USER: **WEEKS, SUSAN M (smw)**

FOLDER: **P920015 - 376 pages (Subset of Folder)**

COMPANY: **MEDTRONIC INC. (MEDTRONIC)**

PRODUCT: **DEFIBRILLATOR, AUTOMATIC IMPLANTABLE CARDIOVERTER (LWS)**

SUMMARY: **Trade Name: MEDTRONIC(R) TRANSVENE LEAD SYSTEM**

DATE REQUESTED: **Tue Oct 28 16:15:31 2008**

DATE PRINTED: **Tue Oct 28 16:16:53 2008**

PRINTER: **file**

Table of Contents

Pages removed for the following reason: (b)(4)

JUN - 8

Ms. Mary Ellen Best
Principal Regulatory Affairs Specialist
Cardiac Rhythm Management
Medtronic, Inc.
7000 Central Avenue NE
Minneapolis, MN 55432

Re: P920015/S029
Model 6949 and 6931 Leads
Filed: November 6, 2003
Amended: April 1, 2004

Dear Ms. Best:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its evaluation of your premarket approval application (PMA) supplement, which requested approval for addition of a polyurethane overlay. Based upon the information submitted, the PMA supplement is approved. You may begin commercial distribution of the device as modified by your PMA supplement in accordance with the conditions described below and in the "Conditions of Approval" (enclosed).

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

Expiration dating for this device has been established and approved at 2 years. This is to advise you that the protocol used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(7).

CDRH does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws.

Failure to comply with the conditions of approval as attached invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that as soon as possible and before commercial distribution of your device you must submit an amendment to this PMA with copies of all approved labeling in final form. The labeling will not routinely be reviewed by FDA staff when PMA supplement applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have questions concerning this approval order, please contact Kwame Ulmer at (301) 443-8517.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

[DO NOT SHOW ON ORIGINAL]

cc: HFZ-306 (Field Programs Branch - QSR)
HFZ-401 (Document Mail Center)
HFZ-402 (PMA Staff)
HFZ- [ODE Division]
HFZ-100 (OST Reviewer - if appropriate _____)
D.O.

APPROVAL ~~APPROVABLE~~ LETTER FOR A PMA SUPPLEMENT (SAD)
Last Modified 01-31-02

Final:Linda Bessacque:05/21/04

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ 450	ULMER	5/21/04			
HFZ 450	~~[illegible]~~ MOYNAHAN	~~5/21/04~~ 6/2			
450	Ogden	6/7/04			
450	AD/C for ODE	6/3/04			

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 8 2004

Ms. Mary Ellen Best
Principal Regulatory Affairs Specialist
Cardiac Rhythm Management
Medtronic, Inc.
7000 Central Avenue NE
Minneapolis, MN 55432

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Model 6949 and 6931 Leads
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Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Pages removed for the following reason: (b)(4)

P920015/S29/C

Medtronic

Medtronic, Inc.
7000 Central Avenue NE
Minneapolis, MN 55432-3576
www.medtronic.com

tel 763.514.4000

November 5, 2003

FDA/CDRH/PMA
2003 NOV -6 A 10:16

Food and Drug Administration
Center for Devices and Radiological Health
PMA Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Desk Copy (4):
Kwame Ulmer (HFZ-450)

Re: Supplement to P920015 - Model 6949 and 6931 Leads

This supplement requests approval for the Model 6949 and 6931 Leads. The Model 6949 and 6931 leads are downsized versions of the Medtronic Model 6944 Sprint Quattro and 6944 Sprint Quattro Secure leads. These lead models were described in pre-IDE I020145. This pre-IDE resulted in a determination from FDA that no human clinical trials would be required to support approval of these lead models. A copy of the FDA letter is included as Attachment A of this submission. This determination letter included a number of lead model numbers in addition to the Model 6949 and 6931; however, due to resource and timing constraints, Medtronic is submitting only these Model numbers at this time and will submit subsequent Model numbers for approval at a later date.

Two manufacturing facilities are to be used in the assembly, sterilization, and packing of the Model 6949 and 6931 leads for U.S. distribution:

(b)(4)

(b)(4)

This PMA-S includes a categorical exclusion to requirements for environmental impact assessments as described in 21 CFR Part 25.

To the best of our knowledge, Medtronic believes that all data and information contained in this PMA-S, is truthful and accurate and that no material fact has been omitted.

This PMA-S contains confidential and trade secret information. Medtronic respectfully requests that it be given the maximum protection provided by law. If you have any questions, or if further information is required, please contact the undersigned.

Sincerely,

MEDTRONIC, INC.

Mary Ellen Best

Mary Ellen Best
Principal Regulatory Affairs Specialist
Cardiac Rhythm Management
Telephone: (763) 514-4846
Fax: (763) 514-6424
Email: mary.ellen.best@medtronic.com

Table of Contents

CONFIDENTIALITY STATEMENT

This application contains confidential commercial and trade secret information. This is to advise you that certain information contained in the attached PMA Supplement, which has been marked confidential, is being submitted under express claim of confidentiality. It is Medtronic's position that this information is exempt from mandatory disclosure under Exemption 4 of the Freedom of Information Act, 5 U.S.C. 522(B)(4), and the Trade Secrets Act, 18 U.S.C. 1905. This information is not available to our competitors. Disclosure would have an adverse impact on Medtronic's competitive position. If any person requests an inspection or requests a copy of the documents or any portion of them, please give us sufficient advance notice prior to any such disclosure to allow us to pursue appropriate remedies to preserve the confidentiality of this information.

SPONSOR NAME AND ADDRESS

Medtronic, Inc.
7000 Central Avenue N.E.
Minneapolis, MN 55432.3576

Contact:

Mary Ellen Best
Principal Regulatory Affairs Specialist
Cardiac Rhythm Management
Telephone: (763) 514.4846
Fax: (763) 514.6424
Email: mary.ellen.best@medtronic.com

DESCRIPTION

Description of the Model 6949 and 6931 Leads

The Model 6949 and 6931 are steroid eluting, endocardial, silicone/ETFE insulated defibrillation leads with a polyurethane overlay. These leads are intended for use as part of an internal cardioversion/ defibrillation (ICD) system. The Model 6949 is quadripolar and contains both right ventricular (RV) and superior vena cava (SVC) defibrillation electrodes as well as a tip electrode and a ring electrode. The Model 6931 lead is tripolar and includes a tip electrode, a ring electrode and one (RV) defibrillation coil. Both leads are intended for single, long-term use in the right ventricle.

The Model 6949 and 6931 leads are downsized versions of the Medtronic Model 6947 Sprint Quattro Secure (P920015/S24, approved Nov. 20, 2001). The Model 6949/6931 leads include a combination of components used in currently marketed Medtronic leads with some enhancements. Medtronic engineered this new family of downsized leads based on a modular component concept that allows the use of interchangeable components during lead design and manufacture. All functional features of the Model 6949 and 6931 leads have been approved in currently marketed Medtronic leads. (See Table 1)

The Model 6949/6931 lead body utilizes the same silicone, multilumen lead body as is used for Medtronic Sprint leads with some modifications to downsize the lead body diameter. The Sprint compression lumens have been integrated into the pacing lumen of the 6949/6931 leads. (See Fig. 5) The Model 6949/31 and 6947 leads incorporate a polyurethane overlay over the silicone lead body making it isodiametric. The lead body for the Model 6949 and 6931 leads is identical with the exclusion of the SVC defibrillation coil in the Model 6931 lead. All processes and components used for the Model 6949 and 6931 leads are the same with the exception that the Model 6931 does not contain an SVC defibrillation circuit, resulting in a bifurcated connector design with one DF-1 leg instead of two. (See Fig 1 and 2).

The Model 6949 and 6931 leads use the same extendable/retractable helix mechanism as is used for the Medtronic Model 5076 CapSure Fix Novus lead (P930039/S9 and S016).

Functionality

All functional features of the Model 6949/6931 leads have been approved in currently marketed leads

Table 1 Functional Similarities

	Model 6947 (P950012/S24)	**Model 6943 (P950012/S13)**	**Model 6949**	**Model 6931**
Fixation	Active Extendable-retractable helix	Active Extendable-retractable helix	Active Extendable-retractable helix	Active Extendable-retractable helix
Polarity	Quadripolar	Tripolar	Quadripolar	Tripolar
Electrodes for Pacing Sensing Defibrillation	Tip Ring RV Coil SVC Coil	Tip Ring RV Coil	Tip Ring RV Coil SVC Coil	Tip Ring RV Coil
Sensing	True Bipolar	True Bipolar	True Bipolar	True Bipolar
Isodiametric lead body	Yes	No	Yes	Yes
Steroid	Dexamethasone sodium phosphate	Dexamethasone sodium phosphate	Dexamethasone acetate (same as 5076)	Dexamethsone acetate (same as 5076)
Ventricular Use	Yes	Yes	Yes	Yes

List of New Features
(as compared to Sprint Models 6947and 6943)

- **TiN (titanium nitride) Coated Ring and Tip Electrodes**
  - same as 4074 and 5076 leads
- **Extendable/retractable helix mechanism (see Fig 3)**
  - same as the Model 5076 lead
- **Defibrillation Coils (see Table 2)**
  - Smaller diameter
  - Longer RV coil
- **Conductor Cables (see Fig 4)**
  - Blue colorant added to ETFE coating for ease of manufacturing
  - Distinguishes high voltage from low voltage cables
  - Non-tissue contacting
- **Lead body (see Fig 4 & 5)**
  - 6.6 French diameter
  - Integrated vs. isolated compression lumens
  - ETFE liner extends from IS-1 connector to sleeve head
- **Blue Stylet Guide/ Fixation Tool (see Fig 6)**
  - Acts as both a stylet guide and a fixation tool
- **White identification label (see Fig 6)**
  - Located within the DF-1 and IS-1 terminal assemblies
  - material loaded with barium sulfate to improve visibility of label information
  - Non-tissue contacting
- **Anchoring Sleeve**
  - Same shape as Model 5076 anchoring sleeve
  - Same radiopaque material as Model 5944/6947 anchoring sleeve
- **Steroid**
  - Dexamethasone acetate incorporated into MCRD and applied to tip electrode
  - Same as Model 5076

Fig. 1 - Composite View - 6949 Lead

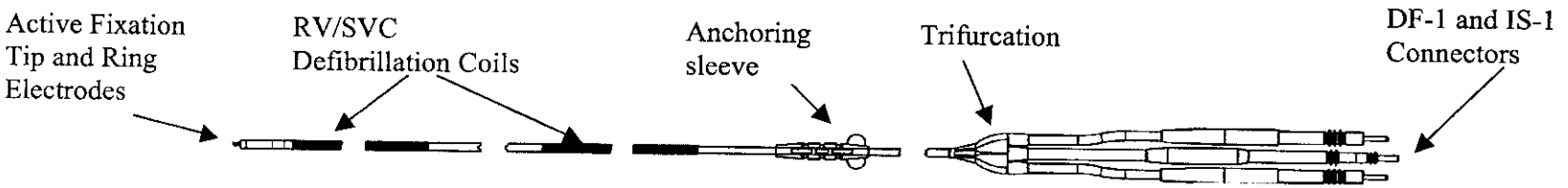


Fig. 2 - Composite View - 6931 Lead

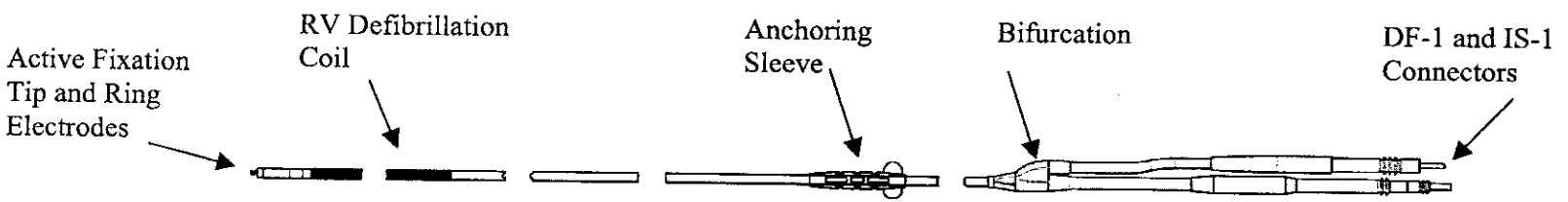


Fig. 3 - Model 6949 and 6931 - Distal Tip

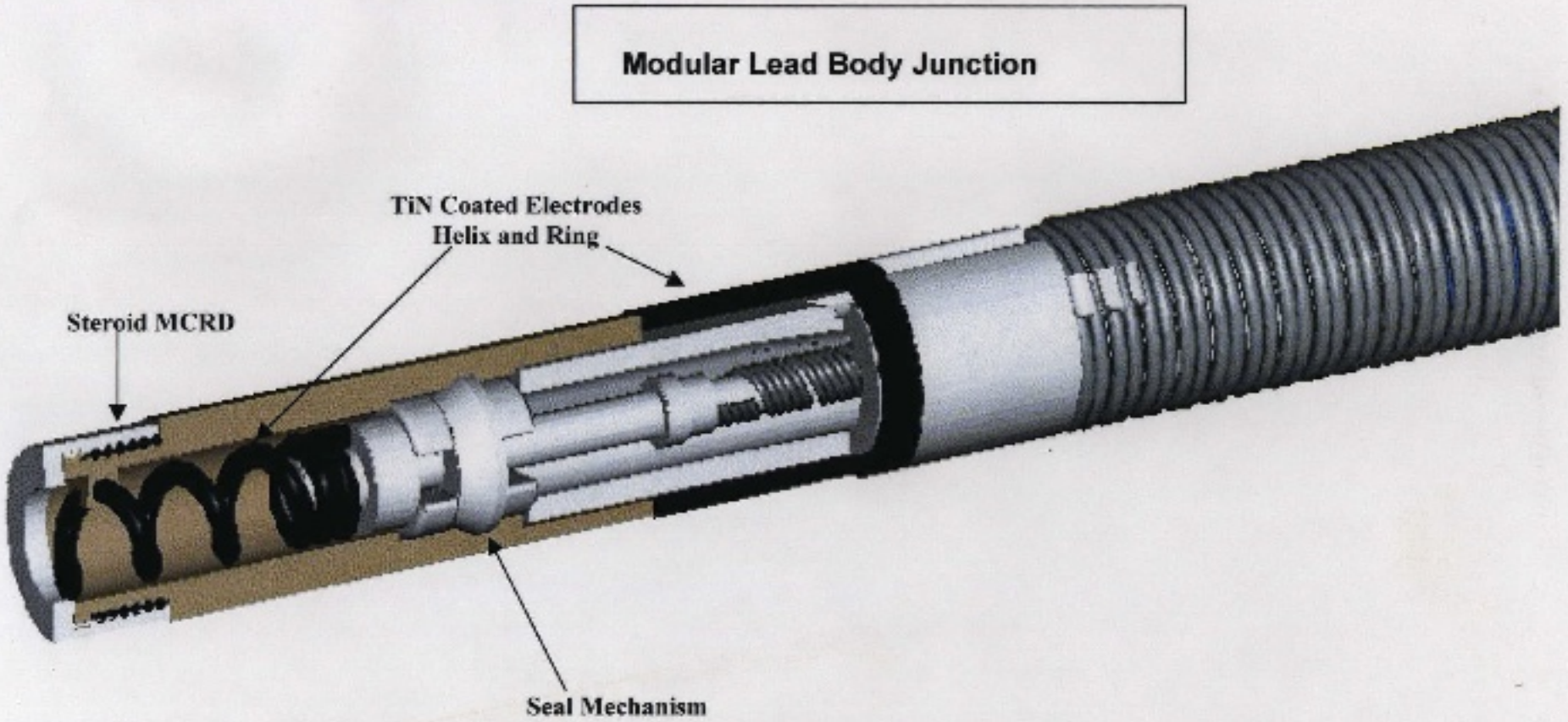
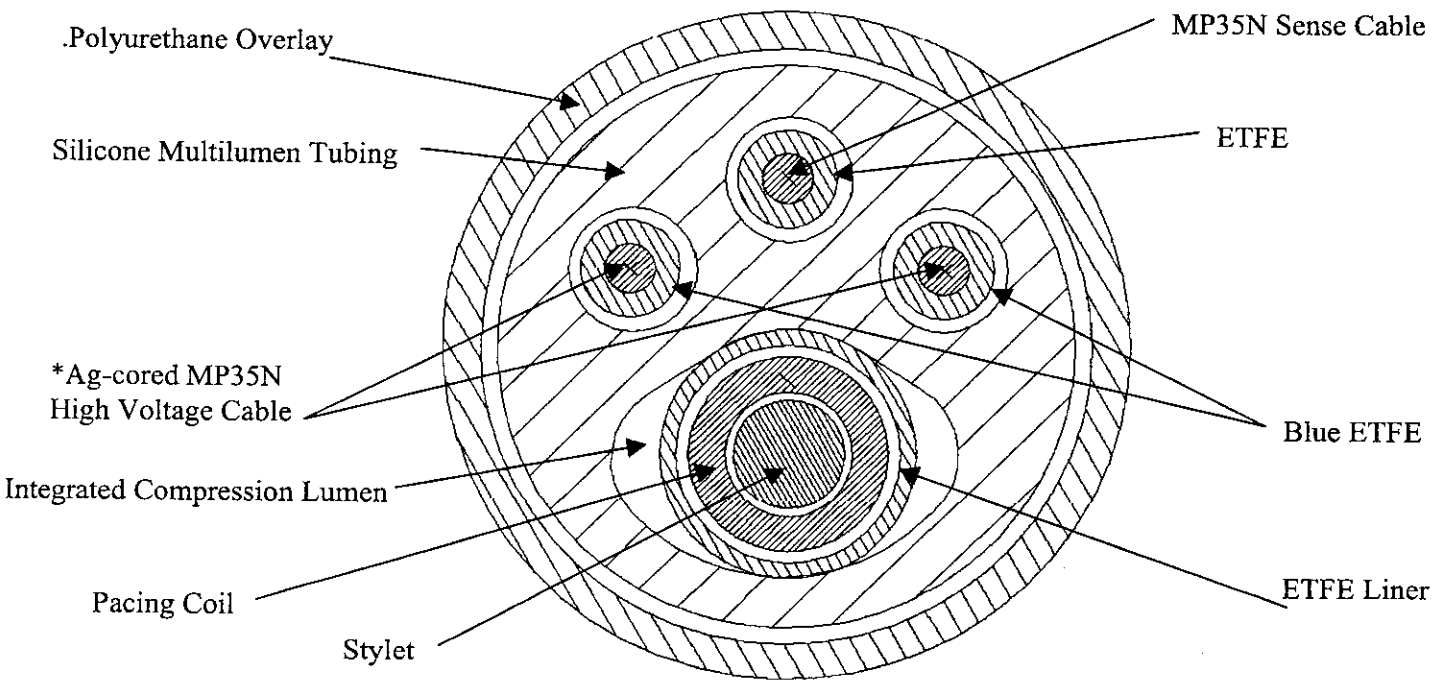


Fig.4 – Model 6949/6931 Lead Body Construction – Cross Section

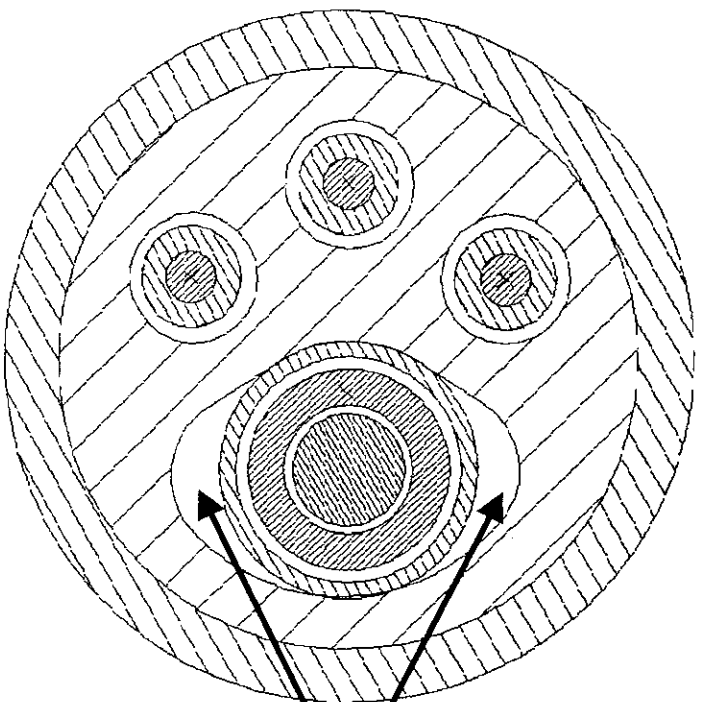


*One lumen remains empty for the Model 6931 lead due to the absence of the SVC defibrillation coil.

