U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(smw)
FOLDER:	K011251 - 169 pages
COMPANY:	AMERICAN MEDICAL SYSTEMS, INC. (AMERMEDISYST)
PRODUCT:	MESH, SURGICAL, SYNTHETIC, UROGYNECOLOGIC, FOR STRESS URINARY INCONTINENCE, RETROPUBIC OR TRANSOBTURATOR (OTN)
SUMMARY:	Product: SPARC SLING SYSTEM
DATE REQUESTED:	Jun 18, 2013
DATE PRINTED:	Jun 18, 2013
Note:	Printed

K011251 (1 of 2)

AUG 1 2001

510(k) Summary
SPARC™ Sling System
510(k) Number _____

Submitter/Contact Person:

Ginger Sackett Glaser
Sr. Regulatory Affairs Specialist
American Medical Systems
10700 Bren Rd. W
Minnetonka, MN 55343

Phone: (952) 930-6541
Fax: (952) 930-6496
Email: ginger.glaser@visitams.com

Device Name and Classification:

Trade Name: SPARC™ Sling System
Common/Usual Name: Surgical Mesh, Sling, Urethral Sling
Classification Name: Surgical Mesh, polymeric
Product Code: FTL
Classification: Class II

Manufacturing Location:

American Medical Systems, Inc.
10700 Bren Rd. West
Minnetonka, MN 55343

Predicate Devices:

Tension Free Vaginal Tape (TVT) System by Ethicon, Inc. - K974098

Indications for Use:

The SPARC™ Sling System is intended for the placement of a pubourethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Device Description:

The SPARC™ Sling System is a sterile, single use procedure kit consisting of:

- Two stainless steel, curved, 22-cm long, needle passers (also called insertion tools).
- One piece of AMS Polypropylene sling mesh with attached dilating connectors. The AMS Polypropylene sling mesh is constructed of polypropylene monofilament that is precut to 1.0cm

width x 50cm length. A fixed blue polypropylene anchoring suture runs through the middle of the sling mesh. Two plastic sheaths that overlap in the center of the sling mesh, cover the sling mesh and protect it during placement.

Dilating connectors are attached to either end of the plastic sheaths. The dilating connectors are used to attach to the vaginal ends of the SPARC™ needle passers during the procedure to facilitate sling placement.

- Two blue colored plastic cystoscopy aids are included in the kit in order to facilitate cystoscopic viewing of the bladder. The use of these cystoscopy aids is optional.

Summary of Testing

The material used in the SPARC™ Sling System has been demonstrated to be biocompatible.

The SPARC™ Sling System has been tested for a variety of physical characteristics including tensile strength and suture pull strength and has been shown to be equivalent to the listed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2001

Ms. Ginger Sackett Glaser
Senior Regulatory Affairs Specialist
American Medical Systems, Inc.
10700 Bren Road West
Minnetonka, Minnesota 55343

Re: K011251
Trade/Device Name: SPARC™ Sling System
Regulation Number: 878.3300
Regulatory Class: II
Product Code: FTL
Dated: June 12, 2001
Received: June 13, 2001

Dear Ms. Glasser:

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 legally marketed predicate 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) 594-4659. 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" (21CFR 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,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011251

Device Name: SPARC™ Sling System

Indications For Use:

The SPARC™ Sling System is intended for the placement of a pubourethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011251

(Optional Format 3-10-98)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2001

Ms. Ginger Sackett Glaser
Senior Regulatory Affairs Specialist
American Medical Systems, Inc.
10700 Bren Road West
Minnetonka, Minnesota 55343

Re: K011251
Trade/Device Name: SPARC™ Sling System
Regulation Number: 878.3300
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Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011251

Device Name: SPARC™ Sling System

Indications For Use:

The SPARC™ Sling System is intended for the placement of a pubourethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011251

(Optional Format 3-10-98)

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service, Food and Drug Administration

From: Reviewer(s) - Name(s) ANTHONY D. WATSON DXK — Memorandum

Subject: 510(k) Number K011251 - 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).
- ☒ Is substantially equivalent to marketed devices. Use standard SE Letter
- ☐ NOT substantially equivalent to marketed devices.
  - De Novo Classification Candidate? ☐ YES ☐ NO
- ☐ 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)? Please fill out form on H Drive 510k/boilers	☐ 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)

Material of Biological Origin ☐ YES ☒ NO

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: 21 CFR 878.3300 Suture, MQM, 79FTL / CLASS II

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

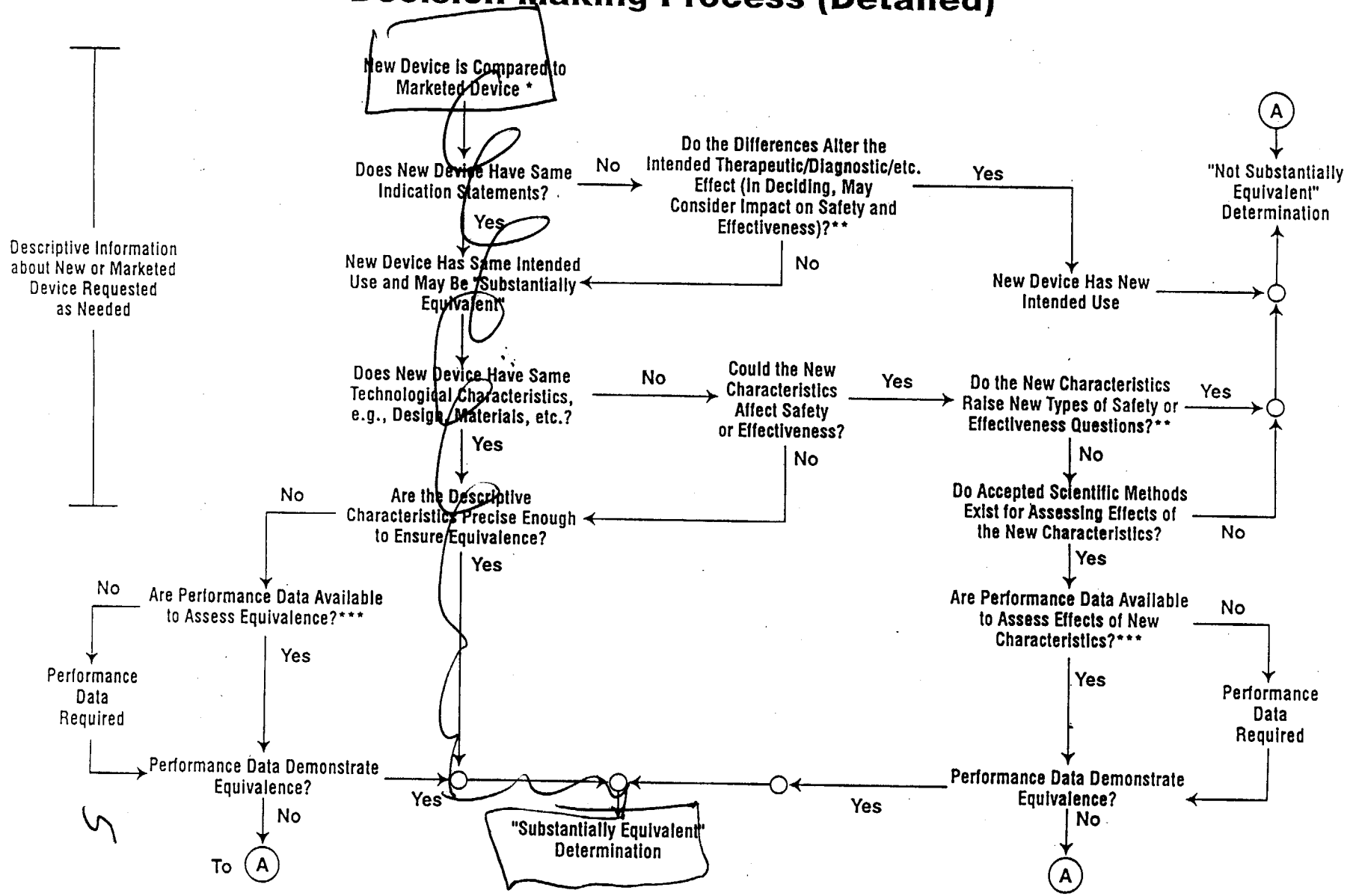
Review: Steve Rhodes (Branch Chief) — PCSB (Branch Code) — 7/31/01 (Date)

Final Review: Mark N Melkerson (Division Director) — 8/1/01 (Date)

4

Revised:8/17//99

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.

REVISED:3/14/95

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

K011251/S1

Reviewer: Anthony D. Watson

Division/Branch: DGRND/PRSB

Device Name: SPARC™ Sling System

Product To Which Compared (510(K) Number If Known): K974098

	YES	NO	
1. Is Product A Device	**X**		If **NO** = Stop
2. Is Device Subject To 510(k)?	**X**		If **NO** = Stop
3. Same Indication Statement?	**X**		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?	**X**		If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?	**X**		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.

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1. Intended Use: **See review.**

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 over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important. **See review.**

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

MEMO TO THE RECORD
510(K) REVIEW
K011251/S1

DATE: July 27, 2001 **OFFICE:** HFZ-410

FROM: Materials Engineer **DIVISION:** DGRD/PRSB

DEVICE NAME: SPARC™ Sling System

COMPANY NAME: American Medical Systems

NARRATIVE DEVICE DESCRIPTION

1. **INTENDED USE:** The system is intended for the placement of pubourethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency. **This indication statement is identical to predicate devices.**

2. **GENERAL INFORMATION:**

a) Is the device:

1. Life-supporting or life-sustaining? No.
2. Implant (short-term or long-term)? Yes.
3. Software-driven? No.
4. Sterile? Yes.
5. Single use? Yes.
6. For home or prescription use? Prescription.
7. Contain a drug or biologic component? No.
8. A kit? No.

b) Device(s) to which equivalence is claimed and its manufacturer(s):

(1) **Tension-Free Vaginal Tape (TVT)** (K974098) by Ethicon, Inc.

3. **SUMMARY**

(Summary consists of a description of the device's design, materials, physical properties, and toxicology profile).

a) **MATERIALS, DEVICE DESCRIPTION, AND TOXICOLOGY:** The device is a sterile, single use procedure system consisting of:

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- Two stainless steel curved, 22 cm long needle passers (also called insertion tools in this submission). Each end of the needle passer is keyed to allow for secure placement of the handles and dilators. Each needle passer has a plastic, ergonomic, rotatable handle attached. The handles of the passer can be rotated in 90° increments, allowing the surgeon to customize the handle/needle positioning.

  Each needle passer consists of 2 major components:

  1. An ergonomically shaped handle made from (b)(4) (b)(4) Each handle has a release button designed to allow needle placement in 90° increments.
  2. An 8.6" needle made from (b) stainless steel, shaped at one end to allow handle attachment and at the other end to allow attachment of the dilator.

- One piece of AMS polypropylene sling mesh with (b)(4) dilating connectors. The AMS polypropylene sling mesh is constructed of polypropylene monofilament that is precut to a 1.0 cm or 1.1 cm width x 50 cm length. The mesh is designed to have bi-directional elasticity to allow adaptation to various stresses encountered when placed as a urethral "backstop" to treat stress urinary incontinence. A fixed blue polypropylene anchoring suture (tensioning suture) runs through the middle of the sling mesh. The suture is used to prevent the sling from stretching prior to final placement of the sling mesh. Once placement is finalized the suture is cut and the loose portion is removed from the patient. Two plastic sheaths that overlap in the center of the sling mesh, cover the sling mesh, and protect it during placement. The plastic sheaths covering the sling mesh initially are designed to minimize the risk of contamination.

  Dilating connectors are attached to either end of the plastic sheaths. The dilating connectors are used to attach to the vaginal ends of the needle passers during the procedure to facilitate sling placement. The AMS polypropylene sling mesh is intended to remain in the body as a permanent implant.

- Two blue colored plastic cytoscopy aids are included in the system in order to facilitate cytoscopic viewing of the bladder. The use of these aids is optional.

Mr. Keith Foy reviewed the original submission.

This system is functionally similar to the TVT System. However, the procedure involves a suprapubic approach as compared to the TVT system, which uses a vaginal approach. Mr. Foy noted this in the original submission. However, he also noted that some of the data had inconsistencies, and the data demonstrated that the device had lower strength properties than the predicate device.

The sponsor states that the discovered that the Instron machine was not functioning properly during the original testing. Therefore, the exact values were incorrect for elongation, although

the relative differences were accurate. The strength values were unaffected by this error, however.

The sponsor has provided the complete test reports with the test conditions. The sponsor also states that lower strength values were a result of inconsistencies in the gage length of the samples from different (b)(4) operators. For this supplement, they used the same operator for all the samples, and the results were much closer between their device and the predicate device. In fact, all the values were very close, including elongation. This time around, however, the SPARC mesh appears to be stringer and more elastic than the TVT mesh.

The sponsor makes a case why ultimate tensile strength (UTS) and ultimate elongation are not clinically relevant factors for a mesh. They base this statement on the fact that the actual forces seen clinically are very small. The most likely event to cause a urinary stress is a cough or other pressure event. Literature previously provided by the sponsor indicates that only about 47% of the pressure from a cough gets transferred to the sling. This indicates that the maximum theoretical force that may be encountered by the sling at a 14mm urethra would be approximately 0.886 lb. The original calculation assumed that 100% of the force would be transferred to the sling. Therefore, there is a factor of 10 between theoretical clinical force and UTS. The argument appears to be reasonable to me. Therefore, I believe the issue of tensile strength has been addressed adequately.

The sponsor also provided photos of both their mesh and TVT mesh being stressed at 0. 2, 5, 10, and 13 pounds. In the range of 0-5 pounds, which is well within the theoretical range discussed above, the mesh fibers do not seem to be highly stressed. However, due to the spring-like nature of the fibers, they appear to present slightly rough edges. Ironically, as the meshes continue to be stressed, these rough edges smooth out for the most part. Overall, the photos seem to indicate that they behave similarly when applied to stresses well beyond the theoretical maximum clinical stresses.

It is my opinion that the sponsor adequately addressed Mr. Foy's concerns. Therefore, I recommend that this device be found substantially equivalent to the TVT system.

b) **STERILITY:** The device is sterilized by (b)(4) The sponsor has provided the levels of (b) nd they do not exceed the maximum levels promulgated by the FDA. The process is validated in accordance with ANSI/AAMI/ISO standards.

c) **PACKAGING:** The system is packaged in a double sterile barrier pouch system. A PETG insert is used to hold the components in place inside the pouches. The sling and dilators are coiled in a separate lexan tray that inserts into the PETG insert but is not intended as a sterile barrier. The insert with the tools and tray is placed into an inner pouch, which is sealed and then placed into the outer pouch. Both pouches are composed of a combination of Tyvek and polyethylene.

d) **LABELING:** The labeling is satisfactory and consistent with other similar devices.

e) **SAFETY AND EFFECTIVENESS INFORMATION:** The sponsor has included a summary of safety and effectiveness information in the submission.

f) **RECOMMENDATION:** Substantially equivalent to **Tension-Free Vaginal Tape (TVT)** (K974098) by Ethicon, Inc., 79 FTL (Surgical Mesh).

g) **CLASSIFICATION:** 21 CFR 878.3300, Class II.

Anthony D. Watson, BSGE
Reviewer
Division of General and Restorative Devices
Plastic and Reconstructive Surgery Branch

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

June 13, 2001

AMERICAN MEDICAL SYSTEMS, INC.
10700 BREN RD., WEST
MINNETONKA, MN 55343
ATTN: GINGER S. GLASER

510(k) Number: K011251
Product: SPARC SLING SYSTEM

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

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K011251-51

AMERICAN MEDICAL SYSTEMS

June 12, 2001

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

Re: K011251 - SPARC™ Sling System

This letter addresses the deficiencies raised regarding the above referenced 510(k) in a fax dated May 25, 2001. In response to this request, AMS performed additional testing in order to complete the table as requested.

Please notice that during the course of this testing, we found evidence that the extensiometer on the Instron machine was not functioning properly during the testing presented originally in K0111251, on page 10. This means that that while the relative values presented for elongation of both SPARC™ and TVT are most likely accurate in the original submission (i.e., elongation increases with increased force and TVT elongated less than SPARC™), there is no way to determine the exact elongation values. Thus, the elongation values presented in the original 510(k) should be considered incorrect. However, the pull forces presented in the original submission were accurate, because the force is a controlled value and not calculated by the extensiometer.

(b)(4)

[redacted]

The data collected in this new testing is presented in Table 1.

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10700 Bren Road West
Minnetonka, MN 55343
Tel: 952.933.4666
Toll Free: 800.328.3881
Fax: 952.930.6157

SK9

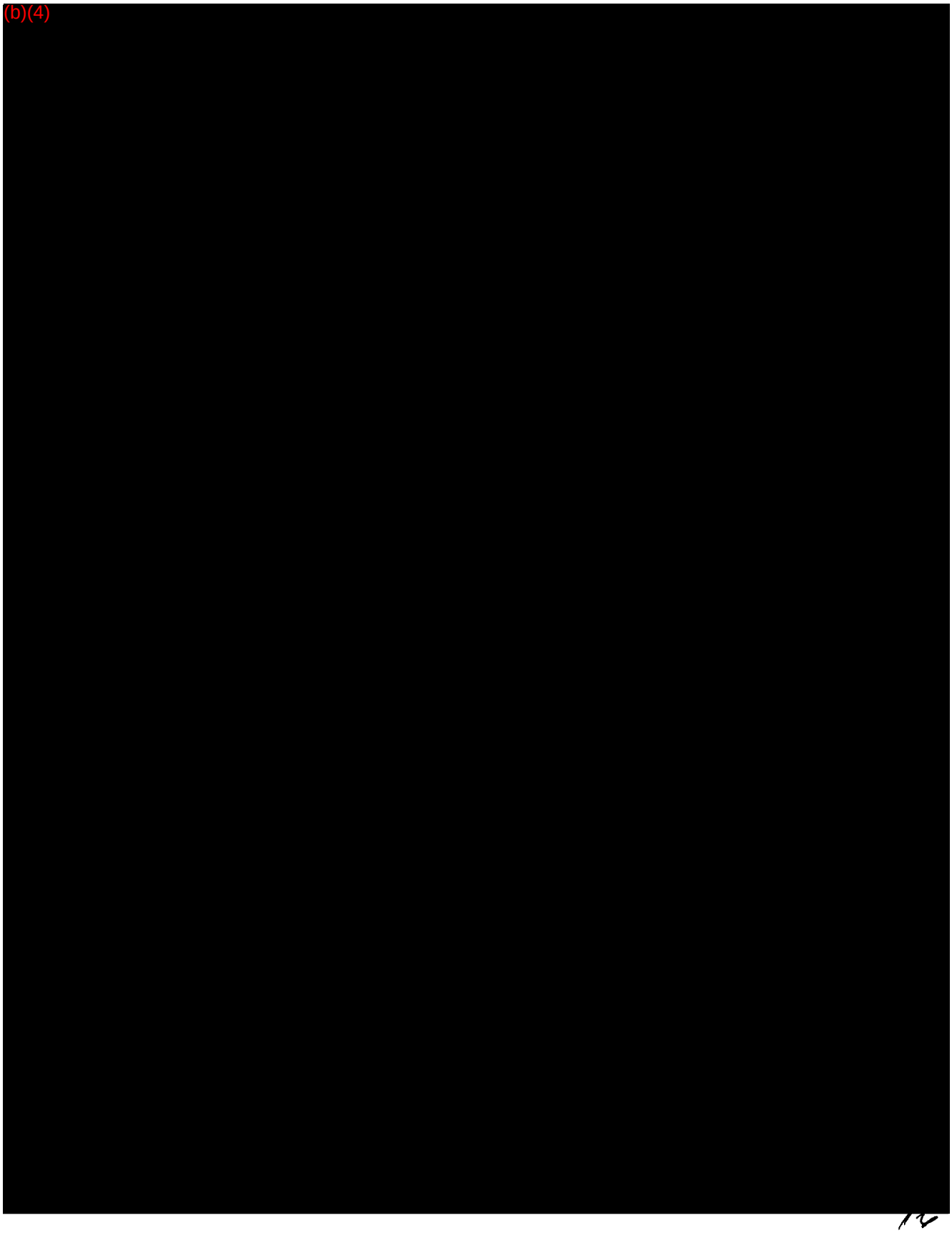
Table 1
SPARC™ vs. TVT Mechanical Testing with New Test Samples

(b)(4)

(b)(4)

[redacted]

15


(b)(4)

(b)(4)

[redacted]

As with the original 510(k), AMS considers this data to be confidential trade secret information and requests that it be treated as such. Should you have any further questions regarding this response or the remainder of K011251, please contact me via phone, fax or email.

