Product Manual

ANGEFLEX™
TRANSVENOUS DEFIBRILLATION LEAD
[Models 4020, 4021, 4020, 4023]

ANGEION CORPORATION

Product Manual, AngeFlex Transvenous Defibrillation Lead -July 1997

The products described in this manual are covered by one or more of the following U.S. Patents: 5,241,960; 5,342,399; 5,366,484; 5,372,605; 5,376,103; 5,431,686, 5,447,521; 5,470,346; 5,540,721; 5,549,643; 5,591,210; 5,601,607; 5,697,953; and 5,709,215. Other U.S. and foreign patents pending.

CAUTION: Federal (U.S.) law restricts this device to sale by or on the order of a physician with appropriate training.

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Document Conventions

This manual describes the Angeion® AngeFlex™ Transvenous Defibrillation Lead (Models 4020, 4021, 4022, and 4023) that is used with Angeion's Implantable Cardioverter Defibrillator (ICD). Use this manual in conjunction with the *System Manual* and the pace/sense lead manual used with the ICD system.

Additional information is presented in three levels of impact in the following formats:

Note: This information adds additional insight and/or instructions for a specific topic.

Caution: This information describes any special care to be exercised for the safe and effective use of the device.

Warning: **This information is an alert to the possible injury or other serious adverse patient reaction, or death, associated with the use or misuse of the device.**

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Device Description

The AngeFlex™ lead is designed for use in combination with the Angeion Implantable Cardioverter Defibrillator (ICD) and a permanent, bipolar, IS-1[1] compatible, active fixation pace/sense lead to treat episodes of bradycardia, ventricular tachycardia, and ventricular fibrillation. The AngeFlex lead is a DF-1 compatible lead, meeting the requirements of the ISO standard[2].

Indications for Use

The Angeion® Sentinel™ Implantable Cardioverter Defibrillator (ICD) System Models 2000/2010/2011/2012 and the Angeion AngeFlex™ Transvenous Defibrillation Lead System Models 4020/4021/4022/4023 (hereinafter called the Sentinel ICD System) are indicated for use in patients who are at risk of sudden death due to ventricular arrhythmias and have experienced one of the following situations:

- Survival of at least one episode of cardiac arrest (manifested by loss of consciousness) due to a ventricular tachyarrhythmia; and
- Recurrent, poorly tolerated, sustained ventricular tachyarrhythmia

Note: The clinical outcome of hemodynamically stable VT patients is not fully known. Safety and effectiveness studies have not been conducted.

Contraindications

The AngeFlex lead is contraindicated for use in those patients with tricuspid valvular disease or any type of tricuspid replacement heart valve (mechanical or tissue).

The Sentinel ICD system is contraindicated for patients who have:

- Ventricular tachyarrhythmias that have demonstrated a reversible cause such as digitalis intoxication, electrolyte imbalance (drug induced) hypoxia, sepsis, or a transient cause attributable to such factors as acute myocardial infarction, electrocution, or drowning.
- A unipolar pacemaker, or a pacemaker that defaults to unipolar mode.

The ICD may also be contraindicated for patients who have:

- Uncontrolled supraventricular tachyarrhythmia (SVT) and excessive ventricular rates despite conventional drug therapy. Depending on the programmed detection criteria, the SVT may cause therapy delivery.
- Ventricular tachyarrhythmias that require frequent shocks. Frequent shocks may cause intolerable patient discomfort and the ICD batteries to deplete more rapidly than is acceptable.

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[1] ISO 5841-3, Cardiac Pacemakers - Part #3: Low-Profile connectors (IS-1) for implantable pacemakers. 1st edition, 1992.

[2] These connectors meet the published international standard for high voltage cardioversion/defibrillation leads (ref. ISO/DIS 11318).

Warnings

General Warnings

- Properly ground any line-powered equipment used near the patient.
- Electrosurgical units (e.g., electrocautery) should not be used near an ICD or its associated leads. Currents generated from electrosurgical devices may cause permanent loss of output, induce ventricular fibrillation, or reset programmed parameters in the ICD. If using electrocautery is unavoidable, however, program the Tachy Therapy parameter to "Off" and be sure the electrocautery discharge does not make direct contact with the ICD or leads. Following electrocautery, determine the functional integrity of the circuitry and programming.
- Do not resterilize the lead if sterility is compromised. Return damaged packages to Angeion Corporation.
- The AngeFlex lead is for one-time use only. Do not implant an explanted lead in another patient.

Specific Warnings

- If using a subclavian approach, position the lead laterally to avoid clamping between the first rib and clavicle. Clamping the lead may cause conductor fracture or insulation damage over time. This may result in inappropriate detection and therapy. (page 5)
- If you notice significant lead resistance during a subclavian approach, do not force the lead. Try an alternate venous route. (page 5)
- Certain anatomic abnormalities, such as thoracic outlet syndrome, may also cause lead clamping and subsequent damage. (page 5)
- Take care to avoid perforation of the ventricular wall. (page 6)

Precautions

General Precautions

- ☐ The tip and ring of the pace/sense lead should be placed at least 2 cm away from the lead's distal electrode. Inadequate spacing may cause inaccurate sensing or inappropriate therapy delivery.
- ☐ Do not kink the lead.
- ☐ Do not attempt to curve the stylet while in the lead.
- ☐ Do not immerse the lead in liquids prior to implant.
- ☐ Do not attempt to alter the lead in any way.
- ☐ Use only the stylets provided by Angeion.
- ☐ Use an anchoring sleeve with all leads to protect lead integrity.

