Product Information for Patients

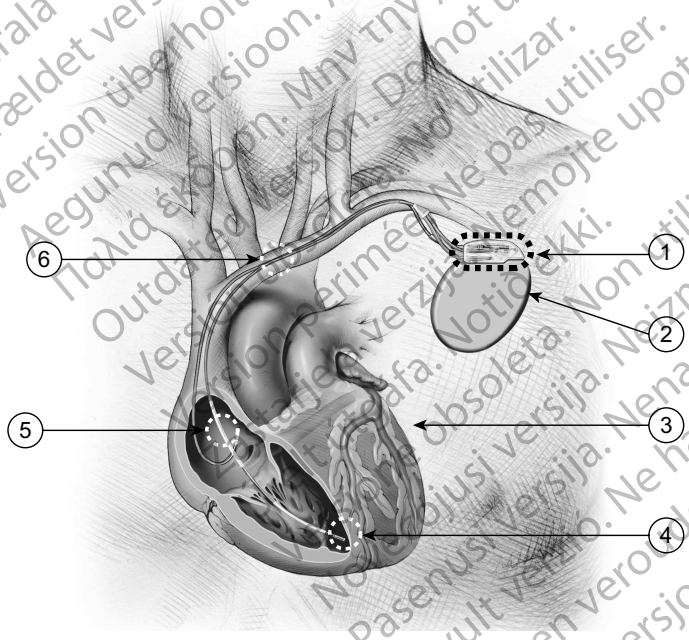
RELIANCE 4-FRONT™

Cardiac Lead

REF 0652, 0653, 0657, 0658, 0672, 0673, 0675, 0676, 0692, 0693, 0695, 0696
0636, 0650, 0651, 0654, 0655, 0662, 0663, 0665, 0682, 0683, 0685, 0686

Device Information

A lead is an insulated wire that is passed into your heart through a vein. One end is implanted in the heart wall and the other end is connected to a pulse generator, which contains electronics and a battery. The lead senses your heartbeat and delivers pacing pulses and/or shocks from the pulse generator to the heart.



1. Lead connected to pulse generator
2. Pulse generator
3. Heart
4. Lead implanted in heart wall
5. Lead within heart
6. Lead in vein

Information on Safe Use

Before implant, tell your healthcare provider if you are sensitive or allergic to any of the materials or substances listed in the "Patient Contacting Materials and Substances" on page 2.

Carry your Implant Card at all times and present it before entering protected environments, such as for an MRI scan.

Tell your healthcare providers, such as your doctor, dentist, or technician, that you have an implanted device, and show them your Implant Card(s) so that they can take any necessary precautions.

Information about your implanted device may be found using the websites shown on the back of your Implant Card. Device information available on the websites varies by region.

Contact your healthcare provider that follows your device:

- If you have an adverse event (in other words, an undesirable side effect) or unusual/unexpected symptoms. These include new symptoms or symptoms like the ones felt before implant of your device.
- After any medical procedure and/or surgery in order to have your device checked.

Warnings and/or Precautions Related to Reciprocal Interference

Some procedures use equipment that can potentially interfere with the operation of your device and vice versa (i.e., reciprocal interference). Talk with your healthcare provider that follows your device before undergoing these types of procedures. Examples of these types of procedures are listed below.

- **Magnetic resonance imaging (MRI):** This is a diagnostic test that uses a strong electromagnetic field. Some devices have been evaluated to allow the patient to undergo MRI scans under specific conditions. Talk to your healthcare provider that follows your device about the eligibility of your device. If your device is not eligible to be scanned (i.e., not part of an ImageReady™ system), or if the required conditions are not met, MRI scans can severely damage your device and should not be performed. Your healthcare provider that follows your device must always confirm that both you and your device are eligible and ready for an MRI scan in order for you to undergo this procedure. Hospitals/healthcare centers keep MRI equipment in rooms marked with signs that indicate magnets are inside. Do not go inside these rooms unless your healthcare provider that follows your device has confirmed that your device is eligible and you meet the requirements for an MRI scan.

  For information about MRI scanning, contact your healthcare provider that follows your device and/or visit the following website:

  www.bostonscientific.com/imageready
- **Diathermy:** This uses an electrical field to apply heat to tissues in the body and could damage your device or injure you. Diathermy should not be performed.

Expected Lifetime and Follow-up

Based on results of testing, the expected lifetime of this lead is typically a minimum of 10 years. Your healthcare provider will monitor the lead and will decide if and when it may need to be replaced.

Discuss a follow-up plan with your healthcare provider that follows your device, including the frequency and type of follow up.

Report any serious incident that involves this lead (i.e., an event requiring medical attention) to your healthcare provider that follows your device, as well as to Boston Scientific using the information on the last page and to the relevant local regulatory authority in your country.

Patient Contacting Materials and Substances

The lead contains the following materials and substances that come in contact with the body:

Material/Substance Models 0652, 0653, 0657, 0658, 0672, 0673, 0675, 0676, 0692, 0693, 0695, 0696	**Percentage (%) of patient-contacting surface area**[a]
Silicone	70% – 90%
Platinum, ePTFE (expanded polytetrafluoroethylene)[b]	5% – 25%
IROX™ (iridium oxide), polyurethane, TiO_2 (titanium dioxide), $BaSO_4$ (barium sulfate), dexamethasone acetate (drug)[c], PEEK (polyetheretherketone), titanium (grade 2), platinum/iridium	Additive, trace amount, and/or <5%

a. Typical total surface area of lead ≈ 45-60 cm^2 (depends on model).

b. GORE™ models (0657, 0658, 0692, 0693, 0695, 0696) only: The platinum shocking coils are covered with an ePTFE coating. This coating is the primary patient-contacting surface. Both the platinum and ePTFE are included in the surface area percentage. GORE is a trademark of W.L. Gore and Associates.

c. 0.96 mg for models 0652, 0653, 0657, 0658, 0672, 0673, 0675, 0676, 0692, 0693, 0695, 0696

Material/Substance Models 0636, 0650, 0651, 0654, 0655, 0662, 0663, 0665, 0682, 0683, 0685, 0686	**Percentage (%) of patient-contacting surface area**[a]
Silicone	75% – 95%
Platinum, ePTFE (expanded polytetrafluoroethylene)[b]	5% – 25%
IROX™ (iridium oxide), polyurethane, TiO_2 (titanium dioxide), $BaSO_4$ (barium sulfate), dexamethasone acetate (drug)[c], titanium (grade 2), platinum/iridium, PEG (polyethylene glycol)	Additive, trace amount, and/or <5%

a. Typical total surface area of lead ≈ 45-60 cm^2 (depends on model).

b. GORE™ models (0654, 0655, 0682, 0683, 0685, 0686) only: The platinum shocking coils are covered with an ePTFE coating. This coating is the primary patient-contacting surface. Both the platinum and ePTFE are included in the surface area percentage.

c. 0.97 mg for models 0636, 0650, 0651, 0654, 0655, 0662, 0663, 0665, 0682, 0683, 0685, 0686

Symbols Table

The following symbols are used for patient information:

Symbol and Definition		**Patient Information**
	Date	Date of device implant
	Health Care Center or Doctor	Name and contact information of healthcare institution where device implanted or clinician who performed implant
	Person Identification	Name of patient receiving implanted device
	Reference Number	Model number of implanted device
	Manufacturer	Company that made implanted device
	Authorized Representative in the European Community	European contact information for company that made implanted device
	Serial Number	Serial number of implanted device
	Use by date	Date the device must be implanted by
	Date of Manufacture	Date the device was made
	Unique Device Identifier	Barcode with information about the device

EC REP

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