

A3441-22 SPINAL 22G QUINCKE - regional anesthesia kit
Smiths Medical ASD, Inc.

Drug Facts

3M DURAPREP SURGICAL (iodine povacrylex and isopropyl alcohol) solution
[3M Health Care]

Drug Facts

Active ingredients

Iodine povacrylex (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, 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



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. **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 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.



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.

Package Label Display Panel

WARNING	Flammable	<p>Keep away from fire or flame.</p> <p>To reduce the risk of fire, PREP CAREFULLY:</p> <ul style="list-style-type: none"> • 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. • Do not allow solution to pool. • Remove all solution-stained material.
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Use: See Drug Facts

Made in U.S.A. for
 3M Health Care
 St. Paul, MN 55144-1000
 1-800-228-3957
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NDC 17518-011-09



DuraPrep™

Surgical Solution

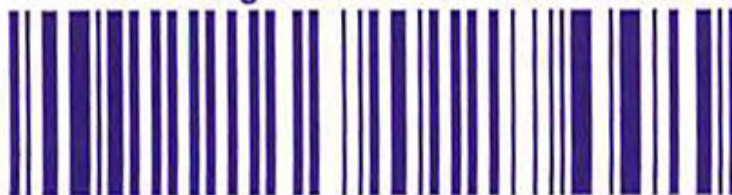
Iodine Povacrylex (0.7% Available Iodine) and Isopropyl Alcohol (74% w/w)
 Patient Preoperative Skin Preparation *for head, neck, and small prep areas*

8635 ^{REF} 0.2 fl oz • 6 mL

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




1. SNAP
2. PAINT, DO NOT SCRUB




(01) 0 03 17518 01109 2

Package Label Display Panel



REF A3441-22
SPINAL
22G QUINCKE



PROCEDURAL COMPONENTS:

- 3 Drapes
- 4 Gauze Sponges
- 1 19G x 1 1/2 in. Needle
- 1 22G x 1 1/2 in. Needle
- 1 Quincke Spinal Needle (22G x 3 1/2 in.)
- 1 Plastic Syringe (30ml, Luer Lock)
- 1 Plastic Syringe (3ml, Luer Lock)

PREP COMPONENTS:

- 1 *DuraPrep™ Surgical Solution

***STERILITY NOTE:** Duraprep™ 6ml Self Disinfecting Iodine Povacrylex Solution with Sterile Outer Applicator

WARNING(S):

- A needle stick with a contaminated needle may cause infectious disease.


PRECAUTIONS:

- **Use Aseptic technique.**
- To help prevent needle-stick injuries, needles should not be recapped or purposely bent. If excessive resistance is met during needle insertion, do not force the needle as damage may occur. To help avoid needle breakage, do not attempt to straighten a bent needle; discard it and complete the procedure with a replacement needle.
- After use, place sharps in a suitable sharps container. Dispose of contaminated product in a safe manner according to Centers for Disease Control and Prevention (USA) and Federal/State/Local regulations (EPA, OSHA) and health care facility guidelines or local equivalent.
- Do NOT Resterilize.
- To be used only by individuals familiar with spinal procedures. For specific techniques and procedures, refer to standard textbooks.


STORE AT CONTROLLED ROOM TEMPERATURE

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(01) 0 0351688 07007 7




STERILE EO Rx ONLY

Caution - Do Not Reuse - Does not contain Natural Rubber Latex - Do not use if package is damaged - Sterilized using ethylene oxide - **Caution** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician

Smiths Medical ASD, Inc.
Keene, NH 03431 USA
Made in USA
www.smiths-medical.com

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smiths medical

SPINAL
22G QUINCKE



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A3441-22





A3441-22 SPINAL 22G QUINCKE

regional anesthesia kit c47916

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:51688-9481
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:51688-9481-2	10 in 1 CASE		
1		1 in 1 PACKAGE, COMBINATION		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 APPLICATOR	6 mL

Part 1 of 1

3M DURAPREP SURGICAL

iodine povacrylex and isopropyl alcohol solution

Product Information

Item Code (Source)	NDC:17518-011
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Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Iodine povacrylex (UNII: 6E43AWY083) (Iodine - UNII:9679TC07X4)	Iodine povacrylex	6.02 mg in 1 mL
Isopropyl alcohol (UNII: ND2M416302) (Isopropyl alcohol - UNII:ND2M416302)	Isopropyl alcohol	636.4 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17518-011-09	6 mL in 1 APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021586	09/29/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K965017	10/14/2006	

Labeler - Smiths Medical ASD, Inc. (137835299)**Establishment**

Name	Address	ID/FEI	Business Operations
Smiths Medical ASD, Inc.		137835299	relabel, manufacture

Establishment

Name	Address	ID/FEI	Business Operations
3M Company		054236443	manufacture