15 Trafalgar Square Suite 101, Nashua, NH 03063 Investigational device. Limited by Federal (or United States) law to investigational use.

**UOITUAD** 

MANUFACTURER Conformal Medical, Inc.

# conformal

### **CLAAS®**

### LAA Closure Device

In case of medical questions or an emergency, please contact the Implant Physician listed on the back of this card.



# MRI SAFETY INFORMATION



The CLAAS Implant is MR Conditional. A patient with the CLAAS Implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

#### MR CONDITIONAL

PARAMETER	CONDITION
Nominal Values of Static Magnetic Field (T)	1.5-T and 3.0-T
Maxium Spatial Field Gradient (T/m and gauss/cm)	40-T/m(4,000-gauss/cm)
Type of RF Excitation	Circularly Polarized (CP) (i.e., quadrature -driven)
Type of RF Coil Information	There are no transmit RF coil restrictions. Accordingly, the following may be used: body transmit RF coil and all other RF coil combinations (i.e., body RF coil combined with any receive-only RF coil, transmit/receive head RF coil, transmit/receive knee RF coil, etc.)
Operating Mode of MR System	Normal Operating Mode
Maximum Whole Body Averaged SAR	2-W/kg (Normal Operating Mode)
Limits of Scan Duration	Whole body averaged SAR of 2-W/kg for 60 minutes of continuous RF exposure (i.e., per pulse sequence or back to back sequences/ series without breaks)
MR Image Artifact	The presence of this implant produces an imaging artifact. Therefore, carefully select pulse sequence parameters if the implant is located in the area of interest.