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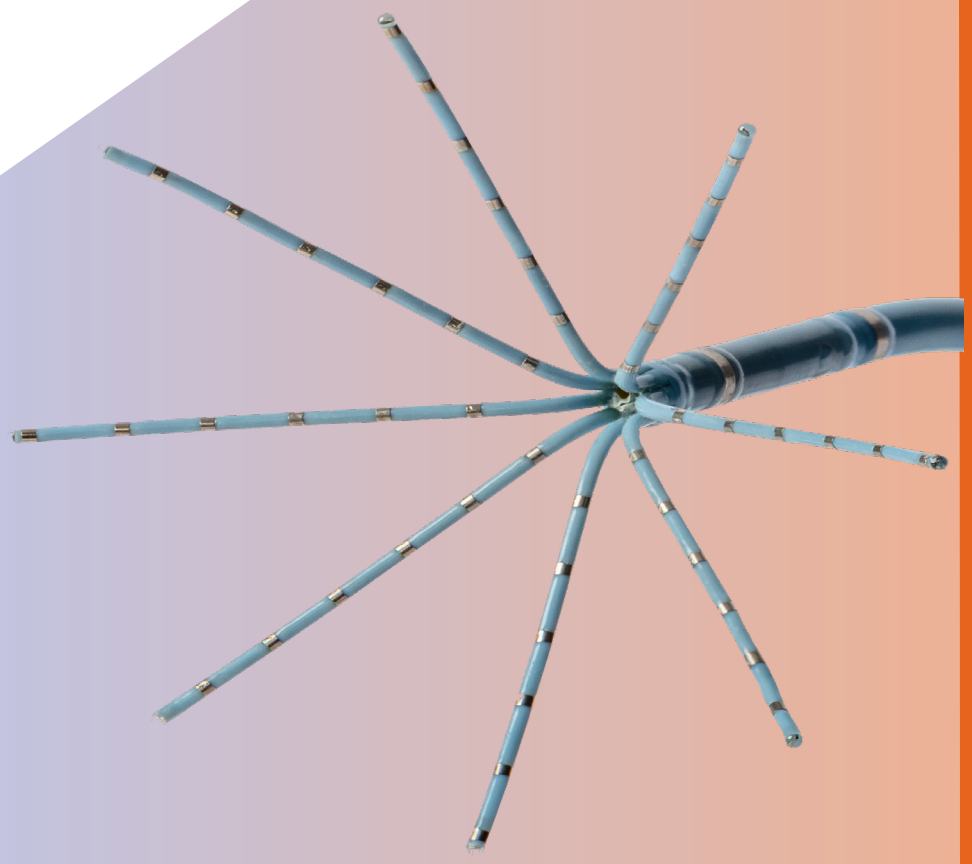
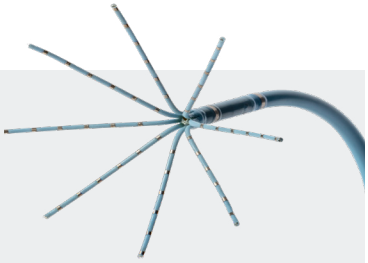
OCTARAY™ Mapping Catheter with TRUEref™ Technology



OCTARAY™ MAPPING CATHETER WITH TRUEREF™ TECHNOLOGY



The OCTARAY™ Mapping Catheter with the CARTO PRIME™ Mapping Module provides an efficient solution with rapid mapping, improved accuracy, and enhanced map-point density to identify triggers for guiding ablation of complex arrhythmias.[3,a]

Mapping of arrhythmias including paroxysmal atrial fibrillation (PAF), persistent AF (PsAF), ventricular tachycardia (VT) and complex atrial tachycardia may be complicated due to poor map quality, including low-density maps that may contribute to false arrhythmia identification and contribute to procedure inefficiencies.

