

EGGNEST[®]

XR

User and Service Manual



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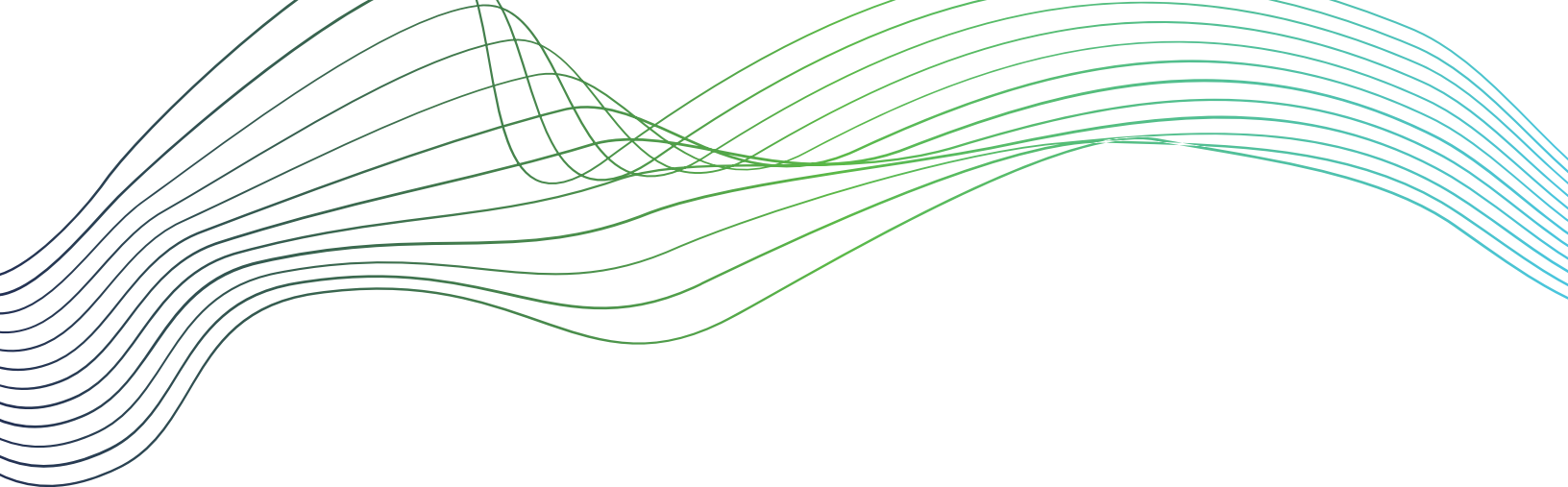


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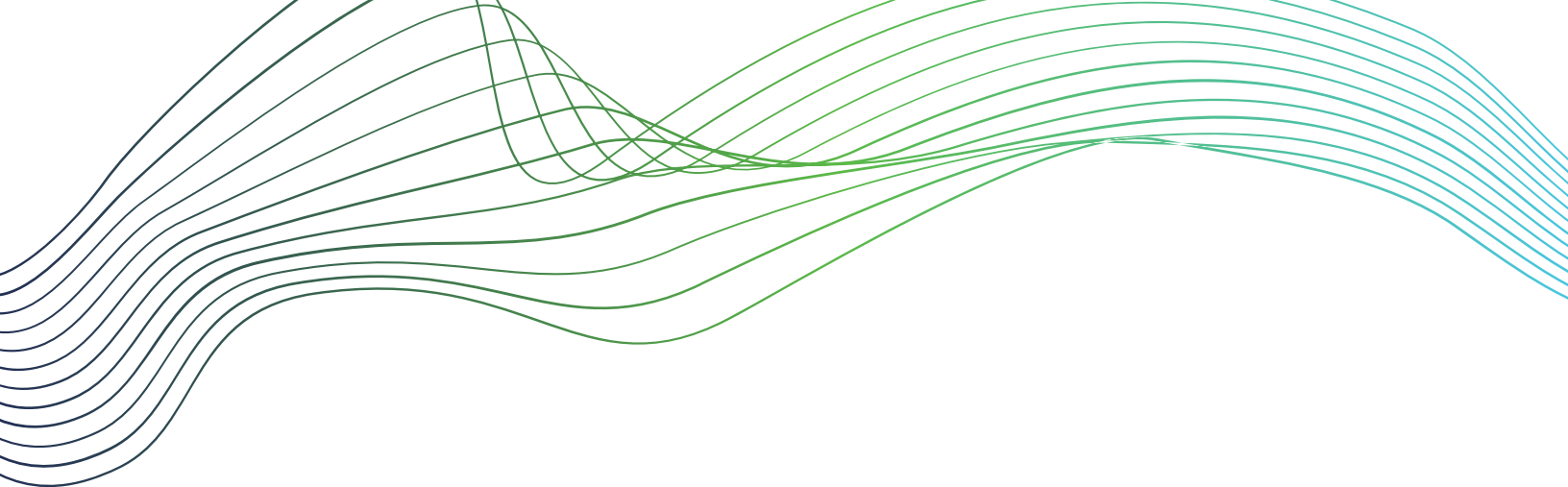
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Our goal at Egg Medical is to reduce the scatter radiation exposure of physicians, nurses, technicians and others who use X-Ray imaging to perform life-saving diagnostic and therapeutic procedures for patients.

Please contact us at <https://eggmedical.com/info> or email us at info@eggmedical.com.

Please see <https://eggmedical.com/documents> to access the most up-to-date manuals and additional information



EGGNEST[®]

XR

CONTENTS

Description of EggNest® XR.....	7
Components of the EggNest XR System.....	8
Base Platform.....	8
Arm Boards.....	9
Side and Head Flex Shields.....	10
Workbench.....	11
Hip Flip Shields.....	12
Clear Spot Shield.....	12
Structural Head Shield.....	13
Installation of the EggNest XR System	
Step 1: Prepare the X-ray table.....	14
Step 2: Place the EggNest XR Base Platform on the X-ray table.....	14
Step 3: Secure the EggNest XR Base Platform to the X-ray table.....	14
Step 4: Place Mattress Topper on top of Base Platform.....	15
Step 5: Attach the Side and Head Flex Shields.....	15
Step 6: Insert the Workbench onto the large side leg rail.....	17
Step 7: Insert the Hip Flip Shields.....	17
Step 8: Insert the Arm Boards.....	18
Step 9: Insert the Clear Spot Shield.....	18
Step 10: Place Head Box on Mattress Topper.....	19
Patient Loading.....	20
Draping the Clear Spot Shield.....	22
Operation during Procedure.....	24
Precautions.....	25
Care and Maintenance.....	27
Egg Medical Product Warranty.....	29
EggNest XR Component Weights.....	30

LIST OF SYMBOLS

	Caution		Manufacturer
	CE Mark		Date of Manufacture
	Part Number		Consult Instructions for Use
	Lot Number		Serial Number

Description of EggNest® XR

EggNest XR Scatter Radiation Protection Platform

The EggNest XR is an integrated scatter radiation protection shielding system. The intended purpose of the EggNest XR is to protect all healthcare workers in the x-ray procedure room from scatter radiation during medical procedures employing imaging in the range of 70-100 keV energy levels [1], as well as to limit radiation exposure to the head of the patient during cardiac procedures.

