SPINERY

SPINE RECOVERY DEVICE

Instructions for use

SPINERY® Cooling Connection
SPINERY® RF Generator Accessory

Class IIb active medical device

CE 0051

Manufacturer:

AXON S.r.l.

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REVISIONS

DATE	REVISION	DESCRIPTION
31/07/2025	00	First release

INDEX

1 DEVICE IDENTIFICATION

1.1 Device Name

Spinery® Cooling Connection (REF: SP-CSEU, SP-CDEU)

1.2 Device configurations/variants

Spinery® Cooling Connection is an accessory of the Spinery® RF Generator, is available in the following variants:

- REF: SP-CSEU
  Single connection cooling tubes, intended for use with single bipolar probe.
- REF: SP-CDEU
  Dual connection cooling tubes, intended for use with two simultaneous bipolar probes (parallel or cross ablation configuration).

Both variants are supplied sterile and disposable.
The sterilization method is ethylene oxide (EtO), validated according to ISO 11135:2014.

The Spinery® Cooling Connection device is a disposable, sterile accessory designed to allow the connection of bipolar probes to the integrated cooling components of the Spinery® RF Generator, ensuring adequate temperature control during radio frequency (RF) energy delivery. These are sterile, single-use accessories that allow the connection of bipolar probes to an external cooling system. They ensure adequate temperature control during energy delivery. Operation is via the peristaltic pump integrated in the Spinery® RF Generator, which converts the mechanical energy of the generator into kinetic energy of the circulating fluid. The latter modifies the thermal profile of the probe through heat exchange, ensuring that the proximal rod maintains temperatures below critical thresholds.
The Spinery® Cooling Connection device should only be used in conjunction with:

- the Spinery® RF Generator (see dedicated IFU)
- the Spinery® Kit device (see dedicated IFU)

To ensure safe and compliant use of the system as a whole, it is also mandatory to consult:

- the IFU of the Spinery® RF Generator, which describes in detail the operation of the peristaltic pump, the RF energy delivery methods, the clinical parameters and the operating screens;
- the IFU of the Spinery® Kit device, which provides instructions regarding probe placement, bone access, and procedure preparation.

2 MANUFACTURER'S INFORMATION


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3 SYMBOLS

3.1 Label Symbols

SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION
	Medical device		Ethylene oxide sterilized: Indicates a medical device that has been sterilized with ethylene oxide.
	UDI: Indicates the UDI code of the medical device.		Double Sterile Barrier System
	Lot: Indicates the batch of the medical device.		Double Sterile Barrier System with protective packaging outside
	CE Mark: Identifier for CE mark		Keep dry
	Model: Indicates the model of the medical device.		Keep away from sunlight
	See the instructions for use: Indicates the need for the user to consult the operating instructions.		Indicates the temperature range to which the medical device can be safely exposed.
	Manufacturer: Indicates the manufacturer of the medical device		Humidity limitation Indicate acceptable upper and lower limits of relative humidity for transportation and storage
	Date of production		Applied Part Type BF Identifies a Type BF applied part that complies with IEC 60601-1
	Expiry date: Indicate the date by which the medical device should be used.		Do not reuse A medical device intended to be used only once or on a single patient during a single procedure.

Table 1 – Spinery® Cooling Connection Label Symbols

3.2 Guide to using the manual

This manual contains essential information for the safe, effective and compliant use of the Spinery® Cooling Connection medical accessory device, sterile and disposable, designed to allow cooling of Spinery® Kit. The device should only be used by qualified and adequately trained healthcare professionals, in accordance with local legislation in force and in accordance with Regulation (EU) 2017/745 (MDR). Before use, it is essential that you carefully read and understand the instructions contained in this IFU.

This manual is an integral part of the Spinery® Cooling Connection device and should be kept in an accessible place for future reference.

The following terms may be used herein:

CAUTION:
Highlights a security issue. Always follow this information to prevent injury to patients and/or healthcare personnel.

ATTENTION:
Highlights a problem related to the reliability of the product. Always follow this information to prevent damage to the product.

NOTES:
Supplements and/or clarifies procedural information.

