AeroPace® Neurostimulation Catheter Kit

For use only with a compatible Lungpacer System

Rx Only

Introduction

The AeroPace Neurostimulation Catheter Kit contains one AeroPace Neurostimulation Catheter and accessories that may be used for insertion of the Catheter. The AeroPace Neurostimulation Catheter is a component of a Lungpacer Temporary Transvenous Diaphragm Activation System ("System"). The Catheter Kit contains the following items:

Catheter Kit Component	Qty	Catheter Kit Component	Qty
AeroPace Neurostimulation Catheter, 8.5Fr. (2.8mm) x 23cm	1	Primary Cable Clamp	1
Needle, 18G x 2.75in (1.3mm x 70mm)	1	Guidewire Tip Protector	1
Scalpel, #11	1	Dressing, Tegaderm, 4in x 4.75in (10cm x 12cm)	1
Sharps Receptacle	1	Gauze, 4in x 4in (10cm x 10cm)	5
Syringe, 3ml, Luer Lock with 25G x 1in (0.5mm x 25mm) Needle	1	Suture, 3-0 Silk, C7 Reverse Cutting Needle	1
Syringe, 5ml, Luer Slip	2	Drape, 24in x 36in (60cm x 90cm), with 4in (10cm) Fenestration	1
Needle-Free Male Luer Lock Injection Site	3	Catheter Clamp Fastener	1
Guidewire Dispenser	1	Guidewire J-Tip, EHD 0.032in (0.81mm) x 70cm	1
Guidewire J Straightener	1	Dilator, 8Fr. x 4in (2.7mm x 10cm)	1
Catheter Clamp	1	Needle Holder, 5in (13cm)	1

The Catheter is sterilized by exposure to ethylene oxide (EO) gas and is for single use up to 30 days. Accessories in the Catheter Kit are provided sterile and are for single use only.

Refer to the System User Guide for information on the clinical trials conducted using the AeroPace Neurostimulation Catheter.

Intended Use

The AeroPace Neurostimulation Catheter is intended for use as part of a Lungpacer System, and for short-term (< 30 days) central venous access for administering IV fluids, blood products, medications, and parenteral nutrition solutions, as well as blood withdrawal, central venous pressure monitoring, and power injection of contrast media.

The AeroPace Neurostimulation Catheter is intended to be used with a Lungpacer System for stimulation of the phrenic nerve(s). Refer to the System User Guide for the intended use of the System.

The AeroPace Neurostimulation Catheter is intended for use in hospitals and hospital-type facilities by qualified, trained personnel under the direction of a physician.

Indication for Use

Refer to the System User Guide for the indications for use of the System.

Potential Complications

The potential complications associated with central venous catheters are:

- Adverse tissue response
- Allergic reaction
- Arrhythmia
- Bleeding / Hemorrhage
- Bradycardia
- Bruising, swelling or seroma at insertion site
- Cardiac structure damage
- Central line-associated blood stream infection
- Cerebrovascular event
- Discomfort
- Embolism
- Hematoma
- Hemothorax
- Hypertension / hypotension
- Inadvertent arterial or venous puncture
- Infection
- Lung injury
- Lymphatic / thoracic duct injury
- Mediastinal injury
- Nerve injury
- Pain, tenderness, swelling, discomfort at access site
- Pneumohematoma
- Pneumomediastinum
- Pneumothorax
- Procedural complications
- Pseudo aneurysm or AV fistula at access site
- Sepsis
- Seroma
- Skin irritation
- Syncope
- Thrombosis / stenosis
- Tissue inflammation, fibrosis or damage
- Vessel occlusion
- Vessel wall damage / perforation
- Wound healing issues
- Wound infection / phlebitis

The potential complications associated with diaphragm or phrenic nerve stimulation are:

- Arrhythmia
- Bradycardia
- Diaphragm injury
- Discomfort
- Hypercapnia / hypocapnia
- Hypoxia
- Liberation of lung mucus plugs/secretions
- Muscle fatigue or discomfort
- Nerve injury
- Pain or discomfort during stimulation
- Inappropriate stimulation
- Phrenic nerve damage or injury
- Syncope

Warnings

WARNING: Read all AeroPace Neurostimulation Catheter warnings, cautions, and instructions prior to use. Failure to observe warnings may result in severe injury or death:

- The portion of the AeroPace Neurostimulation Catheter inside the patient's tissue or veins should not be exposed to therapeutic levels of ultrasound energy, as the device may inadvertently concentrate the ultrasound field and cause harm.

