



DualWave™ Arthroscopy Pump

User's Guide

The *Arthrex DualWave™ Arthroscopy Pump User's Guide* provides safety operation information for all components of the Arthrex DualWave Arthroscopy Pump (model AR-6480), including accessories. All operating personnel must read this *User's Guide* for version 1.7 or higher thoroughly prior to using this system and follow all safety warnings, cautions, and precautions.

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Arthrex, Inc.

1370 Creekside Blvd.

Naples, FL 34108-1945 USA

Toll Free: 1-(800) 934-4404

www.arthrex.com

EC REP Arthrex GmbH

Erwin-Hielscher-Strasse 9

81249 München, Germany

Tel: +49 89 909005-0

www.arthrex.de

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4.1 Skysio ištraukimo kasetė skirta skysčių surinkimui iš seiverio rankenos kaniulės ir prailginimo linijos;

2.0 Product Description

2.1 Product Description and Intended Use

The Arthrex AR-6480 DualWave Arthroscopy Pump is a system that maintains constant, non-pulsed control of intra-articular rinsing and distention pressure throughout all phases of an arthroscopic surgical procedure. The AR-6480 is intended to provide continuous pulse-free flow that reacts immediately to changes in the intra-articular pressure so that joint distention can be sustained even under high shaver extraction volumes or secondary outflow.

W A R N I N G !

All fluid inflow devices, including gravity assist, may cause fluid extravasations into the surrounding tissues. This extravasation may be mild, moderate, or severe. In severe cases, the resulting edema may result in a serious adverse patient event which may include compartment syndrome, nerve compromise, or death. Undiagnosed capsular defects will exacerbate fluid extravasation conditions.

When utilizing any fluid management device, the patient (extremity and surrounding area) must be monitored closely by the surgical team for signs of excess fluid buildup. Fluid usage volumes should be monitored and compared to similar surgical procedures. With all arthroscopy pumps, correct setup and proper user operation is required. Always select the lowest possible pressures in order to achieve the required intra-articular distention. All alarms or alerts must be acknowledged and the appropriate troubleshooting procedure followed.

W A R N I N G !

FAILURE TO FOLLOW THE SETUP INSTRUCTIONS AND/OR CONTINUING TO USE THE PUMP WITHOUT RESOLVING AN ALARM CONDITION COULD RESULT IN A SERIOUS PATIENT ADVERSE EVENT.

Failure to adhere to the setup instructions and use of Arthrex certified tubing may result in inaccurate pressure sensing and monitoring by the device. It is imperative that the user is aware that patient safety may be compromised when an alarm on the pump is ignored or silenced incorrectly. NEVER ignore or silence alarms. Follow the appropriate troubleshooting procedures and carefully monitor the patient. Only Arthrex certified tubing must be used.

W A R N I N G !

This device is only for use in normal arthroscopic procedures as described in the User's Guide, 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.

