CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
21-586

LABELING
DuraPrep™
Surgical Solution
Iodine Povacrylex (0.7% Available Iodine) and Isopropyl Alcohol (74% w/w)
Patient Preoperative Skin Preparation for large prep areas below the neck

Keep away from fire or flame.
To reduce the risk of fire:
• Do not use 26-mL applicator for head and neck surgery.
• Do not use on an area smaller than 8 in. x 10 in.
• Use a small applicator instead.
• 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 leak much longer to dry or may not dry completely.
• Do not allow solution to pool.
• Remove solution-stained material from prep area.

Single Use
Sterile Contents:
Applicator w/urethane sponge (1)
Cotton-tipped swabs (2)
Sterility of sterile contents guaranteed unless package is damaged or open.

DuraPrep Surgical Solution is a film-forming iodophor complex. Each unit dose applicator contains 0.9 fl oz (26mL) of solution which covers a 15 in. x 30 in. area (approximately from shoulder to groin in an average size adult).

For procedures requiring less coverage, a smaller applicator is available (8635). It contains 0.2 fl oz (6mL) of solution which covers an approximate 8 in. x 10 in. area. Do not use more than required for the area.

3M recommends all users participate in product in-service training prior to use. In-service is available on video from our 3M sales representative, or at the 3M website (www.3m.com).

Cat. No. 8630 0.9 fl oz • 26 mL

(01) 0 03 17518 01108 5
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Patient Take Home Instructions
Your surgeon used 3M™ DuraPrep Surgical Solution, a bacteria-killing skin preparation. It is recommended that this film remain on the site after the procedure. The film will gradually wear away. If, however, early removal is desired:
• Apply 8610 or 8611 3M™ Remover Lotion to the prep area keeping away from the wound edge or puncture site. Wipe off with a disposable towel, or
• Soak gauze with 70% isopropyl alcohol and place on the prepared area for at least 40 seconds. Gently scrub to remove the solution.

If you have questions, call 1-800-222-3577.

Artwork #: 38-9001-8943-2
Date: 9/21/06
Author: S Barker
Supersedes 38#: 38-9001-7489-7
Pkg. Spec. Reference: 34-7060-
Structure: INS

Scale | | | | | | | | | |
1 inch

Prints
= PMS 032
= PMS 346
= PMS 2685
and Black

FOR PRINTER USE ONLY
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3M™ DuraPrep™ Surgical Solution 8630

Drug Facts

Active ingredients: Isopropyl alcohol, 70% v/v.

Purpose
Antisepctic

Uses
Preoperative skin preparation: for preparation of the skin prior to surgery

Warnings
For external use only. Flammable. Keep away from fire or flame. To reduce the risk of fire
- Do not use 25-ml applicator for head and neck surgery
- Do not use on airways smaller than 6-8 mm. Use a small applicator sinus
- Solution contains alcohol and may cause irritation
- Do not apply to or within 1 inch of the eyes
- Do not apply to skin that is sensitive to alcohol
- Do not use on open wounds, mucous membranes or as a general skin cleanser
- Do not use in infants less than 2 months old due to the risk of excessive skin irritation and transient hypoglycemia

Hypersensitivity
When using this product
- Keep out of eyes, ears, and mouth. May cause serious injury if swallowed or inhaled. If contact occurs, flush with cold water right away and contact a doctor
- In case of eye contact: Avoid skin irritation: skin may be taken when removing excess, tears, etc.; applied over nose
- Use with caution in women who are breast feeding due to the potential for transient hypoglycemia in the nursing infant

Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition. If use continues, use of this product has been associated with skin tightening. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions (follow all directions for use)
- At the end of the 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.

Getting Patient Ready for Solution:
- Use in well-ventilated area
- Do not immerse or heat the solution applicator
- Apply only to completely dry, hair-free, intact skin
- When hair removal is necessary, use a surgical clipper or the shaving solution. If a wet shave is used, thoroughly remove all soap residues.

