



M1128®- RTV RADIATION SHIELDING SOFT ACCESSORY KIT (M1128-RAK) USER GUIDE

This document should be stored with, or in the immediate vicinity of the M1128 radiation shield, the medical team using the unit and the *M1128 Radiation Shield User Guide*.

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Within the bounds of legal requirements, the manufacturer is only responsible for the technical safety characteristics of this device if the maintenance, repairs, and modifications to this apparatus are performed by Rampart^{IC} or an approved Rampart^{IC} representative.

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TRAINING

Training videos and a PDF version of this user guide are available at www.RAMPARTic.com/training. A password is required to access these materials and is available on the training portal access card included with the *M1128 Radiation Shield User Guide*.

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Overview

Congratulations on your purchase of the Rampart[®] M1128[®] radiation shielding soft accessory kit (also known by the end three characters of the product part number, “RAK”). This accessory kit contains two radiation shielding curtains that extend your M1128’s lead protective coverage area by attaching to the bottom of the radial and lower extremity panels, a sturdy handle bar to help you better-manuever the modified M1128 and supporting brackets, washers and screws.

Once fully assembled and installed, the components of the M1128 radiation shielding soft accessory kit become a part of the M1128 radiation shield, and all safety, liability, warning and operational instruction information in the *M1128 Radiation Shield User Guide* fully pertain to the enhanced M1128 radiation shield unless otherwise indicated in this user guide.

This user guide provides guidance for the proper installation and use of the Rampart^{IC} M1128 radiation shielding soft accessory kit and must be stored with the *M1128 Radiation Shield User Guide*. Please carefully read this guide and the *M1128 Radiation Shield User Guide* for a full understanding of how to operate the M1128 radiation shield and for training personnel. Pay special attention to the warnings and caution statements identified throughout and summarized under *Safety & General Symbols* (see p. 7) before using the M1128.



WARNING!

To reduce risk of injury to user(s) and patient(s), user(s) must read and understand this user guide and the *M1128 Radiation Shield User Guide*, and be trained prior to using the M1128.

Note: Training videos and a PDF version of both user guides are available at www.RAMPARTic.com/training. A password is required to access these materials and is available on the training portal access card included with the *M1128 Radiation Shield User Guide*.

INTENDED USE

The M1128-RTV radiation shielding soft accessory kit is designed for installation on the M1128 radiation shield for the purpose of enhancing the device’s lead protective capabilities and maneuverability. The pliable curtain with 0.5 mm lead-equivalent protection reduces radiation scatter from potential draft areas by conforming to a variety of body shapes and access needs. Installing this radiation shielding soft accessory kit widens the M1128 radiation shield’s operational capabilities beyond radial, femoral and pedal access fluoroscopic procedures to additional procedures including radial by-the-hip and left radial (snuffbox) approaches.

SAFETY & GENERAL SYMBOLS

Please pay special attention to important safety information marked with **WARNING**, **CAUTION** or **ATTENTION** keywords and symbols.



WARNING!

Indicates a potentially hazardous situation which could result in the *serious risk* of injury or death to the patient or operator, and/or damage to equipment or property.

- To reduce risk of injury to user(s) and patient(s), user(s) must carefully read and understand this user guide and be trained prior to using the M1128.
- Repairs must only be performed by Rampart^{IC} authorized personnel.



**WARNING:
Radiation
Exposure**

- Failure to set M1128 lead acrylic panels and curtains at the proper height and position may cause radiation exposure. The M1128 is designed to be used with under-table and above-table lower body protection.
- According to the *Expert Consensus Document on Optimal Use of Ionizing Radiation in Cardiovascular Imaging*¹, proper radiation protection is in place when a minimum of 0.5 mm lead equivalency is placed between the radiation source and medical personnel. When used correctly, the Rampart^{IC} M1128 lead acrylic panels and curtains provide a protection level of 1 mm of lead equivalency against radiation exposure.
- The lead acrylic panels and curtains must be handled with care so they are not damaged due to contact with other objects. If the panels are damaged, they must be rechecked according to the *M1128 Radiation Shield User Guide*.



**CAUTION:
Heavy
Equipment-
Injury Risk**

- Personnel working with the M1128 system(s) must be properly trained.
- M1128 assembly, repairs and maintenance may only be performed by Rampart^{IC} personnel or people authorized by Rampart^{IC}. At least one other individual would be advised to be present during installation of the curtains due to the size and weight of the M1128 components.



**CAUTION:
Pinch Point**

When making final adjustments to the panels and while the patient is in position, always monitor the lower edge of the panel and curtains in relation to the patient to prevent injury.

Always maintain visual contact with panels and other equipment, in relation to the patient, when panels or other equipment are being adjusted.

¹ J. W. Hirshfeld and V. A. Ferrari, "2018 ACC/HRS/NASCI/SCAI/SCCT Expert Consensus Document on Optimal Use of Ionizing Radiation in Cardiovascular Imaging: Best Practices for Safety and Effectiveness," 2018, <http://www.onlinejacc.org/content/early/2018/04/30/j.jacc.2018.02.016> (accessed August 10, 2019).



