The Arctic Front Advance™ Cryoballoon can provide a safe and effective first procedure in appropriately selected patients suffering from persistent AF.

**PVI IS THE CORNERSTONE OF AF ABLATION**

PVI as first line therapy for AF ablation is increasingly common in persistent AF. STAR AF II reported no benefit in AF reduction with additional ablation beyond PVI.

**DURABLE PVI**

Use of the 28-mm Cryoballoon results in the formation of WACA lesions. Arctic Front Advance PV lesion durability is among the highest in catheter AF ablation.

**STRONG EFFICACY IN PERSISTENT AF**

Freedom from AF can be achieved in 60-71% of patients suffering from persistent AF following an index Cryoballoon procedure.
STUDY DETAILS OF ARCTIC FRONT ADVANCE™ CRYOBALLOON EFFICACY DATA IN PERSISTENT AF:

<table>
<thead>
<tr>
<th>Author</th>
<th>Pts</th>
<th>Follow-up</th>
<th>On or Off AADs</th>
<th>AF/AT/AFL Evaluated</th>
<th>Single Procedure Success</th>
<th>Reported Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lemes et al.</td>
<td>49</td>
<td>Mean 416±178</td>
<td>13 pts on AAD after blanking</td>
<td>AF, AT, AFL</td>
<td>69%</td>
<td>No major complications 1 femoral pseudoaneurysm</td>
</tr>
<tr>
<td>Climente et al.</td>
<td>50</td>
<td>12 months</td>
<td>Off</td>
<td>AF, AT, AFL</td>
<td>60%</td>
<td>2 phrenic nerve palsy (PNP); 1 femoral pseudoaneurysm</td>
</tr>
<tr>
<td>Koecktert et al.</td>
<td>100</td>
<td>Mean 10 Mean 6±6.3 months</td>
<td>4/67 pts on AAD at last FU</td>
<td>AF, AT, AFL</td>
<td>67%</td>
<td>3 PNP; 4 femoral pseudoaneurysm; 3 post-procedural mild pericardial effusion</td>
</tr>
<tr>
<td>Guhl et al.</td>
<td>61</td>
<td>1 Year</td>
<td>7 (12%) recurrence-free patients were on AAD at 365 days</td>
<td>AF,AT,AFL</td>
<td>62.5% (CB2 only) 58.5% (CB2 and CB1)</td>
<td>Major complication rate: 2.8% 1 AV fistula 1 PNP beyond discharge</td>
</tr>
<tr>
<td>Dorwarth et al.</td>
<td>243</td>
<td>12±6 months</td>
<td>Not reported</td>
<td>AF</td>
<td>68%</td>
<td>Overall complications for PAF and persistent AF population (n=543 pts) 1.8% major complications 1.8% minor complications</td>
</tr>
<tr>
<td>Perrotta et al.</td>
<td>21</td>
<td>Median 352</td>
<td>Not reported</td>
<td>AF (w/o 3m blanking period)</td>
<td>71%</td>
<td>Not reported</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(234-541) days</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

PVI = Pulmonary vein isolation

References:
5. Late Breaking Clinical Trials session i at the EHRA EUROPACE 2013 meeting in Athens, Greece
8. Neuville et al. Electrical reconnection after pulmonary vein isolation is contingent on contact force during initial treatment: results from the EFFICAS I study. Circ Arrhythm Electrophysiol. 2013;327-33
10. Ahmed et al. The permanency of pulmonary vein isolation using a balloon cryoablation catheter: J Cardiovasc Electrophysiol. 2010;21(7):731-7;
16. Dorwarth et al. Heart Rhythm, Vol. 12, No. 5, May Supplement 2015. PO04-100; PO05-103

Indications:
The Arctic Front Advance Cardiac CryoAblation Catheter is indicated for the treatment of patients with atrial fibrillation.

Contraindications:
Use of Arctic Front Advance Cryoballoon is contraindicated:
• In patients with active systemic infections
• In patients with active systemic infections
• In conditions where the manipulation of the catheter within the heart would be unsafe (e.g., intracardiac mural thrombus).
• In patients with cryptoglobulinemia
• In patients with one or more pulmonary vein stents

Brief Statement
See the device manuals for detailed information regarding indications, contraindications, warnings, precautions, and potential adverse events.

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