USER MANUAL

OAKWORKS®
Spine Positioning System II

made in the
with US & imported

OAKWORKS® MEDICAL PRODUCTS

Notice

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

OAKWORKS®, Inc. encourages requests for technical specifications and the like documentation to ensure accuracy. The appropriate documentation is available upon request.

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.

Printed in U.S.A.

TABLE OF CONTENTS

INTRODUCTION

The Spine Positioning System II is an integral component of the pain management fluoroscopy suite. With this system procedural set up time is reduced, patient comfort is enhanced and unwanted movement is minimized. Most importantly, the target anatomy is more readily visualized which allows the physician to perform spine procedures in a more efficient and secure manner. In collaboration with leading pain management physicians, Oakworks designed the Spine Positioning System II in an effort to achieve the critical balance between optimal imaging and patient comfort. The radiolucent adjustable frame and versatile padding system provide a metal free imaging support platform capable of quickly positioning a wide variety of patient physiques for extended periods of time. The adjustable face rest position provides individualized positioning for all types of cervical procedures and anatomy. The contoured torso support pad is complimented by a host of uniquely shaped and sized adjuster pads and wedges that enable a multitude of positioning combinations for ideal patient comfort and imaging needs for all spinal column procedures.

PRODUCT USE DESCRIPTION

The Oakworks® Spine Positioning System II is a patient cradle device for use in diagnostic and therapeutic procedures of the spine. It is intended to be used by a healthcare professional in a medical environment 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 Spine Positioning System II, its secondary components, and optional components are suitable for use in fluoroscopy suites. No special training is required but a review of the following Safety Instructions is important for the safety of the operator and patient. The healthcare professional should read and understand this entire manual before use with a patient.

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 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 21.

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.

This symbol is used to indicate that the operator should consult the user manual.

IMPORTANT SAFETY INSTRUCTIONS

CAUTION

READ AND SAVE THESE INSTRUCTIONS

A patient safety strap is required during all procedures. Follow normal and required safety protocol for all procedures where the patient is in an elevated position for the procedure (straps, attendants, etc.). 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. Due to the increased distance between the patient and the table surface, additional safety measures are recommended when the table top is not used in a level position due to the risk of the patient falling off the table.

The Oakworks® Spine Positioning System II is 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 Spine Positioning System II is not designed for use with magnetic resonance imaging systems. The Spine Positioning System II is not intended for use in cranial procedures.

Do not overhang the radiolucent frame beyond the warning line on the frame.

Operate the C-arm of the fluoroscopy system with the Spine Positioning System II in place before using the device with a patient for the first time. Make sure there is adequate clearance 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 Pad in an effort to lift themselves up while dismounting the platform and/or the table.

The Spine Positioning System II should generally not be used when a patient is under general anesthesia, especially when prolonged cases are performed. This will reduce the risk of ocular or facial nerve injury.

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.

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 indicate otherwise. A disposable face rest cover should be used to cover the Face Rest Pad. Contact Oakworks for ordering information. 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 cam locks are secure before relinquishing support of the positioning assembly.

DANGER

The Cervical Support System has metal parts that can cause back scatter of x-rays, see Product Description for photo.

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

The Spine Positioning System II is constructed using metal pins in the Quick Cam Locks and aluminum tubing in the support structure. These are out of the field of view in most A-P and oblique tilted views. 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.

The Spine Positioning System II is designed to be a standalone product used with radiographic equipment. It must not be modified or incorporated into any other equipment.

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.

Do not use the Face Rest Support Arms as a handle to carry the Spine Positioning System II.

Follow maintenance instructions found near the end of this manual. Mechanical components should be checked periodically to insure that they are functioning properly to insure the safety of the patient.

SPS II weight limit: 350 lbs. (159 kg.) Crescent Face Pad Support weight limit: 25 lbs. (11 kg.)

