Boston Scientific

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Constellation®

Multiple Electrode Recording and Pacing Catheter

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℞ ONLY

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

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

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 which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device 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.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Carefully read all instructions prior to use. Observe all contraindications, warnings and precautions noted in these directions. Failure to do so may result in patient complications. Boston Scientific relies on the physician to determine, assess and communicate to each patient all foreseeable risks of the procedure.

DEVICE DESCRIPTION

The Boston Scientific Constellation Multiple Electrode Recording and Pacing Catheter allows the physician to map and record intracardiac electrograms. The catheter is used to detect electrical potentials from the endocardial surfaces of the heart. The catheter may also be used to deliver externally generated pacing stimuli. The distal, expandable "basket" assembly contains between 32 and 64 electrodes, in unipolar (evenly spaced), bipolar (paired electrodes), and low density arrays. The device allows the physician to map and record intracardiac electrograms by rapidly sampling numerous endocardial locations. A complete map of right or left atrium may therefore be obtained with a minimal number of catheter manipulations. The catheter can be used to map electrical potentials in either unipolar or bipolar mode. Technical Specifications for the catheter are listed in Table 1.

Table 1. Constellation Multiple Electrode Recording and Pacing Catheter Technical Specifications

Component	Nominal Dimensions
Basket Diameter (mm)	31, 38, 48, 60, 75
Constellation Catheter Diameter	8F (2.66 mm)
Length	90 cm – 130 cm
Electrodes (N)	32 - 64
Material	Platinum/Iridium
Configurations	Unipolar, Bipolar or low density
Cable Connectors	One (1) or Two (2) 44-pin Male Amphenol Connectors

The Constellation Multiple Electrode Recording and Pacing Catheter consists of three major components:

- The basket is made of eight resilient structures called splines. The flexible splines conform to the shape and movements of the heart chamber. Each spline has either four (4) or eight (8) electrodes depending on the model of the Constellation Multiple Electrode Recording and Pacing Catheter. The electrode rings on all splines and the selected marker bands are radiopaque. There are marker bands on splines to help position the catheter under fluoroscopy.
- The 8F (2.66 mm) catheter shaft and introducer sleeve facilitate the placement and support of the basket.
- The cable connector provides the interface to connect the Constellation Multiple Electrode Recording and Pacing Catheter to the recording system. See Figures 1, 2, and 3. For more information, refer to the directions for use (DFU) for the Constellation cable you are using.

USER INFORMATION

Cardiac mapping procedures should be performed only by physicians thoroughly trained in electrophysiologic techniques in a fully equipped electrophysiology laboratory.

CONTENTS

One (1) sterile Constellation Multiple Electrode Recording and Pacing Catheter

INTENDED USE / INDICATIONS FOR USE

For use in right and left atrial electrophysiology procedures to assist in the diagnosis of complex arrhythmias that may be difficult to identify using conventional mapping systems alone (i.e., linear mapping catheters). The Constellation Multiple Electrode Recording and Pacing Catheter System may also be used for delivery of externally generated pacing stimuli.

CONTRAINDICATIONS

The Constellation Multiple Electrode Recording and Pacing Catheter is contraindicated in patients:

- who cannot be anticoagulated or infused with heparinized saline or have heparin-induced thrombocytopenia;
- who have vena cava embolic protection filter devices and/or known femoral thrombus who require catheter insertion from the femoral approach;
- for whom catheter placement is in or through a chamber where any permanent leads are present;

Boston Scientific (Master Brand DFU Template 8.2677in x 11.6929in A4, 90105918AM), eDFU, Constellation Mapping Catheter, 90905078-01B

- with atrial thrombus or myxoma, or inter-atrial baffle or patch for transseptal approach;
- with recurrent/active sepsis or with hypercoagulable state should not be considered candidates for transvascular catheters because the catheter could serve as a focal point for septic or blood thrombus formation;
- with echocardiographically-confirmed visual presence of thrombus;
- for whom the inability of obtaining vascular access exists;
- with hemodynamic instability or shock.

WARNINGS

The use of this device in conjunction with radiofrequency ablation, as part of the diagnosis and treatment of cardiac arrhythmias, may pose an increased risk of adverse events, such as cardiac perforation, myocardial infarction, air embolism, and hematoma requiring surgical repair and/or blood transfusion.

