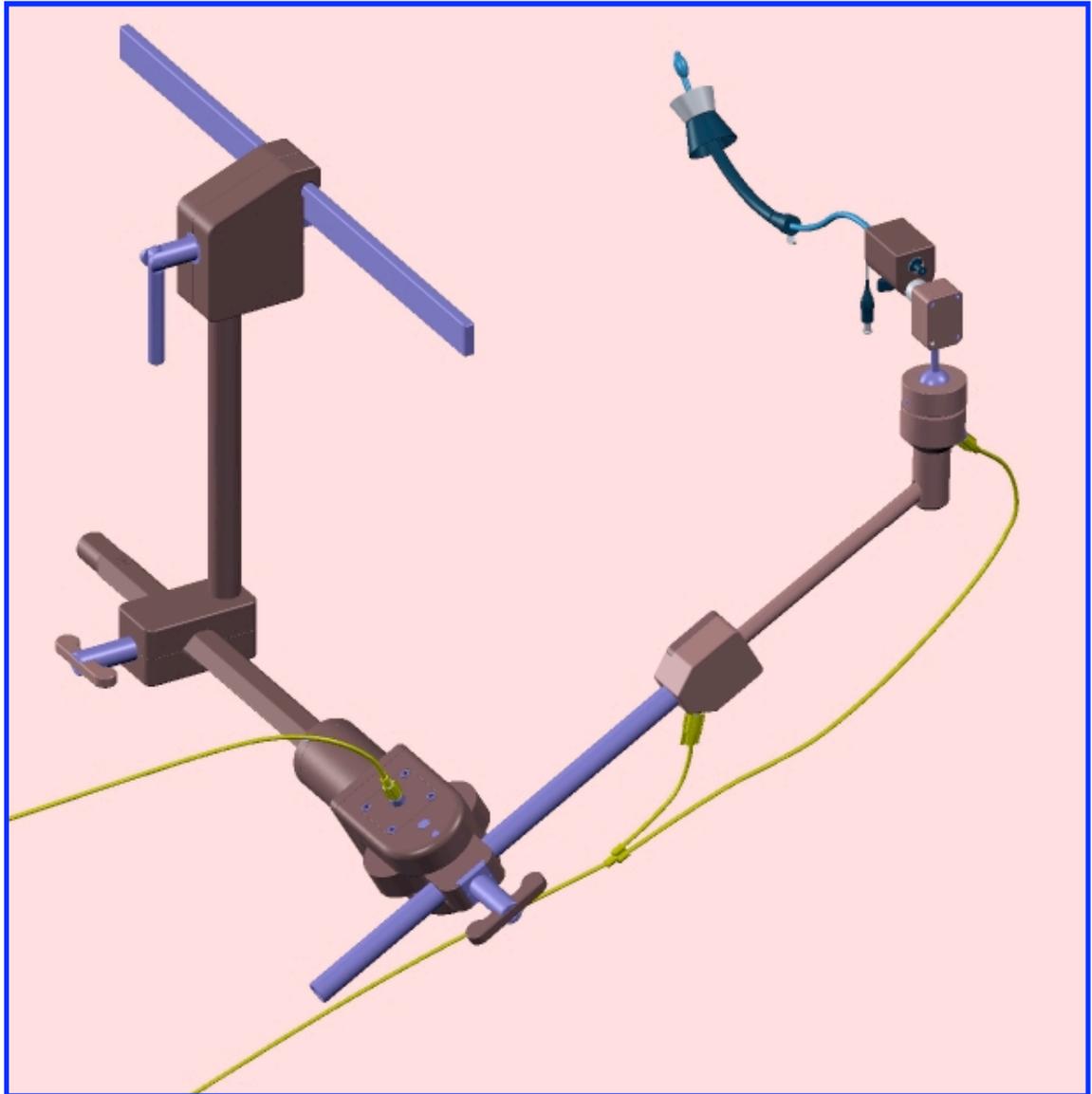


The KRONNER SIDE-KICK

A uterine manipulator Holder

for holding the VCare® uterine manipulator*

Instructions for use



United States Patent 8,485,484.B2

*Manufactured by ConMed

60-6085-200	VCare®, Small (32mm) Cervical Cup
60-6085-201	VCare®, Medium (34mm) Cervical Cup
60-6085-202	VCare®, Large (37mm) Cervical Cup
60-6085-203	VCare®, X-Large (40mm) Cervical Cup

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** which is a **uterine manipulator Holder** firmly holds the V-care and other uterine manipulators during laparoscopic surgery on female pelvic organs, thereby freeing a person 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 it.

With proper adapters the Side-Kick may be used with various other manipulators, such as the RUMI, and the Arch Koh.

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 switch is turned off the Side-Kick joints are decompressed.

Pressing a foot pedal, which 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 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 and contraindications.

