

510(k) SUMMARY**Mitek Arthroscope****APR 18 2014**

Recognized Manufacturer: Medos International SarL
Puits Godet 20
CH 2000 Neuchâtel
Switzerland

Submitter: DePuy Mitek, Inc.
a Johnson & Johnson company
325 Paramount Drive
Raynham, MA 02767

Contact Person: Susan Kagan
Project Manager,
Regulatory Affairs
DePuy Mitek, Inc.
a Johnson & Johnson company
325 Paramount Drive
Raynham, MA 02767, USA

Telephone: 508-880-8097
Facsimile: 508-977-6911
e-mail: SKagan@its.jnj.com

Name of Medical Device: Proprietary Name: SwingScope
Classification: Arthroscope
Name:
Common Name: Arthroscope

Substantial Equivalence: Mitek Arthroscopes are substantially equivalent to the predicate devices listed in Table1.

Table 1: Predicate Devices

Company	Description	510(k)
Acclarent	Cyclops Multiangle Endoscope	K110097
Acclarent	Cyclops Multiangle Endoscope	K100577
Stryker	Stryker Arthroscope	K093677
Arthrex	Arthrex Arthroscopes	K030096

Device Classification	Classification: FDA Product Code: Regulation:	Class II HRX Arthroscope 21 CFR 888.1100
------------------------------	---	--

Device Description

The Mitek Arthroscope is a multi-angle, rigid 4.3 mm arthroscope that has the capability of varying direction of view from 10° to 90° which enables surgeons to maximize and optimize their field of view inside the joint from any given port. This reduces the need for multiple fixed-angle arthroscopes.

The direction of view is altered by the direction of view dial; the direction of view is indicated by markings on the scope body. The Mitek Arthroscope provides a 55° field of view and a depth of field from 5mm to 40mm. The device shaft can also rotate by rotating the device (typically by the light post). A standard eyepiece located on the proximal end of the device is compatible with a standard camera coupler. The light post on the subject device is compatible with an ACMI light source.

There are two light post stainless steel adaptors that accompany the Mitek Arthroscope. Two adapters are provided to facilitate connection with medical light source cables with a diameter of 5.0mm and smaller.

The Mitek Arthroscope is a reusable device and must be cleaned and sterilized according to the user manual prior to every use.

Indications for Use

Mitek Sports Medicine Arthroscopes are indicated for use in arthroscopic procedures (such as the knee, shoulder, hip, ankle, elbow) to provide visualization during surgery.

Non-Clinical Testing

No clinical studies are required to demonstrate safety and efficacy of the device in support of an application for premarket clearance. The Mitek Arthroscope does not differ from the predicate device in fundamental scientific technology or intended use.

Verification tests of the Mitek Arthroscope included performance, cleaning validation and biocompatibility to show that the device meets its product specifications over a range of operating conditions.

Verification testing conforms to the following Standards and Guidance documents listed in Table 2.

Safety and Performance

Table 2. Standards and Guidance Documents

Standard/ Guidance	Description
EN 60601-18	Medical electrical equipment -- Part 18: Particular Requirements for Basic Safety and Essential performance of endoscopic equipment
ANSI/AAMI/ISO 17665-1	Sterilization of Healthcare Products-Moist Heat-Part 1: Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices
ISO 11135-01	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing
ISO 17664	Sterilization of medical devices. Information to be provided by the manufacturer for the processing of re sterilizable medical device
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
DIN ISO 8600-3:2004	Optics and optical instruments -- Medical endoscopes and endoscopic accessories -- Part 3: Determination of field of view and direction of view of endoscopes with optics

Table 3 provides a summary of testing parameters and results.

Table 3. Summary of Testing

Test	Results
Field of View	Passed
Fixed Focus	Passed
Direction of View Range	Passed
Direction of View Torque	Passed
Rotation of View	Passed
Illumination	Passed
Scope Resolution	Passed
Visual Inspection	
Hermetic sealing	Passed

Free from aberrations	Passed
-----------------------	--------

Results of performance testing have demonstrated that the proposed device is suitable for its intended use.

Based on the indications for use, technological characteristics, and comparison to the predicate devices, the proposed The Mitek Arthroscope has shown to be substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.



April 18, 2014

Medos International SARL - DePuy Mitek Incorporated
Ms. Susan Kagan
Project Manager Regulatory Affairs
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K133941
Trade/Device Name: Arthroscopes (SwingScope)
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: March 4, 2014
Received: March 10, 2014

Dear Ms. Kagan:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Page 2 – Ms. Susan Kagan

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133941

Device Name: Mitek Arthroscopes

Indications for Use:

Mitek Sports Medicine Arthroscopes are indicated for use in arthroscopic procedures (such as the knee, shoulder, hip, ankle, elbow) to provide visualization during surgery.

Prescription Use (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S

medos international

December 27, 2013

Food and Drug Administration
 Center for Devices and Radiological Health
 Document Control Center (WO66-G609)
 10903 New Hampshire Avenue
 Silver Spring, MD 20993-0002

FDA CDRH DMC
 DEC 30 2013
 Received

Re: Traditional: 510(k) Notification – Mitek Arthroscopes-eCopy Hold-K133941

Dear Sir/Madam,

Pursuant to the requirements of Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended, DePuy Mitek (hereafter referred to as "Mitek"), a Johnson & Johnson company, hereby submits this **Traditional 510(k)** for the **Mitek Arthroscopes** on behalf of Medos International.

- Trade name: Mitek Arthroscope
- Common name: Arthroscope
- Classification and Panel: HRX(Class II) General & Plastic Surgery Devices
- Prior submissions: N/A – there are no prior submissions
- Bundled devices: N/A – this is not bundled submission
- Clinical Data: N/A – this submission does not contain clinical data

The Mitek Arthroscope was developed as a new device based on the Acclarent Cyclops Endoscope.

The Mitek Arthroscope described in this submission is substantially equivalent to the following currently marketed predicate devices:

510(k)	Description	Manufacturer	Indications
K100577	Cyclops Multiangle Endoscope	Acclarent, Inc. a Johnson and Johnson company	ENT
K110097	Cyclops Multiangle Endoscope	Acclarent, Inc. a Johnson and Johnson company	ENT
K093677	Stryker Arthroscope	Stryker Inc.	Arthroscopy
K030096	Arthrex Arthroscopes	Arthrex Inc.	Arthroscopy

12

medos international

A complete discussion of predicate devices may be found within the body of this submission in the 510(k) Summary and Section 5: Substantial Equivalence.

The followings are enclosed in this submission package.

- One Paper Copy
- One CD of eCopy which is an exact duplicate of the paper copy.

We consider the intent to market this device as confidential commercial information and request that it be considered as such by FDA. We have taken precautions to protect the confidentiality of the intent to market the device. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C 331(q).

Please note that a copy of the Medical Device User Sheet has been provided in this submission and payment for review of the premarket notification has been forwarded to FDA's St. Louis office (payment identification reference number **(MD 6072590-956733)**).

Thank you in advance for your consideration of our application. If there are any questions during the review of this application, please feel free to contact me at (508) 880-8097 or skagan@its.jnj.com.

Sincerely,



12/27/13

Jeffrey Dzialo
Coordinator of International Regulatory Affairs

medos international

December 19, 2013

Food and Drug Administration
 Center for Devices and Radiological Health
 Document Control Center (WO66-0609)
 10903 New Hampshire Avenue
 Silver Spring, MD 20993-0002

K133944
 FDA CDRH DMC
 DEC 23 2013
 Received

Re: Traditional: 510(k) Notification – Mitek Arthroscopes

Dear Sir/Madam,

Pursuant to the requirements of Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended, DePuy Mitek (hereafter referred to as "Mitek"), a Johnson & Johnson company, hereby submits this **Traditional 510(k)** for the **Mitek Arthroscopes** on behalf of Medos International.

- Trade name: Mitek Arthroscope
- Common name: Arthroscope
- Classification and Panel: HRX(Class II) General & Plastic Surgery Devices
- Prior submissions: N/A – there are no prior submissions
- Bundled devices: N/A – this is not bundled submission
- Clinical Data: N/A – this submission does not contain clinical data

The Mitek Arthroscope was developed as a new device based on the Acclarent Cyclops Endoscope.

The Mitek Arthroscope described in this submission is substantially equivalent to the following currently marketed predicate devices:

510(k)	Description	Manufacturer	Indications
K100577	Cyclops Multiangle Endoscope	Acclarent, Inc. a Johnson and Johnson company	ENT
K110097	Cyclops Multiangle Endoscope	Acclarent, Inc. a Johnson and Johnson company	ENT
K093677	Stryker Arthroscope	Stryker Inc.	Arthroscopy
K030096	Arthrex Arthroscopes	Arthrex Inc.	Arthroscopy

00

medos international

A complete discussion of predicate devices may be found within the body of this submission in the 510(k) Summary and Section 5: Substantial Equivalence.

The followings are enclosed in this submission package.

- One Paper Copy
- One CD of eCopy which is an exact duplicate of the paper copy.

We consider the intent to market this device as confidential commercial information and request that it be considered as such by FDA. We have taken precautions to protect the confidentiality of the intent to market the device. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C 331(q).

Please note that a copy of the Medical Device User Sheet has been provided in this submission and payment for review of the premarket notification has been forwarded to FDA's St. Louis office (payment identification reference number **(b)(4) TS/CCI**).

Thank you in advance for your consideration of our application. If there are any questions during the review of this application, please feel free to contact me at (508) 880-8097 or skagan@its.jnj.com.

Sincerely,



Susan Kagan
Project Manager, Regulatory Affairs

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. 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 Secret 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/mdufma/cover sheet.html		
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) DEPUY MITEK 325 PARAMOUNT DR RAYNHAM MA 02767 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)	2. CONTACT NAME Susan Kagan 2.1 E-MAIL ADDRESS skagan@its.jnj.com 2.2 TELEPHONE NUMBER (include Area code) 508-880-8097 2.3 FACSIMILE (FAX) NUMBER (Include Area code)	
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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm) 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"/> 30-Day Notice		
3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)		
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:		
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)		
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially		
7. 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		
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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 the address below. Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]		
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4) Trade Secret		06-Dec-2013

Form FDA 3501 (01/2007)

"Close Window" Print Cover sheet

December 19, 2013

Food and Drug Administration
 Center for Devices and Radiological Health
 Document Control Center (WO66-0609)
 10903 New Hampshire Avenue
 Silver Spring, MD 20993-0002

Re: Traditional: 510(k) Notification – Mitek Arthroscopes

Dear Sir/Madam,

Pursuant to the requirements of Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended, DePuy Mitek (hereafter referred to as "Mitek"), a Johnson & Johnson company, hereby submits this **Traditional 510(k)** for the **Mitek Arthroscopes** on behalf of Medos International.

- Trade name: Mitek Arthroscope
- Common name: Arthroscope
- Classification and Panel: HRX(Class II) General & Plastic Surgery Devices
- Prior submissions: N/A – there are no prior submissions
- Bundled devices: N/A – this is not bundled submission
- Clinical Data: N/A – this submission does not contain clinical data

The Mitek Arthroscope was developed as a new device based on the Acclarent Cyclops Endoscope.

The Mitek Arthroscope described in this submission is substantially equivalent to the following currently marketed predicate devices:

510(k)	Description	Manufacturer	Indications
K100577	Cyclops Multiangle Endoscope	Acclarent, Inc. a Johnson and Johnson company	ENT
K110097	Cyclops Multiangle Endoscope	Acclarent, Inc. a Johnson and Johnson company	ENT
K093677	Stryker Arthroscope	Stryker Inc.	Arthroscopy
K030096	Arthrex Arthroscopes	Arthrex Inc.	Arthroscopy



A complete discussion of predicate devices may be found within the body of this submission in the 510(k) Summary and Section 5: Substantial Equivalence.

The followings are enclosed in this submission package.

- One Paper Copy
- One CD of eCopy which is an exact duplicate of the paper copy.

We consider the intent to market this device as confidential commercial information and request that it be considered as such by FDA. We have taken precautions to protect the confidentiality of the intent to market the device. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C 331(q).

Please note that a copy of the Medical Device User Sheet has been provided in this submission and payment for review of the premarket notification has been forwarded to FDA's St. Louis office (payment identification reference number (b)(4) TS/CCI [REDACTED])

Thank you in advance for your consideration of our application. If there are any questions during the review of this application, please feel free to contact me at (508) 880-8097 or skagan@its.jnj.com.

Sincerely,

Susan Kagan
Project Manager, Regulatory Affairs

Mitek Arthroscopes: Traditional 510(K)

Preliminary Questions	Yes	No
<p>1. Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)?</p> <p>If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. Provide a summary of the Jurisdictional Officer's/Liaison's determination. If the product does not appear to be a device or such a combination product, mark "No."</p>	√	
<p>2. Is the application with the appropriate Center?</p> <p>If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. Provide a summary of the Jurisdictional Officer's/Liaison's determination. If application should not be reviewed by your Center mark "No."</p>	√	
<p>3. If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following:</p> <p>a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?</p> <p>b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?</p> <p>If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. Provide summary of Jurisdictional Officer's/Liaison's determination. If the answer to either question above is no, mark "No." If there was no RFD, skip this question.</p>		√
<p>4. Is a 510(k) the appropriate regulatory submission?</p> <p>If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."</p>	√	
<p>5. Is there a pending PMA for the same device with the same indications for use?</p> <p>If there is a pending PMA for the same device, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.</p>		√
<p>6. If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)?</p> <p>If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections</p>		√

Mitek Arthroscopes: Traditional 510(K)

and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm .		
--	--	--

Organizational Elements	Yes	No
a. Submission contains Table of Contents	√	
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	√	
c. All pages of the submission are numbered All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2...).	√	
d. Type of 510(k) is identified– traditional, abbreviated, or special If type of 510(k) is not designated, review as a traditional	√ Cover Letter	

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)		Yes / Section #	N/ A	No
A. Administrative				
1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	√		
2.	Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	√		
	a. Device trade name or proprietary name	√		
	b. Device common name	√		
	c. Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	√		
3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also 801.109) <i>Submitter should use format appropriate for the reviewing Center/Office (CDRH/ODE, CDRH/OIVD, CBER/OBRR, CBER/OCTGT). If not provided in correct format, request the correct format during substantive review.</i>	√		
4.	Submission contains 510(k) Summary or 510(k) Statement <i>Either a) or b) must be answered "Yes" to be considered complete. Identify any missing element(s) as Comments.</i>	√		
	a. Summary contains all elements per 21 CFR 807.92 <i>See also 510(k) Summary Checklist</i>	√		
	b. Statement contains all elements per 21 CFR 807.93		√	
5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) <i>See recommended format. Select "Yes" if statement is present</i>	√		

Mitek Arthroscopes: Traditional 510(K)

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)		Yes / Section #	N/ A	No
	<i>and includes the text in the recommended format, and is signed by a responsible person of the firm (not consultant).</i>			
6.	Submission contains Class III Summary and Certification <i>See recommended content</i> Form should be signed by a responsible person of the firm, not a consultant. CDRH is not currently able to accept a digital signature. "N/A" only if submission is not a Class III 510(k).		√	
7.	Submission contains clinical data Select "N/A" if the submission does not contain clinical data. If "N/A" is selected, parts a and b below are omitted from the checklist.		√	
	a. Submission includes completed Financial Certification (FDA Form 3454) or Disclosure (FDA Form 3455) information for each covered clinical study included in the submission. <i>Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the Guidance for Industry Financial Disclosures by Clinical Investigators</i>		√	
	b. Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. <i>Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec. 801(j)</i>		√	
8.	If submission relies upon a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (FDA Form 3654) or includes detailed information about how and the extent to which the standard has been followed <i>There should be a completed form for each referenced national or international standard. Select "N/A" only if submission does not reference any standards.</i>	√		
9.	The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for PreSubmission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device. <i><u>This information may be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions).</u> Alternatively, a list of submission numbers may be found in</i>			√

Mitek Arthroscopes: Traditional 510(K)

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)		Yes / Section #	N/ A	No
	<i>Section F (prior related submissions section) of the CDRH Coversheet form (Form 3514) to address this criterion. Please be advised that if this section of the form is left blank, it should not be considered a statement that there were no prior submissions.</i>			
	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. <i>To address this criterion, the submission may include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that the adequacy of how the feedback was addressed should be assessed during the substantive review. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm310375.htm). Once finalized, this guidance will represent the Agency's current thinking on this topic. Select "N/A" if the submitter states there were no prior submissions in criterion above.</i>		√	
B. Device Description				
10.	a. If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement. <i>Select "N/A" if there are no applicable requirements in a device specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.</i>			√
	b. If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. <i>Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative</i>			√

Mitek Arthroscopes: Traditional 510(K)

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)			Yes / Section #	N/ A	No
		<i>approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.</i>			
11.		Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:			
		a. A description of the principle of operation and mechanism of action for achieving the intended therapeutic/diagnostic effect.	√ Section 4		
		b. A description of proposed conditions of use such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	√ Section 4		
		c. A list and description of each model for which clearance is requested. <i>Select "N/A" if there is only one mode "Device" may refer to models, part numbers, or various sizes, etc.</i>	√ Section 4		
12.		Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions. <i>In lieu of drawings, schematics, etc. of each device to be marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed. Select "N/A" if the submitter provided a rationale for why the submission does not contain engineering drawings, schematics, etc. (e.g., device is a reagent and figures are not pertinent to describe the device).</i>	√ Attachment A		
13.		If device is intended to be marketed with multiple components, accessories, and/or as part of a system, <i>Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system.</i>			
		a. Submission includes a list of all components and accessories to be marketed with the subject device.	√ Section 4		
		b. Submission includes a description (as detailed in item 11.a. and b. and 12 above) of each component or accessory. <i>Select "N/A" if the component(s)/accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.</i>	√ Section 4		

Mitek Arthroscopes: Traditional 510(K)

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)			Yes / Section #	N/ A	No
		c. A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. <i>Select "N/A" if the submission states that the component(s)/ accessory(ies) does not have a prior 510(k) clearance or the component(s)/accessory(ies) is 510(k) exempt.</i>		√	
C. Substantial Equivalence Discussion					
	14.	Submitter has identified a predicate(s) device			
		a. Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. <i>Information regarding documenting preamendment status is available online(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ComplianceActivities/ucm072746.htm).</i>	√ Section 5		
		b. The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	√ Section 5		
	15.	Submission includes a comparison of the following for the predicate(s) and subject device			
		a. Indications for use	√ Section 5		
		b. Technology, including features, materials, and principles of operation	√ Section 5		
	16.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)) <i>If there is no difference between the subject and predicate(s) with respect to indications for use or technology, this should be explicitly stated, in which case "N/A" should be selected. Select "No" only if the submission does not include an analysis of differences as described above or a statement that there are no differences. Note that the adequacy of the analysis</i>	√ Section 5		

Mitek Arthroscopes: Traditional 510(K)

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)			Yes / Section #	N/ A	No
		<i>should be assessed during the substantive review; only the presence of such an analysis is required for acceptance. In addition, note that due to potential differences in manufacturing that may not be known to the submitter, the fact that no differences are identified does not necessarily mean that no performance testing is needed.</i>			
D. Proposed Labeling (see also 21 CFR part 801)					
	17.	Submission includes proposed labels, labeling (e.g., instructions for use, package insert, operator's manual) that describe a description of the device, its intended use, and the directions for use	√		
		a. Indications for use stated in labeling (21 CFR 801.61) and identical to IFU form and 510(k) Summary (if applicable)	√ Section 10 Attachment C		
		b. Submission includes directions for use that include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) AND Includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D	√ Attachment C		
	18.	If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [<i>See also Alternative to Certain Prescription Device Labeling Requirements</i>] <i>Select "N/A" if not indicated for prescription use.</i>	√ Section 10 Attachment B & C		
	19.	General labeling provisions			
		a. Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)	√ Attachment B & C		
		b. Labeling includes device common or usual name (21 CFR 801.61) <i>Select "N/A" if device is for prescription use only.</i>	√ Attachment B & C		
	20.	a. If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement. <i>Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does</i>		√	

Mitek Arthroscopes: Traditional 510(K)

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)		Yes / Section #	N/ A	No
	<i>not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.</i>			
	b. If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. <i>Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.</i>		√	
	c. If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. <i>Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.</i>		√	
	21. If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. <i>Select "N/A" if not an in vitro diagnostic device.</i>		√	
E. Sterilization				
	<i>If in vitro diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.</i>			
	Submission states that the device and/or accessories are: <i>(one of the below must be checked)</i> <input type="checkbox"/> provided sterile <input checked="" type="checkbox"/> provided non-sterile but sterilized by the end user <input type="checkbox"/> non-sterile when used			

Mitek Arthroscopes: Traditional 510(K)

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)		Yes / Section #	N/ A	No
	This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If "non-sterile when used" is selected, the sterility-related criteria below are omitted from the checklist.</i> <i>If information regarding the sterility status of the device is not provided, select "No."</i>			
22.	Assessment of the need for sterilization information			
	a. Identification of device, and/or accessories, and/or components that are provided sterile.		√	
	b. Identification of device, and/or accessories, and/or components that are end user sterilized	√ Section 9		
	c. Identification of device, and/or accessories, and/or components that are reusable and cleaning/disinfection instructions are provided.	√ Section 9		
23.	If the device, and/or accessory, and/or a component is provided sterile: <i>Select "N/A" if no part of the device, accessories, or components is provided sterile, otherwise complete a-e below.</i>			
	a. Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)		√	
	b. A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. <i>Note, the sterilization validation report is not required.</i>		√	
	c. For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits. <i>Select "N/A" if not sterilized using chemical sterilants.</i>		√	
	d. Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)		√	
	e. Sterility Assurance Level (SAL) stated		√	
24.	If the device, and/or accessory, and/or a component is end user sterilized: <i>Select "N/A" if no part of the device, accessories, or components are end user sterilized, otherwise complete a-d below.</i>			
	a. Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	√ Section 9		
	b. A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided	√ Section 9		

Mitek Arthroscopes: Traditional 510(K)

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)			Yes / Section #	N/ A	No
		for each proposed sterilization method. <i>Note, the sterilization validation is not required.</i>			
		c. Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	√ Section 10		
		d. Submission includes sterilization instructions for end user	√ Attachment C		
	25.	a. If there are requirements regarding sterility, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement. <i>Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.</i>	√ Section 9		
		b. If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. <i>Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.</i>	√ Section 9		
		c. If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. <i>Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any</i>		√	

Mitek Arthroscopes: Traditional 510(K)

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)		Yes / Section #	N/ A	No
	<i>alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.</i>			
F. Shelf Life				
26.	Proposed shelf life/ expiration date stated <i>Select "N/A" if the device is not provided sterile and the submitter states that storage conditions could not affect device safety or effectiveness.</i>		√	
27.	For sterile device, submission includes summary of methods used to establish that device sterility will remain substantially equivalent to that of the predicate through the proposed shelf life, or a rationale for why testing to establish shelf life is not applicable. <i>Select "N/A" if the device is not provided sterile.</i>		√	
28.	For sterile device, submission includes summary of methods used to establish that device sterility will remain substantially equivalent to that of the predicate through the proposed shelf life, or a rationale for why testing to establish shelf life is not applicable. <i>Select "N/A" if the device is not provided sterile.</i>		√	
G Biocompatibility				
	<i>If in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.</i>			
	Submission states that there: <i>(one of the below must be checked)</i> <input checked="" type="checkbox"/> are <input type="checkbox"/> are not direct or indirect (e.g., through fluid infusion) patient-contacting components. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If "are not" is selected, the biocompatibility-related criteria below are omitted from the checklist. If information regarding whether the device is patient-contacting is not provided, select "No."</i>			
29.	Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	√ Section 8		
30.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration)	√ Section 8		
31.	Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test,	√ Section 8 provides a summary		

Mitek Arthroscopes: Traditional 510(K)

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)		Yes / Section #	N/ A	No
	OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).			
H Software				
	Submission states that the device: <i>(one of the below must be checked)</i> <input type="checkbox"/> does <input checked="" type="checkbox"/> does not contain software/firmware. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If "does not" is selected, the software-related criterion is omitted from the checklist. If information regarding whether the device contains software is not provided, select "No."</i>			
	32. Submission includes a statement of software level of concern and rationale for the software level of concern		√	
	33. All appropriate categories of software verification and validation documentation provided based on stated level of concern, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices , or the submitter has provided documentation that it has otherwise met the applicable statutory or regulatory criteria through an alternative approach. (i.e., the submitter has identified an alternate approach with a rationale).		√	
I. EMC and Electrical Safety				
	Submission states that the device: <i>(one of the below must be checked)</i> <input checked="" type="checkbox"/> does <input type="checkbox"/> does not require EMC and Electrical Safety evaluation. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If "does not" is selected, the EMC-related and Electrical Safety-related criteria below are omitted from the checklist. If information regarding whether the device requires EMC and Electrical Safety evaluation is not provided, select "No."</i> There are no electrical components in the Mitek Arthroscope, therefore electrical safety and EMC testing was not required. However there are small rare earth magnets in the scope body so EMC testing was performed.			
	34. Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, the device-specific standard), OR submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has			√ Section 7

Mitek Arthroscopes: Traditional 510(K)

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)		Yes / Section #	N/ A	No
	otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).			
35.	Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) OR submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	√ Section 7		
J. Performance Data - General				
	<i>If in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected. Performance data criteria relating to IVD devices will be addressed in Section K.</i>			
36.	Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence. <i>Full test reports provided for all completed tests/evaluations (e.g., bench evaluations, comparative performance tests, etc.). Select "N/A" if the submission does not include performance data.</i>	√ Section 6 provides a summary		
37.	a. If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement. <i>Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.</i>	√ Section 6 provides a summary		
	b. If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable		√	

Mitek Arthroscopes: Traditional 510(K)

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)		Yes / Section #	N/ A	No
	<p>statutory or regulatory criteria through an alternative approach.</p> <p><i>Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.</i></p>			
	<p>c. If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.</p> <p><i>Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.</i></p>		√	
38.	<p>If literature is referenced in the submission, submission includes:</p> <p><i>Select "N/A" if the submission does not reference literature. Note that the applicability of the referenced article to support a substantial equivalence finding should be assessed during the substantive review; only the presence of a discussion is required to support acceptance.</i></p>		√	
	a. Legible reprints or a summary of each article		√	
	b. Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.		√	
39.	<p>For each completed nonclinical (i.e., animal) study conducted, <i>Select "N/A" if no animal study was conducted. Note that this section does not address biocompatibility evaluations, which are assessed in Section G of the checklist,</i></p>		√	
	a. Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120		√	
	b. Submission includes final study report which includes all elements outlined in 21 CFR 58.185		√	
	c. Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study		√	

Mitek Arthroscopes: Traditional 510(K)

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)		Yes / Section #	N/ A	No
	was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.			
K. Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))				
	<p>Submission indicates that device: <i>(one of the below must be checked)</i></p> <p><input type="checkbox"/> is</p> <p><input checked="" type="checkbox"/> is not</p> <p>an in vitro diagnostic device (IVD).</p> <p><i>If "is not" is selected, the performance data-related criteria are omitted from the checklist.</i></p>			

End of document

TABLE OF CONTENTS

001_Form FDA 3601 – Medical Device User Fee Cover Sheet
002_Cover Letter to the FDA
003_FDA Acceptance Checklist
004_Table of Contents
005_Form FDA 3514 – CDRH Premarket Review Submission Cover Sheet
006_Form FDA 3654 – Standards Data Report for 510(k)s
007_510(k) Screening Checklist
008_Indication for Use Statement
009_Truthful and Accurate Statement
010_510(k) Summary
011_ 510(k) Premarket Notification Mitek Arthroscopes
Section 1: Introductory Information
Section 2: Executive Summary
Section 3: Indications for Use
Section 4: Device Description
Section 5: Substantial Equivalency
Section 6: Verification and Validation
Section 7: Electrical Rationale
Section 8: Biocompatibility
Section 9: Sterilization
Section 10: Packaging & Shelf Life
Section 11: Labeling
012_Attachment A: Drawing (Proposed devices)
013_Attachment B: Labeling
014_Attachemet C: Instructions for Use
015_Attachment D: Predicate 510(k)s
016_Attachment E: Predicate IFU's

Error - Couldn't merge file with following reason - PdfReader not opened with owner password
09002621816f5958.pdf

System attempted to attach the file. Please look at attachments to open this file manually.

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

AAMI/ANSI/ISO 17665-1: Sterilization of Health care products-Moist heat-Part 1 requirements for the development, validation a

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #14-261

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 17665-1: Sterilization of Health care products-Moist heat-Part 1 requirements for the development, validation and routine

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER ALL Applicable	SECTION TITLE	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------------------------	---------------	--

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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 number.

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 17664 Sterilization of medical devices-information to be provided by manufacturer for processing of re sterilizable devices

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #N/A

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 17664 Sterilization of medical devices-information to be provided by manufacturer for processing of re sterilizable devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER ALL Applicable	SECTION TITLE	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------------------------	---------------	--

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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 number.

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 11135-1:2007 Sterilization of health care products-Ethylene oxide-Part 1

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #14-228

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 11135-01 Sterilization of health care products-Ethylene oxide-Part 1

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER ALL Applicable	SECTION TITLE	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------------------------	---------------	--

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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 number.

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

AAMI/ANSI/ISO 10993-1: Biological Evaluation of Medical Devices Part 1, Evaluation and Testing

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #2-179

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation an

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information, which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
AAMI/ANSI/ISO 10993-1: Biological Evaluation of Medical Devices Part 1, Evaluation and Testing

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER ALL Applicable	SECTION TITLE	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------------------------	---------------	--

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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 number.

Department of Health and Human Services
 Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
 (To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

AAMI/ANSI/IEC 60601-1-2:2007 Medical electrical equipment-Part 1-2:General requirements for safety-Collateral: EMC

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #5-34

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
 If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
AAMI/ANSI/IEC 60601-1-2:2007 Medical electrical equipment-Part 1-2:General requirements for safety-Collateral: EMC

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL Applicable		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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 number.

Department of Health and Human Services
 Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
 (To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 8600-3: Optics and optical Instruments-Medical endoscopes and endoscopic accessories

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #9-38

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
 If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 8600-3: Optics and optical Instruments-Medical endoscopes and endoscopic accessories

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL Applicable		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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 number.

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

IEC 60601-2-18: Medical electrical equipment Part 2-18: particular requirements for endoscopic equipment

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #9-42

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

IEC 60601-2-18: Medical electrical equipment Part 2-18: particular requirements for endoscopic equipment

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL Applicable		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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 number.

PRE-MARKET NOTIFICATION 510(k) REVIEWER'S SCREENING CHECKLIST

Device Name: <i>Mitek Arthroscopes</i>				
Submitter (Company): <i>DePuy Mitek</i>				
Section 1: Required elements for All Types of 510(k) Submissions	YES	NO	N/A	LOCATION
Cover Letter clearly identifies Submission as: Traditional 510(k)	✓			Cover Letter
Table of Contents	✓			Table of Contents
Truthful and Accurate Statement	✓			Truthful and Accurate Statement
Device's Trade Name, Device's Classification Name and Establishment Registration Number	✓			Section 1
Device classification Regulation Number and Regulatory Status	✓			Section 1
Proposed labeling	✓			Section 11 Attachment B
Statement of Indications for Use that is on a separate page in the premarket submission	✓			Statement of Indications for Use
Substantial Equivalence Comparison, including comparisons of the new device with the predicate	✓			Section 5
510(k) Summary or 510(k) Statement	✓			510(k) Summary
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals	✓			Section 4
Identification of legally marketed predicate device	✓			510(k) Summary Section 5
Compliance with performance standards	✓			Form 3514 & Section 1
Class III Certification and Summary			✓	Class II Device
Financial Certification or Disclosure Statement for 510(k) notifications with clinical study			✓	N/A
510(k) Kit Certification			✓	N/A
Section 2: Required Elements for a SPECIAL 510(k) Submission	YES	NO	N/A	LOCATION
Name and 510(k) number of the sponsor's own, unmodified predicate device			✓	N/A
A description of the modified device and a comparison to the sponsor's predicate device			✓	N/A
A statement that the intended use(s) and indication of the modified device, as described in its labeling, are the same as the intended uses and indications for the sponsor's unmodified predicate device			✓	N/A
A statement that the modification has not altered the fundamental technology of the sponsor's predicate device			✓	N/A
A Design Control Activities Summary that includes the following elements.			✓	N/A
a. Identification of Risk Analysis method(s) used to assess the impact of the modifications on the device and its components, and the results of the analysis			✓	N/A
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.			✓	N/A
c. A Declaration of Conformity with design controls that includes the following statements			✓	N/A
i. Statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined			✓	N/A

PRE-MARKET NOTIFICATION 510(k) REVIEWER'S SCREENING CHECKLIST

acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.				
ii. A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.			✓	N/A

Indications for Use

510(k) Number (if known):

Device Name: Mitek Arthroscopes

Indications for Use:

Mitek Arthroscopes are indicated for use in arthroscopic procedures to provide visualization during surgery.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

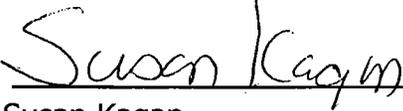
TRUTHFUL AND ACCURATE STATEMENT

Premarket Notification

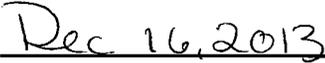
Truthful and Accurate Statement

(As Required By 21 CFR 807.87(j))

We certify that, in our capacities as Project Manager, Regulatory Affairs and Staff Engineer, we believe to the best of our knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted



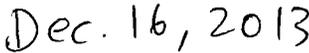
Susan Kagan
Project Manager, Regulatory Affairs
DePuy Mitek



Date



Bethany Grant
Principal Engineer
DePuy Mitek



Date

510(k) SUMMARY

Mitek Arthroscope

Recognized Manufacturer: Medos International SarL
Puits Godet 20
CH 2000 Neuchâtel
Switzerland

Submitter: DePuy Mitek, Inc.
a Johnson & Johnson company
325 Paramount Drive
Raynham, MA 02767

Contact Person Susan Kagan
Project Manager,
Regulatory Affairs
DePuy Mitek, Inc.
a Johnson & Johnson company
325 Paramount Drive
Raynham, MA 02767, USA

Telephone: 508-880-8097
Facsimile: 508-977-6911
e-mail: SKagan@its.jnj.com

Name of Medical Device Proprietary Name: Mitek Arthroscope
Classification Name: Arthroscope
Common Name: Arthroscope

Substantial Equivalence Mitek Arthroscopes are substantially equivalent to the predicate devices listed in Table1.

Table 1: Predicate Devices

Company	Description	510(k)	Indications
Acclarent	Cyclopes Multiangle Endoscope	K110097	ENT
Acclarent	Cyclopes Multiangle Endoscope	K100577	ENT
Stryker	Stryker Arthroscope	K093677	Arthroscopy
Arthrex	Arthrex Arthroscopes	K030096	Arthroscopy

Device Classification	Classification: FDA Product Code: Regulation:	Class II HRX Arthroscope 21 CFR 888.1100
------------------------------	---	--

Device Description

The Mitek Arthroscope is a multi-angle, rigid 4.3 mm arthroscope that has the capability of varying direction of view from 10° to 90° which enables surgeons to maximize and optimize their field of view inside the joint from any given port. This reduces the need for multiple fixed-angle arthroscopes.

The direction of view is altered by the direction of view dial; the direction of view is indicated by markings on the scope body. The Mitek Arthroscope provides a 55° field of view and a depth of field from 5mm to 40mm. The device shaft can also rotate by rotating the device (typically by the light post). A standard eyepiece located on the proximal end of the device is compatible with a standard camera coupler. The light post on the subject device is compatible with an ACMI light source.

There are two light post stainless steel adaptors that accompany the Mitek Arthroscope. Two adapters are provided to facilitate connection with medical light source cables with a diameter of 5.0mm and smaller.

The Mitek Arthroscope is a reusable device and must be cleaned and sterilized according to the user manual prior to every use.

Indications for Use

Mitek Sports Medicine Arthroscopes are indicated for use in arthroscopic procedures to provide visualization during surgery.

Non-Clinical Testing

No clinical studies are required to demonstrate safety and efficacy of the device in support of an application for premarket clearance. The Mitek Arthroscope does not differ from the predicate device in fundamental scientific technology or intended use.

Verification tests of the Mitek Arthroscope included performance, cleaning validation and biocompatibility to show that the device meets its product specifications over a range of operating conditions.

Verification testing conforms to the following Standards and Guidance documents listed in Table 2.

Safety and Performance

Table 2. Standards and Guidance Documents

Standard/ Guidance	Description
EN 60601-18	Medical electrical equipment -- Part 18: Particular Requirements for Basic Safety and Essential performance of endoscopic equipment
ANSI/AAMI/ISO 17665-1	Sterilization of Healthcare Products-Moist Heat-Part 1: Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices
ISO 11135-01	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing
ISO 17664	Sterilization of medical devices. Information to be provided by the manufacturer for the processing of re sterilizable medical device
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
DIN ISO 8600-3:2004	Optics and optical instruments -- Medical endoscopes and endoscopic accessories -- Part 3: Determination of field of view and direction of view of endoscopes with optics

Table 3 provides a summary of testing parameters and results.

Table 3. Summary of Testing

Test	Results
Field of View	Passed
Fixed Focus	Passed
Direction of View Range	Passed
Direction of View Torque	Passed
Rotation of View	Passed
Illumination	Passed
Scope Resolution	Passed
Visual Inspection	
Hermetic sealing	Passed
Free from aberrations	Passed

Results of performance testing have demonstrated that the proposed device is suitable for its intended use.

Based on the indications for use, technological characteristics, and comparison to the predicate devices, the proposed The Mitek Arthroscope has shown to be substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.

SECTION 1: INTRODUCTORY INFORMATION

Name of the Device Common Name: Arthroscope
Trade Name /Proprietary Name: Mitek Arthroscope

Submitter Susan Kagan
Project Manager, Regulatory Affairs
DePuy Mitek, Inc.
a Johnson & Johnson company
325 Paramount Drive
Raynham, MA 02767
Telephone: 508-880-8097
Facsimile: 508-977-6911
e-mail: skagan@iys.jnj.com

Recognized Manufacturer: Medos International SARL
Chemin-Blanc 38, Case Postale
CH 2400
Le Locle, Switzerland

Owner/Operator: 10031083
FDA Registration #: 3008114965

Manufacturing Facility (b)(4) Trade Secret Process


Sterilization Facility Device is provided non-sterile

Device Classification Classification Name: Arthroscope
FDA Regulation No: 21 CFR 888.1100 Class II
FDA Product Code: HRX

Review Panel Orthopedic Review Panel

**Consensus
Standards and
Guidance
Documents**

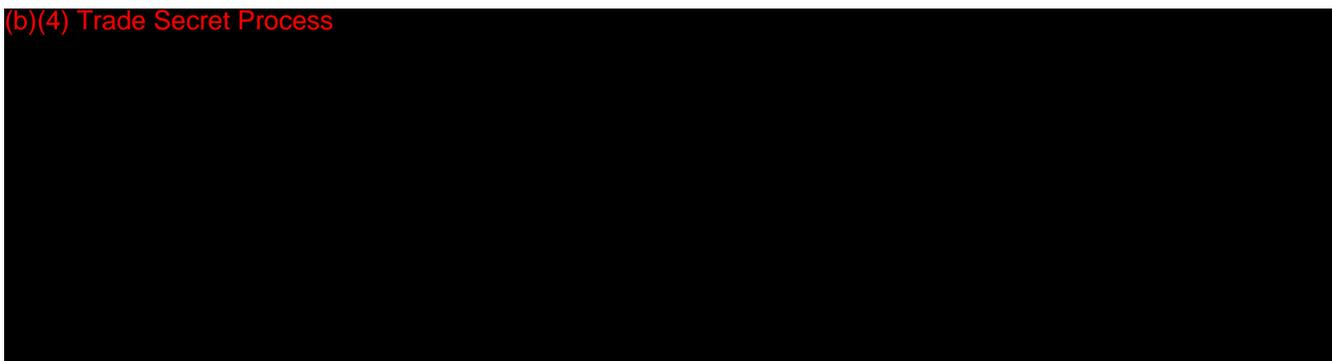
- ISO 10993-1:2009, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.
- ISO 17664:2004 Sterilization of medical devices. Information to be provided by the manufacturer for the processing of re sterilizable medical device
- ISO 11135-1: 2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ANSI/AAMI/ISO 17665-1:2006, Sterilization of Health Care Products - Moist Heat - Part 1: Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices
- IEC 60601-2-18:2009, Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- DIN ISO 8600-3:2004, Optics and optical instruments -- Medical endoscopes and endoscopic accessories -- Part 3: Determination of field of view and direction of view of endoscopes with optics

SECTION 2: EXECUTIVE SUMMARY

The Mitek Arthroscope is intended to provide a physician with an endoscopic means to view joints during arthroscopic procedures. Different angle endoscopes, which include arthroscopes, such as 0°, 30°, and 70°, are available to surgeons for visualization during arthroscopic surgery in order to change the direction of view. In current practice, surgeons need to remove the arthroscope and re-insert a different angled arthroscope. This can result in a loss of orientation and longer duration of procedure. With the Mitek Arthroscope the direction of view is changed through a mechanical means of rotating the prism angle, the image is continuous because changes in the shaft rotation and direction of view are completed without removing the scope from the joint.

The Mitek Arthroscope is a multi-angle, rigid 4.3 mm arthroscope that has the capability of varying direction of view from 10° to 90°. If the surgeon enters the joint at 10°, they can turn the shaft toward the area of interest and then change the direction of view until the desired area is visualized. This enables surgeons to maximize and optimize their field of view inside the joint from any given portal thereby reducing the need for using multiple fixed-angle arthroscopes during a single operative procedure. The Mitek Arthroscope provides a 55° field of view and a depth of field from 5 mm to 40mm.

