Synovis Micro Companies Alliance, Inc.

a subsidiary of Baxter International Inc.

MRI Usage with Synovis MCA GEM COUPLER Device

Background

The COUPLER Rings (HDPE with 316L Stainless steel pins) do not contain ferromagnetic properties. Knowing that the ring is a permanent implant and MRI is often needed during patient post-op care, the COUPLER Rings were tested in three orthogonal planes within a 1.5 Tesla Magnetic Field for evidence of displacement. The materials used for testing consisted of paired rings from a 1.5mm, and 2.0mm and a 2.5mm COUPLER device. The results were documented in The Journal of Reconstructive Microsurgery / Volume 13, Number 8 November 1997 by Mark D. DeLacure and Henry Z. Wang.

Results: The paired rings were examined for movement or change in alignment in any of the three orthogonal planes. There was no change in movement or alignment for any of the three sizes.

Conclusion: DeLacure and Wang concluded that there is no appreciable movement of the COUPLER rings at 1.5Tesla.

Updated Testing with 3.0 Tesla MRI

Over the last decade, the 3.0 Tesla MRI machine has become more standard in hospitals. The COUPLER rings have been evaluated again for Displacement, Induced Torque, Heating, and Image Distortion. For displacement force and induced torque testing, the product with the largest mass fraction of stainless steel to HDPE represents the worst-case configuration.

1.0 Displacement Force

The detailed analysis and results for Displacement Force testing was performed per ASTM F2052-15. All the measurements for the device exposed to a local magnetic field strength of 2.423 T and a local spatial gradient of 3.920 T/m (392.0 G/cm), resulted in a magnetically induced deflection forces less than the force of the device due to gravity, meeting defined acceptance criteria.

The conservative worst-case extrapolation (extrapolated value minus one standard deviation) of the deflection measurements across all devices tested yielded allowable maximum spatial gradients of 23.2 T/m (2,320 G/cm) for 1.5 T systems and 11.6 T/m (1,160 G/cm) for 3.0 T systems.

Result – Pass; The 1.0mm Coupler ring has the largest mass fraction of stainless steel to HDPE plastic and passed. The results of the 1.0mm ring are applicable to all sizes 1.0 through 4.0mm in size.

2.0 Induced Torque

The detailed analysis and results for Induced Torque testing was performed per ASTM F2213-17. There was no detectable torque observed for any orientation of the device tested in an external magnetic field of 3.0 T. These results are consistent with the low amount of translational force for the same devices on the same MR system. It is concluded that the magnetically-induced torque on the device was less than the product of the weight and the longest effective dimension of the device, meeting defined acceptance criteria.

Result – Pass; The 1.0mm Coupler ring has the largest mass fraction of stainless steel to HDPE plastic and passed. The results of the 1.0mm ring are applicable to all sizes 1.0 through 4.0mm in size.

3.0 RF Heating

The device with the largest mass represents the worst-case configuration and is representative of all product sizes (Nyenhuis, J.A., et al). For this study, the 4.0 mm Coupler rings were used for testing. The detailed analysis and results for RF Heating was performed per ASTM F2182-11. The summary of the peak temperature measurement results for 1.5 T (64 MHz) and 3.0 T (128 MHz) MR environments are defined in the following table.

Measurements	Results
Peak temperature change at 64 MHz (1.5 T)	1.1 +/- 0.1°C @ 360 s 2.5 +/- 0.2°C @ 900 s
Location of peak heating at 64 MHz (1.5 T)	Edge of device (see figure E9 in Attachment 1)
Peak temperature change at 128 MHz (3.0 T)	1.5 +/- 0.1°C @ 360 s 3.4 +/- 0.3°C @ 900 s
Location of peak heating at 128 MHz (3.0 T)	Top of device (see figure F9 in Attachment 1)

The highest temperature increase of 3.4°C+/- 0.3°C identified during RF Heating testing meets the acceptance criteria of an increase less than 4.5°C.

Result – Pass; the 4.0mm had acceptable results and met the acceptance criteria. Therefore, the results or the 4.0mm ring are applicable to all Coupler sizes 1.0mm through 4.0mm in size.

4.0 Image Distortion

The detailed analysis and results for Image Distortion testing was performed per ASTM F2119-07. The largest image artifact extended not more than 9 +/- 1 mm from the construct when scanned in nonclinical testing using the Gradient Echo (GE) sequence in a 3 T MRI system. There are no acceptance criteria for Image Distortion testing.

Result – N/A

Conclusion

Summary: Non-clinical testing has demonstrated the Coupler Rings, including all sizes 1.0mm through 4.0mm in size, are MR Conditional.

A patient with the Coupler device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 3.0 T or less;
- Maximum spatial field gradient of 1,160 G/cm (11.6 T/m);
- Maximum MR system-reported, whole-body averaged specific absorption rate (SAR) of 4 W/kg (First Level Control Mode).

Under the scan conditions defined above, the Coupler Rings are expected to produce a maximum temperature rise of less than 3.4 ºC after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 9 mm from the Coupler Rings when imaged with a gradient echo pulse sequence and a 3 T MRI system.

Signed: _____ Date: _____

(Shannon Witkowski / Sr. Principal R&D Engineer for SMCA)