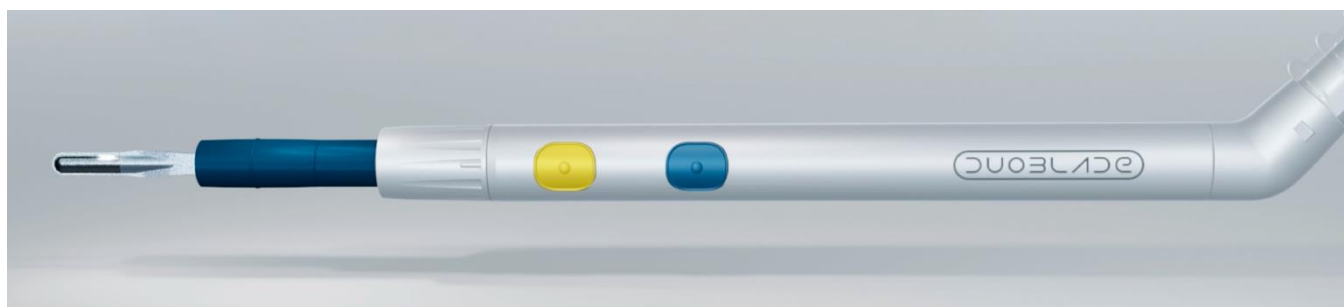




**REF** DB1SEP, DB1SEP-H, DB1SEP-T, DB1SEP-TH  
Advanced Energy Blade with Smoke Evacuation

Instructions for Use



## Description

- Duoblade Electrosurgical Device is a disposable, single-use device
- Consists of an all-in-one blade with a rotatable and adjustable length shaft
- Designed for use with an FDA cleared electrosurgical unit (ESU)
- Operable by integrated hand switches or ESU footswitch.
- Includes a suction tube for smoke evacuation.

## Indications for Use

The Duoblade is intended for general electrosurgical applications, including cutting and coagulation, and (Models: DB1SEP, DB1SEP-H, DB1SEP-T, DB1SEP-TH) for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system.

## Contraindications

Refer to Instructions for Use provided with the ESU.

## For Use With

### **WARNING**

- Always use the device only with a monopolar electrosurgical unit (ESU) that has been tested, and conforms with its relevant IEC 60601 series of standards including its collaterals, particulars, national deviations and differences e.g. IEC 60601-1, IEC 60601-2-2, EN 60601-1, EN 60601-2-2, etc.

## Safety Directives

### General Safety

#### **WARNING**

- A healthcare professional should be thoroughly familiar with the Instructions for Use and the operation of this product before use.
- The healthcare professional conducting the procedure is responsible for determining the suitability of this product and the specific technique used for each patient. Cresen does not recommend any medical/surgical procedure or technique.
- Always inspect the product and all system components for damage upon initial receipt and before each use. Do not use damaged product.
- Always store, transport, and operate the product within the specified environmental conditions.

