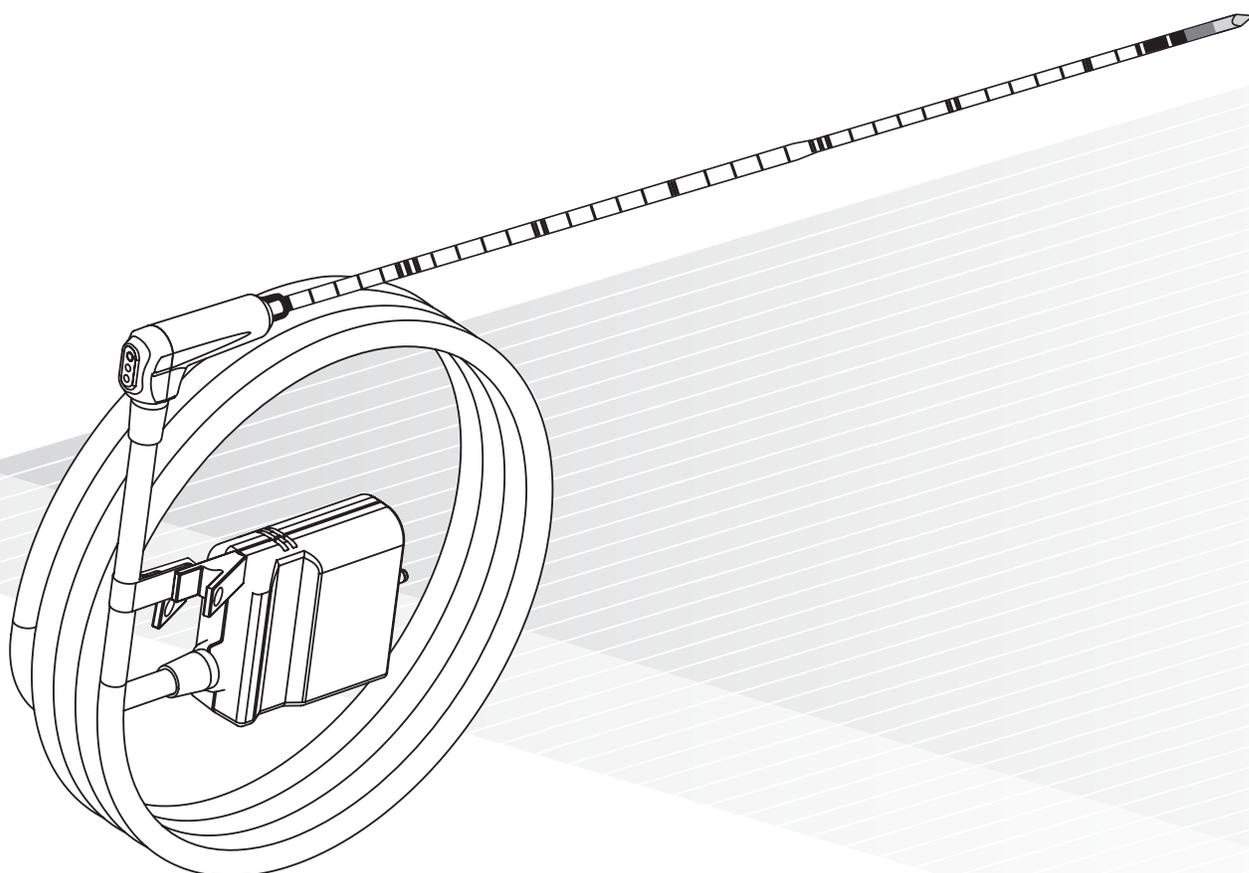


NeuWave™

Ablation Probes, Instructions for Use

www.e-ifu.com: [en](#)

