

PRODUCT GUIDE & USER MANUAL

RT-4525HGA Hand Grip Array







Advena Limited

Malta

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Made in the USA by

Qfix

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GENERAL PRECAUTIONS

WARNING STATEMENTS

! WARNING! NO MODIFICATION OF THIS EQUIPMENT IS ALLOWED. IF ANY PART OF THIS DEVICE EXPERIENCES A CATASTROPHIC LOAD, APPEARS DAMAGED OR FUNCTIONS IMPROPERLY, DISCONTINUE USE IMMEDIATELY AND CONTACT QFIX AT +1 484-720-6054 OR TECHSUPPORT@QFIX.COM.

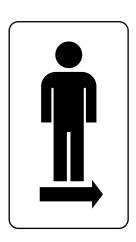
! CAUTION! DO NOT SIT ON THE HAND GRIP ARRAY, DOING SO MAY CAUSE THE HAND GRIP ARRAY TO BREAK, RESULTING IN INJURY TO THE PATIENT.

SERIOUS INCIDENTS

Please report any serious incidents (e.g. incidents which result in or have the potential to result in death or serious injury) to both Qfix and your country's Competent Authority.

WARNING LABELS & DESCRIPTIONS

Refer to Qfix.com for a listing of symbols and their definitions.



PATIENT LEFT

Refers to the patient's left side, and is the side on which that particular adapter should be installed.*

*This adapter may be installed to the opposite side during treatment for smaller patients.



PATIENT RIGHT

Refers to the patient's right side, and is the side on which that particular adapter should be installed.*

*This adapter may be installed to the opposite side during treatment for smaller patients.

GENERAL PRECAUTIONS

WARNING LABELS & DESCRIPTIONS



DO NOT SIT

Standing or sitting on the Hand Grip Array may damage the Hand Grip Array or cause injury.

INTENDED USE

This device is intended to immobilize, position and reposition patients undergoing radiation therapy.

! NOTE! United States Federal law restricts this device to sale by or on the order of a physician.

Patient Target Groups

Patients undergoing radiation therapy or diagnostic imaging procedures.

Intended Users

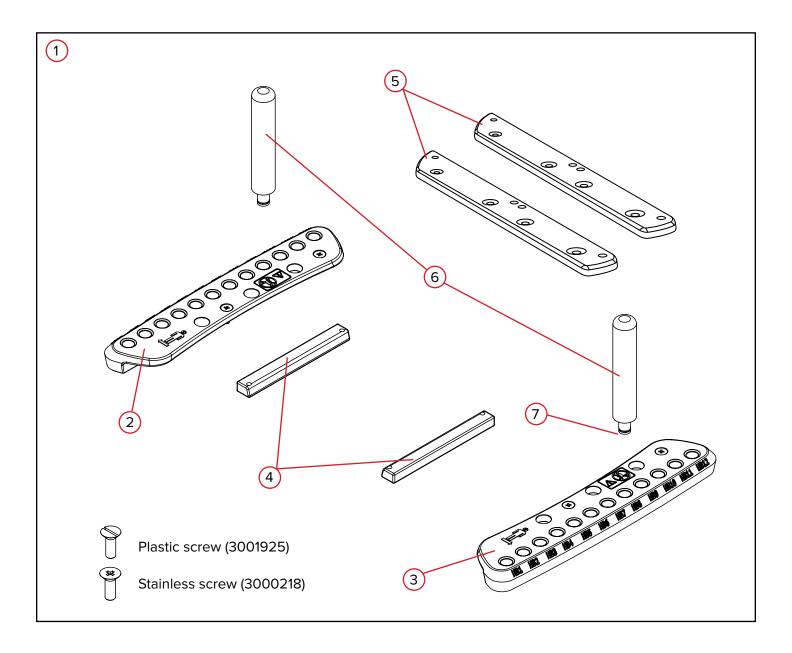
The intended user for the products is a person qualified in accordance with the requirements of the regulatory region.

FEATURES

DESCRIPTION

The Hand Grip Array provides dependable indexed positioning of the patient's hands. This optional device helps ensure accurate patient alignment from simulation to treatment.