The effectiveness of the EggNest XR in blocking scatter radiation depends on proper use of the shielding system. The EggNest XR should be configured for best operation in the x-ray laboratory environment in which it is used. When used properly, testing has shown that scatter radiation can be reduced by more than 91% to the staff on average (up to 97% for some positions) in the procedure room while dose to the head of the patient can be reduced by more than 80% during a procedure.

**Optional shields and or replacement of your OEM Table shields can be designed for specific procedures to maximize healthcare staff protection. Please contact Egg Medical if you would like custom shielding.*

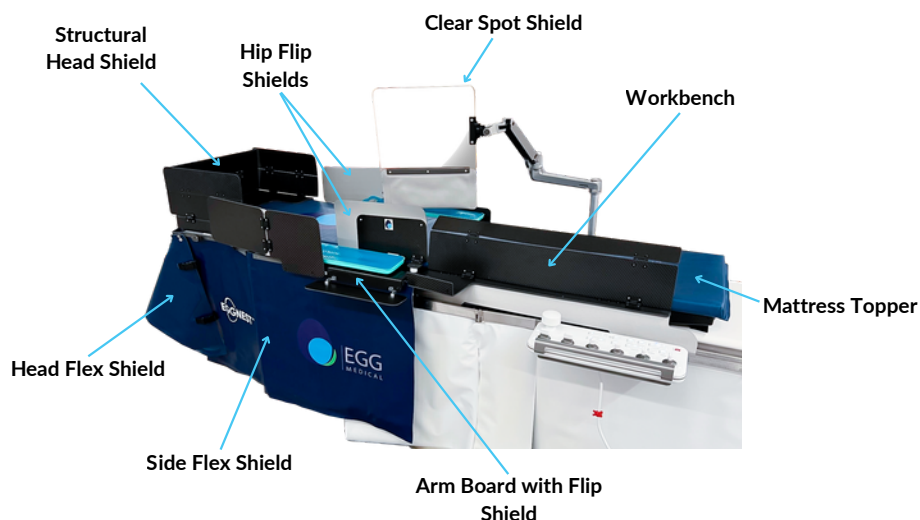


Figure 1: EggNest XR with all its system components to block scatter radiation

[1] The EggNest XR is not intended for use to protect users from radiation with energies >120 keV or in the gamma radiation range

Components of the EggNest® XR System

Base Platform

The **Base Platform** is a carbon fiber shell with internal radiation shielding material and a foam insert, covered by a detachable vinyl-covered mattress pad. The **Base Platform** has an attached **Head Rail** around the upper half and left and right side rails on the lower half.

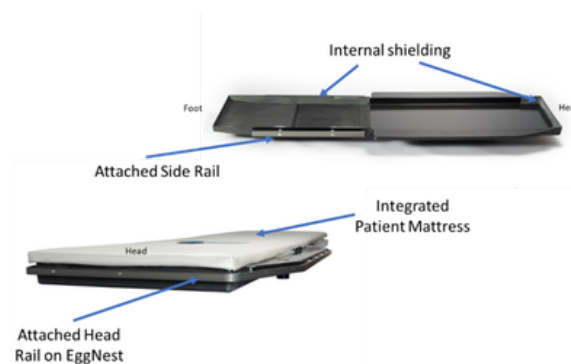


Figure 2: Carbon fiber base platform showing the internal shielding and the attached rails.

The **Base Platform** sits on the x-ray table in the place of the existing patient mattress. The radiation protection components attach to the **Base Platform**.

A detailed description of the components are as follows:

- I. The carbon fiber shell consists of two carbon fiber pieces: an upper shell that has integrated supports for the arm boards, and a lower shell.
 - a. The two shells are joined together during installation at initial set up.
 - b. There are arm board **Receiving Cylinders** on each side of the base platform. These cylinders receive the carbon fiber **Arm Boards** to facilitate radial procedures or to support the arm position during femoral access cases. The receiving cylinders allow rotation of the inserted **Arm Boards**. Additionally, the cylinders are open at the bottom to facilitate cleaning.
- II. The EggNest XR has a two-tier split mattress system made of vinyl that is impermeable to fluids.
- III. The **Head Rail** and **Side Rails** are attached to the upper carbon fiber shell. The **Flex Shields** below the table attach to the **Head** and **Side Rails**.

Base Platform with Two-Tier Mattress

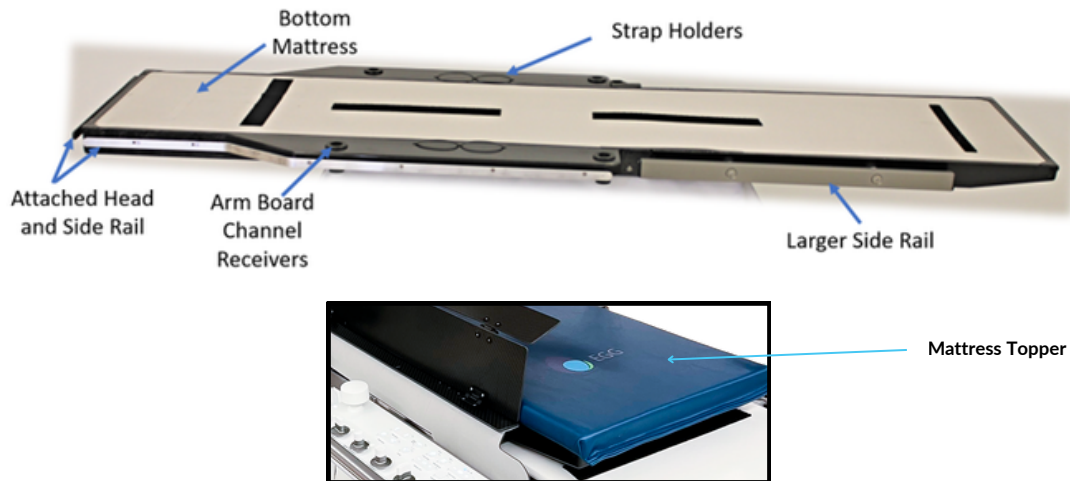


Figure 3: Carbon-fiber base platform with a two-tier foam mattress.

