

FEB 28 2006

K 060033

Attachment IV

510(k) Summary

Submitter: Sciton, Inc.
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Contact Person: Jay M. Patel, VP of Regulatory Affairs
Date Prepared: January 4, 2006
Device Trade Name: Profile Multi-Platform System
Common Name: Laser/Light Powered Surgical Device (and Accessories)
Classification Name: Laser Surgical Instrument, 21 CFR 878.4810.
Legally Marketed Predicate Device: K023881: Profile 1064 Laser System and Accessories
K041879: Palomar Lux 1064 Nd:YAG Handpiece
K032459: Profile 1320 Laser System
K051434: CoolTouch NS-160 Nd:YAG Laser System
K043046 - CoolTouch CT3S Nd:YAG Laser System
K042000: Lovely II and Lovely III
K050738: FT Fiber Optic Delivery Systems
K040005: Profile 2000 and Profile 3000 Laser Systems
K051167: Revolix and RevOLix Jr.
K040005: Profile 2000 and Profile 3000 Laser Systems
K040270: OpusDent Family Dental Laser
K032460: Profile BBL System
K051268: Radiancy Acne System

Description of Profile Multi-Platform System
The Profile Multi-Platform System is a modular, multi-wavelength laser/light system. The system uses scanning and focusing optics to deliver a pattern of thermal energy to the treatment site. The system consists of control console which houses the power supply, cooling system, fiber optic delivery system and/or articulated arm delivery system with handpiece and/or scanner.

Intended Use: *1064 nm Indications for Use:*
The Profile Multi-Platform Systems and Accessories are intended for use in the medical specialties of general and plastic surgery, dermatology, endoscopic/laposcopic general surgery, gastroenterology, gynecology, otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, pulmonary/thoracic surgery and urology for surgical and aesthetic applications.
Dermatology:
Coagulation and hemostasis of benign vascular lesions such as, but not limited to port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lake, leg veins and spider veins. The lasers are also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), café au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue/black tattoos) and plaques. Additionally, the lasers are indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser/light treatments.

Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

Removal of unwanted hair, for the stable long term, or permanent hair reduction through selective targeting of melanin in hair follicles, and for the treatment for pseudofolliculitis barbae (PFB). The Profile 1064 Laser Systems and Accessories are indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin.

The Profile 1064 Laser Systems and Accessories are indicated for the treatment of facial wrinkles.

The intended use of the contact cooling system in the Profile handpiece is to provide cooling of the skin prior to, during and after laser treatment, for the epidermal protection and reduction of pain during laser treatment, to allow for the use of higher fluences for laser treatments such as hair removal and vascular lesions, and to reduce the potential side effects of laser treatments.

Surgical Applications:

Incision/excision and cutting, ablation, coagulation/hemostasis of soft tissue in the performance of surgical applications in endoscopy/laparoscopy, gastroenterology, general surgery, head and neck/otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, plastic surgery, pulmonary/thoracic surgery, gynecology (e.g. menorrhagia) and urology.

1320 nm Indications for Use:

The Profile Multi-Platform Systems and Accessories are intended for use in general surgery and dermatology for the incision, excision, ablation, vaporization, coagulation and hemostasis of soft tissue. It is indicated for the treatment of fine lines and wrinkles. It is also indicated for the treatment of back acne, atrophic acne scars and mild to moderate inflammatory acne vulgaris.

Profile Multi-Platform System with fiber delivery is indicated for the treatment of reflux of saphenous veins associated with varicose veins and varicosities.

Profile 2000 nm Indications for Use:

The Profile Multi-Platform Systems and Accessories are indicated for incision, excision, resection, ablation, vaporization, coagulation and hemostasis, with or without an endoscope, in contact and non-contact with tissue, with or without a hand piece, in the following indications:

Dermatology and Plastic Surgery

Dermatologic and Plastic Surgery of soft, mucosal, fatty and cartilaginous tissue, in therapeutic plastic, therapeutic dermatological and aesthetic surgical procedures, including: scars, tattoo removal, vascular lesions (including port wine stains, hemangioma, telangiectasias [facial, leg] and 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.

