

INSTRUCTION MANUAL

Spinal Imaging Platform



Surgical Head Rest



© Copyright 2009

OAKWORKS® Medical Equipment,
a division of OAKWORKS®, Inc.

Manual Part # MMMNUP0001
rev. 08.28.09
5th Edition, August, 2009
Printed in U.S.A.

All rights are reserved. No part of this document may be photocopied, reproduced or translated to another language without prior written consent of OAKWORKS® Medical Equipment, a division of OAKWORKS®, Inc.

OAKWORKS® is a registered trademark of OAKWORKS®, Inc.

Notice

The information contained in this document is subject to change without notice and should not be construed as a commitment by OAKWORKS®, Inc.

OAKWORKS®, Inc. assumes no responsibility for any errors that may appear in this document nor does it make expressed or implied warranty of any kind with regard to this material, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose.

OAKWORKS®, Inc. shall not be liable for incidental or consequential damages in connection with or arising out of the furnishing, performance, or use of this document and the program material which it describes.

TABLE OF CONTENTS

Introduction	pg 3
Warnings & Precautions	pg 4
Symbol Identification	pg 6
Description of Components	
Primary Components	pg 7
Secondary Components	pg 8
Optional Components	pg 10
Directions for Use	pg 12
Cleaning & Disinfecting	pg 21
List of Parts	pg 22
Specifications	pg 23
Warranty	pg 24
Contact Information	IBC

INTRODUCTION

SPINAL IMAGING PLATFORM

The OAKWORKS® Spinal Imaging Platform is a patent pending patient cradle device for use in diagnostic and therapeutic treatment procedures of the spine. It is designed to comfortably provide cervical flexion to extension and any position in between. The Spinal Imaging Platform was designed to be used with fluoroscopy systems for spinal injections, vertebroplasty or kyphoplasty procedures, and for imaging procedures where a contrast agent must be contained below the upper cervical area.

SURGICAL HEAD REST

The OAKWORKS® Surgical Head Rest is designed to alleviate pressure on the eyes and sinus cavities while providing cranial support during pre-op sedation or post-op recovery. It includes a radiolucent carbon fiber frame, crescent face pad and 2” positioning pad for additional positioning options.

INDICATIONS

SPINAL IMAGING PLATFORM

The OAKWORKS® Spinal Imaging Platform is a patient cradle device for use in diagnostic and therapeutic treatment procedures of the spine. It is intended to be used solely for the purpose of aiding in patient positioning and comfort during non-surgical imaging or spinal injection procedures. It may also be used during minimally invasive surgical procedures such as vertebroplasty or kyphoplasty. The Spinal Imaging Platform, its secondary components and optional components are suitable for use with fluoroscopy systems.

SURGICAL HEAD REST

The Oakworks Surgical Head Rest functions in prone or supine positioning, supports patients during pre-op sedation or post-op recovery and alleviates eye pressure with ergonomic design. This device can be used on any table.

CONTRAINDICATIONS

The OAKWORKS® **Spinal Imaging Platform** and **Surgical Head Rest** are not designed for use with diagnostic x-ray systems where the x-ray generator is located above the radiographic table and the film cassette or image intensifier is located below the radiographic table. The X-Ray generator **MUST BE** located below the radiographic table.

The Spinal Imaging Platform and Surgical Head Rest are not designed for use with magnetic resonance imaging systems.

The Spinal Imaging Platform and Surgical Head Rest are not intended for use in cranial procedures.

**WARNINGS/
PRECAUTIONS**

WARNINGS

The cushioning foam contained within the Torso Support will lose its ability to spring back to the original position over time and the amount of foam compression will increase. Therefore, the Torso Support should be replaced periodically to ensure the device functions as intended. (Spinal Imaging Platform only)

Operate the C-arm of the fluoroscopy system with the Spinal Imaging Platform or Surgical Head Rest in place before using the device with a patient for the first time. Make sure there is adequate clearance room to permit free C-arm rotation for both the patient and the positioning device.

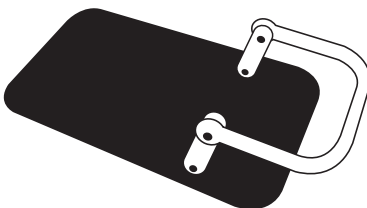
Do not permit the patient to push down on the Crescent Face Cushion in an effort to lift themselves up while dismounting the platform and/or the Fluoroscopy Table.