Warnings:

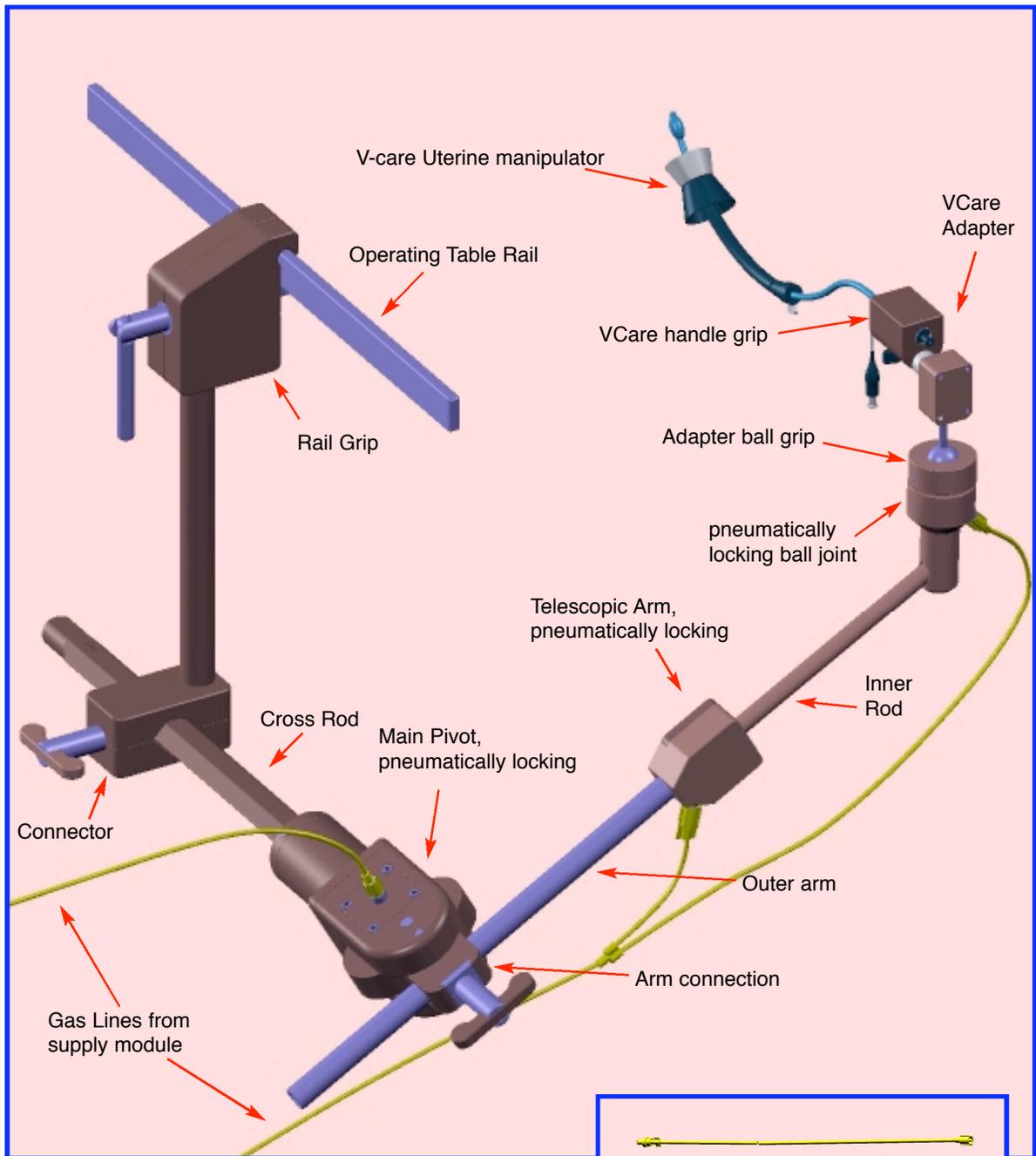
1. Do not use with pressure greater than 150 psi.
2. Do not detach the gas supply module from the gas supply while the manipulator is attached.
3. Do not shut off the gas supply module switch while the manipulator is attached.
4. Do not use substitute flexible gas lines.
5. Do not use if gas leaks are 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, insert a straight Kelly clamp into the luer. Do not displace the stem sideways. Do not use a plastic component for this step.
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

