

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

1. Perform aseptic preparation of the surgical area and put up surgical drapes.
2. Place the end cap (8) on the plastic end of the Luer lock connector (7).

Positioning of the Tuohy needle

WARNING! The Tuohy needle (4) has a sharp tip. There is a risk of injury if the Tuohy needle (4) is not handled carefully.

1. Ensure that the distal end of the core (3) is firmly locked in place in the Tuohy needle (4).
2. Remove the protective hose from the Tuohy needle (4).
3. Carefully insert the Tuohy needle (4) with the core being used (3).
4. Check the correct positioning based on the flow of cerebrospinal fluid by pulling the distal end of the core (3).
5. For repositioning: Reinsert the core by pushing on the distal end (3). When doing so, ensure that the distal end of the core (3) is firmly locked in place in the Tuohy needle (4).
6. Fully remove the core after correct positioning by pulling the distal end of the core (3).

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

Insertion of the lumbar catheter

1. Insert the lumbar catheter into the Tuohy needle (4) with the drainage holes (1) at the front.
2. Determine the correct depth using the printed scale (2).
3. Check the correct positioning based on the flow of cerebrospinal fluid.

⚠ **WARNING! The lumbar catheter may not be pulled back through the Tuohy needle (4) because this may damage the hose.**

Removing the Tuohy needle

1. Pull the Tuohy needle (4) out slowly and carefully. When doing so, gently push the lumbar catheter through the Tuohy needle (4) in order to prevent the lumbar catheter from being pulled out.
2. Once the Tuohy needle (4) has been removed from the patient, secure the lumbar catheter and pull the Tuohy needle (4) entirely over the lumbar catheter in a distal direction.

Attaching the connector

1. Release both halves of the Luer lock connector (6+7) by turning the proximal half (6) anticlockwise until the connection is loose.
2. Separate both parts of the Luer lock connector (6+7) by pulling them apart.
3. Push the proximal half (6) onto the lumbar catheter so that the thread is pointing in a distal direction.
4. Push the distal end of the lumbar catheter over the entire length of the metal part of the Luer lock connector (7).
5. Close the connection of both halves of the Luer lock connector (6+7) by turning the proximal half clockwise until significant resistance can be felt and the connection is secure.

Securing the lumbar catheter

1. Position the slotted suture attachment (5) on the lumbar catheter.
2. Affix the slotted suture attachment (5) to the patient’s skin.

ⓘ **NOTE! The slotted suture attachment (5) should not be affixed in a straight line to the entry point. Rather, it should be secured in such a way that the hose forms a semicircle shape.**

ⓘ **NOTE! The resulting loop should be covered with a bandage when closing the wound to prevent it from becoming caught on the hose and the lumbar catheter being pulled out.**

⚠ **WARNING! The suture used to attach the slotted suture attachment (5) must not be overtightened. Otherwise the hose may be constricted, resulting in decreased drainage function.**

Connection to an EVD set

1. Remove the end cap (8) from the Luer lock connector (7).
2. Connect the Luer lock connector (7) to the connector on the EVD set.
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! Visual checks of the connection to the EVD set must be carried out on a regular basis.

Checking the function of the lumbar catheter

Check the function of the lumbar catheter using the CSF flow.

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

Drainage of CSF

CSF in the lumbar subarachnoid space passes through the drainage holes (1) into the EVD set. If there is no flow of CSF, the hose system must be checked for kinks or constriction.

NOTE! Kinks and constriction in the lumbar catheter must be avoided to prevent drainage restrictions.

Disconnecting the EVD set

1. Turn the Luer lock connector (7) counter clockwise.
2. Quickly cap the Luer lock connector (7) with the end cap (8).

Replacing the EVD set

1. Disconnect the Luer lock connector (7) and the EVD set.
2. Quickly cap the Luer lock connector (7) with the end cap (8).
3. Replace the EVD set according to the manufacturer’s instructions.
4. Remove the end cap (8) from the Luer lock connector (7).
5. Connect the Luer lock connector (7) to the EVD set.

Closing the wound

After the proper function of the lumbar catheter has been confirmed, the wound is covered with a plaster or gauze pad. The material to be used should be selected by the surgeon.

NOTE! When covering the wound, care must be taken not to pull out or damage the lumbar catheter.

NOTE! The wound is to be covered in a manner which does not constrict the lumbar catheter. Otherwise the drainage may become blocked.

NOTE! The loop created by suturing the lumbar catheter also needs to be covered.

Determining the position of the lumbar catheter

The position of the lumbar catheter can be checked using imaging techniques.

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

Removal of the lumbar catheter

NOTE! Proceed slowly and carefully when removing the lumbar catheter. It must be ensured that no tissue is damaged and that the slotted suture attachment (5) has been detached.

NOTE! The lumbar catheter 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 lumbar catheter must not be pulled over sharp or uneven edges during removal to avoid damaging the hose and possibly tearing the lumbar catheter.

1. Disconnecting the lumbar catheter and the EVD set.
2. Loosen the fixings attaching the lumbar catheter to the patient.
3. Pull out the lumbar catheter.
4. Check that the lumbar catheter has been removed completely and that the tissue has not been damaged.
5. Observe the condition of the patient.

NOTE! No components of the lumbar catheter 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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