(b)(4) Trade Secret Process



A standard eyepiece located on the proximal end of the device is compatible with a standard camera coupler. The light post is compatible with an ACMI light source. Two stainless steel light post adaptors that accompany the Mitek Arthroscope adaptors are provided to facilitate connection with medical light source cables with a diameter of 5.0mm and smaller.

The Mitek Arthroscope is a reusable device that will be packaged and sold to physicians as a non-sterile device. The device must be sterilized prior to use via steam sterilization, STERRAD® or Ethylene Oxide (EO, or EtO) EO sterilization. Instructions for sterilization are provided in the package insert.

SECTION 3: INDICATION FOR USE STATEMENT

Below is a summary of the proposed Mitek Arthroscope as compared to its' predicts.

<p>Mitek Arthroscope Subject Device</p>	<p>Acclarent Cyclops Multiangle Endoscope (Gen2) (K100577)</p>	<p>Acclarent Cyclops Multiangle Endoscope (K110097)</p>	<p>Stryker Arthroscope (K093677)</p>	<p>Arthrex Arthroscopes (K030096)</p>
<p>Arthroscopy</p>	<p>ENT</p>	<p>ENT</p>	<p>Arthroscopy</p>	<p>Arthroscopy</p>
<p>Mitek Arthroscopes are indicated for use in arthroscopic procedures to provide visualization during surgery.</p>	<p>The Acclarent Cyclops Multi-Angle Endoscope is intended to provide an endoscopic means to view the nasal cavity and nasopharynx</p>	<p>The Acclarent Cyclops Multi-Angle Endoscope is intended to provide an endoscopic means to view the nasal cavity and nasopharynx</p>	<p>Stryker Arthroscopes are endoscopic devices introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy. Arthroscopes are indicated for use in arthroscopic procedures performed in the hip, knee, shoulder, wrist (carpel tunnel syndrome), temporal mandibular joint, ankle, elbow, and feet (plantar fascia release).</p>	<p>The Arthrex Arthroscopes are indicated for use in diagnostic and operative arthroscopic procedures to provide illumination and visualization of the shoulder, knee, elbow, ankle, wrist, and jaw, and also to provide illumination and visualization during arthroscopic diagnostic procedures and removal of loose bodies and soft tissue within the hip joint as size/length appropriate.</p>

SECTION 4: DEVICE DESCRIPTION

A. Intended Use

Mitek Arthroscopes are indicated for use in arthroscopic procedures to provide visualization during surgery.

B. Mitek Arthroscope (also referred to as **SwingScope**)

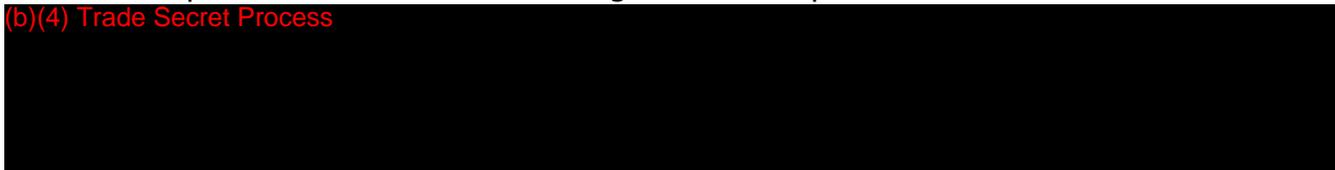
Table 1 Description of Model numbers

P/N	Description
288000	SwingScope

The Mitek Arthroscope is similar in fundamental technology and material as the predicate device: Cyclops Endoscopes (Acclarent, a Johnson and Johnson company, (K100577 and K110097)). Refer to the device specification, **Table 2** and material list **Table 3** below. Both the Cyclops Endoscope and the Mitek Arthroscope are intended to provide a physician with an endoscopic means to view the interior of the body. The major difference is the indication for use. The Acclarent Cyclops is indicated for ENT applications whereas the Mitek Arthroscope is indicated for arthroscopic procedures.

The Mitek Arthroscope is intended to provide a physician with an endoscopic means to view joints during arthroscopic procedures. Different angle arthroscopes such as 0°, 30°, and 70°, are available to surgeons for visualization during arthroscopic surgery in order to change the direction of view. In current practice, surgeons need to remove the arthroscope and re-insert a different angled arthroscope. This can result in a loss of

(b)(4) Trade Secret Process



The Mitek Arthroscope is a multi-angle, rigid 4.3mm arthroscope that has the capability of varying direction of view from 10° to 90°. If the surgeon enters the joint at 10°, the

(b)(4) Trade Secret Process



The device shaft (**Figure 1, B**) is fixed to the Scope Body, and can rotate by rotating the device (typically by the light post). A standard eyepiece (**Figure 1, E**) located on the proximal end of the device is compatible with a standard camera coupler or universal C-mount couplers. The light post (**Figure 1, F**) is compatible with an ACMI light source. There are two stainless steel light post adaptors (**Figure 1, G & H**) that accompany the Mitek Arthroscope. Two adaptors are provided to facilitate connection with medical light source cables with a diameter of 5.0mm and smaller.

A product description of the Mitek Arthroscope is described below and illustrated in **Figure 1**: identified the by the letters A-I.

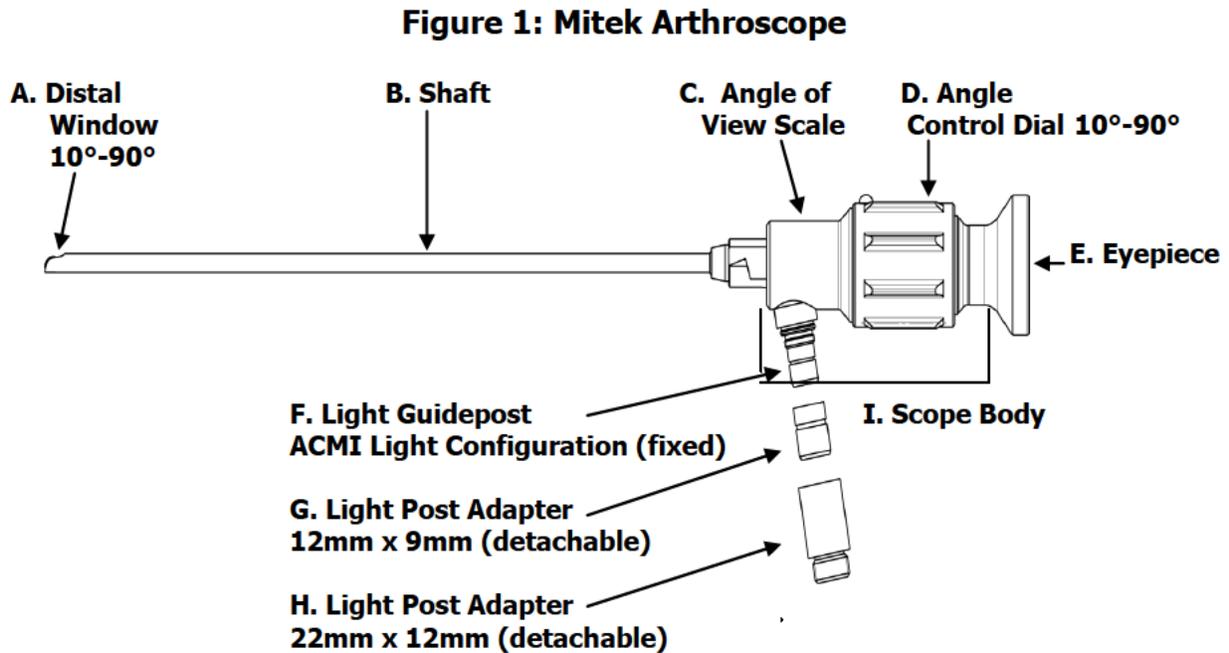


Figure 2: Angle Control

10° Angle of View



90° Angle of View



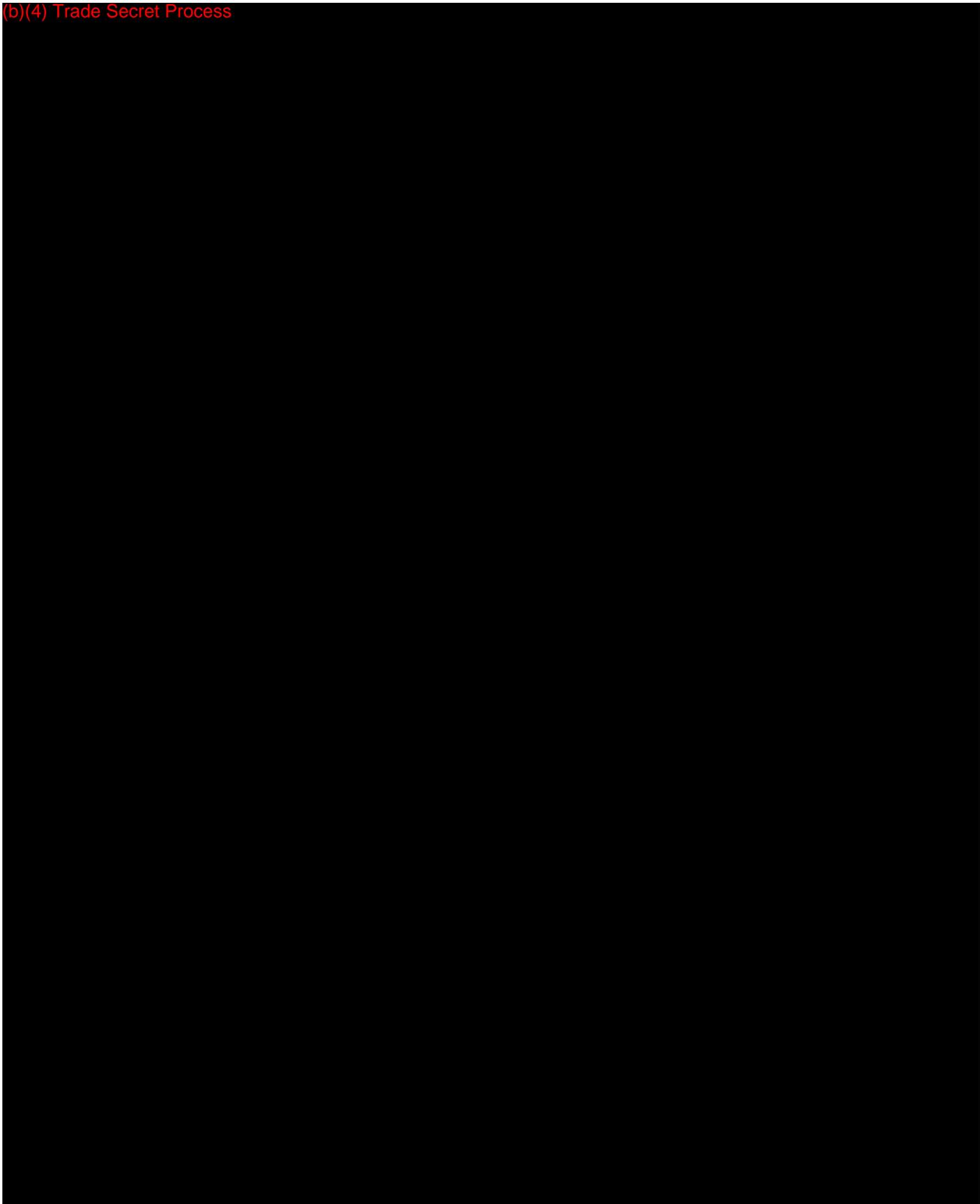
The Mitek Arthroscope is a reusable device that will be packaged and sold to physicians as non-sterile. The device must be sterilized prior to use via steam sterilization, STERRAD or Ethylene Oxide (EO) sterilization. Instructions for cleaning and sterilization are detailed in the Instructions for Use. See **Section 9** for additional information regarding cleaning, disinfection and sterilization.

Verification and Validation testing has been conducted on Mitek Arthroscope on sterile samples to illustrate conformance with the device specifications. A discussion of testing and results can be found in **Section 6**.

C. Principal of Operations

(b)(4) Trade Secret Process

(b)(4) Trade Secret Process



D. Device Specifications

Device specifications for the Mitek Arthroscope were developed based on clinical feedback and internal design control requirements. The intended use and fundamental scientific technology of the subject device are similar to predicate devices and are discussed in Section 5: Substantial Equivalency. The Mitek Arthroscope device specifications are listed in **Table 2**.

Table 2 Device Specifications

Attributes	Device Specification
Distal Shaft Diameter	4.3 mm
Working Length	205mm
Field of View	55°
Depth of Field	5-40 mm
Illumination	(b)(4) Trade Secret Process
Brightness	Optical (b)(4) Trade Secret Process
Direction of View	(b)(4)

E. Materials Identification

The Mitek Arthroscope utilizes materials that are common in the medical device industry. **Table 3** identifies the materials used in the subject device. A discussion on the biocompatibility of the contact materials may be found in **Section 8** of this submission.

Table 3 Materials

Component	Material
Cover glass	(b)(4)
Outer tube (Shaft)	(b)(4) Trade Secret Process
Illumination fibers	(b)(4)
Adhesives	(b)(4)
Solder	(b)
Locking system	(b)(4) Trade Secret Process
Eyepiece	(b)(4)
Swing prism dial	(b)(4)
Main body	(b)(4) Trade Secret Process
Light connector	(b)(4) Trade Secret Process
Lightpost adapter	(b)(4) Trade Secret Process
Prism	(b)(4) Trade

G. Conclusion

The Mitek Arthroscope is substantially equivalent to the Accelerant Cyclops variable angle endoscope (K100577 and K110097), Stryker fixed angle arthroscope (K093677, and the Arthrex fixed angle arthroscopes (K030096). A comparison and discussion of the Mitek Arthroscope to its predicates can be found in Section 5 of this submission: Substantial Equivalency.

SECTION 5: SUBSTANTIAL EQUIVALENCY

A. Introduction

The Mitek Arthroscope is a multi-angle, rigid 4 mm arthroscope that has the capability of varying direction of view from 10° to 90° which enables surgeons to maximize and optimize their field of view inside the joint from any given port.

An arthroscope is a type of endoscope used to visualize joints during arthroscopic procedures, whereas an endoscope is fundamentally the same instrument but used to visualize body cavities and organs. Although they have different intended uses they have similar technological characteristics.

- A rigid or flexible tube, various OD and lengths and angle of view,
- An eyepiece
- A light delivery system to illuminate the anatomical area being inspected. The light source is normally outside the body and the light is typically directed via an optical fiber system
- A lens system transmitting the image from the lens to a viewer

The predicate device: Cyclops Endoscope (Acclarent, a Johnson and Johnson company, K100577 and K110097) and the Mitek Arthroscope are similar in fundamental technology and material. (**Refer to Tables 3 above and 4 below**). The major difference is the indication for use. The Acclarent Cyclops is indicated for ENT applications whereas the Mitek Multi-Angle Arthroscope is indicated for arthroscopic procedures.

Both the Cyclops Endoscope and the Mitek Arthroscope are intended to provide a physician with an endoscopic means to view the interior of the body. Currently different angle endoscopes such as 10°, 30°, and 70°, are available to surgeons for visualization during arthroscopic procedures in order to change the direction of view. In both the Cyclops Endoscope and Mitek Arthroscope, the image is continuous because changes in the shaft rotation and direction of view are completed without removing the

(b)(4) Trade Secret Process

The performance characteristics and the fundamental scientific technology of the Mitek Arthroscope do not raise any significant issues of safety or effectiveness when compared to the predicate devices, as demonstrated by the substantial equivalency table (**Table 4**).

B. Predicate Devices

The Mitek Multi-Angle Arthroscope is substantially equivalent to the Accelerant Cyclops Variable Angle Endoscope (K100577 and K110097), the Stryker fixed angle arthroscope (K093677), and the Arthrex fixed angle arthroscope (K030096).

A comparison of the Mitek Arthroscope with the predicate devices is provided in Table 4. This table demonstrates that the subject device is substantially equivalent to the predicate devices for its indication for use, performance, and technological characteristics.

Table 4 Comparison to Predicate Devices

	Mitek Arthroscope Subject Device	Cyclops Multiangle Endoscope (Gen2) (K100577)	Cyclops Multiangle Endoscope (K110097)	Arthroscope (K093677)	Arthroscopes (K030096)
	Medos International	Acclarent	Acclarent	Stryker	Arthrex
Indication	Arthroscopy	ENT	ENT	Arthroscopy	Arthroscopy
Indication for Use	Mitek Arthroscopes are indicated for use in arthroscopic procedures to provide visualization during surgery.	The Acclarent Cyclops Multi-Angle Endoscope is intended to provide an endoscopic means to view the nasal cavity and nasopharynx	The Acclarent Cyclops Multi-Angle Endoscope is intended to provide an endoscopic means to view the nasal cavity and nasopharynx	Stryker Arthroscopes are endoscopic devices introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy. Arthroscopes are indicated for use in arthroscopic procedures performed in the hip, knee, shoulder, wrist (carpel tunnel syndrome), temporal mandibular joint, ankle, elbow, and feet (plantar fascia release).	The Arthrex Arthroscopes are indicated for use in diagnostic and operative arthroscopic procedures to provide illumination and visualization of the shoulder, knee, elbow, ankle, wrist, and jaw, and also to provide illumination and visualization during arthroscopic diagnostic procedures and removal of loose bodies and soft tissue within the hip joint as size/length appropriate.
Rigidity	Rigid	SAME	SAME	SAME	SAME
Viewing Optics	Lens	SAME	SAME	SAME	SAME
Depth of Field	5-40 mm	SAME	SAME	N/A	N/A
Field of View	55°	SAME	60°	65°, 80° 105°	30° or 70°
Direction of View	(b)(4) Trade Secret Process				
Camera Coupler (Eyepiece)	Attached	SAME	SAME	SAME	SAME
Shaft Diameter	4.3mm	4.0mm	4.0mm	1.9mm, 2.3mm, 2.7mm, 4mm	1.9mm, 2.4mm, 2.7mm, 3mm, 3.5mm, 4mm *

Working Length	205mm	175mm	175mm	58mm, 72mm, 75mm, 120mm, 140mm, 165mm	72mm, 75mm, 152mm, 156mm, 202mm, 206mm *
Illumination Fibers	Glass Fibers	SAME	SAME	SAME	SAME
Illumination	(b)(4) Trade Secret Process	SAME	SAME	N/A	N/A
Optical Brightness	(b)(4)	SAME	SAME	N/A	N/A
Presence of magnets	Yes	SAME	SAME	N/A	N/A
Maximum Magnetic Field Strength	≤ 10 gauss at 2 cm	SAME	SAME	N/A	N/A
Light Source	Medical light source	SAME	SAME	SAME	SAME
Sterilization Method	Steam Sterilization/ STERRAD®/EtO	SAME	SAME	Steam Sterilization	Steam Sterilization/STE RRAD®/EtO ***
Single Use or Reusable	Reusable	SAME	SAME	SAME	SAME
Primary Materials	Glass, stainless steel, sapphire, PEEK	SAME	Glass, stainless steel, titanium, sapphire, PPSU	Stainless Steel, PEEK, Titanium, Sapphire, Glass	Stainless Steel Shaft

* Reference Arthrex product website: <https://www.arthrex.com/imaging-resection/arthroscopes/products>

** Reference Section 9: Verification Testing

***Reference IFU, Arthrex Autclavable Rigid Medical Endoscopes

C. Performance

Performance testing on Mitek Arthroscope was conducted using sterilized samples. The results met device specifications as demonstrated in **Section 6**.

D. Materials Identification

All patient contact materials used in the subject device are found in the predicate device: Acclarent Cyclops (K100577 and K110097), as demonstrated in **Table 3 above**.

E. Summary

The Mitek Arthroscope is substantially equivalent to the predicate devices in indication for use, performance, and fundamental scientific technology.

F. Supporting Question from SE Flowchart

To further evaluate the substantial equivalence of the proposed Mitek Multi-Angle Arthroscope to the predicate Acclarent Cyclops Endoscope, the FDA 510(k) "Substantial Equivalence Decision-Making Process" decision tree process (**Table 5**) was employed. The answers to seven questions from this decision tree lead to a determination of substantial equivalence for this device. The flowchart follows these responses to the questions.

NOTE: The numbering scheme follows the corresponding numbers found on the decision tree

Table 5: FDA Decision Tree Questions

<p><i>3. Does the new device have the same indication statements? Does the new devices have the same Intended Use and may be Substantially Equivalent?</i></p> <p><u>No.</u> The Mitek Arthroscope is intended to be used during for Arthroscopic procedures where the Acclarent Cyclops Endoscopes (K100577 and K110097) are intended to view the nasal cavity and nasopharynx.</p> <p>The Mitek Arthroscope does have the same intended use as the Stryker (K093677) and Arthrex (K030096) Arthroscopes: visualization during arthroscopic procedure.</p>
<p><i>4. Do the differences alter the intended therapeutic/diagnostic/etc. Effect (in deciding, may consider impact on safety and effectiveness?)</i></p> <p>No. The differences do not alter the intended therapeutic effect when compared against the Stryker (K093677) and Arthrex (K030096) Arthroscopes</p>
<p><i>5. Does the new device have the same technological characteristics, e.g., design, materials, etc.?</i></p> <p>Yes. The Mitek Arthroscope has the same design, fundamental technology and materials as the Acclarent Cyclops Multi-Angle Endoscope and the Stryker and Arthrex Arthroscopes.</p>
<p><i>7. Are the Descriptive Characteristics precise enough to ensure equivalence?</i></p>

Yes. The descriptive characteristics are precise enough based on design and materials of the currently marketed predicate Cyclops Endoscope.

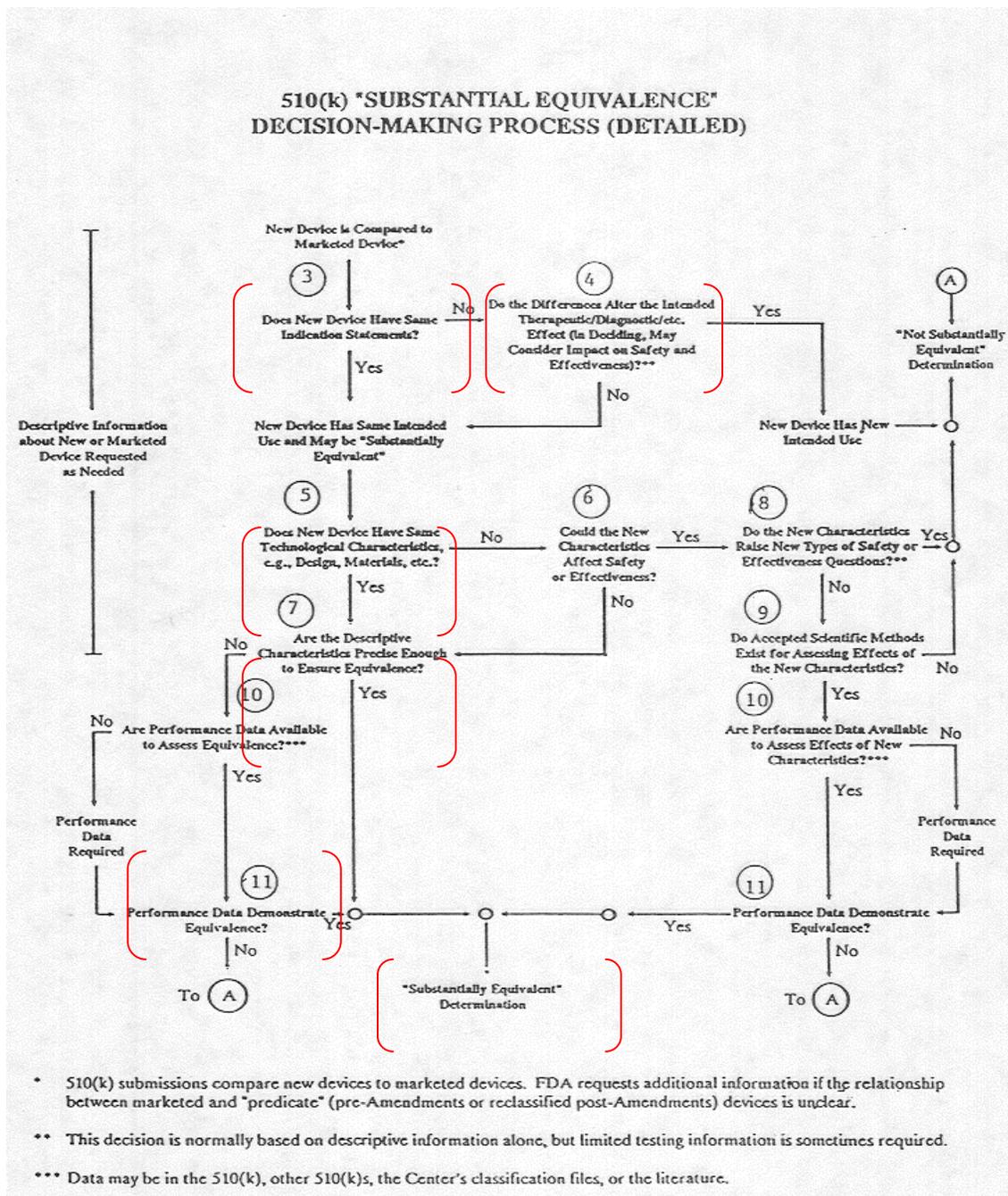
The major difference between the predicate Cyclops and the Mitek Arthroscope is the intended use. Base on this additional performance testing was done to verify the additional stress on the shaft due to insertion into the joint. (**See Section 6**)

10 & 11. Performance data demonstrate equivalence?

Yes. The performance data verify that the proposed device is substantially equivalent to the currently marketed devices discussed in this application. (**See Section 6**)

In summary, based on the Substantial Equivalence Comparison Table and answers to the questions from the "Substantial Equivalence Decision Tree", as shown below, Mitek believes that the proposed The Mitek Arthroscope is substantially equivalent to the predicate devices.

Figure 4 FDA Substantial Equivalency Flowchart



SECTION 6: VERIFICATION and VALIDATION

(b)(4) Trade Secret Process

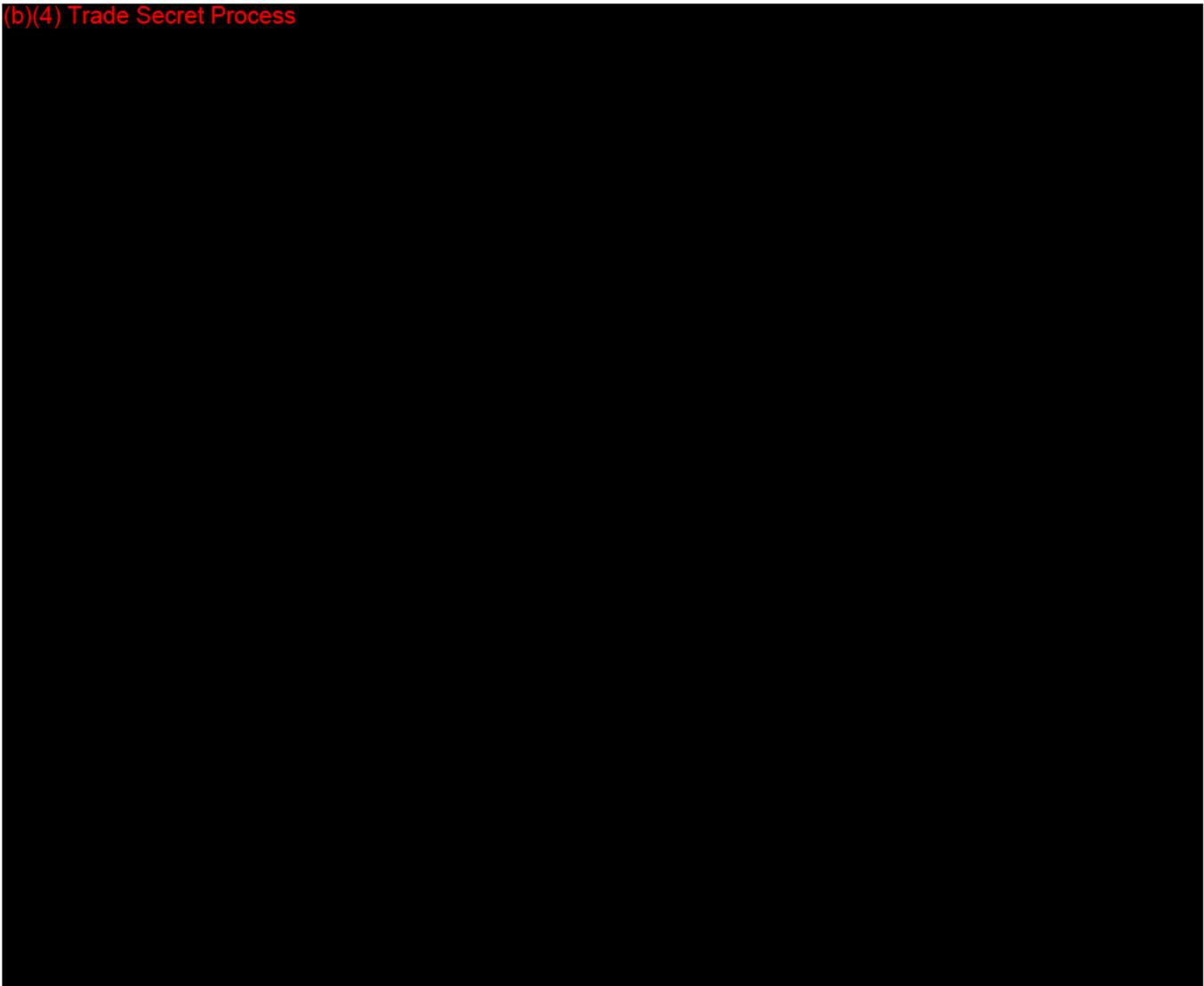


Table 6: Cyclops Gen 2 Test Specifications and Results

Attribute	Cyclops Specification	Results (Non-Sterile)	Results (Sterile)	Proposed Device
Field of View	(b)(4) Trade Secret Process	N/A	5/5 Pass	SAME
Depth of Field		5/5 Pass	5/5 Pass	SAME
Direction of View		N/A	5/5 Pass	SAME
Scope Resolution		5/5 Pass	5/5 Pass	
Temperature, patient contact		1/1 Pass	N/A	SAME

Attribute	Cyclops Specification	Results (Non-Sterile)	Results (Sterile)	Proposed Device
	(b)(4) Trade Secret Process			
Temperature, operator contact		1/1 Pass	N/A	SAME
Maximum Magnetic Field Strength		3/3 Pass	N/A	SAME

A summary of the complete functional testing performed on the Cyclops Gen 2 including the test name, description, and results can be found below.

B1. Field of View

(b)(4) Trade Secret Process

- **Results:** All samples passed.

B2. Fixed Focus

(b)(4) Trade Secret Process

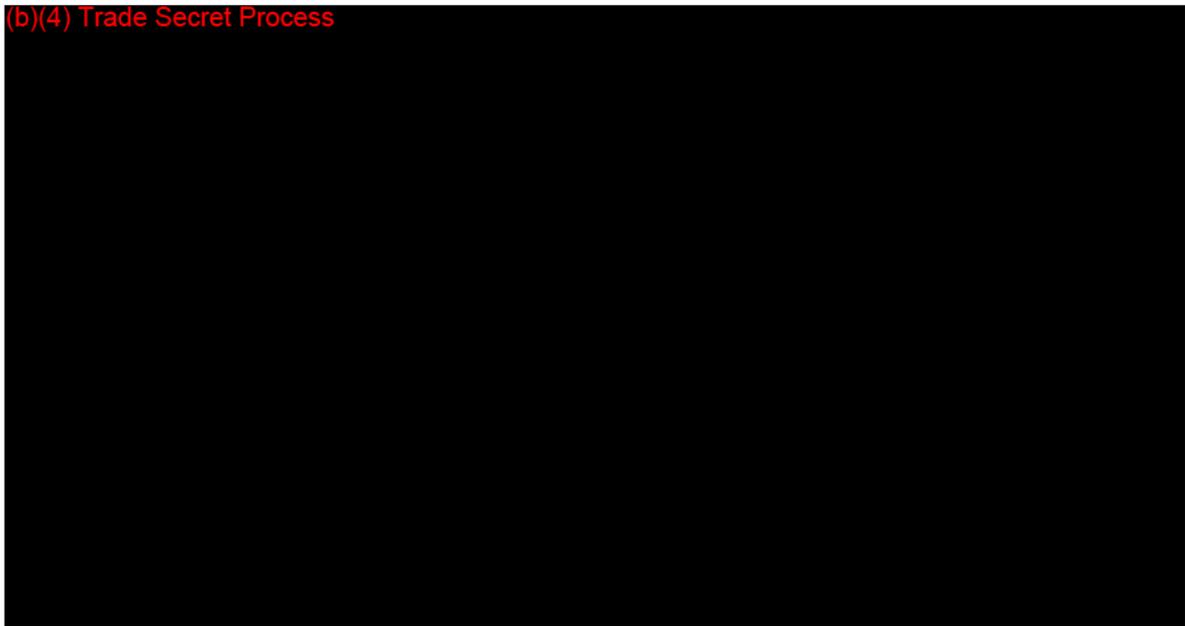
- **Results:** All samples passed.

B3. Direction of View

(b)(4) Trade Secret Process

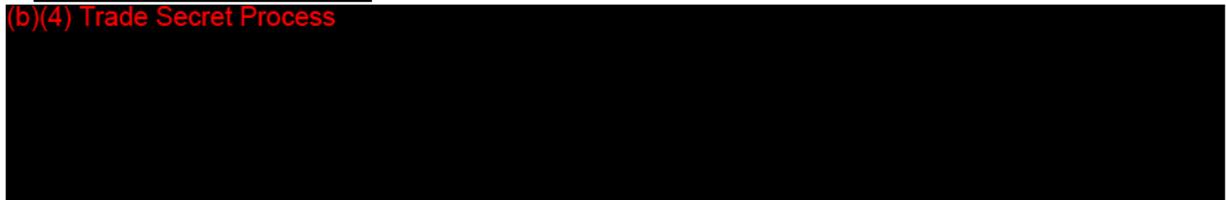
- **Results:** All samples passed.

(b)(4) Trade Secret Process



B6. Scope Resolution

(b)(4) Trade Secret Process



- **Results:** All samples passed.

Table 9: Summary of Scope Resolution Results

Angle	Non-Sterile Result (Min to Max) (Group/Element from USAF 1951 target)	Sterile Result (Min to Max) (Group/Element from USAF 1951 target)
--------------	--	--

(b)(4) Trade Secret Process



(b)(4) Trade Secret Process

Table 10: Summary of Maximum Field Strength

Device Maximum Field Strength (gauss)
(b)(4) Trade Secret Process

(b)(4) Trade Secret Process

- **Results:** All samples passed.

(b)(4) Trade Secret Process

(b)(4) Trade Secret Process

Table 11: Summary of Temperature Testing

Measurement Location	3.5mm Fiber Optic Cable (°C)	5.0mm Fiber Optic Cable (°C)
(b)(4) Trade Secret Process		

(b)(4) Trade Secret Process

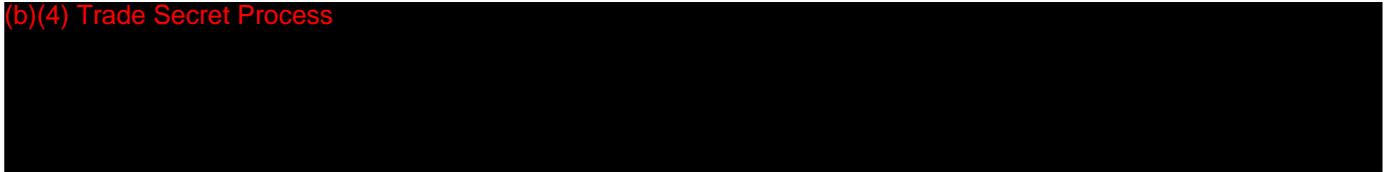
C. Mitek Arthroscope Testing

C 1. Clinical Load Determination

The Mitek Arthroscope and predicate Cyclops Endoscopes (Acclarent, a Johnson and Johnson company, K100577 and K110097) are similar in fundamental technology and material. The major difference is the indication for use. The Acclarent Cyclops is indicated for ENT applications whereas the Mitek Arthroscope is indicated for arthroscopic procedures.

The Mitek Arthroscope may be used for any arthroscopic surgery, and is not specific to any joint. Relevant clinical data, therefore, consider all scenarios of use and determine worst case. Mitek has historical experience with clinical models developed for devices such as dilators, capsulotomy blades, and radiofrequency ablation electrodes. In these models, the hip joint proved to be the worst case for evaluating product specifications and

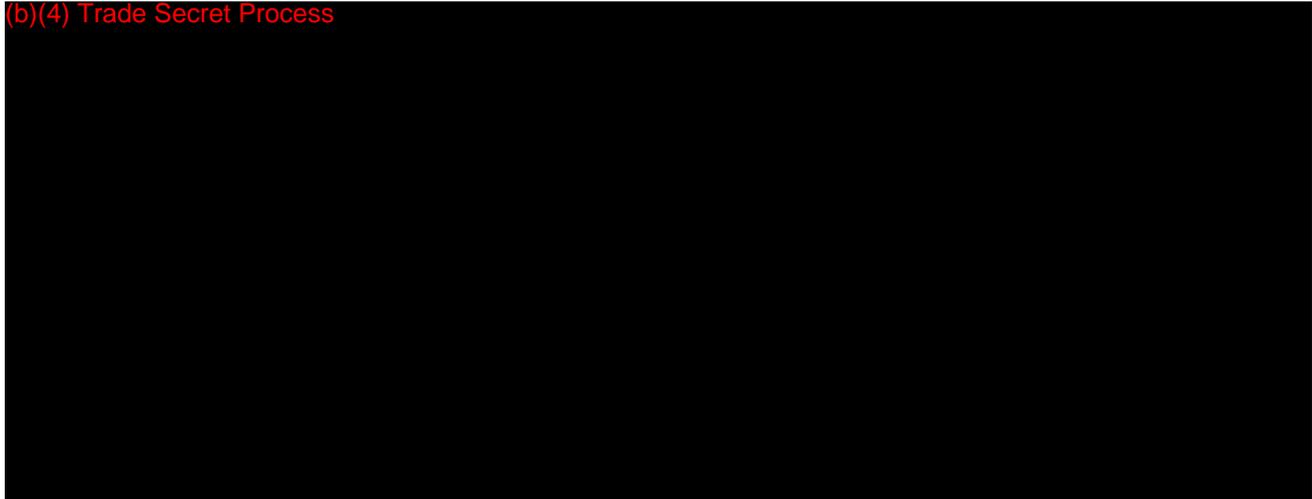
(b)(4) Trade Secret Process



To verify that the Mitek Arthroscope can withstand the clinical loads experienced by surgeon use in orthopedic surgery an evaluation of the loads exerted on an arthroscope in a clinical setting a cadaver study was conducted with 6 different surgeons. This evaluation included surgeons with different levels of experience and location of practice. Materials, methods, and results are discussed below.

C 1.1 Test Method

(b)(4) Trade Secret Process



The results in **Table 12** below were used to determine the loads to be used during verification testing which are summarized below.

