



**USER:** PATTERSON, CLIFTON A (cxp)

**FOLDER:** K050418 - 141 pages (FOI:08008925)

**COMPANY:** TFS MANUFACTURING PTY LTD (TFS)

**PRODUCT:** MESH, SURGICAL, POLYMERIC (FTL)

**SUMMARY:** Product: TISSUE FIXATION SYSTEM

**DATE REQUESTED:** Tue Mar 30 24:00:00 2010

**DATE PRINTED:** Fri Jan 28 15:02:41 2011

**Note:** FOI Working Copy

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MAY 16 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Alastair Dowling  
QA Manager  
TFS Manufacturing Pty Ltd  
18 Kincaid Avenue  
North Plympton, South Australia 5037  
Australia

Re: K050418

Trade/Device Name: Tissue Fixation System (TFS Device)  
Regulation Number: 21 CFR 878.3300  
Regulation Name: Surgical mesh  
Regulatory Class: II  
Product Code: FTL  
Dated: March 24, 2005  
Received: March 28, 2005

Dear Mr. Dowling:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Alastair Dowling

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Miriam C. Provost, Ph.D.

Acting Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**INDICATIONS FOR USE STATEMENT**

**510(k) Number:** To be assigned

**Device Name:** Tissue Fixation System (TFS Device)

**Indications for Use:** The TFS Device is intended to be used in females to position a polypropylene mesh tape for the treatment of Genuine Stress Urinary Incontinence, mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency, and vaginal vault prolapse.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number   K050418



MAY 16 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Alastair Dowling  
QA Manager  
TFS Manufacturing Pty Ltd  
18 Kincaid Avenue  
North Plympton, South Australia 5037  
Australia

Re: K050418  
Trade/Device Name: Tissue Fixation System (TFS Device)  
Regulation Number: 21 CFR 878.3300  
Regulation Name: Surgical mesh  
Regulatory Class: II  
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Dated: March 24, 2005  
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Sincerely yours,



Miriam C. Provost, Ph.D.  
Acting Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**INDICATIONS FOR USE STATEMENT**

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Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
Division of ~~Medical~~ Restorative  
and Neurological Devices  
510(k) Number  K050418

Page 1 of  1

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

March 03, 2005

TFS MANUFACTURING PTY LTD  
18 KINCAID AVENUE  
NORTH PLYMPTON SA,  
AUSTRALIA 5037  
ATTN: ALASTAIR DOWLING

510(k) Number: K050418  
Product: TISSUE FIXATION  
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. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at [www.fda.gov/cdrh/ode/a02-01.html](http://www.fda.gov/cdrh/ode/a02-01.html).

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. Please note our guidance document entitled, "Guidance for Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>. 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 International and Consumer Assistance (DSMICA) 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

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

February 22, 2005

TFS MANUFACTURING PTY LTD  
18 KINCAID AVENUE  
NORTH PLYMPTON SA,  
AUSTRALIA 5037  
ATTN: ALASTAIR DOWLING

510(k) Number: K050418  
Received: 18-FEB-2005  
Product: TISSUE FIXATION  
SYSTEM

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), 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 May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(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. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at [www.fda.gov/cdrh/ode/a02-01.html](http://www.fda.gov/cdrh/ode/a02-01.html).

You should be familiar with the regulatory requirements for medical device available at Device Advice <http://www.fda.gov/cdrh/devadvice/>. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301)594-1190.

Sincerely yours,

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

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

February 18, 2005

TFS MANUFACTURING PTY LTD  
18 KINCAID AVENUE  
NORTH PLYMPTON SA,  
AUSTRALIA 5037  
ATTN: ALASTAIR DOWLING

510(k) Number: K050418  
Received: 18-FEB-2005  
Product: TISSUE FIXATION  
User Fee ID Number: 17270

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), 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. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), specifies that a submission shall be considered incomplete and shall not be accepted for filing until fees have been paid (Section 738(f)). Our records indicate that you have not submitted the user fee payment information and therefore your 510(k) cannot be filed and has been placed on hold. Please send a check to one of the addresses listed below:

By Regular Mail

By Private Courier (e.g., Fed Ex, UPS, etc.)

-----  
Food and Drug Administration  
P.O. Box 956733  
St. Louis, MO 63195-6733.

-----  
U.S. Bank  
956733  
1005 Convention Plaza  
St. Louis, MO 63101  
(314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (301) 594-2977 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at <http://www.fda.gov/oc/mdufma>.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file an application with FDA or what type of application to file, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)443-6597 or its toll-free number (800)638-2041, or contact them at their Internet address <http://www.fda.gov/cdrh/dsmamain.html>, or you may submit a 513(g) request to the Document Mail Center at the address above. If you have any questions concerning the contents of this letter, you may contact me at (301) 594-1190.

Sincerely yours,

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

15050418

**TFS MANUFACTURING PTY LTD**

15 February 2005

Document Control Center (HFZ-401)  
Center for Devices and Radiological Health  
Office of Device Evaluation  
Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, MD, 20850  
USA

FDA/CDRH  
2005 FEB 15 A 9 10

Dear Representative

**Re: 510(k) Application - TFS device**

Attached is a 510(k) application for this device.

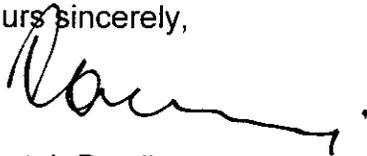
We initially submitted this application in September 2004, however there was no acknowledgment from the FDA of receipt, nor was the bank check for the fee presented to our bank.

Recent email correspondence and telephone calls with CDRH indicate that there may have been confusion with another company with a similar name, viz. TFS Manufacturing Services of Redmond, Washington.

We are now re-submitting the application and have forwarded another bank check to cover the filing fee to the appropriate office.

In view of the problems and delay that we have experienced, we respectfully request that you expedite review of the application.

Yours sincerely,



Alastair Dowling  
QA Manager

TFS Manufacturing Pty Ltd  
18 Kincaid Avenue  
North Plympton  
South Australia 5037  
Australia

SU  
H  
X-12 103

31 August 2004

Document Control Center (HFZ-401)  
Center for Devices and Radiological Health  
Office of Device Evaluation  
Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, MD, 20850  
USA

**Re: Initial 510(k) Filing of the  
TFS Device**

Dear Representative,

Please review the attached initial 510(k) of the **TFS Manufacturing Pty Ltd TFS Device** together with support documentation and advise us of the 510(k) number assigned to this file.

We believe this device to be a simple Tier 2 review. Please notify the General and Restorative Division of our assessment.

Thank you for your assistance in this matter.

Yours sincerely,

Mr Alastair Dowling  
QA Manager  
TFS Manufacturing Pty Ltd

Attached: 2 copies 510(k) - TFS Device

→ FDA

6/9

*Note indicates  
date sent to FDA*

15 February 2005

Document Control Center (HFZ-401)  
Center for Devices and Radiological Health  
Office of Device Evaluation  
Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, MD, 20850  
USA

**Re: Initial 510(k) Filing of the  
TFS Device**

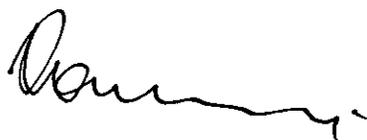
Dear Representative,

Please review the attached initial 510(k) of the **TFS Manufacturing Pty Ltd TFS Device** together with support documentation and advise us of the 510(k) number assigned to this file.

We believe this device to be a simple Tier 2 review. Please notify the General and Restorative Division of our assessment.

Thank you for your assistance in this matter.

Yours sincerely,



Mr Alastair Dowling  
QA Manager  
TFS Manufacturing Pty Ltd

Attached: 2 copies 510(k) - TFS Device

Form Approved: OMB No. 0910-0511 Expiration Date: August 31, 2006. See instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>	PAYMENT IDENTIFICATION NUMBER: <b>017270 - 956733</b> Write the Payment Identification Number on your check.
A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:	
<ol style="list-style-type: none"> <li>1. Electronically submit the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.</li> <li>2. Include a printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.</li> <li>3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the application.)</li> <li>4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)</li> <li>5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: <a href="http://www.fda.gov/cdrh/mdufma/faqs.html#3a">http://www.fda.gov/cdrh/mdufma/faqs.html#3a</a>. You are responsible for paying all fees associated with wire transfers.</li> <li>6. Include a copy of the completed Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.</li> </ol>	
1. COMPANY NAME AND ADDRESS (Include name, street address, city, state, country, and post office code)  TFS MANUFACTURING PTY LTD 18 KINCAID AVENUE PLYMPTON , 5037 AUSTRALIA  1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	2. CONTACT NAME ALASTAIR DOWLING  2.1 E-MAIL ADDRESS dowing@space.net.au  2.2 TELEPHONE NUMBER (Include Area Code) +61 8 9330 8102  2.3 FACSIMILE (FAX) NUMBER (Include Area Code) +61 8 9330 8102
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: <a href="http://www.fda.gov/oc/mdufma">http://www.fda.gov/oc/mdufma</a> )	
Select an application type: <input checked="" type="checkbox"/> Premarket notification (510(k)); except for third party reviews <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR)	3.1 Select one of the types below: <input checked="" type="checkbox"/> Original Application  Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status.) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business  4.1 If Yes, please enter your Small Business Decision Number:	
5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.	
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms  <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population  <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially
6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)  <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	
7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)  \$3,502.00	

Form FDA 3601 (08/2003)

106

15 February 2005

Document Mail Centre (HFZ-401)  
Center for Devices and Radiological Health  
Division of General and Restorative Devices  
Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, MD, 20850, USA

**Re: 510(k) Notification - Tissue Fixation System**

Dear Reviewer,

Pursuant to the requirements of Section 510 (k) of the Federal Food, Drug and Cosmetic Act, **TFS Manufacturing Pty Ltd**, of 14 Kincaid Avenue, North Plympton, South Australia, 5037, Australia, proposes to introduce into interstate commerce for commercial distribution devices intended for human use and hereby reports the same to the Food and Drug Administration as required by the Act. This pre-market notification, under 21 CFR 807.93, is being made prior to the date upon which **TFS Manufacturing Pty Ltd** proposes to begin the introduction of the device into interstate commerce, with the proposed labelling as described herein.

The following information on the device ( according to Title 21, Subpart E, Part 807, of the Code of Federal Regulations) is submitted for your consideration.

**1. Submitters Details**

Submitters name: **TFS Manufacturing Pty Ltd**

Address: **Head Office:**  
18 Kincaid Avenue  
North Plympton  
South Australia 5037  
Australia

**Production Facility:**  
As above

Contact person: Mr Alastair Dowling

Contact Details: telephone + 61 8 8351 0644  
facsimile + 61 8 8351 0855

Date of Application: 15 February 2005

**2. TFS Manufacturing Pty Ltd** has a fully compliant, Australian owned cGMP medical device production facility in Australia, which is in the process of being registered the FDA. TFS Manufacturing was assessed in 2003 by the Australian Therapeutic Goods Administration as being compliant with the requirements of the Australian Therapeutic Goods (Medical Devices) Regulations 2002. In accordance with the MRA between TGA and the EU, a CE mark certification has been authorised.

**3. The name of the device**

Trade name: **Tissue Fixation System**

Common name: **TFS Device**

Classification: Class III

**4. Included in this submission are:**

- Exhibit A: Indications for Use Statement and Draft labelling
- Exhibit B: Manufacturers Statement of Substantial Equivalence
- Exhibit C: Product Specifications
- Exhibit D: Information on Predicate Devices
- Exhibit E: Premarket Notification Statement and Truthful and Accurate Statement

**TFS Manufacturing Pty Ltd** believes that the **TFS Device** manufactured in its facility in Australia is substantially equivalent to

**Gyne Ideas Minitape RP Device**

manufactured by Gyne Ideas Ltd of 150 Aran Hill Rd. Fairfield , CT 06824 (K023898)

and

**Pubourethral Sling (TVT System)**

manufactured by Ethicon, Inc. of PO Box 151, Somerville, NJ 08876 0151 (K974098)

## **Product Regulatory Summary**

The **TFS Device** assembled at the facility in Australia is made to the design, specifications and to the requirements of ISO 13485:2003, MDD93/42/EEC and is used for the same purpose as the existing devices, Gyne Ideas Minitape ( K023898) and Pubourethral Sling (K974098).

Based on the indications for use and substantial equivalency to an identified and pre-existing predicate device, **TFS Manufacturing Pty Ltd** therefore requests a market clearance for the **TFS Device** manufactured by **TFS Manufacturing Pty Ltd** in Australia. **TFS Manufacturing Pty Ltd** believes that this should be done under a 510(k), Tier 2 submission format , consistent with current FDA regulations and applicable DREARD programs.

### **SMDA 510(k) Statement, ( §513(l) of the 'Act')**

In addition and with the requirements of "The Safe Medical Devices Act of 1990" , ( §513 (l) of the 'Act' ), **TFS Manufacturing Pty Ltd** affirms that the information contained in this submission , relating to the general safety and effectiveness of the **TFS Device**, will be made publicly available upon request.

## CONCLUSION

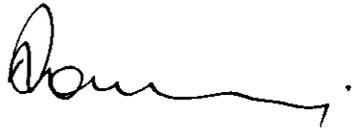
**TFS Manufacturing Pty Ltd** believes that the foregoing information and referenced Exhibits will be sufficient for the FDA to determine that the **TFS Device**, manufactured by TFS Manufacturing Pty Ltd in Australia, to be a Tier 2 regulated device, substantially equivalent to the referenced predicate devices. Should any further information be required it will promptly be furnished upon request.

Details for Contact:

Mr Alastair Dowling  
QA Manager  
TFS Manufacturing Pty Ltd  
18 Kincaid Avenue  
North Plympton  
South Australia 5037  
Australia

telephone + 61 8 8351 0644  
facsimile + 61 8 8351 0855

Yours sincerely,



Mr Alastair Dowling  
QA Manager  
TFS Manufacturing Pty Ltd

# EXHIBIT A

## INDICATIONS FOR USE STATEMENT

**510(k) Number:** To be assigned

**Device Name:** Tissue Fixation System (TFS Device)

**Indications for Use:** The TFS Device is intended to be used in females to position a polypropylene mesh tape for the treatment of Genuine Stress Urinary Incontinence, mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency, and vaginal vault prolapse.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of \_\_\_\_\_

# TFS TISSUE FIXATION SYSTEM\*



TISSUE FIXATION SYSTEM

CE  
0805

STERILE EO



SINGLE  
PATIENT  
USE



PRIOR TO  
USE SEE  
INSTRUCTIONS

\*Trademark  
© 2004 Kyvno Centre  
All Rights Reserved. Made in Australia  
MANUFACTURER: TFS PTY LTD, ADELAIDE, SOUTH AUSTRALIA  
European Representative Advena Ltd PO Box 30 Leominster HR6 0ZQ, U.K.  
**CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON ORDER OF A PHYSICIAN**

Do not use if unit package is opened or damaged. Do not re-sterilize.  
Ne pas utiliser si l'emballage est ouvert ou endommagé. Ne pas restériliser.  
Nur verwenden, wenn die Packung ungeöffnet und unbeschädigt ist. Nicht restertilisieren.

Store in a dry place below 25°C

Non utilizzare se la confezione è aperta o danneggiata. Non ristertilizzare.  
No utilizar si el envase está abierto o dañado. No reesterilizar.  
Använd ej om förpackningen är öppnad eller skadad. Får ej omsteriliseras.  
Gebruik de sonde niet wanneer de verpakking open of beschadigd is. Steriliseer de sonde niet opnieuw.  
Não utilize se a embalagem estiver aberta ou danificada. Não re-esterilizar.  
Et saa käyttää, jos pakkaus on aukkai vaurioitunut. Et saa steriloia uudelleen.  
Må ikke anvendes, hvis pakningen er åbnet eller beskadiget. Må ikke restertileres.

# EXHIBIT B

## STATEMENT OF SUBSTANTIAL EQUIVALENCE

**1. Similar Indication statements ?**

Yes, the new device has the same indication statements.

**2. Has the device the same intended use ?**

Yes, the intended use is exactly the same as the predicate devices.

**3. Does the device have the same technological characteristics ?**

Yes, the three predicate devices and the TFS Device  
Have similar design of the same design and use the same materials.

**4. Are the descriptive characteristics precise enough to ensure equivalence ?**

Yes, the predicate and new devices are intended for the same use.

# EXHIBIT C

## DEVICE SPECIFICATION

The TFS Tissue Fixation System consists of a polypropylene mesh tape with polypropylene anchors.

The device is supplied sterile and is sterilised by a properly validated Ethylene Oxide procedure.

Stainless steel accessories for accurate placement of the device are available separately and are provided non-sterile and are re-usable.

The device has been subjected to in-vitro and in-vivo testing and histological studies which has demonstrated that the device functions as intended.

The device is intended to be used in females for the treatment of Genuine Stress Urinary Incontinence, Mixed Incontinence resulting from urethral hypermobility or Intrinsic Sphincter Deficiency and Vaginal Vault Prolapse.

The TFS device is manufactured in a fully compliant ISO 13485:2003 production facility that is approved by the Therapeutic Goods Administration (TGA) of Australia and is in the process of registration with the FDA. In view of compliance with the necessary standards, the device has been CE marked by the TGA.

# EXHIBIT D

## **PREDICATE DEVICES**

The device which is subject of this submission has the same technological characteristics as other legally marketed predicate devices.  
The features, materials and mode of use are the same or equivalent.  
Any differences in the two devices do not raise any new questions of safety or effectiveness.

Predicate Device #1:  
**Gyne Care Minitape (K023898)**

Predicate Device # 2  
**TVT System (K974098)**

# **PREDICATE DEVICE**

**# 1**



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**510(k) Premarket Notification Database**

<b>Device Classification Name</b>	<a href="#">Mesh, Surgical, Polymeric</a>
<b>510(K) Number</b>	K023898
<b>Regulation Number</b>	878.3300
<b>Device Name</b>	GYNE IDEAS MINITAPE RP DEVICE
<b>Applicant</b>	<a href="#">GYNE IDEAS LTD.</a> 150 Aran Hill Rd. Fairfield, CT 06824
<b>Contact</b>	Louis Mazzaresse
<b>Product Code</b>	FTL
<b>Date Received</b>	11/22/2002
<b>Decision Date</b>	06/18/2003
<b>Decision</b>	Substantially Equivalent (SE)
<b>Classification Advisory Committee</b>	General & Plastic Surgery
<b>Review Advisory Committee</b>	General & Plastic Surgery
<b>Statement/Summary/Purged Status</b>	Summary Only
<b>Summary</b>	<a href="#">Summary</a>
<b>Type</b>	Traditional
<b>Reviewed By Third Party</b>	No
<b>Expedited Review</b>	No

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Center for Devices and Radiological Health / CDRH

K023898

Gyne Ideas Ltd.  
510(k) Notification

**STATEMENT FOR INDICATIONS FOR USE**

The subject device is intended to be used as a pubourethral sling for the treatment of female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Miriam C. Provost  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices  
510(k) Number K023898

JUN 1 8 2003

Gyne Ideas Ltd.  
510(k) Notification

K023898

### 510(k) SUMMARY OF SAFETY & EFFECTIVENESS

SUBMITTER	Gyne Ideas, Ltd. West of Scotland Science Park Glasgow, U.K.
CONTACT PERSON	Louis J. Mazzaresse (U.S. Agent for GyneIdeas, Ltd.)
DATE PREPARED	November 20, 2002
CLASSIFICATION	Polymeric Surgical Mesh
COMMON NAME	Urethral Sling
PROPRIETARY NAME	Gyne Ideas Minitape RP™
PREDICATE DEVICES	K974098 – Tension Free Vaginal Tape (TVT) System (Ethicon, Inc.) K010553 – Biosling (Injetx, Inc.) K020007 – SAFYRE Sling (Corniche, LLC) K020110 – Surgical Mesh (Boston Scientific) K020652 – T-Sling (Herniamesh USA, Inc.) K020705 – SiiS#1 Tissue Suspension System (T.A.G. Medical Products, Ltd.) K021263 - SPARC Sling System (American Medical Systems)
DEVICE DESCRIPTION	The device consists of a polypropylene sling with integral serrated anchoring arms. The sling has an overall length of 14cm. It is supplied with two metal needles to aid in surgical placement of the device. The device is supplied sterile.
INTENDED USE	To be used as a pubourethral sling for the treatment of female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.
TESTING	The device has been subjected to in-vitro and in-vivo testing which demonstrate the ability of the device to adequately restrain urethral tissue under conditions in excess of those encountered during normal clinical use.



JUN 18 2003

Gyne Ideas, Ltd.  
c/o Mr. Louis J. Mazzaresse  
150 Aran Hill Road  
Fairfield, Connecticut 06824-1712

Re: K023898

Trade/Device Name: Gyne Ideas Minitape RP™  
Regulation Number: 21 CFR 878.3300  
Regulation Name: Surgical mesh  
Regulatory Class: II  
Product Code: FTL  
Dated: April 4, 2003  
Received: April 7, 2003

Dear Mr. Mazzaresse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Mr. Louis J. Mazzaresse

This letter will allow you to begin marketing your device as described in your Section 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), 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 Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

*Miriam C. Provost*  
for 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

# **PREDICATE DEVICE**

**# 2**



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**510(k) Premarket Notification Database**

<b>Device Classification Name</b>	<a href="#">Mesh, Surgical, Polymeric</a>
<b>510(K) Number</b>	K974098
<b>Regulation Number</b>	<a href="#">878.3300</a>
<b>Device Name</b>	PUBOUURETHRAL SLING
<b>Applicant</b>	<a href="#">ETHICON, INC.</a> P.O. Box 151 Somerville, NJ 08876 0151
<b>Contact</b>	Gregory R Jones
<b>Product Code</b>	FTL
<b>Date Received</b>	10/30/1997
<b>Decision Date</b>	01/28/1998
<b>Decision</b>	Substantially Equivalent (SE)
<b>Classification Advisory Committee</b>	General & Plastic Surgery
<b>Review Advisory Committee</b>	General & Plastic Surgery
<b>Statement/Summary/Purged Status</b>	Summary/Purged 510(K)
<b>Summary</b>	<a href="#">Summary</a>
<b>Type</b>	Traditional
<b>Reviewed By Third Party</b>	No
<b>Expedited Review</b>	No

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Center for Devices and Radiological Health / CDRH

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  
(Per 21 CFR 801.109)

OR

Over-The Counter Use

(Optional Format 1-2-9G)

(Division Sign Off)  
Division of General Re  
510(k) number

2974090

Tension Free Vaginal Tape (TVT) System  
ETHICON, Inc.

K974098

## SUMMARY OF SAFETY AND EFFECTIVENESS, Continued

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<b>Indications Statement</b>	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.
<b>Technological Characteristics</b>	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.
<b>Performance Data</b>	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.
<b>Conclusions</b>	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.
<b>Contact</b>	Gregory R. Jones Director Regulatory Affairs ETHICON, Inc. Rt. #22 West Somerville, NJ 08876-0151
<b>Date</b>	October 28, 1997

---

Tension Free Vaginal Tape (TVT) System  
ETHICON, Inc.

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 shaft 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



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.

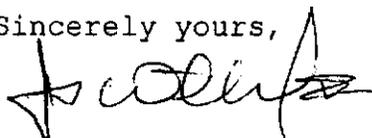
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Gregory R. Jones

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,

  
f 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

# EXHIBIT E

# TRUTHFUL AND ACCURATE STATEMENT

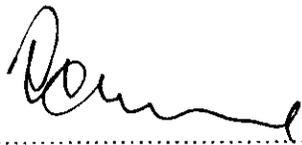
21 CFR 807.87(j)

TFS Device

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I certify that, in my capacity as QA Manager of TFS Manufacturing Pty Ltd, I believe to the best of my knowledge, that the above statements and all data and information submitted in this pre-market notification are truthful and accurate and that no material fact has been omitted.

Official Correspondent



.....(signature)

Mr Alastair Dowling

.....(printed name)

15 February 2005

.....(date)

# PREMARKET NOTIFICATION 510(K) STATEMENT

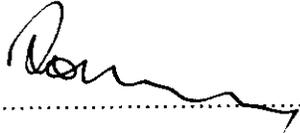
21 CFR 807.93

TFS Device

---

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

Official Correspondent

  
.....(signature)

Mr Alastair Dowling  
.....(printed name)

15 February 2005  
.....(date)

Premarket Notification 510(k) number: *to be assigned*

From: Reviewer(s) - Name(s) Herbert Lerner, MD

Subject: 510(k) Number K050418/S'

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.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Section 522 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

- Truthful and Accurate Statement  Requested  Enclosed
- A 510(k) summary OR  A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) ✓

Animal Tissue Source  YES  NO 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):

Class II, 878.3100 Surgical Mesh FTL

Review: [Signature] PCSB 7/10/05  
(Branch Chief) (Branch Code) (Date)

Final Review: [Signature] 5/16/05  
(Division Director) (Date)

## Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?	N	A
4. If, not, has POS been notified?		
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?	✓	✓
7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

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

Reviewer: K 050418  
Herbert Lerner MD  
 Division/Branch: DBRMD / PRSB  
 Device Name: Tissue fixation System  
 Product To Which Compared (510(K) Number If Known): K010035

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

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

1. Intended Use:
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device 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.

