

Tava Surgical

Instruction and Maintenance Manual

L31 Series – Pulse Lavage
A90-000 – Air/Nitrogen Hose

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Thank you for choosing Tava Surgical as supplier of your powered instrument and accessory need.

The information and procedures described in this manual are intended to assist the healthcare professionals in the use, care, cleaning, sterilization and long term maintenance of the Tava Surgical L32 Model Pulse Lavage handpiece.

General Instructions, Cautions

Only medical professionals who are thoroughly familiar with the instrument's function, application and instructions for use should operate any Tava Instrument.

Tava's L31 series Pulse Lavage instrument to be powered by air or nitrogen that is dry, 99.7% pure and filtered to five (5) microns.

Always use the recommended operating pressure and verify it at the regulator pressure gauge. The recommended operating pressure setting for optimum performance is 80-105 psi (5.6-7.3 kg/cm²). Lower settings can be used for slower speed requirements, if necessary. Do not exceed 105 psi (7.3 kg/cm²) operating pressure for this instrument.

Use of eye, face protection device(s) recommended while operating powered instruments.

When instrument is connected to power supply and not being used care must be taken to avoid unintended activation of the instrument.

Application of excessive force to instrument may cause damage to instrument and/or accessory or injury to patient and /or operator.

Test the instrument before loading pump cartridge. With face protected activate it for 5-10 seconds. Check for rapid temperature rise, unusual noise(s) and other visible malfunctions.

Never use a malfunctioning, damaged or suspected to be damaged instrument. Return it to Tava for prompt service.

Disconnect instrument from air/nitrogen supply hose before loading pump cartridge.

A new, sterile pump set accessory is required for every procedure.

Check pump set accessories for damage before and during use. If pump set seems to be damaged, discontinue it's use.

Do not drop, throw or hit instrument against any surface.

Do not immerse instrument. Never clean a powered instrument in Ultrasonic Cleaner.

Do not start a surgical procedure if the nitrogen tank pressure is less than 500 psi (35.16 kg/cm²)

Do not pinch clamp, crimp or kink the air or nitrogen supply hose or the liquid delivery tubing of the pump cartridge.

Cleaning Procedures

Leaving the hose attached or the insertion of the appropriate plug (cleaning plug) into the hose connector of the Pulse Lavage hand piece will help keeping liquid out of the instrument. Before cleaning the accessory (pump set) must be removed and disposed of properly.

1. Scrub the instrument thoroughly with mild soap and water, using a nylon brush. Remove all traces of blood and debris.
2. With the hose or appropriate connector plug still attached, rinse of all traces of contaminants and detergent under running water. DO NOT IMMERSE. If accidental immersion occurs please refer to section: Accidental Immersion.
3. Shake the instrument free of excess water and dry surfaces with clean, lint free towel.
4. Connect air hose (remove cleaning plug, if used and attach hose to instrument) to dry air or nitrogen supply (regulated to 80-105 psi or 5.6-7.3 kg/cm²). Activate the instrument for 10-15 seconds.
5. Disconnect hose from instrument.
6. Place 1-2 drops of Tava Lube (Tava item #M001) into the inlet pipe of the instrument hose connector.
7. Reconnect hose to instrument and activate instrument for 3-5 seconds.
8. Disconnect air hose from instrument and prepare the instrument for sterilization.

Accidental Immersion

If accidental immersion occurred please follow these recommended procedures:

- a. Immediately wash, rinse instrument under running water.
- b. Attach the instrument to nitrogen or dry air (see #4. in previous section) and operate it for a minimum of 45 seconds.
- c. Follow steps #5-8. of previous section.

Sterilization Procedures Recommended

Steam sterilization has been found both safe and effective for the sterilization of Tava's L31 Series Pulse Lavages. The instruments are capable of withstanding the recommended exposure times and temperatures of steam sterilization.

Gas sterilization (Ethylene Oxide) is not recommended for Tava instrumentation.

