



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (kml)
FOLDER: K974479 - 248 pages
COMPANY: SILIMED, LLC. (SILIMED)
PRODUCT: STENT, VAGINAL (KXP)
SUMMARY: Product: SILIMED VAGINAL STENT

DATE REQUESTED: Aug 2, 2016

DATE PRINTED: Aug 2, 2016

Note: Printed





AUG 5 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Silimed L.L.C.
c/o Mr. E. J. Smith
Smith Associates
P.O. Box 4341
Crofton, MD 21114

Re: K974479
Silimed Vaginal Stent
Dated: June 12, 1998
Received: June 12, 1998
Regulatory Class: II
21 CFR 884.3900/Procode: 85 KXP

Dear Mr. Smith:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):K974479

Device Name: Silimed Vaginal Stent

Classification Panel: 85 KXP, 884.3900

Indications for Use:

The *Silimed Vaginal Stent* is designed to maintain the vaginal canal following radiological treatment or surgical procedures to restore, enlarge or create a vagina.

The surgeon is responsible for proper choice of size to meet the clinical and aesthetic needs of each case.

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use or Over-the-Counter Use

Coleman Pollard

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number

K974479/5002



AUG 5 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Silimed L.L.C.
c/o Mr. E. J. Smith
Smith Associates
P.O. Box 4341
Crofton, MD 21114Re: K974479
Silimed Vaginal Stent
Dated: June 12, 1998
Received: June 12, 1998
Regulatory Class: II
21 CFR 884.3900/Procode: 85 KXP

Dear Mr. Smith:

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Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):K974479

Device Name: Silimed Vaginal Stent

Classification Panel: 85 KXP, 884.3900

Indications for Use:

The *Silimed Vaginal Stent* is designed to maintain the vaginal canal following radiological treatment or surgical procedures to restore, enlarge or create a vagina.

The surgeon is responsible for proper choice of size to meet the clinical and aesthetic needs of each case.

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use or Over-the-Counter Use

Coleman P. Hall

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number

K974479/5002



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

Memorandum

1: Reviewer(s) - Name(s) Mridulita Virmani
Subject: 510(k) Number K 974479/S2

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Accepted for review 6/15/98.
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate?

YES NO NA

Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? YES NO

This 510(k) contains:

- Truthful and Accurate Statement Requested Enclosed (required for originals received 3-14-95 and after)
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices NA
- The indication for use form (required for originals received 1-1-96 and after)

Material of Biological Origin YES NO NA

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with class:
85 KXP class II
CFR 884: 3900

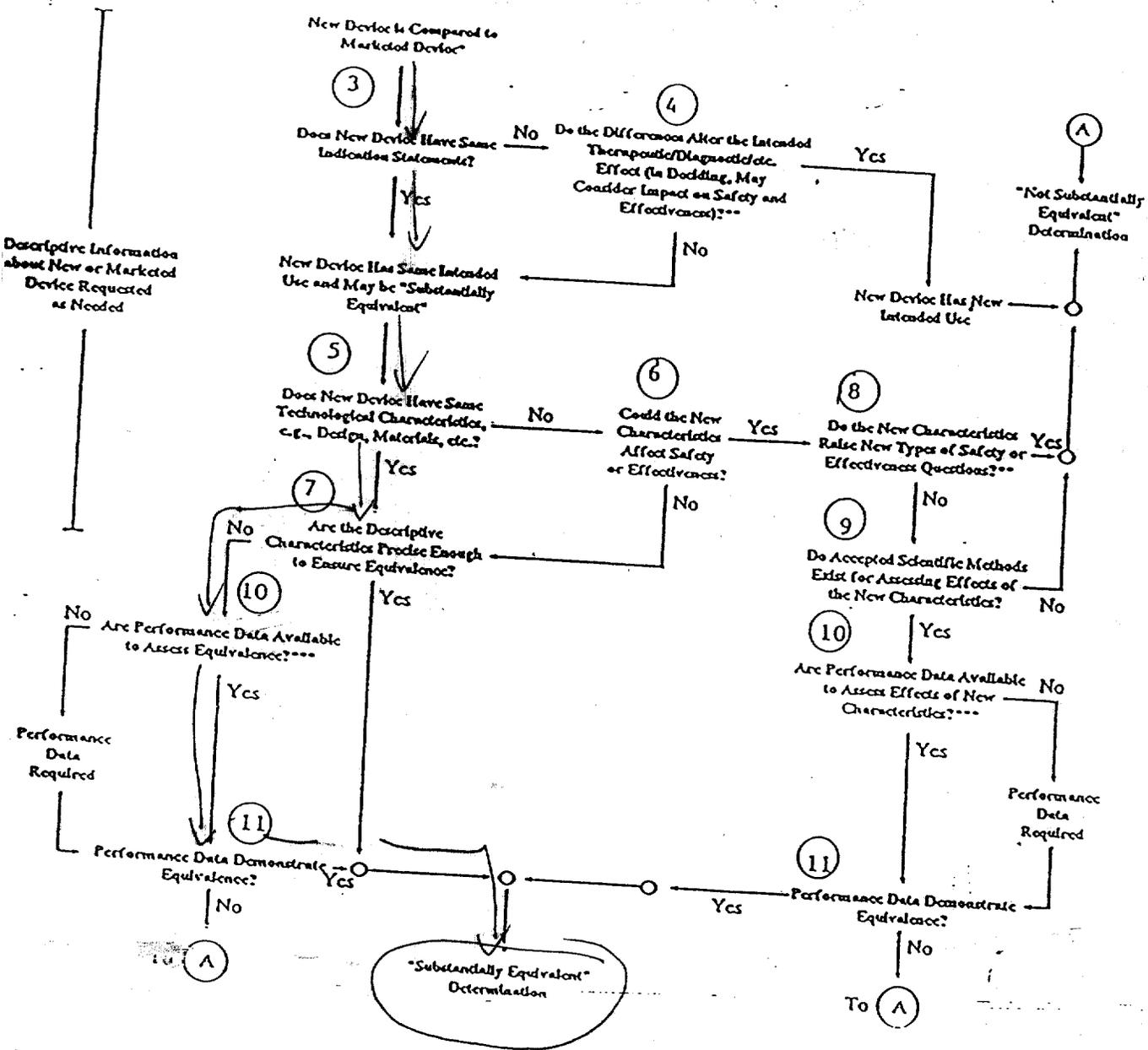
Additional Product Code(s) with panel (optional):

View: Colin M. Ballard CGDB 8/5/98
(Branch Chief) (Branch Code) (Date)

(Jm)
B

Review: for R. GATLING
(Division Director) (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear. This decision is normally based on descriptive information alone, but limited testing information is sometimes required. Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

June 12, 1998

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

SILIMED, LLC
C/O SMITH ASSOCIATES
P.O BOX 4341
CROFTON, MD 21114
ATTN: E J. SMITH

510(k) Number: K974479
Product: SILIMED VAGINAL
STENT

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

K974479

Reviewer: Mridulika Virmani, Ph.D.
Chemist

Division/Branch: DRAERD/OGDB
(HFZ-470)

Trade Name: Silimed Vaginal Stent

Common Name: Stent, vaginal

Predicate Device: Heyer-Schulte Adjustable Vaginal Stent

Applicant: Smith Associates
P.O. Box 4341
Crofton, Maryland 21114

Contact: E.J. Smith

Phone: (410) 451-0639

Fax: (410) 793-0448

INTENDED USE:

The Silimed Vaginal Stent is designed to maintain the vaginal canal following radiological treatment or surgical procedures to restore, enlarge or create a vagina. The surgeon is responsible for choice of size to meet the clinical and aesthetic needs of each case. It comes in four sizes, ranging from 70-300 cm³.

	YES	NO
Life-supporting or life-sustaining?		✓
Implanted (long-term or short-term)?		✓
Uses software?		✓
Sterile?	✓ *	
Single use?	✓ *	
Home use?	✓	
For prescription?	✓	
Contains drug or biologic?		✓
Kit?		✓

*single patient use, additional cleaning instructions for removal and replacement.

Reason for Submission of 510(k)

- New device X
- New indications No
- Changes in technology No
- Other:

Device Description

The Silimed Vaginal stent consists of silicone elastomer shell filled with polyurethane foam. The shell has a internal drain tube and a inflation tube with a valve for opening and closing of inflation tube. Stent can be filled with the help of a syringe, which can be connected at the end of inflation tube, [REDACTED] (b) [REDACTED]

[REDACTED] Silimed has provided Master file number for silicone. This Master File includes list of chemical, physical and biocompatibility testing done for this silicone material. (b)(4)Product Specs [REDACTED]

[REDACTED] It is stays in place for 3-6 months. Stent can be taken out for cleaning twice daily for a period not to exceed 15 minutes. The stent must be replaced by a new stent every 12 weeks.

Review History

For this device company has used Mentor/heyer-Schulte as a predicate device. Sponsor has provided a 510K # (K863439), this 510(k) is for a uterine balloon and not for stent. Submission included a brochure for labeling from a predicate device marketed by HeyerSchute the adjustable vaginal stent. The subject device intended use, description and materials are quite similar to predicate device.

(b)(4)Product Specs [REDACTED]

Review Analysis

Additional information required letter was sent to company on January 11, 1998 and April 13, 1998. This submission is the response to the letter of April 13, 1998. Ms. Price and Dr. Smith have reviewed this submission. Their reviews are attached.

MATERIALS AND BIOCOMPATIBILITY

Basic materials of the subject device are quite similar to the predicate device. Both use silicone elastomer shell filled with polyurethane. The shell of predicate device is \cong 0.5 mm thick silicone

membrane. Biocompatibility testing is provided for silicone elastomer from the supplier A (b) (4) and for same material in similar use in other devices.

Materials, manufacturing process and additives used during this process information, as well as chemistry of material is provided and satisfactory. Dr. Tsai reviewed this part of submission. His review is attached. The polyurethane foam is filled in the water tight shell of the elastomer, this shell is connected with a tube which has a valve and also is the fill tube for inflating the shell with sterile saline. Engineering drawing, polyurethane amount and how it is filled in the shell is provided and adequate. Sponsor provided a sample of device, which explains lot of concerns. According to sponsor, this device has a history of use in Europe for past 10 years, and now they want to market this device in U.S.

PERFORMANCE

The stent is inserted in the vagina in its collapsed (flat) position, after insertion the stent is filled with sterile solution (not provided), using a syringe (not provided) until it is secured in position. The amount of solution added is at the desecration by the physician. (b) (4)Product Specs

Performance data has been reviewed by Ms. Price and she finds it satisfactory. Her reviews are attached.

STERILIZATION

Device is provided sterilized for single patient use. Sterilization method is Ethylene Oxide (ETO). Sterility Assurance Levels mentioned in the submission is ten to the sixth. Sponsor forgot the minus sign. It was reminded to him and he was advised to correct in his files the SAL to 10⁻⁶. The labeling will not require device to be pyrogen free. Although they will do the testing for pyrogenicity.

The certification reprocessing instruction validation is provided in the A5. They will do the validation before starting the marketing of device. A validation protocol is included in the submission. For sterility and cleaning validation, I have consulted with Mr. Kuchinski, and he has seen all the data and cleaning validation protocol and finds these satisfactory.

Patient cleaning instruction are included in A5 (exhibit 6,page2). Dr. Smith has reviewed the cleaning instructions and finds them satisfactory.

LABELING

Modified physician and patient labeling is included in the additional information A5. (b)(4)Product Specs I have to consult several times with Dr. Smith and than relayed the questions raised in clinical review to sponsor. After several revised faxes from

the company, (b) (4) Product Dr. Smiths reviews are attached.

ADMINISTRATIVE

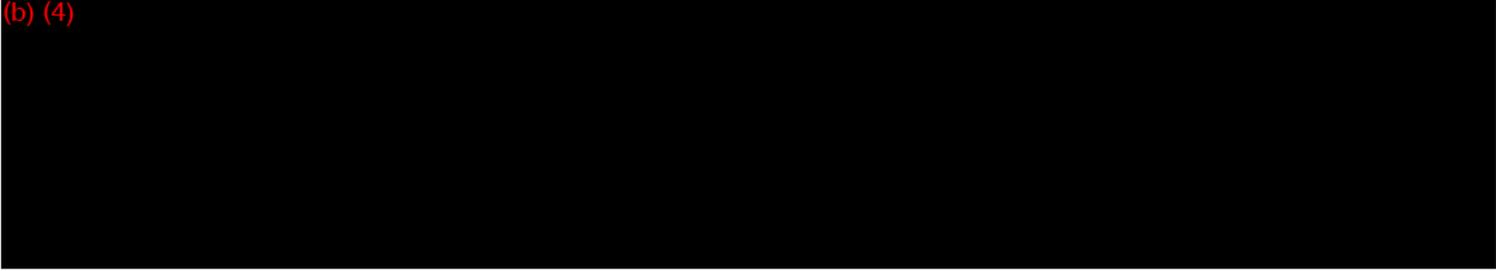
The following documents are included in the submission:

- 510(k) statement
- Truthful and Accurate Statement
- Indications for Use

Substantial Equivalence (SE) Decision Making Documentation

	YES	NO	
1. Is product a device?	<u>X</u>	—	IF NO, STOP
2. Device subject to 510(k)?	<u>X</u>	—	IF NO, STOP
3. Same indication statement?	<u>X</u>	—	IF YES, GOTO 5
4. Do differences alter the effect or raise new issues of safety or effectiveness?	—	<u>X</u>	IF YES, STOP->NSE
5. Same technological characteristics?	—	<u>X</u>	IF YES, GOTO 7
6. Could the new characteristics Affect safety or effectiveness?	—	—	IF YES, GOTO 8
7. Descriptive characteristics precise enough?	—	<u>X</u>	IF YES, STOP->SE
8. New <u>types</u> of safety and effectiveness questions?	—	<u>X</u>	IF YES, STOP->NSE
9. Accepted scientific methods exist?	<u>X</u>	—	IF NO, STOP->NSE
10. Performance data available?	<u>X</u>	—	IF NO, REQ. DATA
11. Data demonstrate equivalence	<u>X</u>	—	IF YES, STOP->SE

(b) (4)



REVIEWER RECOMMENDATION

Substantially Equivalent

ProCode: 85 KXP
Class: II
CFR #: 21 CFR §884.3900

> t:
f

Mridulika Virmani 8/3/98
Mridulika Virmani, Ph.D. Date

Colin M. Pollard 8/5/98 ✓
Colin M. Pollard / / Concur
Chief, Ob/Gyn Devices Branch / / Do not concur.
Date Comments:

I N T E R O F F I C E M E M O R A N D U M

Date: 21-Jul-1998 05:27am EST
From: Allen Herman
deborah@eni.net@SMTP@CVAX3
Dept:
Tel No:

TO: Virmani, Mridulika 594-1180 ext. 14 (MSV@CDRH.FDA.GOV@SMTP@CVAX3)

Subject: Re: Labeling for Silimed Stent

The modest corrections I indicated can be corrected and then I think it is appropriate to proceed with the SE letter.

I will be out of town beginning Wednesday 7/22 for the next 3 weeks . so please fax me the other material if in fact I need to review it so I can check before my departure.

Thanks

At 09:39 AM 7/20/98 -0400, you wrote:

>
> Dr. Smith
>
> Thanks for your comments for Silimed's Stent. If sponsor make
> thses latest changes in the labeling, than this document is ok
> for Substantially Equivalent decision from clinical point of
> view. If yes than after making sure that (b) (4) r [REDACTED]
> [REDACTED] d [REDACTED] n [REDACTED] g, I will send a SE letter to
> company.
>
> I also, recieved the corrections from Dr. Koch for G820012/S42
> for their informed consent form. Please let me know, if you
> are coming here this week or you want me to fax the revised
> form to you? This IDE supplement is due on July 24. Thanks.

Mridu

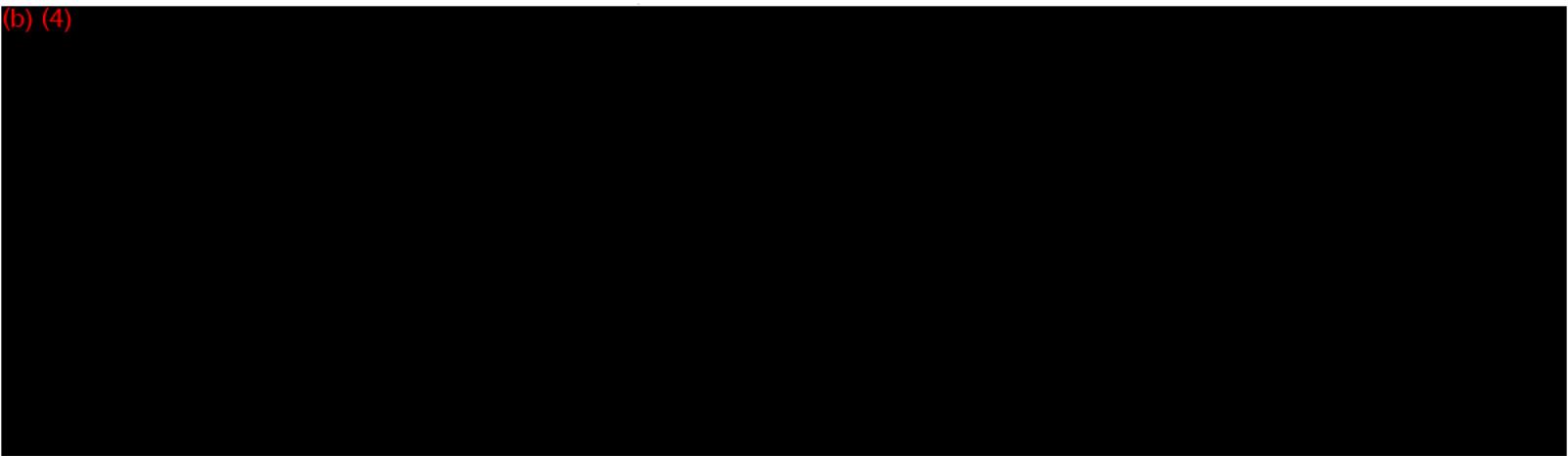
I N T E R O F F I C E M E M O R A N D U M

Date: 20-Jul-1998 06:36am EST
From: Deborah M. Smith
deborah@eni.net@SMTP@CVAX3
Dept:
Tel No:

TO: MSV (MSV@CDRH.FDA.GOV@SMTP@CVAX3)
CC: CMP (CMP@CDRH.FDA.GOV@SMTP@CVAX3)
Subject: Labeling for Silimed Stent

I have reviewed the revised labeling submission dated July 14, 1998 and have the following comments:

(b) (4)



Thank you.
Deborah M. Smith, MD. MPH
Telephone Number: 301.589.6864
Fax Number: 301.589.2135

7/21
called G. Smith and asked him to make all the
corrections discussed so far, which he has sent me by Fax as well as
include these changes (7/20 from Dr. Smith), copy of reviewing
certification, and device will not be labelled as Pyrogen free.
He should send a hard copy of every FAX and all this
information, no later than 7/28/98. If I will not get by
then I will keep file on HOLD.

Heather

CLINICAL REVIEW MEMORANDUM

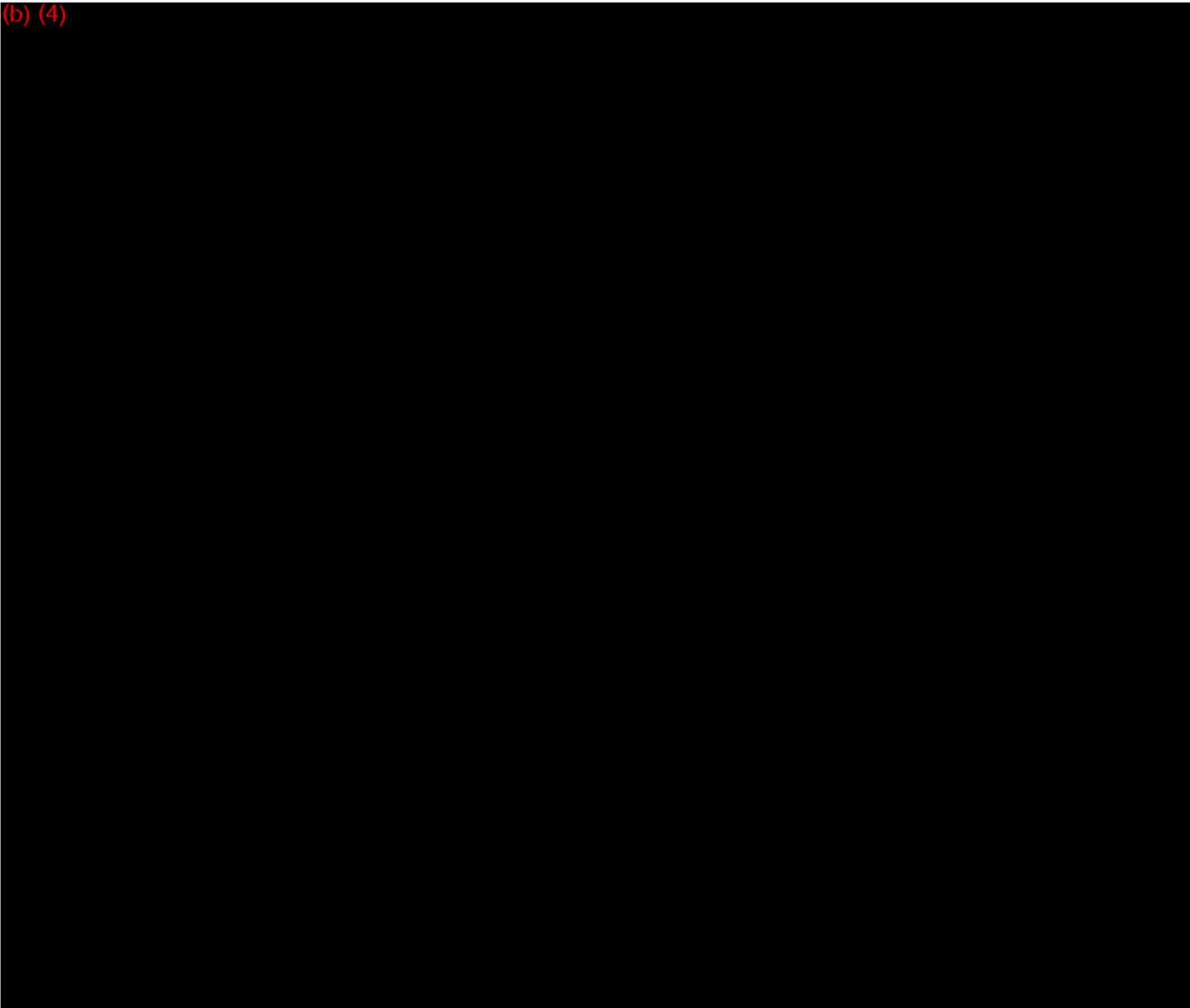
FROM: Deborah M. Smith, M.D. *Deborah M. Smith*
TO: ✓ Miridulika Virmani, Ph.D.
CC: Colin Pollard
Date: July 7, 1998

Subject: 510(k) K974479/S2 Silimed Vaginal Stent

An updated review of the labeling changes for this device is requested.

The most recent submission is dated June 26, 1998 and includes modifications to the product information and patient instruction sections of the labeling.

(b) (4)



(b) (4)





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

DATE: July 16, 1998

FROM: Veronica Price, Biomedical Engineer
DRAERD/ADOU/OGDB

TO: Mridu Virmani, Ph.D.
Chemist
DRAERD/ADOU/OGDB

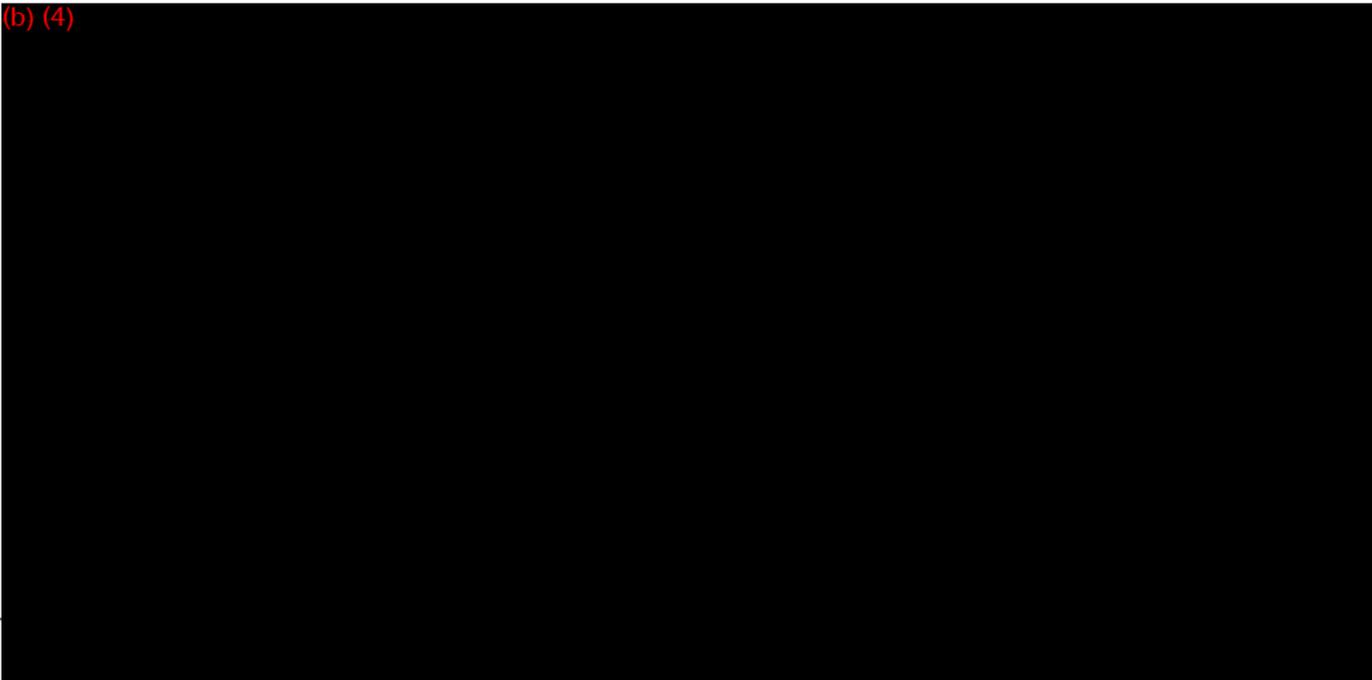
RE: K974479/A3&A4; Silimed Vaginal Stent
Silimed, Inc.

Introduction:

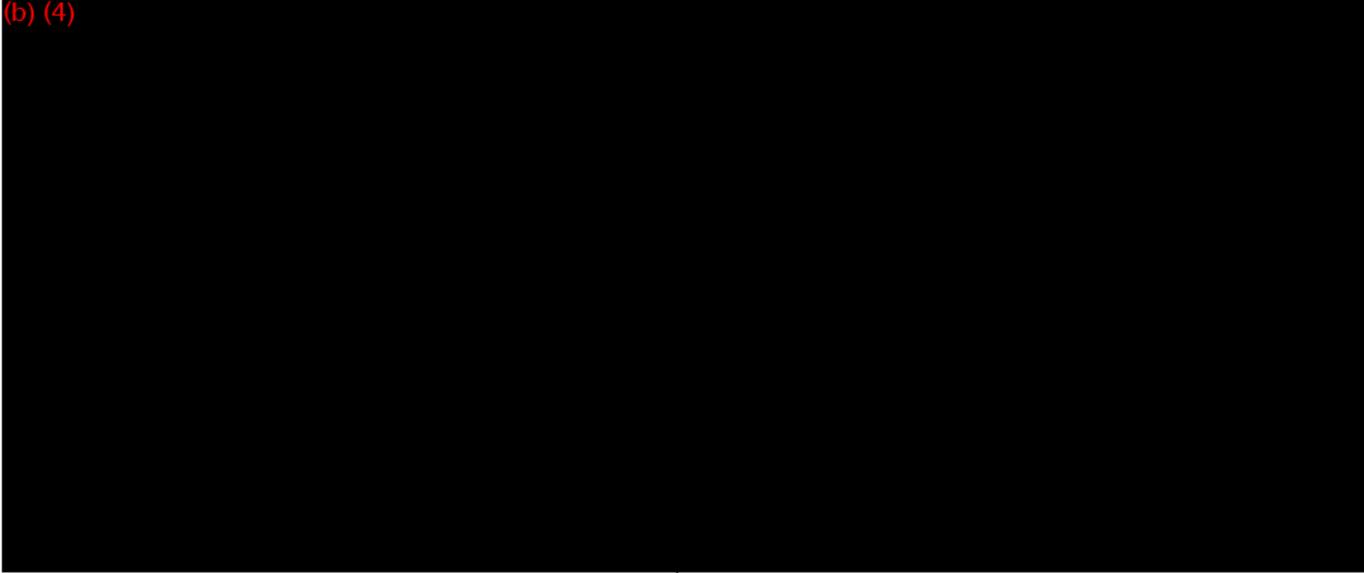
The manufacturer has made several attempts to address concerns regarding the testing conducted on the Vaginal Stent and the labeling. After review of the June 12, 1998, response, the contact for the manufacturer was called to clarify (b) (4). Two amendments have been submitted in an attempt to address these issues.

Response to Deficiencies:

(b) (4)



(b) (4)



Veronica A Price 7/16/98
Veronica Price Date



Memorandum

DATE: June 18, 1998

FROM: Veronica Price, Biomedical Engineer
DRAERD/ADOU/OGDB

TO: Mridu Virmani, Ph.D.
Chemist
DRAERD/ADOU/OGDB

RE: K974479/S2; Silimed Vaginal Stent
Silimed, Inc.

Scope:

The scope of this review is intended to cover the performance characteristics of the Silimed Vaginal Stent and the adequacy of the engineering information provided. Letters requesting additional information on this device were sent to the contact on January 21, and May 13, 1998. The contact has provided this supplement to address the issues raised in the May 13th letter. My review will focus on the adequacy of the requested bench testing and revised patient labeling.

Intended Use:

The Silimed Vaginal Stent is indicated for use:

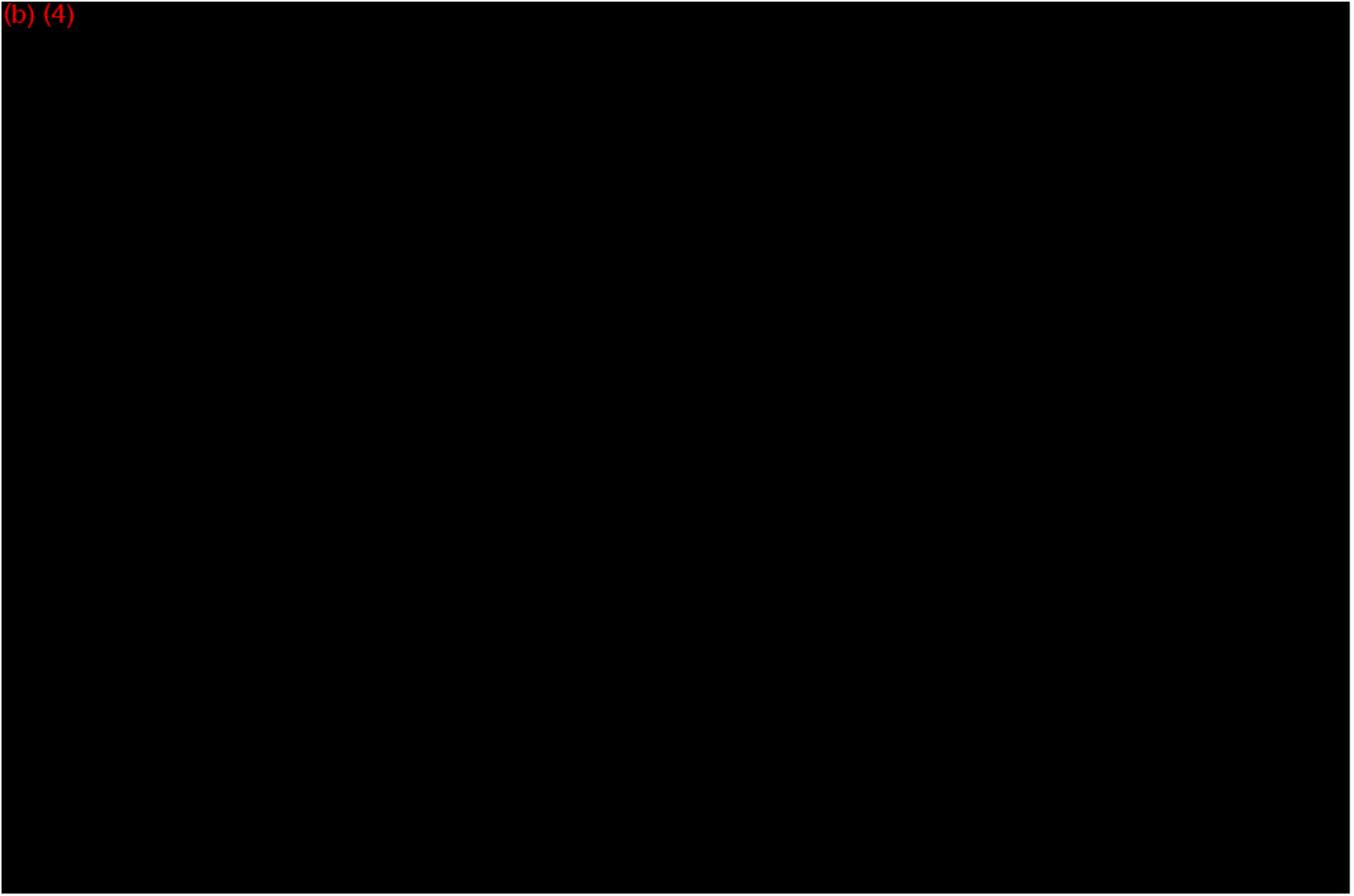
1. As a pressure dressing after vaginal surgery to hold pedicle flaps or free skin grafts in close apposition to the receptor site.
2. As an obturator or dilator to maintain the vaginal canal and reduce the possibility of contracture and stenosis following vaginal surgery and/or radiological treatment.

Response to Deficiencies:

(b) (4)



(b) (4)



Veronica Price 6/18/98

Veronica Price Date

OGDB

K974479/A2

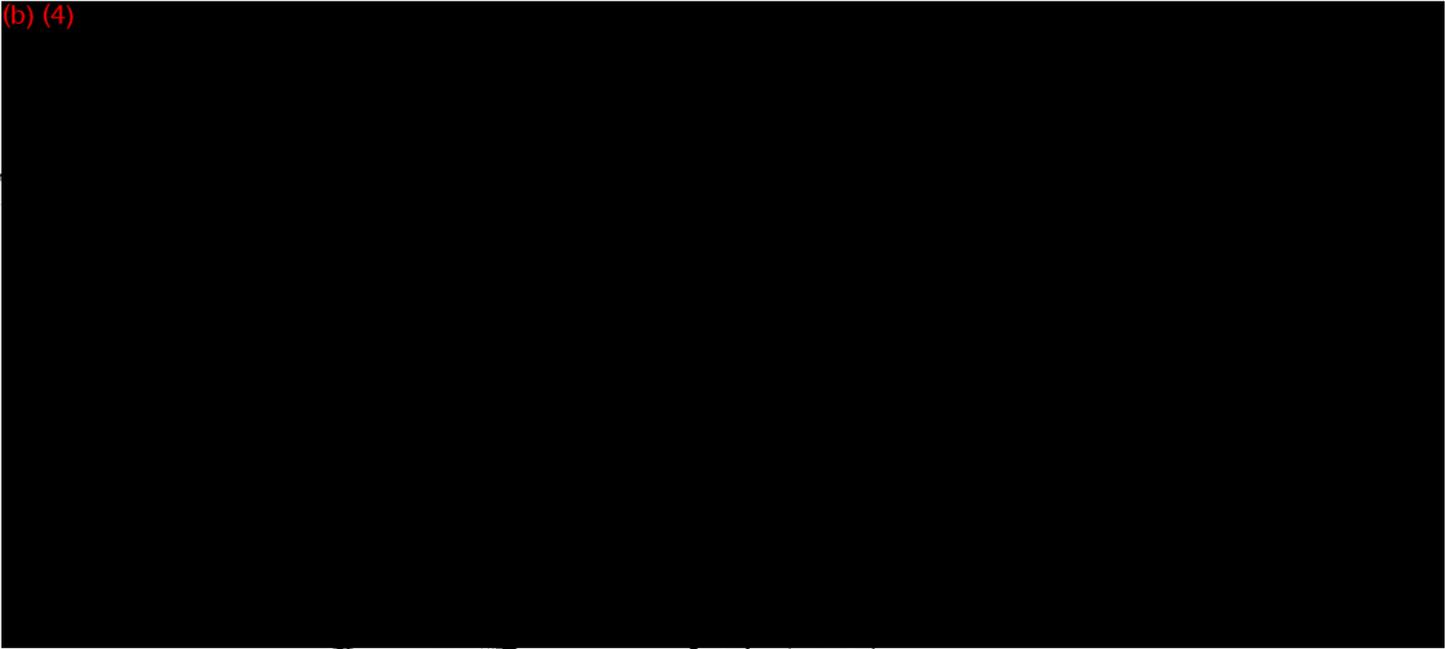
Subject: Consulting Review

Reviewer: Miin-Rong Tsai, Ph.D. **Division/Branch:** DRAERD/ADOU/OGDB
Chemist (HFZ-470)

This is the reviewed on the applicant's response to FDA's Jan 21, 1998 request for additional information. As requested, this review is on the applicant's response to deficiency #3 of the Device Description. The requested information are listed in *italics* as following:

Device Description:

(b) (4)



Miin-Rong Tsai, Ph.D.

9/2/98
Date

Chief, Ob/Gyn Devices Branch Date
Mr. Colin Pollard

// Concur

// Do Not Concur

To,

Mr. E. J. Smith

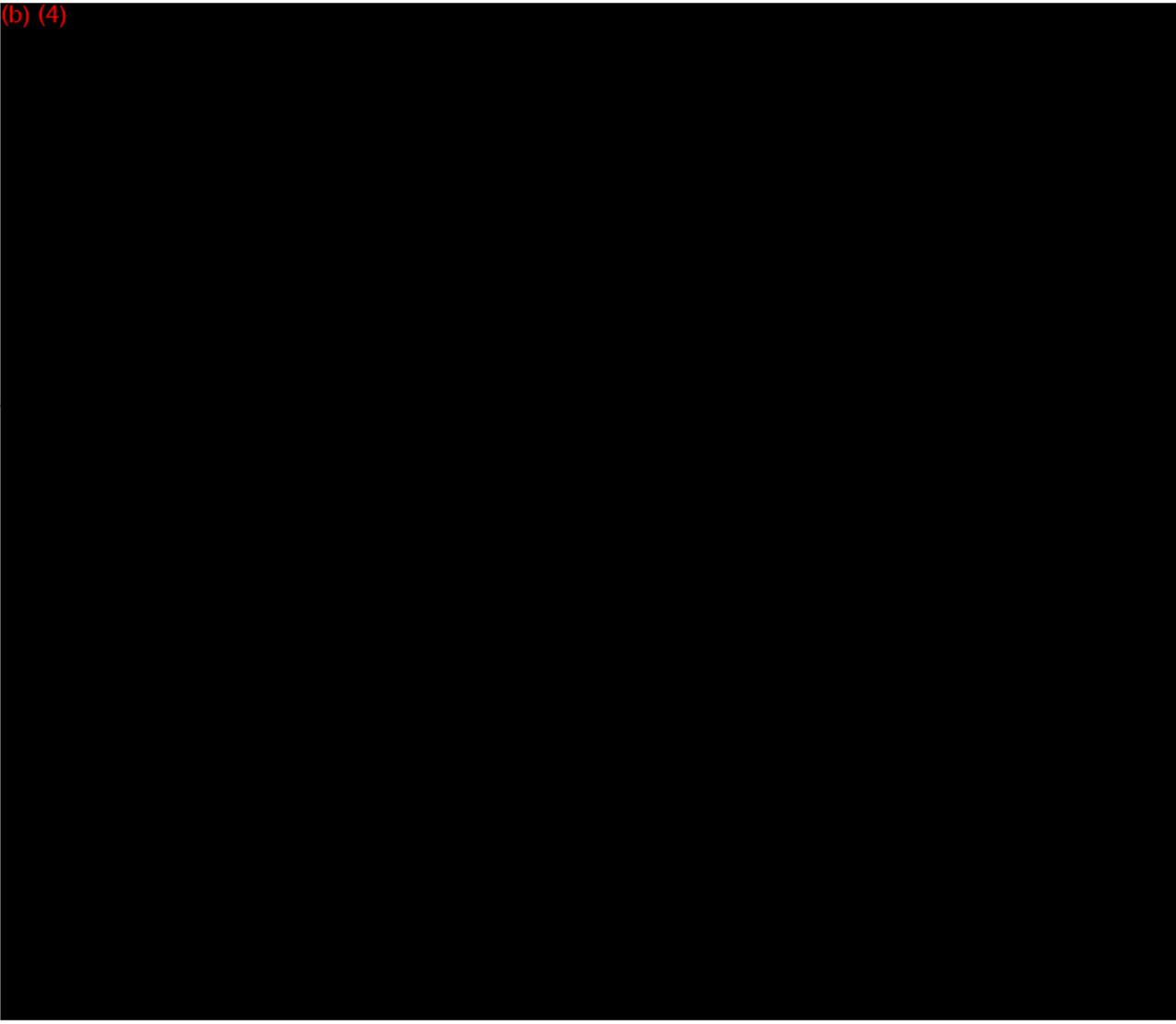
From: Maida Virman ^{MV 7/8/98}

The points which I discussed with you this morning.

An updated review of the labeling changes for this device is requested.

The most recent submission is dated June 26, 1998 and includes modifications to the product information and patient instruction sections of the labeling.

(b) (4)



(b) (4)



DUPLICATE

K974479/A5

Smith Associates

Specializing in Regulatory Affairs

July 28, 1998

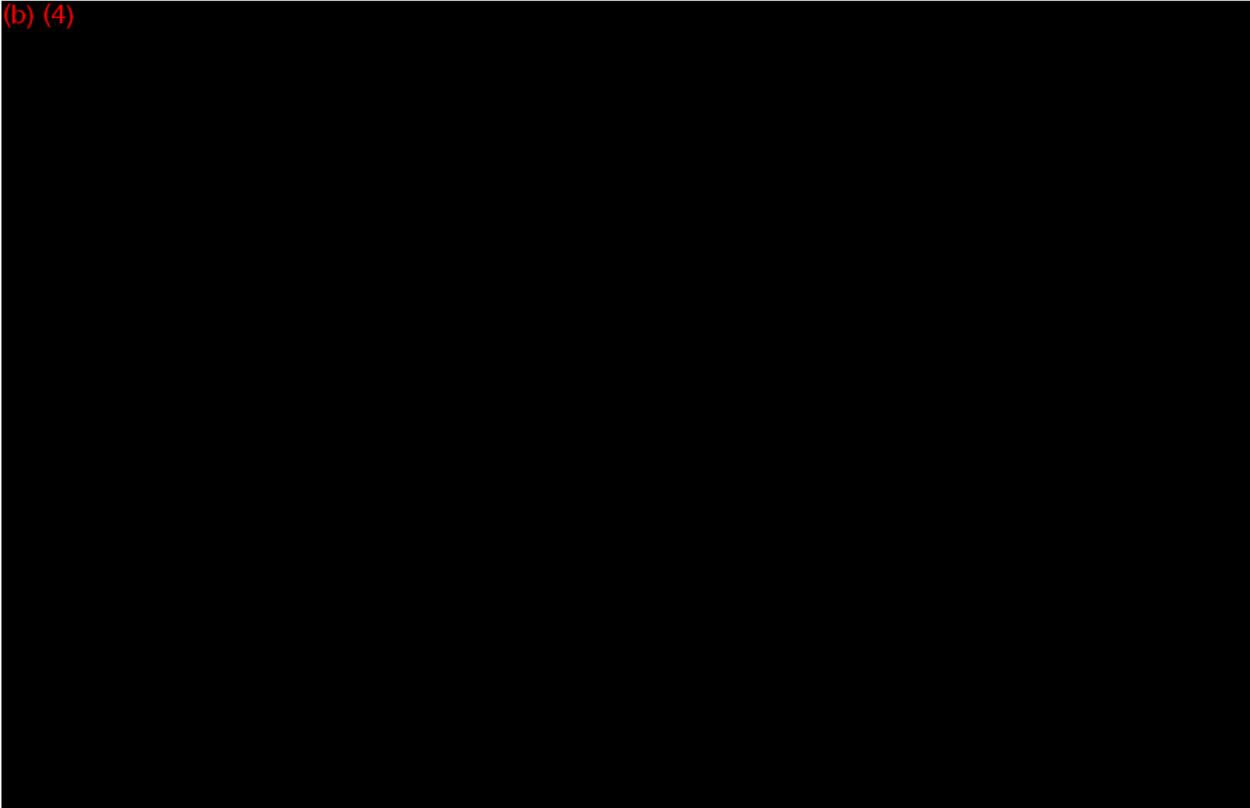
Food and Drug Administration
Document Control Center
9200 Corporate Blvd.
Rockville, Maryland 20850

Reference: K974479

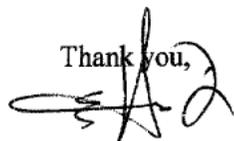
Dear Dr. Virmani:

Attached please find our responses to your most recent questions.

(b) (4)



Thank you,



E.J. Smith

510(k) Number (if known):K974479

Device Name: Silimed Vaginal Stent

Classification Panel: 85 KXP, 884.3900

Indications for Use:

The *Silimed Vaginal Stent* is designed to maintain the vaginal canal following radiological treatment or surgical procedures to restore, enlarge or create a vagina.

The surgeon is responsible for proper choice of size to meet the clinical and aesthetic needs of each case.

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____

or

Over-the-Counter Use _____

**PRODUCT INFORMATION
VAGINAL STENT**

Description:

The Silimed Vaginal Stent described in this insert is intended for use only as supplied. Under no circumstances should this device be altered, modified or revised in any way prior to or during its' use.