CAUTION

- Potential drag may occur when the radiation shielding curtains are moved during a procedure. Ensure that the curtain flaps are lying flat against the patient's abdomen, pointing towards the patient's head, to allow for the best visibility and intervention to access points.
- When cleaning lead acrylic panels or curtains, never use rough or abrasive-faced sponges, steel wool, brushes, or cleaning pads.
- When cleaning any component of the M1128, never use scrapers or metal tools of any kind.



WARNING:
Tipping
Hazard

- CONFIGURATION DURING USE: The M1128 lead acrylic panels and attached curtains can be placed safely at any needed angle during use, *so long as one leg is positioned in the general direction of each panel* to provide proper weight distribution and stabilization of the equipment, and to prevent the equipment from tipping.
- CONFIGURATION DURING TRANSIT: To move the M1128 to another location, the M1128 must be placed into transit mode. First, the mast must be collapsed to the lowest position and the panels and attached curtains folded together and locked forward in the direction of travel. Then, all four legs should be positioned according to the leg angle label adhered to the base of the M1128 and locked into place to prevent legs from changing angle during transit. The person moving the device should carefully walk on the side of the device with Rampart^{IC} logo to push and guide the M1128 during transit. When in Transit Mode and moved correctly, the M1128 is narrow enough to fit through standard walkways.



WARNING!

- Before transport, the Rampart^{IC} M1128 must already be fully assembled, in Transit Mode and disconnected from charging according to the *M1128 Radiation Shield User Guide*.
- When replacing M1128 brackets with brackets A, B or C, be careful to keep loosened screws inserted and in place. If removed, the shelf may destabilize and fall.
- Heed all caution and warning statements in the *M1128 Radiation Shield User Guide* regarding the movement of this medical device

The M1128 lead acrylic panels and curtains will be permanently damaged if cleaned with abrasive cleaners. **When cleaning lead acrylic panels, DO NOT clean with the following cleaning supplies:**

ATTENTION!

- Paper towels or linen washcloths
- Alcohol wipes, CavWipes² or Sporicidan³ Disinfectant Towelettes
- Rough or abrasive-faced sponges, brushes, cleaning pads, scrapers, or metal tools
- Strong detergents or abrasives such as scouring powders
- Aerosol cleaners with Butyl Cellosolve⁴
- Hydrocarbon or chlorinated solvents, ammonia, or strong alkali cleaners
- Cleaners that are designed for grease cutting
- Excessively hot water or steam

2 CavWipes® is a registered trademark of Metrex Research LLC.

3 Sporicidan® is a registered trademark of Contec, Inc.

4 Cellusolve™ is a trademark of the Dow Chemical Company.

IDENTIFICATION TAG

The M1128-RTV radiation shielding soft accessory kit identification tag can be found on the edge of the radial curtain, just above the curtain sheets. It provides the following information:

- Product Name
- Reference Number (Product Part Number)
- Serial Number
- Bar Code
- Manufacturer Name
- Manufacturer City, State and Zip
- Manufacturer Website
- Manufacturer Phone



PARTS LIST

Part Number	Description
M1128-RAK	M1128-RTV Radiation Shielding Soft Accessory Kit (also known as "RAK")
M1128-RCT	M1128-RTV Radial Curtain (RC) (includes proximal and distal sheets)
M1128-LEC	M1128-RTV Lower Extremity Curtain (LEC) (includes proximal and distal sheets)
M1128-RCM	M1128-RTV RC Mount
M1128-LCM	M1128-RTV LEC Mount
M1128-RCR	M1128-RTV RC Retainer
M1128-LER	M1128-RTV LEC Retainer
M1128-PSC	M1128-RTV Polycarbonate Screws (Set of 25)
M1128-RBK	M1128-RTV RC Bracket Kit (includes Brackets A and B)
M1128-LBK	M1128-RTV LEC Bracket Kit (includes Brackets A and C)
M1128-SLK	M1128-RTV RAK Lock Kit (includes 3 F-Locks and 1 Slide-Lock)
M1128-BTL	M1128-RTV Block Tool
M1128-LAK	M1128-RTV RAK Label Kit
M1128-LEH	M1128-RTV LE Handle Bar
M1128-LEB	M1128-RTV LE Handle Bar Brackets (Set of 2)
M1128-SCR	M1128-RTV M6 Screws (Set of 100)
M1128-WAS	M1128-RTV LE Handle Bar Washers (Set of 1)
M1128-RUG	M1128-RTV Radiation Shielding Soft Accessory Kit User Guide (IFU) (MOQ 20)

Installation

Installation instructions must be completed by a Rampart^{IC}-authorized individual and an assistant. The assistant will help manage heavy components, screws and washers during installation of the curtains and the handle bar. A 5 mm Allen wrench not included with your M1128 purchase will be required for assembly.

As depicted in *What Comes Out-of-the-Box on page 12*, the radiation shielding soft accessory kit will include:

- **Four white replacement brackets** (brackets A, bracket B and bracket C): each new bracket replaces an original M1128 bracket, two on the lower extremity panel and two on the radial panel, preparing these panels to receive a curtain.
- **Two radiation shielding curtains**: one for the lower extremity panel and a second for the radial panel. Once brackets A, B and C are installed, the curtains hang easily onto the correct panel.
- **Four clear plastic locks** (F-locks and slide lock): secure newly hung curtains onto the replacement brackets.
- **Lower extremity (LE) handle bar assembly** (handle bar brackets, handle bar rod and supporting M6 screws and plastic washers): together make up the handle bar to be attached to the lower extremity panel.

