

CLEARGLIDE^{*} Precision Bipolar Device

Provides controlled coagulation and cutting in one step. Minimizes instrument exchange to accelerate Endoscopic Vessel Harvesting procedure time. Compression provides improved vessel sealing vs. existing bipolar devices. Integrates seamlessly with CLEARGLIDE Optical Vessel Dissector and ULTRARETRACTOR^{*} — Provides smooth dissection with minimal force — “Open” CO₂ system does not depend on gas insufflation to maintain tissue separation.

See reverse side for Instructions for Use.

CLEARGLIDE* Precision Bipolar Device

INDICATIONS

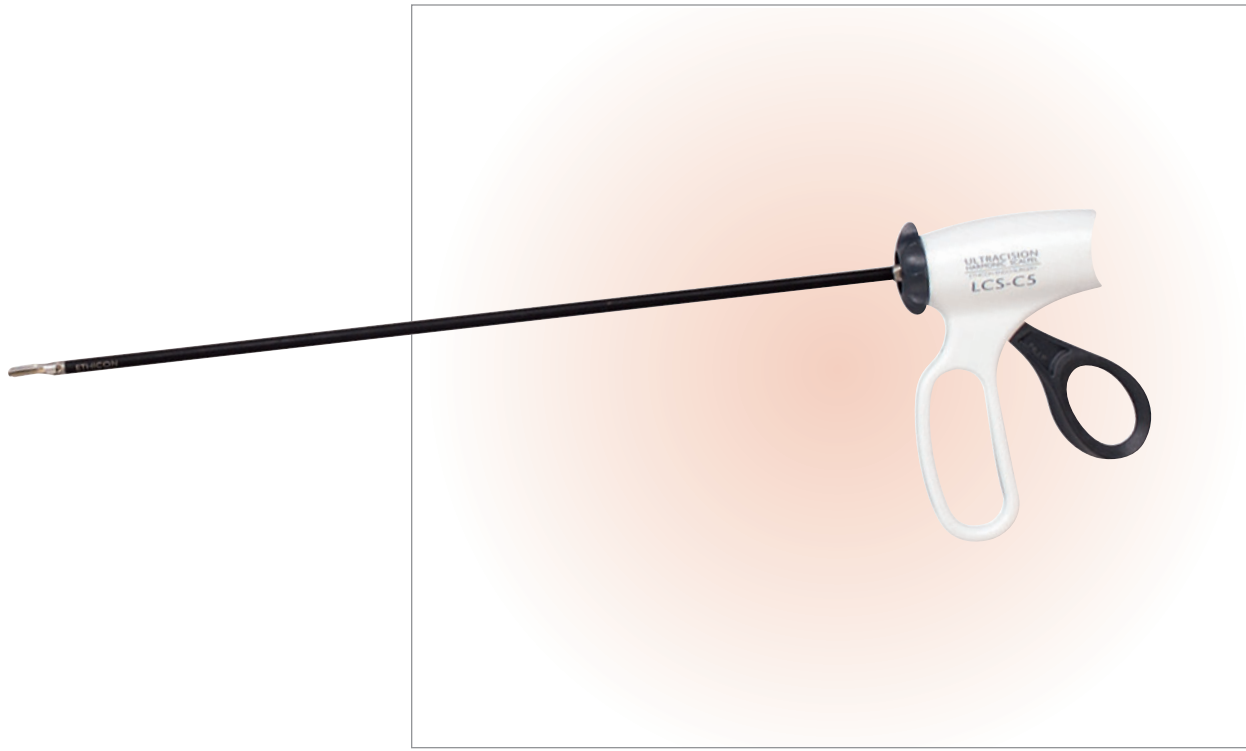
The CLEARGLIDE Precision Bipolar Device is indicated for endoscopic and open tissue dissection, bipolar coagulation, and transection of vessels.

CONTRAINDICATIONS

- Do not use when bipolar coagulation is contraindicated.
- Device is not intended for use when minimally invasive and/or endoscopic techniques are contraindicated.
- Device should not be used on tissue structures upon which metal ligating clips would not normally be used.
- Device is not recommended for coagulation and transection of the proximal saphenous vein at or near the saphenofemoral junction. Diameter of the vein in this location exceeds vessel size limit for safe coagulation.
- The instruments are not intended for contraceptive coagulation of fallopian tissue.

WARNINGS AND PRECAUTIONS

- Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.
- A thorough understanding of the principles and techniques involved in laparoscopic electrosurgical procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Ensure that electrical insulation or grounding is not compromised. Do not immerse electrosurgical instruments in liquid unless the instruments are designed and labeled to be immersed. The CLEARGLIDE Precision Bipolar Device is not designed to be immersed.
- Minimally invasive instruments may vary in diameter from manufacturer to manufacturer. When minimally invasive instruments and accessories from different manufacturers are employed together during a procedure, verify compatibility prior to initiation of the procedure.
- Sterility: The product is sterile unless the package is opened or damaged. The device is designed for one time use. Do Not Reuse or Resterilize. Resterilization may compromise the integrity of this product which may result in unintended injury.
- This instrument is not designed for monopolar application. Do not attempt to connect to a mono-polar source. Damage to the instrument and harm to the patient or medical personnel could result.
- Do not introduce or withdraw the instrument through a trocar sleeve with the jaws open.
- Do not plug the instrument into an electrical outlet (mains outlet) or electrical power cord (mains power cord). Connect only to bipolar electrosurgical generators.
- Do not apply bipolar electrosurgical current directly to staples or clips.
- The instrument will operate with electrosurgical generators having a maximum high frequency peak voltage of 1000 volts. Refer to the electrosurgical generator's specification to verify compatibility, and for indications and instructions. Ensure that all safety precautions are followed.
- Do not activate the instrument without tissue between the jaws.
- Do not activate the knife before closing the jaws.
- Damage to the instrument may occur if cutting of staples or clips is attempted.
- When using electrosurgery, ensure the jaws are fully visible to avoid inadvertent tissue damage. The jaws must be considered electrically active when the instrument is activated.
- After removing the instrument, examine the tissue for hemostasis. If hemostasis is not present, appropriate techniques should be used to achieve hemostasis.
- Dispose of all opened products whether used or unused. Do Not Resterilize the instrument. Resterilization may compromise the integrity of this product which may result in unintended injury.
- The Bipolar Device should only be energized when in contact with target tissue where cutting and coagulation is desired.
- Avoid contact with any and all metal or plastic instruments or objects when the instrument is activated.
- To avoid inadvertent delivery of electrosurgical current, avoid contact of the energized jaw blades with nontargeted tissue.
- As with any electrosurgical device, during or after extended activation, the jaws of the device may be at a temperature which could result in thermal energy damage to nontargeted tissue. Avoid inadvertent contact with users or with nontargeted tissue, surgical drapes, or with other flammable material.
- When the device is not in use, place the jaws on a clean, dry, nonconductive, and highly visible area away from the patient. The unused active bipolar device should never be placed on the patient.
- Do not perform electrosurgery in the presence of flammable anesthetics or other flammable gases, near flammable objects, or in the presence of oxidizing agents, as fire could result.



