The versatile laser system to extend & develop your range of ENT procedures …

A precise, effective instrument for minimally invasive procedures with dedicated solutions in …

- Nasal Surgery
- Oro-pharynx
- Dacryocystorhinostomy (DCR)
- Vascular Lesions
- Otology
- Larynx
- Treatment of tumours
- Paediatric surgery
- Micro-Endoscopy
represents evolution, development and a new frontier in laser surgery

**EVOLVE™** is an innovative diode laser system with a compact design for an effective and safe use in ENT surgical procedures. Specifically designed for the various applications, the system by biolitec offers a wide range of possibilities for minimally invasive laser therapy in ENT, for both hospitals and practices. It will allow you to expand your range of applications based on your individual requirements.

**EVOLVE™ – Tissue Interaction**

The 980-nm wavelength is well absorbed by both water and haemoglobin. Compared to the Nd:YAG laser, the thermal penetration is less deep enabling safe and precise procedures close to delicate structures while protecting the surrounding tissue.

Compared to the CO2-laser, this special wavelength provides a significantly better haemostasis allowing a bloodless operating field, even in highly vascular areas such as nasal polyps and haemangioma.

The **EVOLVE™** system can accomplish a precise excision, incision and vaporisation of hyperplastic and tumorous tissue in contact or non-contact mode.

**Advantages of EVOLVE™**
- microsurgery precision
- tactile feedback from the laser fibre
- good haemostasis
- optimal visualisation of the operating field
- less postoperative nursing time

**EVOLVE™ in ENT-Diode laser system**

**Features:**

The **EVOLVE™** system from **biolitec** incorporates a range of user-friendly features:
- dedicated software for surgical and transcutaneous applications
- unique 220 µm core fibre enables use in micro-endoscopy and DCR (only 15 Watt system)
- mobile system trolley with drawer and integrated cable channel
- quick to set up and easy to use
- low running costs
- reliable diode technology with no routine maintenance required
- compact, portable and ideal for use in either a clinic or operating theatre
- operates from a standard electrical outlet
- attractive extended warranty options available

**Technical Specification**

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specification</th>
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<tr>
<td>Wavelength</td>
<td>980 nm</td>
</tr>
<tr>
<td>Optical Power</td>
<td>15 Watt, 25 Watt or 50 Watt at distal end of laser fibre (7.5 W using 220 µm laser fibre)</td>
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<td>Aiming Beam</td>
<td>635 nm, 4 mW</td>
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<tr>
<td>Operating Mode</td>
<td>cw-mode, pulse-mode, handpiece-mode</td>
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<tr>
<td>Pulse Duration / Interval</td>
<td>0.01 – 99.9 sec</td>
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<tr>
<td>Dimensions</td>
<td>18 cm x 22 cm x 37 cm (15 W and 25 W system)</td>
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<tr>
<td>Weight</td>
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Out-patient & Day case procedures

Nasal Surgery ...

Endoscopic surgery is well established as the current method of treatment for nasal & sinus conditions. Surgical interventions in this area can be challenging owing to the vascular nature of the mucosal tissue. This can result in a less than optimal surgical outcome owing to poor operating field of vision, prolonged nasal packing and thus increased overall costs for both clinician & patient.

Owing to the tissue interaction of the 980 nm wavelength of the EVOLVE™ system, the surrounding mucosal tissue is well preserved leading to rapid re-epithelisation of tissue and bone structures.

As a result of the good haemostatic effect, precise procedures are undertaken with a clear view of the operating area. Fine and flexible biolitec optical laser fibres allow easy access to all areas of the nose.

Advantages:
- microsurgery precision
- minimal post-operative swelling
- good haemostasis
- no nasal packing required
- clear view of operating field
- low side effects
- only local anesthesia required
- optimum preservation of surrounding mucosal tissue

Accessories:
- laser handpiece set with applicator in various shapes and lengths (autoclaveable)
- dual channel laser handpiece with integrated suction connector for smoke evacuation (autoclaveable)
- laser fibres with core diameters from 220 µm to 600 µm, compatible with the majority of endoscopic instrumentation

Applications:
- Turbinate reduction
- Papilloma
- Nasal & sinus polypectomy
- Cysts & Mucoceles
- Epistaxis & Morbus Osler
- Haemangioma, telangiectasia
- Stenosis & synechia
- Septum deformation
- Concha bullosa
- Sinus surgery

Oro-pharyngeal surgery . . .

