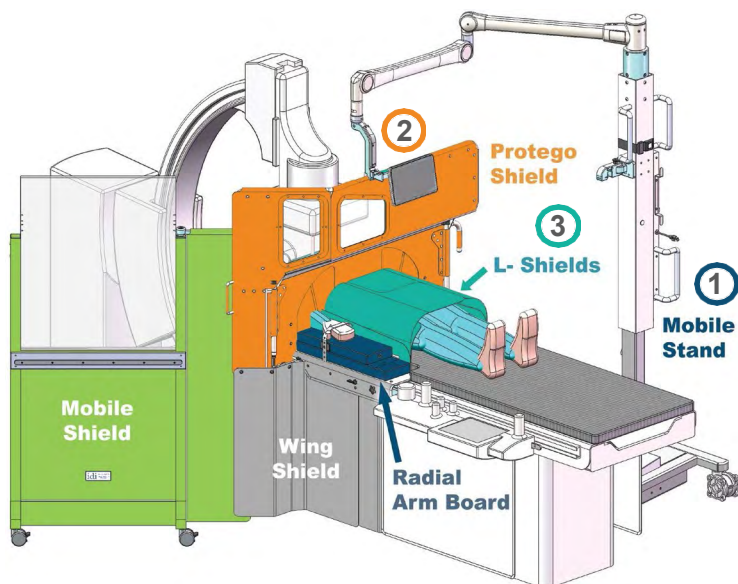


Q-CARD: Procedure Set-Up



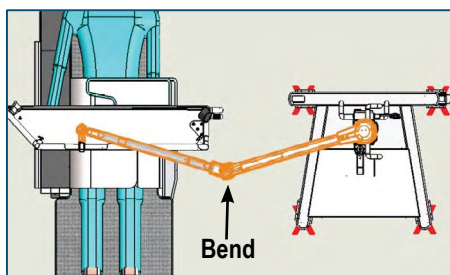
DO NOT USE the Protego® Radiation Protection System until having completed training and read the manual.

BEFORE THE PATIENT IS IN THE ROOM



1 MOBILE STAND POSITIONING

1. Place Mobile Stand on the predetermined marks on the floor for the stand.
2. Lock two casters.
3. There will be a bend in the support arm of the Protego Main Shield. Locate the direction of the bend towards the patient's feet to avoid conflicts with other equipment.
4. Plug Protego into the wall outlet. Plug is located on the Mobile Stand



The support arm must have some bend in it to pan properly.
(Support arm indicated by orange color in image above)

2 TURN MONITOR ON

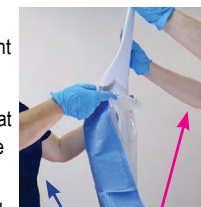
- Power button is located on the bottom of small monitor (see image to the right)
- Allow ~60 seconds to boot
- Tap the touchscreen to cycle through image layouts (single left, single right, left-right split)
- Lock two casters on the Mobile Stand



3 DRAPE THE L-SHIELDS

- A. Sterile person cuffs the sterile drape under fingers and holds it with clear side facing towards the non-sterile person
 - B. Non-sterile person opens the L-Shield with grommets vertically; with small side in left hand
 - C. Non-sterile person folds the L-Shield towards them with tag facing them, grommets on the right
 - D. Non-sterile person places shield into the sterile drape pocket
 - E. Non-sterile person unfolds shield when it is 2/3 of the way into the sterile drape and drops it flat into the drape bag. Sterile person must make sure to have a good grip on the sterile drape as the L-Shield is heavy.
 - F. Bring the L-Shield in the sterile drape over to the back table. Lay it down on a flat surface, peel back and fold down as close to L-Shield edge as possible.
- Place fully draped L-Shields on back table and place gowns and gloves on top of them.

A. TWO PERSON TASK



Sterile Non-Sterile

B.

Non-sterile person holds L-Shield with tag facing them

C.

Fold small (left) side toward you with grommets on right

D.

E.

