

SECTION 5. 510(K) SUMMARY**Submission Correspondent and Owner**

Instratek, Inc.
210 Springhill Drive
Suite 130
Spring, TX 77386

DEC 08 2008

Phone: 281-890-8020
Fax: 281-890-8068
Email: jeff@instratek.com
Contact: Mr. Jeff Seavey
Vice President

Date summary prepared:

August 15, 2008

Device trade name:

HAV-Lok Bunion Correction System

Device common name:

Button/Suture

Device classification name:

Washer, Bolt Nut, HTN at 21 CFR 888.3030

Legally marketed device to which the device is substantially equivalent:

Arthrex Mini TightRope Repair Kit, K061925

Description of the device:

The HAV- Lok Kit is designed to assist in the reduction and control of increased pathologic intermetatarsal angles. HAV-Lok may eliminate the necessity of a traditional osteotomy in the correction of Hallux Valgus deformities within the indicated criteria. The implanted device consists of three (3) components:

1. Medial Oblong Plate
2. Lateral Oblong Plate
3. #3/4 Suture

There are 4 accessories required to implant the device

1. Suture Lasso
2. K-wire
3. Cannulated Drill Bit
4. Drill Guide

To achieve reduction of intermetatarsal angles, two suture paths are drilled through the first and second metatarsals. The oblong plates are positioned on the outside of the first and second metatarsals and the sutures are used to draw the plates together thereby reducing the intermetatarsal angle.

Intended use of the device:	The Instratek HAV-Lok Bunion Correction System is intended for the following surgical indications: <ul style="list-style-type: none"><li data-bbox="714 305 1347 382">• To assist in the biomechanical reduction of abnormal intermetatarsal angle.
Technological characteristics:	The technological characteristics between the predicate and proposed devices are the same.
Conclusions:	There are no significant differences between the proposed and predicate device; therefore, the proposed device does not raise any questions regarding safety and effectiveness. The HAV-Lok Bunion Correction System, as designed, is as safe and effective as the predicate devices. Comparisons have been made to a legally marketed predicate device, and the device is determined to be substantially equivalent to the referenced predicate device currently on the market.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Instratek Inc.
% Mr. Jeff Seavey
210 Springhill Drive
Suite 130
Spring, Texas 77386

DEC 08 2008

Re: K082384

Trade/Device Name: HAV-Lok Bunion Correction System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation
appliance and accessories

Regulatory Class: II

Product Code: HTN

Dated: November 18, 2008

Received: November 18, 2008

Dear Mr. Seavey:

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. Jeff Seavey

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4. INDICATIONS FOR USE STATEMENT

510(k) Number:

K082384 (pg 111)

Device Name:

HAV-Lok Bunion Correction System

Indications for Use:

The Instratek HAV-Lok Bunion Correction System is intended for the following surgical indications:

- To assist in the correction of Hallux Valgus deformities by providing reduction of the 1st intermetatarsal angle.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil M. Dyer for me

(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K082384



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Instratek Inc.
% Mr. Jeff Seavey
210 Springhill Drive
Suite 130
Spring, Texas 77386

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Re: K082384

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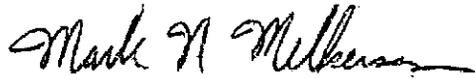
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Sincerely yours,



Mark N. Melkerson

Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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K082384 (pg 1/1)

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(21 CFR 807 Subpart C)

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

Concurrence of CDRH; Office of Device Evaluation (ODE)

Neil M. Dyer, Sr. MD

(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K082384

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-40)
9200 Corporate Blvd.
Rockville, Maryland 20850

August 20, 2008

INSTRATEK, INC.
210 SPRINGHILL DR.
SUITE 130
SPRING, TX 77386
ATTN: JEFF SEAVEY

510(k) Number: K082384
Received: 19-AUG-2008
Product: HAV-LOK BUNION
CORRECTION SYSTEM

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) 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.

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 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/cdrh/mdufma/index.html> for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) need to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. ' 282(j)), which expanded the current database known ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form (<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf>) accompany 510(k)/HDE/PMA submissions. The agency has issued

a draft guidance titled: "Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" (http://www.fda.gov/oc/initiatives/fdaaaa/guidance_certifications.html). According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review:

- 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1655.pdf>. Please refer to this guidance for information on a formalized interactive review process.
- 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electron copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/electsub.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/. If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsma/dsmastaf.html>. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

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

August 19, 2008

INSTRATEK, INC.
210 SPRINGHILL DR.
SUITE 130
SPRING, TX 77386
ATTN: JEFF SEAVEY

510(k) Number: K082384
Received: 19-AUG-2008
User Fee ID Number: 6037957
Product: HAV-LOK BUNION
CORRECTION 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 all 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 Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and the FDA Amendments Act of 2007 (FDAAA) (Public Law 110-85), authorizes FDA to collect user fees for certain types of 510(k) submissions. The submission cannot be accepted for review until the fee is paid in full ; therefore, the file has been placed on hold. When your user fee payment has been received , review of the 510(k) will resume as of that date. Alternatively, you may request withdrawal of your submission. 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	U.S. Bank
P.O. Box 956733	956733
St. Louis, MO 63195-6733.	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 (240)276-4025 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 www.fda.gov/oc/mdufma.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, or HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/electsub.html.

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 a 510(k) Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (240) 276-3150 or its toll-free number (800)638-2041, or contact them at their Internet address www.fda.gov/cdrh/dsma/dsmastaf.html, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Christina Zeender at Christina.Zeender@fda.hhs.gov. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

Diane M. Garcia
Public Affairs Specialist
Office of Device Evaluation
Center for Devices and
Radiological Health

1082384

FDA CDRH DMC

AUG 19 2008

Received

510(k) Premarket Notification

Date: August 15, 2008

Submitted By: Jeff Seavey
Vice President
Instratek, Inc



Phone: 281-890-8020
Fax: 281-890-8068
E-mail: jeff@instratek.com

141

1031
OR
II

SECTION 3. 510(K) COVER LETTER**510(k) Notification****3.1. Administrative Information**

See the CDRH Premarket Review Submission Cover Sheet in Section 2 of this application for the following information: submission type, 510(k) submitter information, submitter contact information, recommended classification regulation, product classification, panel, product code and any former correspondence numbers.

3.2. Basis for Submission

This 510(k) is being submitted because the subject device, the HAV-Lok Bunion Correction System, is a new medical device.

3.3. Design and Use of the Device

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?	-	-
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

TABLE OF CONTENTS

SECTION 1. MEDICAL DEVICE USER FEE COVER SHEET (FORM FDA 3601) 4

SECTION 2. CDRH PREMARKET REVIEW SUBMISSION COVER SHEET 5

SECTION 3. 510(K) COVER LETTER 10

 3.1. ADMINISTRATIVE INFORMATION 10

 3.2. BASIS FOR SUBMISSION 10

 3.3. DESIGN AND USE OF THE DEVICE 10

SECTION 4. INDICATIONS FOR USE STATEMENT 11

SECTION 5. 510(K) SUMMARY 12

SECTION 6. TRUTHFUL AND ACCURACY STATEMENT 14

SECTION 7. CLASS III SUMMARY AND CERTIFICATION 15

SECTION 8. FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT 16

SECTION 9. DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS 17

SECTION 10. EXECUTIVE SUMMARY 18

 10.1. DEVICE DESCRIPTION INCLUDING INDICATIONS FOR USE AND TECHNOLOGY 18

 10.2. DEVICE COMPARISON TABLE 19

 10.3. PERFORMANCE TESTING SUMMARY 21

SECTION 11. DEVICE DESCRIPTION 22

 11.1. DEVICE DESCRIPTION 22

 11.1.1. Procedure Description 22

 11.1.2. Photographs 24

 11.1.3. Engineering Drawings 32

 11.2. MODELS, ACCESSORIES AND COMPONENTS 41

 11.3. PATIENT CONTACTING COMPONENTS AND MATERIALS 41

SECTION 12. SUBSTANTIAL EQUIVALENCE DISCUSSION 42

SECTION 13. PROPOSED LABELING 45

SECTION 14. STERILIZATION AND SHELF LIFE 46

SECTION 15. BIOCOMPATIBILITY 47

SECTION 16. SOFTWARE 48

SECTION 17. ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY 49

SECTION 18. PERFORMANCE TESTING – BENCH 50

SECTION 19. PERFORMANCE TESTING – ANIMAL 51

SECTION 20. PERFORMANCE TESTING – CLINICAL 52

SECTION 21. OTHER.....53

SECTION 1. MEDICAL DEVICE USER FEE COVER SHEET (FORM FDA 3601)

See following pages.

Form Approved OMB No. 0910-0117 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4)Trade Write the Payment Identification number on your check.				
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/ndufma/coversheet.html						
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) INSTRATEK INC 210 SPRING HILL DRIVE 130 THE WOODLANDS TX 77386 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 760336028	2. CONTACT NAME William McLain 2.1 E-MAIL ADDRESS bmclain@crogroup.com 2.2 TELEPHONE NUMBER (include Area code) 717-8569656 2.3 FACSIMILE (FAX) NUMBER (Include Area code) null-null					
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: http://www.fda.gov/dc/ndufma) <table border="0"> <tr> <td style="vertical-align: top;"> Select an application type: <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <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) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice </td> <td style="vertical-align: top;"> 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) </td> </tr> </table>			Select an application type: <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <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) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice	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)		
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4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input checked="" type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number: SBD087161						
5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <table border="0"> <tr> <td><input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms</td> <td><input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population</td> </tr> <tr> <td><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</td> <td><input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially</td> </tr> </table>			<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"/> The sole purpose of the application is to support conditions of use for a pediatric population	<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 application is submitted by a state or federal government entity for a device that is not to be distributed commercially
<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"/> The sole purpose of the application is to support conditions of use for a pediatric population					
<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 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 (b)		11-Aug-2008				

Form FDA 3601 (01-2007)

"Close Window" Print Cover sheet

SECTION 2. CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CDRH PREMARKET REVIEW SUBMISSION COVER SHEET		Form Approval OMB No. 9010-0120 Expiration Date: August 31, 2010. See OMB Statement on page 5.	
Date of Submission 8/15/2008	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known)	
SECTION A TYPE OF SUBMISSION			
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement Report <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information
			Meeting <input type="checkbox"/> Pre-510(k) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
			Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):
Have you used or cited Standards in your submission? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No (If Yes, please complete Section I, Page 5)			
SECTION B SUBMITTER, APPLICANT OR SPONSOR			
Company / Institution Name Instratek, Inc		Establishment Registration Number (if known) 1645311	
Division Name (if applicable) N/A		Phone Number (including area code) (281) 890-8020	
Street Address 210 Springhill Drive, Suite 130		FAX Number (including area code) (281) 890-8068	
City Spring	State / Province TX	ZIP/Postal Code 77386	Country USA
Contact Name Mr. Jeff Seavey			
Contact Title Vice President		Contact E-mail Address jeff@instratek.com	
SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)			
Company / Institution Name			
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason (specify):		
SECTION D2 REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor <input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Other Reason (specify):		
SECTION D3 REASON FOR SUBMISSION - 510(k)		
<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input type="checkbox"/> Other Reason (specify):		

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS							
Product codes of devices to which substantial equivalence is claimed						Summary of, or statement concerning, safety and effectiveness information	
1	HIN	2		3		4	
5		6		7		8	
Information on devices to which substantial equivalence is claimed (if known)							
	510(k) Number		Trade or Proprietary or Model Name		Manufacturer		
1	K061925	1	Mini Tightrope Repair Kit, Model AR-8911 DS	1	Arthrex, Inc.		
2	K960537	2	KMI K2 Bone Screw System	2	KMI originally. Currently Instratek		
3		3		3			
4		4		4			
5		5		5			
6		6		6			
SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS							
Common or usual name or classification Button/Suture							
	Trade or Proprietary or Model Name for This Device				Model Number		
1	HAV Lok Bunion Correction System				1	HL6010	
2					2		
3					3		
4					4		
5					5		
FDA document numbers of all prior related submissions (regardless of outcome)							
1	2	3	4	5	6		
N/A							
7	8	9	10	11	12		
Data Included in Submission							
<input checked="" type="checkbox"/> Laboratory Testing <input type="checkbox"/> Animal Trials <input type="checkbox"/> Human Trials							
SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS							
Product Code	C.F.R. Section (if applicable)			Device Class			
HTN	21 CFR 888.3030			<input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified			
Classification Panel							
Orthopedic							
Indications (from labeling)							
The Instratek HAV-Lok Bunion Correction System is intended for the following surgical indications: <ul style="list-style-type: none"> - To assist in the biomechanical reduction of abnormal intermetatarsal angle. 							

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

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION
(b)(4) Trade Secret Process

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City	State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title	Contact E-mail Address	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City	State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I UTILIZATION OF STANDARDS					
Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.					
1	Standards No.	Standards Organization	Standards Title	Version	Date
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date
Please include any additional standards to be cited on a separate page.					
<p>Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:</p> <p style="text-align: center;">Food and Drug Administration CDRH (HFZ-342) 9200 Corporate Blvd. Rockville, MD 20850</p> <p><i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control</i></p>					

SECTION 4. INDICATIONS FOR USE STATEMENT**510(k) Number:****Device Name:**

HAV-Lok Bunion Correction System

Indications for Use:

The Instratek HAV-Lok Bunion Correction System is intended for the following surgical indication:

- To assist in the biomechanical reduction of abnormal intermetatarsal angle.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

SECTION 5. 510(K) SUMMARY

Submission Correspondent and Owner	Instratek, Inc. 210 Springhill Drive Suite 130 Spring, TX 77386 Phone: 281-890-8020 Fax: 281-890-8068 Email: jeff@instratek.com Contact: Mr. Jeff Seavey Vice President
Date summary prepared:	August 15, 2008
Device trade name:	HAV-Lok Bunion Correction System
Device common name:	Button/Suture
Device classification name:	Washer, Bolt Nut, HTN at 21 CFR 888.3030
Legally marketed device to which the device is substantially equivalent:	Arthrex Mini TightRope Repair Kit, K061925
Description of the device:	<p>The HAV- Lok Kit is designed to assist in the reduction and control of increased pathologic intermetatarsal angles. HAV-Lok may eliminate the necessity of a traditional osteotomy in the correction of Hallux Valgus deformities within the indicated criteria. The implanted device consists of three (3) components:</p> <ol style="list-style-type: none"> 1. Medial Oblong Plate 2. Lateral Oblong Plate 3. #3/4 Suture <p>There are 4 accessories required to implant the device</p> <ol style="list-style-type: none"> 1. Suture Lasso 2. K-wire 3. Cannulated Drill Bit 4. Drill Guide <p>To achieve reduction of intermetatarsal angles, two suture paths are drilled through the first and second metatarsals. The oblong plates are positioned on the outside of the first and second metatarsals and the sutures are used to draw the plates together thereby reducing the intermetatarsal angle.</p>

Intended use of the device:	The Instratek HAV-Lok Bunion Correction System is intended for the following surgical indications: <ul style="list-style-type: none"><li data-bbox="695 293 1325 357">• To assist in the biomechanical reduction of abnormal intermetatarsal angle.
Technological characteristics:	The technological characteristics between the predicate and proposed devices are the same.
Conclusions:	There are no significant differences between the proposed and predicate device; therefore, the proposed device does not raise any questions regarding safety and effectiveness. The HAV-Lok Bunion Correction System, as designed, is as safe and effective as the predicate devices. Comparisons have been made to a legally marketed predicate device, and the device is determined to be substantially equivalent to the referenced predicate device currently on the market.

SECTION 6. TRUTHFUL AND ACCURACY STATEMENT

I certify that in my capacity as the Vice President of Instratek, Inc., I believe to the best of my knowledge that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.



Jeff Seavey
Vice President
Instratek, Inc.

8-15-08

Date

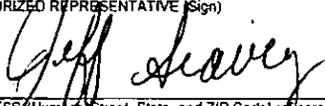
SECTION 7. CLASS III SUMMARY AND CERTIFICATION

The device is not Class III.

SECTION 8. FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

No clinical data are presented with this submission. FDA form 3674, Certification of compliance under 42 U.S.S. Sect 282(j) is located below.

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616. Expiration Date: 09-30-2008

 <p>DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration</p> <p>Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))</p>		
<p>(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)</p>		
SPONSOR / APPLICANT / SUBMITTER INFORMATION		
1. NAME OF SPONSOR/APPLICANT/SUBMITTER Jeff Seavey	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES August 15, 2008	
3. ADDRESS (Number, Street, State, and ZIP Code) 210 Springhill Drive, Suite 210 Spring, TX 77386	4. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) 281-890-8020 (Fax) 281-890-8068	
PRODUCT INFORMATION		
5. FOR DRUGS/BIOLOGICS: Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s) FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s) (Attach extra pages as necessary)		
HAV-Lock HAV-Lok Bunion Correction System Washer, Bolt Nut, HTN at 21 CFR 888.3030		
APPLICATION / SUBMISSION INFORMATION		
6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES <input type="checkbox"/> IND <input type="checkbox"/> NDA <input type="checkbox"/> ANDA <input type="checkbox"/> BLA <input type="checkbox"/> PMA <input type="checkbox"/> HDE <input checked="" type="checkbox"/> 510(k) <input type="checkbox"/> PDP <input type="checkbox"/> Other		
7. INCLUDE IND/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (if number previously assigned) Not assigned.		
8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES N/A		
CERTIFICATION STATEMENT / INFORMATION		
9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation)		
<input checked="" type="checkbox"/> A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial. <input type="checkbox"/> B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies. <input type="checkbox"/> C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.		
10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)" UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary) NCT Number(s):		
The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331; section 301 of the Federal Food, Drug, and Cosmetic Act. Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.		
11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign) 	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) <u>Jeff Seavey</u> (Title) <u>V.P.</u>	
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12) 210 Springhill Dr. Suite 130 Spring, TX 77386	14. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) <u>281-890-8020</u> (Fax) <u>281-890-8068</u>	15. DATE OF CERTIFICATION <u>8-15-08</u>

FDA-3674 (1/08) (FRONT)

PSC Graphics (201) 413-1390

SECTION 9. DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

This 510(k) premarket notification does not utilize consensus standards, therefore, no declarations of conformity or summary reports are enclosed.

SECTION 10. EXECUTIVE SUMMARY

10.1. Device Description Including Indications for Use and Technology

The Instratek HAV-Lok Bunion Correction System is intended to assist in the biomechanical reduction of abnormal intermetatarsal angle.

The HAV- Lok Kit is designed to assist in the reduction and control of increased pathologic intermetatarsal angles. HAV-Lok may eliminate the necessity of a traditional osteotomy in the correction of Hallux Valgus deformities within the indicated criteria. The implanted device consists of three (3) components:

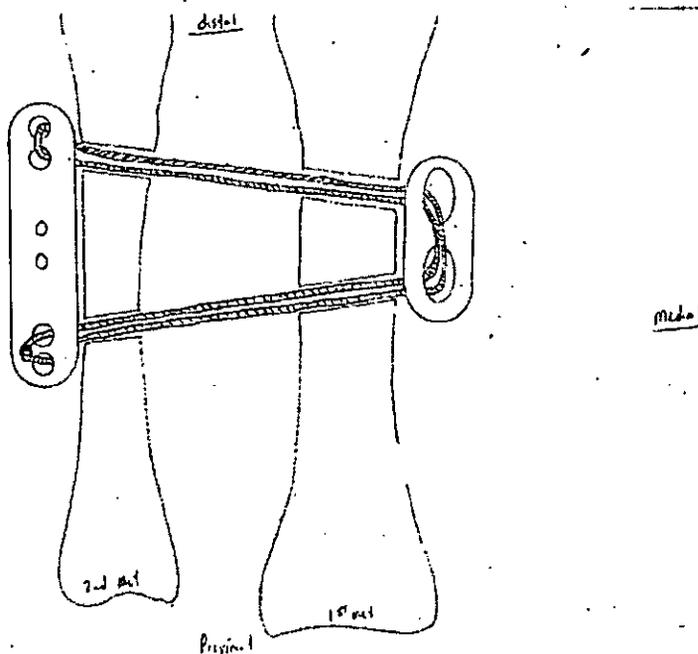
1. Medial Oblong Plate – Ti-6Al-4v
2. Lateral Oblong Plate – Ti-6Al-4v
3. #3/4 Suture – Ultra High Molecular Weight Polyethylene

There are 4 accessories required to implant the device

1. Suture Lasso – Stainless Steel
2. K-wire – Stainless Steel
3. Cannulated Drill Bit – Stainless Steel
4. Drill Guide - Stainless Steel

To achieve reduction of intermetatarsal angles, two suture paths are drilled through the first and second metatarsals. The oblong plates are positioned on the outside of the first and second metatarsals and the sutures are used to draw the plates together thereby reducing the intermetatarsal angle.

The following sketch depicts the device as implanted.



10.2. Device Comparison Table

Characteristics	Proposed Device	Predicate Device Mini TightRope FT Repair Kit K061925	Material Predicate Device K3 Bone Screw System K960533	Differences
Design	Two "buttons" or plates joined by suture material	Same	N/A	None
Indication for Use (Paraphrased)	Biomechanical reduction of abnormal intermetatarsal angles	<p>Fixation during the healing process following: Syndesmotic trauma such as fixation of dorsal distal radioulnar ligament disruptions. Tarasometatarsal (TMT) injury, such as fixation of foot soft tissue separations due to a Lisfranc injury (Midfoot Reconstruction); and Hallux Valgus reconstruction (correction) by providing the reduction of 1st and 2nd metatarsal intermetatarsal angle.</p>	Fixation / stabilization of small bone hand or small bone forefoot fractures.	Instratek is choosing to only list the indication for use related to reduction of the 1 st and 2 nd metatarsal angles.
Plate (bone contacting) material	Titanium 6Al-4V	Stainless steel (specific grade unknown)	Titanium 6Al-4V	The KMI material is bone-contacting and is identical to the plate materials in the proposed device.
Suture material	Ultra High Molecular Weight Polyethylene	Ultra High Molecular Weight Polyethylene	N/A	This material is addressed in Teleflex submissions K033654, K04072, K063778.

Characteristics	Proposed Device	Predicate Device Mini TightRope FT Repair Kit K061925	Material Predicate Device K3 Bone Screw System K960533	Differences
Accessories	Suture Lasso K-wire Cannulated Drill Bit Drill Guide	Micro Suture Lasso Guide Pin/Wire Cannulated Drill Bit Drill Guide	N/A	The proposed device and the Arthrex predicate device have similar components for insertion.

10.3. Performance Testing Summary

Performance (bench) testing for the proposed device consisted of (b)(4)Trade Secret Process

[Redacted]

(b)(4)Trade Secret Process

SECTION 11. DEVICE DESCRIPTION**11.1. Device Description****11.1.1. Procedure Description**

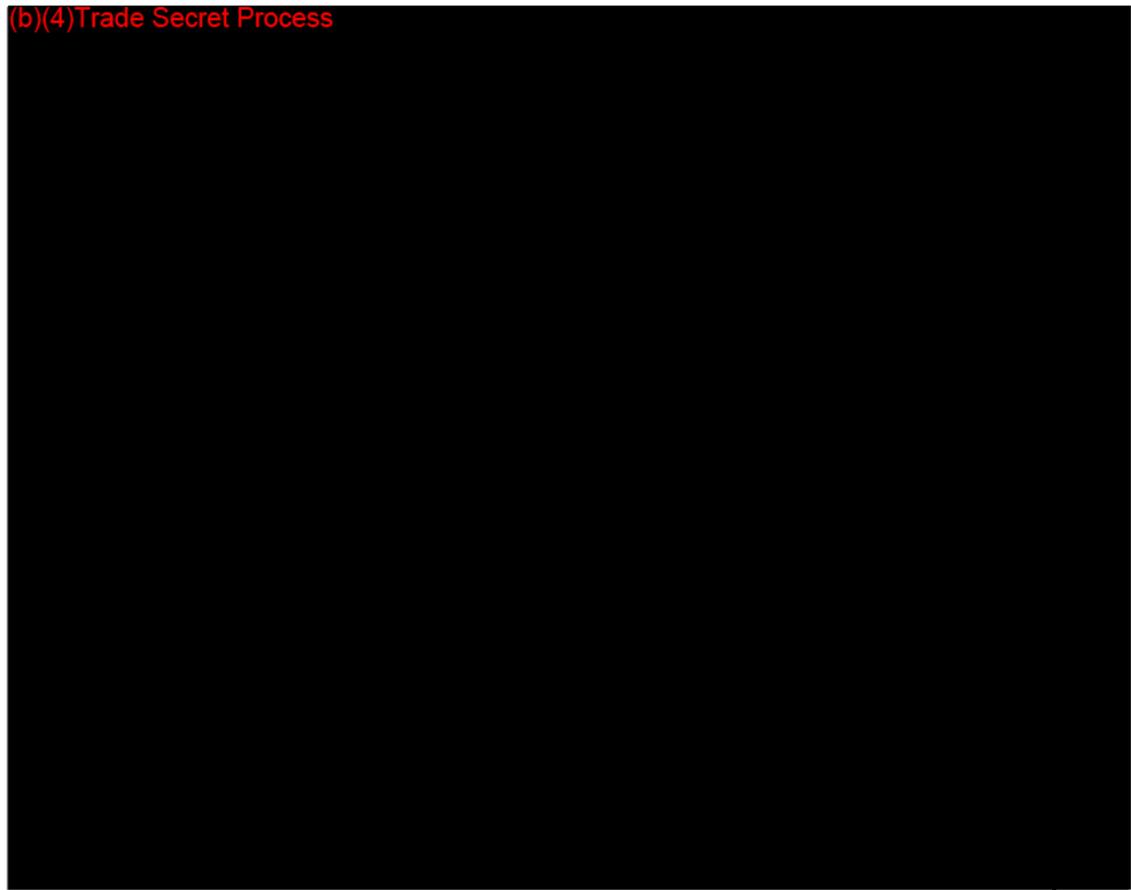
The HAV- Lok Kit is designed to assist in the reduction and control of increased pathologic intermetatarsal angles. HAV-Lok may eliminate the necessity of a traditional osteotomy in the correction of Hallux Valgus deformities within the indicated criteria. The implanted device consists of three (3) components:

1. Medial Oblong Plate – Ti-6Al-4v
2. Lateral Oblong Plate – Ti-6Al-4v
3. #3/4 Suture – Ultra High Molecular Weight Polyethylene

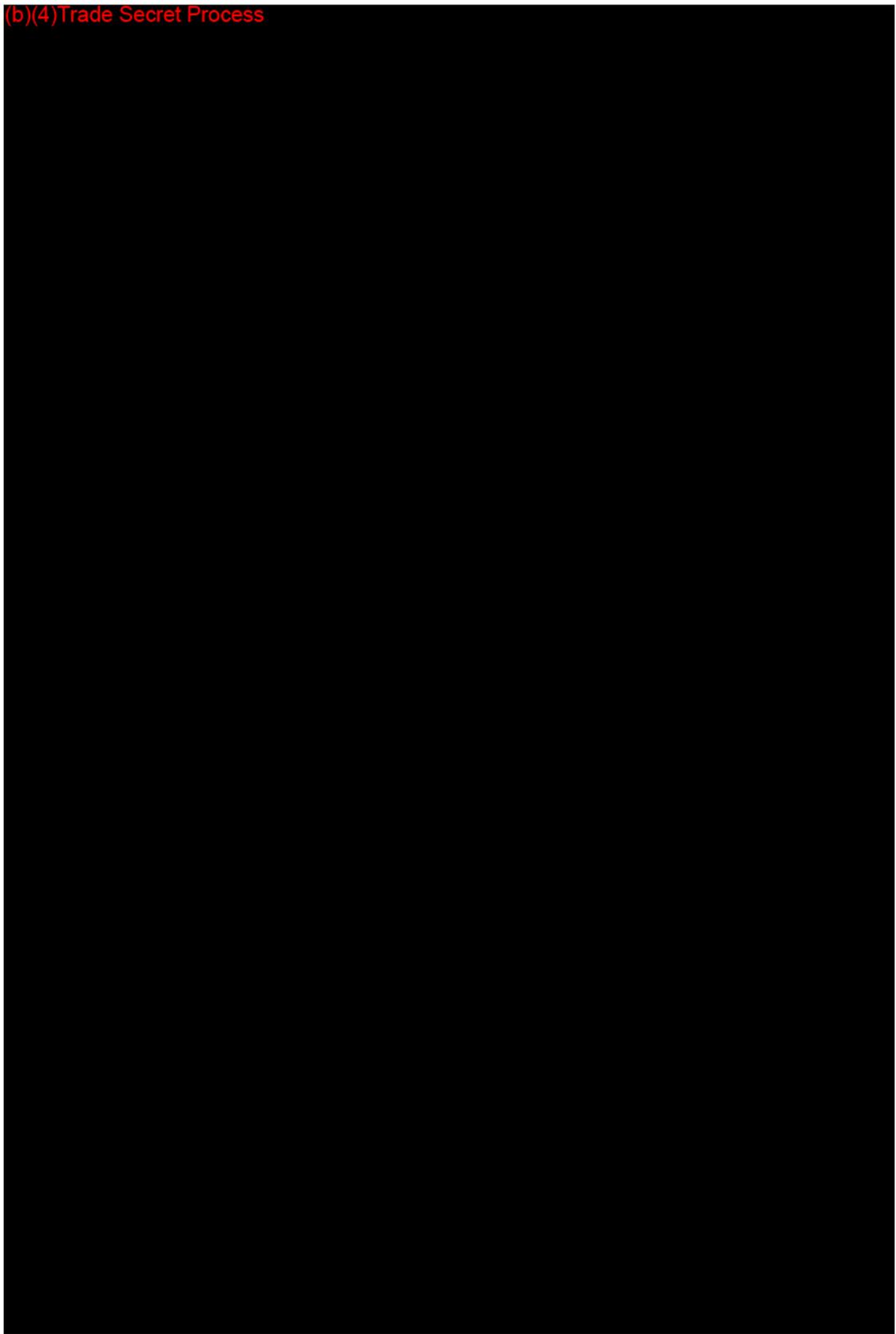
There are 4 accessories required to implant the device

1. Suture Lasso – Stainless Steel
2. K-wire – Stainless Steel
3. Cannulated Drill Bit – Stainless Steel
4. Drill Guide - Stainless Steel

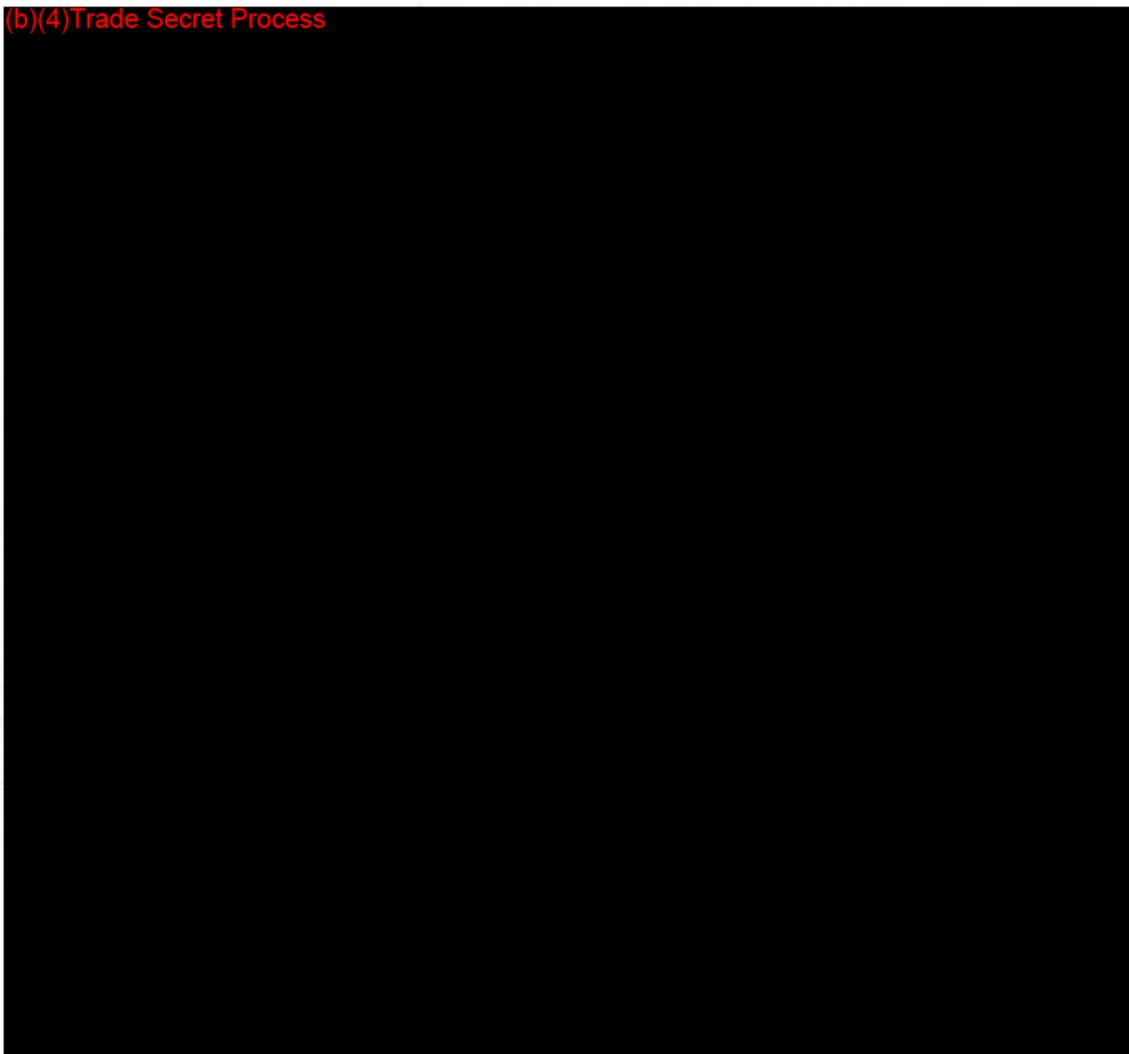
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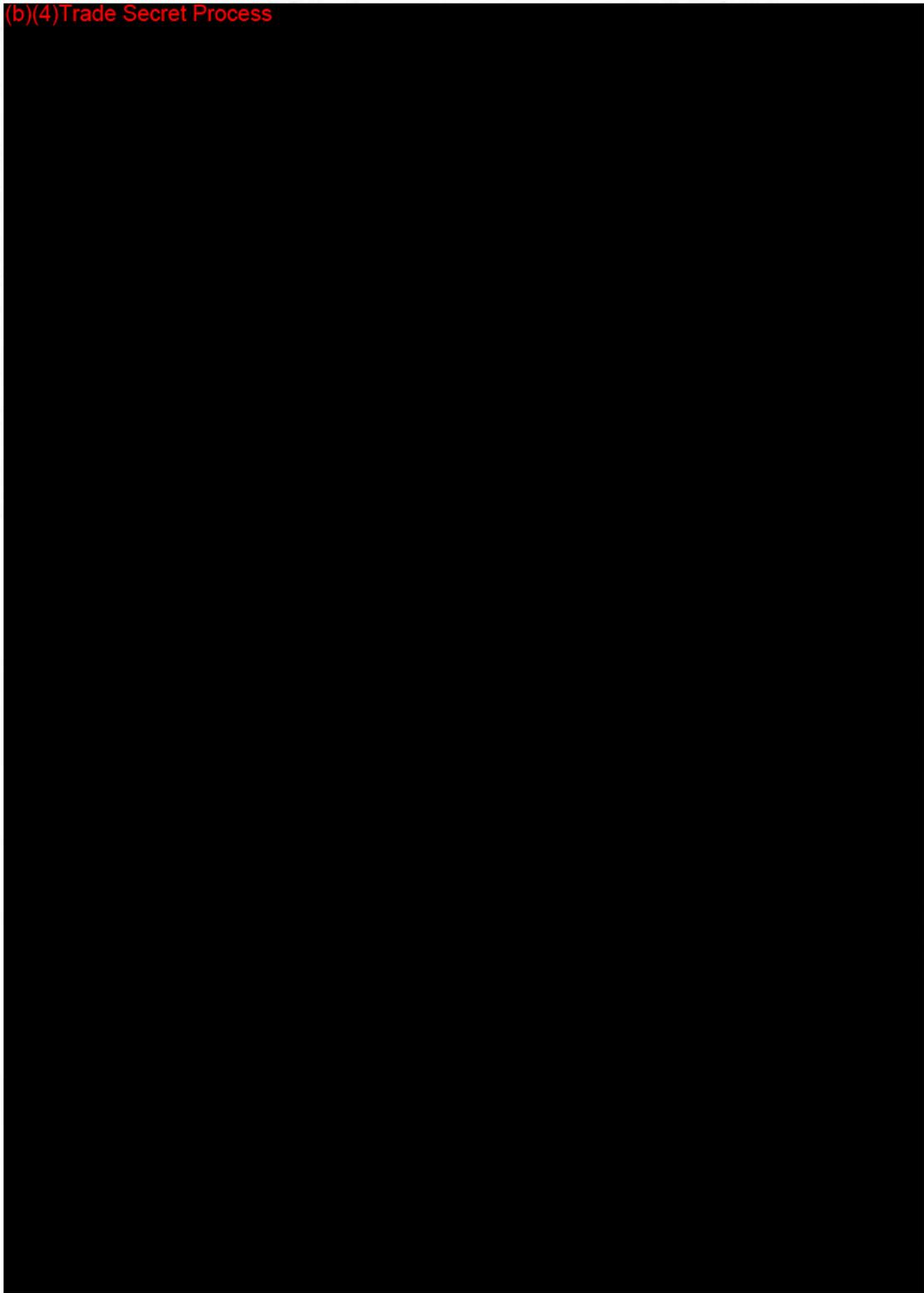
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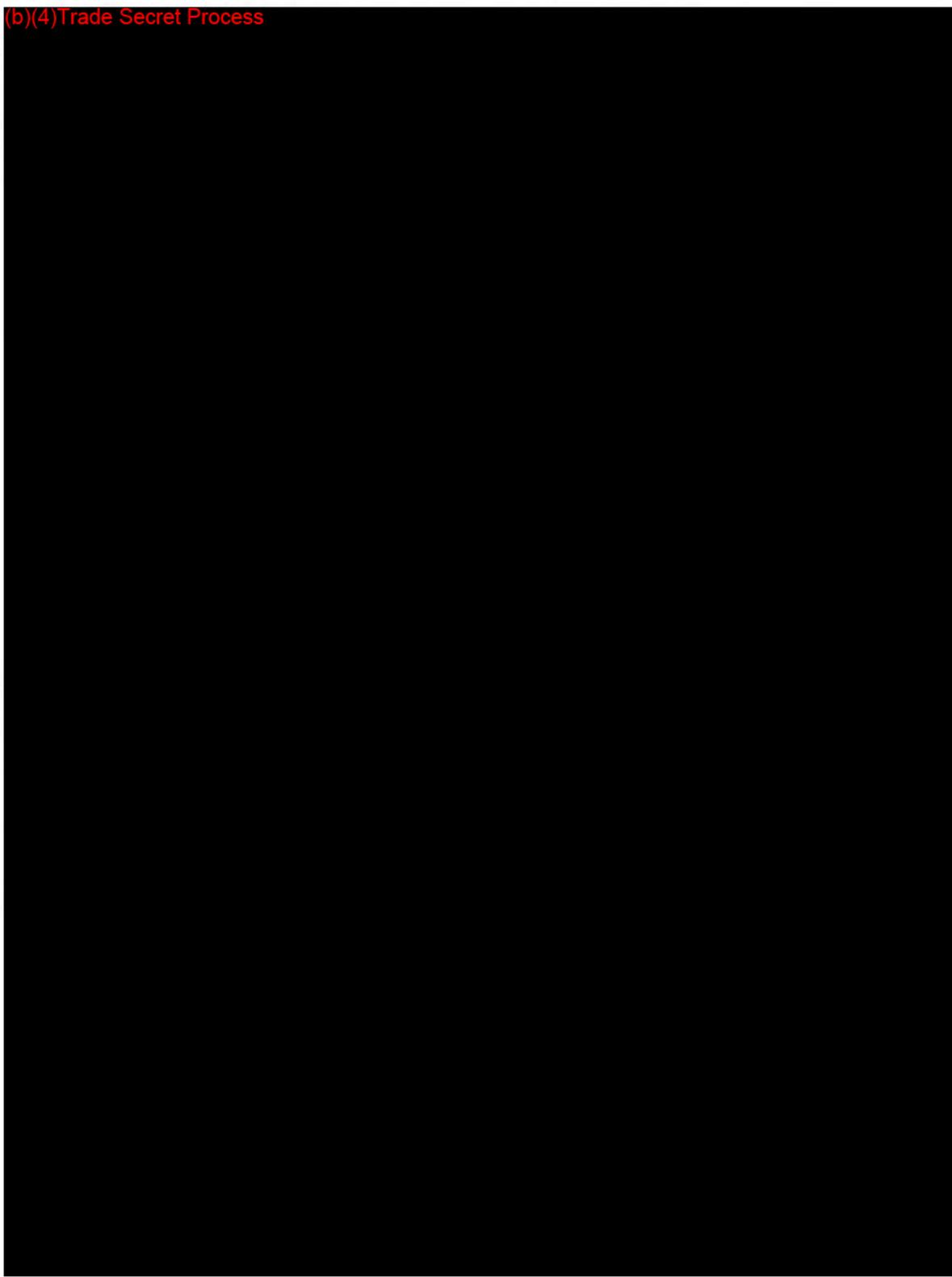
(b)(4)Trade Secret Process