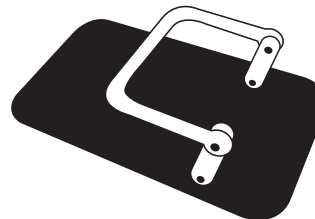
IMPORTANT



WARNING: Headrest Support must be set-up as shown below; horizontal bar must be below the forehead, not the neck area.



CORRECT



INCORRECT

PRECAUTIONS



The Spinal Imaging Platform and Surgical Head Rest should not be used when the patient is under general anesthesia without the use of an auxiliary restraint. The patient may roll off the device and be injured.



Always be certain that attending staff is aware of the patient's position while the device is in use. Reposition the patient if necessary to promote stability.



To prevent the potential of cross-contamination, it is strongly advised to use barrier techniques when the device is in use. A disposable or laundered patient gown, or disposable pad are satisfactory for use as a barrier for the Torso Support and other components and accessories, except when the patient presents with pathology that would otherwise indicate. A disposable face rest cover should be used to cover the Face Rest Cushion. Contact Oakworks for ordering information.

PRECAUTIONS (cont.)



Barrier techniques should be used in addition to disinfection procedures, not in lieu of them.



Be sure to support the weight of the patient’s head while making adjustments to the cervical positioning feature of the Platform Frame. Make sure all three (3) cam locks are secure before relinquishing support of the positioning assembly.



The Spinal Imaging Platform and Surgical Head Rest are constructed using metal pins in the Quick Cam Locks and aluminum tubing in the support structure. These are out of field of view in A-P and most caudal views. However, in an oblique view they may create artifacts in the image. Place the positioning assembly according to the recommendations in the directions for use to eliminate, or reduce any artifacts. If artifacts still remain to the extent that they would compromise the efficacy of needle placement, discontinue use of the device during the affected procedure.



If enhanced patient stability is required, the use of OAKWORKS® Air Bolsters, OAKWORKS® *ButterflyCushion*™ or OAKWORKS® Lateral Stabilizer Bolsters are recommended.



All materials used in the construction of the device and accessories are safe for temporary and moderately frequent human contact. The device is not intended for prolonged contact.



When x-rays are present, wear a suitable radiation barrier.

IMPORTANT

Do not use the Face Rest Support Arms as a handle to carry the Spinal Imaging Platform or Surgical Head Rest frame.

SYMBOL IDENTIFICATION



This symbol, when used in this manual and on product labels, represents a caution warning. Be sure to read and comply with all precautions and warnings.



This symbol, when used in this manual and on product labels, indicates the potential of exposure to harmful x-rays. Be sure to read and comply with all warnings.



This symbol, when used in this manual and on product labels, indicates that the table and components are a Type B Applied Part pursuant to IEC 601.1 and EN 60601-1: 1990.



This symbol when used in this manual or on product labels, warns that when stacking containers during transport and storage, there should be do not stack more than 5 containers high.



This symbol, when used in this manual or on product labels, indicates that the product should be protected from moisture. The humidity specifications for Transport & Storage are listed on page 23.



This symbol, when used in this manual or on product labels, indicates that information is given regarding the recommended temperature limits during transport and storing.



This symbol, when used in this manual or on product labels, indicates the date of manufacture of the device.

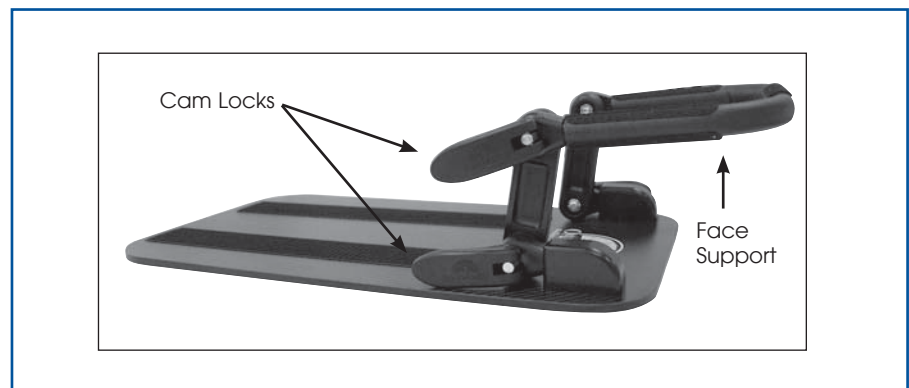
DESCRIPTION OF COMPONENTS

The Spinal Imaging Platform consists of three (3) primary (**A,B,C**) and three (3) secondary (**D x 2, E**) components.

The Surgical Head Rest consists of two (2) primary (**A,C**) and one (1) secondary (**F**) component.

