



**Biosense Webster**  
a Johnson & Johnson company

**CELSIUS™ DS Diagnostic/Ablation Catheter**  
**INSTRUCTIONS FOR USE**

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## CELSIUS™ DS Diagnostic/Ablation Catheter

### INSTRUCTIONS FOR USE

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

**SINGLE USE ONLY. DO NOT RESTERILE.**

#### 1. DEVICE DESCRIPTION

The Biosense Webster CELSIUS™ DS Diagnostic/Ablation Catheter (8 mm tip electrode) is a steerable, multi-electrode catheter with a deflectable tip. This catheter is used in conjunction with a Stockert 70 radiofrequency (RF) Generator, compatible interface cables, and a grounding (dispersive) pad.

The CELSIUS™ DS Diagnostic/Ablation Catheter is 7 F in diameter and has a usable length of 115 cm. The catheter has a high-torque polyurethane shaft with a deflectable tip section that includes an array of platinum electrodes. The deflectable tip of the DS catheter has one 8 mm platinum/iridium tip electrode and three platinum/iridium ring electrodes used for pacing and recording ECG signals. The spacing will be 0.5 - 1.0 mm between the tip and 1st ring electrode, 4.5 - 5.5 mm between the 1st and 2nd ring electrodes, and 2 - 2.5 mm between the 2nd and 3rd ring electrodes. All electrodes may be used for recording and pacing, but only the tip electrode can be used to deliver RF energy from the generator.

The catheter measures temperature at two locations via a pair of thermocouples. This catheter does not have a magnetic location sensor embedded in the tip electrode and, therefore, cannot be used with the CARTO™ EP Navigation System.

Catheter tip deflection is controlled by a proximal handpiece that features a thumb operated sliding piston connected to a “puller-wire.” The shape of the catheter curve depends on the length of the deflectable tip (1.5 to 4”) and the point of attachment of the puller-wire. Seven curve types designated “B”, “C”, “D”, “E”, “F”, “J”, and “L” are available. The plane of the curved tip may be rotated during use.



For further description of the Stockert 70 RF Generator, refer to the operating instructions for this instrument.

## **2. INDICATIONS AND USAGE**

The CELSIUS™ DS Catheter and related accessory devices are indicated for catheter-based cardiac electrophysiological mapping (stimulation and recording), and when used with the Stockert 70 (model S7001 with software version 001/033) for the treatment of Type I atrial flutter in patients age 18 or older.

## **3. CONTRAINDICATIONS**

Do not use this device:

- In patients with active systemic infection; or
- Via the transseptal approach in patients with left atrial thrombus or myxoma and
- Via the retrograde approach in patients with aortic valve replacement.

## **4. WARNINGS AND PRECAUTIONS**

- This device may not be suitable for patients that have had a ventriculotomy or atriotomy within the four weeks preceding the procedure.
- The long-term risks of protracted fluoroscopy and creation of RF induced lesions have not been established. Careful consideration must therefore be given for the use of the device in prepubescent children. Furthermore, the risk/benefit in asymptomatic patients has not been studied.
- To avoid thromboemboli, intravenous heparin may be used during ablation, and physicians may prescribe aspirin, less often warfarin, for about 3 months afterward. No consensus yet exists about the need for short-term anticoagulation after ablation.
- Cardiac ablation procedures should be performed by appropriately trained personnel in a fully equipped electrophysiology laboratory.



- When using the Biosense Webster CELSIUS™ DS catheter you should use careful catheter manipulation in order to avoid cardiac damage, perforation, or tamponade. Do not use excessive force to advance or withdraw the catheter when resistance is encountered.
- Always pull the thumb knob back to straighten the catheter tip before insertion or withdrawal of the catheter.
- Inspect the catheter packaging prior to use. If the package is open or damaged, return the catheter to Biosense Webster.
- When RF current is interrupted for either a temperature or an impedance rise (the set limit is exceeded), the catheter should be removed, and the tip cleaned of coagulum. When cleaning the tip electrode, be careful not to twist the tip electrode with respect to the catheter shaft; twisting may damage the tip electrode bond and loosen the tip electrode.
- Apparent low power output, high impedance reading or failure of the equipment to function correctly at normal settings may indicate faulty application of the dispersive electrode(s) or failure of an electrical lead. Do not increase power before checking for obvious defects or misapplication.
- Do not attempt to operate the Biosense Webster CELSIUS™ DS Catheter or the Stockert 70 RF Generator prior to completely reading and understanding the applicable directions for use.
- 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.
- The Biosense Webster CELSIUS™ DS Diagnostic/Ablation Deflectable Tip Catheter is indicated for use only with the Stockert 70 RF Generator, Biosense Webster cables, and other appropriate interface cables and connectors.
- The Biosense Webster Celsius™ DS catheter, used in conjunction with the Stockert 70 RF Generator are capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the catheter and dispersive electrode, particularly when



operating the device. During energy delivery, the patient should not be allowed to come in contact with grounded metal surfaces. If during ablation, temperature does not rise, discontinue ablation immediately and replace catheter.

- If the generator does not display temperature, verify that the appropriate cable is plugged into the generator. If temperature is still not displayed, there may be a malfunction in the temperature sensing system, which must be corrected prior to applying RF power.
- It is recommended that no more than seventy (70) one-minute applications of RF energy be performed per catheter.
- The sterile packaging and catheter should be inspected prior to use. The Biosense Webster CELSIUS™ DS Catheter is intended for single patient use only. Do not resterilize and reuse.
- The risk of igniting flammable gases or other materials is inherent in electrosurgery. Precautions must be taken to restrict flammable materials from the electrosurgical site.
- Electromagnetic interference (EMI) produced by the Biosense Webster CELSIUS™ DS Catheter used in conjunction with the Stockert 70 RF Generator during normal operation may adversely affect the performance of other equipment.
- Electrodes and probes for monitoring and stimulating devices can provide paths for high frequency current. The risk of burns can be reduced but not eliminated by placing the electrodes and probes as far away as possible from the ablation site and the dispersive electrode. Protective impedances may reduce the risk of burns, and permit continuous monitoring of the electrocardiogram during energy delivery.
- Regularly inspect and test re-usable cables and accessories.
- Implantable pacemakers and Implantable Cardioverter/Defibrillators (ICDs) may be adversely affected by RF current. It is important to have temporary external sources of pacing and defibrillation available during ablation, and to temporarily reprogram the pacing system to minimum output or OFF mode to minimize risk of inappropriate pacing. Exercise extreme caution during ablation when in close proximity to atrial or ventricular permanent



leads, to program the ICD to the OFF mode during the ablation procedure, and to perform complete implantable device analysis on all patients after ablation.