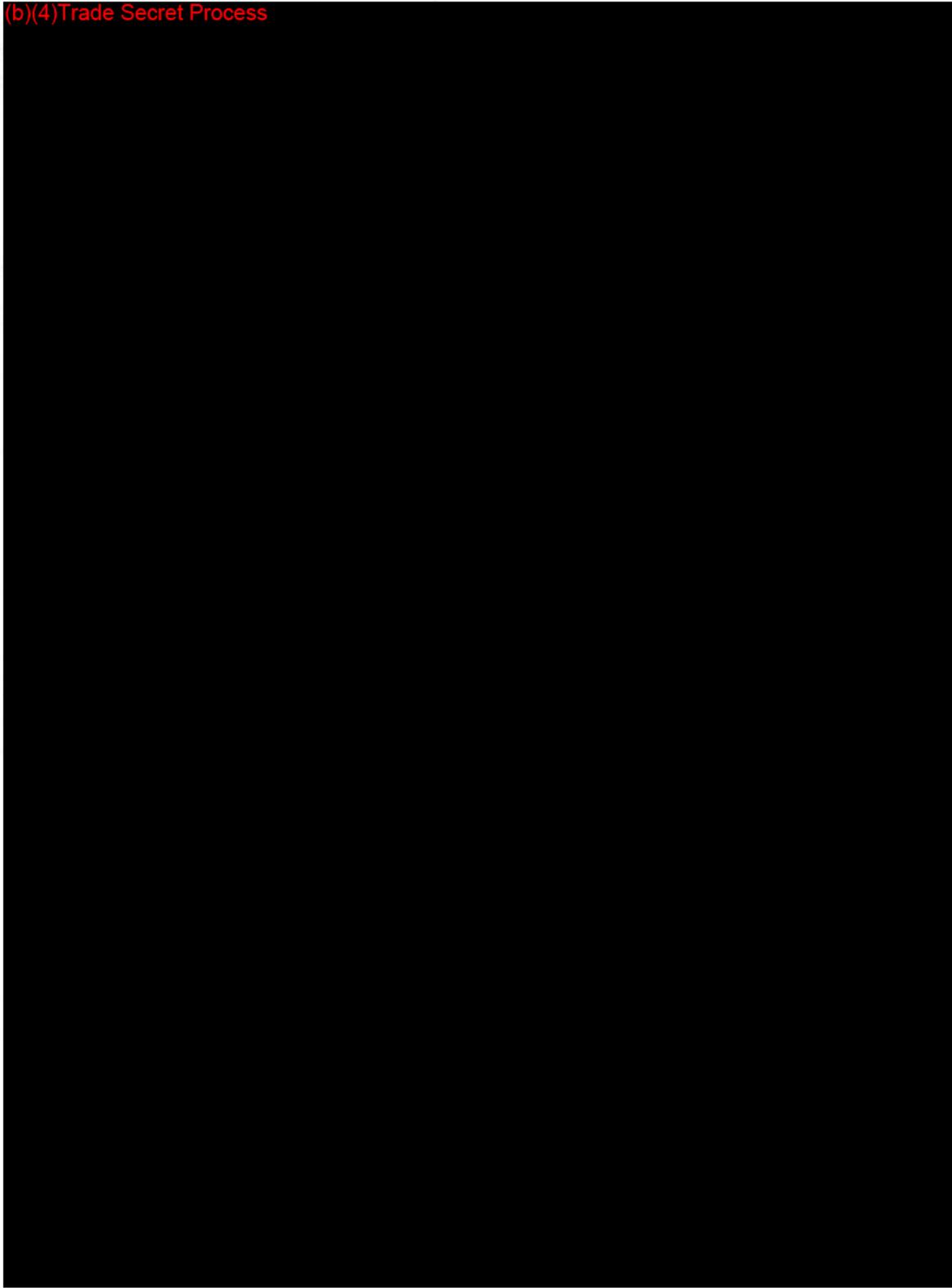
(b)(4)Trade Secret Process



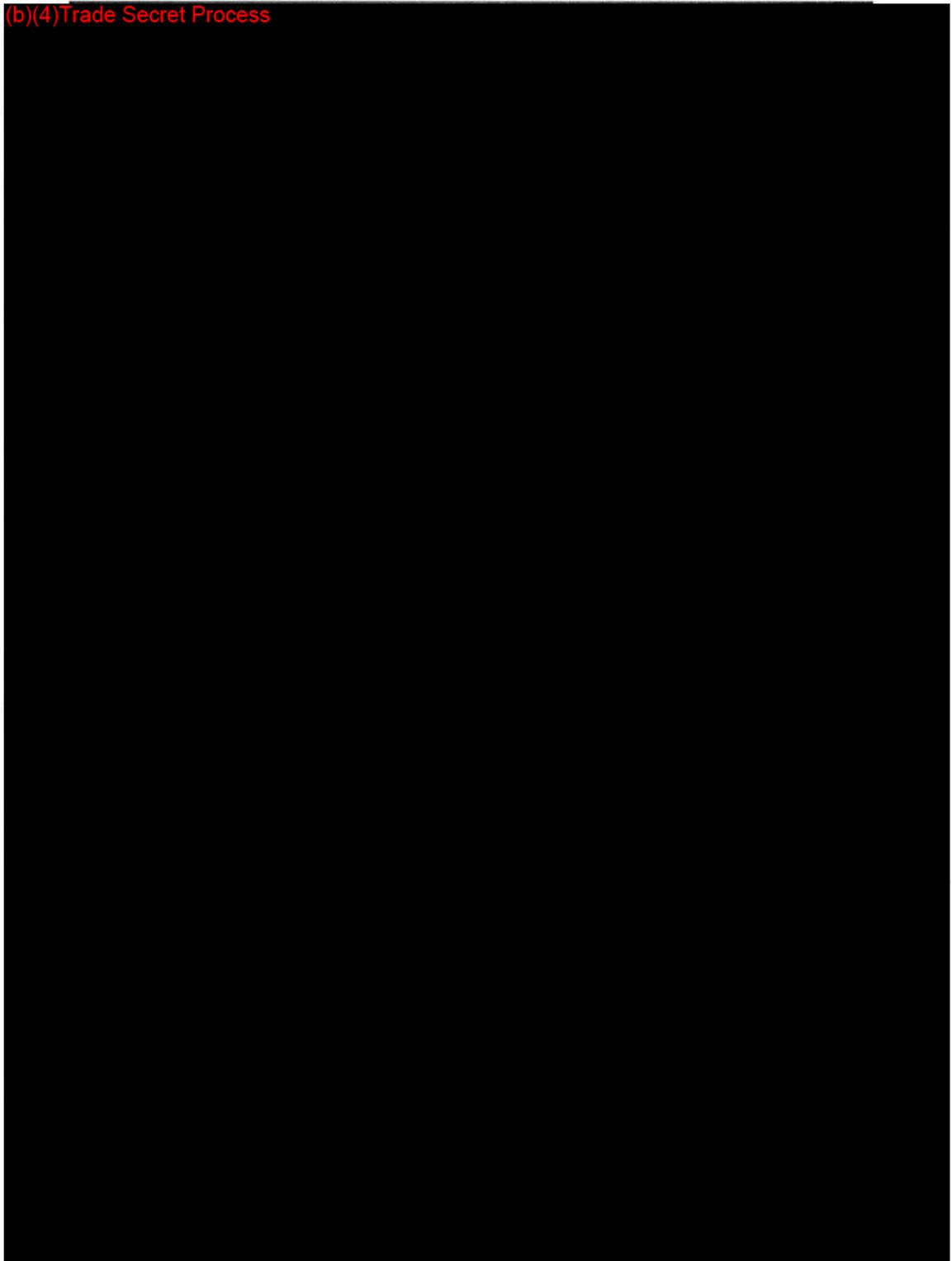
(b)(4)Trade Secret Process



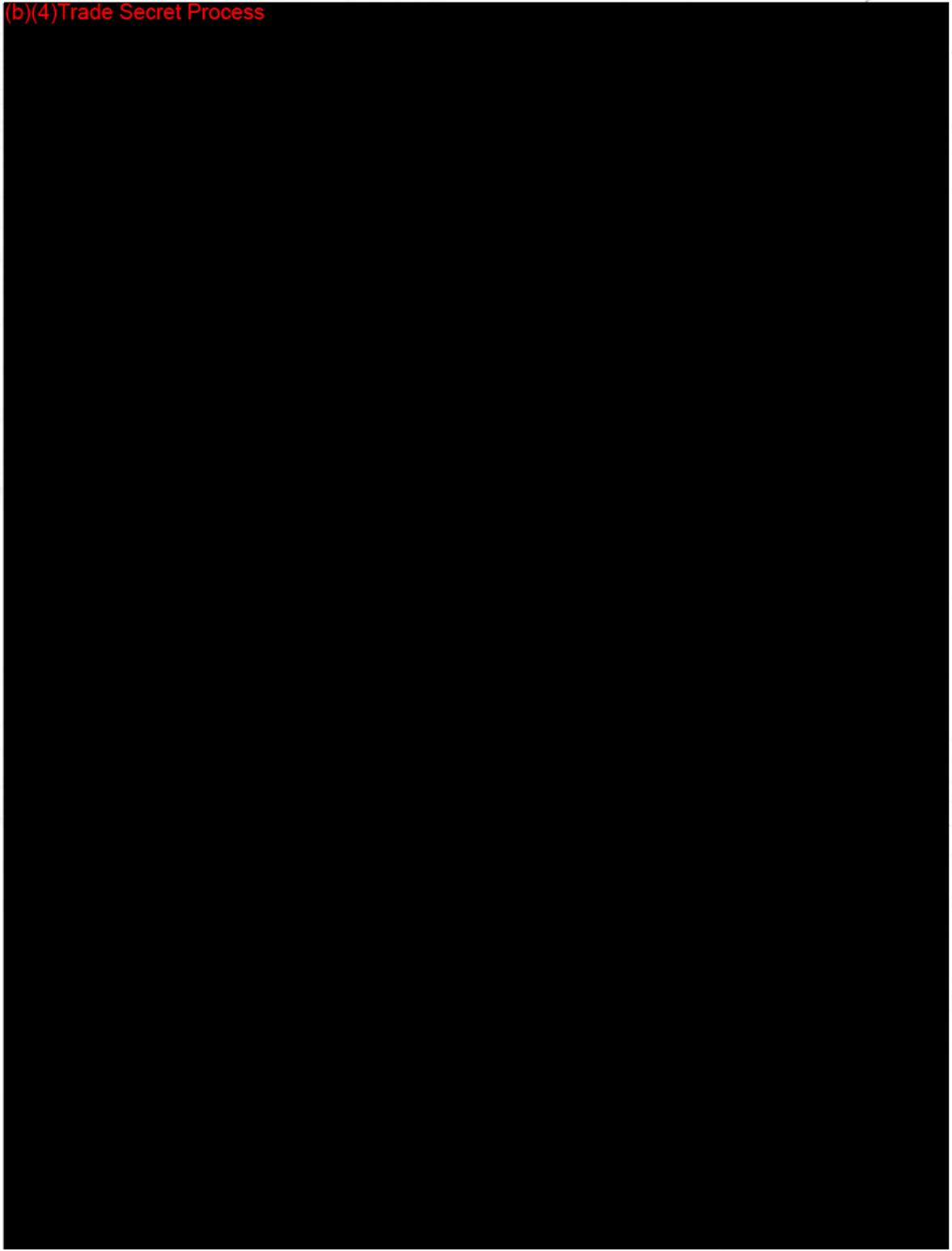
(b)(4)Trade Secret Process



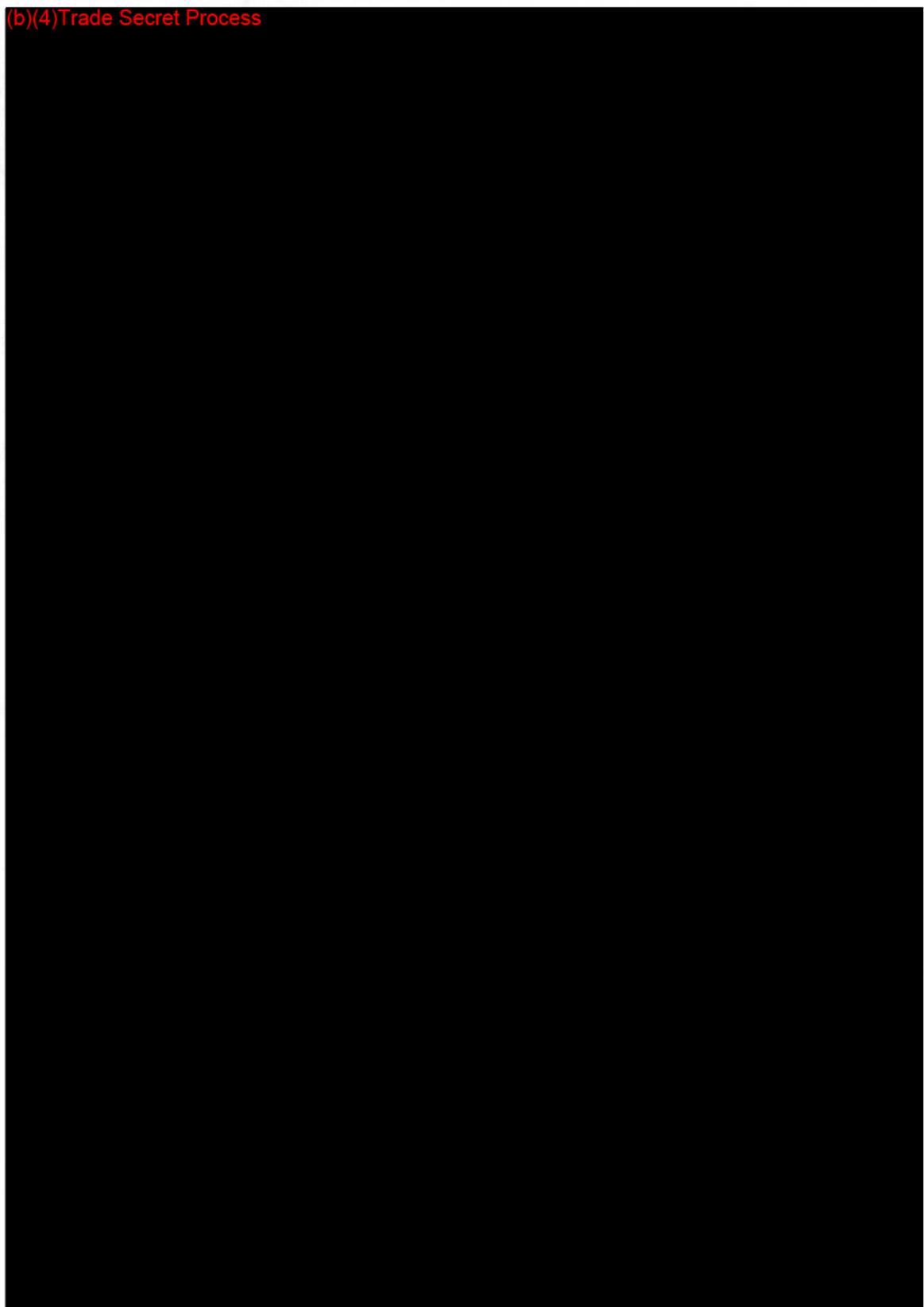
(b)(4)Trade Secret Process



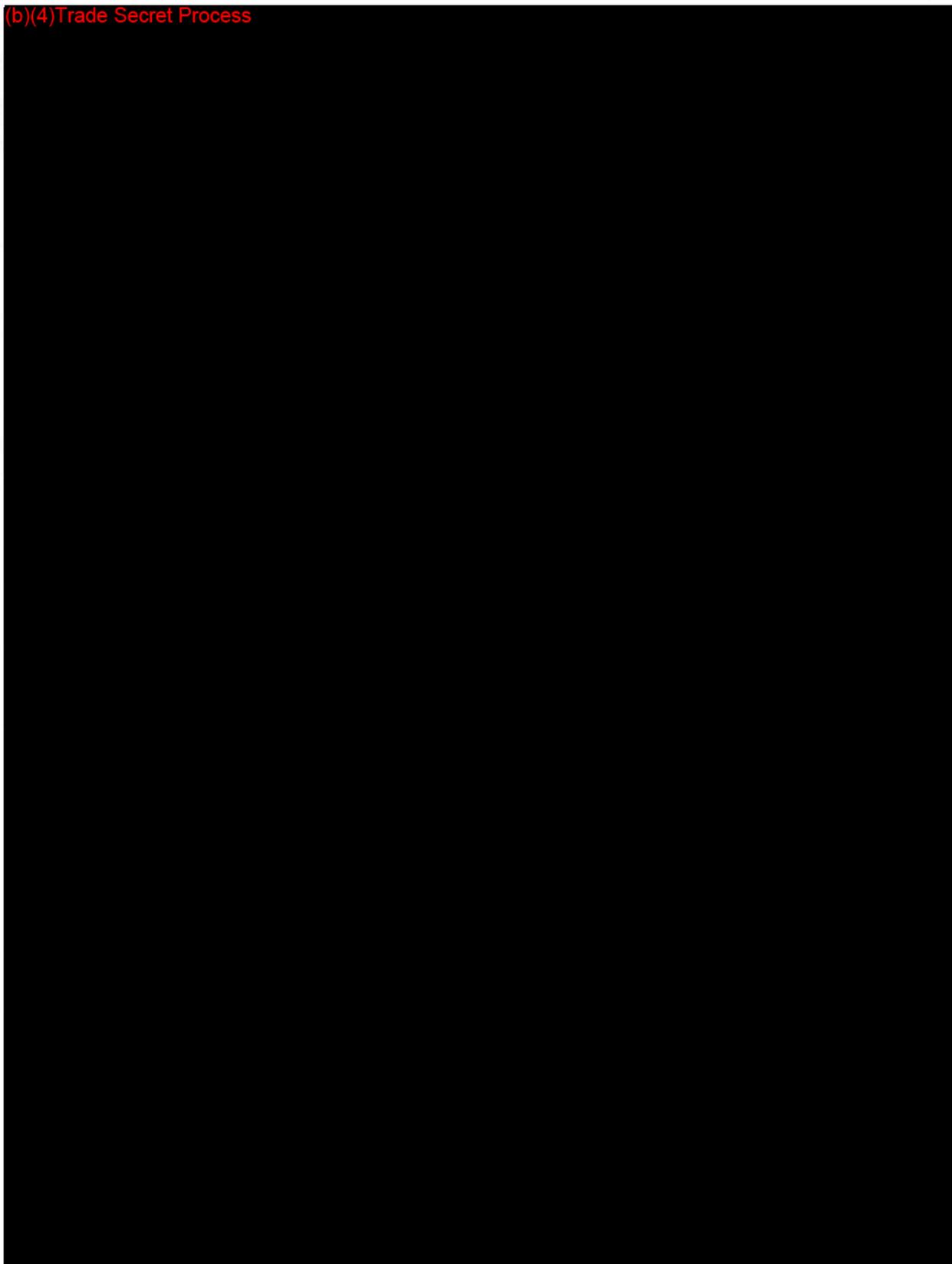
(b)(4) Trade Secret Process



(b)(4)Trade Secret Process



(b)(4)Trade Secret Process



11.1.3. Engineering Drawings

Engineering drawings of the system components are located on the following pages.

11.2. Models, Accessories and Components

The HAV-Lok Bunion Correction System is available in one model, HL6010. With the exception of instruments for making surgical incisions and for advancing the k-wire and the drill guide, the kit contains all of the components and accessories to insert the device. This includes the K-wire, cannulated drill bit, medial and oblong plates, and suture material.

The drill bit, k-wire and the suture material are not manufactured by Instratek, but are cleared via the 510(k) numbers identified below.

11.3. Patient Contacting Components and Materials.

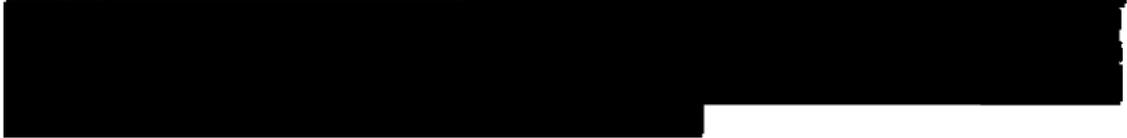
The following table describes patient contacting materials.

Table 1. Patient Contacting Materials

Component	Material
(b)(4)Trade Secret Process - Product Specs	

SECTION 12. SUBSTANTIAL EQUIVALENCE DISCUSSION

The HAV-Lok Bunion Correction System is substantially equivalent to the Mini TightRope™ Repair Kit cleared under K061925 manufactured by Arthrex, Inc. The predicate information is taken from promotional literature, the instructions for use and the SE letter and 510(k) summary associated with K061925. (b)(4)Trade Secret Process - Product Specs



Characteristics	Proposed Device	Predicate Device Mini TightRope FT Repair Kit K061925	Material Predicate Device K3 Bone Screw System K960533	Differences
Design	Two "buttons" or plates joined by suture material	Same	N/A	None
Indication for Use (Paraphrased)	Biomechanical reduction of abnormal intermetatarsal angles	Fixation during the healing process following: Syndesmotic trauma such as fixation of dorsal distal radioulnar ligament disruptions. Tarasometatarsal (TMT) injury, such as fixation of foot soft tissue separations due to a Lisfranc injury (Midfoot Reconstruction); and Hallux Valgus reconstruction (correction) by providing the reduction of 1 st and 2 nd metatarsal intermetatarsal angle.	Fixation / stabilization of small bone hand or small bone forefoot fractures.	Instratek is choosing to only list the indication for use related to reduction of the 1 st and 2 nd metatarsal angles.
Plate (bone contacting) material	Titanium 6Al-4V	Stainless steel (specific grade unknown)	Titanium 6Al-4V	(b)(4) Trade Secret Process - Product Specs
Suture material	Ultra High Molecular Weight Polyethylene	Ultra High Molecular Weight Polyethylene	N/A	

Characteristics	Proposed Device	Predicate Device Mini TightRope FT Repair Kit K061925	Material Predicate Device K3 Bone Screw System K960533	Differences
Accessories	Suture Lasso K-wire Cannulated Drill Bit Drill Guide	Micro Suture Lasso Guide Pin/Wire Cannulated Drill Bit Drill Guide	N/A	The proposed device and the Arthrex predicate device have similar components for insertion.

The table above shows that the proposed and predicate devices are very similar. They have similar materials, similar methods of use and the same technological characteristics. This information supports the substantial equivalence claim for the proposed and predicate devices.

SECTION 13. PROPOSED LABELING

The labeling for the HAV-Lok Intermetatarsal Angle Reduction System consists of two pouch labels, a shelf box label and an instruction sheet. Drafts of the preliminary labeling are enclosed as Attachment 2. Predicate information is enclosed as Attachment 1.

SECTION 14. STERILIZATION AND SHELF LIFE

The device is sterilized by 100% ethylene oxide (EtO), utilizing the overkill approach. Sterilization (b)(4)Trade Secret Process - Product.

(b)(4)Trade Secret Process - Product Specs validated annually using a half-cycle microbial challenge procedure, which meets the criteria described in AAMI/ANSI/ISO 11135-1:2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.

The sterility assurance level of the device is 10^{-6} .

The device will be affixed to a high density polyethylene holding card which is double pouched in two LEDP/Tyvek® pouches.

EtO residuals: Instratek complies with ethylene oxide and ethylene chlorohydrin limits as specified in ANSI/AAMI/ISO 10993 Part 7 plus AAMI TIR are as follows.

Table 2. Ethylene oxide and ethylene chlorohydrin limits

Residue	Average Delivered Dose (mg/day)		
	Limited Exposure (< 24 hr.)	Prolonged Exposure (24 hr. to 30 day)	Permanent Contact (> 30 days to life)
EtO	20	2	0.1
ECH	12	2	2

The device will not be labeled as fluid path components being non-pyrogenic.

SECTION 15. BIOCOMPATIBILITY

Biocompatibility is assured through conformance to recognized consensus standards for titanium and stainless steel. Evidence of conformance to this standard is required with each shipment. The implanted titanium materials are identical to the listed predicate devices.

(b)(4)Trade Secret Process - Product Specs

Instratek further warrants that no coatings, dyes or other processes which might impact biocompatibility characteristics are added to or performed on the materials as part of the manufacturing process.

SECTION 16. SOFTWARE

There is no software associated with this device.

SECTION 17. ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

The HAV-Lok Bunion Correction System is not electrical.

SECTION 18. PERFORMANCE TESTING – BENCH

Performance (bench) testing for the proposed device consisted of (b)(4)Trade Secret Process

[Redacted]

[Redacted]

[Redacted]

(b)(4)Trade Secret Process

[Redacted]

SECTION 19. PERFORMANCE TESTING – ANIMAL

No animal testing was performed on the HAV-Lok Bunion Correction System.

SECTION 20. PERFORMANCE TESTING – CLINICAL

Clinical data were not collected for this submission.

SECTION 21. OTHER

No other information is provided in this submission.

Attachment 1: Predicate Device Information

- Clearance information and instruction sheet for the Arthrex Mini TightRope product, cleared via K061925.
- Clearance information for K960537, K2 Bone Screw System



Mini TightRope® For Hallux Valgus Correction
and Lisfranc Ligament Repair

Surgical Technique



Mini TightRope

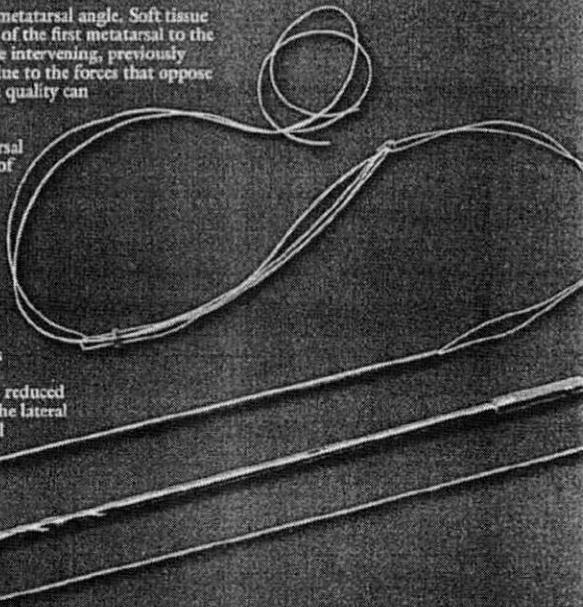
Introduction

The treatment of hallux valgus deformity includes the assessment of the hallux valgus angle, the intermetatarsal angle and the contribution of an interphalangeus deformity. Additionally, there must be an assessment of the presence or absence of arthritic involvement of both the first metatarsocuneiform joint and the first metatarsophalangeal joint. Other considerations are the orientation of the distal metatarsal articular angle and the orientation and stability of the first metatarsocuneiform joint.

Various methods have been described to correct the intermetatarsal angle. Soft tissue correction can be achieved by suturing the lateral capsule of the first metatarsal to the medial capsule of the second metatarsal, incorporating the intervening, previously released adductor tendon. A loss of reduction can occur due to the forces that oppose the suture repair as well as the possibility that poor tissue quality can contribute to a loss of reduction.

In the presence of more rigid deformities the intermetatarsal angle is reduced by using a distal or proximal osteotomy of the first metatarsal. Such osteotomies can be technically challenging. A rather daunting list of consequences and potential complications include delayed union, malunion, nonunion, excessive shortening of the first metatarsal, avascular necrosis, hardware failure and prolonged protected ambulation.

The Mini TightRope is useful as an alternative and adjunct method for reduction of the intermetatarsal angle. A FiberWire® and button construct is placed across (distally or proximally) the first and second metatarsals. As the FiberWire is tightened, the intermetatarsal angle is reduced to a normal angle (less than 9-11°). The suture tied over the lateral button maintains a secure reduction of the intermetatarsal angle. Used alone or in conjunction with the distal soft tissue intermetatarsal repair, this technique affords a greater degree of strength and security than can be achieved with the soft tissue repair alone. Additionally, the Mini TightRope System provides a more technically straightforward method of reducing and maintaining the intermetatarsal angle than with conventional osteotomies while avoiding the complications associated with osteotomies.



Pre-Op
(weight-bearing)



One Month Post-Op
(nonweight-bearing)

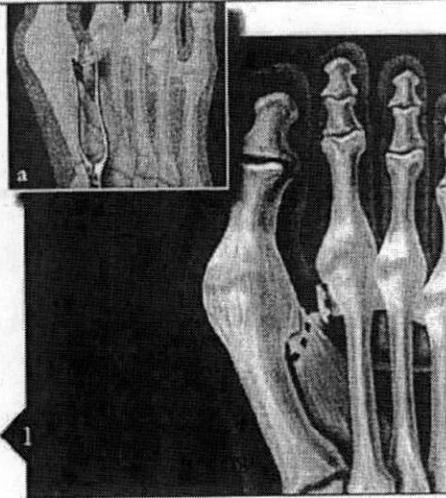
Post-Op Instructions

Following bunion correction using the Mini TightRope, the patient is placed in a soft dressing and is allowed to bear weight with a walking boot or a postoperative stiff soled shoe. Change the dressing weekly with suture removal at week two or three, pending the status of the incisions. Most patients are allowed to wear a comfortable shoe with a wide toebox about 4-5 weeks post-op. Postoperative instructions may vary for patients undergoing other procedures (i.e. hammertoe repair).

In contrast, patients undergoing distal or proximal osteotomies generally require protected weight-bearing with a post-op shoe or boot for a period of 8-12 weeks, depending on the rate of bony healing following the osteotomy. Therefore, the TightRope can dramatically reduce the post-op morbidity with respect to footwear for patients.

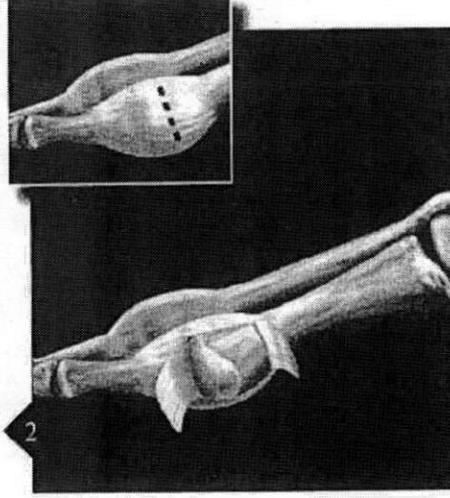


Surgical Technique: Mini TightRope® For Hallux Valgus Correction and I

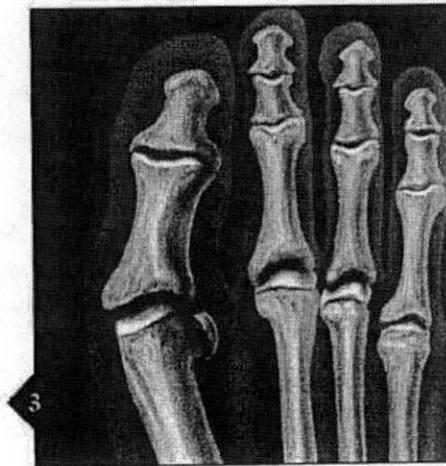


To realign the fibular sesamoid, detach the adductor tendon from the base of the proximal phalanx and fibular sesamoid. Release the deep intermetatarsal ligament. If needed, free any sesamoid adhesions to the intermetatarsal ligament. Manually test the angular deformity following the release of the adductor tendon, release of the lateral capsule of the first metatarsophalangeal joint and release of the intermetatarsal ligament between the 1st and 2nd metatarsals.

For the distal approach, the incision is made between 1st and 2nd metatarsals and inner space release is performed (a).

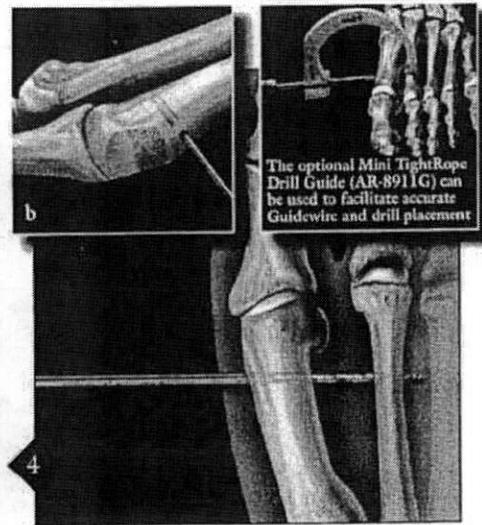


Make a longitudinal incision over the medial aspect of the 1st metatarsophalangeal joint, exposing the entire medial eminence.



Remove the medial eminence preserving the sesamoid groove on the plantar aspect of the 1st metatarsal, avoiding excessive resection of the medial eminence.

Fig. 4 - Using the C-Arm for guidance, insert the 1.2 mm Guidewire across the 1st metatarsal and through the 2nd metatarsal. Start the Guidewire pilot hole just proximal to the excised medial eminence. An adjustment in plantar-to-dorsal direction may assist in the accurate placement of pin allowing the pin to engage the 2nd metatarsal in the midpoint between its dorsal and plantar borders. The entry point on the 2nd metatarsal should be about 2-5 mm



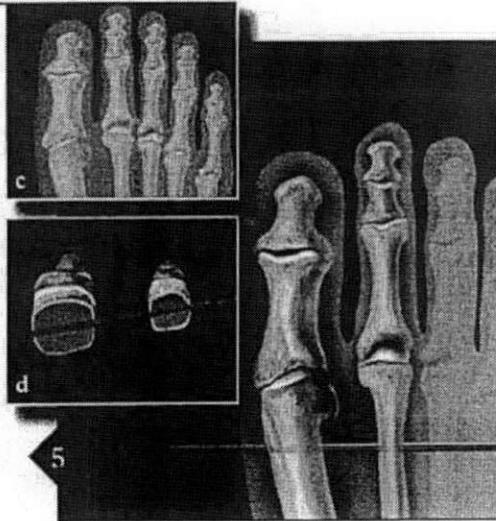
The optional Mini TightRope Drill Guide (AR-8911G) can be used to facilitate accurate Guidewire and drill placement

Note: Place Guidewire while visualizing 1st - 2nd metatarsal web space. A Freer elevator can direct Guidewire penetration at 2nd metatarsal midpoint.

Alternatively, the 1.2 mm Guidewire can be placed from the 2nd metatarsal across and through the 1st metatarsal. This enhances the ease of accurately bisecting the 2nd metatarsal with reference to the dorsal and plantar aspects of the metatarsal.

Using the 2.7 mm Cannulated Drill Bit, drill the tunnel for the Mini TightRope over the Guidewire in a medial to lateral direction. Confirm proper placement with the C-Arm.

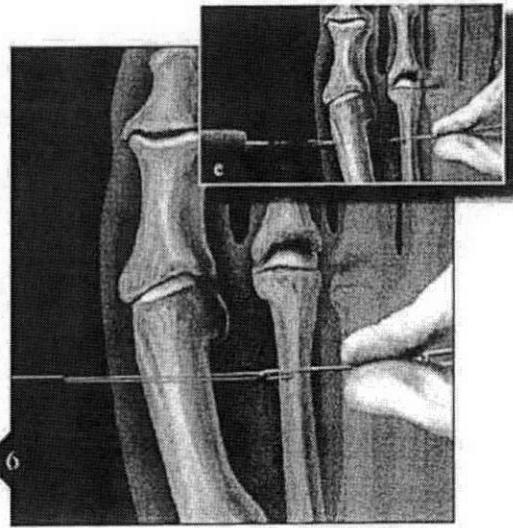
1st/2nd Metatarsal Ligament Repair



5 Pass the 1.6 mm guide pin with pull-through suture (attached to the Mini TightRope) from lateral (2nd metatarsal) to medial (1st metatarsal) and stop before the button enters the drill hole.

Inset (c) shows a small incision for passage of needle and TightRope construct.

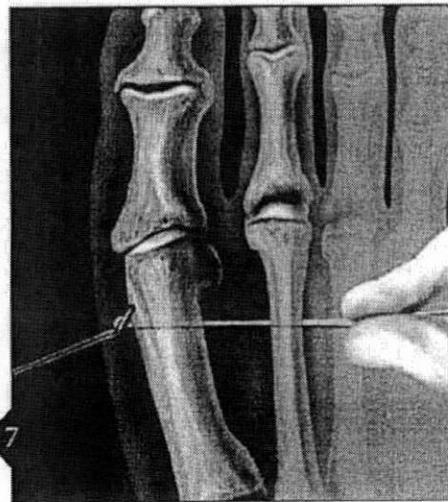
Inset (d) shows the proper orientation of the needle and drill hole.



6 The pull-through suture can now be advanced while the guide pin is pulled medially. At the same time, apply lateral tension on the blue suture just behind the oblong button. This will help the oblong button to lie sideways, and pass easily through both bone tunnels.

Suture Passing Option (e):

The guide pin can be removed, leaving just the white pull-through suture. A straight Micro SutureLasso™ can then be used to pass the suture through both bone tunnels.



7 The Oblong Button is flipped upon exiting the medial side of the first metatarsal cortex. Apply lateral tension on the blue suture. This will help seat the Oblong Button against the bone.

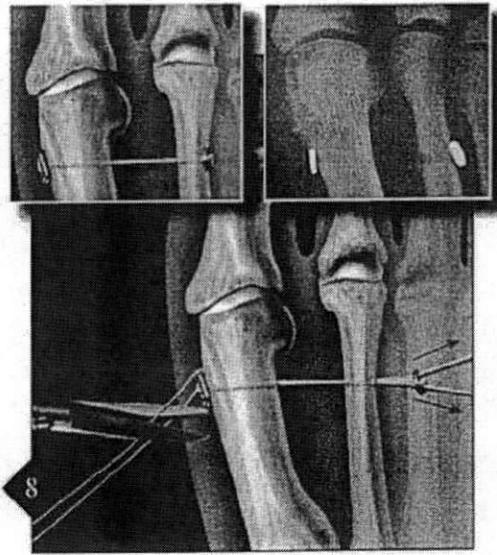
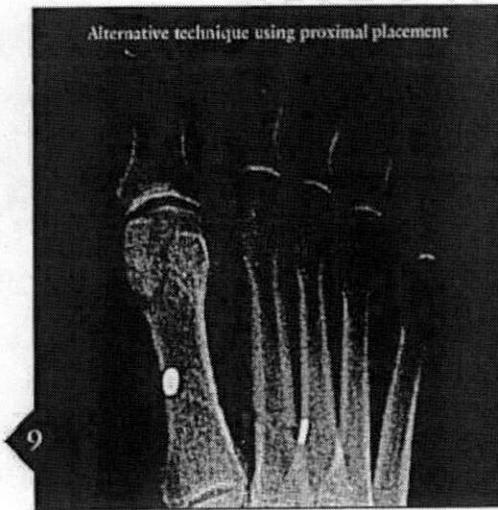


Fig. 8 - The white pull-through suture is cut and removed. The surgeon should manually push the 1st metatarsal and the 2nd metatarsal together to correct the intermetatarsal

angular deformity. Once fluoroscopy confirms proper positioning, the trailing Round Button is tightened down by applying gradual tension on the remaining two strands of blue suture. Tie 2-3 half hitches and cur the suture. Any previously placed sutures incorporating the lateral capsule of the 1st metatarsal, the adductor tendon and the medial capsule of the 2nd metatarsal are now tied thus completing the repair.



Alternative technique using proximal placement

Proximal Placement Option:
Place the device using the Guidewire and drill steps starting between 2.5 cm and 3.5 cm distal to metatarsal-cuneiform joint on first metatarsal just below midline. Angle the direction of the Guidewire and drill into the superior 2nd metatarsal metaphyseal bone. Observe under the C-arm. Plantarflexion of the 3rd metatarsal will allow passage of the 1.6 mm guide pin. The fixation is now completed by the tightening of the FiberWire and button construct.

The Lisfranc joint(s) are approached through a dorsal longitudinal incision. Anatomic reduction is achieved after thorough debridement of the interposing soft tissue or debris. Reduction of the 2nd metatarsal can be maintained by use of the Mini TightRope. The Guidewire is directed from the medial aspect of the first or medial cuneiform obliquely toward the base of the 2nd metatarsal. The Round Button is placed at the base of the 2nd metatarsal, while the Oblong Button is seated over the medial aspect of the first cuneiform. Using the same line of approach, the Round Button can be placed against the first cuneiform with the Oblong Button seated over the lateral aspect of the base of the 2nd metatarsal (distal to the articulation between the 2nd and 3rd metatarsals).

Alternate reduction orientations include:

- 1st metatarsal to 2nd metatarsal
- Cuneiforms (1st, 2nd and 3rd)
- 2nd metatarsal to 2nd cuneiform

Ordering Information

Mini TightRope Repair Kit, sterile, single use AR-8911DS

Kit Contents:

- 1 - Cannulated Drill Bit
- 1 - Round Button, 5.5 mm
- 1 - Oblong Button, 2.6 mm
- 1 - TightRope Guide Pin, 1.6 mm
- 1 - Guidewire

Accessories:

- 1 - Micro SutureLasso, straight AR-8703
- 1 - Drill Guide, reusable AR-8911G



Arthrex, Inc.
1370 Creekside Boulevard, Naples, Florida 34108-1945 • USA
Tel: 239-643-5553 • Fax: 239-598-5534 • Web site: www.arthrex.com

Arthrex GmbH
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Tel: +49-8131-59570 • Fax: +49-8131-5957-565

Arthrex Iberoamérica
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Tel: 310-670-6080 • Fax: 310-670-6087

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Arthrex Mexico, S.A. de C.V.
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Arthrex Swiss, AG
Müllerstrasse 3, 8604 Volterwil • Switzerland
Tel: +41-43-399-45-20 • Fax: +41-43-399-45-29

This description of technique is provided as an educational tool and clinical aid to assist properly licensed medical professionals in the usage of specific Arthrex products. As part of this professional usage, the medical professional must use their professional judgment in making any final determinations in product usage and technique. In doing so, the medical professional should rely on their own training and experience and should conduct a thorough review of pertinent medical literature and the product's Directions For Use.

U.S. PATENT NO. 6,716,294; 6,991,656 and PATENT PENDING
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[CFR Title 21](#) | [Advisory Committees](#) | [Assemblies](#) | [Recalls](#) | [Guidance](#) | [Standards](#)

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510(k) Premarket Notification Database

Device Classification Name	Washer, Bolt, Nut
510(K) Number	K061925
Device Name	MINI TIGHTROPE REPAIR KIT, MODEL AR-8911DS
Applicant	ARTHREX, INC. 1370 Creekside Blvd. Naples, FL 34108 1945
Contact	Sally Foust
Regulation Number	888.3030
Classification Product Code	<u>HTN</u>
Date Received	07/07/2006
Decision Date	10/31/2006
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Orthopedic
Review Advisory Committee	Orthopedic
Statement/Summary/Purged Status	Summary Only
Summary	<u>Summary</u>
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

Database Updated 11/07/2007

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Center for Devices and Radiological Health / CDRH

11/8/2007

K061925 page
1/2

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Mini TightRope™ Repair Kit

OCT 31 2006

NAME OF SPONSOR: Arthrex, Inc.
1370 Creekside Boulevard
Naples, Florida 34108-1945

510(K) CONTACT: Sally Foust, RAC
Regulatory Affairs Project Manager
Telephone: (239) 643-5553 ext. 1251
FAX: (239) 598-5539

TRADE NAME: Mini TightRope™ Repair Kit

COMMON NAME: Button/Suture

DEVICE PRODUCT CODE/CLASSIFICATION:

HTN: Single/multiple component
metallic bone fixation appliances and
accessories:
21 CFR 888.3030

PREDICATE DEVICES

K041189: TRIM-IT Family (Arthrex, Inc.)
K052776: TightRope AC Device (Arthrex, Inc.)
K043248: TightRope Syndesmosis Device (Arthrex, Inc.)

DEVICE DESCRIPTION AND INTENDED USE

The Mini TightRope™ Repair Kit is designed as two differently sized metal buttons and FiberWire™ suture. The buttons are pre-threaded with FiberWire suture, looped twice through the buttonholes. A pull-through FiberWire suture is looped through one button.

The Mini TightRope™ Kit is intended as an adjunct in fracture repair involving metaphyseal and peritricular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.

page 2/2

Specifically, the Arthrex Mini TightRope Repair Kit is intended to provide fixation during the healing process following:

- 1) Syndesmotic trauma, such as fixation of dorsal distal radioulnar ligament (DRUL) disruptions;
- 2) Tarasometatarsal (TMT) injury, such as fixation of foot soft tissue separations due to a Lisfranc injury (Midfoot Reconstruction); and
- 3) Hallux Valgus reconstruction (correction) by providing for the reduction of 1st metatarsal – 2nd metatarsal intermetatarsal angle.

SUBSTANTIALLY EQUIVALENCE

Arthrex has determined that the Mini TightRope™ Repair Kit is substantially equivalent to the predicate devices where basic features and intended uses are the same. Any design differences between the Arthrex Mini TightRope™ Repair Kit when compared to predicate devices used in the standard medical practice for the treatment of DRUL disruptions in syndesmotic trauma, TMT, (Lisfranc) injuries, and reduction for the 1st metatarsal – 2nd metatarsal intermetatarsal angle following Hallux Valgus reconstruction (correction) are considered minor and do not raise any questions concerning safety and effectiveness. Any differences have been found to have no apparent effect on the performance, function, or intended use of the device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Arthrex, Inc.
% Ms. Sally Foust, RAC
Regulatory Affairs Project Manager
1370 Creekside Boulevard
Naples, Florida 34108

OCT 3 1 2006

Re: K061925
Trade/Device Name: Mini TightRope™ Repair Kit
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HTN
Dated: September 27, 2006
Received: September 28, 2006

Dear Ms. Foust:

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.

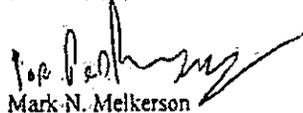
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 - Ms. Sally Foust, RAC

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) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 240-276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061925

Device Name Mini TightRope™ Repair Kit

Indications for Use:

The Mini TightRope™ Repair Kit is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.

Specifically, the Arthrex Mini TightRope™ Repair Kit is intended to provide fixation during the healing process following:

- 1) Syndesmotic trauma, such as fixation of dorsal distal radioulnar ligament (DRUL) disruptions;
- 2) Tarasometatarsal (TMT) injury, such as fixation of foot soft tissue separations due to a Lisfranc injury (Midfoot Reconstruction); and
- 3) Hallux Valgus reconstruction (correction) by providing for the reduction of 1st metatarsal -2nd metatarsal intermetatarsal angle.

Prescription Use X
(Per 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use No
(21 CFR 801 Subpart C)

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

Concurrence of CDREH, Office of Device Evaluation (ODE)

~~(Division Sign-Off)~~

Division of General, Restorative,
and Neurological Devices

510(k)

K061925



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510(k) Premarket Notification Database

Device Classification Name	Screw, Fixation, Bone
510(k) Number	K960537
Device Name	K2 BONE SCREW SYSTEM
Applicant	KINETIKOS MEDICAL, INC. 3950 Sorrento Valley Blvd., San Diego, CA. 92121
Contact	Mark G Urbanski
Regulation Number	888.3040
Classification Product Code	HWC
Date Received	02/07/1996
Decision Date	03/25/1996
Decision	Substantially Equivalent For Some Indications (SN)
Classification Advisory Committee	Orthopedic
Review Advisory Committee	Orthopedic
Statement/Summary/Purged Status	Summary/purged 510(k)
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

Database Updated 08/06/2008

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COPY

MAR 25 1990

K960537

Confidential

FDA Notification of: Summary of Safety and Effectiveness Information
Product: K2 Bone Screw System™

Summary of Safety and Effectiveness Information

For Release Upon Request Only

Regulatory Authority:

Safe Medical Devices Act of 1990, 21 CFR 807.92

Company Name / Contact:

Company: KMI (Kinetikos Medical Inc.)
3950 Sorrento Valley Blvd
San Diego, Ca 92110

Contact: Regulatory Affairs Department
KMI
3950 Sorrento Valley Blvd
San Diego, Ca 92110
(619) 558-2233

Establishment Registration Number: 2028840

Classification Name: Smooth or Threaded Bone Fixation
Fastener

Common Used Name: Bone Screw

Trade Proprietary Name: K2 Bone Screw System™

The FDA has classified similar products as a Class II device by the Orthopedic Device Section of the Surgical and Rehabilitation Devices Panel at Section 888-304. The product code generally referred to is HWC (Product Code: HWC), and KMI submits this application under this designation.

3950 SORRENTO VALLEY BLVD., SAN DIEGO, CALIFORNIA 92121 TELEPHONE: (619)558-2233 FACSIMILE: (619)558-0838



Confidential

COPY

FDA Notification of:

Summary of Safety and Effectiveness Information
Product: K2 Bone Screw System™

Performance Standards:

No performance standards applicable to the Bone Screw have been established by the FDA. However, the titanium alloy 6AL-4V ELI alloy used to manufacture the KMI screws meets the chemical and mechanical requirements in voluntary standards established by the American Society for Testing and Materials (ASTM F136-84).

Package and Labeling:

Package labeling has been developed to industry standards. Packaging is also standard commercially available type quality and is stored in a fashion which prevents damage to the container or package the device is in.

System Description:

The KMI K2 Bone Screw System™ will be offered in Ti-6Al-4V ELI. It will be available in common styles and assorted lengths for bone fracture fixation and stabilization. Initially, a range of eleven screw lengths will be made available in 2.8 mm diameter (10-30 mm), and eight screw lengths will be made available in the 2.4 mm (6-20 mm) diameter screw. Both screw types are implantable using a standard (e.g. American Orthopedic) hexhead screwdriver, which is cannulated at center.

Indications for Use:

The KMI K2 Bone Screw System™ will be used on indications that are common with presently marketed devices. The indications for use of the K2 Bone Screw System™ are fixation/stabilization of small bone hand or small bone forefoot fractures.

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FDA Notification of:

Summary of Safety and Effectiveness Information
Product: K2 Bone Screw System™

Substantial Equivalent Devices:

This product is substantially equivalent in design, composition and function to other orthopedic screws manufactured and approved for market.

Ace Medical Company:	K903810
Alphatec Medical:	K921622
Howmedica:	K931524
Aesculap:	K940207
Osteomed:	K924018
Zimmer:	K792022
A.O. Synthes	K792291
Johnson & Johnson	K?
ISI Manufacturing	K?

The KMI K2 Bone Screw System™ meet the ASTM standards (ASTM B348-83, F136-84, F67-88) for material and design for medical application. The bone screws are of the same thread configuration and length as offered by Ace Medical, A.O. Synthes, Zimmer, Johnson & Johnson, Alphatec and many other orthopaedic companies. The minor and major diameters as well as the head size are comparable.

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FDA Notification of:**Summary of Safety and Effectiveness Information
Product: K2 Bone Screw System™****Instrumentation:**

KMI K2 Bone Screw System™ instrumentation used for the preparation and insertion of the K2 Bone Screws is considered to be general orthopaedic instrumentation. The system includes standard manual orthopaedic surgical instruments of the appropriate size and type. All K2 System instruments are manufactured from stainless steel meeting ASTM F899-84 standards.

Product Sterilization:

KMI will supply all instruments and implants **Non-Sterile**. Non-Sterile implants are packaged in "clean only" condition. The labeling of the implants and instruments clearly indicates their sterility status. The package insert contains a sterilization/re-sterilization guideline.

Summary:

Substantial Equivalence for the KMI K2 Bone Screw System™ may be found in comparison with devices from a number of manufactures. Bone Screw systems in general have been used for many years, and the clinical performance is well known and documented.

Another measure of the Safety and Effectiveness of a medical device is how it performs in long term use. The basic design concept of bone screws for use in the fixation and stabilization of fractures has had over 75 years of clinical evaluation. Uses, Indications, limitations and surgical techniques are well understood. Standardized manufacturing methods, design practices, material selections and testing techniques are known and represented within the guidelines of this submittal.

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211

Attachment 2: Proposed Labeling

- Proposed package labeling
- Proposed instruction sheet

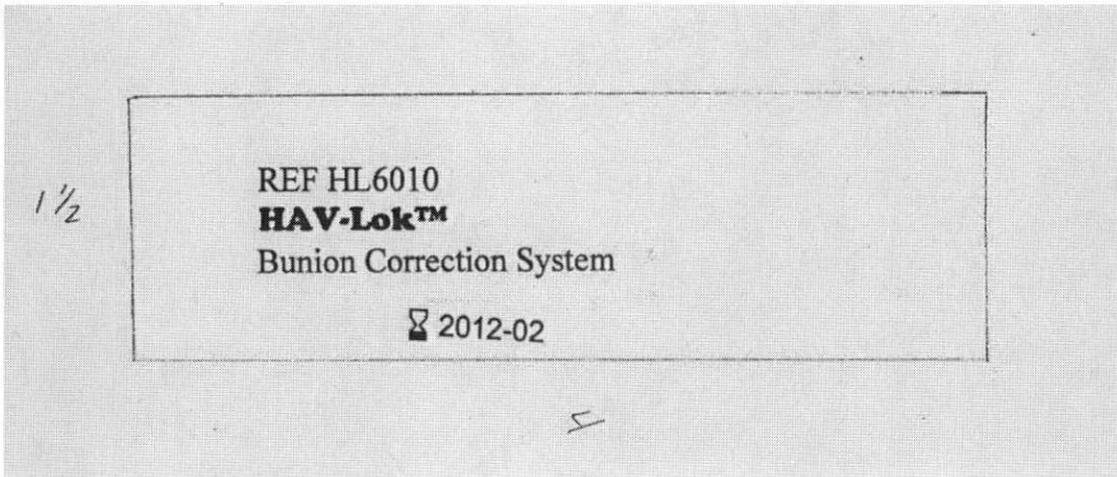


Figure 16. Label for external pouch.

