Polaris Dx™, Steerocath Dx™, EPT Dx™
Steerable Diagnostic Catheter

Boston Scientific
EP TECHNOLOGIES™

Cathéter de diagnostic orientable
Steuerbarer diagnostischer Katheter
Catéter de diagnóstico maniobrable
Catetere diagnostico manovrabile
Stuurbare diagnostiekkatheter
Styrbart diagnostisk kateter
Styrbar diagnostisk kateter
Cateter de Diagnóstico Orientável
Κατευθυνόμενος Διαγνωστικός Καθετήρας
ステアラブル診断用カテーテル

Directions For Use

Mode d'emploi
Gebrauchsanweisung
Instrucciones de uso
Istruzioni per l'uso
Gebruiksaanwijzing
Brugsanvisning
Bruksanvisning
Instruções para Utilização
Οδηγίες Χρήσης
取扱説明書

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

Boston Scientific
EP TECHNOLOGIES™

2710 Orchard Parkway
San Jose, CA 95134 USA

11280-001 EAW Ver. AD (2/00)

CE 0197

Issued Patents (United States): 5195968; 5230349; 5254088; 5257451; 5257635; 5336182; 5363861; 5364351; 5363874; 5351652; 5373535; 5358478; 5395327; 546682; 5531686 and other Patents Pending; foreign counterparts also pending.

Distributed in Europe by:
Boston Scientific International
91, Boulevard National
92257 La Garenne Colombes Cedex
France

Made in USA

Carefully read all instructions prior to use. Observe all contraindications, warnings and precautions noted in these instructions. 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.

Description:

The Boston Scientific/EP Technologies™ steerable diagnostic catheters are comprised of the Polaris Dx™, Steerocath Dx™ and the EPT Dx™ product lines. The catheters are designed for use in intracardiac pacing and recording only.

The catheters have been designed to carry electrical signals for the purpose of endocardial stimulation (pacing) or recording. The Polaris Dx and the EPT Dx product lines are uni-directional steerable products, while the Steerocath Dx product line provides bi-directional steering.

The Polaris Dx is actuated by means of a patented thumb-slide (see Fig. 1) while the EPT Dx and Steerocath Dx are actuated by means of a steering lever (see Fig. 2 and 3).

Indications:

The catheter is intended for temporary use in electrophysiology studies for intracardiac stimulation (pacing) and/or recording of electrical potentials.

Contraindications:

Caution should be exercised, in the use of this or any other catheter, in patients with prosthetic valves. Patients with recurrent sepsis or with hypercoaguable state should not be considered candidates for transvascular catheters, since the catheter could serve as a focal point for septic or blood thrombus formation.

Warnings:

- 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.
- The device(s) should be used by physicians thoroughly trained in the techniques of invasive cardiology and in the specific approach to be used.
- Care must be taken to ensure that any equipment used in connection with the EP Catheters meets IEC 601-1 and IEC 601-1-2 Safety Standards.
- 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 of connectors could result in electrocution of the patient or operator.
- Diagnostic electrophysiology involves x-ray exposure that present the potential risk for somatic and genetic effects, to both patients and laboratory staff due to the x-ray beam and intensity and duration of the fluoroscopic imaging. Steps should be taken to minimize this exposure as much as possible.
- Careful catheter manipulation must be performed to avoid cardiac damage, perforation, or tamponade. Catheter advancement should be performed under fluoroscopic guidance. Do not use excessive force to advance or withdraw the catheter when resistance is encountered.
- The device is not intended for use as an ablation catheter.

Precautions:

- Excessive bending or kinking of the catheter shaft may damage internal wires. Manual prebending of the distal curve can damage the steering mechanism and/or electrical wires, and may cause patient injury.

Adverse Reactions:

The following potential risks or discomforts may be associated with diagnostic EP procedures. The frequency and severity of these adverse events can vary, and may necessitate additional medical intervention, including surgery.

Adverse Reactions: (continued)

Allergic reaction
Arrhythmias
Cardiac or respiratory arrest
Cardiac valve damage
Catheter entrapment/entanglement
Chest pain
Damage to vessel intima or cardiac structures
Death
Embolus, air embolus
Hematoma/ecchymosis
Hemorrhage
Hypotension
Infection
Myocardial infarction
Perforation
Pericardial effusion
Pericarditis / pleuritis
Pneumothorax
Pseudoaneurysm
Pulmonary edema
Sinus or AV node injury
Stroke
Stroke or cerebral vascular accident
Tamponade
Thrombosis
Vasovagal reaction
X-ray exposure

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. Patient should be connected to an ECG recording system prior to commencing the procedure in order to permit arrhythmia monitoring.
2. Remove components from package and place in a sterile work area.
3. Create a vascular access by either cut down or percutaneous technique. The catheter may be used from femoral, brachial, subclavian or jugular access sites through a sheath/dilator (7 Fr. [2,3 mm] for Steerocath Dx and 6 Fr. [2,0 mm] for EPT Dx or Polaris Dx).
4. Continue to advance the catheter under fluoroscopic guidance to the desired intracardiac position.
5. Once inside the vessel, the tip can be deflected as necessary to facilitate advancement into the selected heart chamber. The degree of tip deflection is controlled by the steering knob or the steering lever.

   EPT Dx

   If the steering knob is rotated from its zero position, the tip will curve proportionately in one direction. Alternatively rotating the steering knob back to its zero position will cause the tip to deflect back to the straight position (Fig. 2).

   Steerocath Dx

   If the steering lever is pushed forward from its neutral position, the tip will curve proportionately a maximum of 270° in one direction. Alternatively, pulling the steering lever back will cause the tip to deflect similarly in the opposite direction (Fig. 3).

   The EPT Dx and Steerocath Dx catheters have an adjustable tension control wheel which may be tightened to hold the tip in the desired position. The catheter is shipped with the tension adjustment in the '(-)' position which is the minimum available tension. In this position, the catheter steers freely and will not hold a preset curve.

   In the '(+)' position, maximum tension/resistance is achieved. To increase steering resistance and/or hold a preset curve, the tension control wheel is rotated as necessary.

   To prevent over-stressing the tip, the steering knob/lever is limited by handle design.

   Polaris Dx

   The tip can be deflected to allow for curve changes instantly by using the thumb slide mechanism. By pushing the thumb slide up, the curve becomes tighter. By pushing the thumb slide down, the curve straightens. (Fig. 1)
6. For intracardiac recordings, connect the appropriate quick connect or lead tip pins of the connector to the appropriate electronic recording equipment and perform the study.

   NOTE: Closer spaced electrodes may enhance localization of aberrant path ways.
7. For pacing, connect the distal catheter terminal to the negative terminal of an external pulse stimulator and any proximal ring electrode to the positive terminal. The standard pacing stimuli is set at twice diastolic threshold with a duration of 1.5 to 2 msec. If the pacing threshold is greater than 1 to 2 mA, repositioning of the catheter should be considered.