Table 12: Clinical Load Determination

	Mean	Max	Mitek Specification
--	-------------	------------	----------------------------

(b)(4) Trade Secret Process - Testing

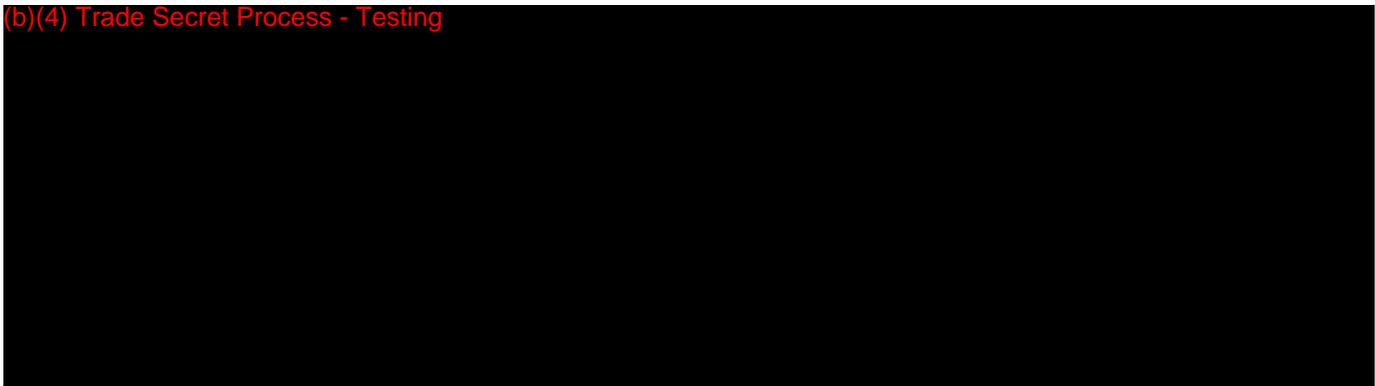


(b)(4) Trade Secret Process - Testing



Figure 5: Body diagram of arthroscope bending loading scenario

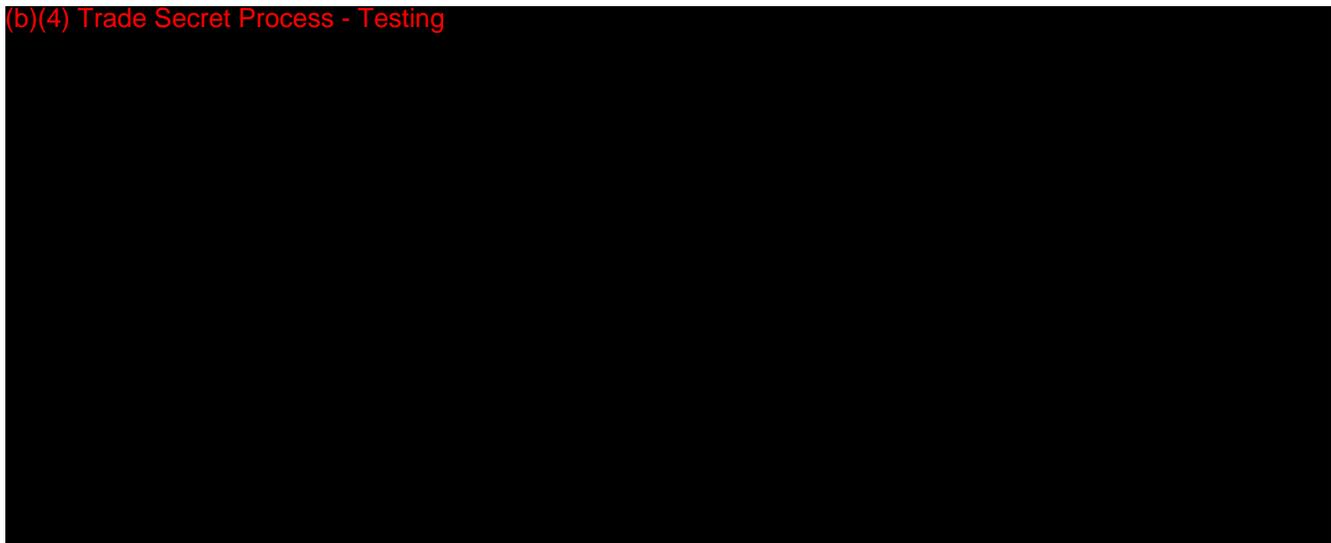
(b)(4) Trade Secret Process - Testing



(b)(4) Trade Secret Process - Testing

Testing

(b)(4) Trade Secret Process - Testing



(b)(4) Trade Secret Process - Testing

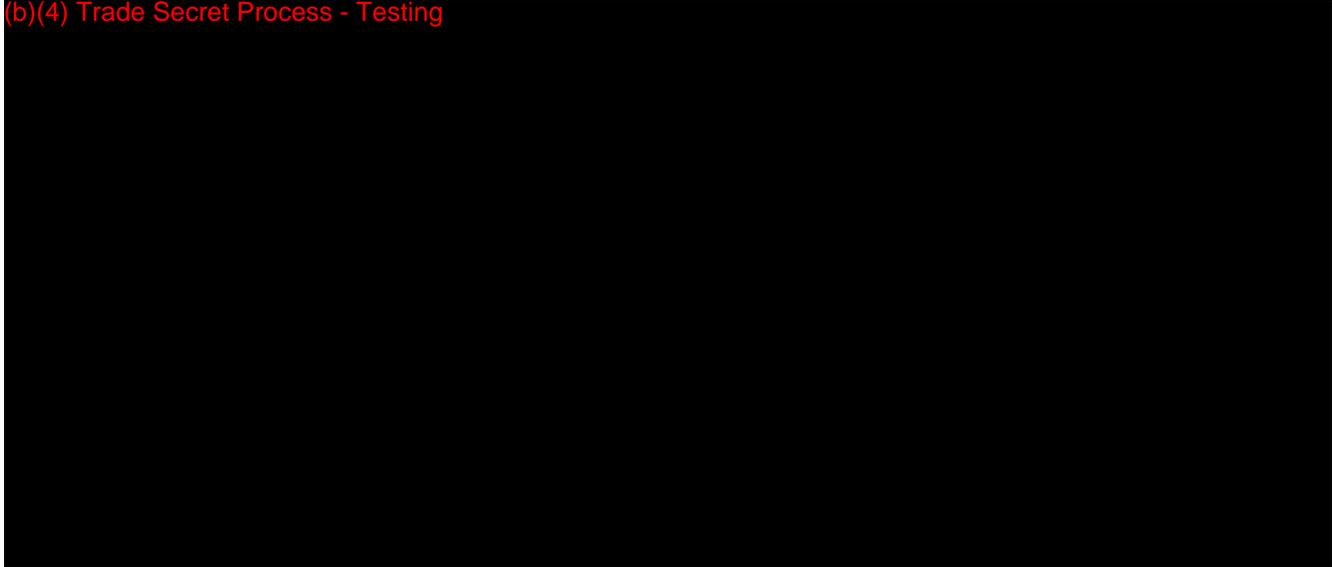
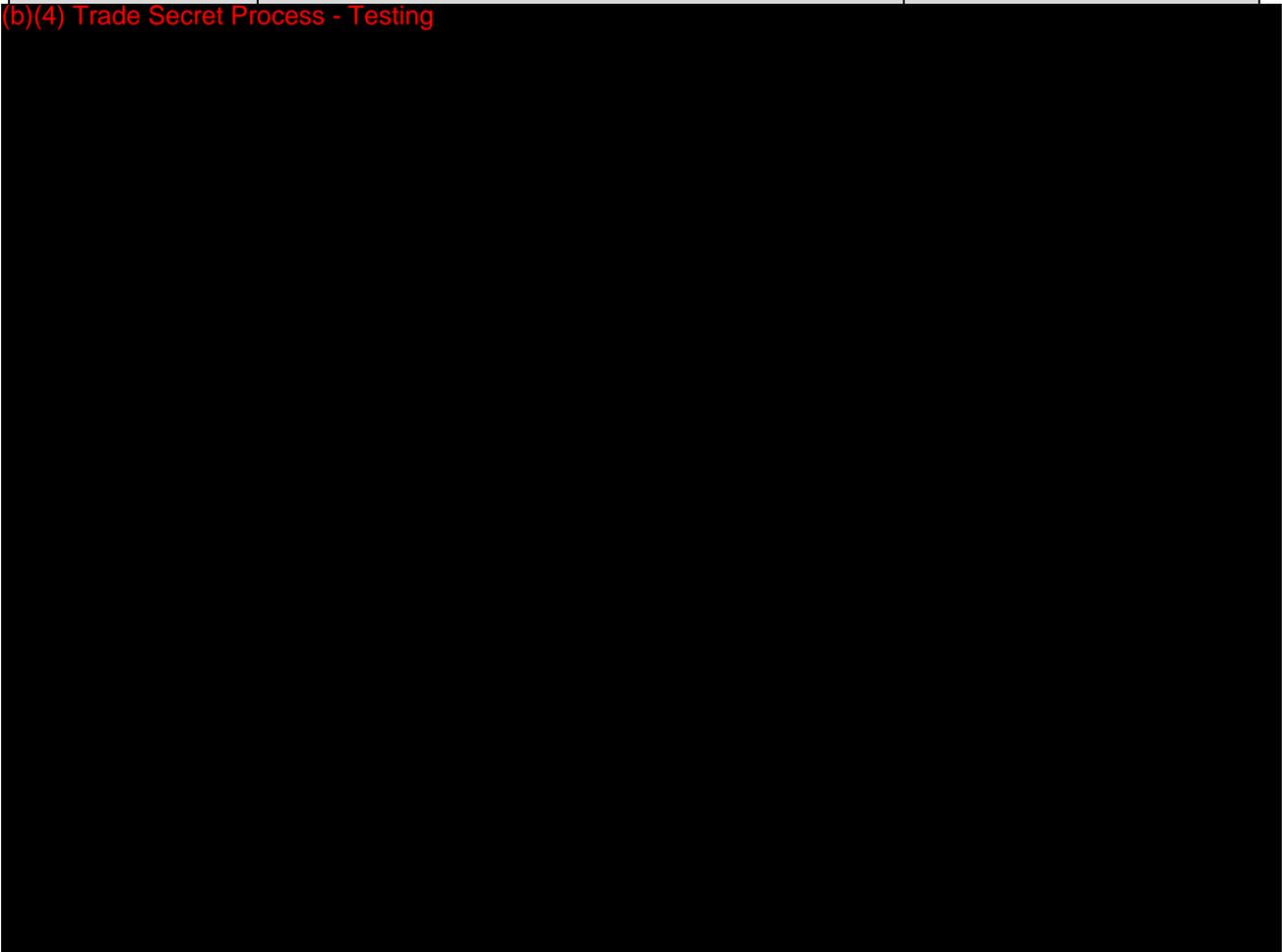


Table 13: Durability Test Results

Test	Acceptance Criteria	Result
------	---------------------	--------

(b)(4) Trade Secret Process - Testing



(b)(4) Trade Secret Process - Testing

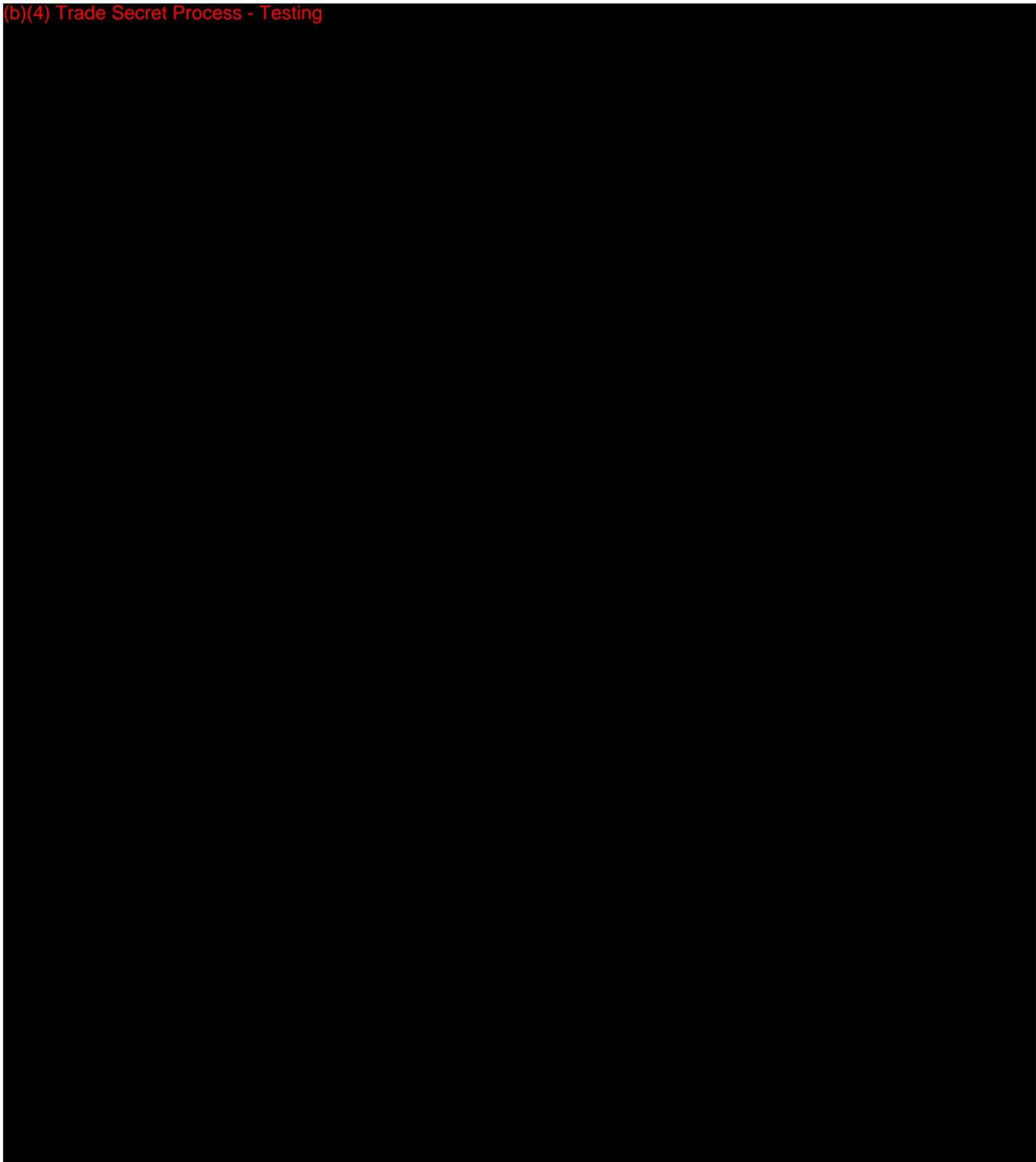
E. Conclusion

These results support the conclusion that the Mitek Arthroscope passes both axial and bending requirements for the device after subjected to loading representative of the worst case orthopedic conditions. (b)(4) Trade Secret Process - Testing

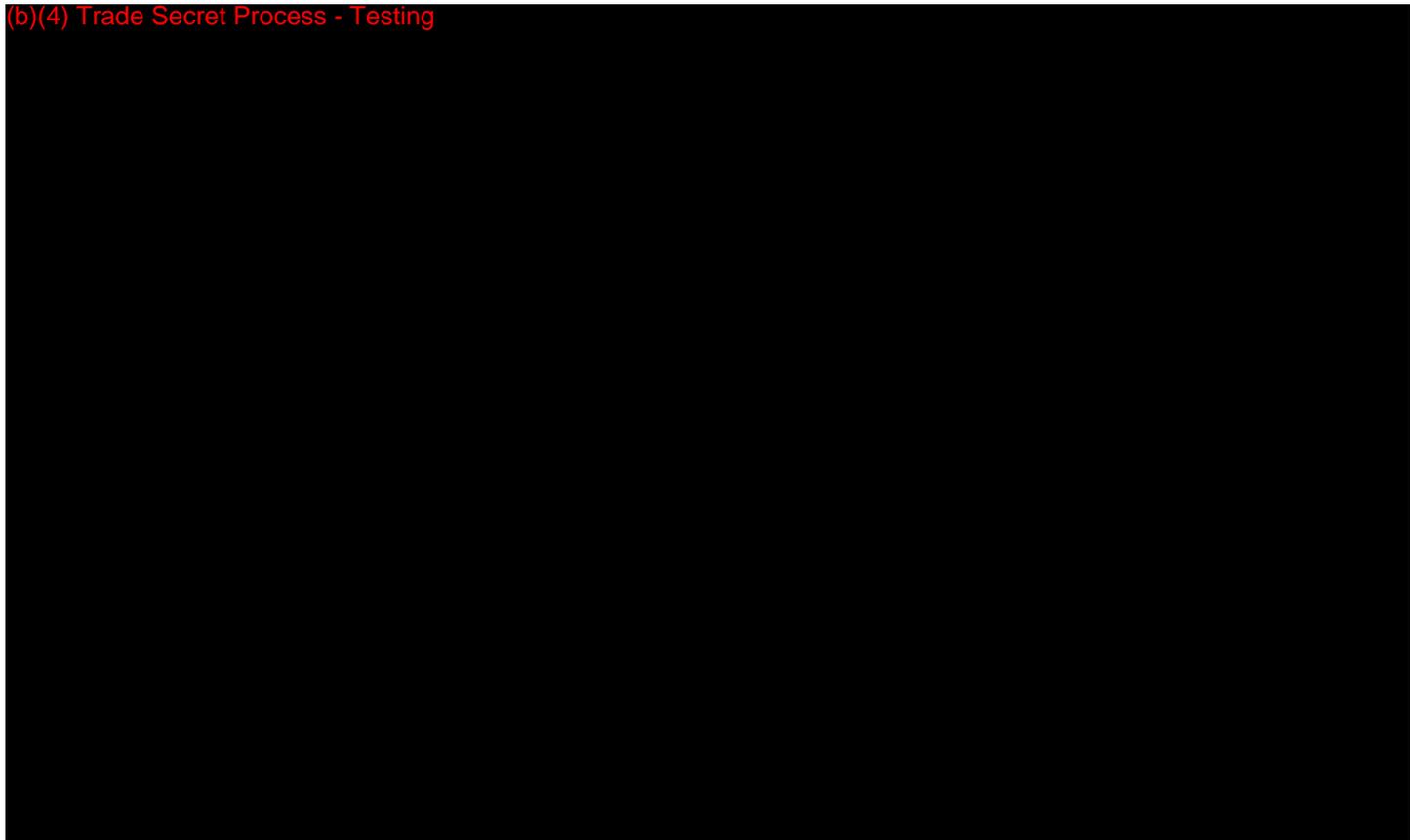
[Redacted]

[Redacted].

(b)(4) Trade Secret Process - Testing

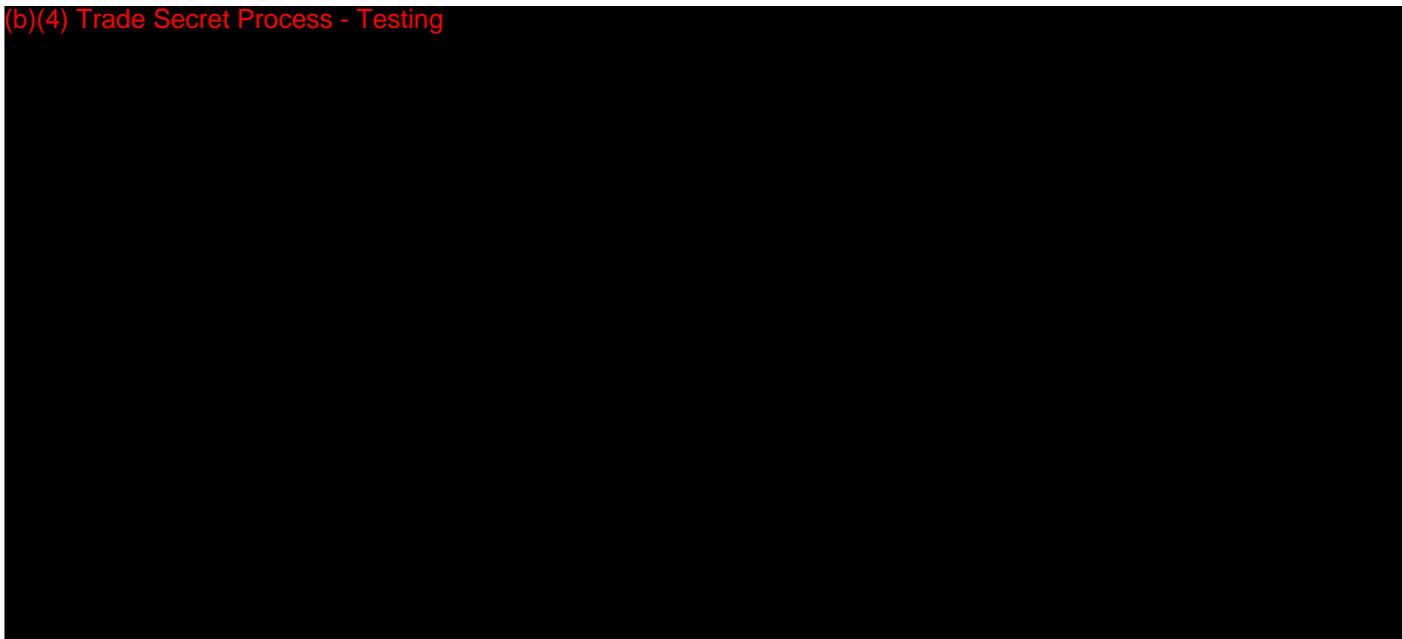


(b)(4) Trade Secret Process - Testing



Picture 2: Positioning of the tip on the wooden support

(b)(4) Trade Secret Process - Testing



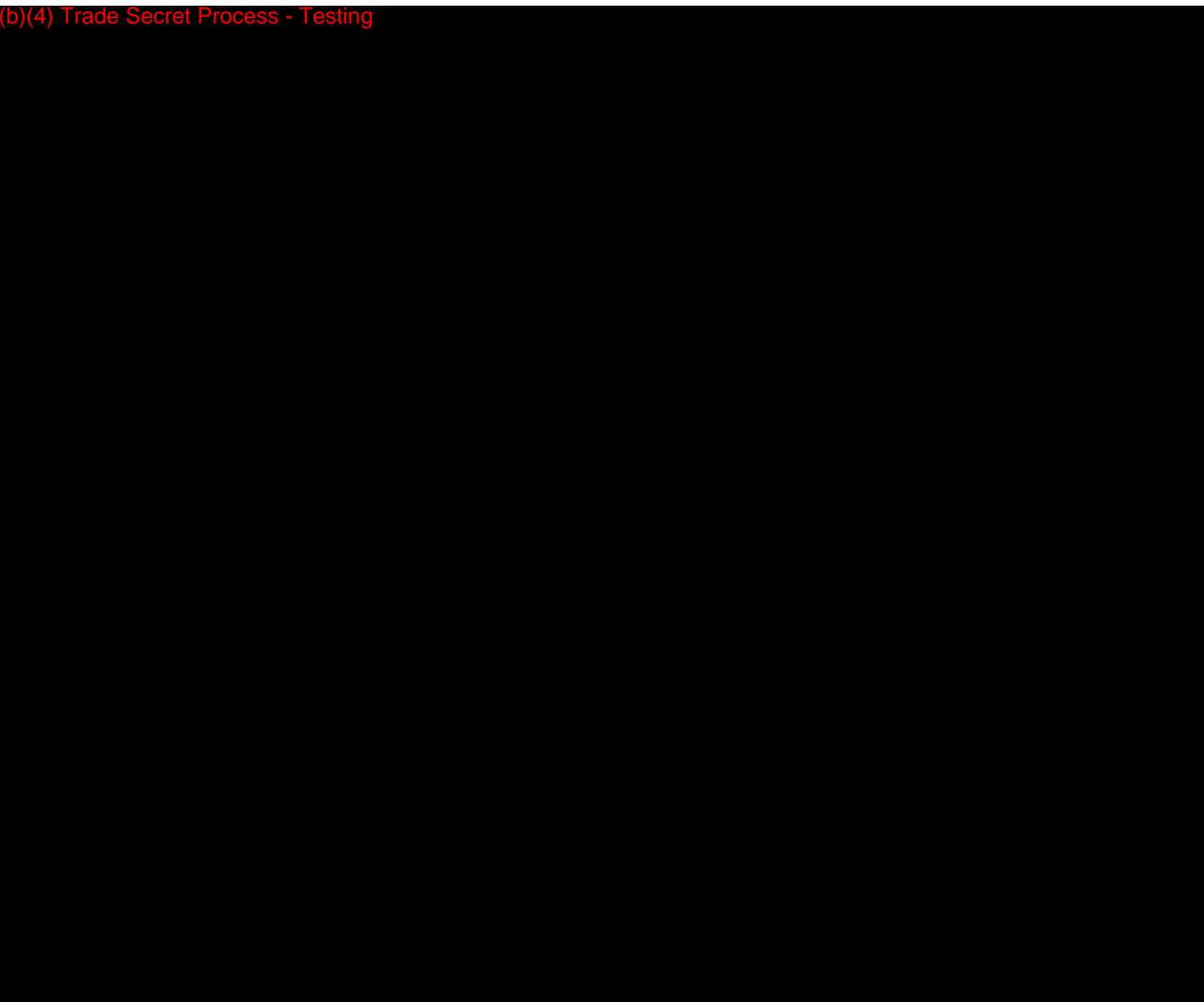
Picture 3: Setup bending test

(b)(4) Trade Secret Process - Testing

A large black rectangular redaction box covering the majority of the page's content.

(b)(4) Trade Validation Testing

(b)(4) Trade Secret Process - Testing

A large black rectangular redaction box covering the majority of the page's content.

(b)(4) Trade Secret Process - Testing

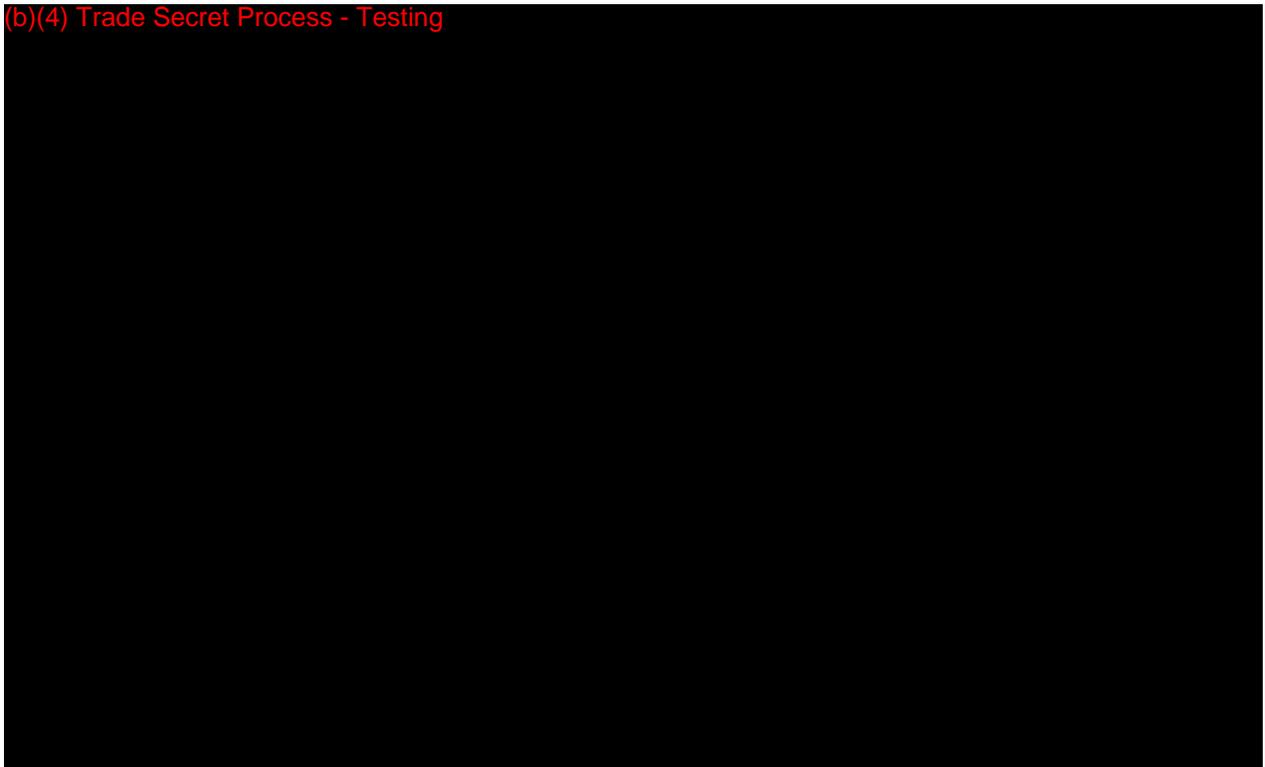
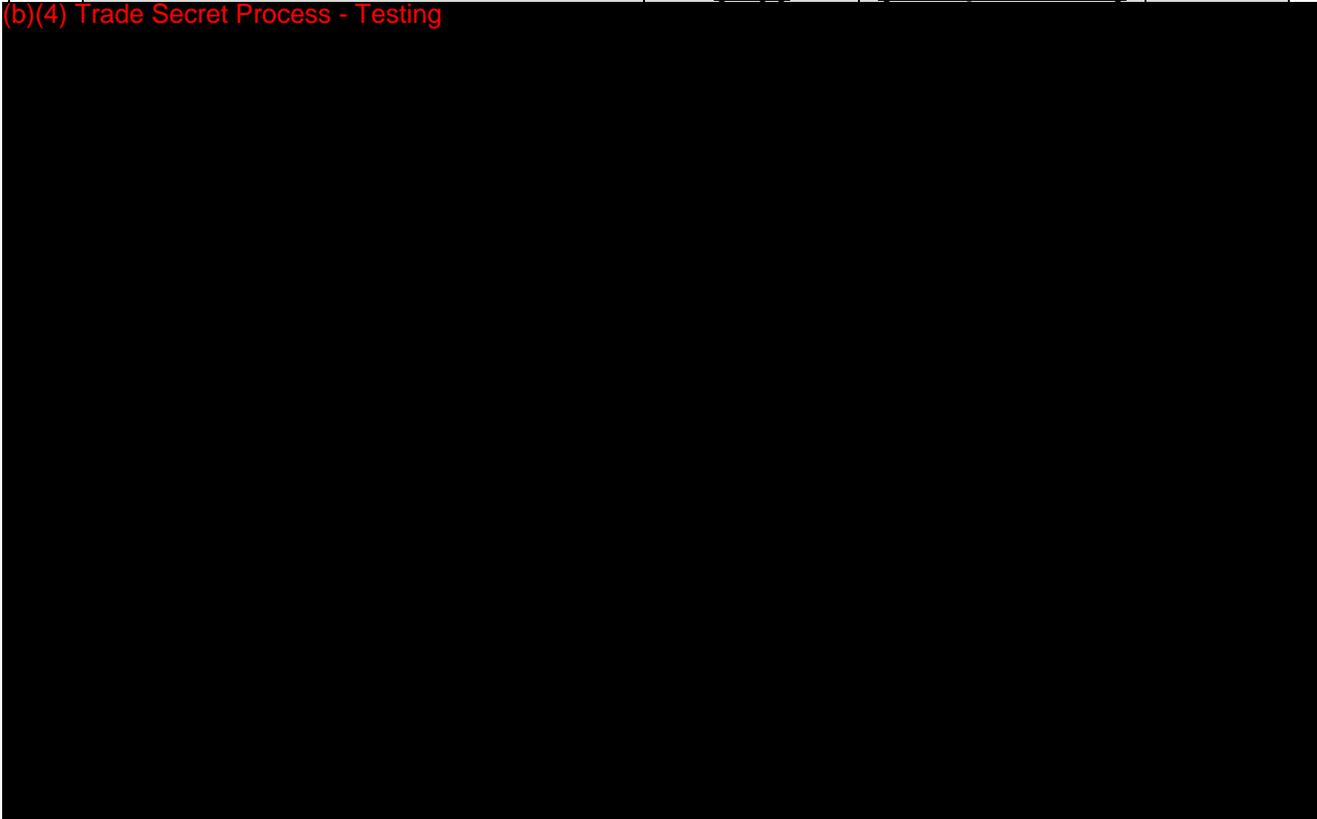


Table 14: Validation Results

#	<u>Usability Question Asked</u>	<u>Response (Hip)</u>	<u>Response (Knee/Shoulder)</u>	<u>Results</u>
---	---------------------------------	-----------------------	---------------------------------	----------------

(b)(4) Trade Secret Process - Testing



(b)(4) Trade Secret Process - Testing



SECTION 7: ELECTRICAL SAFETY and ELECTROMAGNETIC COMPATIBILITY

A. Justification For Not Doing IEC

The Mitek Arthroscope is not designed to be a conduit for electrical energy and, as such, is not intended to be connected to electrical supplies/mains. It is a rigid endoscope that is composed of optical and mechanical components and contains no electrical energy source.

The eyepiece that connects to the camera head is composed of a non-electrical conducting material (PEEK) and insulates the subject device from the camera. Also, light cables are not designed to transmit electricity and are made of materials that do not conduct electricity.

As electrical safety only applies to those devices which produce or generate electrical energy and there is no electrical energy produced or generated by the Mitek Arthroscope, electrical safety and electromagnetic compatibility testing is not applicable to the subject device

B. Electromagnetic Compatibility

As there are magnets in the subject device EMC testing was performed by an outside testing lab on the predicate device: Acclarent Cyclops (K100577 and K110097). Conformance to IEC 60601-1-2 was evaluated by InterTek Testing Services and resulted in testing the subject device for the following:

- radiated emission (CISPR 11, CISPR 16-1);
- electrostatic discharge immunity (IEC/EN 61000-4-2);
- radiated, radio-frequency, electromagnetic field immunity (IEC/EN 6100-4-3); and
- conducted, radio-frequency, electromagnetic field immunity (IEC/EN 61000-4-6)

Testing occurred in a 3 meter anechoic chamber that meets the requirements of CISPR-1. The Acclarent Cyclops Endoscope was connected to a video box via an endoscopic camera, and to a 300 Watt Xenon light box to simulate actual use conditions. The tests demonstrated that the Acclarent Cyclops Endoscope meets the pre-determined acceptance criteria for each test. A summary of results can be found in **Tables 15, 16, 17 and 18.**

Summary of Electromagnetic Compatibility Testing

Table 15: Radiated Emission

(b)(4) Trade Secret Process - Testing



Table 16: Electrostatic Discharge

T

(b)(4) Trade Secret Process - Testing



Table 17: Radiated, Radio-Frequency, Electromagnetic Field Immunity

(b)(4) Trade Secret Process - Testing

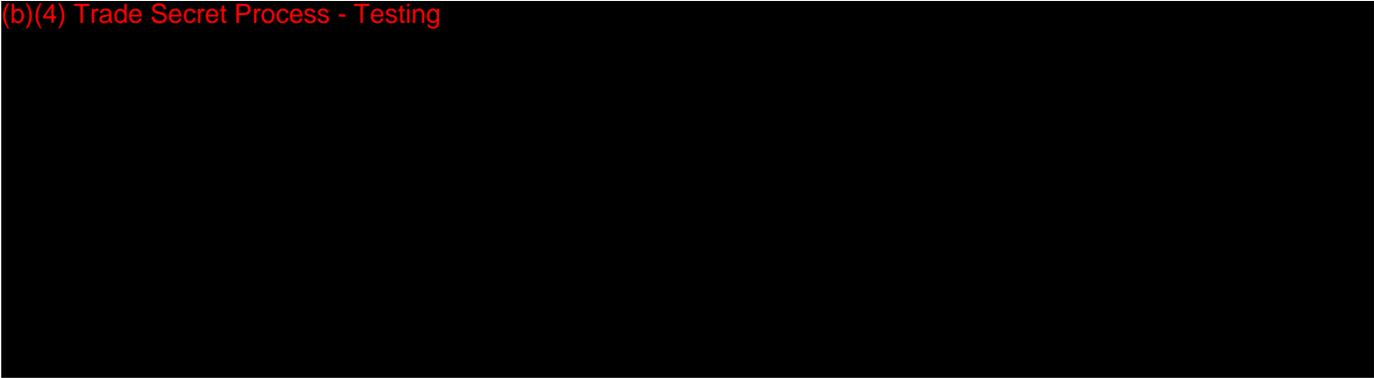


Table 18: Conducted, Radio-Frequency, Electromagnetic Field Immunity

(b)(4) Trade Secret Process - Testing



(b)(4) Trade Secret Process - Testing



SECTION 8: BIOCOMPATIBILITY

A. Biological Evaluation

The proposed Mitek Arthroscope is designed to enable visualization during arthroscopic surgery. Arthroscopes are used with accessories such as an inflow outflow sheath which deliver irrigation fluid to the patient. Thus, from a biocompatibility perspective, arthroscopes are considered externally communicating devices which have limited contact (< 24 hours) with the patient's bone and tissue. The biocompatibility testing recommended by ISO 10993-1 and FDA's G95-1 Memorandum on Biocompatibility Testing includes in vitro cytotoxicity, guinea pig sensitization, intracutaneous irritation, and acute systemic toxicity tests.

The materials used in the Mitek Arthroscope are well known and commonly used in the medical device industry. The proposed Mitek Arthroscope has the same body contact classification as the predicate Accelerant Cyclops device (K100577 and K110097): externally communicating devices with limited contact with tissue/bone/dentin. Additionally, direct patient contact materials, components, and processes (cleaning and sterilization) used for the subject device are identical in nature to those of the predicate device, Accelerant Cyclops.

As the proposed Mitek Arthroscope and Cyclops are constructed using identical materials and from the same suppliers (Refer to **Table 19** below) Mitek leveraged biocompatibility testing performed on the Cyclops to support this submission. A summary of test results can be found in **Table 20**.

Table 19: Material Comparison Mitek Arthroscope to Cyclops

(b)(4) Trade Secret Process - Testing

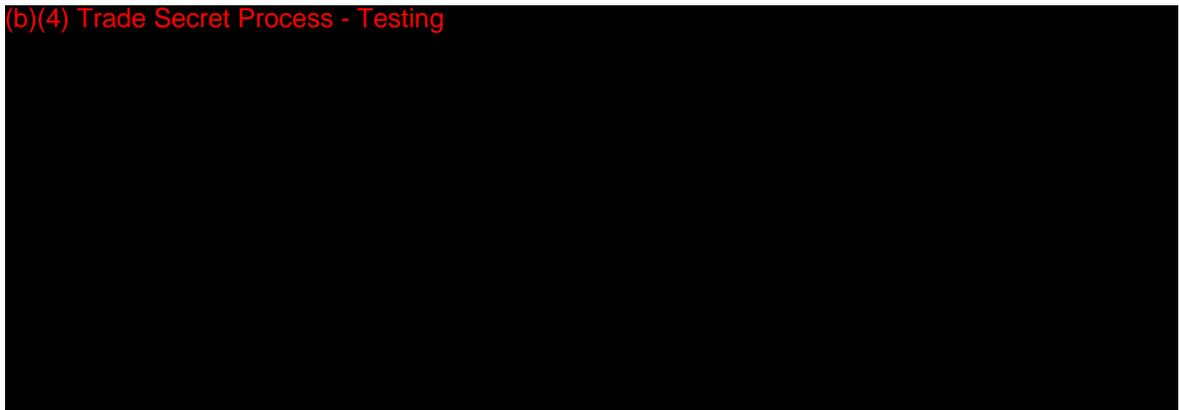


Table 20: Arthroscope Patient Contact Materials and Test Results

Component Description	Material specification	Biological Effects Considered	Results
(b)(4) Trade Secret Process - Testing			

B. Discussion

The biocompatibility testing performed demonstrates that the proposed Mitek Arthroscope is considered biocompatible and meets the requirements of ISO 10993-1 and FDA G95-1 for an externally communicating device with limited contact (less than 24 hours) with tissue/bone/dentin.

SECTION 9: CLEANING & STERILIZATION INFORMATION

Overview

Mitek considers the Mitek Arthroscope to be a semi critical device according to the definitions presented in AAMI TIR12:2004 and "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance", which was issued by FDA in April 1996 (UCM080268). The Draft Guidance for Industry and FDA Staff - Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling issued in May 2011 was also considered. Under these standards, semi critical devices should be cleaned and sterilized, to provide reasonable assurance during reprocessing.

As the Mitek Arthroscope and Cyclops are identical in fundamental technology and material (Refer to **Tables 21** below), Mitek leveraged the cleaning and sterilization validations performed on the Cyclops (Gen 1K100577 and Gen 2 K110097).

Table 21: Material Comparison Mitek Arthroscope to Cyclopes

(b)(4) Trade Secret Process - Testing



The Mitek Arthroscope was tested to the cleaning and sterilization standards listed in **Table 22** below.

Table 22: Standards

Standard	Title
AAMI TIR12: 2010	Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
AAMI TIR 30:2011	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
ISO 17664:2004	Sterilization of medical devices: Information to be provided by the manufacturer for the processing of re sterilizable medical device
ANSI/AAMI/ISO 17665-1:2006	Sterilization of Health Care Products - Moist Heat - Part 1: Requirements for The Development, Validation And Routine Control of a Sterilization Process For Medical Devices
ISO 11135-1:2007	Sterilization of health care products-Ethylene oxide-Part 1

Cleaning and Sterilization Methods

The Mitek Arthroscope will be provided non-sterile to the customer and must be cleaned and sterilized prior to use. The Mitek Arthroscope can be sterilized via Steam Sterilization, STERRAD® or Ethylene Oxide sterilization.

Information regarding cleaning and sterilization method and parameters are provided in the Instructions for Use (**Appendix C**), and are in accordance with "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance", which was issued by FDA in April 1996 (UCM080268).

Below is a summary of testing performed for manual and automated cleaning and sterilization by STERRAD® or Ethylene Oxide sterilization.

Summary of Manual Cleaning Validation

A summary of the validation for the manual cleaning is provided below in **Table 23 and Figure 6**. The automated cleaning instructions for the Mitek Arthroscope are identical to the predicate device, Acclarent Cyclops Multi-Angle Endoscope.

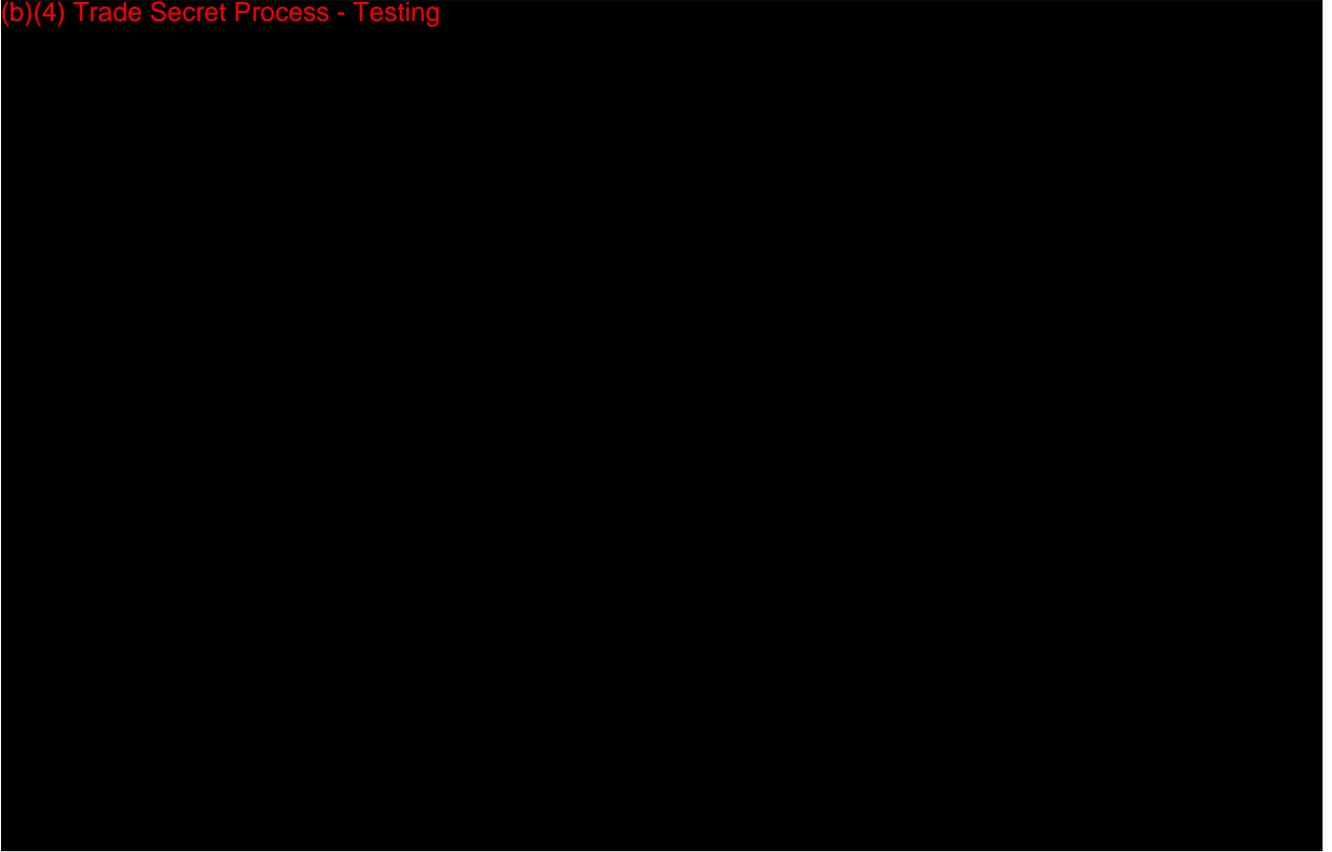
Table 23: Summary of Manual Cleaning Validation

Attribute	Cyclops (and therefore Mitek Arthroscope)
Test Devices	(b)(4) Trade Secret Process - Testing [Redacted]
[Redacted]	[Redacted]
[Redacted]	<ul style="list-style-type: none"> [Redacted]
[Redacted]	<ul style="list-style-type: none"> [Redacted] [Redacted] [Redacted] [Redacted]
[Redacted]	<ul style="list-style-type: none"> [Redacted] [Redacted]
[Redacted]	<ul style="list-style-type: none"> [Redacted] [Redacted] [Redacted] was fully immersed in test soil. The

(b)(4) Trade Secret Process - Testing



(b)(4) Trade Secret Process - Testing



Test 1: Visual inspection as specified by AAMI TIR 12 and Residual carbohydrate to confirm removal of the soil.