The HARMONIC SCALPEL* Shear

The HARMONIC SCALPEL Shear uses ultrasonic technology, the unique energy form that allows both precise cutting and controlled coagulation with minimal lateral thermal tissue damage.

It offers safer dissection near vital structures compared to electrosurgery or lasers. Fewer instrument changes are needed, less tissue charring and desiccation occur, and visibility in the surgical field is improved. Introduced commercially in 1993, the HARMONIC SCALPEL Shear and the LAPAROSONIC* Coagulating Shears (LCS) have now been used by thousands of surgeons worldwide in laparoscopic and open surgical procedures.

See reverse side for Instructions for Use.

HARMONIC SCALPEL* Products

INDICATIONS

The HARMONIC SCALPEL Instruments are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electro cautery, lasers, and steel scalpels.

CONTRAINDICATIONS

- The instruments are not indicated for incising bone.
- The instruments are not indicated for contraceptive tubal occlusion.

WARNINGS AND PRECAUTIONS

General

- A thorough understanding of the principles and techniques involved in laser, electrosurgical and ultrasonic procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Ensure that electrical insulation or grounding is not compromised. Do not immerse electrosurgical instruments in liquid.
- Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.
- Minimally invasive instruments may vary in diameter from manufacturer to manufacturer. When minimally invasive instruments and accessories from different manufacturers are employed together in a procedure verify compatibility prior to initiation of the procedure.
- As with all energy sources (Electrosurgery, Laser, or Ultrasound) there are concerns about the carcinogenic and infectious potential of the by-products, such as tissue smoke plume and aerosols. Appropriate measures such as protective eyewear, filtration masks, and effective smoke evacuation.
- Do not attempt to bend, sharpen or otherwise alter the shape of the blade. Doing so may cause blade failure and user or patient injury.
- To avoid user or patient injury in the event that accidental activation occurs, the HARMONIC SCALPEL instrument blades should not be in contact with the patient, drapes or flammable materials while not in use. During prolonged activation in tissue, the instrument blades may become hot. Avoid unintended blade contact with tissue, drapes, surgical gowns, or other unintended sites of activation.
- Use only HARMONIC SCALPEL Foot Switch, Hand Piece, blade accessories, and power cord to ensure that they are compatible with the Generator.
- Products manufactured or distributed by companies not authorized by Ethicon Endo-Surgery, Inc. may not be compatible with the HARMONIC SCALPEL System. Use of such products may lead to unanticipated results and possible injury to the user or patient.
- After removing the instrument, examine the tissue for hemostasis. If hemostasis is not present, use appropriate techniques to achieve hemostasis.
- Dispose of all disposable opened instruments whether used or unused. Do Not Resterilize the instrument. Cleaning and resterilization of single patient use HARMONIC SCALPEL devices can damage internal components resulting in abnormally high sheath temperatures and burn injury to user or patient when the blade is activated.

Blades

- Blood and tissue buildup between the blade and sheath may result in abnormally high temperatures at the distal end of the sheath. To prevent burn injury, remove any visible tissue buildup at the distal end of the sheath.
- The blade has been designed to meet the international safety standard EN60601-1 based on an intermittent operation of 15-second on/off intervals. For activation time of longer duration and under certain fault conditions, the blade sheath may become hot. To prevent burn injury, avoid direct tissue contact with the blade sheath or take preventative measures to protect tissue that comes in contact with the sheath. Monitor the sheath temperature if direct tissue contact cannot be avoided.

Hand Piece

- The HARMONIC SCALPEL Hand Piece is supplied non-sterile. Sterilize prior to use.
- The Hand Piece is designed to meet the international safety standard EN60601-1 based on intermittent operation at a 50% duty cycle.
- Handle the Hand Piece carefully, as damage may shift resonant frequency.
- Do not bang or drop the Hand Piece.
- Do not clean the Hand Piece electrical connector with alcohol.

