positioning
patients for life.®

PRODUCT GUIDE & USER MANUAL

RT-4535BOS & RT-4535BOSMRI

BoS™ Headframe

Base of Skull

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CE

EC REP	Advena Limited Tower Business Centre, 2nd Flr Tower Street, Swatar, BKR 4013 Malta

Made in the USA by
Qfix
440 Church Rd, Avondale, Pennsylvania, USA
+1 610-268-0585 www.Qfix.com

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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.

! WARNING ! DOSE DEPTH, DEPOSITION, AND TRANSITION AREA EFFECTS MUST BE EVALUATED DURING PLANNING AND TREATMENT WITHIN A PROTON THERAPY ENVIRONMENT.

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.

ADDITIONAL WARNINGS

- Always secure the BoS Headframe to the treatment table using the appropriate mounting adapters.
- DO NOT modify the BoS in any way.
- DO NOT use the BoS if it appears to have been modified or damaged in any way.
- Never put weight on the cantilevered portion of the device without a patient lying on it. The cantilevered portion of the device is designed to support only the weight of a patient's head. DO NOT allow the patient to lean on this portion of the device.
- Always assist the patient on and off of the BoS by supporting their upper body and head regions.
- Make sure the patient is secured before moving the couch top.

MRI SAFETY INFORMATION

The powerful magnetic field of the MRI system will attract ferromagnetic objects and may cause them to move suddenly and with great force. DO NOT use metal screws for attaching adapters to the BoS MRI. DO NOT use in conjunction with any ferromagnetic or electrically conductive components or accessories.

LOAD RATING

DO NOT exceed 159 kg (350 lb) uniformly distributed load at maximum cantilever position indicated on board.

! NOTE ! When combined with the OEM couch base, the load rating is the lower of the two safe working loads. The kVue Couch Top load should NOT exceed the original couch base manufacturer's specifications. Please refer to the product literature provided by the original manufacturer.

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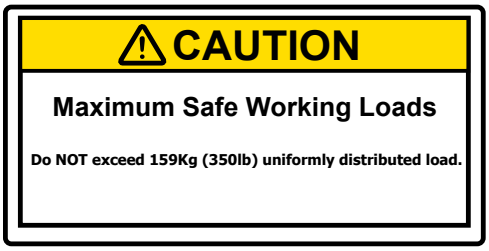
GENERAL PRECAUTIONS

WARNING LABELS & DESCRIPTIONS

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



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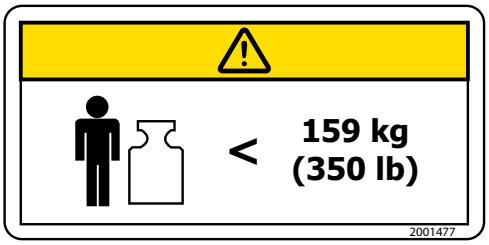
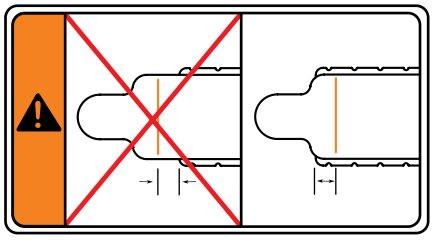


LOAD RATING

DO NOT exceed 159 kg (350 lb) uniformly distributed load at maximum cantilever position indicated on board.



WARNING

DO NOT extend the BoS off the couch top past the orange line. The cantilevered portion of the device is designed to support only the weight of a patient's head; the weight limit of this portion is 10 kg (22 lb).

MR

MRI SAFE

An item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically non-conductive, nonmetallic and nonmagnetic.

MRSecure™

MRI SECURE

When present, this graphic indicates that the device or accessory is MRI safe, and may be used with other MR Secure or MR safe devices. DO NOT use in MRI if MR Secure accessory is being used with a MR Unsafe or NON-MR Secure Device.

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

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.