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: *Device characteristics unchanged*
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

510 (k) Memorandum  
K050418

To: The Record  
From: Herbert Lerner, Md  
Subject: TFS Device  
Sponsor: TFS Manufacturing Pty Ltd  
Contact: Mr. Alastair Dowling  
[dowling@SPACE.NET.AU](mailto:dowling@SPACE.NET.AU)

Procode: FTL  
Regulation number: 878.3300  
Regulation name: Surgical mesh-polymeric  
Class: II

**Predicates:**

Gyne Ideas Minitape RP	K023898
Pubourethral Sling- Ethicon	K974098
US Surgical IVS Tunneller	K010035

This device contains no drugs or biologicals.

**Recommendation:** Substantially equivalent to the predicates.

**Indication for Use:**

Subject: The TFS Device is intended to be used in females to position a polypropylene mesh tape for the treatment of Genuine Stress Urinary Incontinence, mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency, and vaginal vault prolapse.

Predicate: The US Surgical IVS Tunneler has the identical Indication for Use statement. The Gyne Ideas System is intended to be used as a pubourethral sling for the treatment of female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The Ethicon TVT has essentially the same statement.

Discussion: All three predicates have identical or very similar statements: for the treatment of female urinary stress incontinence. There are no clinical issues, or regulatory issues with these statements, therefore they are SE to the predicates..

**Technological Characteristics**

The subject device is a polypropylene mesh tape with polypropylene anchors. It is the exact material sold in the US by (b) (4), (b) (4)). The sponsor purchases these materials and then incorporates the mesh into their own system. Supporting

documentation is provided by the sponsor. The mesh is approximately 0.44mm thick, 8mm wide and 35 mm long. It is knitted from multifilament yarns 20-30 microns thick. The anchors are made of the same polypropylene material and measure 6.1 x 11.7 mm and are designed to be able to be anchored into the supporting tissues to hold the mesh in place. Provided separately is a stainless steel introducer for placement of the mesh behind the ureter before anchoring.

Predicates: The mesh appears to be identical as the subject device and the mechanism of placement and anchoring is also similar.

Discussion: As the materials are identical, and the anchoring system similar, using the same mesh material, I have no issue with the technological characteristics of the device and they are SE to the predicates.

### **Comparative Performance Data**

The sponsor has provided documentation that their device, the polypropylene mesh, has been purchased from (b) (4), and that all biocompatibility testing has been passed. Documentation is provided in the form of the material Quantification report for mutagenicity, intramuscular implant, intracutaneous injection, skin sensitization, systemic toxicity, hemolysis and skin irritation.

Discussion: I feel that this is adequate to support the biocompatibility and performance data needed for clearance.

### **Sterilization:**

Method: Ethylene Oxide

Validation: ISO 11135

SAL:  $10^{-6}$

EtO residuals:

Ethylene oxide-	<250 ppm
Ethylene chlorhydrin-	<250 ppm
Ethylene glycol-	<5000ppm

Packaging: Tyvek/ Nylon Pouch in a cardboard carton.

Shelf life- validated to 60 months.

### **Labeling**

The device is available by prescription only

Package Insert (Appendix 2 of April 7, 2005 communication)

Carton/Pouch Labels (Appendix 3 of April 7, 2005 communication)

### **Administrative requirements-**

- Truthful and Accurate Statement (Exhibit E )
- 510(k) Statement (Exhibit E )

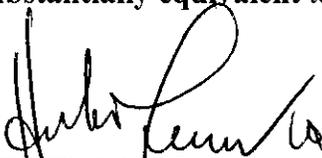
- Indication for Use Page (Exhibit A)

Discussion: The sponsor has provided adequate documentation that supports his claim that the device is exactly the same as the (b) (4) device, including biocompatibility and sterilization details. The trocar for insertion is a class I exempt device and is provided separately. The instructions for use are adequate, as are the product labels.

**Correspondence history:**

The initial submission, received February 15, 2005 was placed on hold for gross deficiencies. Attached immediately following this review memo are the e-mail correspondences with the sponsor attempting to gather and submit the additional materials needed. Following that are numerous pages of additional material submitted to support equivalence.

At this point I feel that the sponsor has addressed all deficiencies, and that the device is **substantially equivalent** to the predicate devices.



Herbert Lerner, MD

**Lerner, Herbert P.**

---

**From:** dowling [dowling@space.net.au]  
**Sent:** Monday, May 09, 2005 9:01 PM  
**To:** Lerner, Herbert P.  
**Subject:** Re: K050418

Dear Dr Lerner,

Thank you for your message.

I confirm that each manufacturing lot of the TFS Device shall be LAL tested to demonstrate endotoxin levels of

(b) (4)

A satisfactory result of the LAL testing shall form part of the Release for Sale procedure for the TFS Device.

The LAL testing will be performed by a TGA (Australia) Approved/Licensed laboratory.

Sincerely,  
Alastair Dowling  
QA Manager,  
TFS Manufacturing Pty Ltd

----- Original Message -----

**From:** Lerner, Herbert P.  
**To:** 'dowling@space.net.au'  
**Sent:** Tuesday, May 10, 2005 2:31 AM  
**Subject:** K050418

Mr. Dowling.

I am sorry that it has taken so long to get this out, it has been out of my hands for several weeks.

Please e-mail me a statement that you will do a LAL test on a lot by lot basis to demonstrate endotoxin levels of

(b) (4)

We require this for implantable meshes.  
A simple statement that you plan to do this will suffice.  
With this statement, we will clear the 510 (k) .  
Again, I am sorry for the delay.

Herb Lerner

*Herbert Lerner, MD*

CDRH/ODE/DGRND/PRSB  
9200 Corporate Blvd.  
HFZ-410  
Rockville, MD 20850  
HPL@CDRH.FDA.GOV (current)  
herbert.lerner@fda.hhs.gov (current/future)  
301-594-3090 x207

5/10/2005

13

**Lerner, Herbert P.**

**From:** dowling [dowling@space.net.au]  
**Sent:** Friday, April 01, 2005 3:45 AM  
**To:** Lerner, Herbert P.  
**Subject:** Re: 510 (k)

Dear Dr Lerner,

In reply to your queries:

The mesh is purchased directly from (b) (4) and is then incorporated into the TFS device at the TGA and CE accredited TFS Manufacturing Pty Ltd facility in South Australia.

The anchors are moulded by TFS Manufacturing contractor in South Australia from (b) (4).  
 (b) (4) This resin is also purchased from (b) (4) and is the same implantable quality (b) (4) used by (b) (4) for their sutures.

(b) (4)

Yours sincerely,

Alastair Dowling  
 TFS Manufacturing Pty Ltd

I

----- Original Message -----  
**From:** Lerner, Herbert P.  
**To:** 'Dowling@space.net.au'  
**Sent:** Thursday, March 31, 2005 1:03 AM  
**Subject:** 510 (k)

Mr. Dowling,

I have received your material. Thank you.

Am I to understand that you purchase both the mesh and anchors from (b) (4) and you intend to package them and market your system here?

(b) (4) I cannot find reference to one in your submission.

Thanks

Herb Lerner

*Herbert Lerner, MD*

CDRH/ODE/DGRND/PRSB  
 9200 Corporate Blvd.

4/4/2005

14

**Lerner, Herbert P.**

---

**From:** Lerner, Herbert P.  
**Sent:** Monday, April 04, 2005 9:02 AM  
**To:** 'Dowling@space.net.au'  
**Subject:** K050418

Good day, and thanks for the quick responses to my questions.  
There are two additional items needed before I can clear the device:

- 1) a mechanical drawing of the anchor
- 2) Instructions for Use of the system- especially how to place the anchors and secure the mesh to the anchors.

Additionally, you note in Appendix 4 that the anchors are made of a (b) (4) supplied by (b) (4). A statement from (b) (4), indicating that this is the same material they use in their sutures or mesh, is needed to assure you are using the same material that is in an already cleared device. Your statement is too vague.

Thanks

Herb Lerner

*Herbert Lerner, MD*

CDRH/ODE/DGRND/PRSB  
9200 Corporate Blvd.  
HFZ-410  
Rockville, MD 20850  
HPL@CDRH.FDA.GOV (current)  
herbert.lerner@fda.hhs.gov (current/future)  
301-594-3090 x207

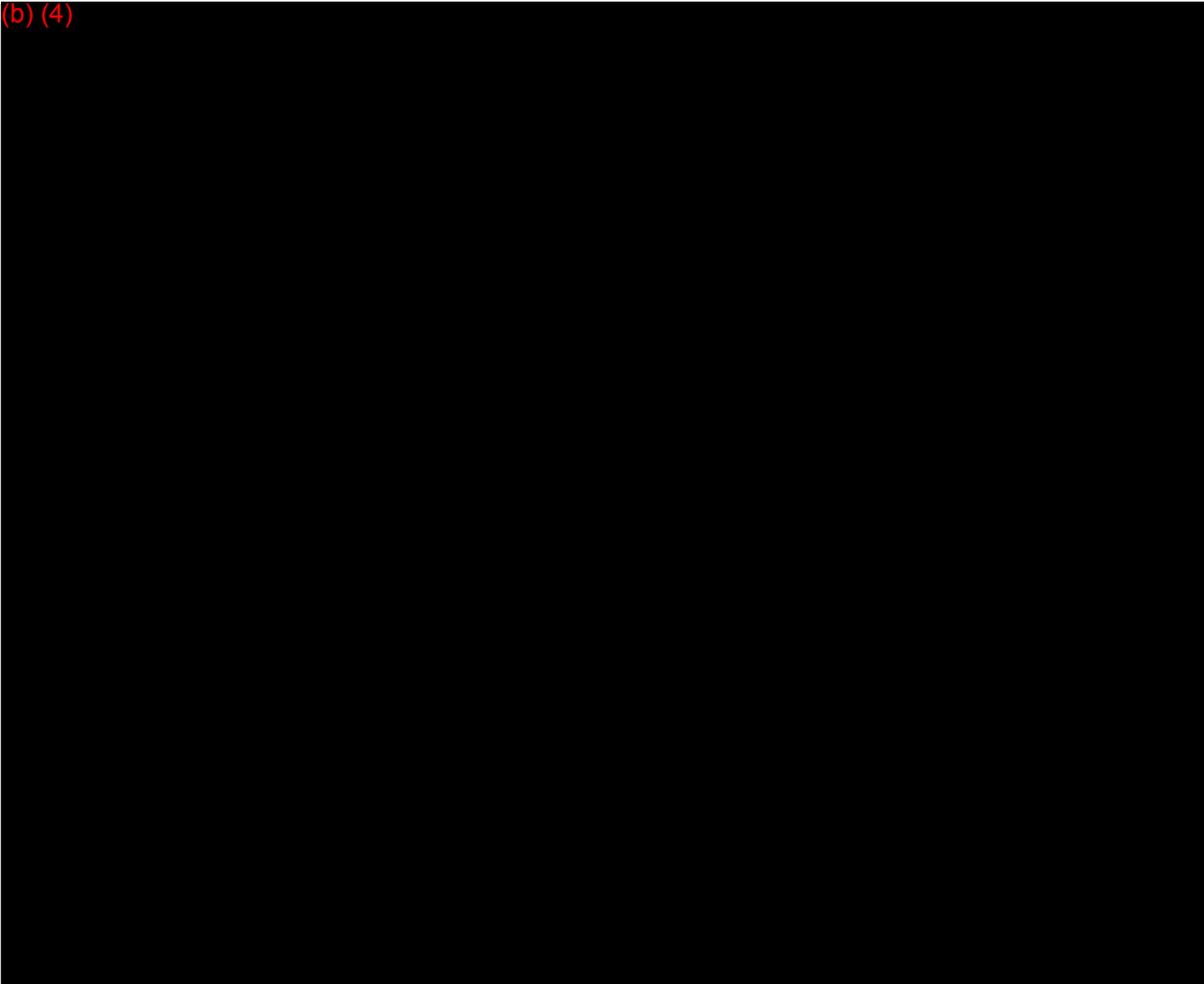
**TFS Manufacturing Pty Ltd**

7 April 2005

Herbert Lerner MD  
CDRH/ODE/DGRND/PRSB  
HFZ-410  
9200 Corporate Boulevard  
Rockville, MD 20850

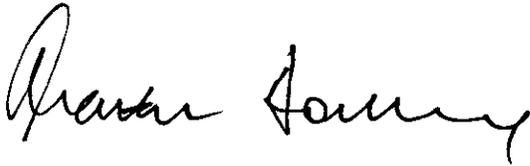
Dear Dr Lerner,

(b) (4)



(b) (4)

Yours sincerely,

A handwritten signature in black ink, appearing to read "Alastair Dowling". The signature is fluid and cursive, with the first name being more prominent.

Alastair Dowling  
QA Manager  
TFS Manufacturing Pty Ltd  
18 Kincaid Avenue  
North Plympton, South Australia 5037  
Australia  
Tel + 61 8 8351 0644  
Fax + 61 8 8351 0855

Page 2 of 2

## **Appendix 1**

Mechanical Drawings of the anchor and placement instrument

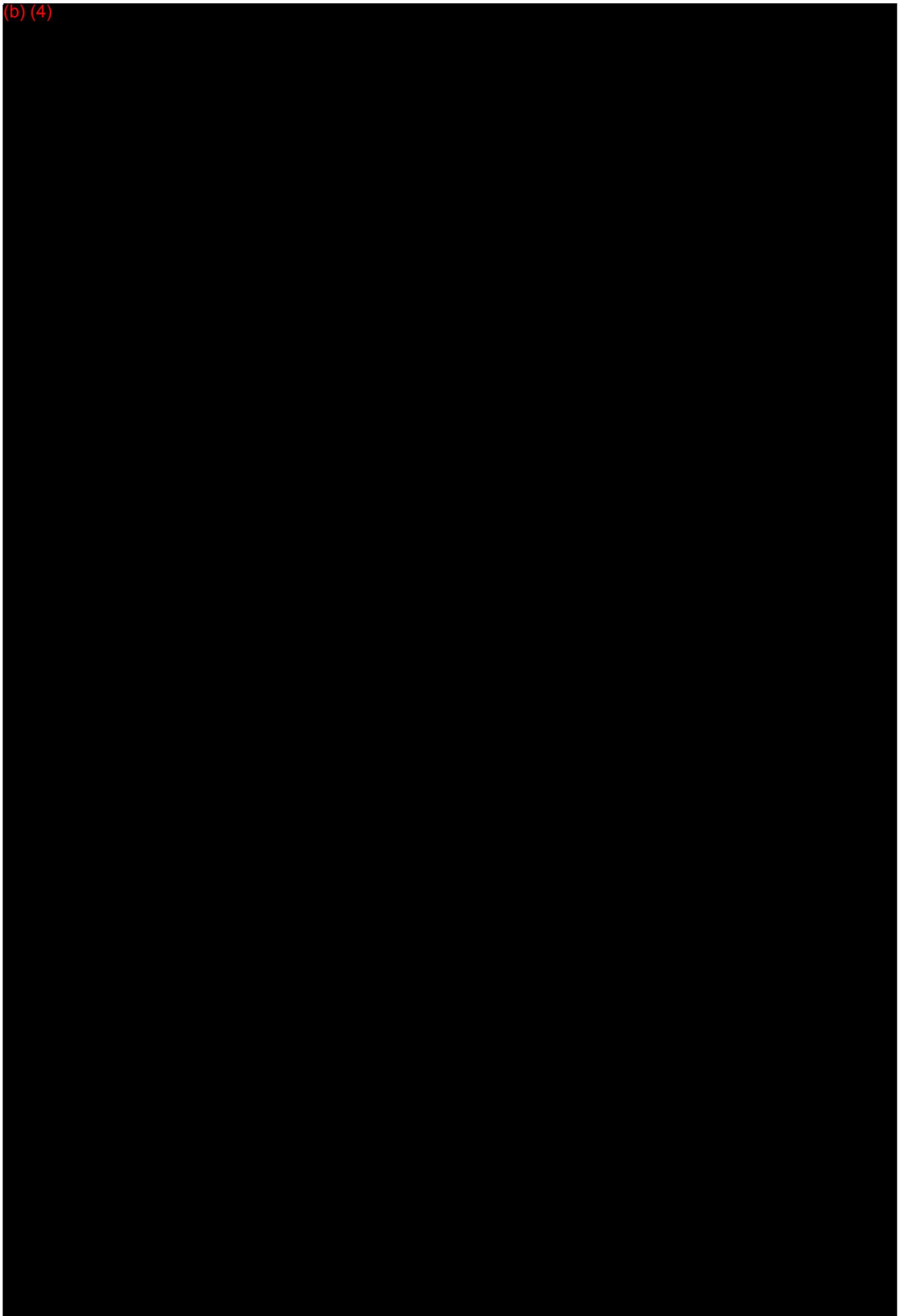
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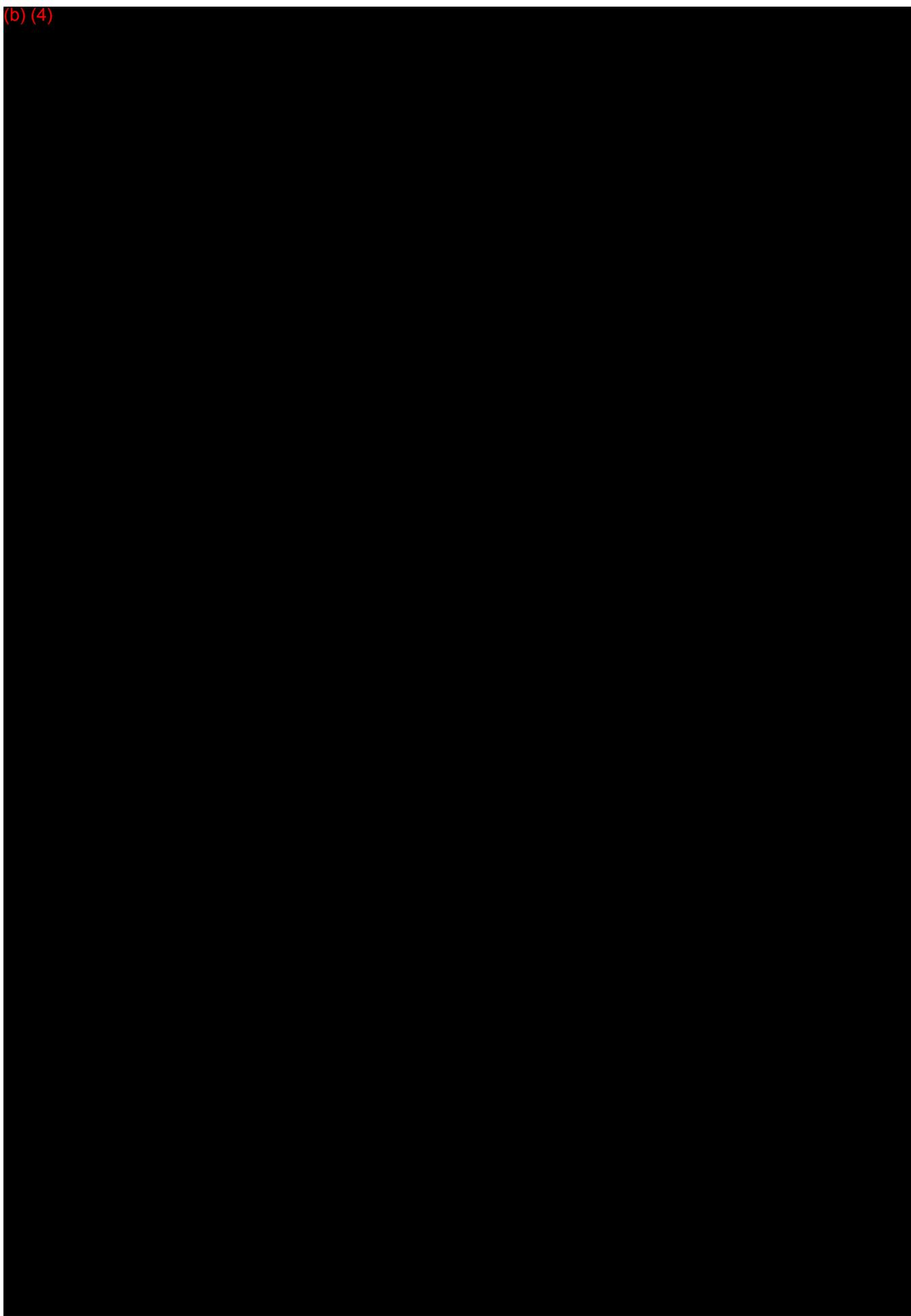
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(b) (4)			