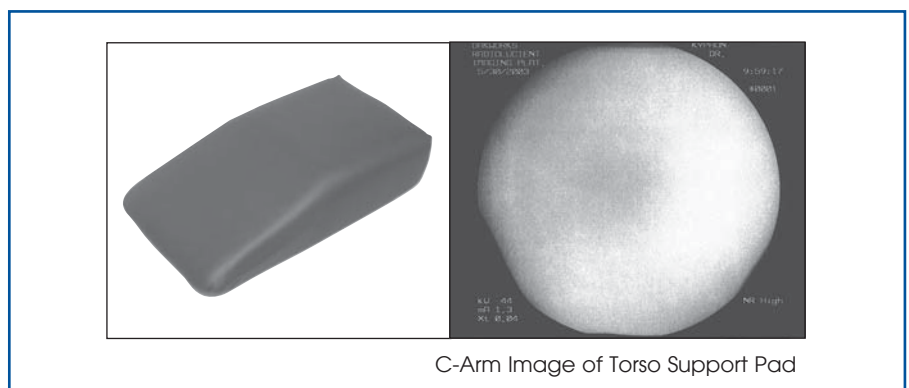
PRIMARY COMPONENTS:

A - Platform Frame



Used to support the Torso Support and Face Cushion. A multiple cam lock face support system facilitates cervical flexion or extension.

B - Torso Support



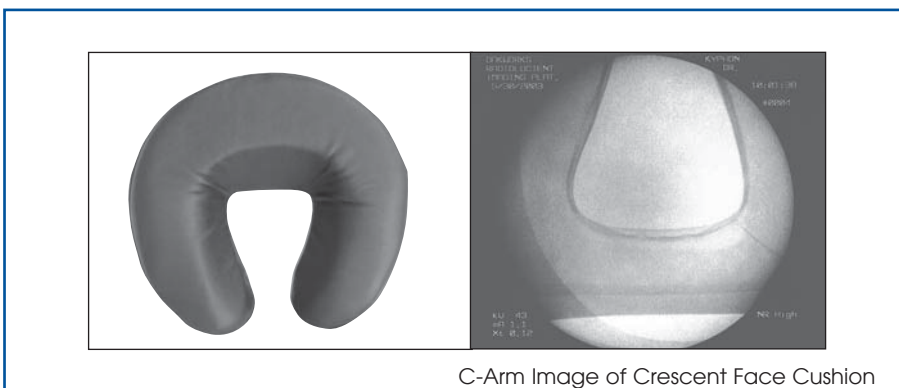
C-Arm Image of Torso Support Pad

The Torso Support is constructed of dense foam in the center flanked by softer foam and covered in a fabric designed to withstand today's disinfectants. The softer foam permits the patient shoulder's to naturally round down on the sides of the support. This provides enhanced patient stability and conveniently reduces shoulder interference during cervical procedures. The tapered shape at the lower portion of the Torso Support reduces pressure on the upper abdomen to facilitate unhindered diaphragmatic breathing.

- Primary Components

PRIMARY COMPONENTS (cont.)

C - Crescent Face Cushion

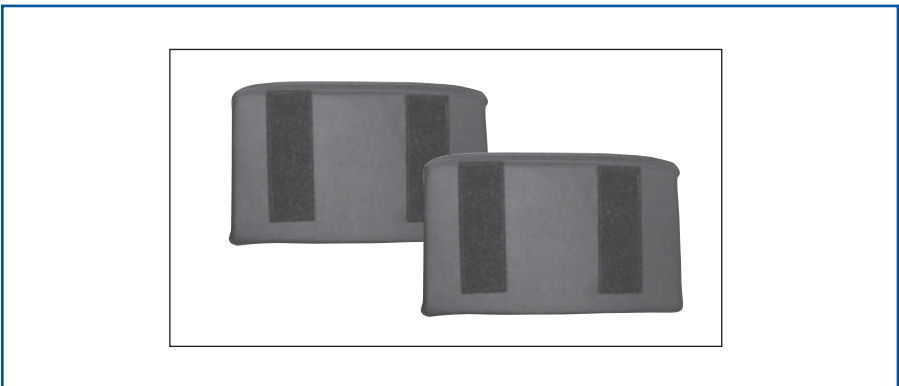


Supports the patient's face in a prone position without compromising air space for breathing. As with the Torso Support, the Crescent Face Cushion may also be disinfected.

SECONDARY COMPONENTS

D - Adjuster Pads (2)

The Spinal Imaging Platform includes two Adjuster Pads. The Adjuster Pads are used either individually or combined to reduce lumbar lordosis and increase pedicular space. These pads offer a wide range of flexibility for general patient positioning and stabilization.



