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REVIEW

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Process mapping strategies to prevent subcutaneous implantable cardioverter-defibrillator infections

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Abstract

Background: Infection remains a major complication of cardiac implantable electronic devices and can lead to significant morbidity and mortality. Implantable devices that avoid transvenous leads, such as the subcutaneous implantable cardioverter-defibrillator (S-ICD), can reduce the risk of serious infection-related complications, such as bloodstream infection and infective endocarditis. While the 2017 AHA/ACC/HRS guidelines include recommendations for S-ICD use for patients at high risk of infection, currently, there are no clinical trial data that address best practices for the prevention of S-ICD infections. Therefore, an expert panel was convened to develop a consensus on these topics.

Abbreviations: ATP, anti-tachycardia pacing; CIED, cardiovascular implantable electronic device; CRT, cardiac resynchronization therapy; EP, electrophysiologist; ICD, implantable cardioverter-defibrillator; PADIT, prevention of arrhythmia device infection trial; S-ICD, subcutaneous implantable cardioverter-defibrillator; TV, transvenous; VT, ventricular tachycardia; WRAP-IT, The worldwide randomized antibiotic envelope infection prevention trial.

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Methods: An expert process mapping methodology was used to achieve consensus on the appropriate steps to minimize or prevent S-ICD infections. Two face-to-face meetings of high-volume S-ICD implanters and an infectious diseases specialist, with expertise in cardiovascular implantable electronic device infections, were conducted to develop consensus on useful strategies pre-, peri-, and postimplant to reduce S-ICD infection risk.

Results: Expert panel consensus on recommended steps for patient preparation, S-ICD implantation, and postoperative management was developed to provide guidance in individual patient management.

Conclusion: Achieving expert panel consensus by process mapping methodology for S-ICD infection prevention was attainable, and the results should be helpful to clinicians in adopting interventions to minimize risks of S-ICD infection.

KEYWORDS
antibiotic prophylaxis, antibiotics, defibrillator, infection, mapping, prevention, subcutaneous implantable cardioverter-defibrillator, surgical site infection

1 | INTRODUCTION

The subcutaneous implantable cardioverter-defibrillator (S-ICD) offers a beneficial choice for ICD-indicated patients, providing safety and efficacy comparable to transvenous (TV)-ICDs without the risks inherent to vascular leads.[1–4] AHA/ACC/HRS guidelines published in 2017 include a Class I recommendation for S-ICD use in patients who are at high risk for infection, and in whom pacing for bradycardia or ventricular tachycardia termination or as part of cardiac resynchronization therapy is neither needed nor anticipated.[5] While the use of the S-ICD reduces the risk of life-threatening complications, such as bloodstream infection and infective endocarditis due to the lack of vascular exposure, infections still occur. The size, location, and additional incisions and surgical tunneling required for implantation of the S-ICD harbor an increased risk for infection, which, while generally nonsystemic and safer to extract compared to TV lead infections, still require additional medical care with an increased financial burden.

Current practices for the treatment of S-ICD infections tend to follow recommendations for TV-ICD infections, which stipulate complete device and lead extraction once the infection is confirmed,[6] yet there has been no clinical data published to guide best practices specifically for the prevention and management of S-ICD infection. The unique S-ICD implantation technique and its nonvascular location present a different risk potential for both the development and treatment of infection. As the number of S-ICD implantations increases to involve more patients and close to 100 000 S-ICD implanted, it is important to establish best practices for both S-ICD implantation as well as postimplant patient management to minimize the risk of device infection to assure optimal device efficacy and patient safety.