The inflatable Silimed Vaginal Stent is designed for neovaginal and reconstructive surgery. The Vaginal Stent has an internal drain that allows drainage of the surgical wound without withdrawing the silicone body, obturating sphere and tubing.

The Vaginal Stent is presented in a set of sizes (base, height and volume) that appear in Silimed's commercial catalog. This sizing is the result of many years of research with the medical profession.

Indications for Use:

The Silimed Vaginal Stent is indicated for use:

1. as a pressure dressing after vaginal surgery to hold pedicle flaps or free skin grafts in close apposition to the receptor site;
2. as an obturator or dilator to maintain the vaginal canal and reduce the possibility of contracture and stenosis following vaginal surgery and/or radiological treatment.

How Supplied:

Silimed Vaginal Stents are supplied sterile and are contained in:

- transparent or opaque double plastic "blister" sealed with special paper, which is permeable to ethylene oxide.
- double peel pouch packaging permeable to ethylene oxide.

The packages are stored in a cardboard box with a plastic protective film. Outer package label will contain the following information: description of the product, catalog number, lot number and expiration date.

Sterilization: Ethylene Oxide

An individual confirmation of sterilization of each batch is carried out, as well as a quarterly validation of the latter performed by an independent laboratory.

Instructions for Use:

Care when opening the package is of utmost importance: The high dielectric value of silicone can generate static charges responsible for the attraction of particles existing in the atmosphere, such as dust, lint, and talc to mention a few examples.

Care should also be taken with all the accessories of the product, be they documents such as inserts, labels, parts of products such as valves and filling tubes, etc..

The "blister" packages are double packages, which allows the user to open them in two stages:

- first remove the special paper protection from the outer "blister" gaining access to the to the sterile inner package.
- secondly, remove the special paper protection from the inner "blister" next to the surgical field.

When the implant is packaged in a double peel pouch:
-proceed in the same way as the "blister" package.

Instructions for Use:

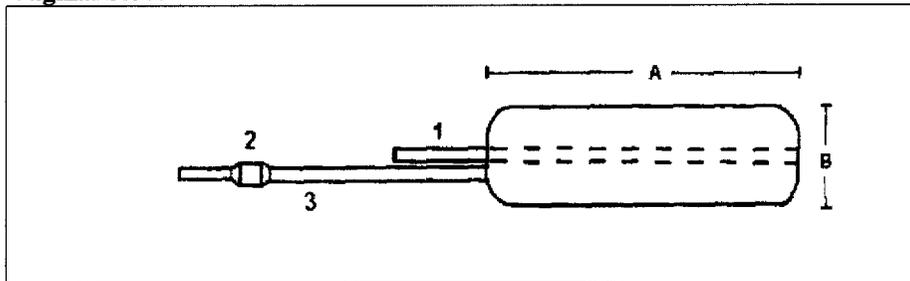
Directions for deflating and filling the stent during the surgical procedure:

1. Prior to inserting the stent, deflate the device completely by squeezing or aspirating with a syringe.
2. Close the valve by moving the ball to the closed position, i.e., toward the filling orifice.
3. Using a syringe filled with sterile, normal saline, inflate the device to the desired contour, but keep the device small enough that it may be introduced into the vagina. Approximately 50-60ml.
4. Close the valve.
5. Fill the unit in situ to the desired volume.
6. Adjust volume in the stent by opening the valve and using a syringe to introduce or withdraw saline or air. Close the valve.

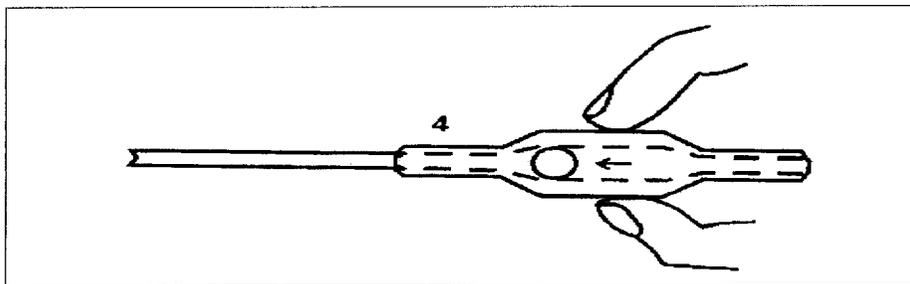
Surgical Procedure:

A variety of surgical techniques may be employed during the use of the Silimed Vaginal Stent; therefore, the surgeon is best advised to use the method which his own practice and discretion dictate to be best for the patient.

Inflatable Vaginal Stent



- 1- Internal Drain
- 2-The valve (silicone body and obturating sphere)
- 3-Tubing

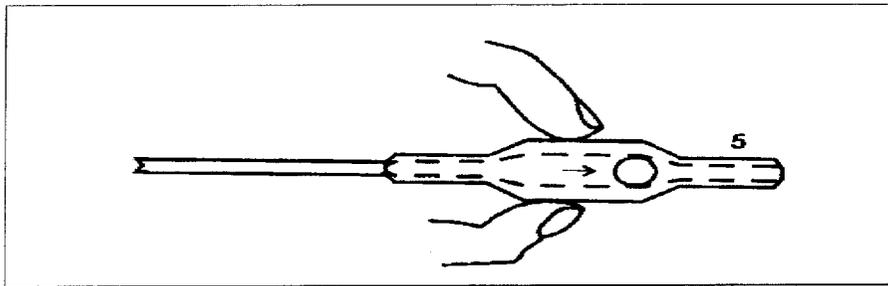


Open Position 4

Open Position:

To fill up or deplete the expander, shift the sphere towards the side of the tubing (4) with a slight compression between the thumb and index finger. When the sphere is in position, one can fill or empty the stent with the help of a syringe connected to the extremity of the valve.

Exhibit 5 Page 2



Closed Position 5

Closed Position :

To close the valve displace the sphere using the thumb and index finger to move the sphere towards its free extremity (5). The pressure within the valve coming from the stent will facilitate its airtight closure by the sphere.

Resterilization:

Silicone Vaginal Stents are meant for single patient use; resterilization is thus forbidden by international standards.

Important Recommendations:

Maintenance of Sterility: It is essential that the vaginal stent be used under conditions of absolute asepsis and sterility

Packaging Inspection: The packaging of the vaginal stent must be carefully examined. If the package has been damaged in any way, the stent cannot be used.

Stent used only as supplied: The vaginal stent can only be used in its original form, without any alterations to its original characteristics.

ALL SILICONE VAGINAL STENTS MUST BE USED IN ONE PATIENT ONLY

Durability:

The vaginal stent is a temporary device for treatment time not to exceed 12 weeks.

Contraindications and Precautions:

Procedures to create, enlarge or restore the vagina are contraindicated in the presence of local or systemic infection or in the presence of an anomaly of the urinary system which could be damaged by such procedures or by subsequent sexual intercourse. Congenital anomalies of the urinary tract frequently associated with congenital absence of the vagina include pelvic, kidney, anomalous insertion of the ureter and ureteral duplication.

The use of the vaginal stent is contraindicated when for any reason the patient has the inability to operate the device or to understand how the device is operated, or when the patient is apt to be uncooperative in maintaining the stent within the vagina for the prescribed length of time.

Warning:

The silicone elastomer shell of the Silimed Vaginal Stent is thin in order to achieve desired properties. Punctures, surface cuts, nicks, crushing or overstressing can lead to a tear. The device may be easily penetrated by needle or scalpel or ruptured by manipulation with a blunt instrument. Care must be exercised during handling to prevent such events. A damaged stent must not be placed. For this reason, a standby device should be available at the time of surgery.

ATTACHMENT I

**Silimed Vaginal Stent
Patient Instructions**

Page 2, section:

Cleaning Your Vaginal Stent:

1. Remove the deflated stent with talc free gloved hands.
2. To prevent soap or water from entering the interior of the stent, pinch the valve ball into the "closed" position.
3. Wash the stent thoroughly in a hot water using Ivory soap solution
4. **DO NOT USE SYNTHETIC DETERGENTS OR OIL-BASED SOAPS**
5. Rinse the stent well in sterile water, taking care to flush the opening of the drain tube.

ATTACHMENT I

Silimed Vaginal Stent Patient Instructions

Page 2, section:

Cleaning Your Vaginal Stent:

1. Remove the deflated stent with talc free gloved hands.
2. To prevent soap or water from entering the interior of the stent, pinch the valve ball into the "closed" position.
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5. Rinse the stent well in sterile water, taking care to flush the opening of the drain tube.

Smith Associates P.O. Box 4341 Crofton, Maryland 21114
Fax (410) 793-0448 Phone (410) 451-0639

FAX

DATE: July 14, 1998

MEMO TO: Dr. Virmani

FAX: (301)594-2339

FROM: E.J.Smith

SUBJECT: K974479

Number of Pages: _8_ including cover page

Dear Dr. Virmani:

Enclosed are "DRAFT" copies of the revised labels for the Silimed Vaginal Stent and the 510(k) number for the Silimed Tissue Expander that uses the same materials as the Stent.

Exhibit 5 Revised Physician Label

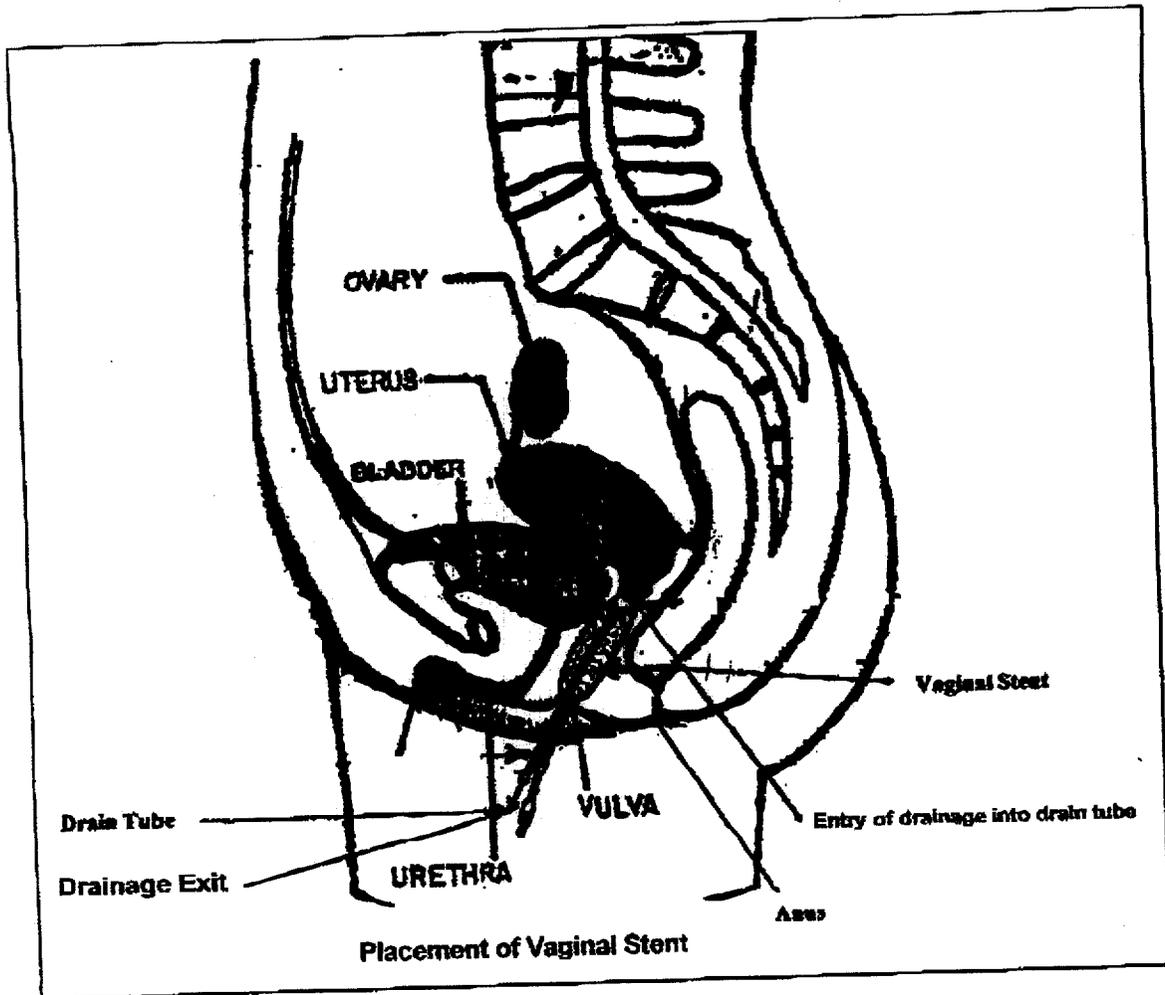
Exhibit 6 Revised Patient Label

Illustration: Revised wording
Silimed LLC will have an artist re-draw the illustration which will shadow the ovary, uterus, anus, bladder and uretha and clearly draw the vagina with the vaginal stent.

If you have any questions I can be reached at (410)451-0639.

Thank you,

E.J.Smith



DRAFT**PRODUCT INFORMATION
VAGINAL STENT****Description:**

The Silimed Vaginal Stent described in this insert is intended for use only as supplied. Under no circumstances should this device be altered, modified or revised in any way prior to or during its' use.

The inflatable Silimed Vaginal Stent is designed for neovaginal and reconstructive surgery. The Vaginal Stent has an internal drain that allows drainage of the surgical wound without withdrawing the silicone body, obturating sphere and tubing.

The Vaginal Stent is presented in a set of sizes (base, height and volume) that appear in Silimed's commercial catalog. This sizing is the result of many years of research with the medical profession.

Indications for Use:

The Silimed Vaginal Stent is indicated for use:

1. as a pressure dressing after vaginal surgery to hold pedicle flaps or free skin grafts in close apposition to the receptor site;
2. as an obturator or dilator to maintain the vaginal canal and reduce the possibility of contracture and stenosis following vaginal surgery and/or radiological treatment.

How Supplied:

Silimed Vaginal Stents are supplied sterile and are contained in:

- transparent or opaque double plastic "blister" sealed with special paper, which is permeable to ethylene oxide.
- double peel pouch packaging permeable to ethylene oxide.

The packages are stored in a cardboard box with a plastic protective film. Outer package label will contain the following information: description of the product, catalog number, lot number and expiration date.

Sterilization: Ethylene Oxide

An individual confirmation of sterilization of each batch is carried out, as well as a quarterly validation of the latter performed by an independent laboratory.

Instructions for Use:

Care when opening the package is of utmost importance: The high dielectric value of silicone can generate static charges responsible for the attraction of particles existing in the atmosphere, such as dust, lint, and talc to mention a few examples.

Care should also be taken with all the accessories of the product, be they documents such as inserts, labels, parts of products such as valves and filling tubes, etc..

The "blister" packages are double packages, which allows the user to open them in two stages:

- first remove the special paper protection from the outer "blister" gaining access to the to the sterile inner package.
- secondly, remove the special paper protection from the inner "blister" next to the surgical field.

DRAFT

When the implant is packaged in a double peel pouch:
-proceed in the same way as the "blister" package.

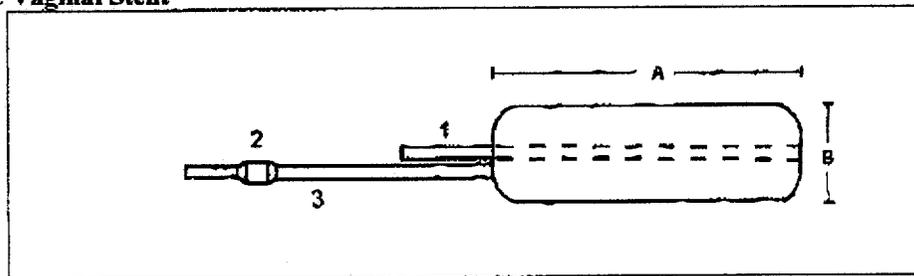
Instructions for Use:

Directions for deflating and filling the stent during the surgical procedure:

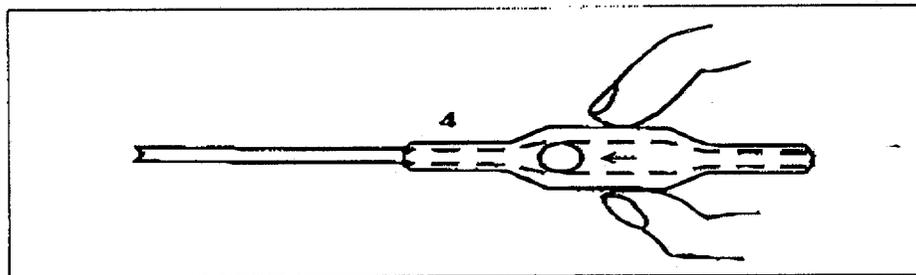
1. Prior to inserting the stent, deflate the device completely by squeezing or aspirating with a syringe.
2. Close the valve by moving the ball to the closed position, i.e., toward the filling orifice.
3. Using a syringe filled with sterile, normal saline, inflate the device to the desired contour, but keep the device small enough that it may be introduced into the vagina. Approximately 50-60ml.
4. Close the valve.
5. Fill the unit in situ to the desired volume.
6. Adjust volume in the stent by opening the valve and using a syringe to introduce or withdraw saline or air. Close the valve.
- 7.

Surgical Procedure:

A variety of surgical techniques may be employed during the use of the Silimed Vaginal Stent; therefore, the surgeon is best advised to use the method which his own practice and discretion dictate to be best for the patient.

Inflatable Vaginal Stent

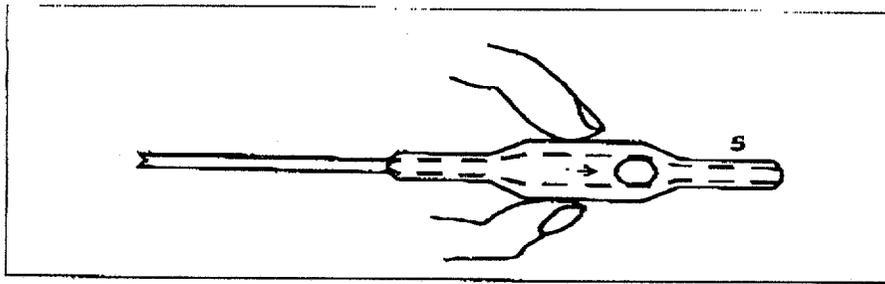
- 1- Internal Drain
2-The valve (silicone body and obturating sphere)
3-Tubing

**Open Position 4****Open Position:**

To fill up or deplete the expander, shift the sphere towards the side of the tubing (4) with a slight compression between the thumb and index finger. When the sphere is in position, one can fill or empty the stent with the help of a syringe connected to the extremity of the valve.

Exhibit 5 Page 2

DRAFT



Closed Position 5

Closed Position :

To close the valve displace the sphere using the thumb and index finger to move the sphere towards its free extremity (5). The pressure within the valve coming from the stent will facilitate its airtight closure by the sphere.

Restertization:

Silicone implants are meant for single patient use; restertization is thus forbidden by international standards.

Important Recommendations:

Maintenance of Sterility: It is essential that the vaginal stent be used under conditions of absolute asepsis and sterility

Packaging Inspection: The packaging of the vaginal stent must be carefully examined. If the package has been damaged in any way, the stent cannot be used.

Stent used only as supplied: The vaginal stent can only be used in its original form, without any alterations to its original characteristics.

ALL SILICONE VAGINAL STENTS MUST BE USED IN ONE PATIENT ONLY**Durability:**

The vaginal stent is a temporary device for treatment time not to exceed 12 weeks.

Contraindications and Precautions:

Procedures to create, enlarge or restore the vagina are contraindicated in the presence of local or systemic infection or in the presence of an anomaly of the urinary system which could be damaged by such procedures or by subsequent sexual intercourse. Congenital anomalies of the urinary tract frequently associated with congenital absence of the vagina include pelvic, kidney, anomalous insertion of the ureter and ureteral duplication.

The use of the vaginal stent is contraindicated when for any reason the patient has the inability to operate the device or to understand how the device is operated, or when the patient is apt to be uncooperative in maintaining the stent within the vagina for the prescribed length of time.

Warning:

The silicone elastomer shell of the Silimed Vaginal Stent is thin in order to achieve desired properties. Punctures, surface cuts, nicks, crushing or overstressing can lead to a tear. The device may be easily penetrated by needle or scalpel or ruptured by manipulation with a blunt instrument. Care must be exercised during handling to prevent such events. A damaged stent must not be placed. For this reason, a standby device should be available at the time of surgery.

DRAFT

Postoperatively, care must be taken not to over inflate the stent, as urethral erosion or fistula and graft tissue necrosis may result. Suprapubic drainage, rather transurethral catheterization, may be advisable.

Failure to maintain the stent within the vaginal canal for the prescribed length of time can promote contracture and stenosis of the vagina.

Lint fingerprints, talc and other surface contaminants can cause foreign body reactions. Utmost caution should be taken to avoid contaminants.

Transportation and Storing:

Silimed products and packages are extremely resistant and if handled with normal minimum of care will not present any problems. However, they should not be transported or stored with other types of material that may cause mechanical damage to the packaging and thus invalidate their sterile condition.

Clarification and Consent of Patient:

Silimed relies on the surgeon to clarify with their patients any risk factors inherent in surgery of this type before obtaining the patient's formal consent.

Warranty:

Silimed has stipulated a three year warranty for manufacturing defect provided the packaging has been preserved intact prior to use.

Silimed will replace any defective product. Since proper registration is made of each unit of raw material, stages of manufacture, and atmospheric and operational conditions, an individual number is given to each item that identifies it at any time, As a result, it absolutely necessary that any complaint be accompanied by the CONTROL NUMBER of the relevant item that appears on the package and by the PATIENT'S LABEL supplied to the doctor and detachable from the label of each package.

The warranty on Silimed products does not cover the simple decision of the patient or surgeon to change the product.

Silimed L.L.C.

14014 Sullyfield Circle Suite C

Chantilly, Virginia 20151

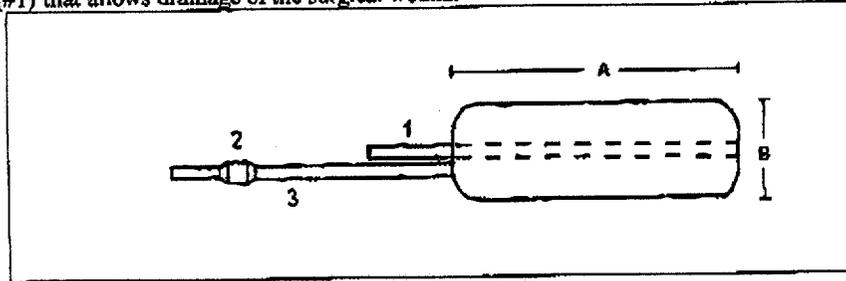
DRAFT

SILIMED VAGINAL STENT PATIENT INSTRUCTIONS

Description:

The Silimed Vaginal Stent described in this insert is intended for use only as supplied. Under no circumstances should this device be altered, modified or revised in any way prior to or during its' use.

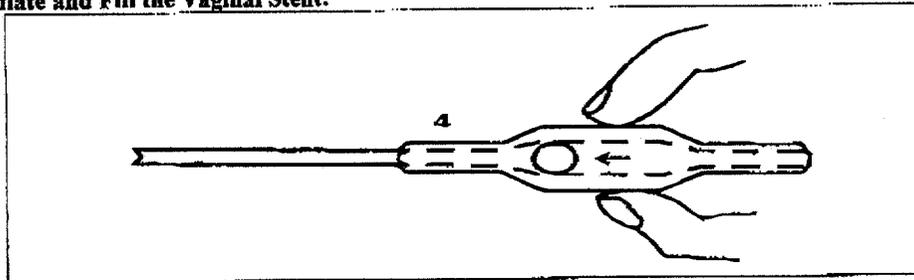
The inflatable Silimed Vaginal Stent is designed for neovaginal and reconstructive surgery. The Vaginal Stent has an internal drain (#1) that allows drainage of the surgical wound.



Silimed Vaginal Stent

- 1- Internal Drain
- 2-The valve (silicone body and obturating sphere)
- 3-Tubing

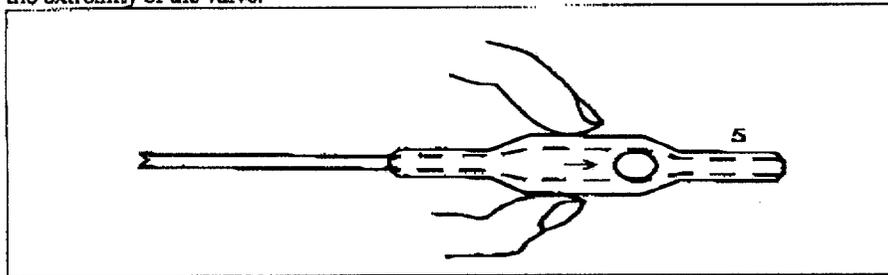
How to Deflate and Fill the Vaginal Stent:



Open Position #4

Open Position:

To fill up or empty the expander, shift the ball towards the side of the tubing (#4) with a slight compression between the thumb and index finger. When the ball is in position, one can fill or empty the stent with the help of a syringe connected to the extremity of the valve.



Closed Position #5

Closed Position :

To close the valve displace the ball using the thumb and index finger to move the ball towards its froc extremity (#5). The pressure within the valve coming from the stent will facilitate its airtight closure by the ball.

DRAFT

Removing and Reinsertion Instructions:

1. Prior to inserting the stent, deflate the device completely by squeezing or aspirating with a syringe.
2. Open the valve #2 by moving the ball towards the stent.
3. Inflate the stent to the desired contour with sterile normal saline, but keep the stent small enough that it may be introduced into the vagina. Approximately 50-60ml.
4. Close the ball by moving it towards the syringe once the stent has reached the desired volume.
5. Wound drainage, if any, will require cleaning the drain tube according to the cleaning instructions #5 below.

Cleaning Your Vaginal Stent:

1. Remove the deflated stent with talc free gloved hands.
2. To prevent soap or water from entering the interior of the stent, pinch the valve ball into the "closed" position.
3. Wash the stent thoroughly in a hot water using Ivory soap solution.
4. DO NOT USE SYNTHETIC DETERGENTS OR OIL-BASED SOAPS.
5. Rinse the stent well in sterile water, taking care to flush the opening of the drain tube.

Facts About Your Vaginal Stent:

You may remove the stent for cleaning and sexual intercourse. Sexual intercourse is permitted after two months if healing is complete and your physician has advised you on this matter. It is important to be aware that the stent may need to be used for as long as six months to prevent vaginal constriction. The vagina may contract if the stent is left out longer than 10-15 minutes at a time.

Consult with your physician for information concerning the proper use of this device if you are still having a menstrual period.

There should be little to no drainage from the surgical procedure, however, if excessive drainage occurs contact your Physician.

The visual difference between menstrual drainage and wound drainage is:

- Wound Drainage is a Clear-Reddish Color
- Menstrual Period Drainage is Dark Red Color

Use of the Vaginal Stent:

Intermittent use of the stent to maintain the vaginal canal is usually required for six months, and may be required indefinitely. *The stent must be replaced with a new stent every 12 weeks.* Consult with your physician.

If you have any questions or concerns about your vaginal stent call Silimed's help line (800) xxx-xxxx for assistance.

Silimed L.L.C.

14014 Sullyfield Circle Suite C

Chantilly, Virginia 20151

K974479/A4

Smith Associates

Specializing in Regulatory Affairs

July 2, 1998

Food and Drug Administration
Document Control Center
9200 Corporate Blvd.
Rockville, Maryland 20850

RECEIVED

7 JUL 98 13 46

FDA/CDRH/ODE/DMC

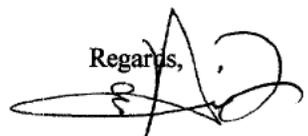
Reference: K974479

Dear Dr. Virmani:

(b) (4)

If you have any questions I can be reached at (410)451-0639.

Regards,



E.J. Smith

JK-59



SILIMED - Silicone e Instrumental Médico-Cirúrgico e Hospitalar Ltda.

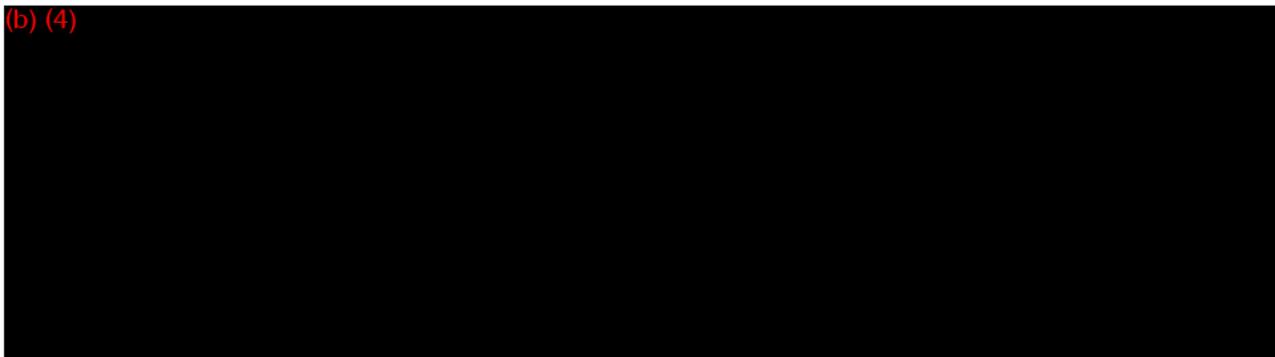
Rio de Janeiro, July 02, 1998

SUBJECT: Declaration regarding the Vaginal Stent

DECLARATION

TO WHOM IT MAY CONCERN:

(b) (4)



Wesley Schultz
WESLEY SCHULTZ
Industrial Director



SILIMED - Silicone e Instrumental Médico-Cirúrgico e Hospitalar Ltda.

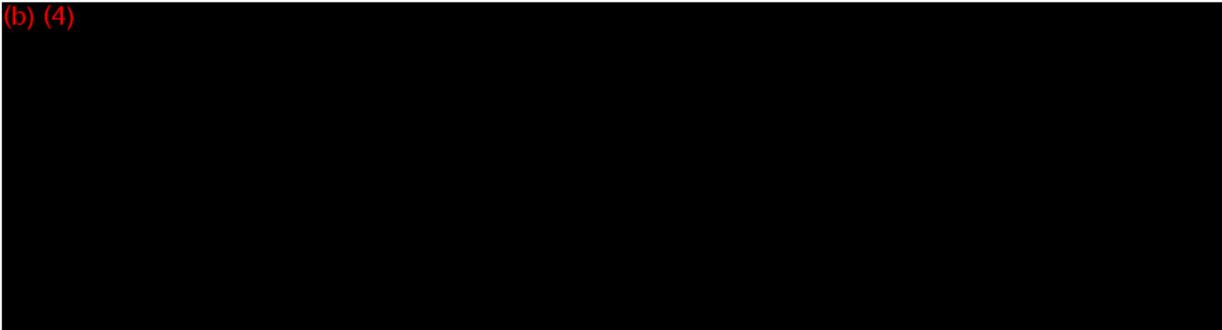
Rio de Janeiro, July 02, 1998

SUBJECT: Declaration regarding the Vaginal Stent

DECLARATION

TO WHOM IT MAY CONCERN:

(b) (4)



Wesley Schultz
WESLEY SCHULTZ
Industrial Director

K974479 / A3

Smith Associates

Specializing in Regulatory Affairs

June 29, 1998

Food and Drug Administration
Document Control Center
Center for Devices
9200 Corporate Blvd.
Rockville, Maryland 20850

RECEIVED

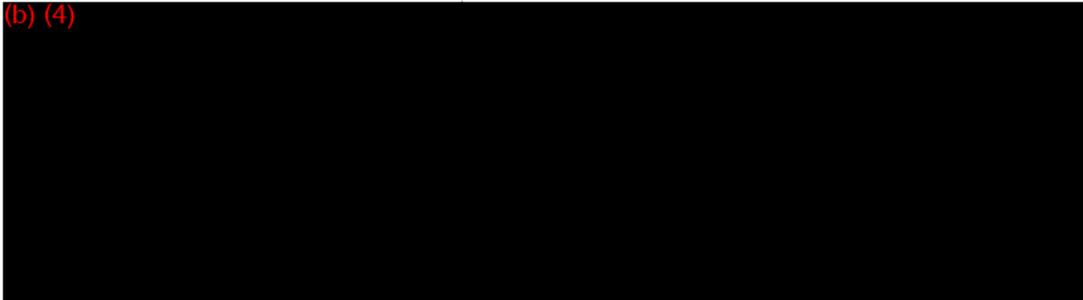
30 JUN 98 14 45

FDA/CDRH/ODE/DMC

Reference: K974479

Dear Dr. Virmani:

Attached is the revised Physician and Patient labeling you requested for the Silimed Vaginal Stent. I now have the answers to the technical questions.



If you have additional questions I can be reached at (410)451-0639.

Regards,

A handwritten signature in black ink, appearing to be "E.J. Smith", is written over the typed name.

E.J. Smith

OK-38

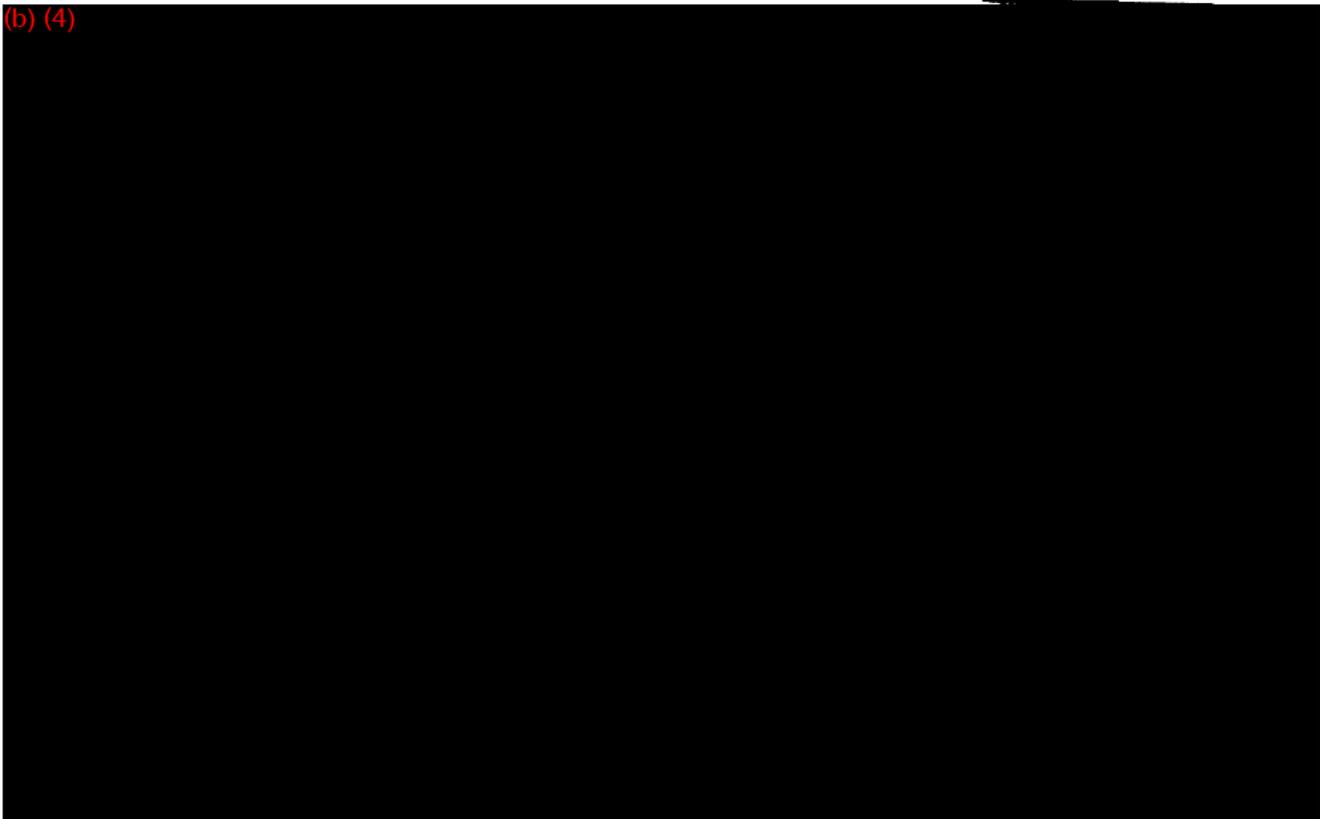
53

EXHIBIT 1

SILIMED - Silicons e Instrumental Médico-Cirúrgico e Hospitalar Ltda.



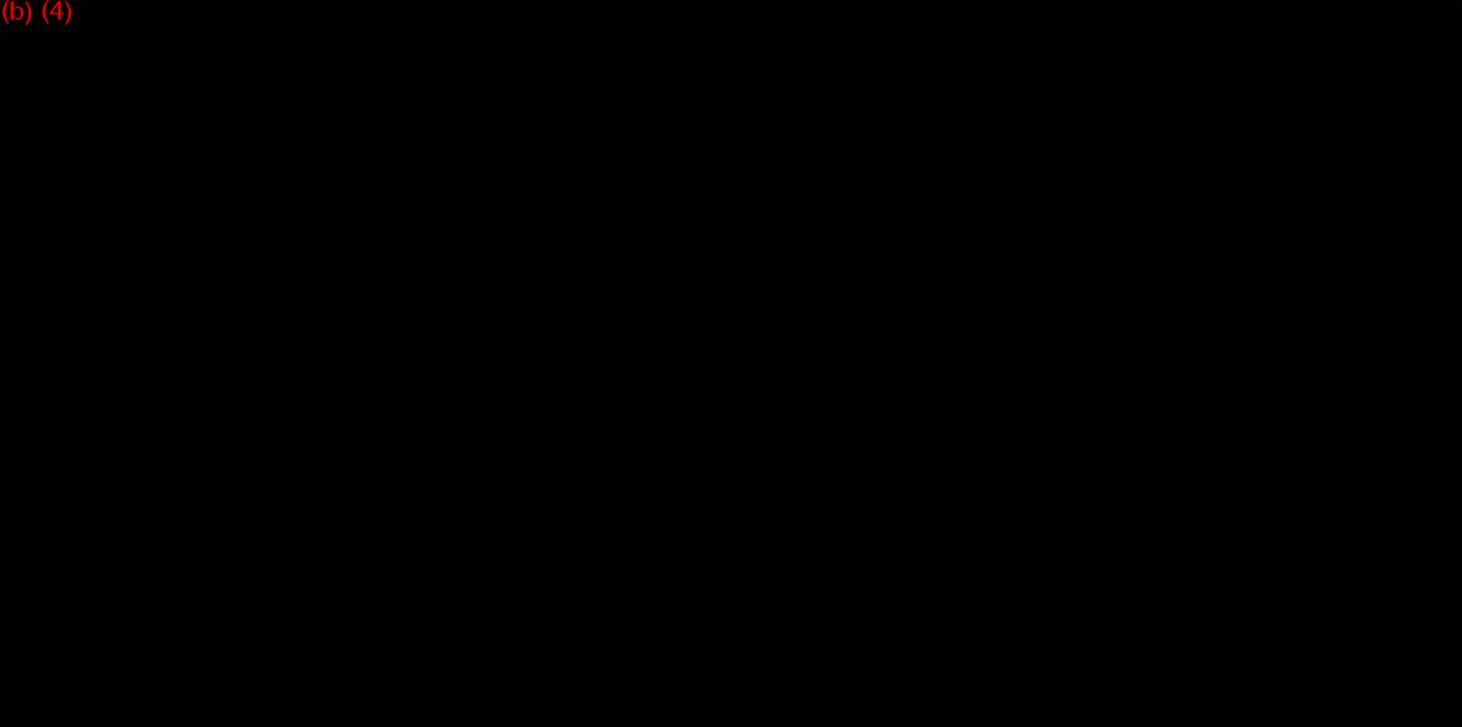
(b) (4)



Wesley Allen Schultz
Wesley Allen Schultz
Industrial Director

EXHIBIT 2

(b) (4)



The "blister" packages are double packages, which allows the user to open them in two stages:

- first remove the special paper protection from the outer "blister" gaining access to the sterile inner package.
- secondly, remove the special paper protection from the inner "blister" next to the surgical field.

When the implant is packaged in a double peel pouch:

- proceed in the same way as the "blister" package.

Instructions for Use:

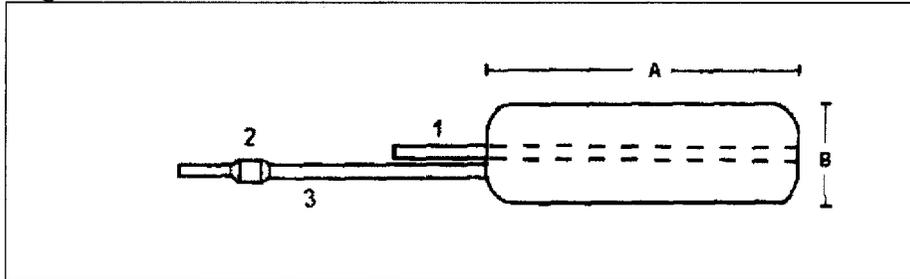
Directions for deflating and filling the stent during the surgical procedure:

1. Prior to inserting the stent, deflate the device completely by squeezing or aspirating with a syringe.
2. Close the valve by moving the ball to the closed position, i.e., toward the filling orifice.
3. Using a syringe filled with sterile, normal saline, inflate the device to the desired contour, but keep the device small enough that it may be introduced into the vagina.
4. Close the valve.
5. Fill the unit in situ to the desired volume.
6. Adjust volume in the stent by opening the valve and using a syringe to introduce or withdraw saline or air. Close the valve.
- 7.

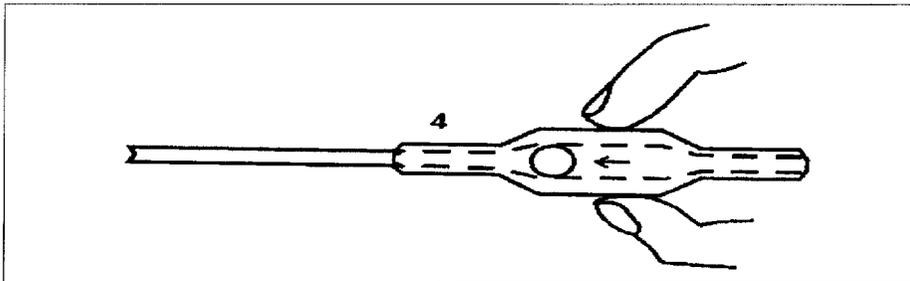
Surgical Procedure:

A variety of surgical techniques may be employed during the use of the Silimed Vaginal Stent; therefore, the surgeon is best advised to use the method which his own practice and discretion dictate to be best for the patient.

Inflatable Vaginal Stent



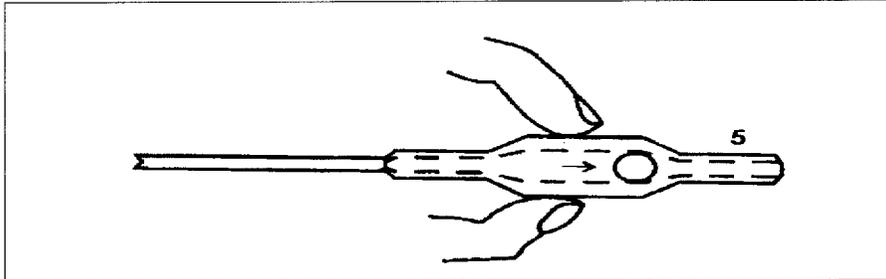
- 1- Internal Drain
- 2-The valve (silicone body and obturating sphere)
- 3-Tubing



Open Position

Open Position:

To fill up or deplete the expander, shift the sphere towards the side of the tubing with a slight compression between the thumb and index finger. When the sphere is in position, one can fill or empty the stent with the help of a syringe connected to the extremity of the valve.



Closed Position

Closed Position :

To close the valve displace the sphere using the thumb and index finger to move the sphere towards its free extremity. The pressure within the valve coming from the stent will facilitate its airtight closure by the sphere.

Resterilization:

Silicone implants are meant for single patient use; resterilization is thus forbidden by international standards.

Important Recommendations:

Maintenance of Sterility: It is essential that the vaginal stent be used under conditions of absolute asepsis and sterility.

Packaging Inspection: The packaging of the vaginal stent must be carefully examined. If the package has been damaged in any way, the stent cannot be used.

Stent used only as supplied: The vaginal stent can only be used in its original form, without any alterations to its original characteristics.

ALL SILICONE VAGINAL STENTS MUST BE USED IN ONE PATIENT ONLY

Durability:

The vaginal stent is a temporary device for treatment time not to exceed 12 weeks.

Contraindications and Precautions:

Procedures to create, enlarge or restore the vagina are contraindicated in the presence of local or systemic infection or in the presence of an anomaly of the urinary system which could be damaged by such procedures or by subsequent sexual intercourse. Congenital anomalies of the urinary tract frequently associated with congenital absence of the vagina include pelvic, kidney, anomalous insertion of the ureter and ureteral duplication.

The use of the vaginal stent is contraindicated when for any reason the patient has the inability to operate the device or to understand how the device is operated, or when the patient is apt to be uncooperative in maintaining the stent within the vagina for the prescribed length of time.

Warning:

The silicone elastomer shell of the Silimed Vaginal Stent is thin in order to achieve desired properties. Punctures, surface cuts, nicks, crushing or overstressing can lead to a tear. The device may be easily penetrated by needle or scalpel or ruptured by manipulation with a blunt instrument. Care must be exercised during handling to prevent such events. A damaged stent must not be placed. For this reason, a standby device should be available at the time of surgery.

Postoperatively, care must be taken not to over inflate the stent, as urethral erosion or fistula and graft tissue necrosis may result. Suprapubic drainage, rather transurethral catheterization, may be advisable.

Failure to maintain the stent within the vaginal canal for the prescribed length of time can promote contracture and stenosis of the vagina.

Lint fingerprints, talc and other surface contaminants can cause foreign body reactions. Utmost caution should be taken to avoid contaminants.

Transportation and Storing:

Silimed products and packages are extremely resistant and if handled with normal minimum of care will not present any problems. However, they should not be transported or stored with other types of material that may cause mechanical damage to the packaging and thus invalidate their sterile condition.