Specific Precautions

- ☐ Do not handle the lead with surgical instruments and avoid contact with sharp surgical instruments while handling the lead. (page 6)
- ☐ Keep gloves and stylets free of blood and body fluids to minimize friction between the stylet and the lead. (page 6)
- ☐ Do not use a sharp object to curve the stylet. (page 6)
- ☐ Do not leave the stylet in the lead after permanent placement. (page 6)
- ☐ If using epicardial pace/sense leads, keep them as far away from the defibrillation electrode(s) as possible. (page 6)
- ☐ If you need to make an additional percutaneous stick when inserting the pace/sense lead, be careful to avoid damaging the AngeFlex defibrillation lead. (page 6)
- ☐ R-wave amplitudes less than 5 mV may cause inaccurate rate counting in the chronic state, resulting in an inability to sense a ventricular fibrillation or the misinterpretation of a normal rhythm as abnormal. (page 7)
- ☐ Do not suture directly onto the lead body. Always use the suture sleeve to secure the new lead. (page 7)

Potential Adverse Events

Potential lead complications may include, but are not limited to: lead dislodgment, exit block, lead conductor fracture, electrode fracture, and insulation failure.

Device Features

The AngeFlex lead series includes four different models (4020, 4021, 4022, 4023). There are two lead lengths and two different electrode spacings [distance from the tip to the distal end of the proximal (SVC) defibrillation electrode]. These lengths and electrode spacings are reflected in Figure 1 and Table 1.

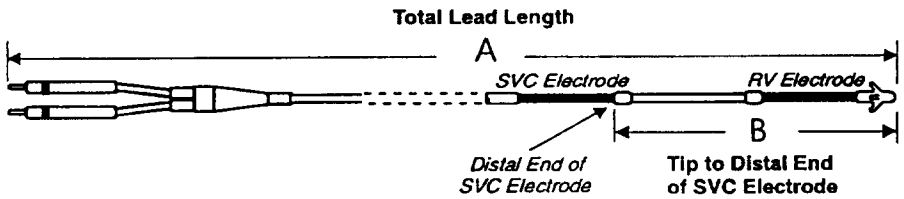

Figure 1: AngeFlex Lead

Table 1: AngeFlex Lead Dimensions

	58 cm Lead Length (A)	69 cm Lead Length (A)
13 cm Tip to SVC (B)	Model 4020	Model 4022
17 cm Tip to SVC (B)	Model 4021	Model 4023

During the ICD implantation, the lead is used with the Angeion Defibrillation Test System (DTS) to verify lead signals and establish defibrillation thresholds. The lead may also be used with a subcutaneous electrode.

Package Information

Contents of Sterile Package

- ☐ 1 lead (4020, 4021, 4022, or 4023)
- ☐ 2 firm stylets (1 pre-inserted) consistent with the lead model (see Table 2)
- ☐ 1 extra firm stylet consistent with the lead model (see Table 2)
- ☐ 1 vein pick
- ☐ 2 suture sleeves (1 on lead)
- ☐ 2 lead caps

Table 2: Packaged Stylets

	Short (58 cm)		Long (69 cm)	
	Model 4020	Model 4021	Model 4022	Model 4023
Firm (0.016)	☐ Grey Handle ☐ Green Cap	☐ Grey Handle ☐ Green Cap	☐ Grey Handle ☐ Red Cap	☐ Grey Handle ☐ Red Cap
Extra Firm (0.017)	☐ Black Handle ☐ Green Cap	☐ Black Handle ☐ Green Cap	☐ Black Handle ☐ Red Cap	☐ Black Handle ☐ Red Cap

Handling Instructions

The AngeFlex lead is shipped in sterile condition.

- ☐ Check the sterile package for any damage that compromises sterility or physically affects the product.
- ☐ Do not implant the lead if sterility is compromised, or if there is physical damage to the product.

Resterilization

The AngeFlex lead has been ethylene oxide (EtO) sterilized, and is for *one time use only.*

- ☐ Do not resterilize the lead if sterility is compromised.
- ☐ Return damaged packages to Angeion Corporation.

Temperature Usage and Storage

- ☐ Use the AngeFlex lead at body temperatures between 34°C and 40°C (93° F and 104° F).
- ☐ Store the AngeFlex lead at temperatures between -10°C and 55°C (14° F and 131° F).

Instructions for Use

Note: The entire ICD system implant procedure is provided in the *Sentinel System Manual*. Also refer to the applicable pace/sense lead manual.

Equipment Preparation

The following equipment should be available during the implant procedure:

- ☐ An external defibrillator (self-adhesive defibrillator electrodes are recommended)
- ☐ Angeion ICD, DTS, and Patient Cable
- ☐ Fluoroscopy equipment
- ☐ Cardiac monitoring equipment
- ☐ A pacing system analyzer (PSA) and cables
- ☐ A multi-channel chart recorder
- ☐ One 10.0 (10.5 with guide wire) French introducer kit for the AngeFlex lead
- ☐ AngeFlex Transvenous Defibrillation Lead
- ☐ Pace/sense lead (IS-1 compatible with active fixation)
- ☐ One introducer kit consistent with the requirements of the pace/sense lead

Implant Procedure

Note: This section includes implant steps for the leads only. Refer to the *Sentinel System Manual* for the entire ICD implantation process.

Step 1: Select Insertion Site

Warning: **If using a subclavian approach, position the lead laterally to avoid clamping between the first rib and clavicle. Clamping the lead may cause conductor fracture or insulation damage over time. This may result in inappropriate detection and therapy.**

Warning: **If you notice significant lead resistance during a subclavian approach, *do not* force the lead. Try an alternate venous route.**

Warning: **Certain anatomic abnormalities, such as thoracic outlet syndrome, may also cause lead clamping and subsequent damage.**

The lead may be passed through several venous routes, including the right or left cephalic vein and the internal or external jugular vein.

Step 2: Insert the AngeFlex Defibrillation Lead

Caution: Do not handle the lead with surgical instruments and avoid contact with sharp surgical instruments while handling the lead.

Caution: Keep gloves and stylets free of blood and body fluids to minimize friction between the stylet and the lead.

1. Insert the AngeFlex defibrillation lead through the insertion site using a cutdown or Seldinger technique.
   - ☐ Check the "use before" date on the front of the package. If this date has expired, return the package to your Angeion representative.
   - ☐ Be sure the package seal has not been broken. If the package or its contents appear to be damaged, the sterility of the contents may be compromised. Do not re-sterilize the lead. (Return the package to your Angeion representative.)

Caution: ***Do not*** use a sharp object to curve the stylet.

