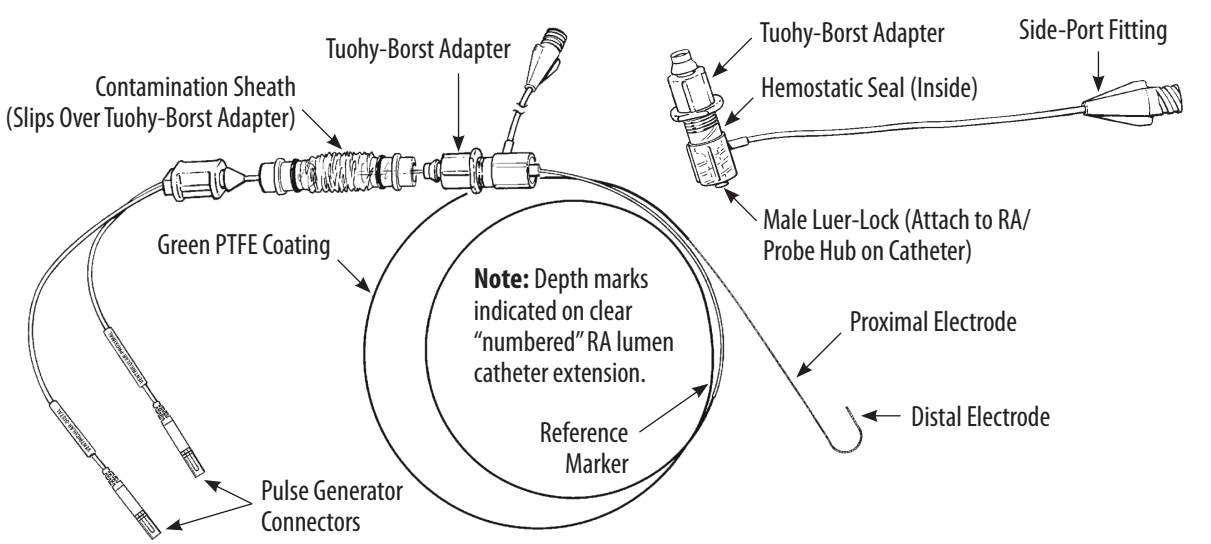
Edwards Lifesciences

Flex-Tip Transluminal A-Pacing Probe
D98500



Flex-Tip Model D98500 Transluminal A-Pacing Probe

For Single Use Only

For figures 1 through 9 please refer to pages 4 and 5.

Use only with Swan-Ganz thermodilution A-V Paceport catheter (Model 991F8). For atrial pacing only.

Concept/Description

The Model D98500 Flex-Tip transluminal A-Pacing probes, when used with a Swan-Ganz thermodilution A-V Paceport catheter (Model 991F8), are used for temporary atrial or A-V sequential 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 A-V 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 A-pacing probe is inserted into the A-V Paceport catheter's RA lumen and advanced into the atrium for endocardial pacing. The bipolar, coaxial, J-tip wire probe is composed of a stainless steel round wire and a PTFE (polytetrafluoroethylene)-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 Flex-Tip transluminal A-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 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 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 atrial probe is not intended for use with any catheter except the Swan-Ganz thermodilution 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 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 A-V Paceport catheter (Model 991F8) can be inserted at the patient's bedside without fluoroscopy by continuous pressure monitoring from the distal and right ventricular lumens. A unipolar electrocardiogram can be recorded from the A-probe's distal tip electrode by connection to a V lead of a properly isolated electrocardiograph. Use of the Edwards introducer will facilitate optimal insertion of the probes up to 72 hours after catheter insertion. Use of other manufacturer's introducers will not guarantee probe passage through the catheter within this 72-hour period.

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 thermodilution 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 (if A-V pacing is desired)
4. Flex-Tip transluminal A-Pacing probe, Model D98500
5. Demand external pulse generator (atrial or A-V sequential as appropriate for pacing needs)
6. External pulse generator cable adapters
7. ECG recorder
8. Sterile flush system and pressure transducers
9. 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 or cutdown through a jugular, subclavian, femoral, or antecubital vein.

