

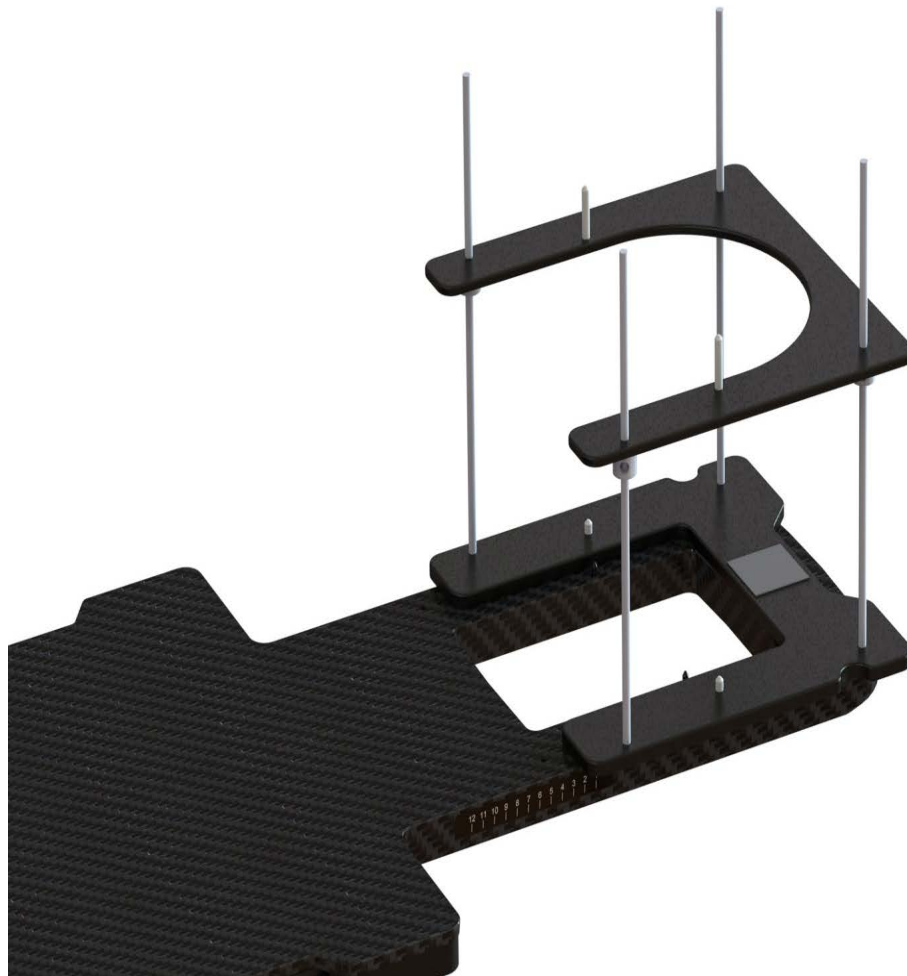


positioning
patients for life.®

PRODUCT GUIDE & USER MANUAL

RT-4521CSA

Prone Cranial Spinal Axis Treatment Kit





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Fibreplast® is a registered trademark of Qfix.

kVue, AccuFix, Cantilever Board, Aquaplast RT and Tilt-Pro are trademarks of Qfix.

Clorox® is a registered trademark of The Clorox Company.

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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.

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.

INTENDED USE

This device is intended for use during patient set-up, allowing the user to create a thermoplastic mask for use in the prone position. This is not a treatment device.