Warranty and Limitations

Boston Scientific/EP Technologies warrants that this product has been manufactured, packaged, and tested with reasonable care and will be free from defects in workmanship and material. EP Technologies further warrants that sterile products will remain sterile for a period described on the product's label provided that the original packaging remains intact. This product is designed for single use only, and it is not designed for reuse. This warranty shall not apply to products which have been resterilized, repaired, altered, or modified in any way, or to products which have been improperly stored or improperly installed, operated or maintained. EP Technologies will not be liable for any incidental, special or consequential loss, damage, or expense resulting, directly or indirectly, from the use of this product. EP Technologies sole obligation shall be to repair or replace, at its option, any device that EP Technologies determines was defective at time of shipment if notice thereof is received within the "use before" or expiration date described on such product's label. Buyer assumes all liability, whether based upon warranty, contract, negligence, or otherwise, for damages resulting from the handling, possession, use or misuse (including reuse) of this product. Because EP Technologies has no control over the operation, inspection, maintenance, or use of its products after sale and has no control over the selection of patients, **THIS WARRANTY IS EXPRESSLY IN LIEU OF ANY OTHER EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE, AND OF ANY OTHER OBLIGATION ON THE PART OF THE SELLER.** The remedies set forth in this Warranty and Limitations shall be the exclusive remedy available to any person. No agent, employee, or representative of EP Technologies has any authority to change any of the foregoing or assume or bind EP Technologies to any additional liability or responsibility in connection with this product. Buyer's use of this product shall be deemed acceptance of the terms and conditions of this Warranty and Limitations.

Polaris Dx™

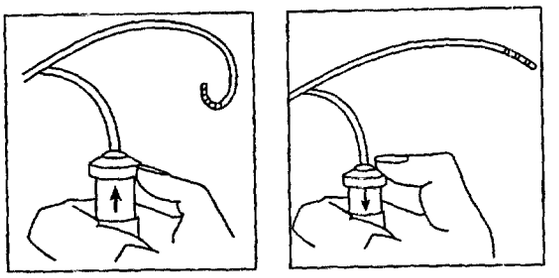

Figure 1. Figure 1. Abbildung 1. Figura 1. Figura 1. Figuur 1. Figur 1. Figur 1. Figura 1. Εικόνα 1. 図 1

EPT Dx™

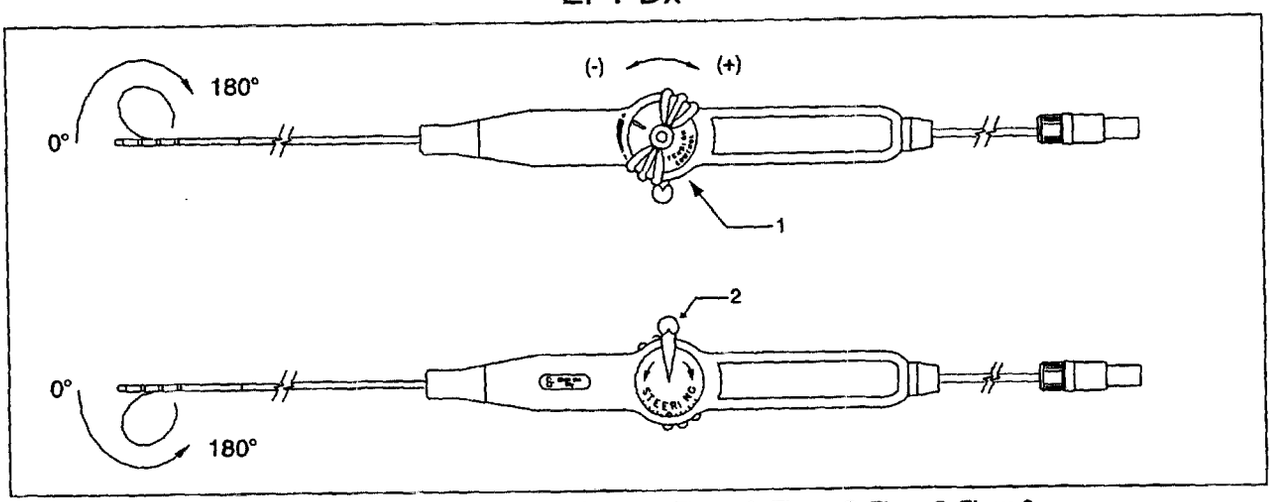

Figure 2. Figure 2. Abbildung 2. Figura 2. Figura 2. Figuur 2. Figur 2. Figur 2. Figura 2. Εικόνα 2. 図 2

Steerocath Dx™

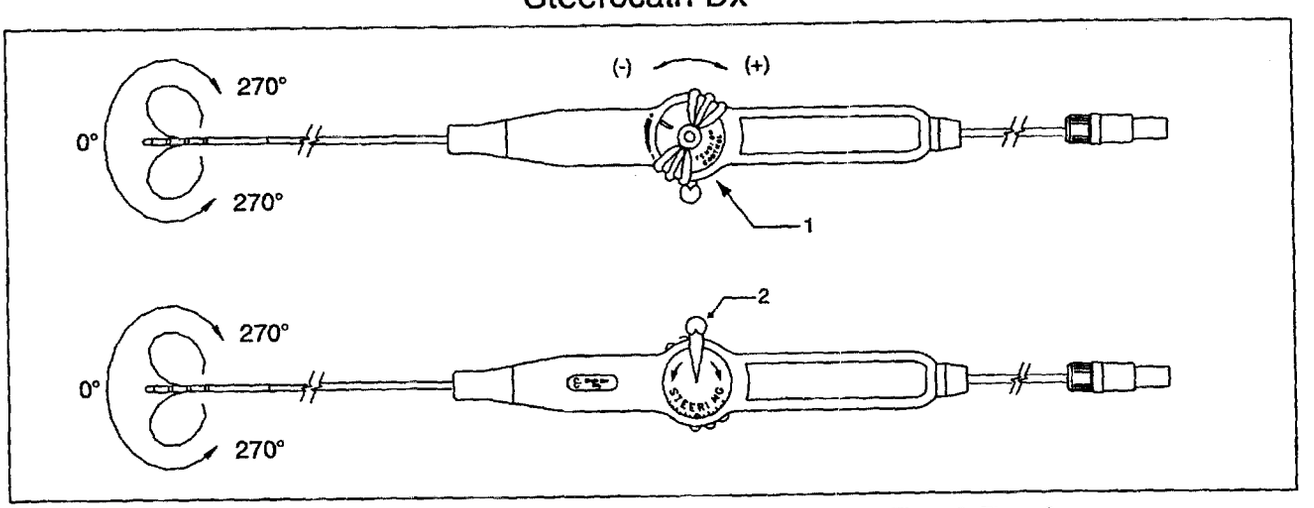

Figure 3. Figure 3. Abbildung 3. Figura 3. Figura 3. Figuur 3. Figur 3. Figur 3. Figura 3. Εικόνα 3. 図 3