Sincerely,

Ginger Sackett Glaser
Sr. Regulatory Affairs Specialist

Phone: (952) 930-6541
Fax: (952) 930-6496
Email: ginger.glaser@visitams.com

17

Exhibit I

Burst Strength Equivalency Data

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

Exhibit II

ANOVA for SPARC™ & TVT
Burst Strength and Ultimate Elongation -

Based on New Data

(b)(4) Testing

(b)(4) Testing

Exhibit III

Photographs of SPARC™ and TVT Mesh
At Various Pull Forces

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

SPARC™

Production Mesh Sample

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

SPARC™

Engineering Sample

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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Radiological Health
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June 01, 2001

AMERICAN MEDICAL SYSTEMS, INC.
10700 BREN RD., WEST
MINNETONKA, MN 55343
ATTN: GINGER S. GLASER

510(k) Number: K011251
Product: SPARC SLING SYSTEM

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate 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 telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

If after 30 days the requested information, or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

DATE 5-25-01

Memorandum

om: Reviewer(s) - Name(s) KEITH Fay DXK

Subject: 510(k) Number K011251

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

- ☐ Refused to accept.
- ☒ Requires additional information (other than refuse to accept). Phone hold
- ☐ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
  - De Novo Classification Candidate? ☐ YES ☐ NO
- ☐ 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)? Please fill out form on H Drive 510k/boilers	☐ 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

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

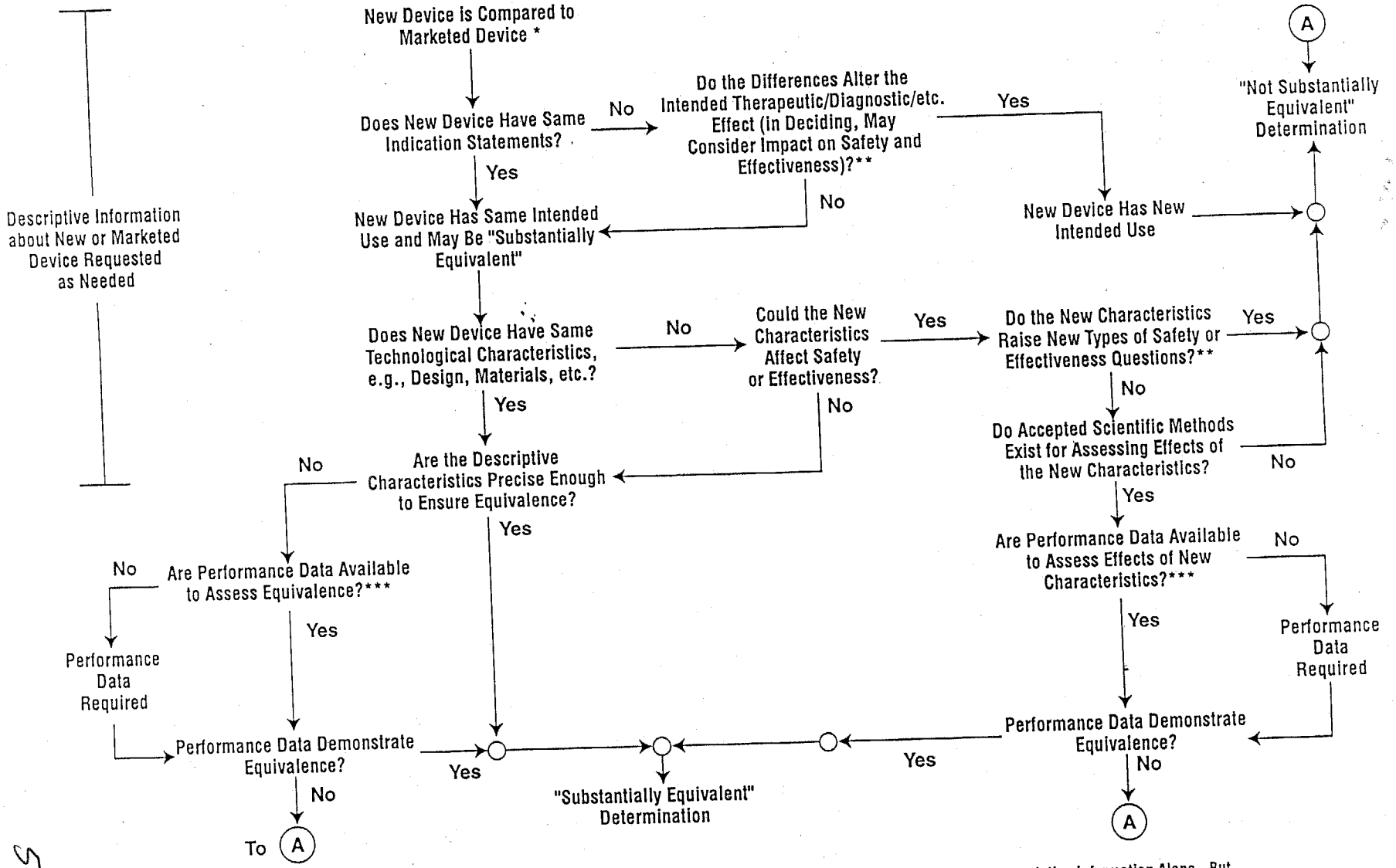
Review: Steph Rhode (Branch Chief) PRSB (Branch Code) 5/31/01 (Date)

Final Review: _____ (Division Director) (Date)

55

Revised:8/17//99

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.

K011251

Reviewer: Keith Foy, MS
Materials/Mechanical Engineer
Division/Branch: DGRD/PRSB
(HFZ-470)

Proprietary Trade Name: SPARC™ Sling System
Common Name: Surgical Mesh
Procode: § 878.3300, FTL Surgical Mesh, Polymeric, Class II
Product(s) to which compared:
(K974098) – Tension Free Vaginal Tape (TVT) Ethicon, Inc.
(K972651) – In-SLING, Influence, Inc.

Applicant: American Medical Systems
10700 Bren Rd. W.
Minnetonka, MN 55343
Contact: Ginger Sackett Glaser, Sr. Regulatory Affairs Specialist
Phone: (952) 930-6541 **FAX:** (952) 930-6496

Indications for Use

The SPARC™ Sling System is intended for the placement of a pubourethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

- Per the clinician's comments and from a review of the predicate, this indications statement is acceptable.

	YES	NO
· Is the device life-supporting or life sustaining?	___	X
· Is the device implanted (short-term or **long-term**)?	X	___
· Does the device design use software?	___	X
· Is the device sterile?	X	___
· Is the device single use?	X	___
· Is the device home use?	___	X
· Is the device for prescription?	X	___
· Does the device contain a drug or biological product as a component?	___	X
· Is this device a kit?	___	X

Device Description

The SPARC™ Sling System is a sterile, single use polypropylene (PP) sling mesh w/ SS needles, needle passer, dilating connectors, suture anchor (tensioning suture) and blue colored plastic cystoscopy "viewing aids". The PP sling is ~ 50 cm long, 1-1.1 cm wide and 0.0236" thick. Mesh pore size was identified as 0.061" x 0.047".

- In the performance testing under a) Suture Pull Strength, the sponsor stated that the device is an

anchorless urethral sling system and that sutures should never be attached to the device. This was in reference to additional sutures, different from the tensioning suture included into the device.

Performance Testing (May 22nd emailed test data and page 9, section D)

(b)(4) Testing

[redacted]

Sterilization/ (Appendix G)

(b)(4) Testing

[redacted]

(b)(4) Testing

[redacted]

Shelf-life (page 31)

(b)(4) Testing

[redacted]

Biocompatibility (pages 19-30)

The sponsor supplied various biocompatibility tests, for each of the device components. These results supported the biocompatibility of the device. Furthermore, the predicate device also is a PP material mesh. No issues.

Predicate Comparison (Tables 1 - 7)

The sponsor supplied a number of comparisons to the TVT predicate (K974098). The comparisons included physical, procedural, and performance attributes of each device.

The SPARC Sling was identified in Table 1 & 2 as having:

- a slightly longer mesh (50 cm rather than 45 cm);
- a slightly thinner mesh (0.0236" vs 0.0252" measured);
- a slightly smaller pore size (0.061" x 0.047" versus 0.061" x 0.049");
- a slightly smaller sling density (0.167 g/cm^3 vs 0.172 g/cm^3), and
- as using a slightly larger insertion tool (22 cm vs 18 cm).

On page 5 the procedural differences were summarized. Basically, this device uses a suprapubic approach rather than a vaginal approach. The sponsor stated that this gives the physician better control/positioning/visibility.

- I've advised the sponsor that this statement that I do not consider this a marketing/labeling superiority claim that has been supported. It's essentially a matter of procedural/clinical opinion.

Labeling

(b) (6) commented that the labeling instructions were clear and pertinent. No issues remain.

Review Analysis

The device uses a previously cleared polypropylene mesh (K915526) and an introducer/stylette system that is similar to the TVT predicate (K974098).

(b) (6) provided a clinical consult and had no recommendations/changes to make.
(b) (6) comments are attached.

(b)(4)

Reviewer Recommendation Phone Hold

ProCode: FTL Surgical Mesh, Polymeric
Class: Class II
CFR: §878.3300

Keith Foy, MS
Materials Engineer, PRSB

Date May 25, 2001

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K011251

Office of Device Evaluation
9200 Corporate Blvd.
Rockville, MD 20850

Fax

To: Ginger Sackett Glaser **From:** Keith E. Foy

Fax: (952) 930-6496 **Pages:** 2

Phone: (952) 930-6541 **Date:** May 25, 2001

Re: K011251, SPARC™ Sling System **CC:**

☐ **Urgent** ☐ **For Review** ☐ **Please Comment** X **Please Reply** ☐ **Please Recycle**

● **Comments:**

Ms. Glaser,
Please respond to the following deficiency.

(b)(4)

[redacted]

May 25, 2001

K011251

(b)(4) [redacted]

Your document has been placed on hold until a hard-copy of your responses is received. Once received, the document will automatically be released and I will review your document immediately.

Please call if I can be of assistance.

Keith Foy
(301) 594-3090 x132

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****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	1014
CONNECTION TEL	919529306496
SUBADDRESS	
CONNECTION ID	
ST. TIME	05/25 14:45
USAGE T	00'54
PGS. SENT	2
RESULT	OK

Office of Device Evaluation
9200 Corporate Blvd.
Rockville, MD 20850

Fax

To: Ginger Sackett Glaser **From:** Keith E. Foy

Fax: (952) 930-6496 **Pages:** 2

Phone: (952) 930-6541 **Date:** May 25, 2001

Re: K011251, SPARC™ Sling System **CC:**

☐ **Urgent** ☐ **For Review** ☐ **Please Comment** X **Please Reply** ☐ **Please Recycle**

• **Comments:**

Ms. Glaser,
Please respond to the following deficiency.

(b)(4)

[redacted]

Foy, Keith

From: Ginger Glaser [Ginger.Glaser@visitams.com]
Sent: Tuesday, May 22, 2001 9:30 AM
To: KXF@CDRH.FDA.GOV
Subject: SPARC Tension Testing - K011251

Keith,

(b)(4) [redacted]

Sincerely,

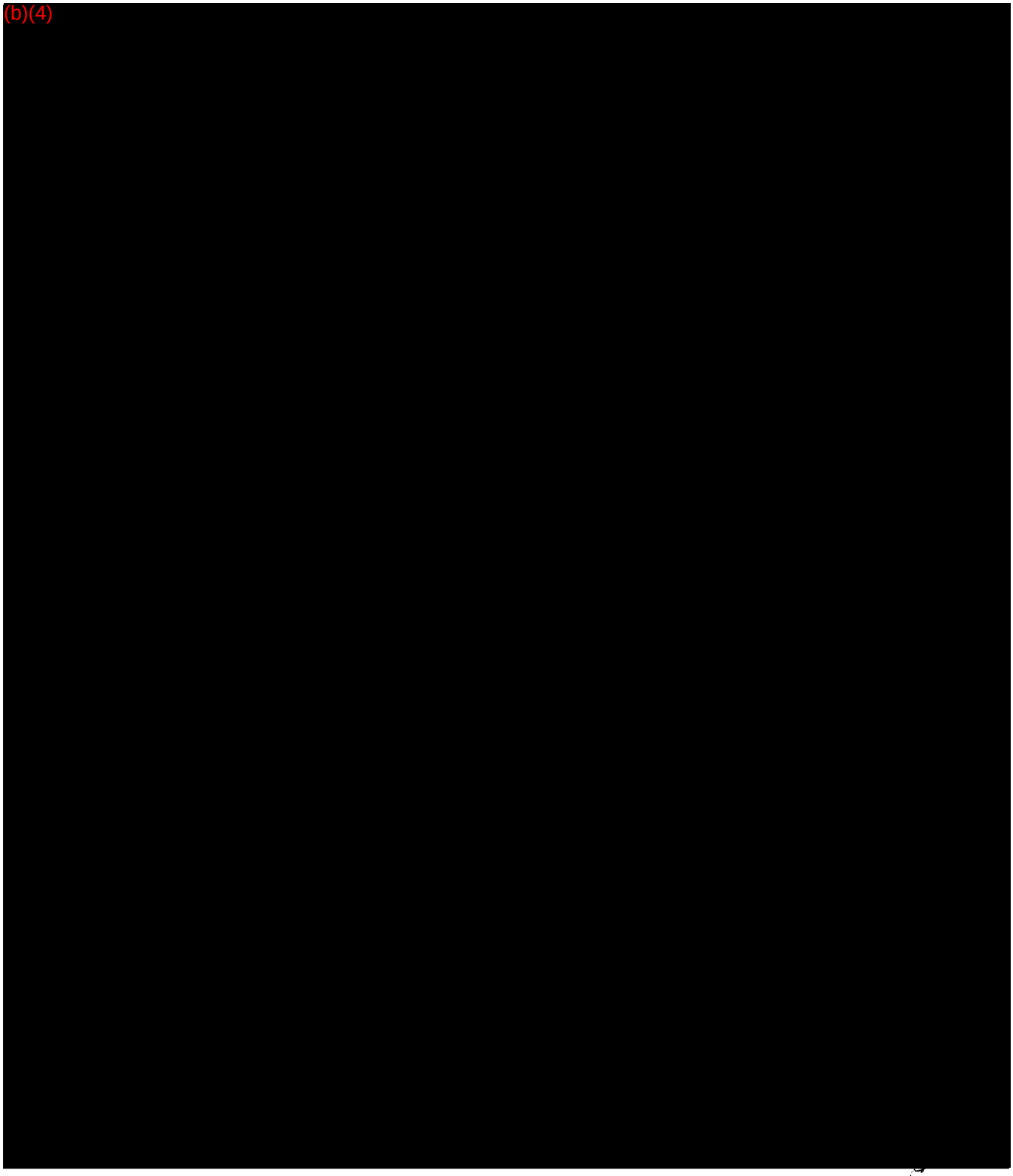
Ginger Sackett Glaser
Sr. Regulatory Affairs Specialist
American Medical Systems

mech_response.doc

AMERICAN MEDICAL SYSTEMS

May 22, 2001

(b)(4)



Foy, Keith

From: Ginger Glaser [Ginger.Glaser@visitams.com]
Sent: Friday, May 18, 2001 1:10 PM
To: KXF@CDRH.FDA.GOV
Subject: SPARC Shelf Life (K011251)

Keith,

(b)(4)

[redacted]

Sincerely,

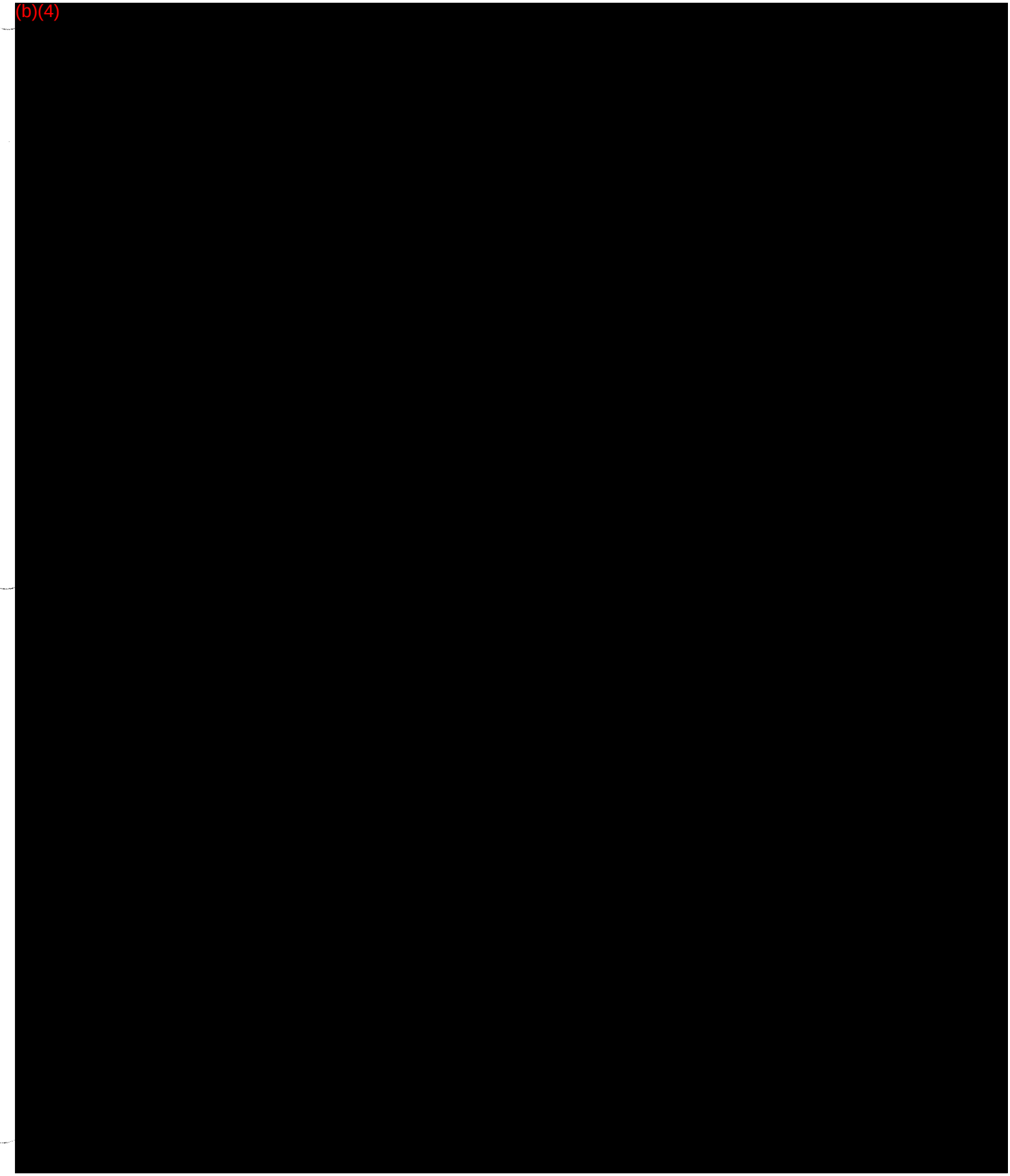
Ginger Sackett Glaser
Sr. Regulatory Affairs Specialist
American Medical Systems

shelf_life_rationale.doc

66

SPARC™ System Shelf Life

(b)(4)



Date: May 10, 2001

From: (b)(4) [redacted]
DRARD/ULDB/ODE

To: Keith E. Foy
ODE/DGRD

Subject: K011251
Spark Sling System
American Medical System

CONSULTATION

I have conducted a clinical and labeling review of this 510(k) and I have the following comments to make.

Device Description:

The SPARC ™ Sling System is a sterile, single-use procedure kit consisting of two stainless steel, curved, 22-cm long, needle passers. Each needle passer has a plastic, ergonomic rotatable handle attached, made from acetal, has also a 8.6" needle made from 316 stainless steel shaped on one end to allow handle attachment.
One piece of AMS Polypropylene sling mesh with attached texapol dilating connectors. There is a fixed blue polypropylene anchoring suture that runs through the middle of the sling mesh (prevents the sling from stretching prior to final placement). Dilating connectors are attached to the vaginal ends of the needle passers during the sling placement.
Two blue colored plastic cystoscopy aids are included in the kit to facilitate cystoscopic viewing of the bladder (use is optional).

Intended Use
The SPARC is intended for the placement of pubo-urethral sling for the treatment of female urinary incontinence(SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Comments

From Urological stand point and in accordance to previous cleared devices for the same indication: the device indications are correct, the description of the procedure for using the device are clear and pertinent.

From the clinical stand point, I do not have any objections for approval of this submission for marketing.

(b) (6)

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

April 24, 2001

AMERICAN MEDICAL SYSTEMS, INC.
10700 BREN RD., WEST
MINNETONKA, MN 55343
ATTN: GINGER S. GLASER

510(k) Number: K011251
Received: 24-APR-2001
Product: SPARC SLING SYSTEM

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,

10

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

K011251

AMERICAN MEDICAL SYSTEMS

April 23, 2001

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

Re: Section 510(k) Premarket Notification

Pursuant to 21 CFR 807.81, enclosed are 2 copies of the 510(k) Premarket Notification for American Medical Systems' SPARC™ Sling System. This notification is intended to inform the Food and Drug Administration of American Medical Systems' intent to market the SPARC™ Sling System, which is substantially equivalent to other urethral slings and surgical meshes currently available through interstate commerce.

This information, and the existence of this notification, is considered confidential, trade secret information. As such, we request the existence of this supplement be kept confidential pursuant to 21 CFR 807.95. Should you have any questions regarding this amendment, please feel free to contact me by phone, fax or email.