2 | METHODS

A modified process mapping methodology was employed during one initial and one follow-up face-to-face meeting of experienced electrophysiologists (EPs) and an infectious diseases specialist who has expertise in the field of cardiovascular device infections. Details of the modified process mapping approach have been outlined in a prior publication that examined anesthesia for S-ICD implantation.[7] In brief, a focused review of a stepwise approach to the unique steps of S-ICD implantation and specific approaches to minimize infection permitted input from all participants on both behavioral workflow and cognitive decision-making steps in individual patient prevention of S-ICD infections. This consensus paper, although sponsored by Boston Scientific, shows no influence of theirs on the final writing of the manuscript. During the face-to-face meeting, their presence was to facilitate note-taking of the mapping process. Figure 1 provides an overview of the phases of infection prevention, while a checklist and a glimpse figure of the full map are shown in Supporting Information: Figures 1–3.

2.1 | Shared decision-making

Several studies have evaluated patient-, device-, and procedure-related factors that are predictive of cardiovascular implantable

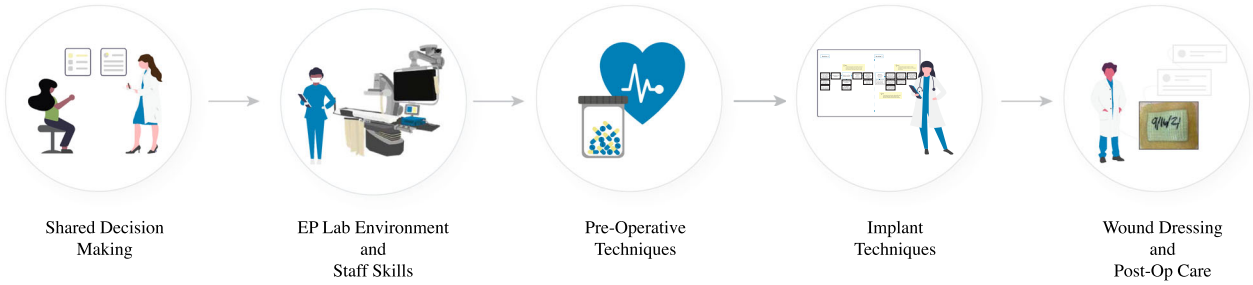

FIGURE 1 Overview of the steps for preventing subcutaneous implantable cardioverter-defibrillator infections

electronic device (CIED) infection.[8,9] Because current guidelines indicate the S-ICD for patients at high risk of infection, it is critical to fully evaluate the patients' comorbidities to identify potential infection risk factors that can be minimized with clinical intervention. While the shared decision-making between TV-ICD and S-ICD involves many factors, including the need (or possible future need) for pacing or anti-tachycardia pacing (ATP), it is equally important to evaluate a patient's current and future potential risk of device infection, such as renal disease that may progress to the need for chronic hemodialysis, which has been identified as a major risk factor associated with TV CIED infection.[10] Also, an important consideration at implant is acknowledging the higher risk of serious complications of a TV-ICD system in relation to S-ICD. Assessing these risks at initial consultation should help guide the decision for the optimal device for each patient. The current or future risk of a need for vascular access, other implanted devices including mechanical valves, as well as the need for brady pacing or ATP should be considered to define the optimal ICD for patients.

2.2 | EP lab environment and staff skills

A major step in preventing infection occurs long before the patient arrives for the scheduled procedure. Every EP laboratory and all staff involved, including anesthesia personnel, should be fully aware of the need for infection prevention and control (Figure 1). Catheter-based EP procedures traditionally have not required the highest level of attention to aseptic technique, but with increased incisions and tunneling required for S-ICD implantation, the procedure necessitates meticulous aseptic practice as applied to all surgical procedures. Moreover, procedures should be established for training and continuous improvement of EP lab staff aseptic techniques, including implementation of new, improved techniques where needed, and thorough training for new employees. Limiting the number of people in the room, reducing the number of times a lab door is opened, and discouraging staff changes during the procedure can all contribute to a reduction in infection risk. Creation and consistent use of pre-, peri-, and postoperative checklists incorporating infection prevention measures can enhance consistency. Indeed, implementation of an infection-control protocol for the implantation of cardiac devices has been shown to reduce infection by 54%.[11]

2.3 | Preoperative techniques

Once the choice of an S-ICD is established, there are several preoperative steps that can help reduce the risk of implant-related infections; see Supporting Information: Figure 1.

