SOPHYSA
At the heart of the **brain**

Instructions for Use

PRESSIO® MONITORING KIT VENTRICULAR TUNNELING

ICP monitoring: Model PSO-VT
ICP and ICT monitoring: Model PSO-VTT

NT550_NCE(USA)
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Table of contents

Figure 1: Pressio® ICP Monitoring Kit, Ventricular Tunneling (Model PSO-VT)

A: Pressio® Catheter for intracranial pressure measurement with its dongle B: Luer-Lock connector C: Stylet D: Fixation tab E: Allen key F: Drill bit with adjustable stop G: Tunneling trocar with sheath

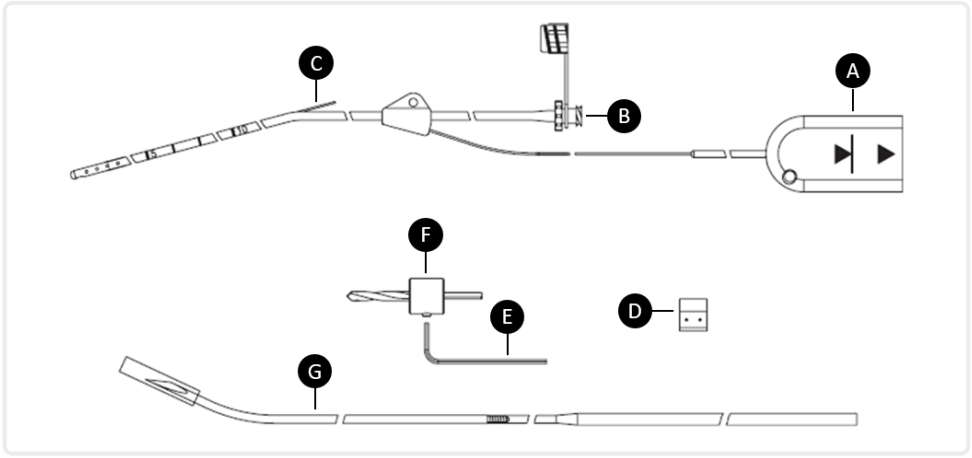
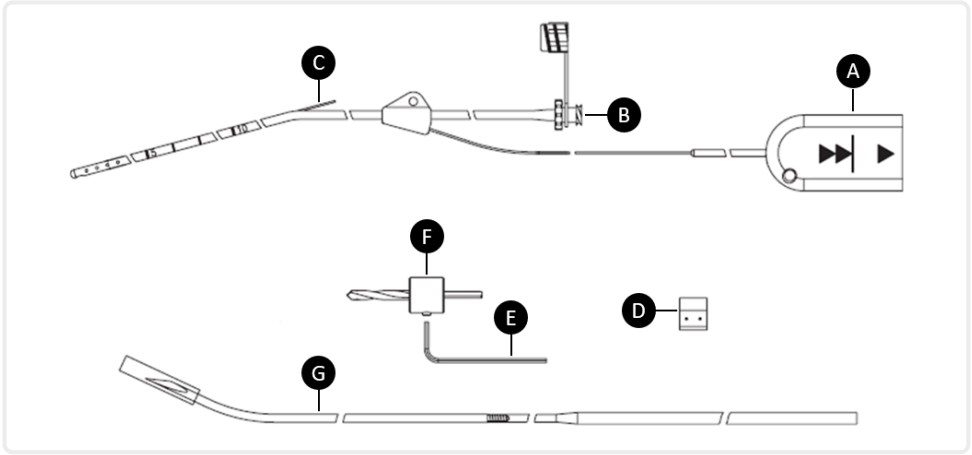


Figure 2: Pressio® ICP and ICT Monitoring Kit, Ventricular Tunneling (Model PSO-VTT)

A: Pressio® Catheter for intracranial pressure and temperature measurement with its dongle B: Luer-Lock connector C: Stylet D: Fixation tab E: Allen key F: Drill bit with adjustable stop G: Tunneling trocar with sheath



Warning

Read the instructions for use carefully before using the Pressio® Monitoring Kit, Ventricular Tunneling (PSO-VT or PSO-VTT).

Read the instructions for use before using the Pressio® ICP Monitor (PSO-3000), the Pressio® 2 ICP Monitor (PSO-4000), or the Pressio® Interface (PSO-IN00).

Caution

Federal (USA) law restricts this device to sale by or on the order of a physician.

1. Indications

The use of a Pressio Monitoring Kit (hereinafter referred to as Monitoring Kit) is indicated in patients requiring continuous monitoring of intracranial pressure (ICP). Depending on the type of catheter used, the Monitoring Kit can also be indicated in patients requiring continuous monitoring of intracranial temperature (ICT):

— Monitoring Kit, Ventricular Tunneling (PSO-VT) for ventricular ICP monitoring,

— Monitoring Kit, Ventricular Tunneling (PSO-VTT) for ventricular ICP and ICT monitoring.

The use of a ventricular kit also allows simultaneous drainage of the cerebrospinal fluid.

The Monitoring Kit is indicated for use by trained personnel of (neuro) intensive care units and neurosurgery departments.

Note

The ICP and ICT values indicated on the Pressio® Monitoring Systems do not prejudge the condition of the patient.

