SOPHYSA
At the heart of the **brain**

EN

POLARIS® ADJUSTMENT KIT-2 (PAK2)

Instructions for Use

CE

NT140_EN_US
Rev000_2023-11

Table of Contents

This page is intentionally left blank.

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

CAUTION
Read these Instructions for Use carefully before adjusting the valve operating pressure.

1. Intended use

The Polaris Adjustment Kit-2 is intended to read and change the operating pressure of a Polaris valve in order to adapt to the clinical need and evolution of the patient.

2. Indications

The Polaris Adjustment Kit-2 is indicated for patients implanted with a Polaris valve to treat hydrocephalus, subarachnoid cysts, or idiopathic intracranial hypertension (IIH), also called Pseudotumor cerebri.

3. Patient populations

The device can be used on patients of all ages, including pre-term infants.

4. Environment of use

Post-operative follow-up is done at the hospital (consultation, imaging service, emergency room), clinic or doctor's office.

The device must only be used by a neurosurgeon. It is not intended for use in a patient's home. Patients are never expected to use the device by themselves.

5. Contraindications

This device is not intended for any use other than those indicated in these Instructions for Use.

6. Description

The rotor of the Polaris valve is fitted with a patented magnetic locking system made up of two mobile micro-magnets.

Changing the operating pressure of the Polaris valve is performed through the skin via a magnetic field using an adjustment kit made up of 3 parts:

– Locating instrument (hereinafter referred to as Locator),
– Reading instrument (hereinafter referred to as Compass),
– Setting instrument (hereinafter referred to as Magnet).

For simplicity, for the rest of these Instructions for Use, the “operating pressure of the valve” will be referred to as “pressure”.

Figure 1. Polaris Adjustment Kit-2

Contains a Magnet, a Locator, a Compass, the present Instructions For Use and a Quick Start Guide.

The Polaris Adjustment Kit-2 (hereinafter referred to as PAK2) is designed specifically for setting the pressure of the Polaris valves.

It is not made with natural or synthetic latex.

The components of the PAK2 are packaged non-sterile in a reusable box with magnetic shielding.

CAUTION
The PAK2 must not be used in an MRI environment.

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.

6.1. Locator

The Locator is used to locate the valve through the skin.

It is designed to work with Polaris valves regardless of their pressure range (see *Table 1*).

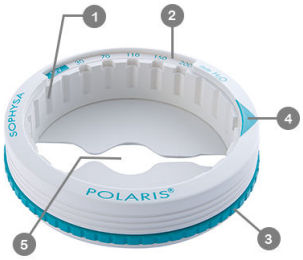
It houses the Compass and the Magnet in turn.

The Locator is the only component to be in contact with the patient's skin for a limited time (a few minutes) when checking or adjusting the pressure. When used post-operatively, the Locator must be used through a dressing to avoid direct contact with the scar tissue.

Table 1. Table of pressures for Polaris valves

Valve model listed on the Locator	**SPV-140**	**SPV**	**SPV-300**	**SPV-400**
References concerned	SPV-140, SPV-140-SX, SPVA-140, SPVA-140-SX	**SPV, SPV-2010, SPV-SX, SPVA, SPVA-2010, SPVA-SX, SPVB, SPVB-2010**	SPV-300 SPVA-300	SPV-400 SPVA-400
Radiographic identification of the model	0 point	**1 point**	2 points	3 points

Valve model listed on the Locator		SPV-140	SPV	SPV-300	SPV-400
Available pressures (mmH_2O)	1	10	**30**	50	80
	2	40	**70**	100	150
	3	80	**110**	150	230
	4	110	**150**	220	330
	5	140	**200**	300	400
* The pressures are expressed in mmH_2O. 1 mmH_2O corresponds to 9.807 Pa or 0.074 mmHg.					



[1] Vertical grooves. Used to ensure the correct positioning of the Compass and the Magnet inside the Locator.

[2] Reading area. Shows the valve model on the left and each of the five pressure levels associated with this reference.

[3] Rotating ring. Used to select the reading area corresponding to the valve model to be adjusted.

See *Table 1* to determine the valve model and the pressure range to be displayed.

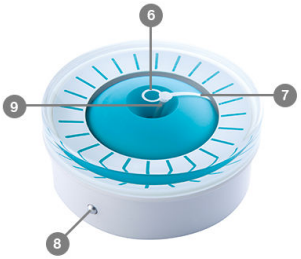
[4] Arrow showing the direction of the CSF flow. Used to position the Locator correctly in relation to the valve.

