

Instructions for Healthcare Facilities: Assembly, Disassembly and Disinfection of the CAMIC

The U.S. Food and Drug Administration (FDA) has authorized an Emergency Use Authorization (EUA) for the emergency use of the COVID-19 Airway Management Isolation Chamber (hereafter referred to as the CAMIC), to be used by healthcare providers (HCP) as an extra layer of barrier protection in addition to personal protective equipment (PPE) to prevent HCP exposure to pathogenic biological airborne particulates during the transport of patients with suspected or confirmed diagnosis of COVID-19, at the time of definitive airway management, or when performing medical procedures on such patients during the COVID-19 pandemic.

The CAMIC is authorized for use by HCP as an extra layer of barrier protection to prevent HCP exposure to pathogenic biological airborne particulates; it is an adjunct to PPE for HCP during the COVID-19 pandemic and does not replace the need for PPE. The CAMIC has not been FDA-approved or cleared for this use; FDA authorized it for emergency use for the duration of the COVID-19 public health emergency (unless it is otherwise terminated or revoked sooner).

The CAMIC system is a barrier device constructed by draping a large clear plastic bag over a box-like frame made of common polyvinyl chloride (PVC) piping. The CAMIC consists of a PVC hollow frame and a clear large plastic (polyethylene) bag that is placed over the head, neck, and shoulders of the patient to isolate airborne particulates. The CAMIC cycles out air through holes in the PVC frame. The CAMIC captures and removes particles emitted from a patient's nose and mouth using a flow of medical air, which comes in through holes in the PVC frame on one side and is sucked out by a vacuum on the other. The CAMIC is authorized for use with hospital vacuum lines, as well as portable vacuum pumps with in-line High-Efficiency Particulate Air (HEPA) filters.

The CAMIC is comprised of the following components:

- Hollow, perforated PVC piping (reusable);
- Plastic (polyethylene) bag (disposable);
- Wall-mounted vacuum pump, or portable vacuum pump with in-line HEPA filter;
- Portable or wall-mounted medical air.

The CAMIC is authorized for use during patient transport. During patient transport, the CAMIC maintains negative pressure via a portable vacuum pump with an in-line HEPA filter, and oxygenation is supplied via a portable medical air tank.

Healthcare personnel (HCP) should follow these instructions, as well as procedures at their healthcare facility, to use the CAMIC.



The instructions below are to assist in build, assembly, disassembly and Disinfection using the CAMIC. The CAMIC is not meant to be a stand-alone unit of PPE. The CAMIC should always be used with PPE recommended by your institution and pursuant to the guidance of your institution.

Inspect CAMIC prior to use. Any wear/tear of the chamber or other signs of degradation on the CAMIC must promptly be reported to U.S. Army Medical Research and Development Command (USAMRDC), the healthcare facility must not use on patients, and must dispose of such CAMIC.

All connections should be tightly secured and checked frequently. When a patient is within the CAMIC, direct observation is required.

Rx only

WARNINGS and CAUTIONS:

- Flammability of the CAMIC has not been tested. No interventions that could create a spark or be a flammable source should be used within the CAMIC.
- Remove the CAMIC and use standard of care if there is difficulty visualizing or identifying anatomic landmarks or inability to intubate after the first try.
- Prolonged use of the CAMIC may induce hypercarbia in a spontaneously breathing patient. The CAMIC should only be used with a spontaneously breathing patient with medical air flow and suction both on and working, under direct observation, and with end-tidal CO₂ monitoring if available. If end-tidal CO₂ monitoring is not available, then the use of the CAMIC should be limited to no more than a short duration of time no longer than 30 minutes with medical air flow and suction both on and under direct observation.
- Use caution prior to use on non-sedated or lightly sedated patients with severe claustrophobia and/ or confined space anxiety

CONTRAINDICATIONS:

- For emergent endotracheal intubation with severe hypoxemia
- On patients with anticipated or known history of difficult airway
- On patients with other anatomical abnormalities that might interfere with clinical care including decreased neck mobility from arthritis or other causes
- On individuals with communication disorders that might interfere with clinical care
- On children under 45 lbs.

