

ETHICON

PART OF THE *Johnson & Johnson* FAMILY OF COMPANIES

Product Codes: GST60W, GST60B, GST60D, GST60G, GST60T

Endopath Echelon™ Endoscopic Linear Cutter Reload with Gripping Surface Technology (ECHELON FLEX™ GST System)



MR Conditional

Non-clinical testing has demonstrated the implantable staple made of titanium (Ti3Al2.5V) alloy in the ENDOPATH ECHELON 60 mm Endoscopic Linear Cutter Reload with Gripping Surface Technology reloads is MR Conditional. A patient with the implanted staples can be scanned safely under the following conditions:

- Static magnetic field of 3 Tesla or less.
- Highest spatial magnetic gradient field of 7.5 Tesla/m.
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.99 W/kg for 15 minutes of scanning (per pulse sequence).

MRI Related Heating

In non-clinical testing, staple lines produced a temperature rise of less than 2 °C using the following conditions:

- At 3-Tesla (Signa Hdxt General Electric Medical Systems MR scanner, software version 15.0_M4_910.a), a maximum MR system-reported whole body averaged SAR of 2.0 W/kg.
- 15 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 ENDOPATH ECHELON 60 mm Endoscopic Linear Cutter Reload with Gripping Surface Technology staple line. Therefore, optimization of MR imaging parameters to compensate for the presence of these staples may be necessary.

The worst case signal void size for the longest staple line (60 mm) was:

Pulse Sequence	SE	SE	GRE	GRE
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular
Signal Void Size (mm ²)	548	69	713	114

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 using a different imaging test. Always consider risk versus benefit potential.