Activating the Applicator:
- With spout facing parallel to the floor, press the clip end of the applicator. Solution will begin to flow into the squeegee.
- Well for fluid level to reach indicator line of applicator barrel

When Applying Solution:
- RINSE GENTLY: Pour a single, uniform application and do not tamp area
- Do not allow solution to pool. Use spout applicator to absorb excess solution and continue to apply a uniform coating. If solution accidentally gets outside of prep area, remove excess with gauze
- Gently wipe applicator with alcohol 70% (70% alcohol by volume) before applying. (Moisten applicator by pressing against solution-soaked sponge applicator)
- Do not spread solution beyond the edges of the neck to absorb excess solution. Remove towels before drying
- Avoid getting solution into hair roots. If this occurs, wipe hair with towel. Solution may take much longer to dry or may not dry completely
- When prepping skin folds, toes, or fingers, use a sterile-gloved hand to hold skin until completely dry. Otherwise, skin may adhere to itself.

After Applying Solution:
- To reduce the risk of fire, wait until solution is completely dry (minimum of 3 minutes on hairless skin). Solution will turn from a shiny to a dull appearance on skin allowing the user to determine that the solution is completely dry and no longer flammable.

While Waiting for Solution to Completely Dry:
- Do not rub or use air/water device (e.g., air, ozone, foam)
- Check for proper solution. Use sterile gauze to test on gauze solution. Do not test because it may remove solution from skin
- Remove solution-stained materials. Replace if necessary

After Solution is Completely Dry:
- To reduce the risk of fire, begin dressing and/or using cautery only after solution is completely dry. An additional layer of solution and all solution-stained materials are removed
- If access drapes are used, apply directly to dry prep. On completion of surgical procedure, removal of access drapes will remove film
- Apply dressing following standard practices

Other Information:
- Solution is not water soluble and may stain. If clothing is stained, wash with a non-bleach detergent or soap

Inactive ingredients:
- Isopropyl alcohol, water

Questions? Call 1-800-228-3957. Monday to Friday 7AM-6PM CST. 3M.com
DuraPrep™ Surgical Solution
Iodine Povidone Iodine (0.7% Available Iodine) and Isopropanol Alcohol (74% w/v)
Patient Preoperative Skin Preparation for head, neck, and small prep areas

Keep away from fire or flame.

To reduce the risk of fire:
• Solution contains alcohol and gives off flammable vapors
  • Do not dress or use ignition source (e.g., candle, lighter) until solution is completely dry (minimum 3 minutes on skinless 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 solution-stained material from prep area.

Single Use
Sterile Contents:
Applicator swab (1)
Sterility of sterile contents guaranteed unless package is damaged or open.

DuraPrep Surgical Solution is a 1:10 dilution of povidone-iodine. Each 1/2 oz applicator pad contains 2.2 oz (60mL) of solution which covers an approximate 9 in. x 9 in. area.

3M recommends to users participate in product training prior to use.

In servicing is available on order from your 3M sales representative, or at the 3M website (www.3M.com).

Cat. No. 8635 0.2 fl oz = 6 mL

Patient Take Home Instructions
Your surgeon used 3M™ DuraPrep™ Surgical Solution, a bacterial killing skin preparation. It is recommended that the films remain on the skin after the procedure. The films will gradually wear away. If, however, early removal is desired:

• Apply 8610 or 8611 3M™ Remover Lotion to the prep area keeping away from the wound edge or puncture site. Wipe off with a disposable towel, or
• Soak gauze with 70% isopropanol alcohol and place on the prep area for at least 60 seconds. Lightly scrubs to remove the solution.

If you have questions, call 1-800-228-3957

Prints
• PMS 032
• 30% PMS 346
• PMS 2685

and Black

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# 3M™ DuraPrep™ Surgical Solution 8635

## Drug Facts

**Active ingredients**
- Iodoform 1.23% (7.7% available iodine)
- Iodophor 1.23%
- Ethanol alcohol 74%

**Uses**
- Aids in the preparation of skin prior to surgery

**Warnings**
- Do not use on patients with known allergy to iodine or any other component in this product
- Do not use in areas of maceration or dermatitis, or as a general skin cleanser.
- In infants less than 2 months old due to the risk of excessive skin irritation and transient hypothermia.

**Directions**

1. Before using, check the expiration date on the label and make sure the solution is not cloudy or discolored.
2. Before use, remove all eye, mouth, or body contact lenses.
3. When applying solution, do not apply around eyes, mouth, or nose, or on exposed mucous membranes.
4. When applying, be sure to apply the solution to the entire area to be treated.
5. After applying, wash hands thoroughly with soap and water.