2. Contraindications

Contraindications to the use of a Monitoring Kit are the following:

— Established or suspected infections in the tissues in direct contact with Monitoring System components (meningitis, ventriculitis, septicaemia or bacteraemia), or any infection present in any part whatsoever of the body.
— Patients on anticoagulant therapy or presenting with bleeding diathesis.

Warning

Do not use the Monitoring Kit if there are no trained personnel available to provide continuous observation.

3. Description

The Monitoring Kits are made up of:

— a Pressio® Catheter (hereinafter referred to as Catheter),
— accessories allowing the Catheter to be implanted and kept in position.

3.1. CATHETERS

Catheters are single-use implantable devices intended to be used only with a Pressio Monitoring System (hereinafter referred to as Monitoring System):

— a Pressio ICP Monitor PSO-3000 or PSO-4000 (hereinafter referred to as Monitor),
— a Pressio Interface PSO-IN00 (hereinafter referred to as Interface).

The Catheters are of the “BF” type.

Warning

Catheters are not protected against defibrillation and may be damaged as a result.
Before defibrillation, withdraw the Catheter. If this is not possible, for safety reasons, change the Catheter after defibrillation to continue monitoring.

The Monitoring Kit, **Ventricular Tunneling PSO-VT (Figure 1)** allows continuous monitoring of ICP.

The Monitoring Kit, **Ventricular Tunneling PSO-VTT (Figure 2)** allows continuous monitoring of ICP and ICT.

Both kits allow simultaneous drainage of the cerebrospinal fluid.

The Catheter, designed to be placed in a cerebral ventricle, has three distinct lumina:

— The first contains a Catheter equipped with a capsule at its end, enclosing a pressure sensor (and a temperature sensor for the PSO-VTT model).
— The second contains the pre-inserted introduction stylet.
— The third is for the drainage of the cerebrospinal fluid.

The two kits can be distinguished visually by their respective arrows on the Catheter dongle. The presence of a red arrow indicates that it is a Catheter for monitoring both ICP and ICT.

In both kits, the Catheter has a marking every centimeter between 5 and 10 cm from the proximal end, and a marker at 15 cm.

The external drainage Catheter has a Luer-Lock connector at its distal end, for connection to an external drainage system.

The end of the Catheter, opposite the sensor, has a connector to connect the Catheter to a Monitoring System via a Catheter extension cable:

— Catheter extension cable PSO-EC20 to connect a Catheter to a Pressio ICP Monitor or a Pressio Interface.
— Catheter extension cable PSO-EC30 to connect a Catheter to a Pressio 2 ICP Monitor.

The Catheter extension cable transmits the measurement signals from the sensor(s) to the Monitoring System, in the form of analog signals.

The Catheter also exchanges a digital signal with the Monitoring System. This signal contains data, such as sensor calibration, or value and date on which the Catheter was zeroed.

Data is memorised in the Catheter dongle and is thus independent of the Monitoring System used.

Note

If a Pressio 2 ICP Monitor is used, the ICP or ICP + ICT data for the first fifteen days of monitoring are recorded in the Catheter memory. Beyond 15 days, no more new data is recorded in the Catheter memory.
This data may be consulted only with a Pressio 2 ICP Monitor by using the “History” function.

Specific case for the PSO-VTT

To monitor both ICP and ICT, the Monitoring System must either be a Pressio ICP monitor, software version V2, or a Pressio 2 ICP Monitor.

Note

The software version can be identified when powering on the Monitor: the Sophysa logo and software version display on the Monitor touch screen.

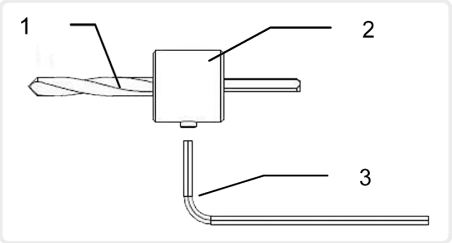
If you do not have a Pressio 2 ICP Monitor or a Pressio ICP monitor, software version V2, you can still use the Catheter on one of the other Monitoring Systems (Pressio ICP monitor, software version V1 or Pressio Interface). In this case, only the pressure will be displayed, the temperature will not be displayed. The performances of the pressure sensor will be identical.

3.2. ACCESSORIES

The different accessories described below enable the Catheters to be be implanted.

— [1] Drill bit for intracranial access.
— [2] Adjustable stop and its locking screw to set a drilling depth.
— [3] Allen key to set the position of the adjustable stop.

1: Drill bit 2: Adjustable stop 3: Allen key

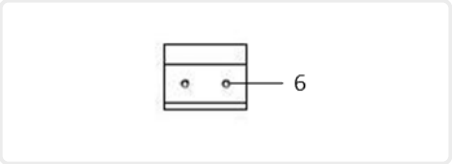


— [4] Tunneling trocar to create a passage for the Catheter under the scalp
— [5] Sheath to help pass the Catheter under the scalp.

4: Tunneling trocar 5: Sheath

The silicone fixation tab [6] enables the fixation of the Catheter to the scalp.

6: Fixation tab



A sterile disposable drill (PSO-DR) to perforate the skull is also available to order. It can be used in combination with the drill bit supplied in each Monitoring Kit.

4. Sterilisation - Decontamination

The Monitoring Kits are packed individually in double peel-off, sterile, pyrogen-free packaging. They are sterilized with ethylene oxide.

Warning

Do not use the products if the sterile packaging is open or damaged, or if the expiry date has passed.