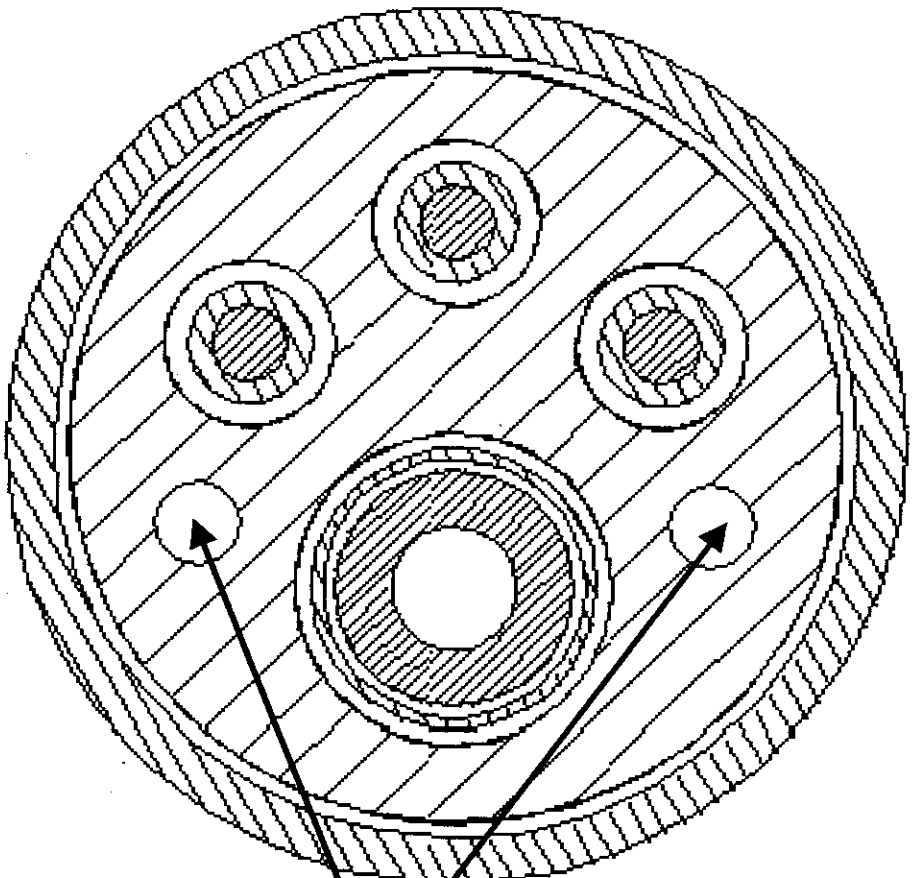
Fig. 5 – Comparison of Model 6949 to Model 6947

Model 6947 (8.6 Fr)

Model 6949 (6.6 Fr)

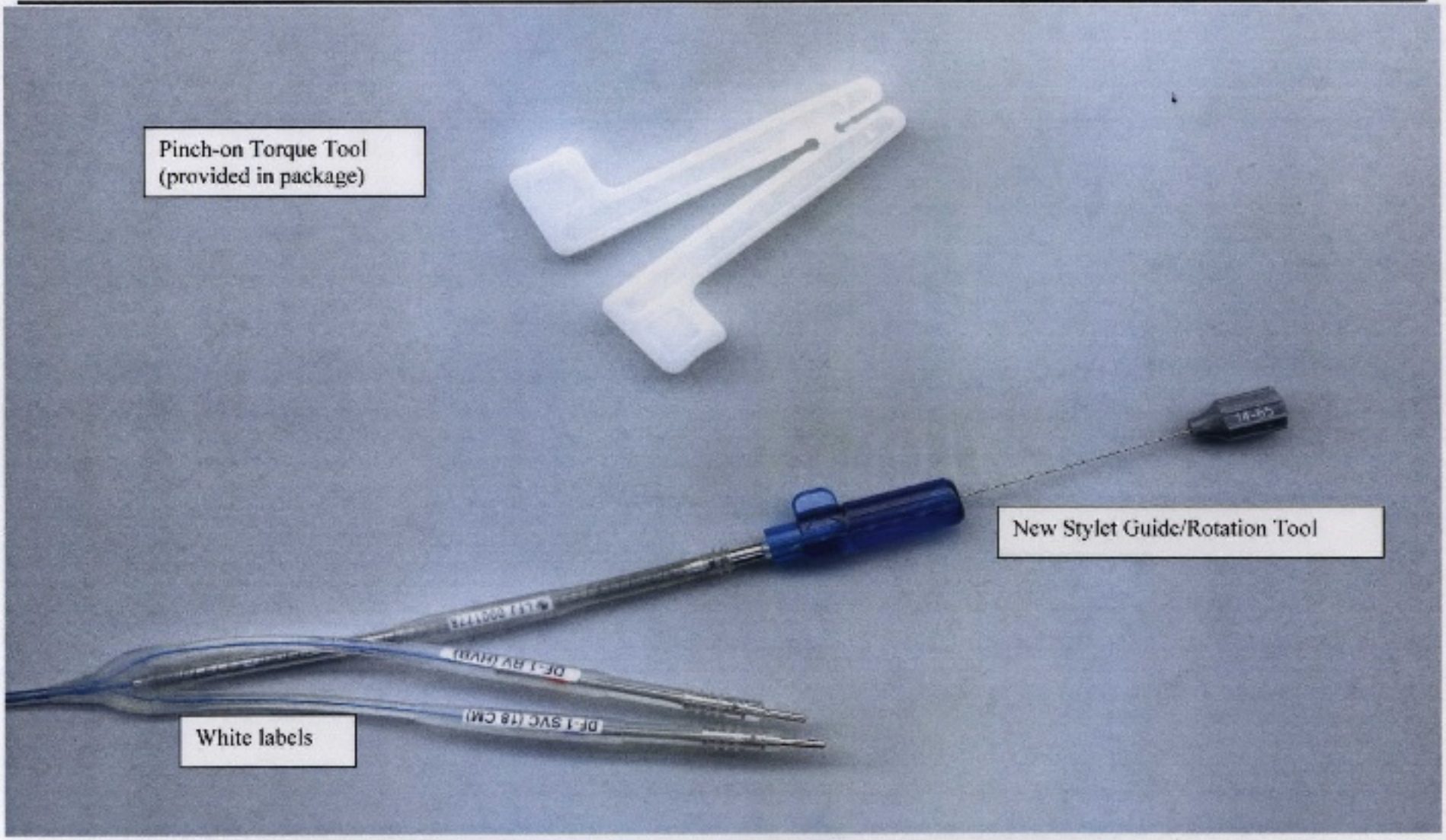


Integrated Compression Lumens



Isolated Compression Lumens

Fig.6 – Model 6949 Improved Accessories



Detailed Comparison

Table 2 Detailed Comparison of Model 6949 and 6931

ELECTRODES		
Tip Electrode	**6949/6931**	**Comparison**
Helix mechanism	Extendable/retractable helix	Same as Model 5076
Helix extension/retraction indicator	Visual gap closes when helix extends	Same as Model 6947,6945,6943
Material	TiN coated Platinum Iridium	Same as Model 4074 and 5076
Fixation depth	0.072"	Same as Model 5076
Helix diameter	0.046"	Same as Model 5076
Wire diameter	0.010"	Same as Model 5076
Tip surface area	4.2 mm^2	Same as Model 5076
Ring Electrode	**6949/6931**	**Comparison**
Material	TiN coated Platinum Iridium	Same as Model 4074 and 5076
Ring surface area	20.1 mm^2	Model 5076 = 22 mm^2 6947 = 25.2 6944 = 17 6943 = 23.3
RV Defib. Coil Electrode	**6949/6931**	**Comparison**
Material	Platinum iridium clad tantalum wire wound in a bifilar configuration	Same as Models 6944 and 6947
Length	RV = 6.2 cm	Models 6947 and 6944 = 5.7 cm Model 6945/6943 = 5.0 cm
Diameter	RV = 2.2 mm	Model 6947 = 2.84 mm Model 6744 = 2.72 mm Model 6945/6943 = 3.12 mm
Surface Area	RV = 513 mm^2	Model 6947 = 614 mm^2 Model 6944 = 585 mm^2 Model 6945/6943 = 350 mm^2
SVC Defib. Coil Electrode	**Model 6949**	**Comparison**
Material	Platinum iridium clad tantalum wire wound in a bifilar configuration	Same as Models 6947 and 6944
Length	8 cm	Same as 6944 and 6947

Diameter	2.2 mm	Model 6947 = 2.84 mm Model 6944 = 2.72 mm Model 6945 = 3.12 mm
Surface Area	663 mm^2	Model 6947 = 860 mm^2 Model 6944 = 819mm^2 Model 6945 = 568 mm^2
Shadow Area	556 mm^2	Model 6947 = 709 mm^2 Model 6944 = 677 mm^2 Model 6945 = 785 mm^2
Electrode Spacing	**Model 6949/6931**	**Comparison**
Tip-to-Ring Tip-to-RV Tip-to-SVC	8 mm 12 mm 18 cm (6949 only)	Same as 6944 and 6947
CONDUCTORS		
Pacing Conductor Coil	**Model 6949/6931**	**Comparison**
	6 filar, MP35N 0.0045" wire ETFE liner	6947 uses 4 filar, MP35N, 0.0055" wire 6947/6944 use PTFE liner
Sense Conductor Cable	1X19 MP35N cable, ETFE coated	Same as Model 6944 (Model 6947 uses 7X7 cable, ETFE coated)
Defib Conductor Cables	1X19 MP35N Ag-cored cables coated with blue ETFE	Model 6944 and 6947 use 7X 7 MP35N Ag-cored cables coated with ETFE

LEAD BODY	6949/6931	Comparison
		Similar to Model 6944 and 6947
Lead body diameter	6.6 Fr	Model 6947 = 8.6 Fr Model 6944 = 8.2 Fr
Lead body design	Multilumen design with integrated compression lumens	Multilumen design with isolated compression lumens
Lead body insulation	HP silicone rubber with inner and outer surface Siloxane treated	Model 6947 and 6944use HP silicone rubber with inner surface Siloxane treated /outer surface Silacure treated Model 5076 uses silicone rubber with Siloxane treated outer surface
Lead body overlay	Polyurethane	Model 6944 and 6947 use

		Polyurethane

CONNECTORS	Model 6949/6931	
	One IS-1 and two DF-1 connectors	Same as Models 6944 and 6947

STYLETS	Model 6949/6931	
	Gray (0.014" tapered) Blue (0.014" straight)	Same as Model 5076

STEROID	Model 6949/6931	
	Dexamethasone acetate MCRD / helix surface coated	Same as Model 5076

EXECUTIVE SUMMARY

General Information

Device Generic Name	Transvenous, steroid eluting, active fixation, pace/sense, ventricular lead
Device Trade Name	Medtronic Model 6949 and 6931 Leads
Applicant's Name and Address	Medtronic, Inc. 7000 Central Avenue N.E. Minneapolis, MN 55432-3576
PMA Number	P920015 /SXXX

Indications and Usage

The indications and usage of the Model 6949 and 6931 leads are the same as those for the Model 6947 lead. They are indicated for single, long-term use in the ventricle. These leads have application for patients in which arrhythmia management systems are indicated.

Device Description

The Model 6949 and 6931 are steroid eluting, endocardial, silicone/ETFE insulated defibrillation leads with a polyurethane overlay. These leads are intended for use as part of an internal cardioversion/ defibrillation (ICD) system. The Model 6949 is quadripolar and contains both right ventricular (RV) and superior vena cava (SVC) defibrillation electrodes as well as a tip electrode and a ring electrode. The Model 6931 lead is tripolar and includes a tip electrode, a ring electrode and one (RV) defibrillation coil. Both leads are intended for single, long-term use in the right ventricle.

The Model 6949 and 6931 leads are downsized versions of the Medtronic Model 6947 Sprint Quattro Secure. The Model 6949 and 6931 leads include a combination of components used in currently marketed Medtronic leads with some enhancements.

Manufacturing Information

The Model 6949 and 6931 are manufactured, packaged, and sterilized using processes similar to those used for the Model 6947. A flowchart describing the manufacturing process and a description of the ethylene oxide sterilization process is included in the Manufacturing Section of this submission.

Shelf Life

Shelf life of the Model 6949 and 6931 leads is 2 years. (See Bench Test Summary)

Summary of Test Results

Bench Testing

Medtronic has thoroughly evaluated the Model 6949 and 6931 leads and subassemblies through in vitro testing to assure suitability and reliability for their intended use. The Model 6949 and 6931 leads are identical in construction with the exception that the Model 6931 has only one defibrillation coil (RV) and subsequently, one DF-1 leg. Most Model 6931 features are verified by similarity to the Model 6949. All leads were subjected to environmental conditioning prior to conducting the mechanical and electrical tests. The major areas of in vitro testing include the following categories:

- Enviornmental conditioning
- Mechanical testing
- Electrical testing
- Steroid elution testing
- Package / shelf life testing.

Canine Testing

The Model 6949 lead was implanted in the right ventricle of eight canines. The implants were performed using stylet delivery techniques with no issues noted. Chronic stability of the Model 6949 was confirmed using radiographs. Monitors were performed at implant and at weeks 1, 2, 3, 8, and 12 weeks post-implant. This study was conducted in accordance with Good Laboratory Practices.

The Model 6949 lead demonstrated electrical performance similar to the Model 6947. The data from this study demonstrates that pacing/sensing performance and

delivery of defibrillation therapy provided by the Model 6949 in the right ventricle is similar to the performance of the Model 6947 lead.

Biocompatibility

Medtronic certifies that the materials used in the Medtronic Model 6949 and 6931 leads that are directly exposed to body or tissue and/or blood are identical to the materials used in the previously approved Medtronic leads.

Warnings / Precautions / Contraindications

The warnings, precautions and contraindications for the Model 6949 and 6931 leads are the same as those provided for the Model 6947 lead. Details are included the Labeling Section of this submission.

Product Labeling

The labels and technical manuals for the Model 6949 and 6931 leads have been provided in the Labeling Section of this submission. The labeling is based on the product labeling for the Model 6947 lead, which was revised to reflect the differences in the lead model designs. A copy of the Model 6947 manual with the redlined changes has also been provided.

Marketing History

The Model 6949 and 6931 leads are not commercially available and have not been distributed inside or outside the United States. An application for investigational testing has been applied for in Canada to conduct a clinical handling evaluation of the Model 6949 while this submission is under review.

TESTING RESULTS

Pages removed for the following reason: (b)(4)-Testing and Manufacturering Processes.

PRODUCT LABELING

The labeling for the Model 6949 and 6931 leads is based on the Model 6947 labeling. This section contains the following information:

- Package Label for the Model 6949 lead
- Package Label for the Model 6931 lead
- List of changes made to the Model 6947 Technical Manual
- Technical Manual for the Model 6949 / 6931 lead
- Red-lined copy of the Model 6947 Technical Manual

Package Label for Model 6949

A02127-002

SPRINT™ 6949 - 000cm
Steroid eluting, screw-in, ventricular lead
with defibrillation coil electrodes

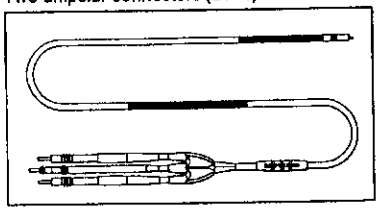
USE BY 2000-00-00 YR-MO-DA
SN SERIAL NUMBER WWW000000W

Medtronic

SPRINT™ 6949 - 000cm

Steroid eluting, screw-in, ventricular lead with defibrillation coil electrodes

One inline bipolar connector (IS-1),
Two unipolar connectors (DF-1)



Model: 6949

SN SERIAL NUMBER WWW000000W

USE BY 2000-00-00 YR-MO-DA

LEAD LEAD LENGTH 000cm

MANUFACTURING DATE 2000-00

Recommended Medtronic lead introducer size: } 7.0 French without guidewire / 9.0 French with guidewire

CONTENTS: One silicone lead with accessories and documentation.

ATTENTION: SEE ACCOMPANYING DOCUMENTS

+40°C +104°F MAXIMUM STORAGE TEMPERATURE

STERILE EO STERILIZATION: Ethylene Oxide Gas

PIN:0000W00-00W
A02127-002

Medtronic, Inc.
Minneapolis, MN 55432
USA

Medtronic

SPRINT™ 6949 - 000cm

Steroid eluting, screw-in, ventricular lead with defibrillation coil electrodes

USE BY 2000-00-00 YR-MO-DA
SN SERIAL NUMBER WWW000000W

CONTENTS: One silicone lead with accessories.

The contents of this package are **STERILE.** If the package is damaged or opened see the technical manual for information.

Recommended Medtronic lead introducer size: } 7.0 French without guidewire / 9.0 French with guidewire

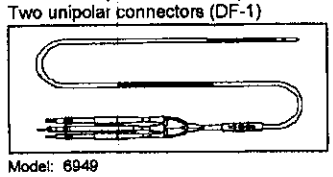
+40°C +104°F MAXIMUM STORAGE TEMPERATURE

STERILE EO STERILIZATION: Ethylene Oxide Gas

ATTENTION: SEE ACCOMPANYING DOCUMENTS

A02127-002

One inline bipolar connector (IS-1),
Two unipolar connectors (DF-1)



Model: 6949

SN SERIAL NUMBER WWW000000W

USE BY 2000-00-00 YR-MO-DA

LEAD LEAD LENGTH 000cm

MANUFACTURING DATE 2000-00

DO NOT REUSE

Medtronic

Medtronic, Inc.
Minneapolis, MN 55432
USA

SPRINT™ 6949 - 000cm
Steroid eluting, screw-in, ventricular lead
with defibrillation coil electrodes

A02127-002

Peel off this label for your records after product has been used.

Medtronic SPRINT™ 6949 000cm
SN SERIAL NUMBER WWW000000W

FW
A02127-002
REV 100

194252-003

Package Label for Model 6931

MMM000000MMM00000+

000000000000000M+

SPRINT™ 6931 - 000cm
Steroid eluting, screw-in, ventricular lead
with defibrillation coil electrodes

USE BY 2000-00-00 YR-MO-DA

SN SERIAL NUMBER WWW000000W

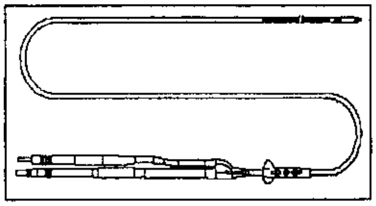
A02125-001

Medtronic

SPRINT™ 6931 - 000cm

Steroid eluting, screw-in, ventricular lead with defibrillation coil electrodes

One inline bipolar connector (IS-1),
One unipolar connector (DF-1)



Model: 6931

SN SERIAL NUMBER WWW000000W

USE BY 2000-00-00 YR-MO-DA

LEAD LEAD LENGTH 000cm

MANUFACTURING DATE 2000-00

Recommended Medtronic lead introducer size: 7.0 French without guidewire; 9.0 French with guidewire

CONTENTS: One silicone lead with accessories and documentation.

ATTENTION: SEE ACCOMPANYING DOCUMENTS

+40°C +104°F MAXIMUM STORAGE TEMPERATURE

STERILE EO STERILIZATION: Ethylene Oxide Gas

PIN:0000W00-00W
A02125-001

Medtronic, Inc.
Minneapolis, MN 55432
USA

Medtronic

SPRINT™ 6931 - 000cm

Steroid eluting, screw-in, ventricular lead with defibrillation coil electrodes

CONTENTS: One silicone lead with accessories.

The contents of this package are **STERILE**. If the package is damaged or opened see the technical manual for information.

Recommended Medtronic lead Introducer size: 7.0 French without guidewire; 9.0 French with guidewire

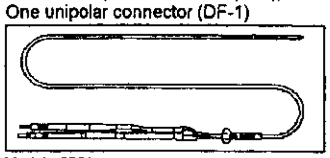
+40°C +104°F MAXIMUM STORAGE TEMPERATURE

STERILE EO STERILIZATION: Ethylene Oxide Gas

ATTENTION: SEE ACCOMPANYING DOCUMENTS

A02125-001

One inline bipolar connector (IS-1),
One unipolar connector (DF-1)



Model: 6931

SN SERIAL NUMBER WWW000000W

USE BY 2000-00-00 YR-MO-DA

LEAD LEAD LENGTH 000cm

MANUFACTURING DATE 2000-00

DO NOT REUSE

Medtronic

Medtronic, Inc.
Minneapolis, MN 55432
USA

Peel off this label for your records after product has been used.