## Product Safety

### WARNING

- Both oxygen and nitrous oxide support combustion. Avoid enriched atmospheres, which may result in fires and burns to patients or surgical personnel.
- The following substances contribute to increase the risk of fire and explosion in the operating room:
  - Flammable substances (such as alcohol-based skin prepping agents and tinctures)
  - Naturally occurring flammable gases, which is in body cavities such as the bowel, may accumulate in the operating room.
  - Sparking and heating associated with electrosurgery can provide an ignition source. Always follow fire precautions. When using electrosurgery in the same room with any of these substances or gases, prevent their accumulation or pooling under surgical drapes, or within the area where electrosurgery is performed.
- Make sure that all oxygen circuit connections are leak free before and during the use of electrosurgery. Make sure that endotracheal tubes are leak free, and the cuff is properly sealed to prevent oxygen leaks.
- Follow all surgical fire cautions and hospital safety procedures. Do not use the device in the presence of flammable gases such as nitrous oxide and oxygen. Do not activate the device until vapors from alcohol-based skin prepping agents have dissipated.
- Proper patient return electrode application is very important. Refer to the ESU and patient return electrode Instructions for Use for guidance regarding the patient return electrode selection, placement, and application procedures. Do not rely entirely on the ESU impedance sensing feature as it can be affected by a damaged (shorted) patient return electrode. It is recommended that the operator verify appropriate placement and contact of the patient return electrode. Improper placement or application of patient return electrode may cause patient injury.
- Depending on the desired tissue effect, the lowest energy settings should be applied. Do not use any combination of power setting and mode that results in an output voltage of greater than 4500V. To determine the voltage output characteristics for different power settings and modes, please refer to the user manual of the electrosurgical unit (ESU).
- Operate the device using the lowest power settings and the shortest tissue-contact time required for the desired effect, as electrosurgery may cause unintended damage to surrounding tissue.
- During use, do not allow the surface of the Duoblade to be obstructed or rest on tissue.
- Tissue buildup (eschar) on the tip of an active electrode poses a fire hazard, especially in oxygen-enriched environments, such as in throat or mouth procedures. Eschar plus high oxygen may create embers. Keep the electrode clean and free of all debris.
- While activating energy, be aware of critical anatomy that is in contact with the blade or telescoping shaft. The telescoping shaft should not be touching or retracting tissue while activating energy.
- Only contact the patient with the blade of the device. Do not insert the device into tissue beyond the blade, as unintended injury or damage to the device may occur.
- If patients have electronic implants such as cardiac pacemakers, do not use the device without first consulting a qualified professional (e.g. cardiologist). Possible danger exists because interference with the action of the electronic implant may occur, the implant or implantable leads may be damaged /affected.
- Do not place active accessories near or in contact with flammable materials, flammable gases, or high levels of oxygen. Electrosurgical accessories that are activated or hot from use can cause a fire.
- Do not contact metal objects or instruments with the Duoblade while the cut or coagulation function

is activated, including sutures, staples or clips, as this may cause patient or user injury, tissue damage, or damage to the device.

- Do not activate energy unless the active edge of the blade is in direct contact with tissue. Failure to ensure the active edge of the blade is in direct contact with target tissue while activating energy could result in patient injury, including burns.
- Do not touch the blade while the cut or coagulation function is activated, as this may result in injury.
- Do not use the Duoblade on small appendages, as monopolar electrosurgery may cause thrombosis or unintended tissue injury.
- Do not operate electrosurgery in the presence of flammable anesthetics.
- Stop using the device if energy discharge is observed from any other areas besides the active edge of the blade.
- If tissue builds up on the blade of the device, use soft wet gauze to clean the device electrode during the procedure. Do not use sharp or abrasive objects, such as a scratch pad, on the Duoblade, as it may damage the device.
- If the level of suction becomes excessive, immediately disconnect the suction source to prevent tissue damage.
- Do not attempt to service or repair the Duoblade.

## Caution

- The Duoblade should be handled and operated by hospital personnel familiar with and trained in its use. Handle all instruments with care.
- Use of instruments for any purpose or in any manner other than described in this Instructions for use may cause instrument damage or failure, which could result in patient or user injury.
- Before use, inspect the device packaging. Do not use if the packaging is opened or if the device has passed the labeled expiration date.
- Before use, inspect the device and do not use the device if there are breaks, chips, cracks, scratches, tears or missing insulation on the blade or telescoping shaft of the device. See Figure 1.

