



DRAPE SUPPORT

AM1000

INSTRUCTIONS FOR USE

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Revision: E



EC REP



EC Representative

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Product Registration



Register today to ensure your product is covered by warranty, and for easy access to product services and general support.

www.adeptmedical.com/form/product-registration



Warranty

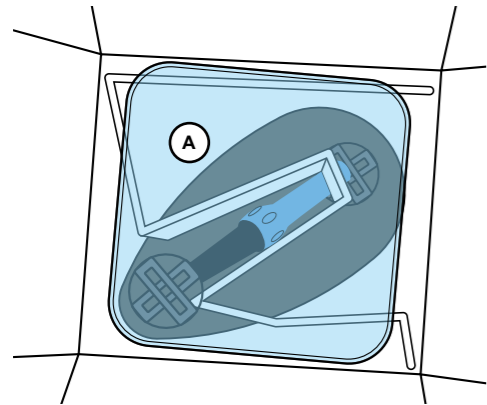


Service



Support

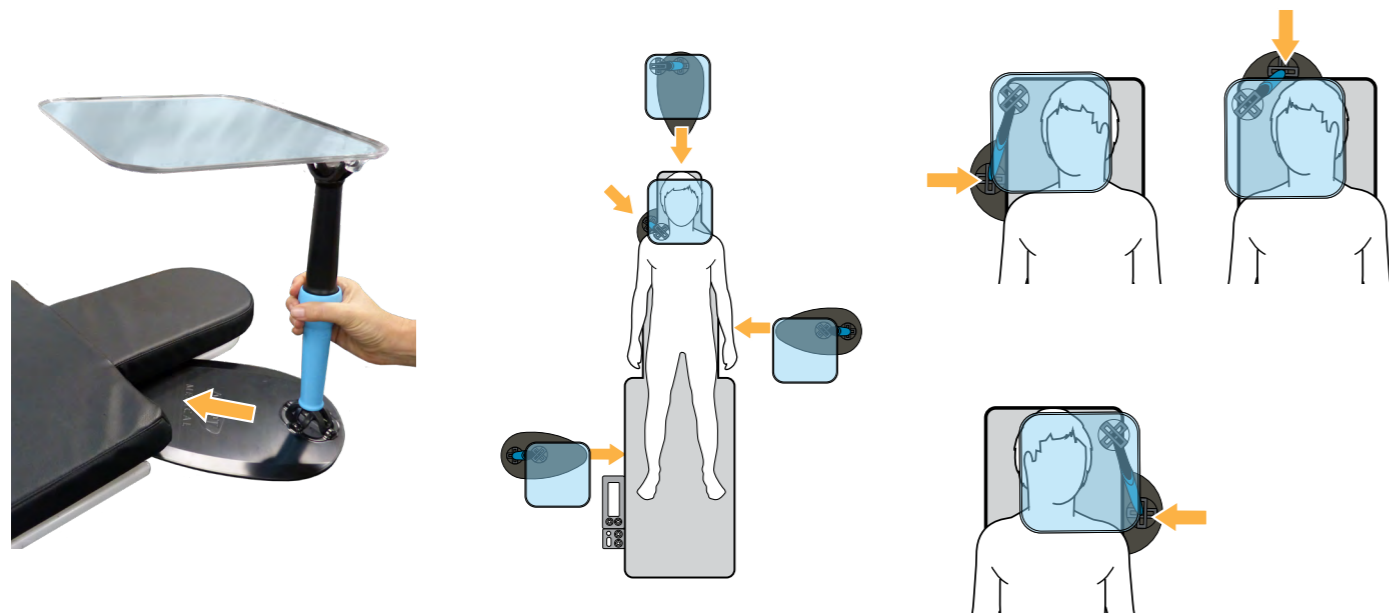
Unboxing



A Drape Support x1



Setup



Pinch Hazards

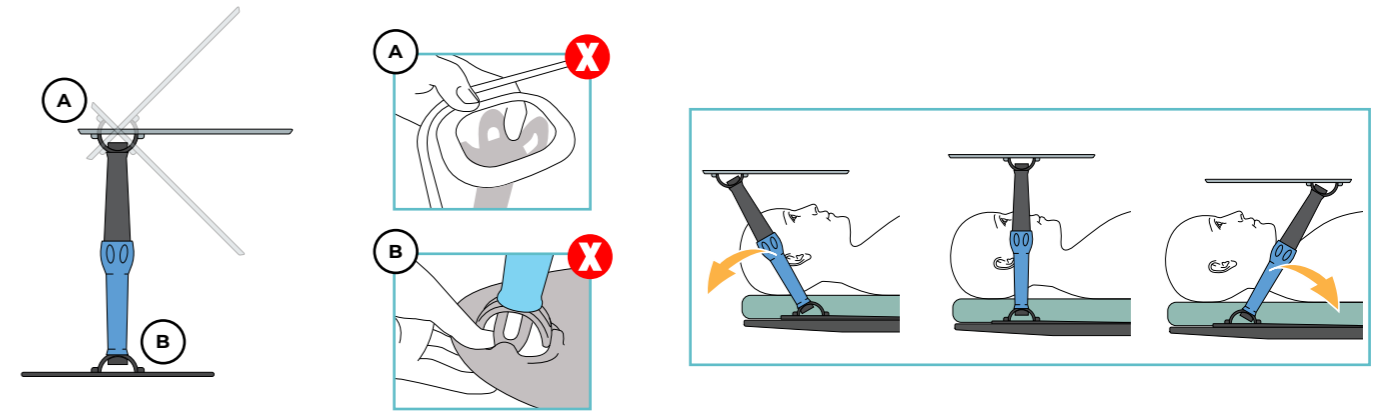
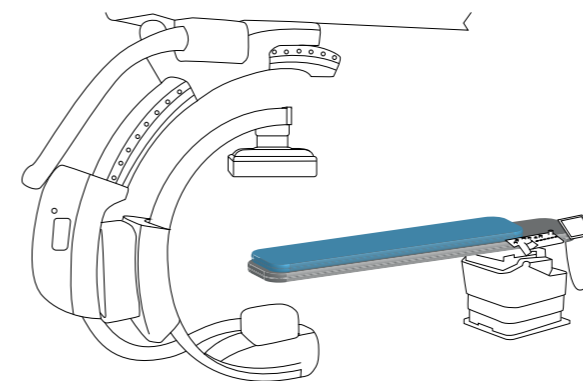


Image Table Verification



The product has been risk assessed to operate within the below specifications

Table Angulation: +/- 15° lateral & longitudinal
Table Surface: Flat

Essential Information

Information

Intended Purpose

To support the sterile drape over the patient.

Intended User/Training Requirement

Intended to be used by trained medical professionals.

Patient Target Group

Adult male or female patient requiring diagnostic imaging and image guided therapy.

Contraindications

Not for paediatric use.

Warnings and Cautions

- Ensure IFU is read prior to use.
- Ensure Preparatory Cleaning is conducted.
- Ensure Preparatory Product Check is conducted.
- Ensure the Clear Support Surface is supported during manipulation.
- Ensure all items placed on the Support Surface do not exceed a total weight of 0.5 kg.
- Do not place fingers in the rotating mechanism.
- Not for paediatric use.

Incident Reporting Guidelines

For product complaints and incidents, please complete form on: www.adeptmedical.co.nz/repairs

Initial Checks & Cleaning

Cleaning

Refer to Disinfection Instructions.

Product Checks

- No visible damage or sharp edges, e.g. cracks.
