

Clinical Data Summary for Paroxysmal and Continuous AF

				
	GENius™ Multi-Channel RF Ablation Generator	PVAC® Pulmonary Vein Ablation Catheter®	MASC® Multi-Array Septal Catheter®	MAAC® Multi-Array Ablation Catheter®
Paroxysmal	✓	✓		
Continuous^a	✓	✓	✓	✓

PAF Clinical Evidence Summary

Deneke, Wiczorek, Mulder et al.

CAF Multi-Center Study Summary

Scharf et al., JACC 2009¹

EFFECTIVE

- Effective PVs isolation reported in **93%** of all 1889 targeted PVs²
- Complete isolation of all PVs achieved in **84.5%** of 660 patients²
- Freedom from AF in **81.6%** of 523 patients^{2,c}

- Reduction in AF burden^b in **80%** of CAF patients at **6 months**, and in **64%** patients free of AADs
- Reduction in AF burden^b in **66%** of CAF patients at **20 months** and in **45%** patients free of AADs

SAFE

- Fluoroscopy time: **21 ± 13 minutes**³
- Overall complication rate of **1.8%*** (14/763)²

- Fluoroscopy time: **55 ± 35 minutes**
- 3 complications**ⁿ

EFFICIENT

- Total PAF procedure time: **86 ± 28 minutes**⁴
- RF application duration average ranges from **22.4 ± 2.9 to 40 ± 11 minutes**²

- Total CAF procedure time: **155 ± 40 minutes**
- RF application time:
 - PVAC: **32 ± 12**
 - MASC: **8 ± 3**
 - MAAC: **13 ± 5**

Phased RF Treatment Compared to Updated Worldwide Survey on AF Treatment⁵

	Updated Worldwide Survey over 18 (3-24) month follow up period ⁵	Phased RF Peer Reviewed Studies
PAF Efficacy	➔ 74% Success rate free of AADs	79% Success rate free of AADs at 12 month follow up ^{3,d}
CAF Efficacy	➔ 63.1% Success rate free of AADs in continuous AF patients	64% Success rate free of AADs at 6 months; 45% at 20 months ¹
Complication Rate	➔ 4.5% Complication	1.8%* Lower complication rate than conventional treatment ²

Author(s)	N	Disease	Outcome	Follow-Up Method	Fluoro Time (Mins)	Complications	Procedure Time (Mins)
Fredersdorf⁶ <i>JCE</i> October 2009	21	PAF CAF	86% ^e	6 months 3d Holter	32 ± 10	0	121 ± 19
Wieczorek³ <i>JCE</i> November 2009	88	PAF	79% ^d	12 months 7d Holter	21 ± 13	0	125 ± 28
<i>Mulder/ Boersma⁴</i> <i>Europace</i> <i>Abstract 2009</i>	210	PAF	76% ^f	12 months 7d Holter	23 ± 16	0	86 ± 28
Beukema⁷ <i>Europace</i> February 2010	102	90 PAF 12 CAF	60.8% ^g 83% SR with AADs	12 months 7d Holter	32 ± 11	0	139 ± 38
Deneke⁸ <i>Hospital Chronicles</i> March 2010	152	106 PAF 46 CAF	65% 47% ^h	6 months 7d Holter	20 ± 8	0	100 ± 26
Scharf¹ <i>JACC</i> October 2009	50	CAF	80% 66% ^b	6 months 20 months 7d Holter	55 ± 35	3 ⁿ	155 ± 40
<i>Mulder/ Boersma⁹</i> <i>Heart Rhythm</i> <i>Session 2009</i>	66	CAF	69% ^k	12 months 7d Holter	30 ± 25	0	116 ± 36
<i>Dang¹⁰</i> <i>Europace 2008</i> <i>Abstract</i>	39	CAF	83% ^m	6 months 7d Holter	48 ± 12	1 ^p	150 ± 35

 Abstract

References

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^a CAF: Includes Persistent and Longstanding Persistent >1 year (Continuous) patients

^b Defined as > 80% reduction in AF burden on the 7-day ECG recording

^c Freedom from AF in 81.6% of 523 patients with 24-hr Holter monitoring

^d Freedom from AF defined as absence of AF/lutter/tachycardia lasting >30 seconds after a single ablation procedure, in the absence of antiarrhythmic drug therapy

^e Freedom from AF defined as free of arrhythmia; prior AADs were reinitiated

^f Absence of AF assessed with a 7-day Holter

^g Free of AF & AADs: In sustained SR without AADs

^h No AF documented after single ablation procedure during median follow up of 6 months

^k Freedom from AF based on any recording at 12 months

^m Free of persistent AF, including patients in sinus rhythm on AAD therapy and patients who have self terminating AF episodes

ⁿ 3 complications: 1 AV fistula, 1 Tamponade, 1 TIA

^p 1 Tamponade

^{*} Inclusive of both Paroxysmal and Continuous AF patients

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