WARNING: Read instructions

Do not place the Catheter (or allow it to remain) in the right atrium or right ventricle.

Failure to follow these instructions may result in severe injury or death.

- Ensure patency of distal lumen prior to high-pressure power injection due to the risk of Catheter failure and other potential complications.
- Do not exceed maximum pressure or maximum flow rate during high-pressure injection through the distal lumen due to the risk of Catheter failure and/or potential complications.
- Discontinue high-pressure power injection at first sign of extravasation or Catheter deformation. Follow your institutional protocol for appropriate medical intervention.
- Do not use excessive pressure during fluid delivery through the injection lumen for the proximal and medial lumens due to the risk of Catheter damage. These lumens are not rated for high-pressure power injection.
- The Catheter tip must be located in the central circulation when administering >10% glucose solution, total parenteral nutrition, continuous vesicant therapy, infusates with an osmolarity above 600 mOsm/L, or any medication known to be irritating to vessels proximal to the vena cava.
- Use only securely tightened luer lock connections to guard against any inadvertent disconnection that may result in air embolism and blood loss.

Preparing for Catheter Insertion Warnings:

- Ensure there is no damage to the Catheter or its packaging that could compromise sterility of the device. Do not use the AeroPace Neurostimulation Catheter Kit if its packaging is damaged. Discard the Catheter Kit if there is visible damage to the packaging.
- Do not use the AeroPace Neurostimulation Catheter Kit beyond the use-by date on the label. Use after the use-by date may increase the risk of infection.
- Do not cut the Catheter to alter length. Cutting the Catheter will damage it and could cause severe injury or death.
- Ensure there are no leaks from the hub or near the extension line connection. Such leaks may contribute to infection.
- Do not use a guidewire with a diameter in excess of 0.81 mm (0.032 inches). Using a guidewire with a diameter that is too large may damage the Catheter.

Catheter Insertion Warnings:

- Do not leave open needles or uncapped, unclamped catheters in central venous puncture site. This can cause air embolism.
- Do not use a guidewire with a diameter in excess of 0.81 mm (0.032 inches). Using a guidewire with a diameter that is too large may damage the Catheter.
- Do not use excessive force to advance or withdraw the guidewire as this can lead to vessel damage.
- Do not aspirate with the guidewire in place, as air may enter syringe.
- Do not advance the guidewire into the heart or allow it to be placed or remain in the right atrium. This may result in cardiac injury, arrhythmia, or tamponade.
- Do not withdraw the guidewire against the needle bevel to minimize the risk of severing or damaging the guidewire.
- Do not cut the guidewire. A rough wire could cause vessel damage.
- Do not leave the tissue dilator in place as an indwelling catheter due to the risk of vessel wall perforation.

Catheter Advancement Warnings:

- Do not use undue force to remove the guidewire, as the application of force may damage or break the guidewire and cause vessel damage. Do not attach the Catheter clamp until the guidewire is removed, as it may create resistance during removal.
- Open the clamp prior to infusion of fluid through lumen to minimize the risk of damage to the extension line from excessive pressure.

Catheter Placement Warnings:

- The AeroPace Neurostimulation Catheter is for use only with compatible Lungpacer Systems. Refer to the System User Guide for warnings and cautions related to use of the System.
- Do not tie sutures directly around the Catheter shaft. Use the suture tabs provided on the Catheter manifold. Sutures directly around the Catheter shaft may damage or break it, and may cause embolism, leakage, and increased risk of infection.
- Do not position the Catheter (or allow it to remain) in the right atrium, right ventricle, or in a position that may induce cardiac arrhythmia. Incorrect positioning of the Catheter may result in cardiac injury, arrhythmia, or cardiac tamponade.
- Do not run Mapping on the Console without assessing the placement of the Catheter in compliance with hospital/institutional practices or current guidelines.

MRI Warning: The AeroPace Neurostimulation Catheter is MR Conditional, but the Console and other System components are MR Unsafe. Conditions under which the AeroPace Neurostimulation Catheter is MR compatible and may be scanned safely are described in the MRI Safety Information. Always disconnect the Catheter from the Console before conducting MRI, and keep the Console away from MR equipment. Failure to follow these instructions while performing MRI may result in physical trauma.