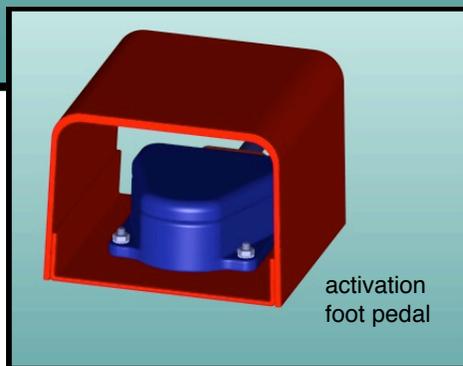
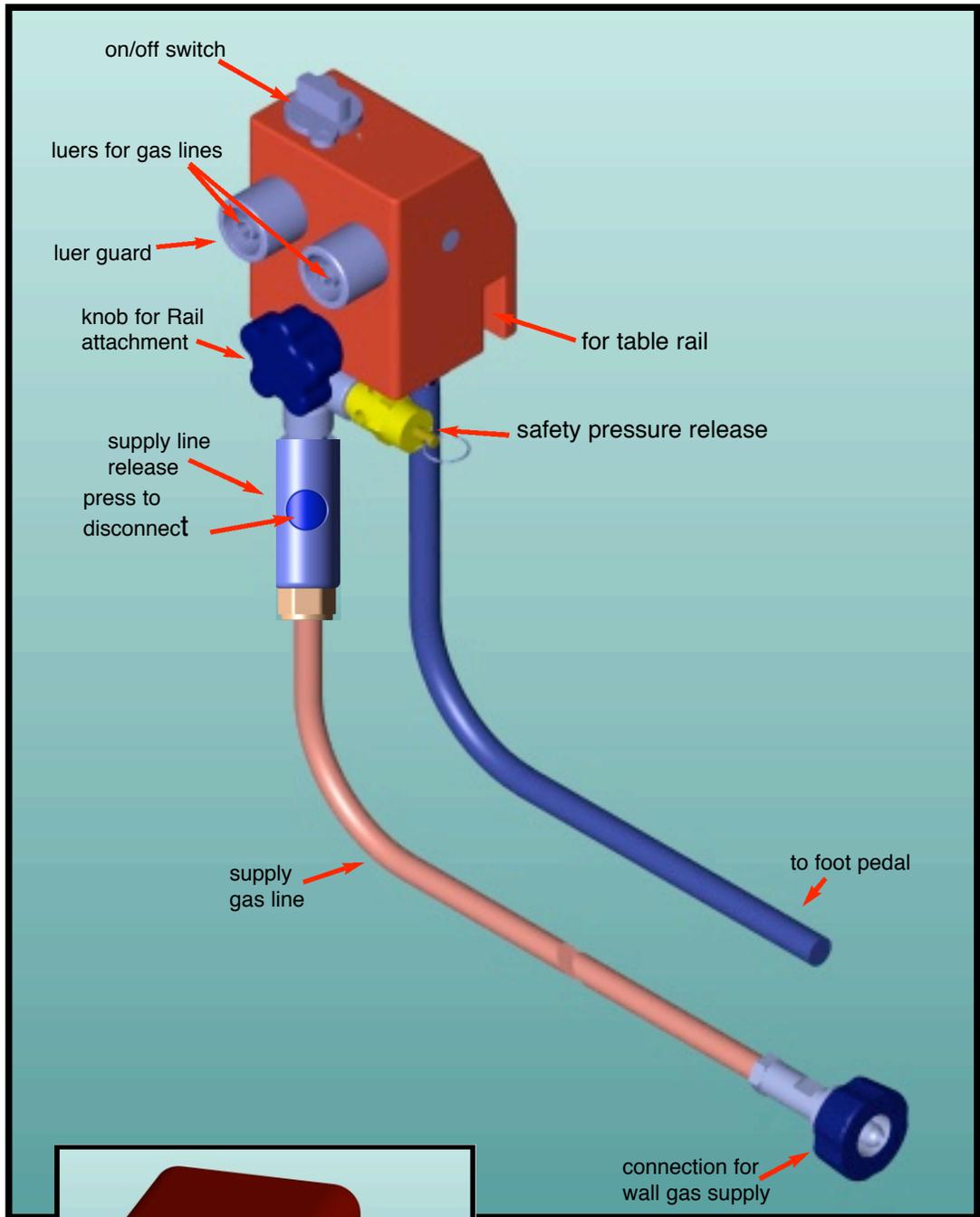


GAS LINES

supplied sterile,
shelf life 3 years,
see package label



GAS SUPPLY MODULE



Foot Pedal Control

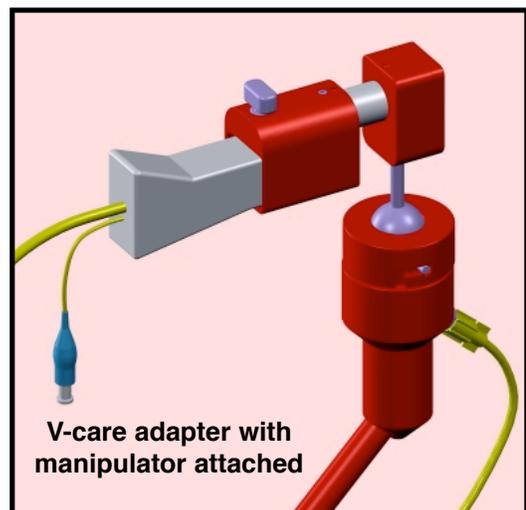
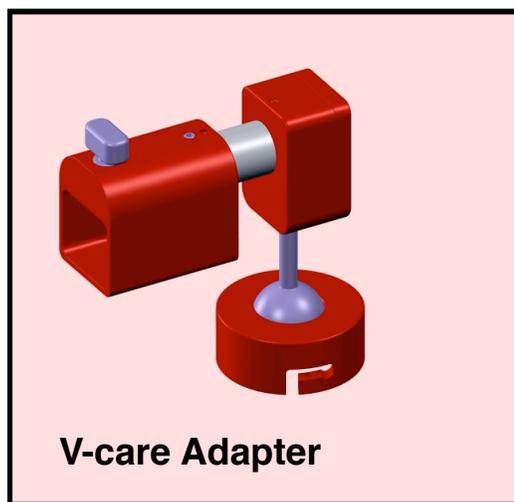
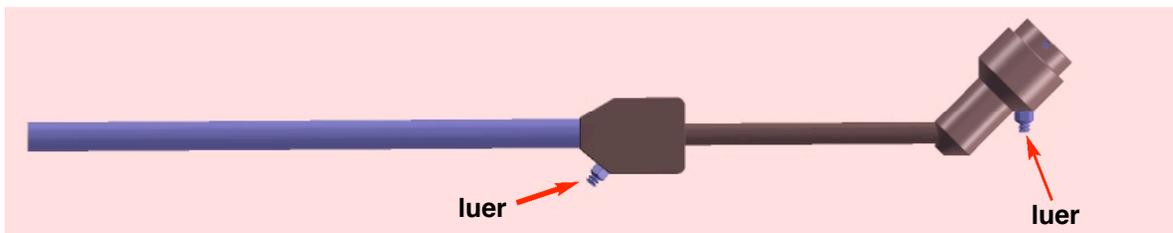
STERILIZABLE COMPONENTS