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FEATURES

DESCRIPTION

The BoS is specifically designed to meet the unique requirements of proton therapy for patient immobilization and beam transmission. It can also be used for Photon (Linac), X-ray based diagnostic imaging and simulation. The MR Safe version can also be used in an MRI machine.

REQUIRED ACCESSORIES

Aquaplast RT™ or Fibreplast® Mask for BoS Headframe.

OPERATING INSTRUCTIONS

INSTALLATION

BOS INSTALLATION

1. Place the BoS on the treatment, simulator, or CT couch top.
2. Locate the indexing adapter on the inferior portion of the device. For other mounting methods, please contact Qfix at +1 484-720-6054 or info@Qfix.com.
3. Insert the indexing adapter into the indexing scallops on the treatment couch top. The BoS will lock to the couch top under slight pressure.
    - For treatment couch tops without indexing scallops, use a mounting adapter that fits snugly against the sides of the board and under the rail standoffs.
    - If using a removable tennis racket couch top insert, it may be necessary to reverse the insert to achieve the proper fit.

OPERATING INSTRUCTIONS

REMOVAL INSTRUCTIONS FOR BOS™ 2.1 PIN

1. To remove, use a ⅛" flat blade screwdriver to remove the top screw. (Fig 1).
2. Using the flat-jaw Pliers, grasp the Bos Pin 2.1 on the flat sides and pull down to remove. (Fig 2).
3. After completing Steps 1 and 2, proceed to Installation Instructions for BoS™ 2.1 Pin.

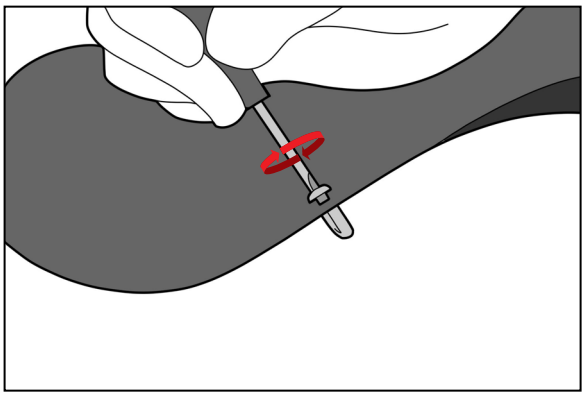

Fig. 1

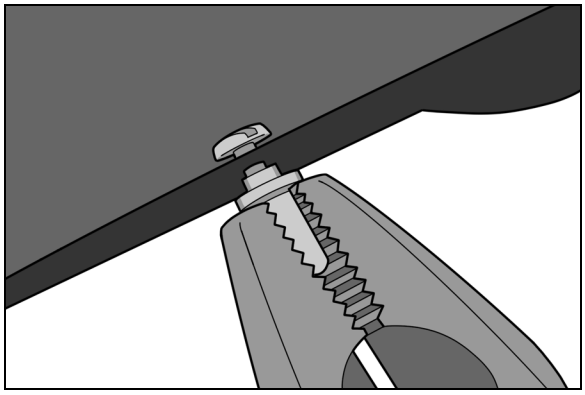

Fig. 2

INSTALLATION INSTRUCTIONS FOR BOS™ 2.1 PIN

Place (1) M3 PHS through the hole with the head of the screw on the inside surface. Hold the head of the screw in place with the pad of your finger. (Fig 3).

