Biosense Webster
a Johnson & Johnson company

NAVI-STAR® Diagnostic/Ablation Catheter
INSTRUCTIONS FOR USE

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

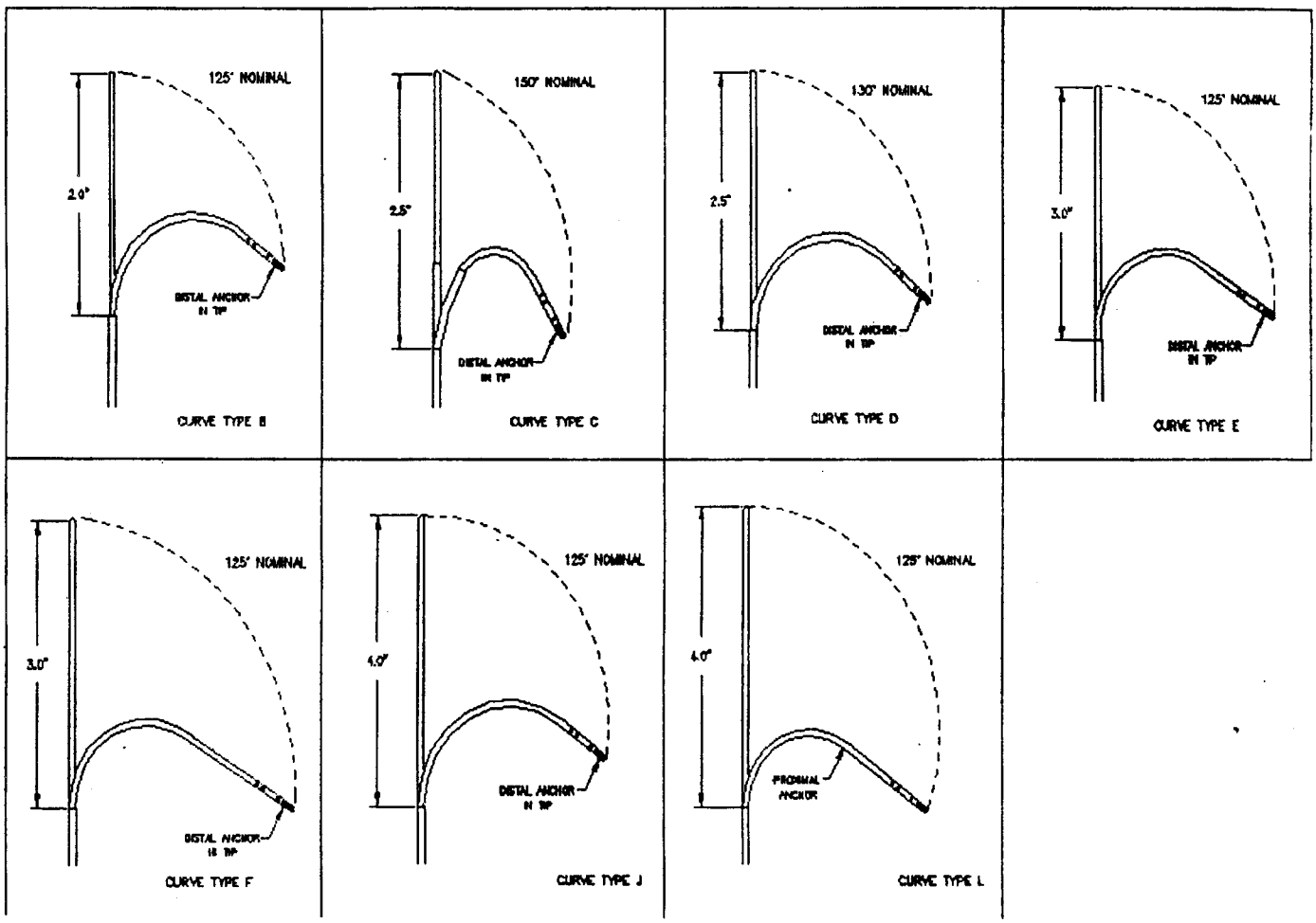
1. DEVICE DESCRIPTION

The NAVI-STAR® Diagnostic/Ablation Catheter is a steerable, multi-electrode catheter with a deflectable tip designed to facilitate electrophysiological mapping of the heart and to transmit radiofrequency current to the catheter tip electrode for ablation purposes. For mapping, the catheter is used with the CARTO® system (a magnetic field location technology) and a REF-STAR® reference device. For ablation, the catheter is used in conjunction with a compatible radiofrequency generator and a grounding (dispersive) pad.