This product is **for single use only**. It is intended to be used once only for a single patient.

Do not re-sterilize or re-use after opening the packaging and/or after explantation.
Resterilization may damage the product, which could cause lesions to the patient.
Reusing this device may change its mechanical or biological features and may provoke failure, or the development of allergic reactions or bacterial infections.

Note

Sophysa cannot be held responsible for the performance of any product that has been re-sterilized, or for any complications which might result from this.

5. Setting-up the Monitoring System

Precaution

The Monitoring System should only be used by trained personnel.

— Power on the Monitoring System.
— Connect the Catheter extension cable to the Monitoring System.

6. Preparing, Implanting and Monitoring

Warning

Read the instructions for use of the Monitoring System in use before using a Monitoring Kit.

Caution

The implantation of the Catheter should be performed **immediately** after the Catheter is zeroed. Therefore, prepare the Monitoring System and the implantation site **before** zeroing the Catheter.

Do not perform the implantation of a Catheter without having a replacement Monitoring Kit available in case it is required.

Only connect Catheters to calibrated Monitoring Systems.

6.1. PREPARING THE CATHETER IMPLANTATION SITE

Observe aseptic neurosurgical techniques to prepare the Catheter implantation site.

Surgeons will perform the most appropriate technique depending upon their experience and the clinical status of the patient.

Use the insertion accessories supplied by Sophysa in the

Monitoring Kit.

6.1.1. Choice of the Implantation Area

As an example, the right and left prefrontal areas are the main implantation areas. These areas enable the patient to turn his/her head from one side to the other whilst remaining in decubitus without interfering with the intracranial pressure surveillance function.

In most cases, the incision is made behind the hairline, which is acceptable from an aesthetic point of view.

6.1.2. Intracranial Access

Once the implantation site has been chosen, the area is shaved and prepared aseptically. A local anesthetic is applied in the incision area, generally 2 to 3 centimeters in front of the coronal suture on the mid-pupillary line.

1. Make an incision of about 1 cm down to the bone.
2. Expose the bony plate and perform haemostasis on the wound edges.
3. Loosen the locking screw with the Allen key to set the position of the adjustable stop on the drill bit, depending upon the drilling depth chosen.
4. Once the adjustable stop is correctly positioned, retighten the locking screw.

> **Warning**
>
> Incomplete tightening of the locking screw will prevent the adjustable stop from playing its role, with the risk of drilling too deeply.

5. Fix the helical drill bit to a drill.
6. Perforate the internal and external skull plates avoiding any possibility of a parenchymal injury when passing through the internal plate.
7. Having crossed the internal plate, remove the drill bit.
8. Irrigate the burr hole with sterile saline solution and remove the debris.
9. Pierce the dura mater.

6.2. ZEROING THE CATHETER

Zeroing the Catheter involves calibrating the Catheter in relation to atmospheric pressure.

> **Warning**
>
> Perform the zeroing procedure on each new Catheter, **before** implanting it in the patient.

> **Caution**
>
> Observe aseptic technique throughout the entire zeroing procedure.

> **Notice**
>
> Do not allow the Catheter extension cable connector to come into contact with liquid.

> **Note**
>
> The ICT sensor is calibrated in the factory. Therefore, the temperature setting does not need prior zeroing.

Prerequisites

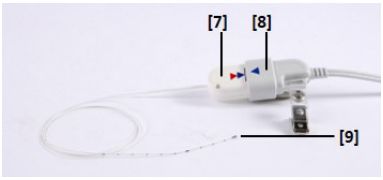
- Power on the Monitoring System.
- Connect the Catheter extension cable to the Monitoring System:
  - if using a Monitor, a message inviting you to connect the Catheter displays on the Monitor screen,
  - if using an Interface, the zeroing diode flashes slowly.

Procedure

1. Unpack the Catheter (sterile) within sterile field.
2. Prepare a shallow cup of sterile saline solution (less than 5 mm).

> **Caution**
>
> Using a deep receptacle could lead to hydrostatic pressure greater than atmospheric zero, which would then lead to an erroneous reference zero.

3. Observing aseptic technique, connect the Catheter extension cable (non-sterile) to the Catheter, aligning the blue arrow on the Catheter dongle [7] with the blue arrow on the Catheter extension cable connector [8].



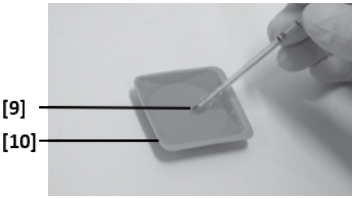
The Catheter dongle must be completely inserted into the Catheter extension cable connector. A blue line on the Catheter dongle indicates the point of complete insertion.

When correctly inserted:

- if using a Monitor, a message displays on the screen,
- if using an Interface, the zeroing diode flashes quickly.

> **Note**
>
> The appearance of error codes, “E001”, “E002”, or “E005” on the Monitor after connecting the Catheter to the Catheter extension cable may be a sign of an incorrect connection. In this case, make sure that the Catheter dongle is pushed right up to the stop in the Catheter extension cable, and that the latter is correctly connected to the Monitor.

4. Within the sterile field, immerse the sensor (metal tip) of the Catheter [9] in the cup of sterile saline solution [10], without touching the cup.



Precautions

Avoid any contact with the sensor during zeroing procedure, as this could adversely affect the calibration, resulting in an inaccurate zero reference.