Spine Positioning System II

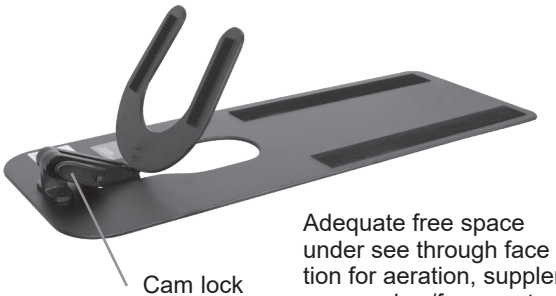
STANDARD SPECIFICATIONS	
Weight	16 lbs. (7 kg.)
Frame with Face Rest	12” (30 cm.) Wide x 32.5” (84 cm.) Long
Crescent Face Pad	12” (30 cm.) diameter
Contoured Torso Support Pad	6.5” x 23” x 30” (17 x 58 x 76 cm.)
Contoured Torso Wedge	22” x 29” x 2” (56 x 74 x 5 cm.)
Large Rectangular Adjuster Pad	8” x 22” x 2” (20 x 56 x 5 cm.)
Small Rectangular Adjuster Pad	7” x 12” x 1.5” (18 x 30 x 4 cm.)
8” (20 cm.) Semi-Round Bolster	6” x 8” x 26” (15 x 20 x 66 cm.)
Carry Case	Transports the SPS II System
Warranty	2 years - Frame, Fabric and padding
Safety Listings	FDA and CE marked

PRODUCT DESCRIPTION

RADIOLUCENT FRAME

Used to support the Torso Support and Crescent Face Pad. One cam lock facilitates cervical flexion and extension.

Cervical Support System



Cam lock

Adequate free space under see through face section for aeration, supplemental oxygen, jaw/face contact as necessary; prevents patient overheating, can more easily communicate with the patient without sound muffling.

CRESCENT FACE PAD

The Crescent Face Pad supports the patient's face in a prone position without compromising air space for breathing. The face pad can be moved in situations to prevent imaging of the locking mechanism when performing upper cervical procedures that require substantial imaging angulation.

CONTOURED TORSO SUPPORT PAD

The Contoured Torso Support is constructed of dense foam in the center, flanked by softer foam. The softer foam accommodates to the patient's shoulders and/or breasts to maximize comfort. This helps provide enhanced patient stability while allowing for the shoulders to descend for optimal cervical and thoracic imaging.

The Distal end of the torso support pad is hollowed out under the abdomen to enhance patient comfort and stability. Additionally, the Distal end of the torso support pad is wider to enhance patient stability by reducing sway while in the device.

Distal end

PRODUCT DESCRIPTION

CONTOURED TORSO WEDGE

The Contoured Torso Wedge is constructed of dense foam This provides enhanced patient stability and conveniently reduces shoulder interference during cervical procedures.

SMALL RECTANGULAR ADJUSTER PAD

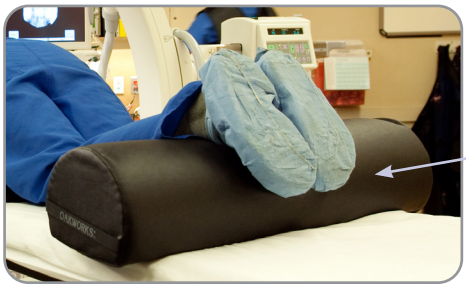
The 7” x 12” (18 x 30 cm.) Small Rectangular Adjuster pad is used to reduce lumbar lordosis and/or increase chest height to allow for shoulders to naturally descend out of the plane of the cervical and thoracic spine. This pad offers a wide range of flexibility for general patient positioning and stabilization.

LARGE RECTANGULAR ADJUSTER PAD

The wider 8” x 22” (20 x 56 cm.) Large Rectangular Adjuster pad can be used to allow those with a shorter humerus to allow the forearm and elbow to rest and stabilize on a flat surface. Additionally, this can be used as the Small adjuster pad is utilized, with a wider support.

8” (20 cm.) SEMI-ROUND BOLSTER

This bolster may be placed under the patient’s ankles to enhance positioning stability.



