The procedure guide is an education and training supplement and is not intended to be a substitute for training. For more information, please refer to the Operator's Manual and Instructions for Use, or contact your Medtronic representative.

**Brief Statement**

See the device manuals for detailed information regarding indications, contraindications, warnings, precautions, and potential adverse events.
## Table of Contents

- Overview ................................................................. 2
- EP Lab Setup ............................................................ 3
- Periprocedural Anticoagulation ........................................ 6
- Selective Angiography .................................................. 8
- Pulmonary Vein Ablation Catheter™ GOLD (PVAC™ GOLD) ... 9
- Multi-Array Septal Catheter™ (MASC™) .......................... 22
- Multi-Array Ablation Catheter™ (MAAC™) ......................... 28
- Managing Temperature and Power .................................... 34
- Troubleshooting ....................................................... 36
- Important Procedural Reminders ...................................... 37
- Appendix .................................................................. 39
- References ............................................................... 40
This guide was designed to give you a visual overview of Duty-Cycled Phased RF ablation procedures.

**Before you begin using the products:**
- Please familiarize yourself with the Operator’s Manual and Instructions for Use of the
  - GENius Multi-Channel RF Ablation Generator—Model #990018
  - PVAC GOLD—Pulmonary Vein Ablation Catheter—Model #990078
  - MASC—Multi-Array Septal Catheter—Model #990001
  - MAAC—Multi-Array Ablation Catheter—Model #990000
- Consult with your Medtronic AF Solutions representative to learn about training opportunities

**Procedural guide scope:**
- Set up the Phased RF system
- Manage periprocedural anticoagulation
- Interpret generator interface
- Strategize angiography approaches
- Deploy and use the PVAC GOLD, MASC and MAAC catheters
- Troubleshoot procedural challenges

**Important note:**
- This guide is not intended to be a substitute for training
- For more information, please refer to Operator’s Manual and Instructions for Use, or contact your Medtronic representative

---

**EP LAB SETUP**

### System Setup and Components

**Medtronic Supplied Components:**
1. Catheters
   - Pulmonary Vein Ablation Catheter GOLD (PVAC GOLD)—Model #990078
   - Multi-Array Septal Catheter (MASC)—Model #990001
   - Multi-Array Ablation Catheter (MAAC)—Model #990000
2. GENius Multi-Channel RF Ablation Generator—Model #990018
3. Power cord
4. ECG Interface Box—Model #990028
5. ECG Interface Box Cable—Model #990020
6. ECG Amplifier Cable—Model #990027
7. Catheter Interface Cable—Model #990004

**Required Accessories:**
8. Two Valleylab™ Patient Return Electrodes—Model #E7506

**Not Shown:**
- Transseptal Sheath (9.5 Fr or greater inner diameter)
- PV-Tracker™ or equivalent (0.032” outer diameter, 200 cm length with 3 mm J tip guide wire)—Model #990045

**Medtronic Optional Accessories:**
9. GENius Jr. Remote Control—Model #990029
10. Remote Control Cable, 15 ft—Model #990041 or 25 ft—Model #990042
2 EP Recording System Setup

<table>
<thead>
<tr>
<th>Feature</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gain</td>
<td>One step more than the value used for a diagnostic circular mapping catheter</td>
</tr>
<tr>
<td>High pass</td>
<td>100 Hz</td>
</tr>
<tr>
<td>Low pass</td>
<td>500 Hz</td>
</tr>
</tbody>
</table>

- Close pacing channels, where possible and when not actively delivering pacing stimuli

3 Patient Preparation

- Firmly press along the entire electrode area during placement
- Avoid areas with adipose tissue, bony prominences, fluid invasion, scar tissue and excess hair (shave area as necessary)
- Do not attempt to reposition; replace if necessary
- Do not reuse (single use only)
- Insert blue connectors firmly into ECG box

4 GENius-ECG Box Setup

Step 1: Connect the power cord at the back of the GENius generator
Step 2: Connect the ECG interface box cable from generator to ECG box (both ends of the cable are identical and does not matter which end is connected to which part)