- Patients undergoing ablations on the septal side of the isthmus may be at risk for complete AV block, which requires the implantation of a permanent pacemaker. Permanent pacing may be required in patients who experience inadvertent complete AV block as a result of RF ablation.
- Catheter ablation procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as increased risk for somatic and genetic effects, to both patients and laboratory staff due to the x-ray beam intensity and duration of the fluoroscopic imaging. Catheter ablation should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure, and steps taken to minimize this exposure. Careful consideration must therefore be given for the use of the device in pregnant women.
- The catheters are sterilized with Ethylene oxide gas and should be used by the “Use By” date on the device package. Do not use the device if past the “Use by” date.
- Do not use near MRI equipment since movement or heating of the catheter may occur and the image on the Stockert 70 display may become distorted.
- Use both fluoroscopy and electrogram data to monitor catheter advancement and reduce risk of tissue injury.
- Do not use the catheter if the small vent hole at the connector end of the handpiece is occluded as evidenced by difficulty in deflecting the catheter tip and the inability of the catheter to hold a curve.
- The displayed temperature is not the temperature of the tissue. It is the temperature of the tip electrode only and does not represent tissue temperature.
- This device has not been shown to be safe at electrode temperatures above 60°C.

- Do not expose catheter to organic solvents such as alcohol.
- Do not autoclave the catheter.
- Do not immerse proximal handle or cable connector in fluids; electrical performance could be affected.
- Do not scrub or twist the distal tip electrode during cleaning.
- The catheters are sterilized with Ethylene oxide gas and should be used by the “ Use By” date on the device package. Do not use the device if past the “Use by” date.
- Do not use near MRI equipment since movement or heating of the catheter may occur and the image on the Stockert 70 display may become distorted.
- Use both fluoroscopy and electrogram data to monitor catheter advancement and reduce risk of tissue injury.
- Do not use the catheter if the small vent hole at the connector end of the handpiece is occluded as evidenced by difficulty in deflecting the catheter tip and the inability of the catheter to hold a curve.

## 5. ADVERSE EVENTS

**Note that data on adverse events are from the clinical study on the NAVISTAR™ DS Diagnostic/Ablation Catheter (8 mm). See justification for the equivalency of the CELSIUS™ DS AND NAVISTAR™ DS Diagnostic/Ablation Catheters (8 mm) on Page 2.**

### 5.1 Observed Adverse Events

In the clinical study of 191 enrolled patients described in the Section 6, there were 13 patients with major complications. See Section 6, “ Summary of Clinical Studies”, below for a complete description of the adverse events encountered during the study

## 6. SUMMARY OF CLINICAL STUDIES

**Note that these data on clinical results are from the clinical study on the NAVI STAR™ DS Diagnostic/Ablation Catheter (8 mm). See justification for the equivalency of the CELSIUS™ DS AND NAVI STAR™ DS Diagnostic/Ablation Catheters (8 mm) on Page 2.**

The clinical testing described below was performed with the NaviStar™ DS catheter, and not with the Celsius™ DS catheter. Since the ablation capabilities of both NaviStar and Celsius™ DS Catheters were shown with pre-clinical testing to be similar, clinical testing results from the NaviStar™ study, as reported below, may be extrapolated to what would be expected when using the Celsius™ DS catheter.

### A. Objective

The objective of the study was to determine if the NaviStar™ DS catheter, when used in conjunction with the Stockert 70 RF generator and related accessory devices, is safe and effective for the treatment of Type 1 atrial flutter in patients age 18 or older.

### B. Study Design

The study was a prospective, non-randomized, unblinded, multi-center study conducted at 16 investigational sites.

#### B.1. - Study Endpoints:

The endpoints for the study were as follows:

- **procedural safety** - defined by the absence of serious complications associated with the use of the investigational device within seven days of the ablation procedure; and
- **acute procedural success** - defined as complete bi-directional conduction block across the isthmus, and the inability to induce typical atrial flutter post-procedure.

Long-term freedom from atrial flutter recurrence was not specifically identified as a study endpoint. Instead, FDA allowed acute procedural success to be used as a surrogate endpoint for this parameter. Long-term (defined as 6-months post-treatment) freedom from atrial flutter recurrence information was also collected, in order to enable FDA to assess whether the surrogate endpoint was reasonable.

B.2. - Objective Performance Criteria (OPC):

Objective performance criteria (OPC) were prospectively established for all atrial flutter studies by FDA, based on prior experience with supraventricular tachycardia (SVT) ablation studies and consideration by the FDA Circulatory System Devices Panel. The OPC are defined below:

- **Safety:** major adverse events within 7 days of the procedure occur at a **2.7%** rate or less with a **7%** one-sided 95% confidence bound;
- **Acute success:** **88%** with an **80%** one-sided 95% confidence bound.

B.3 - Patient Accountability

The table below documents the accountability of patients throughout the study.

**Table 13(a) - Patient Accountability**

Patients enrolled in study	191
Patients not ablated	9
Patients ablated with NaviStar	182
Patients ablated <b>only</b> with NaviStar	166
Patients ablated with NaviStar and non-investigational catheter*	15
Patients found to have atypical atrial flutter post ablation**	1

\* Patients were first ablated with the NaviStar only. If flutter procedure could not be completed, then physicians used another catheter to complete procedure.

\*\* This patient was considered acute effectiveness failure, as documented in Table 16 below.

B.4 - Patient Demographics

The table below summarizes the demographic information of patients enrolled in the study.

