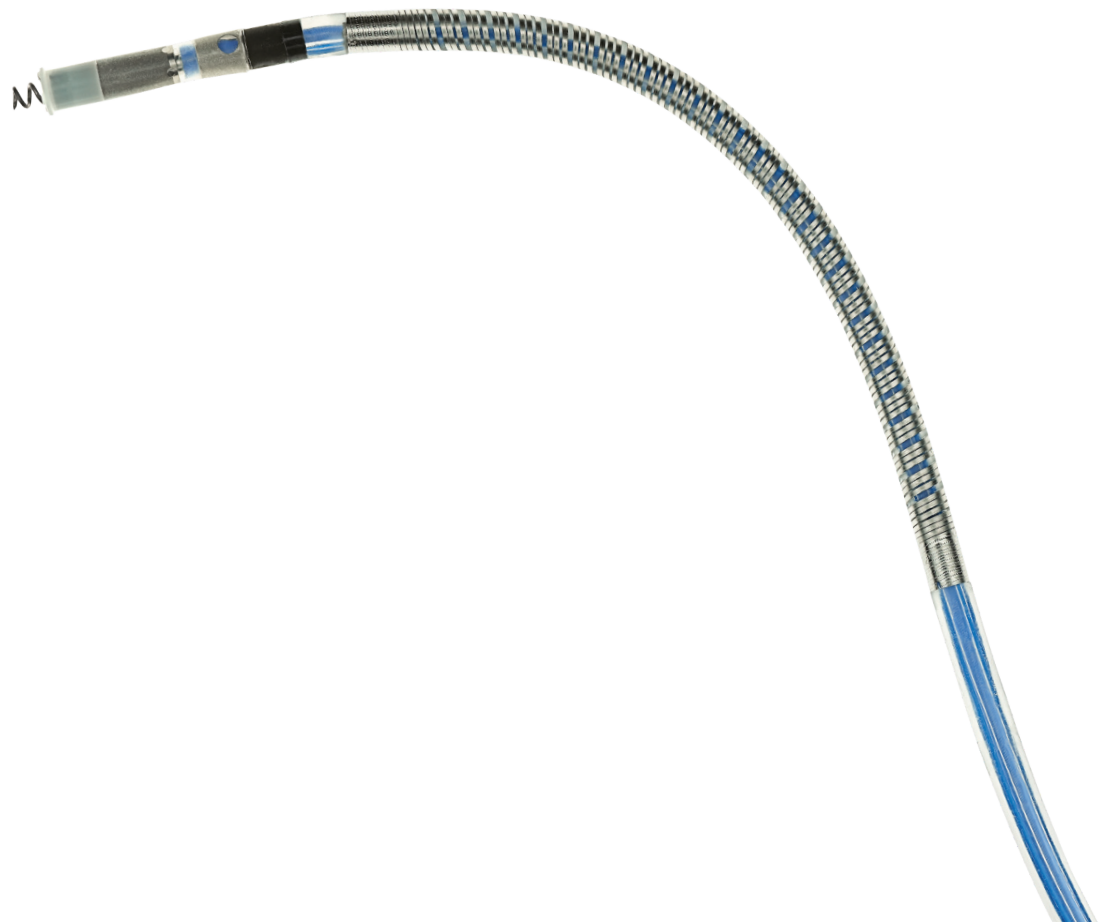




Optim™ Lead Insulation
Lead Technology
CLINICAL COMPENDIUM

PROVEN RELIABILITY AND PERFORMANCE

Long-term survival rates reported from multiple independent and prospective registries confirming Optim™ lead insulation in clinical use.



People are living longer with their cardiac rhythm management (CRM) devices,

MAKING LEAD DECISIONS EVEN MORE IMPORTANT TO YOU AND YOUR PATIENT.

AT ABBOTT, WE UNDERSTAND THE IMPORTANCE OF LEAD MATERIAL IN PROVIDING THE PERFORMANCE AND LONGEVITY YOU AND YOUR PATIENTS EXPECT FROM LEADS.

We have invested in Optim™ lead insulation as our material of choice and continue to track the clinical performance of this material. We have tracked more than 10 years of lead data because we are committed to understanding the clinical performance of Optim™ lead insulation to ensure it is meeting the needs of those living with CRM devices.