[5] Central cut-out area. Used to center and position the Locator accurately and as closely as possible to the valve.

6.2. Compass

The Compass fits into the Locator and enables direct reading of pressure values.

The needle indicates the exact orientation of the valve rotor. When used in conjunction with the Locator, the Compass enables the valve pressure to be read.



[6] Central target. Used to refine the position of the Compass above the valve.

[7] Needle. Indicates the orientation of the valve rotor.

[8] Lateral lugs. Used to vertically guide the Compass into the internal grooves of the Locator.

[9] Compass needle shaft. To be centered in the target.

6.3. Magnet

CAUTION
Keep the Magnet away from electromedical devices for care or diagnosis (i.e. pacemaker, patient monitor, electronic measuring devices, imaging devices, etc.). The magnetic field of the Magnet could provoke electromagnetic disturbance and altere their operation.

CAUTION
Do not store or handle the Magnet near any device likely to be altered by a powerful magnetic field.

CAUTION
Do not move the Magnet close to a powerful magnetic field (e.g. MRI). It could become a dangerous projectile or its performance could be affected.

CAUTION
Handle the Magnet with care near metal objects (e.g. hospital furniture). They could become violently attracted.

The Magnet is made up of a specific assembly of magnets designed to enable the rotor to be unlocked and the pressure of the Polaris valve to be adjusted.

To operate correctly, the Magnet must be properly centered above the valve and aligned with the valve rotor.

The Magnet fits into the Locator.

It makes it possible to adjust the pressure by rotating the Magnet.

[10] Blue mark. Used to align the Magnet with the valve rotor using the indication given by the Compass.

[11] Lateral lugs. Used to vertically guide the Magnet into the internal grooves of the Locator.

[12] Handle.

The Magnet handle can be off-centered towards the front or the back to be able to make backwards and forwards movements.

Removing the Magnet causes automatic re-locking of the valve rotor via mutual attraction of the two mobile micro-magnets.

CAUTION
Always remove the Magnet from the Locator vertically. This ensures that the rotor is optimally locked in its new pressure. Failure to do so may cause the selected pressure to change and/or result in incorrect locking of the rotor.

6.4. Demonstration valve

A demonstration valve is supplied in the adjustment kit. It provides training for adjusting the valve while displaying changes in the position of the rotor during the adjustment procedure.

7. Cleaning and disinfection procedure

7.1. Introduction

The adjustment kit is delivered clean, but the Locator is not disinfected.

While the risk of infection is low (limited contact with the skin, either healthy skin or scar tissue), clean all the adjustment kit components and disinfect the Locator before first use and between each patient, as described in this section.

CAUTION
Do not sterilize or immerse the adjustment kit components. Irreversible alterations to the markings, distortion of the plastic parts and/or demagnetization of the Magnet risk rendering the adjustment kit unusable.

CAUTION
Non-adherence to the disinfection rules described in this section could induce a risk of microbial contamination.

NOTICE
Do not use solvents or cleaning/disinfectant agents which could damage the kit components:

- phenol-based cleaning/disinfectant agents,
- cleaning/disinfection by boiling,
- cleaning/disinfection with hot air/steam,
- acetone, ammonia, benzene, bleach, chlorine, chlorinated water, water above 60°, paint thinners, 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 residue from the external surfaces of the adjustment kit components.

1. Clean the components for at least 1 minute using pre-soaked wipes with 70% isopropyl alcohol (IPA), to remove any visible residue. Change the wipe between each component.
2. Inspect the components.
   If residue remains, take a new pre-soaked wipe with 70% isopropyl alcohol (IPA) and wipe the surfaces again.

   NOTE
   Repeat this step until all visible residues are removed from all components.
3. Disinfect the Locator as described in the following section.

7.4. Disinfection procedure

The purpose of this procedure is to remove any microorganisms present on the Locator.

WARNING
Disinfect the Locator before first use and between each patient. Failure to do so may provoke an infection, leading to surgery.

1. Thoroughly wipe the Locator using pre-soaked wipes with 70% isopropyl alcohol (IPA). It must remain visibly wet for at least 2 minutes.
   Take extra care when disinfecting the base of the Locator which is in contact with the patient's skin.
   If needed, use additional wipes to ensure continuous 2 minutes of wet contact time.
2. Let the Locator completely air dry for 1 hour before using it again.