8” (20cm) SEMI-ROUND BOLSTER

PREPARATION FOR USE

CAUTION Do not overhang the platform frame beyond the WARNING line on the frame.

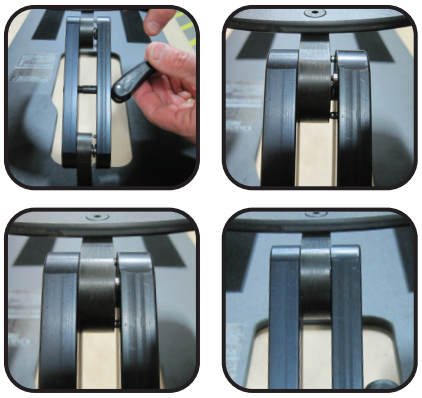
Unpack and inspect all components. Identify the components and their use with the pictures located in the Product Description Section of this manual.

All components are shipped in a clean but not sterile condition. If the Spine Positioning System II will be used for an indicated surgical procedure, be sure to disinfect the components prior to use.

FACE REST PLATFORM ADJUSTMENT

Step 1 - Open cam

Step 2 - Grasp platform and raise to desired position



Step 3 - Begin to close the cam making sure that the small locking pins enter corresponding positioning holes (Minor platform “rocking” may be necessary for the pins to enter the holes). *Do not force the cam to close*

Step 4 - Continue to close cam.

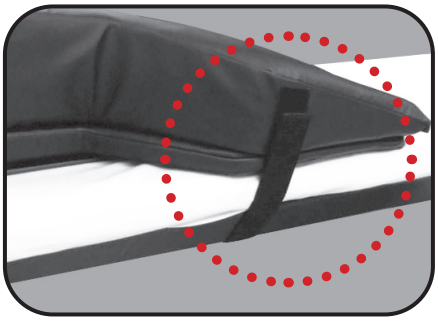
Step 5 - Close cam to the final position.

Step 6 - Double check platform by applying downward force to ensure your face rest platform is securely locked.

TORSO PAD STRAP

WARNING A patient safety strap must be used during all procedures.

To secure the Torso Pad to the table, wrap the Velcro® strap under the table top and attach securely.



TRANSPORTING THE SPINE POSITIONING SYSTEM II

Open the cam lock on the adjustable face rest and rotate the face rest flat against the base frame. This will protect the face rest support platform during transport.

When placing the Spine Positioning System II in the Carry Case, put some pads, wedges or bolsters on both sides of the base frame.

IMAGING SCENARIOS

WARNING A patient safety strap must be used during all procedures.

The following imaging scenarios of patients will demonstrate:

1. Various body types using the Spine Positioning System II (SPS II)
2. Their positioning and specific configurations of the SPS II used in particular clinical situations
3. Various fluoroscopic images of these factitious patients that exemplify the value of the SPS II

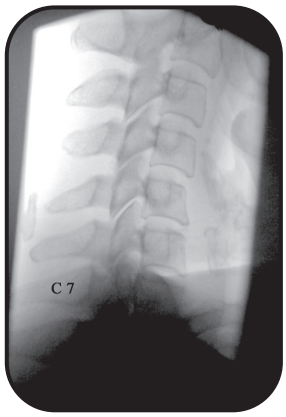
PATIENT - ALICIA

Components used: Radiolucent Frame, Crescent Face Pad, Contoured Torso Support Pad, Contoured Torso Wedge, Small Adjuster Pad, 8” Semi-Round Bolster (not pictured)

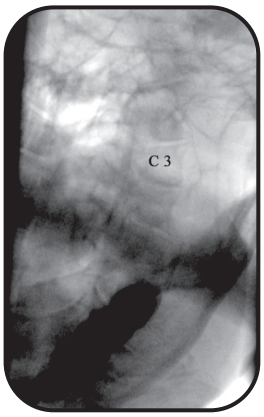
SPS II set up for Alicia shown here

Alicia in the SPS II while obtaining a C3 pillar view

Demonstrates the generous amount of space under the head/face while laying comfortably in the SPS II



Lateral view of the cervical spine. The C2-3 to C7-T1 interspaces are easily visualized for all posterior approach cervical procedures.



