Multispecialty Applications
Professional Use Information

OmniPulse MAX™ 80 Watt Holmium Laser
Model 1210-VHP

OmniPulse™ 40 Watt Holmium Laser
Model 1210

OmniPulse Jr.™ 30 Watt Holmium Laser
Model 1230-30

Trimedyne, Inc.
15091 Bake Parkway
Irvine, CA 92606
USA

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1 Introduction to Multispecialty Applications

Caution: Before using the Holmium:YAG Laser System clinically, the physician must become fully acquainted with the unique surgical effects produced by the laser. For example, its depth of tissue penetration may be different than that of Nd:YAG, Argon or CO₂ lasers.

The information provided in this manual is not intended to be all-inclusive nor is it intended to replace physician training or experiments.

The Trimedyne Holmium:YAG Laser Systems are designed for use in conjunction with Trimedyne Inc.'s Tapertip™ disposable holmium arthroscopic handpieces, the Omni™ Switchtip System arthroscopic laser handpieces, and other optical fiber delivery devices designed for use with Trimedyne Inc.’s proprietary connector. Applications for these laser systems include incision, excision, resection, ablation, coagulation, hemostasis, and vaporization, with or without an endoscope, in the following indications:

- General Surgery of Soft Tissues
- Genitourinary Surgery / Urology
- Otorhinolaryngology (ENT) Surgery
- Gynecological Surgery
- Lithotripsy and Percutaneous Urinary Lithotripsy
- Orthopedic Surgery
- Percutaneous Cervical, Lumbar, and Thoracic Disc Decompression / Discectomy
- Therapeutic Dermatological, Therapeutic Plastic, and Aesthetic Surgical Procedures
- Gastroenterological / Gastrointestinal Surgery

This Multispecialty Applications / Professional Use Information manual includes detailed information about each of these indications. It is also important to refer to the instructions for use accompanying each optical fiber delivery device.
Note: Please contact the Trimedyne Customer Service department or visit our website at http://www.trimedyne.com for an updated listing of indications and to download the most recent Multispecialty Applications Professional Use Information manual.

Endoscopes, which can be either flexible or rigid, may be used for visualization during laser procedures. The outer diameter of the fiber optic delivery device used will determine the minimum working channel requirement for insertion through the endoscope. During single eyepiece endoscopic procedures, use caution since depth perception may be altered.

For additional information, the document ANSI Z136.3-1996, "For the Safe Use of Lasers in Healthcare Facilities," is recommended for reference.

The laser system should be used only by physicians and staff who have been appropriately trained and who are thoroughly familiar with the instructions and safety precautions given in the operator manual. A review of the published literature is strongly encouraged.
2 Dermatology and Plastic Surgery

For use with or without an endoscope with or without a working channel. Prior to use, physicians must be fully acquainted with endoscopic procedures.

2.1 Indications

Incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft, mucosal, fatty, and cartilaginous tissues, with or without an endoscope, in therapeutic plastic, therapeutic dermatological, and aesthetic surgical procedures, including:

- Scars
- Tattoo removal
- Vascular lesions, including:
  - Port wine stains
  - Hemangioma
  - Telangiectasia (facial, leg)
  - Rosacea
- Corns
- Papillomas
- Basal cell carcinomas
- Lesions of skin and subcutaneous tissue
- Plantar warts
- Periungual and subungual warts
- Debridement of decubitus ulcer
- Skin tag vaporization
2.2 Warnings

**General**

Refer to the safety section of the operation manual for general laser-safety precautions.

**Specific**

1. Holmium:YAG laser radiation (2.1 micrometers) will ablate biological tissues to depths different from the radiation of CO₂ (10.6 micrometers), Argon (514.5 nanometers), or Nd:YAG (1.064 micrometers) lasers. Extreme caution should be used until the physician is completely familiar with the biological interactions of the laser energy with tissues of various types.

2. Tissue perforation can occur if excessive laser energy is applied, whether through the use of excessive laser-beam power or the application of power for excessive periods of time.

3. Use the laser only on tissues that are fully observable. Do *not* use the laser if the desired operating field is obscured.

4. Aim the laser only at tissues intended for treatment; otherwise, damage to surrounding tissues may result.

5. Screen abnormalities, such as tumors, that are in close proximity to known arteries or veins by pretreatment work-ups to precisely locate these circulatory structures.

6. Use low energy and low pulse-rate settings until fully familiar with the capabilities of the laser system. If higher energies are required, increase the energy in the smallest available increments until the desired level is achieved. Smaller diameter fibers will require less energy and larger diameter fibers will require higher energy to achieve the same laser fluence. These starting energy recommendations apply regardless of the particular surgical fiber optic energy delivery system configuration. Refer to the instructions for use supplied with each surgical fiber for specific maximum operating parameters.
7. "Flash" fire can occur. Do not operate the laser system in the presence of flammable anesthetics or volatile substances such as alcohol or elevated levels of oxygen. Under no circumstances should flammable gases be present when operating the laser.

8. The risks of combustion, perforation and laser-induced hemorrhage, all of which could cause death, must be fully explained to the patient.

9. As with conventional endoscopic treatment, adverse reactions such as fever, chills, sepsis, edema and hemorrhage may occur following laser treatment. In extreme cases, death may occur due to procedural complications, concurrent illness or the application of laser radiation.

10. During surgical procedures, the use of a smoke evacuator or equivalent is recommended (as required) to minimize airborne particulates to avoid possible biohazard.

11. During surgical treatment over the eyelid area, it is recommended that the patient's eyes be protected by placing metal or other types of Holmium wavelength (2.1 \( \mu \text{m} \)) rated eye shields on top of the cornea.

### 2.3 Precautions

1. Use caution when treating patients who have had difficulty with previous endoscopic procedures.

2. Extra precautions should be taken when radiotherapy and laser therapy are to be used concurrently, including more stringent postoperative monitoring than usual. Clinical studies have shown that patients who have undergone radiotherapy present a greater risk of perforation or tissue erosion.

3. Discontinue laser therapy immediately if the patient develops any cardiopulmonary problems.

4. Trimedyne, Inc., has no clinical information or experience concerning the use of Ho:YAG laser systems on pregnant women or nursing mothers.

5. Patients who have experienced discomfort during previous laser treatment may require analgesics.

6. During single eyepiece endoscopic procedures, use caution since depth perception may be altered.
7. Remove the endoscope from the treatment area prior to lasing to avoid damage to the scope.

2.4 Complications / Risks

1. As is true of other forms of medical treatment, some of the complications that may be encountered in laser therapy are serious and could result in death. They include the following:

a. Non-laser related

- Perforation
- Aspiration
- Induced hemorrhage
- Allergic reaction to medication
- Hypertension
- Arrhythmia
- Pain
- Gas overdistension, pneumothorax
- Air embolism

b. Laser related

Acute

- Induced hemorrhage
- Ulceration
- Perforation
• Edema
• Pain
• Fever, leukocytosis
• Chills

**Chronic**

• Delay in healing
• Perforation
• Stricture
• Delayed hemorrhage
• Sepsis

2. **Pain:** Short-lived pain may occur immediately following laser therapy and may persist for as long as 48 hours.

3. **Fever and Leukocytosis:** Immediately after laser therapy, the patient may experience fever and leukocytosis, which are commonly associated with tissue destruction. These generally resolve without treatment. Cultures are indicated to exclude the possibility of infection.

4. **Bleeding:** Patients may experience bleeding at the site of the laser therapy or from erosion of a tumor during or after laser therapy. Post treatment hematocrit is recommended to identify this potential complication.

5. **Sepsis:** Laser-ablated tissue may become infected after therapy. If a question of sepsis exists, a culture should be taken and other appropriate evaluations made.

