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Antibacterial Pouch Salvage for Ulcerated Defibrillator Pockets without Proven Infection

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Abstract

Cardiac implantable electronic device (CIED) infection with pocket erosion or exposed hardware is generally considered a definite system contamination, for which major societies recommend complete device extraction. However, a minority of patients present with highly focal pocket ulceration, negative microbiology, and no systemic features of infection, yet face prohibitive risks with transvenous lead extraction. We report two such patients: a middle-aged man with longstanding ICD leads and a frail older woman with CRT-D and a tip-down sleeve–related focal ulcer, both without clinical, laboratory, or echocardiographic evidence of infection. Each underwent excision of the ulcerated segment, exploration of the original pocket, relocation of the generator to an adjacent pocket with better soft tissue coverage, and placement in a TYRX™ absorbable antibacterial envelope as a prophylactic adjunct. Both patients had uneventful recoveries and remained free of local or systemic infections during the 10- and 32-month follow-up, respectively. These cases illustrate that in exceptional scenarios that meet stringent clinical and microbiological criteria and involve disproportionate extraction risk, conservative salvage with debridement, adjacent pocket relocation, and antibacterial envelope use may be considered but should not be viewed as an alternative to guideline-directed extraction for proven or suspected CIED infection.

Keywords: Cardiac implantable electronic device infection; Defibrillator pocket erosion; TYRX antibacterial envelope; Conservative pocket revision; Case report

Introduction

Cardiac implantable electronic device (CIED) infection is a serious complication associated with high morbidity and mortality, and a frequent need for repeat intervention. International consensus documents from the HRS and EHRA state that visible erosion or exposure of the generator or leads generally implies system contamination and should be treated as definite CIED infection, for which complete system extraction is recommended. Conservative pocket-only approaches are discouraged in proven infection because retained hardware may harbor biofilms and predispose patients to relapse or systemic complications.

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Despite this clear standard, a small subset of patients with localized, apparently mechanical pocket ulceration, no purulence or inflammatory changes, negative microbiology, and no systemic features of infection simultaneously face substantial procedural risk with lead extraction. In such situations, clinicians must weigh strict guideline-directed extraction against individualized, less invasive strategies. This report describes two such patients managed with excision of the ulcerated area, relocation of the generator to a new adjacent pocket, and placement in an absorbable antibacterial envelope, emphasizing that this represents an exceptional salvage approach rather than an alternative to guideline-based treatment of proven infection.

Case Presentation

Case History/Examination

Case 1:

A 48 year old man had a transvenous implantable cardioverter-defibrillator implanted in 2002 for monomorphic ventricular tachycardia, with multiple subsequent revisions for battery depletion and lead upgrades. The most recent procedure was performed in March 2022 because of battery depletion. In August 2025, he presented with focal skin ulceration over the generator pocket but no fever, malaise, or hemodynamic instability. Examination revealed superficial ulceration directly over the device, without erythema, fluctuance, purulence, or surrounding induration, suggesting chronic mechanical pressure and tissue thinning rather than a manifest pocket infection (Figure 1A).

Microbiological assessments, including pocket swabs, blood cultures, and tissue cultures, were repeatedly negative, and there were no signs of systemic infection. Given the longstanding transvenous system, prior revisions, and anticipated high extraction burden, a conservative strategy was considered after multidisciplinary evaluation and discussion with the patient (Table 1).

