SPINERY

SPINE RECOVERY DEVICE

Instructions for use

SPINERY® Kit
SPINERY® RF Generator Accessory

Class IIb active medical device

CE 0051

Manufacturer:

AXON S.r.l.

Via Lepanto I Traversa 18,

80045 Pompei (NA) – Italy

REVISIONS

DATE	REVISION	DESCRIPTION
31/07/2025	00	First release

INDEX

1 DEVICE IDENTIFICATION

1.1 Device Name

Spinery® Kit (REF: SP-BI0704EU, SP-BI1005EU)

1.2 Device configurations

The Spinery® Kit, an accessory of the Spinery® RF Generator, is available in the following variants:

- REF: SP-BI0704EU includes:
    - Bipolar cooled probe with electrodes length of 7 mm and an electrode spacing of 4 mm (18mm active part)
    - Irrigation components
    - Bone Access Components (22mm Drill-Cannula Coupling)
- REF: SP-BI1005EU includes:
    - Bipolar cooled probe with electrodes length of 10 mm and an electrode spacing of 5 mm (25mm active part)
    - Irrigation components
    - Bone Access Components (29mm Drill-Cannula Coupling)

Irrigation components are used to circulate saline through the probe during RF delivery, improving ablation control and thermal safety. Bone access components are the tools required for percutaneous access to the vertebral body (e.g., cannula, stylet, bone drill).
Both component variants are supplied sterile and are intended for single use only. The sterilization method is ethylene oxide (EtO), validated according to ISO 11135:2014.
The procedure is performed under image guidance (CT or fluoroscopy) with a maximum RF delivery duration of 20 minutes for each treatment session.
Spinery® RF Generator, used in combination with selected accessories, is indicated to provide thermal ablation treatment and pain relief in patients suffering from metastatic spinal tumors. The system supports both single-probe and dual-probe ablation techniques (in parallel or crossover configuration), depending on the size of the lesion, its location, and clinical strategy.
Under image guidance (e.g., CT or fluoroscopy), cooled bipolar probes are introduced percutaneously into the target vertebral area. RF energy is then applied for up to 20 minutes per treatment session.

<u>Sterility and disposables:</u>

Both variants of the device are supplied sterile and intended for single use (single-use) only.
The sterilization method adopted is ethylene oxide (EtO), validated according to ISO 11135:2014.

<u>Use in combination:</u>

The Spinery® Kit should only be used in conjunction with the Spinery® RF Generator (see dedicated IFU) and the Spinery® Cooling Connection (see dedicated IFU).
The procedure is performed under image guidance (CT or fluoroscopy) with a maximum RF delivery duration of 20 minutes for each treatment session.

2 MANUFACTURER'S INFORMATION

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

Tel. +39 081 229 0044

info@axonmedicalsystems.com

https://www.axon.productions

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 ® Kit Label Symbols

3.2 Guide to using the manual

This manual contains essential information for the safe, effective and compliant use of the Spinery® Kit medical accessory device, sterile and disposable, for use only in combination with the Spinery® RF Generator.
The device should only be used by qualified and adequately trained healthcare professionals, in accordance with current local legislation and MDR guidelines (EU Regulation 2017/745).
Before using the device, please read and understand the instructions in this IFU carefully. For a compliant, safe and complete use of the system, it is also mandatory to consult and scrupulously follow the IFU dedicated to the Spinery® RF Generator, which describes in detail the operating functions, user interfaces, clinical settings and RF energy delivery methods.
This manual is an integral part of the Spinery® Kit accessory 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® Kit accessory device should only be used by qualified healthcare professionals, who must have read and understood these instructions for use in full before handling and use.

  The healthcare professional responsible for the procedure must thoroughly assess the clinical suitability of the Spinery® Kit for each individual patient. AXON, as a manufacturer, does not recommend or prescribe specific surgical techniques or interventional procedures.
- Never modify the components of the kit (probe, bone access components, irrigation components): any alteration could compromise the safety, efficacy and sterility of the device.
- Store and transport the device only under the recommended environmental conditions indicated on the packaging.
- Do not use the kit after the expiration date printed on the sterile packaging, as sterility, safety, and efficacy may not be guaranteed.
- Always carry out a visual check of the integrity of the sterile package before use. Do not use the kit if the package appears damaged, opened, or compromised in any way.
- Always make a visual inspection of the kit components before use, checking for any damage caused by storage or transport.

- For detailed information on connecting the kit components to the generator and cooling components, refer to the relevant dedicated IFUs (Spinery® RF Generator and Spinery® Cooling Connection).
- In the event of any obvious abnormality (breakage, deformation, missing materials), do not use the device and contact AXON or the authorized technical assistance service immediately.

4.2 Magnetic Resonance Imaging (Mri) Safety

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

⚠ ATTENTION

Do not introduce or use any component of the kit 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® Kit is a sterile, single-use medical device intended to be used exclusively in combination with the Spinery® RF Generator for radiofrequency (RF) thermal ablation procedures in patients with metastatic tumors located in the bone structures (vertebrae, sacrum, ileum, acetabulum).

It is a surgically invasive device intended for temporary (transient) use. The kit allows percutaneous access and introduction of the ablation probe into the target anatomical site through minimal surgical incision. The components of the kit remain in place only for the time necessary for the treatment (about 20 minutes).

Spinery® Kit includes the following types of components:

- Bipolar cooled probe:

designed for RF energy delivery directly to the target area, ensuring precise control of the temperature and shape of the ablated area (active part length 18mm/25mm).

- Irrigation components:

used for the continuous infusion of sterile saline solution through the probe, in order to keep the treated tissue constantly hydrated and prevent charring and high impedance phenomena.

  - Insulating and irrigating cannula, for electrical insulation and management of saline solution;
  - Sterile syringe for manual infusion of saline.

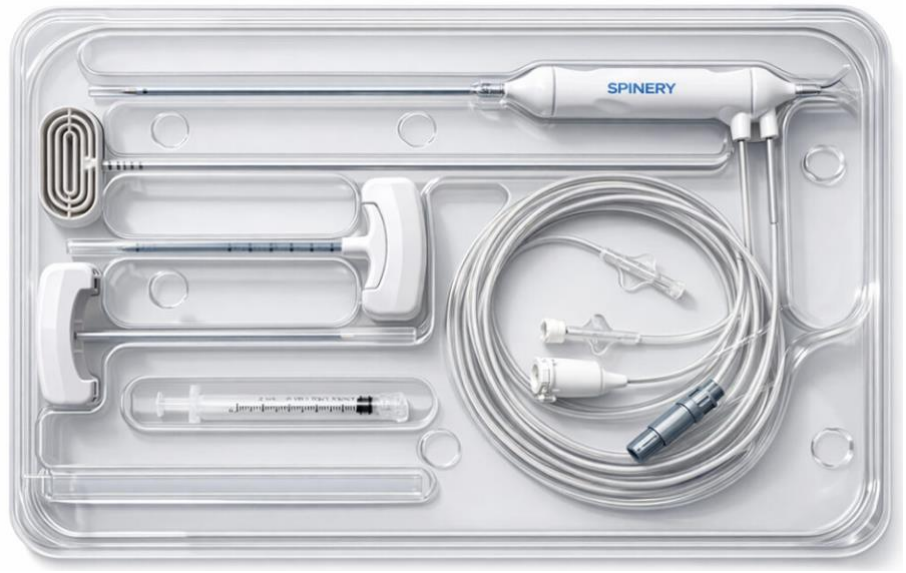
- Bone Access Components:

Tools required to obtain precise percutaneous access to the target bone site:

  - Bone drill (Drill-Cannula Coupling 22 or 29 cm, depending on the kit configuration) for the preparation of the access canal;
  - Introducer cannula, to stabilize access and safely insert the RF probe;
  - Trocars with oblique tip and Trocars with diamond tip, to facilitate and guide positioning;

The device is sterilized by ethylene oxide (EtO), according to a validated procedure in accordance with ISO 11135:2014. It is supplied in sterile and sealed individual packages, with clear labelling for the batch, expiry date and UDI identifier.

⚠ NOTE: The Spinery® Kit is not intended for use on the central nervous system.



Spinery® Kit (Spinery® RF Generator Accessory):

Spinery® Kit	
REF	COMPONENT
SP-BI0704EU	• Cooled bipolar probe with 7 mm long electrodes and 4 mm intra-electrode length (18mm active part) • Drill – drill/cannula coupling 22 mm • Trocar with oblique tip • Trocar with diamond tip • Syringe • Insulating and Irrigating Cannula
SP-BI1005EU	• Cooled bipolar probe with 10 mm long and 5 mm intra-electrode length electrodes (25mm active part) • Drill – drill/cannula coupling 29 mm • Trocar with oblique tip • Trocar with diamond tip • Syringe • Insulating and Irrigating Cannula

Table 2 - SPINERY® Kit and its components

5.1 Spinery Probe

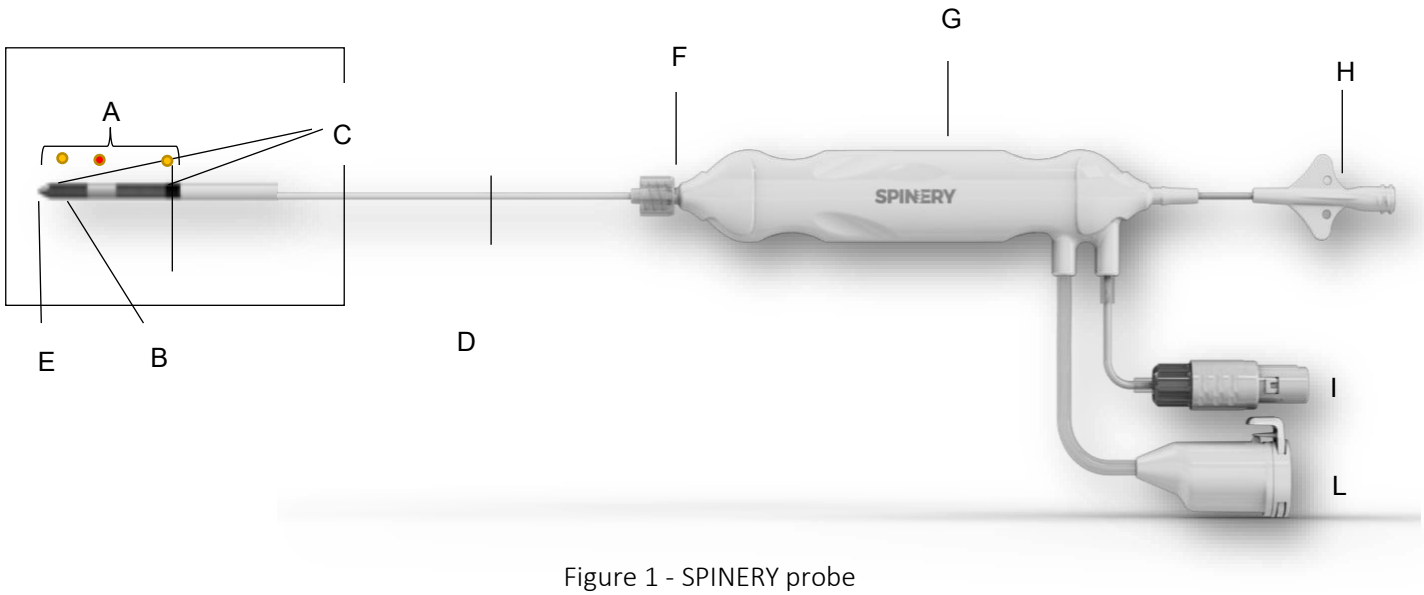


Figure 1 - SPINERY probe

Features of the SPINERY probe	
A	Active Tip Length - Describes the length of the emission surface used to transmit RF energy to the ablation site. (18mm/25mm)
B	Radiopaque Probe Electrodes - Allow visualization of emitted RF energy surfaces using X-ray imaging or fluoroscopy technology.
C	Thermocouples - Allow temperature measurement at the ablation site and at the edge of the ablation site
D	Probe Needle (16 gauge) - Provides the path for RF energy and saline to the ablation site. It also allows you to collect temperature information at the ablation site and provide it to the generator.
E	Distal Irrigation Probe Orifice — Delivers saline from the 1 mL syringe to the ablation site.
F	Luer Lock System – Allows you to secure the needle probe with insulation and irrigation cannula
G	Probe Hub - Provides generator connection interface, infusion connection, and cooling components
H	Luer Lock Syringe Port - Used with 1 mL syringe allows distal irrigation at the ablation site
I	Probe electric cable - Provides the electrical connection between the generator and the probe.
L	Cooling cable connector - Provides recirculation of closed cooling water between the probe saline water bag via the peristaltic pump located on the generator

