

Managing CIED infections

< 2 in 10 CIED infection patients receive guideline-driven care¹



A guide for healthcare professionals

How to manage CIED infections

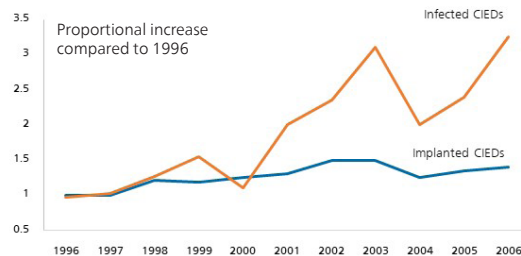
Managing a CIED patient

Device-related infection is **one of the most serious complications** of CIED therapy². CIED's (Cardiac Implantable Electronic Devices) include pacemaker devices (PPM, ICD, CRT-P, CRT-D). Over 1 million CIED leads are implanted each year³.

1 in 20 of these patients develop CIED infection within 3 years⁴.

CIED infection rates are disproportionately rising compared to implantation rates⁵.

49.5% of CIED infections occur > 1 year after pocket manipulation⁶



Source: Voigt, A. et al. Continued Rise in Rates of Cardiovascular Implantable Electronic Device Infections in the United States: Temporal Trends and Causative Insights. Pacing and Clinical Electrophysiology, 2010,33: 414-419.

2-7% increased risk of CIED infection related to repeated manipulation or upgrade surgeries of device pockets^{7,8}



< 2 in 10 CIED infection patients receive guideline-driven care¹

CIED infection can present in different ways

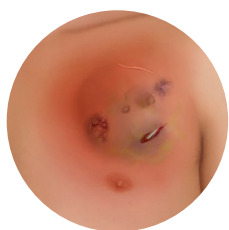
Pocket infection⁹



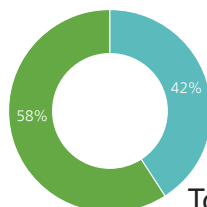
Early signs of infection may appear as redness, swelling or a hot feeling¹⁰



Infections may become swollen, and lesions or skin ulcers can develop¹⁰



Advanced infection may cause the device to protrude or come out of the body¹⁰



Systemic infection⁹

Infection can be systemic from the beginning, without progression from CIED pocket¹¹

Top 5 overlooked infection presentations include¹²:



Pansinusitis



Pneumonia



Podiatry infection

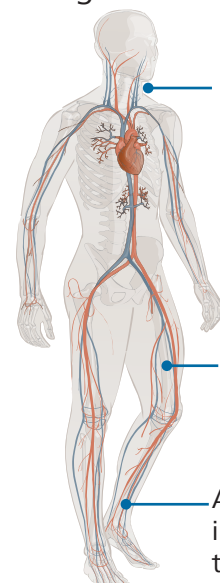


Aortic mitral endocarditis



Urinary tract infections

Infection could originate from:



A dental procedure

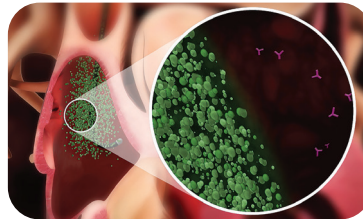
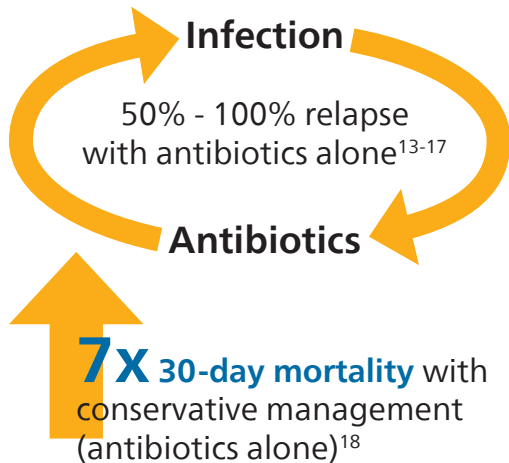
A leg wound that just won't heal

Any other infection in the body

Factors which play a role in the pathogenesis of CIED infections can be related to the host, the device, or the microorganism.²

Antibiotics alone are associated with high relapse rate and increased mortality¹³⁻¹⁸

Biofilms on leads: circle of antibiotic treatment.