1. Tension Adjust Knob. Molette de réglage de la tension. Spannungseinstellungsknopf. Perilla de ajuste de tensión. Rotella di regolazione della tensione. Weerstandregelingswieltje. Greb til spændingsindstilling. Vred för spänningsjustering. Botão de ajuste da tensão. Επιλογέας Ρύθμισης Τάσης. 張力調整ノブ
2. Steering Lever. Manette d'orientation. Steuerhebel. Palanca de dirección. Leva di pilotaggio. Stuurhendel. Styrearm. Styrspak. Alavanca de direcção. Μοχλός Οδήγησης. ステアリング・レバー

Explorer™

Fixed Curve Diagnostic Catheter

Cathéter de diagnostic à courbure fixe
Diagnostischer Katheter mit fester Krümmung
Catéter de diagnóstico de curva fija
Catetere diagnostico a curva fissa
Diagnostiekkatheter met vaste curve
Diagnostisk kateter med fast kurve
Diagnostisk kateter med fixerad kurva
Cateter de Curva Fixa para Diagnóstico
Διαγνωστικός Καθετήρας Αμετάβλητης Καμπύλης
冠動脈イメージングカテーテル

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Directions For Use

Mode d'emploi
Gebrauchsanweisung
Instrucciones de uso
Istruzioni per l'uso
Gebruiksaanwijzing
Brugsanvisning
Bruksanvisning
Instruções para Utilização
Οδηγίες Χρήσης
取扱説明書

CE 0197

Boston Scientific
EP TECHNOLOGIES™

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(8/99)

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Carefully read all instructions prior to use. Observe all contraindications, warnings and precautions noted in these instructions. 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.

Description:

The Catheter is designed for use in intracardiac pacing and recording only. The following suggested technique is supplied to explain the use of this catheter. The physician may elect to vary the insertion technique in accordance with their judgment and experience. The catheter may be introduced either by cut down technique or via a percutaneous sheath introducer.

The Catheter has been designed to carry electrical signals for the purpose of endocardial stimulation or recording. The Catheter is designed for single use only.

The contents supplied are sterile as long as the package is undamaged or unopened.

Indications:

The Catheter is intended for temporary use in electrophysiology studies for intracardiac stimulation and/or recording of electrical potentials.

Contraindications:

Caution should be exercised, in the use of this or any other catheter, in patients with prosthetic valves. Patients with recurrent sepsis or with hypercoaguable state should not be considered candidates for transvascular catheters, since the catheter could serve as a focal point for septic or blood thrombus formation.

Warnings:

- 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.
- The device(s) should be used by physicians thoroughly trained in the techniques of invasive cardiology and in the specific approach to be used.
- Care must be taken to ensure that any equipment used in connection with the EP Catheters meets IEC 601-1 and IEC 601-1-2 Safety Standards.
- The risk of vascular perforation exists with any intracardiac catheter. Do not advance the catheter if resistance is encountered.
- This catheter is not indicated for use in cardiac ablation or coronary artery mapping procedures.
- This use of catheters or cables with unprotected male connectors present a risk of electrical hazard. Inadvertent attachment of pin connectors to power supply sockets of connectors could result in electrocution of the patient or operator. The users of components with unprotected male connectors must exercise caution during device set-up to prevent patient or operator injury.

Complications:

The following potential risks or discomforts may be associated with diagnostic EP procedures. The frequency and severity of these adverse events can vary, and may necessitate additional medical intervention, including surgery.

Allergic reaction	Myocardial infarction
Arrhythmias	Perforation
Cardiac or respiratory arrest	Pericardial effusion
Cardiac valve damage	Pericarditis / pleuritis
Catheter entrapment/entanglement	Pneumothorax
Chest pain	Pseudoaneurysm
Damage to vessel intima or cardiac ultrastructures	Pulmonary edema
	Sinus or AV node injury
Death	Stroke
Embolus, air embolus	Stroke or cerebral vascular accident
Hematoma/ecchymosis	Tamponade
Hemorrhage	Thrombosis
Hypotension	Vasovagal reaction
Infection	X-ray exposure

Strict adherence to the foregoing instructions before use will help reduce the incidence of complications.

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. Patient should be connected to an ECG recording system prior to commencing the procedure in order to permit arrhythmia monitoring.
2. Remove components from package and place in a sterile work area.
3. Create a vascular access by either cut down or percutaneous technique. The catheter may be used from femoral, brachial, subclavian or jugular access sites.
4. Continue to advance the catheter under fluoroscopic guidance to the desired intracardiac position.
5. For intracardiac recordings, connect the appropriate lead tip pins of the connector assembly to the appropriate electronic recording equipment and perform the study.

   NOTE: Closer spaced electrodes may enhance localization of aberrant path ways.
6. For pacing, connect the distal catheter terminal (D) to the negative terminal of an external pulse stimulator and any proximal ring electrode to the positive terminal. The standard pacing stimuli is set at twice diastolic threshold with a duration of 1.5 to 2 msec. If the pacing threshold is greater than 1 to 2 mA, repositioning of the catheter should be considered.

References:

Available upon request.

Warranty and Limitations

EP Technologies, Inc. warrants that this product has been manufactured, packaged, and tested with reasonable care and will be free from defects in workmanship and material. EPT further warrants that sterile products will remain sterile for a period described on the product's label provided that the original packaging remains intact. This product is designed for single use only, and it is not designed for reuse. This warranty shall not apply to products which have been resterilized, repaired, altered, or modified in any way, or to products which have been improperly stored or improperly installed, operated or maintained. EPT will not be liable for any incidental, special or consequential loss, damage, or expense resulting, directly or indirectly, from the use of this product. EPT's sole obligation shall be to repair or replace, at its option, any device that EPT determines was defective at time of shipment if notice thereof is received within the "use before" or expiration date described on such product's label. Buyer assumes all liability, whether based upon warranty, contract, negligence, or otherwise, for damages resulting from the handling, possession, use or misuse (including reuse) of this product. Because EPT has no control over the operation, inspection, maintenance, or use of its products after sale and has no control over the selection of patients, **THIS WARRANTY IS EXPRESSLY IN LIEU OF ANY OTHER EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE, AND OF ANY OTHER OBLIGATION ON THE PART OF THE SELLER.** The remedies set forth in this Warranty and Limitations shall be the exclusive remedy available to any person. No agent, employee, or representative of EPT has any authority to change any of the foregoing or assume or bind EPT to any additional liability or responsibility in connection with this product. Buyer's use of this product shall be deemed acceptance of the terms and conditions of this Warranty and Limitations.

Constellation™

Multiple Mapping Catheter

Boston Scientific
EP TECHNOLOGIES™

Directions For Use

Boston Scientific
EP TECHNOLOGIES™

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Boston Scientific Product is
Distributed in the U.S. by:
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(800) 552-6700

Issued Patents: 5,651,780; 5,647,870 and other
Patents Pending; foreign counterparts also pending.