Acceptance criteria:

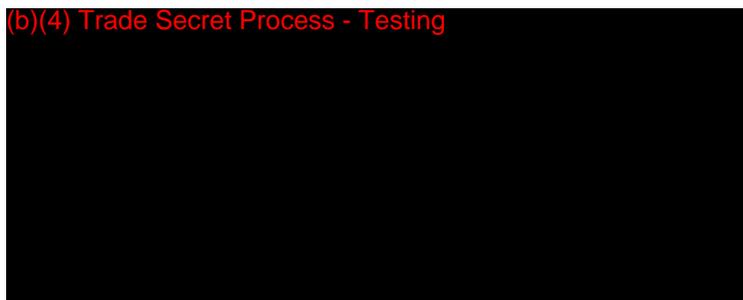
- All visual soil was removed as determined using visual inspection without magnification under ambient lighting and inspected at a distance of 20 cm. A lint free cloth was used to wipe the endoscope to assist in checking for the presence of retained soil.
- The carbohydrate level of the immersion extraction test device following cleaning of $\leq 1.8 \mu\text{g}/\text{cm}^2$ within the limit of resolution of the technique.

Results:

Visual soil was removed as determined using visual inspection
The positive control had an extraction efficiency 85.0%

Table 24: Carbohydrate Test Results

(b)(4) Trade Secret Process - Testing

A large black rectangular redaction box covers the content of Table 24. The text "(b)(4) Trade Secret Process - Testing" is written in red at the top left corner of the redacted area.

Test 2: Visual inspection as specified by AAMI TIR 12 and Residual TOC to confirm removal of the soil

Acceptance criteria:

- All visual soil was removed as determined using visual inspection without magnification under ambient lighting and inspected at a distance of 20 cm. A lint free cloth was used to wipe the endoscope to assist in checking for the presence of retained soil.
- The TOC level of the immersion extraction test device following cleaning of $\leq 10.8 \mu\text{g}/\text{cm}^2$ within the limit of resolution of the technique.

Results:

The positive control had an extraction efficiency of 94%.
Visual soil was removed as determined using visual inspection.

Table 25: TOC Test Results

(b)(4) Trade Secret Process - Testing



Test 3: Visual inspection as specified by AAMI TIR 12 and the Residual protein and Residual hemoglobin to confirm removal of the soil.

Acceptance Criteria:

- Visual soil was removed as determined using visual inspection.
- The protein level of the immersion extraction test device following cleaning was $\leq 6.4 \mu\text{g}/\text{cm}^2$.
- The hemoglobin level of the immersion extraction test device following cleaning was $\leq 2.2 \mu\text{g}/\text{cm}^2$.

Results:

The positive control had an extraction efficiency of $\geq 90.0\%$.

Table 26: Hemoglobin Test Results

(b)(4) Trade Secret Process - Testing

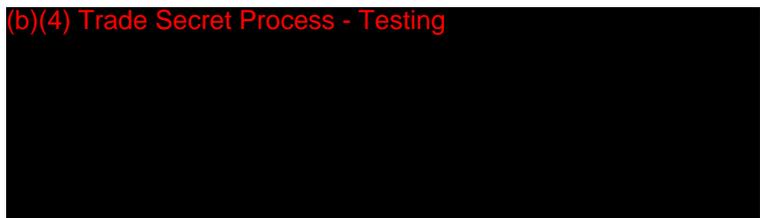


Table 27: Protein Test Results

(b)(4) Trade Secret Process - Testing



The positive control had an extraction efficiency of 87.8%

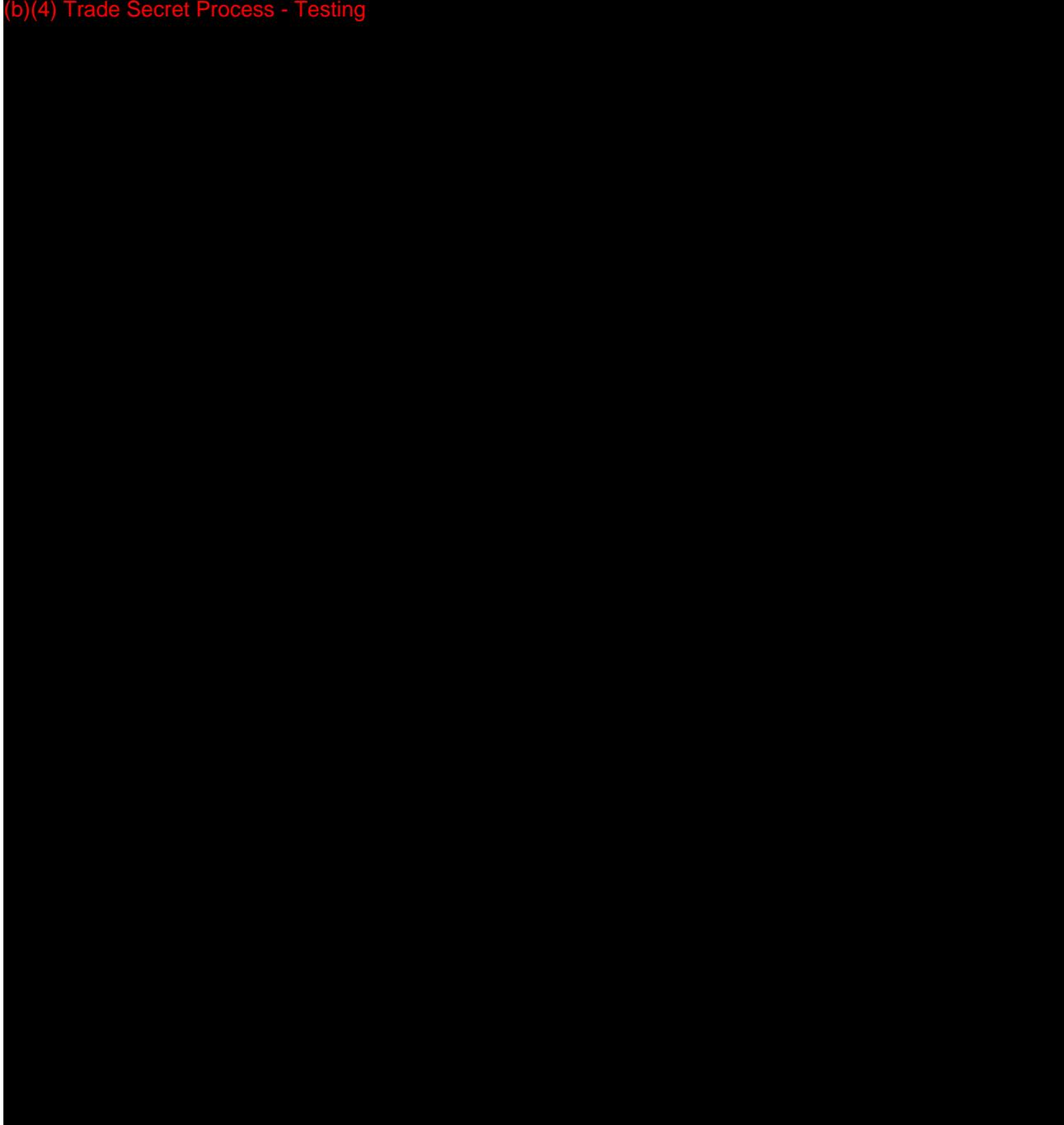
- Visual soil was removed as determined using visual inspection.

Automated Cleaning

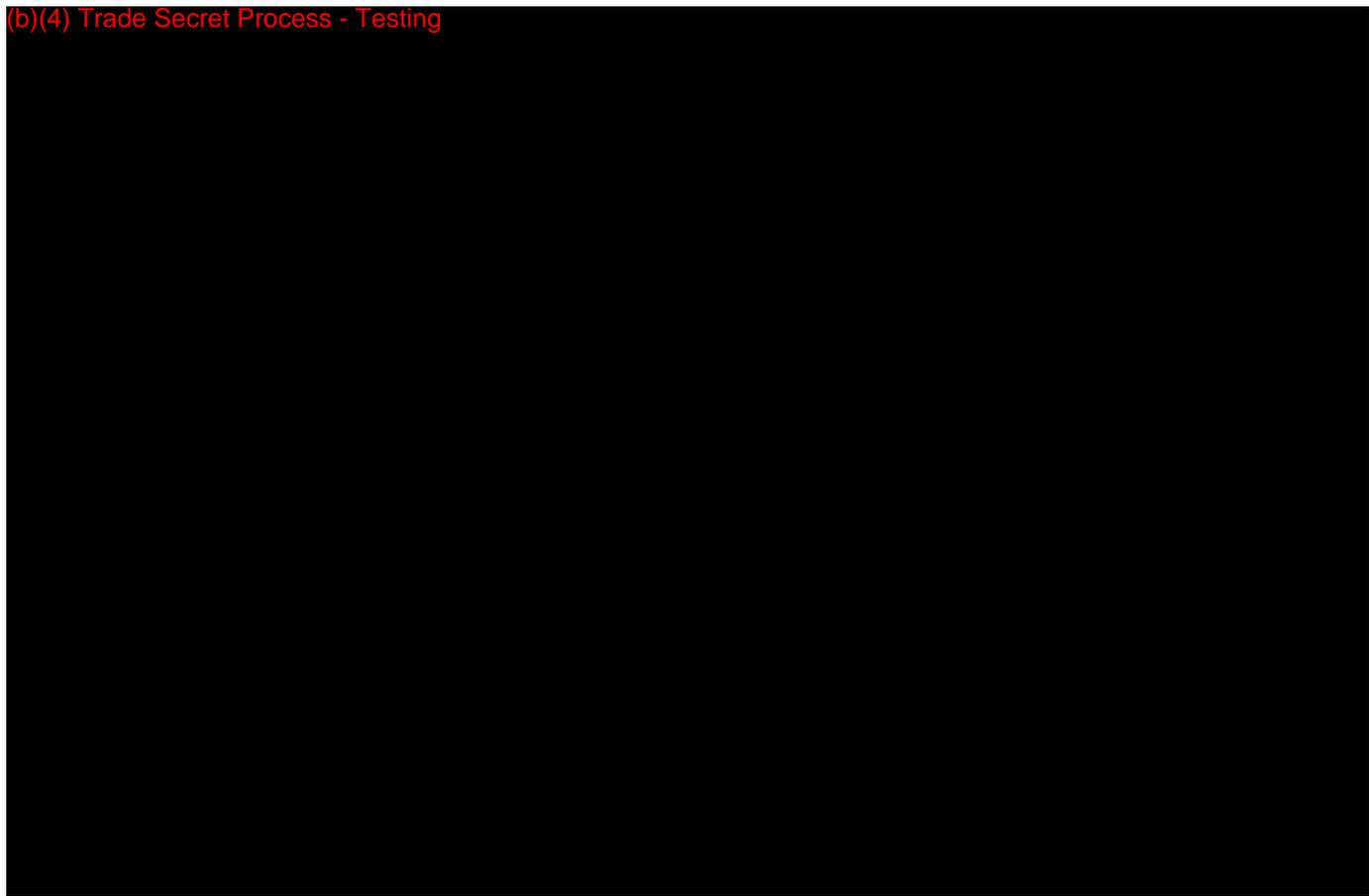
A summary of the validation for the automated cleaning is provided below in **Table 28 and Figure 7 and 8**. The automated cleaning instructions for the Mitek Arthroscope are identical to the predicate device, Acclarent Cyclops Multi-Angle Endoscope.

Table 28: Summary of Automated Cleaning Validation

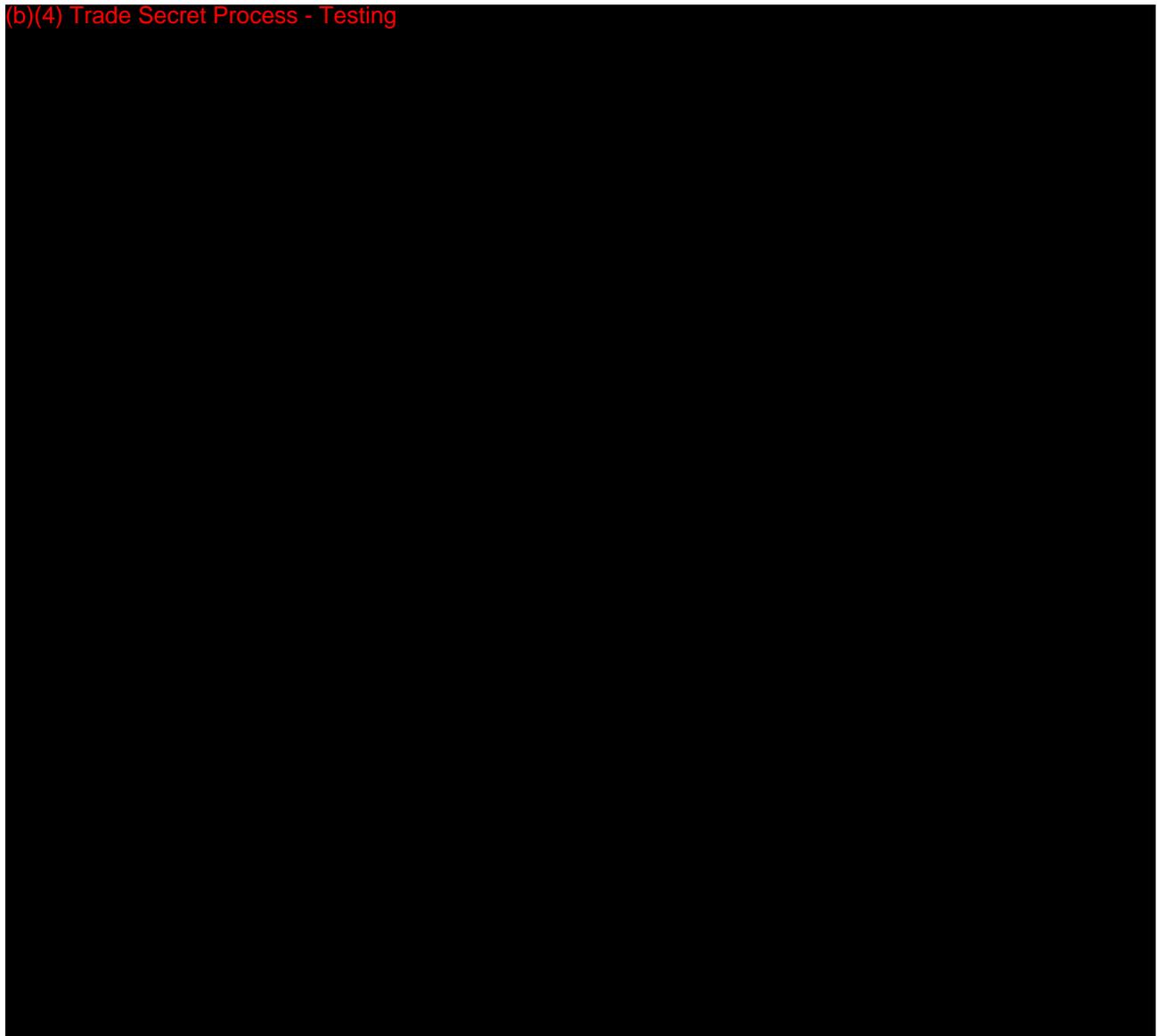
(b)(4) Trade Secret Process - Testing



(b)(4) Trade Secret Process - Testing



(b)(4) Trade Secret Process - Testing



ATTACHMENT A
DRAWING

ATTACHMENT B
LABELING

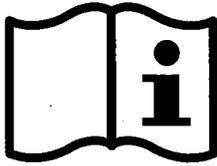
DRAFT

 <p>Multi-angle arthroscopes, 2 Lightpost Adapters 121123456</p>	<p>SWINGSCOPE™</p> <p>Multi-angle arthroscopes, 2 Lightpost Adapters Arthroscopie multi-angulaire, 2 adaptateurs à p cable lumineux Mehrwinkel-Arthroskop, 2 Lichtadapter Multihoek arthroscop, 2 lichtpaal adapters Artroscopia multiangolare, 2 adattatori punto luce Artroscopia multi-ângulo, 2 adaptadores poste de luz Artroscop multi-ângulo, 2 Adaptadores de Haste Lumínosa Artroskop wielokątowy, 2 adaptéry światłowodowe Víceúhlový arthroscop, 2 adaptéry osvětlení</p> <p>DePuy Synthes MITEK SPORTS AMERICA Medos International SARL Chemin-Blanc 38 2400 Le Lode, Switzerland</p> <p>REF 288000 SN 123456 QTY 1 MADE IN Germany CE 0066</p> <p>For patent information about this product, go to www.depuy-synthes.com/patent-marking</p>
---	---

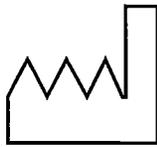
REF

Catalogue number

DRAFT



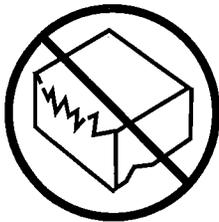
Consult instructions for use



Date of manufacture



Caution



Do not use if package is damaged



Latex Free

REF

288000

REV A

ATTACHMENT C

DRAFT INSTRUCTIONS FOR USE



DePuy Synthes

MITEK SPORTS MEDICINE

COMPANIES OF *Johnson & Johnson*

**SwingScope™
Multi-Angle Arthroscope
and
SwingScope™ Light Guide Cable Adapters**

CE0086

- 288000 SWINGSCOPE™ Arthroscope
- 288008 Lightpost Adapter 22mm x 12mm
- 288009 Lightpost Adapter 12mm x 9mm

READ ALL INSTRUCTIONS CAREFULLY

P/N: 111716

Rev: A Issued 10/2013

©DePuy Synthes Mitek Sports Medicine
a division of DOI 2013. All rights reserved.

SWINGSCOPE™ MULTI-ANGLE ARTHROSCOPE AND LIGHT GUIDE CABLE ADAPTERS

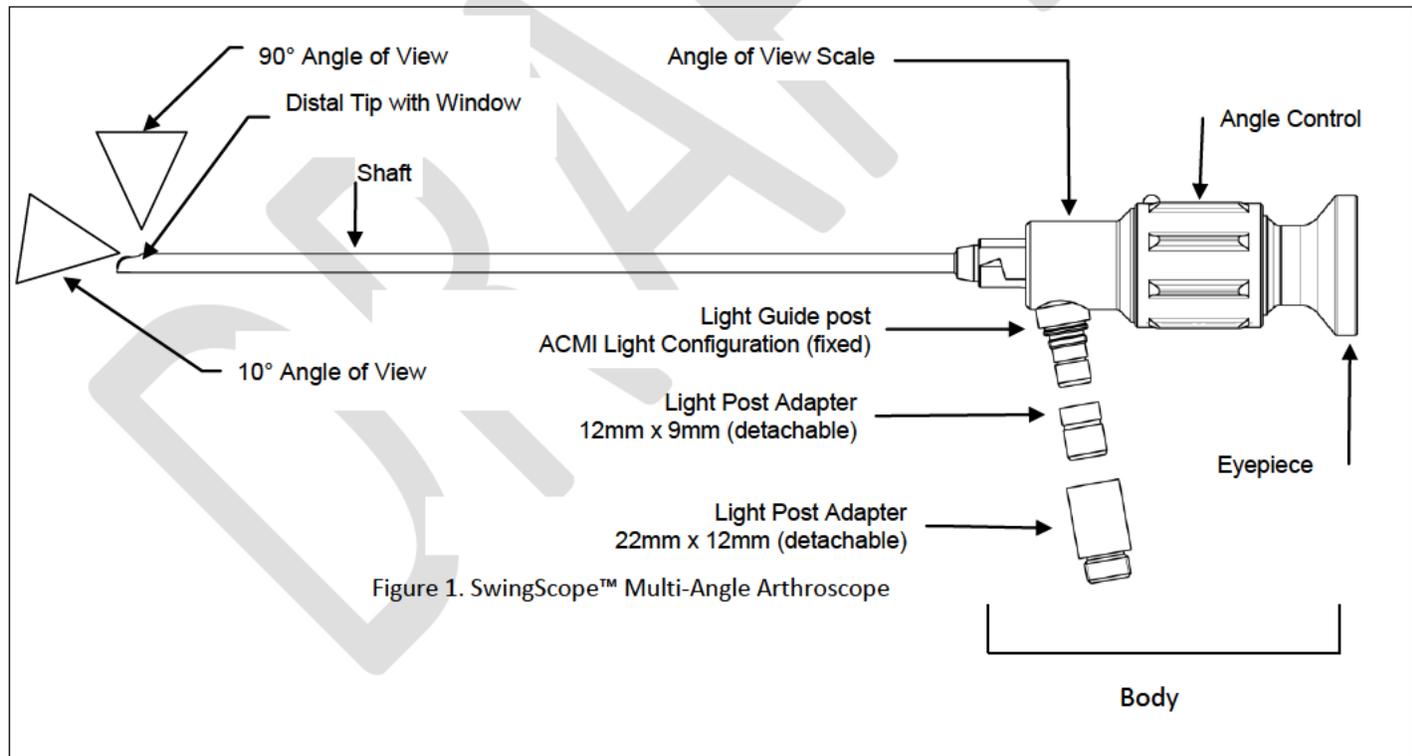


CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

DESCRIPTION

The SwingScope™ Multi-angle arthroscope (“arthroscope”) has the following features:

- Working Length: 205mm
- Shaft Diameter: 4.3mm
- Angle of View: between 10° and 90°
- Two detachable Light Post Adapters are provided (sizes 12mm x 9mm and 22mm x 12mm)
- The Eyepiece of the endoscope is compatible with C-mount camera couplers.



INDICATIONS FOR USE

Mitek Sports Medicine arthroscopes are indicated for use in arthroscopic procedures to provide visualization during surgery.

COMPATIBILITY

The arthroscope B-cup eyepiece is compatible with cameras or universal C-mount camera couplers. Use only light cables with a diameter of 5.0mm and smaller to prevent overheating of the distal tip. Use the arthroscope with Xenon or LED (up to 300W or equivalent) light sources.

INTENDED USE

Arthroscopes are intended for use by personnel trained in arthroscopy in a surgical setting.

CONTRAINDICATIONS

- Do not use the arthroscope on patients who have active implanted devices that would be affected by a magnetic field (e.g. pacemaker, implantable cardioverter-defibrillator, cochlear implant and deep brain stimulator) because the arthroscope contains small rare-earth permanent magnets.
- Do not use the arthroscope on patients with inferior vena cava filters that were implanted within the previous two weeks.



WARNINGS

- **Arthroscope may become hot.** Use care when handling and do not rest the scope directly on a patient or flammable material. The connection between the arthroscope and the light source can become very hot.
- To avoid burn injury during surgery, do not place the tip of the arthroscope on the patient or surgical drape.
- To avoid burns to the patient or user, do not use light cables with a diameter greater than 5.0mm. When operated at maximum brightness, surface temperature may exceed 41°C. A 3.5mm fiber optic light cable is recommended. Always adjust the light source to the minimum light output necessary to illuminate the endoscopic image.
- **NON-STERILE:** The arthroscope is provided NON-STERILE, and must be cleaned and sterilized prior to its first use, before each subsequent use, and after returning from repairs. Use instructions below for cleaning and sterilization.
- Do not use the arthroscope if you are unable to clean and sterilize according to the validated procedures contained in these instructions.
- Do not use a damaged or defective arthroscope. Inspect the arthroscope prior to each examination or procedure and before sterilization based on the instructions below.
- Turn off the light source and allow the arthroscope to cool for at least two (2) minutes prior to disconnecting the fiber optic cable or allowing the staff to handle the arthroscope.
- Do not use the arthroscope with Xenon light sources greater than 300W.
- Discard the arthroscope after surgery in patients with Creutzfeldt Jakob Disease (CJD), or suspected possible variants of CJD. Dispose according to hospital procedures.

- These Instructions for Use facilitate arthroscope use, and are not instructions for performing arthroscopic procedures.
- Do not attempt to modify the arthroscope. Modifying the device in a manner other than specified by in this document may result in injury. In the US, contact Customer Service at 1-800-382-4682 for service requests. In the European Union, contact your local affiliate.



PRECAUTIONS

- Do not bend the arthroscope.
- Do not hold the arthroscope by its shaft; this may cause damage.
- The arthroscope provides multiple angles of view; use caution when advancing the scope.
- Do not accelerate cooling; this may damage the arthroscope.
- To maintain optical quality, do not clean the arthroscope or light cable adapters in an ultrasonic bath.
- Cleaning and sterilization is guaranteed only if the arthroscope is cleaned and sterilized according to properly validated methods. This IFU provides minimum cleaning and sterilization procedures. It is the user's responsibility to qualify any deviations from the recommended procedures.
- Perform the cleaning and sterilization steps each time the arthroscope and light cable adapters are used.

INSPECTION, TESTING, AND MAINTENANCE

1. Remove and discard the protection caps from the distal tip, eyepiece and light guide post immediately upon receipt. Inspect the arthroscope immediately upon receipt, and before and after every procedure.
2. Inspect the distal window and eyepiece for scratches, chips, fingerprints or residual debris by observing reflected light on the surfaces of the distal window and eyepiece.
3. Examine the lumen through the eyepiece for condensation to make sure that the endoscope is free of internal moisture.
4. Examine the light guide post for damage.
5. **Test the image quality.** Look through the eyepiece. The image should be clear and distinct. If the distal window, eyepiece lens and light guide post surface are cloudy, dirty or scratched, or if the shaft is bent, scratched, dented, corroded, pitted or exhibits other surface irregularities, the image may not be clear. If the image is unclear, do not use the arthroscope. Send for repair or remove from service.
6. **Check light transmission.** Apply a light source to the distal tip with window of the arthroscope (shown in Figure 1). Inspect the light transmitting surface of the light guide post (or through the adaptor as shown in Figure 1). Uneven illumination indicates that glass light fibers are broken. Individual broken fibers do not necessarily result in a noticeable reduction in image quality;

however, do not use the arthroscope if approximately 25% of the transmitting surface of the light guide post is illuminating unevenly. Send for repair or remove from service.

7. **Test the controls.** Rotate the angle control and shaft controls while looking through the eyepiece. Ensure that the image changes appropriately. The arthroscope requires no lubrication to maintain proper function. If the image does not change appropriately, do not use the arthroscope.

Report damage immediately to a Sales Consultants or call Customer Service in the USA at +1-800-382-4682. Save all packing materials to use in the event you must return product(s) to Mitek Sports Medicine. Outside the United States, contact your local affiliate.

DRAFT

INSTRUCTIONS FOR USE

Assembly at Point of Use

Refer to Figure 1.

1. Connect the camera coupler to the eyepiece. The standard B-cup eyepiece is compatible with cameras or C-mount camera couplers.
2. Connect the light cable adapter. Slide the adapter over the light guide post (align the screw threads) and tighten in place.



CAUTION: Use only light cables with a diameter of 5.0mm and smaller to prevent overheating of the distal tip.

- **NOTE:** Observe the manufacturer's instructions for use when using the arthroscope with other implements, instruments or optical cables.
- **NOTE:** Do not allow the distal window, eyepiece lens or light guide post surface to contact abrasive surfaces.



CAUTION: Handle the arthroscope with care. Hard impacts, particularly to the distal end, may cause damage or cracks.

SwingScope Functions

Changing the Angle of View. To change the arthroscope angle of view, rotate the **Angle Control** (shown in Figure 1). The angle indicator on the Angle Control aligns with the set of reference markings on the body of the arthroscope and displays the approximate angle of view selected by the user.

Note: When the angle control is set to greater than 70°, the illumination provided by the SwingScope arthroscope becomes less intense.

Disconnecting the Arthroscope

To disconnect the arthroscope, hold the device by the body and unscrew light cable. Clean and sterilize according to the following procedure.

CLEANING AND STERILIZATION

General Considerations for Arthroscope Processing

- Observe point of use and transport procedures as described below.
- Complete each procedure: Preparation for Cleaning, Manual Cleaning or Automated Cleaning and Sterilization when reprocessing the arthroscope and light cable adapters.
- Personnel trained in the appropriate reprocessing techniques and safety should complete all reprocessing. Wear appropriate protective equipment (gloves, eye protection, etc.) when reprocessing any medical device.



CAUTION: The arthroscope contains small rare earth permanent magnets.

Do not place the arthroscope directly on, or next to an active implantable device that may be affected by magnetic fields.

Point of Use Cleaning

After concluding surgery, wipe any visible debris with wet gauze or a lap sponge and sterile water.

Transport to Processing Area

Keep the arthroscope and light cable adapters continuously moist until Manual or Automated Cleaning can commence at the point of central reprocessing. To keep the device moist, add a moist towel to the transport container.

Complete the cleaning procedures for the arthroscope and the light cable adapters within 30 minutes following their use.

Preparation for Cleaning

Disassemble the device.

1. Disconnect the light cable from the light guide post.
2. Disconnect the camera-coupling device from the eyepiece.
3. Remove any light cable adapters from the endoscope.
4. Disassemble the arthroscope from any devices or accessories used during the procedure.
5. Perform either the Manual Cleaning Procedure or the Automated Cleaning procedure below.

MANUAL CLEANING

Perform the following steps at the point of central reprocessing:

1. Rinse the arthroscope and the light cable adaptors under cold running tap water for a minimum of three (3) minutes. Brush all surfaces of the SwingScope arthroscope and light cable adaptors during the rinse. Rotate the image adjustment controls a minimum of five (5) times while brushing with a soft bristle brush during the rinse.
2. Prepare an enzymatic detergent according to the manufacturer's instructions. Use a fresh mixture of cleaning solution for each set of arthroscope and light cable when cleaning.
3. Immerse the arthroscope and light cable adapters completely in the detergent solution for at least 45 minutes.
4. After the first 15 minutes immersion time, use a soft bristle brush to remove any debris / soil from the arthroscope, and a soft bristled pipe cleaner for the light cable adapters while they are submerged. Brush for a minimum of 3 minutes. Ensure that the brush and the pipe cleaner can access the hard to reach areas such as cracks, crevices and threads on the light guide post and light guide adapters. Remove all visible debris.
5. Fill a syringe with the enzymatic detergent and use to flush crevices and threads while submerged.
6. Repeat the Brushing step (Step 2). Repeat the Flushing step. (Step 6) for an additional 2 times.

7. Rinse the arthroscope and light cable adapters under cold running tap water for at least three (3) minutes. Rotate the image adjustment controls a minimum of five (5) times while brushing with a soft bristle brush during the rinse. Brush all surfaces for the remaining rinsing time.
8. Soak the devices for a minimum of three (3) minutes in sterile water and dry with a lint-free soft cloth.

Automated Cleaning Instructions

Equipment Required. Washer-disinfector with fundamentally approved efficiency (e.g. CE mark or FDA approval according to ISO 15883), properly installed, qualified and regularly subjected to maintenance and testing.

Perform the following steps at the point of central reprocessing after completing Manual Pre-cleaning.

1. Prepare an enzymatic detergent per the manufacturer's instructions. Prepare a fresh mixture of cleaning solution for each use.
2. Disconnect the light cable adapters from the arthroscope and immerse the arthroscope and light cable adapters entirely in the detergent solution for at least 15 minutes.
3. Use a soft bristle brush to remove any debris / soil from the arthroscope. Use a soft bristled pipe cleaner to remove debris from the light cable adapters while they are submerged. The brush and pipe cleaner must be able to access areas that are difficult to reach, such as cracks, crevices and threads on the light guide post, and light guide adapters. Remove all visible debris.
4. Rinse the arthroscope and light cable adapters under cold running tap water for at least one (1) minute.
5. Place the arthroscope and its light cable adapters into a separate mesh basket. Ensure that the arthroscope and light cable adapters do not touch each other when placed into the basket.
6. Place a mesh screen over the basket to contain the arthroscope and light cable adapters in the basket during processing.
7. Place the mesh basket with arthroscope and light cable adapters into a general instrument washer-disinfector to clean the arthroscope and light cable adapters.
8. Select an enzymatic detergent and a neutral pH instrument cleaner. Prepare according to the instructions of the detergent manufacturer. Prepare a fresh mixture of cleaning solution for each use.
9. Run the washing machine cycle per the instructions provided by the manufacturer. The minimum cleaning cycle is described below in Table 1:

Table 1: Automatic Cleaning Parameters:

Phase	Recirculation Time	Water Temperature	Detergent Type
Pre Wash	3 minutes	Cold tap water	N/A
Enzyme Wash	5 minutes	Hot tap water	enzymatic detergent
Wash 1	5 minutes	65°C (Set Point)	Neutral pH instrument cleaner
Rinse 1	2 minutes	Hot tap water	N/A

Dry Phase	7 minutes	115°C	N/A
-----------	-----------	-------	-----

10. Remove the arthroscope and light cable adapters from the washing machine following the cleaning cycle. Allow sufficient time for the devices to cool for safe handling.

Inspection

After either Manual Cleaning or Automated Cleaning, visually inspect the arthroscope and light cable adapters to verify the absence of visible soil, stains and debris. If soil is present after cleaning, repeat cleaning procedure.

Steam Sterilization



CAUTION: Do not “flash” sterilize the arthroscope or light cable adapters.

1. Disassemble the arthroscope and light cable adapters before sterilization as described above.
2. Either double-wrap the arthroscope and light cable adapters with 1-ply polypropylene wrap, or place the arthroscope and light cable adapters into the appropriate sterilization tray and double-wrap the sterilization tray with 1-ply polypropylene wrap.
3. Complete sterilization per AAMI ST79. Table 2 lists the validated parameters.

Table 2: Parameters for Steam Sterilization

Sterilization Method	Pre-Vacuum
Pulses (minimum)	3
Temperature	132°C / 270° F
Exposure time	4 minutes
Drying Time	20 minutes

4. After sterilization, allow the arthroscope and light cable adapters to cool to room temperature. Do not accelerate cooling; this may damage the arthroscope.

STERRAD® Sterilization

1. Ensure the arthroscope and light cable adapters are disassembled before sterilization.
2. The arthroscope and light cable adapters are compatible with the STERRAD® 100S, STERRAD® 100NX and STERRAD® NX sterilization systems.
3. Clean and thoroughly dry the arthroscope and light cable adapters per the Cleaning Section.
4. Place the arthroscope and light cable adapters into the instrument tray compatible with the STERRAD 100S, NX and 100NX sterilization systems.
5. Double wrap the trays in 1-ply polypropylene wrap.
6. Include a STERRAD® indicator strip in the wrapped package.
7. Load the devices into the STERRAD® sterilizer.
8. Run the STERRAD® machine per the manufacturer’s instructions. DePuy recommends the following cycles:
 - STERRAD® 100NX: Standard cycle
 - STERRAD® 100S: Standard cycle
 - STERRAD® 100NX: Standard cycle

Ethylene Oxide (EtO) Sterilization

Perform EtO sterilization according to AAMI TIR 12.

1. Ensure the arthroscope and light cable adapters are disassembled before sterilization.
2. Clean and thoroughly dry the arthroscope and light cable adapters per the Cleaning Section.
3. Double-wrap the trays in 1-ply polypropylene wrap.
4. Complete pre-conditioning (Temperature: 130° ± 5°F b. Time: 30 min)
5. Complete processing. Cycle parameters:
 - Temperature : 55°C /130° ± 5°F
 - Relative Humidity: 50-80%
 - EtO Dwell Exposure time: 60 minutes

- EtO Concentration: 725-735mg/l (100% EtO)
- Aeration: temperature of 120 – 140°F (49°C – 60°C) for 12 hours

STORAGE

Store the arthroscope in a dry, clean and safe place at room temperature, in its wrapped sterilization container. Mitek Sports Medicine does not recommend storing the arthroscope and light cable adapters in the shipping box.

DISPOSAL

Dispose of surgical devices according to standard hospital procedures.

REPAIRS

- Contact the Repair Service Center at 1-800-382-4682 for service requests. Outside the United States, contact your local affiliate.
 - Before returning any product to Mitek Sports Medicine, please contact Customer Service to obtain a return goods authorization and product return packaging.
 - Please clean, disinfect, and sterilize the Arthroscope as described in this document and mark it as “Sterilized” prior to return.

Accessories and Spare Parts

Product Code	Description	Contact the Service Center at 1-800-382-4682. Outside the US, contact your local affiliate.
288008	Lightpost Adapter 22mm x 12mm	
288009	Lightpost Adapter 12mm x 9mm	

GRAPHIC SYMBOLS USED IN DEVICE LABELING



Quantity



On Order of Physician Only



Consult Instructions For Use



Product Code



Serial Number



Manufacturing Date



Contains No Natural Rubber Latex



Manufacturer



CE Mark

DRAFT

SPECIFICATIONS AND PERFORMANCE CHARACTERISTICS

Light Cable Diameter	5.0 mm or smaller (3.5 mm recommended)
ACMI Light Source (recommended)	300 W Xenon
Working Length	190.0 mm
Shaft Diameter	4.0 mm
Angle of View	Between 10° and 90°
Camera Coupler	Universal C-Mount
Recommended Light Source	Xenon or LED (up to 300W)



Medos International SARL
Chemin-Blanc 38, 2400
Le Locle, Switzerland

ATTACHMENT D
PREDICATE 510(k)'s



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

MAY 27 2011

Acclarent, Inc.
c/o Ms. Keri Yen,
Regulatory Affairs Manager
1525-B O'Brien Drive
Menlo Park, CA 94025

Re: K110097

Trade/Device Name: Acclarent Cyclops Multi-Angle Endoscope (Model CYE002)
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible or Rigid)
Regulatory Class: Class II
Product Code: EOB
Dated: April 26, 2011
Received: April 27, 2011

Dear Ms. Yen:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

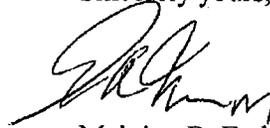
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110097

Device Name: Acclarent Cyclops Multi-Angle Endoscope (Model CYE002)

Indications For Use: The Acclarent Cyclops Multi-Angle Endoscope is intended to provide an endoscopic means to view the nasal cavity and nasopharynx in an operating room setting.

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 LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Rudy CRNP

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

Page 1 of _____

510(k) Number K110097

510(k) SUMMARY

Sponsor/Submitter: Acclarent, Inc.
1525-B O'Brien Drive
Menlo Park, California 94025

Contact Person: Keri Yen
Regulatory Affairs Manager
Phone: (650) 687-5874
Fax: (650) 687-4449

Date of Preparation: May 20, 2011

**Device Trade Name/
Model Number:** Acclarent Cyclops Multi-Angle Endoscope
CYE002

Common Name: Endoscope

Device Classification: Class II

Regulation Number: 21 CFR 874.4760

Classification Name: Nasopharyngoscope (Flexible or Rigid)

Product Code: EOB

Predicate Devices: Acclarent Cyclops Multi-Angle Endoscope (K100577)

Device Description: The Acclarent Cyclops Multi-Angle Endoscope is a 4mm rigid unchanneled endoscope that has the capability of varying direction of view from 10° to 90°, which is altered by the direction of view dial. The direction of view is indicated by visible markings on the scope body. Cyclops provides a 55° field of view and a depth of focus from 5 mm to 40mm. The device shaft can also rotate 320° to allow for visualization of structures without rotating the device; this is controlled by the shaft rotation dial. Small rare-earth permanent magnets are incorporated into the proximal scope control body (≤10 gauss at 2cm) and drive the change in the direction of view. A standard eyepiece located on the proximal end of the device is compatible with a standard camera coupler. The light post on the subject device is compatible with an ACMI light source.

There are two stainless steel adapters that accompany the Acclarent Cyclops Multi-Angle Endoscope to facilitate connection with Wolf or Storz/Olympus medical light sources.

The adapters connect to the light post. The Acclarent Cyclops Multi-Angle Endoscope is a reusable device and must be cleaned and sterilized according to the user manual prior to every use.

Indications for Use: The Acclarent Cyclops Multi-Angle Endoscope is intended to provide an endoscopic means to view the nasal cavity and nasopharynx in an operating room environment.

