

MR Safe

OVERHEAD ARM SUPPORT

AM4000 - AM4100

INSTRUCTIONS FOR USE

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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

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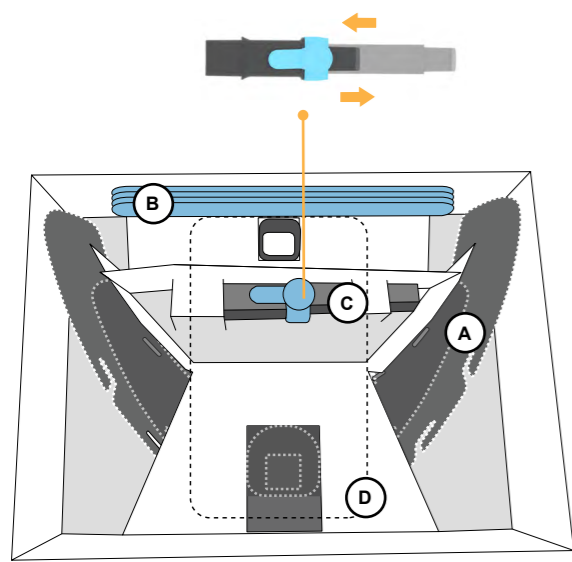
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Product Code Warning

- Overhead Arm Support with an **AM2000** Product Code contains an inner metal spring and IS NOT MRI compatible.
- Overhead Arm Support with an **AM4000 & AM4100** Product Code have passed MRI compatibility testing. The **AM4000** model is approved for use in MR imaging centres with bore sizes of 700 mm and larger, and the **AM4100** model for bore sizes of 600 mm and larger.