USE BY 2000-00-00 YR-MO-DA

SN SERIAL NUMBER WWW000000W

SPRINT™ 6931 - 000cm
Steroid eluting, screw-in, ventricular lead
with defibrillation coil electrodes

A02125-001

Medtronic SPRINT™ 6931 000cm	SN SERIAL NUMBER WWW000000W	Medtronic SPRINT™ 6931 000cm	SN SERIAL NUMBER WWW000000W	Medtronic SPRINT™ 6931 000cm	SN SERIAL NUMBER WWW000000W
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FW
A02125-001
REV A02

102

194252-003

Technical Manual for Model 6949/ 6931

Change Table for Model 6947 Technical Manual

From: Stacy Eichenlaub, Technical Writer

Date: 23 October 2003

Manual section	Action	Rationale
Cover	Removed the "Quattro Secure" brand name and replaced model 6947 with 6949/6931.	New leads in the Sprint family. Brand name for new leads not yet finalized.
Inside front cover	Added trademark statement	Allows us to remove trademark information throughout the manual.
Device description	Modified description to accommodate a dual lead manual layout and also to clarify the differences between the 6949 and 6931 leads.	Emphasizes that SVC coil electrode only on the 6949 lead.
Device description	Changed steroid name to dexamethasone acetate.	Different steroid used on these leads.
Contents of package	Removed the style guide and included the new blue stylet guide/fixation tool.	New tool for these leads.
Accessory descriptions	Removed the style guide description and added the blue stylet guide/fixation tool definition.	
Contraindications	Changed steroid name to dexamethasone acetate.	Different steroid used on these leads.
Warnings and Precautions	Added the warning "For single use only – Do not resterilize and reimplant an explanted lead."	Warning being included in all new lead manuals.
Warnings and Precautions	Changed steroid name to dexamethasone acetate.	Different steroid used on these leads.
Adverse events	Removed the "Observed adverse events"	Pertains to the 6947 clinical study.
Clinical studies	Removed the clinical studies.	Studies were for the 6947 lead.
Directions for use	Added steps to "Verifying the mechanical functioning of the helix electrode" and "Securing the helix electrode in the endocardium."	Incorporated necessary instructions for the new blue stylet guide/fixation tool.

Manual section	Action	Rationale
Directions for use	Removed "or the inferior vena cava" from "Positioning the lead" section.	Inaccurate.
Directions for use	Modified step 1 in both "Taking electrical measurements and defibrillation efficacy measurements" and "Connecting the lead."	Necessary to incorporate blue stylet guide/fixation tool instruction.
Detailed device description	Updated the specifications (nominal).	Included new specifications for the 6949 and 6931 leads.
Detailed device description	Updated the specifications for the 6949 drawing.	Changes made to the lead dimensions.
Detailed device description	Added a specification drawing for the 6931 lead.	Necessary to depict the difference of the 6931 lead.
Special notice	Removed this section from the manual.	This text is now located on the warranty card.
Medtronic warranty	Added a warranty statement referring users to the warranty documents in the package.	Separate document now includes all relevant warranty information.
Back cover addresses	Addresses updated to reflect current addresses.	
General	Editorial changes throughout the manual in accordance with Medtronic CRM Technical Communications standardization efforts.	Consistency of text will assist users.

Pages removed for the following reason: Draft Label - Final Label Available on FDA Internet

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PERFORMANCE STANDARDS

Performance standards have not been promulgated for implantable cardioverter defibrillators. Therefore, no action is required under Section 514, Performance Standards

ENVIRONMENTAL ASSESSMENT

Medtronic claims a categorical exclusion to requirements for environmental impact assessments as described in 21 CFR Part 25. Medtronic considers the use of the Medtronic Model 6949 and 6931 leads as not "significantly affecting the quality of the human environment." Devices are intended to be used in a manner in which waste will be controlled or the amount of waste expected to enter the environment may reasonably be expected to be non-toxic.

ATTACHMENTS

Attachment A

FAX COVER SHEET

U.S. FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF DEVICE EVALUATION

DIVISION OF CARDIOVASCULAR, RESPIRATORY DEVICES
9200 CORPORATE BOULEVARD HFZ-450
ROCKVILLE, MD 20850

NO. OF PAGES: 3 (including cover sheet) DATE: 5/13/03

TO: Mary Ellen Best

COMMENTS: I020145/S002

SENDER'S NAME: Wil Usher

FROM:

		PHONE NUMBER	FAX NUMBER
☐ Office of the Director		301-443-8320	301-594-3076
☐ Pacing & Electrophysiology Group	(PEDG)	301-443-8517	301-594-3076
☐ Program Management/Special Review Group	(PMSRG)	301-443-8320	301-594-3076
☐ Anesthesiology,Defibrilllator & Respiratory Group	(ADDG)	301-443-8609	301-480-4204
☐ Circulatory Support & Prosthetics Group	(CSPG)	301-443-8262	301-827-4351
☐ Interventional Cardiology Group	(ICDG)	301-443-8243	301-480-4204

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PLEASE ADVISE IF TRANSMISSION IS ILLEGIBLE

I:/Ode/dcrd/Fax Cover Sheet

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 2003

Ms. Mary Ellen Best
Medtronic Cardiac Rhythm Management
Medtronic, Inc.
7000 Central Avenue NE
Minneapolis, MN 55432-3576

Re: I020145/S002
Steroid Eluting ICD Leads Model Numbers 6948, 6949, 6930, 6930A, 6931, 6931A, 6978, and 6979
Received: February 11, 2003

Dear Ms. Best:

Under provision of section 513(a)(3)(D) of the Food, Drug, and Cosmetic Act (act), you requested a meeting to determine the type of valid scientific evidence necessary to establish reasonable assurance that the Steroid Eluting ICD Leads are effective under its proposed conditions of use. The focus of such a meeting is to examine the broad outline of the clinical trial design. The determination process explores whether clinical studies with concurrent randomized controls, concurrent non-randomized controls, historical controls, or other types of evidence would be considered the least burdensome way of evaluating device effectiveness that has a reasonable likelihood of success in resulting in approval. FDA has also considered whether there is data that would otherwise be required for approval of an application that can be reduced through reliance on postmarket controls.

The Steroid Eluting ICD Leads are leads that are proposed for long term, single use in the right ventricle and have application for patients in which arrhythmia management systems are indicated. The platform will include quadripolar leads with RV and SVC defibrillation electrodes (Models 6949, 6948, 6978, and 6979) and tripolar leads with only one (RV) defibrillation electrode (Models 6930, 6930A, 6931, and 6931A). In addition, this platform will offer either active fixation (extendable /retractable helix) versions (Models 6949, 6979, 6931, and 6931A) or passive fixation (tined) versions (Models 6948, 6978, 6930, and 6930A). The first version of each platform will have a polyurethane (b)(4) overlay to provide additional mechanical protection to the underlying silicone. The second version of the two platforms will utilize the same mechanical and electrical design, but will incorporate a Surface Modified End Group

Group (SME) overlay in place of the polyurethane overlay. The SME polyurethane is composed of (b)(4) Silicone SME.

To make the determination decision, we considered the information that was submitted, the requirements of the act as described above, and the previous regulatory approaches for this type of device. We have determined that the following represents the most appropriate means for establishing the effectiveness of the Steroid Eluting ICD Leads:

1. **Design Verification Testing**

   Testing will provided as defined on page 7 of the pre-IDE amendment dated February 10, 2003.

2. **Materials Testing**

   a. No further biocompatibility testing for the leads with (b)(4) polyurethane overlay will be necessary asall materials have been previously utilized and tested.

   b. Mechanical, electrical and chemical characterization, full biocompatibility testing, and material quality assurance testing of (b)(4) polyurethane will be provided.

   c. A test report for accelerated environmental stress cracking (ESC) testing of (b)(4) polyurethane will be provided. The report should include the test purpose, methods, description of samples for testing, test results, and conclusions reached.

3. **Canine Testing**

   a. One-year study, evaluating a minimum of 20 leads with (b)(4) polyurethane overlay as outlined on pages 9 -13 of the pre-IDE dated February 10, 2003

   b. Interim (b)(4) data will be submitted for the polyurethane lead models

4. **No Human Clinical Trials required for either (b)(4) Polyurethane or (b)(4) Polyurethane models**

This determination is considered binding on the Center for Devices and Radiological Health (CDRH) and cannot be changed unless such a determination would be contrary to public health.

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If you have any comments or questions regarding this letter, please contact Geretta Wood at 301-443-8320, ext. 143.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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Pages removed for the following reason: (b)(4)-Clinical Section and Raw Data.

P920015/S29/A2/C1

Medtronic

Medtronic, Inc.
7000 Central Avenue NE
Minneapolis, MN 55432-3576
www.medtronic.com

763.514.4000

August 9, 2004

Food and Drug Administration
Center for Devices and Radiological Health
PMA Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Re: Amendment to P920015/S029
Final Approved Labeling for the Medtronic Model 6949 and 6931 Sprint Fidelis leads

This amendment provides the final labeling for the products approved in P920015/S029. The following information is included:

- Labeling Certification which includes a description of changes made to the labeling included in the original PMA supplement
- Final technical manual for the Model 6949 and 6931 Sprint Fidelis Leads
- Final package labeling for the Model 6949 and 6931 Sprint Fidelis Leads
- Information card to be packaged directly with the product to provide customer access to labeling via the Medtronic Website. This instruction card is generic in nature and has been previously reviewed by FDA.

This document is submitted in triplicate. For additional information concerning this submission, please contact the undersigned.

Sincerely,
MEDTRONIC, INC.

Mary Ellen Best

Mary Ellen Best
Principal Regulatory Affairs Specialist
Medtronic Cardiac Rhythm Management
Telephone: 763-514-4846
Fax: 763-514-6424
E-mail: mary.ellen.best@medtronic.com

SP5

Labeling Certification

Application Number: P920015/S029

Device Name: Medtronic Fidelis Lead Models 6949 and 6931

I certify that the labeling provided in this submission is identical in content to the labeling provided in the original PMA-S with changes outlined in attached Tables 1 and 2. The original submission contained one manual which contained both model numbers. This submission contains separate manuals for each model number.

The Technical manuals will be provided in either paper or electronic form (CD Rom or Website). To provide customer access to labeling via the Medtronic Website, an instruction card will be packaged directly with the product. This instruction card is generic in nature and has been previously reviewed by FDA. It is included in this submission as part of the final draft labeling.

Signed: Mary Ellen Best Date: August 9, 2004
By: Mary Ellen Best
Title: Principle Regulatory Affairs Specialist
Cardiac Rhythm Management
Medtronic, Inc.

Table 1. Changes Made to Technical Manuals

Changes Made	Reason for Change
The brand name changed from "Sprint" to "Sprint Fidelis"	Product branding was not complete until after the submission date.
Editorial format changes	To make separate manuals for each model number and to improve clarity.
"Blue stylet guide/fixation tool" changed to "Quick Twist Tool"	Branding not complete until after submission date
Clinical data added	Per FDA request. Information provided was submitted to FDA for review.
Directions for Use lists steps for implant procedure. Post-implant evaluation was added to the end of the list.	Post-implant evaluations are part of the implant procedure.
Directions for use, Anchoring the lead: Add the following: *NOTE: The anchoring sleeves contain a radiopaque substance, which allows visualization of the anchoring sleeve on a standard x-ray and may aid in follow-up examinations.*	Additional information adds clarity.
Directions for use, Taking electrical measurements and defibrillation efficacy measurements: Revise section describing process to follow when electrical measurements deviate from recommended values.	To improve clarity of instruction.
Detailed Device Description: Electrodes (pace, sense): Titanium nitride coated platinum alloy change to Titanium nitride coated platinum iridium Correct resistance symbols	Provides a more complete and accurate description

Table 2. Changes Made to Package Labeling

Changes Made	Reason for change
Brand Name changed from "Sprint" to "Sprint Fidelis"	Name change determined after submission
New lead graphics used Change information layout	Update to new labeling format.
Add the following caution statements: CAUTION: Inserting the lead using a lead introducer that features a hemostasis valve may require a larger introducer than the size recommended on the labeling. Do not withdraw the lead through a hemostasis valve to avoid distortion of the coil electrode. CAUTION: To prevent suture site damage, the anchoring sleeve provided must be used. See the technical manual for details.	Statements were used in previous Sprint lead models and also applies to the Sprint Fidelis leads.
Add: "Manufactured at: Villalba, Puerto Rico, USA"	Additional information to match new labeling format
Add: "Rx only"	To correct omission in original submitted labeling
Add new tracking symbol	For inventory control system
The symbols for opening the package has been removed	This symbol is now printed directly on the labeling box

Medtronic

SPRINT FIDELIS™ 6949

Steroid eluting, quadripolar, screw-in, ventricular lead
with RV/SVC defibrillation coil electrodes

Technical manual

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

The following are trademarks of Medtronic: Medtronic, Sprint Fidelis, Sprint Quattro Secure, Quick Twist

Table of contents

Device description

The Medtronic Sprint Fidelis Model 6949 lead is a steroid eluting, quadripolar, screw-in, ventricular lead with right ventricular (RV) and superior vena cava (SVC) defibrillation coil electrodes. This lead is designed for pacing, sensing, cardioversion, and defibrillation therapies.

The lead features an extendable/retractable helix electrode, silicone insulation with overlay, parallel conductors, titanium nitride coated platinum iridium tip and ring electrodes, and RV and SVC coil electrodes. See "Specifications drawing (nominal)" on page 26 for a lead drawing.

- The helix electrode is common to the connector pin of the IS-1[1] bipolar leg.
- The ring electrode is common to the connector ring of the IS-1 bipolar leg.
- The RV coil electrode is common to the DF-1[2] leg of the trifurcation, labeled and marked with a red band.
- The SVC coil electrode is common to the DF-1 leg of the trifurcation, labeled and marked with a blue band.

The RV and SVC coils deliver cardioversion and defibrillation therapies. Pacing and sensing occur between the helix and ring electrodes.

The IS-1 bipolar leg of the trifurcation features a lumen for stylet passage. The DF-1 connector legs will not accept a stylet.

The helix electrode can be actively fixed into the endocardium. The helix electrode can be extended or retracted by rotating the IS-1 connector pin with either the Quick Twist tool assembled on the lead or the white fixation tool.

The distal tip contains a maximum of 1.0 mg of dexamethasone acetate. Exposure to body fluids elutes the steroid from the lead tip. The steroid is known to suppress the inflammatory response that is believed to cause threshold rises typically associated with implanted pacing electrodes.

[1] IS-1 refers to the International Connector Standard (ISO 5841-3) whereby pulse generators and leads so designated are assured of a basic mechanical fit.

[2] DF-1 refers to the International Connector Standard (ISO 11318) whereby pulse generators and leads so designated are assured of a basic mechanical fit.

Contents of package

The lead and accessories are provided sterile. Each package contains the following:

- 1 lead with 1 radiopaque anchoring sleeve[1], stylet, and Quick Twist tool
- 1 vein lifter
- 1 slit anchoring sleeve
- 1 white fixation tool
- 2 pin caps
- extra stylets
- product literature

Accessory descriptions

Stylet – A stylet provides additional stiffness and controlled flexibility for maneuvering the lead into position. Each stylet knob is labeled with the stylet diameter and length.

Anchoring sleeve – An anchoring sleeve secures the lead from moving and protects the lead insulation and conductors from damage caused by tight sutures.

Slit anchoring sleeve – A slit anchoring sleeve secures excess lead length in the device pocket.

Pin cap – A pin cap covers and insulates unused connector pins.

Vein lifter – A vein lifter facilitates lead insertion into a vessel.

White fixation tool – The white fixation tool facilitates connector pin rotation.

Quick Twist tool – The Quick Twist tool facilitates both connector pin rotation and stylet insertion into the lead. This tool comes assembled on the lead.

Indications

The lead is intended for single, long-term use in the right ventricle.

This lead has application for patients for whom implantable cardioverter defibrillators are indicated.

[1] Two radiopaque anchoring sleeves are provided with leads 85 cm or longer.

Contraindications

Atrial use – The lead is contraindicated for the sole use of detection and treatment of atrial arrhythmias.

Ventricular use – The lead is contraindicated for ventricular use in patients with tricuspid valvular disease or a tricuspid mechanical heart valve.

Transient ventricular tachyarrhythmias – The lead is contraindicated for patients with transient ventricular tachyarrhythmias due to reversible causes (drug intoxication, electrolyte imbalance, sepsis, hypoxia) or other factors (myocardial infarction, electric shock).

Steroid use – The lead is contraindicated in patients for whom a single dose of 1.0 mg of dexamethasone acetate may be contraindicated.

Warnings and precautions

For single use only – Do not resterilize and reimplant an explanted lead.

Inspecting the sterile package – Inspect the package prior to opening.

- If the seal or package is damaged, contact your local Medtronic representative.
- Do not use the product after its expiration date.

Ethylene oxide resterilization – The lead has been sterilized with ethylene oxide prior to shipment. If the integrity of the sterile package has been compromised prior to the expiration date, resterilize using ethylene oxide. Avoid resterilization techniques that could damage the lead.

- Refer to sterilizer instructions for operating instructions.
- Use an acceptable method for determining sterilizer effectiveness, such as biological indicators.
- Do not exceed temperatures of 55°C (131°F).
- Do not resterilize more than 1 time.
- After resterilization, allow the device to aerate ethylene oxide residues.

Electrophysiologic testing – Prior to lead implant, it is strongly recommended that patients undergo a complete cardiac evaluation, which should include electrophysiologic testing. Also, electrophysiologic evaluation and testing of the safety and efficacy of the proposed pacing, cardioversion, or defibrillation therapies are recommended during and after the implant of the system.

Steroid use – It has not been determined whether the warnings, precautions, or complications usually associated with injectable dexamethasone acetate apply to the use of this highly localized, controlled-release device. For listing of potentially adverse effects, refer to the *Physician's Desk Reference.*

Steroid tip – Reducing the available amount of steroid may adversely affect low-threshold performance. Avoid reducing the amount of steroid available prior to lead implant.

- Do not allow the electrode surface to come in contact with surface contaminants.
- Do not wipe or immerse the electrode in fluid, except blood, at the time of implant.

Handling the lead – Handle the lead with great care at all times.

- Protect the lead from materials shedding particles such as lint and dust. Lead insulators attract these particles.
- Handle the lead with sterile surgical gloves that have been rinsed in sterile water or a comparable substance.
- Do not severely bend, kink, or stretch the lead.
- Do not use surgical instruments to grasp the lead or connector pins.
- Do not immerse leads in mineral oil, silicone oil, or any other liquid, except blood, at the time of implant.
- Do not implant the lead without first verifying the mechanical functioning of the helix electrode. Refer to the section "Verifying the mechanical functioning of the helix electrode" on page 14, for complete instructions.
- Do not exceed the recommended maximum number of rotations to extend or retract the helix electrode. Exceeding the maximum number may result in fracture or distortion of the inner conductor or helix electrode. The number of rotations required to fully extend or retract the helix electrode is variable; refer to the section "Specifications (nominal)" on page 25, for the recommended maximum number of rotations.
- Inserting the lead using a lead introducer that features a hemostasis valve may require a larger introducer than the size recommended. To avoid distortion of the coil electrode, do not withdraw the lead through a hemostasis valve.

Handling the stylets – Use care when handling stylets.

- Do not use excessive force or surgical instruments when inserting a stylet.
- Avoid overbending and kinking.
- Use a new stylet when blood or other fluids accumulate on the stylet. Accumulated fluids may cause lead damage or difficulty in passing the stylet through the lead.
- Do not use a sharp object to impart a curve to the distal end of the stylet.

Necessary hospital equipment – Keep external defibrillation equipment nearby for immediate use during the acute lead system testing, implant procedure, or whenever arrhythmias are possible or intentionally induced during post-implant testing.

Line-powered equipment – An implanted lead forms a direct current path to the myocardium. During lead implant and testing, use only battery-powered equipment or line-powered equipment specifically designed for this purpose, to protect against fibrillation that may be caused by alternating currents. Line-powered equipment used in the vicinity of the patient must be properly grounded. Lead connector pins must be insulated from any leakage currents that may arise from line-powered equipment.

Second anchoring sleeve – Leads 85 cm or longer feature 2 anchoring sleeves. Use both anchoring sleeves to assure adequate fixation, see the section "Anchoring the lead" on page 22.

Concurrent devices – Output pulses, especially from unipolar devices, may adversely affect device sensing capabilities. If a patient requires a separate stimulation device, either permanent or temporary, allow enough space between the leads of the separate systems to avoid interference in the sensing capabilities of the devices. Previously implanted pulse generators, implantable cardioverter defibrillators, and leads should generally be explanted. Refer to "Chronic repositioning or removal" on page 9, for further information on explanting leads.

Diathermy – People with metal implants such as pacemakers, implantable cardioverter defibrillators (ICDs), and accompanying leads should not receive diathermy treatment. The interaction between the implant and diathermy can cause tissue damage, fibrillation, or damage to the device components, which could result in serious injury, loss of therapy, or the need to reprogram or replace the device.

Chronic repositioning or removal – Chronic repositioning or removal of leads may be difficult because of fibrotic tissue development. Return all removed leads, or lead segments, to Medtronic. If a lead must be removed or repositioned, proceed with extreme caution.

- Lead removal may result in avulsion of the endocardium, valve, or vein.
- Lead junctions may separate, leaving the lead tip and bare wire in the heart or vein.
- Chronic repositioning may adversely affect the low-threshold performance of a steroid eluting lead.
- Cap abandoned leads to avoid transmitting electrical signals.
- For leads that have been severed, seal the remaining lead end and suture the lead to adjacent tissue.

- If a helix electrode does not disengage from the endocardium by rotating the connector pin, rotating the lead body counterclockwise may withdraw the helix electrode and decrease the possibility of damage to the cardiovascular structures during removal.