Cautions

⚠ **General Catheter Cautions:**

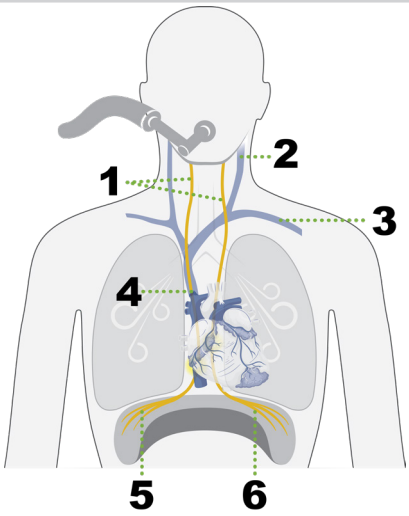
- Improper handling of the Catheter extension lines and/or the insertion site, use of a non-sterile Catheter, use of the Catheter beyond its recommended use period (30 days), and/or failure to adhere to aseptic catheter insertion technique may result in infection.
- If external defibrillation or any medical treatment in which electrical current is passed through the patient's body from an external source is necessary, disconnect the Catheter from the Catheter Cable first. Failure to disconnect the Catheter before exposure to electrical current may result in non-effective defibrillation, and/or irreparable damage to the System. If a defibrillation event occurred with the Catheter connected to the Console, contact Lungpacer before subsequent use of the System.
- When disconnected, ensure all Catheter and Catheter Cable connector pins are not in contact with operator, or with any other active or electrically grounded surface. Touching or electrically grounding the contacts of the Catheter's electrical connector (including the contacts of the Catheter Cable connector while connected to the Catheter) may result in cardiac arrhythmia.
- Excessive bending, torquing or kinking of the Catheter may cause damage to the device including its electrical conductors.
- Multiple replacements of the Catheter increase the risk of vessel wall damage, perforation or infection.
- Ensure sharp procedure implements do not cut or damage the Catheter.

Pre-Insertion and Patient Assessment Activities

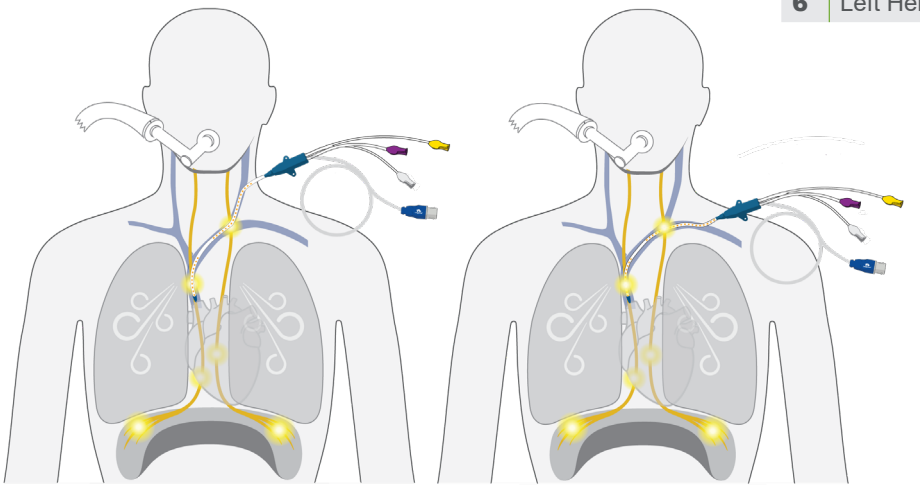
⚠ CAUTION:

- Do not use a right-side venous access point for the AeroPace Neurostimulation Catheter insertion as this will adversely impact the likelihood of phrenic nerve capture.
- The US Centers for Disease Control and Prevention recommend catheter placement using a subclavian site rather than a jugular site in adult patients to minimize infection risk.

1. Conduct a clinical assessment of the patient to ensure no medical or anatomical conditions (such as nerve damage) or device interactions exist that may prevent use of the Catheter for the intended use.
2. Perform hand hygiene as required.
3. Verify physician order by confirming the correct patient and procedure.
4. The physician order must include post-placement assessment of the Catheter tip location (direct visualization technique or other method according to hospital/institutional practices or current guidelines).
5. Identify the insertion site. The Catheter can be inserted in either the left subclavian vein or the left jugular vein. Use direct ultrasound to visualize the location of the left subclavian vein or left jugular vein.
6. Position the patient as appropriate for the insertion site. The patient should be in slight Trendelenburg position, as tolerated, to reduce the risk of air embolism and enhance venous filling.
7. Prepare work area.



#	Anatomy
1	Phrenic Nerves
2	Left Jugular Vein
3	Left Subclavian Vein
4	Superior Vena Cava (SVC)
5	Right Hemidiaphragm
6	Left Hemidiaphragm



Jugular Catheter Insertion

Subclavian Catheter Insertion

Preparing for Catheter Insertion

The Catheter can be inserted into either the left subclavian vein or the left jugular vein using an over-the-wire procedure and is marked with numerals to indicate the distance from the tip of the Catheter in centimeters. The integrated electrodes are activated via the Console to stimulate the left and right phrenic nerves, and strengthen the diaphragm to facilitate weaning.