2.3.1 | Antibiotic prophylaxis

The choice of pre-, peri- and postoperative antibiotics is one that should be considered well in advance of the implantation date. One dose of intravenous cefazolin given within 30 min to 1 h before procedure is recommended. For patients with a past history of penicillin or beta-lactam allergy, further evaluation is required as a large number (~90%) of these patients will be eligible for cefazolin prophylaxis. Therefore, consultation with a specialist in allergic diseases should be obtained before device placement. If a patient is deemed a noncandidate for cefazolin prophylaxis, then vancomycin is often selected. Due to the current interest in limiting vancomycin use to diminish the likelihood of selection of antibiotic resistance, its lack of gram-negative coverage, and questions about its prophylaxis efficacy, allergy consultation should be obtained early to avoid vancomycin use. Clindamycin is another alternative, but because of its risk of *Clostridioides difficile* infection and its complications, avoidance of clindamycin is recommended.

Antimicrobial prophylaxis in the peri- and postoperative periods has been further addressed in Section 2.4.

2.3.2 | Anticoagulant use

For patients on oral anticoagulant (OAC) medications, an important step to reduce the risk of infection is to establish a perioperative plan for OAC use. The use of OACs increases the risk of surgical bleeding and hematoma formation,[12,13] which is strongly associated with an increased risk of TV device-related infections.[14] Because perioperative interruption of OACs may lead to an unacceptable risk of clotting sequelae, heparin bridging has been used as an alternative to OAC continuation during surgery, but this too is associated with an increased risk of hematoma formation.[15,16] Alternatively, OAC interruption preoperatively for 24–48 h without heparin bridging

may be a viable option to reduce infection risk for those patients able to tolerate this approach without undue clotting risk. Otherwise, uninterrupted anticoagulation should be considered.[17] Careful consideration of the opposing risks of hematoma formation and subsequent infection risk with that of clotting or thromboembolic event need to be weighed for each patient before implantation.

2.3.3 | Optimal implant technique consideration

Since the introduction of the S-ICD, implant techniques have been refined, including the two-incision technique with the electrode delivery system in which the supra-sternal incision is avoided, leaving just the pocket and xiphoid incisions.[18–20] Reducing the number of incisions may reduce the risk of superficial incisional infections, and it can also reduce the overall procedure time[21,22] without adversely impacting the rate of complications.[23] The intermuscular technique, in which the defibrillator device is placed in between the latissimus dorsi and serratus anterior muscle layers, has been developed to provide the optimal placement for the generator in the axillary pocket.[19,20,24] This placement can assure optimal location for appropriate rhythm detection, and potentially provide better cosmesis due to the deeper location. Optimal placement of the device, along with an objective assessment of device placement using the Praetorian score,[25] may also improve sensing and reduce inappropriate shock while providing high conversion success,[26] thus also reducing the potential need to reposition the device either during the implant after conversion testing, or subsequent revision surgery, both of which will greatly increase infection risk. The use of blunt dissection to separate the muscle layers will help avoid nicking the muscle layers, which could result in excessive and unnecessary bleeding with increased infection risk.

2.3.4 | Patient optimization

Preoperative bloodwork 3–30 days before implant procedure is often obtained. The most common preoperative blood testing includes complete blood count (CBC), chemistry, and blood glucose levels. These will facilitate the evaluation of anemia or an occult infection and serum creatinine concentration will guide the dosing of antibiotics and anesthetic. An elevated glucose concentration may alert the implanter of possible postponement of the implant if it is above 250 mg/dl.

Important steps can be taken with the patient, as before any surgical procedure, to reduce infection risk in the days leading up to the implant.

In addition, patients should be instructed on the use of an antibacterial cleanser to reduce bacterial skin colonization for the few days preceding and the morning of the implantation.

