APLICARE®

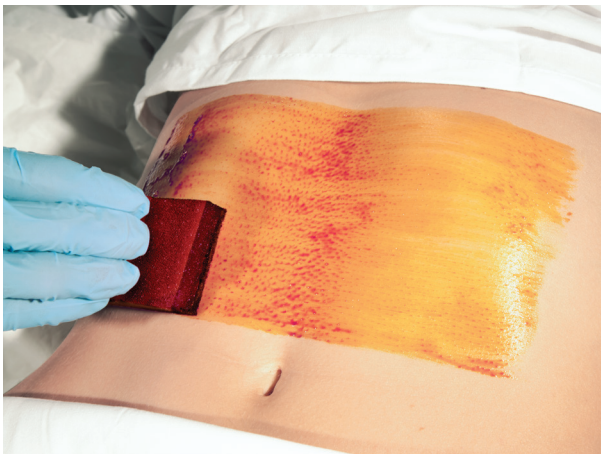
Povidone-Iodine Products for Compliant Skin Antisepsis

CLOROX HEALTHCARE™

When to Use Povidone-Iodine for Skin Antisepsis Compliance

Selection of the right skin antisepsis product is key to delivering better patient outcomes. It is important to be aware of and follow drug facts when leading chlorhexidine gluconate-based products are contraindicated.

For procedures that correspond to the contraindications listed on manufacturers' product labels, povidone-iodine is a proven and safe skin antiseptic for patient preoperative skin preparation.



COMPLIANT SKIN ANTISEPSIS

A fact-based primer for when leading chlorhexidine-based products are contraindicated. For these contraindications, povidone-iodine can be used in place of CHG-based products.

Leading chlorhexidine gluconate (2%) / isopropyl alcohol (70%) product[1]	Leading chlorhexidine gluconate (4%) / product[2]	Common procedures impacted	Hospital locations include:
Do not use CHG/IPA in children less than 2 months of age because of the potential for excessive skin irritation and increased drug absorption.	**Use with care** in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.	• Central venous catheter insertions and site maintenance • Open heart surgery • Congenital malformation repairs	• NICU • Operating Room • Radiology
Do not use for lumbar puncture or in contact with the meninges, on open skin wounds or as a general skin cleanser.	**Do not use in contact with the meninges.**	• Lumbar punctures, including spinal taps • Procedures contacting the meninges • Craniotomy • Placement of ventricular catheters/ shunts	• Operating Room • Labor and Delivery • Radiology
Keep out of eyes, ears and mouth. May cause serious or permanent injury if permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a doctor.	**Do not use as a patient preoperative skin preparation of the head and face.**	• Tympanoplasty • Ear tube placement • Cochlear implant • Oral surgery of any kind	• Operating Room • Emergency Room
Flammable. Keep away from fire or flame.	Not flammable.	Care should be taken during all usage occasions.	All locations where product is used

1. http://www.carefusion.com/pdf/Infusion/IP_CP_10_5ml_InService.pdf, as of June 2012. Product brochure, June 2012. MRK-12002.
2. Source: http://www.molnlycke.com/Old/Global/Surgical_Products/US/HiBi/Hibiclens%20information%20sheet.pdf. Product brochure, June 2012. MHC-2012-0020.

The Aplicare® Difference

Aplicare's commitment to product quality and safety has helped us become the leading, most trusted povidone-iodine brand used for medical and procedural kits.

- **Manufacturing quality and safety**
- **Packaging integrity**
- **Meets FDA standards for sterility**

Manufacturing quality and safety

Each batch of Aplicare® povidone-iodine is manufactured and packaged in the United States and not outsourced to overseas suppliers. Aplicare sets and maintains rigorous quality controls over each povidone-iodine product we produce for your facility.

Packaging integrity

Aplicare's easy-to-open, no-leak foil packages and plastic bottles enable high product performance by preventing product waste and spillage, ensuring product formula stability and by helping to maintain the sterile field.

Meets FDA standards for product sterility

At its plant in Connecticut, Aplicare is the only manufacturer that takes an extra step to terminally sterilize its foil-packed povidone-iodine products using a specialized heating process. Each production batch is monitored closely and tested to confirm that it meets the FDA's standards for sterility at a 6-log reduction. In addition, Aplicare's production and quality engineers conduct annual reviews to revalidate the proprietary sterilization process to further ensure continuous product sterility.

Why is sterility critical to patient and staff safety?

Product sterility — the assurance that your product is not contaminated — is key to delivering better patient outcomes and ensuring the safety of your medical team. Incidences of product contamination have led to tragic patient outcomes. In addition, such incidences can be costly to a healthcare facility and its patient safety record.

While virtually all antiseptic solutions can be subject to bacterial contamination, Aplicare's terminal sterilization of unit-of-use packages is designed to help decrease the risk of these organisms from finding their way to already compromised patients.

