

AUG 08 2009

**Arthrex** TRADITIONAL 510(k): Arthrex Dual Wave Arthroscopy Fluid Management Device

**3 510(k) Summary of Safety and Effectiveness**

<b>Manufacturer/Distributor/Sponsor</b>	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
<b>510(k) Contact</b>	Sally Foust Regulatory Affairs Project Manager Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1251 Fax: 239/598.5508 Email: sfoust@arthrex.com
<b>Trade Name</b>	Arthrex Dual Wave Arthroscopy Fluid Management Device
<b>Common Name</b>	Pump
<b>Product Code –Name –Reference</b>	HRX – Arthroscope - CFR 888.1111
<b>Predicate Device</b>	Arthrex Continuous Wave Arthroscopy Pump, K024291 FMS DUO, K954465
<b>Device Description and Intended Use</b>	<p>The Arthrex Dual Wave Arthroscopy Fluid Management Device is a roller, peristaltic, arthroscopic pump designed with a universal input grade switching power supply. The Arthrex Dual Wave Arthroscopy Fluid Management Device senses the connection and use of the Arthrex Shaver Adapter System (K932699) and provides an outflow function to support the same.</p> <p>Arthrex Dual Wave Arthroscopy Fluid Management Device is intended to provide consistent, non-pulsing control of intra-articular irrigation and distention pressuring during all phases of arthroscopic surgery.</p>
<b>Substantial Equivalence Summary</b>	<p>The Arthrex Dual Wave Arthroscopy Fluid Management Device is substantially equivalent to the predicate devices Arthrex Continuous Wave III Arthroscopy Pump and the FMS DUO in which the basic features and intended uses are the same or very similar. Any differences between the Arthrex Dual Wave Arthroscopy Fluid Management Device and the predicate devices Arthrex Continuous Wave III Arthroscopy Pump and FMS DUO are considered minor and do not raise questions concerning safety and effectiveness. Based on the information submitted, Arthrex, Inc. has determined that the new Arthrex Dual Wave Arthroscopy Fluid Management Device is substantially equivalent to the currently marketed predicate devices.</p>

## 4 Administrative Information

### 4.1 Manufacturer / Distributor / Sponsor / Contact

#### 4.1.1 Manufacturer/Distributor / Sponsor

Arthrex, Inc.  
1370 Creekside Boulevard  
Naples, Florida 34108-1945 USA  
Establishment Registration Number: 1220246

#### 4.1.2 Contact

Sally Foust  
Regulatory Affairs Project Manager  
Arthrex, Inc.  
1370 Creekside Boulevard  
Naples, Florida 34108-1945 USA  
*Telephone:* 239/643.5553, extension 1251  
*Fax:* 239/598.5508  
*Email:* sfoust@arthrex.com

### 4.2 Device Identification

#### 4.2.1 Proprietary Name

Arthrex Dual Wave Arthroscopy Fluid Management System

#### 4.2.2 Common Name

Pump

#### 4.2.3 Classification Name and Reference

21 CFR 888.1111: Arthroscope

#### 4.2.4 Regulatory Class

Based on the recommendation of the Orthopedic and Rehabilitation Device Panel, the FDA has classified this device as a Class II medical device.

**Arthrex** TRADITIONAL 510(k): Arthrex Dual Wave Arthroscopy Fluid Management Device

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#### **4.2.5 Device Product Code**

- HRX

#### **4.3 Compliance with Special Controls**

Sections 513 and 514 of the act, as amended under the Safe Medical Devices Act of 1990, do apply to this type of device.

Arthrex, Inc. is not aware of any requirements for post-market surveillance or other special controls for this device.

#### **4.4 Conformance to Voluntary Standards**

The Arthrex Dual Wave Arthroscopy Fluid Management Device will conform to the following voluntary standards:

EN -55011B (EMC 89/336/CEE): Emission Requirements

IEC-60601-1 (73/23/CEE): Medical electrical equipment, General Requirements for Safety



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Arthrex, Inc.  
% Ms. Sally Frost  
Regulatory Affairs Project Manager  
1370 Creekside Boulevard  
Naples, Florida 34108

AUG 03 2009

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Re: K083707

Trade/Device Name: Arthrex Dual Wave Arthroscopy Fluid Management Device  
Regulation Number: 21 CFR 888.1100  
Regulation Name: Arthroscope  
Regulatory Class: II  
Product Code: HRX  
Dated: July 13, 2009  
Received: July 15, 2009

Dear Ms. Forst:

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 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.

Page 2 – Ms. Sally Frost

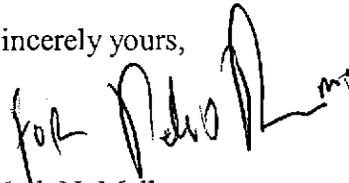
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOFFICES/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "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 (240) 276-3150 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





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Arthrex, Inc.  
% Ms. Sally Frost  
Regulatory Affairs Project Manager  
1370 Creekside Boulevard  
Naples, Florida 34108

AUG 03 2009

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Re: K083707

Trade/Device Name: Arthrex Dual Wave Arthroscopy Fluid Management Device  
Regulation Number: 21 CFR 888.1100  
Regulation Name: Arthroscope  
Regulatory Class: II  
Product Code: HRX  
Dated: July 13, 2009  
Received: July 15, 2009

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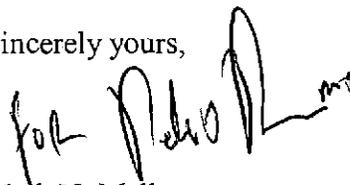
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Page 2 – Ms. Sally Frost

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 (240) 276-3150 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

DJA 00003

ArthroX TRADITIONAL 510(k): ArthroX Dual Wave Arthroscopy Fluid Management Device

**2 Indications for Use Form**

**Indications for Use**

510(k) Number: \_\_\_\_\_

Device Name: ArthroX Dual Wave Arthroscopy Fluid Management Device

The ArthroX Dual Wave Arthroscopy Fluid Management Device is intended to provide consistent, non-pulsing control of intra-articular irrigation and distention pressuring during all phases of arthroscopic surgery.

Prescription Use  AND/OR Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

PAGE 1 of 1

*Niall R. O'Brien*  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K083707



July 16, 2009

ARTHREX, INC.  
1370 CREEKSIDE BLVD.  
NAPLES, FLORIDA 34108-1945  
UNITED STATES  
ATTN: SALLY FOUST

510k Number: K083707

Product: ARTHREX DUAL WAVE

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at [www.fda.gov/cdrh/ode/a02-01.html](http://www.fda.gov/cdrh/ode/a02-01.html). On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

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

Sincerely yours,

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



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, Maryland 20850

March 06, 2009

ARTHREX, INC.  
1370 CREEKSIDE BLVD.  
NAPLES, FLORIDA 34108-1945  
UNITED STATES  
ATTN: SALLY FOUST

510k Number: K083707

Product: ARTHREX DUAL WAVE ARTHROSCOPY

Extended Until: 07/24/2009

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

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

Sincerely yours,

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

DJA 00017



Regulatory Affairs Department  
1370 Creekside Boulevard  
Naples, Florida 34108-1945 USA

**MARCH 3, 2009**

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

MAR - 6 2009  
Received

**RE: K083707, Arthrex Dual Wave Arthroscopy Fluid Management Device: Request for Extension**

**ATTN: Mr. Chowdhury**

Dear Mr. Chowdhury,

*Request for Extension*

Arthrex, Inc. hereby requests a four month extension (**120 days**) to respond to the additional information requests outlined in your e-mail dated February 23, 2009 for K083707.

Should there be questions or issues regarding this letter please contact Sally Foust by either e-mail at [sfoust@arthrex.com](mailto:sfoust@arthrex.com) or by telephone at (239) 643-5553 extension 1251.

Sincerely,

Sally Foust, RAC (US & EU)  
Regulatory Affairs Project Manager  
Arthrex, Inc.

TC44

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, Maryland 20850

February 25, 2009

ARTHREX, INC.  
1370 CREEKSIDE BLVD.  
NAPLES, FLORIDA 34108-1945  
UNITED STATES  
ATTN: SALLY FOUST

510k Number: K083707

Product: ARTHREX DUAL WAVE ARTHROSCOPY

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at [www.fda.gov/cdrh/ode/a02-01.html](http://www.fda.gov/cdrh/ode/a02-01.html).

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

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

DJA 00021

Records Processed under FOIA Request 2013-7213. Released by CDRH on 09/01/2015.  
Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

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

Sincerely yours,

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



December 16, 2008

ARTHREX, INC.  
1370 CREEKSIDE BLVD.  
NAPLES, FLORIDA 34108-1945  
UNITED STATES  
ATTN: SALLY FOUST

510k Number: K083707

Received: 12/15/2008

Product: ARTHREX DUAL WAVE ARTHROSCOPY

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

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

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

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

DJA 00035

Records Processed under FOIA Request 2013-7213; Released by CDRH on 09/01/2015  
Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”  
([http://www.fda.gov/oc/initiatives/fdaaa/guidance\\_certifications.html](http://www.fda.gov/oc/initiatives/fdaaa/guidance_certifications.html)). According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

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

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

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

Sincerely yours,

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



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, Maryland 20850

December 15, 2008

ARTHREX, INC.  
1370 CREEKSIDE BLVD.  
NAPLES, FLORIDA 34108-1945  
UNITED STATES  
ATTN: SALLY FOUST

510k Number: K083707

Received: 12/15/2008

User Fee ID Number: 6040277

Product: ARTHREX DUAL WAVE ARTHRO

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and the FDA Amendments Act of 2007 (FDAAA) (Public Law 110-85), authorizes FDA to collect user fees for certain types of 510(k) submissions. The submission cannot be accepted for review until the fee is paid in full ; therefore, the file has been placed on hold. When your user fee payment has been received , review of the 510(k) will resume as of that date. Alternatively, you may request withdrawal of your submission. You now have the option to pay online by credit card. We recommend this form of payment. Credit card payments are directly linked to your user fee cover sheet and are processed the next business day. You may also pay by check. If you choose to mail a check, please send a check to one of the addresses listed below:

By Regular Mail

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

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

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

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (240)276-4025 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at [www.fda.gov/oc/mdufma](http://www.fda.gov/oc/mdufma).

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

DJA 00037

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (240) 276-3150 or its toll-free number (800)638-2041, or contact them at their Internet address [www.fda.gov/cdrh/dsma/dsmastaf.html](http://www.fda.gov/cdrh/dsma/dsmastaf.html), or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Diane Garcia at [Diane.Garcia@fda.hhs.gov](mailto:Diane.Garcia@fda.hhs.gov) or directly at (240)276-4027. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

Diane M. Garcia  
Public Affairs Specialist  
Pre-market Notification Section  
Office of Device Evaluation  
Center for Devices and Radiological Health

*1st copy* *K083707*  
*1 of 2 copies*

DJA 00038



**11 DECEMBER 2008**

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

FDA CDRH DMC

DEC 15 2008

Received

*K-57*

**RE: 510(k) Pre-market Notification:  
Arthrex Dual Wave Arthroscopy Fluid Management Device**

Dear Madame/Sir:

Pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the ACT) and in accordance with subpart E of Part 807 of Title 21 of the Code of Federal Regulations, Arthrex, Inc. submits this **510(k) pre-market notification**, in duplicate, to obtain clearance for a new device, the Arthrex DualWave Arthroscopy Fluid Management Device for U.S. distribution.

Pursuant to 21 CFR 807.95 (c) (3) Arthrex, Inc. considers this pre-market submission to be confidential commercial information.

Questions regarding this submission may be directed to Sally Foust by e-mail at [sfoust@arthrex.com](mailto:sfoust@arthrex.com) and by telephone at (239) 643-5553 extension 1251.

Sincerely,

*Sally Foust*  
Sally Foust

Regulatory Affairs Project Manager

Arthrex, Inc. • 1370 Creekside Boulevard • Naples, FL 34108-1945 USA

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4) 3 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: <a href="http://www.fda.gov/oc/mdufma/coversheet.html">http://www.fda.gov/oc/mdufma/coversheet.html</a>																						
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)  ARTHREX INC 1370 CREEKSIDE BLVD. - NAPLES FL 34108 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 061121728	2. CONTACT NAME Sally Foust 2.1 E-MAIL ADDRESS sfoust@arthrex.com 2.2 TELEPHONE NUMBER (include Area code) 239-643 5553 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 239 -598 5508																					
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: <a href="http://www.fda.gov/oc/mdufma">http://www.fda.gov/oc/mdufma</a> )  Select an application type: <table border="0"> <tr> <td><input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party</td> <td>3.1 Select a center</td> </tr> <tr> <td><input type="checkbox"/> 513(g) Request for Information</td> <td><input checked="" type="checkbox"/> CDRH</td> </tr> <tr> <td><input type="checkbox"/> Biologics License Application (BLA)</td> <td><input type="checkbox"/> CBER</td> </tr> <tr> <td><input type="checkbox"/> Premarket Approval Application (PMA)</td> <td>3.2 Select one of the types below</td> </tr> <tr> <td><input type="checkbox"/> Modular PMA</td> <td><input checked="" type="checkbox"/> Original Application</td> </tr> <tr> <td><input type="checkbox"/> Product Development Protocol (PDP)</td> <td>Supplement Types:</td> </tr> <tr> <td><input type="checkbox"/> Premarket Report (PMR)</td> <td><input type="checkbox"/> Efficacy (BLA)</td> </tr> <tr> <td><input type="checkbox"/> Annual Fee for Periodic Reporting (APR)</td> <td><input type="checkbox"/> Panel Track (PMA, PMR, PDP)</td> </tr> <tr> <td><input type="checkbox"/> 30-Day Notice</td> <td><input type="checkbox"/> Real-Time (PMA, PMR, PDP)</td> </tr> <tr> <td></td> <td><input type="checkbox"/> 180-day (PMA, PMR, PDP)</td> </tr> </table>			<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party	3.1 Select a center	<input type="checkbox"/> 513(g) Request for Information	<input checked="" type="checkbox"/> CDRH	<input type="checkbox"/> Biologics License Application (BLA)	<input type="checkbox"/> CBER	<input type="checkbox"/> Premarket Approval Application (PMA)	3.2 Select one of the types below	<input type="checkbox"/> Modular PMA	<input checked="" type="checkbox"/> Original Application	<input type="checkbox"/> Product Development Protocol (PDP)	Supplement Types:	<input type="checkbox"/> Premarket Report (PMR)	<input type="checkbox"/> Efficacy (BLA)	<input type="checkbox"/> Annual Fee for Periodic Reporting (APR)	<input type="checkbox"/> Panel Track (PMA, PMR, PDP)	<input type="checkbox"/> 30-Day Notice	<input type="checkbox"/> Real-Time (PMA, PMR, PDP)		<input type="checkbox"/> 180-day (PMA, PMR, PDP)
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	<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 <a href="http://www.fda.gov/cdrh/mdufma">http://www.fda.gov/cdrh/mdufma</a> for additional information)																						
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <table border="0"> <tr> <td><input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates</td> <td><input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population</td> </tr> <tr> <td><input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only</td> <td><input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially</td> </tr> </table>			<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population	<input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially																
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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																						
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4)		11-Dec-2008																				

Form FDA 3501 (01/2007)

"Close Window" Print Cover sheet

DJA 00040

Online Payment

Step 3: Confirm Payment

1 | 2 | 3

Thank you.  
Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: FDA User Fees

Pay.gov Tracking ID: 24V56U9F

Agency Tracking ID: 6040277

Transaction Date and Time: 12/11/2008 12:57 EST

Payment Summary

Address Information

Account Holder Name: Frank Maas  
1370 Creekside  
Billing Address: Blvd

Billing Address 2:  
City: Naples  
State / Province: FL  
Zip / Postal Code: 34108  
Country: USA

Account Information

Card Type: American Express  
Card Number: \*\*\*\*\*1003  
Expiration Date: 2 / 2010

Payment Information

Payment Amount: \$3,693.00  
Transaction Date 12/11/2008 12:57  
and Time: EST

KO 83707



11 DECEMBER 2008

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

**RE: 510(k) Pre-market Notification:  
Arthrex Dual Wave Arthroscopy Fluid Management Device**

Dear Madame/Sir:

Pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the ACT) and in accordance with subpart E of Part 807 of Title 21 of the Code of Federal Regulations, Arthrex, Inc. submits this **510(k) pre-market notification**, in duplicate, to obtain clearance for a new device, the Arthrex DualWave Arthroscopy Fluid Management Device for U.S. distribution.

Pursuant to 21 CFR 807.95 (c) (3) Arthrex, Inc. considers this pre-market submission to be confidential commercial information.

Questions regarding this submission may be directed to Sally Foust by e-mail at [sfoust@arthrex.com](mailto:sfoust@arthrex.com) and by telephone at (239) 643-5553 extension 1251.

Sincerely,

Sally Foust

Regulatory Affairs Project Manager

Arthrex, Inc. • 1370 Creekside Boulevard • Naples, FL 34108-1945 USA

DJA 00042

 TRADITIONAL 510(k): Arthrex Dual Wave Arthroscopy Fluid Management Device

**Arthrex, Inc.**

Arthrex, Inc. Telephone 239/643,5553  
1370 Creekside Boulevard Toll Free: 800/933,7001  
Naples, FL 34108-1945 Fax: 239/598,5508

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# 510(k) Premarket Notification

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## Arthrex Dual Wave Arthroscopy Fluid Management Device

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**ArthroCare** TRADITIONAL 510(k): Arthrocare Dual Wave Arthroscopy Fluid Management Device

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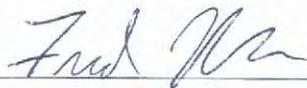
DJA 00044

 TRADITIONAL 510(k): Arthrex Dual Wave Arthroscopy Fluid Management Device

## 1 Truth and Accuracy Statement

PREMARKET NOTIFICATION  
TRUTHFUL AND ACCURATE STATEMENT  
*As Required by 21 CFR 807.87(k)*

I certify that, in my capacity as Vice President, Quality Assurance and Regulatory Affairs, at Arthrex, Inc., I believe, to the best of my knowledge, that all data and information submitted in this **510(k)** **premarket notification** (Arthrex Dual Wave Arthroscopy Fluid Management Device) is truthful and accurate and that no material fact has been omitted.



Signature

Frank Maas, *Vice President, Engineering, Quality Assurance, and Regulatory Affairs*

12/11/08

Date

DJA 00045

 TRADITIONAL 510(k): Arthrex Dual Wave Arthroscopy Fluid Management Device

## 2 Indications for Use Form

### Indications for Use

510(k) Number: \_\_\_\_\_

Device Name: Arthrex Dual Wave Arthroscopy Fluid Management Device

The Arthrex Dual Wave Arthroscopy Fluid Management Device is intended to provide consistent, non-pulsing control of intra-articular irrigation and distention pressuring during all phases of arthroscopic surgery.

Prescription Use  AND/OR Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

PAGE 1 of 1

DJA 00046

 TRADITIONAL 510(k): Arthrex Dual Wave Arthroscopy Fluid Management Device

### 3 510(k) Summary of Safety and Effectiveness

<b>Manufacturer/Distributor/Sponsor</b>	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
<b>510(k) Contact</b>	Sally Foust Regulatory Affairs Project Manager Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1251 Fax: 239/598.5508 Email: sfoust@arthrex.com
<b>Trade Name</b>	Arthrex Dual Wave Arthroscopy Fluid Management Device
<b>Common Name</b>	Pump
<b>Product Code –Name –Reference</b>	HRX – Arthroscope - CFR 888.1111
<b>Predicate Device</b>	Arthrex Continuous Wave Arthroscopy Pump, K024291 FMS DUO, K954465
<b>Device Description and Intended Use</b>	<p>The Arthrex Dual Wave Arthroscopy Fluid Management Device is a roller, peristaltic, arthroscopic pump designed with a universal input grade switching power supply. The Arthrex Dual Wave Arthroscopy Fluid Management Device senses the connection and use of the Arthrex Shaver Adapteur System (K932699) and provides an outflow function to support the same.</p> <p>Arthrex Dual Wave Arthroscopy Fluid Management Device is intended to provide consistent, non-pulsing control of intra-articular irrigation and distention pressuring during all phases of arthroscopic surgery.</p>
<b>Substantial Equivalence Summary</b>	<p>The Arthrex Dual Wave Arthroscopy Fluid Management Device is substantially equivalent to the predicate devices Arthrex Continuous Wave III Arthroscopy Pump and the FMS DUO in which the basic features and intended uses are the same or very similar. Any differences between the Arthrex Dual Wave Arthroscopy Fluid Management Device and the predicate devices Arthrex Continuous Wave III Arthroscopy Pump and FMS DUO are considered minor and do not raise questions concerning safety and effectiveness. Based on the information submitted, Arthrex, Inc. has determined that the new Arthrex Dual Wave Arthroscopy Fluid Management Device is substantially equivalent to the currently marketed predicate devices.</p>

## 4 Administrative Information

### 4.1 Manufacturer / Distributor/ Sponsor / Contact

#### 4.1.1 Manufacturer/Distributor / Sponsor

Arthrex, Inc.  
1370 Creekside Boulevard  
Naples, Florida 34108-1945 USA  
Establishment Registration Number: 1220246

#### 4.1.2 Contact

Sally Foust  
Regulatory Affairs Project Manager  
Arthrex, Inc.  
1370 Creekside Boulevard  
Naples, Florida 34108-1945 USA  
*Telephone:* 239/643.5553, extension 1251  
*Fax:* 239/598.5508  
*Email:* sfoust@arthrex.com

### 4.2 Device Identification

#### 4.2.1 Proprietary Name

Arthrex Dual Wave Arthroscopy Fluid Management System

#### 4.2.2 Common Name

Pump

#### 4.2.3 Classification Name and Reference

21 CFR 888.1111: Arthroscope

#### 4.2.4 Regulatory Class

Based on the recommendation of the Orthopedic and Rehabilitation Device Panel, the FDA has classified this device as a Class II medical device.

DJA 00048

## 5 Device Description

### 5.1 Device Materials

#### Pump

Front Panel:

Top Cover:

Bottom Cover Panel:

Front panel Touch Screen

Other:

Tubing Door Covers:

#### Remote Footswitch

#### Remote Control

#### Pump Tubing

Tubing:

Tubing Bonding Agent:

Outflow Tubing Fixture:



## 5.2 Device Description

The *Arthrex Dual Wave Arthroscopy Fluid Management Device* employs a universal input grade switching power supply.

The Arthrex Dual Wave Arthroscopy Fluid Management Device senses the connection and use of the Arthrex Shaver Adapteur System (K932699) and provides an outflow function to support the same, Shaver Adapteur System (K932699).

The Arthrex Dual Wave Arthroscopy Fluid Management Device has optional remotes, hand-control and footswitch (foot pedal).

### ***Dimensions of the Arthrex Dual Wave Arthroscopy Fluid Management Device are:***

Width:	16.25 in. (41.3 cm)
Height:	7.5 in. (19.0 cm)
Depth:	12.0 in. (30.0 cm)
Weight:	25 lbs. (11.8 kgs.)

### ***Specifications of the Arthrex Dual Wave Arthroscopy Fluid Management Device are:***

Flow Rate Inflow:	0-1600 mL/min.
Maximum Flow Rate: set at 100%:	1600 mL/min $\pm$ 100 mL/min
Pressure:	0-180 mmHg
Electric Pressure Check:	Continuous
Flow Rate Outflow:	0-800 mL/min.
Maximum Flow Rate: set at 100%:	800 mL/min $\pm$ 100 mL/min

The Arthrex Dual Wave Arthroscopy Fluid Management Device employs a 5.7" QVGA color display with 4 wire resistance type touch for high visibility, and for user inputs. Two new functions have been defined, LAVAGE and RINSE. When "lavage" is activated the inflow peristaltic will increase flow for a defaulted set time and rate. When "rinse" is activated the outflow peristaltic will increase flow for a defaulted set time and rate. Both functions will automatically stop after presets have been met.

There are two main functional screens with a maximum of seven control buttons.

DJA 00050

 TRADITIONAL 510(k): Arthrex Dual Wave Arthroscopy Fluid Management Device

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### ***Operational Modes***

There are two operational modes, "Inflow/Outflow Mode" and "Inflow Only Mode"

#### Inflow/Outflow Mode

*When pump is not running:*

- \* Flow
- \* Shaver
- \* Pressure Up
- \* Pressure Down
  - \* Run/Stop
  - \* Menu

*When pump is running:*

- \* Flow
- \* Shaver
- \* Pressure Up
- \* Pressure Down
  - \* Run/Stop
  - \* Lavage
  - \* Rinse

#### Inflow Only Mode

*When pump is not running:*

- \* Pressure Up
- \* Pressure Down
  - \* Run/Stop
  - \* Menu

*When pump is running:*

- \* Pressure Up
- \* Pressure Down
  - \* Run/Stop

 TRADITIONAL 510(k): Arthrex Dual Wave Arthroscopy Fluid Management Device

---

### 5.3 Device Product Numbers

AR-6480	Dual Wave Arthroscopy Fluid Management Device
AR-6482	Dual Wave Remote
AR-6483	Dual Wave Foot Pedal
AR-6480-SR	Dual Wave with Remote Set (AR-6480, AR-6481, AR-6482)
AR-6480-SF	Dual Wave with Foot Pedal Set (AR-6480, AR-6481, AR-6483)

### 5.4 Accessory Device Information

US Class II pump tubing devices are available as accessories to the Arthrex Dual Wave Arthroscopy Fluid Management Device.

AR-6410	Main Pump Tubing for AR-6475 and AR-6480
AR-6430	Dual Wave Outflow Tube w/fixture
AR-6411	ReDeuce™ Tubing, Pump Tubing
AR-6421	ReDeuce™ Tubing, Patient Tubing
AR-6220	Extension Tubing
AR-6215	Y Tubing

All above tubing except for AR-6430 Dual Wave Outflow Tube w/fixture are previously cleared (K024291) US distributed devices and are compatible with the Arthrex Continuous Wave III Arthroscopy Pump (K024291) and the new Arthrex Dual Wave Arthroscopy Fluid Management Device, subject of this pre-market notification.

US Class I devices that are pre-market notification exempt may be distributed with the device, one example is:

AR-6481	Dual Wave Cart
---------	----------------



## 6 Device Labeling

### 6.1 Device Labels

Representative labels are provided for the Arthrex Dual Wave Arthroscopy Fluid Management Device and tubing (sterile) in the Appendix.

### 6.2 Manual, Instructions for Use (IFU) / Directions for Use (DFU)

A draft Arthrex Dual Wave Arthroscopy Fluid Management Device manual is provided in the Appendix.

Draft DFUs for sterile tubing and the remote (AR-6482) are also provided in the Appendix.

### 6.3 Marketing Materials

Final U.S. marketing materials for the Arthrex Dual Wave Arthroscopy Fluid Management Device have yet to be finalized. The materials will be similar in layout to the current marketing materials for other Arthrex devices cleared for U.S. distribution.

## 7 Shelf Life

### 7.1 Shelf Life

The shelf life of the sterile accessory pump tubing devices remains unchanged at 5-years from that cleared in the Arthrex Continuous Wave III Arthroscopy Pump (K024291).

## **8 Package and Storage**

### **8.1 Packaging and Storage**

The Arthrex Dual Wave Arthroscopy Fluid Management Device non-sterile and sterile packaging materials remain unchanged from those cleared in K024291, the Arthrex Continuous Wave III Arthroscopy Pump.



## 9 Sterility and Pyrogenicity

### 9.1 Sterilization Information

The accessory tubing devices for the Arthrex Dual Wave Arthroscopy Fluid Management Device are provided sterile via ethylene oxide and are single-use devices. This remains unchanged from that which has been cleared for the Arthrex Continuous Wave III Arthroscopy Pump (K024291).

The accessory tubing devices comply with the maximum residual levels specified in ISO 10993-7, Section 4.3.3 for a limited exposure devices for ethylene oxide (EO) and ethylene chlorohydrin (ECH), as follows:

The average daily dose of EO to patient shall not exceed 20 mg.

The average daily dose of ECH to patient shall not exceed 12 mg.

The Sterility Assurance Level (SAL) remains as  $10^{-6}$ .

No pyrogenicity claims are made.

## 10 Clinical Data

### 10.1 Clinical Data

No clinical data is needed to support the determination of substantial equivalence for the ArthroX Dual Wave Arthroscopy Fluid Management Device and its accessories.

No clinical data is submitted.

## 11 Mechanical Data

### 11.1 Mechanical Data

No mechanical data is needed to support the determination of substantial equivalence for the Arthrex Dual Wave Arthroscopy Fluid Management Device and its accessories.

No mechanical data is submitted.

### 11.2 Testing

*EN -55011B (EMC 89/336/CEE): Emission Requirements and IEC-60601-1(73/23/CEE): Medical electrical equipment, General Requirements for Safety* testing is being performed and will be completed prior to marketing release of the device.

EN -55011B (EMC 89/336/CEE): Emission Requirements

IEC-60601-1 (73/23/CEE): Medical electrical equipment, General Requirements for Safety

## 12 Substantial Equivalent Predicate Devices

The fundamental scientific technology of the Arthrex Dual Wave Arthroscopy Fluid Management Device has not changed from the previously cleared Arthrex Continuous Wave III Arthroscopy Pump (K024291); nor is it different than that of the Future Medical Systems Duo Pump (K954465).

The Arthrex Dual Wave Arthroscopy Fluid Management Device is substantially equivalent to the following two predicate devices where basic features and intended uses are the same or very similar.