5 Lead Amplifier Connectivity

Step 1: The 12-lead ECG amplifier connects to the ECG interface box
Step 2: Plug the ECG amplifier cable into the ECG interface box

6 GENius Screen Setup

Step 1: Grasp the screen handle
Step 2: Pull out screen completely
Step 3: Swing screen into place
Step 4: Switch power on
Anticoagulation Strategies

- If the patient has been in AF for 48 hours or longer or for an unknown duration, we (the consensus) require three weeks of systemic anticoagulation at a therapeutic level prior to the procedure, and if this is not the case, we advise that a TEE be performed to screen for thrombus.
- Performance of catheter ablation of AF on a patient who is therapeutically anticoagulated with warfarin should be considered.

| Monitoring Interval after achieving target ACT | 15-30 min |
| ACT target range | 300-400 seconds | 350-400 seconds for significant atrial enlargement |

"... to further reduce the risk of thrombi, it is also recommended that heparinized saline be infused continuously through each transseptal sheath"*

*Activated clotting times (ACT) should be checked at 10- to 15-minute intervals until therapeutic anticoagulation is achieved and then at 30-minute intervals during the procedure. The lower level of anticoagulation should be maintained at an ACT of at least 300-350 seconds throughout the procedure, as it has been demonstrated that less intense anticoagulation is associated with a high prevalence of in situ thrombus adherent to the transseptal sheaths. If significant atrial enlargement or spontaneous echo contrast is observed, many operators target a higher ACT range of 350-400.2

---

**Summary of anticoagulation strategies from select peer-review data on Phased RF**

<table>
<thead>
<tr>
<th>Author</th>
<th>Journal</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fredersdorf</td>
<td>JCE 2009</td>
<td>&quot;...systemic anticoagulation was achieved with intravenous heparin to maintain an activated clotting time of ≥ 300 seconds.&quot;3</td>
</tr>
<tr>
<td>Wieczorek</td>
<td>JCE 2009</td>
<td>&quot;...and heparin was administered intravenously, starting with a bolus of 10,000 IU until an activated clotting time of 300–350 s was obtained.&quot;4</td>
</tr>
<tr>
<td>Scharf</td>
<td>JACC 2009</td>
<td>&quot;After femoral venous access and transseptal puncture, a single 10.5-F sheath was inserted into the left atrium, and heparin was administered to maintain an activated clotting time (ACT) &gt;300 s.&quot;5</td>
</tr>
<tr>
<td>Brunelli</td>
<td>Europace 2011</td>
<td>&quot;Activated clotting time (ACT) was measured every 20 min, and additional doses of heparin were administered to achieve and maintain an ACT of 300–350 s.&quot;6</td>
</tr>
<tr>
<td>Choo</td>
<td>Arch Cardiovasc Dis 2011</td>
<td>&quot;An initial bolus of 10,000 units of heparin was given, followed by 2,500-5,000 units of additional boluses to maintain an activated clotting time of 300–400 seconds. Activated clotting times were determined every 30 minutes.&quot;7</td>
</tr>
<tr>
<td>Khaykin</td>
<td>JICE 2012</td>
<td>&quot;Anticoagulation with intravenous heparin targeted an ACT of &gt; 350 s.&quot;8</td>
</tr>
<tr>
<td>Beukema</td>
<td>Europace 2010</td>
<td>&quot;An initial bolus of 10,000 units of heparin was given and 2,500–5,000 unit IV additional boluses to maintain an activated clotting time (ACT) between 300 and 350 s were given.&quot;9</td>
</tr>
</tbody>
</table>
Possible Approaches

Approach #1: Selective PV Angiography
Deliver contrast to each PV ostium via:
1) The transseptal sheath placed near PV trunk
OR
2) A deflectable and/or multipurpose catheter

Example shown: LSPV in LAO

Approach #2: Entire Left Atrial (LA) Angiography
Deliver contrast to whole chamber via:
1) Administration of bolus (20 mg) adenosine to induce AV block\textsuperscript{10,11}
OR
2) Right-ventricular pacing (~ 300 ms)\textsuperscript{11-13}
THEN
3) Inject ~ 20 ml contrast into LA body or near roof

Example shown: Entire LA in AP

Relationship of the PVs to Catheter Positions

LAO Projection

RAO Projection

Product Specifications

Guide wire compatibility:
- 0.032” outer diameter
- 200 cm length or greater
- 3 mm J tip

Transseptal sheath compatibility:
- 9.5 Fr or greater inner diameter

PVAC™ GOLD shown in neutral position.

