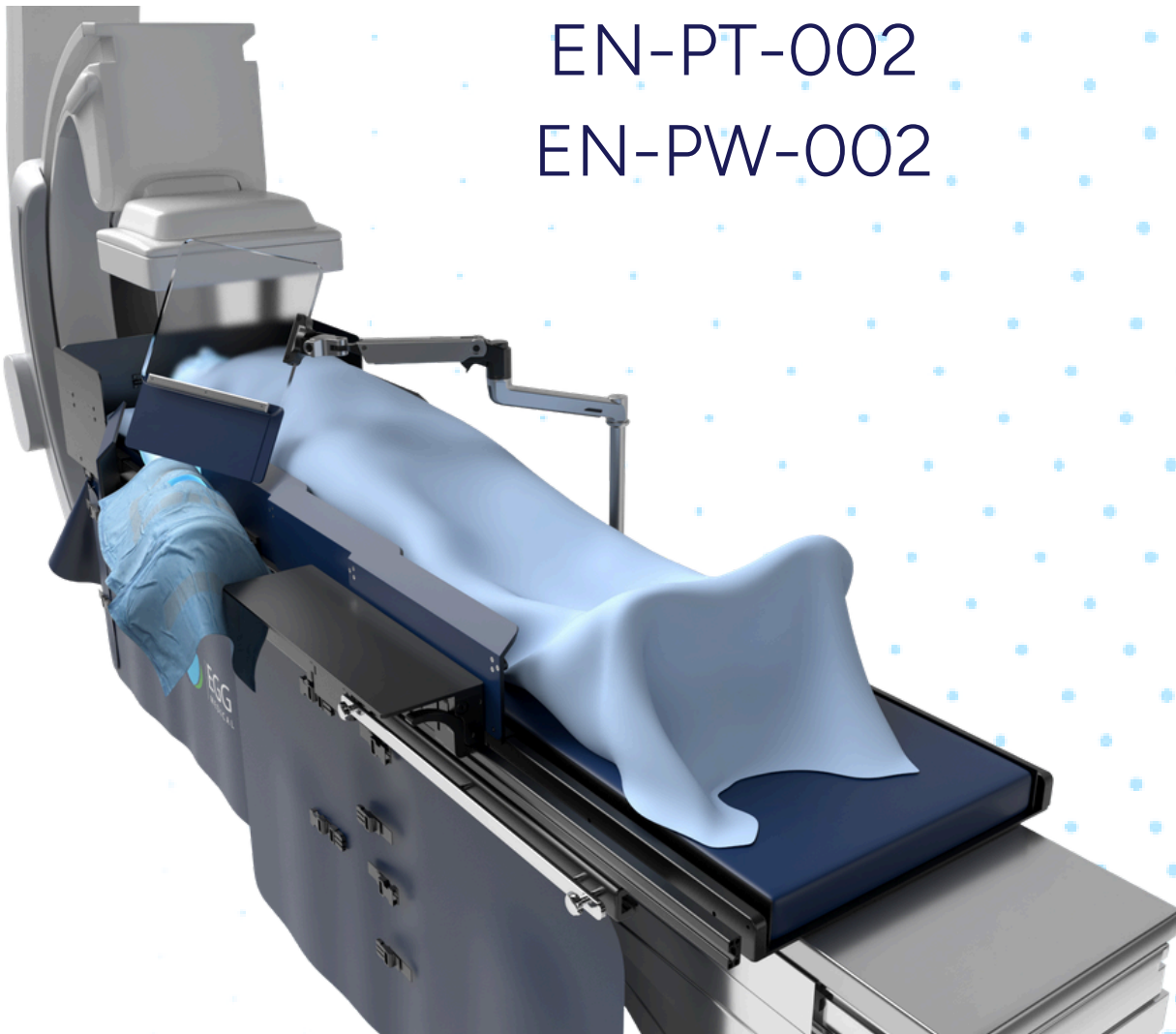


EGG[®] NEST[®] PROTECT 2.0

User and Service Manual for:
EN-PT-002
EN-PW-002



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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.

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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® Protect

EggNest Protect Scatter Radiation Protection Platform

The EggNest Protect is an integrated scatter radiation protection shielding system. The intended purpose of the EggNest Protect 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 Protect in blocking scatter radiation depends on proper use of the shielding system. The EggNest Protect 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 89% to the staff on average (up to 98% for some positions) in the procedure room.

The EggNest Protect is designed and manufactured by Egg Medical, Inc.



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

Components of the EggNest® Protect

Base Platform

The Base Platform sits on the X-ray table in place of the existing patient mattress. The Base Platform is comprised of a series of carbon fiber plates with integrated rails and receivers for the attachment of shielding around the system. The Base Platform (Figure 1) is covered with a detachable low-attenuation mattress that provides for patient comfort.



Figure 1: Base Platform

A detailed description of the components are as follows:

- I.** The upper carbon fiber base is composed of a single sheet of carbon fiber.
- II.** Carbon fiber tubes are mounted to the underside of the patient left and right sides of the upper base system. These slotted tubes are used to contain connectors that attach to the flex shielding below the table.
- III.** The lower carbon fiber base is a single carbon fiber sheet to which a series of rails are mounted. Polymeric rails on the left and right side of the lower base unit are connected as well to the upper base unit at installation.
- IV.** The rails provide for attachment points for the Arm Positioning System, the Workstation, the Sliding Hip Shield System and the Clear Spot Shield rail system.

Side Hanging Flex Shields

The Side Hanging Flex Shields are vinyl-covered curtains that contain material that has the radiation-shielding equivalent of 0.5mm lead. These shields are mounted to connectors that reside within the carbon fiber tubing of the Base System upper half as shown in Figure 2.

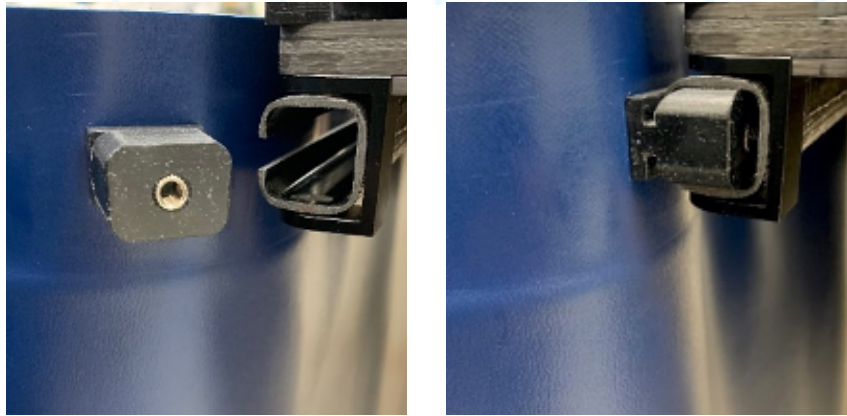


Figure 2: Side Hanging Flex Shield Connectors

The Side Hanging Flex Shields are designed to be flexible in order to move with the motion of the X-ray gantry to allow for imaging angles. The shields contain semi-flexible stays that maintain the shape of the shielding and prevent them from impinging on the X-ray emitter and blocking the X-ray images of the patient.