Note: The instruments received from Tava Surgical or it's authorized representatives, new instruments, loaner instruments or instruments returned from service/repair must be sterilized by the facility it is delivered to, prior to use.

- Hose, cleaning cap must be removed from instrument to be sterilized.
- If instrument to be wrapped, two double thick #140 thread count wrappers (or equivalent) should be utilized.
- Recommended duration and temperatures in steam autoclave units:

Gravity displacement System: 60 minutes @ 250°/121°C or 35 minutes @ 270°/132°C

High Speed Pre-vacuum System: 4 minutes @ 270-275°F/132-135°C

Note: The sterilizer manufacturer's written instruction for cycle parameters and load configuration and AAMI guidelines for Steam Sterilization should be followed.

- Utilize a drying cycle of at least 10 minutes by exposure to room temperature, covered with a dry, sterile towel. Do not operate instrument while it is warm.

Warranty

Tava Surgical warrants the L31 Series Pulse Lavage Instruments to be free from defects in material and workmanship for a period of one (1) year from the original purchase date. Tava air/nitrogen hoses are warranted for 6 (six) months from the original purchase date. The warranty is limited to the repair or replacement of the product without charge.

This warranty is void in the event of any of the followings: abuse, misuse or use in other than a normal surgery environment, disassembly, alteration or unauthorized repair.

Repair Service

Due to continuous cleaning/washing and autoclave cycles of the instruments, it is recommended that all instruments be returned for preventative maintenance. In general, an annual servicing is recommended for normal use.

Tava warrants any service or repair work performed will be free from defects in material or workmanship for the period of 3 (three) months from date of service or repair. This warranty applies to the actual work performed.

Procedure to return instruments for service

Note: It is unlawful to ship contaminated, non-sterilized instruments and accessories

When returning owned or loaned instruments it is the sender's responsibility to decontaminate and sterilize them.

U.S. and Canada: Please call Customer Service: 800/569-6738 or fax: 912/921-7579 for Return Goods Authorization Number. Please be prepared to provide the model and serial number of the instrument. If loaner instrument is required, please request one at this time.

In other countries: Please notify and return instrument to the Tava Dealer/Distributor in your country. If unable to do so, return it to Tava Surgical directly.

When returning products from outside of U.S.: Per Customs requirement please indicate on shipping documents the followings: "U.S. manufactured goods returned for factory service/repair."

Please enclose with the return a brief statement describing the reason for return, a purchase order or reference number, contact person's name and telephone number and the RGA number provided by Tava Customer Service. Package instruments properly to prevent damage during shipping/handling. Please send shipping charges prepaid.

International Customers please send shipping charges prepaid via UPS Express or UPS Expedited delivery service.

Shipping address:

Tava Surgical Instruments
Service Department
4837 McGrath Street, Unit J
Ventura, CA 93003 USA

The L31 series Pulse Lavage

The Tava L31 series Pulse Lavage is an air or nitrogen powered instrument that pumps sterile fluids with a distinct pulse. It requires the use of a sterile packaged, disposable pump set consisting of the pump cartridge, nozzle(s) and 10 feet (3 meters) long delivery tubing with bag spike. The pump cartridge isolates the fluid from the instrument.

- **Operating Procedure**

When instrument is not in use but connected to operating air/nitrogen supply, care must be taken to avoid unwanted or accidental activation of instrument.