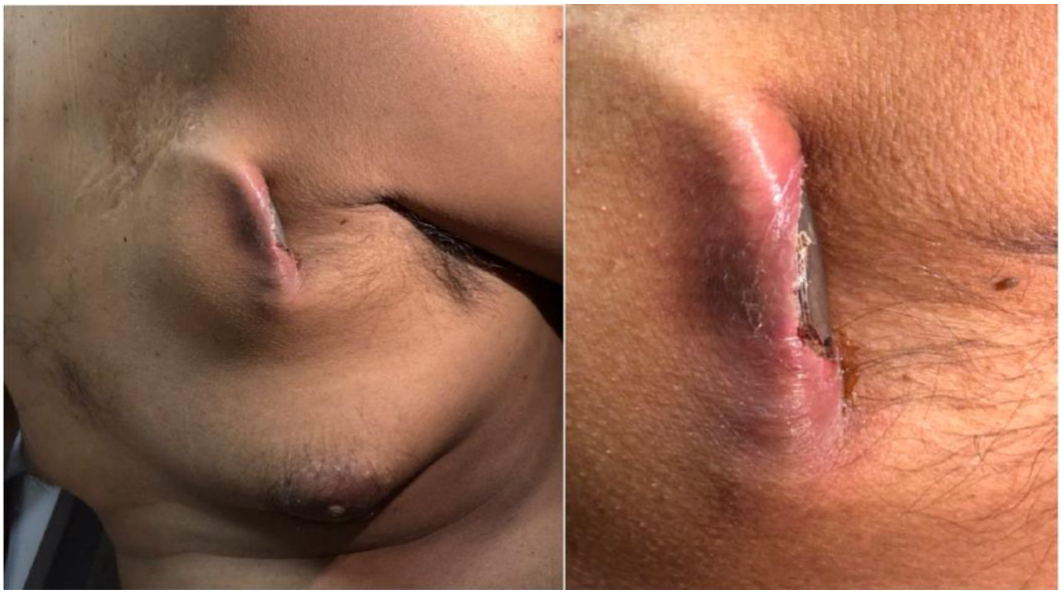

Figure 1A: (Patient 1, Preoperative): Preoperative appearance of a 48-year-old man with cardiac device pocket erosion. The image demonstrates focal skin thinning and ulceration directly over the generator, without erythema, purulence, or fluctuance, which is consistent with a mechanical rather than infectious etiology.

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Table 1: Case 1 Infectious work-up and follow-up after conservative pocket revision.

Date/ timing	Temperature (°C)	WBC (×10^9/L)	Neutrophils absolute (×10^9/L)	Neutrophils relative (%)	CRP (mg/L)	Procalcitonin (ng/mL)	Blood cultures	Pocket/skin swab culture	Tissue culture	TEE result
15 days before procedure	36.7	6.9	4.0	58	2.1	0.03	2 sets, no growth at 5 days	No growth	No growth	
7 days before procedure	36.8	6.7	3.9	58	1.9	0.03	2 sets, no growth at 5 days	No growth	No growth	No valve-related infective findings
Day 7 after procedure	36.6	6.5	3.7	57	1.5	0.02	Not repeated; no clinical indication	Not applicable	Not applicable	
Day 15 after procedure	36.5	6.3	3.6	57	1.2	0.02	Not repeated; no clinical indication	Not applicable	Not applicable	
Day 30 after procedure	36.6	6.1	3.5	56	1.0	0.02	Not repeated; no clinical indication	Not applicable	Not applicable	
6 months after procedure	36.6	6.0	3.4	56	0.8	0.02	Not repeated; no clinical indication	Not applicable	Not applicable	No vegetation or lead mass; stable cardiac findings

Reference ranges used: Temperature 36.5-37.5 °C (afebrile adult range), WBC 4.5-11.0 ×10^9/L, neutrophils absolute 1.5-8.0 ×10^9/L, neutrophils relative 40-60%, CRP <5 mg/L, procalcitonin <0.05 ng/mL for low likelihood of localized pocket infection in the DIRT validation study.

Case 2:

An 87 year old (DOB Oct 18, 1937). Previous history: prior mitral valve replacement (St. Jude #29) and LIMA→LAD CABG (January 2002). Long standing left bundle-branch block. The postoperative course was initially uneventful. However, recurrent heart failure symptoms with the requirement for diuretic and ACE inhibitor therapy after February 2003 and rapid symptomatic improvement after treatment initiation were noted. Documented conduction disease: persistent LBBB with marked PR prolongation (PR ≈ 300 ms) and QRS duration of ≈ 180 ms on surface ECG. A CRT-D device was implanted in 6/2006 with a super-responder response; EF increased to 52%. The patient underwent three device replacements. At the last procedure on September 1, 2021, a minor insulation defect in the LV lead was managed with a tip-down protective sleeve and device replacement. 24 months later, she developed a small focal ulcer directly over the sleeve with progressive externalization of the protective material. Clinical examination revealed localized erosion with viable surrounding tissue, but no purulent discharge, erythema, induration, or fluctuance. The patient remained afebrile and was clinically stable (Figure 2).