SECONDARY COMPONENTS (cont.)

E - Ankle Bolster (8" x 26")

The Ankle Bolster may be placed under the patient's ankles to enhance positioning stability. It may also be used alone for miscellaneous patient positioning.



F - 2" Positioning Pad

The 2" Position pad is included for additional positioning options.
2" (5cm) thick x 12" (31cm) (square)



OPTIONAL COMPONENTS

ButterflyCushion™

The *ButterflyCushion™* is a unique support device that was primarily designed to enhance comfort where breast sensitivity or size is an issue during treatment procedures. The cushion has 2 separate inflatable bladders that can be adjusted to support patients in a host of configurations ranging from breast, neck and lumbar positions to a variety of waist stabilizing positions.



Air Bolster (8" x 26")

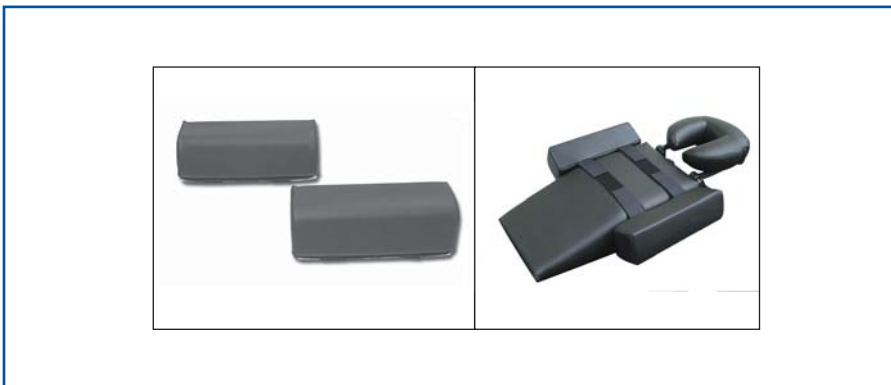
An inflatable bolster for assisting with patient positioning and support. Can be used to enhance patient stability or to elevate patient's torso if necessary. Like the *ButterflyCushion™*, it can be used individually for a variety of positioning requirements.



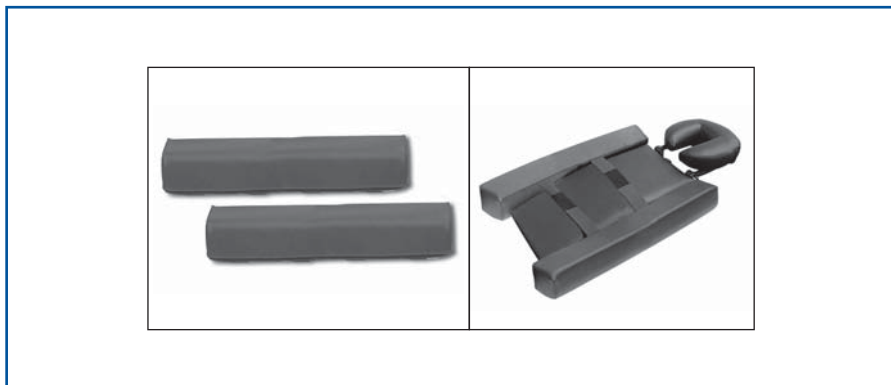
Lateral Stabilizer Bolsters

There are two sets of bolsters that can be used with the Spinal Imaging Platform. Each set is designed to attach to the Spinal Imaging Platform and provide flanking support for various size patients. The sets can also attach together and be used as an immobilizing aid.

Set 1: 4.75" dia. x 13"L :



Set 2: 4.75" dia. x 26"L :



DIRECTIONS FOR USE

- Preparation
- Assembly

DIRECTIONS FOR USE

PREPARATION FOR USE

Unpack and inspect all components. Identify the components and their use with the pictures located in the Description Section of these instructions.

All components are shipped in a clean but not sterile condition. If the Spinal Imaging Platform or Surgical Head Rest will be used for an indicated surgical procedure, be sure to disinfect the components prior to use. Disinfectants that can be used are described in the Cleaning & Disinfecting Section of these instructions.

ASSEMBLING COMPONENTS

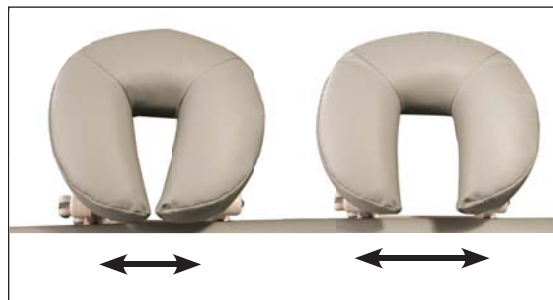
Items 1,2,3,4,5 apply to the Spinal Imaging Platform.