**Table 13(b) - Patient Demographics (n=182)**

<b>Gender</b>	<b>N</b>	<b>%</b>
Female	39	21.43%
Male	143	78.57%
<b>Age (in years)</b>		
mean + standard deviation	64.27 ± 10.20	
Median	65.00	
range	37-87	

In addition, seventy-eight (78) patients were reported with a total of 131 reported concomitant arrhythmias. The most common arrhythmia was atrial fibrillation, reported in 85 cases.

**C. Results**

**C.1. - Intraprocedural Data**

The table below describes the intraprocedural data:

**Table 14 - Power, Temperature and Impedance Data**

<b>Description</b>	<b>Mean ± Standard Deviation</b>	<b>Range</b>
# RF applications/procedure <sup>1</sup> (n=182 procedure)	24.1 ± 19.7	4-134
maximum power (Watts)/application <sup>2</sup> (n=4368 RF applications)	52.5 ± 10.4	10-87
maximum temperature (°C)/application <sup>2</sup> (n=4387 RF applications)	52.3 ± 7.4	23-85
maximum impedance (Ohms)/application <sup>2</sup> (n=4346 RF applications)	92.4 ± 17.0	37-258

- <sup>1</sup>-One patient had a second ablation procedure.
- One patient was missing RF information.
  - One patient received 134 applications  $\geq$  5 seconds.
  - One patient was ablated for a non-protocol arrhythmia.

<sup>2</sup>Power, temperature, and impedance not documented for several RF applications.

**Table 15 - Fluoroscopy/Procedure Time (minutes)**

Description	Mean $\pm$ Standard Deviation	Range
total fluoroscopy time/procedure <sup>1</sup> (n=176 procedures)	31 $\pm$ 30	2-198
total procedure time/procedure <sup>1</sup> (n=178 procedures)	164 $\pm$ 145	36-595

<sup>1</sup>Incomplete fluoroscopy times were reported for six (6) patients and incomplete procedure times were reported for four (4) patients.

### C.2. - Acute Procedural Success

Acute procedural success evaluation was based on 182 patients treated with the NaviStar. The table below describes this information:

**Table 16 - Acute Ablation Outcomes (n=182)**

	# Success/# Patients Ablated	Percentage (1-sided 95% confidence bound) <sup>1</sup>
Acute Study Results	164/182	90.11% (87.22%)
OPC		88% (80%)

<sup>1</sup>Exact binomial using a commercially-available software package.

### C.3. - Freedom from Atrial Flutter Recurrence at Six-Month Follow-Up



Freedom from atrial flutter recurrence was evaluated in patients in whom bi-directional tricuspid isthmus conduction block (BDB) was achieved and for whom 6-month post-ablation information was available. Based on these criteria, information was available on a total of 112 patients.

Results are described in Table 17 below.

**Table 17 - Freedom from Atrial Flutter at 6 months**

<b>Description</b>	<b>N</b>
Patients with successful BDB	112
# patients free from recurrence	105 (93.75%)
# patients with recurrence of atrial flutter	7
# patients free from both recurrence and medication change (percentage based on N=112)	98 (87.50%)
# patients with anti-arrhythmic drugs (AAD) changes to treat atrial fibrillation	9
Patients ablated <b>only</b> with NaviStar and successful BDB	108
# patients free from recurrence	102 (94.44%)
# patients with recurrence of atrial flutter	6
# patients free from both recurrence and medication change (percentage based on N=108)	95 (87.96%)
# patients with AAD changes to treat atrial fibrillation	8
# patients with anti-arrhythmic drugs to treat VT	1

These results provide reasonable evidence that acute procedural success serves as an appropriate surrogate for long-term freedom from atrial flutter recurrence.

C.4. - Adverse Events/Complications and Deaths



An adverse event was determined to be any undesirable experience occurring to a subject during the course of the study, whether or not it is related to the device or procedure. A serious adverse event was defined as any clinical event resulting in death, a life-threatening complication, or a persistent or significant disability/incapacity that requires inpatient hospitalization or prolongs hospitalization or requires intervention to prevent a permanent impairment of a body function or damage to a body structure.

Major Adverse Events

Of the 182 patients treated with the NaviStar, fourteen (14) major adverse events were reported in thirteen (13) patients.

Major Complications

The major complication rate observed with the use of the NaviStar™ DS catheter was 7.14% (13/182), and the 95% upper confidence bound was 10.97%. A risk/benefit analysis was performed and a detailed review of each adverse event was completed. Several patients had adverse events related to pre-existing non-cardiac disease. Several patients had adverse events related to having an invasive procedure but do not relate specifically to an ablation procedure or the investigational device. The table below summarizes the adverse event (AE) information.

**Table 18 - Adverse Events, within 7 days post-ablation**

	# AEs <sup>1</sup>
Dysrhythmias	
Exacerbation of pre-existing atrial fibrillation <sup>2</sup>	3
Temporary complete heart block, required pacing <sup>2</sup>	1
Ventricular tachycardia during electrophysiology study, required ICD	1
Atypical flutter <sup>2</sup>	1
Exacerbation of pre-existing disease	
Pulmonary	1
Congestive heart failure	1
Neurological	2
Vascular entry related	



	Pneumothorax	1
	Pseudoaneurysm	1
	Anemia	1
Sedation/restraint related		
	Rotator cuff tendon tear	1

<sup>1</sup> One patient had 2 events (exacerbation of pre-existing atrial fibrillation and pneumothorax).

<sup>2</sup> Possibly related to use of device.

As noted in the above table, a total of five (5) adverse events were determined to be possibly device-related (for an AE rate of 5/182 or 2.7%).

Two patients died during the course of the study. Neither death was temporally related to the ablation procedure. One death was unwitnessed and occurred 5 months after the ablation procedure in a 59 year old man who also had hypertension, diabetes, peripheral vascular disease, congestive heart failure, atrial fibrillation and coronary artery disease. No autopsy was performed. The other patient death occurred two months after the procedure in an 82 year old man due to pneumocystis pneumonia thought to be secondary to his pre-existing chronic lymphoid leukemia.

