

February 19, 2021

Dear Customer,

In response to the inquiry regarding compatibility and MRI safety after having COR-KNOT® titanium fasteners implanted, we want to assure you that our COR-KNOT® technology uses COR-KNOT® fasteners (knots) that are made from Commercially Pure (CP) grade titanium which is non-magnetic and should not be impacted by the magnetic field in the MRI environment. Our experimental studies concluded that this material is safe according to ASTM Standards and is not expected to exhibit clinically significant RF-induced temperature rise. Although any interference in the diagnosis from MR Imaging is highly unlikely due to the relatively small size of the knots, they may cause some insignificant distortion in the image near their proximity.

Please also refer to the COR-KNOT® technology Instructions for Use (product inserts) on page 5 under MRI Testing where it states, “Based on MRI testing information, titanium COR-KNOT® FASTENERS will not present an additional hazard or risk to a patient undergoing an MRI procedure using a scanner operating with a static magnetic field of 3-Tesla or less and under the MRI-related heating conditions (MRI for 15 min. at an MR system reported whole body averaged specific absorption rate, SAR, value of 3-W/kg).” Thus, at these specified conditions, a patient can safely be scanned immediately after placement of titanium fasteners.

Thank You,



Robert E. Bartz

LSI SOLUTIONS®

Vice President and Chief Growth Officer