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

PATIENT TARGET GROUPS

Patient's 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

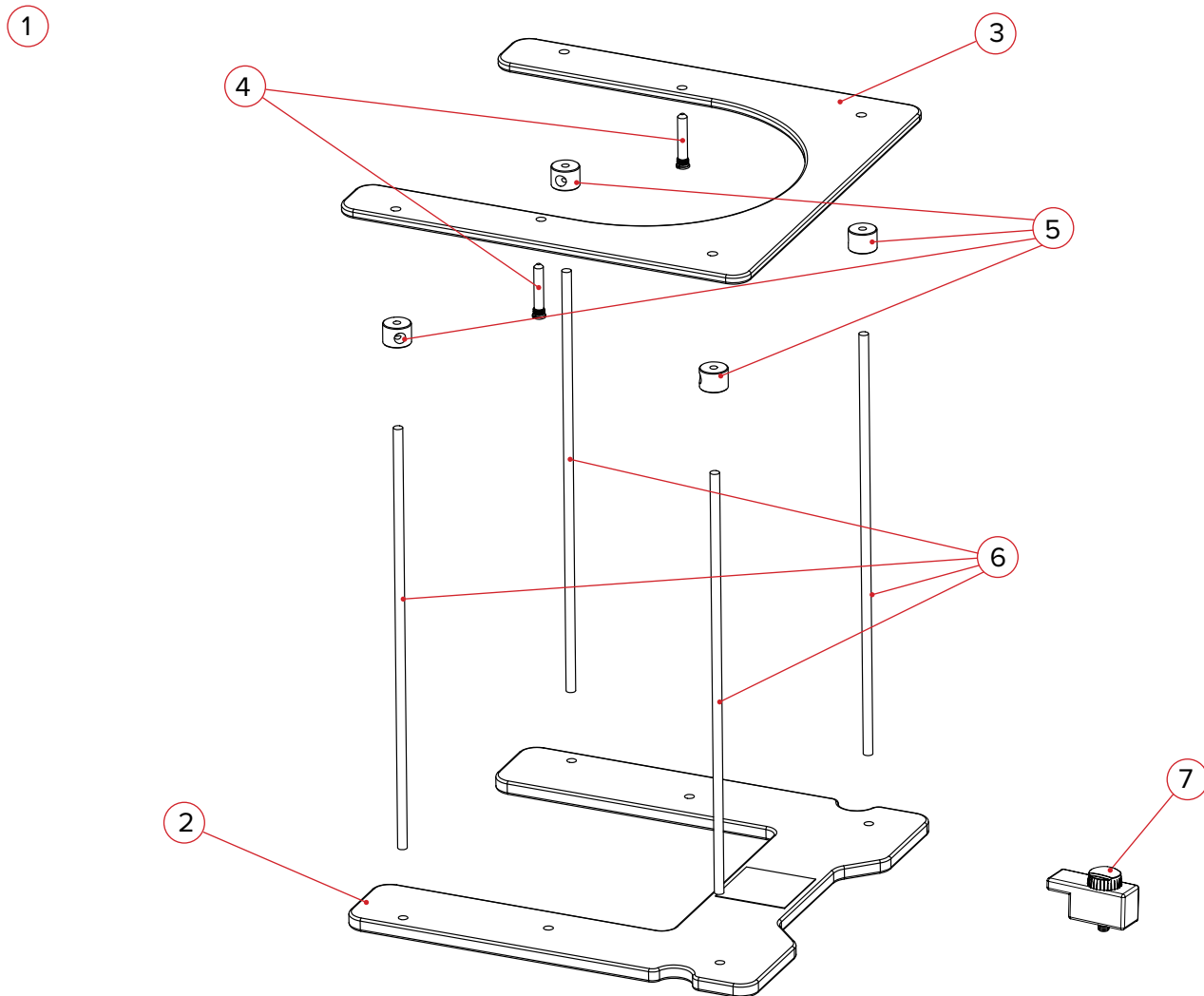
The Prone CSA Kit greatly simplifies the molding of prone masks for use with the Tilt-Pro Base or AccuFix™ Cantilever Board for Prone Cranial Spinal Axis (CSA) treatment. This kit includes a molding fixture for forming prone masks, prone mask foam to cushion the prone mask, and double high nylon swivel locks for securing two masks at once.

REQUIRED ACCESSORIES

- Tilt-Pro™ Tilting Base or
- AccuFix™ Cantilever Board – Featherline Edition or
- kVue™ AccuFix™ Cantilever Board™ Insert

FEATURES

COMPONENTS



FEATURES

COMPONENTS

1. PRONE CSA KIT RISER SYSTEM

A complete kit for forming Aquaplast RT™ / Fibreplast® masks for prone treatment on the Tilt-Pro™ base.

2. BASEPLATE

The Baseplate attaches to a compatible head and neck device using the white indexing pins mounted on the head and neck to locate and hold the Prone CSA Kit in place.

3. UPPERPLATE

The upperplate is used to position the Aquaplast RT™ / Fibreplast® mask on the patients face.

4. WHITE INDEXING PINS

The white indexing pins are used to locate and hold the Aquaplast RT™ / Fibreplast® U-Frame on the upper plate of the Prone CSA Kit.