6. **Perforation:** Perforation can occur as a result of excessive exposure to laser radiation. Perforation can also occur from tumor erosion, or as a result of endoscopic procedures. To clinically diagnose perforation, patients must be monitored postoperatively through physical signs, hematocrit and radiography.

7. **Gas Overdistension, Pneumothorax:** Patients may experience gastrointestinal distension or pneumothorax during or after therapy.
2.5 Contraindications

- Patients who are not good surgical candidates (e.g. intolerance to anesthetics, etc.).
- Obstruction of the desired operating field of view.
3 Gastroenterological/Gastrointestinal Surgery

For use with or without an endoscope with or without a working channel. Prior to use, physicians must be fully acquainted with endoscopic procedures.

3.1 Indications

Incision, excision, resection, ablation, vaporization, coagulation, and hemostasis, with or without an endoscope, of gastroenterological/gastrointestinal tissue, including:

- Cholecystectomy
- Lysis of adhesions
- Appendectomy
- Biopsy
- Pylorostenotomy
- Benign and malignant lesions
- Rectal polyps of sigmoid colon
- Gall bladder calculi
- Biliary/bile duct calculi
- Benign and malignant neoplasm
- Polyps
- Colitis
- Ulcers
• Angiodysplasia
• Hemorrhoids
• Varices
• Esophagitis
• Esophageal ulcer
• Mallory-Weiss tear
• Gastric ulcer
• Duodenal ulcer
• Non-bleeding ulcer
• Gastric erosions
• Colorectal cancer
• Gastritis
• Bleeding tumors
• Pancreatitis
• Vascular malformations
• Telangiectasias
• Telangiectasias of the Osler-Weber-Rendu disease

3.2 Warnings

**General**

Refer to the safety section of the operation manual for general laser-safety precautions.
Specific

1. Holmium:YAG laser radiation (2.1 micrometers) will ablate biological tissues to depths different from the radiation of CO₂ (10.6 micrometers), Argon (514.5 nanometers), or Nd:YAG (1.064 micrometers) lasers. Extreme caution should be used until the physician is completely familiar with the biological interactions of the laser energy with tissues of various types.

2. Tissue perforation can occur if excessive laser energy is applied, whether through the use of excessive laser-beam power or the application of power for excessive periods of time.

3. Use the laser only on tissues that are fully observable. Do not use the laser if the desired operating field is obscured.

4. Aim the laser only at tissues intended for treatment; otherwise, damage to surrounding tissues may result.

5. Screen abnormalities, such as tumors, that are in close proximity to known arteries or veins by pretreatment work-ups to precisely locate these circulatory structures.

6. Use low energy and low pulse-rate settings until fully familiar with the capabilities of the laser system. If higher energies are required, increase the energy in the smallest available increments until the desired level is achieved. Smaller diameter fibers will require less energy and larger diameter fibers will require higher energy to achieve the same laser fluence. These starting energy recommendations apply regardless of the particular surgical fiber optic energy delivery system configuration. Refer to the instructions for use supplied with each surgical fiber for specific maximum operating parameters.

7. "Flash" fire can occur. Do not operate the laser system in the presence of flammable anesthetics or volatile substances such as alcohol or elevated levels of oxygen. Under no circumstances should flammable gases be present when operating the laser.

8. The risks of combustion, perforation and laser-induced hemorrhage, all of which could cause death, must be fully explained to the patient.

9. As with conventional endoscopic treatment, adverse reactions such as fever, chills, sepsis, edema and hemorrhage may occur following laser treatment. In extreme cases, death may occur due to procedural complications, concurrent illness or the application of laser radiation.
10. During surgical procedures, the use of a smoke evacuator or equivalent is recommended (as required) to minimize airborne particulates to avoid possible biohazard.

### 3.3 Precautions

1. Use caution when treating patients who have had difficulty with previous endoscopic procedures.

2. Extra precautions should be taken when radiotherapy and laser therapy are to be used concurrently, including more stringent postoperative monitoring than usual. Clinical studies have shown that patients who have undergone radiotherapy present a greater risk of perforation or tissue erosion.

3. Discontinue laser therapy immediately if the patient develops any cardiopulmonary problems.

4. Trimedyne, Inc., has no clinical information or experience concerning the use of Ho:YAG laser systems on pregnant women or nursing mothers.

5. Patients who have experienced discomfort during previous laser treatment may require analgesics.

6. During single eyepiece endoscopic procedures, use caution since depth perception may be altered.

7. Remove the endoscope from the treatment area prior to lasing to avoid damage to the scope.

### 3.4 Complications / Risks

1. As is true of other forms of medical treatment, some of the complications that may be encountered in laser therapy are serious and could result in death. They include the following:
a. Non-laser related

- Perforation
- Aspiration
- Induced hemorrhage
- Allergic reaction to medication
- Hypertension
- Arrhythmia
- Pain
- Gas overdistension, pneumothorax
- Air embolism

b. Laser related

Acute

- Induced hemorrhage
- Ulceration
- Perforation
- Edema
- Pain
- Fever, leukocytosis
- Chills

Chronic

- Delay in healing
- Perforation
- Stricture
- Delayed hemorrhage
- Sepsis

2. **Pain:** Short-lived pain may occur immediately following laser therapy and may persist for as long as 48 hours.

3. **Fever and Leukocytosis:** Immediately after laser therapy, the patient may experience fever and leukocytosis, which are commonly associated with tissue destruction. These generally resolve without treatment. Cultures are indicated to exclude the possibility of infection.

4. **Bleeding:** Patients may experience bleeding at the site of the laser therapy or from erosion of a tumor during or after laser therapy. Post treatment hematocrit is recommended to identify this potential complication.

5. **Sepsis:** Laser-ablated tissue may become infected after therapy. If a question of sepsis exists, a culture should be taken and other appropriate evaluations made.

6. **Perforation:** Perforation can occur as a result of excessive exposure to laser radiation. Perforation can also occur from tumor erosion, or as a result of endoscopic procedures. To clinically diagnose perforation, patients must be monitored postoperatively through physical signs, hematocrit and radiography.

7. **Gas Overdistension, Pneumothorax:** Patients may experience gastrointestinal distension or pneumothorax during or after therapy.

### 3.5 Contraindications

- Obstructions due to extrinsic compression
- Acute cholecystitis
- Jaundice

### Relative contraindications

- Obesity
4 General Surgery (Soft Tissue)

For use with or without an endoscope with or without a working channel. Prior to use, physicians must be fully acquainted with endoscopic procedures.

4.1 Indications

Incision, excision, resection, ablation, coagulation, hemostasis and vaporization, with or without an endoscope, in general surgery of soft tissue including:

- Skin incision
- Tissue dissection
- Excision of external tumors and lesions
- Complete or partial resection of internal organs
- Tumors and lesions
- Tissue ablation
- Mastectomy
- Hepatectomy
- Pancreatectomy
- Splenectomy
- Thyroidectomy
- Parathyroidectomy
- Herniorrhaphy
- Tonsillectomy
• Lymphadenectomy
• Partial nephrectomy
• Pilonidal cystectomy
• Resection of lipoma
• Pelvic adhesiolysis
• Debridement of decubitus ulcers
• Hemorrhoids
• Pilodidal cyst removal and repair
• Debridement of statis ulcers
• Biopsy

4.2 Warnings

General

Refer to the safety section of the operation manual for general laser-safety precautions.

Specific

1. Holmium:YAG laser radiation (2.1 micrometers) will ablate biological tissues to depths different from the radiation of CO₂ (10.6 micrometers), Argon (514.5 nanometers), or Nd:YAG (1.064 micrometers) lasers. Extreme caution should be used until the physician is completely familiar with the biological interactions of the laser energy with tissues of various types.

