

Study Title: Attain StarFix Model 4195 Left Ventricular Lead System. Multi-center, non-randomized study to evaluate the safety and effectiveness of the Attain StarFix Model 4195 LV lead.

Short Title: Model 4195

Study Description: The purpose of this study is to determine if the Model 4195 Lead is safe and effective. The function of the Model 4195 Lead will be studied during the study. The pacemaker, defibrillator and the two right heart leads that are used with the Model 4195 are not investigational leads. This study requires that a Medtronic lead is used for the right ventricle (lower right chamber) and a Medtronic CR device (Pacemaker/Defibrillator). The Medtronic CR device will have the features necessary to fully evaluate the performance of the Model 4195 lead. Because the Model 4195 is an investigational device, this study is regulated and reviewed by the FDA.

Location:

Baylor Heart and Vascular Hospital

62 I N. Hall Ste.400

Dallas, TX. 75226

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For further information about this study, please contact: 214-820-3319.