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ADAPTable System

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1. Product Handling

All of the components used, except the positioning arm, which is used with a sterile cover, may only be used in a sterile condition. The Retractor Holder Kit, Quick Connect Coupling, Knee Bracket and Leg Bracket are supplied in a non-sterile condition and must be cleaned and sterilized before each use. The Leg Disposable Kit, Retractor Holder Disposable Sleeve Kit and the Knee Positioner Disposable Kit are supplied as a sterile kit. Sterile components should always be stored unopened in their respective peel packs. Prior to use, inspect packages for damage that may compromise sterility. If packaging has been opened or damaged upon receipt, contact the manufacturer's rep. Also inspect labeling to verify that expiration date has not passed. If product is expired, contact Customer Service and do not use. When removing sterile product from its packaging, observe relevant aseptic technique. The sterile components are part of a system and should only be used with related original Adaptable Arm positioning systems.

High temperatures, moisture and humidity can damage the reusable Adaptable Arm product. Protect the product against moisture and humidity, clean by wipe disinfection only. Do not store close to radiators and protect from high solar radiation. Do not expose the product to large impacts and vibrations, the product is not designed for impulse loads.

2. Product Description and Materials

The ADAPTABLE Arm is mounted to the accessory rail of operating tables and it's used to support and position patient's limbs during surgical procedures. The device is quickly and easily locked and unlocked using a one-hand operation trigger. Depending on the application, ensure sterility.

The ADAPTABLE Arm may only be used in conjunction with the following accessories:

- Quick Connect (803-33-001)
- Leg Bracket (803-33-003)
- Knee Bracket (803-33-010)
- Leg Positioner Disposable Kit (803-33-105)
- Knee Positioner Disposable Kit (803-33-115)
- Retractor Holder Kit (803-33-200)
- Retractor Holder Disposable Sleeves (803-33-205)
- Home Base Assembly (803-33-301)
- Home Base Pad Assembly (803-33-302)
- Perineal Post, Short (803-33-303)
- Perineal Post Pad, Short Assembly (803-33-304)
- Perineal Post, Long (803-33-305)
- Perineal Post Pad, Long Assembly (803-33-306)

Quick Connect (803-33-001)

The Quick connect (803-33-001) is used as intermediate element designed to couple The Leg Bracket (803-33-003) or The Knee Bracket (803-33-010) to the ADAPTABLE arm.

Leg Bracket (803-33-003)

The Leg Bracket (803-33-003) is used as intermediate element designed to couple the Quick Connect (803-33-001) to the Leg Positioner Disposable Kit (803-33-105)

Knee Bracket (803-33-010)

The Knee Bracket (803-33-010) is used as intermediate element designed to couple Quick connect (803-33-001) to the Knee Positioner Disposable Kit (803-33-115).

Leg Positioner Disposable Kit (803-33-105)

The Leg Positioner Disposable Kit (803-33-105) is used to cover the operative leg and secure the patient's leg to the Leg Bracket (803-33-003).

The disposable kit includes:

- 1 x Camera Drape
- 1 x Roll of Self-Adhesive Wrap
- 1 x Disposable Leg Pad

Knee Positioner Disposable Kit (803-33-115)

The Knee Positioner Disposable Kit (803-33-115) is used to cover the operative knee and secure the patient's knee to the Knee Bracket (803-33-010).

The disposable kit includes:

- 1 x Camera Drape
- 1 x Roll of Self-Adhesive Wrap
- 1 x Knee Positioner Disposable

Retractor Holder Kit (803-33-200)

The Retractor Holder Kit (803-33-200) is used to hold one or more retractors during surgical procedures.

Disposable Sleeve Kit (803-33-205)

The Disposable Sleeve Kit (803-33-205) is used cover the Adaptable Arm. The kit includes one sleeve (camera drape).

3. Indications

The ADAPTABLE Arm and all related components and attachments listed above are indicated for patients undergoing hip, knee and other lower extremity surgery.

4. Intended Use

The ADAPTABLE Arm (803-33-000) is used, in combination with specific accessories, to accommodate a patient's leg immediately before, during and after surgical interventions as well as for examination and treatment and retractor holding applications.

5. Contraindications

Leg positioning with the ADAPTABLE Arm is contraindicated where the patient's leg is injured or incapable of safely enduring the fixation of the leg securing Leg Positioner Disposable Kit or Knee Positioner Disposable Kit.

6. Precautions and Warnings

Vital functions may be impaired through improper use and/or positioning of the product. Service and modification to the device is to be provided by trained personnel only. This device should be inspected and proper function verified before each use. Ensure that this user manual is readily available to all personnel at all times.