To ensure proper placement of the atrial probe, the catheter's RV port should first be positioned by pressure monitoring 1 to 2 cm distal to the tricuspid valve.

To facilitate subsequent insertion of the atrial and/ or ventricular probes, insertion of the A-V Paceport 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. Radiopaque markers are provided at the RV and RA ports to confirm port placement by X-ray film or fluoroscopy.

It is recommended that femoral insertion of the A-V Paceport catheter (Model 991F8) and Flex-Tip and Chandler probes be done under fluoroscopy. Also, femoral insertion should be used only when short-term pacing is required (e.g., cath lab procedures), because of the possible placement of the Chandler probe in the RV outflow tract.

Please note that with the femoral approach, the RA pacing port may be positioned in the inferior vena cava. This position may prohibit proper atrial probe placement or may require an extended length of probe insertion to obtain atrial capture. Refer to the Paceport (Models 991F8, 931F75) catheter package insert for detailed instructions on insertion.

A protective catheter shield is recommended to aid in maintaining sterility when repositioning of the catheter is necessary.

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.

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 atrial probe is inserted only into the RA/probe lumen (clear extension tube with yellow Luer-lock hub)**. Do not insert the probe into the proximal injectate, RV/probe, or distal (PA) lumens.

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 RA probe 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). This will position the RA pacing/infusing port in the right atrium (See page 4, Fig. 1). To prevent catheter movement, secure the catheter at the insertion site. (A Chandler V-Pacing probe may be inserted into the RV lumen at this time using the instructions provided with the Chandler probe.)
3. Open the probe package, gently remove the protective blue tube from the probe tip, and retract the probe "J"-tip into the Tuohy-Borst (T-B) adapter **by turning the carousel clockwise**.
4. Connect the T-B adapter to the yellow RA lumen hub. **Be careful not to damage the probe tip** (See page 4, 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 RA lumen (See page 4, Fig. 3). Because of manufacturing tolerances, the tip of the probe is now between the RA port and a point 2 cm proximal to the port. The probe is ready to be advanced into the right atrium.

   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 RA port. Resistance at any other point may indicate that the catheter is kinked. Do not force the probe if resistance is met.

   Note: The J-tip atrial probe encounters more friction than the straight V-Pacing probe as it

is passed into the catheter lumen. Insertion difficulty may be related to crimping of the catheter tubing at the hemostasis valve of the introducer. If this occurs, slight manipulation of the catheter relative to the introducer will usually allow probe passage.

Precaution: The green 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 shield to the yellow T-B adapter. Remove the T-B adapter and probe from the dispenser and attach the other end of the shield to the proximal end of the probe (See page 4, Fig. 4).

7. Connect the distal and proximal electrodes to the negative and positive terminals of a pulse generator, respectively, setting the desired mA and rate for atrial capture (See page 5, Fig. 5).

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

8. Advance the probe several centimeters until atrial capture is achieved, and determine pacing threshold (See page 5, Fig. 6). The mean initial threshold in clinical studies was 4.4 mA (range 1.1 to 12.0 mA).

   In clinical studies, the best initial pacing position was with the probe an average of 5.7 cm (range 2 to 11 cm) out of the RA port.

   Note: The atrial appendage and coronary sinus are often used pacing sites in the atrium. However, the probe does not necessarily go to the atrial appendage - it may go to the lateral atrial wall. It may not be necessary to deploy the full "J" into the atrium.

   Note: To enhance long-term pacing stability, advance the probe 2 cm extra beyond the best initial pacing position. This creates pressure against the atrial wall and may help maintain pacing in the event of excessive patient movement, vigorous respirations, and changes in patient's position.