Table 3 - Spinery Probe Features

⚠ CAUTION - Condition of components at the time of delivery

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

5.2 Cannula and syringe for isolation and irrigation

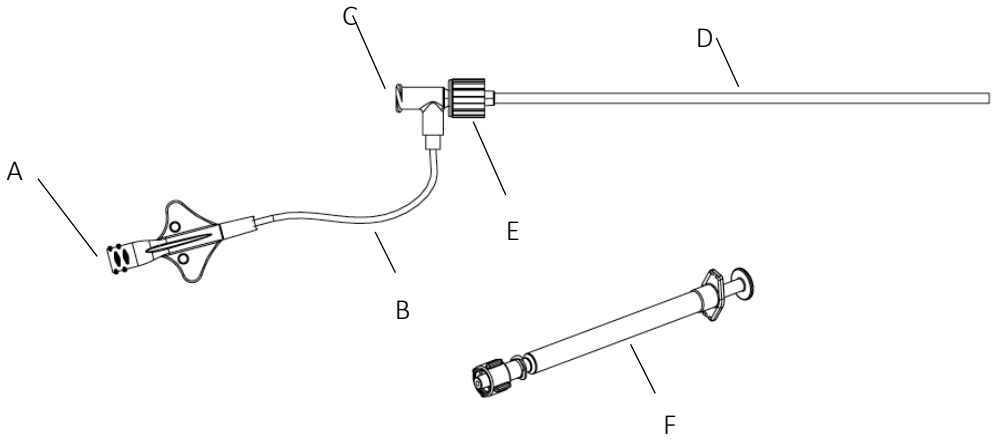


Figure 2 – Cannula and syringe for isolation and irrigation

Features of the cannula and syringe for Isolation and irrigation	
A	Luer Lock Syringe Holder - Used with 1 mL syringe, allows proximal irrigation at the ablation site
B	Microcatheter — Allows manual delivery of regulated saline flow to the ablation site.
C	Luer Lock System – Allows you to secure the insulation and the irrigation cannula with a needle probe
D	Isolation and Irrigation Cannula – Allows the flow of saline to the ablation site
E	Luer Lock System – Allows the insulation and irrigation cannula to be attached to the Introducer
F	1 mL Syringe – Allows irrigation proximal to the ablation site via the Luer Lock C System

Table 4 - Isolation and Irrigation Cannula and Syringe Characteristics

⚠ CAUTION - Condition of components at the time of delivery

The irrigate and Insulating cannulas are supplied sterile (they are subjected to a validated ethylene oxide sterilization process) and are disposable. Their reuse can cause harm to the patient and/or the transmission of infections from one patient to another.

5.3 Bone Access Components - Drill

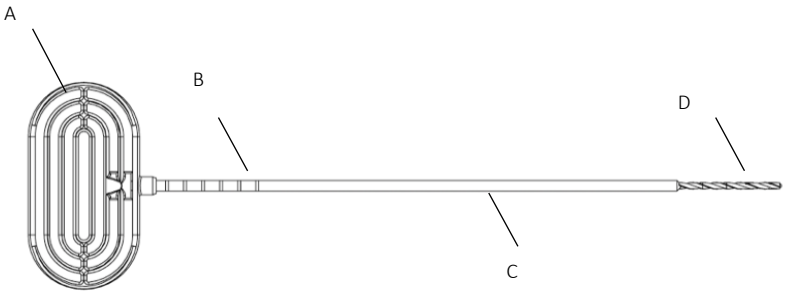


Figure 3 – Drill

Features of the Drill	
A	Handle - Advances the drill into the bone tissue when rotated clockwise. It makes it easy to pull the drill out of the introducer.
B	Laser bands: The visual signal indicates that the correct depth has been reached for a specific length of the probe
C	Drill shaft - The solid shaft with a sharp tip cut through bone tissue.
D	Tip: Cut the cancellous bone in the vertebral body.

Table 5 - Drill characteristics

⚠ CAUTION - Condition of components at the time of delivery

The bone access components (Drill, Trocar, Introducer, 1 mL Syringe and Irrigant and Insulating Cannula) are supplied sterile (they undergo a validated ethylene oxide sterilization process) and are disposable. Their reuse can cause harm to the patient and/or the transmission of infections from one patient to another.

5.4 Bone Access Components – Introducers and Trocars

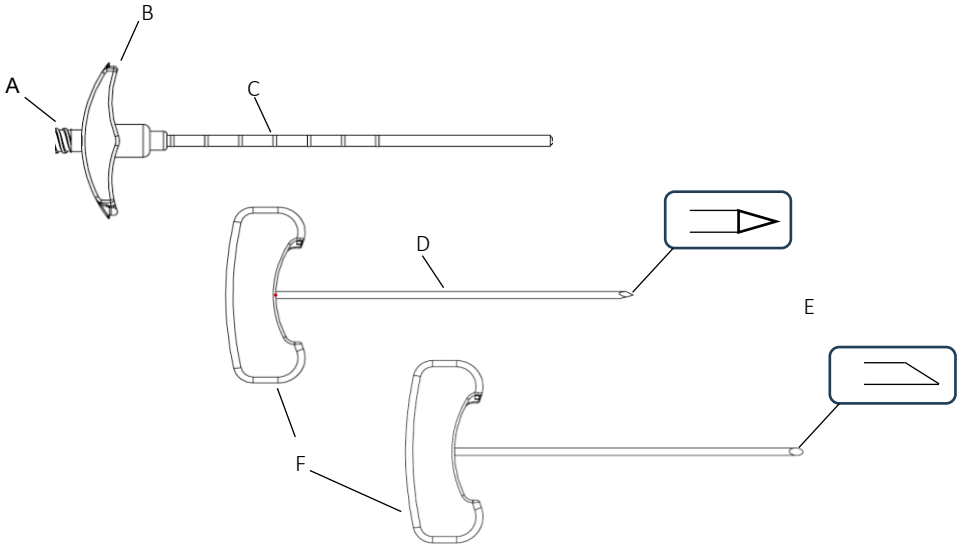


Figure 4 - Bone access tools

Features Bone Access Kit	
A	Luer Port/Connection - Allows you to insert and lock the trocar in the introducer
B	Handle - Rotate and advance the introducer into the bone tissue. Rotate and remove the introducer from bone tissue
C	Introductory Cannula - Provides and maintains access to the surgical site
D	Trocar - A solid rod with a sharp tip; It penetrates the bone tissue when it is installed in the introducer.
E	Oblique and Diamond Tip - Provides the sharp tip/edge to cut tissue when installed in the introducer.
F	Trocar Handle - Allows the Trocar to penetrate into bone tissue when installed in the introducer.

Table 6 – Characteristics of bone access components

6 INTENDED USE

The Spinery® Kit - available in two variants (REF: SP-BI0704EU and SP-BI1005EU)- is a sterile, single-use, disposable accessory intended to be used exclusively with the Spinery® RF Generator (REF: SPINE-GEN).
It is designed to enable percutaneous access, positioning, and controlled delivery of bipolar radiofrequency (RF) energy for the palliative thermal ablation and coagulation of bone metastases located in the vertebral bodies, sacrum, iliac bone, and peri-acetabular region.
The Kit comprises:

- a bipolar probe, a transient-use, surgically invasive component inserted percutaneously into the target bone tissue to deliver RF energy during ablation;
- irrigation components, which circulate sterile saline to enhance thermal control and minimize carbonization at the electrode–tissue interface;
- bone access components (e.g., cannula, trocar, introducer, drill) that provide safe and precise access to the vertebral target under fluoroscopic or CT guidance.

The Spinery® Kit has no stand-alone function and operates in functional dependence with the Spinery® RF Generator and its sterile connection accessory - Spinery® Cooling Connection. Its use is necessary and mandatory to achieve the clinical purpose of the main active device, i.e., the palliative treatment of cancer patients experiencing pain due to bone metastases through targeted RF ablation and coagulation of bone tissue. The device allows for customization of the ablation shape and volume, thanks to the availability of two bipolar probe configurations with different electrode geometries and dimensions, adaptable to various metastasis sizes and anatomical locations.
Clinical purpose:

- To alleviate intractable pain associated with bone metastases in patients who have not responded to, or are not candidates for, standard therapies;
- To coagulate and ablate bone tissue during minimally invasive interventional procedures performed under image guidance, with a palliative intent for pain relief.

