

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-586

LABELING

3MSTERILE EO
NDC 17518-011-082 Do Not
Reuse**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 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 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-servicing is available on video, from your 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

DuraPrep is a trademark of 3M
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Made in U.S.A. for
3M Health Care
St. Paul, MN
55114 1000
1-800-228-9957
Solutions:
US Patent 4,584,192
34-7060-XXXX-X**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 skin after the procedure. The film will gradually wear away. If, however, early removal is desired:

- Apply B610 or B611 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 1-800-228-9957

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

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 take much longer to dry or may not dry completely.
- Do not allow solution to pool.
- Remove solution-stained material from prep area.



(01) 0 03 17518 01108 5

Prints

■ = PMS 032
 ■ = 30% PMS 346
 ■ = PMS 2685
 and Black

FOR PRINTER USE ONLY

This barcode symbol was produced using a bar width adjustment of -0.002. If this does not meet the needs of the printing process or equipment to be used, the printer is responsible to recreate the file using the appropriate bar width adjustment while meeting 3M quality requirements.

3M™ DuraPrep™ Surgical Solution 8630

Drug Facts

Active ingredients

Iodine povidone (0.7% available iodine)
Isopropyl alcohol, 74% w/w

Purpose

Antiseptic
Antiseptic

Uses

patient preoperative skin preparation: • for preparation of the skin prior to surgery
• helps reduce bacteria that potentially can cause skin infection

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
- do not use on an area smaller than 8 in. x 10 in. Use a small applicator instead
- solution contains alcohol and gels off Flammable 2, 3
- 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 solution-stained material from prep area



Do not use

- on patients with known allergies to iodine or any other ingredients in this product
- on open wounds, on mucous membranes, or as a general skin cleanser
- in infants less than 2 months old due to the risk of excessive skin irritation and transient hypothyroidism

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 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.

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 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:

- 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 line of applicator barrel

When Applying Solution:

- **DO NOT SCRUB.** Paint a single, uniform application and do not reprep 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.
- clean umbilicus with enclosed swabs when applicable. (Moisten swabs 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 completely 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 not 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.



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

Other information • store between 20-25°C (68-77°F) • avoid excessive heat above 40°C (104°F) • solution is not water soluble and may stain. Therefore, avoid contact with reusable items (basins, instruments).

Inactive ingredients ethyl alcohol, water

Questions? call 1-800-228-3957 (Monday to Friday 7AM - 6PM CST), www.3M.com

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.
 • 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).
 • Solution may take much longer to dry in hairy areas.
 • Do not allow solution to pool.
 • Remove all solution-stained material.

Use: See Drug Facts

3M **DuraPrep™** **STERILE EO** **NDC 175 18-011-08**
 (2) No Hex Resin

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

8630 0.9 fl oz • 26 mL

External Use Only
Professional Use Only
Read Drug Facts
Information before use.

Made in U.S.A. for
 3M Health Care
 St. Paul, MN 55144-1000
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(01) 0 03 17518 01108 5

34-7060-XXXX-X

Artwork #: 38-9001-8944-0
 Date: 9/25/06
 Author: S Barker
 Supersedes 38#: 38-9001-7488-9
 Pkg. Spec. Reference : 34-7060-
 Structure: Label

Scale | | | | | | | | 1 Inch

Prints
 ■ = PMS 032
 ■ = PMS 2685
 and Black

FOR PRINTER USE ONLY
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Appears This Way
 On Original

Keep away from fire or flame.
To reduce the 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 solution-stained material from prep area.





(01) 0 03 17518 01107 8

3M STERILE EO
NDC 17518-011-07

DuraPrep™
Surgical Solution
Iodine Povacrylex (0.7% Available Iodine)
and Isopropyl Alcohol (74% w/w)
Patient Preoperative Skin Preparation
for head, neck, and small prep areas

② Do Not Rinse

Keep away from fire or flame.
To reduce the 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 solution-stained material from prep area.




Single Use
Sterile Contents:
Applicator w/urethane sponge(1)
* 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 0.2 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-service is available on video, from your 3M sales representative, or at the 3M website (www.3m.com).

Cat. No. 8635 0.2 fl oz • 6 mL



(01) 0 03 17518 01107 8

3M Made in U.S.A. for 3M Health Care St. Paul, MN 55144-1000 1-800-228-3957

DuraPrep is a trademark of 3M ©3M 2006 All rights reserved. Solution U.S. Patent 4,584,192 34-7060-XXXX-X

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 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

Artwork #: 38-9001-8946-5
Date: 9/21/06
Author: S Barker
Supersedes 38#: 38-9001-7482-2
Pkg. Spec. Reference : 34-7060-
Structure: INS

Scale | | | | | 1 Inch

Prints

- = PMS 032
 - = 30% PMS 346
 - = PMS 2685
- and Black

FOR PRINTER USE ONLY

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3M™ DuraPrep™ Surgical Solution 8635

Drug Facts

Active Ingredients

Iodine povidone (0.7% available iodine)
Isopropyl alcohol, 74% w/w

Purpose

Antiseptic
Antiseptic

Uses

patient preoperative skin preparation: • for preparation of the skin prior to surgery
• helps reduce bacteria that potentially can cause skin infection

Warnings

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

To reduce the 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 solution-stained material from prep area



Do not use

- on patients with known allergies to iodine or any other ingredients in this product
- on open wounds, on mucous membranes, or as a general skin cleanser
- in infants less than 2 months old due to the risk of excessive skin irritation and transient hypothyroidism

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 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.