5. HEIGHT ADJUSTMENT NUT

The height adjustment nuts travel along the posts to set the height of the upperplate of the Prone CSA Kit. The height adjustment allows the kit to accommodate to multiple patient heights.

6. BASEPLATE POSTS

The threaded posts are used by the height adjustment nuts to set the height of the Prone CSA Kit.

7. DOUBLE-HIGH NYLON SWIVEL LOCKS

The double-high nylon swivel locks allow for two masks to be locked down to the Tilt-Pro Base to properly immobilize the patient.

OPERATING INSTRUCTIONS

INSTALLATION

PRONE CSA KIT

1. Install a compatible device onto the couchtop. Once installed remove the four swiveling locks from the insert (Fig 1 & 2).



Fig. 1

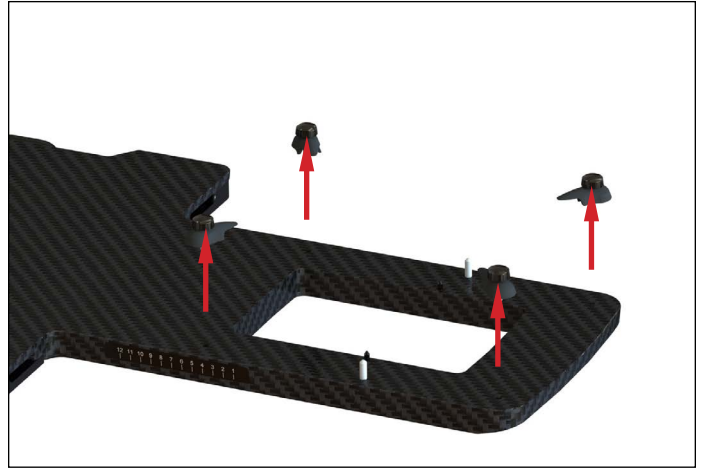


Fig. 2

2. Position patient supine on the device using an appropriate sized Silverman headrest.
3. With the patient in place mount the Prone CSA kit using the white indexing pins on the device to line up with the holes on the base plate of the Prone CSA Kit (Fig 3 & 4).

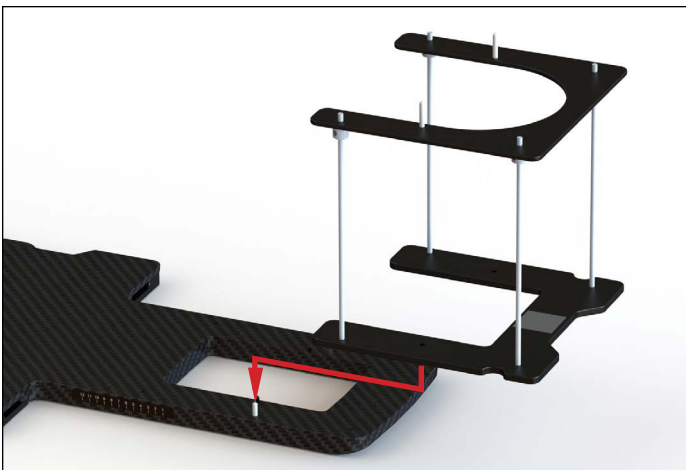


Fig. 3

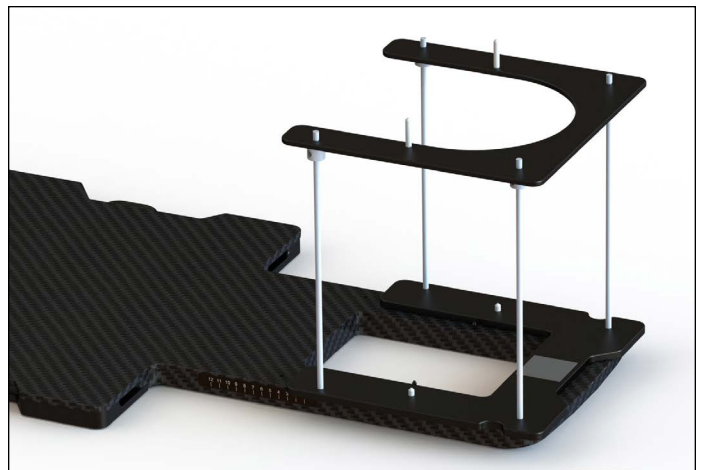


Fig. 4

OPERATING INSTRUCTIONS

SET UP

HEIGHT ADJUSTMENT

To adjust the height of the upper base plate move the four height adjusters up and down. To use the height adjusters, press the button on the side of the adjuster nut and slide it to the desired height. Alternatively spinning the height adjusters will also move them up and down (Fig. 5 & 6).