*Note: L-Shield is heavy, have a firm grip as it drops into the sterile drape

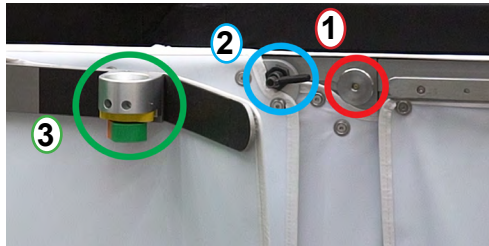
F.

Sterile person peels back, folds the drape as close to shield as possible and sticks it

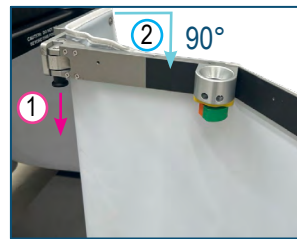
Note: Drape the L-Shields before the back table is set up to avoid space conflicts as the case starts.

AFTER THE PATIENT IS ON THE TABLE

1. MOUNT WING SHIELDS TO RAIL, EXTEND WINGS



- Slide Wing Shield onto table rails and lock by tightening knob (fig 1).
- Turn black lever 180° so the lever faces the foot end (fig 2).
- Turn magnet lock to green facing outwards (fig 3).



- Pull down on black knob to release wing
- Swing Wing out 90° until wing locks in place.
(Opening the wing helps with next step)

2. POSITION ARMBOARD SHIELDING SYSTEM



WARNING: ALWAYS use the right-side Radial Armboard as it provides necessary radiation shielding.

- Place long Radial Armboard first.
- Then add extension piece of board, ensuring the cascading shielding overlaps.
- Place the patient side shield in the patient's armpit and make sure the patient's arm does not lie on the Armboard



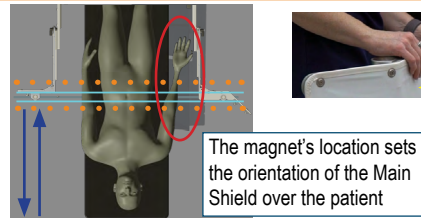
Wing and Radial Armboard reference point



Patient side shield location

3. GENERAL ORIENTATION

- Ensure Wing Shields are aligned to patient umbilicus by sliding the Wing Shield toward head/foot.
- Check patient's arm length is accommodated.



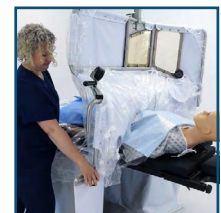
The magnet's location sets the orientation of the Main Shield over the patient



(Wing Shield provides 8" of movement for ease of repositioning)



Moving the Main Shield toward patient's feet can increase the potential angulation of C-Arm and accommodate radial access.



Prep the access site and place the surgical drape over the patient as usual.

4. DRAPE PROTEGO MAIN SHIELD

Each Protego ProKit contains:

1 Protego Main Shield and 2 L-Shield Drapes

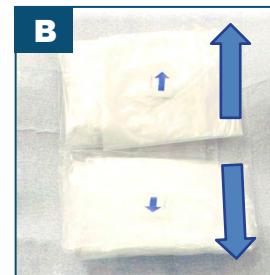
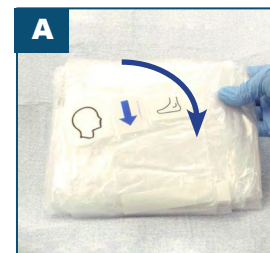
Unfold Protego Shield Drape

- Place the Protego Main Shield drape with the head label toward the patient's head to the left and the foot label toward the patient's feet to the right. (Fig. A) and unfold in the direction indicated by arrow.
- IMPORTANT** - unfold in the direction of the arrows being careful to keep the right side above the top of the table, as shown in Figure B. Throw the top arrow towards the non-sterile draper.
- The sterile and non-sterile sides should spread the drape "like a bed sheet," as wide as possible plus locate the blue dots near the magnet pole.
- The non-sterile side should locate the Protego Main Shield over the drape using the drape seam and bilateral blue dots, as shown in Figure C.



WARNING: Drape sterility will be compromised if the drape falls below the tabletop.