C.5. - Statistical Analysis

The table below summarizes the effectiveness of the device when compared to the control group OPC established for safety and acute success.

**Table 19 - Comparison of Endpoints between NaviStar™ DS Study and OPC**



Endpoint	OPC		NaviStar™ DS Study	
	%	One-sided 95% Confidence Bound <sup>1</sup>	% (N)	One-sided 95% Confidence Bound <sup>1</sup>
Acute Success	88%	80%	90.11% (164/182)	87.22% (Lower bound)
Major Complications	2.7%	7%	7.14% (13/182)	10.97% (Upper bound)

<sup>1</sup>Exact binomial using a commercially-available software package.

By comparing the lower bounds of the acute success endpoints (87.22% vs. 80%), the results demonstrate that the NaviStar™ DS Catheter met the OPC for acute success. As previously explained, although the device exceeded the upper bound of major complications, review of the specific events revealed that most events were not device-related; accordingly, the adverse event rate was acceptable.

## 7. HOW SUPPLIED

- The CELSIUS™ DS Diagnostic/Ablation Catheter is supplied STERILE (EtO).
- The catheter is supplied with a choice of seven curve types: B, C, D, E, F, J, and L.
- The Stockert 70 RF Generator with appropriate interface cables is supplied separately.
- A grounding (dispersive) pad is supplied separately.

### 7.1 Packaging

The CELSIUS™ DS Diagnostic/Ablation Catheter is provided in sterile packaging. The catheter is secured to a mounting card placed in a sealed polyethylene/Tyvek® pouch. The



sealed pouch is placed in a second sealed pouch and this assembly is packaged inside a cardboard box. Both the inner pouch and the shipping container are labeled sterile.

## 7.2 Storage

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

## 7.3 Shelf-Life

The CELSIUS™ DS Diagnostic/Ablation Catheter has a shelf-life of one (1) year.

## 8. DIRECTIONS FOR USE

1. RF ablation is performed during either sustained Typical Atrial Flutter, or during proximal coronary sinus or low anterolateral right atrial pacing (medial and lateral aspects of the TA-IVC isthmus, respectively).
2. Remove the CELSIUS™ DS Diagnostic/Ablation Catheter from the package and place in a sterile work area.
3. Create a vascular access site in a large central vessel using aseptic techniques and insert an 8 F introducer sheath.
4. Connect the catheter to the appropriate Biosense Webster cable with Redel interlocking connectors on both ends. Connect the catheter to the Stockert 70 RF Generator via the 10-pin Redel connector. If electrogram recording equipment is used, the catheter tip electrode must be switched from the electrogram equipment (via the generator controls or an external switch) to the RF generator power output for ablation. To complete the electrical circuit, connect a dispersive pad to the reference electrode input on the generator.
5. Turn the CATHETER SELECTION KNOB on the Stockert 70 RF Generator to the “Dual Temp 8 mm” option.

6. Insert the catheter through the 8 F introducer sheath.
7. Advance the catheter to the area of the endocardium under investigation. Use both fluoroscopy and electrograms to aid proper positioning.
8. Deflect the catheter tip to facilitate positioning by using the thumb knob on the handle to vary tip curvature. Push the thumb knob forward to bend the catheter tip; pull the thumb knob back to straighten the catheter tip.
9. Ensure that the tip electrode achieves stable contact with the intended ablation site.
10. Verify that the CATHETER SELECTION KNOB on the Stockert 70 RF Generator is on the "Dual Temp 8 mm" option, the circuit impedance is approximately 80 ohms, and the starting Temperature is near 37° C before applying RF energy. Monitor the Temperature throughout a procedure. The peak Temperature should be maintained at 55 - 60° C during RF energy delivery, and the maximum Temperature should not exceed 60° C. The displayed temperature represents the temperature of the electrode only, not the temperature of the tissue.
11. Start a procedure at  $\leq 50$  Watts up for a maximum of 60 seconds per RF application. Increase power up to 70 Watts only if bi-directional conduction block cannot be achieved at  $\leq 50$  Watts. When power delivery is over 50 Watts (51 to 70 Watts), limit the application time to a maximum of 30 seconds per RF application.
12. Deliver the RF energy. RF energy may be reapplied to the same or alternate sites using the same catheter.
13. If the RF generator does not display temperature, verify that the appropriate cable is plugged into the generator. If the generator still does not display temperature, there may be a malfunction in the temperature sensing system. Correct this malfunction prior to reapplying RF energy.
14. If preset temperature or impedance levels are exceeded during operation, design safety features of the RF generator cause the RF energy to stop. A likely cause of this may be accumulated coagulum on the tip electrode. Withdraw the catheter and examine the tip



electrode. If coagulum accumulation is present, clean the tip electrode by gently wiping with a sterile gauze pad dampened with sterile saline. Use caution to not twist the tip electrode relative to the catheter shaft during cleaning because this may damage the tip electrode bond and loosen the tip electrode.

15. Apparent low power output, high impedance reading, or failure of the equipment to function correctly at normal settings may indicate faulty application of the dispersive electrode(s) or failure of an electrical lead. Check the system for obvious defects or misapplications before continuing a procedure.

**Operation of the Stockert 70 Generator in the automatic temperature controlled mode:**

1. Press the “F1” key located above and left of the CATHETER SELECTION KNOB and turn the CATHETER SELECTION KNOB to the set the maximum Temperature limit of 60° C.
2. Press the “F2” key located above and right of the CATHETER SELECTION KNOB and turn the CATHETER SELECTION KNOB to set the maximum Power limit at 50 Watts. Increase the Power 70 Watts only if bi-directional conduction block cannot be achieved at 50 Watts.
3. Use the TIMER KEYS located below the TIME display to set the maximum Time duration at 60 seconds when the maximum Power limit is 50 Watts. When the Power limit is increased to 70 Watts, limit the maximum Time duration to 30 seconds.



## **DISCLAIMER OF WARRANTY AND LIMITATION OF LIABILITY**

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The CELSIUS™ DS Diagnostic/Ablation Catheter and accessories are protected under one or more of the following U.S. Patent Nos.: 5,827,278; 5,6,171,277, and other patents pending in the U.S. and other countries.