Figure 6 Two-Piece Tubing Configuration

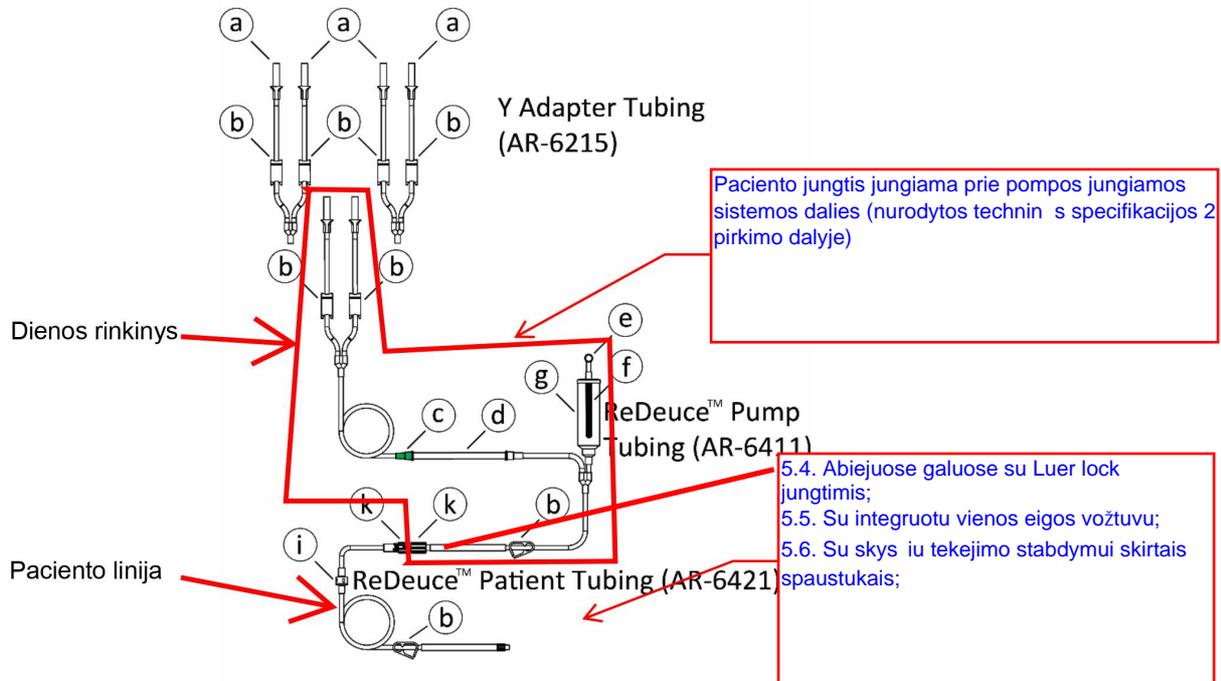


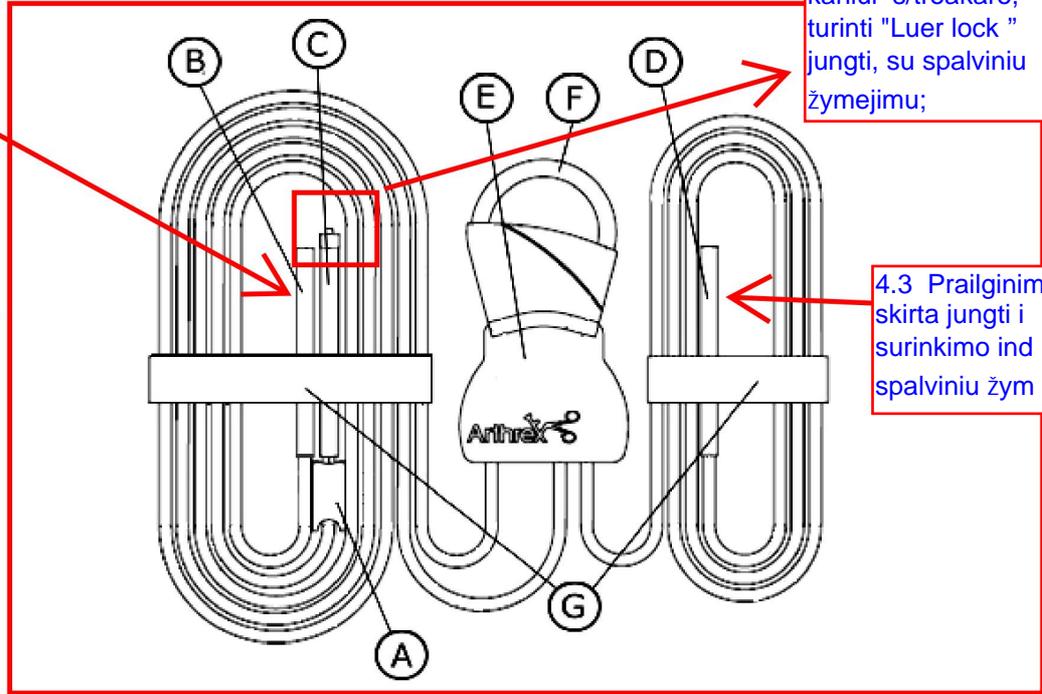
Table 7 Elements of the Two-Piece Tubing Configuration