2. Remove the pre-inserted firm (grey knob) stylet. If you desire to curve the stylet, use a blunt instrument to form the curve.
3. Use fluoroscopy to advance the AngeFlex lead through the tricuspid valve and into the upper right ventricle.

Warning: **Take care to avoid perforation of the ventricular wall.**

4. Gently advance the lead as far as possible into the ventricular apex and lodge the tines under the surrounding trabeculae.

Caution: ***Do not*** leave the stylet in the lead after permanent placement.

5. Withdraw the stylet and use fluoroscopy to verify that the lead is in the proper position.
6. Monitor the stability of the lead using fluoroscopy.

Notes:

- ☐ Ensure that there is enough slack to avoid dislodgment from normal physical activity, but not enough for the lead to buckle out of the posterior groove.
- ☐ Ensure that the distal third of the SVC electrode extends just into the junction of the superior vena cava and upper right atrium.
- ☐ Ensure that the RV electrode is in the right ventricle below the tricuspid valve and along the posterior groove.

Step 3: Insert the Transvenous Pace/Sense Lead

Caution: If using epicardial pace/sense leads, keep them as far away from the defibrillation electrode(s) as possible.

Caution: If you need to make an additional percutaneous stick when inserting the pace/sense lead, be careful to avoid damaging the AngeFlex defibrillation lead.

Position the pace/sense lead according to the instructions in the pace/sense lead manual, considering that the final pace/sense lead position should be in the right ventricle. Be sure to maintain a distance of at least 2 cm between the distal defibrillation electrode and the pace/sense lead tip.

Step 4: Take Pace/Sense Lead Measurements

1. Connect the pace/sense lead to a pacing system analyzer (PSA) via the sterile PSA cables. (Refer to the PSA manual for detailed connection instructions.)

Note: Initial intraoperative measurements may deviate from recommended values because of acute cellular trauma. Should this occur, wait 5 to 10 minutes and repeat the testing procedure.

2. Use the PSA to determine the pacing threshold, R-wave amplitude, and pacing impedance. The recommended bipolar pace/sense lead measurements appear in Table 3.
3. Once you obtain acceptable pace/sense lead measurements, disconnect the pace/sense lead from the PSA.

Caution: R-wave amplitudes less than 5 mV may cause inaccurate rate counting in the chronic state, resulting in an inability to sense a ventricular fibrillation or the misinterpretation of a normal rhythm as abnormal.

Table 3: Recommended Lead Measurements at Implant (per PSA)

Parameter	Recommended Value
Bipolar R-wave amplitude	≥ 5 mV
Bipolar pacing voltage threshold (at 0.5 ms pulse width)	≤ 1.5 V endocardial
Bipolar pacing lead impedance	300 - 1200 ohms
Pacing pulse width threshold (at 5.0 volts)	≤ 0.2 ms

Step 5: Establish Defibrillation Efficacy

Refer to the *System Manual* for detailed testing instructions.

Step 6: Anchor the Leads

Caution: Do not suture directly onto the lead body. Always use the suture sleeve to secure the new lead.

Caution: *Do not* secure the lead too tightly. Tight sutures may cause damage to the lead.

Once you have established acceptable defibrillation and pace/sense efficacy, use the suture sleeve on the lead to anchor the AngeFlex lead as follows. Use the second suture sleeve for additional stability. (Refer to the pace/sense lead manual for its anchoring procedure.)

1. Insert the most distal end of the suture sleeve into the vein.
2. Suture the most distal anchoring groove to the vein. (Use the middle anchoring groove to tighten the suture sleeve to the lead.)

3. Suture the most proximal anchoring groove to the surrounding tissue.
4. After securing the suture sleeve, manually grasp it and carefully attempt to move the lead in either direction to verify lead security. (Figure 2 depicts an anchored AngeFlex lead.)

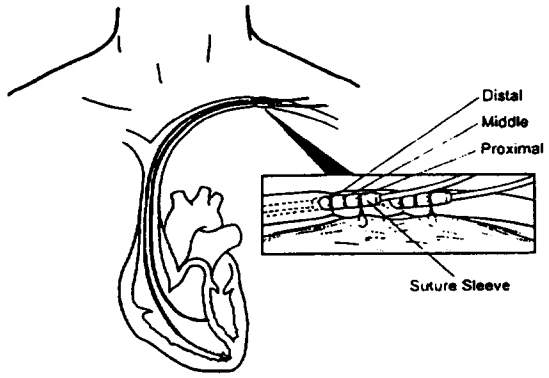

Figure 2: Anchoring the AngeFlex Lead

Step 7: Connect the Leads to the ICD

Refer to the *System Manual* for detailed connection instructions.

Post Implant Procedures

Product Registration

Complete the Product Registration Form (the serial number is on the yoke of the lead and on the sterile package label) within 7 days of implant and return it in the envelope provided to:

Angeion Corporation
Product Registration
7601 Northland Drive
Minneapolis, MN, USA 55428-1088

Returning Explanted Leads

Refer to the *System Manual* for explant instructions.

AngeFlex Lead Specifications

Models 4020/4021/4022/4023 Transvenous Defibrillation Leads	
Total Length: 4020/4021 4022/4023	 58 cm 69 cm
Distance - Lead Tip to Distal End of SVC Electrode: 4020/4022 4021/4023	 13 cm 17 cm
Fixation Method:	Passive, Tined
Connector Type:	DF-1
Material: Conductor Insulation Electrode Connector Pins Tines	 Platinum Iridium Coated MP35N -Ag Composite / Non-coated MP35N-Ag Composite / DBS 316 ss Cable Silicone/PTFE Platinum Iridium Stainless Steel Silicone (4)
Electrode Surface Area: Proximal Electrode Distal Electrode	 358 mm² 268 mm²
Body Diameter:	7.2 French
Stylets: Firm (0.016) Extra Firm (0.017)	 58 cm, grey handle, green cap 69 cm, grey handle, red cap 58 cm, black handle, green cap 69 cm, black handle, red cap
Lead Introducer Size:	10.0 French (10.5 with guide wire)

Notes

13 Notes

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Sentinel®

SYSTEM MANUAL

(MODEL 2000)

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Sentinel® System Manual (Model 2000)

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

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Document Conventions

This manual gives guidance and direction in the use, maintenance, and troubleshooting of the devices that comprise the Angeion Sentinel® System. It should be used in conjunction with the individual product manuals for the Sentinel® Implantable Cardioverter Defibrillator (Model 2000), Programmer Model 3007, Defibrillation Test System, Smart Wand Programming Head, Patient Cable, Test Electrode, and pace/sense and defibrillation lead systems. (Refer to the product manuals for device specifications.)