7.5. Inspection

After each cleaning and disinfection procedure, visually inspect the components for any damage. See *Section 9.1. Visual checks (p. 11)*.

8. Reading and adjusting the valve

CAUTION
Do not use the adjustment kit in the operative field. As the adjustment kit cannot be sterilized, using it during the operation would cause a high risk of infection for the patient.

CAUTION
Changing the valve pressure must only be done by a neurosurgeon.

CAUTION
When reading or adjusting the pressure, make sure that the Magnet, or any other ferromagnetic object, is located more than 50 cm away from the Compass so that this reading cannot be falsified by the influence of magnetic fields.

CAUTION
Do not use an adjustment kit without previously checking under the Locator that it corresponds to the valve model used.

Overdrainage or underdrainage can result from taking a reading and/or adjustment with a pressure range on the Locator different from that of the implanted valve model.

Figure 2. Bottom of the Locator

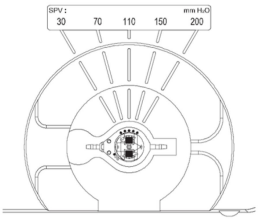
The reference "PAK2-LI" and the sentence "Designed exclusively for use with POLARIS® SPV series" are there to make sure to use the Locator with the right valve model.

8.1. Adjusting the pressure prior to implantation

WARNING
Do not unpack or implant the valve without having checked its integrity and functioning, and without previously adjusting it to the initial operating pressure defined by the neurosurgeon.

Before opening the sterile packaging, it is necessary to adjust the rotor in the position that corresponds to the pressure selected by the surgeon for the implantation.

The double sterile packaging for each Polaris valve includes a housing specifically for adjusting the valve through the packaging.



8.1.1. Checking the compatibility between the valve and adjustment kit

1. Check the model and pressure range of the valve to be adjusted against the label on the packaging.
2. Check under the Locator that it is compatible with the valve model used:
   - reference is PAK2-LI,
   - sentence says "Designed exclusively for use with POLARIS® SPV series".

8.1.2. Displaying the correct pressure range on the Locator

CAUTION
Do not use an adjustment kit without ensuring that the pressure range visible on the Locator corresponds to the valve model to be implanted.

1. Check that the pressure range displayed in the Locator reading area corresponds to the previously identified valve model.
2. If this is not the case, display the pressure range which corresponds to the model of the valve to be implanted:
   a. Hold the Locator with one hand.
   b. Turn the rotating ring until a "click" is heard. This click guarantees that a complete pressure range is displayed.
   c. Repeat the operation until the valve model used appears at the left end and the 5 pressures are visible.

8.1.3. Positioning the Locator

Position the Locator in the place provided on the shell of the outer packaging, centered above the valve, with the arrow of the Locator pointing in the direction of the CSF flow as shown by the arrow on the valve.

8.1.4. Reading the pressure

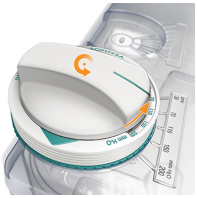
1. Insert the Compass fully into the Locator.
   Align the lines on the Compass with the pressure values printed on the Locator, if this is not already the case.
2. On the Locator, read the pressure value shown by the Compass needle.

NOTE
Reading of the pressure can also be performed visually without using the adjustment kit, as the rotor and the radiopaque points are visible through the valve and the double sterile packaging.

8.1.5. Adjusting the pressure

1. Remove the Compass.
2. Align the mark of the Magnet with the pressure read in the previous section, and slide the Magnet vertically into the Locator without changing the orientation of the Magnet.
3. Turn the Magnet until it reaches the position chosen as the pressure for the valve to be implanted.

NOTE
Do not attempt to turn the Magnet if it is not completely inserted into the Locator. The unlocking of the valve rotor and its drive could otherwise be compromised.



4. Place the Magnet more than 50 cm from the valve.

8.1.6. Checking the pressure setting

Reinsert the Compass in order to check the pressure, or check the setting visually on the valve.

8.1.7. Recording the pressure selected for the implantation

Note the pressure value read in the previous step on the Patient Identification Card (PC-AJUS) and make sure to hand the card to the patient.

8.2. Reading and/or changing the valve pressure after implantation

CAUTION
The operation scar and/or post-operative edema can make positioning the Locator painful and inaccurate. This could then cause difficulties in adjustment or even make it temporarily impossible.