Items 1,2,5 apply to the Surgical Head Rest.

1. Place the Frame on the Table.
2. Position the Crescent Face Cushion with the opening facing to the posterior of the platform frame and mount it onto the adjustable framework. It is held in place by Velcro™.



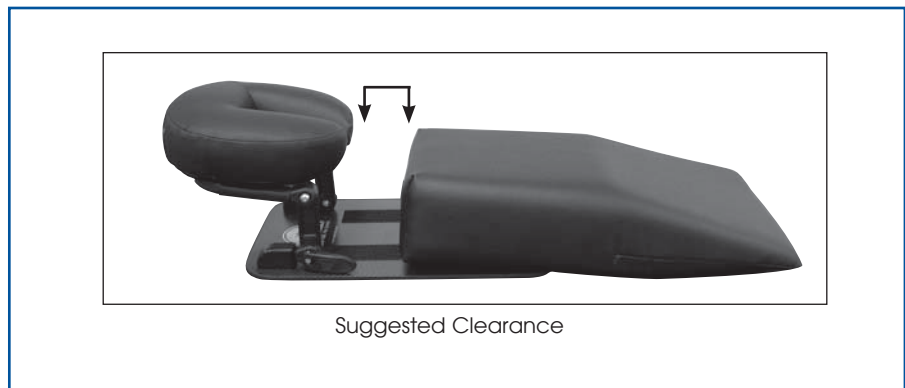
Crescent Face Cushion shown in correct position.



The Crescent Face Cushion can be flexed in and out to accommodate various patient face sizes.

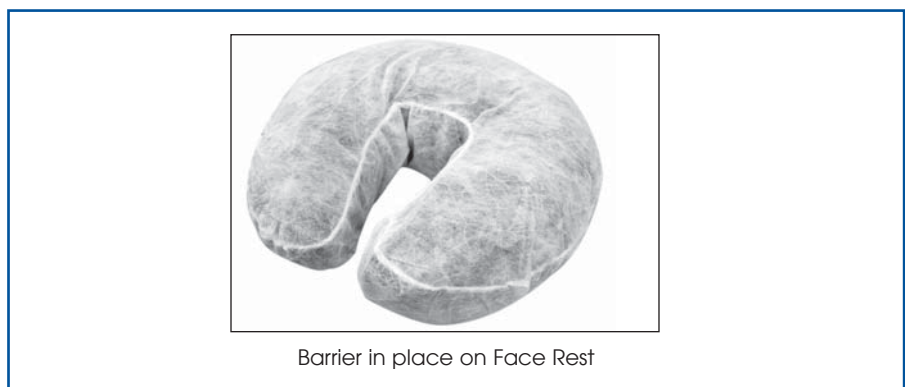
ASSEMBLING COMPONENTS (CONT):

3. Position the Torso Support onto the Spinal Imaging Platform Frame with the higher portion located just posterior of the adjustable framework. Allow enough clearance so that the framework can be fully rotated in either direction, keeping the length of the patient's neck in mind.



4. Set the Adjuster Pads (if equipped), the Ankle Bolster (if equipped), and any accessories nearby in a clean, easy to reach place.
5. Apply Barriers.

Place a barrier cover onto the Face Rest Cushion. Fitted face rest covers are recommended. If desired, use a disposable patient gown or other pad to cover the Torso Support.



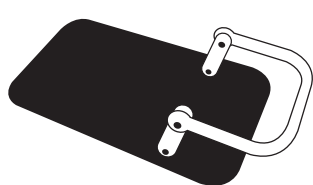
POSITIONING THE FACE SUPPORT:

(In the following photographs, the Crescent Face Cushion has been removed to demonstrate operation of the Face Support.)

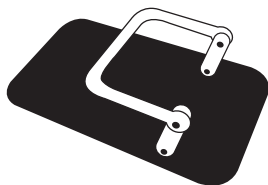
- Adjustments are controlled by the Cam Locks and Vertical Arms of the Face Support. (Fig. 1)



WARNING: Headrest Support must be set-up as shown below; horizontal bar must be below the forehead, not the neck area.