This manual is divided into six parts:

- Sentinel System Overview
- Sentinel System Operation
- ICD Implant
- Post-Implant Procedures
- Troubleshooting
- Reference Material

To help you use this information resource effectively:

- The 16 labeled Programmer keys are always in boldface and enclosed in straight brackets. For example: **[BACK]**.

- Additional information is presented in three levels of importance in the left text column as follows:

Note: This information adds additional insight and/or instructions for a specific topic.

Caution: This information describes any special care to be exercised for the safe and effective use of the device.

***Warning:* This information is an alert to the possible injury or other serious adverse patient reaction, or death, associated with the use or misuse of the device.**

- The acronyms used in this manual are defined below.

Acronym	*Definition*	*Acronym*	*Definition*
AC	Alternating current	LL	Left leg
ASF	Automatic sheet feeder	MRI	Magnetic resonance imaging
ATP	Anti-tachycardia pacing	NIPS	Non-invasive programmed stimulation
BOL	Beginning of life	NSR	Normal sinus rhythm
BPM	Beats per minute	PPM	Pulses per minute
CAN	ICD case	P/S	Pace/sense
DEF	Defibrillation	PSA	Pacing system analyzer
DTS	Defibrillation Test System	RA	Right arm
ECG	Electrocardiogram	RF	Radio frequency
EGM	Electrogram	RL	Right leg
EMI	Electromagnetic interference	RV	Right ventricle
EOL	End of life	SQ	Subcutaneous
EP	Electrophysiological	SVC	Superior vena cava
EPG	External pulse generator	SVT	Supraventricular tachyarrhythmia
ERI	Elective replacement indicator	VF	Ventricular fibrillation
ICD	Implantable Cardioverter Defibrillator	VT	Ventricular tachycardia
LA	Left arm	VVI	Ventricular ventricular inhibited

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Chapter 1 —

System Overview

The Sentinel® system consists of the following devices:

- Sentinel Implantable Cardioverter Defibrillator (ICD) Model 2000
- Programmer Model 3007
- Defibrillation Test System (DTS)
- Smart Wand Programming Head
- Patient Cable
- Test Electrode
- Leads

The above devices are supported by a variety of accessories.

Indications for Use

The Angeion® Sentinel™ Implantable Cardioverter Defibrillator (ICD) System Model 2000 and the Angeion AngeFlex™ Transvenous Defibrillation Lead System Models 4020/4021/4022/4023 (hereinafter called the Sentinel ICD System) are indicated for use in patients who are at risk of sudden death due to ventricular arrhythmias and have experienced one of the following situations:

Note: The clinical outcome for hemodynamically stable VT patients is not fully known. Safety and effectiveness studies have not been conducted.

- Survival of at least one episode of cardiac arrest (manifested by loss of consciousness) due to a ventricular tachyarrhythmia
- Recurrent, poorly tolerated, sustained ventricular tachyarrhythmia

Contraindications

The Sentinel ICD System is contraindicated for patients who have:

- Ventricular tachyarrhythmias that have demonstrated a reversible cause such as digitalis intoxication, electrolyte imbalance (drug induced), hypoxia, sepsis, or a transient cause attributable to such factors as acute myocardial infarction, electrocution, or drowning.
- A unipolar pacemaker, or a pacemaker that defaults to unipolar mode.

The ICD may also be contraindicated for patients who have:

- Uncontrolled supraventricular tachyarrhythmia (SVT) and excessive ventricular rates despite conventional drug therapy. Depending on the programmed detection criteria, the SVT may cause therapy delivery.
- Ventricular tachyarrhythmias that require frequent shocks. Frequent shocks may cause intolerable patient discomfort and the ICD batteries to deplete more rapidly than is acceptable.

The Programming Head, Test Electrode, and Patient Cable are contraindicated for use with any device other than the Sentinel ICD or Defibrillation Test System (DTS), or with any external stimulators that do not meet electrical specifications for the non-invasive programmed stimulation (NIPS) interface.

Lead use is contraindicated for those patients with tricuspid valvular disease or any type of tricuspid replacement heart valve (mechanical or tissue).

Warnings

General Warnings

- ***Accidental Discharge:*** To prevent accidental discharge during implant or explant of the ICD, verify that the Tachy Therapy parameter is set to "Off" prior to the procedure.
- ***Disease Progression:*** Although there has been a satisfactory response to defibrillation therapies during clinically conducted electrophysiological (EP) studies, progression of the underlying or accompanying disease may alter the heart's electrophysiologic characteristics. This is particularly applicable if the patient's drug therapy regimen is modified. Over time, the programmed automatic therapies may become ineffective, and even harmful, to the patient (e.g., therapy may initiate an atrial tachyarrhythmia or accelerate a ventricular tachyarrhythmia to flutter or fibrillation).
- ***Disposal:*** Do not incinerate an explanted ICD because the batteries and capacitor could explode. Return explanted ICDs to the manufacturer.

Note: Due to the dynamic nature of the electrical environment, it is impossible to list all electromagnetic interference sources and their effects. If you have a particular concern, contact your Angeion representative or Angeion Technical Services.

- ***Electromagnetic Interference (EMI):*** Exposure to EMI may cause the ICD to sense incorrectly, withhold therapy, or deliver inappropriate therapy. Delivery of inappropriate therapy could provoke life-threatening arrhythmias such as VT or VF. Shock wave lithotripsy, microwave diathermy, and ionizing radiation may cause permanent damage to the ICD. In addition, since the ICD communicates with the Programmer using radio frequency (RF) telemetry, EMI may cause short telemetry interruptions or cause an electrical reset of the ICD. Advise patients to seek medical guidance prior to entering environments that may contain sources of EMI. (If the Magnet Mode parameter is set to "Enabled," presence of a strong magnetic field may withhold therapy.)