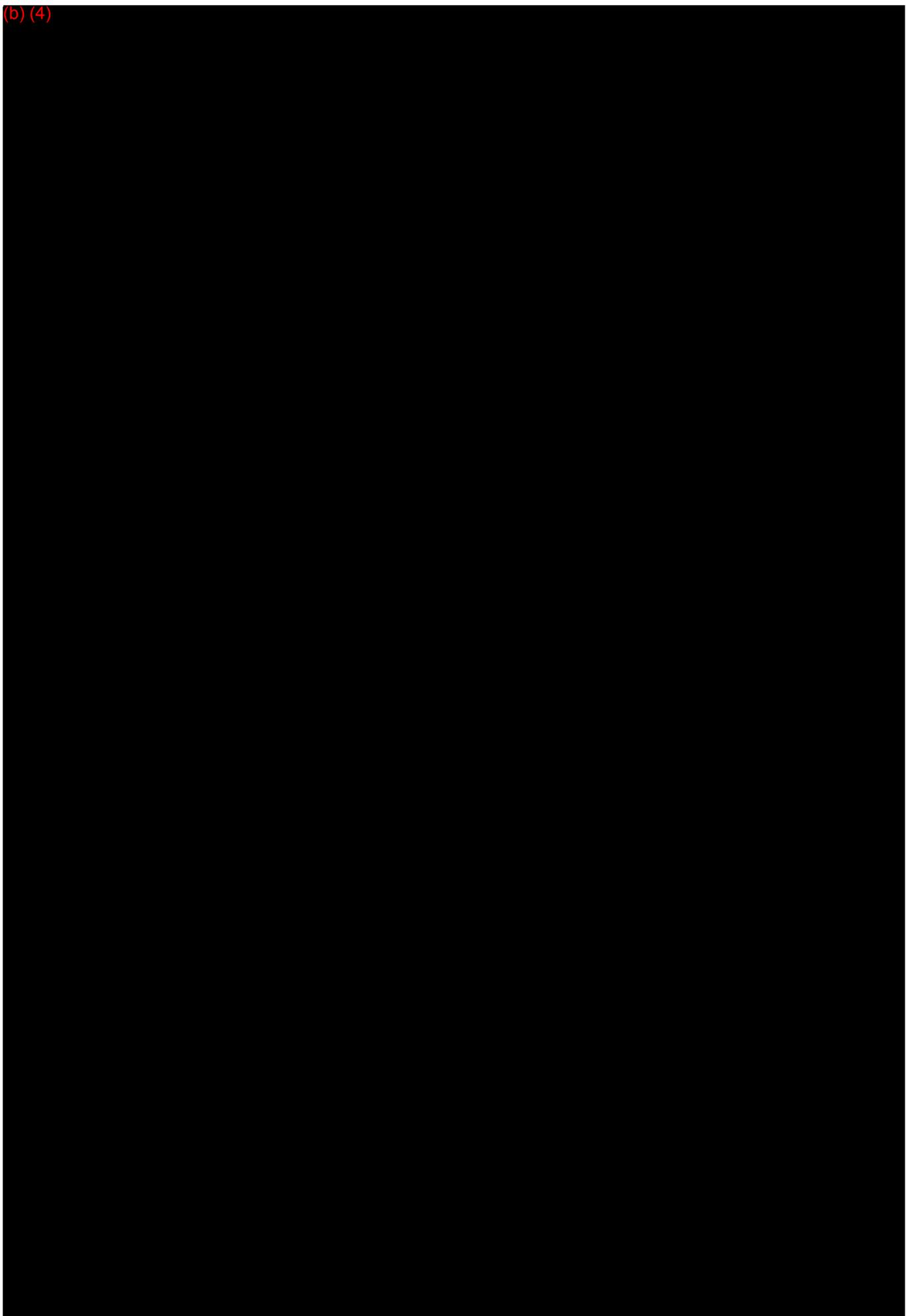
TFS INSTRUMENT - PARTS LIST

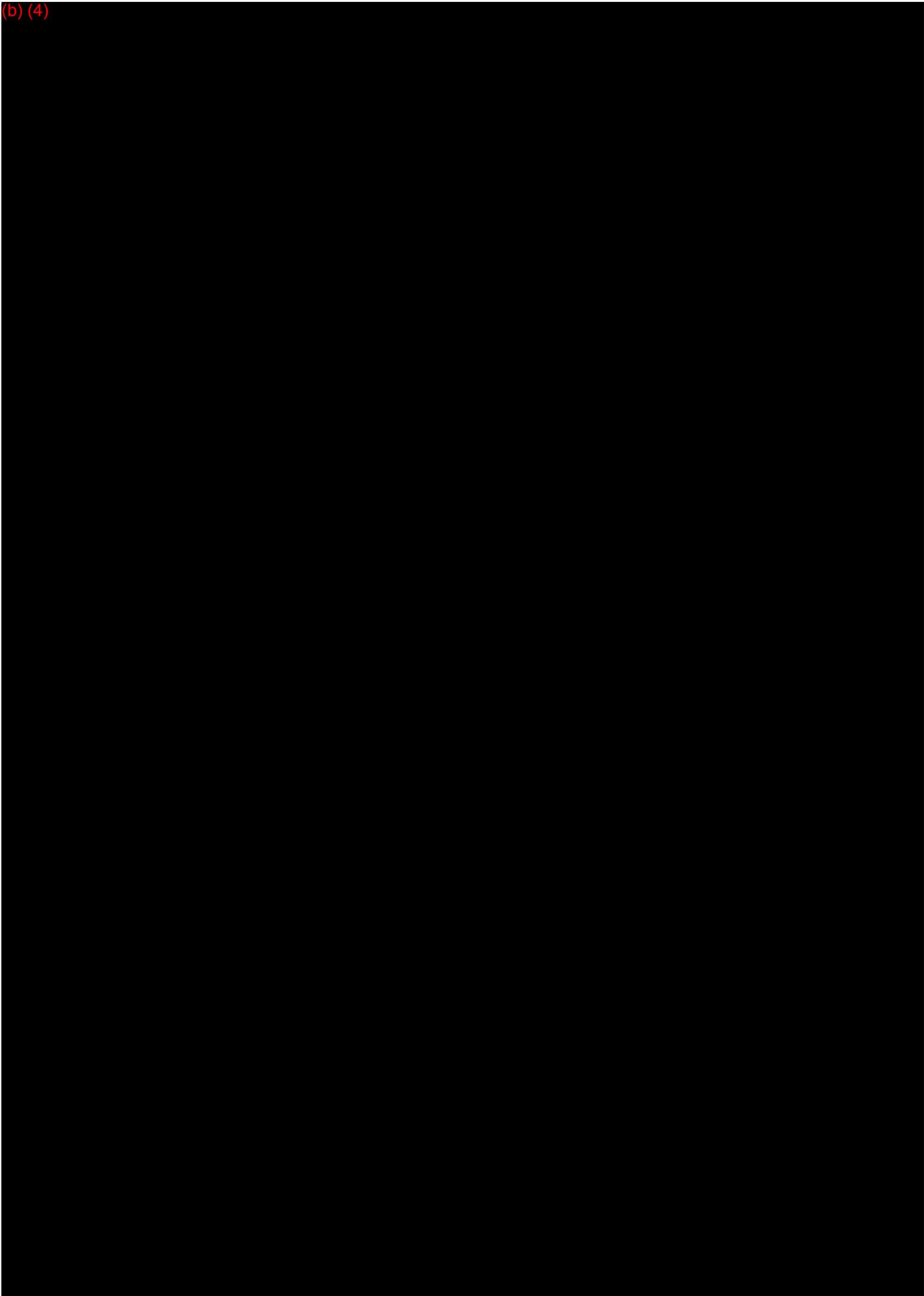
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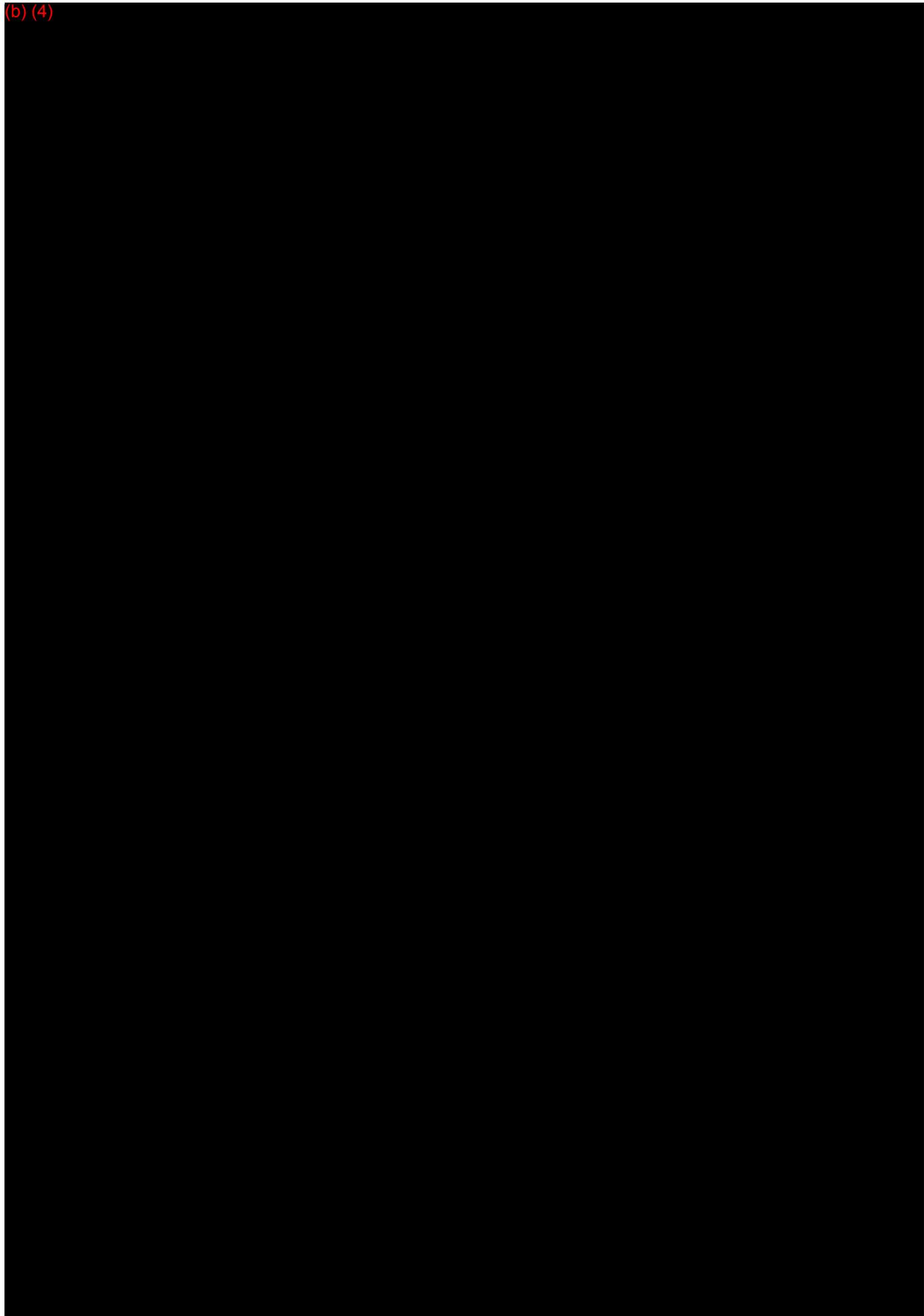
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(b) (4)				

