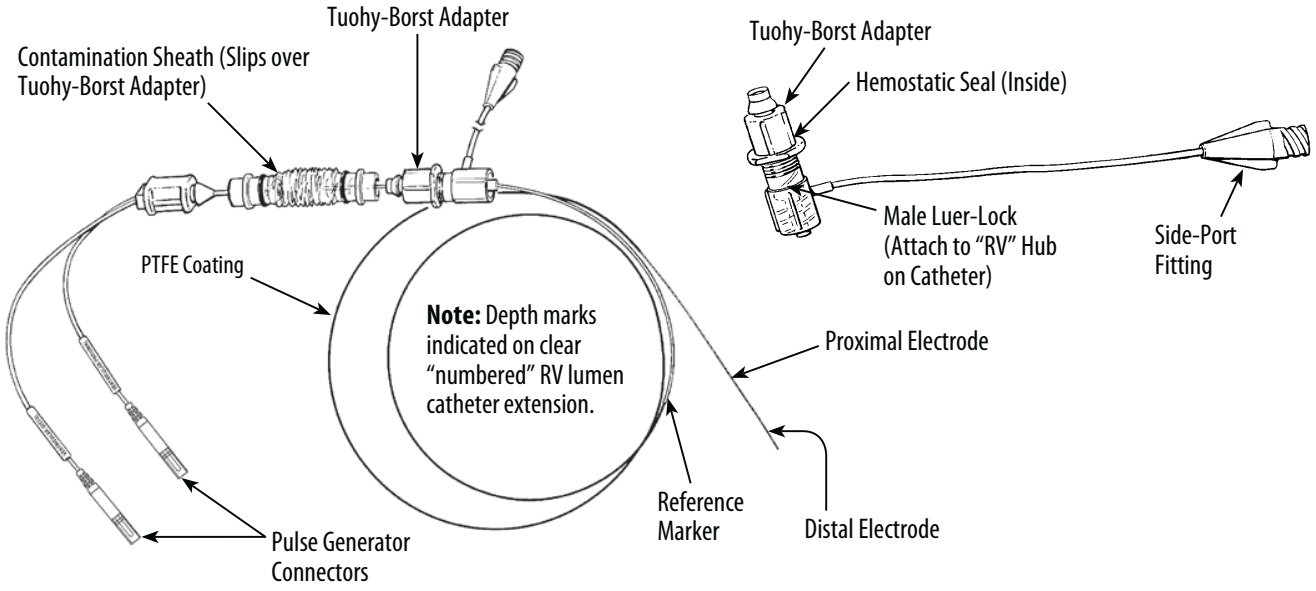
Edwards Lifesciences

Chandler Transluminal V-Pacing Probe
D98100



Model D98100 Chandler Transluminal V-Pacing Probe

DC2010-26
DC2154-1

For Single Use Only

For figures 1 through 8 please refer to pages 5 and 6.

For use with Swan-Ganz Paceport (Model 931F75) or A-V Paceport (Model 991F8) catheters for ventricular pacing only.

Developed in collaboration with John P. Chandler, M.D., Assistant Clinical Professor of Medicine, Yale School of Medicine, New Haven, CT.

Concept/Description

The Model D98100 Chandler transluminal V-Pacing probe, when used with any Swan-Ganz Paceport (Model 931F75) or A-V Paceport (Model 991F8) catheter, is used for temporary ventricular pacing. The probe can be inserted with or without the aid of fluoroscopy. The probe can also be used for intraventricular ECG detection (during placement).

The Chandler transluminal V-Pacing probe is recommended for use *in situ* for up to 72 hours.

After the Paceport catheter is inserted and floated into the pulmonary artery with the right ventricular (RV) port (19 cm from the distal tip) properly placed 1 to 2 cm distal to the tricuspid valve, the pacing probe is inserted into the Paceport or A-V Paceport catheter's RV lumen and advanced into the ventricle for endocardial pacing.

The probe is a bipolar, coaxial, wire construction composed of a stainless steel round wire and a PTFE coated, coiled flat wire.

As part of the insertion procedure this product is used for ECG detection during placement, but is not intended for ECG monitoring.

