

FDA
approved

Approved NDA 21-586
September 29, 2006

3M™ DuraPrep™ Surgical Solution

(Iodine Povacrylex [0.7% available iodine]
and Isopropyl Alcohol, 74% w/w)

Patient Preoperative
Skin Preparation



effective in a
SINGLE
painted coat



nothing is
FASTER,



nothing is
EASIER

3M Medical
from the 3M Health Care family

3M

EFFECTIVE

DuraPrep surgical solution eliminates the need for a time consuming scrub and paint application by combining two proven, broad-spectrum antimicrobial agents: alcohol for fast kill and fast drying*, and iodine povacrylex for persistence in a water-insoluble film.

Efficacy studies have proven that DuraPrep solution:

- Dries to a water-insoluble film that resists washing away by blood and saline
- *In vivo*, DuraPrep solution meets the TFM requirements of a 2-log reduction on the abdomen (Fig. 3) and a 3-log reduction on the groin (Fig. 4) at 10 minutes. Additionally, DuraPrep solution actually achieves a 2-log reduction on the abdomen as soon as 2 minutes post-prep*
- Effectively kills antibiotic-resistant bacteria (*in vitro*), a growing problem in hospitals.^{3,4} (Note: 70% of bacteria causing nosocomial infections are resistant to at least one commonly prescribed antibiotic⁵)
- Is more effective in a shorter period of time (*in vitro*) than the leading aqueous iodophor solution against gentamicin-resistant and vancomycin-resistant *Enterococci* (VRE) (Fig. 5). Enterococci are the third leading cause of surgical wound infection according to the CDC²
- Kills methicillin-resistant *Staphylococcus aureus* (MRSA) and *S. epidermidis* (MRSE) in one minute (*in vitro*) (Fig. 6)

*In clinical practice, however, DuraPrep solution is flammable until completely dry (minimum of 3 minutes on hairless skin).