Boston Scientific Product is
Distributed in Europe by:
Boston Scientific International
91, Boulevard National 92257
La Garenne Colombes Cedex
France

12809-001 EAW Ver AA (2/00)

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

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 Constellation Multiple Electrode Recording and Pacing Catheter (Constellation Catheter) allows the physician to map and record intracardiac electrograms. The distal, expandable "basket" assembly contains an array of 64 electrodes. Two configurations are available, unipolar and bipolar, with electrodes evenly spaced (unipolar) or arranged in 32 pairs (bipolar).

Indications for Use

For use in right 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

Both the heparin-coated and uncoated version of the Constellation Catheter and the Constellation Guiding Catheter are contraindicated in patients who cannot be anticoagulated or infused with heparinized saline.

Additionally, use of the Constellation Catheter is contraindicated in patients with any of the following:

- Permanent leads or prosthetic or stenotic valves present;
- Active systemic infection;
- Echocardiographically-confirmed visual presence of thrombus;
- For whom the inability of obtaining vascular access exists;
- Heparin-induced thrombocytopenia;
- hemodynamic instability or shock.

Warnings and Precautions

The use of this device in conjunction with radiofrequency ablation, as part of the diagnosis and therapeutic treatment of atrial 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 chamber except the right atrium.
- Maintain activated clotting time (ACT) levels above 300 seconds at all times during the procedure and monitor throughout Constellation 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.

Precautions Specific to Constellation Catheter

- 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 large diameter (11 Fr) Guiding Catheter, carefully monitor the vascular puncture site.
- To minimize risk of air embolus, flush the Guiding Catheter to remove all air before introduction into vasculature. The introduction of the Constellation Catheter into the Guiding Catheter also has the potential to introduce air into the Guiding Catheter. Therefore, during the introduction of the Constellation Catheter into the Guiding Catheter, again aspirate fluid to expel any air.
- If other catheters are used concurrently with the Constellation Catheter, remove those catheters before removing or repositioning the Constellation Catheter.
- The Constellation Catheter is NOT intended for use as an ablation catheter.
- Carefully manipulate the catheter to avoid causing cardiac damage, perforation, or tamponade. Advance the catheter under fluoroscopic guidance. Do not advance or withdraw the catheter against excessive resistance. Do not torque the catheter while it is fully deployed.
- Excessive bending or kinking of the catheter shaft may damage internal wires. Manual prebending of the distal assembly can damage the basket assembly and may cause patient injury.

Precautions During Catheter Use

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

- The soft tip of the Guiding Catheter has limited radiopacity. Do not advance against resistance.
- 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 microAmps under any circumstances.
- 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. Those who use components with unprotected male pin connectors must exercise extreme caution during device setup to prevent patient or operator injury.

Handling and Sterilization

The Constellation Catheter is intended for single patient use only. Do not reprocess or reuse. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another.

The Guiding Catheter is intended for single patient use only. Do not reprocess or reuse. Reuse can cause patient injury and/or the communication of infectious diseases from one patient to another.

Adverse Events

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 [7.2%, 21.4%]. The adverse events are listed in Table 1. *See last page for all Tables.*

Potential Adverse Events

Adverse events (in alphabetical order) which may be associated with catheterization.

- air embolism
- arrhythmias
- AV fistula
- cardiac perforation
- hemothorax
- nerve palsy or weakness
- pneumothorax
- pseudoaneurysm
- tamponade
- thrombi
- thromboembolism
- thrombosis
- valvular damage
- vascular bleeding/local hematomas
- vasovagal reactions
- visual blurring

Clinical Study

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 Catheter (Constellation Group) or a commercially available diagnostic EP catheter (Standard Catheter Group). Forty-seven patients were randomized to the Constellation, 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.

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 to the endocardial surface. Unsuccessful capture was therefore indicative of either: (1) non-contact of the basket and basket electrodes to 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.

Procedure and Fluoroscopy Times

Data were available with respect to procedure time and fluoroscopy time for the

Standard Catheter Group (n=24) and Constellation G[illegible] (n=88), as shown in Table 4

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 Catheter use. Do not leave the catheter in situ more than three hours for the cumulative duration of catheter placement. The Constellation Guiding Catheter 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 Catheter 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.

Instructions

Before the procedure, perform two dimensional echocardiography to determine the approximate diastolic dimensions of the right atrium. A correctly sized catheter may appear slightly compressed. The electrode/tissue contact can be evaluated by standard pacing protocols.

Cross reference the long and short axes diameters of the right atrium to an appropriate Constellation Catheter size (38 to 75 mm diameter). Characteristic right atrial dimensions are presented in Table 5 , and suggested basket sizes for corresponding atrial dimension are presented in Table 7.

Maintaining Device Effectiveness

- The Constellation Catheter is designed for single use only.
- DO NOT RE-USE OR RE-STERILIZE.
- The Constellation Guiding Catheter is intended for single patient use only.
- DO NOT REPROCESS OR REUSE.
- Regularly inspect and test reusable Accessory Cables. The Accessory Cables may only be sterilized up to 20 times by ethylene oxide sterilization.
- Keep the Constellation Pacing Switchbox dry and out of the sterile field.

Patient Counseling Information

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

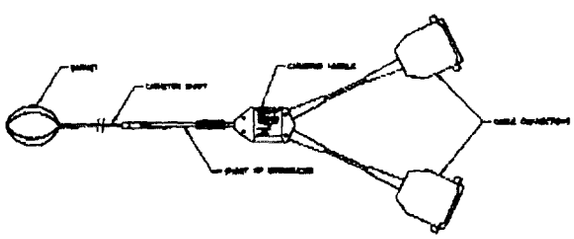

Figure 1 - The Constellation Catheter

Detailed Device Description

The EP Technologies (EPT) Constellation Multiple Electrode Recording and Pacing Catheter may be used to detect electrical potentials from the endocardial surfaces of the right atrium, and may also be used to deliver externally generated pacing stimuli. The distal, expandable "basket" assembly contains 64 electrodes with electrodes evenly spaced (unipolar) or arranged in 32 pairs (bipolar). Technical Specifications for both the catheter and the Constellation Guiding Catheter are described in Table 6.

An illustration of the Constellation Catheter System is presented in Figure 3, showing the connections between the Constellation Catheter, Accessory Cables, Constellation Pacing Switchbox, Pacing Stimulus Generator, and EP Recorder.