One of the most common operations in the oro-pharynx is the reduction or resection of hyperplastic tonsillar tissue.

With the EVOLVE™ system this operation is becoming a bloodless and safe day case procedure, performed under local anesthesia.

The favourable 980 nm tissue interaction allows tumours or dysplasia to be treated with minimal bleeding and with good preservation of the surrounding tissue. As a result of bloodless treatment and the reduced oedema, the post-operative nursing requirements are minimal.

Advantages:
- bloodless and precise treatment
- reduced treatment discomfort
- local anesthesia
- lower rate of recurrences

Accessories:
- laser handpiece set with applicator in various shapes and lengths (autoclaveable)
- dual channel laser handpiece with integrated suction connector for smoke evacuation (autoclaveable)
- laser fibres with core diameters from 220 µm to 600 µm, compatible with the majority of endoscopic instrumentation

Applications:
- Velopharyngoplasty
- Uvulopalatoplasty (LAUP)
- Tonsillotomy, Tonsillectomy
- Glossectomy
- Diffuse buccal dysplasia
- Tumour vapourisation
Out-patient & Day case procedures

Dacryocystorhinostomy (DCR) ...

Watering eyes caused by blockage of the lacrimal duct is a relatively common condition, particularly amongst the elderly. The traditional method of treatment is an external, surgical removal of the stenosis. This is a lengthy procedure with considerable side effects such as postoperative bleeding and scarring.

biolitec has developed a patented DCR application set which turns the re-opening of the lacrimal duct into a safer and minimally invasive procedure. Thanks to the atraumatic introducer, the clinician is able to perform the surgery and the intubation set can be applied through the same device. The treatment can be performed under local anaesthetic and leaves no visible scar.

Advantages:
- atraumatic procedure
- limited complications and side-effects
- under local anesthesia
- no postoperative bleeding
- no infection
- no scars

Accessories:
DCR application set including:
- Lacrimal Intubation hand-piece (patented)
- Laser fibre (220 µm and 360 µm core)
- DCR hand-piece for endo-nasal approach

Vascular Lesions ...

Compared to alternative treatment methods, the laser application has proven to be significantly more effective with a superior aesthetic result.

With the EVOLVE™ 25-watt system, cosmetically undesirable vascular lesions such as telangiectasia and haemangioma can also be treated effectively, using the focusing handpiece for transcutaneous treatment in conjunction with a special handpiece mode of the laser.

Larger, cavernous haemangioma should be treated interstitially. Following the puncture with a thin needle, the laser fibre is introduced and the haemangioma is coagulated in a controlled fashion at low laser energy.

Advantages:
- Low-pain therapy, usually no anesthesia required
- Good aesthetic result, often after just a single treatment
- Low side effects

Accessories:
Focusing hand-piece with interchangeable spot size:
- Spot size: 0.6 / 1.0 / 1.5 mm
- Ergonomically designed grip for exact laser beam guidance
- High-quality optics for homogeneous energy distribution within the laser spot.
In-patient procedures

### Otology ...

The **EVOLVE™** system and its fine laser fibre (220 µm core) can be used with security and precision in the inner ear, close to delicate structures. Using this “contact” method, the possibility of laser energy inadvertently affecting other areas is virtually eliminated.

Laser energy is delivered in very short pulses with the laser fibre touching the target tissue. This results in a narrow zone of adjacent thermal coagulation thanks to the fact that the entire laser energy is absorbed at the tip of the fibre. **biolitec** is currently investing to expand and consolidate the clinical know-how in this important application field.

**Advantages:**
- good control of thermal penetration depth
- bloodless excision & vaporisation
- high precision (220 µm fibre)
- microendoscopic access to all anatomic structures

**Applications:**
- Myringotomy
- Cholesteatoma
- Surgery of the stapes
- Tumors of the inner ear

**Accessories:**
- special laser handpiece for otological procedures, autoclaveable
- laser fibres with core diameters from 220 µm to 600 µm, compatible with the majority of endoscopic instrumentation

### Larynx ...

In laryngeal applications, it is essential that scarring or tissue damage is avoided, as this can significantly affect phonetic function.

This is where the pulsed application mode of the **EVOLVE™** system is used. In this manner, the thermal penetration depth can be further reduced; tissue vaporisation and tissue resection can be performed exactly and in a controlled fashion even for very sensitive structures while optimally protecting the surrounding tissue.