### **K024291: Arthrex Continuous Wave III Arthroscopy Pump**

### **K954465: Future Medical System Duo Pump**

Any design differences between the Arthrex Dual Wave Arthroscopy Fluid Management Device and the originally cleared Arthrex Continuous Wave III Arthroscopy Pump are considered minor and do not raise any new questions concerning safety and effectiveness.

### 13 Similarities and Differences with Marketed Devices

By definition, substantial equivalence means that a device has the same intended use and technological characteristics as a predicate device. It might also have the same intended use and different technological characteristics, and demonstrate that it is as safe and effective as a predicate device without raising questions regarding safety and effectiveness.

The fundamental scientific technology of the Arthrex Dual Wave Arthroscopy Fluid Management Device has not changed from the previously cleared Arthrex Continuous Wave III Arthroscopy Pump (K024291).

The Arthrex Dual Wave Arthroscopy Fluid Management Device is substantially equivalent to the predicate device where basic features and intended uses are the same. Any design differences between the Arthrex Dual Wave Arthroscopy Fluid Management Device and the originally cleared Arthrex Continuous Wave III Arthroscopy Pump (K024291) are considered minor and do not raise any new questions concerning safety and effectiveness.

In addition, the Arthrex Dual Wave Arthroscopy Fluid Management Device is substantially equivalent to a predicate competitor device, the Future Medical Systems (FMS) DUO arthroscopy pump (K954465) (marketed by DePuy

(b)(4)

Based on the information submitted, Arthrex, Inc. has determined that the Arthrex Dual Wave Arthroscopy Fluid Management Device is substantially equivalent to the cleared Arthrex Continuous Wave III Arthroscopy Pump (K024291) and the cleared FMS DUO arthroscopy pump (K954465).

Refer to Table 13-1 for a comparison of the similarities and differences between the cleared Arthrex Continuous Wave III Arthroscopy Pump (K024291), the cleared FMS DUO arthroscopy pump (K954465) and the new device, the Arthrex Dual Wave Arthroscopy Fluid Management Device.

DJA 00060

 TRADITIONAL 510(k): Arthrex Dual Wave Arthroscopy Fluid Management Device

Table 13-1 Comparison of the Predicate Device to the Modified Device

<b>Similarities and Differences</b>	<b>Arthrex Dual Wave Arthroscopy Fluid Management Device AR-6480 Current SPECIAL submission</b>	<b>Arthrex Continuous Wave III Arthroscopy Pump AR-6475 CLEARED submission (K024291)</b>	<b>Future Medical Systems DUO arthroscopy pump CLEARED submission (K954465)</b>
<b>Intended Use</b>	Identical	Identical	Similar
<b>Indications for Use</b>	Identical	Identical	Similar
<b>Pump Type</b>	Roller	Roller	Roller
<b>Tubing Material</b>	PVC	PVC	PVC
<b>Flow Rate</b>	(b)(4)	Inflow: 0-1600 mL/min Outflow: NA	Inflow: 0-1600 mL/min Outflow: 0-800 mL/min
<b>Regression</b>	Identical	Identical	Unknown
<b>Pressure</b>	0-180 mmHg	0-180 mmHg	0-180 mmHg
<b>Electronic Pressure Check</b>	Continuous	Continuous	Continuous
<b>Senses Shaver</b>	Yes	No	Yes
<b>Footswitch Control</b>	Yes	No	Yes
<b>Remote Control</b>	Yes	Yes	No
<b>Manufacturing</b>	Similar	Similar	Similar
<b>Power</b>	80-264 VAC 47-63HZ 150 VA 6.5 amps	100-240VAC 50/60 Hz 100 VA 2.0 amps	120-230 VAC 50/80 Hz 500 VA 5.0 amps
<b>Packaging</b>	Identical	Identical	Similar
<b>Non-sterile/Sterile</b>	Identical	Identical	Identical
<b>Shelf Life</b>	Identical	Identical	Identical

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**Dual Wave Arthroscopy Fluid Management Device**

*Draft*  
*12/11/2008*

REF AR-6480

LOT XXXXXX

QTY 1

Rx ONLY

PNXXXXX RX



00001 OF 1

  
Arthrex, Inc.  
Naples, FL 34109, USA  
(800) 934-4404



EC REP

Arthrex Med. Inst GmbH  
85767 Karlsfeld, Germany  
+49 8131 5957-0



REF AR-6480



LOT XXXXXX



QTY 1

 XXXX-XX

**Dual Wave Arthroscopy Fluid Management Device**

REF AR-6480

LOT XXXXXX

QTY 1





TABLE 'A'							
REF NO	PART NO	USED ON	QTY	DESCRIPTION	GRAPHIC	CE MARK	DFU
AR-6210	PB641001-00	POUCH	1	Arthroscopy Pump Tubing	A		
AR-6210	PB641001-01	BOX	10	Arthroscopy Pump Tubing	A		
AR-6220	PB641001-02	POUCH	1	Arthroscopy Extension Tubing	B	CE 0066	⚠
AR-6220	PB641001-03	BOX	20	Arthroscopy Extension Tubing	B	CE 0066	⚠
AR-6410	PB641001-04	POUCH	1	Arthroscopy Pump Tubing	A	CE 0065	⚠
AR-6410	PB641001-05	BOX	10	Arthroscopy Pump Tubing	A	CE 0065	⚠
AR-6411	PB641001-06	POUCH	1	ReDeuce™ Tubing System, Pump	C	CE 0066	⚠
AR-6411	PB641001-07	BOX	10	ReDeuce™ Tubing System, Pump	C	CE 0066	⚠
AR-6421	PB641001-08	POUCH	1	ReDeuce™ Tubing System, Patient	D	CE 0066	⚠
AR-6421	PB641001-09	BOX	20	ReDeuce™ Tubing System, Patient	D	CE 0066	⚠

GRAPHIC (FROM TABLE 'A')			
GRAPHIC 'A'	GRAPHIC 'B'	GRAPHIC 'C'	GRAPHIC 'D'
<p>ASSEMBLY TO PUMP</p> <p>TO PATIENT OR EXTENSION TUBING (REF AR-6220)</p>	<p>ASSEMBLY TO MAIN TUBING</p> <p>CONNECT TO MAIN TUBING</p> <p>TO PATIENT</p>	<p>ASSEMBLY TO PUMP</p> <p>TO PATIENT OR EXTENSION TUBING (REF AR-6421)</p>	<p>ASSEMBLY TO MAIN TUBING</p> <p>CONNECT TO AR-6411</p> <p>TO PATIENT</p>

<p><b>Arthrex</b> 1370 Creekside Blvd. Naples, FL 34108-1945 USA Phone (239) 643-5553 Fax (239) 591-6994</p>	DWG NO: <b>PB641001</b>	
	SHEET # <b>2 OF 2</b>	REV # <b>8</b>
APPROVED BY: S. Riley	DATE: 06/12/07	



# Dual Wave Arthroscopy Pump

## *User's Guide*

The *Arthrex Dual Wave Arthroscopy Pump User's Guide* provides important information for the safe operation of all components of the Arthrex Dual Wave Arthroscopy Pump (Model AR-6480), including accessories. Read this *User's Guide* thoroughly prior to using this system and keep it in an easily accessible place for use by all operating personnel. Read and follow all safety warnings, cautions, and precautions.

U.S. Patent No. 5,520,638

■ Arthrex, Inc.

Naples, FL 34108-1945 USA

Toll Free: +1 800 934-4404

[www.arthrex.com](http://www.arthrex.com)

**EC REP** Arthrex Med. Inst. GmbH

85757 Karlsfeld, Germany

Telephone: +1 49 81 31 59 57 290

[www.arthrex.de](http://www.arthrex.de)

# AR-6480

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**ArthroCare** Dual Wave Arthroscopy Pump User's Guide

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## 1.0 Read This First!

### 1.1. Important Symbols and Conventions

The *Dual Wave Arthroscopy Pump User's Guide* identifies critical, important, and useful information using these symbols and conventions. Your familiarity with these symbols and conventions is required.

## W A R N I N G !

The WARNING! symbol identifies *critical information* that must be followed precisely to avoid injury or death. The WARNING! symbol is the most important safety symbol.



The CAUTION! symbol identifies *important methods and procedures* that must be followed to avoid damaging the device or causing it to malfunction.

**NOTE:** This symbol identifies useful information that can simplify the setup and operation of this device.

[x] Square brackets that enclose a letter, a number, or a lower-case roman numeral reference a callout on a line drawing. Section 2.2, Product Features, includes line drawings of all products associated with the AR-6480. Each line drawing has its own callout system to identify important elements of each product.

### 1.2. Shipping, Unpacking, and Warranty Information

Prior to use in a surgical procedure, carefully unpack and inspect the components for any sign of damage that may have occurred during shipping. If shipping damage is suspected, notify Arthrex or any authorized Arthrex distributor immediately. Any such damage could compromise patient safety.

If shipping or first-installation damage is not reported within seven business days of receiving the device, the warranty could be rendered void. Refer also to our General Terms of Business.

Arthrex assumes a warranty to the first purchaser for a twelve month period with regard to defects or failure of its medical devices. All defective products covered by the warranty are repaired or replaced free of charge by Arthrex at their discretion. The warranty does not cover any damage caused by unlawful use or improper handling of a product.

The warranty becomes invalid when Arthrex products are changed in any way or repairs are performed by any party other than Arthrex.

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**Arthrex** Dual Wave Arthroscopy Pump User's Guide

Arthrex will answer any questions referring to the quality, reliability and/or shelf life of any product identified in this *User's Guide*.

### 1.3. Important Safety Information

## W A R N I N G !

This device is to be used only under the supervision of a trained and licensed physician. This device should not be used by untrained personnel or used for indications other than those described in this *User's Guide*.



**U.S. Federal Law restricts this device to use only by or on order of a physician.**



**DO NOT—under any conditions or for any reason—remove the cover of the AR-6480.**

*NOTE: Read this User's Guide thoroughly before attempting to operate the device and retain for future reference.*

Users of this device are encouraged to contact their Arthrex representatives if, in their professional judgment, they require a more comprehensive surgical technique.

## 2.0 Product Description

### 2.1. Functional Description and Intended Use

The Arthrex AR-6480 Dual Wave Arthroscopy Pump is a safe, reliable, user-friendly system that maintains constant, non-pulsed control of intraarticular rinsing and distention pressure throughout all phases of an arthroscopic surgical procedure.

The AR-6480 includes:

- A universal input-grade switching power supply that allows the pump to function automatically at voltage ranges found worldwide;
- A reprogrammable micro controller with upgradeable software that supports multilingual messaging;
- Touch panel display for user inputs
- A Lavage function for providing elevated pressure to stop bleeding and Rinse function to clear joint spaces quickly.

- Universal shaver-detect system design to automatically control aspiration through the shaver hand piece.

The AR-6480 is intended to provide continuous pulse-free flow that reacts immediately to changes in the intraarticular pressure so that joint distention can be sustained even under high shaver extraction volumes or secondary outflow. The user-defined settings for inflow pressure and outflow rates are adjustable through controls located on the touch panel screen or on the remote control.

There are **four pump tubing options** for the AR-6480:

1. *Main Pump Tubing Set only.* This tubing, when used alone, must be replaced after each patient.
2. *Main Pump Tubing Set and Extension Tubing combination.* The Main Pump Tubing Set can be reused for an entire surgical day, while the Extension Tubing must be replaced after each patient.
3. *ReDeuce™ Pump Tubing and ReDeuce™ Patient Tubing combination.* The ReDeuce™ Pump Tubing can be reused for an entire surgical day, while the ReDeuce™ Patient Tubing must be replaced after each surgical procedure. The ReDeuce™ system offers a higher flow rate than the Main Pump Tubing Set/Extension Tubing combination.
4. *Outflow Tubing.* When the Outflow tubing is attached to the AR-6480, the pump changes from an inflow-only to an inflow-outflow arthroscopy pump.

The optional *Y-Tubing* connects up to four irrigation bags and can be used with all AR-6480 pump tubing options.

The AR-6480 can be used as an inflow-only irrigation pump or when outflow tubing is used the pump function as an inflow/outflow fluid management system.

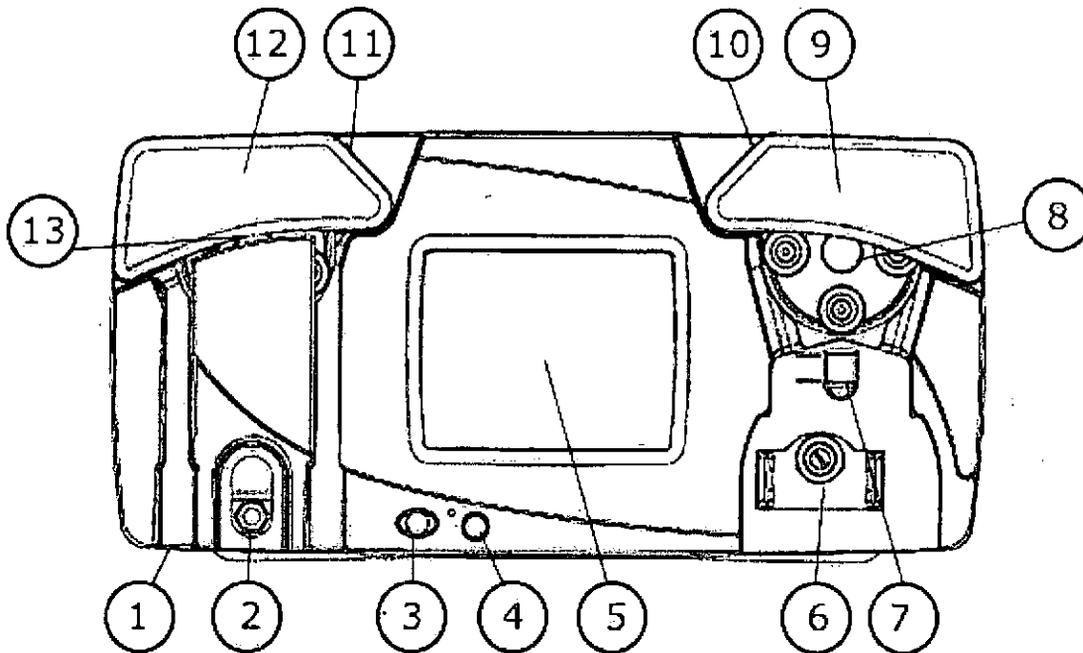
## 2.2. Product Features

### 2.2.1. Console: Front Panel

**Amn** Dual Wave Arthroscopy Pump User's Guide

Figure 1 uses a *numeric* callout system to identify the main elements of the console's front panel, which are listed and labeled in Table 1. These callouts are referenced throughout this *User's Guide*.

**FIGURE 1 FRONT PANEL OF CONSOLE**



**TABLE 1 FRONT PANEL ELEMENTS**

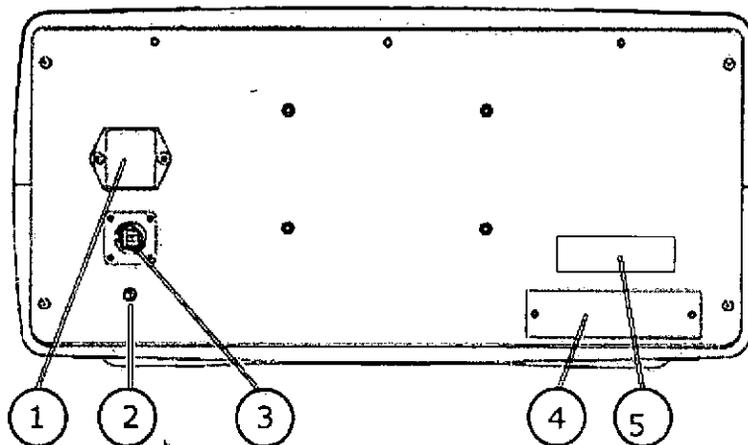
ELEMENT NUMBER	ELEMENT NAME
1	Inflow tubing track
2	Tubing sensor indicator LED: A steady green LED indicates that the tubing is connected properly. A flashing red LED indicates that the tubing is not present or that it is connected incorrectly
3	Main Power switch
4	Remote Control/foot pedal connector
5	Touch Panel Visual Display (TPVD)
6	Suction tubing pinch roller
7	Outflow tubing sensor
8	AC mains power toggle switch
9	Outflow roller assembly
10	Outflow door
11	Outflow door locking mechanism
12	Inflow door locking mechanism
13	Inflow Door

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### 2.2.2. Console: Rear Panel

Figure 2 uses an *alphabetic* callout system to identify the main elements of the console's rear panel for both new and old pump versions. These callouts are also listed and labeled in Table 2 and referenced throughout this *User's Guide*.

**FIGURE 2 REAR PANEL OF CONSOLE**



**TABLE 2 REAR PANEL ELEMENTS**

ELEMENT LETTER	ELEMENT NAME
1	AC mains power plug socket and ratings
2	Equipotential ground connector and symbol
3	Shaver Detect power socket
4	Date of manufacture and serial number label
5	Access panel (on some units)

### 2.2.3. Touch Panel Visual Display: Status and Error Messages

The console's Touch Panel Visual Display (TPVD) [6] conveys information about the status of the AR-6480 and the pressure and flow settings in real time. Table 3 describes each message.

**TABLE 3 TOUCH PANEL VISUAL DISPLAY MESSAGES AND ICONOGRAPHY**

MESSAGE	CAUSE	EXPLANATION
<b>Arthrex Dual Wave</b>	Message displayed when the AC mains power is actuated.	Power on message display
<b>Remote icon</b>	Icon displayed when the remote is attached.	Remote connected
<b>Foot Pedal Icon</b>	Icon displayed when the foot pedal is attached.	Foot pedal connected
<b>+</b>	Pressure increase button.	Pressure set increase
<b>-</b>	Pressure decrease button	Pressure set decrease
<b>* Check Tube *</b>	Message displayed when no tubing is plugged into the Tubing Sensor Coupler [17].	Check tubing installation
<b>* Door Not Closed *</b>	Message displayed when the roller housing door [4] is not fully closed.	Roller housing door is not closed
<b>Self Test V X.XX</b>	Displayed prior to running a self-test.	Pump self-test
<b>Power Supplies OK</b>	Displayed after a successful power supply test.	Power supply test passed
<b>* Over Pressure *</b>	Displayed when the sensed pressure exceeds over-pressure software limit of 300 mmHg.	Software overpressure condition
<b>Critical Failure</b>	Displayed on the first line of the VFD if one of three conditions is met: <b>Failure Condition 1: * Power Failure *</b> Displayed on the TPVD if the power supply self-test fails when the pump is turned on. <b>Failure Condition 2: * OVP Detect Fail *</b> Displayed on the TPVD if the hardware overpressure diagnostic test fails when the pump is turned on. <b>Failure Condition 3: * Sensor Failure *</b> Displayed on the TPVD if the pump detects a problem with the pressure sensors.	Critical failure, cannot continue operation
<b>* Power Failure *</b>	Displayed on the TPVD if the power supply self-test fails when the pump is turned on.	Power supply test fails
<b>* OVP Detect Fail *</b>	Displayed on the TPVD if the hardware overpressure diagnostic test fails when the pump is turned on.	Hardware overpressure diagnostic fails
<b>* Sensor Failure *</b>	Displayed the TPVD if the pump detects a problem with the pressure sensors.	Sensor failure
<b>* Pressure Fault *</b>	Displayed when the pump is unable to reach a desired set pressure within a specific amount of time. This typically indicates improperly installed tubing set or a split in the tube from continuous use.	Insufficient measured pressure
<b>RUN</b>	Displayed when the pump is stopped, if depressed the pump will start running	Motor on and running

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MESSAGE	CAUSE	EXPLANATION
<b>STOP</b>	Displayed when the pump is running, if depressed the pump will stop running	Motor on and flushing
<b>LAVAGE</b>	Displayed when the pump is in inflow/outflow mode, if depressed the pump will increase pressure by a user defined amount for a user defined length of time.	Motor off
<b>RINSE</b>	Displayed when the pump is in inflow/outflow mode, if depressed the pump will increase outflow by a user defined amount for a user defined length of time.	Outflow rate increased
<b>FLUSH</b>	Displayed when the pump is in inflow only mode, if depressed the pump will increase pressure by a user defined amount for a user defined length of time.	Pressure increased
<b>MENU</b>	Displayed when the pump is stopped. If depressed the pump will enter the set-up menu	User setups displayed
<b>OUTFLOW</b>	Displayed when the pump is in inflow/outflow mode. If depressed, The used may define the outflow rate	Outflow rate increased
<b>SHAVER</b>	Displayed when the pump is in inflow/outflow mode. If depressed, The used may define the outflow rate of the shaver.	Shaver suction increased

**2.2.4. Pressure Reading/Setting**

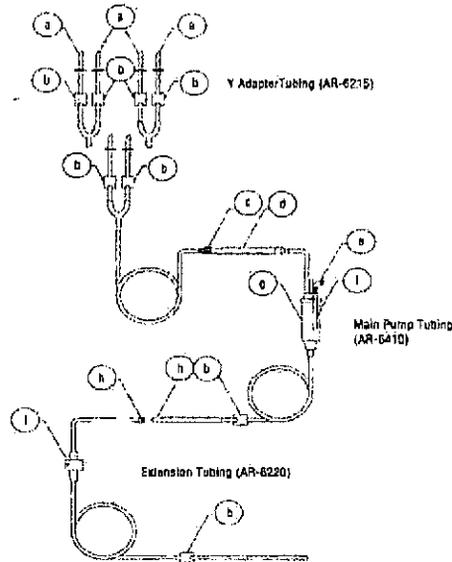
The TPVD displays the pressure reading until either the PRESSURE (+) or the PRESSURE (-) buttons are depressed. On the first actuation of either of these buttons, the displayed pressure reading will change to the pressure setting. Each subsequent actuation of the pressure buttons will change the pressure setting in increments of 5.

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**2.2.5. Tubing: Configurations**

Figure 3, Figure 4, and Figure 5 show the tubing combinations supported by the AR-6480.

**FIGURE 3 MAIN PUMP TUBING CONFIGURATION**

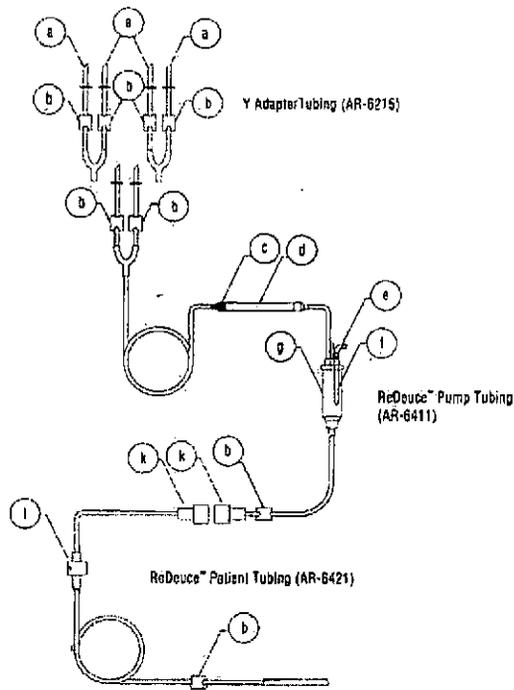


**TABLE 4 ELEMENTS OF THE MAIN PUMP TUBING CONFIGURATION**

ELEMENT	DESCRIPTION	TUBING SET
a	Bag spikes	Y-Adapter Tubing
b	Tubing clamps	Y-Adapter Tubing Main Pump Tubing Extension Tubing
c	Green connector	Main Pump Tubing
d	Tubing boot	Main Pump Tubing
e	Pressure line connector	Main Pump Tubing
f	Neoprene tube for sensing pressure fluctuations	Main Pump Tubing
g	Sensor chamber	Main Pump Tubing
h	Connector fittings	Main Pump Tubing Extension Tubing
i	Backflow check valve	Extension Tubing

Article 6 Dual Wave Arthroscopy Pump User's Guide

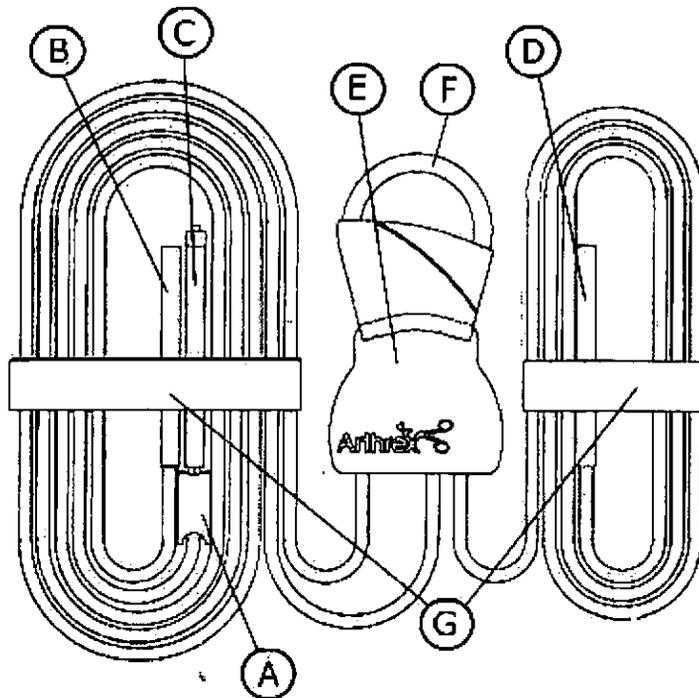
**FIGURE 4** ReDeuce™ TUBING CONFIGURATION



**TABLE 5** ELEMENTS OF THE ReDeuce™ TUBING CONFIGURATION

ELEMENT	DESCRIPTION	TUBING SET
a	Bag spikes	Y-Adapter Tubing
b	Tubing clamps	Y-Adapter Tubing ReDeuce Pump Tubing ReDeuce Patient Tubing
c	Green connector	ReDeuce Pump Tubing
d	Tubing boot	ReDeuce Pump Tubing
e	Pressure line connector	ReDeuce Pump Tubing
f	Neoprene tube for sensing pressure fluctuations	ReDeuce Pump Tubing
g	Sensor chamber	ReDeuce™ Pump Tubing
k	High flow, dual lumen connectors	ReDeuce™ Pump Tubing ReDeuce™ Patient Tubing
l	Backflow check valve	ReDeuce™ Patient Tubing

**FIGURE 5** OUTFLOW TUBING CONFIGURATION



**TABLE 6** ELEMENTS OF THE OUTFLOW TUBING CONFIGURATION

ELEMENT	DESCRIPTION	TUBING SET
A	Tubing clamp	Outflow
B	Shaver attachment	Outflow
C	Cannula attachment	Outflow
D	Waste egress	Outflow
E	Outflow Fixture	Outflow
F	Tubing loop for Outflow roller	Outflow
G	Paper retaining strap	Outflow

**2.2.6. Tubing: Main Pump Tubing Set**

The Main Pump Tubing Set offers inflow/pressure measurement tubing that, if used alone, must be *completely discarded* following each surgical procedure. It has the following components in each set: bag spikes, drip chamber, flexible boot for pump rollers, and a Luer connector for a scope sheath or other inflow. The Main Pump Tubing is 13 feet (4.0 meters) in length.

*NOTE:* This User's Guide assumes that you are using either the Main Pump Tubing alone or in combination with the Extension Tubing, below. Refer to the Directions for Use that accompany each tubing set for specific information or contact your Arthrex representative.

**2.2.7. Tubing: Extension Tubing System**

The unique Extension Tubing System provides the economical option of using the Main Pump Tubing Set for an entire surgical day and replacing

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only the Extension Tubing Set after each individual surgery. The backflow check valve built into the Extension Tubing System prevents fluid backflow into the Main Pump Tubing, maintaining a closed sterile fluid environment during tubing replacements. The Extension Tubing is 8.5 feet (2.6 meters) in length.

### 2.2.8. Tubing: ReDeuce™ Pump Tubing

The ReDeuce™ Pump Tubing provides an alternative to complete replacement of the irrigation tubing after each patient. The backflow check valve of the ReDeuce™ Patient Tubing prevents contaminated fluid from reaching the ReDeuce™ Pump Tubing, and permits its use for the entire surgical day. The ReDeuce™ Pump Tubing must be used with the ReDeuce™ Patient Tubing.

### 2.2.9. Tubing: ReDeuce™ Patient Tubing

The ReDeuce™ Patient Tubing must be used in the first arthroscopic procedure of the surgical day and replaced for each subsequent surgical procedure. It is used in conjunction with the ReDeuce™ Pump Tubing.

### 2.2.10. Tubing: Y-Adapter Tubing

The optional Y-Adapter Tubing can connect up to four irrigation bags. It can be used with either the Main Pump Tubing/Extension Tubing combination or the ReDeuce™ Pump Tubing/ReDeuce™ Patient Tubing combination.

### 2.2.11. Tubing: Outflow Tubing

The optional Outflow Tubing can be used with either the Main Pump Tubing Set or the ReDeuce™ Pump Tubing. It provides precisely controlled outflow from the shaver and a carinula (optional) to a waste container.

### 2.2.12. Remote Control Unit (AR-6482)

The AR-6480 Dual Wave Arthroscopy Pump can be remotely controlled with the optional, autoclavable Remote Control (AR-6482). It provides the ability to control pressure adjustments, a Lavage function, a Rinse function, controls shaver suction, and the ability to activate/deactivate the pump motor. The remote control is 9.8 feet (3 meters) in length.



**Do not disconnect the plug of the remote control by pulling on the cable. Remove the remote control plug by grasping and pulling on the body of the connector.**

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Figure 6 uses a lowercase roman numeral callout system to identify the main elements on the remote control, which are listed and labeled in Table 7. These callouts are referenced throughout this User's Guide.