Indications

The Chandler transluminal V-Pacing probe (a transluminal bipolar pacing probe) is a 2.4F probe indicated for transvenous temporary emergency pacing.

Contraindications

Although there are no absolute contraindications to the use of temporary endocardial pacing electrodes, relative contraindications may include patients with recurrent sepsis or with a hypercoagulable state where the electrode could serve as a focus for septic or bland thrombus formation.

Use of the probe is contraindicated in patients with small hearts where the RV port of the Swan-Ganz Paceport or A-V Paceport catheter cannot be placed into the right ventricle without spontaneously wedging the catheter in the pulmonary artery with the balloon deflated. Also, **the probe is not intended for use with any catheter except the Swan-Ganz Paceport or A-V Paceport catheter**.

These products contain metallic components. Do NOT use in a Magnetic Resonance (MR) environment.

Warnings

This device is designed, intended, and distributed for single use only. Do not re-sterilize or reuse this device. There are no data to support the sterility, nonpyrogenicity, and functionality of the device after reprocessing.

Do not modify or alter the product in any way. Alteration or modification may affect patient/ operator safety or product performance.

As part of the insertion procedure this product is used for ECG detection during placement, but is not intended for ECG monitoring.

Cautions

Clinicians using the device should be familiar with the device and understand its applications prior to use.

When handling indwelling leads, the terminal pins or exposed metal (on the product) are not to be touched nor be allowed to contact electrically conductive or wet surfaces, to avoid electrical shock to patient or clinician.

Insertion

The Paceport (Model 931F75) or A-V Paceport (Model 991F8) catheter can be inserted at the patient's bedside, usually without the aid of fluoroscopy, by continuous pressure monitoring from the distal and right ventricular lumens. A unipolar electrocardiogram can be recorded from the distal tip electrode by connection to a V lead of a properly isolated electrocardiograph.

Equipment

Warning: Compliance to IEC 60601-1 is only maintained when the catheter or probe (Type CF applied part, defibrillation proof) is connected to a patient monitor or equipment that has a Type CF defibrillation proof rated input connector. If attempting to use a third party monitor or equipment, check with the monitor or equipment manufacturer to ensure IEC 60601-1 compliance and compatibility with the catheter or probe. Failure to ensure monitor or equipment compliance to IEC 60601-1 and catheter or probe compatibility may increase the risk of electrical shock to the patient/operator.

1. Swan-Ganz Paceport (Model 931F75) or A-V Paceport catheter (Model 991F8)
2. Compatible percutaneous sheath hemostasis valve introducer tray, kit or single assembly.
3. Chandler Transluminal V-Pacing Probe, Model D98100
4. Ventricular demand external pulse generator
5. External pulse generator cable adapters
6. ECG recorder
7. Sterile flush system and pressure transducers
8. Bedside ECG and pressure monitor system

In addition, the following items should be immediately available if complications arise during catheter or probe insertion: antiarrhythmic drugs, defibrillator, and respiratory assist equipment.

Catheter Insertion and Placement

The catheter can be inserted using percutaneous technique cutdown through a jugular, subclavian, or antecubital vein. A protective catheter sheath is recommended to aid in maintaining sterility when repositioning of the catheter is necessary.

To facilitate subsequent insertion of the Chandler probe, insertion of the Paceport (Model 931F75) or A-V Paceport (Model 991F8) catheter is best accomplished by using two pressure transducers; one transducer is connected to the distal (PA) lumen, the other to the right ventricular (RV) lumen, which terminates 19 cm from the tip. The ideal placement of the RV port for probe placement is 1 to 2 cm distal to the tricuspid valve. A radiopaque marker is provided at the RV port to confirm port placement by X-ray or fluoroscopy. Refer to the Paceport or A-V Paceport catheter package insert for detailed instructions on insertion.

Advance the catheter into the pulmonary artery while continuously monitoring both PA and RV lumen pressures. When the catheter tip is at the wedge position, RV port location may vary according to heart size.

1. **Normal Size Hearts:** At the wedge position, the RV lumen shows RV tracing. Deflate the balloon. Pull the catheter back until the RV port is in the right atrium. Then readvance the catheter until the port is 1 to 2 cm distal to the tricuspid valve.