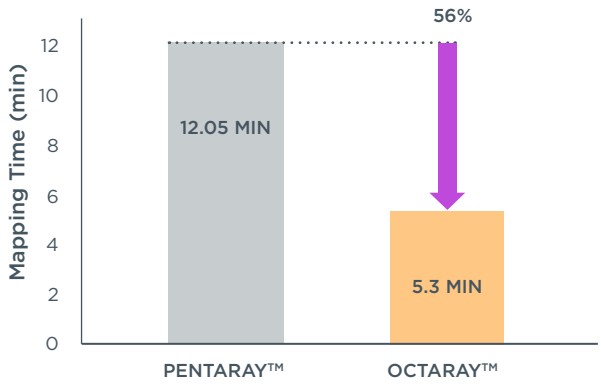
The OCTARAY™ Mapping Catheter and CARTO PRIME™ Mapping Module **may reduce electro-anatomical mapping time and provide better clarity in high-density maps** across multiple arrhythmias in all four chambers of the heart.[3,a]

ENHANCED MAPPING EFFICIENCY

OCTARAY™ Mapping Catheter may provide shorter mapping time through rapid acquisition of high-resolution signals over large areas. This may shorten ablation procedure times.[2,b]

SHORTER MAPPING TIME WITH OCTARAY™ COMPARED TO PENTARAY

In a pre-clinical study, mapping time was 56% shorter with OCTARAY™ Mapping Catheter than with PENTARAY™ Mapping Catheter.[2,c]



Pentaray (12.05 min (standard deviation (SD) 2.2), P=9.015) [2] as compared to Octaray (mean 5.3 min (SD) [1]

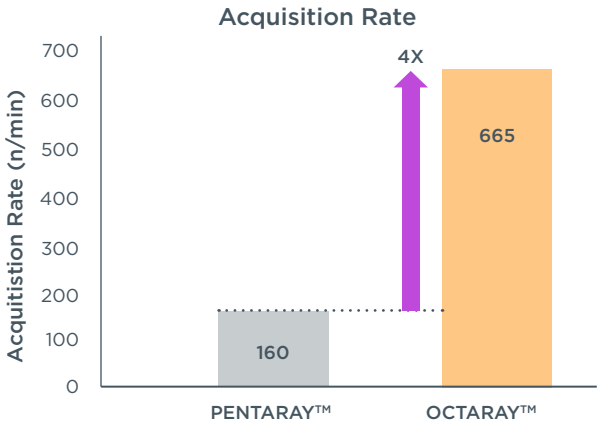
[a] Pre-clinical test data are not necessarily indicative of clinical performance.
[b] Unadjusted comparison of competitive technologies, based on OCTARAY™ Mapping Catheter results from a single arm (n=31) trial and pre-clinical (n=8) results.
[c] Pre-clinical results with swine left ventricles: normal (n=4), with infarction (n=8). Pre-clinical test data are not necessarily indicative of clinical performance.

EFFICIENT MAPPING TIME WITH OCTARAY™

Results from a comparative clinical study[b] showed that the OCTARAY™ Mapping Catheter enabled **efficient mapping times of only 9-minutes** in patients receiving ablation for atrial tachycardias in comparison to PENTARAY™.[4]

FASTER ACQUISITION RATE WITH OCTARAY™

In a pre-clinical study, acquisition rate was **over 4 times faster** with the OCTARAY™ Mapping Catheter compared to the PENTARAY™ Mapping Catheter.[1,3,d]



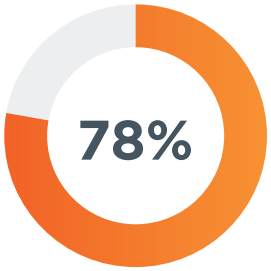
(665 electrogram [EGM]/min [SD 193]) than with PENTARAY™ (160 EGM/min [SD 56]; P ≤ 0.001)

A clinical study[b] with patients undergoing atrial arrhythmia ablations found a faster rate of acquisition with OCTARAY™ Mapping Catheter when compared to PENTARAY™.[4]

- **1332 points/min** with OCTARAY™
- 308 points/min with PENTARAY™

MORE POINTS ARE ACQUIRED WITH THE OCTARAY™ MAPPING CATHETER AND THE MAJORITY OF ACQUIRED POINTS ARE USED FOR MAP CREATION FOR IMPROVED MAPPING EFFICIENCY