**Advantages:**
- good control of thermal penetration depth
- bloodless excision & vaporisation
- tactile feedback

**Applications:**
- Removal of vocal cord polyps and granuloma
- Papilloma
- Cordectomy
- Vascular lesions & malformations
- Laryngeal carcinoma
- Arytenoidectomy
- Epiglottectomy
- Strictures
- Retention cysts, Laryngoceles

**Accessories:**
- laser handpiece set with applicator in various shapes and lengths (autoclaveable)
- dual channel laser handpiece with integrated suction connector for smoke evacuation (autoclaveable)
- laser fibres with core diameters from 220 µm to 600 µm, compatible with the majority of endoscopic instrumentation
In-patient procedures

Paediatric Surgery ...

In paediatric surgery, the clinician is faced with the challenge of working with fine and delicate structures.

The EVOLVE™ system offers distinct advantages as the use of a fine laser fibre, possibly in conjunction with a micro-endoscope, enables access, visibility and treatment with the finest precision. Using EVOLVE™, surgery for recurrent papilloma, a common disorder occurring in children, becomes bloodless and virtually painless. Furthermore, the post-surgery required follow up is reduced.

Advantages:
- microendoscopic access to all structures
- high precision
- good control of thermal penetration depth
- reduced discomfort

Accessories:
- laser handpiece set with applicator in various shapes and lengths (autoclaveable)
- dual channel laser handpiece with integrated suction connector for smoke evacuation (autoclaveable)
- laser fibres with core diameters from 220 µm to 600 µm, compatible with the majority of endoscopic instrumentation

Applications:
- Subglottic haemangioma
- Congenital & Acquired laryngeal stenosis
- Congenital mucous cysts
- Vocal cord synechia and nodules
- Laser eustachian tuboplasty using micro-endoscope

Microendoscopy ...

The biolitec EVOLVE™ ENT system is compatible with all available rigid and flexible endoscopes and micro-endoscopes. biolitec is the only current manufacturer of medical diode laser systems that can be used with the fine biolitec fibre (outer diameter only 275 µm) compatible with a working channel of a 1 mm outer diameter microendoscope. This enables the surgeon to explore new opportunities in areas of endoscopy that were previously not accessible and perform bloodless surgical procedures through the excision, incision & vaporisation of tissue.

Advantages:
- working channel of only 0.3 mm needed
- good hemostasis and clear view of the operating field
- high-precision surgery

Applications:
- Eustachian tube
- Saliva duct
- Tear duct
- Micro ear surgery
- Micro sinus surgery
**FOSCAN® Photodynamic Therapy (PDT) …**

… is a minimally invasive treatment that uses a photosensitising drug activated by exposure to light of a specific wavelength. Illumination of the target tumour site results in destruction of cells by a subsequent phototoxic reaction.

**FOSCAN®** represents an advance in photosensitiser technology and in the treatment of Head & Neck cancer. **FOSCAN®** is activated by the red light emitted by the 652 nm biolitec PDT laser and delivered by a flexible biolitec optical microlens fibre.

**FOSCAN®** is indicated for:

“Palliative treatment of patients with advanced head and neck squamous cell carcinoma failing prior therapies and unsuitable for radiotherapy, surgery or systemic chemotherapy.”

A multinational (US, Europe, India), multi-centre, open-label study of 128 patients with advanced, incurable H & N cancer was performed to assess objective tumour response, clinical benefit, survival and safety following treatment with **FOSCAN®-PDT**. **FOSCAN®** was shown to offer the following benefits:

- Effective tumour destruction
- Significant life improvement
- Survival observations
- Favourable benefit/risk profile
- Preservation of organ function

The **biolitec** group is the only organisation that supplies the complete package of products for an approved PDT indication. It is our objective to offer “one-stop shop” services for cancer treatment centres around the world that will include supply of drug, laser & consumables, clinician & nurse training and technical support & service.

- **FOSCAN® Mediated Photodynamic Therapy (PDT) in the Palliative Treatment of Patients with Advanced Head and Neck Cancer Incurable with Surgery or Radiotherapy.** Merrill Biel, Ear, Nose & Throat Speciality Care, Minneapolis, MN; Anil Cruz, Tata Memorial Hospital, Mumbai, India; Thomas McCaffrey, University of South Florida, Tampa, FL
- **FOSCAN®** is manufactured by biolitec pharma, a firm within the biolitec group.