2. **Small Hearts:** The RV lumen shows a right atrial (RA) pressure tracing at the wedge position. Deflate the balloon. Advance the catheter slowly while closely monitoring the PA and RV lumen pressures until an RV pressure tracing is first obtained from the RV lumen. Continue to advance the catheter 1 to 2 cm distal to the tricuspid valve for optimal placement of the RV port.

   If RV port placement in the right ventricle results in spontaneous wedging, catheter repositioning is required. To insert the probe into the right ventricle, one can advance the probe a centimeter at a time after withdrawing the catheter a centimeter at a time until a pulmonary artery pressure tracing is seen continuously from the distal lumen.

   Warning: In some patients, the catheter might spontaneously wedge (with the balloon deflated) before positioning of the RV port in the right ventricle. Discontinue advancing the catheter. This pacing system is not suitable for use in these patients; however, the catheter can still be used for pressure monitoring, blood sampling, fluid infusion and cardiac output determinations. Do not attempt to insert the probe if the RV port is in the RA. Damage to the tricuspid valve may result.

   Always make certain that the RV port is inside the ventricle before inserting the probe.

3. **Enlarged Hearts:** Wedge position is not yet reached when the RV lumen shows an RV pressure tracing. Continue to advance the catheter to obtain a wedge pressure recording. Note the distance the catheter is advanced between the first RV pressure tracing from the RV lumen and wedge position. Deflate the balloon. Withdraw the catheter until an RA pressure is obtained from the RV lumen, then readvance the catheter until the RV port is 1 to 2 cm distal to the tricuspid valve. The catheter tip should be in the pulmonary artery. In these patients it may not be possible to obtain capture and wedge pressure measurements simultaneously.

   Warning: If the RV port is too distal, then the probe may exit the RV port pointed toward the RV outflow tract. This may result in poor thresholds, unstable pacing, and potential damage to the outflow tract and pulmonic valve.

Pacing Probe Insertion and Placement

Warning: Handle the probe using sterile technique. **Be certain that the probe is inserted only into the RV lumen (clear extension tube with orange Luer-lock hub).** Do not insert the probe into either the proximal (RA) or distal (PA) lumen.

Before inserting the probe make sure that the catheter portion outside the patient is not coiled, as this will make probe insertion difficult.

1. Verify RV lumen patency.
2. Connect the catheter's RV lumen hub to a pressure transducer and verify proper placement of the RV port (1 to 2 cm distal to the tricuspid valve) (See page 5, Fig. 1). To prevent catheter movement, secure the catheter at the insertion site.
3. Open the probe package and retract the probe tip into the Tuohy-Borst (T-B) adapter **by turning the carousel clockwise.**
4. Connect the T-B adapter to the orange RV lumen hub. Be careful not to damage the probe tip (See page 5, Fig. 2).
5. Advance the probe until its depth reference mark (black band) is placed at the zero mark on the clear extension tube of the RV lumen (See page 5, Fig. 3). Because of manufacturing tolerances, the tip of the probe is now between the RV port and a point 2 cm proximal to the port. The probe is ready to be advanced into the RV.

   Note: There may be some resistance as the probe passes through the hemostasis valve of the introducer, curves in the catheter at the subclavian-SVC junction and at the RV port. Resistance at any other point may indicate that

the catheter is kinked. Do not force the probe if resistance is met.

Precaution: The PTFE coating on the probe is a lubricating agent, not an electrical insulator. Do not allow the probe surface to come into contact with any line power equipment because of potential current leakage due to faulty ground, which can cause ventricular fibrillation. When not connected to the external pulse generator, the electrode pin connectors should remain protected.

6. Attach the distal end of the probe contamination sheath to the T-B adapter. Remove the probe and T-B adapter from the dispenser, and, to help maintain sterility of the probe, attach the other end of the sheath to the proximal end of the probe (See page 5, Fig. 4).

7. Connect the distal electrode to a V lead of a properly isolated electrocardiograph (See page 6, Fig. 5). Under continuous ECG monitoring, advance the probe several centimeters until ST segment elevation of the ECG indicates contact with the endocardium.