Gastroenterological/Gastrointestinal Surgery

Open and endoscopic gastroenterologic surgery of soft tissue (for incision, excision, resection, ablation, vaporization, coagulation and hemostasis) 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, and telangiectasias of the Osler-Weber-Rendu disease.

General Surgery

General surgery of soft tissues, including: skin incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors and lesions, and tissue ablations; removal of benign and malignant lesions; mastectomy, hepatectomy, pancreatectomy, splenectomy, thyroidectomy, parathyroidectomy, herniorrhaphy, tonsillectomy, lymphadenectomy, partial nephrectomy, pilonidal cystectomy, resection of lipoma, pelvic adhesiolysis, debridement of decubitus ulcer, hemorrhoids, pilonidal cyst removal and repair, debridement of stasis ulcer, biopsy, appendectomy, pylorostenotomy, removal of polyps of the sigmoid colon, lysis of adhesions, cholecystectomy. Genitourinary

Surgery/Urology

Genitourinary surgery of soft tissue, including: treatment of bladder, urethral and ureteral tumors; superficial urinary bladder tumors; invasive bladder carcinomas; urethral and penile hemangioma; urethral strictures; lesions of the external genitalia; condylomas; bladder neck obstructions.

Endoscopic transurethral incision of prostate, ablation of benign prostatic hypertrophy, transurethral incision of prostate, laser resection of the prostate, laser enucleation of the prostate, laser ablation of the prostate, bladder neck incision of the prostate, laser ablation, enucleation and resection of prostate, hemostasis, vaporization and excision for treatment of benign prostatic hypertrophy.

Gynecological Surgery

Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue, including condyloma acuminata, intra-uterine treatment of submucous fibroids, benign endometrial polyps and uterine septum by incision, excision, ablation and or vessel coagulation, soft tissue excision procedures such as excisional conization of the cervix.

Lithotripsy and Percutaneous Urinary Lithotripsy

Lithotripsy and percutaneous urinary lithotripsy, including: fragmentation of urinary calculi, fragmentation of calculi in the ureter and ureteropelvic junction, fragmentation of kidney calculi, fragmentation of urethral calculi and treatment of distal impacted fragments of steinstrasse when guide wires cannot be passed.

Lumbar Discectomy

Lumbar discectomy in soft, cartilaginous and bony tissue, including: vaporization of the L4-5 and L5-S1 lumbar discs of the vertebral spine; open, percutaneous and endoscopic spine procedures; foraminotomy.

Orthopedic Surgery and Arthroscopy

Orthopedic surgery in soft and cartilaginous tissue in small and large joints, including: knee meniscectomy, knee synovectomy, chondromalacia and tears, loose body debridement, lateral retinacular release, plica removal, ligament and tendon release, contouring and sculpting of articular surfaces, debridement of inflamed synovial tissue, loose body debridement, capsulectomy in the knee, chondroplasty in the knee, chondromalacia ablation, ablation of soft and cartilaginous tissue in minimal invasive spinal surgery including percutaneous laser disc decompression/ discectomy, foraminoplasty, ablation and coagulation of soft vascular and non-vascular tissue in minimally invasive spinal surgery.

Otorhinolaryngological (ENT) Surgery

Otorhinolaryngological (ENT) surgery in soft, mucosal, cartilaginous and bony tissue, including: endosinus surgery, functional endoscopic sinus surgery, turbinate procedures (e.g. turbinoplasty, turbinectomy), dacryocystorhinostomy (DCR), ethmoidectomy, polypectomy, maxillary antrotomy, frontal sinusotomy, sphenoidotomy, hereditary hemorrhagic telangiectasia, septoplasty, lesions or tumors of the oral, nasal, glossal, pharyngeal and laryngeal, tonsillectomy, adenoidectomy.

Thoracic and Pulmonary Surgery

Open and endoscopic thoracic and pulmonary surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue, including laryngeal lesions, airway obstructions including carcinoma, polyps and granulomas, palliation of obstructing carcinomas of the tracheobronchial tree.

