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## Appendix A

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Meroce1 Operations  
Mystic, Connecticut

Document No.: LS418-4-3  
Revision: 3  
Approval Date: 10/09/2002

TITLE: Lamice1 Box Insert (2-sided)  
8-1/2" x 11"

ORIGINAL  
SPECIFICATION  
DO NOT MODIFY



# INSTRUCTIONS

FOR THE USE OF



### Description

Lamice1® OSMOTIC CERVICAL DILATOR is an absorbent polyvinyl acetal sponge, impregnated with less than 500 milligrams of magnesium sulfate (Epsom salt). The sponge is compressed to finished size. Once formed, the dilators become highly hygroscopic and capable of increasing their mass up to three times over a period of time, when placed in an environment where they can absorb fluids. Lamice1® OSMOTIC CERVICAL DILATOR, when placed in the endocervical canal, will provide gradual dilation under circumstances found to be tolerable to most patients, and safer and less traumatic than the rapid dilation and attendant risk of employing rigid mechanical dilators.

### SYMBOLS:

- Lot Number
- Sterilized by irradiation. Do not use if product is opened or damaged.
- REF Catalog Number
- Use Until Date
- Do Not Reuse
- See Insert

### Characteristics of Lamice1®

#### OSMOTIC CERVICAL DILATOR

1. Lamice1® OSMOTIC CERVICAL DILATOR is sterilized by irradiation, and packaged one (1) per package in a moisture proof and bacteria barrier sterile envelope.
2. As provided, Lamice1® OSMOTIC CERVICAL DILATOR is a smooth, salt impregnated Meroce1® sponge 67mm in length. Lamice1® OSMOTIC CERVICAL DILATOR is available in two (2) diameters, 3mm and 5mm.
3. A string looped through the proximal end provides a marker tag to indicate location.
4. Lamice1® OSMOTIC CERVICAL DILATOR is designed for insertion in the uterine cervix, and to absorb endocervical fluids.
5. Gradual swelling of Lamice1® OSMOTIC CERVICAL DILATOR results in accompanying gradual dilation of the endocervical canal. Ripening and dilation generally occur in two (2) hours, with maximum dilation in twelve (12) hours.



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Mystic, CT 06355 U.S.A.  
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## INSTRUCTIONS

### Indications for Use of Lamicel<sup>®</sup> OSMOTIC CERVICAL DILATOR

The use of Lamicel<sup>®</sup> OSMOTIC CERVICAL DILATOR is indicated for dilation or ripening of the cervix uteri for the following surgical procedures:

1. Hysteroscopy: If dilation is necessary to permit the introduction of a hysteroscope through the cervix uteri.
2. Termination of first and early second trimester pregnancy (up to 24 weeks gestation).

### Contraindications

Lamicel<sup>®</sup> OSMOTIC CERVICAL DILATOR is contraindicated for women who exhibit pelvic inflammatory disease, uterine, cervical, or vaginal infection.

### Warnings

1. Lamicel<sup>®</sup> OSMOTIC CERVICAL DILATOR should not be used for dilation or ripening of the cervix for women:
  - a. Who are menstruating.
  - b. Beyond 24 weeks gestation.
2. Do not use if sterile envelope is open or shows signs of damage.
3. Do not re-use Lamicel<sup>®</sup> OSMOTIC CERVICAL DILATOR under any circumstances.
4. Do not use the marker string to remove the device.
5. Do not use x-ray to locate lost device, because it is not radiopaque. Ultrasound should be used to locate the lost device.

### Adverse Effects

The following effects have been reported with the use of Lamicel<sup>®</sup> OSMOTIC CERVICAL DILATOR.

1. Discomfort/uterine cramping
2. Cervical injury
3. Bleeding
4. Syncope

### Precautions

**1. Elevation of Serum Magnesium Level**  
Although clinical trials have not demonstrated any appreciable rise in serum magnesium levels, systemic absorption of magnesium sulfate may occur. The amount of magnesium sulfate in the device, however, is less than the therapeutic dosage indicated for eclampsia (intravenous administration) and constipation (oral administration).

### 2. Allergic Reaction

Although clinical trials have not demonstrated any reactions to the device or its components, hypersensitivity to the materials may result in an allergic reaction.

### 3. Cervical Laceration

Although clinical trials have not demonstrated any cervical lacerations or perforation, device related, careful placement of the device in the cervical canal is required.