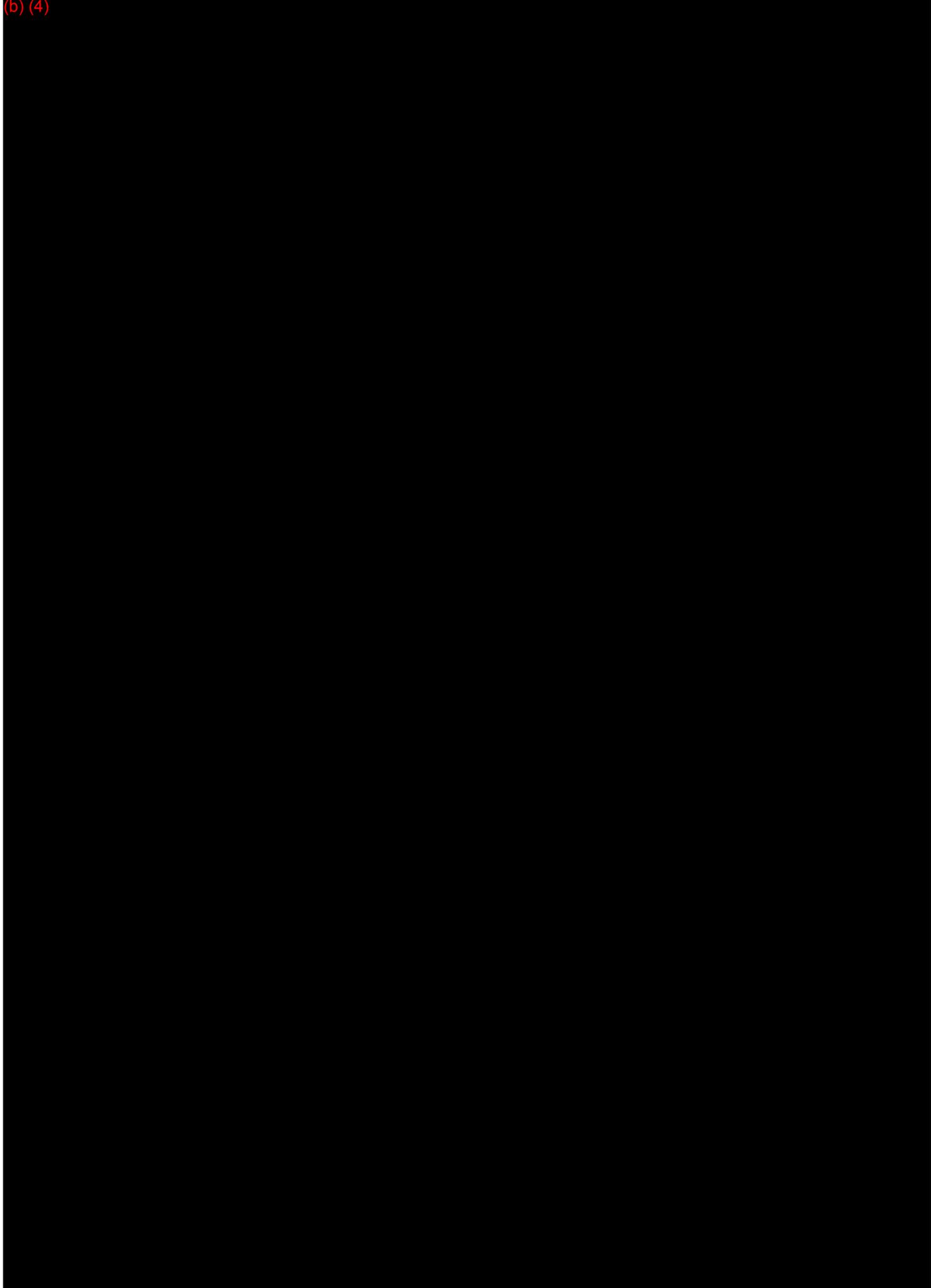


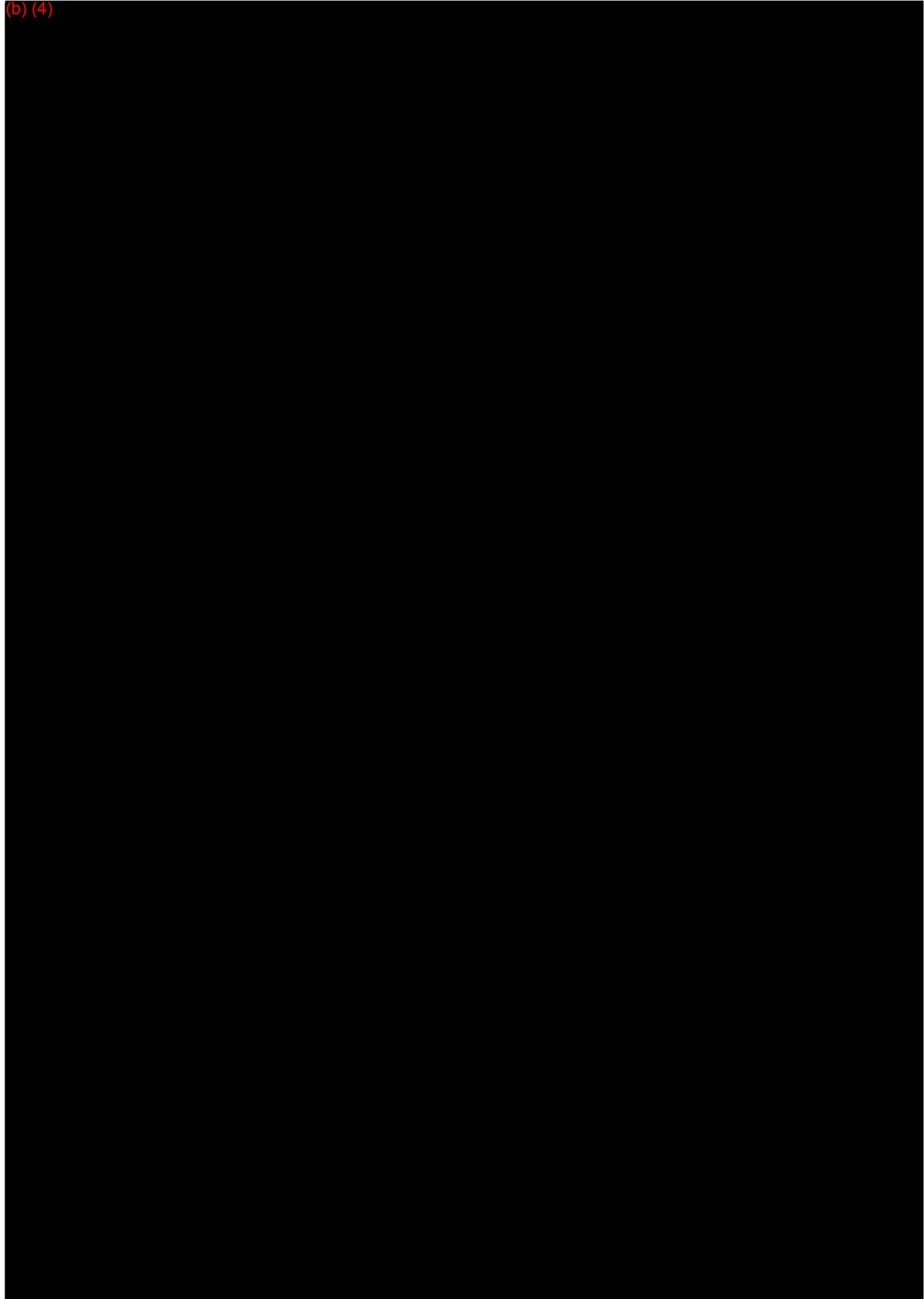


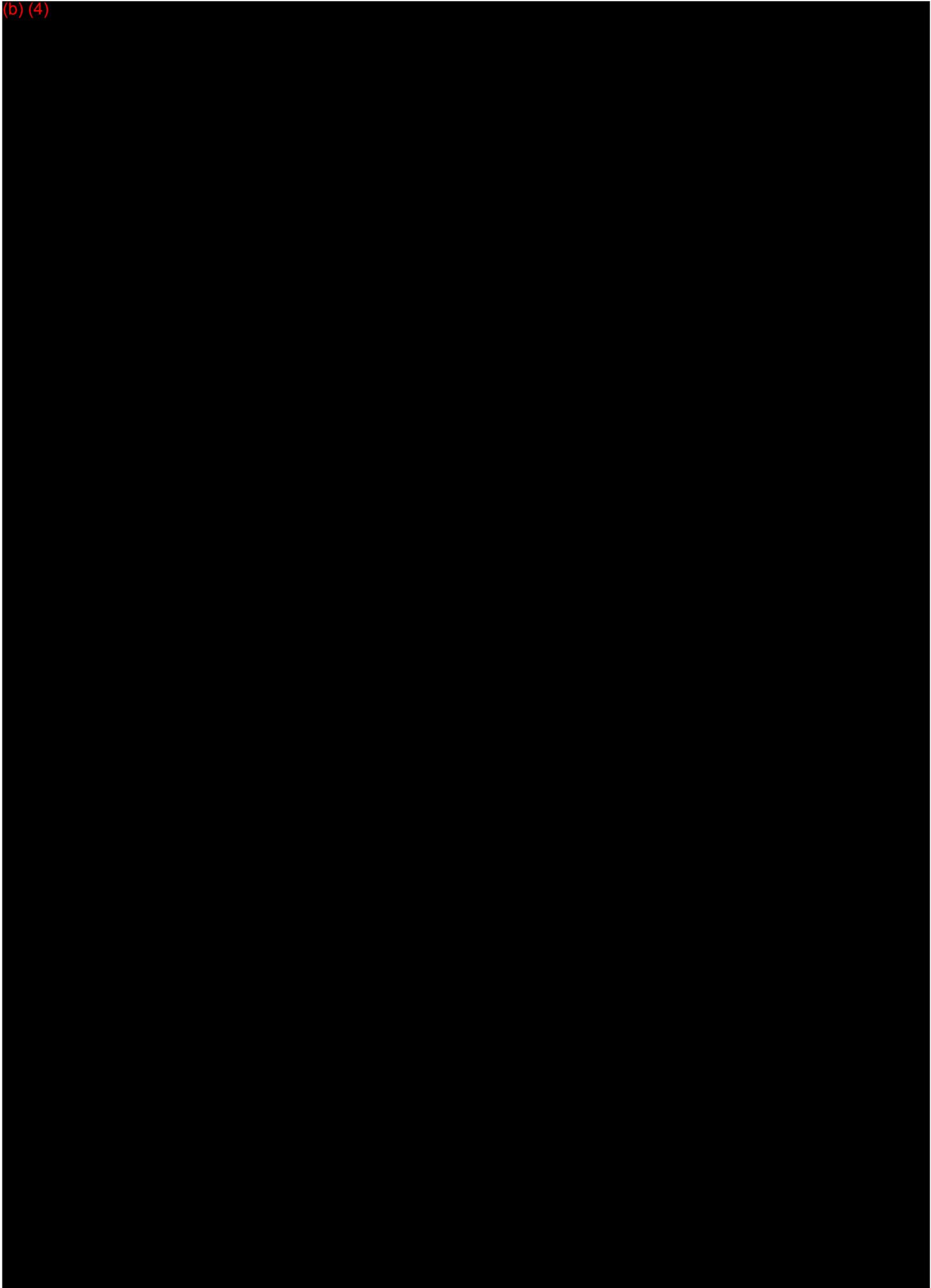


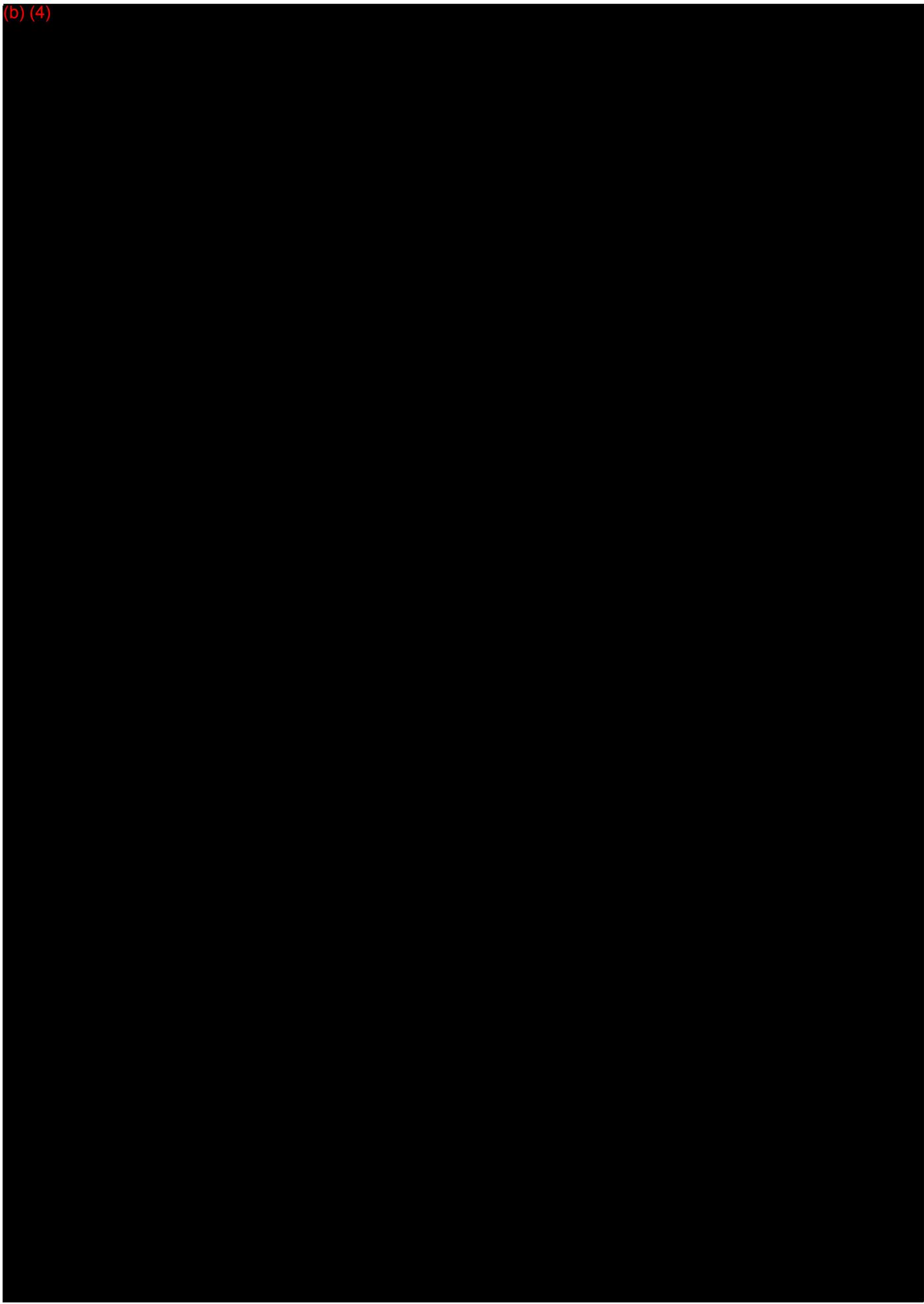


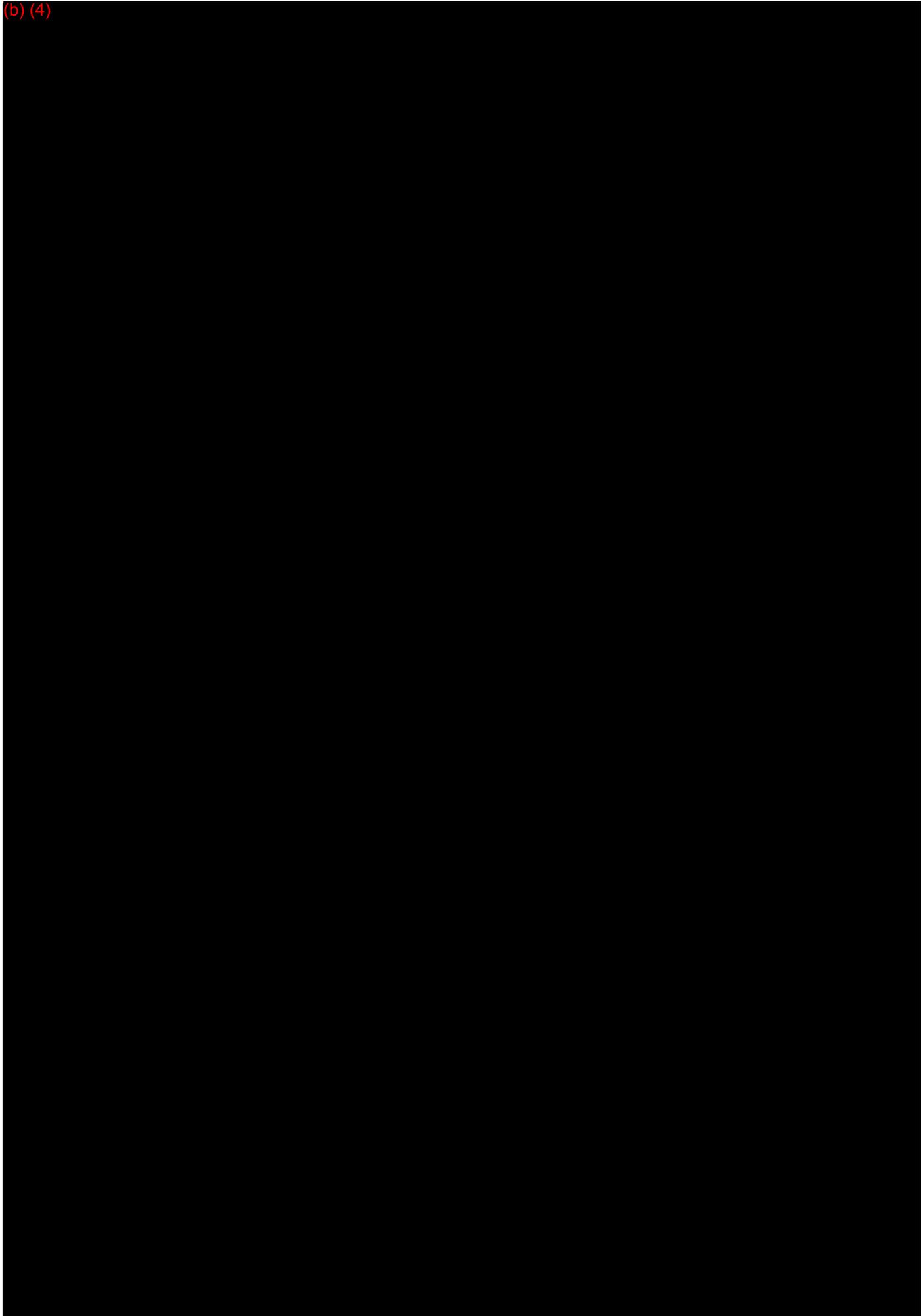


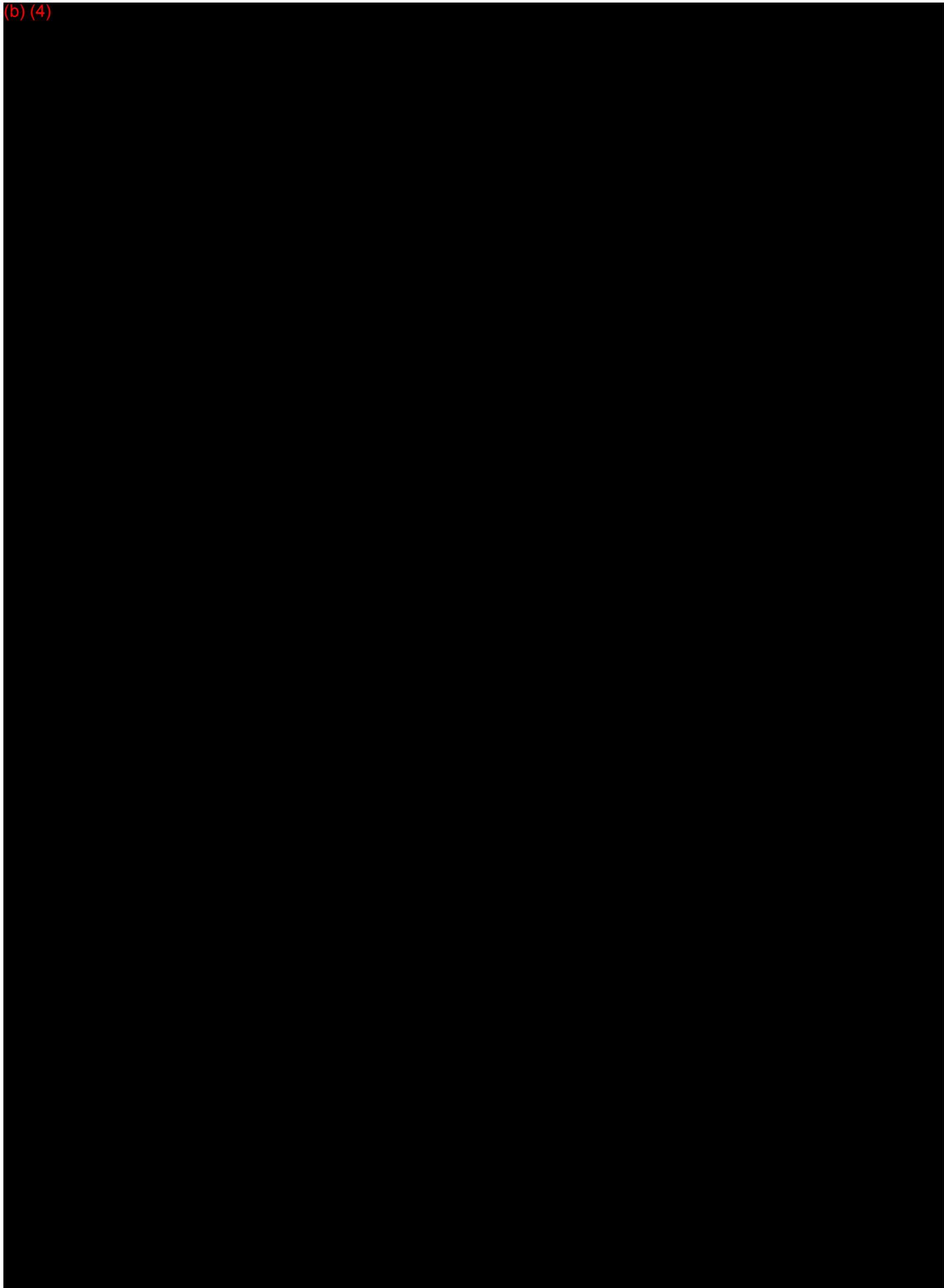




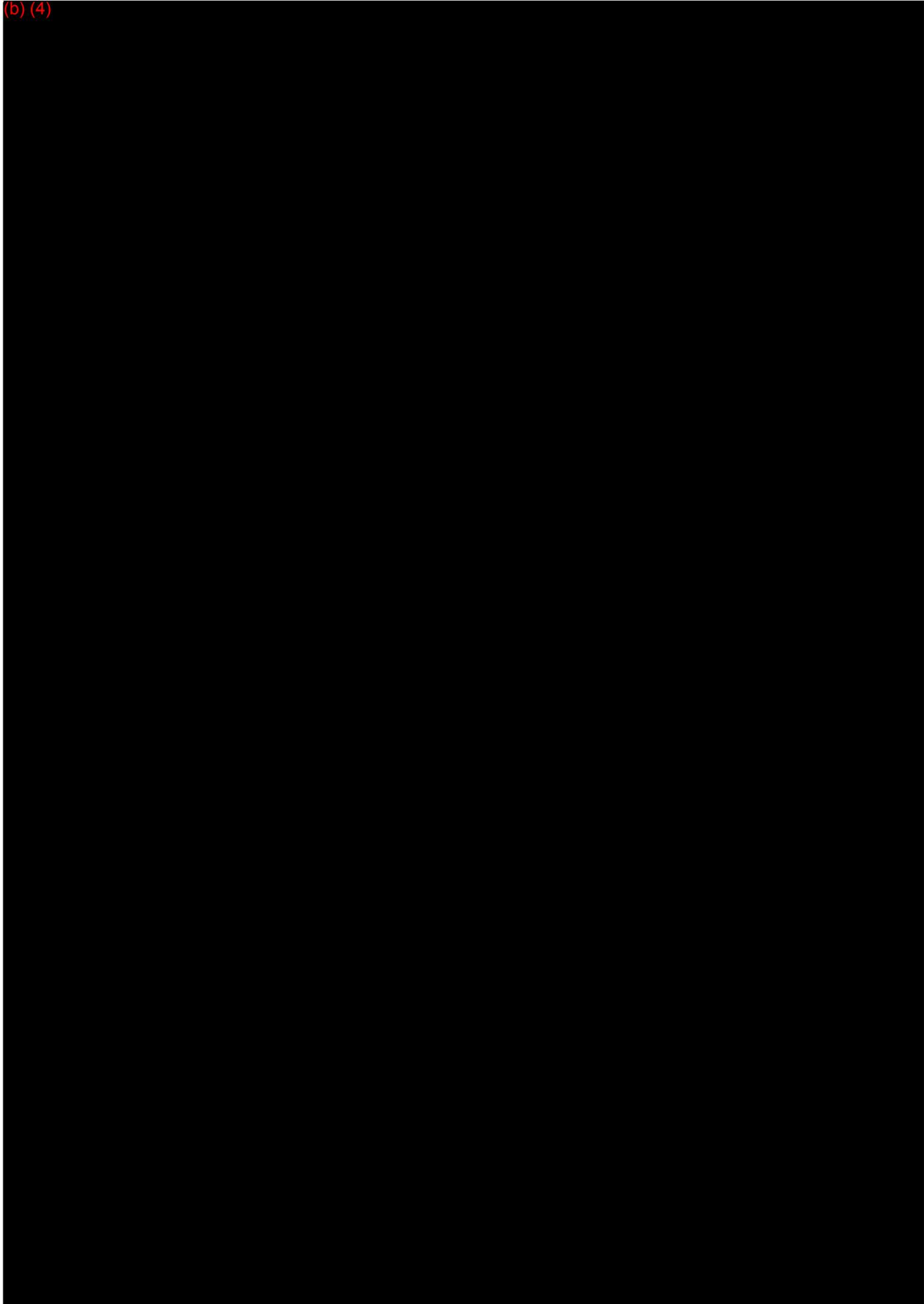


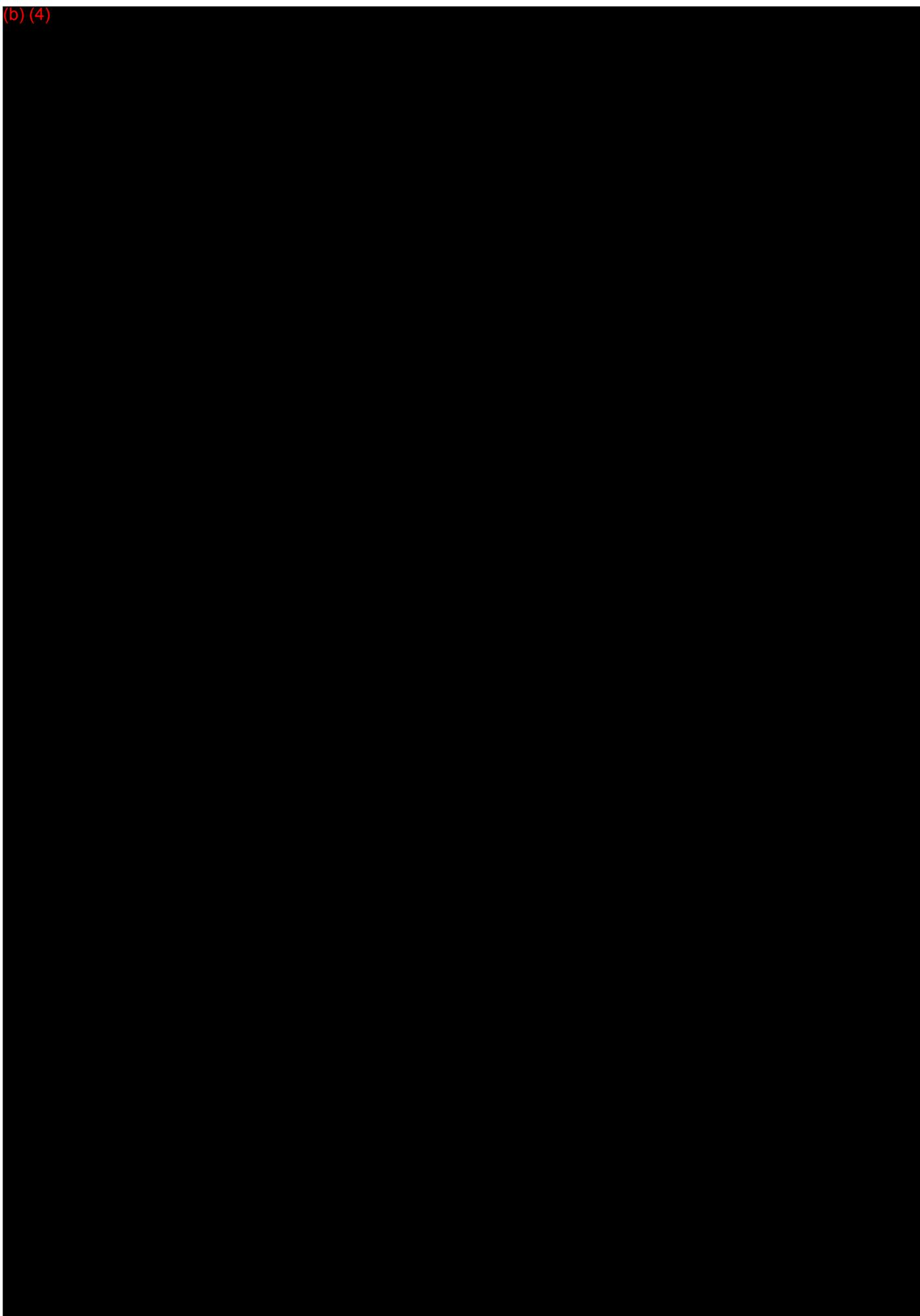


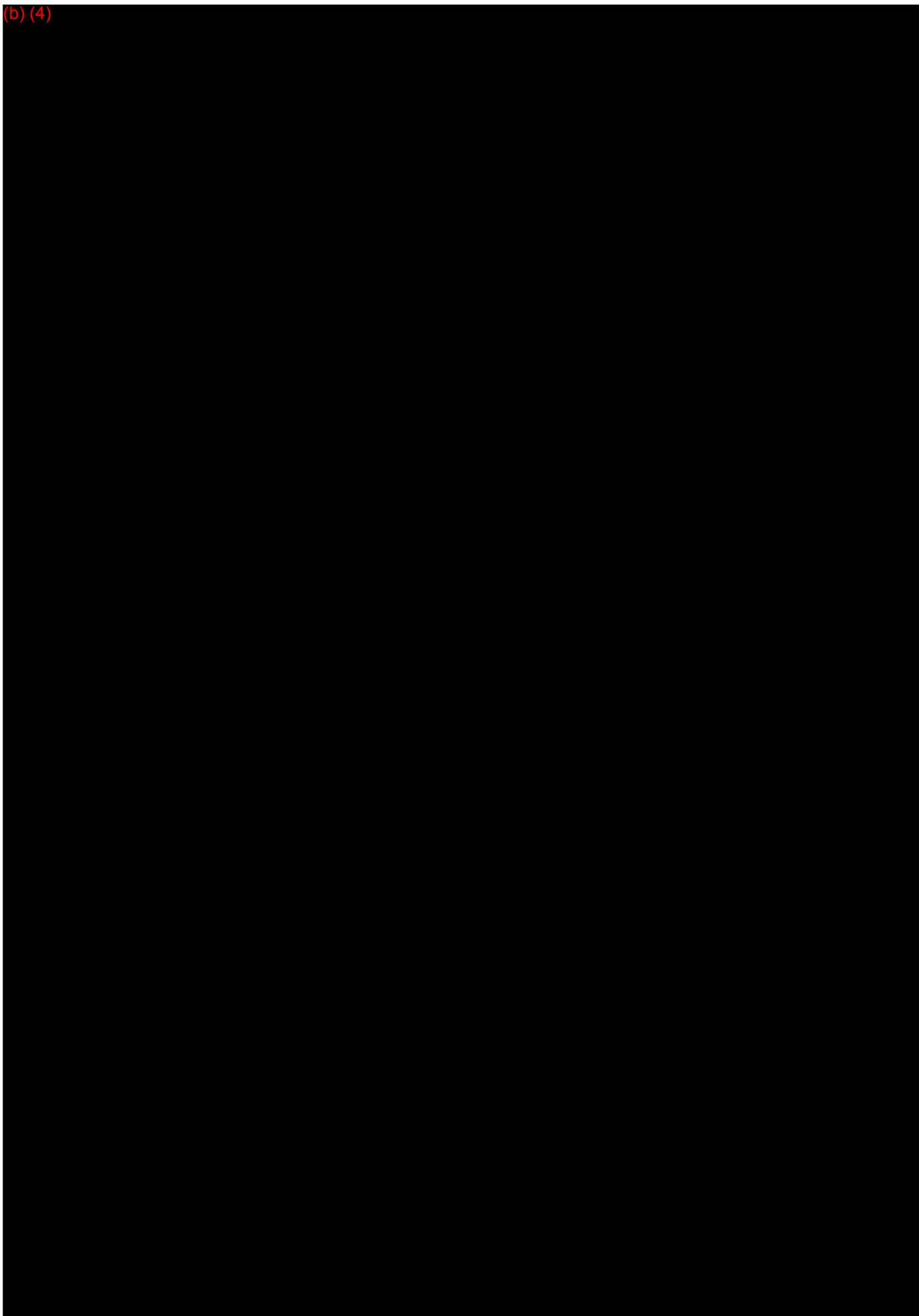












# TFS INSTRUMENT PLUNGER SPRING

DWG NUM: (b) (4)  
REVISION # [REDACTED]

(b) (4) [REDACTED]

Material : (b) (4)  
Spring OD [REDACTED]  
Spring ID: [REDACTED]  
Length (unstressed): (b) (4)  
Number of coils : [REDACTED] (b) (4)  
Number of active coils : (b) (4)  
Pitch of spring: (b) (4)

(b) (4) [REDACTED]

REV#	DATE	DESCRIPTION

**TFS INSTRUMENT  
PUSH ROD SPRING**

**DWG NUM:** (b) (4)  
**REVISION #:** [REDACTED]

(b) (4) [REDACTED]

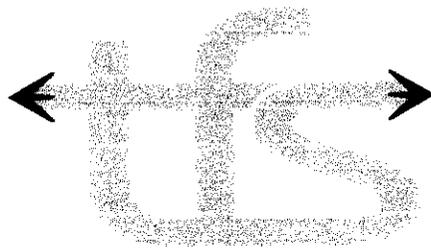
**Material :** (b) (4)  
**Spring OD:** (b) (4)  
**Spring ID:** 3.3mm  
**Length (unstressed):** (b) (4)  
**Number of coils :** (b) (4)  
**Number of active coils** (b) (4)  
**Pitch of spring:** (b) (4)

(b) (4) [REDACTED]

REV #	DATE	DESCRIPTION

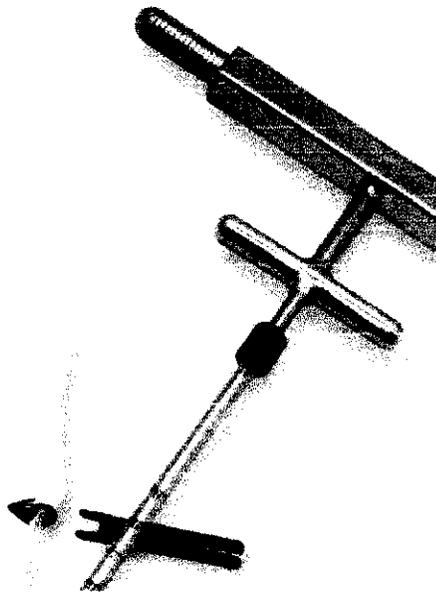
## **Appendix 2**

Instructions for Use



## TISSUE FIXATION SYSTEM

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## **INSTRUCTIONS FOR USE OF THE TISSUE FIXATION SYSTEM (TFS)**

The TFS system is sterilized with ethylene oxide. It is supplied sterile and non-pyrogenic. It remains sterile until the expiration date unless the packaging is damaged. The TFS is for single use only. It may not be re-used or re-sterilized.

**WARNING:** Read all instructions and warnings before use, and do not use if the packaging is damaged.

### **INDICATIONS FOR USE**

The TFS system is a universal connective tissue repair method designed to reinforce damaged ligaments or fascia, and is especially applicable to the pelvic floor. It can be used (by those trained in its use), to reinforce the pubourethral ligaments anteriorly, the uterosacral ligaments posteriorly, the Arcus Tendineus Fascia Pelvis laterally. It can be used alone or in combination with mesh sheets to reinforce pubocervical and rectovaginal fascia.

### **CONTRA INDICATIONS**

The mesh tape will not stretch to accommodate growth, therefore its use may not be appropriate in infants, children, or women who may wish to become pregnant in the future. Any foreign material may potentiate or prolong infection in the presence of bacterial contamination. Therefore use of this mesh tape may not be appropriate in contaminated wounds. Furthermore, the product should be used with the understanding that any post-insertion infection may require removal of the implant. As this product requires adequate anchoring into soft tissue, the operation may not work in patients with poor or atrophied tissues. Alternatively, misplacement of the anchor into an area where there is no adequate tissue may result in an inability of the anchor to "grip", so the operation may fail.

### **PRODUCT DESCRIPTION**

The TFS system consists of a polypropylene mesh tape, two polypropylene saddles, and two polypropylene anchors, and these are applied by a stainless steel applicator.

### **THE SADDLE**

The anchor is set inside a saddle. The prongs of the anchor are covered by extensions from the superior surface of the saddle. The base of the saddle is set onto a stainless steel applicator using a 90 degree locking mechanism which holds it firmly in place. As the anchor prongs are covered by the saddle, the anchor can be withdrawn at any time prior to detachment from the applicator.

### **THE ANCHOR**

The TFS anchor acts much like a grappling hook to hold it into the fascia or ligament. Its base incorporates a unique tape adjustment mechanism.

### **THE MESH TAPE**

The mesh tape is 8mm wide and 35 mm long. Each end of the tape is threaded through the base of an anchor. The mesh tape is non-absorbable, inert and porous. The mesh is knitted from multifilament yarns 20-30 microns in diameter, from the same polypropylene polymer used for surgical sutures. The tape is approximately 0.44mm (0.017") thick. It exhibits high burst strength and tensile strength. In the form of surgical suture, synthetic polypropylene is reported to resist tensile strength loss indefinitely in tissue. The mesh is knitted in such a fashion as to interconnect each multifilament yarn. This allows it to be stretched minimally in both directions and to be cut without unraveling. Histological studies in animals and human demonstrate the permeation of macrophages and fibrovascular tissue between and around the microfibrils of the mesh within 2 weeks of implantation. There is minimal acute inflammatory response to the fibrils.

#### **THE APPLICATOR**

The applicator is made of stainless steel. It is re-sterilizable and re-usable. It is complemented by an assembly spigot.

#### **GENERAL GUIDELINES FOR TFS USAGE**

The TFS system comes with pre-loaded saddles and anchors with the tape already threaded through both anchor bases. The system allows only a one-way passage of the tape. It is recommended that a channel be dissected just before insertion of the anchor and saddle as tissue elasticity may close the channel if dissection is performed well before the insertion. The instrument is checked to ensure the saddle is a) securely set in the shaft b) the thumb and trigger of the applicator are oriented superiorly. The TFS is inserted into the dissected space, the instrument tip is pressed into the tissues. The release mechanism is pressed down. This pushes the anchor forward 0.5cm into the tissues, and the instrument is withdrawn. The tape is pulled with a short sharp movement to "set" the prongs of the anchor. Dissection is then performed on the contralateral side. The saddle and anchor are loaded on the instrument, checked and inserted. The anchor is detached as before, and the instrument is withdrawn approx 1 cm. A short sharp pull is made on the free end of the tape to set the prongs. The instrument is then advanced 1 cm to support the base of the anchor while adjustment for tightness is made by pulling on its free end. It is prudent to check that the tape is sufficiently tightened. If the tape is still too loose, the saddle is reinserted against the base of the anchor and the tape is tightened. Both ends of the tape are then trimmed.

#### **MODE OF ACTION OF THE TFS SYSTEM**

The TFS system is a universal connective tissue repair method designed to reinforce damaged ligaments or fascia. In general terms, an implanted tape irritates the tissues to create a collagenous tissue reaction to form an artificial neoligament. In the first 24-48 hours, a wound reaction occurs and the tape becomes surrounded with fluid exudates. This may cause an unanchored tape to slip, resulting in tape erosion or extrusion. The purpose of the TFS anchor is to minimize this occurrence. The TFS anchor acts much like grappling hook, anchoring the tape for the 10 to 14 days required to form the fibrinous artificial neoligament template which infiltrates the tape and surrounds the anchor.

#### **ANTERIOR TFS SLING**

The anterior TFS sling operation has evolved directly from the 'tension-free' tape operations for cure of stress incontinence. The operation is identical to the first part of a midline "tension-free tape" operation. Local anaesthetic sufficient to provide analgesia is injected into the vaginal and subpubic tissues. A full thickness midline incision is made into the vagina from just below the external urethral meatus to midurethra. The vagina is dissected off the urethra with dissecting scissors, and the dissection is carried down to the perineal membrane. The applicator is placed into the dissected space, pushed firmly against the membrane, and triggered so that the TFS anchor enters the perineal membrane. The tape is set as described earlier in "general guidelines". The procedure is repeated on the contralateral side. The tape is tensioned just sufficiently for the tape to fit snugly on the urethra without indenting it, always over an 18G Foley catheter. Both ends of the tape are cut 1 cm from the TFS anchor.

The vaginal hammock and the ligamentous supports of the external urethral meatus (EUL) are now tightened with 2-0 Dexon sutures. If the cough test is to be used, 300-400 ml saline is placed in the bladder, the catheter is removed and the patient asked to cough prior to tying the hammock and EUL sutures. No cystoscopy is required.

## POSTERIOR TFS SLING

The same 3 level repair as the Posterior IVS is performed.

**Level 1 repair** – strengthening of the uterosacral ligaments (USL). The tissue fixation system (TFS) posterior sling is similar to the McCall operation insofar as it anchors the apical fascia into the uterosacral ligaments themselves. When using local anaesthetic infiltration in the posterior fornix, the surgeon must be aware that it distorts the anatomy especially in the presence of an enterocele. Correct definition of anatomy is critical for the posterior TFS procedure so as to minimize the risk of the tape entering the peritoneal cavity. A full thickness, 2.5cm longitudinal or transverse incision is made in the vaginal apex. (A transverse incision is recommended with a wide apex.) Fine dissecting scissors oriented at 30 degrees to the axis of the vagina create a 4 cm space between the ligamentous remnants and the vaginal skin just below the insertion point of the USLs. The tape is inserted to a depth of 4 cm and the anchor "set" by pulling on the tape. The insertion is repeated on the contralateral side. The tape tightened until it is firm. Both ends are cut 1cm from the TFS anchor. It is advisable to approximate the lax uterosacral ligaments and adjoining fascia above the tape as an extra layer of support for the TFS, especially if the patient has poor tissues.

**Level 2&3 repair** is performed in the standard way according to the surgeon's preferences..

### POTENTIAL SURGICAL COMPLICATIONS

Traumatic injury to the urethra, bladder or rectum, small bowel and blood sinuses may occur during dissection or malpositioning of the TFS device. Other potential problems include haematoma, infection, partial or total rejection of the tape, excess scar formation (lump), sterile abscess, bacterial abscess, and (rarely) some types of pelvic pain. The patient may develop stress or urge incontinence, and other vaginal herniations such as cystocele, rectocele, uterine or vaginal prolapse, sometimes within days or months of the surgery.