CAMIC Instructions on Build, Assembly, Disassembly, and Disinfection

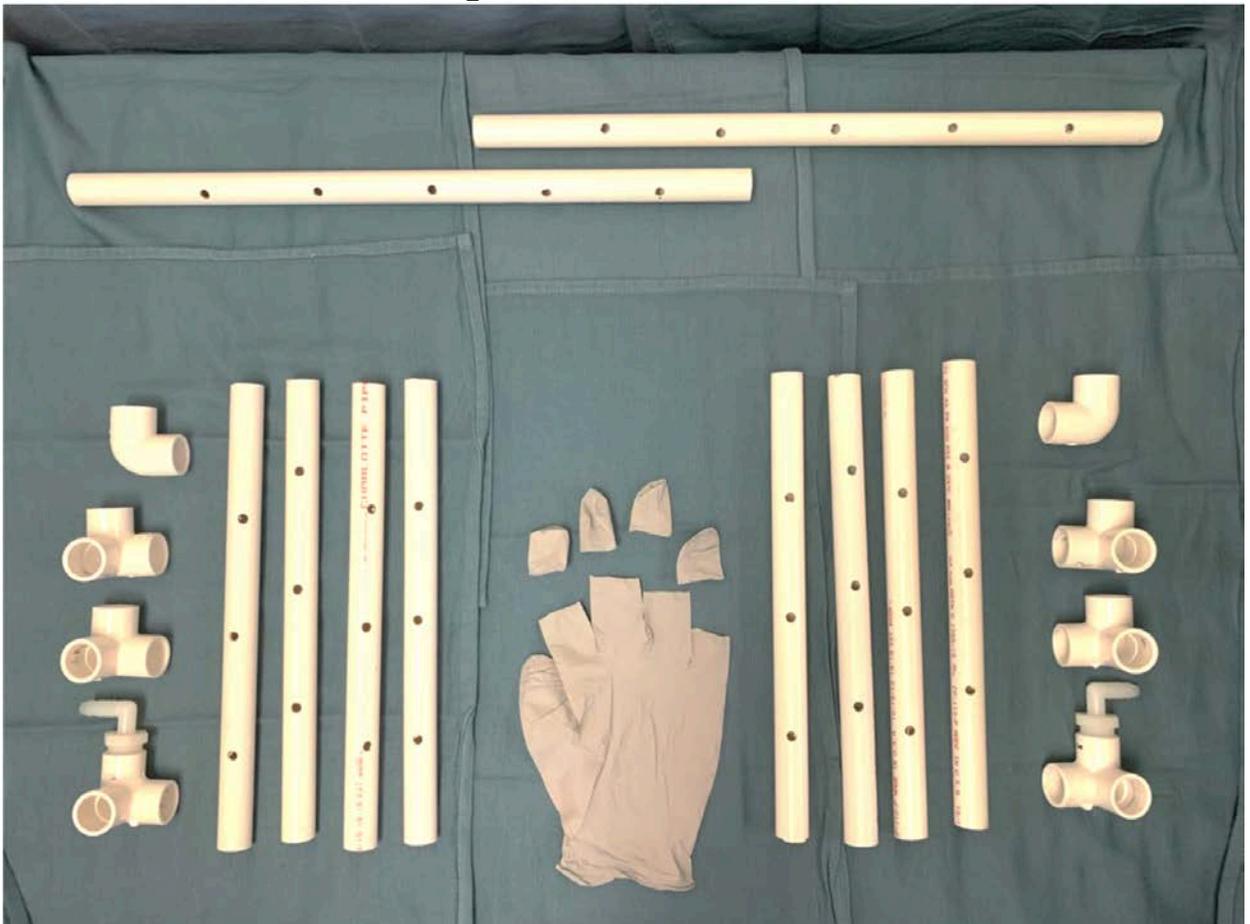
Materials Needed:

- ½" schedule 40 polyvinyl chloride (PVC) pipe - 11 feet total length cut in sections:
 - 8- 12" length PVC pipe sections
 - 2- 18" length PVC pipe sections
- 4- ½" schedule 40 PVC 90° elbow with a side outlet with slip (female socket) x slip x slip connections
- 2- ½" schedule 40 PVC 90° elbow with a side outlet with slip x slip x thread connections
- 2- 3/8" I.D. x ½" NPT plastic barbed tube fitting, 90° elbow
- 1- Surgical glove
- 1- Large clear plastic (polyethylene) bag (a minimum size of 40" x 40")

Tools Required:

- ¼" drill bit with electric drill
- Cutting tool (Hacksaw or PVC cutters)
- Tape measure

Figure 1: Materials





Assembly Instructions

Preparing Pipe Sections:

1. Cut ½" schedule 40 PVC pipes to size (2- 18" length, 8- 12" length)
2. Cut 4 fingertips (distal 2") off surgical glove (Fig. 2)
3. Drill suction/air ports
 - a. Drill one ¼" hole at pipe mid-length, through one surface only and perpendicular to the pipe central axis.
 - b. For 12" length Sections: Drill 2 additional ¼" holes measured 3" from the first hole center, in both directions along the pipe central axis such that all 3-hole axes are coplanar.
 - c. For 12" length Sections: Drill 4 additional ¼" holes measured at 3" and 6" from the first hole center, in both directions along the pipe central axis such that all 5- hole axes are coplanar.
4. Seal the end of 4 separate 12" length pipe sections by stretching 4 of the cut surgical glove fingertips over one end the pipe (Figure 2)