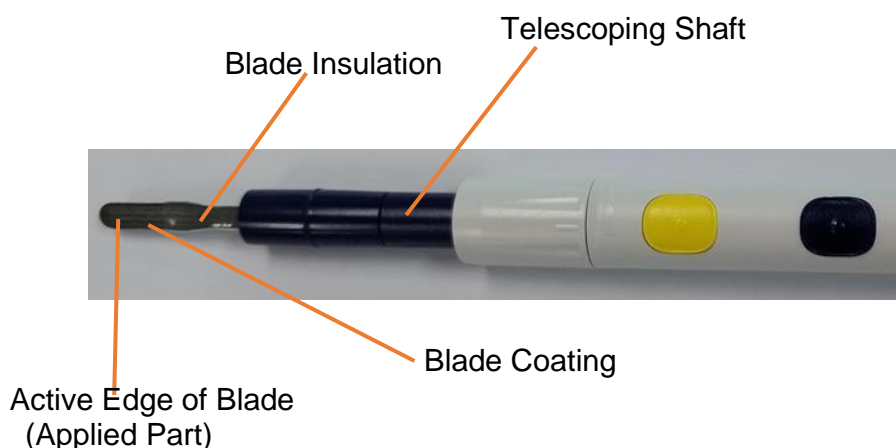


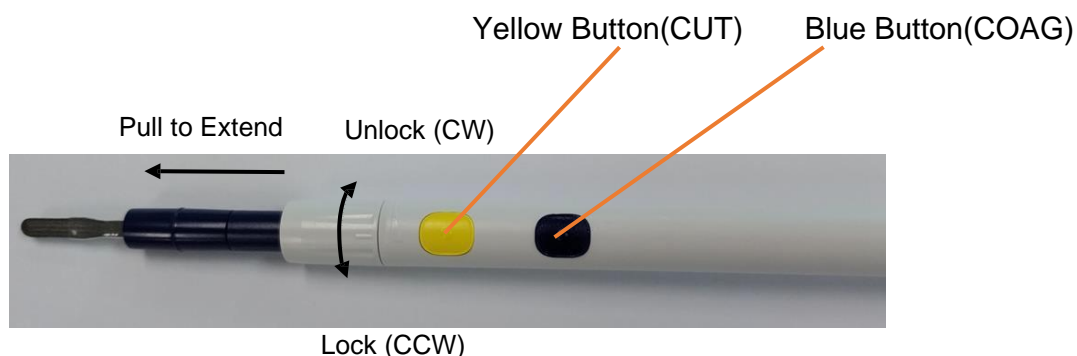
Figure 1 **Duoblade**

- Activation of the device when not in contact with tissue, but close to a conductive object, may cause capacitive coupling.
- Confirm proper electrosurgical generator power settings before proceeding with surgery.
- To prevent contact with the patient or a potential tripping risk, place the cable to the side of the operating table.
- Be careful to keep the device hand switch away from fluid/liquid, as this may cause damage to the device.
- When not in use, keep the device in the provided holster, with the holster securely attached to the surgical drape, or a dry, non-conductive area away from the patient to prevent unintended contact with patient or user.
- Do not activate the device near electrocardiograph electrodes, as the electrical current may result interference.
- Place the patient return electrode cable to prevent contact with the patient or other cables.
- Ensure that the handset is not connected to the electrosurgical generator, or the generator is off or in Standby mode, if available, before installing or removing the patient return electrode.
- Do not re-sterilize or reuse. The Duoblade is provided sterile and intended for single use only.
- After use, dispose of the Duoblade according to hospital procedures and in accordance with local, state, and federal laws and regulations.
- Ensure the Duoblade suction tube is securely connected to the suction source to avoid inadequate suction levels.
- Make sure that the Instructions for Use provided with the Smoke Evacuation Unit are followed, including all user instructions, warnings, and precautions.

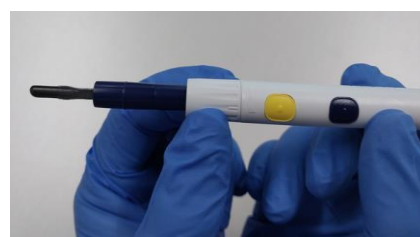
## Setup

1. Place the patient return electrode on the patient and connect to the ESU according to the return electrode Instructions for Use.
2. Remove the Duoblade from the package and inspect the tip of the device for damage. Do not use if damaged.
3. Remove the plastic tip protector.
4. Attach the provided holster to the surgical drape. Place the cable of the device through the cutout in the side of the holster.
5. Attach the Duoblade suction tube to the suction source or smoke evacuator.
6. Turn on the ESU. Follow the manufacturer's manual for setup instructions. Plug the Duoblade monopolar connector into the monopolar port of the ESU.
7. Based on the desired tissue effect the lowest energy settings should be used. Any combination of power setting and mode that results in an output voltage of greater than 4500V should not be used. Consult the user manual of the electrosurgical unit (ESU) to determine the voltage output characteristics for different power settings and modes.

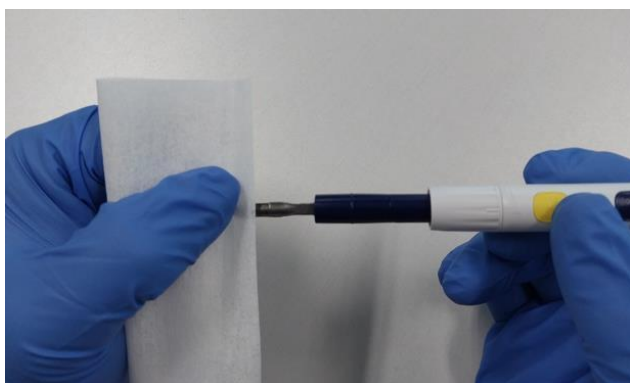
## Use



1. Set the desired length and rotation of the telescoping shaft:
  - a. To extend the shaft, unlock the handle nose collet by rotating it 90° clockwise.
  - b. Pull the shaft distally to the desired length and rotate the shaft to the desired position.
  - c. Lock the nose collet by rotating it 90° counterclockwise. Confirm that shaft is secured in the desired position before proceeding.



