INSTRUCTION MANUAL

SPINE POSITIONING SYSTEM

made in the USA
with US & imported parts

OAKWORKS® MEDICAL

REGULATORY

CE

FDA Listed

Printed in U.S.A.

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INTRODUCTION

The **Spine Positioning System** 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 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.

INDICATIONS

The OAKWORKS® Spine Positioning System is a patient cradle device for use in diagnostic and therapeutic 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 Spine Positioning System, its secondary components and optional components are suitable for use in fluoroscopy suites.

WARNINGS

WARNING

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 measues 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** 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 is not designed for use with magnetic resonance imaging systems. The Spine Positioning System is not intended for use in cranial procedures.

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

Operate the C-arm of the fluoroscopy system with the Spine Positioning System 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 Cushion in an effort to lift themselves up while dismounting the platform and/or the fluoroscopy table.

The Spine Positioning System 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.

CAUTION

CAUTIONS

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 Cushion. 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.

The Cervical Support System (see page 5) has metal parts that can cause back scatter of x-rays.

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

The Spine Positioning System 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.

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.

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.

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.

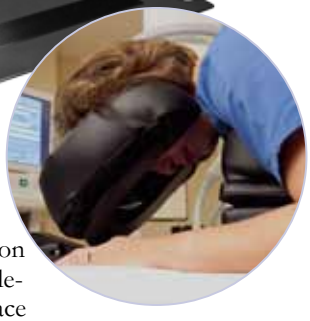
This symbol, when used in this manual or on product labels, indicates that information is given regarding the recommended temperature limits during transport and storing.

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

DESCRIPTION OF COMPONENTS

64878- RADIOLUCENT FRAME

Used to support the Torso support and Crescent face rest pad. One cam lock facilitates cervical flexion and extension.



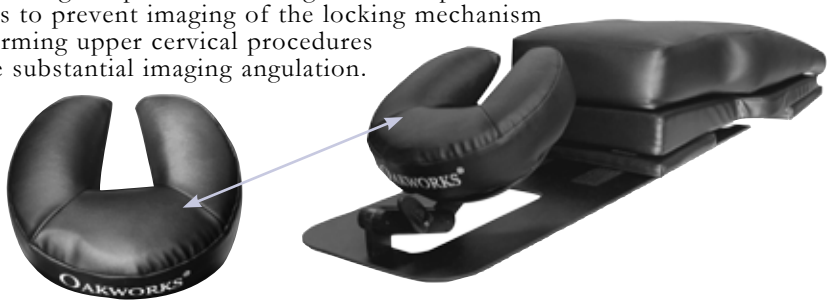
Adequate free space under see through face section for aeration, supplemental O2, jaw/face contact as necessary; prevents patient overheating, can more easily communicate with the patient without sound muffling.

See Caution on page 3.

DESCRIPTION OF COMPONENTS - CONTINUED

EM2410-SP - CRESCENT FACE REST PAD

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



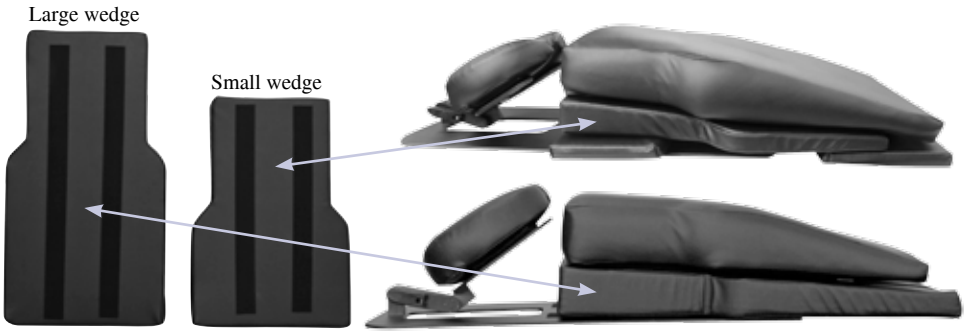
0546-06 CONTOURED TORSO SUPPORT PAD

The Contoured 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 accommodates to the patient's shoulders and/or breasts to maximize comfort. This helps provide enhanced patient stability while allowing for the shoulders to decend 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.