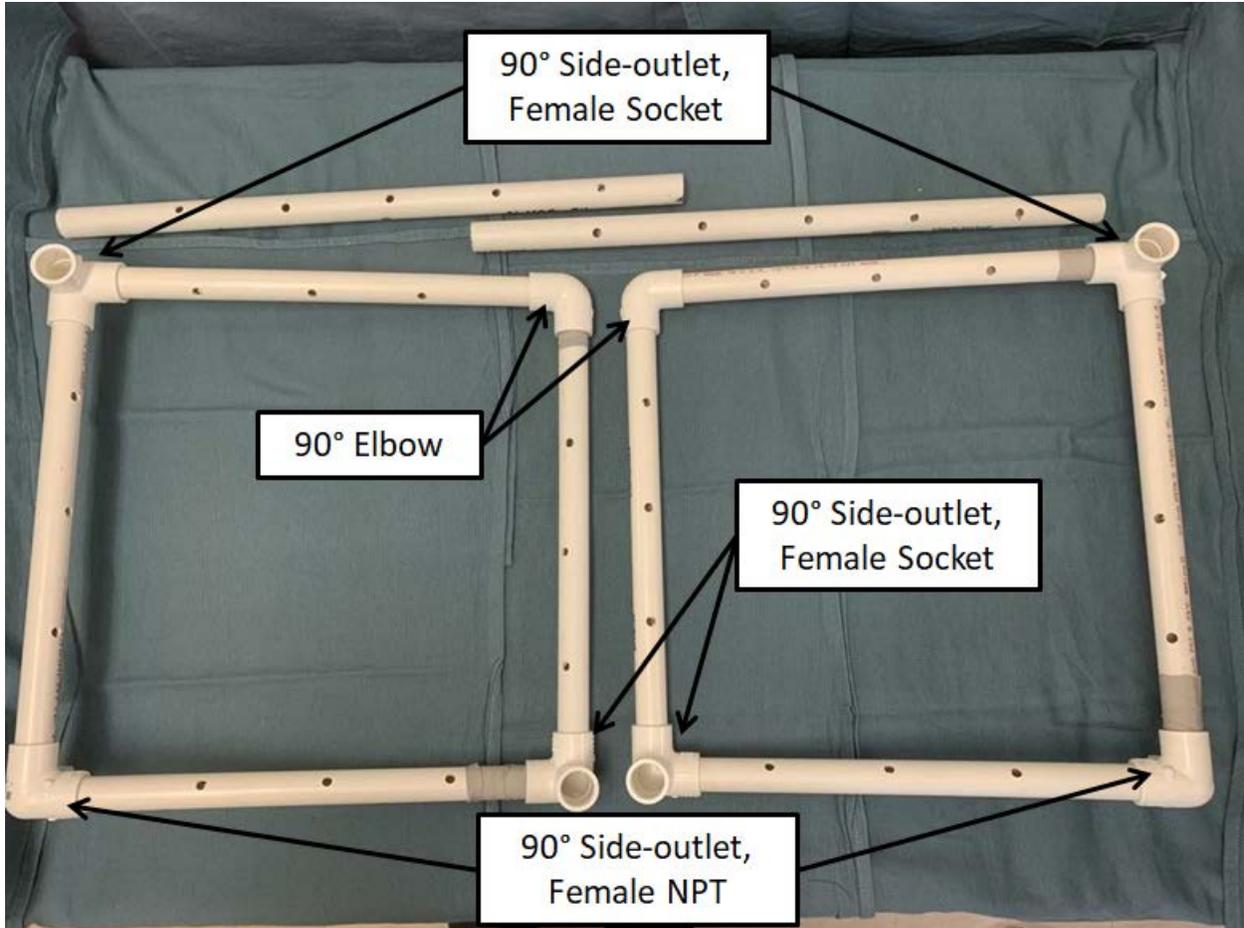
Figure 2: Sealing end of pipe section



Assembling Frame:

1. Using the 12" length sections, assemble the square outer frames shown below (Figure 3) by firmly pressing pipe sections into pipe connectors. Ensure location of the sealed ends of the pipe lengths match the configuration shown below.
 - a. For each pipe, orient the drilled holes such that the plane containing the drilled hole axes are oriented 45° to the plane containing the central axes of the adjacent pipe frame members.

Figure 3: Configuration of outer square frames, built from 12" L Sections



2. Join square outer frames by connecting the 18" length pipe sections as shown in Figure 4.
 - a. For each pipe, orient the drilled holes such that the plane containing the drilled hole axes are oriented 45° to the plane containing the central axes of the adjacent pipe frame members.
3. Screw 2 plastic barbed tube fittings into threaded side ports as shown in Figure 4.

Figure 4: Outer square frames joined with inner 18" length pipe sections and tube fittings connected

