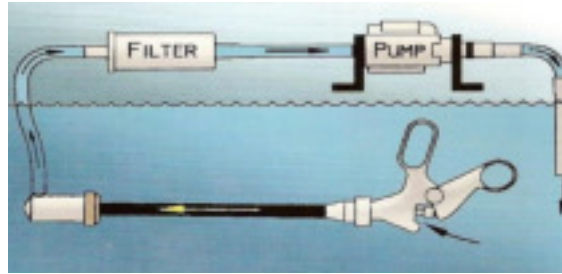


In-service: SurgiSonic® 1211X Tubular Surgical Instrument Cleaning Machine.



The SurgiSonic® 1211X surgical instrument cleaning machine combines ultrasonic action/suction/and filtration to individually clean up to six submersible non-robotic tubular surgical instruments, or three submersible *da Vinci® robotic instruments, inside and out. A basket is included for cleaning loose instruments in a separate cycle.

This basic SurgiSonic® 1211X in-service will:

- I) Identify the machine parts and how to setup and run the machine.
- II) How to clean non-robotic tubular surgical instruments.
- III) How to clean loose instruments.
- IV) How to clean robotic tubular surgical instruments using our patented technology.

PART I: SurgiSonic® 1211X IDENTIFICATION OF COMPONENTS AND SETTING UP THE MACHINE.

The SurgiSonic® 1211X is easy to set up, easy to use, and easy to maintain.



The ultrasonic tank is sitting on a shelf that is attached to the suction pump housing.

NOTE: Rinse all instruments under running water before and after cleaning and rinsing them in the SurgiSonic®.

- 1) **Attach drain tubing:** Reach inside the hole on the left side of the machine and pull out the drain tubing. Attach tubing to drain valve and place open end into a sink. Point handle down to close valve.
- 2) **Plug in machine:** Reach inside the hole on the right side of the machine and ok,, pull out the electric cord that is attached to the timer dial and insert the plug-end into a 110/120 VAC wall outlet.
- 3) **Fill ultrasonic tank:** Fill ultrasonic tank with 5 gallons of warm, **115°**, water.
- 4) **Add enzyme cleaner:** Add 5 ounces of pH neutral SurgiSoak® enzyme cleaner to the ultrasonic bath water.

NOTE: NEVER run ultrasonic tank without 5 gallons of water in the tank and a lid placed on top of it.

NOTE: NEVER hang suction chambers, empty or engaged, outside of tank while pumps are on.

NOTE: NEVER use any type of caustic/corrosive/or coagulating substances in, or on, the SurgiSonic®. Pg.1



The SurgiSonic® comes with six individual, inline, #3312 SurgiSuction® suction chambers, filters, suction pumps, and fluid return tubes already attached to the pump housing unit.

The three in-line suction chambers and filters on the left side are individually attached to pumps #1, #2, and #3. The three in-line suction chambers and filters on the right side are individually attached to pumps #4, #5, and #6.

CONTROLS FOR RUNNING THE MACHINE ARE LOCATED ON THE FRONT OF THE PUMP HOUSING.



On the front of the pump housing there is a circuit breaker, a timer dial, and a pump cleaning cycle switch.

5) Pump switch: The small metal switch to the right of the timer dial controls the suction pump speed.

- The NORMAL, up, pump switch position is used to clean most instruments.
- The OFF, middle, pump switch position turns off the pumps.
- The FAST, down, pump switch position is used for a quicker cleaning time or higher suction power to clean older, clogged, tubular instruments.

NOTE: Set the suction pump cleaning speed BEFORE turning on the timer dial.

NOTE: NEVER change pump speed while machine is on.

6) Timer dial: The timer dial turns on the machine for up to 30 minutes.

NOTE: NEVER turn timer dial past 30 minutes; if turned past 30 minutes the timer dial will break.

NOTE: NEVER turn timer dial on until after:

- 1) The ultrasonic tank has been filled with 5 gallons of cleaning solution,
- 2) the instruments have been setup, according to Part II/III/or IV, and lowered into the ultrasonic bath,
- 3) the lid has been placed on the ultrasonic tank,
- 4) and the speed has been set.

NOTE: Normal cleaning cycles are 15 minutes: Use fast speed 30 minute cycle to clean clogged instruments.

NOTE: NEVER hang suction chambers outside of the ultrasonic bath while the machine is running.

Rinse Cycle:

- 1) With timer off; open drain valve to empty cleaning solution from the ultrasonic tank.
- 2) Close drain valve.
- 3) Refill tank with 5 gallons of water.
- 4) Repeat instrument setup.
- 5) Cover ultrasonic tank with lid.
- 6) Set pump speed to normal.
- 7) Set timer for 5 minutes.