0550-06 SMALL CONTOURED TORSO WEDGE
0554-06 LARGE CONTOURED TORSO WEDGE

The Contoured Torso Wedge is constructed of dense foam and covered in a fabric designed to withstand today's disinfectants. This provides enhanced patient stability and conveniently reduces shoulder interference during cervical procedures. For faster set up, the larger torso wedge can replace the combination of the smaller wedge and rectangular adjuster pads as shown here.



DESCRIPTION OF COMPONENTS - CONTINUED

4402-06 7" X 12" RECTANGULAR ADJUSTER PAD

The 7" x 12" Rectangular Adjuster pads are used either individually or combined to reduce lumbar lordosis and/or increase chest height to allow for shoulders to naturally decend out of the plane of the cervical and thoracic spine. These pads offer a wide range of flexibility for general patient positioning and stabilization.

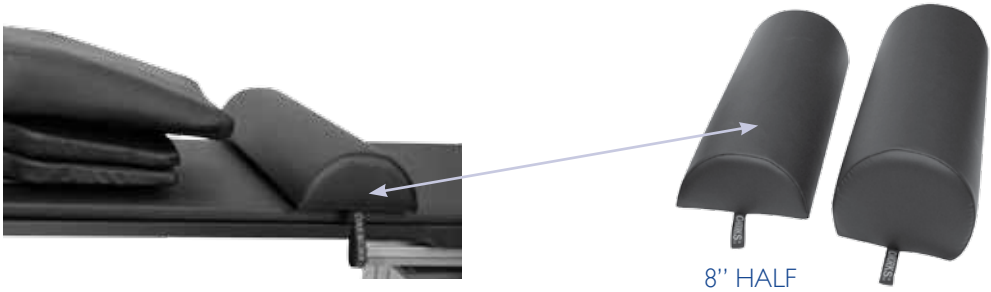
0552-06 8" X 16" RECTANGULAR ADJUSTER PAD

The wider 8" x 16" Rectangular Adjuster pad can be used either individually or combined to allow those with a shorter humerus to allow the forearm and elbow to rest and stabilize on a flat surface. Additionally, these can be used as the 7" x 12 adjuster pads are utilized, with a wider support.

1581-06 8" X 26" HALF ROUND BOLSTER

5932-06 8" X 26" SEMI-ROUND BOLSTER

These bolsters may be placed under the patient's ankles to enhance positioning stability. Two different bolster sizes are provided to allow for patient comfort.



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 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.

CAUTION - Do not overhang the platform frame beyond the warning line on the frame.
WARNING - A patient saftey strap is recommended during all procedures. A patient saftey strap ***must be*** used during procedures where lateral roll function is used.

FACE REST PLATFORM ADJUSTMENT

Step 1 - open cam

Step 2 - Grasp platform and raise to desired position

Step 3 - Begin to close 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). The cam should move freely at this point (Do not force the cam)

Step 4 - Continue to close cam.

Step 4 - Force will increase as cam is near final position. Close cam to the final position

Step 5 - Double check platform by applying downward force (platform will easily support over 80 lbs.). Your face rest platform is now securely locked.

DIRECTIONS FOR USE

SAFE TRANSPORT OF YOUR SPINE POSITIONING SYSTEM

Use the supplied carry case.

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

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

DIRECTIONS FOR USE

FACTITIOUS PATIENTS

The following eight scenarios in factitious patients will demonstrate:

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

WARNING A patient safety strap must be used for all procedures. See warnings on page 2.