The Side Hanging Flex Shields have two additional features that provide for outstanding imaging access while continuing to afford good scatter radiation protection.

I. Flex Shield retraction: If steep X-ray angles, lateral imaging or rotational angiography is desired, the Flex Shields are designed to be retracted to move out of the way of the X-ray unit. The shielding is unlatched from the base unit using the rubber connector at the head of the table (Figure 3) and the Side Shields unbuckled from the Head Hanging Flex Shield (Figure 4).



Figure 3: Shield Unlatched



Figure 4: Shielding Unlatched

The Side Shield can then be slid towards the waist of the patient as shown in Figure 5.



Figure 5: Side Hanging Flex Shields retracted

Using the buckles on either end of the shield, they can be buckled to themselves to bundle the shielding and prevent it from moving during the procedure as shown in Figure 6.



Figure 6: Retracted shields buckled

When the need for steep angled imaging is complete, the shields can be unbuckled and returned to their fully deployed configuration to provide maximum scatter radiation protection.

II. Arm imaging: If imaging of the patient arm is desired during right arm access, the shielding can be moved away from the side of the patient to allow for the desired visualization. When using a radial arm board, side hanging shields need to be moved in order to visualize the patient arm during right arm access (See "Flex Shield Retraction" on pages 9-10).

Head Hanging Flex Shield

The Head Hanging Flex Shield is a vinyl-covered curtain that contains material that has the radiation-shielding 0.5mm Pb equivalent. This shield is mounted to a base plate that mounts to connectors in the base system upper half as shown in Figure 7.



Figure 7: Placement of Head Hanging Flex Shield

The Head Hanging Flex Shield is buckled to the Side Hanging Flex Shields during normal use to maintain the integrity of the continuous shielding around the head of the patient table. The Head Hanging Flex Shield is designed with a split in the center of the shielding to allow the X-ray unit to be easily moved into position under the patient from the head of the table at the start of the procedure.

Table Skirt Shield

The Table Skirt Shield is a vinyl-covered curtain that contains material to provide 0.5mm lead-equivalent shielding. This shield is designed to mount to the table rail on the X-ray system. The Table Skirt Shield can articulate to conform to the shape of the C-arm table to eliminate shielding gaps and can be pivoted to allow for steep angulation of the C-arm.

The Table Skirt Shield is designed with an external rail component to provide for the attachment of accessories that would typically be mounted to the table rail such as C-arm system controls. The Table Skirt Shield can be used in place of any OEM shielding attached to the table rail if already present on the system.

Hip Check Shields

The Hip Check Shields are vinyl-covered curtain components that contains material to provide 0.5mm lead-equivalent shielding. This shields are attached to the Workstation rail on a sliding mount and drape over the top of the Table Skirt Shield to provide protection for any gaps at the table edge, and are designed to stay in position on the outside of the Table Skirt Shield when the Table Skirt Shield is pivoted.

The Hip Check Shield configuration is based on the make and model of the C-arm table to avoid interfering with C-arm controls mounted on the Table Skirt rail. The shields can be repositioned up and down the Workstation rail in an instance where they need to be moved for access or imaging. The Table Skirt Shield with Hip Check Shields are shown in Figure 8 below.

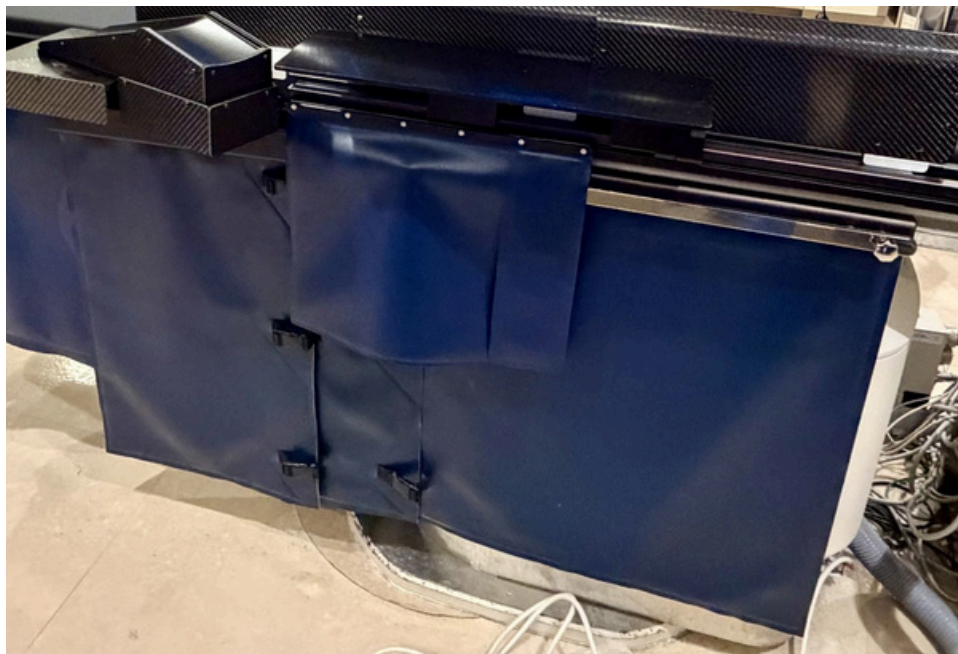


Figure 8: Table Skirt Shield with Hip Check Shields Installed

Arm Positioning System

The Arm Positioning System is designed to hold the right arm of the patient during procedures that require radial, ulnar, brachial or axillary access. This system is designed to reside upon the rail of the upper base system as shown in Figure 9 using the channel components on the underside of the system.

