

<b>STUDY TITLE</b>	<b>Enable MRI Clinical Study</b>
<b>STUDY POPULATION</b>	<p><b>Patient underwent following procedure:</b></p> <ol style="list-style-type: none"> <li><b>1.New implant (ICD or CRTD)</b></li> <li><b>2.Post implant (ICD or CRTD)</b></li> </ol>
<b>PRINCIPAL INVESTIGATOR</b>	Dr. Surinder Kaur Khelae
<b>STUDY COORDINATOR</b>	Siti Nur 'Ain Mahamad Anuar Contact number 03 – 2617 8200 ext 8451
<b>START DATE</b>	3 Feb 2016
<b>END DATE</b>	3 Feb 2019
<b>INCLUSION</b>	<ul style="list-style-type: none"> <li>• Subject will receive or is implanted with an ICD or CRTD pulse generator in the left or right pectoral region</li> <li>• Subject is able and willing to undergo an MRI scan without intravenous sedation (Phase I only)</li> <li>• Subject is willing and capable of providing informed consent and participating in all testing/visits associated with this clinical study at an approved clinical study centre and at the intervals defined by this protocol</li> <li>• Subject is age 18 or more, or of legal age to give informed consent specific to state and national law</li> </ul>

**EXCLUSION**

- Subject implanted with an ICD or CRTD pulse generator with battery at Explant status
- Subject has other active or abandoned implanted cardiac rhythm devices, components or accessories present such as pulse generators, leads, lead adaptors or extenders
- Subject needs or will need a medically necessary MRI scan, before completing the 1-month post-MRI follow-up visit (Phase I only)
- Subject with a history of pacemaker dependence either permanently or intermittently, per physician discretion
- Subject is not clinically capable of tolerating the absence of Bradycardia or Resynchronization therapy support in a supine position for the duration that the pulse generator is in MRI Protection Mode, per Physician discretion
- Subject with a planned RA, RV, or LV lead revision or extraction within 30 days of enrolment (phase I)
- Subject with an implanted lead that is planned to be extracted during the study implant procedure
- Subjects currently requiring dialysis
- Subject has a mechanical heart valve
- Subject has a known or suspected sensitivity to dexamethasone acetate (DXA)
- Subject is currently on the active heart transplant list
- Subject has documented life expectancy of less than 12 months
- Subject is enrolled in a concurrent study, with the exception of local mandatory governmental registries and observational studies/registries, without the approval from Boston Scientific
- Women of childbearing potential who are or might be pregnant and will receive an ICD or CRTD pulse generator