9. Firmly tighten the yellow compression nut on the T-B adapter to seal and secure the probe in place (See page 5, Fig. 7). Using a 3-way stopcock with Luer-lock fitting, connect the sideport of the T-B adapter to a continuous heparinized saline flush device. Using the 5 ml syringe provided, aspirate any air from the sideport (See page 5, Fig. 8). Institute a continuous or intermittent heparinized flush through the sideport fitting of the T-B adapter.

10. Obtain a chest X-ray film as soon as possible after insertion to document initial placement.

MRI Information

MR Unsafe

The Flex-Tip 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, myocardial perforation, vigorous respirations or patient movement. If the probe is pulled off the endocardium, reposition the probe. Transient loss of capture after patient movement may be corrected by placing the patient in a supine position and, if necessary, increasing the threshold or repositioning the probe.

Diaphragmatic Stimulation

Diaphragmatic stimulation may occur due to phrenic nerve stimulation. Either reposition the probe or catheter or both and/or reduce the mA setting on the pulse generator to minimize or eliminate stimulation of the diaphragm.

Inability to Wedge the Balloon

If probe 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.

Atrial Perforation

The incidence of atrial perforation from temporary atrial pacing is unknown. In one study of 100 patients who had a J-tip electrode, no cases of atrial perforation were reported. In rare instances, cardiac tamponade may result. The probe tip is designed to be very soft to minimize injury to the endocardium. However, to prevent potential damage to the endocardium during open heart surgery, withdraw the probe into the catheter before manipulating the heart.

Specifications

Flex-Tip Transluminal A-Pacing Probe (Model D98500)

Use only with a Swan-Ganz A-V Paceport Catheter (Model 991F8).
For atrial pacing only.

Usable length (cm)	
Total	135
In atrium	15
Body Diameter (F)	2.4 (0.80 mm)
Electrodes	Stainless steel with pin connectors 0.080" (0.2 cm) diameter at proximal end
Distal	
Length (cm)	1.3
Proximal	
Length (cm)	15

Contents provided sterile with the probe:

Flex-Tip Transluminal A-Pacing Probe
ECG adapter (See Fig. 9)
Syringe, 5 ml Luer-lock
Sterile drape, folded 18" x 26" (45.72 cm x 66.04 cm)
Contamination sheath
Dispenser carousel

How Supplied

Flex-Tip transluminal A-Pacing probes are supplied sterile, unless otherwise stated. Do not use if package has been previously opened or damaged.

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

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

DC2010-31

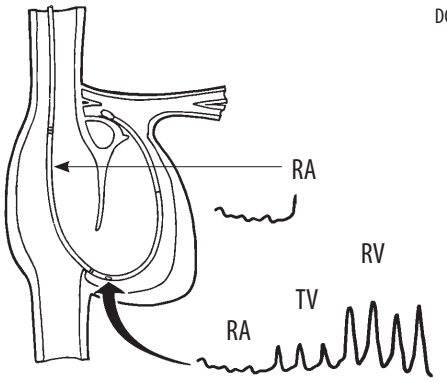


Figure 1. Proper RA port placement

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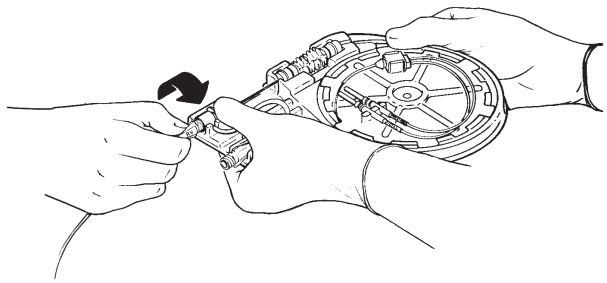