Connector compatibility – Although the lead conforms to the International Connector Standards IS-1 and DF-1, do not attempt to use the lead with any device other than a commercially available implantable defibrillator system with which it has been tested and demonstrated to be safe and effective. The potential adverse consequences of using such a combination may include, but are not limited to, undersensing cardiac activity and failure to deliver necessary therapy.

Potential adverse events

The potential adverse events related to the use of transvenous leads include, but are not limited to, the following patient-related conditions:

- cardiac perforation
- cardiac tamponade
- constrictive pericarditis
- embolism
- endocarditis
- fibrillation or other arrhythmias
- heart wall rupture
- hemothorax
- infection
- pneumothorax
- thrombosis
- tissue necrosis

Other potential adverse events related to the lead include, but are not limited to, the following:

- Insulation failure
- Lead conductor or electrode fracture
- Lead dislodgment
- Poor connection to the device, which may lead to oversensing, undersensing, or a loss of therapy

Clinical study

Clinical data was not collected in the approval process for this lead. Clinical data from the Model 6947 lead supports the safety and efficacy of the Model 6949 lead.

The Model 6949 lead is a downsized version of the Medtronic Sprint Quattro Secure Model 6947 lead. The Model 6949 lead includes a combination of components used in currently marketed Medtronic leads with some enhancements. All functional features of the Model 6949 lead have been approved in these currently marketed Medtronic leads. Previous clinical studies have demonstrated titanium nitride coated electrodes (6949) do not significantly change clinical pacing thresholds or sensing amplitudes as compared to platinized electrodes (6947). The overall surface of the defibrillation electrodes of the Model 6949 falls within the range of currently approved Sprint leads.

Based upon its similarity to the Model 6947, the clinical data from the Model 6947 lead supports the safety and efficacy of the Model 6949 lead (Table 1).

Table 1.

Sprint Fidelis Model 6949 features:	**Sprint Quattro Secure Model 6947 clinical data supports:**
RV/SVC defibrillation electrodes	RV/SVC defibrillation electrodes
Silicone insulation with polyurethane overlay	Silicone insulation with polyurethane overlay
Ring electrode for true bipolar sensing	Ring electrode for true bipolar sensing
Steroid eluting	Steroid eluting
Active fixation extendable/ retractable helix	Active fixation extendable/ retractable helix
Standard[a] electrode spacing	Standard[a] electrode spacing

[a] 8 mm tip to ring spacing, 12 mm tip to RV coil spacing

Model 6947 clinical study

The Model 6947 clinical study was a prospective, nonrandomized, multicenter trial assessing the lead handling and performance of the Sprint Quattro Secure Model 6947 Lead.

The Model 6947 lead was implanted in 80 patients at 15 investigative centers in the United States and at 2 investigative centers in Canada between April 27, 2001 and August 2, 2001.

Patients were included in this study if they met the following criteria: 1) able to receive a pectoral implant and 2) survived at least one episode of cardiac arrest due to a ventricular tachyarrhythmia; or had poorly tolerated, sustained ventricular tachycardia that occurred spontaneously; or had poorly tolerated, sustained ventricular tachycardia that could be induced.

Patients studied

The Model 6947 study population consisted of 63 males and 17 females. The mean age was 64.4 years. The most frequently reported indication for implant was inducible ventricular tachycardia without sudden cardiac death (SCD) (47.5%). The mean ejection fraction was 35.5%. The most frequently reported NYHA classifications were Class I (35.0%) and Class II (36.3%).

Cardiovascular history included coronary artery disease with myocardial infarction (62.5%), hypertension (58.8%), cardiomyopathy (65.0%), congestive heart failure (47.5%), syncope/ presyncope (46.3%) and previous cardiac surgery (68.8%).

Objectives

The objectives of the study were to report the following:

- Pacing thresholds
- R-wave amplitudes
- Pacing impedance
- Lead handling
- Adverse events

Methods

Pulse width thresholds, R-wave amplitudes, and pacing impedances were measured at implant and at one month post-implant. Adverse events were collected throughout the study. A lead handling questionnaire was completed by the implanting physician at each implant. The implanting physicians evaluated the performance of the Model 6947 lead with regard to:

- Ease of lead insertion into the vein
- Ease of helix extension
- Visibility of helix extension
- Steerability
- Torqueability
- Lead placement time
- Ability to traverse the tricuspid annulus
- Comfort level with handling the lead
- Slipperiness of lead surfaces
- Stiffness of the lead
- Ease of obtaining adequate R-wave sensing
- Ease of obtaining adequate VF sensing
- Ease of obtaining adequate DFTs
- Overall ease of lead placement

Results

The mean follow-up duration was 0.96 months (range: 0.00 - 1.71 months) with a cumulative follow-up duration of 76.82 months. The pace/sense measurements are summarized in Table 2.

Table 2. Pace/Sense measurements

	Implant	One month
Pulse-width threshold at one volt		
N	80	61
Median (ms)	0.20	0.20
25th - 75th Percentile	(0.20 - 0.20)	(0.20 - 0.30)
Range	(0.03 - 0.60)	(0.20 - 0.80)
R-wave amplitude (EGM)		
N	78	64
Median (mV)	8.0	9.3
25th - 75th Percentile	(7.0 - 11.0)	(7.5 - 12.8)
Range	(3.0 - 24.0)	(3.5 - 20.0)
Pacing lead impedance		
N	80	66
Median (ohms)	564.0	481.0
25th - 75th Percentile	(481.0 - 611.0)	(444.0 - 521.0)
Range	(378.0 - 985.0)	(323.0 - 985.0)

On the lead handling survey, for all items rated, the adjusted rating of the Model 6947 lead fell between 1 (very good) and 2 (excellent). The adjusted rating for each item is an average across physicians, accounting for multiple responses per physician.

The overall ease of lead placement was considered good, very good, or excellent by all implanting physicians, with an adjusted rating of 1.7 (the minimum rating on the questionnaire was - 2.0 and the maximum rating was 2.0).

Observed adverse events

The Sprint Quattro Secure Model 6947 Lead was utilized in a prospective, nonrandomized, multicenter trial to assess the handling and performance of the Model 6947 lead.

A total of 22 cardiovascular related adverse events were reported. Two of the 22 events were ventricular lead-related and both occurred at implant. One event was a microdislodgement and one was induced VT as a result of lead manipulation.

Two deaths occurred in this patient group during the follow-up period. Both deaths were classified as non-sudden cardiac and were judged to be non-system related by an independent advisory committee.

Model 6947 conclusion

In this clinical study, the Model 6947 lead demonstrated acceptable clinical performance. Through questionnaire responses, implanting physicians verified acceptable overall lead performance and handling during the implant procedure.

Directions for use

Proper surgical procedures and sterile techniques are the responsibility of the medical professional. The following procedures are provided for information only. Each physician must apply the information in these instructions according to professional medical training and experience.

The implant procedure generally includes the following steps:

- Opening the package
- Verifying the mechanical functioning of the helix electrode
- Inserting the lead
- Positioning the lead
- Securing the helix electrode into the endocardium
- Taking electrical measurements and defibrillation efficacy measurements
- Anchoring the lead
- Connecting the lead
- Placing the device and leads into the pocket
- Post-implant evaluation

Opening the package

Use the following steps to open the sterile package and inspect the lead:

1. Within the sterile field, open the sterile package and remove the lead and accessories.
2. Inspect the lead. Leads shorter than 85 cm should have 1 anchoring sleeve on the lead body. Leads 85 cm or longer should have 2 anchoring sleeves on the lead body.

Verifying the mechanical functioning of the helix electrode

Note: The package includes 2 tools, the Quick Twist tool assembled on the lead and the white fixation tool. Either tool may be used to verify the mechanical functioning of the helix electrode. The choice of tool is left to the discretion of the physician.

Before implant, verify the mechanical functioning of the helix electrode using the following steps:

1. Attach either the Quick Twist tool or the white fixation tool to the lead. Ensure that the stylet is inserted into the lead and proceed as indicated, according to the tool being used.
   a. **Quick Twist tool:** Push the Quick Twist tool onto the IS-1 connector pin (Figure 1).

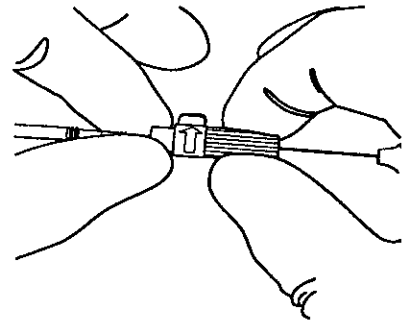


Figure 1.

b. **White fixation tool:** Press both legs of the white fixation tool together and place the most distal hole on the IS-1 connector pin (Figure 2).

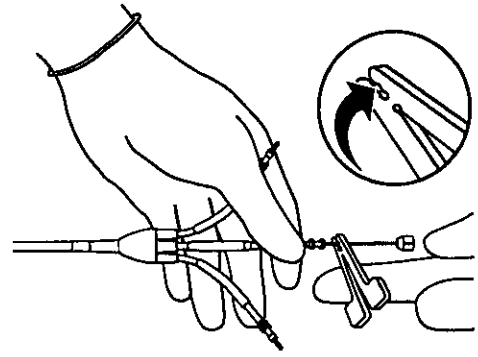


Figure 2.

2. Hold the IS-1 connector leg of the lead with the thumb on one side and 4 fingers on the other side. Keep the lead body and the IS-1 connector leg as straight as possible (Figure 2). Ensure that the stylet is fully inserted, then rotate the selected fixation tool clockwise until the helix electrode is fully extended (Figure 3a or Figure 3b). When the helix electrode is fully extended, approximately 1.5 to 2 helix coils are exposed.

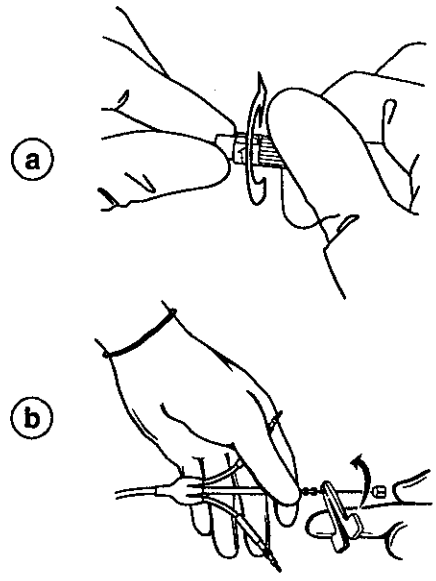


Figure 3.

Caution: Do not severely bend the IS-1 connector leg or the lead body while extending the helix electrode (Figure 4). If the lead is bent on either side of the lead trifurcation during helix electrode extension or retraction, the lead may be damaged.

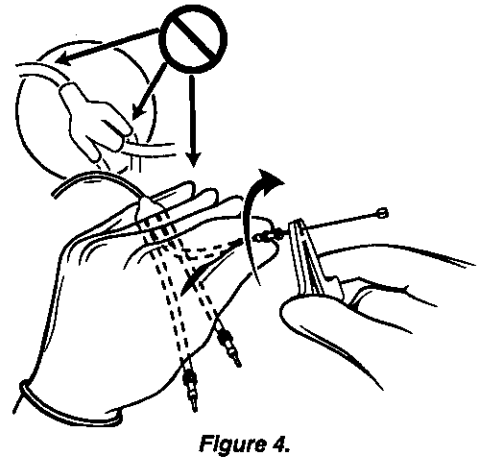


Figure 4.

Caution: Overrotating the connector pin after the helix electrode is fully extended may damage the lead.

Note: To determine the number of rotations applied to the lead, count the number of rotations of the white flap on the Quick Twist tool. The number of necessary rotations is equivalent to the number required for the white fixation tool. See "Specifications (nominal)" on page 25 for the maximum number of rotations to extend or retract the helix electrode.

The number of rotations required to extend the helix electrode increases proportionately with the length of the lead. Additional curvatures made to the stylet may increase the number of rotations needed to extend or retract the helix electrode. Refer to the section "Specifications (nominal)" on page 25, for the maximum number of rotations to extend or retract the helix electrode.

During the initial helix electrode extension, the helix electrode may extend suddenly due to accumulated torque in the lead, or the helix electrode may require additional turns for extension.

3. Disconnect the selected fixation tool from the connector pin and release the proximal end of the lead body. Allow several seconds for relief of the residual torque in the lead.
4. After allowing for relief of the residual torque, reattach the selected fixation tool and rotate it counterclockwise until the helix electrode tip is retracted into the sheath.

Inserting the lead

Caution: Use care when handling the lead during insertion.

- Do not severely bend, kink, or stretch the lead.
- Do not use surgical instruments to grasp the lead or connector pins.

Insert the lead using the following techniques:

1. Select a site for lead insertion. The lead may be inserted by venotomy through several different venous routes, including the right or left cephalic vein or the external or internal jugular vein. Use the cephalic vein whenever possible to avoid lead damage in the first rib or clavicular (thoracic inlet) space.

   Caution: Certain anatomical abnormalities, such as thoracic outlet syndrome, may also precipitate pinching and subsequent fracture of the lead.

   Caution: When using a subclavian approach, avoid techniques that may damage the lead.

   - Place the insertion site as far lateral as possible to avoid clamping the lead body between the clavicle and the first rib (Figure 5).

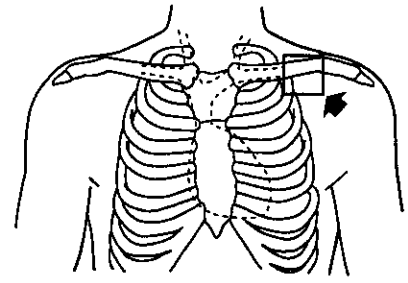


Figure 5.

   - Do not force the lead if significant resistance is encountered during lead passage.

- Do not use techniques such as adjusting the patient's posture to facilitate lead passage. If resistance is encountered, it is recommended that an alternate venous entry site be used.

2. Insert the tapered end of a vein lifter into the incised vein and gently push the lead tip underneath and into the vein (Figure 6).

   Note: A percutaneous lead introducer (PLI) kit may be used to facilitate insertion. Refer to the technical manual packaged with an appropriate percutaneous introducer for further instructions.

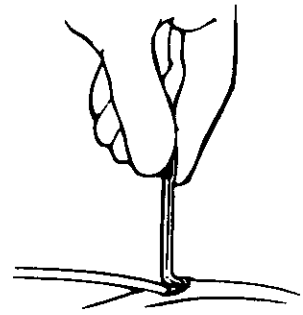


Figure 6.

3. Advance the lead into the right atrium using a straight stylet to facilitate movement through the veins.

Positioning the lead

Caution: Use care when handling the lead during positioning.

- Do not severely bend, kink or stretch the lead.
- Do not use surgical instruments to grasp the lead or connector pins.

Use the following steps to position the lead:

1. After the lead tip is passed into the atrium, advance the lead through the tricuspid valve. Replacing the straight stylet with a gently curved stylet may add control in maneuvering the lead through the tricuspid valve.

   Caution: Do not use a sharp object to impart a curve to the distal end of the stylet. Imparting a curve to the stylet can be accomplished with a smooth-surface, sterile instrument (Figure 7).

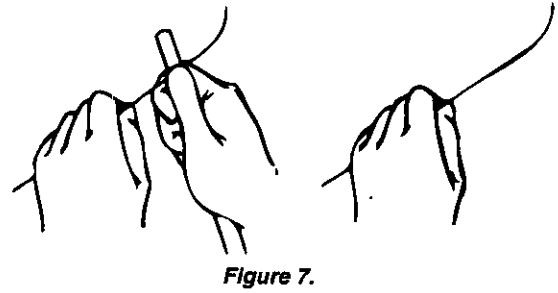


Figure 7.

Note: Passing the lead tip through the tricuspid valve or chordae tendineae may be difficult due to the flexible nature of the lead body. Rotating the lead body as the tip passes through the valve may facilitate passage.

2. After the lead tip is in the ventricle, the curved stylet may be replaced with a straight stylet. Withdraw the stylet slightly, to avoid using excessive tip force while achieving final electrode position. Avoid known infarcted or thin wall areas, to minimize the occurrence of perforation.
3. Proper positioning of the helix electrode is essential for stable endocardial pacing. A satisfactory position usually is achieved when the lead tip points straight toward the apex, or when the distal end dips or bends slightly. Use fluoroscopy (lateral position) to ensure that the tip is not in a retrograde position or lodged in the coronary sinus.

   Note: With the helix electrode retracted, the distal end of the lead may be used to map a desirable site for electrode fixation. Mapping may reduce the need to repeatedly extend and fixate the helix electrode.
4. After placing the lead in a satisfactory position, extend the helix electrode by following the procedure in the section "Securing the helix electrode into the endocardium" on page 19.

Securing the helix electrode into the endocardium

Note: The package includes 2 tools, the Quick Twist tool assembled on the lead and the white fixation tool. Either tool may be used to secure the helix electrode into the endocardium. The choice of tool is left to the discretion of the physician.

Secure the helix electrode using the following techniques:

1. Attach either the Quick Twist tool or the white fixation tool to the lead. Ensure that the stylet is inserted into the lead and proceed as indicated, according to the tool being used.
   a. **Quick Twist tool:** Push the Quick Twist tool onto the IS-1 connector pin. (Figure 1).
   b. **White fixation tool:** Press both legs of the white fixation tool together and place the most distal hole on the IS-1 connector pin (Figure 2).
2. Press the lead tip against the endocardium by gently pushing the stylet and lead at the vein entry site.
3. Rotate the selected fixation tool clockwise until the helix electrode is fully extended (see Figure 3a or Figure 3b).

   Caution: Do not severely bend the IS-1 connector leg or the lead body while extending the helix electrode (Figure 4). If the lead is bent on either side of the lead trifurcation during helix electrode extension or retraction, the lead may be damaged.

   Use fluoroscopy to verify electrode extension (Figure 8). The fluoroscope head may need to be rotated to obtain an adequate view.

Closing of the space between the indicator stop (A) and the indicator ring (B) implies complete extension of the helix electrode.

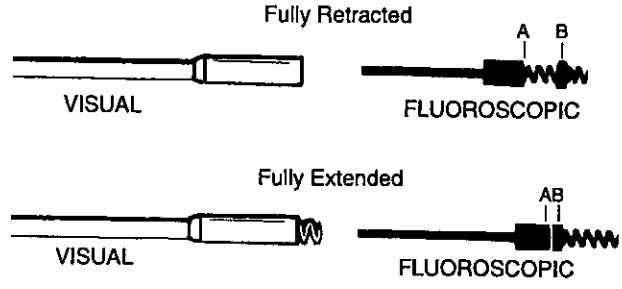


Figure 8.

Caution: Exceeding the maximum number of rotations may damage the lead. The maximum number of rotations required to fully extend or retract the helix electrode is variable; refer to the section, "Specifications (nominal)" on page 25, for the maximum number of rotations.

Caution: Prolonged implant procedures or multiple repositionings may allow blood or body fluids to build up on the helix electrode mechanism. This may result in an increased number of rotations required to extend or retract the helix electrode.

4. Remove the selected fixation tool from the IS-1 connector pin and release the proximal end of the lead body. Allow several seconds for relief of the residual torque in the lead.
5. To assure helix electrode fixation, leave the stylet in place, hold the lead by the connector, and carefully rotate the lead body in 2 clockwise rotations.
6. Partially withdraw the stylet.
7. Obtain electrical measurements to verify satisfactory placement and electrode fixation. Refer to the section "Taking electrical measurements and defibrillation efficacy measurements" on page 21.
8. Verify that the lead is affixed. Gently pull back on the lead and check for resistance to verify fixation. A properly affixed helix electrode will remain in position. If the helix electrode is not properly affixed, the lead tip may become loose in the right ventricle.
9. If repositioning is required, reattach the selected fixation tool and rotate counterclockwise until the helix electrode is retracted. Use fluoroscopy to verify withdrawal of the helix electrode before attempting to reposition.
10. After final positioning, remove the stylet and the Quick Twist tool completely. When removing the Quick Twist tool, grip the lead firmly just below the connector pin to help prevent lead dislodgment.

11. Obtain final electrical measurements. Refer to the section "Taking electrical measurements and defibrillation efficacy measurements" on page 21.

Taking electrical measurements and defibrillation efficacy measurements

Caution: Prior to taking electrical or defibrillation efficacy measurements, move objects made from conductive materials, such as guide wires, away from all electrodes. Metal objects, such as guide wires, can short a lead and an active implantable device, causing electrical current to bypass the heart and possibly damage the implantable device and lead.

Use the following steps to take electrical measurements:

1. Ensure that the Quick Twist tool is disconnected from the IS-1 connector pin.
2. Attach a surgical cable to the lead connector pin.
3. Use a testing device, such as a pacing system analyzer, for obtaining electrical measurements. For information on the use of the testing device, consult the product literature for that device.

   In order to demonstrate reliable defibrillation efficacy, obtain final electrical measurements for the lead system.

