BARD®
Laparoscopic Irrigation Systems

Experience the Power of Performance.

BARD’s extensive, reliable, easy-to-use systems encourage product standardization by exceeding expectations and satisfying the needs of clinicians as well as purchasing professionals and administrators. From the power and simplicity of our X-STREAM™ Irrigation System to the convenience of the HYDRO-SURG™ Plus Irrigator, BARD remains committed to offering you reliable and cost-effective laparoscopic irrigation systems.
**NEZHA-DORSEY™** trumpet valve provides precise, variable flow control from drip to stream.

**SMOKEVAC™** feature automatically removes smoke from its point of origin when activated.

Cojoined tubing facilitates set-up and handling.

**Quick-Disconnect** allows user to change probe tips quickly and easily – with a snap.

**Distal irrigation clears suction path**

**Ergonomically advanced design for versatile, reliable performance.**

- **Pistol Grip**
- **Traditional Trumpet Grip**

BARD’s trumpet valve handpiece offers suction/irrigation, smoke evacuation, and instrument interchangeability. Our trumpet valve is ergonomically designed to conform comfortably to the surgeon’s handling preference (pistol grip or traditional trumpet grip) and the trumpet valve allows for easy reverse configuration for left-handed use.

*Available with the X-STREAM™ Irrigation System*
HYDRO-SURG™ PLUS Irrigation System
Convenient, disposable battery-powered pump
- Efficient pump design for quiet, high performance operation
- ON/OFF switch for pump activation
- Pump attaches directly to I.V. pole for added security
- Pump housing unclips to access batteries for removal
- Standard SMOKEVAC™ feature

X-STREAM™ Irrigation System
Simplicity, power and value
- Drop-n-Go™ activation for almost effortless set-up
- Convenient visual and audio indicators
- Ergonomic design with see-through front panel
- Low maintenance electrical controller
- Controller easily attaches to I.V. pole
- Pump alarms to indicate empty bag

from a leader in surgical irrigation.
**ADVANTAGE™ Tips breadth of line**
All Davol tips have a tactile locking sheath mechanism for increased safety and to allow precision cutting and coagulation in a wide range of laparoscopic procedures.

**Single-use quick-disconnect tips**
Stick-resistant coating facilitates easy cleaning during procedure.

- Corbitt Spatula
- L-Hook
- J-Hook
- Needle

**Reusable quick-disconnect tips**
Can be disassembled for easy cleaning and re-sterilization.

- Corbitt Spatula
- L-Hook
- J-Hook
- Needle

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**NEZHA T-DORSEY™ laparoscopic probe tips**

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<thead>
<tr>
<th>5mm Irrigation Probe Tips with Irrigation Holes</th>
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<tr>
<td>5mm x 28cm</td>
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**ENDO-POOL™ Suction Cannula**

| 5mm x 33cm |

**Stone Extractor**

| 10mm x 33cm |

**ASPIR-VAC™ Probe**

| 5mm x 33cm |
**Hydro-Surg™ Plus Laparoscopic Irrigator with NuMed-Dover™ Skoovac™ Trumpet Valve**

**Indications**

The Hydro-Surg™ Plus Irrigator is designed to be used with the Davol™ Trumpet Valve and tip to provide controlled powered irrigation to, and aspiration of fluids/smoke from, the operative site during laparoscopic surgical procedures (e.g., laparoscopic cholecystectomy and laparoscopic gynecological procedures). It may also be used for resection of filmy adhesions (i.e., hydrosection) and peritoneal lavage. Appropriate fluids include those which have a specific gravity of less than one. Additional specialty probe tips are available from Davol, including insulated and non-conductive tips for use with electrosurgery.

**Suction/irrigation probe tips**, when included, have a non-reflective surface to help avoid laser beam reflection.

With proper adapter, a laser fiber and laser fiber sheath can be passed through the probe handle and tip. Pathology and/or surgeon’s choice will dictate preference of suction/irrigation probe tip configuration.

**Contraindications**

1. **Use of this device for hysteroscopy or for cavity distention is contraindicated.**
2. **Use of this device for intra-abdominal irrigation is contraindicated whenever laparoscopy is contraindicated.** See operator’s manual of your laparoscope for absolute and relative contraindications.
3. **Use of electrosurgery instruments and electrode inserts with an uninsulated metallic tip is contraindicated.**

**Warnings**

1. **This device has been designed for single use only.** Reuse, reprocessing, resterilization or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device and may lead to device failure which may result in injury to the patient. Reuse, reprocessing, resterilization or repackaging may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness or death of the patient or end user.
2. **Do not resterilize.**
3. **Do not dispose of batteries in a fire, recharge, put in backpacks, or mix with used or other battery types – they may explode or leak and cause personal injury.**
4. **As with any surgical procedure where extensive irrigation is utilized, contamination levels should be closely monitored by the attending physician.**
5. **When using electrosurgery tips or electrode inserts, follow all instructions, warnings, precautions, and contraindications provided with these devices.**
6. **Do not use in an oxygen-enriched atmosphere due to explosion hazard.**

**Precautions**

1. **If package is damaged or open, do not use product.**
2. **The pump motor runs continuously when fluid is NOT present in the pump housing.** Prolonged operation without fluid in the system may damage the pump motor and must be avoided. This could occur in two ways: 1.) if the pump is turned on prior to priming, turn pump “OFF” and see Step 5 for Instructions for Gravity Priming the Pump; or 2.) if air enters the pump after bag runs out of fluid, see Step 7 for Instructions for Repriming System in Case of Bag Change.
3. **Use of bottled irrigant is NOT recommended.** Although bottles can be used, performance is significantly diminished by air that is pulled into the pump before it can be vented from the bottle.
4. **Attach pump to I.V. pole before spiking irrigation bag since spike will not securely support pump while in use.**
5. **Adhesions, anatomical anomalies or other conditions may prevent clear visualization of internal anatomy.** Do not perform laparoscopic procedures if the internal anatomy cannot be positively identified.
6. **Laparoscopic procedures should be performed only by persons having adequate training and familiarity with laparoscopic techniques relative to techniques, complications and hazards prior to performance of any laparoscopic procedure.**
7. **This product is for single use and is provided sterile. DO NOT REUSE.**
8. **Follow all of the recommended electrosurgical and laser manufacturers’ instructions and warnings while operating in these modes.**

When passing laser fibers through probe – **Warnings and Precautions:**

1. **CO2 laser energy systems are not compatible for use through the probe handle and tip.**
2. **A thorough understanding of the principles and techniques of laser surgical procedures is necessary to avoid injury to the patient, operator and operating room personnel.**
3. **Pathology and the surgeon’s choice will dictate laser tip configuration.**
4. **Proper eye wear is mandatory before activating the laser.**
5. **Use of this device with laser equipment is indicated only in those procedures for which the selected laser fiber and laser system being used have been approved by the FDA.**
6. **To avoid damage to the laser fiber, do not expose tip until suction/irrigation probe has passed through the laparoscopic trocar.**

**X-S™ Irrigation System**

**Irrigation System in Case of Bag Change.**

1. **If the pump is turned on prior to priming, turn pump “OFF” and see Step 5 for Instructions for Gravity Priming the Pump; or 2.) if air enters the pump after bag runs out of fluid, see Step 7 for Instructions for Repriming System in Case of Bag Change.**

2. When passing laser fibers through probe – **Warnings and Precautions:**

1. **CO2 laser energy systems are not compatible for use through the probe handle and tip.**
2. **A thorough understanding of the principles and techniques of laser surgical procedures is necessary to avoid injury to the patient, operator and operating room personnel.**
3. **Pathology and the surgeon’s choice will dictate laser tip configuration.**
4. **Proper eye wear is mandatory before activating the laser.**
5. **Use of this device with laser equipment is indicated only in those procedures for which the selected laser fiber and laser system being used have been approved by the FDA.**
6. **To avoid damage to the laser fiber, do not expose tip until suction/irrigation probe has passed through the laparoscopic trocar.**
**X-STREAM™ Laparoscopic Irrigation Tubing Set with The Nezhat-Dorsey™, or SingleEvac™ Trumpet Valve**