2.3.5 | Preoperative preparation and antibiotic administration

Upon arrival on the day of the procedure, the patient is brought to the preoperative area, where an updated history and physical is obtained, bloodwork is performed to evaluate CBC, INR, blood chemistry panel, urine pregnancy test, and blood glucose level, and an IV access is secured. A temperature over 100°F is considered a fever and should lead to procedure postponement for further evaluation of a possible infection source. Otherwise, skin in the incision area is carefully examined for rash, eruptions, or evidence of infection. The hair should be removed with an electric clipper with care taken to avoid abrasions, followed by the use of tape to removed clipped hair.

2.3.6 | Prepping and draping

Once the patient is moved into the EP lab, attention to detail in the aseptic skin preparation and draping is key to reducing infection risk (Figure 2). Because the S-ICD implant requires two or three incision sites over a much larger area than TV-ICDs, it is critical that the full area be appropriately, aseptically prepped beyond the incision sites with the recommended aseptic treatment, such as chlorhexidine. In many centers, the device is positioned on the skin with fluoroscopy guidance, then the skin is marked before the aseptic preparation of the skin. Furthermore, care must be taken in placing the defibrillator patches before prepping and draping the patient. That step is usually completed by the scrub nurse, technician, or the physician performing the procedure.

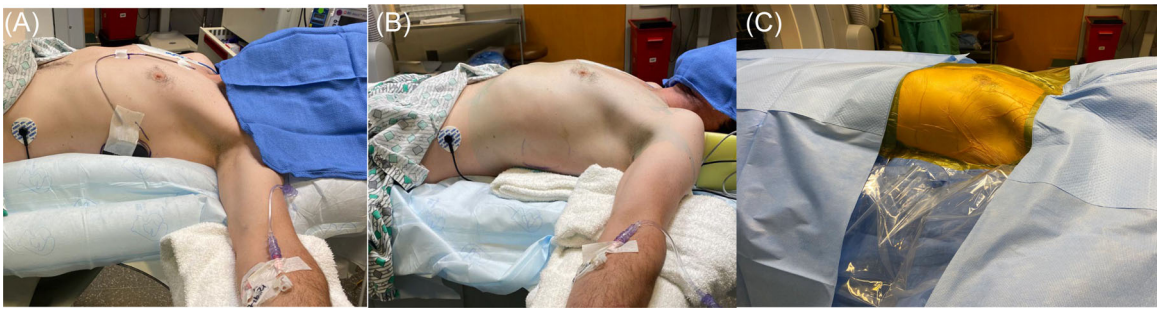

FIGURE 2 Preoperative techniques: Illustrative example of prepping and draping. (A) Initial preparation with markings of the skin prior to prepping. (B) Skin after preparation with chlorohexidine. (C) Large area of surgical exposure.

Draping the patient requires similar meticulous attention to detail. The use of surgical drapes and adhesive dressings, such as Ioban™ antimicrobial incision drapes, are important as they have been proven to reduce infection risk.[27] Placement of the drape well beyond the incision area is important. However, with the additional incisions required for the S-ICD, the larger surgical prep and drape area may require additional time and/or more than one adhesive dressing. The use of pacemaker drapes to create two windows for the two-incision technique has been proposed to assure sufficient aseptic prep with lower overall preparation time.[28] If radiographs are necessary, then use a sterile cover on the radiographic device to maintain the sterility of the surgical site. Ideally, this step is performed initially when the patient is draped and not as an aftermath. Once the draping is complete, it is critical to determine if the final drape placement is optimal, and if not, redo until this is achieved. Everyone in the room plays a crucial role in observing others and verbalizing any concerns.

2.4 | Implant techniques (Supporting Information: Figure 2)

Once the patient is ready for the first incision, it is highly advised to take a surgical time-out and review the antibiotic delivery time to assure the optimal interval has passed but not been exceeded between the start of the IV delivery and the first incision. If necessary, administer a follow-up dose. This is also a good time to recheck the last dose of anticoagulation, if applicable.

