TOPSPINS® INC.

Remit to: Topspins Inc., P.O. Box 7205, Ann Arbor MI, 48107

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Topspins, Inc. certifies that the enclosed SmartTourniquet meets the ASTM Standard F2052-06e1 in terms of testing of the magnetically induced displacement force produced by static magnetic field gradients on medical devices, up to and including 3 Tesla.

SmartTourniquet components:

- Leg wrap: Velcro polyurethane, no metal or conducting components;
- Tubing: Elastomer, no metal or conducting components;
- Connectors: plastic, no metal or conducting components;
- Manometer: plastic externally with small internal bass components. There is no force or torque on exposure to 1.5 or 3T (see report).

Signed Hongler Zhang Date: 12-16-2009

Topspins, Inc. certifies that the enclosed SmartTourniquet meets the ASTM Standard F2503-05 in terms of marking, labeling, and other safety considerations.

Signed Fred Prince Date: 12-15-2009

REPORT

Evaluation of Magnetic Field Interactions at 3-Tesla for SmartTourniquet

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Executive Summary

Based on the MRI testing information, the following product will not present an additional hazard or risk to a patient relative to the use of an MR system operating with a static magnetic field of 3-Tesla or less:

SmartTourniquet model # 002.0m

Therefore, this product is marked 'MR-conditional' according to the labeling guidelines enumerated in ASTM standard F2503-08.

Objectives:

To determine the presence of magnetic field interactions (deflection angle and torque) in association with the use of an MR system.

Name of testing device:

SmartTourniquet model 002.0m (Figure 1)

Materials for each component:

Leg wrap (Figure 2): Velcro polyurethane, no metal or conducting components (no magnetic field attraction, not formally tested);

Tubing (Figure 3): Elastomer, no metal or conducting components (no magnetic field attraction, not formally tested);

Connectors: plastic, no metal or conducting components (no magnetic field attraction, not formally tested);

Manometer (Heine G5, Figure 4): plastic externally with small internal bass components. Thus evaluation of magnetic field interaction was conducted at 3 Tesla on this component. In normal use this component will be outside the MRI scanner bore and not subject to RF or oscillating gradient fields.

Intended use:

To apply a specific amount of pressure to the patient's legs during a peripheral MRA evaluation.

The samples of the products that underwent testing were representative of the manufactured finished versions and not altered prior to or after testing.

Magnetic field interactions:

Testing for magnetic field interactions involved evaluations of translational attraction and torque at 3-Tesla MR system, for the manometer (Heine, G5).

American Society for Testing and Materials (ASTM) International Designation: F2052-06 standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment was carefully followed for this test.

The MR system used in the test was a GE 3T Signa Excite, 14.0 operating system software.

Test site: New York Hospital, New York, NY

The device listed was attached to a special test fixture to measure the deflection angle in the MR system. The device(s) was suspended from a lightweight string weighing less than 1% of the device weight. The opposite end of the string was attached to the test fixture (Figure 5).

Deflection angle measurements were taken at the point in the scanner that produced the greatest magnetically induced deflection. This point for the MR system used in the test was determined using gauss line plots, measurements, and visual inspection. This location was marked by tape for easy identification.

Coordinates recorded during the test were determined using a Cartesian coordinate (*x, y, z*) location of the center of mass of the device during the test using a right handed coordinate system with origin at the isocenter of the magnet.

Results

1. Manometer, Heine, G5: dimensions, drawing with dimensional scale are on file at Topspins, Inc.

2. Device product identification: Sphygmomanometer G 5 no cuff, part # M-00.09.235.1, Batch # 0073620.

3. Materials of construction: brass, Polyamide/TP-Elastomer

4. Photographs showing the configuration of the device during the test has been attached to this report by the test person (Figures 1-4).

5. Number of specimens tested: ***2***
Explanation for the sample size used: little to no variation from specimen to specimen justifies small sample size.

6. Weight of the tested device: ***142.23 g***

7. Weight of the string used to suspend the device from the test fixture: ***0.2g***

8. Cartesian coordinate (*x, y, z*) location of the center of mass of the device during the test using a right handed coordinate system with origin at the isocenter of the magnet: ***0, 0, 0***

9. Values of $|\boldsymbol{B}|$, the magnitude of the magnetic field and $|\pi\boldsymbol{B}|$, the magnitude of the spatial gradient of the magnetic field, at the test location ***3-Tesla***

10. Measured deflection angle, a, at the test location for each repetition of the test ***0***

11. Mean deflection angle calculated using the absolute value of the measured values for deflection angle, a ***0***

12. Mean magnetically induced displacement force, *Fm*, calculated from measured test data for each device tested ***0***

Conclusion

The SmartTourniquet, model # 002.0m may be employed for its intended use, in MR scanners of 1.5T and 3T without any risk to the patient that is associated with magnetic deflection of the device. The SmartTourniquet may be labeled using the ASTM symbol for MR Conditional use with the following text: "The enclosed SmartTourniquet poses no known hazards in 3T and 1.5T environments" (see box and device stickers, Figure 6).