**Preparation**

- Before use, remove all eye, mouth, or body contact lenses.
- When applying solution, do not apply around eyes, mouth, or nose, or on exposed mucous membranes.
- When applying, be sure to apply the solution to the entire area to be treated.
- After applying, wash hands thoroughly with soap and water.

**Other Information**
- Store in a cool, dry place and away from direct sunlight.
- If solution gets into the eyes, wash with plain water.
- If solution is accidentally swallowed, seek medical advice immediately.

**Questions?**
- Call 1-800-228-3927 Monday to Friday 8AM - 8PM CST. www.3M.com
3M™ DuraPrep™ Surgical Solution 8630

Drug Facts

Active ingredients

Purpose

Antiseptic agent (7.5% available iodine) Antiseptic

Uses

Antiseptic preoperative skin preparation; for preparation of the skin prior to surgery.

Warnings

For external use only. Flammable, keep away from fire or flame.

To reduce the risk of fire:

- do not use 70% isopropanol for hand and neck surgery
- do not use on an area smaller than 8 in. (16 cm), a small applicator insert
- use only in a well-ventilated area
- do not use drape up in use (ignition source, e.g., cautery, laser) until solution is completely dry (minimum of 3 minutes on hairless skin)
- avoid getting solution into eyes or mouth. Solution may cause temporary eye or mouth irritation
- do not allow solution to pool
- remove solution stained materials from prep area

Do not use:

- on patients with known allergies to iodine or any other ingrediens at this product
- on open wounds or on mucous membranes, or on a sterile skin preparation
- on areas less than 2 inches due to a risk of corrosive skin irritation and transient hypopigmentation

When using this product:

- keep out of reach of pets, cats, and birds. May cause serious injury if permitted to enter and inhale. If contact occurs, flush with cool water and seek medical attention
- wash skin resale, do not have a lesion or an allergic reaction occurs. These may be signs of a serious condition. On rare occasions, use of this product may be associated with skin irritation
- use with caution in women who are pregnant or breastfeeding due to the potential for transient hypopigmentation in the nursing baby

Stop using the product and consult a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition. On rare occasions, use of this product may be associated with skin irritation.

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

Directions (follow all directions for use)

- at the end of the 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.

Getting Patient Ready for Solution:

- use in well-ventilated area
- do not use in areas with heat or direct sunlight
- apply to clean, dry, sensation-free sites
- when hair removal is necessary, use a surgical clipper on the morning of the surgery. If it is a wet shave, it is saved. Gently remove all razor residue.

Activating the Application:

- with sponge face parallel to the floor, press the cap end of the applicator. Solution will begin to flow into the sponge.
- wait for fluid level to reach indicator level of applicator barrel

When Applying Solution:

- DO NOT SCRUB. Paint a single, uniform application and do not reapply area.
- do not add solution to preop. Use a single applicator for sterile access solution and continue to apply a uniform coating. If solution accidentally gets outside of prep area, remove excess with gentle wash
- clean umbilicus with unsaturated swabs when applicable. (Menzel swabs by passing against solution and allow excess solution to pool on) (option)
- pack preps towels as needed under both sides of the neck to absorb excess solution. Remove towels before dressing.
- patient getting solution into hair area. If this occurs, wipe with towel. Solution may cause temporary irritation or may not dry completely
- when prepping skin, feet, or fingers, use a gentle-glove hand to hold skin apart until complete dry. Otherwise, skin may adhere to glove.

After Applying Solution:

- to remove the risk of fire, wait until solution is completely dry (minimum of 3 minutes on hairless skin). Solution will turn from a shiny to a dull appearance on skin showing the area that the solution is completely dry and no longer flammable.

While Waiting for Solution to Completely Dry:

- do not dry or use any incision source (e.g., cautery, laser)
- check for puddles. Use sterile gauze to absorb puddled solution. Do not bleed. Do not bleed because it may remove solution from skin.
- remove solution-stained materials. Replace if necessary.

After Solution is Completely Dry:

- to remove the risk of fire, begin dressing and/or using cautery only after solution is completely dry and all solution-stained materials are removed
- if injury drains are used, apply directly to dry area. Completion of surgical procedure removes drainage will remove latex
- apply dressing following standard practices.

Other information:

- store between 20-25°C (68-77°F). Avoid excessive heat above 25°C (77°F). Solution is not water soluble and may dewater. Therefore, avoid contact with water-soluble materials (for example, paper, plastic, instruments).