- This device has not been shown to be safe and effective for use in any cardiac chambers except the atria.
- The Constellation® Multiple Electrode Recording and Pacing Catheter requires the use of a guiding sheath for insertion to minimize patient injury and/or damage to the device.
- Position the guiding sheath so that it is positioned where you want to deploy the Basket. Advance the Constellation Multiple Electrode Recording and Pacing Catheter until the distal tip of the catheter is near the distal tip of the guiding sheath. Holding the catheter body stationary, slowly withdraw the guiding sheath to allow the basket assembly to expand into the chamber or adjacent vein (e.g., Superior Vena Cava, Right Superior Pulmonary Vein, etc.); thereby reducing the risk of perforation and/or tamponade.
- Do not ablate over the diagnostic electrodes on the Constellation Multiple Electrode Recording and Pacing Catheter. Contact between the ablation catheter tip and the diagnostic electrode may create or aid in transference of char and/or coagulum and may result in embolism and/or damage to the catheter.
- To reduce the risk of entanglement and/or entrapment with the Constellation Multiple Electrode Recording and Pacing Catheter, insert it as the first catheter into the cardiac chamber. If other catheters are used concurrently with the Constellation Multiple Electrode Recording and Pacing Catheter, remove those catheters before removing or repositioning the Constellation Multiple Electrode Recording and Pacing Catheter. When in the proximity of the tricuspid valve or mitral valve, take care to avoid entanglement with chordae tendineae.
- Carefully manipulate the catheter and/or guiding sheath to avoid causing cardiac damage, perforation, or tamponade. Advance the catheter and/or guiding sheath under fluoroscopic guidance. Do not advance or withdraw the catheter and/or guiding sheath against excessive resistance. Do not torque the catheter while it is fully deployed.
- Maintain activated clotting time (ACT) levels above 300 seconds at all times during the procedure and monitor throughout Constellation Multiple Electrode Recording and Pacing Catheter use. Failure to do so may increase the risk of thrombus formation, which could lead to complications.
- Do not leave the catheter in situ more than three hours for the cumulative duration of catheter placement.
- Catheter mapping 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 defects in both patients and laboratory staff due to the x-ray beam intensity and duration of the fluoroscopic imaging. Catheter mapping should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure, and steps have been taken to minimize this exposure.
- To minimize risk of air embolus, flush the guiding sheath to remove all air before introduction into vasculature. The introduction of the Constellation Multiple Electrode Recording and Pacing Catheter into the guiding sheath also has the potential to introduce air into the guiding sheath. To reduce the risk of introducing air emboli during catheter insertion, aspirate the guiding sheath.
- Manual pre-bending of the distal assembly can damage the basket assembly and may cause patient injury.
- Use only isolated amplifiers, pacing equipment, and ECG equipment or patient injury or death may occur. Leakage current from any connected device to the patient must not exceed 10 micro-amps under any circumstances.
- Ensure that the EGM recorder pacing stimulator is not active when connecting the Constellation Multiple Electrode Recording and Pacing Catheter to reduce the risk of initiating an arrhythmia.
- No modification of this equipment is allowed.
- Because the long-term effects of exposure to ionizing radiation are unknown, careful consideration should therefore be given to pregnant women and pre-pubescent children.

PRECAUTIONS

- Preclinical and clinical testing show that small thrombi may attach to the basket and splines at locations where there is an abrupt change in geometry. However, there were no clinical sequelae. Ensure the patient is appropriately anticoagulated to ensure thrombus formation is minimized.
- As with percutaneous placement of any sheath or catheter, carefully monitor the vascular puncture site.
- The Constellation Multiple Electrode Recording and Pacing Catheter is NOT intended for use as an ablation catheter.
- Excessive bending or kinking of the catheter shaft may damage internal wires.
- Catheter materials are not compatible with magnetic resonance imaging (MRI).
- The use of catheters or cables with unprotected male pin connectors presents a risk of electrical hazard. Inadvertent attachment of pin connectors to power supply sockets or connectors could result in electrocution of the patient or operator. Use of components with shrouded pins is highly recommended. Those who use components with unprotected male pin connectors must exercise extreme caution during device setup to prevent patient or operator injury.
- Keep electrical connections dry.

POTENTIAL ADVERSE EVENTS

Adverse events which may be associated with catheterization:

- Allergic reaction
- Arrhythmias
- Cardiac valve damage
- Catheter entrapment/entanglement
- Chest pain
- Damage to vessel intima or cardiac structures
- Death
- Embolism (air, thrombus, char, coagulum)
- Fistula (A-V) /(esophageal)
- Hematoma/ecchymosis
- Hemorrhage
- Hemothorax
- Hypotension
- Infection
- Myocardial infarction
- Nerve palsy or weakness
- Perforation
- Pericardial/Pleural effusion
- Pericarditis/pleuritis
- Phrenic nerve paralysis
- Pneumothorax
- Pseudoaneurysm
- Pulmonary edema
- Pulmonary vein stenosis
- Radiation
- Sinus or AV node injury
- Stroke
- Tamponade
- Thromboembolism
- Thrombus/Thrombosis
- Valvular damage
- Vascular bleeding/local hematomas
- Vasovagal reactions
- Visual blurring

CLINICAL STUDY

References in this clinical study section for the Constellation Cather are equivalent to the Constellation Multiple Electrode Recording and Pacing Catheter.