Unboxing

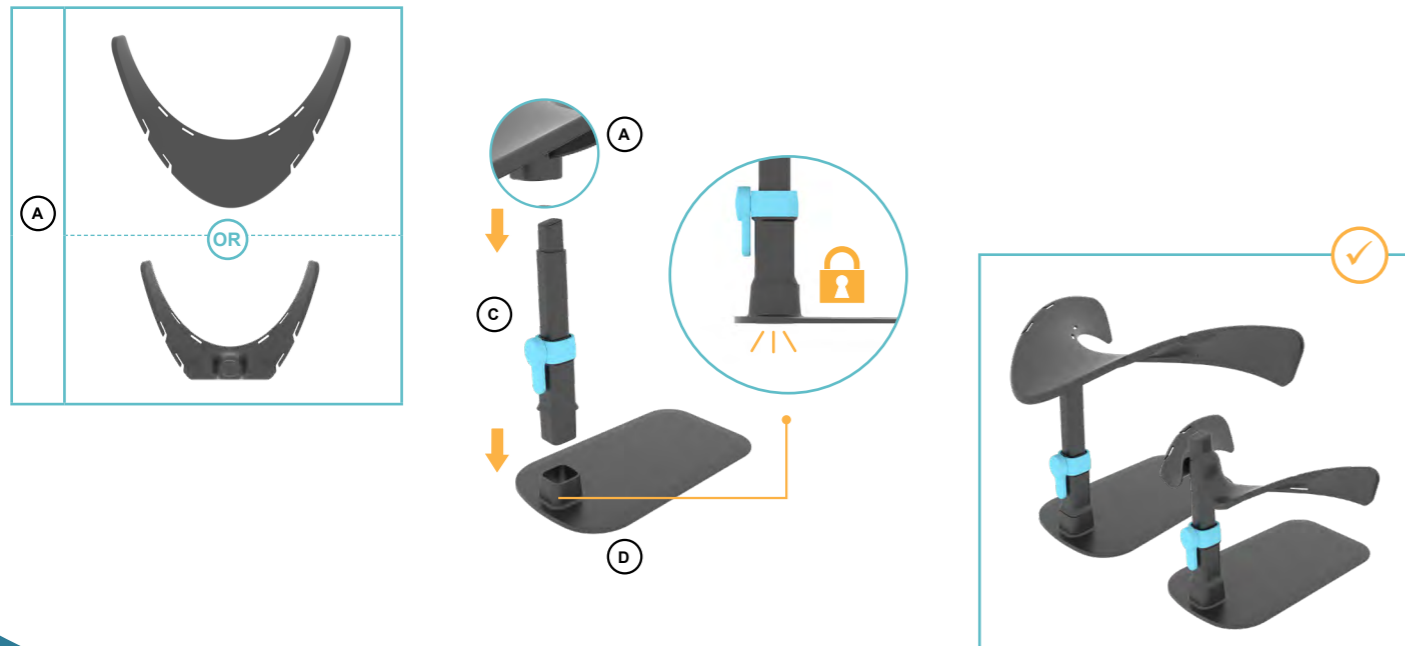


	(A)	OR	Armrest Wing MR Safe x1
	(A)	OR	Armrest Wing MR Safe - Small x1
	(B)		Arm Strap x 4