6.1 Clinical Benefits

Radiofrequency ablation of metastases, especially those located in the spine, can improve patients' quality of life by managing intractable pain, potential pathological fractures, or nerve compression. This palliative intervention is often followed by the addition of bone cement.

7 INDICATIONS, CONTRAINDICATIONS AND WARNINGS

7.1 Indications for Use

The Spinery® Kit is a disposable sterile accessory device designed to be used exclusively in conjunction with the Spinery® RF Generator (REF: SPINE-GEN) for the palliative treatment of patients with metastatic bone tumors located in the vertebral bodies, sacrum, ileum, and periacetabulum. The Kit allows the correct introduction of the cooled bipolar probe and the maintenance of controlled irrigation during radiofrequency (RF) ablation, contributing to the safety and clinical efficacy of the treatment. The device is functionally dependent on the RF generator and does not have an autonomous intended use.

7.2 Contraindications

The use of the Spinery® Kit is contraindicated in the following cases:

- Presence of pacemakers or other implanted electronic devices;
- Pre-existing bone stabilization in the area to be treated;

- Treatment of vertebral bodies at C1-C7 level;
- Systemic or localized infection at the site of intervention;
- Possible pregnancy;
- Pediatric patients;
- Congenital or surgical anatomical alterations that hinder access to the bone target;
- Patients on immunosuppressive therapy or with coagulation disorders.

Note: For a complete list of contraindications related to RF power delivery, see the Spinery® RF Generator IFU.

7.3 Warnings

- The Spinery kit is intended for single use. Do not reuse or resterilize. Reuse can lead to risks of infection, contamination, breakdown of materials, and impairment of functionality.
- Before use, check the integrity of the sterile package. Do not use if damaged or opened.
- Do not modify any component of the kit. Alteration may compromise safety and performance.
- The procedures must be performed by qualified healthcare personnel who are properly trained by AXON.
- Use sterile techniques at all stages of device handling, particularly when filling with saline.
- RF ablation should only be performed under fluoroscopic guidance to avoid damage to critical structures.
- The accessory is intended for professional use in healthcare environments only.

7.4 Precautions

- Use only the complete kit as supplied by AXON. The use of non-genuine components may compromise patient safety.
- Do not use the Kit in patients with sclerotic bones or in the presence of unstable pathological fractures.
- Make sure the probe tip is fully inserted and secured inside the introducer before ablation.
- Avoid any direct contact with the probe tip during ablation.
- To ensure safe ablation, maintain a minimum distance of 1 cm from critical anatomical structures.

7.5 Adverse reactions

Clinical use of the Spinery® Kit, in combination with the generator, may be associated with adverse reactions, including:

- Thermal lesions to adjacent tissues;
- Nerve lesions (radiculopathy, paresis, paralysis);
- Vascular or dural perforations;
- Hemorrhage or hematoma;
- Infections (superficial or deep);
- Pulmonary embolism, pneumothorax, post-operative pain.

Note: Adverse reactions result primarily from RF ablation performed with the Spinery RF Generator. For complete details, please refer to the relevant IFU.

7.6 Limitation of Use

The use of the Spinery® Kit is limited to professional healthcare environments. The device is not compatible with MRI environments (see par. 4.2).

8 PATIENT PROFILE

8.1 Expected patient population and medical conditions to be treated

The Spinery® Kit accessory device intended for use only in combination with the Spinery® RF Generator for the palliative treatment of bone pain in patients suffering from vertebral metastases. Metastatic bone disease is common in advanced cancer patients.

Radiofrequency ablation, particularly when applied to lesions located in the spine, sacrum, ileum, and periacetabulum, is an effective palliative strategy that can improve quality of life, reduce refractory pain, prevent pathological fractures, and decrease the risk of neurological compression. The procedure is often followed by stabilization using bone cement (vertebroplasty or kyphoplasty).

The use of the Kit is intended in the following patient profiles:

- Patients with painful bone metastatic lesions, preferably located in the spine or pelvis;
- Patients with localized pain attributable to no more than two metastatic bone sites to be treated in the same surgery (maximum of two symptomatic vertebral bodies per session);
- Patients with no evidence of impending bone fracture at the site to be treated;
- Patients for whom RF ablation is complementary to standard therapy (e.g., radiation therapy, surgery, drug treatment);
- Patients who do not respond or are not candidates for standard therapy, for whom palliative treatment of pain with analgesic purposes is indicated;
- Patients with lesion sizes consistent with ablation volumes achievable through the available Kit configurations, as shown in Table 27 - Usage Tables (see section 11.7).

Note: The Spinery® Kit is not intended for stand-alone use and is intended for use only with the Spinery® RF Generator as provided in the relevant IFU.

9 INTENDED USERS

The Spinery® Kit is disposable sterile accessory classified ad medical device and should only be used by qualified healthcare professionals, in accordance with the regulations and legal provisions in force in the country in which it is used. In particular, clinical use is reserved for medical professionals with specialization in Neuroradiology or Neurosurgery, regularly qualified to perform surgery in the spinal field.

These operators must be trained in the specific use of the Spinery® Kit device through technical-clinical training sessions provided by AXON authorized personnel. During intraoperative use, the operator may be supported by other qualified healthcare personnel (e.g. operating room nurses, radiology technicians). The training program includes:

- Introduction to the operating principles and technical characteristics of the Spinery® RF Generator and its accessories.
- Overview of kit components (probe, bone access components, irrigation components).
- Training on generator user interface, operating modes, and treatment settings.
- Procedures for preparing the device, connecting accessories and managing ablative phases.
- Safety and risk prevention measures.
- Analysis of temperature curves and thermal distribution tables.

ⓘ Note: No dedicated training is required for the use of the bone access instruments included in the Spinery Kit, as they are standard for percutaneous vertebral intervention. However, the operator must demonstrate familiarity with interventional spinal access techniques.

10 To be used with

⚠ WARNING

- Use with non-validated devices may compromise the safety and performance of the system, resulting in risks to the patient and/or caregiver.
- Reuse, rework, or repackaging of single-use components (such as the probe, drill, cannula, or other sterile kit accessories) is strictly prohibited. Such practices can:
    - Compromise the sterility and mechanical integrity of the device
    - Generate risks of infection, contamination or malfunction
    - Cause device fragmentation while using it
    - Lead to the loss of critical traceability information
- All sterile components of the Kit are sterilized with ethylene oxide (EtO). Before use, check the integrity of the primary package (sterile barrier). Do not use in case of:
    - Visible damage to the packaging
    - Unintentional opening before use
    - Exposure to environmental conditions that do not comply with the specifications

DESCRIPTION OF SPINERY COMPONENTS	REF	TYPE OF USE
SPINERY® 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 7 - Description of the components of the SPINERY® RF Generator and its accessories

11 START OF THE PROCEDURE

Before proceeding to connect the probe to the generator and start the procedure, the operator is recommended to consult the **Instructions for Use (IFU)** of the medical device of which the **Spinery® Kit** is accessory, i.e. the **Spinery® RF Generator**.