Clarification and Consent of Patient:

Silimed relies on the surgeon to clarify with their patients any risk factors inherent in surgery of this type before obtaining the patient's formal consent.

Warranty:

Silimed has stipulated a three year warranty for manufacturing defect provided the packaging has been preserved intact prior to use.

Silimed will replace any defective product. Since proper registration is made of each unit of raw material, stages of manufacture, and atmospheric and operational conditions, an individual number is given to each item that identifies it at any time, As a result, it absolutely necessary that any complaint be accompanied by the CONTROL NUMBER of the relevant item that appears on the package and by the PATIENT'S LABEL supplied to the doctor and detachable from the label of each package.

The warranty on Silimed products does not cover the simple decision of the patient or surgeon to change the product.

Silimed L.L.C.

14014 Sullyfield Circle Suite C

Chantilly, Virginia 20151

**PRODUCT INFORMATION
VAGINAL STENT**

Description:

The Silimed Vaginal Stent described in this insert is intended for use only as supplied. Under no circumstances should this device be altered, modified or revised in any way prior to or during its' use.

The inflatable Silimed Vaginal Stent is designed for neovaginal and reconstructive surgery. The Vaginal Stent has an internal drain that allows drainage of the surgical wound without withdrawing the silicone body, obturating sphere and tubing.

The Vaginal Stent is presented in a set of sizes (base, height and volume) that appear in Silimed's commercial catalog. This sizing is the result of many years of research with the medical profession.

Indications for Use:

The Silimed Vaginal Stent is indicated for use:

1. as a pressure dressing after vaginal surgery to hold pedicle flaps or free skin grafts in close apposition to the receptor site;
2. as an obturator or dilator to maintain the vaginal canal and reduce the possibility of contracture and stenosis following vaginal surgery and/or radiological treatment.

How Supplied:

Silimed Vaginal Stents are supplied sterile and are contained in:

- transparent or opaque double plastic "blister" sealed with special paper, which is permeable to ethylene oxide.
- double peel pouch packaging permeable to ethylene oxide.

The packages are stored in a cardboard box with a plastic protective film. Outer package label will contain the following information: description of the product, catalog number, lot number and expiration date.

Sterilization: Ethylene Oxide

An individual confirmation of sterilization of each batch is carried out, as well as a quarterly validation of the latter performed by an independent laboratory.

Instructions for Use:

Opening the Package: Vaginal Stents are supplied sterile and have been submitted to careful tests that guarantee their biocompatibility and virtual absence of reactions in the organism, the possible rare exceptions occurring on account of specific, individual conditions.

Care when opening the package is of utmost importance: The high dielectric value of silicone can generate static charges responsible for the attraction of particles existing in the atmosphere, such as dust, lint, and talc to mention a few examples. External contaminants that adhere to the membrane surface may provoke foreign-body reactions in the organism thereby increasing fibrosis and the generation of fluids.

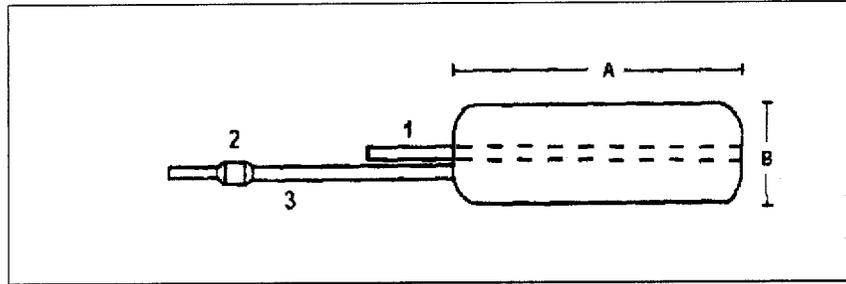
Care should also be taken with all the accessories of the product, be they documents such as inserts, labels for different files, etc., or parts of products such as valves and filling tubes.

SILIMED VAGINAL STENT PATIENT INSTRUCTIONS

Description:

The Silimed Vaginal Stent described in this insert is intended for use only as supplied. Under no circumstances should this device be altered, modified or revised in any way prior to or during its' use.

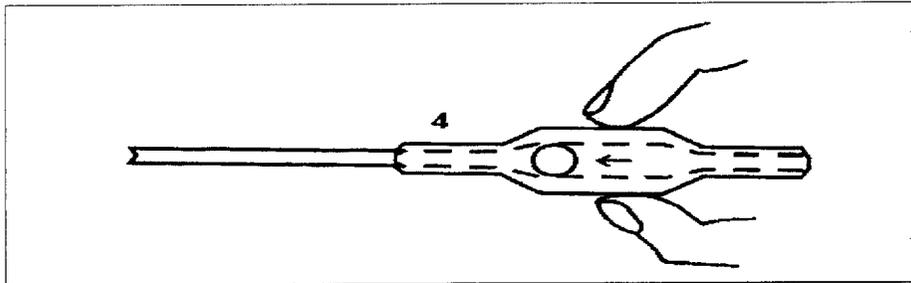
The inflatable Silimed Vaginal Stent is designed for neovaginal and reconstructive surgery. The Vaginal Stent has an internal drain (#1) that allows drainage of the surgical wound.



Silimed Vaginal Stent

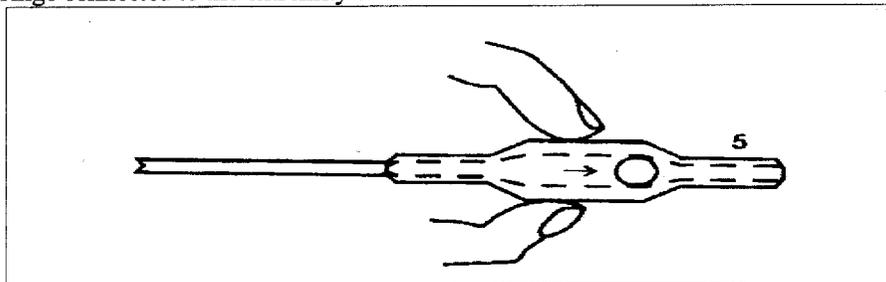
- 1- Internal Drain
- 2-The valve (silicone body and obturating sphere)
- 3-Tubing

How to Deflate and Fill the Vaginal Stent:



Open Position

To fill up or empty the expander, shift the ball towards the side of the tubing with a slight compression between the thumb and index finger. When the ball is in position, one can fill or empty the stent with the help of a syringe connected to the extremity of the valve.



Closed Position

Exhibit 6 Page 1

Closed Position :

To close the valve displace the ball using the thumb and index finger to move the ball towards its free extremity. The pressure within the valve coming from the stent will facilitate its airtight closure by the ball.

Removing and Reinsertion Instructions:

1. Prior to inserting the stent, deflate the device completely by squeezing or aspirating with a syringe.
2. Open the valve (#2) by moving the ball towards the stent..
3. Inflate the stent to the desired contour with sterile normal saline, but keep the stent small enough that it may be introduced into the vagina. Approximately 50-60ml.
4. Close the ball by moving it towards the syringe once the stent has reached the desired volume.
5. Wound drainage, if any, will require cleaning the drain tube according to the cleaning instructions #5 below.

Cleaning Your Vaginal Stent:

1. Remove the deflated stent with talc free gloved hands.
2. To prevent soap or water from entering the interior of the stent, pinch the valve ball into the "closed" position.
3. Wash the stent thoroughly in a hot water using Ivory soap solution.
4. DO NOT USE SYNTHETIC DETERGENTS OR OIL-BASED SOAPS.
5. Rinse the stent well in normal saline, taking care to flush the entire drain tube by injecting normal saline solution into the drain tube until it flows freely end-to-end. Normal Saline is available at your local pharmacy.

Facts About Your Vaginal Stent:***Sexual Intercourse***

You may remove the stent for cleaning, and sexual intercourse is permitted after two months if healing is complete, but until all tendency to vaginal constriction has ceased (approx. six months). The vagina will contract if the stent is left out longer than 10 to 15 minutes at a time.

Menstrual Period

Consult with your Physician for information concerning the proper use of this device during your menstrual period.

Use during menstrual period will require the use of a menstrual pad and periodic cleaning of the vaginal canal. You may remove the device twice daily for a period not to exceed 15 minutes.

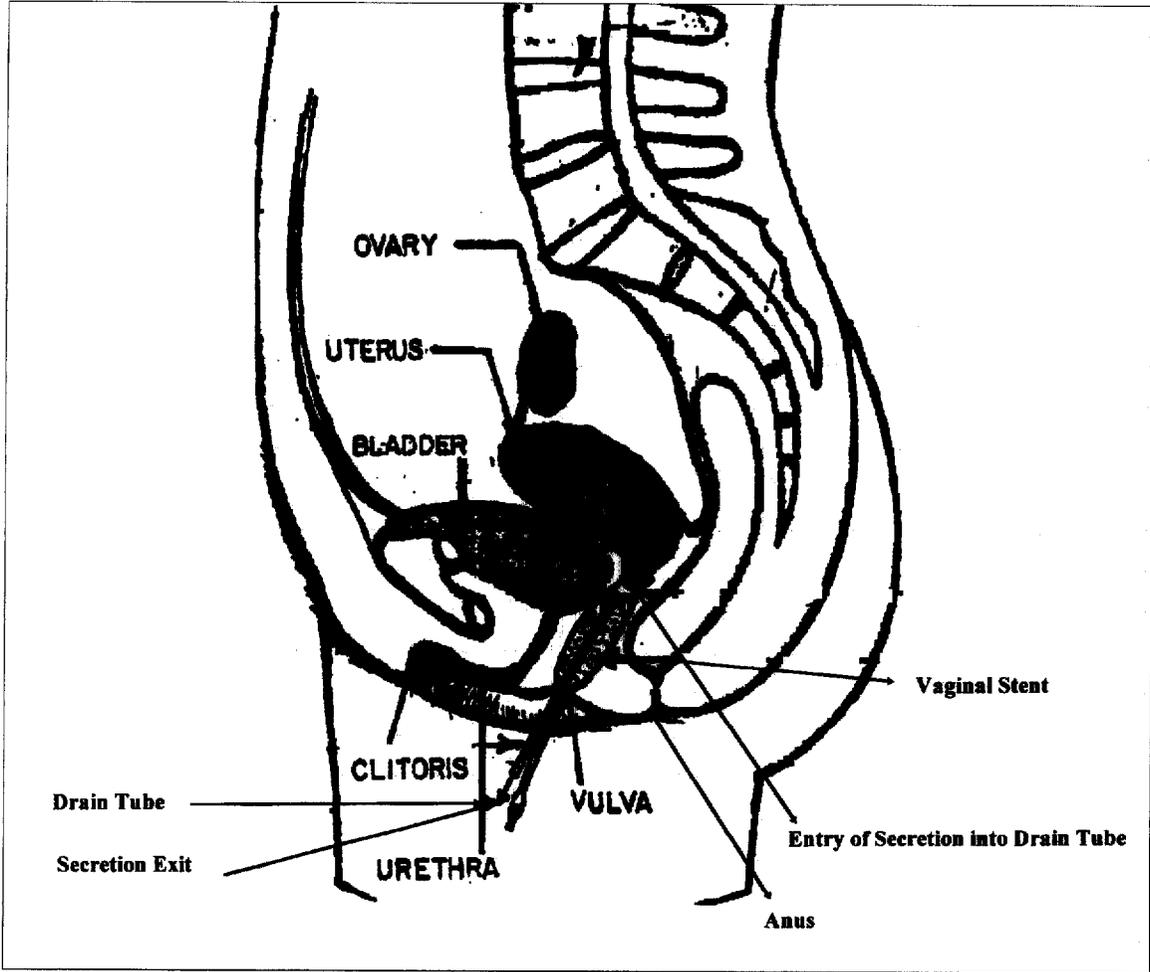
There should be little to no drainage from the surgical procedure, however, if excessive drainage occurs contact your Physician.

The visual difference between menstrual drainage and wound drainage is:

- Wound Drainage is a Clear-Redish color
- Menstrual Period Drainage is Dark Red color

Use of the Vaginal Stent

Intermittent use of the stent to maintain the vaginal canal is usually required for six months, and may be required indefinitely. *The stent must be replaced with a new stent every 12 weeks.* Consult with your physician.



Placement of Silimed Vaginal Stent

If you have any questions or concerns about your vaginal stent call Silimed's help line (800) xxx-xxxx for assistance.

Smith Associates

Specializing in Regulatory Affairs

June 29, 1998

Food and Drug Administration
Document Control Center
Center for Devices
9200 Corporate Blvd.
Rockville, Maryland 20850

Reference: K974479

Dear Dr. Virmani:

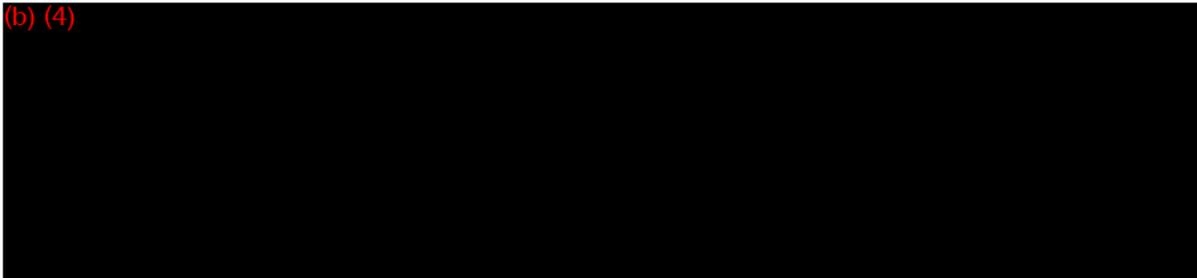
Attached is the revised Physician and Patient labeling you requested for the Silimed Vaginal Stent. I now have the answers to the technical questions.

RECEIVED

30 JUN 98 14 45

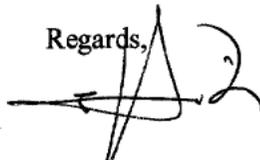
FDA/CDRH/ODE/DHO

(b) (4)



If you have additional questions I can be reached at (410)451-0639.

Regards,



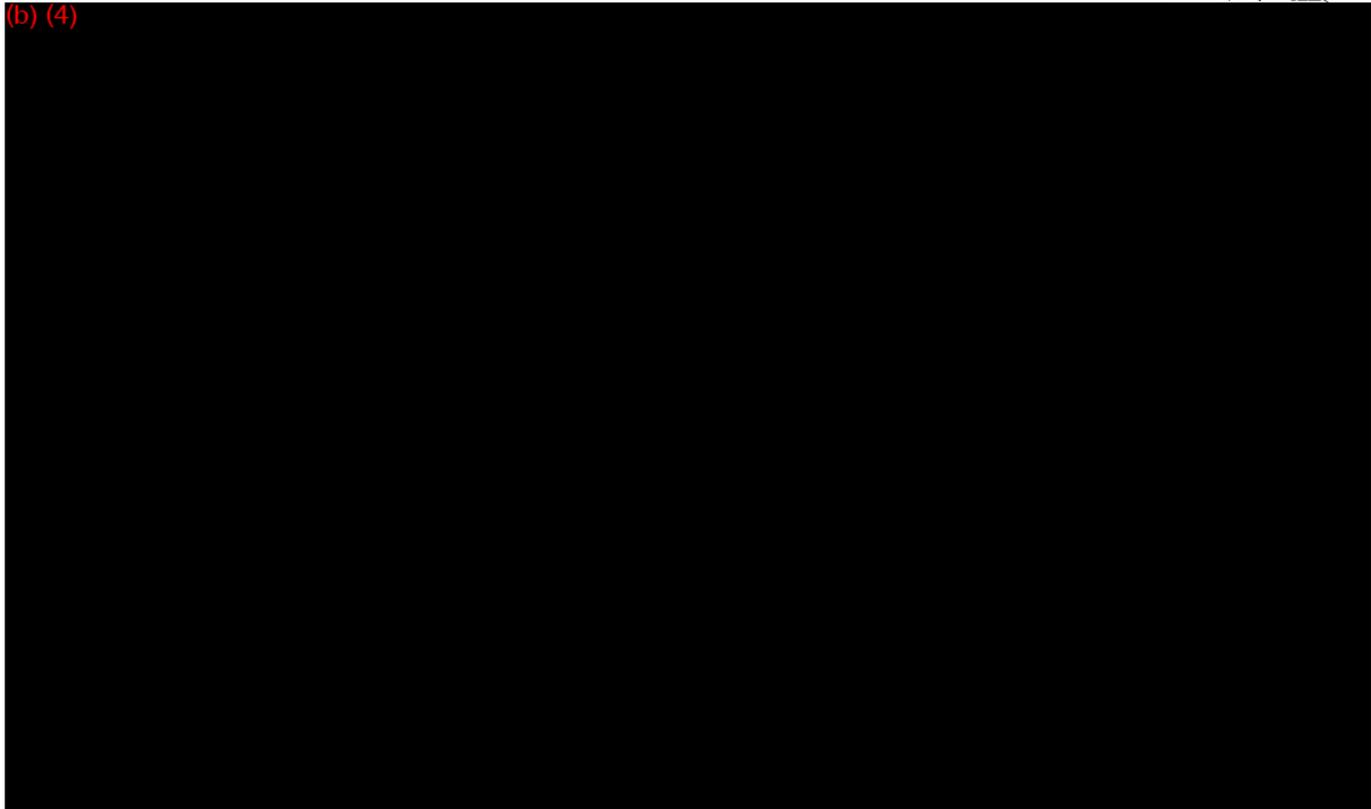
E.J. Smith

66

SILIMED - Silicons e Instrumental Médico-Cirúrgico e Hospitalar Ltda.

SILIMED

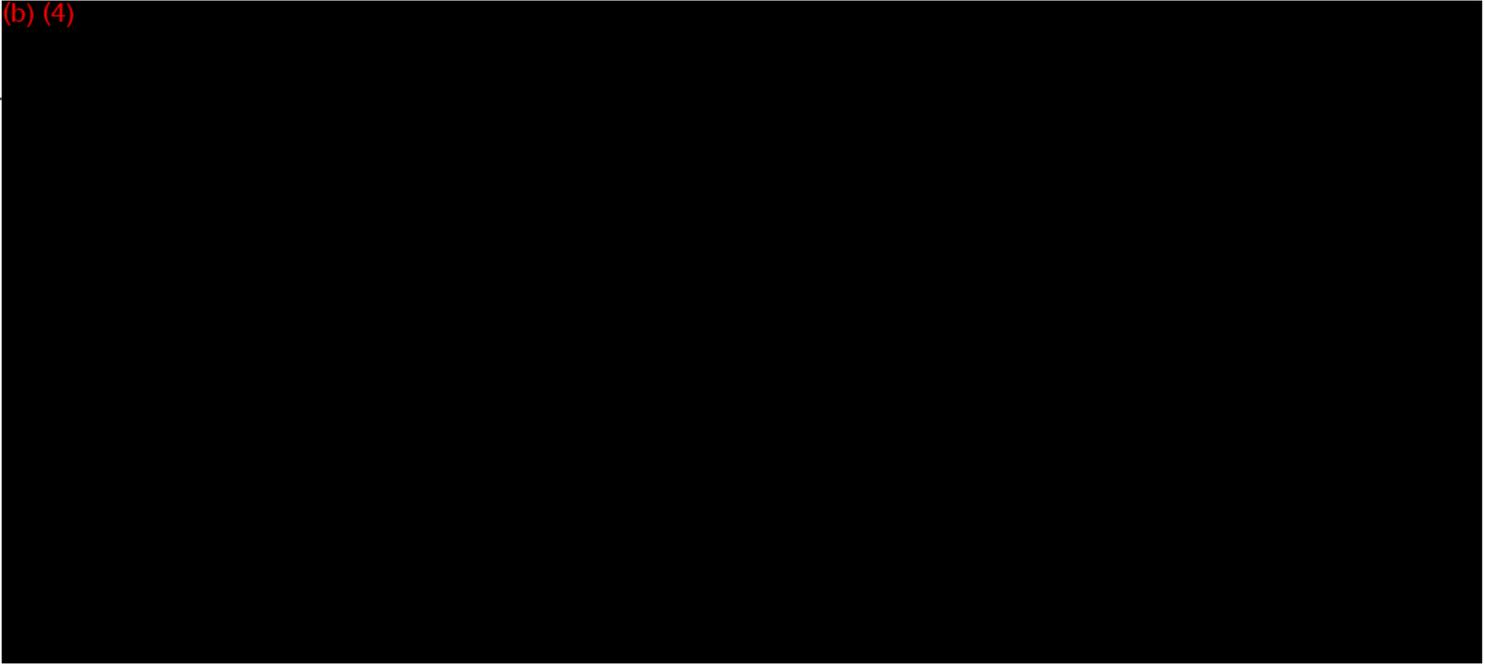
(b) (4)



Wesley Allen Schultz
Wesley Allen Schultz
Industrial Director

FROM : SILIMED LTDA

(b) (4)



**PRODUCT INFORMATION
VAGINAL STENT**

Description:

The Silimed Vaginal Stent described in this insert is intended for use only as supplied. Under no circumstances should this device be altered, modified or revised in any way prior to or during its' use.

The inflatable Silimed Vaginal Stent is designed for neovaginal and reconstructive surgery. The Vaginal Stent has an internal drain that allows drainage of the surgical wound without withdrawing the silicone body, obturating sphere and tubing.

The Vaginal Stent is presented in a set of sizes (base, height and volume) that appear in Silimed's commercial catalog. This sizing is the result of many years of research with the medical profession.

Indications for Use:

The Silimed Vaginal Stent is indicated for use:

1. as a pressure dressing after vaginal surgery to hold pedicle flaps or free skin grafts in close apposition to the receptor site;
2. as an obturator or dilator to maintain the vaginal canal and reduce the possibility of contracture and stenosis following vaginal surgery and/or radiological treatment.

How Supplied:

Silimed Vaginal Stents are supplied sterile and are contained in:

- transparent or opaque double plastic "blister" sealed with special paper, which is permeable to ethylene oxide.
- double peel pouch packaging permeable to ethylene oxide.

The packages are stored in a cardboard box with a plastic protective film. Outer package label will contain the following information: description of the product, catalog number, lot number and expiration date.

Sterilization: Ethylene Oxide

An individual confirmation of sterilization of each batch is carried out, as well as a quarterly validation of the latter performed by an independent laboratory.

Instructions for Use:

Opening the Package: Vaginal Stents are supplied sterile and have been submitted to careful tests that guarantee their biocompatibility and virtual absence of reactions in the organism, the possible rare exceptions occurring on account of specific, individual conditions.

Care when opening the package is of utmost importance: The high dielectric value of silicone can generate static charges responsible for the attraction of particles existing in the atmosphere, such as dust, lint, and talc to mention a few examples. External contaminants that adhere to the membrane surface may provoke foreign-body reactions in the organism thereby increasing fibrosis and the generation of fluids.

Care should also be taken with all the accessories of the product, be they documents such as inserts, labels for different files, etc., or parts of products such as valves and filling tubes.

The "blister" packages are double packages, which allows the user to open them in two stages:

- first remove the special paper protection from the outer "blister" gaining access to the sterile inner package.
- secondly, remove the special paper protection from the inner "blister" next to the surgical field.

When the implant is packaged in a double peel pouch:

- proceed in the same way as the "blister" package.

Instructions for Use:

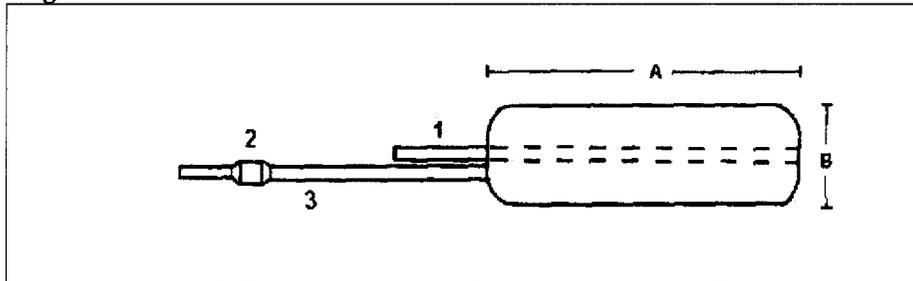
Directions for deflating and filling the stent during the surgical procedure:

1. Prior to inserting the stent, deflate the device completely by squeezing or aspirating with a syringe.
2. Close the valve by moving the ball to the closed position, i.e., toward the filling orifice.
3. Using a syringe filled with sterile, normal saline, inflate the device to the desired contour, but keep the device small enough that it may be introduced into the vagina.
4. Close the valve.
5. Fill the unit in situ to the desired volume.
6. Adjust volume in the stent by opening the valve and using a syringe to introduce or withdraw saline or air. Close the valve.
- 7.

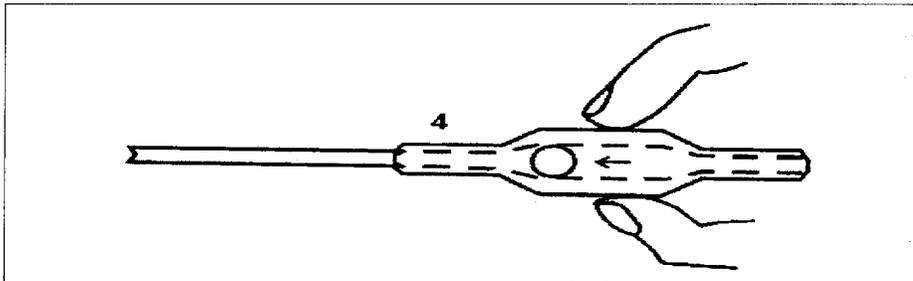
Surgical Procedure:

A variety of surgical techniques may be employed during the use of the Silimed Vaginal Stent; therefore, the surgeon is best advised to use the method which his own practice and discretion dictate to be best for the patient.

Inflatable Vaginal Stent



- 1- Internal Drain
- 2-The valve (silicone body and obturating sphere)
- 3-Tubing

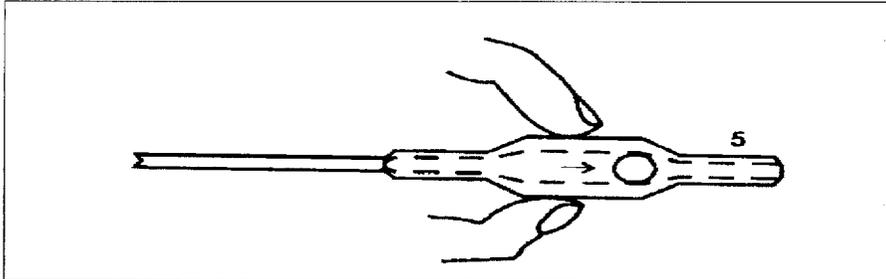


Open Position

70

Open Position:

To fill up or deplete the expander, shift the sphere towards the side of the tubing with a slight compression between the thumb and index finger. When the sphere is in position, one can fill or empty the stent with the help of a syringe connected to the extremity of the valve.



Closed Position

Closed Position :

To close the valve displace the sphere using the thumb and index finger to move the sphere towards its free extremity. The pressure within the valve coming from the stent will facilitate its airtight closure by the sphere.

Resterilization:

Silicone implants are meant for single patient use; resterilization is thus forbidden by international standards.

Important Recommendations:

Maintenance of Sterility: It is essential that the vaginal stent be used under conditions of absolute asepsis and sterility

Packaging Inspection: The packaging of the vaginal stent must be carefully examined. If the package has been damaged in any way, the stent cannot be used.

Stent used only as supplied: The vaginal stent can only be used in its original form, without any alterations to its original characteristics.

ALL SILICONE VAGINAL STENTS MUST BE USED IN ONE PATIENT ONLY

Durability:

The vaginal stent is a temporary device for treatment time not to exceed 12 weeks.

Contraindications and Precautions:

Procedures to create, enlarge or restore the vagina are contraindicated in the presence of local or systemic infection or in the presence of an anomaly of the urinary system which could be damaged by such procedures or by subsequent sexual intercourse. Congenital anomalies of the urinary tract frequently associated with congenital absence of the vagina include pelvic, kidney, anomalous insertion of the ureter and ureteral duplication.

The use of the vaginal stent is contraindicated when for any reason the patient has the inability to operate the device or to understand how the device is operated, or when the patient is apt to be uncooperative in maintaining the stent within the vagina for the prescribed length of time.

Warning:

The silicone elastomer shell of the Silimed Vaginal Stent is thin in order to achieve desired properties. Punctures, surface cuts, nicks, crushing or overstressing can lead to a tear. The device may be easily penetrated by needle or scalpel or ruptured by manipulation with a blunt instrument. Care must be exercised during handling to prevent such events. A damaged stent must not be placed. For this reason, a standby device should be available at the time of surgery.

Postoperatively, care must be taken not to over inflate the stent, as urethral erosion or fistula and graft tissue necrosis may result. Suprapubic drainage, rather transurethral catheterization, may be advisable.

Failure to maintain the stent within the vaginal canal for the prescribed length of time can promote contracture and stenosis of the vagina.

Lint fingerprints, talc and other surface contaminants can cause foreign body reactions. Utmost caution should be taken to avoid contaminants.

Transportation and Storing:

Silimed products and packages are extremely resistant and if handled with normal minimum of care will not present any problems. However, they should not be transported or stored with other types of material that may cause mechanical damage to the packaging and thus invalidate their sterile condition.

Clarification and Consent of Patient:

Silimed relies on the surgeon to clarify with their patients any risk factors inherent in surgery of this type before obtaining the patient's formal consent.

Warranty:

Silimed has stipulated a three year warranty for manufacturing defect provided the packaging has been preserved intact prior to use.

Silimed will replace any defective product. Since proper registration is made of each unit of raw material, stages of manufacture, and atmospheric and operational conditions, an individual number is given to each item that identifies it at any time, As a result, it absolutely necessary that any complaint be accompanied by the CONTROL NUMBER of the relevant item that appears on the package and by the PATIENT'S LABEL supplied to the doctor and detachable from the label of each package.

The warranty on Silimed products does not cover the simple decision of the patient or surgeon to change the product.

Silimed L.L.C.

14014 Sullyfield Circle Suite C

Chantilly, Virginia 20151

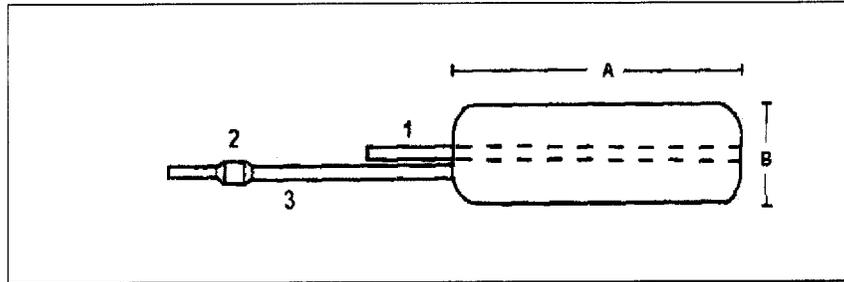
72

SILIMED VAGINAL STENT PATIENT INSTRUCTIONS

Description:

The Silimed Vaginal Stent described in this insert is intended for use only as supplied. Under no circumstances should this device be altered, modified or revised in any way prior to or during its' use.

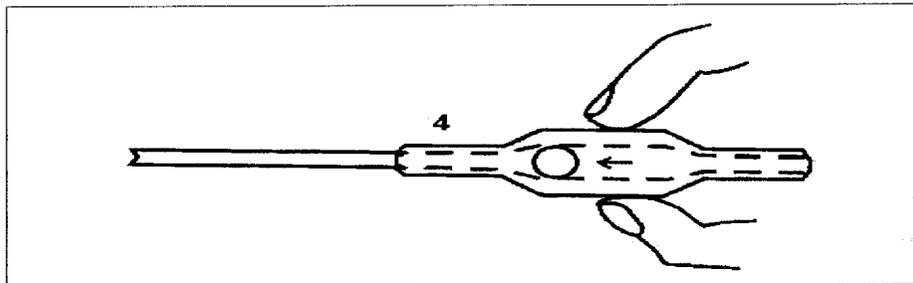
The inflatable Silimed Vaginal Stent is designed for neovaginal and reconstructive surgery. The Vaginal Stent has an internal drain (#1) that allows drainage of the surgical wound.



Silimed Vaginal Stent

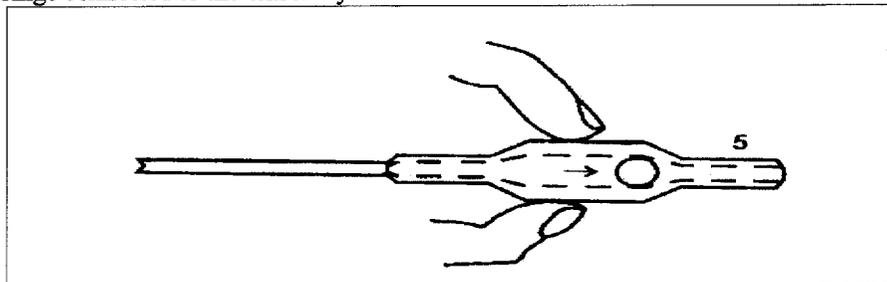
- 1- Internal Drain
- 2-The valve (silicone body and obturating sphere)
- 3-Tubing

How to Deflate and Fill the Vaginal Stent:



Open Position

To fill up or empty the expander, shift the ball towards the side of the tubing with a slight compression between the thumb and index finger. When the ball is in position, one can fill or empty the stent with the help of a syringe connected to the extremity of the valve.



Closed Position
Exhibit 6 Page 1

Closed Position :

To close the valve displace the ball using the thumb and index finger to move the ball towards its free extremity. The pressure within the valve coming from the stent will facilitate its airtight closure by the ball.

Removing and Reinsertion Instructions:

1. Prior to inserting the stent, deflate the device completely by squeezing or aspirating with a syringe.
2. Open the valve (#2) by moving the ball towards the stent..
3. Inflate the stent to the desired contour with sterile normal saline, but keep the stent small enough that it may be introduced into the vagina. Approximately 50-60ml.
4. Close the ball by moving it towards the syringe once the stent has reached the desired volume.
5. Wound drainage, if any, will require cleaning the drain tube according to the cleaning instructions #5 below.

Cleaning Your Vaginal Stent:

1. Remove the deflated stent with talc free gloved hands.
2. To prevent soap or water from entering the interior of the stent, pinch the valve ball into the "closed" position.
3. Wash the stent thoroughly in a hot water using Ivory soap solution.
4. DO NOT USE SYNTHETIC DETERGENTS OR OIL-BASED SOAPS.
5. Rinse the stent well in normal saline, taking care to flush the entire drain tube by injecting normal saline solution into the drain tube until it flows freely end-to-end. Normal Saline is available at your local pharmacy.

Facts About Your Vaginal Stent:***Sexual Intercourse***

You may remove the stent for cleaning, and sexual intercourse is permitted after two months if healing is complete, but until all tendency to vaginal constriction has ceased (approx. six months). **The vagina will contract if the stent is left out longer than 10 to 15 minutes at a time.**

Menstrual Period

Consult with your Physician for information concerning the proper use of this device during your menstrual period.

Use during menstrual period will require the use of a menstrual pad and periodic cleaning of the vaginal canal. You may remove the device twice daily for a period not to exceed 15 minutes.

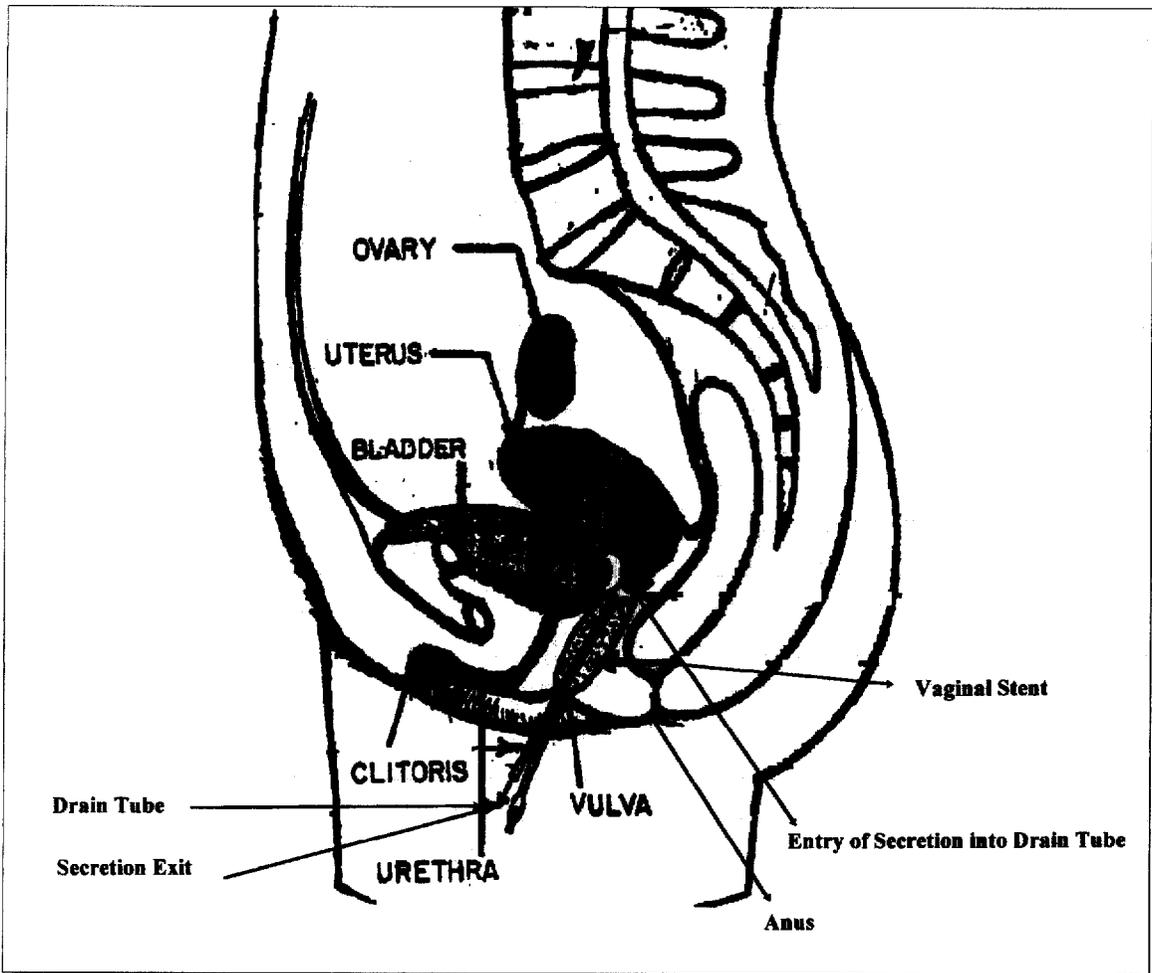
There should be little to no drainage from the surgical procedure, however, if excessive drainage occurs contact your Physician.

The visual difference between menstrual drainage and wound drainage is:

- Wound Drainage is a Clear-Redish color
- Menstrual Period Drainage is Dark Red color

Use of the Vaginal Stent

Intermittent use of the stent to maintain the vaginal canal is usually required for six months, and may be required indefinitely. *The stent must be replaced with a new stent every 12 weeks.* Consult with your physician.



Placement of Silimed Vaginal Stent

If you have any questions or concerns about your vaginal stent call Silimed's help line (800) xxx-xxxx for assistance.

K974479/S2

Smith Associates

Specializing in Regulatory Affairs

June 12, 1998

RECEIVED

2 JUN 98 13 14

FDA/CDRH/ODE/DMC

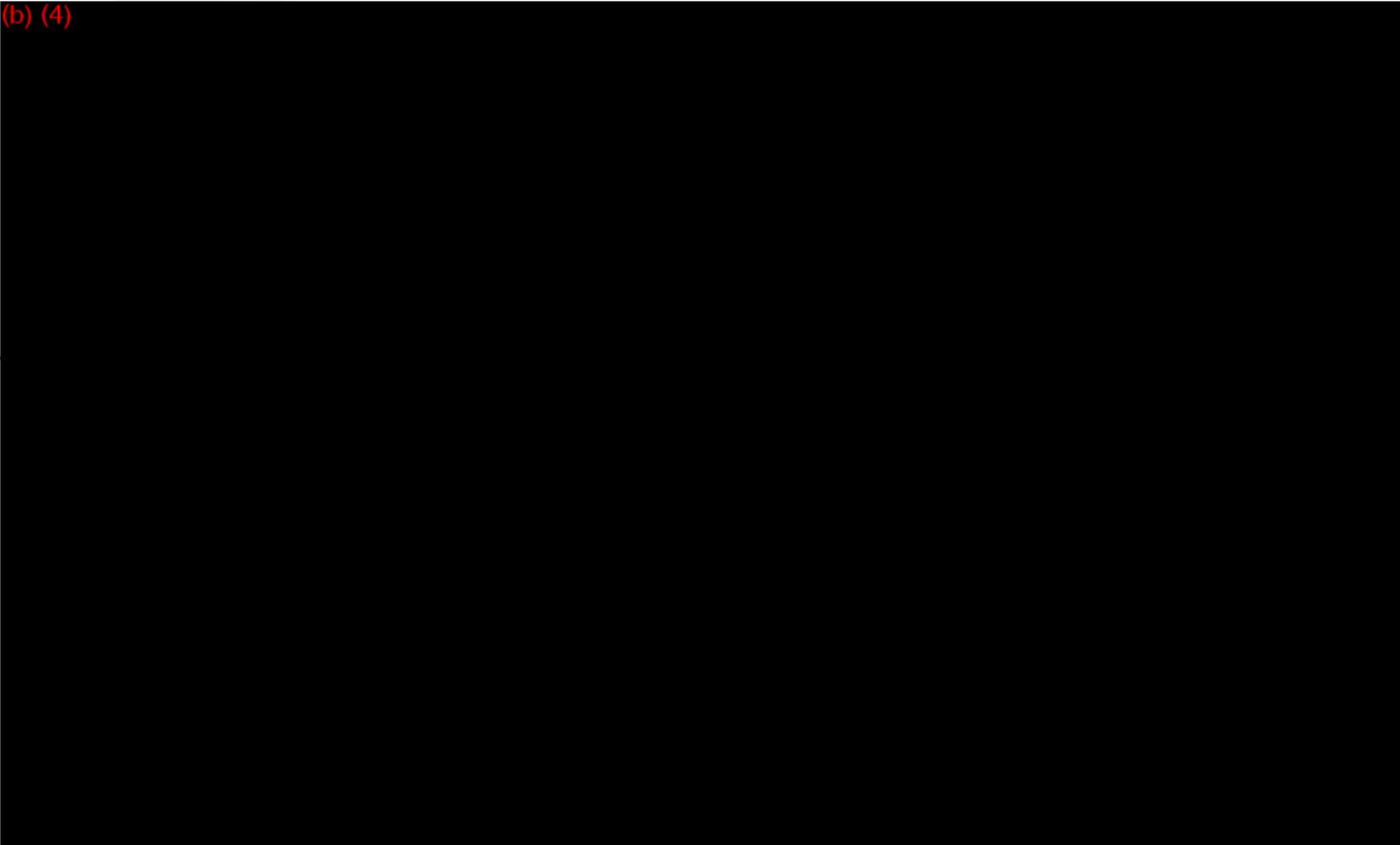
Food and Drug Administration
Document Control Center
9200 Corporate Blvd.
Rockville, Maryland 20850

Reference: K974479

Dear Ms. Virmani, Ph.D.:

This is our response to your letter dated April 13, 1998:

Device performance:



SA-27

Physician labeling:

(b) (4)



Patient labeling:

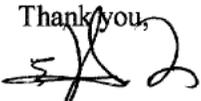
(b) (4)



(b) (4)

If you have additional questions, I can be reached at (410)451-0639.

Thank you,



E.J. Smith

**REVISED
PHYSICIAN LABEL**

**PRODUCT INFORMATION
VAGINAL STENT**

Description:

The Silimed Vaginal Stent described in this insert is intended for use only as supplied. Under no circumstances should this device be altered, modified or revised in any way prior to or during its' use.

The inflatable Silimed Vaginal Stent is designed for neovaginal and reconstructive surgery. The Vaginal Stent has an internal drain that allows drainage of the surgical wound without withdrawing the silicone body, obturating sphere and tubing.

The Vaginal Stent is presented in a set of sizes (base, height and volume) that appear in Silimed's commercial catalog. This sizing is the result of many years of research with the medical profession.

Indications for Use:

The Silimed Vaginal Stent is indicated for use:

1. as a pressure dressing after vaginal surgery to hold pedicle flaps or free skin grafts in close apposition to the receptor site;
2. as an obturator or dilator to maintain the vaginal canal and reduce the possibility of contracture and stenosis following vaginal surgery and/or radiological treatment.

The Constituent Materials:

Membranes: the basic elastomer used is vinyl dimethyl polydimethyl siloxane with a load of pure amorphous fine-crushed silica catalyzed by a platinum compound.

- Filling Product: 0.9% sterile solution, nonpyrogenic and injectable in accordance with national pharmacopedics.
- Shell filling: Polyurethane Foam:
- Connectors and Drain: polydimethyl siloxane.
- Cylindrical Valve: polydimethyl siloxane and 001 stainless steel ball.

How Supplied:

Silimed Vaginal Stents are supplied sterile and are contained in:

- transparent or opaque double plastic "blister" sealed with special paper, which is permeable to ethylene oxide.
- double peel pouch packaging permeable to ethylene oxide.

The packages are stored in a cardboard box with a plastic protective film. Outer package label will contain the following information: description of the product, catalog number, lot number and expiration date.

Sterilization: Ethylene Oxide

An individual confirmation of sterilization of each batch is carried out, as well as a quarterly validation of the latter performed by an independent laboratory.

93

Instructions for Use:

Care when opening the package is of utmost importance: The high dielectric value of silicone can generate static charges responsible for the attraction of particles existing in the atmosphere, such as dust, lint, and talc to mention a few examples. External contaminants that adhere to the membrane surface may provoke foreign-body reactions in the organism thereby increasing fibrosis and the generation of fluids.

Care should also be taken with all the accessories of the product, be they documents such as inserts, labels for different files, etc., or parts of products such as valves and filling tubes.

The "blister" packages are double packages, which allows the user to open them in two stages:

- first remove the special paper protection from the outer "blister" gaining access to the sterile inner package.
- secondly, remove the special paper protection from the inner "blister" next to the surgical field.