The most recent event occurred in 2011 and involved recalls of both alcohol and iodine-based skin antisepsis products, including alcohol prep pads.[3]

3. FDA Recall Letter of February 5, 2011, http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm239319.htm.

Povidone-Iodine Portfolio

Patient skin preparation solutions for every need and occasion

POVIDONE-IODINE SCRUB

Cleanser for patient preoperative skin preparation

- 7.5% povidone-iodine USP, 0.75% available iodine as listed in the FDA Monograph[1]
- Meets CDC, AORN and APIC guidelines for skin antisepsis
- Broad-spectrum efficacy shown against skin pathogens, including Gram-negative and Gram-positive bacteria, fungi, viruses, protozoa and yeasts
- Formulated with detergents for a rich golden lather for enhanced cleaning
- Nonirritating to skin, wounds and mucosa when used as directed
- Nonstaining to skin and fabrics when used as directed

POVIDONE-IODINE SOLUTION (PAINT)

Efficacy for patient preoperative skin preparation

- 10% povidone-iodine USP, 1% available iodine as listed in the FDA Monograph[1]
- Meets CDC, AORN and APIC guidelines for skin antisepsis
- Broad-spectrum efficacy shown against skin pathogens, including Gram-negative and Gram-positive bacteria, fungi, viruses, protozoa and yeasts
- Multipurpose: appropriate for disinfecting of wounds and burns and emergency antiseptic treatment of lacerations and abrasions
- Nonirritating to skin, wounds and mucosa when used as directed
- Nonstaining to skin and fabrics when used as directed

1. Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Products. Federal Register, Vol. 59, No. 116, Friday, June 17, 1994, p. 31402-52 (Proposed Rule). 21 CFR Parts 333 and 369.
2. FDA-approved "Options for Arm Preparation", dated January 29, 2004, original source: http://www.fda.gov/cber/blood/armpreprev.htm.

POVIDONE-IODINE GEL

One-step patient preoperative skin preparation

- 10% povidone-iodine USP, 1% available iodine as listed in the FDA monograph[1]
- Meets guidelines published by the FDA for one-step site preparation prior to blood draw[2]
- Meets CDC, AORN and APIC guidelines for skin antisepsis
- Broad-spectrum against skin pathogens, including Gram-negative and Gram-positive bacteria, fungi, viruses, protozoa and yeasts
- Thicker viscosity helps prevent dripping, running and pooling
- Nonirritating to skin, wounds and mucosa when used as directed
- Nonstaining to skin and fabrics when used as directed

A COMPLETE PORTFOLIO FOR BROAD PATIENT SKIN PREPARATION USAGE

Patient Preoperative Skin Preparation	Patient Site Preparation	Site Preparation Prior to Blood Draw
Can be used for external use surgical procedures, except in case of allergies to iodine	**Catheter care and intravenous site preparation** **Vascular access site preparation and/or care of:** • Peripheral Lines • Midlines • PICCs • Central Lines	**Blood Donor Collection** **Blood Culture** **Hemodialysis** **Biopsy Procedures**
Note for these procedures: Povidone-Iodine Gel can be used as a substitute for Povidone-Iodine Solution (Paint)	**Note for these procedures:** Povidone-Iodine Gel can be used as a substitute for Povidone-Iodine Solution (Paint).	**Note for these procedures:** Povidone-Iodine Gel can be used as a one-step antiseptic.

Do not use in eyes. For external use only.

Povidone-Iodine Facts

Iodine has been used for decades and is one of the oldest known skin antisepsis solutions. Povidone-iodine use dates back to 1955 when it was quickly adopted and widely used as a topical solution for skin antisepsis. Despite its long history of safe, effective usage for skin antisepsis, we want to ensure you have the information needed to use povidone-iodine with confidence.

FICTION: CDC Guidelines require me to use chlorhexidine gluconate-based skin antiseptics; if I do not, I am out of compliance.

FACT: There are three key CDC guidelines that speak to antiseptic use. All support compliant use of povidone-iodine for skin antisepsis.

(1) The 1999 *Guideline for the Prevention of Surgical Site Infections* (SSI) states, "Use an appropriate antiseptic agent for skin preparation (Table 6) (Category 1B)."

(2) The 2009 *Guideline for the Prevention of Catheter-Associated Urinary Tract Infections* (CAUTI) states, "Use sterile gloves, drape, sponges, an appropriate antiseptic or sterile solution for periurethral cleaning, and a single-use packet of lubricant jelly for insertion (Category 1B)."

(3) The 2011 *Guideline for the Prevention of Intravascular Catheter-Related Infections* (CRBSI) states, "Before central venous catheter and peripheral arterial catheter insertion and during dressing changes … an iodophor … can be used … (Category IA)."

FICTION: Povidone-iodine's efficacy is inactivated in the presence of blood, serum or other organic matter.