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**Prescribing information**

**FOSCAN® (temoporfin)**

(please refer to the Summary of Product Characteristics before prescribing)

**Presentation:** Solution for Injection in vials containing 3.5 mL (14 mg temoporfin) or 5 mL (20 mg temoporfin).

**Indication:** Palliative treatment of patients with advanced head and neck squamous cell cancer failing prior therapies and unsuitable for radiotherapy, surgery or chemotherapy.

**Dosage and Administration:** **FOSCAN®** photodynamic therapy must only be administered in specialist oncology centres under the supervision of physicians experienced in photodynamic therapy. **FOSCAN®** is administered as a single slow intravenous injection. The dose is 0.15 mg/kg body weight. The treatment site is to be illuminated with light at 652 nm from an approved laser source 96 hours after the administration of **FOSCAN®**. Light must be delivered to the entire surface of the tumour using an approved microlens fibre optic. A second course of treatment may be given, with a recommended minimum interval of 4 weeks between treatments.

**Contraindications:** Porphyria or other diseases exacerbated by light; hypersensitivity to temoporfin or to any of the excipients; known allergies to porphyrins; tumours known to be eroding into a major blood vessel in or adjacent to the illumination site; planned surgical procedure within the next 30 days; coexisting ophthalmic disease likely to require slit-lamp examination within the next 30 days; existing therapy with a photosensitising agent.

**Warnings and Precautions:** Special care must be taken to prevent extravasation at the injection site. If extravasation occurs, protect the area from light for at least 3 months. Pulse oximeters must be repositioned at least every 10-15 minutes to avoid the risk of local skin burns. Unplanned or emergency surgical procedures where **FOSCAN®** has been administered within the previous 30 days must be undertaken only if absolutely necessary. All precautions must be taken to avoid direct illumination of the patient with surgical lamps during these procedures. All patients who receive **FOSCAN®** will become temporarily photosensitive. Precautions must be taken to avoid exposure of skin and eyes to direct sunlight or bright indoor light during the first 15 days after injection. Skin sensitivity reactions are caused by visible light; therefore ultraviolet sunscreens provide no protection. It is important that patients are re-introduced to normal light gradually.

**Interactions:** Potential for exacerbation of skin photosensitivity if **FOSCAN®** is used with other photosensitising drugs. Such a reaction has been reported with topical 5-fluorouracil.

**Adverse reactions:** Very common effects: pain, haemorrhage, pain in face, injection site pain, scab, mouth necrosis, dysphagia, face oedema, constipation. Common effects: vertigo, anaemia, oedema, trismus; localised infection, fever, mouth ulceration; nausea; blisters; erythema; difficulty in swallowing; injection site reaction; burning sensation; burn; hyperpigmentation; photosensitivity reaction; sunburn; skin necrosis; goddess.

**Pharmaceutical precautions:** **FOSCAN®** must not be mixed with other medicinal products. Do not dilute with aqueous solution.

Registered in the EU with the EMEA by: **Biolitec Pharma**, Edinburgh, UK. PL number: 3.5 mL: EU/1/01/197/002. Date of preparation: June 2002

Marketing authorisation: **Biolitec Pharma Ltd.** 5 3 Research Avenue South Heriot Watt University Research Park Edinburgh EH14 4AB Scotland www.biolitec.com

**FOSCAN®** is a registered trade mark of **Biolitec Pharma Ltd.**
Why biolitec …

biolitec is an established and leading manufacturer and supplier of diode lasers, optical fibres and accessories for application in a wide range of surgical specialties. The biolitec group includes the CeramOptec brand of medical lasers and fibres and it is also involved in the development and production of photosensitisers for use in photodynamic therapy (PDT). biolitec is unique in providing all core competencies for PDT Lasers, fibres and photosensitisers.

Training and After-Sales Support

biolitec products are sold around the world through our network of local sales offices or by exclusive distributors. We have a strong commitment to provide clinicians with training for the safe and successful use of our products either in the form of user workshops or one to one training at a biolitec reference centre.

Your local sales office or distributor is your first point of contact for after-sales support and service to enable you to get the maximum benefit and return on investment from EVOLVE™.

Your Biolitec AG point of contact

<table>
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All medical devices listed in this brochure are supplied in conformance with the Medical Devices Directive 93/42/EEC.

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