Note: The AeroPace Neurostimulation Catheter is not made with natural rubber latex.

WARNING:

- Do not use the AeroPace Neurostimulation Catheter Kit if its packaging is damaged. Discard the Catheter Kit if there is visible damage to the packaging.
- Do not use AeroPace Neurostimulation Catheter Kit beyond the use-by date on the label. Use after the use-by date may increase the risk of infection.
- Do not cut the Catheter to alter length. Cutting the Catheter will damage it and could cause severe injury or death.
- Ensure there are no leaks from the hub or near the extension line connection. Such leaks may contribute to infection.

CAUTION:

- Cessation and reinitiation of subtherapeutic anticoagulation before Catheter insertion should be governed by either local hospital guidelines or published medical society guidelines.
- Ultrasound guidance for placement of the Catheter is recommended.
- Consider reducing ventilator parameters of positive end-expiratory pressure (PEEP) at the time of Catheter insertion within parameters of the physician's experience, hospital and association guidelines to reduce the risk of pneumothorax.
- Inspect the Catheter Kit expiration date before use. Use of expired product may lead to injury.
- Use universal blood and body-fluid precautions in the care of all patients due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood-borne pathogens.
- Properly handle and dispose of sharps in sharps container in accordance with US OSHA or other governmental standards for bloodborne pathogens and/or hospital/institutional policy.
- Do not use the Console to deliver stimulations while the Catheter is inside an introducer sheath, as it may prevent delivery of stimulations and effective Therapy from the Catheter's electrodes.

Note: To maintain the sterile field and sterility of the Catheter during the insertion process, arrange for a second clinician to provide clinical assistance by operating Console outside of the sterile field.

1. Perform hand hygiene as required by your institutional guidelines.
2. Use sterile technique and maximal sterile barrier precautions throughout the procedure, and dress in protective clothing, including a mask, sterile gown, hair cover, eye protection, and sterile gloves.
3. Flush the lumens of the Catheter with sterile saline solution to establish patency and prime the lumen.
4. Prepare the puncture site by cleaning the skin with an appropriate antiseptic agent.
5. Position and secure the sterile drape to the skin at the intended insertion site to maintain the sterile field.
6. Administer local anesthetic per institutional policies and procedures.

Catheter Insertion

WARNING: Do not leave open needles or uncapped, unclamped catheters in central venous puncture site. This can cause an air embolism.

CAUTION: To reduce the risk of infection, consider removing any existing central venous catheter(s) in the patient's left jugular or left subclavian vein before insertion of the AeroPace Neurostimulation Catheter.

Assess the patient for possible implants and the potential for entrapment of the guidewire by any implanted device in the circulatory system (e.g., vena cava filters, stents, and/or catheters). Care should be taken regarding the length of the guidewire inserted. If the patient has a circulatory system implant, the catheterization procedure should be performed under direct visualization to minimize the risk of guidewire entrapment.

1. Gain and verify initial venous access. Using ultrasound as needed, locate the left subclavian vein or left jugular vein relative to the intended insertion site.
2. Insert introducer needle percutaneously into the vein and confirm access.
3. Insert guidewire through the needle and into the vein.

WARNING:
- Do not use excessive force to advance or withdraw guidewire as this can lead to vessel damage.
- Do not aspirate with guidewire in place, as air may enter syringe.
- To minimize the risk of severing or damaging the guidewire, do not withdraw the guidewire against the needle bevel.

CAUTION:
- Hospital/institutional practices or current guidelines must be used to confirm appropriate Catheter placement and the absence of pneumothorax or hemothorax.
- Maintain a firm grip on the guidewire at all times. Keep sufficient guidewire length exposed at hub for handling purposes. A non-controlled guidewire can lead to wire embolism.
- Do not reinfuse blood to minimize the risk of blood leakage from rear (cap) of syringe.
- Improper vein access technique may result in vessel wall damage or perforation.

Note: Pulsatile flow is usually an indicator of inadvertent arterial puncture during the insertion procedure.

4. Remove the introducer needle while ensuring the guidewire is still in the vein.
5. Make a small incision in the skin where the guidewire enters. Take care not to cut the guidewire with the scalpel.

WARNING: Do not cut the guidewire. A rough wire could cause vessel damage leading to severe injury or death.