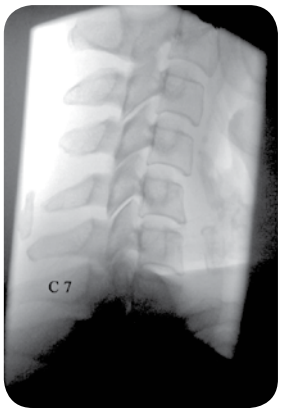
PATIENT - ALICIA

COMPONENTS USED: Platform Frame (1), Crescent Face Cushion (1), Contoured Torso Support Pad (1), Small Contoured Torso Wedge (1), 7" x 12" Rectangular Adjuster Pad (1), 8" Semi-Round Bolster (1)

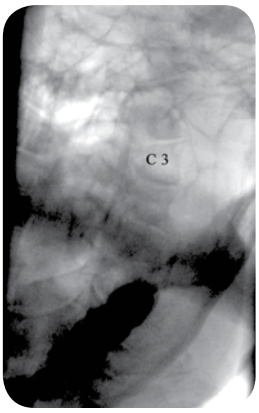
Alicia

Alicia in the SPS while obtaining a C3 pillar view.

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



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.

DIRECTIONS FOR USE

WARNING A patient safety strap must be used for all procedures.
See warnings on page 2.

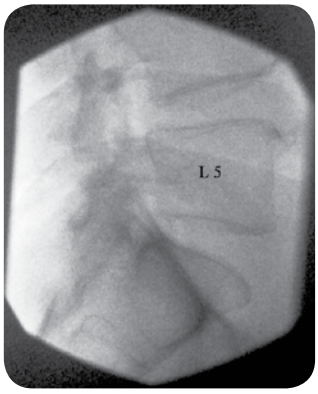
PATIENT - DON

COMPONENTS USED: Platform Frame (1), Crescent Face Cushion (1), Contoured Torso Support Pad (1), Small Contoured Torso Wedge (1), 8" x 16" Rectangular Adjuster Pad (2), 8" Half Round Bolster (1)

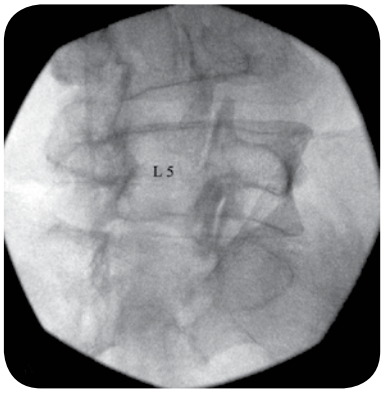
Don

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

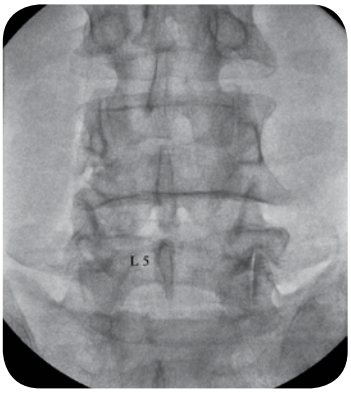
SPS configured with two extra adjuster pads under the lumbar spine as a method to reduce lumbar lordosis and enhance comfort.



Lateral image of the lumbar spine.



Right oblique image of the lumbar spine.



AP image of the lumbar spine.

DIRECTIONS FOR USE

WARNING A patient safety strap must be used for all procedures.
See warnings on page 2.

PATIENT - LIZ

COMPONENTS USED: Platform Frame (1), Crescent Face Cushion (1), Contoured Torso Support Pad (1), Small Contoured Torso Wedge (1), 7" x 12" Rectangular Adjuster Pad (1), 8" x 16" Rectangular Adjuster Pad (1), 8" Semi-Round Bolster (1)