The device has a high-torque polyurethane shaft with a deflectable tip section containing an array of platinum electrodes. All electrodes may be used for recording and stimulation, but only the tip electrode may be used to deliver RF energy from the generator. A magnetic location sensor embedded in the tip electrode transmits location information to the CARTO system. The catheter is available with either a thermocouple or thermistor temperature sensor.

Tip deflection is controlled at the proximal end by a tubular handpiece in which a piston slides; a thumb knob on the piston controls piston travel. The plane of the curved tip can be rotated and the shape of the curve depends on the deflectable tip length (1.5" to 4") and the location of the puller-wire anchor in the deflectable tip. Seven curve types, designated "B" through "F," "J," and "L" are available as shown in Figure 1.

Figure 1. Curve types for the NAVI-STAR® Diagnostic/Ablation Catheter.



The catheter interfaces with the CARTO system and a compatible RF generator via interface cables and a junction box.

For use in mapping procedures, refer to the instructions for the CARTO system.

For use in radiofrequency ablation procedures, refer to the radiofrequency generator operating instructions.

2. INDICATIONS AND USAGE

The Biosense Webster NAVI-STAR® Diagnostic/Ablation Catheter, and related accessory devices are indicated for catheter-based atrial and ventricular cardiac mapping. and when used with a compatible RF generator in adults and children 4 years of age and older for:

- interruption of accessory atrioventricular (AV) conduction pathways associated with tachycardia, including persistent junctional re-entrant tachycardia (PJRT) and Mahaim fibers;
- the treatment of AV nodal re-entrant tachycardia; and
- creation of complete AV nodal block in patients with a difficult to control ventricular response to an atrial arrhythmia.

When used with the CARTO EP Navigation System, the NAVI-STAR® Diagnostic/Ablation catheter provides location information.

3. CONTRAINDICATIONS

Do not use this device:

- in patients with active systemic infection;
- via the transseptal approach in patients with left atrial thrombus or myxoma, or interatrial baffle or patch;
- via the retrograde approach in patients with aortic valve replacement.

4. WARNINGS and PRECAUTIONS

- Avoid placement of the ablation catheter in the coronary vasculature. Ablation from within a coronary artery can cause myocardial injury and death. Adequate fluoroscopic visualization is necessary during the transaortic approach.

- Closely monitor patients during the post-ablation period for clinical manifestations of embolic events. Stroke or myocardial infarction may occur in patients undergoing left-sided ablation procedures.

- ICDs should be deactivated during ablation. Implantable pacemakers and implantable cardioverter/defibrillators (ICDs) may be adversely affected by RF ablation. Have temporary external sources of pacing and defibrillation available during ablation. Exercise extreme caution during ablation when in close proximity to device leads and perform a complete analysis of the implanted device after ablation.

- Closely monitor AV conduction during RF energy delivery and immediately terminate energy delivery if partial or complete AV block is observed. Complete AV block can occur when ablating septal accessory pathways or in the treatment of AVNRT. Using catheters with distal pair electrode spacing greater than 2 mm may increase the risk of AV nodal damage.

- Take all appropriate measures to minimize x-ray exposure to both patients and clinical staff. Significant x-ray exposure, can result in acute radiation injury as well as increased risk for somatic and genetic effects due to the x-ray beam intensity and duration of the fluoroscopic imaging.

- Pregnancy –Careful consideration should be given to the use of this device in pregnant women because of the risk of significant exposure to x-rays.

- Cardiac ablation procedures should be performed only by appropriately trained personnel in a fully-equipped electrophysiology laboratory.

- Do not attempt to operate the Biosense Webster NAVI-STAR® Diagnostic/Ablation Catheter or the radiofrequency generator prior to completely reading and understanding the applicable instructions for use.

- The long-term risks of protracted fluoroscopy have not been established. Careful consideration must therefore be given for the use of the device in prepubescent children.

- The long-term risks of lesions created by RF ablation have not been established. In particular, any long-term effects of lesions in proximity to the specialized conduction system or coronary vasculature are unknown.

4.1 Catheter Compatibility

- The NAVI-STAR® Diagnostic/Ablation Catheter is intended for use with a compatible RF generator (see section 11.5) and Biosense Webster accessories only.

- Read and follow the dispersive electrode manufacturer's instructions for use; the use of dispersive electrodes, which meet or exceed ANSI/AAMI requirements (HF18). is recommended.