NOTE: THIS PROCESS IS STERILE



C. Lift up and bring the Protego Shield over the patient. Keep it hovering over the patient.

Align the Protego Main Shield with drape's seam to where the shield will be placed. (curved part) Align the drape's blue dots with where magnets are located.



Spread wide like a bed sheet.

Drape Protego Main Shield

Locate Protego Shield over the groin area of the patient. The Shield should be located over the drape's seam, and the **bilateral blue dots** should be at or near the Wing Shield Magnet Locks.

- Center Protego Shield's aperture flaps over the drape's center seam. The drape's blue dots should be near the magnet locks.
- On the patient foot side, place the drape over both top corners of the Protego Shield as shown in **Figure A**.
- The Sterile tech should keep the tape tabs pulled away from the front surface to avoid contamination when wrapping the drape around the handle.** Make sure the blue dots are aligned close to the magnet poles.
- On the C-arm side, wrap elastic area over the shield's side handle. **(Fig B)** Locate the second elastic section and place it over the patient-side hook under the Shield windows. **(Fig C)** Repeat draping procedure on the left side.
- Using tape tabs provided, carefully enclose each side of the Protego Shield.
- Determine your approach*:
Radial approach: place the Protego Shield into the opposite side Wing Shield magnet lock or float until access.
Groin/femoral access: Float the shield low over the patient. The left side can be left unlocked and cantered towards the foot.
- Drape should not cover the C-arm side cameras or foot-side monitor. Look for obvious distortions of the aperture flaps, they should lay flat on the patient facing the foot end of the table. Correct as necessary.



Place drape over top corners of foot-side of Protego Shield



Place drape over side handles while holding the tape side out from the front of the shield to keep sterility



Protego Shield Properly Draped, Foot Side



Place drape on hooks on head-side of Protego Shield



Tape drape closed over the shield



Protego Shield Properly Draped, Head Side



Important! - Techs must pay close attention to ensure sterility as they drape each section of the Main Shield.

RADIAL ACCESS*

- Either keep the Main Shield floating **or** lower the Main Shield into the right side Wing Shield magnet lock, the left side can float to aid steep angulation.
- Sweep the Main Shield over the patient, ensuring aperture flaps are facing toward the patient's feet. Ensure there are no leak points.
- Place the L-Shields using the L-Shield placement guide on page 4.

*(Also see Protego Manual)

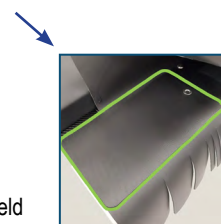
FEMORAL ACCESS - MAPPING*

- Palpate the hip, place a metal forcep over the area of influence.
- Raise the Main Shield, pan towards the head, lower the Main Shield, image the area.
- Raise the Main Shield and pan back the table.
- Obtain access via ultrasound guidance.
- Insert your short wire, confirm it has passed the bifurcation then insert the sheath.
- Raise the Main Shield, confirm location of sheath and wire. Then pan the table back and lower the Shield.
 - **Coronary Case** - Lock Protego Main Shield into magnets
 - **Structural Case** - Keep system floating
- Place the L-Shields using the L-Shield placement guide on page 4.

*(Also see Protego Manual)

BRACHIAL ACCESS

- Remove brachial shield located underneath the top of the Radial Armboard.
- Float the Main Shield above the elbow to locate the access point.
- Obtain access, insert extended transition sheath.
- Obtain pressure, return Main Shield and lock into magnets
- Place L-Shields using L-Shield placement guide on page 4.

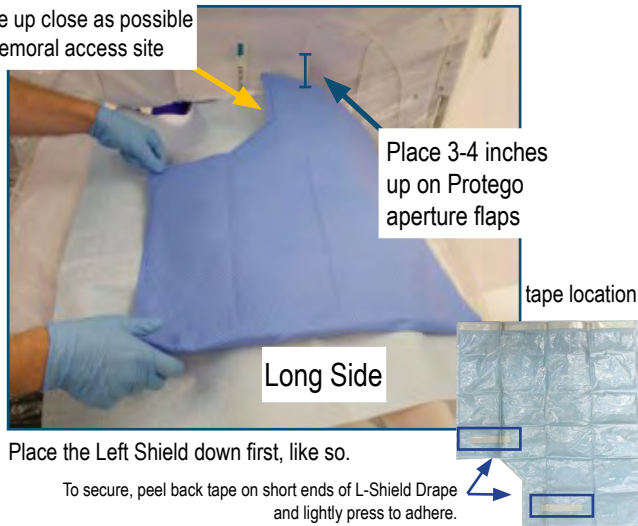


(See Protego Manual)

