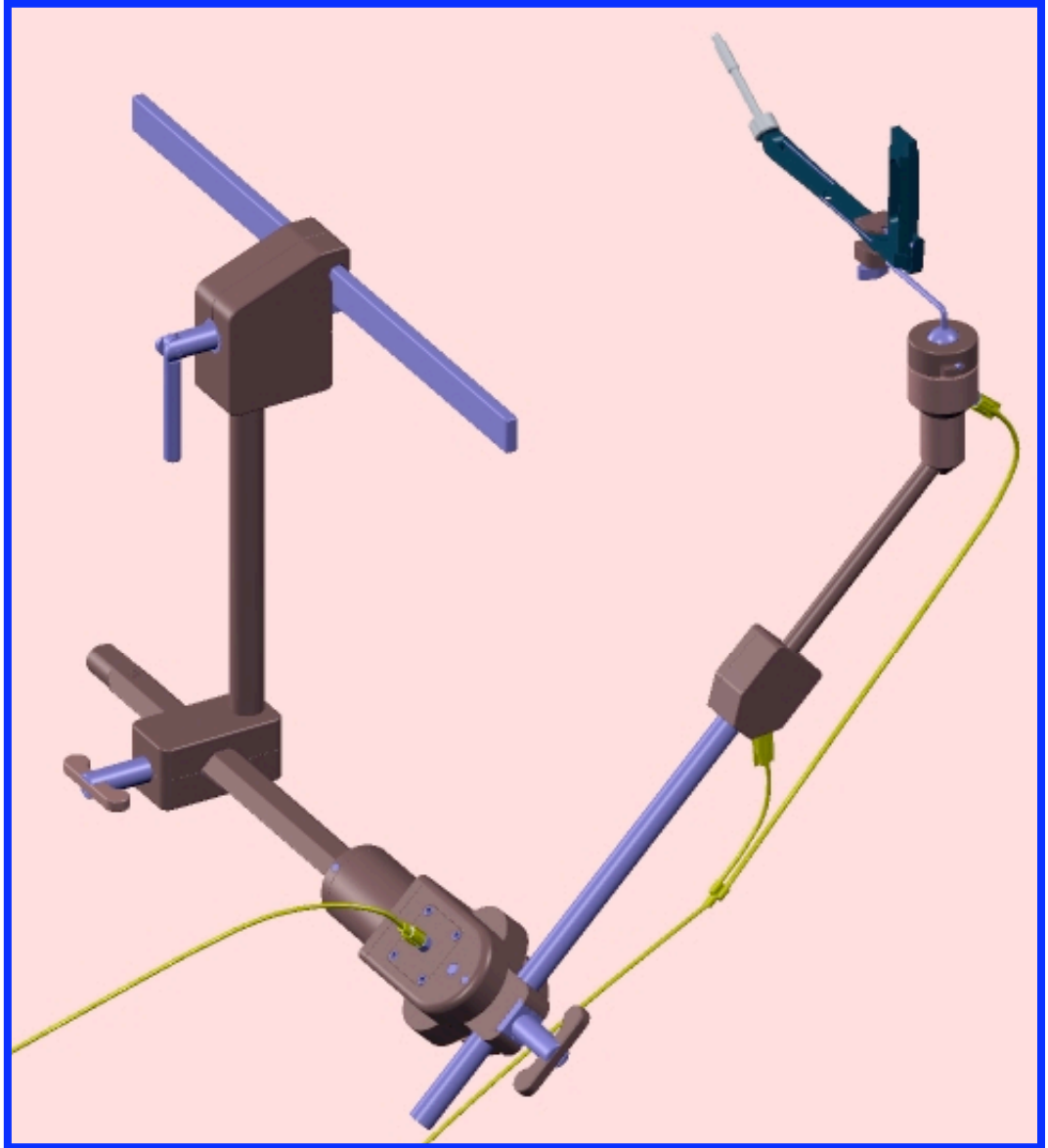


The KRONNER SIDE-KICK

A uterine manipulator Holder

for holding
the RUMI uterine manipulator*

Instructions for use



United States Patent 8,485,484.B2

* RUMI Model UMH 600, manufactured by CooperSurgical

The KRONNER SIDE-KICK A uterine manipulator Holder

Richard F. Kronner MD FACS

A description of the device and the intended use.

The **Kronner SIDE-KICK uterine manipulator Holder** firmly holds the RUMI and other uterine manipulators* during laparoscopic surgery on female pelvic organs, thus freeing staff for performing other tasks. The Side-Kick does not interfere with re-positioning the uterus with the attached manipulator.

The Side-Kick is attached to either operating table rail behind the leg stirrup attachment.

The manipulator is inserted into the patient using standard technique, then the Side-Kick is joined to the manipulator.

With proper adapters the Side-Kick may be used with various other manipulators, such as the VCare®, the Arch Koh, Advincula, Kronner Retractor and VCM (Kronner Vaginal Cuff Manipulator).

A gas supply module, which can also be attached to the operating table rail, transfers nitrogen or compressed air from the hospital wall or a portable tank to the Side-Kick through two flexible lines. When the module switch is turned on, the Sidekick joints lock. When the module switch is turned off the Side-Kick joints are decompressed.

Pressing a foot pedal, that is connected to the gas supply module, releases all the Side-Kick joints for position changes. When the foot pedal is released the joints lock.

A branched gas line connects the supply module to two luers of the arm assembly. A single gas line joins the gas supply module to the main pivot. Only the arm components and adapters are steam sterilized. The disposable gas lines are supplied sterile.

Intended use:

The Kronner Side-Kick Uterine Manipulator Holder is intended to assist the surgical staff in mounting, positioning and holding a uterine manipulator during gynecological laparoscopic surgical procedures. It is intended for use by trained operating room personnel in an operating room environment.

"Caution: Federal law restricts this device to sale by or on the order of a physician."

Indications for use:

The Kronner Side-Kick Uterine Manipulator Holder is intended to assist the surgical staff in mounting, positioning and holding a uterine manipulator during gynecological laparoscopic surgical procedures. It is intended for use by trained operating room personnel in an operating room environment.