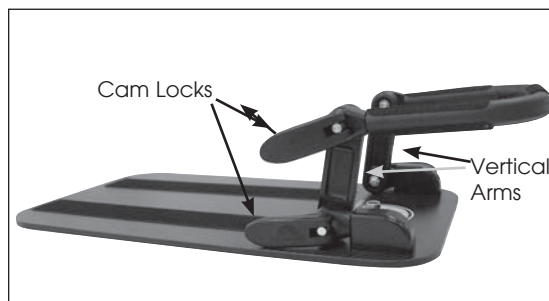


CORRECT



INCORRECT

Fig. 1



The Face Support adjustments support cervical positions from extreme flexion to extreme extension. (Fig. 2)

Fig.2



Cervical Flexion

Cervical Extension

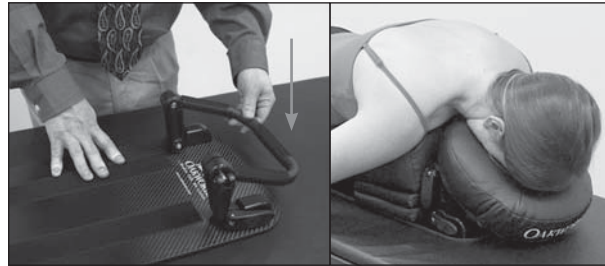
- To adjust, release all cam locks.

Fig. 3



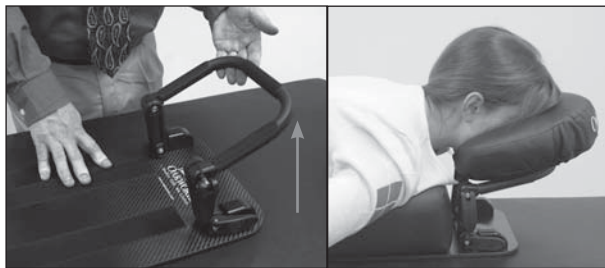
3. Rotate the Face Support Arm downward to invoke cervical flexion.
(Fig. 4)

Fig. 4



- Rotate the Face Support Arm upward to invoke cervical extension.
(Fig 5)

Fig. 5



4. The height of the Face Support is controlled by the position of the vertical arms. (Fig 6)

Fig. 6



Vertical Arms shown in
highest position

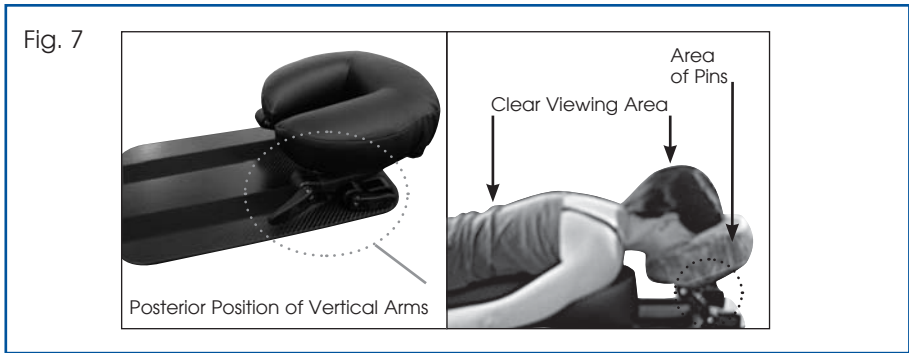
Vertical Arms shown in
lowest position

Vertical Arms shown in
flat position

DIRECTIONS FOR USE

- Positioning the Face Support

Note: Our Cam Lock System incorporates metal pins for added durability. A posterior position setting (Fig. 7) for the Face Rest Frame and Torso Support Pad are recommended to eliminate potential artifacts from the image field for upper cervical procedures.

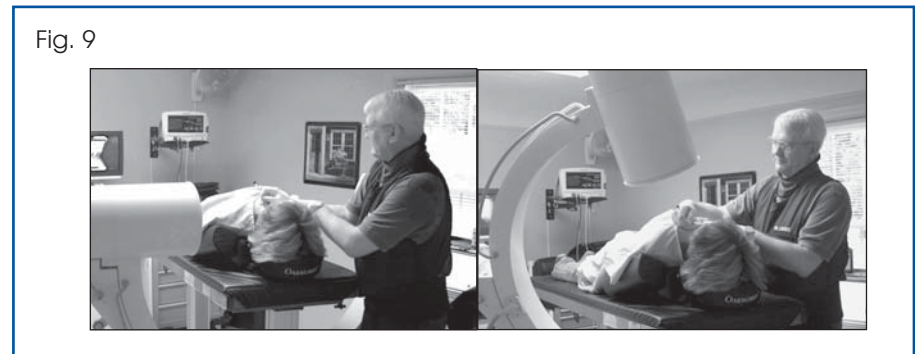


If an anterior position setting (Fig. 8) is used, the oblique angle of view in the upper cervical region may be limited at an angle of 60° due to interference by the metal pins or platform frame.