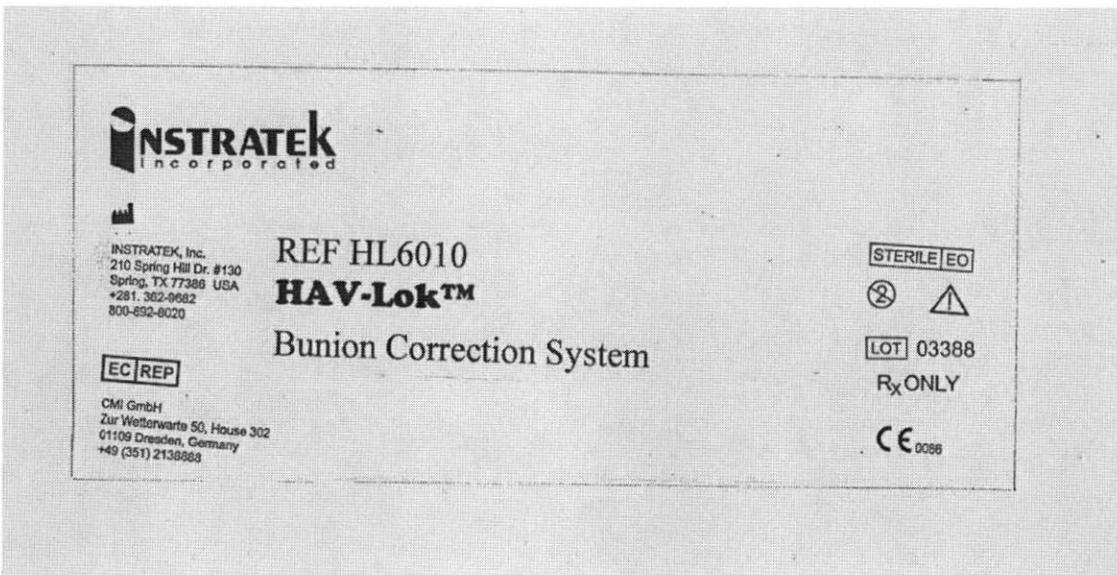


Figure 17. Label for internal pouch.

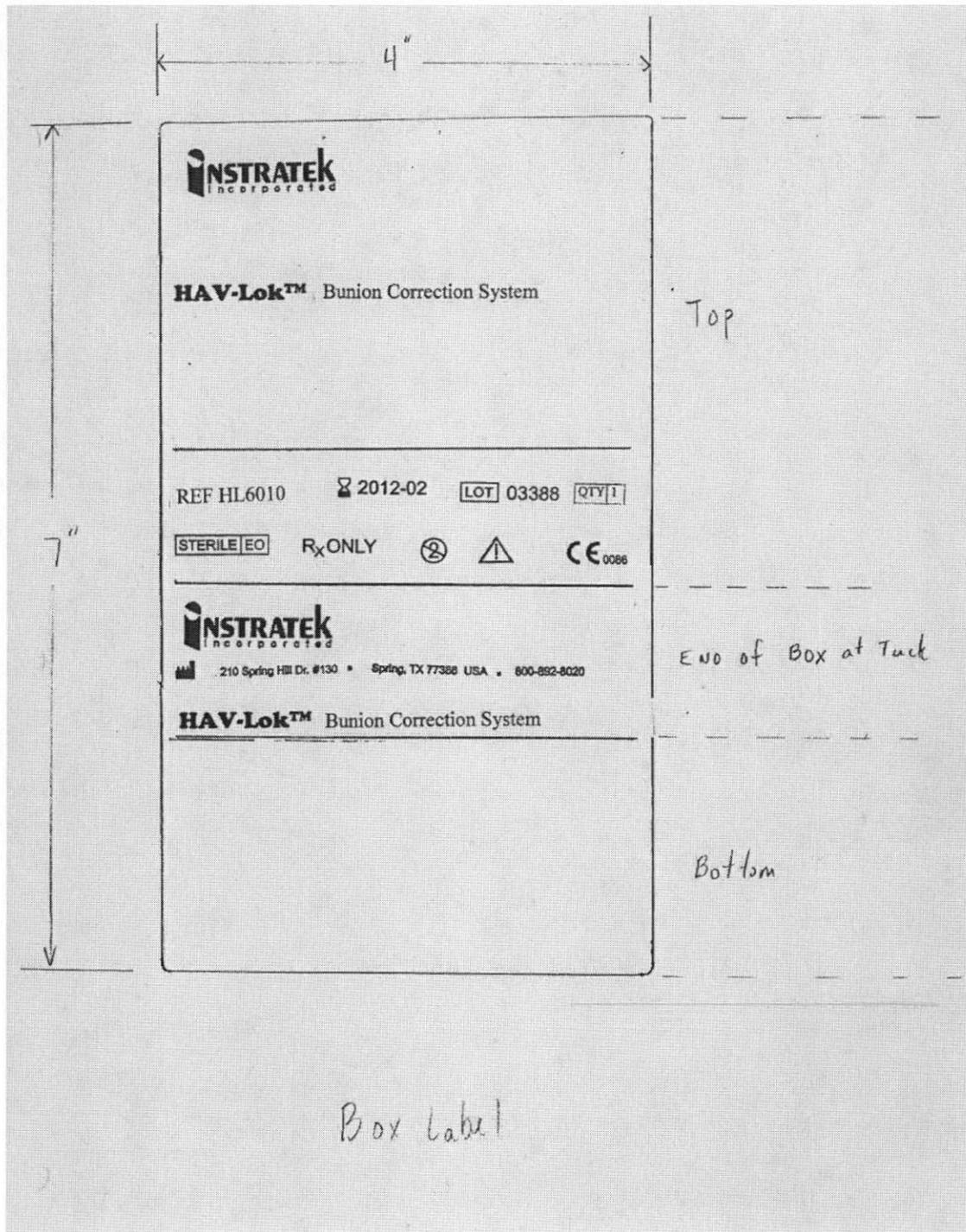


Figure 18. Box label.

Instructions for Use

Description

The HAV- Lok Kit is designed to assist in the reduction and control of increased pathologic intermetatarsal angles. HAV-Lok may eliminate the necessity of a traditional osteotomy in the correction of Hallux Valgus deformities within the indicated criteria.

The Instratek HAV-Lok device is intended for the following surgical indications:

- To assist in the biomechanical reduction of abnormal intermetatarsal angles.

Contraindications

- Active or previous infections
- Poor bone quality
- Osteoporotic bone that is susceptible to fracture
- Conditions that limit the patient's ability or willingness to follow postoperative instructions with the healing regimen.
- Foreign body sensitivity or hyper reactivity
- Physical conditions that retard the healing process
- Surgical procedures not indicated for the device.
- Skeletal immature bone may not be suitable
- Structurally rigid non reducible Hallux Valgus deformities

Warnings

- Do not reuse device
- Do not re-sterilize device
- Do not expose to heat
- Knowledge of the surgical technique is extremely important. Pre operative and operative planning is a necessity. Patient selection and implant placement are important considerations for successful outcomes with this device
- Reduction devices are used as an aid to healing, they are not a substitute for normal intact bone and tissue.
- Full weight bearing prior to healing is inadvisable.
- Instructions for patients should be strictly followed to prevent adverse implant stress that inevitably will break device.
- Excessive post op ambulation prior to healing may lead to stress fractures of the adjacent metatarsal.

Adverse Effects

- Metal sensitivity or known foreign body sensitivity
- Soft tissue reactions in proximity of implants
- Infections, both deep and superficial
- Implant may require removal in event of severe post op infection

Sterilization

- The device supplied is sterile. The method of sterilization is noted on the package label.
- Device is intended for single (one time) use only. Do not re-sterilize
- Do not use if package has been previously opened or damaged

Material Specifications

- Plates – Ti-6Al-4V
- #3/4 Suture – Ultra High Molecular Weight Polyethylene (UHMWPE)
- Suture Lasso – Stainless Steel
- Kwire – Stainless Steel
- Cannulated Drill Bit – Stainless Steel

Packaging and Labeling

- Components should only be accepted with factory packaging and labeling intact

Instructions For Use

- Knowledge of the surgical technique is extremely important. Pre operative and operative planning is a necessity. If you require additional information, please contact an Instratek representative

Hallux Valgus Repair**Suture Path Drilling Steps**

1. Prior to incision orient topographically a kwire path for first suture hole from the medial aspect of the 1st metatarsal anatomical neck with an inclination to the distal 1/3 diaphyseal bone in the 2nd metatarsal verifying by fluoroscopy. Use a marking pen to plot the trajectory of the kwire on dorsal soft tissue.
2. Do to the varying pathology of Hallux Valgus, perform the release of the lateral capsule structures as indicated. Perform resection of medial hyperostotic eminence structure prior to the next step.
3. Using your topographical markings from step 1, plot a 2.5cm longitudinal incision over lateral 2nd metatarsal cortex. Incision should begin distally on topographical pen marking and progress proximally over the 2nd metatarsal lateral cortex. Reflect the soft tissue and periosteum. Insert drill guide for controlled kwire placement orienting and securing the drill guide centrally on both the medial and lateral cortex of the 1st and 2nd metatarsal.
4. Advance the supplied 1.14mm x 305mm kwire, from the medial aspect of the first metatarsal (approximately at the level of the 1st metatarsal anatomical neck) through the lateral cortex of the second metatarsal. Orient kwire trajectory in the direction proximal of the distal 1/3 diaphyseal bone in the transverse plane. In the sagittal plane, the kwire should be centrally placed within both metatarsals. Via fluoroscopy, confirm kwire placement intra operatively in AP and Lateral planes. The kwire should advance 3mm beyond the lateral cortex.
5. Remove drill guide leaving kwire in position. Plan second suture hole path with pen markings on medial 1st metatarsal cortex 4mm proximal of distal first suture hole path and 14mm proximal on 2nd metatarsal first suture hole path centrally.
6. Position the 2.0mm cannulated drill bit over first suture hole path kwire and drill medial to lateral, advancing the lateral cortex of the second metatarsal.
7. Remove cannulated drill bit and kwire by retrograding medially.
8. Prepare second suture hole path. Position drill guide on cortical pen markings and advance 1.14mm x 305mm kwire medial to lateral through lateral cortex of second metatarsal.
9. Remove drill guide leaving kwire in position
10. Position the 2.0mm cannulated drill bit over second suture hole path kwire and drill medial to lateral, advancing the lateral cortex of the second metatarsal
11. Remove cannulated drill bit and kwire by retrograding medially

Implant Insertion Steps

1. Insert the suture lasso, lateral to medial in distal 1st and 2nd metatarsal suture hole path drill holes, leaving the loop exposed laterally. Using plate and suture assembly provided, place both free suture ends through suture lasso loop.
2. Pull suture lasso medially transporting both suture ends until sutures are visible medial of 1st metatarsal. Manually pull sutures seating the lateral assembled oblong plate flush on the lateral cortex of the 2nd metatarsal.
3. Insert both suture ends together through one hole of the small 8mm oblong plate. Reverse path of both suture ends and pull through second hole of 8mm oblong plate.
4. Insert the suture lasso, medial to lateral in proximal second suture hole path leaving loop exposed medially. Place both suture ends through suture lasso loop.
5. Pull suture lasso laterally transporting both suture ends until sutures are visible lateral of 2nd metatarsal.
6. Separately thread one suture through each of the two most proximal bone plate holes.
7. Reduce the intermetatarsal angle to the desired biomechanical position. A reduction forcep or assistant may be helpful in maintaining the first metatarsal and second metatarsal angle while being secured.
8. Tightly secure a standard surgeons knot (three or more) over the oblong lateral plate. Trim suture in standard manner.
9. Close surgical site in usual fashion



COVER SHEET MEMORANDUM

From: Reviewer Name Tara Shepherd
Subject: 510(k) Number K082384/S
To: The Record

- Please list CTS decision code SE
- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
 - Hold (Additional Information or Telephone Hold).
 - Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	✓	
510(k) Summary /510(k) Statement	Attach Summary	✓	
Truthful and Accurate Statement.	Must be present for a Final Decision	✓	
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			✓
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, <i>Certification with Requirements of ClinicalTrials.gov Data Bank</i> ? (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			✓
Nanotechnology			✓

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	Contact OSB.	<input checked="" type="checkbox"/>
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.	<input checked="" type="checkbox"/>

Regulation Number 988,3030 Class* II Product Code HTN
(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: [Signature] 0JDB 12/8/08
(Branch Chief) (Branch Code) (Date)

Final Review: [Signature] for mmm 12/9/08
(Division Director) (Date)



Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional

K082384 S001

Date: December 5, 2008

To: The Record

Office: DGRND

From: Tara N. Shepherd M.S. TNS 12/5/08

Division: OJDB

510(k) Holder: Instratek, Inc.

Device Name: HAV-Lok Bunion Correction System

Contact: Jeff Seavey

Phone: 281 890-8020

Fax: 281 890-8068

Email: jeff@instratek.com

I. Purpose and Submission Summary

The 510(k) holder would like to introduce the HAV-Lok Bunion Correction System into interstate commerce.

The HAV-Lok Kit is designed to assist in the reduction and control of increased pathologic intermetatarsal angles. To achieve reduction of intermetatarsal angles, two suture paths are drilled through the first and second metatarsals. The oblong plates are positioned on the outside of the first and second metatarsal and the sutures are used to draw the plates together thereby reducing the intermetatarsal angle.

(b)(4)Trade Secret Process

History

- Submission was placed on hold (AI) on October 24, 2008

Recommendation

Based on the information provided and the similarities to the predicate device, I recommend the HAV-Lok Bunion Correction System be found **Substantially Equivalent (SE)** to legally marketed predicate devices.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form			X

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?	X		
Does the device design use software?		X	
Is the device sterile?	X		
Is the device reusable (not reprocessed single use)?		X	
Are "cleaning" instructions included for the end user?			

The Instratek HAV-Lok Bunion Correction System is intended to assist in the biomechanical reduction of abnormal intermetatarsal angle.

The HAV-Lok Kit is designed to assist in the reduction and control of increased pathologic intermetatarsal angles. HAV-Lok may eliminate the necessity of a traditional osteotomy in the correction of hallux valgus deformities within the indicated criteria. The implanted device consists of three components:

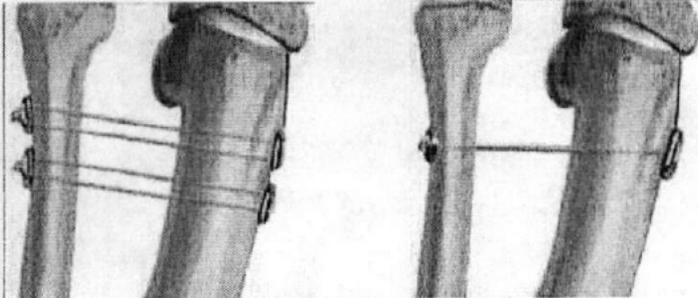
- medial oblong plate (Ti-6Al-4V, ASTM F132-02a),
- lateral oblong plate (Ti-6Al-4V, ASTM F132-02a),
- #3/4 suture (UHMWPE, K033654, K04072, K063778).

There are four accessories required to implant the device:

- Suture lasso (Stainless Steel)
- K-wire (316 Stainless Steel, ASTM F138)
- Cannulated Drill Bit (17-4 Stainless Steel)
- Drill Guide (420 Stainless Steel, DIN 1.4021)

To achieve reduction of intermetatarsal angles, two suture paths are drilled through the first and second metatarsals. The oblong plates are positioned on the outside of the first and second metatarsal and the sutures are used to draw the plates together thereby reducing the intermetatarsal angle.

The drill bit, k-wire and the suture material are not manufactured by Instratek, but are cleared via the 510(k) numbers identified. The kit contains all of the components and accessories to insert the device. This includes the k-wire, cannulated drill bit, medial and oblong plates, and suture material.



(Predicate: K061925)



(b)(4)Trade Secret Process

(Proposed device)

Reviewer's Comments: Both the proposed device and the predicate device use a UHMWPE #3/4 suture to secure the buttons.

The proposed device is manufactured of titanium conforming to ASTM F132 while the predicate device is manufactured from stainless steel. However, the use of titanium does not present new concerns since it has been used in other medical devices (e.g. plates). Both devices use the same implant accessories.

IV. Indications for Use

The Instratek HAV-Lok Bunion Correction System is intended for the following surgical indication:

- To assist in the correction of Hallux Valgus deformities by providing reduction of the 1st intermetatarsal angle.

Reviewer's Comments: Adequate. Indications are the same as the predicate device.

V. Deficiencies

- You have performed (b)(4)Trade Secret Process. You have provided a table that summarizes the results from the testing.

- However, you have no

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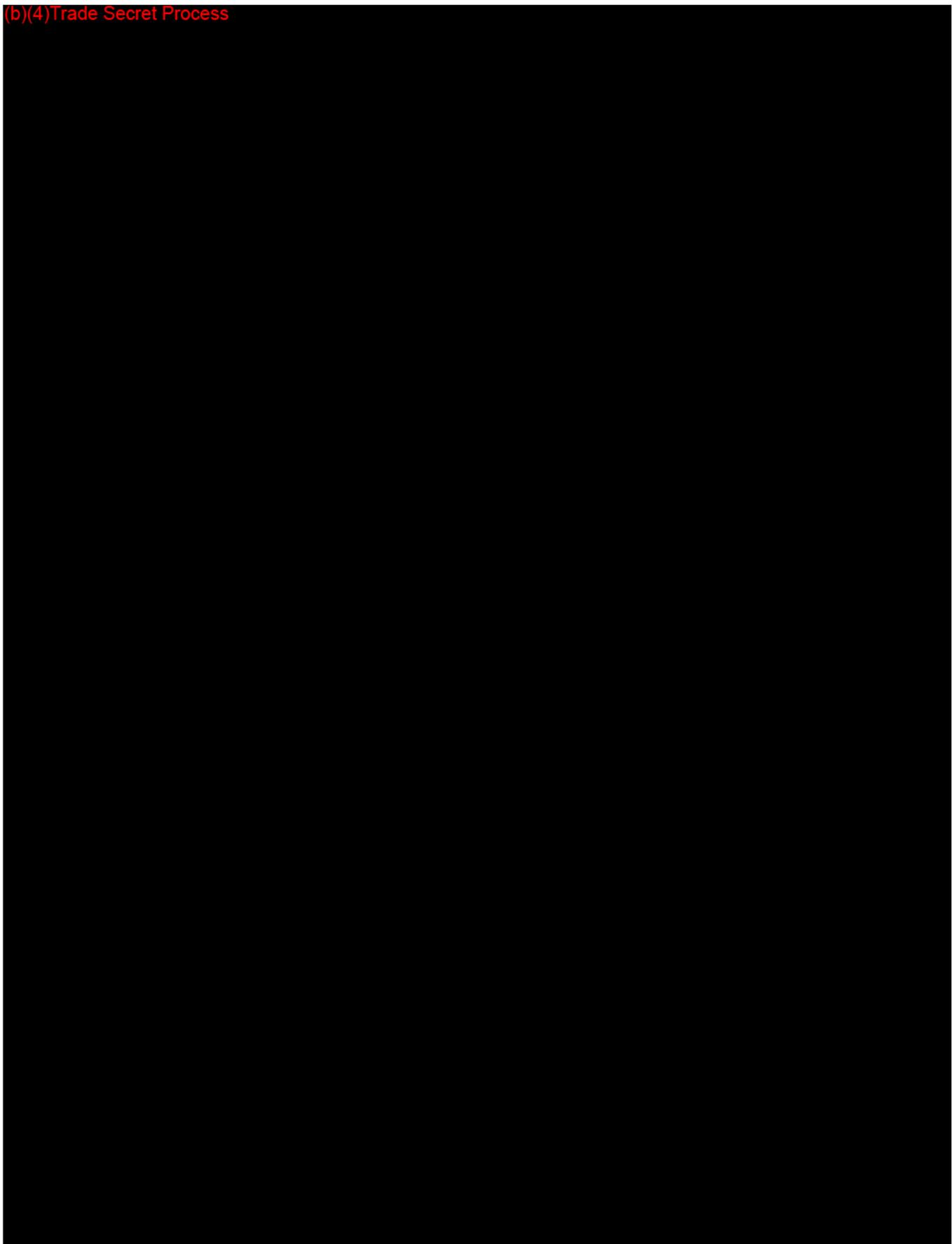


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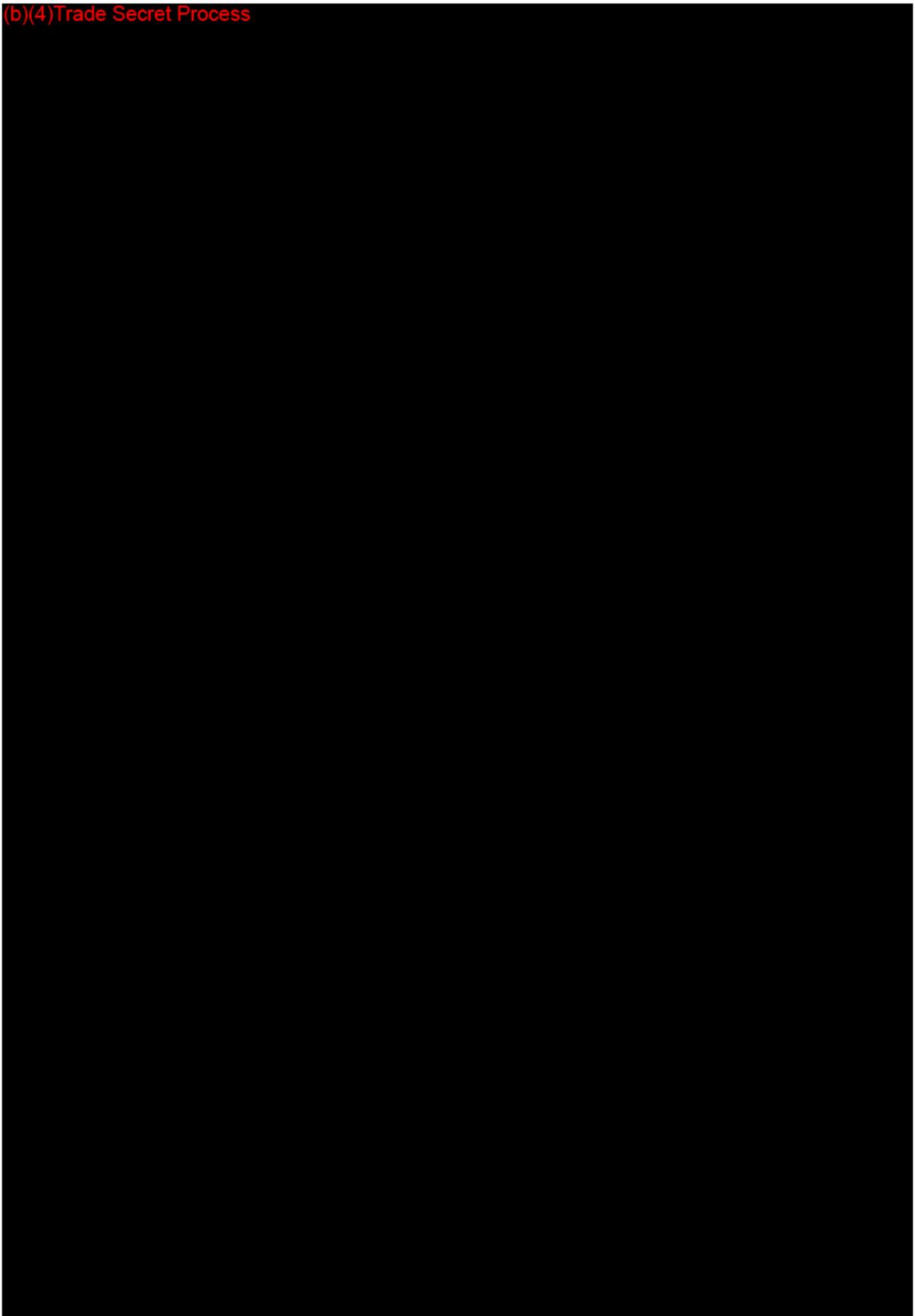


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(b)(4)Trade Secret Process



(b)(4)Trade Secret Process

(b)(4)Trade Secret Process Adequate response. (b)(4)Trade Secret Process

(b)(4)Trade Secret Process

- c. However, you have not provided the test reports that support your results. In order to fully understand the testing that was conducted complete test reports are necessary. Therefore, please provide the test reports for your

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(b)(4)Trade Secret Process

Reviewer's Comments: Adequate. Test reports clarify testing that was performed.

2. Your proposed indications for use are "to assist in biomechanical reduction of abnormal intermetatarsal angle". (b)(4)Trade Secret Process

which your device may be used. For example, The HAV-Lok Bunion Correction System
(b)(4)Trade Secret Process

Sponsor's Response: The indications for use have been updated.

Reviewer's Comments: Adequate response. Indications are the same as the predicate device.

(b)(4)Trade Secret Process

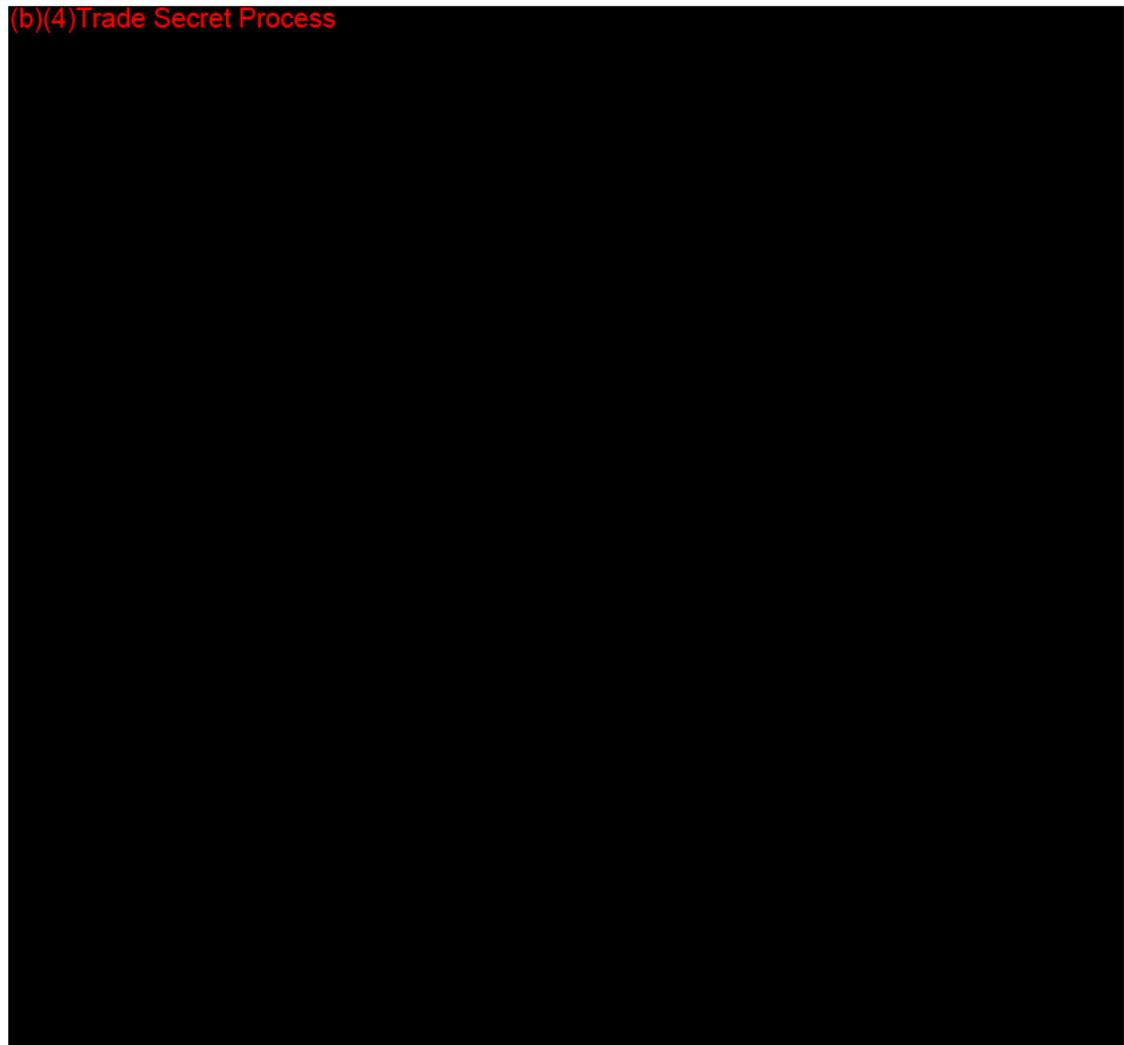
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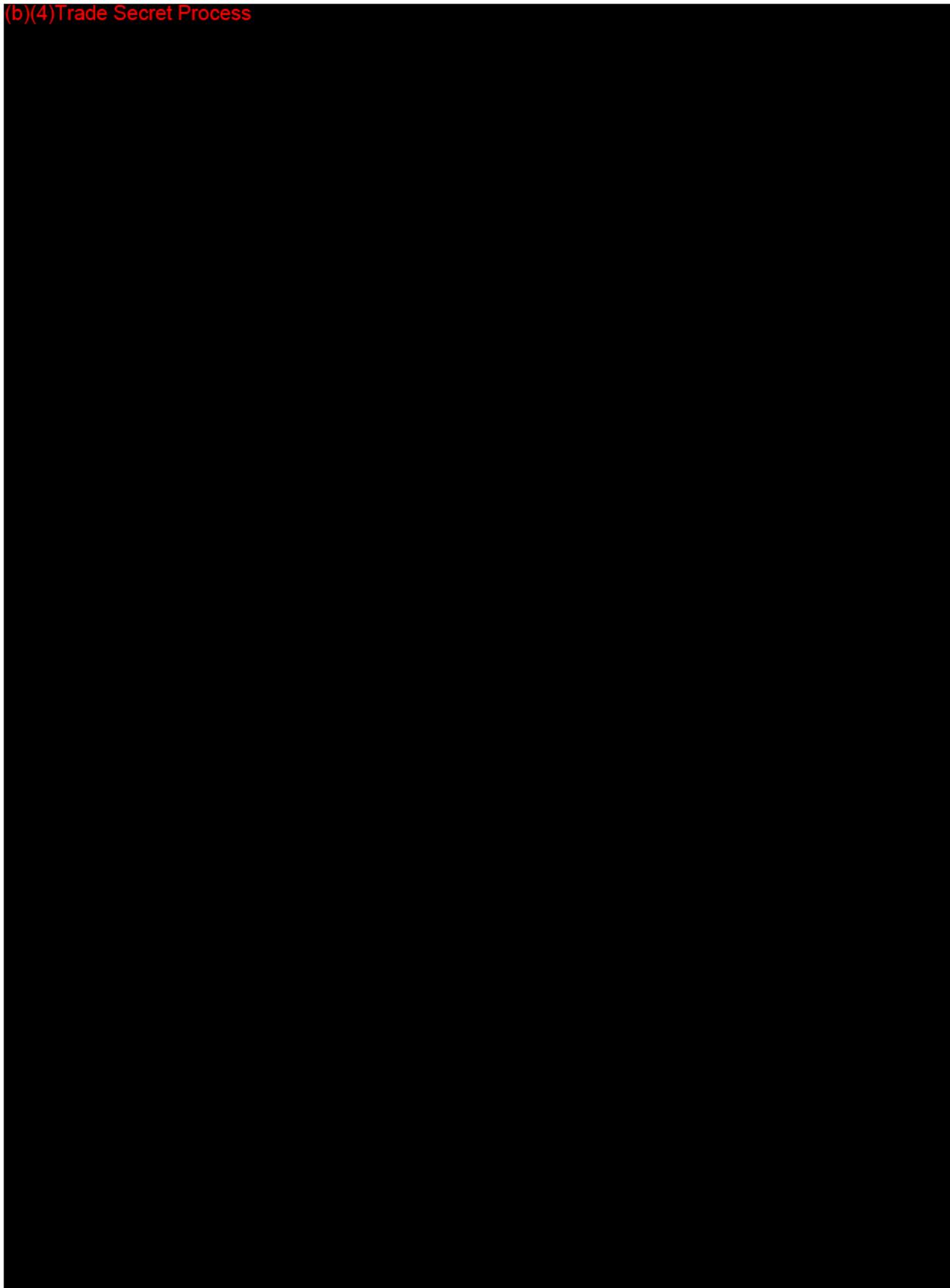
3. The first metatarsal is substantially thicker in width and circumference than the second metatarsal. The first metatarsal also has a tri planar range of motion (flexion/extension, abduction/adduction and inversion/eversion) while the second metatarsal, designated as the midline (or axis) of the foot, only has single range of motion (flexion/extension). The predicate device uses a single suture pass which allows for range of motion that will not be present in your proposed device due to the double lasso suture path.

- a. We are concerned (b)(4)Trade Secret Process
- 

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Reviewer's Comments: Adequate response.

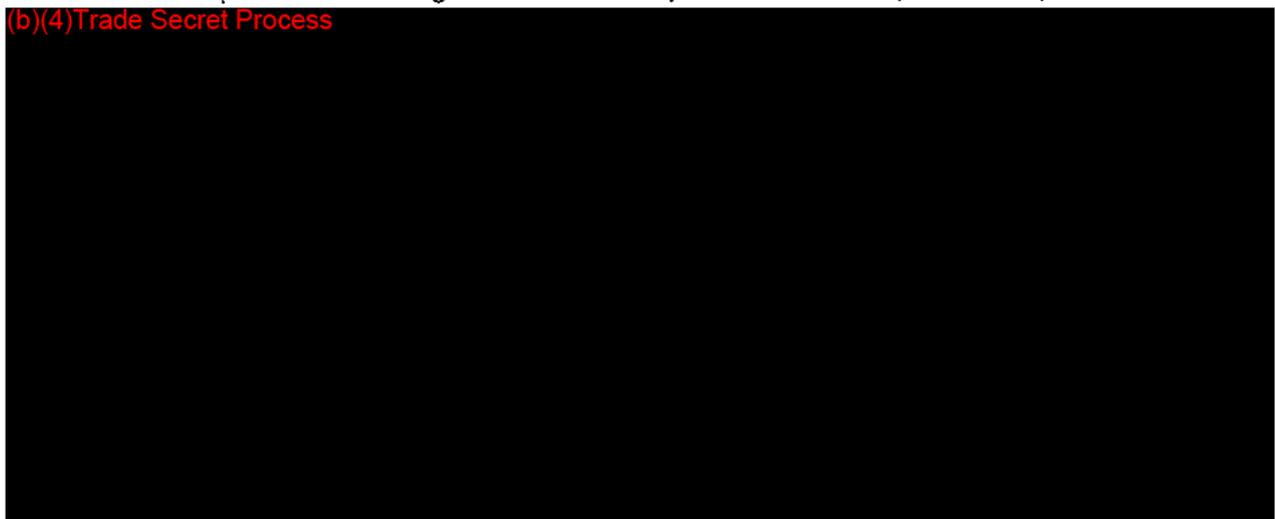
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4. You have provided drawings of the basic implantation technique that depicts the device

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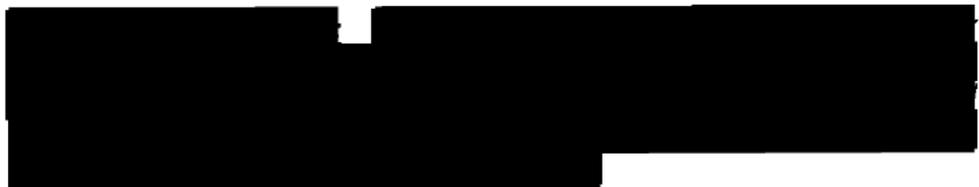
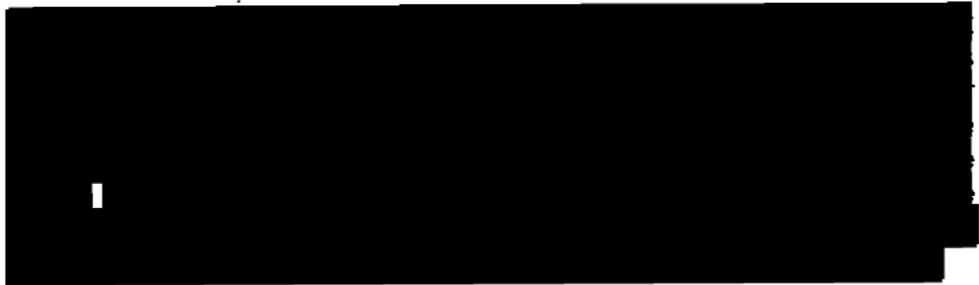


Reviewer's Comments: Adequate. .

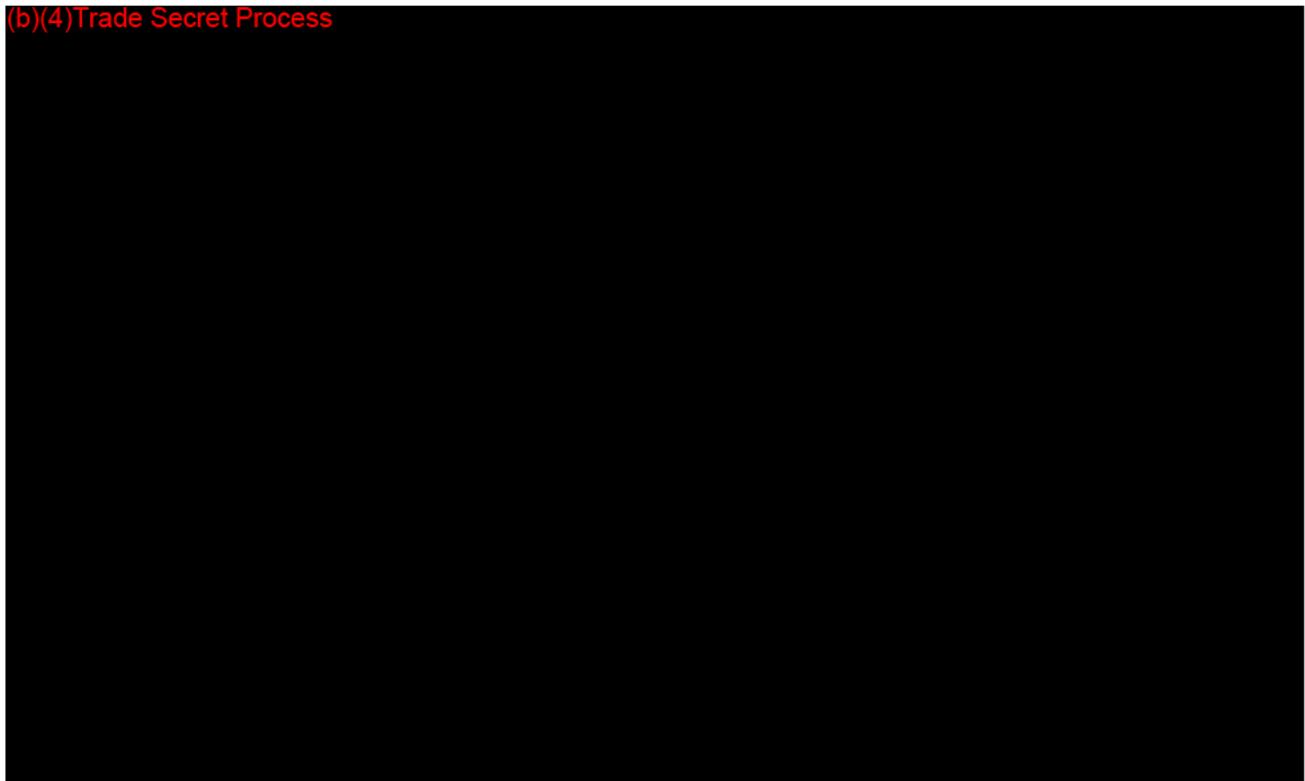
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Reviewer's Comments: Adequate.

5. You have provided a package insert that includes a surgical technique that explains how your device is to be used.
 - a. Your package insert states that “full weight bearing prior to healing is inadvisable.” However, most subjects undergoing a hallux valgus correctional procedure will be allowed to bear weight immediately following surgery.
 - i. Therefore, we are concerned that the increase in forces above and below the plates will increase the risk of fracture if full weight bearing is not restricted. Please discuss what will happen when this device is subject to the normal biomechanical forces during gait if weight bearing is not restricted until healing has occurred. Alternatively, please update your package insert to indicate that full weight bearing is prohibited until healing has occurred.

Sponsor's Response: While it is true that some patients who have a hallux valgus deformity (b)(4)Trade Secret Process



(b)(4)Trade Secret Process

Reviewer's Comments: Adequate response. The proposed rehabilitation is the same as the predicate device.

(b)(4)Trade Secret Process

Reviewer's Comments: Adequate. (b)(4)Trade Secret Process

(b)(4)Trade Secret Process

(b)(4)Trade Secret Process

Sponsor's Response: The instructions for use have been updated accordingly.

Reviewer's Comments: Adequate response. (b)(4)Trade Secret Process

(b)(4)Trade Secret Process

Reviewer's Comments: Adequate.

(b)(4)Trade Secret Process

Sponsor's Response: The instructions for use have been updated accordingly.

Reviewer's Comments: Adequate.

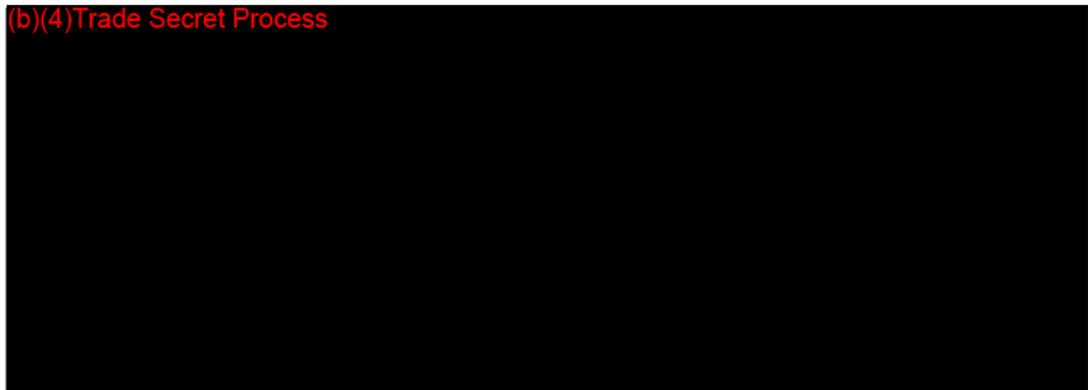
(b)(4)Trade Secret Process

kit that contains all of the components (medial and oblong plates, suture) and accessories (k-wire, cannulated drill bit) to insert the device.

- a. Further you have stated that the k-wire (b)(4)Trade Secret Process

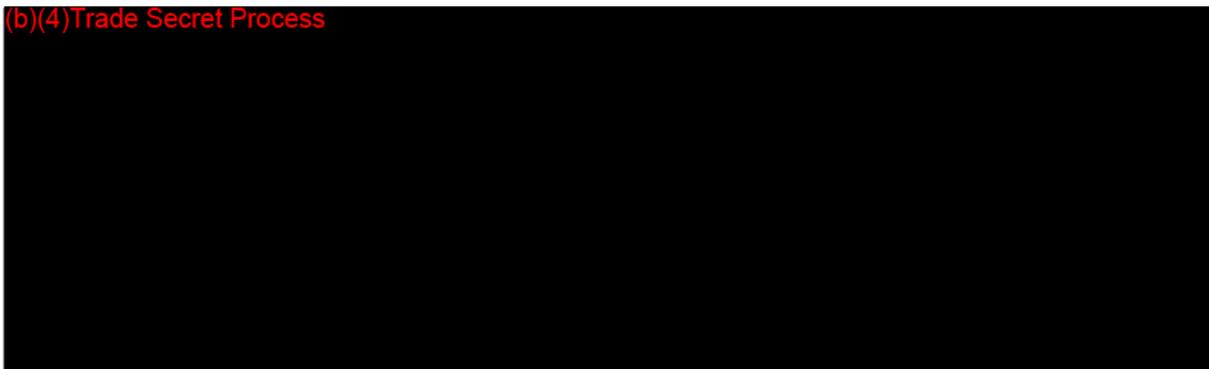


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Reviewer's Comments: Adequate.

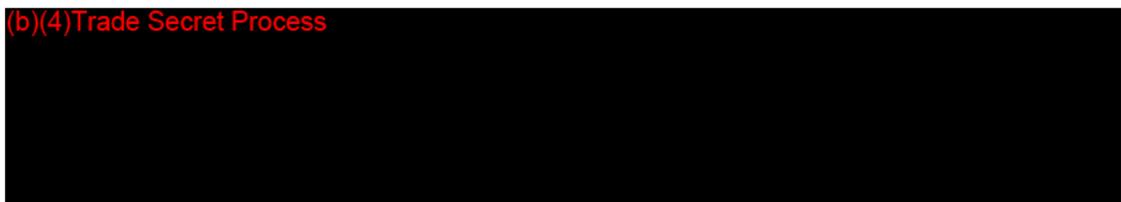
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Reviewer's Comments: Adequate.

- c. Effective January 2, 2008, all firms that choose to use a standard in the review of any new 510k (Traditional, Abbreviated or Special), need to fill out the new standards form (Form 3654) and submit it with their 510(k). The new standards form can be found at <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf>. Please provide an electronic copy of this form as it pertains to this submission (i.e. ASTM F132-02a, ASTM F138, etc).

(b)(4)Trade Secret Process



Reviewer's Response: Adequate.

(b)(4) Trade Secret Process

Reviewer's Comments: Adequate.

VI. Substantial Equivalence Discussion

	Yes	No
1. Same Indication Statement?	X	If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		If YES = Stop NSE
3. Same Technological Characteristics?	X	If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		X If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?		If YES = Stop NSE
7. Accepted Scientific Methods Exist?		If NO = Stop NSE
8. Performance Data Available?	X	If NO = Request Data
9. Data Demonstrate Equivalence?	X	Final Decision: SE

5. Explain how descriptive characteristics are not precise enough:
Further information needed on device design, mechanical testing

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:
Testing and device description demonstrate that the device will perform similar to the predicate device.

VII. Contact History

- Spoke with sponsor on November 4, 2008 to discuss AI Letter. Sponsor was seeking clarification of the deficiencies and wanted to discuss their potential response.

- Spoke with sponsor on December 5, 2008 to discuss IM angle contraindication.

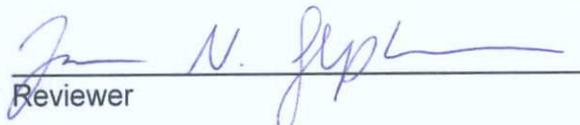
VIII. Recommendation

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: Class II

Product Code: HTN



Reviewer

DEC 5, 2008

Date



Branch Chief

12/8/08

Date

Shepherd, Tara N

From: Jeff Seavey [jeff@instratek.com]
Sent: Friday, December 05, 2008 11:26 AM
To: Shepherd, Tara N
Subject: RE: K082384 - HAV Lok Bunion Correction System
Attachments: Attachment 6 Instructions for use.doc

Tara,

Attached is the modified package insert/IFU for your review.