Note: Training videos and a PDF version of this user guide and the M1128 Radiation Shield User Guide are available at www.RAMPARTic.com/training. A password is required to access these materials and is available on the training portal access card included with the M1128 Radiation Shield User Guide.



WARNING!

- Before transport, the Rampart^{IC} M1128 must already be fully assembled, in Transit Mode and disconnected from charging according to the *M1128 Radiation Shield User Guide*.
- Heed all caution and warning statements in the *M1128 Radiation Shield User Guide* regarding the movement of this medical device.

PREPARATION

1. **Move the M1128 radiation shield and the packaged M1128 radiation shielding soft accessory kit into a well-lit room** with a level floor that is at least 8 feet tall and 10 feet by 10 feet wide. This ensures a stable surface, adequate visibility and enough space to accommodate the maximum dimensions of the M1128.
2. **Adjust the four legs** of the M1128 radiation shield to the **45° position** and **lock all four casters** to prevent the base and leg assembly from moving during installation.
3. **Unpack the radiation shielding soft accessory kit and verify you have all parts** that come out-of-the-box:
 - Two (2) bracket As
 - One (1) bracket B
 - One (1) bracket C
 - Three (3) F-locks
 - One (1) slide lock
 - Two (2) lower extremity handle bar brackets
 - One (1) lower extremity handle bar
 - Two (2) M6 screws
 - Two (2) plastic washers
 - One (1) lower extremity curtain
 - One (1) radial curtain

Notes: *What Comes Out-of-the-Box components are visually represented on the next page, categorized by the three assemblies to be installed on the M1128. Please note that the screws and washers are packaged already attached to the handle bar.*

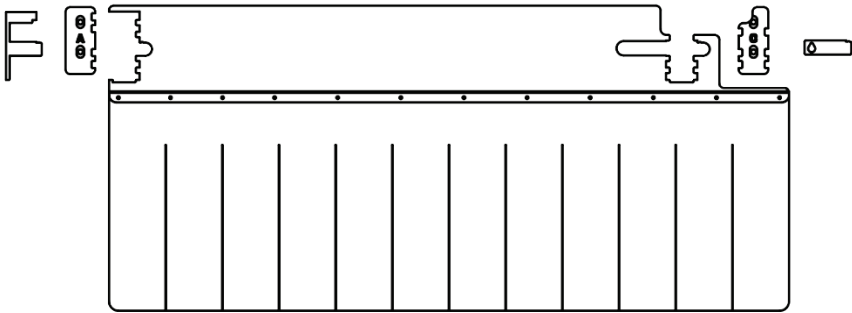
4. **Follow installment sections in order from pages 13 through 18** to install the radiation shielding curtains and the handle bar.