A clinical trial was performed to establish the safety of the Constellation Catheter, in which 118 patients were enrolled from 18 centers. The patient population included any adult patient needing an electrophysiology (EP) study, for whom electrode recording and pacing catheters would be required in the right atrium. Early in the trial patients were randomized (2:1) to an EP Study with either the Constellation Multiple Electrode Recording and Pacing Catheter (Constellation Group) or a commercially available diagnostic EP catheter (Standard Catheter Group). Forty-seven patients were randomized to the Constellation Group, while 24 patients were enrolled in the Standard Catheter Group. All patients were followed to hospital discharge. Near the midway point of the trial, randomized enrollment was terminated and prospective enrollment for the Constellation Group began. Thirty-seven patients were subsequently enrolled for the Constellation Group, prospectively. An additional 10 patients were prospectively enrolled who received both standard catheters and the Constellation Catheter during the same procedure, for direct performance comparisons. These 10 patients were censored from the safety analysis (none experienced a complication). The Standard Catheter Group therefore included 24 patients, while the Constellation Catheter Group totaled 84 patients. See Table 3 for patient population details.

PACING THRESHOLDS AND ELECTROGRAM RECORDING PERFORMANCE

For the Constellation Group, the capability of the Constellation Catheter to deliver pacing stimuli (at either 3 mA or 10 mA) was studied. Of 2667 total pacing attempts, 1393 of the electrodes (52%) captured. For unsuccessful capture, the basket electrode was most likely not in contact with the endocardial surface. Unsuccessful capture was therefore indicative of either: (1) non-contact of the basket and basket electrodes with variable endocardial surfaces, or (2) an unknown percentage of the basket electrodes may have been situated directly over the tricuspid valve orifice, where endocardial contact was not possible. See Table 4 for pacing and electrogram recording performance.

OBSERVED ADVERSE EVENTS

The Constellation Catheter was studied in 84 patients undergoing electrophysiologic (EP) mapping and ablation. The number of patients with adverse events (major or minor) was 12 of 84 (14.3%). The difference of 14.3% has a 95% confidence interval of [6.8%, 21.8%]. The observed adverse events are listed in Table 2.

PROCEDURE AND FLUOROSCOPY TIMES

Data were available with respect to procedure time and fluoroscopy time for the Standard Catheter Group (N = 24) and Constellation Group (N = 88), as shown in Table 5.

Table 2. Observed Adverse Events in the Constellation® Multiple Electrode Recording and Pacing Catheter Group (N=84)

Event Type	Number of Patients Experiencing Adverse Events (N)	Total Number of Patients (N)	Proportion of Patients with Events (N)/ Total Number of Patients (N)	95% Confidence Interval
All	12	84	0.143 (14.3%)	0.068 – 0.218
Major	3	84	0.036 (3.6%)	0 – 0.076
Minor	9	84	0.107 (10.7%)	0.041 – 0.173

Table 3. Patient Population

Patient Population	Constellation Catheter Group (N)	Standard Group (N)
Randomized (2:1)	47	24
Non-Randomized Constellation Only Both Devices	 37 10*	 N/A 10*
Total	84	24

*These patients were excluded from the safety analysis; none had any complications.

Table 4. Pacing and Electrogram Recording Performance

Pacing Performance (N=44 patients)	(N)	Proportion (N Useable / Total Attempted) %
Pacing Success	1393	52
Pacing Failure	1274	48
Total	2667	100
Electrogram Recording Performance (Signal Quality; N=53 Patients)		
Acceptable (N)	1126	81
Unacceptable (N)	268	19
Total	1394	100

Table 5. Procedure and Fluoroscopy Times

	Average	Standard Deviation	Minimum	Maximum
Fluoroscopy Times (minutes)				
Constellation Catheter Group	35.02	32.8	2	179
Standard Catheter Group	41.04	33.95	9	159
Procedure Time (hours)				
Constellation Catheter Group	4.39	1.92	1.38	9.8
Standard Catheter Group	3.69	1.69	1.25	7.8

Table 6. Characteristic Right Atrial Dimensions from Multicenter Clinical Study
Right Atrial Diameters

Basket Size	Number of Patients who received each device (N)	Short Axis Diameter Mean ± SD (mm)	Min (mm)	Max (mm)	Long Axis Diameter Mean ± SD (mm)	Min (mm)	Max (mm)
38	37	34.09 ± 5.2	25.0	43.7	41.61 ± 4.9	31.0	52.0
48	37	34.09 ± 5.2	25.0	43.7	41.61 ± 4.9	31.0	52.0
60	35	41.86 ± 7.2	30.0	65.0	49.22 ± 8.2	36.0	66.0
75	8	44.29 ± 7.4	33.0	52.0	49.29 ± 8.0	38.0	60.0