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NAVISTAR™ DS Diagnostic/Ablation Catheter  
INSTRUCTIONS FOR USE

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#### 1. DEVICE DESCRIPTION

The Biosense Webster NAVISTAR™ DS Diagnostic/Ablation Catheter (8 mm tip electrode) is a steerable, multi-electrode catheter with a deflectable tip. For electrophysiological mapping, the catheter is used with the CARTO™ EP Navigation System (a magnetic field location technology) and a REFSTAR™ with QWIKPATCH™ Reference Patch. For therapeutic ablation, the catheter is used in conjunction with a Stockert 70 radiofrequency (RF) Generator, compatible interface cables, and a grounding (dispersive) pad.

The NAVISTAR™ DS Diagnostic/Ablation Catheter is 7 F in diameter and has a usable length of 115 cm. The catheter has a high-torque polyurethane shaft with a deflectable tip section that includes an array of platinum electrodes. The deflectable tip of the DS catheter has one 8 mm platinum/iridium tip electrode and three platinum/iridium ring electrodes used for pacing and recording ECG signals. The spacing will be 0.5 - 1.0 mm between the tip and 1st ring electrode, 4.5 - 5.5 mm between the 1st and 2nd ring electrodes, and 2 - 2.5 mm between the 2nd and 3rd ring electrodes. All electrodes may be used for recording and pacing, but only the tip electrode can be used to deliver RF energy from the generator."

This catheter measures temperature at two locations via a pair of thermocouples. A feature of this catheter is that it has a magnetic location sensor embedded in the tip electrode that transmits location information to the CARTO™ EP Navigation System.

Catheter tip deflection is controlled by a proximal handpiece that features a thumb operated sliding piston connected to a "puller-wire." The shape of the catheter curve depends on the length of the deflectable tip (1.5 to 4") and the point of attachment of the puller-wire. Seven



curve types designated “B”, “C”, “D”, “E”, “F”, “J”, and “L” are available. The plane of the curved tip may be rotated during use.

For further description of the Stockert 70 RF Generator, refer to the operating instructions for this instrument.

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

## 2. INDICATIONS AND USAGE

The NAVISTAR™ DS Catheter and related accessory devices are indicated for catheter-based cardiac electrophysiological mapping (stimulation and recording), and when used with the Stockert 70 (model S7001 with software version 001/033) for the treatment of Type I atrial flutter in patients age 18 or older.

The NAVISTAR DS Catheter provides location information when used with the Carto EP Navigation System.

## 3. CONTRAINDICATIONS

Do not use this device:

- In patients with active systemic infection; or
- Via the transseptal approach in patients with left atrial thrombus or myxoma, and
- Via the retrograde approach in patients with aortic valve replacement.

## 4. WARNINGS AND PRECAUTIONS

- This device may not be suitable for patients that have had a ventriculotomy or atriotomy within the four weeks preceding the procedure.



- The long-term risks of protracted fluoroscopy and creation of RF induced lesions have not been established. Furthermore, the risk/benefit in asymptomatic patients has not been studied.
- To avoid thromboemboli, intravenous heparin may be used during ablation, and physicians may prescribe aspirin, less often warfarin, for about 3 months afterward. No consensus yet exists about the need for short-term anticoagulation after ablation.
- Cardiac ablation procedures should be performed by appropriately trained personnel in a fully equipped electrophysiology laboratory.
- When using the Biosense Webster NAVISTAR™ DS Catheter with the CARTO™ system, you should use careful catheter manipulation in order to avoid cardiac damage, perforation, or tamponade. Do not use excessive force to advance or withdraw the catheter when resistance is encountered.
- Always pull the thumb knob back to straighten the catheter tip before insertion or withdrawal of the catheter.
- Inspect the catheter packaging prior to use. If the package is open or damaged, return the catheter to Biosense Webster.
- When RF current is interrupted for either a temperature or an impedance rise (the set limit is exceeded), the catheter should be removed, and the tip cleaned of coagulum. When cleaning the tip electrode, be careful not to twist the tip electrode with respect to the catheter shaft; twisting may damage the tip electrode bond and loosen the tip electrode.
- Apparent low power output, high impedance reading or failure of the equipment to function correctly at normal settings may indicate faulty application of the dispersive electrode(s) or failure of an electrical lead. Do not increase power before checking for obvious defects or misapplication.



- Do not attempt to operate the Biosense Webster NaviStar™ DS Catheter or the Stockert 70 RF Generator prior to completely reading and understanding the applicable directions for use.
- 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.
- The Biosense Webster NaviStar™ DS Diagnostic/Ablation Deflectable Tip Catheter and Celsius™ DS Diagnostic/Ablation Deflectable Tip Catheter are indicated for use only with the Stockert 70 RF Generator, Biosense Webster cables, and other appropriate interface cables and connectors.
- The Biosense Webster NaviStar™ DS Catheter and the Celsius™ DS catheter, used in conjunction with the Stockert 70 RF Generator are capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the catheter and dispersive electrode, particularly when operating the device. During energy delivery, the patient should not be allowed to come in contact with grounded metal surfaces. If during ablation, temperature does not rise, discontinue ablation immediately and replace catheter.
- If the generator does not display temperature, verify that the appropriate cable is plugged into the generator. If temperature is still not displayed, there may be a malfunction in the temperature sensing system, which must be corrected prior to applying RF power.
- It is recommended that no more than seventy (70) one-minute applications of RF energy be performed per catheter.
- The sterile packaging and catheter should be inspected prior to use. The Biosense Webster NaviStar™ DS Catheter and RefStar with QwikPatch devices are intended for single patient use only. Do not resterilize and reuse.
- The risk of igniting flammable gases or other materials is inherent in electrosurgery. Precautions must be taken to restrict flammable materials from the electrosurgical site.