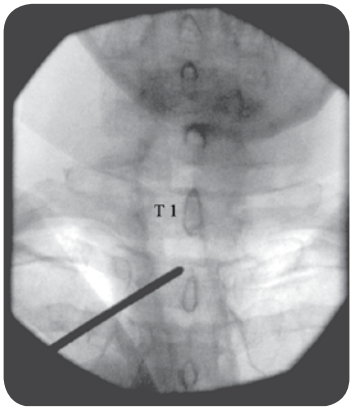
Liz

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

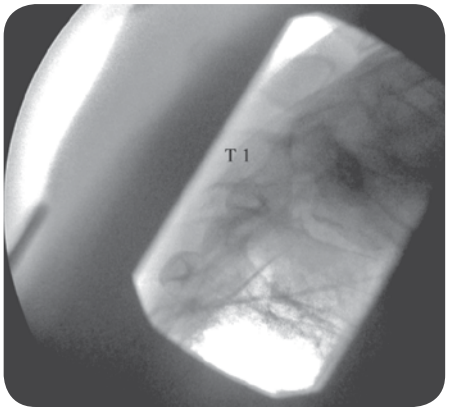
Liz in the SPS while obtaining a lateral image of the upper thoracic spine.

Configuration of the SPS for positioning Liz.

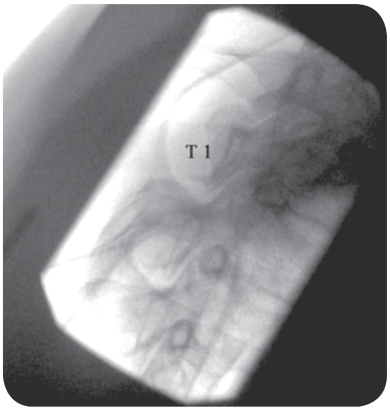
OPTIONAL SET UP:
Platform Frame (1), Crescent Face Cushion (1) Contoured Torso Support Pad (1), Large Contoured Torso Wedge (1), 8" Semi-Round Bolster (1)



AP image visualizing the T1-2 interlaminar space.



Lateral image primarily through the C7—T2 segments.



Contralateral oblique showing the upper thoracic facet joints.

DIRECTIONS FOR USE

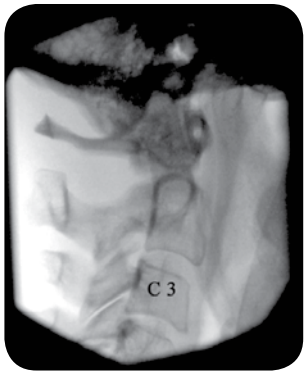
WARNING A patient safety strap must be used for all procedures.
See warnings on page 2.

PATIENT - MARY

COMPONENTS USED: Platform Frame (1), Crescent Face Cushion (1), Contoured Torso Support Pad (1), Small Contoured Torso Wedge (1), 7" x 12" Rectangular Adjuster Pad (1), 8" Half Round Bolster (1)

Mary

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



Lateral image through the C1-3 segments.

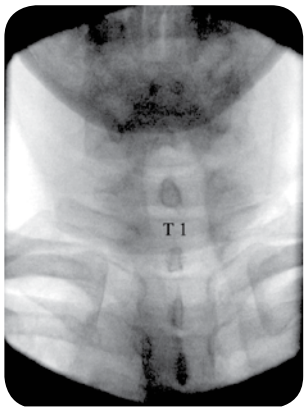
AP image through the C1-2 joints.

PATIENT - SUZIE

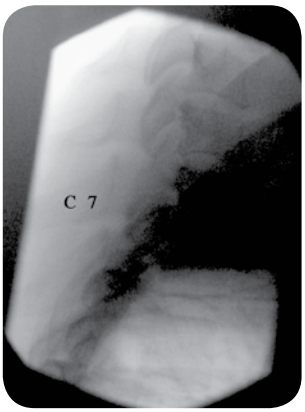
COMPONENTS USED: Platform Frame (1), Crescent Face Cushion (1), Contoured Torso Support Pad (1), Small Contoured Torso Wedge (1), 8" Half Round Bolster (1)

Suzie

Suzie in the SPS while obtaining a lateral image through the C7-T1 segment.



AP image visualizing the C6-7 and C7-T1 interlaminar spaces.