When the implant is packaged in a double peel pouch:

- proceed in the same way as the "blister" package.

Instructions for Use:

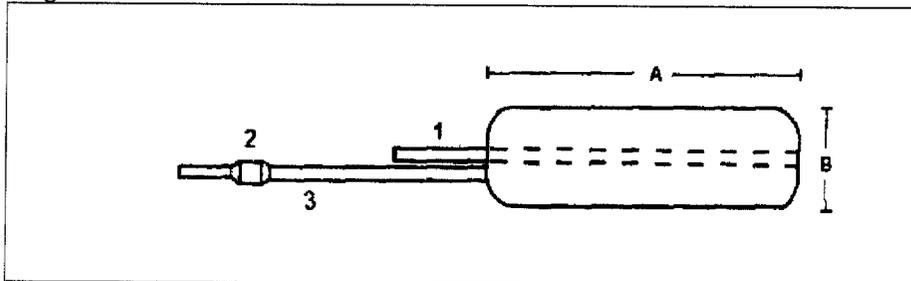
Directions for deflating and filling the stent during the surgical procedure:

1. Prior to inserting the stent, deflate the device completely by squeezing or aspirating with a syringe.
2. Open the valve (#2) by moving the ball towards the stent.
3. Using a syringe filled with sterile, normal saline, inflate the device to the desired contour, but keep the device small enough that it may be introduced into the vagina.
4. Close the valve (#2) by moving the ball back towards the syringe.
5. Fill the unit once positioned to the desired volume.
6. Adjust volume in the stent by opening the valve and using a syringe to introduce or withdraw saline or air. Close the valve (#2).

Surgical Procedure:

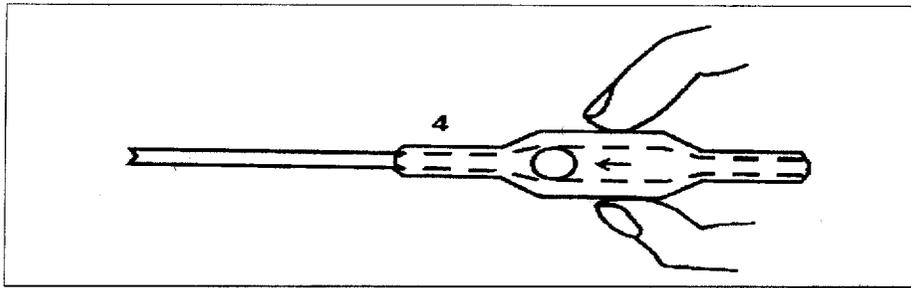
A variety of surgical techniques may be employed during the use of the Silimed Vaginal Stent; therefore, the surgeon is best advised to use the method which his own practice and discretion dictate to be best for the patient.

Inflatable Vaginal Stent



- 1- Internal Drain
- 2-The valve (silicone body and obturating sphere)
- 3-Tubing

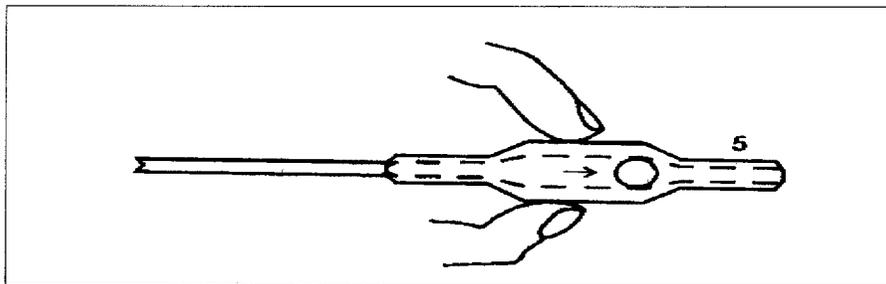
an



Open Position

Open Position:

To fill up or deplete the expander, shift the ball towards the side of the tubing with a slight compression between the thumb and index finger. When the ball is in position, one can fill or empty the stent with the help of a syringe connected to the extremity of the valve.



Closed Position

Closed Position :

To close the valve displace the ball using the thumb and index finger to move the ball towards its free extremity. The pressure within the valve coming from the stent will facilitate its airtight closure by the ball.

Resterilization:

Silicone implants are meant for single patient use; resterilization is thus forbidden by international standards.

Important Recommendations:

Maintenance of Sterility: It is essential that the vaginal stent be used under conditions of absolute asepsis and sterility

Packaging Inspection: The packaging of the vaginal stent must be carefully examined. If the package has been damaged in any way, the stent cannot be used.

Stent used only as supplied: The vaginal stent can only be used in its original form, without any alterations to its original characteristics.

ALL SILICONE VAGINAL STENTS MUST BE USED IN ONE PATIENT ONLY

Durability:

The vaginal stent is a temporary device for treatment time not to exceed 12 weeks. After the 12th week a new vaginal stent is required.

95

Contraindications and Precautions:

Procedures to create, enlarge or restore the vagina are contraindicated in the presence of local or systemic infection or in the presence of an anomaly of the urinary system which could be damaged by such procedures or by subsequent sexual intercourse. Congenital anomalies of the urinary tract frequently associated with congenital absence of the vagina include pelvic, kidney, anomalous insertion of the ureter and ureteral duplication.

The use of the vaginal stent is contraindicated when for any reason the patient has the inability to operate the device or to understand how the device is operated, or when the patient is apt to be uncooperative in maintaining the stent within the vagina for the prescribed length of time.

Warning:

The silicone elastomer shell of the Silimed Vaginal Stent is thin in order to achieve desired properties. Punctures, surface cuts, nicks, crushing or overstressing can lead to a tear. The device may be easily penetrated by needle or scalpel or ruptured by manipulation with a blunt instrument. Care must be exercised during handling to prevent such events. A damaged stent must not be placed. For this reason, a standby device should be available at the time of surgery.

Postoperatively, care must be taken not to over inflate the stent, as urethral erosion or fistula and graft tissue necrosis may result. Suprapubic drainage, rather transurethral catheterization, may be advisable.

Failure to maintain the stent within the vaginal canal for the prescribed length of time can promote contracture and stenosis of the vagina.

Lint fingerprints, talc and other surface contaminants can cause foreign body reactions. Utmost caution should be taken to avoid contaminants.

Transportation and Storing:

Silimed products and packages are extremely resistant and if handled with normal minimum of care will not present any problems. However, they should not be transported or stored with other types of material that may cause mechanical damage to the packaging and thus invalidate their sterile condition.

Clarification and Consent of Patient:

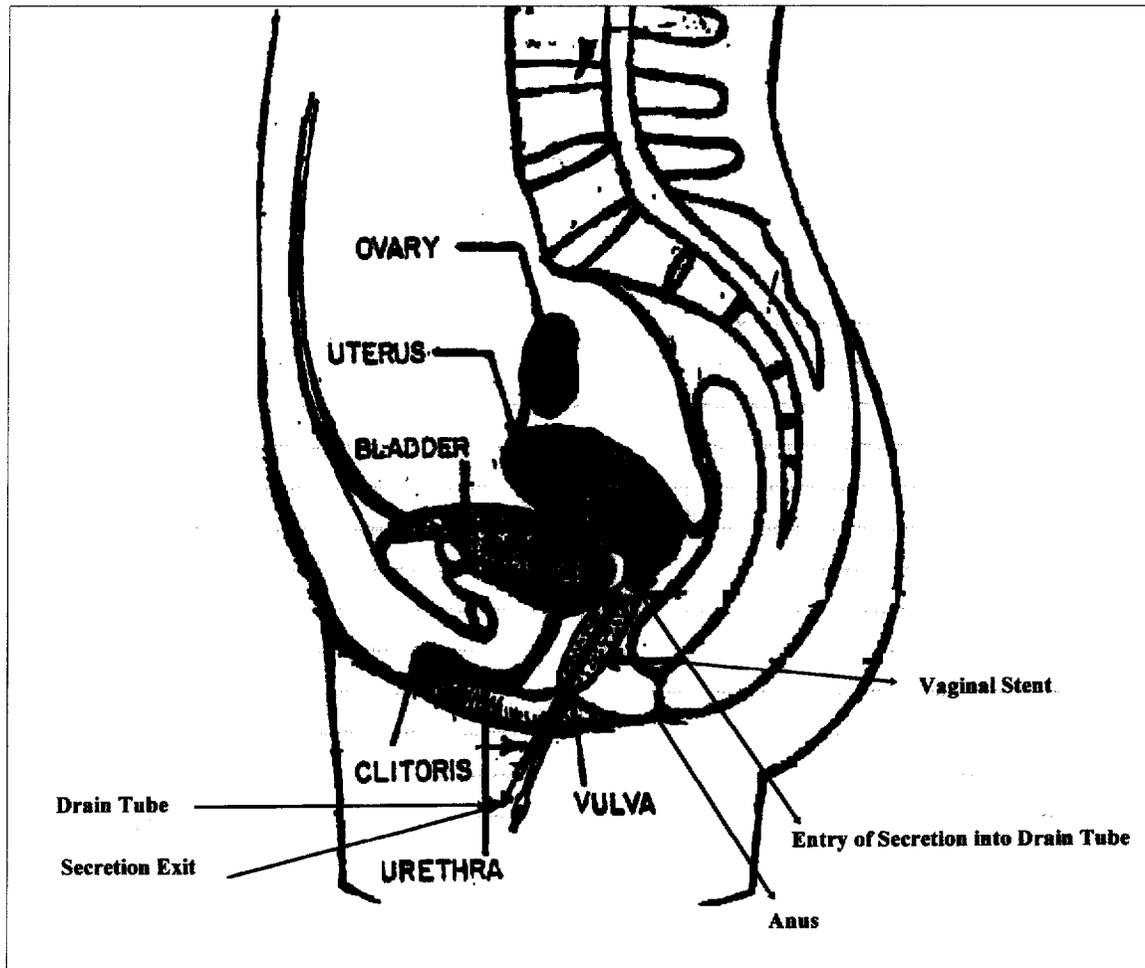
Silimed relies on the surgeon to clarify with their patients any risk factors inherent in surgery of this type before obtaining the patient's formal consent.

Warranty:

Silimed has stipulated a three year warranty for manufacturing defect provided the packaging has been preserved intact prior to use.

Silimed will replace any defective product. Since proper registration is made of each unit of raw material, stages of manufacture, and atmospheric and operational conditions, an individual number is given to each item that identifies it at any time, As a result, it absolutely necessary that any complaint be accompanied by the CONTROL NUMBER of the relevant item that appears on the package and by the PATIENT'S LABEL supplied to the doctor and detachable from the label of each package.

The warranty on Silimed products does not cover the simple decision of the patient or surgeon to change the product.



Placement of Silimed Vaginal Stent

Special Instructions:

Managing Drainage:

Silimed L.L.C. 14014 Sullyfield Circle Suite C Chantilly, Virginia 20151

Exhibit 5 Page 5

97

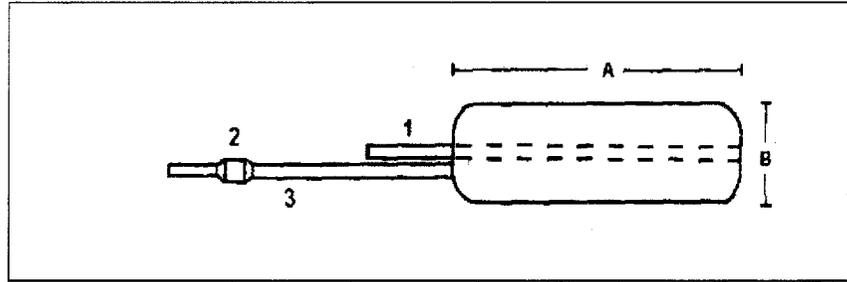
**REVISED
PATIENT LABEL**

**SILIMED VAGINAL STENT
PATIENT INSTRUCTIONS**

Description:

The Silimed Vaginal Stent described in this insert is intended for use only as supplied. Under no circumstances should this device be altered, modified or revised in any way prior to or during its' use.

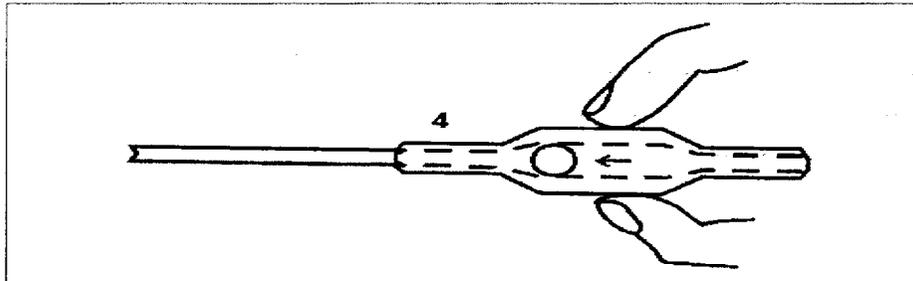
The inflatable Silimed Vaginal Stent is designed for neovaginal and reconstructive surgery. The Vaginal Stent has an internal drain (#1) that allows drainage of the surgical wound.



Silimed Vaginal Stent

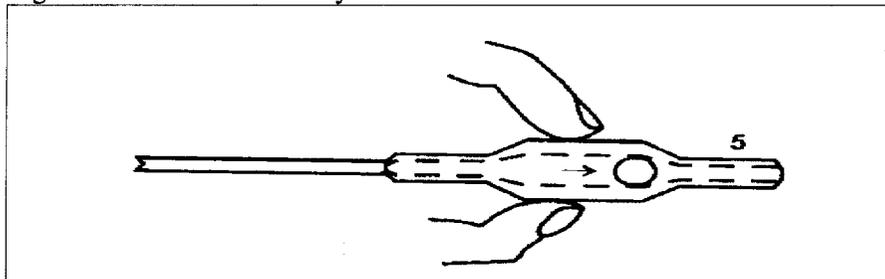
- 1- Internal Drain
- 2-The valve (silicone body and obturating sphere)
- 3-Tubing

How to Deflate and Fill the Vaginal Stent:



Open Position

To fill up or empty the expander, shift the ball towards the side of the tubing with a slight compression between the thumb and index finger. When the ball is in position, one can fill or empty the stent with the help of a syringe connected to the extremity of the valve.



Closed Position

Closed Position :

To close the valve displace the ball using the thumb and index finger to move the ball towards its free extremity. The pressure within the valve coming from the stent will facilitate its airtight closure by the ball.

Removing and Reinsertion Instructions:

1. Prior to inserting the stent, deflate the device completely by squeezing or aspirating with a syringe.
2. Open the valve (#2) by moving the ball towards the stent..
3. Inflate the stent to the desired contour with sterile normal saline, but keep the stent small enough that it may be introduced into the vagina.
4. Close the ball by moving it towards the syringe once the stent has reached the desired volume.
5. Wound drainage, if any, will require cleaning the drain tube according to the cleaning instructions #5 below.

Cleaning Your Vaginal Stent:

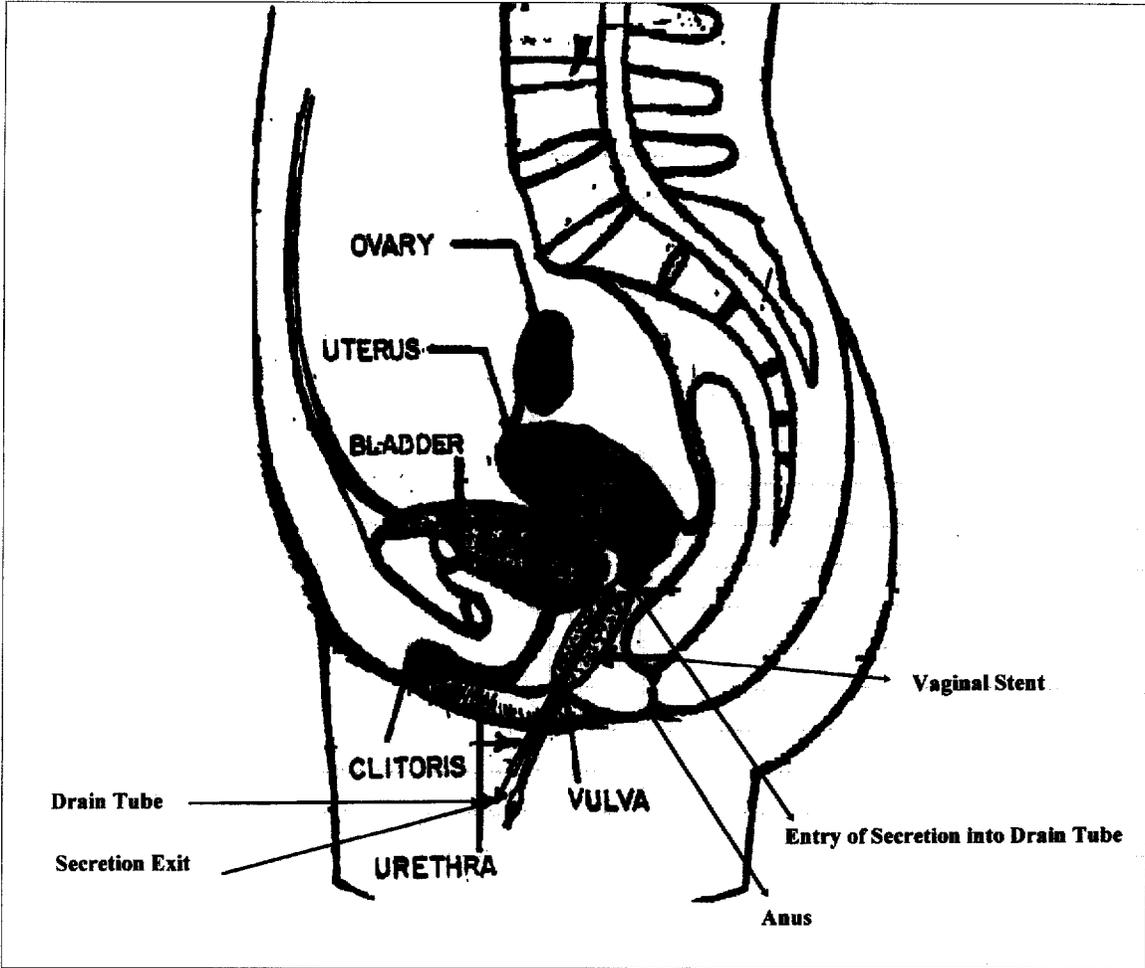
1. Remove the deflated stent with talc free gloved hands.
2. To prevent soap or water from entering the interior of the stent, pinch the valve ball into the "closed" position.
3. Wash the stent thoroughly in a hot water using Ivory soap solution.
4. DO NOT USE SYNTHETIC DETERGENTS OR OIL-BASED SOAPS.
5. Rinse the stent well in sterile water, taking care to flush the opening of the drain tube.

Facts About Your Vaginal Stent:

You may remove the stent for cleaning, and sexual intercourse is permitted after two months if healing is complete, but until all tendency to vaginal constriction has ceased (approx. six months). **The vagina will contract if the stent is left out longer than 10 to 15 minutes at a time.**

Intermittent use of the stent to maintain the vaginal canal is usually required for six months, and may be required indefinitely. *The stent must be replaced with a new stent every 12 weeks.* Consult with your physician.

If you have any questions or concerns about your vaginal stent call Silimed's help line (800) xxx-xxxx for assistance.



Placement of Silimed Vaginal Stent

VALVE DRAWINGS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 13 1998

Silimed LLC
c/o Mr. E. J. Smith
Smith Associates
P.O. Box 4341
Crofton, MD 21114

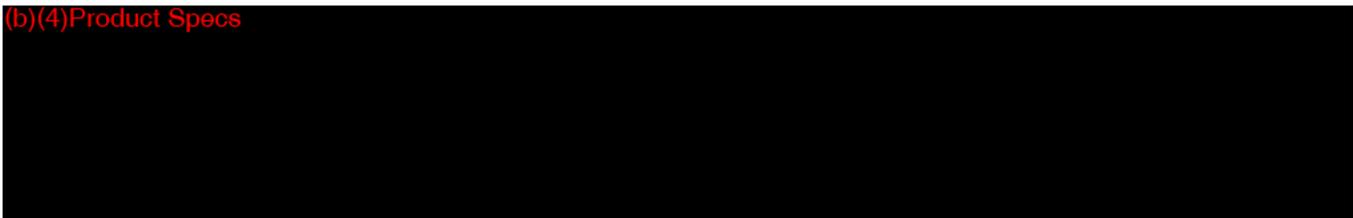
Re: K974479
Silimed Vaginal Stent
Dated: February 20, 1998
Received: February 20, 1998

Dear Mr. Smith:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device because you did not completely respond to the deficiencies listed in our January 11, 1998, letter. To complete the review of your submission, we require the following additional information.

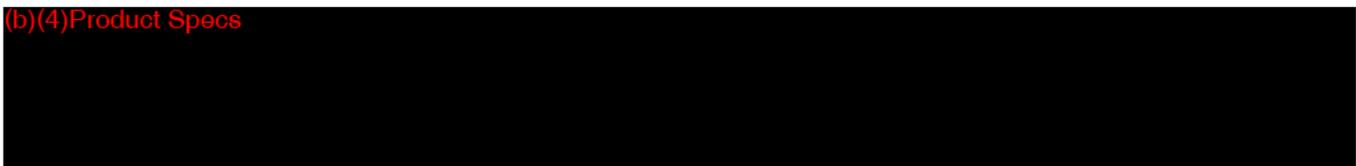
Device performance:

(b)(4)Product Specs



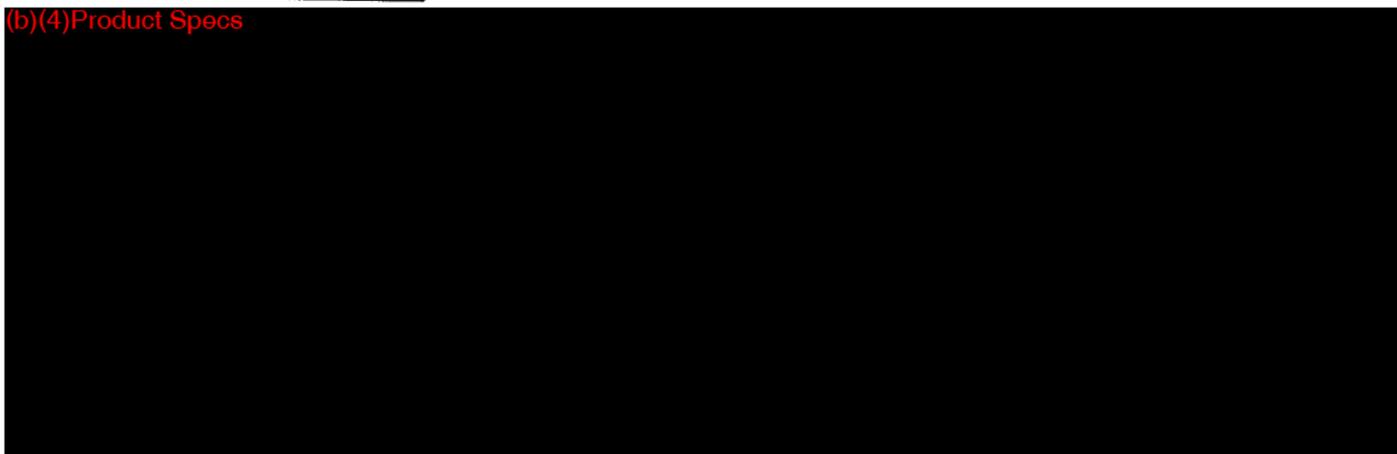
Labeling:

(b)(4)Product Specs



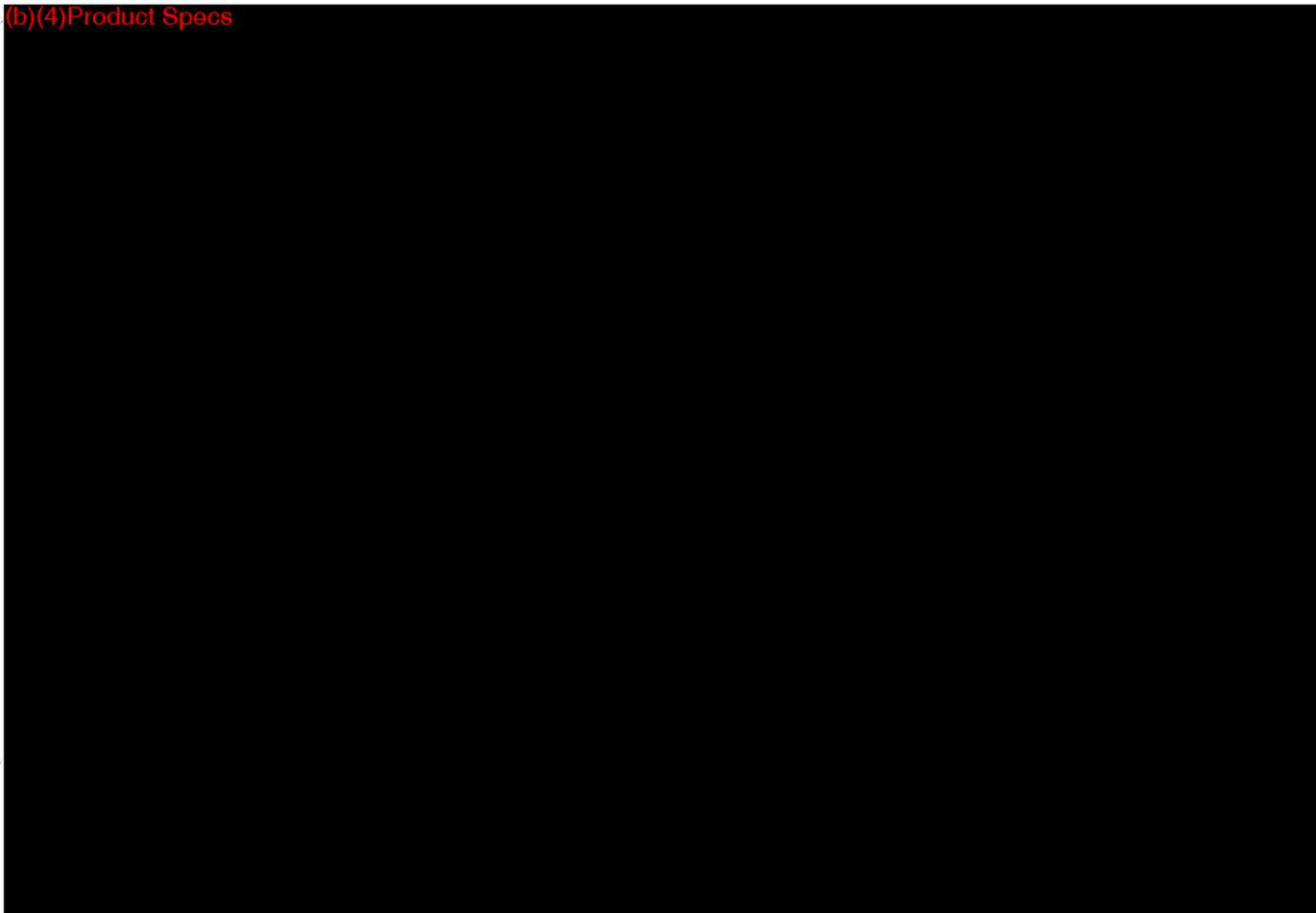
Physician labeling:

(b)(4)Product Specs



Patient labeling:

(b)(4)Product Specs



We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(k), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

Page - 3 - Mr. E. J. Smith

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of this letter, please contact Mridulika Virmani, Ph.D. at (301) 594-1180. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Colin M. Pollard
Chief, Obstetrics and Gynecology
Devices Branch
Division of Reproductive, Abdominal,
Ear, Nose and Throat, and
Radiological Devices
Center for Devices and
Radiological Health

APR 13 1998

Silimed LLC
c/o Mr. E. J. Smith
Smith Associates
P.O. Box 4341
Crofton, MD 21114

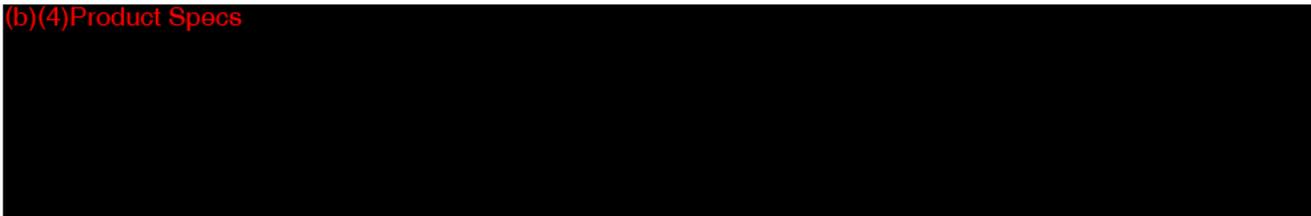
Re: K974479
Silimed Vaginal Stent
Dated: February 20, 1998
Received: February 20, 1998

Dear Mr. Smith:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device because you did not completely respond to the deficiencies listed in our January 11, 1998, letter. To complete the review of your submission, we require the following additional information.

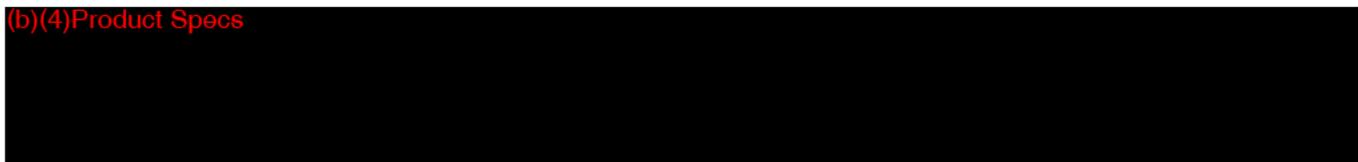
Device performance:

(b)(4)Product Specs

A large black rectangular redaction box covering the content of the 'Device performance' section.

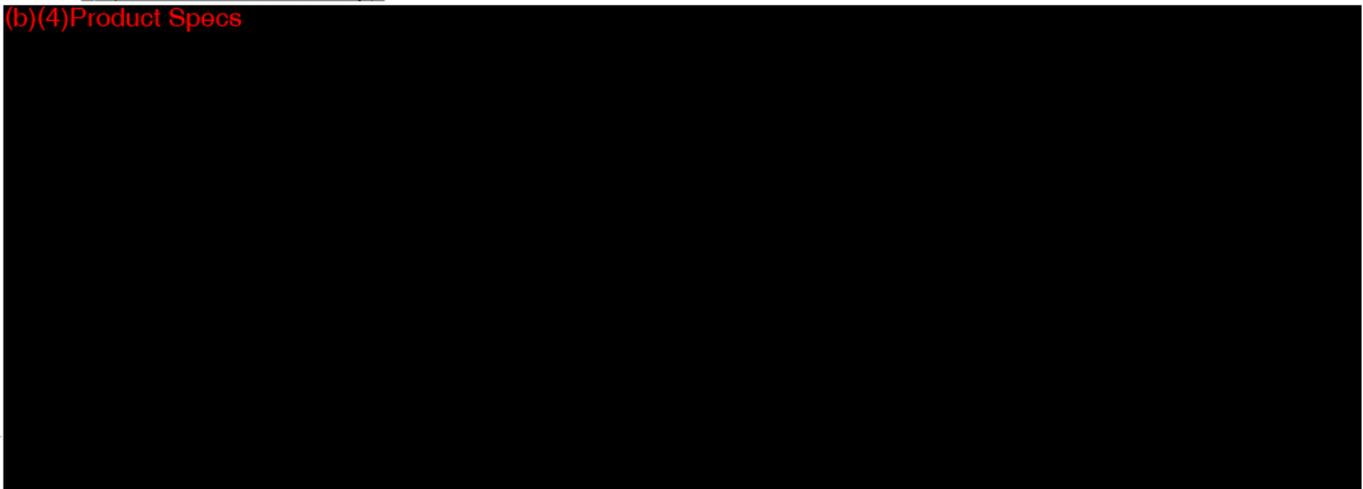
Labeling:

(b)(4)Product Specs

A large black rectangular redaction box covering the content of the 'Labeling' section.

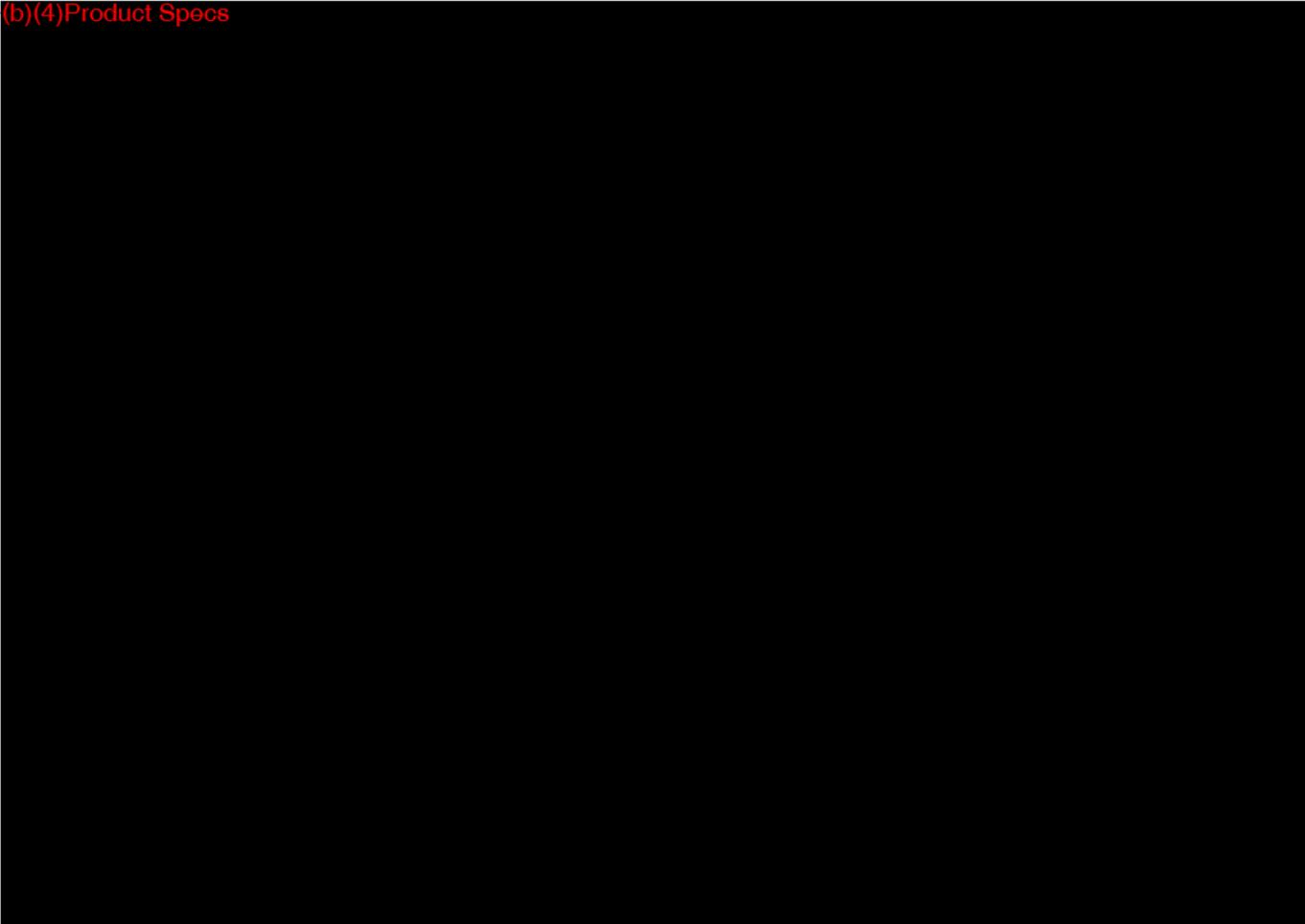
Physician labeling:

(b)(4)Product Specs

A large black rectangular redaction box covering the content of the 'Physician labeling' section.

Patient labeling:

(b)(4)Product Specs



We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(k), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

Page - 3 - Mr. E. J. Smith

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
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 Document Mail Center (HFZ-401)
 9200 Corporate Boulevard
 Rockville, Maryland 20850

If you have any questions concerning the contents of this letter, please contact Mridulika Virmani, Ph.D. at (301) 594-1180. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

/s/

Colin M. Pollard
 Chief, Obstetrics and Gynecology
 Devices Branch
 Division of Reproductive, Abdominal,
 Ear, Nose and Throat, and
 Radiological Devices
 Center for Devices and
 Radiological Health

cc: HFZ-401
 HFZ-404
 HFZ-470
 D.O.

MSV:lrn:4.10.98

FILE
 COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ-470	Virmani	4/10/98						
2470	Pollard	4/10/98						

|||



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Mridulika Virmeni

Subject: 510(k) Number K974479/S1

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Accepted for review _____.
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance? YES NO

Is this device subject to the Tracking Regulation? YES NO

Was clinical data necessary to support the review of this 510(k)? YES NO

Is this a prescription device? YES NO

Was this 510(k) reviewed by a Third Party? YES NO

This 510(k) contains:

- Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with panel and class: Additional Product Code(s) with panel (optional):

Review: Colin M Pollard 06DOB 4/10/98 (FME)
 (Branch Chief) (Branch Code) (Date)

Final Review: _____
 (Division Director) (Date)

Spell check!
OGDB

K974479

Reviewer: Mridulika Virmani, Ph.D.
Chemist

Division/Branch: DRAERD/OGDB
(HFZ-470)

Trade Name: Silimed Vaginal Stent

Common Name: Stent, vaginal

Predicate Device: Heyer-Schulte Adjustable Vaginal Stent

Applicant: Smith Associates
P.O. Box 4341
Crofton, Maryland 21114

Contact: E.J. Smith

Phone: (410) 451-0639

Fax: (410) 793-0448

INTENDED USE:

The Silimed Vaginal Stent is designed to maintain the vaginal canal following radiological treatment or surgical procedures to restore, enlarge or create a vagina. The surgeon is responsible for choice of shape and size to meet the clinical and aesthetic needs of each case.

	YES	NO
Life-supporting or life-sustaining?		✓
Implanted (long-term or short-term)?	✓	
Uses software?		✓
Sterile?	✓*	
Single use?	✓*	
Home use?	✓	
For prescription?	✓	
Contains drug or biologic?		✓
Kit?		✓
Reason for Submission of 510(k)		
• New device	X	
• New indications	No	
• Changes in technology	No	
• Other:		

* Add'l cleaning instructions for removal and replacement during

Device Description

How is inflation accomplished? air? water? something else? ✓

The Silimed Vaginal stent consists of silicone elastomer shell filled with polyurethane foam. The shell has a internal drain tube and a inflation tube with a valve for opening and closing of inflation tube. The stent is manufactured from implant grade silicone supplied by Applied Silicone Corporation. Silimed has provided Master file number for silicone. They have also provided a list of chemical, physical and biocompatibility testing done for this silicone material. The cylindrical valve of inflation tube is made of silicone and stainless steel ball. The stainless steel ball is covered with silicone elastomer. The stent is available in four sizes.

Review History

How long ~~long~~ is the device intended to remain in place? What are the dimensions? Are there different?

For this device company has u

(b) (4) Product Specs

Review Analysis

Additional information required letter was sent to company on January 11, 1998. This submission is the response to that letter. ~~Besides me,~~ Ms. Price, Dr. Tsai, and Dr. Smith have also reviewed this submission. Their reviews are attached.

MATERIALS AND BIOCOMPATIBILITY

Basic materials of the subject device are quite similar to the predicate device. Both use silicone elastomer shell filled with polyurethane. The silicone elastomer shell is water tight. (b)(4) Product Specs

[Redacted]

Materials, manufacturing process and additives used during this process information, as well as chemistry of material is provided and satisfactory. Dr. Tsai reviewed this part of submission. His review is attached.

The polyurethane foam is filled in the water tight shell of the (b)(4) Product Specs Engineering drawing, polyurethane amount and how it is filled in the shell is provided and adequate. Sponsor provided a sample of device, which explains lot of concerns. According to sponsor these devices are on market in Europe for past 10 years.

with? ✓

What about U.S.?

11h

PERFORMANCE

The stent is inserted in the vagina in its collapsed (flat) position, after insertion the stent is filled with sterile solution (not provided), using a syringe (not provided) until it is secured in position. The amount of solution added is at the discretion of physician. Sponsor has provided performance data to how much liquid device can take. Also the inflation capacity of the elastomer membrane shell. ✓

(b)(4)Product Specs



STERILIZATION

Device is provided sterilized for single patient use.

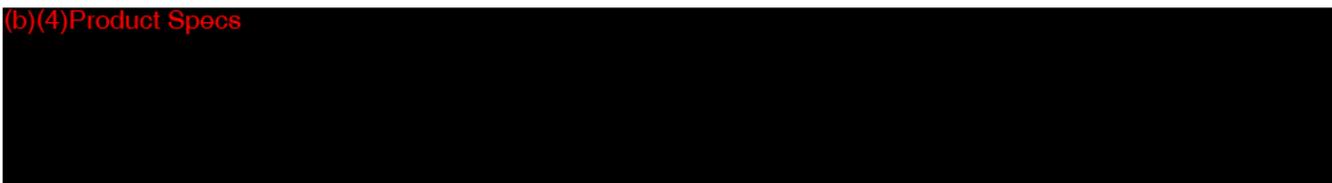
In additional information, sponsor has included cleaning instructions for patient as following: Remove deflated stent with gloved hands. Wash the stent thoroughly in hot water and soap solution. Do not use synthetic soap. Rinse stent with distilled water. In this section it should be made clear that gloves should be talc free. Are sterile gloves to be used? What is a synthetic soap? The user needs a specific instruction as to what soap to use. Why is distilled water used and is this different from what is used to inflate (sterile saline) the device? ✓

(b)
(4)Pro
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S

LABELING

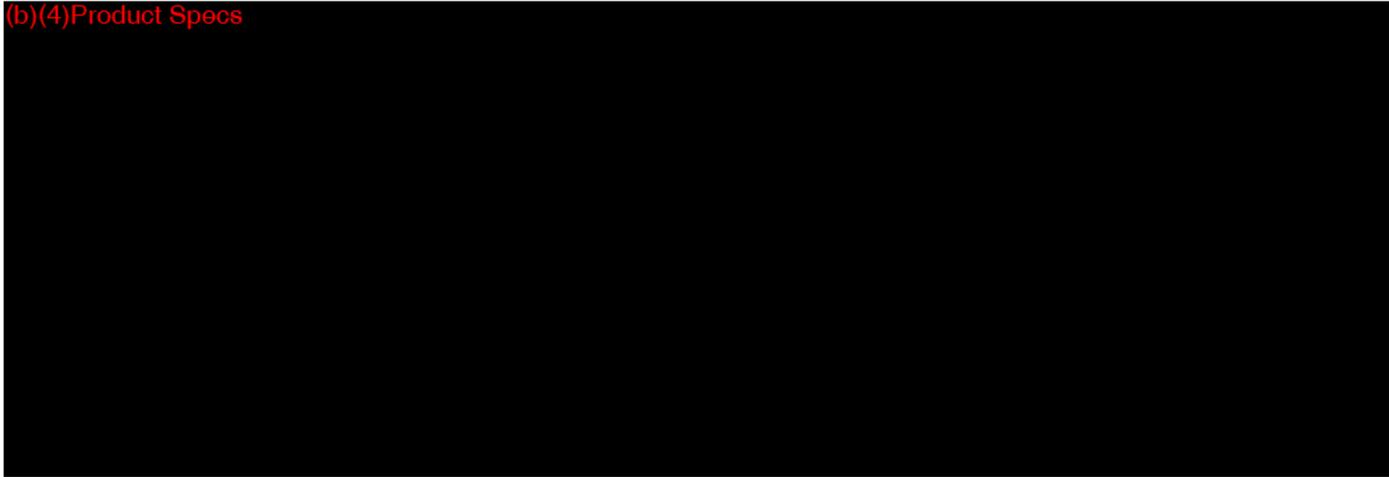
Modified physician and patient labeling is included in the additional information. Dr. Smith reviewed this section, still lot of improvement is needed for this section of submission. Following questions should be sent to the sponsor:

(b)(4)Product Specs



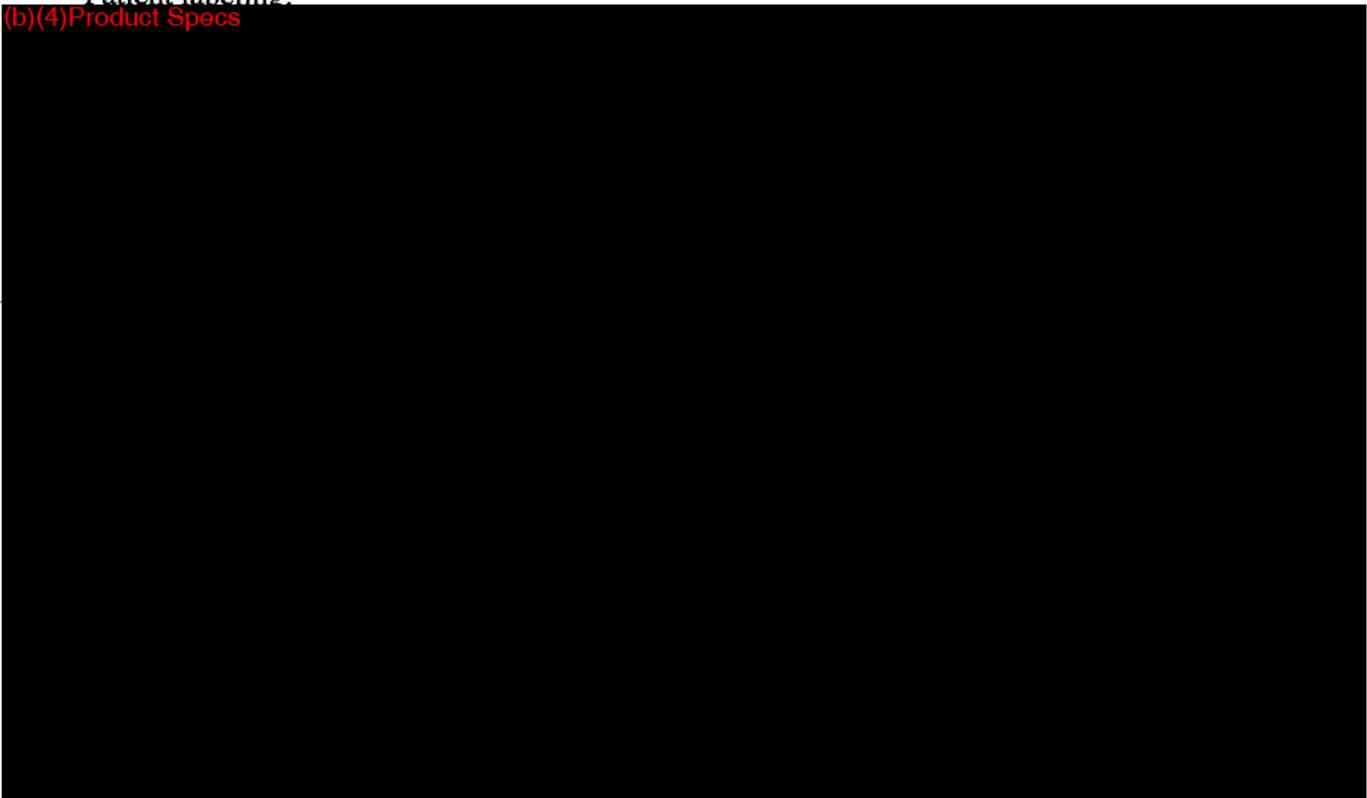
Physician labeling:

(b)(4)Product Specs



Patient labeling:

(b)(4)Product Specs



1.

