Instructions for Use
for the
Numeris® Tethered Coagulation System
with VisiTrax®

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Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

IFU for Coagulation Kit
LBL-1774 US Rev. B
**INSTRUCTIONS FOR USE**

**Y CAUTION:** Restricted to use during procedures involving coagulation of cardiac tissue.

**Product Description**

Components of the Coagulation System:

1. Numeris® Tethered Coagulation System with VisiTrax® Device
2. CS-3000 RF Generator plus accessories
3. CS-2000 Coagulation Extension Cable

**ACCESSORIES PROVIDED SEPARATELY:**

- CS-1201 Coagulation Device, 1cm
- CS-1202 Coagulation Device, 2cm
- CS-1203 Coagulation Device, 3cm

**INDICATIONS:**

- Patients with presence of left atrial thrombus, a systemic infection, active endocarditic, or another infection local to the surgical site at the time of surgery.

**CONTRAINDICATIONS:**

- The Coagulation System is intended for the coagulation of cardiac tissue using radiofrequency (RF) energy during open-heart cardiac surgery.

**Indications:**

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**Contraindications:**

- Patients with presence of left atrial thrombus, a systemic infection, active endocarditic, or another infection local to the surgical site at the time of surgery.

**Y Warnings and Precautions:**

- Care should be taken to ensure that the device is not in contact with tissue that is not going to be coagulated (e.g. vascular and nerve tissue), in order to avoid inadvertent tissue damage.
- Avoid contact with other surgical instruments, staples or other objects while coagulating. Inadvertent contact with objects while coagulating could lead to conduction of RF energy or heat and unintentional coagulation of tissues in contact with those objects.
- The device is provided sterile and is intended for single patient use only. Do not reprocess or reuse. Reuse can cause damage to device, patient injury and/or the communication of infectious disease(s) from one patient to another.
- The coils on the distal end of the device must be kept clean of coagulum during surgery to avoid loss of power. Do not clean coagulum off the electrode of the device with an abrasive cleaner or electrosurgical tip cleaner. The electrodes could be damaged, resulting in device failure.
- If the device is used near a pacemaker, a potential hazard exists due to possible interference with the action of the pacemaker and potential damage to the pacemaker. A pacemaker in a patient undergoing any surgery with RF energy must be turned off before applying RF energy.
- Implantable cardioverter / defibrillators can also be adversely affected by RF signals.
- Interference produced by the operation of high-frequency surgical equipment may adversely affect the operation of other electronic medical equipment such as monitors and imaging systems. This can be minimized or resolved by rearranging monitoring device cables so they do not overlap the Coagulation System cables.
- The use and proper placement of an Indifferent Electrode is a key element in the safe and effective use of electrosurgery, particularly in the prevention of patient burns. Ensure entire area of electrode is reliably attached to the patient’s body.
- To avoid unintentional coagulation, care should be taken to ensure overlapping structures are separated and thermally isolated when anatomy allows.
- Inspect the device and packaging prior to use. If any breach of the packaging is found the sterility of the product cannot be ensured. Do not use product if breach is found.
- While the distal portion of the device is designed to be malleable to conform to the anatomy of the area to be coagulated, excessive manipulation, rough shaping or forcing the movement of the device may damage or deform the distal end and cause potential patient harm.
- Care should be taken when handling the distal end of the device near the electrode with surgical instruments – do not squeeze or clamp the electrode. Do not cut or tear silicone.
- The risk of igniting flammable gases or other materials is inherent in the application of RF energy. Precautions must be taken to restrict flammable materials from the area where tissue coagulation is performed.
- The coagulation device is only compatible with the nContact Surgical generator, cables and accessories. Use of another manufacturer’s accessories may cause damage to the device and/or injury to the patient.
- Coagulation devices have been tested and have pre-set power and time settings for optimal coagulation. Changing these settings may cause coagulation dimension to vary from the values given in this document.
- Care should be taken to ensure device is not moved during RF power delivery. Device movement may cause loss of suction and unintentional coagulation.
- Care should be taken to ensure no vessels (or other structures) are restricted during device manipulation. Vessel restriction could cause hemodynamic instabilities or patient harm.
- Care should be taken to ensure device is not twisted during procedure. Twisting/torquing device can cause the lumen to collapse, loss of suction, disconnection of perfusion/IV tubing, kinked perfusion/IV tubing, or patient harm.
- Connection of multiple devices to one vacuum unit may reduce vacuum functionality.
- Care should be taken to ensure the path to position the device is large enough to advance the device easily – forcing the device may cause device damage, tissue damage or patient harm.

