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3M

STERILE EO

NDC 17518-011-08
MAL09032040XR

DuraPrep™

Surgical Solution

Iodine Povacrylex (0.7% Available Iodine) and Isopropyl Alcohol (74% w/w)

Patient Preoperative Skin Preparation

Non-sterile Solution

Applicator is sterile if package is intact

For large prep areas below the neck

Do Not Reuse

LATEX
Not Made With Natural Rubber Latex

⚠WARNING
Flammable

Keep away from fire or flame.

To reduce the risk of fire, PREP CAREFULLY:

- 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; up to 1 hour in hair).
- Avoid getting solution into hairy areas. **Wet hair is flammable.** Hair may take up to 1 hour to dry.
- Do not allow solution to pool.
- Remove solution-stained material from prep area.

Single Use

DuraPrep Surgical Solution is a film-forming iodophor complex. Each unit dose 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 (8635).
t 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.

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

REF 8630

0.9 fl oz • 26 mL

(01) 0 03 17518 01108 5

3M
Made in U.S.A. by
3M Health Care
2510 Conway Ave.
St. Paul, MN 55144
1-800-228-3957

 34-8716-1049-8

Patient Take Home Instructions

Your surgeon used 3M™ DuraPrep™ Surgical Solution 8630, a bacteria-killing skin preparation. It is recommended that this film remain on the skin after the procedure. The film will gradually wear away. If, however, early removal is desired:

- Apply 8610 or 8611 3M™ Remover Lotion to the prepped 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 prepped area for at least 40 seconds. Lightly scrub to remove the solution.

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

3M

STERILE EO

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- Do not allow solution to pool.
- Remove solution-stained material from prep area.

Cautery

POOLING

Single Use

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REF 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 8630, a bacteria-killing skin preparation. It is recommended that this film remain on the skin after the procedure. The film will gradually wear away. If, however, early removal is desired:

- Apply 8610 or 8611 3M™ Remover Lotion to the prepped 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 prepped area for at least 40 seconds. Lightly scrub to remove the solution.

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

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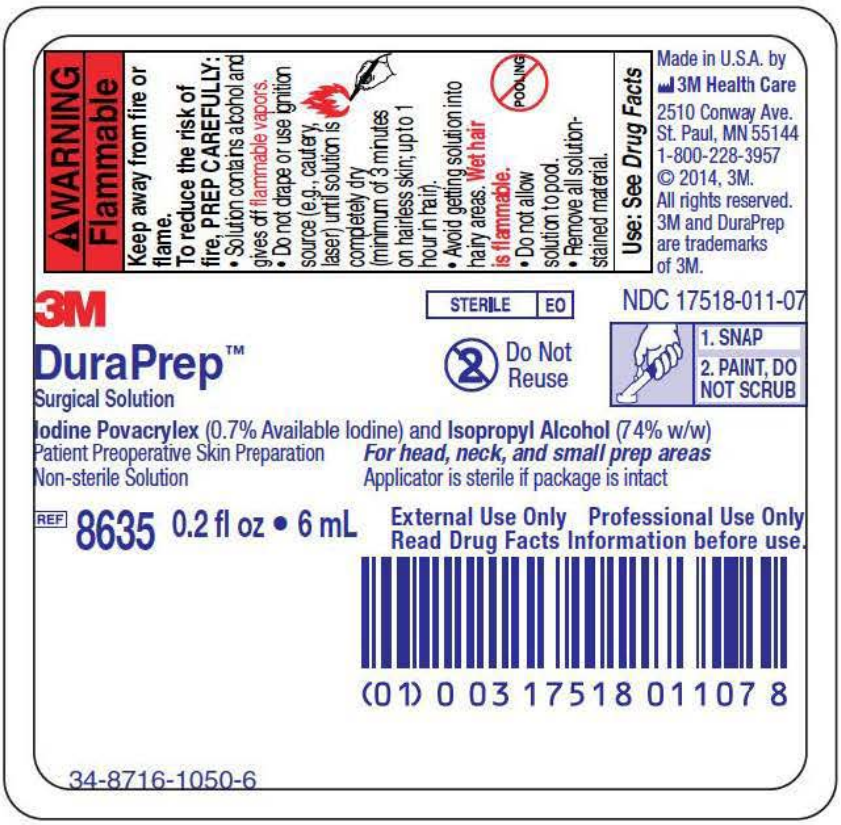

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3M

STERILE EO

NDC 17518-011-07
MAL09032040XR

DuraPrep™

Surgical Solution

Iodine Povacrylex (0.7% Available Iodine) and Isopropyl Alcohol (74% w/w)

Patient Preoperative Skin Preparation

Non-sterile Solution

Applicator is sterile if package is intact

For head, neck, and small prep areas

Do Not Reuse

Not Made With Natural Rubber Latex

⚠WARNING
Flammable

Keep away from fire or flame.
To reduce the risk of fire, PREP CAREFULLY:

- 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; up to 1 hour in hair).
- Avoid getting solution into hairy areas. **Wet hair is flammable.** Hair may take up to 1 hour to dry.
- Do not allow solution to pool.
- Remove solution-stained material from prep area.