   Note: ST elevation is usually seen with the probe out 4 to 5 cm. If the probe is out more than 10 cm, the probe may be in the RV outflow tract. Pull the probe back to 4 to 5 cm and reposition in the RV apex.

8. Connect the distal and proximal electrodes to the negative and positive pulse generator terminals, respectively (See page 6, Fig. 6), and determine the pacing threshold. A threshold of 1.0 to 2.0 mA is generally an indication of proper electrode placement. An initial threshold greater than 5 mA indicates poor probe placement, possibly in the RV outflow tract. Withdraw the probe several centimeters and reposition the probe in the RV apex. Best pacing thresholds are obtained with the probe approximately 5 cm out of the RV port. Stable pacing cannot usually be obtained with the probe out less than 3 cm.

   Note: If transient multifocal PVCs or V tach persist during (or after) probe insertion, pull the catheter back 1 to 2 centimeters and advance the probe to the RV apex. (See **PVCs During/After Insertion**.)

   Notice: To facilitate a connection between the probe and pulse generator, a cable adapter may be required.

9. Firmly tighten the compression nut to secure the probe in place (See page 6, Fig. 7). Aspirate any air from the side port. Institute a continuous or intermittent heparinized flush through the side-port fitting of the T-B adapter.

10. Using a 3-way Luer-Lock stopcock, connect the side port of the T-B adapter to a continuous saline flush device. Using the 5 ml syringe provided, aspirate any air from the sideport, then flush the lumen (See page 6, Fig. 8).

    Note: When the probe is in the RV lumen, do not infuse solutions at a rate greater than 30 ml/hr because the solution may back up into the probe contamination sheath.

11. Obtain a chest x-ray film as soon as possible after insertion to document the initial placement.

MRI Information

MR Unsafe

The Chandler device is MR unsafe as the result of the device containing metallic components, which experience RF-induced heating in the MRI environment; therefore the device poses hazards in all MRI environments.

Complications

Loss of Capture

Loss of capture may occur due to inadvertent pulling of the probe off the endocardium, poor initial placement (probe in RV outflow tract), myocardial perforation, vigorous respirations, or patient movement. If the probe is pulled off the endocardium, is in the RV outflow tract, or has perforated the myocardium (see **Ventricular Perforation**), reposition the probe in the RV apex. Transient loss of capture after patient movement is corrected by placing the patient in a supine position and, if necessary, increasing the threshold or repositioning the probe.

PVCs During/After Probe Insertion

Transient multifocal PVCs or V tach may occur due to irritation of the endocardium by the probe tip. Additional probe advancement or catheter manipulation usually resolves the PVCs. If PVCs or V tach persist, pull the catheter back 1 to 2 cm and advance the probe toward the RV apex.

Inability to Wedge the Balloon

If placement required that the catheter be pulled back from initial wedge position, then it may not be possible to obtain wedge pressure upon balloon inflation. Monitor the PA diastolic pressure instead of wedge whenever possible. Intermittent pacing may occur following balloon inflation for wedging. However, capture is usually regained upon balloon deflation without increasing the pacing threshold. If wedging is required and pacing is no longer needed, advance the catheter to wedge position after turning the pulse generator off and withdrawing the probe completely into the catheter.

Inadvertent Atrial Pacing

Atrial pacing may result if the RV port is in the atrium rather than in the ventricle. In addition, atrial pacing may occur due to catheter or probe movement into the right atrium. Withdraw the probe completely into the catheter and advance the catheter's RV port into the ventricle. Readvance the probe into the ventricle.

Inadequate Sensing

Inadequate sensing of the demand pulse generator may occur if the probe is partially in the atrium. Reposition the probe in the RV apex to improve sensing after withdrawing the probe into the catheter and advancing the catheter 1 to 2 cm distal to the tricuspid valve.

Ventricular Perforation

Ventricular perforation has been reported with temporary transvenous pulse generator electrodes and usually results in intermittent or failed cardiac pacing. Treatment of ventricular perforation is withdrawal of the electrode back into the ventricle. Perforation can be diagnosed by connecting the distal electrode to the V lead of a battery-powered electrocardiograph. As the electrode is slowly withdrawn, a ventricular ectopic beat occurs when the tip is in the myocardium. The ST segment is markedly elevated and the T wave deeply inverted, producing an endocardial "current of injury" pattern. In rare instances, cardiac tamponade may result. The probe tip is designed to be very soft to minimize injury to the ventricular endocardium. However, to prevent potential damage to the endocardium during open heart surgery, withdraw the probe into the catheter before manipulating the heart.