Inactive ingredients:

- ethyl alcohol, water

Questions? call 1-800-228-3657 (Monday to Friday 7AM - 6PM CST). www.3M.com.
PRODUCT TITLE
3M™ DuraPrep™ Surgical Solution
Iodine Povacrylex (0.7% Available Iodine) and Isopropyl Alcohol (74% w/w)
Patient Preoperative Skin Preparation

DESCRIPTION
3M™ DuraPrep™ Surgical Solution is a film-forming iodophor complex that provides fast acting, persistent, broad-spectrum antimicrobial activity. DuraPrep solution is indicated for use as a patient preoperative skin preparation, for the preparation of the skin prior to surgery and to help reduce bacteria that can potentially cause skin infection.

DuraPrep solution contains alcohol and gives off flammable vapors. Pooled solution or solution-stained materials can lead to fire. Follow all instructions in product insert.
CLINICAL PHARMACOLOGY

In vitro Microbiology Studies

The following in vitro data are available but their clinical significance is unknown.

Time Kill Studies (LIMS 8919):
In an independent Time Kill Study, the speed of the microbicidal activity of DuraPrep solution was measured using a select battery of microorganisms including antibiotic resistant organisms. As shown in Table 1, DuraPrep solution demonstrated rapid bactericidal activity against the broad range of microorganisms tested.

<table>
<thead>
<tr>
<th>Microorganism</th>
<th>% Microbial Kill 15 Seconds</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Enterococcus faecalis</em> (ATCC 29212)</td>
<td>99.99</td>
</tr>
<tr>
<td><em>Escherichia coli</em> (ATCC 11229)</td>
<td>99.99</td>
</tr>
<tr>
<td><em>Escherichia coli</em> (ATCC 25922)</td>
<td>99.99</td>
</tr>
<tr>
<td><em>Micrococcus luteus</em> (ATCC 7468)</td>
<td>98.90</td>
</tr>
<tr>
<td><em>Pseudomonas aeruginosa</em> (ATCC 15442)</td>
<td>99.99</td>
</tr>
<tr>
<td><em>Pseudomonas aeruginosa</em> (ATCC 27853)</td>
<td>99.99</td>
</tr>
<tr>
<td><em>Serratia marcescens</em> (ATCC 14756)</td>
<td>99.99</td>
</tr>
<tr>
<td><em>Staphylococcus aureus</em> (ATCC 29213)</td>
<td>99.99</td>
</tr>
<tr>
<td><em>Staphylococcus aureus</em> (ATCC 6538)</td>
<td>99.99</td>
</tr>
<tr>
<td><em>Staphylococcus epidermidis</em> (ATCC 12228)</td>
<td>99.99</td>
</tr>
<tr>
<td><em>Staphylococcus aureus</em> (MRSA) (ATCC 33592)</td>
<td>99.99</td>
</tr>
<tr>
<td><em>Enterococcus faecalis</em> (VRE) (ATCC 51299)</td>
<td>99.99</td>
</tr>
<tr>
<td><em>Enterococcus faecium</em> (MDR) (ATCC 51559)</td>
<td>99.99</td>
</tr>
<tr>
<td><em>Staphylococcus epidermidis</em> (MRSE) (ATCC 51625)</td>
<td>99.99</td>
</tr>
<tr>
<td><em>Candida albicans</em> (ATCC 10231)</td>
<td>99.84</td>
</tr>
</tbody>
</table>

MRSA – methicillin-resistant *Staphylococcus aureus*

MDR – multiple drug resistant (ampicillin, ciprofloxacin, gentamicin, rifampin, teicoplanin, vancomycin)

VRE – vancomycin-resistant *Enterococcus sp.*

MRSE – methicillin-resistant *Staphylococcus epidermidis*
In an independent Time Kill Study (LIMS 7311) where bacteria (~10^7 CFU) were placed on top of the dried film, the speed of the microbicidal activity was measured using a select battery of microorganisms including antibiotic resistant organisms. As shown in Table 2, DuraPrep solution demonstrated rapid bactericidal activity against the broad range of microorganisms tested.