Biofilm: dead (red colored) cells forming 'shielding' film over living (green colored) cells.¹⁹ Antibiotics are often ineffective.

Source: Philips document D059901-00



Endocarditis can be caused by biofilms. Endocarditis leads to vegetations which can make extraction of pacemaker leads difficult.^{20,21,24}

Source: Philips document D016923-03



Results of a large-scale, real-world analysis robustly confirm undertreatment of CIED infection patients.¹

Swedish Single Center review demonstrated a 5-fold underreporting of CIED infections.²²

CIED Infection is a **Class I indication** for complete system removal^{2,23-26}

Expert consensus statements recommend timely referral to a qualified extractor²⁴

| Isolated pocket infection | Systemic infection | |
|--|---|---|
| | Without vegetation on leads or valves ± pocket infection | CIED endocarditis with vegetation on leads and/or valves ± embolism |
| Removal / Extraction + antibiotic therapy (10-14 days) | Removal / Extraction + antibiotic therapy 4 weeks (2 weeks if negative blood culture) | Removal / Extraction + antibiotic therapy 4-6 weeks (+oral antibiotics therapy FU if indicated by secondary infectious focus) |

Source: Blomström-Lundqvist C, et al. (European Heart Rhythm Association (EHRA) international consensus document on how to prevent, diagnose, and treat cardiac implantable electronic device infections—endorsed by the Heart Rhythm Society (HRS), the Asia Pacific Heart Rhythm Society (APHRS), the Latin American Heart Rhythm Society (LAHRS), International Society for Cardiovascular Infectious Diseases (ISCVID) and the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS)). Europace (2020) 22, 515–516 and European Heart Journal (2020) 41, 2012–2032