The patient may be repositioned in a posterior setting to minimize this interference. (Fig. 7)

The metal pins can be successfully positioned out of the view of the C-Arm with a series of simple adjustments based on the patient's position and the angulation of the C-Arm (Fig. 9)



POSITIONING THE PATIENT:

Providing patient comfort, stability and positioning is critical to the success of any procedure. This platform was designed to provide the flexibility to adjust and secure the position of the patient, resulting in real working comfort for the practitioner through long hours with minimum strain and discomfort. Taking the time to properly adjust and secure the best patient position will ensure a more pleasurable procedure for both doctor and patient.

Items 1,2,3,4,5 apply to the Spinal Imaging Platform.

Items 1,2,5 apply to the Surgical Head Rest.

1. Using generally accepted patient transfer procedures, position the patient onto the Spinal Imaging Platform or Surgical Head Rest. Make sure the patient is comfortable, can breathe normally and communicate with attending staff.
2. When adjusting the face support to the necessary angle, it is important to have the patient in a relaxed and comfortable state. Please be sure to support the weight of the patient's head while positioning and adjusting the face support (Fig. 10).



CAUTION

Do not permit the patient to push down on the Crescent Face Cushion in an effort to lift themselves up while dismounting the Spinal Imaging Platform and/or the Fluoroscopy Table.

Fig. 10



3. Place the Ankle Bolster under the patient's ankles to enhance stability. (Fig. 11)

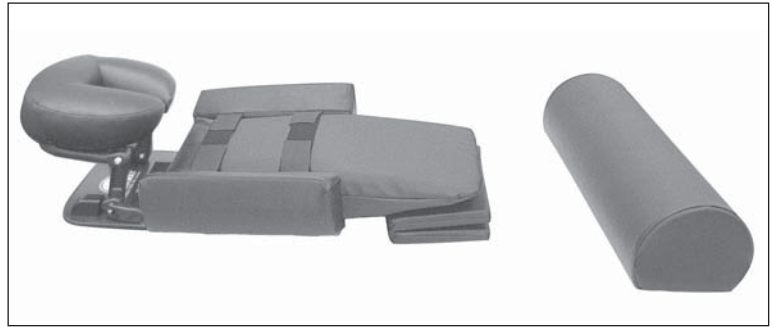
Fig. 11



Ankle Bolster in use.

4. The Spinal Imaging Platform and accompanying accessories used together provide optimum comfort and stability for the patient (Fig. 12).

Fig. 12



4. For lumbar procedures where reduction of the natural lordosis will make intervertebral access easier, there are two (2) recommended pad-positioning scenarios. One is to place up to 2 adjuster pads under the base of the Torso Support (Fig 13). The other method is to reverse the Torso Support by pointing the tapered end of the Torso Support towards the lowered Face Support (Fig. 13a).

Fig. 13



Placement of Adjuster Pads for lumbar procedure / Position 1

Fig. 13a



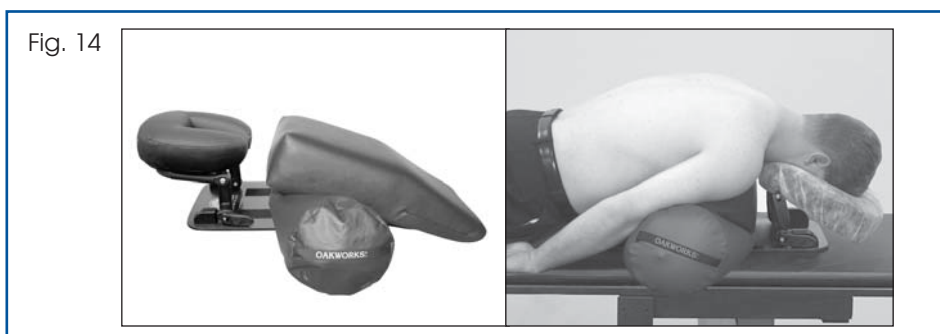
Placement of Adjuster Pads for lumbar procedures/ Position 2

DIRECTIONS FOR USE

- Positioning the Patient
- Post Procedure

5. For cervical procedures where a greater flexion angle is desired, the use of a partially inflated Air Bolster is recommended rather than the placement of an additional Adjuster Pad (Fig. 14). The partially inflated Air Bolster will also provide lateral stability of the patient when elevation to this increased angle is desired. The OAKWORKS® 8" x 26" (20 x 66 cm) Air Bolster, part number 2121-03, is recommended.

A partially inflated Air Bolster can also be used to increase Kyphosis.