6. Insert the dilator over the guidewire and dilate the incision as needed.

WARNING: Do not leave the tissue dilator in place as an indwelling catheter due to the risk of vessel wall perforation.

7. Remove the dilator while ensuring the guidewire is still in the vein.

Catheter Advancement

The Catheter's distal tip must be located on the right side of the mediastinum in the superior vena cava (SVC) above its junction with the right atrium and parallel to the vessel wall, and its distal tip positioned at a level above either the azygos vein or the carina of the trachea, whichever is better visualized.

⚠ **CAUTION:** Do not apply excessive force while advancing or retracting the Catheter.

Note: The Console has an optional intravascular electrogram (ECG) feature that can be used during or immediately after insertion of the Catheter, which may be used to assist in placing the Catheter in its target position. The Catheter is marked with numerals to indicate distance from the tip in centimeters.

1. Insert the Catheter by advancing it over the guidewire while maintaining a grip on the guidewire.
2. Position the Catheter so that the tip is placed in the distal SVC by advancing or retracting the Catheter as needed.
3. If the optional ECG feature will be used while placing the Catheter, connect the Catheter's electrical connector to the Catheter Cable while maintaining the sterile field. Then, refer to the System User Guide for details on using the ECG feature.

⚠ **CAUTION:** Ensure that the heart rhythm is not affected when the Catheter is being advanced. If an atrial arrhythmia is detected that could be produced by the Catheter tip having entered the atrium, retract the Catheter tip back into the SVC.

4. Hold the Catheter at the desired depth and remove the guidewire.

⚠ **WARNING:** Do not use undue force to remove the guidewire, as the application of force may damage or break the guidewire and cause vessel damage. Do not attach the Catheter clamp until the guidewire is removed, as it may create resistance during removal.

⚠ **CAUTION:** If resistance is encountered when attempting to remove the guidewire, it may be kinked. If so, pulling on it may result in guidewire breakage. If resistance is encountered, withdraw the Catheter relative to the guidewire about 2-3 cm and attempt to remove the guidewire again. If resistance persists, remove the guidewire and the Catheter simultaneously.

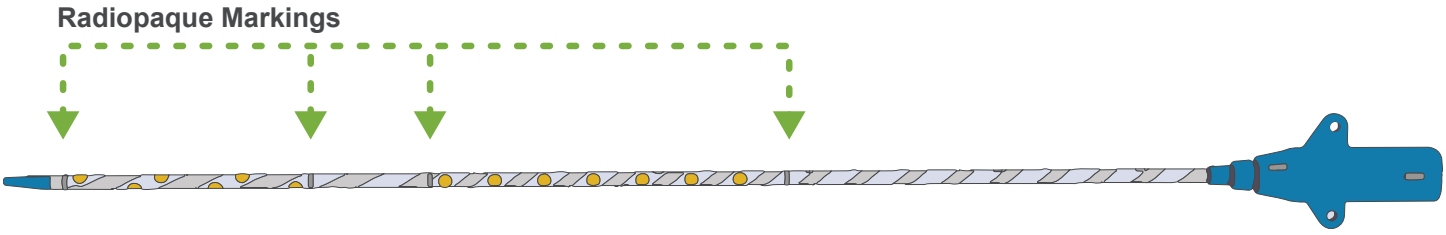
5. Verify that the entire guidewire is intact upon removal.
6. Check placement by attaching a syringe to an extension line and aspirating until free flow of venous blood is observed. If lumens exhibit excessive resistance to blood aspiration, the Catheter may need to be rotated or repositioned to obtain adequate blood flow.
7. Flush the lumens with sterile saline to completely clear blood from the Catheter.
8. To maintain patency of the Catheter, create a heparin lock in the Catheter lumens before clamping the extension lines. Follow institutional guidelines for heparin concentration.
9. Unused ports may be "locked" through luer-activated connectors following your institutional guidelines. Clamps are provided on the extension lines to occlude flow through the lumens during line and injection site changes.

⚠ **WARNING:** Open the clamp prior to infusion of fluid through lumen to minimize the risk of damage to the extension line from excessive pressure.

Performing Placement Using the Console

WARNING: The AeroPace Neurostimulation Catheter is for use only with compatible Lungpacer Systems. Refer to the System User Guide for warnings and cautions related to use of the System.