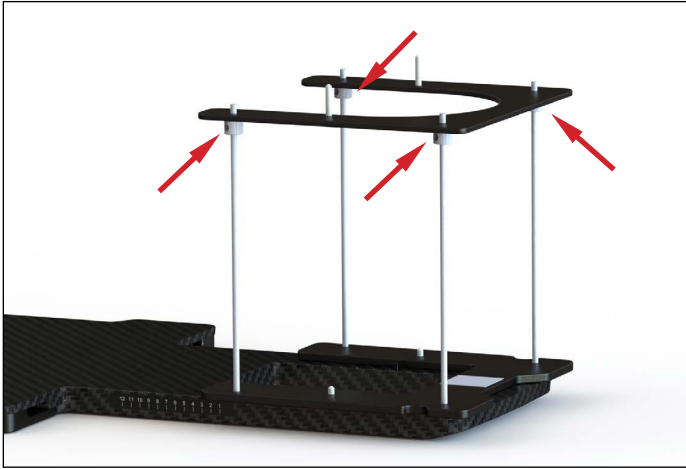


Fig. 5

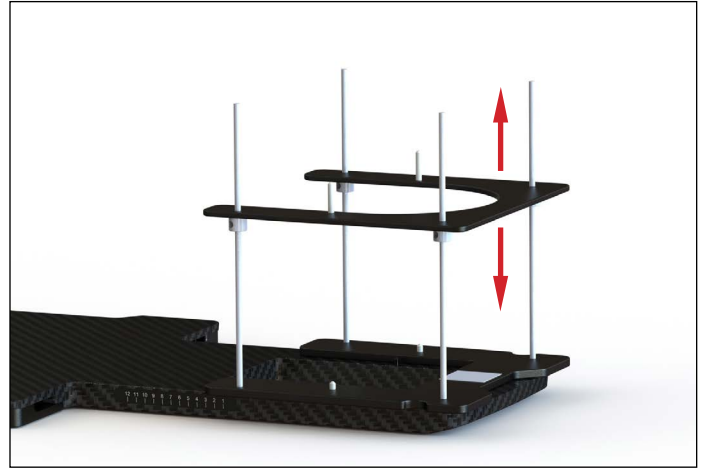


Fig. 6

! NOTE ! When positioned properly the patient's nose should protrude from the top plane of the CSA upper plate as shown in Fig. 7.

! NOTE ! Ensure that the top plate is level before moving onto the next step Fig. 7.

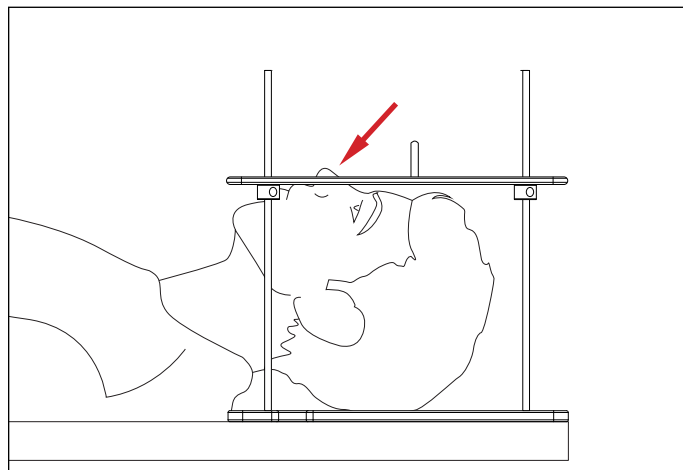


Fig. 7

OPERATING INSTRUCTIONS

SET UP

PRONE AQUAPLAST RT MASK

1. To create a prone mask, first prepare a special thickness Aquaplast RT™ mask for placement over the patients face. Once prepared, place the Aquaplast RT mask over the anterior surface of the patients face using the white indexing pins to locate the mask on the upper plate.

! NOTE ! Refer to the Product Guide and User Manual for Aquaplast RT & Fibreplast (P/N 2002890) for operating instructions, product features, specifications, warnings, cautions, and other general precautions related to the use of the Aquaplast RT.