2. Tissue perforation can occur if excessive laser energy is applied, whether through the use of excessive laser-beam power or the application of power for excessive periods of time.

3. Use the laser only on tissues that are fully observable. Do not use the laser if the desired operating field is obscured.
4. Aim the laser only at tissues intended for treatment; otherwise, damage to surrounding tissues may result.

5. Screen abnormalities, such as tumors, that are in close proximity to known arteries or veins by pretreatment work-ups to precisely locate these circulatory structures.

6. Use low energy and low pulse-rate settings until fully familiar with the capabilities of the laser system. If higher energies are required, increase the energy in the smallest available increments until the desired level is achieved. Smaller diameter fibers will require less energy and larger diameter fibers will require higher energy to achieve the same laser fluence. These starting energy recommendations apply regardless of the particular surgical fiber optic energy delivery system configuration. Refer to the instructions for use supplied with each surgical fiber for specific maximum operating parameters.

7. "Flash" fire can occur. Do not operate the laser system in the presence of flammable anesthetics or volatile substances such as alcohol or elevated levels of oxygen. Under no circumstances should flammable gases be present when operating the laser.

8. The risks of combustion, perforation and laser-induced hemorrhage, all of which could cause death, must be fully explained to the patient.

9. As with conventional endoscopic treatment, adverse reactions such as fever, chills, sepsis, edema and hemorrhage may occur following laser treatment. In extreme cases, death may occur due to procedural complications, concurrent illness or the application of laser radiation.

10. During surgical procedures, the use of a smoke evacuator or equivalent is recommended (as required) to minimize airborne particulates to avoid possible biohazard.

### 4.3 Precautions

1. Use caution when treating patients who have had difficulty with previous endoscopic procedures.

2. Extra precautions should be taken when radiotherapy and laser therapy are to be used concurrently, including more stringent postoperative monitoring than usual. Clinical studies have shown that patients who have undergone radiotherapy present a greater risk of perforation or tissue erosion.
3. Discontinue laser therapy immediately if the patient develops any cardiopulmonary problems.

4. Trimatedyne, Inc., has no clinical information or experience concerning the use of Ho:YAG laser systems on pregnant women or nursing mothers.

5. Patients who have experienced discomfort during previous laser treatment may require analgesics.

6. During single eyepiece endoscopic procedures, use caution since depth perception may be altered.

7. Remove the endoscope from the treatment area prior to lasing to avoid damage to the scope.

4.4 Complications / Risks

1. As is true of other forms of medical treatment, some of the complications that may be encountered in laser therapy are serious and could result in death. They include the following:

a. Non-laser related

- Perforation
- Aspiration
- Induced hemorrhage
- Allergic reaction to medication
- Hypertension
- Arrhythmia
- Pain
- Gas overdistension, pneumothorax
- Air embolism


b. Laser related

**Acute**

- Induced hemorrhage
- Ulceration
- Perforation
- Edema
- Pain
- Fever, leukocytosis
- Chills

**Chronic**

- Delay in healing
- Perforation
- Stricture
- Delayed hemorrhage
- Sepsis

2. **Pain:** Short-lived pain may occur immediately following laser therapy and may persist for as long as 48 hours.

3. **Fever and Leukocytosis:** Immediately after laser therapy, the patient may experience fever and leukocytosis, which are commonly associated with tissue destruction. These generally resolve without treatment. Cultures are indicated to exclude the possibility of infection.

4. **Bleeding:** Patients may experience bleeding at the site of the laser therapy or from erosion of a tumor during or after laser therapy. Post treatment hematocrit is recommended to identify this potential complication.
5. **Sepsis:** Laser-ablated tissue may become infected after therapy. If a question of sepsis exists, a culture should be taken and other appropriate evaluations made.

6. **Perforation:** Perforation can occur as a result of excessive exposure to laser radiation. Perforation can also occur from tumor erosion, or as a result of endoscopic procedures. To clinically diagnose perforation, patients must be monitored postoperatively through physical signs, hematocrit and radiography.

7. **Gas Overdistension, Pneumothorax:** Patients may experience gastrointestinal distension or pneumothorax during or after therapy.

### 4.5 Contraindications

- Obstructions due to extrinsic compression
- Acute cholecystitis
- Jaundice
- Stone in the common bile duct
- The need for common bile duct exploration

### Relative contraindications

- Obesity
- Previous abdominal surgery
5 Genitourinary Surgery/Urology

For use with or without an endoscope with or without a working channel. Prior to use, physicians must be fully acquainted with genitourinary/urology procedures.

5.1 Indications

Incision, excision, resection, ablation, coagulation, hemostasis and vaporization, with or without an endoscope, of genitourinary/urology tissue including:

- Lesions of the external genitalia
- Condylomas
- Urethral and penile hemangioma

5.2 Warnings

The Trimedyne holmium laser systems and fiber optic laser energy delivery systems are not licensed under a United States patent covering their use in laser resection or enucleation of the prostate, the treatment of strictures, or transurethral incision of the prostate. The following list of warnings is provided with the understanding that these devices are not recommended for such uses.

General

Refer to the safety section of the operation manual for general laser-safety precautions.
Specific

1. Holmium:YAG laser radiation (2.1 micrometers) will ablate biological tissues to depths different from the radiation of CO₂ (10.6 micrometers), Argon (514.5 nanometers), or Nd:YAG (1.064 micrometers) lasers. Extreme caution should be used until the physician is completely familiar with the biological interactions of the laser energy with tissues of various types.

2. Tissue perforation can occur if excessive laser energy is applied, whether through the use of excessive laser-beam power or the application of power for excessive periods of time.

3. Use the laser only on tissues that are fully observable. Do not use the laser if the desired operating field is obscured.

4. Aim the laser only at tissues intended for treatment; otherwise, damage to surrounding tissues may result.

5. Screen abnormalities, such as tumors, that are in close proximity to known arteries or veins by pretreatment work-ups to precisely locate these circulatory structures.

6. Use low energy and low pulse-rate settings until fully familiar with the capabilities of the laser system. If higher energies are required, increase the energy in the smallest available increments until the desired level is achieved. Smaller diameter fibers will require less energy and larger diameter fibers will require higher energy to achieve the same laser fluence. These starting energy recommendations apply regardless of the particular surgical fiber optic energy delivery system configuration. Refer to the instructions for use supplied with each surgical fiber for specific maximum operating parameters.

7. "Flash" fire can occur. Do not operate the laser system in the presence of flammable anesthetics or volatile substances such as alcohol or elevated levels of oxygen. Under no circumstances should flammable gases be present when operating the laser.

8. The risks of combustion, perforation and laser-induced hemorrhage, all of which could cause death, must be fully explained to the patient.

9. As with conventional endoscopic treatment, adverse reactions such as fever, chills, sepsis, edema and hemorrhage may occur following laser treatment. In extreme cases, death may occur due to procedural complications, concurrent illness or the application of laser radiation.
10. During surgical procedures, the use of a smoke evacuator or equivalent is recommended (as required) to minimize airborne particulates to avoid possible biohazard.

5.3 Precautions

The Trimedyne holmium laser systems and fiber optic laser energy delivery systems are not licensed under a United States patent covering their use in laser resection or enucleation of the prostate, the treatment of strictures, or transurethral incision of the prostate. The following list of precautions is provided with the understanding that these devices are not recommended for such uses.

1. Use caution when treating patients who have had difficulty with previous endoscopic procedures.

2. Extra precautions should be taken when radiotherapy and laser therapy are to be used concurrently, including more stringent postoperative monitoring than usual. Clinical studies have shown that patients who have undergone radiotherapy present a greater risk of perforation or tissue erosion.

3. Discontinue laser therapy immediately if the patient develops any cardiopulmonary problems.

4. Trimedyne, Inc., has no clinical information or experience concerning the use of Ho:YAG Laser Systems on pregnant women or nursing mothers.