1. Have the non-sterile operator connect the AeroPace Neurostimulation Catheter to the Console, and consult the System User Guide for instructions on using the Console to perform Placement.
2. Perform Placement and verify that the left phrenic nerve can be recruited by the AeroPace Neurostimulation Catheter as placed.
3. If the left phrenic nerve cannot be recruited during Placement, assess the placement of the Catheter in compliance with institutional guidelines.
4. The AeroPace Neurostimulation Catheter contains radiopaque markings that indicate the start and end of the left and right electrode arrays, and may be used in positioning the arrays relative to anatomical landmarks.



5. Upon confirmation of successful placement, secure the Catheter manifold to the patient's skin with sutures or other preferred fixation device. Secure the Catheter using additional catheter clamp and fastener as needed.

WARNING: Do not tie sutures directly around the Catheter shaft. Use the suture tabs provided on the Catheter manifold. Sutures directly around the Catheter shaft may damage or break it, and may cause embolism, leakage, and increased risk of infection or severe injury.

CAUTION: Minimize Catheter manipulation throughout the procedure to maintain proper tip position. Movement of the Catheter tip from its proper location may injure the patient or result in ineffective Therapy.

6. Ensure insertion site is dry before applying dressing. Apply skin protectant as needed.

CAUTION: Do not routinely apply prophylactic topical antimicrobial or antiseptic ointment or cream to the insertion site because of the potential risk of promoting fungal infections and antimicrobial resistance and because of potential damage to the Catheter materials.

7. Dispose of single-use accessories.
8. Remove sterile drape.
9. Assess placement of Catheter tip and ensure it has not entered the heart by following institutional guidelines. If assessment of Catheter placement indicates that the distal end of the Catheter is located in the right atrium or right ventricle, retract the Catheter such that tip is placed in the distal SVC and run Placement again.

WARNING:

- Do not position the Catheter (or allow it to remain) in the right atrium, right ventricle, or in a position that may induce cardiac arrhythmia. Incorrect positioning of the Catheter may result in cardiac injury, arrhythmia, or cardiac tamponade and result in severe injury or death.
- Do not run Mapping on the Console without assessing the placement of the Catheter in compliance with hospital/ institutional practices or current guidelines.

CAUTION: Secure the Catheter to prevent movement after Placement has completed successfully. Movement of the Catheter during Therapy may result in inappropriate Therapy or overstimulation and injury of the diaphragm.

10 If the Catheter tip is malpositioned, reposition the Catheter using standard sterile techniques, re-dress, and re-verify proper placement in compliance with your institutional guidelines.

Note: Once inserted according to instructions, the AeroPace Neurostimulation Catheter is ready for use as part of the System. Refer to the System User Guide before proceeding further.

Note: Assess the patient to determine if use of high-pressure power injection through the Catheter is appropriate for their condition. Confirm the Catheter tip position prior to each high-pressure power injection. Pressure-injection procedures must be performed by trained personnel well-versed in safe technique and its potential complications.

Catheter Specifications

The AeroPace Neurostimulation Catheter contains one distal lumen for the guidewire, for over-the-wire insertion. The maximum guidewire diameter is 0.81 mm (0.032 inches). After guidewire removal, three lumens are available for fluid and/ or medication delivery. The distal lumen is rated for high-pressure injection.

AeroPace Neurostimulation Catheter Lumen Flow Rates

Catheter Lumen	Flow Rate	Maximum Pressure-Injection Flow Rate	Maximum Catheter Pressure During Max. Flow Rate	Maximum Indicated Pressure-Injection Flow Rate	Maximum Catheter Pressure During Max. Flow Rate.	Average Static Burst Pressure[1]	Range of Static Burst Pressures[1]
		Using maximum viscosity media 12.1 cP at 37° C					
		At 300 psi (2070 kPa) Injection Pressure Setting		At 400 psi (2760 kPa) Injection Pressure Setting Max Indicated Catheter Rating			
Distal	42 ml/min	5 ml/s	74 psi (510 kPa)	5 ml/s	78 psi (540 kPa)	212 psi (1460 kPa)	139 – 272 psi (960 – 1875 kPa)
Medial	17 ml/min	Not rated for high-pressure power injection.					
Proximal	17 ml/min	Not rated for high-pressure power injection.					

[1] Static burst pressure is the pressure at the failure point of the Catheter.

Catheter Care and Maintenance

Catheter entry site must be prepared and maintained in a manner consistent with standard procedure for central venous catheterization. Maintain Catheter patency according to hospital/institutional policies, procedures, and practice guidelines. Apply appropriate central venous catheter care and management to prolong the catheter's dwell time and prevent injury.

⚠ **CAUTION:** Damage to the Catheter or occlusion of any of its lumens may increase the risk of embolism.