CONFIRM TRIAL

The Constellation Catheter Safety and Effectiveness data for use in the left atrium are reported from the results of the CONFIRM (Conventional Ablation With or Without FIRM) trial[1]. The trial identified two limiting factors when performing ablations of atrial fibrillation that contributed to multiple and lengthy procedures resulting in high costs. The first limiting factor is that current tools may not create transmural, sustaining lesions as evidenced by high recurrence rates with pulmonary vein reconnection and conduction gaps in the linear lesions. The second limiting factor is that the mechanisms that perpetuate the arrhythmia are not always fully identified since there may be focal impulses and electrical rotors. Narayan hypothesized that human atrial fibrillation, even with a wide range of presentations, is sustained by localized sources whose targeted elimination may improve outcome after atrial fibrillation ablation. Narayan tested his hypothesis using a computational mapping approach, employing the Constellation Multiple Electrode Recording and Pacing Catheter to detect localized sources. He then verified whether ablation of the local impulses and/or electrical rotors, specifically, focal impulse and rotor modulation (FIRM), acutely modulates atrial fibrillation (either by terminating the rhythm or maintaining a slowing of the rate of atrial fibrillation), and improves the long term success of conventional ablation. These acute and long term data were captured in a clinical trial called CONFIRM.

In the CONFIRM trial, the Constellation Multiple Electrode Recording and Pacing Catheter was advanced via an 8.5 F (2.83 mm) sheath to map the left atrium with a wide field of view in all patients. 92 patients were enrolled to undergo ablation for atrial fibrillation in 107 consecutive ablation procedures. In 73 patients, a second Constellation Multiple Electrode Recording and Pacing Catheter was also used for mapping in the right atrium. In addition to the sheath, ablation catheters (ThermoCool® or Blazer®) were used in all patients. In this article, there was no distinction of any specific causal relationship of any catheter/sheath to any of the reported complications. One of the most concerning potential complications in left-sided procedures is the potential for stroke. In this article, Narayan reports compelling data showing no strokes or TIAs from either group with the use of multiple catheters, including the Constellation Multiple Electrode Recording and Pacing Catheter in the left atrium in all patients, and in the right atrium in 73 patients. Permanent diaphragmatic paralysis, symptomatic pulmonary vein stenosis, and atrioesophageal fistula are known complications of RF ablation primarily associated with ablation of atrial fibrillation; however, these are not known complications resulting from use of diagnostic mapping catheters. The remaining complications, groin bleeding requiring transfusion and cardiac tamponade, are also anticipated complications of cardiac catheterization generally related to access of any catheter and/or sheath.

The safety data (all cases) were reported in two groups: Conventional Ablation and FIRM-Guided Ablation as shown in Table 7, which contains excerpts from the article's Table 2- Acute Results in All Cases or Those with Sustained AF during Their Procedure.

Table 7. Conventional Ablation and FIRM-Guided Ablation

Type of Complication	Conventional Ablation	FIRM-Guided Ablation
Complications, all cases	6 (8.0%)	2 (6.0%)
Cardiac Tamponade	2	1
Groin Bleed Requiring Transfusion	3	1
Vascular Injury requiring Surgical Repair	0	0
Permanent Diaphragmatic Paralysis	0	0
Symptomatic Pulmonary Vein Stenosis	1 (required stent)	0
Stroke/TIA	0	0
Atrioesophageal Fistula	0	0
Death	0	0

[1] Narayan SM, Krummen DE, Shivkumar K, Clopton P, Rappel WJ, Miller JM. **Treatment of atrial fibrillation by the ablation of localized sources: CONFIRM (Conventional Ablation for Atrial Fibrillation With or Without Focal Impulse and Rotor Modulation) trial. J Am Coll Cardiol**. 2012; 60 (7): 628-36

PATIENT SELECTION AND TREATMENT

Individualization of Treatment

Maintain activated clotting time (ACT) levels above 300 seconds at all times during the procedure and monitor throughout Constellation Multiple Electrode Recording and Pacing Catheter use. Do not leave the catheter in situ more than three hours for the cumulative duration of catheter placement. The guiding sheath should be flushed with heparinized saline solution prior to use, and immediately connected to a heparinized saline IV infusion drip. Start the heparinized saline drip and continuously flush the guiding sheath at an approximate drip rate of 100 ml/hr throughout the procedure. Failure to do so may increase the risk of thrombus formation, which could lead to complications.

Use in Specific Populations

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

ECHOCARDIOGRAPHIC EXAMINATIONS

Before the procedure, a two-dimensional echocardiography examination should be performed to determine the approximate diastolic dimensions of the target heart chamber. A correctly sized catheter may appear slightly compressed. The electrode/tissue contact can be evaluated by standard pacing protocols. Characteristic right atrial dimensions are presented in Table 6. Cross reference the long and short axes diameters of the atrium to an appropriate Constellation Multiple Electrode Recording and Pacing Catheter size (31mm to 60 mm diameter). Suggested basket sizes for corresponding dimension are presented in Table 8. Suggested configurations and models numbers are presented in Tables 9 and 10.