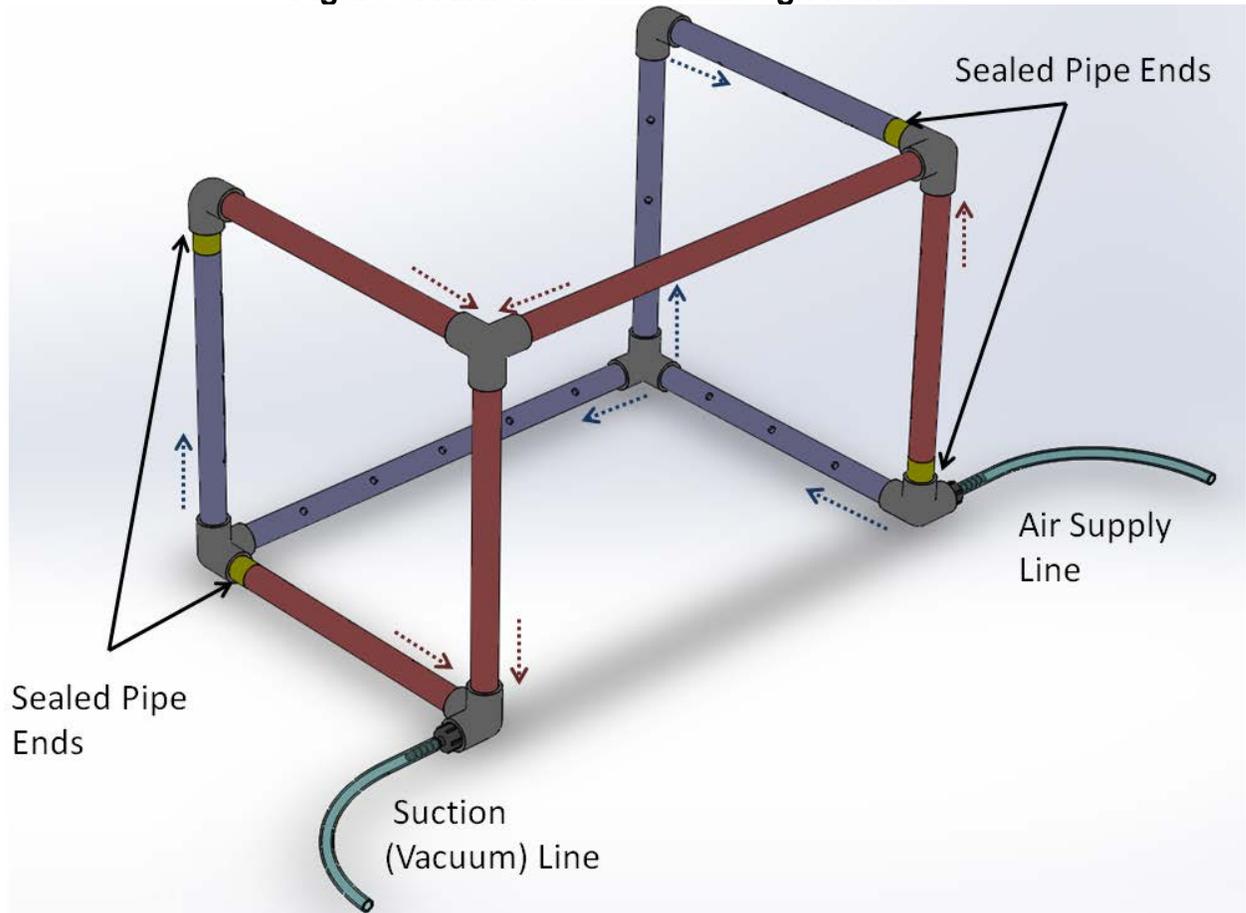


Airflow through Frame:

1. Confirm placement of sealed pipe ends to direct airflow appropriately (Figure 5):
 - Blue= medical air
 - Red= suction
 - Yellow= airflow blocked at pipe end by surgical glove fingertip sleeve over pipe
2. Attach suction line to blue side (at least 120 mmHg).

3. Ensure the suction is connected to vacuum source that has a HEPA filter or the vacuum is part of a hospital wall vacuum system that evacuates the vacuumed air safely to the environment per institutions building codes and regulations.
4. Attach air supply line (medical air) with 10L/min flow rate.

Figure 5: Airflow direction through frame



Final Assembly:

1. Place large clear bag (polyethylene) over frame (minimum size of 40" x 40" clear bag). If the bag has a drawstring, orient the bag such that the drawstring can be cinched around the shoulders or chest of the patient (Figure 6). If the bag does not have a drawstring, roll the edge of the excess bag (at least 3 inches) inward and tuck this excess gently around the patient's chest, shoulders and arms.