- Electromagnetic interference (EMI) produced by the Biosense Webster NAVISTAR™ DS Catheter used in conjunction with the Stockert 70 RF Generator during normal operation may adversely affect the performance of other equipment.
- Electrodes and probes for monitoring and stimulating devices can provide paths for high frequency current. The risk of burns can be reduced but not eliminated by placing the electrodes and probes as far away as possible from the ablation site and the dispersive electrode. Protective impedances may reduce the risk of burns, and permit continuous monitoring of the electrocardiogram during energy delivery.
- Regularly inspect and test re-usable cables and accessories.
- Implantable pacemakers and Implantable Cardioverter/Defibrillators (ICDs) may be adversely affected by RF current. It is important to have temporary external sources of pacing and defibrillation available during ablation, and to temporarily reprogram the pacing system to minimum output or OFF mode to minimize risk of inappropriate pacing. Exercise extreme caution during ablation when in close proximity to atrial or ventricular permanent leads, to program the ICD to the OFF mode during the ablation procedure, and to perform complete implantable device analysis on all patients after ablation.
- Patients undergoing ablations on the septal side of the isthmus may be at risk for complete AV block, which requires the implantation of a permanent pacemaker. Permanent pacing may be required in patients who experience inadvertent complete AV block as a result of RF ablation.
- Catheter ablation procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as increased risk for somatic and genetic effects, to both patients and laboratory staff due to the x-ray beam intensity and duration of the fluoroscopic imaging. Catheter ablation should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure, and steps taken to minimize this exposure. Careful consideration must therefore be given for the use of the device in pregnant women.



- The catheters are sterilized with Ethylene oxide gas and should be used by the “ Use By” date on the device package. Do not use the device if past the “Use by” date.
- Do not use near MRI equipment since movement or heating of the catheter may occur and the image on the Stockert 70 display may become distorted.
- Use both fluoroscopy and electrogram data to monitor catheter advancement and reduce risk of tissue injury.
- Do not use the catheter if the small vent hole at the connector end of the handpiece is occluded as evidenced by difficulty in deflecting the catheter tip and the inability of the catheter to hold a curve.

**WARNING:** The displayed temperature is not the temperature of the tissue. It is the temperature of the tip electrode only and does not represent tissue temperature.

This device has not been shown to be safe at electrode temperatures above 60°C.

- Do not expose catheter to organic solvents such as alcohol.
- Do not autoclave the catheter.
- Do not immerse proximal handle or cable connector in fluids; electrical performance could be affected.
- Do not scrub or twist the distal tip electrode during cleaning.
- The catheters are sterilized with Ethylene oxide gas and should be used by the “ Use By” date on the device package. Do not use the device if past the “Use by” date.
- Do not use near MRI equipment since movement or heating of the catheter may occur and the image on the Stockert 70 display may become distorted.
- Use both fluoroscopy and electrogram data to monitor catheter advancement and reduce risk of tissue injury.



- Do not use the catheter if the small vent hole at the connector end of the handpiece is occluded as evidenced by difficulty in deflecting the catheter tip and the inability of the catheter to hold a curve.

## 5. ADVERSE EVENTS

### 5.1 Observed Adverse Events

In the clinical study of 191 enrolled patients described in the Section 6, there were 13 patients with major complications. See Section 6, “Clinical Studies”, below for a complete description of the adverse events encountered during the study

## 6. SUMMARY OF CLINICAL STUDIES

The clinical testing described below was performed with the NaviStar™ DS catheter, and not with the Celsius™ DS catheter. Since the ablation capabilities of both NaviStar and Celsius™ DS Catheters were shown with pre-clinical testing to be similar, clinical testing results from the NaviStar™ study, as reported below, may be extrapolated to what would be expected when using the Celsius™ DS catheter.

### A. Objective

The objective of the study was to determine if the NaviStar™ DS catheter, when used in conjunction with the Stockert 70 RF generator and related accessory devices, is safe and effective for the treatment of Type 1 atrial flutter in patients age 18 or older.

### B. Study Design

The study was a prospective, non-randomized, unblinded, multi-center study conducted at 16 investigational sites.

#### B.1. - Study Endpoints:

The endpoints for the study were as follows:

- **procedural safety** - defined by the absence of serious complications associated with the use of the investigational device within seven days of the ablation procedure; and
- **acute procedural success** - defined as complete bi-directional conduction block across the isthmus, and the inability to induce typical atrial flutter post-procedure.

Long-term freedom from atrial flutter recurrence was not specifically identified as a study endpoint. Instead, FDA allowed acute procedural success to be used as a surrogate endpoint for this parameter. Long-term (defined as 6-months post-treatment) freedom from atrial flutter recurrence information was also collected, in order to enable FDA to assess whether the surrogate endpoint was reasonable.

#### B.2. - Objective Performance Criteria (OPC):

Objective performance criteria (OPC) were prospectively established for all atrial flutter studies by FDA, based on prior experience with supraventricular tachycardia (SVT) ablation studies and consideration by the FDA Circulatory System Devices Panel. The OPC are defined below:

- **Safety:** major adverse events within 7 days of the procedure occur at a **2.7%** rate or less with a **7%** one-sided 95% confidence bound;
- **Acute success:** **88%** with an **80%** one-sided 95% confidence bound.

#### B.3 - Patient Accountability

The table below documents the accountability of patients throughout the study.

**Table 13(a) - Patient Accountability**

Patients enrolled in study	191
Patients not ablated	9
Patients ablated with NaviStar	182
Patients ablated <b>only</b> with NaviStar	166
Patients ablated with NaviStar and non-investigational catheter*	15
Patients found to have atypical atrial flutter post ablation**	1

\* Patients were first ablated with the NaviStar only. If flutter procedure could not be completed, then physicians used another catheter to complete procedure.

\*\* This patient was considered acute effectiveness failure, as documented in Table 16 below.

#### B.4 - Patient Demographics

The table below summarizes the demographic information of patients enrolled in the study.

**Table 13(b) - Patient Demographics (n=182)**

<b>Gender</b>	<b>N</b>	<b>%</b>
Female	39	21.43%
Male	143	78.57%
<b>Age (in years)</b>		
mean + standard deviation	64.27 ± 10.20	
Median	65.00	
range	37-87	

In addition, seventy-eight (78) patients were reported with a total of 131 reported concomitant arrhythmias. The most common arrhythmia was atrial fibrillation, reported in 85 cases.