Sincerely,

Ginger Sackett Glaser

Ginger Sackett Glaser
Sr. Regulatory Affairs Specialist

Phone: (952) 930-6541
Fax: (952) 930-6496
Email: ginger.glaser@visitams.com

SU II

FDA/CDRH/ODE/DSC

71

10700 Bren Road West
Minnetonka, MN 55343
Tel: 952.933.4666
Toll Free: 800.328.3881
Fax: 952.930.6157

SK1

CDRH Submission Cover Sheet

Date of Submission:

FDA Document Number:

Section A Type of Submission

PMA	PMA Supplement	PDP	510(k)	Meeting
☐ Original submission ☐ Modular submission ☐ Amendment ☐ Report ☐ Report Amendment	☐ Regular ☐ Special ☐ Panel Track ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA Supplement	☐ Presubmission summary ☐ Original PDP ☐ Notice of intent to start clinical trials ☐ Intention to submit Notice of Completion ☐ Notice of Completion ☐ Amendment to PDP ☐ Report	☑ Original submission: ☑ Traditional ☐ Special ☐ Abbreviated ☐ Additional information: ☐ Traditional ☐ Special ☐ Abbreviated	☐ Pre-IDE meeting ☐ Pre-PMA meeting ☐ Pre-PDP meeting ☐ 180-day meeting ☐ Other (specify):

IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	Other Submission
☐ Original submission ☐ Amendment ☐ Supplement	☐ Original submission ☐ Amendment ☐ Supplement ☐ Report	☐ Original submission ☐ Additional information	☐ Original submission ☐ Additional information	Describe submission:

Section B Applicant or Sponsor

Company / Institution name: American Medical Systems

Establishment registration number: 2183959

Division name (if applicable):

Phone number (include area code): (952) 930-6541

Street address: 10700 Bren Rd. West

FAX number (include area code): (952) 930-6496

City: Minnetonka State / Province MN Country: USA

Contact name: Ginger Sackett Glaser

Contact title: Sr. Regulatory Affairs Specialist

Contact e-mail address: ginger.glaser@visitams.com

Section C Submission correspondent (if different from above)

Company / Institution name:

Establishment registration number:

Division name (if applicable):

Phone number (include area code): ( )

Street address:

FAX number (include area code): ( )

City: State / Province: Country:

Contact name:

Contact title:

Contact e-mail address:

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Section D1 — Reason for Submission — PMA, PDP, or HDE

- ☐ New device
- ☐ Withdrawal
- ☐ Additional or expanded indications
- ☐ Licensing agreement

- ☐ Process change
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other (specify below)

- ☐ Response to FDA correspondence:
  - ☐ Request for applicant hold
  - ☐ Request for removal of applicant hold
  - ☐ Request for extension
  - ☐ Request to remove or add manufacturing site

- ☐ Other reason (specify):

- ☐ Change in design, component, or specification:
  - ☐ Software
- ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
- ☐ Other (specify below)

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
- ☐ Shelf life
- ☐ Trade name
- ☐ Other (specify below)

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Distributor

- ☐ Report submission:
  - ☐ Annual or periodic
  - ☐ Post-approval study
  - ☐ Adverse reaction
- ☐ Device defect
- ☐ Amendment

- ☐ Change in ownership
  - ☐ Change in correspondent

Section D2 — Reason for Submission — IDE

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion / extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Notification of emergency use
- ☐ Compassionate use request
- ☐ Treatment IDE
- ☐ Continuing availability request

- ☐ Other reason (specify):

- ☐ Change in:
  - ☐ Correspondent
  - ☐ Design
  - ☐ Informed consent
  - ☐ Manufacturer
  - ☐ Manufacturing process
  - ☐ Protocol – feasibility
  - ☐ Protocol – other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current investigator
  - ☐ Annual progress
  - ☐ Site waiver limit reached
  - ☐ Final

- ☐ Response to FDA letter concerning:
  - ☐ Conditional approval
  - ☐ Deemed approved
  - ☐ Deficient final report
  - ☐ Deficient progress report
  - ☐ Deficient investigator report
  - ☐ Disapproval
  - ☐ Request extension of time to respond to FDA
  - ☐ Request meeting

Section D3 — Reason for Submission — 510(k)

- ☑ New device
- ☐ Additional or expanded indications
- ☐ Other reason (specify):

- ☐ Change in technology
- ☐ Change in design

- ☐ Change in materials
- ☐ Change in manufacturing process

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Section E Additional Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

1 FTL	2	3	4
5	6	7	8

Summary of, or statement concerning, safety and effectiveness data:
☑ 510(k) summary attached
☐ 510(k) statement

Information on devices to which substantial equivalence is claimed:

	510(k) Number	Trade or proprietary or model name	Manufacturer
1	K974098	Tension Free Vaginal Tape (TVT) System	Ethicon Division of Johnson & Johnson
2			
3			
4			
5			
6			

Section F Product Information — Applicable to All Applications

Common or usual name or classification name:

	Trade or proprietary or model name	Model number
1	SPARC Sling System	NA
2		
3		
4		
5		

FDA document numbers of all prior related submissions (regardless of outcome):

1	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: ☑ Laboratory testing ☑ Animal trials ☐ Human trials

Section G Product Classification — Applicable to All Applications

Product code FTL | C.F.R. Section: 878.3300

Classification panel: General and Plastic Surgery

Device class:
☐ Class I ☑ Class II
☐ Class III ☐ Unclassified

Indications (from labeling):
The SPARC™ Sling System is intended for the placement of a pubourethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

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Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number:

Section H Manufacturing / Packaging / Sterilization Sites Relating to a Submission

☑ Original ☐ Add ☐ Delete	FDA establishment registration number:	☑ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name: American Medical Systems		Establishment registration number: 2183959	
Division name (if applicable):		Phone number (include area code): (952) 930-6541	
Street address: 10700 Bren Rd. West		FAX number (include area code): (952) 930-6496	
City: Minnetonka	State / Province: MN		Country: USA
Contact name: Ginger Sackett Glaser			
Contact title: Sr. Regulatory Affairs Specialist		Contact e-mail address: ginger.glaser@visitams.com	
☑ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☑ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name: (b)(4) [redacted]		Establishment registration number:	
Division name (if applicable):		Phone number (include area code): ( )	
(b)(4) [redacted]		FAX number (include area code): ( )	
(b)(4) [redacted]			Country: USA
Contact name:			
Contact title:		Contact e-mail address:	
☑ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☑ Contract sterilizer ☐ Repackager / relabeler
(b)(4) [redacted]			
Contact name:			
Contact title:		Contact e-mail address:	

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510(k) Number (if known): K011251

Device Name: SPARC™ Sling System

Indications For Use:

The SPARC™ Sling System is intended for the placement of a pubourethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

SPARC™ Sling System

Premarket Notification [510(k)]

American Medical Systems

April 23, 2001

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SPARC™ Sling System 510(k)

I. General Information

A. Product Identification

Trade Name: SPARC™ Sling System
Common/Usual Name: Surgical Mesh, Sling, Urethral Sling
Classification Name: Surgical Mesh, polymeric
Product Code: FTL

B. Manufacturing Location

American Medical Systems, Inc.
10700 Bren Rd. West
Minnetonka, MN 55343

C. Establishment Registration Number

The establishment registration number for American Medical Systems is 2183959.

D. Device Classification

According to 21 CFR 878.3300, the FDA has classified surgical mesh as a Class II device.

E. Performance Standards

The FDA has established no performance standards applicable to surgical mesh.

F. Contact Person

Ginger Sackett Glaser
Sr. Regulatory Affairs Specialist
American Medical Systems
10700 Bren Rd. W
Minnetonka, MN 55343

Phone: (952) 930-6541
Fax: (952) 930-6496
Email: ginger.glaser@visitams.com

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II. Substantial Equivalence Information

A. Predicate Devices

Tension Free Vaginal Tape (TVT) System by Ethicon, Inc. - K974098

B. Indications for Use

The SPARC™ Sling System is intended for the placement of a pubourethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

According to the 510(k) summary and available labeling, this indication is the same as that for the Ethicon Tension Free Vaginal Tape (TVT) System. For copies of the predicate labeling see Appendix A. A copy of the relevant 510(k) summary is included in Appendix B.

C. Device Description

1. General Description

As shown in Appendix C, the SPARC™ Sling System is a sterile, single use procedure kit consisting of:

- Two stainless steel, curved, 22-cm long, needle passers (also called insertion tools in this submission). Each end of the needle passer is keyed to allow for secure placement of the handles and dilators. Each needle passer has a plastic, ergonomic rotatable handle attached. The handles of the needle passers can be rotated in 90° increments, allowing the surgeon to customize the handle/needle positioning.

  Each needle passer consists of 2 major components:

  1. An ergonomically shaped handle made from (b)(4) (b)(4) Each handle has a release button designed to allow needle placement in 90° increments.
  2. A 8.6" needle made (b)(4) stainless steel, shaped at one end to allow handle attachment and at the other end to allow attachment of the dilator

- One piece of AMS Polypropylene sling mesh with (b)(4) dilating connectors. The AMS Polypropylene sling mesh is constructed of polypropylene monofilament that is precut to a 1.0cm

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or 1.1 cm width x 50cm length. The mesh is designed to have bi-directional elasticity to allow adaptation to the various stresses encountered when placed as a urethral "backstop" to treat stress urinary incontinence. A fixed blue polypropylene anchoring suture (also called a tensioning suture) runs through the middle of the sling mesh. This suture is used to prevent the sling from stretching prior to final placement of the sling mesh. Once placement is finalized the suture is cut and the loose portion is removed from the patient. Two plastic sheaths that overlap in the center of the sling mesh, cover the sling mesh and protect it during placement. The plastic sheaths covering the sling mesh initially are designed to minimize the risk of contamination.

Dilating connectors are attached to either end of the plastic sheaths. The dilating connectors are used to attach to the vaginal ends of the SPARC™ needle passers during the procedure to facilitate sling placement. The AMS Polypropylene sling mesh is intended to remain in the body as a permanent implant and is not absorbed or degraded by the action of tissue ingrowth or tissue enzymes.

- Two blue colored plastic cystoscopy aids are included in the kit in order to facilitate cystoscopic viewing of the bladder. The use of these cystoscopy aids is optional.

This configuration is similar to the TVT System, which also consists of an implantable polypropylene sling mesh that is covered with a plastic sheath during the implantation procedure, a stainless steel insertion tool with handle, and other accessories. As with the SPARC™ mesh, the TVT mesh has a bi-directional elasticity due to the mesh weave. With the TVT System, the mesh comes preconnected to the insertion tool, rather than using a dilator to make the attachment after passing the needles through the body.

Table 1 compares physical features of the SPARC™ Sling System and the predicate TVT.

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Table 1
Comparison of Physical Features of SPARC™ Sling System and TVT

Feature	SPARC™ Sling System	TVT
Sling Mesh Material	polypropylene	polypropylene
Sling Mesh Size	50 cm x 1 cm (or 1.1 cm)	45 cm x 1.1 cm
Sling Mesh thickness	0.0236"	0.027" (labeled)) 0.0252" (measured)
Sling Mesh Pore size	0.061" x 0.047"	0.061" x 0.049"
Sling Density	0.167 g/cm^3	0.172 g/cm^3
Polypropylene yarn width	6 mil (0.006")	6 mm (0.006")
2-piece Plastic Sheath covers Mesh	Yes	Yes
Plastic Sheath Material	polyethylene	polyethylene
Anchor suture to allow adjustment after sheath removal	Yes	No
Sterilization	(b)	(b)
Resterilization ok?	No	No
Insertion Tool Length	22 cm	18 cm
Maximum Tool Diameter	0.26"	0.26"
Insertion Tool Material	(b) Stainless Steel	Stainless steel

Figure 1 shows a picture of the SPARC™ Sling System Mesh and the TVT Mesh, demonstrating the equivalent nature of the mesh materials. The SPARC™ Mesh was called SST during development work and is labeled as such on the picture.

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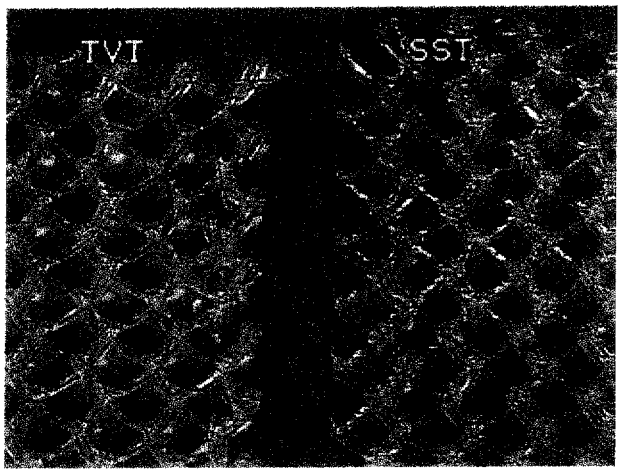

Figure 1
Comparison of SPARC™ and TVT Mesh

2. SPARC™ Procedure Description

Like the predicate procedure, the SPARC™ procedure can be carried out under local, spinal or general anesthesia. When local anesthesia is used, the patient may assist the physician in properly placing the sling by coughing, which allows the physician to position the sling mesh where no urine leakage is seen. Like with TVT, the dissection required is minimal. A small transverse incision is made in the anterior vaginal wall followed by paraurethral dissection. Two small transverse suprapubic incisions are also made for needle entry. At the physician's discretion, a larger, single incision may be used. The needle passers are passed through the suprapubic incision and exited through the vaginal incision(s). Placement of the TVT mesh also requires small vaginal and suprapubic incisions. However, in that system the needles are entered through the vaginal incision and exited through the suprapubic incision. This is one of the major differences in the two devices.

AMS has designed to SPARC™ Sling System to use the suprapubic approach rather than a transvaginal approach in order to give the physician more precise control of the needles in the area posterior to the rectus fascia. This area contains a higher density of anatomical structures such as nerves, blood vessels and bowel segments than the area closer to the vagina. Additionally, the suprapubic approach allows the physician to track the needles along the pubic bone, keeping it in contact at all times. This means the physician knows where the tip of the needle is at all times. With the transvaginal approach, the physician must work "blind" until the needle punctures through the fascia. Working blind increases the potential that a needle will get off track and hit a

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nerve, blood vessel or the bowel. The use of a smaller needle in the SPARC™ System than is used in the TVT System also decreases the likelihood of nicking a nearby anatomical structure.

The procedure for using the SPARC™ System, as given in the IFU, is described below.

1) Make a sagittal incision about 0.5 cm long approximately 1.0 cm from the urethral meatus, on the anterior vaginal wall.
2) Make 2 small paraurethral dissections just above the symphysis, not more than 4-5 cm apart, to allow a finger to pass and meet the needle.
3) Make two abdominal incisions of about 1 cm on each side of the midline, near the back of the pubic bone. At the physician's discretion, a larger single incision may be used.
4) Grasp the handle of the first needle. The push button on the needle handle releases the handle from the needle, allowing you to rotate the handle to the position you prefer. Be sure that both handles are attached to the needles in a secure manner.
5) Ensure that the bladder is empty. Pass the needle through one of the suprapubic incisions and pass it down the posterior side of the pubic bone toward the vaginal incision.
6) Use the index finger of the other hand to meet the tip of the needle, guiding it through the endopelvic fascia and into the vaginal incision.
7) When the first needle is in place, pass the second needle in the same way on the contra lateral side.
8) If there is a desire to use the cystoscopy aid, one should be passed up each needle. If there is urine flowing out of either needle, it is likely that the bladder was punctured.
9) Whether or not the cystoscopy aids are used, cystoscopy should be performed to confirm bladder integrity once both needles are in place.
10) Attach the dilating connectors (that are pre-attached to the AMS Polypropylene sling mesh material) to the needles. One dilating connector should be attached to each of the needles on the end protruding from the vagina. Orient the blue markings on the sheath facing outward, away from the urethra. Be sure that the sling mesh lies flat and that the sling mesh is not twisted prior to attaching the second dilating connector, as the dilating connectors cannot be removed once they are snapped into place. The dilating connectors are keyed at 90° intervals and may need to be rotated to snap on easily.
11) Verify that the dilating connectors are snapped securely in place to ensure that they do not fall off as the needles are pulled up through the body.
12) Once the sling mesh is attached, pull the needles up through the suprapubic incisions.

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13) Secure each end of the sling mesh with a clamp. Cut the sling mesh approximately 3 cm away from the dilating connectors, assuring that you have cut inside the blue markings at each end of the plastic sheath, and discard the needles, handles and dilating connectors.
14) Position the sling mesh under the midurethra without tension. The blue marking on the sheath is located in the center of the sling mesh and can be used for centering the sling mesh under the midurethra.
15) Once desired placement is achieved, remove the plastic sheath from the sling mesh by pulling up from both sides, one side at a time. To avoid over–tightening the sling mesh while removing the plastic sheath from the sling, keep a forceps or other instrument between the tape and urethra during removal.
16) The blue tensioning suture of the sling mesh may be used for further tensioning adjustment once the plastic sheath is removed.

    To loosen the sling mesh:
    Place a device such as a clamp between the sling mesh and the urethra. Ensure that both the mesh and the tensioning suture are located beneath the clamp. Use the clamp to pull down and loosen the sling mesh as desired.

    To tighten the sling mesh:
    Place a device such as a clamp, across the sling mesh, suprapubically. Be sure that both the tensioning suture and complete width of the sling are captured within the clamp. The sling mesh may be rolled around the clamp to improve the grip. Pull up to tighten the sling mesh as desired. If desired, this can be repeated on the contralateral side.

17) Following any adjustments of the sling mesh tension, cut the tensioning suture lateral to the urethra on both sides and remove.
18) Trim the sling mesh to size.
19) Close the suprapubic and vaginal incisions.
20) At the physician's discretion, a Foley catheter or suprapubic tube can be utilized until the patient is able to void.

Table 2 summarizes the similarities and differences between the SPARC™ procedure and the TVT procedure.

Table 2
Comparison of SPARC™ and TVT™ Procedures

SPARC™ Sling System	TVT
Polypropylene mesh	Prolene™ Mesh (polypropylene)
Open mesh weave allows fixation to occur by tissue ingrowth	Open mesh weave allows fixation to occur by tissue ingrowth
Uses small suprapubic and vaginal incisions	Uses small suprapubic and vaginal incisions
May use local, epidural or general anesthesia	May use local, epidural or general anesthesia
Maximum tool diameter/ channel size =0.26"	Maximum tool diameter/channel size =0.26"
Mesh length - 50 cm, cut to length during procedure	*Mesh length - 45 cm*, cut to length during procedure
Mesh width - 1.0 cm or 1.1 cm	Mesh width 1.1 cm
Sling mesh covered with plastic sheath, with midpoint marked	Sling mesh covered with plastic sheath
Plastic sheath removed to place sling	Plastic sheath removed to place sling
Sling placed in U shape below mid urethra, without tension	Sling placed in U shape below midurethra, without tension
Suprapubic approach to allow more precise steering	*Transvaginal approach*
Disposable insertion tool	Insertion tool with *reusable handles*, disposable needle
Antegrade passage of needles may reduce complications such as bowel, nerve, arterial perforation	*Retrograde* passage of needles
Does not rely on native connective tissue to effect treatment. Relying on connective tissue may have decreased efficacy if tissue is weakened.	Does not rely on native connective tissue to effect treatment. Relying on connective tissue may have decreased efficacy if tissue is weakened.
Cystoscopy recommended to check for bladder patency	Cystoscopy *recommended after each needle insertion* to check for bladder patency
No catheter guide included	*Catheter guide included*
Cystoscopy aid included	*No cystoscopy aid included*
Uses 2 metal "needle passers" to place sling	Uses 2 metal "trocars" to place sling
Can be done in out patient setting	Can be done in out patient setting

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D. Performance Testing

1. Sling Mesh

(b)(4) Testing

[redacted]

a. Suture Pull Strength

(b)(4) Testing

[redacted]

b. Material (tensile) Strength

(b)(4) Testing

[redacted]

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Table 3
Material Strength Test Results

(b)(4) Testing

[redacted]

(b)(4) Testing

[redacted]

c. **Device Material Stiffness**

(b)(4) Testing

[redacted]

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Table 4
Material Stiffness Test Results

(b)(4) Testing

[redacted]

Table 5
Sling Stiffness Data

(b)(4) Testing

[redacted]

d. Cyclic Pull Testing

(b)(4) Testing

[redacted]

(b)(4) Testing

[redacted]

e. Sling Adjustability Testing

(b)(4) Testing

[redacted]

2. Insertion Tool, Dilator, Sheath and Interface

(b)(4) Testing

[redacted]

a. Handle to Needle Attachment

(b)(4) Testing

[redacted]

(b)(4) Testing

b. Needle to Dilator Attachment

(b)(4) Testing

(b)(4) Testing

[redacted]

c. Needle Strength

(b)(4) Testing

[redacted]

d. Dilator to Sheath Attachment

(b)(4) Testing

[redacted]

e. Sheath Strength Test

(b)(4) Testing

[redacted]

(b)(4) Testing

[redacted]

Table 6
Sheath Material Strength

(b)(4) Testing

[redacted]

3. Cystoscopy Aid Mechanical Tests

(b)(4) Testing

[redacted]

a. Tip Compression Force

(b)(4) Testing

[redacted]

b. Passage over Needles

(b)(4) Testing

[redacted]

c. Drainage Testing

(b)(4) Testing

[redacted]

E. Cadaver Testing

(b)(4) Testing

[redacted]

1. Preliminary Studies

(b)(4) Testing

[redacted]

(b)(4) Testing

Table 7
Forces on Tool Components during Cadaver Sling Placement Procedures

(b)(4) Testing

2. Cadaver Laboratory Experience

(b)(4) Testing

III. Device Characterization

A. Materials

The materials used in the SPARC™ Sling System have been used for a number of years in medical devices and have been extensively tested and characterized. The base sling material is polypropylene mesh. This is the same material that is used to make several brands of surgical sutures. The material used for the dilators is an (b)(4) [redacted]. This is the (b)(4) [redacted] (b)(4) [redacted] The needles are made of (b) [redacted] Stainless Steel, which is widely used in a large variety of surgical tools, including several tools (tubing passers, Quick Connect Tool) sold as accessories to the (b)(4) [redacted] The sheath is made of a commonly used polyethylene material like that of the predicate device.