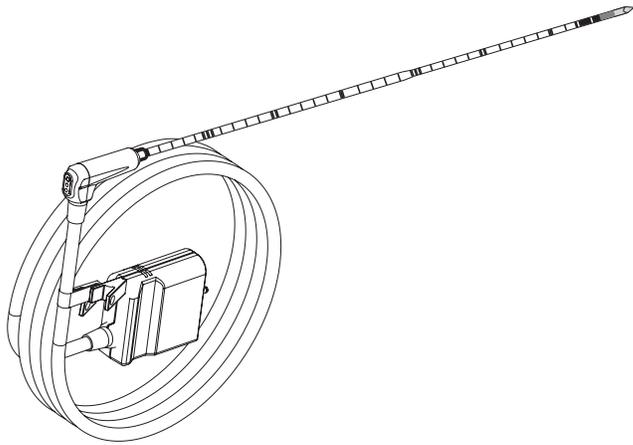


REF PRS35

ETHICON™

Johnson & Johnson SURGICAL TECHNOLOGIES

NEUWAVE™ Surgical PR Probe
35CM 11/13ga



Read this entire document and any accessory documents prior to use.

NEUWAVE Ablation Probes are provided sterile. Follow facility procedures for sterile device handling.

CAUTION Federal law restricts this device to sale by or on the order of a physician. Outside the U.S.A., check local laws for any restrictions that may apply.

NEUWAVE™ is a trademark of NeuWave Medical, Inc.

Other brand names or product names used in these instructions for use are trademarks or registered trademarks of their respective holders.

Indications For Use

The NEUWAVE™ Microwave Ablation System and Accessories are indicated for the ablation (coagulation) of soft tissue in percutaneous, open surgical and in conjunction with laparoscopic surgical settings, including the partial or complete ablation of non-resectable liver tumors.

The NEUWAVE Microwave Ablation System is not indicated for use in cardiac procedures.

Patient Target Groups

The NEUWAVE Microwave Ablation System (NEUWAVE System) is intended to be used on the general population undergoing ablation of soft tissue in percutaneous, open surgical or in conjunction with laparoscopic surgical settings.

The system should not be used on:

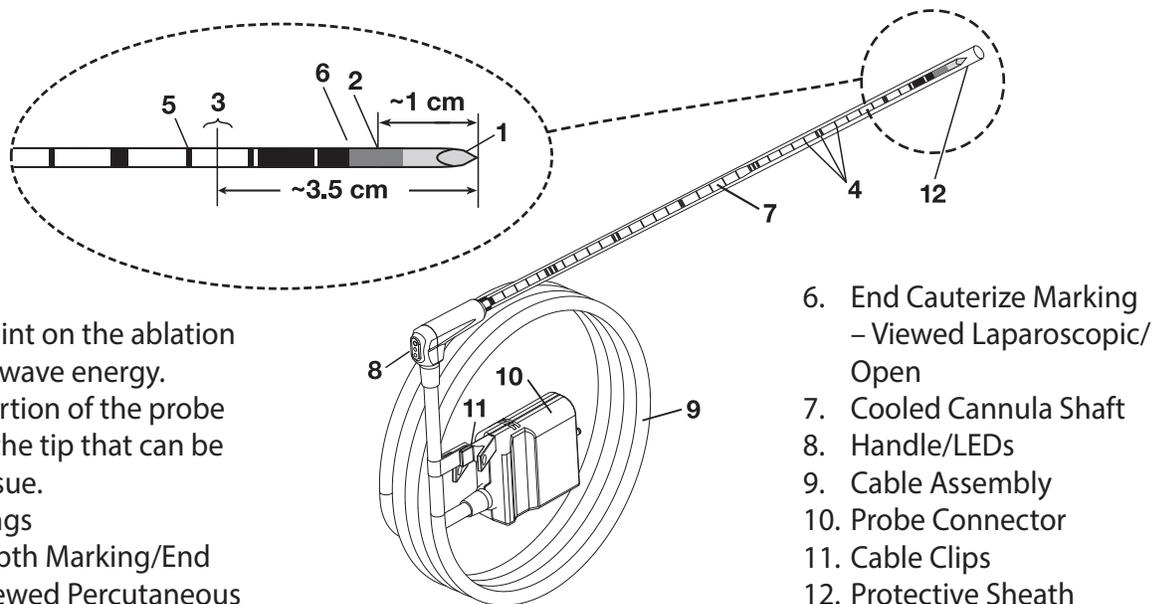
- pregnant patients, and,
- patients with implantable pacemakers or other electronic implants.