Figure 6: Final assembly, clear bag over frame



Additional Diagrams:

Figure 7: Exploded view of frame assembly

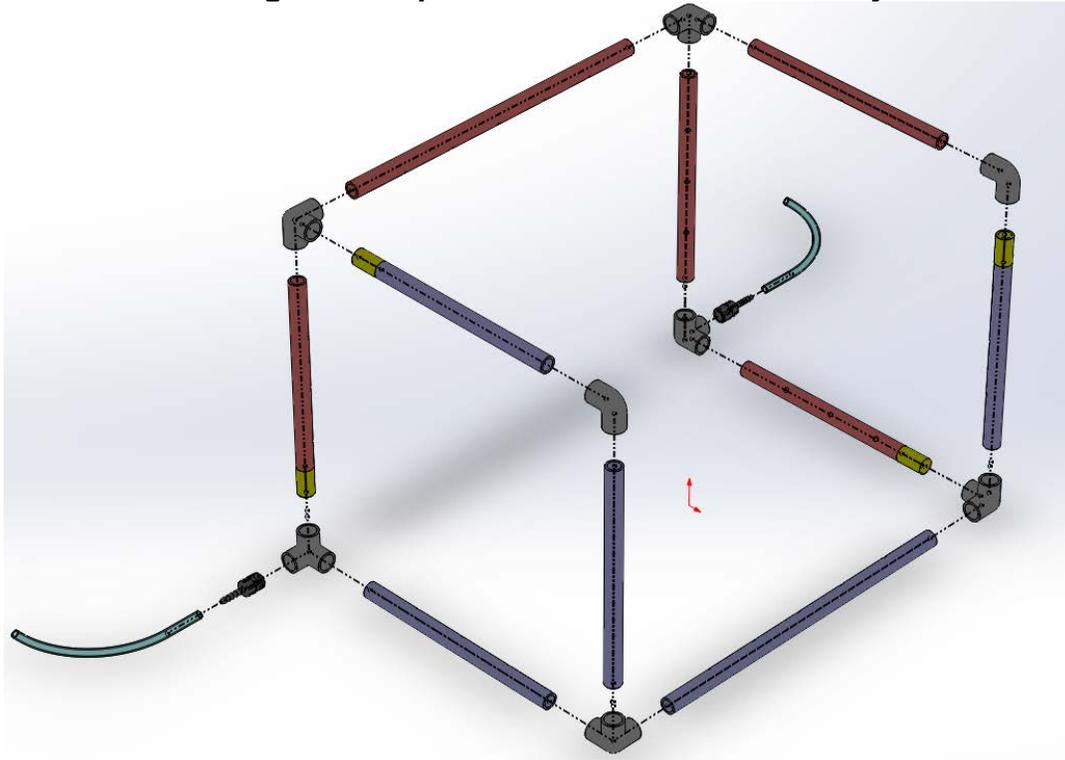


Figure 8: View of completed frame assembly



U.S. Army Medical Research and Development Command (USAMRDC)

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NOTES:

- ① SEAL THE END OF 4 SEPARATE 12" PVC SECTIONS BY STRETCHING 4 OF THE CUT SURGICAL GLOVE FINGERTIPS OVER ONE END THE PIPE
- ② JOIN PIPE SECTIONS BY FIRMLY PRESSING INTO ELBOW CONNECTIONS. ORIENT PIPE SUCH THAT PLANE CONTAINING THE DRILLED HOLE AXES ARE 45° TO THE PLANE CONTAINING THE CENTRAL AXES OF THE ADJACENT PIPE FRAME MEMBERS.
- ③ ATTACH SUCTION LINE TO BLUE SIDE (AT LEAST 120 MMHG)
- ④ ATTACH AIR SUPPLY LINE (MEDICAL AIR VS O2) AT LEAST 10L/MIN FLOW RATE
5. PLACE A LARGE CLEAR BAG WITH DRAWSTRING OVER FRAME (40X40" CLEAR BAG WITH DRAWSTRING WORKS BEST). ORIENT THE BAG SUCH THAT THE DRAWSTRING CAN BE CINCHED AROUND THE PATIENT'S TORSO.