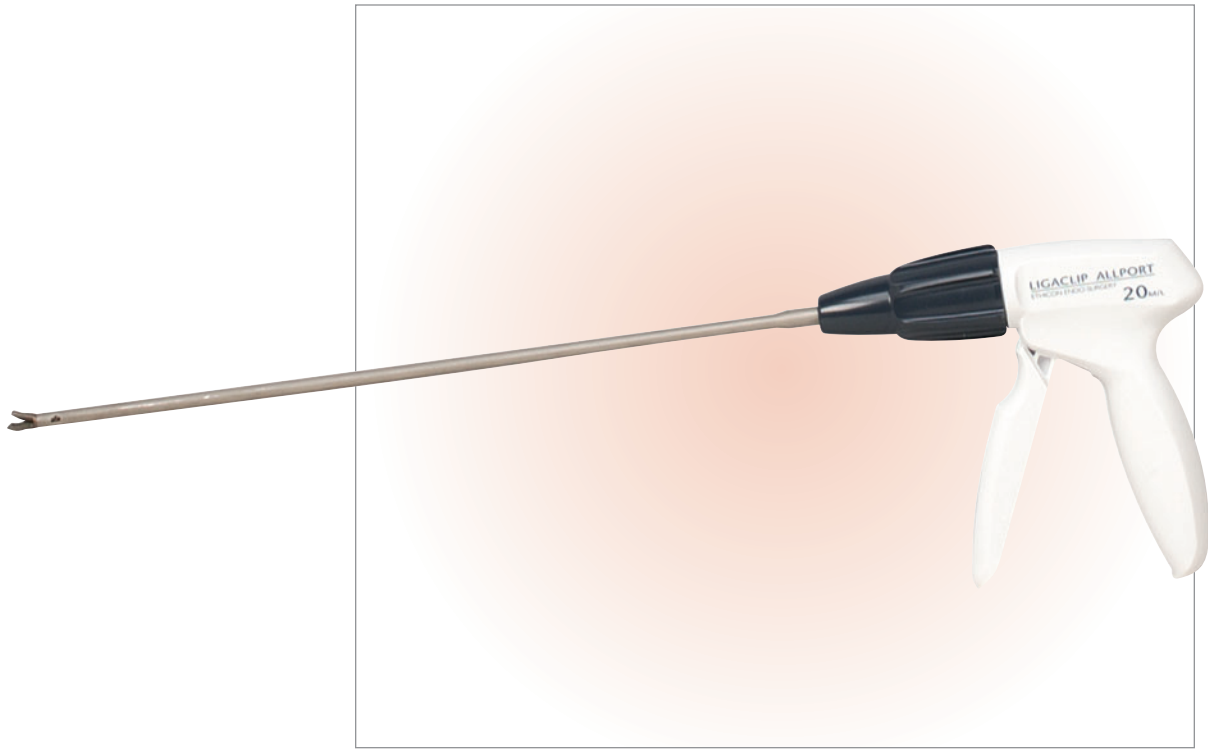
- Use only with Ethicon Endo-Surgery, Inc. model GEN01, GEN22, or GEN32 generators and accessories to ensure compatibility.
- Do not use the Hand Piece with the HS2 or DSH10 blade system. Use of this blade on the Hand Piece may result in excessive temperatures and risk of burns.

Blades and Hand Piece

- Audible high-pitched tones are an abnormal condition and an indicator that the blade or Hand Piece is not operating properly. The tones may be an indicator that the Hand Piece is beyond its useful life or that the blade has not been attached properly, which may result in abnormally high sheath temperatures and user or patient injury.
- Do not use the HARMONIC SCALPEL blades without the proper adapter. Failure to use the proper adapter may result in user or patient burn injury.

CS and LCS

- Care should be taken not to apply pressure between the CS or LCS blade and tissue pad without having tissue between them. This can result in dampening or possible damage to the blade system. Both conditions may cause a system failure signaled by a continuous beep when either of the foot pedals is depressed.
- The entire exposed blade tip is active and will cut/coagulate tissue when the CS or LCS blade is activated. Be careful to avoid inadvertent contact between all exposed blade surfaces and surrounding tissue when using the CS or LCS.
- Avoid contact with any and all metal or plastic instruments or objects when the instrument is activated.



ALLPORT* Clip Applier

Created for side and main branch ligation, ALLPORT provides clip security with its exclusive 5 mm SMART* clip design. It delivers 30 pre-formed titanium clips. This pre-loaded, single-trigger instrument offers an efficient means of ligation through a 5 mm trocar, through a 5 mm reducer.

See reverse side for Instructions for Use.

ALLPORT* Clip Appliers

INDICATIONS

The ALLPORT and ALLPORT LS Endoscopic Rotating Multiple Clip Appliers have application for use on tubular structures or vessels. The tissue being ligated should be consistent with the size of the clip.

CONTRAINDICATIONS

- DO NOT use the instruments on tissue structures upon which metal ligating clips would not normally be used.
- DO NOT use the instruments for contraceptive tubal occlusion.

INSTRUCTIONS FOR USE

Verify compatibility of all instruments and accessories prior to using the instrument (refer to Warnings and Precautions).

1. Using sterile technique, remove the instrument from the package. To avoid damage, do not flip the instrument into the sterile field.
2. Partially squeeze the trigger to close the jaws of the instrument before inserting it through the trocar or incision.
Note: Partially squeezing the trigger (the first stage of the firing sequence) closes the jaws but does not advance a clip or fire the instrument.
3. Insert the instrument through a 5 mm trocar, through a larger diameter trocar with a 5 mm reducer cap, or through an incision.
4. Release the trigger, opening the jaws. Verify that no clip is within the jaws prior to placing over tissue. If a clip is in the jaws, remove the clip prior to closing the jaws. Position the jaws of the instrument so that they completely enclose the tissue to be ligated.
5. Partially squeeze the trigger to close the jaws and check tissue position. If the positioning is inadequate, the trigger may be released to open the jaws and reposition the tissue.
Note: Partially squeezing the trigger (the first stage of the firing sequence) closes the jaws but does not advance a clip or fire the instrument.
6. After ensuring that the tissue is properly positioned, fully squeeze the trigger (second stage of the firing sequence) until it stops. A clip will advance onto the tissue structure.
Caution: Failure to fully squeeze the trigger may cause improper clip advancement which may prevent the jaws from opening.
Caution: Check to ensure that each clip securely encloses the tissue being ligated.
Note: When there is 1 clip remaining in the applier, the indicator bar will appear orange.
7. To remove the instrument from the trocar or incision, close the jaws of the instrument by partially squeezing the trigger and withdrawing the instrument.

WARNINGS AND PRECAUTIONS

- Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.
- Minimally invasive instruments may vary in diameter from manufacturer to manufacturer. When minimally invasive instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure.
- A thorough understanding of the principles and techniques involved in laser and electrosurgical procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Ensure that electrical insulation or grounding is not compromised. Do not immerse electrosurgical instruments in liquid.
- Before firing the instrument, inspect the jaws to ensure that they are properly positioned and that the tissue structure is completely enclosed within the jaws of the instrument.
- Ensure that each clip has been securely and completely positioned around the tissue being ligated.
- Upon each clip application, fully squeeze the trigger of the instrument to completely fire the instrument.
- If a clip does not automatically advance, remove the instrument from the patient. Completely squeeze the trigger to refire the instrument and then continue product use after successful firing.
- Dispose of all fired instruments. Do Not Resterilize the instrument. Resterilization may compromise the integrity of the instrument which may result in its malfunctioning.



