SOPHYSA
At the heart of the **brain**

EN

PRESSIO® MRI SUPPORT

For optimum positioning of Pressio® Catheters during an MRI examination

Instructions for Use

CE

NT501_EN_US
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CAUTION
Federal (USA) law restricts this device to sale by or on the order of a physician.

Read the Instructions for Use carefully before using the Pressio MRI Support.

If necessary refer to the Instructions for Use for the Pressio ICP monitoring kit being used: PSO-PB, PSO-PT, PSO-VT, PSO-PBT, PSO-PTT, PSO-VTT.

1. Preamble

These Instructions for Use detail all the information required for the implementation, use and maintenance of the Pressio MRI Support (PSO-MRI), hereinafter referred to as MRI Support.

Any request for information or modification relating to these instructions should be sent to: Sophysa – 5, rue Guy Moquet – 91400 Orsay – France.

2. Intended use

The MRI Support is intended to make it possible to position Pressio Catheters in an optimum position for an MRI examination. It is indicated for use in patients implanted with a Pressio range Catheter who require an MRI examination.

3. Indications

Patients implanted with a Pressio Catheter are those requiring continuous monitoring of intracranial pressure (ICP), or who are brain-injured with a risk of intracranial hypertension and who cannot be evaluated clinically.

The MRI Support must be used in an hospital environment equipped with an MRI room, by qualified personnel only (such as nurses, radio operators or radiologists).

NOTE
The MRI support is not expected to provide any clinical benefit. Potential risks associated with the use of the MRI support could be mispositioning of the MRI support, lack of coiling or no coiling, and wrong dongle fixing.

4. Contraindications

There are no medical contraindications to the use of the MRI Support.

5. Description

NOTE
This product is a reusable device, it is not intended for single use. It must be cleaned before first use and between each patient.

The MRI Support is packaged in a parcel containing the following items:

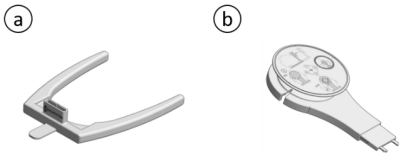
– The two unassembled MRI Support parts.
– The Instructions for Use of the MRI Support

When unpacking the parcel, check that it contains all these items and that none of them have been damaged during transport.

The MRI Support consists of two sub-assemblies delivered unassembled:

– The foot (Figure 1a), intended to be placed on the examination table and making it possible to stabilize the MRI Support assembly.
– The body of the support (Figure 1b) making it possible to coil and fix the Catheter.

Figure 1. Description of the MRI Support



6. Assembling the MRI Support

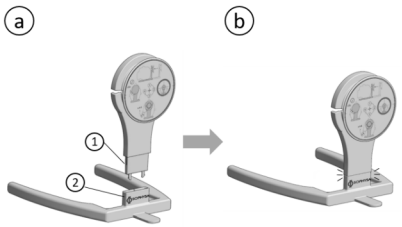
CAUTION
The two sub-assemblies of the MRI Support must be assembled before use. Once assembled, the MRI Support must no longer be dismantled.

To assemble the MRI Support proceed as follows:

1. Take the foot and body of the MRI Support out of their packaging.
2. Check that neither part has been damaged during transport.

   CAUTION
   If one or both sub-assemblies are damaged, do not assemble the MRI Support. Contact Sophysa or your local distributor.
3. Assemble the body of the MRI Support with its foot respecting the direction shown in Figure 2. The tab found on the end of the body of the MRI Support (Point 1 - Figure 2a) must be inserted up to the stop in the location provided for this on the MRI Support foot (Point 2 - Figure 2a) until a “click” is heard.
4. Make sure that the MRI Support is correctly assembled by checking that a slight traction on the body of the MRI Support does not allow the assembly to come apart.

Figure 2. Assembly of the MRI Support



7. Cleaning the MRI Support

NOTE
The MRI Support is not for single use. No sterilization is required.

CAUTION
Do not use the MRI Support if there is any soiling or visible residues on the external surface of the device.

7.1. Introduction

The MRI Support is delivered clean, but not disinfected.

Clean the MRI Support before first use and between each patient, as described here.

WARNING
Do not clean the MRI Support when in use on the patient.

WARNING
Do not sterilize, immerse, autoclave or soak the MRI Support in a liquid. Its performance could be affected.

NOTICE
Do not use solvents or cleaning agents which could damage the MRI Support, such as:

- cleaning agents based on phenols,
- cleaning by boiling,
- cleaning by hot air/steam,
- acetone, ammonia, benzene, bleaching agent, chlorine, chlorine water, water above 60°, paint solvents, trichloroethylene.

For more information, contact Sophysa Customer Service at contact@sophysa.com, or contact your local distributor.