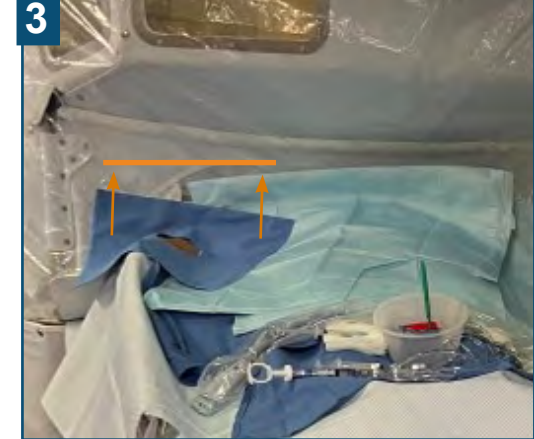
L-Shield Draping Techniques

RADIAL ACCESS

1 Line up close as possible to femoral access site

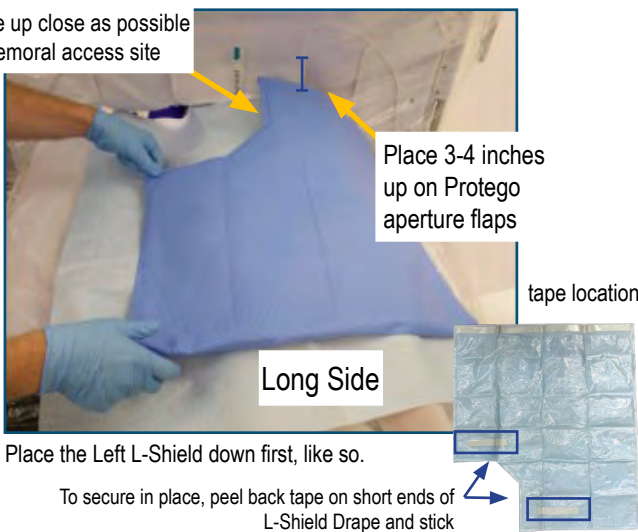


Next, place Right L-Shield, overlapping to form a square. Offset it towards the Radial Armboard.



FEMORAL ACCESS*

1 Line up close as possible to femoral access site

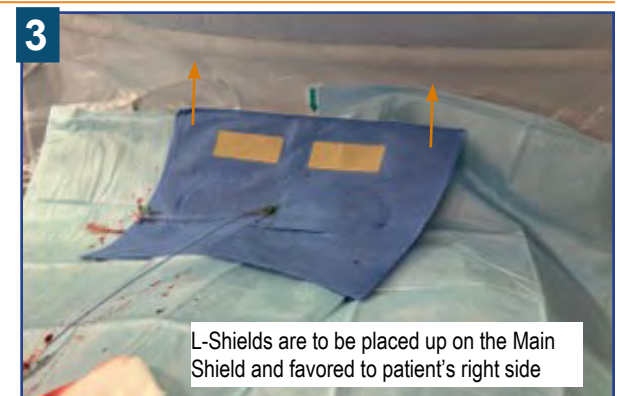


*Femoral Access Notes:

Floating the Shield is required for:

- Femoral head shot
- Wire and Cath Crossing

Lock the shield in place when catheter pass is confirmed, then place the femoral pad



Final look after the Femoral Pad is seated

To convert from Radial to Femoral:

Rotate the top L-Shield 90° counterclockwise



5. POSITION L-SHIELDS TO HELP BLOCK PATIENT SCATTER

See Protego Manual p. 20. *Shields are shown without their sterile drapes for clarity.*

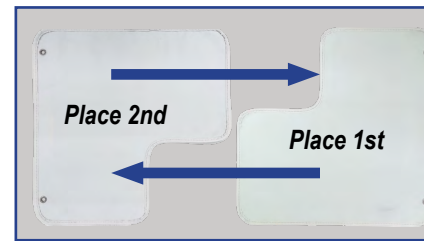
WARNING: L-Shields, bilateral groin access shield, and radial arm shield must all overlap the Protego Shield aperture flaps.