FIGURE 6 REMOTE CONTROL (AR-6482)

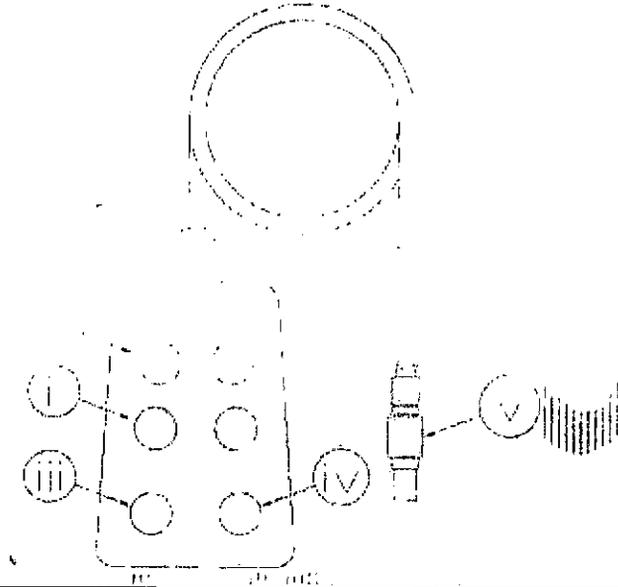


TABLE 7 REMOTE CONTROL ELEMENTS (AR-6482)

ELEMENT NUMERAL	ELEMENT NAME
i	R and L. Rinse and Lavage. R increases the outflow rate by a rate and time selected by the user. L increases the pressure by a percentage and time selected by the user.
ii	Pressure Set buttons and symbol. Increase or decrease target pressure in the joint space by five mmHg on a scale of 10 to 120 mmHg.
iii	Run/Stop.
iv	Cycles through the available shaver suction settings.
v	Lemo connector to attach to the corresponding plug on the rear panel of the AR-6480.

2.2.13. Foot Pedal Unit (AR-6482)

The AR-6480 Dual Wave Arthroscopy Pump can be remotely controlled with the optional, Foot Pedal (AR-6483). It provides a Lavage function and a Rinse function. See Figure 7 and Table 8.

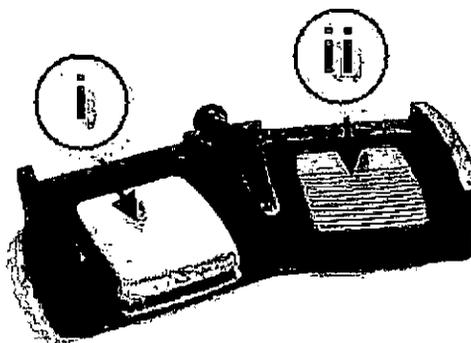


**Do not disconnect the plug of the foot pedal by pulling on the cable. Remove the foot pedal plug by grasping and pulling on the body of the connector.**

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**FIGURE 7 FOOT PEDAL UNIT (AR-6482)**



**TABLE 8 REMOTE CONTROL ELEMENTS (AR-6482)**

ELEMENT NUMERAL	ELEMENT NAME
i	R increases the outflow rate by a rate and time selected by the user.
ii	L increases the pressure by a percentage and time selected by the user.

**2.3. Technical Specifications**

**TABLE 9 CONTROL UNIT (AR-6480) SPECIFICATIONS**

<b>Width</b>	14.5 inches (36.5 cm)
<b>Height</b>	5.0 inches (12.5 cm)
<b>Depth</b>	12 inches (30 cm)
<b>Weight</b>	18 pounds (8.2 kg)
<b>Maximum Flow rate</b>	1500 ml/minute minimum
<b>Pressure</b>	Measured in percent with a range of 10-100 percent in increments of 10 percent. Default flow rate at power-up is 100 percent
<b>Overpressure control</b>	0-120 mmHg
<b>Pressure control</b>	Measured in mmHg in increments of 1 mmHg. Default pressure set at power-up is 0 mmHg
<b>Operating mode</b>	300mmHg
<b>Water protection</b>	Continuous pressure checking.
<b>Main cable</b>	Permanent
<b>Connector</b>	IPX1
<b>Jack</b>	10 A/250 V
<b>Power supply</b>	CEE 7/7
<b>Fuse</b>	IEC 320/C13
<b>Cleaning</b>	100-240 V, 50/60 Hz, 2A
<b>Sterilization</b>	2.0A 250V
	Surface cleaning with mild detergent
	Surface disinfection with mild disinfectant

**TABLE 10 AMBIENT CONDITIONS FOR OPERATION**

<b>Temperature</b>	50° to 104°F (10° to 40°C)
<b>Relative Humidity</b>	0% to 100%, non-condensing
<b>Air pressure</b>	10.15 PSI (700 hPa) to 15.37 PSI (1060 hPa)

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**TABLE 11 AMBIENT CONDITIONS FOR STORAGE (IN SHIPPING PACKAGING)**

<b>Temperature</b>	-40° to 158°F (-40° to +70°C)
<b>Relative Humidity</b>	0% to 100%, non-condensing

**TABLE 12 REMOTE CONTROL (AR-6481) SPECIFICATIONS**

<b>Width</b>	2.5 inches (63.5 mm)
<b>Height</b>	3.8 inches (95.3 mm)
<b>Depth</b>	0.9 inches (22.2 mm )
<b>Weight</b>	0.5 lbs. (0.23 kg)
<b>Cable length</b>	9.8 feet (3 m )
<b>Cleaning</b>	Surface cleaning with mild detergent
<b>Sterilization</b>	Autoclave

**FOOT PEDAL (AR-6482) SPECIFICATIONS**

<b>Width</b>	13 inches (330 mm)
<b>Height</b>	7 inches (178 mm)
<b>Depth</b>	3 inches (76 mm )
<b>Weight</b>	11 lbs. (0.23 kg)
<b>Cable length</b>	10 ft feet (3 m )
<b>Cleaning</b>	Surface cleaning with mild detergent
<b>Sterilization</b>	No

## 3.0 Setup

Users of this device are encouraged to contact their Arthrex representatives if, in their professional judgment, they require a more comprehensive surgical technique.

### 3.1. AC Power Safety Considerations

The AR-6480 is powered by a medically rated universal AC input switching power supply, which allows the console to be connected to any local AC mains outlet provided that you use the appropriate plug and a reliable ground conductor.

Three power cords are supplied by default with the AR-6480: one for the electrical standards of the U.S., one for the electrical standards of Germany and one to supply power to a shaver system. Contact your Arthrex representative if you need a power cord that must meet the electrical standards of another country.

*NOTE: Extension cords must meet local electrical standards.*

The console has been designed to meet power-saving guidelines. The console has an AC mains switch on the front panel [8]. When the AC mains switch is OFF, no electrical power is drawn by the console.

When the AC mains switch is ON, the console automatically executes a brief series of self-diagnostic tests. Upon successful completion of these tests, the console displays on the TPVD [6] the name and model number, *Arthrex AR-6480*. If the tests discover a problem, an error message will be displayed on the TPVD. Refer to Table 3 for a complete list of TPVD Messages.

In the event of an AC power interruption, the console can run continuously without fault for up to 10 milliseconds. If an AC power failure lasts longer than 10 milliseconds, the system will reset to default settings when AC power is restored.

## W A R N I N G !

If high-frequency devices are in use, or defibrillation of the patient is required, ensure that the device is not in direct contact with the patient.

### 3.2. How to Determine if the AR-6480 is Causing Interference to Other Devices



This device has passed testing for EMI / RFI radiation and susceptibility and EMC compatibility. However, if not set up and used in accordance with the instructions provided by ArthroCare, this device may cause interference to other devices in the vicinity.

1. Power OFF the AC mains power switch [8] and then ON again. Try to correct the interference by following one or more of these measures:
2. Reorient or relocate the receiving device.
3. Increase the separation between devices.
4. Connect the device to an outlet on a circuit different from that to which the other device(s) are connected.
5. Consult the manufacturer or field service technician for the receiving device for guidance.

### 3.3. Basic Setup Procedure for the AR-6480

**NOTE:** Section 4.0, Operation, explains how to use the pump.

1. Place the AR-6480 on a flat, dry surface, such as an arthroscopy equipment cart or a small instrument table.
2. Connect the female end of the power cord for the AR-6480 into the AC socket [A] and the male end to the facility AC mains supply. Turn on the AR-6480 [8].
3. Verify the status of the AR-6480 displayed in the TPVD [6].
4. Connect the tubing in accordance with Section 3.4 or 3.5.
5. Close the roller housing doors.
6. If applicable, attach the Remote Control [v, C].
7. Refer to Section 4.0, Operation, for specific information on how to operate the AR-6480, including pressure and flow settings.
8. Press the Run/Stop button [10] to activate the pump motor.

### 3.4. How to Set Up the Pump Tubing

**NOTE:** These instructions describe the procedure to set up the Main Pump Tubing or the ReDeuce™ Pump Tubing.

1. Remove the orange cap from the Pump Tubing and insert the connector fitting [e] of the Pump Tubing into the Tubing Sensor Coupler [17]. **This step must be completed first to ensure accurate pressure measurements.**
2. Open the inflow door completely. Allow the door to rest against the stop. The roller mechanism is now exposed.
3. Place the green-collared section of the Pump Tubing [c] into the Tubing IN Guide [1] indicated by the green dot [2].
4. Guide the tubing boot [d] over the rollers and insert the output side of the tubing boot into the Tubing OUT Guide [1].

**NOTE:** The Pump Tubing is connected properly when the green connector [c] on the Main Pump Tubing is aligned with the green dot [2] on the front panel of the console.

5. Close the inflow door.

**NOTE:** If door is not closed securely an internal safety switch prevents the AR-6480 from operating.

6. Puncture the fluid bags with the spikes on the tubing. If only one fluid bag is being used, seal the second fluid line by closing the clamp nearest the unused spike.

### 3.5. How to Set Up the Two-Piece Tubing System

**NOTE:** These instructions describe the procedure to set up the Extension Tubing or ReDeuce™ Patient Tubing.

## WARNING!

The Extension or Patient Tubing must be changed for each patient.

1. The surgical staff removes the sterile Extension or Patient Tubing from its sterile pack and hands the connector [h or k] for the Pump Tubing set to the circulating nurse.
2. The circulating nurse connects the two tubing systems together [h to h in Figure 3 or k to k in Figure 5].
3. Attach the sterile connector cap (supplied with each Extension or Patient Tubing set) to the patient-end of the Pump Tubing.

**NOTE:** Following each surgery, detach and discard the Extension or Patient Tubing Set.

## WARNING!

The sterile connector cap must be used to cover the Pump Tubing Set connector after each surgical procedure. This maintains sterility of the Pump Tubing and assures its safe operation throughout the entire surgical day.

### 3.6. How to Set up the Outflow Tubing

1. Open outflow door completely.
2. Placing looped tubing around the roller assembly.
3. Pull tube set down until it slides into the outflow tubing receiver.
4. If pump is on, the pump should now detect the tubing and change the pump setting to inflow and outflow controls.
5. Close the outflow door.

### 3.7. How to Change the Language Setting

The AR-6480 supports English, French, German, Italian, and Spanish. The default language is English. To change the language setting for VFD messaging, follow these instructions.

1. Power ON the AC mains power switch [8] on the AR-6480.
2. Press the Menu button.
3. Press the language button.
4. Select desired language.
5. Press ok, the language is now stored in memory

### 3.8. How to Test the Power Supply Voltages and VFD

1. Power ON the AC mains power switch [8] on the AR-6480.
2. Press the Menu button.
3. Press The Diagnostics button
4. Pump should run a diagnostics test and display the results.

### 3.9. How to Verify Safe Setup and Performance before Use

#### 3.9.1. Pressure Reading on the Display

The pump runs as an **open system** in nearly all applications: inflow and outflows are open (the outflow on the sheath or the outflow over the optical and working portals).

Under this system, the 50 mmHg shown on the display corresponds to the actual pressure in the joint. If there is a fall in pressure, the pump increases pressure up to 50 mmHg and then stops.

In contrast is the case of the **closed system** (100% impermeable joint and no egress of water whatsoever via the portals; occurs, for example, at a pressure measurement at the end of the applied part.

A dynamic pressure arises here which is increased by a factor of 2.2 (at a setting of 50 mmHg there is thus a max. of 110 mmHg). The pump stops when this value is reached. Refer to Table 13.

TABLE 13 PRESSURE READINGS FOR A CLOSED SYSTEM

Joint	Pressure reading on display	Actual pressure in open systems	Theoretical maximum pressure in closed systems
Knee	35 – 60 mmHg	35 – 60 mmHg	77 – 132 mmHg
Hip	35 – 60 mmHg	35 – 60 mmHg	77 – 132 mmHg
Shoulder	60 – 80 mmHg	60 – 80 mmHg	132 – 176 mmHg
Small joints	50 – 70 mmHg	50 – 70 mmHg	110 – 154 mmHg
Overpressure	136 mmHg	136 mmHg	300 mmHg

#### 3.9.2. Pressure Verification Procedure for the AR-6480 Arthroscopy Pump

Pressure verification of the AR-6480 is accomplished in the following manner. For best results, a "quick tips" section follows the procedural information.

1. Set up the AR-6480 as specified on the Directions For Use card contained in the tubing packaging, or as specified in the Operating Instruction Manual on pages 18 and 19.
2. Set the PRESSURE at 35 mmHg.

3. Prime the tubing set by turning on the pump and running fluid through the tubing until a steady flow of water exits the end of the tubing. Stop the pump by closing the clamp.
4. Attach a pressure meter to the outflow luer fitting and open the clamp. The meter should have the capability to measure up to 300 mmHg. Refer to Table 14 for meter readings.

**TABLE 14 PRESSURE VERIFICATION**

Pressure Set (mmHg)	Meter Display ( $\pm 10\%$ )
35	77
50	110
75	165
100	220
120	264

The "Pressure Set" figures shown above are arbitrary settings for information only. Recommended test settings are 35 mmHg and 75 mmHg. These two settings cover the lower and upper range of the most commonly used pressures.

As this is a static pressure reading, it is possible for the momentum of the rollers to create a higher pressure than the allowable limit, especially when the test is performed with a high flow rate. The AR-6480 was designed to maintain an average intra-articular pressure equal to the set pressure on the pump face. Without allowing an outflow, as is the case with a static test, an average pressure reading is not possible.

To obtain the best test results, please consider the following tips:

1. Use a new tubing to insure that it is at normal atmospheric pressure before the testing.
2. Follow the pump set-up procedures carefully. This will also prevent pressure from being inadvertently created within the tubing before your test begins.
3. Use the lowest flow setting (10%) when performing the test to minimize the roller momentum.
4. Start at the lowest test pressure setting and increase it to perform additional tests. If the test is started high and then lowered, the pump will not reduce its pressure, and the reading on the meter will remain the same.
5. Use reasonable pressure settings for your test. Most arthroscopies are performed at pressures between 35 and 75 mmHg.

### 3.9.3. Abnormal Operation

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The AR-6480 employs a robust dual-pressure sensor design. Microcontroller-based internal circuitry monitors the sensors, as well as other circuit parameters, to ensure that the pump remains within normal operating limits. In the event of a fault, the pump motor is automatically disabled and an error message is displayed on the TPVD [6]. See Table 3 for a complete list of TPVD messages and Section 8.0 for troubleshooting information.

*NOTE: If abnormal console operation cannot be corrected, disinfect the pump, re-package in the original shipping materials, and return to Arthroflex, accompanied by a brief description of the malfunction. Prior to shipment, it is necessary to obtain a Return Authorization Number from Arthroflex.*

### 3.9.4. Overpressure Sensing

The sensing circuitry in the AR-6480 measures the pressure of the fluid in the tubing. The overpressure alarm can be activated when the flow is abruptly interrupted or the joint is suddenly positioned in a way which reduces the joint capsule volume (e.g., bending the knee joint to the "Figure 4" position).

If an overpressure event occurs (300 mmHg within tubing and joint), a warning message reading **\*Over Pressure\*** will flash on the TPVD and an audible alarm will sound. The pump motor is automatically disabled until the pressure returns to the set range.

To reduce the pressure in a joint, open an outflow and/or manipulate the joint to a stress-free position.

### 3.9.5. Roller Housing

The pump motor automatically deactivates when the roller housing door is opened. A locking mechanism prevents access to the rotating parts while the device is operating.

### 3.9.6. Tubing Sensor Coupler

The pump motor automatically deactivates when the tubing is disconnected from the pump. If the tubing is disconnected during a case it must be replaced by new tubing. Do not reconnect the tubing to the pump as it could lead to unreliable pressure measurements.

**W A R N I N G !**

If the tubing is disconnected from the pump in the middle of a procedure it must be replaced. Do not attempt to reconnect the tubing to the pump as it could lead to unreliable pressure measurements.

**4.0 Operation**

There are four modes of operation for the AR-6480:

<b>Normal</b>	Inflow Only
<b>FLUSH</b>	Inflow Only
<b>LAVAGE</b>	Inflow/Outflow Mode
<b>RINSE</b>	Inflow/Outflow Mode

Users of this device are encouraged to contact their Arthrex representatives if, in their professional judgment, they require a more comprehensive surgical technique.

**4.1 Initial Pressure Settings**

**W A R N I N G !**

The safety and effectiveness of the AR-6480 is verified and documented; however, the AR-6480 must be used with an awareness of the risk of extra-articular edemas for patients with pathologically changed articular capsules and for procedures involving an opening of the capsule (e.g. lateral release).

Slight swellings are complications which have been observed and described in the literature in cases where roller pumps are used in arthroscopy. This build-up of fluid can lead to postoperative swellings and pathological changes in patients. It is therefore of the utmost importance that the surgeon monitors both the system and the patient closely whilst the roller pump is in operation.

Always start with the lowest possible pressure to achieve the desired joint distention. Continue to increase distention pressure until a clear liquid medium is obtained.

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Table 12 specifies the initial pressure settings that are recommended for surgery. The ideal intraarticular pressure depends on the indications for the arthroscopic procedure, bleeding tendency, and the possibility of ischemia.

**TABLE 15 INITIAL PRESSURE SETTINGS**

<b>Knee arthroscopy</b>	35 mmHg
<b>Shoulder arthroscopy</b>	50 mmHg
<b>Small joint arthroscopy</b>	35 mmHg

All settings are based on the use of a high-flow sheath or secondary inflow portal (suprapatellar, etc.). Normally, pressure settings of 10 mmHg above the patient's diastolic pressure are adequate to control capillary bleeding.

To obtain a clear fluid environment, slowly increase distention pressure beginning with the initial pressure settings in Table 12.

#### 4.2. How to Operate the AR-6480 in Normal Mode

### W A R N I N G !

The Extension or Patient Tubing must be replaced before each new surgical procedure.

1. After adjusting the required pressure using the Pressure Set buttons [14 or u], remove the cap from the patient end of the tubing.
2. Open all appropriate tubing clamps.
3. Activate the pump motor by pressing RUN [10 or iv].
4. Fill the entire length of the tubing with fluid to remove any air bubbles.

*NOTE: It is not necessary to remove the air within the Sensor Chamber [g] on the Pump Tubing Set.*

5. After the air has been purged from the tubing, close the clamp at the patient end of the tubing. The rollers [3] should stop turning. This is a safety check to ensure that the sensor system is working properly.
  - If the rollers do not stop, ensure clamp is firmly closed.
  - If the rollers turn continuously, the connector fitting [e] may not be functioning properly. Replace the Pump Tubing.

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6. Connect the tubing to the inflow cannula.

*NOTE: A high-flow arthroscope sheath should be used for optimum flow when rinsing through the inflow cannula.*

7. Open the clamp on the tubing to release the flow.

Once the set pressure is reached, the pump will reduce flow to maintain the set pressure. When the pressure drops, the flow automatically increases until the set pressure is achieved. If the set pressure cannot be attained, (i.e. no fluid restriction at the end of distal-end of tubing) flow will not exceed the user setting [11].

8. When the procedure is completed, close all clamps and disable the pump motor [10].

#### **4.3. How to Operate the AR-6480 in FLUSH Mode**

The AR-6480 pump has a FLUSH function for haemostatic purposes.

### **W A R N I N G !**

User programmed "Pressure Set" values are increased by as much as fifty percent to a maximum of 120 mmHg during the FLUSH function. Exercise caution to avoid injury to the patient.

1. Press the FLUSH button [9 or iii] to enable this function. The FLUSH button should turn color and begin a countdown. The pressure will be increased to the factory default of a 50% increase for 120 seconds or to the user defined parameters.
2. The FLUSH mode will stop when the countdown reaches zero, or if the user presses the FLUSH button a second time.

#### **4.4. How to Operate the AR-6480 in LAVAGE Mode**

The AR-6480 pump has a LAVAGE function for haemostatic purposes.

### **W A R N I N G !**

User programmed "Pressure Set" values are increased by as much as fifty percent to a maximum of 120 mmHg during the LAVAGE function. Exercise caution to avoid injury to the patient.

1. Press the LAVAGE button [9 or iii] to enable this function. The FLUSH button should turn color and begin a countdown. The

pressure will be increased to the factory default of a 50% increase for 120 seconds or to the user defined parameters.

2. The LAVAGE mode will stop when the countdown reaches zero, or if the user pressure the LAVAGE button a second time.

#### 4.5. How to Operate the AR-6480 in RINSE Mode

The AR-6480 pump has a RINSE function for irrigation purposes.

1. Press the RINSE button [9 or iii] to enable this function. The RINSE button should turn color and begin a countdown. The Outflow will be increased to the factory default of a 100% increase for 120 seconds or to the user defined parameters.
2. The RINSE mode will stop when the countdown reaches zero, or if the user pressure the RINSE button a second time.

### 5.0 Cleaning and Sterilization

#### 5.1. Console (AR-6480)

The AR-6480 is provided non-sterile and should not be sterilized.

The AR-6480 console can be cleaned/disinfected using commercially available surfactants/surface disinfectants. Always comply with the instructions issued by the manufacturer of the surfactant/disinfectant. The AR-6480 must not be submersed in any liquid.



**NEVER use liquid to clean the remote control connector contacts on the rear panel of the pump. Remove dust regularly with dry compressed air.**

#### 5.2. Remote Control (AR-6481)

The Remote Control (AR-6481) is supplied non-sterile.

The Remote Control can be autoclaved for sterilization.

Gravity displacement cycles:

270° F to 275° F (132° C – 135° C): exposure time 18 minutes

250° F (121° C): exposure time 60 minutes

Prevacuum cycle:

270° F – 275 °F (132° C – 135° C): 5 Minutes

Sterilizers vary in design and performance characteristics. Cycle parameters and load configuration should always be verified against the sterilizer manufacturer's instructions.

Cooling – The device must be adequately cooled after being removed from the sterilizer. Do not touch the device during the cooling process. Do not place the device on a cold surface or immerse it in a cold fluid.

The Remote Control can be cleaned/disinfected using commercially available surfactants/surface disinfectants. Always comply with the instructions issued by the manufacturer of the surfactant/disinfectant. It is not designed to be submersed in Glutaraldehyde, Steris®, or Sterrad® disinfectants.



**NEVER use liquid to clean the connector contacts of the remote control connector. Remove dust regularly with dry compressed air.**

### 5.3. Tubing

## W A R N I N G !

The Extension or Patient Tubing must be replaced before each new surgical procedure.

The tubing is supplied pre-packaged *sterile* by EO sterilization. Do not resterilize.

*Every Extension or Patient Tubing Set is supplied with a sterile connector cap for the Pump Tubing Set connection. Use this connector cap to cover the Pump Tubing Set connector after each surgical procedure to maintain sterility and assure safe use throughout the entire surgical day.*

## 6.0 Maintenance

Other than keeping the console and remote control clean (see Section 5.0), there is *no recommended maintenance schedule*. If the AR-6480 should malfunction, contact an ArthroCare representative or ArthroCare Technical Support.

## 7.0 Technical Support

For assistance in using the products identified in this *User's Guide*, contact an Arthrex representative or call the **Arthrex Technical Support Hotline** at 1-888-420-9393, Monday through Friday from 9:00 AM to 5:00 PM EST.

### 7.1. How to Display the Software Version

Technical Support may request the software version of the pump. These instructions explain how to display the software version.

1. Power On the AC mains power switch [8] on the AR-6480.
2. Press the Menu button.
3. Press the INFO button
4. The software version should be displayed on the TPVD.

## 8.0 Troubleshooting

Arthrex Technical Support should be informed immediately in the event of any damage or malfunction of the equipment. Attempt the remedies listed in Table 13 in the order in which they are presented.

**TABLE 16 COMMON PROBLEMS AND REMEDIES**

PROBLEM	SOLUTION
<b>* Check Tube *</b>	<ol style="list-style-type: none"> <li>1. Tubing sensor indicator not seated.</li> <li>2. Ensure that the tubing pressure plug is seated completely.</li> <li>3. Change tubing.</li> <li>4. Return to Arthrex for repair.</li> </ol>
<b>Console fails Self Diagnostic Test</b>	<ol style="list-style-type: none"> <li>1. Ensure no tubing is connected to the pump during power on sequence.</li> <li>2. Return to Arthrex for repair.</li> </ol>
<b>Console won't power up</b>	<ol style="list-style-type: none"> <li>1. Check AC mains power cord.</li> <li>2. Try alternate power outlet.</li> <li>3. Check AC mains fuses.</li> <li>4. Return to Arthrex for repair.</li> </ol>
<b>Distention liquid bloody or cloudy</b>	<ol style="list-style-type: none"> <li>1. Increase outflow.</li> <li>2. Increase pressure.</li> </ol>
<b>Doesn't pump when activated</b>	<ol style="list-style-type: none"> <li>1. Open all tubing clamps and shut-off valves.</li> <li>2. Ensure actual pressure is below target pressure.</li> <li>3. Check if the tubing is pinched, kinked, or blocked.</li> <li>4. Check whether the pressure sensor plug is seated completely and correctly.</li> <li>5. Return to Arthrex for repair.</li> </ol>
<b>* Door Not Closed *</b>	<ol style="list-style-type: none"> <li>1. Roller Housing not secured – ensure locking lever is properly secured.</li> <li>2. Return to Arthrex for repair.</li> </ol>
<b>Inadequate pressure</b>	<ol style="list-style-type: none"> <li>1. Increase pressure.</li> <li>2. Reduce outflow.</li> <li>3. Use high-flow cannulas.</li> </ol>
<b>No (or inadequate) flow</b>	<ol style="list-style-type: none"> <li>1. Check that all tubing clamps are open.</li> <li>2. Check the settings for flow and pressure.</li> <li>3. Check if the tubing is pinched, kinked or blocked.</li> <li>4. Secure the roller housing door.</li> <li>5. Check that tubing seats correctly over the rollers.</li> <li>6. Verify use of high-flow cannulas.</li> <li>7. If failure remains, return to Arthrex for repair.</li> </ol>
<b>* Overpressure *</b>	<ol style="list-style-type: none"> <li>1. Increase outflow.</li> <li>2. Manipulate joint to stress-free position.</li> </ol>
<b>* Pressure Fault *</b>	<ol style="list-style-type: none"> <li>1. Ensure adequate fluid supply.</li> <li>2. Decrease outflow.</li> <li>3. Check tubing for damaged and if it is pinched, kinked or blocked.</li> <li>4. Check tubing for proper connections.</li> <li>5. Replace tubing.</li> <li>6. If failure remains, return to Arthrex for repair.</li> </ol>

## 9.0 Repair Policy

Contact Arthrex for a Return Authorization Number and instructions *prior* to returning the device.

## 10.0 Contact Information

### ■ Arthrex, Inc.

Naples, Florida 34108-1945 USA

Tel: +1 239-643-5553

Fax: +1 239-643-6218

Toll-Free Technical Support: +1 888-420-9393 Monday through Friday,  
9:00 AM – 5:00 PM ET.

Website: [www.arthrex.com](http://www.arthrex.com)



### Arthrex Med. Inst. GmbH

85757 Karlsfeld, Germany

Tel: +1 49 81 31 59 57 29 0

Fax: +1 49 81 31 59 57 63 1

Website: [www.arthrex.de](http://www.arthrex.de)

## 10.1. Compliance Information

The Dual Wave Arthroscopy Pump (AR-6480) is designed and tested in accordance with 60601-1.

According to 60601 this device is Type BF, Class 1, IPX1 rating.

According to MDD93/42/EEC, Annex IX, Rule 11, this device is classified as a Class IIa device.