**Additional warnings and precautions can be found in the nContact Coagulation System Radiofrequency (RF) Generator Unit Model CS-3000 Operators Manual (LBL-1095).**

**Potential Complications of the Coagulation Procedure**

- Infection
- Cardiac tamponade
- Pulmonary vein stenosis
- Vessel injury
- Pericardial effusion
- Excessive bleeding
- Tissue perforation
- Phrenic nerve injury
- Left atrial rupture
- Esophageal fistula
- Myocardial infarction
- New arrhythmias
- Thromboembolic complication
- Neurologic complication
- Death
- Complete heart block requiring permanent pacemaker implantation

**INSTRUCTIONS FOR USE**

**Required Equipment/Supplies Provided by Hospital**

- 0.9% Normal Saline Solution (250 mL bag recommended)
- Sterile Perfusion / IV Tubing Set (10 Drops/mL)
- Sterile Vacuum Tubing Set
- Vacuum regulated to -400 mmHg (-533 mbar: -15.75 inHg: -40 cmHg: -7.73 psi: -400 torr: -53.5 kPa)

**Required Equipment/Supplies Provided by nContact Surgical, Inc.**

- Valleylab™ PolyHesive Patient Return Electrode (REF E7506)
IFU for Numeris® Tethered Coagulation System with VisiTrax®

Device Set Up
1. Place the indifferent, dispersive electrode on patient, per figure 3 and connect cable to front of generator (Figure 2, number 2). Ensure entire area of electrode is reliably attached to the patient's body.

2. Place generator footswitch near the surgeon and connect the footswitch cable to front of generator. Refer to Figure 2, number 3.

3. Inspect all trays, pouches, cartons and packaging to ensure there has been no package damage, which may result in product contamination. If package damage is discovered, do not use – replace the product.
   a) Outside the sterile field, remove the tray with the device from the carton.
   b) Inside the sterile field, remove device from the tray (Figure 4) in the following order:
      i. Remove the device from the tray by releasing the tabs (3)

   Y CAUTION: Do not pull the tether to remove, as this may result in product damage.

4. Prepare the Vacuum
   a) Referring to Figure 5, attach one end of the sterile vacuum tubing to the graduated fitting where indicated on device handle by the vacuum symbol (‘VAC’) and the other to the vacuum trap. Use the stopcock to apply and release the vacuum to the distal assembly.
      i. If graduated fitting is not attached or fails from sterile field, use the extra graduated fitting and attach it to the stopcock (Figure 4, number 4).
   b) Ensure the vacuum unit pressure can reach -400 mmHg.

   Y CAUTION: Do not exceed -550 mmHg for vacuum use – exceeding this pressure may reduce suction capabilities, reduce tissue contact or cause tissue damage.

5. Prepare the 0.9% Normal Saline Bag
   a) Place unpressurized saline IV bag at patient height or above.
   b) Connect perfusion tubing to female Luer connection where indicated on device handle by the perfusion “droplet” symbol (Figure 5, number 1). Verify IV line is fully open.
   c) Insert IV tubing set into 0.9% normal saline bag.
   d) Turn on vacuum pressure and prime device by engaging the suction with a sterile surface (gloved hand).
      i. Ensure perfusion flow is functioning by observing drops in IV tubing. Make sure the device is primed by observing perfusion at distal end of coagulation device before starting operation of device. Ensure IV line is fully open.

Figure 5. Coagulation Device Key Features

(1) Perfusion Port, (2) To Saline Bag, (3) RF Cable, (4) Unused port, (5) Stopcock, (6) To Vacuum Tube

Y CAUTION: Verify that IV line is fully open. Do not pressurize saline bag; that is, do not use an infusion pump for delivery or a pressure bag. Pressurizing saline or partially open perfusion tubing can vary perfusion rate causing loss of suction and the coagulation dimensions to vary from values listed.

Y CAUTION: Ensure device is primed prior to first RF power delivery.

Y CAUTION: Use ONLY normal 0.9% normal saline.

6. Connect nContact RF cable (CS-2000 – provided separately) to device handle where indicated on device handle by “RF” symbol - blue connection to blue connection, (Figure 5, number 3).

Y CAUTION: Ensure arrows on cable and handle are aligned and cable is completely connected. Device will not register on generator if cable is incorrectly connected.

a) Connect the black end of the RF cable to the black Bessel receptacle of the generator front panel connector (Figure 2, number 1).

Y CAUTION: Do not pull excessively on the tether.

b) Hold device on desired location using light pressure until vacuum is engaged.

Y CAUTION: Care should be taken when handling the distal end of the device near the electrode with surgical instruments – do not squeeze or clamp the electrode. Do not use tools on the electrode coil, place tools on silicone only.

Y CAUTION: To avoid product damage, do not pull excessively on the tether.