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 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:

- 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 reprep 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.
- 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 completely 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 not 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.



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

Other information

• store between 20-25°C (68-77°F) • avoid excessive heat above 40°C (104°F) • solution is not water soluble and may stain. Therefore, avoid contact with reusable items (basins, instruments).

Inactive ingredients ethyl alcohol, water

Questions? call 1-800-228-3957 (Monday to Friday 7AM - 6PM CST), www.3M.com.

Appears This Way
On Original

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Keep away from fire or flame. Do not use if you notice the risk of fire.

Solution contains alcohol and gives off flammable vapors. Do not use near open flames or use with caution (e.g., cautery, laser) until solution is completely dry.

Do not use on irritated or broken skin.

Solution may take much longer to dry on hairy areas.

Do not use on solution to pool.

Remove all solution-stained material.

Use: See Drug Facts

3M **DuraPrep™** **STERILE** **1.0** **NDC 17518-011-07**

Surgical Solution

Iodine Povacrylex (0.7% Available Iodine) and Isopropyl Alcohol (74% w/w) Patient Preoperative Skin Preparation for head, neck, and small prep areas

Do Not Rub

1. SNAP
2. PAINT, DO NOT SCRUB

8635 **0.2 fl oz • 6 mL** **External Use Only Professional Use Only**
Read Drug Facts Information before use.



(01) 0 03 17518 01107 8

34-7060-XXXX-X

Appears This Way
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Artwork #: 38-9001-8948-1
Date: 9/25/06
Author: S Barker
Supersedes 38#: 38-9001-7480-6
Pkg. Spec. Reference : 34-7060-
Structure: Label

Scale | | | | | | | | 1 Inch

Prints
■ = PMS 032
■ = PMS 2685
and Black

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3M™ DuraPrep™ Surgical Solution 8630

Drug Facts

Active ingredients

Iodine povidone (0.7% available iodine)
Isopropyl alcohol, 74% w/w

Purpose

Antiseptic
Antiseptic

Uses

patient preoperative skin preparation. • for preparation of the skin prior to surgery
• helps reduce bacteria that potentially can cause skin infection

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
- do not use on an area smaller than 3 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 take much longer to dry or may not dry completely.
- do not allow solution to pool
- remove solution-stained material from prep area



Do not use

- on patients with known allergies to iodine or any other ingredients in this product
- on open wounds, on mucous membranes, or as a general skin cleanser
- in infants less than 2 months old due to the risk of excessive skin irritation and transient hypothyroidism

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 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.

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 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 shaver is used, thoroughly remove all soap residues.

Activating the Applicator:

- 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 line of applicator barrel

When Applying Solution:

- **DO NOT SCRUB.** Paint a single, uniform application and do not reprep 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.
- clean umbilicus with enclosed swabs when applicable. (Moisten swabs 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 completely 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 not 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.



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

Other information • store between 20-25°C (68-77°F) • avoid excessive heat above 40°C (104°F) • solution is not water soluble and may stain. Therefore, avoid contact with reusable items (basins, instruments).

Inactive ingredients ethyl alcohol, water

Questions? call 1-800-228-3957 (Monday to Friday 7AM - 6PM CST). www.3M.com.

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3M™ DuraPrep™ Surgical Solution 8635

Drug Facts

Active ingredients

Iodine povidone (0.7% available iodine)
Isopropyl alcohol, 74% w/w

Purpose:
Antiseptic
Antiseptic

Uses

patient preoperative skin preparation: • for preparation of the skin prior to surgery
• helps reduce bacteria that potentially can cause skin infection

Warnings

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

To reduce the 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 solution-stained material from prep area



Do not use

- on patients with known allergies to iodine or any other ingredients in this product
- on open wounds, on mucous membranes, or as a general skin cleanser
- in infants less than 2 months old due to the risk of excessive skin irritation and transient hypothyroidism

When using this product

- keep out of eyes, ears, and mouth. May cause serious injury if permitted to enter and remain in contact occurs. Flush with cold water right away and contact a doctor.
- to avoid skin injury, care should be taken when removing 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.

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 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:

- 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 reprep 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.
- 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 completely 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 not 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.



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

Other information • store between 20-25°C (68-77°F) • avoid excessive heat above 40°C (104°F) • solution is not water soluble and may stain. Therefore, avoid contact with reusable items (basins, instruments).