The Spinery® RF Generator IFUs contain all the complete instructions regarding system configuration, operating sequences, safety alerts, user interface, and error messages.

This document contains an excerpt of the procedure referring only to the use of the **Spinery® Kit** and its components:

- **RF probe**
- **Bone access components**
- **Irrigation components**

11.1 Connect the probe(s) to the generator

CAUTION:

- When connecting or disconnecting a cable, always grasp the cable by the connector or plug when installing or removing.

i Note

- Make sure the generator is properly positioned outside the sterile field, powered on, and ready for use.
- The generator display screen will provide illustrated instructions regarding the proper connection of the probe(s) and accessories (cooling components).
- The generator will only recognize AXON-approved components and accessories.

1. Connect the probe to the generator (Figure 5).

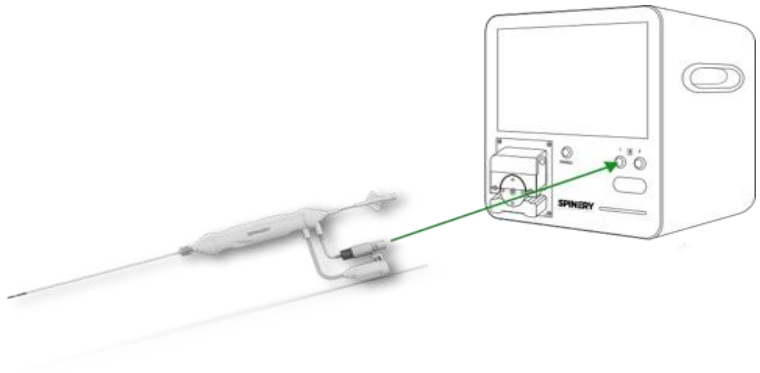


Figure 5 – Connecting the Probe to the RF Generator

2. Once the probes have been connected to the RF Generator, the display indicates the probe lot and the recognized serial number and shows the temperatures detected by the distal (TD) and proximal (TP) thermocouples

Figure 6 - Single probe recognition screen

Figure 7 - Dual probe recognition screen

3. Select the Next button to proceed with initializing the peristaltic pump.

   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.

4. The illustrated instructions (Figure 8/9) ask you to connect the cooling connection tip to the saline bag from one end to the probe at the other end and to place the propulsion tube in the peristaltic pump.

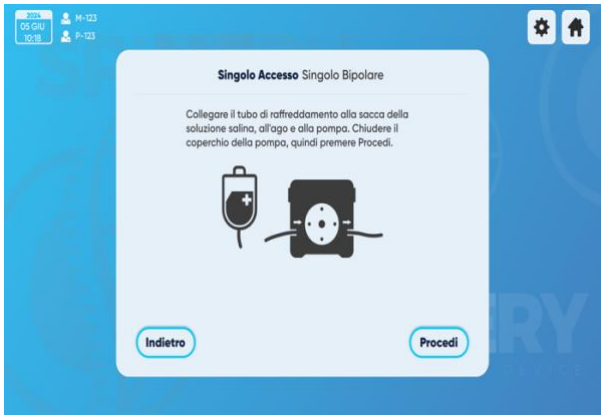


Figure 8 – Single Access Cooling Connection Screen

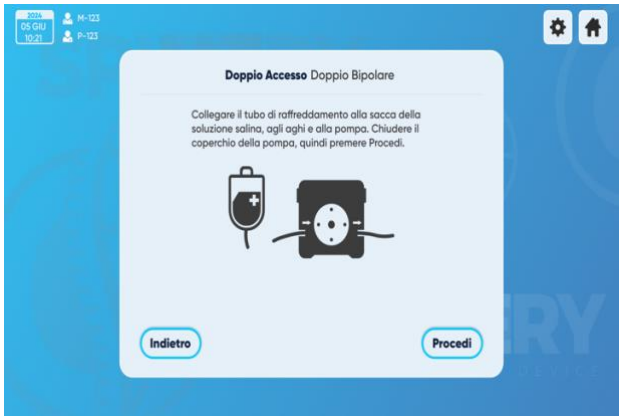


Figure 9 – Dual-Access Cooling Connection Screen

To complete the preparation of the cooling components, you must perform the steps described in the Spinery® Cooling Connection IFU.

11.2 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.

11.3 Access to the vertebra using the introducer, trocar and drill – Bone Access Components

WARNING

- Use only components and accessories approved by AXON to ensure a safe and effective combination.
- Always use visualization imaging, such as fluoroscopy, to confirm proper placement of the probe/introducer.
- Always fully insert the insulation and irrigation cannula into the introducer and secure them with the luer lock system.
- Always insert the probe fully into the isolation and irrigation cannula and secure them with the luer lock system. Failure to comply will prevent the probe tip from being properly positioned and may result in burns to the patient.
- Always remove the probe before positioning, repositioning, or removing the introducer. Failure to comply may result in damage to the probe or introducer or the insulating and irrigation cannula.

Note

- If desired, incision of the surgical site to facilitate insertion of the introducer/trocar.
- If you want to use the oblique tip trocar, unlock and remove the diamond tip trocar from the introducer and install the oblique point trocar before insertion.

11.3.1 Inserting the introducer/trocar

WARNING

- To preserve structural integrity, do not advance the introducer without the Trocar fully inserted and locked.

1 Inspect sterile packaging of single-use devices to ensure sterile barrier integrity. Replace any device if the sterile barrier is compromised.

2 Remove the contents of the sterile package and inspect all devices. Replace any device if damage is evident.

3 Remove the protective sheath from the introducer/trocar.

4 Under fluoroscopic guidance, insert the introducer/trocar into the surgical site.

5 Rotate the introducer/trocar or use a gentle hammering technique to advance the introducer/access trocar into the cortical bone of the vertebral body, under fluoroscopic guidance.

