

ATTACHMENT 2
Instructions for Use

Cordis Webster INC.

Cordis
a Johnson & Johnson company

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STERILE EO

Sterilized with ethylene oxide gas.
Stérilisé à l'oxyde d'éthylène.
Sterilisiert mit Ethylenoxid - Gas.
Sterilizzato con ossido di etilene.
Esterilizado con óxido de etileno.
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カタログ番号



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Se reporter au mode d'emploi joint.
Beigefügte Gebrauchsanleitung beachten.
Attenersi alle istruzioni interne per l'uso.
Consultar las instrucciones de uso adjuntas.
Raadpleeg de bijgevoegde gebruiksaanwijzing.
Se vedlagte brugsanvisning.
Katso mukana ole via käyttöohjeita.
Consulte as instruções inclusas soore o Instruções de Uso.
Se bifogad bruksanvisning.
Δείτε τις εσωκλειόμενες Οδηγίες Χρήσης
同封の使用方法を参照。



For one use only.
A usage unique.
Nur zum Einmalgebrauch.
Da usare una volta sola.
Para un solo uso.
Voor eenmalig gebruik.
Kun til engångsburg.
Kertakäyttöinen.
Apenas para uma única utilização.
Endast för engångsbruk.
Για μια μόνο χρήση.
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Cordis Webster Electrophysiology Catheter: Fixed Curve

- **STERILE.** Sterilized with ethylene oxide gas.
- For single use only.
- Do not use if the package is open or damaged.

Catheter Description

The Cordis Webster fixed curve electrophysiology (EP) catheter has been designed to facilitate electrophysiological mapping of cardiac structures. The catheter has a high-torque shaft with an array of platinum electrodes at the distal tip that can be used for stimulation and recording. The tip section has a preformed curve with a nylon tip protector. (Standard curve types are identified by a color band on the shaft near the proximal end - see catalog).

The high-torque shaft allows the plane of the distal curve to be manually rotated to assist in positioning the catheter tip at the desired site.

The catheter interfaces with standard recording equipment via interface cables with the appropriate connectors.

CONSULT THE LOCAL DISTRIBUTOR OR MANUFACTURER FOR THE APPROPRIATE INTERFACE CABLES.

Indications

The catheter is indicated for electrophysiological mapping of cardiac structures; i.e., stimulation and recording only.

Contraindications

The Cordis Webster fixed curve EP catheter has not been shown to be safe and effective for electrical ablation or for use in the coronary vasculature other than the coronary sinus ostium.

Use of the catheter may not be appropriate for patients with prosthetic valves. A relative contraindication for cardiac catheter procedures is active systemic infection.

Precautions

Do not attempt to operate the Cordis Webster fixed curve EP catheter prior to completely reading and understanding these directions for use.

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

Careful catheter manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade. Catheter advancement and placement should be done under fluoroscopic guidance. Do not use excessive force to advance or withdraw the catheter when resistance is encountered.

Store in a cool, dry place; the sterile packaging and catheter should be inspected prior to use. Cordis Webster EP catheters are intended for single patient use only. Do not resterilize and reuse.

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

Warnings

Cardiac catheterization procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as increased risk for somatic and genetic effects, for both patients and laboratory staff due to the x-ray beam intensity and duration of the fluoroscopic imaging. Cardiac catheterization should only be performed after adequate attention has been given to potential radiation exposure associated with the procedure, and steps taken to minimize this exposure. Careful consideration must therefore be given for the use of this catheter in pregnant women.

- Do not immerse the proximal handle or cable connector in fluids; electrical performance could be affected.
- Do not expose the catheter to organic solvents such as alcohol.
- Do not autoclave the catheter.

"Use By" Date

Use the device prior to the "Use By" date on the package label.

Suggested Directions for Use

- Remove the catheter from its package and place it in a sterile work area. Remove nylon tip protector.
- Create a vascular access in a large central vessel using aseptic techniques and insert the catheter.
- Connect the lead pins or connectors to the appropriate recording equipment.
- Advance the catheter to the area of the endocardium under investigation. Use both fluoroscopy and electrograms to aid in proper positioning. The electrode catheter shaft may be gently hand rotated to facilitate positioning at the desired mapping site.
- Remove the catheter and dispose it in an appropriate manner. Do not resterilize and reuse.

If there are any questions regarding the use or performance of this product, please consult with the local distributor or the manufacturer.

Adverse Reactions

A number of serious adverse reactions have been documented for cardiac catheterization procedures including pulmonary embolism, myocardial infarction, stroke, cardiac tamponade, and death. The following complications associated with cardiac catheterization have also been reported in the literature: vascular bleeding, local hematomas, thrombosis, AV fistula, pseudoaneurysm, thromboembolism, vasovagal reactions, cardiac perforation, air embolism, arrhythmias, valvular damage, pneumothorax and hemothorax.

English

Cordis Webster Electrophysiology Catheter: Fixed Curve

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THERE IS NO EXPRESS OR IMPLIED WARRANTY,
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WARRANTY OF MERCHANTABILITY OR FITNESS FOR A
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 Sterilizzato con ossido di etilene.
 Esterilizado con óxido de etileno.
 Gesteriliseerd met ethyleenoxidegas.
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 Se vedlagte brugsanvisning.
 Katso mukana ole via käyttöohjeita.
 Consulte as instruções inclusas soore o Instruções de Uso.
 Se bifogad bruksanvisning.
 Δείτε τις εσωκλειδμενες Οδηγίες Χρήσης
 同封の使用方法を参照。



For one use only.
 A usage unique.
 Nur zum Einmalgebrauch.
 Da usare una volta sola.
 Para un solo uso.
 Voor eenmalig gebruik.
 Kun til engångsburg.
 Kertakäyttöinen.
 Apenas para uma única utilização.
 Endast för engångsbruk.
 Για μια μόνο χρήση.
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Cordis Webster Electrophysiology Catheter: Deflectable Tip

- **STERILE.** Sterilized with ethylene oxide gas.
- **For single use only.**
- **Do not use if the package is open or damaged.**

Catheter Description

The Cordis Webster deflectable tip electrode catheter has been designed to facilitate electrophysiological mapping of the heart. The catheter has a high-torque shaft with a deflectable tip section containing an array of platinum electrodes that can be used for stimulation and recording. Several tip configurations are available. (Standard curve types are identified by a color band on the shaft near the proximal end - see catalog.)

