ESOPHASTAR™ Esophageal Mapping Catheter

Caution: **Federal (USA) law restricts this device to sale by or on the order of a physician.**

SINGLE USE ONLY. DO NOT RESTERILIZE.

DEVICE DESCRIPTION
The Biosense Webster ESOPHASTAR™ Esophageal Mapping Catheter is a mapping catheter to be used exclusively for anatomically mapping points within the esophagus using CARTO™ System technology to indicate the relative anatomical relationship between the esophagus and posterior wall of the left atrium. The ESOPHASTAR™ Catheter is intended to be used in addition to other tools and techniques used to assist the physician in obtaining generalized location information of the esophagus with respect to the heart. The device is introduced through the patient's nose or throat into the esophagus. Once in the desired position, the device's location sensor is used to "map" the 3-D position of the catheter in the esophagus, using Biosense Webster's location software and hardware system, as the device is slowly pulled towards the initial entry port.

The ESOPHASTAR™ Esophageal Mapping Catheter is 8 F in diameter and is 125 cm long. The catheter has a flexible polyurethane shaft with an atraumatic tip section. This catheter has a magnetic location sensor embedded in the tip and, therefore, is used with the CARTO™ EP Navigation System (a magnetic field location technology) and a REFSTAR™ with QWIKPATCH™ External Reference Patch to map the esophagus.

For further description of the CARTO™ EP Navigation System, refer to the operating instructions for this system.

INDICATIONS AND USAGE
The Biosense Webster ESOPHASTAR™ Esophageal Mapping Catheter and related accessory devices are indicated for catheter-based anatomic mapping of the esophagus. When used during an electrophysiology ablation procedure, the ESOPHASTAR™ is intended to be used in addition to other tools and techniques used to assist the physician in obtaining generalized location information of the esophagus with respect to the heart. The device is not intended to provide absolute esophageal wall location information. The Biosense Webster ESOPHASTAR™ Esophageal Mapping Catheter is placed in the esophagus via the transpharyngeal or transnasal approach.

CONTRAINDICATIONS
Do not use this device:
- In patients with anomalies or diseases of the nose, throat or esophagus
- In patients with known sensitivity or allergies to device materials
- In patients with active systemic infection

WARNINGS AND PRECAUTIONS
- Location data obtained using the ESOPHASTAR™ Esophageal Mapping Catheter may not delineate the actual location of the esophageal wall.
- The esophagus is a pliable anatomical structure and may move. The user should be aware that the position of the esophageal wall may have changes since the previously acquired map.
- The device should be used by appropriately trained personnel in a fully equipped electrophysiology laboratory.
- Do not operate the ESOPHASTAR™ Esophageal Mapping Catheter prior to thorough reading and understanding the applicable Instructions for Use. Likewise, refer to appropriate Instructions for Use for proper connection of cables, operation of the CARTO™ EP Navigation System, and appropriate use of all other accessories.
- During device introduction care must be taken to avoid device migration into the trachea. Damage to the lung could occur should the device be introduced into the tracheo/bronchial tree. If any resistance is felt during device introduction, remove the device and reinsert.
- Give careful consideration for use of this device in prepubescent children. Intestinal perforations have been reported in infants with the use a nasogastric tube devices.
- The ESOPHASTAR™ Esophageal Mapping Catheter is indicated for use only with the Biosense Webster CARTO™ XP or CARTO™ Systems, and Biosense Webster interface cables. Use of other equipment may not be compatible and may result in malfunction.
- Use a lubricant to facilitate introduction of the device into the esophagus. Do not use petroleum-based lubricants with the ESOPHASTAR™ Esophageal Mapping Catheter.
- Do not expose catheter to organic solvents such as alcohol, which may damage catheter.
- Do not immerse proximal handle or cable connectors in fluids, which may affect electrical performance.
- Regularly inspect and test reusable cables and accessories.