Arm Boards

The EggNest® XR system comes with included **Right** and **Left Arm Boards**.

Each **Arm Board** attaches to **Base Platform** using a cylindrical connector that fits into the **Receiving Channels** on the **Base Platform**. The body of the arm board is radiolucent to facilitate radial access imaging. The sides of the **Arm Boards** have three **Flip Shields** that flip down for patient loading and up for radiation protection during the procedure. The **Arm Board Flip Shields** have three components that are hinged to each other. This allows the user to adjust the shields to optimize workflow during and after the procedure.



Figure 4: Right Arm Board and Flip Shield



Figure 5: Left-sided carbon-fiber arm board with Flip Shields;
Up for radiation protection and down for patient loading

Side and Head Flex Shields

The **Head Flex Shield** and **Side Flex Shields** attach to the **Head and Side Rails** on the **Base Platform**. These shields block scatter radiation from below the table at the head end of the table.



Figure 6: Head Flex Shield and Right Side Flex Shield attached to the Head and Side Rails

Side Flex Shields (Left and Right)

There are two **Side Flex Shields**, one right and one left. Each **Side Flex Shield** has a channel that fits over and attaches to a **Side Rail** using low profile knobbed screws that lock the **Side Flex Shield** to the **Side Rail**. The **Side Flex Shields** have internal stays to maintain shape and prevent interaction with the X-ray tube housing.

Head Flex Shield

There is a single **Head Flex Shield** that integrates with the **Side Flex Shields**. The **Head Flex Shield** also has a channel that fits over and attaches to the **Head Rail** using low profile knobbed screws that lock the **Head Flex Shield** to the **Head Rail**. There are clips on the right and left side of the **Side Flex Shield** that clip into matching clips on the **Side Flex Shields**.

Workbench

The **Workbench** attaches to the larger **Side Rail** on the patient right side of the **Base Platform**. This provides a work surface and shielding to the operator and scrub assistant. (The length of this work surface can be customized to meet your table side control needs.)



Figure 7: Standard Workbench with Flip Shield raised

The **Workbench** shields radiation and serves as a work surface. The **Workbench** has three shielded pieces and can unfold to an adjustable worktable. The **Workbench** is attached to the **Side Rail** of the **Base Platform**. This is typically on the right side next to the X-ray table and C-arm controls. The top carbon fiber **Flip Shield** is attached with position hinges that hold their position when rotated. The middle surface is a work surface for the operator. Egg Medical provides four size options depending on the table side controls position. The lower shield hangs under the **Workbench** to block scatter radiation emitting from under the table.

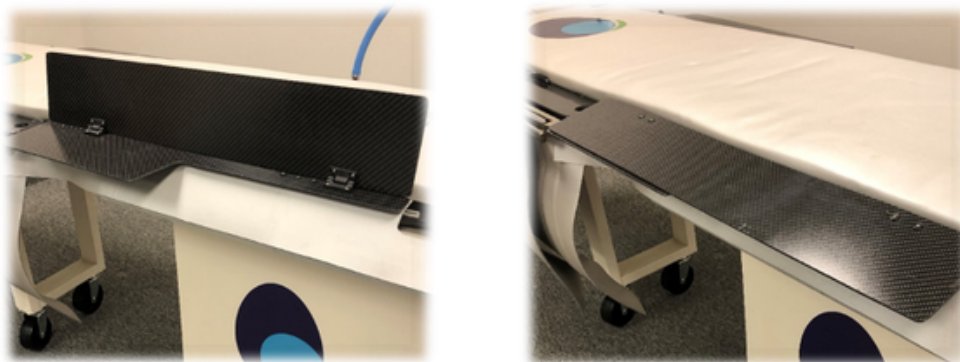


Figure 8: Workbench attached to the side rail with Flip Shielding raised for radiation protection (left) and lowered for patient loading (right)

Hip Flip Shields

The **Hip Flip Shields** are inserted on the **Left and Right** of the **Base Platform**. These shields block scatter radiation above the table near the hip of the patient and serve as versatile radiation shields during radial procedures.

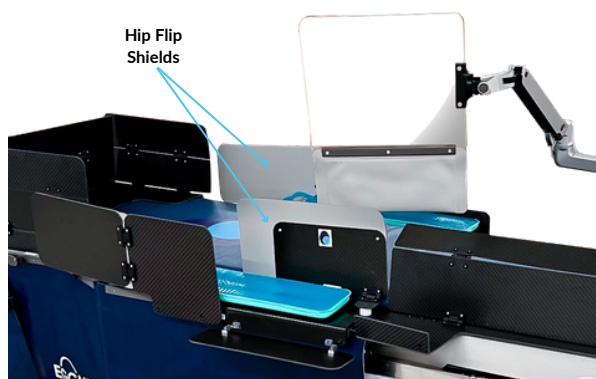


Figure 9: Hip Flip Shields

Clear Spot Shield

The **Clear Spot Shield** is a transparent acrylic radiation shield that is used to block radiation from the patient's abdomen and pelvis. The **Clear Spot Shield** is mounted on an adjustable, flexible arm. In addition, the **Clear Spot Shield** has a hanging drape that expands the area of coverage from scatter radiation. The base of the **Clear Spot Shield** is inserted into a designated mount on the left side rail. The support mount can be moved up and down the rail and the flexible arm of the **Clear Spot Shield** can be adjusted for ideal positioning. The **Clear Spot Shield** is designed to work in tandem with the ceiling hanging shield. The **Clear Spot Shield** requires a sterile drape (sold by Egg Medical) to cover both the shield, protective drape and the flexible arm.