To care for the AeroPace Neurostimulation Catheter during use:

- Solution and frequency of flushing a venous access catheter should be performed in accordance with hospital/institutional policy.
- Any unused lumens/ports should be maintained and/or "locked" in accordance with hospital/institutional policy.
- Prior to using any lumen that is already "locked", lumen should be flushed with sufficient volume of saline in accordance with hospital/institutional policy.
- Lumens should be flushed with sufficient volume of saline in accordance with hospital/institutional policy between administrations of different infusates.
- Lumens should be flushed with sufficient volume of saline in accordance with hospital/institutional policy before reestablishing "lock."
- If needed, clean the Catheter using chlorhexidine (2% in 70% alcohol) or povidone-iodine (Betadine) (10% solution).

⚠ **CAUTION:** Do not disinfect, re-sterilize, or reuse single-patient use or sterile components. Reuse or re-sterilization of sterile components may impair the structural integrity and/or performance of the System and may cause injury or infection.

Removal of Catheter

1. Disconnect the AeroPace Neurostimulation Catheter from the Catheter Cable if it is connected.
2. Stop drips or infusion pumps, as applicable.
3. Don sterile gloves.
4. Tighten the clamps and remove the drip/infusion pump lines.
5. Remove the dressing and any fixation devices used to secure the Catheter.
6. Place sterile gauze at the insertion site and remove the Catheter when there is positive intrathoracic pressure.
7. Apply pressure to the gauze and remove the Catheter.
8. Apply a pressure dressing per standard procedure.
9. Ensure bleeding has stopped and apply a sterile dressing to the wound.
10. In cases where the Catheter or Catheter Kit components are to be discarded, adhere to local procedures for disposal of biohazardous waste.

⚠ **CAUTION:** After use, the Catheter or Catheter Kit Components may be potential biohazards. Handle and dispose in accordance with accepted medical practice and applicable local, state, and federal laws for biohazardous waste.

MRI Safety Information

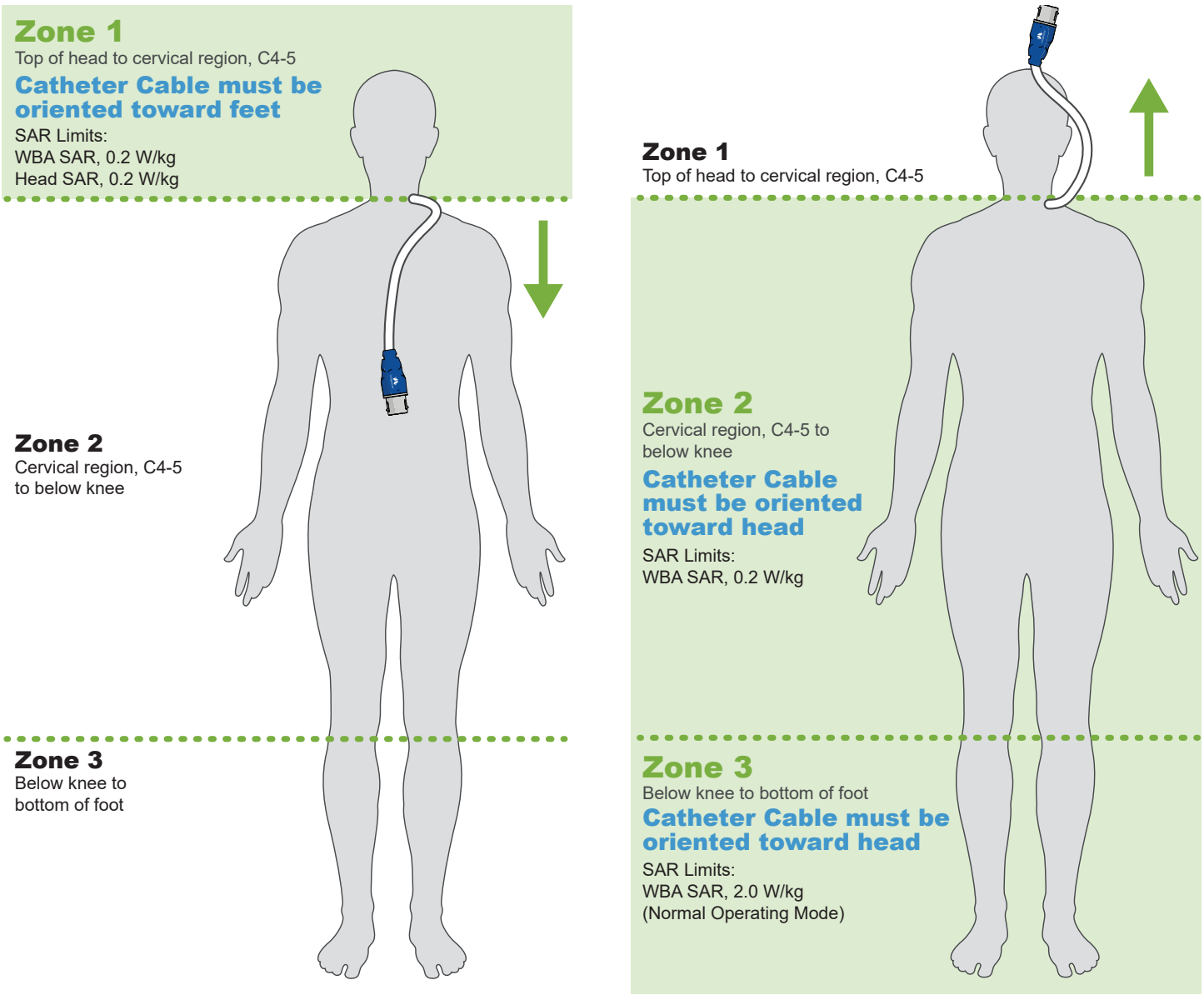
The AeroPace Neurostimulation Catheter is MR Conditional. A patient with the AeroPace Neurostimulation Catheter may be safely scanned under the following conditions. Failure to follow these conditions may result in physical trauma to the patient.