<table>
<thead>
<tr>
<th>Microorganism</th>
<th>Organisms Placed on Top of Dried DuraPrep Film</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>% Microbial Kill</td>
</tr>
<tr>
<td></td>
<td>1 Minute</td>
</tr>
<tr>
<td><strong>Acinetobacter baumannii</strong> (ATCC 19606)</td>
<td>99.99</td>
</tr>
<tr>
<td><strong>Acinetobacter lwoffi</strong> (ATCC 15309)</td>
<td>99.99</td>
</tr>
<tr>
<td><strong>Burkholderia cepacia</strong> (ATCC 25416)</td>
<td>99.92</td>
</tr>
<tr>
<td><strong>Enterobacter aerogenes</strong> (ATCC 13048)</td>
<td>88.39</td>
</tr>
<tr>
<td><strong>Escherichia coli</strong> (ATCC 25922)</td>
<td>99.77</td>
</tr>
<tr>
<td><strong>Klebsiella oxytoca</strong> (ATCC 43165)</td>
<td>99.97</td>
</tr>
<tr>
<td><strong>Klebsiella pneumoniae</strong> (ATCC 11296)</td>
<td>99.13</td>
</tr>
<tr>
<td><strong>Pseudomonas aeruginosa</strong> (ATCC 9027)</td>
<td>99.99</td>
</tr>
<tr>
<td><strong>Serratia marcescens</strong> (ATCC 14756)</td>
<td>99.61</td>
</tr>
<tr>
<td><strong>Corynebacterium jeikeium</strong> (ATCC 43734)</td>
<td>99.99</td>
</tr>
<tr>
<td><strong>Enterococcus faecalis</strong> (ATCC 19433)</td>
<td>99.82</td>
</tr>
<tr>
<td><strong>Enterococcus faecium</strong> (ATCC 19434)</td>
<td>82.12</td>
</tr>
<tr>
<td><strong>Micrococcus luteus</strong> (ATCC 4698)</td>
<td>99.95</td>
</tr>
<tr>
<td><strong>Staphylococcus aureus</strong> (ATCC 6538)</td>
<td>97.72</td>
</tr>
<tr>
<td><strong>Staphylococcus aureus</strong> (MRSA) (ATCC 33592)</td>
<td>84.93</td>
</tr>
<tr>
<td><strong>Staphylococcus epidermidis</strong> (ATCC 12228)</td>
<td>99.99</td>
</tr>
<tr>
<td><strong>Staphylococcus haemolyticus</strong> (ATCC 29970)</td>
<td>99.99</td>
</tr>
<tr>
<td><strong>Staphylococcus hominis</strong> (ATCC 27844)</td>
<td>99.99</td>
</tr>
<tr>
<td><strong>Staphylococcus saprophyticus</strong> (ATCC 15305)</td>
<td>99.61</td>
</tr>
<tr>
<td><strong>Streptococcus pneumoniae</strong> (ATCC 6303)</td>
<td>99.99</td>
</tr>
<tr>
<td><strong>Streptococcus pyogenes</strong> (ATCC 19615)</td>
<td>96.08</td>
</tr>
<tr>
<td><strong>Candida albicans</strong> (ATCC 10231)</td>
<td>80.59</td>
</tr>
</tbody>
</table>

**MRSA** – methicillin-resistant *Staphylococcus aureus*
**VRE** – vancomycin-resistant *Enterococcus* sp.
Minimum Bactericidal Concentration (MBC) (LIMS 7720):
In an independent study conducted at one laboratory, MBCs were measured for DuraPrep solution against 1051 isolates while the vehicle control and reference product were tested against 211 isolates of the organisms listed in Table 3 below. DuraPrep solution demonstrated antiseptic activity against all organisms tested.