Element	Description	Tubing Set
a	Bag spikes	AR-6215
b	<u>Tubing clamps</u>	AR-6215 AR-6411/AR-6420 AR-6421/AR-6425
c	Green connector	AR-6411/AR-6420
d	Tubing boot	AR-6411/AR-6420
e	Pressure line connector	AR-6411/AR-6420
f	<u>Neoprene tube for sensing pressure fluctuations</u>	AR-6411/AR-6420
g	Sensor chamber	AR-6411/AR-6420
k	High flow, dual lumen connectors	AR-6411/AR-6420 AR-6421/AR-6425
i	<u>Backflow check valve</u>	AR-6421/AR-6425

Figure 7 Outflow Tubing Configuration (AR-6430)

4.3 b) Prailginimo linija, kuri jungiasi prie šeiverio rankenos, su spalviniu žymejimu;

4. Vienkartines artroskopines irigacines sistemos - skys io ištraukimo kasete



4.3 a) Linija, kuri jungiasi prie kaniul s/troakaro, turinti "Luer lock" jungti, su spalviniu žymejimu;

4.3 Prailginimo linija, skirta jungti i surinkimo ind , su spalviniu žym jimu.

Table 8 Elements of the Outflow Tubing Configuration

Element	Description	Tubing Set
A	Tubing clamp	AR-6430
B	<u>Shaver attachment</u>	AR-6430
C	<u>Cannula attachment</u>	AR-6430
D	<u>Waste egress</u>	AR-6430
E	Outflow cassette	AR-6430
F	Tubing loop for outflow roller	AR-6430
G	Paper retaining strap	AR-6430

2.5.2 Main Pump Tubing Set (AR-6410: Region A)

The *Main Pump Tubing Set* offers inflow and pressure sensing tubing. If used alone, the tubing must be *completely discarded* following each surgical procedure. From the pump, the tubing is 4 meters (13 ft.) in length.

NOTE: *This User's Guide assumes that the AR-6410 is used alone or in combination with the AR-6220, described below. For specific information about each tubing set, refer to the Directions for Use that are included with each set or contact your Arthrex representative.*

3.0 Technical Specifications

3.1 Console

Table 10 Control Unit (AR-6480) Specifications

Width	42 cm (16.5 in.)
Height	19 cm (7.5 in.)
Depth	35.5 cm (14 in.)
Weight	12.25 kg (27 lbs.)
Maximum flow rate	≥ 150 mmHg
Pressure	10 – 120 increments of 5.
Overpressure control	300 mmHg ± 5
Pressure control	Continuous pressure checking
Protection	IP22
Main cable	10 A/250 V
Connector	CEE 7/7
Jack	IEC 320/C13
Power supply	100-240 V, 50/60 Hz, 6.5A
Mains fuse	T8LA250V (5 x 20 mm)
Shaver supply fuse	T5AL250VP (5 x 20 mm)
Applied part type	CF
Cleaning	Surface cleaning with mild detergent
Sterilization	Surface disinfection with mild disinfectant

Table 11 Ambient conditions for operation

Temperature	10° to 40 °C (50° to 104 °F)
Relative Humidity	20% to 75%, non-condensing
Barometric pressure	700 hPa (10.15 PSI) to 1060 hPa (15.37 PSI)

Table 12 Ambient conditions for storage (in shipping packaging)

Temperature	-30° to +70°C (-22° to 158°F)
Relative Humidity	10% to 90%, non-condensing
Barometric pressure	500 hPa (7.25 PSI) to 1060 hPa (15.37 PSI)

2.5.3 „ReDeuce™“ siurblio vamzdelių rinkinys (AR-6411: A regionas)

„ReDeuce“ siurblio vamzdelių rinkinys skirtas naudoti su „ReDeuce“ paciento vamzdelių rinkiniu (AR-6421) kaip įtekėjimo ir slėgio jutiklio vamzdeliai. Jis neskirtas naudoti kaip atskiras produktas. „ReDeuce“ siurblio vamzdelių rinkinį galima naudoti visą operacijų dieną, jei nepažeidžiamas sterilumas. Vamzdelių ilgis nuo siurblio 0,5 metro (1,7 pėdos).

