

ETHICON

PART OF THE *Johnson & Johnson* FAMILY OF COMPANIES

Product Codes: TX30V, XR30V, TX30B, XR30B, TX30G, XR30G, TX60B, XR60B, TX60G, XR60G

PROXIMATE® Reloadable Vascular Linear Stapler and Reloads, PROXIMATE® Reloadable Linear Stapler and Reloads



MR Conditional

Non-clinical testing has demonstrated the implantable staples made of titanium (Ti6Al4V) alloy in these devices are MR Conditional. A patient with the implanted staples can be scanned safely immediately after placement of these staples, 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 1.1 W/kg for 20 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 (Magnetom Trio Siemens Medical Solutions MR scanner, software version Numaris/4 syngo MRA30), a maximum MR system-reported whole body averaged SAR of 1.1 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 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) | 356 | 29 | 539 | 64 |

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.