

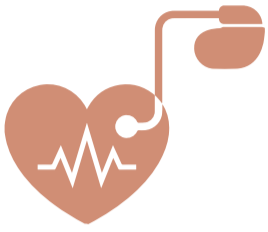
WRAP-IT: Antibacterial Envelope to Prevent Cardiac Implantable Device Infection



AMERICAN COLLEGE of CARDIOLOGY

multicenter, randomized, controlled, prospective, single-blind trial

Objective: To assess the safety and efficacy of an absorbable, antibiotic-eluting envelope in reducing the incidence of infection associated with cardiac implantable electronic devices (CIED) implantations.



Patients with CIEDs



Absorbable, antibiotic-eluting envelope



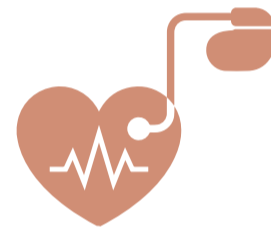
Clinical outcomes



6,983 patients undergoing CIED generator replacement or a system upgrade with or without new leads, those undergoing CIED pocket or lead revision, and those undergoing an initial CRT-D procedure.



CIED envelope
(n=3,495)



Control group
(n=3,488)

Primary Outcome

0.7% Infection, long-term antibiotic therapy with infection recurrence, or death, within 12 months **1.2%**
HR 0.60; 95% CI, 0.36 to 0.98; P=0.04

Secondary Outcome

6.0% Procedure-related or system-related complications within 12 months **6.9%**
HR 0.87; 95% CI, 0.72 to 1.06; P<0.001 for noninferiority

32 Major CIED-related infections (n) **51**
HR 0.63; 95% CI, 0.40 to 0.98

Adjunctive use of an antibacterial envelope significantly lowers incidence of major CIED infections versus standard-of-care infection prevention strategies alone, without a higher incidence of complications.