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Cultures from the pocket and blood remained negative, inflammatory markers were within reference ranges, and there was no clinical or imaging evidence of device-related endocarditis, including TEE. However, no PET-CT scan was performed because there was no evidence of infection (Table 2).

Given the advanced age, multiple prior procedures, and elevated extraction risk, conservative management was again considered a non-standard option after careful discussion of the risks and alternatives.

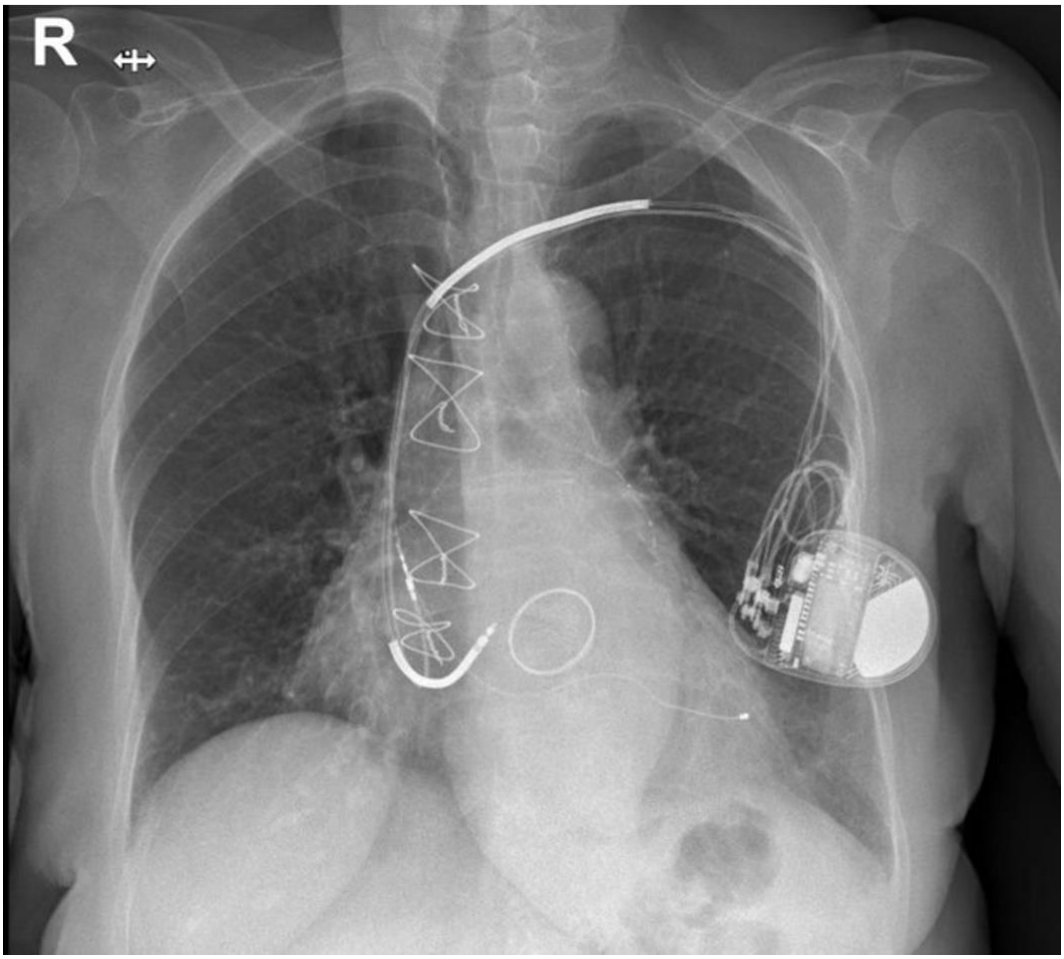

Figure 2A: (Patient 2, Preoperative Chest Radiograph): Preoperative chest radiograph demonstrating the implanted pulse generator and transvenous leads in situ.

Table 2: Case 2 Infectious work-up and follow-up after conservative pocket revision.