The Constellation Catheter consists of three major components:

- **The basket.** The basket is made of eight resilient support structures, called splines. The flexible splines conform to the shape and movements of the right atrium. Each spline has between two (2) and eight (8) electrodes. The electrode rings on all splines and the proximal marker bands are radiopaque.
  There are seven marker bands, one each on spline 'A' through 'G'. The marker band on spline 'A' is adjacent to the number 1 electrode, and the marker band position is offset by 1 on [illegible] of the following splines (adjacent to electrode 2 on the 'B' spline, electrode 3 on the 'C' spline, etc). The splines are oriented in a clockwise manner from the distal perspective (looking at the leading tip of the catheter.
- **The catheter shaft.** Electrical connections from the electrodes run the length of the catheter shaft to the catheter handle. A short-tip sheath is pre-mounted on the shaft to collapse the basket for introduction.
  DuraFlo Coating. The basket is available in both coated and non-coated versions. For the coated version, the basket and catheter shaft are coated with DuraFlo Coating.[1]
- **The catheter handle.** The catheter handle is used for guiding the catheter through the sheath for positioning. The cable connection relays electrical signals to the electrophysiological recording and pacing equipment.
- **The Constellation Guiding Catheter.** The Constellation Guiding Catheter provides a conduit for introducing or withdrawing the Constellation Catheter to the right atrium. A non-tapered soft tip is included at the distal end of the Constellation Guiding Catheter. A side port on the Constellation Guiding Catheter allows for infusion of liquids (e.g., medications, heparin/saline flush, etc.) through the sheath. The sheath is not coated with DuraFlo Coating. The Constellation Catheter is intended for use only with this specific Constellation Guiding Catheter.

An ancillary component to the catheter is the Constellation Pacing Switchbox. Endocardial signals transmitted via the catheter and connected extension cables are relayed to the Constellation Pacing Switchbox, which transfers the unprocessed signals to a data acquisition and display system for evaluation and recording by the physician. The Constellation Pacing Switchbox allows the physician to pace from the Constellation Catheter, via a commercially available external pacemaker pulse generator. Refer to Figure 3 for an overview of the Constellation Catheter and accessory Constellation Pacing Switchbox. Instructions for using the Pacing Switchbox are included in the Constellation Pacing Switchbox section below.

The Constellation Catheter should be used only with the Constellation Guiding Catheter 11F and accessory cables. The Constellation Pacing Switchbox is optional. Other required equipment (not supplied) includes an 11F introducer with tapered hemostatic valve, a pressurized IV of heparinized normal saline solution, and a 20 ml syringe. Other optional equipment includes a long (150 cm) .038 cm guidewire and pigtail catheter (not supplied).

The Constellation Catheter is constructed in a variety of sizes and configurations designed to meet the requirements of variable patient anatomy and physician preference for use. Dimensional characteristics are given in Table 5. The catheter can be used to map electrical potentials in either monopolar or bipolar mode. Figure 1 depicts the Constellation Catheter.

Suggested Directions for Use

1. With the approximate diastolic dimensions of the right atrium having been previously determined via two dimensional echocardiography, cross reference the long and short axes diameters of right atrium to a corresponding size as restated in Table 7.
2. Flush the Constellation Guiding Catheter with heparinized saline. Displace all air inside the Constellation Guiding Catheter.
3. Obtain percutaneous access by the Seldinger technique or surgical cutdown. Place an 11 F catheter introducer into the vessel, being careful to position the introducer at an oblique angle (approximately 30°) to the vessel axis. Verify that the initial bend of the introducer is not bent sharply. If a sharp bend exists, replace the introducer.
4. Insert the .038" guidewire into an 8 F pigtail catheter. Next, insert the pigtail/guidewire combination into the Constellation Guiding Catheter of the Constellation Catheter, until the pigtail catheter protrudes approximately 10 cm beyond the Constellation Guiding Catheter tip. Additionally, the guidewire should extend about 10 cm beyond the end of pigtail catheter. Flush the Constellation Guiding Catheter, pigtail catheter, and guidewire assembly again with heparinized saline to verify the removal of all entrapped air. Insert the loaded Constellation Guiding Catheter into the 11 F introducer. Under fluoroscopy, first pass the guidewire into the right atrium and pass the pigtail over the guidewire and into the right atrium. Pass the Constellation Guiding Catheter over the pigtail into position. Orient any pre-curve bias at the distal end of the Constellation Guiding Catheter to facilitate the transit through the relevant peripheral and systemic vasculature.
5. Place the distal end of the Constellation Guiding Catheter near the atrial appendage under fluoroscopic guidance (there is no tip marker).
6. Continuously watch for mechanically induced premature ventricular contractions (PVC's) or premature atrial contractions (PAC's). Withdraw the Constellation Guiding Catheter system if PVC's or PAC's are observed.
7. Once the Constellation Guiding Catheter is placed into position, remove the guidewire and pigtail catheter while maintaining the position of the Constellation

Guiding Catheter.

8. Attach a syringe at the Constellation Guiding Catheter side-port, draw a vacuum to remove excess air, close the stopcock, and flush the Constellation Guiding Catheter with heparinized saline solution.
9. Immediately connect a heparinized saline IV infusion drip to the Constellation Guiding Catheter side-port. Start the heparinized saline drip and continuously flush the Constellation Guiding Catheter at an approximate drip rate of 100 ml/hr.
10. An intravenous bolus of heparin should be administered before introducing the Constellation Catheter into the right atrium. Maintain ACT over 300 seconds.
11. Prior to insertion, collapse the splines of the basket by advancing the short-tip sheath assembly provided on the catheter body over the basket. Allow approximately 1-2 mm of the constrained basket assembly to extend beyond the end of the short-tip sheath to allow crossing the hemostatic valve with the soft tip of the short-tip sheath.
12. Insert the pre-flushed short-tip sheath containing the collapsed basket assembly through the hemostatic valve of the Constellation Guiding Catheter. Advance the short-tip sheath approximately 2 cm into the Constellation Guiding Catheter until the short-tip sheath engages (the sheath will "stop") the Constellation Guiding Catheter. DO NOT force the short-tip sheath beyond this point. If the spline assembly will not advance into the Constellation Guiding Catheter, withdraw the short-tip sheath slightly until the basket assembly advances easily into the Constellation Guiding Catheter.

    When the catheter has been advanced approximately 5 cm into the Constellation Guiding Catheter, permit backflow of blood for a few seconds to expel any remaining air from the sheath. Continue advancing to approximately 25 cm into the Constellation Guiding Catheter, then carefully pull the short tip sheath. Finally, slowly withdraw the short-tip sheath out of the hemostatic valve and slide the short tip sheath all the way back to the catheter handle.
13. Advance the catheter through the Constellation Guiding Catheter. Under fluoroscopic guidance, examine the catheter and the Constellation Guiding Catheter for kinks or sharp bends. Remove and inspect the Constellation Guiding Catheter if necessary. DO NOT force the basket assembly through the Constellation Guiding Catheter. The catheter should advance smoothly, with only an increase in resistance when the basket assembly begins to traverse a curve.
14. As stated in Step 4, the Constellation Guiding Catheter should have been previously positioned near the distal wall of the right atrium. Advance the catheter until the distal tip of the Constellation Catheter is also positioned near the distal wall of the atrium. Holding the catheter body stationary, slowly withdraw the Constellation Guiding Catheter to allow the basket assembly to expand into the atrium.
15. If PAC's are observed, recapture and reposition the Constellation Catheter as outlined in the next section.
16. Connect the two 44-pin D-Sub male connectors to the appropriate extension cable or to the accessory Pacemaker Switch Box. The "A" connector corresponds to splines A to D and the "B" connector corresponds to splines E to H. See Constellation Pacing Switchbox for complete instructions on using the accessory Constellation Pacing Switchbox.

