Product Information for Patients

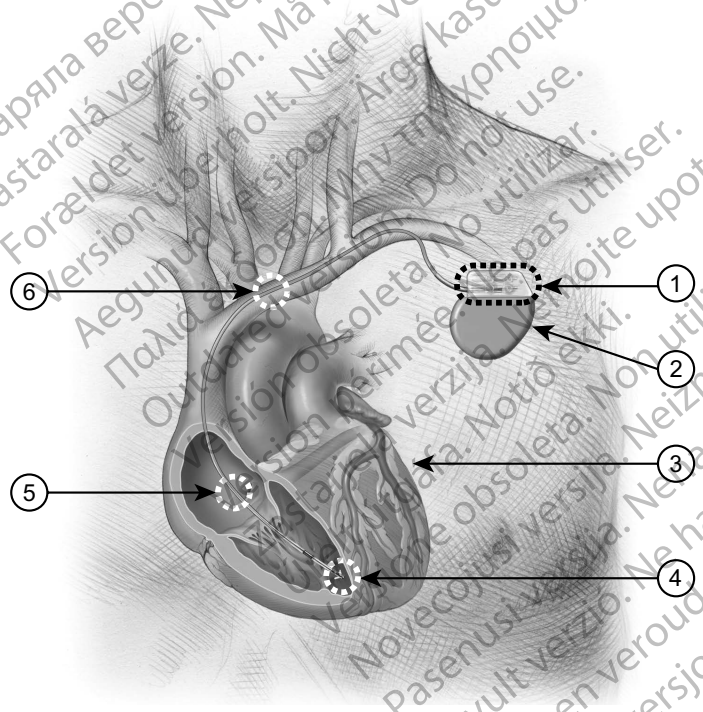
INGEVITY™

Pace/Sense Lead

REF 7731, 7732, 7735, 7736, 7740, 7741, 7742, 7840, 7841, 7842

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 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

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 are sensitive or allergic to any of the materials or substances listed in the "Patient-Contacting Materials and Substances" on page 2.
- If you experience unusual or unexpected symptoms, such as new symptoms or symptoms like the ones experienced prior to implant of your device.
- After any medical procedure and/or surgery in order to have your device checked.

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.

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.

Patient-Contacting Materials and Substances

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

Material/Substance	Percentage (%) of patient-contacting surface area [a]
Polyurethane	70% - 80%
Silicone	20% - 30%
IROX™ (iridium oxide), PEEK (polyetheretherketone) [b], MP35N™ [b, c, d], TiO_2 (titanium dioxide), $BaSO_4$ (barium sulfate), PEG (polyethylene glycol) [e], dexamethasone acetate (drug)	Additive, trace amount, and/or < 5%

a. Typical total surface area of lead ≈ 25-40 cm^2 (depends on model).

b. Only models 7740, 7741, 7742, 7840, 7841, 7842.

c. This material contains cobalt. Based on animal studies, the European Commission has classified cobalt as a substance that may:
   - cause cancer, or
   - interfere with normal reproduction.

   However, research shows that metal alloys containing cobalt used in medical devices do not cause an increased risk of these effects in humans. Talk with your doctor if you have questions about your device.

d. MP35N is a trademark of SPS Technologies, Inc.

e. Only models 7731, 7732, 7735, 7736.

Symbols Table

The following symbols may be on this document and the Implant Card.

Symbol and Definition	Meaning
 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 the device must be implanted by
 Date of Manufacture	Date the device was made
 Unique Device Identifier	Barcode with information about the device

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CE 2797

50944538-028 en EU 2021-11