Instructions for Use

REF **Áristos Orthopaedic Extension**
800-0325-SM

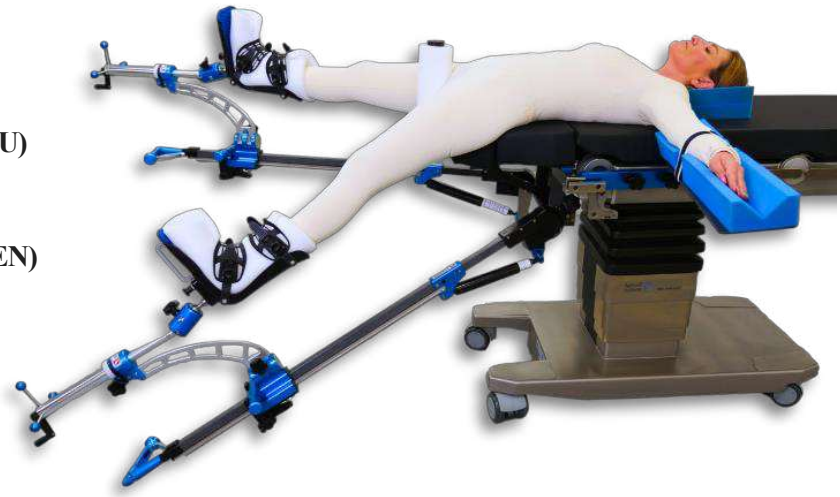
REF **Áristos Orthopaedic Extension (EU)**
800-0325-SM-EU

REF **Áristos Orthopaedic Extension (DEN)**
800-0325-SM-DEN

REF **Áristos Orthopaedic Extension (UK)**
800-0325-SM-UK

REF **Áristos Orthopaedic Extension (JPN)**
800-0325-SM-JPN

REF **Áristos Orthopaedic Extension (SWISS)**
800-0325-SM-SWISS



INTENDED USE

The Áristos Orthopaedic Extension is intended for the distraction of the patient's hip joint and positioning of the lower limbs. The table allows for direct anterior approach (DAA), hyperextension, abduction, adduction, and external rotation of the legs for femoral component placement.

GENERAL SPECIFICATIONS

Figure 1 – Range of Motion Diagram

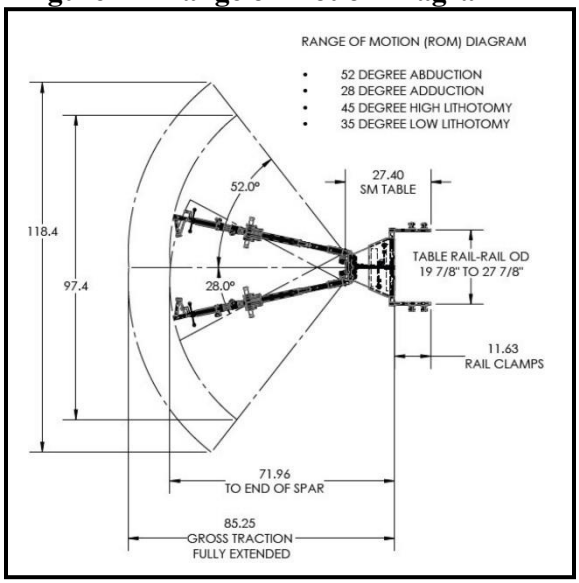
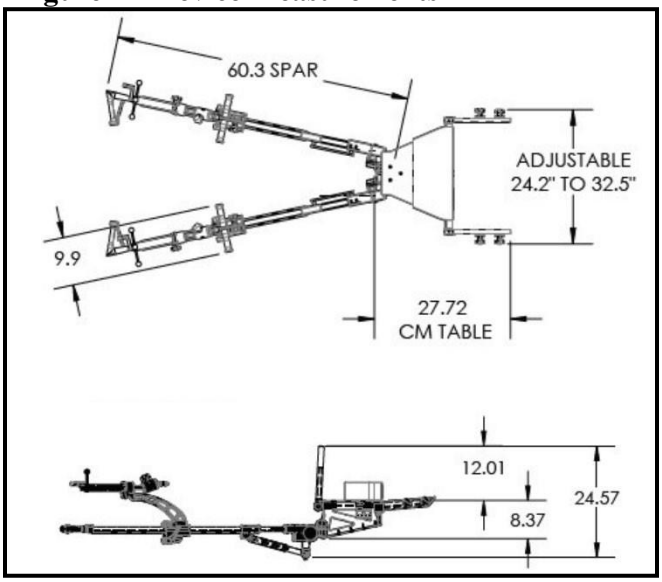