4.2 Handling and Sterilization

SINGLE USE ONLY. DO NOT RE-STERILIZE.

Catheter damage may occur due to:

- autoclaving

- resterilizing
- exposure to organic solvents
- immersing proximal handle or cable connector in fluids

Observe "Use By" Date. Sterilized with ethylene oxide gas.

The sterile packaging and catheter should be inspected prior to use. If the package or the catheter appears damaged, do not use. Contact your local Biosense Webster representative.

4.3 Environmental and EMI

- Do not use in the proximity of magnetic resonance imaging (MRI) equipment because the MRI equipment may induce movement of the catheter, resulting in perforation. Also, the MRI equipment may adversely impact the function of the generator, and may result in image distortion.
- During ablation procedures, this catheter is used in conjunction with an RF generator. Electromagnetic interference (EMI) produced by the radiofrequency (RF) generator during the delivery of RF power may adversely affect the performance of other equipment. This device is a non-ionizing emitter of radiation and may cause electromagnetic interference with other devices. In order to minimize the electromagnetic interference, the generator should be placed at least 1meter away from any other electronic device.

4.4 Precautions During Catheter Use

- The patient should not contact grounded metal surfaces. Leakage current from any connected device to the patient must not exceed 10 microAmps (μA) under any circumstances. Use only isolated amplifiers, pacing equipment, and ECG equipment or patient injury or death may occur.

- Do not use excessive force to advance or withdraw the catheter. Careful catheter manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade.

- Do not insert or withdraw the catheter without straightening the catheter tip (pulling the thumb knob back).

- Do not use the catheter if the small vent area at the connector end of the handpiece is clogged since air may be forced into the catheter lumen and into the bloodstream.

- Use both fluoroscopy and electrograms to monitor the advancement of the catheter to the area of the endocardium under investigation to avoid vascular or cardiac damage.

4.5 Precautions During Ablation

- Do not increase power before checking for lead connection and appropriate dispersive electrode application. Effective contact between the patient and the dispersive electrode must be verified whenever the patient is repositioned.

- Do not deliver RF energy with catheter outside the target site. The RF generator can deliver significant electrical energy and may cause patient or operator injury.

- Avoid use of electrodes and probes of monitoring and stimulating devices which could provide paths for high frequency current. Reduce the burn hazard by placing the electrodes and probes as far away as possible from the ablation site and the dispersive electrode.

- In the event of a generator cutoff (impedance or temperature), the catheter must be withdrawn and the tip electrode cleaned of coagulum before RF current is re-applied. Use only sterile saline and gauze pad to clean the tip.

- Do not scrub or twist the tip electrode as damage may cause catheter failure or patient injury.

- Discontinue ablation immediately and replace catheter if tip temperature fails to rise during ablation.

- The temperature sensor of the catheter measures electrode tip temperature, not tissue temperature. If the generator does not display temperature, verify that the appropriate cable is plugged into the generator. If temperature still is not displayed, there may be a malfunction in the temperature sensing system which must be corrected prior to applying RF power.

5. ADVERSE EVENTS

5.1 Observed Adverse Events

The Biosense Webster NAVI-STAR® Diagnostic/Ablation Catheter was studied in 320 enrolled patients undergoing electrophysiologic (EP) mapping and RF catheter ablation to eliminate atrioventricular (AV) accessory pathways (AP) associated with tachycardia due to Wolff-Parkinson-White (WPW) syndrome, AV nodal re-entrant tachycardia (AVNRT), or creation of complete AV nodal (AVN) block in patients with difficult to control ventricular response to an atrial arrhythmia.

Three hundred twenty (320) patients were enrolled in the clinical study. Two hundred eighty-one (281) enrolled patients underwent RF ablation. These patients were followed for a mean of 8.22

months with a standard deviation of 4.37. The maximum length of follow-up was 20.39 months. All 281 patients undergoing RF ablation were included in the safety database.

Sixteen adverse events were reported for the 281 patients who received ablation therapy; seven of these events were classified as major adverse events. Major and minor adverse events were classified according to the FDA's recommended definitions for evaluating ablation safety. The major adverse events, occurring within seven days post ablation. included complete heart block that required placement of a permanent pacemaker (2 patients); atrial puncture caused by a transseptal sheath (1 patient); retroperitoneal hemorrhage resulting from a groin stick for venous access (1 patient); minor (non-q-wave) myocardial infarction (1 patient), cardiac tamponade (1 patient), and pulmonary edema (1 patient).