2940 nm Indications for Use:

The Profile Multi-Platform Systems and Accessories are designed for use in surgical applications requiring the excision, incision, ablation, vaporization, and coagulation of soft tissue, and for skin resurfacing. Soft tissue includes skin, subcutaneous tissue, striated and smooth tissue, muscle, cartilage, cartilage meniscus, calculi or fragments, mucous membrane, lymph vessels and nodes, organs and glands. Surgical specialties and applications include general surgery, plastic surgery, aesthetic surgery, dermatology, urology, gynecology, genitourinary, ENT, pulmonary surgery, thoracic surgery, podiatry, oral & maxillofacial surgery, ophthalmology (including oculoplasty), small and large joint arthroscopy, microdissectomies, and endoscopic procedures.

Aesthetic Surgery

Skin resurfacing and treatment of wrinkles.

Dental Application of Er:YAG

It is indicated for a variety of hard tissue (tooth and bone) applications, and for the incision, excision, cutting, ablation, vaporization, and coagulation of soft tissue in oral and maxillofacial surgery and dentistry.

Hard Tissue Indications of Er:YAG Laser Energy: Caries removal, cavity preparation, enamel etching, enameloplasty, excavation of pits and fissures for placement of sealant.

Bone Indications of Er:YAG Laser Energy: Contact and non-contact cutting, shaving, contouring, and resection of oral osseous tissue, apicoectomy, osseous crown lengthening, cutting bone to prepare a window access to the apex of the root, osseoplasty, osteotomy.

Soft Tissue and Periodontal Indications of Er:YAG Laser Energy: Excisional and incisional biopsies, exposure of unerupted teeth, incision and drainage of abscesses, gingival incision and excision, gingivoplasties, gingivectomies, gingivectomy in case of hyperplasias of the gingival or excision of hyperplasias, gingival troughing for crown impressions, hemostasis, implant recovery, frenectomies and frenotomies, fibromatosis, benign and malignant lesion removal, operculectomy, oral papillectomies, reduction of gingival hypertrophy, soft tissue crown lengthening, preprosthetic surgery (flabby alveolar ridge, vestibuloplasty, exposure of implants, hyperplasia, epulides, papilomas, fibromatoses, benign growths), vestibuloplasty, sicular debridement.

Endodontal Applications of Er:YAG Laser Energy: Tooth preparation to obtain access to root canal, pulpotomy, pulpotomy as an adjunct to root canal therapy, pulp extirpation, root canal debridement and cleaning, root canal preparation including enlargement.

Dermatology & Plastic Surgery

Indications include, epidermal nevi, telangiectasia, spider veins, actinic cheilitis, keloids, verrucae, skin tags, anal tags, keratoses, scar revision, debulking benign tumors, decubitus ulcers. It is also used for laser assisted site preparation for hair transplantation.

Gastroenterology

Gastroenterologic surgery of soft 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, and telangiectasias of the Osler-Weber-Rendu disease.

General Surgery

The Er:YAG is intended for the surgical incision/excision, vaporization and coagulation of soft tissue during any general surgery application where skin incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors, tissue ablation and/or vessel coagulation.

Genitourinary/Urology

Genitourinary surgery of soft tissue, including: treatment of bladder, urethral and ureteral tumors; superficial urinary bladder tumors; invasive bladder carcinomas; urethral and penile hemangioma; urethral strictures; lesions of the external genitalia; condylomas; bladder neck obstructions.

Endoscopic transurethral incision of prostate, bladder neck incision of the prostate, laser ablation, enucleation and resection of prostate, hemostasis, vaporization and excision for treatment of benign prostatic hypertrophy.

Gynecology

Indications include cervical intraepithelial neoplasia (CIN), herpes simplex, endometrial adhesions, cysts and condyloma.

Ophthalmology

Indications include soft tissue surrounding the eye and orbit and anterior capsulotomy.

Oral/Maxillofacial

Indications include oral/dental procedures for incision, excision, ablation, vaporization and hemostasis of soft tissue during gingivoplasties, gingivectomies, frenectomies, benign and malignant lesion removal, biopsies, leukoplakia and fibrotomy.

Otorhinolaryngological (ENT) Surgery

Otorhinolaryngological (ENT) surgery in soft, mucosal, cartilaginous and bony tissue, including: endosinus surgery, functional endoscopic sinus surgery, turbinate procedures (e.g. turbinoplasty, turbinectomy), dacryocystorhinostomy (DCR), ethmoidectomy, polypectomy, maxillary antrotomy, frontal sinusotomy, sphenoidotomy, hereditary hemorrhagic telangiectasia, septoplasty.

