# URGENT – Field Safety Notice

CARTO VIZIGO™ 8.5F Bi-Directional Guiding Sheath

Catalog Numbers (D138501, D138502, D138503)

February 2021

Dear Valued Customer,

At Biosense Webster, Inc. we continuously monitor the performance of our products to help ensure patient safety and compliance. We want to make you aware of an issue we have detected involving the CARTO VIZIGO™ 8.5F Bi-Directional Guiding Sheath.

You are receiving this letter because you have been identified as a site that is using the CARTO VIZIGO™ 8.5F Bi-Directional Guiding Sheath. This product is not being removed from the field and does not need to be returned.

Initial field experience has shown a higher than anticipated number of complaints where the hemostatic valve dislodged while introducing the dilator or devices into the VIZIGO™ sheath. With a dislodged hemostatic valve, there is a potential loss of hemostasis that would be expected to result in minor bleeding. In an extremely rare circumstance, entrainment of air could lead to air embolism. Biosense Webster has received reports of minor bleeding associated with this issue, but we have not received any reports of air embolism, or any other serious patient adverse events.

We would like to remind you of the precautions on inserting the dilator or catheters in the VIZIGO™ sheath from the Instruction For Use (IFU).

**Precaution on inserting a dilator into VIZIGO Bi-Directional Guiding Sheath:**

- Use best practices for inserting or retracting any device at the hemostatic valve.
- **Do Not** remove dilator or catheter rapidly. Damage to hemostatic valve may occur.
- Aspirate slowly, only from the sideport.
- Slowly remove or insert the dilator or other devices.
- Once the sheath is inserted into the vasculature and the dilator is removed, aspirate until steady blood return is achieved prior to flushing or infusion.
- Prior to inserting the device into the patient, pre-assemble sheath, dilator and stylet on the table. Advance the needle through the dilator and check for excessive resistance as the tip of the needle advances through the curvature of the sheath/dilator assembly.
- Before inserting the sheath into the patient, flush the sheath and dilator with heparinized normal saline to remove air bubbles and any potential particulate. After the sheath is in the left atrium of the patient, maintain a constant flow of heparinized normal saline to the sheath to minimize the risk of air emboli.

Always **insert a dilator straight** into the center of the sheath's valve to prevent damage to the valve. **Do not** insert a dilator at an angle, as damage to the sheath valve may occur (refer to Figure 1)

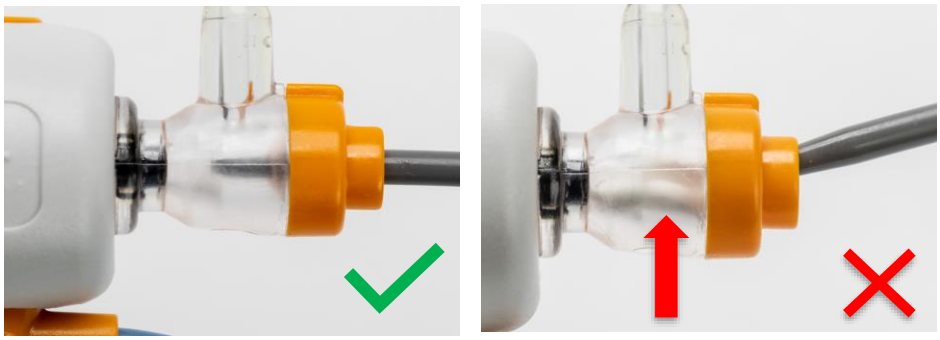
**Figure 1**

a. Correct dilator insertion

b. Incorrect dilator insertion

Incorrect insertion of the dilator may result in dislodgment of the valve, that can be identified in the clear hub (refer to Figure 2).

**Figure 2**



a. Correct dilator insertion, clear hub

b. Incorrect dilator insertion, valve dislodge (arrow) inside clear hub

**Next Steps**

1. Please review this letter carefully and share it with anyone in your facility that needs to be informed.
2. Please complete, sign, and ***return the Business Reply Form***

We have communicated this information to the applicable regulatory authorities.
If you have additional questions about this letter, please contact your Biosense Webster Inc. representative.

Sincerely,

Maria Jose Arana
Sr. Director, Quality & Compliance Biosense Webster, Inc
31 Technology Drive, Suite 200 Irvine, CA 92618 USA
www.biosensewebster.com

Items highlighted in yellow will be updated to follow local regulations & process

# BUSINESS REPLY FORM

**URGENT – Field Safety Notice**

CARTO VIZIGO™ 8.5F BI-DIRECTIONAL GUIDING SHEATH

**Catalog Number** (D138501, D138502, D138503)

Please complete this Business Reply Form and return it via E-mail to Biosense Webster Inc. (BWI) using the information listed below **within 3 business days upon receipt of this letter**.

Biosense Webster, Inc.
**Attn:** update locally
**E-Mail Address:** update locally

**Please check and complete the following box to acknowledge receipt of notification:**

☐ I have read and understand the notification

| | |
|---|---|
| Print Name of Person Completing BRF: | Facility/Business Name: |
| Signed*: | Date: |
| Facility/Business or shipping Address, City: | |
| Biosense Webster Sales Representative (if applicable): | |
| **Date the notification was received:** | |
| Telephone Number: | |
| **Your signature provides confirmation that you have received and understood this notification.* | |