### POTENTIAL PROBLEMS WITH USING THE TFS DEVICE

**The anchor slips and comes out of the tissues.** The anchor is simply loaded back onto the saddle and re-inserted into the dissection plane, taking care to ensure the anchor is "set" adequately.

**The insertion instrument jamming ("sticking" of the handle).** This may occur, though rarely. It is corrected by inserting the assembly spigot into the central hole at the base of the handle, pushing upwards and depressing the handle so as to re-activate the spring mechanism.

**Tape does not "run" on pulling the lateral end.** The handle of the applicator may have been rotated during insertion, so that the tape becomes twisted and medial. Remove the saddle. Pull sharply on one end of the tape so that the anchor prongs dig into the tissues. Pull the lateral end of the tape. The anchor and tape may have to be withdrawn, reloaded and re-inserted, ensuring that the trigger is positioned superiorly.

**The anchor pulls out on "setting"**

This is more likely to occur with the posterior TFS or during repair of the pubocervical or rectovaginal fascia TFS. Generally "slipping out" indicates the insertion is in the wrong plane or wrong position. The site of insertion is checked. A new dissection may need to be made. The anchor is re-loaded, and re-inserted.

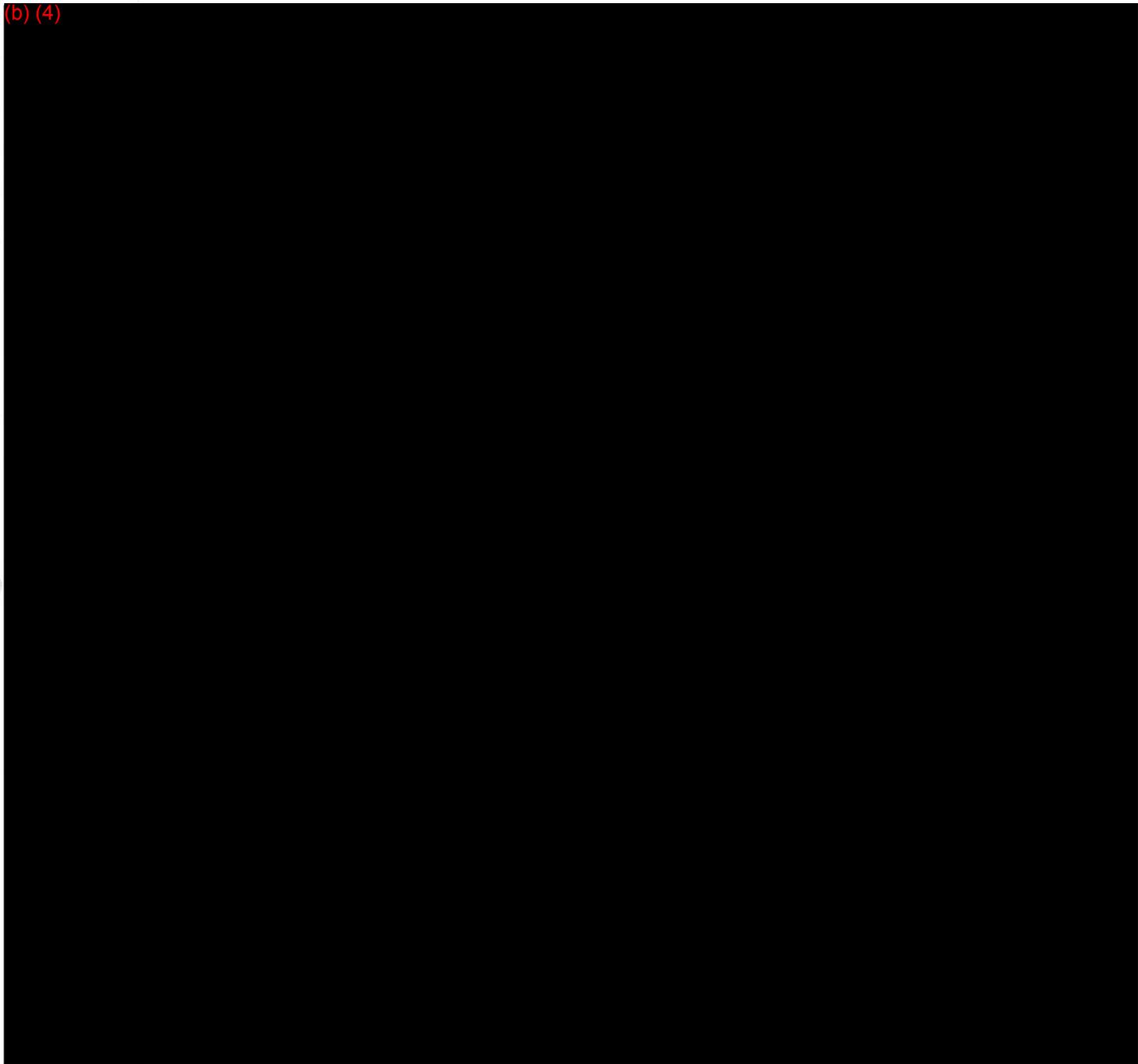
**Excessive force.** The one way system needs an activating force of 150gm, and a force of 1Kg to pull it through in the opposite direction. Once a resistance is encountered, the surgeon should pause and inspect, because a force applied in excess of 1kg during tightening may pull the tape out from the opposite anchor.

## Appendix 3

(b) (4)



(b) (4)



(b) (4)



<b>TFS Manufacturing - Device Master Record Tissue Fixation System (TFS)</b>	authorised document stamp
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(b) (4)

Overview

The TFS is an implantable device used to treat incontinence in females. (b) (4)

(b) (4)

Product Description

(b) (4)

Batch Manufacturing Instructions

(b) (4)

Mesh Tape

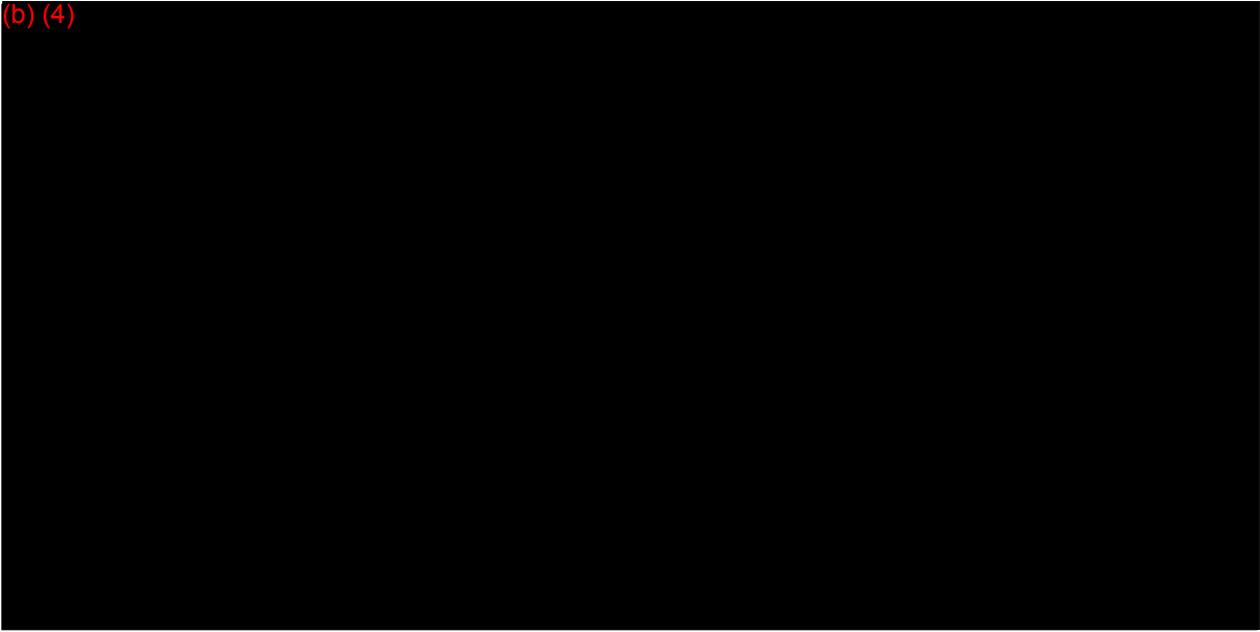
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<b>TFS Manufacturing - Device Master Record Tissue Fixation System (TFS)</b>	authorised document stamp
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**TFS: Batch Production**

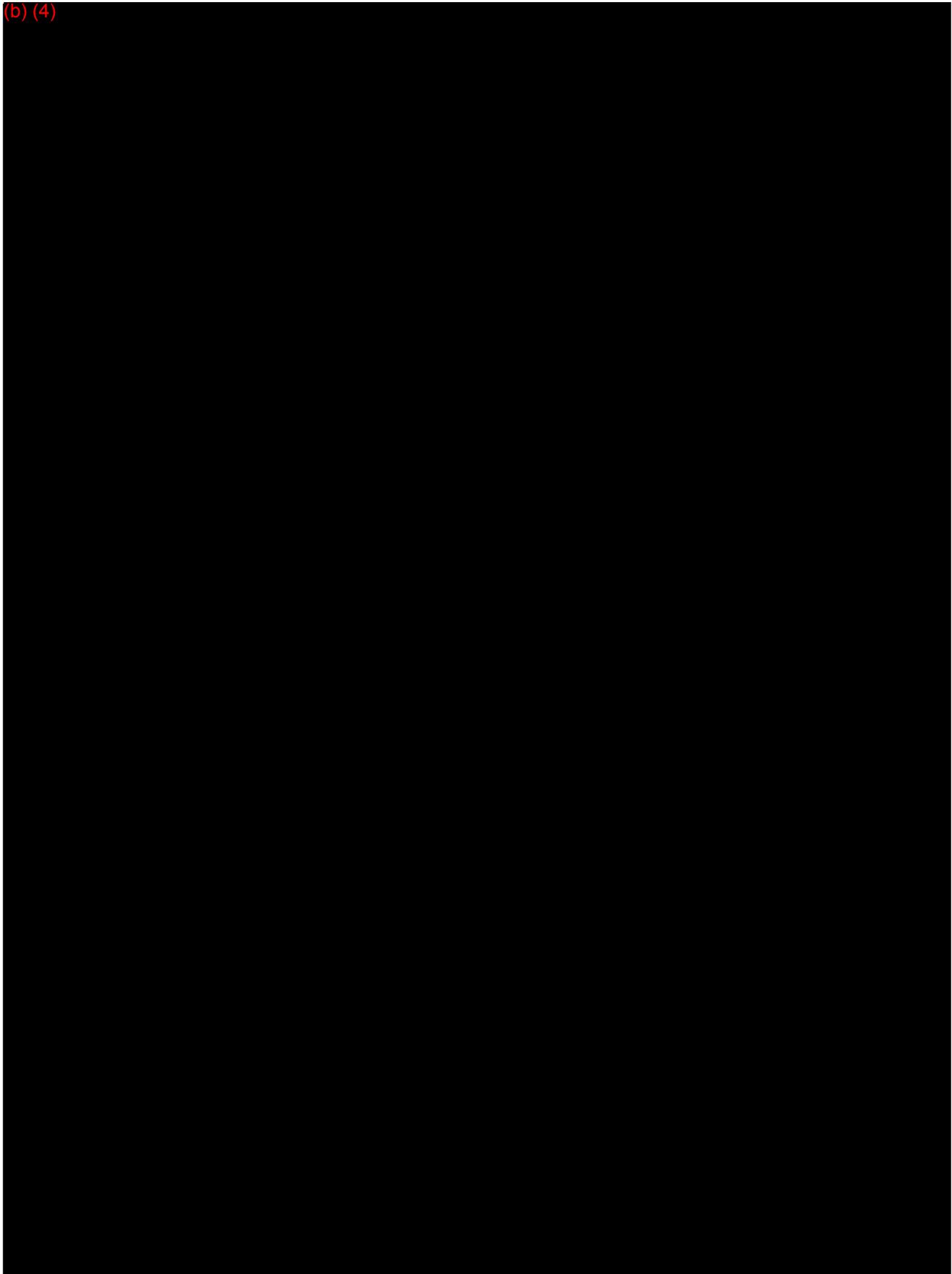
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**TFS Manufacturing - Device Master  
Record  
Tissue Fixation System (TFS)**

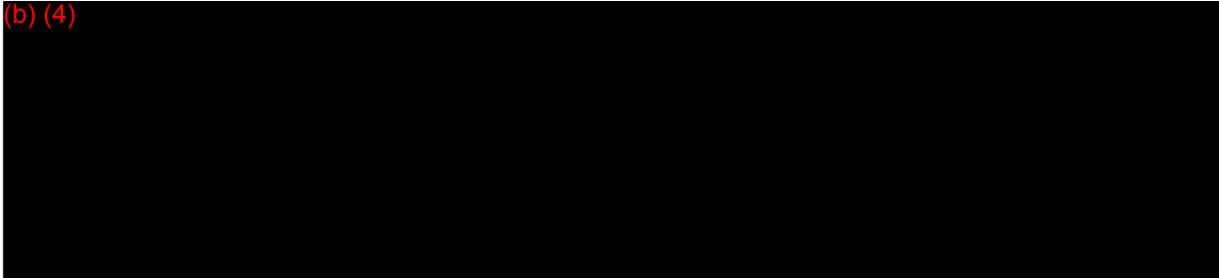
authorised document stamp

(b) (4)



<b>TFS Manufacturing - Device Master Record Tissue Fixation System (TFS)</b>	authorised document stamp
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(b) (4)

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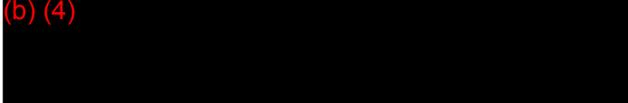
**Sterilisation**

(b) (4)

A large black rectangular redaction box covering the content under the 'Sterilisation' heading.

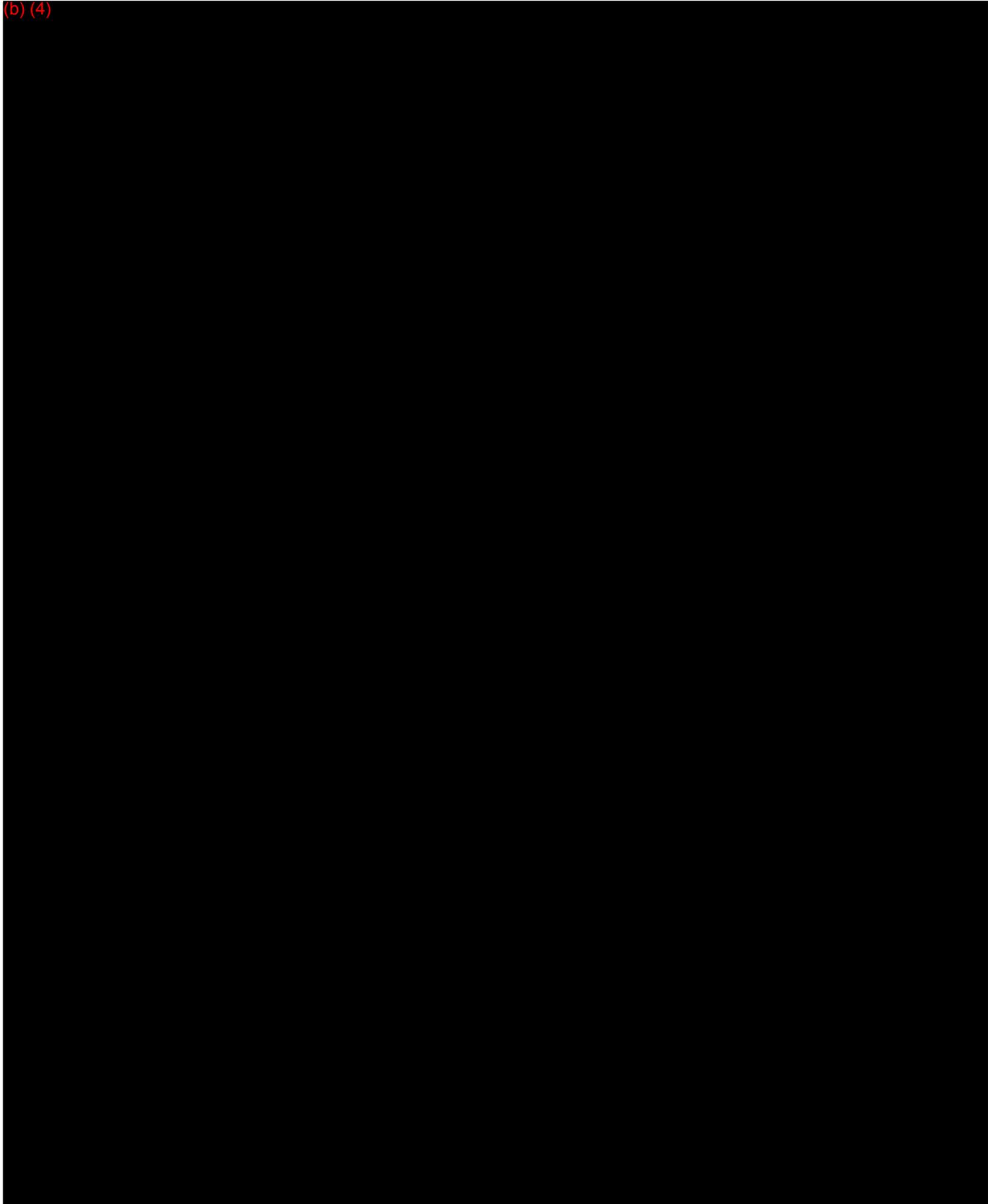
## Appendix 4

(b) (4)



Commercial Invoice ECI

(b) (4)



(b) (4)



April 15, 2003

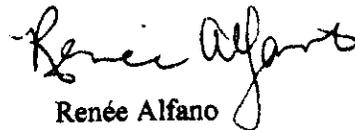
Tom Taylor  
6 Stratford Place  
Kingsley, Western Australia 6026

Dear Tom:

(b) (4)

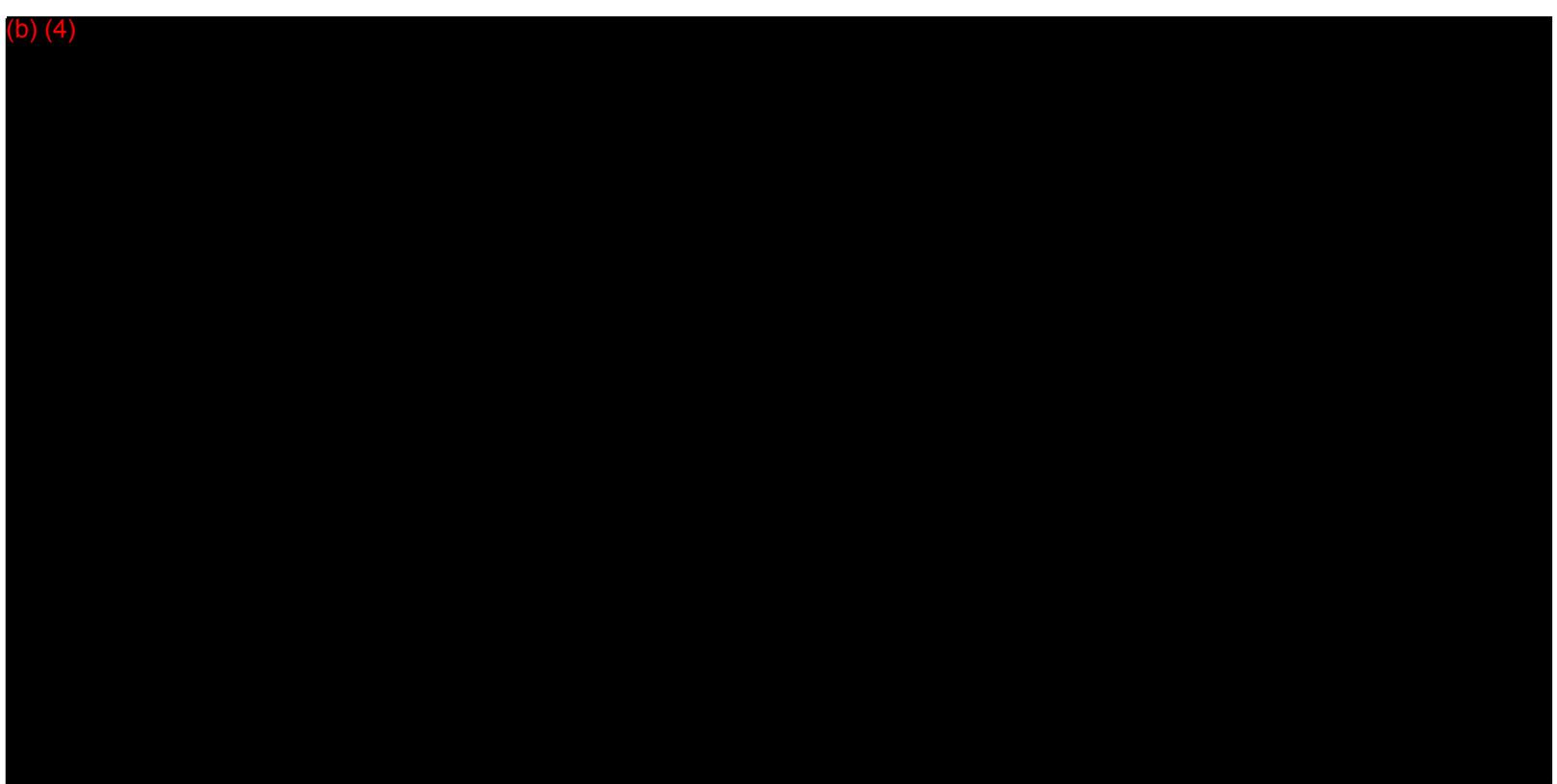


Sincerely,

  
Renée Alfano

Cc  
Mike Ball  
Dave Coope

(b) (4)



Regards,  
*Michael Ball*  
Michael Ball  
Manager, Technical Services

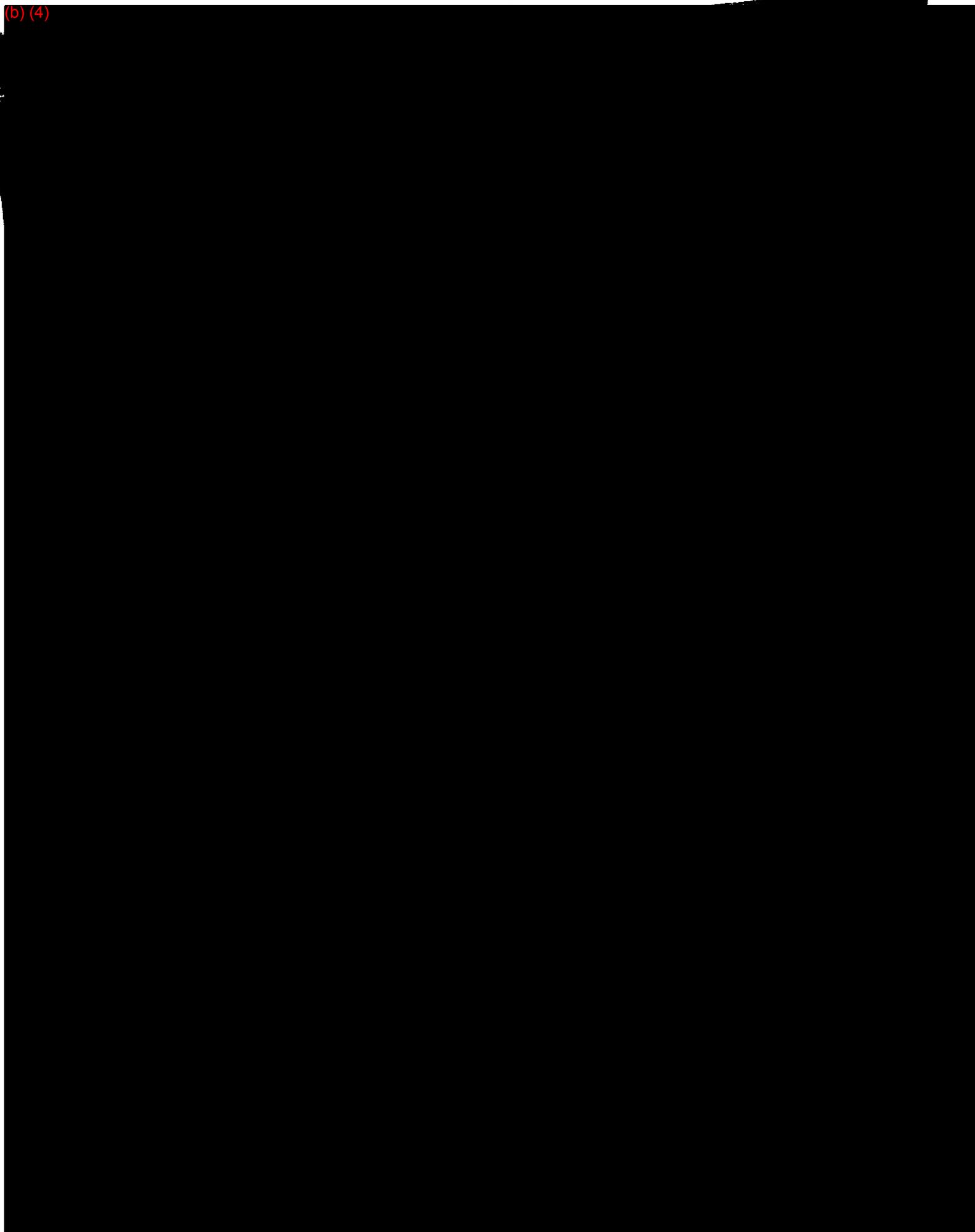
(b) (4)

Polypro cert

(b) (4)

(b) (4)

(b) (4)



From: Reviewer(s) - Name(s) Herb Lerner

Subject: 510(k) Number K050418

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.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Grossly  
Deficient

- Is this device subject to Section 522 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

- Truthful and Accurate Statement  Requested  Enclosed
- A 510(k) summary OR  A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source  YES  NO 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 Rhodes PR JB 3/2/05  
(Branch Chief) (Branch Code) (Date)

Final Review: \_\_\_\_\_  
(Division Director) (Date)

**Lerner, Herbert P.**

---

**To:** Dowling@space.net.au  
**Subject:** K050418

Good morinig Mr. Dowling.