ADMINISTRATIVE

The following documents are included in the submission:

- 510(k) statement
- Truthful and Accurate Statement
- Indications for Use

Recommendation

Following questions should be sent to the sponsor.

Device performance:

(b)(4)Product Specs



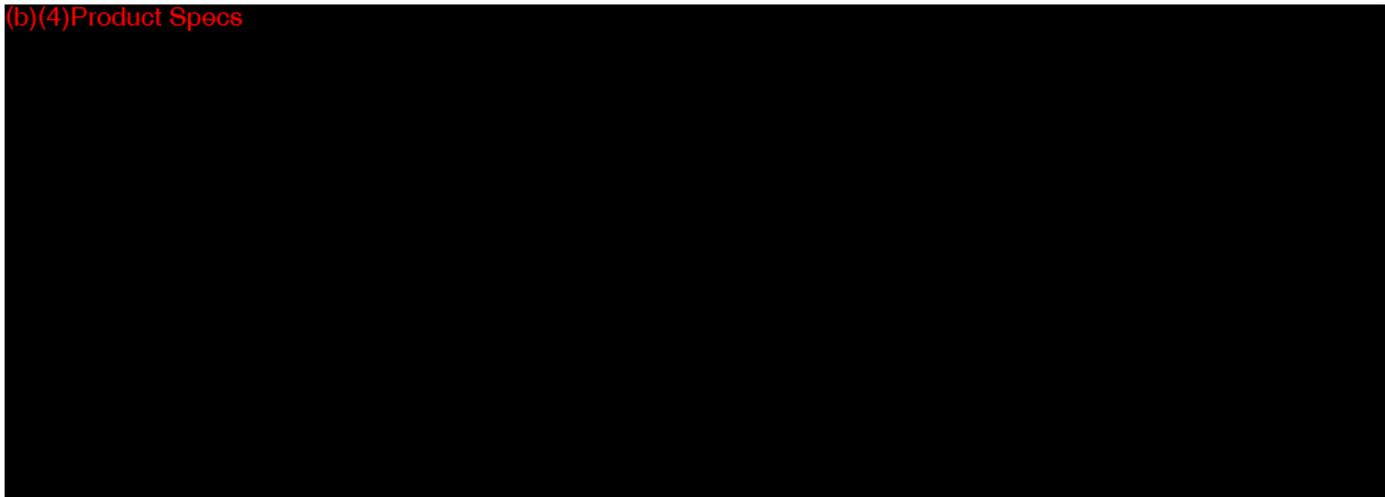
Labeling

(b)(4)Product Specs



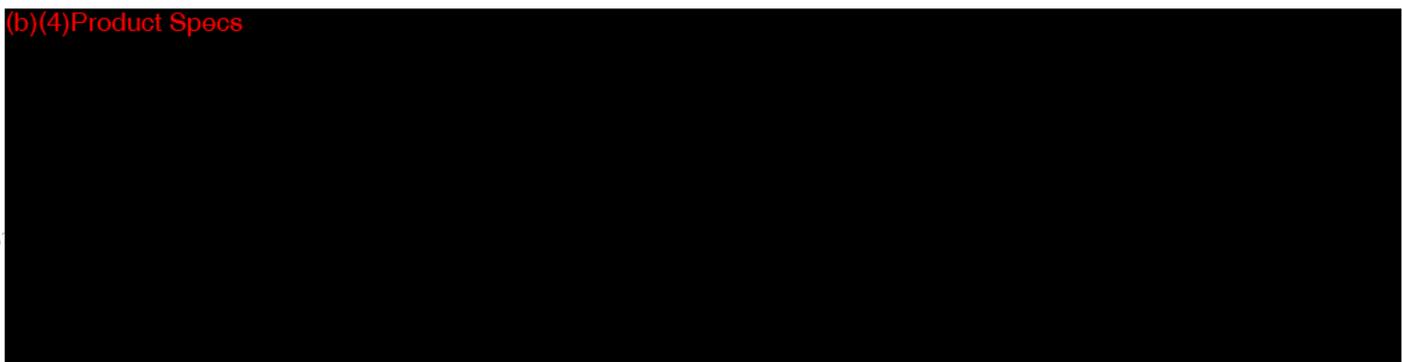
Physician labeling:

(b)(4)Product Specs



Patient labeling:

(b)(4)Product Specs



(b)(4)Product Specs

I recommend that the file be placed on hold pending receipt of additional information.

Mridulika Virmani 4/2/98
Mridulika Virmani, Ph.D. Date

Colin M. Pollard 4/9/98
Colin M. Pollard Date
Chief, OGDB

/ Concur
 / Do not concur
Comments:

OGDB

K974479/A2

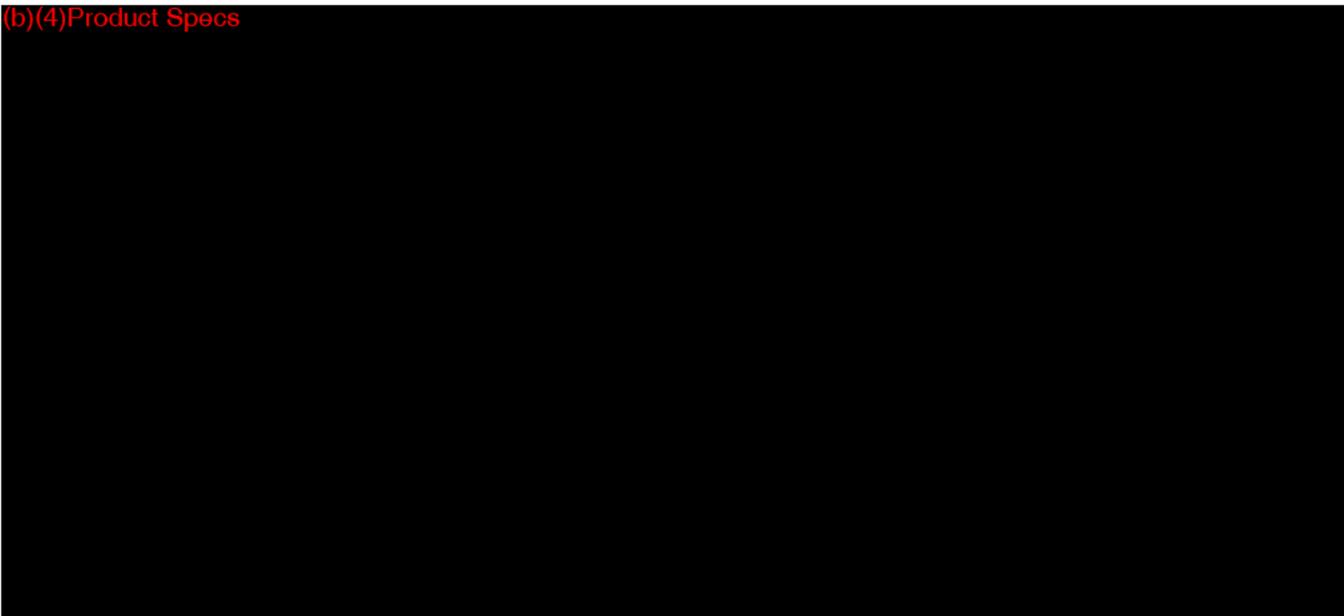
Subject: Consulting Review

Reviewer: Miin-Rong Tsai, Ph.D. **Division/Branch:** DRAERD/ADOU/OGDB
Chemist (HFZ-470)

This is the reviewed on the applicant's response to FDA's Jan 21, 1998 request for additional information. As requested, this review is on the applicant's response to deficiency #3 of the Device Description. The requested information are listed in *italics* as following:

Device Description:

(b)(4)Product Specs



Miin-Rong Tsai, Ph.D.

4/2/98
Date

Chief, Ob/Gyn Devices Branch Date
Mr. Colin Pollard

// Concur

// Do Not Concur

119

Review Memorandum

To: Mridu Virmani, Ph.D.

From: Deborah Smith, M.D. *(Signature)*

Date: 3/25/98

Subject: K974479 S001
Silimed Vaginal Stent

My review focused on Exhibits 5 and 6 which are the product information and patient instructions respectively. In general, the presentation of information is unacceptable. Specific comments are outlined below.

Exhibit 5 Product Information

(b)(4)Product Specs

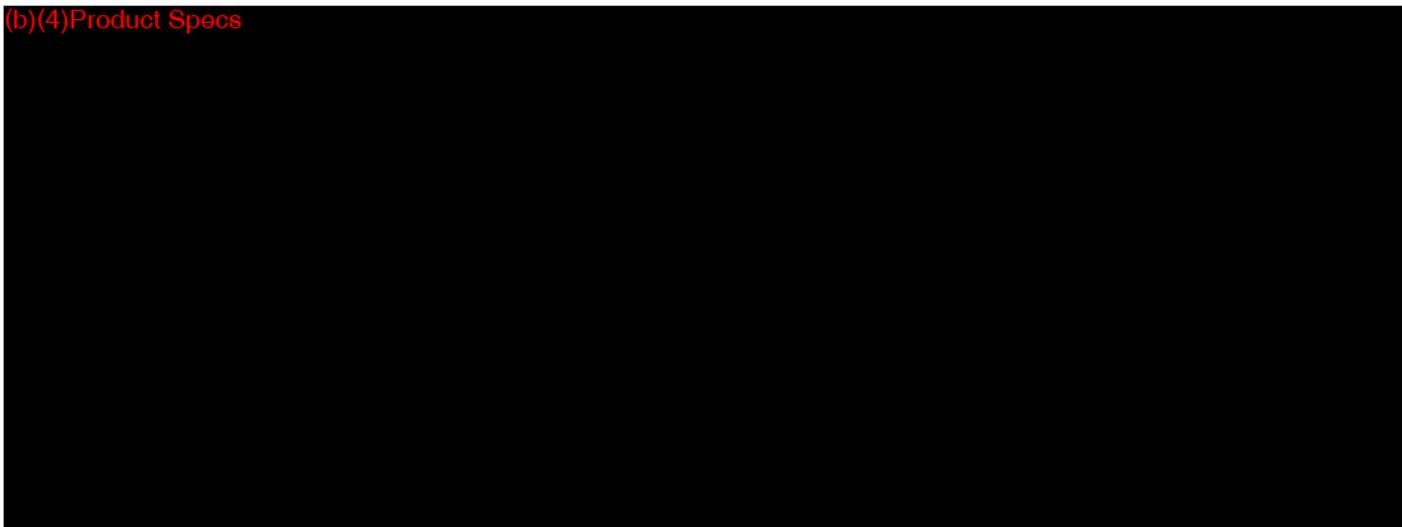
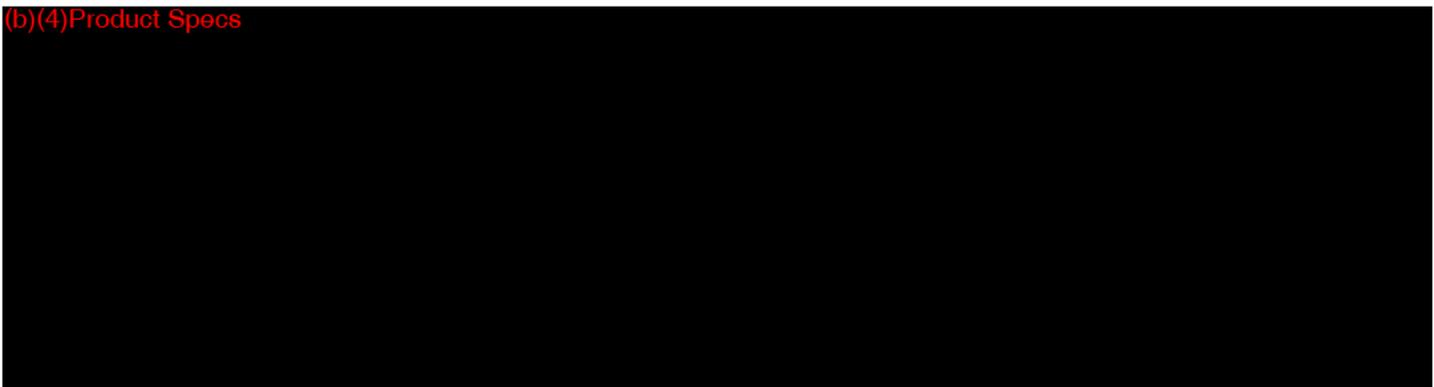


Exhibit 6 Patient Instructions

(b)(4)Product Specs

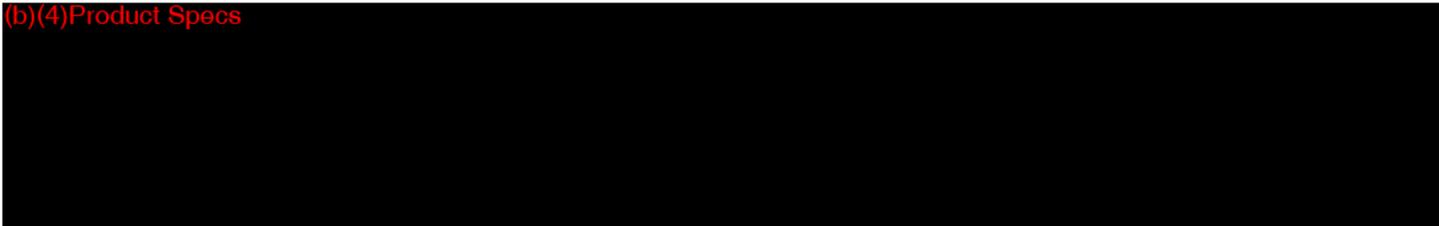


(b)(4)Product Specs



Additional General Comments

(b)(4)Product Specs





Memorandum

DATE: March 11, 1998

FROM: Veronica Price, Biomedical Engineer
DRAERD/ADOU/OGDB

TO: Mridu Virmani, Ph.D.
Chemist
DRAERD/ADOU/OGDB

RE: K974479/S1; Silimed Vaginal Stent
Silimed, Inc.

Scope:

The scope of this review is intended to cover the performance characteristics of the Silimed Vaginal Stent and the adequacy of the engineering information provided. A letter requesting additional information on this device was sent to the contact on January 21, 1998. The contact was asked to [REDACTED] This review will focus on the responses to the questions raised by the lead reviewer.

Intended Use:

The Silimed Vaginal Stent is indicated for use:

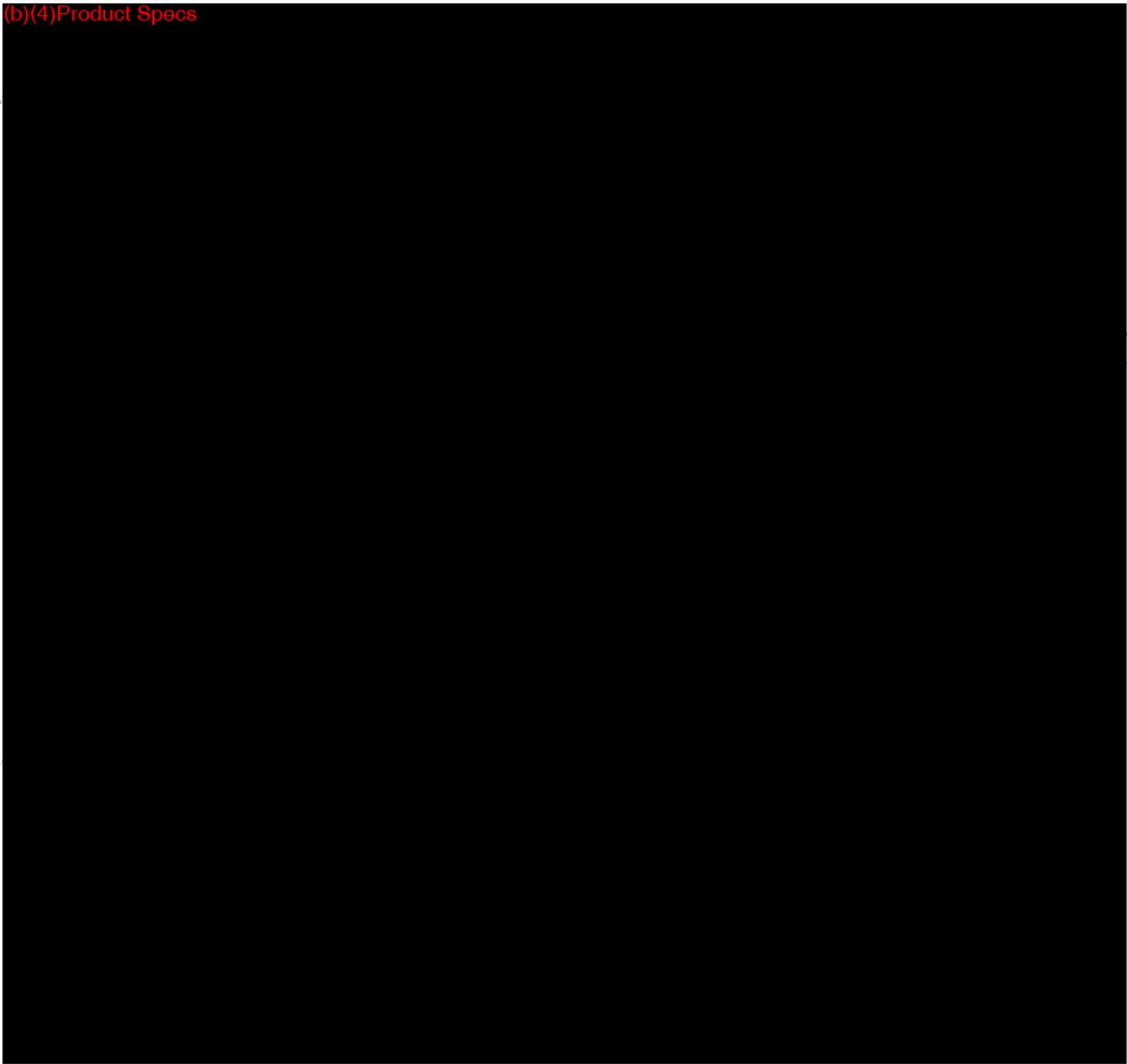
1. As a pressure dressing after vaginal surgery to hold pedicle flaps or free skin grafts in close apposition to the receptor site.
2. As an obturator or dilator to maintain the vaginal canal and reduce the possibility of contracture and stenosis following vaginal surgery and/or radiological treatment.

Response to Deficiencies:

(b)(4)Product Specs

The manufacturer has provided this information and it is adequate.

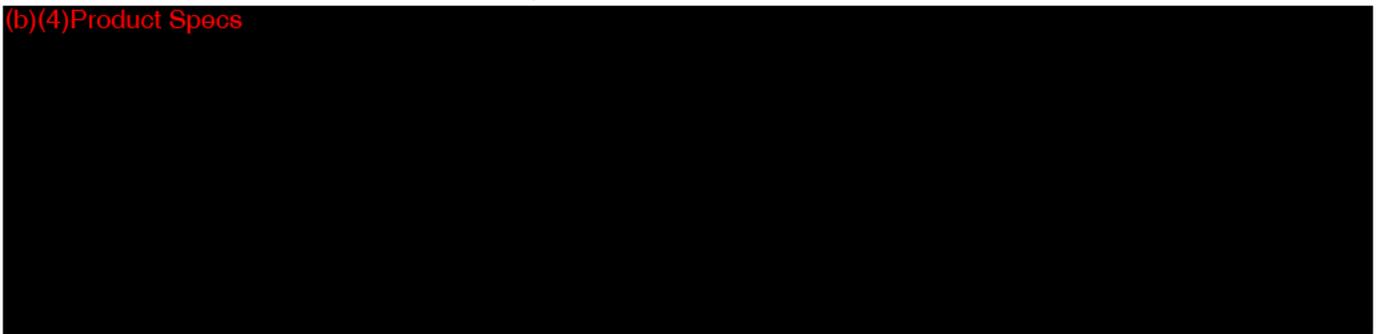
(b)(4)Product Specs



you
will simulate
for this

Recommendation:

(b)(4)Product Specs



(b)(4)Product Specs

Veronica Price 3/11/98
Veronica Price Date

K974479/A2

DUPLICATE

Smith Associates
Specializing in Regulatory Affairs

FDA/CDRH/ODE/DMC

6 Mar 98 12 55

RECEIVED

March 6, 1998

Food and Drug Administration
Document Control Center
9200 Corporate Blvd.
Rockville, Maryland 20850

Reference: K974479

Dear Dr. Virmani:

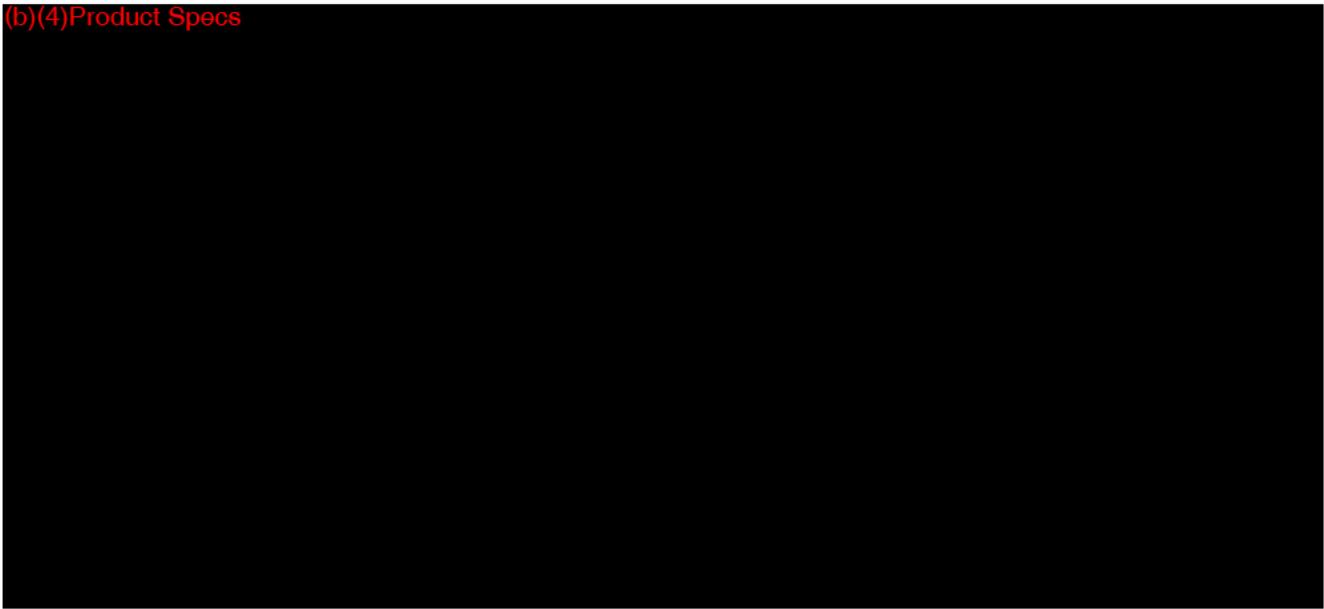
Enclosed are three copies of the above submission plus all correspondence that has transpired since last December. I have also enclosed 2 samples of the vaginal stent.

This is our response to your questions:



DS

(b)(4)Product Specs



If you have additional questions I can be reached at (410)451-0639.

Sincerely

A handwritten signature in black ink, appearing to read "E.J. Smith", is written over the word "Sincerely". The signature is stylized and somewhat cursive.

E.J. Smith

DS

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

February 23, 1998

SILIMED, LLC
C/O SMITH ASSOCIATES
P.O BOX 4341
CROFTON, MD 21114
ATTN: E J. SMITH

510(k) Number: K974479
Product: SILIMED VAGINAL
STENT

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

K 974479/S1

Smith Associates

Specializing in Regulatory Affairs

February 20, 1998

Food and Drug Administration
Document Control Center
9200 Corporate Blvd.
Rockville, Maryland 20850

Reference: K974479

Dear Dr. Virmani:

This is our response to your letter dated January 21, 1998:

RECEIVED

20 FEB 98 15 58

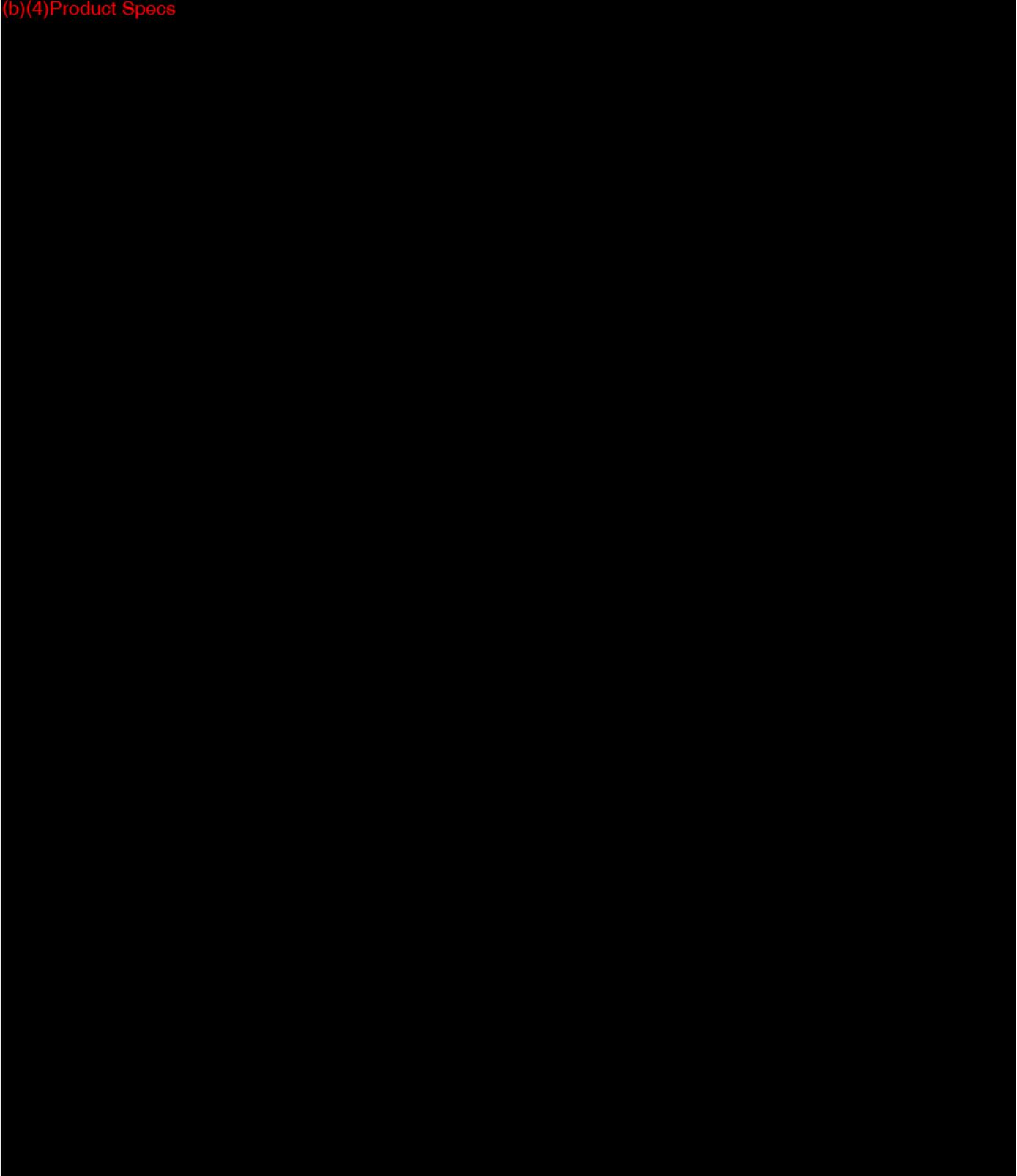
FDA/CDRH/ODE/DMC

(b)(4)Product Specs

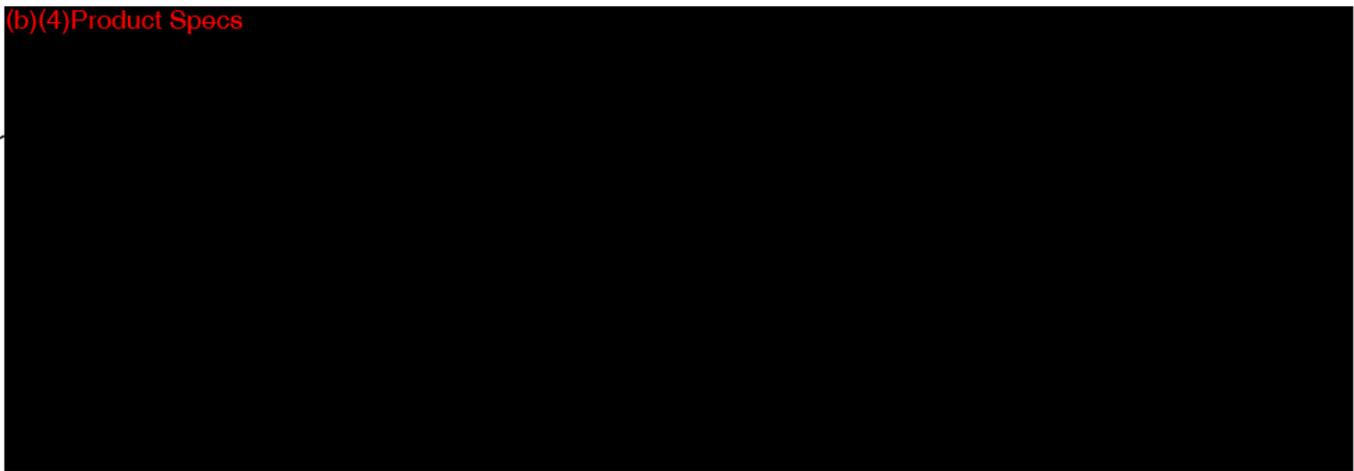


SK-61

(b)(4)Product Specs



(b)(4)Product Specs



Sincerely,

E.J. Smith

5071

EXHIBIT 1

EXHIBIT 2

EXHIBIT 3

EXHIBIT 4

EXHIBIT 5

**PRODUCT INFORMATION
VAGINAL STENT**

Description:

The Silimed Vaginal Stent described in this insert is intended for use only as supplied. Under no circumstances should this device be altered, modified or revised in any way prior to or during its' use.

The inflatable Silimed Vaginal Stent is designed for neovaginal and reconstructive surgery. The Vaginal Stent has an internal drain that allows drainage of the surgical wound without withdrawing the silicone body, obturating sphere and tubing.

The Vaginal Stent is presented in a set of sizes (base, height and volume) that appear in Silimed's commercial catalog. This sizing is the result of many years of research with the medical profession.

Indications for Use:

The Silimed Vaginal Stent is indicated for use:

1. as a pressure dressing after vaginal surgery to hold pedicle flaps or free skin grafts in close apposition to the receptor site;
2. as an obturator or dilator to maintain the vaginal canal and reduce the possibility of contracture and stenosis following vaginal surgery and/or radiological treatment.

The Constituent Materials:

Membranes: the basic elastomer used is vinyl dimethyl polydimethyl siloxane with a load of pure amorphous fine-crushed silica catalyzed by a platinum compound.

- Filling Product: 0.9% sterile solution, nonpyrogenic and injectable in accordance with national pharmacopedics.
- Shell filling: Polyurethane Foam:
- Connectors and Drain: polydimethyl siloxane.
- Cylindrical Valve: polydimethyl siloxane and 001 stainless steel ball.

How Supplied:

Silimed Vaginal Stents are supplied sterile and are contained in:

- transparent or opaque double plastic "blister" sealed with special paper, which is permeable to ethylene oxide.
- double peel pouch packaging permeable to ethylene oxide.

The packages are stored in a cardboard box with a plastic protective film. Outer package label will contain the following information: description of the product, catalog number, lot number and expiration date.

Sterilization: Ethylene Oxide

An individual confirmation of sterilization of each batch is carried out, as well as a quarterly validation of the latter performed by an independent laboratory.

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Instructions for Use:

Opening the Package: Vaginal Stents are supplied sterile and have been submitted to careful tests that guarantee their biocompatibility and virtual absence of reactions in the organism, the possible rare exceptions occurring on account of specific, individual conditions.

Care when opening the package is of utmost importance: The high dielectric value of silicone can generate static charges responsible for the attraction of particles existing in the atmosphere, such as dust, lint, and talc to mention a few examples. External contaminants that adhere to the membrane surface may provoke foreign-body reactions in the organism thereby increasing fibrosis and the generation of fluids.

Care should also be taken with all the accessories of the product, be they documents such as inserts, labels for different files, etc., or parts of products such as valves and filling tubes.

The "blister" packages are double packages, which allows the user to open them in two stages:

- first remove the special paper protection from the outer "blister" gaining access to the sterile inner package.
- secondly, remove the special paper protection from the inner "blister" next to the surgical field.

When the implant is packaged in a double peel pouch:

- proceed in the same way as the "blister" package.

Instructions for Use:

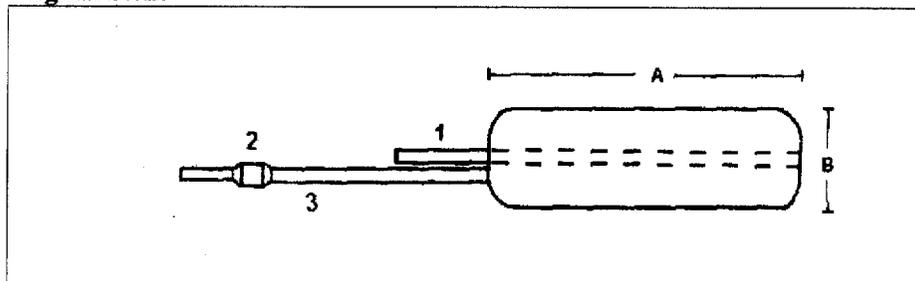
Directions for deflating and filling the stent during the surgical procedure:

1. Prior to inserting the stent, deflate the device completely by squeezing or aspirating with a syringe.
2. Close the valve by moving the ball to the closed position, i.e., toward the filling orifice.
3. Using a syringe filled with sterile, normal saline, inflate the device to the desired contour, but keep the device small enough that it may be introduced into the vagina.
4. Close the valve.
5. Fill the unit in situ to the desired volume.
6. Adjust volume in the stent by opening the valve and using a syringe to introduce or withdraw saline or air. Close the valve.

Surgical Procedure:

A variety of surgical techniques may be employed during the use of the Silimed Vaginal Stent; therefore, the surgeon is best advised to use the method which his own practice and discretion dictate to be best for the patient.

Inflatable Vaginal Stent

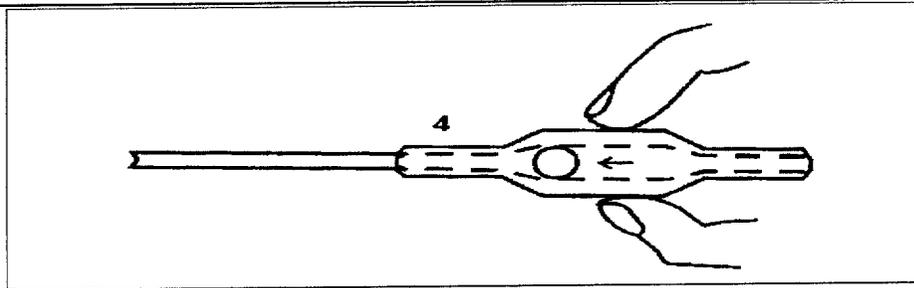


- 1- Internal Drain
- 2-The valve (silicone body and obturating sphere)
- 3-Tubing

Exhibit 5 Page 2

Volume

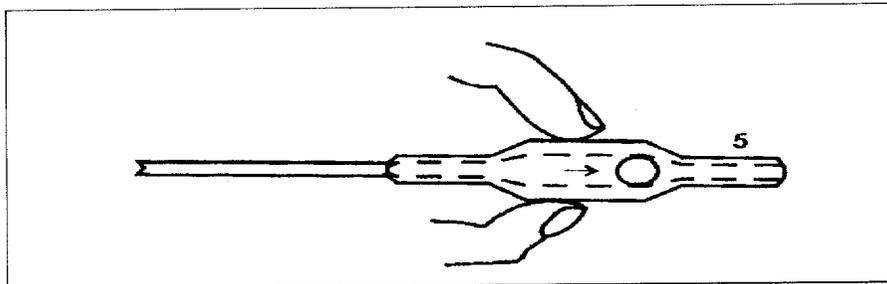
1/11



Open Position

Open Position:

To fill up or deplete the expander, shift the sphere towards the side of the tubing with a slight compression between the thumb and index finger. When the sphere is in position, one can fill or empty the stent with the help of a syringe connected to the extremity of the valve.



Closed Position

Closed Position :

To close the valve displace the sphere using the thumb and index finger to move the sphere towards its free extremity. The pressure within the valve coming from the stent will facilitate its airtight closure by the sphere.

Restertilization:

Silicone implants are meant for single patient use; restertilization is thus forbidden by international standards.

Important Recommendations:

Maintenance of Sterility: It is essential that the vaginal stent be used under conditions of absolute asepsis and sterility

Packaging Inspection: The packaging of the vaginal stent must be carefully examined. If the package has been damaged in any way, the stent cannot be used.

Stent used only as supplied: The vaginal stent can only be used in its original form, without any alterations to its original characteristics.

ALL SILICONE VAGINAL STENTS MUST BE USED IN ONE PATIENT ONLY

Durability:

The vaginal stent is a temporary device for treatment time not to exceed 12 weeks.

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Contraindications and Precautions:

Procedures to create, enlarge or restore the vagina are contraindicated in the presence of local or systemic infection or in the presence of an anomaly of the urinary system which could be damaged by such procedures or by subsequent sexual intercourse. Congenital anomalies of the urinary tract frequently associated with congenital absence of the vagina include pelvic, kidney, anomalous insertion of the ureter and ureteral duplication.

The use of the vaginal stent is contraindicated when for any reason the patient has the inability to operate the device or to understand how the device is operated, or when the patient is apt to be uncooperative in maintaining the stent within the vagina for the prescribed length of time.

Warning:

The silicone elastomer shell of the Silimed Vaginal Stent is thin in order to achieve desired properties. Punctures, surface cuts, nicks, crushing or overstressing can lead to a tear. The device may be easily penetrated by needle or scalpel or ruptured by manipulation with a blunt instrument. Care must be exercised during handling to prevent such events. A damaged stent must not be placed. For this reason, a standby device should be available at the time of surgery.

Postoperatively, care must be taken not to over inflate the stent, as urethral erosion or fistula and graft tissue necrosis may result. Suprapubic drainage, rather transurethral catheterization, may be advisable.

Failure to maintain the stent within the vaginal canal for the prescribed length of time can promote contracture and stenosis of the vagina.

Lint fingerprints, talc and other surface contaminants can cause foreign body reactions. Utmost caution should be taken to avoid contaminants.

Transportation and Storing:

Silimed products and packages are extremely resistant and if handled with normal minimum of care will not present any problems. However, they should not be transported or stored with other types of material that may cause mechanical damage to the packaging and thus invalidate their sterile condition.

Clarification and Consent of Patient:

Silimed relies on the surgeon to clarify with their patients any risk factors inherent in surgery of this type before obtaining the patient's formal consent.

Warranty:

Silimed has stipulated a three year warranty for manufacturing defect provided the packaging has been preserved intact prior to use.

Silimed will replace any defective product. Since proper registration is made of each unit of raw material, stages of manufacture, and atmospheric and operational conditions, an individual number is given to each item that identifies it at any time. As a result, it is absolutely necessary that any complaint be accompanied by the CONTROL NUMBER of the relevant item that appears on the package and by the PATIENT'S LABEL supplied to the doctor and detachable from the label of each package.

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The warranty on Silimed products does not cover the simple decision of the patient or surgeon to change the product.

Silimed L.L.C. 14014 Sullyfield Circle Suite C Chantilly, Virginia 20151

Exhibit 5 Page 5

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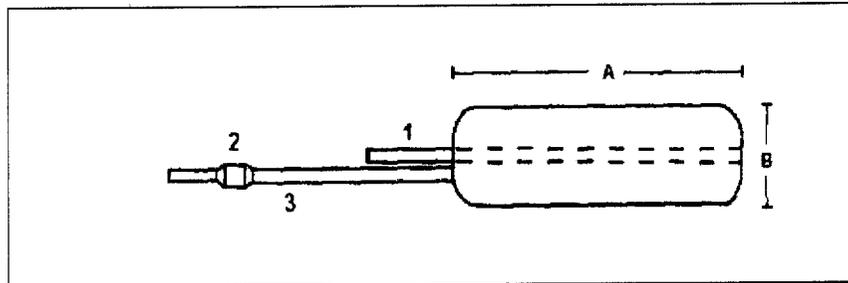
EXHIBIT 6

SILIMED VAGINAL STENT PATIENT INSTRUCTIONS

Description:

The Silimed Vaginal Stent described in this insert is intended for use only as supplied. Under no circumstances should this device be altered, modified or revised in any way prior to or during its' use.

The inflatable Silimed Vaginal Stent is designed for neovaginal and reconstructive surgery. The Vaginal Stent has an internal drain that allows drainage of the surgical wound without withdrawing the silicone body, obturating sphere and tubing.



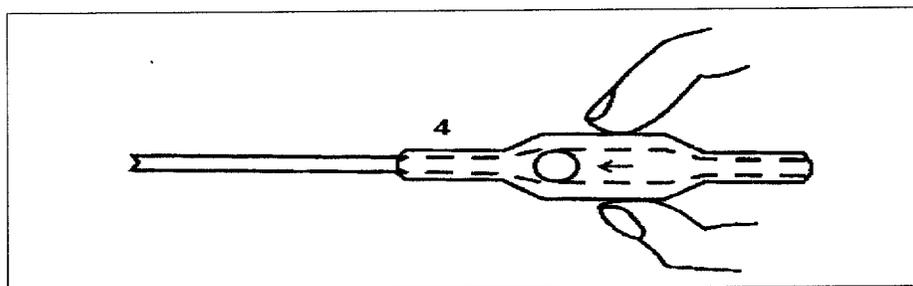
Silimed Vaginal Stent

- 1- Internal Drain
- 2-The valve (silicone body and obturating sphere)
- 3-Tubing

Instructions for Use:

The patient may remove the stent for cleaning, and sexual intercourse is permitted after two months if epithelization is complete, but until all tendency to vaginal constriction has ceased (approx. six months). The patient must understand that the vagina will contract if the stent is left out longer than 10 to 15 minutes at a time. Intermittent use of the stent to maintain the vaginal canal is usually required for six months and may be required indefinitely.

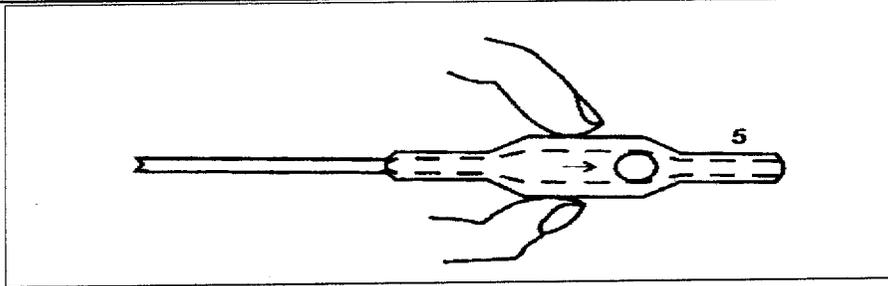
How to Deflate and Fill the Vaginal Stent:



Open Position

To fill up or deplete the expander, shift the sphere towards the side of the tubing with a slight compression between the thumb and index finger. When the sphere is in position, one can fill or empty the stent with the help of a syringe connected to the extremity of the valve.

1h6



Closed Position

Closed Position :

To close the valve displace the sphere using the thumb and index finger to move the sphere towards its free extremity The pressure within the valve coming from the stent will facilitate its airtight closure by the sphere.

Important Reminders:

1. Prior to inserting the stent, deflate the device completely by squeezing or aspirating with a syringe.
2. Inflate the stent to the desired contour, but keep the stent small enough that it may be introduced into the vagina.
3. Adjust volume in the stent by opening the valve and using a syringe to introduce or withdraw saline or air. Close the valve.

Facts About Your Vaginal Stent:

You may remove the stent for cleaning, and sexual intercourse is permitted after two months if epithelization is complete, but until all tendency to vaginal constriction has ceased (approx. six months). **The vagina will contract if the stent is left out longer than 10 to 15 minutes at a time.** Intermittent use of the stent to maintain the vaginal canal is usually required for six months, and may be required indefinitely.

Cleaning Your Vaginal Stent:

1. Remove the deflated stent with gloved hands.
2. To prevent soap or water from entering the interior of the stent, pinch the valve ball into the "closed" position.
3. Wash the stent thoroughly in a hot water and soap solution.
4. **DO NOT USE SYNTHETIC DETERGENTS OR OIL-BASED SOAPS.**
5. Rinse the stent well in distilled water, taking care to flush the lumen of the through drain.