EN-55011B (EMC 89/336/CEE): Emission Standards

IEC-60601-1 (73/23/CEE): Medical electrical equipment, General Requirements for Safety

UL 544: Standard for Safety, Medical and Dental Equipment, being replaced by UL-2601-1

UL 2601-1: Medical Electrical Equipment, General Requirements, US

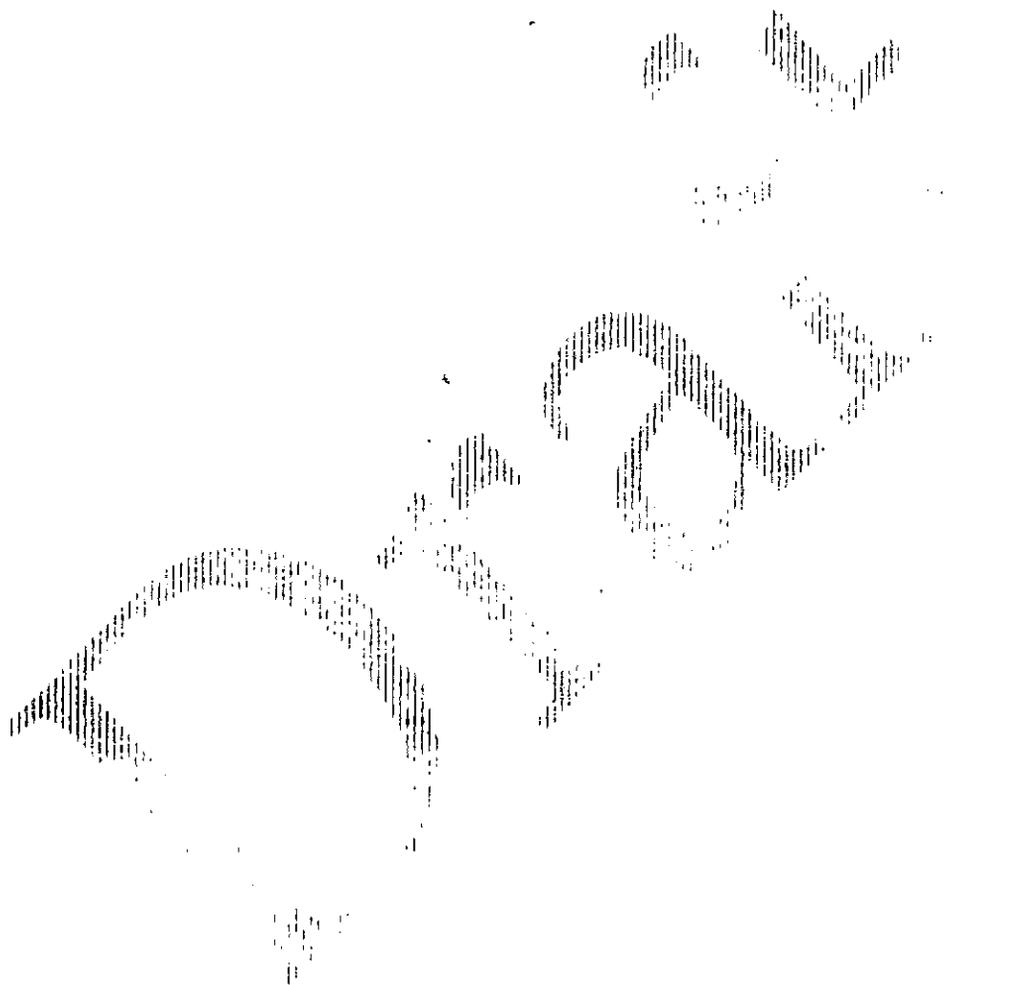
CUL-2601.1: Medical Electrical Equipment, General Requirements, Canada

## 10.2. Related Documents

LAI6302, *Pump Stand and Assembly*

LM0602, *Arthrex Dual Wave Arthroscopy Pump – Set Up and Operation and Troubleshooting*

AR-6480 *Block Diagrams*



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## AR-6482 Remote Control Unit

DFU-0165

### NEW REVISION 0

#### A. DESCRIPTION

The autoclavable Remote Control Unit (AR-6482) can operate the AR-6480 Dual Wave Arthroscopy Pump. The AR-6482 cannot be used with the AR-6475, Continuous Wave III Arthroscopy Pump or the AR-6400/AR-6450, Continuous Wave II Arthroscopy Pump.

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The Remote Control Unit lets you adjust the settings from a maximum distance of 9.8 feet (3 meters) from the control unit of the pump.

#### B. WARNINGS

1. Do not disconnect the remote control by pulling on the cable. Remove the remote control plug by grasping the body of the connector.
2. NEVER use liquid to clean the connector contacts of the remote control connector. Remove dust regularly with dry compressed air.

#### C. CLEANING AND DISINFECTION

The Remote Control can be cleaned and disinfected using commercially available surface disinfectants. Always comply with the instructions issued by the manufacturers of the cleaners and disinfectants.

#### D. STERILIZATION

The Remote Control (AR-6482) is supplied non-sterile.

The Remote Control can be autoclaved for sterilization. It is designed to survive a minimum 300 cycles of steam sterilization in an autoclave.

Gravity displacement cycles:

- 270° F to 275° F (132° C – 135° C): exposure time 18 minutes
- 250° F (121° C): exposure time 60 minutes

Prevacuum cycle:

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- 270° F – 275 °F (132° C – 135° C): 5 Minutes

Sterilizers vary in design and performance characteristics. Cycle parameters and the load configuration should always be verified against the sterilizer manufacturer's instructions.

Cooling – The device must be adequately cooled after being removed from the sterilizer.

After autoclave sterilization, the device must be fully dry before use.

#### E. PACKAGING AND LABELING

1. Arthrex devices should be accepted only if the factory packaging and labeling arrive intact.
2. Contact Customer Service if the package has been opened or altered.

#### F. STORAGE CONDITIONS

Products must be stored in the original unopened packaging. Ambient conditions for storage are -20° C to 70° C.

#### G. INFORMATION

For more information, or a demonstration, contact your local Arthrex representative.

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## PUMP TUBING

DFU-0140

NEW REVISION 1

### Panel One: AR-6410 Main Pump Tubing

#### A. PREPARATION FOR USE

1. Prepare the Arthrex Continuous Wave Arthroscopy Pump per the operator's manual.

**WARNING:** USING FLUID TO DISTEND ANY JOINT CARRIES WITH IT THE POSSIBILITY OF FLUID EXTRAVASATION INTO SURROUNDING TISSUE. Always use the lowest possible pressure settings to achieve the desired amount of distension and control of bleeding.

**WARNING:** PROPER OPERATION OF THIS DEVICE REQUIRES THE ESTABLISHMENT OF ADEQUATE FLUID OUTFLOW AND MONITORING OF THE SURGICAL FIELD. At pressures exceeding 10 mmHg above the patient's diastolic pressure, carefully monitor and maintain fluid outflow and assess the patient regularly to avoid extravasation or any other adverse patient condition.

2. Prepare the Arthroscope or the Cannula for use with the tubing set.
3. Using sterile technique, carefully remove the tubing set from the package and pass it onto the sterile field.
4. The sterile assistant should close all clamps, check the integrity of the remaining connections, and pass the bag spikes off the field to the circulating nurse.
5. Remove the orange clip and connect the pressure sensor line on top of the drip chamber to the front panel receptacle marked "SENSOR" until an audible "click" is heard. Insure that the drip chamber hangs in a vertical position.

**CAUTION:** Do not disconnect the sensor line unless the tubing set is to be discarded. The pressure sensor calibration may become inaccurate if

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(b)(4)

**reconnected. If the sensor line becomes disconnected for any reason, discard the tubing set.**

6. Using the green connector on the tubing set and the green dot on the pump roller housing as references, wrap the tubing boot (the larger diameter, more flexible section of the tubing set) around the pump rollers in a clockwise manner. Avoid twisting the tubing boot as it is wrapped around the rollers and take care to center it on the rollers before closing the roller cover.

7. Spike the bags in the normal sterile fashion, all clamps on the tubing set should be opened.

**NOTE:** When only one bag of liquid is to be connected, the unused bag spike must remain clamped.

8. Activate the pump by depressing the button marked "RUN/STOP" (AR-6475), "PUMP" (AR-6400, AR-6450), or "RUN" (AR-6480) on the front of the control panel. Fluid should begin to flow through the tubing and out of the open end. The drip chamber should fill to an appropriate level depending upon the flow setting.

9. To avoid air bubbles in the system, let fluid flow through the tubing until all air is purged. When the air is purged from the tubing, clamp the end nearest the open luer lock.

**CAUTION:** Prior to each use, it is important to check the setup of the pump to ensure proper function. A red light will flash near the tubing connection if a secure connection is not made. The pump will not run if this condition persists. If the pump runs continuously after the tubing has been clamped (see step above), check all luer connections. If the pump still runs continuously, replace the tubing.

**WARNING:** DO NOT DISCONNECT AND RECONNECT THE SAME TUBING SET UNDER ANY CIRCUMSTANCES. ONCE DISCONNECTED FROM THE PUMP, THE TUBING SET MUST BE DISCARDED AND A NEW TUBING SET INSTALLED.

**FAILURE TO DO SO MAY RESULT IN PUMP FAILURE AND PATIENT INJURY.**

Failure to follow these instructions may pose a danger to the patient. Do not use the unit if the rollers turn continuously after the tubing has been clamped. If the pump still fails to perform as designed, it should be returned (with the pump tubing set) to Arthrex for inspection.

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(b)(4)

10. The tubing set can be used in conjunction with the extension tubing (see step 11), or it can be directly connected to the arthroscope sheath or other inflow cannula. This connection is established by utilization of the luer lock fitting or by cutting off the luer lock fitting and pushing the tubing directly onto the cannula or sheath.
11. When using the tubing set in conjunction with the AR-6220 extension piece, the AR-6410 is used for the entire surgical day. Cut the main length of tubing to a manageable length and insert a luer lock fitting into the open end of the tubing. A luer lock fitting is packaged individually along with the main tubing set for this purpose. Next, connect the AR-6220 extension piece to the luer lock fitting on the main tubing set per the instructions in the AR-6220 packaging. Only the extension piece is discarded after each surgery.

## B. STERILIZATION

The tubing set is a single use item and is shipped sterile. Do not resterilize.

## C. STORAGE

Store in a cool, dry place.

(b)(4)

## Panel Two: AR-6220 Extension Tubing

### A. PREPARATION FOR USE

1. The AR-6220 Extension Tubing is to be used in conjunction with the Arthrex Main Pump Tubing. The Extension Tubing Set is to be replaced at each subsequent arthroscopic procedure.
2. Prepare the arthroscope or the cannula for use with the tubing set.
3. Using sterile technique, carefully remove the tubing set from the package and pass it onto the sterile field.
4. Connect the Extension Tubing Set to the Pump Tubing Set at the luer fittings.
5. Release the tube clamp from the pump tubing and bleed the entire tubing system to eliminate any air pockets or bubbles in the tubing.
6. Connect the patient end of the tubing set to the arthroscope or cannula to begin irrigation of the joint.

**WARNING:** PROPER OPERATION OF THIS DEVICE REQUIRES THE ESTABLISHMENT OF ADEQUATE FLUID OUTFLOW AND MONITORING OF THE SURGICAL FIELD. At pressures exceeding 10 mmHg above the patient's diastolic pressure, carefully monitor and maintain fluid outflow and assess the patient regularly to avoid extravasation or any other adverse patient condition.

**NOTE:** If the pump fails to perform as designed, it should be returned (with the pump tubing set) to Arthrex for inspection.

### B. STERILIZATION

The tubing set is a single use item and is shipped sterile.

Do not resterilize or reuse.

### C. STORAGE

Store in a cool, dry place.

(b)(4)

## Panel Three: AR-6411 ReDeuce™ Pump Tubing

### A. PREPARATION FOR USE

1. The AR-6411 ReDeuce™ Tubing System, Pump Tubing is used in conjunction with the AR-6421 ReDeuce™ Tubing System, Patient Tubing. The Patient Tubing must be used in the first arthroscopic procedure and replaced for each subsequent procedure.
2. Prepare the Arthrex Continuous Wave Arthroscopy Pump per the Operator's Manual.

**WARNING: USING FLUID TO DISTEND ANY JOINT CARRIES WITH IT THE POSSIBILITY OF FLUID EXTRAVASATION INTO SURROUNDING TISSUE. Always use the lowest possible pressure setting to achieve the desired amount of distention and control of bleeding.**

**WARNING: PROPER OPERATION OF THIS DEVICE REQUIRES THE ESTABLISHMENT OF ADEQUATE FLUID OUTFLOW AND MONITORING OF THE SURGICAL FIELD. At pressures exceeding 10 mmHg above the patient's diastolic pressure, carefully monitor and maintain fluid outflow and assess the patient regularly to avoid extravasation or any other adverse patient condition.**

3. Prepare the arthroscope or inflow cannula for use with the tubing set.
4. Using sterile technique, carefully remove the tubing set from the package and pass it onto the sterile field.
5. The sterile assistant should close all clamps and connect the Patient Tubing to the Pump Tubing at the large-bore, shielded connectors. Check the integrity of the remaining connections and pass the bag spikes off the field to the circulating nurse.
6. Remove the orange clip and connect the pressure sensing line on top of the drip chamber to the front panel receptacle marked "SENSOR" until an audible "click" is heard. Be sure that the drip chamber hangs in a vertical position.

**CAUTION: Do not disconnect the sensor line until the last procedure is completed. The pressure sensor calibration may become inaccurate if reconnected. If the sensor line becomes disconnected for any reason, discard the tubing set.**

(b)(4)

7. Using the green connector on the tubing set and the green dot on the console near the roller assembly as references, wrap the tubing boot (the larger diameter, more flexible section of the tubing set) around the pump rollers in a clockwise manner. Avoid twisting the tubing boot as it wrapped around the rollers and take care to center the tubing boot on the rollers before closing the roller cover.
8. Spike the bags in the normal sterile fashion, open all clamps on the tubing sets.  
**NOTE:** When only one bag of liquid is to be connected, the unused bag spike must remain clamped.
9. Activate the pump by depressing the button marked "RUN/STOP" (AR-6475) or "PUMP" (AR-6400, AR-6450) on the front of the control panel. Fluid should begin to flow through the tubing and out of the open end. The drip chamber will fill to the appropriate level depending upon the flow setting.
10. To avoid air bubbles in the system, let fluid flow until all air is purged. Close the clamp on the outflow end of the Patient Tubing.

**CAUTION:** Prior to each use, it is important to check the setup of the pump to ensure proper function. A red light will flash near the tubing connection if a secure connection is not made. The pump will not run if this condition persists. If the pump runs continuously after the tubing has been clamped (see step above), check all luer connections. If the pump still runs continuously, replace the tubing.

**WARNING:** DO NOT DISCONNECT AND RECONNECT THE SAME TUBING SET UNDER ANY CIRCUMSTANCES. ONCE DISCONNECTED FROM THE PUMP, THE TUBING SET MUST BE DISCARDED AND A NEW TUBING SET INSTALLED.

**FAILURE TO DO SO MAY RESULT IN PUMP FAILURE AND PATIENT INJURY.**

Failure to follow these instructions may pose a danger to the patient. Do not use the unit if the rollers turn continuously after the tubing has been clamped. If the pump still fails to perform as designed, it should be returned (with the pump tubing set) to Arthrex for inspection.

11. Connect the outflow end of the Patient Tubing to the arthroscope or inflow cannula. To begin irrigation, open the tubing clamp on the outflow end of the Patient Tubing.

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12. Upon completion of the arthroscopic procedure, close all tubing clamps and disconnect the Patient Tubing at both ends. Discard the Patient Tubing in an accepted waste container.
13. Prepare the Pump Tubing for a subsequent procedure. Using sterile technique, place the sterile connector cap (packaged with the Patient Tubing) onto the large-bore shielded connector on the Pump Tubing. Secure the tubing to prevent contamination.

#### **B. STERILIZATION**

The Pump Tubing is shipped sterile and is to be used for 1 surgical day. Do not resterilize or reuse for more than 1 day.

#### **C. STORAGE**

Store in a cool dry place.

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Last Revised: 11 DECEMBER 2008 2:23 PM

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(b)(4)

## Panel Four: AR-6421 ReDeuce™ Patient Tubing

### A. PREPARATION FOR USE

1. The AR-6421 ReDeuce™ Tubing System, Patient Tubing is used in conjunction with the AR-6411 ReDeuce™ Tubing System, Pump Tubing. The Patient Tubing must be used in the first arthroscopic procedure and replaced for each subsequent procedure.
2. Prepare the arthroscope or inflow cannula for use with the tubing set.
3. Using sterile technique, carefully remove the tubing set from the package and pass it onto the sterile field.
4. Connect the Patient Tubing to the Pump Tubing at the large-bore, shielded connectors.
5. Release the tube clamp on the outflow end of the Pump Tubing and purge the entire tubing system to eliminate any air pockets or bubbles within the tubing. Close the tubing clamp on the outflow end of the Patient Tubing.

**WARNING: PROPER OPERATION OF THIS DEVICE REQUIRES THE ESTABLISHMENT OF ADEQUATE FLUID OUTFLOW AND MONITORING OF THE SURGICAL FIELD. At pressures exceeding 10 mmHg above the patient's diastolic pressure, carefully monitor and maintain fluid outflow and assess the patient regularly to avoid extravasation or any other adverse patient condition.**

**NOTE:** If the pump fails to perform as designed, it should be returned (with the pump tubing set) to Arthrex for inspection.

6. Connect the outflow end of the Patient Tubing to the arthroscope or inflow cannula. To begin irrigation, open the tubing clamp on the outflow end of the Patient Tubing.
7. Upon completion of the arthroscopic procedure, close all tubing clamps and disconnect the Patient Tubing at both ends. Discard the Patient Tubing in an accepted waste container.
8. Prepare the Pump Tubing for a subsequent procedure. Using sterile technique, place the sterile connector cap onto the large-bore shielded connector on the Pump Tubing. Secure the tubing to prevent contamination.

### B. STERILIZATION

The Patient Tubing is a single-use item and is shipped sterile. Do not resterilize or reuse.

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**C. STORAGE:**

Store in a cool dry place.

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Last Revised: 11 DECEMBER 2008 2:23 PM

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DJA 00004



**COVER SHEET MEMORANDUM**

From: Reviewer Name Atig Chowdhury  
Subject: 510(k) Number K083707/S1  
To: The Record

Please list CTS decision code SE

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

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

DJA 00005

Transitional Adolescent B (18 <= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <a href="http://www.fda.gov/cdrh/comp/guidance/169.html">http://www.fda.gov/cdrh/comp/guidance/169.html</a> )		Contact OC.	

Regulation Number	Class*	Product Code
21 CFR 455.1100	II	HRS
(*If unclassified, see 510(k) Staff)		

Additional Product Codes: \_\_\_\_\_

Review: Neil R. Dyer (Branch Chief)      G5DB (Branch Code)      7/31/09 (Date)

Final Review: Bob (Division Director)      7/31/09 (Date)

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

**K083707/S1**

**DATE:** July 29, 2009

**TO:** The Record

**FROM:** Atiq Chowdhury (Biomedical Engineer)

**OFFICE:** ODE

**DIVISION:** DSORD

**510(K) HOLDER:** Arthrex, Inc

**DEVICE NAME:** Arthrex Dual Wave Arthroscopy Fluid Management Device

**CONTACT:** Sally Foust - Regulatory Affairs Project Manager

1370 Creekside Blvd.

Naples, FL

**PHONE:** 239-643-5553 Ext. 1251

**FAX:** 239-598-5508

**EMAIL:** sfoust@arthrex.com

**I. Purpose and Submission Summary:**

The 510(k) holder would like to introduce the Arthrex Dual Wave Arthroscopy Fluid Management Device. Under this submission the sponsor is seeking clearance to market this new device for Prescription Use and as a Class II device. I recommend that the subject device, Dual Wave Arthroscopy Fluid Management Device, is found SE to its predicates in regard to indications of use, technical specifications, biocompatibility, materials, sterility, performance testing, labeling, safety and effectiveness. There are no significant differences which raise issues of safety.

**II. Administrative Requirements**

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

**III. Device Description**

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		

DJA 00007

	Yes	No	N/A
Is the device sterile?	X		
Is the device reusable (not reprocessed single use)?	X		
Are "cleaning" instructions included for the end user?			

The sponsor states the device is a roller, peristaltic, arthroscopic pump designed with a universal input grade switching power supply. The device sense the connection and use of the Arthrex Shaver Adapteur System (K932699) and provides outflow function to support the same. In Section 5.3 pg 12, the sponsor lists the components of the device: The device, Dual Wave Remote, Dual Wave Foot Pedal, Main Pump Tubing, Dual Wave Outflow Tube w/fixture, ReDeuce Tubing Patient/Pump Tubing, Extension Tubing, and Y Tubing. For device specifications please refer to Section 5.2 pg 10.

**S1 Cycle:**

The sponsor has provided (S1, Section 2) engineering drawings and a device description (Section 5, pg 9). This is found adequate.

**IV. Indications for Use**

The indication for use as given in the IFU statement (Section 2, pg 5), "The Arthrex Dual Wave Arthroscopy Fluid Management Device is intended to provide consistent, non-pulsing control of intra-articular irrigation and distention pressuring during all phases of arthroscopic surgery."

**S1 Cycle:**

These Indications for use are found similar to the predicates and is found adequate.

**V. Predicate Device Comparison**

The sponsor has identified two predicate devices and is claiming substantial equivalence to them, K024291 – Arthrex Continuous Wave III Arthroscopy Pump, and K954465 – Future Medical Systems DUO Arthroscopy Pump. The sponsor has provided comparison tables in their Substantial Equivalence Section (section 13, pg 21) discussing the similarities of the device and its predicates in the areas of: intended use, irrigation flow, power and pressure specifications, design features, packaging and shelf life. However, the sponsor is being asked to provide an updated Device Comparison that compares the device's components to the predicate's components for the peristaltic pump system, and a comparison of the tubing in the areas of: size, diameter, and the type of irrigation solution used.

**S1 Cycle:**

The sponsor has provided (S1, Section 1, pg 11-13) a revised Device Comparison Table that includes a comparison of the pumps in the system and their function, along with a comparison of tubing in the areas of: size, diameter, and the type of irrigation solution used. This was found adequate.

AQC 000008

**VI. Labeling**

The sponsor has provided the draft labels and draft package inserts for device that include necessary directions for use, indications for use, safety instructions, warnings, and warranty statements. This is found adequate.

**VII. Sterilization/Shelf Life/Reuse**

The sponsor has indicated that the device is supplied non-sterile and reusable for the Pump System Interface and sterile single use for the Tubes. The device is sterilized by EO in accordance with ISO 10993-7, with an SAL Level of  $10^{-6}$ , and states that the device complies with maximum residual levels – EO shall not exceed 20mg/day, ECH shall not exceed 12 mg/day. However, the sponsor is being asked to provide the Maintenance for the console portion of the device, and the an explanation as to why some Tubing can be reusable.

**S1 Cycle:**

The sponsor has stated (S1, pg 5) that the disposable single-use/single-day usage of the device is not uncommon in orthopedic industry, is not reprocessed, and this practice is used by the predicate, K024291. The sponsor also states the pump's performance was validated in 2005 to check: the main pump tubing, extension tubing, ReDeuce pump tubing, and ReDeuce patient tubing. This is found adequate.

The sponsor has stated they have revised the Operator's Manual (S1, pg 6) to include the console may be cleaned/disinfected with a cloth and commercially available surfactants. This is found adequate.

**VIII. Biocompatibility**

The sponsor has not addressed the biocompatibility issue for the patient contacting materials of the device and is being asked to describe the patient contacting materials of the device and provide the biocompatibility test results of your patient contacting materials, or provide predicates.

**S1 Cycle:**

The sponsor has stated (S1, pg 4,5) that the patient contacting materials are the same as predicate K024291 which are: stainless steel, PVC, ABS, and acrylic cryolite which have a history of use and is found adequate.

**IX. Software**

**S1 Cycle:**

The sponsor states that this device has a moderate level of concern.

Version:		
Level of Concern: Moderate		
	Yes	No
Software description:	X	

DJA 00009

Device Hazard Analysis:	X	
Software Requirements Specifications:	X	
Architecture Design Chart:	X	
Design Specifications:	X	
Traceability Analysis/Matrix:	X	
Development:	X	
Verification & Validation Testing:	X	
Revision level history:	X	
Unresolved anomalies:	X	

The sponsor has provided the applicable software documentation (S1, pg 6, 7 & Appendices 3-4). All software sections contained within this submission are found to be acceptable documentation of the software and meet the software concerns as described in the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, dated May 29, 1998.

**X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety**

The sponsor has completed adequate testing per the following standards:

Standards	Standard Title
IEC 60601-1	Medical Electrical Equipment, Part 1, General Requirements for Safety

This is found adequate.

**XI. Performance Testing – Bench**

*None Provided.*

**XII. Performance Testing – Animal**

*None Provided*

**XIII. Performance Testing – Clinical**

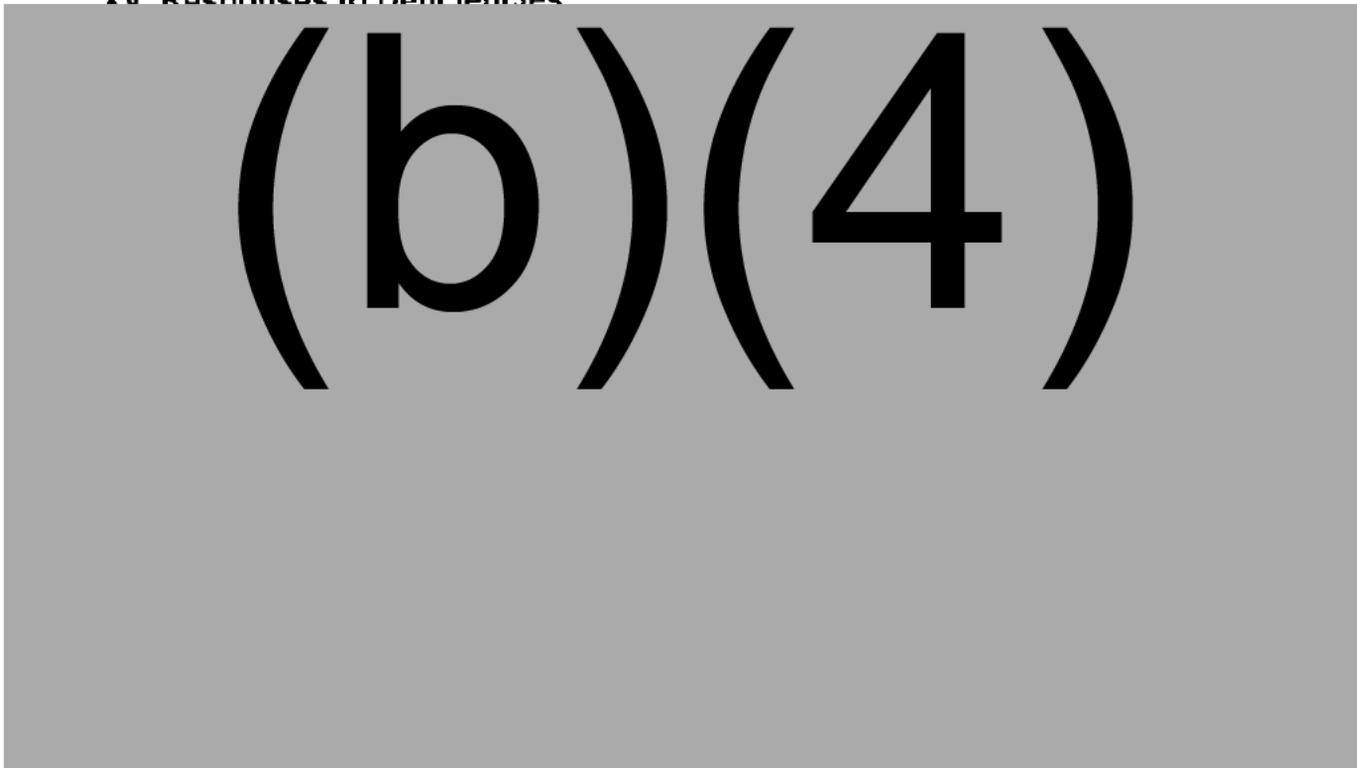
*None provided.*

DCA 00010

**XIV. Substantial Equivalence Discussion**

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

**XV. Responses to Deficiencies**



DCA 00011

2. Revised Device Description

(b)(4)

3. Biocompatibility

(b)(4)

4. Tubing Clarification

(b)(4)

DJA 00012

(b)(4)

6. Operator's Manual - Maintenance

(b)(4)

7. Software Documentation

(b)(4)

(b)(4)

**XVI. Contact History**

2/23/2009 – An email sent to the sponsor regarding the request for AI.

**XVII. Recommendation** *SE*

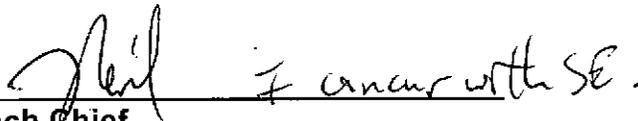
Regulation Number: 21 CFR 888.1100  
Regulation Name: Arthroscope  
Regulatory Class: Class II  
Device Code: HRX

DJA 00014



**Reviewer**  
**Atiq Chowdhury**  
**Biomedical Engineer**  
**General and Surgical Devices Branch**  
**Division of Surgical, Orthopedic, and Restorative Devices**

7/29/09  
**Date**



**Branch Chief**  
**Neil Ogden**  
**General and Surgical Devices Branch**  
**Division of Surgical, Orthopedic, and Restorative Devices**

7/31/09  
**Date**

**Sally Foust**

---

**From:** Sally Foust  
**nt:** Tuesday, March 03, 2009 12:28 PM  
**o:** 'atiq.chowdhury@fda.hhs.gov'  
**Subject:** FW: 510(k) submission - Arthrex Dual Wave Arthroscopy Fluid Management Device (K083707)  
**Attachments:** 5. 120-day Extension Ltr.3.3.2009.pdf

Good morning Mr. Chowdhury,

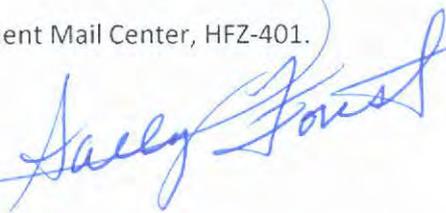
Attached please find a letter requesting a 120 day extension to respond to the additional information requests outlined in e-mail dated February 24, 2009.

