



www.medtronic.com/patientimplantinfo



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Pipeline™ Flex Embolization Device with Shield Technology™

Pipeline™ Flex Embolization Device with Shield Technology™

Please carry at all times

MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION

Non-clinical testing has demonstrated that the Pipeline™ Flex Embolization Device with Shield Technology™ is MR Conditional for single and overlapping stents up to 70 mm in length.

A patient with the Medtronic Pipeline™ Flex Embolization Device with Shield Technology™ can be scanned safely in an MR system immediately after placement under the following conditions. Failure to follow these conditions may result in injury.

Parameter	Condition of Use / Information
Static Magnetic Field Strength (B ₀) [T]	1.5T, 3T
Type of Nuclei	Hydrogen Proton
Static Magnetic Field (B ₀) Orientation	Horizontal, Cylindrical bore
Maximum Spatial Field Gradient (SFG) [T/m] and [gauss/cm]	30 T/m (3000 gauss/cm)
RF Polarization	Circularly Polarized (CP) (i.e., quadrature drive)
RF Transmit Coil	Integrated Whole Body Transmit RF Coil Detachable Extremity Transmit / Receive RF coil
RF Receive Coil	Any receive-only RF coil may be used
MR System (RF) Operating Modes or Constraints	Normal Operating Mode
Whole Body Averaged SAR [W/kg]	≤ 2 W/kg
Head SAR [W/kg]	≤ 3.2 W/kg

Parameter	Condition of Use / Information
Scan Duration	60 minutes of continuous radiofrequency (RF) (a sequence or back to back series/scan without breaks) followed by a wait time of 5 minutes if this limit is reached.
Anatomy at Isocenter	Any anatomic location at isocenter is acceptable
Patient position in scanner	Any patient position is acceptable
MR Image Artifact	In non-clinical testing, the image artifact caused by the Pipeline™ Flex Embolization Device with Shield Technology™ extends approximately 11.0 mm from this implant when imaged using a T1-weighted spin echo pulse sequence and a 3-Tesla MR system. Local field artifact from the Pipeline™ Flex Embolization Device with Shield Technology™ may decrease the accuracy of the MR angiogram in assessing vessel luminal patency. MR image quality may be compromised if the area is in the exact same area or relatively close to the position of the Pipeline™ Flex Embolization Device with Shield Technology™. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

CAUTION: The MRI safety when using a detachable head transmit/receive RF coil to image a patient with the Pipeline™ Flex Embolization Device with Shield Technology™ has not been evaluated. Use of the integrated whole body transmit coil with a receive-only head coil is acceptable.

Patient Name: _____

Patient Phone Number: _____

Date of Implant: _____ / _____ / _____
MONTH DAY YEAR

Implant Location: _____

Pipeline™ Flex Embolization Device with Shield Technology™

Lot Numbers:

Medication:

1. _____

2. _____

3. _____

CONSULT YOUR PHYSICIAN BEFORE YOU CHANGE OR DISCONTINUE ASPIRIN AND/OR CLOPIDOGREL

Implanting Physician Name: _____

Physician Phone Number: _____

If you experience any of the following adverse events, call your physician immediately: severe headache, bleeding, loss of vision, sudden weakness of the arm or leg, sudden inability to speak, loss of consciousness.