7.2. Prerequisites

1. Put on gloves and keep them throughout the procedure.
2. Take pre-soaked wipes with 70% isopropyl alcohol (IPA).

7.3. Cleaning procedure

The purpose of this procedure is to remove any soiling and visible residues on the external surface of the MRI Support.

NOTE
Do not put excessive pressure on the product labels.

1. Clean the MRI Support for at least 1 minute using pre-soaked wipes with 70% isopropyl alcohol (IPA), to remove any visible residues.
2. Inspect the MRI Support.
   If residues remain, take a new pre-soaked wipe with 70% isopropyl alcohol (IPA) and wipe the surfaces again.

NOTE
If residues persist after multiple cleanings, stop using the device and send it back to Sophysa for replacement.

7.4. Inspection

After each cleaning procedure, visually inspect the MRI Support for any damage. Make sure that:

- markings are still visible on the device,
- both parts of the MRI Support are properly assembled,
- no crack can be found,
- there is no missing plastic part.

8. Using the MRI Support

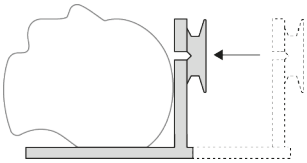
CAUTION
The Pressio Monitor (PSO-3000), Pressio 2 Monitor (PSO-4000), Catheter Extension Cable (PSO-EC20 and PSO-EC30) and the pressure (PSO-MCxx) and temperature (PSO-MCT-Y) cables are considered to be MR Unsafe (not MRI compatible) and must not be exposed to an MRI environment. Consequently, the Catheter must be disconnected from the Monitor before any MRI examination.

CAUTION
Do not use the MRI Support if the device is not properly assembled or if it is not properly placed behind the patient's head. See *Section 8.1. Preparation for the MRI examination (p. 6)*.

8.1. Preparation for the MRI examination

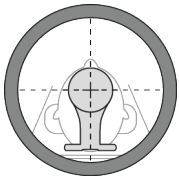
Step 1. Once the patient is installed on the MRI table, place the MRI Support on the table itself (the foot of the support in contact with the table) and place the MRI Support as close as possible to the patient's head (Figure 3).

Figure 3. Positioning of the MRI Support



Step 2. Move the MRI Support so that it is placed in the center of the table (Figure 4).

Figure 4. Centering of the MRI Support



WARNING
Make sure that the MRI Support is aligned compared to the patient's head. Do not move the MRI support compared to the patient's body axis.

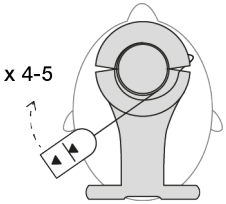
Positioning the MRI Support in a different way may induce heating of the Catheter higher than 2.2°C.

Step 3. Pass the non-implanted part of the Catheter via one of the side notches found on the body of the MRI Support, and then coil it. Depending on its length the Catheter may be coiled up to 4 or 5 times around the MRI Support (see Figure 5).

CAUTION
When rolling the Catheter handle it with care to avoid any excessive traction that could damage the Catheter.

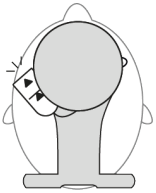
CAUTION
When handling the Catheter avoid any liquid spray on the connector as this may damage it.

Figure 5. Coiling the Catheter around the MRI Support



Step 4. Fix the Catheter dongle by clipping it laterally on the circular part of the MRI Support (see Figure 6).

Figure 6. Fixing the dongle to the MRI Support



Step 5. Before starting the MRI examination make sure the MRI Support is correctly centered and perpendicular to the primary magnetic field. If this is not the case, adjust its position.

WARNING
The MRI Support is not compatible with every Head Coil. If the device is not compatible, opt for a manual coiling of the Catheter. 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.

8.2. Performance of the MRI examination

The MRI Support is MR Safe.

The MRI specifications are described in Intracranial Pressure Catheter's Instructions for Use NT530, NT540, NT550.

8.3. Uninstalling the MRI Support

To remove the MRI Support proceed as follows:

1. Gently remove the Catheter dongle from the MRI Support.
2. Uncoil the Catheter carefully.
3. Remove the Catheter from the side notch of the MRI Support.
4. Remove the MRI Support.
5. Clean the MRI Support following the indications in *Section 9. Maintenance of the MRI Support (p. 7)*.
6. Store the MRI Support according to the indications in *Section 10.2. Storage and shipping (p. 7)*.

9. Maintenance of the MRI Support

Clean the MRI Support after each use and check the integrity of the device before using it on a new patient. Proceed to a visual inspection of the device as detailed in *Section 7.4. Inspection (p. 6)*.

If any defect is found out, proceed to the MRI Support elimination (see *Section 11. Processing the product after use (p. 7)*).

WARNING
The MRI Support must not be cleaned during use on a patient or in the presence of the Catheter.