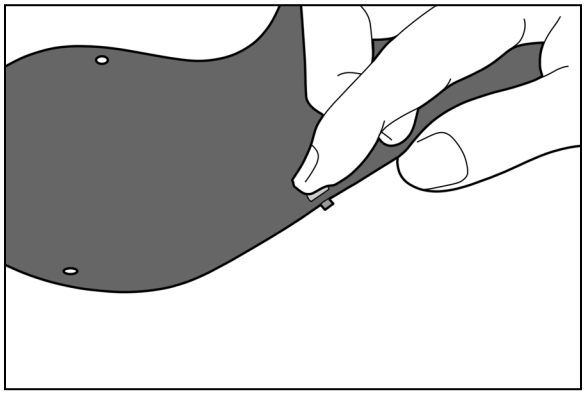

Fig. 3

OPERATING INSTRUCTIONS

BOS PIN REPLACEMENT

1. Screw (1) BoS Pin 2.1 onto the protruding tip of the screw several turns. (Fig 4).

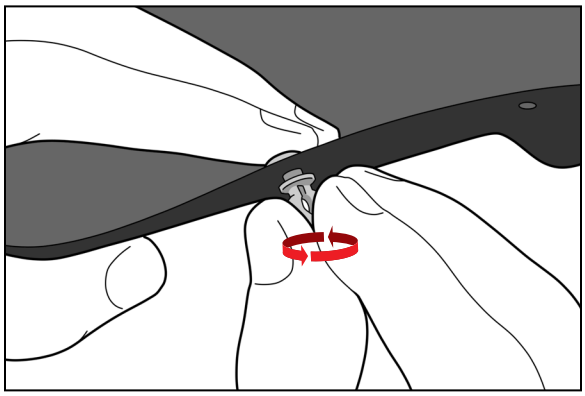

Fig. 4

! NOTE ! DO NOT TIGHTEN. The pin assembly should be loose in the hole. (Fig 5).

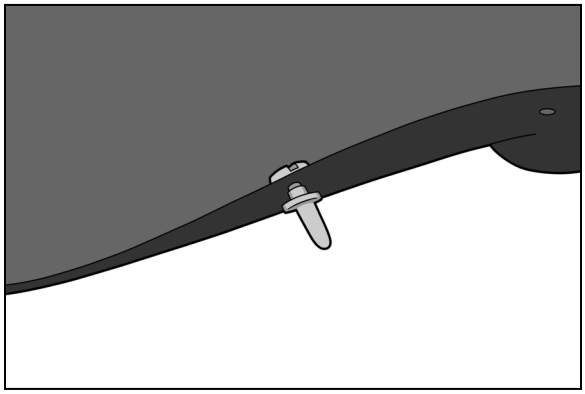

Fig. 5

2. Using the flat-jaw Pliers, grasp the Bos Pin 2.1 on the flat sides. (Fig 6).

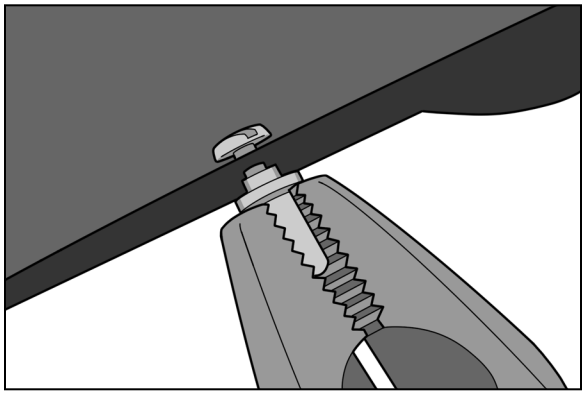

Fig. 6

3. Carefully align the assembly to the hole and force the pin neck into the hole (Fig 7).

! NOTE ! Excessive force or misalignment can damage the pin neck, preventing the pin from sitting flush.

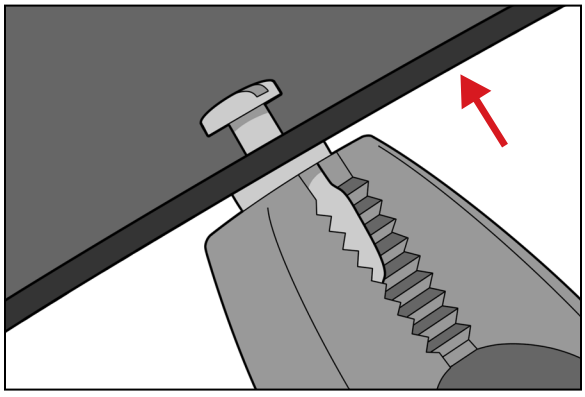

Fig. 7

OPERATING INSTRUCTIONS

BOS PIN REPLACEMENT

4. Tighten the screw using ⅛" flat blade screwdriver until snug. (Fig 8).

! NOTE ! Do not overtighten as this can make replacement difficult.