Please contact me with any questions. We look forward to resolving this ASAP.

Sincerely,

Jeff Seavey
Vice President
Instratek Inc.
210 Springhill Drive, Suite 130
Spring, Texas 77386
Ph: 1-800-892-8020
Cell: 832-257-0845
jeff@instratek.com
www.instratek.com

From: Shepherd, Tara N [mailto:Tara.Shepherd@fda.hhs.gov]
Sent: Thursday, December 04, 2008 4:38 PM
To: jeff@instratek.com
Subject: K082384 - HAV Lok Bunion Correction System

Mr. Seavey,

We are in the process of reviewing your response to our request for additional information. Before we can complete our review we would like to schedule a very brief (approx 5min) telephone conversation to discuss potential changes to your package insert. Please let me know if you are available tomorrow, Friday December 5, at 11am EST.

Thanks,
Tara

Tara N. Shepherd, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
U.S. Food and Drug Administration
240-276-3683 (phone)
240-276-3761 (fax)

tara.shepherd@fda.hhs.gov

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Description

The HAV- Lok Bunion Correction System is intended to assist in the correction of Hallux Valgus deformities by providing reduction of the 1st intermetatarsal angle. HAV-Lok may eliminate the necessity of a traditional osteotomy in the correction of Hallux Valgus deformities within the indicated criteria.

The Instratek HAV-Lok Bunion Correction System is intended for the following surgical indications:

- To assist in the correction of Hallux Valgus deformities by providing reduction of the 1st intermetatarsal angle.
-

Contraindications

- Active or previous infections
 - Poor bone quality
 - Osteoporotic bone
 - Fractured bone
 - Conditions that limit the patient's ability or willingness to follow postoperative instructions with the healing regimen.
 - Foreign body sensitivity or hyper reactivity
 - Physical conditions that retard the healing process
 - Surgical procedures not indicated for the device.
 - Skeletal immature bone may not be suitable
 - Structurally rigid non reducible 1st intermetatarsal angles
 - 1st intermetatarsal angles >16 deg., limited to mild or moderate Hallux Valgus
 - Arthritic 1st metatarsalphalangeal joint
 - Degenerative 1st metatarsalphalangeal joint
 - Hallux rigidus and limitus
 - Irregular or incongruent 1st metatarsal phalangeal joint
-

Warnings

- Do not reuse device
 - Do not re-sterilize device
 - Do not expose to heat
 - Knowledge of the surgical technique is extremely important. Pre operative and operative planning is a necessity. Patient selection and implant placement are important considerations for successful outcomes with this device
 - Reduction devices are used as an aid to healing, they are not a substitute for normal intact bone and tissue.
 - Full weight bearing prior to healing is inadvisable.
 - Instructions for patients should be strictly followed to prevent adverse implant stress that inevitably will break device.
 - Excessive post op ambulation prior to healing may lead to stress fractures of the adjacent metatarsal
-

Post Operative Protocol Following Hallux Valgus Surgery

Post operative Week 1

- Below knee (BK) walking cast boot, rocker bottom sole, weight bearing heel only

Post operative weeks 1-4

- Below knee (BK) walking cast boot, rocker bottom sole, weight bearing heel only

Post operative weeks 4-6

- Full ambulation in (BK) walking cast boot

Post operative weeks 6-12

- Integration of regular daily activities in athletic shoe based on patient tolerance

Post operative week 12 and beyond

- Normal activities

Adverse Effects

- Metal sensitivity or known foreign body sensitivity
 - Soft tissue reactions in proximity of implants
 - Infections, both deep and superficial
 - Implant may require removal in event of severe post op infection
-

Sterilization

- The device supplied is sterile. The method of sterilization is noted on the package label.
 - Device is intended for single (one time) use only. Do not resterilize
 - Do not use if package has been previously opened or damaged
-

Material Specifications

- Plates – Ti-6Al-4V
 - #3/4 Suture – Ultra High Molecular Weight Polyethylene (UHMWPE)
 - Suture Lasso – Stainless Steel
 - Kwire – Stainless Steel
 - Cannulated Drill Bit – Stainless Steel
-

Packaging and Labeling

- Components should only be accepted with factory packaging and labeling intact
-

Instructions For Use

- Knowledge of the surgical technique is extremely important. Pre operative and operative planning is a necessity. If you require additional information, please contact an Instratek representative

Hallux Valgus Repair**Suture Path Drilling Steps**

1. Prior to incision orient topographically a kwire path for first suture hole from the medial aspect of the 1st metatarsal anatomical neck with an inclination to the distal 1/3 diaphyseal bone in the 2nd metatarsal verifying proper orientation by fluoroscopy. Use a marking pen to plot the trajectory of the k-wire on dorsal soft tissue.
2. Do to the varying pathologic anatomy of Hallux Valgus, perform the release of the lateral capsule structures as indicated. Perform resection of medial hyperostotic eminence structure prior to the next step.
3. Using your topographical markings from step 1, plot a 2.5cm longitudinal incision over the lateral aspect of the 2nd metatarsal cortex. The incision should begin distally on topographical pen marking and progress proximally over the 2nd metatarsal lateral cortex. Reflect the soft tissue and periosteum. Insert drill guide for controlled kwire placement orienting and securing the drill guide centrally on both the medial and lateral cortex of the 1st and 2nd metatarsal.
4. Advance the supplied 1.14mm x 305mm k-wire, from the medial aspect of the first metatarsal (approximately at the level of the 1st metatarsal anatomical neck) through the lateral cortex of the second metatarsal. Orient k-wire trajectory in the direction proximal of the distal 1/3 diaphyseal bone in the transverse plane. In the sagittal plane, the k-wire should be centrally placed within both metatarsals. Via fluoroscopy, confirm k-wire placement intra operatively in both the AP and Lateral planes. The k-wire should advance 3mm beyond the lateral cortex.
5. Remove drill guide leaving kwire in position. Plan second suture hole path with pen markings on medial 1st metatarsal cortex 4mm proximal of distal first suture hole path and 14mm proximal on 2nd metatarsal first suture hole path centrally.
6. Position the 2.0mm cannulated drill bit over first suture hole path k-wire and drill medial to lateral, advancing the lateral cortex of the second metatarsal.
7. Remove cannulated drill bit and k-wire by retrograding medially.
8. Prepare second suture hole path. Position drill guide on cortical pen markings and advance 1.14mm x 305mm k-wire medial to lateral through lateral cortex of second metatarsal.

9. Remove drill guide leaving k-wire in position
10. Position the 2.0mm cannulated drill bit over second suture hole path k-wire and drill medial to lateral, advancing the lateral cortex of the second metatarsal
11. Remove cannulated drill bit and k-wire by retrograding medially

Implant Insertion Steps

1. Insert the suture lasso, lateral to medial in distal 1st and 2nd metatarsal suture hole path drill holes, leaving the loop exposed laterally. Using plate and suture assembly provided, place both free suture ends through suture lasso loop.
2. Pull suture lasso medially transporting both suture ends until sutures are visible medial of 1st metatarsal. Manually pull sutures seating the lateral assembled oblong plate flush on the lateral cortex of the 2nd metatarsal.
3. Insert both suture ends together through one hole of the small 8mm oblong plate. Reverse path of both suture ends and pull through second hole of 8mm oblong plate.
4. Insert the suture lasso, medial to lateral in proximal second suture hole path leaving loop exposed medially. Place both suture ends through suture lasso loop.
5. Pull suture lasso laterally transporting both suture ends until sutures are visible lateral of 2nd metatarsal.
6. Separately thread one suture through each of the two most proximal bone plate holes.
7. Reduce the intermetatarsal angle to the desired biomechanical position. A reduction forcep or assistant may be helpful in maintaining the first metatarsal and second metatarsal angle while being secured.
8. Tightly secure a surgeons knot (three or more) over the oblong lateral plate. Trim suture in standard manner.
9. Close surgical site in usual fashion



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

To: The Record

From: Lynda Terry-Choyke, D.P.M., Medical Officer

FDA/CDRH/ODE/DGRND/Orthopaedic Joint Devices Branch (HFZ-410)

Date: December 1, 2008.

Device Name: HAV-LOK Bunion Correction System

Study: 510 (k) numbers: K082384

Company: Instratek, Inc.

210 Springhill Drive

Suite 130

Spring, Texas 77386.

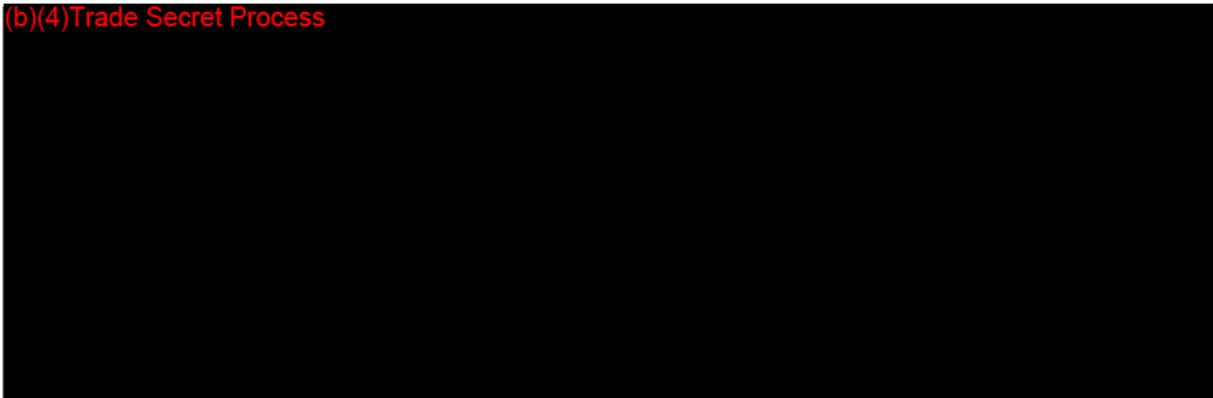
281-890-8020

Contact: Jeff Seavey

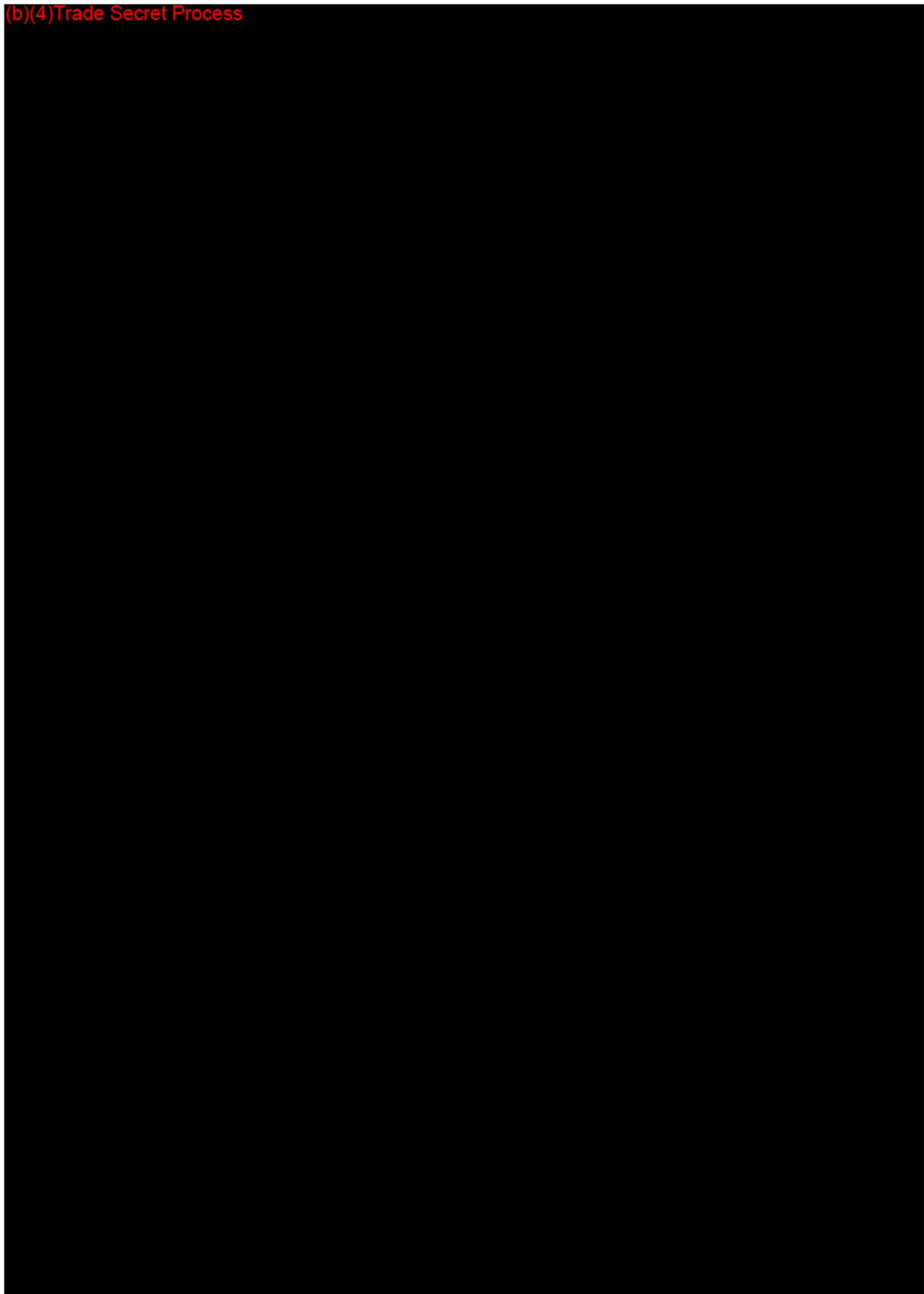
The HAV-Lok Bunion Correction System has a Class II product Classification and is a new device.

I have been asked to provide a clinical review of the surgical technique, indications for use and device design of the HAV-Lok Bunion Correction System. A review of each of these sections is provided below with deficiencies that should be provided to the sponsor.

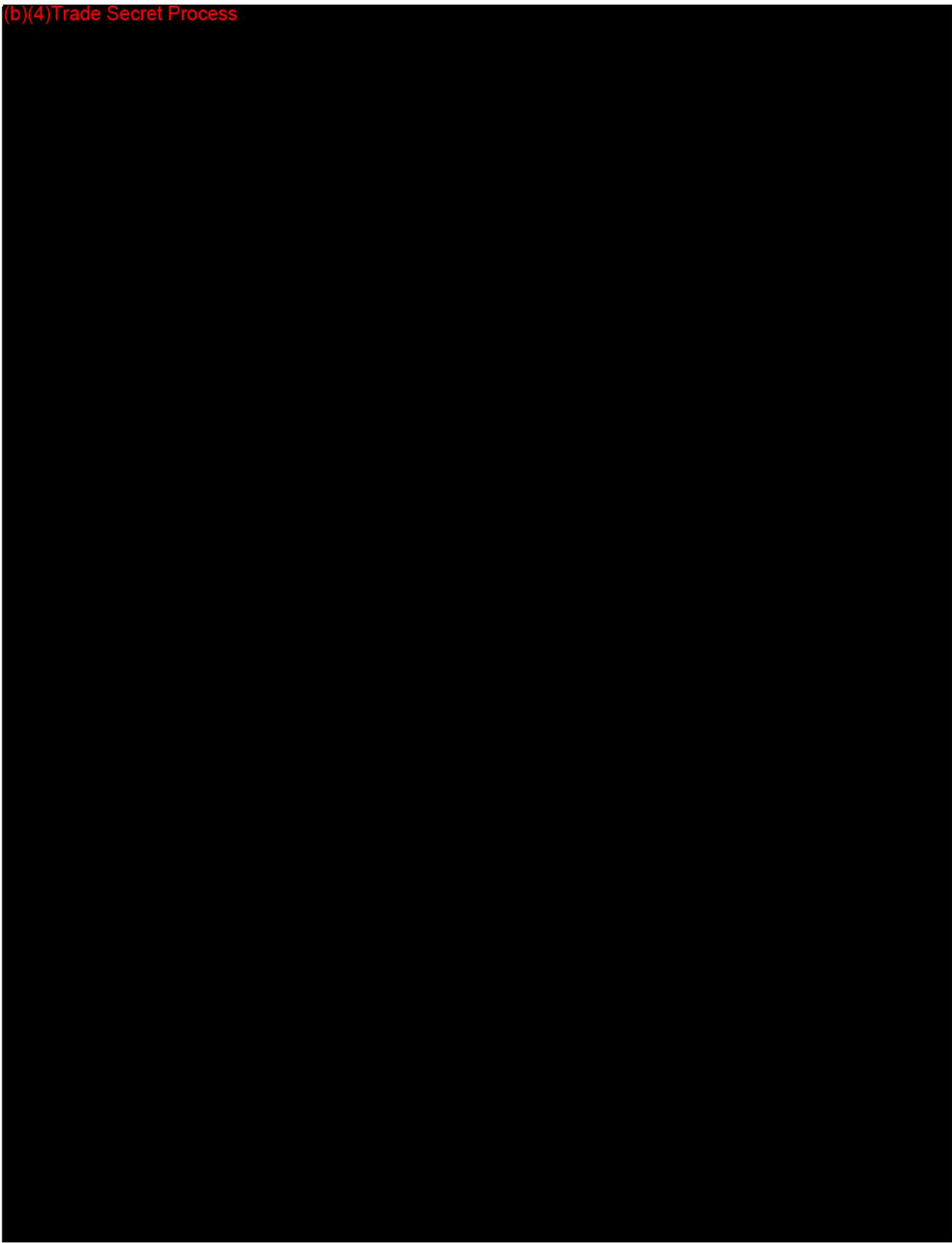
(b)(4)Trade Secret Process



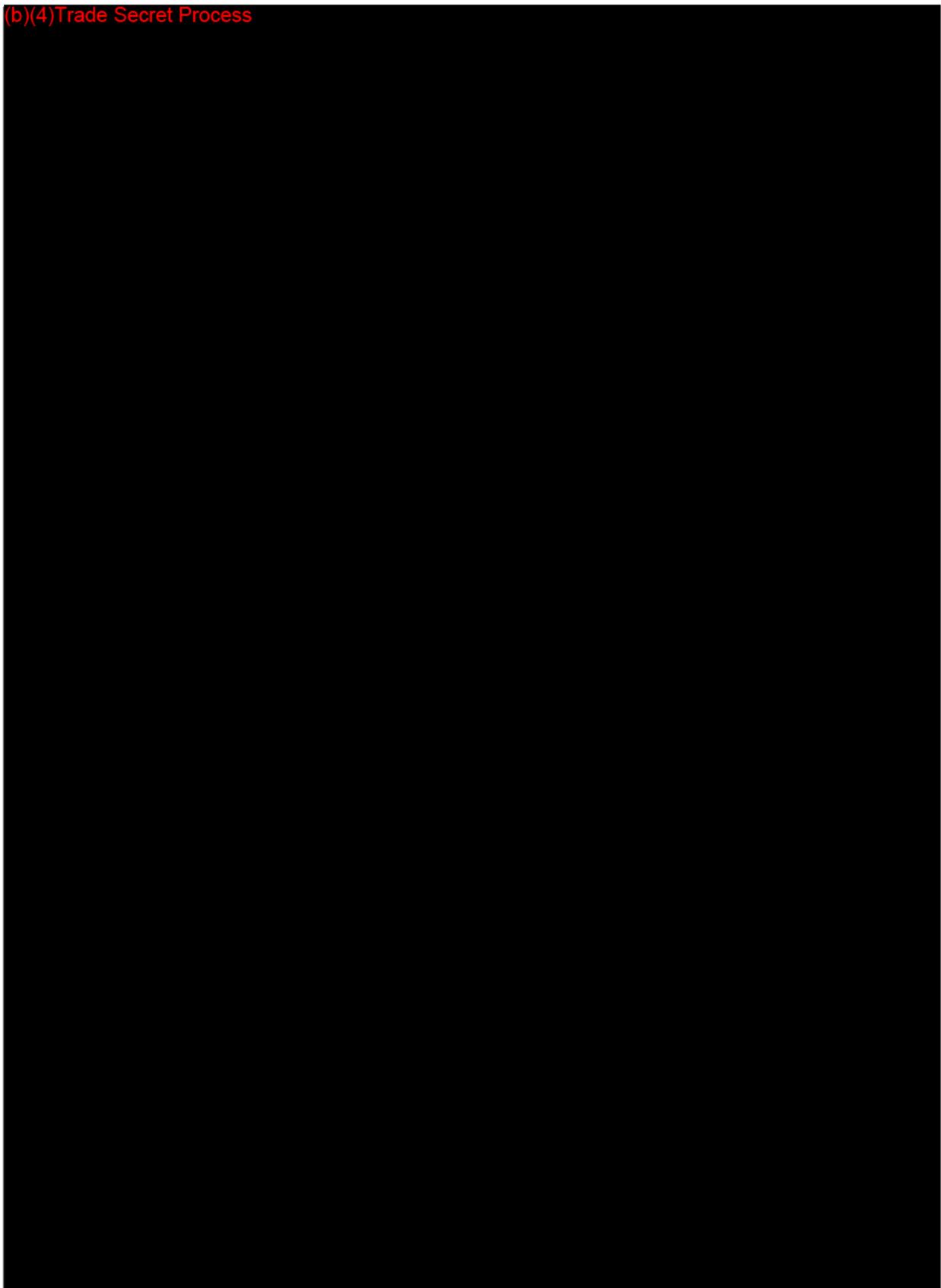
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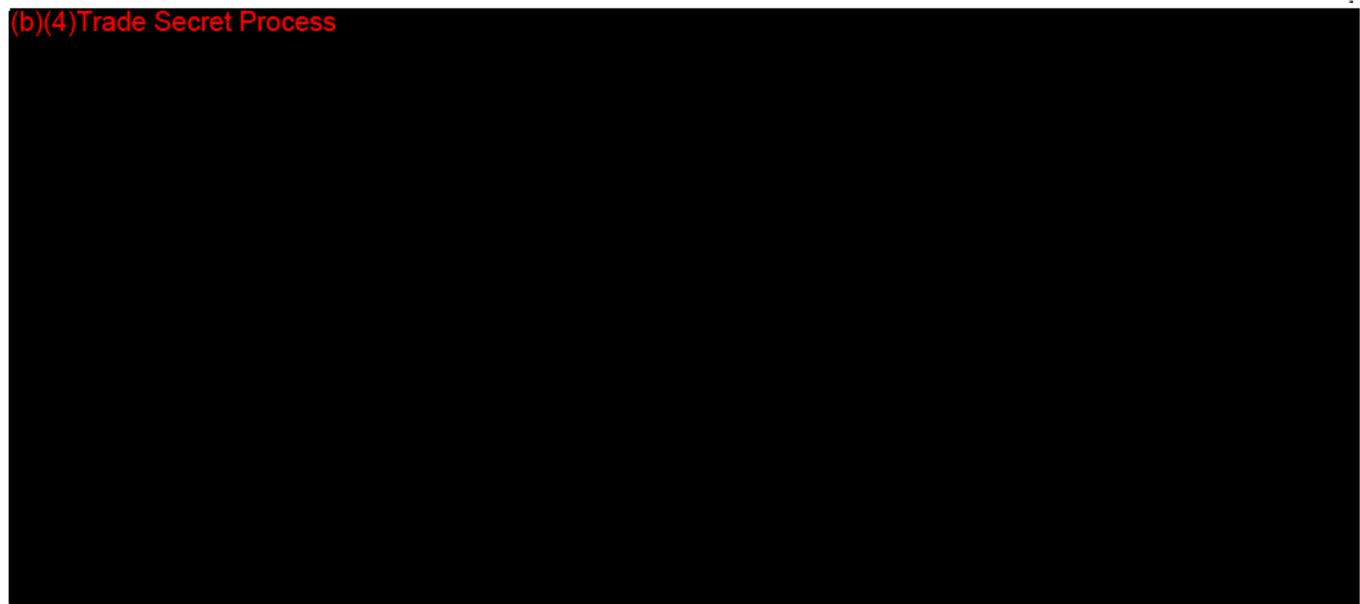
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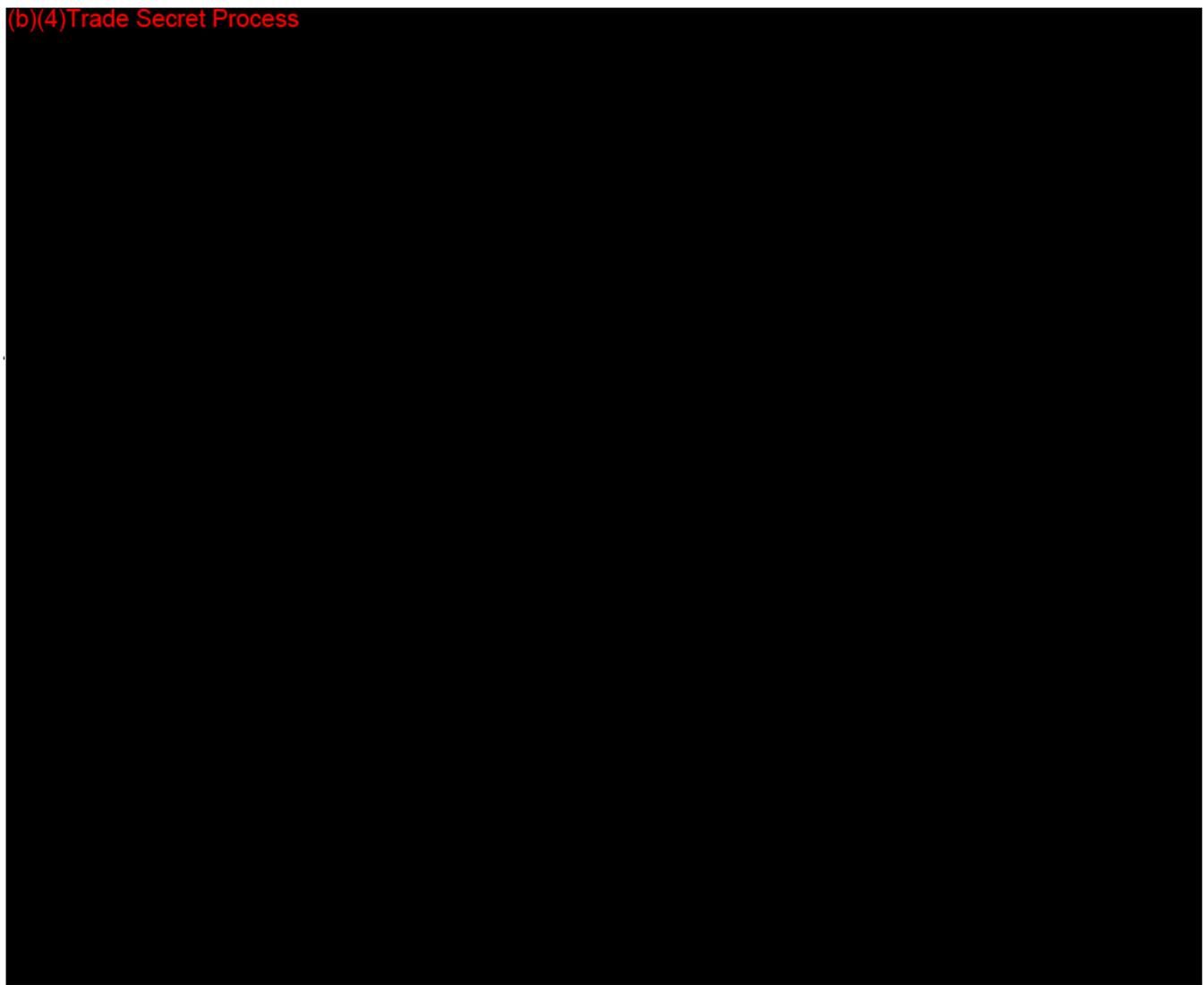


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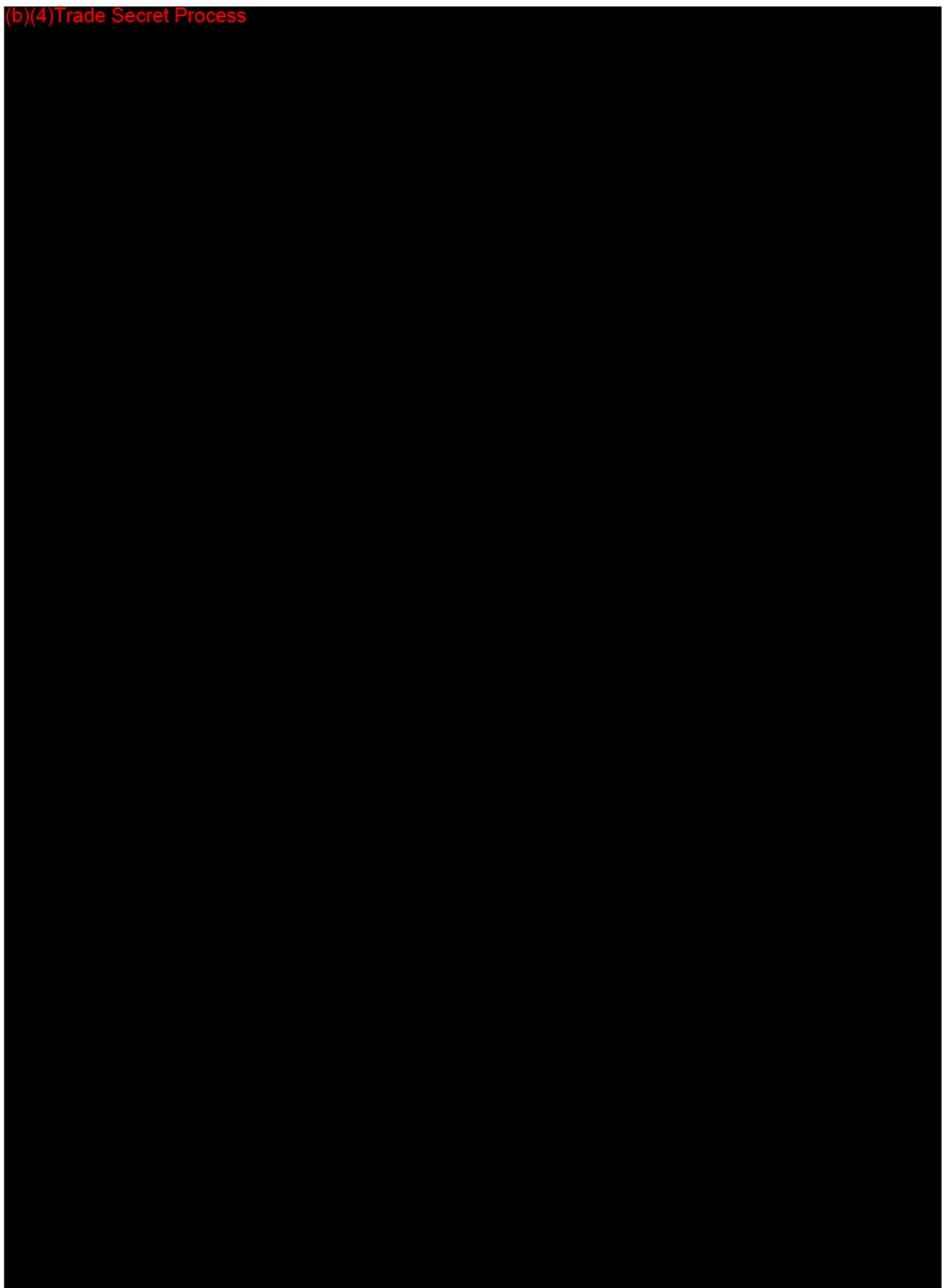


Comment: The sponsors' response is accepted.

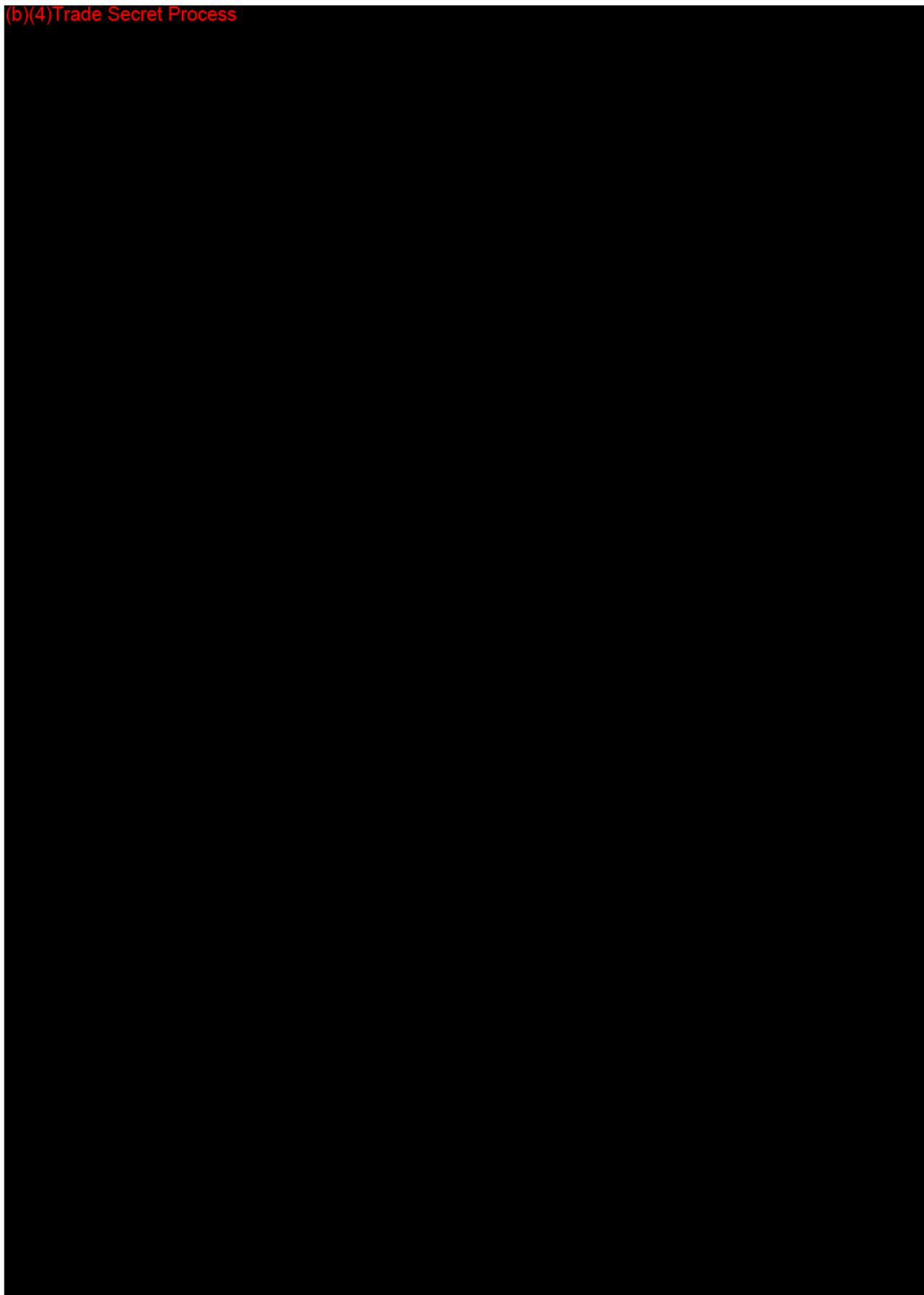
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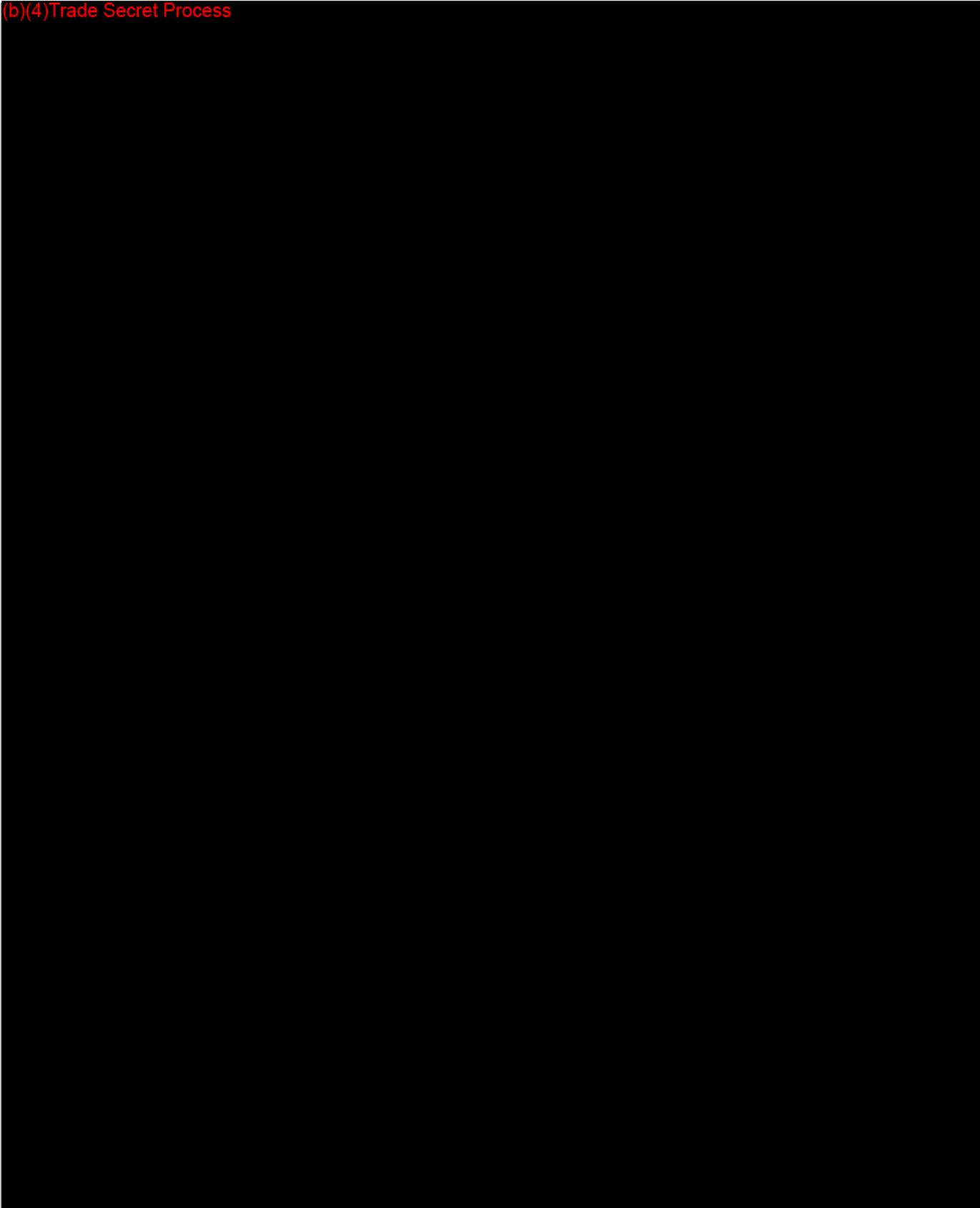
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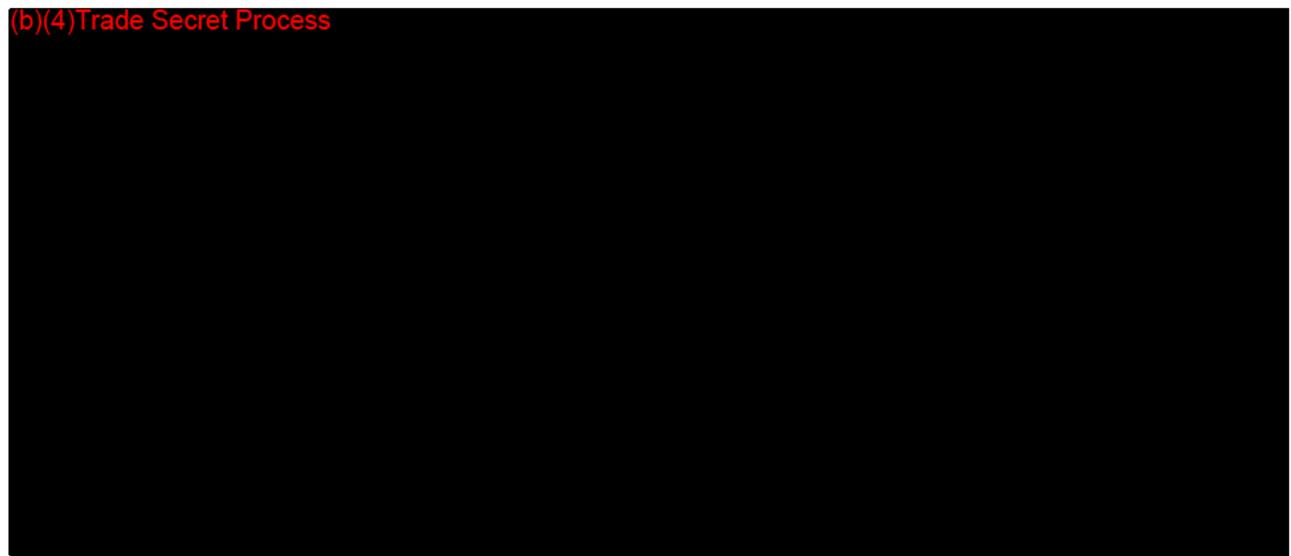
(b)(4)Trade Secret Process



(b)(4) Trade Secret Process



(b)(4) Trade Secret Process





COVER SHEET MEMORANDUM

From: Reviewer Name Tara Shepherd
Subject: 510(k) Number K082384
To: The Record

Please list CTS decision code A1

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- Hold (~~Additional Information~~ or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU		
510(k) Summary /510(k) Statement	Attach Summary		
Truthful and Accurate Statement.	Must be present for a Final Decision		
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/CO-MBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, <i>Certification with Requirements of ClinicalTrials.gov Data Bank</i> ? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			



Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

**Premarket Notification [510(k)] Review
Traditional**

K082384

Date: October 21, 2008

To: The Record

From: Tara N. Shepherd M.S. TNS 10/21/08

Office: DGRND

Division: OJDB

510(k) Holder: Instratek, Inc.

Device Name: HAV-Lok Bunion Correction System

Contact: Jeff Seavey

Phone: 281 890-8020

Fax: 281 890-8068

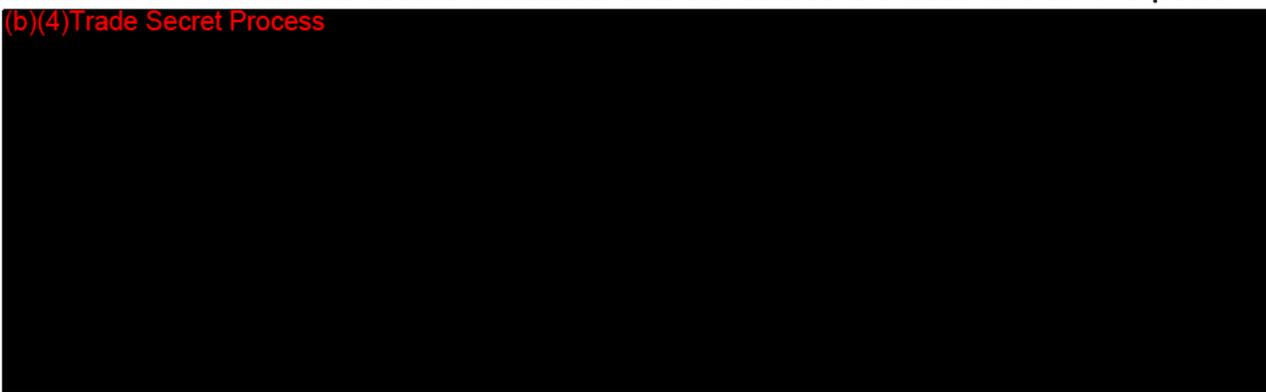
Email: jeff@instratek.com

I. Purpose and Submission Summary

The 510(k) holder would like to introduce the HAV-Lok Bunion Correction System into interstate commerce.

The HAV-Lok Kit is designed to assist in the reduction and control of increased pathologic intermetatarsal angles. To achieve reduction of intermetatarsal angles, two suture paths are drilled through the first and second metatarsals. The oblong plates are positioned on the outside of the first and second metatarsal and the sutures are used to draw the plates

(b)(4)Trade Secret Process



II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form		X	

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III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?	X		
Does the device design use software?		X	
Is the device sterile?	X		
Is the device reusable (not reprocessed single use)?		X	
Are "cleaning" instructions included for the end user?		X	

The Instratek HAV-Lok Bunion Correction System is intended to assist in the biomechanical reduction of abnormal intermetatarsal angle.

The HAV-Lok Kit is designed to assist in the reduction and control of increased pathologic intermetatarsal angles. HAV-Lok may eliminate the necessity of a traditional osteotomy in the correction of hallux valgus deformities within the indicated criteria. The implanted device consists of three components:

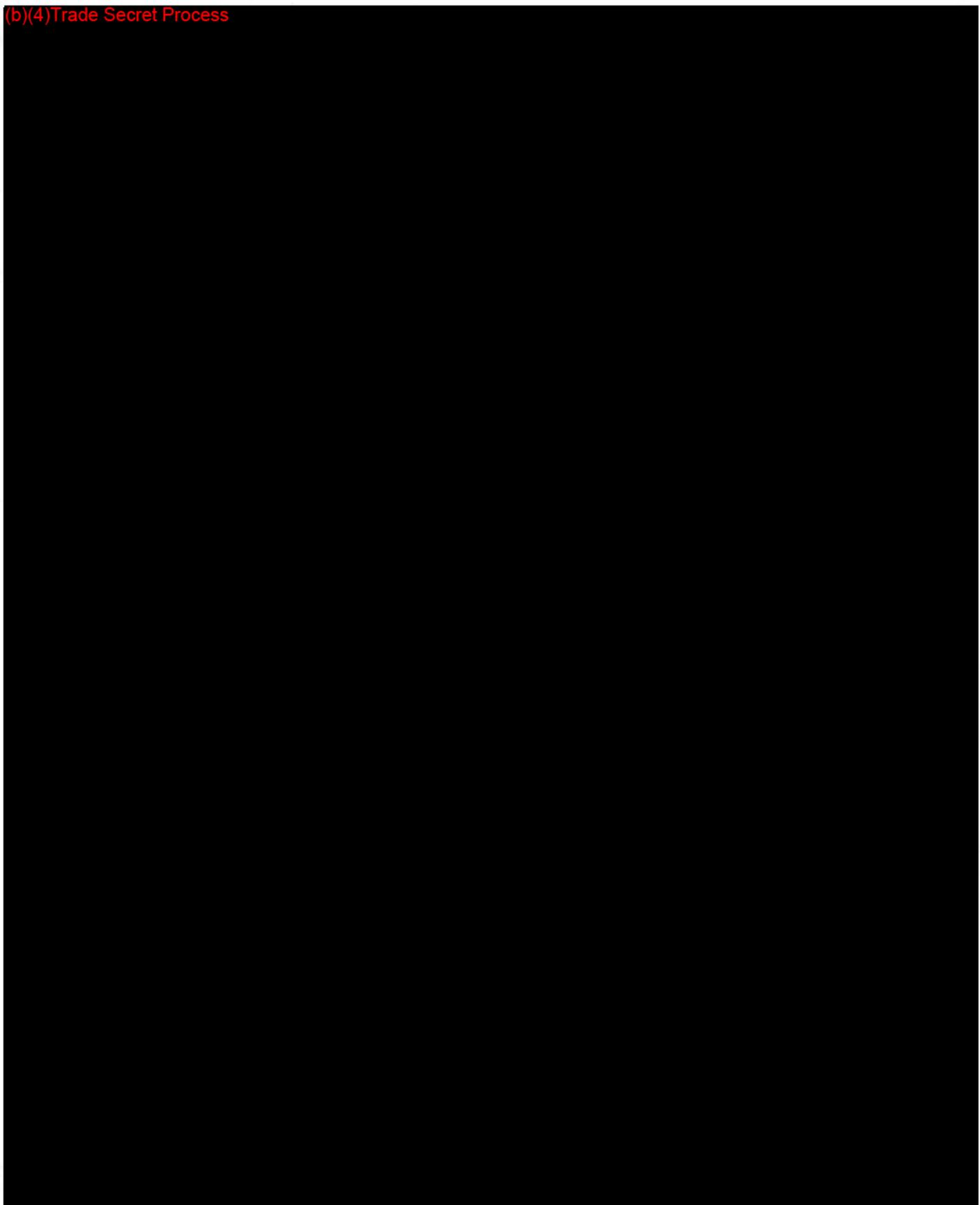
- medial oblong plate (Ti-6Al-4V, ASTM F132-02a),
- lateral oblong plate (Ti-6Al-4V, ASTM F132-02a),
- #3/4 suture (UHMWPE, K033654, K04072, K063778).