Guide wire compatibility:
- 0.032” outer diameter
- 200 cm length or greater
- 3 mm J tip

Transseptal sheath compatibility:
- 9.5 Fr or greater inner diameter
**Capture**

1. Insert the proximal end of the 0.032" guide wire into the distal end of the PVAC GOLD
   - The guide wire must exit the proximal end of the PVAC GOLD

2. **Note:** It is recommended that the array be captured while it is submerged, in order to help reduce the possibility of air becoming entrapped around the electrode array during capture and catheter insertion.
   - Remove the capture device from the handle
   - Slide up to the spiral array

3. Hold the capture device against the spiral array
   - Use the other hand to advance the slide control knob forward on the handle (approximately ¼ of the travel)

4. Slide the capture device forward to capture the spiral array on the distal end
   - Continue to advance the slide control forward as capture device is advancing forward
   **Note:** Always lead the tip of the PVAC GOLD ahead of the capture device to prevent kinking of the distal lumen

5. The spiral array should look like the figure below
   - If not, pull back slightly on the capture device, advance the slide control fully forward while capturing the tip of the spiral array with the capture device

Refer to Appendix on page 39 for Colored Arrow Chart

---

**Insertion**

1. Retract the guide wire to the distal tip of the PVAC GOLD
   - Insert the capture device into the hemostasis valve
   - Insert the guide wire halfway into the transseptal sheath
   - Advance the array into the sheath before removing and replacing the capture device onto the handle

2. Advance the catheter through the transseptal sheath until the array enters the atrium
   - Before fully deploying the catheter, verify that the guide wire is in the left pulmonary vein
   - To ensure the guide wire exits the sheath correctly, confirm that entrapment does not occur in any existing side holes
**Deployment**

1. As the fourth electrode exits the distal end of the sheath, slowly pull back on the slide control knob while continuing to advance the PVAC GOLD to deploy the spiral array.

2. Retract the distal end of the transseptal sheath into the right atrium to allow for full deflection of the distal segment of the PVAC GOLD, as needed.

**Navigation**

1. Advance the guide wire into the selected PV.

2. Do not retract guide wire tip completely into array in order to prevent kinking of the distal tip.

3. Do not attempt to steer the PVAC GOLD within the sheath.
Catheter Maneuvers to Navigate the PVAC GOLD Array at the PV Antrum

- Use the following maneuvers to improve tissue contact
- Do not reposition, rotate, slide, or drag the catheter during ablation

1. **Steering**
   - Brings the array to different areas of the antrum
   - Changes the plane of contact
   - Increases the area of antral ablation

2. **Rotating**
   - Moves the electrode array to different antral positions

3. **Pulling or pushing**
   - Adjusts contact pressure with tissue

4. **Sliding**
   - Improves the electrode-tissue contact
   - Places the array within the vein for mapping and verifying isolation

Navigating from Left- to Right-Sided Veins

1. To access right PVs, retract the guide wire to the tip of the PVAC GOLD

2. Point and steer the PVAC GOLD in an acute curve toward the LIPV
   - Tighten the tension knob enough to hold a tight curve

3. Rotate clockwise to bring the array **posteriorly** toward the right PV
Navigating Common Ostia

1. Placing guide wire into different vein branches allows for approaching the antrum using different planes.\(^\text{14}\)

2. Slightly advance the slide control knob
   - Apply counterclockwise torque to expand array
   - Always unlock the tension control knob when navigating at the PV antrum

Mapping Inside the Veins

1. Retract the PVAC GOLD from the antrum of the vein
   - Advance the slide control knob halfway forward

2. Advance the spiral array into the vein while rotating the PVAC GOLD counter clockwise
Recommended Setting for Ablating with PVAC GOLD