**Intended Use**
The Nezhat-Dorsey™, or SingleEvac™ Trumpet Valve Irrigation and Suction Tubing Set, when fitted to a Davol Suction/Irrigation Probe Tip, is intended for the delivery of irrigation fluid, and aspiration of fluids/smoke from, the operative site during laparoscopic surgical procedures. Additional specialty probe tips are available from Davol, including insulated and nonconductive tips for use with electrosurgery.

Suction/irrigation probe tips, when included, have a non-reflective surface to help avoid laser beam reflection. With proper adapter, a laser fiber and laser fiber sheath can be passed through the probe handle and tip.

**X-STREAM™ Laparoscopic Irrigation Controller**

**Indications**
The X-STREAM™ Laparoscopic Irrigation Controller is a versatile and reusable electromechanical controller (Figure 1, Page 4). It is small, lightweight, and pole-mounted. It has two easily adjustable flow rate settings, and may be used with any of the Davol™ X-STREAM™ Laparoscopic Irrigation Tubing Sets.

**Warnings**
1. The performance of the X-STREAM™ Laparoscopic Irrigation Controller depends on proper setup. Please refer to tubing set instructions for Use for setup instructions.
2. Use of any modified or unauthorized disposables with the X-STREAM™ Laparoscopic Irrigation Controller is contraindicated and may result in undesirable system performance.
4. The X-STREAM™ Laparoscopic Irrigation Controller contains internal components that could cause electrical shock hazard. Do not open the housing of the Controller or attempt to service the system.
5. The power supply cord is not reviewable. Please return X-STREAM™ Laparoscopic Irrigation Controller to Davol Inc. for servicing.
6. To avoid the possibility of electrical shock, always remove the tubing set and disconnect the power cord prior to cleaning.
7. The line cord is the supply (MAINS) disconnect (ISOLATION) device.
8. Do not use the X-STREAM™ Laparoscopic Irrigation Controller in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR or WITH OXYGEN or NITROUS OXIDE.
9. Do not autoclave or steam sterilize the X-STREAM™ Laparoscopic Irrigation Controller or subject the pump to temperatures in excess of 70°C. To avoid possibility of electric shock, always disconnect the power cord prior to cleaning.
10. Do not touch the X-STREAM™ Laparoscopic Irrigation Controller and the patient simultaneously.
11. No user serviceable items. Return X-STREAM™ Laparoscopic Irrigation Controller to Davol Inc., for all repairs.
12. The tubing set will provide gravity flow if the pumping chamber is not properly loaded into the controller’s pumping chamber receptacle.

**Precautions**
1. Read all the instructions provided with the X-STREAM™ Laparoscopic Irrigation Tubing Set prior to use.
2. The controller automatically turns “ON” when the tubing set is loaded into the controller. The logo and “PRIME” LED’s will light to indicate that the controller is on. There is no ON/OFF switch.
3. Do not remove the square, metal contact label located at the top back of the tubing set pumping chamber.
4. Solvents should not be used on the controller’s logo and keypad as they could cause damage to the device.
5. When air enters the system, the controller returns to the “PRIME” state, the “PRIME” text will blink, and the audio indicator will sound.
6. Gravity prime and perform all priming with the probe tip outside of patient.

**Davol™ Advantage Single-Use Electrosurgical Attachments, Monopolar 5mm (Sterile)**

**Intended Use**
The disposable Electrosurgical Attachments are intended for evacuation of body fluids and electrosurgical cutting/coagulation during general laparoscopic procedures (e.g., laparoscopic cholecystectomy, appendectomy and hysterectomy). They are not intended for use in hysteroscopy or for contraceptive coagulation of the fallopian tube. Pathology and/or surgeon’s choice will dictate preference of distal tip configuration.