Technological Characteristics:

Attribute	Predicate Device (Acclarent Cyclops Multi-Angle Endoscope)	Subject Device (Acclarent Cyclops Multi-Angle Endoscope)
510(k) number	K100577	K110097
Model Number	CYE001	CYE002
Rigidity	Rigid	Same
Viewing Optics	Lens (Sapphire cover)	Same
Depth of View	5-45 mm	Same
Field of View	60°	55°
Direction of View	10° to 100°	10° to 90°
Shaft Body Diameter	4mm	Same
Working Length	6.89 inches (175mm)	Same
Magnetic Strength	≤10 gauss at 2cm	Same
Illumination Fibers	Glass Fibers	Same

Performance Data: Performance testing of the Acclarent Cyclops Multi-Angle Endoscope consisted of bench testing and a cadaver study. Bench testing met all acceptance criteria for attributes such as distal shaft diameter, working length, field of view, fixed focus, direction of view, rotation of view, illumination, scope resolution, dial actuation forces, temperature testing, field strength testing of magnets, electrical safety, EMC testing, durability testing, environmental conditioning, compression testing, random vibration testing, and shock (free fall drop) testing. Temperature testing consisted of attaching thermocouples at nine locations using adhesive and measuring the temperature at steady state. Test samples were connected to a 300W Xenon light source at 100% light output with both 3.5mm and 5.0mm light cables. The time to heat and time to cool was also evaluated. Clinical data was not necessary for the subject device. The performance data demonstrates that the Acclarent Cyclops Multi-Angle Endoscope performs as

intended according to IEC 60601-2-18, IEC 60601-1-2, ISO10993-1, ISO 8600-3, ISO 8600-5.

Validated Reprocessing Methods:

- Full manual cleaning with extended enzymatic soak plus general instrument automated washer
- Pre-vacuum steam sterilization (wrapped)

In validating the above, the following standards were referenced: AAMI/ANSI ST35, AAMI TIR 12, AAMI TIR 30, and ANSI/AAMI ST79 A1/A2, ANSI/AAMI ST8, ANSI/AAMI ST81, ASTM E1766.

Summary of Substantial Equivalence:

The Acclarent Cyclops Multi-Angle Endoscope is substantially equivalent to the predicate devices as confirmed through relevant performance tests and attributes.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

JAN 6 2011

Acclarent, Inc.
c/o Ms. Keri Yen
Regulatory Affairs Manager
1525-B O'Brien Dr.
Menlo Park, CA 94025

Re: K100577

Trade/Device Name: Acclarent Cyclops Multiangle Endoscope
Regulation Number: 21 CFR 874.4680
Regulation Name: Nasopharyngoscope, Flexible or Rigid
Regulatory Class: II
Product Code: EOB
Dated: 12/23/2010
Received: 12/27/2010

Dear Ms. Yen:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K100577

Trade Name: Acclarent Cyclops Multi-Angle Endoscope

Common Name: Endoscope

Indications For Use: The Acclarent Cyclops Multi-Angle Endoscope is intended to provide an endoscopic means to view the nasal cavity and nasopharynx in an operating room environment.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

Prescription Use X
(Per 21 CFR 801.109)

510(k) Number K100577

510(k) SUMMARY

Sponsor/Submitter: Acclarent, Inc.
1525-B O'Brien Drive
Menlo Park, California 94025

Contact Person: Keri Yen
Regulatory Affairs Manager
Phone: (650) 687-5874
Fax: (650) 687-4449

Date of Preparation: January 5, 2011

**Device Trade Name/
Model Number:** Acclarent Cyclops Multi-Angle Endoscope
CYE001

Common Name: Endoscope

Device Classification: Class II

Regulation Number: 21 CFR 874.4760

Classification Name: Nasopharyngoscope (Flexible or Rigid)

Product Code: EOB

Predicate Devices: OPTIM Inc. ENTity Nasoview Nasopharyngoscope (K080622)
Pollux Endoscopy Inc. Sinuscope (K002214)
Optus Sinuscope (K944656)
Karl Storz Hopkins Rigid Autoclavable Telescope (K935279)
Stryker Endoscopy Arthroscope (K093677)

Device Description: The Acclarent Cyclops Multi-Angle Endoscope is a 4mm rigid endoscope that has the capability of varying direction of view from 10° to 100°, which is altered by the direction of view dial. The direction of view is indicated by visible markings on the scope body. Cyclops provides a 60° field of view and a depth of focus from 5 mm to 40mm. The device shaft can also rotate 320° to allow for visualization of structures without rotating the device; this is controlled by the shaft rotation dial. Small rare-earth permanent magnets are incorporated into the proximal scope control body (≤ 10 gauss at 2cm) and drive the change in the direction of view. A standard eyepiece located on the proximal end of the device is compatible with a standard camera coupler. The light post on the subject device is compatible with an ACMI light source.

There are two stainless steel adapters that accompany the Acclarent Cyclops Multi-Angle Endoscope to facilitate connection with Wolf or Storz/Olympus medical light sources. The adapters connect to the

light post. The Acclarent Cyclops Multi-Angle Endoscope is a reusable device and must be cleaned and sterilized according to the user manual prior to every use.

Indications for Use:

The Acclarent Cyclops Multi-Angle Endoscope is intended to provide an endoscopic means to view the nasal cavity and nasopharynx in an operating room environment.

Technological Characteristics:

Attribute	Predicate Device (OPTIM Inc ENTity Nasoview Nasopharyngoscope)	Predicate Device (Pollux Endoscopy, Inc Sinuscope)	Predicate Device (Optus Sinuscope)	Subject Device (Acclarent Cyclops Multi-Angle Endoscope)
510(k) number	K080622	K002214	K944656	K100577
Rigidity	Flexible and Steerable	Rigid	Rigid	Same, Rigid
Viewing Optics	Lens	Lens	Lens	Same, Lens
Depth of View	5-50mm	5mm-45mm	Unknown	Same, 5-45 mm
Field of View	70°	95°	71° to 83°	60°
Direction of View	0° to 135°	0°, 30°, 45°, 70°	0°, 30°, 70°	10° to 100°
Shaft Body Diameter	3.6mm	2.7mm or 4mm	2.7mm or 4mm	Same, 4mm
Working Length	11.8 inches (30cm)	9.06 inches (230mm)	6.89 inches	Same, 6.89 inches (175mm)
Illumination Fibers	Glass Fibers	Glass Fibers	Glass Fibers	Same, Glass Fibers
Light Source	Integrated LED	Medical light source	Medical light source	Same, Medical light source

Performance Data:

Performance testing of the Acclarent Cyclops Multi-Angle Endoscope consisted of bench testing and a cadaver study. Bench testing met all acceptance criteria for attributes such as distal shaft diameter, working length, field of view, fixed focus, direction of view, rotation of view, illumination, scope resolution, dial actuation forces, temperature testing, field strength testing of magnets, electrical safety, EMC testing, durability testing, environmental conditioning, compression testing, random vibration testing, and shock (free fall drop) testing. Clinical data was not necessary for the subject device. The performance data demonstrates that the Acclarent Cyclops Multi-Angle Endoscope performs as intended.

**Validated Reprocessing
Methods:**

- Full manual cleaning with extended enzymatic soak plus general instrument automated washer
- Pre-vacuum steam sterilization (wrapped)

**Summary of Substantial
Equivalence:**

The Acclarent Cyclops Multi-Angle Endoscope is substantially equivalent to the predicate devices as confirmed through relevant performance tests and attributes.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Stryker Endoscopy
% Shibir Desai
Regulatory Affairs Analyst
5900 Optical Court
San Jose, California 95136

MAR - 5 2010

Re: K093677

Trade/Device Name: Stryker Arthroscope
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: February 25, 2010
Received: March 2, 2010

Dear Shibir Desai:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

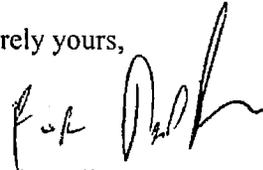
Page 2 - Shibir Desai

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



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

Enclosure

INTENDED USE

Device Name: Stryker Arthroscope

510(k) Number if known: K093677

Stryker **Arthroscopes** are endoscopic devices introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy. Arthroscopes are indicated for use in arthroscopic procedures performed in the hip, knee, shoulder, wrist (carpel tunnel syndrome), temporal mandibular joint, ankle, elbow, and feet (plantar fascia release).

No known contraindications.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093677

4/1

K093677



510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Endoscopy

Device Name

Proprietary Name: Stryker Arthroscope
 Common and Usual Names: Stryker Arthroscope
 Classification Name: Arthroscope (21 CFR § 888.1100, Product Code HRX)

Intended Use: Stryker Arthroscopes are endoscopic devices introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy. Arthroscopes are indicated for use in arthroscopic procedures performed in the hip, knee, shoulder, wrist (carpel tunnel syndrome), temporal mandibular joint, ankle, elbow, and feet (plantar fascia release).

Device Description: Stryker Arthroscopes are endoscopic devices introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy. The Stryker Arthroscope is a long tube containing a series of lenses. At the distal end, an objective lens captures the image of the object. Lens along the rod relay the image. At the proximal end, a proximal coupling lens relays the image to a CCD (Camera).

The Stryker Arthroscopes come in various diameters including 1.9mm, 2.3mm, 2.7mm, and 4.0mm. Larger size arthroscopes are used for general viewing, while smaller diameter arthroscopes are used for restricted surgical sites. The Stryker Arthroscopes come in several directions of view including, 0°, 30°, 45°, 70°. The direction of view enables viewing of different parts. Materials of the Arthroscope include stainless steel, titanium, PEEK, Glass, and Sapphire.

Technological Characteristics: The Stryker Arthroscopes are substantially equivalent in construction and materials to the predicate Henke Sass Wolf Arthroscopes (K080560).

	Proposed Device	Predicate Device	Equivalence	Impact on Safety and Effectiveness
Device	Stryker Arthroscope	HSW Arthroscope		
Technological Characteristics (Design)				
Field of View (FOV), Degrees	105°, 80°, 65°	85°, 105°	Different	The differences in the Field of view do not affect the safety and efficacy of the device.
Direction of View	0°, 30°, 45°, 70°	0°, 30°, 45°, 70°, 110°	Same	N/A

Outer Diameter	4mm, 2.7mm, 2.3mm, 1.9mm	4mm, 2.3mm-2.9mm, 1.7-1.9mm	Same	N/A
Working Length	165mm, 140mm, 120mm, 75mm, 72mm, 58mm	195mm, 185mm, 140mm, 70mm, 60mm	Different	The lengths are within the range of the predicate. The differences in the length do not affect the safety and efficacy of the device.
Single Use or Reusable	Reusable	Reusable	Same	Equivalent
Light Guide End Adapter	Storz and Olympus	ACMI, Storz, Olympus, Wolf & Dyonics	Same	N/A

Voluntary Safety and Performance Standards: The Stryker Arthroscopes conform to the voluntary standards including but not limited to (Refer to Section 5.1):

Biological Evaluation of Medical Devices

10993-1: Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing

10993-10: Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Delayed-Type Hypersensitivity

Electrical Safety Requirements Per 60601

IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

IEC 60601-2-18: Medical Electrical Equipment - Part 2: Particular Requirements for the safety of endoscopic equipment

AAMI/ISO Standards for Sterilization of Medical Devices

TIR 12: Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities

ISO 14937: Sterilization of Health Care Products - General Requirements for Characterization of a Sterilizing Agent and the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices

Optics

ISO 8600-1: Optics and photonics — Medical endoscopes and endotherapy devices — Part 1: General requirements

ISO 8600-3: Optics and optical instruments: Medical endoscopes and endoscopic accessories Part 3: Determination of field of view and direction of view of endoscopes with optics

ISO 8600-5: Optics and photonics-Medical Endoscopes and Endoscopic Accessories-Part 5: Determination of Optical Resolution of rigid endoscopes with optics.

Performance Testing: The subject device has been subjected to and passed electrical safety, sterilization, and biocompatibility testing requirements. The patient contacting materials are identical to the materials used in the predicated device (Henke Sass Wolf Arthroscope K080560). The Stryker Arthroscopes met all specified design and performance requirements.

Predicate Devices: The Stryker Arthroscopes are substantially equivalent in terms of safety and effectiveness to the currently marketed device, Henke Sass Wolf Arthroscopes (K080560).

Substantial Equivalence: The technological differences between the Stryker Arthroscope and Henke Sass Wolf Arthroscopes do not raise new questions of safety or effectiveness. Therefore the Stryker Arthroscopes are substantially equivalent to the previously cleared Henke Sass Wolf Arthroscope (K080560). Refer to Section 7.0 for a detailed comparison.

Contact:



Feb 25, 2010

Date:

Shibir Desai
Stryker Endoscopy
5900 Optical Court
San Jose, CA 95138
Phone: 408-754-2784
Fax: 408-754-2521
Email: Shibir.Desai@stryker.com



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 18 2003

Ms. Sally Foust, RAC
Regulatory Affairs Specialist
Arthrex, Inc.
2885 S. Horsehoe Drive
Naples, Florida 34104

Re: K030096
Trade/Device Name: Arthrex Arthroscopes
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscopes and accessories
Regulatory Class: II
Product Code: HRX
Dated: January 9, 2003
Received: January 10, 2003

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.

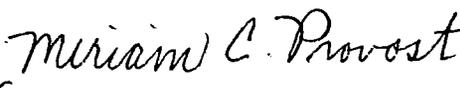
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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.

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

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

Enclosure

510(k) Number (if known) K030096

INDICATIONS FOR USE:

The Arthrex Arthroscopes are indicated for use in diagnostic and operative arthroscopic procedures to provide illumination and visualization of the shoulder, knee, elbow, ankle, wrist, and jaw, and also to provide illumination and visualization during arthroscopic diagnostic procedures and removal of loose bodies and soft tissue within the hip joint as size/length appropriate.

Hip diagnostic procedures may include:

Staging of avascular necrosis

Chondral injuries

Joint sepsis

Synovial chondromatosis

Unresolved hip pain

Labral tears

Concurrence of CDRH, Office of Device Evaluation

Prescription Use X OR

Over-The-Counter

Use

(Per 21 CFR 801.109)

Miriam C. Provost

(Division Sign-Off)

Division of General, Restorative
and Neurological Devices

510(k) Number K030096

000006

K030096

MAR 18 2003

PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS
Arthrex Arthroscopes

NAME OF SPONSOR: Arthrex, Inc.
2885 S. Horseshoe Drive
Naples, Florida 34104

510(K) CONTACT: Sally Foust, RAC
Regulatory Affairs Specialist
Arthrex, Inc.
Telephone: (239) 643-5553 extension 1251
FAX: (239) 430-3494

TRADE NAME: Arthrex Arthroscopes

COMMON NAME: Arthroscope

CLASSIFICATION: Arthroscope
21 CFR 888.1100

DEVICE PRODUCT CODE: HRX

DEVICE DESCRIPTION AND INTENDED USE:

Arthrex Arthroscopes are rigid, fixed arthroscopes with a wide-angle view. Arthrex Arthroscopes have surgical stainless steel shafts and lens housings for durability and are available with a 30 or 70 degree angle view. The optical components are sealed to provide a durable focusing mechanism. The arthroscopes may be attached to a video camera and are available in various sizes, diameters and lengths, to provide for differences in arthroscopic surgical site and surgeon preference.

The Arthrex Arthroscopes are indicated for use in diagnostic and operative arthroscopic procedures to provide illumination and visualization of the shoulder, knee, elbow, ankle, wrist, and jaw, and also to provide illumination and visualization during arthroscopic diagnostic procedures and removal of loose bodies and soft tissue within the hip joint as size/length appropriate.

SAFETY AND EFFECTIVENESS

The Arthrex, Inc. Arthroscopes are similar to the predicate devices in design, materials, and intended use and as such are considered by Arthrex, Inc. to be substantially equivalent to devices currently available in U.S. distribution. The expansion of the indications of the Arthrex, Inc. Arthroscopes to include elbow and hip, those of the Smith & Nephew predicate device, does not raise new issues of safety and effectiveness.

000007

ATTACHMENT E
PREDICATE INSTRUCTIONS for USE

cyclops

Acclarent™

Instructions For Use

**Acclarent Cyclops™
Multi-Angle Endoscope**

Acclarent Cyclops™ Light Guide Cable Adapters

Acclarent Cyclops™ Models covered
by these Instructions for Use:

CYE002

Check www.Acclarent.com at least annually for the current version of the Instructions
for Use

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE.

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

PACKAGING

STERILITY:

NON-STERILE: The Acclarent Cyclops endoscope is provided NON-STERILE. The Acclarent Cyclops endoscope must be cleaned and sterilized prior to its first use, before each subsequent use and after returning from repairs. See instructions below for cleaning and sterilization.

DESCRIPTION

The Acclarent Cyclops endoscope is a rigid endoscope. It incorporates two image adjustment controls.

Specifications	
Working Length	175mm
Shaft Diameter	4 mm
Shaft Direction Control	Allows shaft to be rotated between 0° and 160° in either direction from the 12 o'clock rotation position.
Angle Control	Angle of view can be adjusted between 10° and 90°.

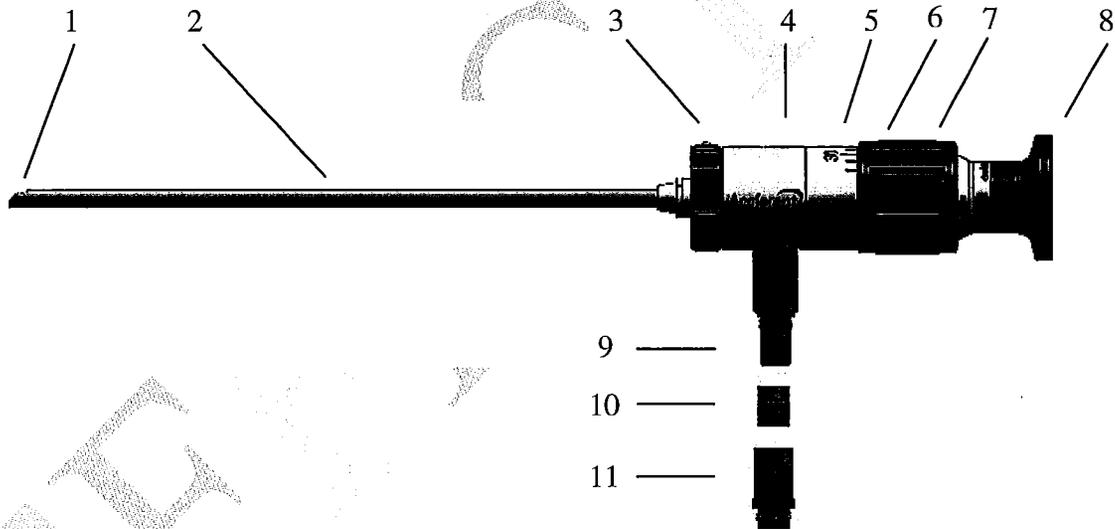


Figure 1. Acclarent Cyclops Multi-Angle Endoscope

Legend:

- | | |
|---|--|
| 1) Distal Window | 7) Angle Control |
| 2) Shaft | 8) Eyepiece |
| 3) Shaft Direction Control | 9) Light Guide Post - ACMI Light Cable Configuration (fixed) |
| 4) Scope Body | 10) Wolf Light Cable Adapter (detachable) |
| 5) Angle of View Scale | 11) Olympus / Storz Light Cable Adapter (detachable) |
| 6) Angle Indicator (small bump on surface of Angle Control) | |

INDICATIONS FOR USE

The Acclarent Cyclops Multi-Angle Endoscope is intended to provide an endoscopic means to view the nasal cavity and nasopharynx in an operating room environment.

CONTRAINDICATIONS

Do not use Acclarent Cyclops on patients who already have active implanted devices that would be affected by a magnetic field (e.g. pacemaker, implantable cardioverter-defibrillator, cochlear implant and deep brain stimulator) because Acclarent Cyclops contains small rare-earth permanent magnets. Additionally, do not use Acclarent Cyclops on patients with inferior vena cava filters that have been implanted within the previous two weeks.

WARNINGS

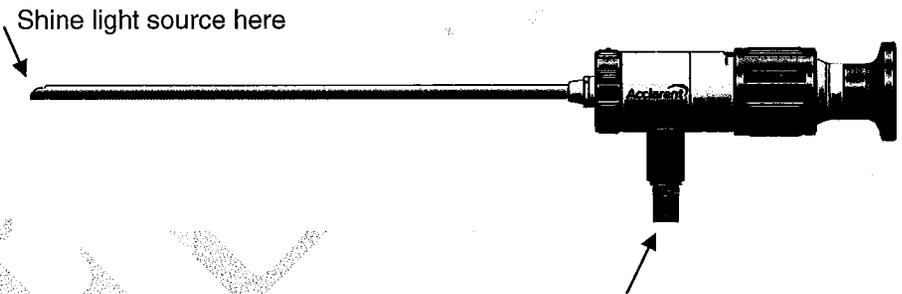
- ⚠ **NON-STERILE:** The Acclarent Cyclops endoscope is provided **NON-STERILE**. The Acclarent Cyclops endoscope must be cleaned and sterilized prior to its first use, before each subsequent use and after returning from repairs. See instructions below for cleaning and sterilization.
- ⚠ Do not use the Acclarent Cyclops endoscope if you are unable to clean and sterilize according to the validated procedures contained in these instructions.
- ⚠ Do not use a damaged or defective Acclarent Cyclops endoscope. Inspect the Acclarent Cyclops endoscope prior to each examination or procedure and before sterilization based on the instructions below.
- ⚠ The connection between the Acclarent Cyclops endoscope and the light source can become very hot. Use care when handling and do not rest the scope directly on a patient or flammable material.
- ⚠ Surface temperature may exceed 41°C if the device is operated at maximum brightness. To avoid burns to the patient or user, do not use light cables with a diameter greater than 5.0mm. Acclarent recommends the use of a 3.5mm fiber optic light cable. Always adjust the light source to the minimum light output necessary to illuminate the endoscopic image.
- ⚠ Turn off the light source and allow the endoscope to cool for at least two minutes prior to disconnecting the fiber optic cable or allowing the staff to handle the endoscope.
- ⚠ Do not use the Acclarent Cyclops with Xenon light sources greater than 300W.
- ⚠ These Instructions for Use are meant to facilitate use of the Acclarent Cyclops and are not instructions on how to perform endoscopic procedures.

PRECAUTIONS

- ⚠ Do not bend the Acclarent Cyclops.
- ⚠ Do not hold the Acclarent Cyclops by its shaft, as this can cause damage.
- ⚠ The minimum angle of view allowed by the Acclarent Cyclops is 10°. Use caution when advancing the scope.
- ⚠ To maintain optical quality, do not clean the Acclarent Cyclops or light cable adapters in an ultrasonic bath.
- ⚠ Do not accelerate the cooling of the Acclarent Cyclops, as this can cause damage.
- ⚠ Do not flash sterilize the Acclarent Cyclops.

- ⚠ Cleaning and sterilization can only be guaranteed if the Acclarent Cyclops is cleaned and sterilized according to properly validated methods. The minimum cleaning and sterilization procedures are provided in this IFU. The Automated Cleaning procedure has not been validated as effective in accomplishing disinfection. It is the responsibility of the user to qualify any deviations from the recommended procedures.
- ⚠ Manual Cleaning PLUS Automated Cleaning must be performed each time the Acclarent Cyclops and light cable adapters are reprocessed.
- ⚠ If the Acclarent Cyclops was used in a patient with Creutzfeld-Jakob disease (CJD), suspected CJD or possible variants of CJD, Acclarent recommends safely disposing of the Acclarent Cyclops. For disposal instructions, see Section D.
- ⚠ When the angle control is set to greater than 70°, the illumination provided by the Acclarent Cyclops becomes less intense.

INSTRUCTIONS FOR USE

<p>A. Inspection and Testing</p>	<ol style="list-style-type: none"> 1) Remove and discard the protection caps from the distal tip, eyepiece and light guide post immediately upon receipt. 2) Inspect the endoscope immediately upon receipt, and before and after every procedure. 3) Inspect the distal window and eyepiece for scratches, chips, fingerprints or residual debris by observing reflected light on the surfaces of the distal window and eyepiece. 4) To test image quality, look through the eyepiece. The image should be clear and distinct. If the distal window, eyepiece lens and light guide post surface are cloudy, dirty or scratched, or if the shaft is bent, scratched, dented, corroded, pitted or exhibits other surface irregularities, the image may not be clear. If the image is not clear, the Acclarent Cyclops should not be used, and should be sent in for repair or taken out of service. 5) Check light transmission by pointing the distal window of the Acclarent Cyclops at a light source and inspecting the light transmitting surface of the light guide post connector (see Figure 2). If the glass light fibers are broken, the light transmitting surface of the light guide post will illuminate unevenly. Individual broken fibers do not necessarily result in a noticeable reduction in image quality. However, if approximately 25% of the transmitting surface of the light guide post is illuminating unevenly, the endoscope should not be used, and should be sent in for repair or taken out of service. <div style="text-align: center;">  <p>The diagram shows the Acclarent Cyclops endoscope. An arrow on the left points to the distal end of the shaft, labeled 'Shine light source here'. Another arrow on the right points to the light guide post connector, labeled 'Inspect light transmitting surface of the light guide post here'.</p> </div> <p style="text-align: center;">Figure 2. Method for checking light transmission</p> <ol style="list-style-type: none"> 6) Test the controls. Rotate the angle control and shaft control while looking through the eyepiece. Ensure that the image changes appropriately. Acclarent Cyclops requires no lubrication to maintain proper function. If the image does not change appropriately, the endoscope should not be used, and should be sent in for repair or taken out of service.
<p>B. Point of Use:</p>	<ol style="list-style-type: none"> 1) Assembly: <ol style="list-style-type: none"> a. Connect appropriate light cable adapters as required. <ol style="list-style-type: none"> i. To connect the Wolf light cable adapter, slide the adapter over the light guide post and tighten in place using the screw threads. ii. To connect the Olympus / Storz light cable adapter, slide the adapter over the light guide post and tighten in place using the screw threads. b. If a camera is utilized, connect the camera coupler to the eyepiece.

- i. The standard B-cup eyepiece can be used with cameras or universal C-mount camera couplers .
 - c. Connect the light guide cable to the light guide post/adaptor. Only light cables with a diameter of 5.0mm and smaller should be used to prevent overheating of the distal tip.
- 2) Usage:
- a. Observe the respective manufacturer's instructions when using the Acclarent Cyclops endoscope with other implements, instruments or optical cables.
 - b. Acclarent recommends use with Xenon (up to 300W) light sources.
 - c. Make sure that the distal window, eyepiece lens or light guide post surface do not contact abrasive surfaces. Anti-fog solution (e.g. Covidien's FRED™ or DeRoyal DeFogger™) may be used with Acclarent Cyclops to help prevent fogging of the distal window and eyepiece lens.
 - d. Handle the Acclarent Cyclops endoscope with care. Hard impacts, particularly to the distal end, may result in damage or cracks.

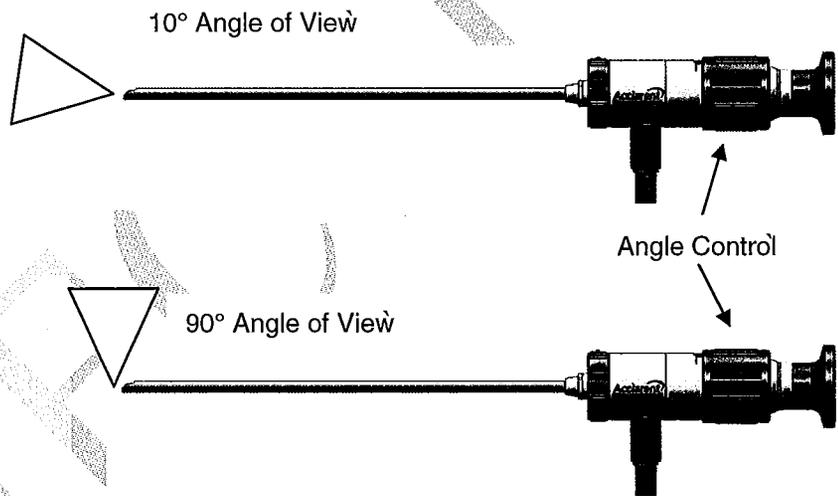


Figure 3. Acclarent Cyclops Angle of View

- e. To change the Acclarent Cyclops endoscope's angle of view, rotate the Angle Control. The angle indicator on the Angle Control aligns with the set of reference markings on the body of the endoscope and displays the approximate angle of view selected by the user. The Acclarent Cyclops endoscope displays angles between 10° and 90° as shown in Figure 3.
- f. To rotate the Acclarent Cyclops endoscope's shaft, rotate the Shaft Direction Control. The scope allows shaft rotation of 160° in both directions from the 12 o'clock rotational position. A marker that displays the 12 o'clock rotational position is visible in the endoscopic view. An indicator on the Shaft Direction Control dial illustrates the location of the 12 o'clock rotational position.

C. Point of Use Cleaning

The following steps are to be performed at the point of use:

- 1) During surgery, keep the device moist by periodically wiping with a wet gauze

	<p>or a lap sponge and sterile water.</p> <p>2) After surgery has concluded, use a wet gauze or a lap sponge and sterile water to wipe off any visible debris. Keep the device moist by adding a moist towel to the transport container until it can be cleaned according to the reprocessing instructions described below. Cleaning should be completed on the Acclarent Cyclops and the light cable adapters within 30 minutes following their use.</p>
<p>D. General Considerations for Endoscope reprocessing:</p>	<p>Complete Preparation for Cleaning, Manual Cleaning plus Automated Cleaning and Sterilization each time when reprocessing the Acclarent Cyclops and light cable adapters.</p> <p>1) All reprocessing should be completed by personnel trained in the appropriate reprocessing techniques and safety. All reprocessing personnel should don appropriate personal protective attire.</p> <p>2) Cleaning should be completed on the Acclarent Cyclops and the light cable adapters within 30 minutes following their use. Keep device continuously moist with a moist towel prior to cleaning.</p> <p>3) If the Acclarent Cyclops endoscope was used in a patient with Creutzfeld-Jakob disease (CJD), suspected CJD or possible variants of CJD, Acclarent recommends safely disposing of the Acclarent Cyclops endoscope. The safest and most unambiguous method for ensuring that there is no risk of residual infectivity on contaminated instruments and other materials is to discard and destroy them by incineration. For more information regarding exposure to Creutzfeld-Jakob disease (CJD) or possible variants of CJD, and for information about disposing contaminated devices, please see the following references:</p> <p>a. Brown, S. A., Merritt, K., Woods, T. O., & Busick, D. N. (2005). Effects on instruments of the World Health Organization – Recommended protocols for decontamination after possible exposure to transmissible spongiform encephalopathy contaminated tissue. <i>Appl Biomater</i>, 72B, 186-190. DOI 10.1002/jbm.b.30125.</p> <p>b. World Health Organization Infection Control Guideline for Transmissible Spongiform Encephalopathies. Geneva, Switzerland, March, 1999 available from: http://www.who.int/csr/resources/publications/bse/WHO_CDS_CSR_APH_2000_3/en/</p> <p> CAUTION: Do not place the Acclarent Cyclops directly on or next to an active implantable device that may be affected by magnetic fields as the device contains small rare earth permanent magnets.</p>
<p>E. Preparation for Cleaning</p>	<p>1) Disassembly</p> <p>a. Disconnect the light cable from the light guide post.</p> <p>b. If a camera was utilized, disconnect the camera coupling device from the eyepiece.</p> <p>c. Remove any light cable adapters used.</p> <p>d. Keep Acclarent Cyclops and light cable adapters continuously moist until Manual Cleaning can commence at the point of central reprocessing. The device may be kept moist by adding a moist towel to the transport container.</p>
<p>F. Cleaning: Manual</p>	<p>The following steps are to be performed at the point of central reprocessing:</p>

	<p>1) Manual Cleaning:</p> <ol style="list-style-type: none"> a. Prepare a neutral pH enzymatic detergent (e.g. Enzol®) per the manufacturer's instructions (e.g. for Enzol®) mix 1 oz/gal with lukewarm tap water). Prepare a fresh mixture of cleaning solution for each use. b. Immerse the Acclarent Cyclops and light cable adapters entirely in the detergent solution for at least 15 minutes. c. Use a soft bristle brush (e.g. a standard size tooth brush) to remove any debris / soil from the Acclarent Cyclops and a soft bristled pipe cleaner for the light cable adapters while they are submerged. Ensure that the brush and the pipe cleaner can access the hard to reach areas such as cracks, crevices and threads on the light guide post and light guide adapters. Ensure that all visible debris is removed.. d. Rinse the endoscope and light cable adapters under cold running tap water for at least 1 minute. <p> CAUTION: Manual Cleaning PLUS Automated Cleaning must be performed each time the Acclarent Cyclops and light cable adapters are reprocessed.</p> <p> CAUTION: The Automated Cleaning reprocessing parameters have not been validated as effective in accomplishing <i>disinfection</i> of the Acclarent Cyclops.</p>								
<p>G. Cleaning: Automated</p>	<p>The following steps are to be performed at the point of central reprocessing after completion of Manual Cleaning (described above):</p> <p>1) Automated Cleaning:</p> <ol style="list-style-type: none"> a. Place the Acclarent Cyclops together with its light cable adapters into a separate mesh basket. Ensure that the Acclarent Cyclops and light cable adapters do not touch each other when placed into the basket. b. Place a mesh screen over the basket to prevent the Acclarent Cyclops and light cable adapters from coming out of the basket during processing. c. Place the mesh basket with Acclarent Cyclops and light cable adapters into a general instrument washer-disinfector (e.g. Amsco Steris 444 Washer / Disinfector) to clean the Acclarent Cyclops and light cable adapters. d. Select a neutral pH enzymatic detergent (e.g. Enzol) and a neutral pH instrument cleaner (e.g. RenuKlenz™). Prepare per the instructions of the detergent manufacturer (for example, Enzol 1oz/gal and RenuKlenz ¼oz/gallon). Prepare a fresh mixture of cleaning solution for each use. e. Run the washing machine cycle per the instructions provided by the manufacturer. The minimum cleaning cycle is described below in table 1: <p style="text-align: center;">Table 1: Automatic Cleaning Parameters:</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Phase</th> <th>Recirculation Time</th> <th>Water Temperature</th> <th>Detergent Type</th> </tr> </thead> <tbody> <tr> <td>Pre Wash</td> <td>3 minutes</td> <td>Cold tap water</td> <td>N/A</td> </tr> </tbody> </table>	Phase	Recirculation Time	Water Temperature	Detergent Type	Pre Wash	3 minutes	Cold tap water	N/A
Phase	Recirculation Time	Water Temperature	Detergent Type						
Pre Wash	3 minutes	Cold tap water	N/A						

	<table border="1"> <tr> <td>Enzyme Wash</td> <td>5 minutes</td> <td>Hot tap water</td> <td>Neutral pH enzymatic detergent</td> </tr> <tr> <td>Wash 1</td> <td>5 minutes</td> <td>65°C (Set Point)</td> <td>Neutral pH instrument cleaner</td> </tr> <tr> <td>Rinse 1</td> <td>2 minutes</td> <td>Hot tap water</td> <td>N/A</td> </tr> <tr> <td>Dry Phase</td> <td>7 minutes</td> <td>115°C</td> <td>N/A</td> </tr> </table> <p>f. Remove the Acclarent Cyclops and light cable adapters from the washing machine following the cleaning cycle and after allowing sufficient time for the devices to cool so they can be safely handled.</p> <p>g. Inspect the devices to ensure that all visible soil, stains and debris have been removed.</p> <p> CAUTION: Manual Cleaning PLUS Automated Cleaning must be performed each time the Acclarent Cyclops and light cable adapters are reprocessed.</p> <p> CAUTION: The Automated Cleaning reprocessing parameters have not been validated as effective in accomplishing <i>disinfection</i> of the Acclarent Cyclops.</p>	Enzyme Wash	5 minutes	Hot tap water	Neutral pH enzymatic detergent	Wash 1	5 minutes	65°C (Set Point)	Neutral pH instrument cleaner	Rinse 1	2 minutes	Hot tap water	N/A	Dry Phase	7 minutes	115°C	N/A
Enzyme Wash	5 minutes	Hot tap water	Neutral pH enzymatic detergent														
Wash 1	5 minutes	65°C (Set Point)	Neutral pH instrument cleaner														
Rinse 1	2 minutes	Hot tap water	N/A														
Dry Phase	7 minutes	115°C	N/A														
H. Post-cleaning Inspection and Testing	1) After cleaning is complete, inspect the Acclarent Cyclops per the instructions in Section A.																
I. Sterilization: Steam:	<p>1) Do not "Flash" sterilize the Acclarent Cyclops or light cable adapters.</p> <p>2) Ensure the Acclarent Cyclops and light cable adapters are disassembled before sterilization.</p> <p>3) Double wrap the Acclarent Cyclops and light cable adapters with 1-ply polypropylene wrap (e.g. Kimguard KC600).</p> <p>4) Complete sterilization per AAMI ST79:2006, A1:2008, A2:2009. The validated parameters are listed in Table 2.</p> <p style="text-align: center;">Table 2: Parameters for Steam Sterilization</p> <table border="1"> <thead> <tr> <th>Sterilization Method</th> <th>Pre-Vacuum</th> </tr> </thead> <tbody> <tr> <td>Pulses (minimum)</td> <td>3</td> </tr> <tr> <td>Temperature</td> <td>132°C / 270° F</td> </tr> <tr> <td>Exposure time</td> <td>4 minutes</td> </tr> <tr> <td>Drying Time</td> <td>20 minutes</td> </tr> </tbody> </table> <p>5) After sterilization, allow the Acclarent Cyclops, and light cable adapters to cool down to room temperature. Do not accelerate cooling, as this may damage the Acclarent Cyclops endoscope.</p>	Sterilization Method	Pre-Vacuum	Pulses (minimum)	3	Temperature	132°C / 270° F	Exposure time	4 minutes	Drying Time	20 minutes						
Sterilization Method	Pre-Vacuum																
Pulses (minimum)	3																
Temperature	132°C / 270° F																
Exposure time	4 minutes																
Drying Time	20 minutes																
J. Storage	<p>1) Store the Acclarent Cyclops endoscope in a dry, clean and safe place at room temperature, in its wrapped sterilization container.</p> <p>2) Acclarent does not recommend storing the Acclarent Cyclops and light cable adapters in their shipping box.</p>																
K. Disposal	1) For disposal, observe standard protocols for disposal of surgical devices (see Section D for references).																

Technical service, maintenance or repairs:

- Contact Acclarent Customer Service:
- Acclarent, Inc.
1525-B O'Brien Drive
Menlo Park, CA 94025
U.S.A.
- Toll Free: 1-877-SPLASTY (1-877-775-2789)
- Before returning any product to Acclarent, please contact Acclarent Customer Service to obtain a return goods authorization and product return packaging.
- Please clean and sterilize the endoscope and mark it as "Sterilized" prior to return.

GRAPHIC SYMBOLS CONTAINED IN DEVICE LABELING



Non-Sterile



Working Length



Consult Instructions For Use

Rx ONLY

On Order of Physician Only



Scope Outer Diameter



Product Code



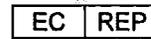
Serial Number



Light Cable Adapter



Contains No Natural Rubber Latex



European Authorized Representative



CE Mark



Keep Away from Sunlight



Manufacturer



Manufacturing Date



Acclarent Cyclops Multi-Angle Endoscope



Caution

©2010 Acclarent, Inc. All rights reserved.

Manufactured for:
Acclarent, Inc.
1525-B O'Brien Drive
Menlo Park, CA 94025

USA

Toll Free: 1-877-SPLASTY (1-877-775-2789)

EXPIRES



**Autoclavable Rigid
Medical Endoscopes
Instructions for Use and
Processing Instructions**

DFU-950-0030-00

Rigid Medical Endoscopes



**Arthrex California Technology,
Inc.**

460 Ward Drive
Santa Barbara, CA
93111
(800) 934-4404

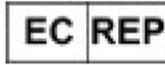
Device Symbols Used:



Manufacturer



See Instructions
for Use



Authorized
Representative
in the European
Community

R_x ONLY

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



Non sterile



Storage
Temperature
Range

DFU Symbols used:



Warning:
Instructions for
preventing
personal injury



Information to
facilitate
understanding
of workflow



Instructions for
preventing
Material
Damage



Instruction

INSTRUCTIONS FOR USE

1. About this document

This document describes the correct handling, functioning and reprocessing of the rigid endoscope.

This document may not be used to carry out examinations or surgeries, nor may it be used for training purposes.

The current version of this document can be found on the internet at www.arthrex.com.

You can also request this document from Arthrex.

Users of these endoscopes are encouraged to contact their representatives if, in their professional judgment, they require more comprehensive information on their use and care.

2. Intended Use

Arthrex rigid medical endoscopes are used to visualise body cavities. Each endoscope was developed for diagnostic and surgical procedures in one of the following fields of application:

- Arthroscope: arthroscopic procedures
- Laryngoscope: laryngoscopic procedures
- Laparoscope: laparoscopic procedures

For the benefit and safety of patients, physicians must select

a method which they consider suitable based on their experience. Users of these endoscopes are encouraged to contact their Arthrex representatives if, in their professional judgment, they require more comprehensive information on their use and care. The Arthrex website (www.arthrex.com) also provides detailed information.

3. Safety Information

The endoscope may only be used by trained medical professionals in medical facilities.

- After receipt of device(s), inspect the endoscope for completeness and damage.
- Read, observe and store these instructions and any other applicable instructions.
- Use endoscopes only as intended.

For storage, transport and processing, ensure that the endoscope is not subjected to mechanical strain, particularly to prevent damage to the sensitive lens system.



WARNING: Risk of injury, contamination or infection to the patient or medical professionals!

The endoscopes are delivered unsterile as reusable products. The state-of-the-art and national laws require the observance of validated processes. In general, users are responsible for the validation of their cleaning and sterilisation processes.