Figure 2 – Device Measurements



DEVICE MEASUREMENTS
Spar length 60.3”
Table section length 27.72”

DEVICE WEIGHT
Table section: 23.6 lbs
Weight of two spars without boots: 58.4 lbs
Weight of two spars with boots: 62.4 lbs
Total combined weight: 86 lbs

ADDITIONAL ACCESSORIES

Item	Description
800-0390	Áristos Orthopedic Boot
508-1550	Áristos Foot Pad – Disposable 10ct
800-0077-H	Áristos Transfer Board
800-0397	Áristos Counter Traction Post
508-1501-SM	Áristos Premium Perineal Post Pad
508-1524-SM	Áristos Perineal Post Pad
800-0041-SM	Áristos Knee Crutch

INSTRUCTIONS
Become familiar with the features of patient positioning device before use with a patient. Always practice using a nurse, physician, or appropriate volunteer prior to using clinically.

PRODUCT DIAGRAMS
Table lists components illustrated in Figures 3 through 5

NO.	Letter(s)	PART	DESCRIPTION
1	B, C	Base with Rails	Secures the Áristos to the surgical table
2	C	Base Knobs	Allows for the base to slide left and right
3	E, F, G	Spars	Supports the patient’s legs when attached to Áristos
4	B	Spar Knobs	Locks spars in place
5		Gross Traction Handle	Allows for gross traction adjustment
6		Fine Traction	Allows for incremental changes in traction
7		Boot Release	Allows boot flexion
8		Spar Handle	Allows for spar to be moved in multiple directions
9	D	Perineal Post Slider	Slide and lock perineal post
10	A	Perineal Post	Used to apply counter force on the patient’s leg during distraction
11		Perineal Post Pad	Used to relieve pressure on patient during distraction
12		In-line Axial Rotation	Allows for changes in axial rotation
13		Boot Plunger	Used to release boot from the spar
14		Lateral Rotation Arm Release Knob	Used to laterally rotate the boot out from over the spar

CONNECTING THE ÁRISTOS TO THE OPERATING TABLE

1. Select the proper table configuration based on operating table rail size.
2. Slide the side rail clamps of the table section onto the operating table side rails.
3. To slide the table section left and right. Loosen base knobs.
4. Slightly lift the table section.
5. Slide left or right as desired.
6. Tighten base knobs in desired position.
7. Secure the table section by tightening the rail knobs.
8. Insert the male end of each spar into the corresponding female end of the base. Lift up on the middle of the spar with one hand while tightening the knob with the other hand to securely attach the spar to the base.
9. Ensure that all knobs and levers are secure.
10. Insert the patient's foot into the disposable boot liner (508-1550)
11. If loading the patient preoperatively, you will need to open the straps by adjusting each side where the strap feeds through the buckles.
12. To prepare the straps on the boot (800-0390), place one hand on the boot buckle securing it, and your other hand on the release lever. Feed the strap through the buckle while pressing the release clip/lever of the buckle and pull the strap and buckle with your other hand.
13. Position the heel of the boot so that the bottom of the heel lines up with the bottom of the boot. The boot is now prepared to accept a patient's foot.
14. Make sure the patient's feet are wrapped appropriately to help avoid any bunching of the disposable boot liner which may cause undesired pressure on the patient's foot.
15. To maintain foot flexion and keep the heel from slipping you should ensure the patient's heel is set firmly into the boots heel section.
16. Make certain that the inserted disposable liner is positioned above the patient's heel and that the patient's foot is flat against the buckle straps.
17. Tighten straps through buckle in the direction of the patient. Pull each side upward toward patient till tensioned and secured.
18. Ensure each buckle is centered over each boot liner and that each liner is centered over the midline of the patient's bootstrap. This should be tensioned just enough so that the patient's foot moves only a minimal distance in the sole of the boot.
19. Verify visually that the patient's heel and that the patient's foot is properly positioned and securely held in the boot.