If you have any questions or concerns about your vaginal stent call Silimed's help line (800) xxx-xxxx for assistance.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 21 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Silimed, L. C., Inc.
c/o E. J. Smith
Consultant
Smith Associates
P.O. Box 4341
Crofton, Maryland 21114

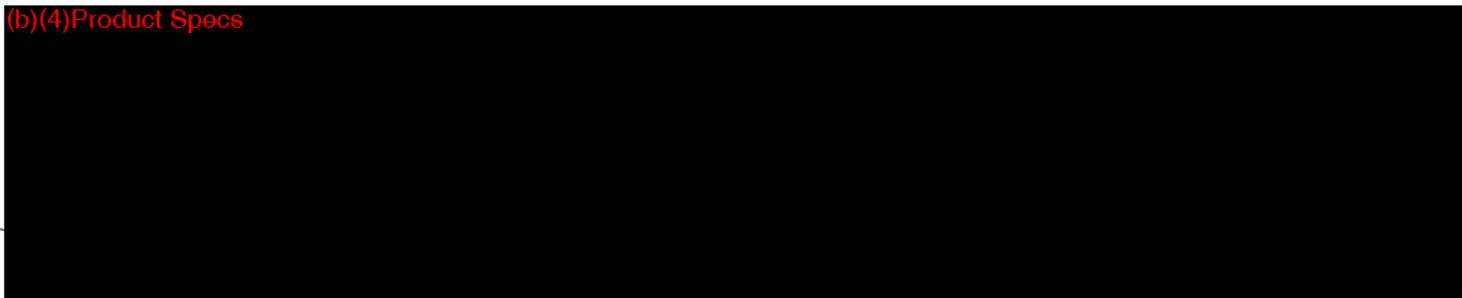
Re: K974479
Silimed Vaginal Stent
Dated: November 26, 1997
Received: November 26, 1997

Dear Mr. Smith:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following additional information:

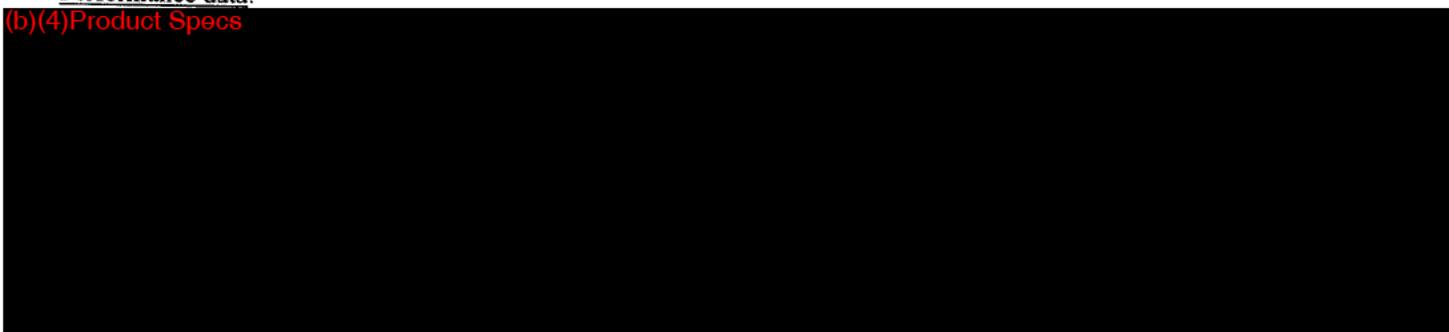
Device description:

(b)(4)Product Specs



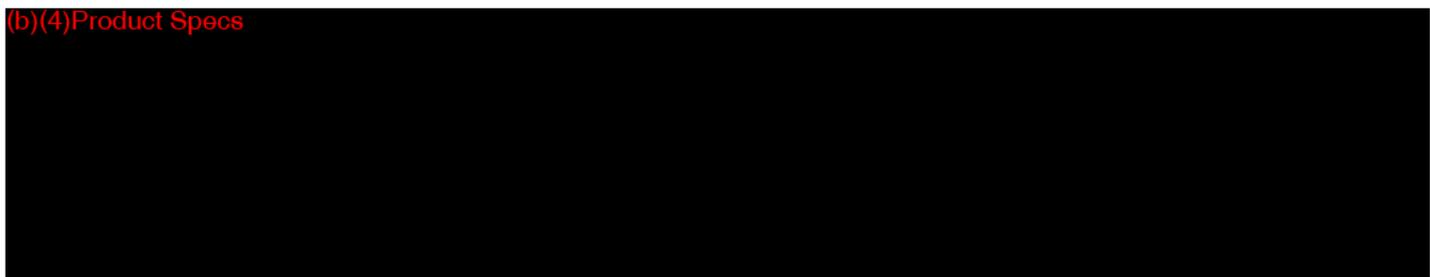
Performance data:

(b)(4)Product Specs



Labeling:

(b)(4)Product Specs



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We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(k), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

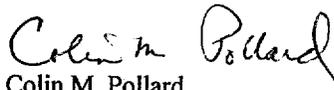
If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of this letter, please contact Mridu Virmani, Ph.D. at (301)594-1180. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Colin M. Pollard
Chief, Obstetrics and Gynecology Devices Branch
Division of Reproductive, Abdominal,
Ear, Nose and Throat, and
Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

150

Silimed, L. C., Inc.
c/o E. J. Smith
Consultant
Smith Associates
P.O. Box 4341
Crofton, Maryland 21114

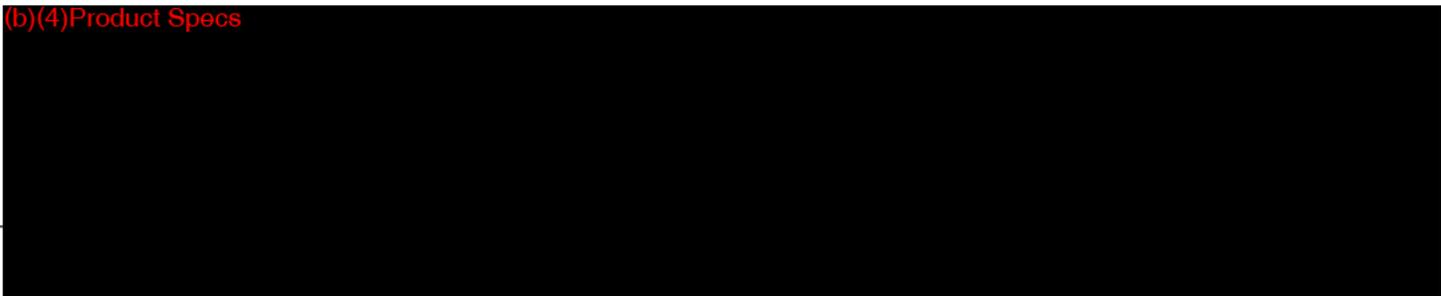
Re: K974479
Silimed Vaginal Stent
Dated: November 26, 1997
Received: November 26, 1997

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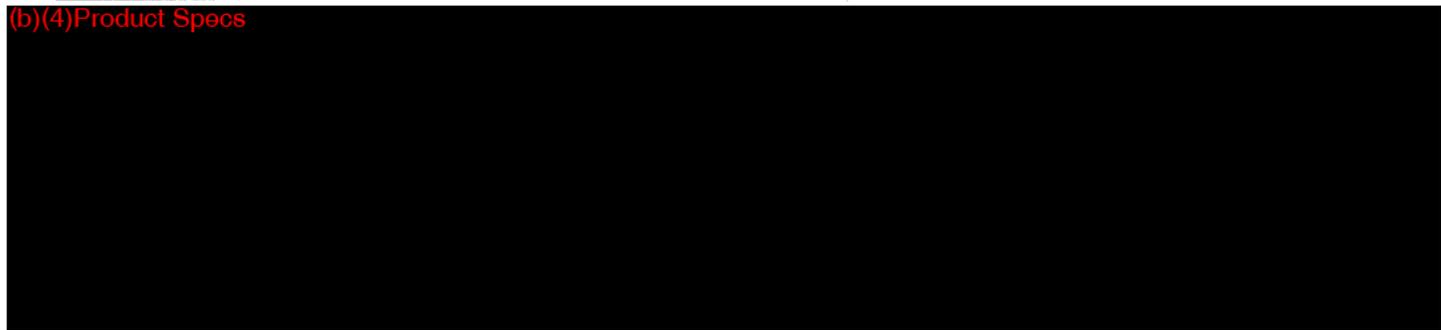
Device description:

(b)(4)Product Specs

A large black rectangular redaction box covers the entire content of the 'Device description' section.

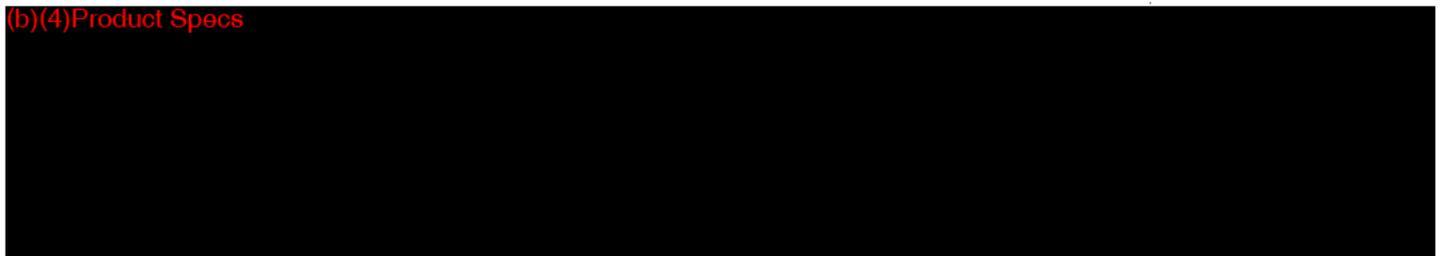
Performance data:

(b)(4)Product Specs

A large black rectangular redaction box covers the entire content of the 'Performance data' section.

Labeling:

(b)(4)Product Specs

A large black rectangular redaction box covers the entire content of the 'Labeling' section.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Page - 2 - Mr. E. J. Smith

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The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

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Sincerely yours,

(S)

Colin M. Pollard
 Chief, Obstetrics and Gynecology Devices Branch
 Division of Reproductive, Abdominal,
 Ear, Nose and Throat, and
 Radiological Devices
 Office of Device Evaluation
 Center for Devices and
 Radiological Health

cc: HFZ-401 DMC
 HFZ-404 510(k) Staff
 HFZ-470
 D.O.

Draft:MSV:lrn:1.12.98
 Final:MSV:lrn:1.16.98

FILE
 COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ-470	Virmani	1/20/98						
2470	Pollard	1/20/98						

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ADOU ROUTING SLIP

Document No. K974479 Due _____

(Circle one)

Typist: ^{LRM} ~~SLJ, ENS~~ CST: VME

Date: 1-16-98

Date: 1/21/98

	INITIALS	DATE
Reviewer: <u>Mridu Vermani</u>	<u>MV</u>	<u>1/24/98</u>
Medical Officer: _____	_____	_____
Chief: <u>CMP</u> , CYN, or DJS	<u>CMP</u>	<u>1/20/98</u>
Robert Gatling	_____	_____
Pat Miller	_____	_____
Mattie Sauls	_____	_____
Dr. Lillian Yin	_____	_____
Rita Rubendall	_____	_____
Pete Zaudtke	_____	_____
POS Staff: IDE, PMA, <u>510(k)</u>	_____	_____
Other: _____	_____	_____

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service
Food And Drug Administration

Memorandum

From: Reviewer(s) - Name(s) MRIPULIKA VIRMANI

Subject: 510(k) Number K974479

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Accepted for review _____
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO

This 510(k) contains:

- Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with class and tier: _____ Additional Product Code(s) with panel (optional): _____

Review: Cohen M Pollard 069DB 1/20/98 (FME)
(Branch Chief) (Branch Code) (Date)

Review: _____
(Division Director) (Date)

15h

K974479

Reviewer: Mridulika Virmani, Ph.D.
Chemist

Division/Branch: DRAERD/OGDB
(HFZ-470)

Trade Name: Silimed Vaginal Stent

Common Name: Stent, vaginal

Predicate Device: Heyer-Schulte Adjustable Vaginal Stent

Applicant: Smith Associates
P.O. Box 4341
Crofton, Maryland 21114

Contact: E.J. Smith

Phone: (410) 451-0639

Fax: (410) 793-0448

INTENDED USE:

The Silimed Vaginal Stent is designed to maintain the vaginal canal following radiological treatment or surgical procedures to restore, enlarge or create a vagina. The surgeon is responsible for choice of shape and size to meet the clinical and aesthetic needs of each case.

	YES	NO
Life-supporting or life-sustaining?		<u>✓</u>
Implanted (long-term or short-term)?	✓	<u> </u>
Uses software?		<u>✓</u>
Sterile?	✓	
Single use?	✓	
Home use?	✓	
For prescription?	✓	
Contains drug or biologic?		<u>✓</u>
Kit?		<u>✓</u>
 Reason for Submission of 510(k)		
• New device	X	
• New indications	No	
• Changes in technology	No	
• Other:		

Device Description

The Silimed Vaginal stent consists of silicone elastomer shell filled with polyurethane foam. The shell has a internal drain tube and a inflation tube with a valve for opening and closing of inflation tube. The stent is manufactured from implant grade silicone supplied by Applied Silicone Corporation. Silimed has provided Master file number for silicone. They have also provided a list of chemical, physical and biocompatibility testing done for this silicone material. The cylindrical valve of inflation tube is made of silicone and stainless steel ball. The stainless steel ball is covered with silicone elastomer. The stent is available in four sizes.

Review History

For this device company has u

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duct
Specs

Review Analysis

MATERIALS AND BIOCOMPATIBILITY

Basic materials of the subject device are quite similar to the predicate device. Both use silicone elastomer shell filled with polyurethane. The silicone elastomer shell is water tight. The shell of predicate device is like a membrane. The thickness of the silicone shell is not provided for the subject device. Biocompatibility testing is provided for silicone elastomer from the supplier Applied Silicone Corporation. Biocompatibility is not provided for the final finished product.

(b)(4)Product Specs

The polyurethane foam is filled in the water tight shell of the elastomer, this shell is connected with a tube which has a valve and also is the fill tube for inflating the shell. It is not clear whether this foam is bound to the shell or it is free, and how much foam is their, how much it will swell when sterile solution will be added to the shell through inflatable tubing.

(b)(4)Product Specs

PERFORMANCE

The stent is inserted in the vagina in its collapsed (flat) position, after insertion the stent is filled with sterile solution (not provided), using a syringe (not provided) until it is secured in position. The amount of solution added is at the discretion of physician. (b)(4)Product Specs

[Redacted]

(b)(4)Product Specs

STERILIZATION

Device is provided sterilized for single patient use.

(b)(4)Product Specs

LABELING

Physician labeling is included in the submission. (b)(4)Product Specs

[Redacted]

(b)(4)Product Specs

(b)(4)Product Specs



ADMINISTRATIVE

The following documents are included in the submission:

510(k) statement
Truthful and Accurate Statement
Indications for Use

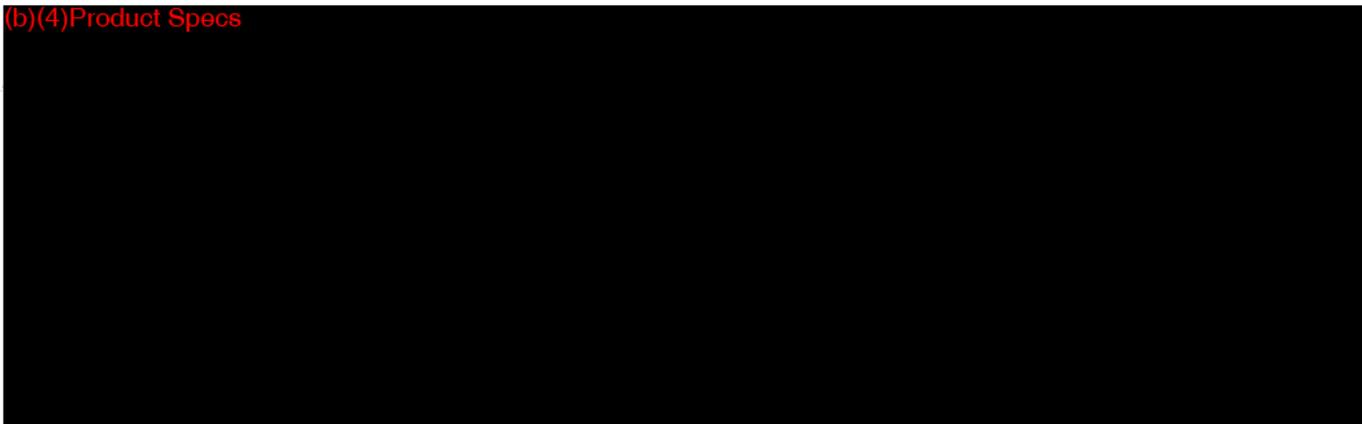
Recommendation

I recommend that the file be placed on hold pending receipt of additional information.

Following questions should be sent to the sponsor.

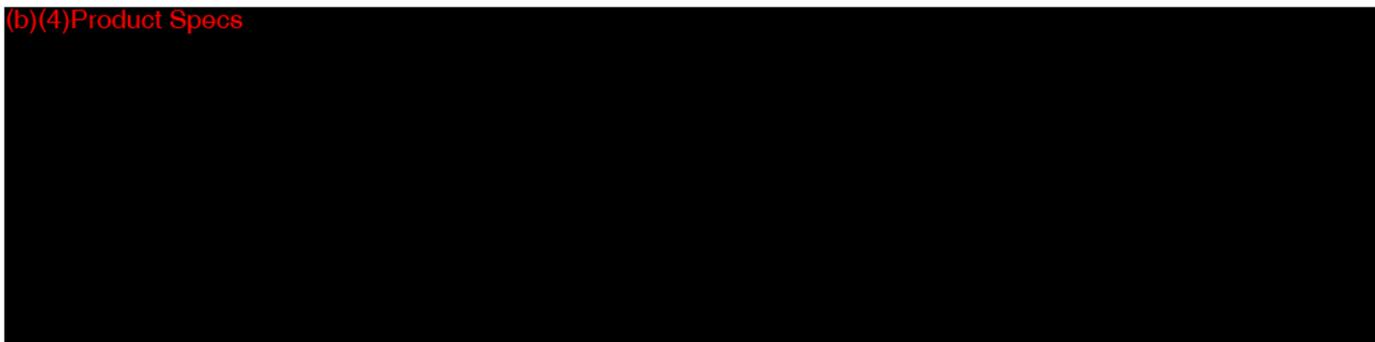
Device description:

(b)(4)Product Specs



Performance data:

(b)(4)Product Specs

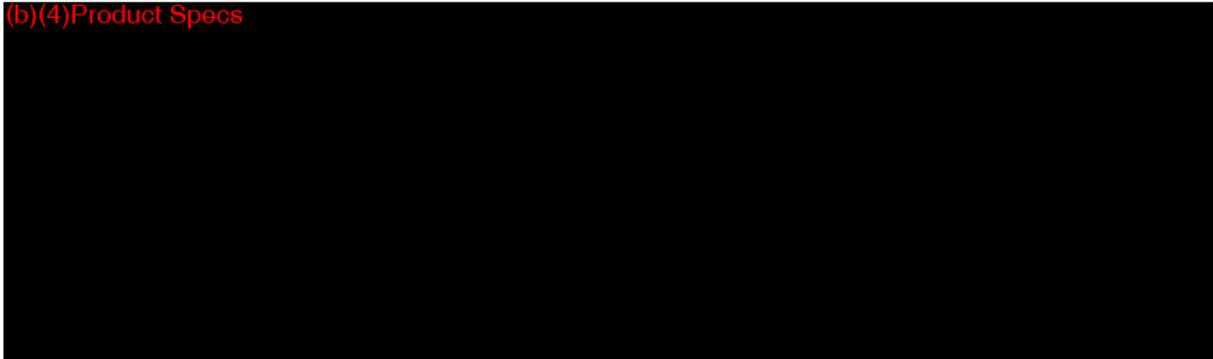


(b)(4)Product Specs



Labeling:

(b)(4)Product Specs



Mridulika Virmani 1/12/98
Mridulika Virmani, Ph.D. Date

Colin M. Pollard 1/20/98
Colin M. Pollard Date
Chief, OGDB

/ Concur
 / Do not concur
Comments:

K974479/A1

Smith Associates

Specializing in Regulatory Affairs

FDA/CDRH/OOE/DMC

5 JAN 98 09 25

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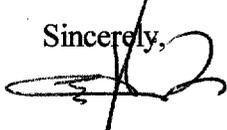
December 31, 1997

Food and Drug Administration
Office of Devices
Document Control Center
9200 Corporate Blvd.
Rockville, Maryland 20850

Reference: K974479

This is our response to Dr. Virmani request for additional information.

Sincerely,



E.J. Smith
President

SIC-36

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Smith Associates P.O. Box 4341 Crofton, Maryland 21114
Fax (410) 793-0448 Phone (410) 451-0639

FAX

DATE: 12/31/97

MEMO TO: Dr. Virmani

FAX: (301)594-2339

FROM: E.J.Smith

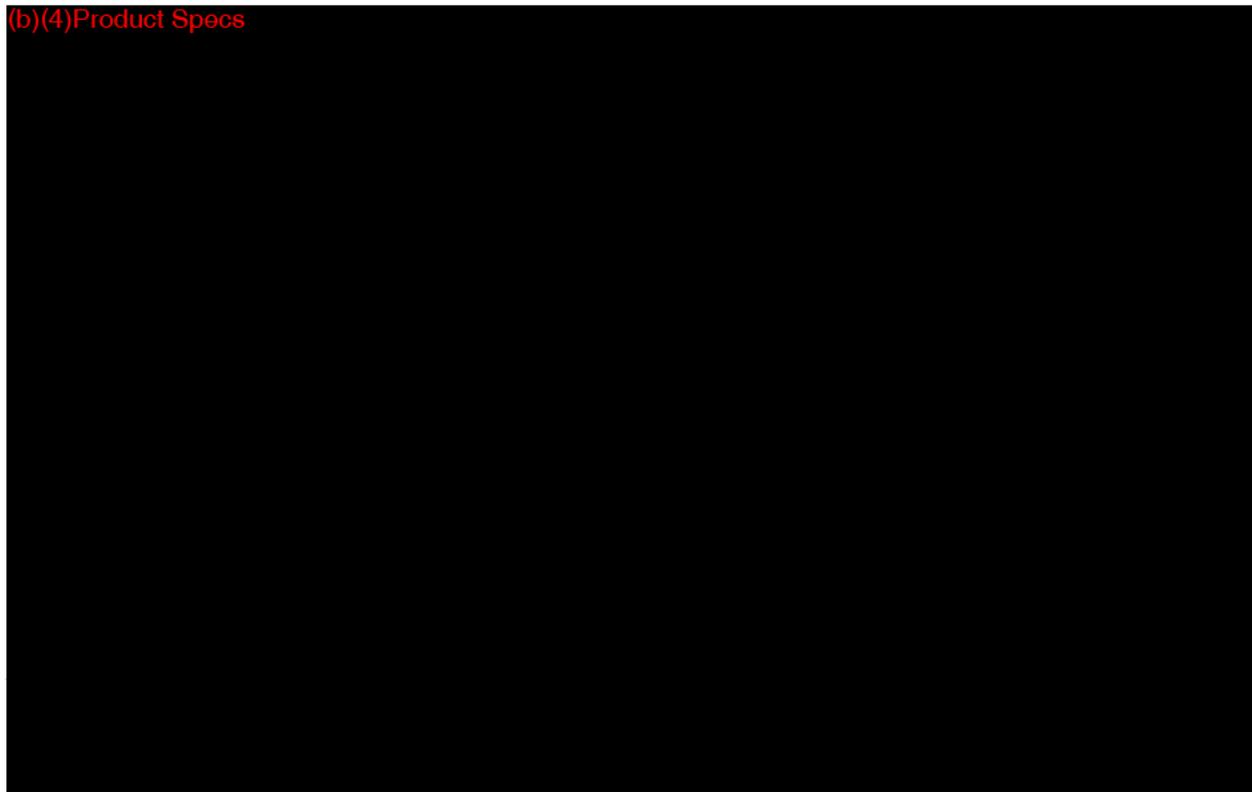
SUBJECT: K974479

Number of Pages: _5_ including cover page

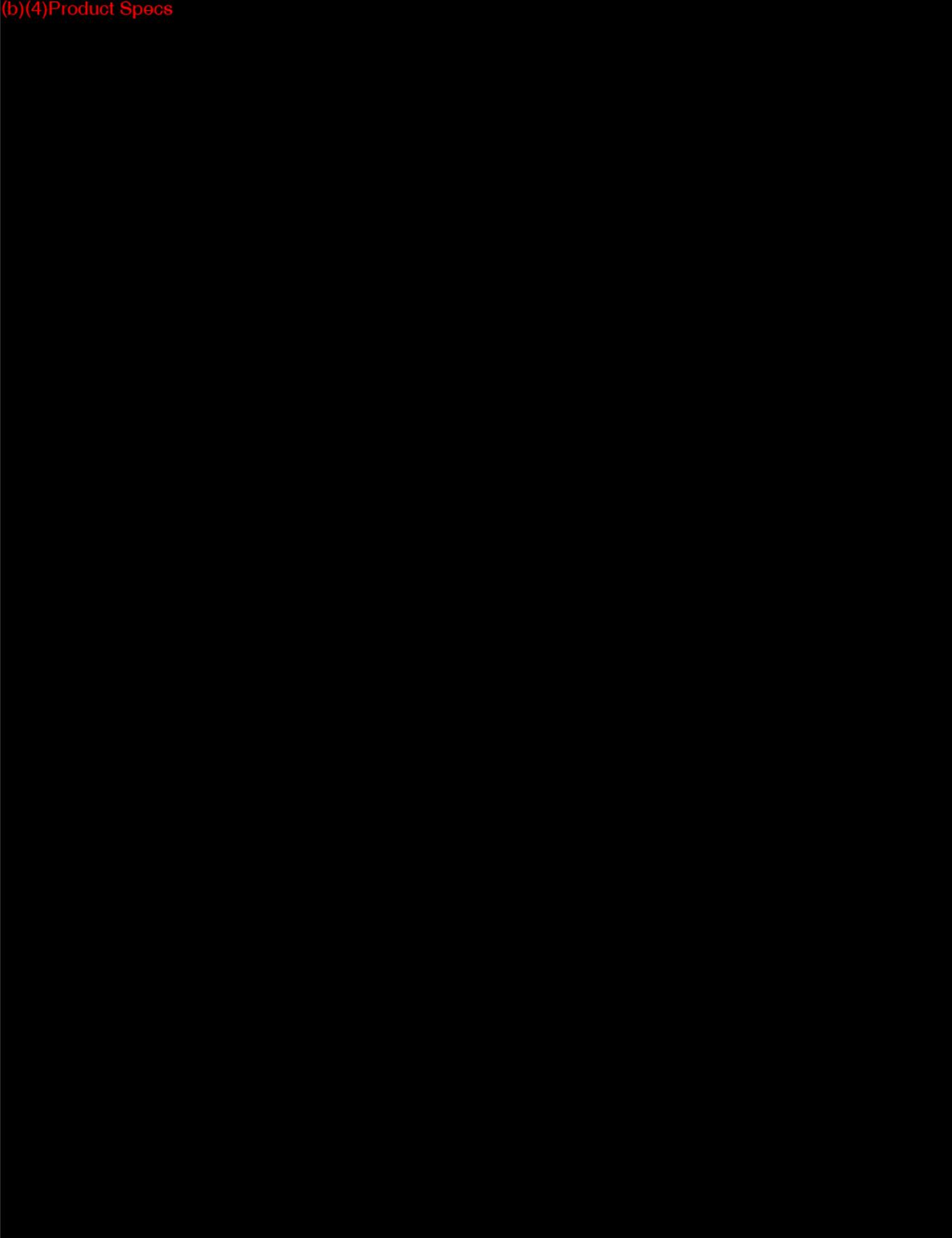
Dear Dr. Virmani:

This is our response to your call of last week concerning the above submission.

(b)(4)Product Specs



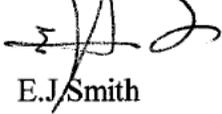
(b)(4)Product Specs



(b)(4)Product Specs



Thank you,

A handwritten signature in black ink, appearing to read "E.J. Smith", is written over the typed name. The signature is stylized with a large, sweeping flourish that extends to the right.

E.J. Smith

Table 5.1: Predicate Product Comparison Chart

Parameters	Silimed	Mentor/Heyer-Schulte
Proprietary Name:	Silimed Vaginal Stent	Adjustable Vaginal Stent
510(k) Number:		K863439
Indications for Use:	designed to maintain the vaginal canal following radiological treatment or surgical procedures to restore, enlarge or create a vagina.	designed to maintain the vaginal canal following radiological treatment or surgical procedures to restore, enlarge or create a vagina.
Single Patient Use:	Yes	Yes
Material Choices:		
Shell:	Silicone Elastomer	Silicone Elastomer
Fill Material:	Polyurethane Foam	Polyurethane Foam
Obturing Sphere	Stainless Steel Ball	Stainless Steel Ball
Styles:		
Adjustable	Yes	Yes
Flexible	Yes	Yes
Sizes:		
3.0cm x 9.5cm	Yes	Yes
4.0cm x 12.0cm	Yes	Yes
4.5cm x 14.0cm	Yes	Yes
5.0cm x 16.0cm	Yes	Yes
Product Shipped Sterile:	Yes	No
Sterilization Method:	ETO	N/A

5.4 Comparisons:

The differences between the Silimed Vaginal Stent and Mentor/Heyer-Schulte Vaginal Stent:

- Silimed's Vaginal Stents are supplied sterile vs Heyer-Schulte's vaginal stent which is supplied non-sterile.

166

K974479/A1

DUPLICATE

Smith Associates P.O. Box 4341 Crofton, Maryland 21114
Fax (410) 793-0448 Phone (410) 451-0639

FAX

DATE: 12/31/97

MEMO TO: Dr. Virmani

FAX: (301)594-2339

FROM: E.J.Smith

SUBJECT: K974479

Number of Pages: _5_ including cover page

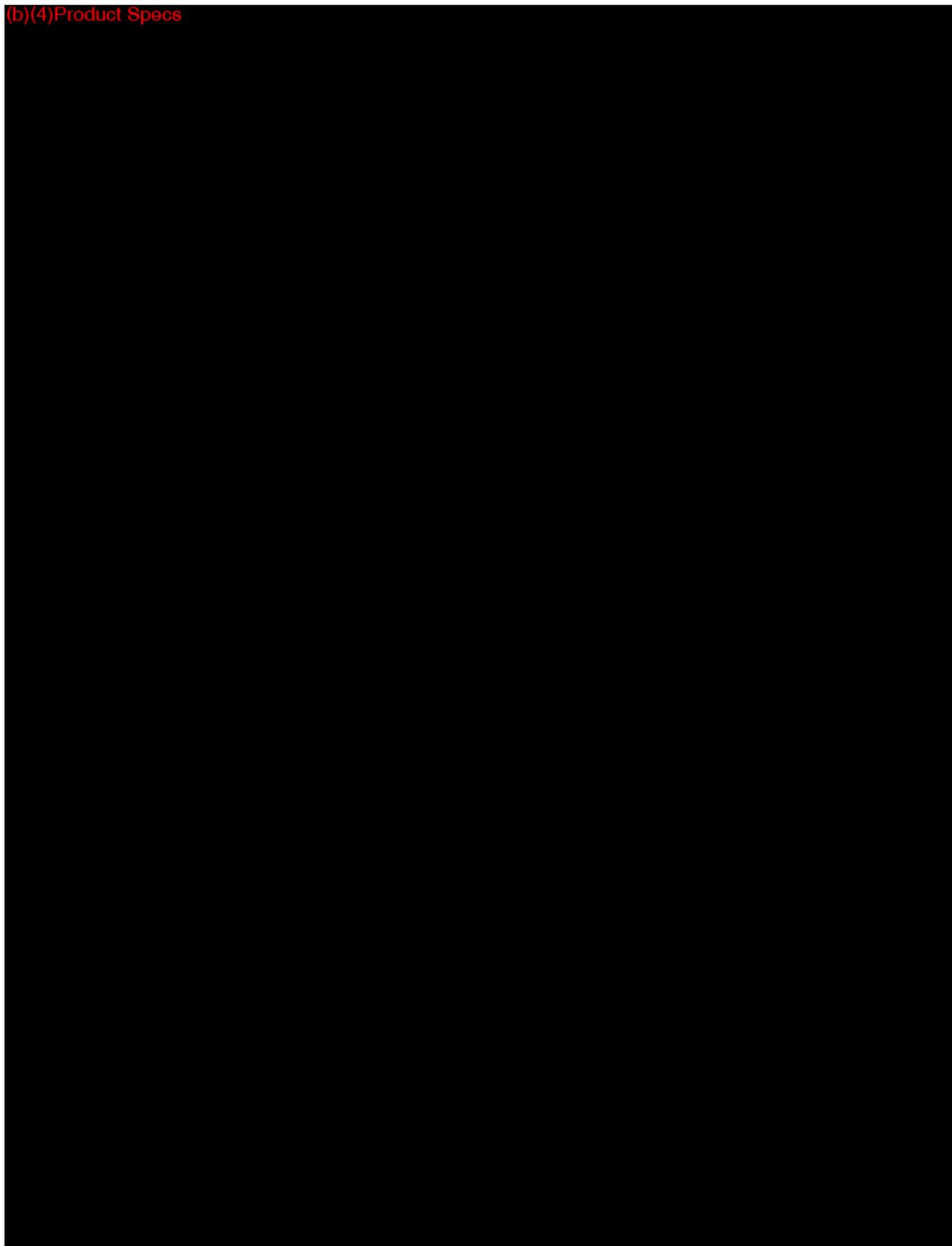
Dear Dr. Virmani:

This is our response to your call of last week concerning the above submission.

(b)(4)Product Specs



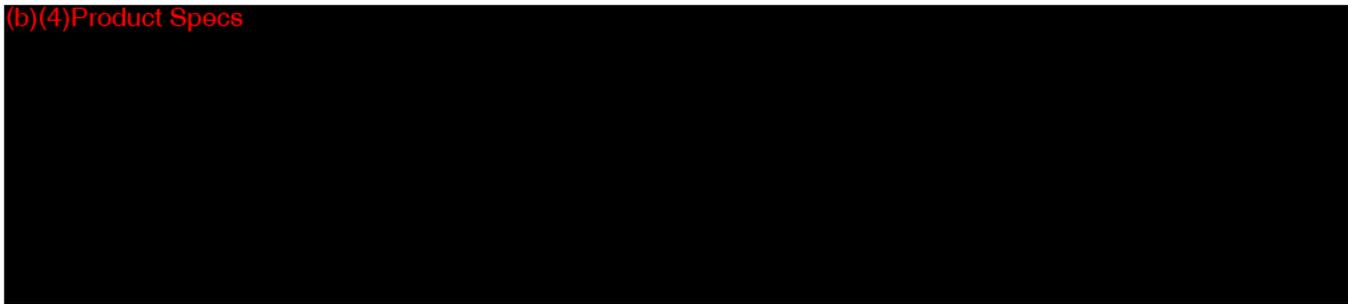
(b)(4)Product Specs



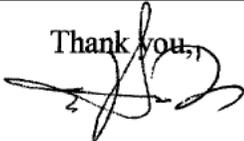
In this case
attached all
the things

168

(b)(4)Product Specs



Thank you,



E.J. Smith

Table 5.1: Predicate Product Comparison Chart

Parameters	Silimed	Mentor/Heyer-Schulte
Proprietary Name:	Silimed Vaginal Stent	Adjustable Vaginal Stent
510(k) Number:		K863439
Indications for Use:	designed to maintain the vaginal canal following radiological treatment or surgical procedures to restore, enlarge or create a vagina.	designed to maintain the vaginal canal following radiological treatment or surgical procedures to restore, enlarge or create a vagina.
Single Patient Use:	Yes	Yes
Material Choices:		
Shell:	Silicone Elastomer	Silicone Elastomer
Fill Material:	Polyurethane Foam	Polyurethane Foam
Obturator Sphere	Stainless Steel Ball	Stainless Steel Ball
Styles:		
Adjustable	Yes	Yes
Flexible	Yes	Yes
Sizes:		
3.0cm x 9.5cm	Yes	Yes
4.0cm x 12.0cm	Yes	Yes
4.5cm x 14.0cm	Yes	Yes
5.0cm x 16.0cm	Yes	Yes
Product Shipped Sterile:	Yes	No
Sterilization Method:	ETO	N/A

5.4 Comparisons:

The differences between the Silimed Vaginal Stent and Mentor/Heyer-Schulte Vaginal Stent:

- Silimed's Vaginal Stents are supplied sterile vs Heyer-Schulte's vaginal stent which is supplied non-sterile.

510(k) Number & Device Name _____

Company _____

ITEM	PRESENT		NEEDED
	Yes	No	(Y/N/2)
1. General information (i.e., trade & classification name, Est. Reg. No., device class, meets special controls or a performance standards, etc.)	—	—	—
Reason for 510(k) - new device or modification	—	—	—
Identification of legally marketed equivalent device	—	—	—
Truthful and accurate statement	—	—	—
SMDA 510(k) summary or statement	—	—	—
2. Proposed Labeling, Labels, Advertisements	—	—	—
Description of new device/modification	—	—	—
Intended use statement	—	—	—
Diagrams, Engineering Drawings, Photographs	—	—	—
Indication for Use Statement	—	—	—
3. Comparison of similarities/differences to named legally marketed equivalent device	—	—	—
Equivalent Device Labeling, Labels, Advertising	—	—	—
Intended use of equivalent device	—	—	—
4. List of all patient contacting materials in new device	—	—	—
Comparison of materials to equivalent device	—	—	—
5. Biocompatibility information/data for patient contacting materials, OR	—	—	—
Certification - identical material/formulation	—	—	—
6. Performance data: Bench data	—	—	—
Animal data	—	—	—
Clinical data	—	—	—
7. Sterilization information	—	—	—
8. Software validation & verification	—	—	—
9. If Class III, Class III Certification & Summary	—	—	—
10. If kit, kit certification	—	—	—

FOR REVIEWER'S USE ONLY

RRG 9/24/93
Rev. 5/8/95

DRAERD Premarket Notification 510(k)
SUPPLEMENTAL Screening Checklist

DRAERD has been given the go ahead to continue with the DRAERD Premarket Notification 510(k) Screening Checklist program rather than switching to the ODE Premarket Notification (510(k)) Checklist for Acceptance Decision. However, some items appear in the ODE Checklist that were not in the early version of the DRAERD Checklist or Explanation of the Checklist. Therefore, the following items should be included as part of the DRAERD screening process:

510(k) Number: _____ TIER (Circle) I / II / III

Expedited Review Requested: Y/N Granted: Y/N OR, FDA Identified Expedited: Y/N

ITEM	Yes	No
1. Is the product a device?	—	—
2. Is the device exempt from 510(k) by regulation or policy?	—	—
3. Are you aware that this device has been the subject of a previous NSE decision? If yes, does this new 510(k) address the NSE Issue(s) (e.g., performance data)?	—	—
4. Are you aware of the submitter being the subject of an integrity investigation? If yes, consult the ODE Integrity Officer, and has the ODE Integrity Officer given permission to proceed with the review?	—	—
5. Is there a specific guidance document for this device or device issue(s)?	—	—
6. Is this a file that was determined to be substantially equivalent (SE) by ODE, but placed on hold due to GMP violations and deleted after 12 months on hold? If yes, a new review by ODE is not required, please forward to POS.	—	—

In addition, the following item is going to be required as part of a revision to the 510(k) regulation. However, it is not required now, but the Explanation of the DRAERD Screening Checklist has been modified to include this information.

7. Address of manufacturing facility/facilities, and if applicable, sterilization site(s). _____

Administrative Reviewer Signature: _____ Date: _____

**DRAERD REVIEWER RECORD FOR ORIGINAL 510(K)S,
AND PMA AND IDE SUPPLEMENTS**

Document No. _____ Reviewer _____ Date Assigned _____

*CONSULTING REVIEWS DESIGNATED, AS APPROPRIATE, BY BRANCH CHIEF AND LEAD REVIEWER,
AT THE BEGINNING OF THE REVIEW:*

<u>SPECIALTY</u>	<u>REVIEW NEEDED?</u>		<u>REVIEWER</u>	<u>DATES</u>	
	YES	NO		SENT	RETURNED
CLINICAL	_____	_____	_____	_____	_____
ENGINEERING/ PHYSICS	_____	_____	_____	_____	_____
CHEMISTRY/ BIOMATERIALS	_____	_____	_____	_____	_____
SOFTWARE	_____	_____	_____	_____	_____
BIOLOGICAL/ STERILITY	_____	_____	_____	_____	_____
TOXICOLOGY/ BIOCOMPATIBILITY	_____	_____	_____	_____	_____
STATISTICS	_____	_____	_____	_____	_____
OTHER _____	_____	_____	_____	_____	_____

COMMENTS:

**REVISED 1/2/96 LMS
ON LAN AS REVREC.FRM**

17h

QUALITY CONTROL OVERVIEW OF DOCUMENT

A. ASSOC. DIRECTOR QC OVERVIEW: MEDICAL QC OF SUBMISSION IS NECESSARY?

YES _____ NO _____ INITIALS/DATE _____

B. IF YES IS NOTED ABOVE, MEDICAL OFFICER QC OVERVIEW:

1. Examination of the specialty reviews indicate there are remaining clinical issues that should be addressed (See attached sheet for summary).

INITIALS/DATE _____

2. In my opinion, all pertinent clinical issues have been adequately addressed.

FINAL SIGNOFF: MEDICAL OFFICER/DATE _____

FINAL SIGNOFF: ASSOC. DIRECTOR/DATE _____

REVISED: 1/2/96 LMS
LOCATED ON LAN AS REVREC.FRM

I. CRITICAL ELEMENTS:	YES PRESENT OMISSION JUSTIFIED	NO INADEQUATE OMITTED
A. Is The Product A Device?	<input type="checkbox"/>	<input type="checkbox"/>
B. Is The Device Exempt From 510(k) By Regulation Or Policy?	<input type="checkbox"/>	<input type="checkbox"/>
C. Is Device Subject To Review By CDRH?	<input type="checkbox"/>	<input type="checkbox"/>
D. (i) Are You Aware That This Device Has Been The Subject Of A Previous NSE Decision? (ii) If Yes, Does This New 510(k) Address The NSE Issue(s) (E.G., Performance Data)?	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
E. (i) Are You Aware Of The Submitter Being The Subject Of An Integrity Investigation? If Yes, Consult The ODE Integrity Officer. (ii) Has The ODE Integrity Officer Given Permission To Proceed With The Review? (Blue Book Memo #I91-2 And Federal Register 90N-0332, September 10, 1991.)	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
F. Does The Submission Contain The Information Required Under Sections 510(k), 513(f), And 513(i) Of The Federal Food, Drug, and Cosmetic Act (Act) And Subpart E Of Part 807 In Title 21 Of The Code Of Federal Regulations?:	<input type="checkbox"/>	<input type="checkbox"/>
1. Device Trade Or Proprietary Name	<input type="checkbox"/>	<input type="checkbox"/>
2. Device Common Or Usual Name Or Classification Name	<input type="checkbox"/>	<input type="checkbox"/>
3. Establishment Registration Number (Only Applies If Establishment Is Registered)	<input type="checkbox"/>	<input type="checkbox"/>
4. Class Into Which The Device Is Classified Under (21 CFR Parts 862 to 892)	<input type="checkbox"/>	<input type="checkbox"/>
5. Classification Panel	<input type="checkbox"/>	<input type="checkbox"/>
6. Action Taken To Comply With Section 514 Of The Act	<input type="checkbox"/>	<input type="checkbox"/>
7. Proposed Labels, Labeling And Advertisements (If Available) That Describe The Device, Its Intended Use, And Directions For Use (Blue Book Memo #G91-1)	<input type="checkbox"/>	<input type="checkbox"/>

8. A 510(k) Summary Of Safety And Effectiveness Or A 510(k) Statement That Safety And Effectiveness Information Will Be Made Available To Any Person Upon Request	<input type="checkbox"/>	<input type="checkbox"/>
9. For Class III Devices Only, A Class III Certification And A Class III Summary	<input type="checkbox"/>	<input type="checkbox"/>
10. Photographs Of The Device	<input type="checkbox"/>	<input type="checkbox"/>
11. Engineering Drawings For The Device With Dimensions And Tolerances	<input type="checkbox"/>	<input type="checkbox"/>
12. The Marketed Device(s) To Which Equivalence Is Claimed Including Labeling And Description Of The Device	<input type="checkbox"/>	<input type="checkbox"/>
13. Statement Of Similarities And/Or Differences With Marketed Device(s)	<input type="checkbox"/>	<input type="checkbox"/>
14. Data To Show Consequences And Effects Of A Modified Device(s)	<input type="checkbox"/>	<input type="checkbox"/>
15. Truthful And Accurate Statement	<input type="checkbox"/>	<input type="checkbox"/>
II. Additional Information That <u>Is</u> Necessary Under 21 CFR 807.87(h):	<input type="checkbox"/>	<input type="checkbox"/>
A. Submitter's Name And Address	<input type="checkbox"/>	<input type="checkbox"/>
B. Contact Person, Telephone Number And Fax Number	<input type="checkbox"/>	<input type="checkbox"/>
C. Representative/Consultant If Applicable	<input type="checkbox"/>	<input type="checkbox"/>
D. Table Of Contents With Pagination	<input type="checkbox"/>	<input type="checkbox"/>
E. Address Of Manufacturing Facility/Facilities And, If Appropriate, Sterilization Site(s)	<input type="checkbox"/>	<input type="checkbox"/>
III. Additional Information That <u>May Be</u> Necessary Under 21 CFR 807.87(h):	<input type="checkbox"/>	<input type="checkbox"/>
A. Comparison Table Of The New Device To The Marketed Device(s)	<input type="checkbox"/>	<input type="checkbox"/>
B. Action Taken To Comply With Voluntary Standards	<input type="checkbox"/>	<input type="checkbox"/>
C. Performance Data	<input type="checkbox"/>	<input type="checkbox"/>
MARKETED DEVICE:	<input type="checkbox"/>	<input type="checkbox"/>
Bench Testing	<input type="checkbox"/>	<input type="checkbox"/>
Animal Testing	<input type="checkbox"/>	<input type="checkbox"/>
Clinical Data	<input type="checkbox"/>	<input type="checkbox"/>
NEW DEVICE:	<input type="checkbox"/>	<input type="checkbox"/>
Bench Testing	<input type="checkbox"/>	<input type="checkbox"/>
Animal Testing	<input type="checkbox"/>	<input type="checkbox"/>

Clinical Data	<input type="checkbox"/>	<input type="checkbox"/>
D. Sterilization Information	<input type="checkbox"/>	<input type="checkbox"/>
E. Software Information	<input type="checkbox"/>	<input type="checkbox"/>
F. Hardware Information	<input type="checkbox"/>	<input type="checkbox"/>
G. If This 510(k) Is For A Kit, Has The Kit Certification Statement Been Provided?	<input type="checkbox"/>	<input type="checkbox"/>
H. Is This Device Subject To Issues That Have Been Addressed In Specific Guidance Document(s)?	<input type="checkbox"/>	<input type="checkbox"/>
If Yes, Continue Review With Checklist From Any Appropriate Guidance Documents.	<input type="checkbox"/>	<input type="checkbox"/>
If No, Is 510(k) Sufficiently Complete To Allow Substantive Review?	<input type="checkbox"/>	<input type="checkbox"/>
I. Other (Specify)	<input type="checkbox"/>	<input type="checkbox"/>

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE". (SE) DECISION MAKING DOCUMENTATION

K _____

Reviewer: _____

Division/Branch: _____

Device Name: _____

Product To Which Compared (510(K) Number If Known): _____

YES NO

	YES	NO	
1. Is Product A Device			If NO = Stop
2. Is Device Subject To 510(k)?			If NO = Stop
3. Same Indication Statement?			If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?			If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the device's design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

November 28, 1997

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

SILIMED, L.C.
C/O SMITH ASSOCIATES
P.O BOX 4341
CROFTON, MD 21114
ATTN: E J. SMITH

510(k) Number: K974479
Received: 26-NOV-97
Product: SILIMED VAGINAL
STENT

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation

182

SILIMED, L.C.
14014 Sullyfield Circle, Suite C
Chantilly, Virginia 22021
(703) 802-3446

6974499

Food and Drug Administration
Document Control Center
Office of Medical Devices
9200 Corporate Blvd.
Rockville, Maryland 20850

Attention: Document Mail Clerk

This is to notify you of the intention, by Silimed, L.C., to Manufacture and market the following device:

RECEIVED
Nov 26 11 54 AM '97
FDA/ODRM/OE/DMC

Classification Name: Stent, Vaginal
Common/Usual Name: Vaginal Stent
Proprietary Name: Silimed Vaginal Stent
Establishment Registration Number: []
Classification: Class II
Classification Panel: 85KXP, 884.3900
Performance Standard: N/A

Labeling/Product Performance/Promotional Material:

Labeling: Instruction and Package inserts are attached as appendix 1.
Product Information: Product performance and Product Specifications attached as Appendix 2.1-2.9.
Sterilization Information: Sterilization Information attached as Appendix 3.
Promotional Material: Advertisement and catalog listings attached as Appendix 4.