B. Biocompatibility

1. Sling Mesh Material

(b)(4) Testing [redacted]

(b)(4) Testing

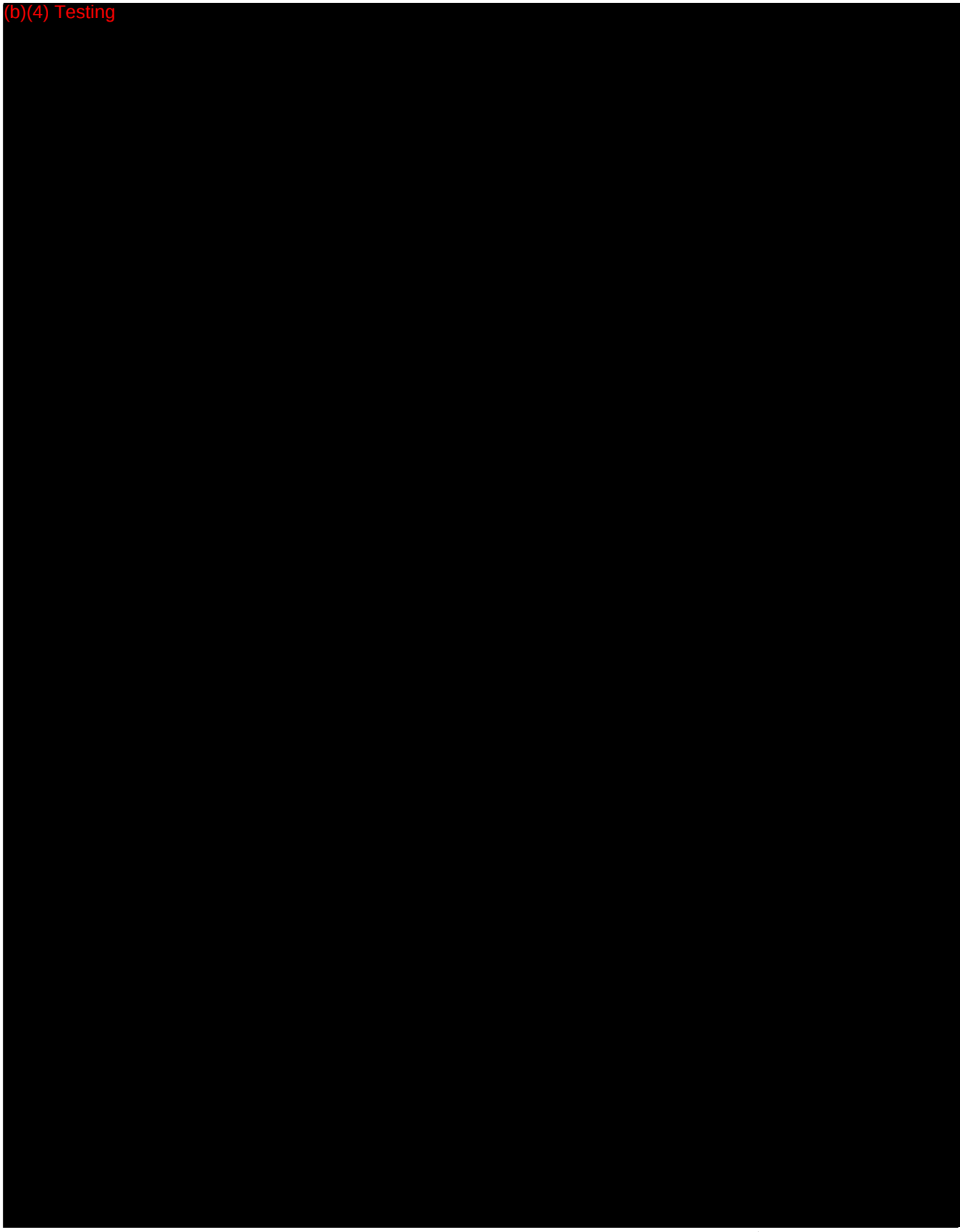
[redacted]

Table 8
Summary of Cytotoxicity Test Results

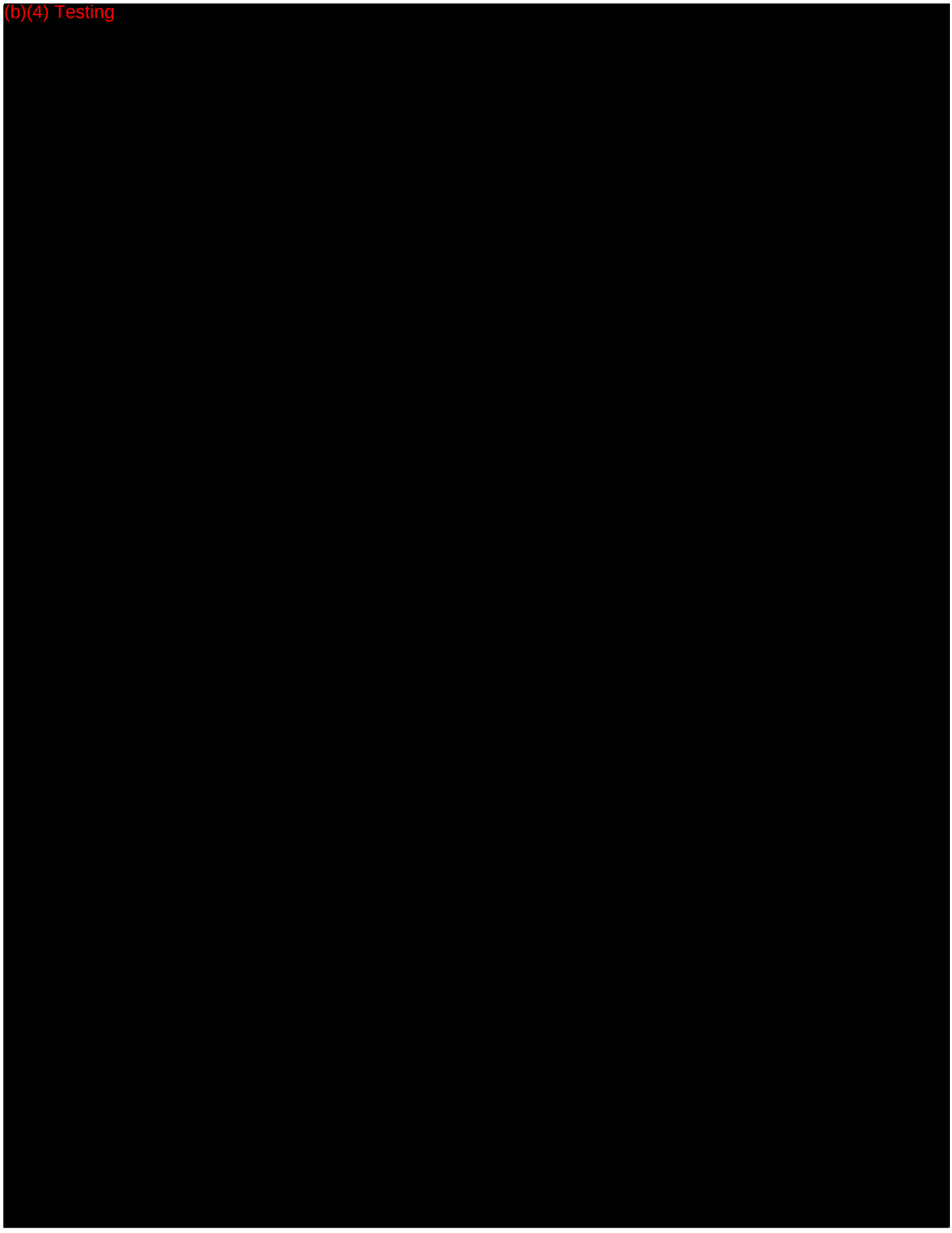
(b)(4) Testing

[redacted]

(b)(4) Testing



(b)(4) Testing



(b)(4) Testing

[redacted]

2. Polypropylene Tensioning Suture

(b)(4) Testing

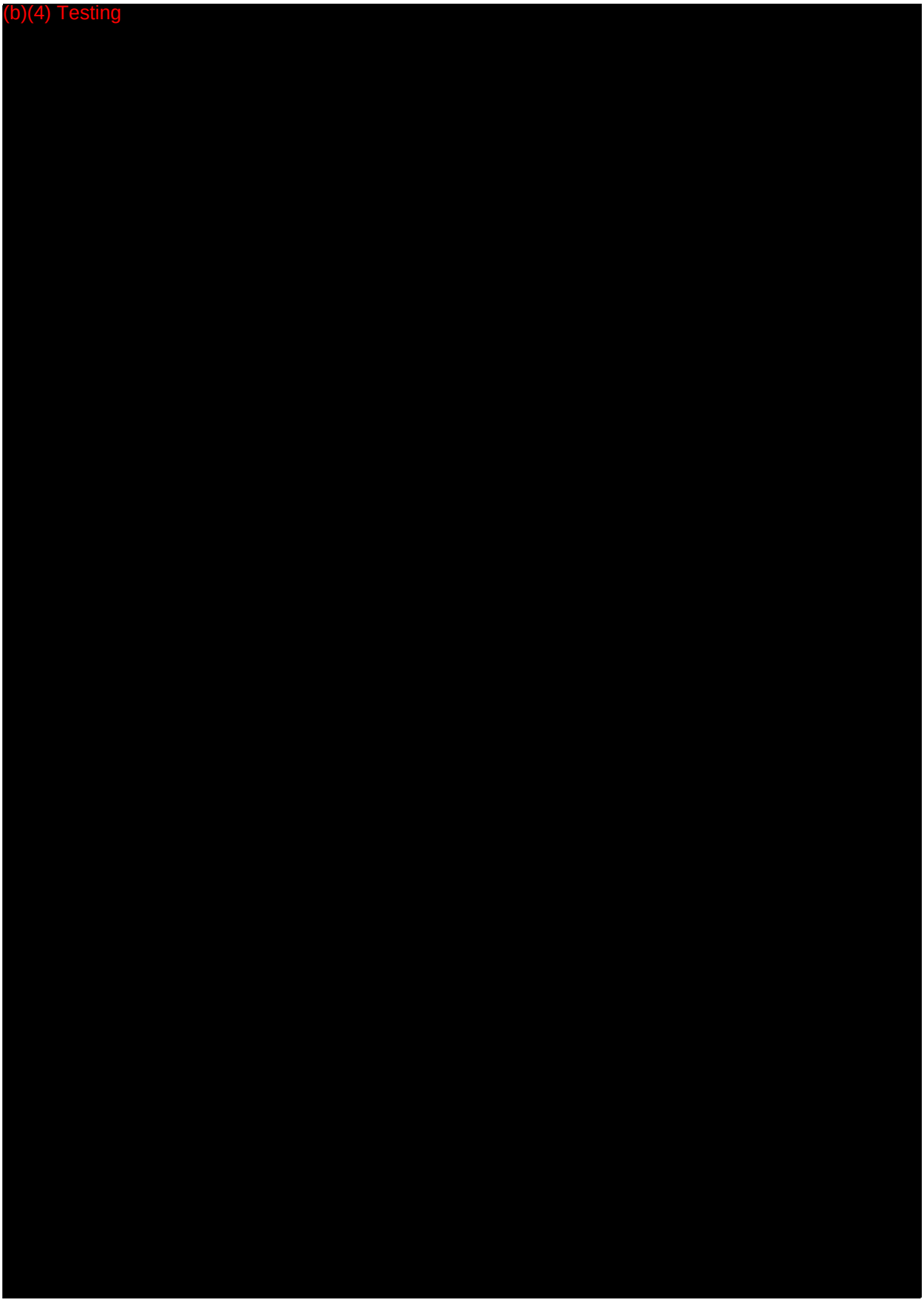
[redacted]

3. Handle and Dilator

(b)(4) Testing

[redacted]

(b)(4) Testing



(b)(4) Testing

[redacted]

4. Needle

(b)(4) Testing

[redacted]

5. Sheath

(b)(4) Testing

[redacted]

(b)(4) Testing

[redacted]

Table 9
Summary of Sheath Cytotoxicity Test Results

(b)(4) Testing

[redacted]

(b)(4) Testing

[redacted]

6. Cystoscopy Aids

(b)(4) Testing

[redacted]

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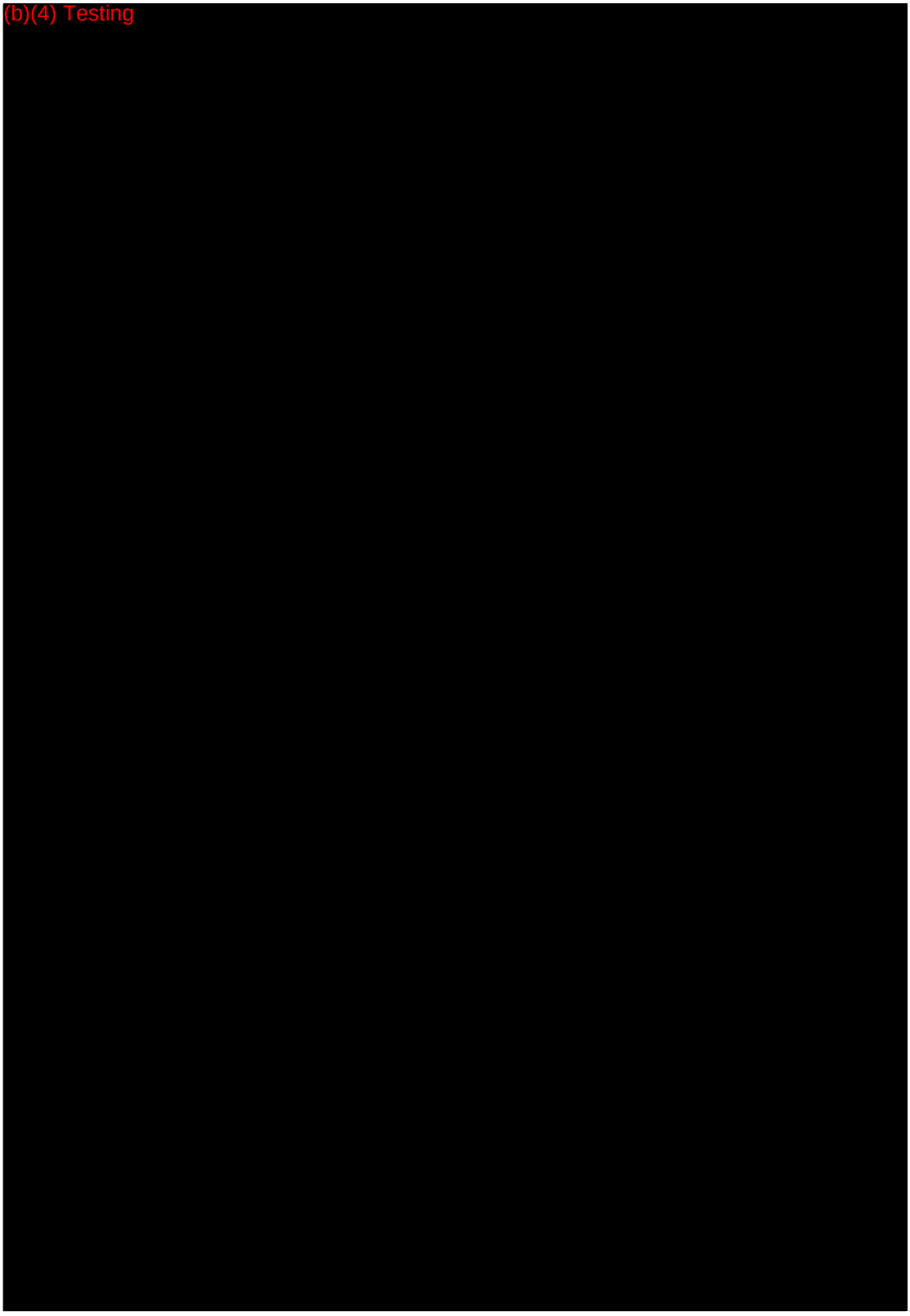
Table 10
Summary of Sheath Cytotoxicity Test Results

(b)(4) Testing



(b)(4) Testing

[redacted]

7. **Summary**

(b)(4) Testing

[redacted]

C. Sterilization

(b)(4) Testing

[redacted]

D. Packaging

(b)(4) Testing

[redacted]

(b)(4) Testing

[redacted]

E. Shelf Life

The SPARC™ Sling System will be labeled with a one-year shelf life. This shelf life will be validated according to industry standards.

IV. Proposed Labeling

Draft copies of labeling for the SPARC™ Sling System are included as Appendix H. Labeling included consists of box and pouch labels, as well as the Instructions for Use.

V. Truthful and Accurate Statement

A Truthful and Accurate Statement is included in Appendix I.

VI. 510(k) Summary

Appendix J contains the 510(k) Summary.

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Appendix A

Predicate Device Labeling

TVT

Tension-free
Vaginal Tape

(D) TVT Implantat -Einweg-
TVT Einführungsinstrument – wiederverwendbar
TVT Metall Katheter-Führung – wiederverwendbar

(DK) Sterilt TVT-bånd til engangsbrug
TVT-indfører til flergangsbrug
Stiv TVT guidewire til flergangsbrug

(E) Dispositivo de un solo uso TVT
Introductor reutilizable TVT
Guía rígida reutilizable para el catéter TVT

(F) Dispositif TVT à usage unique
Introducteur TVT réutilisable
Guide de sonde rigide TVT réutilisable

(FIN) TVT-neula, kertakäyttöinen
TVT -toistokäyttöinen sisäänvievä
TVT -toistokäyttöinen jäykkä katetrinohjain

(GB) TVT Single Use Device
TVT Reusable Introducer
(USA) TVT Reusable Rigid Catheter Guide

(GR) Συσκευή μιας χρήσης TVT
Εισαγωγέας TVT πολλαπλής χρήσης
Οδηγός Δύσκαμπτου Καθετήρα πολλαπλής χρήσης TVT

(I) Dispositivo TVT monouso
Introduttore polituso per dispositivo TVT
Guida rigida polituso per catetere TVT

(NL) TVT instrument voor éénmalig gebruik
TVT reusable inbrenghandvat
TVT reusable cathetervoerder

(P) Dispositivo TVT — Uso único
Introdutor TVT — Reutilizável
Guia rígido de cateter TVT — Reutilizável

(S) TVT nålar med inkontinensband för engångsbruk
TVT handtag för flergångsbruk
TVT kateterguide för flergångsbruk

(J) TVTディバイス
TVTイントロデューサー
TVTマンドリン

Authorized Representative • Autoriseret repræsentant
Erkende vertegenwoordiger • Valtuutettu edustaja
Représentant autorisé • Autorisierter Vertreter
Rappresentante autorizzato • Representante autorizado
Representante autorizado • Auktoriserad representant
Εξουσιοδοτημένος Αντιπρόσωπος

ETHICON GmbH
Robert-Koch-Strasse 1
D-22851 Norderstedt
Deutschland

EC
Legal Manufacturer
ETHICON SaRL
Rue du Puits Godet 20, CH-2000
Neuchatel, Switzerland

CE 0123

Status 2/00

P15506

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TOIMITUSTAPA
TVT-väline toimitetaan steriilinä (etyleenioksidi). Se on kertakäyttöinen. Sitä ei saa steriloida uudelleen. Tuotetta ei saa käyttää jos pakkaus on auki tai vaurioitunut. Hävitä avatut, käyttämättä jääneet pakkaukset.

Toistokäyttöisiä TVT-sisäänviejiä ja TVT -jäykkä katetrinohjaimia toimitetaan erikseen, steriloimattomina. Nämä lisätarvikkeet on puhdistettava ja steriloitava ennen kutakin toimenpidettä yllä mainitulla tavalla.

SÄILYTYS
Kertakäyttöisiä TVT-neulaa on säilytettävä alle 25 °C:n lämpötilassa, suojattuna kosteudelta ja lämmönlähteiltä. Tuotetta ei saa käyttää viimeisen käyttöpäivän jälkeen.

Huomautus: Yhdysvaltain laki rajoittaa tämän tuotteen myynnin vain lääkärin toimesta tai määräyksestä tapahtuvaksi.

Jakelu:

JOHNSON & JOHNSON
Metsänneidonkuja 8. 02130 Espoo

GB USA Tension-free Vaginal Tape (TVT) System — Instructions for Use

TVT Single Use Device
TVT Reusable Introducer
TVT Reusable Rigid Catheter Guide

Please read all information carefully.
Failure to properly follow instructions may result in improper functioning of the device and lead to injury.