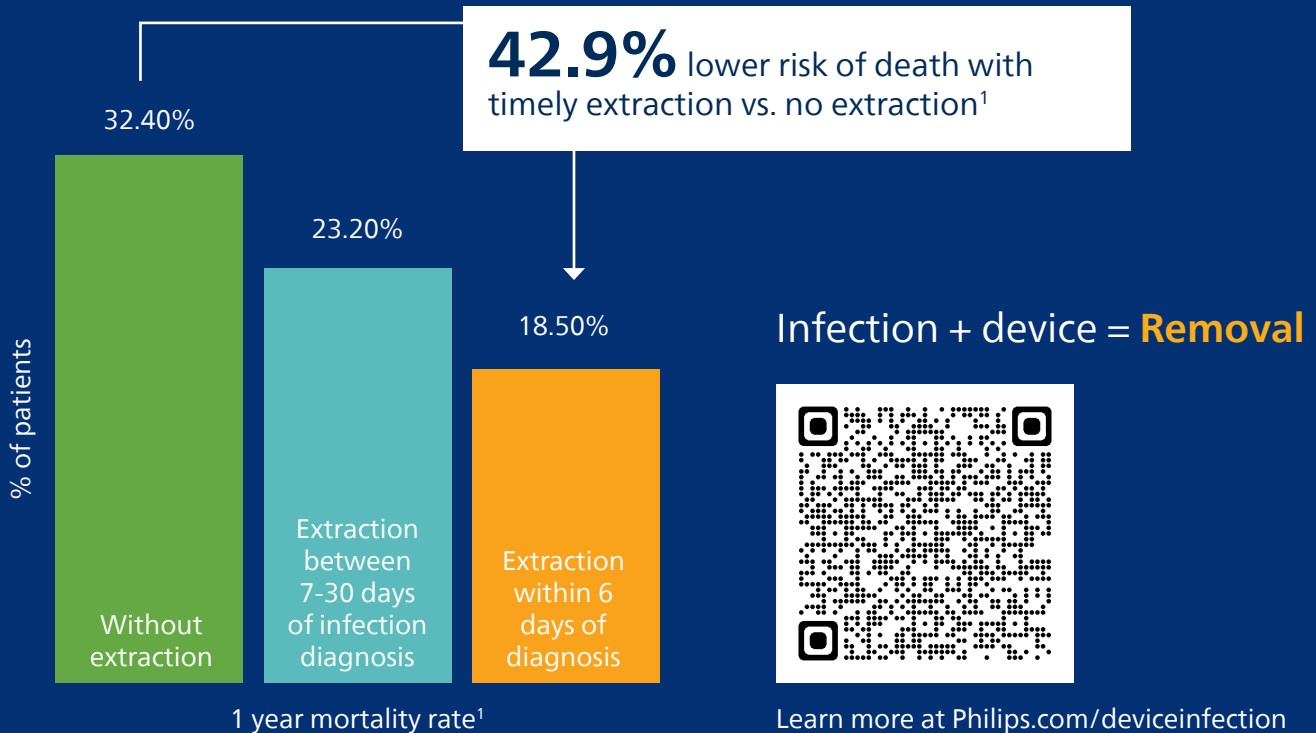


- EHRA Infection Consensus Statement (2020)²
- Sandoe et al. Guidelines for diagnosis, prevention and management of CIED (2015)²³
- HRS Expert Consensus Statement on Lead Management Extraction (2017)²⁴
- EHRA Guidelines for the management of infective endocarditis²⁵
- Update on cardiovascular implantable electronic device infections and their management: a scientific statement from the American Heart Association (2010)²⁶

Act quickly: early extraction saves lives



ACC.22 Late-breaking clinical trial Duke data confirms: **any extraction was associated with lower mortality when compared to no extraction** (adj HR 0.73, 95% CI 0.67-0.81, $p < 0.001$).¹
Over 1 million of patients with CIEDs, 14 years of data (2006-2019).