Table 3. Recommended measurements at implant (when using a pacing system analyzer)

Measurements required	Acute[a] lead system	Chronic[b] lead system
Capture threshold (at 0.5 ms pulse width)	≤ 1.0 V	≤ 3.0 V
Pacing impedance	200 - 1000 ohms	200 - 1000 ohms
Filtered R-wave amplitude (during sinus rhythm)	≥ 5 mV	≥ 3 mV
Slew rate	≥ 0.75 V/s	≥ 0.45 V/s

[a] ≤ 30 days after implant.
[b] > 30 days after implant.

If initial electrical measurements deviate from the recommended values, it may be necessary to repeat the testing procedure 15 minutes after final positioning. Initial electrical measurements may deviate from the recommended values:

- Initial impedance values may exceed the measuring capabilities of the testing device, resulting in an error message.
- Values may vary depending upon lead type, implantable device settings, cardiac tissue condition, and drug interactions.

If electrical measurements do not stabilize to acceptable levels, it may be necessary to reposition the lead and repeat the testing procedure.

In order to keep patient morbidity and mortality to a minimum, patients should be rescued promptly with an external defibrillator if the implanted lead system fails to terminate a VF episode. At least 5 minutes should elapse between VF inductions.

For more information on obtaining electrical measurements, consult the technical manual supplied with the testing device.

Anchoring the lead

Caution: Use care when anchoring the lead.

- Use only nonabsorbable sutures to anchor the lead.
- Do not attempt to remove or cut the anchoring sleeve from the lead body.
- During lead anchoring, take care to avoid dislodging the lead tip.
- Do not secure sutures so tightly that they damage the vein, lead, or anchoring sleeve (Figure 9).
- Do not tie a suture directly to the lead body (Figure 9).

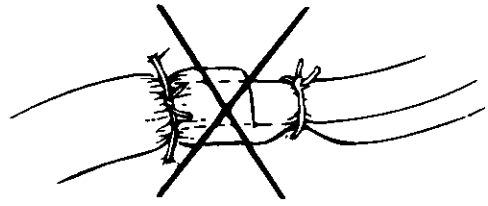


Figure 9.

Use the following steps to anchor the lead using all 3 grooves:

Note: The anchoring sleeves contain a radiopaque substance, which allows visualization of the anchoring sleeve on a standard x-ray and may aid in follow-up examinations.

1. Position the distal anchoring sleeve against or near the vein.
2. Secure the anchoring sleeve to the lead body by tying a suture firmly in each of the 3 grooves (Figure 10).

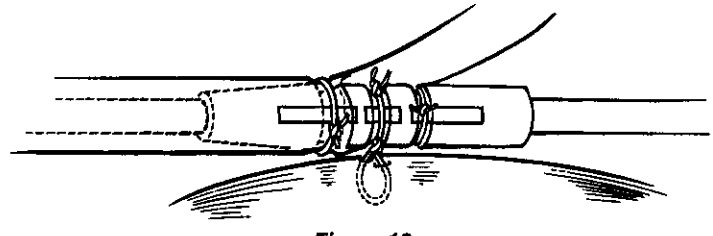


Figure 10.

3. Use at least 1 additional suture in 1 of the grooves to secure the anchoring sleeve and lead body to the fascia.

4. A second anchoring sleeve is provided with leads 85 cm or longer. For abdominal implants, redundant lead body (for example, a curve for strain relief) should be placed just proximal to the first anchoring sleeve. Then, the second anchoring sleeve may be lightly sutured to the lead body and fascia to hold the curve in place. This procedure helps isolate the vein entry site from tension on the proximal end of the lead body.
5. A slit anchoring sleeve may be used in the device pocket to secure excess lead length. First, secure the anchoring sleeve to the lead body. Then, orient the slit toward the fascia and secure the anchoring sleeve to the fascia with sutures.

Connecting the lead

Use the following steps to connect the lead to an implantable device:

1. Carefully remove the stylet and Quick Twist tool. When removing the stylet and Quick Twist tool, grip the lead firmly just below the connector pin, to prevent dislodgment.
2. Insert the lead connectors into the connector block. Consult the product literature packaged with the implantable device for instructions on proper lead connections.

Placing the device and leads into the pocket

Caution: Use care when placing the device and leads into the pocket.

- Ensure that the leads do not leave the device at an acute angle.
- Do not grip the lead or device with surgical instruments.
- Do not coil the lead. Coiling the lead can twist the lead body and may result in lead dislodgment (Figure 11).

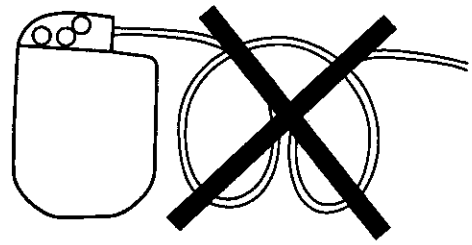


Figure 11.

Use the following steps to place the device and leads into the pocket:

1. To prevent undesirable twisting of the lead body, rotate the device to loosely wrap the excess lead length (Figure 12).

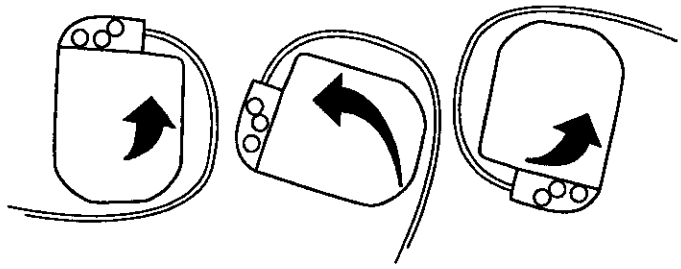


Figure 12.

2. Insert the device and leads into the pocket.
3. Before closing the pocket, verify sensing, pacing, cardioversion, and defibrillation efficacy.

Post-implant evaluation

After implant, monitor the patient's electrocardiogram until the patient is discharged. If a lead dislodges, it usually occurs during the immediate postoperative period.

Recommendations for verifying proper lead positioning include x-rays and pacing/sensing thresholds taken at pre-hospital discharge, 3 months after implant, and every 6 months thereafter.

In the event of a patient death, explant all implanted leads and devices and return them to Medtronic with a completed Product Information Report form. Call the appropriate phone number on the back cover if there are any questions on product handling procedures.

Detailed device description

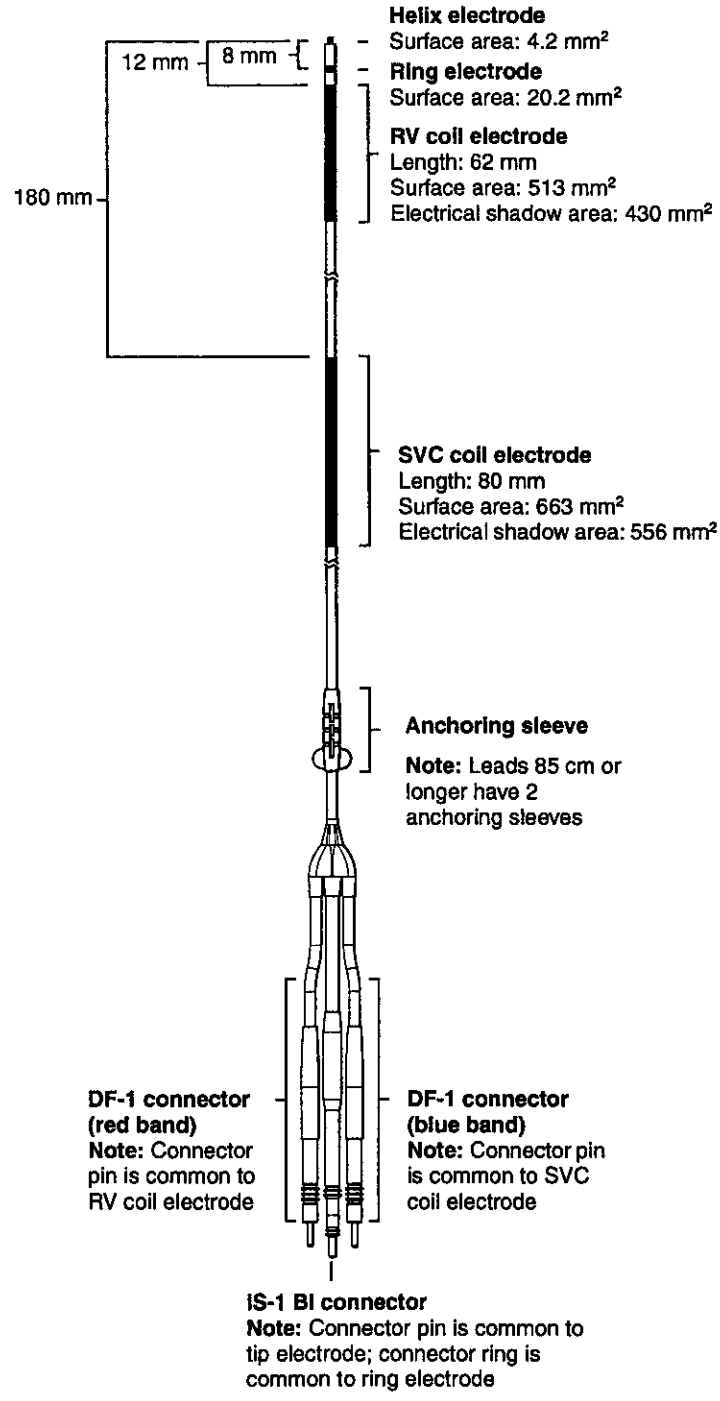
Specifications (nominal)

Parameter		Model 6949
Type		Quadripolar
Position		Right ventricle
Fixation		Extendable/Retractable helix
Length		40-110 cm
Connectors	Unipolar:	DF-1
	Bipolar:	IS-1
Materials	Conductors:	MP35N coil MP35N composite cables
	Insulation:	Silicone, ETFE
	Overlay:	Polyurethane
	Electrodes (pace, sense):	Titanium nitride coated platinum iridium
	RV/SVC coils:	Platinum-clad tantalum
	DF-1 pins:	Stainless steel
	IS-1 pin and ring:	Stainless steel
Steroid	Type:	Dexamethasone acetate
	Amount:	1.0 mg maximum
	Steroid binder:	Silicone
Conductor resistances	Pacing (unipolar):	21.6 Ω (65 cm)
	Pacing (bipolar):	68.6 Ω (65 cm)
	Defibrillation:	<2.4 Ω (65 cm)
Helix length (extended)		1.8 mm
Diameters	Lead body:	2.2 mm
	Tip:	2.2 mm
	Helix:	1.2 mm
Lead introducer (recommended size)		
	without guide wire:	7.0 French
	with guide wire:	9.0 French

Maximum number of rotations to extend or retract the helix electrode

Lead length	Number of rotations
58 cm	18
65 cm	20
75 cm	22
100 cm	27

Specifications drawing (nominal)



Medtronic warranty

For complete warranty information, see the accompanying warranty document.

Service

Medtronic employs highly trained representatives and engineers located throughout the world to serve you and, upon request, to provide training to qualified hospital personnel in the use of Medtronic products. Medtronic also maintains a professional staff to provide technical consultation to product users. For medical consultation, Medtronic can often refer product users to outside medical consultants with appropriate expertise. For more information, contact your local Medtronic representative, or call or write Medtronic at the appropriate address or telephone number listed on the back cover.

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Medtronic

SPRINT FIDELIS™ 6931

Steroid eluting, tripolar, screw-in, ventricular lead with RV defibrillation coil electrode

Technical manual

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

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Table of contents

Device description

The Medtronic Sprint Fidelis Model 6931 lead is a steroid eluting, tripolar, screw-in, ventricular lead with a right ventricular (RV) defibrillation coil electrode. The lead is designed for pacing, sensing, cardioversion, and defibrillation therapies.

The lead features an extendable/retractable helix electrode, silicone insulation with overlay, parallel conductors, titanium nitride coated platinum iridium tip and ring electrodes, and a RV coil electrode. See "Specifications drawing (nominal)" on page 28 for a lead drawing.

- The helix electrode is common to the connector pin of the IS-1[1] bipolar leg.
- The ring electrode is common to the connector ring of the IS-1 bipolar leg.
- The RV coil electrode is common to the DF-1[2] leg of the bifurcation, labeled and marked with a red band.

The RV coil delivers cardioversion and defibrillation therapies. Pacing and sensing occur between the helix and ring electrodes.

The IS-1 bipolar leg of the bifurcation features a lumen for stylet passage. The DF-1 connector legs will not accept a stylet.

The helix electrode can be actively fixed into the endocardium. The helix electrode can be extended or retracted by rotating the IS-1 connector pin with either the Quick Twist tool assembled on the lead or the white fixation tool.

The distal tip contains a maximum of 1.0 mg of dexamethasone acetate. Exposure to body fluids elutes the steroid from the lead tip. The steroid is known to suppress the inflammatory response that is believed to cause threshold rises typically associated with implanted pacing electrodes.

[1] IS-1 refers to the International Connector Standard (ISO 5841-3) whereby pulse generators and leads so designated are assured of a basic mechanical fit.

[2] DF-1 refers to the International Connector Standard (ISO 11318) whereby pulse generators and leads so designated are assured of a basic mechanical fit.

Contents of package

The lead and accessories are provided sterile. Each package contains the following:

- 1 lead with 1 radiopaque anchoring sleeve[1], stylet, and Quick Twist tool
- 1 vein lifter
- 1 slit anchoring sleeve
- 1 white fixation tool
- 2 pin caps
- extra stylets
- product literature

Accessory descriptions

Stylet – A stylet provides additional stiffness and controlled flexibility for maneuvering the lead into position. Each stylet knob is labeled with the stylet diameter and length.

Anchoring sleeve – An anchoring sleeve secures the lead from moving and protects the lead insulation and conductors from damage caused by tight sutures.

Slit anchoring sleeve – A slit anchoring sleeve secures excess lead length in the device pocket.

Pin cap – A pin cap covers and insulates unused connector pins.

Vein lifter – A vein lifter facilitates lead insertion into a vessel.

White fixation tool – The white fixation tool facilitates connector pin rotation.

Quick Twist tool – The Quick Twist tool facilitates both connector pin rotation and stylet insertion into the lead. This tool comes assembled on the lead.

Indications

The lead is intended for single, long-term use in the right ventricle.

This lead has application for patients for whom implantable cardioverter defibrillators are indicated.

[1] Two radiopaque anchoring sleeves are provided with leads 85 cm or longer.

Contraindications

Atrial use – The lead is contraindicated for the sole use of detection and treatment of atrial arrhythmias.

Ventricular use – The lead is contraindicated for ventricular use in patients with tricuspid valvular disease or a tricuspid mechanical heart valve.

Transient ventricular tachyarrhythmias – The lead is contraindicated for patients with transient ventricular tachyarrhythmias due to reversible causes (drug intoxication, electrolyte imbalance, sepsis, hypoxia) or other factors (myocardial infarction, electric shock).

Steroid use – The lead is contraindicated in patients for whom a single dose of 1.0 mg of dexamethasone acetate may be contraindicated.

Warnings and precautions

For single use only – Do not resterilize and reimplant an explanted lead.

Inspecting the sterile package – Inspect the package prior to opening.

- If the seal or package is damaged, contact your local Medtronic representative.
- Do not use the product after its expiration date.

Ethylene oxide resterilization – The lead has been sterilized with ethylene oxide prior to shipment. If the integrity of the sterile package has been compromised prior to the expiration date, resterilize using ethylene oxide. Avoid resterilization techniques that could damage the lead.

- Refer to sterilizer instructions for operating instructions.
- Use an acceptable method for determining sterilizer effectiveness, such as biological indicators.
- Do not exceed temperatures of 55°C (131°F).
- Do not resterilize more than 1 time.
- After resterilization, allow the device to aerate ethylene oxide residues.

Electrophysiologic testing – Prior to lead implant, it is strongly recommended that patients undergo a complete cardiac evaluation, which should include electrophysiologic testing. Also, electrophysiologic evaluation and testing of the safety and efficacy of the proposed pacing, cardioversion, or defibrillation therapies are recommended during and after the implant of the system.

Steroid use – It has not been determined whether the warnings, precautions, or complications usually associated with injectable dexamethasone acetate apply to the use of this highly localized, controlled-release device. For listing of potentially adverse effects, refer to the *Physician's Desk Reference*.

Steroid tip – Reducing the available amount of steroid may adversely affect low-threshold performance. Avoid reducing the amount of steroid available prior to lead implant.

- Do not allow the electrode surface to come in contact with surface contaminants.
- Do not wipe or immerse the electrode in fluid, except blood, at the time of implant.

Handling the lead – Handle the lead with great care at all times.

- Protect the lead from materials shedding particles such as lint and dust. Lead insulators attract these particles.
- Handle the lead with sterile surgical gloves that have been rinsed in sterile water or a comparable substance.
- Do not severely bend, kink, or stretch the lead.
- Do not use surgical instruments to grasp the lead or connector pins.
- Do not immerse leads in mineral oil, silicone oil, or any other liquid, except blood, at the time of implant.
- Do not implant the lead without first verifying the mechanical functioning of the helix electrode. Refer to the section "Verifying the mechanical functioning of the helix electrode" on page 17, for complete instructions.
- Do not exceed the recommended maximum number of rotations to extend or retract the helix electrode. Exceeding the maximum number may result in fracture or distortion of the inner conductor or helix electrode. The number of rotations required to fully extend or retract the helix electrode is variable; refer to the section "Specifications (nominal)" on page 27, for the recommended maximum number of rotations.
- Inserting the lead using a lead introducer that features a hemostasis valve may require a larger introducer than the size recommended. To avoid distortion of the coil electrode, do not withdraw the lead through a hemostasis valve.

Handling the stylets – Use care when handling stylets.

- Do not use excessive force or surgical instruments when inserting a stylet.
- Avoid overbending and kinking.
- Use a new stylet when blood or other fluids accumulate on the stylet. Accumulated fluids may cause lead damage or difficulty in passing the stylet through the lead.
- Do not use a sharp object to impart a curve to the distal end of the stylet.

Necessary hospital equipment – Keep external defibrillation equipment nearby for immediate use during the acute lead system testing, implant procedure, or whenever arrhythmias are possible or intentionally induced during post-implant testing.

Line-powered equipment – An implanted lead forms a direct current path to the myocardium. During lead implant and testing, use only battery-powered equipment or line-powered equipment specifically designed for this purpose, to protect against fibrillation that may be caused by alternating currents. Line-powered equipment used in the vicinity of the patient must be properly grounded. Lead connector pins must be insulated from any leakage currents that may arise from line-powered equipment.

Second anchoring sleeve – Leads 85 cm or longer feature 2 anchoring sleeves. Use both anchoring sleeves to assure adequate fixation, see the section "Anchoring the lead" on page 24.

Concurrent devices – Output pulses, especially from unipolar devices, may adversely affect device sensing capabilities. If a patient requires a separate stimulation device, either permanent or temporary, allow enough space between the leads of the separate systems to avoid interference in the sensing capabilities of the devices. Previously implanted pulse generators, implantable cardioverter defibrillators, and leads should generally be explanted. Refer to "Chronic repositioning or removal" on page 9, for further information on explanting leads.

Diathermy – People with metal implants such as pacemakers, implantable cardioverter defibrillators (ICDs), and accompanying leads should not receive diathermy treatment. The interaction between the implant and diathermy can cause tissue damage, fibrillation, or damage to the device components, which could result in serious injury, loss of therapy, or the need to reprogram or replace the device.

Chronic repositioning or removal – Chronic repositioning or removal of leads may be difficult because of fibrotic tissue development. Return all removed leads, or lead segments, to Medtronic. If a lead must be removed or repositioned, proceed with extreme caution.

- Lead removal may result in avulsion of the endocardium, valve, or vein.
- Lead junctions may separate, leaving the lead tip and bare wire in the heart or vein.
- Chronic repositioning may adversely affect the low-threshold performance of a steroid eluting lead.
- Cap abandoned leads to avoid transmitting electrical signals.
- For leads that have been severed, seal the remaining lead end and suture the lead to adjacent tissue.

- If a helix electrode does not disengage from the endocardium by rotating the connector pin, rotating the lead body counterclockwise may withdraw the helix electrode and decrease the possibility of damage to the cardiovascular structures during removal.

Connector compatibility – Although the lead conforms to the International Connector Standards IS-1 and DF-1, do not attempt to use the lead with any device other than a commercially available implantable defibrillator system with which it has been tested and demonstrated to be safe and effective. The potential adverse consequences of using such a combination may include, but are not limited to, undersensing cardiac activity and failure to deliver necessary therapy.

Potential adverse events

The potential adverse events related to the use of transvenous leads include, but are not limited to, the following patient-related conditions:

- cardiac perforation
- cardiac tamponade
- constrictive pericarditis
- embolism
- endocarditis
- fibrillation or other arrhythmias
- heart wall rupture
- hemothorax
- infection
- pneumothorax
- thrombosis
- tissue necrosis

Other potential adverse events related to the lead include, but are not limited to, the following:

- Insulation failure
- Lead conductor or electrode fracture
- Lead dislodgment
- Poor connection to the device, which may lead to oversensing, undersensing, or a loss of therapy

Clinical study

Clinical data was not collected in the approval process for this lead. Clinical data from the Models 6947 and 6932 leads support the safety and efficacy of the Model 6931 lead.