Contraindications:

1. Adapter unavailable for chosen manipulator
2. Table rail unreliable
3. Gas supply is unreliable or unavailable at required pressure
4. Intended surgery does not require use of a uterine or vaginal manipulator. See the uterine manipulator manufacturers' literature regarding instruction for use, indications, contraindications and safety information.

Warnings:

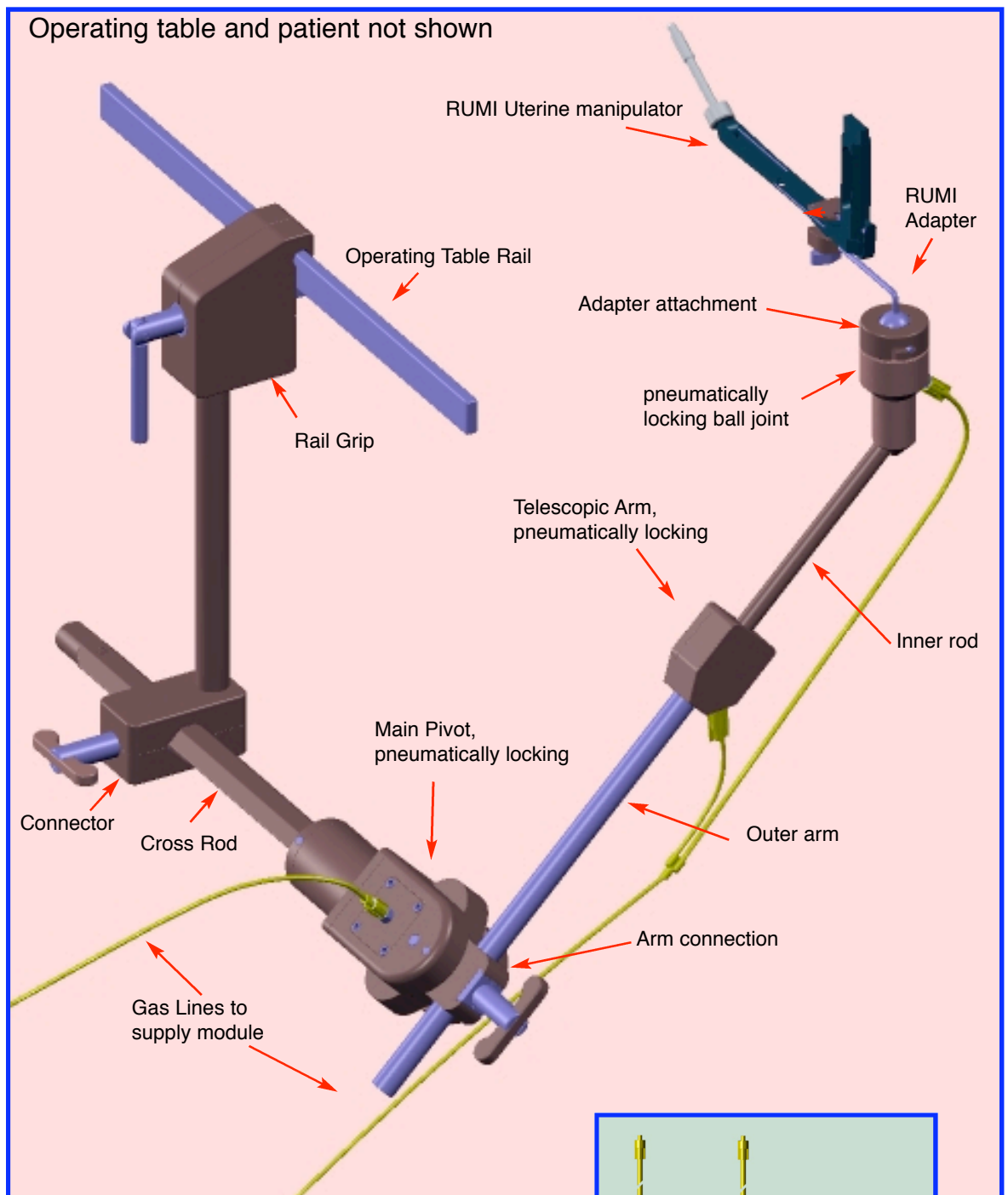
1. Do not use with pressure greater than 150 psi.
2. Do not detach the gas supply module from the gas supply while the manipulator is attached.
3. Do not shut off the gas supply module switch while the manipulator is attached.
4. Do not use substitute flexible gas lines.
5. Do not use if gas leaks are detected.
6. Use only the specified adapter with the chosen manipulator.
7. On older operating tables with motorized perineal rests, make sure the rest is in the down position before adding the main pivot and the remainder of the assembly.
8. The gas module switch must be in the "on" position during use.
9. Do not use the sterile lines if the package is damaged or the 3 year expiration date is passed.
10. Do not attach the holder to a manipulator of a patient that is not under anesthesia or otherwise immobilized.
11. Use only nitrogen or compressed air gas.
12. In the event the Side-Kick was disassembled without turning off the gas module switch, the pneumatic joints may still be pressurized. To decompress, attach a male luer from a branched gas line with one short branch disconnected or use a syringe with the plunger removed.
13. Do not attach the Sidekick rail grip over an attachment of the table rail to the table.
14. Attach the single gas line to the pivot and the branched line to the arm.
15. **Remove the Sidekick arm before raising the lower end of the operating table.**
16. **Do not attach a gas line to a uterine manipulator, extreme danger.**

Precautions:

1. Verify that the operating table rail is not loose.
2. Verify that the operating table end can be lowered or removed.
3. Restrain the patient from sliding on the table when the table is tilted.
4. Prevent the gas supply line from damage due to moving objects.
5. Check the uterine manipulator for defects.
6. Verify that the gas supply is steady and available at 140-150 psi.
7. Securely attach all flexible gas lines to the gas supply module and to the holder.
8. Read the instruction manual prior to use.
9. When making a patient transfer to or from the operating table to a cart with Sidekick in between, remove Sidekick or protect it from the cart.
10. Always support a connected manipulator when stepping on the gas pedal.