There are four accessories required to implant the device:

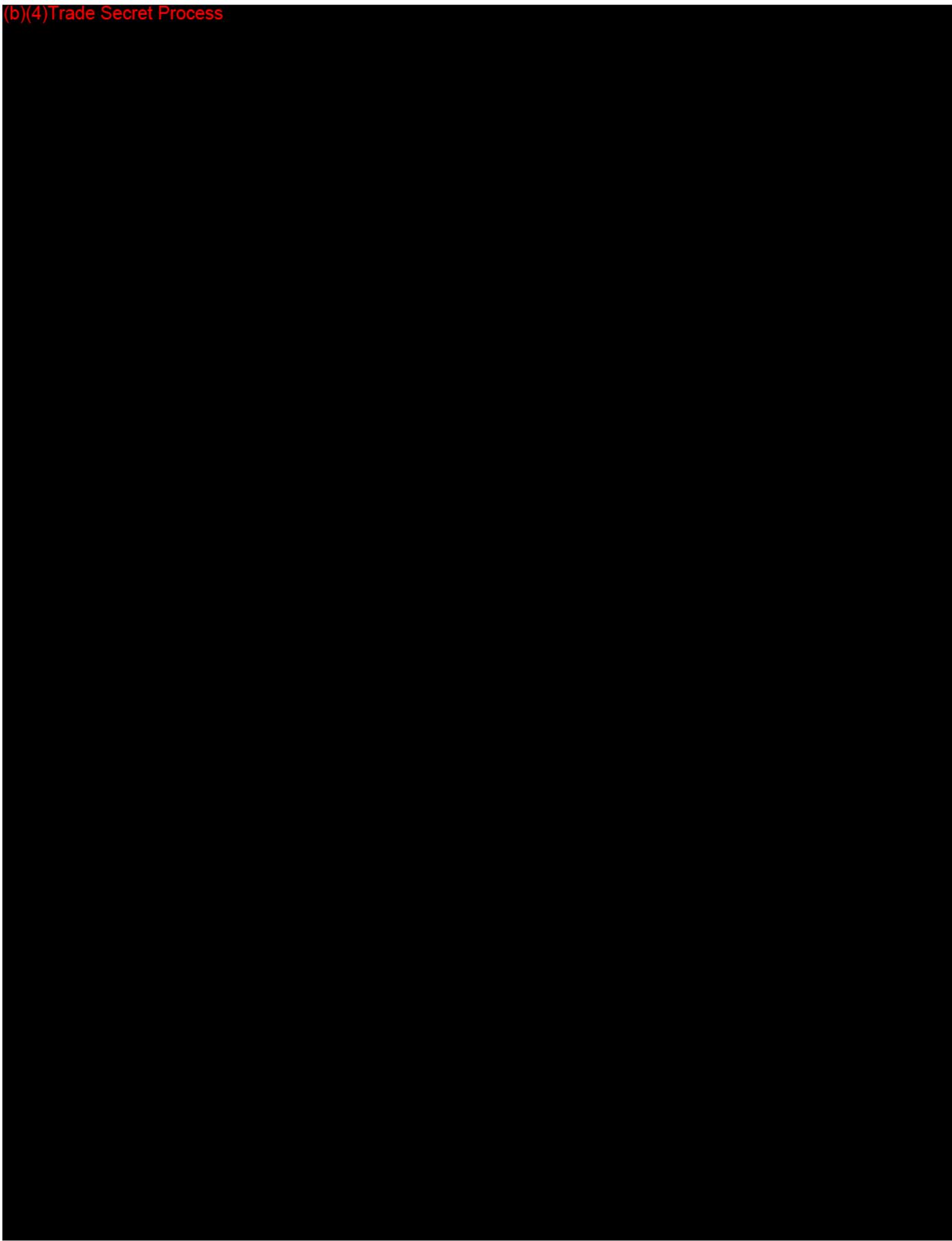
- Suture lasso (Stainless Steel)
- K-wire (316 Stainless Steel, ASTM F138, K903264)
- Cannulated Drill Bit (17-4 Stainless Steel)
- Drill Guide (420 Stainless Steel, DIN 1.4021)

To achieve reduction of intermetatarsal angles, two suture paths are drilled through the first and second metatarsals. The oblong plates are positioned on the outside of the first and second metatarsal and the sutures are used to draw the plates together thereby reducing the intermetatarsal angle.

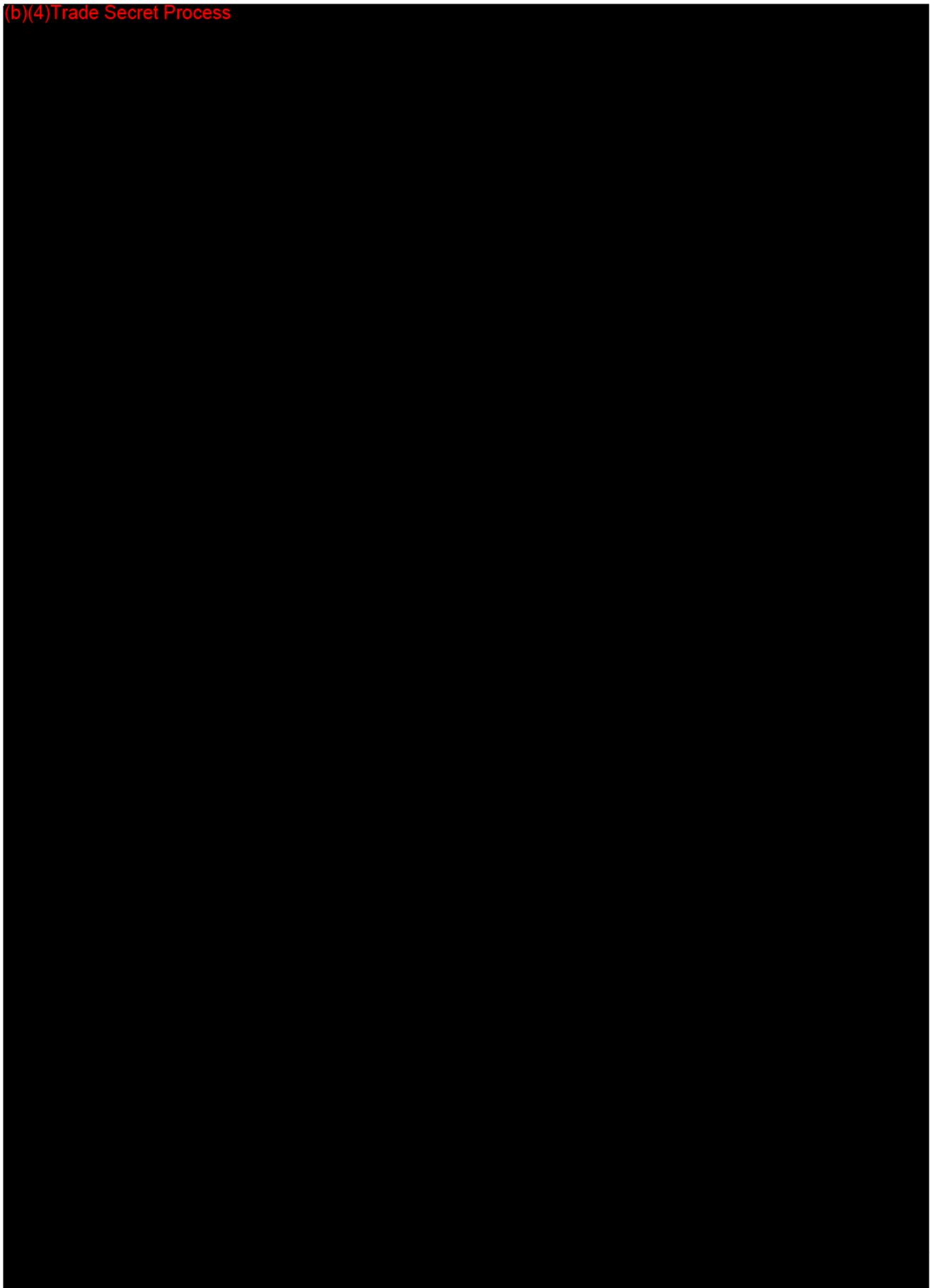
(b)(4) Trade Secret Process



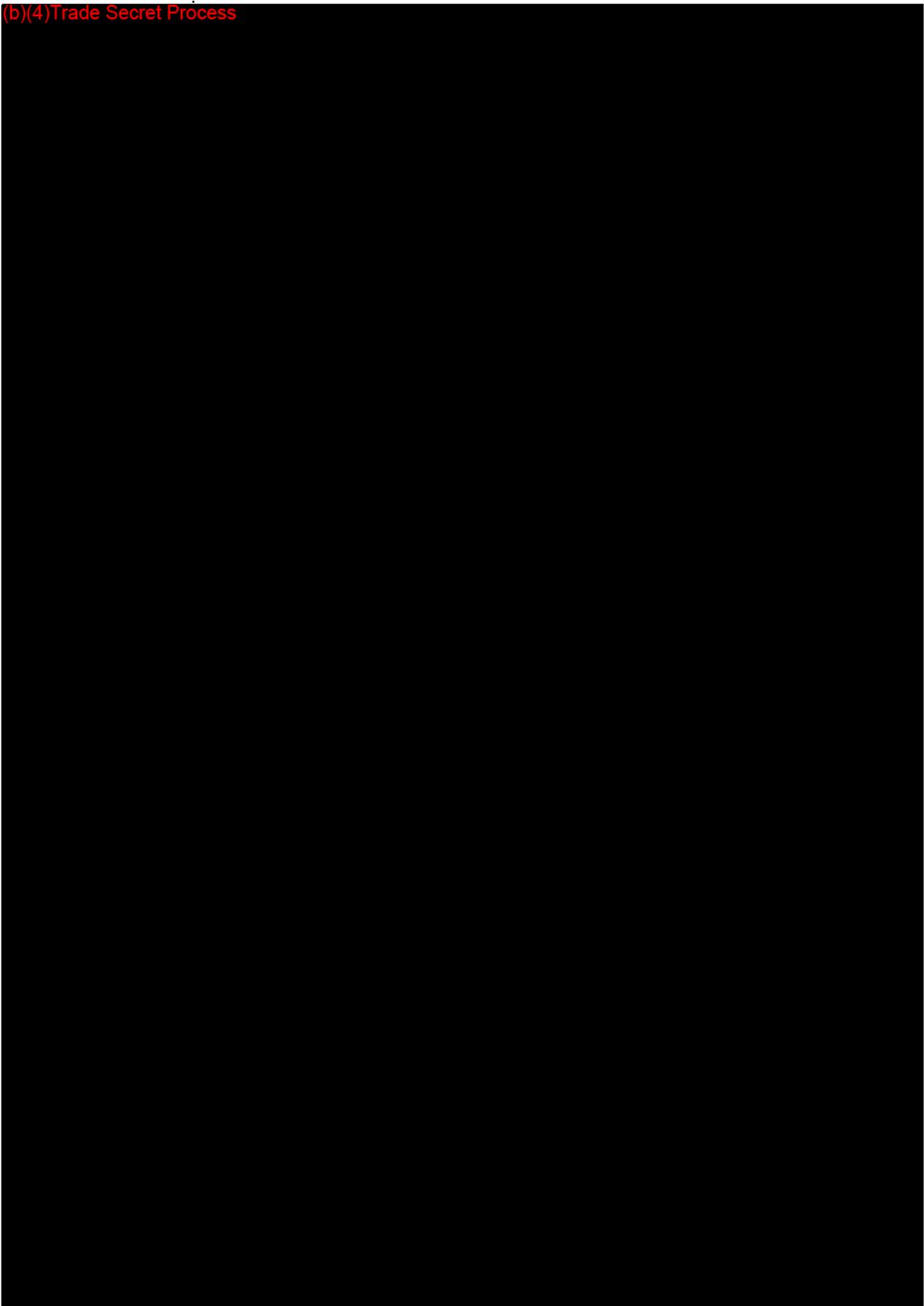
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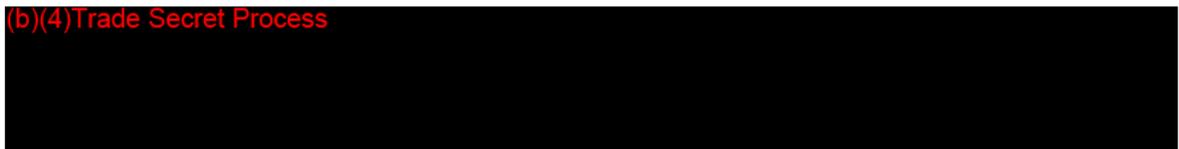
(b)(4) Trade Secret Process



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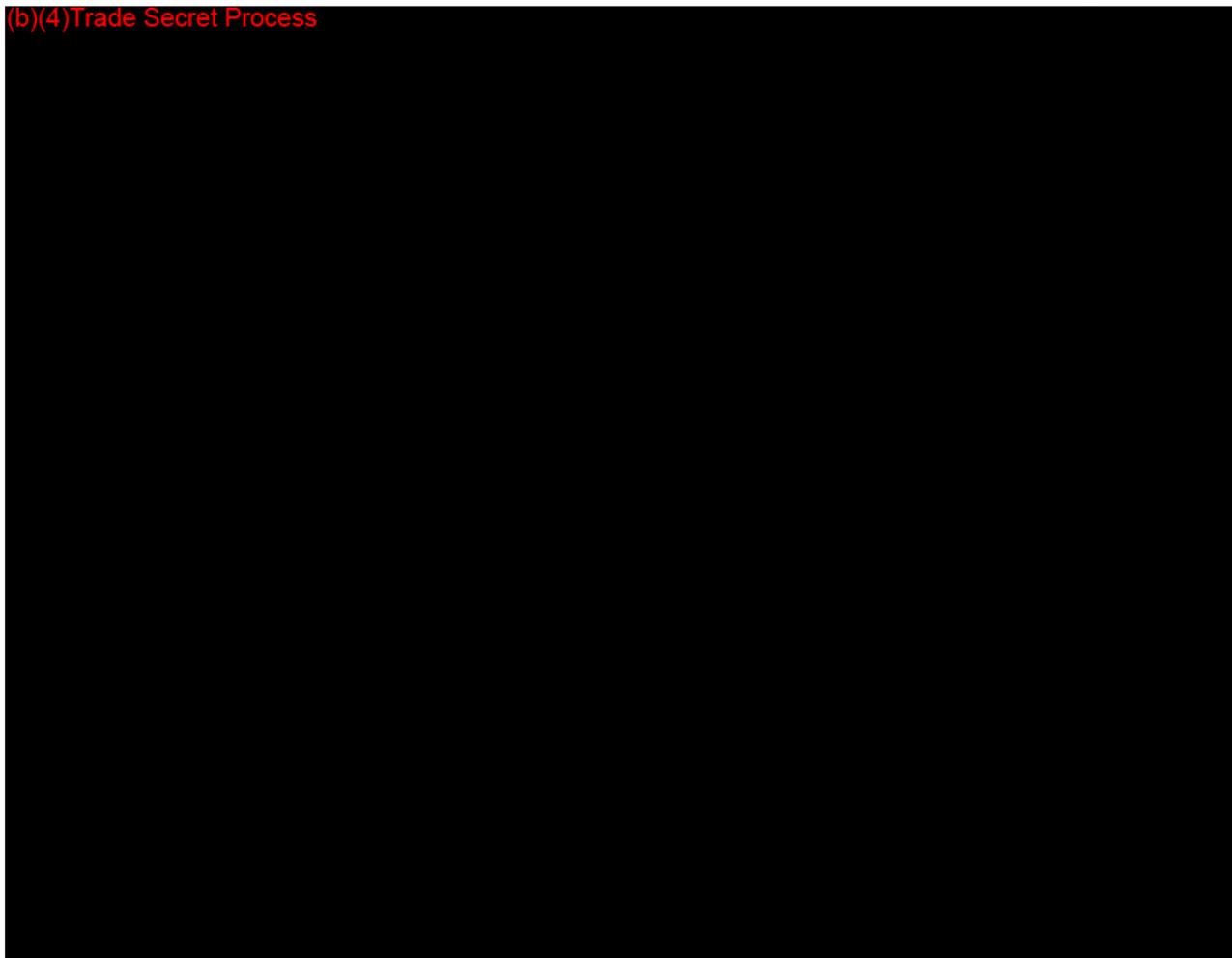


IV. Indications for Use

The Instratek HAV-Lok Bunion Correction System is intended for the following surgical indication:

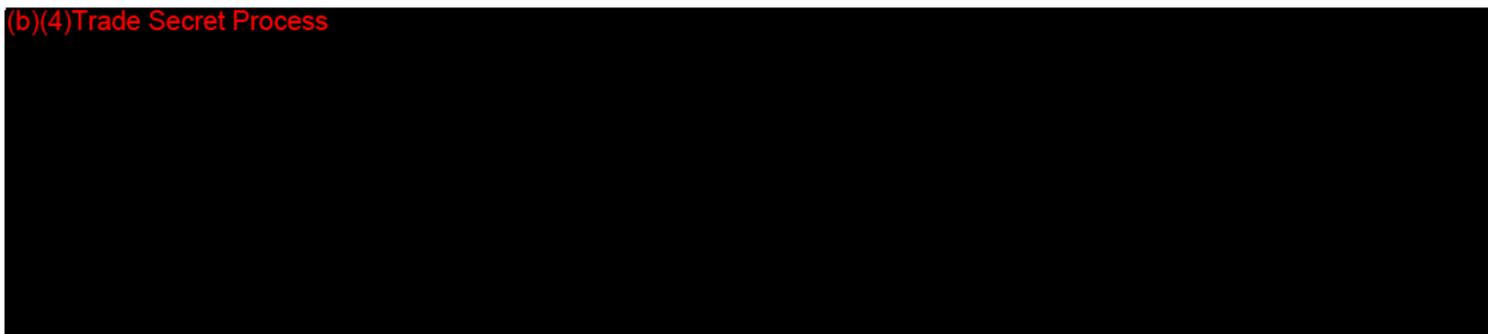
- To assist in the biomechanical reduction of abnormal intermetatarsal angle.

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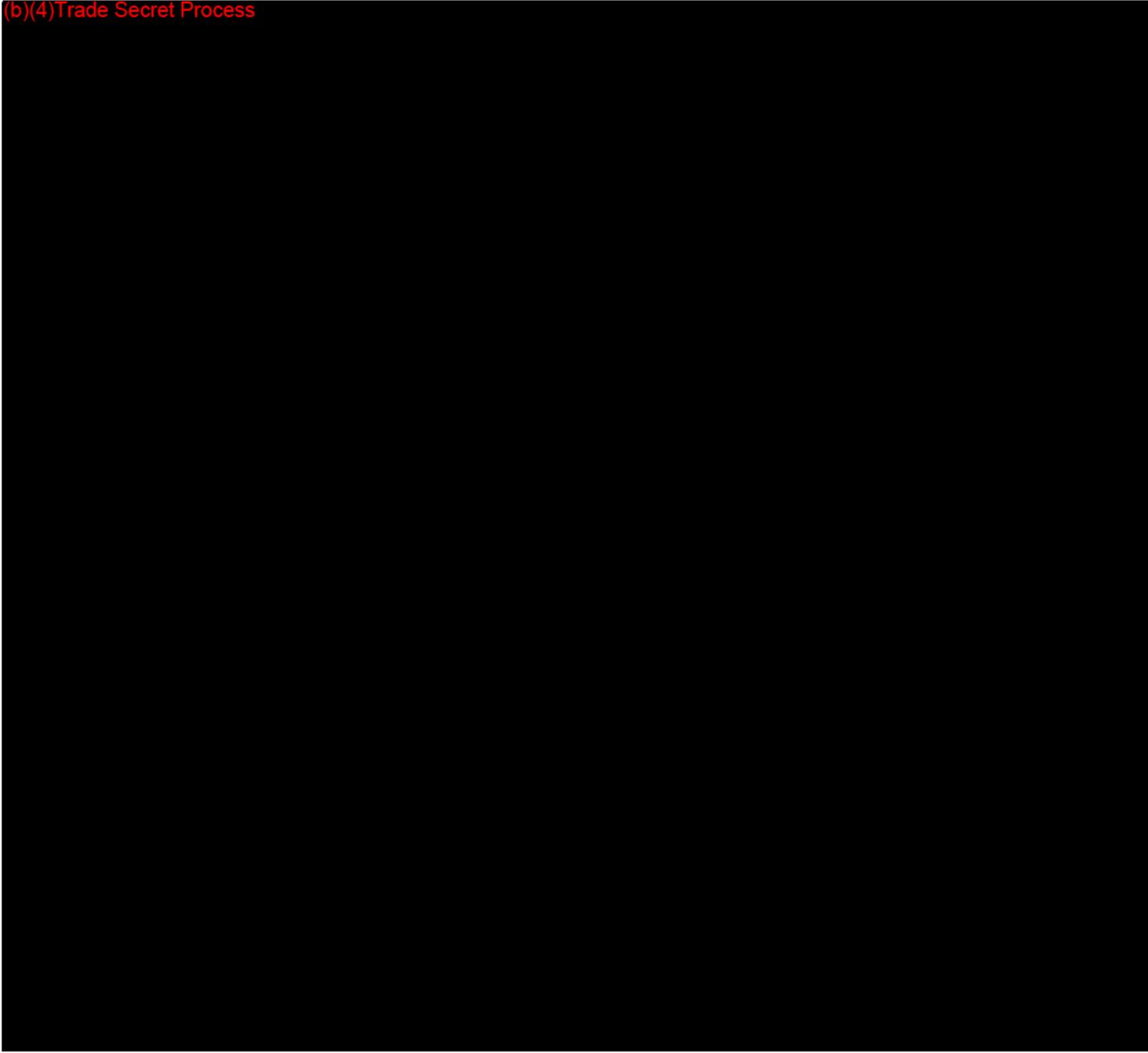


V. Predicate Device Comparison

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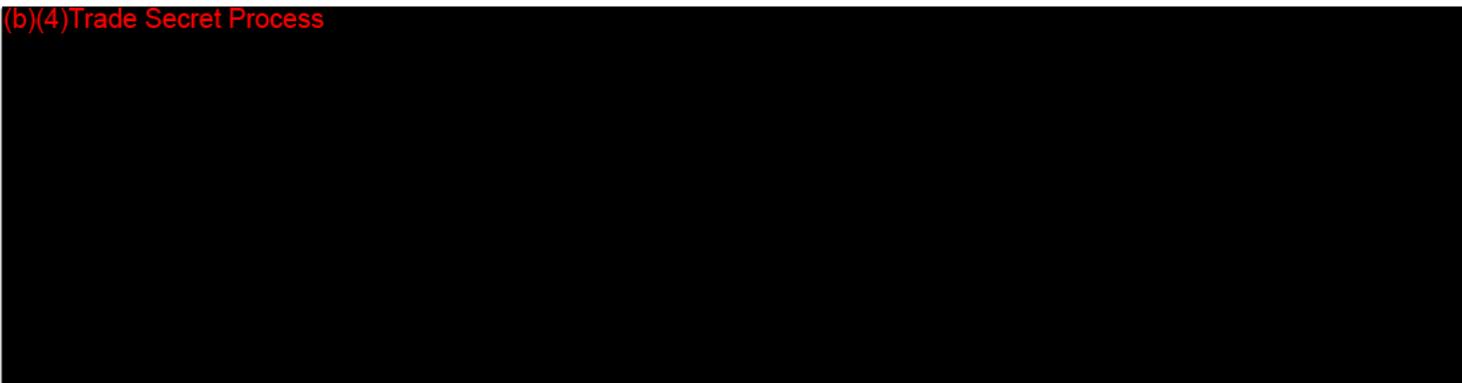


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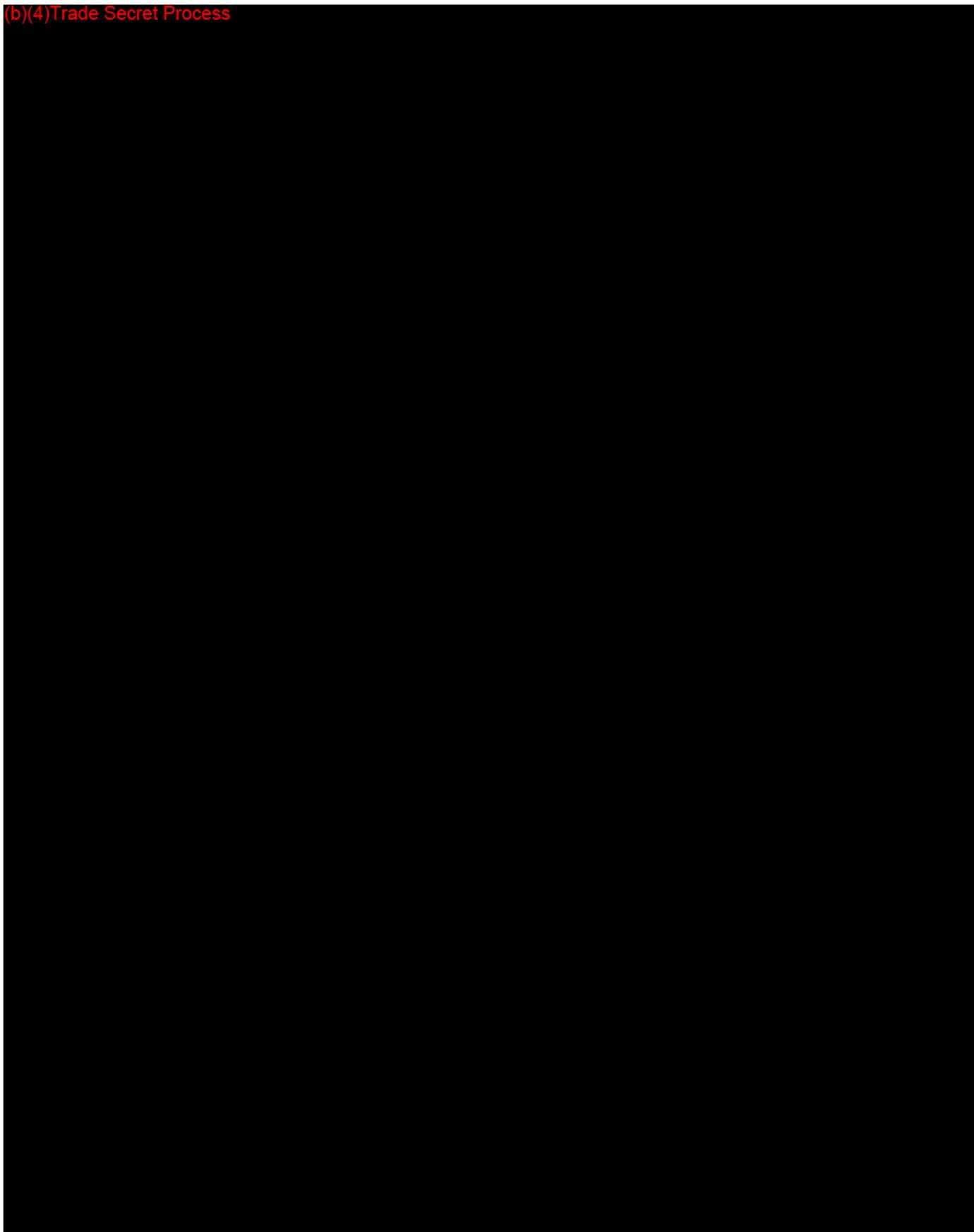


VI. Labeling

(b)(4)Trade Secret Process



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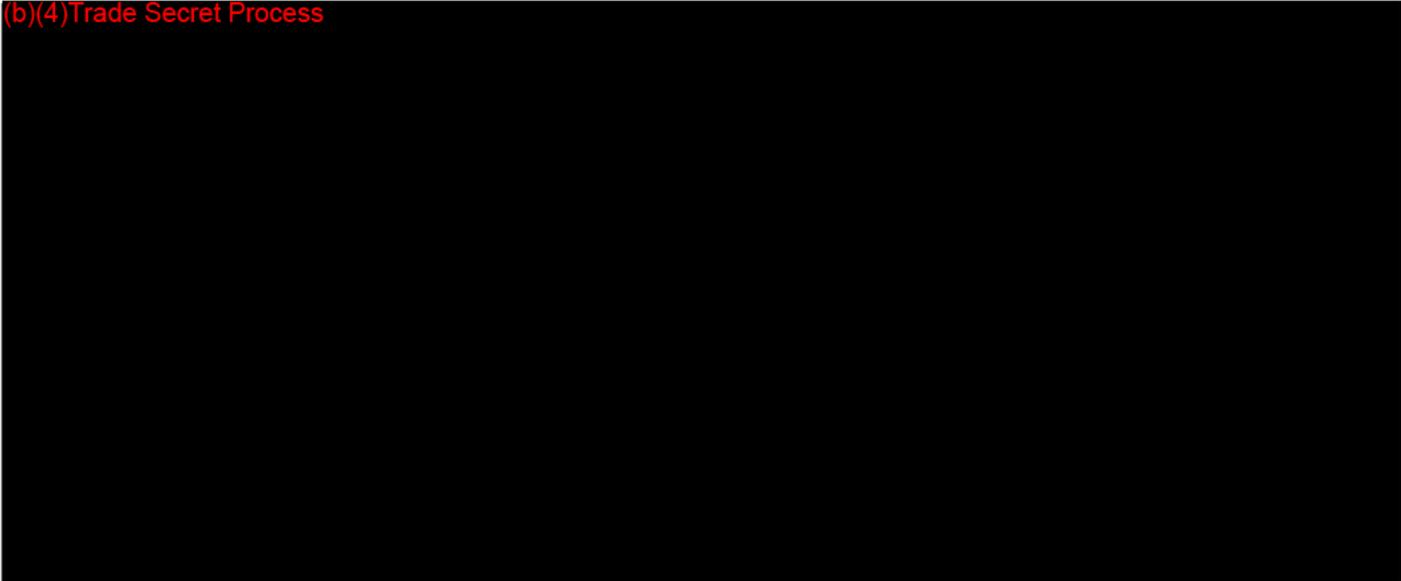


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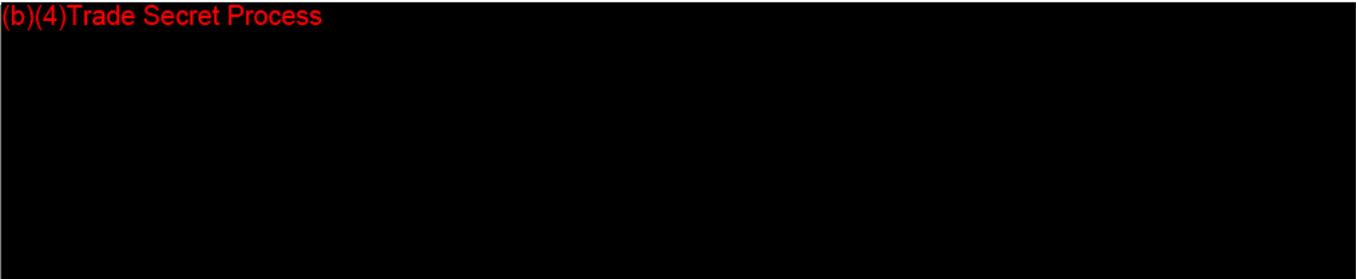
VII. Sterilization/Shelf Life/Reuse

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VIII. Biocompatibility

(b)(4)Trade Secret Process



IX. Software

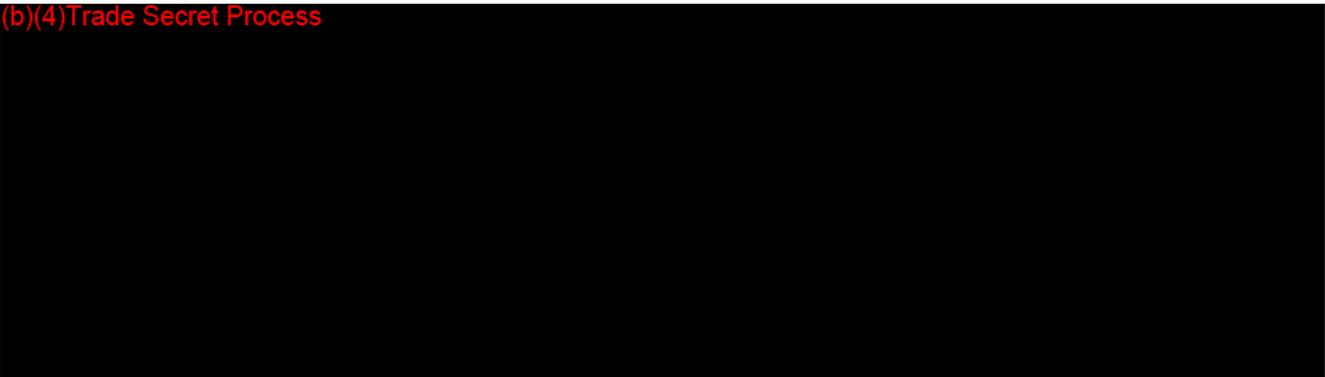
N/A

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

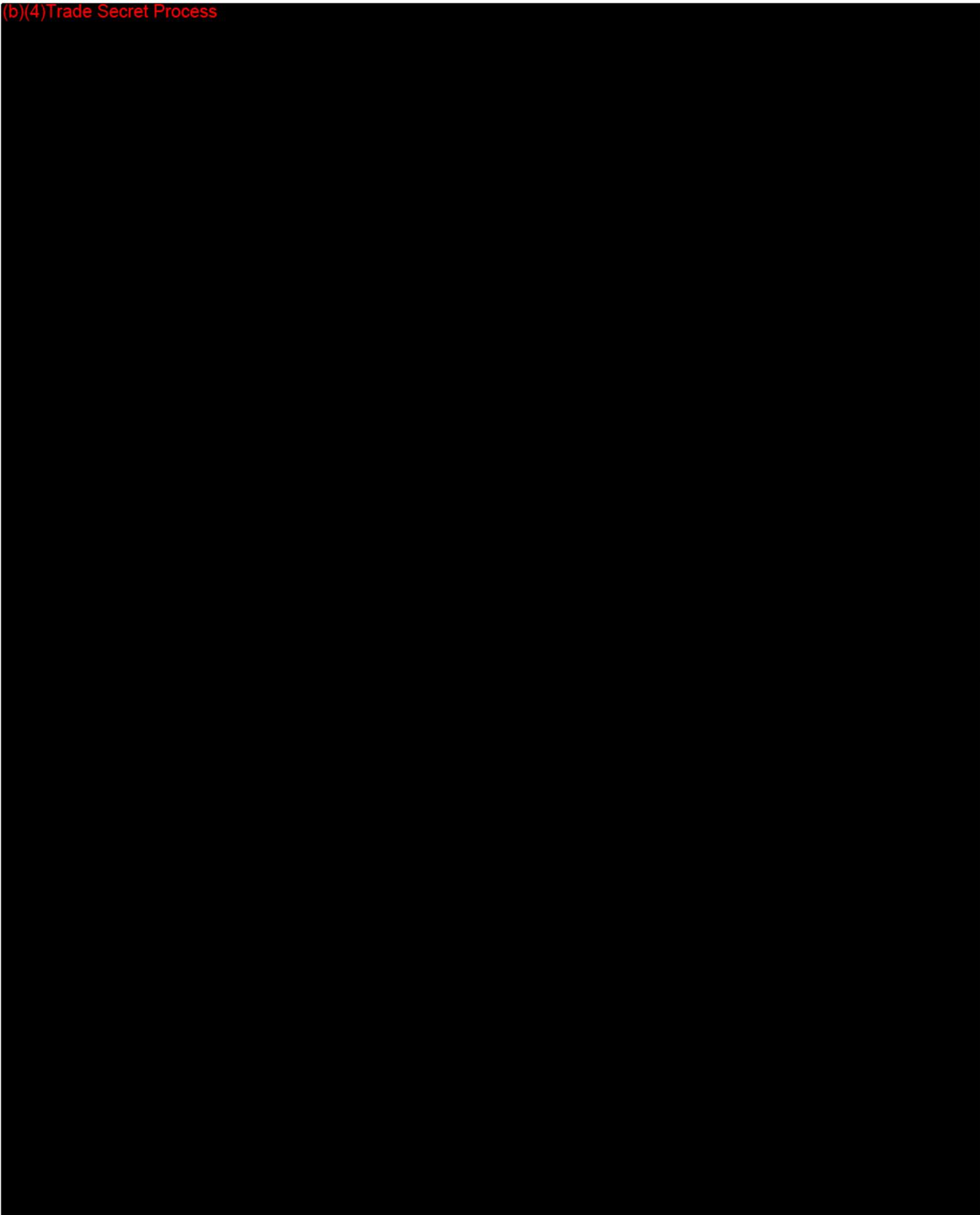
N/A

XI. Performance Testing – Bench

(b)(4)Trade Secret Process



(b)(4)Trade Secret Process



(b)(4)Trade Secret Process

XII. Performance Testing – Animal

N/A

XIII. Performance Testing – Clinical

N/A

XIV. Substantial Equivalence Discussion

	Yes	No
1. Same Indication Statement?		X If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		X If YES = Stop NSE
3. Same Technological Characteristics?	X	If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		X If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?		If YES = Stop NSE
7. Accepted Scientific Methods Exist?		If NO = Stop NSE
8. Performance Data Available?		X If NO = Request Data
9. Data Demonstrate Equivalence?		Final Decision: AI

1. Explain how the new indication differs from the predicate device's indication:

(b)(4)Trade Secret Process

2. Explain why there is or is not a new effect or safety or effectiveness issue:

(b)(4)Trade Secret Process

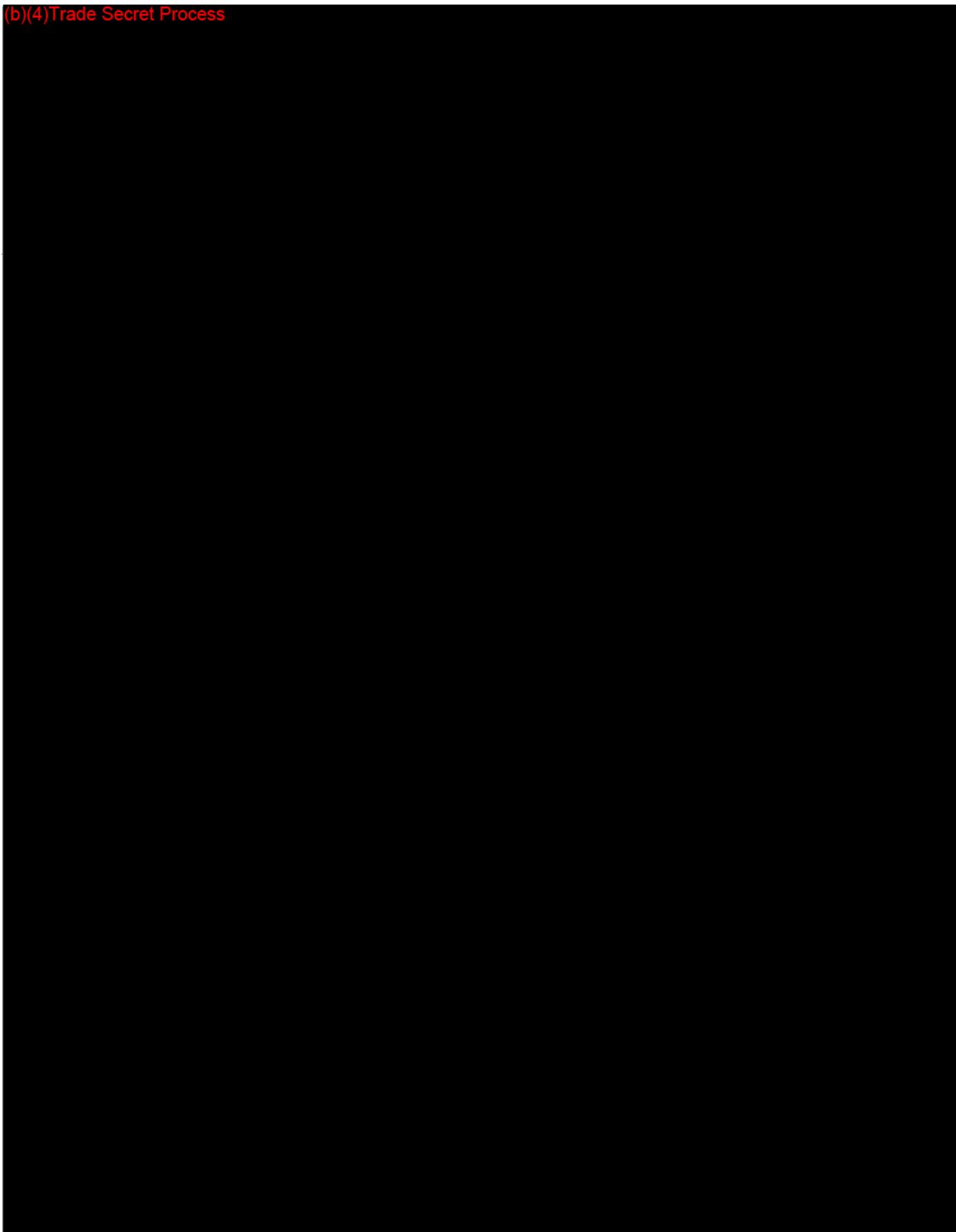
5. Explain how descriptive characteristics are not precise enough:

(b)(4)Trade Secret Process

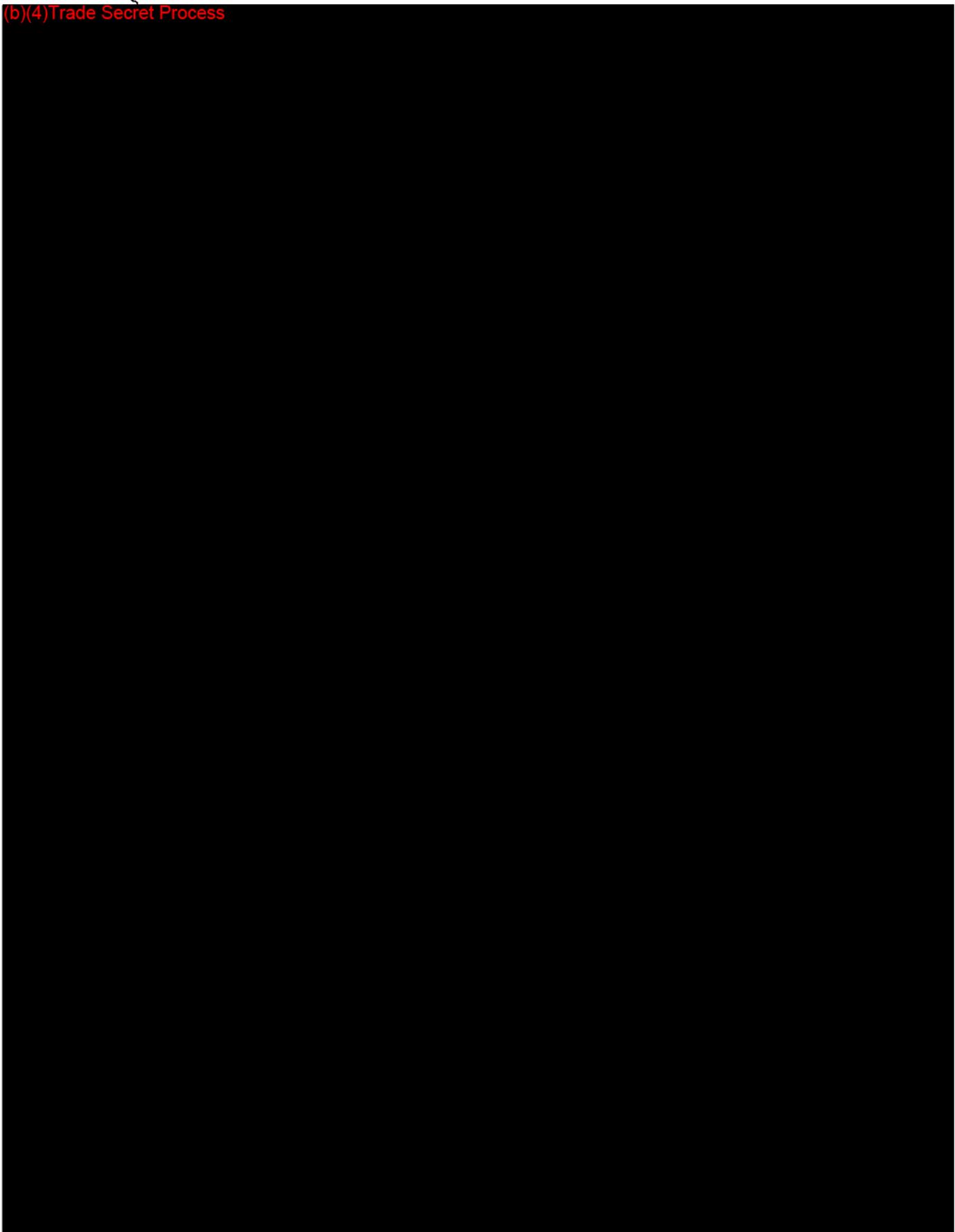
8. Explain what performance data is needed:

(b)(4)Trade Secret Process

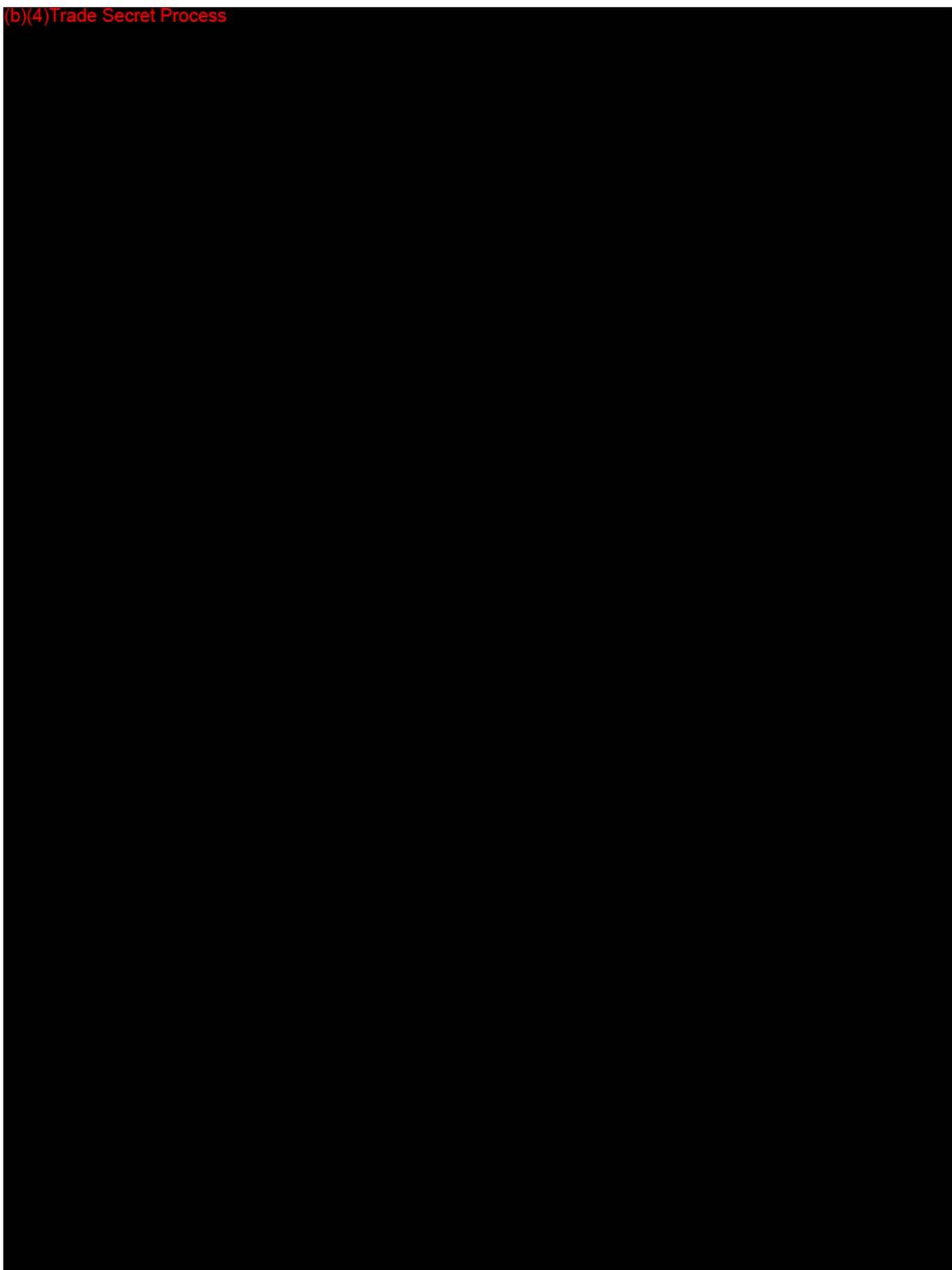
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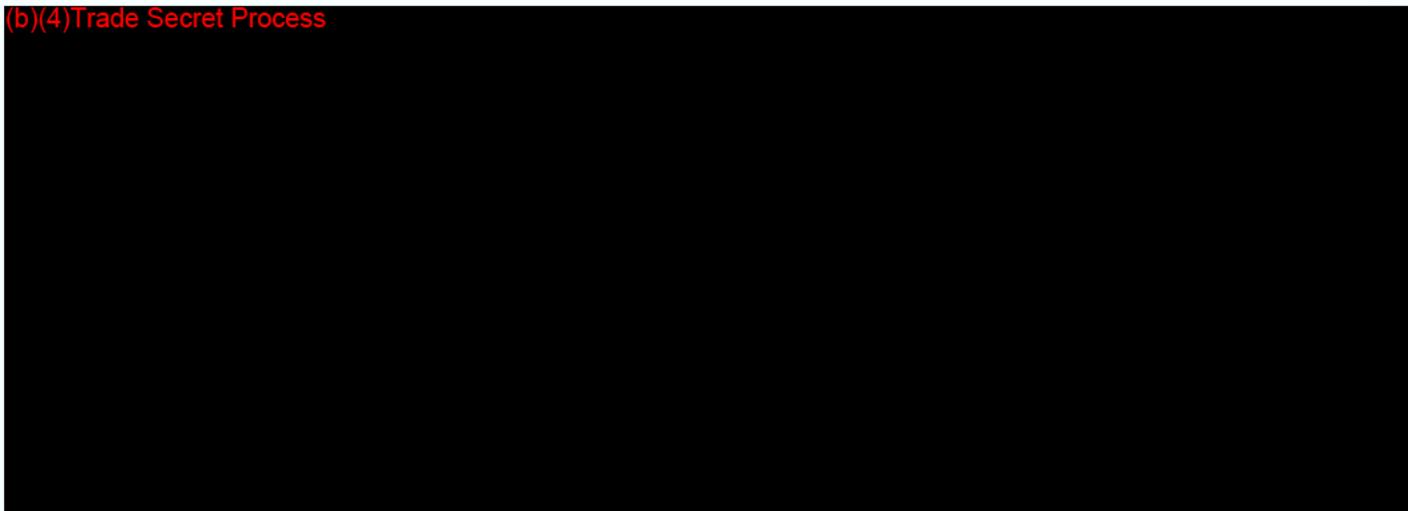


(b)(4) Trade Secret Process



(b)(4) Trade Secret Process





XVI. Contact History

None

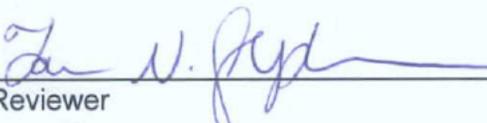
XVII. Recommendation

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: Class II

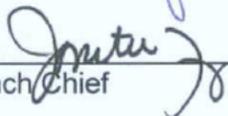
Product Code: HTN



Reviewer

10/21/08

Date



Branch Chief

10/22/08

Date



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

To: The Record

From: Lynda Terry-Choyke, D.P.M., Medical Officer

FDA/CDRH/ODE/DGRND/Orthopaedic Joint Devices Branch (HFZ-410)

Date: October 20, 2008.