Handling and Sterilization Precautions
- This catheter is sterilized using ethylene oxide. Observe the "Use By" date. Do not use device if past "Use By" date.
- Inspect the catheter packaging and the catheter prior to use. If the sterile package is open or damaged or the device is damaged, do not use the device. Contact a Biosense Webster representative to arrange return of entire package with the product.
- This catheter is provided for a one-time use only. This device has not been tested for multiple uses.
- This device is packaged and sterilized for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure that in turn may result in patient injury, illness or death. Also, reprocessing or resterilization of single use devices may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.
- Do not resterilize catheter by any means as catheter may be damaged.

Environmental and EMI Precautions
- Do not use this device near magnetic resonance imaging (MRI) equipment because MRI equipment may induce movement and/or heating of the catheter, which could cause perforations.

Precautions During Catheter Use
- Use fluoroscopy to monitor the advancement of the catheter to avoid placement of the device in the trachea.
- Do not use excessive force to advance or withdraw the catheter when resistance is encountered. Such resistance may lead to damage or perforation of the trachea or esophagus. Determine the cause of the resistance and proceed only as appropriate.

ADVERSE EVENTS

Potential Adverse Events
Potential Adverse Events associated with the use of the catheter are, but are not limited to, the following:

- Esophagus or trachea perforation
- Chest pain/discomfort
- Hemothorax
- Infections
- Laceration
- Aspirational pneumonia
- Local hematomas/ecchymosis
- Pleural effusion
- Pneumothorax
- Pseudoaneurysm
- Pulmonary edema
- Pulmonary embolism
- Vascular bleeding
- Nose bleeds

HOW SUPPLIED
- The ESOPHASTAR™ Esophageal Mapping Catheter is supplied STERILE (EtO).
- The CARTO™ EP Navigation System is supplied separately.
- The REFSTAR™ External Reference Patch is supplied separately.

Packaging
The ESOPHASTAR™ Esophageal Mapping Catheter is provided in sterile packaging. The catheter is secured to a mounting tray. The tray is sealed with a polyethylene/Tyvek* lid. The sealed tray is placed in a sealed pouch and this assembly is packaged inside a cardboard box. The sealed pouch and the shipping container are labeled sterile.

Storage
The ESOPHASTAR™ Esophageal Mapping Catheter must be stored in a cool, dry place. Storage temperature should be between 5 and 25º C (41 and 77º F).

Disposal
Recycle components, or dispose of the product and its residual elements or waste items in accordance with local laws and regulations.

DIRECTIONS FOR USE

1. Remove the ESOPHASTAR™ Esophageal Mapping Catheter from the package and place in a sterile work area.
2. Connect the catheter to the CARTO™ System Patient Interface Unit (PIU) via the appropriate Biosense Webster cable with 25-pin Hypertronics* interlocking connectors on both ends. Connect the CARTO™ System PIU to the CARTO™ EP Navigation System, with appropriate interface cables. Use only Biosense Webster interface cables.
3. Insertion depth may be estimated using the length markers on the ESOPHASTAR™ shaft.
4. Apply an appropriate lubricant to the tip and shaft of the device to facilitate introduction.
5. Introduce the device into the esophagus via the nasal passage or throat. Use fluoroscopy to guide placement as necessary. When the catheter has reached the oropharynx, encouraging the patient to swallow may aid the introduction of the device.
6. Verify with fluoroscopy and CARTO™ System mapping that the device tip is placed at the desired location prior to recording CARTO™ System esophagus points.
7. Record CARTO™ System points as the catheter is withdrawn from the esophagus. Tag the points as esophagus points on the CARTO™ System electroanatomic map. Refer to CARTO™ System users manual for details of CARTO™ System operation.
8. Once the map is complete, the device may be withdrawn and reinserted using the procedure described above or held in situ during the procedure. Fluoroscopic visualization of the catheter shaft will provide esophagus reference location information. Remap the esophagus on the CARTO™ System using the previously described procedure, as required.

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