Podiatry

Indications include warts, plantar verrucae, large mosaic verrucae and matrixectomy.

Pulmonary Surgery

Open and endoscopic pulmonary surgery.

Thoracic Surgery

Intended for the surgical incision/excision, vaporization and coagulation of soft tissue during any thoracic surgery.

Pulsed Light (300-1400 nm) Indications for Use:

The Profile Multi-Platform Systems and Accessories are indicated for use in surgical, aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery and dermatology.

It is intended for use for:

- The treatment of tattoos;
(560nm LP filter, 590nm LP filter)
- The treatment of benign pigmented lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles);
(515nm LP filter, 560nm LP filter)
- The treatment of cutaneous lesions including warts, scars and striae;
(515nm LP filter, 560nm LP filter)
- The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations;
(560nm LP filter, 590nm LP filter)
- Treatment of psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis;
(350nm BP filter)
- The removal of unwanted hair from all skin types, and to effect stable long-term, or permanent, hair reduction; and
(590nm LP filter, 640nm LP filter, 695 LP filter)
- Mild to moderate inflammatory and pustular inflammatory acne vulgaris.
(420nm BP filter, 515nm LP filter, 560 LP filter)

The integral thermo-electric cooler is indicated for use in cooling the epidermis at the treatment site prior to, during and after light or laser treatment in general surgery, plastic surgery and dermatology to:

- Reduce pain during and/or associated with light or laser treatment (via partial anesthesia from cooling);
- Reduce discomfort during and/or associated with light or laser treatment;
- Minimize thermal injury, including thermal necrosis, to non-target skin and skin structures during and/or associated with light or laser treatment, thus reducing possible complications such as scabbing, scarring, hyper- and/or hypopigmentation;
- Allow the use of higher light or laser fluences for light or laser treatments (such as for hair removal and the treatment of vascular or pigmented lesions); and
- Reduce potential side effects of light or laser treatments (such as for hair removal and the treatment of vascular or pigmented lesions).

Technological Characteristics

The Profile Multi-Platform System shares the same indications for use, similar design features (including wavelength, laser/light medium and delivery systems, power supply, cooling and control system), functional features (including power output, repetition rate, energy, spot size and fluence), and is therefore substantially equivalent to the above legally marketed predicate devices.

Safety and

The indications for use are based upon the indications for use for predicate systems.

Effectiveness	Technologically, the Profile Multi-Platform System is substantially equivalent to the listed predicate devices. Therefore, the risks and benefits for the Profile Multi-Platform System are comparable to the predicate devices.
Conclusion	The Profile Multi-Platform System shares similar indications for use, design features, and similar functional features as, and therefore is substantially equivalent to, the currently marketed predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 28 2006

Sciton, Inc.
c/o Mr. Jay M. Patel
Vice President of Regulatory Affairs
925 Commercial Street
Palo Alto, California 94303

Re: K060033

Trade/Device Name: Profile Multi-Platform System

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Regulatory Class: II

Product Code: GEX

Dated: January 4, 2006

Received: January 10, 2006

Dear Mr. Patel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Patel

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "M. Melkerson". The signature is written in a cursive style and is positioned to the left of the typed name.

Mark N. Melkerson, M.S.
Acting Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment III

Statement of Indications for Use

510(k) Number (if known): K 060033

Device Name: Profile Multi-Platform System

Indications for Use:

1064 nm Indications for Use:

The Profile Multi-Platform Systems and Accessories are intended for use in the medical specialties of general and plastic surgery, dermatology, endoscopic/laposcopic general surgery, gastroenterology, gynecology, otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, pulmonary/thoracic surgery and urology for surgical and aesthetic applications.

Dermatology:

Coagulation and hemostasis of benign vascular lesions such as, but not limited to port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lake, leg veins and spider veins. The lasers are also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), café au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue/black tattoos) and plaques. Additionally, the lasers are indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser/light treatments.

Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

Removal of unwanted hair, for the stable long term, or permanent hair reduction through selective targeting of melanin in hair follicles, and for the treatment for pseudofolliculitis barbae (PFB). The Profile 1064 Laser Systems and Accessories are indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin.