Tip deflection is controlled at the proximal end by a tubular handpiece in which a piston slides. When the piston is pushed forward with the thumbknob, the tip is deflected (curved). When the piston is pulled back, the tip straightens. The high-torque shaft allows the plane of the curved tip to be rotated to facilitate accurate positioning of the catheter tip at the desired site.

The catheter interfaces with standard recording equipment via interface cables with the appropriate connectors.

CONSULT THE LOCAL DISTRIBUTOR OR MANUFACTURER FOR THE APPROPRIATE INTERFACE CABLES.

Indications

The catheter is indicated for electrophysiological mapping of cardiac structures; i.e., stimulation and recording only.

Contraindications

The Cordis Webster deflectable tip electrophysiology catheter has not been shown to be safe and effective for electrical ablation or for use in the coronary vasculature other than the coronary sinus ostium.

Use of the catheter may not be appropriate for patients with prosthetic valves. A relative contraindication for cardiac catheter procedures is active systemic infection.

Precautions

Do not attempt to operate the Cordis Webster deflectable tip electrophysiology catheter prior to completely reading and understanding these directions for use. Store in a cool, dry place; the sterile packaging and catheter should be inspected prior to use. Do not resterilize and reuse.

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

Careful catheter manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade. Catheter advancement and placement should be done under fluoroscopic guidance. Do not use excessive force to advance

or withdraw the catheter when resistance is encountered.

Always pull the thumbknob of the catheter back before insertion or withdrawal to assure that the catheter tip assumes its original shape.

Before use, make sure the small vent hole at the connector end of the handpiece is patent. If clogged, air may be forced into the catheter lumen and into the bloodstream.

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

Warnings

Cardiac catheterization procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as increased risk for somatic and genetic effects, to both patients and laboratory staff due to the x-ray beam intensity and duration of the fluoroscopic imaging. Cardiac catheterization should only be performed after adequate attention has been given to potential radiation exposure associated with the procedure, and steps taken to minimize this exposure. Careful consideration must therefore be given for the use of this catheter in pregnant women.

- Do not immerse the proximal handle or cable connector in fluids; electrical performance could be affected.
- Do not expose the catheter to organic solvents such as alcohol.
- Do not autoclave the catheter.

"Use By" Date

Use the device prior to the "Use By" date on the package label.

Suggested Directions for Use

- Remove the catheter from its package and place it in a sterile work area. Create a vascular access in a large central vessel using aseptic techniques and insert the catheter.
- Connect the interface connectors to the appropriate recording equipment.
- Confirm that the thumbknob is pulled back completely before insertion. Advance the catheter to the area of the endocardium under investigation. Use both fluoroscopy and electrograms to aid in proper positioning. Adjust the radius of curvature as necessary by manipulating the thumbknob. Pushing the thumbknob forward causes the catheter tip to bend (curve); when the knob is pulled back, the tip straightens.
- Prior to removal of the catheter, confirm that the thumbknob has been pulled back completely. Remove the catheter and dispose it in an appropriate manner. Do not resterilize and reuse.
- If there are any questions regarding the use or performance of this product, please consult with the local distributor or the manufacturer.

Cordis Webster Electrophysiology Catheter: Deflectable Tip

Adverse Reactions

A number of serious adverse reactions have been documented for cardiac catheterization procedures including pulmonary embolism, myocardial infarction, stroke, cardiac tamponade, and death. The following complications associated with cardiac catheterization have also been reported in the literature: vascular bleeding, local hematomas, thrombosis, AV fistula, pseudoaneurysm, thromboembolism, vasovagal reactions, cardiac perforation, air embolism, arrhythmias, valvular damage, pneumothorax and hemothorax.

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Biosense Webster

Diagnostic / Ablation Deflectable Tip Catheter

INSTRUCTIONS FOR USE

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Biosense Webster Diagnostic/Ablation Deflectable Tip Catheter

INSTRUCTIONS FOR USE

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

1. DEVICE DESCRIPTION

The Biosense Webster Diagnostic/Ablation Deflectable Tip Catheter is a multi-electrode device which provides electrophysiological mapping of the heart and transmits radio frequency (RF) current to the catheter tip electrode for ablation purposes. For ablation, the catheter is used in conjunction with a compatible RF generator and a dispersive pad (reference electrode). Both temperature sensing and non-temperature sensing braided and standard non-braided tip models are available.

The catheter has a high-torque shaft with a deflectable tip section containing an array of platinum electrodes. All electrodes may be used for recording and stimulation, but only the tip electrode may be used to deliver RF energy from the generator.

Tip deflection is controlled at the proximal end by a tubular handpiece in which a piston slides; a thumb knob on the piston controls piston travel. The plane of the curved tip can be rotated and the shape of the curve depends on the deflectable tip length. Eleven different curves, designated "A" through "D", posteroseptal D, "E" through "H", "J" and "K" (from 1.5" to 4.0" radius) are available. The catheter interfaces with standard recording equipment and a compatible RF generator via accessory extension cables with the appropriate connectors.

2. INDICATIONS

The Biosense Webster Diagnostic/Ablation Deflectable Tip Catheter is indicated for cardiac electrophysiological mapping and for use with a compatible RF generator (see section 11.5) in adults and children 4 years of age and older for:

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

3. CONTRAINDICATIONS

Do not use this device;

- in patients with active systemic infection;

- via the transseptal approach in patients with left atrial thrombus or myxoma, or interatrial baffle or patch;
 - via the retrograde transaortic approach in patients with aortic valve replacement.
- In addition to the above, do not use the 8 Fr braided-tip catheter:
- in children or in the retrograde approach to the left-sided accessory pathways due to the additional braiding in the catheter and its larger shaft size.

4. WARNINGS

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

Pregnancy -- Careful consideration should be given to the use of this device in pregnant women.

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

Stroke or myocardial infarction may occur in patients undergoing **left-sided ablation procedures**. Patients should be closely monitored during the post-ablation period for clinical manifestations of embolic events.

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

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

To reduce the risk of brachial plexus injury, physicians are advised to position the patient's arms inferiorly in the normal position with the hands down by the hips as opposed to superiorly.

5. PRECAUTIONS

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

Do not attempt to operate the Biosense Webster Diagnostic/Ablation Deflectable Tip Catheter or the RF generator prior to completely reading and understanding the applicable directions for use.

