

# Antiseptic Skin Agents for Percutaneous Procedures

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*Infections associated with percutaneously implanted devices, such as pacemakers, internal cardiac defibrillators, and endovascular prostheses, create difficult and complex clinical scenarios because management can entail complete device removal, antibiotic therapy, and prolonged hospitalization. A source for pathogens is often thought to be the skin surface, making skin preparation at the time of the procedure a critical part of minimizing implantation of infected devices and prostheses. The most common skin preparation agents used today include products containing iodophors or chlorhexidine gluconate. Agents are further classified by whether they are aqueous-based or alcohol-based solutions. Traditional aqueous-based iodophors, such as povidone-iodine, are one of the few products that can be safely used on mucous membrane surfaces. Alcohol-based solutions are quick, sustained, and durable, with broader spectrum antimicrobial activity. These agents seem ideal for percutaneous procedures associated with prosthesis implantation, when it is critical to minimize skin colony counts to prevent hardware infection.*

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**T**he issue of procedural and surgical site infection (PSSI) is becoming increasingly relevant among cardiologists as the number of percutaneously implanted devices, such as pacemakers, internal cardiac defibrillators (ICDs), and endovascular prostheses, increases. The trend toward greater utilization of the percutaneous approach to device placement will increase as devices that are currently under investigation for the percutaneous replacement and repair of cardiac valves become approved therapies. From 1990 to 1999, there was a 42% increase in the number of device implant procedures in the United States, which was associated with a 124% increase in the rate of cardiac

device infections.<sup>1</sup> Reported rates of cardiac device-related infection range from 0.13% to 19.9% for pacemakers and reach 0.8% for ICDs.<sup>2</sup> Device-related infections create difficult and complex clinical scenarios because management usually entails complete device removal in patients who may depend on the uninterrupted function of their device, as well as antibiotic therapy and, often, prolonged hospitalization. The cost for managing device-related infections with device removal and antibiotics can be as high as \$50,000.<sup>3</sup> A single-center experience of device-related infections shows that the most commonly identified bacteria is from the staph family (Figure 1).<sup>4</sup> The source for these pathogens is often thought to be the skin surface, making skin preparation at the time of the procedure a critical part of minimizing implantation of infected devices and prostheses.

In situations where the indication for the device implant was for a life-threatening indication, such as complete heart block or sudden cardiac

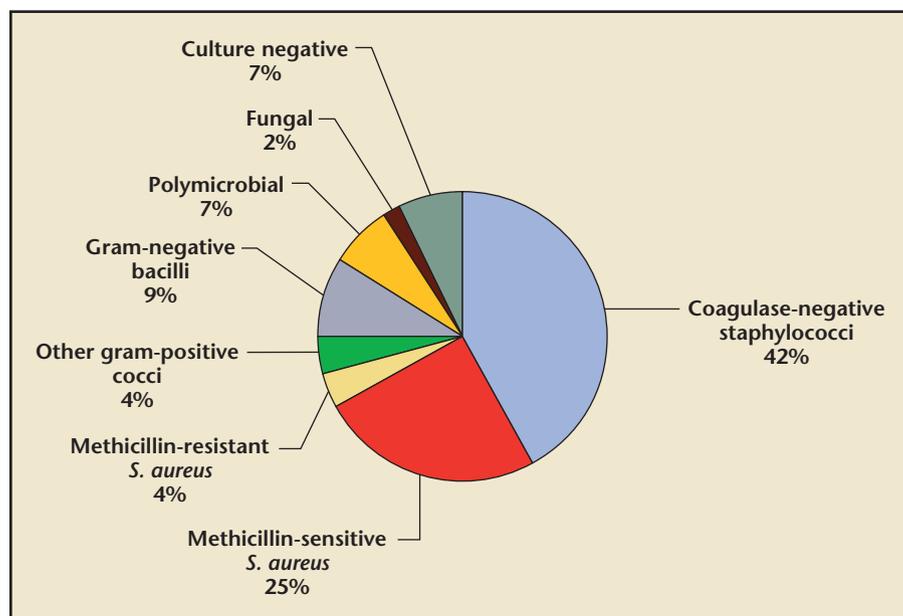
death, device removal creates new issues, including timing of new device implantation. Recognizing this substantial morbidity and economic burden, in 1999 the Centers for Disease Control and Prevention (CDC) issued standardized guidelines for the prevention of surgical infections.<sup>5</sup> The guidelines included specific evidence-based recommendations for modifying patient factors that may predispose to infection, for the use of antimicrobial prophylaxis, for optimizing sterility in the operating room, and for the use of antiseptic agents for skin preparation. The choice of which specific agent to use for skin preparation was not addressed due to the diversity of the sites and approaches in surgery as well as the absence of data on PSSI risk in well-controlled, operation-specific studies. Therefore, the choice of agent should be based primarily on the proceduralist's knowledge of the product's efficacy, cost, and ease of use. This article focuses on skin preparation for the prevention of procedure- and surgery-