5. Patients who have experienced discomfort during previous laser treatment may require analgesics.

6. During single eyepiece endoscopic procedures, use caution since depth perception may be altered.

7. Remove the endoscope from the treatment area prior to lasing to avoid damage to the scope.
5.4 Complications / Risks

The Trimedyne holmium laser systems and fiber optic laser energy delivery systems are not licensed under a United States patent covering their use in laser resection or enucleation of the prostate, the treatment of strictures, or transurethral incision of the prostate. The following list of complications is provided with the understanding that these devices are not recommended for such uses.

1. As is true of other forms of medical treatment, some of the complications that may be encountered in laser therapy are serious and could result in death. They include the following:

a. Non-laser related

- Perforation
- Aspiration
- Induced hemorrhage
- Allergic reaction to medication
- Hypertension
- Arrhythmia
- Pain
- Gas overdistension, pneumothorax
- Air embolism
- Local and/or systemic infection
- Local hematoma
- Dissection
- Urinary tract infection
b. Laser related

Acute

- Induced hemorrhage
- Ulceration
- Perforation
- Edema
- Pain
- Fever, leukocytosis
- Chills
- Discomfort during and/or after energy application
- Urinary retention
- Hematuria
- Dysuria
- Meatal stenosis
- Tissue adherence to reflective tip with resultant distal tip burn-out, melting and/or detachment
- Retrograde ejaculation
- Pain and/or continued symptoms of urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH)

Chronic

- Delay in healing
- Perforation
- Stricture
• Delayed hemorrhage

• Sepsis

• Thermal damage to surrounding structures

• Impotence

• Retrograde ejaculation

• Pain and/or continued symptoms of urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH)

2. **Pain:** Short-lived pain may occur immediately following laser therapy and may persist for as long as 48 hours.

3. **Fever and Leukocytosis:** Immediately after laser therapy, the patient may experience fever and leukocytosis, which are commonly associated with tissue destruction. These generally resolve without treatment. Cultures are indicated to exclude the possibility of infection.

4. **Bleeding:** Patients may experience bleeding at the site of the laser therapy or from erosion of a tumor during or after laser therapy. Post-treatment hematocrit is recommended to identify this potential complication.

5. **Sepsis:** Laser-ablated tissue may become infected after therapy. If a question of sepsis exists, a culture should be taken and other appropriate evaluations made.

6. **Perforation:** Perforation can occur as a result of excessive exposure to laser radiation. Perforation can also occur from tumor erosion, or as a result of endoscopic or laparoscopic procedures. To clinically diagnose perforation, patients must be monitored postoperatively through physical signs, hematocrit and radiography.

7. **Gas Overdistension, Pneumothorax:** Patients may experience gastrointestinal distension or pneumothorax during or after therapy.
5.5 Contraindications

The Trimedyne holmium laser systems and fiber optic laser energy delivery systems are not licensed under a United States patent covering their use in laser resection or enucleation of the prostate, the treatment of strictures, or transurethral incision of the prostate. The following list of contraindications is provided with the understanding that these devices are not recommended for such uses.

- Patients who are not good surgical candidates (e.g. intolerance to anesthetics, etc.)
- Obstruction of the desired operating field of view
- Patients with a known bleeding disorder
- Patients with a current or recent urinary tract infection not treated with antibiotics
- Patients having a prostate specific antigen (PSA) of 10 ng/mL or greater

5.6 Important Benign Prostatic Hyperplasia (BPH) Information:

The Trimedyne holmium laser systems and fiber optic laser energy delivery devices are not licensed under a United States patent covering their use in laser resection or enucleation of the prostate, the treatment of strictures, or transurethral incision of the prostate. The following information is provided with the understanding that these devices are not recommended for such uses.
1. Usage information of the Holmium laser for the treatment of BPH from the medical literature:

   a. *Incision*¹:
      
      - Fiber was used to create a single incision from the ureteral orifice to the verumontanum and out to fat.
      - Lasing was on the surface of the prostate.
      - Fiber used was a 400 µm Ho:YAG bare fiber sheathed in a ureteral catheter.

   b. *Resection*²:
      
      - Fiber was used to resect the prostate to form an effective cavity for voiding in the prostatic urethra, and to incise at the 5 o’clock position from the bladder neck to the verumontanum to the base of the bladder using the left ureteral orifice as a landmark. A similar incision was made at the 7 o’clock position using the right ureteral opening as a landmark. The median lobe was resected with a transverse incision between the aforementioned 2 incisions. The transverse incision was started at the verumontanum and continued under the median lobe along the capsule toward the bladder neck, using the verumontanum as a landmark, and then the resected tissue was floated in the bladder. The incision at the 5 o’clock position was extended upward along the left lateral wall. When this upward incision reached the 3 o’clock position, a downward incision was added at the 1 o’clock position along the lateral wall. The left lobe was then resected and floated in the bladder. The right lobe was resected similarly. The incision at the 7 o’clock position was extended upward to the 9 o’clock position and then a downward incision was added at the 11 o’clock position.
      - Lasing was on the surface of the prostate.
      - Fiber used was a 550 µm forward firing Ho:YAG laser fiber.


c. **Resection**³:

- Fiber was used to incise deeply in the posterior and 7 o’clock positions, and the median lobe BPH tissue was gradually undermined and resected. In a similar fashion, deep template incisions were made anteriorly (at 1 and 11 o’clock) down to the level of the surgical capsule of the prostate, and were combined with similar incisions continued upward from the initial 5 and 7 o’clock incision posteriorly, to undermine and resect gradually the prostatic lateral lobes bilaterally.
- Lasing was on the surface of the prostate.
- Fiber used was a 550 µm end firing silica glass Ho:YAG laser delivery fiber.

d. **Ablation**⁴:

- Holmium ablation of the prostate is a simple, effective technique for small prostates. No information on fiber position is available from this article.
- Lasing was on the surface of the prostate.
- Fiber used was a side firing dual wavelength fiber.

e. **Vaporization**⁵:

- Fiber was inserted through the working port of the cystoscope, which was advanced into the prostatic urethra in an antegrade fashion.
- Lasing was on the surface of the prostate.
- Fiber used was straight end firing or side firing 400, 600, or 1000 µm Ho:YAG fiber with a distal polished quartz internal reflection mechanism.

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f. **Vaporization**:  
- Fiber was used to vaporize with the standard four-point necrosis at 2, 4, 8, and 10 o’clock.
- Lasing was on the surface of the prostate.
- Fiber used was an end firing 550 µm Ho:YAG bare fiber or a side firing Ho:YAG fiber with a beam deflection of 70° and a 30° divergence.

g. **Enucleation**:

- Fiber was used to incise the bladder neck deeply at 5 and 7 o’clock with the incisions brought to the level of the verumontanum on each side. The incisions were then joined distally and the lobe undermined to a depth determined by these previous incisions. The entire lobe was resected back toward the bladder neck, finally disarticulating it in one large fragment back into the bladder. The left lateral lobe was then undermined commencing at the verumontanum. The apex of the resection was first defined and then the bladder neck was incised deeply at the 1 o’clock position. The upper and lower incisions were then joined and the entire lateral lobe peeled off the surgical capsule. The procedure was then repeated on the right side and any small remaining fragments of adenoma were removed to give a smooth cavity. Once the resection was completed, the lobes were morcellated using either the suprapubic or transurethral approach.
- Lasing was on the surface of the prostate.
- Fiber used was a 550 µm end firing Holmium fiber.

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9 Krahn HP (Winnipeg, Manitoba, Canada): Laser Enucleation of the Prostate (HoLEP) – A Pilot Study.

