Medtronic
Neurovascular
9775 Toledo Way
Irvine, CA 92618
www.medtronic.com

MEDICAL DEVICE CUSTOMER LETTER

Confirmation of MRI Safety Information for

Pipeline™ Flex with Shield Technology™

Dear Healthcare Professional:

The purpose of this letter is to provide a clarification to the Magnetic Resonance Imaging (MRI) safety information in the Instructions for Use (IFU) and the MRI Patient Card provided with the Pipeline™ Flex with Shield Technology™ ("Pipeline™ devices"). The clarification relates to the technical terminology describing the MRI equipment as "Quadrature driven RF birdcage only" that is referenced in the IFU and MRI Patient Card. There is no impact to patient safety nor Pipeline™ device product performance.

MRI Safety Information:

Clarification of the MRI Safety Information is as follows: Pipeline™ devices are MR conditional for 1.5T and 3T MR systems, using the **integrated whole-body transmit Radio Frequency (RF) coil** operating in normal operating mode with an RF polarization of **circularly polarized (CP) (i.e., quadrature drive) with any receive-only RF coil**.

Actions Requested:

- Please share or forward this communication with the Healthcare Providers in your organization, including those who support or schedule MRI tests for patients implanted with Pipeline devices.
- Please maintain a copy of this letter for your records.

Additional Information:

If you have any questions regarding this communication, please contact your Medtronic representative or email the Office of Medical Affairs at rs.nvoma@medtronic.com.

Sincerely,

Bruce Van Deman
Sr. Director, Global Clinical Research/Medical Sciences
Medtronic Neurovascular