<table>
<thead>
<tr>
<th>Microorganism</th>
<th>Lab Strains</th>
<th>Clinical Isolates</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>MBC Range (µg/ml)</td>
</tr>
<tr>
<td>Acinetobacter sp.</td>
<td>25</td>
<td>0.25-2</td>
</tr>
<tr>
<td>Bacteroides fragilis</td>
<td>20</td>
<td>0.25-2</td>
</tr>
<tr>
<td>Haemophilus influenzae</td>
<td>25</td>
<td>0.125-2</td>
</tr>
<tr>
<td>Enterobacter sp.</td>
<td>25</td>
<td>0.5-2</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>25</td>
<td>0.5-1</td>
</tr>
<tr>
<td>Klebsiella sp.</td>
<td>25</td>
<td>0.25-1</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>25</td>
<td>0.5-8</td>
</tr>
<tr>
<td>Proteus mirabilis</td>
<td>25</td>
<td>0.5-2</td>
</tr>
<tr>
<td>Serratia marcescens</td>
<td>25</td>
<td>0.5-2</td>
</tr>
<tr>
<td>Staphylococcus aureus including MRSA</td>
<td>25</td>
<td>0.5-2</td>
</tr>
<tr>
<td>Staphylococcus epidermidis including MRSE</td>
<td>25</td>
<td>0.125-2</td>
</tr>
<tr>
<td>Staphylococcus hominis</td>
<td>12</td>
<td>0.5-2</td>
</tr>
<tr>
<td>Staphylococcus haemolyticus</td>
<td>6</td>
<td>0.5-1</td>
</tr>
<tr>
<td>Staphylococcus saprophyticus</td>
<td>5</td>
<td>1-2</td>
</tr>
<tr>
<td>Micrococcus luteus</td>
<td>25</td>
<td>0.5-4</td>
</tr>
<tr>
<td>Streptococcus pyogenes</td>
<td>25</td>
<td>0.25-16</td>
</tr>
<tr>
<td>Enterococcus. faecalis including VRE</td>
<td>25</td>
<td>0.5-4</td>
</tr>
<tr>
<td>Enterococcus faecium including VRE</td>
<td>25</td>
<td>1-4</td>
</tr>
<tr>
<td>Streptococcus pneumoniae</td>
<td>25</td>
<td>0.125-8</td>
</tr>
<tr>
<td>Candida sp.</td>
<td>25</td>
<td>1-16</td>
</tr>
<tr>
<td>Candida albicans</td>
<td>25</td>
<td>2-8</td>
</tr>
</tbody>
</table>

MRSA – methicillin-resistant Staphylococcus aureus
VRE – vancomycin-resistant Enterococcus sp.
MRSE – methicillin-resistant Staphylococcus epidermidis
Clinical Studies

Patient Preoperative Prep Studies: The procedure used was the FDA specified test method for Patient Preoperative Skin Preparation (2). FDA currently requires that patient preoperative skin preparations meet the following effectiveness criteria: a 2-log reduction on the abdomen in 10 minutes, a 3-log reduction on the groin in 10 minutes, and counts not exceeding baseline values at 6 hour post-application. A correlation between these effectiveness criteria and clinical outcomes has not been established.

In Study 1, the bactericidal effect of DuraPrep solution after a single application resulted in a 3.3 log reduction (n = 66) in 10 minutes and a 2.7 (n = 66) log reduction at 6 hours on the groin. In Study 2, the bactericidal effect of DuraPrep solution after a single application resulted in a 2.6 log reduction (n = 61) on the abdomen in 2 minutes and a 2.8 log reduction (n = 70) on the groin in 10 minutes. In Study 3, the bactericidal effect of DuraPrep solution after a single application resulted in a 2.4 log reduction (n = 45) on the abdomen in 2 minutes and a 2.2 log reduction (n = 60) on the groin in 10 minutes.

Safety Studies

In a Human Repeat Insult Patch Test (LIMS 7296), conducted in 204 subjects, DuraPrep solution under occlusive conditions exhibited scattered mild inflammatory responses in several subjects. Additionally, in a few subjects, some of the responses became sufficiently irritated to require moving the test materials to new skin sites. DuraPrep solution exhibited no indication of potential sensitization following challenge application to both the original and naïve skin sites.

In a 21-Day Human Cumulative Irritation Potential Test (LIMS 7294) involving 32 subjects, DuraPrep solution’s Base 10 cumulative irritation score when patched wet under occlusive conditions (the standard procedure for testing of this type) was 453.7 (Class 4: experiment cumulative irritant). When DuraPrep solution was allowed to dry on the skin prior to patch application, reflecting intended use, the Base 10 cumulative irritation score was 307.7 (Class 3: possibly mild in normal use).
INDICATIONS AND USAGE
DuraPrep Surgical Solution is indicated for use as a patient preoperative skin preparation, for the preparation of the skin prior to surgery and to help reduce bacteria that can potentially cause skin infection.

CONTRAINDICATIONS
Do not use DuraPrep Surgical Solution on patients with known allergies to iodine or any other ingredients in this product. Do not use on open wounds, on mucous membranes, or as a general skin cleanser. Do not use in infants less than 2 months old due to the risk of excessive skin irritation and transient hypothyroidism.