10 Krahn HP (Winnipeg, Manitoba, Canada): Complications of Holmium Laser Enucleation of the Prostate (HoLEP).
h. **Excision:**

More than one incision may be performed in order to excise prostatic tissue, thus excision and incision are used interchangeably in Holmium laser application. In addition, excision is synonymous to resection. Therefore, it is reasonable to believe that any information available to the Holmium incision or resection for the treatment of BPH also applies to the Holmium excision of the said treatment.

i. **Hemostasis:**

Hemostasis refers to the cauterization of blood vessels to control bleeding during surgery. Hemostasis is a peripheral effect of the other applications of Holmium:YAG energy, such as ablation, vaporization, incision, and resection. As iterated in Gilling P, et al: The Use of the Holmium Laser in the Treatment of Benign Prostatic Hyperplasia, *Journal of Endourology, Vol. 10, No. 5, October 1996*, the Holmium wavelength of 2.1 µm is strongly absorbed by water and has an absorption length of 0.4 mm, which is sufficient to ensure satisfactory hemostasis in prostatic tissue.

2. Any prostate tissue removed with the Holmium laser should be collected and evaluated by a pathologist for presence of any undifferentiated or poorly differentiated cell.

3. Patients should be advised to return for follow-up visits as determined by their physicians, including one at six months.
6 Gynecological Surgery

For use with or without an endoscope with or without a working channel. Prior to use, physicians must be fully acquainted with gynecological procedures.

6.1 Indications

Incision, excision, resection, ablation, coagulation, hemostasis and vaporization, with or without an endoscope, of soft tissue in gynecology during open and endoscopic procedures, including:

- Condyloma acuminata

6.2 Warnings

General

Refer to the safety section of the operation manual for general laser-safety precautions.

Specific

1. Holmium:YAG laser radiation (2.1 micrometers) will ablate biological tissues to depths different from the radiation of CO$_2$ (10.6 micrometers), Argon (514.5 nanometers), or Nd:YAG (1.064 micrometers) lasers. Extreme caution should be used until the physician is completely familiar with the biological interactions of the laser energy with tissues of various types.

2. Tissue perforation can occur if excessive laser energy is applied, whether through the use of excessive laser-beam power or the application of power for excessive periods of time.
3. Use the laser only on tissues that are fully observable. Do not use the laser if the desired operating field is obscured.

4. Aim the laser only at tissues intended for treatment; otherwise, damage to surrounding tissues may result.

5. Screen abnormalities, such as tumors, that are in close proximity to known arteries or veins by pretreatment work-ups to precisely locate these circulatory structures.

6. Use low energy and low pulse-rate settings until fully familiar with the capabilities of the laser system. If higher energies are required, increase the energy in the smallest available increments until the desired level is achieved. Smaller diameter fibers will require less energy and larger diameter fibers will require higher energy to achieve the same laser fluence. These starting energy recommendations apply regardless of the particular surgical fiber optic energy delivery system configuration. Refer to the instructions for use supplied with each surgical fiber for specific maximum operating parameters.

7. "Flash" fire can occur. Do not operate the laser system in the presence of flammable anesthetics or volatile substances such as alcohol or elevated levels of oxygen. Under no circumstances should flammable gases be present when operating the laser.

8. The risks of combustion, perforation and laser-induced hemorrhage, all of which could cause death, must be fully explained to the patient.

9. As with conventional endoscopic treatment, adverse reactions such as fever, chills, sepsis, edema and hemorrhage may occur following laser treatment. In extreme cases, death may occur due to procedural complications, concurrent illness or the application of laser radiation.

10. During surgical procedures, the use of a smoke evacuator or equivalent is recommended (as required) to minimize airborne particulates to avoid possible biohazard.
6.3 Precautions

1. Use caution when treating patients who have had difficulty with previous endoscopic procedures.

2. Extra precautions should be taken when radiotherapy and laser therapy are to be used concurrently, including more stringent postoperative monitoring than usual. Clinical studies have shown that patients who have undergone radiotherapy present a greater risk of perforation or tissue erosion.

3. Discontinue laser therapy immediately if the patient develops any cardiopulmonary problems.

4. Trimedyne, Inc., has no clinical information or experience concerning the use of Ho:YAG laser systems on pregnant women or nursing mothers.

5. Patients who have experienced discomfort during previous laser treatment may require analgesics.

6. Patients should be monitored for fluid absorption, especially during prolonged procedures.

7. Hysteroscopic insufflation with air or CO₂ is not recommended during use of the Ho:YAG laser system during laser endometrial ablation. Visualization may be achieved via hysteroscopic distension of the uterus with saline or Ringers solution.

8. When fluid is being used for distension, monitor patient for electrolyte balance.

9. During single eyepiece endoscopic procedures, use caution since depth perception may be altered.

10. Remove the endoscope from the treatment area prior to lasing to avoid damage to the scope.

6.4 Complications / Risks

1. As is true of other forms of medical treatment, some of the potential complications that may be encountered in laser therapy are serious and could result in death. They include the following:
a. Non-laser related

- Perforation
- Aspiration
- Induced hemorrhage
- Allergic reaction to medication
- Hypertension
- Arrhythmia
- Pain
- Gas overdistension, pneumothorax
- Air embolism

b. Laser related

Acute

- Induced hemorrhage
- Ulceration
- Perforation
- Edema
- Pain
- Fever, leukocytosis
- Chills

Chronic

- Delay in healing
• Perforation
• Stricture
• Delayed hemorrhage
• Sepsis

2. **Pain:** Short-lived pain may occur immediately following laser therapy and may persist for as long as 48 hours.

3. **Fever and Leukocytosis:** Immediately after laser therapy, the patient may experience fever and leukocytosis, which are commonly associated with tissue destruction. These generally resolve without treatment. Cultures are indicated to exclude the possibility of infection.

4. **Bleeding:** Patients may experience bleeding at the site of the laser therapy or from erosion of a tumor during or after laser therapy. Post treatment hematocrit is recommended to identify this potential complication.

5. **Sepsis:** Laser-ablated tissue may become infected after therapy. If a question of sepsis exists, a culture should be taken and other appropriate evaluations made.

6. **Perforation:** Perforation can occur as a result of excessive exposure to laser radiation. Perforation can also occur from tumor erosion, or as a result of endoscopic procedures. To clinically diagnose perforation, patients must be monitored postoperatively through physical signs, hematocrit and radiography.

7. **Gas Overdistension, Pneumothorax:** Patients may experience gastrointestinal distension or pneumothorax during or after therapy.

### 6.5 Contraindications

• Invasive gynecological cancer
• Any medical condition which could contraindicate hysteroscopy, such as pelvic inflammatory disease
• Patients desiring future child bearing potential
• Obstructions due to extrinsic compression
7 Lithotripsy and Percutaneous Urinary Lithotripsy

For use with or without an endoscope with or without a working channel. Prior to use, physicians must be fully acquainted with lithotripsy and percutaneous lithotripsy procedures.

7.1 Indications

Incision, excision, resection, ablation, coagulation, hemostasis and vaporization, with or without an endoscope, in lithotripsy and percutaneous urinary lithotripsy, including fragmentation of:

- Urinary calculi
- Urethral calculi
- Kidney calculi
- Treatment of distal impacted fragment of steinstrasse when guide wires cannot be passed

7.2 Warnings

General

Refer to the safety section of the operation manual for general laser-safety precautions.
Specific

1. Holmium:YAG laser radiation (2.1 micrometers) will ablate biological tissues to depths different from the radiation of CO2 (10.6 micrometers), Argon (514.5 nanometers), or Nd:YAG (1.064 micrometers) lasers. Extreme caution should be used until the physician is completely familiar with the biological interactions of the laser energy with tissues of various types.