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

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

5.1 Catheter Compatibility

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

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

5.2 Handling and Sterilization

SINGLE USE ONLY. Observe "Use By" Date. Sterilized with ethylene oxide gas.

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

Catheter damage may occur due to

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

5.3 Environmental and EMI

Catheter materials are not compatible with magnetic resonance imaging (MRI).

During ablation procedures, this catheter is used in conjunction with an RF generator. Electromagnetic interference (EMI) produced by the radiofrequency (RF) generator during the delivery of RF power may adversely affect the performance of other equipment.

5.4 Precautions During Catheter Use

The patient should not contact grounded metal surfaces. 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 (μA) under any circumstances.

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

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

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

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

5.5 Precautions during Ablation

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

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

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

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

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

Discontinue ablation immediately and replace catheter if tip temperature fails to rise during ablation (temperature sensing model).

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

6. ADVERSE EVENTS

Note: The adverse events in the following summary were observed in a clinical study involving only the use of the standard Diagnostic/Ablation Deflectable Tip catheters (A-F curves and 4mm tip electrode) without braiding in the tip. The braided-tip catheter with a 5mm tip electrode and additional curves (posteroseptal D and extended reach) have not been tested in a clinical trial. The adverse events indicated in this summary may not reflect clinical experience with the braided-tip catheter models.

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

A total of 938 patients were treated in the clinical studies with the Biosense Webster Catheter models. This safety data base included 755 patients treated in the Thermocouple Study including both temperature and non-temperature sensing catheter models and 183 patients treated in the Thermistor Study. The major complication rate for patients treated in the Thermocouple Study was 1.5% (11/755) and 4.9% (9/183) in the Thermistor Study. The difference (3.5%) has a 95% confidence interval of -0.1% to 6.4% (by normal approximation with continuity correction). Results in Tables 1 and 2 reflect the adverse event rates for the two studies combined.

One patient died about 36 hours after transseptal puncture for left heart ablation. The investigational catheter was not used to deliver energy in this patient.

A second patient died approximately one month after undergoing an AV node ablation. Although an exact cause of death was not determined, the patient had a history of congestive heart failure, diabetes, and advanced renal insufficiency. He had also been diagnosed with long standing dilated cardiomyopathy with advanced Class III symptoms. The death was determine to be unrelated to the investigational device or the procedure.

6.1 Observed Adverse Events

Table 1 is a summary of the observed adverse events and Table 3 lists the fluoroscope time. Twenty (20) patients reported a major device-or procedure adverse event defined as heart block requiring pacemaker or other adverse event requiring medical intervention or prolonged hospitalization. The 20 events included complete heart block in 10 patients (9 requiring a pacemaker), four developed pericardial tamponade, one transient ischemic event, one patient with chronic obstructive lung disease requiring intubation, one deep vein thrombosis, one Muhitz I AV block, one pericarditis, and one loss of capture in a ventricular pacing lead.

Approximately one fifth (21%) of patients reported one or more minor adverse events including dizziness, dyspnea, palpitations, chest pain, gastrointestinal symptoms, vision abnormalities, edema, pseudoaneurysm and claudication.

Table 1. Observed Adverse Events

Categories are mutually exclusive, All patients treated with Biosense Webster catheter

Adverse Event	%	#	95% Confidence Interval	
Minor	21%	(197/938)	18.4%	23.8%
Major	2.1%	(20/938)	1.2%	3.2%
Death	0.21%	(2/938)	0.03%	0.89%

* Confidence intervals by exact (binomial) method

Table 2. Fluoroscopy time

All patients treated with fluoroscopy time measurement (N=580)

Catheter	Indication	Fluoroscopy Time (min) mean \pm SD (range)
Non-Temperature	WPW	36 \pm 37 (1, 248)
Non-Temperature	AVNRT	23 \pm 21 (2, 255)
Temperature-Sensing	WPW	44 \pm 41 (1, 223)
Temperature-Sensing	AVNRT	24 \pm 22 (1, 129)

6.2 Potential Adverse Events

Note: The following potential adverse events are applicable to all catheterization and ablation procedures in general and are not dependent on catheter type.

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

Catheterization/catheter procedure related:

- air embolism
- arrhythmias
- AV fistula
- cardiac perforation
- hemothorax
- pneumothorax
- pseudoaneurysm
- tamponade
- thrombi
- thromboembolism

- thrombosis
- valvular damage
- vascular bleeding/local hematomas
- vasovagal reactions

RF ablation related:

- cardiac perforation/tamponade
- cardiac thromboembolism
- cerebrovascular accident (CVA)
- chest pain/discomfort
- complete heart block
- coronary artery dissection
- coronary artery spasm
- coronary artery thrombosis
- pericarditis
- transient ischemic attack (TIA)
- valvular damage
- ventricular tachyarrhythmia

7. CLINICAL STUDIES

Note: The following clinical study summary involves experience only with the standard Diagnostic/Ablation Deflectable Tip catheters with (A-F curves and 4mm tip electrode) without braiding in the tip. The braided-tip catheter with a 5mm tip electrode and additional curves (posteroseptal D and extended reach) have not been tested in a clinical trial. The data in this summary may not reflect clinical experience with the braided-tip catheter models.

The Biosense Webster Diagnostic/Ablation Deflectable Tip Catheter was studied in 938 patients including the Medtronic CardioRhythm Atakr RF generator (N=171), the EPT RF generator (N=183), and an investigational generator (N=584). The overall acute success rate for patients treated in the Thermocouple Study was 96% (164/171) and 98% (174/178) in the Thermistor Study. The difference (2%) has a 95% confidence interval of -2.4% to 5.0% (by normal approximation with continuity correction). Tables 3 and 4 describe the patient age and the acute success from the two studies combined.

RF ablation was intended to eliminate AV accessory pathways associated with tachycardia due to WPW syndrome, AVNRT, or creation of complete AVN block in patients with difficult to control ventricular response to an atrial arrhythmia.

Methods: In two separate prospective, multicenter (six and eight centers), open label studies, success was defined as the inability to induce the arrhythmia for WPW and AVNRT patients, and complete heart block for AVN patients. The closed loop temperature control mode was used in

the majority of patients (versus temperature sensing or power control mode) at the investigators' discretion.

Results: Of the 365 patients enrolled, 354 patients underwent ablation and provide clinical data for assessment of safety and effectiveness. Slightly more than half (59%) of the patients were female. Table 3 describes the patient population by indication and age.