Respect the following instructions:

– Do not use solvents or cleaning agents which could damage the MRI Support and/or its label. Refer to *Section 7. Cleaning the MRI Support (p. 6)* for more information.
– Do not autoclave the MRI Support.

10. Environmental conditions, storage and shipping

10.1. Environmental conditions

The MRI Support is designed to withstand a temperature below 60°C.

10.2. Storage and shipping

The MRI Support must be stored away from impacts and risks of dropping.

The device is designed to withstand the following conditions:

– Temperature:
  -20°C/-4.0°F
  +60°C/140°F
– Relative humidity:
  < 5%
  > 95%
– Altitude: between - 500 m and 4.600 m (corresponding to a flight altitude up to 12.000 m in a pressurized cabin).

11. Processing the product after use

11.1. Product return

Do not use a MRI Support that is damaged.

As part of its continual improvement program, Sophysa asks its customers to inform it and the legal authority of the country of any unexpected and serious problem that occurs with the product.

If any issue occurs with the MRI Support while the proper conditions of use are met, return the faulty MRI Support for proper investigation. In order to properly assess the returned product, it must be accompanied by an explanatory *Return to Manufacturer* authorization form.

11.2. Product elimination

The used MRI Support should be sent back to Sophysa for proper elimination.

NOTE

Clean the product carefully. Once cleaned (see *Section 7. Cleaning the MRI Support (p. 6)*), pull the body apart from the foot to break the MRI Support before sending it back to Sophysa.

12. Warranty

The performance and safety of the MRI Support is ensured only with the Catheter kits and the accessories designed, tested and manufactured by Sophysa.

Sophysa warrants the performance and safety of this medical device under the normal conditions of the intended use of the device, adapted to its intended purpose and use, and in accordance with these Instructions for Use.

The medical device must be stored and transported in an environment and under conditions that also comply with the information in these Instructions for Use. These storage and transport conditions have been tested and validated by Sophysa. Thus, Sophysa does not grant any other express or implicit guarantee as for the good conservation and the safety of the product in other premises than its own which would not respect these conditions. Likewise, no express or implicit guarantee is granted by Sophysa as to the suitability of the product for the use which will be made of it, or its adaptation to a particular use, except within the indications and the intended purpose of the product, or when it has been transformed, modified or repaired except within the instructions of Sophysa.

Under no circumstances, Sophysa can be held responsible in case of damages, for any incident and/or complication, resulting from damage or prejudice arising directly or indirectly from the unsuitable use of the device and/or a use of the device which fail to conform or the non-respect of its conditions of maintenance, cleaning, storage or transport.

The MRI Support has an expected lifetime of 1 year in normal use. However, the results of the visual checks prevail (see *Section 7.4. Inspection (p. 6).*) These visual checks will indicate whether or not the MRI Support can still be used.

Table 1. Date of first use

Date	

13. Symbols

REF	Catalog number
SN	Serial number
	Manufacturer
	Date of manufacture
CE	CE conformity marking
	Consult Instructions for Use
www.sophysa.us	Consult Instructions for Use on our website: www.sophysa.us
95% 5%	Humidity limitation: 5% to 95%
60°C 140°F -20°C -4°F	Temperature limits: -20°C (-4° F) to 60°C (140°F)
	Align the MRI Support properly behind the patient's head. Do not move the MRI Support compared to the patient's body axis. Wrong positioning could result in overheating.
MD	Medical Device
UDI	Unique Device Identification
MR MR	MR safe
	Keep dry
	Keep away from sunlight
℞ only	By prescription only

14. Performances and characteristics of the MRI Support

14.1. Product Performances

– MRI compatible.
– Quick and easy to assemble.
– No disassembly possible once assembled.
– Steady on the MRI table.
– Manipulation resistant.
– Cleaning resistant.
– Allows coiling of 5 cm for each coil.
– Allows dongle binding at the end of coiling.

14.2. Critical Characteristics

To ensure optimal performance of the MRI Support, check that the following conditions are met.

– Device integrity check before use.
– Proper assembly of the device.
– Device assembly check before use.
– Proper position of the MRI Support on the table.
– Proper position of the MRI Support around patient's head.
– Proper catheter coiling on the MRI Support.
– Proper dongle fixation on the MRI Support.

If the MRI Support stops working:

– Remove the catheter from the MRI Support. See *Section 8.3. Uninstalling the MRI Support (p. 7)*.
– Remove the MRI Support from the head of the patient first and then from the table.
– Clean the MRI Support. See *Section 7. Cleaning the MRI Support (p. 6)*.

15. References

Table 2. Pressio® Catheter Kits

Only use with a Pressio® Monitoring system.	
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*

Table 3. 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*

Table 4. Pressio® Accessories

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-MRI	Pressio® MRI Support

Table 5. Date of first CE marking

PSO-MRI	2017

Technical specifications and list of product references may be modified without notice.

Availability may vary according to country.

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