Single Use

DuraPrep Surgical Solution is a film-forming iodophor complex. Each unit dose applicator contains 0.2 fl oz (6 mL) of solution which covers an approximate 8 in x 10 in area.

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

REF 8635

0.2 fl oz • 6 mL

(01) 0 03 17518 01107 8

3M
Made in U.S.A. by
3M Health Care
2510 Conway Ave.
St. Paul, MN 55144
1-800-228-3957

34-8716-1052-2

Patient Take Home Instructions

Your surgeon used 3M™ DuraPrep™ Surgical Solution 8635, a bacteria-killing skin preparation. It is recommended that this film remain on the skin after the procedure. The film will gradually wear away. If, however, early removal is desired:

- Apply 8610 or 8611 3M™ Remover Lotion to the prepped 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 prepped area for at least 40 seconds. Lightly scrub to remove the solution.

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

3M

STERILE EO

NDC 17518-011-07
MAL09032040XR

DuraPrep™

Surgical Solution

Iodine Povacrylex (0.7% Available Iodine) and Isopropyl Alcohol (74% w/w)

Patient Preoperative Skin Preparation

Non-sterile Solution

Applicator is sterile if package is intact

For head, neck, and small prep areas

Do Not Reuse

Not Made With Natural Rubber Latex

⚠WARNING
Flammable

Keep away from fire or flame.
To reduce the risk of fire, PREP CAREFULLY:

- 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; up to 1 hour in hair).
- Avoid getting solution into hairy areas. Wet hair is flammable. Hair may take up to 1 hour to dry.
- Do not allow solution to pool.
- Remove solution-stained material from prep area.

Cautery

POOLING

Single Use

DuraPrep Surgical Solution is a film-forming iodophor complex. Each unit dose applicator contains 0.2 fl oz (6 mL) of solution which covers an approximate 8 in x 10 in area.

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

REF 8635

0.2 fl oz • 6 mL

(01) 0 03 17518 01107 8

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2510 Conway Ave.
St. Paul, MN 55144
1-800-228-3957

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34-8716-1052-2

Patient Take Home Instructions

Your surgeon used 3M™ DuraPrep™ Surgical Solution 8635, a bacteria-killing skin preparation. It is recommended that this film remain on the skin after the procedure. The film will gradually wear away. If, however, early removal is desired:

- Apply 8610 or 8611 3M™ Remover Lotion to the prepped 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 prepped area for at least 40 seconds. Lightly scrub to remove the solution.

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

3M™ DuraPrep™ Surgical Solution Iodine Povacrylex (0.7% Available Iodine) and Isopropyl Alcohol (74%w/w) Patient Preoperative Skin Preparation
NDA 21-586 – November 25, 2014

Labeling – Target Product Information

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. Wet hair is flammable.

III. Labeling, Continued – Target Product Information

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 1. Microbial Kill for DuraPrep Solution

Microorganism	% Microbial Kill 15 Seconds DuraPrep solution
Enterococcus faecalis (ATCC 29212)	**99.99**
Escherichia coli (ATCC 11229)	**99.99**
Escherichia coli (ATCC 25922)	**99.99**
Micrococcus luteus (ATCC 7468)	**98.90**
Pseudomonas aeruginosa (ATCC 15442)	**99.99**
Pseudomonas aeruginosa (ATCC 27853)	**99.99**
Serratia marcescens (ATCC 14756)	**99.99**
Staphylococcus aureus (ATCC 29213)	**99.99**
Staphylococcus aureus (ATCC 6538)	**99.99**
Staphylococcus epidermidis (ATCC 12228)	**99.99**
Staphylococcus aureus (MRSA) (ATCC 33592)	**99.99**
Enterococcus faecalis (VRE) (ATCC 51299)	**99.99**
Enterococcus faecium (MDR) (ATCC 51559)	**99.99**
Staphylococcus epidermidis (MRSE) (ATCC 51625)	**99.99**
Candida albicans (ATCC 10231)	**99.84**

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*

III. Labeling, Continued – Target Product Information

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 2. Microbial Kill For DuraPrep Film