5. Repeat for the remaining holes.

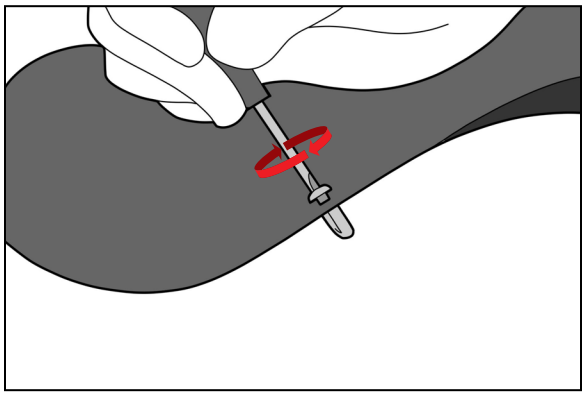

Fig. 8

OPERATING INSTRUCTIONS

SET-UP

1. Place the BoS foam head/neck support onto the neck area of the device.
   - MOLDCARE® may be used instead of the foam head/neck support. Qfix recommends RT-4492U for use with the BoS Headframe.
   - A foam shim (RT-4485) may be used to compensate for shrinkage of the BoS mask.
2. Sit the patient on the lower aspect of the BoS.
3. Lift and rotate the patient's legs onto the treatment couch top. Lay the patient gently backwards until the patient's head and neck are comfortably resting on the foam cushion or MOLDCARE®.
   - **Simulation:** make Aquaplast RT or Fibreplast mask on patient. Refer to Aquaplast RT/Fibreplast IFU (PN 2002890) for more details.
   - **Treatment:** Place premade mask on patient and attach to BoS.

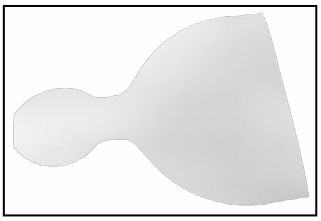

Figure 9: Foam Shim (RT-4485)

! NOTE ! The BoS mask is designed to be molded with the welded side (see Figure 12) of the mask facing out relative to the patient when attaching to the pins on the BoS Device. Place frame side (see Figure 11) of the mask down in the waterbath or oven and toward the patient during mask formation. It is easiest to attach the frame to the BoS by first attaching the pin marked "A" in Figure 10.