Lateral image visualizing the C6-7 and C7-T1 interspaces.

DIRECTIONS FOR USE

WARNING A patient safety strap must be used for all procedures.
See warnings on page 2.

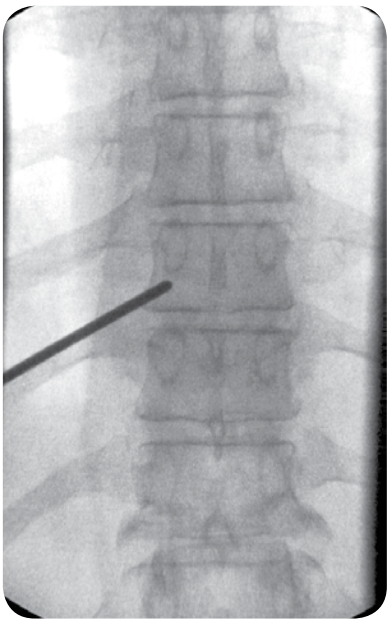
PATIENT - CARL

COMPONENTS USED: Platform Frame (1), Crescent Face Cushion (1), Contoured Torso Support Pad (1), Small Contoured Torso Wedge (1), 7" x 12" Rectangular Adjuster Pad (1), 8" x 16" Rectangular Adjuster Pad (2), 8" Semi-Round Bolster (1)

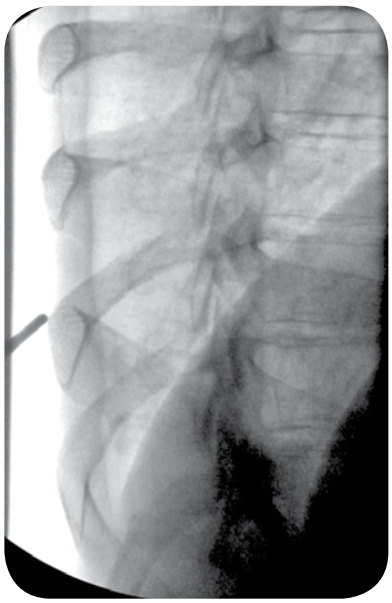
Carl

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

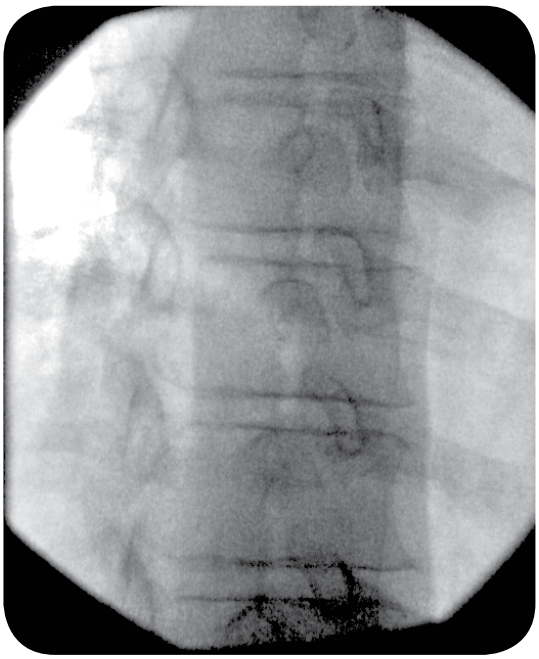
Configuration of the SPS for positioning Carl.



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.



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

DIRECTIONS FOR USE

WARNING A patient safety strap must be used for all procedures.
See warnings on page 2.