4 SAFETY GUIDELINES

4.1 General Safety

 ATTENTION

- The Spinery® Cooling Connection accessory device should only be used by qualified healthcare professionals, who must have read and understood these operating instructions in full prior to handling and use.
- The healthcare professional responsible for the procedure must assess the clinical suitability of the device for each individual patient. AXON, as a manufacturer, does not recommend or prescribe specific surgical techniques or interventional modalities.
- Do not modify or alter the Spinery® Cooling Connection device or its components in any way. Any alteration may compromise the safety, efficacy and sterility of the product.
- Store and transport the device only under the recommended environmental conditions, as stated on the label and packaging.
- Do not use the device beyond the expiration date stated on the sterile packaging. Sterility and functional integrity cannot be guaranteed beyond this date.
- Always perform a visual integrity check of the sterile package before use. If the packaging is damaged, opened or visibly compromised, do not use the device.
- Check the mechanical integrity of the connection hose and connectors before connecting to the generator or probes.
- For correct use in combination, please refer to the dedicated IFUs:
    - to the Spinery® RF Generator, for the settings and management of cooling components;
    - to the Spinery® Kit, for the positioning of the probes and the manual infusion methods.
- In the event of an obvious abnormality (breakage, leakage, deformation), do not use the device and contact AXON or the authorized technical service immediately.

4.2 Magnetic Resonance Imaging (MRI) Safety

- Spinery® Cooling Connection is not compatible with Magnetic Resonance Imaging (MRI).

⚠ ATTENTION

- Do not introduce or use any component within MRI environments or RF shielded rooms dedicated to MR imaging. Use other than those indicated may result in serious injury or death to patients and caregivers. For more information on general electromagnetic safety, see the IFUs dedicated to the Spinery® RF Generator.

5 DEVICE DESCRIPTION

The Spinery® Cooling Connection is an accessory, sterile, disposable medical device designed to be used exclusively in conjunction with the Spinery® RF Generator and the cooled bipolar probes provided in the Spinery® Kit.
Its function is to allow the controlled circulation of sterile saline solution within the probes, in order to ensure continuous cooling during the delivery of radio frequency (RF) energy.
This function is essential to improve thermal safety, reduce the risk of tissue charring and ensure effective energy distribution during the ablation procedure.
Spinery® Cooling Connection is a non-invasive device, external to the patient's body, which operates passively for the transfer of the refrigerant solution through the internal channels of the probes, by means of the generator pumping system.
The device consists of:

- Transparent, sterile, disposable hose with connectors compatible with generator outlet ports and cooled probe inlet ports.
- Any jointing components or fittings, pre-assembled, ready to use.

It is supplied in single, sealed and sterile packages, with indication of the lot, expiry date and UDI code.
Sterilization is carried out using ethylene oxide (EtO), validated according to ISO 11135:2014.

ⓘ NOTE: The Spinery® Cooling Connection does not come into direct contact with the patient but plays an essential role in the proper functioning of the cooled probes during ablation

Spinery® Cooling Connection (Spinery® RF Generator Accessory):

Spinery® Cooling Connection	
REF	COMPONENT
SP-CSEU	Single cooling tube – for use with single probe
SP-CDEU	Dual cooling tube – for use with two probes for double access (parallel or cross)

