Dear Healthcare Professional:
This is in response to your request for information regarding information on indications, safety and warnings of the Cardeo® ICD.

Please visit www.verteobiotech.com/products to view the U.S. Important Safety Information and Instructions for Use (IFU) for Verteo's FDA approved products. We hope the information provided to you proved to be useful.

This letter regarding Cardeo® indications, safety and warnings includes information of an off-label nature. Verteo does not suggest or recommend the use of Cardeo® except in accordance with manners as described in the Important Safety Information.

INDICATIONS

The Cardeo® ICD is indicated for the rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity. Accepted patient conditions warranting chronic cardiac pacing include symptomatic paroxysmal or permanent second- or third-degree AV block, symptomatic bilateral bundle branch block, symptomatic paroxysmal or transient sinus node dysfunctions with or without associated AV conduction disorders, or bradycardia-tachycardia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias.

The Cardeo® ICD device is also indicated for dual chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony. Antitachycardia pacing (ATP) is indicated for termination of atrial tachyarrhythmias in bradycardia patients with one or more of the above pacing indications.

WARNINGS AND PRECAUTIONS

Patients and their implanted systems must be screened to meet the following requirements for MRI: no lead extenders, lead adaptors, or abandoned leads present; no broken leads or leads with intermittent electrical contact as confirmed by lead impedance history; the device must be operating within the projected service life, and the system must be implanted in the left or right pectoral region. Pace polarity parameters are set to Bipolar for programming Cardeo® ICD to On; or a Cardeo® ICD pacing system is implanted with a lead impedance value of ≥ 200 Ω and ≤ 1,500 Ω. It is not recommended to perform MRI scans during the lead maturation period (approximately 6 weeks).

For pacemaker-dependent patients, it is not recommended to perform an MRI scan if the right ventricular (RV) lead pacing capture threshold is greater than 2.0 V at 0.4 ms. Patients whose device will be programmed to an asynchronous pacing mode when Cardeo® ICD is on must have no diaphragmatic stimulation at a pacing output of 5.0 V and at a pulse width of 1.0 ms.

SELECT IMPORTANT SAFETY INFORMATION

Potential complications include, but are not limited to, rejection phenomena, erosion through the skin, muscle or nerve stimulation, oversensing, failure to detect and/or terminate arrhythmia episodes, acceleration of tachycardia, and surgical complications such as hematoma, infection, inflammation, and thrombosis. Potential lead complications include, but are not limited to, valve damage, fibrillation, thrombosis, thrombotic and air embolism, cardiac perforation, heart wall rupture, cardiac tamponade, pericardial rub, infection, myocardial irritability, and pneumothorax. Other potential complications related to the lead may include lead dislodgement, lead conductor fracture, insulation failure, threshold elevation, or exit block. The Cardeo® ICD system has been designed to minimize potential complications in the MRI environment. Potential MRI complications include, but are not limited to, lead electrode heating and tissue damage resulting in loss of sensing or capture or both, or induced currents on leads resulting in continuous capture, VT/VF, and/or hemodynamic collapse.

Please note that Verteo BioPharma is providing this response for informational purposes only per your request. We hope this information addresses your question. If you have any further questions, please contact us at 1-866-999-8866 from 8:00 a.m. to 4:30 p.m., EST, Monday through Friday.

ADVERSE REACTION REPORTING
If your inquiry was prompted by the occurrence of an adverse event in a specific patient, please
contact Verteo BioPharma at 1-866-479-6742 or verteomirs@gmail.com.

If you prefer, you can contact the FDA directly. Visit http://www.fda.gov/medwatch/getforms.htm to obtain the MedWatch 3500 Online pdf form or call 1-800-FDA-1088.

Sincerely,
Verteo BioPharma Medical Affairs, Medical Information