CLEARGLIDE* Optical Vessel Dissector

The CLEARGLIDE Optical Vessel Dissector allows for smooth, atraumatic dissection on anterior and lateral surfaces. Includes a handle, cannula, and a transparent, angled blunt tip. The blunt tip dissects tissue and creates a cavity for instrument passage. The tip is transparent, for visualization during insertion, tunneling, and dissection. CLEARGLIDE is offered with a luer lock connector on the handle for CO₂ gas connection — an aid for maintaining tissue separation.

See reverse side for Instructions for Use.

CLEARGLIDE* Optical Vessel Dissector

INDICATIONS

The CARDIOVATIONS CLEARGLIDE Optical Vessel Dissector has application for use in the creation of an operative cavity in the extraperitoneal spaces such as the retroperitoneal, preperitoneal, and subcutaneous areas. The device may be used in surgical procedures requiring dissection of tissue.

CONTRAINDICATIONS

There are no known contraindications.

INSTRUCTIONS FOR USE

Verify compatibility of all instruments and accessories prior to use (refer to Warnings and Precautions). Prepare access to the surgical site through an incision in accordance with proper surgical technique prior to insertion of the CLEARGLIDE Optical Vessel Dissector.

1. Using sterile technique, remove the instrument from the package. To avoid damage, do not flip the instrument into the sterile field.
2. Ensure that the endoscope is properly connected to its light supply and video equipment as directed in the manufacturer's instructions. Ensure clarity of the picture on the monitor as directed in the manufacturer's instructions.
3. Insert the endoscope into the endoscope insertion port of the handle until it is firmly seated within the handle. Verify proper placement of the endoscope by checking visualization via the video monitor. Connect a CO₂ line to the luer fitting and adjust the flow to provide a constant supply of CO₂. (The recommended flow rate is approximately 1 liter per minute.)
4. Using proper surgical technique, incise the appropriate area adequately to accommodate the transparent tip. Dissect to the desired tissue plane.
5. Insert the CLEARGLIDE Optical Vessel Dissector through the incision. Using controlled pressure on the instrument, advance the optical tip along the vessel. The position of the instrument tip relative to tissue planes and anatomical landmarks can be seen as it separates tissue. Continue insertions on all sides of the vessel as necessary to achieve desired dissection. Be careful to avoid avulsion of side branches.
Caution: Do not use excessive force.
6. After the desired length of dissection has been achieved, remove the CLEARGLIDE Optical Vessel Dissector and endoscope from the incision.
7. Additional incisions and dissection can be performed as required by the surgical procedure.

WARNINGS AND PRECAUTIONS

- Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.
- Minimally invasive instruments may vary in diameter from manufacturer to manufacturer. When minimally invasive instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure.
- A thorough understanding of the principles and techniques involved in laser and electrosurgical procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Ensure that electrical insulation or grounding is not compromised. Do not immerse electrosurgical instruments in liquid.
- Although the CLEARGLIDE Optical Vessel Dissector is designed to allow for viewing during dissection through the tissue, care must be taken to avoid damage to vessels and other anatomic structures.

To minimize the risk of injury, be sure to:

- Properly position the patient to optimize access to the dissection site.
 - Note important anatomical landmarks.
 - Direct the dissector tip away from major vessels and structures.
 - Do not use excessive force.
- Contact with active energy-based modalities may damage the instrument.
 - When using energy-based instruments (Electrosurgery or Laser), there are concerns about the carcinogenic and infectious potential of the by-products, such as tissue smoke plume and aerosols. Appropriate measures such as protective eyewear, filtration masks, effective smoke evacuation equipment should be used in both open and endoscopic procedures.
 - After removing the dissector from the dissected area, always inspect the site for hemostasis. If hemostasis is not present, appropriate techniques should be used to achieve hemostasis.
 - Dispose of product after use. Do Not Resterilize the instrument. Resterilization may compromise the integrity of this product which may result in unintended injury.



Ultra-Retractor

The Ultra-Retractor consists of a handle, covered cannula, and a transparent blunt tip spoon. The spoon dissects tissue and creates a cavity for instrument passage and use. The spoon is transparent, for visualization during insertion, tunneling, dissection, and retraction. The device is offered with a luer lock connector on the handle for the attachment of CO₂ gas — an aid for clearing the endoscope lens.

See reverse side for Instructions for Use.

Ultra-Retractor

INDICATIONS

The CARDIOVATIONS Ultra-Retractor has application for use in the creation and maintenance of an operative cavity in the extraperitoneal spaces such as the retroperitoneal, preperitoneal, and subcutaneous areas. The device may be used in surgical procedures requiring dissection and retraction of tissue.

CONTRAINDICATIONS

There are no known contraindications.

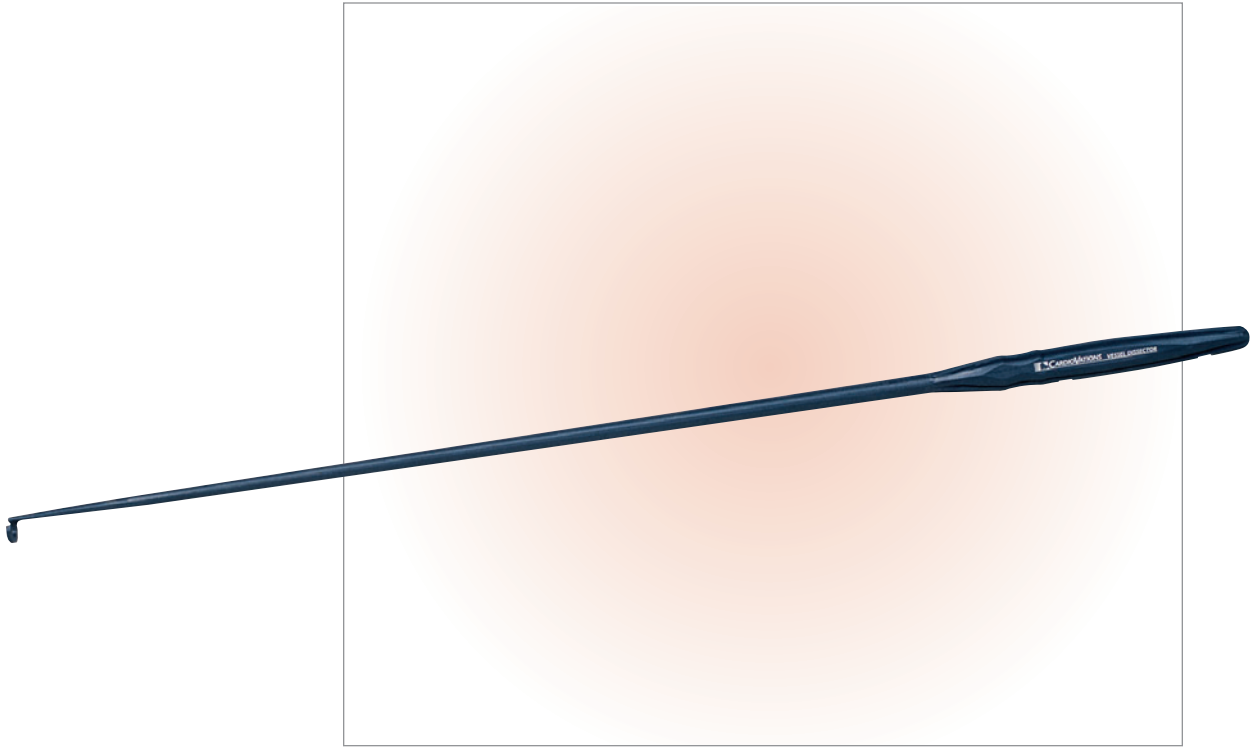
INSTRUCTIONS FOR USE

Verify compatibility of all instruments and accessories prior to use (refer to Warnings and Precautions).

1. Using sterile technique, remove the instrument from the package. To avoid damage, do not flip the instrument into the sterile field.
2. Ensure that the endoscope is properly connected to its light supply and video equipment as directed in the manufacturer's instructions. Ensure clarity of the picture on the monitor as directed in the manufacturer's instructions. If CO₂ is to be used, connect the tubing to the luer lock and adjust the flow to provide a constant flow of CO₂. (The recommended flow rate is approximately 1 liter per minute.)
3. Insert the endoscope into the endoscope insertion port of the Ultra-Retractor handle until it is firmly seated within the handle. Verify proper placement of the endoscope by checking visualization via the video monitor.
4. Using proper surgical technique, insert through the incision previously created for the CARDIOVATIONS CLEARGLIDE* Optical Vessel Dissector. Dissect to the desired tissue plane.
5. Using controlled pressure on the instrument, advance the spoon tip along the vessel and position the Ultra-Retractor at the desired site. Lift the retractor as needed to maintain operative space and perform the surgical procedure while maintaining space with the Ultra-Retractor.
Caution: Do not use excessive force.
6. After the desired length of vessel has been mobilized, remove the Ultra-Retractor and endoscope from the incision.
7. Additional incisions and dissection can be performed as required by the surgical procedure.

WARNINGS AND PRECAUTIONS

- Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.
- Minimally invasive instruments may vary in diameter from manufacturer to manufacturer. When minimally invasive instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure.
- A thorough understanding of the principles and techniques involved in laser and electrosurgical procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Ensure that electrical insulation or grounding is not compromised. Do not immerse electrosurgical instruments in liquid.
- Although the Ultra-Retractor is designed to allow for viewing during dissection through the tissue, care must be taken to avoid damage to vessels and other anatomic structures. To minimize the risk of injury, be sure to:
 - Properly position the patient to optimize access to the dissection site.
 - Note important anatomical landmarks.
 - Direct the retractor tip away from major vessels and structures.
 - Do not use excessive force.
- Contact with active energy-based modalities may damage the instrument.
- When using energy-based instruments (Electrosurgery or Laser), there are concerns about the carcinogenic and infectious potential of the by-products, such as tissue smoke plume and aerosols. Appropriate measures such as protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in both open and endoscopic procedures.
- After removing the Ultra-Retractor from the dissected area, always inspect the site for hemostasis. If hemostasis is not present, appropriate techniques should be used to achieve hemostasis.
- Dispose of product after use. Do Not Resterilize the instrument. Resterilization may compromise the integrity of this product which may result in unintended injury.



Vessel Dissector VSSD1

The Vessel Dissector has application for the use in the blunt dissection of tissues such as veins, arteries, nerves, and other tubular structures. In THE WATCHBAND PROCEDURE*, the Vessel Dissector is used to assure that all side branches have been ligated before transecting and removing the radial artery.

See reverse side for Instructions for Use.