- Rotate the blue locking component in each direction. Ensure that it is free to rotate smoothly to lock and unlock.
- Ensure that the Locking Leg is not free to move when in the locked position.
- Rotate the Locking Leg to ensure it is free to move when in the unlocked position.
- Rotate the Locking Leg about the Clear Support Surface component, ensuring that it is free to rotate when in unlocked position.

Disinfection

Warnings

- Insufficient cleaning may compromise disinfection process and lead to transmission of pathogens.
- Do not use any disinfectant products or abrasive/corrosive agents which are not on the approved cleaners list.
- Always read manufacturer's instructions and consult the manufacturers MSDS for cleaning and disinfectant products.
- Some disinfectants may cause slight discolouration to the blue material used on some components within the product range. This will not affect the strength and the product will remain fit for purpose.

Limitations on Processing

Discontinue use if:

- any cracks or breakages are present.
- any sharp edges develop.

Disinfection Instructions

Initial treatment at the point of use

It is important to clean the product once it is removed from the packaging and after each procedure. Ensure all areas including joints, clips, sockets, brackets and levers are thoroughly cleaned after use to remove all contaminant build-up that may be present following a procedure.

Preparation before cleaning

Remove the Drape Support from beneath the mattress.
www.adeptmedicaltraining.com/productcleaning/Drape-Support

Cleaning: Manual

- If any visible residue is present, rinse under water, but avoid submerging the device.
- A soft bristle brush can be used.
- Ensure the device is completely dried prior to disinfection.

