

Urgent Field Safety Notice

Medtronic Micra™ Delivery System

Packaged as part of Micra™ Transcatheter Pacing System Model: MC1VR01

Instructions for Use Update

August 2019

Medtronic reference: FA878

Dear Physician,

Medtronic records indicate you have been trained to implant the Micra Transcatheter Pacing System (TPS). Medtronic is updating the Micra Instructions for Use (IFU) and the Micra Implant Procedure Tip Card to include specific information on the removal of the tether to release the Micra Pacemaker from the Micra Delivery System during implant.

The functionality of the Micra pacemaker is not affected by this update. No action is needed for patients already implanted with a Micra device, as this update to instructions applies only to new implant procedures.

As of 18-Jul-2019, there have been 52 complaints worldwide involving a tangled tether during tether removal that resulted in prolonged or additional procedures. No deaths have been reported related to this issue.

Medtronic has identified that flushing the delivery system after the tether has been cut may cause the free end of the tether to enter the ventricular chamber and tangle. If this happens, the tangle could potentially prevent tether removal from the delivery system and potentially prevent release of the Micra pacemaker. Therefore, Medtronic is updating the IFU and Implant Procedure Tip Card to include the recommendation below:

- **Once the tether is cut, do not flush the delivery system until the tether has been fully removed.**

Note, some amount of resistance during tether removal is normal. Tension or resistance during tether removal is not typically indicative of a tangle. If you feel resistance when pulling out the tether, advance the recapture cone closer and/or more coaxially to the device.

See Appendix A for an image of the updated section of the Implant Procedure Tip Card.

Customer Action

Please implement this new instruction in all future Micra implants.

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

We are committed to patient safety and appreciate your prompt attention to this matter. Please share this notification with others in your organization as appropriate. If you have any questions, please contact your Medtronic Representative at <XXXX>.

Sincerely,

Local/BU manager

Enclosure: Appendix A, Section of Micra Implant Procedure Tip Card WITH UPDATE

Appendix A

Section of Micra Implant Procedure Tip Card WITH UPDATE

Completing the Implant

- With recapture cone extended, apply tension on the tether near the pin and advance delivery system back to the device
- **DO NOT deflect the delivery system with the recapture cone extended**
- Flush the delivery tool and floss the tether. Cut one side of the tether and SLOWLY pull one end of tether out of delivery system while viewing device under fluoro.

NOTE: Cut the side that has higher resistance.

- **Once the tether is cut, DO NOT flush the delivery system until the tether has been fully removed.**

- If tension is felt or observed on the device, stop pulling and determine cause of tension
 - a) Position the delivery system close to the device
 - b) If high tension is still felt, use recapture cone to stabilize device during tether removal
- Remove the delivery system
- If using the figure-of-8 stitch, place stitch prior to removing the introducer
- Remove the introducer and obtain hemostasis