Table 3. Enrollment and patient age by Indication

All patients treated with Medtronic Atakr and EPT generators (N=354)

Indication for treatment	Number of patients		Age of patients (years)	
	%	#	Mean	Range
AVNRT ^{a, b}	55%	(193/354)	47	11, 84
WPW ^b	32%	(112/354)	35	10, 82
AVN Ablation	12%	(44/354)	67	34, 93
Other	1%	(5/354)	38	23, 50
Total	100%	(354/354)	45	10, 93

^a - Both WPW and AVNRT were present in 7 patients included in the AVNRT category

^b - One non-protocol RF ablation system was used in addition to the investigational system in 7 patients (2 for WPW and 5 for AVNRT)

The five "Other" non-protocol arrhythmias treated included focal atrial tachycardia (N=4) and one AVN modification. A total of 2557 RF applications were delivered with a mean number of applications of 9.0 (range 1-42). Table 4 summarizes the acute success by indication.

Table 4. Procedure Success by Indication

All patients treated with Medtronic Atakr and EPT generators (N=354)

Indication	%	#	95% Confidence Interval	
AVNRT	97%	(187/193)	94%	100%
WPW	96%	(108/112)	93%	100%
AVN Ablation	100%	(44/44)	92%	100%
Other	80%	(4/5)	28%	100%
Total	97%	(344/354)	95%	99%

Serious, device-related complications were reported for twenty (20) patients, including complete heart block in 10 patients (9 requiring a pacemaker), four developed pericardial tamponade (two caused by non-investigational diagnostic catheters), one transient ischemic event, intubation required in one patient with chronic obstructive lung disease not considered related either to the device or to the procedure, one deep vein thrombosis not considered related to the device, one Muhtiz I AV block, one post-procedure pericarditis not considered related to the device, and one loss of capture in a ventricular pacing lead.

RETROSPECTIVE SUB-ANALYSIS OF PEDIATRIC PATIENTS

The Diagnostic/Ablation Deflectable Tip Catheters, both thermocouple and thermistor models without braiding in the tip, have undergone extensive clinical testing under the thermocouple and thermistor investigational studies described earlier. The patient population for both of these studies included patients aged 10 years and older. A summary of the pediatric sub-population data is provided below.

A total of 61 pediatric patients were enrolled in the two studies. Five (5) patients were discontinued prior to ablation, thus 56 patients, 23 female and 33 male, with an average age of 16 ± 2 years, underwent an ablation procedure. Three of the patients were treated with a non-protocol RF ablation system and were thus categorized as "Supplemental" patients. Four patients had undergone a previous ablation procedure. The following table describes the patients by arrhythmia:

Table 5. Enrollment and patient age by Indication

All patients treated with Medtronic Atakr and EPT generators (N=56)

Indication for treatment	Number of patients		Age of patients (years)	
	%	#	Mean	Range
AVNRT ^{a,b}	30%	(17/56)	16	11, 20
WPW ^b	70%	(39/56)	16	10, 21
AVN Ablation	0%	(0/56)	N/A	N/A
Other	0%	(0/56)	N/A	N/A
Total	100%	(56/56)	16	10, 21

^a - Both WPW and AVNRT were present in 1 patient included in the AVNRT category

^b - One non-protocol RF ablation system was used in addition to the investigational system in 3 patients (all WPW)

For all patients, total radiofrequency (RF) applications per patient ranged from 1 to 34, with a mean number of 7.4 ± 6.4 applications per patient.

Table 5. Procedure Success by Indication

All patients treated with Medtronic Atakr and EPT generators (N=56)

Indication	%	#	95% Confidence Interval	
AVNRT	100%	(17/17)	81%	100%
WPW	97%	(38/39)	87%	100%
AVN Ablation	N/A	N/A	N/A	N/A
Other	N/A	N/A	N/A	N/A
Total	98%	(55/56)	90%	99%

Two patients required greater than 25 applications. Patient BCHM018 had 27 applications for an AV accessory pathway and was the lone failed ablation. Patient HOPM010 underwent 34 RF applications to successfully treat AVNRT.

Three patients experienced a recurrence of their arrhythmia within the 1-2 month follow-up period (3/56, 7%).

One complication was reported in the 56 pediatric patients undergoing RF ablation (1.8%, 1/56). Patient HOPM034 experienced a moderate pneumothorax that was treated conservatively and resolved without sequelae. This was considered an anticipated complication.

8. INDIVIDUALIZATION OF TREATMENT

8.1 *Antiplatelet or Anticoagulation Use*

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

Left Heart Insertion

Note: Do not use the 8 Fr braided-tip catheter in the retrograde approach to left-sided accessory pathways due to the additional braiding in the catheter and its larger shaft size.

During the clinical study, systemic anticoagulation before intracardiac RF catheter ablation in the left heart was typically an initial intravenous heparin bolus of 3000 - 10,000 Units. Anticoagulation was maintained with an intravenous heparin drip or additional periodic intravenous boluses of heparin as necessary. Oral anticoagulation therapy may have been administered prior to ablation.

Investigators in the clinical trials typically prescribed long term (one to three months) anticoagulation therapy of one aspirin tablet daily, for patients undergoing left heart ablation, unless contraindicated.

Right Heart Insertion

During the clinical study, systemic anticoagulation was variable for patients undergoing intracardiac RF catheter ablation in the right heart. If used, systemic anticoagulation in the clinical study before ablation was typically an initial intravenous heparin bolus of 3000 - 10,000 Units followed by intravenous heparin drip or additional periodic intravenous boluses at a rate of 1000 Units/hour for the duration of the ablation procedure. Oral anticoagulation only, or no anticoagulation prior to ablation was also performed.

Long term anticoagulation therapy for patients undergoing right heart ablation was variable. Long term therapy of one aspirin tablet daily for patients undergoing right heart ablation may or may not be indicated.

