

Lithotripsy and Implantable Pacemaker and Defibrillator Systems

SUMMARY

Consider the following points when using extracorporeal shock wave lithotripsy (referred to herein as lithotripsy) for a pacemaker or defibrillator patient:

- Lithotripsy has the potential to permanently damage the implanted device.
- Specific programming steps may prevent potential interactions.
- Device function should be verified following the procedure.
- Patients and their renal specialist should consult the attending cardiologist or electrophysiologist to fully understand the potential consequences of lithotripsy use relative to the patient's implanted device and specific heart condition.

ICD: Implantable Cardioverter Defibrillator

CRT-D: Cardiac Resynchronization Therapy Defibrillator

CRT-P: Cardiac Resynchronization Therapy Pacemaker

CRM PRODUCTS REFERENCED*
All ICDs, CRT-Ds, CRT-Ps, and pacing systems

*Products referenced herein may not be approved in all geographies. For comprehensive information on device operation, reference the appropriate product labeling.

CRM CONTACT INFORMATION

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Lithotripsy Overview

Lithotripsy is a non-invasive treatment using ultrasonic shock waves (referred to herein as pressure pulses) to disintegrate kidney or ureteric stones to allow passage through the urinary tract system with less discomfort to the patient¹ (Figure 1). The stones are fragmented by focused pressure pulses, which can be delivered in the following modes:³

- Synchronized—triggered by the patient's R-waves, as detected by an external ECG.
- Non-synchronized—delivered at a specified rate (e.g., 96 pulses per minute).

Electromagnetic Interference

Like most electronic devices, lithotripsy equipment generates electromagnetic waves, which can vary in amplitude and frequency. Electromagnetic interference (EMI) may occur when electromagnetic waves from one electronic device disrupt the functioning of another electronic device. If an electronic device interferes with the operation of an implanted pacemaker or defibrillator, the effects of the interference are typically temporary.

Potential Interactions

Lithotripsy produces mechanical and electromagnetic forces that can potentially affect pacemaker and defibrillator function. Mechanical forces generated by lithotripsy dissipate from the focal point of application of the shock waves and could permanently damage an implanted pacemaker or defibrillator if the device is located at the focal point of the lithotripsy beam. The electromagnetic forces generated by lithotripsy may also cause inappropriate sensing of arrhythmias. If the lithotripsy equipment is programmed to synchronize with ventricular contractions, atrial pacing pulses by the implanted device can trigger the lithotripter prematurely.

Programming Recommendations

- If lithotripsy must be used, avoid focusing the lithotripsy beam near the implant site.
- To prevent atrial pacing pulses from triggering the lithotripter, consider the following:
 - **Defibrillators**—depending on the pacing needs of the patient, program the brady pacing mode to Off or to a non-rate response VVI mode.
 - **Pacemakers**—depending on the pacing needs of the patient, program the brady pacing mode to a non-rate response VVI or VOO mode.
- As is the case with any EMI source, if inappropriate shocks are of concern, consider deactivating the tachyarrhythmia detection portion of the implanted defibrillator.
- Following the lithotripsy procedure, program the device back to the appropriate settings and assess the implanted device to verify proper function.

NOTE: Prior to utilizing lithotripsy therapy, a patient and their renal specialist should consult the attending cardiologist or electrophysiologist to fully understand the potential consequences of lithotripsy use relative to the patient's implanted device and specific heart condition. Boston Scientific cannot assure the safe and effective operation of its implantable CRM device or the lithotripsy equipment when used in combination.



Figure 1. Lithotripsy system.²

¹Common procedures page. Essex Urology Web site. Available at <http://www.essexurology.co.uk/patient-info-litho2.htm>. Accessed September 23, 2008.

²Products page. Alibaba Web site. Available at http://www.alibaba.com/catalog/11483665/Extracorporeal_Shockwave_Lithotripsy_System/showing.html. Accessed September 23, 2008.

³Product brochure page. Medispec Web site. Available at <http://www.medispec.com/pdf/E3000%20Lithotripsy%20System%20Specifications.pdf>. Accessed September 23, 2008.