Table 2 – Models of Cooling Connections

5.1 Cooling Connections

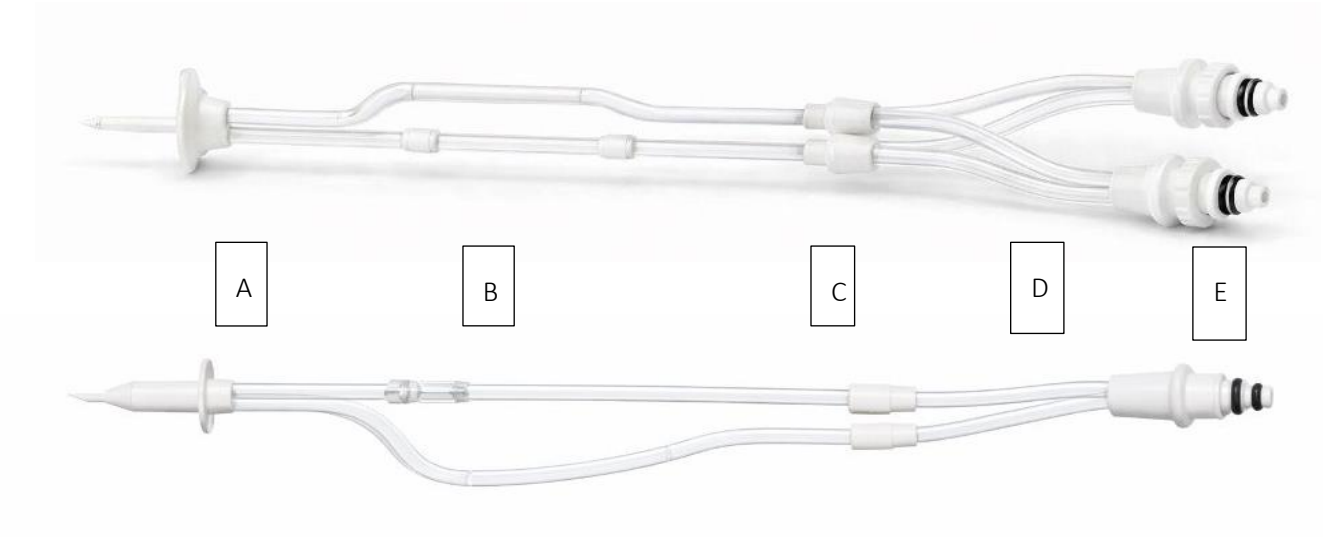

Figure 1 – Spinery® Cooling Connections

Features of cooling component connections	
A	Peak Cooling Link – Allow connection between the cooling link and the saline water pocket.
B	Propulsion hose - specific silicone part of the cooling connection hose to be placed in the peristaltic pump to ensure a return of saline water flowing to the probe
C	Cooling Connection Port – Allow connection between the cooling connections tubing and the probe
D	Inlet Cooling Connection Hose – Allows saline water to flow from the bag to the probe
E	Outlet Cooling Connection Hose – Allows the flow of saline water from the probe to the saline water bag.

Table 3 - Characteristics of the Spinery® Cooling Connections

⚠ WARNING: Condition of components at the time of delivery

The cooling connections are supplied sterile (they undergo a validated ethylene oxide sterilization process) and are single-use. Their reuse can cause harm to the patient and/or the transmission of infections from one patient to another.

6 INTENDED USE

The sterile, single-use Spinery® Cooling Connection accessory device is designed to be used exclusively in conjunction with the Spinery® RF Generator and Spinery® Kit.
Its function is to ensure the continuous cooling of the bipolar probes during the delivery of radiofrequency energy, facilitating the thermal control of the treatment and contributing to the safety and efficacy of the ablative procedure. The device allows the circulation of saline solution inside the probes by means of a direct connection between generator and probe.
The Spinery® Cooling Connection does not have a stand-alone intended use but is functionally dependent on the Spinery® RF Generator.
Its use is necessary to enable the active cooling function integrated into the generator, a critical element to ensure the correct distribution of RF energy and the protection of the surrounding tissues.

The clinical aim of the procedure performed with the Spinery® RF Generator is palliative treatment by thermal ablation of spinal and pelvic bone metastases in cancer patients with refractory pain.
Cooling helps to:

- Check the local temperature during RF dispensing;
- Prevent tissue charring or critical impedance increase;
- Optimize the ablation profile, maintaining the effectiveness of the treatment.

6.1 Clinical Benefits

The active cooling provided by Spinery® Cooling Connection improves the quality of the RF ablation procedure, helping to:

- Increase the precision of ablative treatment;
- Reduce the risks related to overheating of healthy tissues;
- Ensure a wider and more controlled distribution of heat, to support the analgesic effect of the procedure.

7 INDICATIONS, CONTRAINDICATIONS AND WARNINGS

7.1 Indications for Use

The Spinery® Cooling Connection device is indicated for use in combination with the Spinery® RF Generator (REF: SPINE-GEN) and the cooled probes contained in the Spinery® Kit, during radiofrequency thermal ablation procedures in patients with metastatic bone tumors located in the spine, sacrum and pelvis.
The Cooling Connection allows the controlled passage of saline solution through the probes, ensuring constant cooling during RF dispensing. The device is functionally dependent on the generator and does not have an autonomous intended use.