8.2 Choosing Temperature or Power Control Mode

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

8.3 Specific Patient Populations

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

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

9. PATIENT COUNSELING INFORMATION

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

10. HOW SUPPLIED

The Biosense Webster Diagnostic/Ablation Deflectable Tip Catheter is available with and without temperature sensing with the following options:

Eleven curve types:	A, B, C, D, posteroseptal D, E, F, G, H, J, and K
Tip electrode:	4 mm tip: large (straight) or grooved (concave); 5 mm tip: large straight (available in 7 and 8 Fr braided-tip temperature sensing catheter models only)
Connector type:	Redel 10-pin connector (temperature sensing model) Nexus plug (non-temperature sensing model)
Spacing:	Standard 2-5-2 spacing (center to center measurement of ring electrode spacing)

10.1 Packaging

The Biosense Webster Diagnostic/Ablation Deflectable Tip Catheter is supplied STERILE. The catheter is placed into a thermoformed plastic tray designed to retain the catheter from movement. The tray is sealed with a Tyvek®/plastic laminate lid which in turn is placed into a plastic header pouch with a Tyvek header. Both are heat sealed.

10.2 Storage

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

10.3 Shelf-Life

Accelerated aging tests support an expiration date of three years.

11. DIRECTIONS FOR USE

11.1 Physician Training

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

11.2 Detailed Device Description

The Biosense Webster Diagnostic/Ablation Deflectable Tip Catheter and Biosense Webster interface cable are used in conjunction with a compatible RF generator which has been shown to be safe and effective for cardiac ablation and a dispersive pad (reference electrode). The catheter is available in both standard and braided-tip models with or without temperature sensing. The 5mm tip model is only available with temperature sensing.

The temperature sensing model of the catheter is identical to the non-temperature sensing model with the addition of a temperature sensor and connecting wires. The braided-tip model incorporates a stainless steel braid in the tip of the catheter for added lateral stability. This braid is inside of the catheter and is not visible to the user. A schematic diagram of the non-temperature sensing and temperature sensing models of the catheter and their connection to the compatible RF generator appears on the following page (Figure 1).

The distal tip of the Biosense Webster deflectable catheter is available with one 4mm tip electrode with straight or concave walls or a 5mm tip electrode with straight walls, and three smaller ring electrodes. The spacing between the tip electrode and first ring electrode is fixed at 2mm. The standard spacing between the first ring electrode and second ring electrode is 5mm; the standard spacing between the second ring electrode and third ring electrode is 2mm. All four electrodes may be used for recording and stimulation, however, only the tip electrode can be used to deliver radiofrequency current to the desired ablation site.

The distal tip of the catheter can be curved by advancing or retracting an internal "puller" wire which is controlled by the handpiece at the proximal end of the catheter. A piston in the handpiece is attached to the puller wire and can be moved via a thumb-knob. When the thumb-knob is pushed forward, the catheter tip bends; when the thumb-knob is pulled back, the tip straightens. The shape of the curve depends on the deflectable tip length (1.5"-4.0") and the location of the puller wire anchor (proximal or distal) in the deflectable tip. Eleven different curves, designated A, B, C, D, posteroseptal D, E, F, G, H, J, and K (see Figures 2, 3 and 4).

The catheter body is a single lumen tubing with a dual lumen tip portion. Conductor wires from the electrodes pass through the handle and terminate in a Redel 10-pin connector (temperature-sensing model) or a Nexus plug (non-temperature sensing model).

FIGURE 1: Schematic of the Biosense Webster Diagnostic/Ablation Deflectable Tip Catheters, Interface Cables and Compatible RF Generators

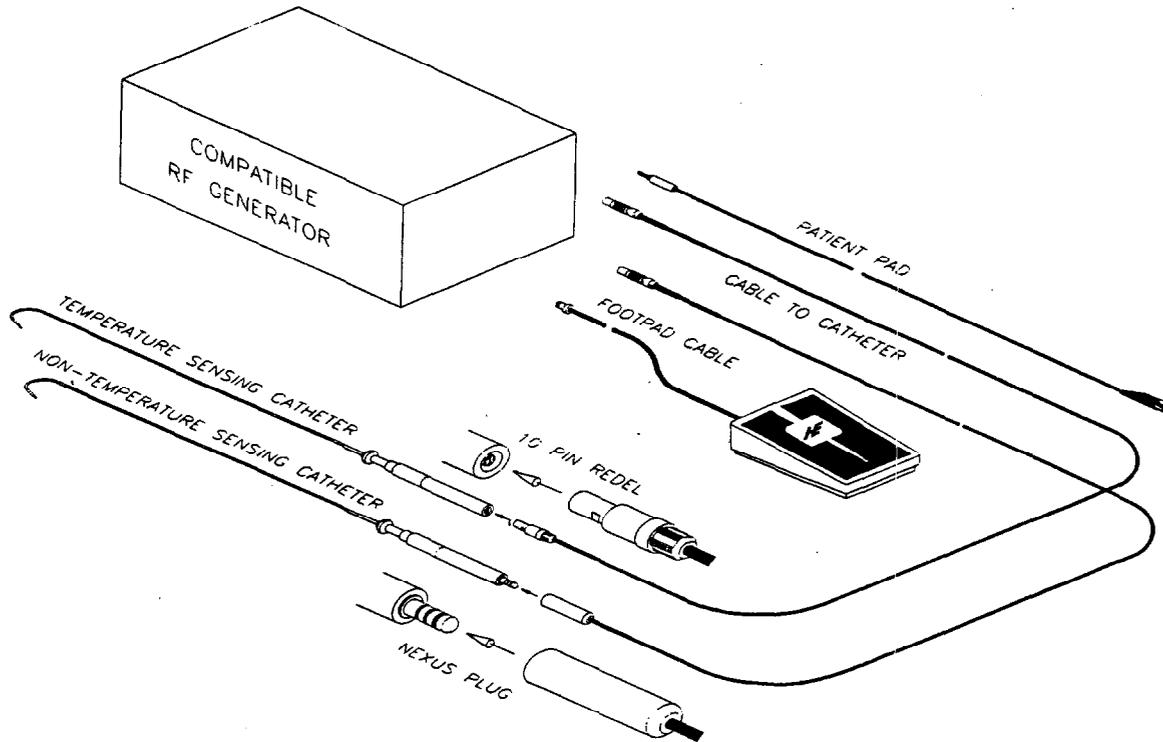


FIGURE 1: Schematic of the Biosense Webster Diagnostic/Ablation Deflectable Tip Catheters, Interface Cables and Compatible RF Generators (Continued)

