

**WILEY SPINAL 199-2340- needle, conduction, anesthetic (w/wo introducer)**  
**Epimed International**

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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

A 7K022 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

# Epimed

INTERNATIONAL, Inc.

Johnstown, NY 12095 USA 800-866-3342 or 518-725-0209 Fax: 518-725-0207

REF:  
**199-2340**

## WILEY SPINAL™

STERILE EO  
Non-pyrogenic

Contents:

- 1 (One) Wiley-Spinal™
- 1 (One) Extension Set with Wik-Wire™
- 1 (One) 2Fr Peel-Away Introducer
- 1 (One) Syringe 3cc Plastic Luer Lock
- 1 (One) Syringe 6cc Plastic Luer Lock
- 1 (One) 18g x 1.5" Infiltration Needle
- 1 (One) 25g x 1.5" Skin Wheel Needle
- 1 (One) 18g x 1.5" Filter Needle
- 1 (One) Epidural Flat Filter
- 1 (One) Insertion Site Support Pad
- 1 (One) Tegaderm™ Transparent Dressing
- 1 (One) Iodophor Swabsticks PVP (3)
- 1 (One) Drape, Clear 24" x 32", 4" Round Fenestration
- 1 (One) Towel, White 18" x 18"
- 5 (Five) Gauze Sponges 3" x 3"



Intended for the administration of anesthetic agents to provide regional anesthesia.  
**WARNING: NOT APPROVED FOR USE WITH CONTINUOUS INFUSION PUMPS.**

**DO NOT USE WITH OTHER INTRODUCERS.**

**DO NOT USE MAGNETIC RESONANCE IMAGING WHILE THIS DEVICE IS IN PLACE WITHIN THE PATIENT.**

**PRECAUTION: NOT FOR USE WITH HYPERBARIC SOLUTIONS.**

Caution: Federal (U.S.A) Law Restricts This Device To Sale By Or On The Order Of A Physician.  
Disposable For Single Use Only.

Sterility: Contents Within The Enclosed Sealed Package Are Sterile Unless Package Has Been Opened Or Damaged.



Item Number



0000 - 00



Quantity



HIBCC

LOT sample



32°C  
10°C

+M81719923400L+

Tegaderm is a trademark of 3M

Wiley Spinal™ and Wik-Wire™ are trademarks of Epimed International, Inc.  
Patents Pending LA- 645 Rev. 1

**WILEY SPINAL 199-2340**

needle, conduction, anesthetic (w/wo introducer) kit

### Product Information

<b>Product Type</b>	MEDICAL DEVICE	<b>Item Code (Source)</b>	NHRIC:60816-2340
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:60816-2340-1	1 in 1 PACKAGE		

### 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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<b>Route of Administration</b>	TOPICAL
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### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Povidone-iodine</b> (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 mg in 1 mL

### Inactive Ingredients

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		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		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K043467	10/08/1996	

**Labeler** - Epimed International (799751953)

## Establishment

Name	Address	ID/FEI	Business Operations
Epimed International		799751953	relabel, manufacture

## Establishment

Name	Address	ID/FEI	Business Operations
Aplicare, Inc.		107255002	manufacture

Revised: 9/2013

Epimed International