Figure 2. Attachment of Tuohy-Borst adapter (T-B) to catheter's RA lumen hub

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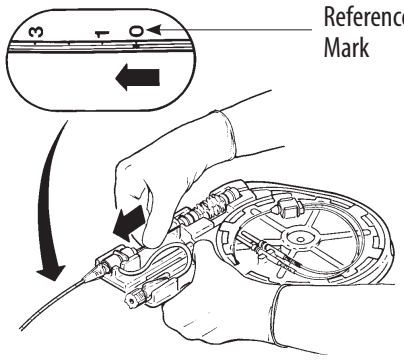

Figure 3. Probe insertion and positioning in catheter

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DC2010-2

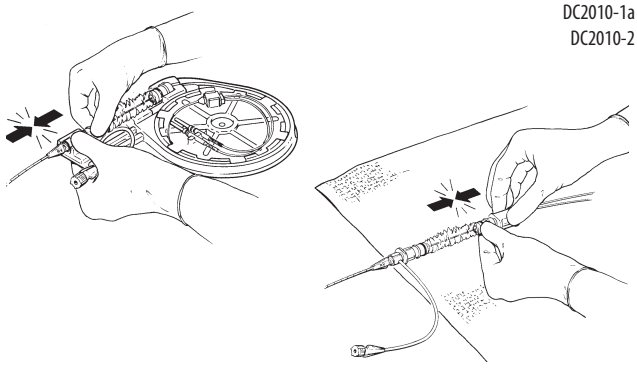

Figure 4. Attachment of contamination sheath to T-B adapter and probe

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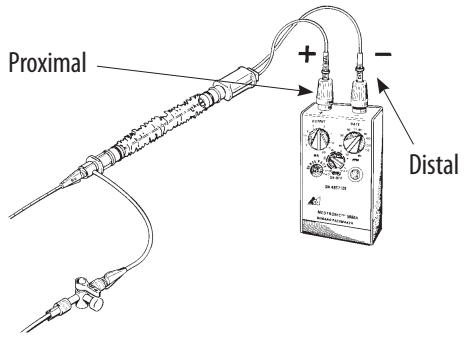

Figure 5. Connection of leads to an external pulse generator

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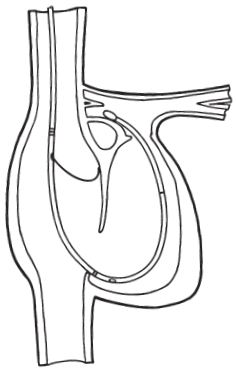

Figure 6. RA Probe placement

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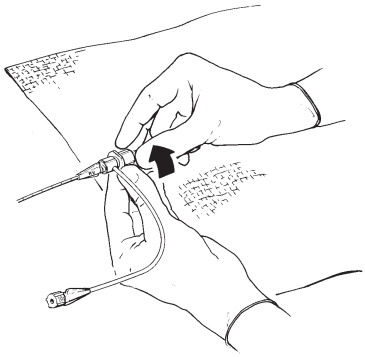

Figure 7. Securing probe to T-B adapter

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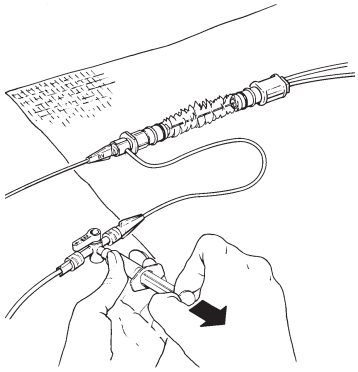

Figure 8. Aspirating and flushing of T-B adapter and RA lumen

Figure 9.

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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		MR Unsafe
	Exterior Diameter		Sterilized Using Ethylene Oxide		MR Safe
	Usable Length		Sterilized Using Irradiation		MR Conditional
	Recommended Guidewire Size		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
	Catalogue Number		Manufacturer		Do not resterilize
	Minimum Introducer Size		Date of Manufacture		Non-pyrogenic
	Caution		Contains or presence of natural rubber latex		Type B Applied Part
	Single use		Contains phthalates		Type CF Applied Part
	Quantity		Size		Do not use if package is opened or damaged.
	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
	Balloon Capacity		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		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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