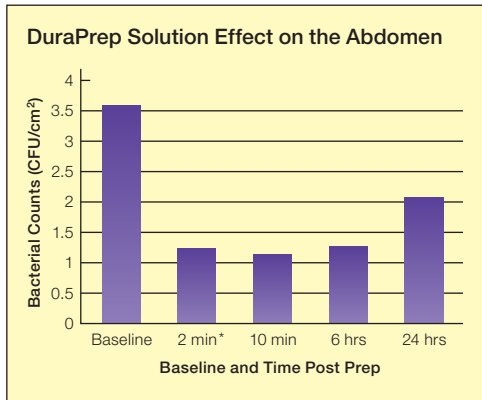


Fig. 3 *In vivo* data

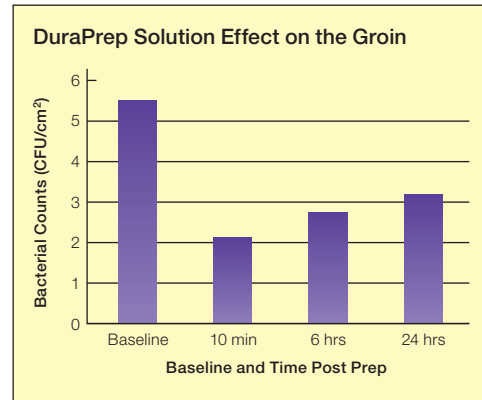


Fig. 4 *In vivo* data

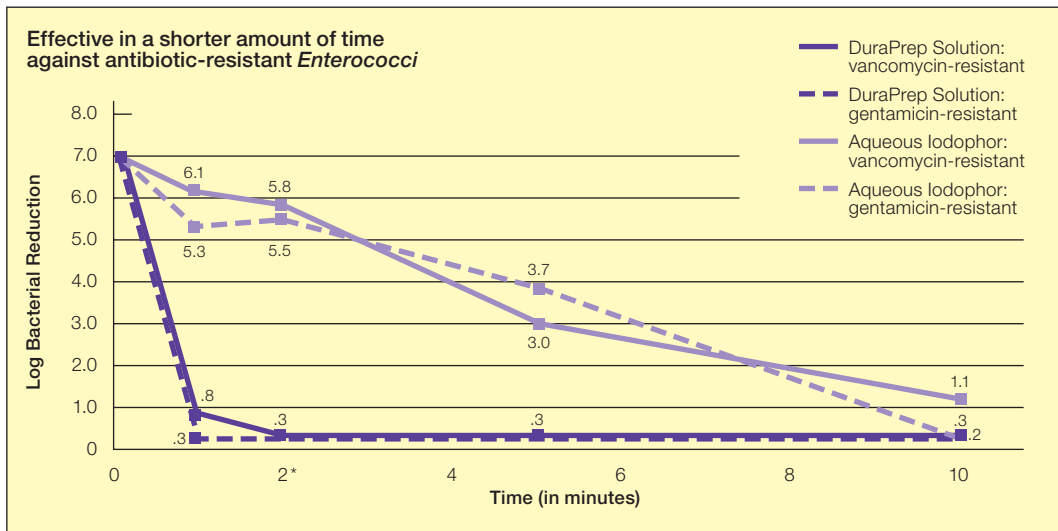


Fig. 5 *In vitro* data[†]

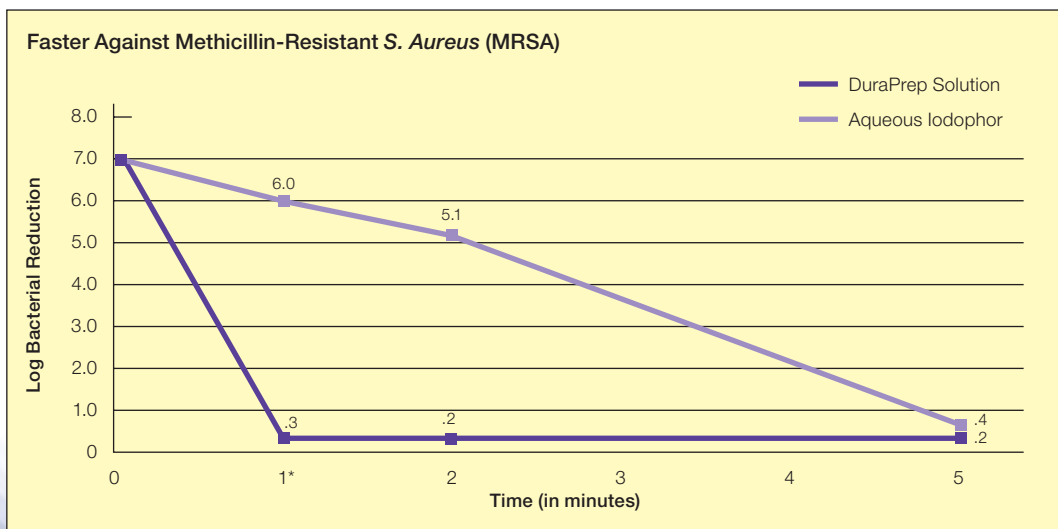


Fig. 6 *In vitro* data[†]

*In clinical practice, however, DuraPrep solution is flammable until completely dry (minimum of 3 minutes on hairless skin).

[†]The clinical significance of *in vitro* data is unknown.



FAST

Not only did 3M design applicators that are fast to activate but also filled them with a skin prepping solution that provides rapid microbial kill.

In vitro[†]

- Kills major pathogens in one minute*
- Kills 99.999% gentamicin-resistant and vancomycin-resistant *Enterococci* (VRE) in one minute* versus a leading aqueous iodophor's kill in 10 minutes

In vivo

- Meets the TFM required log reduction with a single, painted coat

EASY

Available in a self-contained, unit-dose applicator, DuraPrep solution's unique application process simplifies the skin prep procedure. DuraPrep solution saves a minimum of 5 minutes prepping time compared to an iodophor scrub and paint.

Unique ease-of-use benefits include:

- No need for additional sponges, trays, overwraps or bottles
- Controlled flow of solution minimizes drips and mess
- Ensures an even application of prep
- Easy to comply to a standardized prepping procedure

* In clinical practice, however, DuraPrep solution is flammable until completely dry (minimum of 3 minutes on hairless skin).

† The clinical significance of *in vitro* data is unknown.

Activation



Snap or Press

8635

With sponge parallel to floor, snap lever. Allow all fluid to flow into the sponge.

or

8630

With sponge parallel to floor, press the cap end of the applicator. Solution will begin to flow into the sponge.

