Medtronic

Urgent Field Safety Notice

Cardioblate™ Gemini™-s Irrigated RF Surgical Ablation System

Instructions for Use Updates

Product Number	Product Description	Lot Identification
49260	Cardioblate Gemini-s Surgical Ablation Device	All Lots
49351	Cardioblate Gemini-s Surgical Ablation Device	

April 2022,

Medtronic Reference: FA1246

Dear Healthcare Professional,

The purpose of this letter is to inform you that Medtronic is updating the Instructions for Use (IFU) for the Cardioblate™ Gemini™-s Irrigated RF Surgical Ablation System in order to reduce the risk of fractured jaw-tips during use. As a result of an increase in complaints received for the Cardioblate Gemini-s regarding fractured jaw-tips, an investigation was performed by Medtronic. Tip fracture can occur between the silicone guide attachment and the jaws of the Cardioblate Gemini device as illustrated below in Image 1. As part of the investigation, it was determined that this issue is not related to material or manufacturing anomalies, and no product retrieval is necessary. The investigation did conclude that certain use techniques may reduce the risk of possible tip fracture and Medtronic is therefore updating the Cardioblate Gemini-s (IFU) to provide additional guidance for users.

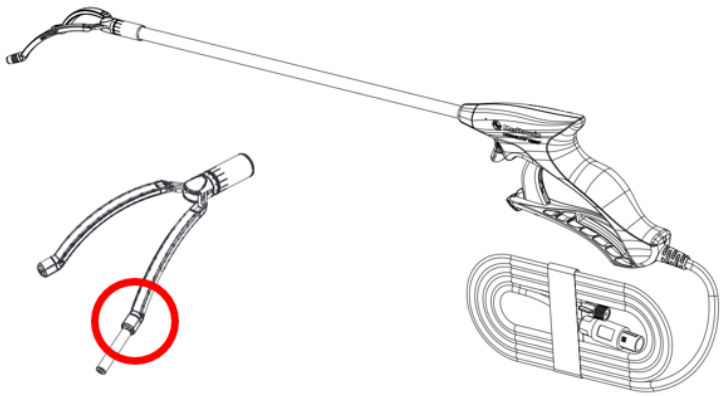
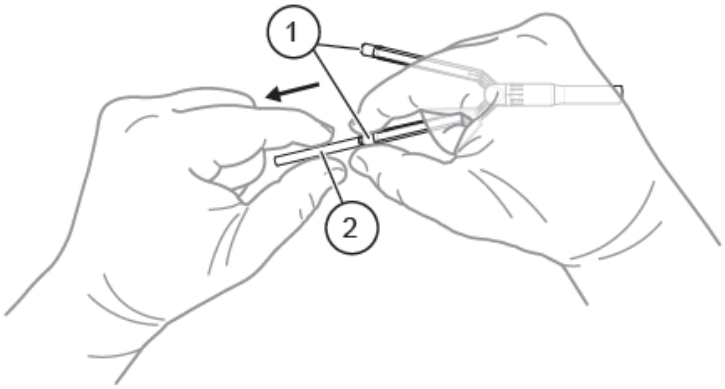


Image 1 – Cardioblate Gemini-s Device

The following are the recommended use techniques to mitigate possible fractured tips:

1) **Removal of device from patient after ablating:**
   a) Press the handle lock release on the handle to unlock the parallel jaws and allow the device to be retracted from the [intended tissue/target tissue]. Once the device is retracted from the tissue, close the parallel jaws and carefully remove the device from the patient.
2) **Disconnection of guides from device after removal from patient:**
   a) Using the thumb and forefinger, pinch the silicone guide attachment to release pressure
   b) With the other hand, hold the guide near the silicone guide attachment. To remove the guide, gently continue pinching the silicone guide attachment and carefully pull the guide away from the silicone guide attachment as depicted in Image 2 – Disconnecting Guide.



1. Silicone guide attachments 2. Guide

Image 2 – Disconnecting Guide

Caution: Do not exert force against the jaws during guide disconnection. Failure to follow these disconnection instructions may damage the jaws.

3) **Use of surgical instruments on jaws and guides:**

Warnings: Do not use surgical instruments to manipulate or position the jaws and guides. Surgical instruments may damage the jaws.

Over a three-year period through April 7th, 2022 there have been twenty-seven (27) complaints of tip fracture. In twenty-six (26) of those instances the tip remained attached to the sheath and the guide frequently resulting in a prolonged procedure. In one (1) of those instances the tip detached falling into the chest cavity and was retrieved resulting in no additional patient harm. Fractured tips of the Cardioblate Gemini-s can potentially lead to cardiac tissue damage, prolonged procedure, generator impedance shut off, and potential of foreign material falling into the chest cavity.

Medtronic is working to release content above into the IFU as soon as possible. The content within this letter is intended to communicate these updates until the new IFU is available.

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Customer Instructions:

Medtronic records indicate that your practice may be impacted by these Instructions for Use changes. As a result, Medtronic requests that you take the following actions:

- Please review the updated guidance on device usage contained in this letter
- Please share this notice with all those who need to be aware within your organization
- Patients who have been previously treated with a Cardioblate Gemini device face no additional risk from the content of this communication and should continue to be monitored by your practice's normal follow-up procedures.
- Please complete the enclosed Customer Acknowledgement Form and email to: rs.dusregulatory@medtronic.com

Medtronic has notified the Competent Authority of your country of this action.

This letter serves as a notification for your records regarding the upcoming updates to the Cardioblate Gemini Instructions for Use.

If you have questions regarding this material, please contact your Medtronic Representative.

Sincerely,

Medtronic (Switzerland) AG

Medtronic

FA1246 Customer Acknowledgement Form - Response is required
Cardioblate™ Gemini™-s Irrigated RF Surgical Ablation System

Please complete this Form in its entirety.

Date: _____

Name of Person Completing this Form: _____

Title: _____

Direct Phone #: _____

Email: _____

Account Name: _____

Account Number: _____

Account Address: _____

City: _____ Zip Code: _____

Country: _____

I have read and understood the instructions provided and acknowledge receipt of the notification regarding the use of the Cardioblate™ Gemini™-s Irrigated RF Surgical Ablation System by signing below (FA1246). I also agree to further distribute and communicate this important information within my facility and to anyone whom I have further distributed Cardioblate™ Gemini™-s Irrigated RF Surgical Ablation System as required.

_____ _____ _____

Name: (print) Signature: Date:

If you have any questions regarding this notification, please contact your Medtronic sales representative.

PLEASE EMAIL THIS ACKNOWLEDGEMENT TO:
rs.dusregulatory@medtronic.com