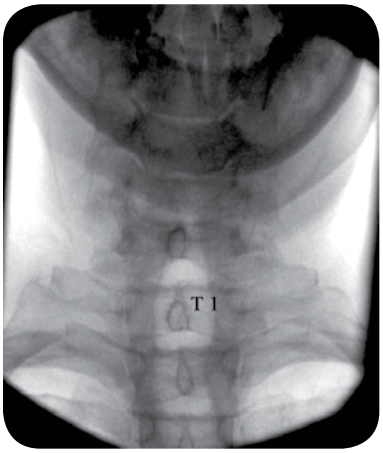
PATIENT - DEBBIE

COMPONENTS USED: Platform Frame (1), Crescent Face Cushion (1), Contoured Torso Support Pad (1), Small Contoured Torso Wedge (1), 7" x 12" Rectangular Adjuster Pad (1), 8" x 16" Rectangular Adjuster Pad (1), 8" Semi-Round Bolster (1)

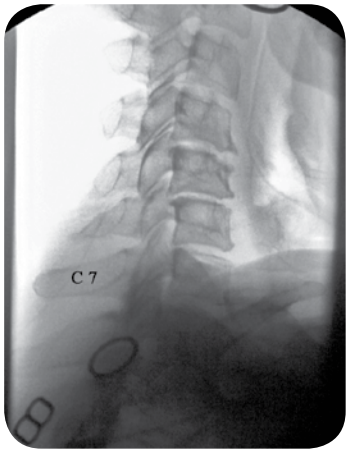
Debbie

Debbie in the SPS while obtaining a lateral cervical image.

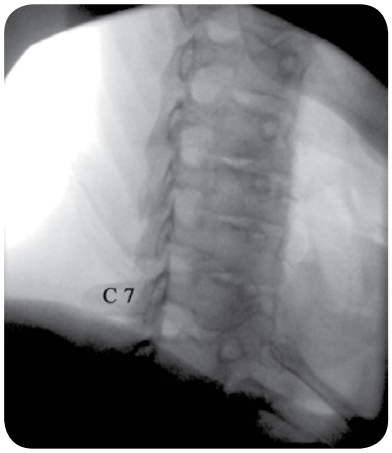
Configuration of the SPS for positioning Debbie.



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.

OPTIONAL SET UP:
Platform Frame (1)
Crescent Face Cushion (1)
Contoured Torso Support Pad (1)
Large Contoured Torso Wedge (1)
8" Semi-Round Bolster (1)

DIRECTIONS FOR USE

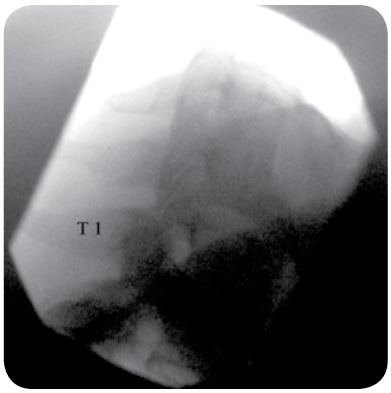
WARNING A patient safety strap must be used for all procedures.
See warnings on page 2.

PATIENT - JANE

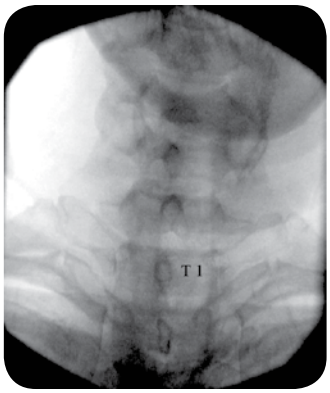
COMPONENTS USED: Platform Frame (1), Crescent Face Cushion (1), Contoured Torso Support Pad (1), Small Contoured Torso Wedge (1), 7" x 12" Rectangular Adjuster Pad (1), 8" x 16" Rectangular Adjuster Pad (1), 8" Semi-Round Bolster (1)

Jane

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



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 radiofrequency neurotomy.



The lower cervical inter-laminar spaces are seen without visualization of the mandible over the target interspaces.