7.2 Contraindications

The device should not be used in the following cases:

- In combination with RF generators other than Spinery® RF Generator;
- In the absence of direct connection to compatible probes (see Spinery Kit IFU);
- In patients for whom thermal ablation is not indicated or who have general contraindications to RF (consult the IFU of the generator).

7.3 Warnings

The device is intended for single use. Do not reuse or resterilize.

- Do not modify any components or connectors: Alteration may affect the performance of cooling components.
- Check the integrity of the package before use. Do not use if the package is damaged or opened.
- Do not use with liquids other than sterile saline.
- Connect and turn on cooling only as indicated in the generator IFU.
- The device should only be used by qualified healthcare professionals.
- The Cooling Connection is not compatible with MRI environments (see §4.2).

7.4 Precautions

- Use only with original AXON components.
- Always check that the hose ends are properly connected to the generator and probe.
- Do not bend or choke the pipes, as this will obstruct the flow of solution.

- Do not use if fluid leakage or occlusion is found.
- During the procedure, visually check the correct cooling flow.

7.5 Adverse reactions

The use of the Cooling Connection may involve indirect risks, resulting from cooling malfunction, including:

- Excessive increase in temperature in the probe;
- Reduced ablation effectiveness;
- Thermal damage to non-target tissues;
- Premature termination of the procedure due to high impedance.

These events are closely linked to the failure of the cooling components. For a complete description of adverse reactions related to RF ablation, refer to the generator IFU.

7.6 Limitation of Use

The use of the Spinery® Cooling Connection is limited to professional healthcare environments. The device should not be used in different environments or with incompatible generators.

8 PATIENT PROFILE

8.1 Expected patient population and medical conditions to be treated

The Spinery® Cooling Connection device is intended for adult patients suffering from painful bone metastases, particularly located in the spine, sacrum and pelvis. The device is used as an integral part of the palliative radiofrequency ablation procedure, always in combination with the Spinery® RF Generator and the Kit.
The Cooling Connection is indicated in the following patient profiles:

- Patients with symptomatic bone metastases that cannot be treated with drug therapy alone;
- Patients who are candidates for minimally invasive analgesic treatment;
- Cancer patients who do not respond to standard therapies (radiotherapy, surgery);
- Patients in whom ablation is indicated to reduce pain, risk of fractures, or spinal cord compression.

Note: The Spinery® Cooling Connection is not intended for stand-alone use and should not be used alone, but only in accordance with the clinical and technical conditions described in the IFU of the Spinery RF Generator and the Spinery Kit.

9 INTENDED USERS

The Spinery® Cooling Connection should only be used by qualified healthcare professionals, in accordance with the regulations in force in the country in which it is used. The user is required to be a medical specialist (e.g., neuroradiologist or neurosurgeon) licensed to perform percutaneous spinal access procedures and spinal ablation treatments.
The clinical use of the Cooling Connection accessory requires specific training in its use in combination with the Spinery® RF Generator and the Spinery® Kit, provided by AXON authorized personnel. This training includes:

- Correct connection of the Cooling Connections to the Spinery® RF Generator;
- Secure connection to bipolar probes supplied with the Spinery® Kit;
- Understanding cooling flow and automatic generator settings;
- Verification of the activation and correct operation of the peristaltic pump;
- Security measures to prevent occlusions, disconnections or malfunctions.

Note: It is mandatory to consult the IFUs dedicated to the Spinery® RF Generator and the Spinery® Kit for a compliant, safe and integrated use of the system as a whole.

10 To be used with

⚠ WARNING

- Use with non-validated devices can compromise the safety and performance of the clinical application, exposing the patient and caregiver to avoidable risks.
- Reuse, reprocessing or repackaging of Cooling Connections (single-use device) is strictly prohibited. Such practices can:
    - Compromising sterility and mechanical integrity
    - Involve risks of infection or contamination
    - Cause the pump or cooling circuit to malfunction
    - Cause temperature errors during ablation
    - Affect the traceability and security of the processing
- The Cooling Connections are sterilized with ethylene oxide (EtO), according to ISO 11135:2014 standard. Always check the integrity of the sterile barrier before use. Do not use if:
    - The packaging appears damaged or opened
    - Exposure to non-conforming environmental conditions (humidity, heat, contamination) is suspected

