## **MRI Safety Statement**



Life Without Limitations

## **MRI CONDITIONAL**

- · ReSolve® Halo System- ReSolve® Halo Vest and ReSolve® Glass-composite Halo Ring with ceramic-tipped skull pins
- ReSolve® Halo System- Ossur Halo Vest and ReSolve® Glass-composite Halo Ring with ceramic-tipped skull pins
- 'LiL Angel® Pediatric Halo System- ReSolve® Halo Vest and ReSolve® Glass-composite Halo Ring with ceramic-tipped skull pins
- 'LiL Angel® Pediatric Halo System- Ossur Halo Vest and ReSolve® Glass-composite Halo Ring with ceramic-tipped skull pins

## OSSUR Reykjavik, Iceland

Non-clinical testing has demonstrated that each product indicated above when used as a cervical fixation or cervical traction device or system is MR Conditional. A patient with this system may undergo MRI safely under the following conditions:

- -Static magnetic field of 3-Tesla or less
- -Maximum spatial gradient magnetic field of 720 Gauss/cm or less
- -Maximum MR system reported, specific absorption rate (SAR) of 3.0 W/kg for 15 minutes of scanning

In non-clinical testing, this system produced maximum temperature changes of 0.6 degrees C or less at a maximum MR system reported, specific absorption rate (SAR) of 3.0 W/kg for 15 minutes of MRI using a 3-Tesla MR system (Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI). MR Image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Skull Pins. Therefore, it may be necessary to optimize MR Imaging parameters for the presence of these metallic objects.

## **MRI UNSAFE**

J-Tongs, V2, and Closed Back Halo are MRI Unsafe due to a substantial increase in temperature (8.5° C or higher) of the titanium pin tips observed during nonclinical testing. This may pose serious problems or injuries to patients undergoing MRI procedures under the conditions described above (3-Tesla, etc). Notably, the presence of sparks and vibration that occured during testing was particularly problematic.

**Important Note:** All of the materials used for the above products included metals with very low magnetic susceptibility (e.g., commercially pure titanium, Titanium alloy, Aluminum, etc.) or are nonmetallic and nonconductors. Accordingly, little or no substantial magnetic field interactions are present for these products in association with the 3-Tesla MR system.

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