    Note: An external pacemaker pulse generator should be utilized to deliver pacing stimuli. During pace/mapping, only one electrode (unipolar configuration) or one electrode pair (bipolar configuration) should be selected to pace. During mapping, only the selected electrode will be connected to the pulse generator's pacing output.
17. Review recordings to ensure connections are adequate.
18. Verify the orientation of the Constellation Catheter basket assembly, using fluoroscopy to view the location of the marker bands on the basket splines. When viewing the basket assembly from the distal end, the splines are oriented clockwise in increasing spline order.

To Recapture Basket Assembly

1. While withdrawing the Constellation Catheter, simultaneously advance the Constellation Guiding Catheter over the basket assembly until 1/3 of the basket becomes constrained. This maneuver should be performed in one smooth, continuous motion.

    CAUTION: Never force the Constellation Catheter against excessive resistance.
2. After the Constellation Catheter is in position, the Constellation Guiding Catheter should be further withdrawn.
3. If repositioning of the basket is required, follow these steps:

    Using fluoroscopy, advance the Constellation Guiding Catheter into the right atrium.

    Withdraw the basket until approximately half of the basket is constrained. Again, under fluoroscopy, slowly torque the catheter to rotate the basket. Re-deploy it into the right atrium.

    CAUTION: To ensure continued electrode continuity and device performance, do not redeploy the catheter more than five (5) times during a procedure.

Catheter Removal

1. To remove the Constellation Catheter, re-position the Constellation Guiding Catheter into the right atrium, advancing it just proximal to the basket assembly.
2. Withdraw the Constellation Catheter, while simultaneously advancing the Constellation Guiding Catheter over the basket assembly until 1/3 of the basket becomes constrained. This maneuver should be performed in one smooth, continuous motion.

    CAUTION: DO NOT tug on the Constellation Catheter. Never force the Constellation Catheter against excessive resistance.
3. After the basket assembly is completely collapsed into the Constellation Guiding Catheter, return the short-tip sheath to its position within the hemostatic valve. Insert the pre-flushed short-tip sheath containing the collapsed basket assembly through the hemostatic valve of the Constellation Guiding Catheter. Advance the short-tip sheath approximately 2 cm into the Constellation Guiding Catheter until the short-tip sheath engages (the sheath will "stop") the Constellation Guiding Catheter. DO NOT force the short-tip sheath beyond this point. Begin a slow withdrawal of the Constellation Catheter.
4. Gently pull the Constellation Catheter until the basket assembly is contained within the short-tip sheath.
5. Remove the short-tip sheath and the basket assembly together as one unit. Once the short-tip sheath and basket assembly have been removed from the Constellation Guiding Catheter, gently slide the collapsing tip sheath back down the catheter shaft, thus expanding the basket assembly into its pre-formed shape.
6. Remove the Constellation Guiding Catheter from the vasculature. Finally, after removal of the vascular introducer, follow local practice norms for appropriate care.

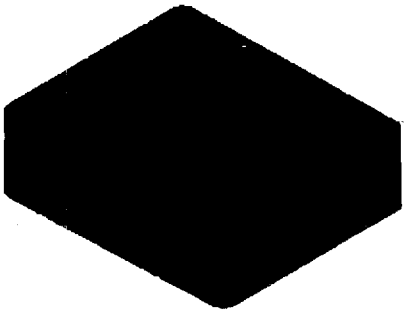

Figure 2 - Constellation Pacing Switchbox

How Supplied

The contents supplied are sterile in their original, unopened package:

- DuraFlo-Coated Constellation Catheters have a thirty month expiration date;
- Non-coated Constellation Catheters have a three year expiration date (from the date of manufacture).
- If the sterile barrier appears broken or compromised, do not use the device.

Detailed Description of the Pacing Switchbox Accessory

The Constellation Pacing Switchbox permits specific access to a particular spline, electrode (or pair of electrodes for bipolar configured catheters) on the Constellation Catheter. The Constellation Pacing Switchbox also allows for delivery of externally generated pacing stimuli, or for detecting and recording electrical potentials from the selected endocardial surfaces of the heart. The Constellation Pacing Switchbox is shown in Figure 2.

Pacing can be initiated from an external stimulator in either bipolar mode (typically used for pace mapping), or unipolar mode (typically used for entrainment or reset mapping). Spline or electrode selection is accomplished by rotating the control knobs on the Constellation Pacing Switchbox until the chosen electrode or spline is connected.

The Constellation Pacing Switchbox is hard-wired. No electrical components are used to switch between electrodes or splines. The Constellation Catheter connects to the extension cable by two female 44-pin high density D-sub connectors, one marked "A" (that corresponds to splines A to D of the catheter), and the other marked "B" (that corresponds to splines E to H.)

An electrophysiology recorder may be connected d... ...y to the catheter, bypassing the switching components of the Switchbox. In this case, connection is accomplished with two male 44-pin high density D-sub connectors, which in turn are connected to the recording system, using the same marking scheme as the connection to the catheter.

A female 2 mm Hirschmann pin plug is used to connect the Switchbox to the negative (-) input from the Constellation Pacing Stimulus Generator; the positive (+) input is connected to the reference electrode. For bipolar pacing, a female 2 mm Hirschmann pin plug is connected to the Switchbox from the positive (+) input from the Pacing Stimulus Generator (male pin).

Two control knobs are used to switch between splines A to H, or electrodes 1 to 8 (each located on a single given spline). Each control knob stops at eight positions, corresponding to the desired spline or electrode position.

A three way switch is used to change from unipolar to bipolar pacing modes. The third position of the switch disconnects the pacing stimuli from the Constellation Catheter.

Suggested Directions to Include the Pacing Switchbox Accessory

Refer to Figure 3 to include the Pacing Switchbox.

If the Pacing Switchbox is not desired, refer to the Suggested Directions to Exclude the Pacing Switchbox Accessory (next section).

1. Connect the sterile extension cable to the Constellation Catheter. Connect the other two ends of the sterilized Extension Cable to the Constellation Pacing Switchbox, on the side marked "CONSTELLATION CATHETER". Ensure that the connector cable labeled "A" connects to the proper "A" receptacle on the Switchbox; likewise, connect the "B" connector cable appropriately.
2. Connect the Constellation Cables, model numbers 901A and 901B, from the Constellation Pacing Switchbox receptacle marked "RECORDER", to the electrophysiology recording system. The cables terminate in 2 mm male pin-type connectors. Plugs may be required to connect to your facility's mapping system.
3. Connect the "A" connector of the Switchbox to the channels of the mapping system corresponding to splines A to D. Connect the "B" connector of the Switchbox to channels corresponding to splines E to H.
4. The electrodes are oriented with the smaller numbers (1) located on the most distal portion of the basket assembly and the larger numbers (8) located on the most proximal portion of the basket assembly.
5. For electrophysiology recording systems with few input channels, the "SPLINE OUTPUT" connector of the Switchbox enables connecting electrodes from a particular Constellation spline to the recording system via instrument cables Model Numbers 857 and 826. The "SPLINE" switch determines which spline's electrodes are routed to the recording system.
6. Switch the "PACING MODE" to the "OFF" position before connecting the pacing stimulus to minimize erratic pacing.
7. Connect the negative (-) lead of the "PACING INPUT" to the negative (-) lead of the Pacing Stimulus Generator via 2 mm male pin-type plugs. Only one of the four pin-type plugs on the Switchbox needs to be connected.
8. To pace in bipolar mode between adjacent spline electrodes, connect the positive (+) lead of the "PACING INPUT" to the positive (+) lead of the Pacing Stimulus Generator via 2 mm male pin-type plugs. Only one of the four pin plugs on the Switchbox needs to be connected.
9. To pace in unipolar mode between a spline electrode and a reference (indifferent) electrode, connect one of the reference pin plugs to the positive (+) lead of the Pacing Stimulus Generator via 2 mm male pin-type plugs. Alternatively, connect the positive (+) lead of the Pacing Stimulus Generator to a positive (+) "PACING INPUT" lead of the Switchbox. Then connect the reference electrode via 2 mm male pin-type plugs to another positive (+) "PACING INPUT" lead of the Switchbox.
10. To deliver pacing stimuli through the Switchbox, select either "UNIPOLAR" or "BIPOLAR", as appropriate, from the "PACING MODE" three-way switch.
11. As illustrated in Figure 3, the control knob marked "SPLINE" switches between Constellation Catheter splines. The first spline, Spline A, can be identified under fluoroscopy, because the basket assembly is marked with one proximal electrode. Spline B, the second spline, is marked with two proximal electrodes (again, visible under fluoroscopy). The rest of the splines are oriented in a clockwise manner from the distal perspective (looking at the leading tip of the catheter).
12. The control switch marked "ELECTRODE OR ELECTRODE PAIR" selects through eight positions, allowing selections between electrodes in the unipolar mode, or between pairs of adjacent electrodes in the bipolar mode. The electrodes begin with "1" located at the distal end of each spline, and "8" located at the proximal end of each spline. "NC" designates no connection.

Suggested Directions ... Exclude the Pacing Switchbox Accessory

1. Connect the sterile extension cable (Model 900) to the Constellation Catheter. Connect the other two ends of the Extension Cable (Model 900) to the Model 901A or Model 901B Instrument Cables.
2. Connect the Instrument Cables, Model numbers 901A and 901B to the electrophysiology recording system. The cables terminate in 2 mm male pin-type connectors. Plugs may be required to connect to your facility's mapping system.
3. Connect the "A" connector of the Constellation Catheter to the channels of the mapping system corresponding to splines A to D. Connect the "B" connector of the Constellation Catheter to channels corresponding to splines E to H.
4. The electrodes are oriented with the smaller numbers (1) located on the most distal portion of the basket assembly and the larger numbers (8) located on the most proximal portion of the basket assembly.
5. Pacing protocols may be selected according to the manufacturer's Operator's Manual for the recording pacing system.
6. The first spline, Spline A, can be identified under fluoroscopy, because the basket assembly is marked with one proximal electrode. Spline B, the second spline, is marked with two proximal electrodes (again, visible under fluoroscopy). The rest of the splines are oriented in a clockwise manner from the distal perspective (looking at the leading tip of the catheter).

Service

EP Technologies/Boston Scientific Corporation representatives are available to provide training to qualified hospital personnel in the use of EPT/BSC products. In addition, EPT/BSC consultants to provide technical and medical consultation to product users. For supplemental information, contact your local EPT/BSC representative, call Customer Service (800.552.6700) or write to either EP Technologies or Boston Scientific Corporation.

Limited Warranty And Disclaimer

EP Technologies and Boston Scientific Corporation (EPT/BSC) warrant 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 expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness. Handling, storage, cleaning and sterilization of this instrument as well as factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond EPT/BSC's control directly affect the instrument and the results obtained from its use. EPT/BSC's obligation under this warranty is limited to the repair or replacement of this instrument and EPT/BSC shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this instrument. EPT/BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument.

Duraflo Coating is a registered trademark of Baxter CVG
Constellation® Multiple Electrode Recording and Pacing Catheter System is a registered trademark of EP Technologies, Inc. / Boston Scientific Corporation: patent numbers 5,651,780 and 5,647,870.

[1] The catheter is coated with DuraFlo Coating, a heparin coating, but tests results do not demonstrate that the coating will provide increased anti-thrombogenicity or hemocompatibility for the Constellation Catheter.