Upon further internal review it was determine that this time is needed to adequately respond to your questions.

The original letter will be sent to the Document Mail Center, HFZ-401.

Regards,

Sally Foust  
Regulatory Affairs Project Manager  
Arthrex, Inc.



---

**From:** Sally Foust  
**nt:** Tuesday, February 24, 2009 1:09 PM  
**o:** 'Chowdhury, Atiq'  
**Subject:** RE: 510(k) submission - Arthrex Dual Wave Arthroscopy Fluid Management Device (K083707)

Dear Mr. Chowdhury,

This e-mail is sent to acknowledge receipt of letter text requesting additional information for K083707, Arthrex Dual Wave Arthroscopy Fluid Management Device.

Arthrex has begun to review the information requests, slowly at first since many of our associates are at AAOS this week. Once they return (next week) we should be able move forward more quickly in preparing a response.

I will plan to contact you next week for any clarification.

Regards,

Sally Foust  
Regulatory Affairs Project Manager  
Arthrex, Inc.  
1370 Creekside Boulevard  
Naples, FL 34108-1945  
(239) 643-5553, ext 1251  
(239) 598-5508, fax  
[ust@arthrex.com](mailto:sust@arthrex.com)

DJA 00018

DJA  
00019

---

**From:** Chowdhury, Atiq [mailto:atiq.chowdhury@fda.hhs.gov]  
**Sent:** Monday, February 23, 2009 3:56 PM  
Sally Foust  
**Subject:** Re: 510(k) submission - Arthrex Dual Wave Arthroscopy Fluid Management Device (K083707)

Ms. Sally Foust,

I have enclosed a copy of the additional information request for the 510(k) submission (K083707). Feel free to contact me for any further clarification. <<AI - K083707.doc>>

Atiq Chowdhury  
Biomedical Engineer  
(240)276-3805  
GSDB/DSORD/ODE/FDA  
[atiq.chowdhury@fda.hhs.gov](mailto:atiq.chowdhury@fda.hhs.gov)

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**COVER SHEET MEMORANDUM**

From: Reviewer Name Atig Chowdhury  
Subject: 510(k) Number K083707  
To: The Record

Please list CTS decision code A7

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

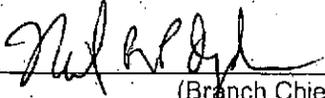
Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	<input checked="" type="checkbox"/>	<input type="checkbox"/>
510(k) Summary /510(k) Statement	Attach Summary	<input checked="" type="checkbox"/>	<input type="checkbox"/>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

DJA 00023

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

Regulation Number                      Class\*                      Product Code  
21 CFR 888.1100                      II                      H-RX  
(\*If unclassified, see 510(k) Staff)

Additional Product Codes: \_\_\_\_\_

Review:                       GSD-B                      2/24/09  
(Branch Chief)                      (Branch Code)                      (Date)

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

DJA 00024

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

**K083707**

**DATE:** February 23, 2009

**TO:** The Record

**FROM:** Atiq Chowdhury (Biomedical Engineer)

**OFFICE:** ODE

**DIVISION:** DSORD

**510(K) HOLDER:** Arthrex, Inc

**DEVICE NAME:** Arthrex Dual Wave Arthroscopy Fluid Management Device

**CONTACT:** Sally Foust - Regulatory Affairs Project Manager

1370 Creekside Blvd.

Naples, FL

**PHONE:** 239-643-5553 Ext. 1251

**FAX:** 239-598-5508

**EMAIL:** sfoust@arthrex.com

**I. Purpose and Submission Summary:**

The 510(k) holder would like to introduce the Arthrex Dual Wave Arthroscopy Fluid Management Device. Under this submission the sponsor is seeking clearance to market this new device for Prescription Use and as a Class II device. The sponsor is being requested additional information regarding following topics and this submission is being put ON HOLD until they provide the requested information.

- Substantial Equivalence – Device Comparison Table
- Revised Device Description
- Biocompatibility
- Tubing Clarification
- Irrigation & Suction
- Operator's Manual - Maintenance
- Software

**II. Administrative Requirements**

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

DJA 00025

**III. Device Description**

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

The sponsor states the device is a roller, peristaltic, arthroscopic pump designed with a universal input grade switching power supply. The device sense the connection and use of the Arthrex Shaver Adapter System (K932699) and provides outflow function to support the same. In Section 5.3 pg 12, the sponsor lists the components of the device: The device, Dual Wave Remote, Dual Wave Foot Pedal, Main Pump Tubing, Dual Wave Outflow Tube w/fixture, ReDeuce Tubing Patient/Pump Tubing, Extension Tubing, and Y Tubing. For device specifications please refer to Section 5.2 pg 10. The sponsor is being asked to provide additional engineering drawings (**See Deficiencies**).

**IV. Indications for Use**

The indication for use as given in the IFU statement (Section 2, pg 5), "The Arthrex Dual Wave Arthroscopy Fluid Management Device is intended to provide consistent, non-pulsing control of intra-articular irrigation and distention pressuring during all phases of arthroscopic surgery." The sponsor is being asked to provide additional comparisons for this IFU with the predicated (**See Deficiencies**).

**V. Predicate Device Comparison**

The sponsor has identified two predicate devices and is claiming substantial equivalence to them, K024291 – Arthrex Continuous Wave III Arthroscopy Pump, and K954465 – Future Medical Systems DUO Arthroscopy Pump. The sponsor has provided comparison tables in their Substantial Equivalence Section (section 13, pg 21) discussing the similarities of the device and its predicates in the areas of: intended use, irrigation flow, power and pressure specifications, design features, packaging and shelf life. However, the sponsor is being asked to provide an updated Device Comparison that compares the device's components to the predicate's components for the peristaltic pump system, and a comparison of the tubing in the areas of: size, diameter, and the type of irrigation solution used (**See Deficiencies**).

**VI. Labeling**

The sponsor has provided the draft labels and draft package inserts for device that include necessary directions for use, indications for use, safety instructions, warnings, and warranty statements. This is found adequate.

DJA 00026

**VII. Sterilization/Shelf Life/Reuse**

The sponsor has indicated that the device is supplied non-sterile and reusable for the Pump System Interface and sterile single use for the Tubes. The device is sterilized by EO in accordance with ISO 10993-7, with an SAL Level of  $10^{-6}$ , and states that the device complies with maximum residual levels – EO shall not exceed 20mg/day, ECH shall not exceed 12 mg/day. However, the sponsor is being asked to provide the Maintenance for the console portion of the device, and the an explanation as to why some Tubing can be reusable (**See Deficiencies**).

**VIII. Biocompatibility**

The sponsor has not addressed the biocompatibility issue for the patient contacting materials of the device and is being asked to describe the patient contacting materials of the device and provide the biocompatibility test results of your patient contacting materials, or provide predicates.

**IX. Software**

The sponsor has not provided software documentation for the device and will be asked to provide this (**See Deficiencies**).

**X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety**

The sponsor has completed adequate testing per the following standards:

Standards	Standard Title
IEC 60601-1	Medical Electrical Equipment, Part 1, General Requirements for Safety

This is found adequate.

**XI. Performance Testing – Bench**

*None Provided.*

**XII. Performance Testing – Animal**

*None Provided*

**XIII. Performance Testing – Clinical**

*None provided.*

DJA 00027

**XIV. Substantial Equivalence Discussion**

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

**XV. Deficiencies**

(b)(4)

DJA 00028

3. Biocompatibility

(b)(4)

4. Tubing Clarification

(b)(4)

5. Irrigation & Suction

Please explain the rationale of how the irrigation and suction will be in balance during the operation of the device.

6. Operator's Manual - Maintenance

Please include in Section 5.1 – Cleaning and Sterilization that the console may be cleaned with a cloth and available surfactant.

7. Software Documentation

(b)(4)

(b)(4)

**XVI. Contact History**

2/23/2009 – An email sent to the sponsor regarding the request for AI.

**XVII. Recommendation**

I recommend that this submission be placed on hold pending the receipt of the response to the above questions.

DJA 00030

\_\_\_\_\_  
**Reviewer**

**Atiq Chowdhury**  
**Biomedical Engineer**  
**General and Surgical Devices Branch**  
**Division of General, Restorative, and Neurological Devices**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Branch Chief**

**Neil Ogden**  
**General and Surgical Devices Branch**  
**Division of General, Restorative, and Neurological Devices**

\_\_\_\_\_  
**Date**

*Neil* *Concur with AI*

*2/24/09*

February 23, 2009

Sally Foust  
Regulatory Affairs Project Manager  
Arthrex, Inc, Naples, FL  
Ph#: 239-643-5553 Ext. 1251  
Fax#: 239-598-5508  
e-mail: sfoust@arthrex.com

Re: 510(k) submission – Arthrex Dual Wave Arthroscopy Fluid Management Device (K083707)

Dear Ms. Sally Foust,

In reviewing the subject submission, we have the following additional questions that need to be clarified to facilitate our review process:

1. Substantial Equivalence – Device Comparison Table

(b)(4)

2. Revised Device Description

You have not provided an adequate Device Description Section. Please include: a description of your device and all its components with their engineering drawings.

3. Biocompatibility

(b)(4)

(b)(4)

4. Tubing Clarification

(b)(4)

5. Irrigation & Suction

Please explain the rationale of how the irrigation and suction will be in balance during the operation of the device.

6. Operator's Manual - Maintenance

Please include in Section 5.1 – Cleaning and Sterilization that the console may be cleaned with a cloth and available surfactant.

7. Software Documentation

(b)(4)

DJA 00033

(b)(4)

The subject submission will be placed on hold pending your response with the requested information. If you need more than 30 days to provide a full and complete response; you should submit a request for an extension of time to Document Mail Center (HFZ 401). For further information on how to apply for an extension and for general 510(k) information, please visit the FDA Website at: [http://www.fda.gov/cdrh/devadvice/31435.html#link\\_6](http://www.fda.gov/cdrh/devadvice/31435.html#link_6)

Sincerely,

Atiq Chowdhury  
Biomedical Engineer  
(240)276-3805  
GSDB/DGRND/ODE/FDA  
atiq.chowdhury@fda.hhs.gov

K083707 Response A1

Copy 2

1 of 418

K083707/S1

electronic copy



13 JULY 2009

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

FDA CDRH DMC

JUL 15 2009

Received

K-42

**RE: K083707 RESPONSE: Dual Wave Arthroscopy Fluid Management Device -A1 – K083707**

**Attn: Atiq Chowdhury**  
Biomedical Engineer GSDB/DSORD/ODE/FDA

Dear Mr. Chowdhury:

The following additional information is provided in duplicate to address the February 23, 2009 request for additional information for the DualWave Arthroscopy Fluid Management Device, K083707. Arthrex acknowledged the receipt of the request on February 24, 2009, received a FDA hold letter dated February 25, 2009, and requested a 120 day extension to respond. FDA granted the 120 day extension to July 24, 2009 in a letter dated March 6, 2009 and received by Arthrex.

The Arthrex, Inc. DualWave Pump, AR-6480, has passed certification testing. Copies of (TUV) Certificate No.U8 09 05 43640 016 and the (TUV) Technical Report No. 090-903266-000 are provided in *Appendix 6* of the response.

Pursuant to 21 CFR 807.95 (c) (3) Arthrex, Inc. considers this pre-market submission to be confidential commercial information.

We trust you will find that these responses and documents will address the deficiencies to your satisfaction. Questions regarding this submission may be directed to Sally Foust by e-mail at [sfoust@arthrex.com](mailto:sfoust@arthrex.com) and by telephone at (239) 643-5553 extension 1251.

Sincerely,  
  
Sally Foust  
Regulatory Affairs Project Manager

**Arthrex, Inc.** • 1370 Creekside Boulevard • Naples, FL 34108-1945 USA



13 JULY 2009

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

**RE: K083707 RESPONSE: Dual Wave Arthroscopy Fluid Management  
Device -A1 – K083707**

**Attn: Atiq Chowdhury**  
Biomedical Engineer GSDB/DSORD/ODE/FDA

Dear Mr. Chowdhury:

The following additional information is provided in duplicate to address the February 23, 2009 request for additional information for the DualWave Arthroscopy Fluid Management Device, K083707. Arthrex acknowledged the receipt of the request on February 24, 2009, received a FDA hold letter dated February 25, 2009, and requested a 120 day extension to respond. FDA granted the 120 day extension to July 24, 2009 in a letter dated March 6, 2009 and received by Arthrex.

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We trust you will find that these responses and documents will address the deficiencies to your satisfaction. Questions regarding this submission may be directed to Sally Foust by e-mail at [sfoust@arthrex.com](mailto:sfoust@arthrex.com) and by telephone at (239) 643-5553 extension 1251.

Sincerely,  
  
Sally Foust  
Regulatory Affairs Project Manager

**Arthrex, Inc.** • 1370 Creekside Boulevard • Naples, FL 34108-1945 USA

**RE: K083707 RESPONSE: Dual Wave Arthroscopy Fluid Management Device  
A1 – K083707**

**Cover Letter**

**INDEX TABLE OF CONTENTS  
RESPONSES TO QUESTIONS**

**Appendix 1**

Device Comparison Table  
Predicate K024291 Arthrex Continuous Wave III Arthroscopy Pump FDA  
Predicate K954465 FMS DUO FDA Document and Instruction Manual

**Appendix 2**

AR-6480 Pump Console Engineering Drawings  
AR-6482 Pump Remote Engineering Drawings  
AR-6483 Pump Foot Pedal Engineering Drawings  
AR-6430 Pump Outflow Tubing w/Cassette Engineering Drawings

Previously cleared devices in either K915721 and/or K024291

AR-6410 Main Pump Tubing Engineering Drawings  
AR-6411 ReDeuce Pump Tubing Engineering Drawings  
AR-6421 ReDeuce Patient Tubing Engineering Drawings  
AR-6215 Tube Adapter “Y” Engineering Drawings  
AR-6220 Extension Tubing Engineering Drawings

**Appendix 3**

AR-6480 DualWave Inflow/Outflow Arthroscopy - Product Specification  
AR-6482 DualWave Remote Control – Product Specification  
RF4.4.4.2.18 - AR-6480 Software Design Criteria  
RF4.4.4.2.22 - AR-6480 Software Requirements Specification  
RF4.4.4.2.11 – DW Display Software Version History  
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**Appendix 4**

RF4.4.0.2 - Risk Analysis Matrix – Reliability  
RF4.4.0.3 - Risk Analysis Matrix – Reliability – Concern Factor

**Appendix 5**

RF4.4.4.1.12 - AR-6480 System Validation  
RF4.4.4.2.17 - AR-6480 Software Validation

**Appendix 6**

**(b)(4)**

Certificate No. U8 09 05 43640 016  
Technical Report No

**(b)(4)**

**1. Substantial Equivalence – Device Comparison Table**

**(b) (4)**

(b)(4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

Table Error! No text of specified style in document.-1 **Comparison of the Predicate Device to the Modified Device (revised)**

<b>Similarities and Differences</b>	<b>Arthrex Dual Wave Arthroscopy Fluid Management Device AR-6480 K083707 Current submission</b>	<b>Arthrex Continuous Wave III Arthroscopy Pump AR-6475 CLEARED submission (K024291)</b>	<b>Future Medical Systems DUO arthroscopy pump CLEARED submission (K954465)</b>
<b>Intended Use/Indications for Use</b>	Intended to provide consistent, non-pulsing control of intra-articular irrigation and distention pressuring during all phases of arthroscopic surgery	Intended to provide consistent, non-pulsing control of intra-articular irrigation and distention pressuring during all phases of arthroscopic surgery	Intended to be used in arthroscopic surgery in the following joints: shoulder, knee, ankle, elbow, wrist
<b>Type</b>	Type B Class 1	Type B Class 1	Type B Class 1
<b>Conformance Standard</b>	EN 60601-1	EN 60601-1	EN 60601-1
<b>Number</b>	(b)(4)	1 Pumps – Inflow only	2 Pumps - Inflow/Outflow
<b>Power</b>	80-240 VAC 50/60 Hz 8.0 amps	100-240VAC 50/60 Hz 2.0 amps	120-230 VAC 50/60 Hz 5.0 amps
<b>Irrigation Fluid</b>	Normal Saline	Normal Saline	Normal Saline
<b>Flow Rate</b>	Inflow: 0-1600 mL/min (b)(4)	Inflow: 0-1600 mL/min Outflow: NA	Inflow: 0-1600 mL/min Outflow: 0-800 mL/min
<b>Pressure</b>	0-180 mmHg	0-180 mmHg	0-180 mmHg
<b>Regression</b>	Inflow Performance Outflow Performance	Inflow Performance Outflow NA	Inflow Performance Outflow Performance
<b>Electronic Pressure Check</b>	Continuous	Continuous	Continuous

# K083707 Response A1

**Arthrex** TRADITIONAL 510(k): Arthrex Dual Wave Arthroscopy Fluid Management Device

<b><i>Similarities and Differences</i></b>	<b>Arthrex Dual Wave Arthroscopy Fluid Management Device AR-6480 K083707 Current submission</b>	<b>Arthrex Continuous Wave III Arthroscopy Pump AR-6475 CLEARED submission (K024291)</b>	<b>Future Medical Systems DUO arthroscopy pump CLEARED submission (K954465)</b>
<b>Foot Pedal</b>	Yes	No	Yes
<b>Remote Control</b>	Yes	Yes	No
<b>Senses Shaver</b>	Yes	No	Yes
<b>Tubing Material</b>	PVC	PVC	PVC
<b>Patient Contact Materials</b>	<b>(b)(4)</b>	PVC ABS Acrylic cryolite Stainless Steel Polypropylene Polycarbonate	PVC Stainless Steel Others unknown
<b>Tubing Size (does not include outflow tubing)</b>	Inner diameter: 0.159 -0.250 in. Outer diameter: 0.214 – 0.375 in. Length: 1-48 in.  Refer to tubing drawing C-0180-1/14 in <i>Appendix 2</i>	Inner diameter: 0.159 -0.250 in. Outer diameter: 0.214 – 0.375 in. Length: 1-48 in.  Refer to tubing drawing C-0180-1/14 in <i>Appendix 2</i>	Not known
<b>Outflow Tubing Size</b>	<b>(b)(4)</b>	No outflow tubing	Not known
<b>Single-use/day Pump Tubing</b>	Yes	Yes	Yes

# K083707 Response A1

 TRADITIONAL 510(k): Arthrex Dual Wave Arthroscopy Fluid Management Device

<b><i>Similarities and Differences</i></b>	<b>Arthrex Dual Wave Arthroscopy Fluid Management Device AR-6480 K083707 Current submission</b>	<b>Arthrex Continuous Wave III Arthroscopy Pump AR-6475 CLEARED submission (K024291)</b>	<b>Future Medical Systems DUO arthroscopy pump CLEARED submission (K954465)</b>
<b><i>Tubing Type</i></b>	Pump, Patient, Outflow	Pump, Patient,	Pump, Patient, Outflow
<b><i>Non-sterile Devices</i></b>	Pump, Foot Pedal, Remote	Pump, Remote	Pump, Foot Pedal, Remote
<b><i>Sterile Packaging</i></b>	(b)(4)	Poly/Tyvek pouches	Not known
<b><i>Sterile Tubing</i></b>	Yes	Yes	Yes
<b><i>Sterile Tubing Shelf Life</i></b>	5-years	5-years	Not known

*Appendix 1*

**K024291: Arthrex Continuous Wave III Arthroscopy Pump**

FDA Database Documents

K024291

MAR 20 2003

**PREMARKET NOTIFICATION  
SUMMARY OF SUBSTANTIAL EQUIVALENCE  
Arthrex Continuous Wave III Arthroscopy Pump**

**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 ext. 1251  
FAX: (239) 430-3494  
E-mail: sfoust@arthrex.com

**TRADE NAME:** Arthrex Continuous Wave III Arthroscopy Pump

**COMMON NAME:** Pump

**CLASSIFICATION:** Arthroscope  
21 CFR 888.1111

**DEVICE PRODUCT CODE:** HRX

**DEVICE DESCRIPTION AND INTENDED USE:**

The Arthrex Continuous Wave III Arthroscopy Pump is a roller, peristaltic, arthroscopic pump designed with a universal input grade switching power supply allowing the pump to function automatically within voltages ranges found in Europe and in the Americas. The pump is designed with upgraded software, employs a combination vacuum fluorescent and dot matrix display for high visibility, uses membrane type switch overlays for user inputs, and has an added flush function.

The Arthrex Continuous Wave III Arthroscopy Pump is intended to provide consistent, non-pulsing control of intra-articular irrigation and distention pressuring during all phases of arthroscopic surgery.

**SUBSTANTIAL EQUIVALENCE**

The Arthrex Continuous Wave III Arthroscopic Pump is a functional equivalent of the currently marketed AR-6400 and the discontinued AR-6300 Arthrex arthroscopic pumps. The subject pump retains current functions and interfaces and is determined by Arthrex, Inc. to be substantially equivalent to its Arthrex pump predecessors and other currently marketed predicate devices.

The addition of a universal input grade switching power supply, of an improved visual display, of an autoclavable remote, and of an upgrade software package does not affect the safety and effectiveness of the subject device when compared to its Arthrex pump predecessors and other predicate devices.

**000005**



DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 20 2003

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

Re: K024291

Trade/Device Name: Arthrex Continuous Wave III Arthroscopy Pump  
Regulation Number: 21 CFR 888.1100  
Regulation Name: Arthroscope and accessories  
Regulatory Class: II  
Product Code: HRX  
Dated: December 20, 2002  
Received: December 24, 2002

Dear Ms. Foust:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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

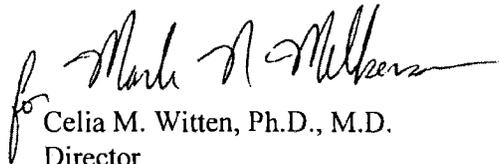
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Page 2 - Ms. Sally Foust, RAC

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (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,



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) K024291

INDICATIONS FOR USE:

The Arthrex Continuous Wave III Arthroscopy Pump is intended to provide consistent, non-pulsing control of intra-articular irrigation and distention pressuring during all phases of arthroscopic surgery.

-----  
Concurrence of CDRH, Office of Device Evaluation

Prescription Use  X  OR Over-The-Counter Use

(Per 21 CFR 801.109)

*f*   
Division Sign-Off

Director of General, Restorative  
and Neurological Devices

510(k) Number K024291

000004

*Appendix 1*

**K954465: FMS DUO**

FDA Database Document  
FMS DUO Manual

*files*

## 510(k) Premarket Notification



[510 \(k\)](#) | [Registration & Listing](#) | [Adverse Events](#) | [PMA](#) | [Classification](#) | [CLIA](#)  
[CFR Title 21](#) | [Advisory Committees](#) | [Assembler](#) | [Recalls](#) | [Guidance](#) | [Standards](#)

[New Search](#)

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<b>Device Classification Name</b>	<u>Arthroscope</u>
<b>510(K) Number</b>	K954465
<b>Device Name</b>	FMS DUO
<b>Applicant</b>	FUTURE MEDICAL SYSTEMS, INC. 205 East 63rd St. Suite 7a New York City, NY 10021
<b>Contact</b>	Patrick Janin
<b>Regulation Number</b>	<u>888.1100</u>
<b>Classification Product Code</b>	<u>HRX</u>
<b>Date Received</b>	09/25/1995
<b>Decision Date</b>	11/09/1995
<b>Decision</b>	Substantially Equivalent (SE)
<b>Classification Advisory Committee</b>	Orthopedic
<b>Review Advisory Committee</b>	General & Plastic Surgery
<b>Statement/Summary/Purged Status</b>	Statement Only
<b>Type</b>	Traditional
<b>Reviewed By Third Party</b>	No
<b>Expedited Review</b>	



Instruction Manual



**Tornado<sup>®</sup>**

Lightweight  
shaver  
handpiece

**fms duo<sup>®</sup>+**

combines a dual pump system  
providing inflow and outflow  
including an integrated  
shaver system

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# Chapter 1: Introduction

---

## 1.1 Product description

### Dual pump system

The fms duo<sup>®</sup>+ supplies both irrigation and suction in one unit. Both roller-pumps are computer-controlled and manage fluid automatically. The integrated suction pump manages both shaver and cannula suction, reducing labor-intensive manipulations.

By controlling both inflow and outflow the fms duo<sup>®</sup>+ accurately regulates pressure and flow.

### Blue pedal (cannula suction)

To increase flow without increasing joint pressure, step on the blue foot pedal. The suction pump will accelerate and the irrigation pump will immediately increase inflow to compensate for the increased fluid loss. This feature is particularly useful when eliminating debris.

### Red pedal (lavage mode)

One of the most critical aspects of arthroscopy is visualization, which is often obstructed by blood and debris. To alleviate this problem the fms duo<sup>®</sup>+ has a lavage mode. By stepping on the red foot pedal you will activate a timed cycle of increased flow and pressure to stop bleeding and clear the field of view. Once the cycle is complete, the fms duo<sup>®</sup>+ will return to its original configuration.

### Integrated shaver system

The fms duo<sup>®</sup>+ is also an integrated shaver console. The Tornado is a lightweight titanium high-speed shaver handpiece. When the shaver rotates, the fms duo<sup>®</sup>+ automatically activates suction through the shaver and clamps off other suction ports. If you prefer to use your current shaver system, the same functions can be provided using an interface cable.

## 1.2 Declaration of conformity

We, at FMS Group declare under our responsibility that the product fms duo<sup>®</sup>+ is in conformity according to CE 93/42/EEC Directives and is compliant to the Food and Drug Administration (FDA) 510K process. This product is manufactured in an ISO 9001 facility.

## 1.3 General warnings and cautions

It is recommended that hospital personnel read this manual before operating, cleaning or sterilizing this product and accessories. Failure to follow these instructions may result in potential injury and damage or malfunction of the equipment.

The manufacturer and licensed seller of this device do not accept any liability for direct or consequential damage or injury caused by improper use or usage of disposables other than FMS products. Any alterations to this device, repair from an unlicensed service center or use of non-FMS disposables, will void CE marking, FMS warranty and product liability coverage.

Warning : The system may be affected by electromagnetic interference from other instruments. Verify that all other instruments and appliances (associated or not with the system) comply with the standard EN 60601-1-2 (EMC).

If the system continues to be affected, isolate it from the offending instrument and connect to a different main output.

The fms duo<sup>®</sup>+ is covered by US patents N° 4 902 277, N° 5 000 733 and N° 5 131 823, European patents N° 0 306 445 and N° 0 448 909 B1, Japanese patents N° 2 107 259 and 2 892 852. Arthro<sup>®</sup> fms and fms duo<sup>®</sup>+ are registered trademarks of Future Medical System SA.

Reproduction, transfer, distribution of part or all of the contents in this document in any form without the prior written permission of FMS is prohibited.

## 1.4 Intended use

The fms duo<sup>®</sup>+ is intended to be used in arthroscopic surgery in the following joints: shoulder, knee, ankle, elbow, wrist.

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

### 1.5 Symbol definitions



**POWER** pad.  
Turns the power on if the main power switch on the back of the pump is on (the green standby light is on).



**ALARM**.  
The red indicator will light up if a safety parameter is violated.



**Lavage** pad.  
This feature automatically sets off a sequence of pressure and flow increases to clear the field of view of blood and debris.



**4 way** Foot-pedal board.  
Four-way colour coded foot-pedal to activate shaver, and pump function.



**2 way** Foot-pedal board.  
Two-way colour coded foot-pedal. Used to activate pump function only.



**Increase**.



**Decrease**.



**On**.



**Off**.



**Shaver handpiece**.



**Shaver handpiece**.  
suction amount.



**Forward**.



**Reverse**.



**Oscillate**.



**Equipotentiality** symbol.



**Type B Class 1**.  
Conforms to standard EN 60601-1.

ENGLISH



Waterproof for projections.



Do not reuse.



CE mark, and identification of notified body.



Reusable only one day.



Warning, see instructions for use.



Date of manufacture year and month.



Explosion hazard.



Store between these temperatures.



Main fuse.



Replace fuses as marked.



Latex free.



Use by year and month.

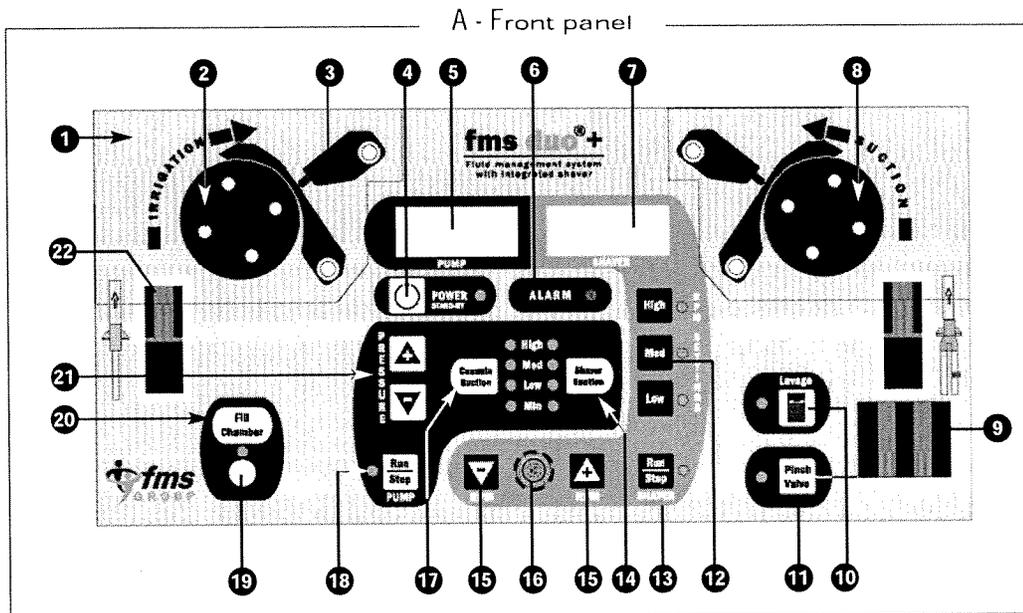


Sterile, unless the package is damaged or open. Sterilization by ethylene oxide.