Important:
This package insert is designed to provide instructions for use of the Tension-free Vaginal Tape single use device, reusable introducer and reusable rigid catheter guide. **It is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence).** The device should be used only by physicians trained in the surgical treatment of Stress Urinary Incontinence. These instructions are recommended for general use of the device. Variations in use may occur in specific procedures due to individual technique and patient anatomy.

DESCRIPTION *(System)*
TVT consists of the following:

- TVT Single-Use Device, provided sterile (available separately)
- TVT Reusable Introducer, provided non-sterile (available separately)
- TVT Reusable Rigid Catheter Guide, provided non-sterile (available separately).

TVT DEVICE
The TVT device is a sterile single use device, consisting of one piece of undyed PROLENE* polypropylene mesh (tape) approximately 1/2 x 18 inches (1.1 x 45 cm), covered by a plastic sheath cut and overlapping in the middle, and held between two stainless steel needles bonded to the mesh and sheath with plastic collars.

PROLENE polypropylene mesh is constructed of knitted filaments of extruded polypropylene strands identical in composition to that used in PROLENE* polypropylene nonabsorbable surgical suture. The mesh is approximately 0.027 inches (0.7mm) thick. This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in surgical use. PROLENE mesh is knitted by a process which locks each fiber junction and which provides for elasticity in both directions. This bi-directional elastic property allows adaptation to various stresses encountered in the body.

TVT INTRODUCER
The TVT introducer is provided non-sterile and is reusable. The introducer is made of stainless steel. It consists of two parts, a handle and an inserted threaded metal shaft. The introducer is intended to facilitate the passage of the TVT device from the vagina to the abdominal skin. It is connected and fixed to the needle, via the threaded end of the shaft, prior to inserting the needle with the tape.

TVT RIGID CATHETER GUIDE
The TVT rigid catheter guide is a non-sterile reusable instrument intended to facilitate the identification of the urethra and the bladder neck during the surgical procedure. It is inserted into a Foley catheter **(recommended size 18 French)** positioned in the bladder via the urethra. To facilitate insertion, it can be lubricated with gel.

INDICATIONS
The TVT device is intended to be used as a pubourethral sling for treatment of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The TVT introducer and rigid catheter guide are available separately and intended to facilitate the placement of the TVT device.

INSTRUCTIONS FOR USE

The procedure can be carried out under local anesthesia, but it can also be performed using regional or general anesthesia. The extent of dissection is minimal, i.e. a vaginal midline entry with a small paraurethral dissection to initially position the needle and two suprapubic skin incisions.

Using forceps, grasp the vaginal wall at each side of the urethra. Using a small scalpel, make a sagittal incision about 1.5 cm long starting approximately 1.0 cm from the outer urethral meatus. This incision will cover the mid-urethral zone and will allow for subsequent passage of the sling (tape). With a small pair of blunt scissors, two small paraurethral dissections (approximately 0.5 cm) are made so that the tip of the needle can then be introduced into the paraurethral dissection. Then, two abdominal skin incisions of 0.5 –1 cm are made, one on each side of the midline **just above** the symphysis not more than 4–5 cm apart. Incision placement and needle passage near the midline and close to the back of the pubic bone are important to avoid anatomic structures in the inguinal area and lateral pelvic sidewall.

The TVT rigid catheter guide is inserted into the channel of the Foley catheter (18 French). The handle of the guide is fixed around the catheter, proximal to its widening. The purpose of the guide is to move the bladder neck and urethra away from where the tip of the needle will pass into the retropubic space. Via use of the Foley catheter and the rigid catheter guide, the urethra and bladder are moved contralaterally to the side of the needle passage. During this maneuver, **the bladder should be empty.** The threaded end of the introducer is screwed into the end of one of the needles.

Using the introducer, the needle is passed paraurethrally penetrating the urogenital diaphragm. Insertion and passage are controlled by using the long or index finger in the vagina under the vaginal wall on the ipsilateral side and fingertip control on the pelvic rim. The curved part of the needle should **rest in the palm** of the "vaginal" hand. If you are right handed this means that the left hand generally is the one to be used for needle guidance. With the other hand grip the handle of the introducer **gently.** Now introduce the needle tip into the retropubic space. Once again observe that this should be done by the palm of the vaginal hand and with the needle tip horizontally i.e. in the frontal plane. After passage of the urogenital diaphragm you will feel that the resistance is significantly reduced. Immediately aim the tip of the needle towards the abdominal midline and lower the handle of the introducer thereby pressing the tip of the needle against the back of the pubic bone. Now, move the needle tip upwards to the abdominal skin incision, keeping in close contact with the pubic bone all the way.

When the needle tip has reached the abdominal incision, cystoscopy is performed to confirm bladder integrity. The bladder must be emptied after the first cystoscopy. The procedure is then repeated on the other side. The needles are then pulled upward to bring the tape (sling) loosely, i.e. without tension, under the midurethra. Cut the tape close to the needles. Now, adjust the tape so that leakage is limited to no more than one or two drops. Use patient feedback i.e. coughing with a full bladder (approximately 300ml) and keep the vaginal incision temporarily closed by a gentle grip with small forceps. The plastic sheaths that surround the tape are then removed. **To avoid putting tension on the tape, a blunt instrument (scissors or forceps) should be placed between the urethra and the tape during removal of the plastic sheaths.** Premature removal of the sheath may make subsequent adjustments difficult. After proper adjustment of the tape, close the vaginal incision. The abdominal ends of the tape are then cut and left in subcutis. Do not suture them. Suture the skin incisions. Empty the bladder. Following this procedure, postoperative catheterization is not typically required. The patient should be encouraged to try to empty the bladder 2-3 hours after the operation.

CONTRAINDICATIONS

As with any suspension surgery, this procedure should not be performed in pregnant patients. Additionally, because the PROLENE polypropylene mesh will not stretch significantly, it should not be performed in patients with future growth potential including women with plans for future pregnancy.

WARNINGS AND PRECAUTIONS

- **Do not use TVT procedure for patients who are on anti-coagulation therapy.**
- **Do not use TVT procedure for patients who have a urinary tract infection.**
- Users should be familiar with surgical technique for bladder neck suspensions before employing the TVT device. It is however important to recognize that TVT is different from a traditional sling procedure in that the tape should be located without tension under mid-urethra.
- Acceptable surgical practice should be followed for the TVT procedure as well as for the management of contaminated or infected wounds.
- The TVT procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to local anatomy and proper passage of needles will minimise risks.
- Retropubic bleeding may occur postoperatively. Observe for any symptoms or signs before releasing the patient from hospital.
- Cystoscopy should be performed to confirm bladder integrity and recognize a bladder perforation.
- The rigid catheter guide should be gently pushed into the Foley catheter so that the catheter guide does not extend into the holes of the Foley Catheter.
- When removing the rigid catheter guide, open the handle completely so that the catheter remains properly in place.
- Do not remove the plastic sheath until the tape has been properly positioned.
- Ensure that the tape is placed with minimal tension under mid-urethra.
- PROLENE mesh in contaminated areas should be used with the understanding that subsequent infection may require removal of the material.
- The patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent.
- Post-operatively the patient is recommended to refrain from heavy lifting and/or exercise (i.e. cycling, jogging) for at least three to four weeks and intercourse for one month. The patient can return to other normal activity after one or two weeks.
- Should dysuria, bleeding or other problems occur, the patient is instructed to contact the surgeon immediately.
- All surgical instruments are subject to wear and damage under normal use. Before use, the instrument should be visually inspected. Defective instruments or instruments that appear to be corroded should not be used and should be discarded.
- Do not contact the PROLENE mesh with any staples, clips or clamps as mechanical damage to the mesh may occur.
- Do not resterilize TVT device. Discard opened, unused devices.

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ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE mesh is designed to minimize the risk of contamination.
- Over correction i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

INSTRUCTIONS FOR CLEANING REUSABLE INSTRUMENTS (TVT Introducer and TVT Rigid Catheter Guide)

To ensure the reliability and functionality of the TVT Introducer and TVT Rigid Catheter Guide, clean the instrument before initial use and after each procedure. The following are suggested manual and automated methods for cleaning the instrument.

Prior to cleaning, the TVT introducer should be separated into its two component parts (handle and threaded shaft). The introducer is reassembled after cleaning and before sterilization.

Manual method

1. Soak the instrument components in an enzyme cleaner suitable for stainless steel instruments.
2. Wash in a surgical detergent and disinfecting solution at a temperature of 86°F to 95°F (30°C to 35°C). Remove any contamination from body fluids or tissues using a soft brush.
3. Place the instrument components in an ultrasonic bath with fresh detergent solution for approximately 10 minutes or follow the instructions below if using an automatic washing cycle.
4. Rinse thoroughly in a stream of fresh tap water followed by towel drying. The instrument components may be treated with instrument lubricant.

Automated Method:

1. Automatic washing cycles are suitable for stainless steel instruments. One recommended cycle is described below:

- Rinse/Wet Cycle Cold Water — 1 minute
- Wash 176°F (80°C) — 12 minutes
- Rinse Cycle — 1 minute
- Rinse Cycle — 12 minutes
- Final Rinse — 2 minutes
- Rinse with Demineralized water 176°F (80°C) — 2 minutes
- Dry 199.4°F (93°C) — 10 minutes

STERILIZATION RECOMMENDATIONS FOR REUSABLE INSTRUMENTS (TVT Introducer and TVT Rigid Catheter Guide)

The TVT Introducer and Rigid Catheter Guide are supplied non-sterile. To sterilize, steam autoclave prior to each use. Steam autoclave at a temperature of 270°F to 284°F (132°C to 140°C) for a minimum of 4 minutes (pre-vacuum). It is the responsibility of the end user to assure sterility of the product when using sterilization process recommended, since bioburden and sterilization equipment will vary.

INSTRUMENT MAINTENANCE

- TVT Introducer

Before each use, inspect the threaded parts of the inner shaft.

- TVT Rigid Catheter Guide

Before each use, inspect the instrument. Check to ensure that the long end which traverses the catheter channel has no sharp edges or burrs.

HOW SUPPLIED

The TVT device is provided sterile (ethylene oxide) for single use. Do not re-sterilize. Do not use if package is opened or damaged. Discard opened, unused devices.

The reusable TVT introducer and TVT rigid catheter guide accessories are supplied separately, and are non-sterile. These accessories are to be cleaned and sterilized prior to each use as described above.

STORAGE

Recommended storage conditions for the TVT single use device are below 25°C, away from moisture and direct heat. Do not use after expiry date.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

EC
Legal Manufacturer
ETHICON SaRL
Rue des Puits Godet 20, CH-2000
Neuchâtel, Switzerland

Distributor (Europe):
ETHICON Ltd
Bankhead Avenue
Edinburgh, EH11 4HE
United Kingdom

Distributor (USA):
Gynecare
a division of Ethicon, Inc.
a Johnson & Johnson Company
Somerville, NJ
08876-0151

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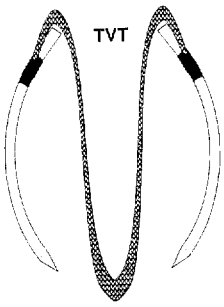
TVT DEVICE

810041

1.1cm x 45cm (0.5in. x 18in.)

1 Packet / 1 Sachet
1 Stück / 1 Confezione
1 Stuk / 1 Sobre / 1 Styck
1 パケット

Undyed PROLENE* (polypropylene) non absorbable tape.
Bandelette PROLENE® (polypropylène) incolore non résorbable.
PROLENE® ungefärbt (polypropylen) nicht resorbierbarer Netzstreifen.
Nastro in PROLENE® (polipropilene) non assorbibile non colorato.
Ongekleurde PROLENE® (polypropyleen) niet resorbeerbaar band.
Cinta de PROLENE® (polipropileno) sin teñir, no absorbible.
Ofärgat, icke - resorberbart PROLENE® (polypropylen) band.
無染色プロリーン* （ポリプロピレン製） 非吸収性テープ



輸入・発売元 ジョンソン・エンド・ジョンソン 株式会社
東京都江東区東陽6丁目3番2号

取扱説明書入り 優参照

EC
Legal Manufacturer
ETHICON SaRL
Rue du Puits Godet 20, CH-2000
Neuchatel, Switzerland

CE 0123
Made in Switzerland

Authorized Representative • Erkende vertegenwoordiger • Représentant autorisé • Autorisierter Vertreter • Rappresentante autorizzato • Representante autorizado • Representante autorizado

ETHICON GmbH
Robert-Koch-Strasse 1
D-22851 Norderstedt
Deutschland

STERILE EO

2 Do Not Reuse/Resterilize

See Instructions For Use

DER GRÜNE PUNKT

For Use Under U.S. Patent No. 5,899,909

Distributor: Europe/Japan

Direct all correspondence to your local distributor. See insert.
Adresser toute correspondance à votre distributeur local. Voir notice.
Kontaktadresse (siehe Gebrauchsanweisung).
Inviare tutta la corrispondenza al vostro distributore locale. Vedi inserto.
Richt al uw correspondentie aan uw locale distributeur. Zie de gebruiksaanwijzing.
Dirija toda la correspondencia a su distribuidor local. Lea el prospecto.
Hänvänd er till den lokala distributören i all korrespondens. Se bruksanvisning.
通信はすべてあなたのローカル供給事業所あてにお願いします。同封紙参照。

Distributor (USA):

GYNECARE
A Division of ETHICON, INC.
a Johnson & Johnson company
Somerville, New Jersey 08876-0151

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

*Trademark

P15508 810041.S01

GYNECARE™

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Appendix B

Predicate Device 510(k) Summary

K974098

JAN 28 1998

SECTION 7

SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) Summary of Safety and Effectiveness

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

New Device Name: Tension Free Vaginal Tape (TVT) System

Predicate Device Name: ProteGen Sling Collagen Impregnated Material

510(K) SUMMARY

Device Description

The Tension Free Vaginal Tape (TVT) System is comprised of three components; the device (TVT device) and its accessories (TVT Introducer and TVT Rigid Catheter Guide). Each is available separately for use at the surgical site. The TVT device is composed of PROLENE polypropylene mesh (tape). The mesh is covered with a polyethylene sheath with a slit in the middle. Both the mesh and sheath are attached to two (2) stainless steel needles. The TVT Introducer (accessory) is made of stainless steel. It is composed of three (3) parts; handle, threaded staft and rubber O-ring. The introducer functions to facilitate passage of the TVT device from the vagina to the abdominal skin. The TVT Rigid Catheter Guide is made of stainless steel and used to add rigidity to the Foley Catheter during the surgical procedure.

Intended Use

The TVT device is intended to be used as a pubourethral sling for treatment of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Continued on next page

K974098

SUMMARY OF SAFETY AND EFFECTIVENESS, Continued

Indications Statement

The TVT device is a sterile, single-use device intended to be used as a pubourethral sling indicated for treatment of stress urinary incontinence, for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The TVT Introducer and Rigid Catheter Guide accessories are intended to facilitate placement of the TVT device. The accessories, available separately, are provided non-sterile and are reusable.

Technological Characteristics

Technologically both the new device and predicate device are the same (i.e. both are meshes that provide pubourethral support). Additionally, both devices utilize accessories for use in the surgical procedure. Any differences between the two devices do not raise new questions of safety and effectiveness.

Performance Data

Results of clinical evaluations were used to show that the TVT System functioned as clinically intended. Sufficient data has been gathered from clinical testing to assess that the TVT System performs as clinically intended.

Conclusions

Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the modified device is substantially equivalent to the existing legally marketed device under the Federal Food, Drug and Cosmetic Act.

Contact

Gregory R. Jones
Director
Regulatory Affairs
ETHICON, Inc.
Rt. #22 West
Somerville, NJ 08876-0151

Date

October 28, 1997

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 28 1998

Mr. Gregory R. Jones
Director, Regulatory Affairs
Ethicon, Inc.
P.O. Box 151
Somerville, New Jersey 08876-0151

Re: K974098
Tension Free Vaginal Tape (TVT) System
Regulatory Class: II
Product Code: FTL
Dated: October 29, 1997
Received: October 30, 1997

Dear Mr. Jones:

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 requirement, 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.

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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) 594-4595. 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/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): _____

Device Name: Tension Free Vaginal Tape (TVT) System

Indications for Use: The TVT device is a sterile, single-use device intended to be used as a pubourethral sling indicated for treatment of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The TVT Introducer and Rigid Catheter Guide accessories are intended to facilitate placement of the TVT device. The accessories, available separately, are provided non-sterile and are reusable.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

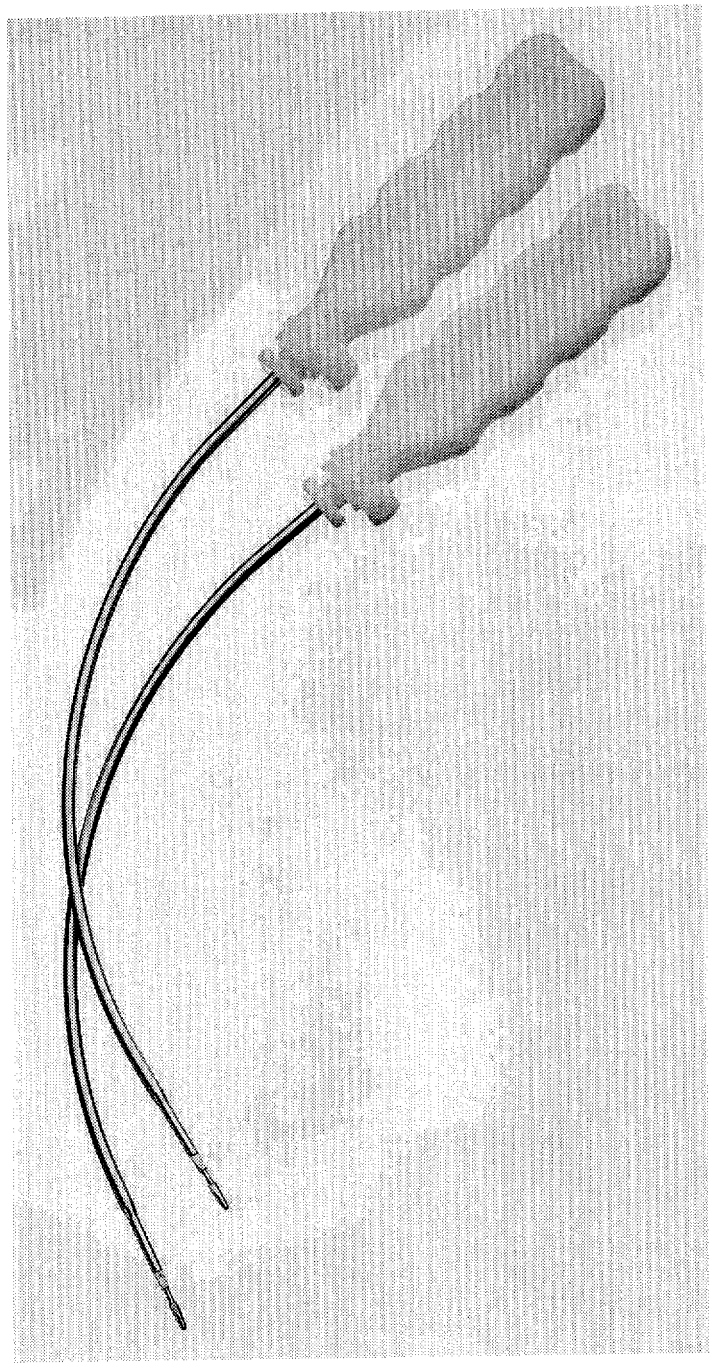
Prescription Use X OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-9G)

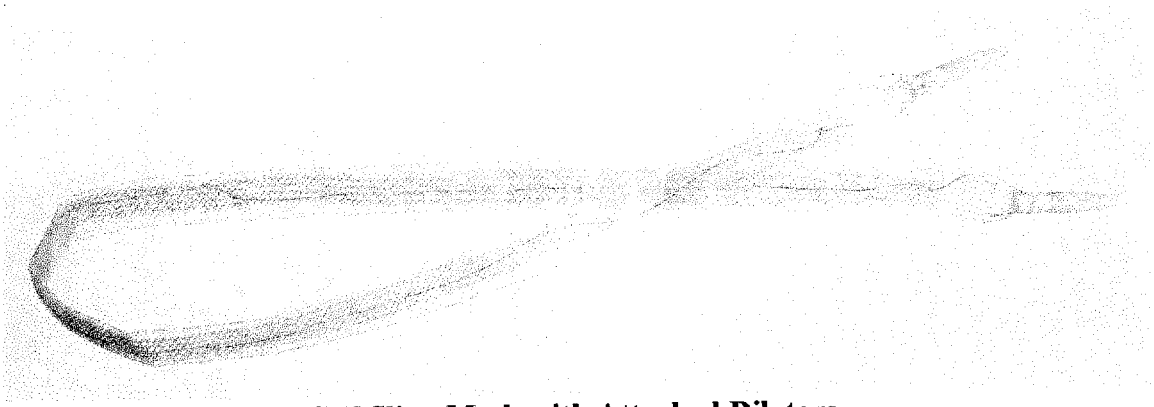
(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K974080

