Genesee
BIOMEDICAL, INC.



MR Conditional

Patient MRI Safety Information

WellsForm™ Tricuspid Annuloplasty Band

This patient has an implanted WellsForm Tricuspid Annuloplasty Band.
This implant is intended for surgical repair of the tricuspid valve.

Name: _____

Address: _____

Clinic/Hospital: _____

Operating Surgeon: _____

Date of Implantation: _____

(Place device label here)

Non-clinical testing has demonstrated that the WellsForm Tricuspid Annuloplasty Band is MR Conditional.

A patient with the WellsForm Tricuspid Annuloplasty Band can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
  - Maximum spatial gradient magnetic field of 5,000-Gauss/cm (50-T/m)
  - Maximum whole body averaged SAR of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode
- Static Magnetic field of 7-Tesla, only
  - Maximum spatial gradient magnetic field of 6,000-Gauss/cm (60-T/m)
  - Important Note: The WellsForm Tricuspid Annuloplasty Band must remain outside of all transmit or transmit/receive RF coils during MRI

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