Generator Software Default Settings

<table>
<thead>
<tr>
<th>Setting</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Temperature</td>
<td>60 °C</td>
</tr>
<tr>
<td>Ablation Duration</td>
<td>60 sec</td>
</tr>
<tr>
<td>Energy Mode</td>
<td>4:1 (use 2:1 if needed to achieve isolation after trying catheter maneuvers)</td>
</tr>
</tbody>
</table>

Suggested Ablation Strategy

- Target electrode pairs with most signals during the first 4-5 ablations per vein
- Select the desired pairs for RF
- If power indications are < 3 W, suggest the operator to reduce contact pressure by slightly pulling back or deselect low power channels*
- Always pull back the array from the antrum before going to the next ablation
- Rotate 45°-90° between consecutive ablations
- Advance the spiral array onto the tissue
- Perform additional ablations to touch up on resistant fascicles
- Use fluoroscopic visualization to navigate the PVAC GOLD to different ablation location
- PVAC GOLD is designed to ablate at pulmonary vein antrum
- Use fluoroscopic visualization to confirm location to prevent ablating the left atrial septum and posterior wall
- PVAC GOLD is designed to ablate at pulmonary vein antrum
- Use fluoroscopic visualization to confirm location to prevent ablating the left atrial wall with PVAC GOLD fully extended
- If it becomes difficult to withdraw the tip of the PVAC GOLD into the distal end of the sheath, remove the sheath with the PVAC GOLD contained inside

Note: Do not allow electrodes 1 and 8 to come in contact with each other. Instead:
- Ensure electrodes are separated by at least as much distance as when the catheter is in neutral position
- If electrodes 1 and 9 are close together, the array may be inside the vein, reposition the catheter
- Perform PVAC GOLD maneuvers (sliding, rotating, steering, pushing or pulling)

*Low power channel is presumably a result of reduced cooling due to the electrode being deeply embedded in tissue. See page 34 for Managing Temperature and Power.
Validation of Pulmonary Vein Isolation (PVI)

**Entrance Block**
- With PVAC GOLD placed distal of the presumed ablation line, check for entrance block by mapping during sinus rhythm, distal CS pacing (for LPVs), proximal CS pacing (for RPVs), or High Right Atrial pacing (for RPVs).\(^\text{15,16}\)

**Differential Pacing**
- Use differential pacing or evaluate the P-wave to avoid misinterpretation due to far-field detection, e.g., LAA in LSPV, RA in RSPV.\(^\text{17}\)

**Exit Block**
- Place the PVAC GOLD array within the targeted PV
- Pace at high output from each of the PVAC GOLD pairs, checking the effect on PV and atrial activations.\(^\text{16,18}\)

---

**Removal**

1. Ensure the PVAC GOLD is straight
   - Verify at least 5 cm of guide wire is inserted into one of the LPVs
   - Slowly advance slide control knob \(\frac{1}{4}\) forward and pull back on the PVAC GOLD shaft to retract the array into the sheath

2. Continue to slowly advance the slide control while simultaneously retracting the PVAC GOLD

3. Insert the capture device into the hemostasis valve
   - Continue slowly retracting the PVAC GOLD until the array is located in the capture device
   - Remove the capture device with the spiral array and the guide wire from the valve of the sheath

---

**Reinsertion**
- Remove the guide wire from the PVAC GOLD
- Flush the guide wire lumen using heparinized saline
- Clean the guide wire and make sure the wire is free of debris
- Reinsert the guide wire into the PVAC GOLD
**Capture and Insertion**

1. **Capture**
   - **Note:** It is recommended that the array be captured while it is submerged, in order to help reduce the possibility of air becoming entrapped around the electrode array during capture and catheter insertion.
   - Remove the capture device from the handle and slide it up to the array
   - Advance the slide control knob on the handle forward completely and hold in position
   - Slide the capture device over the distal array

2. **Insertion**
   - Insert the capture device into the hemostasis valve
   - Advance the MASC into the sheath approximately 15 cm
   - Slide the capture device back into place on the handle