Outer arm, inner rod and uterine manipulator adapter.

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.

Press the luer stem of the outer arm with a metal object such as a straight kelly clamp. Avoid displacing the stem sideways.



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.

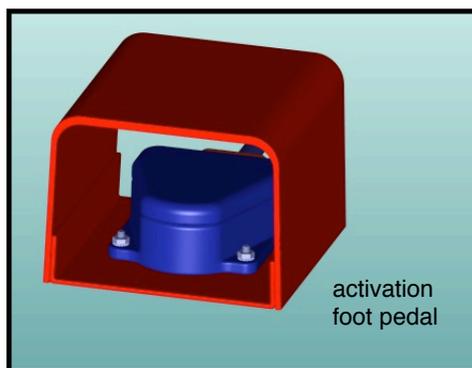
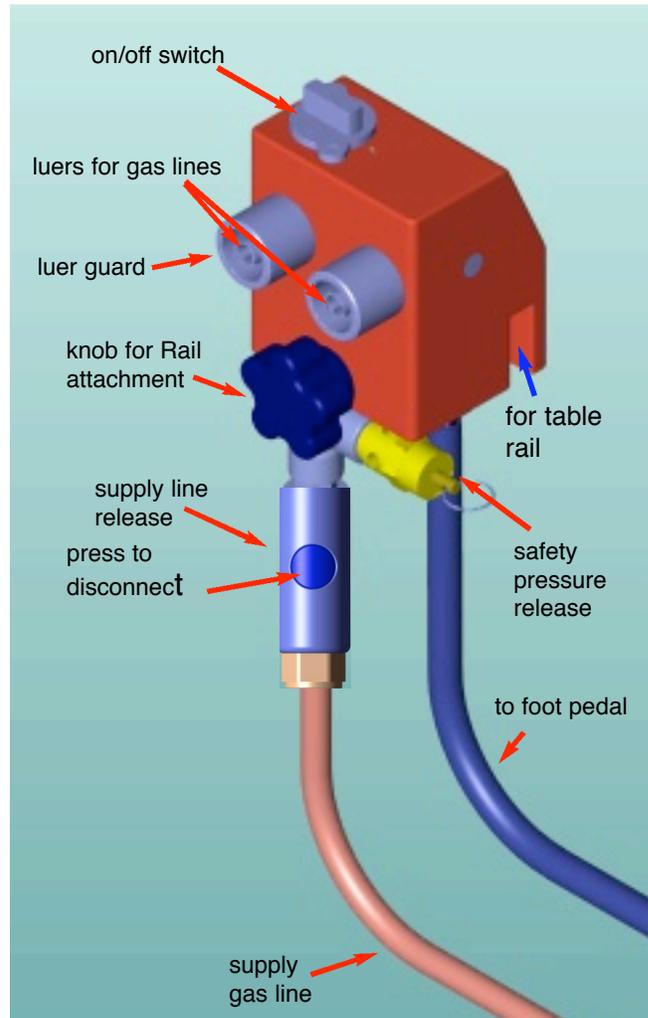
2. Turn off the module switch. This will prevent gas from leaking from the luer connections prior to flexible gas line connection.

3. Connect the gas 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



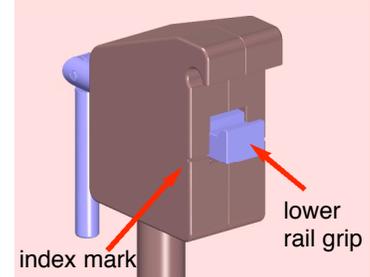
Attaching the Rail Grip assembly to the operating table rail.

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.

