

August 2019

Medtronic reference: FA878

Dear Risk Manager,

Medtronic is informing physicians who have been trained to implant Micra™ Transcatheter Pacing System (TPS) of an update to 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. This delivery system is a non-implantable, disposable component of the Micra TPS. Our records show that one or more Micra TPS devices have been distributed to your facility.

This is not a product retrieval. The functionality of the Micra device is not affected by this update to implant instructions. Please see enclosed copy of the letter sent to trained Micra implanters.

This letter is a courtesy notification, there are no actions required of you.

Sincerely,

Local/BU manager

**Enclosure**

- Urgent Field Safety Notice Letter