Intended Users

The NEUWAVE System should only be used by licensed physicians.

Intended Use and Device Description

The NEUWAVE Surgical PR 35 cm Ablation Probe (NEUWAVE PRS35 Probe) is a sterile, single-patient-use device intended to be used for ablation and coagulation of soft tissue. The device has an 11 ga probe cannula that tapers to a 13 ga tip. The cannula shaft is 35 cm.



1. Trocar
2. Emitting Point – the point on the ablation probe that emits microwave energy.
3. Tissu-Loc™ Zone – a portion of the probe cannula ~3.5 cm from the tip that can be cooled to adhere to tissue.
4. Insertion Depth Markings
5. Minimum Insertion Depth Marking/End Cauterize Marking – Viewed Percutaneous

6. End Cauterize Marking – Viewed Laparoscopic/Open
7. Cooled Cannula Shaft
8. Handle/LEDs
9. Cable Assembly
10. Probe Connector
11. Cable Clips
12. Protective Sheath

A protective sheath is provided installed on the NEUWAVE Ablation Probes to protect the user from the sharp probe tip during removal from the package and to prevent accidental contact of the probe tip with non-sterilized surfaces during setup. The probe protective sheath must be removed prior to probe testing.

Visually inspect all packaging for damage, including a careful inspection of all sterile barrier systems for breaches in package integrity, immediately prior to use.

CAUTION: Do not use if the product sterile barrier system or its packaging is compromised.

Performance Characteristics

NEUWAVE PRS35 Probes were designed to limit the length of the ablation for instances when a shorter ablation zone is desired. NEUWAVE PRS35 Probes were developed to provide physicians with an additional ablation probe designed specifically for ablating smaller targets. NEUWAVE PRS35 Probes are designed to produce ablations that quickly encompass the tip of the probe while limiting the overall length of the ablation.

Up to three (3) probes can be connected to the NEUWAVE System and powered at any time. This can be done to create one larger ablation or three (3) independent ablations. Refer to tables of ex-vivo ablation results and guidelines for minimum and maximum probe separation distances.

The NEUWAVE PRS35 Probe is designed for use exclusively with the NEUWAVE System. Refer to the NEUWAVE System User Manual for complete instructions for use.

Target Ablation Use Guide

Single Probe	
Lung Tissue	See 3 below
Liver Tissue	✓
Kidney Tissue	✓
Other Soft Tissue	See 1 below
Multiple Probes	
Lung Tissue	See 3 below
Liver Tissue	✓
Kidney Tissue	See 1 and 2 below
Other Soft Tissue	See 1 below

1. Performance characteristics of NEUWAVE Ablation Probes have not been established in all probe and tissue type combinations.
2. Multiple probes make larger ablations than single probes. When using multiple probes, ensure that the target tissue is an appropriate size to limit the risk of unintended thermal damage to non-target tissue.

3. Performance characteristics of multiple probes and 15 ga or larger probes have not been established for lung tissue.

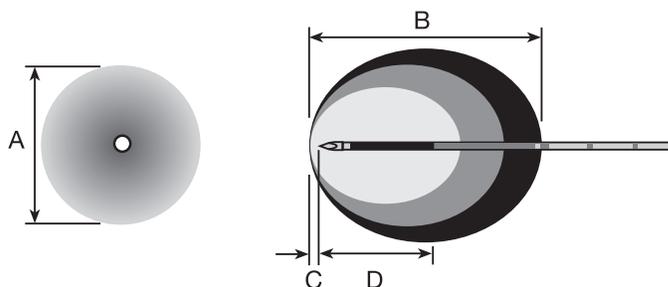
In percutaneous applications, always use imaging to confirm desired ablation results. See tables of ex-vivo ablation results.

Ex-Vivo Ablation Results

The following are examples of ex-vivo ablation results when using single and multiple probes at various power and time settings. These examples are from ex-vivo animal (bovine and porcine) tissue.

The size of ablation zones may vary in clinical settings due to vasculature structure and the cooling effect of blood flow not present in ex-vivo tissue.