DESCRIPTION OF SPINERY® COMPONENTS	REF	TYPE OF USE
SPINERY® RF Generator includes the foot pedal and its electrical cable and the metal rod for saline solution.	SPINE-GEN	Multiple use
SPINERY® Kit (accessory), includes a probe with 10 mm long electrodes, **bone access kit** (drill (29 cm), introducer, oblique trocar and diamond tip), insulating and irrigation cannula and 1 ml syringe.	SP-BI1005EU	Single Use
SPINERY® Kit (accessory), includes a probe with 7 mm long electrodes, bone access kit (drill (22 cm), introducer, oblique trocar and diamond tip), insulating and irrigation cannula and 1 ml syringe.	SP-BI0704EU	Single Use
SPINERY® Cooling Connections (accessory) includes the single connection of cooling components for the use of a single bipolar probe.	SP-CSEU	Single Use
SPINERY® Cooling Connections (accessory) include dual connection of cooling components for the use of a dual bipolar probe.	SP-CDEU	Single Use

Table 4 - Description of the components of the SPINERY® RF Generator and its accessories

11 START OF THE PROCEDURE

Before connecting the cooling line to the generator and probe, the operator is recommended to consult the **Instructions for Use (IFU)** of the medical device of which the **Spinery® Cooling Connection** is an accessory, i.e., the **Spinery® RF Generator**.

The Spinery® RF Generator IFUs contain all the complete information related to system configuration, activation sequences, user interface, temperature control, and safety mechanisms.
This document contains only an excerpt of the procedure relating to the use of the **Spinery® Cooling Connection** and its function within the cooling circuit during radiofrequency ablation procedures.

11.1 Patient Preparation

⚠ WARNING

- Do not touch any exposed metal parts of the generator and the patient at the same time. Failure to comply may result in electric shock.
- Do not allow the patient to come into contact with metal parts, such as an operating table or stands that are grounded or have an appreciable capacity with respect to ground. Always use anti-static covers. Failure to comply may result in burns to the patient.
- Always clean any potentially flammable solutions under the patient's body, or in recesses or body cavities, BEFORE using the equipment. Failure to comply may result in burns to the patient.
- Apply dry gauze between the patient's arms and body if necessary to avoid skin-to-skin contact. Failure to comply may result in burns to the patient.
- Always reduce patient contact with any probe, temperature sensor, or electrical cable (probe cable, temperature sensor cable, splitter cable) as much as possible. Place temporarily unused temperature probes or sensors connected to the generator in a sterile, electrically insulated container.

ⓘ Note

- Orient the patient in the prone position on a surgical table.
- Establish a sterile field on a previously selected patient surface treatment area.
- Transfer the sterile disposable introducer, sterile disposable probe(s) with insulating and irrigation cannula, 1 mL syringe, and the sterile disposable hand drill and trocars into the sterile field as needed.

11.2 Connect Cooling Connection with Generator and Probe

ⓘ Note: Depending on whether one or two probes (code SP-BI0704EU or SP-BI1005EU) have been connected to the Generator, the single cooling connection (code SP-CSEU) or the double cooling connection (code SP-CDEU) must be connected, respectively. The single or double connection circuit should be connected to the room temperature saline bag at one end and the probe(s) at the other end.

1. The illustrated instructions (Figure 2/3) ask you to connect the cooling connection tip to the saline bag from one end to the probe at the other end and place the propulsion tube into the peristaltic pump.