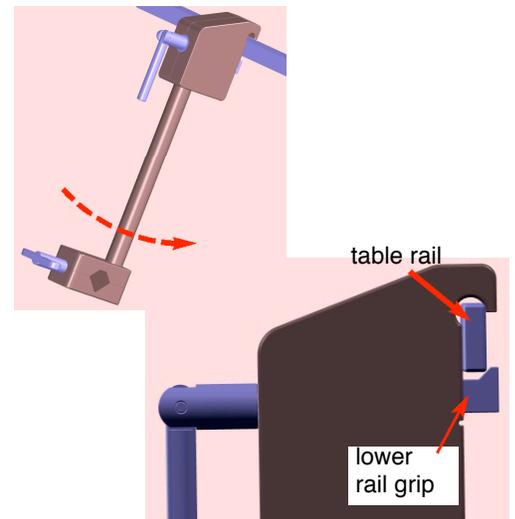


2. Select a position, on the rail, that will place the Holder arm directly below the manipulator.*
3. Tilt the assembly outward and set it on the rail. Pivot it toward the rail until the lower rail grip is below the rail.

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

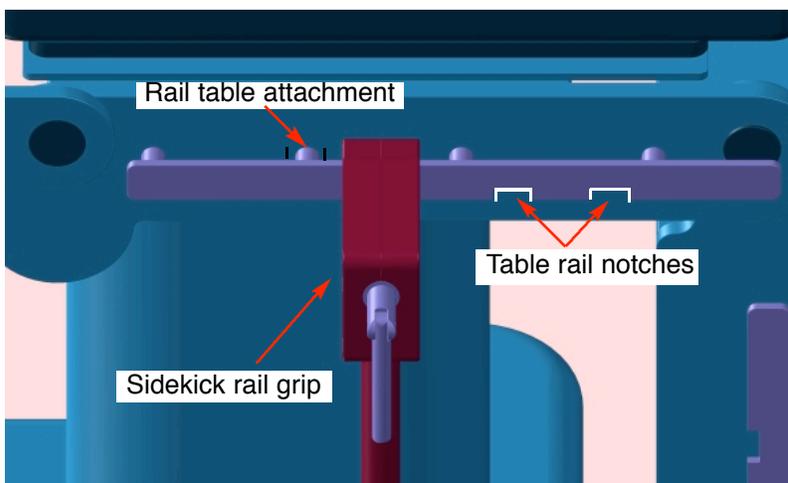
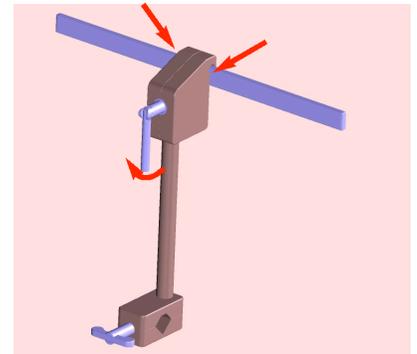
The rail grip can be released and slid on the rail to re-position if necessary.*

*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.

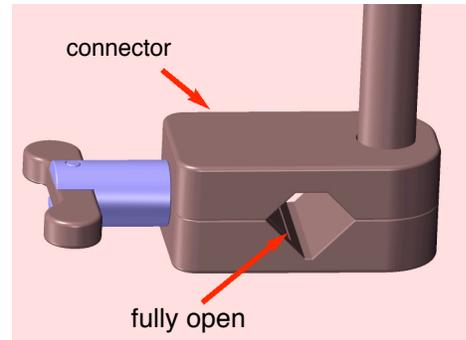
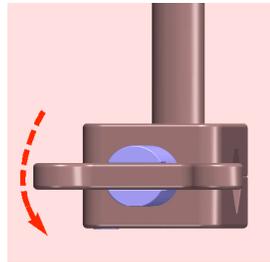


When placing the Sidekick Rail Grip onto the table rail, do not put it over the rail table attachment or a table rail notch.

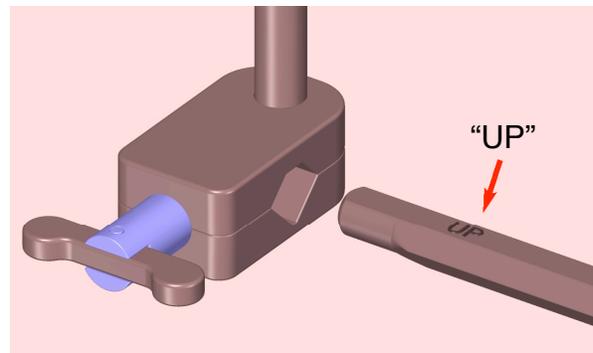
Placing it in these areas could cause an unstable attachment.

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

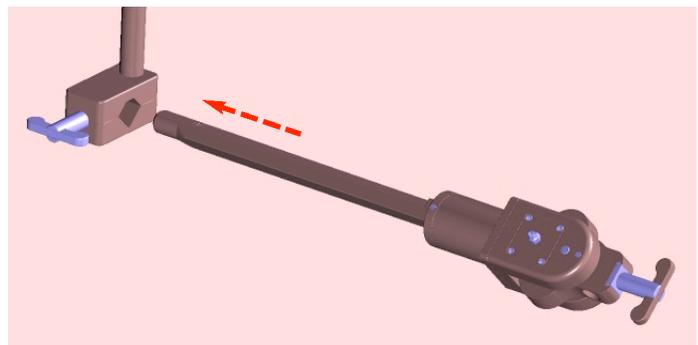
1. Rotate the T-handle counter-clockwise to a stop to open the connection joint for the main pivot cross rod.