**Single Probe Ablations
NEUWAVE Surgical PR Probes (PRS35)**



Bovine Liver – Ex-Vivo

Power (W)	Time (Min)	(B) Length (cm)	(A) Diameter (cm)	(C) Distance Past Tip (cm)	(D) Tip to Center (cm)	Ablation Volume (cm ³)
40	5	2.6	2.0	0.3	1.0	5.5
40	10	3.3	2.5	0.4	1.2	10.8
90	5	3.7	2.7	0.5	1.4	14.1
90	10	4.4	3.3	0.6	1.7	25.1
140	5	4.9	3.4	0.6	1.9	29.7
140	10	5.6	4.0	0.7	2.1	46.9

Porcine Kidney – Ex-Vivo

Power (W)	Time (Min)	(B) Length (cm)	(A) Diameter (cm)	(C) Distance Past Tip (cm)	(D) Tip to Center (cm)	Volume (cm ³)
40	5	2.6	1.7	0.4	0.9	3.9
40	10	3.3	2.2	0.5	1.2	8.4
90	5	3.6	2.4	0.5	1.3	10.9
90	10	4.3	2.9	0.6	1.6	18.9
140	5	4.6	3.0	0.6	1.7	21.7
140	10	5.3	3.5	0.7	1.9	34.0

Multiple Probe Ablations

Based upon ex-vivo results, NeuWave recommends a maximum of 2 cm spacing between probes. This results in a contiguous ablation. Ablations spaced more than 2 cm had non-contiguous results. Ablations spaced a minimum of 8 cm resulted in three independent ablation zones that did not overlap.

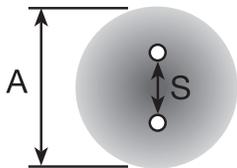
Performance characteristics of multiple probes and 15 ga or larger probes have not been established for lung tissue.

Multiple probes make larger ablations than single probes. When using multiple probes, ensure that the target tissue is an appropriate size to limit the risk of unintended thermal damage.

NEUWAVE Surgical PR Probes (PRS35)

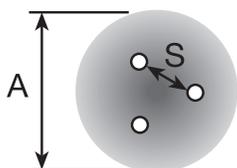
2 Probe: 110 W Power Setting in Bovine Liver, Ex-Vivo

Time (Min)	(B) Length (cm)	(A) Diameter (cm)	(S) Probe Spacing (cm)	Volume (cm ³)
10	5.8	5.0	2	60.9



3 Probe: 80 W Power Setting in Bovine Liver, Ex-Vivo

Time (Min)	(B) Length (cm)	(A) Diameter (cm)	(S) Probe Spacing (cm)	Volume (cm ³)
10	5.7	5.6	2	73.5



Ablation Zone Guidance Factors

The ablation zone data provided on-screen and in the instructions for use are from ablations performed in ex-vivo animal tissue and do not account for the cooling effects of blood flow.

Probe temperatures are highly dependent on tissue variables such as perfusion and vasculature. Probe temperatures are likely to vary from procedure to procedure based on these tissue variables. These temperature variations do not, by themselves, indicate a malfunctioning probe or system.

Blood flow will generally result in a smaller ablation.

Lower power ablations are more impacted by the cooling effects of blood flow.

Additional factors that may impact the final ablation zone include but are not limited to:

Factors that may result in a smaller ablation	Factors that may result in a larger ablation
Increased/high level of vascularity	Decreased/low level of vascularity
Proximity to large blood vessels	Prior treatments such as TACE or embolization

Physicians should consider all factors when determining the appropriate ablation parameters for each case.

Surgical Coagulation Use Guide

NEUWAVE PRS35 Probes can be used for surgical coagulation in single probe configurations only. NEUWAVE PRS35 Probes will not fit into the Surgical Clip (DR-001193/RCPK). See the NEUWAVE System User Manual for more information.