Appendix C

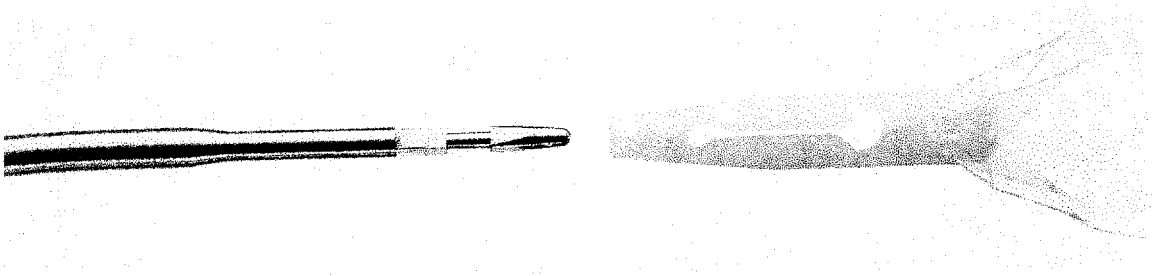
Photographs of SPARC™ System Components



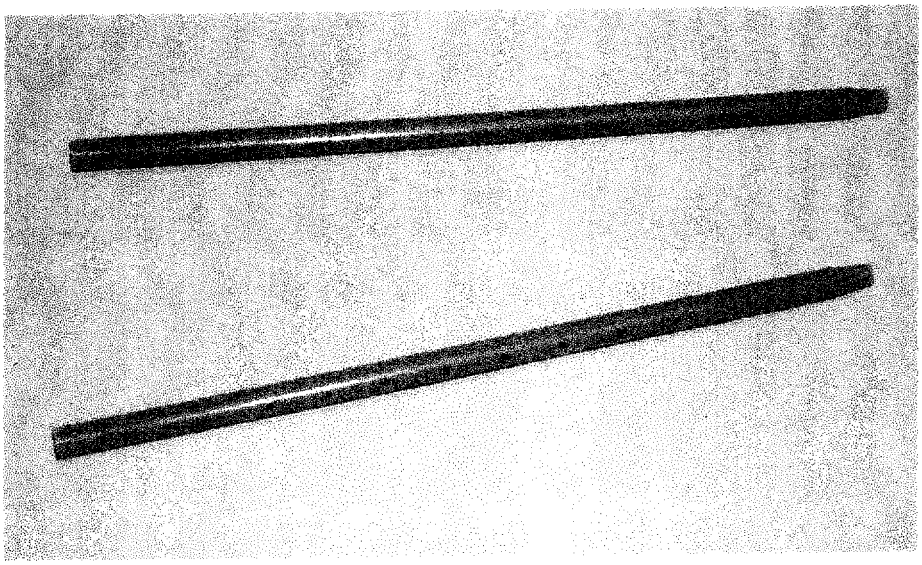
SPARC™ Insertion Tools



SPARC™ Sling Mesh with Attached Dilators



SPARC™ Needle and Dilator



SPARC™ Cystoscopy Aids

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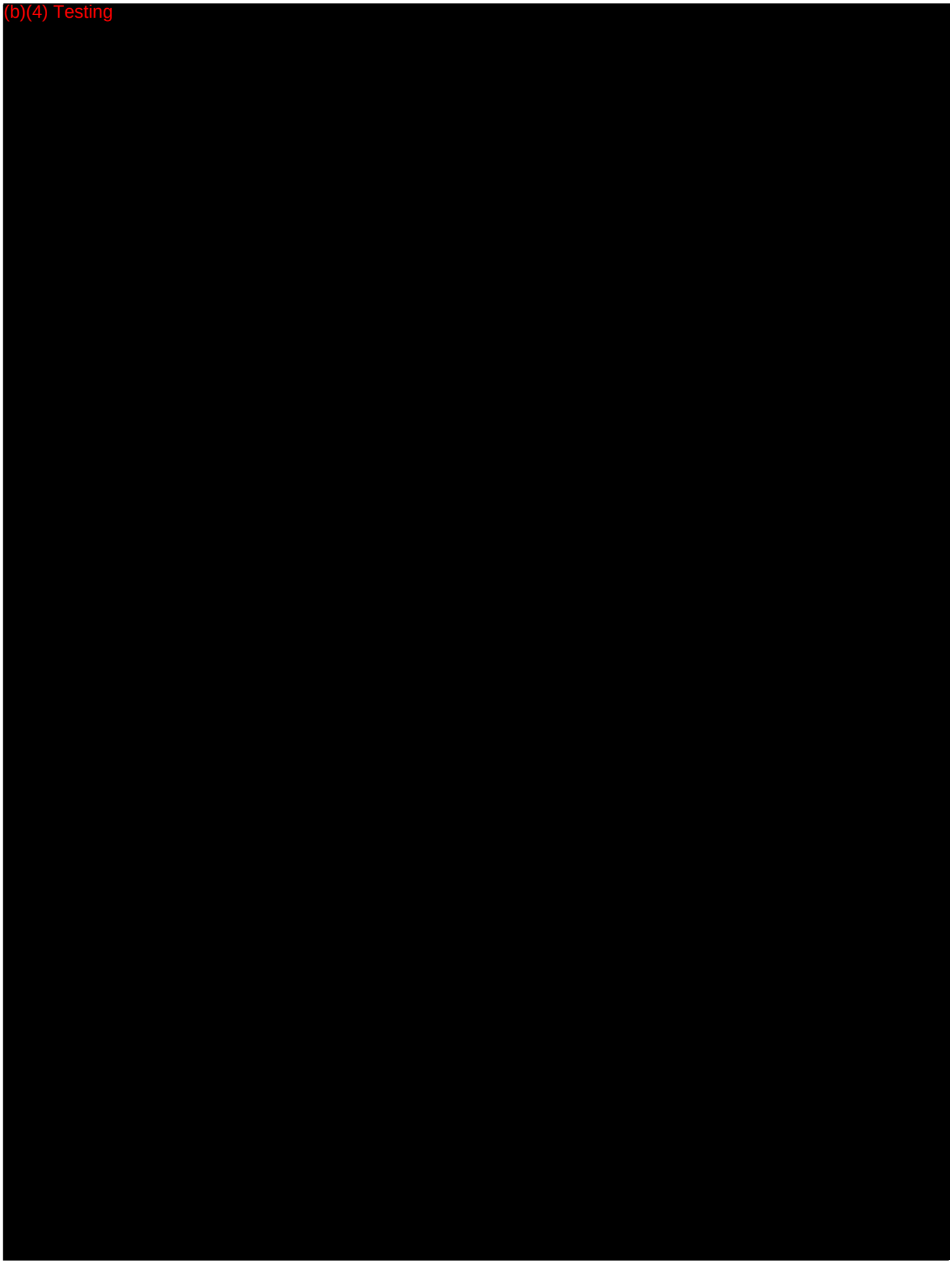
Appendix D

Sling Adjustability in Meat - Test Photos

(b)(4) Testing



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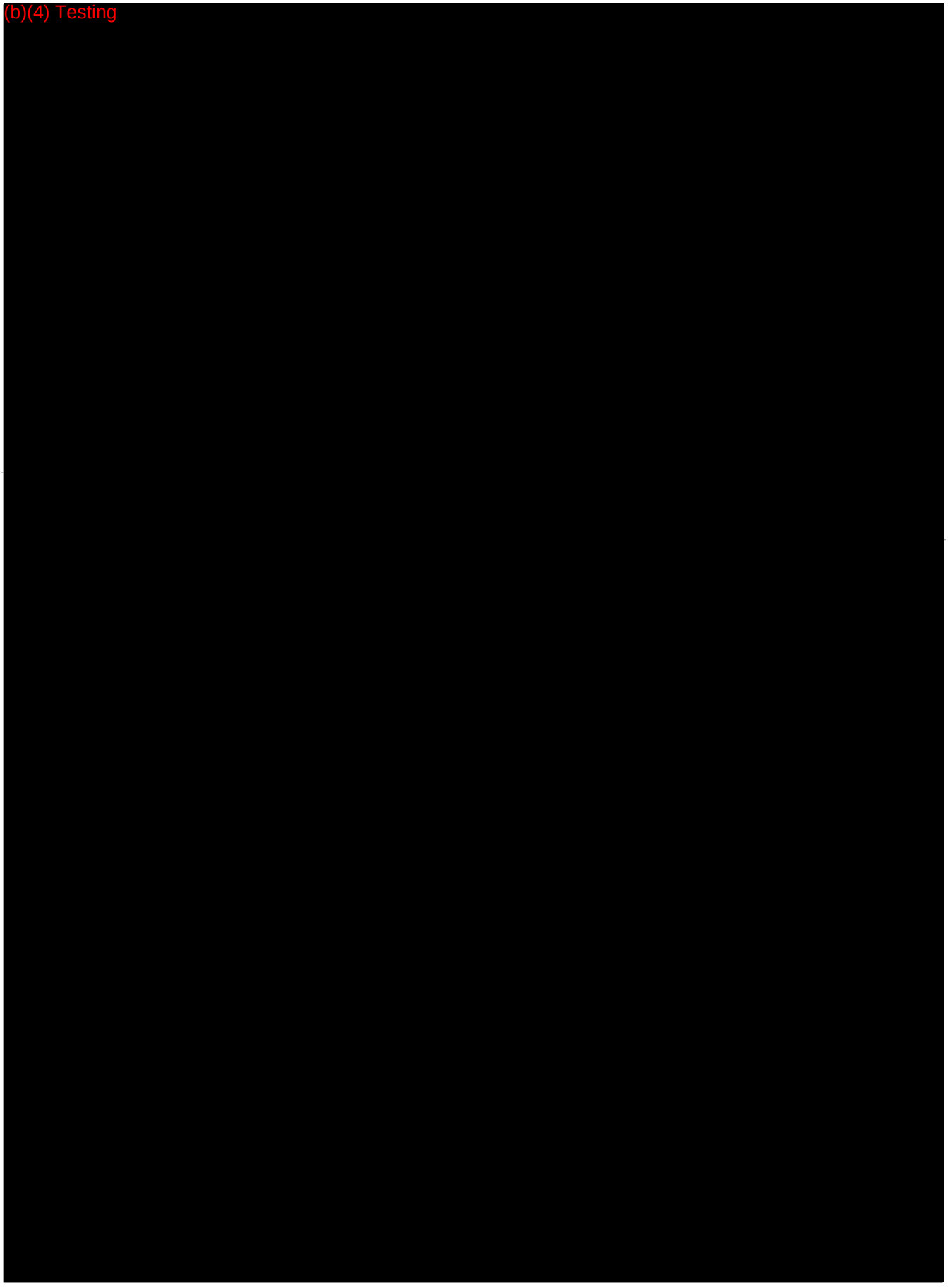
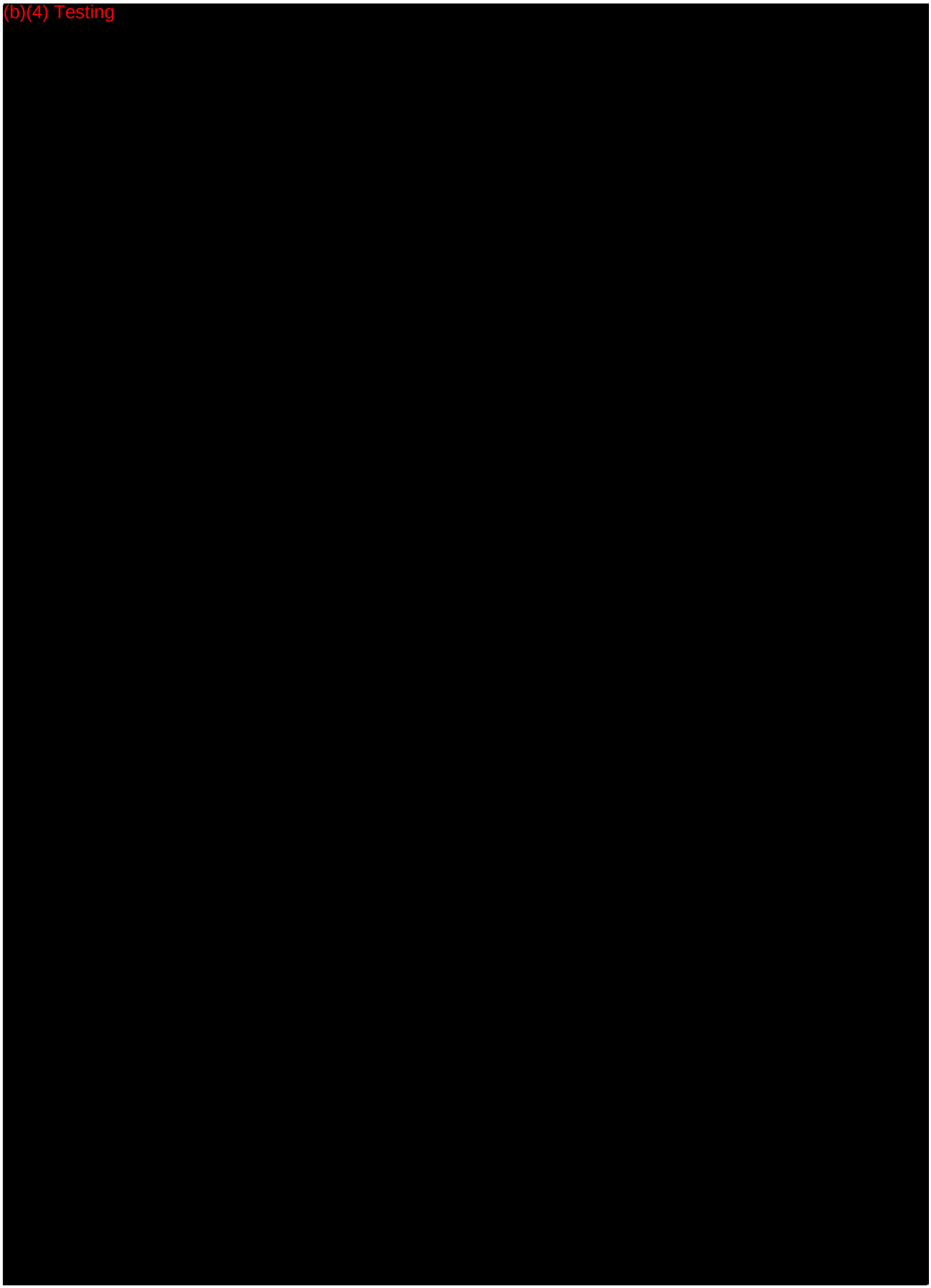
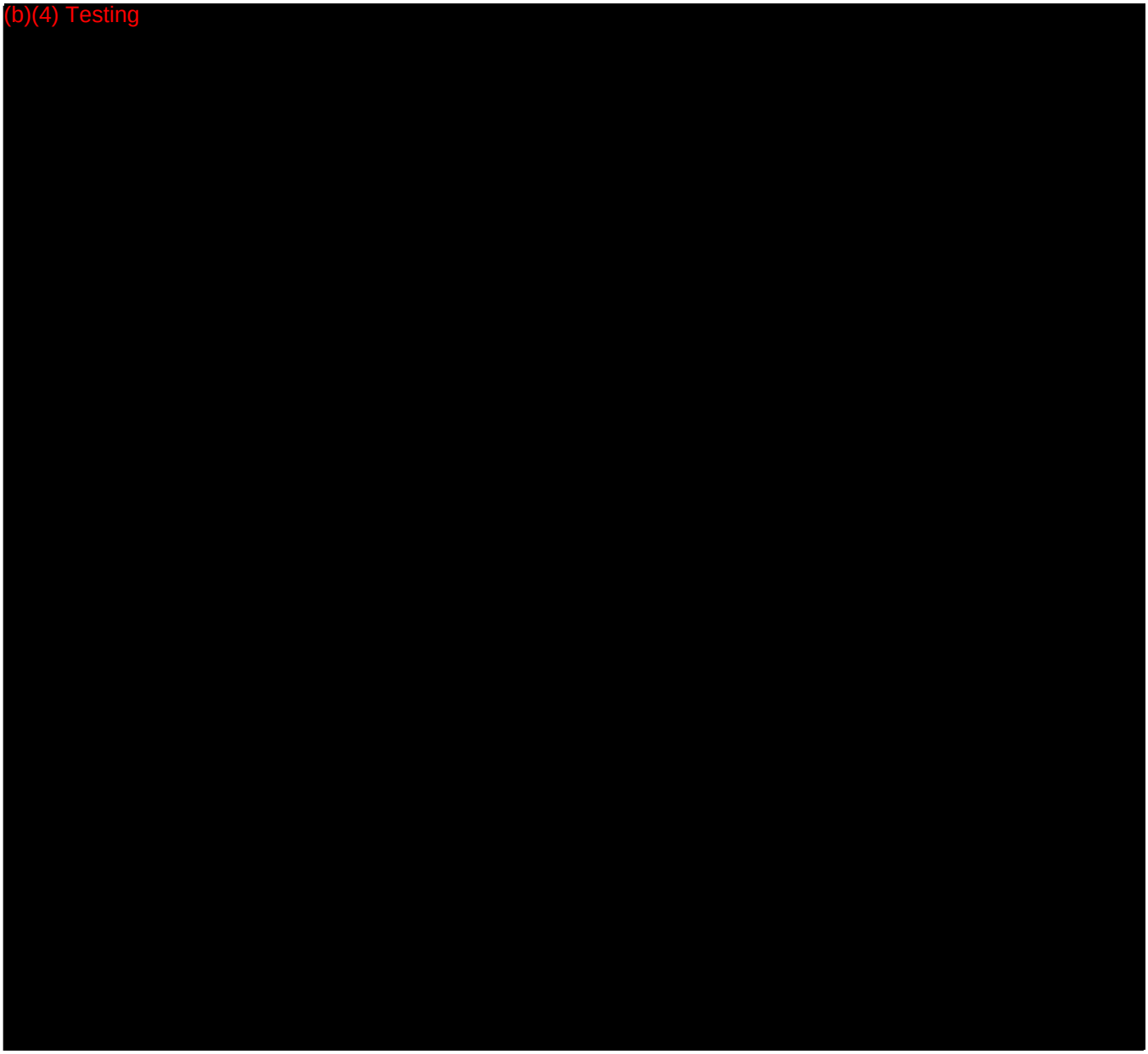


