

CITADEL & CENTURION STUDIES WITH THE TYRX™ ANTIBACTERIAL ENVELOPE*



Significantly Reduced Rate of Cardiac Implantable Electronic Device (CIED) Infection Among High-Risk Patients Implanted with the TYRX Non-Absorbable Antibacterial Envelope at 12-Month Clinical Follow-up¹

DESIGN

Prospective cohort studies were designed to define the major CIED Infection and CIED mechanical complication rates in high-risk Implantable Cardioverter Defibrillator (ICD) or Cardiac Resynchronization Therapy (CRT) patients receiving the TYRX Non-Absorbable Antibacterial Envelope during upgrade or replacement procedures. The studies compared these rates to those of a published control of ICD/CRT replacement patients who did not receive the TYRX Antibacterial Envelope.^{1,2}

METHODS

A total of 1,262 patients were entered into the database of participants in two studies at 55 U.S. study sites: the Citadel Single and Dual Chamber (ICD) Study (n=459) & the Centurion Cardiac Resynchronization Therapy Defibrillator (CRT-D) and Cardiac Resynchronization Therapy Pacemaker (CRT-P) Study (n=670). A total of 133 patients were excluded from analysis because they had ineligible informed consent (44), an ineligible procedure (18), or an ineligible device (71). The remaining 1,129 patients comprised the prospective database.¹

An analysis of the primary efficacy endpoints at 12-month follow-up was performed utilizing an historical comparator study cohort comprised of 451 ICD/CRT implant replacement patients having a mean follow-up of 355 days at 12 Canadian study sites.¹

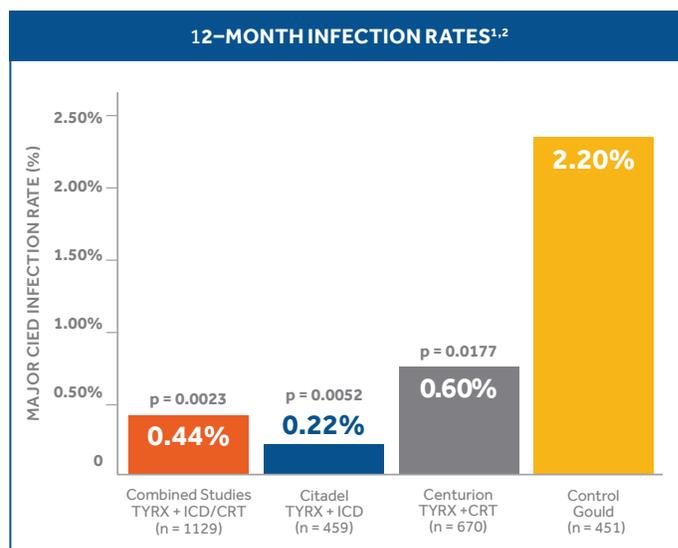
RESULTS

- 12-month follow-up of the 1,129 combined Citadel (ICD+TYRX) & Centurion (CRT+TYRX) patient group identified 5 major infections (0.44%), the primary efficacy endpoint of the study.¹
- 12-month follow-up results for the combined 1,129 patient cohort demonstrated 80% fewer major CIED Infections (0.44% vs. 2.2%; p=0.0023) than the comparator study cohort.^{1,2}
- 12-month follow-up results from the 459-patient Citadel cohort demonstrated 90% fewer major CIED Infections (0.22% vs. 2.2%; p=0.0052) vs. the comparator study cohort.^{1,2}

- 12-month follow-up results from the 670-patient Centurion cohort demonstrated 73% fewer major CIED Infections (0.6% vs. 2.2%; p=0.0177) vs. the comparator study cohort.^{1,2}
- 12-month follow-up data of the combined 1,129 patient cohort identified no significant difference between the rate of major hematomas vs. the comparator study cohort (1.55% vs. 1.60%).^{1,2} Overall rates of mechanical complications were low (4.4%).²
- Neither the Citadel nor the Centurion patient group cohorts experienced unanticipated serious TYRX Envelope-related adverse events during the 12-month follow-up period.¹

CONCLUSIONS

The Citadel & Centurion Studies demonstrated that after implantation of a TYRX Non-Absorbable Antibacterial Envelope in patients at high-risk for CIED Infection, there were significantly fewer major infections at 12 months compared to the published comparator study cohort. There was a 73% to 90% reduction in infection rate vs. the comparator study cohort, and the overall rate of mechanical complications was low.^{1,2}



*Study performed utilizing the TYRX™ Non-Absorbable Antibacterial Envelope.

1. Henrikson CA. Citadel and Centurion Study Results: Use of Antibacterial Envelope is Associated with Low 12-Month CIED Infection Rates. Oral presentation at European Heart Rhythm Association (EHRA) EUROPACE-CARDIOSTIM 2015. 2. Gould PA et al. *Heart Rhythm*. 2008;5(12):1675-1681.

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