Novel Linear Cryoablation Catheter to Treat Atrial Fibrillation*

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Background: A novel 8.5 Fr cryoablation catheter system (Adagio Medical) designed to create long, continuous and focal transmural lesions was used to treat Paroxysmal, Persistent and Long Standing Persistent Atrial Fibrillation (PAF, PsAF and LSPS AF). The system uses Near Critical Nitrogen capable of cooling to -196°C.

Methods: 32 Patients (Pts) have been enrolled (18PAF, 13 PsAF and 1 LSPS AF). All Pts received an antral pulmonary vein isolation (PVI). Additional non-PV triggers were ablated in 12 Pts, with posterior wall “box” lesion set (PW) in 10 Pts and left atrial defragmentation (LAD) in 2. A Cavo-tricuspid isthmus (CTI) line was included in 9 Pts. Multiple 3D mapping systems were used in 23 Pts. 1 Patient was treated under conscious sedation. Acute procedural success is defined as complete PVI, verified 30 min. post ablation. Pts are being followed at 1, 3, 6, 9 and 12 months with continuous ECG monitoring.

Safety Results: There were no deaths, AE fistulas, strokes, cardiac perforations or major bleedings. 2 cases of temporary phrenic nerve palsy (PNP) were observed and completely resolved. Since the introduction of a Cryomapping safety feature, PNP was successfully prevented in the last 19 procedures.

Acute Results: Overall ablation, fluoroscopy and procedure times gradually reduced with the introduction of improved catheter versions as well as an increased physician experience with this device.

Follow-up Results: After the initial experience with Gen-I, from the 13 Pts treated with Gen-II, 90% (10/11) remain free of AF at 6 months FU. No other atrial tachycardia was documented in these Pts. Among the 6 Pts treated with Gen-III, 1 PsAF Pts has already competed the 3 month blanking period, remaining free of AF.

Conclusions:

- Ultra-low temperature cryoablation is technically feasible in a percutaneous setting
- Multiple catheter shapes using pre-formed styles allow versatility to ablate anywhere in the atria without catheter exchanges.
- Safety measures mitigate unwanted damage (Cryomapping, esophageal warming)
- Clinical results demonstrate that the novel near critical nitrogen cryoablation system can deliver long continuous linear and focal transmural lesions to treat AF with excellent safety and efficacy outcomes.
- Initial follow-up results are promising for PAF and PsAF Pts.

** Latest Generation of the Adagio catheters used in clinical trials, with the capability to acquire Multiple Shapes

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*Fig. 2: Adagio AF catheter Gen III***
*Fig. 3: Adagio AF catheter Gen III***

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Table: Procedure and ablation times

<table>
<thead>
<tr>
<th>Procedure/Time inc 30 min</th>
<th>Ablation inc Bonus Freeze</th>
<th>Fluoroscopy No 3D map on 9/32 Pts</th>
<th>All 32 Pts. All Gen. (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12:7/14.2</td>
<td>286/28.6</td>
<td>129/14.8</td>
<td></td>
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<tr>
<td>30 sec PW</td>
<td>9.4/20.9</td>
<td>28.6/11</td>
<td></td>
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**Fig. 8: Adagio AF catheter Gen III**

*Fig. 9: Adagio AF catheter Gen III***

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**Fig. 10: Adagio AF catheter Gen III***

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**Fig. 11: Adagio AF catheter Gen III***

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**Fig. 12: Adagio AF catheter Gen III***

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