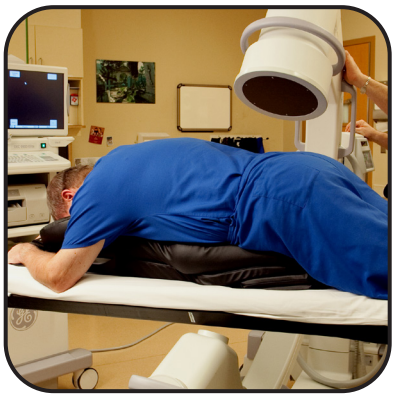
Right C3 and C4 pillar view of Alicia. The target articular pillars are visualized for posterior approach facet/ medial branch procedures.

WARNING A patient safety strap must be used during all procedures.

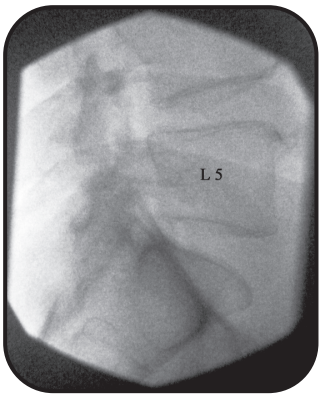
PATIENT - DON

Components used: Radiolucent Frame, Crescent Face Pad, Contoured Torso Support Pad, Large Adjuster Pad, 8” Semi-Round Bolster (not pictured)

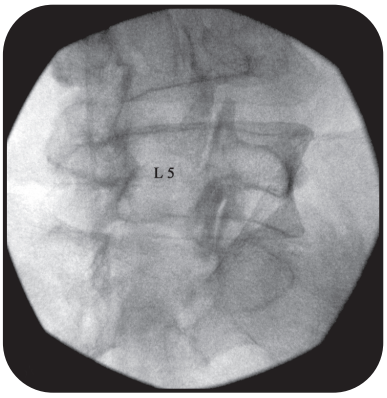
SPS II set up for Don shown here



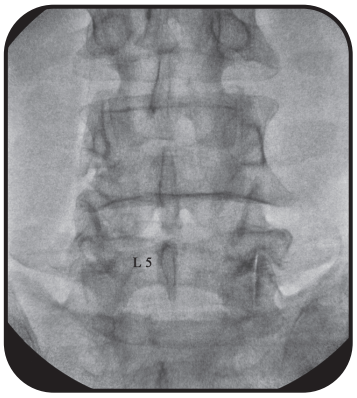
Don in the SPS II while obtaining an oblique image of the lumbar spine



Lateral image of the lumbar spine



Right oblique image of the lumbar spine



AP image of the lumbar spine

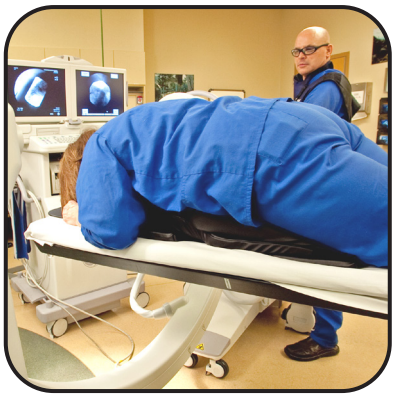
WARNING A patient safety strap must be used during all procedures.

PATIENT - LIZ

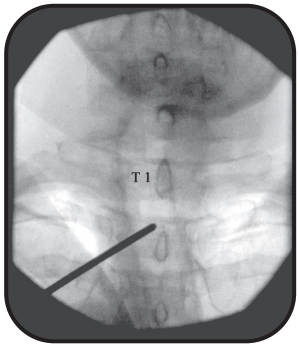
Components used: Radiolucent Frame, Crescent Face Pad, Contoured Torso Support Pad, Contoured Torso Wedge, 8” Semi-Round Bolster (not pictured)

SPS II set up for Liz shown here

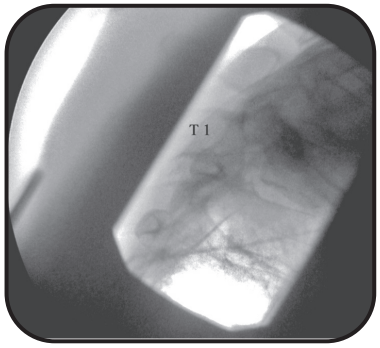
Liz in the SPS II while obtaining an AP image of the upper thoracic spine.



