3M Health Care Business
3M Center
St. Paul, MN 55144-1000

March 11, 2010

Janet Corrigan, PhD, MBA
President and CEO
National Quality Forum
601 Thirteenth St, NW
Suite 500 North
Washington, DC 20005

Request to Remove Recommendation of a Specific Preoperative Skin Preparation

Dear Dr Corrigan,

As background, 3M is committed to patient safety by providing commercial solutions that help reduce risk of surgical site infection (SSI). Additionally, we are committed to continued innovations to further improve patient safety through ongoing discovery, research and development activities. We collaborate with professional associations and experts globally in an effort to bring these solutions to healthcare settings where patients receive care.

In follow-up to previous communications with members of the Safe Practices Committee regarding Safe Practice #22 and its recommendation of a specific surgical skin antiseptic preparation, we are formally requesting an NQF Ad Hoc Review of the recommendation under Criteria #1 and #2.

Criterion #1: "The evidence supporting the focus of the measure, practice, or event has changed and it no longer reflects updated evidence". The Draft Safe Practices notes in the Comments section for Safe Practice 22, "Based on the results of a randomized, controlled trial showing that chlorhexidine gluconate 2% and isopropyl alcohol significantly reduced SSI compared to povidone iodine for preoperative skin antisepsis, the committee recommended this as an additional specification." As we discuss in more detail below, this study did not assess DuraPrep, an iodine povacrylex and alcohol surgical prep, and it cannot be concluded that Chloraprep would perform better than DuraPrep based on this study. Furthermore, the performance of ChloraPrep and DuraPrep was assessed in a recent publication that was not reviewed by the committee, and as we discuss below, DuraPrep performed better than ChloraPrep in this study. 3M believes that these studies suggest the need for additional clinical study before the NQF Safe Practices can recommend one prep over another.

Criterion #2. "There is evidence that the implementation of the measure or practice may result in unintended consequences", Section A. "Use of the measure or practice may result in inappropriate or harmful care." Safe Practice #22 recommends a surgical prep that is contraindicated in meninges, and accordingly it is not appropriate to include it in a general recommendation.

We respectfully request the committee's review of the enclosed reference materials.

The specification of a single surgical skin antiseptic preparation is not supported with an adequate body of evidence published in peer reviewed journals and may compromise patient safety.

Rationale:

- Clinical Evidence. The majority of skin preparation clinical studies conducted over the past decades measured only non-validated surrogate endpoints such as skin flora reduction. Recently two large clinical studies, comparing the effect of different surgical skin preparations on SSI rates in general surgical procedures, have been published.
  1. Swenson et al (1)
     - Quasi-experimental design comparing SSI outcomes by sequential 6 month periods and by prep
     - Compared three commercially available skin preparations:
       - CHG/alcohol (chlorhexidine gluconate 2% and 70% isopropyl alcohol)
       - iodine-povacrylex/alcohol (iodine povacrylex and isopropyl alcohol 74% w/w)
       - PVP-I (povidone iodine) with alcohol paint
     - The use of both iodophor-based preparations resulted in significantly lower SSI rates than the use of CHG/alcohol, concluding that the iodophor preps may be better than CHG/alcohol
     - Limitations: study design is less robust than a randomized trial

  2. Darouiche et al (2)
     - Randomized clinical trial
     - Compared two commercially available skin preparations CHG/alcohol versus aqueous PVP-I (no alcohol)
     - The use of CHG/alcohol preparation resulted in significantly lower SSI rates than the use of PVP-I, concluding that CHG/alcohol is better than PVP-I
     - Limitations:
       - compared CHG/alcohol with a prep containing only PVP-I (two active ingredients versus one)
       - did not include iodine povacrylex/alcohol
       - did not include the use of PVP-I with alcohol

Each of these studies has its limitations and the body of evidence is incomplete. Therefore further studies are required to determine which preps are appropriate in a broader surgical population.