Ensure that the processing, material and personnel are suitable for achieving the results necessary

- Observe any and all valid local operator regulations for all manual cleaning and drying processes.
- Clean/disinfect and sterilise the endoscope prior to initial use, as well as each subsequent use.
- Bring the endoscope to the decontamination area as soon as possible after use. Observe valid protective measures to prevent contaminating the environment.



WARNING: Risk of burns!

The optical fibres emit high-energy light at the distal end of the endoscope. This can cause the temperature of the body tissue to rise to 106 °F (41°C).

- Avoid direct contact of the distal end with body tissue or flammable materials as it can cause burns and fires.
- Reduce the light intensity of the light source when working near body tissue or flammable materials.



WARNING: Risk of injury due to faulty endoscopes!

- Carry out visual inspection and function check prior to each use.
- Only use endoscopes which are in perfect condition.

4. Inspection Handling and Maintenance

1. Arthrex endoscopes are precision medical instruments and must be used and handled with care.
2. Inspect the endoscope for damage prior to use and at all stages of handling thereafter.
3. If damage is detected, do not use the endoscope prior to consulting the manufacturer for guidance.
4. Do not subject the endoscope to impact. Set the endoscope down carefully.
5. Hold endoscope only by the ocular funnel/main part and not by the sheath.
6. Do not bend the sheath or use as a prying tool.
7. After insertion of the endoscope into the body, do not apply additional flexion to the joint. A piece of a broken endoscope can become lodged in soft tissue and/or disappear from the arthroscopic view of the surgical field and can be left in the patient.

Transport endoscopes individually and store them safely by using a screen basket or container.

5. Description

5.1 Construction

1. Distal End
2. Sheath
3. Main part
4. Ocular funnel
5. Proximal end
6. Irradiation surface of the illumination fibers
7. Connection for illumination fiber, type ACMI
8. Adapter for illumination fiber, type Wolf, pre-assembled
9. Adapter for illumination fiber, type Storz / Olympus (see below for assembly instructions).

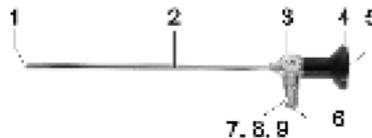


Figure 1-Construction

5.2 Markings on the Main Part

- Article number
- Serial number
- CE mark with identification number of the notified body where applicable: Endoscope conforms to the requirements of the guideline 93/42/EWG.
- For autoclavable endoscopes: Etching of **autoclavable**
- Specification of the direction of view
- Writing GERMANY
- Writing ARTHREX

- For large-screen lenses:
Writing **HM**
- For high-resolution endoscopes developed specifically for the latest Full HD camera generations: **HD**
- Writing **HD**

5.3 Available Designs and Sizes

The endoscopes are available in the following designs and sizes:

- Straight endoscopes
- Angled endoscopes
- Sheath dia. 1.9–11 mm

5.4 Combinable Products

You can combine the endoscopes with common camera systems, illumination fibres and instruments from Arthrex.

6. Preparation For Use

6.1 Visual inspection and function check



WARNING: Risk of injury due to faulty endoscopes!

- Carry out visual inspection and function check prior to initial use and each subsequent use.
- Only use endoscopes which are in perfect condition.
-  Clean/disinfect and sterilise the endoscope prior to initial use, as well as

each subsequent use of the endoscope. If not cleaned properly, contaminants on the irradiation surfaces of the illumination fibers [6] can burn-in during use, which impacts image quality.

- Ensure that the proximal end [5] of the endoscope is dry to prevent the endoscope from fogging up during the examination/procedure.
- Ensure that no parts are missing or loose.
- Ensure that there are no residual cleaning agents or disinfectants on the endoscope.
- Inspect the entire endoscope, particularly the sheath [2], for contaminants and damage of any type, such as dents, scratches, cracks, bending and sharp edges.
- For endoscopes with a locking device: Inspect between the sheath [2] and the main part [3] for contaminants and damage to ensure a fixed and secure connection.
- Inspect distal end [1], proximal end [5] and irradiation surface of the illumination fibres [6] for any

contaminants and scratches.

- Make contaminants and scratches visible using light reflexes by holding the endoscope with the connection for the illumination fibre against the light and inspect whether the illumination fibres illuminate evenly at the distal end [1]
- Check image quality: The image may not be blurry, clouded or dark.
- If necessary, remove deposits on the optical end surface using polishing paste provided (see Removing deposits from optical surfaces below).

6.2 Provisioning

- Clean/disinfect and sterilise the endoscope prior to initial use as well as each subsequent use of the endoscope.
- Ensure that the proximal end of the endoscope is dry to prevent the endoscope from fogging up during the examination/procedure.
- If required, mount the adapter for illumination fiber.

- Mount illumination fibre (see manufacturer's specifications).
- If required, adapt the camera (see manufacturer's specifications).

7. Use



Risk of burns!

- Avoid direct contact of the distal end with body tissue or flammable materials as it can cause burns.
- Reduce the light intensity of the cold light source when working near body tissue or flammable materials.

Prepare the endoscope for processing immediately after use to prevent surface

8. Processing

i The recommended method and the processing instructions as well their provision at the usage site are described in reprocessing instructions in this Manual. **They also include notes on the transport to processing.**

9. Assembly

- 1 Connection for ACMI type illumination fibre
- 2 Adapter for Wolf type illumination fibre
- 3 Adapter for Storz / Olympus type illumination fibre
 - If required, mount the appropriate adapter [2, 3] for the illumination fibre.
 - Ensure that the irradiation surface of the illumination fibre [6] is clean.
 - Mount illumination fibre (see manufacturer's specifications).
 - If required, adjust the camera settings (see manufacturer's specifications).

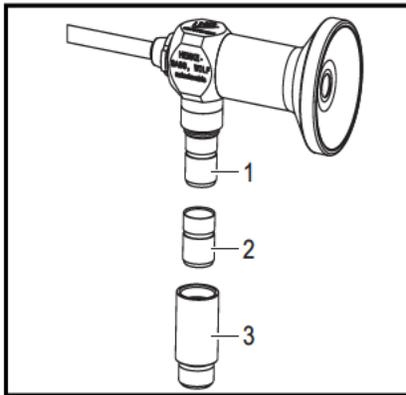


Figure 2-Assembly

10. Disassembly

-  **CAUTION:** Do not remove the ocular funnel [4] or the endoscope will be damaged.



WARNING: Risk of burns!

Prior to removing the illumination fibre, allow sufficient time for it to cool. The ends can get extremely hot and may cause severe burns.

- Remove the illumination fibre.
- Unscrew the adapter [2, 3], if used.

11. Limitations on Reprocessing

- Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use.

- Non-compliance with the manufacturer's specifications can result in damage to the endoscope.
- Do not clean endoscopes with ultrasonic.

12. Storage

As long as endoscopes are stored unsterile in the original packaging, the following storage conditions apply:

- Temperature: -10 to +40 °C
- Humidity: 10-90 %

Additional Storage

Requirements

- Avoid direct sunlight.
- Store endoscope either in the original packaging or in a screen tray/container.
- Ensure that the endoscope is stored securely.
- Apply the respective valid national provisions when storing in a sterile condition.

REPROCESSING

1. Containment & Transportation

It is recommended that endoscopes are reprocessed as soon as is reasonably practical following use. Instrument cases and trays are considered reusable devices. Trays should be inspected for visible soil and must be cleaned prior to use. They can be cleaned manually or in an automatic washer using a detergent.

Always store endoscope securely and transport it to processing in a closed container to prevent damage to the endoscope and contamination of the environment.

2. Cleaning and Disinfection

2.1 Manual cleaning / Pre-cleaning and chemical disinfection



Do not use fixating cleaning agents or hot water (<40 °C) as it can cause fixation of the contaminants and jeopardise successful cleaning.



Do not scratch contaminants off with hard objects as this can cause damage to the optical end surfaces.



Do not clean endoscope in an ultrasonic bath.

- Existing adapters are dismantled (see Instructions for use).
- Remove coarse contamination from the endoscope.
- With a soft brush, clean the endoscope under cold tap water until all visible contamination has been removed.
- Disinfect endoscope. In doing so, observe the specifications of the disinfectant manufacturer regarding temperature, concentration and application time.



Non-compliance with the manufacturer's specifications can result in damage to the endoscope.

- Rinse endoscope with running water.
- Rinse working channel with a water pistol for at least 10 seconds at a pressure of at least 3.8 bar (absolute).
- Dry working channel with compressed air.
- Dry endoscope with a soft cloth.
- Carry out visual inspection, function check and servicing (see Instructions for use).

2.2 Machine cleaning and thermal disinfection

The rigid endoscopes from *Arthrex Inc.* are suitable for prevalent machine methods of cleaning and thermal disinfection. In doing so, use gentle cycles for rigid endoscopes and suitable cleaning agents and disinfectants. The instructions of the machine, cleaning agent and disinfectant manufacturers must be observed. The cleaning and disinfectant result must be confirmed by the machine, cleaning agent and disinfectant manufacturers in cooperation with the user.

The following methods have been validated by *Henke-Sass*,

Wolf for the following rigid endoscopes:

- without working channel

- Fix the endoscopes to the loading rack in such a way that damage is prevented during cleaning.
The following materials and machines were used for the validation:
 - Cleaning agent:
 - Alkaline: Neodisher FA; Dr. Weigert; Hamburg
 - Enzymatic: Endozime, Ruhof
 - Neutraliser:
 - Neodisher Z; Dr. Weigert, Hamburg
 - Cleaning/disinfecting unit:
 - Miele G 7736 CD
 - Loading rack:
 - Loading rack E 327-06
 - MIC rack E 450

- Start cleaning process:
 - Pre-rinse with cold water for 1 minute
 - Drain
 - Pre-rinse with cold water for 3 minutes
 - Drain
 - Clean with 0.5 % alkaline cleaning agent for 5 minutes at 55 °C or with 0.5 % enzymatic cleaning agent at 45 °C

- Drain
- Neutralise for three minutes with warm tap water (<40 °C) and neutraliser
- Drain
- Intermediate rinse for 2 minutes with warm tap water (<40 °C)
- Drain
- Carry out machine thermal disinfection considering the national requirements regarding the A_0 value (see DIN EN ISO 15883).
- Ensure that the exteriors of the endoscope are dry. If necessary, dry with a soft cloth.
- Carry out visual inspection, function check and servicing (see Instructions for use).

2.3 Removing deposits from optical end surfaces

If deposits are detected when checking the image quality, they can be removed with the provided polishing paste as follows:

- i** ➤ Only clean with polishing paste if the image which you see through the endoscope is cloudy and blurry.
- Apply polishing paste to a clean cotton swab.
- For large end surfaces: press cotton swab lightly on the end surface to be cleaned and rub it over the glass.
- For small end surfaces: press cotton swab lightly on the end surface to be cleaned and turn it.

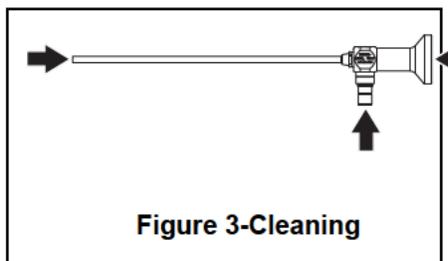


Figure 3-Cleaning

- Clean all optical end surfaces with warm water and mild detergent to remove polishing paste residue.
- Rinse optical end surfaces under running water.
- Dry optical end surfaces with a soft cloth.
- Clean/disinfect and sterilise endoscope if necessary.

Carry out visual inspection. If the deposits were not removed: send in endoscope for repair

3. **Sterilization**

i Prior to each sterilisation, rigid endoscopes must be cleaned and disinfected according to the methods in these cleaning instructions

- Sterilise endoscopes in suitable packaging to prevent subsequent contamination.

3.1 **Steam sterilisation (autoclaving)**

In general, users are responsible for the validation of their processes.

- ! Only endoscopes which are marked with the writing **autoclavable** are intended for autoclaving. The permissible processing methods are explained in the instructions at hand.
 - When selecting the processing method, observe the valid national hygienic regulations and local provisions for hospital hygiene.

- ! ➤ Comply with specified process parameters. The parameters stipulated have been validated to ensure the sterility of the endoscopes. Deviating process parameters could damage the endoscope. In this case, the guarantee and warranty shall become void.

- i Autoclavable endoscopes can be sterilised with the French cycle (134 °C, 18 minutes, 3.1 bar (absolute) without restrictions regarding material compatibility.

Existing adapters are
dismounted (see Instructions
for use).

- Sterilise endoscopes with
one of the following methods:
 - Fractionated pre-vacuum
method.
 - Gravitation method.
- When the sterilisation
process has ended, allow the
endoscopes to cool gradually
to room temperature.

3.2 Fractionated pre-vacuum method

The following process has been validated:

Temperature	132–137 °C (270–278 °F)
Time	at least 3 minutes
Configuration	double packed in sterilisation bags
Drying	at least 10 minutes

3.3 Gravitation method

The following process has been validated:

Temperature	132–137 °C (270–278 °F)
Time	15 minutes
Configuration	double packed in sterilisation bags
Drying	at least 10 minutes

3.4 Hydrogen Peroxide sterilisation (STERRAD® method)

Endoscopes without working channel can be sterilised with the following STERRAD systems:

- STERRAD 100S
 - STERRAD NX
 - STERRAD 100NX
- Observe specifications of the manufacturer (ASP) regarding the corresponding method.

3.5 Ethylene oxide sterilisation

- i** The endoscopes are material compatible with ethylene oxide sterilisation.

**4. Special Precaution:
Transmissible Spongiform
Encephalopathy Agents**

- It is outside the scope of this document to describe in detail the precautions that should be taken for Transmissible Spongiform Encephalopathy Agents.
- The agents for transmission of Creutzfeldt-Jakob disease (CJD) are believed to be resistant to normal processes of disinfection and sterilization and therefore the normal processing methods of decontamination and sterilization as described above may not be appropriate where CJD transmission is a risk.
- In general, the tissues that come into contact with orthopedic surgical instruments are those of low TSE infectivity. However, particular precautions should be taken when handling instruments that have been used on known, suspected, or at-risk patients.

5. Storage and Transport

- Non-sterile metal devices should be stored in a clean, dry environment. The shelf life of non-sterile devices is not limited; the devices are manufactured from non-degradable material, which does not raise any question of device stability when stored under recommended conditions.
- As long as endoscopes are stored unsterile in the original packaging, the following storage conditions apply:
 - Temperature: 14° F to 104° F (-10° C to +40° C)
 - Humidity: 10-90 %
 - Avoid direct sunlight.
 - Store endoscope either in original packaging or in a screen tray/container.
 - Ensure that the endoscope is stored securely.
 - Apply the respective valid national provisions when storing in a sterile condition

6. Storage between Processing

- Verify that the endoscope is disassembled from the illumination fibre and the camera.
- Ensure all adapters, if used, are disassembled from the endoscope.

7. Disposal

- Observe country-specific regulations and laws for the disposal of medical products.

8. Service and Maintenance

Arthrex does not supply original parts to independent workshops or other endoscope manufacturers. Thus only *Arthrex* is in a position to carry out repairs using original parts. The original technical specifications and the operational safety of the endoscope can only be guaranteed by using original parts.

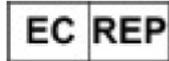
The warranty for *Arthrex* products shall become void if repairs are carried out by an unauthorised workshop. In this case *Arthrex* is also no longer responsible for the technical specifications or safety of the product.

- Have the endoscope repaired by *Arthrex* only. For service, send the defective endoscope to the address of the sales partner.
- Clean, disinfect and sterilise the endoscope thoroughly prior to returning it for repair.
- Ideally, send in the endoscope in its original packaging. If this is not possible, securely package the endoscope for transport.
- *Arthrex* is not liable for damage resulting from improper shipping

9. Accessories/Spare Parts

Designation	Article Number
Polishing paste	Contact your Arthrex Representative
Adapter for illumination fibre, type Wolf	
Adapter for illumination fibre, type Storz / Olympus	

Distributed by:
Arthrex Inc.
Naples, FL 34108, USA
(800) 934-4404
www.arthrex.com



**Arthrex Medizinische
Instrumente GmbH**
Liebigstrasse 13
85757 Karlsfeld-Germany
+49 81 31 59 57 0

K133941/S001

March 4, 2014

Ian Broverman, Reviewer
Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (WO66-G450)
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
MAR 12 2014
Received

**Re: Traditional: 510(k) Notification – K133941 Mitek Arthroscopes
Response to FDA questions**

Dear Mr. Broverman

I hereby submit this amendment response to FDA's comments received on February 20, 2014 regarding the above mention 510(k) premarket notification on behalf of Medos International.

The response includes the following Attachments:

- Attachment A: Revised Indication for Use Form
- Attachment B & B1: Revised 510(k) Summary: redline and clean copy
- Attachment C: Revised SwingScope IFU
- Attachment D: Arthroscopy Accessory IFU
- Attachment E: Literature
- Attachment F: Drawings
- Attachment G: DHF 102351 Memo
- Attachment H: Nelson Lab reports and data
- Attachment I: ASP Memo
- Attachment J: Revised Label

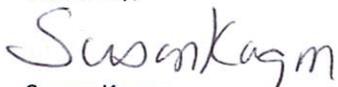
The followings are enclosed in this submission package.

- One Paper Copy
- One CD of eCopy which is an exact duplicate of the paper copy.

Mitek regards this information as confidential and request that FDA not disclose its existence.

If there are any questions during the review of this application, please feel free to contact me at (508) 880-8097 or skagan@its.inj.com.

Sincerely,



Susan Kagan
Project Manager, Regulatory Affairs

25

K133941/8001

medos international

Johnson & Johnson
DANS LE CANTON DE NEUCHÂTEL

March 4, 2014

Ian Broverman, Reviewer
Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (WO66-G450)
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC

MAR 10 2014

Received

**Re: Traditional: 510(k) Notification – K133941 Mitek Arthroscopes
Response to FDA questions**

Dear Mr. Broverman

I hereby submit this amendment response to FDA's comments received on February 20, 2014 regarding the above mention 510(k) premarket notification on behalf of Medos International.

The response includes the following Attachments:

- Attachment A: Revised Indication for Use Form
- Attachment B & B1: Revised 510(k) Summary: redline and clean copy
- Attachment C: Revised SwingScope IFU
- Attachment D: Arthroscope Accessory IFU
- Attachment E: Literature
- Attachment F: Drawings
- Attachment G: DHF 102351 Memo
- Attachment H: Nelson Lab reports and data
- Attachment I: ASP Memo
- Attachment J: Revised Label

This e-mail response will be followed up with one (1) eCopy and (1) paper copy.

Mitek regards this information as confidential and request that FDA not disclose its existence.

If there are any questions during the review of this application, please feel free to contact me at (508) 880-8097 or skagan@its.inj.com.

Sincerely,

Susan Kagan
Project Manager, Regulatory Affairs

39

March 4, 2014

Ian Broverman, Reviewer
Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (WO66-G450)
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

**Re: Traditional: 510(k) Notification – K133941 Mitek Arthroscopes
Response to FDA questions**

Dear Mr. Broverman

I hereby submit this amendment response to FDA's comments received on February 20, 2014 regarding the above mention 510(k) premarket notification on behalf of Medos International.

The response includes the following Attachments:

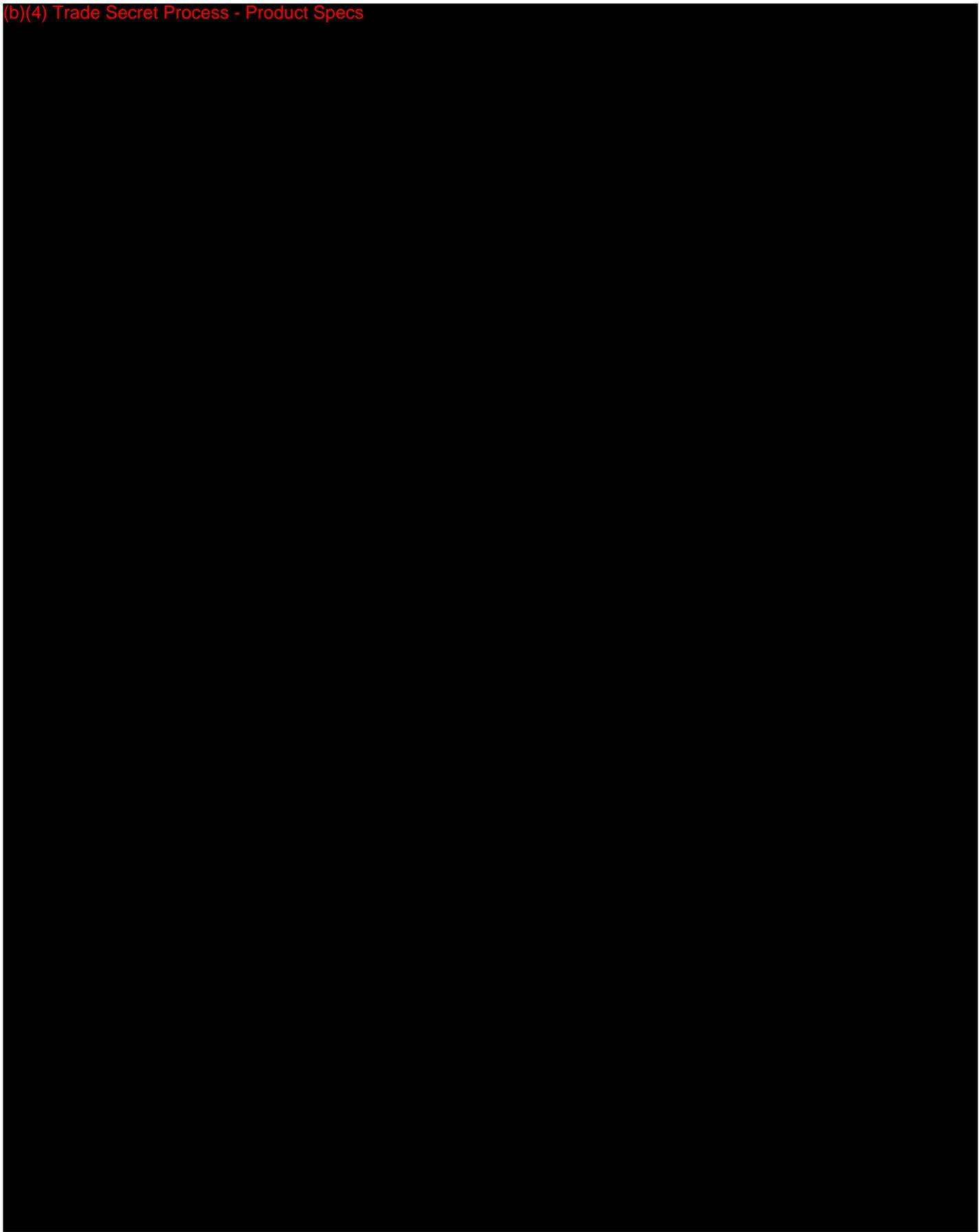
- Attachment A: Revised Indication for Use Form
- Attachment B & B1: Revised 510(k) Summary: redline and clean copy
- Attachment C: Revised SwingScope IFU
- Attachment D: Arthroscope Accessory IFU
- Attachment E: Literature
- Attachment F: Drawings
- Attachment G: DHF 102351 Memo
- Attachment H: Nelson Lab reports and data
- Attachment I: ASP Memo
- Attachment J: Revised Label

This e-mail response will be followed up with one (1) eCopy and (1) paper copy.

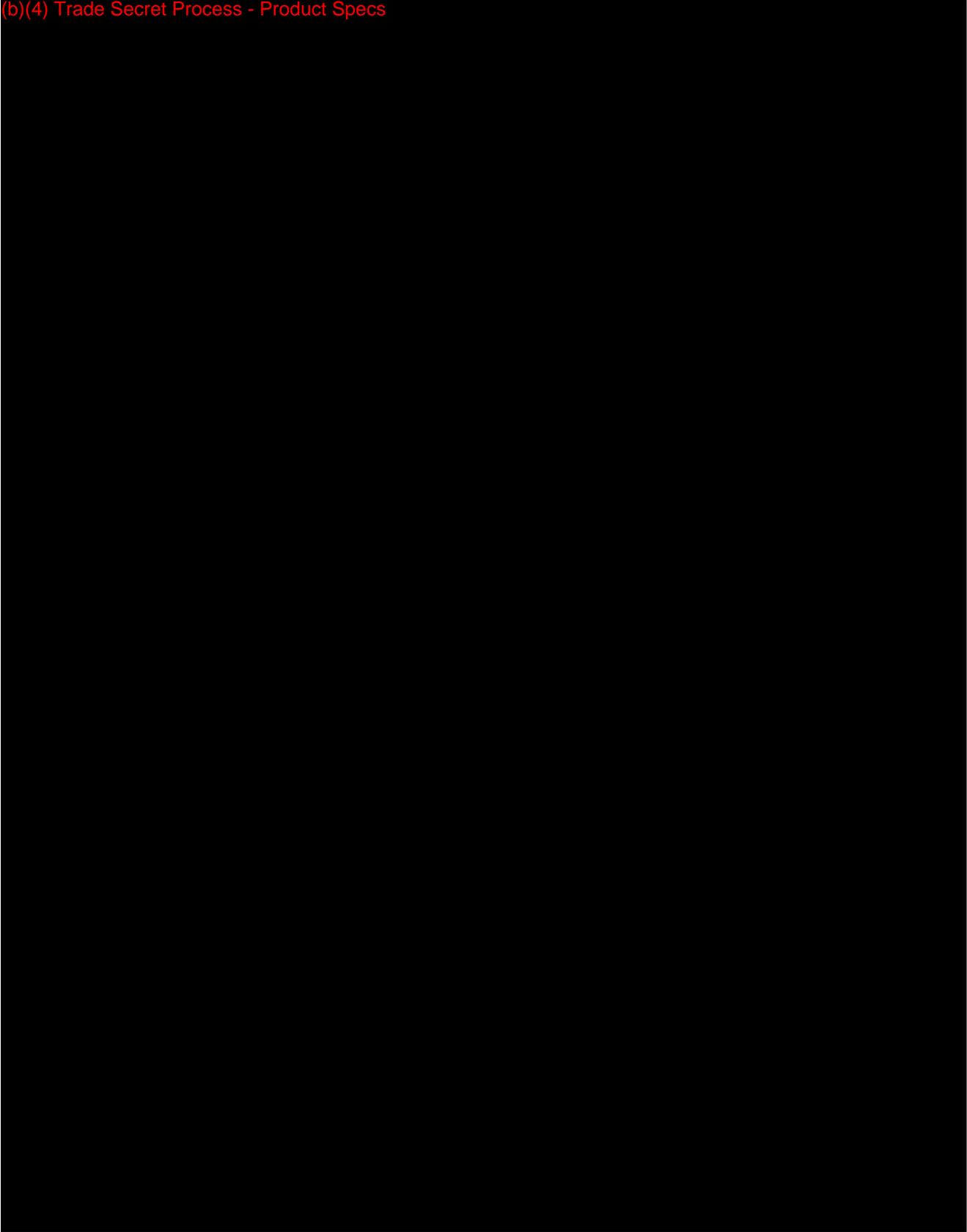
Mitek regards this information as confidential and request that FDA not disclose its existence.
If there are any questions during the review of this application, please feel free to contact me at (508) 880-8097 or skagan@its.jnj.com.

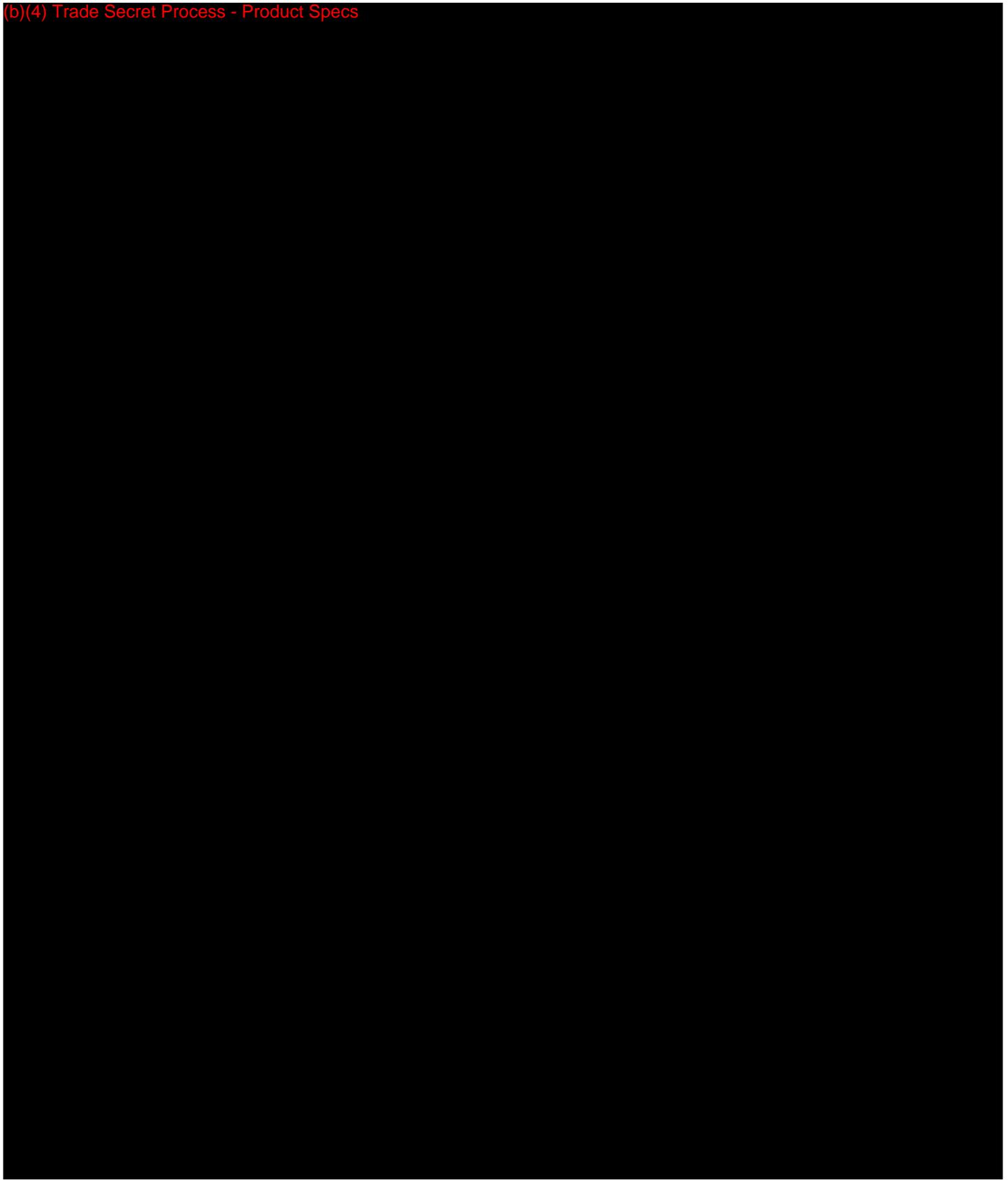
Sincerely,

Susan Kagan
Project Manager, Regulatory Affairs

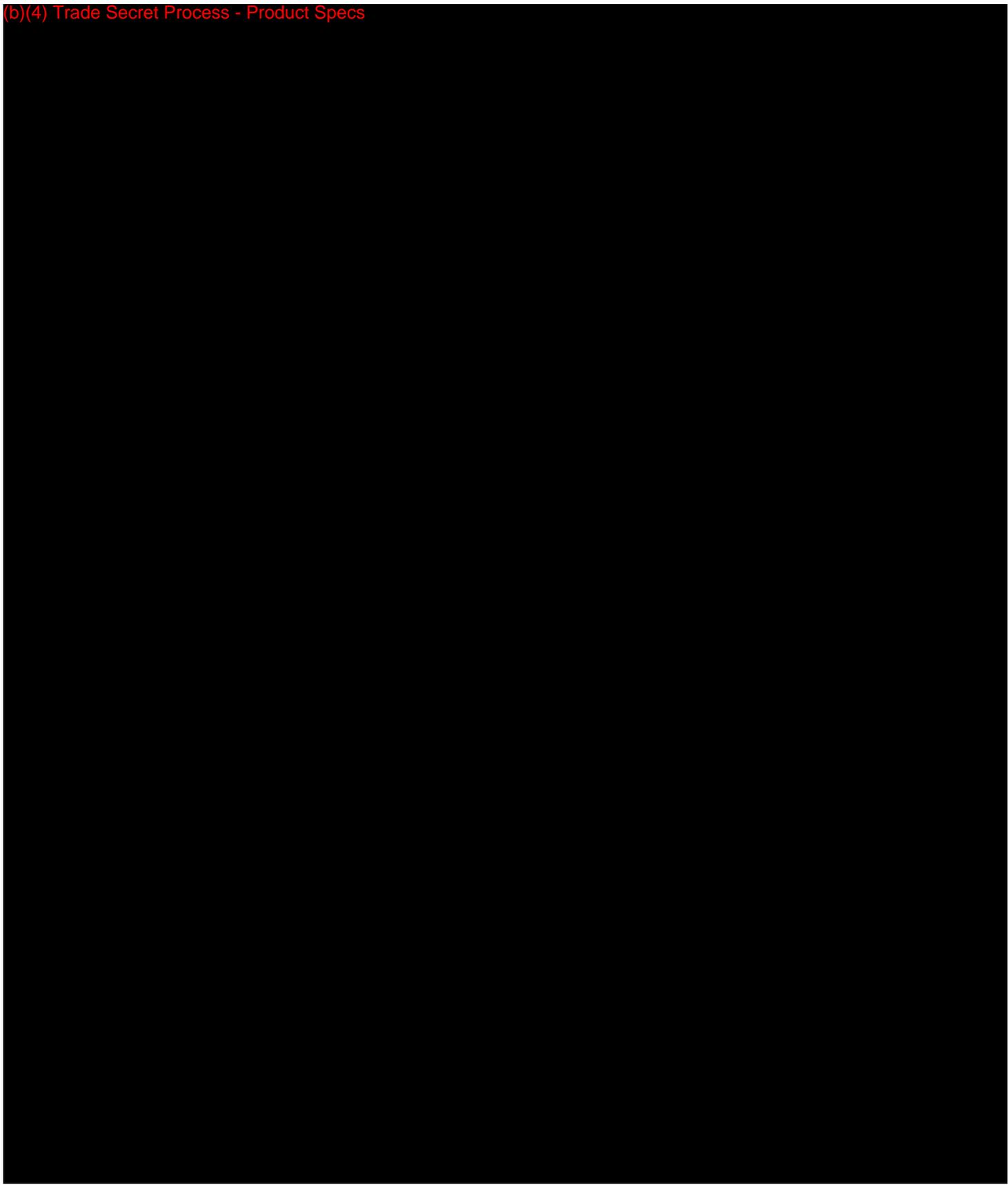


(b)(4) Trade Secret Process - Product Specs

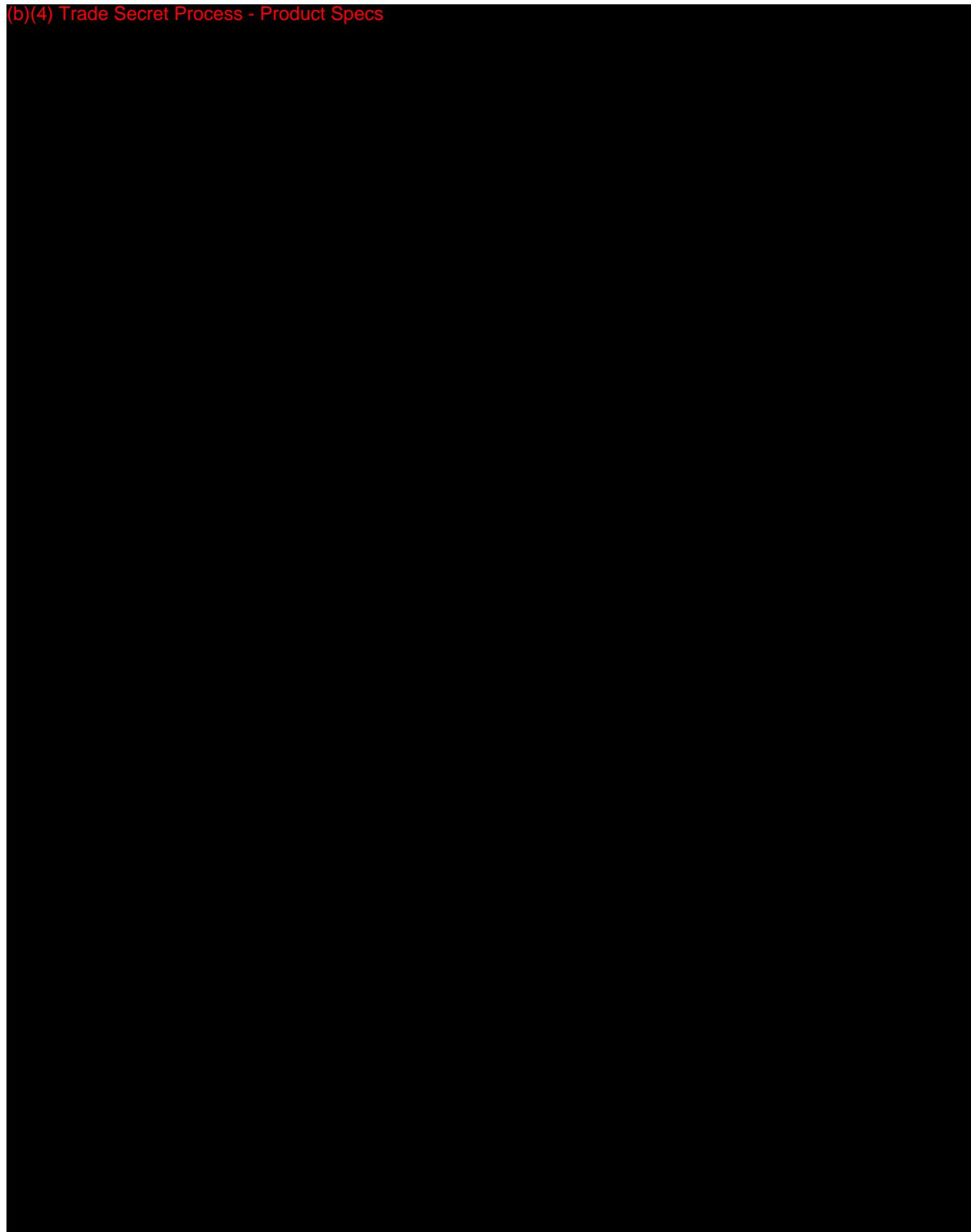




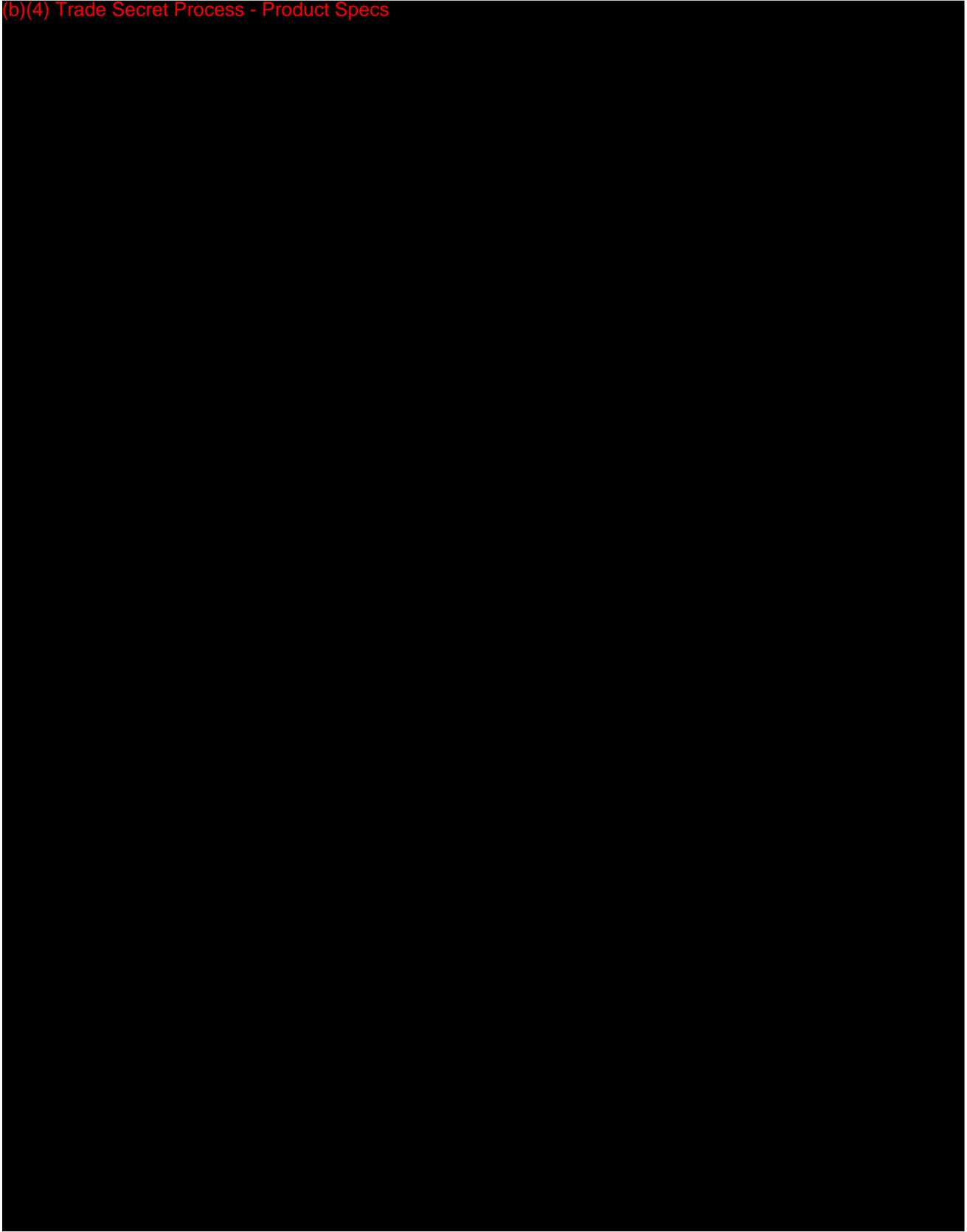
(b)(4) Trade Secret Process - Product Specs