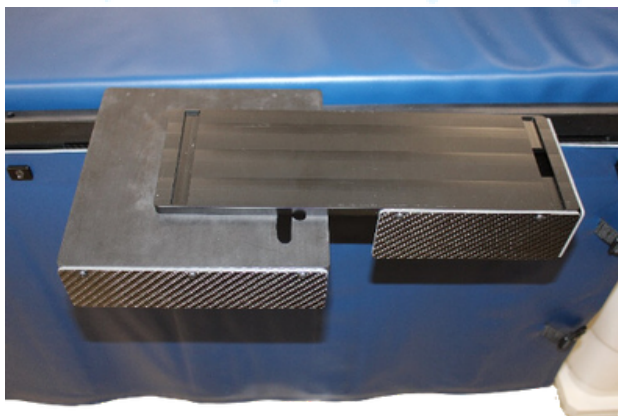
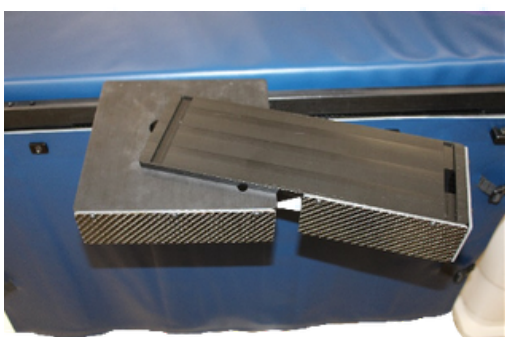
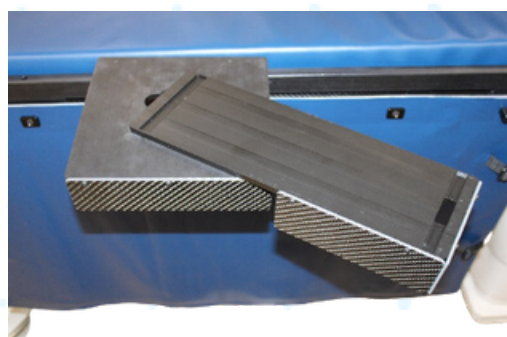


Figure 9: Arm Positioning System Base

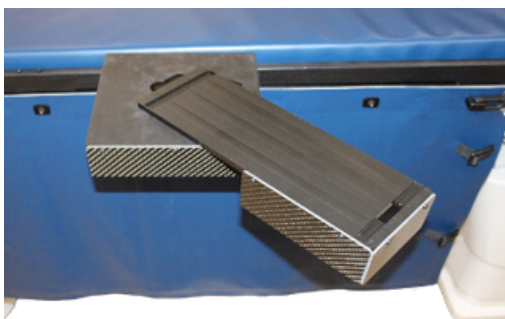
The Arm Positioning System is used to maintain the position of the patient arm at the desired angle for the physician to access it during the procedure. The system has five prescribed angles at which it can be locked – 0° to 60° in fifteen-degree increments. See Figure 10.



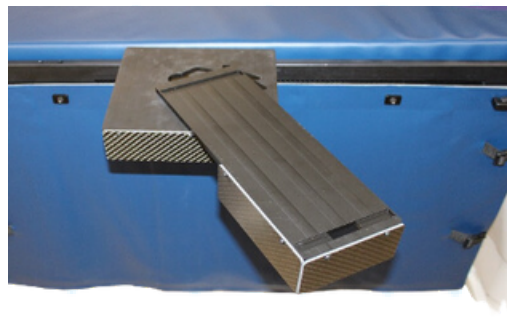
15° angulation



30° angulation



45° angulation



60° angulation

Figure 10: Arm Positions

The Arm Positioning System has an optional Arm Holder that can be used to support the wrist of the patient in an extended position to facilitate radial artery access. This Arm Holder latches into the base of the arm positioning system as shown in Figure 11. If the Arm Holder is not needed for a procedure, it can be removed and the patient arm placed directly on the Arm Positioning Base.

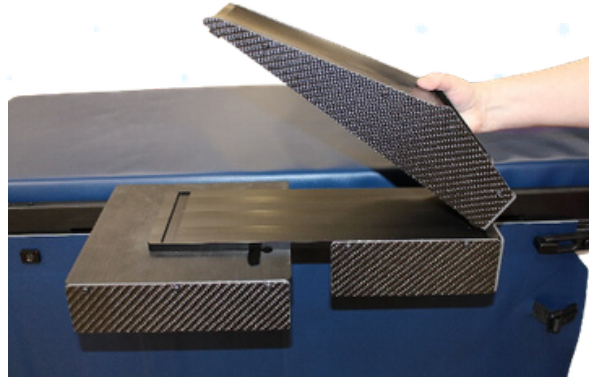


Figure 11: Removable Arm Holder

Components of the Arm Positioning System contain shielding material to reduce the scatter radiation that can be emitted at or near the patient arm. The shielding is designed to avoid interference with arm imaging in the PA projection.

The Arm Positioning System can be disassembled for cleaning. The articulating Arm Positioning Base can be removed from the Base Connector as shown in Figure 12.



Figure 12: Arm Positioning System Disassembly

Upper Flip Shields

The Upper Flip Shields are components that can be placed on both the patient left and right sides of the table. They each consist of a radiolucent carbon fiber jam board that is designed to slide under the patient mattress and a shielding flip board that is connected to the jam board with a pair of friction hinges that maintain the shielding position when placed as shown in Figure 13.

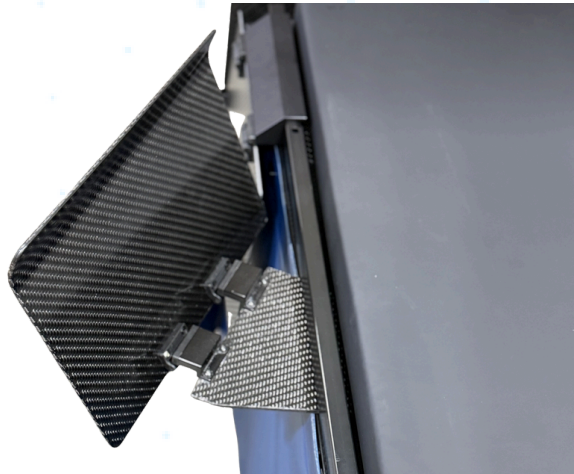


Figure 13: Upper Flip Shield Placement

The shielding flip board consists of 0.5mm Pb equivalent material. The jam board is placed under the patient mattress through a slot in the upper base table rail and can be used in conjunction with other system components such as the Arm Positioning System. The Upper Flip Shields are most effective when placed close to the patient, but can be pulled outward from the patient as needed to accommodate patient body habitus.

Head Flip Shields

The Head Flip Shields are similar components constructed of X-ray shielding material laminated between two sheets of carbon fiber. The Head Flip Side Shields at each of the patient shoulders are mounted to brackets that are designed to recess in matching receiver slots in the upper base rail. These Head Flip Shields are hinged to be allowed to fold down for patient transfer and folded up into position for the procedure in order to protect staff at either side of the head of the patient. See Figure 14.



Figure 14: Head Flip Shield Placement

The Upper Head Flip Shield at the top of the table is mounted to a specially-designed jam board that slides under the mattress and is held in position by grooves at the base of the upper sled rails. This Head Flip Shield component is hinged to the 0.5mm Pb equivalent base plate which protects the patient's head from radiation during procedures. The shield is raised into position to protect staff positioned at the head of the table.

