PVAC® vs. Irrigated RF Comparative Experience

**Effective**

8/8

All Comparative Studies Show Similar or Improved Effectiveness at Follow-Up1-8

6m Single Procedure Success Off Drugs

P = 0.05

PVAC N=38 Carto N=47 NavX N=24

Better Effectiveness with PVAC in a New AF Centre2

65% 42% 38%

Similar Long-Term Effectiveness in an Experienced AF Centre7

65% 55%

PVAC N=79 Carto N=82

**Efficient**

7/8

7 of 8 Comparative Studies Show Reduced and 1 Shows Similar Procedure Time vs. Irrigated RF1-7,9

6 of 8 Comparative Studies Show Reduced and 2 Show Similar Fluoroscopy Time to Irrigated RF1-7,9

**Safe**

Total Reported Complications

- All Comparative Studies1-9
  - PVAC: 2.10%, N=743
  - Irrig. RF: 3.00%, N=557
- Surveys10,11
  - PVAC: 3.90%, N=2738
  - Irrig. RF: 4.54%, N=20825
- Meta-Analyses12,13
  - PVAC: 2.00%, N=1719
  - Irrig. RF: 4.90%, N=1964
This summary contains all peer-reviewed publications comparing the use of PVAC with irrigated RF catheters as of February, 2014. Studies may not necessarily be comparable due to methodological differences.

References
3 Bittner A et al. Randomized study comparing duty-cycled bipolar and unipolar radiofrequency with point-by-point ablation in pulmonary vein isolation. Heart Rhythm 2011;8:1385–90.

Indications for Use

The Pulmonary Vein Ablation Catheter GOLD is designed to be used for the creation of endocardial lesions (focal and linear) during cardiac ablation procedures for the treatment of symptomatic Atrial Fibrillation (AF). The PVAC GOLD is also intended to be used for cardiac electrophysiological (EP) mapping of pulmonary vein potentials, delivery of diagnostic pacing stimuli and verifying electrical isolation of the pulmonary veins post-treatment.

Statement

NavX and Carto are trademarks of St. Jude Medical, Inc. and Biosense Webster, Inc., respectively.

www.medtronic.eu