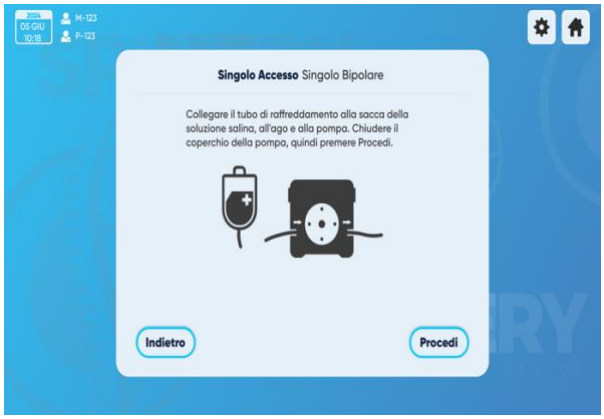

Figure 2 – Single Access Cooling Connection Screen

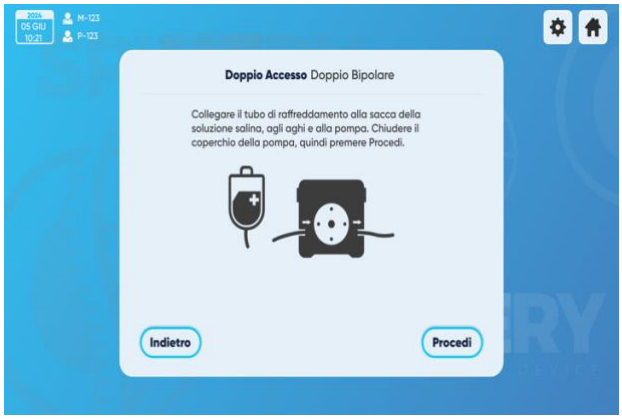

Figure 3 – Dual-Access Cooling Connection Screen

2. To complete the preparation of the cooling components, the following steps must be performed:
   A. Open the plastic door of the peristaltic pump (Figure 4);
   B. Insert the propulsion tube into the appropriate seat, checking the correct direction of travel of the liquid indicated on the pump and on the propulsion tube;

Figure 4 – Peristaltic pump

   C. Close the plastic door of the pump checking that the hose is correctly in place. If this were not the case, the correct functioning of the cooling of the needle probe would be precluded;
   D. Be careful to leave the return hose free;
   E. Insert the tip into the saline bag previously inserted vertically into the appropriate slot on the generator;
   F. Finally, connect the cooling connection port to the probe to close the cooling circuit.

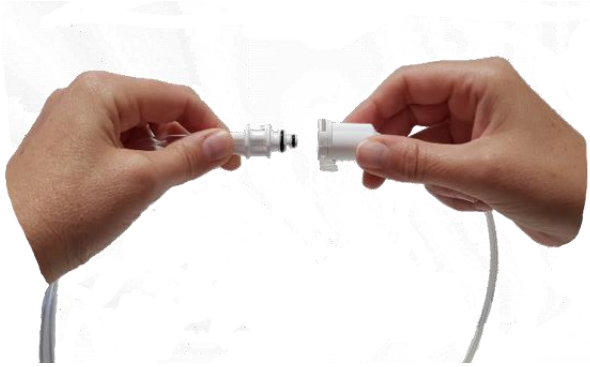

Figure 5 – Cooling Connection Ports

3. When the tubing is inserted and the pump door is closed, you can select the "Next" button.
4. The illustrated instructions (Figure 6/ 7) inform you that the saline water is recirculated in the closed cooling system to ensure total de-bubbling of the pipes.

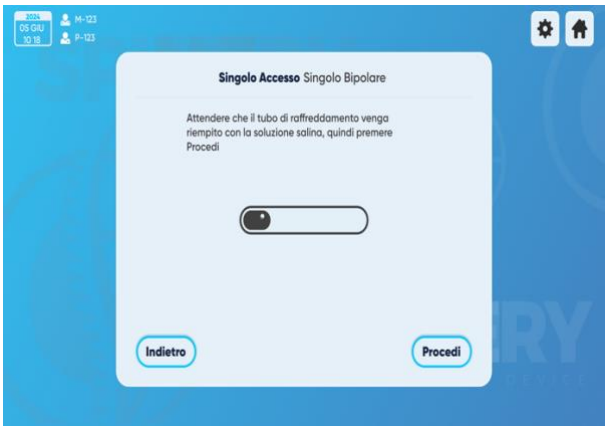

Figure 6 – Single Access De-Bubbling Screen

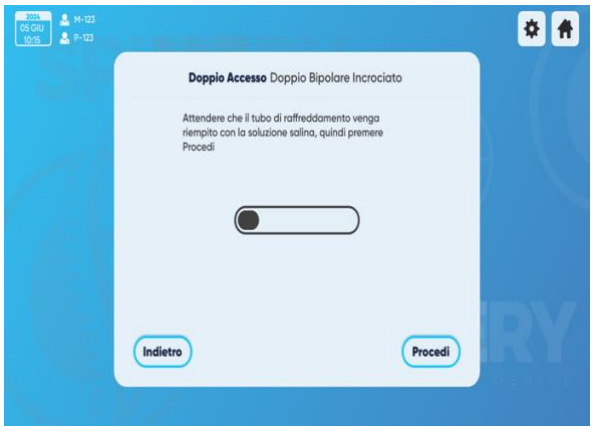

Figure 7 – Dual-access de-bubbling screen

- At the end of the de-bubbling procedure, the operator must verify that the cooling tube is filled with saline. By selecting the "Next" button, you can continue with the procedure.