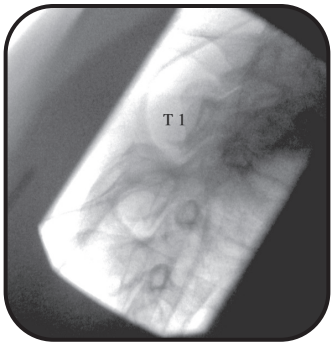
Liz in the SPS II while obtaining a lateral image of the upper thoracic spine.



AP image visualizing the T1-2 interlaminar space.



Lateral image primarily through the C7—T2 segments.



Contralateral oblique showing the upper thoracic facet joints.

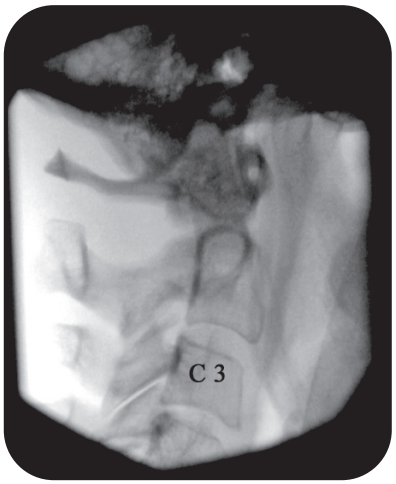
WARNING A patient safety strap must be used during all procedures.

PATIENT - MARY

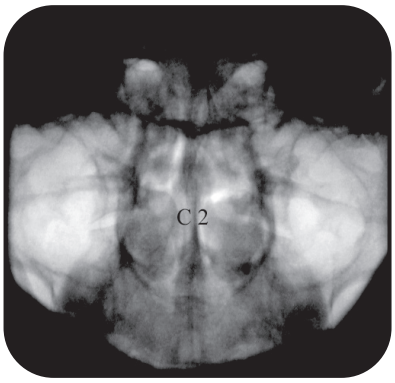
Components used: Radiolucent Frame, Crescent Face Pad, Contoured Torso Support Pad, Contoured Torso Wedge, 7” x 12” Rectangular Adjuster Pad, 8” Semi-Round Bolster (not pictured)

SPS II set up for Mary shown here

Mary in the SPS II while obtaining an AP image through the C1-2 segment



Lateral image through the C1-3 segments



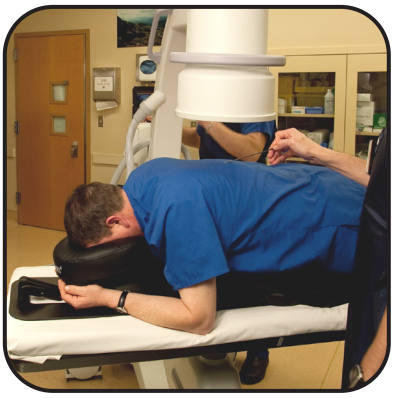
AP image through the C1-2 joints

WARNING A patient safety strap must be used during all procedures.

