HEALTH ECONOMIC ANALYSIS

Cost Savings with Cryoballoon
Fewer total repeat ablations and CV hospitalisations led to lower total care costs for Cryoballoon patients over the trial period.

METHODS
A health economic analysis was performed by analyzing the rate of statistically different healthcare utilization (HCU) events from FIRE AND ICE and then assigning payer costs for each event.

- ICD-10 diagnosis and procedure codes were retrospectively assigned to each healthcare utilisation.
- They were then mapped to country specific DRGs for Germany, UK, and U.S. which determined the payer costs in each healthcare system.

RESULTS
Overall payer costs were significantly lower in the Cryoballoon group compared to the radio frequency group (RFC) across three healthcare systems. Total trial period* cost savings:

- €245K in Germany (€640/patient)
- £140K in the UK (£364/patient)
- $355K in the U.S. ($925/patient)

Higher RFC costs were driven by differences in repeat ablations and CV hospitalisations.

TRIAL PERIOD COST DIFFERENCES BY HEALTHCARE SYSTEM

<table>
<thead>
<tr>
<th>Healthcare Utilisation Type</th>
<th>Germany Δ= €245K</th>
<th>United Kingdom Δ= £140K</th>
<th>United States Δ= $355K</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardioversions</td>
<td>RFC</td>
<td>Cryo</td>
<td>RFC</td>
</tr>
<tr>
<td>Non-CV Hospitalisations</td>
<td>RFC</td>
<td>Cryo</td>
<td>RFC</td>
</tr>
<tr>
<td>CV Hospitalisations</td>
<td>RFC</td>
<td>Cryo</td>
<td>RFC</td>
</tr>
<tr>
<td>Repeat Ablations</td>
<td>RFC</td>
<td>Cryo</td>
<td>RFC</td>
</tr>
</tbody>
</table>

* Mean follow-up: 1.5 years
Maximum follow-up: 33 months

IMPACT
Cryoballoon was the greater value to healthcare systems in the FIRE AND ICE trial and may enable global healthcare systems to treat more patients within existing healthcare budgets.

TOTAL HCU COST BY THERAPY AND HEALTHCARE SYSTEM

<table>
<thead>
<tr>
<th>HCU</th>
<th>Germany (£)</th>
<th>UK (£)</th>
<th>United States ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardioversions</td>
<td>16K</td>
<td>23K</td>
<td>13K</td>
</tr>
<tr>
<td>Non-CV Hospitalisations</td>
<td>125K</td>
<td>114K</td>
<td>303K</td>
</tr>
<tr>
<td>CV Hospitalisations</td>
<td>219K</td>
<td>160K</td>
<td>413K</td>
</tr>
<tr>
<td>Repeat Ablations</td>
<td>660K</td>
<td>389K</td>
<td>1,000K</td>
</tr>
</tbody>
</table>

Medtronic
Multicenter, prospective, 1:1 randomised, non-inferiority, parallel group, open, blinded-endpoint study comparing the efficacy and safety of pulmonary vein isolation using Arctic Front™ catheters (n = 374) versus THERMOCOOL® point-by-point radio frequency catheters with CARTO® 3D mapping system (n = 376) in patients with paroxysmal atrial fibrillation. The trial was conducted at 16 centers in 8 countries.

Trial-period Health Economic Supplementary Analysis from a Payer Perspective
- Based on Healthcare Utilisation (HCU) data collected during the trial – HCUs that were shown to be significantly different between Cryoballoon and RFC are included (hospitalisations, repeat ablations, cardioversions).
- Total HCU costs were calculated by multiplying trial collected HCUs by standard unit costs.
- Analyses were performed for three diverse healthcare systems (Germany, UK, U.S.).
- Total cost differences per patient were calculated by: (Total Costs for the RF group divided by total RF patients) — (Total Costs Cryo for the group divided by total number of Cryo patients).

Cost Assignment Methods
- ICD-10 diagnosis and procedure codes were retrospectively assigned to each HCU.
- Coder was blinded to the therapy randomisation, but had full access to the study HCU data.
- ICD-10 codes were mapped to country specific DRGs which determined the payer costs.

References

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

Consult instructions for use on this website. Manuals can be viewed using a current version of any major Internet browser. For best results, use Adobe Acrobat® Reader with the browser.