Minor adverse events included tricuspid regurgitation (2 patients); transient heart block (1 patient); pericardial effusion (1 patient) and dehydration (1 patient), dermal hypersensitivity (1 patient), femoral pseudoaneurysm (1 patient), mild fever with myalgia (1 patient), and trace pericardial effusion (1 patient).

Three deaths were reported for the study (the patients expired 12 days, 34 days, and 49 days. respectively, post-procedure). All deaths were due to complications associated with the patient's primary disease condition.

A summary of observed adverse events for all ablated patients is provided in the following table:

Observed Adverse Events/Deaths (N=281)

Adverse Event Classification	% patients	Number of patients	95% Confidence Interval*	
Major	2.5%	7/281	0.010	0.053
Minor	3.2%	9/281	0.015	0.061
Death	1.1%	3/281	0.002	0.034

*Confidence intervals by exact (binomial) method

5.2 Anticipated Adverse Events

Adverse events (in alphabetical order) which may be associated with catheterization and ablation include:

- Air embolism
- Arrhythmias
- AV fistula
- Cardiac perforation/tamponade
- Cardiac thromboembolism
- Cerebrovascular accident (CVA)
- Chest pain/discomfort
- Complete heart block
- Coronary artery dissection
- Coronary artery spasm
- Coronary artery thrombosis
- Hemothorax
- Increased phosphokinase level.
- Laceration
- Local hematomas/ecchymosis
- Myocardial Infarction
- Pericardial effusion
- Pericarditis
- Pleural effusion
- Pneumothorax
- Pseudoaneurysm
- Pulmonary edema
- Pulmonary embolism/tamponade
- Thrombi
- Thromboembolism
- Thrombosis
- Transient ischemic attack (TIA)
- Valvular damage
- Vascular bleeding/local hematomas
- Vasovagal reactions
- Ventricular tachyarrhythmia

6. CLINICAL STUDIES

The NAVI-STAR® Diagnostic/Ablation Catheter, when used in conjunction with the CARTO system and related accessory devices was evaluated in a clinical study with the Medtronic CardioRhythm Atakr RF generator, and the EPT RF generator for the treatment of supraventricular tachycardias.

Study Design: The NAVI-STAR® Diagnostic/Ablation Catheter was evaluated in a prospective, non-randomized, multi-center study. Acute success was defined as the inability to induce the arrhythmia for WPW and AVNRT patients, and complete heart block for AVN patients, following the ablation procedure. Chronic (3 month) success was defined as the absence of recurrence of the arrythmia over a 3 month monitoring period.

Patients Studied: Of the 320 patients enrolled, 281 patients underwent ablation and provided clinical data for the assessment of safety. For the effectiveness endpoints, the patient count included all patients treated with the NAVI-STAR® Diagnostic/Ablation Catheter, including those patients where the physician began the procedure using the NAVI-STAR® Diagnostic/Ablation Catheter and then changed to a non-protocol device to complete the procedure. The patients who began treatment with the NAVI-STAR® Diagnostic/Ablation Catheter, but were switched to a non-protocol device were considered treatment failures. Therefore, two hundred seventy-seven (277) patients were treated with the NAVI-STAR® Diagnostic/Ablation Catheter for an arrhythmia indicated in the study and were assessed for effectiveness. The other 39 patients were discontinued prior to ablation for the reasons and occurrence indicated in the table below:

Patients Discontinued Prior to Ablation

Reason for Discontinuation	Number of Patients
Physician chose not to ablate (difficult pathway, close proximity to AV node, unusual location, or other)	3
Unable to induce protocol arrhythmia	22

Non-protocol arrhythmia	14
Total number of discontinued patients:	39

Demographics: Of the 281 patients undergoing RF ablation. 158 (56%) were female and 123 (44%) were male, which is consistent with the prevalence of the disease. The mean age for all patients was 49 years (range 10-86). The distribution of supraventricular tachycardias treated is shown in the following table.

Distribution of Arrhythmias Treated

Indication	Number of patients	
	%	#
WPW	24%	69/281
AVNRT	56%	156/281
WPW/AVNRT	1%	4/281
AVNRT/other arrhythmia	2%	7/281
AV Node Ablation	14%	41/281
Non-study arrhythmia	%	4/281
All Patients	100%	281

Intraprocedural Data: For the 281 patients ablated, RF current was applied a total of 2,289 times during the study with a mean of 8.4 applications per patient (range 1-58) and a mean duration of 40.9 seconds per application (range 1-328). The mean temperature per application was 56.8°C (range 35-100°C). Mean fluoroscopy time was 20.4 minutes, and mean total procedure time was 194.5 minutes.

