Boston Scientific
Advancing science for life™

THE FIRST AND ONLY FULL SPECTRUM OF CARDIAC DIAGNOSTIC SOLUTIONS

to meet the needs of patients and providers across the cardiac care continuum

WE CAN MONITOR PATIENTS FOR DAYS, WEEKS, MONTHS OR YEARS

SHORT-TERM HOLTER

24 - 48 hrs

Data download after study

MEDIUM-TERM AND LONG-TERM HOLTER

>48 hrs - 15 days

Data download after study

CARDIAC EVENT MONITOR

Up to 30 days

Patient/Device triggered near real-time transmission

MOBILE CARDIAC TELEMETRY

Up to 30 days

Continuous near real-time transmission

INSERTABLE CARDIAC MONITOR

Up to 3 years

Daily alert checks, scheduled follow-ups & manual transmissions

Depending on their clinical condition, patients may require short or long-term monitoring.

The BodyGuardian™ products and affiliated services are associated with Boston Scientific Cardiac Diagnostics, Inc., a wholly owned subsidiary of Boston Scientific.

DIAGNOSE, TREAT, MONITOR

By 2030, >12MM people in the U.S. will be diagnosed with Atrial Fibrillation

The average person with Atrial Fibrillation is 3x more likely to develop heart failure and 5x more likely to suffer a stroke

Diagnose

4.6 MM Dx devices are prescribed annually for short- or long-term monitoring

Treat

30% of EP procedures are preceded by at least one cardiac diagnostic monitor

Monitor

30% of ablations are followed by cardiac monitoring

Miyasaka Y, Barnes ME, Gersh BJ, et al. Secular trends in incidence of atrial fibrillation in Olmsted County, Minnesota, 1980 to 2000, and implications on the projections for future prevalence. Circulation. 2006;114:199-225.
Colilla S, Crow A, Petkun W, Singer DE, Simon T, Liu X. Estimates of current and future incidence and prevalence of atrial fibrillation in the U.S. adult population. Am J Cardiol. 2013;112:1142-1147. doi: 10.1016/j.amjcard.2013.05.063.
https://pubmed.ncbi.nlm.nih.gov/124015297. 4. National Stroke Association. Making the Afib-Stroke Connection. https://www.stroke.org/sites/default/files/resources/Afib-Connection%20for%20hcp.pdf. Published 2012. Accessed September 1, 2016.

Scan the QR code to learn more

Indications for Use: Intended Use: The BodyGuardian MINI is intended for use in clinical long-term ambulatory ECG monitoring, data transfer and analysis. BodyGuardian MINI is indicated for adult and pediatric patients who require ECG monitoring inside or outside hospital or healthcare facility environments. The sensor does not provide interpretive statements. Final interpretation and diagnosis is the responsibility of a physician. Contraindications: The sensor is contraindicated for those patients requiring attended, in-hospital monitoring for life threatening arrhythmias and for use on pediatric patients weighing 22 lbs. (10kgs) or less. Safety Precautions: The sensor does not directly provide diagnosis as a supervising physician is responsible for ECG data interpretation. Do not disassemble, try to repair, or modify sensor. Sensor does not have any electrical stimulation capabilities. Warnings: Do not attempt self-diagnosis or self-treatment based on acquired data. Not suitable for use in MRI environment. Patients with known skin allergies or hypersensitivities to adhesives or hydrogel may experience reactions. Patients should consult with their health care professional to select a BodyGuardian MINI Strip or alternate electrode option that is most appropriate for their needs. Apply the BodyGuardian MINI Strip or alternate electrode only to intact, clean skin. Do not apply over open wounds, lesions, infected or inflamed areas. The BodyGuardian MINI Strips are for single patient use only. The device is not intended to be used at the same time with high frequency (HF) surgical equipment or with a defibrillator. Patients who have active implantable medical device (for example a heart pacemaker), should consult supervising physician or doctor before use. When using the MINI ECG monitor connected in Bluetooth mode (in the MINI Plus configuration) the monitor should be kept within 10 feet (approximately 3 meters) to the companion device (smartphone) to facilitate wireless communication. To avoid danger of electrical shock and electromagnetic disturbances, the computer and associated equipment used with the ECG Sensor should comply with IEC/EN 60950 (IT and office equipment safety) or EN60601-1 (Medical electrical equipment safety) standard. If a computer that does not comply with the IEC/EN 60601-1 requirements is used in the patient environment, the computer and peripherals must be plugged in using an isolation transformer that fulfills the requirement. CRM-1424006-AA
Indications for Use: The LUX-Dx™ Insertable Cardiac Monitor (ICM) is intended to monitor and record subcutaneous electrocardiogram (S-ECG). The recorded S-ECG is used for the clinical evaluation and diagnosis of cardiac arrhythmias. The LUX-Dx is indicated for use in patients that have a known heart condition and are at risk of developing an abnormal heart rhythm, or have symptoms that may suggest a cardiac arrhythmia, such as dizziness, palpitations, syncope, chest pain, and/or shortness of breath. The LUX-Dx has not been tested specifically for pediatric use. CONTRAINDICATIONS: There are no known contraindications for the insertion of the LUX-Dx insertable cardiac monitor. However, the patient's particular medical condition may dictate whether or not they can tolerate a subcutaneous, chronically- inserted device. LATITUDE Clarity is contraindicated for use with any device other than a compatible Boston Scientific device. WARNINGS: Concomitant use of the ICM system and implanted electro-mechanical devices [for example implantable neuromodulation/neurostimulation systems, ventricular assist device (VAD), or implantable insulin pump or drug pump] can result in interactions that could compromise the function of the ICM, the co-implanted device, or both. Electromagnetic interference (EMI) or therapy delivery from the co-implanted device can interfere with ICM sensing and/or rate assessment, resulting in failure to monitor or record when needed. Verify sensing configuration, operation modes, surgical considerations and existing placement of all involved devices prior to any co-implant. To help prevent undesirable interactions, test the ICM system when used in combination with the co-implanted device. Do not expose a patient with an ICM system to diathermy. The interaction of diathermy therapy with an insertable cardiac monitor can damage the device and cause patient injury. The influence of medical equipment on implanted devices varies considerably according to the type of unit and energy levels employed. In situations where the risks are known, always interrogate the device and save data before the procedure, and check device function afterwards. Magnet model 6386 has been tested for use with the ICM system. Use of any other magnets has not been tested and could result in failure to initiate communication with the device. The magnet provided with the ICM system may cause interference with devices sensitive to magnetic fields such as hearing aids, pacemakers, and other implanted devices. It can also permanently disable some magnetic strip cards. Keep the magnet at least 15 cm (6 inches) away from items sensitive to magnetic fields, including the ICM device when the magnet is not being used to initiate communication between the device and the patient or clinic app. The mobile devices and magnet are MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices. Unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the inserted device, and significant harm to or death of the patient and/or damage to the inserted device may result. Scanning patients who have other MR Conditional devices is acceptable if all the MR Conditional requirements for each of the implanted devices are met. Do not conduct an MRI scan if any conditions or implants prohibit it. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients. PRECAUTIONS: For specific information on precautions, refer to the following sections of the product labeling: General, Clinical Considerations, Sterilization and Storage, Insertion, Magnet, Device Programming, Environmental and Medical Hazards, Follow-up, Device Removal and Disposal. POTENTIAL ADVERSE EVENTS: Potential adverse events related to insertion of the device may include, but are not limited to, the following: Device migration, erosion, foreign body rejection phenomena, formation of hematomas or seromas, infection, local tissue reaction, tissue damage. For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide. If any adverse events occur, invasive corrective action and/or ICM system modification or removal may be required. 92496928 (Rev. B)
Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.