Keep the sensor immersed in sterile saline solution during the zeroing procedure. Zeroing the sensor in conditions other than those recommended may cause inaccurate pressure readings.

5. While the sensor is immersed, press the Zero button on the Monitor touch screen, or on the Interface:

Zeroing the Catheter requires approximatively 4 seconds. Do not move the Catheter during the zeroing procedure.

- If the zeroing procedure is successful:
  - the Monitor touch screen displays a message indicating that the Catheter is ready to be implanted,
  - the Interface zeroing diode remains lit.
- If the zeroing procedure is not successful:
  - follow the instructions displayed on the Monitor touch screen,
  - the Interface emits a series of beeps and sends a pressure value of 360 mmHg to the patient bedside monitor. For more information, refer to the instructions for use of the Interface.

Note

Zeroing the Catheter can only be performed once. Upon completion, the zero calibration information is stored in the Catheter dongle. It allows the Catheter to be disconnected from a Monitoring System, and re-connected to any Monitoring System, without losing the zero calibration information.

6.3. IMPLANTING THE CATHETER

Before implanting the Catheter, check that the screen of the Monitor (or of the patient bedside monitor if the Interface is used) displays the value “0 mmHg”.

Warning

Limit repeated intracerebral implantation of Catheters. Frequent perforation of the brain to allow Catheter insertion may predispose the brain to oedema and intracerebral haemorrhage resulting in an increase in intracranial pressure.

Caution

Observe aseptic neurosurgical technique when implanting a Catheter.

Surgeons will perform the most appropriate technique depending upon their experience and the patient clinical status.

The final implantation of the device must satisfy the conditions for optimal positioning of the sensor in the ventricle.

Prerequisites

The Catheter must be zeroed.

Procedure

Use the insertion accessories supplied by Sophysa in the Monitoring Kit.

Note

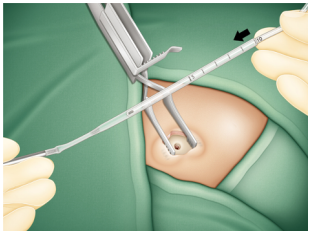
The Catheter must be tunneled under the scalp to improve its fixation and reduce the risks of infection. The Catheter usually emerges 5 cm from the burr hole in a posterior position.

6.3.1. Tunneling the Catheter

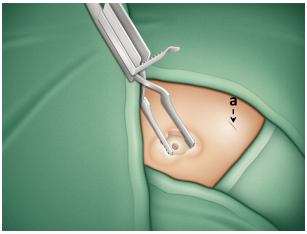
Precaution

The end of the tunneling trocar is sharp, introduce the Catheter very carefully.

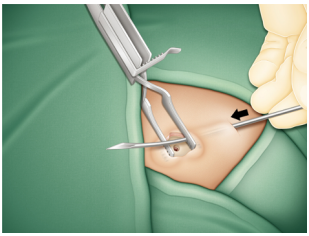
1. Insert the proximal end of the Catheter in the tunneling trocar sheath.



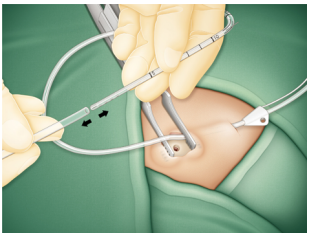
2. Make a small incision at the site chosen for the emergence of the Catheter (incision a).



3. Starting at the emergence site, insert the tunneling trocar between the scalp and the skull towards the burr hole.

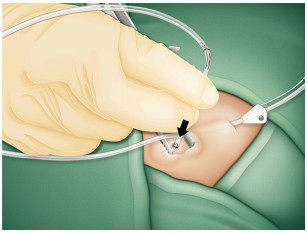


4. Pull the Catheter out of the tunnel making sure that a length of at least 30 cm comes out of the implantation site, and remove the tunneling trocar with the sheath.

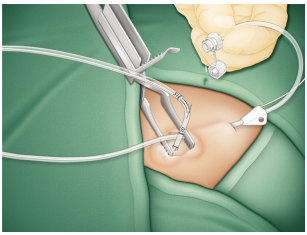


6.3.2. Implanting the Catheter

1. Holding it by the stylet pre-inserted in the specifically designed lumen, implant the zeroed Catheter in the direction of the ventricle in accordance with standard techniques.



2. Remove the protective cap from the Luer-Lock connector at the end of the Catheter drainage tubing.
3. Check correct positioning in the ventricle by observing the return of the cerebrospinal fluid at the drainage connector opening.

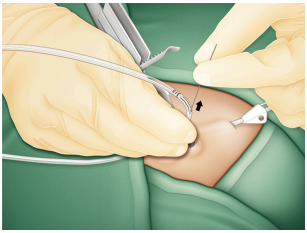


— If a series of air bubbles and liquid segments appear in the Catheter, purge the Catheter letting possible air bubbles move through to the end of the drainage tubing.
— If the ventricles of the patient are swollen, move the Catheter forward by several millimeters beyond the point where the first sample of fluid was taken. This way, the Catheter end will remain in the ventricle during decompression.

Note

If the ventricular approach fails, it is still possible to monitor ICP by leaving the Catheter in place in the parenchyma it has crossed. The ICP values measured will be the intraparenchymal pressure values on the sensor.
In this case, close the Luer-Lock connector to limit the risks of infection.