- The maximum patient weight for use of the product is 350 lbs.
- Improper use and positioning may lead to injury. Follow all instructions for use of the operating table system and ADAPTABLE exactly and maintain observation of patient while product is in use.
- Use only approved accessories with the ADAPTABLE Arm. All accessories must be used in accordance with instructions for use from Quantum OPS. Accessories made by other providers may be used only with written approval from Quantum OPS.
- Risk of burns may occur through contact between the ADAPTABLE Arm and electrical equipment such as computer components and defibrillators. Contact between the patient and metallic surfaces must be avoided.
- The product can be repositioned by opening fastening elements. Prior to initially mounting or repositioning the product, hold the movable segments securely so that they do not fall or move suddenly. Also, be aware that moving the product during initial mounting or repositioning can expose personnel, patient, and other equipment to pinching or shearing. Prior to mounting or repositioning the product, be sure that the patient, all other personnel and equipment are clear of the product so pinching or shearing does not occur.
- Improperly secured products or accessories may result in patient injury. After initial positioning and after every repositioning of the product, check all fastening elements (clamps / handles...etc.) to make sure they are fully closed and secure.
- Do not continue to use the ADAPTABLE Arm if the product is worn, defective, or damaged in any way. Only use the product in full working condition.
- Adjustments made to the product, patient, or operating table system may result in inadvertent contact between the patient and accessories or operating table components. Make any adjustments necessary under careful observation.
- Attaching the product to the operating table may affect the table's center of gravity which may cause the operating table to tip over more easily. Make any adjustments to the operating table under careful observation.
- Do not use any oil or lubricant on the moveable parts of the ADAPTABLE Arm. Using lubricant or oil on the product may result in damage to the product or cause the product to malfunction.
- Do not use the disposable kit if the packaging of the disposable kit is damaged or punctured. Using the disposable kit when the packaging is damaged or punctured may result in a risk of infection.
- The ADAPTABLE Arm is to be used only with accessories specifically designed for the product and approved by Quantum OPS.
- A sterile cover must be used on the ADAPTABLE Arm during surgery to avoid contact with liquids and other substances used in surgery.
- The product is designed to support only the weight of the patient. Do not put any additional force on the Leg Positioning System by leaning or resting on the product.
- Avoid exposing the product to high impacts, vibrations, moisture, humidity, and radiation. The product is designed to be cleaned by wipe disinfection only.
- A risk of infection exists if the product is stored or used in a non-sterile environment. If the product is stored or used in a non-sterile environment, clean the product using the instructions given in the "Cleaning and Disinfection" section.
- An approved sterile disposable kit is required for proper use of the product. The Adaptable Leg Positioner Disposable kit (803-33-105) Retractor Holder Disposable Sleeve Kit (803-33-205) and Arm, and Knee Positioner Disposable Kit (803-33-115) is the only disposable kit approved for use with the ADAPTABLE Arm.
- The product is intended for use in a sterile condition only. The product should be cleaned and disinfected prior to initial use and after each use.

7. Preoperative Planning

Ensure that all sterile components (Quick Connect, Leg Bracket, and Disposable Kit and/or Retractor Holder and/or Knee Bracket Kit) are available before surgery, and that the surgical bed has a side rail that functions with the ADAPTABLE Arm.

8. Adverse Effects

1. Chaffing or redness of the skin of the patient's leg is possible.

9. Sterilization and Cleaning

The Quick Connect, Leg Bracket, Retractor Holder Kit and Knee Bracket are supplied in a non-sterile condition and must be cleaned and sterilized (autoclave) before the first use following the guidelines listed below.

The Leg Disposable Kit, Knee Positioner Disposable Kit and Retractor Holder Disposable Kit are supplied as a sterile kit. Sterile components should always be inspected for damage that may compromise sterility. If packaging has been opened or damaged upon receipt, contact the manufacturer.

Sterilization of the Leg Disposable Kit, Retractor Holder Disposable Sleeve Kit and Knee Positioner Disposable Kit is performed by electron beam radiation at the minimum dosage of 25kGy to achieve sterility. Disposable kits are all single use.

Automatic Cleaning

1. Insure all pre-processing instructions are followed prior to cleaning.
2. Clean the device via the following automatic cleaning parameters:

Phase	Minimum Recirculation Time	Water Temperature
Pre- Wash 1	15 seconds	Tap water 1c - 16c
Enzyme Wash	1 Minute	Hot Tap Water 43c - 82c
Wash 1	2 Minutes	Tap Water 43c-82c
Rinse 1	15 Seconds	Tap Water 43c-82c
Pure Rinse	10 Seconds	Purified Water 43- 82c
Drying	N/A	N/A

3. If visible moisture is present dry the instrument with a clean lint free towel
4. Visually examine each instrument for cleanliness
5. If visible soil remains, repeat cleaning procedures

Inspection/Maintenance

Proper care and handling is essential for satisfactory performance of any Adaptable device. The provided cautions should be taken to ensure long and trouble free service from all your surgical devices. Inspect devices before each use for replacement. Before sterilizing, lubricate complex devices with instrument milk or a steam permeable / water soluble lubricant following the lubricant manufacturer's instructions. Let the devices drip dry for three (3) minutes before packaging for sterilization. Inspect for broken, cracked, tarnished surfaces, movement of hinges and slides, and chipped or worn parts. If any of these conditions appear, do not use the device, return device to an authorized agent for repair or replacement.