Warnings and Cautions

WARNINGS

- The NEUWAVE System should not be used in the following situations:
 - Pregnant patients – potential risks to patient and/or fetus have not been established.
 - Patients with implantable pacemakers or other electronic implants. Implanted electronic devices may be adversely affected by microwave power.
 - Use on the central nervous system.
- Electrosurgical/electrocautery devices may interfere with the NEUWAVE System and cause system errors. Ensure that all NEUWAVE Ablation Probes are removed from the patient prior to using electrosurgical/electrocautery devices.
- Use only NEUWAVE Ablation Probes with the NEUWAVE System. Probes from other manufacturers may cause patient injury or fail to function properly.
- This product should only be used by physicians and staff properly trained in the use of the technology and its associated warnings and cautions.
- NEUWAVE Ablation Probes are provided sterile and are single-use devices. Do not reuse or re-sterilize any product labeled "SINGLE USE". Doing so may result in cross-contamination, injury to the patient or medical staff, or equipment malfunction.
- Do not use damaged probes and probes beyond the expiration date noted on the packaging.
- Examine each probe prior to use. Do not use probes with obvious visual damage. Injury to the user or patient may occur.

- Use medical imaging devices to verify proper probe placement prior to delivering microwave energy to the patient. Do not use the NEUWAVE PRS35 Probe, 35 cm Ablation Probe in a CT imager. Patient injury can occur from the probe handle contacting the CT bore.
- Intraprocedure and/or post-ablation imaging are recommended to assess the extent of tissue coagulation.
- Probe tips are sharp. Handle with care.
- Always inspect probes and cables for chips, cracks, or other damage before each use. Do not use damaged probes.
- Do not defibrillate a patient with a probe inserted. Completely remove the probe from the patient before defibrillation.
- Do not place probes so that the probe cables are draped on or near the patient's head or neck.
- Prior to starting an ablation, use imaging to confirm proper probe placement and that the probe is not bent or broken.
- Do not attempt to bend or reshape probes. Probe malfunction may occur, possibly causing patient injury.
- Probes are provided sterilized. Follow your facility sterile handling guidelines.
- The probe cable can heat and reach 60°C during energy delivery. When placing the probe, verify that the probe cable does not rest on the patient's skin. Use the included clips to secure the probe cable away from the patient's skin as needed.
- The non-active region of the probe cannula can heat and reach 48°C during energy delivery.
- Any undue handling or touching of the probe shaft during or following use could result in a thermal injury to the patient or user.
- Never bend or apply excessive force to the probe. Probe malfunction may occur possibly causing patient injury.
- Never remove a probe from the patient while "Tissu-Loc™" mode is enabled or the displayed temperature is below 0°C. Serious internal injuries may result.
- Never activate a probe function other than "Test" when the probe is not placed in tissue.
- Probes removed from the body may be hot. Handle with care to avoid user and/or patient injury.
- Do not connect ablation probes directly to the back of the cart as potential injury to the patient or user is possible.
- Do not attempt to disconnect a probe when any functions are active.
- Do not handle probes that appear excessively cold.
- NEUWAVE Ablation Probes can be used with needle introducers. If a needle introducer is used, it must be retracted so that it doesn't interfere with the planned ablation zone prior to delivering energy. Failure to retract the needle introducer a sufficient distance may impact energy delivery.
- Do not apply a clamp or hemostat to the probe shaft or cable as this may damage the probe and cause a malfunction.
- Probe movement during ablation is possible. Probe movement can be caused by patient movements from breathing, coughing, etc. and also by pressure applied to the probe when target tissue contracts in response to the ablation. To help prevent probe movement, hold the probe handle in place during the initial period of the ablation (approximately 45 seconds). Monitor the probe for movement throughout the procedure and hold the probe in place as needed. If repositioning of a probe is required, stop energy delivery prior to repositioning the probe.
- Charred tissue may accumulate on the probe tip during planar coagulation. As needed, use a soft sterile soft cloth or soft pad to remove any tissue build up on the probe tip. Probe tip may be hot. Never use a rough surface or scratch pad to clean the probe tip as this may damage the probe and result in errors or malfunction.
- There are temperature sensors on the outside of the probe shaft. If the temperature sensors are damaged during placement or use of the probe, the NEUWAVE System will generate an error and disable the probe. To minimize the risk of damaging the temperature sensors during placement, avoid penetrating rigid structures such as bones and cartilage without the use of an introducer. Sharp instruments and hemostats/clamps should never be used along the probe shaft. Ultrasound guides and needle introducers should be used with caution.
- When using a probe in or near rigid structures such as bones and cartilage, use care not to apply excessive lateral force or excessively bend the probe. Near the probe tip, the probe shaft is made of ceramic, which may break if excessive force is applied. This may result in the probe tip being detached from the probe and possibly remaining in the patient.
- Keep metal objects, including other medical instruments, away from the probe shaft when delivering energy. Energy from the probe may radiate to the metal objects causing them to heat.