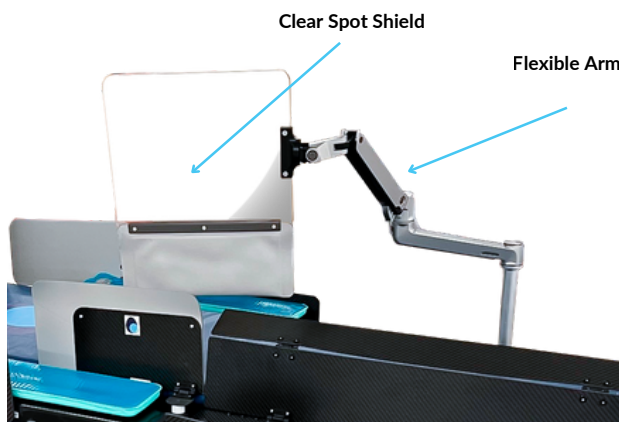


Figure 10: Clear Spot Shield and Flexible Arm

Structural Head Shield

The **Structural Head Shield** provides head and shoulder scatter protection for operators or other staff who may be near the patient's head during procedures. The **Structural Head Shield** slides onto the end of the mattress and engages with an attachment feature near the head of the **Base Platform**. The **Pillow Flip Shield** component can be lowered for patient loading and raised during the procedure to block scatter radiation emitting from the patient's head area. Both the left and right **Flip Shield** components are lowered during patient loading and raised for radiation protection after the patient is loaded and before a sterile drape is placed on the patient.

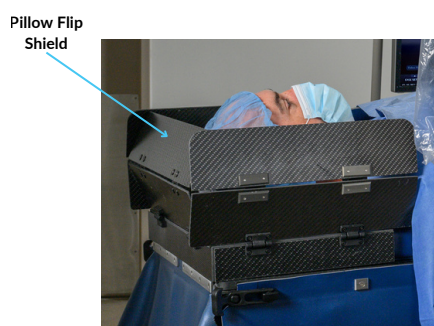


Figure 11: Structural Head Shield in use, Flip Shields raised



Figure 12: Structural Head Shield on full model

Installation of the EggNest® XR System

The EggNest XR is designed to rest on a standard X-ray table by replacing the OEM patient mattress.

Step 1: Prepare the X-ray table

Remove existing X-ray table mattress and thoroughly clean the table surface.

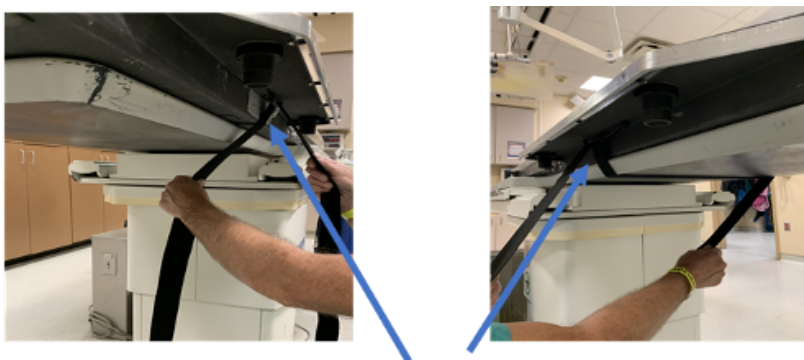
Step 2: Place the EggNest XR Base Platform on the X-ray table

Place the folded head and bottom halves of the **Base Platform** on the X-ray table at their respective sides. Unfold the halves, aligning the screw holes between the halves. Attach the sled halves together using the provided M6 screws with threads removed at the end and Loctite. After sled assembly, attach the rail for the **Clear Spot Shield** using the provided M6 screws and Loctite.

Step 3: Secure the EggNest XR Base Platform to the X-ray table

Turn the EggNest XR over on the X-ray table. Remove the adhesive backing from the 3 Velcro strips on the underside of the **Base Platform**. Flip the EggNest XR over to attach to the X-ray table. The EggNest XR should be centered on the X-ray table with approximately 2 to 5cm of the **Base Platform** overhanging the head of the table. Once the EggNest XR is in the correct position, press down firmly to ensure that the strips are adhered to the table to prevent the **Base Platform** from moving.

There are 2 loops on each side of the **Base Platform**. The head-most loop is used to secure the **Base Platform** to the X-ray table using the Table Strap Velcro strip. Loop the Velcro strip through each of the head-most loops and pull tight. Connect in the middle by pressing the “loop” layer against the “hook” layer



Under Table Loop

Figure 13: Velcro strap loops to secure **Base Platform** to X-ray table

Step 4: Place Mattress Topper on top of Base Platform

Once **Base Platform** is secured on X-ray table, place **Mattress Topper** on **Base Platform**, aligning Velcro patches.



Figure 14: *Mattress Topper placed and secured on Base Platform*

Step 5: Attach the Side and Head Flex Shields

There are two **Side Flex Shields** that attach to the **Side Rails** of the **EggNest XR**. These are marked “Left” and “Right” respectively. In addition, the **Head Flex Shield** attaches and secures to the **Head Rail** at the head of the table.

a. Attach the **Left and Right Side Flex Shields** to the **Side Rail** by placing the “U” channel over the rail on the side of the **Base Platform**. Ensure the channel over the rail is securely in place. Then tighten set screws on the **Side Flex Shields**.

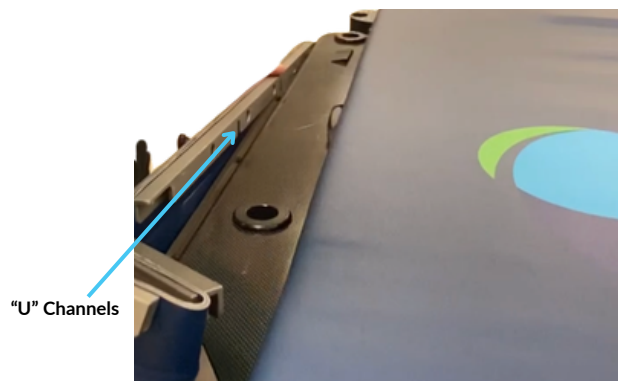


Figure 15: *Attaching Side Flex Shield - “U” channels aligning with Side Rail knobs*

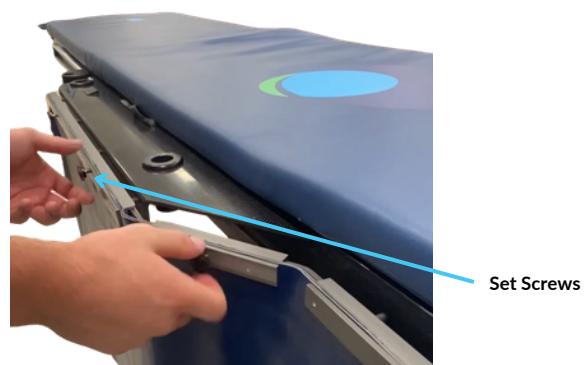


Figure 16: *Attaching Side Flex Shield - tighten set screws against Side Rails*

b. Place **Head Flex Shield** on the head end of the **Base Platform**, attaching to the **Head Rail** by placing the “U” channel over the rail. Ensure the channel over the rail is securely in place. Then tighten set screws on the **Head Flex Shield**.