PART II: SurgiSonic® 1211X INSERVICE FOR CLEANING NON-ROBOTIC TUBULAR INSTRUMENTS.



NOTE: Rinse all instruments under running water before and after cleaning and rinsing them in the SurgiSonic® 1211X.

The SurgiSonic® 1211X comes with six #3312 SurgiSuction® suction chambers. These suction chambers were designed to MAXIMIZE the amount of suction applied to the distal end and interior shaft of the inserted non-robotic tubular instrument. These six suction chambers come fitted with six #3212 medium hole, latex free, rubber nipples for cleaning instruments 5mm to 10mm in diameter, The SurgiSonic® also comes with six #3205 small hole rubber nipples for inserting instruments 1.7mm to 5mm in diameter, and six #3215 large hole rubber nipples for inserting instruments 10mm to 12mm in diameter.

TO CLEAN:

- 1) **Set up machine:** Close drain valve, plug cord into 110/120 outlet, fill tank with 5 gallons of warm, 115°, water.
- 2) **Add Enzyme cleaner:** Add 5 oz of SurgiSoak® pH neutral enzyme cleaner.
- 3) **Fit rubber caps onto suction chambers.** Fit a small/medium/or large hole, latex free, rubber nipple onto each #3312 SurgiSuction® suction chamber to accommodate the shaft diameter of the instrument to be cleaned.
- 4) **Attach instrument:** Insert the entire distal, jaw/hinge, area of the non-robotic tubular surgical instrument into the suction chamber through the properly sized hole in the attached rubber nipple and lower into ultrasonic bath. 5) **Place lid on ultrasonic tank.**
- 6) **Set pump speed:** Place metal switch in up position for normal, middle for off, and down for fast.
- 7) **Set timer dial:** Set for 15 minutes to start cleaning cycle, or 30 minutes for clogged instruments.

TO RINSE: 1) With timer off; open drain valve to empty cleaning solution from the ultrasonic tank. 2) Close drain valve. 3) Refill tank with 5 gallons of water. 4) Repeat instrument setup. 5) Cover tank. 6) Set pump speed normal. 7) Set timer for 5 minutes.

NOTE: A fast speed 30 minute cycle is recommended for cleaning clogged instruments for the first time.

NOTE: NEVER hang suction chambers, empty or engaged, outside of the ultrasonic bath while machine is on.

NOTE: NEVER clean loose instruments at the same time as inserted tubular instruments!

PART III: SurgiSonic® 1211X INSERVICE FOR CLEANING LOOSE INSTRUMENTS.

NOTE: Rinse all instruments under running water before and after cleaning and rinsing them in the SurgiSonic® 1211X.



The #3620 basket for cleaning loose instruments comes with the SurgiSonic® 1211X.

TO CLEAN: 1) Set up machine and add enzymes as stated above. 2) Lower loaded loose instrument basket into the ultrasonic bath over the attached, empty suction chambers. 3) Cover with lid. 4) Set pump speed to normal. 5) Turn timer on for 15 minutes.

TO RINSE: 1) With timer off; open drain valve and empty solution from the ultrasonic tank. 2) Close drain valve. 3) Refill tank with 5 gallons of water. 4) Repeat instrument setup. 5) Cover tank. 6) Set pump speed to normal. 7) Set timer for 5 minutes.

NOTE: NEVER clean loose instruments at the same time as inserted tubular instruments!

PART IV: SurgiSonic® 1211X IN-SERVICE FOR CLEANING *da VINCI® ROBOTIC TUBULAR INSTRUMENTS.



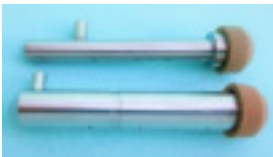
Patented Cleaning Process Independently Tested for Cleaning Effectiveness; exceeded AAMI TIR 30.

Because a tight seal separates the jaw/pulley end from the shaft/control box end, a patented dual hook-up cleaning method was created for independently cleaning both the distal and the proximal segmented areas of a *da Vinci® robotic instrument at the same time. Three *da Vinci® robotic instruments, including the S, Si, or Xi, can be cleaned at the same time using this dual hook-up method.

NOTE: Rinse all instruments under running water before and after cleaning and rinsing them in the SurgiSonic®.

Two different types of suction chambers are used for this patented dual hook-up cleaning method.

TYPE I) The multi-holed #3315 and #3316 SurgiScrub® **scrubbing** chambers apply suction and intense flushing to clean the intricate tool end of segmented robotic instruments.



Before Cleaning



After Cleaning

The **#3315 SurgiScrub® small scrubbing** suction chamber is used for cleaning the segmented distal tool end of robotic instruments. The **#3316 SurgiScrub® Large scrubbing** suction chamber is used for cleaning the segmented distal tool end of robotic staplers.

The multi-holed #3315 SMALL SurgiScrub® **scrubbing** chamber, fitted with the #3212 medium hole latex free rubber nipple, was specifically designed to clean the segmented tool end of a *da Vinci® robotic instrument. The smaller inside diameter and the multiple holes drilled in the SurgiScrub® **scrubbing** chamber allows fluid to be sucked into the chamber in such a way as to maximize the scrubbing and removal of debris from the jaw and pulley areas of the *da Vinci® robotic instrument. Whereas, the multi-holed #3316 LARGE SurgiScrub® **scrubbing** chamber, fitted with the #3215 large hole latex free rubber nipple, was designed to clean the larger tool end robotic staplers. **NOTE: Only use the multi-holed #3315 and #3316 SurgiScrub® scrubbing chambers to clean the distal tool-end of segmented robotic surgical instruments;** because the multiple holes in the SurgiScrub® scrubbing chambers cannot create the kind of unrelenting suction power needed to remove debris from the interior shaft of any type of robotic or non-robotic tubular instruments.

TYPE II) The single-hole #3312 SurgiSuction® **suction** chamber, fitted with #3212 medium hole rubber nipple, applies maximum suction to clean the proximal control box and shaft of segmented robotic instruments. **A male to male luer slip connector is used to connect the #2, output, hole of the robotic control box to the medium hole nipple attached to the #3312 SurgiSuction® suction chamber.**



3200 male to male luer slip connector .

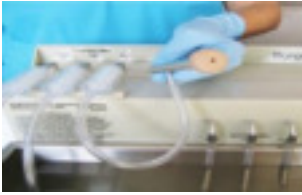


#3312 SurgiSuction® **suction** chamber with a #3212 medium hole nipple.

The #3200 male to male luer slip connector is used to connect the #2 the hole of the control box/shaft of the *da Vinci® robotic instrument to the #3312 SurgiSuction® **suction** chamber/nipple.

The versatile #3312 SurgiSuction® **suction** chamber applies the maximum amount of suction to clean the control box/shaft of robotic Instruments, and the tool end/shaft of non-robotic instruments. Pg.4

SurgiSonic® 1211 X Machine setup for cleaning *da Vinci® robotic tubular instruments.



MACHINE SET UP – LEFT SIDE:

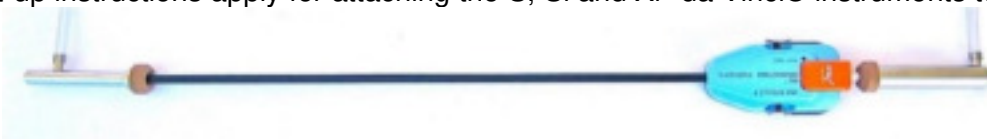
- 1) Remove the three SurgiSuction® suction chambers from the plastic filter tubing on the left hand side.
- 2) Fit a #3212 medium hole rubber nipple onto each of the three small #3315 SurgiScrub® scrubbing chambers.
- 3) Attach three fitted #3315 SurgiScrub® scrubbing chambers to the filter tubing on the left hand side, or attach two fitted #3315 and one large #3316 SurgiScrub® scrubbing chamber with a #3215 large hole nipple to clean a robotic stapler.

MACHINE SET UP – RIGHT SIDE:

- 1) Attach a #3212 medium hole rubber nipple onto each of the three #3312 SurgiSuction® suction chambers that are already attached to the right side filter tubing.

DUAL HOOK UP FOR CLEANING SUBMERSIBLE *da Vinci® ROBOTIC TUBULAR INSTRUMENTS:

The same set-up instructions apply for attaching the S, Si and Xi *da Vinci® instruments to the SurgiSonic®



TO CLEAN:

- 1) Close drain valve.
- 2) Fill ultrasonic tank with 5 gallons of warm 115° water.
- 3) Add 5 oz. of SurgiSoak® enzyme cleaner.
- 4) Plug machine into a 110/120 VAC wall outlet.

INSTRUMENT INSTALLATION - LEFT SIDE

- 5) Insert the entire jaw/pulley area of a *da Vinci® robotic instrument into a SurgiScrub® scrubbing chamber.

INSTRUMENT INSTALLATION - RIGHT SIDE

- 6) Insert one end of the male to male luer slip connector into the #2, output, hole of the *da Vinci® control box. Next, insert the other end of the male to male luer slip connector into the medium hole rubber nipple that has been fitted onto the SurgiSuction® suction chamber. Holding both ends, carefully lower instrument into tank.

- 7) Cover tank with lid.
- 8) Set pump speed to normal.
- 9) Set timer for 15 minutes.

NOTE: A fast speed 30 minute cycle is recommended for cleaning clogged instruments for the first time.

