

Dear Healthcare Professional:

This is in response to your request for information regarding pediatric patients with a CarDeo® Implantable Cardioverter Defibrillator (ICD).

Please visit www.verteobio.com/products to view the U.S. Important Safety Information for Verteo's FDA approved products. We hope the information provided to you proved to be useful.

This letter is regarding CarDeo® in pediatric patients. Verteo does not suggest or recommend the use of CarDeo® in any manner other than as described in the Important Safety Information.

SELECT IMPORTANT SAFETY INFORMATION

The recommended usage information for CarDeo in the “CarDeo and Pediatric patients” section of the Important Safety Information (ISI) is as follows: ¹

ICDs can be implanted in multiple basic ways in children and adolescents. The systems can be: epicardial (leads attached to the outside of the heart) or transvenous (leads inside the veins leading to the heart). With transvenous or epicardial placement, the leads can be attached to the top chamber of the heart (atrium) or the bottom chamber of the heart (ventricle) or both. Sometimes leads are placed on both ventricles. Recovery from implantation of an ICD varies, depending on the child and whether other heart surgery was performed at the time. Typically, a child leaves the hospital one to three days after implantation of an ICD if this is the only surgery performed at the time. Restriction of arm movement may be necessary for certain types of procedures. The type of ICD used is based on your diagnosis and specific needs of the device.

Guidelines

- Activity restrictions or precautions may be recommended depending on your child's heart disease and type of ICD. Your cardiologist will review these recommendations with you.
- Patients with ICDs will require future procedures related to the ICD generator (battery pack) longevity or battery life. The ICD generator (battery pack) typically last 5-10 years.
- The lead(s) only need to be changed if they stop functioning. In some instances, the lead has to be removed and replaced.
- Routine visits with the cardiologist and/or electrophysiologist provide the best care for the ICD. At these appointments the pacemaker/ICD leads, and battery are tested.
- Today's advanced technology provides a way to check an ICD at home (remote monitoring). A monitor will be set up by your child's doctor or pacemaker clinic if it is part of their plan of care.
- The monitor will collect information from the ICD and send it securely over the phone system and internet to the pacemaker clinic. Your child's doctor will determine how

often and when transmissions are to be sent using the monitor versus when you need to come to the hospital to have the ICD checked in person.

Warnings and precautions: Possible risks of implantable cardiac defibrillators (ICDs) or ICD surgery may include:

- Infection at the implant site.
 - Swelling, bleeding, or bruising.
 - Blood vessel damage from ICD wires.
 - Bleeding around the heart, which can be life-threatening.
 - Blood leaking through the heart valve where the ICD lead is placed.
 - Collapsed lung.
 - Movement of the device or leads, which could lead to a rip or cut in the heart muscle.
- This complication, called cardiac perforation, is rare.

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and medical therapy hazards, hospital and medical environments, home and occupational environments, follow up testing, explant and disposal, supplemental precautionary information.

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 DRUG 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 medicalinformation@verteobio.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

References

¹ CARDEO Package Insert. Verteo BioPharma
² CarDEO ISI