COMPONENTS

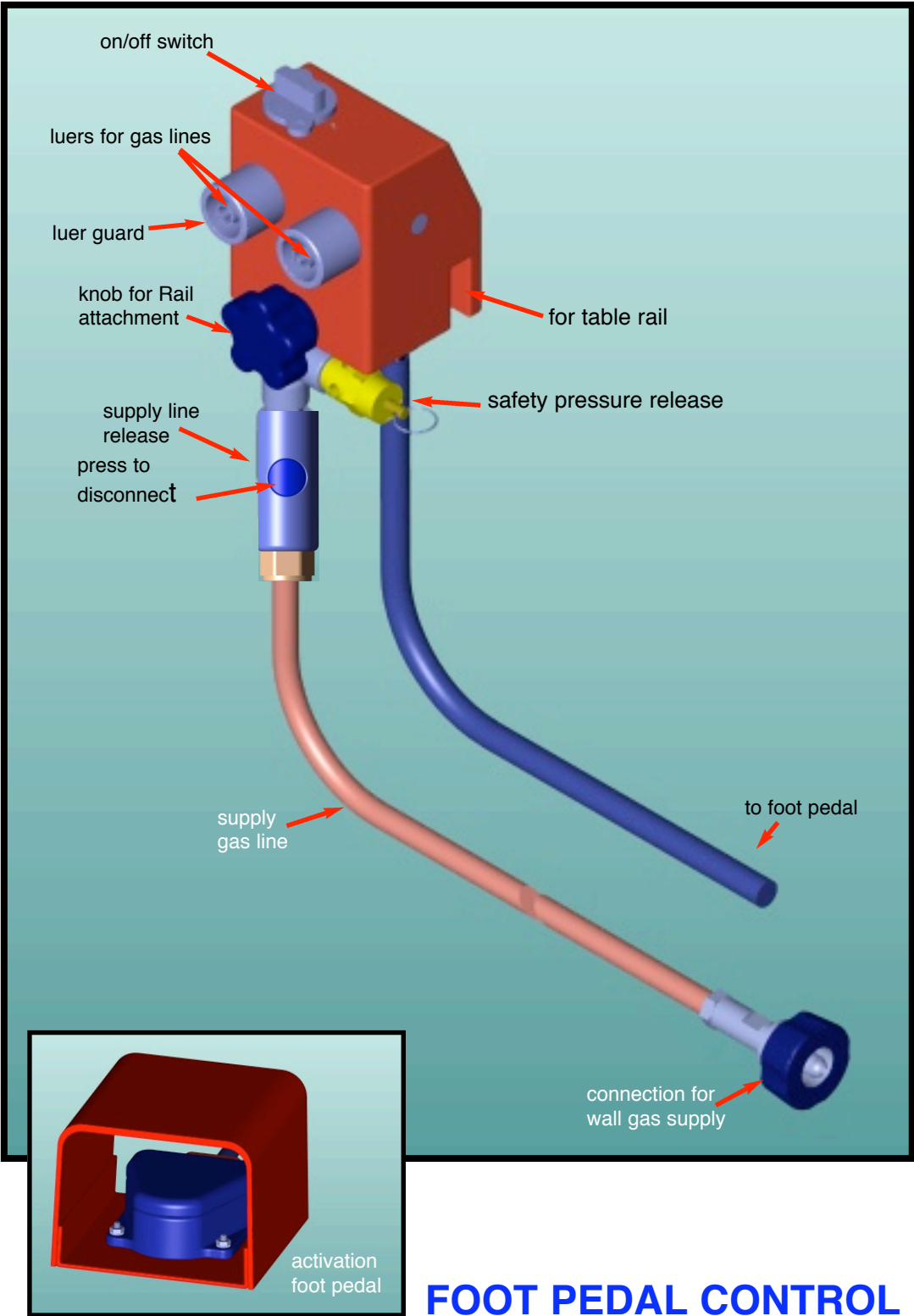
Holder assembly



High Pressure GAS LINES

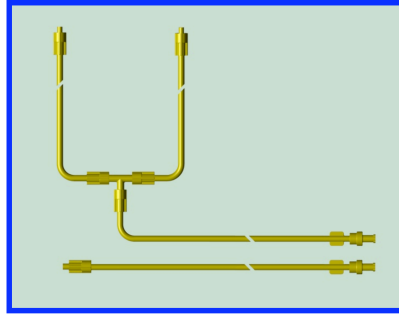
supplied sterile,
shelf life 3 years,
see package label

GAS SUPPLY MODULE

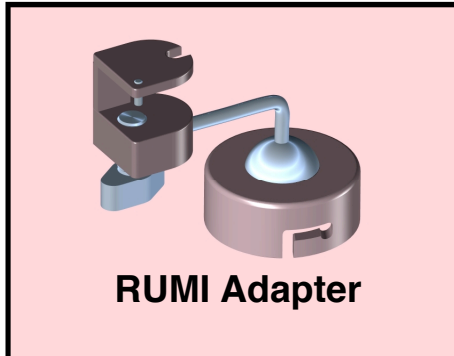


HIGH PRESSURE GAS LINES

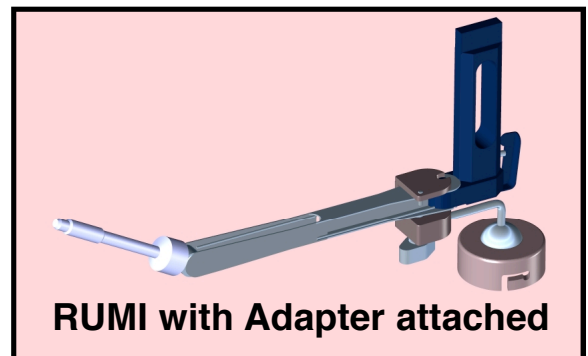
supplied sterile
shelf life three years



RUMI ADAPTER



RUMI Adapter



RUMI with Adapter attached

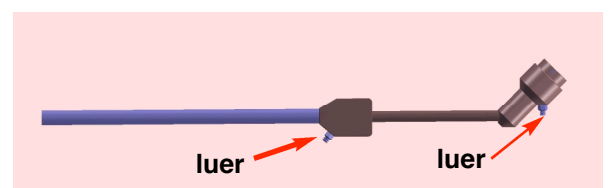
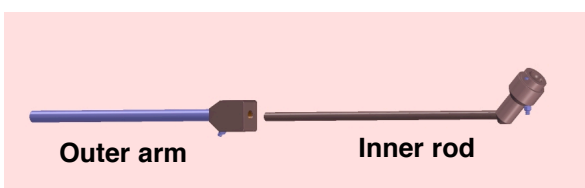
STERILIZABLE COMPONENTS

Outer arm, inner rod, RUMI adapter and screws

Joining the inner rod to the arm.