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ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	1/2" PVC 18"L	1/2" PVC PIPE, 18" L, SCHEDULE 40	2
2	1/2" PVC 12"L	1/2" PVC PIPE, 12" L, SCHEDULE 40	8
3	CORNER JOINT	UNTHREADED SIDE OUTLET ELBOW	4
4	90° ELBOW	90° ELBOW, FEMALE CONNECTOR	2
5	THREADED SIDE OUTLET	THREADED SIDE OUTLET CORNER JOINT	2
6	SUCTION TUBING BARBED FITTING	MALE ADAPTER, 1/4" TUBING TO 1/2" PVC	2
7	1/4" TUBING	1/4" ID SUCTION/AIR TUBING	2
8	AIR BLOCK	AIR BLOCK, CUT FROM SURGICAL GLOVE FINGERTIP	4

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN INCHES

TOLERANCES:

X .120

Ø .010

XXX .030

ANGLES: 1°

INTERPRET GEOMETRIC TOLERANCING PER:

MATERIAL:

FINISH:

DO NOT SCALE DRAWING

DRAWN	NAME	DATE
CHECKED		
ENG. APPR.		
MFG. APPR.		
Q.A.		
COMMENTS:		

TITLE:
COVID19 AIRWAY
MANAGEMENT ISOLATION
CHAMBER (CAMIC)

SIZE DWG. NO. REV
B CAMIC1

SCALE: 1:4 | WEIGHT: | SHEET 1 OF 2

4
3
2
1

B
B

A
A

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN INCHES

TOLERANCES:

X .120

Ø .010

XXX .030

ANGLES: 1°

INTERPRET GEOMETRIC TOLERANCING PER:

MATERIAL:

FINISH:

DO NOT SCALE DRAWING

DRAWN	NAME	DATE
CHECKED		
ENG. APPR.		
MFG. APPR.		
Q.A.		
COMMENTS:		

TITLE:
COVID19 AIRWAY
MANAGEMENT ISOLATION
CHAMBER (CAMIC)

SIZE DWG. NO. REV
B CAMIC1

SCALE: 1:4 | WEIGHT: | SHEET 2 OF 2

Disassembly and Disinfection Instructions



The instructions below are to assist in disassembly and disinfection of the CAMIC frame. The large clear bag (polyethylene) is not for reuse.

Disassembly Instructions:

PPE should be donned during the disassembly of the CAMIC

1. After use, clean the PVC pipes, joints and vacuum/air ports with a hospital approved germicidal wipe (i.e., PDI SaniCloth (purple top)) to remove visible soil from all surfaces, paying careful attention to pipe joints.
2. Disassemble CAMIC completely by first removing all straight pipes from the joints.
3. Then remove and discard the used glove tips
4. Then unscrew the vacuum/air ports from the joints
5. Place the CAMIC pieces into a hospital approved covered dirty transport bin at least 20" length x 8" width x8" height

High-Level Disinfection Instructions:

PPE should be donned during the disinfection of the CAMIC

- 1) At the point of disinfection, transfer CAMIC pieces into a second container at least 20" L x 8" W x8"H
 - a. Prepare a solution of FDA approved high-level disinfectant such as glutaraldehyde, hydrogen peroxide, or peracetic acid that are compatible with PVC.
 - b. Completely immerse the PVC pipes in the FDA approved high-level disinfectant to fill the pipes, points and vacuum/air ports (total volume of necessary to submerge CAMIC pieces will depend on container size).
 - c. Soak the PVC pipes in the high-level disinfectant solution at the temperature and for the exposure time indicated in the manufacturer's label instructions.
 - d. Rinse the PVC pipes with fresh water to remove disinfectant from internal and external surfaces according to the manufacturer's label instructions.
- 2) Allow the CAMIC pieces to dry for 24 hours in an upright position to ensure drainage of water
- 3) Place cleaned pieces into hospital approved clean transport bin at least 20" L x 8" W x8"H, or into appropriately sized clean self-sealing adhesive peel-pack pouches at least 10 x 20 in (or similar size ensuring pouches can be closed) (See picture below)



- 4) Store cleaned CAMIC pieces in hospital approved clean storage location