### 4. Infection

Although clinical trials have not demonstrated any infections, device related or otherwise, contamination of the device during insertion is possible, and precautions should be taken to prevent contamination. Do not allow the device to remain in place for more than twenty-four (24) hours. Do not use device if sterile pouch is open or appears to be damaged.

### 5. Vaso-Vagal Reaction

Any cervical manipulation may cause a vaso-vagal reaction. The patient should be observed for evidence of unusual pallor, nausea, vertigo or weakness.

### 6. Lost Device

Ultrasound may be used to search for a lost device.

### 7. Breakage

In the unlikely event of device breakage, the section(s) may be removed by using one of the following procedures:

- a. Locate and remove section from the cavity with a small "polyp" forceps.
- b. Suction curettage.
- c. Slide a small curette past the Lamicel<sup>®</sup> OSMOTIC CERVICAL DILATOR and then draw it downward.

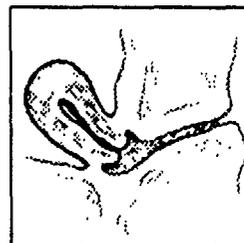
### 8. Use

Caution: Federal Law restricts this device to sale by or on the order of a physician.

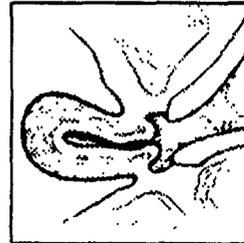
### 9. Shelf Life

Lamicel<sup>®</sup> OSMOTIC CERVICAL DILATOR shelf-life is indicated as the expiration date on the individual package and outer packaging of the device.

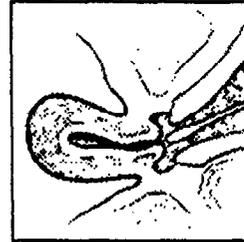
## INSTRUCTIONS AND ILLUSTRATIONS FOR THE INSERTION OF Lamicel<sup>®</sup> OSMOTIC CERVICAL DILATOR



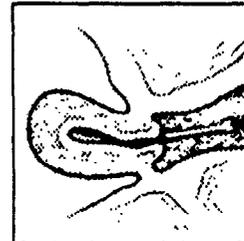
Side view of normal uterus and vaginal vault.



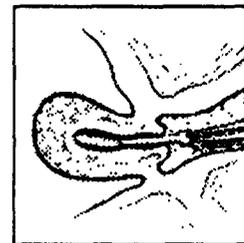
Speculum inserted in vaginal vault to expose cervix.



Cervix and vaginal vault swabbed with suitable antiseptic.

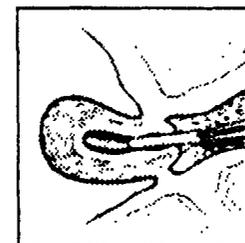


Insertion of dilator using long forceps to grasp string end of dilator.



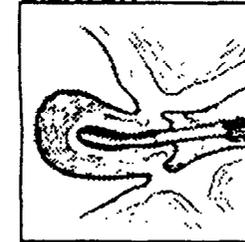
Dilator fully inserted. Distal tip extends just past the internal os.

**ORIGINAL SPECIFICATION DO NOT MODIFY**

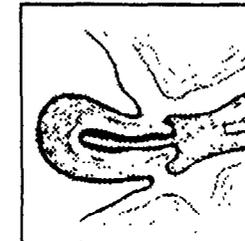


View of expanded dilator in place

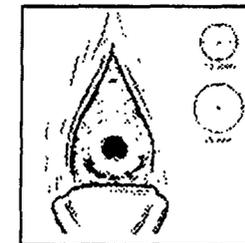
## INSTRUCTIONS AND ILLUSTRATIONS FOR THE REMOVAL OF Lamicel<sup>®</sup> OSMOTIC CERVICAL DILATOR



For removal of dilator, gently pull on exposed tip with uterine forceps.



Side view of uterus showing dilated cervix after removal of dilator.



Front view of face of dilated cervix.  
3 mm dilator yields 12 mm dilation.  
5 mm dilator yields 15 mm dilation.

NOTE: DO NOT USE THE MARKER STRING TO REMOVE THE DEVICE.



