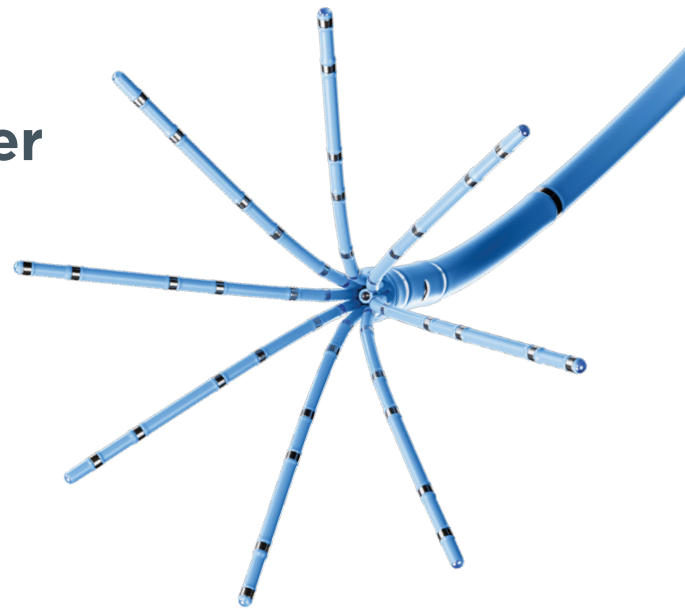


OCTARAY™ Mapping Catheter with TRUEref™ Technology

Key Evidence Summary

1 BETTER IMAGE CLARITY WITH HIGH DENSITY ELECTRODES



Improved intact ablation line characterization via reduction of far-field signals¹

“False gaps,” defined as intact ablation lines with increased voltage amplitude, were more commonly annotated with PENTARAY™ NAV ECO High Density Map Catheter vs. OCTARAY™ Mapping Catheter (6/8 vs 2/8 swine) and resulted from erroneous annotation of far-field EGMs.

Better detection of LAVAs in ventricles with healed infarction²

While voltage distribution within the infarct was similar between the catheters, the absolute and relative number of EGMs displaying LAVAs was greater with the OCTARAY™ Mapping Catheter vs. PENTARAY™ NAV ECO High Density Map Catheter (53±16% [2931/5428 scar EGMs] vs. 34±16% [810/2382 scar EGMs], $P=0.03$).

Better delineation of heterogenous scar with both unipolar and bipolar maps^{3,a}

- Both unipolar and bipolar voltage maps inferred the amount of viable myocardium with a high degree of accuracy against the histology gold standard.
- The morphology of bipolar electrograms collected during sinus rhythm with OCTARAY™ Mapping Catheter more frequently identified areas with 2 layers of surviving myocardium when compared to conventional mapping catheter (84% vs 71%, $P=0.011$), identifying tissue that may be susceptible to initiating/maintaining VT.
- The combination of unipolar and bipolar EGM maps allows for the rapid delineation of scar from healthy tissue and provides insights into the specific geometry of the fibrosis within the scar area.

EGMs; electrograms; LAVAs, local abnormal ventricular electrograms.

^aWhen compared to THERMOCOOL SMARTTOUCH™ SF Catheter.

2 INCREASED MAP DENSITY AND ACQUISITION SPEED

Higher resolution maps at a fraction of the time

OCTARAY™ Mapping Catheter vs. PENTARAY™ NAV ECO High Density Mapping Catheter

2x

EGMs per map

>50%

Decrease in mapping time

>4x

Acquisition rate

Mapping Parameter ^a	Chamber	OCTARAY™ Mapping Catheter	PENTARAY™ NAV ECO High Density Mapping Catheter	P value
EGM per map (n)	RA ¹	2178 ± 637	1046 ± 238	≤ 0.001
	LV ²	4202 ± 962	2255 ± 898	0.024
Mapping time (min)	RA ¹	3.2 ± 0.8	6.9 ± 2.7	≤ 0.05
	LV ²	5.3 ± 0.9	12.05 ± 2.3	0.015
Acquisition rate (EGM/min)	RA ¹	665 ± 193	160 ± 56	≤ 0.001
	LV ²	814 ± 126	148 ± 58	0.015
Acquisition density (EGM/cm ²)	LV ²	38 ± 10.3	20.9 ± 10.4	0.02

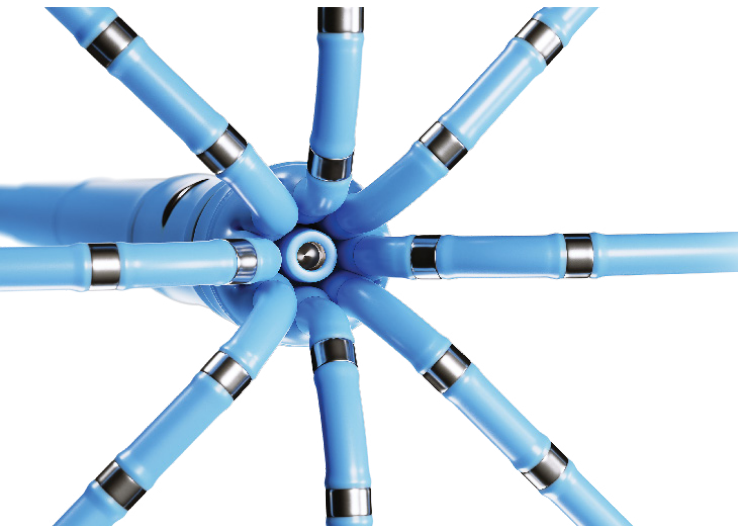
EGMs; electrograms; LV, left ventricle; RA, right atrium.

^aReporting mapping parameters for healthy tissue.

DO NOT use PENTARAY™ NAV ECO High Density Mapping Catheter or OCTARAY™ Mapping Catheter with TRUEref™ Technology in patients with prosthetic valves.

3

FIRST-IN-HUMAN EXPERIENCE RESULTS



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OCTARAY™ Mapping Catheter with TRUeref™ Technology-related serious adverse events ≤7 day of procedure observed in patients with ventricular tachycardia, atrial tachycardia, atypical atrial flutter or atrial fibrillation.⁴

REFERENCES

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2. Barkagan M, Sroubek J, Shapira-Daniels A., et al. A novel multielectrode catheter for high-density ventricular mapping: electrogram characterization and utility for scar mapping. *Europace*. 2020;22(3):440-449.
3. Glashan CA, Tofig BJ, Beukers H, et al. Multielectrode unipolar voltage mapping and electrogram morphology to identify post-infarct scar geometry: Validation by histology. *JACC Clin Electrophysiol*. Online ahead of print January 31, 2022. doi: 10.1016/j.jacep.2021.11.012.
4. Sarkozy A, Vijgen J, De Potter T, et al. An early multicenter experience of the novel high-density star-shaped mapping catheter in complex arrhythmias. *J Interv Clin Electrophysiol*. Online ahead of print March 26, 2022. doi: 10.1007/s10840-022-01176-2.

Important information: Prior to use, refer to the instructions for use supplied with the device for indications, contraindications, side effects, warnings and precautions.

Caution: US law restricts this device to sale by or on the order of a physician.

Scan this QR code for information on Biosense Webster, Inc.
Clinical and Economic Evidence.



Biosense Webster, Inc.
31 Technology Drive, Suite 200
Irvine, CA 92618 USA
Tel: +1-909-839-8500
Tel: +1-800-729-9010
www.biosensewebster.com



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