Vessel Dissector VSSD1

INDICATIONS

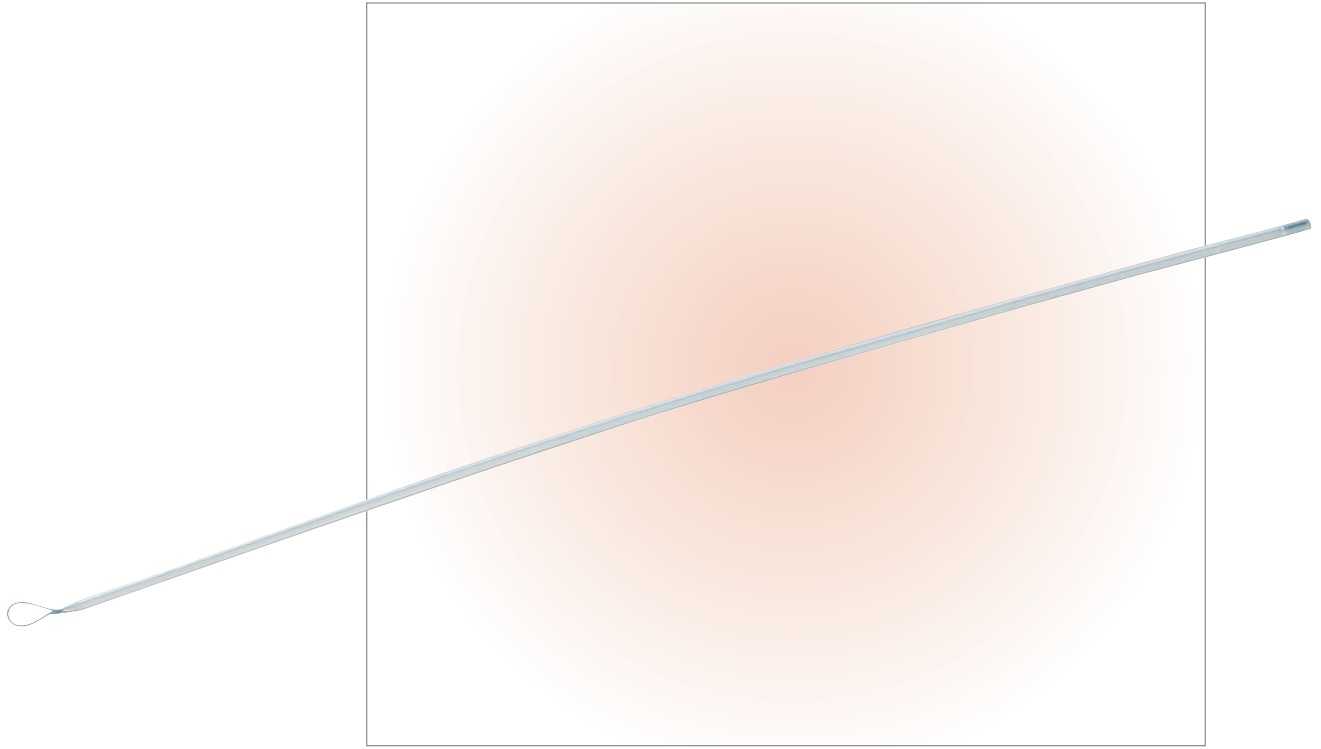
The Vessel Dissector has application for the use in the blunt dissection of tissues such as veins, arteries, nerves, and other tubular structures.

CONTRAINDICATIONS

None Known

WARNINGS AND PRECAUTIONS

- Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications and hazards prior to performance of any minimally invasive procedures.
- Minimally invasive instruments may vary in diameter from manufacturer. When minimally invasive instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure.
- A thorough understanding of the principles and techniques involved in laser and electrosurgical procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Ensure that electrical insulation or grounding is not compromised.
- Although the Vessel Dissector is designed to allow blunt dissection of small tubular structures, care must be taken to avoid damage to other anatomic structures. To minimize the risk of such injury, be sure to:
 - Properly position the patient to optimize access to the dissection site.
 - Note important anatomical landmarks.
 - Use appropriate care to avoid damage to major vessels and structures.
 - Do not use excessive force.
- After removing the Vessel Dissector from the dissected area, always inspect the site for hemostasis. If hemostasis is not present, appropriate techniques should be used to achieve hemostasis.
- Dispose of all opened products whether used or unused. Do Not Resterilize the Vessel Dissector. Resterilization may compromise the integrity of this product, which may result in unintended injury.



ENDOLOOP* Ligature

The ENDOLOOP Ligature, made with ETHIBOND* EXCEL polyester suture, consists of a plastic tube that is narrowed at one end and scored at the other. A length of suture is inserted into the tube, protrudes from the narrow end, and is formed into a ligature loop with a knot which becomes secure after the device is activated. The opposite end of the suture is fastened to the scored end of the tube. The scored end acts as a handle. In THE WATCHBAND INCISION*, the ENDOLOOP ligature is used for the proximal ligation of the radial artery.

See reverse side for Instructions for Use.

ENDOLOOP* Ligature

INDICATIONS

ETHIBOND EXCEL suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

INSTRUCTIONS FOR USE

Standard endoscopic procedures should be followed up to the point of tissue ligation or approximation. The ENDOLOOP ligature is then introduced through a cannula. An appropriate surgical instrument is used to grasp and position the tissue. This may involve either pulling the tissue through the loop or encompassing the tissue with a loop. The ENDOLOOP ligature tube is then broken at the scored point. This allows the tube to slide over the suture and cinches the loop around the tissue. When the ligature has provided hemostasis or approximation, the suture is cut behind the knot leaving an appropriate length of suture "ear". The tube is then removed. Several ligatures may be applied to ensure hemostasis or tissue approximation.

ACTIONS

ETHIBOND EXCEL suture elicits a minimal acute inflammatory reaction in tissue, followed by a gradual encapsulation of the suture by fibrous connective tissue. Implantation studies in animals show no meaningful decline in polyester suture strength over time. Both polyester fiber suture material and the polybutylate coating are pharmacologically inactive.

CONTRAINDICATIONS

None known.

WARNINGS

Users should be familiar with surgical procedures and techniques involving nonabsorbable sutures before employing ETHIBOND EXCEL suture for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used. Do not resterilize. Discard opened packages and unused sutures.

As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. Acceptable surgical practice should be followed for the management of infected or contaminated wounds.

Endoscopic procedures should be performed only by persons having adequate training and familiarity with endoscopic techniques. Consult medical literature relative to techniques, complications and hazards prior to performance of any endoscopic procedure.

PRECAUTIONS

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

ADVERSE REACTIONS

Adverse effects associated with the use of this device include wound dehiscence, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, infection, minimal acute inflammatory tissue reaction and transitory local irritation at the wound site.