I have been assigned your 510 (k) submission for the TFS device, and during my initial review I found it to be missing several important itmes for review. Rather than explain all these, I refer you to our website where a Guidance Document for submitting 510 (K) submission for surgical meshes is available. Please review the guidance and provide all the missing material. I will be placing your submission on "hold" so as to allow adequate time for review once all the material is in. Please acknowledge this e-mail.

<http://www.fda.gov/cdrh/ode/116.html>

Thanks

Herb Lerner

*Herbert Lerner, MD*  
CDRH/ODE/DGRND/PRSB  
9200 Corporate Blvd.  
HFZ-410  
Rockville, MD 20850  
HPL@CDRH.FDA.GOV (current)  
herbert.lerner@fda.hhs.gov (current/future)  
301-594-3090 x207

*Sent 3/2/05*  
*Phone hold*  
*HPL*

## Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		X
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?		
4. If, not, has POS been notified?		
5. Is the product a device?	V	X
6. Is the device exempt from 510(k) by regulation or policy?		
7. Is the device subject to review by CDRH?	V	
8. Are you aware that this device has been the subject of a previous NSE decision?		X
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		X
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

K050418

# PREMARKET NOTIFICATION 510(K) STATEMENT

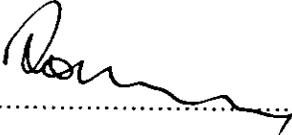
21 CFR 807.93

TFS Device

---

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

Official Correspondent

  
.....(signature)

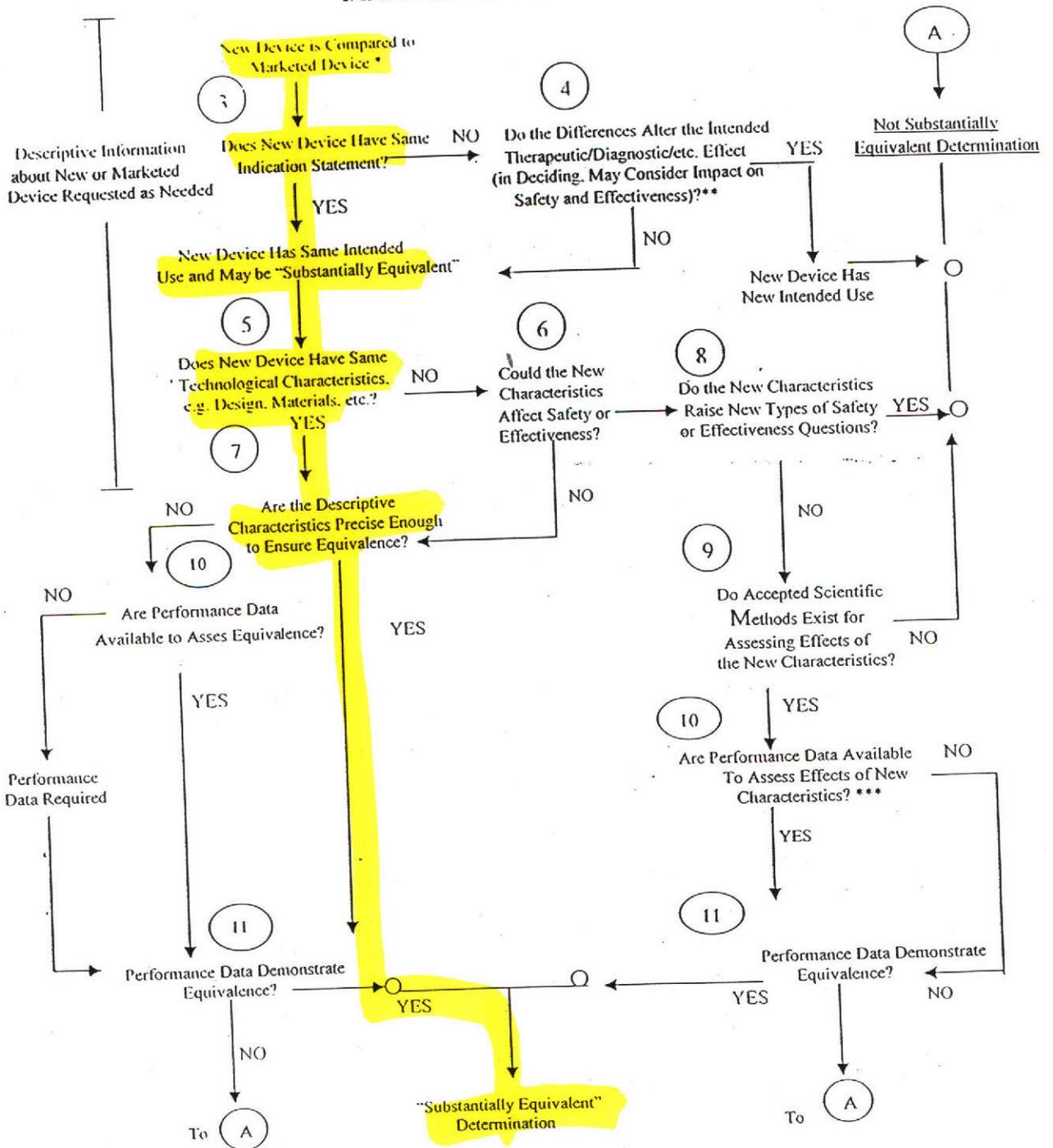
Mr Alastair Dowling

.....(printed name)

15 February 2005  
.....(date)

Premarket Notification 510(k) number: *to be assigned*

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



- \* 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 maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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

March 28, 2005

TFS MANUFACTURING PTY LTD  
18 KINCAID AVENUE  
NORTH PLYMPTON SA,  
AUSTRALIA 5037  
ATTN: ALASTAIR DOWLING

510(k) Number: K050418  
Product: TISSUE FIXATION  
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. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at [www.fda.gov/cdrh/ode/a02-01.html](http://www.fda.gov/cdrh/ode/a02-01.html).

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 International and Consumer Assistance (DSMICA) 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

K050418/S1

TFS Manufacturing Pty Ltd

24 March 2005

Herbert Lerner MD  
CDRH/ODE/DGRND/PRSB  
HFZ-410  
9200 Corporate Boulevard  
Rockville , MD 20850

Dear Dr Lerner,

**Re: 510(k) Submission TFS Device K050418**

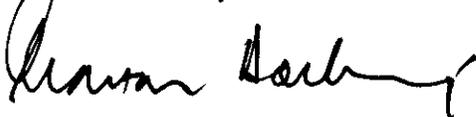
Further to your email of 3 March 2005 requesting further information, the following is attached to support the above 510(k) submission:

1. General Information on TFS Device
2. Details on additional Predicate Device
3. Table of comparison
4. Specifications of the TFS Device
5. Details of Sterilisation
6. Microbiological Testing
7. Ethylene Oxide Residue Testing
8. Description of Packaging
9. Biocompatibility
10. In-Process Testing

Note that we have included a further predicate device because this predicate device utilises exactly the same surgical mesh as the TFS Device.

Should you require further information please contact me again.

Yours sincerely,



Alastair Dowling  
QA Manager  
TFS Manufacturing Pty Ltd  
18 Kincaid Avenue  
North Plympton, South Australia 5037  
Australia  
Tel + 61 8351 0644  
Fax + 61 8351 0855

JK 34

## Appendix No 1

### TFS Device

The TFS device was subjected to the full Conformity Assessment requirements of the Australian Therapeutic Goods Medical Devices Regulations 2003, and to the requirements of ISO 13485:2003 and Medical Device Directive 93/42/EEC.

The Conformity Assessment was performed by inspectors from the Therapeutic Goods Administration (TGA) of the Australian Department of Health.

As required, the inspection included all parts of the device Technical File including design, suitability of materials, validation of processes (including packaging), Risk Analysis, Essential Principles and Clinical evidence.

Subsequently the device was granted CE mark certification by TGA.

TGA, under the terms of the Australian/EU Mutual Recognition Agreement, is entitled to grant CE certification.

The Certificate was issued (b) (4)

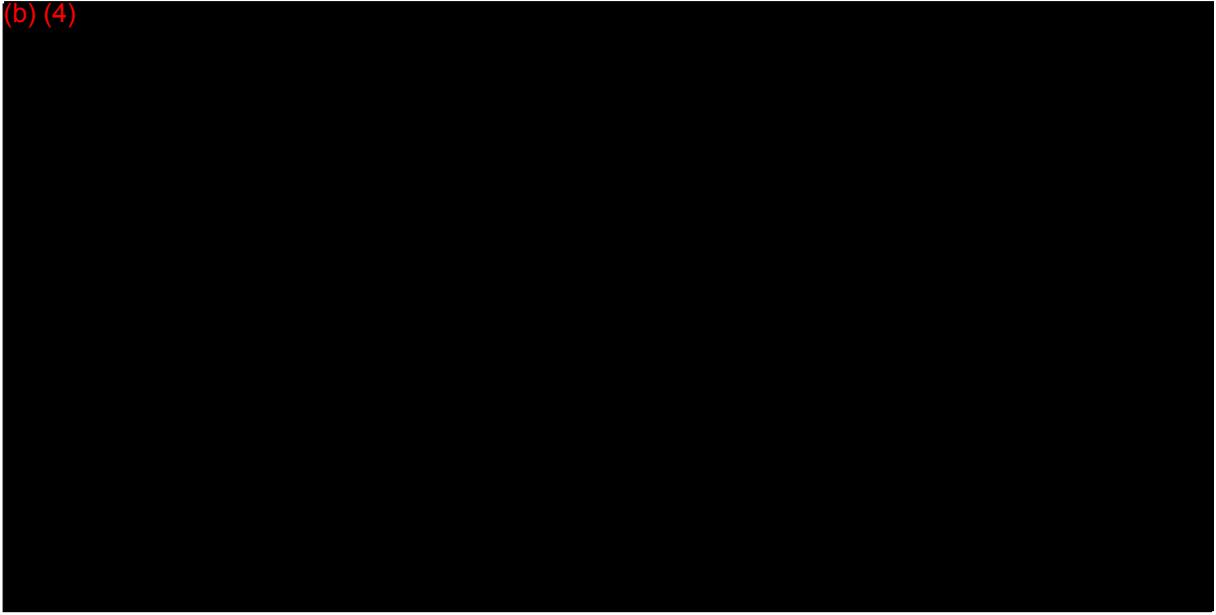
(b) (4)



## Appendix No 2

### Alternative/Additional Predicate Device.

(b) (4)





**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH**

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**510(k) Premarket Notification Database**

<b>Device Classification Name</b>	<a href="#">Mesh, Surgical, Polymeric</a>
<b>510(K) Number</b>	K010035
<b>Regulation Number</b>	<a href="#">878.3300</a>
<b>Device Name</b>	IVS TUNNELLER
<b>Applicant</b>	<a href="#">UNITED STATES SURGICAL, A DIVISION OF TYCO HEALTH</a> 150 Glover Ave. Norwalk, CT 06856
<b>Contact</b>	Chester Mccoy
<b>Product Code</b>	FTL
<b>Date Received</b>	01/04/2001
<b>Decision Date</b>	04/04/2001
<b>Decision</b>	Substantially Equivalent (SE)
<b>Classification Advisory Committee</b>	General & Plastic Surgery
<b>Review Advisory Committee</b>	Neurology
<b>Statement/Summary/Purged Status</b>	Summary Only
<b>Summary</b>	<a href="#">Summary</a>
<b>Type</b>	Traditional
<b>Reviewed By Third Party</b>	No
<b>Expedited Review</b>	No

Database Updated 3/08/2005

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Center for Devices and Radiological Health / CDRH

K010035

INDICATIONS FOR USE

510(k) Number ~~K003446~~ K010035

Device Name: I.V.S. Tunneller

Indications for Use: The I.V.S. Tunneller is intended to be used in females to position a polypropylene mesh for the treatment of genuine stress urinary incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency, and vaginal vault prolapse.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Miriam C. Probst  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number ~~K003446~~ K010035

TECHNOLOGICAL  
CHARACTERISTICS:

Technologically both the new device and predicate device are the same (i.e. both are meshes that provide pubourethral support). Any differences in the two devices do not raise new questions of safety and effectiveness.

PERFORMANCE  
CHARACTERISTICS:

Results of clinical studies were used to show the I.V.S. Tunneller functioned as clinically intended

CONCLUSION:

Based on the information provided with the 510(k), we conclude this device is substantially equivalent to the existing legally marketed device under the Federal Food, Drug and Cosmetic Act.

APR - 4 2001

**510(k) Summary of Safety and Effectiveness**

**SUBMITTER:** US Surgical a Division of Tyco Healthcare Group L.P.  
150 Glover Avenue  
Norwalk, CT 06856

**CONTACT PERSON:** Chester McCoy

**DATE PREPARED:** March 21, 2001

**PROPRIETARY NAME:** I.V.S. Tunneller

**PREDICATE DEVICES:** Tension Free Vaginal Tape (TVT) System (K974098)

**DEVICE**

**DESCRIPTION:** The I.V.S. Tunneller is composed of three components: a stainless steel introducer, a polypropylene stylette and mesh.

The mesh used (SurgiPro™) is a non-absorbable, inert, sterile, porous surgical mesh knitted from multi-filament yarns of a polypropylene polymer from which SurgiPro surgical sutures are manufactured. The mesh measures approximately 0.44mm (0.17") in thickness and exhibits high burst strength and tensile strength in the form of a surgical suture. Synthetic polypropylene is reported to resist tensile strength loss indefinitely in tissue. SurgiPro mesh is knitted in such a fashion as to interconnect each multi-filament yarn and provide bi-directional elasticity.

SurgiPro mesh is used to repair or reinforce defects following surgery or trauma and serves to provide additional support to such wounds during the wound healing period. Animal studies have shown that the polypropylene filaments from which this mesh is manufactured elicit a minimal acute inflammatory reaction in tissue which is then followed by gradual encapsulation by fibrous tissue. Ingrowth of this fibrous tissue is permitted by the porosity of the knitted mesh structure.

**INTENDED  
USE:**

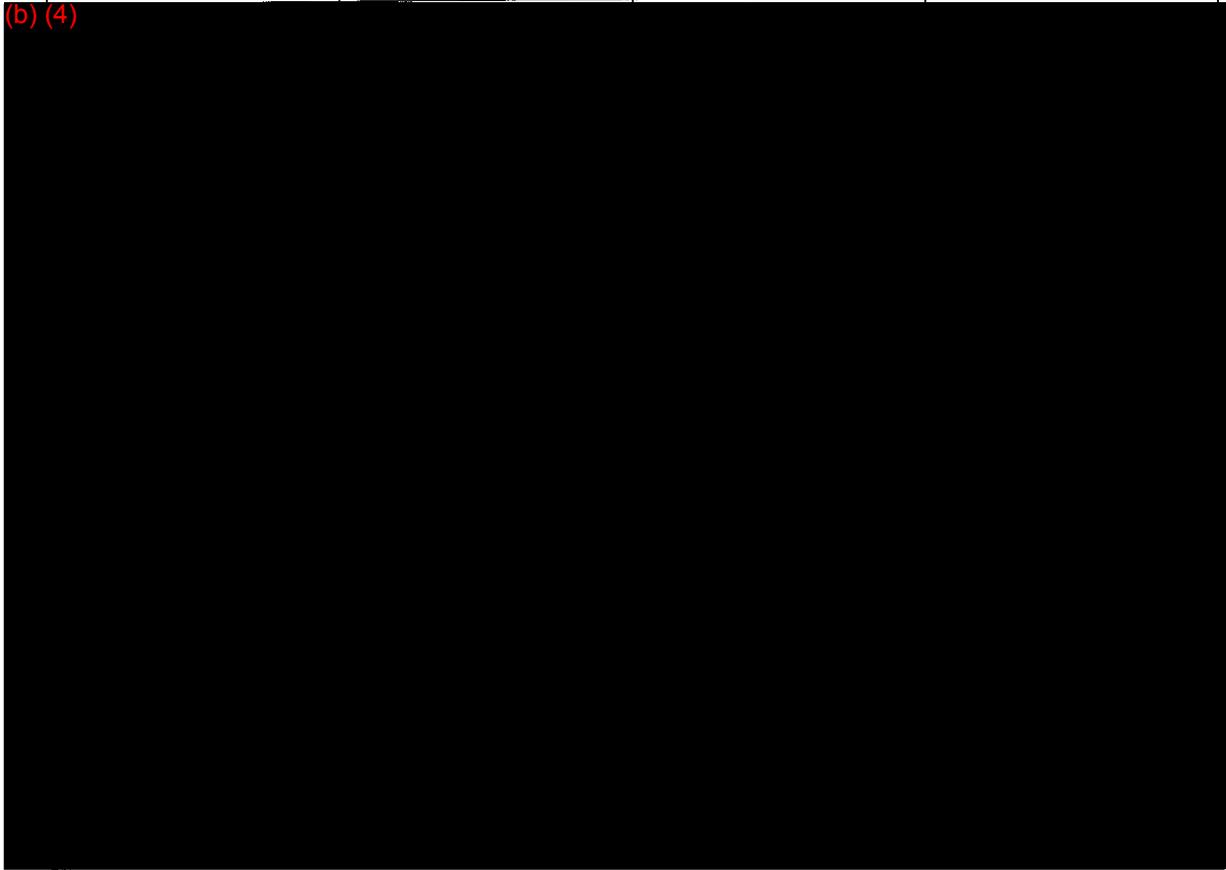
The I.V.S. Tunneller is intended to be used in females to position a polypropylene mesh for the treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency, and vaginal vault prolapse.

## Appendix No 3

### Comparison between TFS Device and Predicate Tyco I.V.S. Tunneller

Detail	TFS Device	Tyco IVS Tunneller	Comment
--------	------------	--------------------	---------

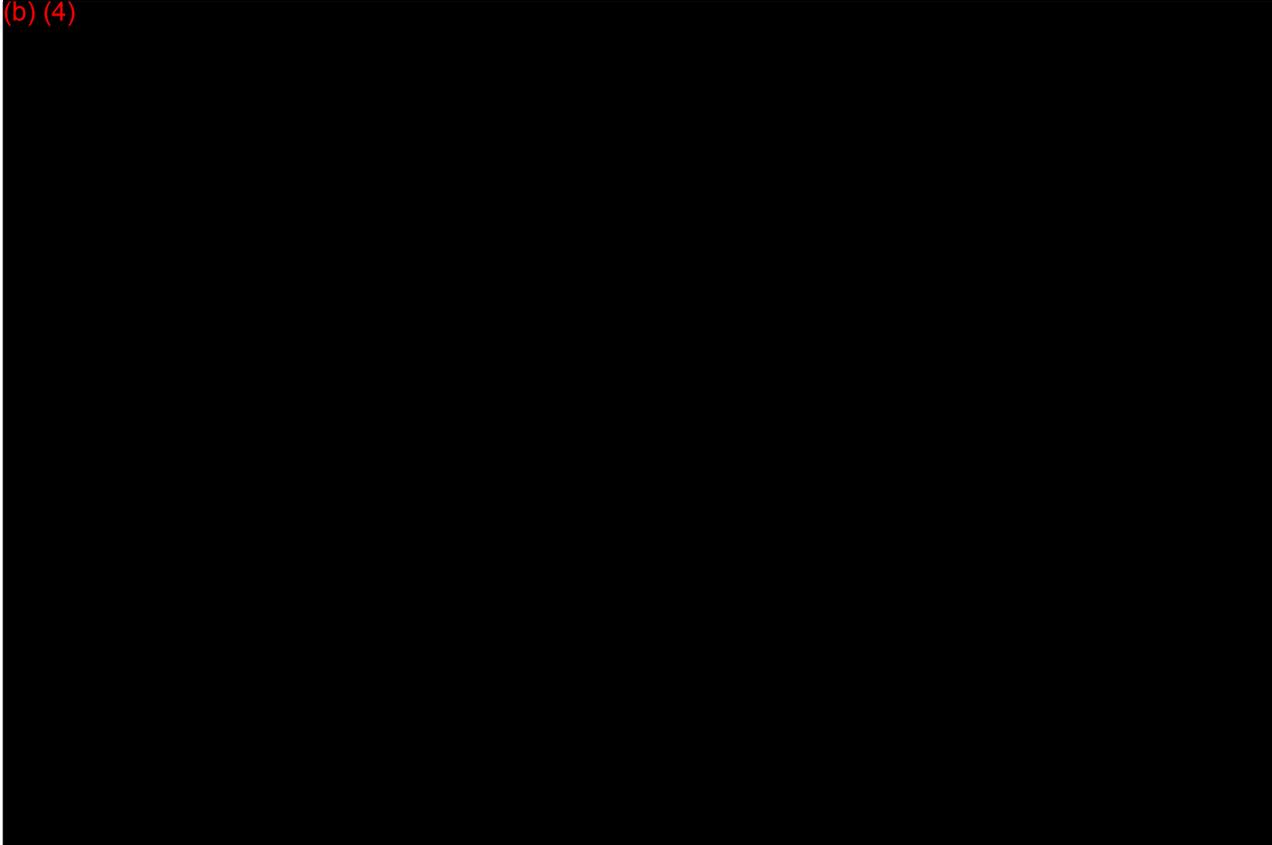
(b) (4)

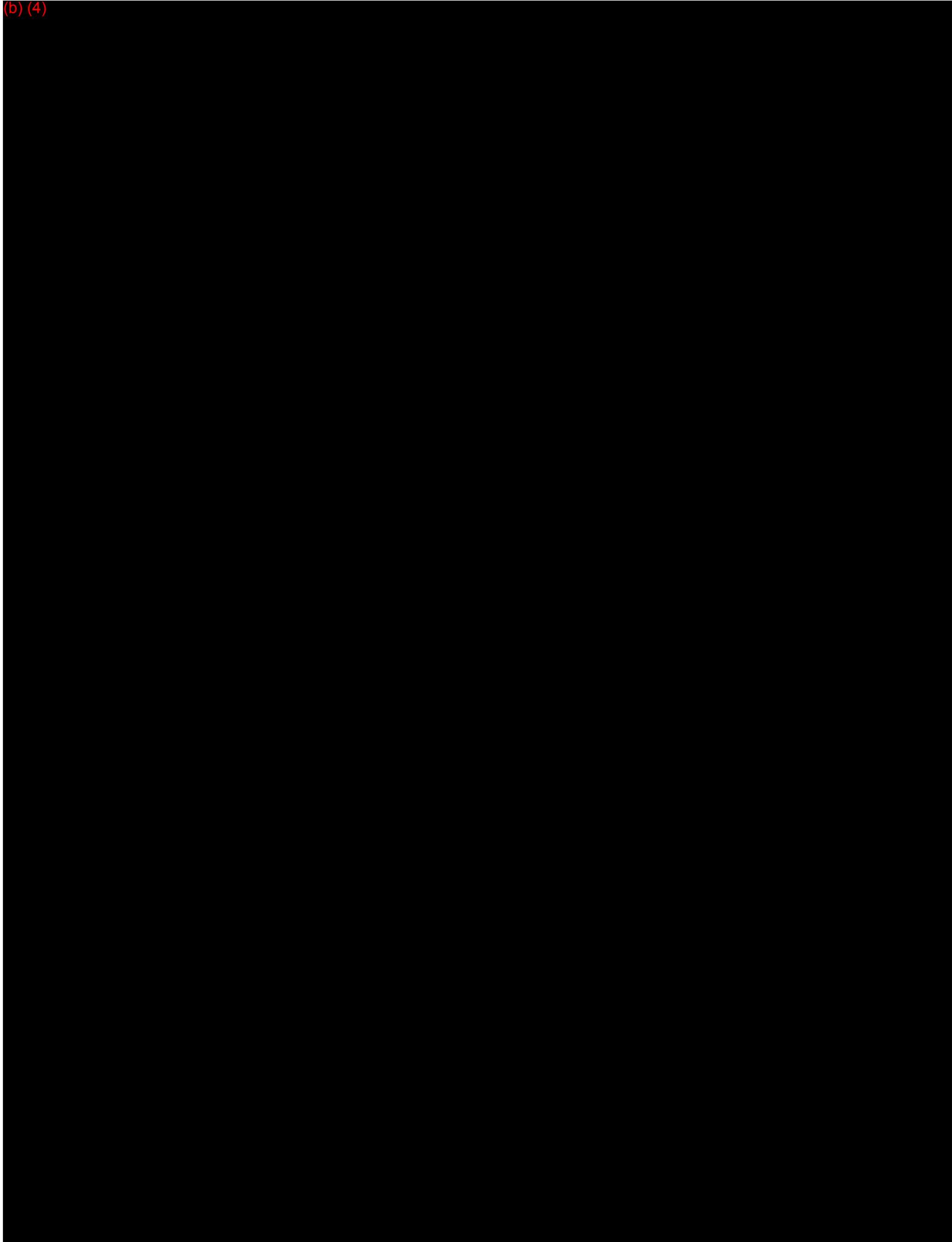


## Appendix No 4

### Specifications of the device

(b) (4)