COMPONENTS



FEATURES

COMPONENTS

1. HAND GRIP ARRAY

The Hand Grip Array provides dependable indexed positioning of the patient's hands. This optional device helps ensure accurate patient alignment from simulation to treatment.

2. HAND GRIP ARRAY—PATIENT RIGHT

The Hand Grip Array—Patient Right is the Hand Grip Array located on the right side of the patient, and is denoted by the graphic on the device. This will be reversed when used for smaller patients.

3. HAND GRIP ARRAY—PATIENT LEFT

The Hand Grip Array—Patient Left is the Hand Grip Array located on the left side of the patient, and is denoted by the graphic on the device. This will be reversed when used with smaller patients.

4. KVUE INSERT ADAPTER

The kVue Insert Adapters are only used when attaching the Hand Grip Array to kVue Inserts that have pre-drilled holes to accept the Hand Grip Array.

5. KVUE Portrait INSERT ADAPTER

The kVue Portrait Insert Adapters are only used when attaching the Hand Grip Array to kVue Portrait Inserts that have pre-drilled holes to accept the Hand Grip Array.

6. HANDLES

The handles index to the Hand Grip Array in one of 12 locations.

7. O-RING

The O-ring attaches to the bottom of each handle to help hold the handle inside the index locations.

INSTALLATION

HAND GRIP ARRAY INSTALLATION

! NOTE! For installation on legacy applications please contact Qfix at +1 610-268-0585.

1. Place Hand Grip Array on device, lining it up with the corresponding holes shown in Fig. 1.

! NOTE! Refer to the General Precautions section for which side each Hand Grip Array goes on.

! NOTE! For most devices the Hand Grip Array will be installed on the 1st and 3rd holes from the head of the device, shown in Fig. 2 unless an adapter is already installed in that location. If that is the case, line up the Hand Grip Array with the next available hole locations.

! NOTE! If installing the Hand Grip Array on a kVue Insert, refer to "Installation for kVue Inserts".

! NOTE! If installing the Hand Grip Array for samller patients, refer to "Smaller Patients" section.



Fig. 1



Fig. 2

2. Use a screwdriver to tighten the screws (3000218) into the corresponding holes using a clockwise motion shown in Fig. 3. (To loosen turn counterclockwise).

! WARNING! IF YOUR DEVICE IS LABELED MR SAFE USE PROVIDED PLASTIC SCREWS (3001925).



Fig. 3

INSTALLATION

INSTALLATION FOR KVUE INSERTS

Use the same method to install the Hand Grip Array onto a kVue Insert as you would any other device (as shown previously). The only exception is that instead of tightening the screw directly into the device the screw will be tightened into the insert adapter (Fig. 4 & 5).

! NOTE! The Hand Grip Array may not work with all adapters.

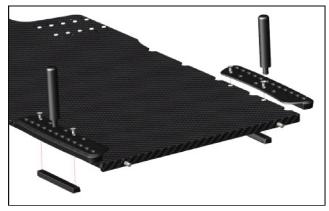


Fig. 4

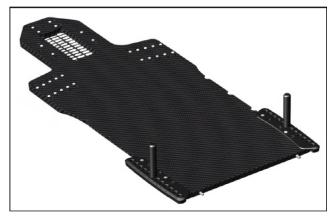


Fig. 5

INSTALLATION FOR SMALLER PATIENTS

The left and right Hand Grip Array may be reversed for small patient setup, shown in Fig. 6.



Fig. 6

INSTALLATION

INSTALLATION FOR KVUE PORTRAIT INSERTS

- 1. Using the two (2) $\frac{1}{4}$ -20 x 1" screws provided, attach the adapter to the kVue. Repeat for the opposite side (Fig. 7).
- 2. Attach the Head Grip Array to each side using the two (2) $\frac{1}{4}$ -20 x $\frac{3}{4}$ " flat head screws provided (Fig. 8).
- ! NOTE! The Head Grip Array may not work with all adapters.