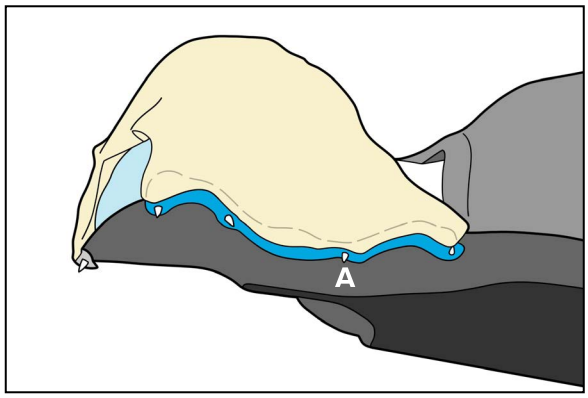

Figure 10

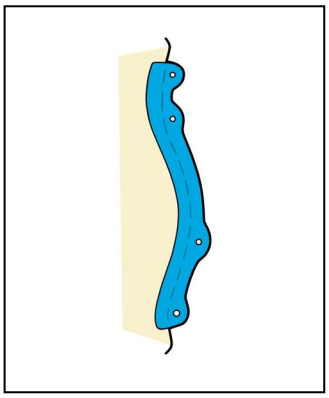

Figure 11: Frame Side

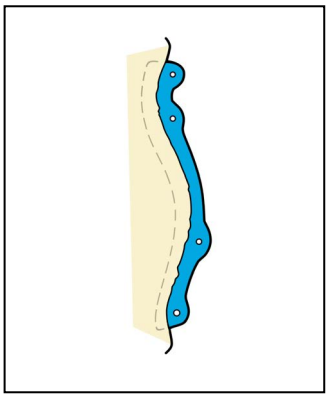

Figure 12: Welded Side

REMOVAL

1. Remove mask from patient.
2. Remove patient from device.
3. Remove device from couch top.
4. Remove indexing adapter from couch top.

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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 BoS Headframe surface. To disinfect the device's surface, refer to specific instructions from the cleaning agent manufacturer.

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

Periodically check all fasteners for tightness

DO NOT place sharp objects on the BoS.