	(C)		Locking Leg Assembly MR Safe x1
	(D)		Daggerboard MR Safe x1

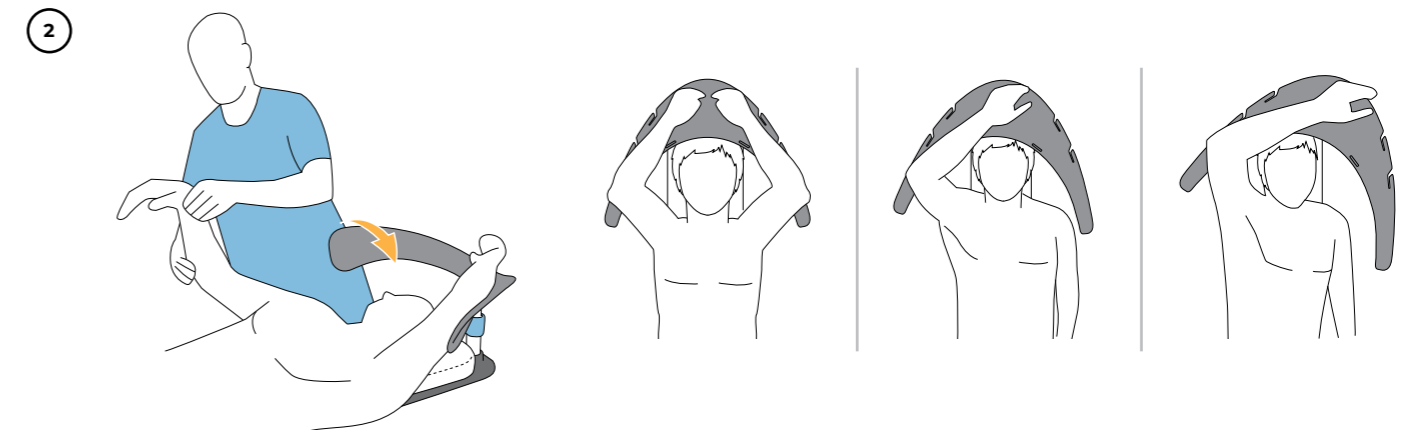
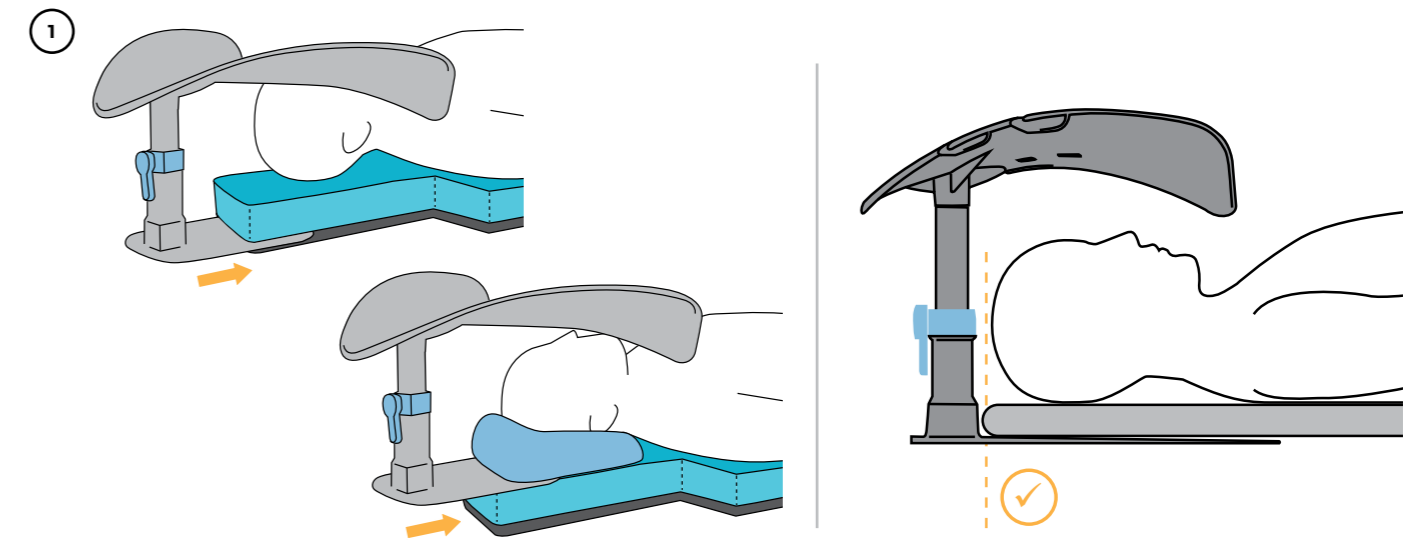
AM4000 / AM4100