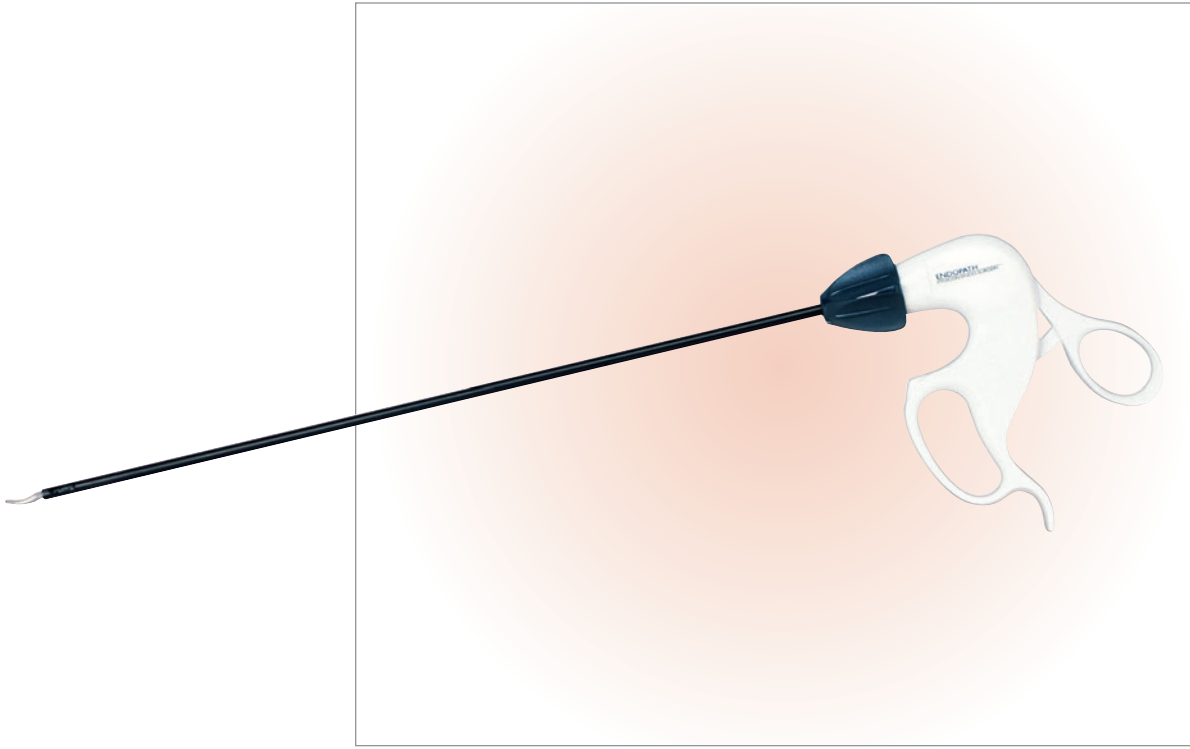
DOSAGE AND ADMINISTRATION

Use as required per surgical procedure.

HOW SUPPLIED

The ENDOLOOP ligature made with ETHIBOND EXCEL polyester suture is available sterile.

The ENDOLOOP ligature made with ETHIBOND EXCEL polyester suture is available in a one dozen box.



V5CS Endoscopic Scissors

The Endoscopic Scissors have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection, and transection of tissue. In THE WATCHBAND INCISION*, the V5CS Endoscopic Scissors can be used in collaboration with the ALLPORT* Clip Applier in the transection of radial artery side branches as well as the proximal and distal transection of the radial artery.

See reverse side for Instructions for Use.

5VCS Endoscopic Scissors

INDICATIONS

The Endoscopic Instruments have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection, and transection of tissue.

CONTRAINDICATIONS

- The instruments are not intended for contraceptive coagulation of fallopian tissue.
- The instruments are not intended for use when minimally invasive techniques are contraindicated.

WARNINGS AND PRECAUTIONS

- Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.
- Minimally invasive instruments may vary in diameter from manufacturer to manufacturer. When minimally invasive instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure.
- A thorough understanding of the principles and techniques involved in laser, electrosurgical, and ultrasonic procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Ensure that insulation or grounding is not compromised. Do not immerse electrosurgical instruments in liquid.
- Refer to appropriate electrosurgical system user manual for indications and instructions to ensure that all safety precautions are followed.
- When using electrocautery, ensure the blades/jaws are fully visible to avoid inadvertent tissue damage.
- Do not use instruments with monopolar cautery as bipolar cautery instruments.
- Do not apply electrosurgical current directly to staples or clips.
- Damage to the instrument may occur if cutting of staples or clips is attempted.
- Do not introduce or withdraw the instrument with the blades/jaws open through a trocar sleeve.
- After removing the instrument, inspect the site for hemostasis. If hemostasis is not present, use appropriate techniques to achieve hemostasis.
- The instrument will operate with electrosurgical generators having a high frequency maximum voltage of 3000 Volts peak. Refer to the electrosurgical generator's specification to verify compatibility and for indications and instructions, and ensure that all safety precautions are followed.
- Dispose of all opened products whether used or unused. Used instruments are considered medical waste. Dispose of in accordance with local guidelines. Do Not Resterilize the instrument. Resterilization may compromise the integrity of the instrument which may result in its malfunctioning.



DERMABOND*

DERMABOND Topical Skin Adhesive is a sterile, liquid topical skin adhesive containing a monomeric (2-octyl cyanoacrylate) formulation and the colorant D & C Violet #2. It is provided in a single use applicator packaged in a blister pouch. The applicator is comprised of a crushable glass ampule contained within a plastic vial with attached applicator tip. As applied to the skin, the liquid adhesive is more viscous than water and polymerizes within minutes. In vitro studies have shown that DERMABOND adhesive acts as a barrier to microbial penetration as long as the adhesive film remains intact. Clinical studies were not conducted to demonstrate microbial barrier properties.

See reverse side for Instructions for Use.

DERMABOND*

INDICATIONS

DERMABOND Topical Skin Adhesive is intended for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. DERMABOND adhesive may be used in conjunction with, but not in place of, subcuticular sutures.

CONTRAINDICATIONS

- Do not use on any wounds with evidence of active infection, gangrene, or wounds of decubitus etiology.
- Do not use on mucosal surfaces or across mucocutaneous junctions (e.g., oral cavity, lips), or on skin which may be regularly exposed to body fluids or with dense natural hair, (e.g., scalp).
- Do not use on patients with a known hypersensitivity to cyanoacrylate or formaldehyde.