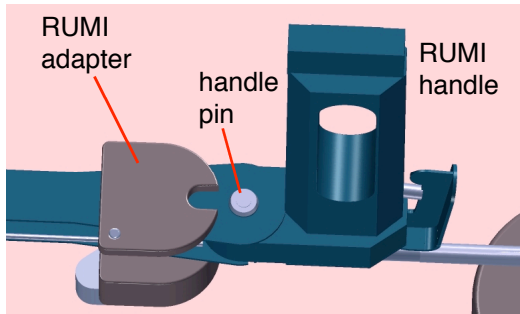
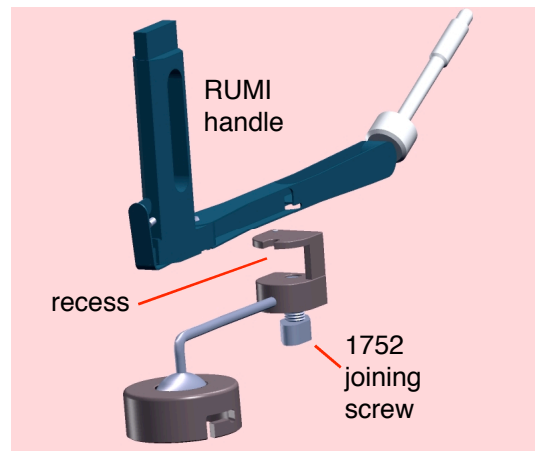
1. After sterilization, insert the inner rod into the outer arm.
2. If resistance is met, gas pressure may not have been released from the luer of the outer arm after the last use.

To remove the gas, attach a male luer from a branched gas line with one short branch disconnected, or use a syringe with the plunger removed.

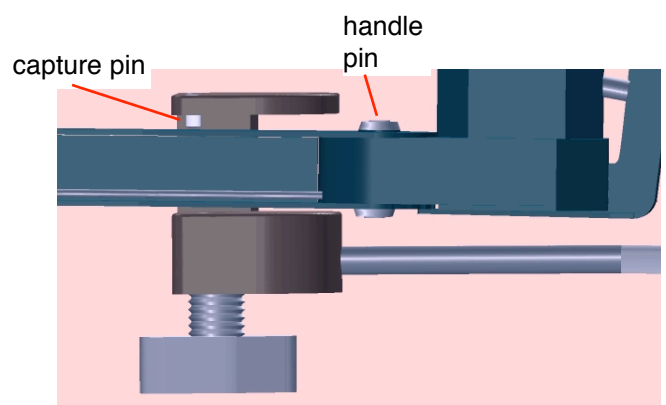


JOINING THE RUMI TO THE ADAPTER

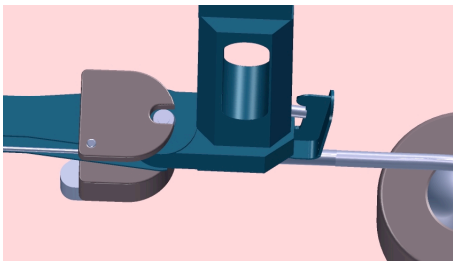
1. Set the joining screw so the RUMI can be slid into the attachment recess.
2. Slide the RUMI into the attachment recess. This connection is made just in front of the RUMI handle.



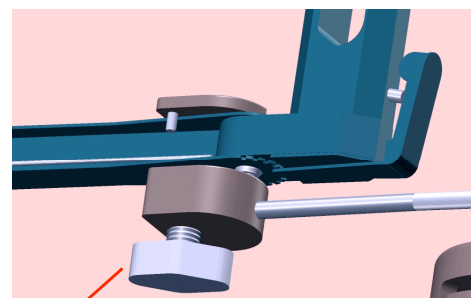
3. Position the RUMI adapter in front of the RUMI handle pin.



4. Make certain the capture pin is past the RUMI edge.



5. Slide the adapter over the RUMI handle pin.



6. Tighten the joining screw.

NON-STERILIZABLE COMPONENTS

Gas supply module, foot pedal assembly, main pivot, rail grip

Setting up the Gas Supply Module

1. Attach the gas supply module to the operating table rail at a position where the flexible gas lines will reach to the Holder gas line connections. Usually this is just beside the planned position for the Holder rail grip.

Whenever possible attach the gas module to the side of the table not used for patient transfer.