6 Once you have reached the desired position, unlock and remove the Trocar handle from the introducer (Figure 10).

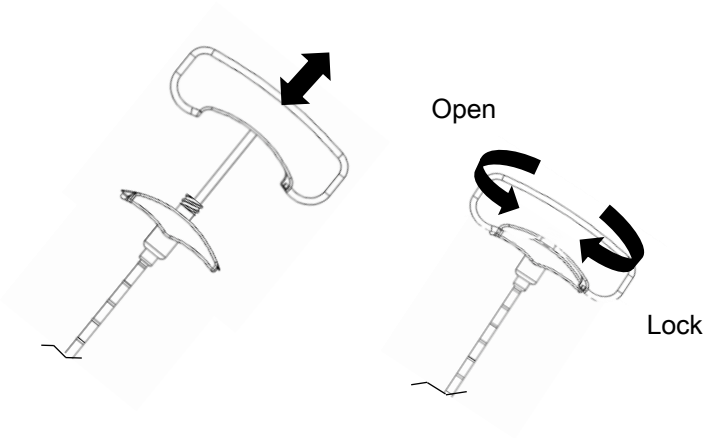


Figure 10 - Trocar insertion and extraction

Note

- The target bone access procedure should be performed once or twice depending on the type of access chosen, single or double respectively.
- An indication of the depth reached is given by the notches on the surface of the Introducer, which are only indicative and do not replace fluoroscopic imaging.
- The insertion depth of the introducer/trocar should always be checked via fluoroscopic imaging to have enough space for drilling (the length of the tip depends on the probe model, e.g. 22 mm (SP-BI0704EU) or 29 mm (SP-BI1005EU).
- The back boundaries in the case of single or double access are shown in Figure 11.

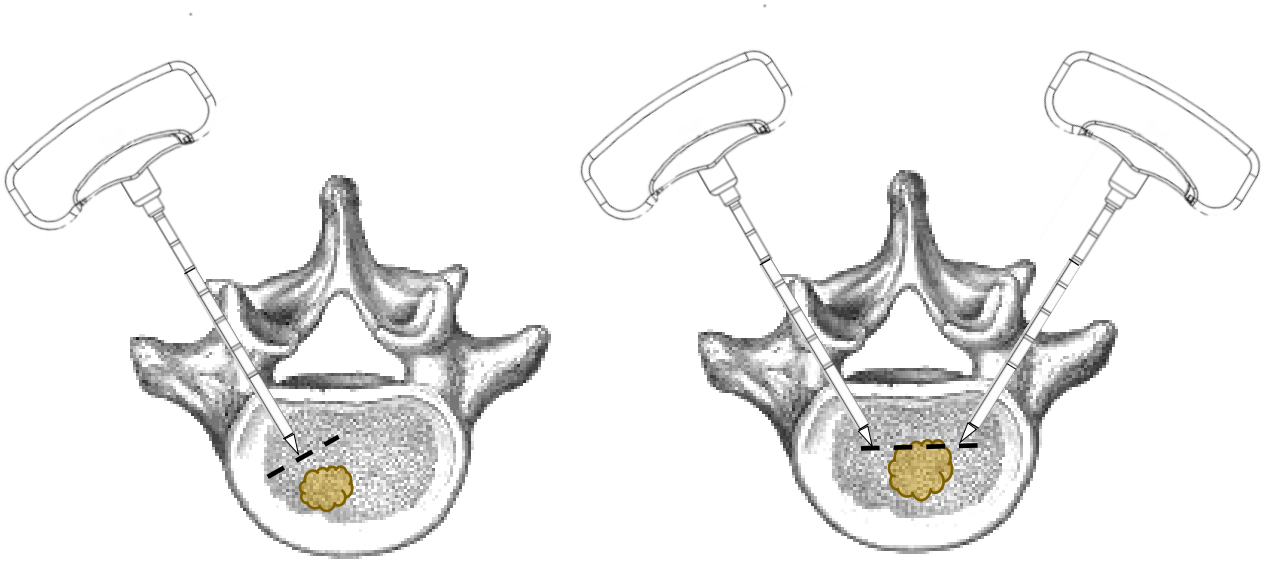


Figure 11 - Access to the back boundaries

11.3.2 Drilling the access channel

⚠ WARNING

- Always use the drill found in the same probe kit. The codes of the bipolar probes (SP-BI0704EU and SP-BI1005EU) have a different bore length (Drill- Cannula coupling 22 mm or 29 mm, respectively).
- During ablation, maintain a 10 mm margin between critical structures in the area.
- When performing ablation with dual bipolar probes, always ensure (via fluoroscopic imaging) that there is an average distance of 4 mm between two perforated paths.
- Do not use the surgical hammer to insert the drill into the bone. The drill must always be screwed clockwise, making sure that the drill handle reaches the handle of the Introducer.

1 Insert the sterile drill into the introducer.

2 Under fluoroscopic guidance, rotate the hand drill clockwise and advance the tip of the hand drill into the cancellous bone of the vertebral body (Figure 12). When the tip of the hand drill has reached the handle of the feeder, remove it from the feeder.

3 Remove the drill from the introducer lumen by turning the handle counterclockwise

4 Insert the insulating and irrigating cannula into the introducer and lock it by screwing the ferrule onto the introducer.

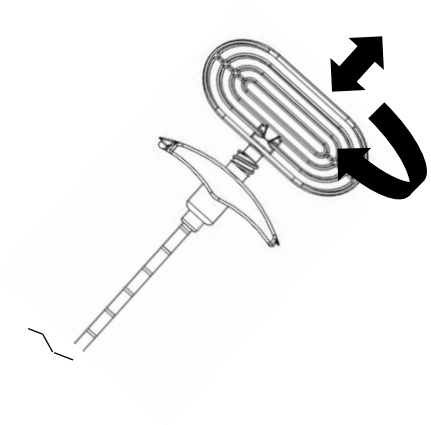


Figure 12 - Inserting and Removing the Tip

ⓘ Note

- Always drill to the end of the drill length to ensure that the active probe tip is outside the introducer.
- Each vertebral access must be performed with dedicated bone access accessories provided with the probe. Each probe has its own different bone accessories in length.
- The probes do not extend beyond the drill tip.

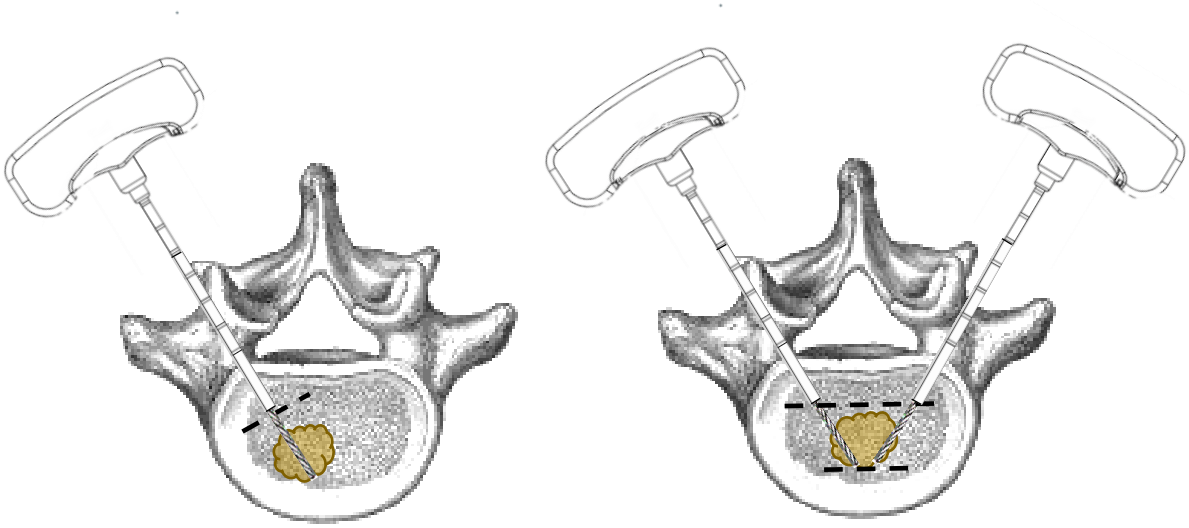


Figure 13 – Rear Limits When Using Drill

ⓘ Note

- The front and rear boundaries must always be respected (Figure 13).
- The ablation will grow to the point where the drill bit is stationary.