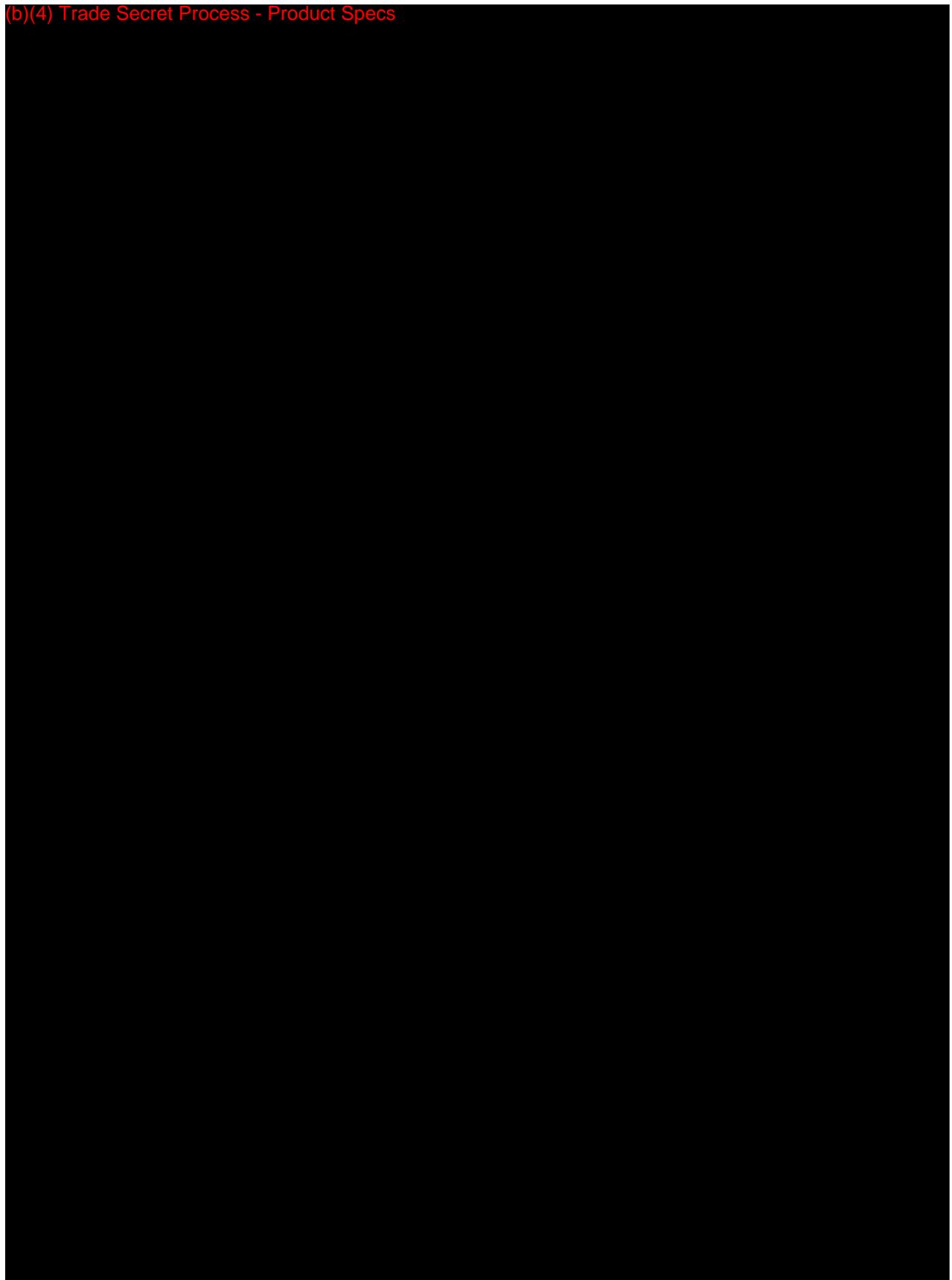
(b)(4) Trade Secret Process - Product Specs

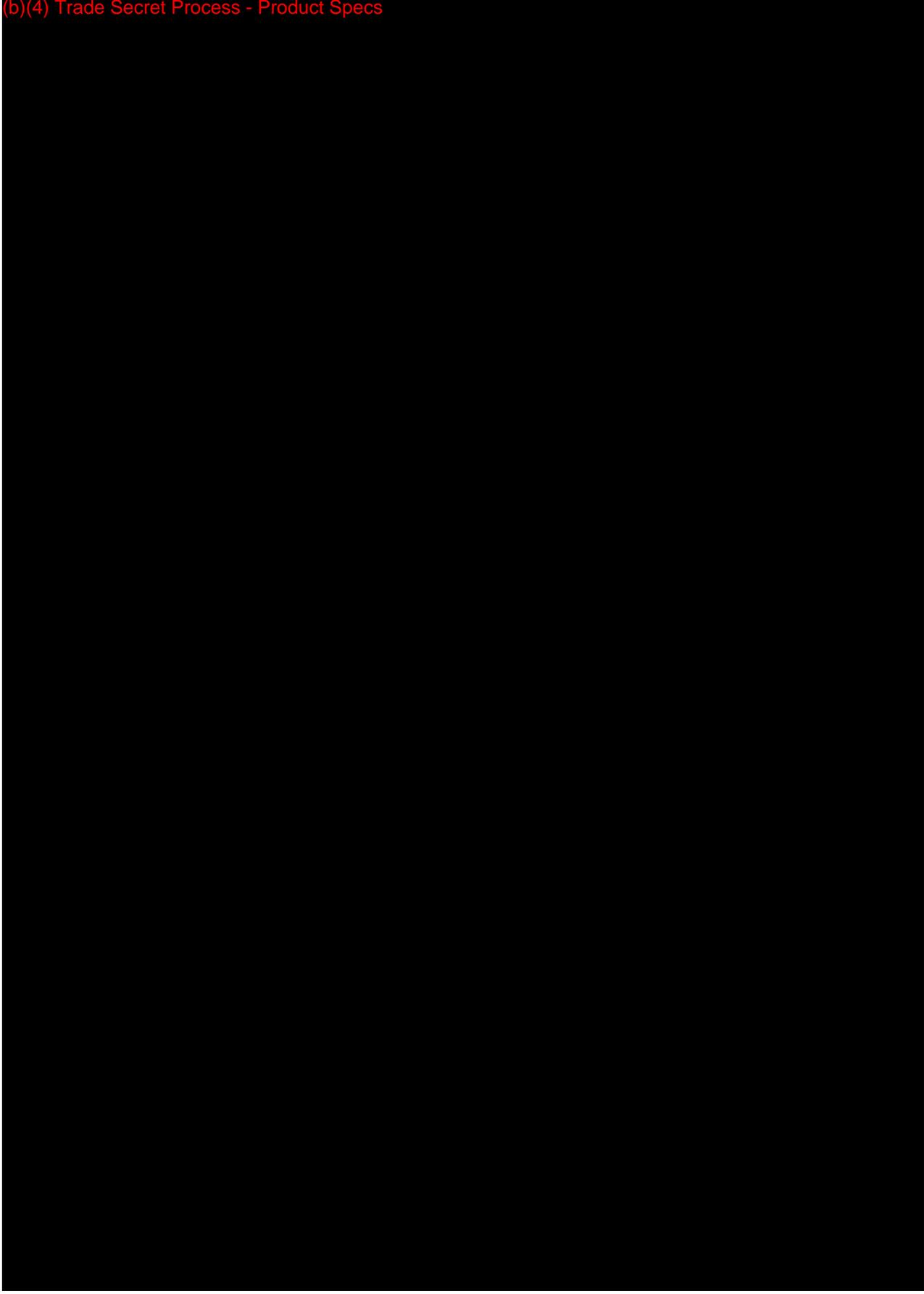


(b)(4) Trade Secret Process - Product Specs

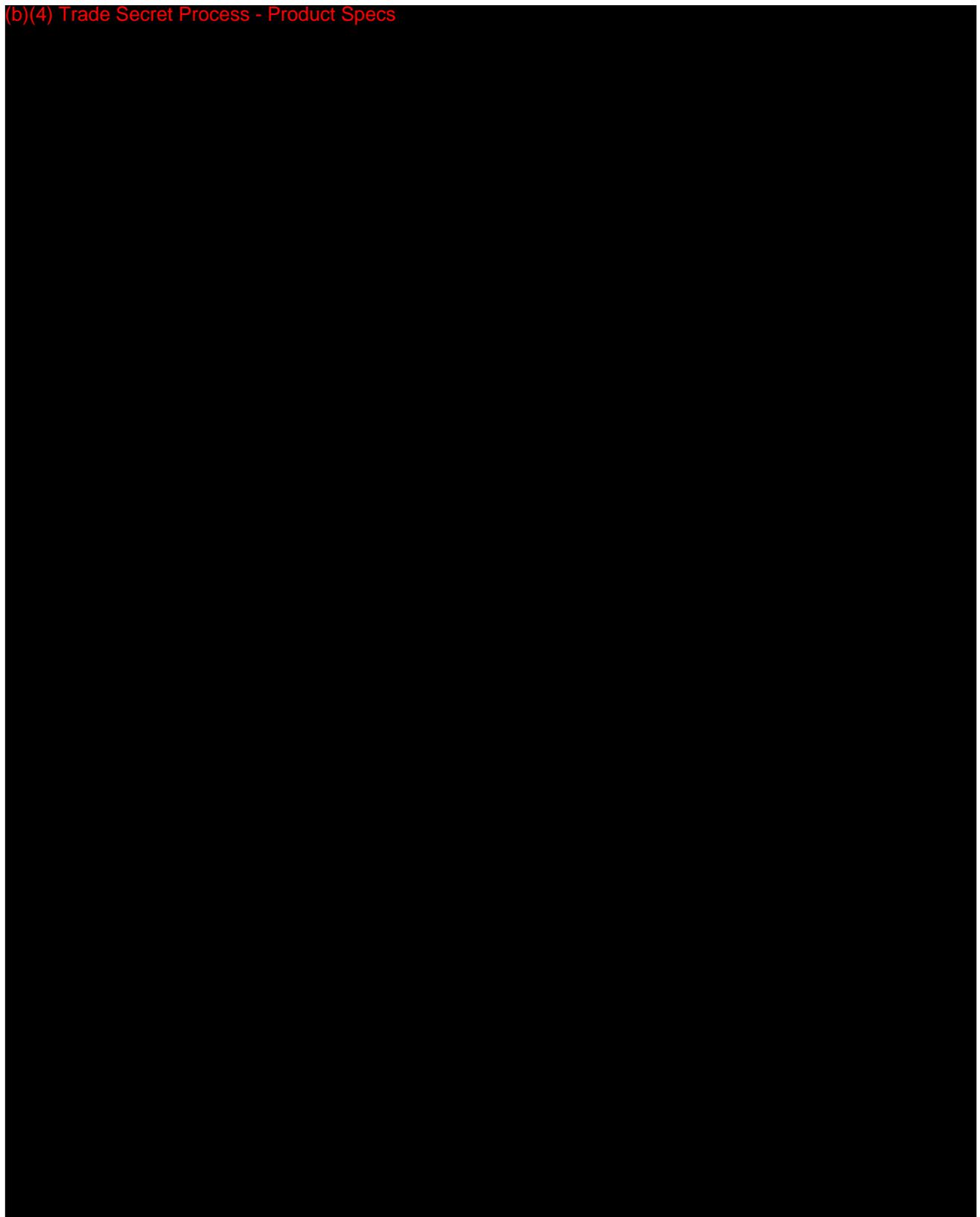


(b)(4) Trade Secret Process - Product Specs

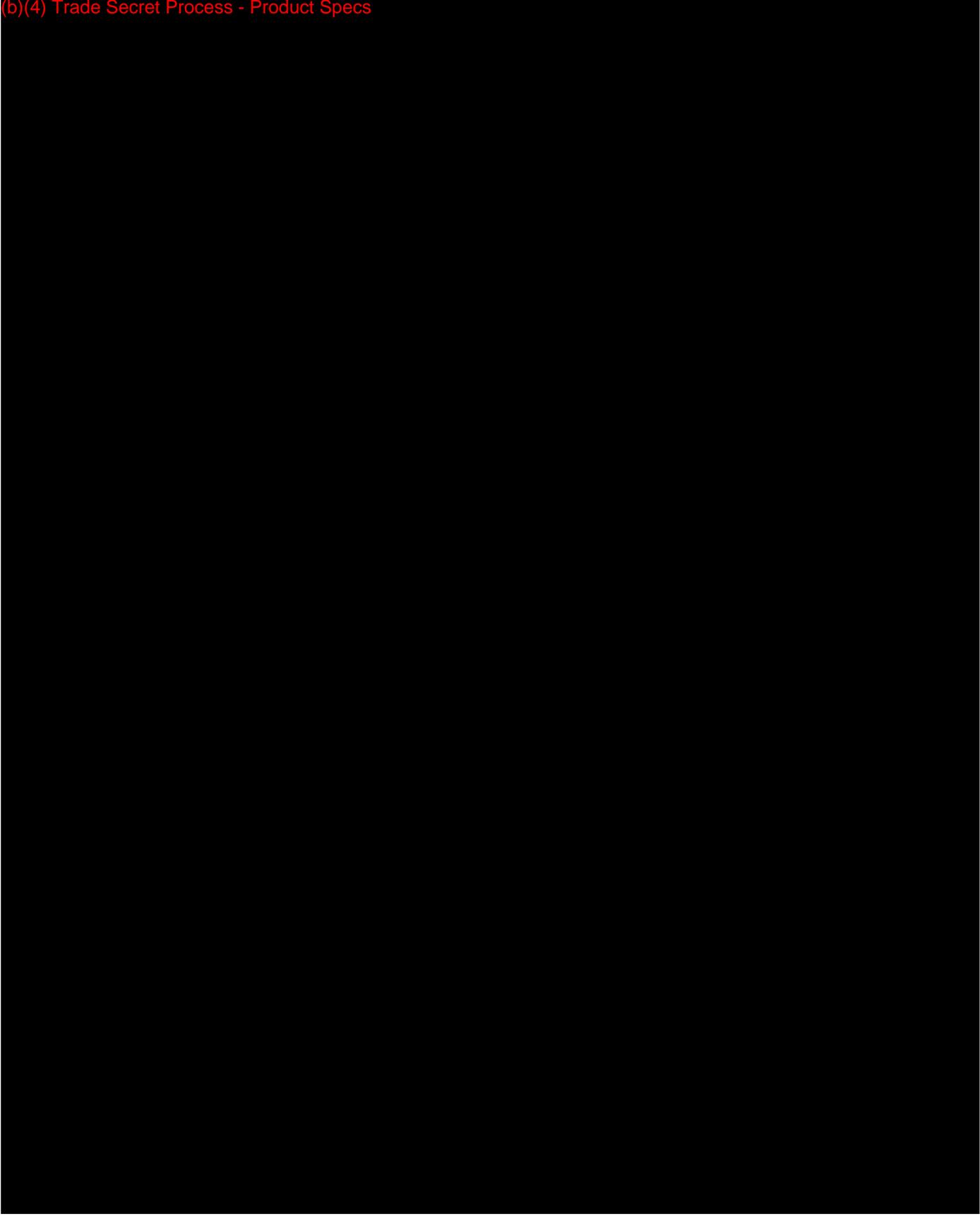




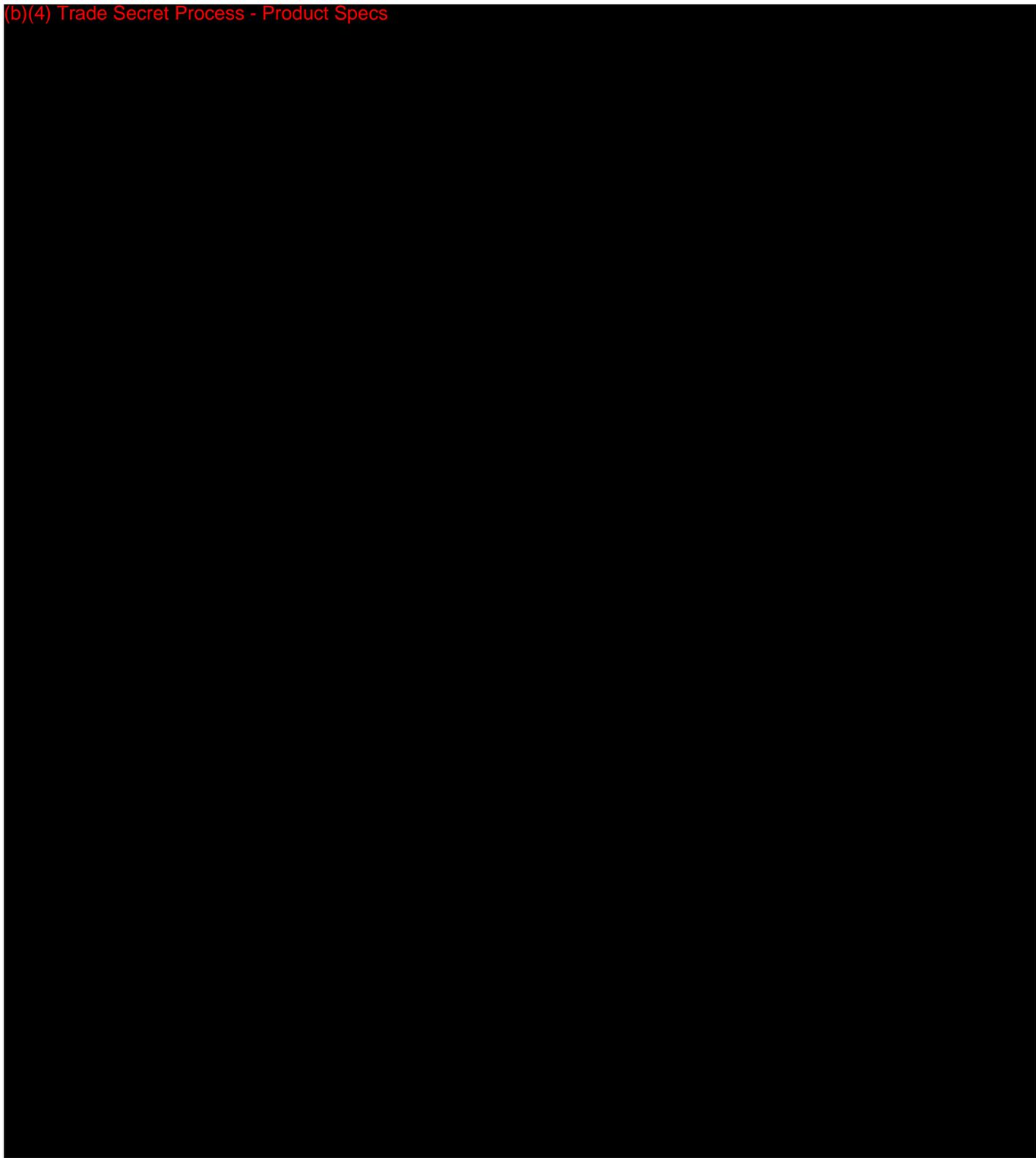
(b)(4) Trade Secret Process - Product Specs



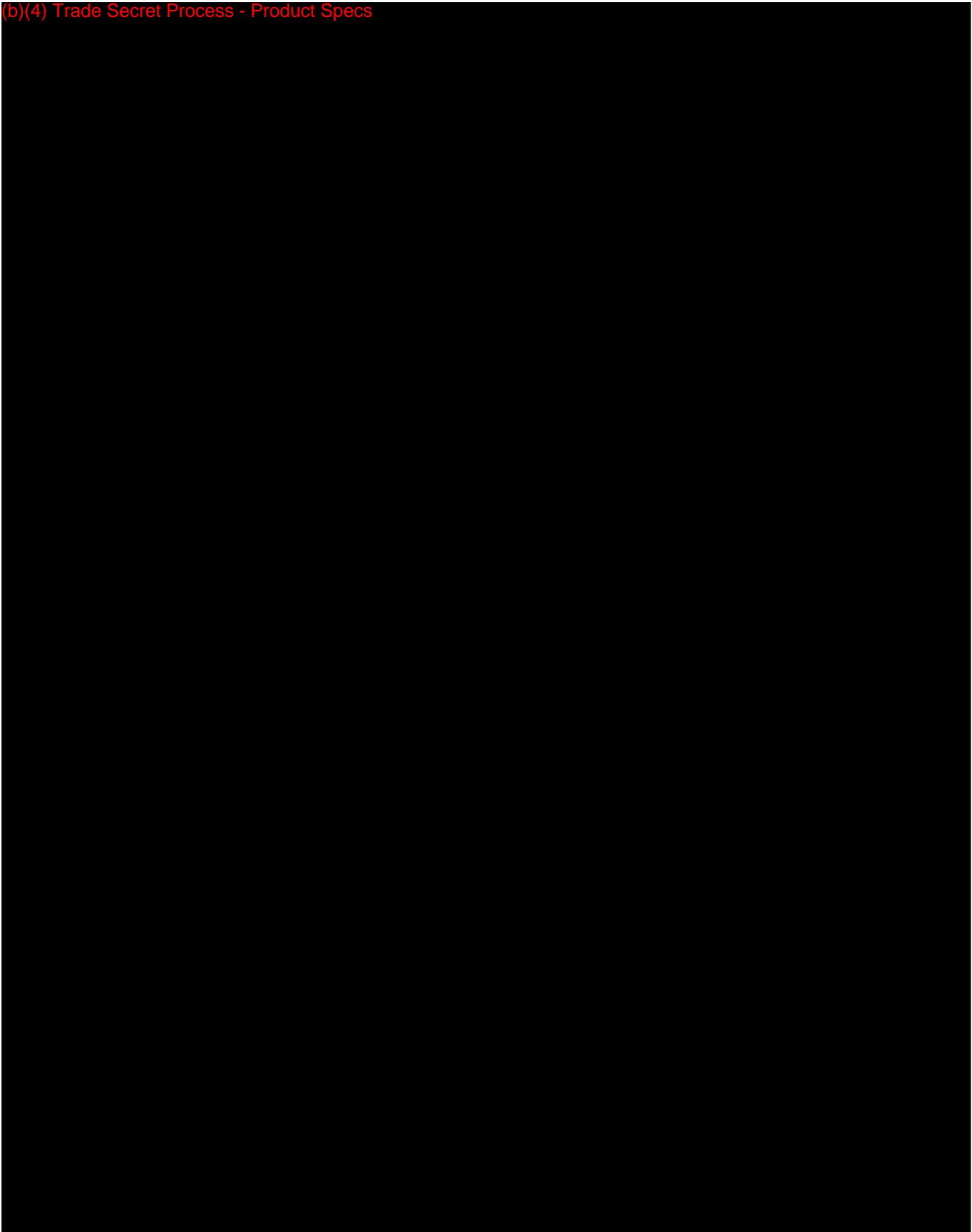
(b)(4) Trade Secret Process - Product Specs

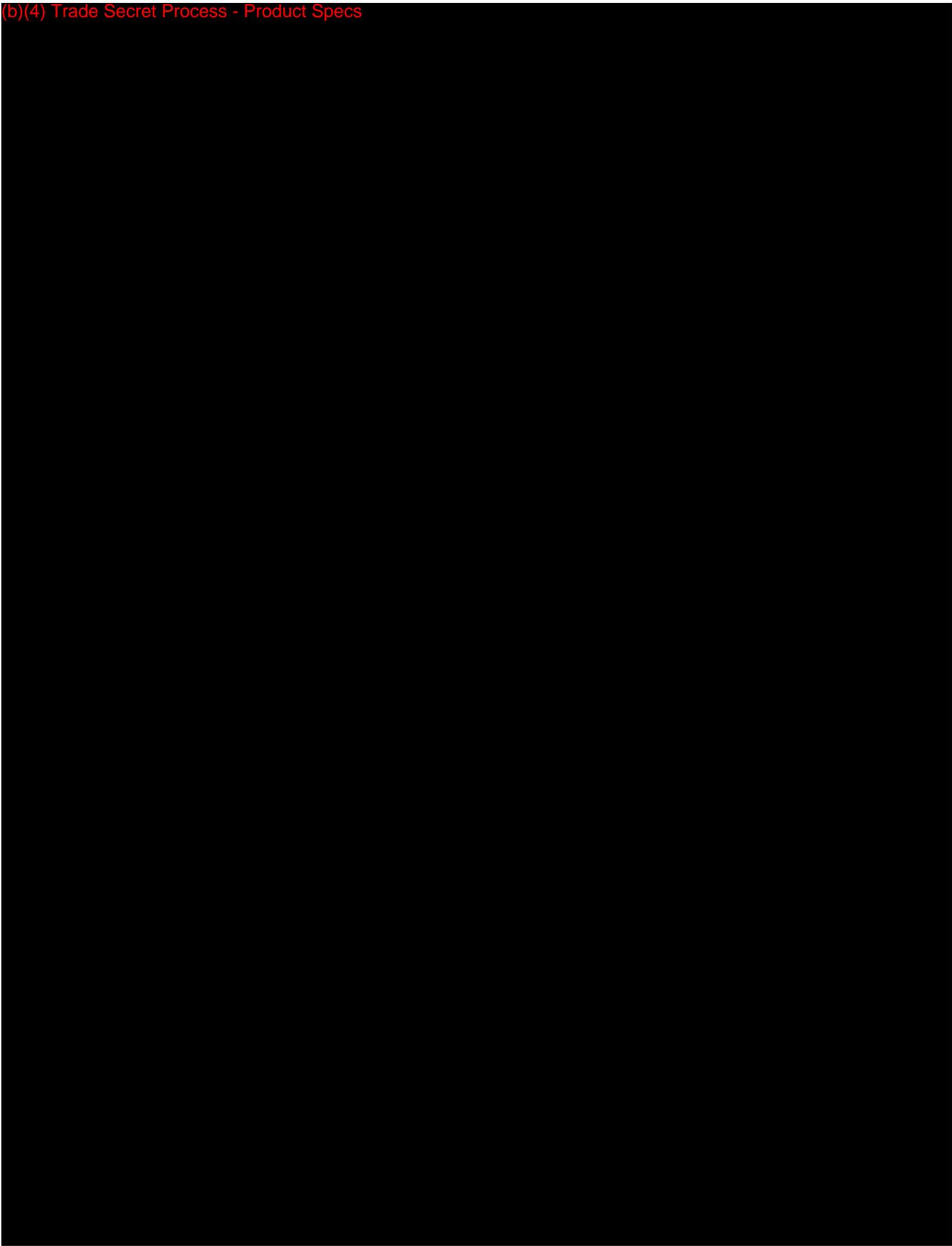


(b)(4) Trade Secret Process - Product Specs

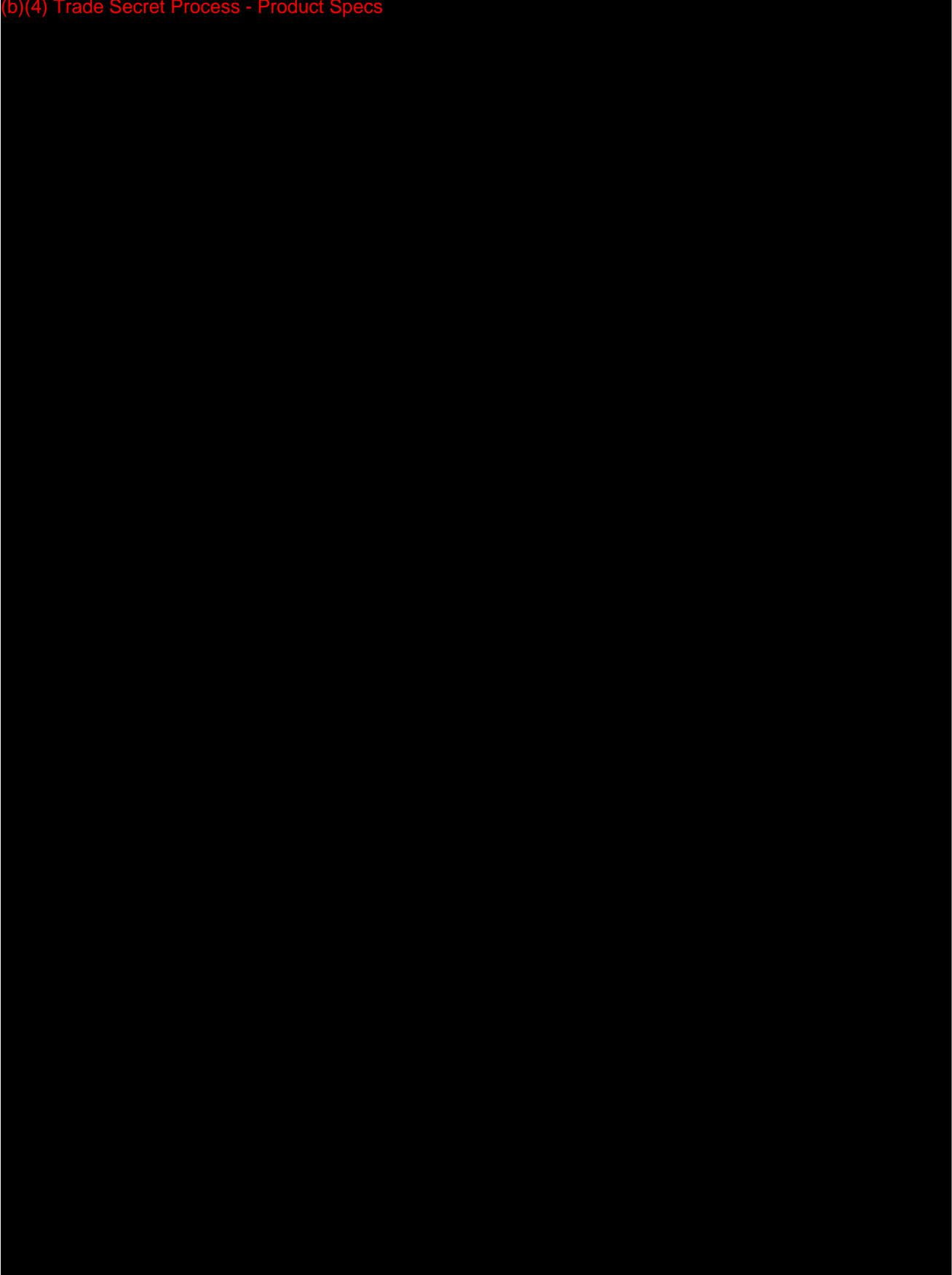


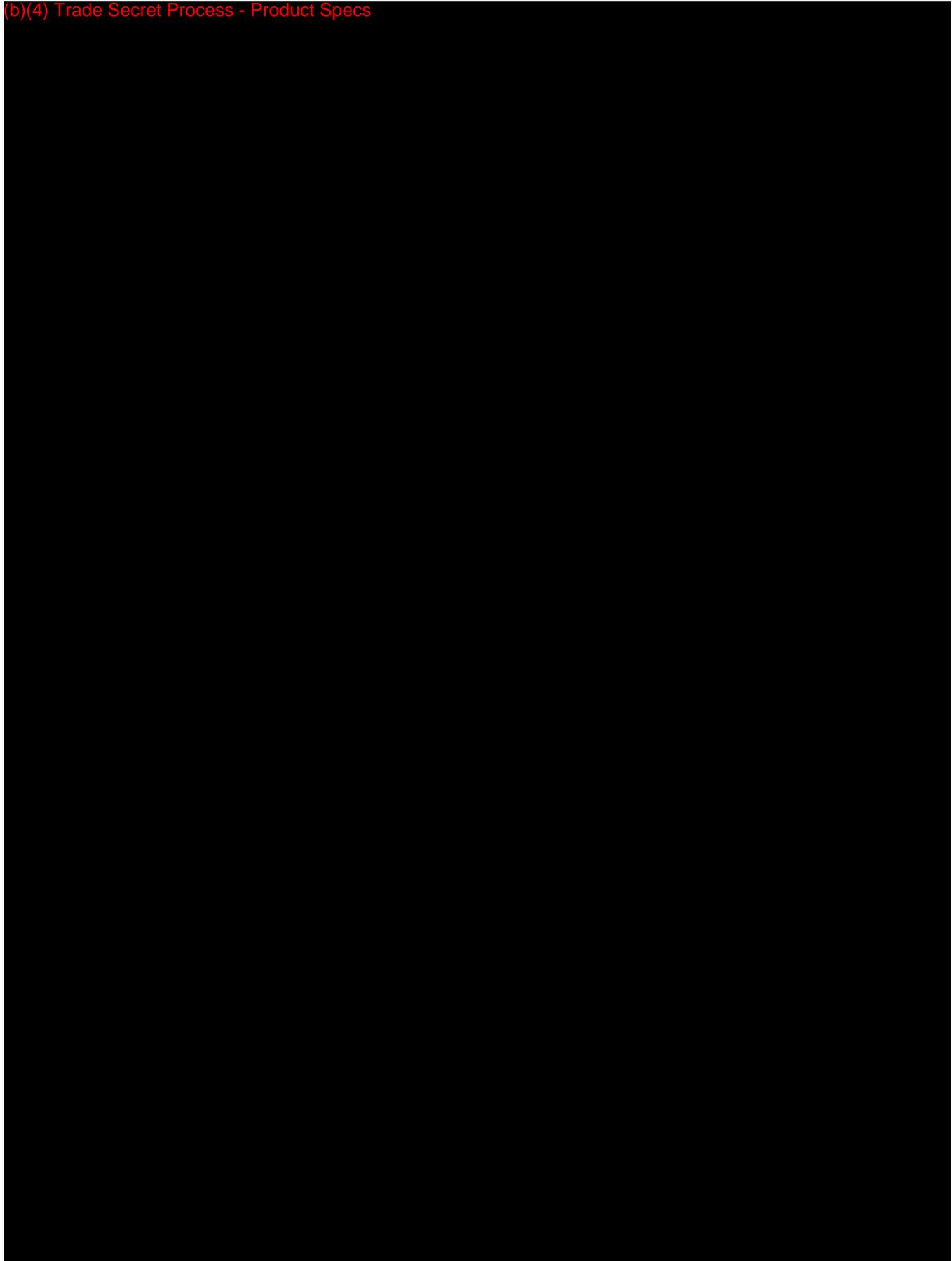
(b)(4) Trade Secret Process - Product Specs



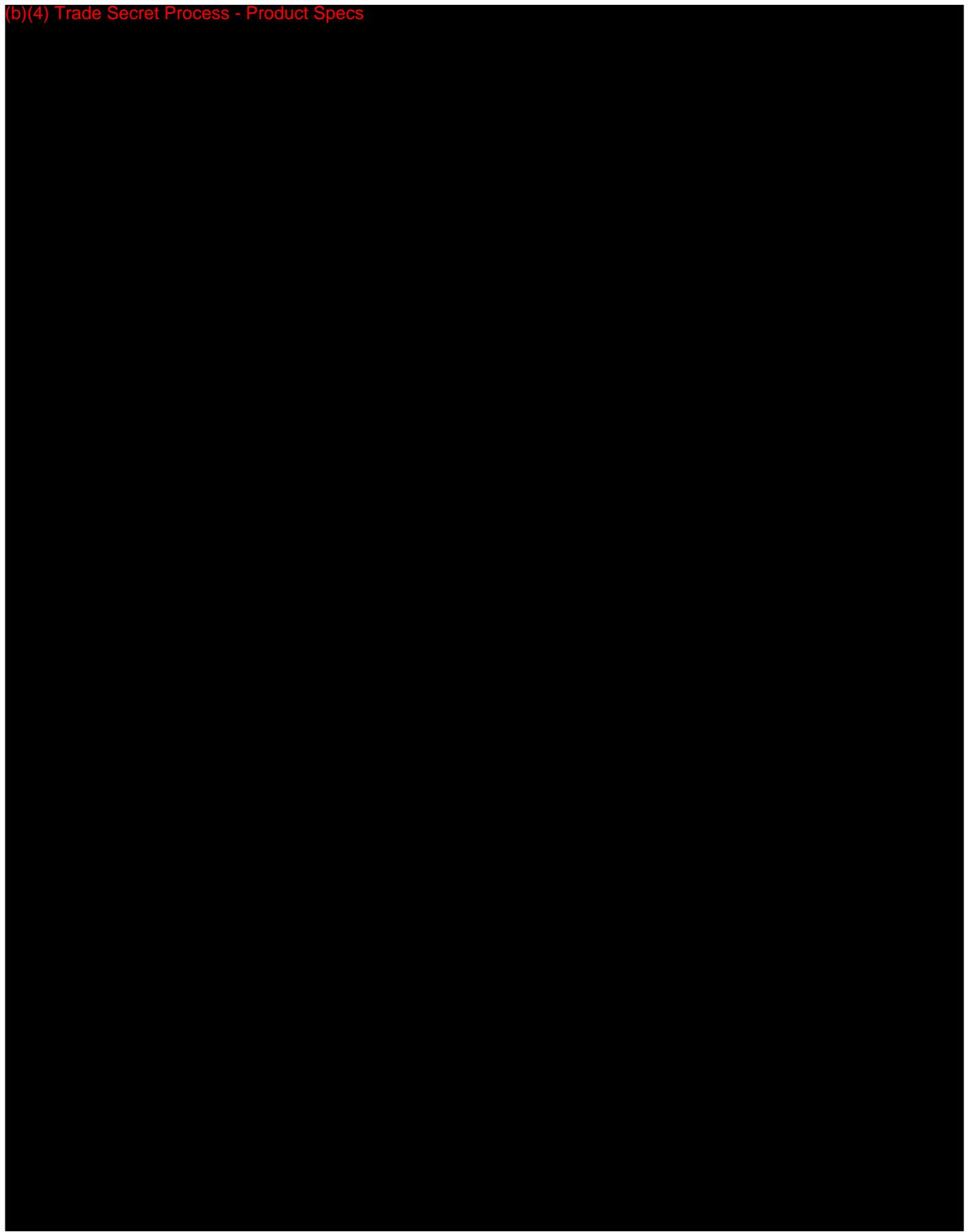


(b)(4) Trade Secret Process - Product Specs

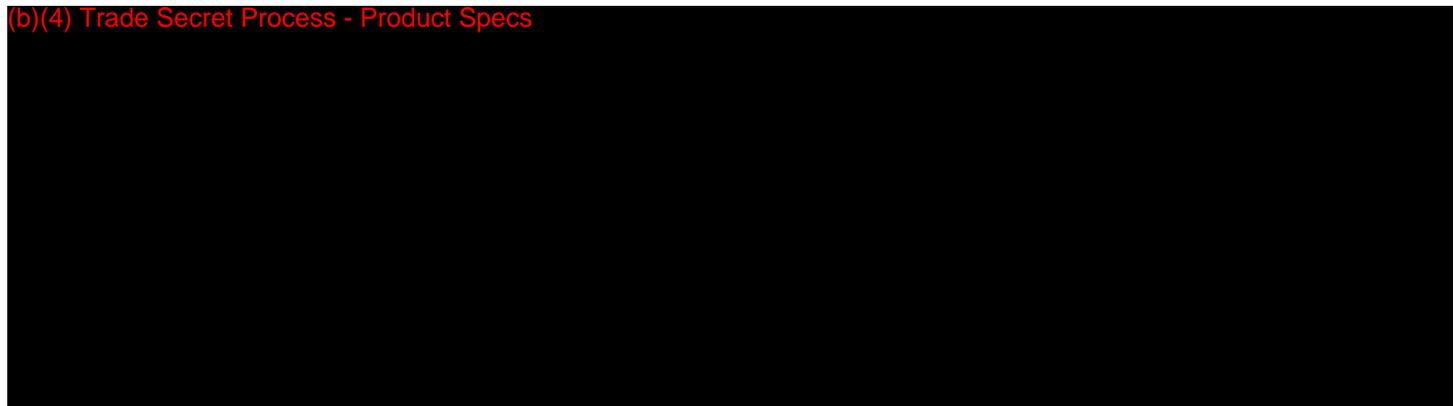




(b)(4) Trade Secret Process - Product Specs



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



Indications for Use

510(k) Number (if known):

Device Name: Mitek Arthroscopes

Indications for Use:

Mitek Sports Medicine Arthroscopes are indicated for use in arthroscopic procedures (such as the knee, shoulder, hip, ankle, elbow) to provide visualization during surgery.

Prescription Use (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY

Mitek Arthroscope

Recognized Medos International SarL

Manufacturer: Puits Godet 20
CH 2000 Neuchâtel
Switzerland

Submitter: DePuy Mitek, Inc.
a Johnson & Johnson company
325 Paramount Drive
Raynham, MA 02767

Contact Person Susan Kagan
Project Manager,
Regulatory Affairs
DePuy Mitek, Inc.
a Johnson & Johnson company
325 Paramount Drive
Raynham, MA 02767, USA

Telephone: 508-880-8097
Facsimile: 508-977-6911
e-mail: SKagan@its.jnj.com

Name of Medical Device Proprietary Name: ~~Mitek Arthroscope~~ SwingScope
Classification Name: Arthroscope
Common Name: Arthroscope

Substantial Equivalence Mitek Arthroscopes are substantially equivalent to the predicate devices listed in Table 1.

Table 1: Predicate Devices

Company	Description	510(k)	Indications
Acclarent	Cyclopes Multiangle Endoscope	K110097	ENT
Acclarent	Cyclopes Multiangle Endoscope	K100577	ENT
Stryker	Stryker Arthroscope	K093677	Arthroscopy
Arthrex	Arthrex Arthroscopes	K030096	Arthroscopy

Device Classification	Classification: FDA Product Code: Regulation:	Class II HRX Arthroscope 21 CFR 888.1100
------------------------------	---	--

Device Description The Mitek Arthroscope is a multi-angle, rigid 4.3 mm arthroscope that has the capability of varying direction of view from 10° to 90° which enables surgeons to maximize and optimize their field of view inside the joint from any given port. This reduces the need for multiple fixed-angle arthroscopes.