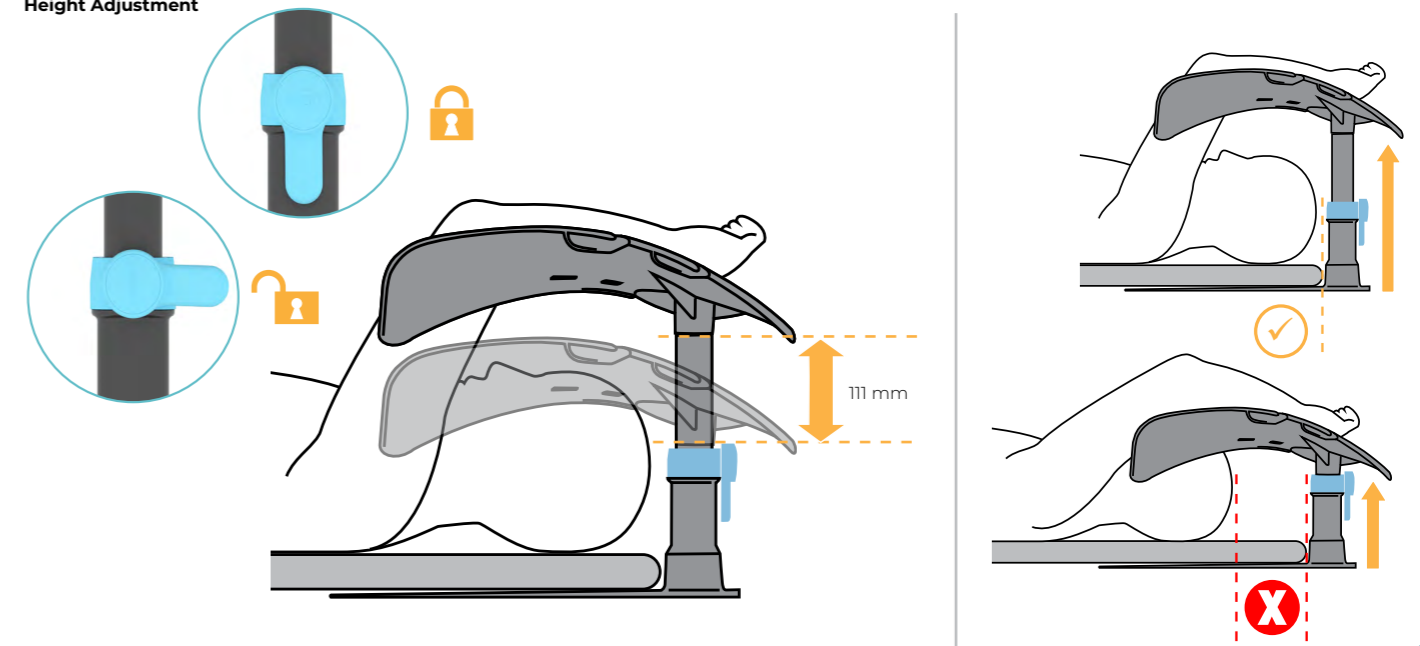
Assembly



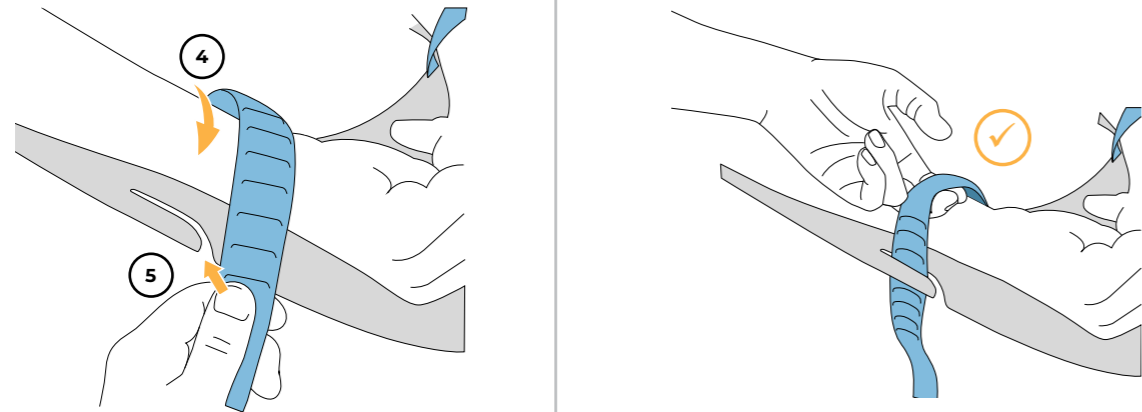
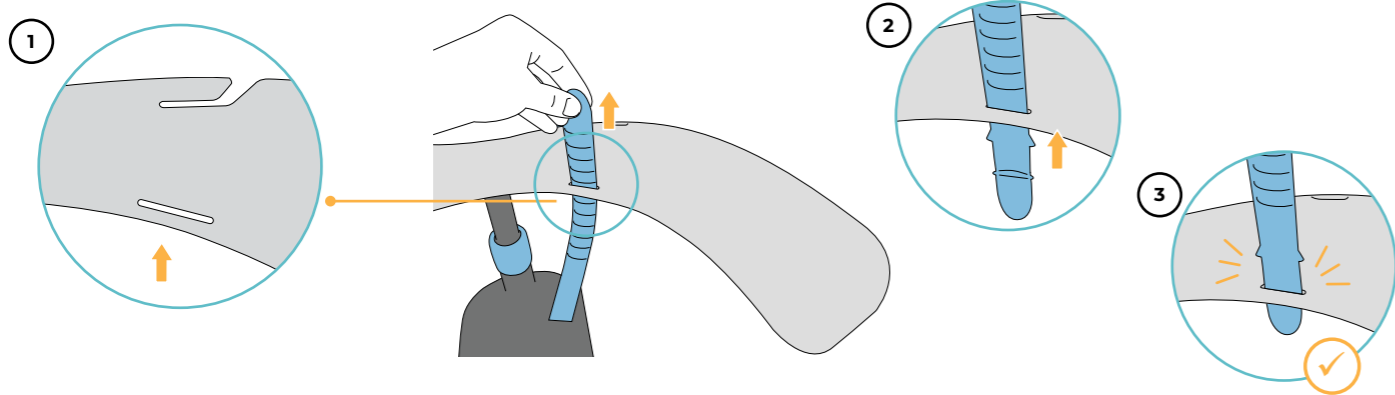
Setup