4. While holding the Catheter in place at the implantation site, remove the stylet by gently bending the Catheter at the two-line marker level.



6.3.3. Connection to an External Drainage System

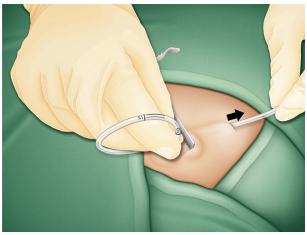
— The Catheter may be connected to different external CSF drainage systems. Connect the Catheter to the external drainage tubing using the Luer-Lock connector.
— If the Catheter is not connected to an external drainage system, close the Luer-Lock connector to limit the risk of infection.

Precaution

Refer to the external drainage system instructions for use.

6.3.4. Fixing the Catheter

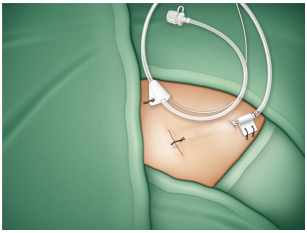
1. Hold the Catheter in place at the implantation site and pull very gently on the end located at the side of the connector until it forms a right angle and rests flat against the skull.



2. Close the incision above the burr hole in compliance with standard hospital procedures.
3. Use the fixation tab supplied to fix the Catheter onto the scalp at the emergence site.
4. To keep the Catheter in place and reduce the tension, roll the Catheter and attach the loop thus formed. Make sure no traction is exerted on the fixation tab during these stages.

Warning

Make sure the loop formed by the Catheter is not too tight (radius of more than 15 mm) or the drainage of the CSF may be slowed.



Once the Catheter is implanted, the Monitor (or patient bedside monitor) displays the mean ICP value in millimeters of mercury (mmHg).

1 mmHg corresponds to 13.60 mmH_2O and to 133 Pa.

Note

The appearance of error codes “- - -”, “999”, “E001”, “E002”, “E005”, or the message “Connect sensor” on the Monitor after the Catheter implantation, when the Catheter is correctly connected may be a sign of damage to the dongle or to the sensor located on the tip of the Catheter.

Specific case for the PSO-VTT

The temperature is also displayed and will stabilise at its accurate value within a maximum of 150 seconds.

Note

A temperature measurement can only be accurate if the sensor is implanted. The sensor is not suitable for measuring the temperature in air.

When the temperature read by the sensor is less than 20 °C or higher than 45 °C, the Monitor displays: “ - - .- “. This means that the measurement is in the sensor measuring range but outside the display ranges of the Monitor.

6.4. MONITORING, CARING AND NURSING OF THE PATIENT

Once the Catheter is correctly implanted and connected to the Monitoring System, take into account the precautions listed below to ensure optimum monitoring.

Precautions

The patient should only be monitored by trained and qualified personnel.

Attach the Catheter extension cable fixation clips to the bed sheets, or to the patient's clothing to limit traction on the implanted Catheter, and reduce the risk of Catheter disconnection.

Move the patient with care in order to avoid disconnecting any cables, or any movement of the implanted Catheter.

After moving the patient, check the connection of the Catheter to the Catheter extension cable, and the connection of the Catheter extension cable to the Monitoring System.

Do not use a Monitoring System and the implanted Catheter at the same time as a high frequency electro-surgical instrument or a defibrillator. The Catheter and/or the Monitoring System could be damaged or have their operation disrupted.

Do not allow any of the connectors to come into contact with liquid, especially during care of the patient.

During monitoring, observe the Catheter implantation site in compliance with standard hospital procedures.

After the first 24 hours, the Monitor displays the duration of the Catheter implantation in the form of the message "Implantation: X days", at the top left corner of the touch screen, for the entire duration of its implantation.

Caution

Catheters are recommended to be implanted for up to 6 days (144 hours).
When this duration is exceeded:

— on a Monitor, the message "Implantation: X days" flashes at the top left corner of the touch screen of the Monitor,

— on the Interface, the diode showing the implantation duration for the Catheter flashes.

The accuracy of the displayed ICP value is no longer guaranteed.

Note

If a Pressio 2 ICP Monitor is used, it is possible to access the records for the last 15 days of monitoring by using the “History” function on the Monitor.

6.5. EXPLANTING THE CATHETER

1. Stop the Monitor, or disconnect the Interface.
2. Disconnect the Catheter from the Catheter extension cable.
3. Carefully explant the Catheter.
4. Check the integrity of the explanted Catheter.

7. Behaviour During an MRI Examination

MRI Safety Information

Non-clinical testing has demonstrated the Monitoring Kit, Ventricular Tunneling (PSO-VT) for ventricular ICP monitoring and the Monitoring Kit, Ventricular Tunneling (PSO-VTT) for ventricular ICP and ICT monitoring are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions:

— Static magnetic field of 1.5 T and 3.0 T.

— Maximum spatial field gradient of 1,900 gauss/cm (19 T/m) (extrapolated).

— Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode).

— The non-implanted part of the catheter must be wrapped around the Pressio® MRI Support when there is one available and the MRI Support must be centered in the scanner beforehand.

Refer to the information in section 7.2 for the positioning of the Catheters with the MRI Support and section 7.3 for Manual Coiling when there is no MRI Support available.