2. To collapse the shaft of the device, loosen the nose collet, push on the shaft to the desired length, then tighten the nose collet.
3. Adjust the length and rotation of the Duoblade shaft as needed throughout the procedure.
4. To cut, press and hold the yellow button continuously on the hand switch.
5. To coagulate, press and hold the blue button continuously on the hand switch.
6. To evacuate smoke, activate the smoke evacuation unit per the manufacturer's instructions.
7. Keep the electrode clean throughout the procedure. Remove tissue build-up with wet gauze pads.



## After Surgery

1. Turn off the smoke evacuation unit and the ESU.
2. Disconnect the Duoblade from the smoke evacuation unit and the ESU.

### Disposal

- Discard the Duoblade according to hospital procedures and in accordance with local, state and federal laws and regulations.
- Do not reuse the device.
- Do not reprocess.

### **WARNING**

- A single use device may not withstand chemical, chemical vapor, or high temperature sterilization reprocessing.
- Design features may make cleaning difficult.
- Reuse may create a contamination risk and compromise structural integrity resulting in operational failure.
- Critical product information may be lost during repackaging.
- Failure to comply may lead to infection or cross infection and result in patient and/or healthcare staff injury.

## Troubleshooting

### **WARNING**

Do not disassemble, modify, or repair this product without the authorization of the manufacturer. Contact Cresen for service.

Observation	Corrective Action
Loss of RF energy	Check Duoblade connection to ESU, check electrical connection to ESU

















<b>Electromagnetic Compatibility</b>		
<b>Guidance and Manufacturer's Declaration – Electromagnetic Emissions</b>		
<p>Duoblade is intended for use in the electromagnetic environment specified below. The customer or user of the Duoblade should ensure that it is used in such an environment.</p>		
<b>Emissions Test</b>	<b>Compliance</b>	<b>Electromagnetic Environment – Guidance</b>
RF Emissions	Group 1	<p>Duoblade by itself uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. When it is connected to HF surgical equipment and when that equipment is activated, it should be considered Group 2.</p> <p>Per CISPR 11 &amp; IEC 60601-1-2 : Duoblade was connected to a High Frequency (HF) surgical generator in standby mode.</p>
RF Emissions	Class A	<p>Duoblade is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:</p> <p><b>WARNING:</b> This equipment is intended for use in a professional healthcare facility environment. This equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the HF system or shielding the location.</p>

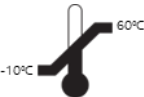

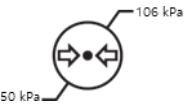


<p>Recommended electromagnetic immunity separation distances between RF communications equipment and Duoblade</p>
<p><b>WARNING:</b> Portable RF equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the HF System including cables specified by the manufacturer. Otherwise, degradation of the performance of the equipment could result.</p>

## Specifications

Model:	DB1SEP, DB1SEP-H, DB1SEP-T, DB1SEP-TH	
Dimensions:	Unextended 21 cm [8.3 inch] length  Extended 27.5 cm [10.8 inch] length  Cord 300 cm [118 inch] length	
Weight	0.186 kg [0.410 lb]	
Mode of Operation:	Refer to specifications of the electrosurgical unit used.	
Applied Part(s):	The electrode at the distal end of the device that comes into physical contact with the patient during normal use as defined by the manufacturer.	
Maximum Rated Accessory Voltage:	4500V Peak	
Environmental Conditions	Operation	Storage and Transportation
Temperature Limits	Between 10 and 40° C	Between -10 and 60° C
Relative Humidity Limits	20 – 85% RH	20 – 85% RH
Atmospheric Pressure Limits	70 – 106 kPa Max elevation 3000m above sea level	50 – 106 kPa Max elevation 5000m above sea level

