



June 20, 2016

To Whom It May Concern:

MRI SAFETY INFORMATION

Re: Product Codes FG-025310, FG-025311, FG-025320, and FG-025321

Non-clinical testing demonstrated that the **MicroCutter Staple is MR Conditional**. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 3-Tesla
- Maximum spatial field gradient of 720 Gauss/cm (7.2 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the First Level Controlled Operating mode of operation for the MR system.

Under the scan conditions defined, the Microcutter Staple is expected to produce a maximum temperature rise of less than 2.2°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the device extends approximately 2 mm from the Microcutter Staple when imaged with a gradient echo pulse sequence and a 3-T MRI system.¹

LATEX STATEMENT

Re: Product codes FG-025302, FG-025310, FG-025311, FG-025320, and FG-025321

All the MicroCutter 5/80 Stapler, MicroCutter 30 Reloads, and their packaging designed & manufactured by Dextera Surgical Inc. DO NOT contain natural rubber latex NOR dry natural rubber. In addition, the gloves used during the manufacturing and assembly process are 100% latex free.¹

PHTHALATE STATEMENT

Re: Product codes FG-025302, FG-025310, FG-025311, FG-025320, and FG-025321

All the MicroCutter 5/80 Stapler, MicroCutter 30 Reloads, and their packaging designed & manufactured by Dextera Surgical Inc. DO NOT contain phthalates.¹

A handwritten signature in blue ink that reads 'Adam Shively'.

Adam Shively
Director, Quality Assurance

¹Data on file at Dextera Surgical Inc.