WARNINGS
FOR EXTERNAL USE ONLY. FLAMMABLE, KEEP AWAY FROM FIRE OR FLAME.

To reduce the risk of fire, do not use 26-mL applicator for head and neck surgery or on an area smaller than 8 in. x 10 in. Use a small applicator instead. DuraPrep 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 DuraPrep solution into hairy areas. Solution may take much longer to dry or may not dry completely. Do not allow DuraPrep solution to pool. Remove solution-stained material from prep area.

When using this product, keep out of eyes, ears, and mouth. May cause serious injury if permitted to enter and remain. If contact occurs, flush with cold water right away and contact a doctor. To avoid skin injury, care should be taken when removing incise drapes, tapes, etc...applied over film. Use with caution in women who are breast-feeding due to the potential for transient hypothyroidism in the nursing newborn.

Stop use and ask a doctor if irritation, sensitization or allergic reaction occurs. These may be signs of a serious condition. On rare occasions, use of this product has been associated with skin blistering.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
ADVERSE REACTIONS
Adverse Reactions from Clinical Trials
The efficacy studies consisted of 6 pivotal studies and 11 pilot studies, and adverse event (AE) data from these studies were pooled for analysis. In the efficacy studies, subjects were exposed to a single application of all treatments to which they were randomized. The safety studies consisted of 2 studies with a total of 288 randomized subjects who were exposed to repeated applications of the treatment over 3 or more weeks. Adverse event data from these studies were pooled for analysis. Data from the efficacy and safety studies were not pooled because of difference in study designs and objectives.

There were no serious AEs (SAEs) related to DuraPrep solution. In safety studies, the number and percentage of subjects with AEs considered by the investigator to be associated with Betadine solution (36 subjects [12.5%]) was similar to DuraPrep solution (48 subjects [16.7%]). The number and percentage of subjects with treatment-related AEs associated with Betadine solution (30 subjects [10.5%]) was similar to DuraPrep solution (43 subjects [15.0%]). Application site pruritus, burning, and pain were the most frequent treatment-related AEs, reported by 41 (14.3%), 18 (6.3%), and 10 (3.5%) total subjects, respectively. Although there was a slight trend for these AEs to be more frequently associated with DuraPrep solution compared with DuraPrep w/o I₂ or Betadine solution, the percentages of DuraPrep solution-treated subjects were low (≤10.8% with each of these AEs).

In the efficacy studies, 8 subjects each had 1 AE; all were mild and none were serious. Six of these AEs were considered probably not or not related to study treatment. One subject had an application site erythema (verbatim term: 2 pin-sized red dots at the scrub site) considered possibly related to DuraPrep solution and one had an application site erythema considered probably related to DuraPrep solution (verbatim term: skin redness upon tape removal).
Postmarketing Complaints
All DuraPrep solution clinical complaints from 1988 through November 30, 2005 based on total units sold are presented in Table 4. The most frequent overall complaint was skin irritation (382 reports). No skin injuries have been reported with the use of DuraPrep solution alone.

Reports of infection or infection rate increase were the second most common with 109 reports. Flammability incidents were the third most prevalent complaint (a total of 97 flammability complaints since 1988, all but one of these was associated with use of the 26 mL applicator). Based on sales per million per year, the annual incidence rate has been < 2.0 since 1993.

