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| <b>STUDY TITLE</b>            | <b>WRAP-IT- World-wide Randomized Antibiotic Envelope Infection Prevention Trial</b>   |
| <b>STUDY POPULATION</b>       | <b>Patient underwent for following procedure:</b><br><b>1.New Implant (CRTD only)</b><br><b>2.Box changes (Pacemaker, CRTP, ICD and CRTD)</b>  |
| <b>PRINCIPAL INVESTIGATOR</b> | Dr. Surinder Kaur  |
| <b>STUDY COORDINATOR</b>      | Siti Norbaya Abd Razak<br>Contact number : 03 – 2617 8200 ext 3122   |
| <b>START DATE</b>             | 15 Oct 2015  |
| <b>END DATE</b>               | 15 Oct 2018  |
| <b>INCLUSION</b>              | <ul style="list-style-type: none"> <li>• Subject is more than 18 years old and willing to provide written informed consent</li> <li>• Subject is schedule to have one of the following procedures: <ul style="list-style-type: none"> <li>- Existing Cardiovascular Implantable Electronic Device (CIED) undergoing IPG,ICD,CRTP and CRTD replacement or upgrade with a new Medtronic Generator</li> <li>- Subject planned to have lead added, or extracted and added for upgrades can be enrolled</li> <li>- De novo CRTD system implant</li> </ul> </li> <li>• Patient has existing study eligible Medtronic Cardiovascular Implantable Electronic Device (CIED) in which the pocket was not accessed within the last 365 days, and is undergoing pocket or lead revision.</li> <li>• Subject is willing to provide contact information for the physician who provide follow-up care for his/her Cardiovascular Implantable Electronic Device (CIED)</li> <li>• Subject is willing and able to comply with scheduled follow-up and study related activities</li> </ul> |

**EXCLUSION**

- Known allergy to minocycline or rifampicin or their derivatives or any other known contraindication to implantation of the TYRX envelope
- Receiving therapy with oral immunosuppressive agents or more than 20mg/day of prednisolone or equivalent
- Hemodialysis or peritoneal dialysis
- Prior cardiac transplantation or existing ventricular assist device (VAD)
- Required long-term vascular access for any reason.
- Prior history of a Cardiovascular Implantable Electronic Device (CIED) infection, other prosthetic device infection, or endovascular infection, including endocarditis, in past 12 month
- Physical, clinical, or laboratory sign and symptom consistent with an active infection (including but not limited to pneumonia, urinary tract, cellulitis, or bacteremia)
- Systemic Lupus erythematosus, because minocycline has been reported to aggravate this condition
- Female patient who is pregnant or of childbearing potential and not on reliable form of birth control. Women of childbearing potential are required to have negative pregnancy test within 7 days prior to device procedure.
- Participant in another study may confound result of this study. Co-enrollment in concurrent trials is only allowed when documented pre-approval is obtained from Medtronic study manager