Figure 1: SmartTourniquet model 002.0m

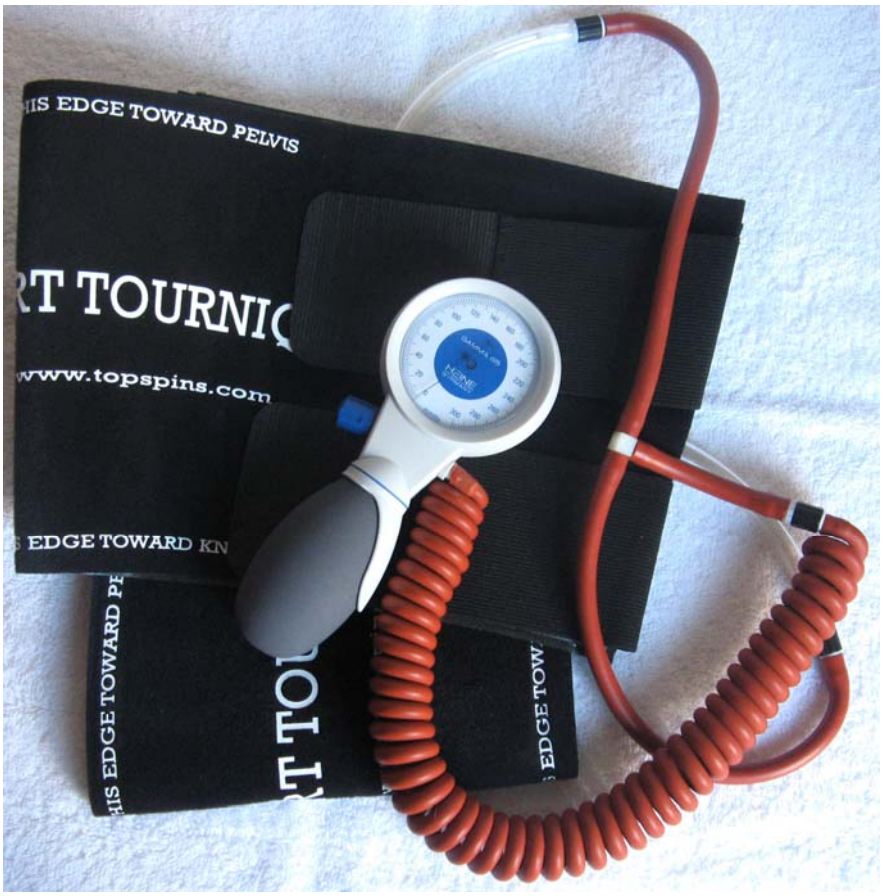


Figure 2: Leg wrap

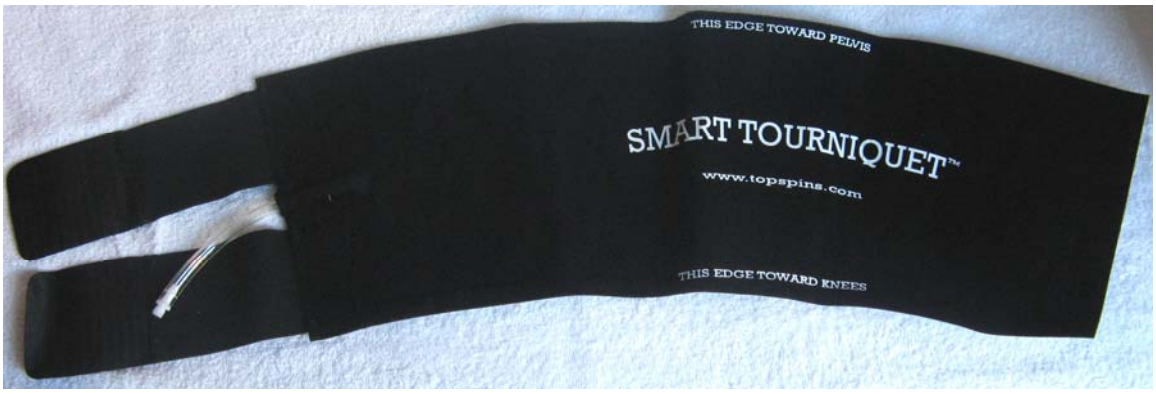


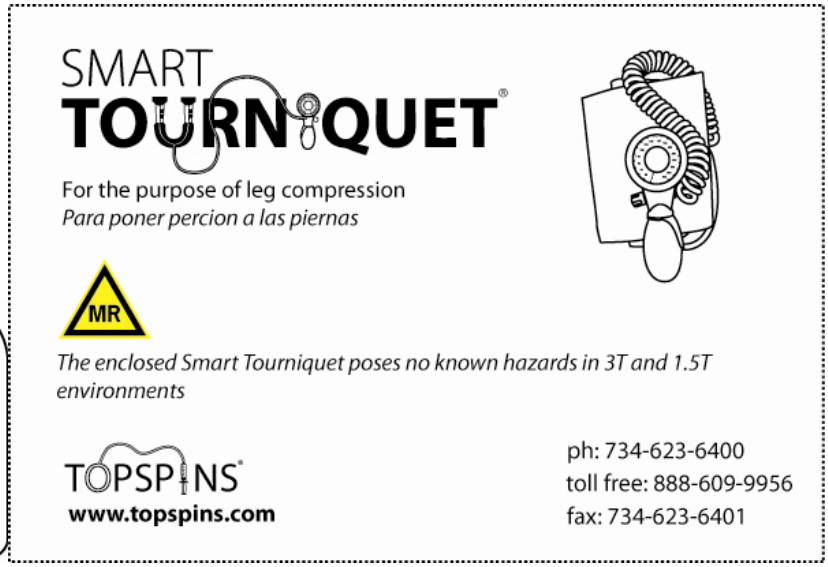
Figure 3: Tubing

Figure 4: Manometer (Heine, G5)

Figure 5: Scanner used in testing the magnetic field interactions (translational attraction and torque) of SmartTourniquet manometer.

Figure 6: MR Conditional Stickers

Device Sticker



Box Sticker