

**Product Code: PPH03**

PROXIMATE® PPH Hemorrhoidal Circular Stapler



**MR Conditional**

Non-clinical testing has demonstrated the implantable staple made of titanium (Ti3Al2.5V) alloy in this device is 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 1.2 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 1.2 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 luminal staple line was:

<b>Pulse Sequence</b>	SE	SE	GRE	GRE
<b>Plane Orientation</b>	Parallel	Perpendicular	Parallel	Perpendicular
<b>Signal Void Size (mm<sup>2</sup>)</b>	1170	216	1340	343

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.