1. Open cover: Slide locking ring towards instrument (hand piece) body. Push/pull protruding corner of cover in a sideways rotating motion (upward and sideways) until cover is positioned just past the upright position.
2. Loading pump cartridge:
 - Hold pump cartridge at the nozzle locking collar area and/or elbow with tubing so, that the cartridge may be placed into cradle with base of elbow resting in side slot of cradle.
 - Place pump lightly on top of cradle with the white “mushroom” end of piston rearward (toward the protruding plunger of the instrument). Rotate cartridge and slide rear end of the piston down of the slanted surface of the plunger. Engage the “mushroom” end in the crescent shaped slot of the plunger.
 - While maintaining connection between the piston and plunger, push cartridge slightly rearward with light downward pressure at the nozzle end to seat elbow in the side slot of the cradle.
 - Insure that the cartridge is fully seated in the cradle by slightly pressing (or squeezing) downward at the base of elbow.
3. Closing cover: Rotate cover over the installed pump cartridge and push and squeeze closed. A light click will be heard when closed. Sliding the locking ring toward the nose of the instrument will result in full closure and lock of the cover.
4. Placing of tubing: Press tubing into slot in side of the hand piece while maintaining a smooth, kink free arc between the elbow and the hand piece slot. Connect the end of tubing with spike to source of liquid to be pumped.
5. Nozzle: Make sure the required nozzle is placed into the pump cartridge and the nozzle locking collar is turned fingertip tight to secure it properly.
6. Turn on: Connect the instrument to the air/nitrogen supply hose. Confirm by checking the regulator pressure gauge that the operating pressure does not exceed 105 psi (7.3kg/cm²).

Note: *Do not run the lavage instrument with the pump cartridge loaded but the tubing not connected to the source of liquid for more than 15-20 seconds (dry run). Dry running may cause damage to seals in the disposable pump cartridge and priming/pumping may not occur.*

7. Priming the pump cartridge: Pressing down of the trigger lever with finger tips will start the instrument and priming of the cartridge with liquid will commence immediately. Complete priming should occur in 4-12 seconds, depending of the operating air/nitrogen pressure.

8. Removing pump cartridge:

- Pull tubing from hand piece slot by starting at the bottom end of the slot by lifting the tubing outward and upward.
- Slide locking ring toward instrument body. Grasp elbow at end of tubing, rotate and lift upward, opening the cover and remove the pump cartridge.

A90-000 Air/Nitrogen Hose

This universal hose is used on all Tava powered instruments with Tava style hose connector.

• **Operating Procedure**

1. Supply side connection: Connect the male Schrader connector on the end of hose by pushing it into the connector fitting of the regulator or the regulated supply source.
2. Connecting instrument: Hold the Pulse Lavage securely in one hand. Hold firmly the connector of the hose in the other hand and align the pins on it with the bayonet slots in the hose connector of the instrument. Push both together and twist the connector so the pins slide into the bayonet slots and seat in the detents for positive locking. Release hose, it will stay attached to the instrument if connection is correct.
3. Operation: Turn on supply valve and adjust operating pressure to 80 to 105 psi (5.6 to 7.3 kg/cm²). The hose is operational at this time.
4. Disconnecting from supply source: The hose can be released from the supply source by firmly holding the hose connector and twisting and/or pushing the supply source Schrader connector sleeve.

Note: To prevent sudden ejection of hose from the supply source, hold the hose connector firmly.
5. Disconnect from the instrument: Hold instrument and connector on hose firmly. Push them slightly together and twist to remove the pins from the detents. Slowly move it away from the instrument. The pins will slide out from the bayonet slots.

Trouble shooting:

- Check air/nitrogen supply system, regulator
- Check the main tank pressure (minimum 500 psi recommended for standard size cylinder)
- Check output pressure while instrument is activated (80 to 105 psi or 5.6 to 7.3 kg/cm²)
Note: To perform this check, remove pump cartridge from instrument before activation, otherwise damage to pump cartridge (dry run) or, if cartridge is connected to liquid, pumping of liquid may occur.
- Check air/nitrogen hose connection to supply output
- Check air/nitrogen hose connection to instrument
- Check hose and tubing for kink or pinch
- Check proper seating of pump cartridge
- Increase of operating pressure may be required when using longer than 12 feet (4 m) air/nitrogen hose to compensate for the pressure drop along the hose, approximately 5 psi (.3-.4 kg/cm²). for every additional 10 feet (3 m)