**Davol™ Advantage Reusable Electrosurgical Attachments, Monopolar 5mm (Non-sterile)**

**Indications**
These instruments are intended for evacuation of body fluids and electrosurgical cutting/coagulation during general laparoscopic procedures (e.g., laparoscopic cholecystectomy, appendectomy and hysterectomy). They are not intended for use in hysteroscopy or for contraceptive coagulation of the fallopian tube.

**Davol™ Advantage Single-Use and Reusable Electrosurgical Attachments**

**Warnings**
1. Although the Electrosurgical Attachment may be used with physiologic electrolyte irrigation solutions, simultaneous activation of the electrosurgical instrument and irrigation is not recommended since the current may be conducted to alternate sites through the shaft area and/or unintentional arcing at the distal end may result, decreasing the effectiveness of the electrosurgical unit, and causing harm to the patient. It is necessary to clear irrigation fluid from the insulated probe cannula and suction fluid pools prior to actuation of the electrosurgical unit.
2. To minimize the potential for patient injury due to capacitive coupling between the active electrosurgical probe and other nearby metal instruments within the peritoneal cavity, the following precautions must be taken:
   a. Use all-metal laparoscopic cannula systems.
   b. Insert the electrosurgical probe through a larger sized cannula, i.e., a 5mm electrosurgical probe should be inserted through a 10mm cannula.
   c. Avoid activation of the electrosurgical probe when the electrode tip is not in contact with target tissue.
3. A metal cannula trocar must always be used in conjunction with an Electrosurgical Attachment with Insulated Probe Sheath and with another Electrosurgical Instrument. Failure to do so increases the potential for capacitive coupling and may result in injury.
4. Due to the potential for capacitive coupling and inadvertent burning at high voltages, keep the voltage/power as low as possible to achieve the desired effect.
5. During electrosurgery, the patient should not be allowed to come in contact with the metal parts that are grounded. It is recognized that this recommendation may not be practical during certain procedures (e.g., those in which uninsulated head frames are used); however, to maximize patient safety during the use of electrosurgical devices, such practices should be minimized.
6. The Electrosurgical Attachments and Electrosurgical Sheath must be cleaned and sterilized prior to each use, including initial use.
7. Prior to each use, inspect the Electrosurgical Attachment and Electrosurgical Sheath for damage. If damage is evident, do not use.
8. If using irrigation with the electrodes, care should be taken to ensure liquid does not enter the connection between the electrosurgical fitting and the electrosurgical generator foot switch cable. There is a high risk for burns to the user if liquid enters the fitting.
9. As with any surgical procedure where extensive irrigation is utilized, extravasation levels should be closely monitored by the attending physician.
10. The electrosurgical attachment tip must be retracted and locked into the electrosurgical sheath when entering and exiting the abdominal cavity, so as not to cause inadvertent harm to organs.
11. Use of electrosurgical devices can cause electrical interference in other devices, particularly cardiac pacemakers; precautions should be taken to ensure that the patient’s well being is maintained in the event of such interference.

**Additional Davol™ Advantage Reusable Electrosurgical Attachments**

**Warning**
1. The shaft of this device must not be used as a laser backstop.
2. Electrodes or probes of monitoring, stimulating, and imaging devices can provide paths for high frequency currents even if they are battery powered, insulated or isolated at 60 Hz. The risk of burns can be reduced, but not eliminated, by placing the electrodes or probes as far away as possible from the electrosurgical site and from the dispersive electrode. Protective impedances incorporated into the monitoring leads may further reduce the risk of these burns. Needles should not be used as monitoring electrodes during such procedures.