Results from the first-in-human study of OCTARAY™ Mapping Catheter in patients receiving ablation for complex arrhythmias (N=31)[a] **found more than two thirds of bipolar points acquired by OCTARAY™ Mapping Catheter were used for LAT map creation.[1,e]**



UP TO 78% OF POINTS ACQUIRED WERE USED FOR MAP CREATION[1,e]

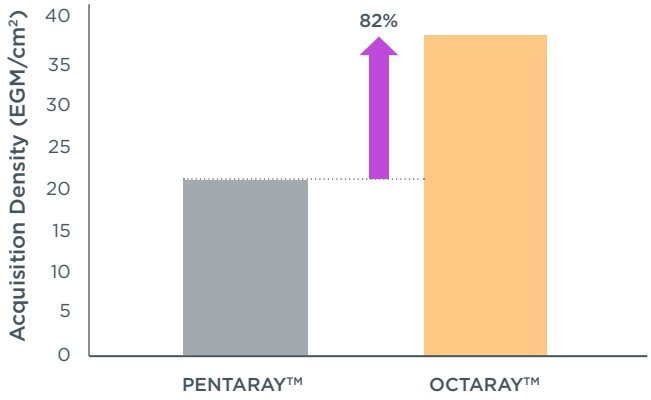
[a] Pre-clinical results with swine left ventricles: normal (n=4), with infarction (n=8).
[b] Clinical study results comparing OCTARAY™ (n=5) to PENTARAY™ (n=5).
[c] Pre-clinical results with swine right atria (n = 8).
[d] Results with swine left ventricles: normal (n=4), with infarction (n=8). Pre-clinical test data are not necessarily indicative of clinical performance.
[e] Based on OCTARAY results from a single arm (n=31) study.
* OCTARAY™ 2,178 EGMs per map [SD 637] vs PENTARAY™ 1,046 EGMs per map [SD 238]; P < 0.001

2x In a pre-clinical study[c], the number of EGMs per map collected with the OCTARAY™ Mapping Catheter **was 2 times higher** than the PENTARAY™ Mapping Catheter.[3*]

HIGH MAP POINT DENSITY

The OCTARAY™ Mapping Catheter provides high map-point density for improved mapping resolution, facilitating rapid and accurate identification of signals to guide efficient ablation workflows.[2]

HIGHER-DENSITY MAPS WITH OCTARAY™

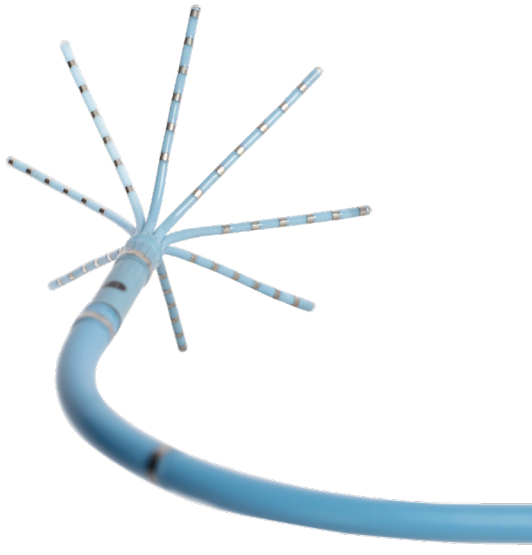


In a pre-clinical study, **acquisition density was 82% higher with OCTARAY™** Mapping Catheter than with PENTARAY™ Mapping Catheter.[2f] Higher-density maps may lead to improved identification of signals facilitating characterization of complex arrhythmias to to guide efficient ablation workflows.[3,g]

OCTARAY™ improves map accuracy with enhanced signal quality facilitating detailed mapping of complex arrhythmias. This may improve signal detection and diagnosis of complex arrhythmias across all chambers.[3g]

OCTARAY™ features a unipolar reference electrode located at the base of the catheter, known as TRUEref™ Technology (Tightly Referenced Unipolar Electrode) that can be used as an alternative unipolar mapping reference.[h] **This may limit the impact of far field signals.**

In a pre-clinical study[a], the sensitivity of OCTARAY™ for identifying ablation gaps was similar to PENTARAY™; however, OCTARAY™ characterized intact ablation lines better than PENTARAY™ because of **a lower susceptibility to influence from far-field signals and creation of false gaps.[3i]**