Do not wet.

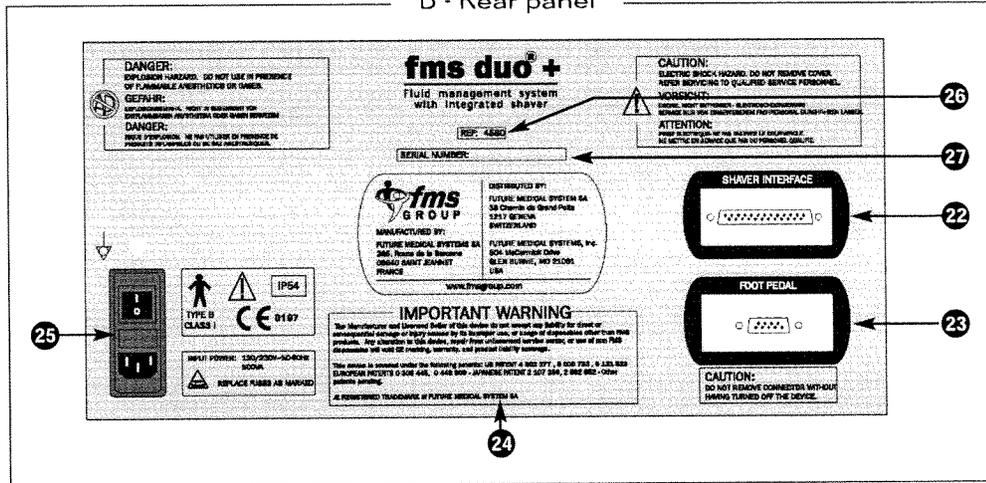
## 1.6 System indicators



- |  |  |
|--|--|
| <p><b>1</b> Transparent safety covers<br/>These covers must be closed for the roller pumps to rotate.</p> <p><b>2</b> IRRIGATION roller pump<br/>This roller pump provides fluid inflow.</p> <p><b>3</b> Tension rocker arms<br/>Holds the tubing on the roller pump heads.</p> <p><b>4</b> POWER pad<br/>Turns the power ON if the main power switch in the back of the pump is on (the green Standby light is ON).</p> | <p><b>5</b> PRESSURE display<br/>Displays the preset pressure when the base pressure is being set and the dynamic pressure (1 sec) following the release of the pressure adjustment pads.</p> <p><b>6</b> ALARM<br/>The red indicator will light up if a safety parameter is violated.</p> <p><b>7</b> SHAVER speed display<br/>Indicates the speed and direction of rotation.</p> |
|--|--|

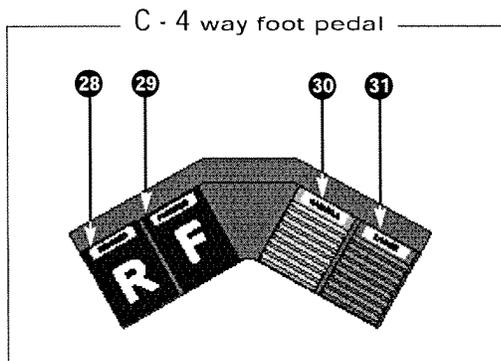
- 8** **SUCTION** roller pump  
This roller pump provides outflow of fluid.
- 9** **Pinch Valve**  
This pinch valve moves automatically when the shaver is in rotation, selecting the appropriate suction tube.
- 10** **Lavage mode pad**  
This feature automatically sets off or stops a sequence of pressure and flow increases to clear the field of view of blood and debris.
- 11** **Pinch Valve pad**  
This automatically opens the pinch valve to insert or remove the shaver suction tubing.
- 12** **SHAVER Speed Selection pads**  
Select the Low, Med or High pre-set speeds.
- 13** **SHAVER Run/Stop pad**  
Used to start or stop the shaver mode when using the FMS Shaver.
- 14** **Shaver Suction setting**  
Indicates the suction rate selected through the shaver.  
Min, Low, Med, High.
- 15** **SHAVER speed increase/decrease.**  
Increase or decrease the shaver rotation speed (RPM). This can also be achieved using the foot pedal.
- 16** **Shaver handpiece connection.**  
Line up the red dots on the male and female connectors to connect the shaver handpiece.
- 17** **Cannula Suction setting**  
Sets the flow rate through the cannula.  
Min, Low, Med, High.
- 18** **PUMP Run/Stop pad**  
Turns the pump on and off. If the pump is activated "PUMP" appears on the pressure display. Green led blinks when pump is on "Stop".
- 19** **Pressure transducer connection**  
A differential transducer is built in the fms duo<sup>®</sup>+. It measures the pressure in the pressure chamber of the irrigation tubing.
- 20** **Fill Chamber pad**  
This is used to automatically fill the chamber and turn off the LOW PRESSURE alarm.
- 21** **PRESSURE adjustment pads**  
Press the arrows to increase or decrease the pressure in increments of 5. The initial setting is 50.
- 22** **Auto-locking device.**  
The patented device allows the disposable tubing to be properly positioned and locked in place around the two roller pumps. For safety reasons it has been colour-coded GREEN for the IRRIGATION and ORANGE for the SUCTION tubing.

B - Rear panel



- 22 Shaver interface connection  
25 pin hand and foot control interface cables connector.
- 23 Foot pedal connection  
9 pin connector to plug four way and two way foot pedals.
- 24 Identification and specifications
- 25 I/O Switch, fuses and power connection
- 26 Reference number
- 27 Serial number:  
The 2 first digits represent the year of manufacturing. The second set of digits represent the week of manufacturing.

ENGLISH



- 28 Reverse
- 29 Forward
- 30 Cannula suction
- 31 Lavage mode

## 1.7 Other Indicators

(Audible tone)

- An audible tone sounds when the "POWER" pad is pressed and the pump turns on.
- An audible tone sounds when the Lavage mode is activated (see section 4.5, page 26 to activate the cycle).
- Two audible tones sounds when the Lavage mode is deactivated (see section 4.5, page 26 to activate the cycle).

## Chapter 2: Operating precautions, checks and warnings

### Warnings:

Electrical safety testing should be performed by a biomedical engineer or other qualified person.

Risk of electrical shock: Do not remove the cover. Refer servicing to qualified or authorized FMS Repair Service Center.

Do not connect the device to a power source that is not properly earthed (grounded).

Disconnect the device from the main power source when cleaning, servicing, or inspecting.

Inspect all equipment and cables periodically for wear. Replace and return to FMS Repair Service Center if damage is noted.

Avoid fluid contact with the fms duo<sup>®</sup>+ and its electrical connectors.

Do not use flammable agents when cleaning and disinfecting the fms duo<sup>®</sup>+

To avoid risk of fire, replace fuses with same type and rating.

### 2.1 Sterile Packaging:

Carefully examine the shipping package and sterile wrap. If the package is damaged, the sterile seal is broken, or the Expiration Date is passed, do not use.

Irrigation tubes "One Day Set" (see section 3.2 page 15), Ref. 4503  can be reused for an entire surgical day not exceeding 8 consecutive hours.

Biological and viral studies have shown the efficacy against contamination from

one patient to the next during the operating day. Sterility is guaranteed only if the tube changing procedures have been performed precisely according to our set-up guide in chapter 3.

Studies can be downloaded on our website at:

In English:

[www.fmsgroup.com/files/sales/viralen.pdf](http://www.fmsgroup.com/files/sales/viralen.pdf)

[www.fmsgroup.com/files/sales/biologicalen.pdf](http://www.fmsgroup.com/files/sales/biologicalen.pdf)

In French:

[www.fmsgroup.com/files/sales/viralfr.pdf](http://www.fmsgroup.com/files/sales/viralfr.pdf)

[www.fmsgroup.com/files/sales/biologicalfr.pdf](http://www.fmsgroup.com/files/sales/biologicalfr.pdf)

All other tubing, are marked with a  indicating that they are single use only.

### 2.2 Storage and Handling:

Storage temperature:

Do not expose the pump to temperatures below -10°C (14 F) and above 50°C (122 F).

Operating Conditions:

Operate the pump in conditions 10°C (50 F) to + 40°C (104 F).

Damage:

Do not use a pump that has been dropped or shows signs of damage.

Disposal:

Do not incinerate the pump.

Return pumps to FMS for safe disposal.

Factory Settings:

Factory settings are based on experience.

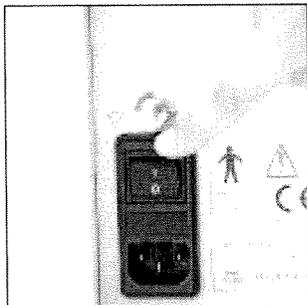
They should only be used as guidelines.

The surgeon is responsible for settings pertaining to the surgical procedure.

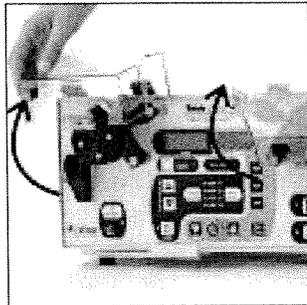
# Chapter 3: Procedure Set-up

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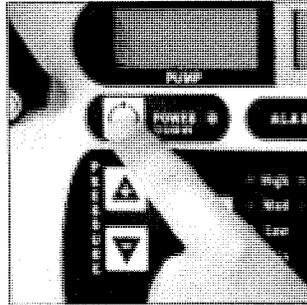
## 3.1 Pump set-up



Power on back of pump on "I".



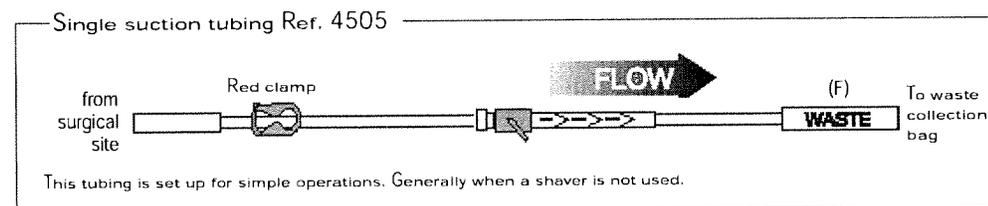
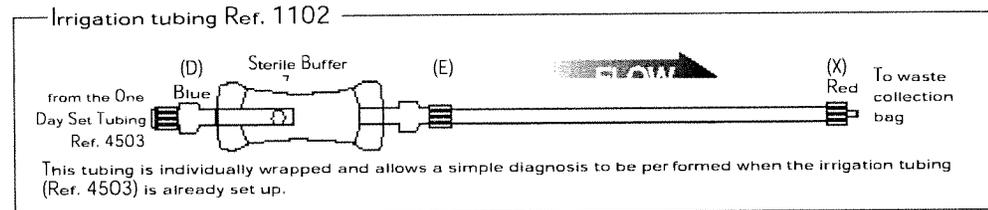
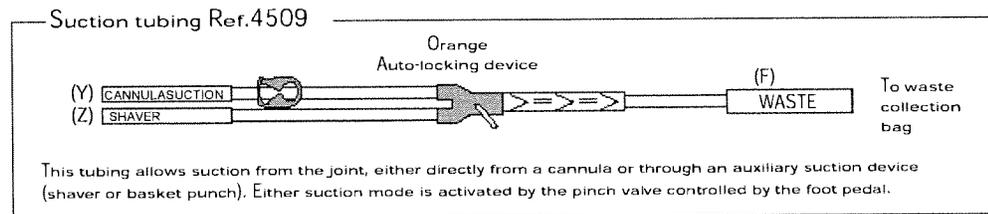
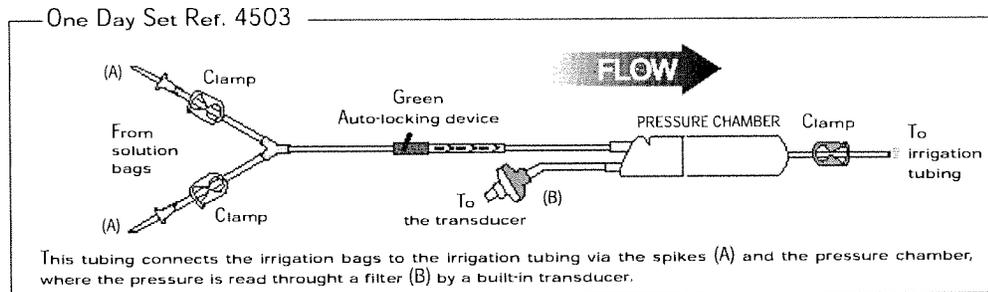
Open both covers.



Press "POWER" pad. The LCD will light up.

### 3.2 Tubing set-up

Disposable tubings used with the fms duo® +

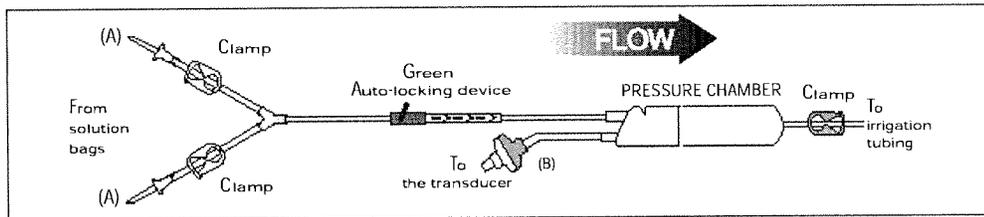


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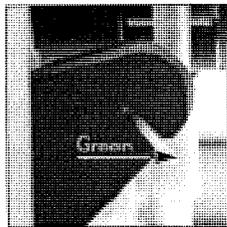
A - Installing the One Day Set Ref. 4503

This tubing connects the saline solution bags to the irrigation tubing. Solution goes from the spikes (A) around the roller pump, through the pressure chamber, where the

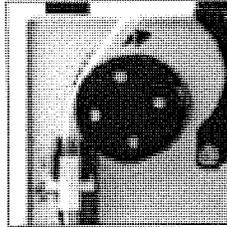
pressure is read through a filter (B) by a built-in pressure transducer, in the fms duo<sup>®</sup>+



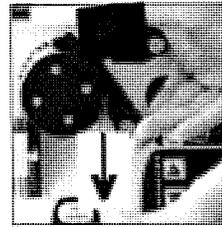
Close all 3 clamps and connect to fluid bags.



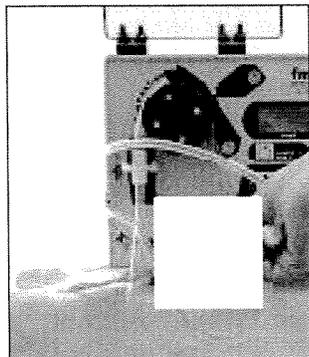
Slide the green half moon of the tubing into the auto-locking device on the pump.



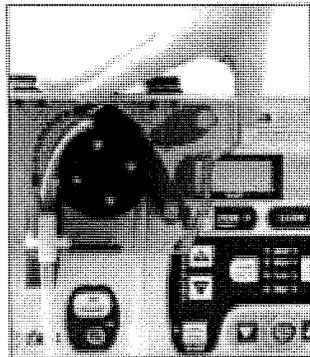
Place and center the tubing around the roller pump.



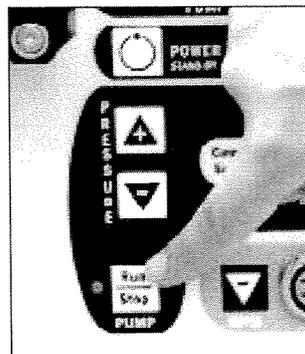
Pull on the tubing and close the tension rocker arm against the tube.



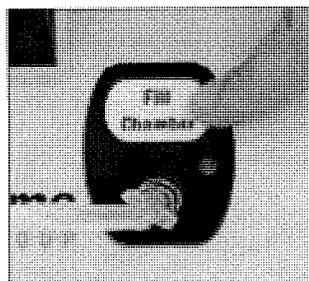
Position the pressure chamber in the holder. Connect the transducer to the pump by gently screwing it in, clockwise.



Close the left cover.



Press on Run/Stop. Green led blinks. Led stops blinking and stays on.



Press FILL CHAMBER pad several times until the chamber is 1/3 full. Green led blinks until pad is pressed.



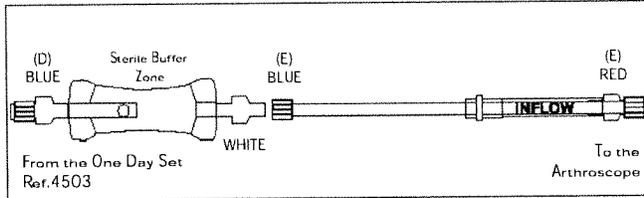
**Warning:**

It is mandatory that the pressure chamber be maintained vertical during the procedure and that the pump be positioned at the same level as the patient.

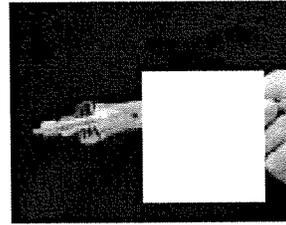
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B - Installing the Patient Set Ref. 4509

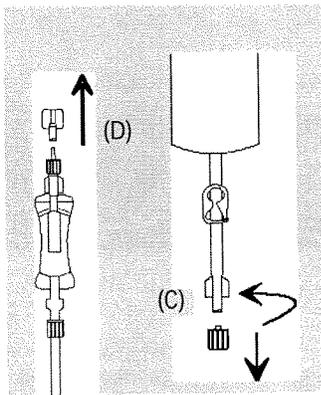
i. Irrigation tubing set up



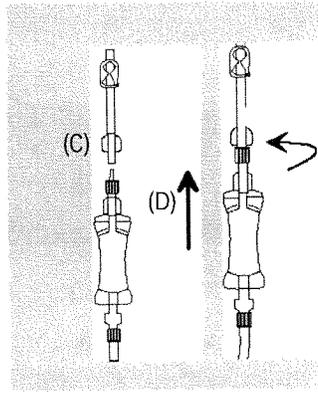
This tubing connects the irrigation tubing to the arthroscope in a sterile manner.



After checking that the luer lock (E) is properly tightened, the sterile nurse takes the irrigation tubing and passes the blue end (D) to a non-sterile person.



The non sterile person removes the blue caps from the irrigation tubing (D) and the One Day Set (C)...

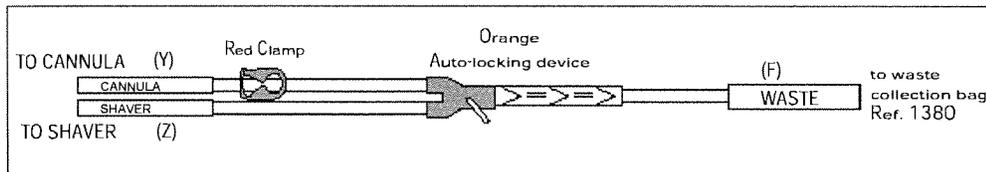


...and immediately connects the One Day Set (C) luer lock, to the irrigation tubing (D) luer lock.



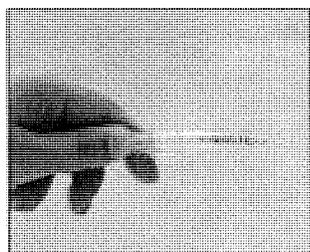
The pump must be in the "Run" mode (18), light on. Prime the intermediary tubing by opening the clamp under the pressure chamber, when primed, close the clamp or the stopcock on the arthroscope (in the sterile zone).

ii. Suction tubing set-up

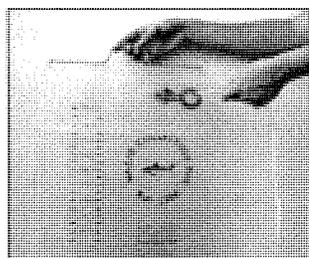


This tubing allows suction from the joint, either from a cannula or through a shaver.

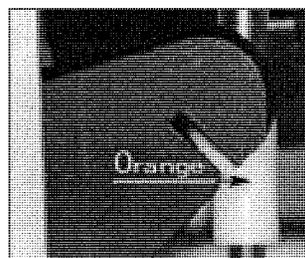
Do not close the red clamp. The red clamp should only be used to reduce or stop flow during surgery.



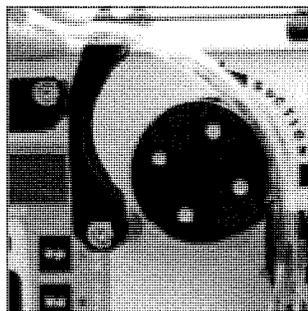
The scrub nurse passes the waste extremity of the suction tube to the non-sterile person (circulating nurse).



The circulating nurse inserts the waste end in a waste collection bag Ref. 1380.

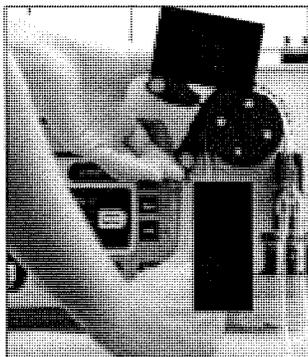


Slide the orange part of the tubing into the auto-locking device on the pump.

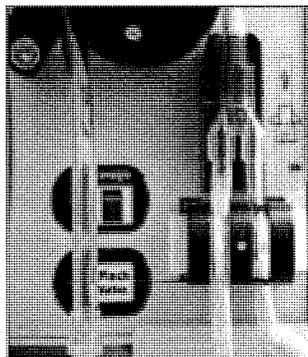


Place and center the tubing around the pump roller.

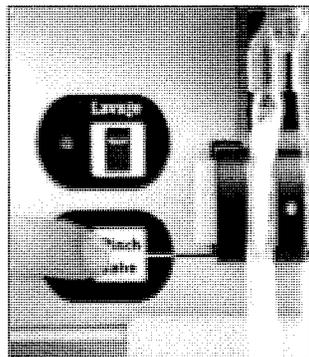
ENGLISH



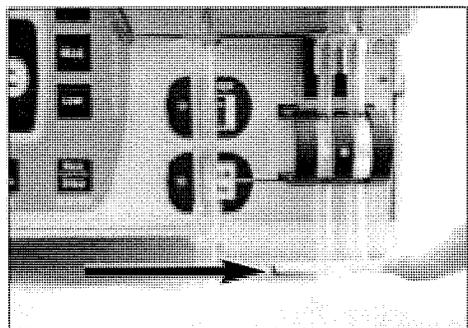
Pull on the tubing.  
Close the tension rocker  
arm against the tube.



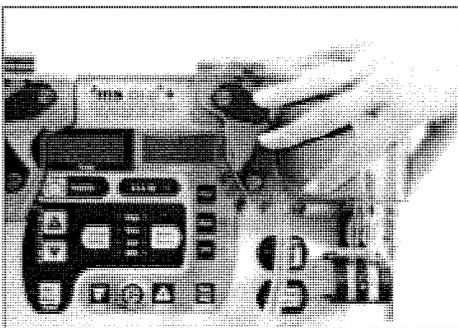
Insert the right tube into the  
right pinch valve slot.



Press on the "Pinch Valve"  
pad and insert the left tube  
into the left pinch valve slot  
(the led will stop blinking).



Slide the tubes behind the tube holder  
under the "Pinch Valve".



Close the right cover.

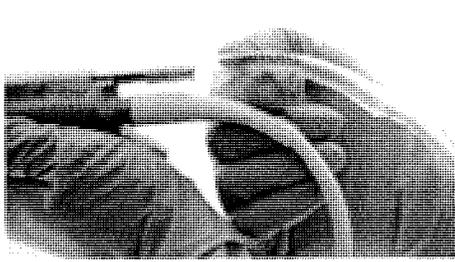
C - Getting started

**STERILE ZONE**



Insert the cannula tubing onto the cannula.

**STERILE ZONE**



Insert the shaver tubing onto the shaver suction port.

**STERILE ZONE**



Connect the luer-lock to the arthroscope.  
Open the stop-cock on the scope.

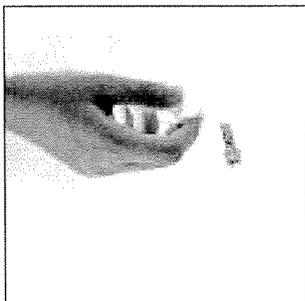
**NON-STERILE ZONE**



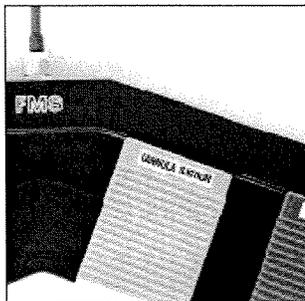
Open the clamp under the chamber.

ENGLISH

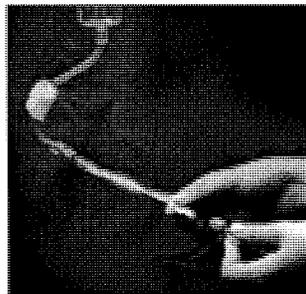
D - End of operation



Close the clamp under the pressure chamber.

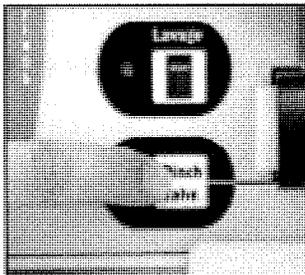


Press on the blue "CANNULA SUCTION" foot pedal to empty the joint (optional).



Disconnect the blue luer lock (E) of the irrigation tubing. The sterile Buffer Zone must remain attached to the One Day Set.

Dispose of the irrigation and suction tubings. To remove the suction tubing, press on the "Pinch Valve" pad to release the tube.

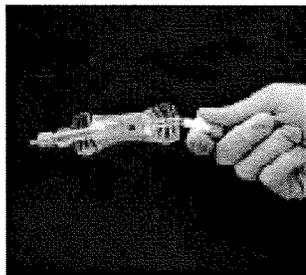


When another surgery is scheduled for the same, operating day, leave the One Day Set in place.

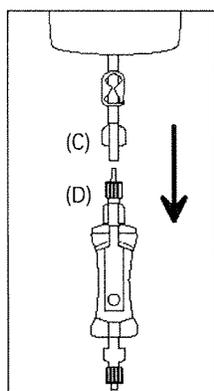
The sterile buffer zone is left on the One Day Set, which ensures sterility between surgeries.

### E- Set-up of next operation

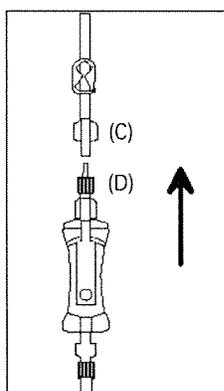
The One Day Set should have been left in place at the end of the previous operation with the sterile buffer zone attached.



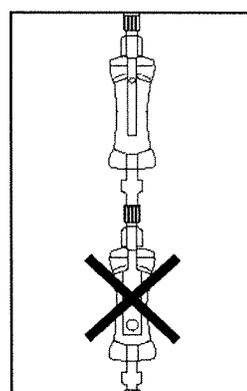
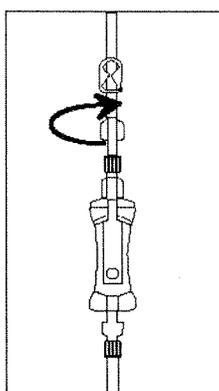
After checking that the luer lock is properly tightened on the new irrigation tubing, the sterile nurse takes the irrigation tubing and passes the blue end (D) to a non-sterile person.



The non-sterile person removes the old sterile buffer zone by disconnecting the luer-locks of the One Day Set (C) and of the irrigation tubing...



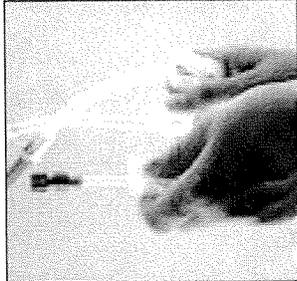
...and immediately connects the blue luer lock (D) of the new irrigation tubing to the blue luer-lock (C) of the One Day Set.



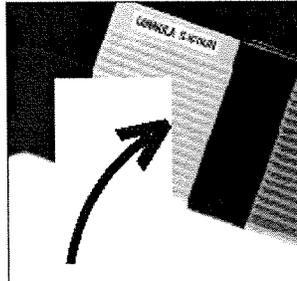
Warning:  
Never attach a buffer zone to another.

ENGLISH

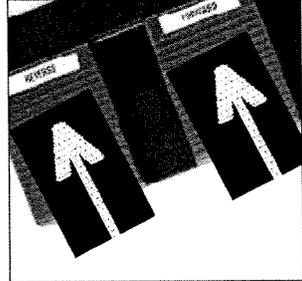
F - End of operating day



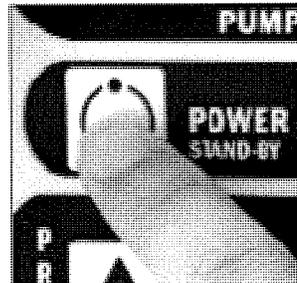
Close all white clamps.



Press on the blue "CANNULA SUCTION" foot pedal to empty the joint. (Optional).