related skin infections and assesses currently available antiseptic products and their application to cardiovascular procedures.

### History

The first use of an antiseptic skin agent in surgery is credited to the English surgeon Joseph Lister (1827-1912). Prior to the mid-19th century, limb amputation was associated with an alarming 50% postoperative mortality from sepsis. Following Louis Pasteur's discovery that tissue decay was caused by microscopic organisms, Lister theorized that the spread of these microbes through surgical wounds was responsible for death in the postoperative period. Lister began treating wounds with carbolic acid (phenol) in an effort to prevent tissue decay and the resultant infectious complications. As a result, the incidence of surgical sepsis fell dramatically, catalyzing the adoption of modern antiseptic techniques, including instrument sterilization, the use of surgical scrubs and rubber gloves, and sterile patient preparation.<sup>6</sup>

**Figure 1.** A single-center experience of device-related infections shows that the most commonly identified bacteria is from the *Staphylococcus* family. Reprinted with permission from Sohail MR et al.<sup>4</sup>



### Modern Surgical Skin Preparation

The most common skin preparation agents used today include products containing iodophors or chlorhexidine gluconate (CHG). Agents are further classified by whether they are aqueous-based or alcohol-based solutions (Table 1).

#### Aqueous-Based Solutions

Aqueous-based iodophors, such as povidone-iodine (PVP-I), contain iodine complexed with a solubilizing agent, allowing for the release of free iodine when in a solution. Iodine acts in an antiseptic manner by destroying microbial proteins and DNA. Iodophor-containing products enjoy widespread use because of their broad-spectrum

Table 1  
Characteristics of Antiseptic Solutions

Antiseptic	Mechanism of Action	Antimicrobial Coverage	Onset	Duration	Application	Examples
Aqueous-iodophor	Free iodine – protein, DNA damage	Excellent for gram + bacteria, good for gram –, fungi, virus, Mtb	Intermediate	2 hours <sup>22</sup>	2-step scrub and paint	Betadine* Scrub Care <sup>†</sup>
Aqueous-CHG	Disrupts membranes	Excellent for gram +, good for gram – and virus, fair for fungus, poor for Mtb	Intermediate	6 hours <sup>23</sup>	2-step scrub and dry, repeat	Hibiclens <sup>‡</sup>
Alcohol-iodophor	Denatures protein, free iodine – protein, DNA damage	Improved gram –, Mtb activity	Rapid	48 hours (DuraPrep solution) <sup>11</sup> 96 hours (Prevail-FX) <sup>24</sup>	1-step paint Dry time: minimum of 3 min on a hairless surface	DuraPrep solution <sup>§</sup> Prevail-FX <sup>†</sup>
Alcohol-CHG	Denatures protein, disrupts membranes	Improved gram –, Mtb, fungal activity	Rapid	48 hours <sup>25,26</sup>	Dry site: 30-sec scrub Moist site: 2-min scrub Dry time: minimum of 3 min on a hairless surface	ChlorPrep <sup>  </sup>

\*Betadine<sup>®</sup> is from Purdue Products, LP (Stamford, CT).