BIOMATERIAL

Implantable cardiac pacemakers and defibrillator leads materials must be biodurable, possessing excellent mechanical and physical properties. Leads need to survive the hostile environment inside the human body, requiring them to resist abrasion, corrosion and degradation, all the while providing maximum performance.

Insulation is used to protect the vulnerable components of the lead body for years. Silicone elastomers and polyurethane (PEU) polymers have historically been the two primary insulation materials used in implantable cardiac pacemaker and defibrillator leads.

Optim™ lead insulation, which was introduced to the market in 2006, was designed to combine the most favorable properties of silicone and PEU materials. With more than 10 years of active registry and real-world data, Optim™ lead insulation continues to demonstrate safety and reliability.

MATERIAL DESIGN

In Optim™ lead insulation, the portion of PEUs most susceptible to oxidation are replaced by biostable non-crosslinked polyether segments.

As a copolymer, Optim™ lead insulation provides exceptional biostability, and much higher mechanical strength, than silicone elastomer lead insulation.¹

PROVEN STRENGTH AND DURABILITY

Studies validate the endurance of Optim™ lead insulation to withstand environmental forces.

LONG-TERM

ABRASION RESISTANCE CONFIRMED VIA FLUOROSCOPIC SCREENING OF OPTIM™ INSULATED LEADS.

Durata™ defibrillation leads (961) were systematically imaged. **In patients that have been implanted for 4.5 +/- 1.1 years:**

- **Leads free of electrical dysfunction (98.1%)²**
- **No externalized conductors²**

No structural defects were seen in 264 ICD leads with Optim™ lead insulation implanted between July 2007 and December 2011 at a single university hospital. Independent analysis of high-resolution cine fluoroscopic images was conducted on average **31 months post-implant.**³

LONG-TERM

BIOSTABILITY AGAINST OXIDATION, HYDROLYSIS AND TEARING.

Leads with Optim™ lead insulation showed **excellent resistance to chemical and physical degradation** in up to eight years of *in vivo* human exposure.¹

- Tensile strength and elongation testing showed slight decreases from 0 to 2–3 years, and no further loss through 6–7 years⁴
- No progressive average molecular weight loss after 2–3 years in leads implanted through 7–8 years⁴

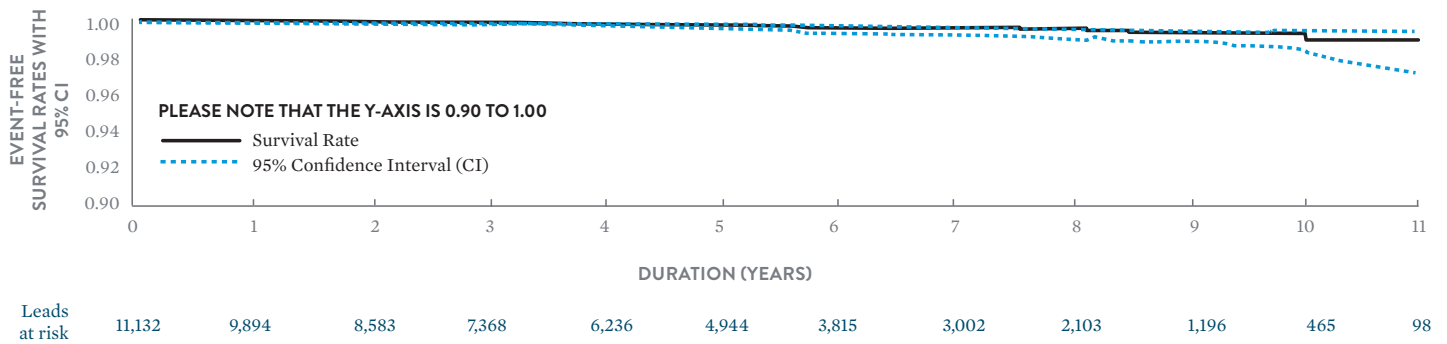


Now with More than 10 Years of Clinical Data

OPTIM™ LEAD INSULATION MATERIALS EVIDENCE

➔ **99.1% FREEDOM** ➔ FROM ALL-CAUSE INSULATION ABRASION.⁵

EVENT-FREE SURVIVAL RATES FOR ALL-CAUSE INSULATION ABRASION IN ICD LEADS WITH OPTIM™ LEAD INSULATION AS CALCULATED BY PHRI⁵ (FOLLOWED TO LAST REPORTED PATIENT CONTACT)