C. Results

C.1. - Intraprocedural Data

The table below describes the intraprocedural data:

**Table 14 - Power, Temperature and Impedance Data**

Description	Mean ± Standard Deviation	Range
# RF applications/procedure <sup>1</sup> (n=182 procedure)	24.1 ± 19.7	4-134
maximum power (Watts)/application <sup>2</sup> (n=4368 RF applications)	52.5 ± 10.4	10-87
maximum temperature (°C)/application <sup>2</sup> (n=4387 RF applications)	52.3 ± 7.4	23-85
maximum impedance (Ohms)/application <sup>2</sup> (n=4346 RF applications)	92.4 ± 17.0	37-258

<sup>1</sup>-One patient had a second ablation procedure.

-One patient was missing RF information.

-One patient received 134 applications ≥ 5 seconds.

-One patient was ablated for a non-protocol arrhythmia.

<sup>2</sup>Power, temperature, and impedance not documented for several RF applications.

**Table 15 - Fluoroscopy/Procedure Time (minutes)**

Description	Mean ± Standard Deviation	Range
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total fluoroscopy time/procedure <sup>1</sup> (n=176 procedures)	31 ± 30	2-198
total procedure time/procedure <sup>1</sup> (n=178 procedures)	164 ± 145	36-595

<sup>1</sup>Incomplete fluoroscopy times were reported for six (6) patients and incomplete procedure times were reported for four (4) patients.

### C.2. - Acute Procedural Success

Acute procedural success evaluation was based on 182 patients treated with the NaviStar. The table below describes this information:

**Table 16 - Acute Ablation Outcomes (n=182)**

	# Success/# Patients Ablated	Percentage (1-sided 95% confidence bound) <sup>1</sup>
Acute Study Results	164/182	90.11% (87.22%)
OPC		88% (80%)

<sup>1</sup>Exact binomial using a commercially-available software package.

### C.3. - Freedom from Atrial Flutter Recurrence at Six-Month Follow-Up

Freedom from atrial flutter recurrence was evaluated in patients in whom bi-directional tricuspid isthmus conduction block (BDB) was achieved and for whom 6-month post-ablation information was available. Based on these criteria, information was available on a total of 112 patients.

Results are described in Table 17 below.

**Table 17 - Freedom from Atrial Flutter at 6 months**

Description	N
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Patients with successful BDB	112
# patients free from recurrence	105 (93.75%)
# patients with recurrence of atrial flutter	7
# patients free from both recurrence and medication change (percentage based on N=112)	98 (87.50%)
# patients with anti-arrhythmic drugs (AAD) changes to treat atrial fibrillation	9
Patients ablated <b>only</b> with NaviStar and successful BDB	108
# patients free from recurrence	102 (94.44%)
# patients with recurrence of atrial flutter	6
# patients free from both recurrence and medication change (percentage based on N=108)	95 (87.96%)
# patients with AAD changes to treat atrial fibrillation	8
# patients with anti-arrhythmic drugs to treat VT	1

These results provide reasonable evidence that acute procedural success serves as an appropriate surrogate for long-term freedom from atrial flutter recurrence.

#### C.4. - Adverse Events/Complications and Deaths

An adverse event was determined to be any undesirable experience occurring to a subject during the course of the study, whether or not it is related to the device or procedure. A serious adverse event was defined as any clinical event resulting in death, a life-threatening complication, or a persistent or significant disability/incapacity that requires inpatient hospitalization or prolongs hospitalization or requires intervention to prevent a permanent impairment of a body function or damage to a body structure.

#### Major Adverse Events



Of the 182 patients treated with the NaviStar, fourteen (14) major adverse events were reported in thirteen (13) patients.

Major Complications

The major complication rate observed with the use of the NaviStar™ DS catheter was 7.14% (13/182), and the 95% upper confidence bound was 10.97%. A risk/benefit analysis was performed and a detailed review of each adverse event was completed. Several patients had adverse events related to pre-existing non-cardiac disease. Several patients had adverse events related to having an invasive procedure but do not relate specifically to an ablation procedure or the investigational device. The table below summarizes the adverse event (AE) information.

**Table 18 - Adverse Events, within 7 days post-ablation**

	# AEs <sup>1</sup>
Dysrhythmias	
Exacerbation of pre-existing atrial fibrillation <sup>2</sup>	3
Temporary complete heart block, required pacing <sup>2</sup>	1
Ventricular tachycardia during electrophysiology study, required ICD	1
Atypical flutter <sup>2</sup>	1
Exacerbation of pre-existing disease	
Pulmonary	1
Congestive heart failure	1
Neurological	2
Vascular entry related	
Pneumothorax	1
Pseudoaneurysm	1
Anemia	1
Sedation/restraint related	



Rotator cuff tendon tear	1
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<sup>1</sup> One patient had 2 events (exacerbation of pre-existing atrial fibrillation and pneumothorax).

<sup>2</sup> Possibly related to use of device.

As noted in the above table, a total of five (5) adverse events were determined to be possibly device-related (for an AE rate of 5/182 or 2.7%).

Two patients died during the course of the study. Neither death was temporally related to the ablation procedure. One death was unwitnessed and occurred 5 months after the ablation procedure in a 59 year old man who also had hypertension, diabetes, peripheral vascular disease, congestive heart failure, atrial fibrillation and coronary artery disease. No autopsy was performed. The other patient death occurred two months after the procedure in an 82 year old man due to pneumocystis pneumonia thought to be secondary to his pre-existing chronic lymphoid leukemia.

C.5. - Statistical Analysis

The table below summarizes the effectiveness of the device when compared to the control group OPC established for safety and acute success.

**Table 19 - Comparison of Endpoints between NaviStar™ DS Study and OPC**

Endpoint	OPC		NaviStar™ DS Study	
	%	One-sided 95% Confidence Bound <sup>1</sup>	% (N)	One-sided 95% Confidence Bound <sup>1</sup>
Acute Success	88%	80%	90.11% (164/182)	87.22% (Lower bound)
Major Complications	2.7%	7%	7.14% (13/182)	10.97% (Upper bound)



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<sup>1</sup>Exact binomial using a commercially-available software package.