68

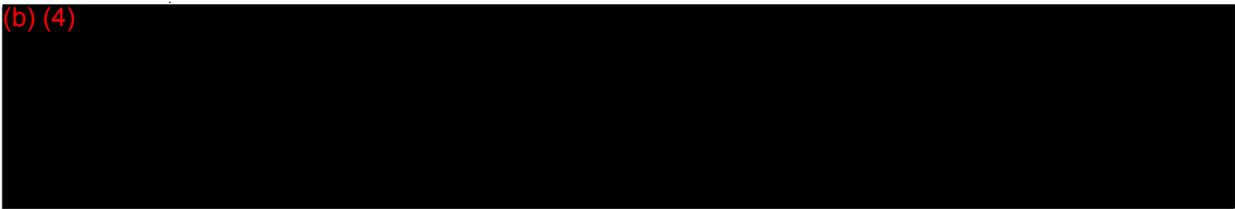


(b) (4)



To: Tom Taylor

(b) (4)



Regards,  
*Michael Ball*  
Michael Ball  
Manager, Technical Services

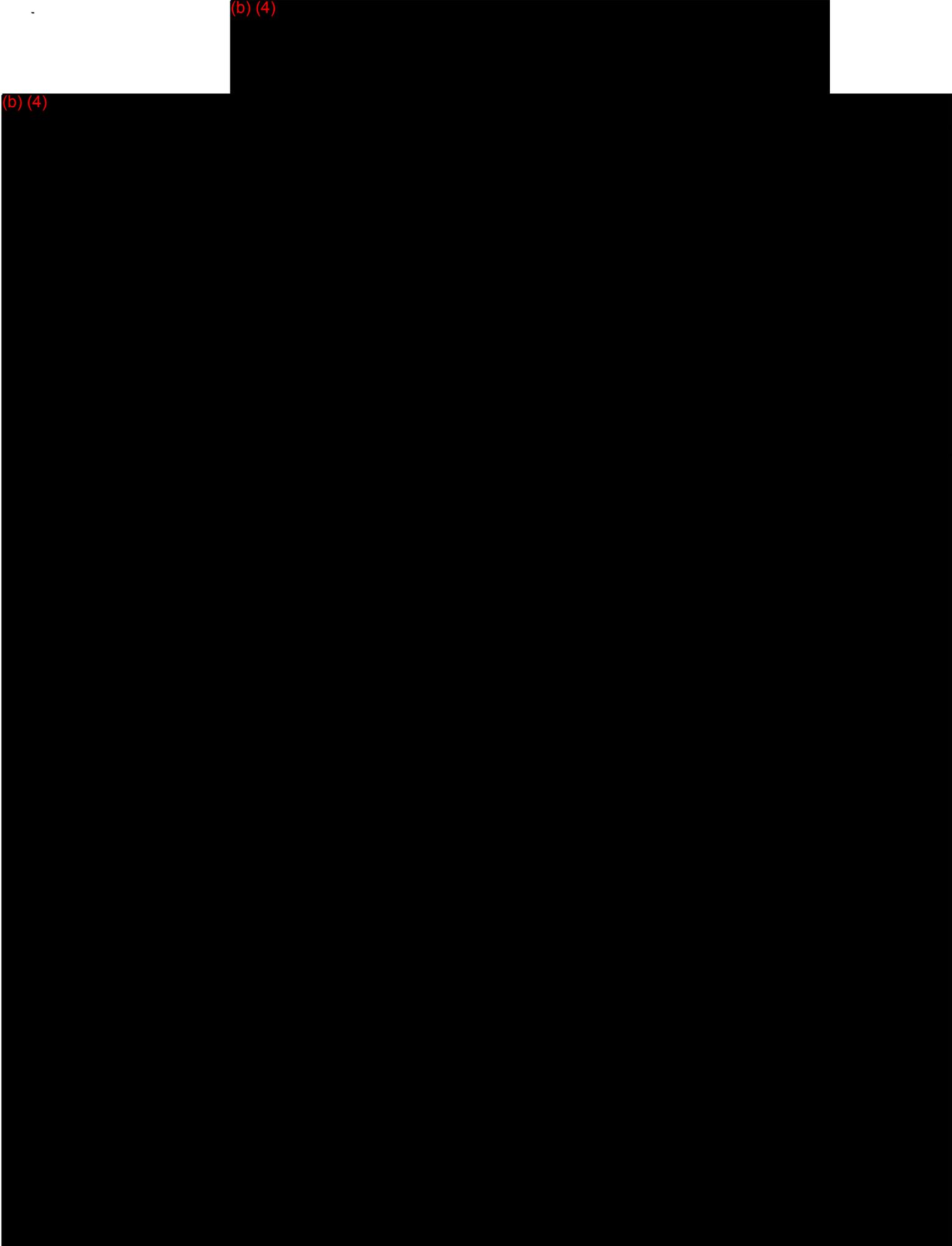
(b) (4)

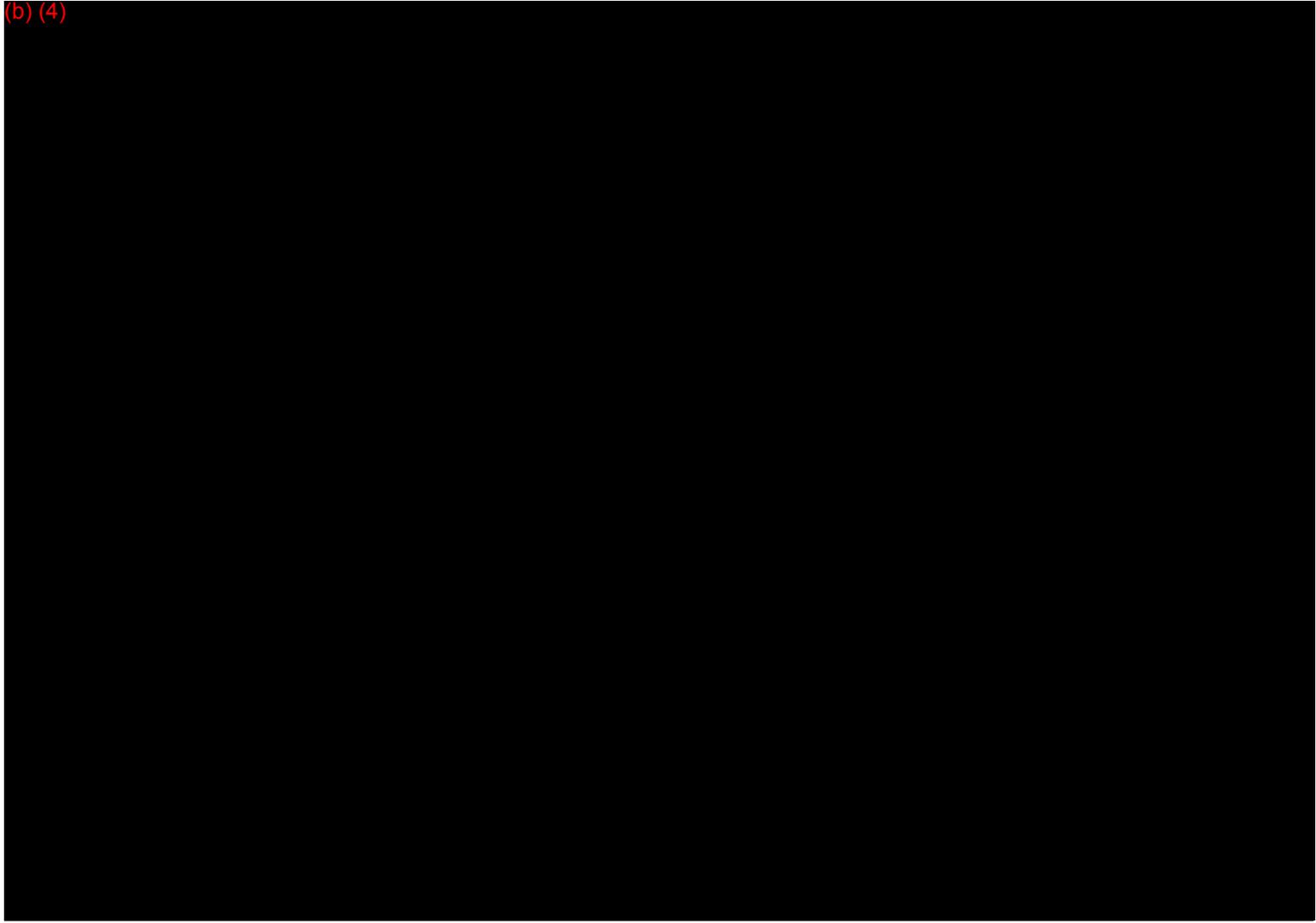


Polypro cert

(b) (4)

(b) (4)





## Appendix No 5

### Sterilisation

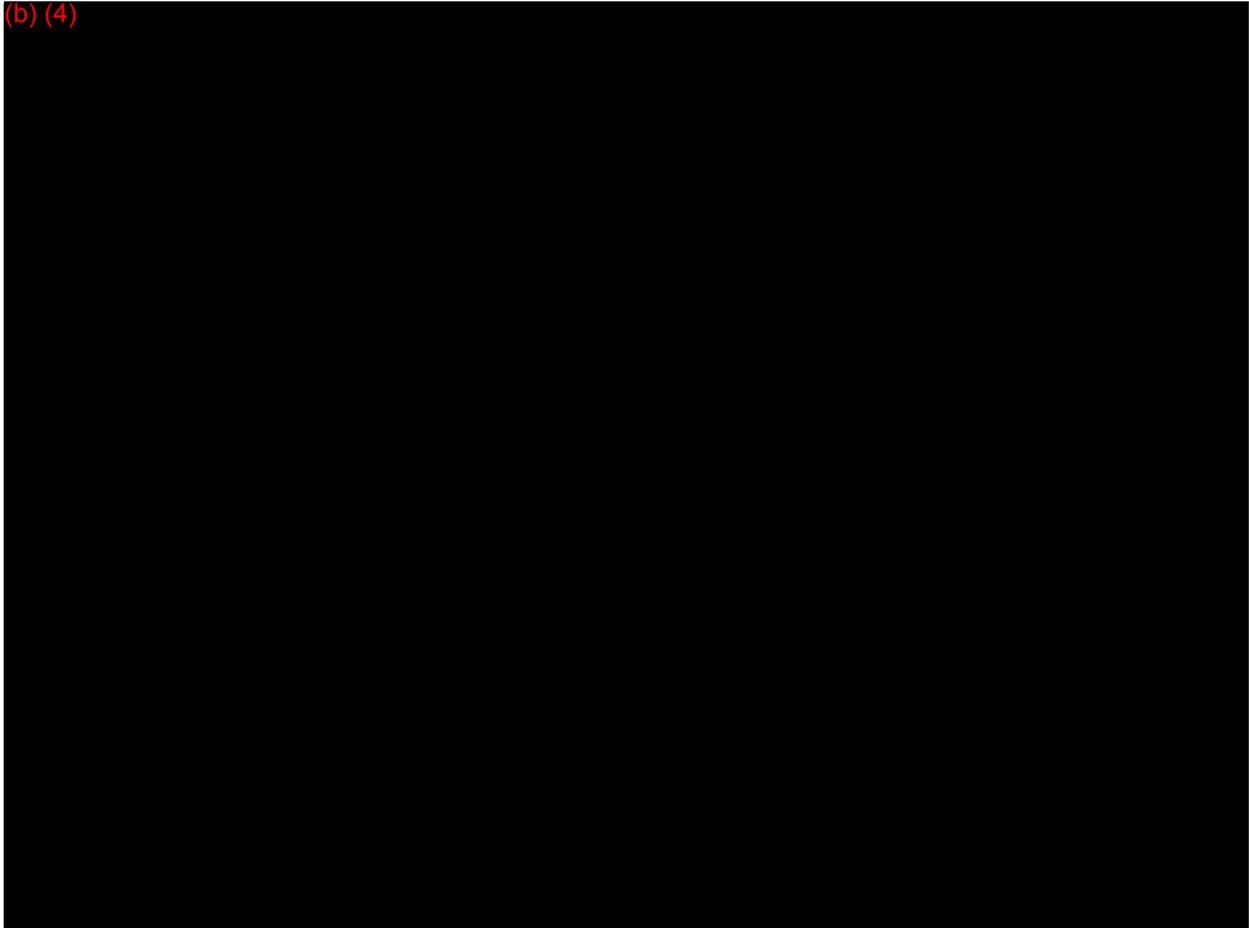
(b) (4)



## Appendix No 6

### Microbiological Testing

(b) (4)



## Appendix No 7

### Ethylene Oxide Residues

(b) (4)



## **Appendix No 8**

### **Description of Packaging**

The devices are packaged in a heat sealed Tyvek/Nylon Pouch pouch.

Sterilised pouches are transported and stored in cardboard outers.

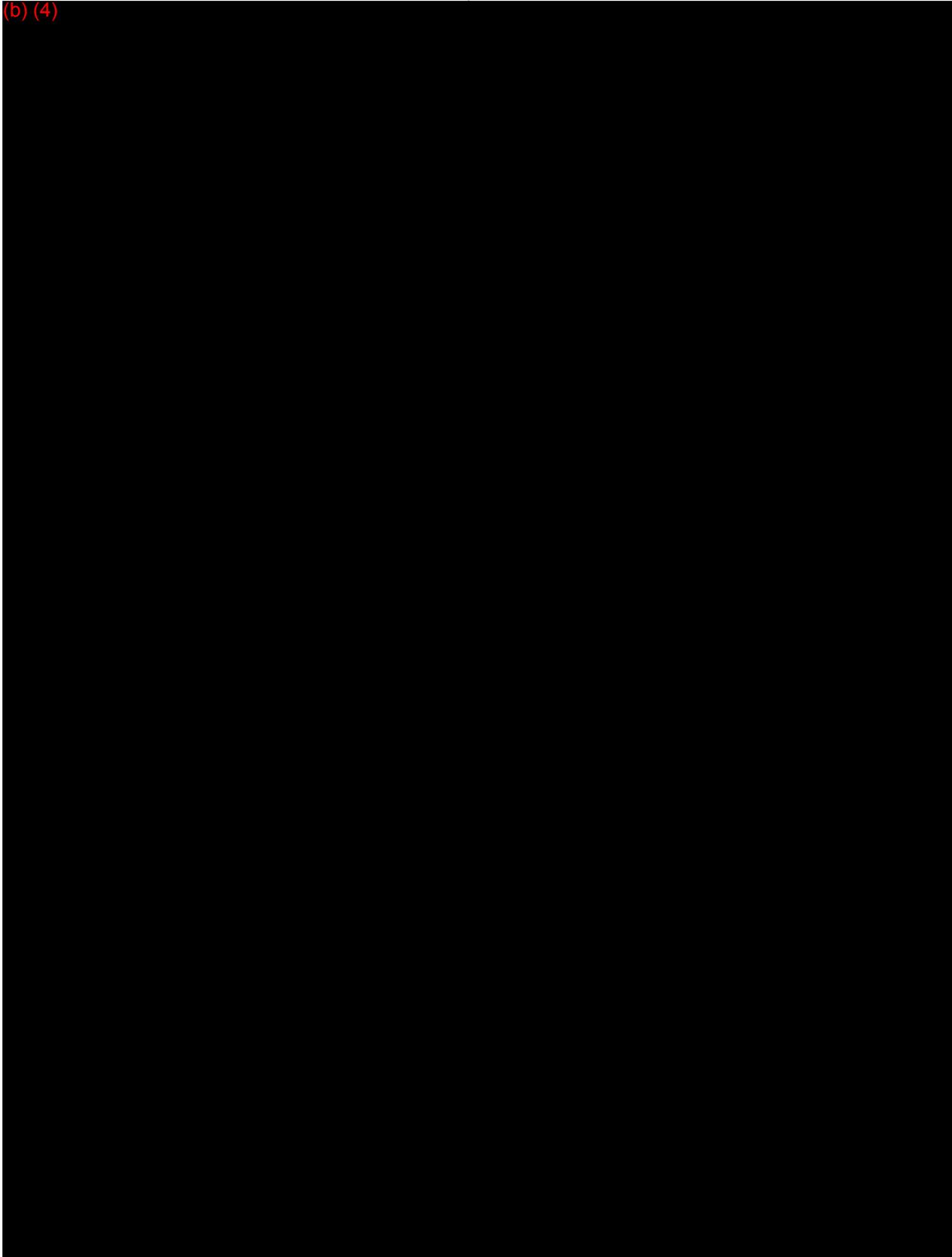
Validation has been performed by the supplier of the pouches, Tolas Healthcare, and a copy of their validation report is attached.

Integrity of the pouches at 60 months has been determined and recorded.

Further testing performed by TFS Manufacturing has confirmed the validation of Tolas Healthcare.

Packaging validation has been assessed by TGA as meeting all regulatory requirements.

<p><b>TFS Manufacturing</b> <b>- Standard Operating Procedure</b> <b>(b) (4)</b> <b>Appendix A: Packaging Specifications</b></p>	<p>Authorised document stamp</p>
--	----------------------------------





# TOLAS Health Care Packaging

905 Pennsylvania Blvd. Feasterville, PA 19053  
phone: 215-322-7900 fax: 215-322-9034  
www.tolas.com email: marketing@tolas.com

## ISO 11607 Compliance Information

ISO 11607: Packaging for Terminally Sterilized Medical Devices "specifies the requirements for single use materials and reusable containers used for packaging of terminally sterilized medical devices...outlines principal requirements for packaging process development and validation for the manufacturer of terminally sterilized medical devices...[and] specifies requirements for essential criteria used to evaluate the performance of packages for sterile medical devices."

This document seeks to demonstrate compliance with required and appropriate sections of this voluntary standard. It outlines material/package properties and characteristics that TOLAS has undertaken to certify in this report and the systems developed to support the company's overall quality.

<b>Table of Contents</b>
TOLAS Health Care Packaging Quality System page 2
Physical and Chemical Properties page 3
Shelf Life Limitations and Storage Conditions page 6
Microbial Barrier Properties for Porous Materials page 12
Microbial Barrier Properties for Impermeable Materials page 13
Compatibility to Sterilization Processes page 14
Process Performance page 16

## 1073B Tyvek®/TPF-0504A Pouches

TOLAS Health Care Packaging's medical grade 1073B Tyvek®/TPF-0504A pouches are highly porous, puncture resistant packages. TPF-0504A is a nylon-based extrusion lamination which allows for good visibility of the product packaged within the pouch. Designed for use in the medical device and pharmaceutical industries, radiation and EtO sterilizable 1073B Tyvek®/TPF-0504A pouches are high quality flexible packages with strong, smooth peelable seals.

### **TOLAS Health Care Packaging's Quality Policy:**

*"Meet or exceed customer expectations,  
Support and practice continuous improvement."*

Tyvek® is a DuPont registered trademark.

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78

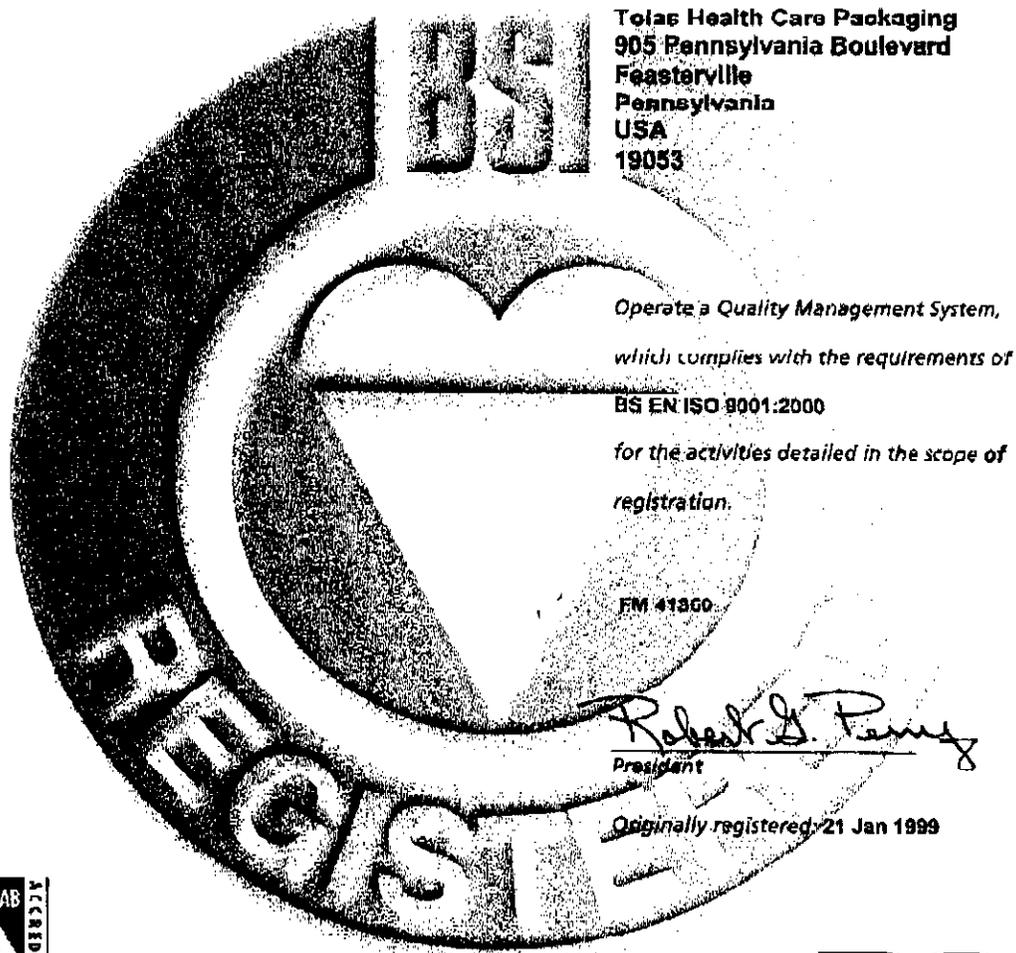
# TOLAS Health Care Packaging Quality System

TOLAS Health Care Packaging Quality System complies with the requirements of BS EN ISO 9001:2000. The company is registered through the British Standards Institution (BSI) under Certificate No. FS 41360.



## CERTIFICATE OF REGISTRATION

### Quality Management System



Tolas Health Care Packaging  
 905 Pennsylvania Boulevard  
 Feasterville  
 Pennsylvania  
 USA  
 19053

Operate a Quality Management System,  
 which complies with the requirements of  
 BS EN ISO 9001:2000  
 for the activities detailed in the scope of  
 registration.

FM 41360

*Robert J. Perry*  
 President

Originally registered: 21 Jan 1999



Management Systems

This is a Presentation Certificate only. This is not a legal document, and cannot be used as such. Only the legal certificate should be used for confirming certificate validity and scope of registration. For further information please contact the certificate holder or BSI, Inc. on 703 437 9000 or www.bsi.com.

Tyvek® is a DuPont registered trademark.

9980198880

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## Physical and Chemical Properties

The following Technical Product Data Sheets cover information specific to 1073B Tyvek® and TPF-0504A. Listed in its contents are the physical makeup of the layers of material, a demonstrated seal curve for a range of sealing temperatures and a recommended start point for studying the sealing parameters optimal for your application.

The chemical content of 1073B Tyvek®/TPF-0504A pouches does not contain substances such as lead, cadmium, mercury or hexavalent chromium as intentional additives in the manufacture of the material.

## Tyvek® Properties and Specifications

Tyvek® spunbonded olefin is manufactured from very fine continuous filaments of high-density polyethylene (HDPE) bonded together by heat and pressure. It is chemically inert, naturally white and contains no binders or fillers. Its unique structure gives it a combination of properties that no other porous sterile packaging material can match.

### Comparison of Sterile Packaging Properties

Property	Units	Tyvek® S-1059B	Tyvek® S-1073B	Autoclave Paper Pouch
<b>Bacterial Penetration<sup>1</sup></b>				
Microbial Barrier**	LRV	4.5	5.3	1.9
<b>Strength and Puncture Resistance<sup>2</sup></b>				
MD Elmendorf Tear	lb	0.73	0.82	0.13
CD Elmendorf Tear	lb	0.75	0.84	0.14
Spencer Puncture	in.-lb/in. <sup>2</sup>	41.0	50.0	8.3
Mullen Burst	in.-lb/in. <sup>2</sup>	150.0	178.0	46.9
MD Tensile Strength	lb/in.	35.4	41.7	33.0
CD Tensile Strength	lb/in.	40.1	47.4	22.0
MD Elongation	%	18.1	20.2	1.7
<b>Peel Quality<sup>3</sup></b>				
Seal Strength	avg lb/in.	1.35	1.75	0.97
Fiber Tear	25 pkg. tested	No fiber tear	No fiber tear	7 pkg. had a fiber tear***
<b>Moisture Resistance<sup>4</sup></b>				
Hydrohead	in. H <sub>2</sub> O	59.0	62.0	18.6
Basis Weight	oz/yd <sup>2</sup>	1.90	2.20	2.04

Data based on limited sampling. A popular type of autoclave paper pouch in use at many hospitals was selected for these comparison tests.

