

ETHICON

PART OF THE *Johnson & Johnson* FAMILY OF COMPANIES

Product Codes: TVC55, TLC55, TCT55, TLC75, TCT75, TVR55, TCR55, TRT55, TCR75, TRT75, TCD75, TRD75

PROXIMATE® Linear and Vascular Linear Cutters and Reloads



MR Conditional

Non-clinical testing has demonstrated the implantable staple made of titanium (Ti3Al2.5V) alloy in the Proximate Linear Cutters is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 3 Tesla.
- Spatial gradient field of 720 Gauss/cm.
- Maximum whole body averaged specific absorption rate (SAR) of 2.7 W/kg for 15 minutes of scanning.

MRI Related Heating

In non-clinical testing, the implantable staple made of titanium (Ti3Al2.5V) alloy in the Proximate Linear Cutters produced a temperature rise of less than 2°C at a maximum whole body averaged specific absorption rate (SAR) of 2.7 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a (3-Tesla/128-MHz, Excite, Software HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR scanner.

Artifact Information

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 Proximate Linear Cutters implantable staple. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (i.e. as seen on the gradient echo pulse sequence) per staple extends approximately 3-mm relative to the size and shape of the implantable staple.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size (mm²)	17-mm ²	5-mm ²	42-mm ²	24-mm ²
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

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.