  Hospital EMI sources include, but are not limited to, the following:

  - Diathermy and lithotripsy equipment
  - External defibrillation equipment
  - Therapeutic radiation

- *Electrocautery:* Avoid using electrosurgical units near an ICD or its associated leads. Currents generated from electrosurgical devices may cause inappropriate detection and noise, permanent loss of output, induce ventricular fibrillation, or reset programmed parameters in the ICD.

  If using electrocautery is unavoidable, however, set the Tachy Therapy parameter to "Off." Following electrocautery, determine the functional status of the circuitry and programming by re-interrogating the device.

- *Magnetic Resonance Imaging (MRI) Equipment:* Do not place a patient with an ICD near an MRI device or subject them to MRI scanning. MRI magnetic fields may disable the ICD's tachyarrhythmia sensing and therapy, cause the ICD to deliver inappropriate therapy, inhibit bradycardia pacing, and/or change programmed ICD parameter values.

  Other sources of EMI that may interfere with the ICD include, but are not limited to:

  - Airport security systems
  - Arc welding equipment
  - Bingo wands
  - Electric smelting furnaces
  - High power radios
  - Induction furnaces and stoves
  - Industrial transformers
  - Internal combustion engines with poorly shielded ignition systems
  - Large or defective industrial motors
  - Remote control transmitters
  - Robotic jacks
  - Stereo speakers
  - Television and radar transmitters

- *Cellular Telephones:* Recent studies have indicated that there may be a potential interaction between cellular phones and ICD operation. Potential effects may be due to either the radio frequency signal or the magnet within the phone, and could include inhibition or asynchronous pacing when the phone is in close proximity (within 6 inches or 15 cm) to the ICD.

It is important to note based on testing to date that any effect resulting from an interaction between the cellular phone and the ICD is temporary. Simply moving the phone away from the implanted device will return it to its previous state of operation. Because of the great variety of cellular phones and the wide variance in patient physiology, an absolute recommendation to cover all patients cannot be made. The following information provides a general guideline to patients with an implanted ICD who wish to operate a cellular phone:

- Patients should hold the phone to the ear opposite the side of the implanted device. Patients should not carry the phone in a breast pocket or on a belt over or within 6 inches (15 cm.) of the implanted device as some phones emit signals when they are turned ON but not in use (i.e., in the listen or standby mode). Storing the phone in a location opposite the side of the implant is recommended.
- Maintain a minimum separation of 6 inches (15 cm.) between a hand-held personal cellular phone and the ICD. Portable and mobile cellular phones generally transmit at higher power levels compared to hand-held models. For cellular phones transmitting above 3 watts, a minimum separation of 12 inches (30 cm.) between the antenna and the implanted device is advised.

- ***Flammable Anesthetics:*** Do not use the Programming Head or DTS in the presence of flammable anesthetics.
- ***Explanted Device:*** Failure to disable the ICD therapy modes before explant may result in inappropriate shocking.
- ***Random Failures:*** Random component or battery failure may occur and cannot be predicted prior to their occurrence. In addition, the system may cease to function at any time due to lead-related problems such as dislodgment, exit block, lead conductor or electrode fracture, insulation failure, fibrotic tissue growth, elevated thresholds, or medical complications.
- ***Resterilization:*** Do not resterilize the device or accessory items if sterility is compromised. Return damaged packages to Angeion Corporation.
- ***Reuse:*** The ICD is for one-time only use. Do not implant an explanted ICD in another patient.
- ***Test Electrode:*** Do not implant or resterilize the Test Electrode. The Test Electrode is designed for one-time use during defibrillation testing only.
- ***Therapeutic Diathermy:*** Do not use therapeutic diathermy at the implant site in patients who have a Sentinel ICD. Heat effects from the diathermy may damage device circuitry.

Specific Warnings

Connecting the Equipment

- This equipment must be protectively earthed (grounded). (page 2-1)
- Always use the Programmer with the provided AC power supply because the battery is insufficient for sustained use. (page 2-3; page 15-8)

Tachyarrhythmia Detection and Therapy

- If the Tachy Therapy parameter is set to "Off" or "Monitor Only," the ICD does not provide tachyarrhythmia therapy. (page 6-2)

Real Time Operation

- When NIPS is not in use, disconnect the external stimulator from the Programming Head. If left connected, inadvertent stimulator activation could cause unintended induction. (page 8-13)

Emergency Functions

- You should have an external defibrillation device available during all programming sessions to serve as a back-up to the other rescue therapy options. (page 10-1)
- Emergency Off disables all ICD tachyarrhythmia detection and therapy. (page 10-4)

Implant Procedure

- If using a subclavian approach, position the lead laterally to avoid clamping between the first rib and clavicle. Clamping the lead may cause conductor fracture or insulation damage over time. (page 12-8)
- If you notice significant lead resistance during a subclavian approach, do not force the lead or adjust the patient's posture to facilitate lead passage. Try an alternate venous route. (page 12-8)
- R-wave amplitudes that are less than 5 mV may cause inaccurate rate counting in the chronic state, and result in an inability to sense a ventricular fibrillation or the misinterpretation of a normal rhythm as abnormal. (page 12-8)

