

Arrow® Staple Anchoring Device

MRI Advisory

MRI Information:

Non-clinical testing demonstrated that Staples are MR Conditional. Patients can be scanned safely immediately after placement under the following conditions:

- static magnetic field of 3.0 Tesla or less
- spatial gradient magnetic field of 720 Gauss/cm or less

MRI-Related Heating:

In non-clinical testing, Staples produced the following temperature rise during MRI performed for 15 minutes of scanning (i.e., per pulse sequence) in a 3.0 Tesla MR system (3.0 Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI):

- highest temperature change +1.6°C

Therefore, MRI-related heating experiments for the Staple at 3.0 Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 2.9 W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.7 W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.6°C.

MR Artifacts:

MR image quality may be compromised if the area of interest is in exact same area or relatively close to position of the 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 gradient echo pulse sequence) extends approximately 15 mm relative to size and shape of the Staple.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	365 mm ²	227 mm ²	782 mm ²	680 mm ²
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

Teleflex, the Teleflex logo, and Arrow are trademarks or registered trademarks of Teleflex Incorporated or its affiliates, in the U.S. and/or other countries. © 2020 Teleflex Incorporated. All rights reserved.

Refer to enclosed product Instructions for Use (IFU) for specific indications, procedural technique(s) and potential complications.

S-15703-108B (2020-07)

 **Arrow International LLC**
Subsidiary of Teleflex Incorporated

3015 Carrington Mill Blvd., Morrisville, NC 27560 USA
USA: 1 866 246 6990 | International: +1 919 544 8000

Teleflex®