

<b>MRI Conditional:</b>	
Non-clinical testing has demonstrated the <b>Memokath 051</b> is MR Conditional. It can be scanned safely under the following conditions:	
Static magnetic field of 1.5 tesla	Static magnetic field of 3.0 tesla
Static magnetic field gradient < 25 T/m	Static magnetic field gradient < 15 T/m
Gradient system amplitude < 33 mT/m	Gradient system amplitude < 50 mT/m
Maximum whole body averaged specific absorption rate (SAR) of 2.03 W/kg for 15 minutes of scanning.	Maximum whole body averaged specific absorption rate (SAR) of 2.03 W/kg for 15 minutes of scanning.
In non-clinical testing, the Memokath 051, product length 250 mm diameter 3.5-6 mm produced a temperature rise of less than 0.1 °C at a maximum whole body averaged specific absorption rate (SAR) of 2.3 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a (field strength 1.5 tesla) (model Intera) (manufacturer Philips Medical Systems) (software version Release 12.6.1.3, 2010-12-02) MR scanner. Background temperature rise at X = 180 mm of 1.6 °C and temperature rise at stent of 1.7 °C placed at X = 180 mm. The calculations did not include the cooling effects due to blood flow.	In non-clinical testing, the Memokath stent, product length 130 mm diameter 3.5-6 mm produced a temperature rise of less than 0.1 °C at a maximum whole body averaged specific absorption rate (SAR) of 2.03 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a (field strength 3.0 tesla) (model Signa HDxt) (manufacturer General Electric Software 16x MR scanner.) Background temperature at X = 190 mm of rise 1.06 °C and temperature rise at stent of 1.12 °C placed at X = 190 mm. The calculations did not include the cooling effects due to blood flow.
MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this implant	