<sup>†</sup>ScrubCare<sup>®</sup> and Prevail-FX<sup>®</sup> are from Cardinal Health (Dublin, OH).

<sup>‡</sup>Hibiclens<sup>®</sup> is from Mölnlycke Health Care US LLC (Norcross, GA).

<sup>§</sup>3M<sup>™</sup> DuraPrep<sup>™</sup> Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation is from 3M Health Care (St. Paul, MN).

<sup>||</sup>ChlorPrep<sup>®</sup> is from CareFusion, Inc. (Leawood, KS).

Mtb, *Mycobacterium tuberculosis*; GU, genitourinary; CHG, chlorhexidine gluconate.

Based on data from Mangram AJ et al.<sup>5</sup>

antimicrobial properties, efficacy, and safety on nearly all skin surfaces regardless of the patient's age. In the aqueous form, most commercially available iodophors require a 2-step application that consists of a scrub-and-paint technique, and their activity is limited by the amount of time the agent is in contact with the skin.<sup>7</sup>

A second product, aqueous-based CHG, works by disrupting bacterial cell membranes. CHG has more sustained antimicrobial activity and is more resistant to neutralization by blood products than the iodophors. CHG is applied in a similar manner to PVP-I but should not be used in the genital region. This agent has gained popularity as an antiseptic used prior to surgery for hand scrub-

bing and showering but also continues to be used as a patient skin-prepping agent.<sup>8</sup>

#### Alcohol-Based Solutions

Ethyl and isopropyl alcohol are 2 of the most effective antiseptic agents available. When used alone, alcohol is fast and short acting, has broad-spectrum antimicrobial activity, and is relatively inexpensive.<sup>5</sup> Alcohol-based solutions that contain CHG or iodophors have sustained and durable antimicrobial activity that lasts long after alcohol evaporation.<sup>9</sup> Because alcohol dries on exposed skin within moments of application, these agents can be applied with a 1-step preparation as opposed to a scrub-and-paint technique. A limitation to the use of alcohol in the

operating room is its flammability on skin surfaces prior to evaporation. There have been a few reports of operating room fires originating from alcohol-based skin preparations resulting in significant injury to patients and staff.<sup>10</sup> Flammability can be avoided by allowing skin to completely dry and by avoiding preparation of areas with excessive body hair that can delay alcohol vaporization. Additionally, alcohol-based solutions should not be applied to mucous membranes and therefore have limited utility as antiseptic agents prior to transurethral or transvaginal surgery. Nevertheless, combination solutions with alcohol and CHG or iodophors have gained popularity among general, cardiac, and orthopedic surgeons and may have additional



Figure 2. Application of DuraPrep solution. Courtesy: 3M Health Care (St. Paul, MN).

utility in certain cardiovascular procedures. Recent studies suggest that these products may have greater efficacy, easier application, improved durability, and a superior cost profile when compared with traditional aqueous-based solutions.

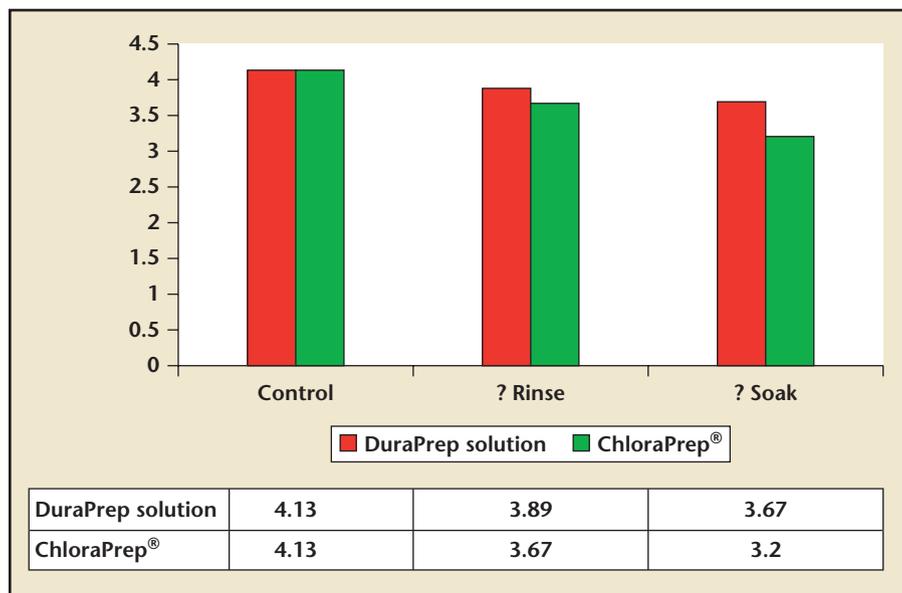
One such product, 3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation (3M Health Care, St. Paul, MN), is an antiseptic skin solution that contains iodine povacrylex and isopropyl alcohol. It is applied in 1 step and has a dry time of a minimum of 3 minutes on hairless skin, leaving a water-insoluble film on the skin surface that maintains antimicrobial activity for up to 48 hours (Figure 2). It resists wash-off by saline and blood products. In vitro studies have demonstrated that DuraPrep solution is effective on a broad range of microorganisms, including those most commonly encountered in genitourinary surgery, including gram-negative rods, *Staphylococcus* species, and enterococcus, as well as multidrug-resistant organisms such as methicillin-resistant *Staphylococcus aureus* (MRSA), methicillin-resistant *S. epidermidis* (MRSE), and vancomycin-resistant enterococci (VRE).<sup>11</sup> Furthermore, DuraPrep solution accomplishes a 6-fold bacterial log reduction within 1 minute of contact, with a greater percentage release of free iodine as compared with the leading aqueous iodophors.<sup>11</sup>

Another potential advantage of this product is its durability in the surgical/procedural environment. In a prospective, randomized surgical simulation study, DuraPrep solution demonstrated better antimicrobial activity after a saline soak when compared with the leading CHG alcohol-based solution (ChloroPrep®, CareFusion, Inc., Leawood, KS), suggesting that it is particularly suitable for use in “wet” surgical environments (Figure 3).<sup>12</sup> Another unique feature of DuraPrep solution is that it enhances adhesion between surgical drapes and the prepared skin surface, theoretically limiting the spread of organisms onto the surgical field. In a

randomized, prospective study comparing drape adhesion in patients undergoing total joint replacement, patients prepared with DuraPrep solution had a significantly smaller area of drape lift than patients prepared with PVP-I: 1.5 cm<sup>2</sup> versus 9.9 cm<sup>2</sup>, respectively ( $P < .0001$ ).<sup>13</sup>

Although there have been no studies in the cardiology literature addressing the effect of this product on procedural site infections, clinical studies have been conducted in general, cardiac, and orthopedic surgery as well as in patients undergoing anesthesia procedures. In a prospective, randomized study of general surgery patients undergoing operations of 3 hours or longer, the use of DuraPrep solution resulted in a 3-fold decrease in PSSI when compared with tincture of iodine.<sup>14</sup> Another study of 3209 general surgical procedures compared the use of 3 skin preparations: a PVP-I scrub-paint combination (Betadine®, Purdue Products, LP, Stamford, CT) (with an isopropyl alcohol application between the steps), ChloroPrep,

Figure 3. Bacterial log reduction after saline challenge.  $P < .003$  for soak condition. DuraPrep solution is from 3M Health Care (St. Paul, MN). ChloroPrep® is from CareFusion, Inc. (Leawood, KS). Reprinted with permission from Stahl JB et al.<sup>12</sup>



and DuraPrep solution.<sup>15</sup> This study used a sequential implementation design, and each agent was used for a 6-month period for all general surgery cases. PSSIs were tracked for 30 days.