6. PLACE MOBILE SHIELD - See Protego Manual p. 21.

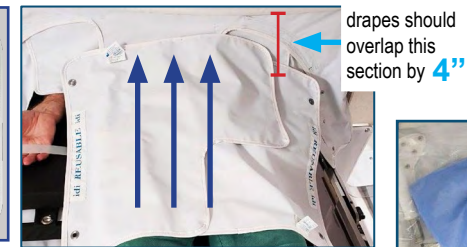
7. FINAL CHECK

- The RADIAL ARMBOARD is seated next to the patient, along with the patient side shield
- The Protego Main Shield's APERTURE FLAPS are facing the patient's feet, overlapping, and there are no obvious leak points.
- The L-SHIELDS are overlapping the flaps, secured with the adhesive strips on bottom of drapes, and extended laterally as far as they can be.
- The RADIAL ARM PAD is up and taped to the face of the Protego.
- The TABLE SIDE SHIELDS must hang freely and overlap to ensure shield integrity. The foot switch should be clear of the panels.
- The DOSIMETRY BADGES are all active, reset, and recognized by the system.
- The MOBILE STAND is positioned as close as possible to the table while permitting access to the patient.
- The PROTEGO SHIELD ARM must have a bend in it to ensure proper panning with the table.

Positioning L-Shields for Radial Approach outside of sterile drape



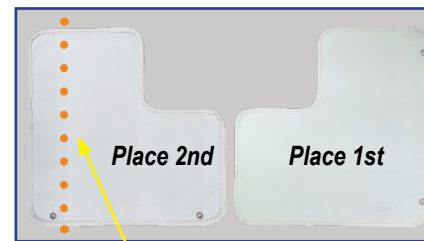
Place patient-left side on patient first. Make a square shape with the patient-right L-Shield



L-Shields must overlap Protego Shield aperture flaps approximately 4", use drape tape to secure



Positioning L-Shields for Femoral Approach outside of sterile drape

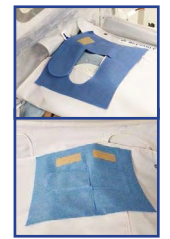


Fold under itself along the dotted orange line if needed



Locate the Left Shield over the patient's arm or access point

Locate the Left Shield close to the access site and the right side close to minimize the gap



8. CONTINUOUS MONITORING OF RADIATION DOSE DURING PROCEDURES

See Protego Manual p. 21.

IMPORTANT! A staff member must be designated to observe the exposure level during the case and call out when radiation levels are noted by the badge. At no time should the exposure levels exceed the Radiation Safety Officer's determined maximum single procedure dose.

These are the steps to take in the event of an unusually high radiation dose reading.

1. Check the L-Shields for possible migration during the case. Reposition if necessary.
2. Verify that aperture flaps of the Main Protego Shield are overlapping and there are no separations causing the radiation leak.
3. The Table Side Shields must be overlapping and unhindered by other equipment in the room. The C-arm foot switch could be causing a shield not to hang correctly.
4. If radiation levels exceed the allowable benchmark and the leak cannot be resolved, team members must put on appropriate personal protective lead shielding.

DO NOT USE the Protego® Radiation Protection System without a real-time radiation monitoring system in an "Apron-Free" environment to monitor radiation exposure levels and protection.

Failure to monitor radiation exposure levels with a real-time radiation monitoring system in an "Apron-Free" environment is a misuse of Protego® Radiation Protection System and can result in serious injury or death.

Radiation exposure is dangerous and cumulative. The protection afforded by the Protego Radiation Protection System cannot reduce the amount of radiation to which an individual has already been exposed or undo any damage an individual has already sustained from previous exposure.



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