Y CAUTION: Ensure device is properly connected – switching connections may cause inadequate tissue contact and reduced functionality.

Tissue Coagulation
1. Ensure all steps of device set-up are performed.
2. Select mode of operation on the generator.
3. Place device in desired location, using tether if desired. Engage vacuum by turning the stopcock.
4. Check to make sure perfusion flow is visible, approximately 1 drop per second.
5. Initiate power by pressing and releasing the footswitch or RF ON/OFF button on generator front panel. An audible signal will sound at the beginning of the RF cycle.
6. Coagulate tissue for pre-determined cycle.

<table>
<thead>
<tr>
<th>Device Code and Size</th>
<th>Power Watts</th>
<th>Time sec</th>
<th>Depth mm</th>
<th>Length mm</th>
<th>Width mm</th>
<th>Volume mm³</th>
</tr>
</thead>
<tbody>
<tr>
<td>CS-1201, 1cm</td>
<td>10*</td>
<td>120*</td>
<td>7</td>
<td>18</td>
<td>10</td>
<td>803</td>
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<tr>
<td>CS-1202, 2cm</td>
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<td>60*</td>
<td>6</td>
<td>28</td>
<td>9</td>
<td>1085</td>
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<tr>
<td>CS-1203, 3cm</td>
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<td>90*</td>
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<td>35</td>
<td>10</td>
<td>1691</td>
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<td>CS-1205, 5cm</td>
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<td>90*</td>
<td>54</td>
<td>54</td>
<td>10</td>
<td>2679</td>
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</tbody>
</table>

*Automatic cycles have been pre-determined for optimal tissue coagulation

7. When the generator completes a cycle, RF energy turns off automatically, and an audible completion beep sounds for 1 second.
8. After the cycle is complete, disengage vacuum from the distal end of the device by turning the stopcock lever.
9. Remove the distal end of coagulation device from tissue and observe completeness of lesion.

10. Place device electrode in next desired location using tether if desired.
11. Repeat steps 3-10 from above as needed until desired lesions have been completed.

Y CAUTION: To avoid interruption of vacuum or perfusion flow, do not leave device tubing clamped during coagulation of tissue.
12. At completion of procedure, remove device from tissue, disconnect all cables and tubes and discard device, tubing sets and cable following local governing ordinances and recycling plans for disposal or recycling of device components.

Maintenance and Troubleshooting

Glossary of Terms

Electro coagulation
Surgical procedures in which high-frequency electric current is used to coagulate tissues.

Coagulation Electrode
The metal conductor in the coagulation device used to transmit radiofrequency energy to tissue.

Indifferent, Dispersive Electrode
Commonly referred to as the “return electrode” or “patient electrode” or “ground pad.” Large surface area indifferent ground used to complete the circuit of the electrical current. Usually placed on the patient’s back or thigh. The indifferent, dispersive electrode is connected to the generator at the Indifferent Connector.

Abbreviations

<table>
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<tr>
<th>RF</th>
<th>Ref</th>
<th>IFU</th>
<th>LBL</th>
</tr>
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<tbody>
<tr>
<td>RF</td>
<td>Radiofrequency</td>
<td>IFU</td>
<td>Instructions for Use</td>
</tr>
<tr>
<td>VAC</td>
<td>Vacuum</td>
<td>LBL</td>
<td>Label</td>
</tr>
</tbody>
</table>

Symbols

- Factory: Manufacturer
- REF: Catalog Number
- Catalog Number
- VAC: Vacuum
- RF: Radiofrequency
- OC: Open Circuit
- Equipment: Defibrillation Proof Type CF
- Applied Part
- Indifferent, Dispersive Electrode: Attention, Consult Accompanying Documents
- Footswitch Connection
- Caution: Electrical Shock Hazard
- Time: Seconds
- Serial Number: Non-ionizing Radiation
- Expiry Date: Sterile by gamma irradiation

M Manufacturer:
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USA
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Customer Service

LIMITED WARRANTY

If the Coagulation System Device has been used properly (in accordance with these Instructions for Use) but proves to be defective through no fault of the purchaser or user, it will be replaced free of charge. nContact’s obligation to replace the product shall expire at the item’s labeled expiry date. The term “purchaser” as used herein refers to any individual or entity that purchases the nContact product from nContact Surgical Inc. or its authorized representatives. The purchaser’s sole and exclusive remedy against nContact Surgical Inc., and nContact Surgical Inc.’s sole and exclusive liability under this Limited Warranty, shall be the replacement of the Coagulation System Device in accordance herewith. The Coagulation System Device has no user-serviceable parts; any attempt to service, repair or alter the Device, or to use the Device except in accordance with these Instructions of Use, will void this Limited Warranty.

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