Device Name: HAV-LOK Bunion Correction System

Study: 510 (k) numbers: K082384

Company: Instratek, Inc.

210 Springhill Drive

Suite 130

Spring, Texas 77386.

281-890-8020

Contact: Jeff Seavey

The HAV-Lok Bunion Correction System has a Class II product Classification and is a new device.

I have been asked to provide a clinical review of the surgical technique, indications for use and device design of the HAV-Lok Bunion Correction System. A review of each of these sections is provided below with deficiencies that should be provided to the sponsor.

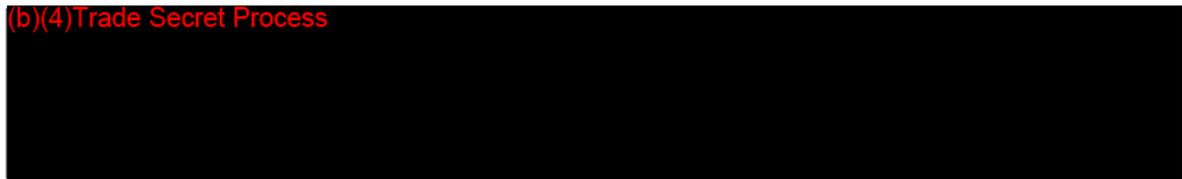
Indications for Use:

The Instratek HAV-LOK Bunion Correction System is intended for the following surgical indication: to assist in the biomechanical reduction of abnormal intermetatarsal angle. This device may eliminate the necessity of a traditional osteotomy in the correction of Hallux Valgus deformities within the indicated criteria.

(b)(4)Trade Secret Process

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(b)(4)Trade Secret Process



Device Description:

The implanted device consists of three (3) components:

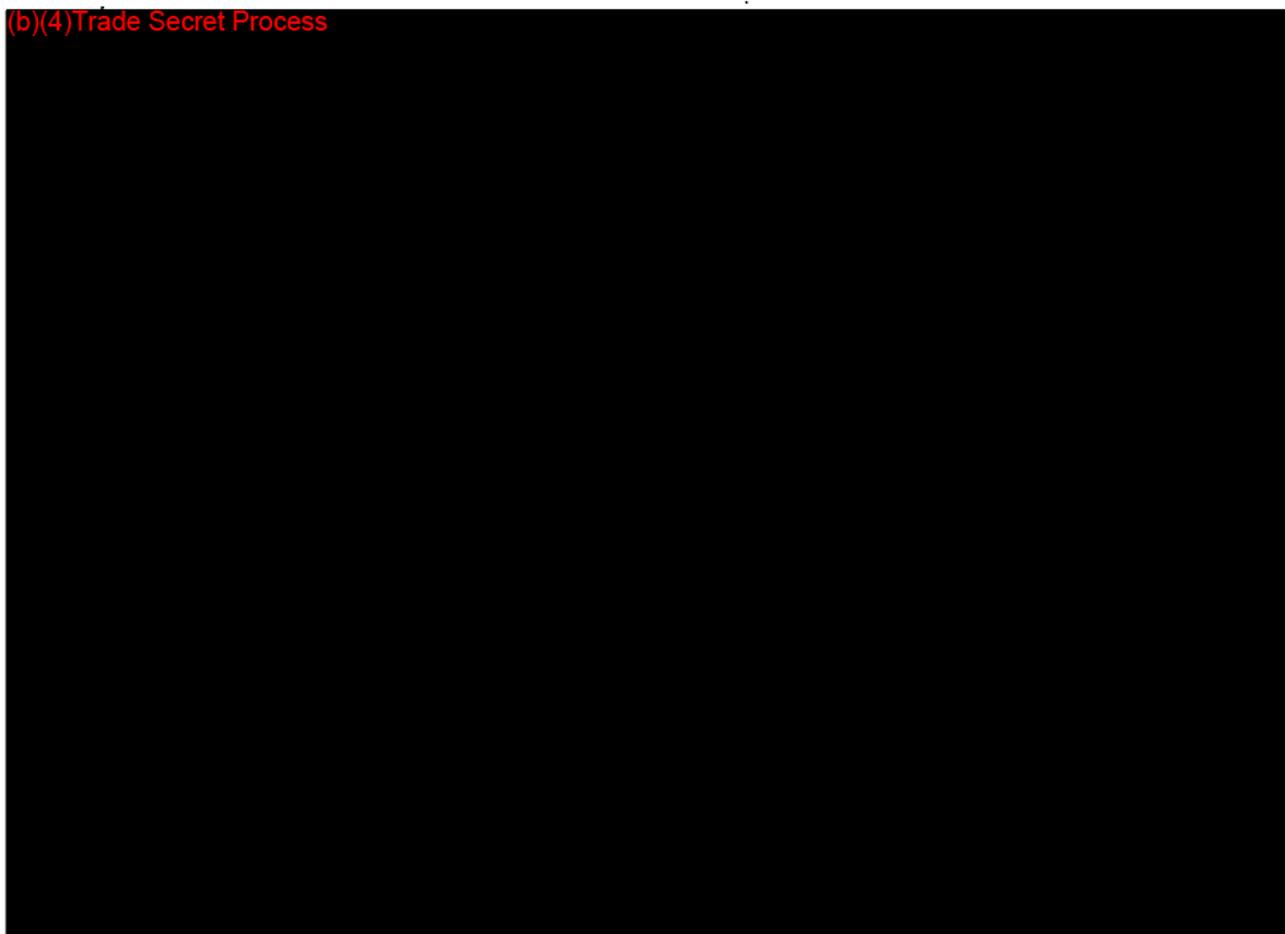
1. Medial oblong plate
2. Lateral oblong plate and
3. #3/4 suture

There are four (4) accessories required to implant the device:

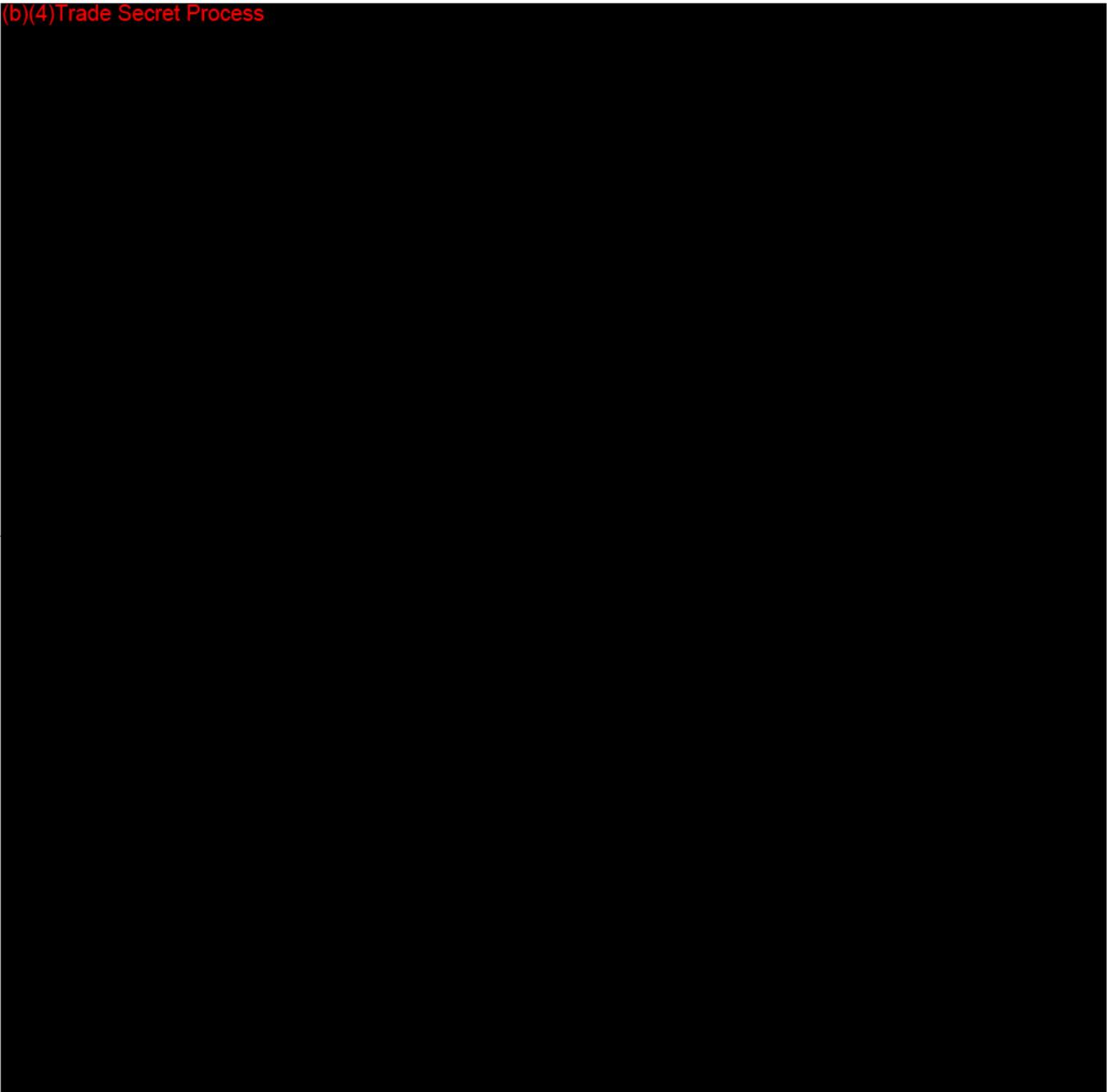
1. Suture lasso
2. K-wire
3. Cannulated Drill Bit and
4. Drill Guide.

To achieve reduction of intermetatarsal angles, two suture paths are drilled through the first and second metatarsals. The oblong plates are positioned on the outside of the first and second metatarsals and the sutures are used to draw the plates together thereby reducing the intermetatarsal angle.

(b)(4)Trade Secret Process



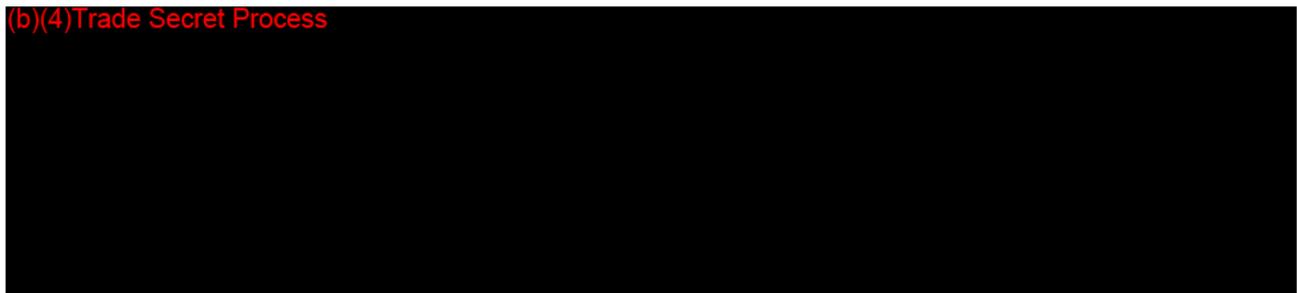
(b)(4)Trade Secret Process



Technological Characteristics:

You have stated that the technological characteristic between the predicate and proposed device are the same.

(b)(4)Trade Secret Process

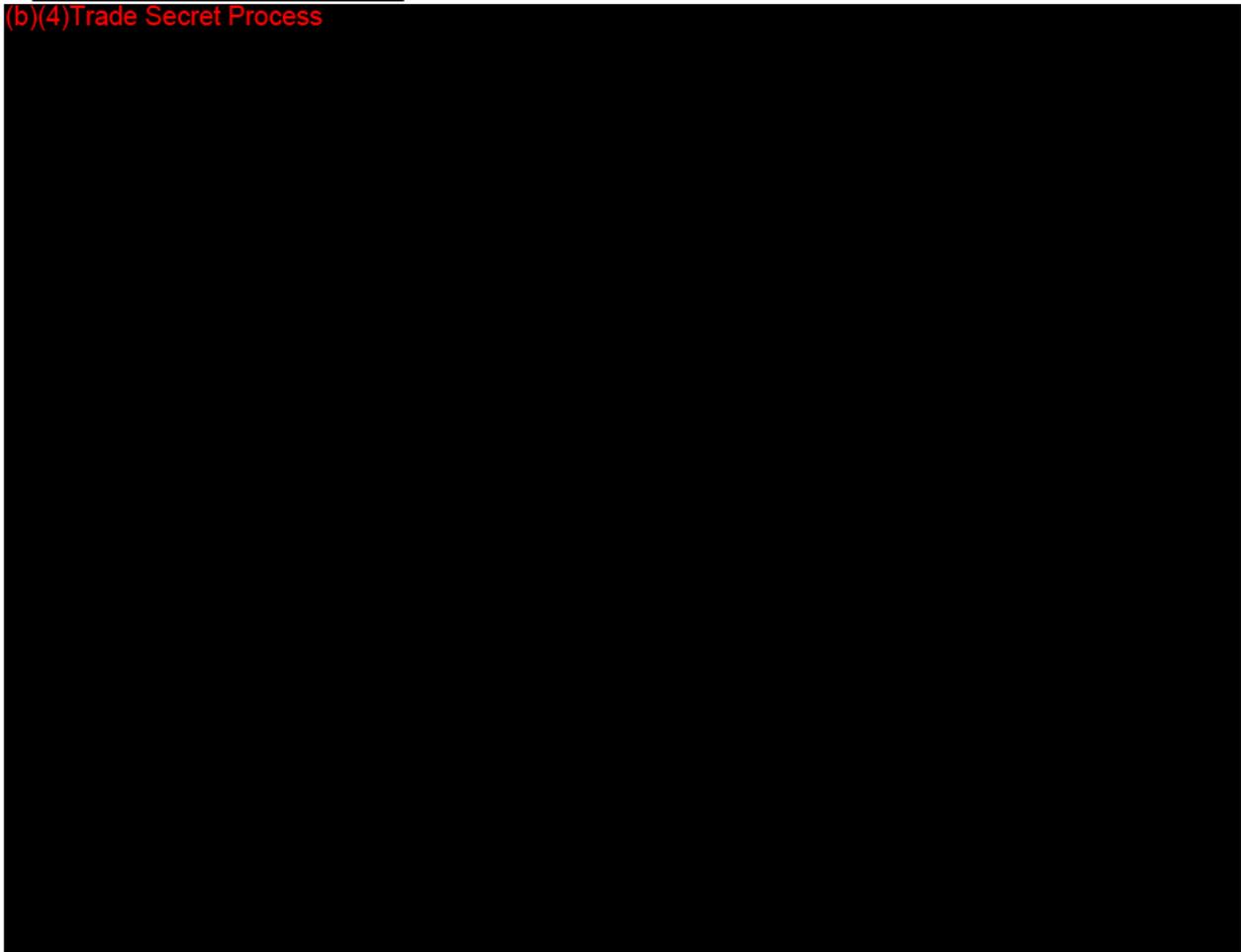


(b)(4)Trade Secret Process

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Surgical Procedure Manual:

(b)(4)Trade Secret Process

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Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

November 18, 2008

INSTRATEK, INC.
210 SPRINGHILL DR. SUITE 130
SPRING, TEXAS 77386
UNITED STATES
ATTN: JEFF SEAVEY

510k Number: K082384

Product: HAV-LOK BUNION CORRECTION

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. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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 in 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 questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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



K082384/S'

*"Superior Instrument Design"
By Surgeons For Surgeons*

Ms. Tara Shepherd
Reviewer
Orthopedic Joint Devices Branch
Division of General, Restorative and Neurological Devices
CDRH
9200 Corporate Boulevard
Rockville, MD 20850

K-12

FDA CDRH DMC

NOV 18 2008

Received

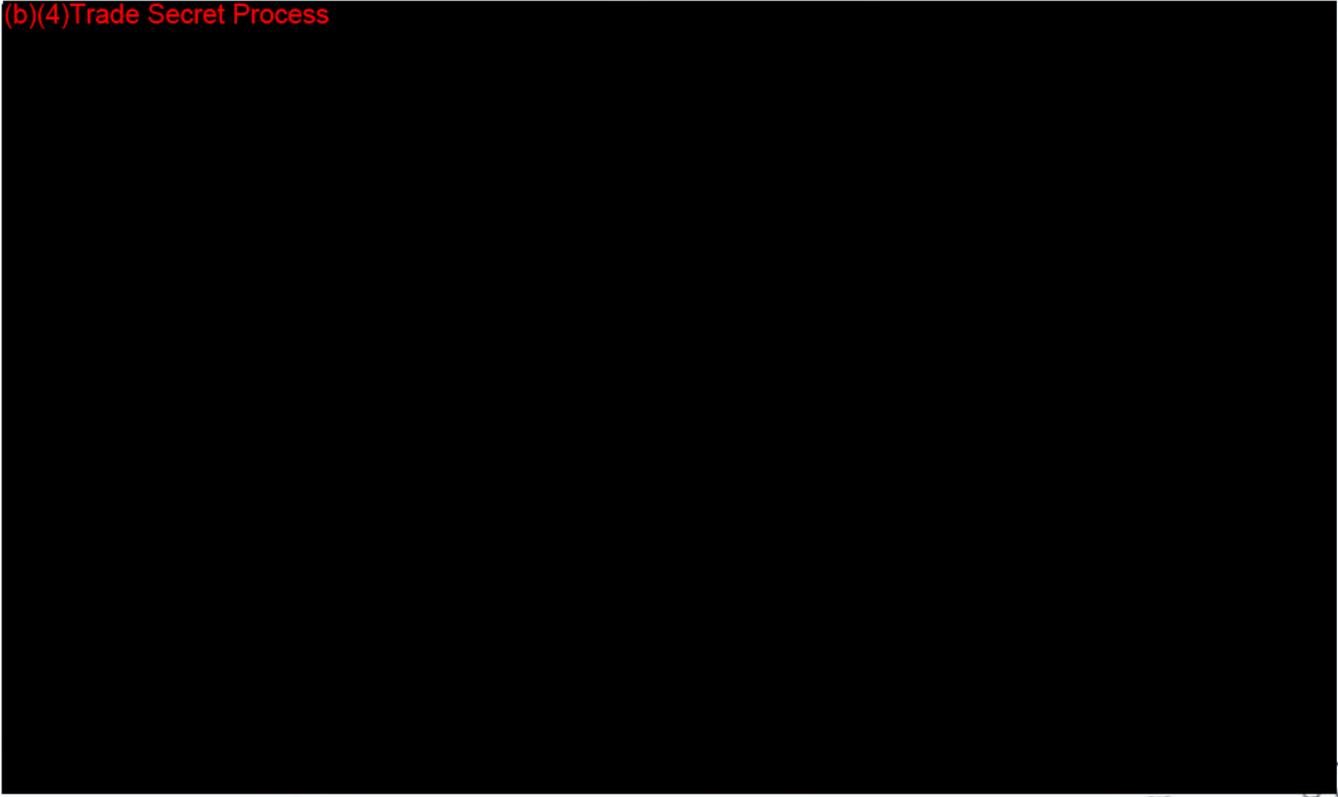
Ms. Shepherd,

Following are our responses to the deficiency letter for K082384 dated October 24, 2008.
If you have any additional questions, please contact me.

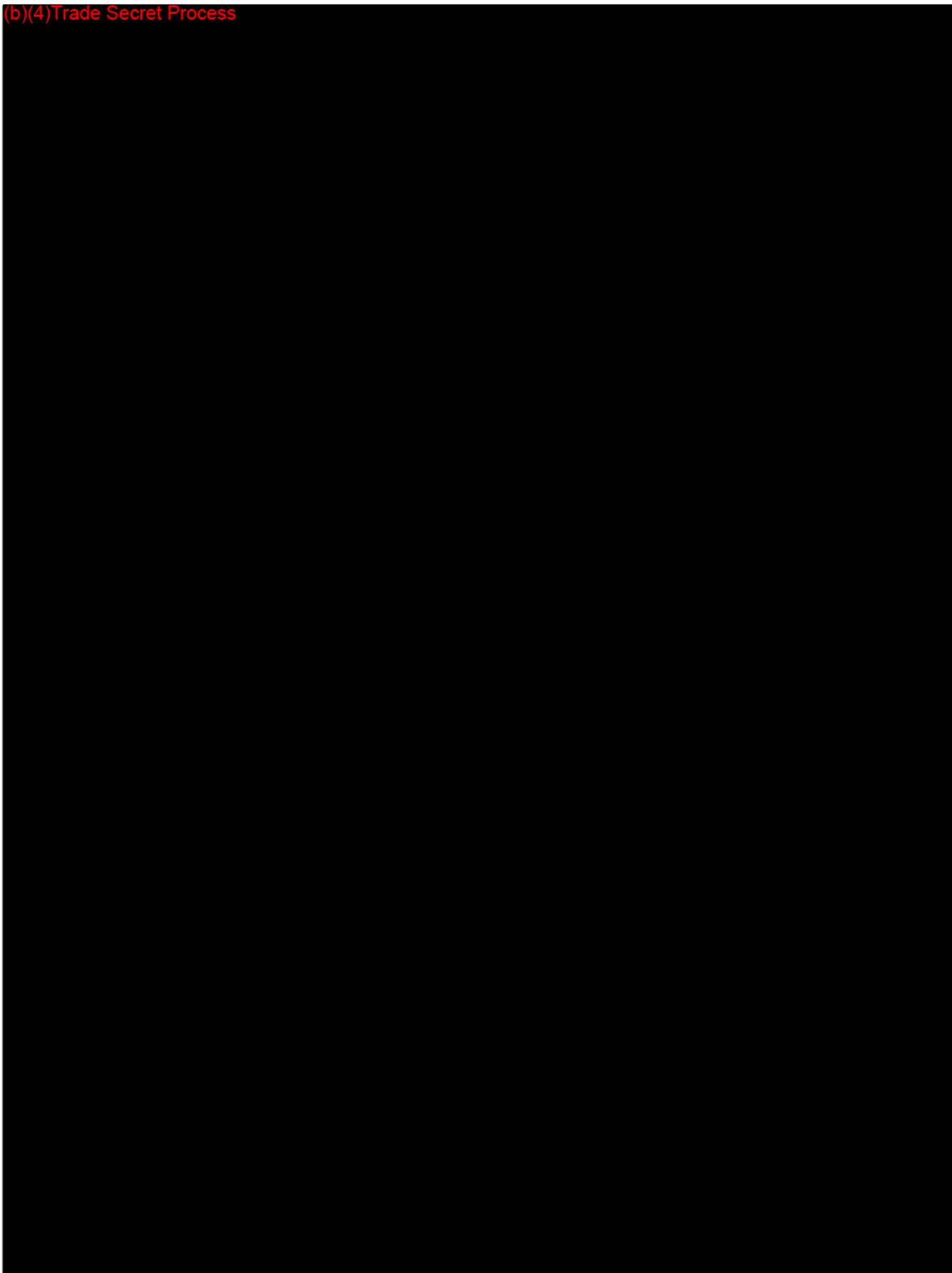
Best regards,

Jeff Seavey
Vice President

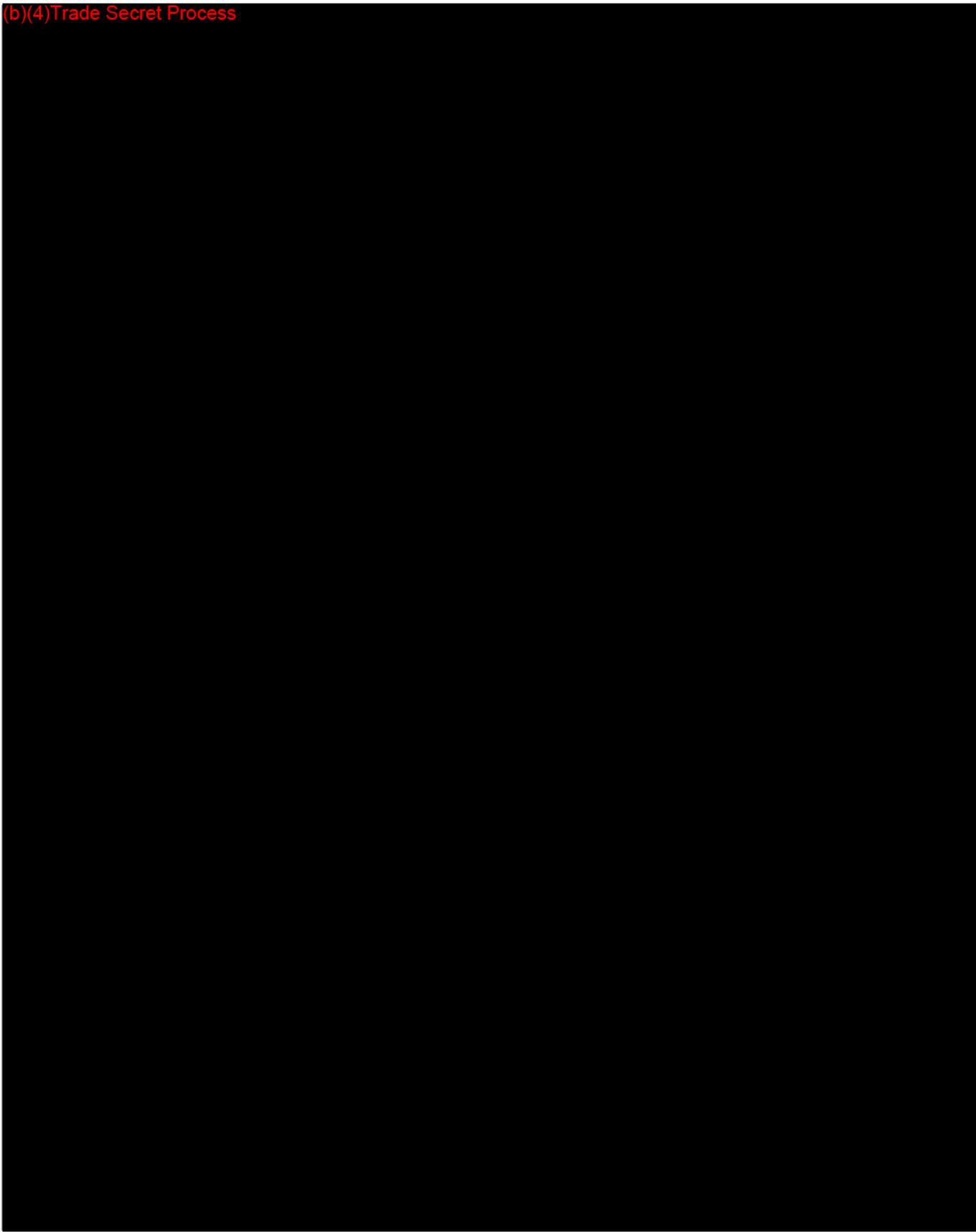
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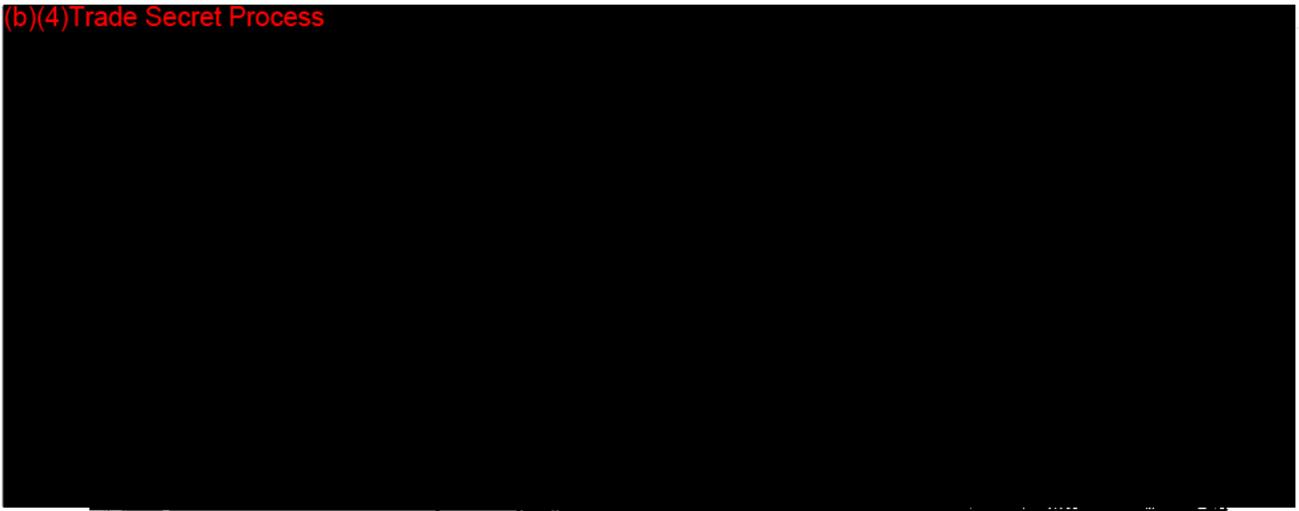
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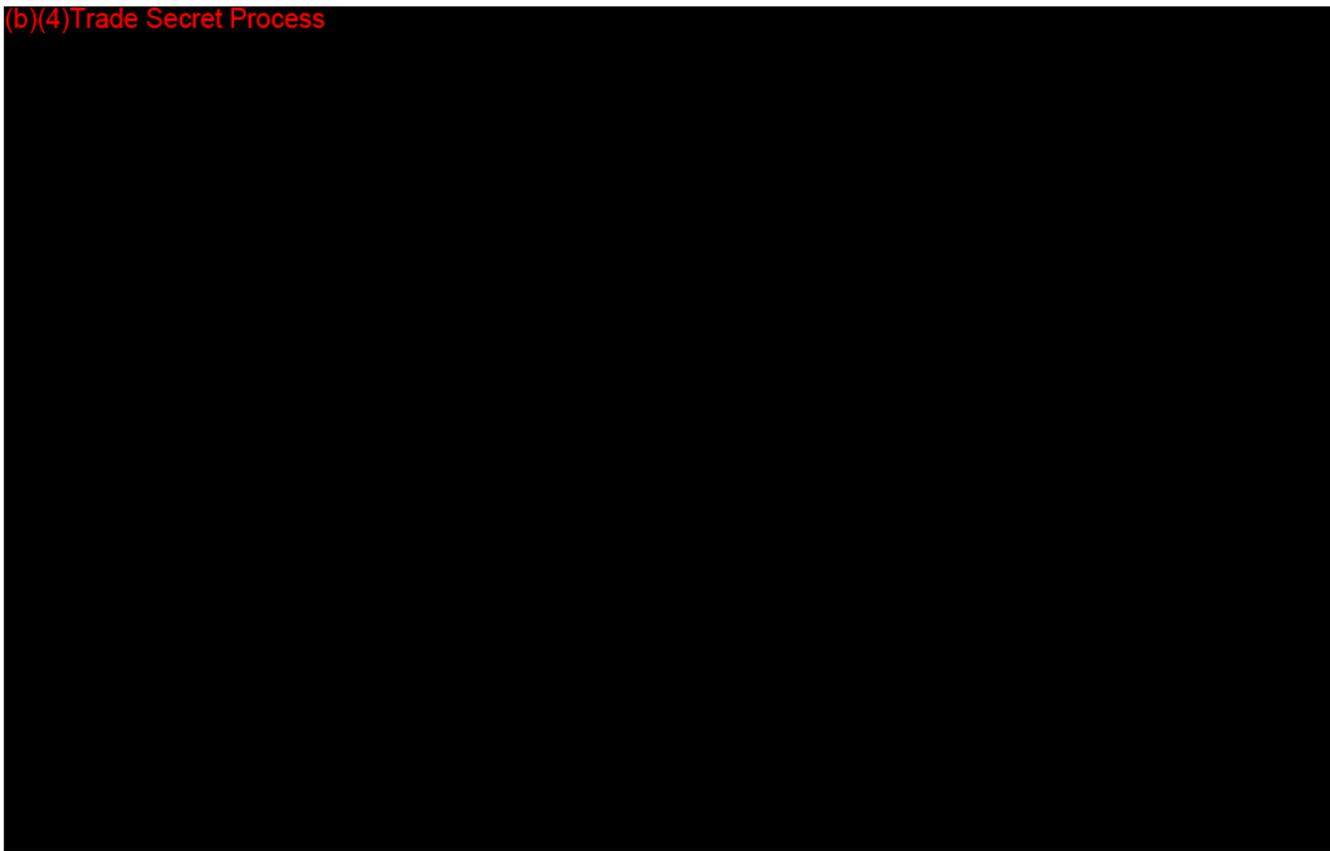


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Issue 2:

(b)(4)Trade Secret Process

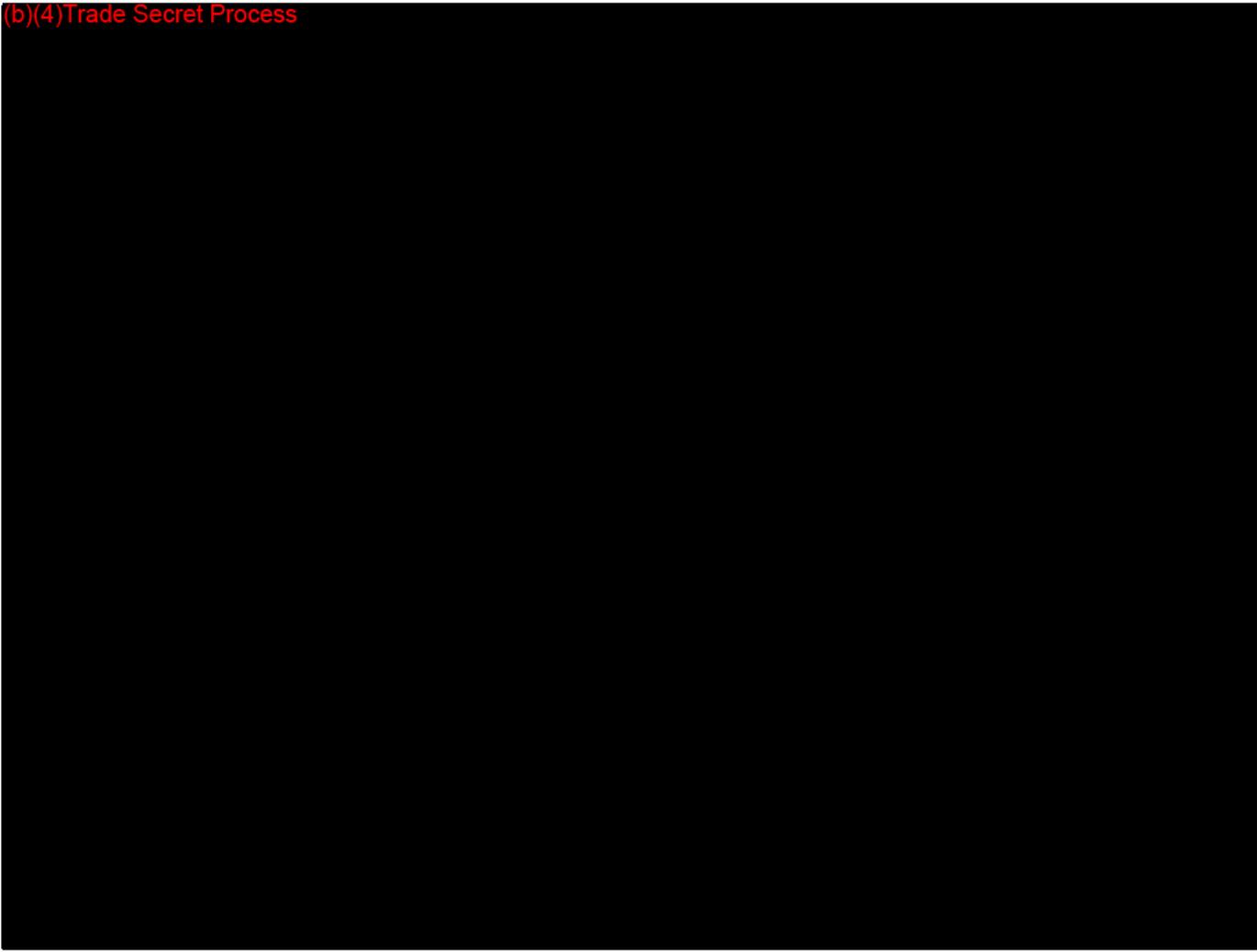


Issue 3a.:

(b)(4)Trade Secret Process



(b)(4)Trade Secret Process



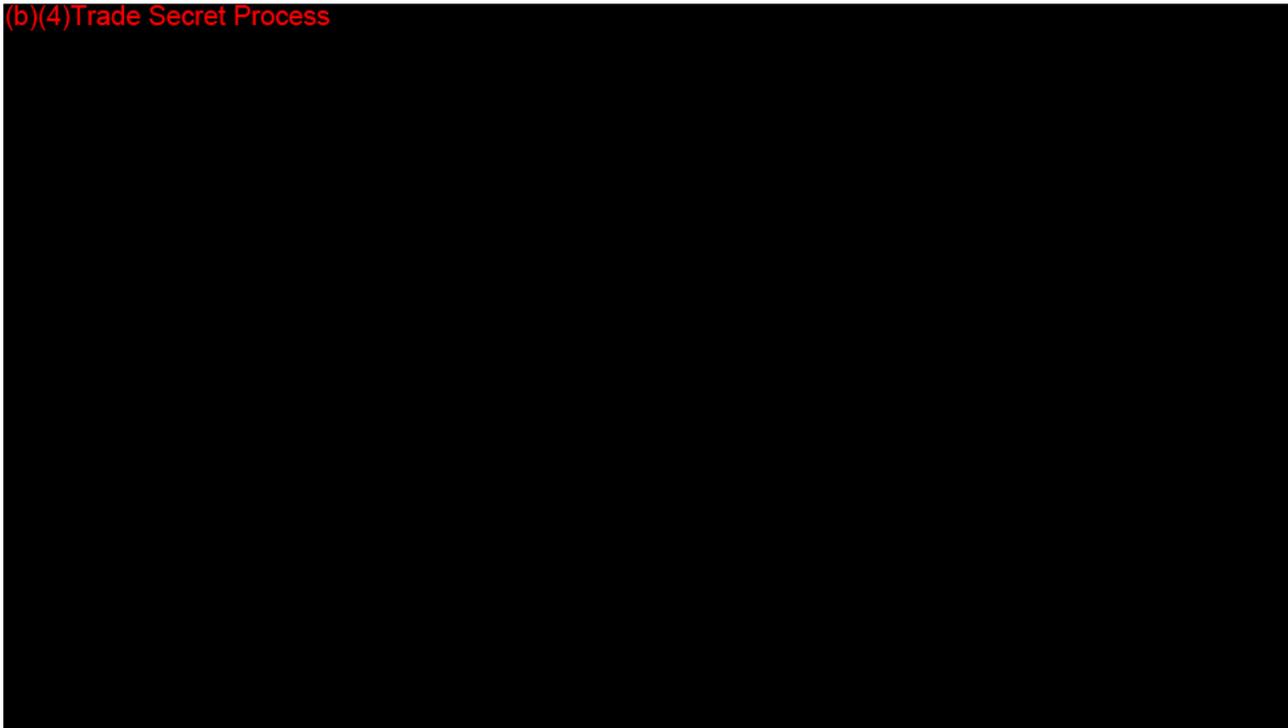
Issue 3b.:

(b)(4)Trade Secret Process



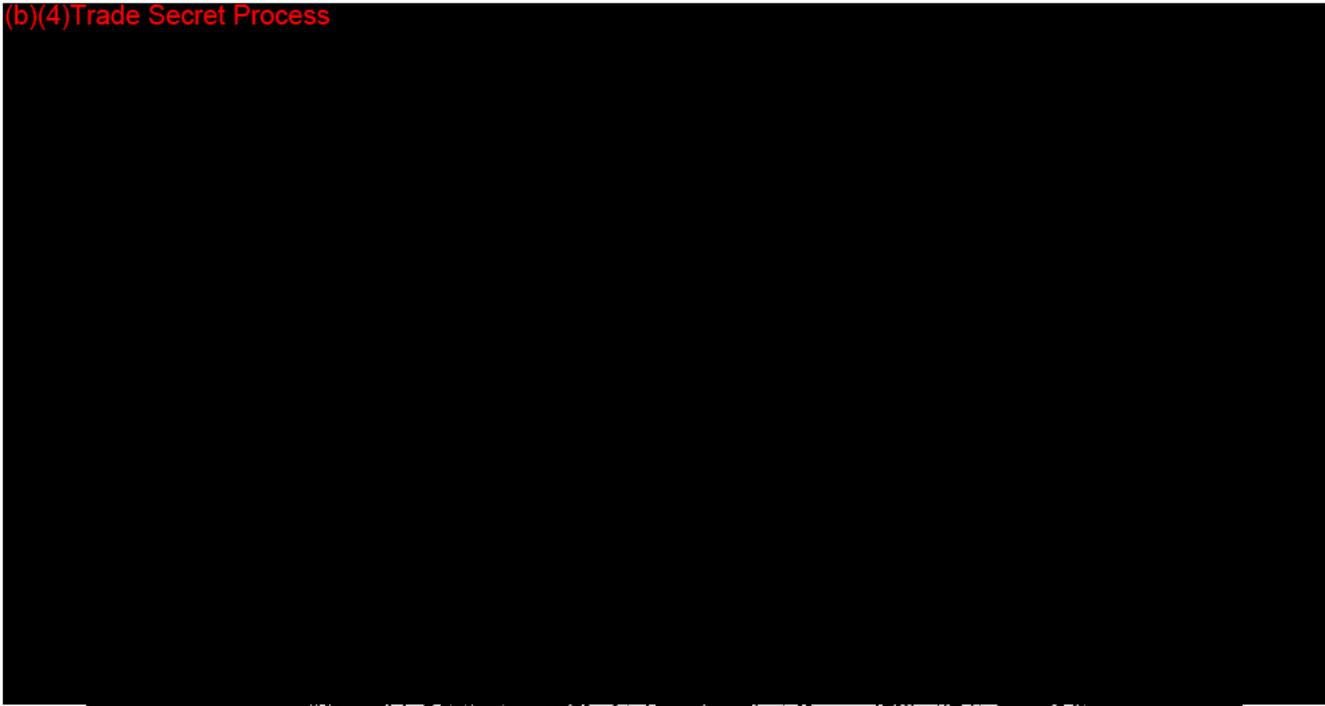
Issue 4a.:

(b)(4)Trade Secret Process



Issue 4b.:

(b)(4)Trade Secret Process

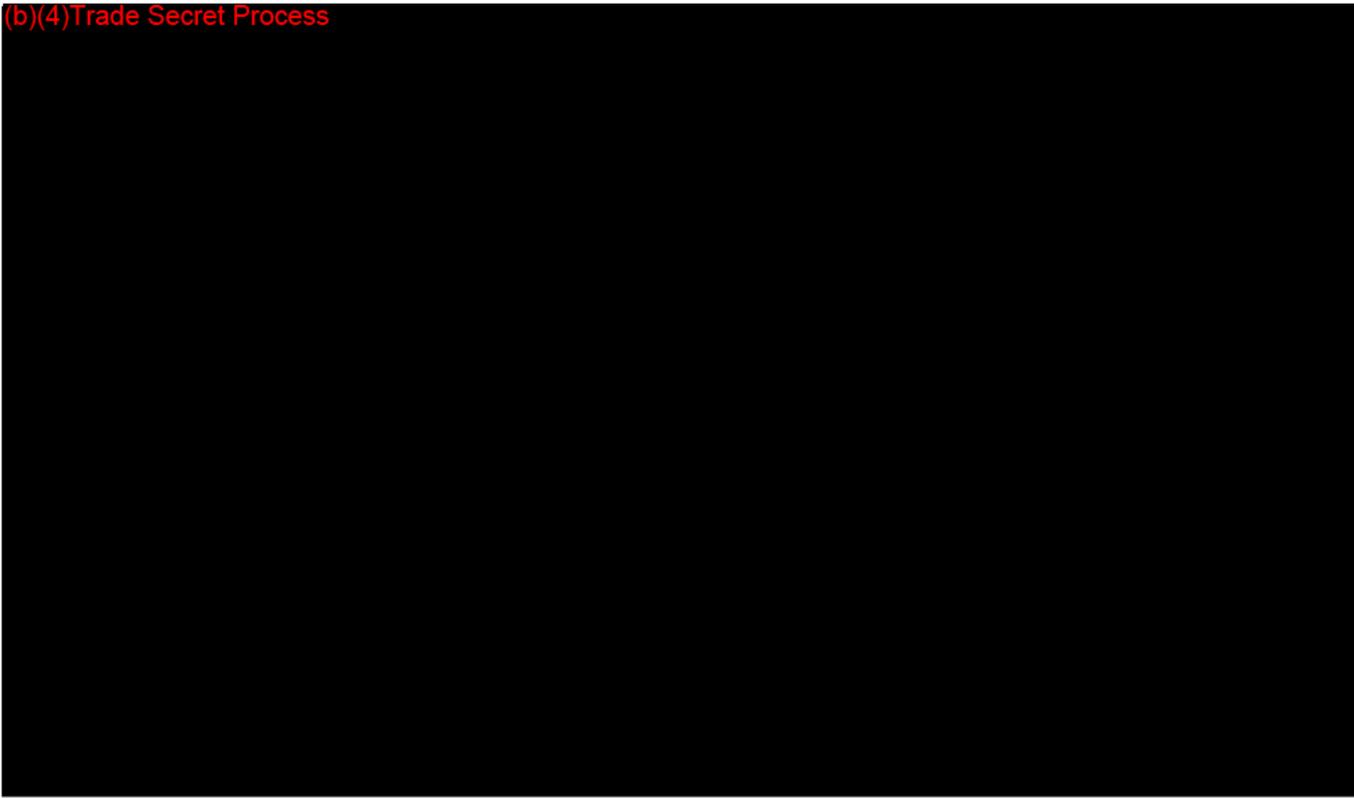


Issue 4c.:

(b)(4)Trade Secret Process

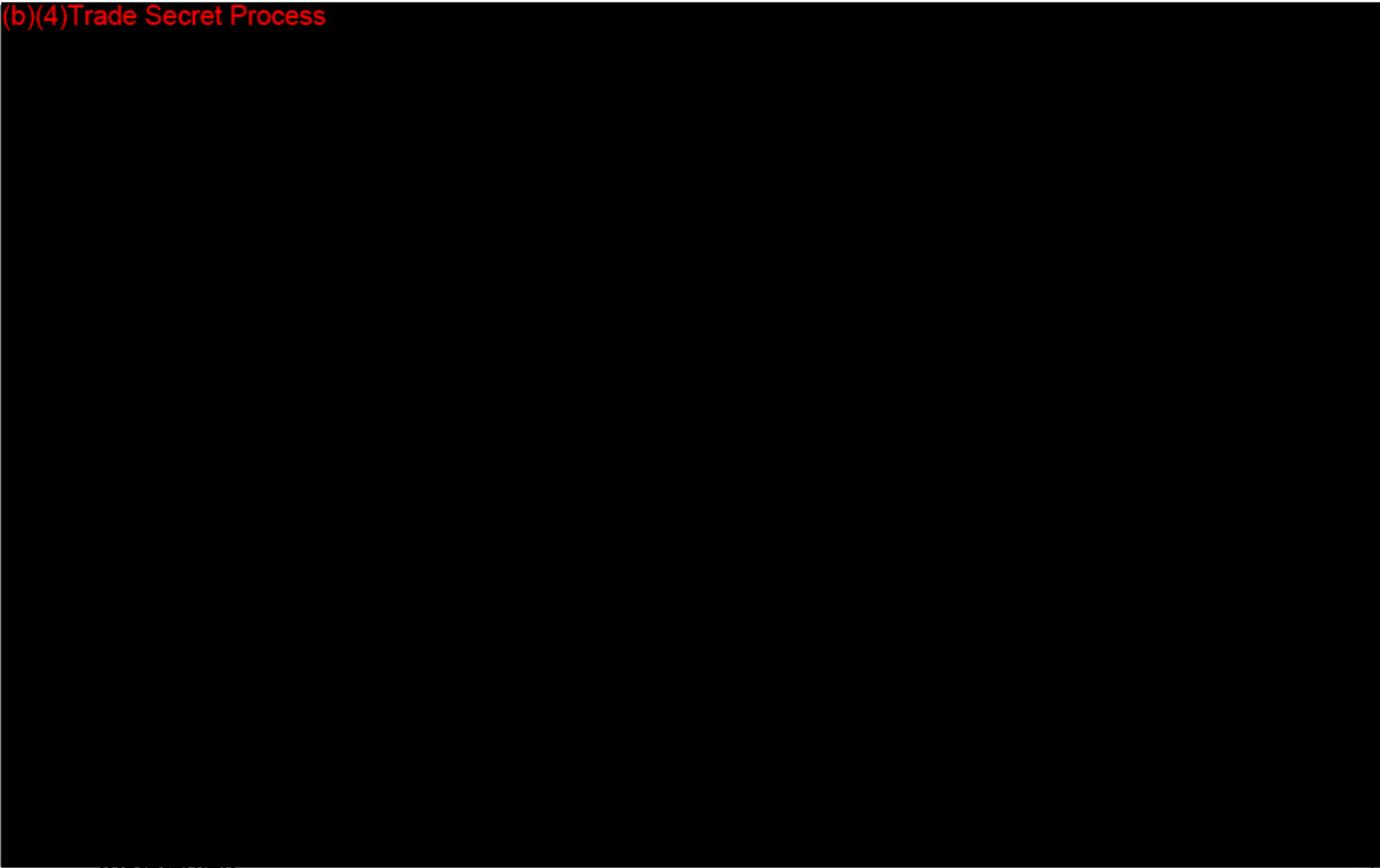


(b)(4)Trade Secret Process



Issue 5.a.i.:

(b)(4)Trade Secret Process

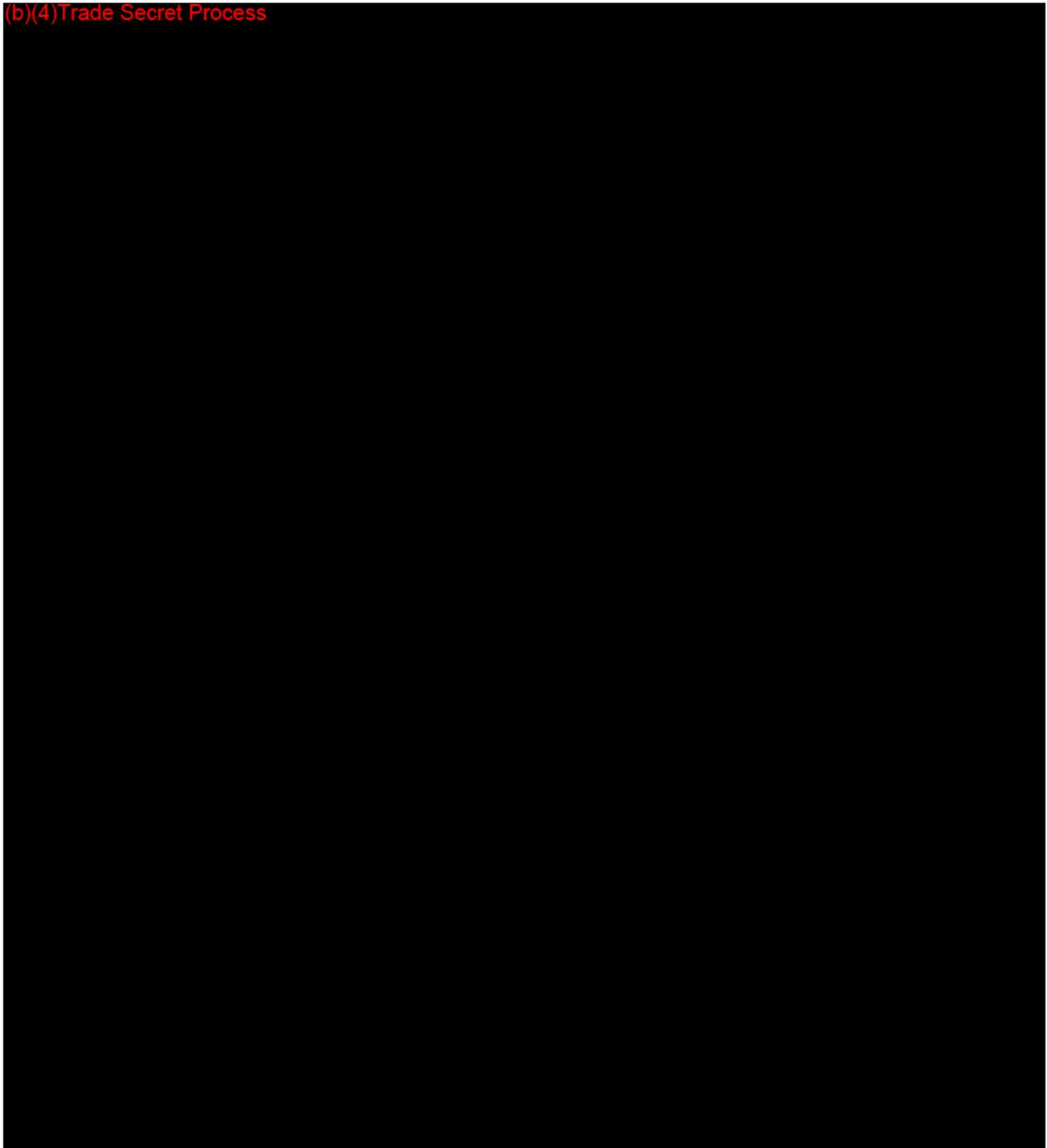


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Issue 5.a.ii.:

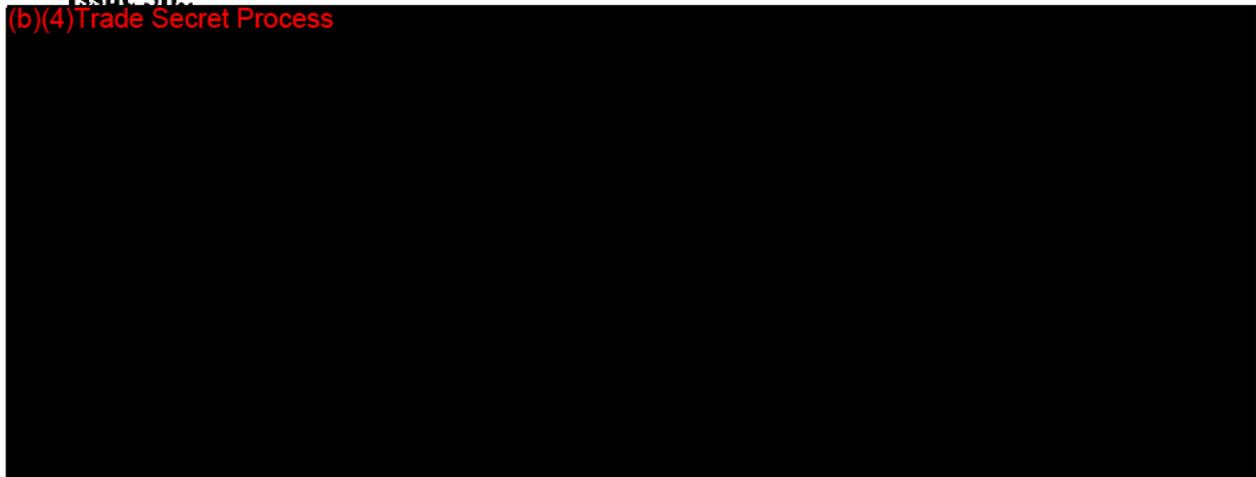
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conceptual units.

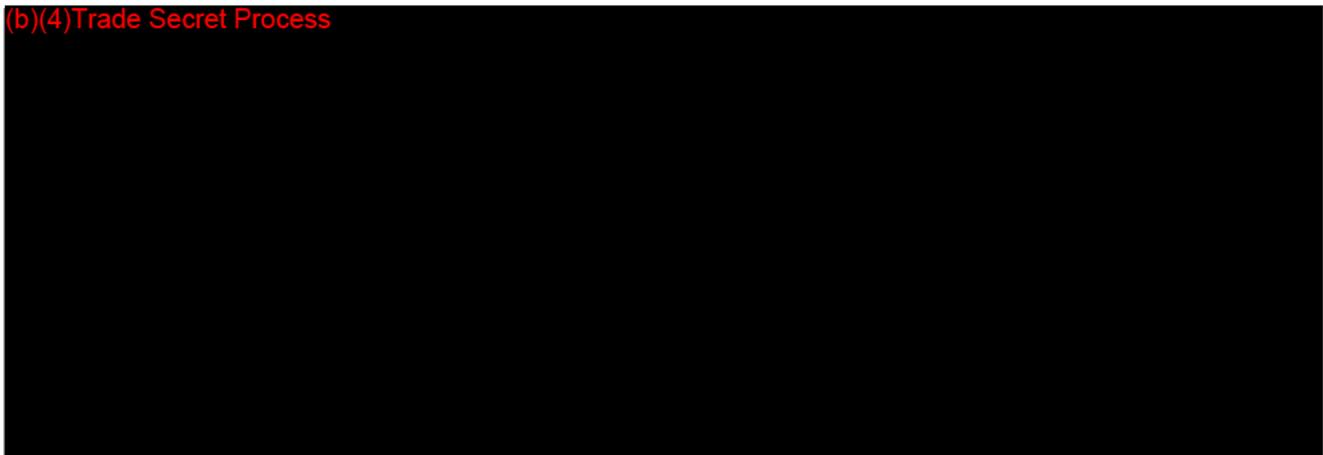
Issue 5b:

(b)(4) Trade Secret Process



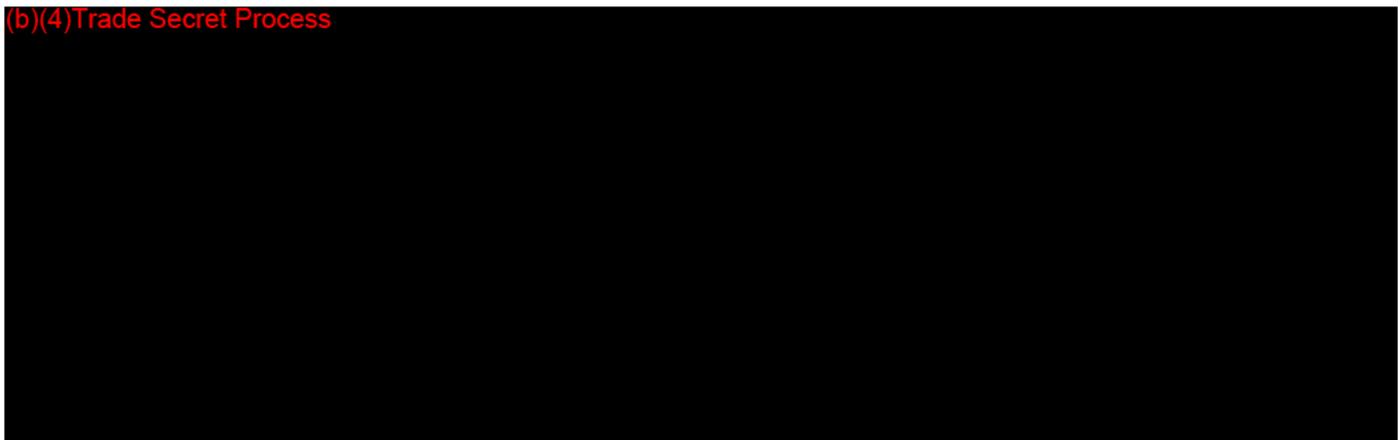
Issue 5c:

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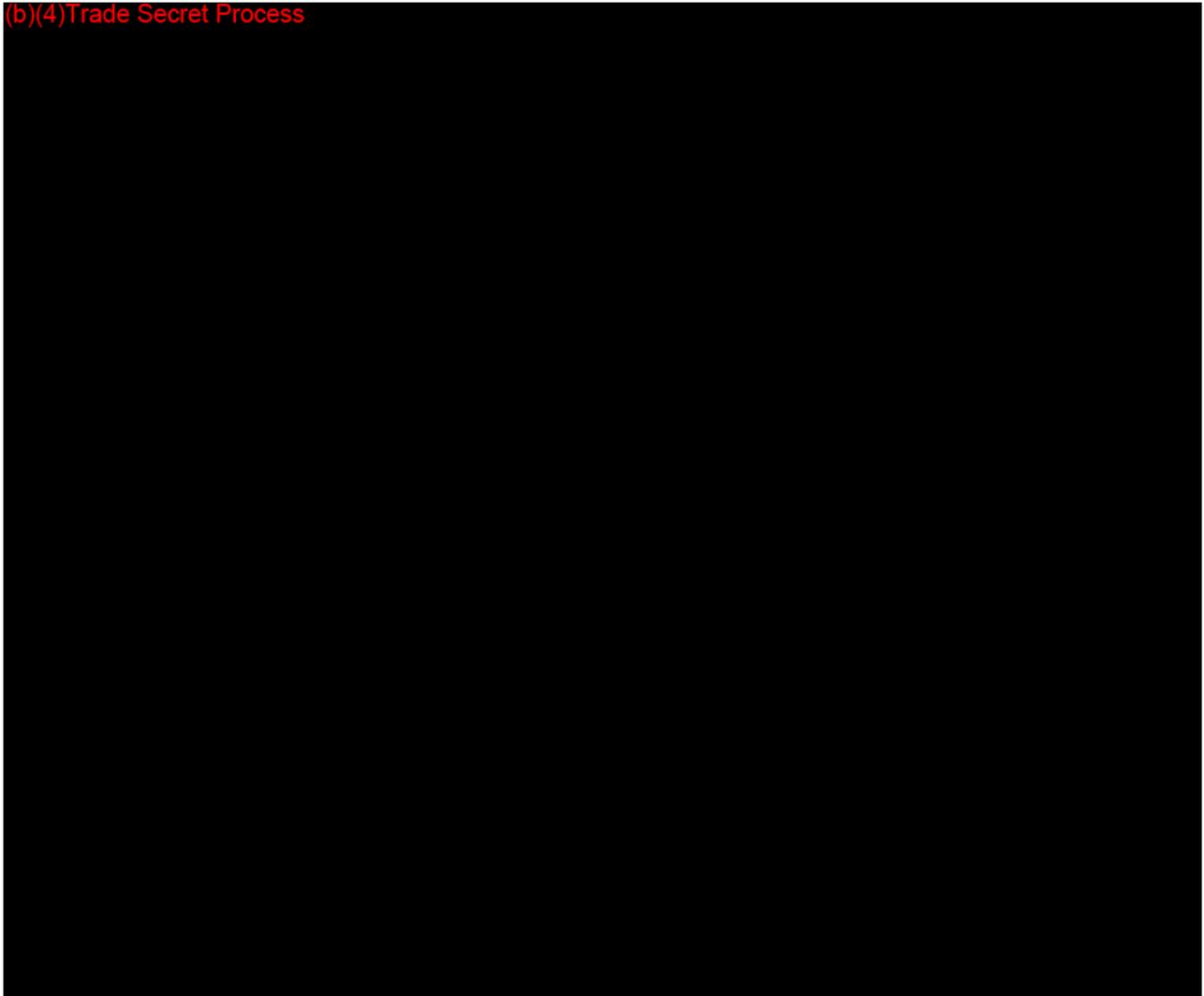
Issue 5d:

(b)(4) Trade Secret Process



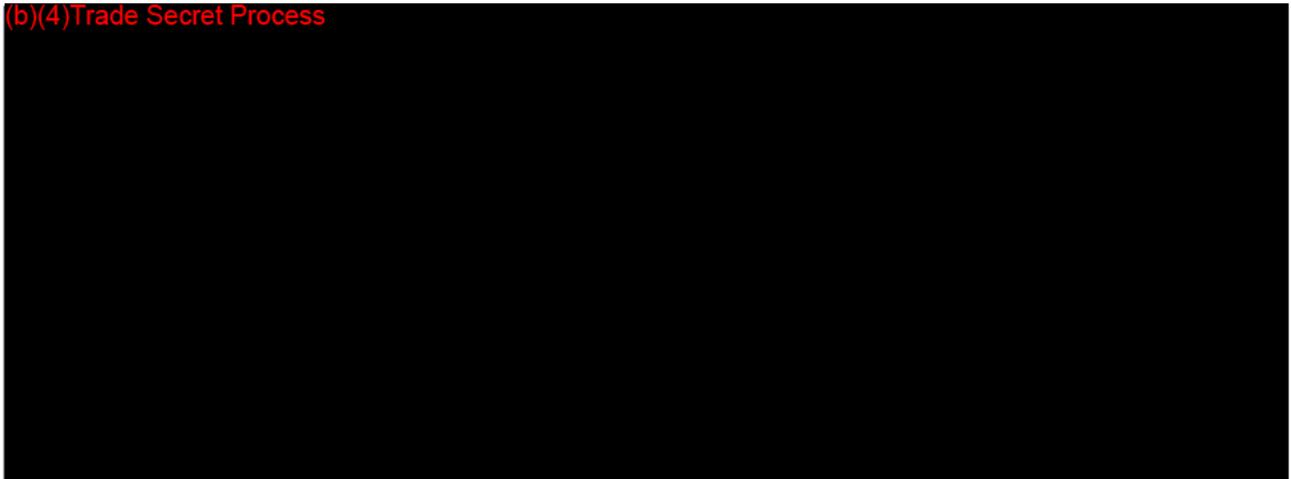
Issue 6a.:

(b)(4)Trade Secret Process



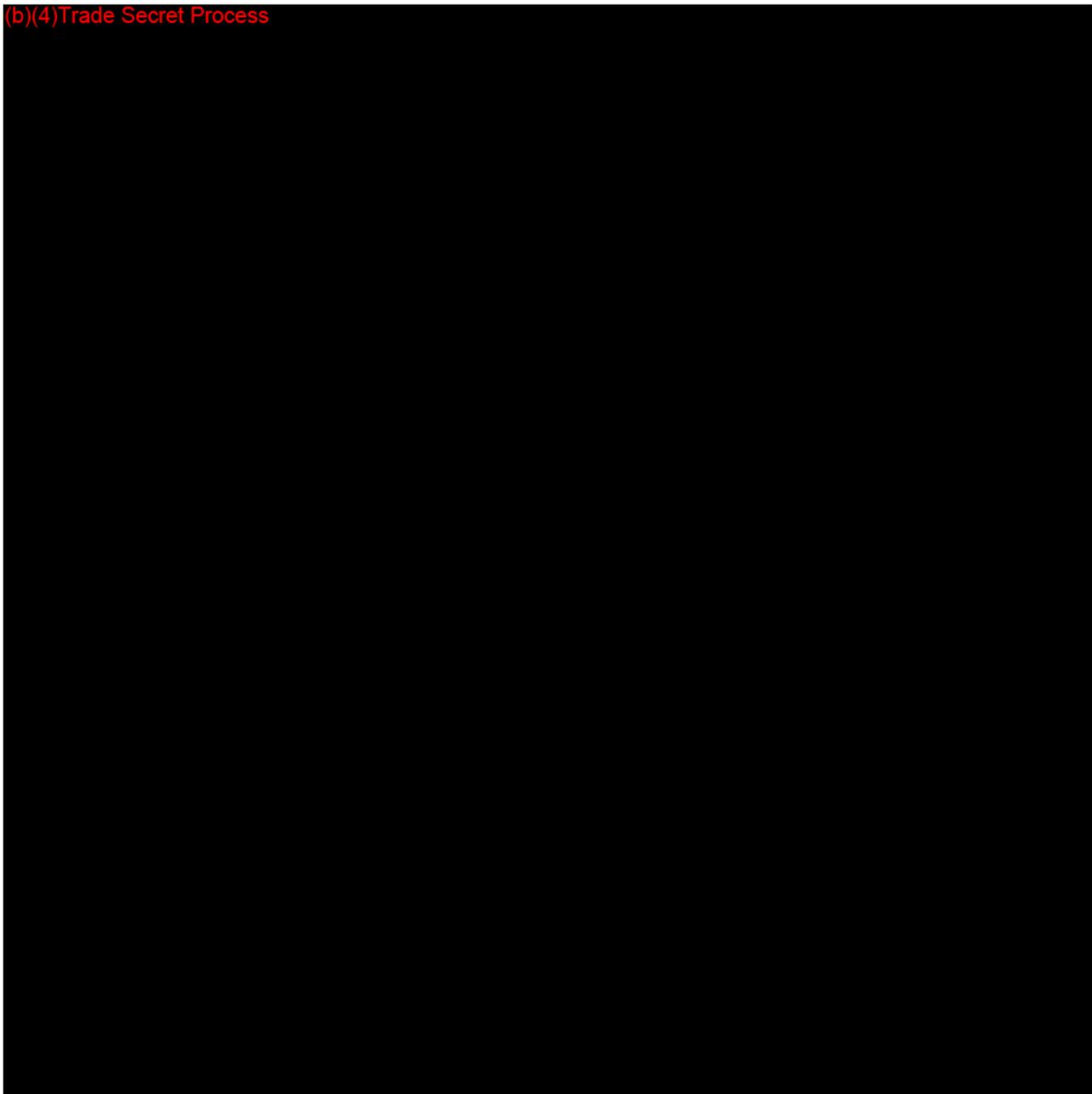
Issue 6b.:

(b)(4)Trade Secret Process



Issue 6c.:

(b)(4)Trade Secret Process



Sthenotech, Inc.
150 South Mountain Rd.
Robesonia, PA 19551
Robert F. Beisel, M.A., President

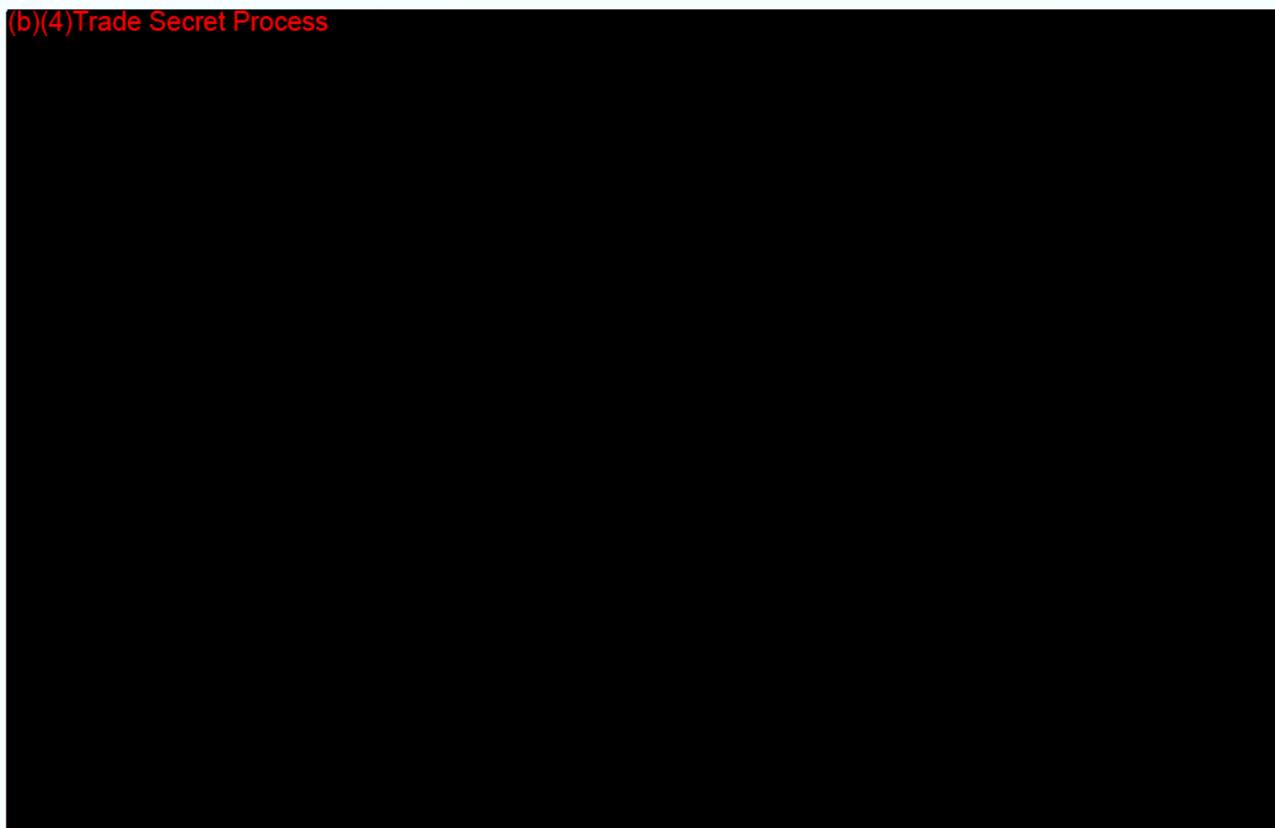
12 November 2008

Jeff Seavey
Vice President
Instratek, Incorporated
210 Springhill Drive, Suite 130
Spring, Texas 77386

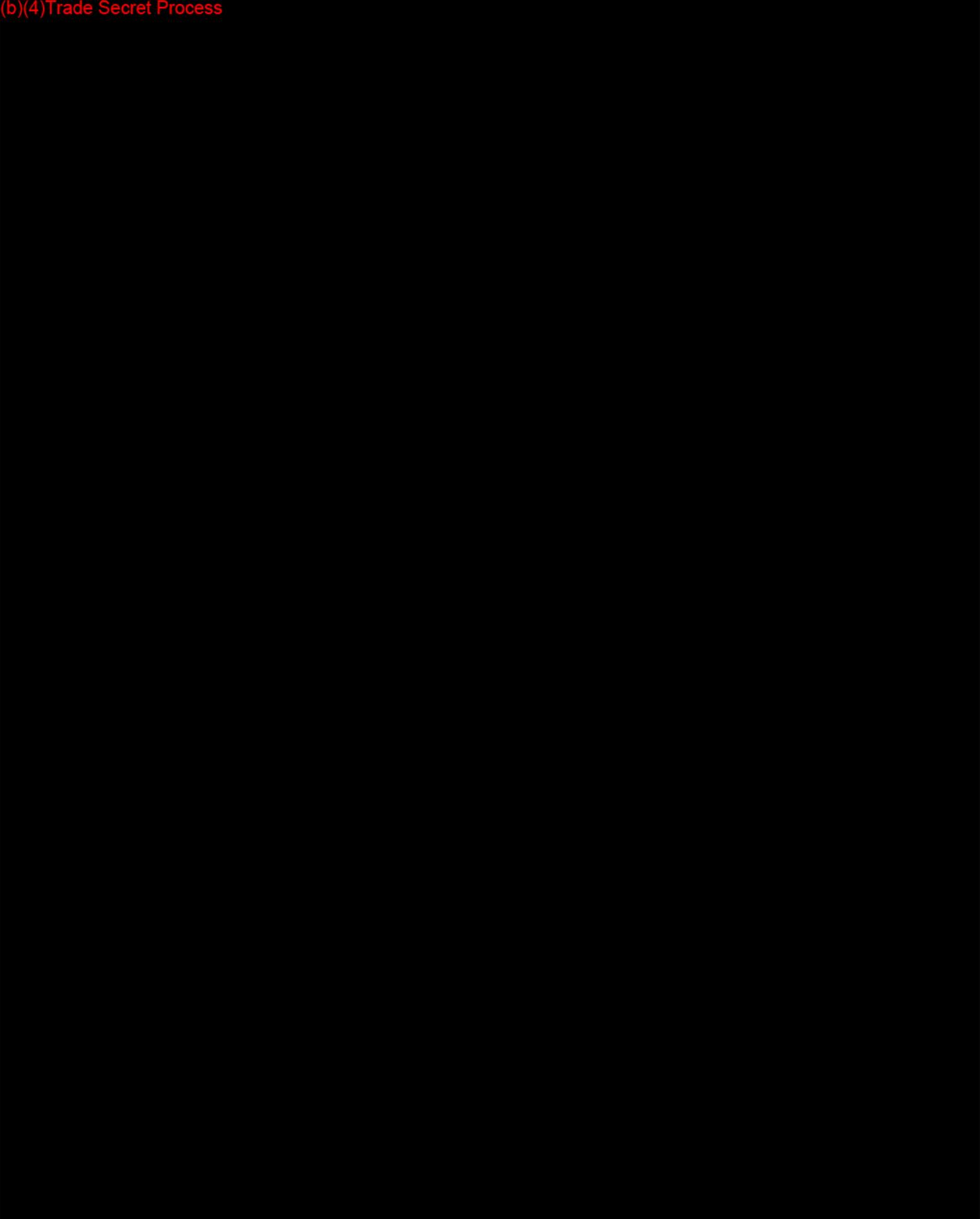
Re: Physical testing of Hav-lok System

Dear Jeff:

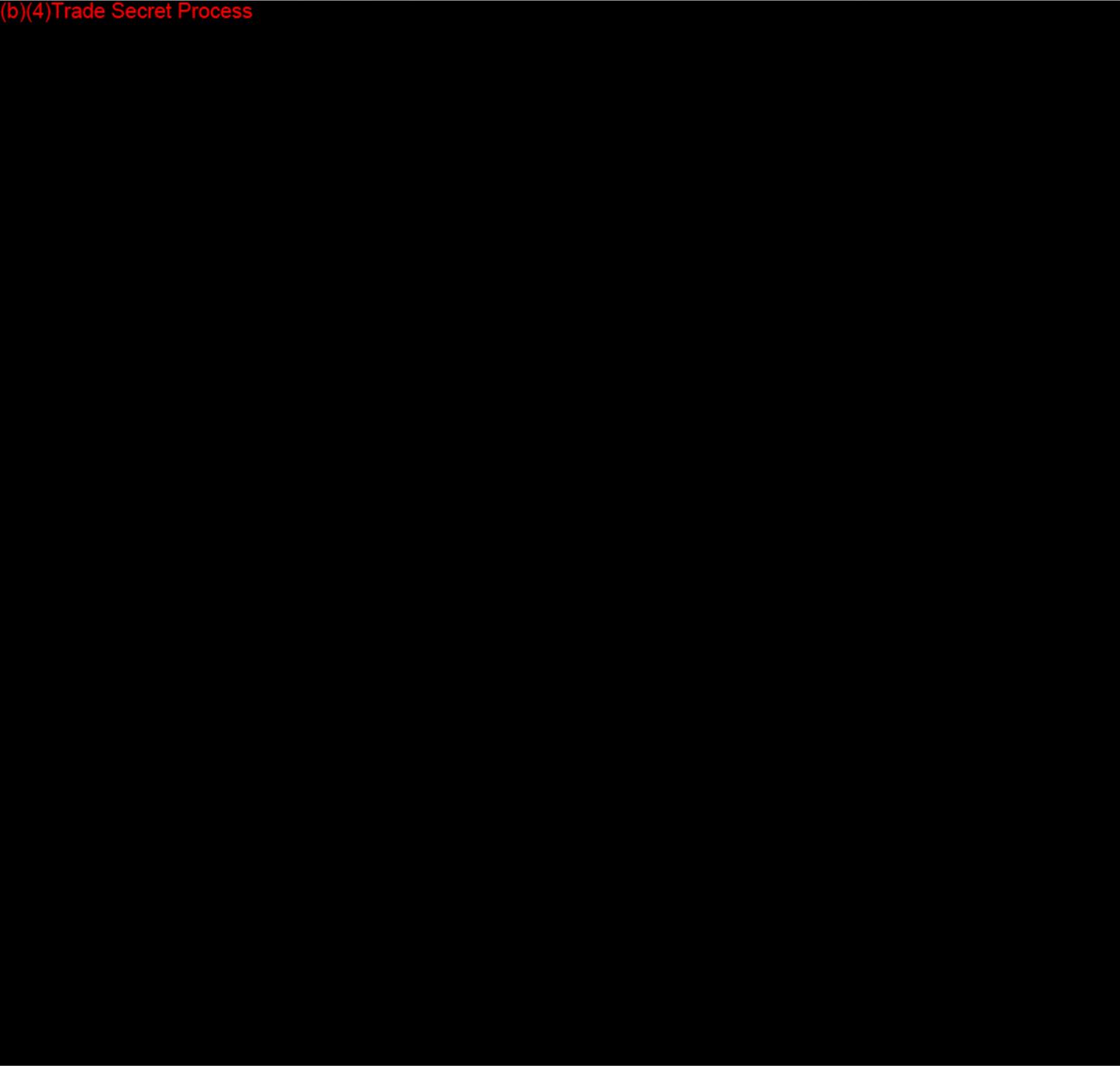
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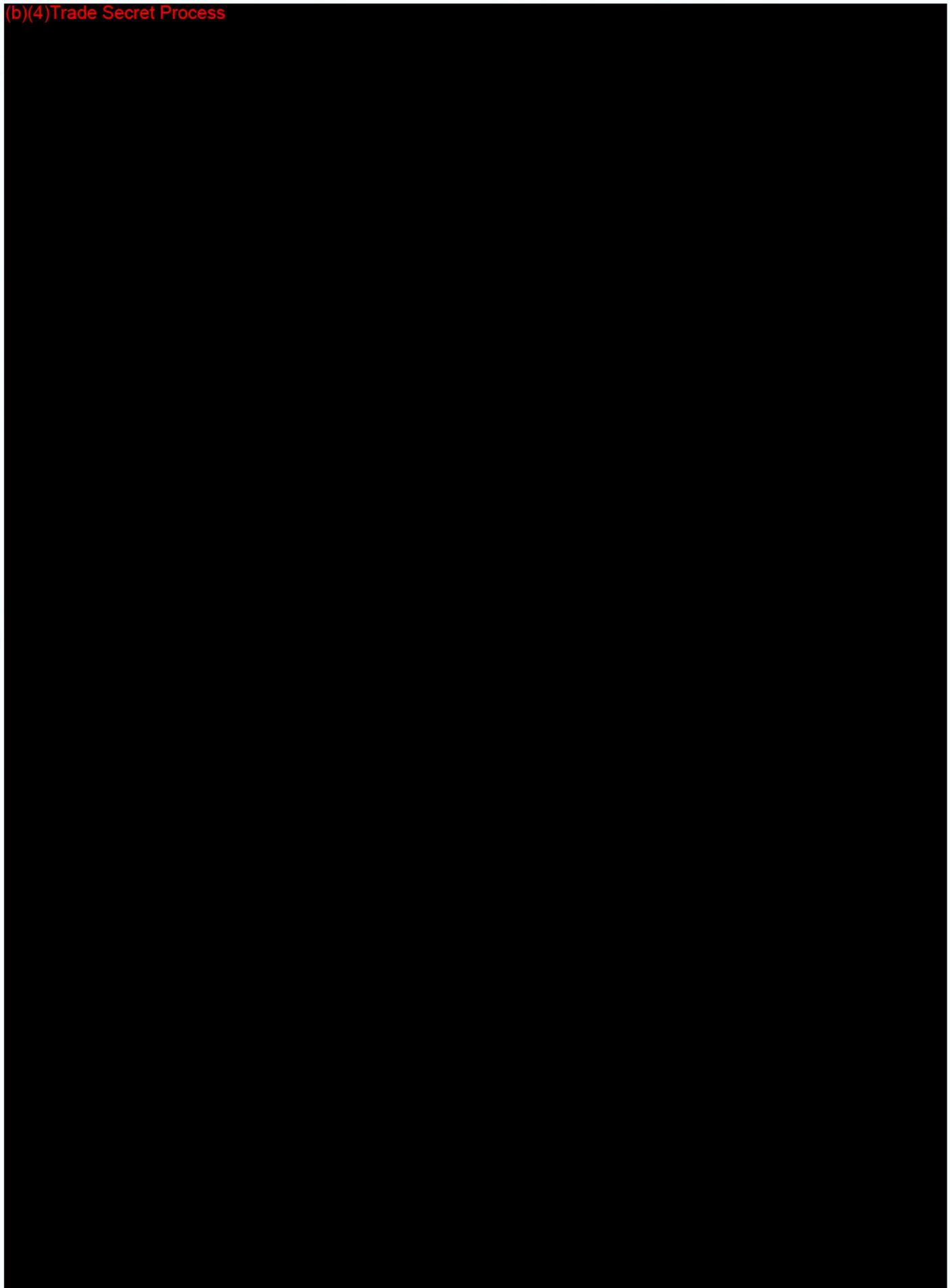
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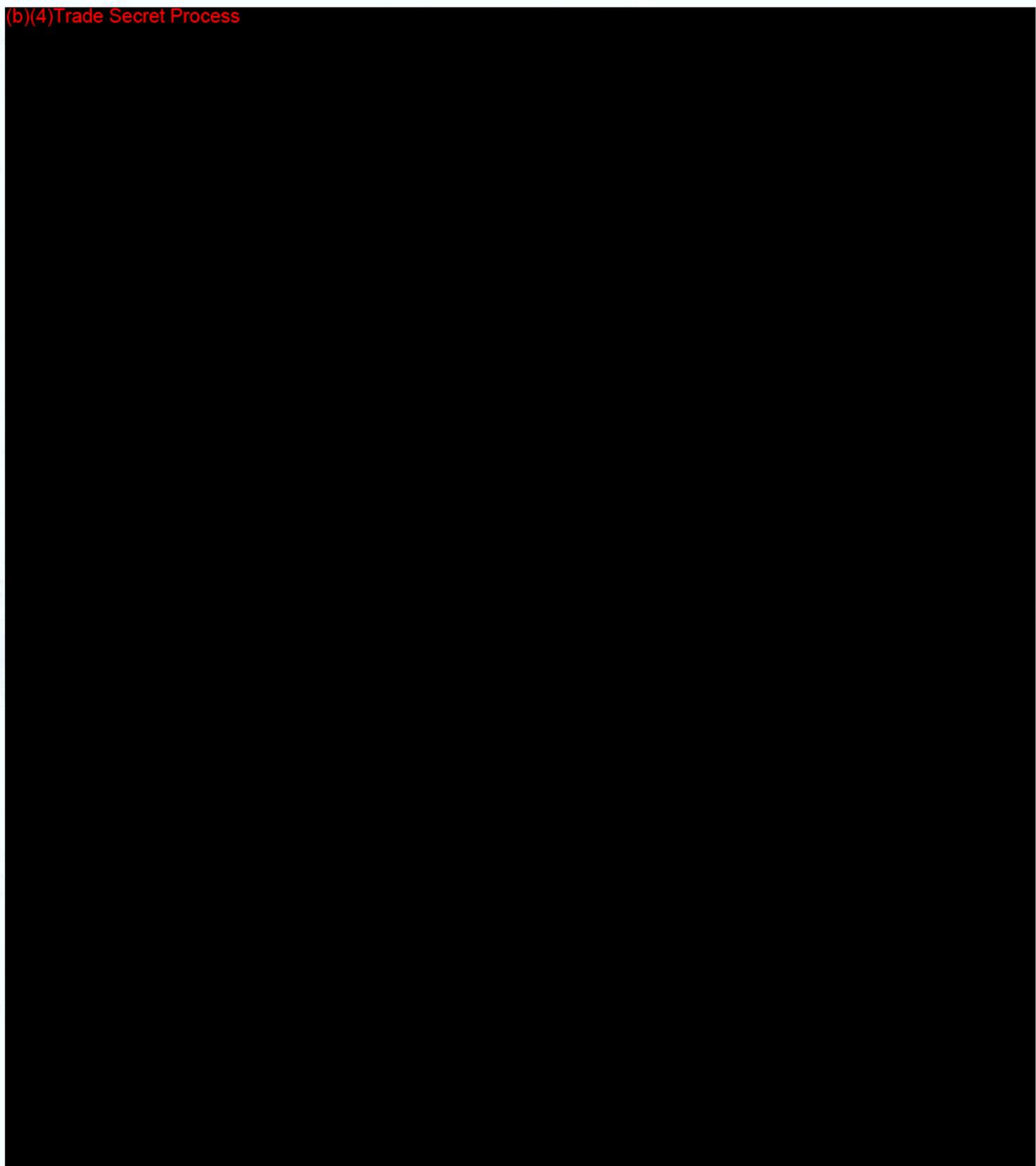
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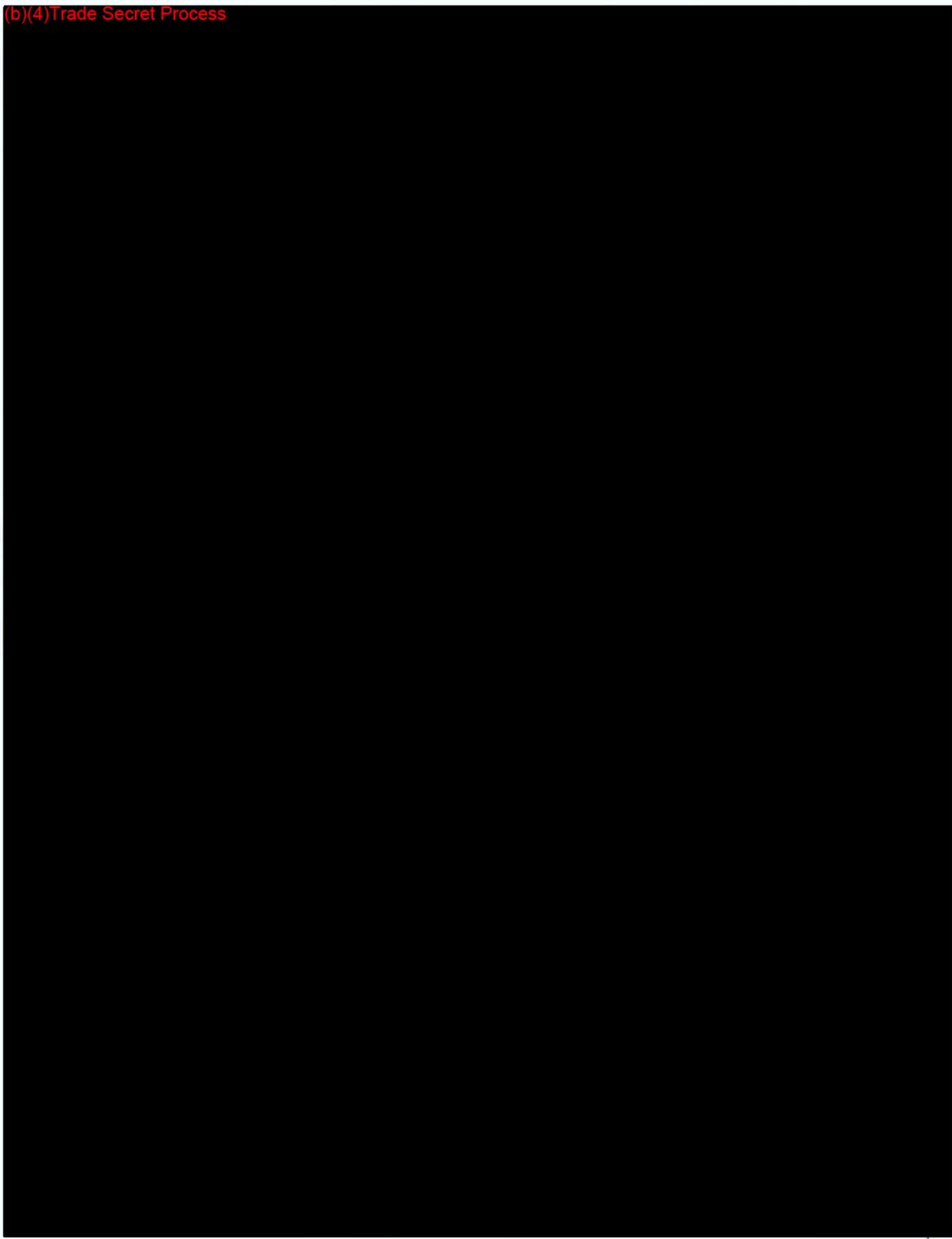
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(b)(4) Trade Secret Process



(b)(4) Trade Secret Process



Respectfully submitted,

Robert F. Beisel, B.S. (Chemistry), M.A., (Physics)
President
Sthenotech, Inc.



