ETHICON

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

Product Code: EL5ML

LIGAMAX™ 5 mm Endoscopic Multiple Clip Applier

MR Conditional

Non-clinical testing has demonstrated the implantable clips made of titanium in the LIGAMAX™ Endoscopic Multiple Clip Applier are MR Conditional. A patient with the implanted clips can be scanned safely immediately after placement of the clips, under the following conditions:

- static magnetic field of 3.0 Tesla or less
- highest spatial magnetic gradient field of 6.5 Tesla/m
- maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1.7 W/kg for 20 minutes of scanning (per pulse sequence).

MRI Related Heating

In non-clinical testing, a clip produced a temperature rise of less than 0.6°C using the following conditions:

- At 3-Tesla (Magnetom Trio Siemens Medical Solutions MR scanner, software version Numaris/4 syngo MRA30), a maximum MR system-reported whole body averaged SAR of 1.7 W/kg
- 20 minutes of continuous MR scanning (per pulse sequence) using transmit/receive RF body coil.

Artifact Information

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the clips. Therefore, optimization of MR imaging parameters to compensate for the presence of the clips may be necessary.

The worst case signal void size for a clip was:

Pulse Sequence	SE	SE	GRE	GRE
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular
Signal Void Size (mm^2)	199	336	378	348

Magnetic Resonance imaging (MRI) produces a powerful magnetic field. In some cases, patients may have surgical implants within their bodies. Any ferromagnetic material in proximity to the MRI can be dangerous and an MRI should not be performed in patients with these types of implants. Increased risk due to the location of the implant needs to also be considered (i.e. central nervous system, cardiac). Be certain of the implant material makeup. If this is an EES manufactured product, and you know the product code or name, we can provide you with material specifications. If you are not certain of the implant material, consider utilizing a different imaging test. Always consider risk versus benefit potential.