Workstation

The Workstation is a tool designed to provide a working surface for the physician who is utilizing the Arm Positioning System for patient arm access. The Workstation is a flat surface that allows for catheters and wires to extend from the arm access site without having to rest across the legs of the patient. See Figure 15.



Figure 15: Workstation Placement

The Workstation can be mounted to the outer side rail of the Base System on the patient right side, as shown in Figure 16. It can be moved up and down the rail into optimal position by simply actuating the lever and sliding the Workstation on the rail. The Workstation should be removed during patient transfer.



Figure 16: Workstation Latch Mechanism

Telescoping Hip Shield

The Telescoping Hip Shield is an interconnected series of rigid shields that are intended to be deployed along the right side of the patient in front of the physician. The shields are constructed of carbon fiber and 0.5mm Pb X-ray shielding material, and are designed to slide along the inner rail on the patient right side of the EggNest® Protect system as shown in Figure 17. They provide the greatest protection when fully extended and moved up into the armpit of the patient under the sterile drape.

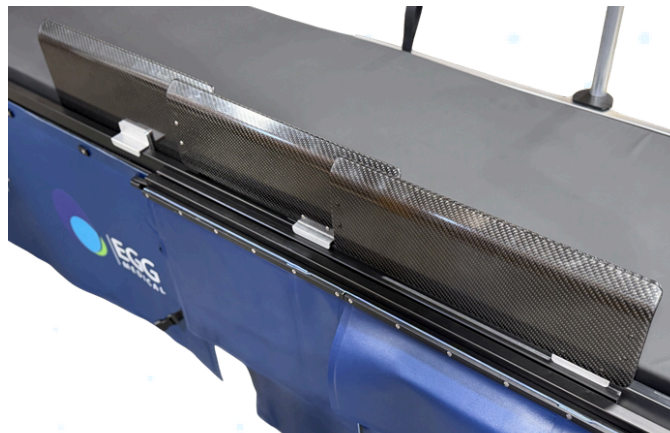


Figure 17: Telescoping Hip Shield

They may be slid down the rail and nested at the foot of the table for patient transfer. Alternatively, they may be removed from the table by simply lifting them off of the rail.

Clear Spot Shield

The Clear Spot Shield is a translucent acrylic shield that contains X-ray shielding material connected to an articulating arm. See Figure 18. This arm is connected to a receiver mounted on a slide within a rail on the patient left side of the table as shown and is designed to be moved up and down the table on the slide to provide protection to the physician in a number of different positions. The Clear Spot Shield may be removed from the system by pulling the Clear Spot pole from the receiver.



Figure 18: Clear Spot Shield

⚠ CAUTION - Care must be taken to prevent the Clear Spot Shield from swinging during installation and removal, as the acrylic material may be damaged if impacted.

Anesthesia Hoop

The Anesthesia Hoop is used to control the sterile drape over the head of the patient during procedures that require general anesthesia. The Anesthesia Hoop is a flexible gooseneck design that can be shaped into a preferred geometry to cover the appropriate portion of the patient anatomy, and connects to the EggNest® Protect using two receiver holes built into the Base System Rail near the shoulders of the patient (Figure 19).

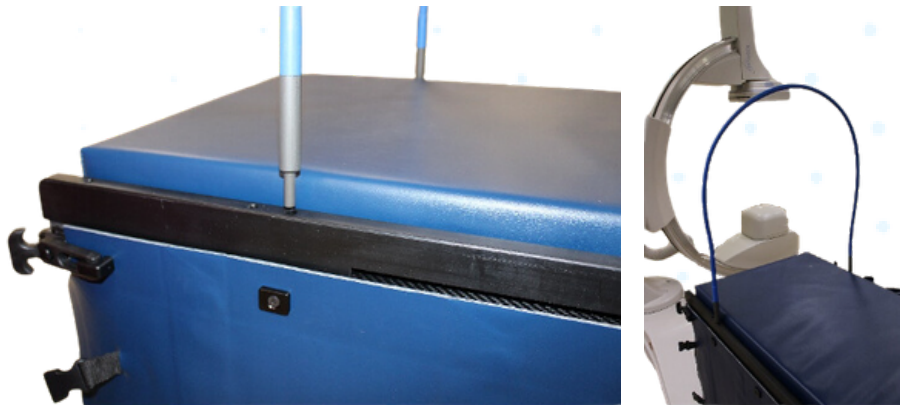


Figure 19: Anesthesia Hoop

Optional Mattress Extender

The Mattress Extender is an optional component used to extend the working surface of the mattress beyond the length of the EggNest Protect Base System. This mattress component is mounted to the table in the X-ray laboratory in a position caudal to the end of the EggNest Protect Mattress.

Installation of the EggNest® Protect System

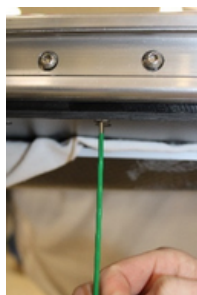
The EggNest Protect is designed to rest on a standard X-ray table by replacing the OEM patient mattress.

Step 1: Prepare the X-ray table

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

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

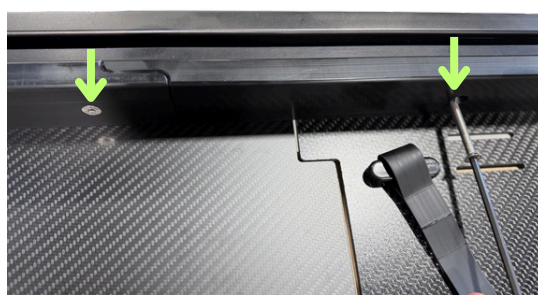
Place the upper and lower halves of the Base Platform on the X-ray table at their respective ends of the table. Abut the inner edges of the two halves of the platform and align the polymer rails. Fasten the two halves together using the provided hardware. The four M4 screws with red thread locker attach the rails together from the underside of the system. Apply Loctite 263 to the remaining fasteners. The four M6 x 30mm long button head screws are used on the patient left side to secure the Clear Spot rail. The two M6 x 45mm flat head screws are used on the patient right side to attach the Workstation rail (Figure 20).



**M4 Screws
(Underside)**



M6 Screws (Left Side)



M6 Screws (Right Side)

Figure 20

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

The EggNest Protect should be centered on the table with approximately 2cm-4cm of the Base Platform overhanging the head of the table. Thread the Table Strap through the outermost slot on each side of the Base Platform upper half as shown in Figure 21. Connect the Velcro strap on the upper surface of the base platform beneath the mattress by affixing the "loop" layer against the "hook" layer.