Packaging

Devices can be loaded into dedicated packaging systems. Sterilization wrap material must be cleared for the applicable sterilization modality by your country's regulatory body. Use in accordance with packaging manufacturers sterilization instructions being sure to protect jaws, hinges, points, and cutting edges from damage.

Sterilization

All devices must be processed in the completely open position or disassembled to allow sterilant contact of all surfaces. All devices with concave surfaces shall be configured so that water/ liquid pooling does not occur.

Pre-vacuum Steam Sterilization Parameters

Minimum Preconditioning Pulses: 4

Minimum temperature: 132c (270f)

Minimum Exposure Time : 4 minutes

Minimum Dry Time: 20 minutes

Sterilization Configuration: Wrapped (2 layer 1-ply or 1 layer 2-ply)

Packaging: sterilizable pouches

Storage

After sterilization, devices must remain in sterilization packaging and be stored in a clean, dry environment.

Pre-processing Instructions

- Initiate cleaning of devices within 2 hours of use. Always use personal protection equipment (PPE) when cleaning gross material or biohazard material from instruments/devices.
 - Remove excess gross soil as soon as possible after use by rinsing or wiping device.
 - All devices must be processed disassembled in the completely open position to allow solutions to contact all surfaces. **Manual Cleaning: (steps 5,6,7,9, and 11 are required for lumen devices only)**
1. Ensure all pre-processing instructions are followed prior to cleaning.
 2. Prepare enzymatic/ neutral PH detergent solution, utilizing a temperature range of 27c to 44c (81f- 111f). Per manufacturer's instructions.
 3. Place device in the open/relaxed position. Completely immerse in the detergent solution and allow device to soak for a minimum of 5 minutes. Actuate all morale pats during the initiation of the soak time.
 4. Using a soft bristled brush, remove all visible soil from the device. Actuate device while brushing paying particular attention to hinges, crevice, and other difficult to clean areas.
 5. For lumen devices, use a soft bristled brush with a brush diameter and length that is equivalent to lumen diameter and length. Scrub the lumen until no visible soil is detected in the lumen rinse step below
 6. For lumen devices, place the device into the open/relaxed/disassembled position with all sharp tips pointed downwards. Flush the device a minimum of 50 ML detergent solution utilizing a temperature range of 27c to 44c (81f to 111f). Repeat the flush process a minimum 2 times ensuring all fluid exiting the lumen is clear from soil and debris.
 7. For lumen devices, place if visible soil is detected during the final lumen flush re- perform brushing and flushing of the lumen.
 8. Rinse the device by completely immersing in tap water with a temperature range of 27c to 44c (81f- 111f) for minimum of 30 seconds to remove any residual detergent and debris.
 9. For lumen devices, following the rinse step, place the device into the open/ disassembled positions with all sharp pointed tips facing down. Flush the device with a minimum of 50ml of tap water utilizing a temperature range of 27c to 44c (81f-111f) repeat the flush process a minimum of 2 times.
 10. Dry the device with a clean lint free towel
 11. For lumen devices, manipulate the device to allow rinse water to drain from the lumen.
 12. Visually examine each device for cleanliness.
 13. If visible soil remains, repeat cleaning procedure. GUIDELINES FOR EACH PRODUCT

Components	Cleaning	Disinfection	Sterilization/ Autoclaving
ADAPTABLE Positioning Arm (803-33-000)	Clean with a cloth soaked with warm soapy water, using a soft toothbrush to remove any dirt or debris as needed. Dry with a soft, clean cloth. DO NOT IMMERSE.	Wipe ADAPTABLE Positioning Arm with disinfectant wipes. Dry with clean and soft cloth.	N/A – NOT STERILIZABLE. DO NOT AUTOCLAVE.
Quick Connect (803-33-001) Leg Bracket (803-33-003) Knee Bracket (803-33-010) Retractor Holder Kit (803-33-200)	Clean with warm soapy water, using a soft bristle brush to remove any dirt as needed. Dry with a soft, clean cloth.	Immerse in disinfection solution (30 minutes) (e.g. Dr. Weigert, 2% (v/v) at 20 °C ± 2 °C in water – minimum quality of drinking water). Before immersion use a disposable syringe (60 ml syringe) to rinse every joint and movable part with 200 ml solution. To remove air bubbles move the components by hand in the solution for 10 seconds at the beginning of immersion. Immerse components in cold, demineralized water (1 minute).	Pre-Vac Steam sterilization: 132 °C min temp; 4 pulses min, 4 min. minimum exposure time, 20 min. minimum dry time.

WARNING! Do not autoclave or immerse the ADAPTABLE positioning leg.

WARNING! Do not re-sterilize the Leg Positioner disposable kit or Retractor Holder Disposable Sleeves.

WARNING! Do not re-sterilize the Knee Positioner disposable kit

10. Trademarks and Patents

ADAPTABLE © QUANTUM OPS® are registered trademarks.

ADAPTABLE Arm system covered by United States Patent Application 20160067080