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



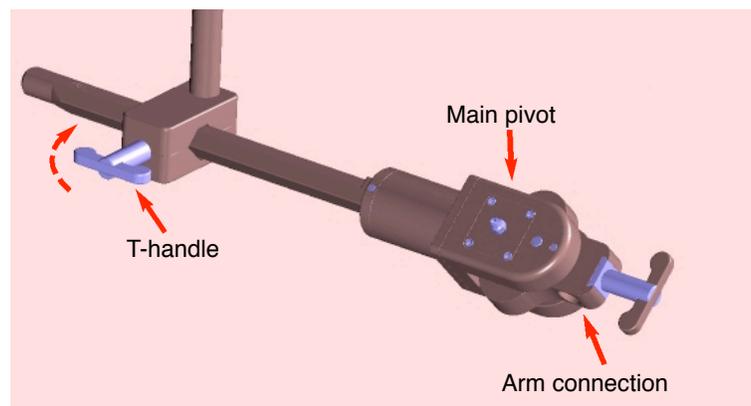
3. Insert the cross rod into the connection joint.



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

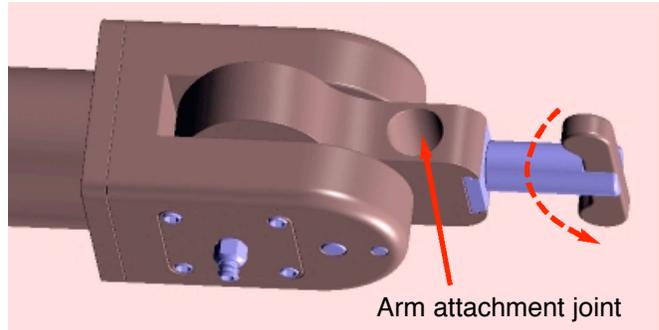
5. Firmly tighten the T-handle clockwise.

This setting can be changed later, if needed.



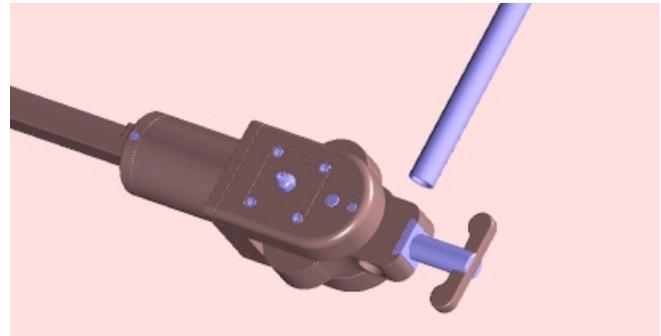
Attaching the arm to the main pivot

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

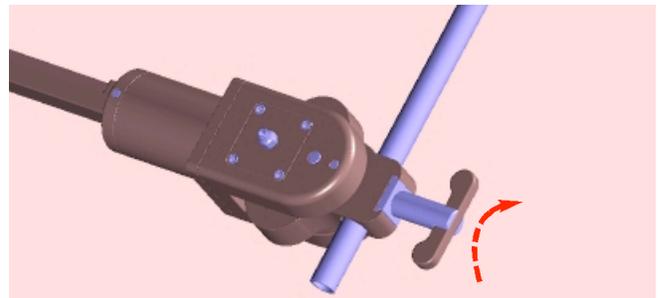


2. Insert the arm assembly into the attachment joint until the telescoping rod will allow for the required manipulator movement.

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.

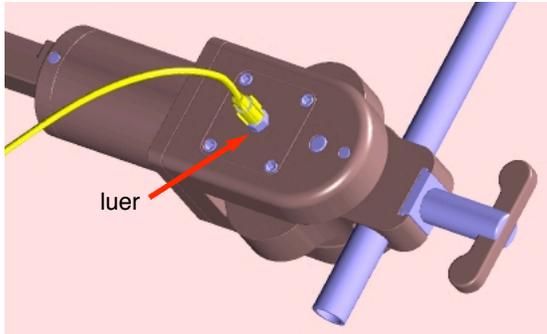
4. Lower the arm sideways to one of the stops or continue to hold it during the next steps.



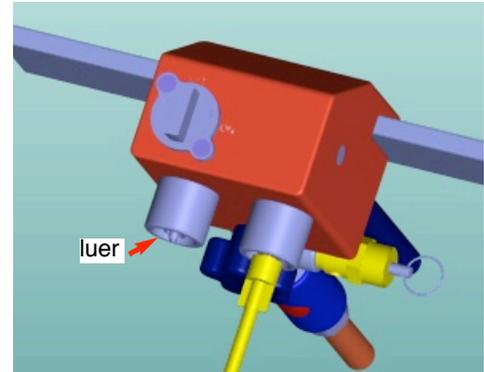
Attaching the gas lines

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

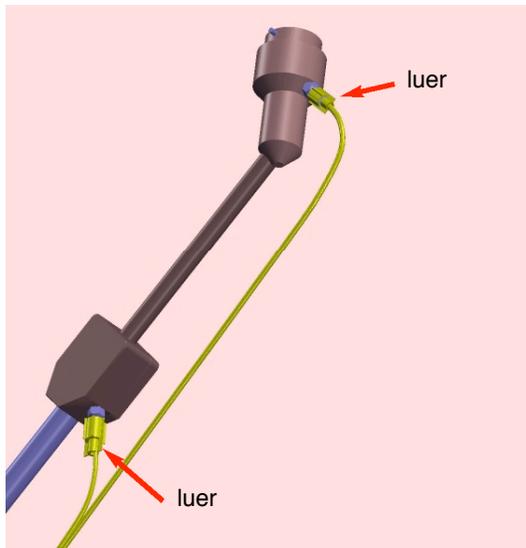
Firmly tighten all gas line luer connections.



