Introducing CARTO VIZIGO™ Bi-Directional Guiding Sheath

Integrating real-time steerable sheath visualization to your CARTO™ System experience

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

This product can only be used by healthcare professionals.

This publication is not intended for distribution outside of the EMEA region.

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**Benefits**

**CARTO VIZIGO™** Bi-Directional Guiding Sheath puts electrophysiologists in command for the ultimate CARTO™ 3 System experience. Confidence in procedures with visualization, efficiencies and optimized performance.

**Visualization:**
- **CARTO VIZIGO™** Sheath allows for sheath visualization on the CARTO™ 3 System map during a procedure without depending solely on fluoro\(^1,2\).

**Efficiency:**
- Visualization may enhance efficiency during mapping and positioning of the ablation catheter\(^1,2\)*

**Performance:**
- Smooth tip-to-dilator transition for optimal transseptal access\(^3+\).

*Efficiency based on design of the sheath and ability to visualize on CARTO™ 3 System.

+ Bench testing performed by Biosense Webster, Inc: VIZIGO n=5, Agilis NxT n=3. Bench test results may not necessarily be indicative of clinical performance. The third-party trademarks used herein are the trademarks of the respective owners. Agilis NxT is a trademark of St. Jude Medical.
BENEFITS

Integrating real-time steerable sheath Visualization

**CARTO VIZIGO™** Sheath allows for sheath visualization on the CARTO® 3 System map during a procedure without depending solely on fluoroscopy.1,2

- Four distal electrodes enable real-time steerable sheath visualization

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1. CARTO VIZIGO™
2. CARTO® 3 System
**Efficiencies** made possible with sheath visualization and optimized performance

**CARTO VIZIGO™** Bi-Directional Guiding Sheath provides electrophysiologists the critical sheath information to enhance efficiency during navigation and positioning of the ablation catheter.¹

- Sheath visualization aids in understanding the spatial relationship between the catheter and the sheath during navigation.¹

- Sheath visualization also aids in understanding the orientation during catheter manipulation.¹
BENEFITS

Designed for optimal Performance

- Smooth tip-to-dilator transition for optimal transseptal access\(^3\)∗
- Optimized deflection performance
- Braided shaft with silicone coating to enable good torque and friction response
- Ergonomic handle design

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BENEFITS

Designed for optimal Performance

Transseptal Access

- Allows for smooth transition profile between dilator and sheath to promote ease of entry into left Atrium during transseptal access
- Requires 33% less force required to advance from dilator to sheath across septum for CARTO VIZIGO™ Sheath compared to Agilis™ NxT

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**FEATURES**

**CARTO VIZIGO™** Sheath proximal end features

- 8.5 Fr Inner Diameter
- 71 cm Length

**Ergonomic Handle Design**

- Clear lure hub
- Dilator snap-fit into hub
**FEATURES**

**CARTO VIZIGO™** Sheath distal end features

- **4 Electrodes for visualization on CARTO™ 3 System**

- **Tapered distal tip**
  - Smooth transition between dilator and sheath

- **Bi-directional deflection**
  - 180 degrees in both directions

- **Three (3) sizes**
  - Options to accommodate for all anatomic chambers

**ORDERING INFORMATION**

- 17mm
- 22mm
- 50mm
**FEATURES**

**CARTO VIZIGO™** Sheath compatibility

**CARTO VIZIGO™** Sheath introduces visualization capabilities to all navigational therapeutic catheters with **shaft-curve visualization**.

Unleash the full visualization potential with the following advanced navigational therapeutic catheters with **shaft-curve visualization**:

- **THERMOCOOL SMARTTOUCH™** Catheter
- **THERMOCOOL SMARTTOUCH™** SF Catheter
- **THERMOCOOL®** SF Catheter with curve visualization

Mechanically compatible with the following catheters:

- **THERMOCOOL™** NAVISTAR Catheter
- **LASSO™** Catheter (all NAV codes)
- **PENTARAY™** NAV ECO High Density Mapping Catheter (all NAV codes)
- **DECANAV™** Mapping Catheter

Physically compatible with the following needles:

- St. Jude Medical BRK needles – (Ref.# 407206 and 407207)
- Merit HeartSpan needles – (Ref.# FND-019-05 and FND-019-06)
- Baylis Medical RF needle – (Ref.# NRG-E-HF-98C0)

Refer to test report (TR-0021924)

The third party trademarks used herein are the properties of their respective owners.
## Ordering Information

### CARTO VIZIGO™ Sheaths

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<tr>
<th>Ordering Number</th>
<th>Description</th>
<th>Outer Diameter</th>
<th>Usable Length</th>
<th>Inner Diameter</th>
<th>Curve Size</th>
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<td>Small Curve</td>
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<td>71 cm</td>
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### Associated Cables

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<th>Description</th>
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<th>Color</th>
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<tbody>
<tr>
<td>CY1212CT</td>
<td>Catheter to CARTO® 3 System PIU</td>
<td>-</td>
<td>Yellow</td>
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<td>CB3412CT</td>
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### Software / System Options

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<tr>
<td>KT-5400-155US</td>
<td>CARTO® 3 System V6 UPGRADE KIT</td>
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### HEARTSPAN™ Transseptal Needles (Optional)

<table>
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<tr>
<th>Ordering Number</th>
<th>Description</th>
<th>Curve Angle</th>
<th>Needle Id</th>
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<td>FND01905</td>
<td>18 gauge x 98 cm</td>
<td>50°</td>
<td>.015 inch Minimum</td>
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<td>FND01906</td>
<td>18 gauge x 98 cm</td>
<td>86°</td>
<td>.015 inch Minimum</td>
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</table>
When you add **Sheath** visualization to your **CARTO™ Experience,**

YOU KNOW WHERE YOU ARE.*

*Catheter advancement and placement through a guiding sheath should be done using a combination of visual aids available, fluoroscopic guidance and/or intracardiac ultrasound.

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3. Engineering Report For 8.5F VIZIGO and Agilis insertion forces; TR - 002202
4. CARTO 3 System Software v. 7.2 [Instructions for use]. Irvine, CA: Biosense Webster, Inc.; 2021.