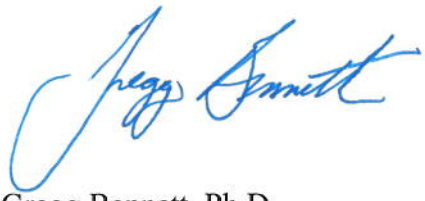
- Additional Limitations/Contradictions. Surgical skin antiseptics containing alcohol are limited in application due to contra-indications for use in open wounds and mucosal tissue. CHG antiseptics are further contra-indicated for use in procedures involving potential exposure to meninges (spine, epidurals, craniotomy procedures), for prepping the head or face and the genital area (Attachment 1). Consequently, this limits the use of CHG and alcohol combination products to ~40% of all surgeries (3).

- Available Surgical Skin Preparations. There are currently many surgical site antiseptics that meet FDA standards on microbial log reduction (ie effective kill of skin flora studies done according to ASTM-1173 methodology). These include but are not limited to:
  - CHG 4% solution
  - PVP-I solution
  - iodine povacrylex/alcohol
  - CHG/alcohol

  This portfolio of surgical skin preparations enables surgeons to safely meet patient needs broadly.

3M respectfully requests that NQF remove the proposed recommendation in Safe Practice Number 22 to use a single preoperative skin preparation. Clearly, the body of clinical evidence supporting the recommendation of any single surgical skin preparation is incomplete at this time and standardization to a single surgical skin antiseptic may compromise patient safety.

Sincerely,



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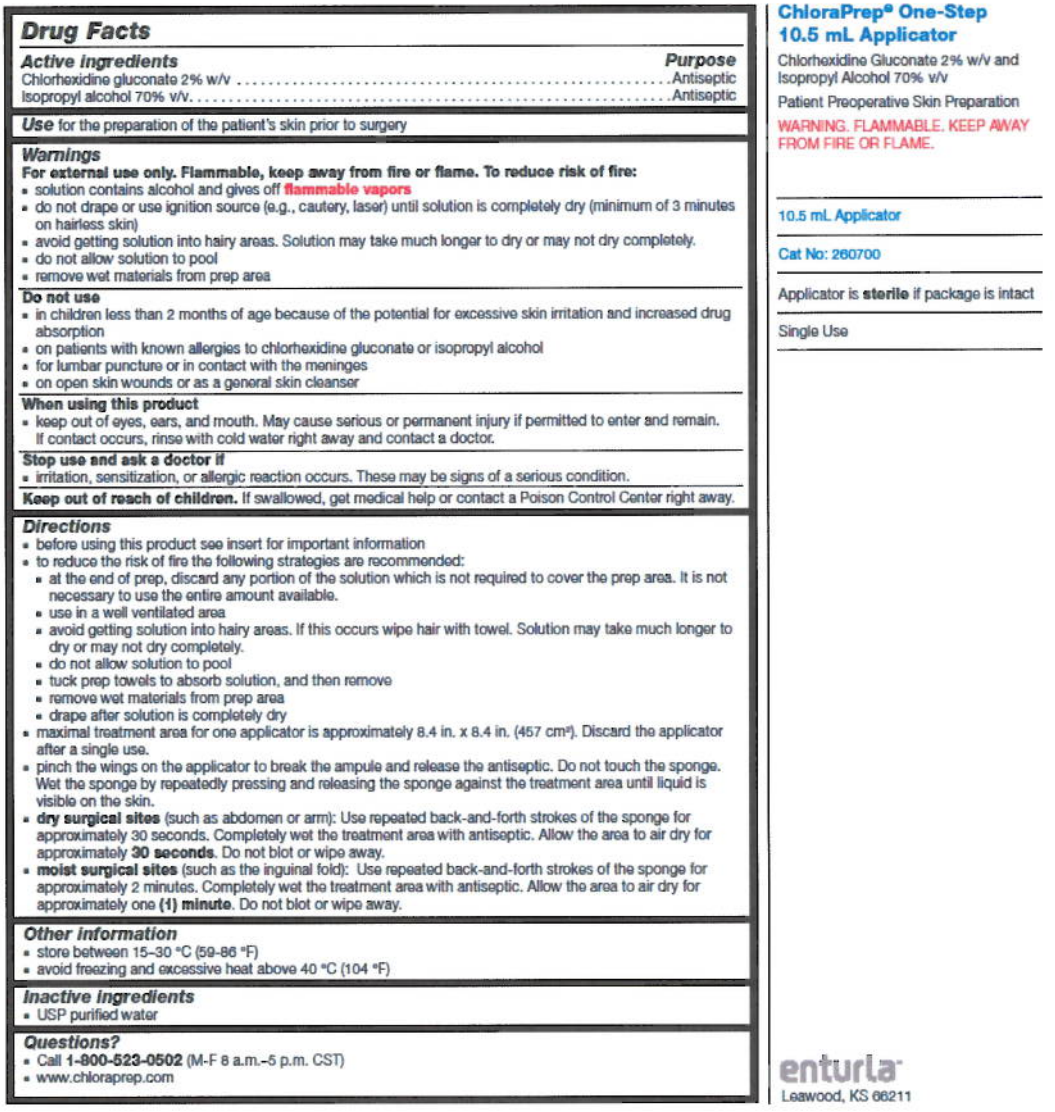
References:

1. Swenson BR, Hedrick TL, Metzger R, Bonatti H, Pruett TL, Sawyet RG. *Infect Control Hosp Epidemiol 2009; 30:964-971*
2. Darouiche RO, Wall MJ, Itani KMF, Oterson MF, Webb AL, Carrick MM, Miller HJ, Awad SS, Crosby CT, Mosier MC, AlSharif A, Berger DH. *N Engl J Med 2010; 362:18-26*
3. National Health Statistics Reports, Number 5, July 30, 2008. Tables 8, 9, 10.

Attachment 1



Drug Facts

Active ingredients	Purpose
Chlorhexidine gluconate 2% w/v	Antiseptic
Isopropyl alcohol 70% v/v	Antiseptic

Use for the preparation of the patient's skin prior to surgery

Warnings

For external use only. Flammable, keep away from fire or flame. To reduce risk of fire:

- solution contains alcohol and gives off **flammable vapors**
- do not drape or use ignition source (e.g., cautery, laser) until solution is completely dry (minimum of 3 minutes on hairless skin)
- avoid getting solution into hairy areas. Solution may take much longer to dry or may not dry completely.
- do not allow solution to pool
- remove wet materials from prep area

Do not use

- in children less than 2 months of age because of the potential for excessive skin irritation and increased drug absorption
- on patients with known allergies to chlorhexidine gluconate or isopropyl alcohol
- for lumbar puncture or in contact with the meninges
- on open skin wounds or as a general skin cleanser

When using this product

- 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.

Stop use and ask a doctor if

- irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- before using this product see insert for important information
- to reduce the risk of fire the following strategies are recommended:
  - at the end of prep, discard any portion of the solution which is not required to cover the prep area. It is not necessary to use the entire amount available.
  - use in a well ventilated area
  - avoid getting solution into hairy areas. If this occurs wipe hair with towel. Solution may take much longer to dry or may not dry completely.
  - do not allow solution to pool
  - tuck prep towels to absorb solution, and then remove
  - remove wet materials from prep area
  - drape after solution is completely dry
- maximal treatment area for one applicator is approximately 8.4 in. x 8.4 in. (457 cm^2). Discard the applicator after a single use.
- pinch the wings on the applicator to break the ampule and release the antiseptic. Do not touch the sponge. Wet the sponge by repeatedly pressing and releasing the sponge against the treatment area until liquid is visible on the skin.
- **dry surgical sites** (such as abdomen or arm): Use repeated back-and-forth strokes of the sponge for approximately 30 seconds. Completely wet the treatment area with antiseptic. Allow the area to air dry for approximately **30 seconds**. Do not blot or wipe away.
- **moist surgical sites** (such as the inguinal fold): Use repeated back-and-forth strokes of the sponge for approximately 2 minutes. Completely wet the treatment area with antiseptic. Allow the area to air dry for approximately one **(1) minute**. Do not blot or wipe away.

Other information

- store between 15–30 °C (59–86 °F)
- avoid freezing and excessive heat above 40 °C (104 °F)

Inactive ingredients

- USP purified water

Questions?

- Call **1-800-523-0502** (M-F 8 a.m.–5 p.m. CST)
- www.chloraprep.com

ChloraPrep® One-Step 10.5 mL Applicator

Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v

Patient Preoperative Skin Preparation

WARNING. FLAMMABLE. KEEP AWAY FROM FIRE OR FLAME.

10.5 mL Applicator

Cat No: 260700

Applicator is **sterile** if package is intact

Single Use

enturia

Leawood, KS 66211