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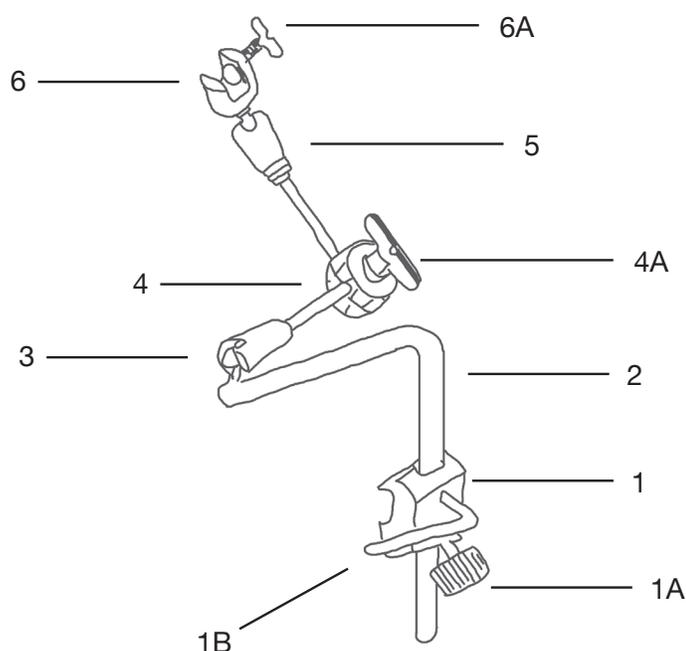
Retract-Robot System

IFU-2017.05.10

Recommendations for the cleaning, maintenance and sterilization of the Retract-Robot System

The Retract-Robot System, though ruggedly built, is a sophisticated yet delicate instrument. Please handle the equipment accordingly.

This manual will acquaint you with the parts of the system and should be read prior to using the system in surgery. Particular attention should be paid to the proper use of the main joint (diagram No. 3) during surgery, as this is the heart of the system.



<u>No.</u>	<u>Description</u>
1	Steril-Clamp Assembly
1A	Knurled knob to tighten Steril-Clamp to the accessory rail of the operating table
1B	Lever handle to tighten the Retract-Robot in the Steril-Clamp
2	Mounting shaft
3	First articulating joint
4	Main articulating joint
4A	Wing nut for main articulating joint
5	Forward articulating joint
6	Instrument holder
6A	Thumb screw to tighten instruments into the holder



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Maintenance Recommendations

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Maintenance Recommendations for Retract Robot

The main articulating joint must never be opened except by a trained surgical instrument or tool and die maker who is capable of working with such devices and with very close tolerances.

If you do open this joint, you may lose important components and/or be unable to reassemble it. It is not necessary to open this joint for cleaning and sterilizing. Normal washing and autoclaving will be sufficient.

The use of silicone spray lubricants is not recommended, due to its ability to hold moisture into the joints. **The use of silicone spray will trap moisture inside these joints, causing corrosion.**

Approximately once every other month (every sixty days), the Retract-Robot should be immersed in instrument milk to keep all of the moving parts lubricated and to protect the stainless steel components. As an alternate, you can use a “spray lube”, following the instructions on the bottle. Once or twice a month, put a few drops of instrument oil into the opening of the wing nut to lubricate the retaining screw (diagram No. 4B).

From time to time (between six months to one year in case of heavy usage), the Retract-Robot should be subjected to preventative maintenance service. We can provide this service to you on a one-day turn-around time basis for a nominal charge.

This service is relatively inexpensive and should be considered similar to the cost of maintaining other sophisticated instruments, as it saves money in the long run.



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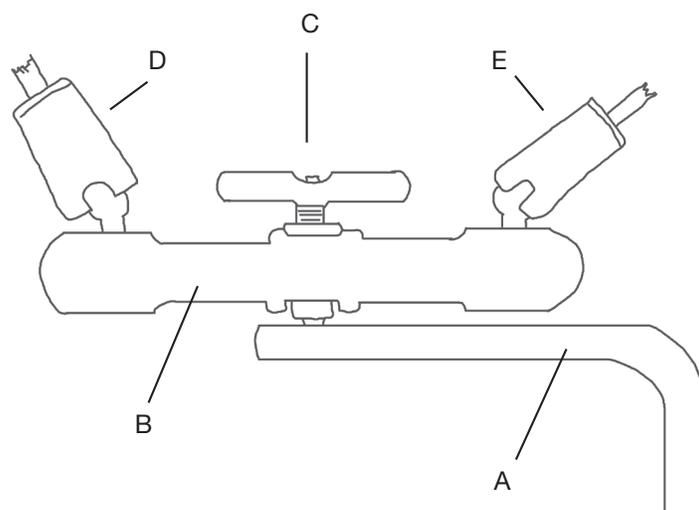
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Operating Instructions

Dual-Arm Retract Robot

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The dual-arm Retract-Robot features two robotic arms, attached to one mounting rod via an articulating, horizontal bar. Follow the operating instructions for the Retract-Robot carefully. In addition, we offer the following information for operation of the dual arm system.