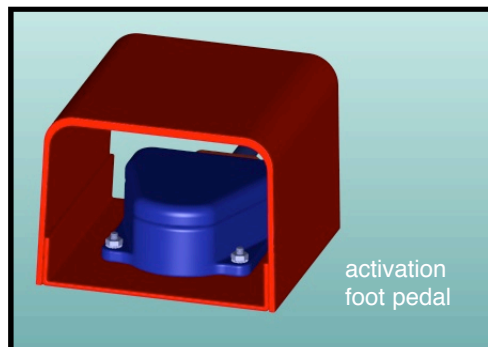
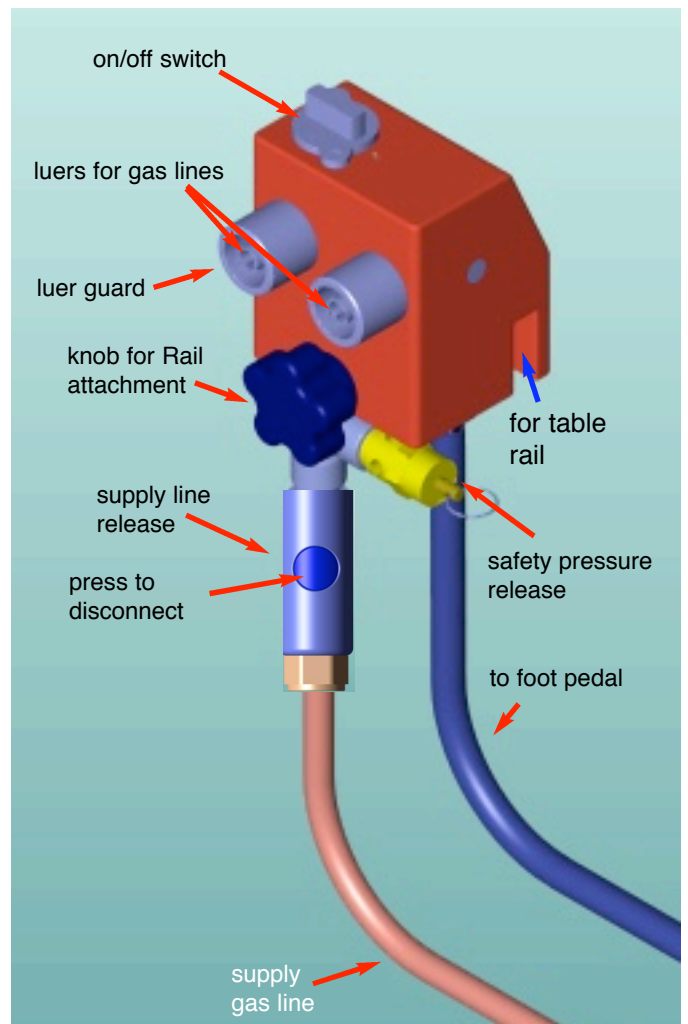
2. Turn off the module switch. This will prevent gas from leaking from the luer connections prior to flexible gas line connection.

3. Connect the gas supply line to the hospital nitrogen* or compressed air supply.

4. Set the supply to 130-150 PSI.

5. Position the attached foot pedal. (Note that it cannot be disconnected from the supply module.)

*not nitrous oxide



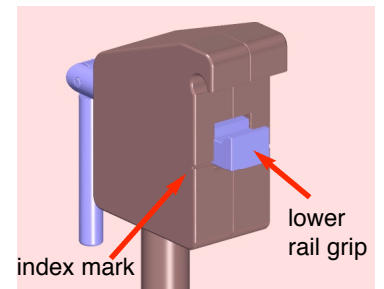
Attaching the Rail Grip assembly to the operating table rail

The rail grip assembly can be placed on either rail behind the attachment for the leg stirrup.

1. Rotate the rail grip handle counter-clockwise until the bottom of the lower rail grip aligns with the index mark.

This setting will allow the rail grip assembly to be attached by tilting it outward.

In order to attach it without tilting, more counterclockwise rotations are required.



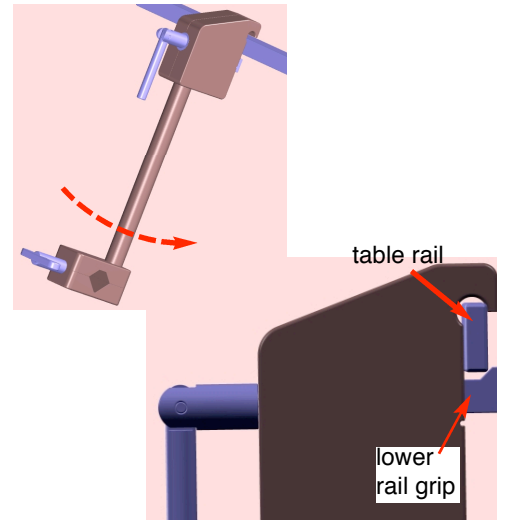
2. Select a position, on the rail, that will place the Holder arm directly below the manipulator.*

3. Tilt the assembly outward and set it on the rail. Pivot it toward the rail until the lower rail grip is below the rail.

Corrections can be made later by repositioning the main pivot assembly.*

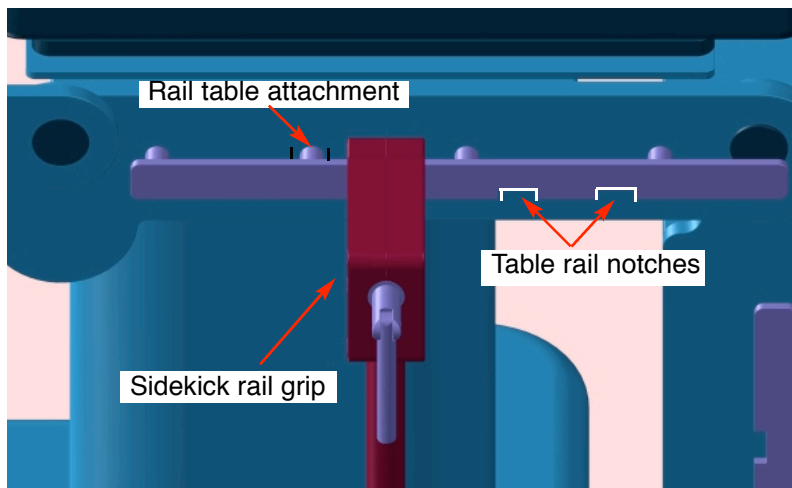
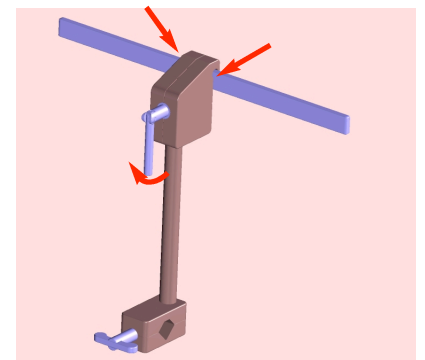
The rail grip can be released and slid on the rail to re-position if necessary.*

*The design of the Holder allows for variability in these settings.