OPTIONAL SET UP:
Platform Frame (1)
Crescent Face Cushion (1)
Contoured Torso Support Pad (1)
Large Contoured Torso Wedge (1)
8" Semi-Round Bolster (1)

CLEANING/DISINFECTING

Cleaning:

All components may be cleaned with a mild detergent solution. Be sure to remove excess solution and dry thoroughly. TerraTouch™ is a PVC free fabric that is both durable and supple. The following disinfectants can safely be used: Protex, MadaCide - FD, MadaWipe - FDN, Accel - Virox

Disinfecting:

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

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

NOTE: Use of Isopropyl Alcohol is not recommended.

MAINTENANCE

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:

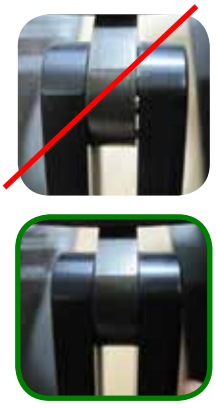
Step 1 - Lock the platform cam

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, cam tightening is required.

Inspect joints

Bad (gap)



Good (no gap)

Face rest platform locking mechanism adjustment is continued on the next page.

MAINTENANCE

MAINTENANCE:

Insert paper between pins & lock cam.

Pull paper.

An alternative method to test the face rest platform locking mechanism is to simply put a thin piece of paper between the 2 pivot parts (avoiding the pins) and pull on the paper. If the paper pulls out, cam tightening is required.

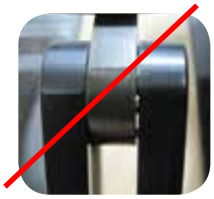
CAM TIGHTENING (IF REQUIRED)

Use 1/2” socket wrench to grasp locknut.

Hold cam with other hand.

Tighten cam until there is no gap between the 2 metal parts.

Bad (gap)



Good (no gap)

LIST OF PARTS

Part No.	Description
Spine Positioning System	
64878	Platform Frame (1)
EM2410-SP	Crescent Face Cushion (1)
0546-06	Contoured Torso Support Pad (1)
0550-06	Small Contoured Torso Wedge (1)
0554-06	Large Contoured Torso Wedge (1)
4402-06	7” x 12” Rectangular Adjuster Pad (2)
0552-06	8” x 16” Rectangular Adjuster Pad (2)
1581-06	8” Half Round Bolster (1)
5932-06	8” Semi-Round Bolster (1)
64705	Carry Case

SPECIFICATIONS

Specifications

Aluminum Equivalence (maximum) of x-ray attenuation:

64878	Platform Frame	1.20 mm @ 100 kVp & HVL of 3.6mm
EM2410-06	Crescent Face Cushion	.72 mm @ 100 kVp & HVL of 3.6mm
0546-6	Contoured Torso Support Pad	1.10 mm @ 100 kVp & HVL of 3.6mm
0550-06	Small Contoured Torso Wedge	.50 mm @ 100 kVp & HVL of 3.6mm
0554-06	Large Contoured Torso Wedge	.70 mm @ 100 kVp & HVL of 3.6mm
4402-06	7" x 12" Adjuster Pad	.35 mm @ 100 kVp & HVL of 3.6mm
0552-06	8" x 16" Adjuster Pad	.35 mm @ 100 kVp & HVL of 3.6mm

Dimensions

64878	Platform Frame (1)	12" x 34"
EM2410-06	Crescent Face Cushion (1)	12" Diameter
0546-06	Contoured Torso Support Pad (1)	5.5" x 16" x 27"
0550-06	Small Contoured Torso Wedge (1)	2.5" x 16" x 23"
0554-06	Large Contoured Torso Wedge (1)	3.5" x 16" x 29"
4402-06	7" x 12" Rectangular Adjuster Pad (2)	1" x 7" x 12"
0552-06	8" x 16" Rectangular Adjuster Pad (2)	1" x 8" x 16"
1581-06	8" Half Round Bolster (1)	4" x 8" x 26"
5933-06	8" Semi-Round Bolster (1)	6" x 8" x 26"
64705	Carry Case	

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. 5		

WARRANTY

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

SPINE POSITIONING SYSTEM

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FDA Listed

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