The Profile 1064 Laser Systems and Accessories are indicated for the treatment of facial wrinkles.

The intended use of the contact cooling system in the Profile handpiece is to provide cooling of the skin prior to, during and after laser treatment, for the epidermal

Prescription Use OR Over-The-Counter Use
(Per 21CFR801)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

El Mall
(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

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510(k) Number K060033

protection and reduction of pain during laser treatment, to allow for the use of higher fluences for laser treatments such as hair removal and vascular lesions, and to reduce the potential side effects of laser treatments.

Surgical Applications:

Incision/excision and cutting, ablation, coagulation/hemostasis of soft tissue in the performance of surgical applications in endoscopy/laparoscopy, gastroenterology, general surgery, head and neck/otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, plastic surgery, pulmonary/thoracic surgery, gynecology (e.g. menorrhagia) and urology.

1320 nm Indications for Use:

The Profile Multi-Platform Systems and Accessories are intended for use in general surgery and dermatology for the incision, excision, ablation, vaporization, coagulation and hemostasis of soft tissue. It is indicated for the treatment of fine lines and wrinkles. It is also indicated for the treatment of back acne, atrophic acne scars and mild to moderate inflammatory acne vulgaris.

Profile Multi-Platform System with fiber delivery is indicated for the treatment of reflux of saphenous veins associated with varicose veins and varicosities.

Profile 2000 nm Indications for Use:

The Profile Multi-Platform Systems and Accessories are indicated for incision, excision, resection, ablation, vaporization, coagulation and hemostasis, with or without an endoscope, in contact and non-contact with tissue, with or without a hand piece, in the following indications:

Dermatology and Plastic Surgery

Dermatologic and Plastic Surgery of soft, mucosal, fatty and cartilaginous tissue, in therapeutic plastic, therapeutic dermatological and aesthetic surgical procedures, including: scars, tattoo removal, vascular lesions (including port wine stains, hemangioma, telangiectasias [facial, leg] and 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.

Gastroenterological/Gastrointestinal Surgery

Open and endoscopic gastroenterologic surgery of soft tissue (for incision, excision, resection, ablation, vaporization, coagulation and hemostasis) 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, and telangiectasias of the Osler-Weber-Rendu disease.

General Surgery

General surgery of soft tissues, including: skin incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors and lesions, and tissue ablations; removal of benign and malignant lesions; mastectomy, hepatectomy, pancreatectomy, splenectomy, thyroidectomy, parathyroidectomy, herniorrhaphy, tonsillectomy, lymphadenectomy, partial nephrectomy, pilonidal cystectomy, resection of lipoma, pelvic adhesiolysis, debridement of decubitus ulcer, hemorrhoids, pilonidal cyst removal and repair, debridement of stasis ulcer, biopsy, appendectomy, pylorostenotomy, removal of polyps of the sigmoid colon, lysis of adhesions, cholecystectomy.

Genitourinary Surgery/Urology

Genitourinary surgery of soft tissue, including: treatment of bladder, urethral and ureteral tumors; superficial urinary bladder tumors; invasive bladder carcinomas; urethral and penile hemangioma; urethral strictures; lesions of the external genitalia; condylomas; bladder neck obstructions.

Endoscopic transurethral incision of prostate, ablation of benign prostatic hypertrophy, transurethral incision of prostate, laser resection of the prostate, laser enucleation of the prostate, laser ablation of the prostate, bladder neck incision of the prostate, laser ablation, enucleation and resection of prostate, hemostasis, vaporization and excision for treatment of benign prostatic hypertrophy.

Gynecological Surgery

Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue, including condyloma acuminata, intra-uterine treatment of submucous fibroids, benign endometrial polyps and uterine septum by incision, excision, ablation and or vessel coagulation, soft tissue excision procedures such as excisional conization of the cervix.

Lithotripsy and Percutaneous Urinary Lithotripsy

Lithotripsy and percutaneous urinary lithotripsy, including: fragmentation of urinary calculi, fragmentation of calculi in the ureter and ureteropelvic junction, fragmentation of kidney calculi, fragmentation of urethral calculi and treatment of distal impacted fragments of steinstrasse when guide wires cannot be passed.