NOTE: Prior to setup ensure that all traction knobs and levers are safely fastened and that the gross traction does not slide.

PATIENT POSITIONING

1. Ensure patient is positioned on surgical table in accordance with the procedure and surgeon.
2. Confirm whether the right or left hip is being operated on.
3. Add the operative leg and non-operative leg into Áristos system.

Note: It is recommended when setting up the Áristos to leave foot location at neutral position (with the axial rotation at 0 degrees).

4. Connect the boots to the spars.
    a. Connect the left boot connector to the left spar boot connector end, by lining up the slot on the left boot connector and inserting it into the left spar boot connector until it clicks into place with T-handle spring plunger.
    b. Connect the right boot connector to the right spar boot connect by lining up the slot on the right boot connector and inserting it into the right spar boot connector until it clicks into place with T-handle spring plunger.
    c. Boots can be adjusted 120° outward and 90° inward along the axis of fine traction, using the clamping knobs.
5. Install perineal post into base.
6. Install disposable perineal post pad. Visually confirm that the pad is flush with the bottom of the post.

TRACTION CONTROL

1. Squeeze the gross traction lever (Figure 1, Number 12), pull back to desired location and release. The gross traction will click into place. Ensure that the gross traction is locked into place by gently pulling and pushing on the gross traction handles.
2. Complete traction by using fine traction. Turn the fine traction handle (Figure 1, Number 5) clockwise to the desired location.
3. To release fine traction, turn the fine traction handle (Figure 1, Number 5) counterclockwise to the desired location.
4. To release gross traction, squeeze the gross traction lever (Figure 1, Number 12), push forward/towards the patient to desired location and release lever.

FINE TRACTION LATERAL POSITIONING

1. Entire fine traction assembly can be rotated laterally up to 90 degrees, to the horizontal position. Loosen boot knob to prevent unwanted rotation of the foot. Hold boot/fine traction assembly with one hand and loosen the lateral positioning knob. Move fine traction assembly to the desired position and tighten the lateral positioning knob. Adjust boot to desired location and tighten boot knob.

TAKE DOWN

After each patient procedure and all procedures are completed for the day: clean, disinfect and disassemble distractor system.

1. Remove the patient from Áristos system.
2. Dispose of single use components such as boot liners and perineal post pad following proper disposal methods.
3. Detach Áristos system from surgical table.

GENERAL INFORMATION

- *This product is not made with Natural Rubber Latex*
- *This device supports a 350 lb. (159 kg) proportional patient load (6'4" (193 cm) tall patient per 99% human body model)*
- *Product warranty covers the product from manufacturing defects for a period of 2 years.*
- *If damaged in shipping, please call Customer Service at (888) 724-8763 or (781) 982-7000 to obtain a Return Material Authorization number. For product warranty issues also contact Customer Service.*
- *CE marked medical device according to MDR (EU) 2017/745*
- *Life of device is 5 years under normal use.*
- *Storage of device shall be between -4°F to +86°F (-20°C to 30°C)*