Appendix E

Polypropylene Genotoxicty Literature Review

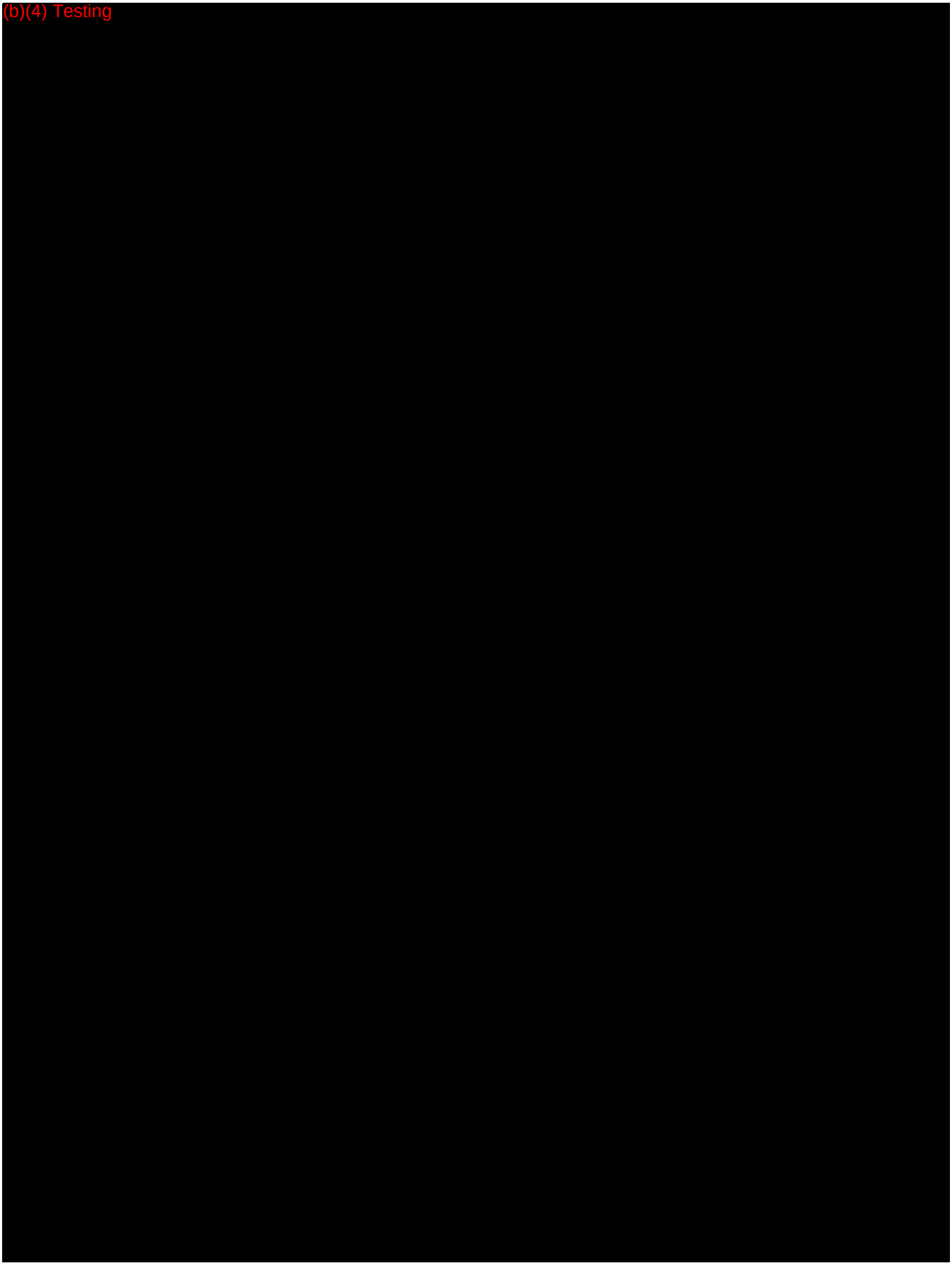
(b)(4) Testing



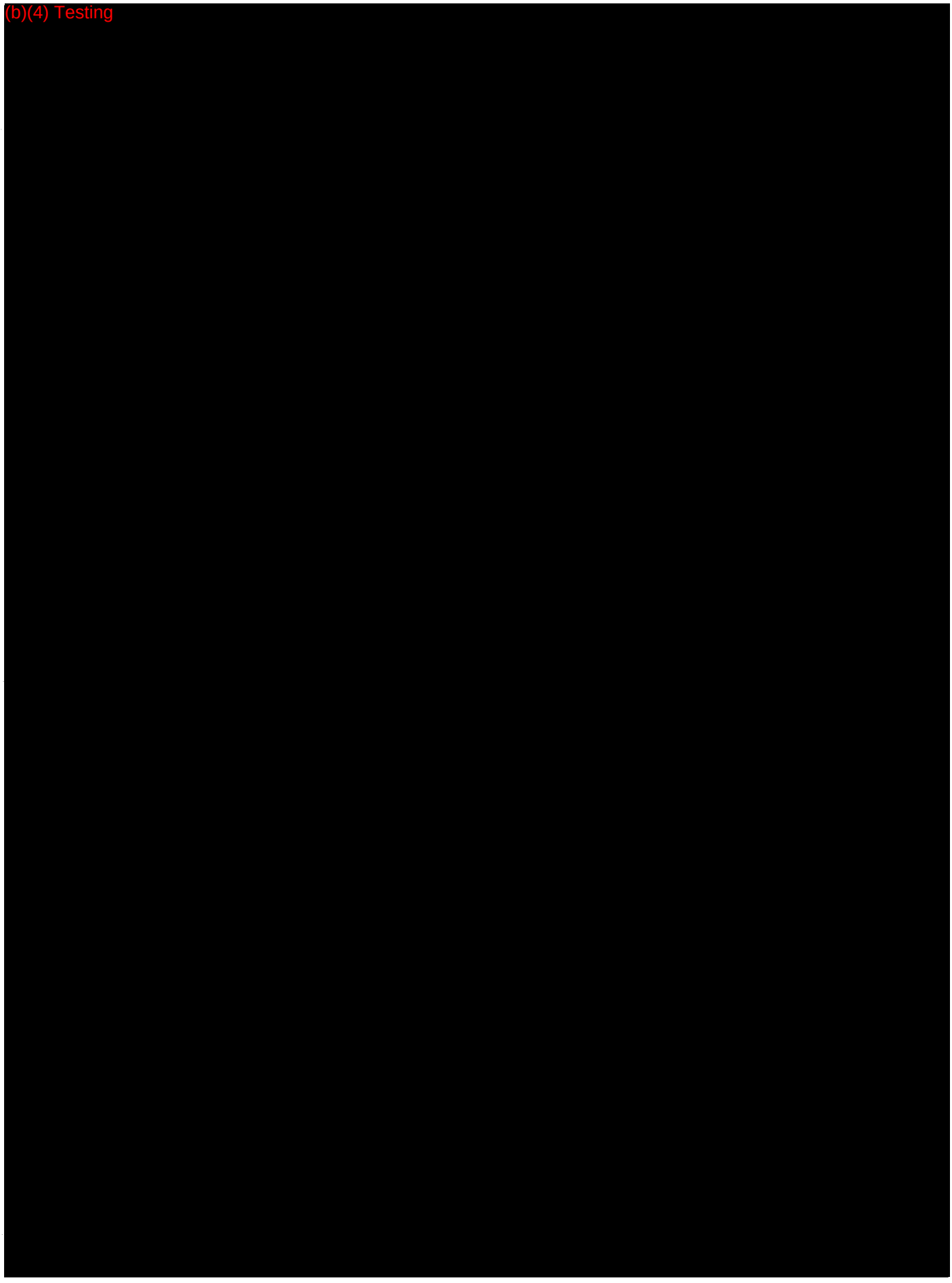

(b)(4) Testing

Appendix F

(b) (4) Stainless Steel Biocompatibility Bibliography


(b)(4) Testing

(b)(4) Testing



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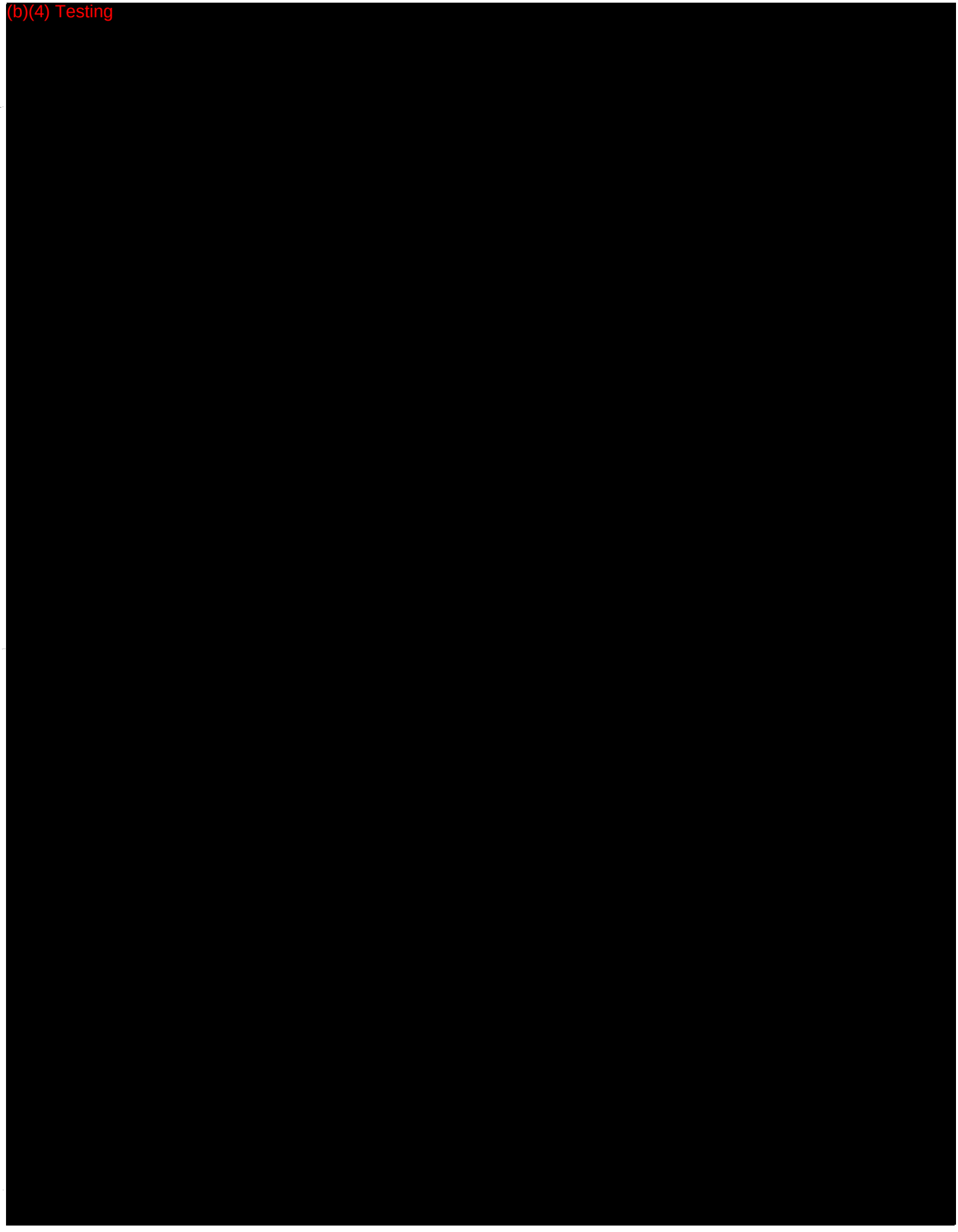
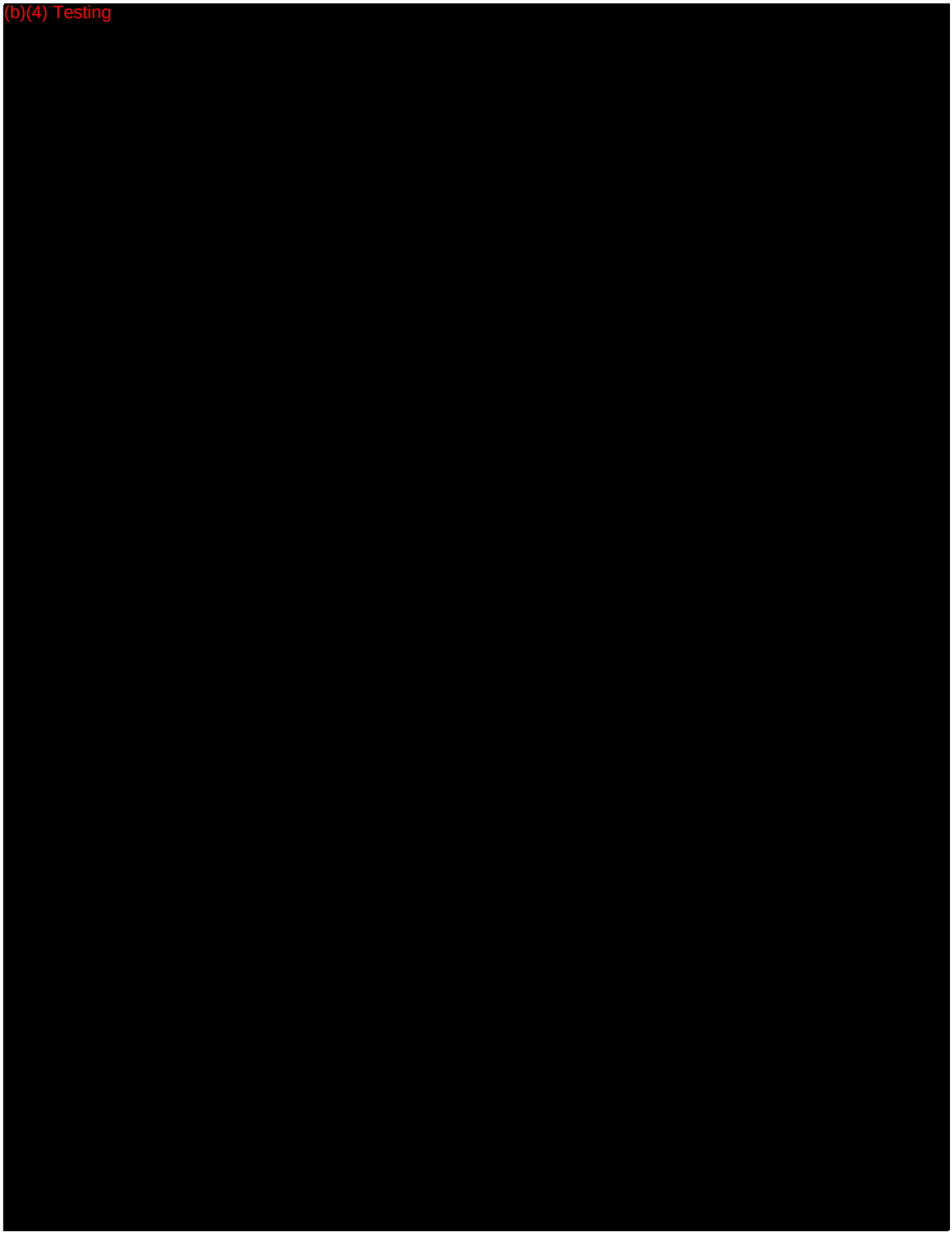


(b)(4) Testing




(b)(4) Testing

Appendix G

Sterilization Rationale and [redacted] Information

(b) (4)

AMERICAN MEDICAL SYSTEMS

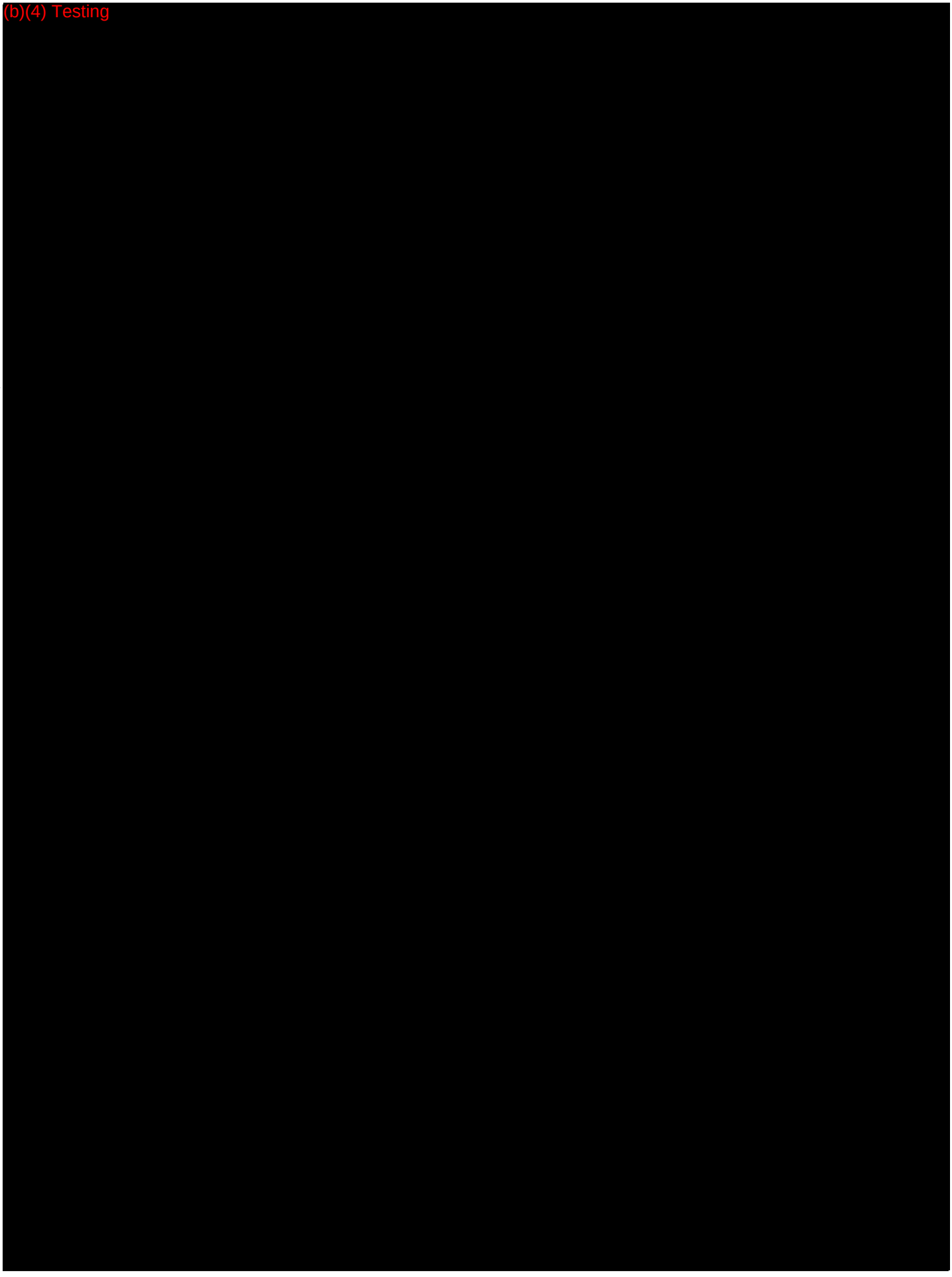
Leaders in Innovation
Dedicated to Customers, Improving Patients' Lives

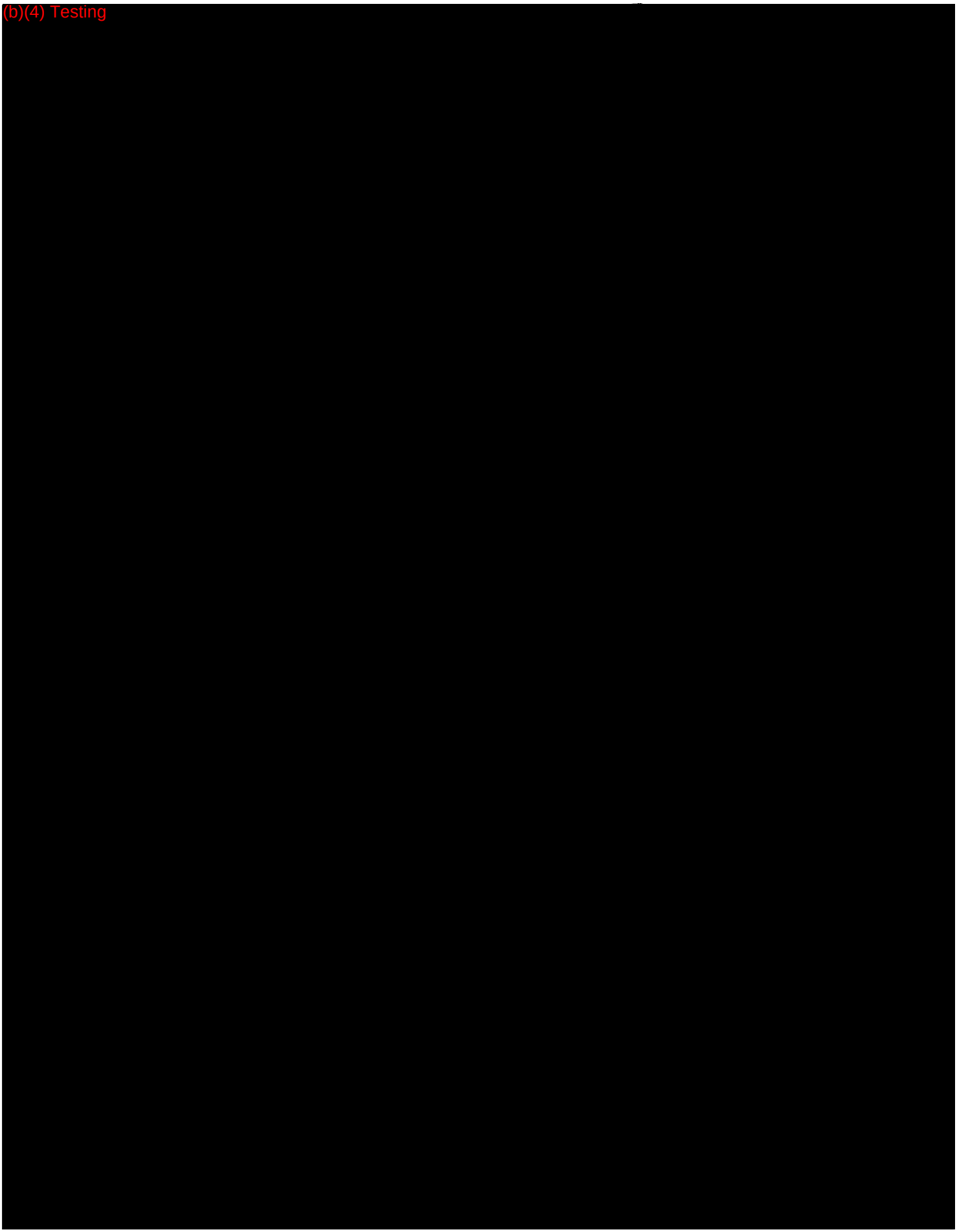
Test Report

(b)(4) Testing

[redacted]

(b)(4) Testing




(b)(4) Testing

(b)(4) Testing

5.0 ATTACHMENTS

5.1 Sealed Polyethylene Bags

(b)(4) Testing

5.2 (b) (4) Test Data

(b)(4) Testing

[redacted]