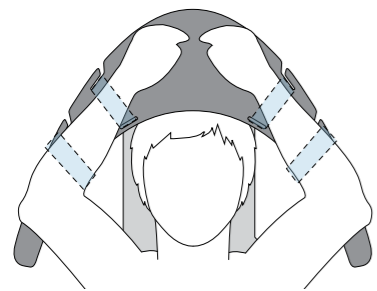
Height Adjustment



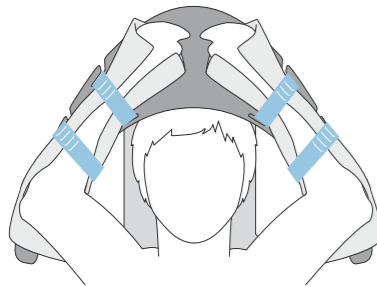
Strapping (Optional)



Strap Placement Options



Padding (Optional)



CT/MRI Safety Clearance



Spare Parts

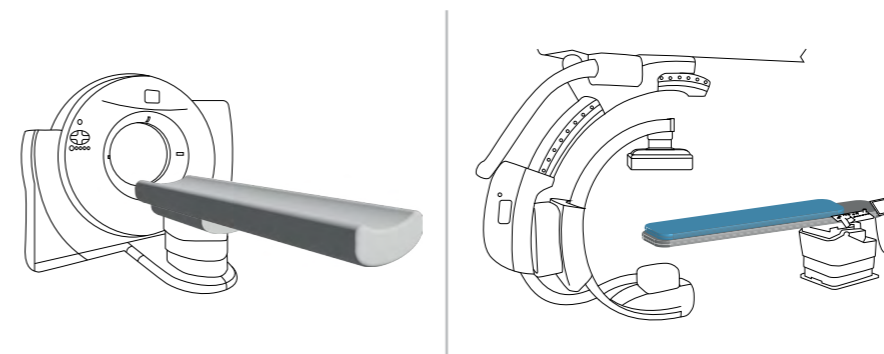
Product Codes

	Overhead Arm Support MR Safe	AM4000
	Overhead Arm Support MR Safe - Small	AM4100

Component Codes

	A	Armrest Wing MR Safe	M5504
OR		OR	OR
		Armrest Wing MR Safe - Small	M5507
	B	Arm Strap x 10	AM0620
	C	Locking Leg Assembly MR Safe	M5505
	D	Daggerboard MR Safe	M5506

Image Table Verification



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

- CT/MRI Bore:**
AM4000: ≥ 700 mm
AM4100: ≥ 600 mm
- Table Angulation:** +/- 15° lateral & longitudinal
- Table Surface:** Flat / Curved

Essential Information

Information

Intended Purpose

To support the patient's arms overhead with controlled shoulder flexion for imaging.

Intended User/Training Requirement

Intended to be used by trained medical professionals.

Patient Target Group

Patient requiring diagnostic imaging and image guided therapy. Below product selection guideline.

AM4000 Overhead Arm Support MR Safe	AM4100 Overhead Arm Support MR Safe - Small
47 kg - 135 kg	13 kg - 47 kg

Contraindications

- Not to be used outside of the recommended patient target group as outlined above.
- Not to be used with patients with existing or historical brachial plexus injury.
- Not to be used outside of the recommended image table verification specifications (refer to page 7).
- Not intended for neonates and infants, perform your own risk assessment.

Warnings and Cautions

- Ensure IFU is read prior to use.
- Ensure Preparatory Cleaning is conducted.
- Ensure Preparatory Product Check is conducted.
- Ensure MRI safety checks are conducted.
- Not to be used outside of the recommended patient target group as outlined above.
- Not to be used outside of the recommended image table verification specifications (refer to page 7).
- Not intended for neonates and infants, perform your own risk assessment.
- Ensure general patient insulation protocol is followed for MRI.
- Padding recommended on support surfaces for patient comfort (refer to page 6).
- Depending on patient age, size, weight, mobility, and duration of procedure, the product may not be suitable or may contribute to brachial plexus injury.
- Check patient for brachial plexus injury regularly.