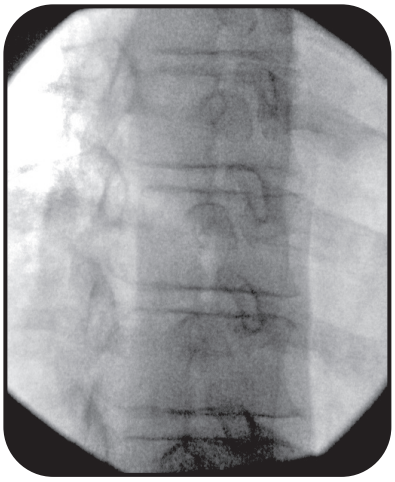
PATIENT - CARL

Components used: Radiolucent Frame, Crescent Face Pad, Contoured Torso Support Pad, Contoured Torso Wedge, 8” Semi-Round Bolster (not pictured)

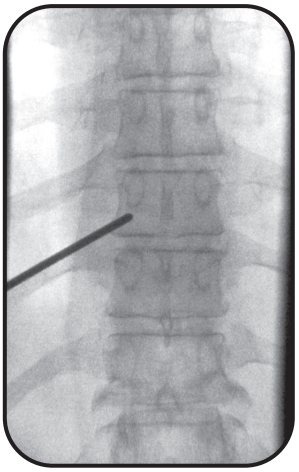
SPS II set up for Carl shown here



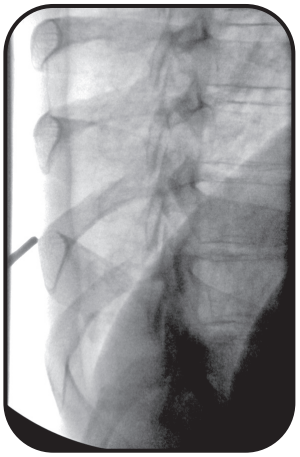
Carl in the SPS II while obtaining an AP image of the mid-thoracic spine



Right thoracic oblique image to visualize the trajectory for a transforaminal injection



AP image of the mid-thoracic spine for planning the trajectory for a left thoracic facet injection



Contralateral oblique showing the trajectory for targeting the mid-thoracic facet joint

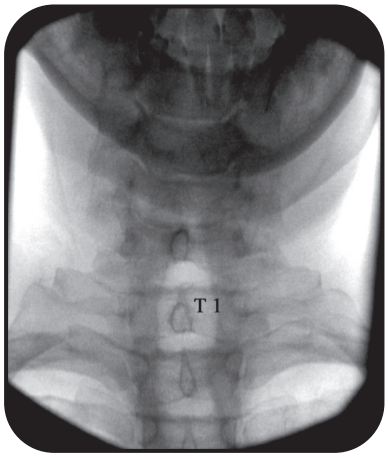
WARNING A patient safety strap must be used during all procedures.

PATIENT - DEBBIE

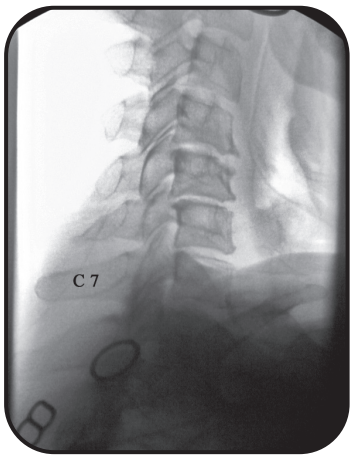
Components used: Radiolucent Frame, Crescent Face Pad, Contoured Torso Support Pad, Contoured Torso Wedge, Small Adjuster Pad, 8” Semi-Round Bolster (not pictured)

SPS II set up for Debbie shown here

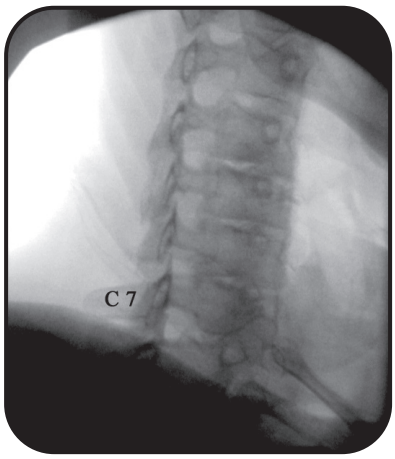
Debbie in the SPS II while obtaining a lateral cervical image.



AP image of the cervical spine while imaging through the C7-T1 interlaminar space.



Complete lateral image of the cervical spine including the C7-T1 segment.



Contralateral oblique of the cervical spine.