WHAT COMES OUT-OF-THE-BOX

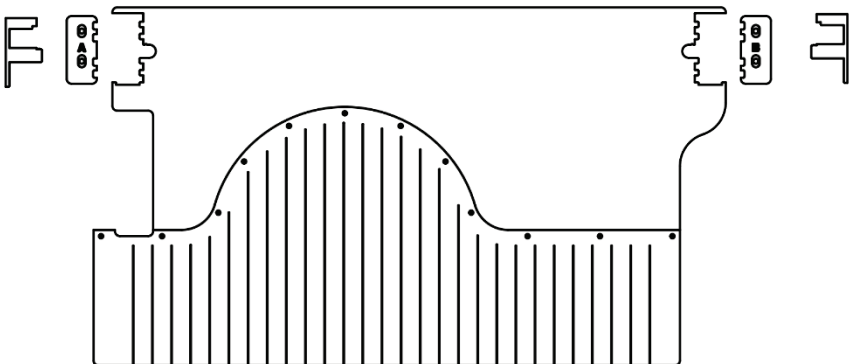
Lower Extremity Handle Bar Assembly



Lower Extremity Curtain Assembly

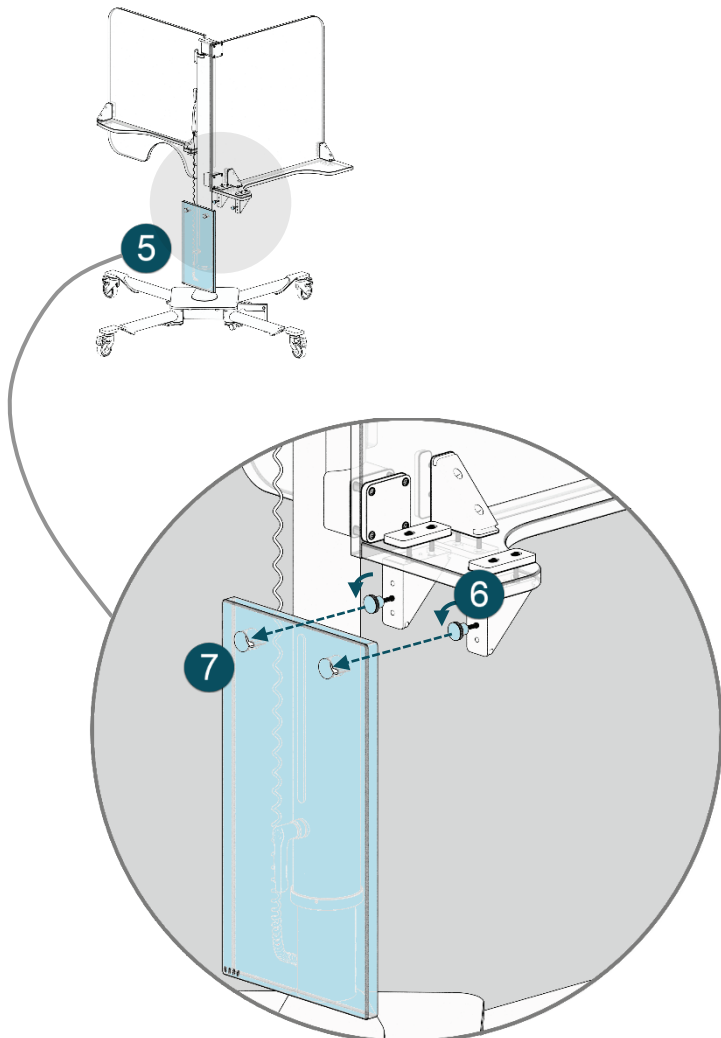


Radial Curtain Assembly



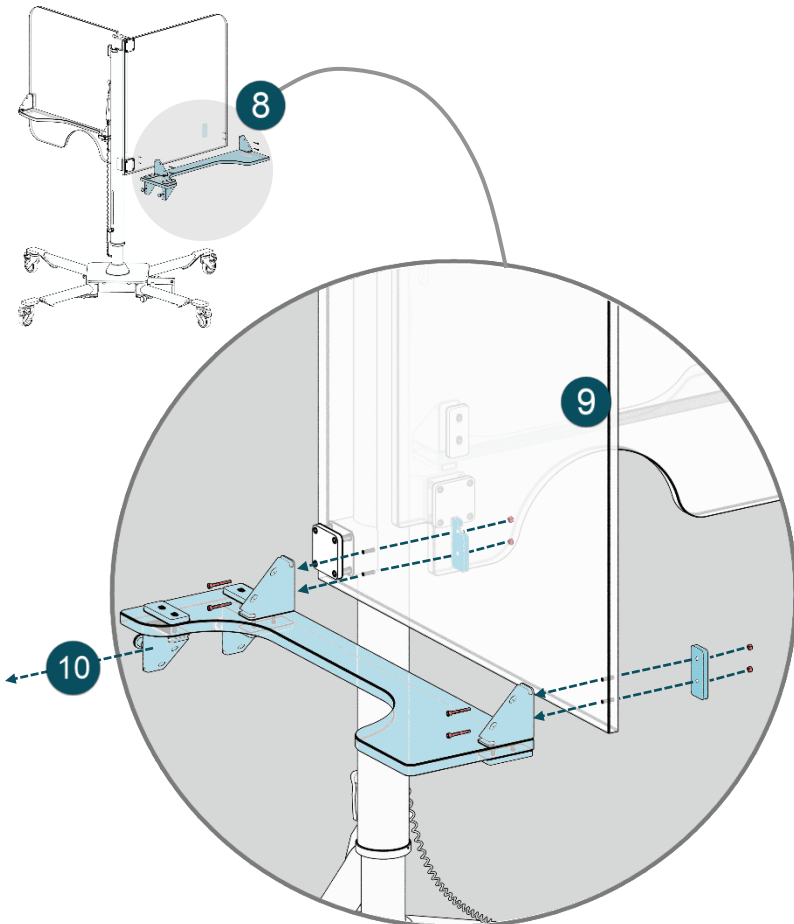
REMOVE LOWER EXTREMITY DROP PANEL

5. **Locate the two metal knobs** securing the lower extremity (LE) drop panel to the M1128.
6. **Turn the two knobs counterclockwise** till the LE drop panel is loose.
7. **Remove the LE drop panel** by shifting it right so the large circular panel holes align with the knobs, and then pulling the panel forward passing the panel through the knobs. The detached LE drop panel can be put aside as it is not needed for the enhanced M1128.