! NOTE ! It is important to make sure that the patients outer canthus is still visible from the lateral view as shown in Fig. 8.

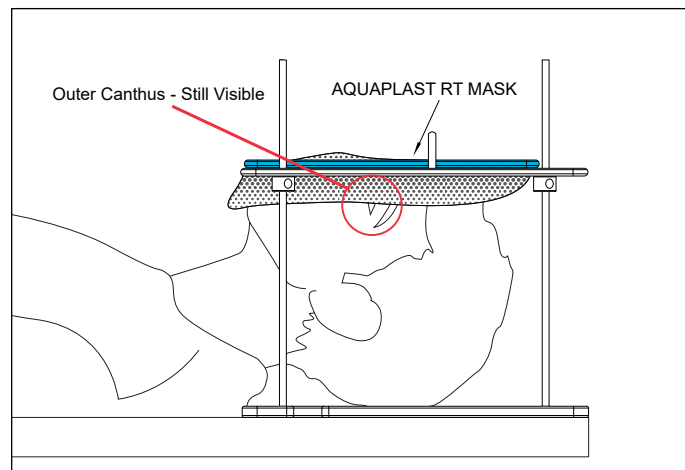


Fig. 8

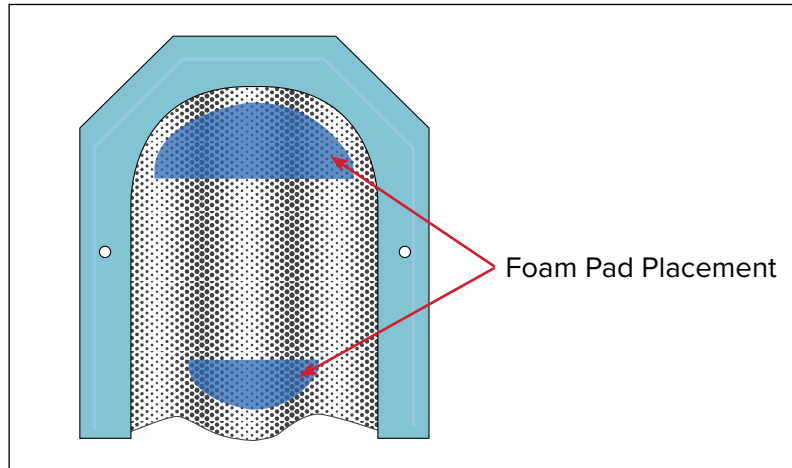
2. Once the mask cools and sets, remove from patients face and dry.

OPERATING INSTRUCTIONS

SET UP

PRONE AQUAPLAST RT MASK FOAM PADDING

Using a pair of scissors cut two (2) semi-circle shapes out of the provided foam padding. To apply foam, peel the protective paper from the adhesive side of the sheet. One semi-circle should be placed on the area of the mask that seats on the patients forehead. The other is intended for the area of the mask that seats on the patients chin. If necessary more foam should be cut and applied in order to ensure patient comfort (Fig. 9).