⚠ For information on completing the ablation procedure, always refer to the IFU of the Spinery® RF Generator and the Spinery® Kit in conjunction with this document.

12 AFTER USE

12.1 Removing components

⚠ WARNING

- Disposal of the components of the Spinery® Cooling Connection must be carried out in accordance with current regulations regarding hazardous medical waste and potentially contaminated disposable devices.
- Reuse of the device or parts of it is prohibited and may result in a risk of infection or harm to the patient.
- The Spinery® Cooling Connection is intended for single use and should be disposed of in its entirety after the procedure. Do not attempt to resterilize or reuse any components.

13 ROUTINE MAINTENANCE

No maintenance or cleaning is required for the Spinery® Cooling Connection, as it is a sterile disposable device. Any maintenance or sanitization operations concern only the Spinery® RF Generator and are described in the relevant IFU.

14 INCIDENT ALERT

The user and/or patient must report any serious incident that has occurred in relation to the device to both the manufacturer and the competent authority of the European Member State in which the user and/or patient is established.

15 CUSTOMER SERVICE AND TECHNICAL SUPPORT

In case of abnormal behavior or malfunction, turn off the device and stop treatment immediately; then contact Axon's customer service and technical assistance to report the problem.

⚠ WARNING

- Only authorized personnel may carry out maintenance and/or repair operations.
- No constructive modifications to the device are permitted.
- Do not disassemble, modify, or repair any component of this system without the manufacturer's authorization. Contact Axon for assistance.
- Use only Axon-approved components and accessories to ensure a safe and effective combination. Failure to comply may result in increased electromagnetic emissions or decreased electromagnetic immunity of the system.
- Failure to comply with these requirements may void the Manufacturer's liability for any damage or malfunction of the equipment.
- Annual general checks: operation of the buttons and ignition controls, lights on the control panel, status of the cables and handpiece to be carried out annually by the user himself.

For any need for assistance, technical support and/or replacement of defective parts, please contact:

Customer service and technical assistance Axon srl

AXON Srl, Via Lepanto I Traversa 18, 80045 Pompei (NA) - Italy

Tel.: +39 081 229 0044

info@axonmedicalsystems.com

https://www.axon.productions

ℹ Note

- Contact the Axon service center to obtain a repair purchase order BEFORE submitting a product return directly to the center.
- To expedite processing, ALWAYS include the following information with your product return:
    - Contact name
    - Contact address
    - Contact phone number
    - Repair purchase order number
    - Part Number(s)
    - Serial number(s)
    - Detailed reason for return
    - Precise information on the problem encountered
- Always recondition (clean, disinfect, sterilize if necessary) all potentially contaminated equipment BEFORE returning it to AXON. AXON will not accept or treat any potentially contaminated equipment.

16 SPECIFICATIONS FOR ENVIRONMENTAL DISPOSAL

⚠ WARNING

Always follow current local recommendations and/or regulations governing environmental protection and risks associated with recycling or disposing of the product at the end of its useful life. Disposable accessories must be considered sanitary waste and disposed of in accordance with current regulations.

17 ACRONYMS

ACRONYM	DEFINITION
RF	Radio frequency
PPE	Personal Protective Equipment
RM	Magnetic Resonance Imaging

Table 5 – Glossary Acronyms

18 IFU IN OTHER LANGUAGES

The Instructions for Use (IFU) for the Spinery® Cooling Connection are available in multiple languages.

For the most up-to-date versions and for IFUs in languages other than English, please visit the manufacturer's official website or scan the QR code provided below.

Accessing the online version ensures consultation of the latest approved revision of the Instructions for Use.

Manufacturer website:

https://www.axon.productions

QR code: