

Dear Healthcare Professional:

This is in response to your request for information regarding information on traveling with the 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 regarding CarDeo® travel 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.

SELECT IMPORTANT SAFETY INFORMATION

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

It's important to know that you can travel safely with an ICD or S-ICD device as long as talk to your doctor and take a few precautions. Learn more about going through airport security, finding a doctor while traveling and other ways to help you have a successful trip with an implanted device.

Airport Security

Going through airport security can be confusing even for people without an implanted device. To help make the process easier, be sure to show your Medical Device ID Card at the first security station. This card identifies you as an implanted device patient. After showing your card, follow the security staff's directions. Depending on the airport, the staff may do one of the following:

- Send you through the security full body scanner. The Advanced Imaging Technology (AIT) full body scanner will not harm your ICD or S-ICD, or change the programmed settings. However, your device contains metal parts that may set off airport security metal detector alarms.
- Use a hand-held security wand. If held over your ICD or S-ICD for too long, airport security wands could temporarily affect your device. If a wand must be used, tell the security officer that you have an implanted device, that the search must be done quickly and not to hold the wand over your device.
- Do a hand-pat search. If you request a hand-pat search, you can ask them to do it in a private area away from public view.

NOTE: The full body scanner will show your device on their image, but it will not sound an alarm while you are inside. You may be asked to show your Medical Device ID Card or they may ask you to stand aside for a hand-pat search.

Medical Device Identification Card

Whether you're running a quick errand or going away for an extended trip, it's important to carry your Medical Device ID Card with you at all times. In an emergency, your card will let medical and security personnel that you have an implanted device.

In addition to your Medical Device ID Card, Verteo Biopharma offers a security card for international travel. The card explains that your implanted device may trigger airport security alarms and is printed in 13 languages. To get a Medical Device Patient Security Card, call us at 1-888-123-3333.

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