

Selection, Handling, Application for Use and Storage of Patient Skin Antiseptic Products for Invasive Procedures Outside the Operating Room

Note: This recommendation does not apply to injections or to urinary catheterization. Follow AHS topic specific documents, e.g., the *Adult Surgical Patient Skin Preparation in the Operating Room/Treatment Areas Practice Direction Manual* for invasive procedures in the operating room; the *Standard for the Administration of Immunizations* for injections and the Clinical Care Topic: *Urinary Catheter Management, All Ages –All Locations*, Infection Prevention and Control section for urinary catheterization.

Terms in bold are defined in the **Definitions** section.

If you have any questions or comments contact IPC at ipcsurvstdadmin@ahs.ca.

Best practice recommendations

Purpose

- To provide recommendations for the selection, handling, application, use and storage of skin **antiseptic** products.
- To standardize patient skin antiseptic products for **invasive procedures** outside of the operating room.
- To reduce the risk of skin antiseptic contamination and infection transmission.

Applicability

- This recommendation applies to all Alberta Health Services (AHS) staff, medical staff, students and other persons acting on behalf of AHS.

1. IPC principles

- 1.1 Use [routine practices](#) including [hand hygiene](#) for all patients, at all times, to reduce the risk of infection.
- 1.2 Maintain aseptic technique when applying skin antiseptics.
- 1.3 Read and follow the product label when selecting, handling, applying, using and storing skin antiseptics.
- 1.4 Consult the [Safety Data Sheet](#) (SDS) for information about safe use of the skin antiseptic product including appropriate personal protective equipment.
- 1.5 **Off-label** use of skin antiseptics is not recommended. Document any off-label use of skin antiseptics in the health record.
- 1.6 Healthcare providers should be educated; trained; and **competent** in the selection; application; use; and storage of skin antiseptics.

2. Skin antiseptics

2.1 General

- Skin antiseptic products obtained for use in AHS must have a drug identification number (DIN) or a natural product number (NPN) as outlined in the 2019 [Health Canada Guidance for Human-Use Antiseptic Drugs](#) document.

Note: Skin antiseptics approved by Health Canada are manufactured according to the 2009 [Good Manufacturing Practices Guideline](#) (refer to **Good Manufacturing Practices** in the **Definitions** section) so skin antiseptics, while not necessarily labelled sterile, are safe for their intended use.

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3. Skin antiseptic

- 3.1 Select the most suitable skin antiseptic product and delivery system, e.g., applicator, sponge pack, container, large or small swabs, large or small wipe, for the task to be performed.
- 3.2 Chlorhexidine 2% with isopropyl alcohol 70% is the preferred antiseptic for skin preparation before invasive procedures on intact skin.
- 3.3 Use povidone iodine 10% as an alternative skin antiseptic when chlorhexidine 2% with alcohol 70% is contraindicated. Povidone iodine 10% should be used:
 - if patients have sensitivities or allergies to chlorhexidine 2% with alcohol 70%;
 - for mucous membranes such as the mouth and vagina;
 - on eyes and ears;
 - for infants less than 2 months old; and
 - in emergent trauma when there is not sufficient time to allow chlorhexidine 2% with alcohol 70% to completely dry before incision.

Notes: The 3M™ chlorhexidine 2% with alcohol 70% product label states “avoid contact with meninges” allowing the clinician to weigh risk versus benefit when using the product for spinal or epidural procedures. To prevent contact with meninges avoid contamination of equipment and gloves used for the lumbar puncture procedure and allow the product to dry before the skin is palpated or punctured.

Patients may absorb povidone iodine and if povidone iodine is used on particularly vulnerable patients, i.e., lactating mothers, pediatric or neonatal patients; consider rinsing the povidone iodine off once the procedure is complete. Chlorhexidine skin antiseptics are generally not rinsed off as they offer excellent residual effect against microorganisms.