**PROOF** W.O.# 10102

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LS736-2-0

■ Pantone 301

**ORIGINAL  
SPECIFICATION  
DO NOT MODIFY**

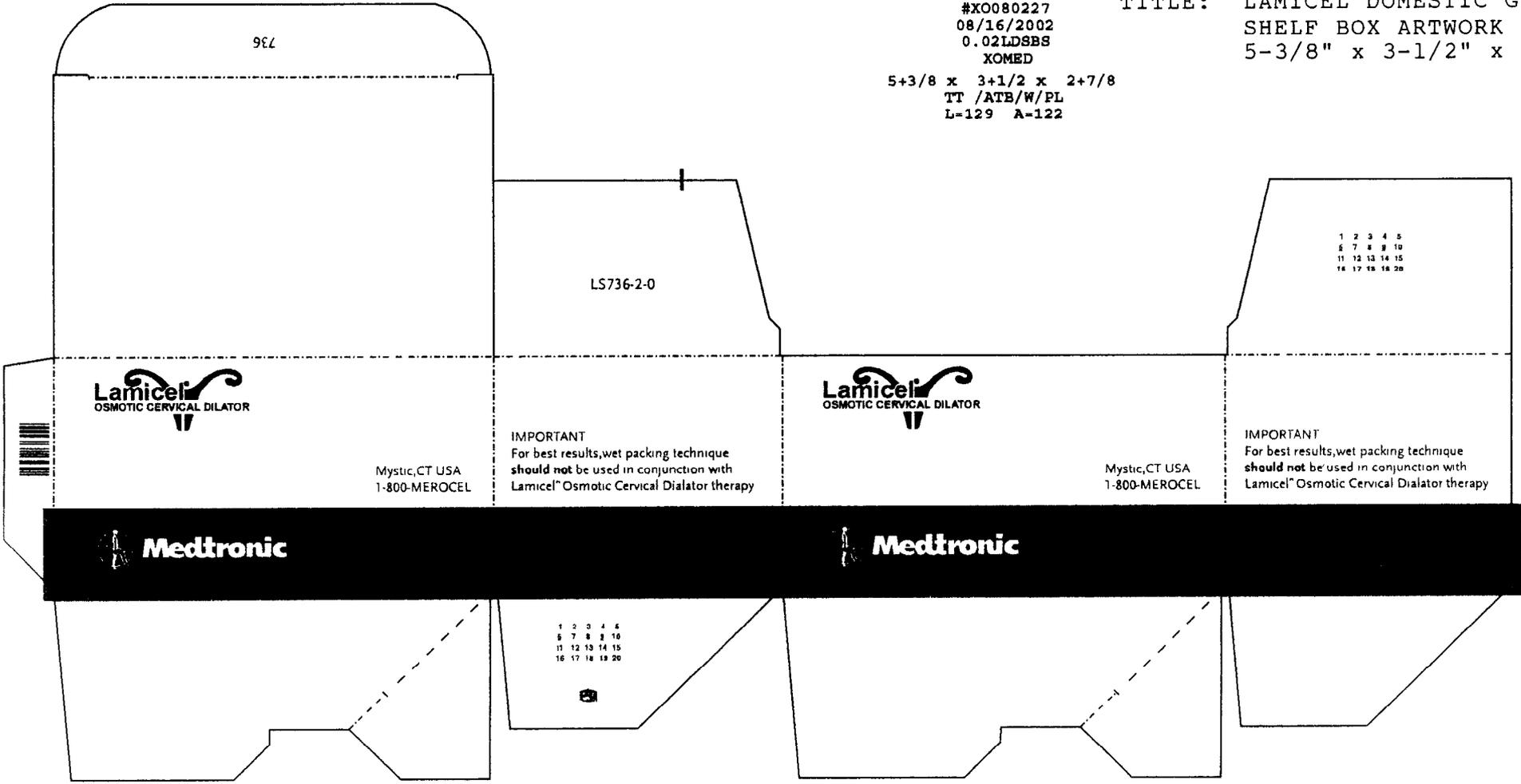
**PLEASE  
DO NOT FOLD  
NOT  
FOR COLOR**

Merocel Operations  
Mystic, Connecticut

Document No.: LS736-2-0  
Revision: New  
Approval Date: 09/17/2002

TITLE: LAMICEL DOMESTIC GENERIC  
SHELF BOX ARTWORK  
5-3/8" x 3-1/2" x 2-7/8"

SCO-DAN  
#X0080227  
08/16/2002  
0.02LDSBS  
KOMED  
5+3/8 x 3+1/2 x 2+7/8  
TT /ATB/W/PL  
L-129 A-122



992

LS736-2-0

1	2	3	4	5
6	7	8	9	10
11	12	13	14	15
16	17	18	19	20



**IMPORTANT**  
For best results, wet packing technique  
should not be used in conjunction with  
Lamicel Osmotic Cervical Dilator therapy

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1	2	3	4	5
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16	17	18	19	20

# Lamcel Process Flow