**Product Specifications**

**Transseptal Sheath Compatibility:**
- 9.5 Fr or greater inner diameter

---

MASC shown in neutral position.
Deployment

1. Advance the MASC through the sheath until the array enters the left atrium
   - The distal portion of the array must exit the sheath prior to retraction of the slide control knob

2. As the slide control knob is retracted, simultaneously retract the sheath back into the RA

Navigation and Ablation

Generator Software Default Settings

<table>
<thead>
<tr>
<th>Setting</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Temperature</td>
<td>60 °C</td>
</tr>
<tr>
<td>Ablation Duration</td>
<td>60 sec</td>
</tr>
<tr>
<td>Energy Mode</td>
<td>1:1</td>
</tr>
</tbody>
</table>

1. Verify the tip of the sheath does not extend into the left atrium

2. Pull the MASC back to engage the electrodes against the left atrial septum

3. Select the desired pairs for RF
   - If power indications are < 3 W, slightly push forward or adjust the slide control knob on the handle. (This is an indication that the electrode is deeply embedded in the left atrial septum.)
Reposition the Array

1. Slightly advance the control knob

2. Push the array forward, away from the septum

3. Rotate the array to a new position

4. Retract the slide control knob back to deploy the array
   - Retract the MASC to engage the electrodes against the septum
   - Ablate as necessary
   - Repeat until the MASC has been rotated 360°

- Do not attempt to rotate the catheter while the array is against the septum
- Use fluoroscopic visualization to confirm the array arms are separated before delivering RF energy

Removal

1. Advance the distal end of the sheath into the left atrium
   - Fully advance the slide control knob and pull back on the MASC shaft to capture the array within the sheath
   - Slowly withdraw the MASC halfway through the transseptal sheath

2. Insert the capture device into the hemostasis valve
   - Continue to slowly withdraw the MASC until the array is located within the capture device
   - Remove the capture device from the hemostasis valve of the sheath

- Advance the distal end of the sheath into the left atrium
- Fully advance the slide control knob and pull back on the MASC shaft to capture the array within the sheath
- Slowly withdraw the MASC halfway through the transseptal sheath
- Insert the capture device into the hemostasis valve
- Continue to slowly withdraw the MASC until the array is located within the capture device
- Remove the capture device from the hemostasis valve of the sheath
Product Specifications

Transseptal sheath compatibility:
• 9.5 Fr or greater inner diameter

1 Capture

Note: It is recommended that the array be captured while it is submerged, in order to help reduce the possibility of air becoming entrapped around the electrode array during capture and catheter insertion.

• Remove the capture device from the handle and slide it up to the array
• Begin sliding the capture device forward to capture the array

2 Insertion

• Insert the capture device into the hemostasis valve
• Advance the MAAC into the sheath approximately 15 cm
• Slide the capture device back into place on the handle
**Deployment**

1. Use fluoroscopic visualization to confirm the distal end of the sheath is **not** against any structure of the heart.
2. Advance the MAAC through the sheath until the array enters the left atrium.

2. As the array exits the distal end of the sheath, advance the MAAC and retract the sheath into the right atrium to enable full deflection of the MAAC.

**Navigation and Ablation**

**Generator Software Default Settings**

<table>
<thead>
<tr>
<th>Setting</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Temperature</td>
<td>60 °C</td>
</tr>
<tr>
<td>Ablation Duration</td>
<td>60 sec (30 sec on thin LA walls)</td>
</tr>
<tr>
<td>Energy Mode</td>
<td>1:1</td>
</tr>
</tbody>
</table>

1. Using the steering knob located on the handle, deflect the tip in the direction of interest within the atrium for mapping and ablation.
2. Tighten the tension control knob to maintain curve configuration.

- Do not attempt to steer the MAAC within the sheath.
MAAC is designed for atrial navigation. If ventricular signals are detected by the MAAC:

- Rotate clockwise towards the postero-lateral wall when in the left atrium
- Use fluoroscopic visualization to ensure anatomical location of MAAC in the left atrial body and away from the area of the mitral valve

3

- Select the desired pairs for RF delivery. If power indications are < 3 W, pull back slightly or adjust the steering control knob on the handle. (This is an indication that the electrode is deeply embedded into the tissue.)