8.2.1. Identifying the valve model

1. Check the model and pressure range of the Polaris valve to be adjusted:
   - on the Patient Identification Card or in the patient's medical record (traceability label),
   - and/or with an X-ray examination of the valve.
     See Instructions for Use *Polaris® valve, Section "Post-operative X-ray examination: identification of the valve model and pressure reading"*.
2. Check under the Locator that it is compatible with the valve model used:
   - reference is PAK2-LI,
   - sentence says "Designed exclusively for use with POLARIS® SPV series".

8.2.2. Displaying the correct pressure range on the Locator

CAUTION
Do not use an adjustment kit without ensuring that the pressure range visible on the Locator corresponds to the valve model to be adjusted.

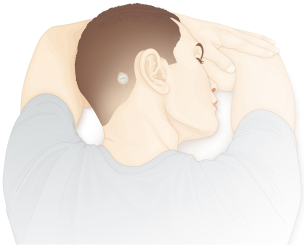
1. Check that the pressure range displayed in the Locator reading area corresponds to the previously identified valve model.
2. If this is not the case, display the pressure range corresponding to the implanted valve model:
   a. Hold the Locator with one hand.
   b. Turn the rotating ring until a "click" is heard. This click guarantees that a complete pressure range is displayed.
   c. Repeat the operation until the valve model used appears at the left end and the 5 pressures are visible.

8.2.3. Positioning the patient

CAUTION
Make sure the patient stays still during the adjustment of the pressure.

If the patient moves, it could lead to a slight offset in relation to the valve, when positioning the Locator. Thus, being off-center could create a gap between the pressure originally selected by the surgeon, and the pressure set in the end, potentially leading to overdrainage or underdrainage.

Position the patient so that the valve is as horizontal as possible and the implantation site is easy to access.



8.2.4. Positioning the Locator

1. Palpate the valve implantation site in order to determine both the location and orientation of the valve.

First find the inlet and outlet connectors, at each end of the valve, and the reservoir (if fitted). These are the easiest components to locate.

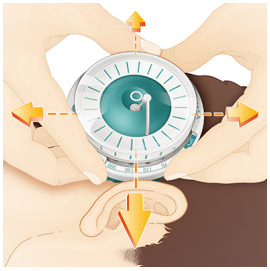
2. Place the Locator on the implantation site with its axis aligned with that of the valve connectors, and with the arrow of the Locator pointing in the direction of the CSF flow.
3. Center the Locator as well as possible over the valve: locate the valve by palpating it through the central cut-out of the Locator.

4. Press the Locator against the valve so as to center and immobilize it above the valve.

NOTE
If palpating the valve is difficult, orienting the Locator in relation to the valve, may be difficult. In this case, the stop method described in *Section 10.2. Stop method (p. 12)* can ensure alignment.

8.2.5. Reading the pressure

1. Hold the Locator with one hand so as not to lose the reference position.
2. Insert the Compass fully into the Locator.
   Align the lines on the Compass with the pressure values printed on the Locator, if this is not already the case.
3. Center the shaft of the Compass needle in the circular target by sliding the Locator-Compass assembly over the skin until it is above the valve.



CAUTION
Being off-center could cause an incorrect pressure reading and/or incomplete unlocking of the valve rotor. This may falsify the change of pressure.

The Compass needle aligns with one of the lines on the contour of the Compass and the corresponding pressure value in the reading area of the Locator.

The Compass needle may be aligned between two positions due to the Locator incorrect orientation. In this case:

   a. Re-perform the positioning of the adjustment kit components from the start.
   b. The Compass should now be aligned on one position only. If there is no change:
      – if the initial pressure is known: turn the Locator-Compass assembly slightly so as to align the Compass needle on the indicator corresponding to the initial pressure,
      – if the initial pressure is unknown: perform the stop method described in *Section 10.2. Stop method (p. 12)*.
4. On the Locator, read the pressure value shown by the Compass needle.

Under the recommended implantation conditions, X-ray examination is optional as the pressure can be read directly via the adjustment kit.

However, since X-ray examination provides absolute proof of the valve adjustment, it is especially recommended in the following cases:

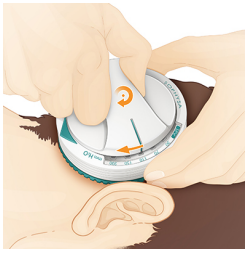
– If there is a disparity between the pressure read and the value listed on the Patient Identification Card (PC-AJUS) and/or on the X-ray used to identify the valve model.
– If the valve was implanted too deeply, under more than 8 mm of subcutaneous tissue. See Instructions for Use *Polaris® valve, Section "Valve"*.
– If the user is not familiar with the use of the adjustment kit.