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.

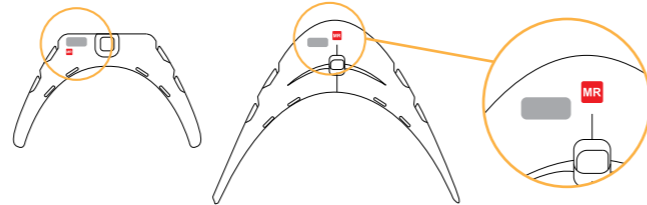
Product Checks

- No visible damage or sharp edges, e.g. cracks.
- Arm Strap: not damaged, e.g. tearing.
- Locking Leg Assembly: ensure that the Locking Leg Assembly is not free to move in the locked position.
- Locking Leg Assembly: Ensure it can move up and down when pushed in the unlocked position.
- Ensure the Locking Leg Assembly is fully inserted into the Daggerboard and the release clip is fully engaged (refer to page 4).
- Ensure the Armrest Wing (Small) is fully inserted onto the Locking Leg Assembly (refer to page 4).

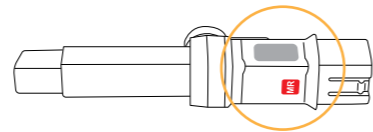
MRI Safety Checks

Ensure each component below has the 'MR Safe' product sticker and engraving in the below locations:

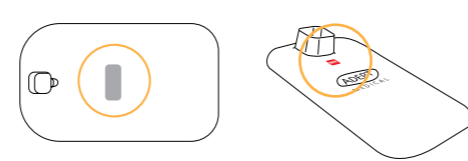
- Armrest Wing (Small):



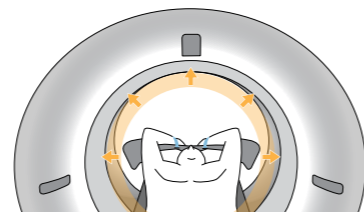
- Locking Leg Assembly:



- Daggerboard:



- Safety Clearance: AM4000: ≥ 700 mm | AM4100: ≥ 600 mm



Patient Management

Ensure insulation protocol is followed according to individual facility guidelines. This includes ensuring sufficient insulation is placed to eliminate skin to skin conductive loops and that the patient's skin does not contact the bore of the magnet, when using the device.

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 soft 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.

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 Overhead Arm Support (Small) from beneath the mattress.
- Remove Arm Straps from Armrest Wing (Small).
- Disassemble Overhead Arm Support (Small) into Armrest Wing (Small), Locking Leg Assembly and Daggerboard.
- Ensure the Locking Leg Assembly is fully extended.

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.

Armrest Wing (Small)

- With a cloth dampened by an approved disinfectant, wipe all surfaces, including inside the Arm Strap slots.

Daggerboard

- With a cloth dampened by an approved disinfectant, wipe all surfaces, including inside of the Locking Leg Assembly slot.

Locking Leg Assembly

- With a cloth dampened by an approved disinfectant, wipe all surfaces, especially the blue lever.

Arm Strap

- With a cloth dampened by an approved disinfectant, wipe all surfaces. www.adeptmedicaltraining.com/productcleaning/Overhead-Arm-Support

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

For all components ensure:

- No visible damage or sharp edges, e.g. cracks.
- Locking Leg Assembly:
 - Ensure blue lever functions smoothly.
 - Ensure when lever is in the unlocked position the Locking Leg Assembly can extend and contract smoothly when force is applied.
 - Ensure when lever is in the locked position the Locking Leg Assembly cannot contract or extend when force is applied.
 - Ensure smooth engagement with daggerboard during assembly.
 - Ensure tight fit with Armrest Wing (Small) during assembly.

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.

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