

## **ACCOLADE**<sup>TM</sup>

Pacemaker L300, L301, L321 L310, L311, L331

### Details About Your Boston Scientific ACCOLADE Pacemaker

#### What is a pacemaker?

A pacemaker is a small, battery-powered device that holds a tiny computer. It is implanted in the body to watch for and treat abnormally slow heart rhythms. Your doctor programs your pacemaker to respond appropriately based on your individual heart rhythm needs.

#### Treating slow heart rhythms

If an abnormally slow heart rhythm occurs, your ACCOLADE pacemaker delivers small electrical signals that help your heart beat more normally. Your pacemaker can also help increase your heart rate to meet your body's needs when you are active.

#### How long will my pacemaker last?

Like anything that operates on a battery, the life of your pacemaker will depend on how much the battery is used. The battery is used every time your device delivers therapy. So the amount of pacing you receive, and the amount of energy your doctor programs into the pacing therapy, affects the life of the battery. An additional consideration is the type of device chosen. Model L300, L301, L310 and L311 ACCOLADE Pacemakers are projected to last 8-12 years and L321 and L331 ACCOLADE Extended Life (EL) pacemakers are projected to last 10-17 years.



#### What happens after my implant procedure?

#### Care and recovery at home

Your doctor or nurse will give you specific instructions to follow when returning home. Full recovery from surgery can take from several days to a few months, depending on your condition. It is important that you are actively involved in your own recovery. Follow your doctor's instructions about caring for the implant site and letting your other doctors, dentists, and emergency personnel know that you have an implanted pacemaker system.

#### Follow-up visits

Once you have a pacemaker, it is important to follow your doctor's guidelines for follow-up visits. Your doctor uses the follow-up visits to check your device and monitor your heart condition, which can change over time. Your doctor may also adjust your device settings.

If you are enrolled in the LATITUDE™ NXT Patient Management System, your doctor can check your ACCOLADE remotely between visits.

#### How small is my pacemaker?

Model	Height	Width	Thickness	Weight
L300,	1.9 in.	1.8 in.	0.3 in.	0.8 oz.
L310	4.8 cm	4.5 cm	0.8 cm	23.6 g
L301,	2.0 in.	1.8 in.	0.3 in.	0.9 oz.
L311	5.0 cm	4.5 cm	0.8 cm	24.8 g
L321,	2.3 in.	1.8 in.	0.3 in.	1.0 oz.
L331	5.9 cm	4.5 cm	0.8 cm	29.1 g

# **SPECIFICATIONS**



Pacemaker L300, L301, L321 L310, L311, L331

#### Important Safety Information

A pacemaker system is designed to monitor and treat your heart rhythm problems, greatly reducing the risks associated with them. These devices are sensitive to strong electromagnetic interference (EMI) and can be affected by certain sources of electric or magnetic fields. Some of the risks encountered during the implant procedure include, but are not limited to, the following: Bleeding, formation of a blood clot, damage to adjacent structures (tendons, muscles, nerves), puncture of a lung or vein, damage to the heart (perforation or tissue damage), dangerous arrhythmias, heart attack, stroke, death. Some of the risks encountered after the system is implanted may include, but are not limited to, the following: Infection, erosion of the skin near your device, lead(s) may move out of place in the heart, device may move from the original implant site, difficulty coping with having an implanted device. The device might be prevented from pacing due to electromagnetic interference. Electrodes on the lead or the pacing pulses may cause an irritation or damaging effect on the surrounding tissues, including heart tissue and nerves. You may receive pacing therapy when it is not needed (unnecessary therapy). The device might not be able to detect or appropriately treat your heart rhythms. The device may exhibit malfunctions that may result in lost or compromised ability to deliver therapy. You may experience some discomfort from the incision as you recover from the surgery. You may experience some discomfort from the incision as you recover from the surgery. With all medical procedures there are risks associated. In rare cases device failure or death can occur. Be sure to talk with your doctor so that you thoroughly understand all of the risks and benefits associated with the implantation of this system. To obtain a copy of the device Patient Handbook for more detailed device safety information, go to www.bostonscientific.com, or you can request a copy by calling 1-866-484-3268 or writing to Boston Scientific, 4100 Hamline Ave. N., St. Paul, MN 55112. Rx only (92481216 Rev. A)

#### **Device Quality and Reliability**

It is Boston Scientific's intent to provide implantable devices of high quality and reliability. However, these devices may exhibit malfunctions that may result in lost or compromised ability to deliver therapy. Refer to Boston Scientific's CRM product performance report on www.bostonscientific.com for more information about device performance, including the types and rates of malfunctions that these devices have experienced historically. While historical data may not be predictive of future device performance, such data can provide important context for understanding the overall reliability of these types of products. Also, it is important that you talk with your doctor about the risks and benefits associated with the implantation of a device. (92481216 Rev. B)



#### Cardiology

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Medical Professionals: 1.800.CARDIAC (227.3422) Patients and Families:

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