Acute Effectiveness: Of the 277 patients treated with the NAVI-STAR® Diagnostic/Ablation Catheter, acute success was achieved in 269 patients (97.1%). The table below summarizes acute success rates by indication and group.

Acute Procedural Success by Indication (n=277)

Indication	%	#	95% Confidence Interval
WPW	95.7%	66/69	[0.878, 0.991]
AVNRT	97.5%	159/163	[0.938, 0.993]
WPW/AVNRT	100%	4/4	[0.398, 1]
AVNRT/supplemental arrhythmia*	100%	4/4*	[0.398, 1]
AV Node Ablation	97.6%	40/41	[0.871, 0.999]
All Patients	97.1%	269/277	[0.944, 0.987]

* Not counted in total

Chronic Effectiveness: Of the 198 patients available for 3-month follow-up, chronic success was achieved in 185 (93.4%). Six-month chronic success was reported for 159 (95.7%) of 166 core patients available for follow-up. The table below summarizes chronic success rates by indication and group.

95% confidence interval Chronic Success by Indication at 3 Months

Indication	3 Months		95% Confidence Interval	
	%	#	Lower Limit	Upper Limit
WPW	95.3%	41/43	0.842	0.994
AVNRT	93.0%	107/116	0.858	0.964
WPW/AVNRT	100%	4/4	0.398	1.000
AVNRT/other arrhythmia	100%	5/5	0.478	1.000
AV Node Ablation	93.1%	27/29	0.772	0.992
AV Node Ablation & Other	100%	1/1	0.025	1.000
All Patients	93.4%	185/198	0.890	0.965

95% confidence interval Chronic Success by Indication at 6 Months

Indication	6 Months		95% Confidence Interval	
	%	#	Lower Limit	Upper Limit
WPW	91.2%	31/34	0.763	0.981
AVNRT	94.7%	89/94	0.880	0.983
WPW/AVNRT	100%	3/3	0.292	1.000
AVNRT/other arrhythmia	100%	2/2	0.158	1.000
AV Node Ablation	100%	25/25	0.863	1.000
AV Node Ablation & Other	100%	1/1	0.025	1.000
All Patients	95.0%	151/159	0.903	0.978

In separate clinical studies for a PMA approved ablation catheter (CELSIUS® P95005), Biosense Webster collected the clinical data shown in the table below.

Device Performance Compared to Control Group

Study Endpoint	NAVI-STAR® Catheter	Control	Exact One-Sided 95% Confidence Bound
Acute Success	97.1%	92.1%	93.9%
Chronic Success	93.4%	91.5%	88.4%
Major Complications	1.8%	3.5%	4.4%

The safety, acute effectiveness, and chronic effectiveness results from the NAVI-STAR® study were demonstrated to be statistically equivalent to the control data.

7. PATIENT TREATMENT

7.1 Antiplatelet or Anticoagulation Use

To avoid thromboemboli, intravenous heparin is used when entering the left heart during ablation, and many physicians prescribe aspirin, less often warfarin, for about 3 months afterward. No consensus yet exists about the need for short-term anticoagulation after ablation.

7.2 Choosing Temperature or Power Control Mode

Please refer to the compatible RF generator's Directions for Use for information in choosing between temperature or power control modes.

7.3 Specific Patient Populations

The safety and effectiveness of cardiac ablation has not been established in:

- Asymptomatic patients;
- patients who are pregnant; or
- nursing mothers.