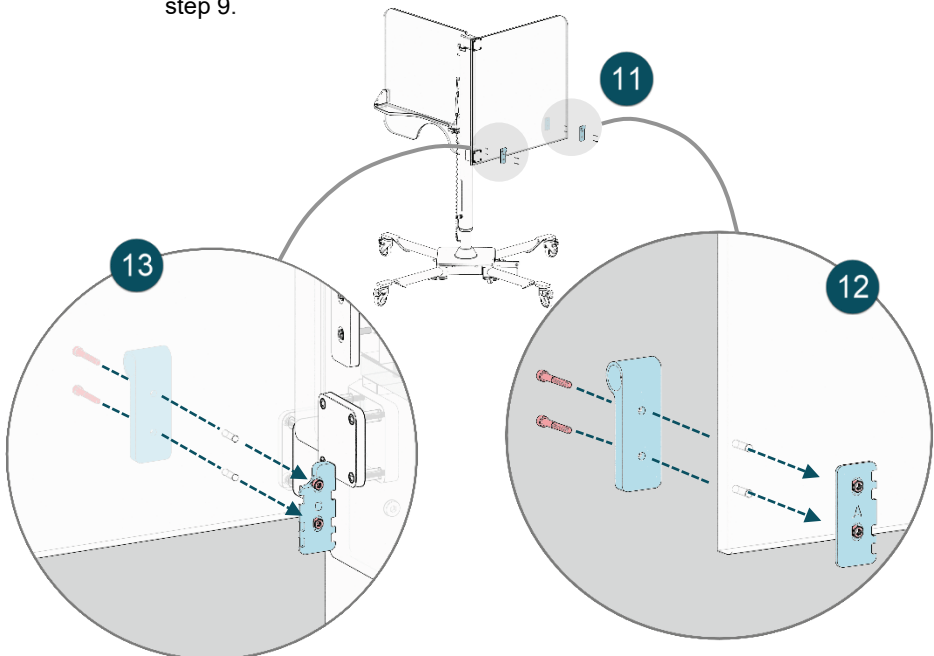
REMOVE LOWER EXTREMITY SHELF

8. **Locate the triangular mounting bracket** securing the lower extremity (LE) shelf to the LE panel.
9. **Carefully remove and retain the four M6 screws and locknuts** from both triangular mounting brackets while the assistant holds the LE shelf assembly. *These screws and locknuts will be used in upcoming steps on page 15.* The following detaches from the M1128:
 - The LE shelf assembly (which includes the LE shelf and attached brackets and hardware)
 - Two separate detached back plates on the opposing face of the LE panel opposite the removed LE shelf assembly
10. **Remove the LE shelf assembly and the two separate detached back plates** as they are not needed for the enhanced M1128.



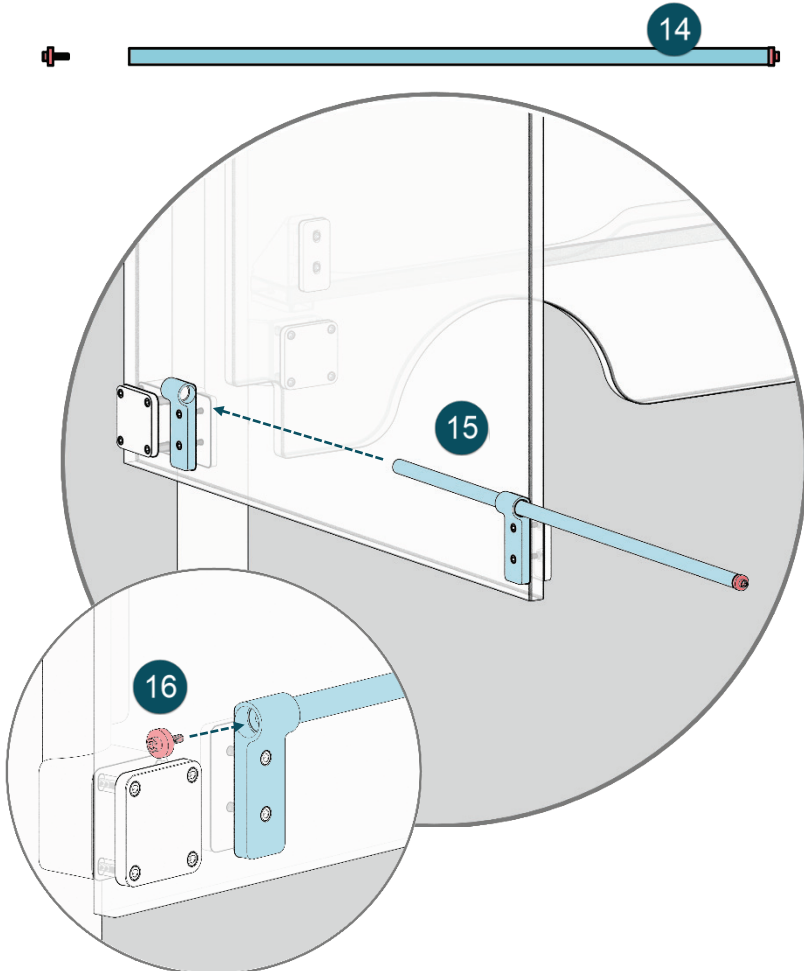
INSTALL NEW LOWER EXTREMITY BRACKETS

11. **Locate the emptied screw holes** on the bottom of the lower extremity (LE) panel.
12. **Facing the outer vertical edge of the LE panel** and addressing the **outer** emptied screw holes:
 - **Position bracket A** (letter facing outward) to the right of the screw holes and a **handle bar bracket** on to the left of the screw holes (bar loop facing up and away from panel).
 - **Thread two screws from step 9** through the screw holes first entering through the handle bar bracket, passing through the LE panel and lastly coming through the bracket A.
 - **Tighten the two screws to two washers** saved from step 9.
13. **Facing the outer vertical edge of the LE panel** and addressing the **inner** emptied screw holes:
 - **Position bracket C** (letter facing outward) to the right of the screw holes and a **handle bar bracket** on to the left of the screw holes (bar loop facing up).
 - **Thread two screws from step 9** through the screw holes first entering through the handle bar bracket, passing through the LE panel and lastly coming through the bracket C.
 - **Tighten the two screws to the second two washers** saved from step 9.