SK-32

183
DE
CLASS
II

Substantial Equivalence:

This Product is similar in design, intended use and function to many other devices on the market. Appendix 5 contains a comparison of Silimed Vaginal Stents with Heyer-Schulte Vaginal Stent. A comparison table and excerpts from labeling and promotional materials of the other similar product is included in Appendix 5.

Comparable products are:

Company	Model	510(k)
Heyer-Schulte	Adjustable Vaginal	Stent

**Quality Assurance and
Quality Control Procedures:**

Attached as Appendix 6.

Mr. E.J. Smith - consultant - of Smith Associates is authorized to represent Silimed, L.C. Inc. In connection with this notification. His contact details are as follows:

Smith Associates
P.O. Box 4341
Crofton, Maryland 21114
Tel: (410) 451-0639
VM: (800) 875-3612 ext. 307
Fax: (410) 793-0448

Please Contact Mr. E.J. Smith with regard to any additional information which may be required.

Sincerely,


Robert A. Bishop, II
Manager

18h

510(k) Number (if known):

Device Name: Silimed Vaginal Stent

Classification Panel: 85KXP, 884.3900

Indications for Use:

The *Silimed Vaginal Stent* is designed to maintain the vaginal canal following radiological treatment or surgical procedures to restore, enlarge or create a vagina.

The surgeon is responsible for proper choice of shape and size to meet the clinical and aesthetic needs of each case.

Federal (U.S.A.) law restrict this device to sale by or on the order of a physician.

Does it come in different shapes also.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-the-Counter Use _____

185

**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
[As Required By 21 CFR 807.87 (j)]**

I certify that, as Manager, Silimed L.C., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



(Signature)

Robert A. Bishop, II

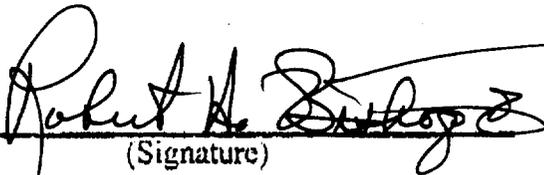
(Typed Name)

(Date)

(Premarket Notification [510(k) Number])

**PREMARKET NOTIFICATION
510(K) STATEMENT
(As Required By 21 CFR 807.93)**

I certify that, as Manager, Silimed L.C., I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.



(Signature)

Robert A. Bishop, II

(Typed Name)

(Date)

(Premarket Notification [510(k) Number])

**Appendix 1: Indication for Use, Description and labeling
Information**

APPENDIX 1: INDICATION FOR USE, PRODUCT DESCRIPTION, INSTRUCTIONS AND LABELING INFORMATION

1.1 Indication for Use:

The *Silimed Vaginal Stent* is designed to maintain the vaginal canal following radiological treatment or surgical procedures to restore, enlarge or create a vagina.

The surgeon is responsible for proper choice of shape and size to meet the clinical and aesthetic needs of each case.

Federal (U.S.A.) law restrict this device to sale by or on the order of a physician.

1.2 Description of the Vaginal Stent:

The *Silimed Vaginal Stent* (figure 1.1) consists of three parts: 1. internal drain, 2. the valve (silicone obturating sphere) and 3. tubing. The membrane's basic elastomer is vinyl dimethyl polydimethyl siloxane with a load of pure amorphous fine crushed silica catalyzed by a platinum compound and the shell is then filled with polyurethane foam. The basic elastomer for the connections and drain is polydimethyl siloxane. The cylindrical valve is made of polydimethyl siloxane and a 001 stainless steel ball. The stent is available in 4 sizes ranging from a volume of 70cm³ to 300cm³.

The Vaginal Stent is supplied sterile and is available in a transparent double "blister" pouch or double peel pouch. Both are sterilized by ETO.

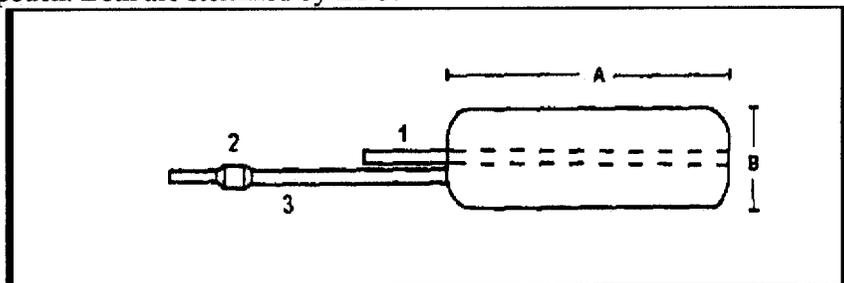


Figure 1.1 Silimed Vaginal Stent

The *Silimed Vaginal Stent* is designed to maintain the vaginal canal following radiological treatment or surgical procedures to restore, enlarge or create a vagina. The stent consists of a watertight silicone elastomer shell filled with polyurethane foam, which has been designed to help protect surrounding tissue against concentrated pressure points. The fill tube with a sliding-ball-valve provides for collapsing the stent to facilitate insertion and removal of the device from the vaginal canal. The fill tube allows for the filling of the stent with 0.9% normal saline, in order to adjust the size of the device and to exert pressure on the vaginal wall.

1.3 Contraindications and Precautions:

Silimed considers the existence of infections in any part of the body as an absolute counter-indication for any operation.

1.4 Clarification and Consent of the Patient:

Considering the risks that are inherent to any surgical operation, and possible complications due to the use of the vaginal stent, Silimed relies on the surgeon to clarify the risk factors before obtaining the patient's formal consent.

1.5 Labeling: Reference Exhibit 1.1

Exhibit 1.1

**PRODUCT INFORMATION
VAGINAL STENT**

Description:

The Silimed Vaginal Stent described in this insert is intended for use only as supplied. Under no circumstances should this device be altered, modified or revised in any way prior to or during its use.

following not description

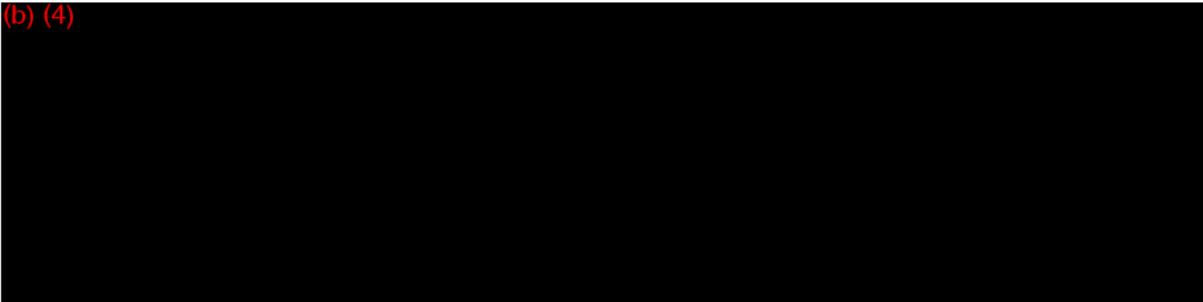
The inflatable Silimed Vaginal Stent is designed for neovaginal and reconstructive surgery. The Vaginal Stent has an internal drain that allows drainage of the surgical wound without withdrawing the silicone body, obturating sphere and tubing.

shown in ...

The Vaginal Stent is presented in a set of sizes (base, height and volume) that appear in Silimed's commercial catalog. This sizing is the result of many years of research with the medical profession.

The Constituent Materials:

(b) (4)

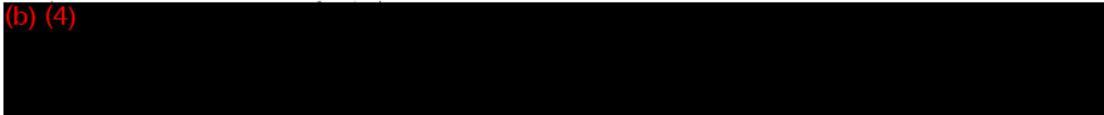


with tube filler

How Supplied:

Silimed Vaginal Stents are supplied sterile and are contained in:

(b) (4)



The packages are stored in a cardboard box with a plastic protective film. Outer package label will contain the following information: description of the product, catalog number, lot number and expiration date.

Sterilization: Ethylene Oxide

An individual confirmation of sterilization of each batch is carried out, as well as a quarterly validation of the latter performed by an independent laboratory.

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Instructions for Use:

*21 kind of
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silicone membrane*

Opening the Package: Vaginal Stents are supplied sterile and have been submitted to careful tests that guarantee their biocompatibility and virtual absence of reactions in the organism, the possible rare exceptions occurring on account of specific, individual conditions.

Care when opening the package is of utmost importance: The high dielectric value of silicone can generate static charges responsible for the attraction of particles existing in the atmosphere, such as dust, lint, and talc to mention a few examples. External contaminants that adhere to the membrane surface may provoke foreign-body reactions in the organism thereby increasing fibrosis and the generation of fluids.

What are the 14 cases

Care should also be taken with all the accessories of the product, be they documents such as inserts, labels for different files, etc., or parts of products such as valves and filling tubes.

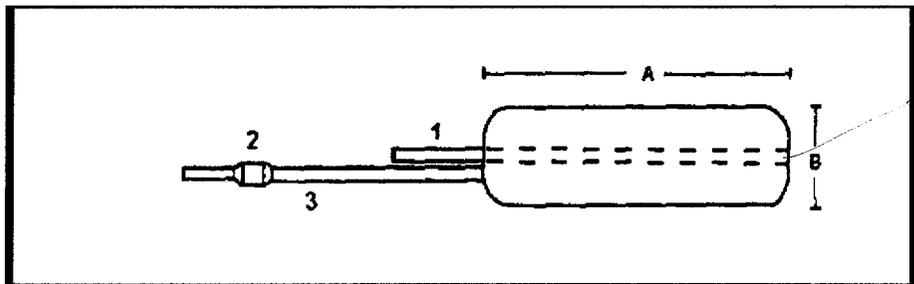
The "blister" packages are double packages, which allows the user to open them in two stages:

- first remove the special paper protection from the outer "blister" gaining access to the to the sterile inner package.
- secondly, remove the special paper protection from the inner "blister" next to the surgical field.

When the implant is packaged in a double peel pouch:

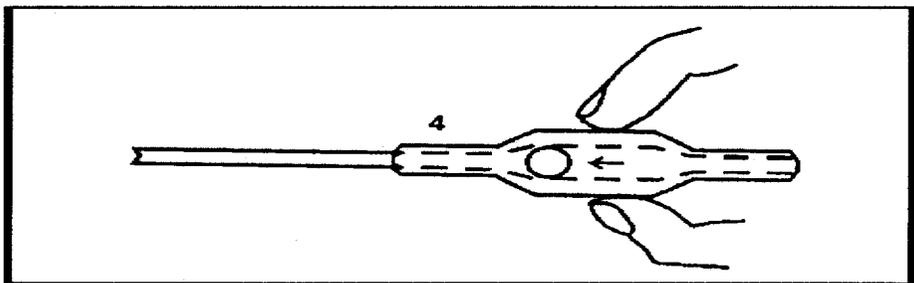
- proceed in the same way as the "blister" package.

Inflatable Vaginal Stent



this open or not

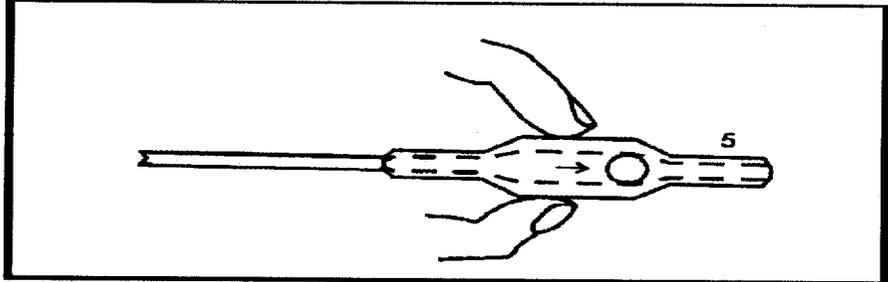
- 1- Internal Drain
- 2-The valve (silicone body and obturating sphere)
- 3-Tubing



Open Position
Exhibit 1.1 Page 2

Open Position:

To fill up or deplete the expander, shift the sphere towards the side of the tubing with a slight compression between the thumb and index finger. When the sphere is in position, one can fill or empty the stent with the help of a syringe connected to the extremity of the valve.



Closed Position

Closed Position :

To close the valve displace the sphere using the thumb and index finger to move the sphere towards its free extremity. The pressure within the valve coming from the stent will facilitate its airtight closure by the sphere.

Resterilization:

Silicone implants are meant for single patient use; resterilization is thus forbidden by international standards.

Important Recommendations:

Maintenance of Sterility: It is essential that the vaginal stent be used under conditions of absolute asepsis and sterility

Packaging Inspection: The packaging of the vaginal stent must be carefully examined. If the package has been damaged in any way, the stent cannot be used.

Stent used only as supplied: The vaginal stent can only be used in its original form, without any alterations to its original characteristics.

ALL SILICONE VAGINAL STENTS MUST BE USED IN ONE PATIENT ONLY

Durability:

The vaginal stent is a temporary device for treatment time not to exceed 12 weeks.

Contraindications and Precautions:

Silimed considers the existence of infections in any part of the body as an absolute contraindication for the use of this product for any operation.

This can be removed in less than 12 weeks once it is taken out

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Transportation and Storing:

Silimed products and packages are extremely resistant and if handled with normal minimum of care will not present any problems. However, they should not be transported or stored with other types of material that may cause mechanical damage to the packaging and thus invalidate their sterile condition.

Clarification and Consent of Patient:

Silimed relies on the surgeon to clarify with their patients any risk factors inherent in surgery of this type before obtaining the patient's formal consent.

Warranty:

Silimed has stipulated a three year warranty for manufacturing defect provided the packaging has been preserved intact prior to use.

Silimed will replace any defective product. Since proper registration is made of each unit of raw material, stages of manufacture, and atmospheric and operational conditions, an individual number is given to each item that identifies it at any time, As a result, it absolutely necessary that any complaint be accompanied by the CONTROL NUMBER of the relevant item that appears on the package and by the PATIENT'S LABEL supplied to the doctor and detachable from the label of each package.

The warranty on Silimed products does not cover the simple decision of the patient or surgeon to change the product.

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Appendix 2.1 Chemical Characterization of Device Components

Chemical Characterization of Device Components

(b)(4)Product Specs

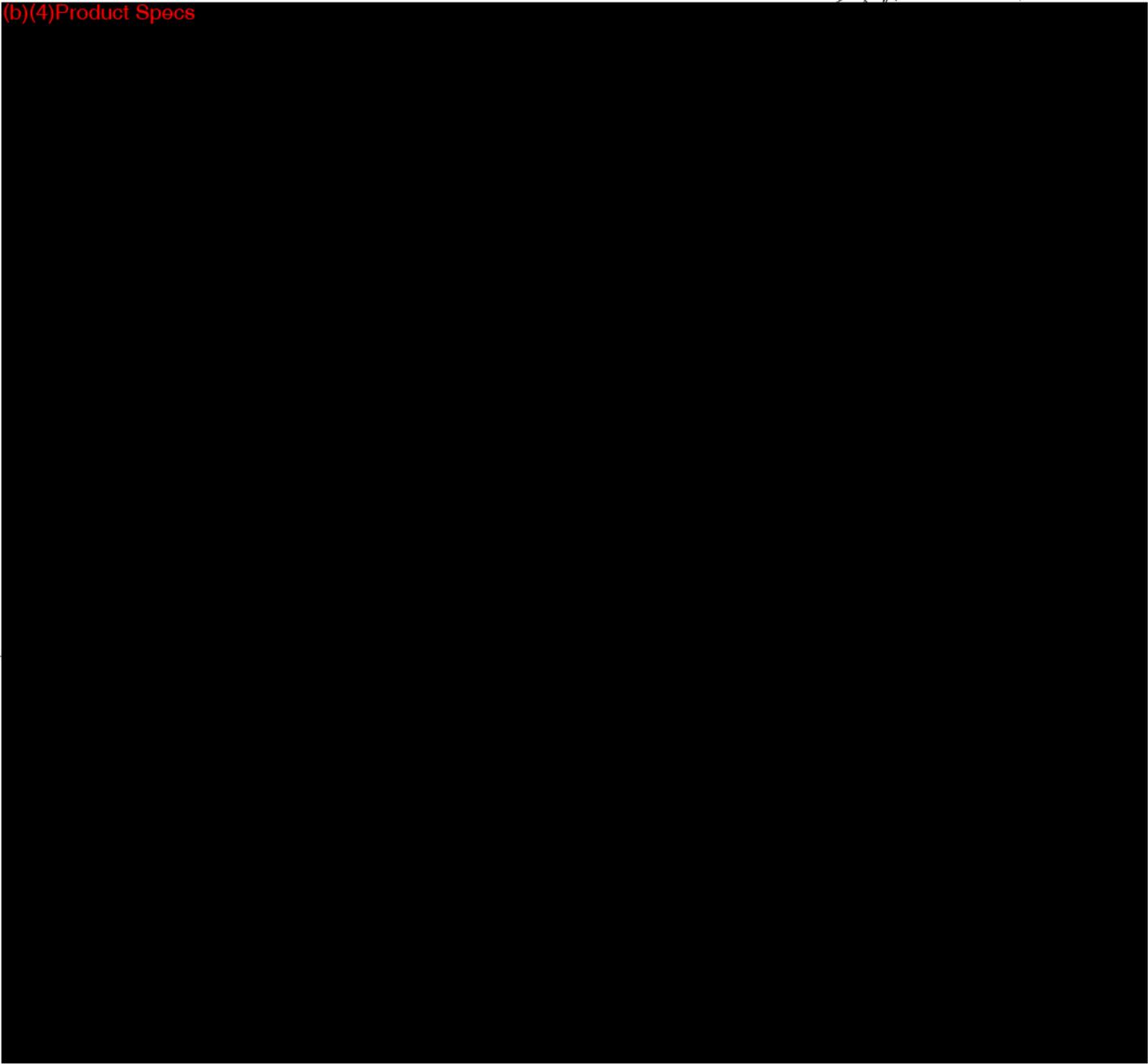


Appendix 2.2 Material Choices, Product Specification and Product Design

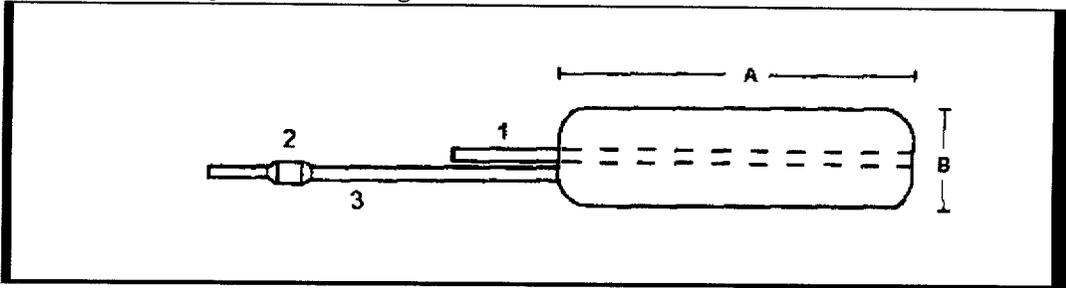
Appendix 2.2 Material Choices, Product Specifications and Design

... that part of work...

(b)(4) Product Specs

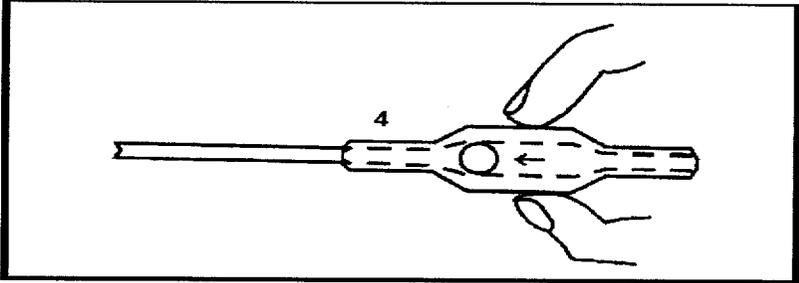


2.2.3 Silimed Vaginal Stent Design:

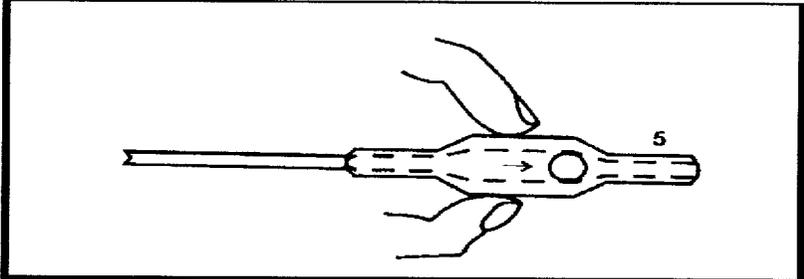


- 1= Internal Drain
- 2= The valve (silicone body and obturating sphere)
- 3= Tubing

2.2.3.1 Open Position:



2.2.3.2 Closed Position:

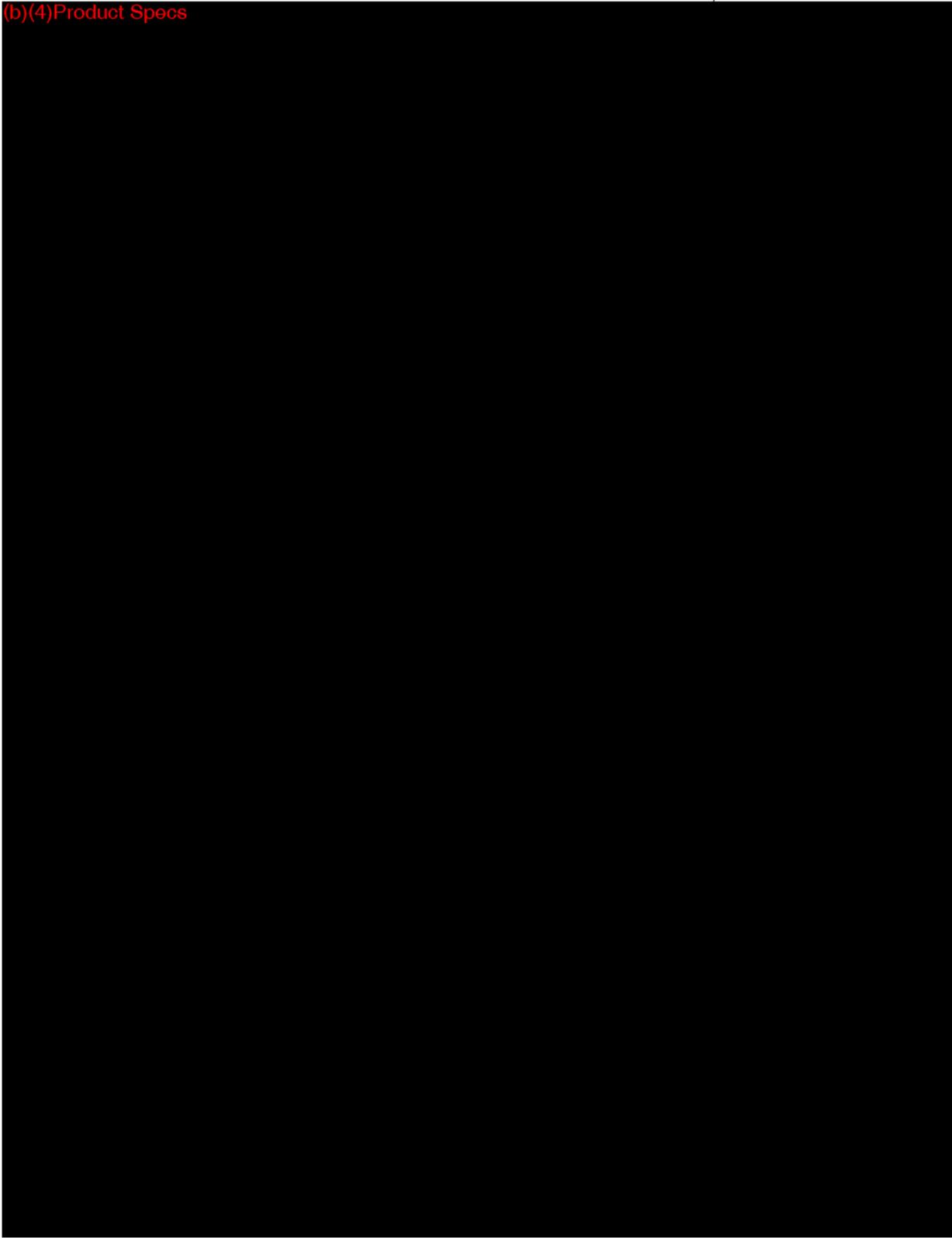


Appendix 2.3: Properties of Bulk Materials

Appendix 2.3 Properties of Bulk Materials

Not final.

(b)(4)Product Specs



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**Appendix 2.4: Molecular Weight Non-Linked Component
Polymers, GPC**

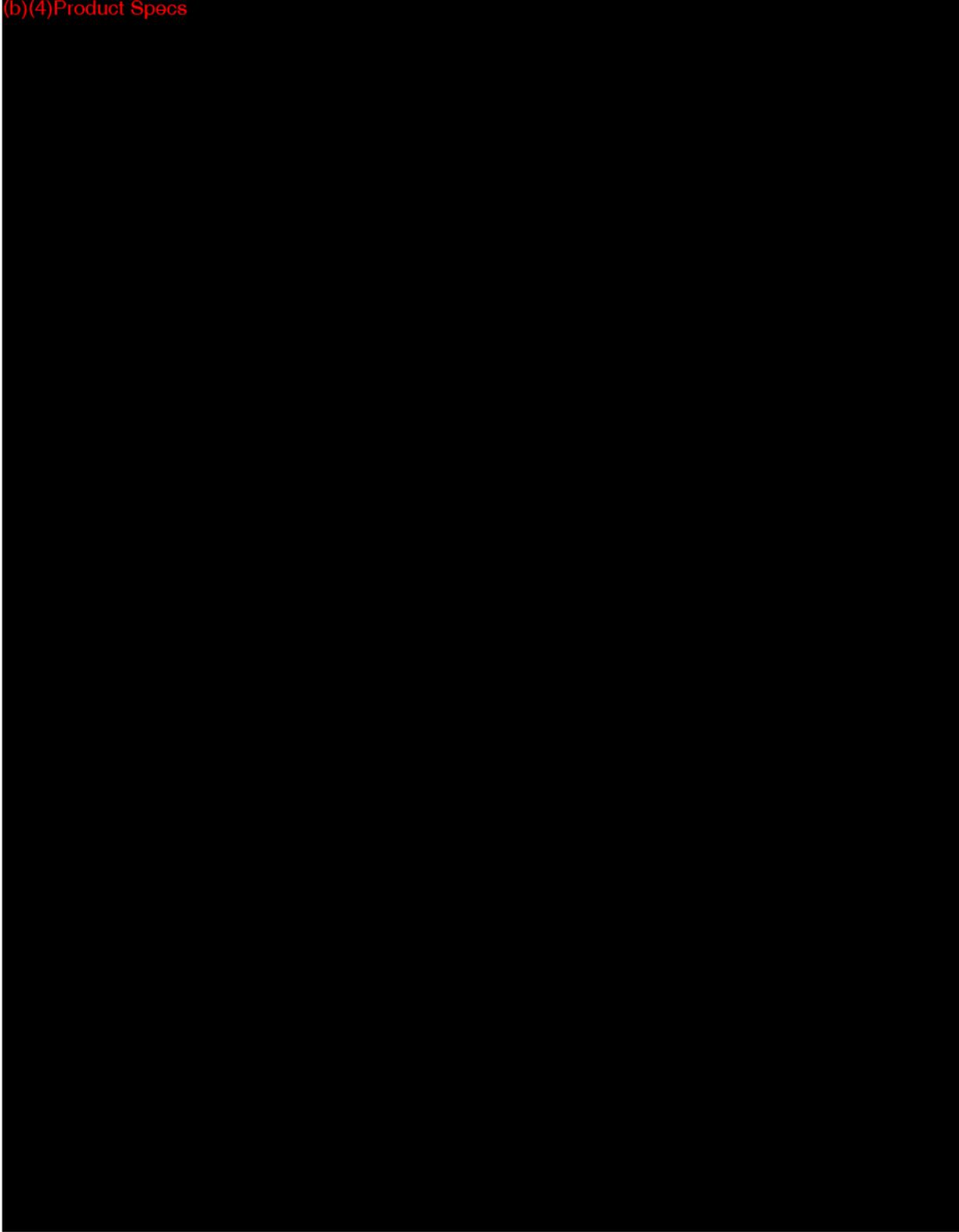
(b)(4)Product Specs



Appendix 2.5: Trace Metals Analysis, ppm

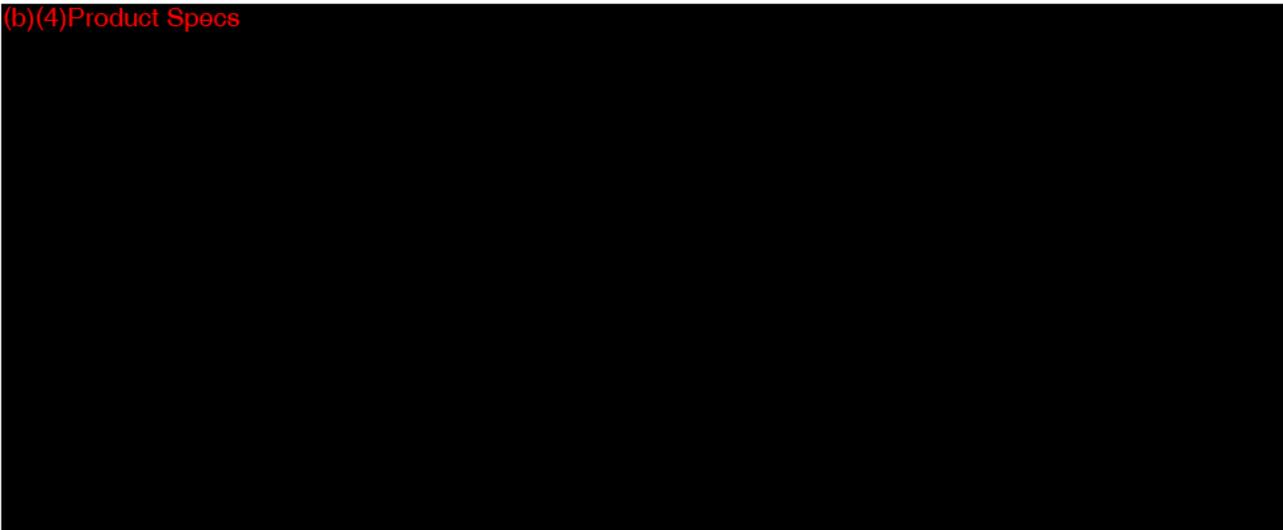
2.5 Trace Metals Analysis, ppm

(b)(4)Product Specs



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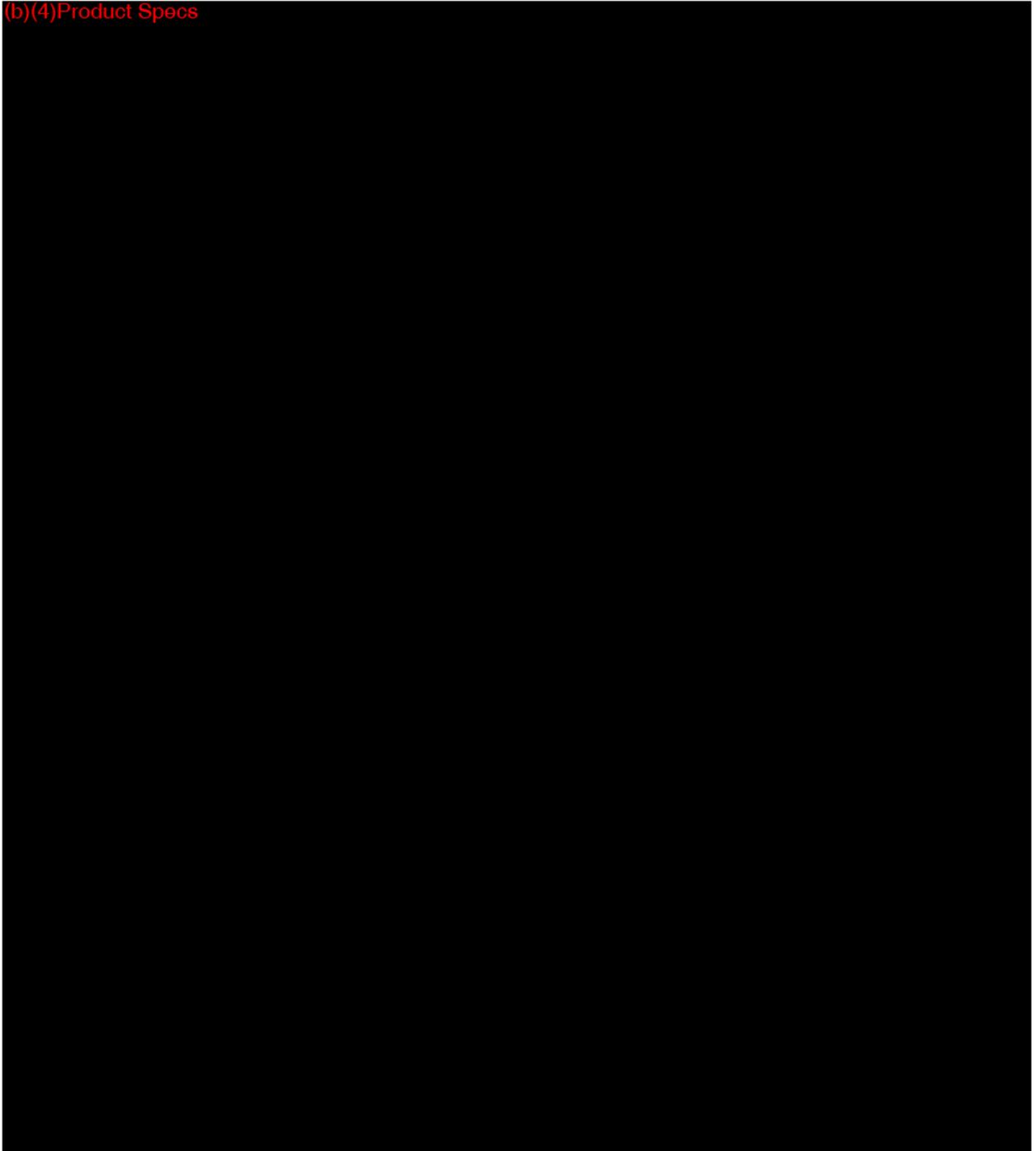
(b)(4)Product Specs