Category	Condition
Nominal Values of Static Magnetic Field (T)	1.5 T
Type of Nuclei	Hydrogen
MR Scanner Type	Cylindrical
Direction of Static Magnetic Field	Horizontal
Maximum Spatial Field Gradient (T/m and gauss/cm)	40 T/m (4,000 gauss/cm)
Type of RF Excitation	Circularly Polarized (CP) (i.e., quadrature-driven)
Operating Mode of MR System	Normal Operating Mode* *Note: Certain conditions require reducing the whole-body averaged and head SAR to values lower than the Normal Operating Mode. Refer to the information above and in *"Positioning Catheter Cabling During MRI Exams" on page 14.*
RF Conditions	1.5 T/64 MHz See information in *"Positioning Catheter Cabling During MRI Exams" on page 14.*
Maximum Head SAR	Certain conditions require reducing the head SAR to a value lower than the Normal Operating Mode. Refer to the information in *"Positioning Catheter Cabling During MRI Exams" on page 14.*
Scan Regions	Depending on the type of MRI examination to be performed, careful consideration must be given to the particular scan region (i.e., zone) and the positioning of the AeroPace Neurostimulation Catheter in order to ensure patient safety. The WBA SAR or head SAR must not be exceeded. Refer to *"Positioning Catheter Cabling During MRI Exams" on page 14.*
Limits on Scan Duration	Maximum whole-body averaged SAR of 0.2 W/kg for 30 minutes of continuous RF exposure with a 30-minute cooling period. Under the scan conditions defined, the Lungpacer AeroPace Neurostimulation Catheter is expected to produce a maximum rise of 6°C after 30 minutes of continuous scanning.
MR Image Artifact	The presence of the AeroPace Neurostimulation Catheter produces an imaging artifact. Therefore, carefully select pulse sequence parameters to minimize artifacts if the Catheter is located in the area of interest. In non-clinical testing, the image artifact caused by the Lungpacer AeroPace Neurostimulation Catheter extends approximately 6 mm from this device when imaged using a gradient echo pulse sequence and a 1.5 T MR system.

Positioning Catheter Cabling During MRI Exams

The following image depicts the orientation of the Catheter cabling during MRI exams with head-first or feet-first patient positioning. The Catheter must be positioned exactly as shown and exit the body along the B0 axis of the scanner and at the XY isocenter during MRI.

WARNING: The Catheter is MR Conditional, but the Console and other System components are MR Unsafe. Always disconnect the Catheter from the Console before conducting MRI, and keep the Console and other System components (including the Airway Sensor) away from MR equipment. Failure to do so may result in serious injury or death.



Symbol Glossary

Symbol	Meaning	Symbol	Meaning
	Caution		Use by
	Warning		Do not re-use
	Consult instructions for use		Sterilized using ethylene oxide
	Keep dry		Do not re-sterilize
	Keep away from sunlight		Temperature limit
	Do not use if package is damaged		Medical device
Rx Only	Prescription only		Open here
	Manufacturer		MR Conditional
	Date of manufacture		Batch code
	Catalogue number		Single sterile barrier system with protective packaging inside

Lungpacer®

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