FACT: This is not true in clinical settings. When iodine comes in contact with organic matter such as blood, it destroys the organic matter and the microorganisms, and in the process gets used up. But each milliliter of povidone-iodine has so much capacity to deliver iodine that, in a clinical setting, there is more than enough to destroy whatever organic material is typically present. Dr. Gottardi — a leading expert in povidone-iodine chemistry — has studied this issue and concluded: "In practice, no substantial decrease in the bacterial efficacy of 10% povidone-iodine preparations is likely with body fluids having a composition similar to plasma …".[1]

FICTION: Aren't most patients and staff — or at least those with shellfish allergies — allergic to povidone-iodine?

FACT: This is not true. While povidone-iodine may cause allergic contact or irritant dermatitis, this is rare and has no correlation to allergy to seafood or contrast media. While it is true that seafood may contain relatively high levels of iodine compared with other foods, the allergenic proteins in seafood are not iodinated and seafood allergy does not depend on the iodine content of the seafood.[2]

1. Gottardi, W. Iodine and iodine compounds. In: Block, SS, ed. Disinfection, Sterilization, and Preservation. 4th ed. Philadelphia: Lea & Febiger; 1991:151-66.
2. Katelaris, CH. 'Iodine allergy' is misleading. Australian Prescriber 2009 32:5 125-128, available at http://www.australianprescriber.com/upload/pdf/articles/1048.pdf and Coakley, FV, Panick, DM. Iodine allergy: an oyster without a pearl? AJR 169:951-2, available at http://www.ajronline.org/content/169/4/951.full.pdf+html.

Product Usage and Ordering Information

	Healthcare personnel handwashing	Surgical hand scrub	Site preparation for injections, IV placement, blood draw	Preparation of patient skin prior to surgery	General skin and wound cleansing	Emergency antiseptic treatment of lacerations and burns
 **Povidone-Iodine Scrub 7.5%** (0.75 Avail. Iodine) Bottles SHELF LIFE: 24 months/30* months	✓	✓	✓	✓	✓	

Reorder #	82-223	82-212*	82-247	82-227	82-279	82-220	82-211
Description	48/2 oz. Screw Cap Bottle	72/4 oz. Screw Cap Bottle	24/8 oz. Flip-Top Bottle	12/16 oz. Screw Cap Bottle	12/16 oz. Pump Bottle	12/32 oz. Screw Cap Bottle	4/128 oz. Screw Cap Bottle

 **Povidone-Iodine Scrub 7.5%** (0.75% Avail. Iodine) Swabsticks SHELF LIFE: 24 months			✓	✓	✓	

Reorder #	S-1102
Description	10 boxes of 50 Single Swabsticks

 **Povidone-Iodine Solution (Paint) 10%** (1.0% Avail. Iodine) Bottles SHELF LIFE: 24* months/36 months			✓	✓	✓	✓	

Reorder #	82-222	82-332*	82-255	82-217	82-226	82-226F*	82-219	82-209
Description	48/2 oz. Screw Cap Bottle	24/2 oz. Pump Spray Bottle	72/4 oz. Flip-Top Bottle	24/8 oz. Screw Cap Bottle	12/16 oz. Screw Cap Bottle	12/16 oz. Flip-Top Bottle	12/32 oz. Screw Cap Bottle	4/128 oz. Screw Cap Bottle

 **Povidone-Iodine Solution (Paint) 10%** (1.0% Avail. Iodine) Swabsticks SHELF LIFE: 24 months			✓	✓	✓	✓

Reorder #	S-1101	S-3101
Description	10 boxes of 50 Single Swabsticks	10 boxes of 25 Triple Swabsticks

 **Povidone-Iodine Gel 10%** (1.0% Available Iodine) Bottle SHELF LIFE: 36 months			✓	✓		

Reorder #	82-269
Description	72/4 oz. Flip-Top Bottle

 **Povidone-Iodine Gel 10%** (1.0% Avail. Iodine) Swabsticks SHELF LIFE: 24 months			✓	✓		

Reorder #	S-1138
Description	10 boxes of 50 Single Swabsticks

FDA-Registered Manufacturer
Registration No. in Connecticut: 1220701
Registration No. in West Virginia: 1120159

3. Guideline for Prevention of Surgical Site Infection, 1999. Available at http://www.cdc.gov/hicpac/pdf/guidelines/SSI_1999.pdf
4. Guideline for Prevention of Catheter-Associated Urinary Tract Infections, 2009. Available at http://www.cdc.gov/hicpac/pdf/CAUTI/CAUTIguideline2009final.pdf
5. CDC Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011. Available at http://www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf

Use as directed.

FDA-Registered Manufacturer
Registration No. in Connecticut: 1220701
Registration No. in West Virginia: 1120159

For more information, contact your Clorox representative at **1-800-760-3236** or email AplicareCustomerService@clorox.com.

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