2. Tissue perforation can occur if excessive laser energy is applied, whether through the use of excessive laser-beam power or the application of power for excessive periods of time.

3. Use the laser only on tissues that are fully observable. Do not use the laser if the desired operating field is obscured.

4. Aim the laser only at tissues intended for treatment; otherwise, damage to surrounding tissues may result.

5. Screen abnormalities, such as tumors, that are in close proximity to known arteries or veins by pretreatment work-ups to precisely locate these circulatory structures.

6. Use low energy and low pulse-rate settings until fully familiar with the capabilities of the laser system. If higher energies are required, increase the energy in the smallest available increments until the desired level is achieved. Smaller diameter fibers will require less energy and larger diameter fibers will require higher energy to achieve the same laser fluence. These starting energy recommendations apply regardless of the particular surgical fiber optic energy delivery system configuration. Refer to the instructions for use supplied with each surgical fiber for specific maximum operating parameters.

7. "Flash" fire can occur. Do not operate the laser system in the presence of flammable anesthetics or volatile substances such as alcohol or elevated levels of oxygen. Under no circumstances should flammable gases be present when operating the laser.

8. The risks of combustion, perforation and laser-induced hemorrhage, all of which can cause death, must be fully explained to the patient.

9. As with conventional endoscopic treatment, adverse reactions such as fever, chills, sepsis, edema and hemorrhage may occur following laser treatment. In extreme cases, death may occur due to procedural complications, concurrent illness or the application of laser radiation.
7.3 Precautions

1. Use caution when treating patients who have had difficulty with previous endoscopic procedures.

2. Extra precautions should be taken when radiotherapy and laser therapy are to be used concurrently, including more stringent postoperative monitoring than usual. Clinical studies have shown that patients who have undergone radiotherapy present a greater risk of perforation or tissue erosion.

3. Discontinue laser therapy immediately if the patient develops any cardiopulmonary problems.

4. Trimedyne, Inc., has no clinical information or experience concerning the use of Ho:YAG laser systems on pregnant women or nursing mothers.

5. Patients who have experienced discomfort during previous laser treatment may require analgesics.

6. During single eyepiece endoscopic procedure, use caution since depth perception may be altered.

7. Remove the endoscope from the treatment area prior to lasing to avoid damage to the scope.

7.4 Complications / Risks

1. As is true of other forms of medical treatment, some of the potential complications that may be encountered in laser therapy are serious and could result in death. They include the following:

   a. Non-laser related

      • Perforation
      • Aspiration
      • Induced hemorrhage
      • Allergic reaction to medication
• Hypertension
• Arrhythmia
• Pain
• Gas overdistension, pneumothorax
• Air embolism

b. Laser related

Acute

• Induced hemorrhage
• Ulceration
• Perforation
• Edema
• Pain
• Fever, leukocytosis
• Chills

Chronic

• Delay in healing
• Perforation
• Stricture
• Delayed hemorrhage
• Sepsis
2. **Perforation, damage, or other injury to the ureter:** Perforation can occur as a result of excessive exposure to laser radiation. Perforation can also occur as a result of endoscopic procedures. To clinically diagnose perforation, patients must be monitored postoperatively through physical signs, hematocrit, and radiography.

3. **Urine leakage:** Patients may experience a significant amount of urine leakage. Insertion of a drain may be necessary.

4. **Bleeding:** Patients may experience bleeding at or near the site of laser therapy. Post treatment hematocrit is recommended to identify this potential complication.

5. **Pain:** Short-lived pain may occur immediately following laser therapy and may persist for as long as 48 hours.

6. **Infection:** There is a risk of infection (or worsening of infection if one is present at the time of surgery). The patient should be treated with the appropriate medications to combat the infection.

7. **Sepsis:** Laser-ablated tissue may become infected after therapy. If a question of sepsis exists, a culture should be taken and other appropriate evaluations made.

8. **Gas Overdistension, Pneumothorax:** Patients may experience gastrointestinal distension or pneumothorax during or after therapy.

9. **Loss of kidney:** Although this complication is very rare, it may occur as a result of the procedure or because of the stone itself.

### 7.5 Contraindications

- Active, untreated urinary infection
- Pregnancy
- Ureteral disorders which might prevent the spontaneous passage of fragments, such as strictures
- Obstruction of the desired operating field of view.
- Poor surgical candidates (e.g. intolerance to anesthetics, etc.)
8 Orthopedic Surgery

For use with or without an endoscope with or without a viewing channel. Prior to use, physicians must be fully acquainted with orthopedic procedures.

8.1 Indications

Incision, excision, resection, ablation, coagulation, hemostasis and vaporization, with or without an endoscope, of pathological soft and cartilaginous tissue in small and large joints, including:

- Knee meniscectomy
- Knee synovectomy
- Chondromalacia and tears
- Loose body debridement
- Lateral retinacular release
- Debridement of the degenerative knee
- Plica removal
- Ligament and tendon release
- Contouring and sculpting of articular surfaces
- Debridement of inflamed synovial tissue
- Capsulectomy in the knee
- Chondroplasty in the knee
- Chondromalacia ablation
8.2 Warnings

General

Refer to the safety section of the operation manual for general laser-safety precautions.

Specific

1. Holmium:YAG laser radiation (2.1 micrometers) will ablate biological tissues to depths different from the radiation of CO₂ (10.6 micrometers), Argon (514.5 nanometers), or Nd:YAG (1.064 micrometers) lasers. Extreme caution should be used until the physician is completely familiar with the biological interactions of the laser energy with tissues of various types.

2. Tissue perforation can occur if excessive laser energy is applied, whether through the use of excessive laser-beam power or the application of power for excessive periods of time.

3. Use the laser only on tissues that are fully observable. Do not use the laser if the desired operating field is obscured.

4. Aim the laser only at tissues intended for treatment; otherwise, damage to surrounding tissues may result.

5. Screen abnormalities, such as tumors, that are in close proximity to known arteries or veins by pretreatment work-ups to precisely locate these circulatory structures.

6. Use low energy and low pulse-rate settings until fully familiar with the capabilities of the laser system. If higher energies are required, increase the energy in the smallest available increments until the desired level is achieved. Smaller diameter fibers will require less energy and larger diameter fibers will require higher energy to achieve the same laser fluence. These starting energy recommendations apply regardless of the particular surgical fiber optic energy delivery system configuration. Refer to the instructions for use supplied with each surgical fiber for specific maximum operating parameters.

7. "Flash" fire can occur. Do not operate the laser system in the presence of flammable anesthetics or volatile substances such as alcohol or elevated levels of oxygen. Under no circumstances should flammable gases be present when operating the laser.
8. The risks of combustion, perforation and laser-induced hemorrhage, all of which could cause death, must be fully explained to the patient.

9. As with conventional endoscopic treatment, adverse reactions such as fever, chills, sepsis, edema and hemorrhage may occur following laser treatment. In extreme cases, death may occur due to procedural complications, concurrent illness or the application of laser radiation.

10. During surgical procedures, the use of a smoke evacuator or equivalent is recommended (as required) to minimize airborne particulates to avoid possible biohazard.

### 8.3 Precautions

1. Use caution when treating patients who have had difficulty with previous endoscopic procedures.

2. Extra precaution should be taken when radiotherapy and laser therapy are to be used concurrently, including more stringent postoperative monitoring than usual. Clinical studies have shown that patients who have undergone radiotherapy present a greater risk of perforation or tissue erosion.

3. Discontinue laser therapy immediately if the patient develops any cardiopulmonary problems.

4. Trimedyne, Inc., has no clinical information or experience concerning the use of Ho:YAG laser systems on pregnant women or nursing mothers.