The Model 6931 lead is a downsized version of the Medtronic Sprint Quattro Secure Model 6947 lead without an SVC defibrillation coil (same as the Sprint Model 6932 lead). The Model 6931 lead includes a combination of components used in currently marketed Medtronic leads with some enhancements. All functional features of the Model 6931 lead have been approved in currently marketed Medtronic leads. Previous clinical studies have demonstrated titanium nitride coated electrodes (6931) do not significantly change clinical pacing thresholds or sensing amplitudes as compared to platinized electrodes (6947). The overall surface of the defibrillation electrode falls within the range of currently approved Sprint leads.

Based upon its similarity to the Model 6947 and 6932 leads, the clinical data from these lead models supports the safety and efficacy of the Model 6931 lead (Table 1).

Table 1.

Sprint Fidelis Model 6931 features:	**Sprint Quattro Secure Model 6947 clinical data supports:**
Silicone insulation with polyurethane overlay	Silicone insulation with polyurethane overlay
Ring electrode for true bipolar sensing	Ring electrode for true bipolar sensing
Steroid eluting	Steroid eluting
Active fixation extendable/ retractable helix	Active fixation extendable/ retractable helix
Standard[a] electrode spacing	Standard[a] electrode spacing
Sprint Fidelis Model 6931 features:	**Sprint Model 6932 clinical data supports:**
Single RV defibrillation coil	Single RV defibrillation coil

[a] 8 mm tip to ring spacing, 12 mm tip to RV coil spacing

Model 6947 clinical study

The Model 6947 clinical study was a prospective, nonrandomized, multicenter trial assessing the lead handling and performance of the Sprint Quattro Secure Model 6947 Lead.

The Model 6947 lead was implanted in 80 patients at 15 investigative centers in the United States and at 2 investigative centers in Canada between April 27, 2001 and August 2, 2001.

Patients were included in this study if they met the following criteria: 1) able to receive a pectoral implant and 2) survived at least one episode of cardiac arrest due to a ventricular tachyarrhythmia; or had poorly tolerated, sustained ventricular tachycardia that occurred spontaneously; or had poorly tolerated, sustained ventricular tachycardia that could be induced.

Patients studied

The Model 6947 study population consisted of 63 males and 17 females. The mean age was 64.4 years. The most frequently reported indication for implant was inducible ventricular tachycardia without sudden cardiac death (SCD) (47.5%). The mean ejection fraction was 35.5%. The most frequently reported NYHA classifications were Class I (35.0%) and Class II (36.3%).

Cardiovascular history included coronary artery disease with myocardial infarction (62.5%), hypertension (58.8%), cardiomyopathy (65.0%), congestive heart failure (47.5%), syncope/ presyncope (46.3%) and previous cardiac surgery (68.8%).

Objectives

The objectives of the study were to report the following:

- Pacing thresholds
- R-wave amplitudes
- Pacing impedance
- Lead handling
- Adverse events

Methods

Pulse width thresholds, R-wave amplitudes, and pacing impedances were measured at implant and at one month post-implant. Adverse events were collected throughout the study. A lead handling questionnaire was completed by the implanting physician at each implant. The implanting physicians evaluated the performance of the Model 6947 lead with regard to:

- Ease of lead insertion into the vein
- Ease of helix extension
- Visibility of helix extension
- Steerability
- Torqueability
- Lead placement time
- Ability to traverse the tricuspid annulus
- Comfort level with handling the lead
- Slipperiness of lead surfaces
- Stiffness of the lead
- Ease of obtaining adequate R-wave sensing
- Ease of obtaining adequate VF sensing
- Ease of obtaining adequate DFTs
- Overall ease of lead placement

Results

The mean follow-up duration was 0.96 months (range: 0.00 - 1.71 months) with a cumulative follow-up duration of 76.82 months. The pace/sense measurements are summarized in Table 2.

Table 2. *Pace/Sense measurements*

	Implant	One month
Pulse-width threshold at one volt		
N	80	61
Median (ms)	0.20	0.20
25th - 75th Percentile	(0.20 - 0.20)	(0.20 - 0.30)
Range	(0.03 - 0.60)	(0.20 - 0.80)
R-wave amplitude (EGM)		
N	78	64
Median (mV)	8.0	9.3
25th - 75th Percentile	(7.0 - 11.0)	(7.5 - 12.8)
Range	(3.0 - 24.0)	(3.5 - 20.0)
Pacing lead impedance		
N	80	66
Median (ohms)	564.0	481.0
25th - 75th Percentile	(481.0 - 611.0)	(444.0 - 521.0)
Range	(378.0 - 985.0)	(323.0 - 985.0)

On the lead handling survey, for all items rated, the adjusted rating of the Model 6947 lead fell between 1 (very good) and 2 (excellent). The adjusted rating for each item is an average across physicians, accounting for multiple responses per physician.

The overall ease of lead placement was considered good, very good, or excellent by all implanting physicians, with an adjusted rating of 1.7 (the minimum rating on the questionnaire was - 2.0 and the maximum rating was 2.0).

Observed adverse events

The Sprint Quattro Secure Model 6947 Lead was utilized in a prospective, nonrandomized, multicenter trial to assess the handling and performance of the Model 6947 lead.

A total of 22 cardiovascular related adverse events were reported. Two of the 22 events were ventricular lead-related and both occurred at implant. One event was a microdislodgement and one was induced VT as a result of lead manipulation.

Two deaths occurred in this patient group during the follow-up period. Both deaths were classified as non-sudden cardiac and were judged to be non-system related by an independent advisory committee.

Model 6947 conclusion

In this clinical study, the Model 6947 lead demonstrated acceptable clinical performance. Through questionnaire responses, implanting physicians verified acceptable overall lead performance and handling during the implant procedure.

Model 6932 (single-coil) clinical study

The following is a summary of the clinical results from the 6932 RV lead study with respect to the primary study objectives and additional performance measurements with Active Can ICDs. All of the results presented are based on an "as randomized" analysis.

Patient characteristics

The results summarize data for 336 patients, who were randomized (1:1) to either the Model 6932 lead (n=168) or the Model 6936 lead (n=168) between 6/9/95 and 3/22/96. Commercially available Medtronic ICDs were the devices used in the study. The mean follow-up was 2.39 ± 1.96 months with a cumulative follow-up of 803.4 months.

Primary endpoints

Patient characteristics by randomized lead

	6932 N=168	6936 N=168
Gender		
% Male	133 (79.2%)	140 (83.3%)
Age at implant		
Mean (years)	59.4	62.1
Standard deviation (years)	±12.9	±11.4
Primary indication		
SCD only	49 (29.2%)	45 (26.8%)
VT only	88 (52.4%)	86 (51.2%)
SCD & VT	20 (11.9%)	28 (16.7%)
Other	11 (6.6%)	9 (5.4%)
Primary cardiovascular disease		
CAD or MI	114 (67.9%)	117 (69.6%)
Cardiomyopathy only	30 (17.9%)	33 (19.6%)
Primary electrical disease	7 (4.2%)	7 (4.2%)
Other	17 (10.1%)	11 (6.6%)
NYHA classification		
Class I/II	142 (84.5%)	137 (81.5%)
Ejection fraction		
Mean	34.8&	34.9%
Standard deviation	±13.0%	±13.4%

Meeting defibrillation implant criterion

Meeting defibrillation implant criterion with the initial lead configuration was defined as having at least one successful defibrillation at ≤ 22 joules in the first three VF inductions (following a binary search protocol), or failing that, two successful defibrillations in the next two VF inductions at ≤ 24 joules. The initial lead configuration was defined as the initial system tested, allowing no polarity or position changes. The rate of meeting defibrillation implant criterion with the initial configuration for the 6932 lead was equivalent to the 6936 lead.

Meeting defibrillation implant criterion with the initial lead configuration by randomized lead

	6932	6936
Observed success rate[a]	99% (143/145)	96% (137/142)
Adjusted success rate[b]	100%	99%
p-value[b]	0.077	

[a] Including only those patients in whom the implant testing protocol was fully completed

[b] Adjusted for age, sex, ejection fraction, NYHA classification and primary indication for implant using logistic regression

Pacing thresholds through three months

A pulse-width threshold was measured at 2.8 V at implant, pre-hospital discharge evaluation (PDE), one month and three months. The pulse-width threshold for the 6932 lead was significantly lower than for the 6936 lead at each time point (p=0.0001).

Complication-free survival through three months

Pacing thresholds through 3 months by randomized lead Pulse width (in msec) @ 2.8 V

Lead		Implant	PDE	1 month	3 month
6932	N	158	152	116	77
	Adjusted mean[a]	0.043	0.049	0.057	0.063
6936	N	150	142	117	80
	Adjusted mean[a]	0.069	0.109	0.205	0.198
	p-value[a]	0.0001	0.0001	0.0001	0.0001

[a] Adjusted for age, sex, ejection fraction and NYHA classification using mixed effects regression

A complication was defined as an adverse event which required invasive intervention. The complication-free survival through three months for the 6932 lead was equivalent to the 6936 lead (p=0.87).

Additional performance measurements with active can ICDs

Implant success

Implant success was achieved if the initial system tested was the system that was implanted (including polarity and position changes). For the 6932 lead, implant success with a single lead-Active Can system was 98% (114/116 patients).

Defibrillation threshold (DFT)

The DFT with the initial lead system was determined following a binary search protocol (starting with a 12 J shock). For the 6932 lead, the mean DFT with a single lead-Active Can system was 8.7 J.

Model 6932 conclusions

All of the stated objectives were met in this study. These findings demonstrate that the Model 6932 lead performance is equivalent to, or better than the Model 6936 lead performance, and that the 6932 lead is safe and effective for human use.

Directions for use

Proper surgical procedures and sterile techniques are the responsibility of the medical professional. The following procedures are provided for information only. Each physician must apply the information in these instructions according to professional medical training and experience.

The implant procedure generally includes the following steps:

- Opening the package
- Verifying the mechanical functioning of the helix electrode
- Inserting the lead
- Positioning the lead
- Securing the helix electrode into the endocardium
- Taking electrical measurements and defibrillation efficacy measurements
- Anchoring the lead
- Connecting the lead
- Placing the device and leads into the pocket
- Post-implant evaluation

Opening the package

Use the following steps to open the sterile package and inspect the lead:

1. Within the sterile field, open the sterile package and remove the lead and accessories.
2. Inspect the lead. Leads shorter than 85 cm should have 1 anchoring sleeve on the lead body. Leads 85 cm or longer should have 2 anchoring sleeves on the lead body.

Verifying the mechanical functioning of the helix electrode

Note: The package includes 2 tools, the Quick Twist tool assembled on the lead and the white fixation tool. Either tool may be used to verify the mechanical functioning of the helix electrode. The choice of tool is left to the discretion of the physician.

Before implant, verify the mechanical functioning of the helix electrode using the following steps:

1. Attach either the Quick Twist tool or the white fixation tool to the lead. Ensure that the stylet is inserted into the lead and proceed as indicated, according to the tool being used.
   a. **Quick Twist tool:** Push the Quick Twist tool onto the IS-1 connector pin (Figure 1).

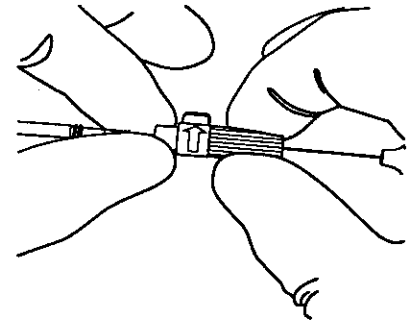


Figure 1.

   b. **White fixation tool:** Press both legs of the white fixation tool together and place the most distal hole on the IS-1 connector pin (Figure 2).

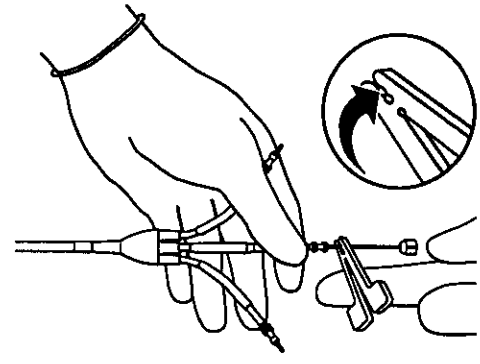


Figure 2.

2. Hold the IS-1 connector leg of the lead with the thumb on one side and 4 fingers on the other side. Keep the lead body and the IS-1 connector leg as straight as possible (Figure 2). Ensure that the stylet is fully inserted, then rotate the selected fixation tool clockwise until the helix electrode is fully extended (Figure 3a or Figure 3b). When the helix electrode is fully extended, approximately 1.5 to 2 helix coils are exposed.

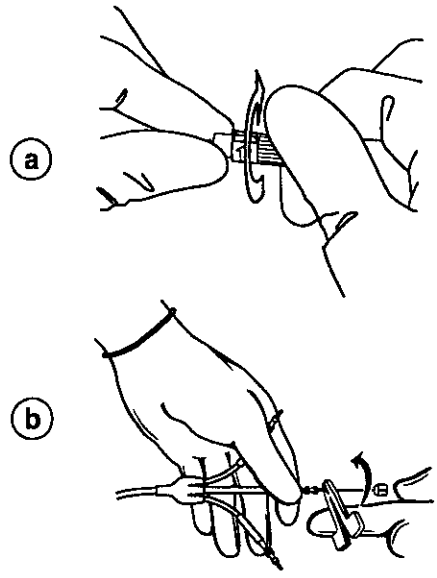


Figure 3.

Caution: Do not severely bend the IS-1 connector leg or the lead body while extending the helix electrode (Figure 4). If the lead is bent on either side of the lead bifurcation during helix electrode extension or retraction, the lead may be damaged.

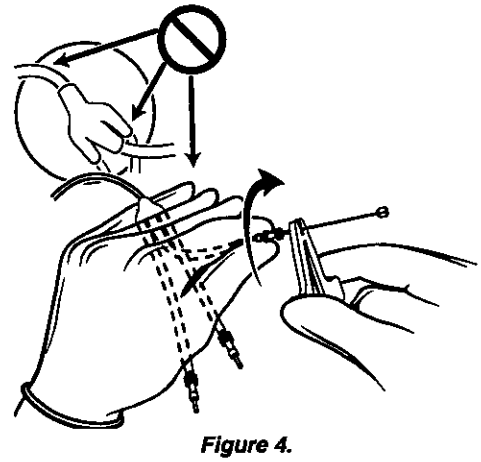


Figure 4.

Caution: Overrotating the connector pin after the helix electrode is fully extended may damage the lead.

Note: To determine the number of rotations applied to the lead, count the number of rotations of the white flap on the Quick Twist tool. The number of necessary rotations is equivalent to the number required for the white fixation tool. See "Specifications (nominal)" on page 27 for the maximum number of rotations to extend or retract the helix electrode.

The number of rotations required to extend the helix electrode increases proportionately with the length of the lead. Additional curvatures made to the stylet may increase the number of rotations needed to extend or retract the helix electrode. Refer to the section "Specifications (nominal)" on page 27, for the maximum number of rotations to extend or retract the helix electrode.

During the initial helix electrode extension, the helix electrode may extend suddenly due to accumulated torque in the lead, or the helix electrode may require additional turns for extension.

3. Disconnect the selected fixation tool from the connector pin and release the proximal end of the lead body. Allow several seconds for relief of the residual torque in the lead.
4. After allowing for relief of the residual torque, reattach the selected fixation tool and rotate it counterclockwise until the helix electrode tip is retracted into the sheath.

Inserting the lead

Caution: Use care when handling the lead during insertion.

- Do not severely bend, kink, or stretch the lead.
- Do not use surgical instruments to grasp the lead or connector pins.

Insert the lead using the following techniques:

1. Select a site for lead insertion. The lead may be inserted by venotomy through several different venous routes, including the right or left cephalic vein or the external or internal jugular vein. Use the cephalic vein whenever possible to avoid lead damage in the first rib or clavicular (thoracic inlet) space.

   Caution: Certain anatomical abnormalities, such as thoracic outlet syndrome, may also precipitate pinching and subsequent fracture of the lead.

   Caution: When using a subclavian approach, avoid techniques that may damage the lead.

   - Place the insertion site as far lateral as possible to avoid clamping the lead body between the clavicle and the first rib (Figure 5).

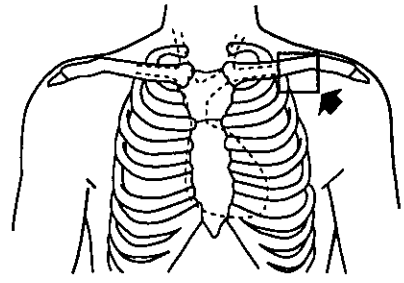


Figure 5.

   - Do not force the lead if significant resistance is encountered during lead passage.

- Do not use techniques such as adjusting the patient's posture to facilitate lead passage. If resistance is encountered, it is recommended that an alternate venous entry site be used.

2. Insert the tapered end of a vein lifter into the incised vein and gently push the lead tip underneath and into the vein (Figure 6).

   Note: A percutaneous lead introducer (PLI) kit may be used to facilitate insertion. Refer to the technical manual packaged with an appropriate percutaneous introducer for further instructions.

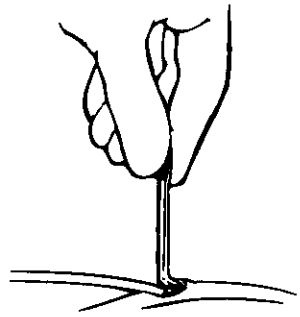


Figure 6.

3. Advance the lead into the right atrium using a straight stylet to facilitate movement through the veins.

Positioning the lead

Caution: Use care when handling the lead during positioning.

- Do not severely bend, kink or stretch the lead.
- Do not use surgical instruments to grasp the lead or connector pins.

Use the following steps to position the lead:

1. After the lead tip is passed into the atrium, advance the lead through the tricuspid valve. Replacing the straight stylet with a gently curved stylet may add control in maneuvering the lead through the tricuspid valve.

   Caution: Do not use a sharp object to impart a curve to the distal end of the stylet. Imparting a curve to the stylet can be accomplished with a smooth-surface, sterile instrument (Figure 7).

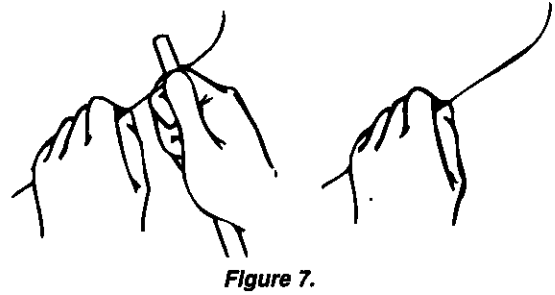


Figure 7.

Note: Passing the lead tip through the tricuspid valve or chordae tendineae may be difficult due to the flexible nature of the lead body. Rotating the lead body as the tip passes through the valve may facilitate passage.

2. After the lead tip is in the ventricle, the curved stylet may be replaced with a straight stylet. Withdraw the stylet slightly, to avoid using excessive tip force while achieving final electrode position. Avoid known infarcted or thin wall areas, to minimize the occurrence of perforation.
3. Proper positioning of the helix electrode is essential for stable endocardial pacing. A satisfactory position usually is achieved when the lead tip points straight toward the apex, or when the distal end dips or bends slightly. Use fluoroscopy (lateral position) to ensure that the tip is not in a retrograde position or lodged in the coronary sinus.

   Note: With the helix electrode retracted, the distal end of the lead may be used to map a desirable site for electrode fixation. Mapping may reduce the need to repeatedly extend and fixate the helix electrode.
4. After placing the lead in a satisfactory position, extend the helix electrode by following the procedure in the section "Securing the helix electrode into the endocardium" on page 21.

Securing the helix electrode into the endocardium

Note: The package includes 2 tools, the Quick Twist tool assembled on the lead and the white fixation tool. Either tool may be used to secure the helix electrode into the endocardium. The choice of tool is left to the discretion of the physician.

Secure the helix electrode using the following techniques:

1. Attach either the Quick Twist tool or the white fixation tool to the lead. Ensure that the stylet is inserted into the lead and proceed as indicated, according to the tool being used.
   a. **Quick Twist tool:** Push the Quick Twist tool onto the IS-1 connector pin. (Figure 1).
   b. **White fixation tool:** Press both legs of the white fixation tool together and place the most distal hole on the IS-1 connector pin (Figure 2).
2. Press the lead tip against the endocardium by gently pushing the stylet and lead at the vein entry site.
3. Rotate the selected fixation tool clockwise until the helix electrode is fully extended (see Figure 3a or Figure 3b).

   Caution: Do not severely bend the IS-1 connector leg or the lead body while extending the helix electrode (Figure 4). If the lead is bent on either side of the lead bifurcation during helix electrode extension or retraction, the lead may be damaged.

   Use fluoroscopy to verify electrode extension (Figure 8). The fluoroscope head may need to be rotated to obtain an adequate view.