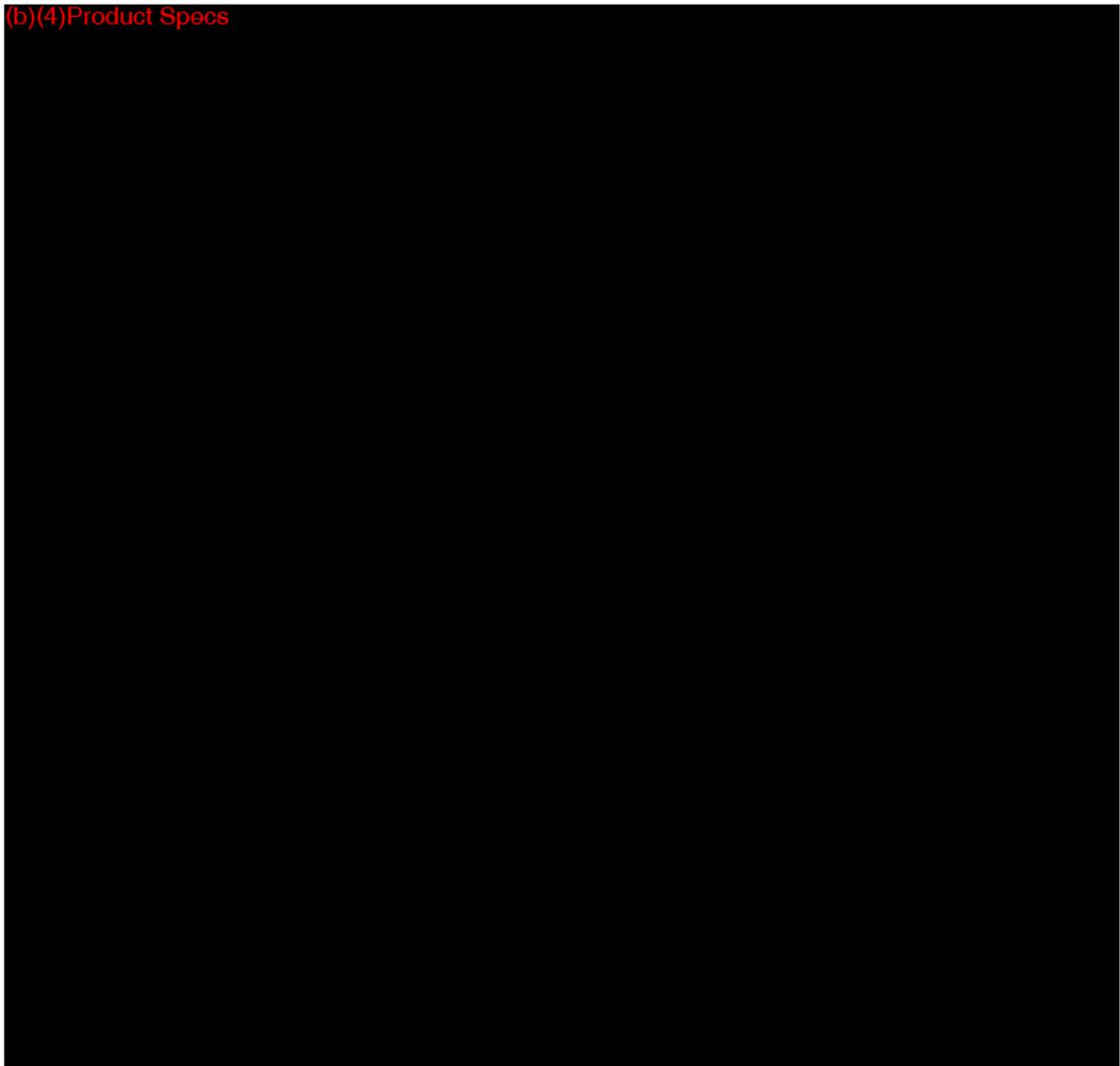
Appendix 2.6: Physical Properties

Appendix 2.6 Physical Properties

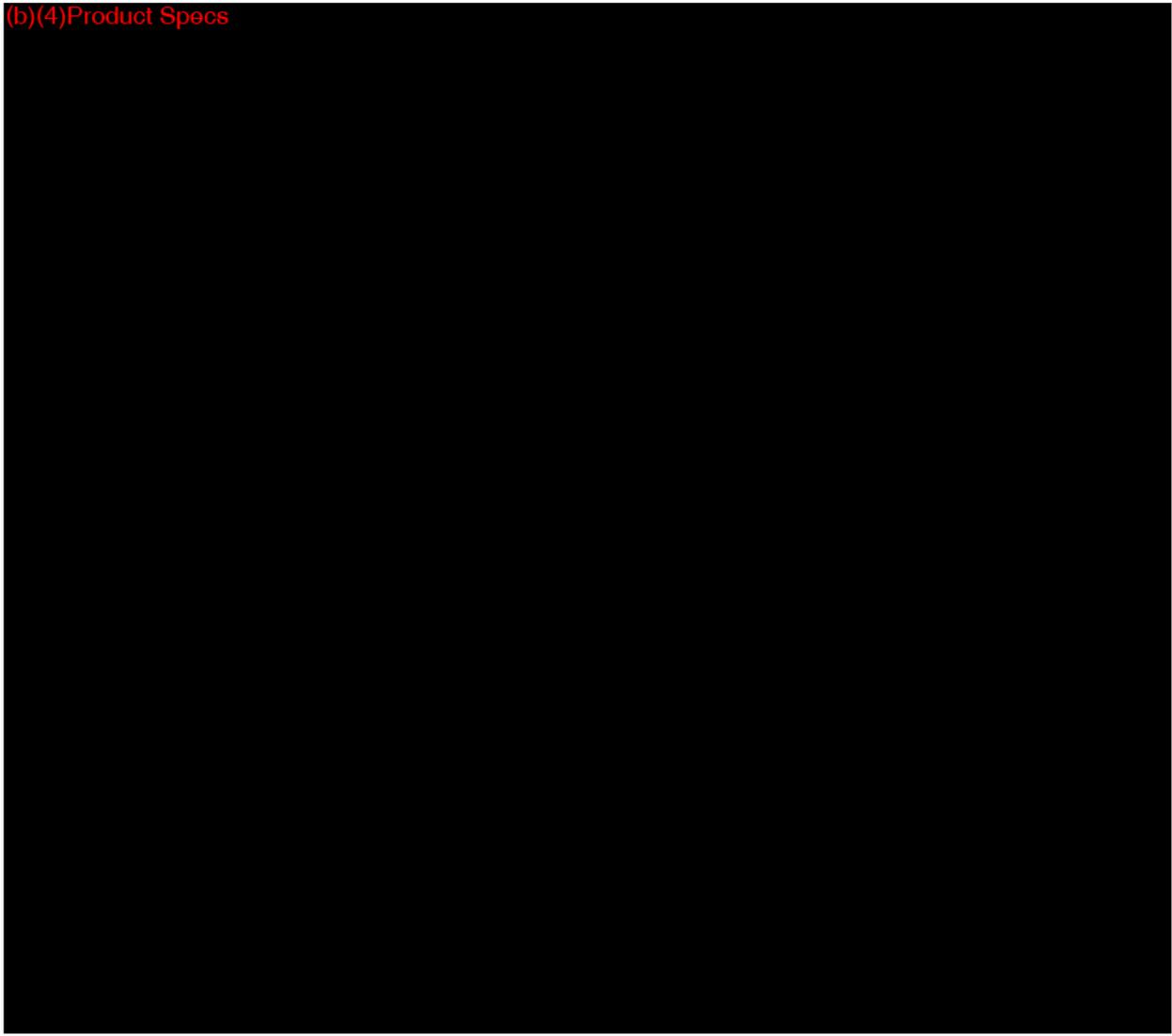
(b)(4)Product Specs



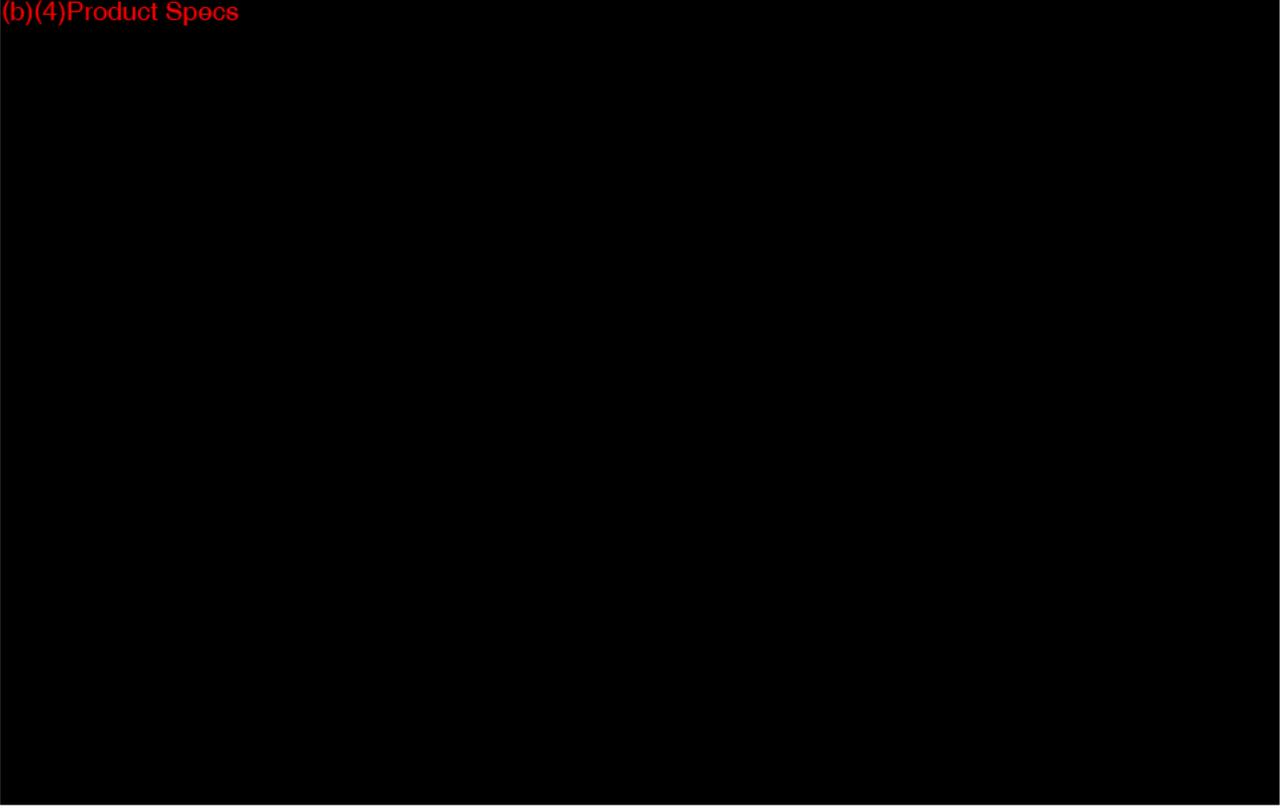
(b)(4)Product Specs



(b)(4)Product Specs



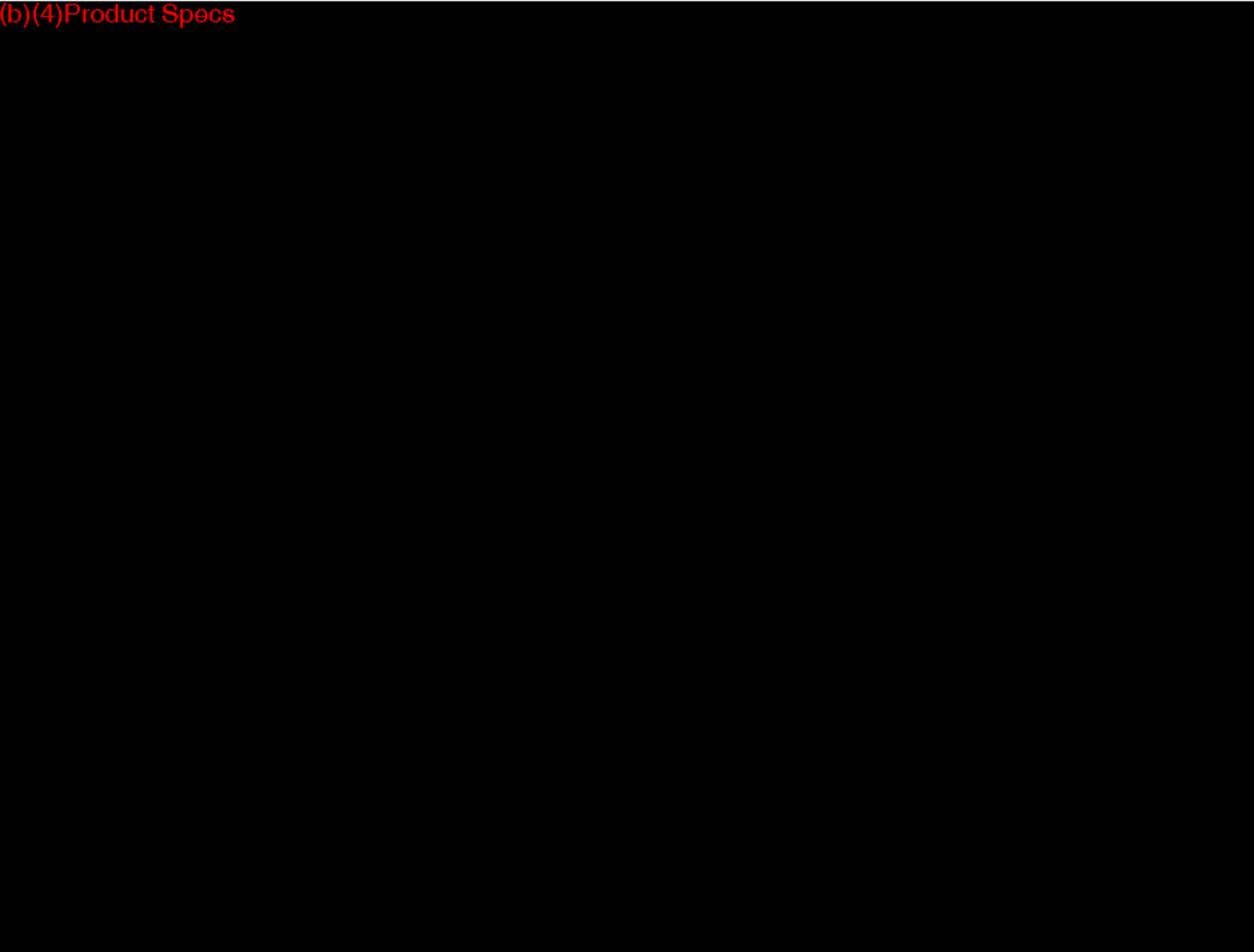
(b)(4)Product Specs



Appendix 2.7: Chemical Properties

Appendix 2.7 Chemical Properties

(b)(4)Product Specs



(b)(4)Product Specs

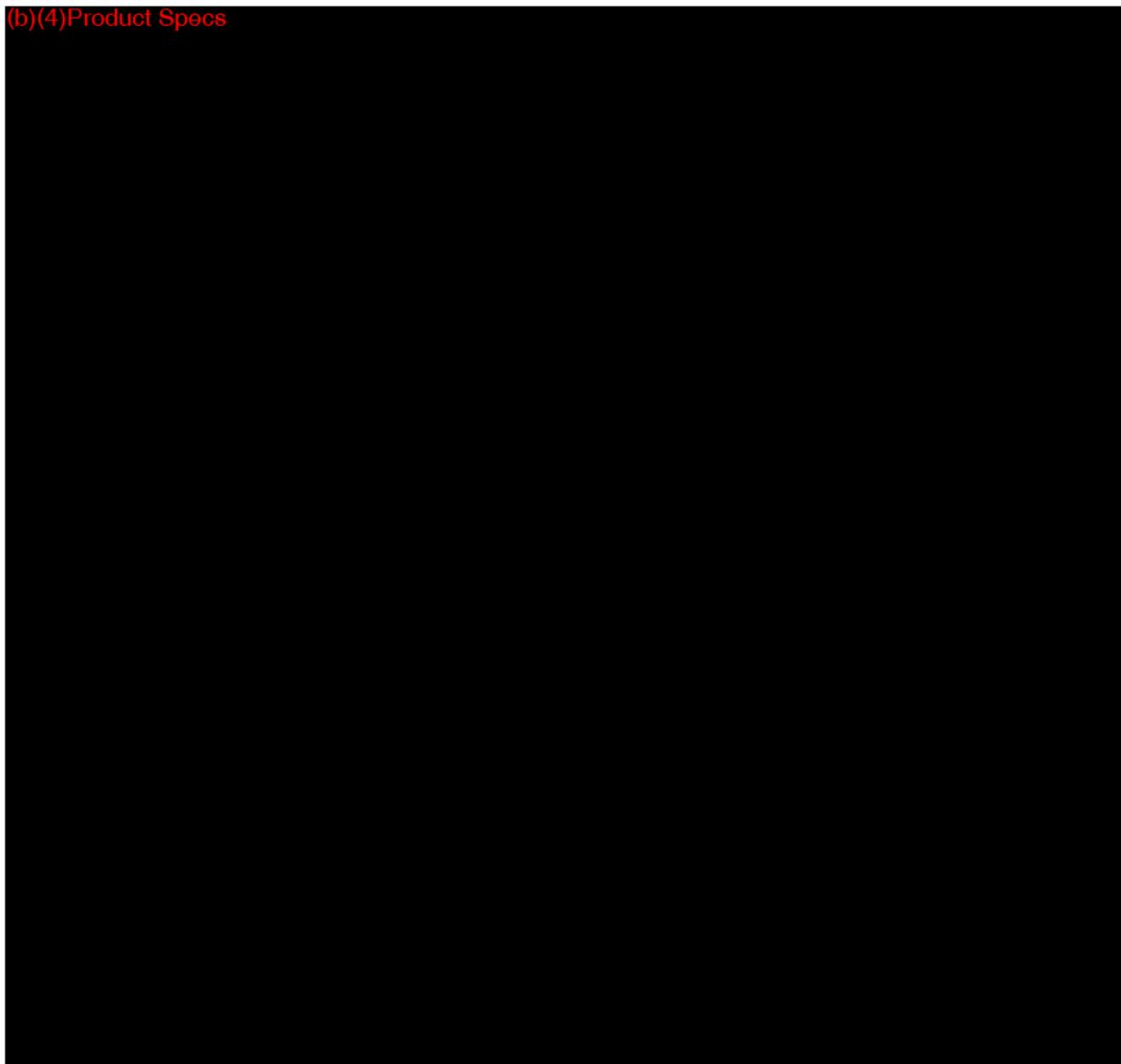


21h

(b)(4)Product Specs



(b)(4)Product Specs



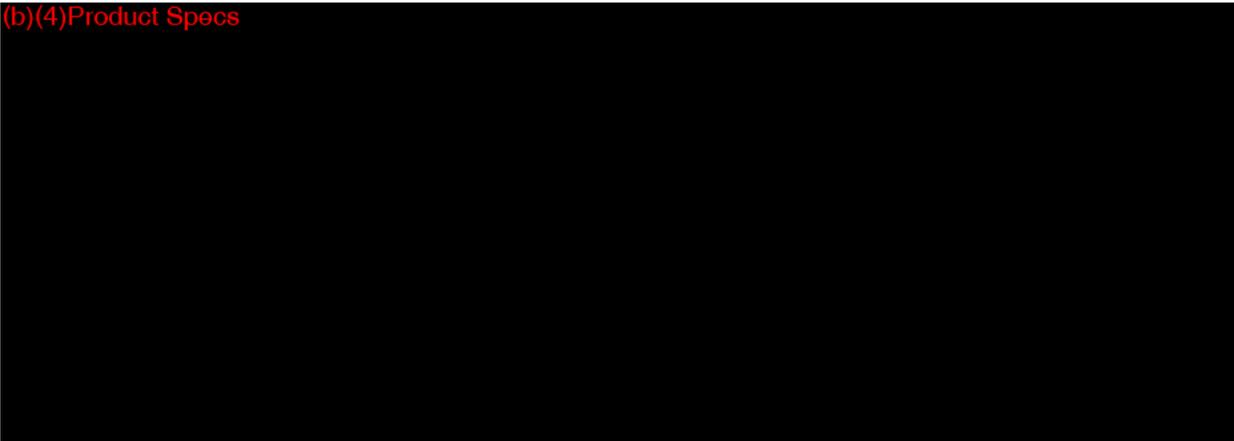
(b)(4)Product Specs



Appendix 2.8: IR Characterization

Appendix 2.8 IR Characterization

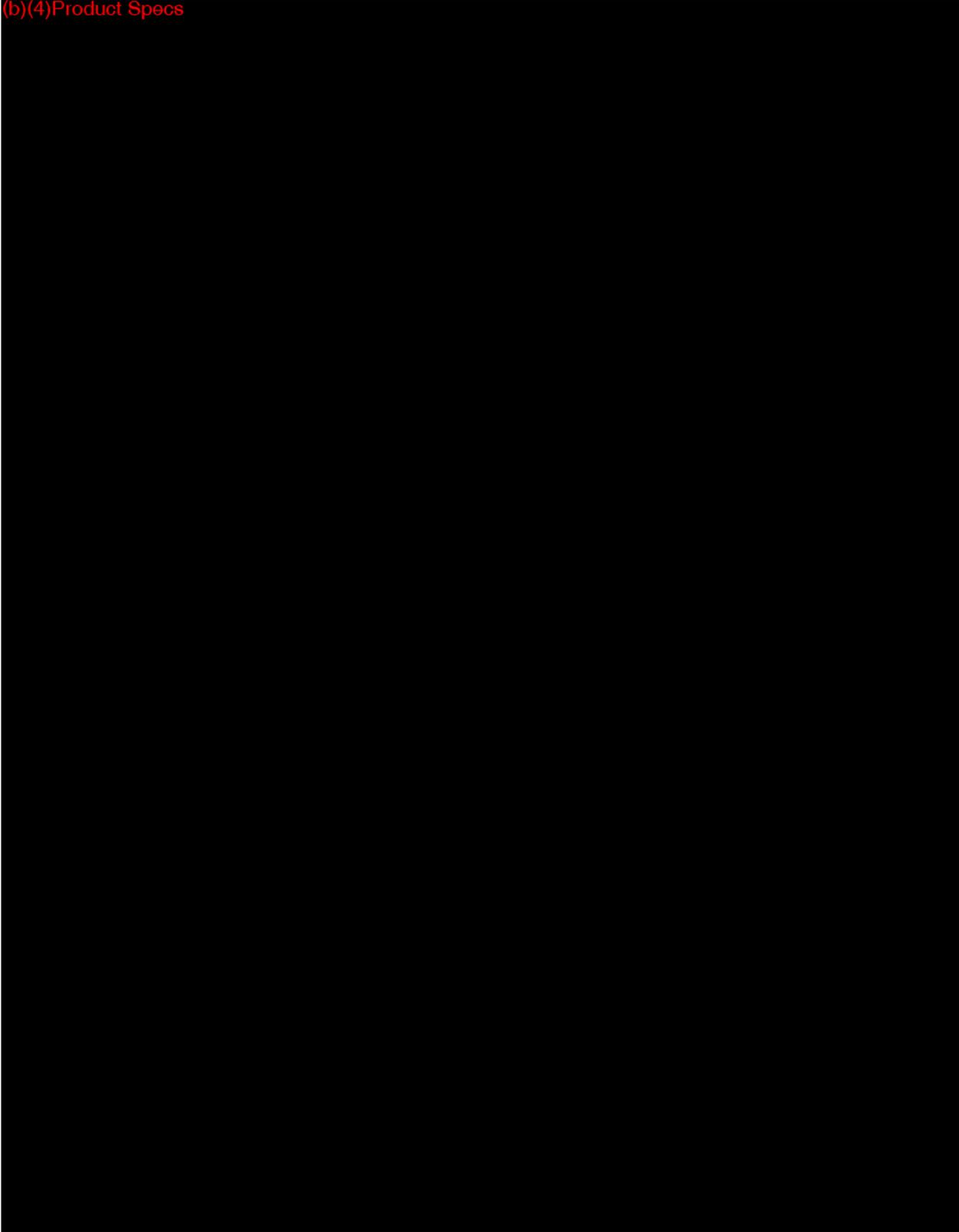
(b)(4)Product Specs



Appendix 2.9: Biocompatibility Tests and Results

Appendix 2.9 Biocompatibility Tests and Results

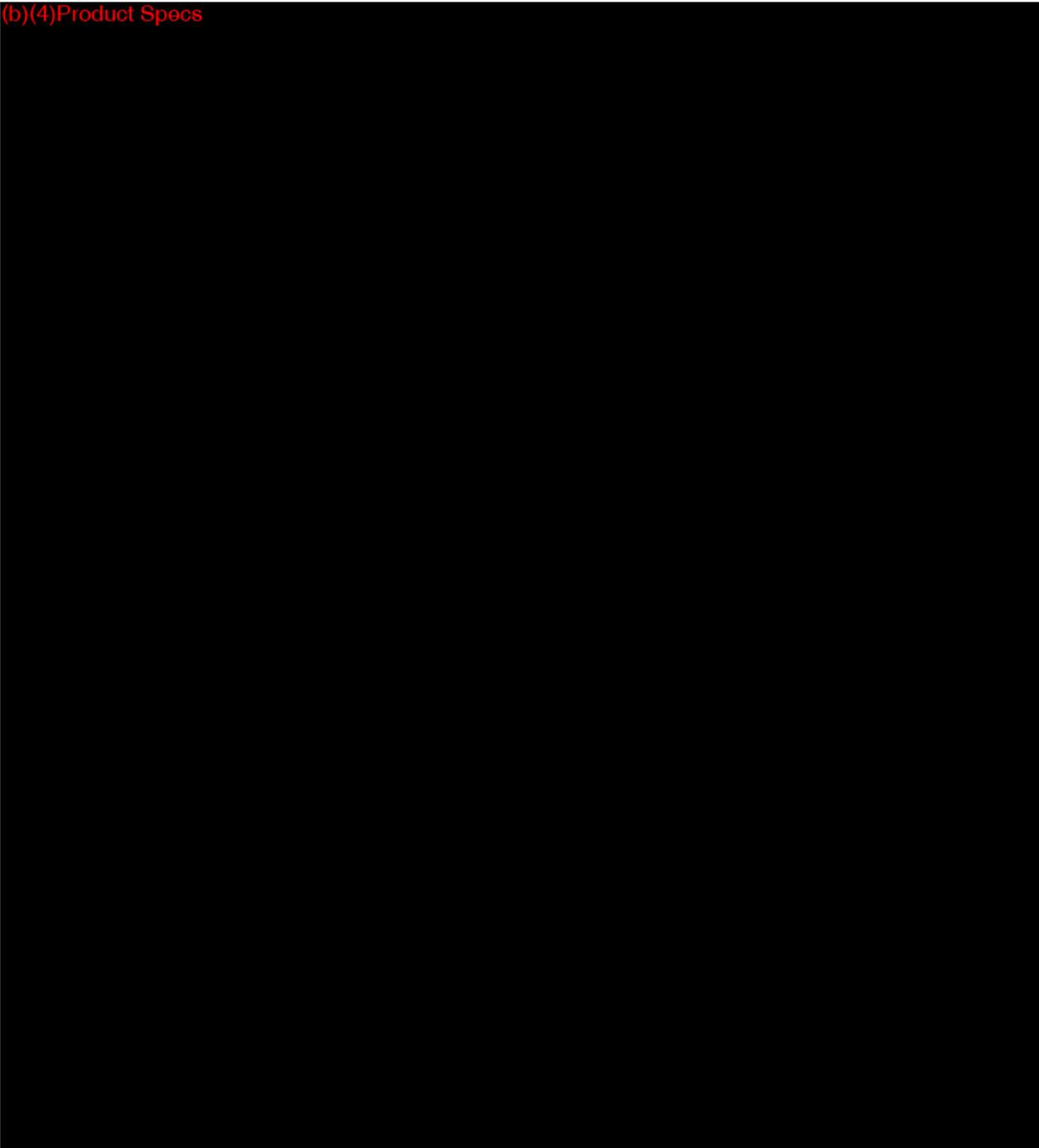
(b)(4)Product Specs



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(b)(4)Product Specs



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Appendix 3: Sterilization Information

Appendix 3: Sterilization Information

(b)(4)Product Specs

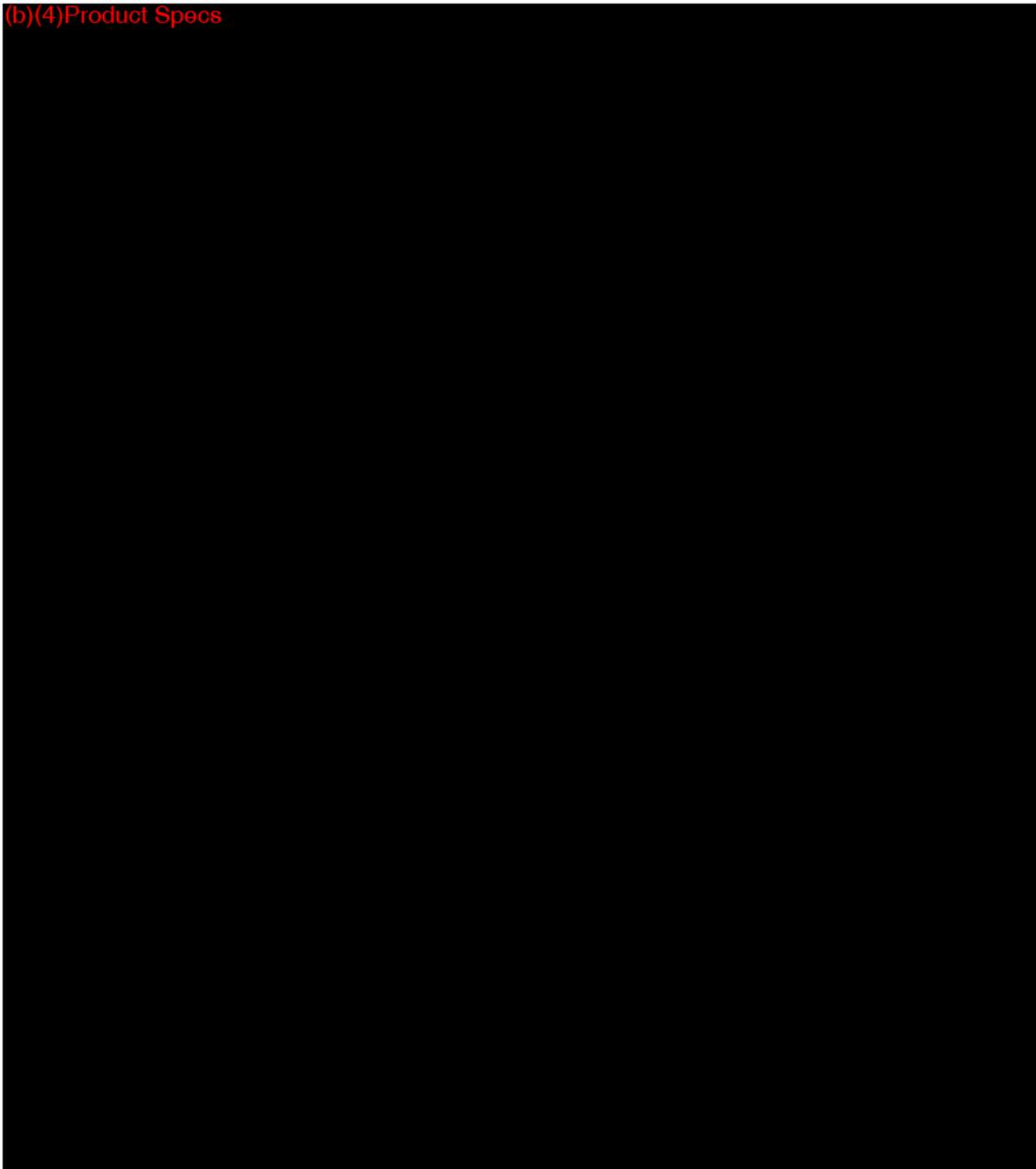


Exhibit 3.1

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Exhibit 3.2

Exhibit 3.3

Appendix 4: Promotional Information

APPENDIX 4: PROMOTIONAL MATERIAL

(b)(4)Product Specs

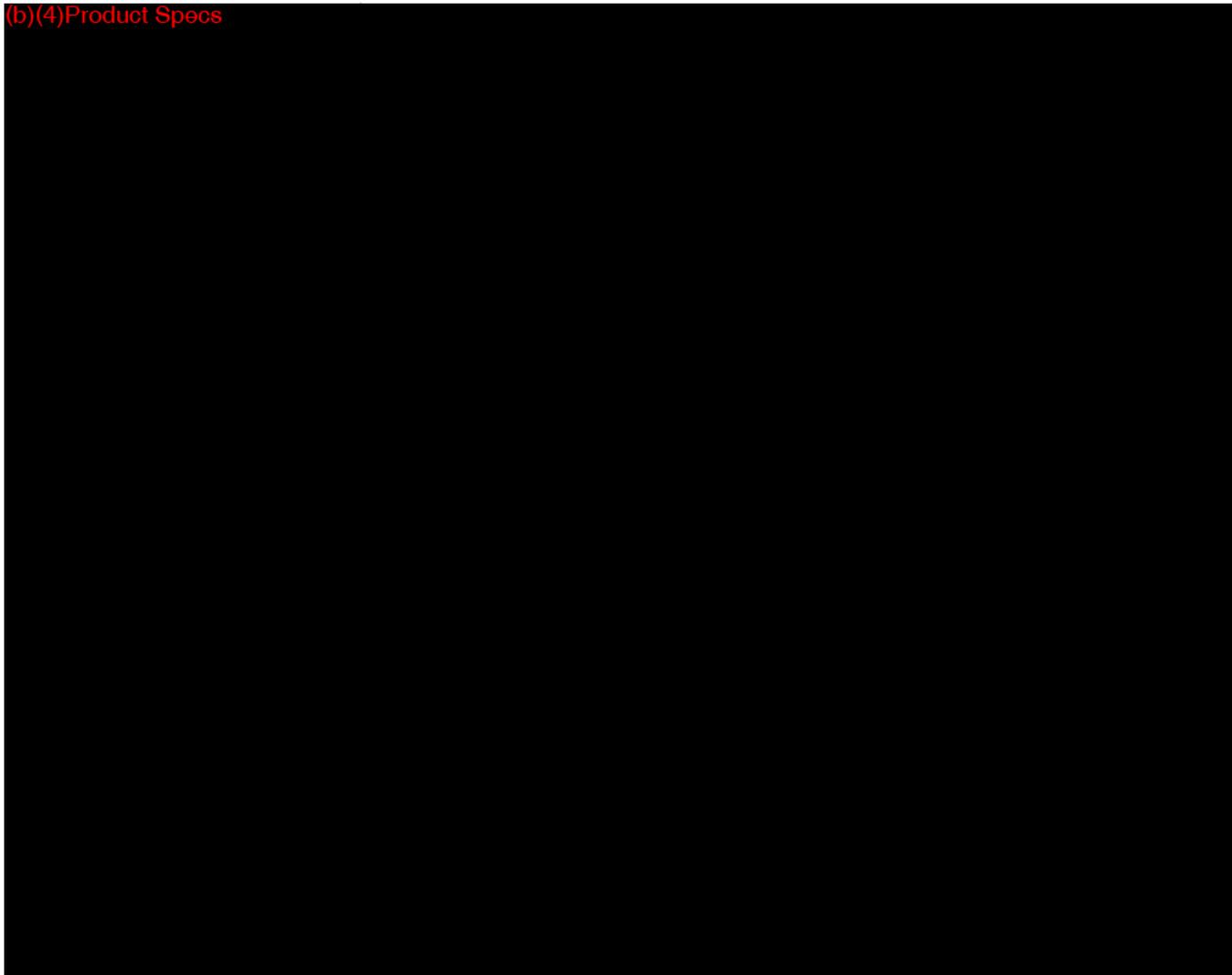
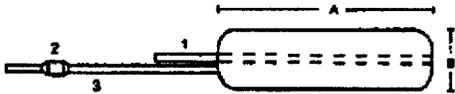


Exhibit 4.1
Silimed Vaginal Stent Catalog Sheet

CONFORMADOR VAGINAL INFLÁVEL: Destinado às cirurgias de neovagina, apresenta um dreno interno que possibilita a assepsia da ferida cirúrgica sem a sua retirada. Fornecido estéril.

CONFORMADOR VAGINAL INFLABLE: Destinado a las cirugias neovaginales, presenta un drenaje interno que permite realizar la asepsia de la herida quirúrgica sin retirarlo. Entregado estéril.

INFLATABLE VAGINAL STENT: Designed for neovaginal surgery, presents an internal drain that allows carrying out the asepsis of the surgical wound without withdrawing it. Supplied sterile.

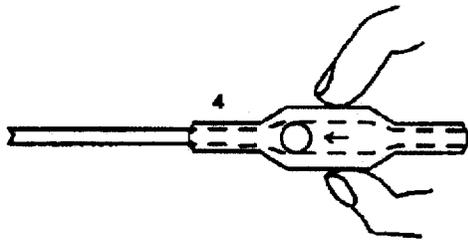


1 - Dreno interno
1 - Drenaje interno
1 - Internal drain

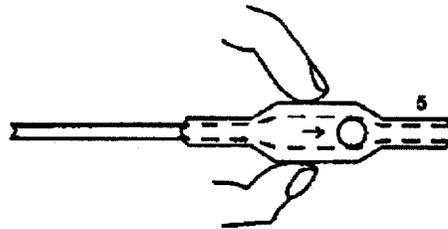
2 - Válvula (corpo de silicone e esfera obturadora)
2 - Válvula (cuerpo de silicona y esfera obturadora)
2 - The valve (silicone body and obturating sphere).

3 - Tubo
3 - Tubo
3 - Tubing

REFERÊNCIA REFERENCIA REFERENCE	VOLUME VOLUMEN VOLUME cm ³	DIMENSÕES DIMENSIONES DIMENSIONS cm	
		A	B
3521-095	70	8,5	3,0
3521-120	150	12,0	4,0
3521-140	220	14,0	4,5
3521-160	300	16,0	6,0



4 - POSIÇÃO ABERTA
4 - POSICIÓN ABIERTA
4 - OPEN POSITION



5 - POSIÇÃO FECHADA
5 - POSICIÓN CERRADA
5 - CLOSED POSITON

APPENDIX 5: COMPARISON OF PREDICATE DEVICES

APPENDIX 5: COMPARISON OF PREDICATE DEVICES

5.1 Indication for Use:

The *Silimed Vaginal Stent* is designed to maintain the vaginal canal following radiological treatment or surgical procedures to restore, enlarge or create a vagina.

The surgeon is responsible for proper choice of shape and size to meet the clinical and aesthetic needs of each case.

Federal (U.S.A.) law restrict this device to sale by or on the order of a physician.

5.2 Description of the Vaginal Stent:

The Silimed Vaginal Stent consists of three parts: 1. internal drain, 2. the valve (silicone obturating sphere) and 3. tubing. The membrane's basic elastomer is vinyl dimethyl polydimethyl siloxane with a load of pure amorphous fine crushed silica catalyzed by a platinum compound and the shell is then filled with polyurethane foam. The basic elastomer for the connections and drain is polydimethyl siloxane. The cylindrical valve is made of polydimethyl siloxane and a 001 stainless steel ball. The stent is available in 4 sizes ranging from a volume of 70cm³ to 300cm³.

The Vaginal Stent is supplied sterile and is available in a transparent double "blister" pouch or double peel pouch. Both sterilized by ETO.

The Silimed Vaginal Stent is designed to maintain the vaginal canal following radiological treatment or surgical procedures to restore, enlarge or create a vagina. The stent consists of a watertight silicone elastomer shell filled with polyurethane foam, which has been designed to help protect surrounding tissue against concentrated pressure points. The fill tube with a sliding-ball-valve provides for collapsing the stent to facilitate insertion and removal of the device from the vaginal canal. The fill tube allows for filling the stent with 0.9% normal saline, in order to adjust the size of the device and the pressure it exerts on the vaginal wall.

5.3 Predicate Devices:

One device on the market are substantially equivalent, in part or in whole, to the Silimed Vaginal Stent. The comparison product is:

Company	Product	510(k)Number
Heyer- Schulte Corporation	Adjustable Vaginal Stent	Unknown

Table 5.1: Predicate Product Comparison Chart, presents a comparison of significant features of these devices. The sub-appendixes here (Appendix 5.1) contain advertisements for the predicate products.

Table 5.1: Predicate Product Comparison Chart

Parameters	Silimed	Heyer-Schulte
Proprietary Name:	Silimed Vaginal Stent	Adjustable Vaginal Stent
510(k) Number:		
Indications for Use:	designed to maintain the vaginal canal following radiological treatment or surgical procedures to restore, enlarge or create a vagina.	designed to maintain the vaginal canal following radiological treatment or surgical procedures to restore, enlarge or create a vagina.
Single Patient Use:	Yes	Yes
Material Choices:		
Shell:	Silicone Elastomer	Silicone Elastomer
Fill Material:	Polyurethane Foam	Polyurethane Foam
Obturing Sphere	Stainless Steel Ball	Stainless Steel Ball
Styles:		
Adjustable	Yes	Yes
Flexible	Yes	Yes
Sizes:		
3.0cm x 9.5cm	Yes	Yes
4.0cm x 12.0cm	Yes	Yes
4.5cm x 14.0cm	Yes	Yes
5.0cm x 16.0cm	Yes	Yes
Product Shipped Sterile:	Yes	No
Sterilization Method:	ETO	N/A

5.4 Comparisons:

The differences between the Silimed Vaginal Stent and Heyer-Schulte Vaginal Stent:

- Silimed's Vaginal Stents are supplied sterile vs Heyer-Schulte's vaginal stent which is supplied non-sterile.

APPENDIX 5.1 HEYER-SCHULTE CORPORATION ADVERTISEMENTS

HEYER
SCHULTE

Adjustable Vaginal Stent



Adjustable Vaginal Stent

Description

The Adjustable Vaginal Stent is designed to maintain the vaginal canal following radiological treatment or surgical procedures to restore, enlarge or create a vagina. The stent is available in four sizes. Cylindrical in shape and rounded at the ends, the stent consists of a watertight silicone elastomer shell filled with polyurethane foam. This design is intended to help protect surrounding tissue against concentrated pressure points. The "through-tube" allows for drainage of the vagina. A fill tube with a sliding-ball valve provides for collapsing the stent to facilitate insertion and removal of the device from the vaginal canal. In addition, the fill tube allows for filling the stent with normal saline, in order to adjust the size of the device and the pressure it exerts on the vaginal wall.

Indications

The Adjustable Vaginal Stent is indicated for use:

1. as a pressure dressing after vaginal surgery to hold pedicle flaps or free skin grafts in close apposition to the receptor site;
2. as an obturator or dilator to maintain the vaginal canal and reduce the possibility of contracture and stenosis following vaginal surgery and/or radiological treatment.

Contraindications

Procedures to create, enlarge or restore the vagina are contraindicated in the presence of local or systemic infection or in the presence of an anomaly of the urinary system which could be damaged by such procedures or by subsequent sexual intercourse. Congenital anomalies of the urinary tract frequently associated with congenital absence of the vagina include pelvic

kidney, anomalous insertion of the ureter and ureteral duplication.

The use of the Adjustable Vaginal Stent is contraindicated when for any reason the patient has the inability to operate the device or to understand how the device is operated, or when the patient is apt to be uncooperative in maintaining the stent within the vagina for the prescribed length of time.

Instructions For Use

Procedures for Deflating and Filling the Adjustable Vaginal Stent

Directions for deflating and filling the unit during the surgical procedure are as follows:

1. Prior to inserting the stent, deflate the device completely by squeezing or aspirating with a syringe.
2. Close the valve by moving the ball to the closed position, i.e., toward the filling orifice.
3. Using a syringe filled with sterile, normal saline, inflate the device to the desired contour, but keep the device small enough that it may be introduced into the vagina.
4. Close the valve.
5. Fill the unit in situ to the desired volume.
6. Adjust volume in the stent by opening the valve and using a syringe to introduce or withdraw saline or air. Close the valve.

Surgical Procedure

A variety of surgical techniques may be employed during the use of the Adjustable Vaginal Stent; therefore, the surgeon is best advised to use the method which his own practice and discretion dictate to be best for the patient.

**Exclusive
United States
Distributor:**

MEDIC SERVICE
Arzt- und Spitalbedarf
8604 Volketswil
Tel. 01 / 945 48 15

The following procedure for creation of an artificial vagina is furnished by Dr. Donald R. Laub* for information purposes.

A pre-operative regimen is used to purge and sterilize the gastrointestinal tract. The genitalia are shaved and thoroughly prepared for surgery by washing with antiseptics.

The anesthetized patient is placed in the prone position. A sufficiently large skin graft, .018 to .022 inch thick, is taken from the buttocks. The donor site is dressed and the patient placed in the lithotomy position. Draping includes a disposable O'Connor Urology Drape, which goes in the rectum, allowing a gloved finger to be placed there for proprioceptive orientation to tissue planes during dissection. A Foley catheter is placed to provide bladder drainage and help identify the urethra during surgery.

The vaginal space required is created using the appropriate incision with blunt and sharp dissection. It is important to achieve absolute hemostasis.

The proper-sized, sterile stent is selected and prepared by partially filling with air (or saline). (See above procedures for deflating and filling the stent.) The skin graft is wrapped evenly, raw side out, around the stent. Excess skin is trimmed at the overlapping edges, and the margins are sutured with a continuous locking suture of 4-0 absorbable suture material. **CARE MUST BE TAKEN NOT TO PERFORATE THE THIN, SILICONE ELASTOMER SHELL OF THE STENT WITH THE NEEDLE.** The skin-covered stent is moistened with saline compresses to facilitate insertion into the vaginal space. Once the stent is in place, the edges of the skin graft can be sutured with interrupted sutures to the edges of the vaginal introitus.

The stent may be inflated with air (or saline) to stretch and hold the graft in place. Only enough pressure to provide slight compression is required. **Excessive pressure must be avoided, as it will inhibit circulation and can cause necrosis of the skin graft and/or the urethra against the catheter and the pubis.** A suprapubic catheter is therefore useful.

The stent may not be self-retaining and should be held in place in an appropriate manner, such as tying the stent to sutures placed in the thigh.

One week after insertion the stent may be deflated by aspirating with a syringe, then removed while the vaginal space is irrigated with saline. The stent must be cleaned and sterilized prior to re-insertion. Thereafter, the patient may remove the stent for cleaning, and sexual intercourse is permitted after two months if epithelization is complete, but until all tendency to vaginal constriction has ceased (approx. six months) the patient must be instructed that the vagina will contract if the stent is left out for longer than 10 to 15 minutes at a time. Intermittent use of the stent to maintain the vaginal canal is usually required for six months, and may be required indefinitely.

How Supplied

This product is supplied **NON-STERILE AND MUST BE CLEANED AND STERILIZED PRIOR TO PLACEMENT WITHIN THE BODY.**

Cleaning and Sterilization Procedures

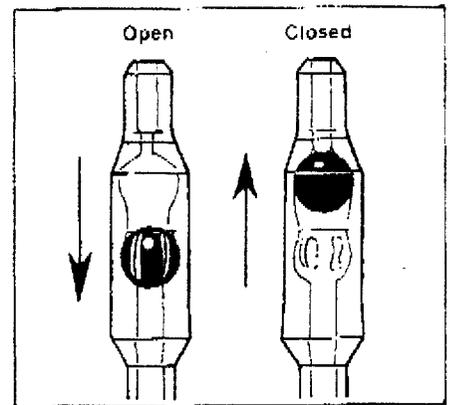
The Adjustable Vaginal Stent is recommended **FOR REUSE IN THE SAME PATIENT ONLY.**

It is recommended that each institution establish the efficacy of its sterilization procedure by a method which includes the sterilization of an intentionally contaminated product.

DO NOT STERILIZE IN THE PACKAGING SYSTEM SUPPLIED.

The following cleaning and sterilization techniques have been found effective and are provided as a guide:

To Clean: Remove the stent from its package in a clean environment using gloved hands. To prevent cleaning solution from entering the interior of the stent, pinch the valve ball into the "closed" position — i.e. the position nearest the opening of the valve tube. (When the valve is in the "closed" position, air cannot be squeezed from the prosthesis.) Wash the prosthesis thoroughly in a hot water and soap solution. **DO NOT USE SYNTHETIC DETERGENTS OR OIL-BASED SOAPS.** Rinse the prosthesis well in distilled water, taking care to flush the lumen of the through drain.



To Sterilize: Pinch the valve ball into the "open" position — i.e., the innermost pocket of the valve chamber away from the filling orifice, and inject approximately 10 cc. of distilled water into the stent. **Make sure the valve remains in an open position to allow air to vent during autoclaving.** Wrap the stent. (A double layer of Hospitex Muslin, Type #140, 68 x 72 Thread has been found acceptable.) Place the unit on a clean, open autoclaving tray and autoclave by one of the following Gravity Displacement Sterilization methods before the interior of the stent becomes dry:

1. STANDARD CYCLE:
30 minutes at 250° F. (121° C.) and 15 psi.
2. OPTIONAL CYCLE:
10 minutes at 270° F. (132° C.) and 30 psi.

DO NOT USE AN ETHYLENE OXIDE STERILIZATION CYCLE.

Warnings

The silicone elastomer shell of the Adjustable Vaginal Stent is thin in order to achieve desired properties. Punctures, surface cuts, nicks, crushing or overstressing can lead to a tear. The device may be easily penetrated by needle or scalpel or ruptured by manipulation with a blunt instrument. Care must be exercised during handling to prevent such events. A damaged stent must not be placed. For this reason, a standby device should be available at the time of surgery.

Postoperatively, if a transurethral catheter is required, care must be taken not to overinflate the stent, as urethral erosion or fistula and graft-tissue necrosis may result. Suprapubic drainage, rather than trans-

*Donald R. Laub, M.D.
Chief, Division of Plastic &
Reconstructive Surgery
Stanford University Medical Center
Stanford, CA 94305

2hd

urethral-catheterization, may be advisable.

Failure to maintain the stent within the vaginal canal for the prescribed length of time can promote contracture and stenosis of the vagina.

Lint, fingerprints, talc and other surface contaminants can cause foreign body reactions. Utmost caution should be taken to avoid contaminants.

Precautions

Prior to surgery, prospective patients or their representatives should be informed of the possible complications associated with the use of this product.

Failure of a surgical attempt to create, enlarge or restore a vagina may be due to insufficient or incorrect use of the stent by an immature, uncooperative or poorly prepared patient; therefore, careful patient selection as well as adequate patient instruction are important to a successful surgical result. Specifically, the patient must be instructed in the proper care of the stent and impressed with the importance of maintaining the patency of the vaginal canal by using the stent in the proper manner and for the recommended period of time.

The stent should fit snugly into the vaginal vault so as to exert even pressure on surrounding tissues, but the device should not be overinflated, as necrosis of surrounding tissue may result.

The stent must remain in position for approximately six months or longer, until all tendency to constriction has ceased, and during that time must be removed only briefly, e.g., 10-15 minutes at a time for cleaning or graft inspection. Thereafter, continued periodic dilation of the vagina may be required indefinitely.

Complications

Complications which may result from the use of this device include the risks associated with the medication and methods utilized in the surgical procedure, as well as the patient's degree of intolerance to any foreign object placed in the body.

Other complications which may occur during the use of the Adjust-

able Vaginal Stent following attempts to create, enlarge, or restore the vagina include:

1. vaginal or urinary tract infection or abscess that may necessitate stent removal;
2. sloughing of a skin graft from hematoma formation or other cause, resulting in granulation tissue;
3. irritation or pressure necrosis of the skin graft or other tissue surrounding the stent;
4. compression of urethra, bladder or rectum by stent pressure, resulting in tissue erosion and recto-, vesico- or urethrovaginal fistula;
5. mechanical failure of the stent due to valve dysfunction or rupture of the device, resulting in leakage of saline;
6. scarring, contracture or stenosis of the vagina from premature removal of the stent;
7. expulsion of a stent inadequately held in place;
8. discomfort to the patient from the stent;
9. absorption of odors into the stent.

Returned Goods Policy

U.S. CUSTOMERS

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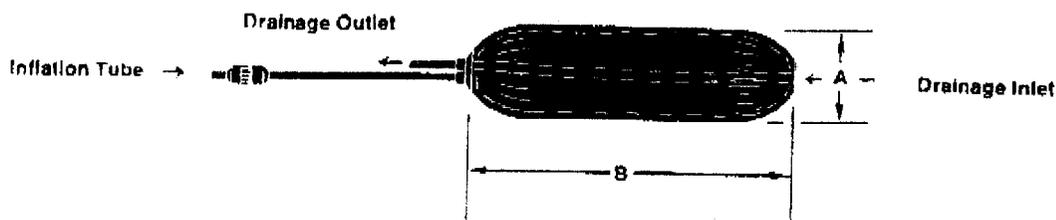
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Specifications (All Dimensions are Nominal.)

The Adjustable Vaginal Stents are supplied individually packaged in the following sizes:

Cat. No.	Size Designation	Dimensions	
		A	B
430-3010	3 x 9.5 cm.	3.0 cm.	9.5 cm.
430-3012	4 x 12 cm.	4.0 cm.	12.0 cm.
430-3014	4.5 x 14 cm.	4.5 cm.	14.0 cm.
430-3016	5 x 16 cm.	5.0 cm.	16.0 cm.



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APPENDIX 6 QUALITY ASSURANCE AND QUALITY CONTROL

APPENDIX 6: QUALITY ASSURANCE AND QUALITY CONTROL

6.1 Incoming Inspection: 100%

All orders received for material ordered will be check for accuracy of material ordered vs material received.

6.2 In-process:100%

Material integrity, size, volume, impurities on surface, mold flashing, etc. are inspected throughout the manufacturing process to insure conformity to specifications..

6.3 Outgoing Inspection:100%

- Serial Number: Serial number on product
- Serial Number: Serial number on package label
- Serial number: Serial number on box
- Device Identification Card with Serial Number is placed in package
- Record maintained of ship to location which will be matched to the patient in which the implant was implanted.

6.4 ISO 9001 Certificate: Reference Exhibit 6.1

Exhibit 6.1
Certificate of Quality System Compliance