Under the scan conditions defined above, the Monitoring Kit, Ventricular Tunneling (PSO-VT) for ventricular ICP monitoring or the Monitoring Kit, Ventricular Tunneling (PSO-VTT) for ventricular ICP and ICT monitoring is expected to produce a maximum temperature rise of less than 2.2 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the length of the implanted Catheter extends approximately 55 mm from the Monitoring Kit, Ventricular Tunneling (PSO-VT) for ventricular ICP monitoring or the Monitoring Kit, Ventricular Tunneling (PSO-VTT) for ventricular ICP and ICT monitoring when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

Warning

Disconnect the Catheter from the Monitor before any MRI examination.

The “MR Conditional” status only concerns Monitoring Kits for ICP or ICP and ICT. The Monitors, Interface, cables and the temperature module are considered to be “*MR Unsafe*” (not MRI-compatible) and must not be exposed to an MRI environment.

Note

The ICP or ICP and ICT Monitoring Kits are considered to be "MR Conditional" according to the definition of the ASTM F2503 standard.

7.1. GENERAL POINTS

A patient implanted with an ICP or ICP and ICT Monitoring Kit may undergo an MRI examination after the implantation of the ICP or ICP and ICT Monitoring Kit .

The results of *in-vitro* tests on ICP or ICP and ICT Monitoring Kit have shown that the ICP or ICP and ICT Monitoring Kits do not present any danger for patients in the following conditions:

— Satic magnetic field of 1.5 Tesla or 3 Tesla.
— Maximum spacial field gradient of 1,900 gauss/cm (19 T/m) (extrapolated).
— Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode) for 15 minutes exposure at 1.5 or 3 T.
— The non-inserted part of the Catheter is coiled around the MRI Support (when you have one available), and the Pressio MRI Support must be centered in the scanner beforehand.
For more information, refer to the indications mentioned in section "Positioning of the Monitoring Kits and the MRI Support" below.
If you do not have a Pressio MRI Support available, you can opt for a manual coiling of the Catheter.
For more information, refer to the indications mentioned in section "Positioning of the Monitoring Kits without the MRI Support" below.

— Do not use an emission/reception head coil (RF emission coil for the head) or a simple RF emission head coil. Only use an RF emission/reception whole body coil or an RF emission whole body coil with a simple RF reception head coil.

— Do not scan a patient with a high body temperature.

7.2. POSITIONING OF THE MONITORING KITS AND THE MRI SUPPORT

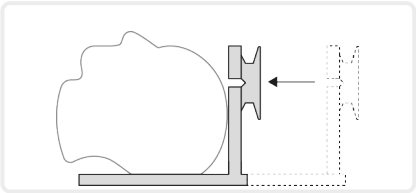
Warning

Read the instructions for use before using the MRI Support.

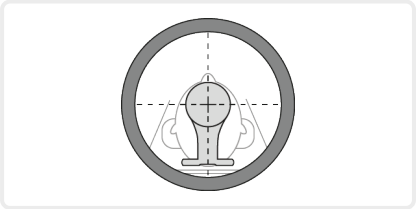
Do not perform an MRI leaving the Catheter uncoiled or in a straight line along the patient's body. This configuration could cause serious injuries to the patient.

Once the patient is installed on the MRI bed:

1. Place the MRI support on the bed, the base of the support in contact with the bed.
2. Place the support as close as possible to the patie head.



3. Move the MRI Support so that it is in the **center** of the bed.

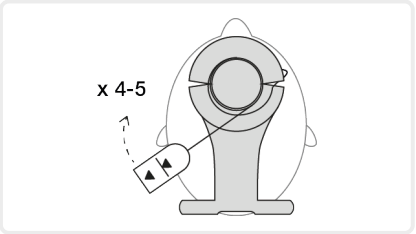


4. Pass the non-implanted part of the Catheter through one of the side notches on the body of the MRI Support, and coil it. Depending on the Catheter length, it may be coiled 4 or 5 times round the MRI Support.

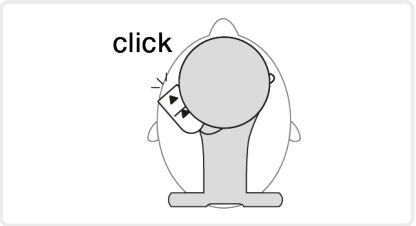
Caution

Handle the Catheter with care when coiling it to avoid any excessive traction on the implanted Catheter.

When handling the Catheter, avoid any liquid spray on the connector as this may damage it.



5. Fix the Catheter dongle by inserting it, as shown below, between the flanges of the MRI Support spool.



6. Before starting the MRI examination, make sure that the MRI Support is correctly centered. If not centered, adjust its position.

7.3. POSITIONING OF THE MONITORING KITS WITHOUT THE MRI SUPPORT

Warning

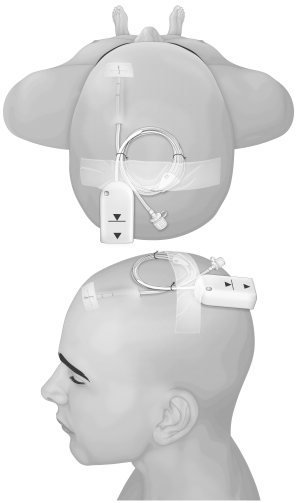
The Catheter must be disconnected from the Pressio®2 Monitor before any MRI examination.

Do not perform an MRI leaving the Catheter uncoiled or in a straight line along the patient's body. This configuration could cause serious injuries to the patient.