(b)(4) Testing

Appendix H

SPARC™ Sling System Proposed Labeling

Package Labels

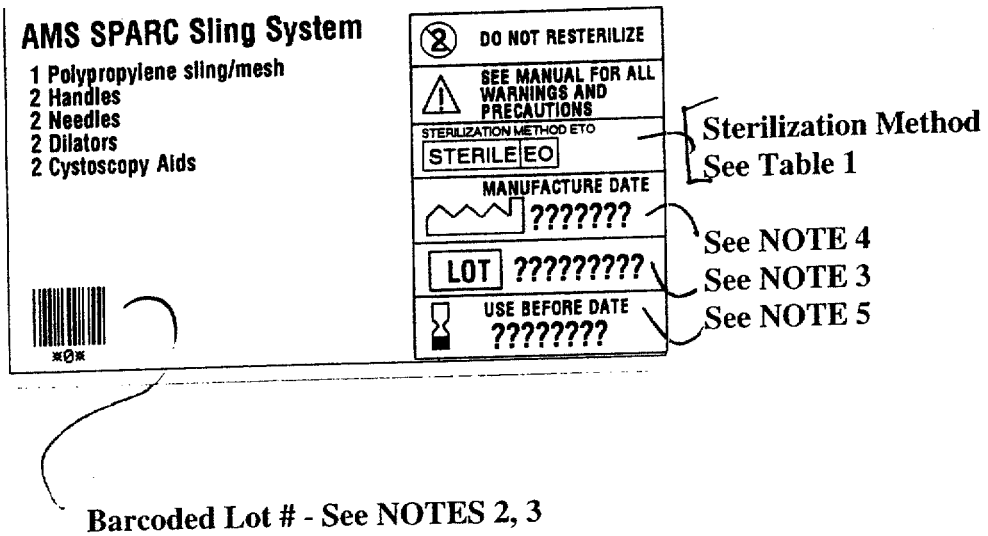

AMS SPARC Sling System
1 Polypropylene sling/mesh
2 Handles
2 Needles
2 Dilators
2 Cystoscopy Aids
DO NOT RESTERILIZE
SEE MANUAL FOR ALL WARNINGS AND PRECAUTIONS
STERILIZATION METHOD ETO
STERILE EO
MANUFACTURE DATE
???????
LOT ?????????
USE BEFORE DATE
????????
Sterilization Method
See Table 1
See NOTE 4
See NOTE 3
See NOTE 5
Barcoded Lot # - See NOTES 2, 3

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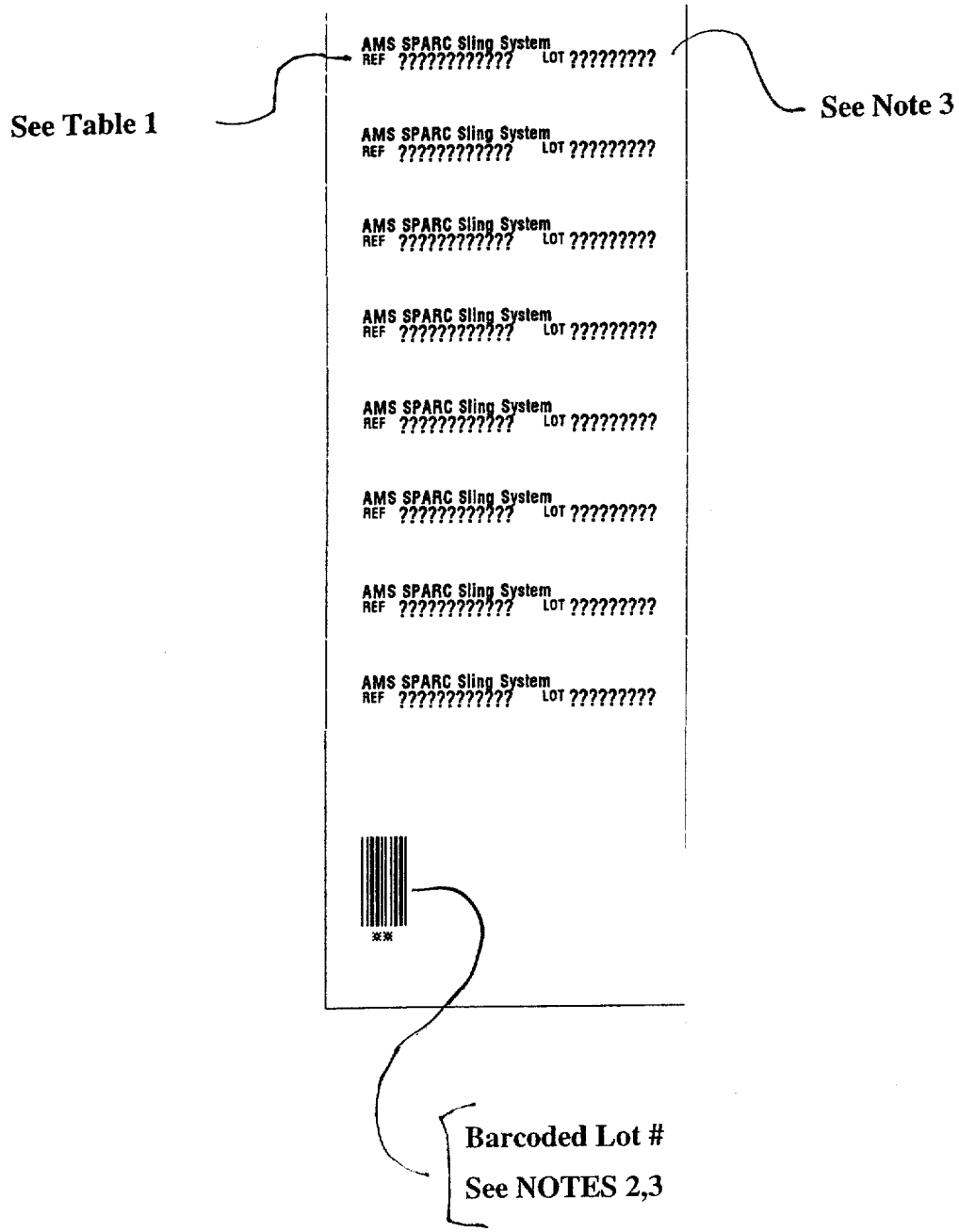
Figure A


See Table 1
AMS SPARC Sling System
REF ????????????
LOT ?????????
See Note 3
AMS SPARC Sling System
REF ????????????
LOT ?????????
AMS SPARC Sling System
REF ????????????
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LOT ?????????
AMS SPARC Sling System
REF ????????????
LOT ?????????
**
Barcoded Lot #
See NOTES 2,3

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Figure B

AMS SPARC Sling System

AMS SPARC Sling System
1 Polypropylene Sling/Mesh
2 Handles
2 Needles
2 Dilators
2 Cystoscopy Aids

Système de bandelette SPARC AMS
1 Bandelette en polypropylène
2 Poignées
2 Aiguilles
2 Connecteurs
2 Aides pour la cystoscopie

AMS SPARC Schlingensystem
1 Polypropylen – Netzgewebeschlinge
2 Griffe
2 Nadeln
2 Konnektoren
2 Zystoskopiehilfen

Sistema di sling AMS SPARC
1 rete di sling in polipropilene
2 impugnature
2 aghi
2 dilatatori
2 accessori per cistoscopia

Sistema de Cabestrillo SPARC AMS
1 Cabestrillo de polipropileno
2 Mangos
2 Agujas
2 Dilatadores
2 Accesorios para cistoscopia

Sistema de suspensão sem ancoragem SPARC AMS
1 dispositivo de suspensão e rede de Polipropileno
2 punhos
2 agulhas
2 dilatadores
2 acessórios para cistoscopia

PRODUCT NUMBER
Numéro de produit
Katalognummer
Numero di codice
Número de producto
Número do Produto
???????? — See Table 1

SEE MANUAL FOR ALL WARNINGS AND PRECAUTIONS

DO NOT RESTERILIZE OR REUSE

STERILIZATION METHOD ETO
STERILE EO — Sterilization Method – See Table 1

MANUFACTURE DATE
?????????? — See NOTE 4

LOT ???????????? — See NOTE 3

USE BEFORE DATE
?????????? — See NOTE 5

American Medical Systems, Inc.
10700 Bren Road West
Minnetonka, MN 55343 U.S.A.
U.S. Toll – Free: (1) 800.328.3881
Telephone: (1) 952.933.4666
Fax: (1) 952.930.6157

CE
0086

AMS France
19 bis avenue du Québec
91951 Courtaboeuf Cedex
France

Caution: Federal law (USA) restricts sale of this device by or on the order of a physician.

AMS SPARC Sling System

LOT ????????? — See NOTE 3
REF ????????????? — See Table 1
?????????? — See NOTE 5

Barcoded Product # – See NOTE 2, Table 1
Barcoded Lot # – See NOTES 2,3

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Figure C

Instructions for Use

DRAFT Rev. E
04/19/01

Instructions for Use
AMS SupraPubic Arc (SPARC™) Sling System

These instructions are recommended for general use of this device for the treatment of stress urinary incontinence or ISD in a sling and/or suspension procedure. Variations in use may occur in specific procedures due to individual technique and patient anatomy.

Description:
SPARC™ System consists of the following:
- Two SPARC™ single-use needle passers, provided sterile
- AMS Polypropylene sling mesh with attached dilators, provided sterile
- Two plastic cystoscopy aids, provided sterile, (optional use)

[drawing of device]

The SPARC™ Sling System is a sterile, single use procedure kit consisting of:

- Two stainless steel, curved, 22-cm long, needle passers. Each end of the needle passer is keyed to allow for secure placement of the handles and dilators. Each needle passer has a plastic, ergonomic rotatable handle attached. The handles of the needle passers can be rotated in 90º increments, allowing the surgeon to customize the handle/needle positioning.
- One piece of AMS Polypropylene sling mesh with attached dilating connectors. The AMS Polypropylene sling mesh is constructed of polypropylene monofilament that is precut to 1.0cm width x 50cm length. Two plastic sheaths that overlap in the center of the sling mesh cover the sling mesh and protect it during placement. The plastic covering initially covering the mesh is designed to minimize the risk of contamination. Dilating connectors are attached to either end of the plastic sheaths. The dilating connector is attached to the vaginal ends of the SPARC™ needle passers during the procedure. The AMS Polypropylene sling mesh is intended to remain in the body as a permanent implant and is not absorbed or degraded by the action of tissue ingrowth or tissue enzymes.
- Two blue colored plastic cystoscopy aids are included in the kit in order to facilitate cystoscopic viewing of the bladder. The use of these cystoscopy aids is optional.

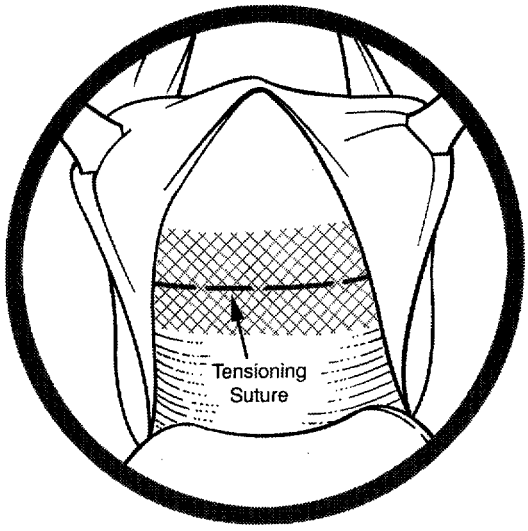
Indications:
The SPARC™ Sling System is intended for the placement of a pubourethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

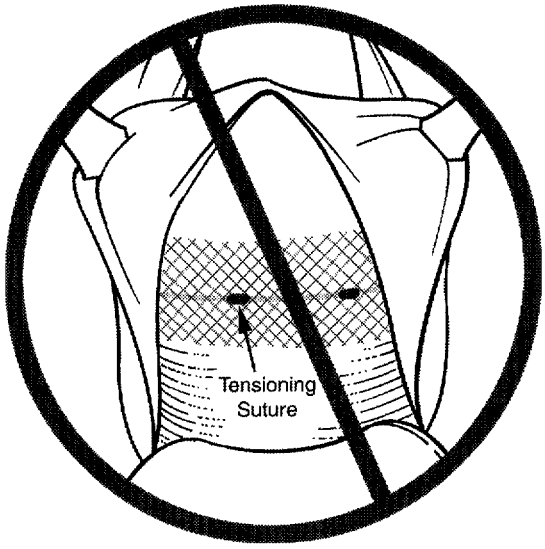
Instructions for Use:
The SPARC™ procedure can be carried out under local, spinal or general anesthesia. The dissection required is minimal. One or 2 small transverse incisions are made in the anterior vaginal wall followed by paraurethral dissection. Two small transverse suprapubic incisions are also made for needle entry. At the physician's discretion, a larger, single incision may be used.

STEPS:

1) Make a sagittal incision about 0.5 cm long approximately 1.0 cm from the urethral meatus, on the anterior vaginal wall.
2) Make 2 small paraurethral dissections just above the symphysis, not more than 4-5 cm apart, to allow a finger to pass and meet the needle.
3) Make two abdominal incisions of about 1 cm on each side of the midline, near the back of the pubic bone. At the physician's discretion, a larger single incision may be used.
4) Grasp the handle of the first needle. The push button on the needle handle releases the handle from the needle, allowing you to rotate the handle to the position you prefer. Be sure that both handles are attached to the needles in a secure manner.
5) Ensure that the bladder is empty. Pass the needle through one of the suprapubic incisions. Using the posterior side of the pubic bone, walk the needle toward the vaginal incision.
6) Use the index finger of the other hand to meet the tip of the needle, guiding it through the endopelvic fascia and into the vaginal incision.
7) When the first needle is in place, pass the second needle in the same way on the contra lateral side.
8) If there is a desire to use the cystoscopy aid, one should be passed up each needle. If there is urine flowing out of either needle, it is likely that the bladder was punctured.
9) Whether or not the cystoscopy aids are used, cystoscopy should be performed to confirm bladder integrity once both needles are in place.
10) Attach the dilating connectors (that are pre-attached to the AMS Polypropylene sling mesh material) to the needles. One dilating connector should be attached to each of the needles on the end protruding from the vagina. Orient the blue markings on the sheath facing outward, away from the urethra. Be sure that the sling mesh lies flat and that the sling mesh is not twisted prior to attaching the second dilating connector, as the dilating connectors cannot be removed once they are snapped into place. The dilating connectors are keyed at 90º intervals and may need to be rotated to snap on easily.

- *CAUTION*: To assure easy access and removal of the tensioning suture, be sure when attaching the dilating connectors to the needle that the sling is oriented such that the visible tensioning sutures will not be against the urethra, but will be facing outward. See diagram.





11) Verify that the dilating connectors are snapped securely in place to ensure that they do not fall off as the needles are pulled up through the body.

12) Once the sling mesh is attached, pull the needles up through the suprapubic incisions.

13) Secure each end of the sling mesh with a clamp. Cut the sling mesh approximately 3 cm away from the dilating connectors, assuring that you have cut inside the blue markings at each end of the plastic sheath, and discard the needles, handles and dilating connectors.

14) Position the sling mesh under the midurethra without tension. The blue marking on the sheath is located in the center of the sling mesh and can be used for centering the sling mesh under the midurethra.

15) Once desired placement is achieved, remove the plastic sheath from the sling mesh by pulling up from both sides, one side at a time. To avoid over–tightening the sling mesh while removing the plastic sheath from the sling, keep a forceps or other instrument between the tape and urethra during removal.

16) The blue tensioning suture of the sling mesh may be used for further tensioning adjustment once the plastic sheath is removed.

To loosen the sling mesh:
Place a device such as a clamp between the sling mesh and the urethra. Ensure that both the mesh and the tensioning suture are located beneath the clamp. Use the clamp to pull down and loosen the sling mesh as desired.

To tighten the sling mesh:
Place a device such as a clamp, across the sling mesh, suprapubically. Be sure that both the tensioning suture and the complete width of the sling are captured within the clamp. The sling mesh may be rolled around the clamp to improve the grip. Pull up to tighten the sling mesh as desired. If needed, this can be repeated on the contralateral side.

17) After sling is tensioned as desired, cut the tensioning suture lateral to the urethra on both sides and remove

Caution: Cut only the tensioning suture, and not the sling mesh, while removing the tensioning suture. It is only necessary to remove the tensioning suture in the area of the urethra.

18) Trim the sling mesh to size.

19) Close the suprapubic and vaginal incisions.

20) At the physician's discretion, a Foley catheter or suprapubic tube can be utilized until the patient is able to void.

Contraindications:

- Do not perform this procedure on pregnant patients
- The risks and benefits of implanting the AMS Polypropylene sling mesh in women planning future pregnancies should be carefully considered.
- The risks and benefits of using the SPARC™ procedure on patients with blood coagulation disorders should be carefully considered.
- The risks and benefits of using the SPARC™ procedure on patients with compromised immune systems or any other conditions that would compromise healing should be carefully considered.
- The risks and benefits of using the SPARC™ procedure on patients with renal insufficiency and upper urinary tract obstruction should be carefully considered.

Warnings and Precautions:

General

- Users should be familiar with surgical procedures and techniques involving non-absorbable meshes before using the SPARC™ device.
- Users should be familiar with surgical technique for bladder slings and suspensions before employing the SPARC™ system.
- Users should note the importance of placing the sling mesh **without tension** under the mid-urethra.
- Good surgical practice should be followed for management of contaminated or infected wounds.
- Use of the SPArc procedure should only be considered for patients whom the physician determines are adequate surgical risks.
- Vaginal or urinary tract infection should be treated prior to implantation.

Procedural

- Do not use the SPARC™ System with a transvaginal surgical approach.
- It is important to verify the tension and placement of the sling mesh prior cutting the tensioning suture, as the sling mesh may be difficult to adjust or remove after the tensioning suture is cut.
- Take care to avoid vessel perforation. Observe patient for any signs of retropubic bleeding.
- Cystoscopy should be performed to confirm bladder integrity or detect bladder perforation.
- Take care to avoid perforation of the urethra or bowel during needle placement.
- The dilating connectors should be pushed on to the needles slowly, moving up toward the needle handle.
- Do not remove the plastic sheath until the sling mesh is in its desired position.
- Do not contact the AMS polypropylene sling mesh with any staples, clips or other instruments that may damage the mesh.

Post Procedure

- If subsequent infection occurs, the entire sling mesh may have to be removed or revised.
- The patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent.
- Patients should be counseled on abstaining from heavy lifting, exercise and intercourse for a minimum of 4 weeks. Patients can return to other normal daily activities at the physician's discretion, often one to two weeks.
- If dysuria, bleeding or other problems occur, the patient should be instructed to call the surgeon immediately.

Device Related

- Do not re-sterilize or reuse this device. The SPARC™ device is intended for single use only. No portion of this procedure kit is reusable.
- Inspect each component of the system prior to use, non-functional instruments should not be used and should be returned to AMS.

- Do not use any part of the SPARC™ procedure kit beyond the indicated expiration date.
- Do not use the SPARC™ procedure kit if the package is opened or damaged, as sterility may be compromised.
- To maintain sterility, only the innermost pouch should be introduced into the sterile field.
- Store the SPARC™ procedure kit in a clean, dry, dark area at room temperature.

Adverse Events

- As with all implants, local irritation at the wound site and/or a foreign body response may occur.
- Tissue responses to the implant could include extrusion, erosion through the urethra or other surrounding tissue, migration of the device from the desired location, fistula formation and inflammation. The occurrence of these responses may require removal of the entire sling mesh.
- Like all foreign bodies, the AMS polypropylene sling mesh may potentiate an existing infection.
- Overcorrection may cause temporary or permanent lower urinary tract obstruction and retention.
- Known risks of surgical procedures for the treatment of incontinence include pain, infection, erosion, device migration, complete failure of the procedure resulting in incontinence and mild to moderate urinary incontinence due to incomplete support or excess bladder contractions.

CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

STERILEIETO (symbol)
AMS addresses

Appendix I

Truthful and Accurate Statement

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT*
(As Required by 21 CFR 807.87(j))

I certify that, in my capacity as Sr. Regulatory Affairs Specialist of American Medical Systems, I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Ginger Sackett Glaser, Sr. Regulatory Affairs Associate

American Medical Systems, April 20 , 2001

Appendix J

510(k) Summary
SPARC™ Sling System

K011251 (1 of 2)

510(k) Summary
SPARC™ Sling System
510(k) Number _____

Submitter/Contact Person:

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American Medical Systems
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Device Name and Classification:

Trade Name: SPARC™ Sling System
Common/Usual Name: Surgical Mesh, Sling, Urethral Sling
Classification Name: Surgical Mesh, polymeric
Product Code: FTL
Classification: Class II

Manufacturing Location:

American Medical Systems, Inc.
10700 Bren Rd. West
Minnetonka, MN 55343

Predicate Devices:

Tension Free Vaginal Tape (TVT) System by Ethicon, Inc. - K974098

Indications for Use:

The SPARC™ Sling System is intended for the placement of a pubourethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Device Description:

The SPARC™ Sling System is a sterile, single use procedure kit consisting of:

- Two stainless steel, curved, 22-cm long, needle passers (also called insertion tools).
- One piece of AMS Polypropylene sling mesh with attached dilating connectors. The AMS Polypropylene sling mesh is constructed of polypropylene monofilament that is precut to 1.0cm

width x 50cm length. A fixed blue polypropylene anchoring suture runs through the middle of the sling mesh. Two plastic sheaths that overlap in the center of the sling mesh, cover the sling mesh and protect it during placement.

Dilating connectors are attached to either end of the plastic sheaths. The dilating connectors are used to attach to the vaginal ends of the SPARC™ needle passers during the procedure to facilitate sling placement.

- Two blue colored plastic cystoscopy aids are included in the kit in order to facilitate cystoscopic viewing of the bladder. The use of these cystoscopy aids is optional.

Summary of Testing

The material used in the SPARC™ Sling System has been demonstrated to be biocompatible.

The SPARC™ Sling System has been tested for a variety of physical characteristics including tensile strength and suture pull strength and has been shown to be equivalent to the listed predicate devices.

FDA/CDRH IMAGING SYSTEM

Page Count Discrepancy Information

The page after page 135 is not numbered.

Verifiers Initials