DuraPrep solution was associated with the lowest infection rate (3.9%, compared with 6.4% for Betadine and 7.1% for ChlorPrep [ $P = .002$ ]). In subgroup analysis, no difference in outcomes was seen between patients prepared with Betadine/alcohol and those prepared with DuraPrep solution, but patients in both these groups had significantly lower PSSI rates compared with patients prepared with ChlorPrep (4.8% vs 8.2% [ $P = .001$ ]).

In the cardiac literature, a comparison of DuraPrep solution with the leading PVP-I in patients at high-risk for PSSI undergoing open heart surgery found that 4 out of 101 patients in the DuraPrep solution group developed wound infections compared with 14 out of 108 patients in the PVP-I group.<sup>16</sup> In another study, the introduction of DuraPrep solution in a cardiac surgery service was associated with a greater than 50% reduction in overall PSSI, sternal wound infection, and repeat surgical intervention for infection.<sup>17</sup> In a study of patients undergoing epidural catheter placement in an obstetrics ward, DuraPrep solution was prospectively compared with PVP-I. The DuraPrep solution group showed a significant decrease in the number of positive skin cultures obtained immediately after disinfection and immediately prior to catheter removal. In addition, bacteria was cultured from 2 epidural catheter tips in patients treated with DuraPrep solution compared with 13 positive cultures from catheter tips in the PVP-I group.<sup>18</sup> This finding suggests that DuraPrep solution may be particularly suitable for percutaneous renal access procedures in

which catheters are frequently left in place postoperatively and thus serve as a potential entry point for infection.

Finally, a prospective clinical study in the orthopedic literature suggests that alcohol-based solutions with iodophor or CHG may have improved efficacy in reducing bacterial counts in “moist” surgical sites or body regions with increased endogenous bacterial colonization. In a study of patients undergoing foot and ankle surgery, 125 subjects were randomized to receive preparation with DuraPrep solution, ChlorPrep, or a traditional aqueous antiseptic. The sites treated with alcohol-based solutions had an average 50% reduction in positive cultures compared with those treated with traditional antiseptic agents. Overall, ChlorPrep performed twice as well as DuraPrep solution, but the findings of this study have been criticized because no neutralization agent was used before cultures were obtained from the surface of the treated areas. ChlorPrep is a nonfilm-forming antiseptic, and without the use of a neutralizer, it is likely that in this group, the antiseptic contaminated other samples and led to ongoing bacterial death and exaggerated efficacy. Additionally, no patients developed PSSI in the DuraPrep solution group.<sup>19</sup> These findings can be generalized to other “moist” surgical sites, suggesting that alcohol-based solutions may be efficacious for use in cardiovascular procedures that use groin access for the femoral artery, especially for implantation of foreign devices, such as prosthetic cardiac valves or vascular endoprosthesis, when minimizing bacterial counts is critical.

In addition to efficacy, other important considerations in the selection of a skin preparation agent are ease of use, cost, and user satisfac-

tion. In a prospective comparison of alcohol-based iodophors with the traditional PVP-I preparation, the alcohol-based solutions had shorter application and drying times. Taking into consideration operating room time and product expenses, the alcohol-containing products had lower overall costs.<sup>20</sup> Other studies have confirmed this finding, showing that the use of DuraPrep solution confers potential savings of \$78 per patient (Table 2).<sup>21</sup> Despite these advantages, operating room personnel preferred PVP-I scrub and paint to the alcohol preparations, citing concerns over flammability as the most important overall deciding factor. Familiarity with PVP-I paint and scrub, however, may have introduced bias into the assessment of user satisfaction because personnel had little to no experience with alcohol-based solutions prior to the study.<sup>20</sup> With safe use and proper instruction, alcohol-based antiseptics may save valuable time and operating room resources.