**Additional Davol™ Advantage Single-Use Electrosurgical Attachments**

**Warning**
1. This device has been designed for single use only. Reuse, repackaging, or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device and may lead to device failure which may result in injury to the patient. lemon, reprocessing, or repackaging may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness or death of the patient or end user.
2. The shaft of this device must not be used as a laser backstop because of uncontrolled reflective properties of the shaft.
3. To avoid accidental injury to the patient and user, do not lay electrode directly on patient or in a pool of fluid. When not in use, keep electrode in a safety holster or on instrument table.
4. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws (USA) and regulations.
5. Electrodes or probes of monitoring, stimulating, and imaging devices can provide paths for high frequency currents even if they are battery powered, insulated or isolated at 60 Hz. The risk of burns can be reduced, but not eliminated, by placing the electrodes or probes as far away as possible from the electrosurgical site and from the dispersive electrode. Protective impedances incorporated into the monitoring leads may further reduce the risk of these burns. Needles should not be used as monitoring electrodes during such procedures as they are not designed to be compatible with monitoring instruments.
Davol™ Advantage™ Single-Use and Reusable Electrosurgical Attachments

Precautions
1. Adhesions, anatomical anomalies or other conditions may prevent clear visualization of internal anatomy. Do not perform laparoscopic procedures if the internal anatomy cannot be positively identified.
2. Laparoscopic procedures should be performed only by persons having adequate training and familiarity with laparoscopic techniques. Consult the medical literature relative to techniques, complications and hazards prior to performance of any laparoscopic procedure.
3. Bending of the electrosurgical tip on this product may damage and/or shorten its life. DO NOT bend the electrosurgical tip.
4. Keep activation times to the minimum required to achieve the desired effect. Avoid prolonged activations without the electrode in contact with the tissue.
5. Refer to your electrosurgical generator manual for application information including warnings and precautions regarding its use.
6. Unshielded electrosurgical leads (active, bipolar, or return) should be positioned so that they cannot come in contact with the patient or other leads connected to the patient and so that they do not run parallel to nearby leads.
7. Reusable accessory cables should be periodically function and safety tested in accordance with the original manufacturer’s instructions.
8. Apparent low power output, or failure of the electrosurgical equipment to function correctly at the normal settings, may indicate faulty application of the dispersive electrode or failure of an electrical lead. Do not increase power output without checking for obvious defects or misapplication. Effective contact between the patient and the dispersive electrode must be verified whenever the patient is repositioned after the initial application of the dispersive electrode.
9. The risk of igniting flammable gases or other materials is inherent in electrosurgery and cannot be eliminated by device design. Precautions must be taken to restrict flammable materials and substances from the electrosurgical site, whether they are present in the form of an anesthetic or skin preparation agent, are produced by natural processes within the body cavities, or originate in surgical drapes or other materials.
10. Potentially hazardous conditions may exist when accessories of similar connector types are intermixed. Be certain that accessories are appropriate for the type of generator output used.

Additional Davol™ Advantage™ Reusable Electrosurgical Attachments

Precautions
1. Electrodes are for monopolar usage. They are not compatible with bipolar cables and generators.
2. Do not lay electrode directly on patient or in a pool of fluid. When not in use, keep electrode in a safety holster or on instrument table.
3. During use, keep tip of electrode clean. Build up of char can cause poor performance.

Additional Davol™ Advantage™ Single-Use Electrosurgical Attachments

Precautions
1. Check for proper grounding of instrumentation prior to use.
2. Verify compatibility of instrumentation and ensure that electrical isolation or grounding is not compromised.
3. Use lowest dial settings on both Cut and Coag modes to achieve hemostasis. Check ground and connectors before increasing generator setting. Increase generator setting slowly if more current is desired.
### **BARD® Pump™ Systems**

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<td>X-Stream™ Laparoscopic Irrigation System Controller</td>
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### **HYDRO-SURG™ Plus Irrigation System**

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### **BARD® Systems Accessories**

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<td>Monopolar High-Frequency Cord, reusable, male-to-female, non-sterile</td>
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**To learn more, contact your local BARD representative or call 1.800.556.6275**

Please consult product labels and inserts for any indications, contraindications, hazards, warnings, precautions, and instructions for use.

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