Microorganism	Organisms Placed on Top of Dried DuraPrep Film		
	% Microbial Kill		
	1 Minute	5 Minutes	15 Minutes
Acinetobacter baumannii (ATCC 19606)	**99.99**	**99.99**	**99.99**
Acinetobacter lwoffii (ATCC 15309)	**99.99**	**99.96**	**99.99**
Burkholderia cepacia *(ATCC 25416)*	**99.92**	**99.61**	**99.99**
Enterobacter aerogenes (ATCC 13048)	**88.39**	**95.07**	**99.99**
Enterobacter cloacae (ATCC 13047)	**99.99**	**99.99**	**99.99**
Escherichia coli (ATCC 11229)	**99.99**	**99.99**	**99.99**
Escherichia coli (ATCC 25922)	**99.77**	**99.99**	**99.99**
Haemophilus influenzae (ATCC 19418)	**99.99**	**99.99**	**99.99**
Klebsiella oxytoca (ATCC 43165)	**99.97**	**99.99**	**99.99**
Klebsiella pneumoniae (ATCC 11296)	**99.13**	**99.99**	**99.99**
Proteus mirabilis (ATCC 7002)	**99.99**	**99.99**	**99.99**
Pseudomonas aeruginosa (ATCC 9027)	**99.99**	**99.99**	**99.99**
Serratia marcescens (ATCC 14756)	**99.61**	**99.99**	**99.99**
Corynebacterium jeikeium (ATCC 43734)	**99.99**	**99.99**	**99.99**
Enterococcus faecalis (ATCC 19433)	**99.82**	**99.99**	**99.99**
Enterococcus faecalis (VRE) (ATCC 51299)	**99.19**	**99.99**	**99.99**
Enterococcus faecium (ATCC 19434)	**82.12**	**99.99**	**99.99**
Micrococcus luteus (ATCC 4698)	**99.95**	**99.99**	**99.99**
Staphylococcus aureus (ATCC 6538)	**97.72**	**99.96**	**99.99**
Staphylococcus aureus (MRSA) (ATCC 33592)	**84.93**	**99.60**	**99.99**
Staphylococcus epidermidis (ATCC 12228)	**99.99**	**99.99**	**99.99**
Staphylococcus haemolyticus (ATCC 29970)	**99.99**	**99.99**	**99.99**
Staphylococcus hominis (ATCC 27844)	**99.99**	**99.99**	**99.99**
Staphylococcus saprophyticus (ATCC 15305)	**99.61**	**99.99**	**99.99**
Streptococcus pneumoniae (ATCC 6303)	**99.99**	**99.99**	**99.99**
Streptococcus pyogenes (ATCC 19615)	**96.08**	**99.99**	**99.99**
Candida albicans (ATCC 10231)	**80.59**	**99.06**	**99.99**

MRSA – methicillin-resistant *Staphylococcus aureus*
VRE – vancomycin-resistant *Enterococcus sp.*

III. Labeling, Continued – Target Product Information

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 3. MBC Ranges for Laboratory Strains and Clinical Isolates

Microorganism	Lab Strains		Clinical Isolates	
	N	MBC Range (µg/ml)	N	MBC Range (µg/ml)
Acinetobacter sp.	25	0.25-2	25	0.25-4
Bacteroides fragilis	20	0.25-2	31	0.25-8
Haemophilus influenzae	25	0.125-2	25	0.125-1
Enterobacter sp.	25	0.5-2	25	0.5-2
Escherichia coli	25	0.5-1	25	0.5-2
Klebsiella sp.	25	0.25-1	25	0.5-2
Pseudomonas aeruginosa	25	0.5-8	25	1-4
Proteus mirabilis	25	0.5-2	25	0.5-4
Serratia marcescens	25	0.5-2	25	0.25-4
Staphylococcus aureus including MRSA	25	0.5-2	25	0.5-4
Staphylococcus epidermidis including MRSE	25	0.125-2	25	0.25-1
Staphylococcus hominis	12	0.5-2	38	0.25-4
Staphylococcus haemolyticus	6	0.5-1	44	0.5-2
Staphylococcus saprophyticus	5	1-2	45	0.5-2
Micrococcus luteus	25	0.5-4	25	0.5-4
Streptococcus pyogenes	25	0.25-16	25	0.5-8
Enterococcus. faecalis including VRE	25	0.5-4	25	1-4
Enterococcus faecium including VRE	25	1-4	25	1-4
Streptococcus pneumoniae	25	0.125-8	25	0.25-4
Candida sp.	25	1-16	25	2-16
Candida albicans	25	2-8	25	2-8

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

III. Labeling, Continued – Target Product Information

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).

III. Labeling, Continued – Target Product Information

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 month 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, PREP CAREFULLY: 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; up to 1 hour in hair). Avoid getting DuraPrep solution into hairy areas. **Wet hair is flammable**. Hair may take up to 1 hour to dry. 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.

III. Labeling, Continued – Target Product Information

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 I_2 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).

III. Labeling, Continued – Target Product Information

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. **Wet hair is flammable**. Hair may take up to 1 hour to dry.
- 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 completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair)**. 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 sterile gauze to soak up pooled solution. Do not blot because it may remove solution from skin.
- Remove solution-stained materials. Replace if necessary.

III. Labeling, Continued – Target 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.
Store between 20-25°C (68-77°F). Avoid excessive heat above 40°C (104°F).

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. by
3M Health Care
2510 Conway Ave.
St. Paul, MN 55144-1000
(U.S.A.) 1-800-228-3957
www.3M.com

III. Labeling, Continued – Target Product Information

REFERENCES

1. Roberts AJ, Wilcox K, Devineni R, Harris RB, and Osevala MA. Skin preparations in CABG surgery: a prospective randomized trial. Comp Surg 1995 Nov/Dec; 14(6): 724, 741-744, 747.
2. Tentative Final Monograph for Health Care Antiseptic Products; Federal Register; Vol. 59, No. 116, Friday, June 17, 1994.