Date/timing	Temperature (°C)	WBC (×10^9/L)	Neutrophils absolute (×10^9/L)	Neutrophils relative (%)	CRP (mg/L)	Procalcitonin (ng/mL)	Blood cultures	Pocket/skin swab culture	Tissue culture	TEE result
15 days before procedure	36.9	7.4	4.6	62	3.8	0.04	2 sets, no growth at 5 days	No growth	No growth	
7 days before procedure	36.8	7.1	4.3	61	3.1	0.04	2 sets, no growth at 5 days	No growth	No growth	No lead- or valve-related infective findings
Day 7 after procedure	36.7	6.9	4.1	60	2.6	0.03	Not repeated; no clinical indication	Not applicable	Not applicable	

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Day 15 after procedure	36.6	6.8	4.0	59	2.2	0.03	Not repeated; no clinical indication	Not applicable	Not applicable	Not repeated; no clinical indication
Day 30 after procedure	36.7	6.6	3.8	58	1.8	0.03	Not repeated; no clinical indication	Not applicable	Not applicable	
6 months after procedure	36.5	6.5	3.7	57	1.5	0.03	Not repeated; no clinical indication	Not applicable	Not applicable	cardiac findings

Reference ranges used: Temperature 36.5-37.5 °C (afebrile adult range), WBC 4.5-11.0 ×10^9/L, neutrophils absolute 1.5-8.0 ×10^9/L, neutrophils relative 40-60% (some laboratories accept up to 70%), CRP <5 mg/L, procalcitonin <0.05 ng/mL for low likelihood of localized pocket infection in the DIRT validation study.

Methods: (Differential Diagnosis, Investigations and Treatment)

Differential Diagnosis and Infectious Work Up:

In both patients, the primary differential diagnosis was mechanical erosion versus occult pocket infection. Features favoring a mechanical process included focal skin breakdown, absence of purulence or spreading erythema, stable clinical status, and negative microbiological results. Serial assessments of temperature, white blood cell count, neutrophil count, C-reactive protein, and procalcitonin levels remained within the reference ranges, and transesophageal echocardiography (TEE) showed no vegetations or lead masses.

Tables 1 and 2 summarize the serial infectious work up and follow-up data for each case, demonstrating persistently normal inflammatory markers and the absence of microbiological growth over time. Throughout the preoperative assessment and follow-up, no findings were suggestive of systemic or device-related infections.

Surgical Technique and Treatment:

In both cases, surgery followed the same principles: complete excision of the ulcerated skin segment, careful exploration of the original pocket, and relocation of the generator into a newly created adjacent pocket with improved soft tissue coverage. The generator and leads were placed inside a Medtronic TYRX™ absorbable antibacterial envelope, a mesh designed to elute minocycline and rifampin for at least 7 days and to be absorbed over approximately 9 weeks, while also helping to stabilize the device position.

The objective of envelope use was prophylactic, to reduce the risk of early postoperative contamination in the newly created pocket, rather than to sterilize an infected site.

In Case 1, the ulcerated area was excised, and the ICD generator was relocated on August 25, 2025 (Figure 1B).

Case 2 was similar; the CRT-D generator was excised and relocated in September 2023. Standard perioperative antimicrobial prophylaxis was administered in accordance with institutional practices, and the wounds were closed primarily.

Discussion

These cases highlight a challenging scenario: apparent mechanical pocket ulceration in patients without overt clinical or microbiological infection, yet with substantial procedural risk if guideline-directed complete system extraction is pursued. Current HRS, EHRA, and AHA guidelines remain clear that pocket erosion or exposed hardware should generally be considered CIED infection because communication with the skin implies system contamination, and complete generator and lead extraction is the accepted treatment for definite pocket infection, erosion with exposed hardware, or device-related endocarditis.

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Therefore, this report should be interpreted as strictly hypothesis-generating . It does not challenge guideline-based extraction for infected or contaminated systems; rather, it describes exceptional individualized management when multiple factors Favor a mechanical etiology—focal breakdown, absence of purulence or inflammatory signs, negative microbiology, and no systemic involvement—and when longstanding leads, prior revisions, advanced age, or frailty amplify the extraction burden. A central limitation of any conservative approach is the possibility of occult biofilm-related infection; negative cultures do not fully exclude colonization, and delayed infection with eventual need for extraction remains possible.

The TYRX envelope has evidence for infection prevention in high-risk CIED procedures, including randomized data from WRAP-IT and meta-analytic studies showing reductions in major and pocket infections when used in addition to standard prophylaxis. However, its role is preventive rather than therapeutic, and it is not used to sterilize a contaminated pocket or treat established CIED infection. In the present cases, the envelope served as a prophylactic adjunct after debridement and relocation to a new pocket, not as a definitive therapy for a proven infected system.