**Footnotes**

\*\*Per ASTM F1608-95 for microbial ranking of porous packaging materials.

\*\*\*Seven of the 25 pouches tested had fibers from the paper attached to the film after opening. Furthermore, the filter tore on each of the 25 pouches during opening.

1. Bacterial Penetration- The higher the log reduction value (LRV), the more resistant the packaging is to bacteria and micro-organisms. (A log difference of 3 signifies a difference of 1000 units.)

2. Strength and Puncture Resistance- The higher the value, the better the package integrity. (MD signifies machine direction; CD signifies cross direction.)

3. Peel Quality- High Seal Strength combined with no fiber tear means a clean, strong peel, decreasing the risk of contamination.

4. Moisture Resistance- The higher the value, the more resistant the package is to water and other liquids.

The above information was taken from DuPont's website at [www.dupont.com](http://www.dupont.com).

Tyvek® is a DuPont registered trademark.

0883510855

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# TECHNICAL PRODUCT DATA

905 Pennsylvania Blvd., Feasterville, PA 19053 Phone: 215-322-7900 Fax: 215-322-9034 www.tolas.com

**Product** **1073-B TYVEK®  
MERGE 18025 {E.I. DuPont}**

1073-B Tyvek® is a product of E.I DuPont with application in the packaging of sterile disposable medical devices.

Merge 18025 is the designation of the specific type used in the medical field.

Tyvek® is a spun bonded olefin, paper like material. It exhibits outstanding strength, bacterial barrier properties and moisture resistance, therefore making it a high performance medical packaging material.

The information listed below is indicative of typical physical characteristic of this product and is not intended to be material specification.

**AVERAGE PHYSICAL PROPERTIES {TYPICAL: UNCOATED TYVEK®}**

PHYSICAL PROPERTY	TYPICAL VALUES	TEST METHOD
Basis Weight 3" x 3" Sample	2.2 ± .11 oz. per sq. yd.	T-410-05-61
Thickness	8 mil ± 3 mil	T-411-05-44
Elmendorf Tear	1.2 lb. per in. ± .4 M.D. and C.D.	T-414-M-49
Strip Tensile One-inch Strip	52 lbs. per in. M.D. 45 lbs. per in. C.D.	T-404-M-50
Elongation To Break	25% M.D., 29% C.D.	T-404-M-50
MIT Flex {Cycles}	100M Cycles	T-424
Porosity-Gurley 1-Inch Orifice	19 Seconds {6-50 Sec. Range}	T-191B Method 5452
Hydrostatic Head	64.1" x 3" dia.	ASTM-D-583-58
Eddy Opacity	88%, 100% is complete opacity	T-424-M-60

DuPont Tyvek® will remain stable through steam & dry-heat cycle at 30 psi for 30 minutes at a maximum temperature of 260°F or 127°C.

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# TECHNICAL PRODUCT DATA

905 Pennsylvania Blvd., Feasterville, PA 19053 Phone: 215-322-7900 Fax: 215-322-9034 www.tolas.com

## TPF-0504A Nylon Based Lamination

### Typical Application

- Peel pouches or other film packaging.

### Functional Characteristics

- Tough, puncture resistant film effectively contains angular shaped devices.
- Wide range sealability to uncoated Tyvek®.
- Moderate clarity for good product visibility.
- Nylon outer layer prevents "sticking" to heat seal rolls and platens.

### Typical Physical Data

STRUCTURE	Test Method	Calliper		Weight	
				lbs / 3Mft <sup>2</sup>	grams / M <sup>2</sup>
Nylon / Primer LD Polyethylene  <b>Totals</b>		0.60 mils	15.20 μ	10.6 lbs.	17.2 gms
		2.00 mils	50.80 μ	29.0 lbs.	47.3 gms
		2.60 mils	66.00 μ	39.6 lbs.	64.5 gms
CHARACTERISTICS	Test Method	Units		Typical	
MVTR*	Mocon	g/100 si /24 hr.	—	0.9	—
O <sub>2</sub> TR*	Mocon	cc/100 si /24 hr.	—	5.0	—
Nominal Yield	Tolas	sq. in./lb. m <sup>2</sup> /kg	—	10,909 15.5	—
Seal Conditions			<b>Min.</b>	<b>Typical</b>	<b>Max.</b>
Temperature		degrees F	210	230	350
		degrees C	99	110	177
Dwell		seconds	0.5	1.5	3.0
Pressure		psi	40	50	90

Optimum sealing conditions are highly dependent upon the materials being sealed, the equipment, and production rates. Our recommendation is to begin testing at 240–270°F (115–132°C), 1.5 seconds, 50 psi. Structure weight/thickness may vary by ± 10%.

\* Calculated

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## Shelf Life Limitations and Storage Conditions

TOLAS Health Care Packaging Storage and Shelf Life Recommendations for Packaging and Labeling Materials:

Most adhesive-type materials, including heat sealable, pressure sensitives and cohesives, are designed for stability over long periods of time provided good storage and handling practices are exercised. In general, manufactured materials have a minimum shelf life of two years upon leaving TOLAS' shipping dock, depending on customer storage conditions.

General storage guidelines are as follows:

- |                       |  |  |
|-----------------------|--|--|
| <b>1. Temperature</b> | <b>Max. 85°F</b><br><b>Min. 45°F</b>   | Although temperatures lower than 45°F will not harm the product, condensate may form if the material is taken from a very cold area into a warm area and used immediately. |
| <b>2. Humidity</b>    | <b>Max. 60% RH</b><br><b>Min. 40% RH</b>   | Our materials can usually take wider extremes, however this range is recommended for good manufacturing control.   |
| <b>3. Pressure</b>    | Keep all packaging materials in original containers or wrappers until ready for use.   |  |
|                       | Avoid stacking of skids or cartons that might cause collapse of boxes or bring excessive load to bear on the contents.   |  |
| <b>4. Environment</b> | Avoid storing materials in environments where the product may come into contact with organic solvent vapors, oxidizing chemicals, oils or odor causing substances. |  |

There may be products with specific functional characteristics requiring special handling and storage. In such cases, recommendations will be spelled out in technical data and marked on packaging containers. Please check with your customer representative for information regarding special handling and storage recommendations.

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Sterility Maintenance of Medical Packaging: A Report On Five-Year Shelf Life Tests of DuPont Tyvek® follows on page 7.

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A Shelf Life Study performed with 1073B Tyvek®/TPF-0504A samples that have been aged real time for a minimum of 2 years demonstrates an effective product response (no statistically significant differences) (see page 9).

## Sterility Maintenance of Medical Packaging: A Report On Five-Year Shelf Life Tests of DuPont Tyvek®

Sterile medical devices often sit on the shelf for extended periods between the time they are packaged, sterilized and then put into use. It's not uncommon for some items to remain in distribution and storage for more than a year.

Medical device users want unquestionable assurance that the package they pull from the shelf or out of the cabinet is sterile. That's why the effects of long-term shelf storage are of primary interest to end users, as well as to manufacturers and distributors of sterile medical devices.

Currently, there is no industry standard for determining how long a packaged device will resist microbial penetration while in storage. Because of this void, and to complement its rigorous testing of Tyvek® spun-bonded olefin in the Bacterial Test Chamber (BTC), DuPont developed a procedure to measure contamination levels of sealed packages stored for periods of up to five years.

### Background

The first shelf-life studies for DuPont Tyvek® were conducted in 1972 by U.S. Testing Laboratories. The results indicated that packaging of Tyvek® could resist penetration by airborne bacterial spores for at least one year. To extend that investigation, DuPont initiated a long-term shelf-life study in 1978 for two sterile packaging grades of Tyvek® (1059B and 1073B). To make the study more meaningful than the study conducted in 1972, samples were repeatedly challenged with high bio-contamination levels for months and years at a time.

The results of this more rigorous study showed that Tyvek® is a remarkably reliable sterile barrier. In fact, the study proved conclusively that Tyvek® can maintain sterility for at least five years if package integrity is maintained.

### The Five-Year Testing Process

Open petri dishes, representing medical devices, were heat sealed inside specially designed packages made of Tyvek® and poly-MYLAR® film. These packages and their contents were then sterilized using ethylene oxide. To ensure sterility of the specimens prior to testing, random samples were checked for contamination using the U.S. Pharmacopeia (U.S.P.) methods for identifying anaerobic and aerobic bacteria.

To protect against contamination from outside sources, the packages containing sterile petri dishes were placed on shelves inside special metal storage cabinets, which were maintained at controlled temperature and relative humidity. Every four months, the packages were sprayed with a uniform, massive dose of *B. circulans* spores. Spraying, from an aerosol suspension, lasted for four seconds and deposited 4,000 to 5,000 spores on the surface of each package.

To check sterility during the five years of testing, 10 packages were withdrawn randomly every six months and the outside surface of the poly-MYLAR® was disinfected. A small hole was then made through the film with a hot, pencil-tip soldering iron. Then, 15 mL of sterile nutrient agar was injected into the petri dish,

*continued on page 8*

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## Sterility Maintenance of Medical Packaging: A Report On Five-Year Shelf Life Tests of DuPont Tyvek® *continued*

and the entry hole was covered with biocidal tape. If any spores had penetrated the lid made of Tyvek®, they would have grown on the culture medium after incubation.

The final part of the test procedure was to determine that the packages were indeed challenged with the bacterial spores on the outside of the lid of Tyvek®. To do this, a small swatch of Tyvek® from the package lid was cut out and placed on an agar medium. After evidence of bacteria growth, the swatches were examined under a microscope and colonies of *B. circulans* were counted. This served as a check for the number of viable spores that were actually on the surface of the Tyvek®. It also ensured that the density of spores was consistently maintained over the many years of the test.

### Conclusion

When combined with the convincing results of DuPont's earlier BTC tests, this five-year shelf-life study confirms the superiority of Tyvek® as a sterile packaging material for medical devices. In these and other tests, Tyvek® has clearly demonstrated an inherent ability to withstand microbial penetration-- even under the most rigorous conditions. This feature, combined with an ability to maintain sterility even after five years of exposure to contamination by microorganisms, has made Tyvek® the standard of excellence in sterile packaging.

The above information was taken from DuPont's website at [www.dupont.com](http://www.dupont.com).

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### TOLAS 1073B Tyvek®/TPF-0504A Shelf Life Study

Samples	Actual time	Real Time	Samples	Actual time	Real Time
	2000	2002		2000	2002
1	2.16	2.01	17	2.15	2.02
2	2.01	2.21	18	1.9	2.14
3	2.22	2.4	19	1.65	2.09
4	2.28	2.08	20	1.8	2.04
5	1.86	1.96	21	2.12	2.35
6	1.99	2.05	22	2.42	2.38
7	2.5	2.18	23	2.57	2.09
8	2.05	2.33	24	2.26	1.98
9	1.73	1.85	25	1.75	2.12
10	1.88	1.89	26	2.32	1.99
11	1.83	1.91	27	1.94	2.28
12	1.96	2.18	28	2.03	2.03
13	2.01	2.44	29	2.11	2.17
14	1.99	2.45	30	2.23	1.92
15	2.11	2.25	31	2.17	2.02
16	2.27	2.13	32	1.67	1.76

**Average of 32 samples**

<b>Average</b>	<b>2.06</b>	<b>2.12</b>
<b>Stdev.</b>	<b>0.23</b>	<b>0.18</b>

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## TOLAS 1073B Tyvek®/TPF-0504A Shelf Life Study *continued*

### Analysis Summary

Sample 1: Actual time 2000  
Sample 2: Real time 2002

Sample 1: 32 values ranging from 1.65 to 2.57  
Sample 2: 32 values ranging from 1.76 to 2.45

### The StatAdvisor

This procedure compares the data in 2 columns of the current data file. It constructs various statistical tests and graphs to compare the samples. The F-test in the ANOVA table will test whether there are any significant differences amongst the means. If there are, the Multiple Range Tests will tell you which means are significantly different from which others. If you are worried about the presence of outliers, choose the Kruskal-Wallis Test which compares medians instead of means. The various plots will help you judge the practical significance of the results, as well as allow you to look for possible violations of the assumptions underlying the analysis of variance.

### ANOVA Table

Analysis of Variance					
Source	Sum of Squares	Df	Mean Square	F-Ratio	P-Value
Between groups	0.0484	1	0.0484	1.14	0.2897
Within groups	2.63157	62	0.0424448		
Total (Corr.)	2.67997	63			

### The StatAdvisor

The ANOVA table decomposes the variance of the data into two components: a between-group component and a within-group component. The F-ratio, which in this case equals 1.14031, is a ratio of the between-group estimate to the within-group estimate. Since the P-value of the F-test is greater than or equal to 0.05, there is not a statistically significant difference between the means of the 2 variables at the 95.0% confidence level.

### Kruskal-Wallis Test

	Sample Size	Average Rank
Actual time 2000	32	30.0
Real time 2002	32	35.0

Test statistic = 1.15432 P-Value = 0.282644

### The StatAdvisor

The Kruskal-Wallis test tests the null hypothesis that the medians within each of the 2 columns is the same. The data from all the columns is first combined and ranked from smallest to largest. The average rank is then computed for the data in each column. Since the P-value is greater than or equal to 0.05, there is not a statistically significant difference amongst the medians at the 95.0% confidence level.

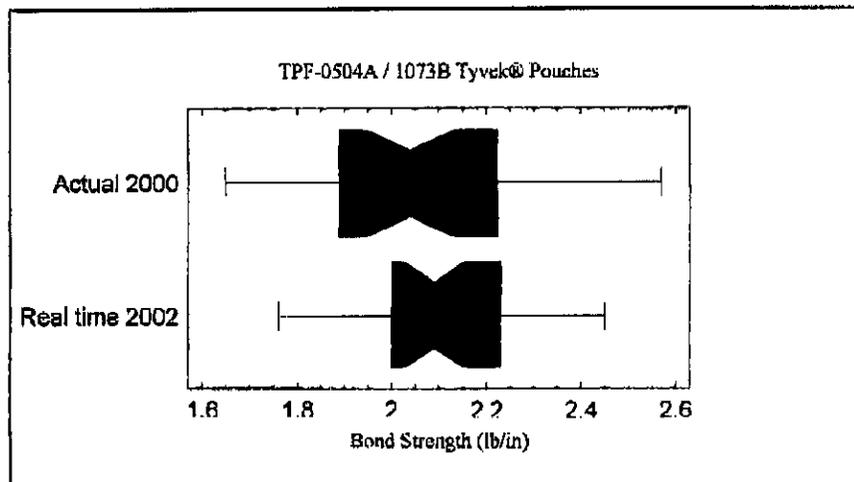
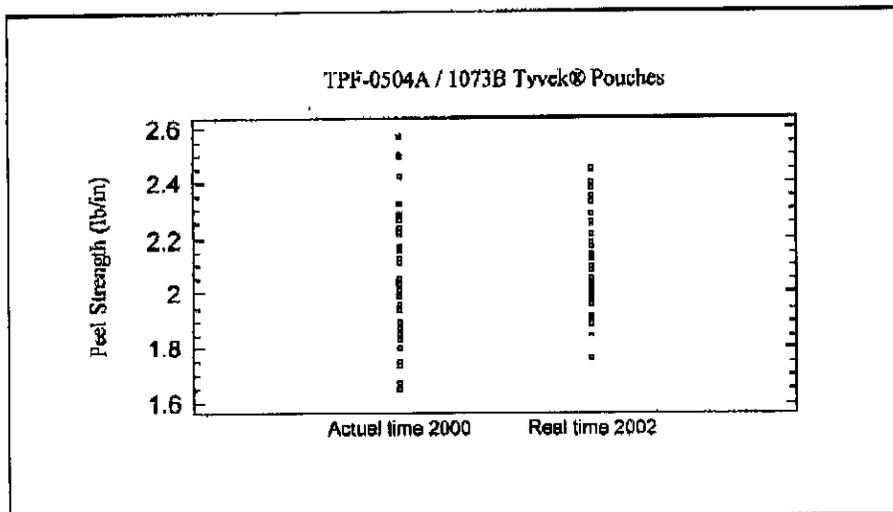
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### TOLAS 1073B Tyvek®/TPF-0504A Shelf Life Study *continued*



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## Microbial Barrier Properties for Porous Barrier Materials

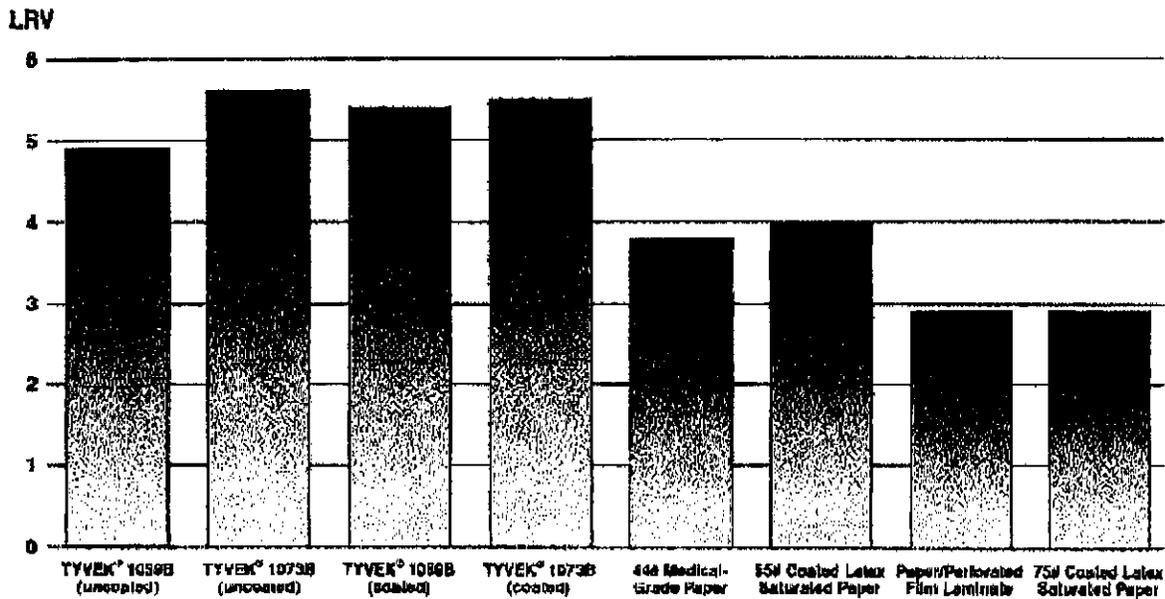
Medical grade Tyvek® has noted success as a microbial barrier. When tested using ASTM F1608-95, Tyvek® demonstrates a high resistance to bacteria and microorganisms.

### Excellent Microbial Barrier Resistance

The number-one priority in selecting packaging materials for medical devices is the ability of the package to maintain sterility from the point of sterilization until a product reaches its end use.

Even under the most rigorous conditions of high stress, Tyvek® is highly resistant to bacteria spores and other contaminating microorganisms. Bacteriological tests clearly demonstrate that Tyvek® outperforms other commercially available porous packaging materials, including medical-grade paper. What's more, comprehensive shelf-life studies have shown that Tyvek® can maintain sterility for at least five years if package integrity is not compromised.

Microbial Barrier Test Results



*Note: Per ASTM F1608-95. The higher the log reduction value (LRV), the more resistant the packaging is to bacteria and microorganisms. A log difference of 3 signifies a difference of 1,000 units.*

The above information was taken from DuPont's website at [www.dupont.com](http://www.dupont.com).

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## Compatibility to Sterilization Processes

TOLAS Recommended Usage:

1073B Tyvek®/TPF-0504A pouches can be used effectively with EtO and radiation sterilization methods.

Only Tyvek® is compatible with all of the most commonly used sterilization methods. No matter which method is used -- EtO, gamma, E-beam, steam<sup>1</sup>, or the new gas plasma sterilization systems -- Tyvek® retains its protective properties, color and flexibility.

### Sterilization and Material Compatibility

	Tyvek®		
Ethylene Oxide (EtO)	Yes	No	
Gamma Radiation	Yes		
E-Beam Radiation	Yes		
Steam	Yes <sup>1</sup>	No	
Sterrad®	Yes	No	No

<sup>1</sup> Under controlled conditions

### Ethylene Oxide (EtO)

Films are not compatible with gas sterilization, and Tyvek® outperforms other porous packaging materials at outgassing. EtO residuals dissipate from packages made with Tyvek® much sooner than they do from ordinary medical-paper packages. With packages of Tyvek®, no measurable amounts of EtO remain after just one week.

### Radiation (Gamma and E-beam)

Under normal radiation sterilization doses, Tyvek® maintains outstanding mechanical strength and flexibility, with minimal color change and no sacrifice in low-linting performance when packages are opened. In fact, Tyvek® retains superior microbial resistance after exposure to 5.0 megarads (50 kGy), twice the normal sterilizing dose.

### Steam

Tyvek® retains dimensional stability and integrity at 250° to 260°F (121°-127°C) at 30 psi for 30 minutes

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## Compatibility to Sterilization Processes *continued*

with no discoloration. Rigid or semi-rigid trays restrict potential shrinkage and wrinkling which can result in a smoother/tighter lid. The porous structure of Tyvek® allows steam to enter and leave the package freely under pressure, and helps minimize pressure stress fluctuations in the package structure while maintaining bacterial barrier properties. (For maximum porosity, zone heat seal coatings are recommended.)

### **Sterrad®**

Tyvek® is suitable for use with the Sterrad® Sterilization System from Advanced Sterilization Products, a Johnson & Johnson company. This environmentally safe sterilization alternative uses low-temperature gas plasma to avoid the degrading effects of steam or the residues of ethylene oxide. Medical-grade papers, including autoclave paper pouches, are not acceptable for use with the Sterrad® system.

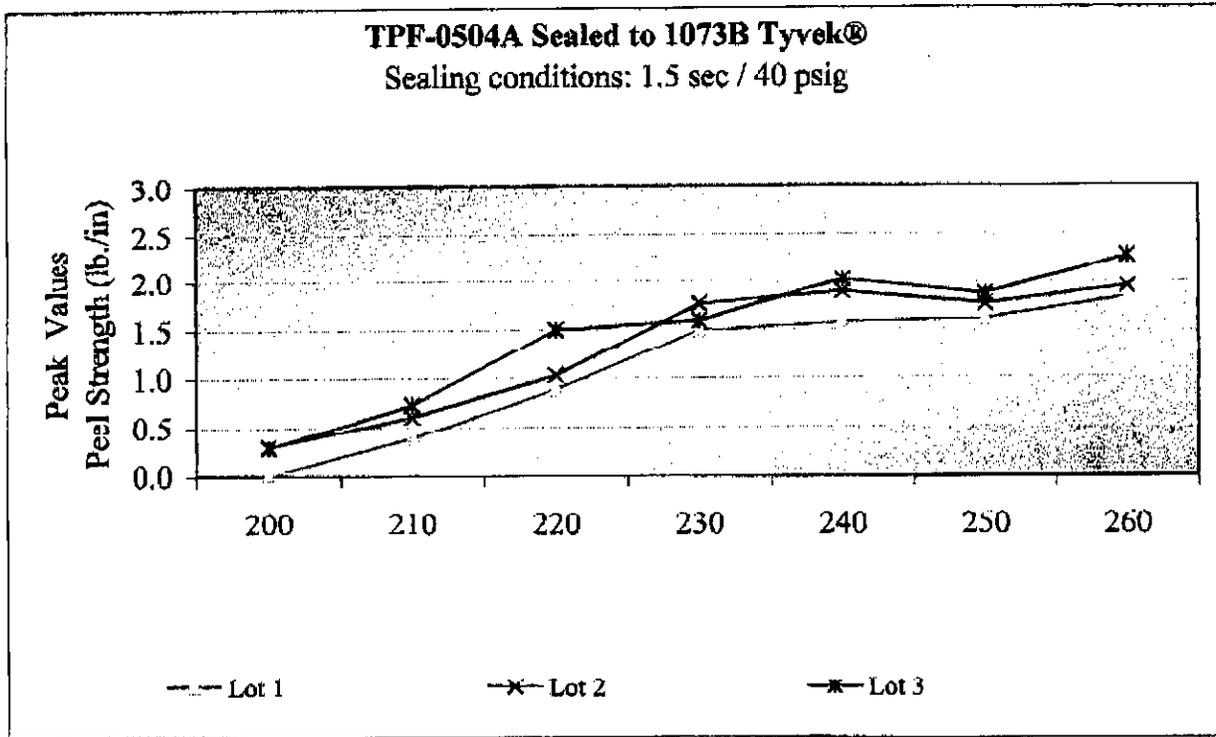
The above information was taken from DuPont's website at [www.dupont.com](http://www.dupont.com).

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### Process Performance

Multiple lot data shows effective levels of seal strength adherence to specification in pounds/inch width.



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## Appendix No 9

### Biocompatibility

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## Appendix No 10

In Process testing

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