8.2.6. Setting a new pressure

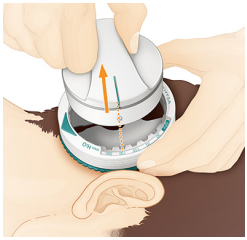
1. To avoid losing the reference position, hold the Locator with one hand until the end of the procedure.
2. Remove the Compass, memorizing the pressure that it indicates.
3. Insert the Magnet, aligning the mark on the memorized pressure.

4. Turn the Magnet until it reaches the position chosen as the new valve pressure.

> **NOTE**
> Clockwise rotation increases the pressure of the valve, while counter-clockwise rotation reduces it.



5. Remove the Magnet vertically to ensure effective re-locking of the valve rotor in the selected position.



6. Place the Magnet more than 50 cm from the valve.

8.2.7. Checking the pressure setting

Verification is performed using the Compass in accordance with the procedure described previously.

> **CAUTION**
> Adjusting the pressure using an adjustment kit requires experience. If you are not familiar with the kit, it is recommended that you check the pressure adjustment via X-ray.

> **CAUTION**
> The pressure setting may not always be performed on first attempt. Do not hesitate to repeat the adjustment procedure several times from the beginning, starting from the positioning of the Locator, in order to be sure that the desired pressure setting is obtained.

In case of difficulties with adjustment, make sure that:

- the patient is positioned so that the valve is fully horizontal,
- the centering operations were properly carried out.

If adjustment difficulties persist, see *Section 10. Solutions in case of difficult adjustment (p. 11)*, which explains the measures to be taken if adjustment is difficult.

8.2.8. Recording the new pressure

Note the pressure value read during verification on the Implant Card.

8.2.9. Post-adjustment monitoring

It is advisable to monitor the patient carefully for 24 hours following any change in pressure setting.

9. Checking the performances of the adjustment kit

Although, there is no maintenance to perform on the adjustment kit, it is recommended to check it with each use. The following checks will ensure that the adjustment kit is fully functional, and that it is not damaged in any way.

Failure to perform the checks described in this section may cause injuries to the patient, the major risk being overdrainage or underdrainage, which would require medical treatment.

> **NOTE**
> The use of the adjustment kit has been tested over 5 years. However, the results of the following checks prevail. They will indicate whether or not the adjustment kit can still be used.

9.1. Visual checks

Perform the following visual checks:

- Make sure the markings and labels on the components of the kit are complete and legible.
- Check that the Magnet handle moves properly to perform backwards and forwards motions.

> **NOTE**
> Air bubbles may appear inside the Compass. They do not have any impact on the product performances.

9.2. Functional check

Perform several adjustments on the demonstration valve supplied with the adjustment kit to make sure the adjustment kit works properly.

10. Solutions in case of difficult adjustment

The following situations may lead to inaccurate reading of the pressure by the Compass and/or adjustment difficulties with the Magnet:

- the patient is in a position that prevents the valve from being horizontal,
- the Locator is offset from the center of the valve by more than 2 mm,
- the Locator is poorly oriented in relation to the flow path,
- the base of the Locator and the surface of the valve are not parallel.

Before doing anything else, check that the Locator is correctly positioned and oriented above the valve. See *Section 8.2.3. Positioning the patient (p. 9)* and *Section 8.2.4. Positioning the Locator (p. 9)*.

However, other causes may intervene and cause adjustment difficulties.

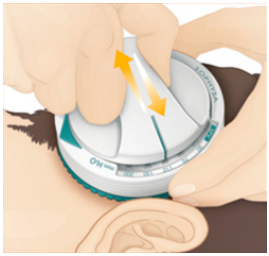
Special procedures, described below, may then be applied to facilitate adjustment of the valve, possibly using fluoroscopic control.

10.1. Backwards and forwards movement of the Magnet

Unlocking the mobile micro-magnets within the Polaris valve may be difficult if the CSF is viscous or contains debris.

In this case, performing multiple backwards and forwards motions can facilitate the unlocking of the micro-magnets:

1. Using the Compass, position the Locator above the valve as described for normal operation.
2. To avoid losing the reference position, hold the Locator with one hand until the end of the procedure.
3. Remove the Compass.
4. Align the mark on the Magnet on the pressure read to insert the Magnet vertically in the Locator.
5. Slide the handle of the Magnet back and forth along the axis of the pressure read.