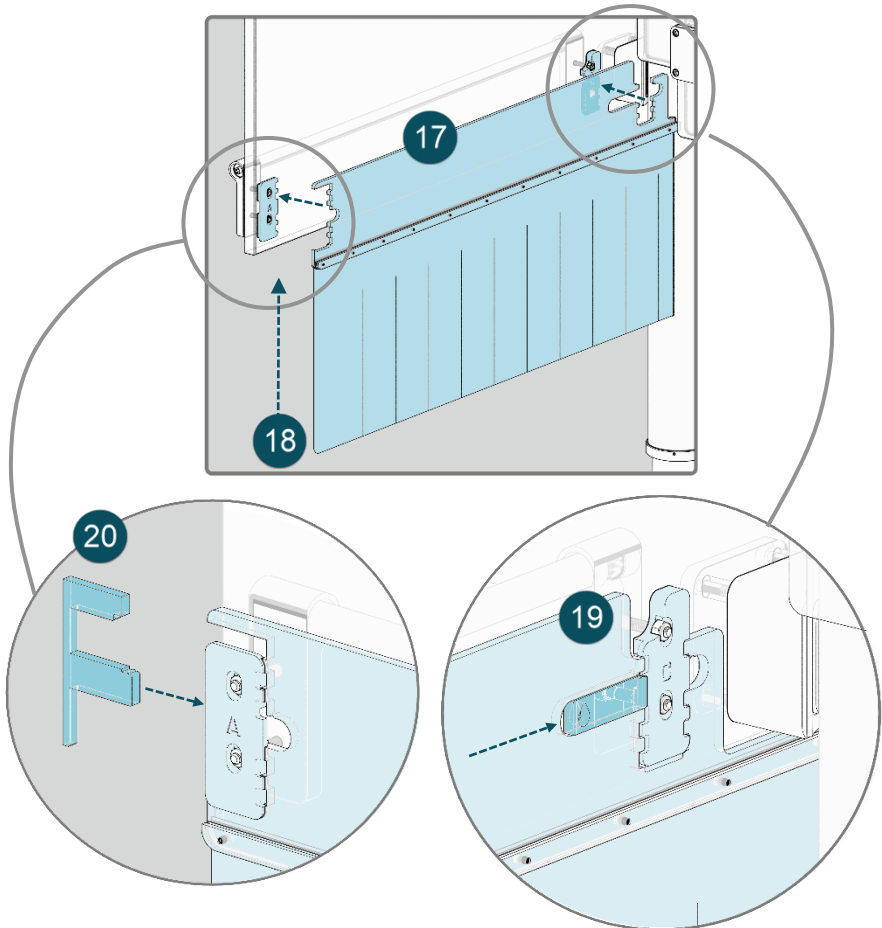
INSERT & SECURE HANDLE BAR

14. **Locate the handle bar.** It should have a screw and washer attached to each end.
 - Tighten the screw and washer on one end.
 - Remove the **screw and washer** on the other end and save for use in step 16.
15. **Slide the handle bar (end without screw and washer) through both handle bar brackets.**
16. **Tighten the saved screw through the saved washer and into the handle bar (end without screw and washer).**



