

**A3150-17 CONTINUOUS EPIDURAL 17G TUOHY - regional anesthesia kit  
Smiths Medical ASD, Inc.**

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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.

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

Reorder No. L-3001

EXP 10-10


TEAR HERE  
POUR

<b>Drug Facts (continued)</b>
<b>Warnings</b>
Ask a doctor before use if injuries are ■ deep or puncture wounds ■ serious burns
<b>Stop use and ask a doctor if</b>
■ redness, irritation, swelling or pain persists or increases ■ infection occurs
<b>Do not use in eyes</b>
<b>Avoid pooling beneath patient</b>
Keep out of reach of children. In case of accidental ingestion, seek professional assistance or consult a poison control center immediately.
<b>Directions</b> apply locally as needed
<b>Other information</b>
■ 1% titratable iodine ■ latex free ■ for hospital or professional use only
<b>Inactive ingredients</b> citric acid, disodium phosphate, nonoxynol-9, sodium hydroxide, water
<b>Questions or comments?</b>
☎ 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  
www.aplicare.com  
0407

Package Label Display Panel



**REF A3150-17**  
**CONTINUOUS EPIDURAL**  
**17G TUOHY**



**PROCEDURAL COMPONENTS:**

- 1 Tuohy Epidural Needle (17G x 3 in. T.W.)
- 1 20G Portex® Nylon Epidural Catheter with Stylet, Closed End, 3 Eyes for use with 16G or 17G Needle
- 1 EpiFuse® Catheter Connector
- 1 Catheter Insertion Device
- 1 Glass L.O.R. Syringe (5ml, Metal Luer Slip)
- 1 Fenestrated Drape
- 2 Epidural Catheter I.D. Labels
- 1 22G x 1 1/2 in. Needle
- 1 25G x 5/8 in. Needle
- 2 Point-Lok® Devices
- 1 Disc Filter, .2µ
- 1 Plastic Syringe (20ml, Luer Slip)
- 1 Plastic Syringe (3ml, Luer Lock)

**PREP COMPONENTS:**

- 3 Gauze Sponges
- 3 Sponge Applicators
- 1 Povidone-Iodine Solution, 3% oz.
- 1 Towel

**DEVICE INFORMATION:**  
**CATHETER CONNECTOR**  
 See enclosed Instructions For Use.


**WARNINGS:**

- 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 Re-sterilize.
- 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; Portex; EpiFuse; and Point-Lok are trademarks of Smiths Medical. The symbol © indicates the trademark is registered in the U.S. Patent and Trademark Office and certain other countries.




**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      PTA3150-17 REV. 003 10/11      © 2011 Smiths Medical. All rights reserved.



(01) 0 0351688 06568 4

**PORTEX**  
**CONTINUOUS EPIDURAL**  
**17G TUOHY**  
  
**A3150-17**  
 Use by: 0000-00  
 Exp. by: yy/mm  
 L01 000000  


## A3150-17 CONTINUOUS EPIDURAL 17G TUOHY

regional anesthesia kit kit

### Product Information

<b>Product Type</b>	MEDICAL DEVICE	<b>Item Code (Source)</b>	NHRIC:51688-9427
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:51688-9427-2	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

<b>Item Code (Source)</b>	NDC:52380-0001
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Route of Administration

TOPICAL

DEA Schedule

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (IODINE)	POVIDONE-IODINE	0.10 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE	
SODIUM PHOSPHATE, DIBASIC	
SODIUM HYDROXIDE	
NONOXYNOL-9	
WATER	

**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