When making the incisions, utmost care should be taken to create clean incisions with minimal tissue damage or lacerations to improve wound healing. Avoid aggressive retractions, and avoid dissecting into the muscle layers, which could lead to excessive bleeding. Take the time to achieve thorough hemostasis. The use of cautery tools such as the lighted PhotonBlade™ can help illuminate the deep pocket to detect and stop any bleeding. In addition, the use of the two- versus three-incision technique has been shown to reduce implant time,[21] which may reduce the infection risk.

The procedure used to place the electrode between the device pocket and the xihpoid incision, and between the xihpoid and suprasternal incisions in the three-incision technique, require subcutaneous tunneling, a technique not required for other CIED implants. Research into techniques used for dermal filler injections demonstrates that infection incidence varies with injection technique, with the fanning technique in which the needle is pulled back, then advanced in a new direction immediately before the needle is withdrawn, producing the highest infection incidence.[29] These results suggest that a consistent forward motion, without pulling back and advancing again, may provide the lowest infection risk during S-ICD electrode tunneling.

Many EPs utilize a variety of antibacterial pocket washes once an implant pocket is created. While there is no known adverse effect of this practice, there are no prospective, clinical trial data to support its use; this includes the prevention of arrhythmia device infection trial (PADIT) that is addressed below. Such practices may involve flushing the implant pocket with an antibiotic solution, both before and after device insertion into the pocket, and/or placing antibiotic-soaked lap sponges in the pocket during the implant procedure, although specific details about the antibiotic, dose, and volume vary. The PADIT trial compared conventional antibiotic prophylaxis (cefazolin or vancomycin single-dose IV preimplant infusion) to a more extensive, incremental antibiotic prophylaxis regimen (cefazolin + vancomycin, and an intraoperative pocket wash with bacitracin, and a postoperative oral antibiotic for 2 days) in a prospective, randomized cross-over design study of over 19 000 patients across 28 centers undergoing CIED implant. While the numbers of infections and infection-related hospitalizations were lower in the incremental treatment group, the differences did not achieve statistical significance,[30] possibly due, in part, to the lower-than-expected overall infection rate that reduced statistical power.

The use of an antimicrobial pouch for generator placement to prevent CIED infection has also been evaluated. The efficacy of a second-generation absorbable pouch was evaluated in the WRAP-IT study, which demonstrated effectiveness at reducing infection in TV CIED implants, reducing infections from 1.2% in the control group to 0.7% in the TyRx group.[31] It should be noted that certain high-risk patients, such as those with a previous device infection or those with renal disease on dialysis, were excluded from the study. In addition, the antibacterial drug is released from the mesh over the first 7 days, designed to provide prevention of surgical infection, but it is not designed to address potential subsequent infections from a distant seeding site, such as indwelling catheters. In addition, when considering the number needed to treat analysis[32] and the cost of the pouch, this is not likely a feasible option for most patients, but it should be strongly considered for patients at higher risk of surgical site infection. It is noteworthy that the use of the antibiotic envelope decreased CIED infection by 82% in patients who developed hematoma in the WRAP-IT trial,[14,16] so it could be considered in patients at high bleeding risks such as those treated with dual antiplatelet therapy or antiplatelet and anticoagulant therapy. Given these results, the use of an antibiotics pouch is recommended for patients with high risk for hematoma formation, including patients taking oral anticoagulation or have a coagulopathy as well as patients with diabetes and patients undergoing a pulse generator replacement.

2.5 | Wound dressing and postoperative care (Figure 3 and Supporting Information: Figure 3)