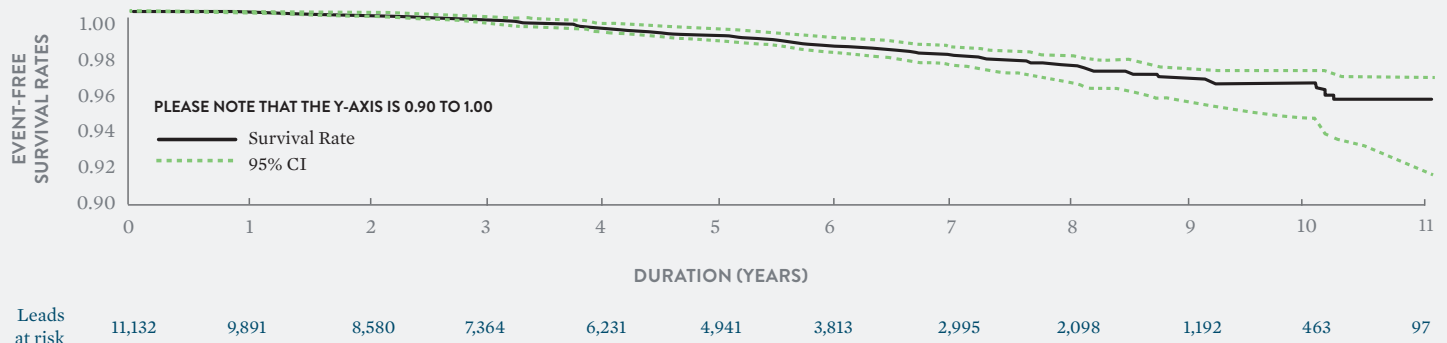


➔ **96.1% FREEDOM** ➔ FROM ALL-CAUSE MECHANICAL FAILURE.⁵

Data on 11,130 ICD leads with Optim™ lead insulation from three actively monitored prospective registry studies with more than 10 years of follow-up.

Calculated by PHRI, an independent third party.

EVENT-FREE SURVIVAL RATES FOR ALL-CAUSE MECHANICAL FAILURE IN ICD LEADS WITH OPTIM™ LEAD INSULATION AS CALCULATED BY PHRI⁵ (FOLLOWED TO LAST REPORTED PATIENT CONTACT)



PUBLISHED REAL-WORLD CLINICAL DATA

Multiple published studies demonstrate the strong performance of Optim™ insulated leads in independent clinical practices.

2.1% OVERALL FAILURE RATE OF DURATA™ DEFIBRILLATION LEADS

(n = 1001) vs. 3.4% for Endotak Endurance[‡]/Endotak Reliance[‡]/Endotak DSP[‡] (n = 537) and 4.2% for Sprint[‡]/Sprint Quattro[‡] leads (n = 1033).⁶

Data from an independent, retrospective comparative leads survival study including a total of 1,004 Durata™ defibrillation leads amongst 4,078 Abbott, Boston Scientific and Medtronic ICD leads implanted at a single, large New York hospital over 15 years.

2% ESTIMATED SEVEN-YEAR FAILURE RATE FOR DURATA™ DEFIBRILLATION LEADS

(n = 340) vs. 9.6% for silicone-only Biotronik Linx[‡] leads (n = 408).⁷

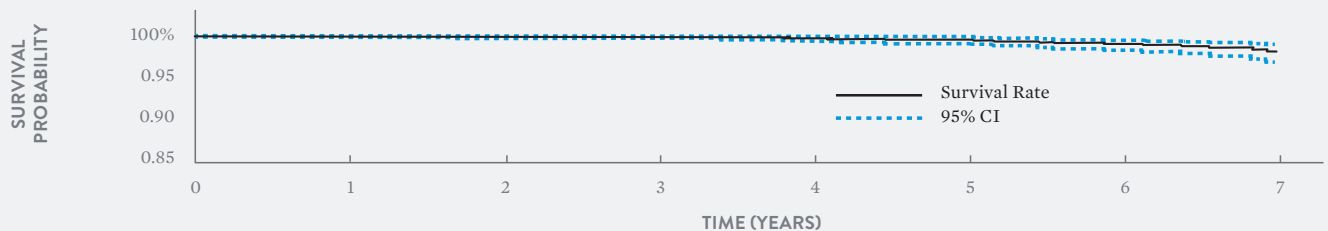
A single-center, prospective registry study from Rotterdam, Netherlands, including high voltage ICD leads implanted from April 2000–May 2012.

