

**A2924-18 CONTINUOUS EPIDURAL 18G HUSTEAD - regional anesthesia kit
Smiths Medical ASD, Inc.**

APLICARE POVIDONE-IODINE SOLUTION (povidone-iodine solution) solution
[Aplicare, Inc.]

3/4 Ounce Povidone Iodine Packet

Povidone-iodine 10%

Antiseptic

Warnings

Do not use

- if allergic to iodine
- in the eyes

For external use only

Ask a doctor before use if injuries are

- deep or puncture wounds
- serious burns

Stop use and ask a doctor if

- redness, irritation, swelling or pain persists or increases
- infection occurs

Avoid pooling beneath patient

Keep out of reach of children. In case of accidental ingestion, seek professional assistance or consult a poison control center immediately.

Package Label Display Panel

NDC 52380-0001-3
DIN 02076144

TEAR HERE
POUR



3/4 FLUID OUNCE
POVIDONE-IODINE
SOLUTION

0.75 Fl. oz. (22.5 mL)

STERILE unless opened or damaged.

Drug Facts	
Active ingredient	Purpose
Povidone-iodine USP 10%	Antiseptic
Use antiseptic skin preparation	
Warnings	
Do not use if allergic to iodine	
For external use only	

Reorder No. L-3001

EXP 10-10

TEAR HERE
POUR

Drug Facts (continued)

Warnings

Ask a doctor before use if injuries are
■ deep or puncture wounds ■ serious burns

Stop use and ask a doctor if

■ redness, irritation, swelling or pain persists or increases
■ infection occurs

Do not use in eyes

Avoid pooling beneath patient

Keep out of reach of children. In case of accidental ingestion, seek professional assistance or consult a poison control center immediately.

Directions apply locally as needed

Other information

■ 1% titratable iodine ■ latex free
■ for hospital or professional use only

Inactive ingredients citric acid, disodium phosphate, nonoxynol-9, sodium hydroxide, water

Questions or comments?

☎ 1-800-760-3236 (Mon to Fri 8:30 AM-5:00 PM EST)



APLICARE, INC.
MERIDEN, CT 06450
U.S.A.

DOLLARD-des-ORMEAUX,
QUEBEC H9G 2S3
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0407

Package Label Display Panel

REF A2924-18
CONTINUOUS EPIDURAL
18G HUSTEAD



PROCEDURAL COMPONENTS:

- 1 Hustead Epidural Needle (18G x 3 1/2 in.)
 - 1 20G Teflon Epidural Catheter Radiopaque with Stylet, Open End, No Eyes
 - 1 EpiFuse™ Catheter Connector
 - 1 Glass L.O.R. Syringe (5mL, Luer Slip)
 - 1 25G x 1 1/2 in. Needle
 - 1 25G x 3/4 in. Needle
 - 1 Plastic Syringe (10mL, Luer Lock)
 - 1 Plastic Syringe (3mL, Luer Slip) with 18G x 1 1/2 in. Needle (Attached)
 - 1 Catheter Support Pad
 - 1 0.2 Micron Procedural Filter
 - 1 Needle Stick Pad
 - 1 Epidural Catheter I.D. Label
 - 1 Fenestrated Drape
- PREP COMPONENTS:**
- 2 Towels
 - 4 Gauze Sponges
 - 3 Sponge Applicators
 - 1 Povidone-Iodine Solution, 1/4 oz

DEVICE INFORMATION:

- EPIDURAL CATHETER WITH STYLET**
 Withdraw stylet 3 to 4 cm before inserting catheter in needle. For ease of stylet removal, stylet should not pass beyond tip of needle (withdraw further if necessary).
- CATHETER CONNECTOR**
 See enclosed Instructions For Use.
- 0.2 MICRON PROCEDURAL FILTER**
FLUID RETENTION IS APPROXIMATELY 0.5 ML
1. Fill syringe with anesthetic.
 2. Attach filled syringe to female Luer fitting of filter.
 3. Hold filled syringe in upright position and apply pressure to displace air from inlet chamber of filter unit and to ensure complete wetting of filter. ALWAYS WET FILTER THOROUGHLY BEFORE INJECTING ANESTHETIC. Incompletely wetted filters can cause air lock, reducing or stopping flow of anesthetic.
 4. Attach filter to catheter adapter or needle hub, aspirate and inject desired dose of anesthetic.
- If Using Filter with Indwelling Catheter, Proceed to the Following Two Steps:**
5. Remove syringe leaving filter unit attached to catheter. Insert Luer plug into female Luer fitting. Secure catheter and filter to patient in normal manner. DO NOT DISCONNECT FILTER UNIT FROM CATHETER WHILE IN USE.
 6. For repeat injections, remove Luer plug, reattach syringe to filter inlet, aspirate and administer additional anesthetic as needed.

WARNINGS:

- A needle stick with a contaminated needle may cause infectious disease.
- The use of excessive force while placing needles into the stick pad may cause the needle to protrude through the bottom of the tray which may result in a contaminated needle stick.

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.
- Never withdraw the catheter back through the epidural needle as this may cause the catheter to kink or shear.
- To be used only by individuals familiar with continuous epidural procedures. For specific techniques and procedures, refer to standard textbooks.

The Smiths Medical and Portex design marks, and EpiFuse are trademarks of the Smiths Medical family of companies. The symbol ® indicates the trademark is registered in the U.S. Patent and Trademark Office and certain other countries.



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 Made in USA
 www.smiths-medical.com

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STERILE EO **Rx ONLY**
Caution - Do Not Reuse - Latex Free - 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

PLTA2924-18 REV. 003 09/10

smiths medical

A2924-18 CONTINUOUS EPIDURAL 18G HUSTEAD

regional anesthesia kit kit

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:51688-9175
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:51688-9175-2	10 in 1 CASE		
1		1 in 1 PACKAGE, COMBINATION		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 PACKET	22.5 mL

Part 1 of 1

APLICARE POVIDONE-IODINE

povidone-iodine solution

Product Information

Item Code (Source)	NDC:52380-0001
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Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52380-0001-3	22.5 mL in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/01/1984	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K965017	12/14/2005	

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
Aplicare, Inc.		107255002	manufacture