Closing of the space between the indicator stop (A) and the indicator ring (B) implies complete extension of the helix electrode.

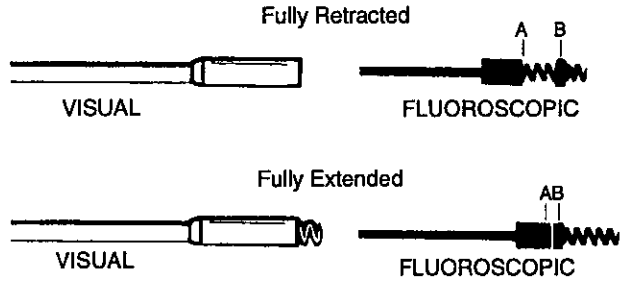


Figure 8.

Caution: Exceeding the maximum number of rotations may damage the lead. The maximum number of rotations required to fully extend or retract the helix electrode is variable; refer to the section, "Specifications (nominal)" on page 27, for the maximum number of rotations.

Caution: Prolonged implant procedures or multiple repositionings may allow blood or body fluids to build up on the helix electrode mechanism. This may result in an increased number of rotations required to extend or retract the helix electrode.

4. Remove the selected fixation tool from the IS-1 connector pin and release the proximal end of the lead body. Allow several seconds for relief of the residual torque in the lead.
5. To assure helix electrode fixation, leave the stylet in place, hold the lead by the connector, and carefully rotate the lead body in 2 clockwise rotations.
6. Partially withdraw the stylet.
7. Obtain electrical measurements to verify satisfactory placement and electrode fixation. Refer to the section "Taking electrical measurements and defibrillation efficacy measurements" on page 23.
8. Verify that the lead is affixed. Gently pull back on the lead and check for resistance to verify fixation. A properly affixed helix electrode will remain in position. If the helix electrode is not properly affixed, the lead tip may become loose in the right ventricle.
9. If repositioning is required, reattach the selected fixation tool and rotate counterclockwise until the helix electrode is retracted. Use fluoroscopy to verify withdrawal of the helix electrode before attempting to reposition.
10. After final positioning, remove the stylet and the Quick Twist tool completely. When removing the Quick Twist tool, grip the lead firmly just below the connector pin to help prevent lead dislodgment.

11. Obtain final electrical measurements. Refer to the section "Taking electrical measurements and defibrillation efficacy measurements" on page 23.

Taking electrical measurements and defibrillation efficacy measurements

Caution: Prior to taking electrical or defibrillation efficacy measurements, move objects made from conductive materials, such as guide wires, away from all electrodes. Metal objects, such as guide wires, can short a lead and an active implantable device, causing electrical current to bypass the heart and possibly damage the implantable device and lead.

Use the following steps to take electrical measurements:

1. Ensure that the Quick Twist tool is disconnected from the IS-1 connector pin.
2. Attach a surgical cable to the lead connector pin.
3. Use a testing device, such as a pacing system analyzer, for obtaining electrical measurements. For information on the use of the testing device, consult the product literature for that device.

   In order to demonstrate reliable defibrillation efficacy, obtain final electrical measurements for the lead system.

Table 3. *Recommended measurements at implant (when using a pacing system analyzer)*

Measurements required	Acute[a] lead system	Chronic[b] lead system
Capture threshold (at 0.5 ms pulse width)	≤ 1.0 V	≤ 3.0 V
Pacing impedance	200 - 1000 ohms	200 - 1000 ohms
Filtered R-wave amplitude (during sinus rhythm)	≥ 5 mV	≥ 3 mV
Slew rate	≥ 0.75 V/s	≥ 0.45 V/s

[a] ≤ 30 days after implant.

[b] > 30 days after implant.

If initial electrical measurements deviate from the recommended values, it may be necessary to repeat the testing procedure 15 minutes after final positioning. Initial electrical measurements may deviate from the recommended values:

- Initial impedance values may exceed the measuring capabilities of the testing device, resulting in an error message.
- Values may vary depending upon lead type, implantable device settings, cardiac tissue condition, and drug interactions.

If electrical measurements do not stabilize to acceptable levels, it may be necessary to reposition the lead and repeat the testing procedure.

In order to keep patient morbidity and mortality to a minimum, patients should be rescued promptly with an external defibrillator if the implanted lead system fails to terminate a VF episode. At least 5 minutes should elapse between VF inductions.

For more information on obtaining electrical measurements, consult the technical manual supplied with the testing device.

Anchoring the lead

Caution: Use care when anchoring the lead.

- Use only nonabsorbable sutures to anchor the lead.
- Do not attempt to remove or cut the anchoring sleeve from the lead body.
- During lead anchoring, take care to avoid dislodging the lead tip.
- Do not secure sutures so tightly that they damage the vein, lead, or anchoring sleeve (Figure 9).
- Do not tie a suture directly to the lead body (Figure 9).

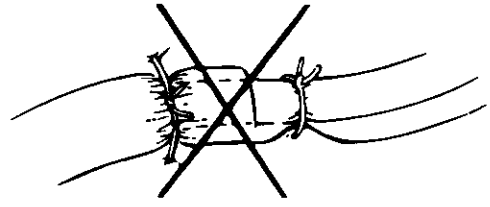


Figure 9.

Use the following steps to anchor the lead using all 3 grooves:

Note: The anchoring sleeves contain a radiopaque substance, which allows visualization of the anchoring sleeve on a standard x-ray and may aid in follow-up examinations.

1. Position the distal anchoring sleeve against or near the vein.
2. Secure the anchoring sleeve to the lead body by tying a suture firmly in each of the 3 grooves (Figure 10).

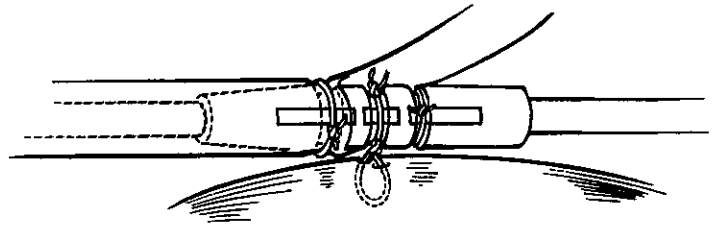


Figure 10.

3. Use at least 1 additional suture in 1 of the grooves to secure the anchoring sleeve and lead body to the fascia.

4. A second anchoring sleeve is provided with leads 85 cm or longer. For abdominal implants, redundant lead body (for example, a curve for strain relief) should be placed just proximal to the first anchoring sleeve. Then, the second anchoring sleeve may be lightly sutured to the lead body and fascia to hold the curve in place. This procedure helps isolate the vein entry site from tension on the proximal end of the lead body.
5. A slit anchoring sleeve may be used in the device pocket to secure excess lead length. First, secure the anchoring sleeve to the lead body. Then, orient the slit toward the fascia and secure the anchoring sleeve to the fascia with sutures.

Connecting the lead

Use the following steps to connect the lead to an implantable device:

1. Carefully remove the stylet and Quick Twist tool. When removing the stylet and Quick Twist tool, grip the lead firmly just below the connector pin, to prevent dislodgment.
2. Insert the lead connectors into the connector block. Consult the product literature packaged with the implantable device for instructions on proper lead connections.

Placing the device and leads into the pocket

Caution: Use care when placing the device and leads into the pocket.

- Ensure that the leads do not leave the device at an acute angle.
- Do not grip the lead or device with surgical instruments.
- Do not coil the lead. Coiling the lead can twist the lead body and may result in lead dislodgment (Figure 11).

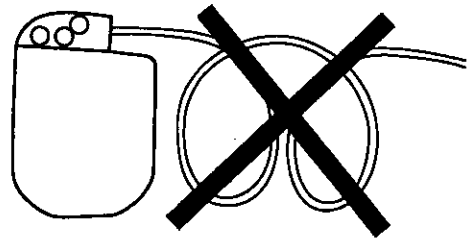


Figure 11.

Use the following steps to place the device and leads into the pocket:

1. To prevent undesirable twisting of the lead body, rotate the device to loosely wrap the excess lead length (Figure 12).

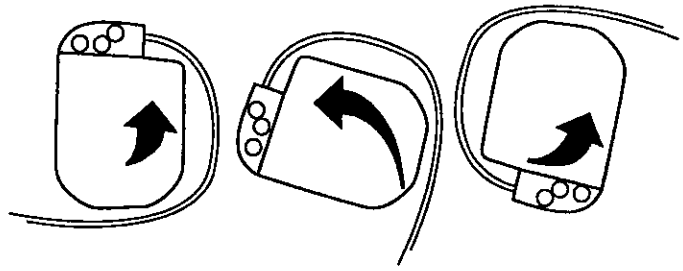


Figure 12.

2. Insert the device and leads into the pocket.
3. Before closing the pocket, verify sensing, pacing, cardioversion, and defibrillation efficacy.

Post-implant evaluation

After implant, monitor the patient's electrocardiogram until the patient is discharged. If a lead dislodges, it usually occurs during the immediate postoperative period.

Recommendations for verifying proper lead positioning include x-rays and pacing/sensing thresholds taken at pre-hospital discharge, 3 months after implant, and every 6 months thereafter.

In the event of a patient death, explant all implanted leads and devices and return them to Medtronic with a completed Product Information Report form. Call the appropriate phone number on the back cover if there are any questions on product handling procedures.

Detailed device description

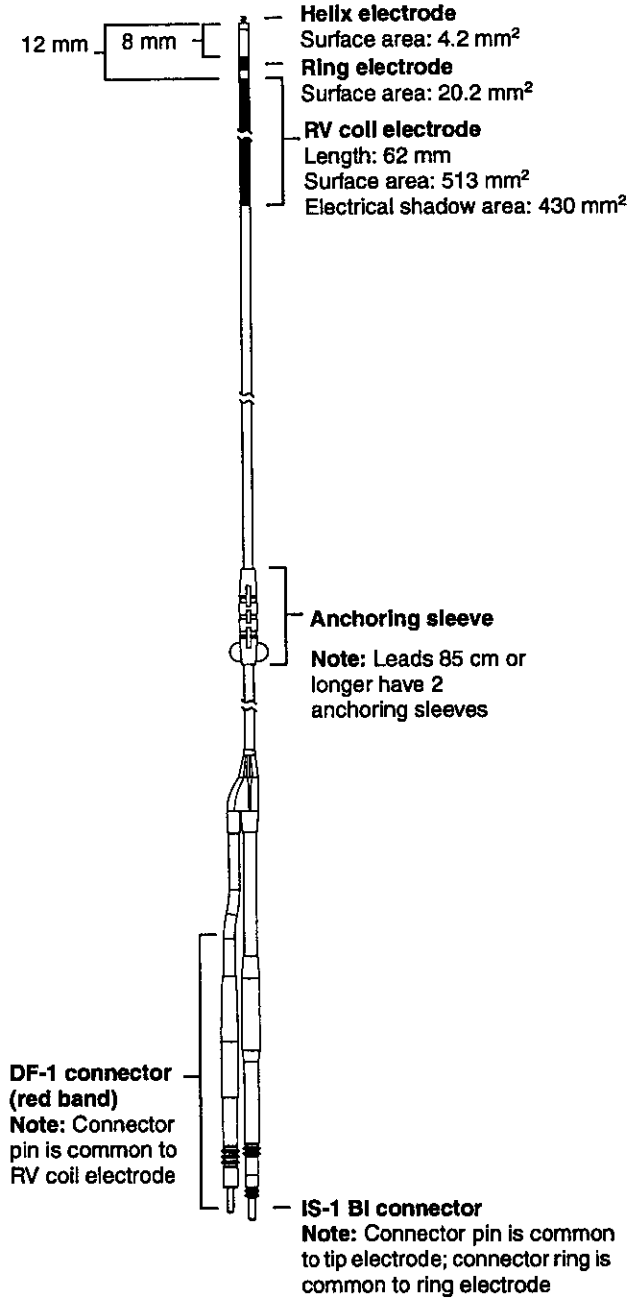
Specifications (nominal)

Parameter		Model 6931
Type		Tripolar
Position		Right ventricle
Fixation		Extendable/Retractable helix
Length		40-110 cm
Connectors	Unipolar:	DF-1
	Bipolar:	IS-1
Materials	Conductors:	MP35N coil MP35N composite cables
	Insulation:	Silicone, ETFE
	Overlay:	Polyurethane
	Electrodes (pace, sense):	Titanium nitride coated platinum iridium
	RV coil:	Platinum-clad tantalum
	DF-1 pin:	Stainless steel
	IS-1 pin and ring:	Stainless steel
Steroid	Type:	Dexamethasone acetate
	Amount:	1.0 mg maximum
	Steroid binder:	Silicone
Conductor resistances	Pacing (unipolar):	21.6 Ω (65 cm)
	Pacing (bipolar):	68.6 Ω (65 cm)
	Defibrillation:	<2.4 Ω (65 cm)
Helix length (extended)		1.8 mm
Diameters	Lead body:	2.2 mm
	Tip:	2.2 mm
	Helix:	1.2 mm
Lead introducer (recommended size)		
	without guide wire:	7.0 French
	with guide wire:	9.0 French

Maximum number of rotations to extend or retract the helix electrode

Lead length	Number of rotations
58 cm	18
65 cm	20
75 cm	22
100 cm	27

Specifications drawing (nominal)



Medtronic warranty

For complete warranty information, see the accompanying warranty document.

Service

Medtronic employs highly trained representatives and engineers located throughout the world to serve you and, upon request, to provide training to qualified hospital personnel in the use of Medtronic products. Medtronic also maintains a professional staff to provide technical consultation to product users. For medical consultation, Medtronic can often refer product users to outside medical consultants with appropriate expertise. For more information, contact your local Medtronic representative, or call or write Medtronic at the appropriate address or telephone number listed on the back cover.

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When Life Depends on Medical Technology

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A03521001
2004-07-07

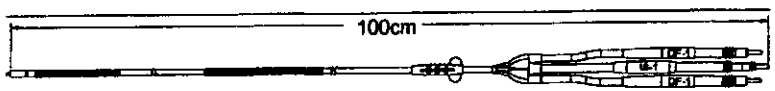
Medtronic

SPRINT FIDELIS™ 6949 - 100cm

Steroid eluting, quadripolar, screw-in, ventricular lead with RV/SVC defibrillation coil electrodes

CONTENTS: One silicone lead with accessories and documentation

One inline bipolar connector (IS-1)
Two unipolar connectors (DF-1)



Recommended Medtronic lead introducer size { 7.0 French without guide wire / 9.0 French with guide wire

The contents of this package are STERILE. If the package is damaged or opened see the product information manual for information.

CAUTION: To prevent suture site damage, the anchoring sleeve provided must be used. See the technical manual for details.

CAUTION: Inserting the lead using a lead introducer that features a hemostatsis valve may require a larger introducer than the size recommended on the labeling. Do not withdraw the lead through a hemostasis valve to avoid distortion of the coil electrode.

Rx Only

Attention: See Accompanying Documents

Storage temperature: Store below 40° C /104° F

STERILE EO Sterilization: Ethylene Oxide Gas

SN TDG000028R
Serial Number

2003-07-14
Use By

LEAD 100cm
Lead Length

Medtronic, Inc.
Minneapolis, MN 55432 U.S.A.

Manufactured at:
Villalba, Puerto Rico, USA

PIN No. 6949000028V

Medtronic
SPRINT FIDELIS™ 6949-100cm
Steroid eluting, quadripolar, screw-in, ventricular lead with RV/SVC defibrillation coil electrodes

A08053-A08514

(01)00721902360320(17)030714(21)TDG000028R
UPN Use By Serial Number

Medtronic

SPRINT FIDELIS™ 6949 - 100cm

Steroid eluting, quadripolar, screw-in, ventricular lead with RV/SVC defibrillation coil electrodes

CONTENTS (STERILE): One silicone lead with accessories
One inline bipolar connector (IS-1) Two unipolar connectors (DF-1)

Recommended Medtronic lead introducer size { 7.0 French without guide wire / 9.0 French with guide wire

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CAUTION: Inserting the lead using a lead introducer that features a hemostatsis valve may require a larger introducer than the size recommended on the labeling. Do not withdraw the lead through a hemostasis valve to avoid distortion of the coil electrode.

Storage temperature: Store below 40° C /104° F

STERILE EO Sterilization: Ethylene Oxide Gas

Rx Only

Attention: See Accompanying Documents

Medtronic, Inc.
Minneapolis, MN 55432

SN TDG000028R
Serial Number

2003-07-14
Use By

LEAD 100cm
Lead Length

A08053-A08514

Medtronic 6949-100cm TDG000028R

A08053-A08514

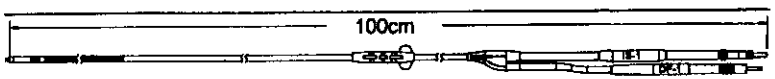
Medtronic

SPRINT FIDELIS™ 6931 - 100cm

Steroid eluting, tripolar, screw-in, ventricular lead with RV defibrillation coil electrode

CONTENTS: One silicone lead with accessories and documentation

One inline bipolar connector (IS-1)
One unipolar connector (DF-1)



Recommended Medtronic lead introducer size { 7.0 French without guide wire / 9.0 French with guide wire

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CAUTION: To prevent suture site damage, the anchoring sleeve provided must be used. See the technical manual for details.

CAUTION: Inserting the lead using a lead introducer that features a hemostatsis valve may require a larger introducer than the size recommended on the labeling. Do not withdraw the lead through a hemostasis valve to avoid distortion of the coil electrode.

Rx Only

Attention: See Accompanying Documents

Storage temperature: Store below 40° C /104° F

STERILE EO Sterilization: Ethylene Oxide Gas

SN TDG000028R
Serial Number

2003-07-14
Use By

LEAD 100cm
Lead Length

Medtronic, Inc.
Minneapolis, MN 55432 U.S.A.

Manufactured at:
Villalba, Puerto Rico, USA

PIN No. 6931000800V

Medtronic
SPRINT FIDELIS™ 6931-100cm
Steroid eluting, tripolar, screw-in, ventricular lead with RV defibrillation coil electrode

A06053-A06613

(01)00721902350320(17)030714(21)TDG000028R
UPN Use By Serial Number

Medtronic

SPRINT FIDELIS™ 6931 - 100cm

Steroid eluting, tripolar, screw-in, ventricular lead with RV defibrillation coil electrode

CONTENTS (STERILE): One silicone lead with accessories
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Recommended Medtronic lead introducer size { 7.0 French without guide wire / 9.0 French with guide wire

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CAUTION: Inserting the lead using a lead introducer that features a hemostatsis valve may require a larger introducer than the size recommended on the labeling. Do not withdraw the lead through a hemostasis valve to avoid distortion of the coil electrode.

Storage temperature: Store below 40° C /104° F

STERILE EO Sterilization: Ethylene Oxide Gas

Attention: See Accompanying Documents

Rx Only

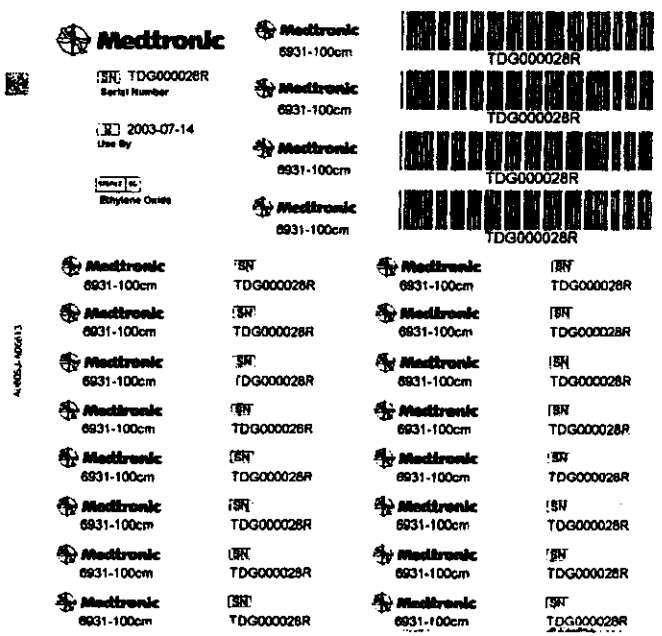
Medtronic, Inc. Minneapolis, MN 55432

SN TDG000028R Serial Number

2003-07-14 Use By

LEAD 100cm Lead Length

A06053-A06613



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Fax: 1-763-514-4879

Medtronic E.C. Authorized Representative
Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

Tel. 31-45-566-8000
Fax 31-45-566-8668

For Technical Consultation
Medtronic USA, Inc.
Toll-free in the USA
(24-hour technical consultation for physicians and medical professionals)

Bradycardia: 1-800-505-4636
Tachycardia: 1-800-723-4636

Europe/Africa/Middle East Headquarters
Medtronic Europe Sàrl
Route du Molliau 31
Case Postale
CH-1131 Tolochenaz
Switzerland

Internet: www.medtronic.co.uk
Tel. 41-21-802-7000
Fax 41-21-802-7900

Medical professionals should review manuals before implanting a device, using a device, or performing a follow-up.