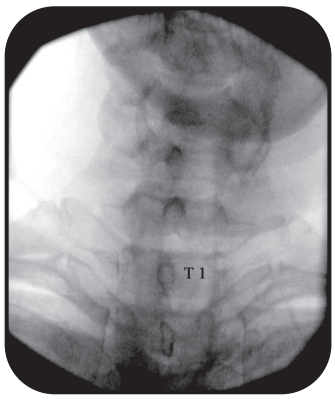
WARNING A patient safety strap must be used during all procedures.

PATIENT - JANE

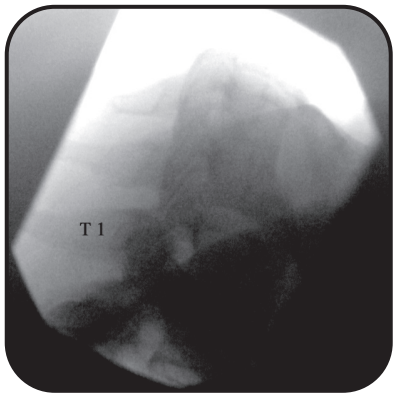
Components used: Radiolucent Frame, Crescent Face Pad, Contoured Torso Support Pad, Contoured Torso Wedge, 8” Semi-Round Bolster (not pictured)

SPS II set up for Jane shown here

Jane in the SPS II while obtaining a lateral image of the cervical spine.



The lower cervical interlaminar spaces are seen without visualization of the mandible over the target interspaces



Lateral collimated image of the cervical spine. The C6-7-T1 interspaces are appreciated for all posterior approach cervical procedures such as interlaminar epidural steroid injections, facet injections, medial branch blocks and medial branch radio frequency neurotomy.

RECOMMENDED CLEANERS/DISINFECTANTS

Reference the Recommended Cleaners and Disinfectant list (MMINML0008-EN) that came with the table. This information can also be found at www.oakworksmed.com under product information.

All cleaners and disinfectants have the ability to degrade the upholstery to some extent. However, following the recommended cleaner and disinfectant list and cleaning process will provided the best care for your product and support a long product life.

OAKWORKS® recommends a prepackaged wipe for cleaners/disinfectants to ensure best distribution of disinfectant for the required kill time, without leaving excess residue and/or overexposing components therefore minimizing the potential for damage to materials. Please read and follow disinfectants manufacturers' directions for cleaning and disinfection.

OAKWORKS® does NOT recommend the use of cleaners/disinfectants containing Hydrogen Peroxide, Acetic Acid, or Phenolics. These chemicals can cause damage to the appearance and/or material integrity of various components. Also, while the recommended cleaners/disinfectants list includes products containing Quaternary Ammonium compounds ("quats"), not all products containing quats are approved for use. Some contain additional detergents and/or surfactants which can damage some materials.

A note on Bleach: While a 10% sodium hypochlorite (household bleach) solution (EPA No.: 5813-100 or equivalent) can be an effective disinfectant and is dilute enough to be benign to most materials, it alone is not an effective cleaner and a separate product must be used for the initial cleaning steps of the procedure. Because of possible chemical incompatibilities between various cleaning products and bleach, utmost care must be taken by the user to avoid potential exposure to harmful or toxic by-products of the combination. Also, because bleach leaves a potentially corrosive residue as it evaporates, it must be rinsed with clean water after disinfection.

Use of non-approved cleaners or disinfectants may lead to damage to upholstery and other materials found on the table and will void the warranty.

CLEANING PROCESS

Follow the cleaners/disinfectant manufacturers' directions for use. Please note that cleaning and disinfecting an OAKWORKS® product is a two part process. First it must be cleaned of any visible soil, then it can be disinfected. Please follow this procedure for best results:

1. Using an approved cleaner or mild liquid soap and water, clean any visible soil off of the product, working from the top to the bottom of the product. It is recommended that the upholstery be cleaned at least once a week to prevent disinfectant build up.
2. Rinse with clean water and dry with a clean cloth or towel.
3. Using an approved disinfectant, thoroughly disinfectant all surfaces of the product and any high-contact areas, making sure they remain wet for the disinfectant manufacturer's recommended contact time. Do not allow disinfectant to pool on the upholstery after the recommended contact time.
4. Wipe off any excess liquid with a cloth or towel and clean water.
5. Dry all surfaces with a clean cloth or towel.

