



**Medtronic International, Ltd. (Singapore Branch)**

(Co. Reg. No. S98FC5604C)  
50 Pasir Panjang Road  
#04-51  
Mapletree Business City  
Singapore 117384  
www.medtronic.com

tel 65.6870.5300  
fax 65.6482.0300

## **URGENT MEDICAL DEVICE UPDATE**

Instructions for Use Update

**Medtronic Micra™ Delivery System**

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

7 August 2019

**Attention: Risk management Director and O.R Materials Management**

**CC: The Chairman Medical Board and relevant Head of Departments**

Dear Healthcare Professional,

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.

Upon regulatory approval, the updated IFU will be available online at<<http://manuals.medtronic.com/manuals/main>>.

See Appendix A for an image of the updated section of the Implant Procedure Tip Card in English. The updated Tip Card includes a revision date of August 2019 or later, and can be accessed at <http://www.medtronic.com/micratpstipcard>, or by contacting your local Medtronic Representative.

**Your Actions:**

- 1) Please implement this new instruction in all future Micra Implants.
- 2) Medtronic requests that you to complete the provided Confirmation Form and return it to your local Field Representative which indicates you received this instruction update.

Please maintain a copy of this notice in your records. We are committed to patient safety and welcome any questions you may have regarding this communication. Please contact your Medtronic representative with questions.

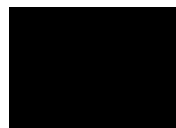
This notification is being issued or will be notified to relevant regulatory bodies according to applicable regulations.

We appreciate your attention to this matter and apologize for any inconvenience this issue may have caused. We are committed to patient safety and appreciate your prompt attention to this matter.

Sincerely,



Diana Teo  
QRA Lead  
SEA Region (Cluster 1)



Chloe Tan  
QRA Lead  
SEA Region (Cluster 2)

*Enclosures:*

- 1) *Customer Confirmation Form*



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**Physician Confirmation Form  
Instructions for Use Update  
Medtronic Micra™ Delivery System  
Packaged with the Micra™ Transcatheter Pacing System (TPS)  
Model MC1VR01**

**ALL CUSTOMERS PLEASE COMPLETE THE FORM IN ITS ENTIRETY**

Customer Contact Details	Medtronic Contact Details
<b>Physician:</b>	<b>Name:</b>
	<b>Contact:</b>
<b>Address:</b>	<b>Email:</b>
<b>Phone no:</b>	
<b>E-mail:</b>	

Medtronic records indicate that you are trained to implant the Micra TPS. As a result, Medtronic requests that you respond to this notification by completing this Confirmation Form and either returning it to your Field Rep indicating that you have received the updated information regarding specific tether flushing instructions for the Micra TPS Delivery System. This is not a product retrieval. It is an update to implant instruction.

*In the event you no longer implant patients with Micra TPS, please provide an explanation in the space below so that Medtronic's records can be updated accordingly. Thank you!*

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**Note: The addressee may continue to receive reminders of this notice until a response is received**

**By signing this form, I confirm that I have read the Instructions for Use Update Notification Letter, dated 7 August 2019 from Medtronic regarding the Micra Delivery System Update related to flushing instructions.**

Name: \_\_\_\_\_ (print) Signature: \_\_\_\_\_ Stamp: \_\_\_\_\_ Date: \_\_\_\_\_

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

004-F265 v2.0



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**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