A03463001 Rev B

Medtronic, Inc.
7000 Central Avenue NE
Minneapolis, MN 55432-3576
www.medtronic.com

763.514.4000

SP-7

Medtronic

P920015/S32

C1

September 1, 2005, 2005

Food and Drug Administration
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850
ATTN: 30-day Notice

CC: Food and Drug Administration
Office of Compliance
Field Programs Branch (HFZ-606)
2098 Gaither Road
Rockville, Maryland 20850

FDA/CDRH/OIVD
2005 SEP -2 P 4:43

RE: 30-DAY NOTICE PMA Supplement to P920015

Pursuant to 21 CFR 814.39, this 30-day PMA Supplement is being submitted in triplicate: one copy provided to the Office of Compliance and two copies to the Office of Device Evaluation. This PMA supplement is being submitted to notify FDA of a change in aeration time following the sterilization cycle for the Sprint Fidelis leads (P920015/S029 and S030 approved June 8, 2005).

1. Description of Change

Optimize the aeration process used to remove sterilant residuals for the Medtronic Sprint Fidelis lead models 6949, 6948, 6931, and 6930 following ethylene oxide (EO) sterilization performed at the Medtronic (b)(4) (b)(4)

2. Reason for Change

The Sprint Fidelis leads are currently qualified for sterilization on the 30-minute (b)(4) (b)(4) (b)(4) The previously qualified aeration process of (b)(4) (b)(4) was verified as adequate for the Sprint Fidelis leads and very effective in reducing retained residuals to comply with ISO (b)(4) and (b)(4) (b)(4) requirements. However (b)(4) of aerator time creates a bottleneck and greatly slows throughput of product.

3. Rationale for Implementation via the 30-day Notice

This change involves a modification in the aeration process used to reduce EO residuals following the sterilization of the Sprint Fidelis leads. Product will continue to meet all required EO residual standards that are currently met. The sole purpose of the change is to optimize manufacturing flow. This change does not affect the design, intended use, or specifications of the products involved.

4. Summary of Data or Information Supporting the Change

The attached process qualification report includes a sterilant residual study which demonstrates that aeration of Sprint Fidelis leads may be performed for a minimum of (b)(4) (b)(4) following all (b)(4) sterilization cycles. Using this aeration process is

effective in reducing product sterilant residuals on the Sprint Fidelis leads in compliance with the requirements stated in ISO (b)(4) (b)(4)

5. **Responses to bullet points from 30-Day Notice Guidance Document**

- **A summary of the procedures established for the identification, documentation, validation, review and approval of the manufacturing changes covered by the notice.**

The attached validation report has been approved by Medtronic Sterilization Specialists and the Principal Manufacturing Engineer. The change will be implemented into the manufacturing process through Medtronic's process control system and will require the appropriate approvals prior to actual implementation.

- **If the changed procedures are to be routinely verified by sampling and independent measurement, summarize the statistical rationale for the sampling method.**

There is no resulting sampling plan.

- **If the changed procedures are validated, the process parameters should be monitored and controlled. The 30-day notice should summarize how this will be done.**

Aeration procedures are monitored through annual EO residual reverification testing and controlled following the specific aeration time detailed on the Sterilization Certification. Annually, EO residual testing of representative lead models from each product family and package configuration is performed to re-verify that product retained EO residuals are below the maximum allowable levels. This reverification study demonstrate that the aeration process is effective in reducing sterilant residuals in the leads in compliance with the EO residual requirements following single and multiple sterilization.
The Sterilization Certification Report contain the full list of leads models and the specific minimum aeration time for each lead model (as determined in previous qualifications) in order to assure compliance with EO residuals requirements. Each annual reverification study re-qualify the minimum aeration time for the representative product lines.

- **A summary of the completed validation study that demonstrates that the manufacturing change be made without significantly changing the final device operation.**

As all the Fidelis lead models are similar in design, testing performed on the 6949 equally represents the other Sprint Fidelis models (6949, 6948, 6931, 6930). Test samples were obtained from the production facility and packaged in accordance with current specifications. All sterilization is performed using the (b)(4) (b)(4) Testing is performed in two phases: first, establishment of a (b)(4) (b)(4) and second, performance and evaluation of verification testing.
Testing concludes that aeration processing must be performed for a minimum of (b)(4) (b)(4) (b)(4) following (b)(4) repeated sterilization cycles.
The complete validation report is attached as part of this submission.

- **If the manufacturing change involves changes in components or raw material, a summary of the procedures established for evaluation of new suppliers, if any. Describe the type and extent of control to be exercised over the component or raw material, including specifications for the incoming material.**

There are no changes in the vendor or incoming material specifications.

- **If the change involves use of a new contractor for manufacturing or quality control testing, a summary of the procedures and criteria established for evaluation of that contractor.**

There are no new contractors for manufacturing or quality control testing.

- **Summarize the change controls necessary for modifying the manufacturing or quality control instructions or specifications for the device.**

There are no changes in the device specifications or manufacturing quality control.

6. Statement of Conformity Quality System /GMP Regulations Requirements

To the best of our knowledge, the facilities in which these products are manufactured conform to the Quality System / GMP regulation (21 CFR 820) regarding change control, validation, and document control.

Medtronic respectfully considers the contents of this PMA-S 30-day Notice to be CONFIDENTIAL. Medtronic respectfully requests that this information be given the maximum protection provided by law.

Sincerely,

MEDTRONIC, INC.

Mary Ellen Best

Mary Ellen Best
Principal Regulatory Affairs Specialist
Cardiac Rhythm Management
Telephone: (763) 514-4846
Fax: (763) 514-6424
E-mail: mary.ellen.best@Medtronic.com

Pages removed for the following reason: (b)(4)-Testing

LtB

30-Days

PMA SUPPLEMENT ROUTE SLIP

PMA NUMBER P920015/S032 PANEL CV DIVISION DCD BRANCH PDLB

TRADE NAME MEDTRONIC SPRINT FIDELIS LEADS MODELS,6949,6948,6931,6930

GENERIC NAME TRANSVENOUS,STEROID ELUTING,QUADRIPOLAR,ACTIVE FIXATION, P

PRODUCT CODE LWS DEFIBRILLATOR, AUTOMATIC IMPLANTABLE CARDIOVERTER

APPLICANT MEDTRONIC, INC.
SHORT NAME MEDTRONIC
CONTACT LYNN JENSEN
DIVISION
ADDRESS 7000 CENTRAL AVE. N.E.
MINNEAPOLIS, MN 55432
PHONE NO. (763) 514-3673 FAX NO. (763) 514-6424

MANUFACTURER	REG NO.
MEDTRONIC, INC.	
MEDTRONIC INC. CARDIAC RHYTHM	2182208
MEDTRONIC, INC.	
MEDTRONIC, INC.	2182208
MEDTRONIC PUERTO RICO OPERATIO	2649622
MEDTRONIC B.V.	
MEDTRONIC NEUROLOGICAL	2182207
MEDTRONIC PUERTO RICO OPERATIO	2649622

******* REVIEW TIME SUMMARY *******

DATE ON SUBMISSION 01-SEP-2005

CYCLE # 1
DATE RECEIVED IN ODE 02-SEP-2005 CYCLE START 02-SEP-2005

DATE FILING DUE

	ELAPSED	LAST CYCLE
FDA TIME	4	4
MFR TIME	0	0

DATE DECISION DUE 02-OCT-2005

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

DEC 1 2005

Mary Ellen Best
Principal Regulatory Affairs Specialist
Medtronic, Inc.
1015 Gramsie Road
MS-Z-110
St. Paul, Minnesota 55126-3082

Re: P920015/S032
Medtronic Sprint Fidelis Leads Models 6930/6931, 6948/6949
Filed: September 2, 2005
Amended: October 17, 2005

Dear Ms. Best:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its evaluation of your premarket approval application (PMA) 135-day supplement, which requested approval to change the aeration time following sterilization of the Sprint Fidelis Leads. Based upon the information submitted, the PMA 135-day supplement is approved subject to the conditions described within the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device as modified by your PMA 135-day supplement upon receipt of this letter.

Failure to comply with the conditions of approval as attached invalidates this approval order. Commercial distribution of a device that does not comply with these conditions is a violation of the Federal Food, Drug, and Cosmetic Act.

Amendments should be submitted in triplicate, unless otherwise specified, to the address below and reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have questions concerning this approval order, please contact Steven E. Budabin, M.S., Consumer Safety Officer, Cardiovascular & Neurological Devices Branch (HFZ-341) at (240) 276-0120.

Sincerely yours,

Christy Foreman for

Gladys Rodriguez
Director
Division of Enforcement B
Office of Compliance
Center for Devices and
Radiological Health

Enclosure

CONDITIONS OF APPROVAL

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e) or (f). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

Not all situations that require a PMA supplement can be briefly summarized; therefore, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report (see below). FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

Alternate submissions permitted under 21 CFR 814.39(f) for manufacturing process changes include the use of a 30-day Notice. The manufacturer may distribute the device 30 days after the date on which the FDA receives the 30-day Notice, unless the FDA notifies the applicant within 30 days from receipt of the notice that the notice is not adequate.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

1. Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

2. Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

   a. unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

   b. reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports are required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

1. A mix-up of the device or its labeling with another article.

2. Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and:

   a. has not been addressed by the device's labeling; or

   b. has been addressed by the device's labeling but is occurring with unexpected severity or frequency.

3. Any significant chemical, physical or other change or deterioration in the device, or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION.
The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984. This regulation was replaced by the reporting requirements of the Safe Medical Devices Act of 1990 which became effective July 31, 1996 and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for a PMA, the manufacturer shall submit the appropriate reports required by the MDR Regulation within the time frames as identified in 21 CFR 803.10(c) using FDA Form 3500A, i.e., 30 days after becoming aware of a reportable death, serious injury, or malfunction as described in 21 CFR 803.50 and 21 CFR 803.52 and 5 days after becoming aware that a reportable MDR event requires remedial action to prevent an unreasonable risk of substantial harm to the public health. The manufacturer is responsible for submitting a baseline report on FDA Form 3417 for a device when the device model is first reported under 21 CFR 803.50. This baseline report is to include the PMA reference number. Any written report and its envelope is to be specifically identified, e.g., "Manufacturer Report," "5-Day Report," "Baseline Report," etc.

Any written report is to be submitted to:

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
PO Box 3002
Rockville, Maryland 20847-3002

Copies of the MDR Regulation (FOD # 336&1336) and FDA publications entitled "An Overview of the Medical Device Reporting Regulation" (FOD # 509) and "Medical Device Reporting for Manufacturers" (FOD #987) is available on the CDRH WWW Home Page. They are also available through CDRH's Fact-On-Demand (F-O-D) at 800-899-0381. Written requests for information can be made by sending a facsimile to CDRH's Division of Small Manufacturers International and Consumer Assistance (DSMICA) at 301-443-8818.

MEMORANDUM

30-Day Notice Converted to 135-Day Supplement

DATE: October 24, 2005

TO: The File

FROM: Steven E. Budabin, CSO
CNDB, HFZ-341
DOE-B, OC, CDRH

THROUGH: Erin I. Keith, Acting Chief
CNDB, HFZ-341
DOE-B, OC, CDRH

RE: P920015/S032 – Medtronic Sprint Fidelis Leads
(Models 6930, 6931, 6948, 6949)

FIRM: Medtronic, Inc.
1015 Gramsie Road
MS-Z-110
St. Paul, Minnesota 55126-3082
FEI: 1000123711

CONTACT: Mary Ellen Best
Principal Regulatory Affairs Specialist
763-505-7869
FAX: 763-505-7877

BACKGROUND:

Medtronic submitted this PMA Supplement on September 1, 2005, in accordance with section 515(d)(6) of the Act and followed the requirements in ODE's guidance document titled, 30-Day Notices and 135-Day Supplements for Manufacturing Methods or Process Changes, Guidance for Industry and CDRH. The supplement requests approval to change the aeration time following the sterilization cycle for the Sprint Fidelis Leads. The submission qualifies as a 30-Day Notice. Appropriate attachments with supporting data are included in the submission. The sponsor states there will be no changes to vendors or incoming material specifications, contractors for manufacturing or quality control testing, or changes to design, specifications, or intended use.

A detailed explanation of the change follows:

Medtronic Sprint Fidelis Leads (Fidelis Leads) are currently qualified for sterilization using a (b)(4) The sterilization medium is (b)(4) (b)(4) Medtronic seeks to modify the aeration process used to reduce (b)(4) residuals following the sterilization of the Fidelis Leads in order to optimize manufacturing flow. The plan is to reduce the time from (b)(4)

In support of the change, Medtronic submitted a validation test report titled, Aeration Process Qualification Report for Medtronic Model 6948/6949 & 6930/6931 Sprint Fidelis Lead Sterilized and (b)(4) Aerators at the Medtronic (b)(4) Sterilant residual testing was performed on (b)(4) samples per protocol (b)(4) at the (b)(4) Samples were tested by exposing them to a variety of different aeration times and configurations using (b)(4) Based upon the results of the dissipation curve, Medtronic concludes that an aeration time of (b)(4) is adequate for rendering Fidelis Leads in compliance with (b)(4) following (b)(4) sterilization on the (b)(4) Additionally, sponsor concludes the results demonstrated (b)(4) aeration proves adequate to comply with the (b)(4)

In order to verify that Medtronic had chosen the correct aeration process, they conducted verification testing on additional samples following the (b)(4) testing. Sterilant residual verification testing was performed on (b)(4) samples each following the (b)(4) sterilization process. Sponsor states the results demonstrated that the (b)(4) aeration process is effective in reducing product sterilant residuals on Medtronic Fidelis Leads. Medtronic states that all equivalent sterilizers and aerators may be used for routine sterilization and aeration processing of Fidelis Leads. Furthermore, they state that product may be released via (b)(4) process control.

COMPLIANCE REVIEW:

The Office of Compliance received this PMA submission dated September 1, 2005, on September 6, 2005. The filing date is September 2, 2005, and the due date is October 2, 2005.

The supplement included a description of the change, reason for the change, rationale for implementation via the 30-day notice, a summary of the data or information supporting the change, a summary of the procedures established for the identification, documentation, validation, review and approval of the manufacturing changes covered by the notice, and a statement of conformity to the QS/GMP regulations under 21 CFR 820.

However, the following deficiencies were found: (1) there was insufficient information to demonstrate that the (b)(4) are equivalent; (2) Medtronic did not explain how environmental controls at (b)(4) are equivalent; (3) Medtronic did not provide a summary of how sterilant residual testing in-

house is equivalent at (b)(4) (b)(4) (4) there is a contradiction in the submission as to the actual location of where Fidelis Leads are sterilized and aerated; (5). There was no information on whether residual testing was performed for substances other than (b)(4) (b)(4) A deficiency letter was issued to the sponsor on September 30, 2005 and requested the following:

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

DECISION

Based on our review of the submission and the amendment of October 12, 2005, we recommend approval of the supplement.

SUMMARY

A copy of the 30-Day Notice Checklist, the e-mails, a copy of the September 30, 2005 deficiency letter, and a copy of the approval letter to the manufacturer, which was sent on _____is attached.

Steven E. Budabin, CSO

Draft:SBudabin:10/24/05
Reviewed:EKeith:10/24/05
Final:SZB:10/24/05

cc:

HFZ-306	(Larry Comela)
HFZ-340	(Gladys Rodriguez, Christy Foreman, DOE B Chron)
HFZ-341	(Steve Budabin, c/f)
HFZ-402	(Lisa Fisher)
HFZ-450	(Megan Moynahan)

OC Track #116893

FAX#: 763-505-7877
Phone#: 763-505-7869
FPB #301

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 30 2005

Mary Ellen Best
Principal Regulatory Affairs Specialist
Medtronic, Inc.
7000 Central Avenue NE
Minneapolis, Minnesota 55432-3576

Re: P920015/S032
Filed: September 2, 2005

Dear Ms. Best:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) 30-day Notice. The submission requested approval to change the aeration time following sterilization of the Sprint Fidelis Leads. We have determined a detailed review of the data supporting the change must be performed. Therefore, your 30-day Notice has been converted to a 135-Day PMA Supplement.

The following deficiencies were identified during the review of the 30-day Notice. Because of the lack of this information, review of the PMA cannot continue and, accordingly, we have listed the following deficiencies, which require the responses as indicated:

(b)(4)

(b)(4)

(b)(4)

(b)(4)

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your PMA application can be completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 515 of the Federal Food, Drug, and Cosmetic Act for determining reasonable assurance of safety and effectiveness of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center webpage at:
http://www.fda.gov/cdrh/modact/leastburdensome.html

This letter reflects the current progress of our review of your application. You may not begin commercial distribution of the device as modified by this PMA 135-day supplement until you have received an approval order. Further review of your application and/or any response to this letter may result in additional deficiencies. CDRH will issue an approval order for the 135-day PMA supplement after the requested information has been reviewed and determined to be acceptable.

Because FDA considers the information submitted with the 30-day Notice as meeting the content requirements for PMA supplements, the time spent reviewing the submission as a 30-day Notice will be deducted from the 135 day period.

You may amend the PMA 135-day supplement to provide the above requested information (3 copies), voluntarily withdraw the PMA (3 copies) or request an extension. The required copies of the amended PMA 135-day supplement should include the FDA reference number to facilitate processing.

One copy should be sent to:

Food and Drug Administration
Office of Compliance
Field Programs Branch (HFZ-306)
2098 Gaither Road

One copy should be sent to:

Food and Drug Administration
Office of Compliance
Field Programs Branch (HFZ-306)
2098 Gaither Road
Rockville, Maryland 20850

The remaining **two copies** should be sent to:

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this letter, please contact Steven E. Budabin, M.S., Consumer Safety Officer at 240-276-0120 or via E-mail at steve.budabin@fda.hhs.gov.

Sincerely yours,

Gladys Rodriguez
Director
Division of Enforcement B
Office of Compliance
Center for Devices and
Radiological Health

Pages removed for the following reason: (b)(4) and (b)(5)

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

September 06, 2005

MARY ELLEN BEST
MEDTRONIC, INC.
7000 CENTRAL AVE. NE
MINNEAPOLIS, MN 55432

Dear MARY ELLEN BEST:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) acknowledges receipt of your PMA SUPPLEMENT. This PMA SUPPLEMENT has been assigned the following unique document control number. Failure to reference this assigned number in future correspondence may result in processing delays.

PMA Number: P920015/S032
Dated: 01-SEP-2005
Received: 02-SEP-2005
Device: MEDTRONIC SPRINT FIDELIS LEADS MODELS 6949,

Any questions concerning this submission should be directed to the undersigned at (301)443-8320. All future correspondence regarding this PMA should be identified with the PMA number assigned above and should be submitted with the required number of copies to:

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

Sincerely yours,

Senora F. Smallwood
Consumer Affairs Specialist
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Pages removed for the following reason: (b)(4) - Testing

P920015 532 A1 C2

LTM

30-DAY/135-DAY

PMA AMENDMENT ROUTE SLIP

PMA NUMBER P920015/S032/A001 PANEL CV DIVISION DCD BRANCH PDLB

TRADE NAME MEDTRONIC SPRINT FIDELIS LEADS MODELS,6949,6948,6931,6930

GENERIC NAME TRANSVENOUS,STEROID ELUTING,QUADRIPOLAR,ACTIVE FIXATION, P

PRODUCT CODE LWS DEFIBRILLATOR, AUTOMATIC IMPLANTABLE CARDIOVERTER

APPLICANT MEDTRONIC, INC.
SHORT NAME MEDTRONIC
CONTACT LYNN JENSEN
DIVISION
ADDRESS 7000 CENTRAL AVE. N.E.
MINNEAPOLIS, MN 55432
PHONE NO. (763) 514-3673 FAX NO. (763) 514-6424

MANUFACTURER	REG NO.
MEDTRONIC, INC.	
MEDTRONIC INC. CARDIAC RHYTHM	2182208
MEDTRONIC, INC.	
MEDTRONIC, INC.	2182208
MEDTRONIC PUERTO RICO OPERATIO	2649622
MEDTRONIC B.V.	
MEDTRONIC NEUROLOGICAL	2182207
MEDTRONIC PUERTO RICO OPERATIO	2649622

******* REVIEW TIME SUMMARY *******

DATE ON SUBMISSION 14-OCT-2005

CYCLE # 1

DATE RECEIVED IN ODE 17-OCT-2005 CYCLE START 02-SEP-2005

DATE FILING DUE _____

	ELAPSED	LAST CYCLE
FDA TIME	28	28
MFR TIME	17	17

DATE DECISION DUE _____

AMENDMENT/ CORRESPONDENCE	REASON	START	STOP
C001	FILE	02-SEP-2005	
C002	MCAD	30-SEP-2005	

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

October 17, 2005

MARY ELLEN BEST
MEDTRONIC, INC.
7000 CENTRAL AVE. NE
MINNEAPOLIS, MN 55432

Dear MARY ELLEN BEST:

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Sincerely yours,

-S-

Senora F. Smallwood
Consumer Affairs Specialist
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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