Wound closure is a critical step in infection prevention. With multiple incisions to close, including a larger incision for the device pocket than required for TV-ICDs, the S-ICD closure technique must be optimized to prevent wound dehiscence and resulting pocket infection. While no published data exist indicating the superiority of specific techniques, and techniques vary between EPs, generally recommended best practices are presented. Due to the deeper

location of the device pocket, particularly with the adoption of the intermuscular technique, a three-layer closure is recommended for the pocket incision, with two layers used for the internal layers, along with the superficial skin closure. The use of interrupted stitches with 2-0 vycril for deep layers may be preferred. Superficial layer closure must be both strong and cosmetically acceptable, with the use of surgical glue, ZipLine closure devices, or 4-0 sutures with steri-strips being well-accepted options (Figure 3). For the subcuticular plane, a good alternative is barbed sutures, such as 4-0 V-Loc™, to provide great cosmetic results and avoid skin dehiscence. Note that if conversion testing is to be performed, many EPs choose to perform conversion testing after the closure of the inner device pocket layers to assure a secure placement of the device, but before the outer layer closure in case repositioning needs to occur. A two-layer closure is typically acceptable for the xihpoid and supra-sternal incisions. Once all incisions are closed, it is recommended to obtain a digital photograph of each incision to use as a baseline against which to evaluate subsequent photos for wound checks.

Choice of wound dressing is another area lacking specific data to support certain techniques or products for S-ICD implants. Occlusive dressings left on at least overnight to 48 h should be considered. The use of antibiotic-impregnated dressings may be of value but has not been tested in S-ICD cases. Pressure dressings may be considered postoperatively for procedures at higher risk of hematoma formation. If pre- and intraoperative antibiotic regimens and aseptic techniques are rigorously maintained throughout the procedure, then post-operative antibiotic administration as prophylaxis should be unnecessary.

The patient should be discharged with very specific instructions on dressing removal and changes, along with any instructions for restarting any anticoagulation or other medication that may have been held for the procedure. A postoperative wound check should be scheduled for 1–2 weeks postimplant, with very specific instructions for obtaining cell phone photographs of each incision site if the appointment will be remote. Specific early infection signs to assess at the postimplant wound check are: hot or tender to the touch, edema, erythema, fever, hematoma, or wound dehiscence. Signs that may appear later include most of these early signs along with erosion and pocket pain. As discussed in Baddour et al.,[33] if an S-ICD infection is suspected, then there is typically less urgency to immediately extract the device and electrodes as there is with a TV-ICD, which involves a risk of bloodstream infection that has been rarely described among patients with S-ICD infection. An individualized approach is warranted; nevertheless, complete device extraction should be done promptly.

3 | DISCUSSION

The S-ICD has been a viable option for patients at risk of sudden cardiac death for almost 10 years in the United States and 13 years in Europe. As with any new technique, there is a learning curve for mastering S-ICD implantation, during which time complication rates have been found to decrease.[34] This manuscript is written to summarize techniques for S-ICD implantation of experience culminated from implanting physicians and infectious disease experts. For the ease of the reader, this document integrates recommended techniques that are unique to S-ICD implantation, common between S-ICD and transvenous device implantation, and practices recommended for infection prevention for all surgical procedures.

No prospective clinical trials have been conducted to date to evaluate different potential infection prevention measures pre-, peri-, and post-S-ICD implantation, a modified process mapping methodology with high-volume S-ICD implanters and an infectious disease specialist was convened to establish best practices for the prevention and management of S-ICD infections. The panel's consensus on the diagnosis and management of S-ICD infections was recently published.[33] This report describes the consensus developed through this panel's mapping process in the development of best practice guidelines for the prevention of S-ICD infection.