3M™ DuraPrep™ Surgical Solution

Controlling skin bacteria can help reduce the risk of bacterial contamination of the surgical site. DuraPrep solution provides rapid bacterial kill, persistent antimicrobial activity and a simplified application process. That's why it is still the leading skin prep kit in the United States.¹

Benefits:

- Effective in a single, painted coat
- Effective after exposure to blood
- Resists removal by blood and irrigating solutions
- Enhances drape adhesion to promote sterile surface to the wound edge (Fig. 1 and 2)
- Indicated for use on intact skin procedures including lumbar puncture

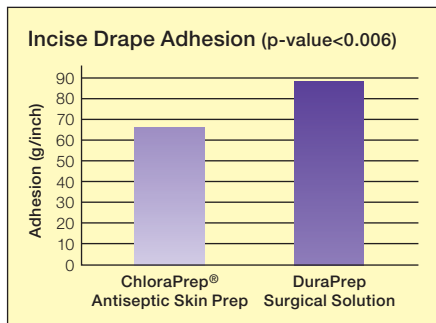


Fig. 1

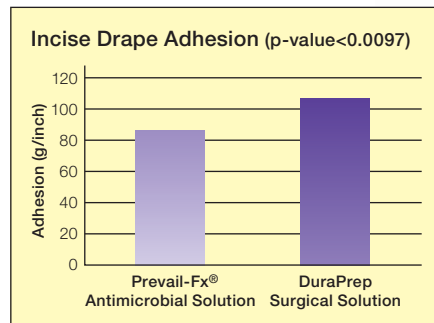


Fig. 2

Two ways to reduce surgical-site infection risk in one quick step.

Two convenient sizes of DuraPrep solution let you choose the product that matches your need—and avoid excess waste—in a wide variety of applications.



The **8630** large-size applicator (26 mL) covers 450 sq. in. (15 in. x 30 in.) and is appropriate for procedures that include thoracic and CV, spine, total hip and knee, C-section, and major abdominal surgeries. Do not use the 26 mL applicator for head and neck surgeries.

The **8635** mid-size applicator (6 mL) covers at least 80 sq. in. (8 in. x 10 in.), which is ideal for procedures requiring less coverage such as angiography, head and neck procedures, foot and hand procedures.




Ordering Information

3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation is indicated for topical use as a persistent, film-forming preoperative skin preparation with fast, broad-spectrum antimicrobial activity.

	Catalog Number	Description	Coverage	Size	Items/box	Boxes/case
	8630	DuraPrep surgical solution	Applicator covers 450 sq. in. (15 in. x 30 in.); ideal for large procedures—Thoracic and CV, spine, total hip and knee, C-section, major abdominal.	26 mL	20	1
	8635	DuraPrep surgical solution	Applicator covers 80 sq. in. (8 in. x 10 in.); ideal for mid-size procedures—biopsies, foot and hand, angiography, head and neck procedures.	6 mL	50	1

DuraPrep film is intended to be left on the skin and will gradually wear away. If desired, prep can be removed with 3M™ Remover Lotion.

	Catalog Number	Description	Size	Items/box	Boxes/case
	8610	3M Remover Lotion	.5 fl. oz. (15 mL)	20 packets	5
	8611	3M Remover Lotion	4 fl. oz. (118 mL)	12 bottles	1

Warning:

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 26 mL applicator 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.

References:

1. HPIS, Inc., 2005.
2. Centers for Disease Control, Guidelines for Prevention of Surgical Site Infection, 1999, *Am J Infect Control* April, 1999.
3. Boyce JM. Methicillin-resistant *Staphylococcus aureus* in hospitals and long-term care facilities: Microbiology, Epidemiology and Preventative Measures, *Infect Control Hosp Epidemiol*, December 13, 1992 (No. 12): pp. 725–737.
4. Alexander DM, Jeawon RH and Persad S. Disinfectant resistance in antibiotic-resistant organisms, *Research Letters. South African Journal of Science*, Vol. 87, November/December 1991, pp. 614–617.
5. Federal Register, May 8, 1998. Volume 63, Number 89: p. 25484.

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 of age due to risk of excessive skin irritation and transient hypothyroidism.

Please Recycle

3M

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