5. Patients who have experienced discomfort during previous laser treatment may require analgesics.

6. During single eyepiece endoscopic procedures, use caution since depth perception may be altered.

7. Remove the endoscope from the treatment area prior to lasing to avoid damage to the scope.

8. When fluid is being used, monitor patient for electrolyte balance.

9. Fluid should be used as coaxial coolant for tips requiring coolant.
8.4 Complications / Risks

1. As is true of other forms of medical treatment, some of the complications that may be encountered in laser therapy are serious and could result in death. They include the following:

a. Non-laser related

- Perforation
- Aspiration
- Induced hemorrhage
- Allergic reaction to medication
- Hypertension
- Arrhythmia
- Pain
- Gas overdistension, pneumothorax
- Air embolism

b. Laser related

Acute

- Induced hemorrhage
- Ulceration
- Perforation
- Edema
- Pain
- Fever, leukocytosis
- Chills
Chronic

- Delay in healing
- Perforation
- Stricture
- Delayed hemorrhage
- Sepsis

2. **Pain:** Short-lived pain may occur immediately following laser therapy and may persist for as long as 48 hours.

3. **Fever and Leukocytosis:** Immediately after laser therapy, the patient may experience fever and leukocytosis, which are commonly associated with tissue destruction. These generally resolve without treatment. Cultures are indicated to exclude the possibility of infection.

4. **Bleeding:** Patients may experience bleeding at the site of the laser therapy. Post treatment hematocrit is recommended to identify this potential complication.

5. **Sepsis:** Laser-ablated tissue may become infected after therapy. If a question of sepsis exists, a culture should be taken and other appropriate evaluations made.

6. **Perforation:** Perforation can occur as a result of excessive exposure to laser radiation. Perforation can also occur from tumor erosion, or as a result of endoscopic procedures. To clinically diagnose perforation, patients must be monitored postoperatively through physical signs, hematocrit and radiography.

7. **Gas Overdistension, Pneumothorax:** Patients may experience gastrointestinal distension or pneumothorax during or after therapy.

### 8.5 Contraindications

- Patients who are not good surgical candidates (e.g. intolerance to anesthetics, etc.)
- Obstruction of the desired operating field of view.
9 Otorhinolaryngology (ENT) Surgery

For use with or without an endoscope with or without a working channel. Prior to use, physicians must be fully acquainted with otorhinolaryngology procedures.

9.1 Indications

Incision, excision, resection, ablation, coagulation, hemostasis and vaporization, with or without an endoscope, of soft, mucosal, cartilaginous and bony tissue in otorhinolaryngology surgery including:

- Endosinus surgery
- Functional endoscopic sinus surgery
- Turbinate procedures (e.g., turbinectomy)
- Dacryocystorhinostomy (DCR)
- Ethmoidectomy
- Polypectomy
- Maxillary antrostomy
- Frontal sinusotomy
- Sphenoidotomy
9.2 Warnings

General

Refer to the safety section of the operation manual for general laser-safety precautions.

Specific

1. Holmium:YAG laser radiation (2.1 micrometers) will ablate biological tissues to depths different from the radiation of CO₂ (10.6 micrometers), Argon (514.5 nanometers), or Nd:YAG (1.064 micrometers) lasers. Extreme caution should be used until the physician is completely familiar with the biological interactions of the laser energy with tissues of various types.

2. Tissue perforation can occur if excessive laser energy is applied, whether through the use of excessive laser-beam power or the application of power for excessive periods of time.

3. Use the laser only on tissues that are fully observable. Do not use the laser if the desired operating field is obscured.

4. Aim the laser only at tissues intended for treatment; otherwise, damage to surrounding tissues may result.

5. Screen abnormalities, such as tumors, that are in close proximity to known arteries or veins by pretreatment work-ups to precisely locate these circulatory structures.

6. Use low energy and low pulse-rate settings until fully familiar with the capabilities of the laser system. If higher energies are required, increase the energy in the smallest available increments until the desired level is achieved. Smaller diameter fibers will require less energy and larger diameter fibers will require higher energy to achieve the same laser fluence. These starting energy recommendations apply regardless of the particular surgical fiber optic energy delivery system configuration. Refer to the instructions for use supplied with each surgical fiber for specific maximum operating parameters.
7. "Flash" fire can occur. Do not operate the laser system in the presence of flammable anesthetics or volatile substances such as alcohol or elevated levels of oxygen. Under no circumstances should flammable gases be present when operating the laser.

8. The risks of combustion, perforation and laser-induced hemorrhage, all of which could cause death, must be fully explained to the patient.

11. As with conventional endoscopic treatment, adverse reactions such as fever, chills, sepsis, edema and hemorrhage may occur following laser treatment. In extreme cases, death may occur due to procedural complications, concurrent illness or the application of laser radiation.

12. During surgical procedures, the use of a smoke evacuator or equivalent is recommended (as required) to minimize airborne particulates to avoid possible biohazard.

9.3 Precautions

1. Use caution when treating patients who have had difficulty with previous endoscopic procedures.

2. Extra precautions should be taken when radiotherapy and laser therapy are to be used concurrently, including more stringent postoperative monitoring than usual. Clinical studies have shown that patients who have undergone radiotherapy present a greater risk of perforation or tissue erosion.

3. Discontinue laser therapy immediately if the patient develops any cardiopulmonary problems.

4. Trimedyne, Inc., has no clinical information or experience concerning the use of Ho:YAG laser systems on pregnant women or nursing mothers.

5. Patients who have experienced discomfort during previous laser treatment may require analgesics.

6. During single eyepiece endoscopic procedures, use caution since depth perception may be altered.

7. Remove the endoscope from the treatment area prior to lasing to avoid damage to the scope.
9.4 Complications / Risks

1. As is true of other forms of medical treatment, some of the complications that may be encountered in laser therapy are serious and could result in death. They include the following:

a. Non-laser related

- Perforation
- Aspiration
- Induced hemorrhage
- Allergic reaction to medication
- Hypertension
- Arrhythmia
- Pain
- Gas overdistension, pneumothorax
- Air embolism

b. Laser related

Acute

- Induced hemorrhage
- Ulceration
- Perforation
- Edema
- Pain
- Fever, leukocytosis
- Chills
**Chronic**

- Delay in healing
- Perforation
- Stricture
- Delayed hemorrhage
- Sepsis

2. **Pain:** Short-lived pain may occur immediately following laser therapy and may persist for as long as 48 hours.

3. **Fever and Leukocytosis:** Immediately after laser therapy, the patient may experience fever and leukocytosis, which are commonly associated with tissue destruction. These generally resolve without treatment. Cultures are indicated to exclude the possibility of infection.

4. **Bleeding:** Patients may experience bleeding at the site of the laser therapy or from erosion of a tumor during or after laser therapy. Post treatment hematocrit is recommended to identify this potential complication.

5. **Sepsis:** Laser-ablated tissue may become infected after therapy. If a question of sepsis exists, a culture should be taken and other appropriate evaluations made.

6. **Perforation:** Perforation can occur as a result of excessive exposure to laser radiation. Perforation can also occur from tumor erosion, or as a result of endoscopic or laparoscopic procedures. To clinically diagnose perforation, patients must be monitored postoperatively through physical signs, hematocrit and radiography.

7. **Gas Overdistension, Pneumothorax:** Patients may experience gastrointestinal distension or pneumothorax during or after therapy.

### 9.5 Contraindications

- Patients who are not good surgical candidates (e.g. intolerance to anesthetics, etc.)
- Obstruction of the desired operating field of view.
10 Percutaneous Cervical, Lumbar, and Thoracic Disc Decompression / Discectomy

For use with or without an endoscope with or without a working channel. Prior to use, physicians must be fully acquainted with discectomy procedures and fluoroscopic guidewire needle placement.