4. Rotate the handle clockwise until it is tight, approximately three full rotations.

Be sure the assembly is hanging straight downward in both planes during this step and the rail grip upper notch is touching the rail on both sides of the rail grip.

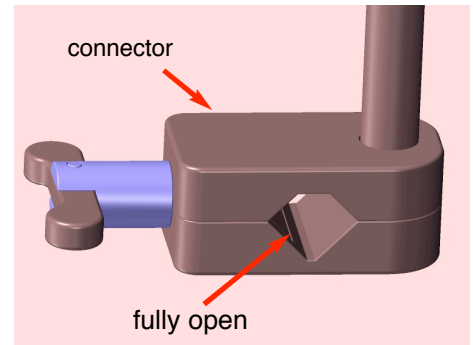
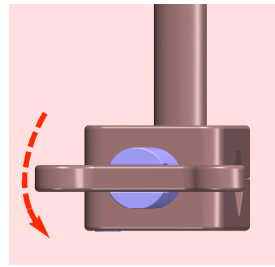


When placing the Sidekick Rail Grip onto the table rail, do not put it over the rail table attachment or a table rail notch.

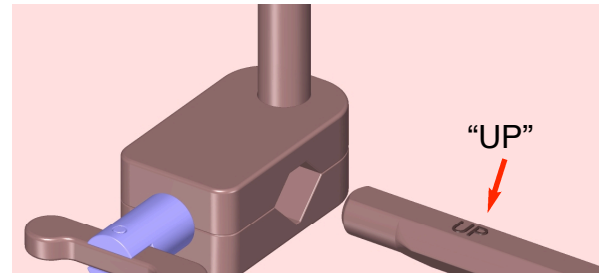
Placing it in these areas could cause an unstable attachment.

Attaching the main pivot assembly to the connector of the rail grip assembly

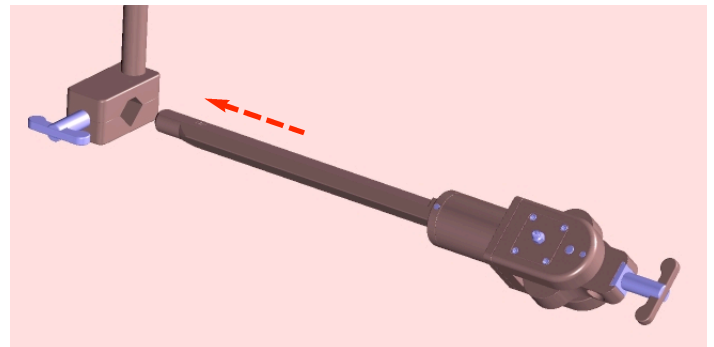
1. Rotate the T-handle counter-clockwise to a stop to open the connection joint for the main pivot cross rod.



2. Position the main pivot and cross rod so "UP" is positioned upward.



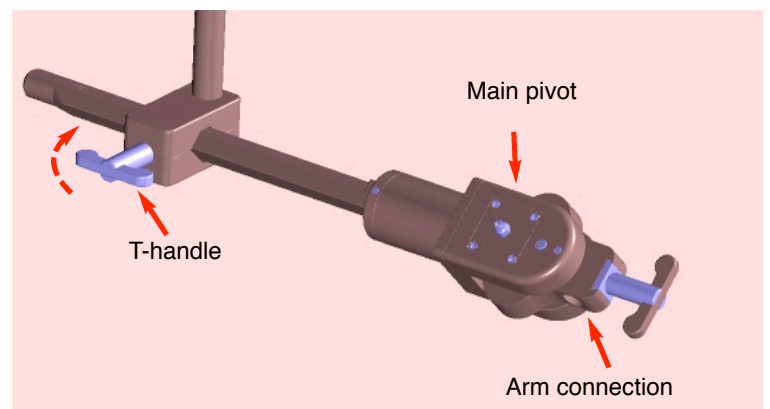
3. Insert the cross rod into the connection joint.



4. Slide the main pivot until the arm connection is located below the planned connection to the manipulator.

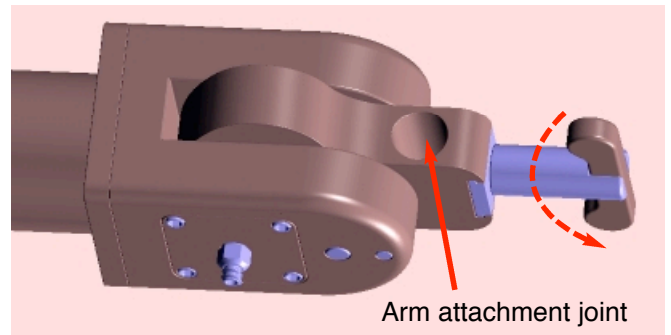
5. Firmly tighten the T-handle clockwise.

This setting can be changed later, if needed.



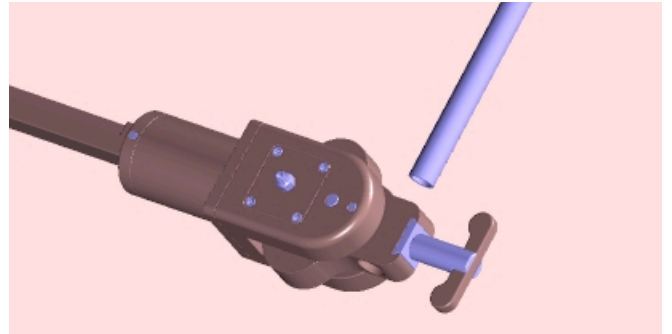
Attaching the arm to the main pivot

1. Rotate the main pivot handle counter-clockwise to a stop to open the attachment joint.

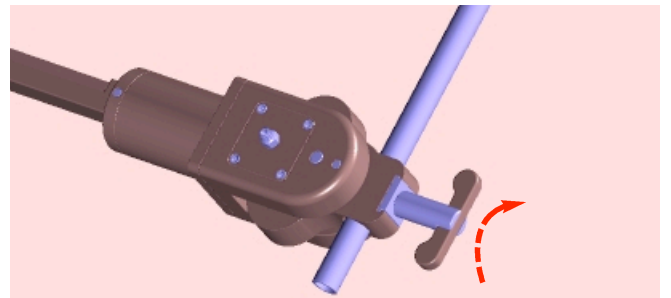


2. Insert the arm assembly into the attachment joint until the telescoping rod will allow for the required manipulator movement.