CAUTION

Do not permit the patient to push down on the Crescent Face Cushion in an effort to lift themselves up while dismounting the platform and/or the Fluoroscopy Table.

POST PROCEDURE

Upon completion of the procedure, assist the patient in exiting the Table using generally accepted patient transfer techniques.

Clean and disinfect all components using the recommended materials described in the Cleaning and Disinfecting Section of these instructions.

CLEANING / DISINFECTING

Cleaning:

All components may be cleaned with a mild detergent solution. Be sure to remove excess solution and dry thoroughly.

Disinfecting:

All components may be disinfected using a 10% sodium hydrochlorite (bleach) solution. Be sure to remove excess solution and dry thoroughly.

All fabric covered components may be disinfected using phenols, gluteraldehydes (if not contraindicated), and quaternary ammonium compounds. Avoid contact of these materials with the Spinal Imaging Platform Frame, as deterioration will occur. Use only a 10% sodium hypochlorite solution for disinfection of the Frame.

MAINTENANCE:

Inspect the Platform and components periodically to ensure that they have not been damaged. Also check the Torso Support (Spinal Imaging Platform only) to be sure that the foam cushioning has not worn to the extent that patient support would be compromised. Replace any damaged or worn components.

LIST OF PARTS

Part No.	Description
----------	-------------

Spinal Imaging Platform Package:

3607-1	Spinal Imaging Platform Frame (1)
3608-1	Surgical Headrest Platform Frame (1)
4403-03	Radiolucent Torso Support (1)
4402-03	Adjuster Pad (2)
EM2410-03	Crescent Face Cushion (1)
9914-03	Ankle Bolster (1)

Optional Accessories:

4042-03	<i>ButterflyCushion™</i> w/Air Pump
2121-03	Air Bolster 8"x26" (20cm x 66cm)
0136-03	Lateral Stabilizer Bolster Set (2 - 13"L)
3327-03	Lateral Stabilizer Bolster Set (2 -26"L)

SPECIFICATIONS

Specifications

Aluminum Equivalence (nominal) of x-ray attenuation:

Imaging Platform	1.2 mm @ 100 kVp & HVL of 3.6mm
Torso Support	.82 mm @ 100 kVp & HVL of 3.6mm
Adjuster Pad	.17 mm @ 100 kVp & HVL of 3.6mm

Imaging Platform:	11" x 18"
Torso Support:	12" x 23"
Crescent Face Cushion:	12" diameter
Adjuster Pad:	7" x 12"
Air Bolster:	8" x 26"
Ankle Bolster:	8" x 26"
Lateral Stabilizer Bolsters:	4.75" W x 13"L 4.75"W x 26"L
2" positioning pad	2" H x 12" W x 12" L

Storage & Transport



Temperature: -10° C - 60° C

Humidity: 60% relative humidity

Pressure: no limitations known

During transport, DO NOT stack containers more than 5 high.

WARRANTY

Please reference our website www.oakworks.com for current warranty information.

All warranties are limited to factory-provided replacement parts, factory repair or replacement, at the discretion of OAKWORKS®. OAKWORKS® only covers parts and labor on field repair of stationary products.

All warranties exclude damage caused by improper set-up, accident, abuse, misuse, neglect, use for other than intended purpose or reasonable wear such as tears in the upholstery.

All warranties are invalidated by non-factory modifications and unauthorized repairs, which will immediately terminate all liability by OAKWORKS® for the product or damages caused by its use.

The buyer and its customers shall be responsible for proper set-up and use of the products as well as any supervision required for safety. In no event shall OAKWORKS® be liable for any special, indirect, consequential, incidental, exemplary or punitive damages or costs. Use of non-approved cleaning solutions voids the guarantee on all fabrics.

The warranties set forth herein are the sole and exclusive warranties provided by OAKWORKS®. There are no other warranties, representations or guarantees provided by OAKWORKS® either expressed or implied, including warranties of merchantability and fitness for a particular purpose. Warranty valid with proof of purchase.

CONTACT INFORMATION:

OAKWORKS® Medical Equipment,
a division of OAKWORKS®, Inc.

923 East Wellspring Road
New Freedom, PA 17349

Toll Free (USA only): 800-558-8850
Phone: 717-235-6807

Toll Free FAX (USA only): 877-562-4787
FAX: 717-235-6798

www.oakworks.com

European Representative:

Emergo Europe

P.O.Box 149
4300 AC Zierikzee
The Netherlands

Tel: 31 1114 11515
FAX: 31 1114 10104

Spinal Imaging Platform & Surgical Head Rest