10.1 Indications

Users must be properly trained with this device and for these indications. Incision, excision, resection, ablation, coagulation, hemostasis and vaporization, with or without an endoscope, in the following:

- Percutaneous Lumbar Disc Decompression/Discectomy in soft, cartilaginous, and bony tissue, including:
  - Foraminoplasty

- Percutaneous Cervical Disc Decompression/Discectomy in soft tissue, in patients with:
  - Uncomplicated ruptured or herniated discs
  - Neck pain with radiation down the arm
  - Symptoms and signs of sensory loss, tingling, numbness, muscle weakness, and/or decreased deep tendon reflexes
  - MRI, CT, myelogram, or discogram findings of disc herniation consistent with patient signs and symptoms
  - Positive electromyography and/or nerve conduction studies
  - No improvement after 12 weeks of conservative therapy (i.e., physical therapy, traction, bed rest, exercises, and medication)
• Percutaneous Thoracic Disc Decompression/Discectomy in soft tissue, in patients with:
  - Uncomplicated ruptured or herniated discs
  - Thoracic and intercostal intractable pain
  - Paresthesias at levels appropriate to the herniated discs visualized on MRI and CT-myelography
  - MRI, CT, myelogram, or discogram findings of disc herniation consistent with patient signs and symptoms
  - No improvement after 12 weeks of conservative therapy (i.e., physical therapy, traction, bed rest, exercises, and medication)

10.2 Warnings

General

Refer to the safety section of the operation manual for general laser-safety precautions.

Specific

1. Holmium:YAG laser radiation (2.1 micrometers) will ablate biological tissues to depths different from the radiation of CO$_2$ (10.6 micrometers), Argon (514.5 nanometers), or Nd:YAG (1.064 micrometers) lasers. Extreme caution should be used until the physician is completely familiar with the biological interactions of the laser energy with tissues of various types.

2. Tissue perforation can occur if excessive laser energy is applied, whether through the use of excessive laser-beam power or the application of power for excessive periods of time.

3. **Use the laser only on tissues that are fully observable. Do not use the laser if the desired operating field is obscured.**

4. Aim the laser only at tissues intended for treatment; otherwise, damage to surrounding tissues may result.

5. Free-beam applications emit more backward and forward scatter resulting in a larger area of necrosis than in contact beam applications.
6. Screen abnormalities, such as tumors, that are in close proximity to known arteries or veins by pretreatment work-ups to precisely locate these circulatory structures.

7. Use low energy and low pulse-rate settings until fully familiar with the capabilities of the laser system. If higher energies are required, increase the energy in the smallest available increments until the desired level is achieved. Smaller diameter fibers will require less energy and larger diameter fibers will require higher energy to achieve the same laser fluence. Refer to the instructions for use supplied with each surgical fiber for specific maximum operating parameters.

8. "Flash" fire can occur. Do not operate the laser system in the presence of flammable anesthetics or volatile substances such as alcohol or elevated levels of oxygen. Under no circumstances should flammable gases be present when operating the laser.

9. The risks of combustion, perforation and laser-induced hemorrhage, all of which could cause death, must be fully explained to the patient.

10. As with conventional percutaneous disc decompression/discectomy, adverse reactions such as fever, chills, sepsis, edema and hemorrhage may occur following laser treatment. In extreme cases, death may occur due to procedural complications, concurrent illness or the application of laser radiation.

10.3 Precautions

1. Use caution when treating patients who have had difficulty with previous surgical procedures.

2. Extra precautions should be taken when radiotherapy and laser therapy are to be used concurrently, including more stringent postoperative monitoring than usual. Clinical studies have shown that patients who have undergone radiotherapy present a greater risk of perforation or tissue erosion.

3. Discontinue laser therapy immediately if the patient develops any cardiopulmonary problems.

4. Trimedyne, Inc., has no clinical information or experience concerning the use of Ho:YAG laser systems on pregnant women or nursing mothers.

5. Patients who have experienced discomfort during previous laser treatment may require analgesics.
6. During single eyepiece endoscopic procedures, use caution since depth perception may be altered.

7. Prior to lasing, ensure that the distal end of the laser delivery device is extended beyond the introducer and that the scope is retracted from the treatment area (i.e., is within the introducer) to avoid damage to the scope.

10.4 Complications / Risks

1. As is true of other forms of medical treatment, some of the complications that may be encountered in laser therapy are serious and could result in death. They include the following:

a. **Non-laser related**

- Perforation
- Aspiration
- Induced hemorrhage
- Allergic reaction to medication
- Hypertension
- Arrhythmia
- Pain
- Gas overdistension, pneumothorax
- Air embolism

b. **Laser related**

*Acute*

- Induced hemorrhage
• Ulceration
• Perforation
• Edema
• Pain
• Fever, leukocytosis
• Chills

**Chronic**

• Delay in healing
• Perforation
• Stricture
• Delayed hemorrhage
• Sepsis

2. **Pain:** Short-lived pain may occur immediately following laser therapy and may persist for as long as 48 hours.

3. **Fever and Leukocytosis:** Immediately after laser therapy, the patient may experience fever and leukocytosis, which are commonly associated with tissue destruction. These generally resolve without treatment. Cultures are indicated to exclude the possibility of infection.

4. **Bleeding:** Patients may experience bleeding at the site of the laser therapy or from erosion of a tumor during or after laser therapy. Post treatment hematocrit is recommended to identify this potential complication.

5. **Sepsis:** Laser-ablated tissue may become infected after therapy. If a question of sepsis exists, a culture should be taken and other appropriate evaluations made.

6. **Perforation:** Perforation can occur as a result of excessive exposure to laser radiation. Perforation can also occur from tumor erosion, or as a result of endoscopic procedures. To clinically diagnose perforation, patients must be monitored postoperatively through physical signs, hematocrit and radiography.
7. **Gas Overdistension, Pneumothorax:** Patients may experience gastrointestinal distension or pneumothorax during or after therapy.

### 10.5 Contraindications

#### General

- Patients who are not good surgical candidates (e.g. intolerance to anesthetics, etc.)
- Obstruction of the desired operating field of view.

#### Specific

Endoscopic or Percutaneous Cervical Disc Decompression/Discectomy is contraindicated in cases where the following are present:

- Acute or progressive degenerative spinal cord disease
- Neurological or vascular pathologies mimicking a herniated disc
- Advanced arthritis of the spinal joints
- Significant bony spurs that could block needle entry into the disc space
- Advanced spondylosis, myelopathy, or vascular pathologies
- Large herniations or sequestered discs

Endoscopic or Percutaneous Thoracic Disc Decompression/Discectomy is contraindicated in cases where the following are present:

- Signs of spinal cord compression
- Evidence of intrinsic spinal cord disease
- Vascular or other neurologic pathologies mimicking a herniated disc
- Advanced spondylosis with disc space narrowing or other spine deformities
- Significant bony spurs that could block needle entry into the disc space
- Large herniations or sequestered discs
10.6 **Recommended Laser Parameters for Endoscopic or Percutaneous Cervical or Thoracic Disc Decompression / Discectomy**

- Use pulse repetition rate of 10 Hertz.
- Apply energy for 5 seconds, with at least a 5 second "off" period between lasings.
- Holmium energy has a penetration depth of approximately 0.4 mm in tissue and is fully absorbed in 2 mm of aqueous fluid. Therefore, to prevent potential damage to adjoining neurostructures, maintain a distance of at least 2 mm of aqueous fluid between the emission point of the fiberoptic delivery device and nerve tissue.

### Energy Levels for Endoscopic and Percutaneous Cervical or Thoracic Disc Decompression/Discectomy

<table>
<thead>
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<th>Level</th>
<th>Stage</th>
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</tr>
<tr>
<td>Thoracic</td>
<td>Second of Two</td>
<td>5</td>
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</tr>
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