## Glossary of Symbols

Symbol	Symbol Title	Explanatory Text
	Catalogue number (ISO 15223-1, 5.1.6)	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Manufacturer (ISO 15223-1, 5.1.1)	Indicates the medical device manufacturer.
	Refer to instruction manual/booklet (ISO 7010-M002)	Refer to instruction manual/ booklet
	Do not resterilize (ISO 15223-1, 5.2.6)	Indicates a medical device that is not to be resterilized.
	Do not reuse (ISO 15223-1, 5.4.2)	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Do not use if package is damaged (ISO 15223-1, 5.2.8)	Indicates a medical device that should not be used if the package has been damaged or opened.
	Prescription only (21 CFR 801.109)	Requires prescription in the United States.
	Keep dry (ISO 15223-1, 5.3.4)	Indicates a medical device that needs to be protected from moisture.
	Not made with natural rubber latex (ISO 15223-1, Annex B)	Not made with natural rubber latex.
	Sterilized using ethylene oxide (ISO 15223-1, 5.2.3)	Indicates a medical device that has been sterilized using ethylene oxide.
	Batch code (ISO 15223-1, 5.1.5)	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Recycle: Electronic Equipment (EN 50419)	Do not dispose of this product in unsorted municipal waste stream.
	Use-by date (ISO 15223-1, 5.1.4)	Indicates the date after which the medical device is not to be used.
	Caution: Read all warnings and precautions in instructions for use (ISO 15223-1, 5.4.4)	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Non-pyrogenic (ISO 15223-1, 5.6.3)	Indicates a medical device that is non-pyrogenic.
	Consult instructions for use (ISO 15223-1, 5.4.3)	Indicates the need for the user to consult the instructions for use.

	<p>Temperature limitation [Transfer and Storage] (ISO 15223-1, 5.3.7)</p>	<p>Indicates the temperature limits to which the medical device can be safely exposed</p>
	<p>Humidity limitation [Transfer and Storage] (ISO 15223-1, 5.3.8)</p>	<p>Indicates the range of humidity to which the medical device can be safely exposed</p>
	<p>Atmospheric pressure limitation [Transfer and Storage] (ISO 15223-1, 5.3.9)</p>	<p>Indicates the range of atmospheric pressure to which the medical device can be safely exposed.</p>
	<p>Medical Device (ISO 15223-1, 5.7.7)</p>	<p>Indicates the item is a Medical Device</p>
	<p>Sterile Barrier (ISO 15223-1, 5.2.11)</p>	<p>Indicates a single sterile barrier system</p>

## Warranty

Cresen warrants, for the earlier of (i) the expiration date, if applicable, or (ii) one (1) year from the date of purchase, that this medical device is free from defects in both material and workmanship when used normally for its intended purposes. Suitability of the medical device for any surgical procedure shall be determined by the user alone (in light of relevant instructions for use) and not by Cresen, and such user shall be responsible for understanding how to use the device for its intended purpose. In the event that purchaser believes that any Cresen medical device is defective, purchaser will promptly notify Cresen. Any Cresen brand named instrument delivered from Cresen proving to be defective will, as purchaser's sole and exclusive remedy, be replaced at no charge or the amount paid refunded, at Cresen's discretion, so long as the defect is discovered and reported to Cresen within the earlier of thirty (30) days of discovery or one (1) year of purchase, and Cresen determines that the product is defective and is covered by the warranty. Notwithstanding, Cresen shall not be responsible for normal wear and tear, including minor cosmetic damage compromise or defect caused by re-sterilization. Cresen does not repair, sharpen, recoat or otherwise refurbish any used product. The foregoing limited warranty and limited obligation of replacement is void and of no effect in the event that there is any modification made to the medical device or the medical device is used for any purpose other than its intended purpose.

**Limitation of liability. Cresen does not accept liability to customer or any third party beyond the remedies expressly set forth herein, including any liability for products not being available for use. In no event shall Cresen be liable for lost profits, loss of business, loss of use, costs of procurement of substitute goods, or any other consequential, exemplary, incidental, special, indirect or punitive damages, however caused and under any theory of liability, whether based in contract, tort (including negligence) or otherwise even if advised of the possibility of such damages, or for any claim by any third party, except as expressly provided herein.**

**Customer acknowledges understanding that no other representation or warranty of any kind, express or implied, with respect to the product as to its merchantability, fitness for a particular purpose or any other matter, even when applied or utilized in accordance with its instructions, are made or given by Cresen. And Cresen expressly disclaims all such representations and warranties.**