- Ensure that all lead connections are secure and correct. Incorrect lead connections could cause cardiac damage and/or an inability to deliver therapy. (page 12-11)
- Always perform induction testing with a standard external defibrillator immediately available as backup rescue support. (page 12-19)
- Successful conversion of ventricular fibrillation or ventricular tachycardia during arrhythmia conversion testing does not assure that conversion will occur post-operatively. Changes in the patient's condition, drug regimen, and other factors may still result in nonconversion of the arrhythmia post-operatively. (page 12-19)
- Do not induce through the pace/sense lead tip if using alternating current. This may damage the myocardium and result in inadequate sensing and pacing. (page 12-22)
- If the shock was ineffective, use [MANUAL THERAPY] or [RESCUE] or press the red DTS Rescue button to deliver additional shock therapy as required to convert the arrhythmia. (page 12-22)
- Be sure the Tachy Therapy parameter is set to "Off" to avoid inappropriate shocks while connecting the lead system. (page 12-12)
- Do not implant the ICD if the seal plugs appear to be damaged to avoid leakage. (page 12-12)
- Make sure any unconnected lead terminal pins are capped and any unused ports are plugged before closing the pocket. Failure to do so may compromise ICD sensing. (page 12-14)
- Electrosurgical units should not be used near an ICD or its associated leads. Direct contact may damage leads and/or the ICD. Current flow from electrocautery may cause permanent loss of output, induce ventricular fibrillation, damage the myocardium, or reset the programmed parameter values. But if using electrocautery is unavoidable while closing the pocket: (1) avoid contact with the ICD and leads, and (2) use bipolar cautery, if possible). (page 12-26)

Explant and Disposal

- Removing leads could result in endocardial avulsion, valve or vein damage, or lead junction separation (leaving the lead tip and wire behind). (page 14-2)

Troubleshooting

- If you need to perform an emergency rescue, press the red DTS RESCUE button. (page 15-7)

Cautions

General Cautions

- ***External Defibrillation:*** The ICD may be damaged by direct or transthoracic defibrillation discharges.
  - When delivering direct heart defibrillation, keep the paddles away from the exposed metal surface of any electrode.
  - When delivering transthoracic defibrillation, do not place a paddle directly over the ICD.

  Interrogate the ICD after exposure to direct or transthoracic defibrillation discharges to determine the functional integrity of the circuitry and programming. Reprogramming or replacement may be necessary.

- ***Pacemaker and ICD Interaction:*** A pacemaker can affect the tachyarrhythmia detection of the ICD by causing undersensing. in which therapy may not be delivered, or oversensing, in which inappropriate therapy may be delivered. With undersensing, an arrhythmia may be undetected if a pacing artifact is instead recognized as a ventricular beat and resets the sensitivity of the ICD. With oversensing, the pacing stimulus and the ventricular depolarization can be double counted, resulting in a false high rate detected by the ICD.

  Unipolar pacemakers are contraindicated. A bipolar pacemaker should be tested for interaction with an ICD by high rate asynchronous pacing in conjunction with ICD testing to ensure appropriate detection of the ventricular arrhythmia. Additionally, place ICD rate sensing lead separate and apart from pacemaker pacing electrodes to minimize interaction.

- ***Safety Margin:***The maximum shock energy is 27 joules. The ICD must deliver a successful conversion at 17.1 joules to provide a 10-joule safety margin. Therefore, program the ICD to ensure a 10-joule safety margin above the defibrillation threshold.

Specific Cautions

Connecting the Equipment

- Use only the medical grade power supplies and cables shipped with each Programmer model and external printer. Attempting to switch power supplies or cables between models could damage the devices. (page 2-1)
- If you encounter resistance, do not force the plug. Reposition the plug, check that you have the correct port, and re-attempt the connection. (page 2-3)

Using the Programmer

- Do not use the FN key while using the Command keys. For example, if you hold the FN key and press [RESCUE] or the F11 key, the Programmer screen goes blank. (page 3-8)

Printing and Storing Information

- You cannot program or use emergency functions while printing a report or saving a report on a disk. To interrupt the printing process, turn the Programmer off, wait 5 seconds, and turn it back on. (page 4-5)

Sensing

- If a unipolar pace/sense lead is implanted, the Sense Lead Configuration parameter should *only* be ptorgrammed to "Tip to RV." Otherwise, the ICD may not sense properly. (page 5-1)

Tachyarrhythmia Detection and Therapy

- If Sustained High Rate is set to "Infinite," the ICD allows a Low Zone gradual inception arrhythmia to continue indefinitely, unless the rhythm accelerates or moves above the High Zone rate. (page 6-8)

Real Time Operation

- Ensure that the DTS capacitors are fully charged before performing an induction using NIPS or therapy could be delayed. (page 8-12)

Diagnostic Data

- If ICD capacitor charging exceeds 24 seconds, schedule a replacement as soon as possible. The battery is approaching EOL. (page 9-6)
- If ICD capacitor charging exceeds 32 seconds, explant and replace the device because the battery is exhausted. (page 9-6)
- Following complete battery depletion, the ICD attempts capacitor charging for 2 minutes. After that time, the ICD terminates capacitor charging, resets detection, and stores a status message. (page 9-6)

Emergency Functions

- ☐ The rescue shock is not issued until [SELECT] is pressed. (page 10-2)
- ☐ After a Rescue command is initiated, the capacitors will require up to 20 seconds to charge and synchronize prior to shock delivery. (page 10-2)
- ☐ While the ICD capacitors are charging, the ICD may not receive the Emergency Off command because of capacitor charging noise. If the shock therapy is not desired and the Magnet Mode is set to "Enabled," place a donut-shaped defibrillator magnet over the ICD before charging is complete to abort shock delivery. Then, press [EMERG OFF] before removing the magnet to protect against further shocks. (page 10-4)
- ☐ Emergency Off is not issued until [SELECT] is pressed. (page 10-4)

Implant Preparation

- ☐ Check the packaging on all pre-sterilized items to be used during the procedure. Do not use any of the items after the expiration date. If a package is open or a product appears to be damaged in any way, do not use it. (page 11-3)
- ☐ If the ICD battery is low (< 6.4 volts and/or battery status other than "OK"), or the ICD is not programmed to factory nominal parameter values, DO NOT implant the device. (page 11-3)

Implant Procedure

- ☐ Consult your Angeion representative or Angeion Technical Services to verify lead compatibility. (page 12-8)
- ☐ If you feel resistance, reposition the Patient Cable plug and reattempt. Forcing the connection may damage the DTS or Patient Cable. (page 12-10)
- ☐ Do not use force when inserting the lead pin, and ensure that the outer seal of the lead is flush with the Patient Cable connector block, or lead seal and/or insulation damage may result. (page 12-10)

