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THE VALUE OF THE CARTO VIZIGO™ BI-DIRECTIONAL GUIDING SHEATH FOR CATHETER ABLATION OF ATRIAL FIBRILLATION

Delivering consistent contact force application can be difficult with conventional fixed-curve sheaths due to challenges with cardiac motion and catheter movement during atrial fibrillation (AF) ablation. The use of deflectable sheaths provides improved control over catheter stability and navigation, which may lead to more efficient workflows without compromising safety and efficacy.[1-5] The use of a visualizable deflectable sheaths may further increase catheter stability compared to conventional deflectable sheaths.[6]

The CARTO VIZIGO™ Bi-Directional guiding sheath provides improved catheter stability and with this may lead to greater efficiency during the ablation phase due to the visualization on the CARTO 3-D electro-anatomic mapping (EAM) system.[6-8]

PROCEDURE EFFICIENCY

UP TO 10% REDUCTION IN TOTAL PROCEDURE TIME

A retrospective analysis of 60 patients undergoing catheter ablation for non-valvular AF found a **10% reduction in total procedure time** when using the CARTO VIZIGO™ Bi-Directional Guiding Sheath compared to a conventional deflectable sheath, mainly driven by a reduction of the ablation phase for the right PVI [6]
(136 min vs. 151 min, p=0.08)

Effective radiofrequency ablation is dependent on catheter stability, contact force, power output, ablation time, and temperature.[9] Lengthy application of RF power may increase the risk of damage to surrounding tissue.[10]

UP TO 16% REDUCED RADIOFREQUENCY APPLICATION TIME

A retrospective analysis of 317 patients undergoing paroxysmal AF catheter ablation found a **significant 16% reduction in radiofrequency time** when procedures were performed with the CARTO VIZIGO™ Bi-Directional Guiding Sheath.[7]
(P<0.0001)

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IMPROVED CATHETER STABILITY

A retrospective analysis of 60 patients undergoing catheter ablation for non-valvular AF showed **significantly improved catheter stability** with the CARTO VIZIGO® Bi-Directional Guiding Sheath compared to a conventional deflectable sheath (Contact Force Standard Deviation (g): 4.5 ± 2.7 vs. 4.9 ± 3.1; p<0.001).[6]

IMPROVED CLINICAL OUTCOMES WITH USE OF THE VISITAG SURPOINT™ MODULE

The VISITAG SURPOINT™ Module **utilizes contact force, stability, and power criteria** to facilitate improved clinical outcomes, including reduced radiofrequency and ablation time.[11-13]

LOW FLUOROSCOPY EXPOSURE

The CARTO VIZIGO™ Bi-Directional Guiding Sheath integrates real-time deflectable sheath visualization during AF catheter ablation procedures without depending solely on fluoroscopy.

LOW FLUOROSCOPY EXPOSURE FOR AF ABLATION

A retrospective analysis of 60 patients undergoing catheter ablation for non-valvular AF showed **significantly low fluoroscopy use** with the CARTO VIZIGO™ Bi-Directional Guiding Sheath compared to a conventional deflectable sheath.[6]

(p<0.001 and p=0.008 per respective study group)

SAFETY

Evidence shows that ablations performed with a deflectable sheath are equally as safe as procedures performed with a conventional sheath, with low rates of complications.[6]

LOW RATE OF COMPLICATIONS

A retrospective analysis of 60 patients undergoing catheter ablation for non-valvular AF illustrated **no major complications and low minor complications** with use of the CARTO VIZIGO™ Bi-Directional Guiding Sheath and a conventional deflectable sheath.[6]

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CARTO VIZIGO™ 8.5F Bi-Directional Guiding Sheath Biosense Webster
The Biosense Webster CARTO VIZIGO™ 8.5F Bi-Directional Guiding Sheath is designed to provide accessibilty and maneuverability in the cardiac anatomy.

INDICATIONS FOR USE
The Biosense Webster CARTO VIZIGO™ 8.5F Bi-Directional Guiding Sheath is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.
The sheath curve can be visualized when used with compatible CARTO™ 3 EP Navigation Systems.

CONTRAINDICATIONS
Do not use this device when there are: Previous intra-atrial septal patch, known or suspected atrial myxoma, myocardial Infarctions within the last two weeks, unstable angina, recent Cerebral Vascular Accident (CVA), patients who do not tolerate anticoagulation therapy, patients with an active infection, presence of atrial thrombus, environments with Stereotaxis Systems or Niobe magnets.

WARNINGS
Do Not alter this device in any way.Do Not immerse the proximal handle or cable connector in fluids; electrical performance could be affected. Do Not expose the sheath to organic solvents such as alcohol. Doing so may compromise the structural integrity of the device and/or lead to device failure.The sheath is intended for single use only. Do not resterilize and reuse the sheath. Reusing, reprocessing or resterilizing this device may compromise the structural integrity of the device and/or lead to device failure. Do Not route pacing to the electrodes of the sheath. Each physician must apply the information in these instructions according to professional medical training and experience when using the device for transseptal accecss.

Before using the CARTO VIZIGO™ sheath, completely read and understand Instructions for use = IFU.

This summary has been written by Biosense Webster (Europe), a division of Johnson & Johnson Medical NV/SA based on the referenced article, and is provided for information purposes only.
Important information: Prior to use, refer to the instructions for use supplied with the device for indications, contraindications, side effects, warnings and precautions

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