Mechanistically, erosion in Case 1 likely reflects progressive fibrosis, tissue thinning, and reduced soft tissue coverage following repeated pocket manipulations over many years. In Case 2, the focal ulceration was plausibly related to chronic pressure and friction from the tip-down sleeve placed to protect a minor lead insulation defect, with a highly localized distribution rather than diffuse hypersensitivity. Both cases underscore the importance of distinguishing mechanical compromise from overt infection, while acknowledging that this distinction can be imperfect in real-world practice.

From a practical perspective, any consideration of salvage therapy should be restricted to rare situations that meet stringent criteria: absence of systemic signs and objective local inflammatory features (purulence, fluctuance, spreading erythema), negative microbiological investigations, no evidence of device-related endocarditis, and a clearly disproportionate extraction risk. Even then, conservative debridement, adjacent pocket relocation, and prophylactic envelope use should be reserved for exceptional patients following multidisciplinary discussion and explicit informed consent, with close long-term follow-up, because late infection remains possible.

Conclusions and Results

Outcome and Follow Up:

In Case 1, the postoperative course was uneventful, with satisfactory early wound healing and no erythema, drainage, or tension at two weeks. At the last follow-up, 10 months after revision, the pocket remained fully healed with a stable scar and no recurrence of erosion or evidence of local or systemic infection (Figure 1B).

In Case 2, early wound healing was also uncomplicated. Serial clinical reviews showed no recurrence of skin breakdown, and the patient remained free of local or systemic complications after 32 months, showing durable pocket healing without subsequent infection (Figure 2B).

Serial laboratory and echocardiographic evaluations remained unremarkable in both patients, supporting the absence of occult infection during follow-up (Figure 1B and 2B).

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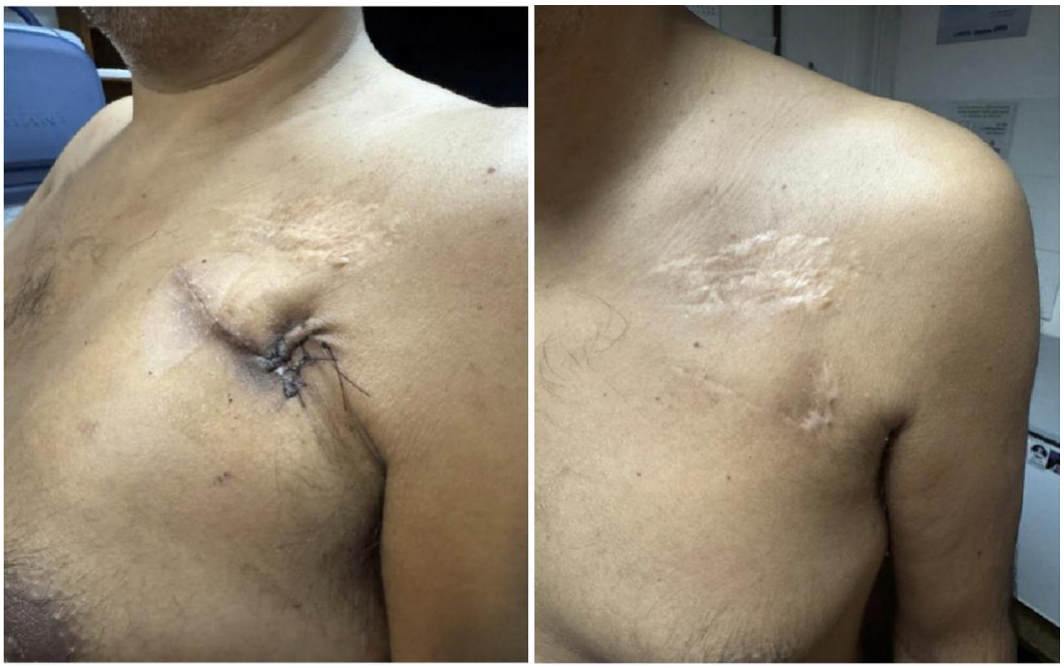

Figure 1B: (Patient 1, Follow up): Postoperative course after conservative device salvage surgery. Left: Two weeks after the procedure, the generator was relocated to an adjacent pocket within a TYRX antibacterial envelope, and the ulcerated skin was excised with primary closure using nylon sutures.