Press on the "FORWARD" or "REVERSE" foot pedal to empty the shaver tubing. (Optional).



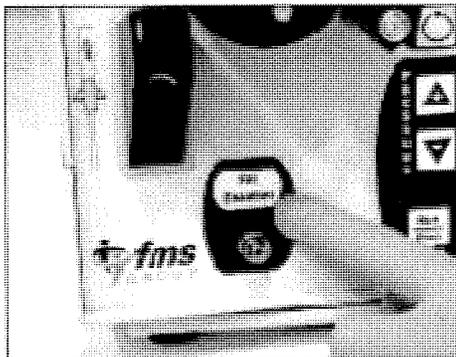
Turn the pump off by pressing the "POWER" pad. Throw away all the tubings.

## Chapter 4: Pump system functions



### 4.1 Preset pressure

Numbers in ( ), refer to diagram on page 8. The pressure is displayed in brackets (eg. <<50>>) on the LCD (5) for 2 seconds when one of the pressure pads is pressed, then the actual pressure is displayed (pressure settings are in levels). Level 50, equals 5 feet of gravity pressure or the equivalent of 112.5 mmHg ( $\pm 10\%$ ). The pump will maintain the pre-set level. When operating, use the " + " and " - " pads (21) to increase and decrease the level. The factory preset level is 50.



### 4.2 Filling the chamber

Press the "Fill Chamber" pad to fill the pressure chamber initially or during the course of the surgery as necessary. The chamber should never be over 1/3 full.

### 4.3 Pressure alarms

Numbers in ( ), refer to diagram on page 8 and 10.



#### High pressure alarm

If the high pressure safety level of 140 is exceeded, the pump stops and the red ALARM (6) Led lights up. The operator should lower the pressure to let the pump automatically restart.

If the pump does not restart when the pressure drops below 140, turn the pump off and on again by pressing the POWER pad (4).

#### Low pressure alarm

If the pressure falls below the low pressure safety level of 10, the red ALARM led lights up "Pres L" flashes on the LCD display, and the pump stops.

Check that the luer-lock and the filter close to the pressure transducer are in proper working order.

If both are satisfactory press "Fill Chamber" to stop the ALARM and Run/Stop pad to restart the unit.



**CAUTION:**  
If water has accidentally entered the tubing leading to the pressure transducer change the irrigation tubing and restart the system.

#### 4.4 Suction settings (Min, Low, Med, High)

Press the "Cannula Suction" (17) or "Shaver Suction" (14) pads to increase the preset suction levels. The adjacent green indicators will light up to show the actual suction setting (Min, Low, Med, High).



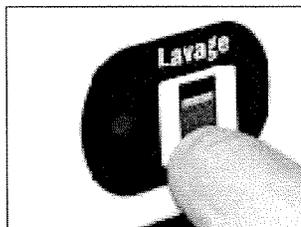
##### A - Cannula suction:

This suction mode is activated when the blue "CANNULA SUCTION" (30) foot-pedal is pressed. The adjacent indicator light setting will blink when the cannula suction is activated as long as you press on the foot pedal.

##### B - Shaver suction:

Step on the black FORWARD (29) or REVERSE (28) foot-pedal to activate your shaver, with your preset suction level. The adjacent indicator light will blink when the shaver suction is activated.

#### 4.5 Lavage mode (red pedal)



The lavage mode is activated by:

- Pressing the "Lavage" pad (10) on the front panel once.
- Stepping on the red LAVAGE (31) foot-pedal for 1,5 second. The led will blink until the lavage pressure and flow cycles are completed.

To cancel an unwanted or lengthy lavage cycle, simply step on the blue "CANNULA" Suction foot-pedal (30) or press the "Lavage" pad (10) on the front panel.

It is possible to use the shaver while the lavage cycle is under way.



##### CAUTION :

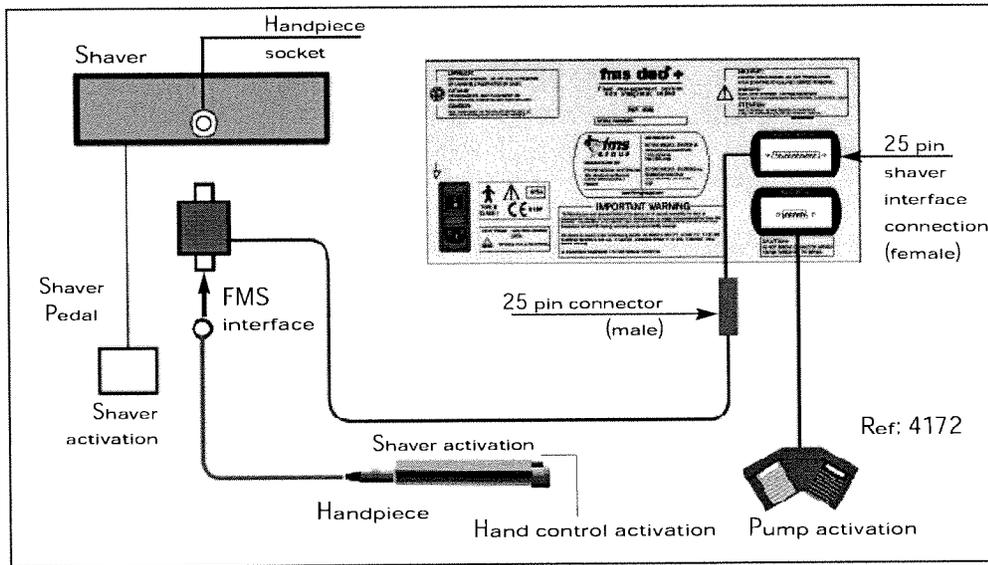
The lavage mode should only be activated if an outflow cannula or working cannula is used.

(Use fms 4.5 mm cannula Ref. 1580).

ENGLISH

### 4.6 Interfaces cables

#### A. Hand control interface.



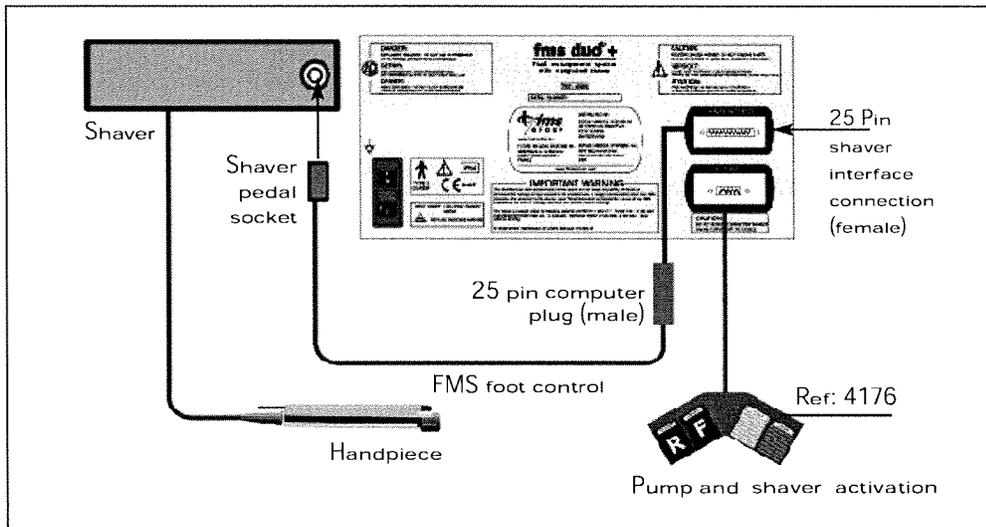
For installation of the cable or control unit, please refer to the instructions provided with the interface

SHAVER (manufacturer)	MODEL	fms hand control interface
LINVATEC	APEX	Ref. 4107
LINVATEC	MICROCHOICE	Ref. 4103
LINVATEC	ADVANTAGE	Ref. 4104
DYONICS	EP-1	Ref. 4112
DYONICS	POWER	Ref. 4122
STRYKER	QUADRACUT	Ref. 4113
STRYKER	SE 5	Ref. 4127
STRYKER	TPS	Ref. 4113
STRYKER	TPS12K	Ref. 4117

When using the following shaver hand control interface, the activation of the pump functions is achieved through a 2 way foot pedal. The activation of the shaver is achieved using the shaver manufacturers hand control (button on shaver) or shaver foot pedal.

If your current shaver is not listed, contact FMS.

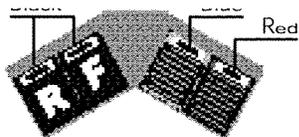
B. Foot control interface



SHAVER (manufacturer)	MODEL	fms foot control interface
LINVATEC CONCEPT	9930/9950	Ref. 4142
LINVATEC CONCEPT	9963E INTRA-ARC	Ref. 4147
LINVATEC	APEX	Ref. 4198
LINVATEC	ADVANTAGE	Ref. 4130
DYONICS	PS3500/PS3500EP	Ref. 4144
DYONICS	EP-1/POWER	Ref. 4190
STRYKER	SE3/SE4	Ref. 4195
STRYKER	QUADRACUT	Ref. 4196
STRYKER	SE5	Ref. 4197
OLYMPUS	PSU II	Ref. 4189
WOLF	RIWO DRIVE	Ref. 4129
STORZ	POWER UNIT S1	Ref. 4148

When using the following shavers, the activation of the pump and shaver can be made from the FMS foot pedal.

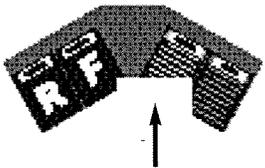
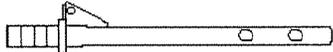
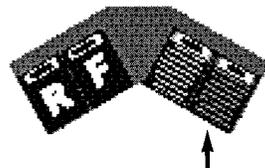
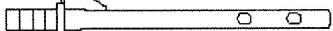
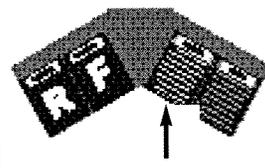
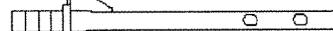
If your current shaver is not listed, contact FMS.



**4.7 Foot pedal**

	PRESS ON THE FOOT PEDAL	SUCTION THROUGH	ACTION ON THE SHAVER
SHAV ER RO TA TI ON DI RE CT I ON			Reverse
			Forward
			Oscillate
SHAV ER RO TA TI ON SP EE D		No suction	Speed decrease
		No suction	Speed increase

The four way foot pedal also controls the fms duo<sup>®</sup>+ features.

	PRESS ON THE FOOT PEDAL	SUCTION THROUGH	ACTION ON THE SHAVER
S U C T I O N		<p>Increased suction</p>  <p>Increased suction by cannula at the pre-set level</p>	none
L A V A G E	 <p>Impulse (2)</p>	<p>Start lavage</p>  <p>Increased pressure and intermittent variation of flow</p>	none
M O D E	 <p>Impulse</p>	<p>Stop lavage (before end of cycle)</p>  <p>Return to normal suction 100ml/mn</p>	none

**⚠ CAUTION:**  
 Only use LAVAGE MODE with adequate outflow.  
 Use an FMS 4.5mm Outflow Cannula Ref. 1580.

## 4.8 Pressure

### Preset pressure

Numbers in ( ), refer to diagram on page 8. The pressure is displayed in brackets (eg. <<50>>) on the LCD (5) for 2 seconds when one of the pressure pads is pressed, then the actual pressure is displayed (pressure settings are in levels).

Level 50, equals 5 feet of gravity pressure or the equivalent of 112.5 mmHg (± 10 %). The pump will maintain the preset level. When operating, use the up and down pads (21) to increase and decrease the level. The factory preset level is 50.

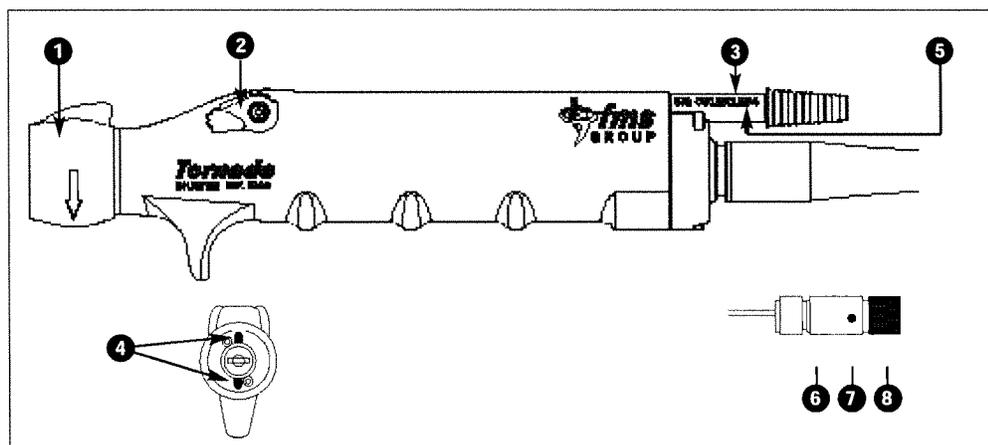
### RECOMMENDED INITIAL SETTINGS\* FOR THE fms duo\*+

Joint	Pressure level with Tourniquet	Pressure level without Tourniquet	Cannula suction	Shaver suction
Shoulder Joint		60	Low or Med	Low or Med
Acromioplasty		60	Low or Med	Med or High
Knee Joint	65	30	Low or Med	Low or Med
Hemarthrosis	50 - 60	50 - 60	Low or Med	Med or High
Wrist	30	65	Low or Med	Low or Med
Elbow, Ankle	40	65	Low or Med	Low or Med

If bleeding occurs, activate lavage mode or increase pressure.

\* These initial settings are based on experience, they should only be used as guidelines. Settings will differ from surgeon to surgeon.

## Chapter 5: Shaver system functions

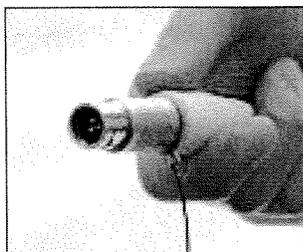


The shaver system can be used in combination with the pump system or independently.

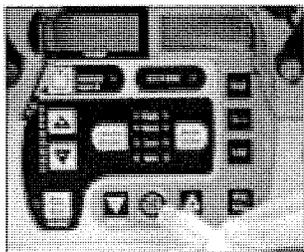
**Warning:** Prior to use, the system components should be checked for any damage. Do not use if any damage is apparent.

- 1** Blade locking ring : Holds blade in place.
- 2** Suction toggle: Controls suction through the suction port.
- 3** Suction port: The suction tubing is connected to the suction port.
- 4** Blade aligning slots: Allow you to insert the blade face up or down.
- 5** Serial number.
- 6** Connector sleeve: Pull on sleeve to remove the cable from the control unit.
- 7** Connector alignment dot: Matches with the dot on the control unit to indicate proper connector alignment.
- 8** Protective cap: Remove the protective cap by holding the connector sleeve and pulling it back towards the cord. While holding the sleeve back, remove the protective cap. Place the cap over the connector end of the handpiece before sterilizing or soaking.

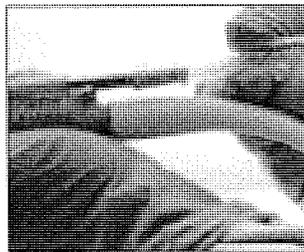
### 5.1 Handpiece set-up



Receive the shaver connector from the sterile field.

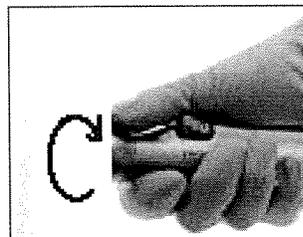


Hold the connector and remove cap, align red dots and connect to front panel.

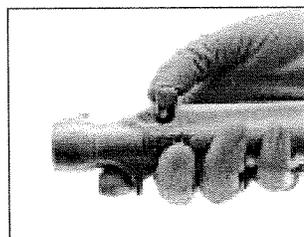


Insert the shaver suction tubing onto the shaver suction port.

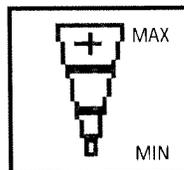
### 5.2 Handpiece operation



To insert and remove the shaver blade, rotate the locking ring to the left.



To increase and decrease suction level, manipulate the suction toggle switch. If the shaver is used with the fms duo<sup>®</sup>+ keep the suction toggle to the "max" position



Shaver handpiece suction

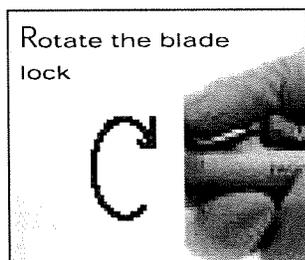
during the entire surgical procedure. Modify your suction levels on the front panel (Section 1.6).

When the control unit is switched on, 4000 RPM appears in the display. The "Low" selection pad gives a pre-set speed of 2000 RPM. Pressing the "Med" (4000 RPM) or "High" (7000 RPM) selection pads provides pre-

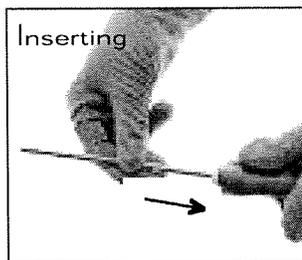
set speeds for use with BURS. The maximum forward and reverse speed is 8000 RPM. The maximum oscillating speed for CUTTERS is 1500 RPM. The rotation speed can be set by pressing the "+" or "-"

pads or by using the foot-pedal (see instructions section 4.1). Blade rotation is activated by pressing the foot-pedals (described on section 4.7).

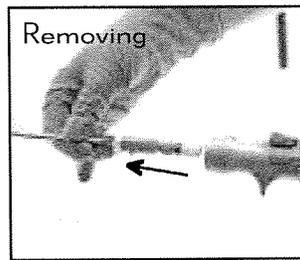
### 5.3 Inserting and removing shaver blades and burs



With your thumb rotate the blade locking ring to the left.



Align blade locking pin with handpiece locking slot (face up or down depending on user preference) and push in.



With your thumb rotate the blade locking ring to the left and pull. Remove blade.

## 5.4 Maintenance: Cleaning and decontamination

### Handpiece cleaning and decontamination

- 1 Place the protective cap securely onto the shaver handpiece connector.
- 2 Leave the suction toggle in the open max position.
- 3 Immerse the handpiece and it's cable (with its protective cap) in a detergent/decontaminant solution.
- 4 Rinse the handpiece in running water.
- 5 Clean with a brush:

The locking system (inner and outer parts). Open and close the locking system to ensure that it is free of foreign bodies.

The suction port (with the suction toggle switch in fully open position). Pass running water through the suction port.

The toggle switch.

Open and close it several time.

- 6 Rinse the inner and the outer parts thoroughly.
- 7 Dry with compressed air (if available), especially the inside of the suction tubing and the locking system.

Note: For best results an ultra sound bath may be used prior to manual cleaning.

The handpiece can be cleaned in a washing machine but the suction port must be manually cleaned with a brush.

### Sterilization

The handpiece is factory sealed and is completely sterilizable using either a steam autoclave, ETO, or soaking.

#### Steam sterilization:

Steam at 134°C for 18 minutes.

The sterilization parameters (temperature and cycle times) may vary from one country to another. Please respect the sterilization directives which apply in your country.

#### Soaking:

The handpiece may be immersed in a chemical sterilizing bath for disinfecting and sterilization. Refer to the manufacturer's instructions.

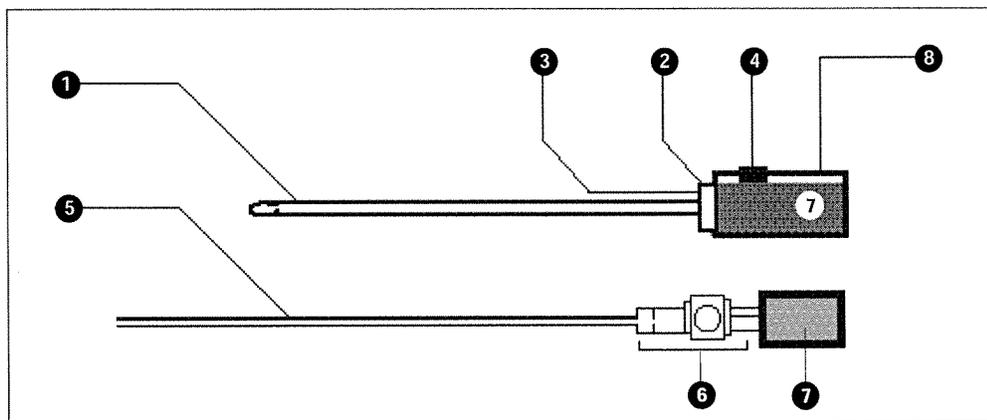
#### Warning:

These guidelines do not guarantee that the device is sterile after the procedure.



The institution is responsible for sterility assurance validation.

5.5 Shaver blades indicators



- 1 Outer blade.
- 2 Tab to track number of uses.
- 3 Ring: Colour indicates the type of blade.
- 4 Locking pin.
- 5 Inner blade.
- 6 Cap: Colour indicates blade diameter (see 7).
- 7 Body: Colour indicates blade diameter:  
 Light grey = 3,5 mm  
 White = 4,0 mm  
 Dark grey = 5,0 mm  
 Black = 5,5 mm
- 8 Outer hub.

Reusable shaver blades are designed for limited re-use (up to 5 times).  
 The blades are manufactured with 100% medical grade stainless steel.  
 The plastic hubs are autoclavable 50 times.

Note : Colour of Ring #3 and Cap #6 should always match.

## 5.5 Limited reusable shaver blades and burs cleaning and decontamination

### Cleaning / decontamination

The inner blade must be removed from the outer blade for cleaning and sterilization. To do so, grasp the end of the inner blade and pull it until it snaps out of the outer blade.

To re-insert the inner blade into the outer blade, push until a click is heard, indicating that it has snapped into place. Match colour coding of inner and outer blades to reassemble.

Before and after each use, disassemble the inner blade from the outer blade and clean the blades using brushes with a mild pH balanced detergent. Ensure that all components are free from blood, tissue, fats or foreign materials. Immerse blades in a solution of water and detergent/decontaminant, refer to detergent instructions for length of immersion time. Rinse well with water and dry.

NOTE: FMS recommends re-using the same blade a maximum of five times. Remove one of the tabs on coloured ring with a scalpel after each use to track usage.

### Shaver blade sterilization

Steam sterilization: 134°C for 18 minutes.

ETO Sterilization: The blades can also be Ethylene Oxide (gas) sterilized using the hospital's operating parameters for the gas and aeration cycles.

Shaver blades should be autoclaved a maximum of 50 times.

NOTE: These guidelines do not guarantee that the device is sterile after the procedure. The institution is responsible for sterility assurance validation.

## Chapter 6: Trouble shooting

PROBLEMS	CAUSE	POSSIBLE SOLUTIONS
The pump stops. Red Alarm Led lights up.	The HIGH PRESSURE safety has activated.	Lower base pressure. Press on the "Run/Stop" pad to restart the pump.
	The LOW PRESSURE safety has activated : "PRES. L" blinks.	Check if luer lock is tight Press on "Fill Chamber" to stop the alarm and press on the Run/Stop pad to restart the pump.
	Hydrophobic filter is wet.	Replace the One Day Set.
	No more irrigation fluid.	Spike new bag and press "Fill Chamber".
No cannula suction.	The cannula is obstructed.	Reposition or clean the cannula.
	The red clamp is closed.	Open red clamp.
No shaver suction.	The shaver blade is obstructed.	Disassemble the blade and clean it.
	The pinch valve is not functioning.	Check the positioning of the suction tubing. Check the interface cable connection.
The roller pump heads do not rotate.	Power is on "O" or is on "Stop".	Check that the main power switch on the back of the pump is on the "I" position and that the "Run/Stop" pad green light is on.
Blades continue to rotate when pedal is released.	Circuit problem.	Turn off unit ("I/O" switch, on the back panel). Wait a minute. Restart pump.

**ENGLISH**

PROBLEMS	CAUSE	POSSIBLE SOLUTIONS
No irrigation.	The stop-cock on the sheath or a clamp is closed. No outflow.	Check the inflow line from the bags to the joint. Open any closed clamps or stop cocks.
The irrigation pump starts spinning frantically, excessive noise.	No more irrigation fluid.	Replace saline solution bags and/or check the clamps under the bags. Press "Fill Chamber" if chamber is lower than 1/3.
The irrigation pump goes on and off erratically. Abnormal pressure fluctuation.	Water may have entered into the pressure sensing line.	Change the One Day Set tubing. If the water has entered the pressure sensing line.
Too much water in the pressure chamber.	Air leak in the line.	Check that the luer locks on the irrigation and pressure sensing tube are closed. If necessary, change the irrigation tubing and start again.
Insufficient pressure.	Irrigation problem.	Check the stop-cock on the arthroscope, the clamps under the saline bags and under the pressure chamber.
Insufficient irrigation.	The cannula has been incorrectly placed (in the sub-cutaneous tissue) or is obstructed.	Reposition or clean the cannula. Verify that the arthroscopic sheath allows sufficient flow. Use High Flow FMS arthroscopic sheaths.

# Chapter 7: Product specifications and ordering information

## SPECIFICATIONS

### Composition

Ref: 4580 fms duo<sup>®</sup> +

### Dimensions

Height: 21 cm

Width: 38 cm

Depth: 37 cm

Weight: 18 kg

### Performance Specifications

- Pressure levels (\*)
  - 10-140 (increments of 5)
- Precision (± 10%) at 0 flow rate
- Cannula flow rate: 100-600ml/mn  
Pre-selected
- Precision (± 15%) of max. flow rate
- Shaver flow rate: 200-800 ml/mn  
Pre-selected
- Precision (± 15%) of max. flow rate
- Shaver speed: 400-8000 rpm  
(increments of 100)

Check the pressure and flow rates annually.  
Contact the FMS After Sales Services if rates differ from those specified.

### Electrical specifications

Input power: 120/230 V<sub>~</sub>

Frequency: 50-60Hz

Current Draw: 500VA

Fuses: 5 A Time Delay

Conforms to standard EN 60601-1  
(Electromagnetic Compatibility)

### Storage conditions

Temperatures: -10° C (14 F) to + 50° C (104 F)

### Operating conditions

Temperatures: +10° C (50 F) to + 50° C (104 F)

Relative humidity: 30 to 75%

## ORDERING INFORMATION

### EQUIPMENT

	Ref
fms duo <sup>®</sup> + (alone)	4580
4 way foot pedal	4176
2 way foot pedal	4172
Tornado Shaver Handpiece (8000rpm)	8022

### DISPOSABLES

	Ref
Shaver Cutters and Burs	<small>see page 41</small>
One Day Set	4503
Patient Set	4509
Single Suction Tubing	4505
Irrigation Tubing	1102
FMS Waste collection bag (10 liter)	1380
Suction cannula 4.5 mm	1580

### ACCESSORIES:

Trocar for cannula Ref.1580	1581
Obturator for cannula Ref. 1580	1583

### HIGH-FLOW SHEATHS:

With trocar and obturator		
Diam. 6mm	STRYKER 2-stopcock	1033
Diam. 6mm	DYONICS 2-stopcock	1026
Diam. 6mm	STORZ 2-stopcock	
	LINVATEC 2-stopcock	
	FMS 2-stopcock	1332

### FMS BRUSHES:

Brush for shaver blades	3mm	7193
Box of 50 Pcs (10X5) X1	4mm	7194
	5mm	7195
	6mm	7196

(\*) Pressure measured in pressure chamber

ENGLISH

## FMS Cutter & Bur guide

### Cutters

Optimal mode: Oscillate - 800 to 1500 RPM

**FULL RADIUS:** Light Yellow.  
Excellent for all general debridement.



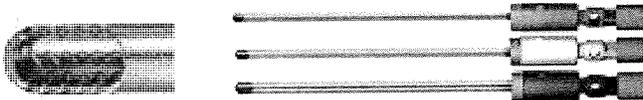
LIMITED REUSE		STERILE
Diam.	Ref.	Ref.
3.5 mm	7300	7305
4.0 mm	7400	7405
5.0 mm	7500	7505

**AGGRESSIVE:** Light Orange.  
Aggressive meniscal trimming, plica and synovium removal.



LIMITED REUSE		STERILE
Diam.	Ref.	Ref.
3.5 mm	7310	7315
4.0 mm	7410	7415
5.0 mm	7510	7515

**ULTRA AGGRESSIVE:** Light Green.  
Ultra aggressive meniscal trimming, plica and synovium removal.



LIMITED REUSE		STERILE
Diam.	Ref.	Ref.
3.5 mm	7320	7325
4.0 mm	7420	7425
5.0 mm	7520	7525

**MENISCUS CUTTER:** Light Turquoise.  
Good for meniscal trimming and joint debridement.



LIMITED REUSE		STERILE
Diam.	Ref.	Ref.
4.0 mm	7430	7435
5.0 mm	7530	7535

**Burs**

Optimal mode: Forward - 2500 to 8000 RPM

**ROUND BUR: Dark Green**

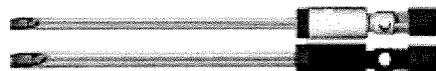
Bone, cartilage and osteochondral debridement and osteophyte.



LIMITEDREUSE		STERILE
Diam.	Ref.	Ref.
4.0 mm	7750	7755
5.5 mm	7850	7855

**BARREL BUR: Dark Blue**

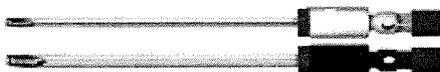
Ideal for resecting bone and cartilage during acromioplasty and notchplasty.