By comparing the lower bounds of the acute success endpoints (87.22% vs. 80%), the results demonstrate that the NaviStar™ DS Catheter met the OPC for acute success. As previously explained, although the device exceeded the upper bound of major complications, review of the specific events revealed that most events were not device-related; accordingly, the adverse event rate was acceptable.

## 7. HOW SUPPLIED

- The NAVISTAR™ DS Diagnostic/Ablation Catheter is supplied STERILE (EtO).
- The catheter is supplied with a choice of seven curve types: B, C, D, E, F, J, and L.
- The Stockert 70 RF Generator with appropriate interface cables is supplied separately.
- A grounding (dispersive) pad is supplied separately.
- The CARTO™ EP Navigation System is supplied separately.
- The REFSTAR™ with QWIKPATCH™ Reference Patch is supplied separately.

### 7.1 Packaging

The NAVISTAR™ DS Diagnostic/Ablation Catheter is provided in sterile packaging. The catheter is secured to a mounting card placed in a sealed polyethylene/Tyvek® pouch. The sealed pouch is placed in a second sealed pouch and this assembly is packaged inside a cardboard box. Both the inner pouch and the shipping container are labeled sterile.

### 7.2 Storage

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



### 7.3 Shelf-Life

The NAVISTAR™ DS Diagnostic/Ablation Catheter has a shelf-life of one (1) year.

## 8. DIRECTIONS FOR USE

1. RF ablation is performed during either sustained Typical Atrial Flutter, or during proximal coronary sinus or low anterolateral right atrial pacing (medial and lateral aspects of the TA-IVC isthmus, respectively).
2. Remove the NAVISTAR™ DS Diagnostic/Ablation Catheter from the package and place in a sterile work area.
3. Create a vascular access site in a large central vessel using aseptic techniques and insert an 8 F introducer sheath.
4. Connect the catheter to the junction box via the appropriate Biosense Webster cable with 25-pin Hypertronics interlocking connectors on both ends. Connect the junction box to the Stockert 70 RF Generator via the Biosense Webster cable with 10-pin Redel connectors on both ends. Connect the junction box to appropriate recording and mapping systems, including the CARTO™ EP Navigation System, with appropriate interface cables. Use only Biosense Webster interface cables. If electrogram recording equipment is used, the catheter tip electrode must be switched from the electrogram equipment (via the generator controls or an external switch) to the RF generator power output for ablation. To complete the electrical circuit, connect a dispersive pad to the reference electrode input on the generator.
5. Turn the CATHETER SELECTION KNOB on the Stockert 70 RF Generator to the “Dual Temp 8 mm” option.
6. Insert the catheter through the 8 F introducer sheath.
7. Advance the catheter to the area of the endocardium under investigation. Use both fluoroscopy and electrograms to aid proper positioning.



8. Deflect the catheter tip to facilitate positioning by using the thumb knob on the handle to vary tip curvature. Push the thumb knob forward to bend the catheter tip; pull the thumb knob back to straighten the catheter tip.
9. Ensure that the tip electrode achieves stable contact with the intended ablation site.
10. Verify that the CATHETER SELECTION KNOB on the Stockert 70 RF Generator is on the "Dual Temp 8 mm" option, the circuit impedance is approximately 80 ohms, and the starting Temperature is near 37° C before applying RF energy. Monitor the Temperature throughout a procedure. The peak Temperature should be maintained at 55 - 60° C during RF energy delivery, and the maximum Temperature should not exceed 60° C. The displayed temperature represents the temperature of the electrode only, not the temperature of the tissue.
11. Start a procedure at  $\leq 50$  Watts up for a maximum of 60 seconds per RF application. Increase power up to 70 Watts only if bi-directional conduction block cannot be achieved at  $\leq 50$  Watts. When power delivery is over 50 Watts (51 to 70 Watts), limit the application time to a maximum of 30 seconds per RF application.
12. Deliver the RF energy. RF energy may be reapplied to the same or alternate sites using the same catheter.
13. If the RF generator does not display temperature, verify that the appropriate cable is plugged into the generator. If the generator still does not display temperature, there may be a malfunction in the temperature sensing system. Correct this malfunction prior to reapplying RF energy.
14. If preset temperature or impedance levels are exceeded during operation, design safety features of the RF generator cause the RF energy to stop. A likely cause of this may be accumulated coagulum on the tip electrode. Withdraw the catheter and examine the tip electrode. If coagulum accumulation is present, clean the tip electrode by gently wiping with a sterile gauze pad dampened with sterile saline. Use caution to not twist the tip electrode relative to the catheter shaft during cleaning because this may damage the tip electrode bond and loosen the tip electrode.



15. Apparent low power output, high impedance reading, or failure of the equipment to function correctly at normal settings may indicate faulty application of the dispersive electrode(s) or failure of an electrical lead. Check the system for obvious defects or misapplications before continuing a procedure.

**Operation of the Stockert 70 Generator in the automatic temperature controlled mode:**

1. Press the “F1” key located above and left of the CATHETER SELECTION KNOB and turn the CATHETER SELECTION KNOB to set the maximum Temperature limit of 60° C.
2. Press the “F2” key located above and right of the CATHETER SELECTION KNOB and turn the CATHETER SELECTION KNOB to set the maximum power limit at 50 Watts. Increase the power above 50 Watts (W) and up to 70 W only if bi-directional conduction block cannot be achieved at 50 W or below.
3. Use the TIMER KEYS located below the TIME display to set the maximum Time duration at 60 seconds when the maximum Power limit is 50 W. When the Power limit is increased to 70 W, limit the maximum time duration to 30 seconds.



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The NAVISTAR™ DS Diagnostic/Ablation Catheter and accessories are protected under one or more of the following U.S. Patent Nos.: 5,391,199; 5,443,489; 5,480,422; 5,546,951; 5,558,091; 5,568,809; 5,694,945; 5,713,946; 5,718,241; 5,738,096, and other patents pending in the U.S. and other countries.

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