This setting can be changed later, if necessary.

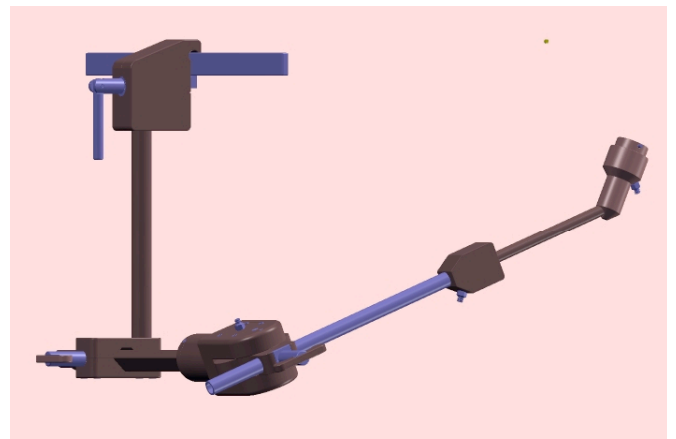


3. Tighten the main pivot handle clockwise.



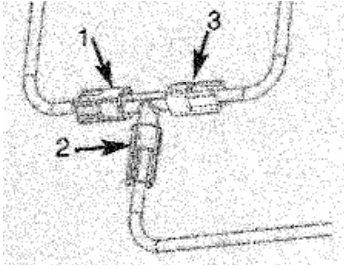
Stops prevent the arm from falling prior to pressurizing the system. Do NOT overcome these stops.

4. Lower the arm sideways to one of the stops or continue to hold it during the next steps.

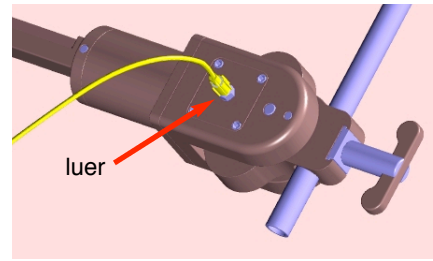


Attaching the gas lines

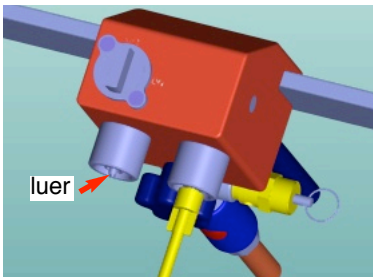
Warning: Do not attach a gas line to a uterine manipulator, extreme danger.



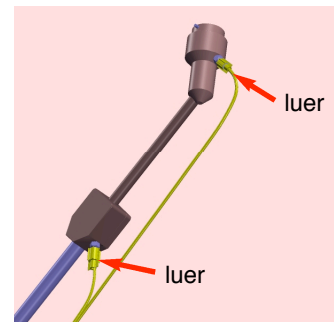
1. Check these three gas line luer connections and firmly tighten if loose.



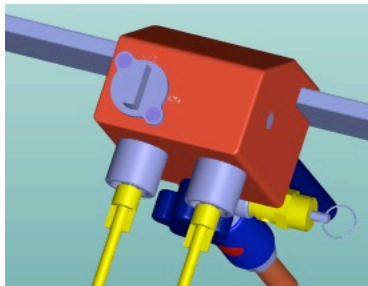
2. Connect the single gas line to the main pivot luer.



3. Connect the other end of the single gas line to one of the gas output luers of the supply module.



4. Connect the branched line to the two luers of the arm assembly.



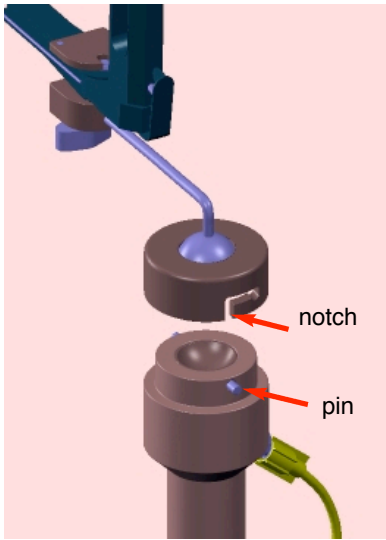
5. Connect the other end to the remaining luer of the supply module.

Note: The gas line connections to the arm may be made prior to joining the arm to the main pivot assembly.

The single gas line may be connected to the pivot and the supply module prior to arm attachment.

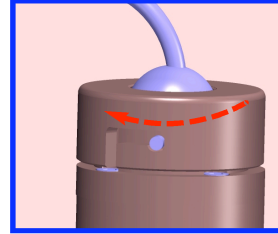
To avoid confusion, make these connections prior to inserting the manipulator into the patient.

Attaching the adapter with manipulator to the Holder



1. Insert the RUMI into a properly anesthetized and restrained patient.

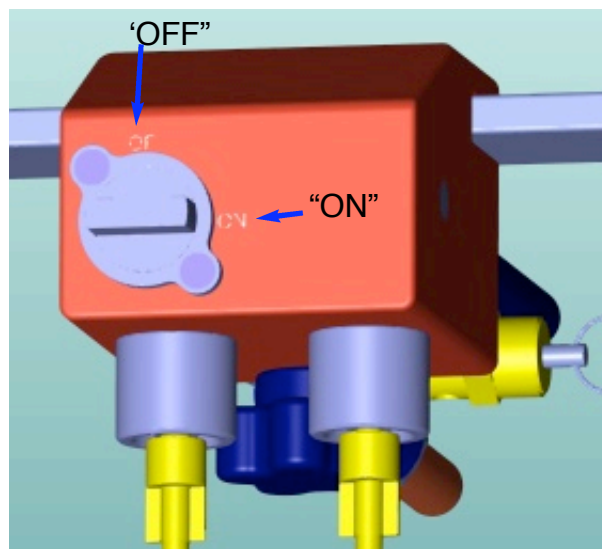
2. Connect the adapter to the arm by sliding the two adapter notches over the arm pins and rotating the adapter clockwise. Gas pressure must be off during this step.