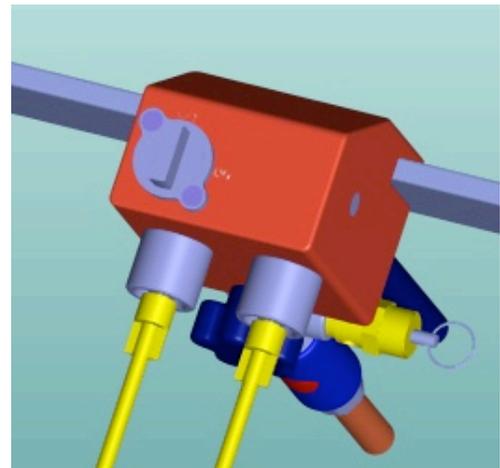
1. Connect the single gas line to the main pivot luer.



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



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



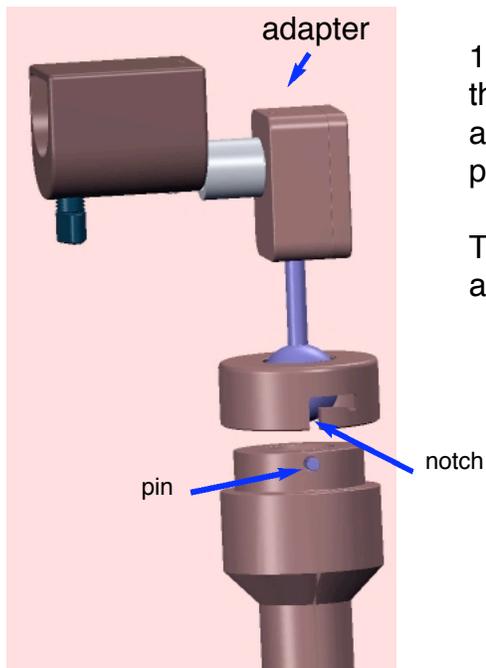
4. Connect the other end to the remaining luer of the supply module.

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.

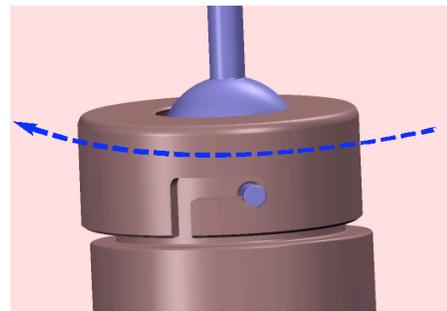
To avoid confusion, make these connections prior to inserting the manipulator into the patient.

Attaching the adapter to the Holder



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

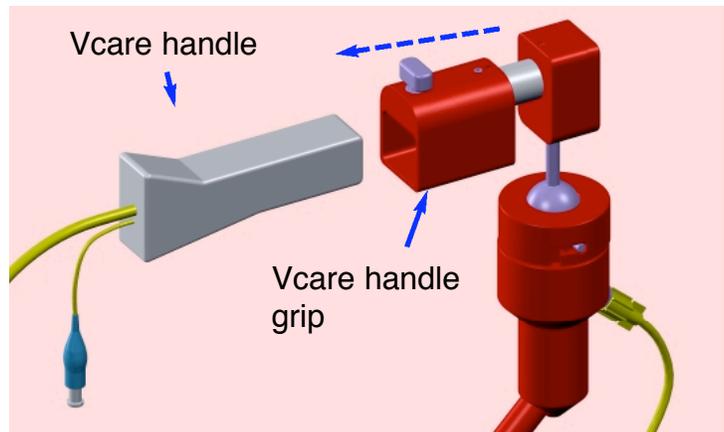
The adapter may be attached when the arm is assembled.



Attaching the adapter to the V-Care manipulator

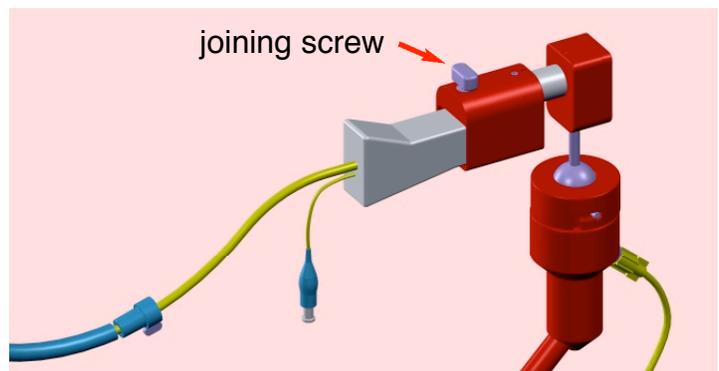
1. Insert the manipulator into a properly anesthetized and restrained patient.

