



User and Service Manual



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Patents

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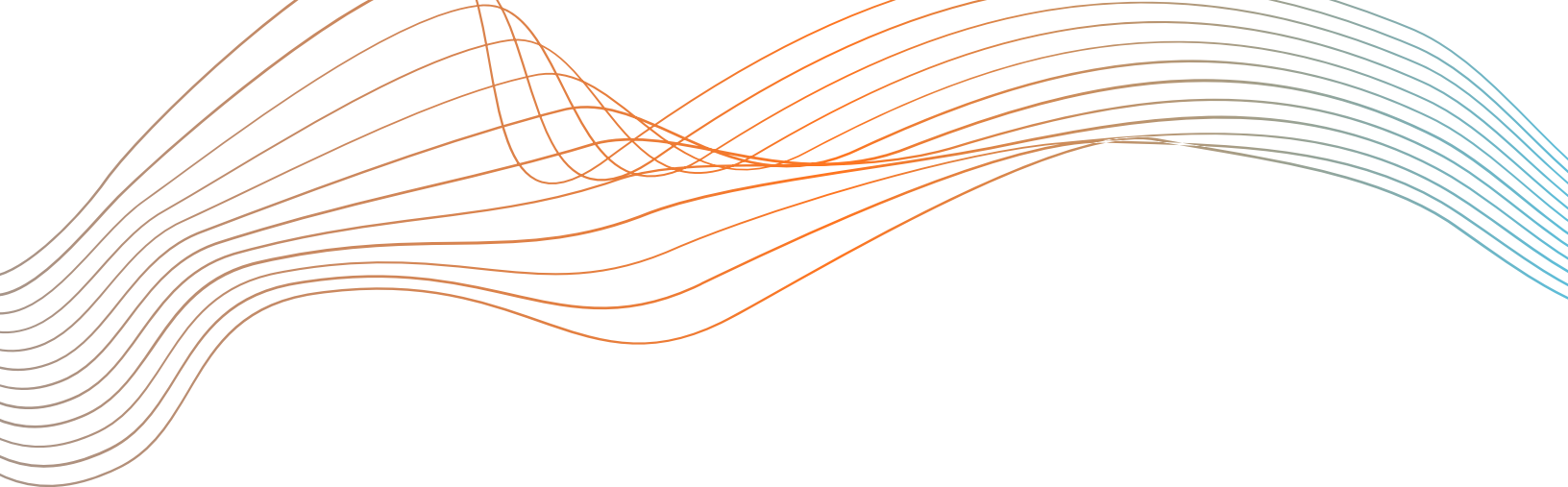
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4344rC



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 612-916-6616
or email us at info@eggmedical.com.

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

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LIST OF SYMBOLS

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

Description of EggNest™ Complete Flex Shield

The EggNest Complete Flex Shield is a scatter radiation protection shielding system. The intended purpose of the EggNest Complete Flex Shield is to protect healthcare workers that are behind the shield in the x-ray procedure room from scatter radiation during medical procedures employing imaging in the range of 70-100 keV energy levels [1].

The effectiveness of the EggNest Complete Flex Shield in blocking scatter radiation depends on proper use of the shielding system. The EggNest Complete Flex Shield 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 behind the shield can be reduced.



Figure 1: EggNest Complete Flex Shield shown with EggNest Protect base system

The EggNest Complete Flex Shield is designed and manufactured by Egg Medical, Inc.

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

Components of the EggNest™ Complete Flex Shield

Shield Assembly

The Shield Assembly is primarily constructed of panels of an acrylic resin impregnated with lead oxide, resulting in a lead equivalency of 0.5 mm Pb. The panels are framed with a series of stainless steel and aluminum components that protect the acrylic from damage while allowing for attachment of the system to a boom arm.

Shield Fringe

The Shield Fringe is a soft shielding component attached to the lower edge of the Shield Assembly to allow for conformance to patient anatomy.

Shield Adapter

The Shield Adapter is designed to attach the EggNest Complete Flex Shield to a ceiling-mounted boom arm.

Shield Handle

The Shield Handle is designed to provide a location to grasp the Complete Flex Shield and manipulate it into position.

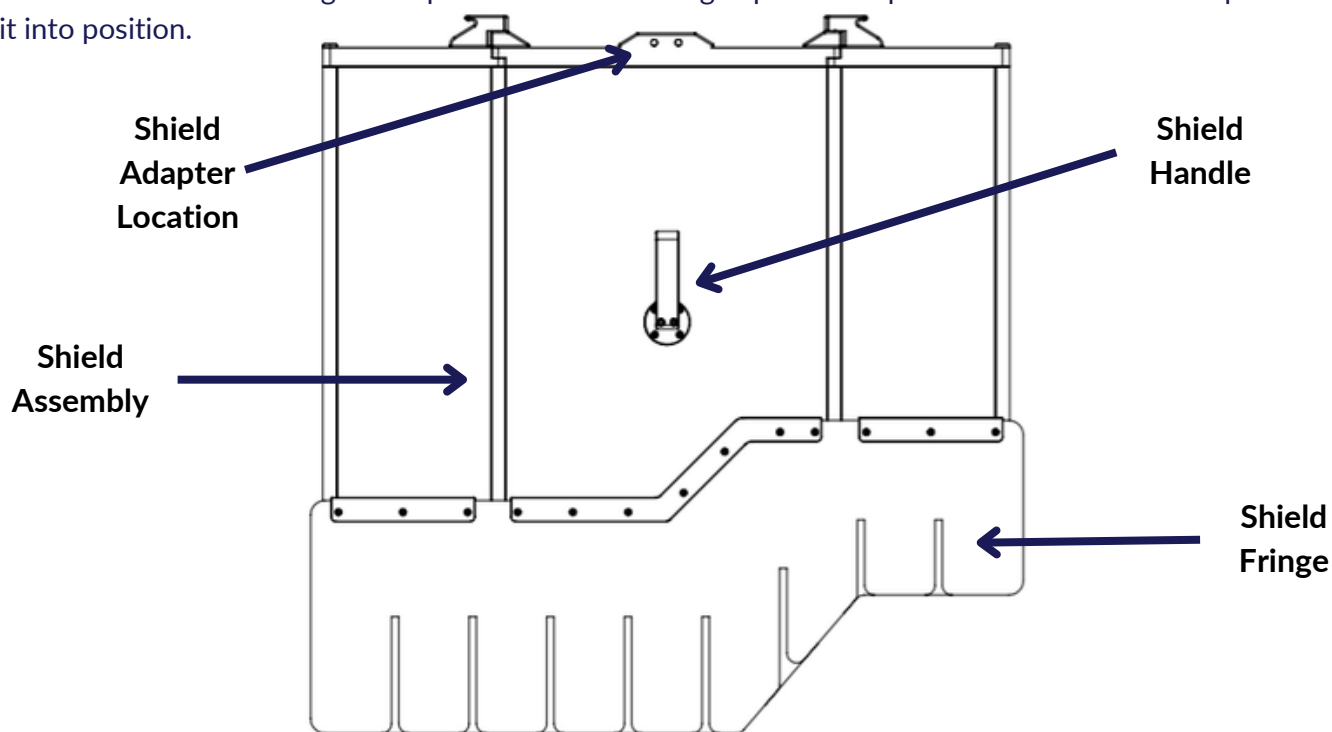


Figure 2: EggNest Complete Flex Shield Components

Installation of the EggNest™ Complete Flex Shield System

The EggNest Complete Flex Shield is designed to connect to a ceiling-mounted boom arm.

Step 1: Connect the Complete Flex Shield Adapter to the Boom Support Tube

The Complete Flex Shield Adapter is attached to the Boom Support Tube of the existing ceiling-mounted boom using three screws provided by the boom manufacturer. Install in place after placing the included Loctite thread locking compound on the screw threads.

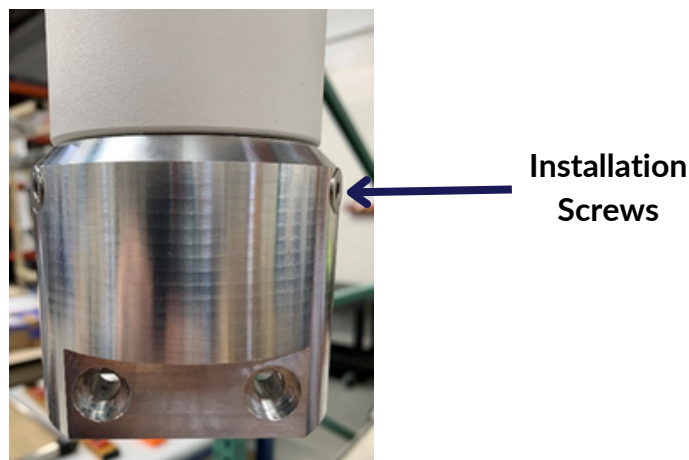


Figure 3: Attach Adapter to Boom Arm Vertical Support Tube

Step 2: Connect the EggNest Complete Shield to the Complete Shield Adapter

The EggNest Complete Flex Shield is lifted into place with the Adapter over the mating slot in the Complete Shield upper rail. Attach the Shield to the Adapter using the two included stainless steel shoulder bolts with the included Loctite thread locking compound on the bolt threads.

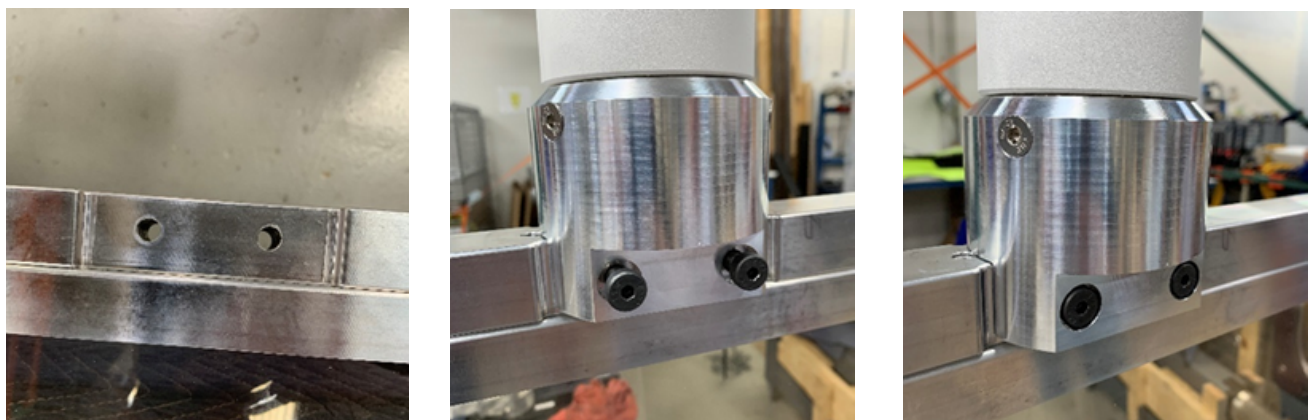


Figure 4: Connecting the Complete Flex Shield to the Adapter

Step 3: Install the Complete Flex Shield Handle on the Shield Assembly

The Complete Flex Shield Handle is attached to the Shield assembly using the two included M5 socket head screws preloaded in the handle. Use the included Loctite thread locking compound on the bolt threads. Place handle facing up per image below.

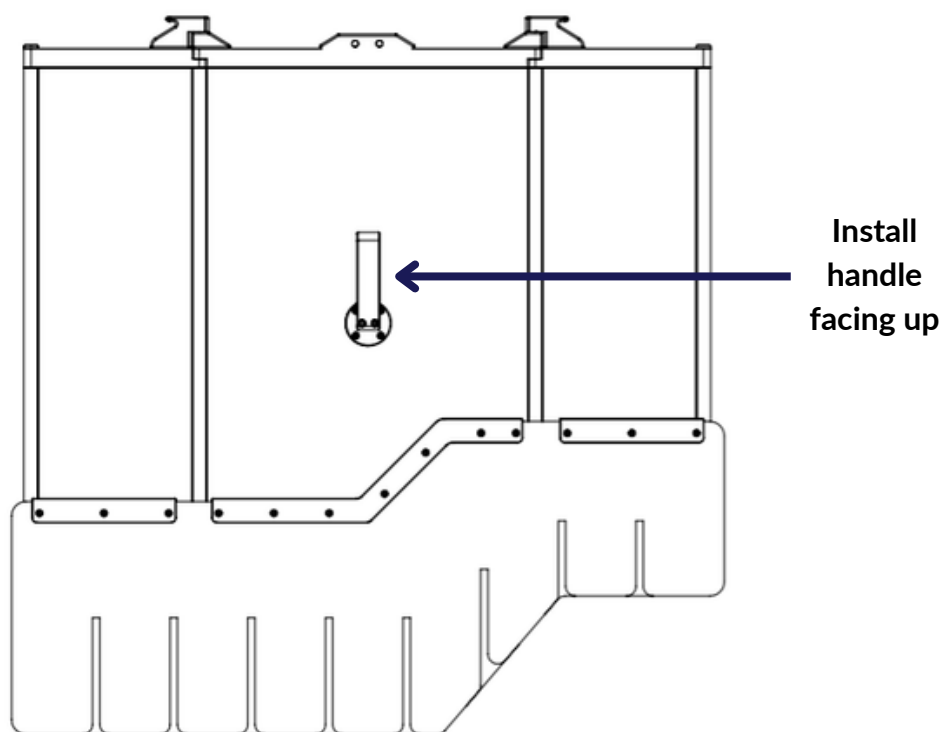


Figure 5: Correct Handle Installation

Step 4: Remove Protective Film from the EggNest™ Complete Flex Shield

The leaded acrylic panels of the Complete Flex Shield are shipped with a protective paper film to prevent scratching or marring of the shield finish. Once the shield is fully installed, remove the film from the shield to allow for full visibility.

Use of the EggNest™ Complete Flex Shield

Loading the Patient

Prepare the EggNest Complete Flex for patient loading as follows:

1. Move the EggNest Complete Flex Shield away from the patient loading area to provide room for the patient to be transferred to the patient table.
2. Position the Shield in an area that is clear of any sterile preparation tables and position it for draping.

Draping the Complete Flex Shield

1. Open sterile pouch and set in the sterile field.
2. The Complete Flex Shield should be rotated with the handle facing the sterile operator.
3. Using proper sterile technique, cover the Complete Flex Shield with sterile drape. A second non-sterile operator can be helpful for shield draping to assist in moving components into position and manipulating the sterile drape from the (non-sterile) inside of the drape.
4. Fully extend sterile drape to the upper edge of the Complete Flex Shield. The hooks on the upper edge of the Complete Flex Shield are intended to hold the elastic band of the drape to prevent the drape from bunching the Complete Flex Shield Fringe.
5. Rotate the Complete Flex Shield into position over the patient access site.



Figure 6: Draping the Shield Assembly

Operation During Procedure

In general, the EggNest Complete Flex Shield 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 Complete Flex Shield when rotated out of the PA projection. The Complete Flex Shield may be moved as needed to allow for this x-ray system movement.

Placement of the draped Fringe component of the Complete Flex Shield directly on the draped patient will reduce the scatter radiation emanating from the patient towards the operator.

Rotating Side Panels

Both the left and right side panels of the Complete Flex Shield have the ability to rotate in both directions. To move the side panels, grasp the shield handle with one hand while rotating the side panel to the desired angle. **Note: The shield will provide the largest area of protection when the shield is flat (panels are not angled).**

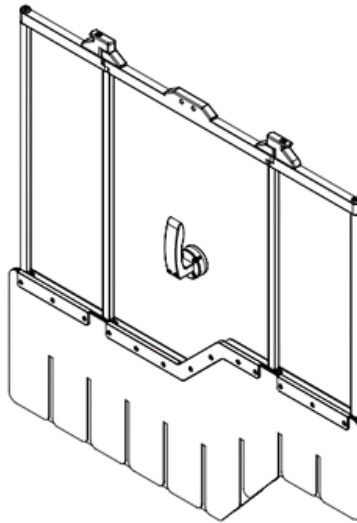


Figure 7: Side Panel Rotation

Precautions

Safe operation of the EggNest™ Complete Flex Shield depends on proper use of the system.

Scatter Radiation Protection

The most effective scatter radiation shielding depends on using the EggNest Complete Flex Shield according to the directions.

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

Contact with the X-Ray System

If the EggNest Complete Flex Shield comes into contact with the x-ray tube housing or detector, the Complete Flex Shield should move out of the way. If the interaction prevents movement of the c-arm, move the table or x-ray gantry in order to disengage the system or move the Complete Flex Shield away from the x-ray unit.

CAUTION: If the x-ray detector comes into contact with the EggNest Complete Flex Shield, move the x-ray table or the c-arm to disengage. **DO NOT** force the EggNest Complete Flex Shield or c-arm components past each other.

Safely Using the Complete Flex Shield

The Complete Flex Shield should always be sterilely draped and rotated with care. Movement of the Complete Shield in the laboratory must always be performed with careful intent in order to avoid collisions with monitors and other equipment in the room.

CAUTION: Proper placement and usage of the Complete Flex Shield is required. Failure to do so may result in the Complete Flex Shield colliding with other objects in the room.

The Complete Flex Shield is manufactured from a polymer that contains lead oxide. If the Complete Flex 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 and components of the EggNest Complete Flex Shield. Keep fingers or skin folds away from moving edges and areas of movement.

Care and Maintenance

Cleaning and Disinfection Procedure

1. Only use wipe disinfectants. Spray disinfectants must not be used.
2. Disinfection procedures must comply with applicable regulations and hospital infection control protocols.
3. If surfaces become contaminated with potentially infectious materials (e.g., blood or other bodily fluids), they should be disinfected immediately.
4. Perform routine disinfection according to the hygiene and infection control plan established by the operator.
5. Use only cleaning and disinfecting agents that will not negatively affect the materials or surfaces of the system. ***Solutions containing chlorine, ammonia, alcohol and acetone compounds, as well as abrasive cleaning products and scouring agents, may damage surfaces or materials, affecting transparency of the acrylic shield.***
6. Verify compatibility of cleaning agents with the device materials (e.g., stainless steel, aluminum, plastics, lead acrylic surfaces).
7. If uncertain about compatibility, test the disinfectant on a small, inconspicuous area before full application.

Be sure to clean all surfaces in order to prevent transmission of infectious agents or biohazardous materials to staff or between patients.

ATTENTION

All procedures must follow applicable hospital hygiene regulations and institutional infection control policies. The system components are not designed for sterilization.

Product Disposal

If the EggNest Complete Flex is to be removed from service at the end of useful life, it must be returned to Egg Medical for disposal.

Egg Medical Product Warranty

What the Warranty Covers

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

This includes:

- Structural defects in the EggNest Complete Flex Assembly (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 go to the website <https://eggmedical.com> and click the “Contact Us” tab. 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.