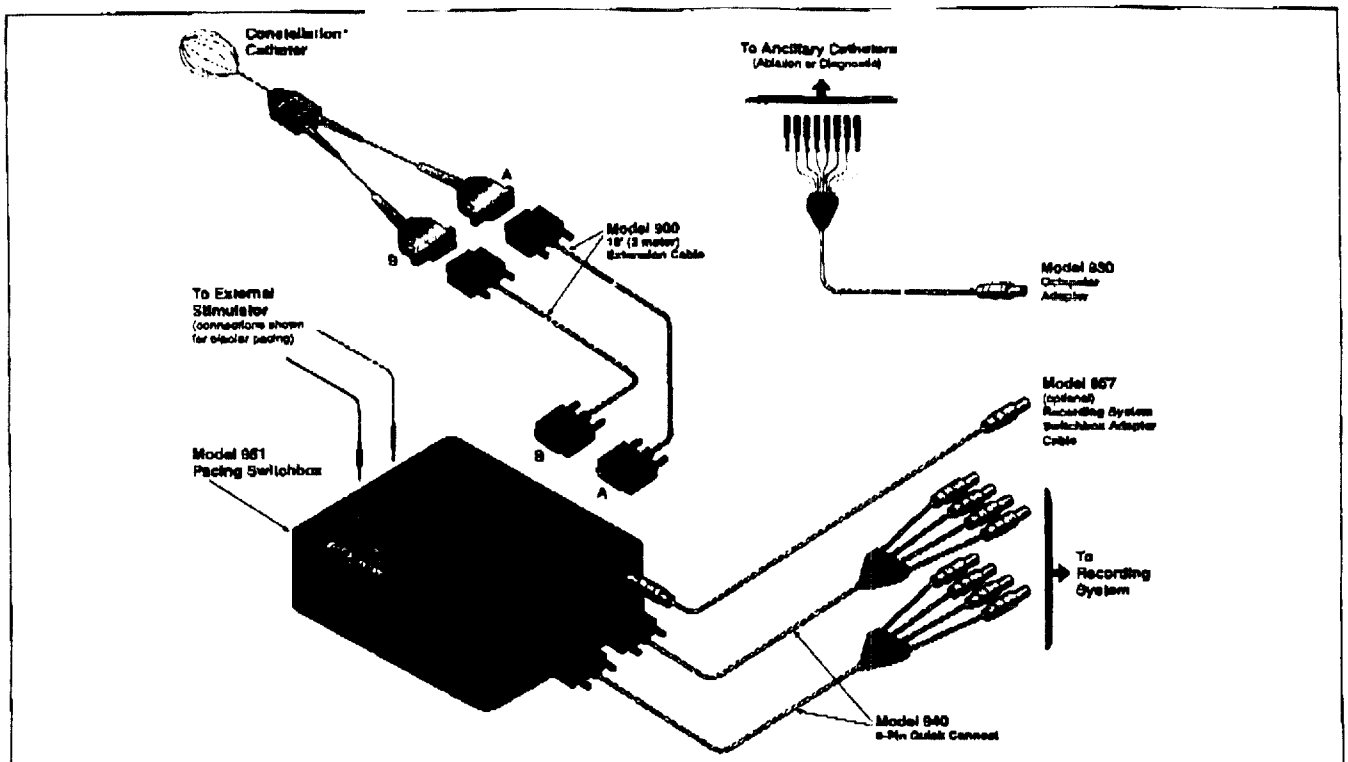

Figure 3 - The Constellation Catheter and Cable Connections

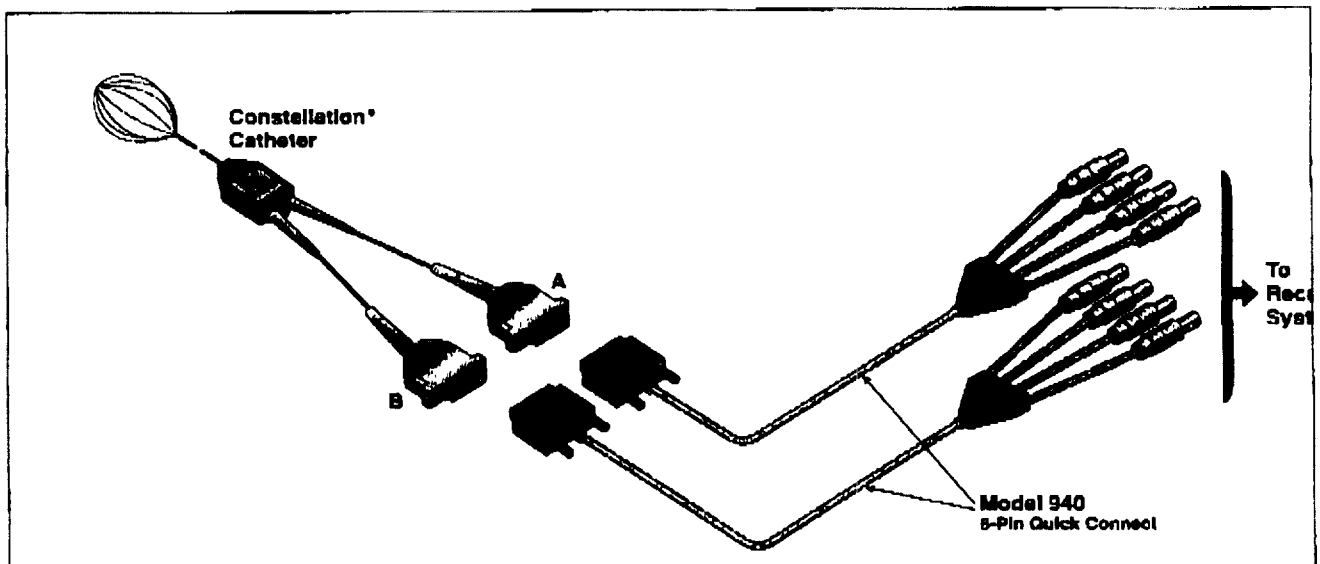

Figure 5 - The Constellation Catheter excluding Pacing Switchbox

Clinical Data

Table 1 - Observed Adverse Events in the Constellation 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 Lower Boundary, Upper Upper Boundary [Proportion]
All	12	84	0.143 (14.3)	0.072 - 0.214
Major	3	84	0.036 (3.6)	0 - 0.076
Minor	9	84	0.095 (9.5)	0.049 - 0.166

Table 2 - Patient Population

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

* - Denotes patients who received both the Constellation and Standard Catheters, for direct comparison. However, these patients were not counted for the safety analysis.

Table 3 - Pacing and Electrogram Recording Performance

Pacing Performance (N=44 patients)	N	Proportion (N useable / Total Attempted) %
Pacing Success	1383	52
Pacing Failure	1274	48
Total	2657	100
Electrogram Recording Performance (Signal Quality; N=53 Patients)		
Acceptable (N)	1126	81
Unacceptable (N)	268	19
Total	1394	100

Table 4 - Procedure and Fluoroscopy Times

	Average (minutes)	Standard Deviation (minutes)	Minimum (minutes)	Maximum (minutes)
Fluoroscopy Time				
Constellation Group	35.02	32.8	2	179
Standard Catheter Group	41.04	33.96	9	169
Procedure Time				
Constellation Group	4.39	1.92	1.38	9.8
Standard Catheter Group	3.69	1.89	1.25	7.8

Table 5 - Characteristic Right Atrial Dimensions from Multicenter Clinical Study

Basket Size (N)	Number of Patients Who Received Each Device	Right Atrial Diameters (mm) ± SD: 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
64	35	41.86±7.2	30.0	65.0	49.22±8.2	38.0	66.0
75	8	44.29±7.4	33.0	52.0	49.29±8.0	38.0	60.0

Table 6 - Technical Specifications

Component	Nominal Dimension
Basket Diameter (mm)	38, 48, 64, 75
Constellation Catheter Diameter (F)	8
Length (cm)	90 - 130
Electrodes (N)	64
Material	Platinum / Iridium
Configurations	Unipolar or Bipolar
Cable Connectors	Two (2) 44-pin Male Amphenol Connectors
Guiding Catheter Outer Diameter (F)	11
Guiding Catheter Useable Length (cm)	80 - 110

Table 7 - Constellation Catheter Sizing Recommendations

Long Axis (mm)	Short Axis (mm): 20	30	40	50	60	70	80	90
30	--	8038	8048	8048	8048	8048	8060	8060
40	8038	8048	8048	8048	8048	8048	8060	8075
50	8038	8048	8048	8060	8060	8075	8075	–
60	8048	8048	8060	8060	8075	8075	8075	–
70	8060	8060	8060	8075	8075	8075	–	–
80	8060	8060	8075	8075	8075	–	–	–
90	8075	8075	8075	–	–	–	–	–
100	8075	–	–	–	–	–	–	–