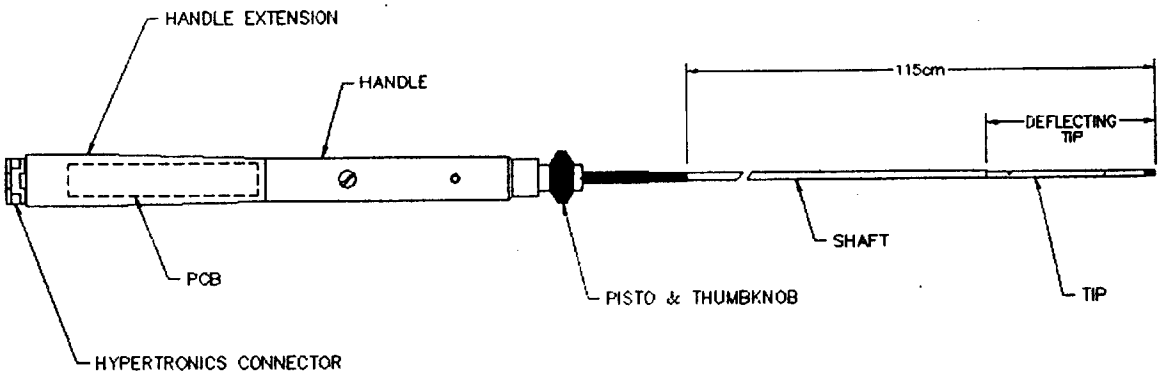
8. PATIENT COUNSELING INFORMATION

Patients may require anticoagulation and/or antiplatelet therapy for an indefinite period based on the patient's condition.

9. HOW SUPPLIED

The NAVI-STAR™ Diagnostic/Ablation Catheter is provided sterile (EtO). The device is a 7 F catheter with a usable length of 115 ± 3 cm, and the following features:

Curve types:	B, C, D, E, F, J, L
Tip electrode:	4 mm
Connector type:	Hypertronics interlocking
Spacing:	1-7-4


HANDLE EXTENSION
HANDLE
115cm
DEFLECTING TIP
PCB
SHAFT
PISTO & THUMBKNOB
TIP
HYPERTRONICS CONNECTOR

9.1 Packaging

The Biosense Webster NAVI-STAR® Diagnostic/Ablation Catheter is supplied STERILE. The catheter is secured onto a mounting card and placed into a polyethylene/Tyvek® pouch and sealed. The sealed pouch is placed into a second sealed pouch and placed in a box. Both the inner pouch and the shipping container are labeled sterile unless the package is damaged or opened.

9.2 Storage

The Biosense Webster NAVIAR Diagnostic/Ablation Catheter must be stored in a cool, dry place. Storage temperature should be between 5° and 25°C (41° and 77°F).

9.3 Shelf-Life

Accelerated aging tests support an expiration date of one year.

10. DIRECTIONS FOR USE

10.1 Physician Training

Physicians must be familiar with the techniques and appropriately trained for cardiac mapping and ablation procedures. All mapping and ablation procedures must be performed in a fully-equipped electrophysiology laboratory.

10.2 Compatible RF Generators and Accessories

The NAVI-STAR™ Diagnostic/Ablation Catheter should be used only with a legally marketed RF generator which has been shown to be safe and effective for cardiac ablation.

Specifications for Compatible RF Generators:

Refer to the RF generator manual for detailed generator operating instructions for RF catheter ablation.

Generator	Specification
Thermometry	Thermocouple or Thermistor
Temperature Limit, Maximum	100°C
Modes: (must operate in all 3 modes)	Temperature Control Temperature Monitoring Power Control
Maximum Output Power	50 Watts
RF Output Frequency	450kHz – 550kHz
Impedance Cut-off	High: 250Ω Low: 40Ω

Accessories: Use appropriate Biosense Webster accessory cables to connect the NAVI-STAR® Diagnostic/Ablation catheter to the CARTO system and a compatible RF generator. Refer to the CARTO system User's Manual for detailed instructions for mapping procedures.

Accessory	Specification
Catheter Interface Cable	5-foot cable with Hypertronics interlocking connectors
Reference Device	REF-STAR catheter or REF-STAR External Reference Patch

10.3 Handling and Preparation

Before use, inspect the packaging. Do not use if open or damaged.
Using aseptic technique, remove the catheter from its package and place it in a sterile working area. Inspect the catheter carefully for electrode integrity and overall condition.

10.4 Operating Instructions

1. Create a vascular access in a large central vessel using aseptic techniques and insert the catheter.

2. Connect the catheter to the interface cables, the CARTO system, a compatible RF generator, and standard recording equipment using the appropriate interface cables.

3. Advance the catheter to the area of the endocardium under investigation. Use both fluoroscopy and electrograms to aid in proper positioning.

4. The catheter tip can be deflected to facilitate positioning by using the thumb knob to vary tip curvature. Pushing the thumb knob forward causes the catheter tip to bend; when the knob is pulled back, the tip straightens.

5. When it has been determined that the tip electrode is in stable contact with the intended ablation site, the catheter tip electrode connection must be switched from the recording equipment to the RF generator in preparation for delivery of RF current. Circuit impedance should be approximately 100 ohms upon initiation of radiofrequency current.

6. RF current may be re-applied to the same or alternate sites using the same catheter.

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