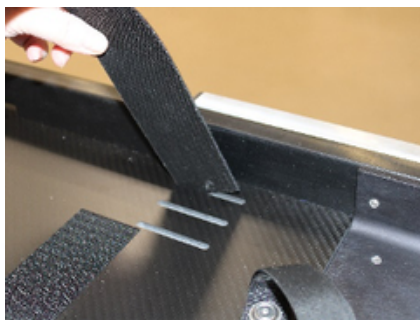


Figure 21: Table Strap Placement

Step 4: Place Mattress Topper on top of Base Platform

Once the Base Platform is secured on the X-ray table, place the Mattress on the Base Platform. See (Figure 22). Ensure that the Velcro strips on the underside of the Mattress align with the Velcro strips on the Base Platform.



Figure 22: Mattress Placement

Step 5: Attach the Side Hanging Flex Shields

The Left and Right Side Hanging Flex Shields are installed by sliding the shield connectors through the slotted carbon fiber tube on the Base System as shown in Figure 23.



Figure 23: Side Hanging Flex Shield placement

Advance the shields through the tube until the proximal latch mechanism can be attached at the end of the tube as shown in Figure 24.



Figure 24: Proximal Latch

Insert the connector stop on the head end of the tube and attach the distal latch mechanism as shown in Figure 25.



Figure 25: Connector and Distal Latch

Step 6: Attach the Head Hanging Flex Shield

The Head Hanging Flex Shield is installed by aligning the tabs on the Head Hanging Flex Shield hardware with receivers in the head of the Base System and dropping them into place. See Figure 26.



Figure 26: Head Hanging Flex Shield placement

The Head Hanging Flex Shield is attached to the Side Hanging Flex Shields using the buckles on either end of both shields as shown in Figure 27.

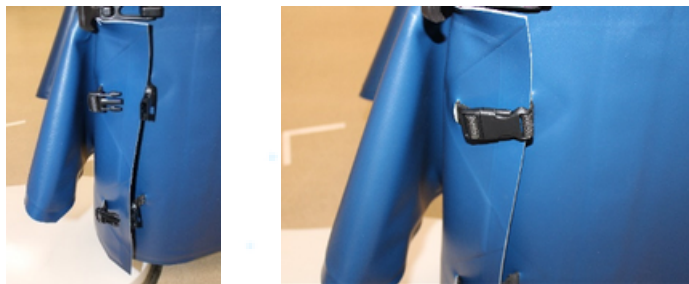


Figure 27: Shield Buckling

Step 7: Attach the Workstation to the Side Rail

The Workstation is mounted to the outer Side Rail on the patient right side of the table. Installation is performed by depressing the lever arm beneath the right side of the Workstation and placing the Workstation clips on the rail before releasing the lever (Figure 28). The Workstation should be removed for patient transfer.



Figure 28: Workstation placement

The Workstation may be moved up and down the rail by depressing the lever and sliding the Workstation to the desired position.

Step 8: Mount the Clear Spot Shield

The Clear Spot Shield is mounted to the EggNest® Protect by inserting the cylindrical base of the pole into the receiver mount found on the slide rail attached to the patient left side of the system as shown in Figure 29. Once the Clear Spot Shield is mounted on the system, ensure that the slide is functional by moving the Clear Spot Shield up and down the left side of the table.



Figure 29: Clear Spot Shield Placement

Step 9: Install the Upper Flip Shields

The Upper Flip Shields are removable shields that are placed in the slot found at the base of the rail in the upper half of the Base System. Insert the carbon fiber component of the Upper Flip Shield in the slot so that the carbon fiber component slides between the Mattress and the carbon fiber base sheet as shown in Figure 30.

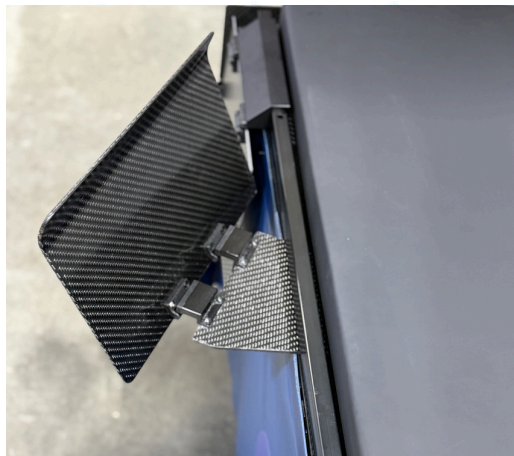


Figure 30: Upper Flip Shield Insertion

These shields can be flipped down for patient transfer and back up for clinical use, or removed from the table for patient transfer if desired.

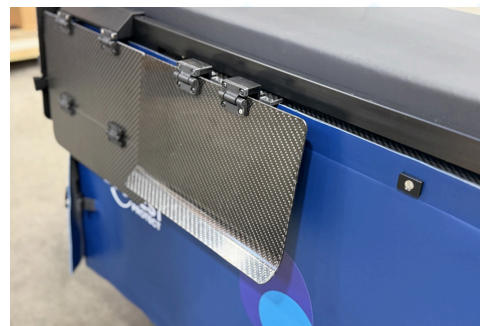
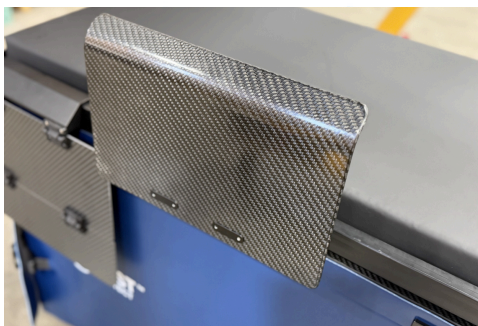


Figure 31: Side Flip Shield articulation

Step 10: Install the Head Flip Shields

The Head Flip Shields are removable shields that are placed around the head of the patient. The Upper Head Flip Shield at the top of the table is placed by inserting the 0.5mm Pb carbon fiber base plate under the patient mattress in the receiver slots at the bottom of the left- and right-side rails. These shielding panels can be rotated up for protection at the head of the table. See Figure 32.



Insertion of Upper Head Flip Shield



Upper Head Flip Shield deployed



Upper Head Flip Shield lowered

Figure 32

The Side Head Flip Shields at the sides of the patient head are placed by aligning the mounting clips into the receiving locations on the left and right side rails. These shields may also be rotated up to provide protection around the sides of the patient head during procedures. See Figures 33 and 34.



Figure 33: Installation of Side Head Flip Shields

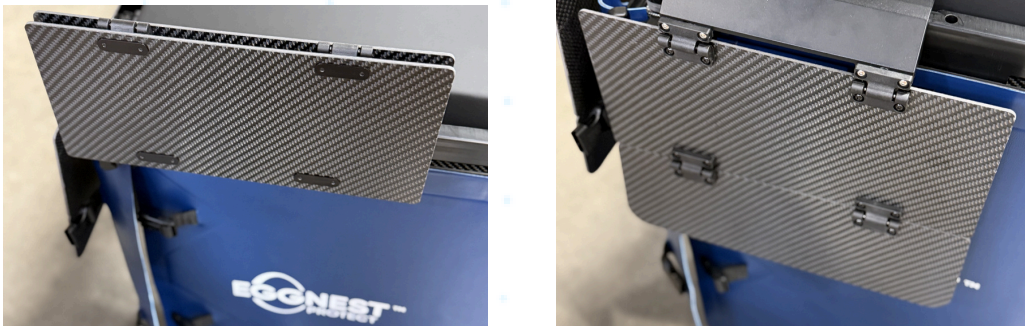


Figure 34: Side Head Flip Shields partially and fully lowered

Step 11: Install the Arm Positioning System

The Arm Positioning System is used when right arm access is desired for the procedure. The Arm Positioning System base is installed by placing the U-Channel clips on the underside of the base onto the right-side rail of the Base System as shown in Figure 35. The Arm Positioning System may be used with or without the Arm Support component.



Figure 35

Step 12: Install the Telescoping Hip Shield

The Telescoping Hip Shield is installed on the inner rail on the patient right side of the Base Platform. All three U-Channel clips must be engaged with the rail to allow for correct component performance. The Telescoping Hip Shield panels can slide up and down the rail and move relative to one another in order to optimize shielding use and placement. Full extension of the telescoping shields maximizes shielding coverage along the patient right side of the table. See Figure 36.

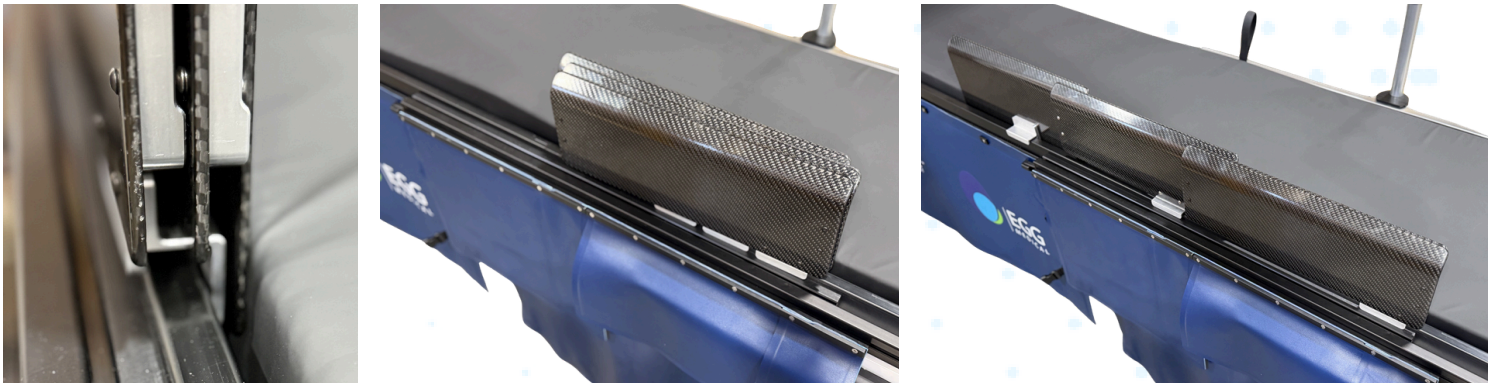


Figure 36: Telescoping Hip Shield

Step 13: Installing the Patient Strap

There are two anchor strap loops installed in the Base System beneath the patient mattress. These loops are intended for use to install a patient strap based on hospital recommendations. Egg Medical provides a Velcro strap that can be used for securing the patient to the table by threading the strap through the loops shown in Figure 37. The anchor strap loops are designed to work with many versions of patient straps per hospital preference.

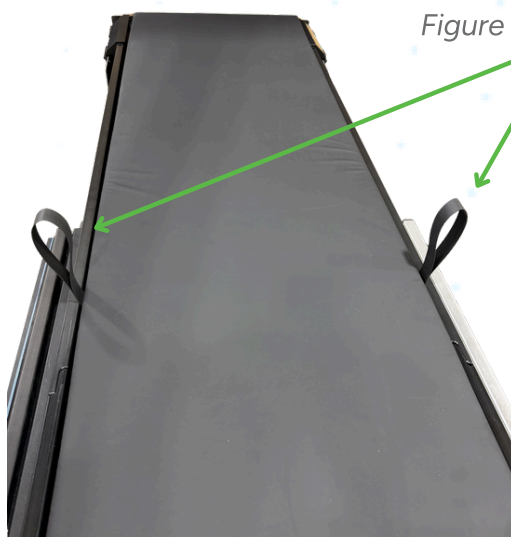


Figure 37: Patient Strap Anchor Loops

Use of the EggNest® Protect System

Loading the Patient

Prepare the EggNest Protect for patient loading as follows:

1. Make sure that the EggNest Protect has been wiped down according to hospital policy to remove foreign or biological material and that the EggNest Protect is attached to the X-ray table.
2. Fold down the Head Flip shields and Upper Flip Shields. The Upper Flip Shields can be removed entirely if desired.
3. Slide the Telescoping Hip Shield down to the foot of the table or remove from the EggNest Protect if loading the patient from the patient right side of the table.
4. Remove the Arm Positioning System and Workstation from the EggNest Protect if loading the patient from the patient right side of the table.
5. If loading from the patient left side of the table, move the Clear Spot Shield to the end of the rail or remove and stow.
6. Cover the EggNest Protect System with a sheet or paper drape prior to loading patient.
7. If loading from a patient bed, slide the bed next to the EggNest Protect.
 - a. Using a sliding board or hover mat, move the patient from the bed to the EggNest Protect.
 - b. Take care that neither the patient bed or the EggNest Protect move as the patient could fall through the gap.
8. With the patient on the EggNest Protect, attach the Patient Safety Strap as directed by your hospital policy.
9. If a radial approach is anticipated, position the Arm Positioning System and Workstation as desired.
10. Before covering the patient with a sterile drape, raise all of the Head Flip Shields, place the Side Flip Shields and slide the Telescoping Hip Shield as far up into the armpit of the patient as practical.
11. After the sterile 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 placed over the patient abdomen to align with the room hanging shield.

Draping the Clear Spot Shield

To maximize radiation protection, it is important to use the Clear Spot Shield (when not using the EggNest® Complete Shield) during the procedure, as this provides significant protection to the head and upper body of the operator. Proper technique is required to drape the Clear Spot Shield correctly and maintain the sterile field.

