

COMMAND

COOPERATIVE MULTICENTER STUDY
MONITORING A CIED ANTIMICROBIAL DEVICE



COMMAND Clinical Study

(COoperative Multicenter study Monitoring a CIED ANtimicrobial Device)

Bloom H *et al.* PACE 2011; 34 (2); 133-142

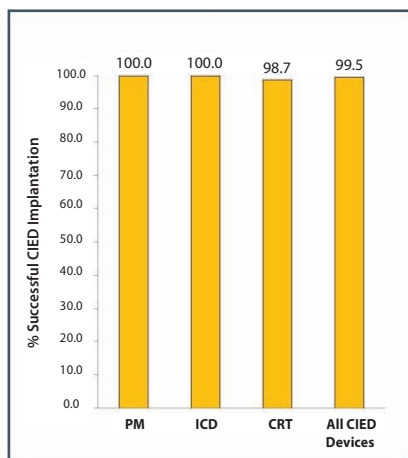
A Multicenter Retrospective Cohort Study of Patients Undergoing CIED Implantation with the AIGISRx® Antibacterial Envelope

Purpose: Define rate of **A) Successful CIED implantation** and **B) CIED infection** in patients undergoing CIED procedures with AIGISRx.

Study Design: Multicenter, retrospective cohort study. Procedures performed after explantation for CIED infection or for off-label indication were excluded from analyses.

Results:

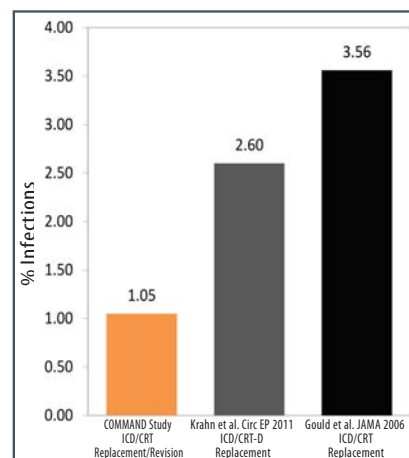
- 642 patients enrolled at 10 U.S. academic, community, and VA medical centers with 1.9 +/- 2.4 months follow-up. 624 patients met criteria for analyses.
- > 99% of all CIEDs were successfully implanted.
- CIED infection rate was 0.48% for all procedures, 0.00% for initial procedures, and 0.71% for replacement/revision procedures.
- 70% fewer infections in highest risk subset of COMMAND Study, ICD/CRT replacement/revisions, vs. other published studies of ICD/CRT replacements (1.05%¹ vs. 2.60%² vs. 3.56%³).



High Rate of Successful CIED Implantation

	PM	ICD/CRT	All CIED Devices
Initial Procedure	0/84 0.00%	0/117 0.00%	0/201 0.00%
Replacement/Revision Procedure	0/137 0.00%	3/286 1.05%	3/423 0.71%
All Procedures	0/221 0.00%	3/403 0.74%	3/624 0.48%

Low Rate of CIED infection



Low Rate of infection in procedures for ICD/CRT Replacements/Revisions

1. Bloom H *et al.* PACE 2011; 34 (2); 133-142 2. Krahn *et al.* Circ EP 2011; 4:136-142 3. Gould *et al.* JAMA 2006 295, 1907-1911

CAUTION: Federal law limits the device to sale by, or on the order of, a licensed practitioner. For full prescribing information, including indications, warnings, cautions and contraindications, see instructions for use.