Putting the risk of extraction into perspective

The extraction procedure

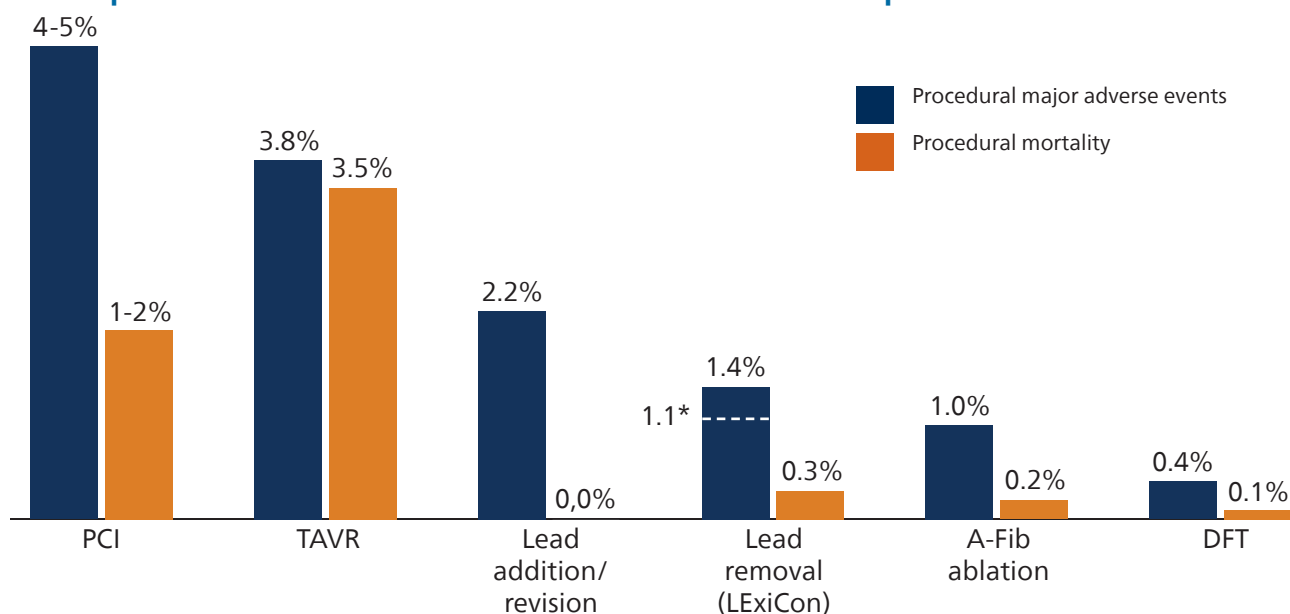
Proven safety of lead extraction²⁹

97.7%
clinical
success^a

1.4%
major
complications

0.28%
procedure
mortality

Comparison of lead extraction vs other common procedures²⁹⁻³⁹



* The LEXiCon study reports a procedural MAE rate of 1.4% as defined by the 2000 NASPE Policy Statement. However, 0.3% (n=4) of the MAEs were bleeding requiring transfusion which is no longer defined as an MAE by the 2009 HRS Expert Consensus Document

Risk of capping

Abandoned leads are a risk for tissue damage or inappropriate cardiac stimulation⁴⁰:

Risk of infection 5 years post-procedure⁴¹

14.2% increase risk of infection at 5 years⁴¹

Risk of failed lead removal⁴²

2x times more likely to have risk of failed lead removal every 3 years⁴²

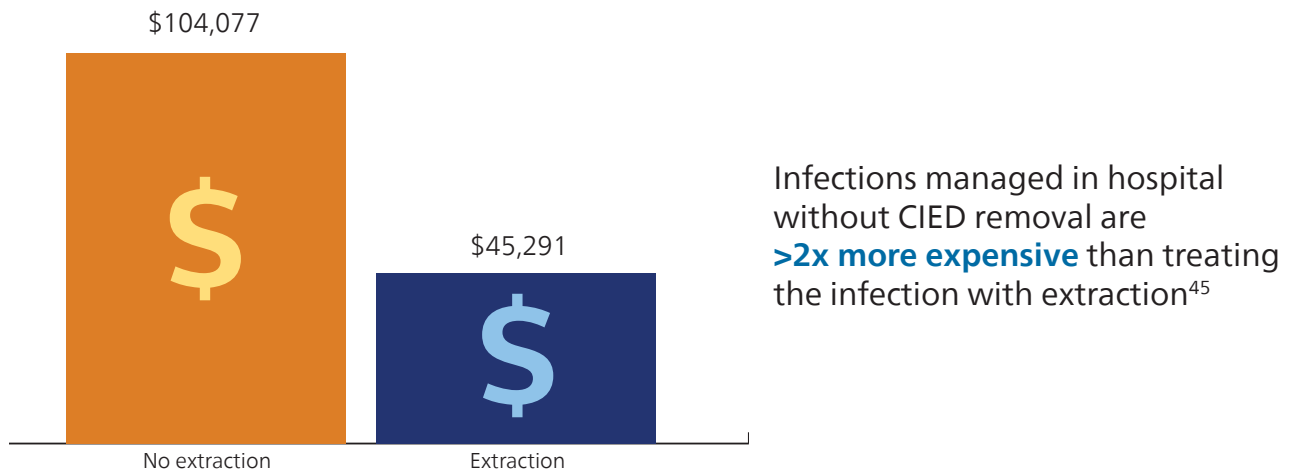
Risk of major adverse event⁴³

2.6x times more likely to have a MAE (Major Adverse Event)⁴³

a: Clinical success was defined as achievement of all clinical goals associated with the indication for lead removal

Putting the cost of conservative treatment into perspective⁴⁴

Infected CIED patients are more costly to treat and create significant additional costs over time⁴⁴



Most CIED infections costs are related to hospitalization costs⁴⁴

Cumulative costs 3-years post infection⁴⁴



The costs of treating a major infection are higher than a minor infection.⁴⁴

Sales representative contact information

Name:

Telephone number:

QR code

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