1. Open sterile pouch and set drape in the sterile field.
2. Clear Spot Shield arm should be slightly extended for ease of draping.
3. Rotate the Clear Spot acrylic panel so that the soft shield is positioned at the top of the shield.
4. Using proper sterile technique, cover the Clear Spot Shield with sterile drape.
5. Fully extend sterile pouch to the base of the pole.
6. Rotate the Clear Spot Shield back into ready position.

Operation During Procedure

⚠️ Raise all Flip Shields and place the Telescoping Hip Shield before draping the patient

In general, the EggNest® Protect 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 Protect 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.

The shielding on the system is modular and easily adjusted during the procedure if needed. The Flip Shields and Telescoping Hip Shield may be moved during the procedure under the sterile drape if needed to accommodate access and optimize shielding protection.

Placement of the draped soft shielding component of the Clear Spot Shield directly on the draped patient will reduce the scatter radiation emanating from the patient towards the operator.

The optional ScatterPro™, ScatterScoop™, EggPad and Egg Blanket accessories can be used as supplemental shielding to protect from scatter radiation emanating from the patient during the procedure.

Precautions

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

Scatter Radiation Protection

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

CAUTION: Failure to adjust shields properly will result in less effective scatter radiation protection.

Patient Loading

Like all patient transfers, transferring a patient from a bed or gurney to the EggNest Protect 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 Protect and the transfer device. Use of auxiliary transfer aids such as a hover mat or a slide board can make the transfer easier and safer. Be sure that the EggNest Protect is firmly attached to the X-ray table and does not move during transfer.

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

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

Patient Stability on the EggNest Protect

It is important to properly position the patient on the EggNest Protect. The patient should be positioned with the head about 3-4 inches from the top of the EggNest Protect and centered on the mattress from left to right. For more safety from roll-off accidents, the use of the accessory Patient Safety belt is recommended, consistent with hospital regulations.

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

Contact with the X-Ray System

If the shields or other EggNest Protect 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 X-ray gantry in order to disengage the systems.

It is expected that the lower X-ray C-arm will push the Flex Shielding 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 the position of the X-ray tube housing and C-arm relative to the EggNest Protect to ascertain the cause of the problem.



If the Flex Shielding or another component of the EggNest® Protect is 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 Shielding is stuck on the C-arm, gently lift the Flex Shielding to disengage. In any case, DO NOT force the EggNest Protect or C-arm components past each other.

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

Safely 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 follow hospital instructions for safe disposal of lead-containing materials, or contact Egg Medical for instructions on proper disposal, repair or replacement.

Pinching Hazards

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

EggNest Protect Compatibility

Considerations for use with the following systems from GE HealthCare: Innova IGS Systems, Discovery IGS Systems, Allia IGS Systems and Allia Pulse IGS Systems

Table Tilt

Table tilt testing was not conducted on the Innova IQ table with the EggNest® Protect system.

WARNING: Table tilt on the Innova IQ table must not be used with the EggNest Protect system installed.

Patient Weight

The EggNest Protect system resides on the surface of the GE table, reducing the weight capacity of the system. Care must be taken to ensure that the table weight capacity is not exceeded. The EggNest Protect is a modular system, allowing for individual components to be removed as needed to ensure safe weight limits are maintained.

WARNING: EggNest Protect system weight must be considered in conjunction with patient weight. See Patient Weight Configuration Tables on subsequent pages for recommended shielding configurations to reduce table weight.

Flex Shield Positioning

The below-table Flex Shields are designed to allow the X-ray tube to pass under the table at the beginning and end of the patient procedure. It is important to ensure that the X-ray tube is between the shields and under the patient at the start of the procedure.

WARNING: Verify that the Flex Shields are around the tube before performing X-rays.

X-Ray System Collision with EggNest

The addition of the EggNest Protect system on the table may increase the risk that the X-ray system can collide with the EggNest.

WARNING: Collision may happen and remains the operator responsibility: GE recommends orienting the X-ray gantry at +90 degrees or -90 degrees during procedure.



3D Acquisition / Cone Beam CT

The EggNest® Protect system is designed to work with 3D acquisition, though accommodations must be made to shield configuration to ensure appropriate imaging.

CAUTION: 3D acquisition (CBCT) not recommended with full shielding installed. Remove shielding in the acquisition area prior to imaging.

Imaging Artifact

The EggNest Protect system is designed to be radiolucent to allow for imaging through the system. Depending on system configuration, some components of the system may be denser than others, leading to potential visibility of EggNest components in the imaging view.

CAUTION: Various shielding support shapes may be visible in images and are not to be confused with artifacts.

CAUTION: The carbon fiber structure of the EggNest base system may be visible in images and are not to be confused with artifacts.