2. With the gas off, join the V-care handle grip over the V-care handle.



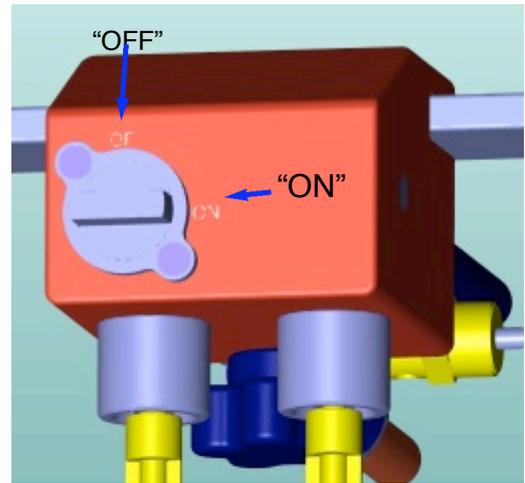
3. Tighten the joining screw.

Support the arm until the gas is turned on.



Turning on the gas

1. Turn the supply module switch to "ON"



To use the Holder

1. To rotate V-care, with the gas on or off, grasp the V-care handle grip that surrounds the V-care handle and rotate V-care. See page 12.
2. To re-position the attached manipulator, grasp the Vcare handle grip.
3. Press the foot pedal and re-position the manipulator.
4. After releasing the foot pedal, allow gas pressure to build prior to releasing the handle grip and the attached manipulator.

Problems with Sidekick:

In the rare event Sidekick 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 3, page 12 (Attaching the adapter to the V-care manipulator)

If necessary, the arm can be detached from the main pivot. Reverse steps 1 to 3 page 10. (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 1-3 page 12 entitled, "**Attaching the adapter to the V-Care manipulator.**"
4. Remove the manipulator following instructions from the manufacturer.
5. Disassemble Side-Kick by reversing the assembly steps
6. **Remove the Sidekick arm before raising the lower end of the operating table.**

Cleaning Components of the Kronner Side-Kick a uterine manipulator holder

**The rail grip, main pivot assembly,
gas supply module with foot pedal are not sterilized.**

Cleaning the sterilizable components:

Outer arm, inner rod, adapter

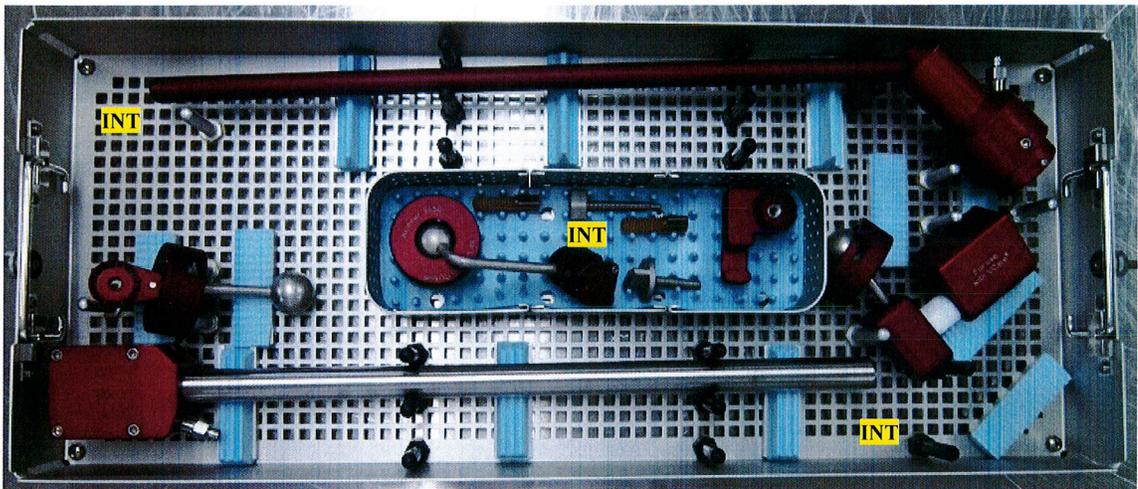
Manual Cleaning:

1. **Remove the inner rod from the outer arm.**
2. **Disconnect the manipulator adapter from the inner rod assembly at the ball joint and remove the manipulator joining screw from the manipulator 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 use an 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.

Sterilizing Components of the Kronner Side-Kick a uterine manipulator holder

Sterilizing the Outer arm, inner rod, and adapter:

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



The Kronner Side-Kick A uterine manipulator Holder

Parts List for the V-Care instrument holder

KSK-5000 The Kronner Side-Kick

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 wall gas outlet)
5. 5400 Outer Arm assembly
6. 5500 Inner rod with pneumatically locking ball joint

Required adapter

1. 5920-2 V-care Tension adapter
2. 1752-2 Replacement manipulator 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

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