MATERIAL SPECIFICATIONS

Áristos (Table Attachment, Carbon Fiber, Fiber Glass, Foam Butt Pad, Perineal Post, Left Leg Spar, and Right Leg Spar): Stainless Steel, Aluminum, Polyester, Polyurethane and Sioen F3283, Carbon Steel, Nylon and Delrin Polymer
Boots: Delrin Polymer, Nylon, Stainless Steel, Aluminum
Boot liners: Polyester Polyurethane, Nylon
Perineal post pads: Polyurethane Foam

DISPOSAL

- *General - Used products or parts may be contaminated. To prevent potential infection, please clean and disinfect the product prior to disposing.*
- *Packaging - Packaging material can be disposed of via household waste in accordance with national requirements.*
- *SchureMed will take back used products or products no longer in service. Products can also be disposed of in accordance with national requirements.*

MAINTENANCE

Regular and proper maintenance of your Áristos Orthopaedic Extension is the best way to protect your investment. It is essential that you properly maintain all Distractor components to retain its optimum performance and reliability, which will reward you with safer, less problematic Distractor performance over time.

Your SchureMed authorized service department is the most knowledgeable about Áristos Orthopaedic Extension and will provide competent and efficient services. Service performed by SchureMed is mandatory to keep your product warranties in effect. Any services and/ or repairs done by any unauthorized repair facility may result in reduced performance of the equipment or equipment failure. (Refer to CUSTOMER SERVICE).

NOTE: It is recommended that the user inspect the Áristos system for normal ware before and after each use. Safety inspection items include but not limited to the following items:

Labels and User’s Manual

Visual check for damage of product and accessories

CLEANING RECOMMENDATION

Follow current Association of periOperative Registered Nurses Journal Guidelines for proper cleaning and disinfection procedure.

PRODUCT USE WARNINGS

WARNING! *It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of the equipment and its associated accessories. Do not use equipment other than intended use.*

WARNING! *Do not use equipment if, upon receipt, package is opened, damaged, or shows any signs of tampering.*

WARNING! *Use only associated SchureMed approved equipment and accessories. Using unapproved accessories may result in improper operation and may result in non-compliance with medical standards.*

WARNING! *Maximum patient weight should not exceed 350 lbs (159 kg).*

WARNING! *Maximum height of patient not to exceed 90 inches (229 cm) and minimum height of 40 inches (102 cm).*

WARNING! *Use care with low-maximum load capacity surgical tables so that accessory rails are not overloaded.*

WARNING! *Adhere to standards for blood-borne pathogens from the Occupational Safety and Health Administration (OSHA). Use recommended protective clothing, gloves, masks, and eye protection to clean equipment.*

WARNING! *Additional warnings include those applicable to any surgical procedure. In general, careful attention must be paid to asepsis and avoidance of anatomical hazards.*

WARNING! *The device is supplied non-sterile and must be cleaned before the first use and after every use.*

WARNING! *Follow current Association of periOperative Registered Nurses Journal Guidelines for proper cleaning.*

WARNING!

Adhere to standards for blood-borne pathogens from the Occupational Safety and Health Administration. Use recommended protective clothing, gloves, masks, and eye protection to clean accessories.

CAUTION
Strictly read/follow manufacturer's directions for cleaning fluids. DO NOT use cleaners containing phenolics.

1. Remove major contaminants from accessories with disposable materials. Follow appropriate bio-hazard waste disposal procedures.
2. Apply cleaning fluid liberally to entire accessory and wipe with clean, lint-free cloth until all moisture and cleaning fluid is removed from accessory
3. Let accessory dry

USER NOTICE
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

eIFU Language Versions

To download and print the Instructions for Use, please go to www.schuremed.com

Symbol Glossary

Symbol	Title
	Manufacturer
	Date of manufacture
	Authorized Representative in the European Community
	Authorized Representative in the Swiss
	Importer
	Catalogue Number
	Serial Number
	Warning
	Medical Device
	Unique Device Identifier
	CE Marking
	Single Patient Use

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