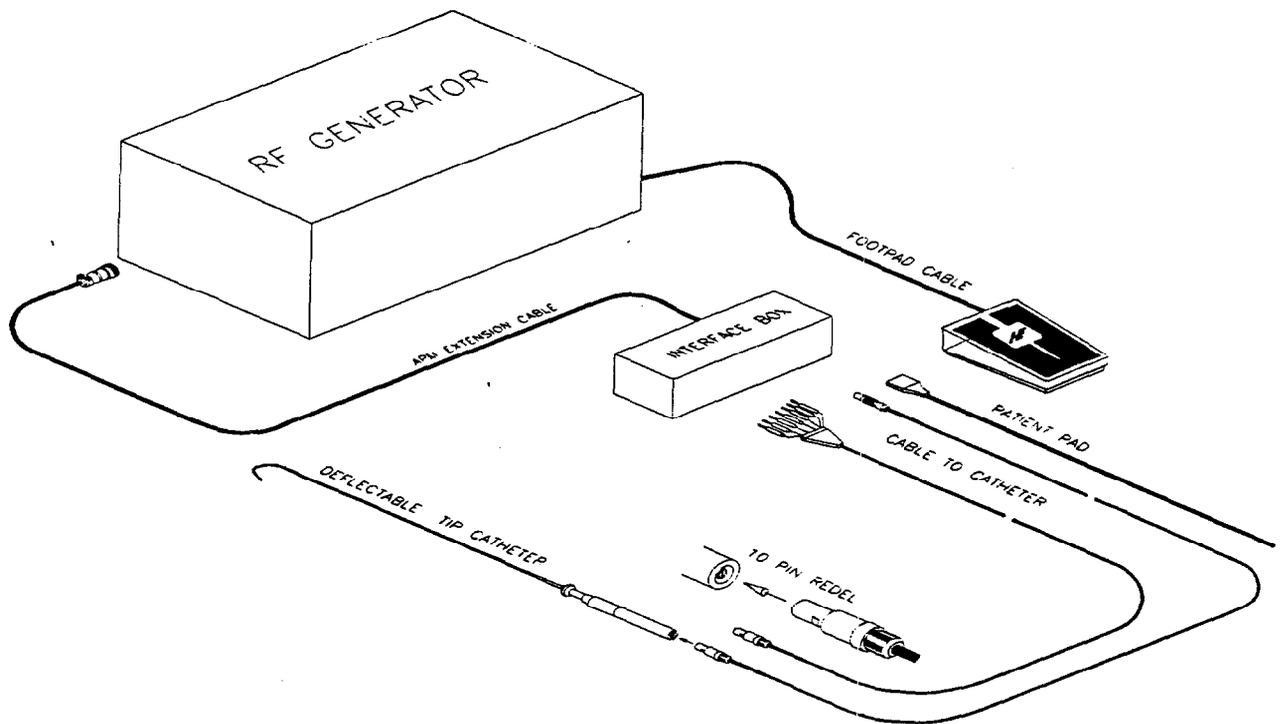


FIGURE 1: Schematic of the Biosense Webster Diagnostic/Ablation Deflectable Tip Catheters, Interface Cables and Compatible RF Generators (Continued)