Table 8. Constellation Catheter Sizing Recommendations

	Short Axis (mm)							
	20	30	40	50	60	70	80	90
Long Axis (mm)								
30	31	38	48	48	48	48	60	60
40	38	48	48	48	48	48	60	75
50	38	48	48	60	60	75	75	--
60	48	48	60	60	75	75	75	--
70	60	60	60	75	75	75	--	--
80	60	60	75	75	75	--	--	--
90	75	75	75	--	--	--	--	--
100	75	--	--	--	--	--	--	--

Table 9. Constellation® Electrode Configuration Selection Guide

Location of Arrhythmogenic Focus	Low Density Electrode Configuration
High Right Atrium	Distal
Mid Right Atrium	Medial
Low Right Atrium	Proximal
Lateral or Septal Anterior wall	Dorsal/Ventral

Note: Basket Repositioning may be Necessary to Bracket Signal.

Table 10. Constellation Catheter Model Numbers- contain a base number related to basket size with a suffix related to basket features

Base Number	Basket Size
8031	31 mm
8038	38 mm
8048	48 mm
8060	60 mm
8075	75 mm

Suffix

B	Bipolar Electrode Spacing
U	Uncoated
D	Distal Array
M	Medial Array
P	Proximal Array
V	Ventral Array
L	Low Density

CONSTELLATION MULTIPLE ELECTODE RECORDING AND PACING CATHETER CONFIGURATION SELECTION GUIDE

If prior information does not indicate location of arrhythmia, a standard high density Constellation Multiple Electrode Recording and Pacing Catheter should be selected. The physician should select electrode configuration based upon knowledge provided by 12-lead ECG vector analysis or other sources of information (for example, patient history and prior procedures such as mapping, ablation, or surgery). If available information indicates that the arrhythmogenic focus resides in a particular region of the atrial chamber, then a low density basket configuration may be selected. Please see Table 9.

Example 1: The 12-lead ECG indicates a high right atrium tachycardia. Then the physician may select a distal array basket to conduct mapping.

Example 2: The patient has had previous surgery in the right atrium and, as a consequence, has developed an incisional tachycardia. A basket configuration with the most adequate coverage of the surgical incision should be selected (e.g. prior surgery on the lateral wall of a medial configuration).

PATIENT COUNSELING INFORMATION

Boston Scientific relies on the physician to determine, assess, and communicate to each individual patient all foreseeable risks of cardiac mapping procedures.

HOW SUPPLIED

The Constellation Multiple Electrode Recording and Pacing Catheter is supplied sterile using an ethylene oxide (EO) process.

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Do not use if past the "Use By" date.

Handling and Storage

Operating Environment

Ambient Temperature: 10° C to 40° C

Relative Humidity: 30% to 75%

Atmospheric Pressure: 70 to 106 kPa

Transport Environment

Temperature: -29° C to 60° C

Relative Humidity: 30% to 85%

Atmospheric Pressure: Uncontrolled

Storage Environment

Ambient Temperature: 20° C to 30° C

Relative Humidity: Uncontrolled

Atmospheric Pressure: Uncontrolled

REQUIRED EQUIPMENT

Intracardiac electrophysiology and cardiac mapping procedures should be performed in a specialized clinical setting equipped with a fluoroscopy unit, radiographic table, physiologic recorder, emergency equipment and instrumentation for gaining vascular access.

- Constellation Multiple Electrode Recording and Pacing Catheter
- Constellation Cables

Ancillary materials required to perform cardiac mapping include:

- A 10 ml or 20 ml syringe
- A 11.5F (3.83 mm) hemostatic introducer sheath (referred to herein as short introducer sheath)
- A pressurized flush bag of heparinized normal saline solution
- An 8.5F (2.83 mm) soft tip guiding sheath (referred to herein as guiding sheath)
- A 0.038 in (0.97 mm) J-tip Guidewire, 150 cm in length
- A Seldinger needle
- An 8F (2.66 mm) dilator

INSPECTION PRIOR TO USE

Carefully inspect the package prior to use for any breach of the sterile barrier or damage to the contents. If the sterile barrier integrity is compromised or the contents damaged, contact your Boston Scientific representative.

DIRECTIONS FOR USE

1. With the approximate diastolic dimensions of the heart chamber having been previously determined via two-dimensional echocardiography, cross reference the long and short axes diameters of the cardiac chamber to an appropriate Constellation Multiple Electrode Recording and Pacing Catheter size as stated in Table 8.
2. Connect the sterile cable, Model # 900, to the Constellation Multiple Electrode Recording and Pacing Catheter. Connect the other two ends of the sterile cable to the 901AS0/901BS0 cables. The Model # 900 cable may also be connected to the Model # 940 cable and then connected to four (4) Model # 626S cables. (See Figures 1, 2, and 3 for cable connection details.) For specific compatibility, please refer to the interconnect specification of the recording system.