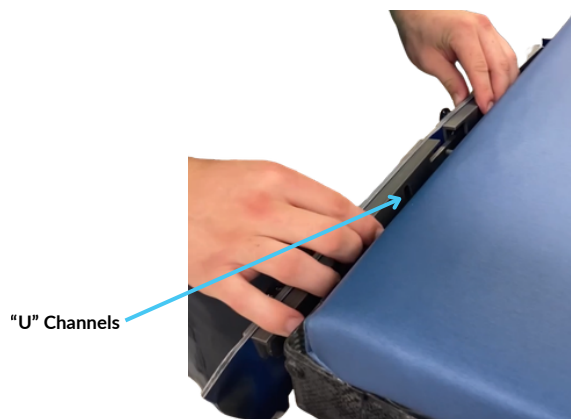


Figure 17: Attaching Head Flex Shield;
“U” channels aligning with Side Rail knobs



Figure 18: Attaching Head Flex Shield;
tighten set screws against **Side Rails**

c. Connect buttons and safety buckles on **Side and Head Flex Shields** together to close the **Flex Shielding**, ensuring maximum protection under the table.



Figure 19: Securing **Flex Shielding**
together for maximum radiation
protection under the table

Step 6: Attach the Workbench to the large Side Rail

Attach the **Workbench** by placing the U channel onto the right large **Side Rail**. Once placed on the rail, the **Workbench** can be adjusted left or right to align with the side flex shielding or the table controls. Ensure that the lower flap running underneath the work bench is “tucked-in” between the EggNest XR and the table top and is out of the way of any controls on the rail. The flip shielding of the **Workbench** can be lowered for patient loading and raised to block scatter radiation.

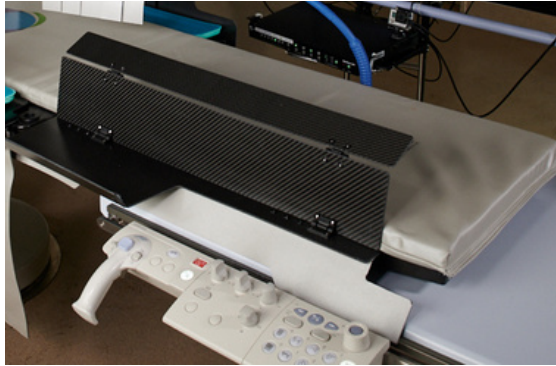


Figure 20: Workbench flip shield raised for radiation protection



Figure 21: Workbench flip shield down for patient loading

Step 7: Insert Hip Flip Shields

To insert **Hip Flip Shields**, identify which **Flip Shield** goes on the patient right or left side, marked with “Left” or “Right” label, Insert the **Hip Flip Shield** post into the receiving cylinder closest to the tail end of the EggNest® XR.

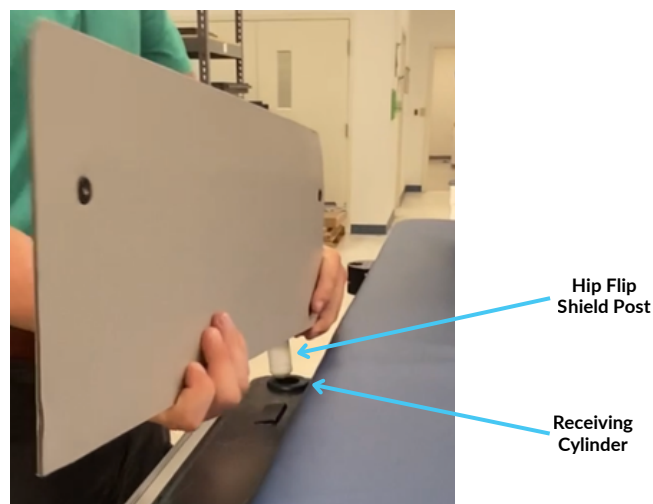


Figure 22: Inserting Left side Hip Flip Shield

Step 8: Insert the Arm Boards

To insert the **Arm Board**, identify which **Arm Board** goes on the patient right or left side. The **Arm Boards** are marked with a label identifying it as “Left” or “Right”. Insert the **Arm Board** post into the receiving cylinder closest to the top of the EggNest® XR. Once it is secured in place, lower the **Flip Shields** and rotate **Arm Board** in for patient loading.

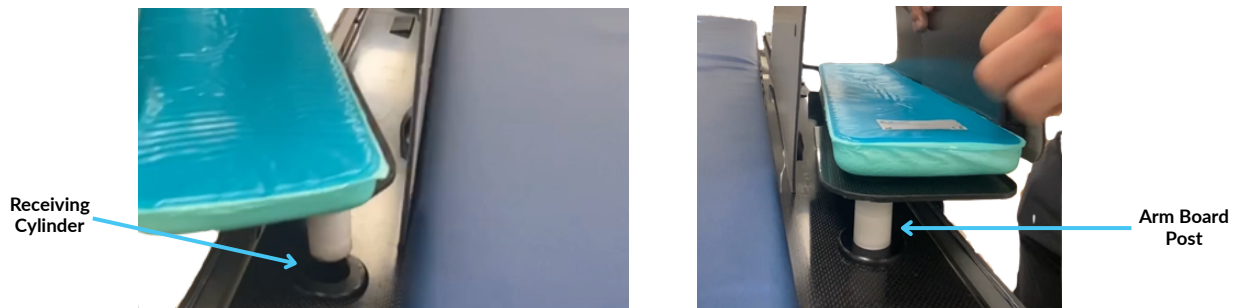


Figure 23: Inserting Left (left) and Right (right) arm boards into receiving cylinder on Base Platform

Step 9: Insert the Clear Spot Shield

The **Clear Spot Shield** mounts in a dedicated mount on the **Clear Spot Rail** of the **Base Platform**.

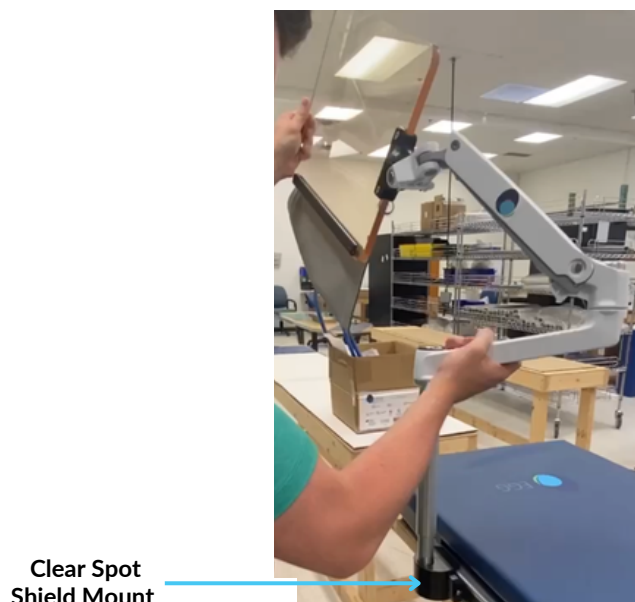


Figure 24: Place the Clear Spot Shield into mount on the left side of the patient

Step 10: Place Structural Head Shield on Mattress Topper

The **Structural Head Shield** slides over the head of the **Mattress Topper** and fits securely in place with features on the **Base Platform**. This does not need to be removed for patient loading. The **Structural Head Shield** has carbon fiber components that provide radiation protection from the x-ray beam coming through the table. The patient's sheet and pillow are placed on top of the carbon-fiber board. The **Structural Head Shield** can easily be removed and reattached if imaging of the neck is required.



Figure 25: Structural Head Shield sliding under and over to fit securely for radiation protection



Figure 26: Structural Head Shield, Flip Shields down for patient loading

Patient Loading

Prepare the EggNest® XR for patient loading as follows:



Figure 27: The EggNest® XR with shields in the “down” position for patient loading

1. Make sure that the EggNest XR has been wiped down according to hospital policy to remove foreign or biological material and that the EggNest XR is attached to the X-ray table
2. Fold the **Arm board** and **Structural Head Shield** components down
3. If loading from the right, fold the **Workbench Flip Shield** down
4. If loading from the left, move the **Clear Spot Shield** to the end of the rail, or remove and stow
5. If loading from a patient bed, slide the bed next to the EggNest XR
 - a. Using a sliding board or hover mat, move the patient from the bed to the EggNest XR
 - b. Take care that neither the patient bed or the EggNest XR move as the patient could fall through the gap
6. With the patient on the EggNest XR, attach the Patient Safety Strap, as directed by your hospital policy

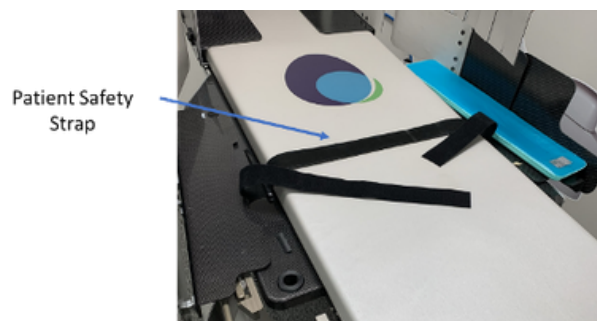
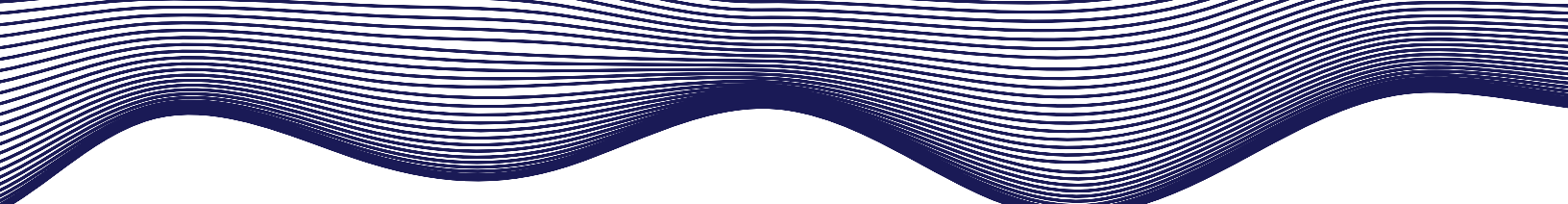


Figure 28: Patient safety Velcro strap

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7. If a radial approach is anticipated, position the **Arm Board** as desired.
 8. Before covering the patient with a sterile drape, raise all the **Flip Shields** (left and right **Arm Board**, **Workbench**, **Hip Shield(s)** and **Structural Head Shield**)
 9. After the sterile patient drape is in place, the **Clear Spot Shield** sterile drape can be placed over the **Clear Spot Shield**, and the **Clear Spot Shield**** can be positioned along patient abdomen to align with the hanging shield.

****By combining the existing hanging shield and the **Clear Spot Shield**, scatter radiation exposure to the primary operator and assistant's head and upper body can be significantly reduced.**

Draping the Clear Spot Shield

To maximize radiation protection, it is important to use the **Clear Spot Shield** during the procedure. Proper technique is required to drape the **Clear Spot Shield** correctly and maintain the sterile field.

1. Open sterile pouch and set in a sterile field
2. Arm should be slightly extended for ease of draping

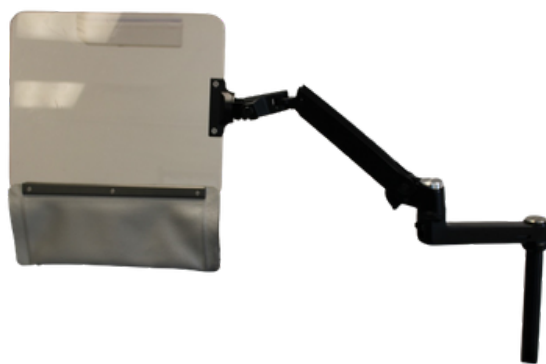


Figure 29: Clear Spot Shield with arm slightly extended in preparation for draping

3. Rotate the Clear Spot glass so that the soft shield is positioned at the top of the shield

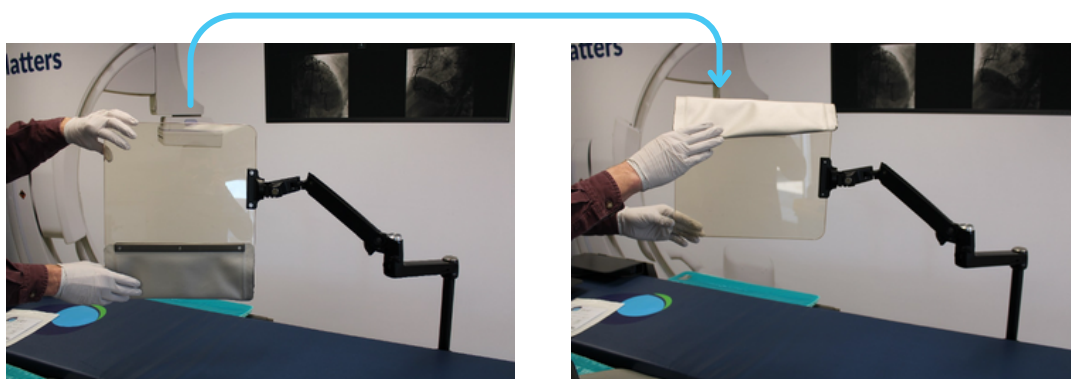


Figure 30: Clear Spot Shield graphic featuring rotating glass so the flap shield is positioned on top