→ **> 99% FIVE-YEAR SURVIVAL PROBABILITY** →

FOR ICD LEADS WITH OPTIM™ LEAD INSULATION.⁸

Data on over 4,400 ICD leads with Optim™ lead insulation with up to seven years of follow-up from the VA National Cardiac Device Surveillance Program, based on independent analysis of national device registry data from over 120 VA medical facilities.

DURATA™ DEFIBRILLATION LEAD AND RIATA™ ST OPTIM™ LEAD SURVIVAL ANALYSIS
(FREEDOM FROM ALL-CAUSE ELECTRICAL FAILURE)⁸

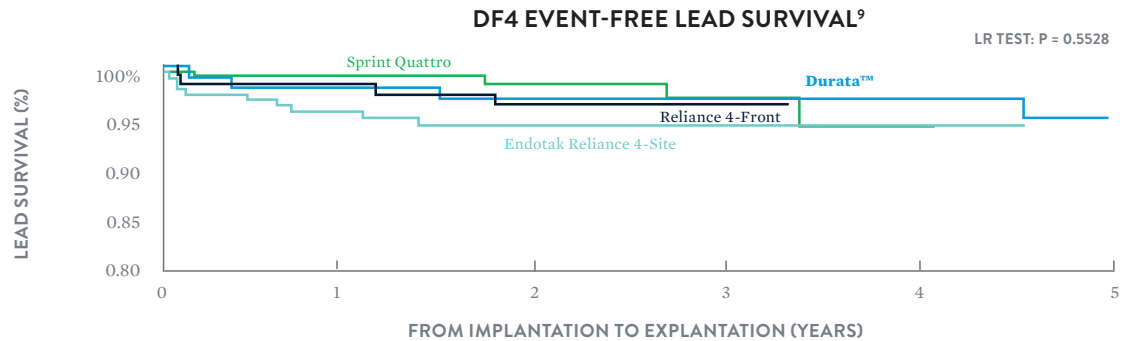


	0	1	2	3	4	5	6	7
Optim™ leads	4,442	3,875	3,101	2,411	1,754	1,092	525	184
Survival		100.0%	99.9%	99.7%	99.4%	99.1%	98.7%	97.7%
95% CI		99.9–100	99.7–100	99.4–99.8	99.0–99.6	98.5–99.4	97.9–99.2	96.0–98.6

→ **97.5%**
CUMULATIVE
THREE-YEAR
SURVIVAL RATE →

FOR ABBOTT DF4 DURATA™ DEFIBRILLATION LEADS.⁹

A single-center prospective study evaluation of ICD DF4 lead performance in 812 consecutive implants. Estimated survival rates at three years of follow-up were 95.6% for Boston Scientific Endotak⁺ Reliance⁺ 4-site, 97.1% for Boston Scientific Reliance⁺ 4-Front, 97.7% for Medtronic Sprint Quattro⁺ and 97.5% for Abbott Durata™ defibrillation leads.⁹



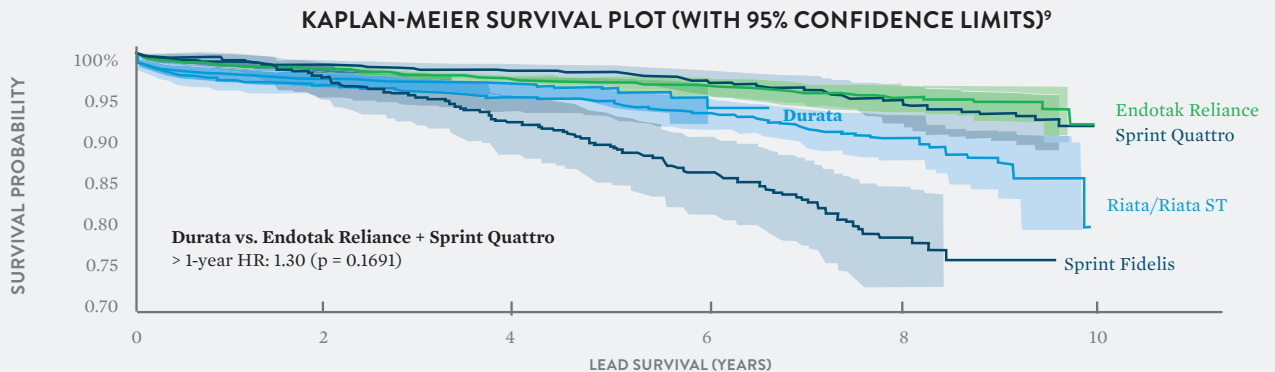
	0	1	2	3	4	5
Number at Risk						
Boston Scientific Reliance ⁺ 4-Front leads	207	187	77	17	-	-
Boston Scientific Endotak Reliance ⁺ 4-Site leads	232	212	193	126	45	-
Medtronic Sprint Quattro ⁺ leads	250	223	167	78	2	-
Abbott Durata™ leads	124	116	109	96	80	41

OPTIM™ INSULATION PERFORMANCE

→ **COMPARABLE**
LONG-TERM
SURVIVABILITY →

IN DURATA™ DEFIBRILLATION LEADS VS. ENDOTAK RELIANCE⁺ + SPRINT QUATTRO⁺ LEADS.¹⁰

Data from a retrospective cohort study of Kaiser Permanente Cardiac Device Registry patients with more than 15,000 leads implanted.



Medtronic Sprint Quattro ⁺ leads	3,088	2,710	2,052	1,416	1,130	935	733	640	556	423
Boston Scientific Endotak Reliance ⁺ leads	4,597	4,208	3,918	3,630	3,026	2,362	1,810	1,203	635	168
Abbott Durata™/Riata™ Optim™ leads	3,722	3,177	2,414	1,661	981	459	73	-	-	-
Abbott Riata™/Riata™ ST leads	2,803	2,477	2,297	2,129	1,948	1,795	1,567	997	443	129
Medtronic Sprint Fidelis ⁺ leads	613	594	572	541	541	468	409	273	133	2

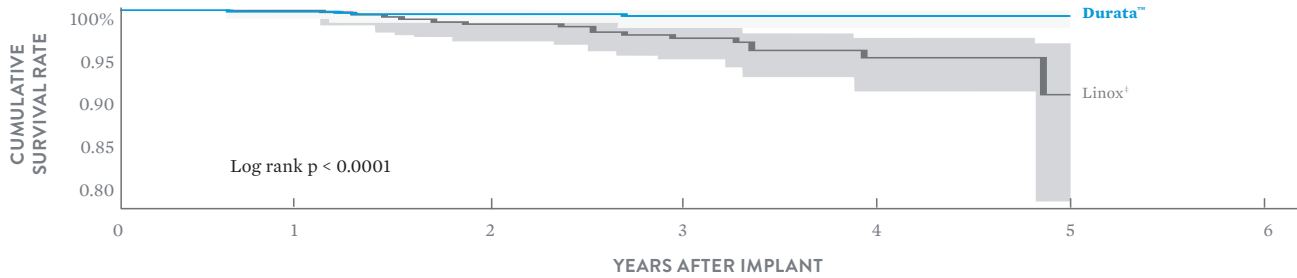
→ **99.4%** →
CUMULATIVE FIVE-YEAR SURVIVAL RATE

OF DURATA™ DEFIBRILLATION LEADS VS. 91.6% FOR SILICONE-ONLY LEADS.¹¹

Independent analysis of British Columbian Cardiac Registry Data on 838 Durata™ defibrillation leads implanted at four institutions.

Over a median of 39 (27–50) months, the failure rate for Durata defibrillation leads was 0.4% (4/838) versus 3.4% (16/477) for contemporary silicone-only Biotronik Linox[‡] leads (p < 0.001).

SURVIVAL FROM ICD LEAD FAILURE¹¹

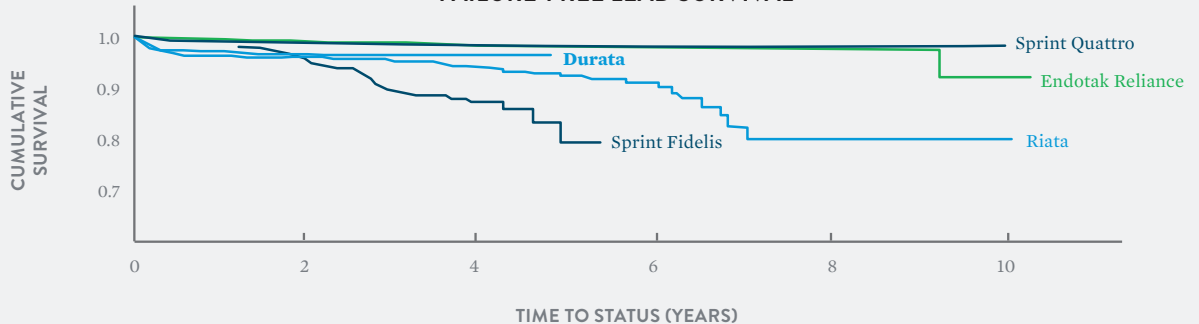


Abbott Durata™ leads	838	770	693	472	294	71
Biotronik Linox [‡] leads	477	435	401	266	120	22

→ **0.3%** →
ELECTRICAL FAILURE RATE PER YEAR.¹²⁻¹⁴

Data on 828 Durata™ defibrillation leads from an independent, retrospective review of all patients receiving ICD leads at University of Pittsburgh Medical Center hospitals over a two-year period.

FAILURE-FREE LEAD SURVIVAL¹²⁻¹⁴

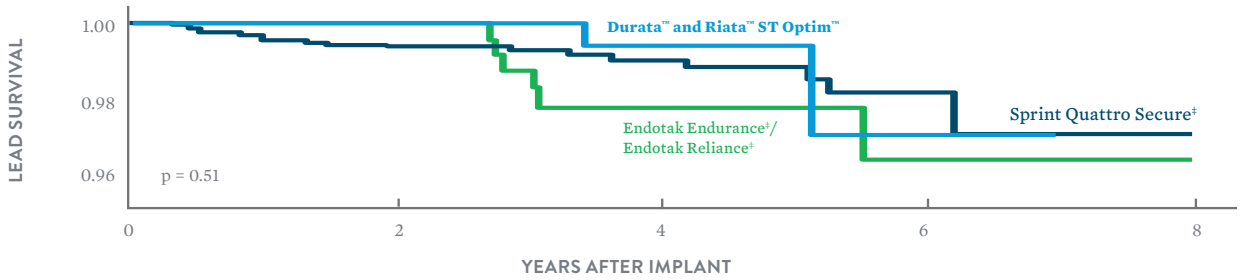


Medtronic Sprint Quattro ⁺ leads	1,020	663	303	205	116	3
Boston Scientific Endotak Reliance [‡] leads	1,821	1,716	1,231	698	299	-
Abbott Durata™ leads	828	506	43	-	-	-
Abbott Riata™ leads	621	429	278	99	15	-
Medtronic Sprint Fidelis ⁺ leads	623	448	107	-	-	-

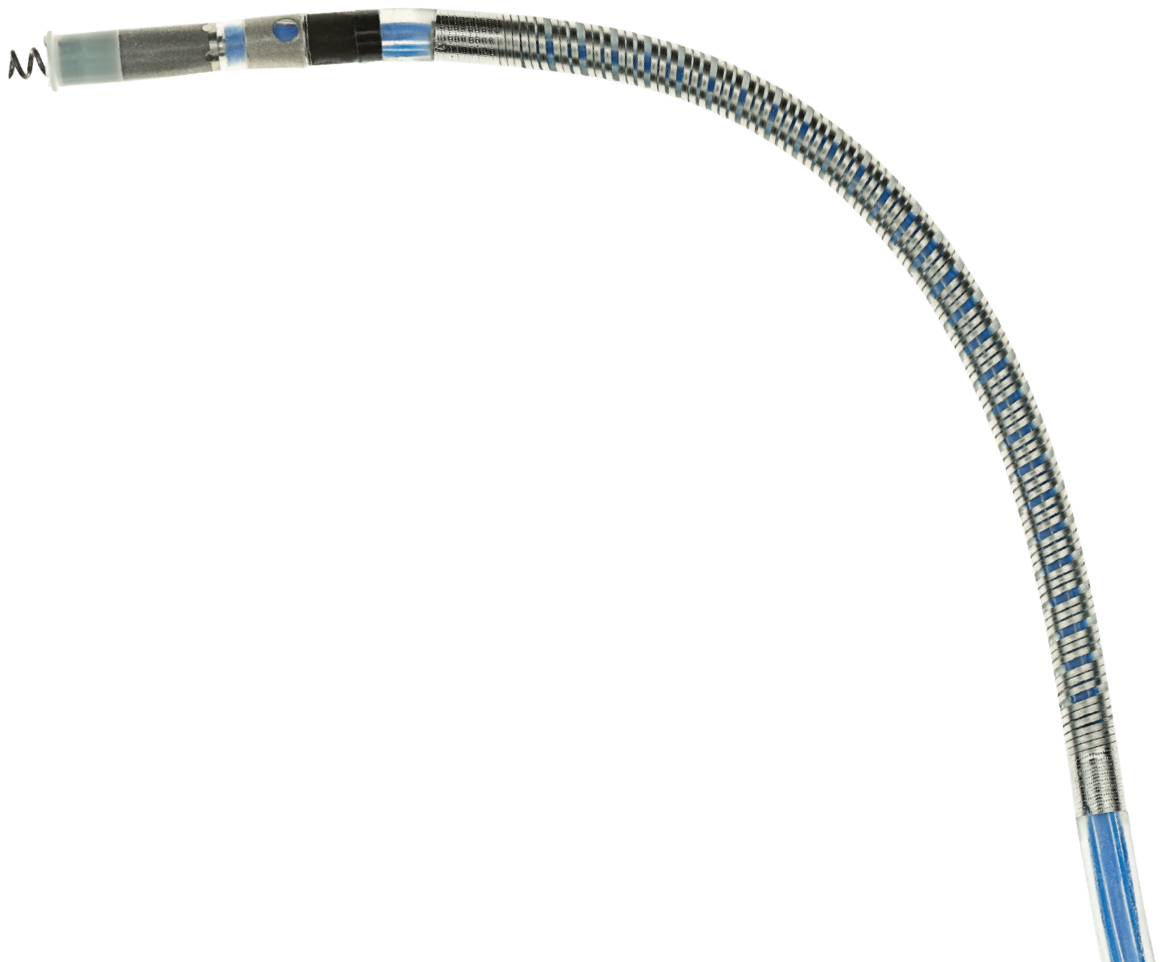
→ **< 0.2%**
FAILURE RATE →
 PER YEAR AND < 1% OVERALL
 FAILURE RATE FOR ICD LEADS
 WITH OPTIM™ LEAD INSULATION.¹⁰

Data on 445 Durata™ defibrillation leads and Riata™ ST Optim™ leads from an independent review of 2,653 patients implanted with contemporary ICD leads at four United States clinical centers after a median of 2.9 years of follow-up.

SURVIVAL FROM ICD LEAD FAILURE¹⁵



Abbott Durata™ and Riata™ ST Optim™ leads	445	417	362	262	156	80	31	2	-
Medtronic Sprint Quattro Secure™ leads	1,821	1,737	1,545	1,177	838	500	232	42	8
Boston Scientific Endotak Endurance™/ Endotak Reliance™ leads	389	365	331	257	194	132	79	31	15



TO LEARN MORE ABOUT ABBOTT LEADS WITH OPTIM™ LEAD INSULATION, SPEAK WITH YOUR ABBOTT REPRESENTATIVE.

These published data represent experience at specific centers, and may not be applicable across all centers.

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Abbott

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Abbott.com

Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

™ Indicates a trademark of the Abbott group of companies.

‡ Indicates a third party trademark, which is property of its respective owner.

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