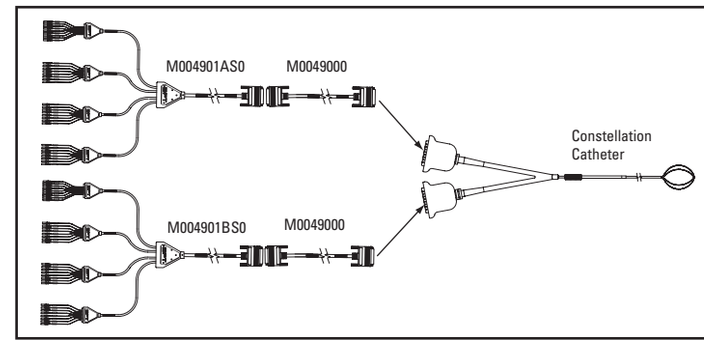

Figure 1. Constellation Cable – Connection by Pin-Out

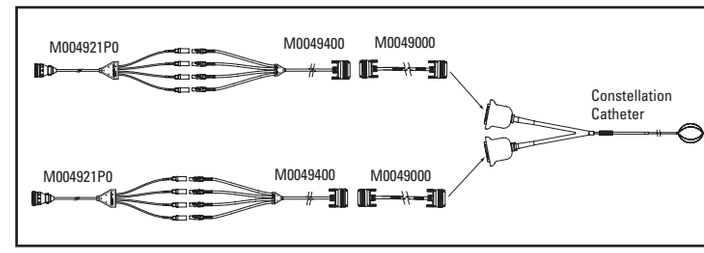

Figure 2. Constellation Cable – Connection to GE Recording System Adapter

Model M004921P0, (Figure 2), is an adapter cable for use with a GE recording system. Equipped with a female connector, this adapter can be plugged directly into GE recording systems that accept a female connector.

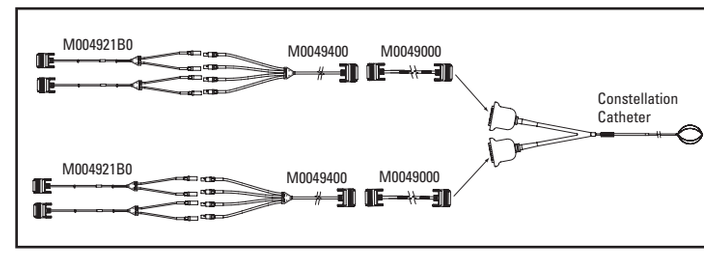

Figure 3. Constellation Cable - Connection to C.R. Bard Inc. Recording System Adapter

Model M004921B0, (Figure 3), is an adapter cable for use with the C.R. Bard Inc. recording system.

3. Connect the shrouded pins from the Constellation Multiple Electrode Recording and Pacing Catheter into the pin-out box for the recording system.
4. The electrodes on each spline are oriented so that the most distal electrode is electrode number 1. The most proximal electrode is electrode number 8. Since the splines are alphabetically oriented from A to H, electrode A1 refers to the most distal electrode on Spline A. Electrode H8 refers to the most proximal electrode on Spline H.

On the 31 mm, 64-electrode model Constellation® Catheter, Spline A is identified by a single proximal marker band. Spline B is identified by the pair of proximal marker bands. Splines C through H are not uniquely marked. See Figure 4.

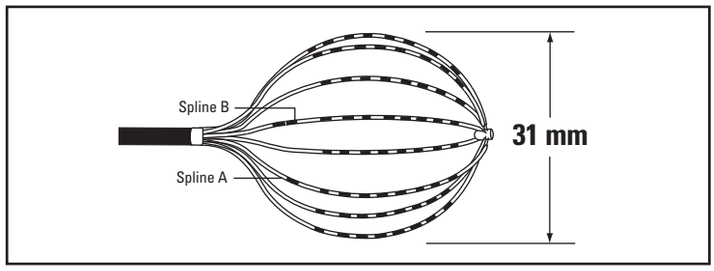

Figure 4. Constellation Multiple Electrode Recording and Pacing Catheter 31 mm Model

On the 38 mm to 75 mm, 64-electrode model Constellation Catheters, an adjacent marker band scheme is used to identify Splines A-H. On Spline A, the eighth electrode (most proximal electrode) is a double electrode. On Spline B, the seventh electrode is a double electrode. On Spline C, the sixth electrode is a double electrode and so on. Spline H is the only spline without any double electrodes. See Figure 5.