Inactive ingredients ethyl alcohol, water

Questions? call 1-800-228-3957 (Monday to Friday 7AM - 6PM CST) www.3M.com

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9/25/2006

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.

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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
<i>Enterococcus faecalis</i> (ATCC 29212)	99.99
<i>Escherichia coli</i> (ATCC 11229)	99.99
<i>Escherichia coli</i> (ATCC 25922)	99.99
<i>Micrococcus luteus</i> (ATCC 7468)	98.90
<i>Pseudomonas aeruginosa</i> (ATCC 15442)	99.99
<i>Pseudomonas aeruginosa</i> (ATCC 27853)	99.99
<i>Serratia marcescens</i> (ATCC 14756)	99.99
<i>Staphylococcus aureus</i> (ATCC 29213)	99.99
<i>Staphylococcus aureus</i> (ATCC 6538)	99.99
<i>Staphylococcus epidermidis</i> (ATCC 12228)	99.99
<i>Staphylococcus aureus</i> (MRSA) (ATCC 33592)	99.99
<i>Enterococcus faecalis</i> (VRE) (ATCC 51299)	99.99
<i>Enterococcus faecium</i> (MDR) (ATCC 51559)	99.99
<i>Staphylococcus epidermidis</i> (MRSE) (ATCC 51625)	99.99
<i>Candida albicans</i> (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*

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In an independent Time Kill Study (LIMS 7311) where bacteria ($\sim 10^7$ 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
<i>Acinetobacter baumannii</i> (ATCC 19606)	99.99	99.99	99.99
<i>Acinetobacter lwoffii</i> (ATCC 15309)	99.99	99.96	99.99
<i>Burkholderia cepacia</i> (ATCC 25416)	99.92	99.61	99.99
<i>Enterobacter aerogenes</i> (ATCC 13048)	88.39	95.07	99.99
<i>Enterobacter cloacae</i> (ATCC 13047)	99.99	99.99	99.99
<i>Escherichia coli</i> (ATCC 11229)	99.99	99.99	99.99
<i>Escherichia coli</i> (ATCC 25922)	99.77	99.99	99.99
<i>Haemophilus influenzae</i> (ATCC 19418)	99.99	99.99	99.99
<i>Klebsiella oxytoca</i> (ATCC 43165)	99.97	99.99	99.99
<i>Klebsiella pneumoniae</i> (ATCC 11296)	99.13	99.99	99.99
<i>Proteus mirabilis</i> (ATCC 7002)	99.99	99.99	99.99
<i>Pseudomonas aeruginosa</i> (ATCC 9027)	99.99	99.99	99.99
<i>Serratia marcescens</i> (ATCC 14756)	99.61	99.99	99.99
<i>Corynebacterium jeikeium</i> (ATCC 43734)	99.99	99.99	99.99
<i>Enterococcus faecalis</i> (ATCC 19433)	99.82	99.99	99.99
<i>Enterococcus faecalis</i> (VRE) (ATCC 51299)	99.19	99.99	99.99
<i>Enterococcus faecium</i> (ATCC 19434)	82.12	99.99	99.99
<i>Micrococcus luteus</i> (ATCC 4698)	99.95	99.99	99.99
<i>Staphylococcus aureus</i> (ATCC 6538)	97.72	99.96	99.99
<i>Staphylococcus aureus</i> (MRSA) (ATCC 33592)	84.93	99.60	99.99
<i>Staphylococcus epidermidis</i> (ATCC 12228)	99.99	99.99	99.99
<i>Staphylococcus haemolyticus</i> (ATCC 29970)	99.99	99.99	99.99
<i>Staphylococcus hominis</i> (ATCC 27844)	99.99	99.99	99.99
<i>Staphylococcus saprophyticus</i> (ATCC 15305)	99.61	99.99	99.99
<i>Streptococcus pneumoniae</i> (ATCC 6303)	99.99	99.99	99.99
<i>Streptococcus pyogenes</i> (ATCC 19615)	96.08	99.99	99.99
<i>Candida albicans</i> (ATCC 10231)	80.59	99.06	99.99

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

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

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

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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).

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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..

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Targeted Product Information

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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 ($\leq 10.8\%$ 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).

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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.

Complaint	Total
Skin irritation (total), includes	381
• Blistering	175
• Rash, hives, itching, burning, irritation	79
• Chemical burn	42
• Skin stripping	39
• Redness/abrasion	19
• Allergy	12
• Wound dehiscence	5
• Bruise	4
• Contact dermatitis	4
• Skin breakdown	2
Infection or infection rate increase	109
Flammability	97
Flaking/rolling/falling into wound	24
Staff skin laceration/cut from glass	15
Staff headache/watery eyes	7
DuraPrep squirted on face	6
Bronchial spasm	5
Skin staining	4
Eye irritation/damage	3
Corneal abrasion	1
Elevated temperature	1
Film/color gone	1
Cellulitis	1
Anaphylaxis	1
Scratch on skin from glass	1
Unidentified Event	2

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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-prepare 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 not 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.

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

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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.

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