- 3.4 Select single-use skin antiseptic preparations whenever possible. Single-use skin antiseptic preparations reduce the risk of exposure to a contaminant, e.g., diluting products with contaminated water or “topping-up” of bulk products.
- 3.5 Discard single-use skin antiseptic preparations after use for a single procedure on an individual patient.

4. Application and drying times

- 4.1 Use one prep sponge or applicator for a single product application on the skin and then discard. Use a new sponge or applicator for each subsequent application of the product to prevent contamination of the incision/puncture site.
- 4.1 Follow the product label regarding the:
 - method of application for the skin antiseptic. Application methods may include swabbing in a circular motion, e.g., from insertion site outwards; or swabbing back and forth horizontally and then vertically. Refer to 3M™ [Summary of Clinical Studies](#) document, page 13 for a visual description. The term hashtag refers to the back and forth application method.
 - required application time. Application time means the length of time the product is actively applied in contrast to contact time which just reflects how long the product is sitting on the skin.
 - required drying time. Dry time is affected by product, product volume, body site, presence or absence of hair, humidity etc., e.g., drying time can vary from 30 seconds for a very small volume applicator; ~2 minutes before central line insertion; and >3 minutes for larger volumes used for surgical site preparation. Areas with excess hair or moist sites such as axillae and groins may take longer to dry.

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4.2 Avoid dripping or pooling of the skin antiseptic on sheets, padding, positioning equipment, adhesive tape, and on or under the patient. Pooling of products can cause skin maceration. Pooling of alcohol-based products can be a fire risk if a spark is present, e.g., cautery.

5. Multi-use containers

Once a multi-use container of antiseptic solution is open there is an increased risk of external contamination. If a multi-use container is used follow these steps:

- 5.1 Check the expiry date of the skin antiseptic and discard if past the date of expiry.
- 5.2 When the multi-use skin antiseptic is first opened record the following information on the container:
 - date of opening;
 - date the container is to be discarded; and
 - initials of the person who opened the container.
- 5.3 Store open multi-use skin antiseptic containers in a clean area protected from contamination. Discard:
 - aqueous skin antiseptic solutions, i.e., povidone iodine, 7 days after opening.
 - alcohol skin antiseptic solutions, i.e., chlorhexidine 2% with alcohol 70%, 30 days after opening.
- 5.4 Do not top-off or refill multi-use containers.
- 5.5 If expired product is being regularly discarded/wasted, consider using single-use products or smaller volume containers that will be used up more quickly.
- 5.6 Do not touch the container neck, rim or inside of the cap. Do not purchase product containers that cannot be opened without touching the container neck, rim or inside of the cap.
- 5.7 Dispense the necessary amount of solution into a sterile container intended for immediate use on a single patient and close the container immediately.
- 5.8 Do not pour skin antiseptics into secondary containers for use on multiple patients. The skin antiseptic should be dispensed at the point-of-use for a specific patient and not left out of sight or unattended.

6. Storage

- 6.1 Follow the storage instructions on the product label.
- 6.2 Store in the original container.

7. Warming

- 7.1 Never heat or warm flammable skin antiseptics, e.g., chlorhexidine 2% with alcohol 70%.
- 7.2 Warm non-flammable, unopened, skin antiseptic solutions only if the product label provides directions on how to safely do so.
- 7.3 Never warm skin antiseptics in a microwave oven or an autoclave.

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Definitions

Antiseptic means a product with antimicrobial activity. Skin antiseptic preparation aids in preventing surgical site infections (SSIs) by removing debris from, and cleansing the skin to reduce the resident and transient microbes to a minimum, and to hinder the growth of microbes during the invasive procedure.