Hold the arm until the gas switch is turned on.

Turning the gas on

1. Turn the supply module switch to "ON".



To use the Holder

1. Grasp the manipulator.
2. Press the foot pedal to re-position the attached manipulator.
3. After releasing the foot pedal, allow gas pressure to build prior to releasing the manipulator.

Problems with Sidekick

In the rare event Side-Kick interferes with required uterine manipulation or fails to hold the uterine manipulator, the uterine manipulator should be disconnected from Side-Kick. Reverse steps 1 to 6, page 7 (Joining the RUMI to the adapter)

If necessary, the arm can be detached from the main pivot. Reverse steps 1 to 3 page 11. (Attaching the arm to the main pivot).

Removing Sidekick

1. Support the arm.
2. Turn off the gas module switch prior to disconnecting the gas lines. This will decompress the holder joints.
3. Detach the Side-Kick adapter from the manipulator, reverse steps 1-6 page 7 entitled **“JOINING THE RUMI TO THE ADAPTER”** or detach the adapter and manipulator from the arm. Reverse step 2 page 13 entitled **“Attaching the adapter with manipulator to the Holder”**.
4. Remove the manipulator following instructions from the manufacturer.
5. Detach the manipulator and disassemble Side-kick by reversing the assembly steps.
- 6. Remove the Sidekick arm before raising the lower end of the operating table.**

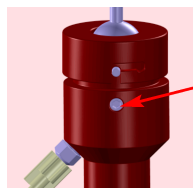
Cleaning the sterilizable components:

Outer arm, inner rod, RUMI adapter, and screws

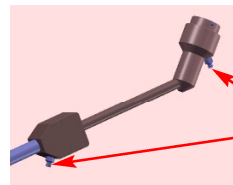
The rail grip, main pivot assembly, gas supply module with foot pedal are not sterilized nor immersed in liquids.

Manual Cleaning:

1. Remove the inner rod from the outer arm.
2. Disconnect the RUMI adapter from the inner rod assembly at the ball joint and remove the joining screw from the RUMI adapter, see pg. 7.
3. Inspect parts for defects, such as parts not fitting together or misshapen parts. Contact Sidekick sales reps. regarding defects.
4. Use Enzol® enzymatic detergent, and prepare according to the manufacture's recommendations of 1 oz. per gallon of warm tap water, (or FDA approved equivalent)
5. Soak the outer arm, inner rod and adapter for five minutes in the prepared solution.
6. Maneuver movable parts to loosen trapped soil. Use a soft bristled brush (M16) to gently scrub to remove any visible soil and actuate all moveable parts while scrubbing in order to loosen trapped soil. Use an appropriate size lumen brush (45-541) for internal channels.
7. Repeat steps 5 and 6 two additional times for a total of three times.
8. Prepare a tap water bath at 38-49° C.
9. Agitate the assembly by hand for a minimum of one minute in the prepared bath.
10. Rinse the assembly under running tap water for at least one minute.
11. Dry the exterior of the assembly with a clean, lint free cloth.



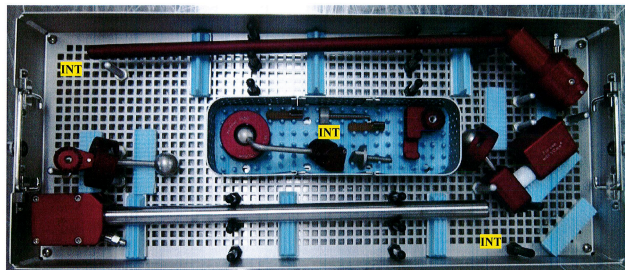
Do not remove this screw



Do not inject liquids into the arm luer.

Sterilizing the Outer arm, inner rod, RUMI adapter and screws

1. Place items in the Kronner Sterilizer tray as illustrated
2. Sterilization wrap : Kingard KC400 (or FDA approved equivalent)
3. Pre-vacuum temperature: 270 F, (132C)
4. Exposure time: 4.0 minutes
5. Drying time: 45 minutes



How to order:

Parts List for the RUMI instrument holder

KSK-5000 The Kronner Side-Kick Uterine Manipulator Holder

- | | | |
|----|----------------|---|
| 1. | 5100-5150-5200 | Rail grip and connector assembly |
| 2. | 5300 | Main pivot assembly |
| 3. | 700-5800 | Pneumatic foot pedal and Gas supply module |
| 4. | K-1120 | Gas supply hose, (attaches to hospital gas wall outlet) |
| 5. | 5400 | Outer Arm assembly |
| 6. | 5500 | Inner rod with pneumatically locking ball joint |

Required adapter

- 1. 5650 RUMI manipulator adapter
- 2. 1752 Replacement joining screw

Disposable components, provided sterile,
(one set required for each procedure)

- 1. HPL1-BL1-V2 Branched gas line set contains:
 - a. Branched line with two male luer-lock fittings on the distal end and one luer-lock female fitting with a luer activated valve on the proximal end, length: 96 inches.
 - b. Straight gas line, with one male luer-lock fitting on the distal end and one luer-lock female fitting with a luer activated valve on the proximal end, length: 96 inches.
 - c. Shelf life: 3 years

Kronner Medical

**1443 Upper Cleveland Rapids Road
Roseburg, Oregon 97471**

**Phone: (800) 706-3533 or (541) 672-2543
Web: www.kronner.com Fax: (541) 672-1074
E-mail: kronner@rosenet.net**