2.5.4 „ReDeuce“ paciento vamzdelių rinkinys (AR-6421: A regionas)

„ReDeuce“ paciento vamzdelių rinkinys skirtas naudoti kartu su „ReDeuce“ siurblio vamzdelių rinkiniu, kad „ReDeuce“ siurblio vamzdelių rinkinį būtų galima naudoti visą operacijų dieną, po kiekvienos atskiros operacijos pakeičiant tik „ReDeuce“ paciento vamzdelių rinkinį. Į „ReDeuce“ paciento vamzdelių rinkinį integruotas atgalinės tėkmės atbulinis vožtuvas neleidžia užterštam skysčiui tekėti atgal į „ReDeuce“ siurblio vamzdelių rinkinį, išlaikydamas uždara sterilus aplinką keičiant vamzdelius. Paciento vamzdelių ilgis 2,4 metro (8 pėdos).

2.5.5 Ilginamųjų vamzdelių sistema (AR-6220: A regionas)

5.7 Paciento jungties ilgis 2,4m.

Ilginamųjų vamzdelių sistema skirta naudoti kartu su pagrindiniu siurblio vamzdelių rinkiniu (AR-6410), kad pagrindinį siurblio vamzdelių rinkinį būtų galima naudoti visą operacijų dieną, po kiekvienos atskiros operacijos pakeičiant tik ilginamąją vamzdelių sistemą. Ilginamųjų vamzdelių ilgis 2,4 metro (8 pėdos).

2.5.6 Vienos dalies vamzdelių rinkinio sistema (AR-6415/AR-6415CL: B regionas)

Vienos dalies vamzdelių sistemoje yra įtekėjimo ir slėgio jutiklio vamzdeliai. Vienos dalies vamzdelių sistema skirta naudoti TIK vienai procedūrai ir ją reikia pakeisti po kiekvieno paciento.

Vienintelis AR-6415 ir AR-6415CL modelių skirtumas yra tas, kad „CL“ modelio maišelio antgaliai yra „CareLock“ antgaliai, naudojami konkrečiai su „Fresenius“ skysčio maišeliais.

2.5.7 Pagrindinis siurblio vamzdelių rinkinys (AR-6420/AR-6420CL: B regionas)

Pagrindinis siurblio vamzdelių rinkinys skirtas naudoti su paciento ilginamųjų vamzdelių sistema (AR-6425) kaip įtekėjimo ir slėgio jutiklio vamzdeliai. Jis neskirtas naudoti kaip atskiras produktas. Pagrindinį siurblio vamzdelių rinkinį galima naudoti visą operacijų dieną, jei nepažeidžiamas sterilumas.

Vienintelis AR-6420 ir AR-6420CL modelių skirtumas yra tas, kad „CL“ modelio maišelio antgaliai yra „CareLock“ antgaliai, naudojami konkrečiai su „Fresenius“ skysčio maišeliais.

5.0 Operation and Frequently Used Functions

Users of this device should contact their Arthrex representative if they require a more comprehensive surgical technique.

5.1 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 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 of the utmost importance that the surgeon monitors both the system and the patient closely while 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.

After the DualWave power-up sequence has finalized, the user will be able to select from four preprogrammed pressure settings for the knee, shoulder, small joint, and hip joint spaces. Once the icon for the selected joint space has been pressed, the DualWave will display the appropriate controls and readings on the operator display. The pressure presets can be adjusted by entering the MENU, then Defaults, then Presets. Selecting "done" will save the adjusted preset in the memory until it is changed.

Table 15 specifies the initial pressure settings that are preprogrammed for surgery. The ideal intra-articular pressure depends on the indications for the arthroscopic procedure, bleeding tendency, and the possibility of ischemia.

Table 15 Initial Pressure Settings

Knee arthroscopy	35
Shoulder arthroscopy	50
Small joint arthroscopy	40
Hip arthroscopy	45

All settings are based on the use of a high-flow sheath or secondary inflow portal (suprapatellar, etc.).

To obtain a clear fluid environment, slowly increase the distention pressure beginning with the initial pressure settings in Table 15.