The direction of view is altered by the direction of view dial; the direction of view is indicated by markings on the scope body. The Mitek Arthroscope provides a 55° field of view and a depth of field from 5mm to 40mm. The device shaft can also rotate by rotating the device (typically by the light post). A standard eyepiece located on the proximal end of the device is compatible with a standard camera coupler. The light post on the subject device is compatible with an ACMI light source.

There are two light post stainless steel adaptors that accompany the Mitek Arthroscope. Two adapters are provided to facilitate connection with medical light source cables with a diameter of 5.0mm and smaller.

The Mitek Arthroscope is a reusable device and must be cleaned and sterilized according to the user manual prior to every use.

Indications for Use Mitek Sports Medicine Arthroscopes are indicated for use in arthroscopic procedures (such as the knee, shoulder, hip, ankle, elbow) to provide visualization during surgery.

Non-Clinical Testing No clinical studies are required to demonstrate safety and efficacy of the device in support of an application for premarket clearance. The Mitek Arthroscope does not differ from the predicate device in fundamental scientific technology or intended use.

Verification tests of the Mitek Arthroscope included performance, cleaning validation and biocompatibility to show that the device meets its product specifications over a range of operating conditions.

Verification testing conforms to the following Standards and Guidance documents listed in Table 2.

Safety and Performance

Table 2. Standards and Guidance Documents

Standard/ Guidance	Description
EN 60601-18	Medical electrical equipment -- Part 18: Particular Requirements for Basic Safety and Essential performance of endoscopic equipment
ANSI/AAMI/ISO 17665-1	Sterilization of Healthcare Products-Moist Heat-Part 1: Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices
ISO 11135-01	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing
ISO 17664	Sterilization of medical devices. Information to be provided by the manufacturer for the processing of re sterilizable medical device
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
DIN ISO 8600-3:2004	Optics and optical instruments -- Medical endoscopes and endoscopic accessories -- Part 3: Determination of field of view and direction of view of endoscopes with optics

Table 3 provides a summary of testing parameters and results.

Table 3. Summary of Testing

Test	Results
Field of View	Passed
Fixed Focus	Passed
Direction of View Range	Passed
Direction of View Torque	Passed
Rotation of View	Passed
Illumination	Passed
Scope Resolution	Passed
Visual Inspection	
Hermetic sealing	Passed

Free from aberrations

Passed

Results of performance testing have demonstrated that the proposed device is suitable for its intended use.

Based on the indications for use, technological characteristics, and comparison to the predicate devices, the proposed The Mitek Arthroscope has shown to be substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.

510(k) SUMMARY

Mitek Arthroscope

Recognized Medos International SarL

Manufacturer: Puits Godet 20
CH 2000 Neuchâtel
Switzerland

Submitter: DePuy Mitek, Inc.
a Johnson & Johnson company
325 Paramount Drive
Raynham, MA 02767

Contact Person Susan Kagan
Project Manager,
Regulatory Affairs
DePuy Mitek, Inc.
a Johnson & Johnson company
325 Paramount Drive
Raynham, MA 02767, USA

Telephone: 508-880-8097
Facsimile: 508-977-6911
e-mail: SKagan@its.jnj.com

Name of Medical Device Proprietary Name: SwingScope
Classification Name: Arthroscope
Common Name: Arthroscope

Substantial Equivalence Mitek Arthroscopes are substantially equivalent to the predicate devices listed in Table1.

Table 1: Predicate Devices

Company	Description	510(k)
Acclarent	Cyclops Multiangle Endoscope	K110097
Acclarent	Cyclops Multiangle Endoscope	K100577
Stryker	Stryker Arthroscope	K093677
Arthrex	Arthrex Arthroscopes	K030096

Device Classification	Classification: FDA Product Code: Regulation:	Class II HRX Arthroscope 21 CFR 888.1100
------------------------------	---	--

Device Description

The Mitek Arthroscope is a multi-angle, rigid 4.3 mm arthroscope that has the capability of varying direction of view from 10° to 90° which enables surgeons to maximize and optimize their field of view inside the joint from any given port. This reduces the need for multiple fixed-angle arthroscopes.

The direction of view is altered by the direction of view dial; the direction of view is indicated by markings on the scope body. The Mitek Arthroscope provides a 55° field of view and a depth of field from 5mm to 40mm. The device shaft can also rotate by rotating the device (typically by the light post). A standard eyepiece located on the proximal end of the device is compatible with a standard camera coupler. The light post on the subject device is compatible with an ACMI light source.

There are two light post stainless steel adaptors that accompany the Mitek Arthroscope. Two adapters are provided to facilitate connection with medical light source cables with a diameter of 5.0mm and smaller.

The Mitek Arthroscope is a reusable device and must be cleaned and sterilized according to the user manual prior to every use.

Indications for Use

Mitek Sports Medicine Arthroscopes are indicated for use in arthroscopic procedures (such as the knee, shoulder, hip, ankle, elbow) to provide visualization during surgery.

Non-Clinical Testing

No clinical studies are required to demonstrate safety and efficacy of the device in support of an application for premarket clearance. The Mitek Arthroscope does not differ from the predicate device in fundamental scientific technology or intended use.

Verification tests of the Mitek Arthroscope included performance, cleaning validation and biocompatibility to show that the device meets its product specifications over a range of operating conditions.

Verification testing conforms to the following Standards and Guidance documents listed in Table 2.

Safety and Performance

Table 2. Standards and Guidance Documents

Standard/ Guidance	Description
EN 60601-18	Medical electrical equipment -- Part 18: Particular Requirements for Basic Safety and Essential performance of endoscopic equipment
ANSI/AAMI/ISO 17665-1	Sterilization of Healthcare Products-Moist Heat-Part 1: Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices
ISO 11135-01	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing
ISO 17664	Sterilization of medical devices. Information to be provided by the manufacturer for the processing of re sterilizable medical device
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
DIN ISO 8600-3:2004	Optics and optical instruments -- Medical endoscopes and endoscopic accessories -- Part 3: Determination of field of view and direction of view of endoscopes with optics

Table 3 provides a summary of testing parameters and results.

Table 3. Summary of Testing

Test	Results
Field of View	Passed
Fixed Focus	Passed
Direction of View Range	Passed
Direction of View Torque	Passed
Rotation of View	Passed
Illumination	Passed
Scope Resolution	Passed
Visual Inspection	
Hermetic sealing	Passed

Free from aberrations

Passed

Results of performance testing have demonstrated that the proposed device is suitable for its intended use.

Based on the indications for use, technological characteristics, and comparison to the predicate devices, the proposed The Mitek Arthroscope has shown to be substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.



DePuy Synthes

MITEK SPORTS MEDICINE

COMPANIES OF *Johnson & Johnson*

**SwingScope™
Multi-Angle Arthroscope
and
SwingScope™ Light Guide Cable Adapters**

CE0086

- 288000 SWINGSCOPE™ Arthroscope
- 288008 Lightpost Adapter 22mm x 12mm
- 288009 Lightpost Adapter 12mm x 9mm

READ ALL INSTRUCTIONS CAREFULLY

P/N: 111716

Rev: A Issued 10/2013

©DePuy Synthes Mitek Sports Medicine
a division of DOI 2013. All rights reserved.

SWINGSCOPE™ MULTI-ANGLE ARTHROSCOPE AND LIGHT GUIDE CABLE ADAPTERS



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

DESCRIPTION

The SwingScope™ Multi-angle arthroscope (“arthroscope”) has the following features:

- Working Length: 205mm
- Shaft Diameter: 4.3mm
- Angle of View: between 10° and 90°
- Two detachable Light Post Adapters are provided (sizes 12mm x 9mm and 22mm x 12mm)
- The Eyepiece of the endoscope is compatible with C-mount camera couplers.

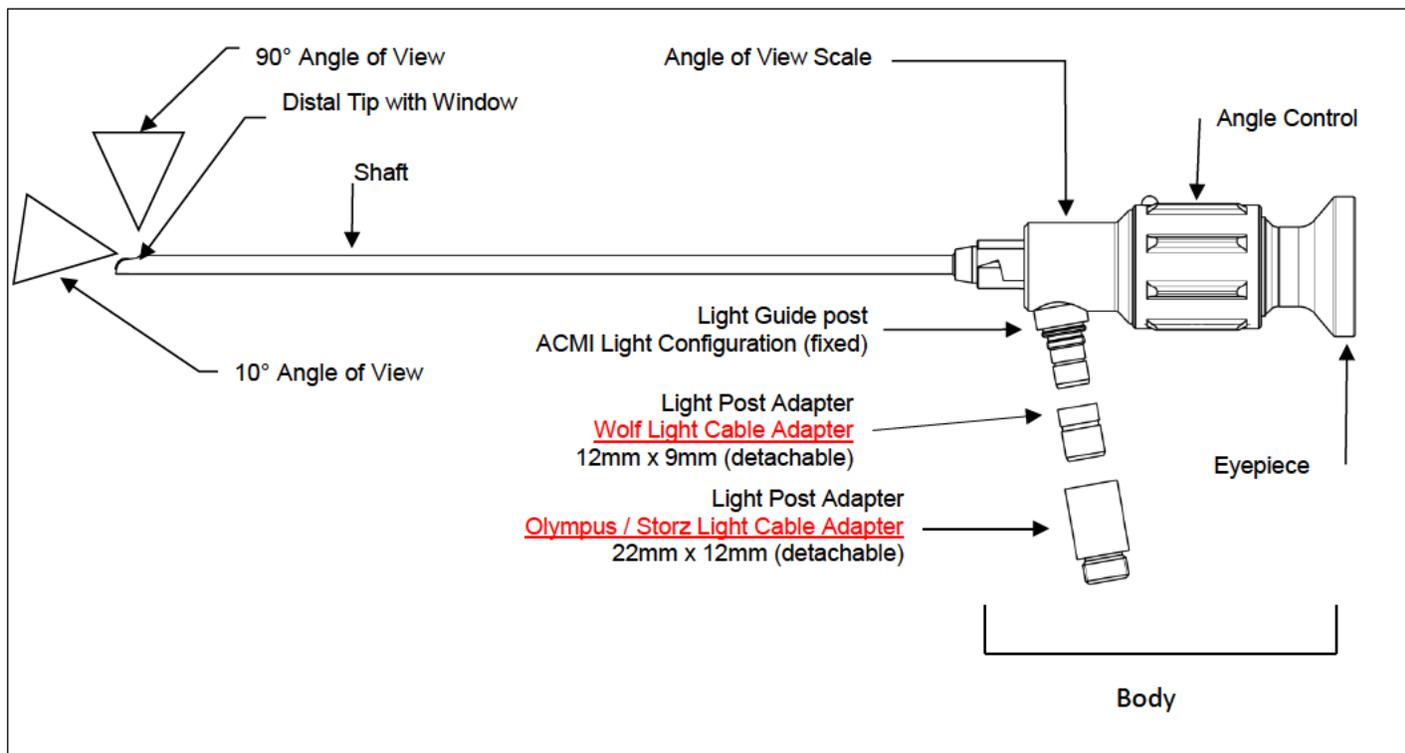


Figure 1. SwingScope™ Multi-Angle Arthroscope

INDICATIONS FOR USE

Mitek Sports Medicine arthroscopes are indicated for use in arthroscopic procedures- (such as shoulder, hip, knee, elbow, ankle) to provide visualization during surgery.

COMPATIBILITY

The arthroscope B-cup eyepiece is compatible with cameras or universal C-mount camera couplers. Use only light cables with a diameter of 5.0mm and smaller to prevent overheating of the distal tip. Use the arthroscope with Xenon or LED (up to 300W or equivalent) light sources.

INTENDED USE

Arthroscopes are intended for use by personnel trained in arthroscopy in a surgical setting.

CONTRAINDICATIONS

- Do not use the arthroscope on patients who have active implanted devices that would be affected by a magnetic field (e.g. pacemaker, implantable cardioverter-defibrillator, cochlear implant and deep brain stimulator) because the arthroscope contains small rare-earth permanent magnets.
- Do not use the arthroscope on patients with inferior vena cava filters that were implanted within the previous two weeks.



WARNINGS

- **Arthroscope may become hot.** Use care when handling and do not rest the scope directly on a patient or flammable material. The connection between the arthroscope and the light source can become very hot.
- To avoid burn injury during surgery, do not place the tip of the arthroscope on the patient or surgical drape.
- To avoid burns to the patient or user, do not use light cables with a diameter greater than 5.0mm. When operated at maximum brightness, surface temperature may exceed 41°C. A 3.5mm fiber optic light cable is recommended. Always adjust the light source to the minimum light output necessary to illuminate the endoscopic image.
- **NON-STERILE:** The arthroscope is provided NON-STERILE, and must be cleaned and sterilized prior to its first use, before each subsequent use, and after returning from repairs. Use instructions below for cleaning and sterilization.
- Do not use the arthroscope if you are unable to clean and sterilize according to the validated procedures contained in these instructions.
- Do not use a damaged or defective arthroscope. Inspect the arthroscope prior to each examination or procedure and before sterilization based on the instructions below.
- Turn off the light source and allow the arthroscope to cool for at least two (2) minutes prior to disconnecting the fiber optic cable or allowing the staff to handle the arthroscope.

- Do not use the arthroscope with Xenon light sources greater than 300W.
- Discard the arthroscope after surgery in patients with Creutzfeldt Jakob Disease (CJD), or suspected possible variants of CJD. Dispose according to hospital procedures.
- These Instructions for Use facilitate arthroscope use, and are not instructions for performing arthroscopic procedures.
- Do not attempt to modify the arthroscope. Modifying the device in a manner other than specified by in this document may result in injury. In the US, contact Customer Service at 1-800-382-4682 for service requests. In the European Union, contact your local affiliate.



PRECAUTIONS

- Do not bend the arthroscope.
- Do not hold the arthroscope by its shaft; this may cause damage.
- The arthroscope provides multiple angles of view; use caution when advancing the scope.
- Do not accelerate cooling; this may damage the arthroscope.
- To maintain optical quality, do not clean the arthroscope or light cable adapters in an ultrasonic bath.
- Cleaning and sterilization is guaranteed only if the arthroscope is cleaned and sterilized according to properly validated methods. This IFU provides minimum cleaning and sterilization procedures. It is the user's responsibility to qualify any deviations from the recommended procedures.
- Perform the cleaning and sterilization steps each time the arthroscope and light cable adapters are used.

INSPECTION, TESTING, AND MAINTENANCE

1. Remove and discard the protection caps from the distal tip, eyepiece and light guide post immediately upon receipt. Inspect the arthroscope immediately upon receipt, and before and after every procedure.
2. Inspect the distal window and eyepiece for scratches, chips, fingerprints or residual debris by observing reflected light on the surfaces of the distal window and eyepiece.
3. Examine the lumen through the eyepiece for condensation to make sure that the endoscope is free of internal moisture.
4. Examine the light guide post for damage.
5. **Test the image quality.** Look through the eyepiece. The image should be clear and distinct. If the distal window, eyepiece lens and light guide post surface are cloudy, dirty or scratched, or if the shaft is bent, scratched, dented, corroded, pitted or exhibits other surface irregularities, the image may not be clear. If the image is unclear, do not use the arthroscope. Send for repair or remove from service.

6. **Check light transmission.** Apply a light source to the distal tip with window of the arthroscope (shown in Figure 1). Inspect the light transmitting surface of the light guide post (or through the adaptor as shown in Figure 1). Uneven illumination indicates that glass light fibers are broken. Individual broken fibers do not necessarily result in a noticeable reduction in image quality; however, do not use the arthroscope if approximately 25% of the transmitting surface of the light guide post is illuminating unevenly. Send for repair or remove from service.
7. **Test the controls.** Rotate the angle control and shaft controls while looking through the eyepiece. Ensure that the image changes appropriately. The arthroscope requires no lubrication to maintain proper function. If the image does not change appropriately, do not use the arthroscope.

Report damage immediately to a Sales Consultants or call Customer Service in the USA at +1-800-382-4682. Save all packing materials to use in the event you must return product(s) to Mitek Sports Medicine. Outside the United States, contact your local affiliate.

INSTRUCTIONS FOR USE

Assembly at Point of Use

Refer to Figure 1.

1. Connect the camera coupler to the eyepiece. The standard B-cup eyepiece is compatible with cameras or C-mount camera couplers.
2. Connect the light cable adapter. Slide the adapter over the light guide post (align the screw threads) and tighten in place.



CAUTION: Use only light cables with a diameter of 5.0mm and smaller to prevent overheating of the distal tip.

- **NOTE:** Observe the manufacturer's instructions for use when using the arthroscope with other implements, instruments or optical cables.
- **NOTE:** Do not allow the distal window, eyepiece lens or light guide post surface to contact abrasive surfaces.



CAUTION: Handle the arthroscope with care. Hard impacts, particularly to the distal end, may cause damage or cracks.

SwingScope Functions

Changing the Angle of View. To change the arthroscope angle of view, rotate **the Angle Control** (shown in Figure 1). The angle indicator on the Angle Control aligns with the set of reference markings on the body of the arthroscope and displays the approximate angle of view selected by the user.

Note: When the angle control is set to greater than 70°, the illumination provided by the SwingScope arthroscope becomes less intense.

Disconnecting the Arthroscope

To disconnect the arthroscope, hold the device by the body and unscrew light cable. Clean and sterilize according to the following procedure.

CLEANING AND STERILIZATION

General Considerations for Arthroscope Processing

- Observe point of use and transport procedures as described below.
- Complete each procedure: Preparation for Cleaning, Manual Cleaning or Automated Cleaning and Sterilization when reprocessing the arthroscope and light cable adapters.
- Personnel trained in the appropriate reprocessing techniques and safety should complete all reprocessing. Wear appropriate protective equipment (gloves, eye protection, etc.) when reprocessing any medical device.



CAUTION: The arthroscope contains small rare earth permanent magnets.

Do not place the arthroscope directly on, or next to an active implantable device that may be affected by magnetic fields.

Point of Use Cleaning

After concluding surgery, wipe any visible debris with wet gauze or a lap sponge and sterile water.

Transport to Processing Area

Keep the arthroscope and light cable adapters continuously moist until Manual or Automated Cleaning can commence at the point of central reprocessing. To keep the device moist, add a moist towel to the transport container.

Complete the cleaning procedures for the arthroscope and the light cable adapters within 30 minutes following their use.

Preparation for Cleaning

Disassemble the device.

1. Disconnect the light cable from the light guide post.
2. Disconnect the camera-coupling device from the eyepiece.
3. Remove any light cable adapters from the endoscope.
4. Disassemble the arthroscope from any devices or accessories used during the procedure.
5. Perform either the Manual Cleaning Procedure or the Automated Cleaning procedure below.

MANUAL CLEANING

Perform the following steps at the point of central reprocessing:

1. Rinse the arthroscope and the light cable adaptors under cold running tap water for a minimum of three (3) minutes. Brush all surfaces of the SwingScope arthroscope and light cable adaptors during the rinse. Rotate the image adjustment controls a minimum of five (5) times while brushing with a soft bristle brush during the rinse.
2. Prepare an enzymatic detergent according to the manufacturer's instructions. Use a fresh mixture of cleaning solution for each set of arthroscope and light cable when cleaning.
3. Immerse the arthroscope and light cable adapters completely in the detergent solution for at least 45 minutes.
4. After the first 15 minutes immersion time, use a soft bristle brush to remove any debris / soil from the arthroscope, and a soft bristled pipe cleaner for the light cable adapters while they are submerged. Brush for a minimum of 3 minutes. Ensure that the brush and the pipe cleaner can access the hard to reach areas such as cracks, crevices and threads on the light guide post and light guide adapters. Remove all visible debris.
5. Fill a syringe with the enzymatic detergent and use to flush crevices and threads while submerged.
6. Repeat the Brushing step (Step [42](#)). Repeat the Flushing step. (Step [56](#)) for an additional 2 times.

7. Rinse the arthroscope and light cable adapters under cold running tap water for at least three (3) minutes. Rotate the image adjustment controls a minimum of five (5) times while brushing with a soft bristle brush during the rinse. Brush all surfaces for the remaining rinsing time.
8. Soak the devices for a minimum of three (3) minutes in [reverse osmosis, sterile deionized, and/or distilled water for final rinsing, sterile water](#) and dry with a lint-free soft cloth.

Automated Cleaning Instructions

Equipment Required. Washer-disinfector with fundamentally approved efficiency (e.g. CE mark or FDA approval according to ISO 15883), properly installed, qualified and regularly subjected to maintenance and testing.

Perform the following steps at the point of central reprocessing after completing Manual Pre-cleaning.

1. Prepare an enzymatic detergent per the manufacturer's instructions. Prepare a fresh mixture of cleaning solution for each use.
2. Disconnect the light cable adapters from the arthroscope and immerse the arthroscope and light cable adapters entirely in the detergent solution for at least 15 minutes.
3. Use a soft bristle brush to remove any debris / soil from the arthroscope. Use a soft bristled pipe cleaner to remove debris from the light cable adapters while they are submerged. The brush and pipe cleaner must be able to access areas that are difficult to reach, such as cracks, crevices and threads on the light guide post, and light guide adapters. Remove all visible debris.
4. Rinse the arthroscope and light cable adapters under cold running tap water for at least one (1) minute.
5. Place the arthroscope and its light cable adapters into a separate mesh basket. Ensure that the arthroscope and light cable adapters do not touch each other when placed into the basket.
6. Place a mesh screen over the basket to contain the arthroscope and light cable adapters in the basket during processing.
7. Place the mesh basket with arthroscope and light cable adapters into a general instrument washer-disinfector to clean the arthroscope and light cable adapters.
8. Select an enzymatic detergent and a neutral pH instrument cleaner. Prepare according to the instructions of the detergent manufacturer. Prepare a fresh mixture of cleaning solution for each use.
9. Run the washing machine cycle per the instructions provided by the manufacturer. The minimum cleaning cycle is described below in Table 1:

Table 1: Automatic Cleaning Parameters:

Phase	Recirculation Time	Water Temperature	Detergent Type
Pre Wash	3 minutes	Cold tap water	N/A
Enzyme Wash	5 minutes	Hot tap water	enzymatic detergent
Wash 1	5 minutes	65°C (Set Point)	Neutral pH instrument cleaner
Rinse 1	2 minutes	Hot tap water	N/A

Dry Phase	7 minutes	115°C	N/A
-----------	-----------	-------	-----

10. Remove the arthroscope and light cable adapters from the washing machine following the cleaning cycle. Allow sufficient time for the devices to cool for safe handling.

Inspection

After either Manual Cleaning or Automated Cleaning, visually inspect the arthroscope and light cable adapters to verify the absence of visible soil, stains and debris. If soil is present after cleaning, repeat cleaning procedure.

Steam Sterilization



CAUTION: Do not [use immediate use steam sterilization \(IUSS\)](#) “flash” [to](#) sterilize the arthroscope or light cable adapters.

1. Disassemble the arthroscope and light cable adapters before sterilization as described above.
2. Either double-wrap the arthroscope and light cable adapters [double wrap the SwingScope and light cable adapters in 1-ply polypropylene wrap \(FDA-cleared sterilization wraps\)](#). ~~with 1-ply polypropylene wrap,~~ or place the arthroscope and light cable adapters into the appropriate sterilization tray and double-wrap the sterilization tray with 1-ply polypropylene wrap [\(FDA-cleared sterilization wrap\)](#).
3. ~~Complete sterilization per AAMI ST79.~~ Table 2 lists the validated parameters.

Table 2: Parameters for Steam Sterilization

- [Use a validated, properly maintained and calibrated steam sterilizer.](#)
- [Effective steam sterilization can be achieved using the following cycle](#)

Cycle Type	Minimum Temperature	Minimum Exposure Time / Dry Time
Pre-Vacuum	270°F (132°C)	4 minutes / 20 minutes dry time

[For further guidance for Sterilization, refer to: ANSI/AAMI ST79 “Comprehensive guide to steam sterilization and sterility assurance in health care facilities.”](#)

Sterilization Method	Pre-Vacuum
Pulses (minimum)	3
Temperature	132°C / 270°F
Exposure time	4 minutes
Drying Time	20 minutes

4. After sterilization, allow the arthroscope and light cable adapters to cool to room temperature. Do not accelerate cooling; this may damage the arthroscope.

STERRAD® Sterilization

1. Ensure the arthroscope and light cable adapters are disassembled before sterilization.
2. The arthroscope and light cable adapters are compatible with the STERRAD® 100S, STERRAD® 100NX and STERRAD® NX sterilization systems.
3. Clean and thoroughly dry the arthroscope and light cable adapters per the Cleaning Section.
4. Place the arthroscope and light cable adapters into the instrument tray compatible with the STERRAD 100S, NX and 100NX sterilization systems.
- 4-5. [Double wrap the trays in 1-ply polypropylene wraps \(FDA-cleared sterilization wraps\) 1-ply polypropylene wraps](#)
- 5-6. Include a STERRAD® indicator strip in the wrapped package.
- 6-7. Load the devices into the STERRAD® sterilizer.
- 7-8. Run the STERRAD® machine per the manufacturer’s instructions. DePuy recommends the following cycles:
 - STERRAD® 100NX: Standard cycle
 - STERRAD® 100S: Standard cycle

- STERRAD® ~~100~~NX: Standard cycle

Ethylene Oxide (EtO) Sterilization

Perform EtO sterilization according to AAMI TIR 12.

1. Ensure the arthroscope and light cable adapters are disassembled before sterilization.
2. Clean and thoroughly dry the arthroscope and light cable adapters per the Cleaning Section.
3. Double-wrap the trays [in 1-ply polypropylene wrap \(FDA-cleared sterilization wraps\).](#)~~in 1-ply polypropylene wrap.~~
4. Complete pre-conditioning (Temperature: 130° ± 5°F b. Time: 30 min)
5. Complete processing. Cycle parameters:
 - Temperature : 55°C /130° ± 5°F
 - Relative Humidity: 50-80%
 - EtO Dwell Exposure time: 60 minutes
 - EtO Concentration: 725-735mg/l (100% EtO)
 - Aeration: temperature of 120 – 140°F (49°C – 60°C) for 12 hours

STORAGE

Store the arthroscope in a dry, clean and safe place at room temperature, in its wrapped sterilization container. Mitek Sports Medicine does not recommend storing the arthroscope and light cable adapters in the shipping box.

DISPOSAL

Dispose of surgical devices according to standard hospital procedures.

REPAIRS

- Contact the Repair Service Center at 1-800-382-4682 for service requests. Outside the United States, contact your local affiliate.
 - Before returning any product to Mitek Sports Medicine, please contact Customer Service to obtain a return goods authorization and product return packaging.
 - Please clean, disinfect, and sterilize the Arthroscope as described in this document and mark it as “Sterilized” prior to return.

Accessories and Spare Parts

Product Code	Description	Contact the Service Center at 1-800-382-4682. Outside the US, contact your local affiliate.
288008	Lightpost Adapter 22mm x 12mm	
288009	Lightpost Adapter 12mm x 9mm	

GRAPHIC SYMBOLS USED IN DEVICE LABELING



Quantity



On Order of Physician Only



Consult Instructions For Use



Product Code



Serial Number



Manufacturing Date



~~Contains No Natural Rubber Latex~~



Manufacturer



CE Mark

SPECIFICATIONS AND PERFORMANCE CHARACTERISTICS

Light Cable Diameter	5.0 mm or smaller (3.5 mm recommended)
ACMI Light Source (recommended)	300 W Xenon
Working Length	190.0 mm
Shaft Diameter	4.0 mm
Angle of View	Between 10° and 90°
Camera Coupler	Universal C-Mount
Recommended Light Source	Xenon or LED (up to 300W)



Medos International S.A.R.L.
Chemin-Blanc 38, 2400
Le Locle, Switzerland

US **REP** [US Representative](#)

[DePuy Synthes Inc.](#)
[325 Paramount Drive](#)
[Raynham, MA 02767](#)
[800-356-4835](#)



General Arthroscope Accessories

C €0086

P/N: 111985
Rev: A Issued 02/2014
© DePuy Synthes Mitek Sports Medicine
a division of DOI 2013. All rights reserved.

General Arthroscope Accessories



DESCRIPTION

The General Arthroscope Accessories are designed for use with arthroscopes, which are used to visualize the joint during surgery. General arthroscopic Sheaths consist of a metal cannula system which includes Sheaths, Obturators and a Bridge for connecting the arthroscope to a fluid management system.

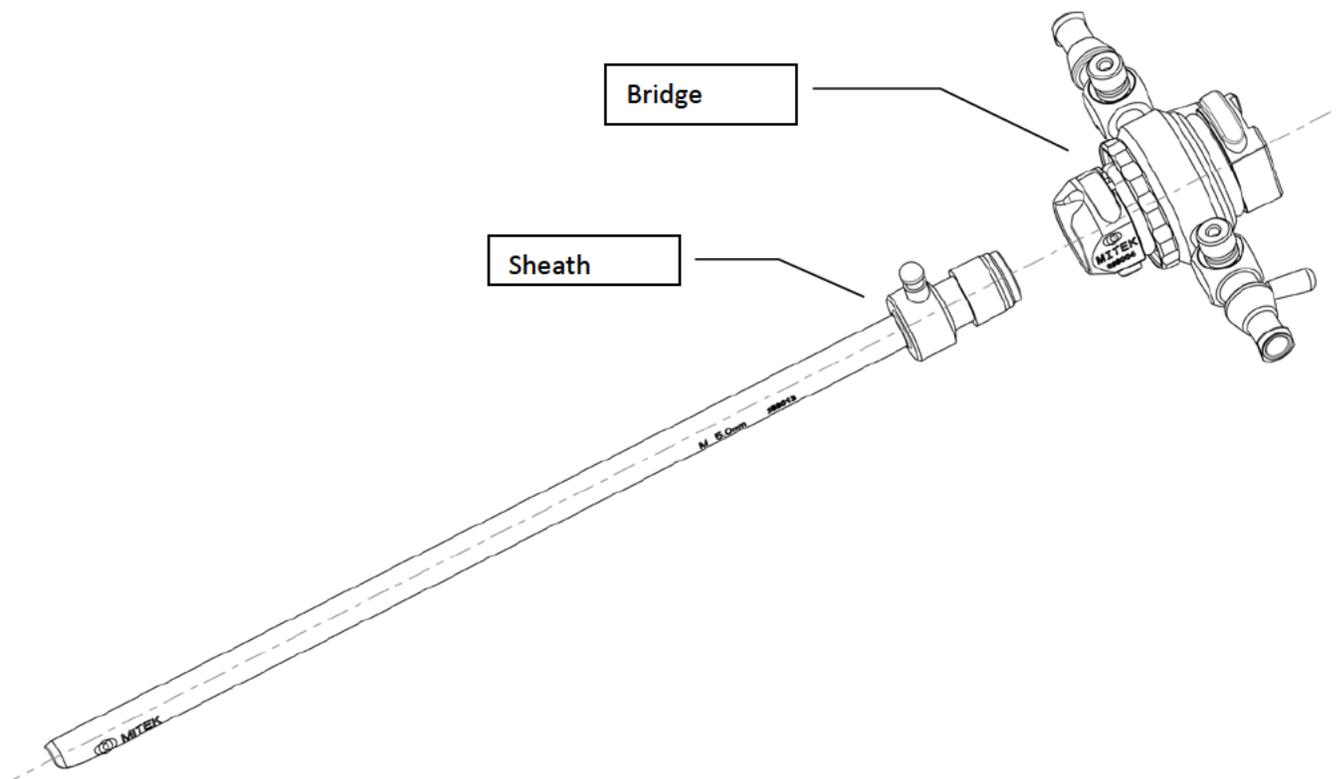


Figure 1 . Arthroscope Accessories (Bridge and Sheath)

NOTE: Figure shows SwingScope™ Accessories. Other arthroscope accessories may have slight differences.

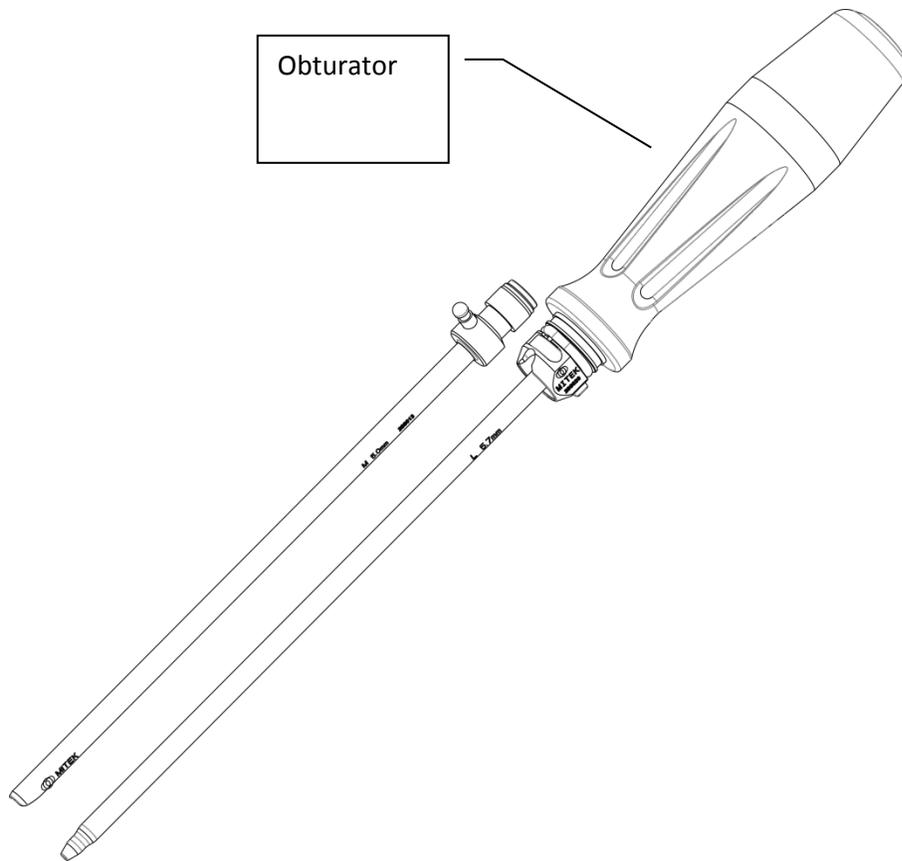


Figure 2. Arthroscope Accessories (Obturator and Sheath)

NOTE: Figure shows SwingScope™ Accessories. Other arthroscope accessories may have slight differences.

INDICATIONS

General arthroscope accessories are indicated for use with arthroscopes, which provide visualization during surgery.

INTENDED USE

Arthroscopes and arthroscope accessories are intended for use by personnel trained in arthroscopy in a surgical setting.

CONTRAINDICATIONS

None known.

WARNINGS

- Before assembly and use, make sure that all O-rings are in place and are not damaged. The system can leak or malfunction if an O-ring is missing or damaged.

PRECAUTIONS

- Carefully inspect before each use for damage. Assemble and disassemble the sheath system before surgery to ensure all parts fit together properly and are not damaged.

- If any damage or excessive wear is noted, please replace part.
- Wet all components before assembly and sterilization to reduce O-ring wear.
- Carefully assemble all components during reassembly. Forced assembly could result in damage and improper function.

INSTRUCTIONS FOR USE

Arthroscope accessories are designed for use with DePuy Mitek arthroscopes. Consult the appropriate manual/Instructions for use for using the accessories with arthroscopes.

ASSEMBLY

NOTE: Clean & Sterilize before each use. Refer to Cleaning and Sterilization Instructions in this document.

To assemble arthroscope accessories:

1. Attach the Sheath to the corresponding Obturator and use for joint entry.
2. Detach the Obturator from the Sheath.
3. Insert the arthroscope into the Sheath and attach the arthroscope Bridge to the Sheath.
4. Repeat Steps 1-4 above for each portal.

NOTE: Pull lightly to ensure that the connection is secure.

NOTE: Make sure stopcocks are closed before use.

DISASSEMBLY FOR CLEANING

NOTE: Refer to Figure 1.

To disassemble for cleaning:

1. Release the Sheath from the Bridge by depressing the latch button and gently pull the Sheath away from the Bridge.
2. Remove the Bridge from the arthroscope.
3. Ensure the stopcocks on the Bridge are in the open position (closed position is perpendicular to the axis of the in/out flow valve)
4. Ensure all Sheaths are disconnected from the Obturators.
5. Clean the device according to the Cleaning and Sterilization Instructions in this document.

CLEANING AND STERILIZATION

Automated Cleaning

NOTE: Clean before and after each use.

Pre-Cleaning

1. The Outer Sheath must be removed as shown in Figure 1 and in Step 1, Disassembly for Cleaning.
2. Open the two Stopcocks on the Bridge as shown in Figure 1.

3. **First Soaking Bath:** Carry out a first soaking bath in a pH neutral detergent (example: CIDEXPLUS®) solution for 15 minutes or an equivalent solution (refer to cleaning agent solution manufacturer's instructions for immersion time and temperature).
4. Carry out five (5) swiping motions with a swab-type brush on all surfaces, paying particular attention to lumens, holes and spring loaded retractable features.
5. Check for remaining debris and remove as needed.
6. **Second Soaking Bath:** Carry out a second soaking bath in a pH neutral detergent (example: CIDEXPLUS®) solution for 15 minutes using an ultrasound bath frequency: 50-60Hz. (refer to cleaning agent solution manufacturer's instructions for immersion time and temperature).
7. Rinse with **de-ionized water** for 30 seconds.
8. Clean in a validated washer disinfecter using the "INSTRUMENTS" cycle and a pH neutral cleaning agent intended for use in automated cleaning. The cleaning cycle should incorporate enzymatic pre-wash, wash, rinse, thermal rinse, and drying steps.

IMPORTANT: Before assembly and use ensure that all O-rings are in place and are not damaged. Remove and replace any O-rings that show any sign of damage or wear. Use a cleaner/lubricant or instrument milk to lubricate parts as necessary. Use a medical grade silicone grease to grease the Stopcocks. Remove any excess lubricant.

Manual Cleaning Instructions

1. The Outer Sheath must be removed as shown in Figure 1, and in Step 1, Disassembly for Cleaning above.
2. Open the two Stopcocks in the body as shown in Figure 1.
3. **First Soaking Bath:** Carry out a first soaking bath in a pH neutral detergent (example: CIDEXPLUS®) solution for 15 minutes or an equivalent solution (refer to cleaning agent solution manufacturer's instructions for immersion time and temperature).
4. Carry out five (5) swiping motions with a swab-type brush on all surfaces, paying particular attention to lumens, holes and spring loaded retractable features.
5. Check for remaining debris and remove as needed.
6. Open and close the locking system to ensure that it is free of foreign bodies.
7. **Second Soaking Bath:** Carry out a second soaking bath in a Neutral pH detergent (example: CIDEXPLUS®) solution for 15 minutes using an ultrasound bath frequency: 50-60Hz. (refer to cleaning agent solution manufacturer's instructions for immersion time and temperature).
8. **Rinse with de-ionized water** for 30 seconds at ambient temperature.
9. Dry with medical air at less than 100°C or 212°F for 30 seconds.

IMPORTANT: Before assembly and use ensure that all O-rings are in place and are not damaged. Remove and replace any O-rings that show any sign of damage or wear. Use a cleaner/lubricant or instrument milk to lubricate parts as necessary.

Use a medical grade silicone grease to grease the Stopcocks. Remove any excess lubricant.

Inspection after Cleaning

1. Inspect before sterilization or storage to ensure the complete removal of soil from all surfaces and holes.
2. If areas are difficult to inspect visually, check for blood by immersing or flushing in a 3% hydrogen peroxide solution. If bubbling is observed, blood is present. Rinse thoroughly after using hydrogen peroxide solution.
3. If soil is still present, repeat cleaning procedure.

STERILIZATION

Steam sterilization

Use a validated, properly maintained and calibrated steam sterilizer.

The following cycles provide effective steam sterilization:

132°C/ 270°F and minimum of a 4 minute Pre-Vac cycle with a 30 minute dry time with both **Stopcocks** in the “open” position (See Detail B).



Quantity



Non Sterile



DePuy Mitek, Inc.
325 Paramount Drive
Raynham, MA 02767, USA
1-800-356-4835



Medos International SARL
Chemin-Blanc 38, 2400
Le Locle, Switzerland

* For recognized manufacturer, refer to product label.



DePuy International Ltd.

St Anthony's Road
Leeds LS11 8DT England
Tel: +44 113 270 0461
Fax: +44 113 272 4101



(21) 123456



(01) 10886705024872



Multi-angle arthroscope, 4.3mm,
2 Lightpost Adapters

Rev A

SWINGSCOPE™ 4.3mm 10°-90°

Multi-angle arthroscope, 2 Lightpost Adapters

Arthroscope multi-angulaire, 2 adaptateurs pr câble lumineux

Mehrwinkel-Arthroskop, 2 Lichtadapter

Multihoeck arthroscoop, 2 lichtpaaladapters

Artroscopio multiangolare, 2 adattatori punto luce

Artroscopio multiângulo, 2 adaptadores poste de luz

Artroscópio multi-ângulo, 2 Adaptadores de Haste Luminosa

Artroskop wielokątowy, 2 adaptery światłowodowe

Viceúhlový artroskop, 2 adaptéry osvětlení

REF 288000

Catalogue number

Rx Only

2014-02

Date of manufacture

SN 123456

Serial number

QTY 1

Quantity

MADE IN Germany



MITEK SPORTS MEDICINE

CONTINUED BY Johnson & Johnson



Caution



Consult instruction for use



Manufacturer

Medos International SARL

Chemin-Blanc 38, 2400

Le Locle, Switzerland

For patent information about this product, go to www.depuysynthes.com/patentmarking