11.4 Preparing the irrigation system

⚠ WARNING

- Always fill the 1 mL syringe with normal sterile saline (0.9% NaCl) only.
- The irrigation system will not operate without the placement of the probe in the isolation and irrigation cannula and introducer.

1. Remove the syringe and insulating and irrigation cannula from the sterile package and inspect all devices. Replace any device if damage is evident.
2. Fill the syringe with only 1 (one) milliliter of sterile saline.
3. Connect the isolation and irrigation cannula to the probe (Figure 14) via the luer lock port.
4. Connect the syringe to the port with the Luer Lock system of insulating cannula and irrigation.

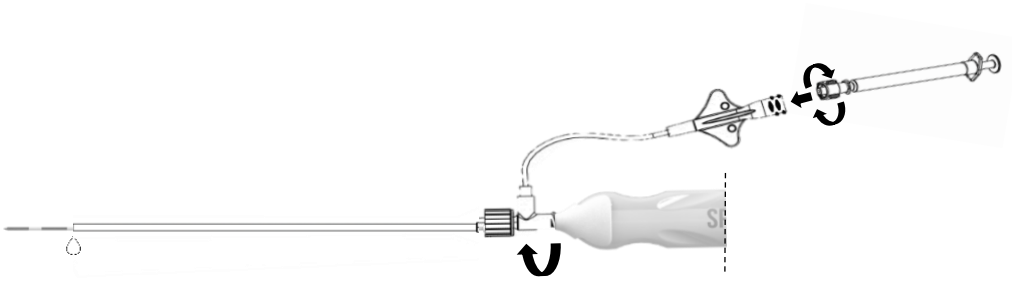


Figure 14 – Connecting the Isolation and Irrigation Needle and Cannula

Note

- Regardless of the type of Probe chosen, the Insulating and Irrigant Cannula is always necessary. The Insulating and Irrigant Cannula always allows the operator to irrigate proximal to the ablation area.

1. Push the plunger of the syringe to fill the isolation and irrigation cannula and observe the flow of saline coming out of the distal portion of the isolation and irrigation cannula, then remove the syringe.
2. Connect the syringe to the syringe port with the probe's luer lock system (Figure 15)

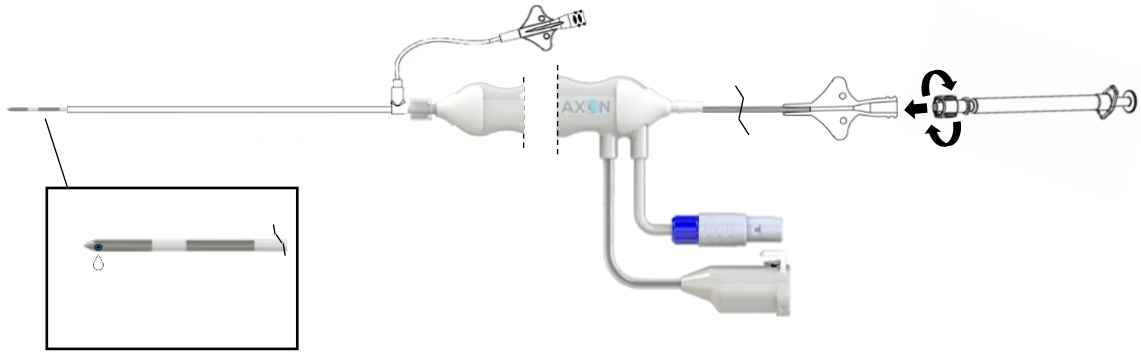


Figure 15 – Connecting the syringe to the distal needle irrigation probe

3. Push the plunger of the syringe to fill the probe irrigation duct and observe the flow of saline coming out of the distal portion of the needle probe, then remove the syringe.

11.5 Preparing for Ablation

WARNING

- Do not perform ablation in the painful osteoporotic vertebra without tumor.
- Do not touch the probe during ablation. RF energy can cause burns.
- Do not pull out the probe while RF energy is being applied during ablation.
- RF energy output does not require continuous activation by the clinician. Once the START button is touched, the RF energy output modulates to create ablation based on the specified time and temperature values selected.
- If the generator experiences an operational failure, an unintentional increase in RF energy production may occur.
- When performing ablation with dual bipolar probes, always ensure (via fluoroscopic imaging) that there is an average distance of 4 mm between the tip of two probes.

1. Fully insert the probes into the positioned introducer and lock it with the introducer's luer lock port (Figure 16).

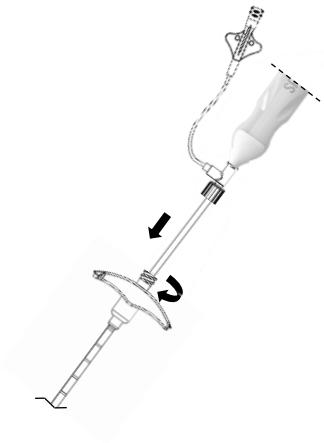


Figure 16 - Inserting the probe into the introducer

2. Refill the syringe with 1 (one) milliliter of sterile saline.
3. Connect the syringe to the Luer Lock port of the isolation and irrigation cannula and inject 0.1 mL of saline into the proximal area of the ablation zone, then remove the syringe.
4. Connect the syringe to the Luer Lock port of the probe and inject 0.1 mL of saline into the distal area of the ablation zone, then remove the syringe.

11.6 Selection of ablation parameters

The selection of clinical ablation parameters (temperature, duration, mode and thermal profile) must be carried out exclusively through the Spinery® RF Generator, according to the indications contained in the relative Instructions for Use.

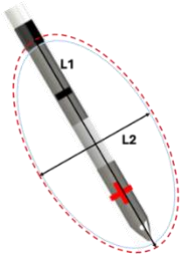
⚠ Caution: Always consult the Spinery® RF Generator IFU for proper setting of ablative parameters, including preset configurations, irrigation requirements, and operating limits.

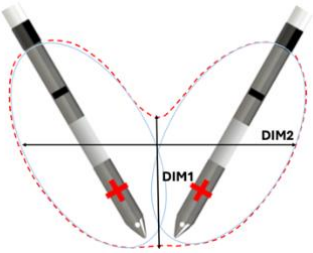
11.7 Usage guide tables

The following table provides an estimate of the ablation size produced by the two variants of the SPINERY® RF Generator probes.