4

MAAC is designed for atrial navigation. If ventricular signals are detected by the MAAC:

- Advance the distal end of the sheath into the left atrium
- Ensure the MAAC is straight
- Neutralize the steering knob and loosen the tension control knob

1

- Slowly retract the MAAC into the sheath to capture the array
- Slowly and deliberately withdraw MAAC approximately halfway through the sheath

2

- Insert the capture device into the hemostasis valve
- Pull the MAAC array into the capture device
- Remove the capture device from the hemostasis valve of the sheath

3

Removal
## GENius Display Interpretation and Options

<table>
<thead>
<tr>
<th>Temp. Range (°C)</th>
<th>Power Level (Watts)</th>
<th>Display—Interpretation</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Displayed</td>
<td>Not Displayed</td>
<td>White bar</td>
<td>No action required during Power Ramp-Up</td>
</tr>
<tr>
<td>50°C ≤ T ≤ 65°C</td>
<td>≥ 3 W</td>
<td>Green bar—Effective contact</td>
<td>Continue ablation</td>
</tr>
<tr>
<td>66°C ≤ T ≤ 70°C</td>
<td>Any Power</td>
<td>Yellow bar—White box</td>
<td>Consider deselecting channel</td>
</tr>
</tbody>
</table>
| 50°C ≤ T ≤ 65°C  | < 3 W              | Yellow bar—Black box   | Consider doing one of the following:  
  ▪ Deselect channel to avoid edema  
  ▪ Ease back to increase power  
  ▪ Continue ablation |
| T < 50°C         | Any Power          | Yellow bar—White box   | Consider doing one of the following:  
  ▪ Deselect channel  
  ▪ Continue ablation |
| 71°C ≤ T ≤ 80°C  | Any Power          | Red bar                | Discontinue ablation |

### General Properties of an Effective Lesion:
- Power > 3 W
- Temperature > 50°C
- Quick Thermal Response at Onset of RF delivery
- Stable Temperature after Initial "Ramp-Up"
- Stable Array Position during RF application

#### Scenario 1 EFFECTIVE Lesion Creation: Good Contact + Good Cooling
- Green bars indicate target temperature range is achieved (≥ 50 °C and ≤ 65 °C)
- Power delivery of ≥ 3 W suggests good contact and electrode cooling  
  (Max Power in 4:1 = 8 W)

#### Scenario 2 INEFFECTIVE Lesion Creation: High Contact/Low Cooling
- Yellow bars indicate target temperature range is achieved (≥ 50 °C and ≤ 65 °C)
- Power delivery of < 3 W suggests low flow or limited cooling ("Buried Electrode")
- Gently DECREASING contact pressure may improve cooling by exposing more electrode surface to blood and result in increased power delivery

#### Scenario 3 INEFFECTIVE Lesion Creation: Low/No Contact
- Yellow bars < 50 °C suggest tissue contact is minimal
- Max power delivery of 8 W suggests Limited Tissue Contact
- Gently INCREASING contact pressure may increase temperature to green range
### General Steps

1. Unplug and replug the catheter cable  
   - Push STOP on GENius
2. Unplug and replug all of the cables from the ECG interface box and from GENius front panel  
   - Push STOP on GENius
3. Replace the catheter cable  
   - Push STOP
4. Replace the catheter  
   - Push STOP