Aseptic technique means the purposeful prevention of transfer of microorganisms from the patient's body surface to a normally sterile body site or from one person to another by keeping the microbe count to an irreducible minimum. Aseptic techniques, sometimes referred to as sterile techniques, are measures designed to render the patient's skin, supplies and surfaces maximally free from microorganisms. Such practices are used when performing procedures that expose the patient's normally sterile sites, e.g., intravascular system, spinal canal, subdural space, urinary tract, in such a manner as to keep them free from microorganisms. Components of aseptic technique prior to a procedure may involve the following: preparing the patient's skin with an antiseptic; hand hygiene, preferably with alcohol based hand rub or, if not accessible, an antimicrobial soap; sterile gloves, gowns, masks, equipment, and drapes; and maintaining a sterile field.

Competent means adequately qualified, suitably trained and with sufficient experience to safely perform work without supervision or with only a minimal degree of supervision.

Expiry date indicates the safe period of use for an unopened product. Degradation of the product or a component of the product may occur after the expiry date of an unopened container or before the expiry date if a product has been opened.

Good Manufacturing Practices (GMP) are manufacturing processes required by Health Canada to ensure that the fabrication, packaging, labelling, distribution, testing and wholesaling of drugs, e.g., human-use skin antiseptics, do not place consumers at risk due to inadequate safety and quality.

Invasive procedure is a procedure that invades (enters) the body, usually by cutting or puncturing the skin or by inserting instruments into the body. For the purpose of these recommendations injections and urinary catheter insertions are not included as invasive procedures. Examples include, but are not limited to: insertion of central venous catheters, chest tubes, and percutaneous drains.

Product label means the validated, written directions provided by the manufacturer or distributor of a medical device or product that contain the necessary information for the safe and effective use of the medical device or product.

Off-label means the use of skin antiseptics for a purpose outside of the manufacturer's instructions, e.g., an indication, age group, dose or form of administration not approved by the manufacturer.

References

1. Campbell J. P., Platt F., Checketts M. R., Bogod D., Tighe S., Moriarty A., Koerner R.. 2014. Safety guideline: skin antisepsis for central neuraxial blockade. Guidelines. Working Party Association of Anaesthetists of Great Britain and Ireland, Obstetric Anaesthetists' Association Regional Anaesthesia UK Association of Paediatric Anaesthetists of Great Britain and Ireland.
2. Health Canada. Guidance Document for Human Use Antiseptic Drugs. 2019. Minister of Health, Health Products and Food Branch. Accessed at http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/antiseptic_guide_ld-eng.php.
3. Operating Room Nurses of Canada. 2019. Guidelines and Position Statements for Perioperative Registered Nursing Practice. 14th Edition. Canadian Standards Association (CSA).
4. Public Health Agency of Canada. 2013. Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Healthcare Settings. Accessed at <https://www.canada.ca/content/dam/phac-aspc/documents/services/publications/diseases-conditions/routine-practices-precautions-healthcare->

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[associated-infections/routine-practices-precautions-healthcare-associated-infections-2016-FINAL-eng.pdf](#).

Resources

1. 3M Solu Prep Brand. 2018. Summary of Clinical Studies for Professional Healthcare Use Approval in Canada. 3M™ SoluPrep™ 2% chlorhexidine gluconate (CHG) and 70% isopropyl alcohol (IPA) preoperative skin antiseptic. Available at <https://multimedia.3m.com/mws/media/1602666O/3mtm-solupreptm-clinical-studies.pdf>.
2. 3M Solu Prep Brand™. 2018. Whitepaper: Quality of 3M Canada Skin Antiseptic Drug Products 3M™ SoluPrep™ 2% chlorhexidine gluconate (CHG) and 70% isopropyl alcohol (IPA). Dr. Michelle Alfa. Available at: <https://multimedia.3m.com/mws/media/1455409O/white-paper-quality-of-3m-canada-drug-products.pdf>.
3. 3M™ videos about skin antiseptics by Dr. Michelle Alfa: [3M™ SoluPrep™ Brand Skin Antiseptic Products – Dr. Alfa: It's the solution that counts - video series](#).

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