## Conclusions

The goal of preoperative skin preparation is to reduce the incidence of procedure- and surgical-related skin infections in a safe, user-friendly, and cost-effective manner. Because cardiologists perform a breadth of different operations accessing a variety of vascular sites, a standard antiseptic agent is unlikely to be uniformly optimal. Traditional aqueous-based iodophors, such as PVP-I, are ideal for transvaginal and transurethral surgery and are one of the few products that can be safely used on mucous membrane surfaces. Likewise, alcohol-based solutions, such as DuraPrep solution, are quick, sustained, and durable, with broader spectrum antimicrobial activity. These agents seem ideal for percutaneous procedures associated with prosthesis implantation, when it is

**Table 2**  
**Comparison of Antiseptic Products**

Antiseptic	OR Durability		Incidence of Surgical Site Infection			Ease of Use	
	Soak Stahl et al <sup>12</sup> N = 36 P = .006	Drape lift Jacobson et al <sup>13</sup> N = 171 P < .0001	General Pinheiro et al <sup>14</sup> N = 214 P < .05	General Swenson et al <sup>15</sup> N = 3209* P = .002	Cardiac Segal and Anderson <sup>16</sup> N = 209 P = .02	Application Armstrong et al <sup>20</sup> N = 25	Cost Roberts et al <sup>21</sup> N = 200 P = .0001
DuraPrep solution <sup>†</sup>	3.7 bacterial log reduction	1.5 cm <sup>2</sup>	4.8%	3.9%	4%	82.8 sec With drape application	\$56.96
Tincture of Iodine	—	—	14.7%	—	—	—	—
Prevail <sup>‡</sup>	—	—	—	—	—	42.2 sec	—
ChloroPrep <sup>§</sup>	3.2 bacterial log reduction	—	—	7.1%	—	—	—
PVP-I	—	9.9 cm <sup>2</sup>	—	6.4%	13%	228 sec	\$135.28

\*Number of procedures.

<sup>†</sup>3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation is from 3M Health Care (St. Paul, MN).

<sup>‡</sup>Prevail-FX® is from Cardinal Health (Dublin, OH).

<sup>§</sup>ChloroPrep® is from CareFusion, Inc. (Leawood, KS).

OR, operating room; PVP-I, povidone-iodine.

Adapted with permission from Roberts AJ et al.<sup>21</sup>

## Main Points

- Device-related infections create difficult and complex clinical scenarios because management usually entails complete device removal in patients who may depend on the uninterrupted function of their device, as well as antibiotic therapy and, often, prolonged hospitalization.
- Aqueous-based iodophors, such as povidone-iodine, contain iodine complexed with a solubilizing agent, allowing for the release of free iodine when in a solution. Iodine acts in an antiseptic manner by destroying microbial proteins and DNA. Iodophor-containing products enjoy widespread use because of their broad-spectrum antimicrobial properties, efficacy, and safety on nearly all skin surfaces regardless of the patient's age.
- Ethyl and isopropyl alcohol are 2 of the most effective antiseptic agents available. When used alone, alcohol is fast and short acting, has broad-spectrum antimicrobial activity, and is relatively inexpensive. Flammability can be avoided by allowing skin to completely dry and by avoiding preparation of areas with excessive body hair that can delay alcohol vaporization.
- Recent studies suggest that alcohol-based solutions may have greater efficacy, easier application, improved durability, and a superior cost profile when compared with traditional aqueous-based solutions.
- DuraPrep solution, an antiseptic skin solution that contains iodine povacrylex in isopropyl alcohol, shows durability in the surgical/procedural environment and enhances adhesion between surgical drapes and the prepared skin surface, theoretically limiting the spread of organisms onto the surgical field.
- Alcohol-based solutions seem ideal for percutaneous procedures associated with prosthesis implantation, when it is critical to minimize skin colony counts to prevent hardware infection.

critical to minimize skin colony counts to prevent hardware infection. Because alcohol is flammable, when these products are used, care must be taken to allow adequate drying time and to remove excessive hair that may delay alcohol vaporization from the prepared field. ■

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