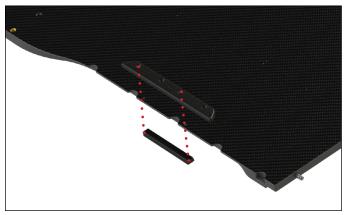


Fig. 7



Fig. 8

SET-UP

HEAD GRIP ARRAY SET-UP

Attach the handle once the patient is in place. Place the handle into the hole so that it can be gripped comfortably by the patient, shown in Fig. 9 & 10, and record its location using attached Patient Setup Record.



Fig. 9



REMOVAL

HEAD GRIP ARRAY REMOVAL

- 1. Remove the handles from Head Grip Array.
- 2. Remove the two screws holding the Head Grip Array onto the device.

MAINTENANCE

CLEANING

The device can be cleaned with a mild, non-abrasive cleaning or disinfecting solution. To clean, apply solution to clean cloth and wipe the surface.

DISINFECTING

The following cleaning materials have been tested and found to be appropriate for cleaning the device surfaces. To disinfect the device, refer to specific instructions from the cleaning agent manufacturer.

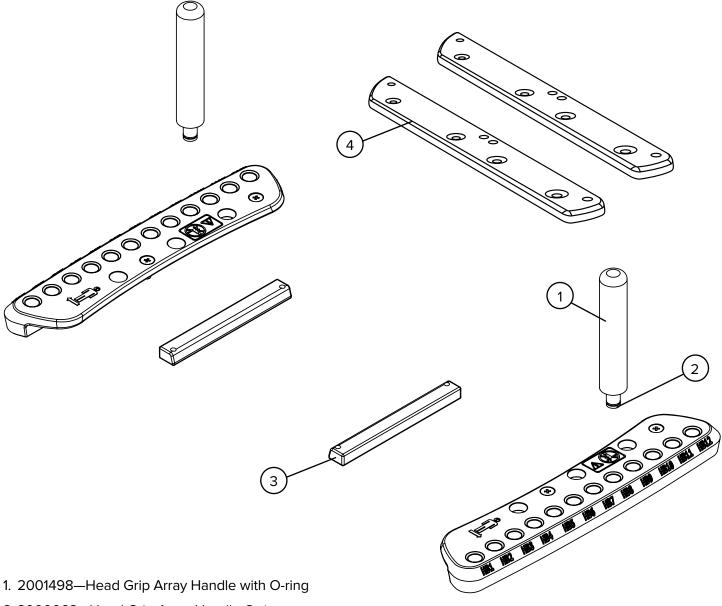
- Water
- 10% Clorox® Bleach Solution
- · Isopropyl Alcohol
- Cidex® 2.4% Activated Dialdehyde Solution
- · Soap and Water

DO NOT spray directly onto the device.

DO NOT place sharp objects on the device.

Periodically check all fasteners for tightness.

PARTS LIST



- 2. 3000063—Head Grip Array Handle O-ring
- 3. 2001774—Head Grip Array kVue Adapter
- 4. 2007708—Head Grip Array kVue Portrait Adapter

SETUP SHEET

RT-4525HGA—HAND GRIP ARRAY

Patient Name:

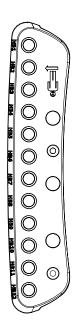
Patient ID #:

Setup by:

Physician:

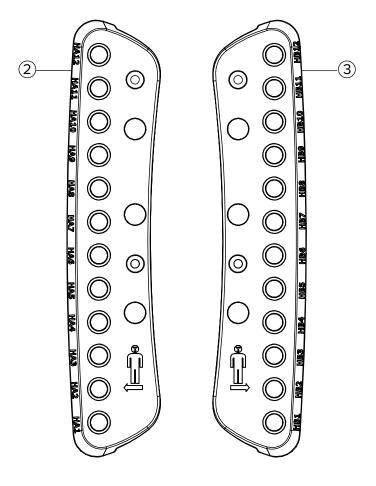
Comments:

 Is Head Grip Array setup in the Small Patient Position? YES NO





Patient's Right Side: HA
 Patient's Left Side: HB





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