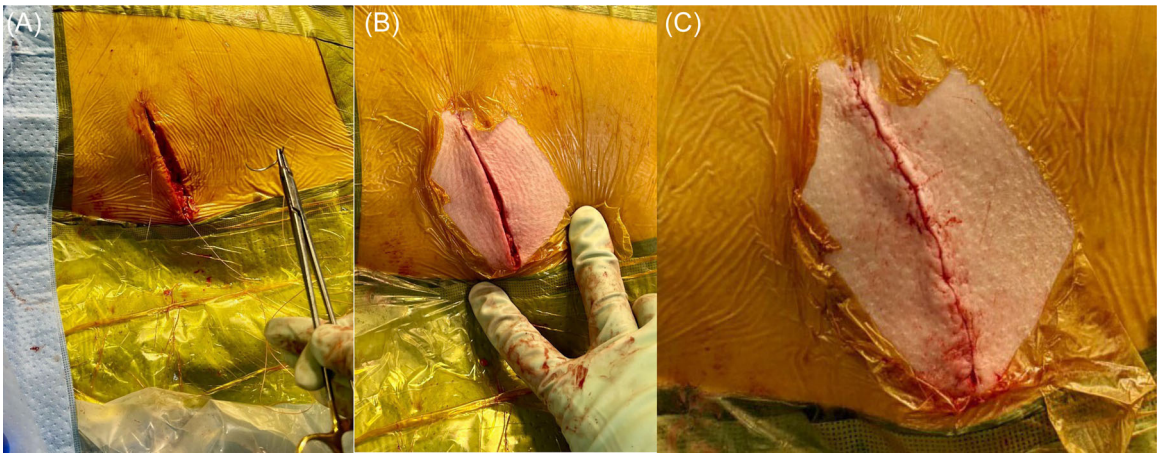

FIGURE 3 Examples of wound closures. (A) Subcutaneous layer closure using 2-0 vycril. Note the perfect hemostasis. (B) Subcutaneous layer completed (note the borders are well approximated and no tension on the skin. (C) Subcuticular layer closure using 4-0 sutures.

The risk of S-ICD infection requiring explant at 1 year was reported as 1.2% and 2.3% in the IDE study[2] and EFFORTESS registry,[35] respectively. The Dutch cohort reported an infection rate of 5.9% in 18 months[36] whereas the UNTOUCHED study of primary prevention patients with a reduced ejection fraction reported an infection rate of 1.1% in the same time frame.[23] The only prospective randomized study to compare infection rates between these device types was the PRAETORIAN trial, which showed 0.9% device infection in the S-ICD arm compared with 1.9% in the TV-arm at 4 years follow-up.[4]

While several studies have reported on overall predictors of S-ICD-related complications, little has been reported specifically on predictors of S-ICD infection. Specifically, the Post Approval Study has reported that patients with a higher risk of S-ICD infection after S-ICD implantation have one or more of the following: a history of diabetes, history of an explanted transvenous device, younger age, and patients who experienced a hematoma post device implantation.[37] Of note, unlike reports of the risk of TV-ICD device infection,[9,10] dialysis was not found to be a risk factor for infection due to S-ICD implantation.

4 | CONCLUSION

Preventing S-ICD infections is multifaceted and should be meticulously planned. Prevention starts with patient selection and involves multiple steps during the pre-, intra-, and postoperative periods by the collaboration of a panoply of specialists with EP clinicians. The mapping process described in this publication details these steps and serves as a contemporary educational tool.

Many steps for preventing infection are shared by TV- and S-ICDs, some of them are more important to the S-ICD group and they are: shared decision-making, skin preparation, decreasing the number of incisions, three layers closure of the pulse generator pocket, and meticulous closure of the skin on all the incisions.

5 | LIMITATIONS

These recommendations are based on a highly experienced group of implanters and a single Infectious Disease Doctor with expertise in CIED, all well versed with the S-ICD literature. These recommendations are not absolute, variations based on implanter experience, equipment availability, local practices, and regional pathogens should be taken into account.

AUTHOR CONTRIBUTIONS

Raul Weiss: Concept/design; data analysis/interpretation; literature review; drafting; critical revision and approval of the manuscript. **George E. Mark, Mikhael F. El-Chami, Timothy McClernon, and Bradley P. Knight**: Concept/design; data analysis/interpretation; critical revision and approval of the manuscript. **Mauro Biffi, Vincent Probst, Pier D. Lambiase, and Marc A. Miller**: Data analysis/interpretation; critical revision and approval of the manuscript. **Linda K. Hansen**: Drafting; critical revision; and approval of the manuscript. **Larry M. Baddour**: Concept/design; data analysis/interpretation; literature review; critical revision and approval of the manuscript.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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