How Supplied

Chandler transluminal V-Pacing probes are supplied sterile (unless otherwise stated) and nonpyrogenic. Do not use if package has been previously opened or damaged.

Note: Probes are for single use only. Do not clean or resterilize a used probe.

Packaging

The probe is provided preloaded in a packaging dispenser designed to aid in probe insertion and to help maintain sterility during insertion. It is therefore recommended that the probe remain inside the package until use.

Storage

Store in a cool, dry place.

Temperature/Humidity Limitations: 0° - 40 °C, 5% - 90% RH

Operating Conditions

Intended to operate under physiological conditions of the human body.

Shelf Life

The recommended shelf life is as marked on each package. Storage beyond the recommended time may result in deterioration.

Note: Resterilization will not extend shelf life.

Technical Assistance

For technical assistance, please call Edwards Technical Support at the following telephone numbers:
Inside the U.S. and Canada
(24 hours): 800.822.9837
Outside the U.S. and Canada
(24 hours): 949.250.2222
In the UK: . . . . . 0870 606 2040 - Option 4
In Ireland: . . . . . 01 8211012 Option 4

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

Disposal

After patient contact, treat the device as biohazardous waste. Dispose of in accordance with hospital policy and local regulations.

Prices, specifications, and model availability are subject to change without notice.

Refer to the symbol legend at the end of this document.

Sterilized Using Ethylene Oxide

Specifications

Chandler Transluminal V-Pacing Probe (Model D98100)

For use with a Swan-Ganz Paceport or A-V Paceport catheter for **ventricular** pacing only.

Usable length (cm)	
Total	135
In ventricle	15
Body Diameter (F)	2.4 (0.80 mm)
Electrodes	Stainless steel with pin connectors (0.08 inch diameter, or 0.2 cm) at proximal end
Distal:	
Length (cm)	1.3
Proximal:	
Length (cm)	15

Contents

Chandler Transluminal V-Pacing Probe
ECG adapter (see figure 9)
Syringe, 5 ml Luer-Lock
Sterile drape, folded, 18" x 26" (45.72 cm x 66.04 cm)
Contamination sheath
Dispenser carousel

All specifications given are nominal values.

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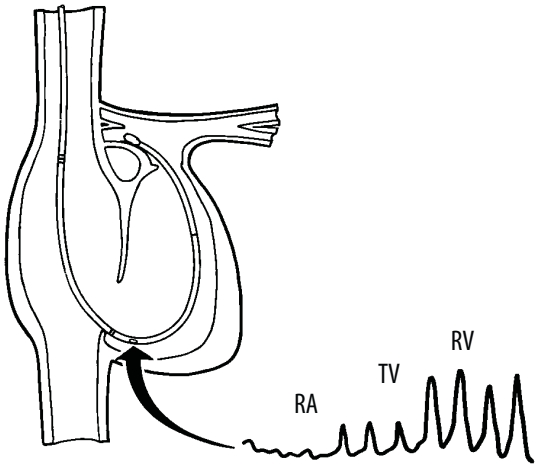

Figure 1. Proper RV port placement (1 to 2 cm distal to tricuspid valve)

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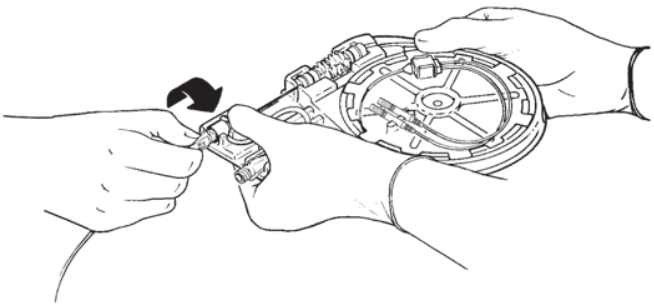

Figure 2.
Attachment of Tuohy-Borst (T-B) adapter to catheter's RV lumen hub

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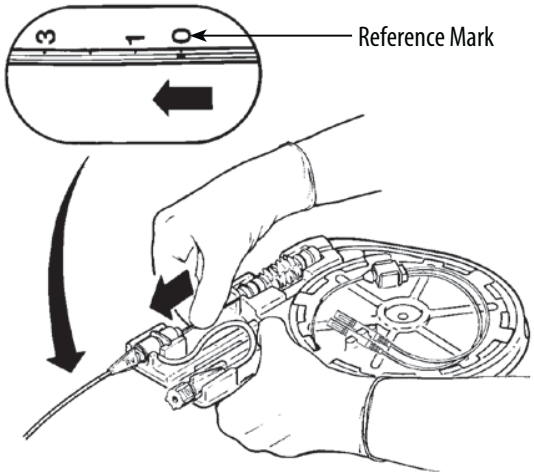

Figure 3. Probe insertion and positioning in catheter

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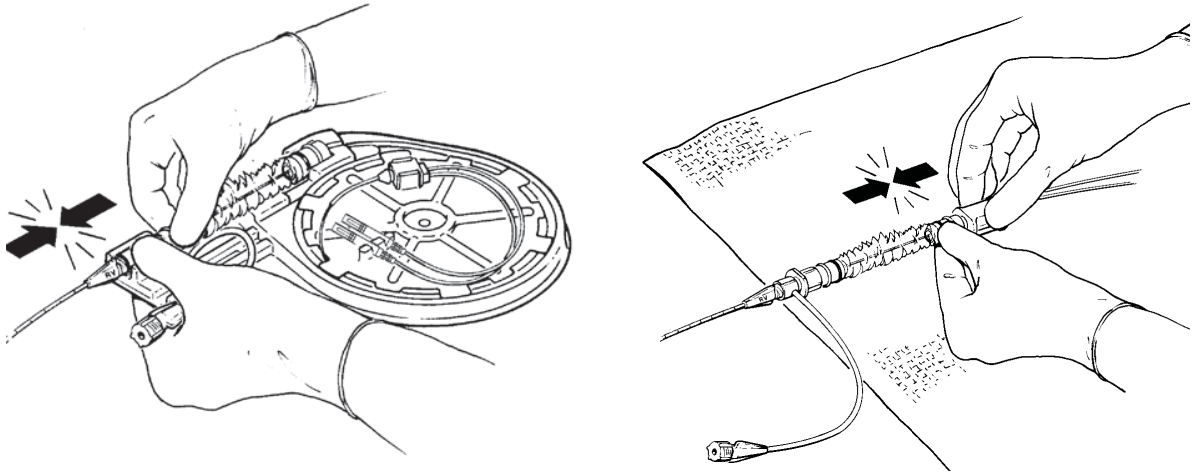

Figure 4. Attachment of contamination sheath to T-B adapter and probe

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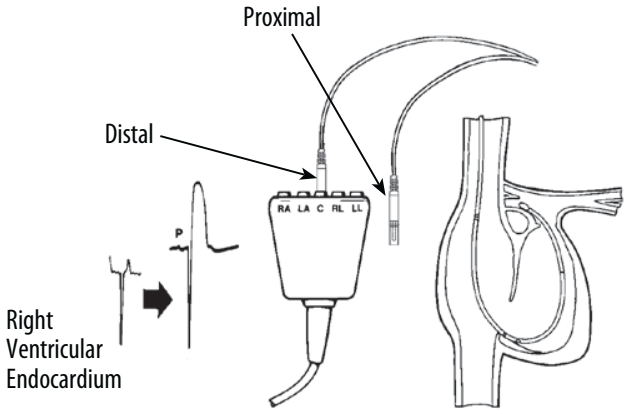