Lumbar Discectomy

Lumbar discectomy in soft, cartilaginous and bony tissue, including: vaporization of the L4-5 and L5-S1 lumbar discs of the vertebral spine; open, percutaneous and endoscopic spine procedures; foraminotomy.

Orthopedic Surgery and Arthroscopy

Orthopedic surgery in soft and cartilaginous tissue in small and large joints, including: knee meniscectomy, knee synovectomy, chondromalacia and tears, loose body debridement, lateral retinacular release, plica removal, ligament and tendon release, contouring and sculpting of articular surfaces, debridement of inflamed synovial tissue, loose body debridement, capsulectomy in the knee, chondroplasty in the knee, chondromalacia ablation, ablation of soft and cartilaginous tissue in minimal invasive spinal surgery including percutaneous laser disc decompression/ discectomy, foraminoplasty, ablation and coagulation of soft vascular and non-vascular tissue in minimally invasive spinal surgery.

Otorhinolaryngological (ENT) Surgery

Otorhinolaryngological (ENT) surgery in soft, mucosal, cartilaginous and bony tissue, including: endosinus surgery, functional endoscopic sinus surgery, turbinate procedures (e.g. turbinoplasty, turbinectomy), dacryocystorhinostomy (DCR), ethmoidectomy, polypectomy, maxillary antrotomy, frontal sinusotomy, sphenoidotomy, hereditary hemorrhagic telangiectasia, septoplasty, lesions or tumors of the oral, nasal, glossal, pharyngeal and laryngeal, tonsillectomy, adenoidectomy.

Thoracic and Pulmonary Surgery

Open and endoscopic thoracic and pulmonary surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue, including laryngeal lesions, airway obstructions including carcinoma, polyps and granulomas, palliation of obstructing carcinomas of the tracheobronchial tree.

2940 nm Indications for Use:

The Profile Multi-Platform Systems and Accessories are designed for use in surgical applications requiring the excision, incision, ablation, vaporization, and coagulation of soft tissue, and for skin resurfacing. Soft tissue includes skin, subcutaneous tissue, striated and smooth tissue, muscle, cartilage, cartilage meniscus, calculi or fragments, mucous membrane, lymph vessels and nodes, organs and glands. Surgical specialties and applications include general surgery, plastic surgery, aesthetic surgery, dermatology, urology, gynecology, genitourinary, ENT, pulmonary surgery, thoracic surgery, podiatry, oral & maxillofacial surgery, ophthalmology (including oculoplasty), small and large joint arthroscopy, microdissectomies, and endoscopic procedures.

Aesthetic Surgery

Skin resurfacing and treatment of wrinkles.

Dental Application of Er:YAG

It is indicated for a variety of hard tissue (tooth and bone) applications, and for the incision, excision, cutting, ablation, vaporization, and coagulation of soft tissue in oral and maxillofacial surgery and dentistry.

Hard Tissue Indications of Er:YAG Laser Energy: Caries removal, cavity preparation, enamel etching, enameloplasty, excavation of pits and fissures for placement of sealant.

Bone Indications of Er:YAG Laser Energy: Contact and non-contact cutting, shaving, contouring, and resection of oral osseous tissue, apicoectomy, osseous crown lengthening, cutting bone to prepare a window access to the apex of the root, osseoplasty, osteotomy.

Soft Tissue and Periodontal Indications of Er:YAG Laser Energy: Excisional and incisional biopsies, exposure of unerupted teeth, incision and drainage of abscesses, gingival incision and excision, gingivoplasties, gingivectomies, gingivectomy in case of hyperplasias of the gingival or excision of hyperplasias, gingival troughing for crown impressions, hemostasis, implant recovery, frenectomies and frenotomies, fibromatosis, benign and malignant lesion removal, operculectomy, oral papillectomies, reduction of gingival hypertrophy, soft tissue crown lengthening, preprosthetic surgery (flabby alveolar ridge, vestibuloplasty, exposure of implants, hyperplasia, epulides, papilomas, fibromatoses, benign growths), vestibuloplasty, subular debridement.

Endodontal Applications of Er:YAG Laser Energy: Tooth preparation to obtain access to root canal, pulpotomy, pulpotomy as an adjunct to root canal therapy, pulp extirpation, root canal debridement and cleaning, root canal preparation including enlargement.