MAINTENANCE

CLEANING THE SYSTEM

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 SYSTEM

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

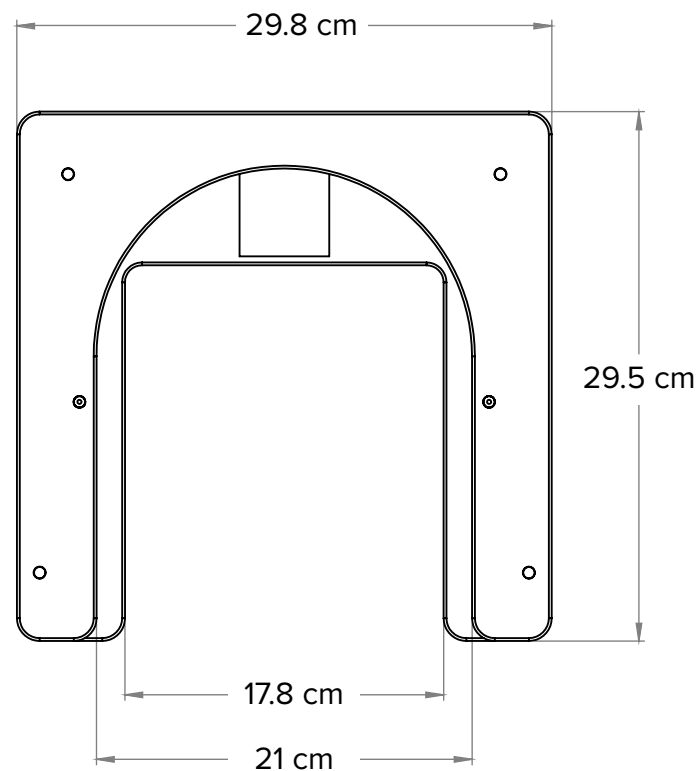
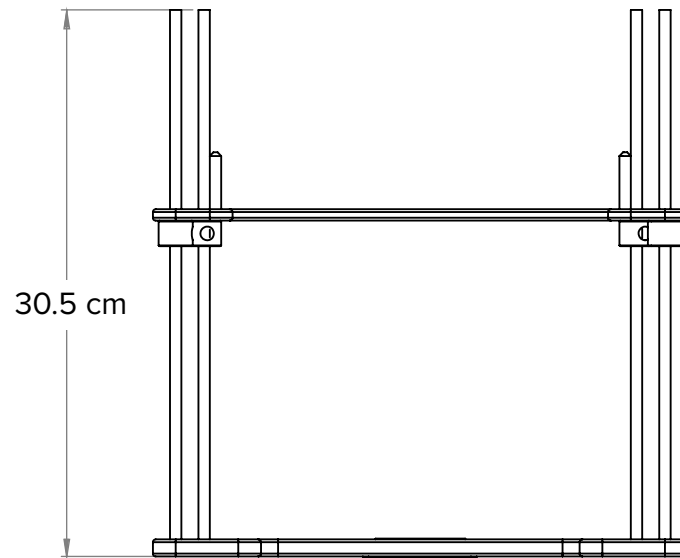
DO NOT spray directly onto the device.

DO NOT place sharp objects on the device.

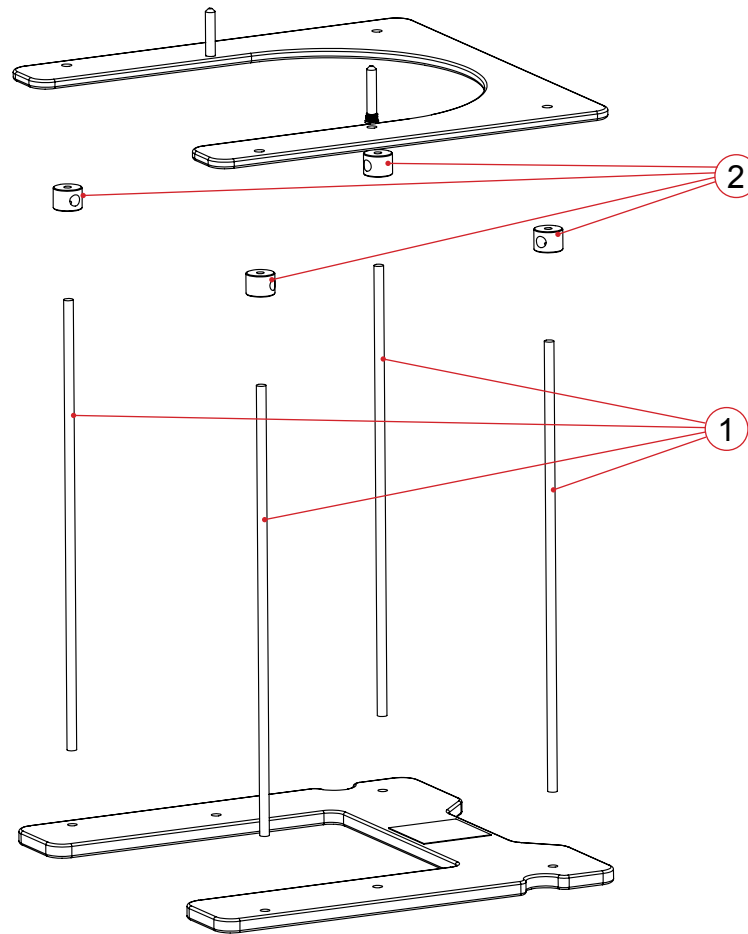
Periodically check all fasteners for tightness.

SPECIFICATIONS

PRONE CRANIAL SPINAL AXIS TREATMENT KIT



PARTS LIST



1. 3000223 – Threaded Baseplate Posts
2. 3001107 – Height Adjustment Nuts



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