WARNINGS

- DERMABOND adhesive is a fast setting adhesive capable of adhering to most body tissue and many other materials, such as latex gloves and stainless steel. Inadvertent contact with any body tissue, and any surfaces or equipment that are not disposable or that cannot be readily cleaned with a solvent such as acetone should be avoided.
- Polymerization of DERMABOND adhesive may be accelerated by water or fluids containing alcohol: DERMABOND adhesive should not be applied to wet wounds.
- DERMABOND adhesive should not be applied to the eye. If contact with the eye occurs, flush the eye copiously with saline or water. If residual adhesive remains, apply topical ophthalmic ointment to help loosen the bond and contact an ophthalmologist.
- DERMABOND adhesive should not be used below the skin because the polymerized material is not absorbed by tissue and can elicit a foreign body reaction.
- DERMABOND adhesive should not be used in high skin tension areas or across areas of increased skin tension, such as knuckles, elbows, or knees, unless the joint will be immobilized during the skin healing period.
- DERMABOND adhesive treated wounds should be monitored for signs of infection. Wounds with signs of infection, such as erythema, edema, warmth, pain, and pus, should be evaluated and treated according to standard practice for infection.
- DERMABOND adhesive should be not used on wound sites that will be subjected to repeated or prolonged moisture or friction.
- DERMABOND adhesive should only be used after wounds have been cleaned and debrided in accordance with standard surgical practice. Local anesthetic should be used when necessary to assure adequate cleansing and debridement.
- Excessive pressure of the applicator tip against wound edges or surrounding skin can force the wound edges apart and allow adhesive into the wound. Adhesive within the wound could delay wound healing and/or result in adverse cosmetic outcome. Therefore, DERMABOND adhesive should be applied with a very light brushing motion of the applicator tip over easily approximated wound edges.
- DERMABOND adhesive polymerizes through an exothermic reaction in which a small amount of heat is released. With the proper technique of applying DERMABOND adhesive in multiple thin layers (at least three) onto a dry wound and allowing time for polymerization between applications, heat is released slowly and the sensation of heat or pain experienced by the patient is minimized. However, if DERMABOND adhesive is applied so that large droplets of liquid are allowed to remain unspread, the patient may experience a sensation of heat or discomfort.
- DERMABOND adhesive is packaged for single patient use. Discard remaining opened materials after each wound closure procedure.
- Do not resterilize DERMABOND adhesive.
- Do not place DERMABOND adhesive in a procedure pack/tray that is to be sterilized prior to use. Exposure of DERMABOND adhesive, after its final manufacture, to excessive heat (as in autoclaves of ethylene oxide sterilization) or radiation (such as gamma or electron beam), is known to increase its viscosity and may render the product unusable.

PRECAUTIONS

- Do not apply liquid or ointment medications or other substances to the wound after closure with DERMABOND adhesive, as these substances can weaken the polymerized film and allow for wound dehiscence. DERMABOND adhesive permeability by topical medications has not been studied.
- DERMABOND adhesive permeability by fluids is not known and has not been studied.

- DERMABOND adhesive is a free flowing liquid slightly more viscous than water. To prevent inadvertent flow of liquid DERMABOND adhesive to unintended areas: (1) the wound should be held in a horizontal position with DERMABOND adhesive applied from above, and (2) DERMABOND adhesive should be applied in multiple (at least 3), thin layers rather than in few large droplets.
- DERMABOND adhesive should be used immediately after crushing the glass ampule, as the liquid adhesive will not flow freely from the applicator tip after a few minutes.
- If unintended bonding of intact skin occurs, peel, but do not pull the skin apart. Petroleum jelly or acetone may help loosen the bond. Other agents such as water, saline, betadine, Hibiclens or soap, are not expected to immediately loosen the bond.
- Safety and effectiveness of DERMABOND adhesive on wounds of patients with peripheral vascular disease, insulin dependent diabetes mellitus, blood clotting disorders, personal or family history of keloid formation or hypertrophy, burst stellate lacerations have not been studied.
- Safety and effectiveness of DERMABOND adhesive on the following wounds have not been studied: animal or human bites, puncture or stab wounds.
- Safety and effectiveness on wounds that have been treated with DERMABOND adhesive and then exposed for prolonged periods to direct sunlight or tanning lamps have not been studied.
- Safety and effectiveness of DERMABOND adhesive on wounds in vermilion surfaces has not been studied.

ADVERSE REACTIONS

Adverse reactions encountered during clinical study:

Clinical Study Outcomes	No Subcuticular Sutures		With Subcuticular Sutures	
	DERMABOND	Control	DERMABOND	Control
	N(%)	N(%)	N(%)	N(%)
Accounting				
N, patients enrolled	240	243	167	168
N, patients treated	239	242	167	168
Patients completed	228 (95%)	215 (88%)	164 (98%)	162 (96%)
Adverse Reactions				
Suspected Infection*	8 (3.6%)	2 (0.9%)	6 (3.6%)	2 (1.2%)
Wound Type				
• # Lacerations	8	2	1	0
• # Incisions	0	0	5	2
Dehiscence with Need for Retreatment	6 (2.5%)	5 (2.1%)	3 (1.8%)	0
Accute Inflammation				
Erythema	26 (11.5%)	74 (33.0%)	52 (31.3%)	75 (45.1%)
Edema	22 (9.7%)	28 (12.5%)	62 (37.3%)	71 (42.8%)
Pain	14 (6.1%)	13 (5.8%)	56 (33.7%)	57 (34.3%)
Warmth	3 (1.3%)	6 (2.6%)	3 (1.8%)	4 (2.4%)

* In the clinical study, presence of infection was to be identified by observation of redness more than 3-5mm from the repaired wound, swelling, purulent discharge, pain, increased skin temperature, fever, or other systemic signs of infection. (See clinical study). Confirmatory culture was not routinely obtained. Among cases of suspected infection for DERMABOND adhesive, 7/14 (50%) were in patients less than 12 years old with traumatic lacerations; overall, 8 of the 14 (approximately 60%) of DERMABOND adhesive wounds with suspected infections were associated with sub-optimal cosmetic outcome.

- Reactions may occur in patients who are hypersensitive to cyanoacrylate or formaldehyde. See CONTRAINDICATIONS.
- The polymerization of DERMABOND adhesive on the skin releases small amounts of heat, which may cause a sensation of heat or discomfort in some patients.

Adverse reactions may be experienced following DERMABOND adhesive contact with the eye.