NOTE: NEVER clean loose instruments at the same time as inserted tubular instruments!



Insert luer slip connector into #2 hole of the control box. Insert other end into the fitted SurgiSuction® suction chamber.

TO RINSE: 1) With timer off; open drain valve to empty solution from the tank. 2) Close drain valve. 3) Refill tank with 5 gallons of water. 4) Repeat instrument setup. 5) Place lid on tank. 6) Set pump speed to normal. 7) Set timer for 5 minutes.

TBJ Incorporated, PH: 717-261-9700 Fax: 717-261-1730 email Email_tate@tbjinc.com www.SurgiClean.com

*da Vinci® is a trademark of Intuitive Surgical Inc. **Independent cleaning test result furnished upon request.** Pg 5

SurgiSonic® 1211X Surgical Instrument Cleaning Machine

OPERATING INSTRUCTIONS

⚠ PRECAUTIONS: ⚠

BEFORE CONNECTING MACHINE TO ELECTRICAL OUTLET:

1. Wear required protective apparel.
2. Close ultrasonic tank drain valve.
3. **Fill tank up to fill line with water.**
4. Do not splash water outside of tank.
5. Only use authorized enzyme additive.
6. Do not clean scopes in the SurgiSonic®.
7. Clean loose instruments in separate cycle.
8. Submerge all suction chambers and instruments.
9. Cover ultrasonic tank with lid before turning on timer.
10. Connect electrical plug to a 3-wire grounded 110/120v outlet.
11. **Set pump speed before turning on timer.**
12. Do not block fluid return tubes.
13. Do not put hands in tank while running.
14. Rinse instruments according to protocol.
15. Do not use unauthorized chemicals to clean machine.
16. **Unplug machine from outlet to service.**

⚠ Caution: Risk of electrical shock.

Acknowledgements

SurgiSonic® Registered Trademark of TBJ Incorporated
SurgiSoak® Registered Trademark of TBJ Incorporated
SurgiClean® Registered Trademark of TBJ Incorporated
SurgiScrub® Registered Trademark of TBJ Incorporated
SurgiSuction® Registered Trademark of TBJ Incorporated

**Section VII
Limited Warranty
TBJ Incorporated**

No.1211X SurgiSonic® Surgical Instrument Cleaning Machine

The SurgiSonic® 1211X Surgical Instrument Cleaning Machine, when used in accordance with operating instructions, is guaranteed for twelve (12) months from date of invoice against defects in material and workmanship.

Warranty Limitations

● **The SurgiSonic® 1211X surgical instrument cleaning machine is to be used to clean submersible hospital surgical instruments; this machine is *not to be used to disinfect or sterilize any hospital surgical instruments.***

● **Only add SurgiSoak® enzyme cleaner, manufactured by TBJ Incorporated, to the SurgiSonic® 1211X ultrasonic tank water during warranty period.**

NOTE: SurgiSoak® is a pH neutral, low suds, low residue enzyme cleaner.

● **Do not use caustic, corrosive, or coagulating substances in the SurgiSonic® 1211X machine.**

● **Do not use Renuzyme® Ultra, manufactured by Getinge USA, Inc., in the SurgiSonic® 1211X.**

NOTE: Unauthorized additives used in the SurgiSonic® have been known to destroy pumps, and/or cause tubing to become hard, brittle, and/or cracked; all of which indicates that an unauthorized cleaning solution is being used in the SurgiSonic® machine; which would void the machine warranty.

● **Filters must be replaced every thirty (30) days or sooner as needed.**

● **Ultrasonic tank must be filled to fill line with five gallons of water BEFORE ultrasonic tank is turned on; if the ultrasonic tank is run without water up to fill line the warranty will be void.**

NOTE: In the event the SurgiSonic® 1211X ultrasonic tank is not filled with water up to the fill line before it is turned on, it will cause the transducers to overheat, delaminate from tank floor and/or crack, and the heating pad will melt and smoke. Even if the tank is filled with water after being run without enough water, the damage is permanent and the transducers and heating pad and heat sensor will need to be replaced at the purchasing facilities expense.

● **Unauthorized alteration of the SurgiSonic® 1211X surgical instrument cleaning machine, or damage caused by accidents, misuse, abuse, or failure of the facility personnel to follow operating instructions is not covered by this warranty.**

NOTE: To save down time, the hospital biomed department is authorized to conduct repairs on the SurgiSonic® Machine. Replacement of switches, pumps or tubing takes about 15 to 30 minutes per component. To repair or order parts for the 1211X machine, refer to the TBJ Incorporated 1211X repair manual and price list, or call TBJ Incorporated directly: Customer service will assist you in how to repair the machine, and how to order the parts required. Defective parts will be shipped by next business day air at no added charge while warranty is in effect.

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