Depending on the site of application (e.g., thoracic or lumbar vertebra), the size of the tumor, and its location within the vertebra, the user can decide whether to use the probe from the SP-BI0704EU or SP-BI1005EU kit, as well as the appropriate ablation mode (parallel or cross ablation).

The following tables present an estimated average of the critical ablation area size for the two product variants and operating modes.

Single Bipolar Access		L1	L2	
SP-BI1005EU	Single Level	25 mm	13 mm	
	Three Levels	25 mm	14 mm	
SP-BI0704EU	Single Level	18 mm	10 mm	
	Three Levels	19 mm	10 mm	

Double Parallel Bipolar Access		DIM1	DIM2	
SP-BI1005EU	Single Level	17 mm	29 mm	
	Three Levels	17 mm	29 mm	
SP-BI0704EU	Single Level	18 mm	20 mm	
	Three Levels	18 mm	20 mm	

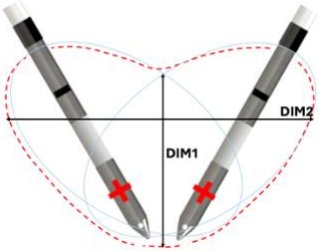
Double Bipolar Cross Access		DIM1	DIM2	
SP-BI1005EU	Single Level	22 mm	19 mm	
	Three Levels	24 mm	24 mm	
SP-BI0704EU	Single Level	18 mm	22 mm	
	Three Levels	18 mm	21 mm	

Table 8 – Usage Tables

Note

- The above dimensions are the result of evaluations of the ablation area following ex-vivo tests on bovine liver.

11.8 Ablation Probe Placement

Example scenarios of overlapping the distance of the probes and the ablation zone are shown in Figure 17 with a range of 60 degrees of angulation, depending on the access vertebrae.

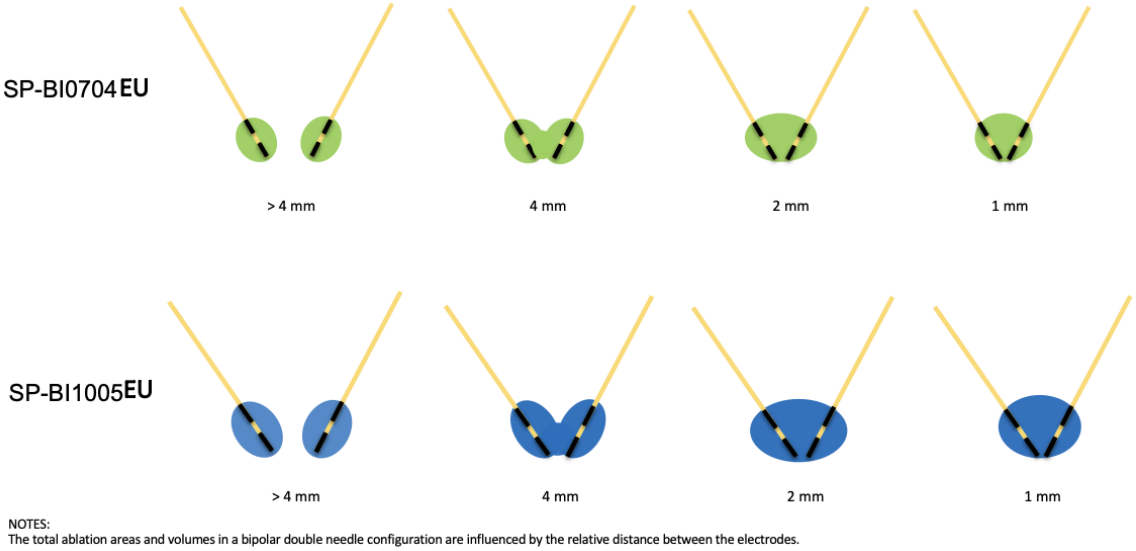


Figure 17 – Examples of overlapping the ablation zone

11.8.1 Bone Access Kit Size References and Needle Ablation

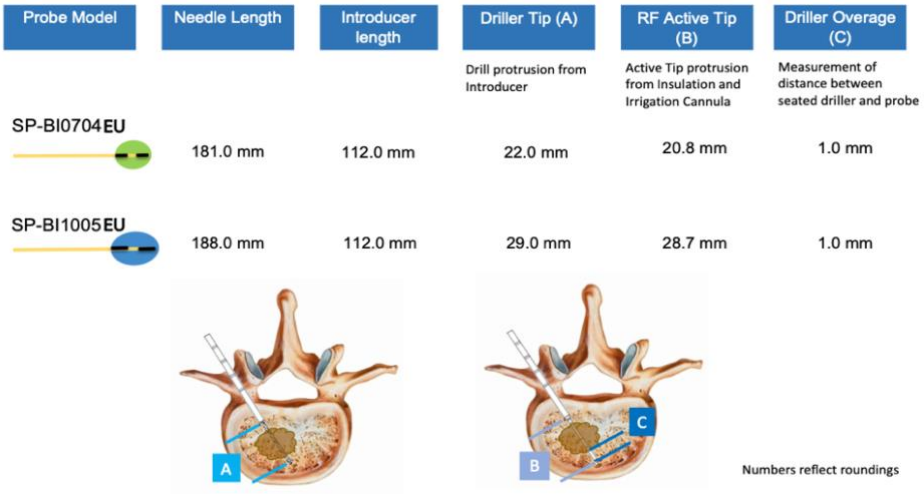


Figure 18 - Probe Access Tools and Measurement References

11.9 Radio Frequency energy supply

⚠WARNING

- Always check that the probe(s) connected via the Kit read/read the body temperature correctly before starting the ablation.
- Do not proceed with ablation in case of abnormal temperature readings or fluctuating values. If this occurs, contact your AXON authorized personnel.
- All ablation setup and control operations must be performed exclusively through the Spinery® RF Generator, following the instructions in the relevant IFU.

The radio frequency power supply is handled by the Spinery® RF Generator. The Spinery® Kit allows the safe connection of the bipolar probe and irrigation channels. At the end of the procedure, proceed with the removal of the probe and with the subsequent phases according to the planned clinical protocol.

- When used in combination with vertebral cementation systems, refer to the specific Instructions for Use of the device used.

12 AFTER USE

12.1 Removing components and disposal

⚠ WARNING

- Disposal of the components of the Spinery® Kit must be carried out in accordance with current regulations relating to 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® Kit 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® Kit, 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.r.l. 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 S.r.l.


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


Tel.: +39 081 229 0044


info@axonmedicalsystems.com


https://www.axon.productions

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 - SPINERY® Kit and SPINERY® Cooling Connection - must be considered sanitary waste and disposal in accordance with current regulations.

17 ACRONYMS

ACRONYM	DEFINITION
RF	Radio frequency
DPI	Personal Protective Equipment
SDS	System Board
RM	Magnetic Resonance Imaging

Table 9 – Glossary Acronyms

18 IFU IN OTHER LANGUAGES

The Instructions for Use (IFU) for the Spinery® Kit 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: