



Emerging radiofrequency balloon technologies for pulmonary vein isolation

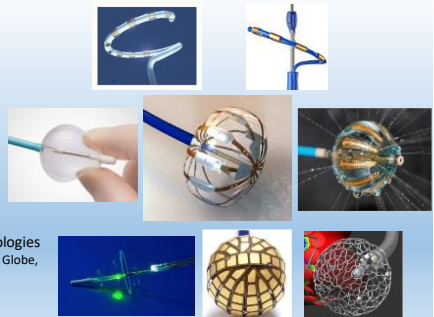
Dr Geoff Clare
Canterbury District Health Board
University of Otago, Christchurch

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Outline



- Multi-polar RF
 - nMARQ, PVAC
- Balloons
 - Satake
 - Apama → Luminize
 - Heli-69 → Heliostar
- Other related technologies
 - HeartLight, Kardium Globe, Sphere-9 (Lattice)



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Disclosures

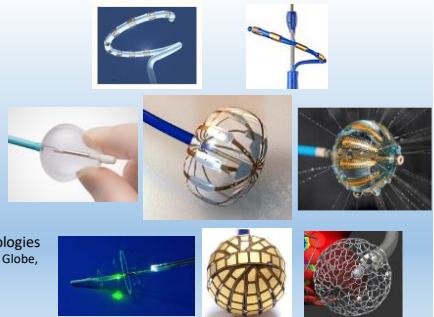
- Previous speakers honoraria: Biosense Webster, Medtronic
- Travel Support: Biosense Webster, Boston Scientific, Medtronic

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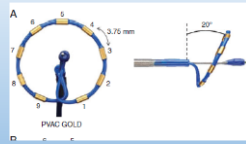
Multipolar RF technologies

nMARQ™ (Biosense Webster Inc.)



- 10 platinum electrodes, adjustable
- Irrigated
- Unipolar (or bipolar)
- Typically 15-20W

PVAC™ Gold (Medtronic Inc.)




- 9 gold electrodes
- Non-irrigated
- Unipolar or bipolar
- Typically 10W (can vary each electrode)

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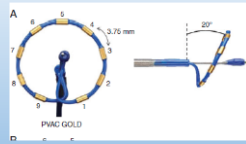
Multipolar RF technologies

nMARQ™ (Biosense Webster Inc.)



- Eg. 75% freedom AF at 6 months (206pts)¹
- Eg. REVOLUTION trial 71% free AF at 8 months (161pts)²

PVAC™ Gold (Medtronic Inc.)




- Eg. PVAC 3 year single procedure freedom AF 65% (161 pts)³
- Eg. Mean 20.3 RFAs for full PVI in PRECISION GOLD study⁴

1. Vurma et al. Europace. 2016;18:1164-69
 2. Deneale et al. J. Cardiovasc. Electrophysiol. 2014;25:339-45
 3. De Groot et al. Europace. 2014;16:820-825
 4. De Groot et al. Europace. 2016;18:487-95.

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Multipolar RF technologies

nMARQ™ (Biosense Webster Inc.)

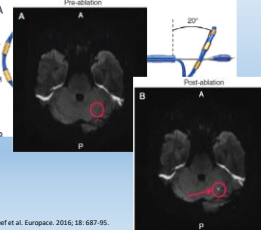


URGENT FIELD SAFETY NOTICE
MEDICAL DEVICE – VOLUNTARY FIELD REMOVAL

Biosense Webster, a division of Johnson & Johnson Medical NV/SA
nMARQ™ Circular Irrigated Catheter
Catalog No. D132214

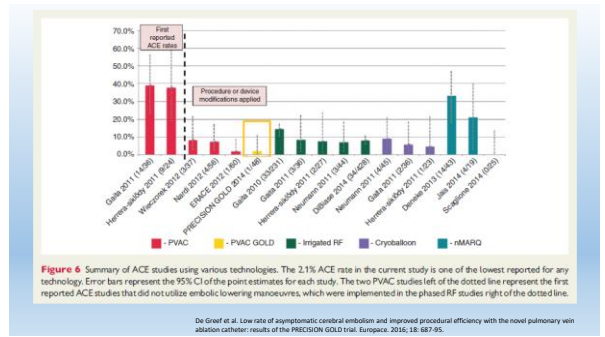
1. Varma et al. Europace. 2016;18:1164-69.

PVAC™ Gold (Medtronic Inc.)



2. De Groot et al. Europace. 2016;18:687-95.

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Satake

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Satake Hot Balloon catheter (Toray Industries, Inc., Tokyo, Japan)

- First published description 2001¹
- 13F compliant balloon catheter within deflectable guiding sheath
- Inflated 26-33mm in diameter with 1:1 contrast / saline

1. Tanaka et al. A new radiofrequency thermal balloon catheter for pulmonary vein isolation. J Am Coll Cardiol 2001;38:2079-86.

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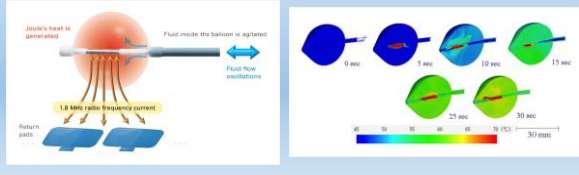
Satake Hot Balloon catheter (Toray Industries, Inc., Tokyo, Japan)

- RF current of 1.8MHz delivered between coil electrode inside balloon and 4 cutaneous electrode patches on patient's back

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Satake Hot Balloon catheter (Toray Industries, Inc., Tokyo, Japan)

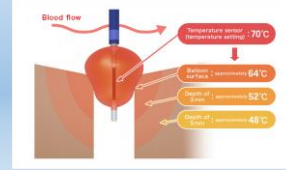
- Thermocouple inside balloon maintains temperature at 40-70 degrees
- Agitation device delivered vibratory waves into the balloon to mix fluid and maintain a uniform temperature



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Satake Hot Balloon catheter (Toray Industries, Inc., Tokyo, Japan)

- Uses thermal energy conducted by the balloon to ablate tissue – i.e. not direct radiofrequency ablation
- Separate catheter for PV signals



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Satake Hot Balloon catheter clinical trials

- 17 Japanese centre RCT¹
- 100 patients hot balloon ablation vs
- 43 patients anti-arrhythmic drugs (34 cross-over at study end)
- Acute PV isolation in 98% (392/400 veins)
- 59% success (no documented AF > 30s) at 12 months



1. Sohma et al. Hot Balloon Ablation of the pulmonary veins for paroxysmal AF: a multicenter randomized trial in Japan. J Am Coll Cardiol 2016; 68: 2747-57.

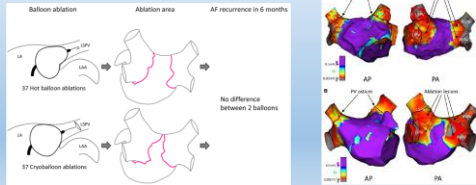
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HBA (n = 100)		TABLE 5 Tabulation of Major Complications	
Conscious sedation (patients)	99/0	Category	Type of Adverse Events
Procedure time, min*	113.9 ± 33.2 (n = 99)	1	Serious adverse events within 7 days of the ablation procedure (day 0-7)
Ablation time, min†	28.0 ± 4.4		Cerebral infarction 1.5 (3)
Fluoroscopy time, min	49.5 ± 27.4		Complete atrioventricular block 0.7 (1)
Ablation time per PV, min			Sick sinus syndrome aggravated 0.7 (1)
			Pseudoaneurysm 0.7 (1)
Right superior	8.1 ± 2.1	2	PV stenosis (>70%) 5.2 (7)
Right inferior	4.5 ± 1.0		Esophageal perforation 0
Left superior	10.2 ± 2.9		Cardiac tamponade 0
Left inferior	5.2 ± 1.6		Phrenic nerve paralysis 3.7 (5)
Number of ablations per PV			Cerebral infarction accompanied with apparent neurological symptoms 0
Right superior	3.5 ± 0.7	3	PV stenosis (<70%) that meets 1 of the following criteria: requires an invasive intervention, such as PV steering, results in clinically significant symptoms
Right inferior	2.1 ± 0.4		
Left superior	3.4 ± 0.9		
Left inferior	2.3 ± 0.7		
Volume in the balloon per PV, ml		Total M.J.C.s rate*	11.2 (15 patients, 17 events)
Right superior	9.5 ± 1.6		
Right inferior	7.9 ± 1.8		
Left superior	10.1 ± 2.0		
Left inferior	8.8 ± 1.6		

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Satake Hot Balloon catheter clinical trials

- Comparison hot balloon and cryoballoon¹

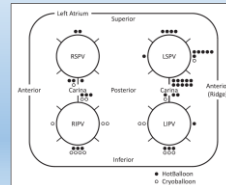


1. Nagashima et al. Hot balloon versus cryoballoon ablation for atrial fibrillation: lesion characteristics and middle-term outcomes. Circ Arrhythm EP 2018;

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Satake Hot Balloon catheter clinical trials

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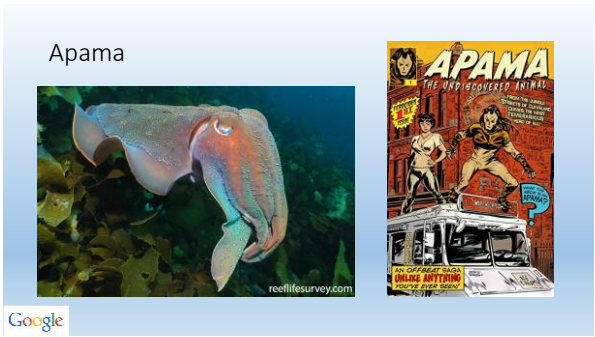


1. Nagashima et al. Hot balloon versus cryoballoon ablation for atrial fibrillation: lesion characteristics and middle-term outcomes. Circ Arrhythm EP 2018;

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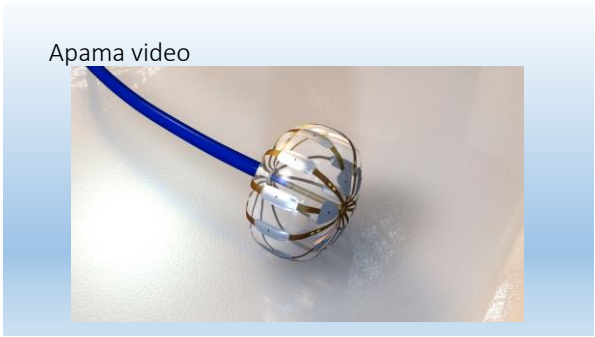


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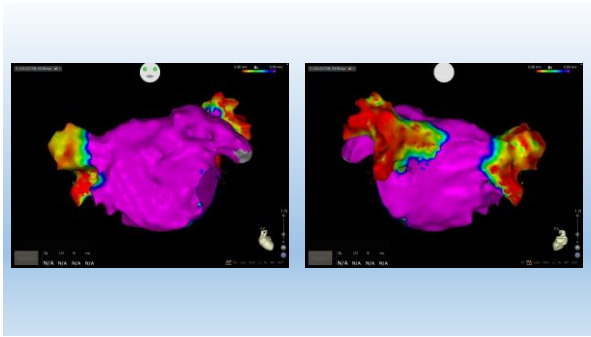
Apama RF balloon catheter system

- Over the wire 12.5Fr 28mm balloon catheter
- Balloon and sheath are steerable and highly manoeuvrable
- Irrigated RF
- 12 proximal (equatorial) electrodes, 6 distal electrodes
 - Modifiable bipolar or unipolar RF delivery
 - Typically 8W
 - Impedance monitoring
- Direct visualisation by 4 cameras and LED illumination
- Mapping and pacing from ablation electrodes and additional 12 pace-sense poles

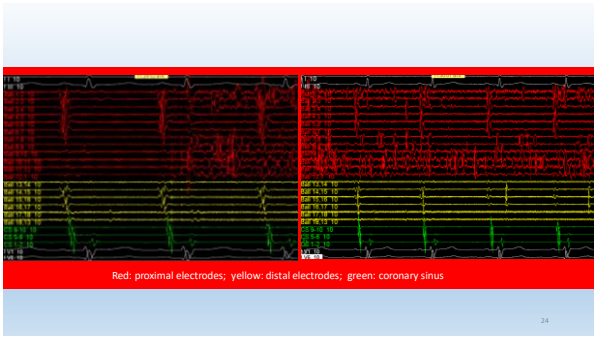
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AF-FICIENT (Apama FIH): Background

AF First In Human RF Balloon Catheter Ablation to Isolate Pulmonary Veins in the Treatment of Paroxysmal Atrial Fibrillation

Clinical Experience from Initial 18 Subjects Treated

STUDY DESIGN	<ul style="list-style-type: none"> Prospective, non-randomized, multi-center, multi-country pilot study
STUDY ENDPOINTS	<ul style="list-style-type: none"> Primary: Acute safety and performance Secondary: Rate of successful PVI, procedural times, absence of SAEs at 30 days, and device functionality
STUDY SITES	<ul style="list-style-type: none"> Christchurch, New Zealand with Dr. Ian Crozier, Dr. Matt Daly, and Dr. Iain Melton Wellington, New Zealand with Dr. Darren Hooks and Dr. Matthew Webber Prague, Czech Republic with Dr. Petr Neuzil and Dr. Vivek Reddy Asuncion, Paraguay* with Dr. Amin Al-Ahmad

* Site limited to initial FIH patients

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AF-FICIENT (Apama FIH): Procedure data

- Successful PV isolation with 98% of all PVs presented isolated
- Met safety endpoints with no device or procedure related SAEs at 7 days and 30 days
- Times comparable to other technologies
- Patients have been followed through 6 months and represent an 80% freedom from AF result in the PAF cohort

Procedural Data from Initial Patients*

% of PV Isolated or Entrance Block Achieved	98%
Average # of Ablations Required to Isolate PV	3.1
Average Balloon Time (h:m)	1:39

* includes all on-protocol patients

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Luminize

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Luminize™ (Boston Scientific)



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AF-FICIENT I study

Late Breaking, EHRA, March, 2019
Al-Ahmad A, Aidietis A, Daly M, Melton I, Crozier I, Rackauskas G, Ebner A, Hooks D, Neuzil P, Reddy V.

Protocol Summary	<p>Design: Prospective, non-randomized, multi-center pilot study</p> <p>Inclusion Criteria: Symptomatic paroxysmal AF, failed Class I or III AAD, ages 18-75</p>
Phase I (n=18) Phase II (n=81)	<p>Device Enhancements:</p> <ul style="list-style-type: none"> Increased sheath steerability from 90 to 125 degrees Activated sensing electrodes on RF balloon catheter
Primary Endpoints	<p>Safety: Acute safety at 30 days post procedure</p> <p>Performance: Rate of successful pulmonary vein isolation with confirmed block</p>
Centers	<p>1) Christchurch, New Zealand; 2) Na Homolce Hospital, Czech Republic; 3) Vilnius Univ. Hospital Santariskiu Klinikos, Vilnius, Lithuania; 4) Wellington Hospital, Wellington, New Zealand; 5) Sanatorio Hospital, Italiano, Paraguay</p>



www.escardio.org/EHRA-Congress

#EHRA2019

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AF-FICIENT I study

Late Breaking, EHRA, March, 2019
Al-Ahmad A, Aidietis A, Daly M, Melton I, Crozier I, Rackauskas G, Ebner A, Hooks D, Neuzil P, Reddy V.


- Safety**
 - No device related serious adverse events 30 days post procedure in phase I or II
 - In patients with available cardiac imaging, there was no evidence of PV stenosis (0 of 32pts)

Performance

Isolation	Phase II
Vein	99.4% (322/324)
Patient	97.5% (79/81)

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Heliostar™ (Biosense Webster)




- Compliant radiofrequency balloon catheter
- 10 flexible gold surface monopolar electrodes
 - Each capable of independently delivering varying levels of power
- Delivered over-the-wire with 13Fr deflectable sheath
- Longer electrodes for greater tissue contact
- Compatible CARTO 3
- Initially measuring simultaneous PVI time during burning not feasible¹

1. Honarbakhsh et al. Ep Europace 19.suppl_1 (2017): i21-i21.

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RADIANCE STUDY – multicentre first in human



- 3 European centres, 9 operators, 30 patients
- 30 sec post. wall, 60 sec ant. wall
- All targeted pulmonary veins isolated (114/114)
- 82% (85/104) isolated within 1 lesion ≤ 1 minute
- Mean procedure time 96min, balloon dwell 32min, fluoroscopy time 4.7min
- 1 phrenic nerve palsy, 2 oesophageal erythema
- UK experience 2/6 patients had small embolic lesion on brain MRI²
- STELLAR study
 - Aiming for 640 patients from up to 40 sites; First patient Feb 2019, - Texas (Natale)

1. Reddy et al. Heart Rhythm 2017. 14: 949-50. 2. Honarbakhsh et al. Ep Europace 19.suppl_1 (2017): i21-i21.

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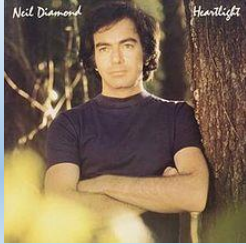
Other related technologies

- HeartLight

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Other related technologies


- HeartLight



Google

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HeartLight™ Endoscopic Laser Ablation (CardioFocus Inc., Marlborough, MA)



- 980nm diode laser and multi-lumen catheter with compliant inflatable balloon
- Balloon inflated with radio-opaque deuterium oxide
- Endoscope introduced into LA for live images
- Infrared laser can be aimed to create point-by-point lesions with a green aiming beam
- First generation 60% clinical success at 1 year¹
- Randomised pivotal trial² 353 patients (1:1) at 19 sites
 - Non-inferior conventional irrigated RF for efficacy: 61.1% vs 61.7%
 - Non-inferior for safety: adverse event rate: 11.8% vs 14.5%
- 5 year 51% freedom from AF (single procedure)³
- 3rd generation X3 60 ptnts 98.7% PVI efficacy and faster⁴
 - 43 min laser time

1. Reddy et al. Circulation. 2009; 120: 12-20. 2. Dukkipati et al. J Am Coll Cardiol. 2015; 66: 1350-60. 3. Reisman et al. Heart Rhythm. 2018. 8:P004-055. 4. Neuzil et al. Heart Rhythm. 2019. 5:4826-01.

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Kardium Globe (Kardium, Burnaby, BC, Canada)



- 16 ribs with semi-compliant array of 122 gold-plated electrodes
- Each electrode can sense, pace, ablate, measure tissue contact, temperature and impedance
- Ablate with up to 24 electrodes simultaneously
- 60 patients in 2 centres¹
 - PVI achieved 234 / 236 veins
 - Procedure time 147 mins, fluoroscopy 11 mins
 - 2 cardiac tamponade
 - No stroke, PV stenosis, oesophageal perf., phrenic
 - 82% efficacy at 6 months

1. Kottkamp et al. Heart Rhythm. 2018; 15: 946-9.

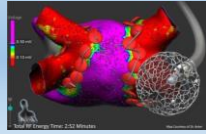
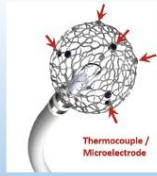
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Lattice catheter - Sphere-9

(Affera Inc., Boston, MA)

- 8F catheter, 9mm spherical nitinol tip
- 9 microelectrodes with surface thermocouples
- Uniform RF current delivery over entire electrode (250mm² surface area)
- Temp controlled irrigated ablation (75-80°C, 3-5 secs)
- 17 patients, mean 35 lesions per patient, mean 155 secs RF¹

1. Reddy et al. Heart Rhythm. 2019; 5:AB08-02.



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Conclusion

- Multiple technologies showing acute procedural success and early clinical 'success'
 - Shorter procedure times
- Smouldering issue of asymptomatic MRI detected cerebral events
 - Need to clearly establish baseline in point by point RF
- Difficulty moving beyond safety and feasibility studies to obtain true potential in a larger study

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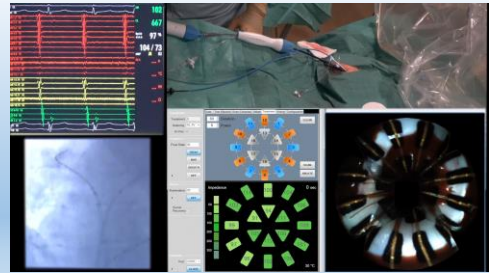
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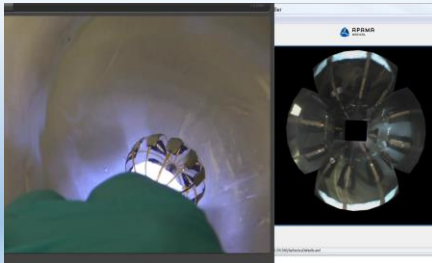
- Electroporation / Pulsed field ablation



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Focal Ablation

- Electrodes can be specifically selected to only ablate areas where additional ablation time is needed



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