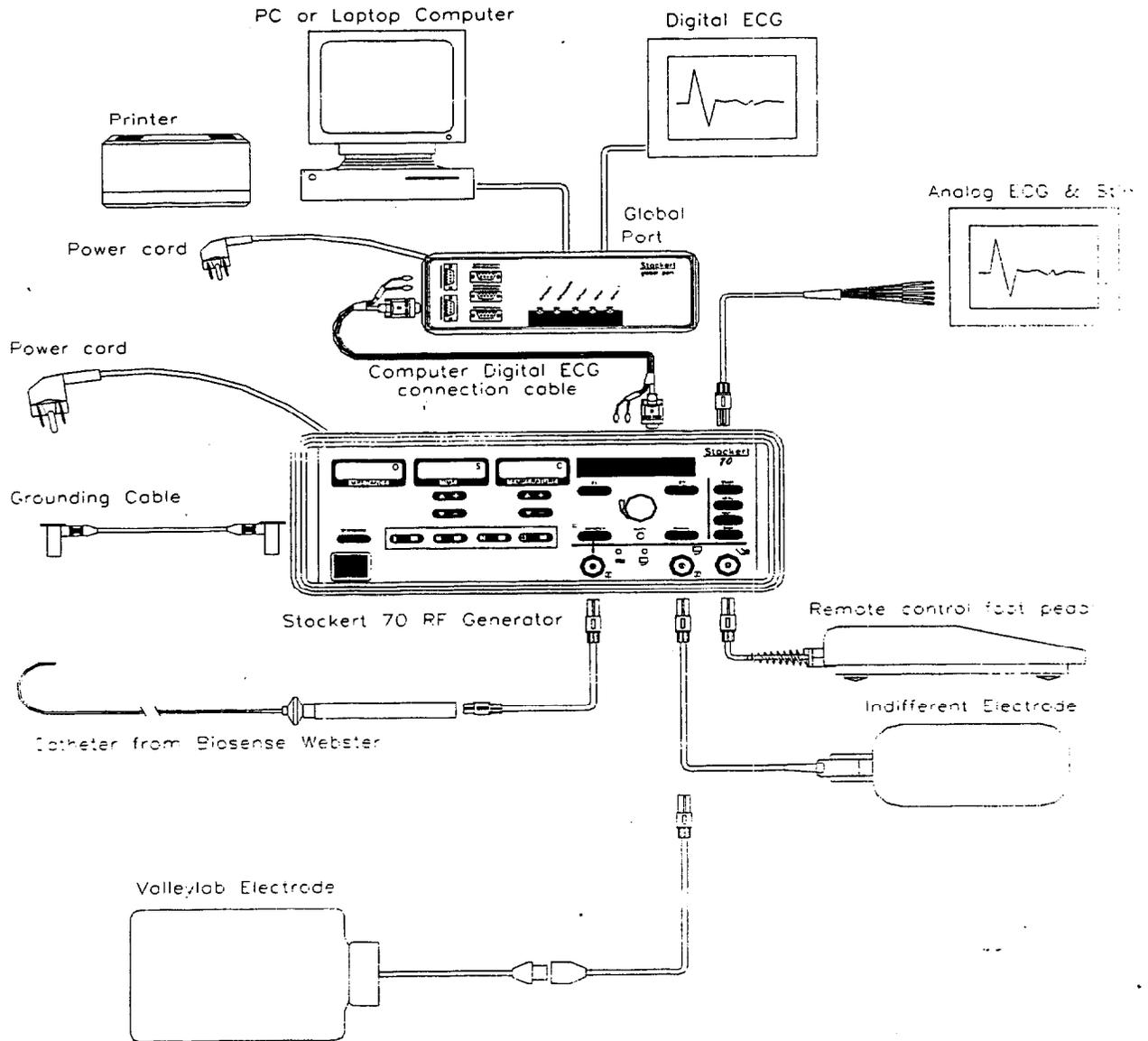
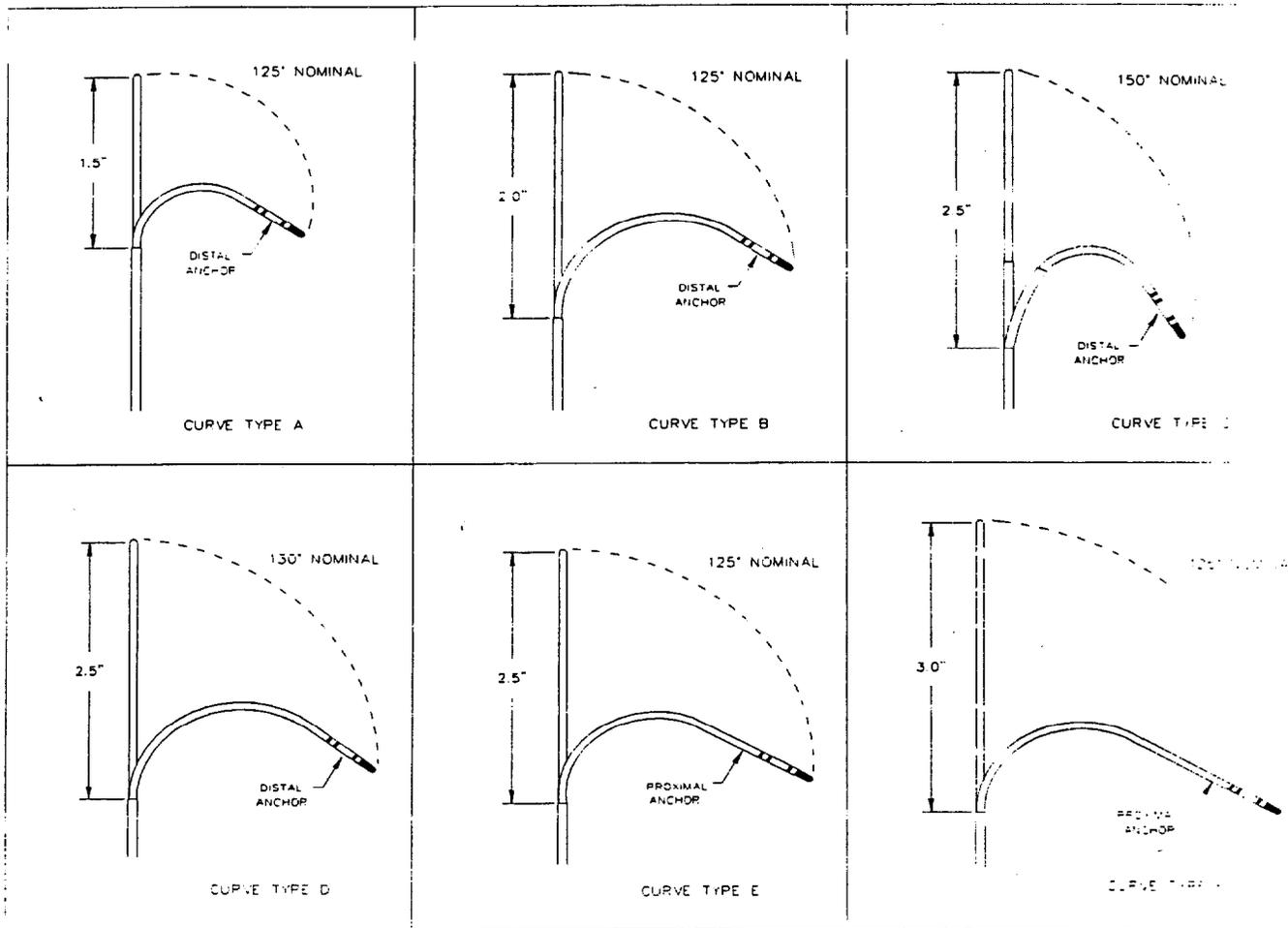


FIGURE 2: Deflectable Tip Catheter Curve Types



Note: Above deflection angles for 7 and 8 F; 6 F deflection angle is 90° minimum for all curves.