[f] Pre-clinical results with swine left ventricles: normal (n=4), with infarction (n=8).
[g] Pre-clinical test data are not necessarily indicative of clinical performance.
[h] Compared to Wilson's Central Terminal (WCT). Based on a benchtop study (n=3).
[i] Based on a single-center, pre-clinical study (n=8), a comparison of OCTARAY™ Mapping Catheter 2-2-2-2-2 vs. PENTARAY™ NAV ECO High Density Mapping Catheter 2-6-2. Pre-clinical test data are not necessarily indicative of clinical performance.

REFEFERENCES

1. Sarkozy, A., et al., An early multicenter experience of the novel high-density star-shaped mapping catheter in complex arrhythmias. J Interven Card Electrophysiol 2022
2. Barkagan M, Sroubek J, Shapira-Daniels A, Yavin H, Jang J et al. (2020) A novel multielectrode catheter for high-density ventricular mapping: electrogram characterization and utility for scar mapping. Europace
3. Sroubek J, Rottmann M, Barkagan M, Leshem E, Shapira-Daniels A et al. (2019) A novel octaray multielectrode catheter for high-resolution atrial mapping: Electrogram characterization and utility for mapping ablation gaps. J Cardiovasc Electrophysiol 30 (5): 749-757.
4. Steinfurt, J, et al. (2022) Initial Clinical Experience With a Novel 8-Spline High-Resolution Mapping Catheter. JACC: Clinical Electrophysiology.

CARTO® OCTARAY™ Mapping Catheter with TRUEref™ Technology

The CARTO® OCTARAY™ Mapping Catheter with TRUEref™ Technology is designed to facilitate electrophysiological mapping of the heart with the CARTO® 3 EP Navigation System. It is designed for deployment in a heart chamber through an 8.5 F guiding sheath.

INDICATIONS
The CARTO® OCTARAY™ Mapping Catheter with TRUEref™ Technology is indicated for multiple electrode electrophysiological mapping of cardiac structures in the heart, i.e., recording or stimulation only.This catheter is intended to obtain electrograms in the atrial and ventricular regions of the heart. The catheter provides location information only when used with compatible versions of the CARTO® 3 EP Navigation System.

CONTRAINDICATIONS
The catheter has not been shown to be safe and effective for radiofrequency (RF) ablation. The transseptal approach is contraindicated in patients with intracardiac thrombus or myxoma, or interatrial baffle or patch. The catheter is contraindicated for patients with the following conditions:
A prosthetic valve. This patient population is subject to increased risk of embolization of components and resultant patient sequelae. A history of, or currently has, blood clotting or bleeding abnormalities, contraindication to systemic anticoagulation (such as heparin, warfarin, dabigatran, or a direct thrombin inhibitor), significant pulmonary disease, cardiac surgeries, unstable angina, uncontrolled heart failure, acute illness or systemic infection. An atrial septal closure patch inserted within last 6 weeks. A condition that precludes vascular access. A hypercoagulable state. Intramural thrombus, tumor, or other abnormality that precludes catheter introduction or manipulation. A pacemaker or ICD leads implanted within the past 6 weeks.

WARNINGS AND PRECAUTIONS
Cardiac catheterization procedures present the potential for significant X-ray exposure, which can result in acute radiation injury as well as increased risk for somatic and genetic effects, to both patients and laboratory staff, due to the X-ray beam intensity and duration of the fluoroscopic imaging. Cardiac catheterization should only be performed after adequate attention has been given to potential radiation exposure associated with the procedure, and steps have been taken to minimize this exposure. Careful consideration must be given for the use of this catheter in pregnant women. Do not immerse the handle or cable connector in fluids; electrical performance could be affected. Do not expose the catheter to organic solvents such as alcohol. Do not autoclave the catheter. Flush the catheter with heparinized normal saline prior to insertion into the body.Do not introduce the catheter into a guiding sheath with the catheter's distal spines folded back toward the handle. Collapse the spines together using the insertion tube prior to insertion. For all details and full list please refer to IFU (instruction for use).

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

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