<table>
<thead>
<tr>
<th>Complaint</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td>Skin irritation (total), includes</td>
<td>381</td>
</tr>
<tr>
<td>• Blistering</td>
<td>175</td>
</tr>
<tr>
<td>• Rash, hives, itching, burning, irritation</td>
<td>79</td>
</tr>
<tr>
<td>• Chemical burn</td>
<td>42</td>
</tr>
<tr>
<td>• Skin stripping</td>
<td>39</td>
</tr>
<tr>
<td>• Redness/abrasion</td>
<td>19</td>
</tr>
<tr>
<td>• Allergy</td>
<td>12</td>
</tr>
<tr>
<td>• Wound dehiscence</td>
<td>5</td>
</tr>
<tr>
<td>• Bruise</td>
<td>4</td>
</tr>
<tr>
<td>• Contact dermatitis</td>
<td>4</td>
</tr>
<tr>
<td>• Skin breakdown</td>
<td>2</td>
</tr>
<tr>
<td>Infection or infection rate increase</td>
<td>109</td>
</tr>
<tr>
<td>Flammability</td>
<td>97</td>
</tr>
<tr>
<td>Flaking/rolling/falling into wound</td>
<td>24</td>
</tr>
<tr>
<td>Staff skin laceration/cut from glass</td>
<td>15</td>
</tr>
<tr>
<td>Staff headache/watery eyes</td>
<td>7</td>
</tr>
<tr>
<td>DuraPrep squirited on face</td>
<td>6</td>
</tr>
<tr>
<td>Bronchial spasm</td>
<td>5</td>
</tr>
<tr>
<td>Skin staining</td>
<td>4</td>
</tr>
<tr>
<td>Eye irritation/damage</td>
<td>3</td>
</tr>
<tr>
<td>Corneal abrasion</td>
<td>1</td>
</tr>
<tr>
<td>Elevated temperature</td>
<td>1</td>
</tr>
<tr>
<td>Film/color gone</td>
<td>1</td>
</tr>
<tr>
<td>Cellulitis</td>
<td>1</td>
</tr>
<tr>
<td>Anaphylaxis</td>
<td>1</td>
</tr>
<tr>
<td>Scratch on skin from glass</td>
<td>1</td>
</tr>
<tr>
<td>Unidentified Event</td>
<td>2</td>
</tr>
</tbody>
</table>
DIRECTIONS FOR USE
Follow all directions for use. At the end of the 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.

Getting Patient Ready for Solution:
- Use in a well-ventilated area.
- Do not microwave or heat the solution applicator.
- Apply to clean, completely dry, residue-free, intact skin.
- When hair removal is necessary, use a surgical clipper on the morning of the surgery. If a wet shave is used, thoroughly remove all soap residues.

Activating the Applicator:
8630 Applicator:
- With sponge face parallel to floor, press the cap end of the applicator. Solution will begin to flow into the sponge.
- Wait for fluid level to reach indicator line of applicator barrel.
8635 Applicator:
- Grasp product by wrapping hand and fingers around the labeled portion of the applicator. Place thumb on the lever.
- With sponge parallel to the floor, snap lever. Allow all fluid to flow into sponge.

When Applying Solution:
- **DO NOT SCRUB.** Paint a single, uniform application and do not re-prep area.
- **Do not allow solution to pool.** Use sponge applicator to absorb excess solution and continue to apply a uniform coating. If solution accidentally gets outside of prep area, remove excess with gauze.
- When using the 8630 applicator, clean umbilicus with enclosed swabs, when applicable. (Moisten swab by pressing against solution-soaked sponge applicator.)
- Tuck prep towels as needed under both sides of the neck to absorb excess solution. Remove towels before draping.
- 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.
- When prepping skin folds, toes, or fingers, use a sterile-gloved hand to hold skin apart until completely dry. Otherwise, skin may adhere to itself.

After Applying Solution:
- To reduce the risk of fire, wait until solution is dry (minimum of 3 minutes on hairless skin). Solution will turn from a shiny to a dull appearance on skin alerting the user that the solution is completely dry and no longer flammable.

While Waiting for Solution to Completely Dry:
- Do no drape or use ignition source (e.g., cautery, laser).
- Check for pooled solution. Use gauze to soak up pooled solution. Do not blot because it may remove solution from skin.
- Remove solution-stained materials. Replace if necessary.

Targeted Product Information
After Solution is Completely Dry:

- To reduce the risk of fire, begin draping and/or using cautery only after solution is completely dry and all solution-stained materials are removed.
- If incise drapes are used, apply directly to dry prep. On completion of surgical procedure, removal of incise drape will remove film.
- Apply dressing following standard practices.

HOW SUPPLIED
DuraPrep Surgical Solution 8630 applicator contains 0.9 fl oz (26 mL) of solution which covers a 15 in. x 30 in. area (approximately from shoulder to groin in an average size adult).

For procedures requiring less coverage a smaller applicator is available. DuraPrep Surgical Solution 8635 applicator contains 0.2 fl oz (6 mL) of solution which covers an approximate 8 in. x 10 in. area. Do not use more than required for the area.


INFORMATION FOR THE USER
DuraPrep Surgical Solution is not water soluble and may stain. Therefore avoid contact with reusable items (basins, instruments).

Made in U.S.A. for
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REFERENCES