4. Using proper sterile technique, cover Clear Spot Shield with sterile drape



Figure 31: Covering Clear Spot Shield glass with sterile pouch

5. Fully extend sterile pouch to the base of the pole



Figure 32: Extending sterile pouch to fit over both Clear Spot glass and base of the pole

6. Rotate Clear Spot Shield back into ready position



Figure 33: Rotated Clear Spot Shield into ready position for operation

Operation During Procedure

! Raise all Flip Shields *before* draping the patient

In general, the EggNest® XR operates passively during the procedure. The C-arm X-ray gantry can be rotated to achieve the desired radiographic views. The X-ray gantry may contact the EggNest XR **Flex Shields** when rotated out of the PA projection. The lower part of the gantry will push the **Flex Shields** away as the gantry turns.

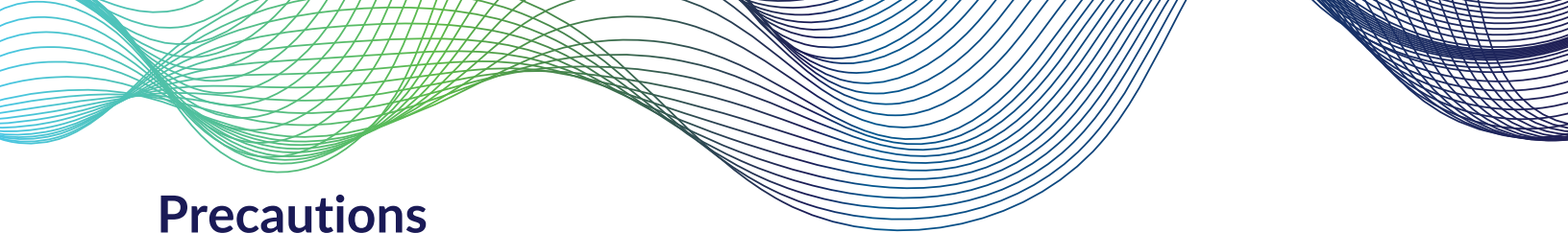
1. The easiest way to rotate from one angle to another is to swing the X-ray gantry through the neutral (PA) position.
2. The **Arm Board Flip Shields** may be adjusted during the procedure under the sterile drape to accommodate access and optimize shielding.

Tips for optimal use of the EggNest XR

Make sure that the patient head is aligned just below the top of the EggNest XR. This will ensure that the patient is aligned with the internal shielding.



Figure 34: EggNest XR with Flip Shields raised and ready for draping



Precautions

Safe operation of the EggNest® XR depends on proper use of the system.

Scatter Radiation Protection

The most effective scatter radiation shielding depends on using the EggNest XR according to the directions.

CAUTION: Failure to adjust shields properly will result in less effective shielding.

Patient loading

Like all patient transfers, transferring a patient from a bed or gurney to the EggNest XR has a risk of patient injury due to falling or pinching during transfer. To minimize the risk of transfer, use care in patient movement and minimize the gap between the EggNest XR and the transfer device. Use of auxiliary transfer aids, such as a hover mat system or sliding board, can make transfer easier and safer. Be sure that the EggNest XR is firmly attached to the X-ray table and does not move during transfer.

WARNING: Cover the EggNest XR with a sheet or paper drape prior to loading patient.

WARNING: Failure to secure the EggNest XR Base Platform can lead to a patient fall or staff injury.

Patient stability on the EggNest XR

It is important to properly position the patient on the EggNest XR. The patient should be positioned with the head about 1-2 inches from the top of the EggNest XR and in the middle of the long axis of the system. For more safety from roll-off accidents, we recommend using the accessory Security Belt attached to the EggNest XR, consistent with hospital regulations.

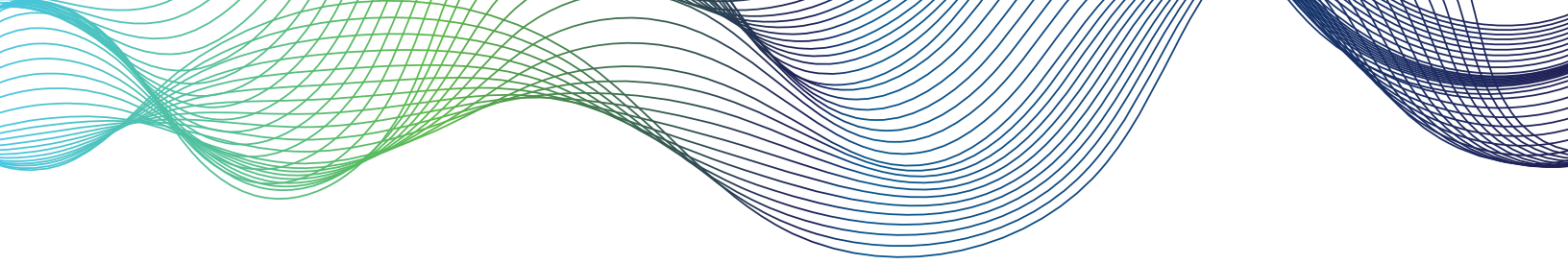
WARNING: Failure to secure the patient on the EggNest XR can lead to a patient fall

Contact with the X-ray system

If the shields or other EggNest XR components come into contact with the x-ray tube housing or detector, do not push or otherwise force the system. Instead, move the table or the x-ray gantry in order to disengage the systems.

It is expected that the lower X-ray C-arm will push the Flex Shield to the side when the gantry is rotated. If the positional detector (also referred to as a collision detector) on the X-ray tube housing is activated, DO NOT continue to rotate the C-arm or move the table in a manner that will cause further interference. Instead, check to position of the X-ray tube housing and C-arm relative to the EggNest XR to determine the problem. If the Flex Shield or other component of the EggNest XR are in contact with the X-ray tube housing, move the table or the X-ray gantry in order to disengage the systems. If the Flex Shield is stuck on the C-arm, gently lift the Flex Shield to disengage. In any case, DO NOT force the EggNest XR or C-arm components past each other.