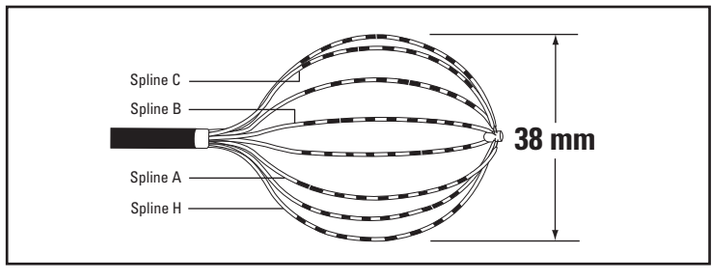

Figure 5. Constellation Multiple Electrode Recording and Pacing Catheter 38 mm to 75 mm Models*

* This is a representative diagram for the 38 mm, 48 mm, 60 mm, and 75 mm models.

On the 31 mm, 32-electrode model Constellation Multiple Electrode Recording and Pacing Catheter, the marker bands are staggered radially. Spline A has two pairs of marker bands on the proximal end of the spline. Spline B has one pair of marker bands at the proximal end of the spline. Splines C through F use an adjacent marker band scheme. On Spline C, the fourth electrode is a double electrode. On Spline D, the third electrode is a double electrode, and so on. Spline G has one pair of marker bands at the distal end of the spline. Spline H has no marker bands. See Figure 6.

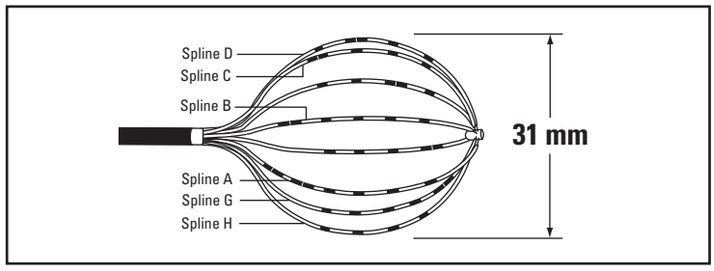

Figure 6. Constellation Multiple Electrode Recording and Pacing Catheter 31 mm, 32-Electrode Model

5. Obtain percutaneous access to the femoral or other vein, by the Seldinger technique or surgical cutdown. Place short introducer sheath into the vessel lumen, being careful to position the short introducer at an oblique angle (approximately 30°) to the axis of the chosen vessel. Carefully inspect the short introducer under fluoroscopy to verify the absence of any sharp bends in the pathway. If any sharp bends are visible, replace the short introducer.
6. Flush the guiding sheath with heparinized saline. Displace all air inside the guiding sheath.
7. Insert the 0.038 in (0.97 mm) guidewire into an 8F (2.66 mm) dilator. Next, insert the dilator/guidewire combination into the guiding sheath, until the dilator protrudes approximately 10 cm beyond the guiding sheath tip. Additionally, the guidewire should extend about 10 cm beyond the end of the dilator. Flush the guiding sheath, dilator, and guidewire assembly again with heparinized saline to verify the removal of all entrapped air. Under fluoroscopy, advance the guidewire into the appropriate heart chamber and then advance the dilator over the guidewire and into the specific chamber. Advance the guiding sheath over the dilator into position. Orient any pre-curve bias at the distal end of the guiding sheath to facilitate the transit through the relevant peripheral and systemic vasculature.
8. Place the distal end of the guiding sheath near the atrial appendage under fluoroscopic guidance.
9. Continuously watch for mechanically induced premature ventricular contractions (PVCs) or premature atrial contractions (PACs). Withdraw the guiding sheath system if PVCs or PACs are observed.
10. Once the guiding sheath is placed into position, remove the guidewire and dilator while maintaining the position of the guiding sheath.
11. Attach a syringe at the guiding sheath side-port, draw a vacuum to remove excess air, close the stopcock, and flush the guiding sheath with heparinized saline solution.
12. Immediately connect a heparinized saline drip to the guiding sheath side-port. Start the heparinized saline drip and continuously flush the guiding sheath at a drip rate of 100 ml/hr.
13. An intravenous bolus of heparin should be administered before introducing the Constellation Multiple Electrode Recording and Pacing Catheter into the heart chamber. Activated Clotting Times (ACT) should be measured at specified intervals and heparin boluses should be administered to maintain an ACT level > 300 seconds.
14. Submerge the basket in heparinized saline. Rinse the basket by advancing and retracting it through the introducer sleeve multiple times.
15. Collapse the splines of the basket by advancing the introducer sleeve (on the catheter body) over the basket. A slight rotation of the introducer sleeve during advancement can facilitate collapse of the basket assembly. Allow approximately 1-2 mm of the constrained basket assembly to extend beyond the end of the introducer sleeve.
16. Insert the introducer sleeve containing the collapsed basket assembly through the hemostatic valve of the guiding sheath. Advance the introducer sleeve approximately 2 cm into the hemostatic valve until the introducer sleeve contacts the guiding sheath. DO NOT force the introducer sleeve beyond this point. Advance the catheter. If the basket assembly will not advance into the guiding sheath, withdraw the introducer sleeve slightly until the basket assembly advances easily into the guiding sheath. When the catheter has been advanced approximately 5 cm into the guiding sheath, permit backflow of blood for a few seconds to expel any remaining air from the sheath. Continue advancing to approximately 25 cm into the guide sheath, and then carefully pull the introducer sleeve. Finally, slowly withdraw the introducer sleeve out of the hemostatic valve and slide it all the way back to the catheter handle.
17. Advance the catheter through the guiding sheath under fluoroscopy until the tip of the Constellation Multiple Electrode Recording and Pacing Catheter is near the distal tip of the guiding sheath. If advancement of the catheter seems difficult, use fluoroscopy to examine the catheter and the guiding sheath for kinks or sharp bends. Remove and inspect the guiding sheath if necessary. In addition, verify the hemostatic valve is sufficiently lubricated. Lubrication of the hemostatic valve can be achieved by withdrawing the catheter 2-3 cm and then re-advancing the catheter. Repeat the withdrawal-advance process as required to place the basket assembly in the target heart chamber. If the valve is lubricated and the catheter will not advance a blockage exists in the guiding sheath. DO NOT force the basket assembly through the guiding sheath. The catheter should advance easily.
18. Advance the guiding sheath until the distal tip of the guiding sheath is also positioned near the distal wall of the target chamber. Advance the catheter until the distal tip of the Constellation Multiple Electrode Recording and Pacing Catheter is also positioned near the distal wall of the atrium. Holding the catheter body stationary, slowly withdraw the guiding sheath to allow the basket assembly to expand into the desired chamber.
19. Verify the orientation of the Constellation Multiple Electrode Recording and Pacing Catheter basket assembly, using Fluoroscopic marker locations on the basket splines. See Figures 4 through 6. When viewing the basket assembly from the distal end, the splines are oriented clockwise in ascending alphabetical order, Spline A through Spline H.
20. After the Constellation Multiple Electrode Recording and Pacing Catheter is in position in the target chamber, the guiding sheath should be further withdrawn.
21. If PACs are observed, recapture and reposition the Constellation Multiple Electrode Recording and Pacing Catheter.