- Ensure the tip of the probe is inserted in tissue to the minimum insertion depth marking prior to activating power.
- Reuse and improper reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure that in turn may result in patient injury or illness.
- Reuse and improper reprocessing or re-sterilization of single-use devices may create a risk of contamination and/or cause infection or cross-infection, including, but not limited to, the transmission of infectious diseases. Contamination may lead to injury, illness, or death.
- System, probes, and accessories should be placed appropriately to prevent cable tripping hazard.
- The Surgical Clip (DR-001193/RCPK) is the only clip that is designed for use with 17 ga and 15 ga probes. To avoid damage to probes, do not use probes larger than 15 ga with the Surgical Clip (DR-001193/RCPK).

CAUTIONS

- Do not use if the product sterile barrier system or its packaging is compromised.
- When performing procedures, always use the lowest power setting and shortest time that will achieve the intended results. Refer to Ex-Vivo Ablation Results for example ex-vivo ablation sizes based on power and time settings.

Undesirable Side Effects and Residual Risks

Undesirable side effects and risks associated with microwave ablation devices may include bleeding, pain, soft tissue injury, unintended thermal damage to adjacent structures/organs, infection, and post ablation syndrome. Serious complications, including organ injury, dysfunction or failure; cardiac arrhythmia; vessel or nerve injury; pleural effusion, pneumothorax/hemothorax, gas embolism, thromboembolism, and fistula, are uncommon, but possible. There is also potential for failure to achieve desirable ablation therapy, which may require additional surgery or lead to inadvertent tumor seeding, foreign body retention, magnetic resonance incompatibility, or electric shock. Additionally, there may be unknown side effects associated with use of the device. All of these undesirable side effects and risks have been classified as remote.

Risk Grading	Grading Range
Remote	≤ 23 in 100,000

MRI Safety

NeuWave Ablation devices are not intended to be used in an MR environment. Do not use the NeuWave Ablation System, Accessories, and Probes in an MRI Scanner.

Expected Clinical Benefit

The expected clinical benefit of the NEUWAVE System is the minimally invasive coagulation of soft tissue.

Probe Disposal

Disconnect all NEUWAVE Ablation Probes from the PDM and dispose of probes according to local requirements and regulations for sharps. Probes which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.

Some internal components of this device contain lead. Disposal should be performed according to local requirements and regulations.

Dispose of all opened instruments whether used or unused. This device is packaged and sterilized for single use only.

Storage and Transport Conditions

Storage Conditions:

- Temperature: ≤+30° C
- Humidity: 5% to 90% RH, non-condensing

Storage and Transport Conditions:

- Keep dry
- Keep away from heat

Serious Incident Reporting

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation EU 2017/745); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

	en: Sterilized using ethylene oxide
	en: Do not re-use
	en: Batch code
	en: Use-by date
	en: Manufacturer/Date of Manufacture
	en: Do not re-sterilize
	en: Do not use if package is damaged and consult instructions for use
	en: Packaging unit
	en: Peel Here
	en: Catalogue number
	en: Caution
	en: Keep dry
	en: Keep away from heat
	en: Single sterile barrier system
	en: Consult instructions for use or consult electronic instructions for use
	en: Type BF applied part

	en: Caution: Federal law restricts this device to sale by or on the order of a physician.
	en: Humidity limitation
	en: Upper limit of temperature
	en: Unique Device Identifier
	en: Date of manufacture



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