- Do not overtighten thumbscrews or damage to the leads and/or Patient Cable may occur. (page 12-11)
- Do not suture directly to the lead body or lead damage may result. Use one or more suture sleeves to anchor each lead. (page 12-23)
- Improper rotation may damage the setscrew seal or allow the screw to fall into the terminal barrel. (page 12-12)
- Do not turn the ICD setscrews prior to connecting the leads. The setscrews are preset to the proper position for lead terminal pin insertion. (page 12-12)
- Do not allow blood or body fluids to enter the lead ports in the ICD connector block. If this does occur, rinse the port with sterile water and dry the port with a sterile gauze. (page 12-13)
- Failure to properly insert the wrench into the pre-slit depression of the seal plug may result in damage to the plug and its sealing properties. Rotate the wrench slightly to facilitate penetration of the seal. (page 12-13)
- Do not overtighten the setscrews (more than three clicks of the wrench) or damage may occur. (page 12-13)
- Do not tighten the setscrew onto the leads' silicone rubber insulation or you may damage the lead. (page 12-14)
- Do not back the setscrews completely out or you will not be able to reset them. (page 12-14)
- Ensure that the leads do not leave the connector block at an acute angle. Sharp angles place undue stress on the lead connector and insulation. (page 12-9)
- If the parameters are not correctly programmed and the Tachy Therapy parameter is set to "On," inappropriate therapy may be delivered. (page 12-24)
- Using internal paddles when the ICD is connected to the implanted lead system may damage the ICD. If using internal defibrillation when the ICD is connected to the leads, make sure defibrillator paddles do not make contact with lead electrodes or ICD. (page 12-25)
- You cannot program or use emergency functions while saving the ICD's code. To interrupt the saving process, turn off the Programmer, wait 5 seconds, and turn it back on. (page 12-26)

Explant and Disposal

- Failure to disable the ICD therapy modes may result in inappropriate shocking. (page 14-1)
- Do not remove the leads with hemostats or any other clamping tool that may cause lead damage. Resort to blunt instruments only if manual manipulation cannot free the lead. (page 14-2)

Maintenance

- With the exception of the maintenance instructions provided in this manual, all services must be provided by Angeion Corporation to maintain device performance integrity. Return devices for servicing to Angeion Corporation. (page C-1)
- The ICD, Patient Cable, and Test Electrode are shipped in a sterile condition and are for one-time, single-patient use only. If sterility is compromised, do not re-sterilize these devices. Return the package and device to Angeion Corporation. (page C-2)
- The Programmer is ordinary equipment without protection against an ingress of liquids. (page C-2)
- Do not sterilize the Programmer because permanent damage may occur. (page C-4)
- Do not use organic solvents, thinners, or alcohol-based compounds to clean the Programmer or the plastic materials may be damaged. (page C-4)
- Use only the same type of battery pack as the one supplied with the Programmer. (page C-6)
- Do not manually move the cartridge holder or the film cable attached to the holder. This could damage delicate mechanical parts. (page C-9)
- Do not immerse the Programming Head into liquids because immersion may cause extensive device damage. (page C-14)
- Do not sterilize the Programming Head because it may be destroyed or the battery may explode. (page C-14)
- Do not sterilize the DTS unit because permanent damage may occur. (page C-15)

Potential Adverse Events

This section applies to the entire Sentinel ICD system. There are no specific potential adverse events listed for individual products.

Physical patient complications related to the use of an ICD system include, but are not limited to:

- ☐ Acceleration of arrhythmias
- ☐ Air embolism
- ☐ Allergic reaction
- ☐ Bleeding
- ☐ Body rejection phenomena
- ☐ Chronic nerve damage
- ☐ Erosion
- ☐ Excessive fibrotic tissue growth
- ☐ Extrusion
- ☐ Fluid accumulation
- ☐ Formation of hematomas or cysts
- ☐ ICD electrical and mechanical complications
- ☐ Inappropriate shocks
- ☐ Infection
- ☐ Keloid formation
- ☐ Lead abrasion
- ☐ Lead discontinuity
- ☐ Lead migration/dislodgment
- ☐ Myocardial damage
- ☐ Pneumothorax
- ☐ Shunting current or insulating myocardium during defibrillation with internal or external paddles
- ☐ Potential mortality due to inability to defibrillate or pace
- ☐ Thromboemboli
- ☐ Venous occlusion
- ☐ Venous or cardiac perforation

Psychological patient complications related to the use of an ICD system include, but are not limited to:

- ☐ Dependency
- ☐ Depression
- ☐ Fear of premature battery depletion
- ☐ Fear of losing shocking therapy capability
- ☐ Fear of shocking while conscious
- ☐ Fear of device failure
- ☐ Fear of another person being injured, during physical contact, if the device discharges
- ☐ Imagined shocking

Complications	Status	Number of Events (E) N=8	Incidence Rate (%E/Device Months)
ICD repositioning due to discomfort (Submuscular to Subcutaneous)	Resolved	1	0.001
Lead/ICD reconnection after pocket closure due to inappropriate sensing	Resolved	1	0.001
Lead repositioned due to high pacing threshold	Resolved	1	0.001
ICD explanted due to inappropriate sensing; ICD replaced	Resolved	1	0.001
Lead/ICD explanted due to inappropriate sensing; ICD pace/sense lead replaced	Resolved	1	0.001
ICD/Adapters explanted due to noise from damaged epicardial leads; ICD replaced	Resolved	1	0.001
ICD explanted due to inappropriate sensing; ICD replaced	Resolved	1	0.001
ICD explanted due to low battery voltage caused by 10μF ceramic capacitor leakage; ICD replaced	Resolved	1	0.001

Table 1: Summary of Clinical Complications

All patients treated: Sentinel ICD series (N=138 patients), AngeFlex lead series (N=70 patients), Endocure lead system (N=56), AngePass lead system (N=4), and chronic lead systems (N=8). Eight complications were reported in seven patients. (Total device months=1130.) Complications, defined as reported events which require invasive resolution, are presented in Table 1.