If repositioning of the basket is required:

Using fluoroscopy, advance the guiding sheath into the heart chamber. While withdrawing the Constellation Multiple Electrode Recording and Pacing Catheter, simultaneously advance the guiding sheath over the basket assembly until one-half (1/2) of the basket becomes constrained. This maneuver should be performed in one smooth, continuous motion.

Again under fluoroscopy, slowly torque the catheter to rotate the basket. Redeploy the catheter into the heart chamber.

To recapture the basket assembly:

Using fluoroscopy, advance the guiding sheath into the heart chamber. While withdrawing the Constellation Multiple Electrode Recording and Pacing Catheter, simultaneously advance the guiding sheath over the basket assembly until the basket is completely constrained. The maneuver should be performed in one smooth, continuous motion.

Caution: Never force the Constellation Multiple Electrode Recording and Pacing Catheter against excessive resistance.

22. After the Constellation Multiple Electrode Recording and Pacing Catheter is in position in the target chamber, connect the one or two 44-pin D-Sub male connector(s) to the appropriate sterile cable(s).

Note: An external pacemaker pulse generator may be utilized to deliver pacing stimuli. During pacing/mapping, only one electrode (unipolar configuration) or one electrode pair (bipolar configuration) should be selected to pace. During mapping, only the selected electrode(s) will be connected to the pulse generator's pacing output.

23. Test to ensure recorded data from the Constellation Multiple Electrode Recording and Pacing Catheter is acceptable.

CATHETER REMOVAL

1. To remove the Constellation Multiple Electrode Recording and Pacing Catheter, using fluoroscopy, advance the guiding sheath into the heart chamber just proximal to the basket assembly.
2. Simultaneously advance the guiding sheath over the basket assembly while withdrawing the Constellation Multiple Electrode Recording and Pacing Catheter, until the basket is completely collapsed. This maneuver should be performed in one smooth, continuous motion.

Caution: DO NOT tug on the Constellation Multiple Electrode Recording and Pacing Catheter. Never force the catheter against excessive resistance.

3. After the basket assembly is completely collapsed into the guiding sheath, begin a slow withdrawal of the Constellation Multiple Electrode Recording and Pacing Catheter.

4. Return the introducer sleeve to its position within the hemostatic valve. Gently pull the Constellation® Multiple Electrode Recording and Pacing Catheter until the basket assembly is contained within the introducer sleeve.
5. Remove the introducer sleeve and the basket assembly together as one unit. Once the introducer sleeve and basket assembly have been removed from the guiding sheath, gently pull off the introducer sleeve, thus expanding the basket assembly into its preformed shape.
6. Remove the guiding sheath. Finally, after removal of the short introducer sheath, follow local practice norms for appropriate care.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

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