EggNest® Protect 2.0 Component Weights

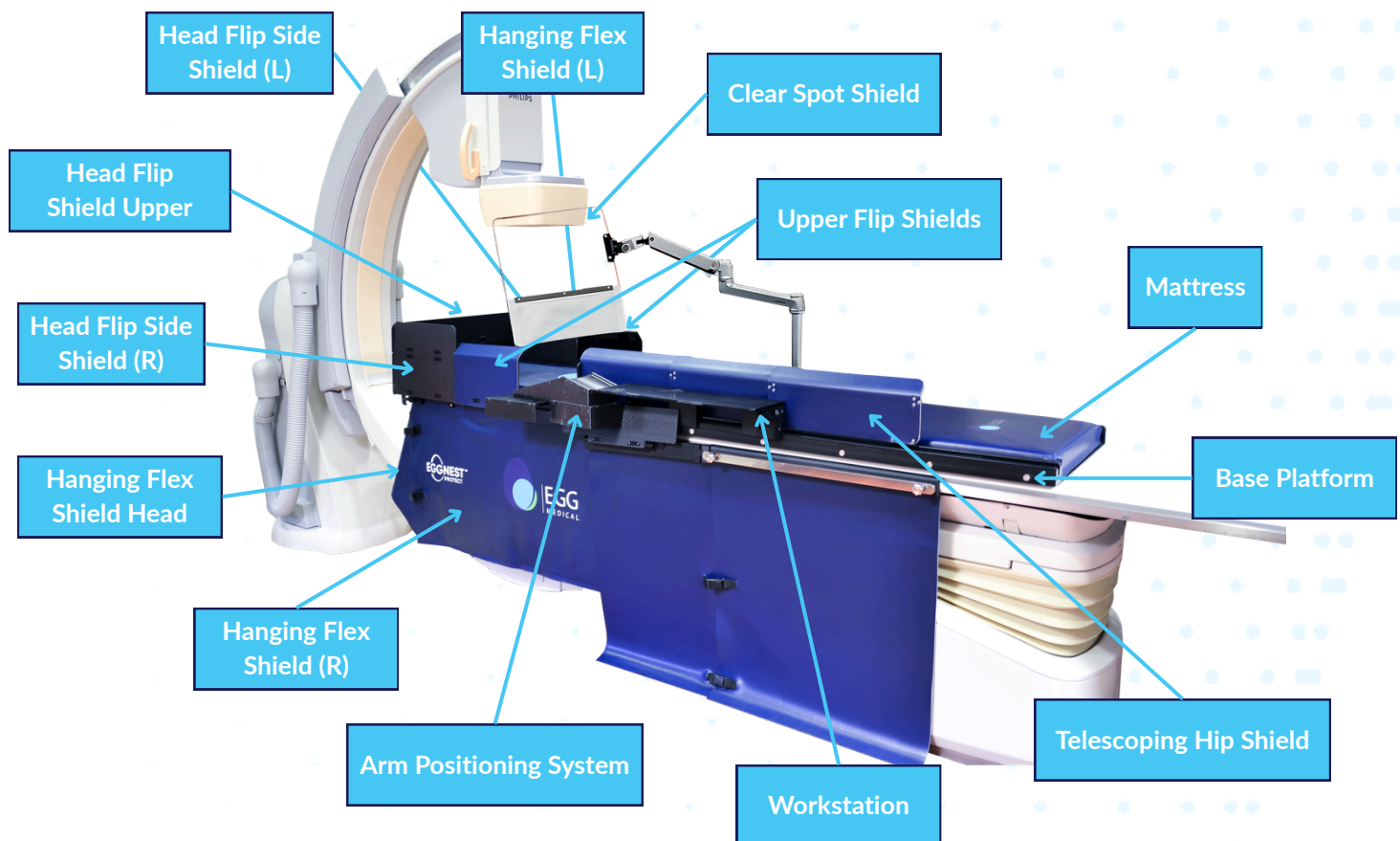
Component	Weight (lb / kg) Standard Width	Weight (lb / kg) Wide Version
Base Platform	53.3 / 24.2	56.6 / 25.7
Mattress	7.1 / 3.2	8.1 / 3.7
Upper Flip Shield (each)	2.7 / 1.2	
Head Flip Side Shield (R)	2.7 / 1.2	
Head Flip Side Shield (L)	2.7 / 1.2	
Head Flip Shield Upper	5.6 / 2.5	6.1 / 2.8
Telescoping Hip Shield	8.2 / 3.7	
Workstation	6.9 / 3.1	
Clear Spot Shield	11.8 / 5.4	
Hanging Flex Shield (R)	10.0 / 4.5	
Hanging Flex Shield (L)	10.0 / 4.5	
Hanging Flex Shield Head	9.0 / 4.1	9.3 / 4.2
Arm Positioning System	6.0 / 2.7	
Hip Check Shield	4.8 / 2.2	
Hardware / Misc.	2.0 / 0.9	

Patient Table Weight Management

GE Innova IQ, Omega IV and Omega V

Maximum allowable patient weight on the GE table is decreased due to the weight of the installed EggNest® Protect system. This weight can be reduced by removing individual components of the EggNest Protect system.

When patients are being treated on a GE table with the EggNest system, use the following system configuration table to determine the appropriate shields to remove from the system to ensure safe weight limits are maintained while maximizing scatter radiation protection.



GE Omega IV and Omega V: Suggested EggNest® Protect 2.0 Components to be Removed

Table Maximum Weight: 204 kg / 450 lb

Increased Weight on Table related to EggNest Protect 2.0: 64 kg / 141 lb

Patient Maximum Weight (full EggNest): 140 kg / 309 lb

Order	Component to remove	Component Weight		Patient Max Weight	
		(lb)	(kg)	(lb)	(kg)
1	Hanging Flex Shield Left	10.0	4.5	317	144
2	Clear Spot Shield	11.8	5.4	328	149
3	Upper Flip Shield Left	2.7	1.2	331	150
4	Head Flip Side Shield Left	2.7	1.2	333	151
5	Hanging Flex Shield Head	9.0	4.1	342	155
6	Head Flip Shield Upper	5.6	2.5	346	157
7	Upper Flip Shield Right	2.7	1.2	348	158
8	Head Flip Side Shield Right	2.7	1.2	357	159
9	All shielding and accessories removed except Base Platform and Mattress			390	177

GE Innova IQ: Suggested EggNest Protect 2.0 Components to be Removed

Table Maximum Weight: 250 kg / 551 lb

Increased Weight on Table related to EggNest Protect 2.0: 56 kg / 124 lb

Patient Maximum Weight (full EggNest): 194 kg / 428 lb

Order	Component to remove	Component Weight		Patient Max Weight	
		(lb)	(kg)	(lb)	(kg)
1	Hanging Flex Shield Left	10.0	4.5	437	198
2	Clear Spot Shield	11.8	5.4	448	203
3	Upper Flip Shield Left	2.7	1.2	450	204
4	Head Flip Side Shield Left	2.7	1.2	452	205
5	Hanging Flex Shield Head	9.0	4.1	461	209
6	Head Flip Shield Upper	5.6	2.5	465	211
7	Upper Flip Shield Right	2.7	1.2	467	212
8	Head Flip Side Shield Right	2.7	1.2	470	213
9	All shielding and accessories removed except Base Platform and Mattress			491	223

Care and Maintenance

Cleaning

The carbon fiber base system is made from materials similar to those used for many X-ray tables. The mattress is durable and cleanable, though it may become discolored if cleaned with an unapproved cleaning agent.

- Only use wipe disinfectants. Spray disinfectants must not be used.
- Disinfection procedures must comply with applicable regulations and hospital infection control protocols.
- If surfaces become contaminated with potentially infectious materials (e.g., blood or other bodily fluids), they should be disinfected immediately.
- Perform routine disinfection according to the hygiene and infection control plan established by the operator.
- 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.
- Verify compatibility of cleaning agents with the device materials (e.g., stainless steel, aluminum, plastics, lead acrylic surfaces).
- 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.

If the mattress develops a cut or a hole, notify Egg Medical for repair. Discontinuity of the 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 Protect® is repaired.

Clear Spot Shield Cleaning

CAUTION: The use of certain disinfectants and cleaning agents can damage the surface and appearance of the Clear Spot Shield acrylic. Refrain from using solutions containing alcohol (e.g. ethanol and isopropanol), oxidizing agents, active chlorine or salt.



CAUTION

The use of certain disinfectants and cleaning agents can damage the surface and appearance of the Clear Spot Shield. Refrain from using solutions containing alcohol (e.g. ethanol and isopropanol), oxidizing agents, active chlorine or salt.



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 six 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® Protect 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 and ScatterScoop™ Radiation Shielding Arm Support

If the Clear Spot Shield or ScatterScoop are damaged, do not use and follow hospital instructions for safe disposal of lead-containing materials, or contact Egg Medical for instructions on proper disposal, repair or replacement.

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 installation.

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.