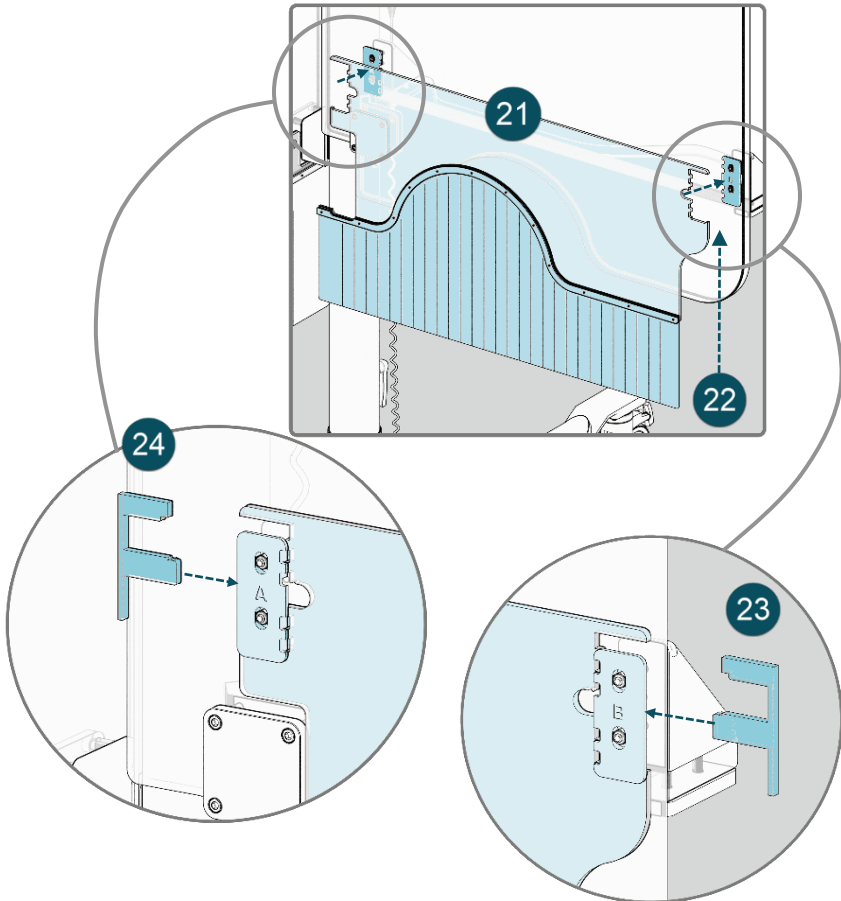
HANG & LOCK LOWER EXTREMITY CURTAIN

17. **Hang the lower extremity (LE) curtain** with the puzzle-like bracket cutouts onto brackets A and C.
18. While the curtain is still positioned over the brackets, have the assistant **push and hold the curtain upwards** so that the bottom of the curtain cutout touches the bottom of brackets A and C. This opens up a space between the LE curtain and the brackets through which locks can slide in. Have the assistant keep curtains raised for the next two locking steps.
19. **Insert the slide lock into bracket C**, entering from the left and pushing until you hear a click.
20. **Insert an F-lock into bracket A**, entering from the left and pushing until you hear a click.



HANG & LOCK RADIAL CURTAIN

21. **Hang the radial (R) curtain** with the puzzle-like bracket cutouts onto brackets A and B.
22. While the curtain is still positioned over the brackets, have the assistant **push and hold the curtain upwards** so that the bottom of the curtain cutout touches the bottom of brackets A and B. This opens up a space between the LE curtain and the brackets through which locks can slide in. Have the assistant keep curtains raised for the next two locking steps.
23. **Insert an F-lock into bracket B**, entering from the right and pushing until you hear a click.
24. **Insert an F-lock into bracket A**, entering from the left and pushing until you hear a click.



Instructions for Use

Once the M1128 radiation shielding soft accessory kit is properly installed onto the M1128 radiation shield, you may move, utilize and care for the enhanced M1128 according to instructions in the *M1128 Radiation Shield User Guide*, heeding all safety, warnings and caution statements therein regarding:

- Transporting
- Instructions for use
- Drape application steps
- Charging
- Maintenance
- Storage
- Cleaning
- Preventative inspection

The enhanced M1128 provides more comprehensive lead protection coverage, is more maneuverable with the built-in handle bar, and can accommodate more patient positions, specific access points, technician location, multiple procedure table types, and other lab equipment in various procedures.



WARNING!

Indicates a potentially hazardous situation which could result in the *serious risk* of injury or death to the patient or operator, and/or damage to equipment or property.

- To reduce risk of injury to user(s) and patient(s), user(s) must carefully read and understand this user guide and be trained prior to using the M1128.
- Repairs must only be performed by Rampart^{IC} authorized personnel.



CAUTION: Pinch Point

When making final adjustments to the panels and while the patient is in position, always monitor the lower edge of the panel and curtains in relation to the patient to prevent injury. Always maintain visual contact with panels and other equipment, in relation to the patient, when panels or other equipment are being adjusted.



CAUTION

Potential drag may occur when the curtain is moved during a procedure. Ensure that the soft shield flaps are lying flat against the patient's abdomen, pointing towards the patient's head, to allow for the best visibility and intervention to access points.



CAUTION: Heavy Equipment- Injury Risk

- Personnel working with the M1128 system(s) must be properly trained.
- M1128 assembly, repairs and maintenance may only be performed by Rampart^{IC} personnel or people authorized by Rampart^{IC}. At least one other individual would be advised to be present during installation of the curtains due to the size and weight of the M1128 components.



**WARNING:
Radiation
Exposure**



**WARNING:
Tipping
Hazard**



WARNING!