6. Recenter the handle of the Magnet.
7. Turn the Magnet until it reaches the position chosen as the pressure for the valve to be implanted.
8. Remove the Magnet vertically to ensure effective relocking of the valve rotor in the selected position.
9. Place the Magnet more than 50 cm from the valve.
10. Insert the Compass fully into the Locator to confirm the new pressure.

10.2. Stop method

The correct orientation of the Locator in relation to the valve's flow path is essential for an accurate reading of the Compass.

Under thick skin, the connectors are sometimes difficult to locate, which makes it difficult to accurately determine the optimum orientation of the Locator.

In this case:

– If the current pressure of the valve is known (up to date Patient Identification Card or recent X-ray), the orientation of the Locator can be corrected with the Compass during the reading, by turning the Locator-Compass assembly slightly so as to align the Compass needle on the known pressure of the valve.

– If the current pressure is not known with certainty, only the stop method described below will ensure correct reading. This entails adjusting the valve to one of its end positions (or stops). This makes it possible to correct the orientation during the reinsertion of the Compass.

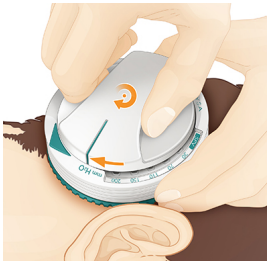
> **NOTE**
> The maximum position is usually selected as the stop so as to favor the reduction of drainage during handling.

Stop method

Following the initial reading, the Locator is centered and the Compass needle indicates a pressure.

Follow the steps described below to ensure the Locator correct orientation:

1. Without moving the Locator:
   a. remove the Compass,
   b. align the mark on the Magnet on the pressure read and insert the Magnet vertically in the Locator.
2. Turn the Magnet until it reaches the extreme position selected.
3. Then move two positions past stop.



4. Remove the Magnet vertically to ensure effective relocking of the valve rotor in the selected position.
5. Place the Magnet more than 50 cm from the valve.
6. Insert the Compass fully into the Locator.

If the valve is now set on the stop, the Compass needle indicates the direction corresponding to the extreme position selected.

If this correctly matches the indication of the Locator, it is correctly oriented and the initial reading was correct.

Otherwise, as described below, it is possible to correct the Locator orientation and to determine what the real initial pressure actually was before correction, based on the model of the implanted valve.

On the Locator, count the number of positions between the previously selected stop and the position showed by the Compass.

– If the needle is to the left of the desired stop, add this number of positions to the position originally read.
– If the needle is to the right of the desired stop, subtract this number of positions to the position originally read.

Example

In this example, the needle is offset by one position to the right (in the reading direction) from the desired stop. Therefore, you need to subtract one position to the initial reading to know the real initial setting.

If a correction is necessary, follow the instructions below:

1. Turn the Locator-Compass assembly until the needle is perfectly aligned with the extreme pressure value selected.
2. If necessary, recenter the shaft of the Compass needle in the target.

From this point forward, the Locator is perfectly positioned in relation to the valve, which makes final adjustment possible.

10.3. Adjusting without the Locator

In case of an implantation deeper than recommended, the standard procedure may be performed without the Locator when adjusting a new pressure. The Magnet is thus closer to the valve.

NOTE
This technique without the Locator concerns pressure adjustment only. Pressure levels must be read and confirmed in accordance with standard procedure and/or by X-ray examination.

1. Follow the usual procedure to position the Locator using the Compass.
2. Draw two marks on the skin with a marker:
   – one indicating the axis corresponding to the current pressure of the valve, indicated by Compass needle,
   – the other indicating the axis corresponding to desired pressure, known with the Locator.
3. Remove the Locator-Compass assembly and place the Magnet in the same place, directly on the implantation site, oriented in the direction corresponding to the current pressure, located in the previous step.
4. Hold the base of the Magnet:
   a. If necessary, slide the handle of the Magnet back and forth multiple times along the axis of the current pressure to unlock the rotor.
      Ensure it remains correctly centered and in the axis of the valve.
   b. Recenter the handle of the Magnet.
5. Keeping the Magnet as centered as possible, turn it until it reaches the axis corresponding to the desired pressure.
6. Remove the Magnet vertically to ensure effective relocking of the valve rotor in the selected position.
7. Check the setting using the Compass and Locator or with an X-ray.