Disinfection

Refer to the Approved Cleaners List for selection of an appropriate disinfecting agent.

- With a cloth dampened by an approved disinfectant, wipe all surfaces including the Daggerboard, Clear Support Surface and Locking Leg.
- Rotate the Locking Leg to ensure all areas of the Daggerboard and Clear Support Surface connection points are cleaned thoroughly.

Approved Cleaners List

Approved Disinfectant by Brands

Liquids:

ORION Laboratories - 70% Isopropyl Alcohol
Jaychem Industries - 2% Chlorhexidine / 70% Alcohol
Betadine - Povidone Iodine (7.5%)
BODE Chemie GmbH - Kohrsolin FF
STERIS - Coverage Spray TB
CaviCide - Metrex Research

Dissolvable:

Du Pont - Rely+On Virkon Tablets

Surface Wipes:

PDI Sani-Cloth Bleach
PDI Sani-Cloth AF3
Reynard Health Supplies - Surface Disinfectant Wipes
Metrex Research - CaviWipes
Clinell Wipes - Universal (Green)
Clorox Hydrogen Peroxide Wipes

Approved Active Disinfectant Ingredients

Acid Based:

≤10% Malic Acid CAS 6915-15-7
≤6% Sulfamic acid CAS 5329-14-6

Alcohol Based:

≤5% 2-Butoxyethanol CAS 111-76-2
≤10% Butyldiglycol CAS 112-34-5
≤70% Isopropyl Alcohol (Propan-2-ol) CAS 67-63-0
≤10% Tridecanol CAS 69011-36-5
<10% Alcohols, C12-14, ethoxylated CAS 68439-50-9
≤70% Denatured Ethanol CAS 64-17-5

Sulphate Based:

≤0.1% PHMB CAS 27083-27-8
≤55% Potassium Peroxymonosulfate CAS 70693-62-8
≤3% Potassium Persulfate CAS 7727-21-1

Ammonium and Chloride Based:

≤5% Benzalkonium Chloride CAS 68424-85-1
≤0.28% Benzethonium Chloride CAS 121-54-0
≤10% Benzyl-C23-18-Alkyl-dimethyl Ammonium Chloride CAS 8001-54-5
≤2% Chlorhexidine CAS 55-56-1
≤10% Didecyl Dimethyl Ammonium chloride CAS 7173-51-5
≤0.5% Quaternary Ammonium Compounds CAS 68956-79-6
<5% Benzyl-C 12-18 alkyldimethylammonium chlorides CAS 63891-01-5

Others:

≤10% Glutaral CAS 111-30-8
≤0.63% Sodium Hypochlorite CAS 7681-52-9
≤7.5% Povidone Iodine CAS 25655-41-8
0.5% Disodium Cocoampho Dipropionate CAS68604-71-7
≤1.4% Hydrogen Peroxide CAS 7722-84-1

Access the latest Approved Cleaners list via www.adeptmedicaltraining.com/downloads

Drying

All components should be dried thoroughly before use.

Maintenance, Inspection and Testing

- Ensure there are no visible damage or sharp edges, e.g. cracks on any component of the Drape Support.
- Rotate Locking Leg component in each direction. Ensure that it is free to rotate smoothly to lock and unlock.
- Ensure when the Locking Leg is in the locked position it is not free to move.
- Rotate the Locking Leg about Daggerboard component ensuring that it is free to rotate when in unlocked position.
- Rotate the Locking Leg about Support Surface component ensuring that it is free to rotate when in unlocked position.

Packaging

It is not required to package the device following disinfection.

Sterilisation

This device should not be subjected to sterilisation processes.

Storage

Once disinfection is complete and all components are dry the device should be stored in a dry environment.

Disposal

Used product is a biohazard, decontaminate according to instruction provided in the Disinfection Instructions and reach out to the manufacturer on adeptmedical@adept.co.nz for material specification, if required. Dispose according to internal clinic policy taking into consideration local regulations.

Serious Incidents

Any serious incident which occurs in relation to the device should be reported immediately to:

- The Competent Authority of the applicable Member State.
- The Manufacturer using the Serious Incident Reporting Form found on the Adept Medical Website: www.adeptmedical.com/form/serious-incident-reporting-form

The instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

Visit the Adept Medical Training Platform for detailed visual instructions related to this device.
www.adeptmedicaltraining.com



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