Dermatology & Plastic Surgery

Indications include, epidermal nevi, telangiectasia, spider veins, actinic cheilitis, keloids, verrucae, skin tags, anal tags, keratoses, scar revision, debulking benign tumors, decubitus ulcers. It is also used for laser assisted site preparation for hair transplantation.

Gastroenterology

Gastroenterologic surgery of soft 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, and telangiectasias of the Osler-Weber-Rendu disease.

General Surgery

The Er:YAG is intended for the surgical incision/excision, vaporization and coagulation of soft tissue during any general surgery application where skin incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors, tissue ablation and/or vessel coagulation.

Genitourinary/Urology

Genitourinary surgery of soft tissue, including: treatment of bladder, urethral and ureteral tumors; superficial urinary bladder tumors; invasive bladder carcinomas; urethral and penile hemangioma; urethral strictures; lesions of the external genitalia; condylomas; bladder neck obstructions.

Endoscopic transurethral incision of prostate, bladder neck incision of the prostate, laser ablation, enucleation and resection of prostate, hemostasis, vaporization and excision for treatment of benign prostatic hypertrophy.

Gynecology

Indications include cervical intraepithelial neoplasia (CIN), herpes simplex, endometrial adhesions, cysts and condyloma.

Ophthalmology

Indications include soft tissue surrounding the eye and orbit and anterior capsulotomy.

Oral/Maxillofacial

Indications include oral/dental procedures for incision, excision, ablation, vaporization and hemostasis of soft tissue during gingivoplasties, gingivectomies, frenectomies,

benign and malignant lesion removal, biopsies, leukoplakia and fibrotomy.

Otorhinolaryngological (ENT) Surgery

Otorhinolaryngological (ENT) surgery in soft, mucosal, cartilaginous and bony tissue, including: endosinus surgery, functional endoscopic sinus surgery, turbinate procedures (e.g. turbinoplasty, turbinectomy), dacryocystorhinostomy (DCR), ethmoidectomy, polypectomy, maxillary antrotomy, frontal sinusotomy, sphenoidotomy, hereditary hemorrhagic telangiectasia, septoplasty.

Podiatry

Indications include warts, plantar verrucae, large mosaic verrucae and matrixectomy.

Pulmonary Surgery

Open and endoscopic pulmonary surgery.

Thoracic Surgery

Intended for the surgical incision/excision, vaporization and coagulation of soft tissue during any thoracic surgery.

Pulsed Light (300-1400 nm) Indications for Use:

The Profile Multi-Platform Systems and Accessories are indicated for use in surgical, aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery and dermatology.

It is intended for use for:

- The treatment of tattoos;
(560nm LP filter, 590nm LP filter)
- The treatment of benign pigmented lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles);
(515nm LP filter, 560nm LP filter)
- The treatment of cutaneous lesions including warts, scars and striae;
(515nm LP filter, 560nm LP filter)
- The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations;
(560nm LP filter, 590nm LP filter)
- Treatment of psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis;
(350nm BP filter)
- The removal of unwanted hair from all skin types, and to effect stable long-term, or permanent, hair reduction; and
(590nm LP filter, 640nm LP filter, 695 LP filter)
- Mild to moderate inflammatory and pustular inflammatory acne vulgaris.
(420nm BP filter, 515nm LP filter, 560 LP filter)

The integral thermo-electric cooler is indicated for use in cooling the epidermis at the treatment site prior to, during and after light or laser treatment in general surgery, plastic surgery and dermatology to:

- Reduce pain during and/or associated with light or laser treatment (via partial anesthesia from cooling);
- Reduce discomfort during and/or associated with light or laser treatment;
- Minimize thermal injury, including thermal necrosis, to non-target skin and skin structures during and/or associated with light or laser treatment, thus reducing possible complications such as scabbing, scarring, hyper- and/or hypopigmentation;
- Allow the use of higher light or laser fluences for light or laser treatments (such as for hair removal and the treatment of vascular or pigmented lesions); and
- Reduce potential side effects of light or laser treatments (such as for hair removal and the treatment of vascular or pigmented lesions).