SPECIFICATIONS

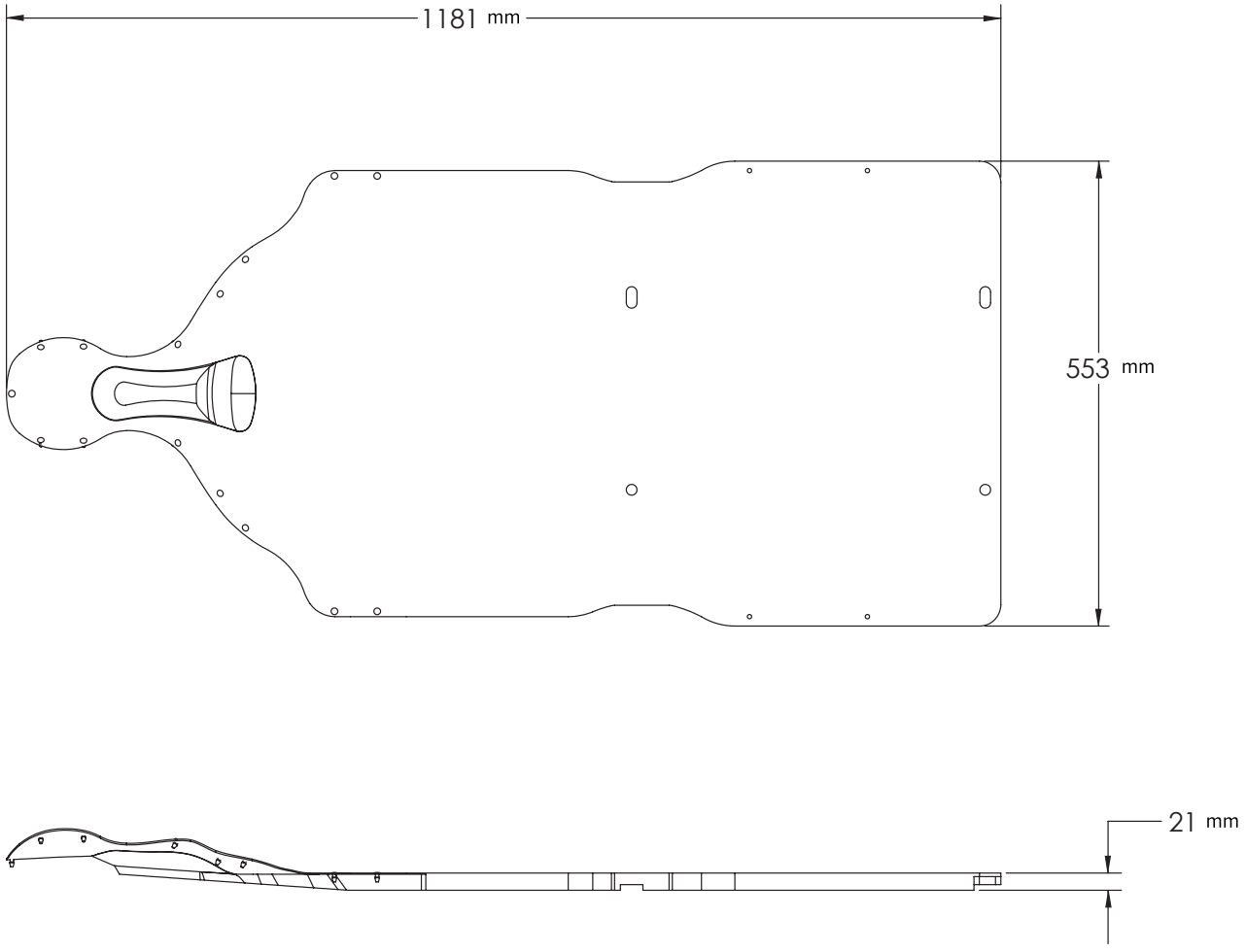
RT-4535BOS & RT-4535BOSMRI

LENGTH: 1181 mm

WEIGHT LIMIT: 159 kg (350 lb) Uniformly Distributed Load at maximum cantilever position indicated on board.

TREATMENT BEAM ATTENUATION

The BoS will attenuate the radiation beam. Treatment through an additional couch top will increase the overall attenuation. Treatment through any device, even one constructed of carbon fiber, will affect the treatment beam and may lead to an increased skin dose. Actual attenuation based on setup should be verified with your particular equipment.



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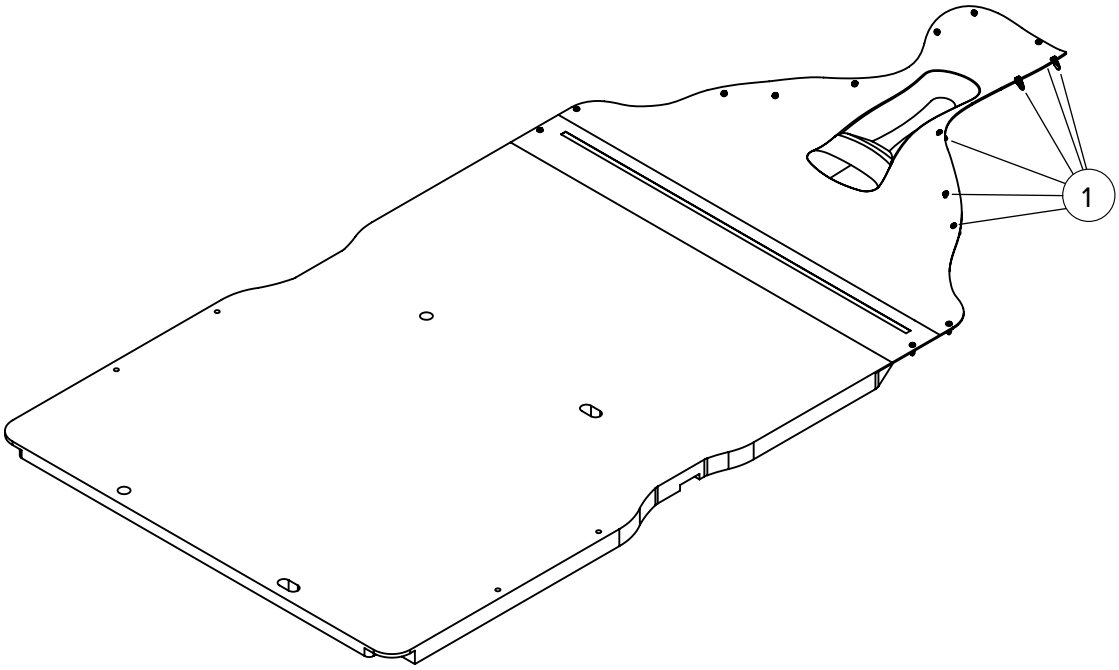
PARTS LIST



1. RT-4485CL2 – BoS Pin Kit

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