When there is no MRI Support available, you can opt for the manual coiling of the Catheter.

Once the patient is installed on the MRI bed, take the non-implanted part of the Catheter and coil it behind the top of the patient's head, in 5 cm loops (up to 4 or 5 loops) and perpendicular to the primary magnetic field.

Manual coiling with the PSO-VT/PSO-VTT Catheter



7.3. IN VITRO TEST CONCLUSIONS

The *in vitro* tests conducted in accordance with the ASTM F2182 standard have shown that in the specific conditions mentioned previously, the increase in temperature resulting from exposure to an MRI examination at 1.5 and 3 Tesla is negligible and has no clinical consequences for the patient (maximum increase measured + 2°C +/- 0.3°C).

The *in vitro* tests conducted in accordance with the ASTM F2052 standard have shown that the displacement forces induced by a magnetic field of 3 Tesla or less do not present any risks for the patient.

The *in vitro* tests conducted in accordance with the ASTM F2213 standard have shown that the torque forces induced by a spatial gradient of the magnetic field less than or equal to 19 T/m do not present any risks for the patient.

The size of the artifacts has been evaluated in accordance with the ASTM F2119 standard.

Note

The *in vitro* tests have shown that the operation of the ICP or ICP and ICT Monitoring Kits is not affected by exposure to a magnetic field of 1.5 to 3 Tesla (30,000 Gauss).

8. Complications / Side Effects

Complications, which may result from the implantation of a Catheter, include the inherent risks in any surgical procedure and the insertion of a foreign body.

These complications require the rapid intervention of a physician.

8.1. INFECTION

An infection is the major complication associated with this type of monitoring.

Risks of infection can be reduced by observing aseptic techniques when handling and implanting the Catheter, and by respecting the maximum duration for the Catheter implantation (6 days or 144 hours). If monitoring must be continued after this duration, implant a new Catheter on another site.

Warning

In case of infection, remove the Catheter and start a specific treatment by a general or intrathecal route.

8.2. CEREBRAL HEMORRHAGE

Cerebral hemorrhage may also be observed with this type of monitoring.

Risks of hemorrhage may be reduced by limiting the number of cerebral incisions during the introduction procedure, and by ensuring that this procedure is only performed by trained and qualified personnel.

8.3. DRAINAGE CATHETER OBSTRUCTION

Obstruction is a complication specific to the use of an intraventricular ICP monitoring Catheter.

The implantation of the Catheter end close to the choroid plexus may cause obstruction of the CSF inlet holes. This phenomenon can also occur when the CSF has a high protein content, contains blood, or if there is intra-ventricular debris such as blood clots or tissues.

This obstruction may have an impact on CSF drainage but will not have any effect on the reliability on the ICP or ICT measurement.

8.4. OVERDRAINAGE

Overdrainage is a complication specific to the use of an intraventricular ICP monitoring Catheter.

Overdrainage can result in a collapse of the ventricles and the appearance of a subdural hematoma.

9. Destruction or Return of Product

Destruction After Use

An unpacked, used or explanted Monitoring Kit should be destroyed in accordance with the procedures in force in the medical establishment.

Return of Products

Note

For more effective analysis, avoid cleaning the device.

If an explanted Monitoring Kit needs to be returned to Sophysa for analysis, indicate whether cleaning has been performed.

In order to assess the returned product properly, it must be accompanied by an explanatory Return to Manufacturer Authorization form.

10. Warranty

The performance of the Monitoring Kits is only warranted with Monitoring Systems and accessories designed, tested and manufactured by Sophysa.

Sophysa warranties that the Monitoring Kits are free of any material and manufacturing defects. Apart from this warranty, Sophysa does not provide any other warranty, express or implicit, including commercialization or adaptation for a particular use. Sophysa cannot be held responsible for any incident, complication, damage or prejudice occurring directly or indirectly from the use of this device. Sophysa does not authorize anyone whomsoever to take responsibility on its behalf for its products.

11. Symbols

Symbol	Meaning
	Catalog reference
	Serial number
	Lot number
	Manufacturer
	Sterilization Method using Ethylene Oxide
	Do not re-use
	Do not re-sterilize

Symbol	Meaning
	The Catheters are not protected against the effects of a cardiac defibrillator.
	Refer to the instructions for use
	Consult Instructions for use on our website: www.sophysa.us
	Use until
	BF TYPE EQUIPMENT: Providing an appropriate degree of protection against electric shock, having a Type BF insulated applied section (floating).
	Temperature conditions for storage and transport
	Keep away from liquids
	Fragile, handle with care
	MR Conditional. It has been demonstrated that the use of ICP or ICP and ICT Monitoring Kits within an MRI setting does not pose any risks as long as the specific conditions of use are complied with.

12. Technical Specifications

General specifications	
Item	Specification
Sensor capsule diameter	1.2 mm
Sensor capsule material	Titanium
Catheter diameter	2.1 Fr (0.7 mm) D(mm) = Fr / 3 Fr = D(mm) x 3
Catheter length	1,000 mm (radiopaque on the entire length)
Catheter sheath material	Polyamide
External drainage catheter sheath material	Silicone
Depth markers	Marking every centimeter between 5 and 10 cm from the proximal end. Additional marking at 15 cm.
Leakage current	Less than 10 µA to 120 V AC
Weight	11 g
Drill bit diameter	3.5 mm
Note The Monitoring Kits are latex- and phthalate-free.	