Avoid using writing instruments or other similar instruments around the upholstery as it can cause permanent staining. If this does occur, do not wipe with an alcohol based cleaner. Instead, blot the stain with a clean cloth/ paper towel. Use a 10% bleach dilution to remove the stain. Follow this with a rinse of clean water.

INSPECTIONS & MAINTENANCE

Inspect Torso Support Pad monthly to be sure that the foam has not lost shape or firmness to the extent that patient support would be compromised.

Inspect the base and components monthly to ensure that they have not been damaged. Replace any damaged or worn components.

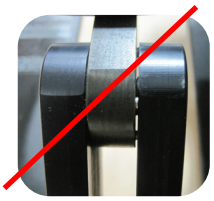
Inspect face rest platform locking mechanism weekly. Use the following procedure:

Step 1 - Lock the platform cam

Step 2 - Rock platform up & down

Gently rock platform up and down and note any “looseness” (some flexing is normal). Look for gaps between the aluminum parts. If you feel “looseness” or see gaps, see Face Rest Platform Cam Tightening.

Inspect joints:



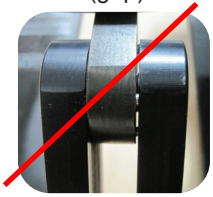
Bad (gap)

Good (no gap)

FACE REST PLATFORM CAM TIGHTENING

1. Use 1/2” socket wrench to grasp the locknut.
2. Hold the cam with other hand.
3. Tighten the cam until there is no gap between the 2 metal parts.

Bad (gap)



Good (no gap)

WARRANTY

View complete warranty details at www.oakworks.com

PRODUCT SPECIFICATIONS		
Component	Aluminum Equivalence	Dimensions
Radiolucent Frame	1.20 mm @ 100 kVp, HVL of 3.6 mm	1/4” x 12” x 32.5” (.6 x 30 x 84 cm.)
Crescent Face Pad	.72 mm @ 100 kVp, HVL of 3.6 mm	12” (30 cm.) diameter
Contoured Torso Support Pad	1.10 mm @ 100 kVp, HVL of 3.6 mm	23” x 30” x 6.5” (58 x 76 x 17 cm.)
Contoured Torso Wedge	.70 mm @ 100 kVp, HVL of 3.6 mm	22” x 29” x 2” (56 x 74 x 5 cm.)
Small Adjuster Pad	.35 mm @ 100 kVp, HVL of 3.6 mm	7” x 12” x 1.5” (18 x 30 x 4 cm.)
Large Adjuster Pad	.35 mm @ 100 kVp, HVL of 3.6 mm	8” x 22” x 2” (20 x 56 x 5 cm.)
8” (20 cm.) Semi-Round Bolster	N/A	6” x 8” x 26” (15 x 20 x 66 cm.)

ENVIRONMENTAL CONDITIONS			
Conditions	Temperature	Humidity	Atmospheric Pressure
Normal Use	50° (10°C) to 104° (40°C)	20% to 60% RH	98 to 105 kPa
Storage & Transport	-20° (-29°C) to 135° (57°C)	20% to 95% RH	98 to 105 kPa

THIS PAGE IS INTENTIONALLY LEFT BLANK

THIS PAGE IS INTENTIONALLY LEFT BLANK

THIS PAGE IS INTENTIONALLY LEFT BLANK

USER MANUAL

OAKWORKS®
Spine Positioning System II

EC REP

EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

FDA Listed

Part No.: MMMNUP0003-EN / Med-RA-PM-90
Revision Level: 2
Revision Date: 10/08/2020

English, Printed in U.S.A.

made in the with US & imported

OAKWORKS® MEDICAL PRODUCTS