Event	Number of Events	Number of Patients	Incidence Rate # Events # Device Months
System Related (27)			
ICD Reprogramming/ Medication Change	10	10	0.009%
ICD Reprogramming	9	9	0.008%
Appropriate Defib Shock Patient Follow-up	1	1	0.001%
DTS Extended Induction Time	1	1	0.001%
High Pacing Thresholds	3	3	0.003%
Endocure/AngeFlex Stylet Incompatibility	1	1	0.001%
ICD Header/Lead Incompatibility	1	1	0.001%
Inappropriate Shock Therapy	1	1	0.001%
Other Observations (39)			
Cardiovascular Medication Change	11	10	0.010%
Witnessed Phantom Shock	2	1	0.002%
Abdominal Discomfort	1	1	0.001%
GI Pain, Deemed to be Severe Constipation	1	1	0.001%
CHF	5	5	0.004%
Palpitations	1	1	0.001%
Mitral Valve Replaced	1	1	0.001%
GI Bleed	2	2	0.002%
CVA	1	1	0.001%
Thrombophlebitis	1	1	0.001%
Pneumonia	2	2	0.002%
Cardioversion (external) for AF	1	1	0.001%
Sepsis	1	1	0.001%
Dysphagia	1	1	0.001%
Incision Pain	1	1	0.001%
Ablation	3	3	0.003%
Pacemaker Implant	3	3	0.003%
Prostate Cancer/Device Turned Off	1	1	0.001%
Total	**66**	**40**	**0.058%**

Table 2: Summary of Clinical Observations

All patients treated: Sentinel ICD series (N=138 patients), AngeFlex defibrillation lead systems (N=70 patients), Endocure lead system (N=56), AngePass lead system (N=4), and chronic lead systems (N=8). Sixty-six observations occurred in a total of 40 patients, some of whom had multiple events. (Total device months=1130.)

Device Descriptions

Implantable Cardioverter Defibrillator

The Sentinel ICD is a fully programmable, two-zone, tiered-therapy device that incorporates anti-tachycardia pacing (ATP), cardioversion, and defibrillation tachyarrhythmia therapies. In addition, the ICD includes a programmable Hot Can™ electrode and bradycardia pacing support. For patient evaluation purposes, the ICD provides coupled shock and NIPS functions to intentionally induce tachyarrhythmias. The device also stores therapy and episode data that physicians can retrieve when necessary.

The ICD's database stores 50 tachyarrhythmia events that can be obtained via device interrogation.

The Sentinel Model 2000 has four ports, located in the device header, for connecting to a defibrillation lead system. Three ports [right ventricle (RV), superior vena cava (SVC), and ICD case (CAN)] accept DF-1 defibrillator high-voltage lead connector pins[1]. The fourth port [pace/sense (P/S)] accepts a standard IS-1 pace/sensing, pacemaker lead connector pin[2].

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[1] ISO 11318, Cardiac Defibrillators - Connector Assembly for Implantable Defibrillators Dimensional and Test Requirements. 1st edition, 1993.

[2] ISO 5841-3, Cardiac Pacemakers - Part 3: Low-Profile connectors (IS-1) for implantable pacemakers. 1st edition, 1992.

Defibrillation Test System

The DTS is used to evaluate the performance of the lead systems and determine defibrillation efficacy before ICD implantation.

The DTS is connected to implanted leads using the Angeion Patient Cable. The Smart Wand Programming Head is placed on the DTS and the Programmer controls DTS operations. The DTS is typically used to induce fibrillation, manually deliver varying levels of therapy, obtain shock lead impedance, provide emergency ventricular inhibited (VVI) pacing, and deliver rescue shocks during the defibrillation testing portion of the ICD implant process. DTS functionality is similar to that of the ICD, except that the DTS:

- Is an external, battery-powered device with replaceable alkaline batteries.
- Has visual indicators for power, sensing, and capacitor charging status.
- Has an audio indicator for sensed events and capacitor charging.
- Can deliver a 50 joule (stored energy) rescue shock.
- Can deliver programmable burst ramp pacing pulses to induce fibrillation.

The DTS does not have:

- Automatic tachycardia detection capability — it delivers therapies only under direct user command.
- Anti-tachycardia pacing capabilities.

Programmer

Note: Use of the Programmer with devices not identified in this manual could compromise the safety of this system.

The Programmer is a notebook computer with custom, application-specific software that provides the user interface to interrogate and program the ICD and DTS. There are two models that use all Angeion Sentinel software:

- *Model 3007* — uses an external printer (Model 3008)

Smart Wand Programming Head

The Smart Wand Programming Head is a microprocessor-controlled communications device powered by a 9V alkaline battery. The Programming Head:

- Communicates with an implanted ICD or the DTS using RF telemetry.
- Communicates with the Programmer using a hardwire connection.
- Has a green proximity indicator light that illuminates when the Programming Head is in telemetry range of the ICD or DTS.
- Has two functional buttons: INTER (interrogate) and PROG (program).
- Produces analog signal outputs for telemetered real-time intracardiac electrogram and event markers that can be recorded onto a multi-channel chart recorder using a BNC connection.
- Has an input for sensing pulses from an external stimulator for NIPS using a BNC connection.

Test Electrode

The Test Electrode emulates the ICD case during defibrillation efficacy testing. It is used in combination with the Patient Cable, the DTS, and the implanted defibrillation leads to establish defibrillation efficacy for lead configurations that use the ICD as an electrode.

Patient Cable

The Patient Cable connects the implanted pace/sense and defibrillation electrodes to the DTS to evaluate lead signals and obtain defibrillation efficacy data. The Patient Cable is used with the DTS and the Test Electrode.

You may use defibrillation or subcutaneous electrodes with DF-1 approved connectors or an active fixation pace/sense lead with an IS-1 approved connector with the Patient Cable.

There are two Patient Cable models:

- Model 5006 — for use when implanting ICD Models 2000, 2010, and 2011.
- Model 5020 — for use when implanting ICD Model 2012.

Leads

A variety of defibrillation leads can be used with the Angeion Sentinel system, depending on the needs of the patient and physician evaluation. Contact your Angeion representative for complete information on lead compatibility.