Comprehensive Solutions for Forefoot and Midfoot
Surgery using the Mini TightRope® System



Five Surgical Techniques



Hallux Valgus Repair

The treatment of hallux valgus deformity includes the assessment of the hallux valgus angle, the intermetatarsal angle (IM angle) and the contribution of an interphalangeus deformity. Additionally, there must be an assessment of the presence or absence of arthritic involvement of both the first metatarsocuneiform joint and the first metatarsophalangeal joint. Other considerations are the orientation of the distal metatarsal articular angle and the orientation and stability of the first metatarsocuneiform joint.

Various methods have been described to correct the intermetatarsal angle. Soft tissue correction can be achieved by suturing the lateral capsule of the first metatarsal to the medial capsule of the second metatarsal, incorporating the intervening, previously released adductor tendon. A loss of reduction can occur due to the forces that oppose the suture repair, as well as the possibility that poor tissue quality can contribute to a loss of reduction.

In the presence of more rigid deformities, the IM angle is reduced by using a distal or proximal osteotomy of the first metatarsal. Such osteotomies can be technically challenging. A rather daunting list of consequences and potential complications include delayed union, malunion, nonunion, excessive shortening of the first metatarsal, avascular necrosis, hardware failure and prolonged protected ambulation.

The Mini TightRope is useful as an alternative and adjunct method for reduction of the IM angle. A FiberWire® and button construct (distal approach) or FiberWire and anchor construct (proximal) are placed across the first and second metatarsals. As the FiberWire is tightened, the IM angle is reduced to a normal value (less than 9-11°). Using the button or anchor construct, the suture is tied over the button, maintaining a secure reduction of the IM angle. Used alone or in conjunction with the distal soft tissue intermetatarsal repair (distal approach), this technique affords a greater degree of strength and security than can be achieved with the soft tissue repair alone.

Hallux Varus Repair

Hallux varus is most often seen as a complication of bunion surgery, but can be related to other conditions as well. To date, the procedures described to correct the deformity involve transfer of either a portion or all the extensor hallucis longus or brevis tendons. These procedures often leave some deficit in extensor function and can necessitate more incisions in addition to those used to perform the original procedure. The use of the Mini TightRope to correct hallux varus does not sacrifice tendons, can be done through two small incisions and is a more isometric reconstruction of the lateral structures of the first metatarsophalangeal joint.

Mini TightRope FT Fixation

The Mini TightRope FT was developed to offer surgeons a new technique for the correction of the IM angle for hallux valgus. As is with the standard Mini TightRope placed distally, the Mini TightRope FT can support correction of the IM angle if used proximally along the 1st metatarsal. The Mini TightRope FT utilizes a 4.5 mm (fully threaded) Bio-Corkscrew® FT, #2 FiberWire and a cupped stainless steel button. The proximally placed anchor/suture button construct will support reduction of the IM angle while allowing soft tissue remodeling and stabilization.

Lisfranc Ligament Repair

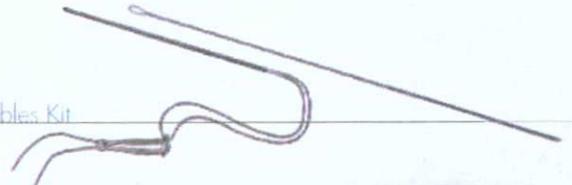
The successful treatment of Lisfranc joint injuries includes the achievement and maintenance of an anatomic reduction. The failure to achieve an anatomic reduction, a failure of fixation or a failure to maintain proper postoperative immobilization can contribute to an unsuccessful outcome.

An early method of fixation involved the use of smooth pins or Kirschner wires. More recently, screw fixation has gained in popularity. The advantages of pin fixation include the relative ease of pin placement along with minimal injury to the articular surfaces. However, pin fixation lacks rigid fixation and usually necessitates a second procedure to remove the pins. There is also the risk of pin tract infection with protruding pins, as well as the risk of pin breakage.

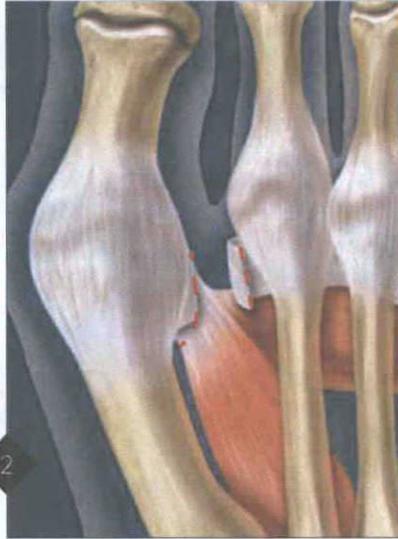
Screw fixation has the advantages of rigid fixation, no protruding hardware and a lower risk of hardware failure. Possibly the major disadvantage of screw fixation is the placement of a screw across articular surfaces of the Lisfranc joints will certainly predispose those joints to the development of posttraumatic arthritis.

The Mini TightRope provides an alternative to both pin and screw fixation. The advantages include: 1) an absence of protruding hardware, 2) a second procedure is not required for its removal, and 3) far less joint disruption than that caused by a 3.5, 4, 4.5, 6.5 or 7.3 mm screw. For more complex fractures this technique can easily be combined with other fixation techniques. The Mini TightRope provides a new approach to treatment of Lisfranc ligament disruptions.

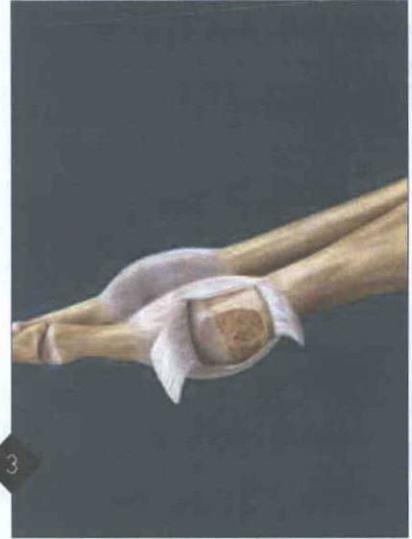
Hallux Valgus Repair Mini TightRope 1.1 mm Disposables Kit



1 For the distal approach, the first interspace release is performed through the incision made between the distal 1st and 2nd metatarsals. A dorsal medial or medial incision can also be used with appropriate distraction of soft tissues.



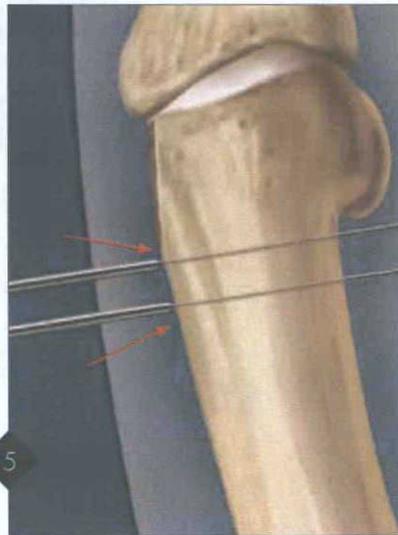
2 To realign the fibular sesamoid, detach the adductor tendon from both the base of the proximal phalanx and the fibular sesamoid. Release the deep intermetatarsal ligament and lateral capsule. Free any sesamoid adhesions to the intermetatarsal ligament. Manually test the reduction of the IM angle following complete soft tissue release.



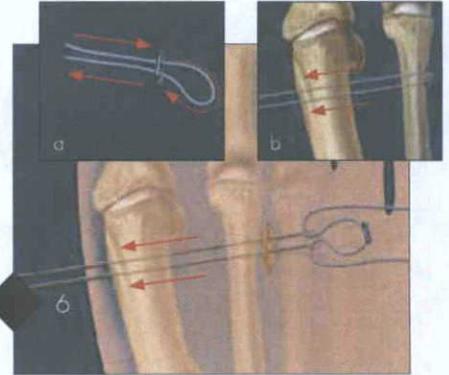
3 Incise the medial capsule, exposing the entire medial eminence. The medial eminence is removed, preserving the sesamoid groove on the plantar aspect of the 1st metatarsal.



4 The lateral second metatarsal is exposed for placement of the Mini TightRope. The first metatarsal is reduced with provisional fixation to the 2nd metatarsal. A C-arm is used to assure proper placement of the 1.1 mm tapered Suture Passing K-wire at the center of the 2nd metatarsal shaft, 2-3 mm proximal to the neck of the 2nd metatarsal. Elevate and expose 2nd metatarsal with freer elevator and small rake retractor (soft tissue) prior to K-wire insertion. Place K-wires from 2nd met through 1st met. The wires should exit just proximal to the excised medial eminence, approximately 5 mm apart. **Note - Place Suture Passing K-wires simultaneously. Do not remove or pass sutures prior to placement of both wires.* For accurate placement of the K-wires, the drill angle should be modified as shown (a).



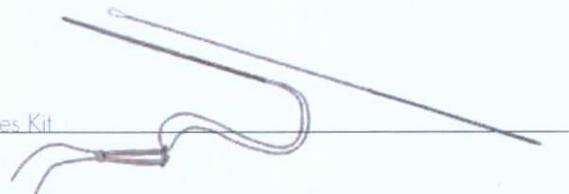
5 With the 1st metatarsal manually reduced, position the K-wires so the tapered portions just exit the medial cortex of the 1st metatarsal. This will allow easy passage of the #2 FiberWire through the drilled holes.



6 The distal construct should consist of two free #2 FiberWire ends threaded through an Oblong Button as shown (a). Insert one free end of the #2 FiberWire through each of the exposed Nitinol wire loops on the lateral side of the 2nd metatarsal. Pull the suture passing K-wires medially, passing the free ends through the 1.1 mm pilot holes (b).

Option: Technique as described will position suture knots on the medial 1st metatarsal. To place knots lateral to 2nd metatarsal, please review optional approach on [side two](#) of this technique.

Hallux Valgus Repair Mini TightRope 1.1 mm Disposables Kit



After the suture has been passed from lateral to medial, rethread one end of the #2 FiberWire through opposite holes in the Oblong Button. (Note: If using the original AR-8911DS kit with Round Buttons, thread the buttons in the same way using opposite holes. See Fig. 8.) The first of two Mini TightRope constructs is tied down with one knot while the second construct is placed 5 - 7 mm proximal from the first construct. Repeat drilling instructions in sections 4, 5 and 6 to place second construct. The surgeon should check the IM angular correction on C-arm prior to final tightening, using three knots for closure.



Construct completed using AR-8911DS disposables kit with four Round Buttons.

Hallux Valgus Post-op Protocol

Surgery & Post-op Day 1-4

Posterior fiberglass splint
Heel weight-bearing only

Post-op Day 4 - 28 (4 weeks)

Heel weight-bearing only
Pneumatic walking boot/Cam walker
Darco bunion splint to maintain position of great toe

Post-op Day 28 (4 weeks - 6 weeks)

Possible start in athletic shoe; only lateral or heel weight-bearing

Post-op Day 42 (6 weeks)

Weight-bear through great toe

Note: Recovery is dependent on soft tissues scarring to hold correction and unload the device. If premature weight-bearing through medial forefoot is initiated, the 2nd metatarsal responds similarly to a stress fracture with long-term edema and mild pain.

Option to step 6 - Suture knots placed lateral to 2nd metatarsal



Pass one limb of suture through distal hole using a Suture Passing K-wire.



Thread free end of #2 suture through both holes of the button. Using a second Suture Passing K-wire, pull through an accessory strand of 2-0 FiberWire (formed as loop) through proximal hole. The 2-0 FiberWire loop will act as a suture shuttle, pulling the #2 suture from medial to lateral.



Cut the nitinol loop portion of the passing wire. Pass the #2 FiberWire strand (about 1") through the 2-0 FiberWire loop and pull laterally. The construct can now be completed with a button and three knots lateral to the 2nd metatarsal.



Double construct complete

Mini TightRope 1.1 mm Disposables Kit

(AR-8914DS) includes:

- 2.6 mm Oblong Button (4)
- FiberWire suture
- 1.1 mm Suture Passing K-wire (4)
- Skin marking pen and ruler
- Suture Passing Wire, 8" long

Accessories:

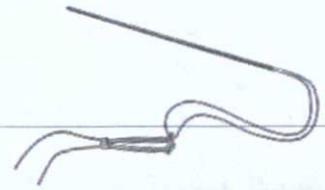
- | | |
|------------------------------|----------|
| 1.1 mm Suture Passing K-wire | AR-8914K |
| 2-0 FiberWire, 38 inches | AR-7221 |
| FiberWire Scissors, small | AR-11797 |



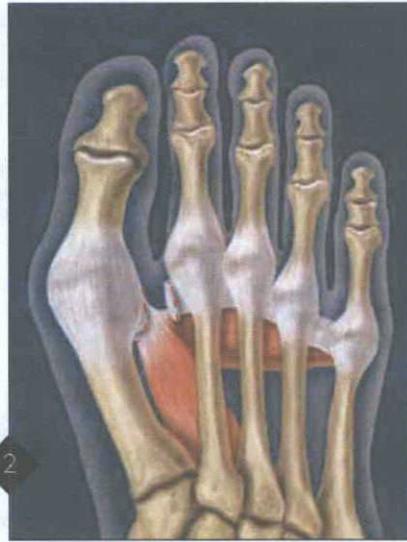
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LT0420A

Hallux Valgus Repair 2.7 mm Drill Hole Technique



1 For the distal approach, the incision is made between the 1st and 2nd metatarsals and inner space release is performed. A medial or dorsal medial incision can also be used with appropriate soft tissue retraction.



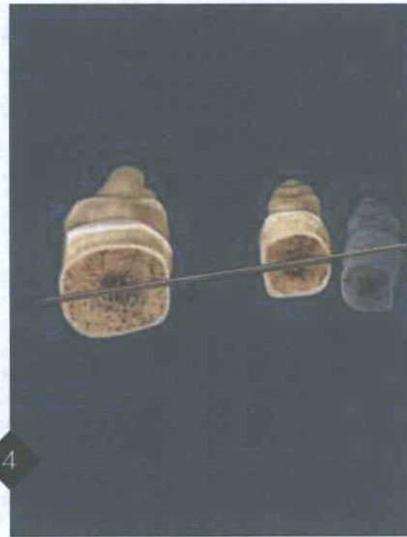
2 To realign the fibular sesamoid, detach the adductor tendon from the base of the proximal phalanx and fibular sesamoid. Release the deep intermetatarsal ligament. If needed, free any sesamoid adhesions to the intermetatarsal ligament. Manually test for the reducibility of the angular deformity following the release of the adductor tendon, release of the lateral capsule of the first metatarsophalangeal joint and release of the intermetatarsal ligament between the 1st and 2nd metatarsals.



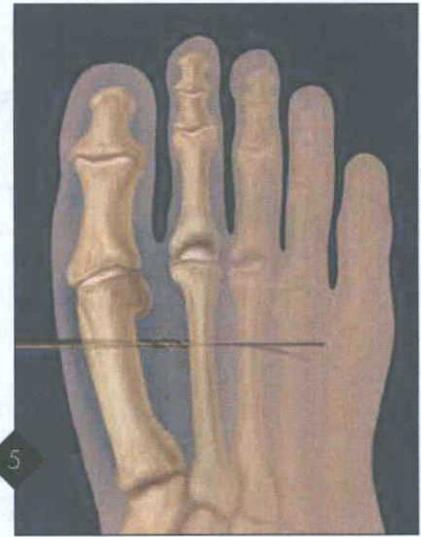
2a Incise the medial capsule, exposing the entire medial eminence. Remove the medial eminence preserving the sesamoid groove on the plantar aspect of the 1st metatarsal, avoiding excessive resection of the medial eminence.



3 Using the C-arm for guidance, insert the 1.2 mm Guidewire from lateral to medial across the 2nd and then 1st metatarsals. This enhances the accuracy of bisecting the 2nd metatarsal with reference to the dorsal and plantar aspects of the metatarsal. The Guidewire should exit the 1st metatarsal just proximal to the excised medial eminence.



4 An adjustment in dorsal to plantar direction may assist in the accurate placement of Guidewire allowing the pin to engage the 1st metatarsal in the midpoint between its dorsal and plantar borders. The entry point on the 2nd metatarsal should be about 2-5 mm proximal to the neck of the 2nd metatarsal head.
Note: Place Guidewire while visualizing 1st - 2nd metatarsal web space. A Freer elevator can direct Guidewire penetration at 1st metatarsal midline if needed.



5 Using the 2.7 mm Cannulated Drill Bit, drill the tunnel for the Mini TightRope over the Guidewire in a medial to lateral direction. Confirm proper placement with the C-arm.

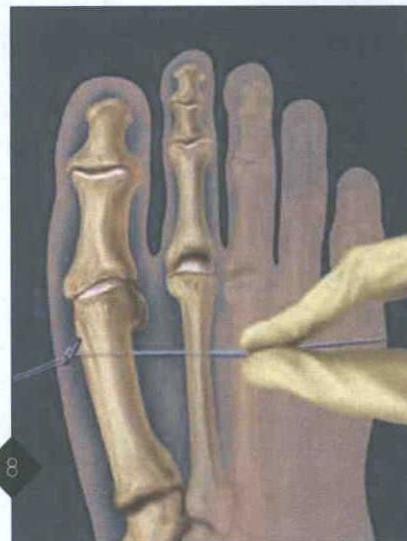
Hallux Valgus Repair 2.7 mm Drill Hole Technique



6 Pass the 1.6 mm Guidepin with pull-through suture (attached to the Mini TightRope) from lateral (2nd metatarsal) to medial (1st metatarsal) and stop before the button enters the drill hole.



7 The pull-through suture can now be advanced while the Guidepin is pulled medially. At the same time, apply lateral tension on the blue suture just behind the Oblong Button. This will help the Oblong Button to lay sideways, and pass easily through both bone tunnels.



8 The Oblong Button is flipped upon exiting the medial side of the first metatarsal cortex. Apply lateral tension on the blue suture. This will help seat the Oblong Button against the bone.



9 Repair is complete.

Note: Recovery is dependent on soft tissues scarring to hold correction and unload the device. If premature weight-bearing through medial forefoot is initiated, the 2nd metatarsal responds similarly to a stress fracture with long-term edema and mild pain.

Post-op Protocol

Surgery & Post-op Day 1-4

Posterior fiberglass splint
Heel weight-bearing only

Post-op Day 4 - 28 (4 weeks)

Heel weight-bearing only
Pneumatic walking boot/Cam walker
Darco bunion splint to maintain position of great toe

Post-op Day 28 (4 weeks - 6 weeks)

Possible start in athletic shoe; only lateral or heel weight-bearing

Post-op Day 42 (6 weeks)

Weight-bear through great toe

The white pull-through suture is cut and removed. The surgeon should manually push the 1st metatarsal and the 2nd metatarsal together to correct the intermetatarsal angular deformity. Once fluoroscopy confirms proper positioning, the trailing Round Button is tightened down by applying gradual tension on the remaining two strands of blue suture. Tie three half-hitches and cut the suture. Any previously placed sutures incorporating the lateral capsule of the 1st metatarsal, the adductor tendon and the medial capsule of the 2nd metatarsal are tied, thus completing the repair.



10 X-ray showing proper placement of medial and lateral button using the 2.7 mm drill hole technique.

Mini TightRope Disposables Kit (AR-8911DS) includes:
 Cannulated Drill Bit, 2.7 mm
 Round Button, 5.5 mm
 Oblong Button, 2.6 mm
 TightRope Guide Pin, 1.6 mm
 K-wire

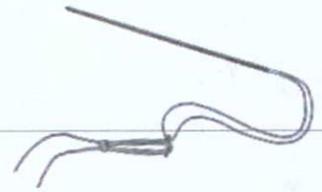
Accessories:
 Micro SutureLasso, straight AR-8703
 Micro SutureLasso, minor bend AR-8701
 FiberWire Scissors, small AR-11797



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LT0421A

Hallux Varus Repair

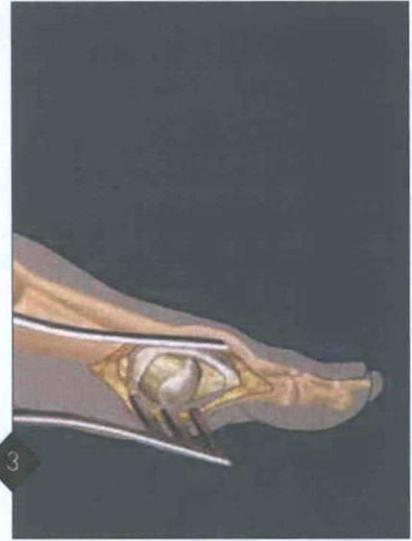
Mini TightRope Disposable Kit



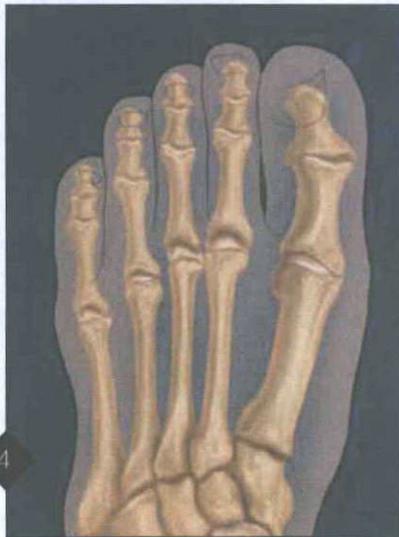
1 Preoperative diagram demonstrating typical hallux varus deformity.



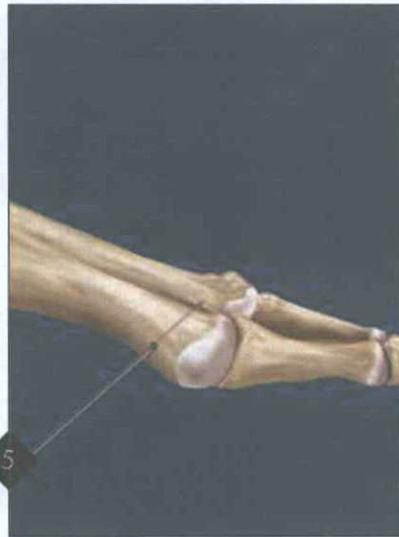
2 Dorsal first webspace incision. A dorsal medial or medial incision can also be used with approach distraction of soft tissues. Careful dissection should be done to expose the lateral base of the proximal phalanx and neck of the first metatarsal.



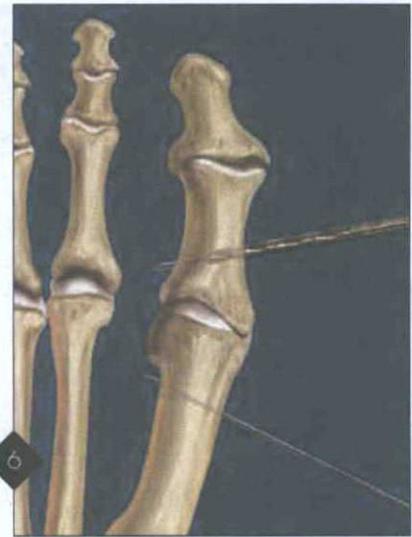
3 The abductor hallucis longus tendon is identified and either released or lengthened from its insertion into the proximal phalanx and tibial sesamoid. The medial capsule is incised as well.



4 Passive correction should now be possible without the surgeon holding the toe. Ideally, the Mini TightRope would just hold the correction obtained with the soft tissue release.



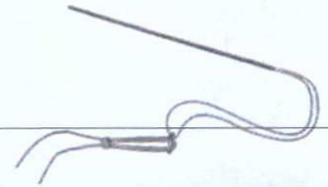
5 The K-wire is then placed in the medial midline of the 1st metatarsal. (Orient both K-wires so they angle obliquely 40° - 50° as shown.) Position should be checked using fluoroscopy. Midline placement of the pin should be checked visually by inspecting entry and exit points on both the medial and lateral sides of the 1st metatarsal.



6 Similarly, a K-wire is placed in the midline of the medial side of the proximal phalanx into the first webspace. Once placement of the K-wires is complete, the 2.7 mm cannulated drill is used over each K-wire. The K-wires are then removed.

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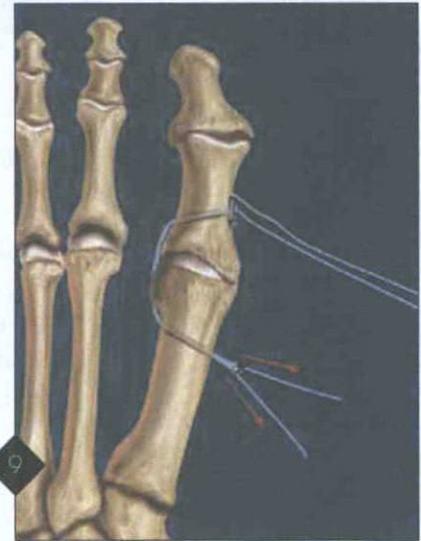
7

The white traction suture is cut from the needle at the swedge point (suture and needle interface). Using the Micro SutureLasso, the white traction suture is pulled through the 1st metatarsal bone tunnel. *Option: The pull-through Guidewire can be bent slightly and passed through the 1st metatarsal bone tunnel and then through the proximal phalanx.*



8

With tension on the suture now in the first web space, and countertension on the FiberWire of the Mini TightRope, the Oblong Button can be passed into the first web space.



9

A similar wire passing method is then used to pass the suture attached to the Oblong Button from the first web space, through the proximal phalanx, exiting the medial side of the phalanx. The white suture attached to the Oblong Button can be removed.



10

With the toe held in a reduced position, pull on the suture attached to the Round Button on the medial side of the first metatarsal. The Oblong Button will now lay flat on the proximal phalanx. Pull simultaneously on the sutures as shown to snug the round washer to the first metatarsal. It is suggested to place a small tubular structure between the small loop and the button to make fine adjustments easier. Check the tension of the suture in the web space directly. Once satisfied, tie the sutures.



Pre-op x-ray



Post-op x-ray

Post-Op Treatment: The patient's foot is placed in a spica wrap, holding the toe in slight valgus. Weight-bearing in a post-op shoe is allowed as tolerated. The spica wrap is changed weekly for six weeks. Transition to a shoe and ROM exercises are started. Patient may progress to activities as tolerated.

Mini TightRope Disposables Kit (AR-8911DS) includes:

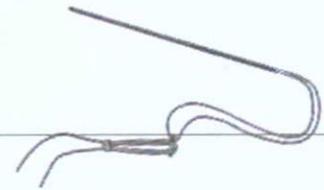
- Cannulated Drill Bit, 2.7 mm
- Round Button, 5.5 mm
- Oblong Button, 2.6 mm
- TightRope Guide Pin, 1.6 mm
- K-wire

Accessories:

- | | |
|-------------------------------|----------|
| Micro SutureLasso, straight | AR-8703 |
| Micro SutureLasso, minor bend | AR-8701 |
| FiberWire Scissors, small | AR-11797 |



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The stability of the second metatarsal articulation with the second cuneiform is maintained by both soft tissue and bone structures. The Lisfranc ligament extends from the first cuneiform to the base of the second metatarsal, helping to maintain the anatomic orientation of the second metatarsal with the adjacent first metatarsal, first cuneiform, second cuneiform, the third metatarsal as well as the third cuneiform. Stability is further imparted by the "keystone" fitting of the second metatarsal between the first and second cuneiforms.



An isolated rupture of the Lisfranc ligament leads to dorsal and/or lateral subluxation and displacement of the base of the second metatarsal. Fig. 1a demonstrates the inferior view of the Lisfranc joints with a tear of the Lisfranc ligament.



A longitudinal, dorsal incision is centered in an area extending from the lateral border of the first metatarsal and the first cuneiform to a line over the dorsal aspect of the second metatarsal. The exact position within this zone is determined by the location of other associated fractures and injuries and the specific location of the dorsalis pedis artery.



The incision is continued through the dorsal retinaculum. Beware of the possible injury to the distal branch of deep peroneal nerve and the dorsalis pedis artery. After the subperiosteal dissection the second metatarsal-cuneiform joint and the space between the base of the second metatarsal and the first metatarsal are cleared of any soft tissues that might restrict anatomic reduction. A bone reduction forceps may now be utilized to secure the reduction.



Fig. 4 demonstrates the insertion of the 1.1 mm K-wire from the lateral aspect of the base of the second metatarsal toward the first cuneiform exiting over the medial aspect of the foot. Exposure of the base of the second metatarsal may be facilitated by using a Hohmann Retractor around the lateral aspect of the second metatarsal. (If the lateral approach is not possible due to anatomic constraints at the lateral base of the second metatarsal, the surgeon may perform the procedure from a medial to lateral direction.)



The bone tunnel for passage of the button is created by overdrilling the K-wire with the 2.7 mm drill bit. It is important to maintain the stability of the reduction during this portion of the procedure.

Lisfranc Ligament Repair Mini TightRope Disposables Kit



6 The leading guide pin connected to the Oblong Button is passed in a lateral to medial direction through the bone tunnel.



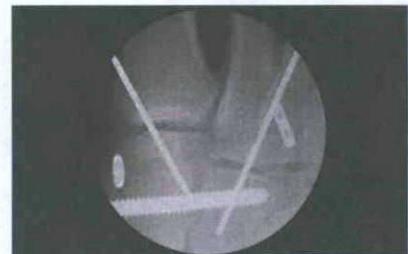
7 After exiting the medial aspect of the medial cuneiform, the button is turned 90° to engage the medial cortex. Confirm that there is no soft tissue interposed between the button and the cortex of the medial (first) cuneiform.



8 The lateral Round Button is tightened to the cortex of the second metatarsal by simultaneously pulling (sometimes with an alternating differential pull) on the two lateral FiberWire sutures. To prevent any possible shearing, the angle between the FiberWire sutures should be no more than about 20°.



9 The adequacy of the reduction is now checked with an intraoperative film.



Oblong Button placed lateral to 2nd metatarsal in this case

Mini TightRope Disposables Kit (AR-8911DS) includes:
 Cannulated Drill Bit, 2.7 mm
 Round Button, 5.5 mm
 Oblong Button, 2.6 mm
 TightRope Guide Pin, 1.6 mm
 K-wire

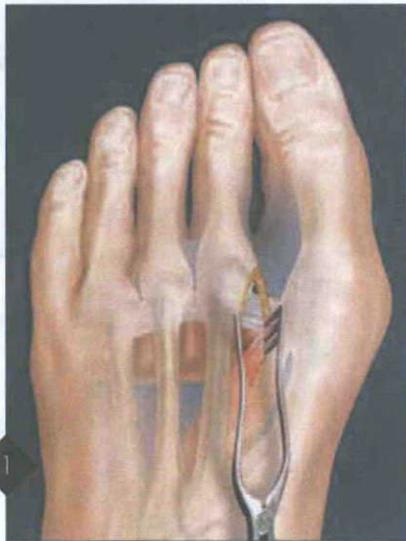
Accessories:
 FiberWire Scissors, small AR-11797



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Hallux Valgus Repair Mini TightRope FT Repair Kit



1 The lateral capsular structures are released followed by the manual reduction of the 1st intermetatarsal space.



2 Insert a K-wire, starting on the medial cortex of the 1st metatarsal, at least 1.5 - 2.5 cm distal to the 1st M-C joint aiming toward the base of the 2nd metatarsal. Surgeon should utilize x-ray or C-arm to ensure proper placement of the pin.



3 Pass the step drill over the K-wire until the pin tip of the drill penetrates the medial cortex of the 2nd metatarsal. Confirm proper alignment with fluoroscopy. Remove the drill bit and the K-wire. Note: Do not penetrate the medial cortex of the 2nd metatarsal farther than 3 mm (length of the step drill). *Optional: For hard bone, advance the 4.5 mm drill through the 1st metatarsal and complete drilling through the 2nd metatarsal with the 2.7 mm drill.*



4 Pass the cutting punch/tap through the 1st metatarsal and the 2nd metatarsal, making sure not to advance the instrument beyond the lateral wall of the 2nd metatarsal base. Confirm on fluoroscopy.



5 Advance the Mini TightRope FT on the driver through the 1st metatarsal and thread the anchor into the 2nd metatarsal. Confirm on fluoroscopy. Note: You can visualize the anchor only by observing the metal tip. The bioabsorbable anchor is 6 mm past the metal driver tip. *Optional: Prior to cinching down, pack the 1st metatarsal with medial eminence from the bunion.*



6 Tighten the trailing medial button over the 1st metatarsal. Use at least three half-hitches to tie off suture and lock button in place medially. Cut the suture ends long enough to allow the knot and suture to lay down, reducing knot prominence. This procedure can also be combined with a Distal Osteotomy (Chevron shown) and secured with 3 mm QuickFix Screws (a).

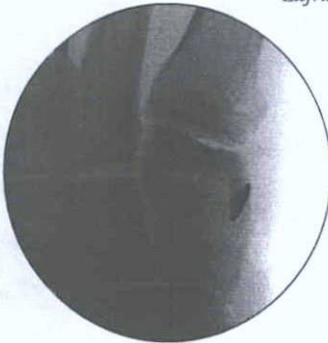
Hallux Valgus Repair Mini TightRope FT Repair Kit



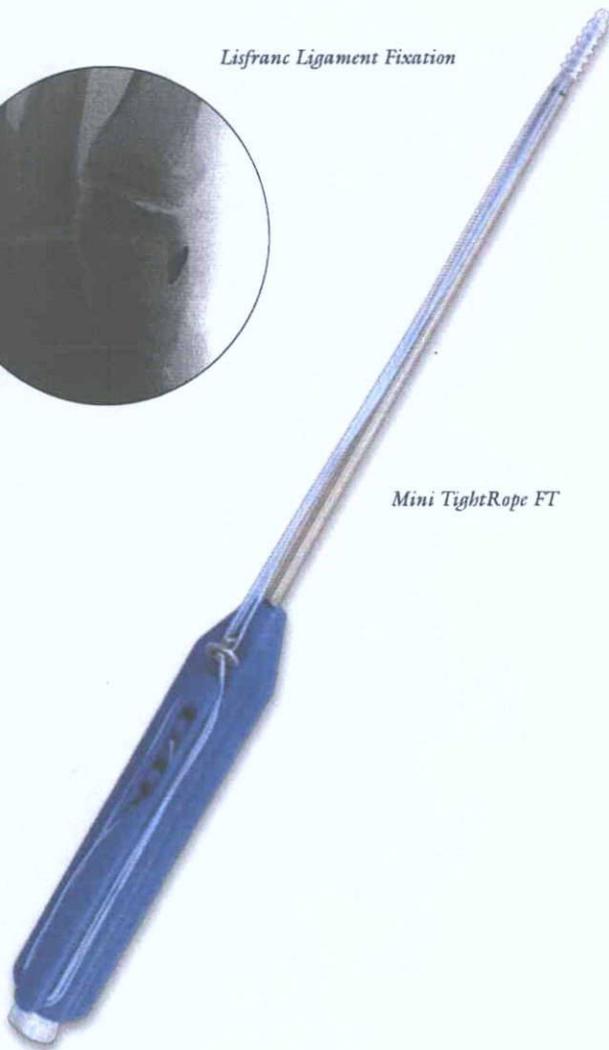
Hallux Valgus Repair



Lisfranc Ligament Fixation



Mini TightRope FT



Advantages:

- Minimally invasive dorsal medial single incision
- Anchor construct stabilizes the metatarsal cuneiform joint and acts as a 'backstop' to help prevent recurrence of the deformity
- IM angle correction with or without an osteotomy. Can be used with a distal osteotomy in cases of larger IM angles or semi-rigid deformities



*Mini TightRope FT
Punch/Tap*

Ordering Information

<u>Mini TightRope FT Repair Kit (AR-8912DS), sterile, includes:</u>	
Bio-Corkscrew FT, 4.5 mm	AR-1927B-45
Cannulated Drill Bit for Mini TightRope	AR-8911DC
Mini TightRope FT Drill Bit	AR-8912DC
Driver for Mini TightRope FT	AR-8912D
Mini TightRope FT Punch/Tap, 4.5 mm	AR-8912T
Cup Button, 7.8 mm	AR-8912
Guidewire	AR-8920P



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67

Description

The HAV- Lok Bunion Correction System is intended to assist in the correction of Hallux Valgus deformities by providing reduction of the 1st intermetatarsal angle. HAV-Lok may eliminate the necessity of a traditional osteotomy in the correction of Hallux Valgus deformities within the indicated criteria.

The Instratek HAV-Lok Bunion Correction System is intended for the following surgical indications:

- To assist in the correction of Hallux Valgus deformities by providing reduction of the 1st intermetatarsal angle.
-

Contraindications

- Active or previous infections
 - Poor bone quality
 - Osteoporotic bone
 - Fractured bone
 - Conditions that limit the patient's ability or willingness to follow postoperative instructions with the healing regimen.
 - Foreign body sensitivity or hyper reactivity
 - Physical conditions that retard the healing process
 - Surgical procedures not indicated for the device.
 - Skeletal immature bone may not be suitable
 - Structurally rigid non reducible 1st intermetatarsal angles
 - 1st intermetatarsal angles >16 deg.
 - Arthritic 1st metatarsalphalangeal joint
 - Degenerative 1st metatarsalphalangeal joint
 - Hallus rigidus and limitus
 - Irregular or incongruent 1st metatarsal phalangeal joint
-

Warnings

- Do not reuse device
 - Do not re-sterilize device
 - Do not expose to heat
 - Knowledge of the surgical technique is extremely important. Pre operative and operative planning is a necessity. Patient selection and implant placement are important considerations for successful outcomes with this device
 - Reduction devices are used as an aid to healing, they are not a substitute for normal intact bone and tissue.
 - Full weight bearing prior to healing is inadvisable.
 - Instructions for patients should be strictly followed to prevent adverse implant stress that inevitably will break device.
 - Excessive post op ambulation prior to healing may lead to stress fractures of the adjacent metatarsal
-

Post Operative Protocol Following Hallux Valgus Surgery

Post operative Week 1

- Below knee (BK) walking cast boot, rocker bottom sole, weight bearing heel only

Post operative weeks 1-4

- Below knee (BK) walking cast boot, rocker bottom sole, weight bearing heel only

Post operative weeks 4-6

- Full ambulation in (BK) walking cast boot

Post operative weeks 6-12

- Integration of regular daily activities in athletic shoe based on patient tolerance

Post operative week 12 and beyond

- Normal activities

Adverse Effects

- Metal sensitivity or known foreign body sensitivity
 - Soft tissue reactions in proximity of implants
 - Infections, both deep and superficial
 - Implant may require removal in event of severe post op infection
-

Sterilization

- The device supplied is sterile. The method of sterilization is noted on the package label.
 - Device is intended for single (one time) use only. Do not resterilize
 - Do not use if package has been previously opened or damaged
-

Material Specifications

- Plates – Ti-6Al-4V
 - #3/4 Suture – Ultra High Molecular Weight Polyethylene (UHMWPE)
 - Suture Lasso – Stainless Steel
 - Kwire – Stainless Steel
 - Cannulated Drill Bit – Stainless Steel
-

Packaging and Labeling

- Components should only be accepted with factory packaging and labeling intact
-

Instructions For Use

- Knowledge of the surgical technique is extremely important. Pre operative and operative planning is a necessity. If you require additional information, please contact an Instratek representative

Hallux Valgus Repair**Suture Path Drilling Steps**

1. Prior to incision orient topographically a kwire path for first suture hole from the medial aspect of the 1st metatarsal anatomical neck with an inclination to the distal 1/3 diaphyseal bone in the 2nd metatarsal verifying proper orientation by fluoroscopy. Use a marking pen to plot the trajectory of the k-wire on dorsal soft tissue.
2. Do to the varying pathologic anatomy of Hallux Valgus, perform the release of the lateral capsule structures as indicated. Perform resection of medial hyperostotic eminence structure prior to the next step.
3. Using your topographical markings from step 1, plot a 2.5cm longitudinal incision over the lateral aspect of the 2nd metatarsal cortex. The incision should begin distally on topographical pen marking and progress proximally over the 2nd metatarsal lateral cortex. Reflect the soft tissue and periosteum. Insert drill guide for controlled kwire placement orienting and securing the drill guide centrally on both the medial and lateral cortex of the 1st and 2nd metatarsal.
4. Advance the supplied 1.14mm x 305mm k-wire, from the medial aspect of the first metatarsal (approximately at the level of the 1st metatarsal anatomical neck) through the lateral cortex of the second metatarsal. Orient k-wire trajectory in the direction proximal of the distal 1/3 diaphyseal bone in the transverse plane. In the sagittal plane, the k-wire should be centrally placed within both metatarsals. Via fluoroscopy, confirm k-wire placement intra operatively in both the AP and Lateral planes. The k-wire should advance 3mm beyond the lateral cortex.
5. Remove drill guide leaving kwire in position. Plan second suture hole path with pen markings on medial 1st metatarsal cortex 4mm proximal of distal first suture hole path and 14mm proximal on 2nd metatarsal first suture hole path centrally.
6. Position the 2.0mm cannulated drill bit over first suture hole path k-wire and drill medial to lateral, advancing the lateral cortex of the second metatarsal.
7. Remove cannulated drill bit and k-wire by retrograding medially.
8. Prepare second suture hole path. Position drill guide on cortical pen markings and advance 1.14mm x 305mm k-wire medial to lateral through lateral cortex of second metatarsal.

9. Remove drill guide leaving k-wire in position
10. Position the 2.0mm cannulated drill bit over second suture hole path k-wire and drill medial to lateral, advancing the lateral cortex of the second metatarsal
11. Remove cannulated drill bit and k-wire by retrograding medially

Implant Insertion Steps

1. Insert the suture lasso, lateral to medial in distal 1st and 2nd metatarsal suture hole path drill holes, leaving the loop exposed laterally. Using plate and suture assembly provided, place both free suture ends through suture lasso loop.
2. Pull suture lasso medially transporting both suture ends until sutures are visible medial of 1st metatarsal. Manually pull sutures seating the lateral assembled oblong plate flush on the lateral cortex of the 2nd metatarsal.
3. Insert both suture ends together through one hole of the small 8mm oblong plate. Reverse path of both suture ends and pull through second hole of 8mm oblong plate.
4. Insert the suture lasso, medial to lateral in proximal second suture hole path leaving loop exposed medially. Place both suture ends through suture lasso loop.
5. Pull suture lasso laterally transporting both suture ends until sutures are visible lateral of 2nd metatarsal.
6. Separately thread one suture through each of the two most proximal bone plate holes.
7. Reduce the intermetatarsal angle to the desired biomechanical position. A reduction forcep or assistant may be helpful in maintaining the first metatarsal and second metatarsal angle while being secured.
8. Tightly secure a surgeons knot (three or more) over the oblong lateral plate. Trim suture in standard manner.
9. Close surgical site in usual fashion

SECTION 4. INDICATIONS FOR USE STATEMENT

510(k) Number:

Device Name:

HAV-Lok Bunion Correction System

Indications for Use:

The Instratek HAV-Lok Bunion Correction System is intended for the following surgical indications:

- To assist in the correction of Hallux Valgus deformities by providing reduction of the 1st intermetatarsal angle.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

REF HL6010
HAV-Lok™
Bunion Correction System
Expiration date February, 2012

Figure 16. Label for external pouch.


Instratek™
incorporated


Instratek Inc.
210 Springhill Dr., #130
Spring, Texas 77386 USA
+281-820-8020
800-892-8020

REF HL6010
HAV-Lok™
Bunion Correction System

Sterilized by Ethylene Oxide
Do Not Reuse
See Instructions for use
0338

LOT

EC REP

RX ONLY

CMI GmbH
Zur Wetterwarte 50, House 302
01109 Dresden, Germany
+49 (351) 2138888

0050

Figure 17. Label for internal pouch.

Label for ^{NON} Sterile Pouch.



Instratek Inc.
210 Springhill Dr., #130
Spring, Texas 77386 USA
+281-820-8020
800-892-8020

REF HL6010
HAV-Lok™
Bunion Correction System

Sterilized by Ethylene Oxide
Do Not Reuse

See Instructions for use
03388

LOT

EC REP

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(€ 0050