<u>No.</u>	<u>Description</u>
A	Mounting Bar
B	Horizontal Bar
C	Wing Nut, for articulating horizontal bar
D	Retract-Robot #1
E	Retract-Robot #2

Install the mounting bar (A) into the Steril-Clamp as previously described. Make certain that the bar is tight and secure inside the clamp.

Loosen the wing nut (C) to enable the articulating horizontal bar to move freely. Move the horizontal bar into the desired position and tighten wing nut (C).

Use Retract-Robot arms 1 and 2 as previously described. If needed, wing nut C may be loosened to make fine adjustments during the procedure. Make certain that wing nut C is tightened again, to maintain stability of the robot arms.

For cleaning and autoclaving, follow the previously described procedures.



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Setting up the Retract Robot

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1. Select the desired position of the Retract-Robot along the side of the operating table.
2. The autoclavable Steril-Clamp is installed over the sterile drape by opening the knurled knob (diagram No. 1A) enough so that the adjustable jaws of the clamp are wide enough to accommodate the width of the accessory rail. Make sure you mount the clamp with the knob (diagram No. 1A) facing down as illustrated. Place the adjustable jaw over the draped accessory rail. Thereafter, turn the knurled knob clockwise to tighten the Steril-Clamp on the accessory rail so that it is completely secure and no further movement is possible.
3. Insert the round mounting shaft (diagram No. 2) into the round opening on the top of the Steril-Clamp.
4. Tighten the lever handle (diagram No. 1B) clockwise until the mounting shaft of the robot is secure and will not move from side to side.
5. Place the instrument to be used into the opening of the robot arm's instrument holder and tighten the thumb screw (diagram No. 6A) until the instrument is secure and will not move from side to side.
6. Making certain that the main articulating joint (diagram No. 4) is not tight, move the robot arm with the instrument in place to the desired position and retract to the necessary tension by pulling back with the main articulating joint's housing. When the desired tension is achieved, turn the wing nut for the main joint (diagram No. 4A) clockwise until tight. The joint will be sufficiently tight when the instrument does not slip out of position as manual tension is released. **Do not over-tighten the main joint.**
7. To release, reverse the above procedure.



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Recommendations for Operation and Sterilization

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Recommendations for Proper Operation

The main articulating joint (diagram No. 4) controls all of the articulating joints of the system. When fixing or repositioning any of these articulating joints, it is absolutely mandatory that the joint be completely loosened by means of the wing nut for the main articulating joint (diagram No. 4A) first. If this is not done and the arm is forced in any way to achieve the desired position, there will be damage to the internal joint mechanism.

Also, when loosening the wing nut for the main joint, it is important not to force it to turn out too far, otherwise the thread will break and the main joint may come apart or fail to tighten. This wing nut has a built in stop which is intended to prevent turning it out too far. **Never force the wing nut counter-clockwise past this stop!**

Sterilization

The Retract-Robot may be steam or gas autoclaved along with other stainless steel instruments. See "Autoclaving Methods".

It is important that the longest drying cycle selection on your sterilizer be used, to minimize the amount of moisture that may accumulate in the joints.

We do not recommend cold soaking, as the moisture from the solution will collect inside the working mechanism and cause corrosion.

PLEASE NOTE

- All Retract-Robot Systems **MUST ONLY** be used for its intended purpose.
- These Retractor Systems are only for use by a qualified physician.
- These Retractor Systems must be inspected prior to each use to make certain they are in proper working order.
- All Retractor System parts must be sterilized before each use.
- Selecting the proper technique will help to preserve the function and extend the life of your surgical instruments.



Autoclaving Methods

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ETO Sterilization

With a pressure reading not to exceed 12 psi, and a temperature not to exceed 68.3 degrees Celsius (155 degrees Fahrenheit), the electrosurgical accessories can be sterilized by ethylene oxide in any standard cycle.

Concerning humidification, vacuum, cycle time, gas concentration and temperature, we recommend following manufacturer's instructions for the ETO sterilization unit:

Steam Autoclaving with Prevacuum and Gravity Sterilizers

If a wrapping method is used, make certain that the instruments are individually wrapped or sealed in a sterile pack. Other metal objects should never come in contact with the insulating material of forceps and handles, or with RF-connection cables. Such points of contact may cause melting of the insulation.

We recommend the following values / parameters but we also suggest following the manufacturer's instructions for steam sterilization:

Cycle	Sterilizing Temp.	Sterilizing Time	Drying Time
Gravity Displacement	250°F [132°C]	15 min	45 min
	270°F [121°C]	30 min	45 min
Prevacuum	270°F [121°C]	4 min	30 min

It is important that the longest drying cycle possible is employed to prevent build up of moisture inside the instrument. If the cycle of your autoclave allows a 30 minute dry time, we recommend it. Corrosion, pitting or intermittent operation are usual signs of a moisture induced corrosion problem.

Flash Autoclaving (fast heating / cooling cycle)

Flash steriliation: minimum exposure time - 4 minutes. Average drying time: 8 to 15 minutes.

Cold Soaking - NOT RECOMMENDED

Sterilization with the Sterrad Process

The STERRAD system uses low temperature plasma to sterilize metal and non-metal instruments. Please adhere to the sterilization instructions provided by the manufacturer of the equipment.

Warning: If this device is/was used in a patient with or suspected of having Creutzfeldt-Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of cross-contamination!