Figure 5. EKG detection from distal electrode

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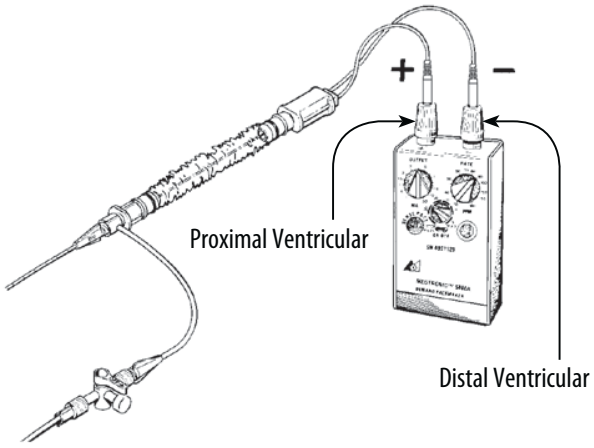

Figure 6. Connection of leads to pulse generator

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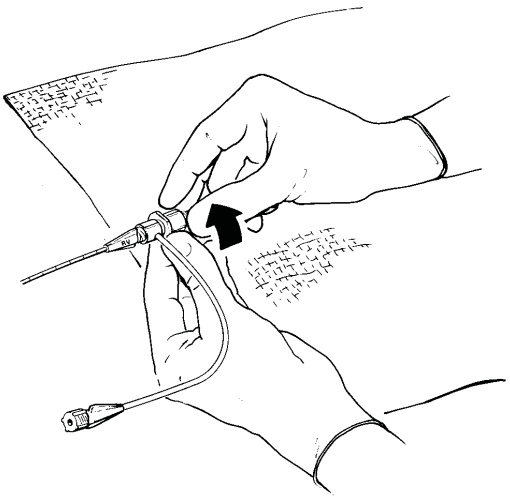

Figure 7. Securing probe to T-B adapter

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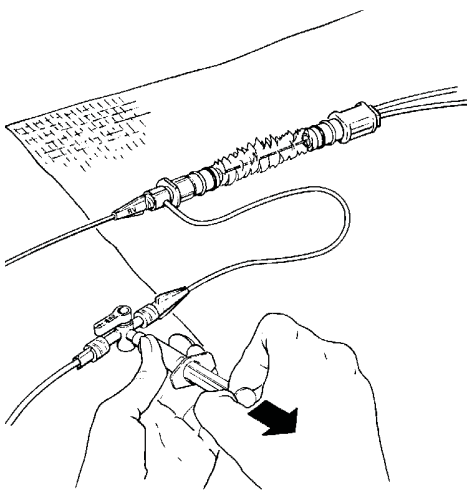


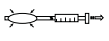
Figure 8. Aspirating and flushing of T-B adapter and RV lumen

Figure 9.

PACING PRODUCTS KITS (Models D98100, D98500)

ECG adapter used to facilitate the use of modified shrouded pin connectors with ECG monitor patient cables is available with pacing product kits.

Symbol Legend

	English		English		English
	Number of Lumens	STERILE	Sterile		MR Unsafe
	Exterior Diameter	STERILE EO	Sterilized Using Ethylene Oxide	MR	MR Safe
cm	Usable Length	STERILE R	Sterilized Using Irradiation		MR Conditional
GW	Recommended Guidewire Size	STERILE	Sterile Using Steam or Dry Heat		Consult instructions for use
	Lumen Size	Rx only	**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.		Consult instructions for use
REF	Catalogue Number		Manufacturer		Do not resterilize
I	Minimum Introducer Size		Date of Manufacture		Non-pyrogenic
	Caution	LATEX	Contains or presence of natural rubber latex		Type B Applied Part
	Single use	PHT	Contains phthalates		Type CF Applied Part
#	Quantity	SZ	Size		Do not use if package is opened or damaged.
LOT	Lot Number		No components of this package or the products it contains are made from natural rubber latex or dry natural rubber.		Open
	Use By		Temperature Limitation		Aspirate Balloon -0.5 cc Before Introduction or Withdrawal.
	Inner Diameter		Humidity Limitation	EC REP	Authorized Representative in the European Community
BC	Balloon Capacity	eifu.edwards.com + 1 888 570 4016	Consult Instructions for use on the website eifu.edwards.com		CE conformity marking per European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
	Keep dry	eifu.edwards.com + 1 888 570 4016	Follow Instructions for use on the website eifu.edwards.com		

Note: Not all symbols may be included in the labeling of this product.

SGNHEMSL8x11.3

Edwards

EC REP

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