Right: Ten months after surgery, the pocket showed a stable, mature scar with no recurrent erosion or evidence of late infection.

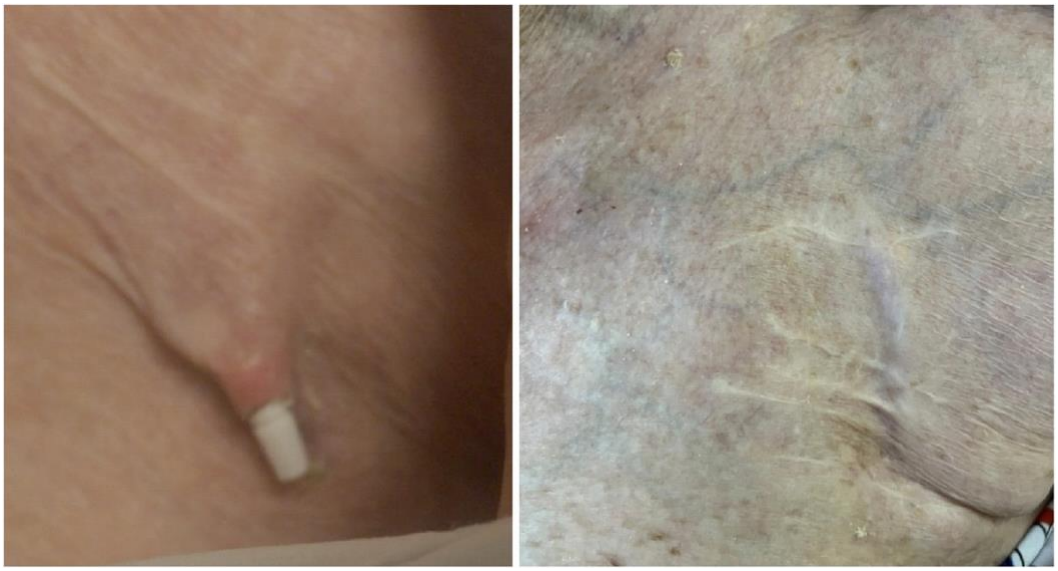

Figure 2B: (Patient 2, Pre and Postoperative appearance): Pre and postoperative views of an 87 year old woman with lead sleeve erosion. Left: Externalization of a protective lead sleeve (tip-down orientation) placed during a prior revision is evident, with the surrounding soft tissue remaining viable and no clinical evidence of pocket infection or purulent discharge.

Right: Clinical appearance at 30 month follow up, demonstrating a fully healed pocket; the patient remained free of local or systemic device-related complications.

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What is unique and what it adds

This case report describes two patients with ulcerated CIED pockets in whom the clinical presentation, serial laboratory and microbiological testing, and echocardiography consistently supported a predominantly mechanical etiology without proven infection, yet the extraction risk was considered prohibitive. Both patients underwent excision of the ulcerated area, adjacent pocket relocation of the generator, and implantation within a TYRX absorbable antibacterial envelope, achieving durable pocket healing and freedom from infection on long-term follow-up. To our current knowledge, reports of antibacterial envelope–assisted generator salvage in ulcerated but non infected defibrillator pockets are scarce, and this experience helps define stringent criteria under which individualized conservative management might be discussed while reinforcing that guideline directed extraction remains the standard for definite CIED infection.

Key Clinical Message (KCM)

In a small, highly selected group of patients with mechanically induced CIED pocket ulceration, absence of signs of local infection, and negative microbiology, conservative management with generator relocation to an adjacent pocket using an absorbable antibacterial envelope may result in pocket healing without recurrence. This strategy falls outside the guideline-endorsed management of CIED infection.

Data Availability Statement

Data sharing does not apply to this article, as no new datasets were generated or analyzed beyond the clinical information presented in the case description and accompanying images.

Funding Statement

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Conflict of Interest Disclosure

The authors declare no conflicts of interest related to this case report.

Ethics Approval Statement

According to the policy of the CASMU-British Hospital in Montevideo, Uruguay, these two case reports did not meet the criteria for human subject research and were granted an ethics review exemption. This report was prepared in accordance with the Declaration of Helsinki and local regulations.

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