10.4. Specific case of valves implanted upside down

Upside-down implantation (but with the flow direction respected) will be recognizable on X-ray.

NOTE
For a valve implanted on the skull, the five radiopaque dots should be either pointing toward the patient's nose (if the valve is implanted on their right side) or pointing away from their nose (if the valve is implanted on their left side).

If the valve is implanted upside down, setting is possible but must be performed using the following sequence:

1. Position the Locator in the opposite direction of the flow (arrow towards the inlet connector).
2. Center the Locator-Compass assembly using the target of the Compass.
3. Carry out the reading and then the adjustment in accordance with the steps described in *Section 8.2. Reading and/or changing the valve pressure after implantation (p. 9)*, using the symmetrical indication on the Locator.
   For example, the indication 200 mmH_2O corresponds to a value of 30 mmH_2O.
4. Check the new adjustment by X-ray examination.

10.5. Reading of valves implanted in conditions other than those recommended

The implantation of a valve not performed under the recommended conditions may lead to a Compass reading of a pressure value inconsistent with the patient's medical record or clinical status.

See the Instructions for Use *Polaris® valve, Section "Implantation Technique*, for more information.

In this case, X-ray examination will dispel any doubts as it provides absolute proof of the correct adjustment of the valve and the correct direction of its implantation.

11. Storage

CAUTION
Due to the power of its magnetic field, the Magnet must be stored in its shielded case when it is not being used.

CAUTION
Do not expose the adjustment kit to temperatures higher than 50°C (122°F). The function of the Magnet could be adversly altered.

CAUTION
Do not store the adjustment kit close to a source of magnetic fields to preserve the ability of the magnet to function properly.

Keep all the components of the adjustment kit together in their original shielded case after use, or when stored.

Store the shielded case in a cool, dry place away from light.

The products are designed to withstand a storage temperature up to 50 °C (122 °F).

12. Processing of the products after use

12.1. Products return

To return a faulty product, contact a Sophysa representative to obtain the explanatory return form to be provided.

Do not do anything to the product so that its condition during analysis is as representative as possible.

Return all the components of the adjustment kit in its original shielded case.

12.2. Products elimination

CAUTION
The Magnet contains components that must be disposed of properly. Failure to do so may lead to environmental pollution.

Clean the product carefully (see *Section 7. Cleaning and disinfection procedure (p. 7)*) and send the product back to Sophysa for proper elimination, in its original shielded case.

13. Monitoring of the product safety

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 problems that occur with the product.

14. Warranty

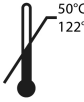
The performance and safety of the adjustment kit is ensured only with the Polaris range of valves, designed, tested and manufactured by Sophysa.

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.

15. Symbols

	Catalogue number
	Serial number
	Medical Device
	Unique Device Identification
	Manufacturer
	Date of manufacture
	Consult Instructions for Use
DO NOT STERILIZE	Do not sterilize
	Keep dry
	Keep away from sunlight
	Upper limit of temperature: up to 50 °C (122 °F)
	Powerful magnet
	MR Unsafe
	By prescription only
	CE conformity marking

16. References

Table 2. Polaris® Adjustment Kit-2 (PAK2)

PAK2-LI	Polaris® Locating Instrument-2
PAK2-SI	Polaris® Setting Instrument-2
PAK2-RI	Polaris® Reading Instrument-2
PAK2	Polaris® Adjustment Kit-2 (including the three previous components)

Year of first CE marking: 2008

This page is intentionally left blank.

This page is intentionally left blank.

This page is intentionally left blank.

SOPHYSA
At the heart of the **brain**

Sophysa
5, rue Guy Moquet
91400 Orsay
France
Tel.: +33 (0)1 69 35 35 00
Fax: +33 (0)1 69 35 36 90
contact@sophysa.com

Sophysa Benelux
Axis Parc
Rue Emile Francqui, 4
B-1435 Mont-Saint-Guibert
Belgium
Tel.: +32 (0)10 81 45 30
Fax: +32 (0) 10 81 43 04
infobenelux@sophysa.com

Sophysa USA
503 E Summit Street, Suite 5
Crown Point, IN 46307
USA
Tel.: +1 219 663 7711
Fax: +1 219 663 7741
contact@sophysa.us

www.sophysa.com

NT140_EN_US
Rev000_2023-11