CAUTION: If the x-ray detector comes into contact with the EggNest XR components, move the X-ray table or the C-arm to disengage. DO NOT force the EggNest XR or C-arm components past each other.



Safety Using the Clear Spot Shield

The **Clear Spot Shield** should always be sterilely draped and rotated with care. Be sure that the **Clear Spot Shield** is properly mounted in the receiving hole.

CAUTION: Proper placement and usage of the Clear Spot Shield is required. Failure to do so may result in the Clear Spot Shield falling on staff or the patient, leading to injury or breakage of the Clear Spot Shield

The **Clear Spot Shield** is manufactured from a polymer that contains lead oxide. If the **Clear Spot Shield** is damaged, do not use the shield and contact Egg Medical for instructions on proper disposal, repair or replacement.

Pinching Hazards

CAUTION: Pinching can occur between surfaces of the EggNest XR. Keep finger or skin folds out moving edges and the areas of movement. Keep fingers and skin folds away from the edges of the rotating surfaces.

Care and Maintenance

Cleaning

The carbon fiber sled is made from material similar to that used for most X-ray tables. The vinyl top is medical grade vinyl which may become discolored if cleaned with an unapproved cleaning agent.

The EggNest® XR should be cleaned between uses with one of the following cleaning solutions:

Cleaning Agent	Manufacturer	Rating		Cleaning Agent	Manufacturer	Rating
303 Fabric/Vinyl Cleaner	303 Products Inc.	4.5		Hydrogen Peroxide Cleaner Disinfectant Wipes	The Clorox Company	4.5
All Purpose Vinyl Cleaner	CMIV Clean	4.5		Lysol Foaming Disinfectant Cleaner	Brand, IC	4
Asepticare TB + II	Ecolab	4.5		Oxivir TB Wipes	Diversey, Inc.	4.5
Bio Kleen Amazing	BioKleen Products, Inc.	4.5		Oxycide Diluted	Ecolab	4.5
Caviwipes XL Packed	Metrex	4		Reposolv Diluted	American Continental Technolabs	4.5
Clorox Healthcare Bleach Germicidal Wipes	The Clorox Company	4.5		Sanicloth AF 3	PDI	4.5
Crystal Simple Green	Sunshine Makers, Inc.	4.5		Simple Green Towels	Simple Green	4.5
Coverage Plus Germicidal Wipes	Spray Nine	4.5		Sodium Hypochlorite Disinfectant/Disinfectant Cleaner Diluted	Process Cleaning Solutions	4.5
Dispatch	Caltech Industries, Inc.	4.5		Stride Floral Neutral Daily Cleaning	Diversey, Inc.	4.5
Fantastik Antibacterial All Purpose Cleaner Heavy Duty	S.C Johnson and Sons, Inc.	4.5		Super Sani-Cloth	PDI	4.5
Formula 409 Antibacterial All Purpose Cleaner	The Clorox Company	4.5		Virex II 256	Diversey, Inc.	4.5
Glance NA Diluted	Diversey, Inc.	4.5		Virex 5 Rtu	Diversey, Inc.	4.5
GP Forward Diluted	Diversey, Inc.	4.5		Wex Cide 128	Wexford Labs, Inc.	4.5

Cleaning agents are rated on a scale of 1-5	1-3: Causes discoloration. Not recommended	4-5: Recommended for use
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Table 1: Cleaning solutions to be used on the EggNest XR

Be sure to thoroughly clean all surfaces in order to prevent transmission of infectious agents or biohazard to staff and between patients.

If the vinyl fabric develops a cut or hole, notify Egg Medical for repair. Discontinuity of the vinyl surface can lead to an infection hazard by allowing biological materials to enter the fabric and foam. Discontinue use or apply an adhesive seal (e.g., 3M™ Tegaderm™ Transparent Film Dressing) to the area until the EggNest® XR is repaired.

Periodic X-ray examination

As with “lead aprons”, all flexible shielding should be periodically examined for cracks or discontinuity in the shielding. Please follow hospital policy regarding examination of shielding.

Egg Medical recommends that the integrity of the Flex Shielding be checked every 6 months or if there is visible damage. If, on fluoroscopic examination, there are cracks or holes, discontinue use of the shielding and contact Egg Medical for repair or replacement.

Product disposal

If the EggNest XR is to be removed from service at the end of useful life, it can be disposed in normal waste streams with the exception of the Clear Spot Shield which must be returned to Egg Medical for disposal.

Egg Medical Product Warranty

What the Warranty Covers

Egg Medical guarantees that the Egg Medical EggNest® product you purchased is free of defects in workmanship for one year after purchase.

This includes:

- Discontinuity of the outer material coming into contact with the patient
- Structural defects in the sled or arm board components (not caused by misuse)
- Material defects in the radiation blocking material

What the Warranty Does Not Cover

Egg Medical products are intended to be used in high flow areas of the hospital. We do not warranty defects that arise from repetitive use and normal “wear and tear.” This includes cosmetic defects, stains, structural failure due to misuse (such as breaking the sled or arm boards from inappropriate movement of the x-ray gantry or dropping the unit on the floor)

Repetitive flexing of any radiation blocking material may result in fractures of the material. The integrity of the shield should be tested periodically in accordance with hospital and local regulatory policies. If the material fails in the warranty period, it will be repaired or replaced by Egg Medical.

Period of Coverage for this Warranty

This warranty extends coverage for 1 year from the date of purchase.

What Egg Medical Will Do to Correct Problems

Egg Medical will replace or repair your product within 30 days of notification of a covered problem. It may be necessary for you to send the defective unit back to Egg Medical. You will be provided with shipping instructions.

Service Contact

To report a Warranty issue or concern, please contact us at customerfeedback@eggmedical.com. Alternatively, you can call 612-916-6616 during business hours (8:00 AM to 5:00 PM Central Time, Monday through Friday).

Egg Medical® reserves the right to change the method of contact.



EggNest® XR Component Weights

Component	Weight (lb / kg)
Base Platform	38 / 17.2
Arm Board	4.5 / 2.0
Side Flex Shield	14 / 6.4
Hanging Head Flex Shield	8.5 / 3.9
Structural Head Shield	13.5 / 6.1
Workbench	varies by model
Clear Spot Shield	12 / 5.4
Hip Flip Shield	2 / 0.9
Mattress Topper	8.5 / 3.9

The edges of the Base Platform shell and Foam Top are lined with shielding material, except the area inside the arm supports (to facilitate diagnostic imaging)