LIMITEDREUSE		STERILE
Diam.	Ref.	Ref.
4.0 mm	7760	7765
5.5 mm	7860	7865

**ROUND TORNADO BUR: Dark Purple**

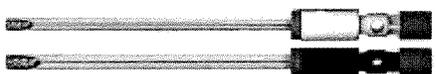
Ultra-aggressive bone, cartilage, osteochondral debridement and osteophyte.



LIMITEDREUSE		STERILE
Diam.	Ref.	Ref.
4.0 mm	7770	7775
5.5 mm	7870	7875

**BARREL TORNADO BUR: Burgundy**

Ultra-aggressive bur, for bone resection during acromioplasty and notchplasty.



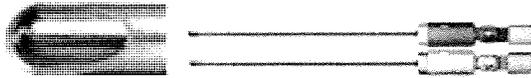
LIMITEDREUSE		STERILE
Diam.	Ref.	Ref.
4.0 mm	7780	7785
5.5 mm	7880	7885

ENGLISH

## Mini blades

### Small Cutters

MINI FULL RADIUS CUTTER: Light Yellow.



LIMITED REUSE			STERILE		
Length	Diam.	Ref.	Length	Diam.	Ref.
80 mm	2.9mm	7250	80 mm	2.9mm	7255
80 mm	3.5mm	7340	80 mm	3.5mm	7345

MINI ULTRA AGGRESSIVE CUTTER: Light Green.



LIMITED REUSE			STERILE		
Length	Diam.	Ref.	Length	Diam.	Ref.
80 mm	2.9mm	7270	80 mm	2.9mm	7275
80 mm	3.5mm	7370	80 mm	3.5mm	7375

MINI WHISKER CUTTER: Light Beige.

LIMITED REUSE			STERILE		
Length	Diam.	Ref.	Length	Diam.	Ref.
80 mm	2.9mm	7290	80 mm	2.9mm	7295

### Small Burs

MINI ROUND BUR: Dark Green.



LIMITED REUSE			STERILE		
Length	Diam.	Ref.	Length	Diam.	Ref.
80 mm	2.0mm	7730	80 mm	2.0mm	7735
80 mm	3.0mm	7740	80 mm	3.0mm	7745

# Chapter 8: Customer service, repairs and warranty

## Customer Service, Repairs and Warranty for purchased or leased equipment

FMS Group guarantees to the first purchaser or lessee of this unit that all parts have been tested, inspected, and shipped in proper working order.

FMS Group guarantees all new equipment to be free from defects and workmanship from the day of purchase for a period of:

fms duo®	Ref.4580	12 Months
4 Way Foot pedal	Ref.4176	12 Months
2 Way Foot pedal	Ref.4172	12 Months
Tornado Handpiece	Ref.8022	12 Months

FMS Warranty repair and labor is free if during the warranty period.

Always return product with Product Return Form (PRF) completed which can be downloaded at: [www.fmsgroup.com/download/prfen.pdf](http://www.fmsgroup.com/download/prfen.pdf)

All equipment must be cleaned and or sterilized before return, whichever is applicable.

Products must be returned, to FMS Service Center in original packaging. If original packaging is not available use protective cartons and packing material. Damage caused to the equipment during transit is not covered under FMS warranty. Consequently we recommend that you insure your shipments appropriately.

FMS warrants all repair work performed on non-warranty items to be free of defects or workmanship for a period of 90 days from the day the equipment is received by the customer.

The Warranty is not applicable to products that have been:

- Used with equipment or disposables not manufactured by FMS.
- Equipment that has been tampered with, altered, abused, or misused.
- Damage caused by user error such as equipment dropped, cables severed, fire and water damage.
- Instruments that were serviced, or repaired by non-FMS authorized service centers.

ENGLISH

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38 Chemin du Grand-Puits  
1217 Geneva  
Switzerland  
Tél. : + 41 22 783 10 70  
Fax : + 41 22 785 04 95

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Future Medical System S.A.  
504 McCormick Drive Glen Burnie  
21061 Maryland  
USA  
Tel. : + 1 410 761 9411  
Fax : + 1 410 761 9422

Manufactured by:  
Future Medical System S.A.  
265 route de la Baronne  
06640 Saint-Jeannet  
France  
Tel. : + 33 4 92 12 04 74  
Fax : +33 4 92 12 04 75

*Appendix 2*

**DUAL WAVE ARTHROSCOPY FLUID MANAGEMENT  
DEVICE**

AR-6480 Console Engineering Drawings

# (b)(4) Engineering Drawing

Records Processed under FOIA Request 2013-7213; Release by CDRH on 09/17/2015

# (b)(4) Engineering Drawing

Records Processed under FOIA Request 2013-7213; Release by CDRH on 09/17/2015

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(b)(4) 3rd Party Manufacturer

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COMPONENT	REVISION
REF-233-01	0

**EC REP**  
 Arthrex GmbH  
 Liebigstrasse 13  
 D-85757 Karlsfeld/München Germany  
 Tel: 49-8131-5957-0

8A  
**S/N: NX030MC**  
 50-60HZ  
**2009-03**

~ 100-240V  
**REF AR-6480**

~ 100-240V  
**S/N: NX030MC**

50-60HZ  
**2009-03**

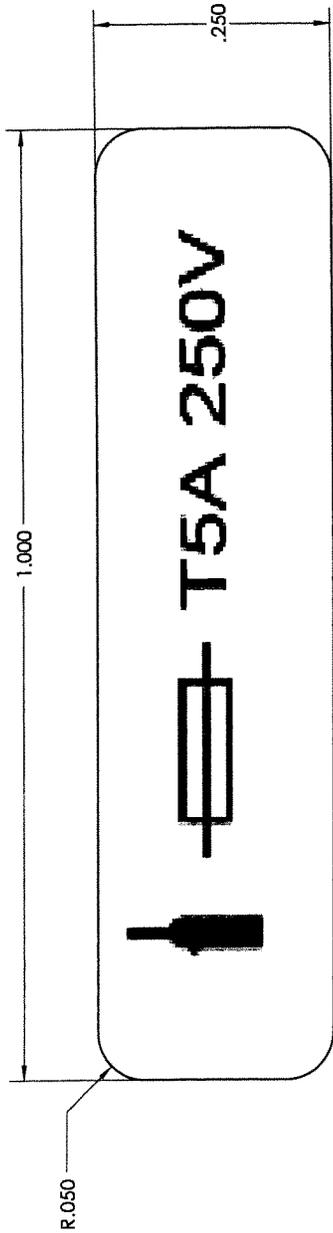
Arthrex, Inc.  
 1370 Creekside Blvd.  
 Naples, FL 34108  
 Customer Service: 800-934-4404

Class I Medical Device (Insulation)  
 IP22  
 PHN 03-1205, Rev A8

NOTES:  
 1. ADHESIVE BACK, SILVER VINYL LABEL.

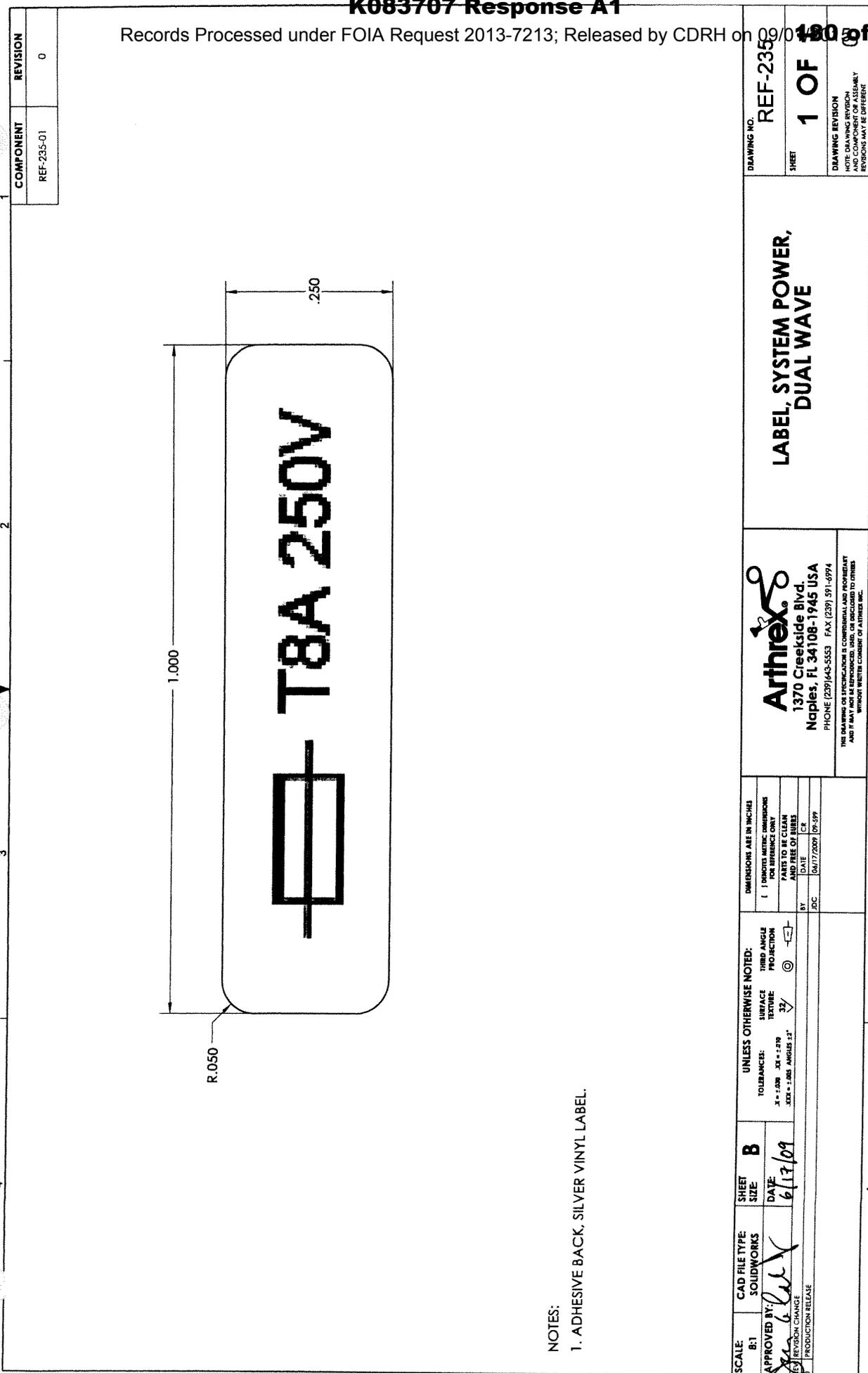
SCALE: 2:1 APPROVED BY: <i>[Signature]</i> DATE: 6/17/09 REVISION CHANGE: 0 PRODUCTION RELEASE	CAD FILE TYPE: SOLIDWORKS SHEET SIZE: B DATE: 6/17/09	UNLESS OTHERWISE NOTED: TOLERANCES: .1 - .125 .125 - .250 .250 - .500 .500 - 1.000 .125 - .250 ANGLES 15°	DIMENSIONS ARE IN INCHES UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES UNLESS OTHERWISE SPECIFIED	REF-233-01 SHEET 1 OF 1 DRAWING REVISION NOTE: DRAWING REVISION AND COMPONENT OR ASSEMBLY REVISIONS MAY BE DIFFERENT	LABEL, SERIAL/CERTIFICATION, DUAL WAVE
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1	COMPONENT	REVISION
	REF-234-01	0



NOTES:  
1. ADHESIVE BACK, SILVER VINYL LABEL.

DRAWING NO. REF-234		SHEET 1 OF 1	
DRAWING REVISION DRAWING REVISIONS ARE FOR THE COMPONENT OR ASSEMBLY. REVISIONS MAY BE DIFFERENT.			
<p><b>Arthrex</b> 1370 Creekside Blvd. Naples, FL 34108-1945 USA PHONE (239) 643-5553 FAX (239) 591-6994</p> <p><small>THIS DRAWING OR SPECIFICATION IS CONFIDENTIAL AND PROPRIETARY AND IT IS NOT TO BE REPRODUCED OR TRANSMITTED IN ANY FORM OR BY ANY MEANS WITHOUT THE WRITTEN CONSENT OF ARTHREX, INC.</small></p>		<p>DIMENSIONS ARE IN INCHES 1. DIMENSIONS IN METRIC DIMENSIONS FOR REFERENCE ONLY 2. DIMENSIONS IN METRIC DIMENSIONS FOR REFERENCE ONLY 3. DIMENSIONS IN METRIC DIMENSIONS FOR REFERENCE ONLY 4. DIMENSIONS IN METRIC DIMENSIONS FOR REFERENCE ONLY</p>	
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APPROVED BY: <i>[Signature]</i>	UNLESS OTHERWISE NOTED: TOLERANCES: X = ±.030 XX = ±.010 XXX = ±.005 ANGLES 13°	<p>UNLESS OTHERWISE NOTED: SURFACE FINISH: R = 0.8 R = 0.4 R = 0.2</p>	
REVISION CHANGE	BY: JPC	DATE: 06/17/2009	PP-599
PRODUCTION RELEASE			



COMPONENT	REVISION
REF-235-01	0

DRAWING NO.	REF-235
SHEET	1 OF 1
DRAWING REVISION	
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**LABEL, SYSTEM POWER, DUAL WAVE**

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 Naples, FL 34108-1945 USA  
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I PREFERRED METRIC DIMENSIONS FOR REFERENCE ONLY	
PARTS TO BE CLEAN AND FREE OF BUBBLES	
BY	DATE
JDC	06/17/2009 09:59

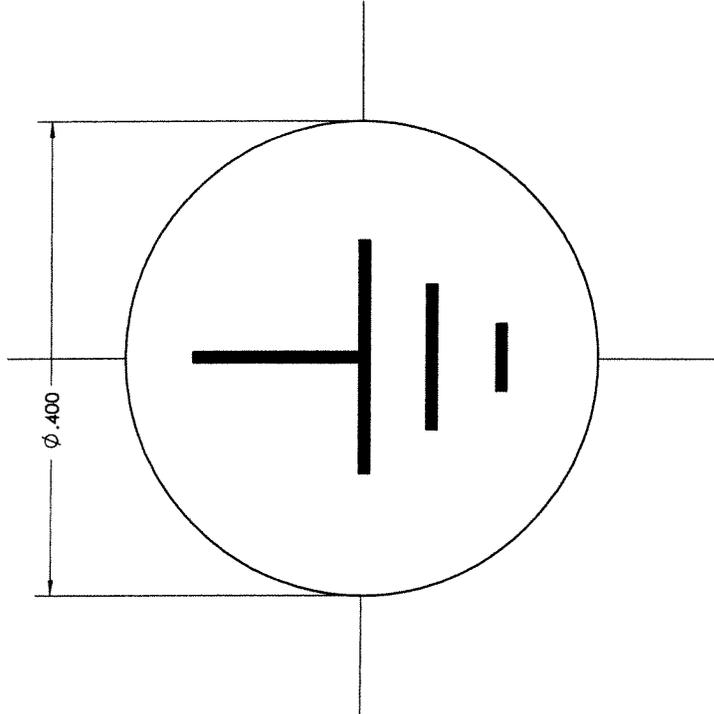
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APPROVED BY: <i>[Signature]</i>	DATE: 6/17/09	REVISION CHANGE		PRODUCTION RELEASE	

NOTES:  
 1. ADHESIVE BACK, SILVER VINYL LABEL.

# K083707 Response A1

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COMPONENT	REVISION
REF-236-01	0



NOTES:  
1. ADHESIVE BACK, SILVER VINYL LABEL.

DRAWING NO. REF-236  
SHEET 1 OF 1  
DRAWING REVISION  
NOTE: DRAWING REVISION AND COMPONENT OR ASSEMBLY REVISIONS MAY BE DIFFERENT

**LABEL, GROUND, DUAL WAVE**

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Naples, FL 34108-1945 USA  
PHONE (239) 443-5553 FAX (239) 591-0794  
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PARTS TO BE CLEANED BY DATE  
BY JDC 10/17/2009 10:59

UNLESS OTHERWISE NOTED:  
TOLERANCES: SURFACE FINISH: THIRD ANGLE PROJECTION  
X ± .008 .01 ± .010 32  
XX ± .004 ANGLES .5°

SCALE: 10:1  
CAD FILE TYPE: SOLIDWORKS  
SHEET SIZE: B  
APPROVED BY: [Signature] DATE: 6/17/09  
REVISION CHANGE: [Signature]  
D PRODUCTION RELEASE

# (b)(4) Engineering Drawing

Records Processed under FOIA Request 2013-7213; Released by CDRH on 09/17/2015

# (b)(4) Engineering Drawing

Records Processed under FOIA Request 2013-7213; Release by CDRH on 09/17/2015

# (b)(4) Engineering Drawing

Records Processed under FOIA Request 2013-7213; Release by CDRH on 09/17/2015

*Appendix 2*

**DUAL WAVE ARTHROSCOPY FLUID MANAGEMENT  
DEVICE**

AR-6482 Remote Engineering Drawings

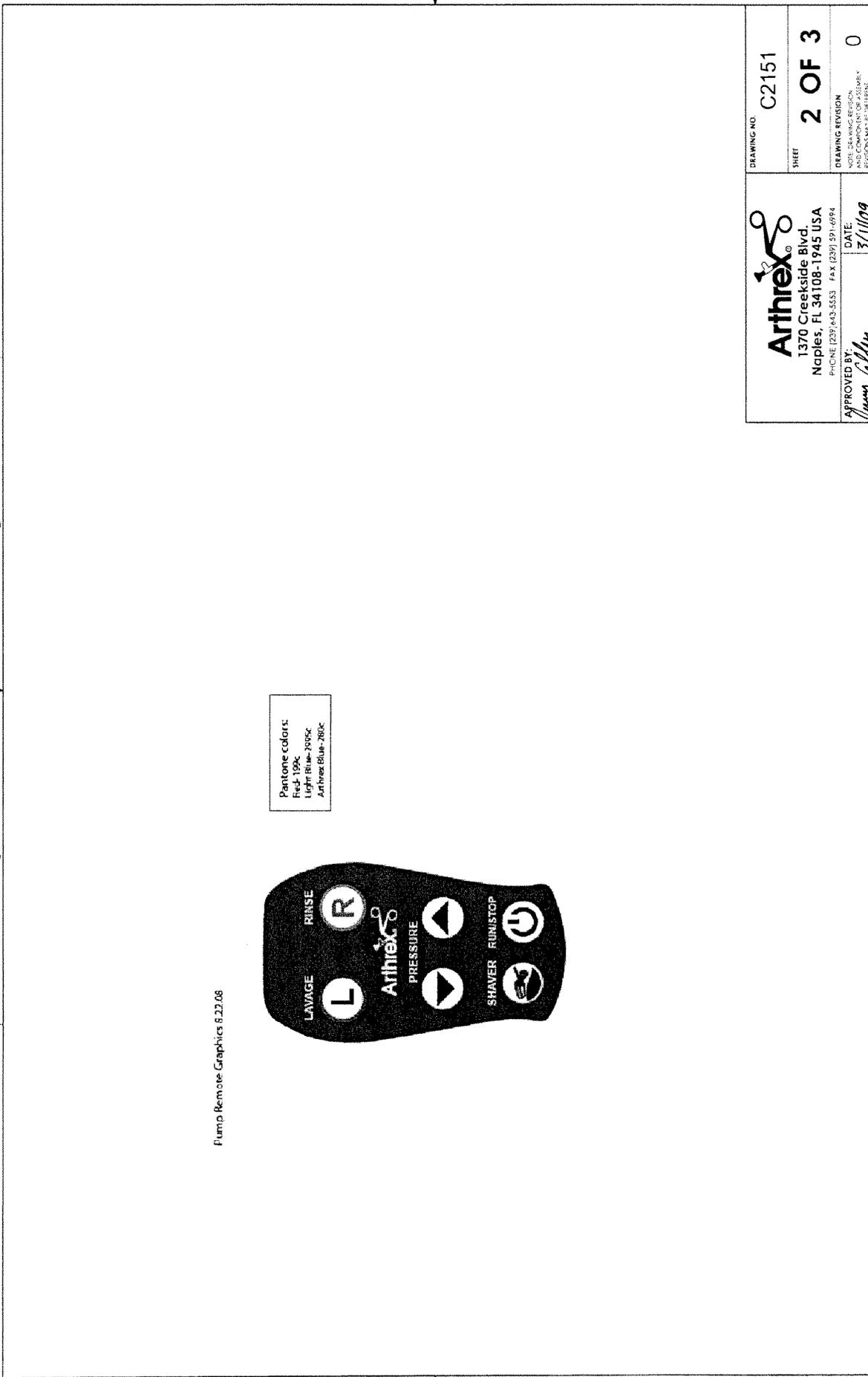
# (b)(4) Engineering Drawing

Records Processed under FOIA Request 2013-7213; Release by CDRH on 09/17/2015

(b) (4)

# K083707 Response A1

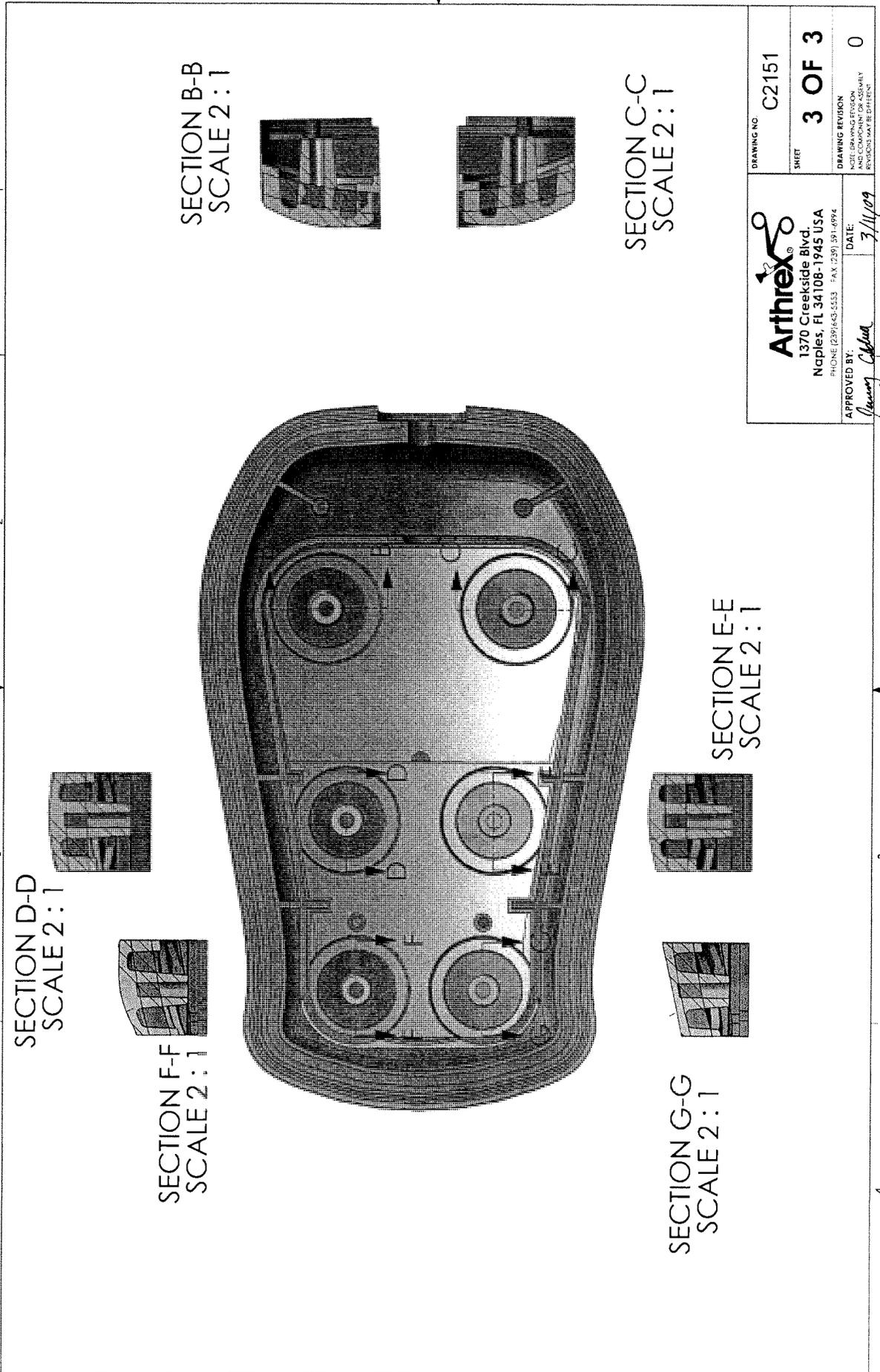
Records Processed under FOIA Request 2013-7213; Released by CDRH on 09/01/2013 of 418



Pump Remote Graphics 6.22.08

Pantone colors:  
Red-199c  
Light Blue-2955c  
Arthrex Blue-285c

<b>Arthrex</b> 1370 Creekside Blvd. Naples, FL 34108-1945 USA <small>PHONE (239) 640-3553 FAX (239) 591-6994</small>	DRAWING NO C2151
APPROVED BY: <i>Jenny Keller</i>	SHEET 2 OF 3
DATE: 7/1/09	DRAWING REVISION NOTE: DRAWING REVISION AND COMPONENT OF ASSEMBLY POSITION MAY BE DIFFERENT.



DRAWING NO. C2151	
SHEET 3 OF 3	
DRAWING REVISION 0	
NOTE: DRAWING POSITION AND COMPONENT OR ASSEMBLY REVISIONS MAY BE DIFFERENT	
<b>Arthrex</b> 1370 Creekside Blvd Naples, FL 34108-1945 USA PHONE (239) 643-5533 FAX (239) 591-6994	DATE: 3/11/09 APPROVED BY: <i>Jeremy Colburn</i>

# (b)(4) Engineering Drawing

Records Processed under FOIA Request 2013-7213; Release by CDRH on 09/17/2015

# (b)(4) Engineering Drawing

Records Processed under FOIA Request 2013-7213; Release by CDRH on 09/17/2015

# (b)(4) Engineering Drawing

Records Processed under FOIA Request 2013-7213; Release by CDRH on 09/17/2015

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Records Processed under FOIA Request 2013-7213; Release by CDRH on 09/17/2015

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Records Processed under FOIA Request 2013-7213; Release by CDRH on 09/17/2015

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**DUAL WAVE ARTHROSCOPY FLUID MANAGEMENT  
DEVICE**

AR-6483 Foot Pedal Engineering Drawings

# (b)(4) Engineering Drawing

Records Processed under FOIA Request 2013-7213; Release by CDRH on 09/17/2015

# (b)(4) Engineering Drawing

Records Processed under FOIA Request 2013-7213; Release by CDRH on 09/17/2015

# (b)(4) Engineering Drawing

Records Processed under FOIA Request 2013-7213; Release by CDRH on 09/17/2015

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Records Processed under FOIA Request 2013-7213; Release by CDRH on 09/17/2015

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**DUAL WAVE ARTHROSCOPY FLUID MANAGEMENT  
DEVICE**

AR-6430 Outflow Tubing with Cassette Engineering Drawings

# (b)(4) Engineering Drawing

Records Processed under FOIA Request 2013-7213; Release by CDRH on 09/17/2015

# (b)(4) Engineering Drawing

Records Processed under FOIA Request 2013-7213; Release by CDRH on 09/17/2015

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Records Processed under FOIA Request 2013-7213; Release by CDRH on 09/17/2015

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**DUAL WAVE ARTHROSCOPY FLUID MANAGEMENT  
DEVICE**

AR-6411 ReDeuce Pump Tubing Engineering Drawings

# (b)(4) Engineering Drawing

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Records Processed under FOIA Request 2013-7213; Release by CDRH on 09/17/2015

*Appendix 2*

**DUAL WAVE ARTHROSCOPY FLUID MANAGEMENT  
DEVICE**

AR-6421 ReDeuce Patient Tubing Engineering Drawings

# (b)(4) Engineering Drawing

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Records Processed under FOIA Request 2013-7213; Release by CDRH on 09/17/2015

*Appendix 2*

**DUAL WAVE ARTHROSCOPY FLUID MANAGEMENT  
DEVICE**

AR-6215 Tube Adapter "Y" (tubing) Engineering Drawings

# (b)(4) Engineering Drawing

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*Appendix 2*

**DUAL WAVE ARTHROSCOPY FLUID MANAGEMENT  
DEVICE**

AR-6220 Extension Tubing Engineering Drawings

# (b)(4) Engineering Drawing

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Records Processed under FOIA Request 2013-7213; Release by CDRH on 09/17/2015

# (b)(4) Engineering Drawing

Records Processed under FOIA Request 2013-7213; Release by CDRH on 09/17/2015

**(b)(4)**

DualWave Inflow/Outflow  
ARTHROSCOPY PUMP

**PRODUCT SPECIFICATION**

REVISION HISTORY

Revision	Date	Description of Change
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**(b)(4)**

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# (b)(4) Product Specification

Record Processed under FOIA Request 2013-7213; Released by CDRH on 09/01/2015

# PRODUCTION SPECIFICATION

CONFIDENTIAL

## DUAL WAVE REMOTE CONTROL

(b) (4)

President		Date:	
Product Engineer		Date:	
Product Manager		Date:	
Quality Engineer		Date:	
Regulatory:		Date:	
Manufacturing:		Date:	

Revision History:

Revision:	Date:	Description of Change:
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(b) (4)

October 31, 2008

Product Specification (b) (4)

ARTHREX, INC

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