---

### General Situations

<table>
<thead>
<tr>
<th>Situations</th>
<th>General</th>
<th>Troubleshooting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improper anticoagulation may increase the risk of thromboembolic events.</td>
<td>Administer appropriate levels of anticoagulation therapy during and following left-sided procedures per guidelines.</td>
<td></td>
</tr>
<tr>
<td>During capture and insertion, air may become entrapped around the array.</td>
<td>Submerged capture of the array is recommended for all catheters.</td>
<td></td>
</tr>
<tr>
<td>During capture, insertion and withdrawal, a vacuum can be created and increase risk of air embolism.</td>
<td>Slowly and deliberately insert, advance and withdraw catheters, dilator and guide wire.</td>
<td></td>
</tr>
<tr>
<td>Failure to maintain adequate separation may increase bipolar current between out-of-phase electrodes, resulting in high temperatures between electrodes.</td>
<td>During ablation, ensure the PVAC GOLD and MASC array is in neutral position.</td>
<td></td>
</tr>
<tr>
<td>Stop ablation prior to performing these actions.</td>
<td>Do not reposition, rotate, slide, drag or otherwise intentionally disengage and then re-engage the catheter electrodes with cardiac tissue while ablating.</td>
<td></td>
</tr>
<tr>
<td>Inadequate adhesion and improper placement may cause potential for superficial lesions due to reduced unipolar current path.</td>
<td>Ensure correct patient return electrode patch model is used and placed appropriately on the body. Do not reuse patches (single use only).</td>
<td></td>
</tr>
<tr>
<td>Use of non-default energy modes may increase risk of collateral damage or other adverse events.</td>
<td>Follow proper use of energy mode for each catheter type.</td>
<td></td>
</tr>
</tbody>
</table>

---

Please refer to the GENius Operator’s Manual or contact your Medtronic representative.
**PVAC GOLD**

| Situations | PVAC GOLD is designed to ablate at PV antrum. Use fluoroscopic visualization to confirm location to prevent ablation in the left atrial septum and posterior wall with PVAC GOLD fully extended.

| Rotate the PVAC GOLD 45°-90° between RF applications. | PVAC electrode 10 is able to map and pace. Energy delivery is disabled. Bipolar energy will not be delivered between electrodes 9 and 6, therefore channel 5 will be deselected except in Unipolar energy mode.

| Move the array to a different location or position before continuing RF application. | Performing rapid sequential RF application may cause inadequate cooling and inaccurate temperature measurements.

| When using PVAC GOLD catheters, deselecting channel 4 will automatically deselect channel 5. | Inaccurate temperature measurement may lead to an increased risk of collateral damage or other adverse events.

**MASC**

| Situation | Attached arms may increase current density and possibly “overdrive” temperatures; may trigger “short circuit” or “channel fault” message.

**MAAC**

| Situation | MAAC in mitral valve may cause risks of entrapment.

---

**Common Abbreviations**

| ACT | Activated clotting time |
| AP | Anterior posterior |
| CS | Coronary sinus |
| LA | Left atrium |
| LAA | Left atrial appendage |
| LAO | Left anterior oblique |
| LIPV | Left inferior pulmonary vein |
| LPV | Left pulmonary vein |
| LSPV | Left superior pulmonary vein |
| PV | Pulmonary vein |
| PVI | Pulmonary vein isolation |
| RA | Right atrium |
| RAO | Right anterior oblique |
| RF | Radiofrequency |
| RIPV | Right inferior pulmonary vein |
| RSPV | Right superior pulmonary vein |

**Colored Arrow Chart**

The directions and manipulations of catheter motions are indicated by the different colors of arrows.

<table>
<thead>
<tr>
<th>Arrow Colors</th>
<th>Definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sliding or tension knob turning</td>
<td>▪ Indicates sliding motion of capture device or sliding knob to capture the spiral array Or ▪ Indicates turning of tension knob to lock or unlock curve configuration</td>
</tr>
<tr>
<td>Steering</td>
<td>▪ Indicates steering of steering knob to navigate the electrode array in the left atrium</td>
</tr>
<tr>
<td>Rotating</td>
<td>▪ Indicates rotating catheter handle to rotate the electrode array</td>
</tr>
<tr>
<td>Pushing or pulling</td>
<td>▪ Indicates pushing or pulling of catheter handle to advance or pull back the shaft</td>
</tr>
<tr>
<td>Reminder</td>
<td>▪ Safe practice recommendations</td>
</tr>
</tbody>
</table>

**APPENDIX**

---

**IMPORTANT PROCEDURAL REMINDERS**

---

38