FIGURE 3: Deflectable Tip Catheter Curve Type – Posteroseptal D

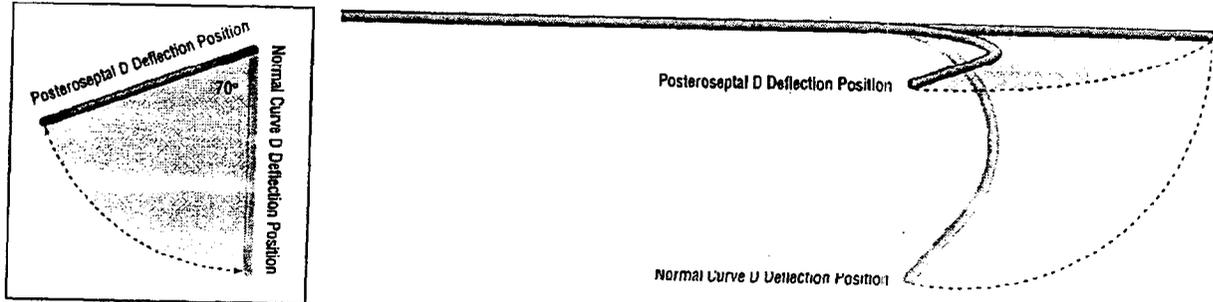
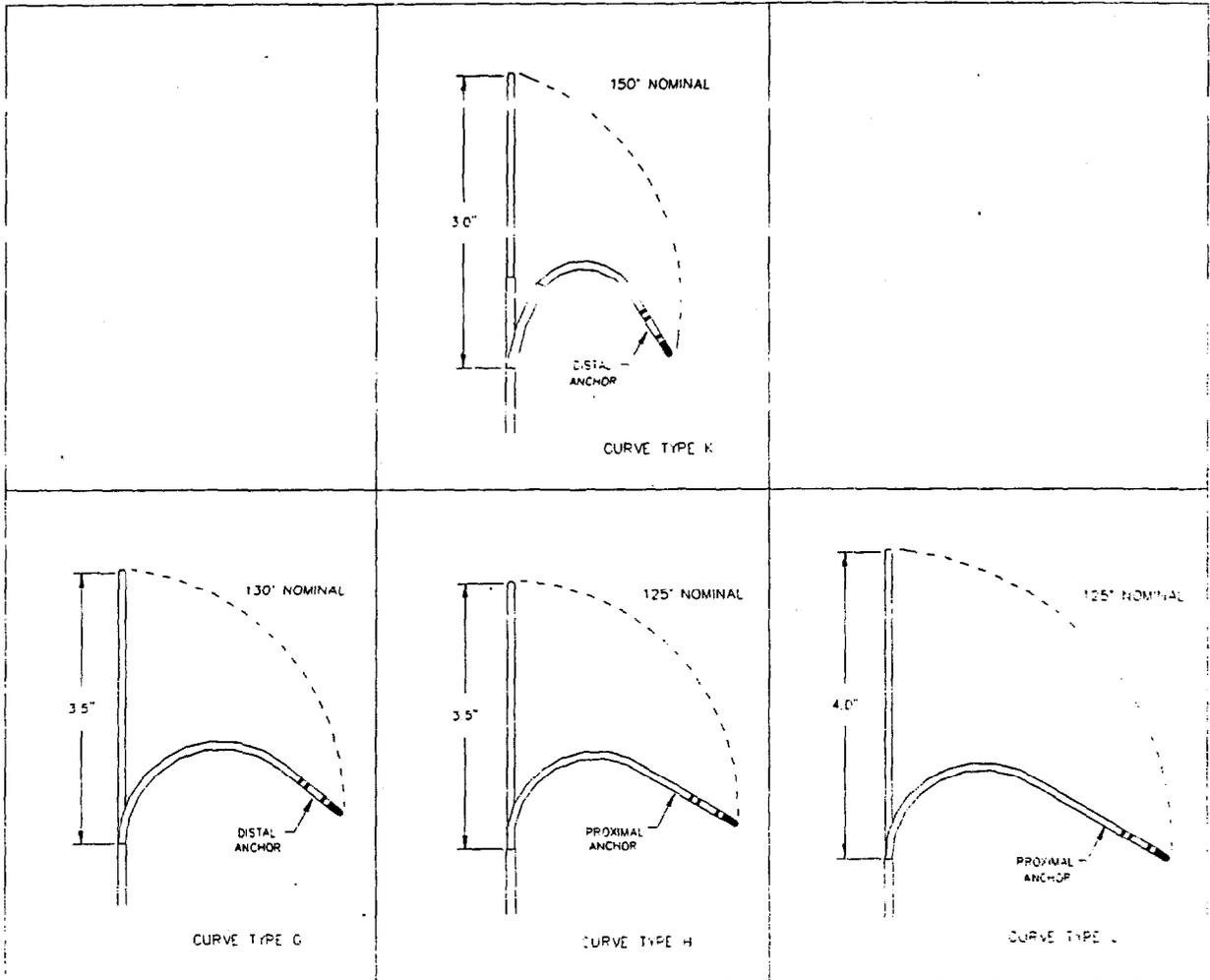


FIGURE 4: Deflectable Tip Catheter Curve Types – Extended Reach



Note: Above deflection angles for 7 and 8 F catheter models.

11.3 Handling and Preparation

Using aseptic technique, remove the catheter from its package and place it in a sterile working area. Inspect the catheter carefully for electrode integrity and overall condition.

11.4 Use During the Mapping and Ablation

1. Create a vascular access in a large central vessel using aseptic techniques and insert the catheter.
2. Connect the catheter to the recording equipment and/or a compatible RF Generator using the appropriate interface cables.
3. Advance the catheter to the area of the endocardium under investigation. Use both fluoroscopy and electrograms to aid in proper positioning.
4. The catheter tip can be deflected to facilitate positioning by using the thumb knob to vary tip curvature. Pushing the thumb knob forward causes the catheter tip to bend; when the knob is pulled back, the tip straightens.
5. When it has been determined that the tip electrode is in stable contact with the intended ablation site, the catheter tip electrode connection must be switched from the recording equipment to the RF generator in preparation for delivery of RF current.
6. RF current may be re-applied to the same or alternate sites using the same catheter.

11.5 Compatible RF Generators and Accessories

The Biosense Webster Diagnostic/Ablation Deflectable Tip Catheter should be used only with an RF generator which has been shown to be safe and effective for cardiac ablation.

Specifications for Compatible RF Generators:

PARAMETER	SPECIFICATION	
Thermometry	Thermocouple	Thermistor
Temperature Limit, maximum	100°C	95°C
Modes: (must operate in all 3 modes)	1. Temperature Control 2. Temperature Monitoring 3. Power Control	
Maximum Output Power	50 Watts	
RF output frequency	450 kHz - 550 kHz	
Impedance cut-off	high: 250 Ω low: 40 Ω	high: 300 Ω low: 50 Ω

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

Specifications for Accessories:

Use appropriate Biosense Webster accessory cable to connect the Biosense Webster Diagnostic/Ablation Deflectable Tip catheter to a compatible RF generator.

PARAMETER	SPECIFICATION
Connectors	Lemo 10 pin male to Redel 10 pin male (thermocouple interface) Lemo 10 pin male to Nexus plug female (non-thermocouple interface) Redel 9 pin male to Redel 10 pin male (thermistor interface) 7 tip pin to Redel 10 pin male (thermistor interface) Redel 9 pin male to Nexus plug female (non-thermistor interface) Redel 10 pin male to Redel 10 pin male (thermocouple/thermistor interface)
Length	6 ft. (183 cm) and 10 ft. (305 cm)
Model numbers	C6-MR10/MLTC-S (temperature sensing interface - thermocouple) C6-FP/ML-S (non-thermocouple interface) C6-MR10-EPTR-S (temperature sensing interface - thermistor) C6-MR10/EPT-S (temperature sensing interface - thermistor) C6-FP/EPTNT-S (non-thermistor interface) C6-MR10/MSTK-S (temperature sensing interface – thermocouple and thermistor) C10-MR10/MSTK-S (temperature sensing interface – thermocouple and thermistor)

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