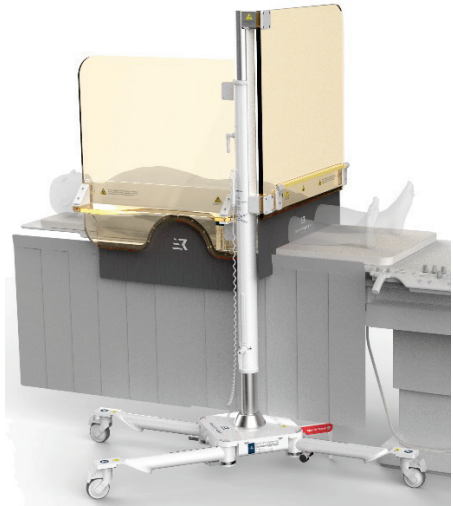
- Failure to set M1128 lead acrylic panels and curtains at the proper height and position may cause radiation exposure. The M1128 is designed to be used with under-table and above-table lower body protection.
- According to the *Expert Consensus Document on Optimal Use of Ionizing Radiation in Cardiovascular Imaging*⁵, proper radiation protection is in place when a minimum of 0.5 mm lead equivalency is placed between the radiation source and medical personnel. When used correctly, the Rampart^{IC} M1128 lead acrylic panels and curtains provide a protection level of 1 mm of lead equivalency against radiation exposure.
- The lead acrylic panels and curtains must be handled with care so they are not damaged due to contact with other objects. If the panels are damaged, they must be rechecked according to the *M1128 Radiation Shield User Guide*.
- CONFIGURATION DURING USE: The M1128 lead acrylic panels and attached curtains can be placed safely at any needed angle during use, *so long as one leg is positioned in the general direction of each panel* to provide proper weight distribution and stabilization of the equipment, and to prevent the equipment from tipping.
- CONFIGURATION DURING TRANSIT: To move the M1128 to another location, the M1128 must be placed into transit mode. First, the mast must be collapsed to the lowest position and the panels and attached curtains folded together and locked forward in the direction of travel. Then, all four legs should be positioned according to the leg angle label adhered to the base of the M1128 and locked into place to prevent legs from changing angle during transit. The person moving the device should carefully walk on the side of the device with Rampart^{IC} logo to push and guide the M1128 during transit. When in Transit Mode and moved correctly, the M1128 is narrow enough to fit through standard walkways.
- Before transport, the Rampart^{IC} M1128 must already be fully assembled, in Transit Mode and disconnected from charging according to the *M1128 Radiation Shield User Guide*.
- Heed all caution and warning statements in the *M1128 Radiation Shield User Guide* regarding the movement of this medical device.

⁵ J. W. Hirshfeld and V. A. Ferrari, "2018 ACC/HRS/NASCI/SCAI/SCCT Expert Consensus Document on Optimal Use of Ionizing Radiation in Cardiovascular Imaging: Best Practices for Safety and Effectiveness," 2018, <http://www.onlinejacc.org/content/early/2018/04/30/j.iaacc.2018.02.016> (accessed August 10, 2019).

SAMPLE CONFIGURATIONS



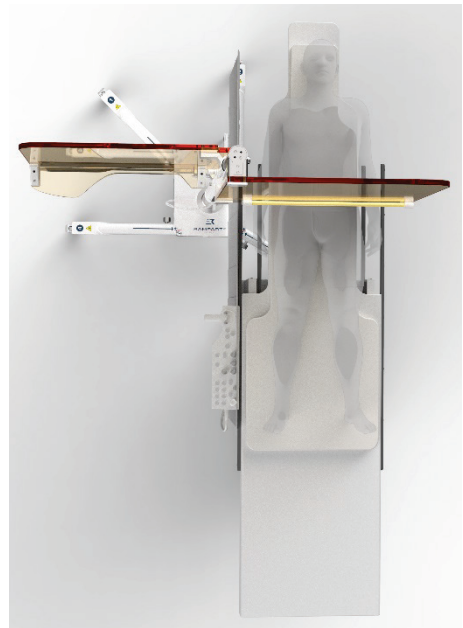
Transit Mode with mast fully collapsed, panels folded together in the direction of travel and legs in transit mode



Panels at 90° pedal configuration



Panels at 90° for radial (bi-radial) and femoral procedures



Panels at 180° to accommodate biplane angles

DRAPING

Follow directions for draping the enhanced M1128 with installed radiation shielding soft accessory kit in the same way as with original M1128 without the accessory kit. Follow the directions for draping the enhanced M1128 according to the *M1128 Radiation Shield User Guide* and using the same drape kit that comes with the original M1128 (M1128-RDK).

When draping the enhanced M1128:

- Do not over cinch the pull cords.
- Allow the drape to adequately encompass the curtains without compressing the curtain flaps.
- Drape #2 in the sterile drape kit for the side drop panel is not needed for radial by the hip and left radial snuffbox procedures.

CLEANING

The M1128 radiation shielding soft accessory kit must be thoroughly cleaned and disinfected in accordance to standard operating room practices and CDC guidelines. Clean each component after use and prior to maintenance. Always use disposable drape kits to maintain sterility during procedures and dispose of them after.

ATTENTION!

The M1128 lead acrylic panels and curtains will be permanently damaged if cleaned with abrasive cleaners. **DO NOT clean with the following supplies:** paper towels, linen washcloths, alcohol wipes, CavWipes⁶ or Sporicidan⁷ Disinfectant Towelettes, rough or abrasive-faced sponges, brushes, cleaning pads, scrapers, or metal tools, strong detergents or abrasives such as scouring powders, aerosol cleaners with Butyl Cellosolve⁸, hydrocarbon or chlorinated solvents, ammonia or strong alkali cleaners, cleaners designed for grease cutting, and excessively hot water or steam.

To clean and disinfect the curtains:

Wipe them with **microfiber towels** using one of the following:

- Water solution with mild dish soap
- Windex⁹ multi-surface antibacterial spray
- 70% isopropyl alcohol (Use only when disinfection is needed, drying panels immediately after application.)

Note: Rampart^{IC} cleaning cloths are designed for safely cleaning M1128 panels and are available for purchase. To purchase, email info@iflproducts.com.

6 CavWipes® is a registered trademark of Metrex Research LLC.

7 Sporicidan® is a registered trademark of Contec, Inc.

8 Cellusolve™ is a trademark of the Dow Chemical Company.

9 Windex® is a registered trademark of S. C. Johnson & Johnson, Inc.,



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M1128

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