Pressure sensor specifications	
Item	Specification
Type of sensor	Piezoresistive with strain gauge type on silicon
Reference pressure	Atmospheric pressure
Display range (complete system)	-40 mmHg to +100 mmHg (PSO-3000) -40 mmHg to +150 mmHg (PSO-4000)
Accuracy of the pressure measurement (linearity and hysteresis) (complete system)	± 2% reading in the range 0 to 100 mmHg
Bandwith	> 100 Hz
Functional range of overpressure without damage	-700 mmHg to +1,250 mmHg
Temperature coefficient	0.1 mmHg/°C max
Input resistance	667 Ohms
Output resistance	810 Ohms
Excitation voltage	1 to 8 V AC or DC
Drift from zero	Less than 1 mmHg during the first day, at 37°C Less than 2 mmHg during the first week, at 37°C

Temperature sensor specifications	
Item	Specification
Type of sensor	Thermistor
Unit	Celsius (°C) or Fahrenheit (°F) °F = °C x (9/5) + 32 °C = (°F - 32) x (5/9) Equivalence in Kelvin (K): K = °C + 273.15 K = °F x (5/9) + 255.37
Display range (complete system)	+20 °C to +45 °C (+68 °F to +113 °F)

Temperature sensor specifications	
Item	Specification
Maximum tolerated error (accuracy) in the reference conditions (complete system)	± 0.2 °C max. from 25 °C to 45 °C (± 0.4 °F max. from 77 °F to 113 °F) ± 0.4 °C max. from 20 °C to 25 °C (± 0.7 °F max. from 68 °F to 77 °F)
Resolution	0.1 °C/0.1 °F

Environmental specifications		
Item	Specification	
Temperature	Operation Storage, transport	+10 °C (50 °F) to +40 °C (104 °F) 0 °C (32 °F) to +50 °C (122 °F)
Humidity	Operation Storage, transport	30% to 75% relative humidity 20% to 95% relative humidity
Atmospheric pressure	Operation Storage, transport	500 hPa to 1060 hPa 500 hPa to 1060 hPa

Catheter history specifications	
Item	Specification
Data accessible	First 15 days of monitoring
ICP data	A value every 20 seconds. This value is an average of the previous 20 seconds.
ICT data	A value every 60 seconds. This value is an average of the previous 60 seconds.
Note Data can only be consulted with a Pressio 2 ICP Monitor.	

13. References

PRESSIO® CATHETER KITS

PSO-PB	**Pressio® ICP Monitoring Kit, Parenchymal with Bolt**
PSO-PBT	**Pressio® ICP and ICT Monitoring Kit, Parenchymal with Bolt**
PSO-PT	**Pressio® ICP Monitoring Kit, Parenchymal Tunneling**
PSO-PTT	**Pressio® ICP and ICT Monitoring Kit, Parenchymal Tunneling**
PSO-VT	**Pressio® ICP Monitoring Kit, Ventricular Tunneling** with external CSF drainage function
PSO-VTT	**Pressio® ICP and ICT Monitoring Kit, Ventricular Tunneling** with external CSF drainage function

PRESSIO® MONITORING SYSTEM

PSO-3000	**Pressio® ICP Monitor** Power cable and Catheter extension cable (PSO-EC20) included
PSO-4000	**Pressio® 2 ICP Monitor** Power cable and Catheter extension cable (PSO-EC30) included
PSO-IN00	**Pressio® ICP Monitoring Interface** Catheter extension cable (PSO-EC20) included

PRESSIO® ACCESSORIES

PSO-EC20	**Catheter extension cable** Use only with a Pressio® ICP Monitor (PSO-3000) or a Pressio® Interface (PSO-IN00)
PSO-EC30	**Catheter extension cable** Use only with a Pressio® 2 ICP Monitor (PSO-4000)
PSO-MCxx	**Pressure cable** Use only with a Pressio® 2 ICP Monitor (PSO-4000) — MC01: PHILIPS (AGILENT) - 12 pins — MC02: SIEMENS (SIRECUST) - 10 pins — MC03: SPACELABS & MINDRAY - 6 pins — MC04: GE DATEX-Ohmeda - 10 pins — MC05: GE Solar (MARQUETTE) - 10 pins — MC08: NIHON KOHDEN - 5 pins
PSO-MCT-Y	**Temperature cable** Use only with a Pressio® 2 ICP Monitor (PSO-4000) — MCT-A: PHILIPS (AGILENT) - 2 pins — MCT-B: SIEMENS - 7 pins — MCT-C: SPACELABS - 10 pins — MCT-E: GE Solar (MARQUETTE), GE DATEX-Ohmeda - 11 pins — MCT-F: HELLIGE, DATEX-Ohmeda, NIHON KOHDEN, MINDRAY & DATASCOPE - JACK 6.35 mm
PSO-MT00	**Intracranial temperature module** Enables temperature values to be displayed on the Pressio® ICP Monitor (PSO-3000).
PSO-TX00	**Standard transmitter** Enables the pressure and temperature value to be transmitted to a computer. Use only with a Pressio® ICP Monitor (PSO-3000)
PSO-DR	**Single use, disposable drill**
PSO-MRI	**Pressio® MRI Support** For positioning Pressio® Catheter during MRI examination

Technical specifications and list of product references may be modified without notice. Availability may vary according to country.

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