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 this device can be scanned safely in an MR system immediately after placement under the following conditions:

- Static magnetic field 1.5 Tesla and 3 Tesla, only.
- Maximum spatial gradient field of 30 T/m (3000 Gauss/cm) or less.
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning in the Normal Operating Mode for the MR system.
- Maximum head SAR of 3.2W/kg.
- Quadrature driven RF birdcage coil only.

Under the scan conditions defined, the Pipeline™ Flex Embolization Device with Shield Technology™ is expected to produce a maximum temperature rise of 3.1 °C after 15-minutes of continuous scanning.

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 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.

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.
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: