

PDT

PHOTODYNAMIC THERAPY

Targeted cancer treatment that clearly improves life quality of your patients



Effective and gentle treatment for oncological problems in

- Head & Neck
- Oncology
- Dermatology
- Pneumology
- Ophthalmology
- Gastroenterology
- Gynaecology
- Urology

▶ PDT in Oncology

biolitec AG is worldwide leading in Photodynamic Therapy (PDT) with all core competencies under a single roof. The minimally invasive and cost effective method offers a lot of advantages for the physician and the patient:

- Effective local tumour destruction
- Significant quality of life improvement
- Increased survival rate
- Favourable benefit/risk profile
- Absence of significant systemic side effects
- Preservation of organ function

Photodynamic therapy is a minimally invasive treatment that uses a photosensitising drug activated by exposure to light of a specific wavelength. Illumination of the tumour site results in targeted destruction of cells by a subsequent phototoxic reaction while limiting damage to surrounding health tissue.

Due to the wide spectrum of different lasers, LED lamps, PDT applicators and accessories the **biolitec** systems offer you a complete solution for main oncological problems in ENT (head & neck cancer), Dermatology (basalioma, skin tumours), Pneumology (lung cancer), Gastroenterology (Barrett's oesophagus), Ophthalmology (AMD), Urology (BPH, prostate cancer), Gynaecology (cervix cancer, dysplasia) and more.

▶ PDT Fibres

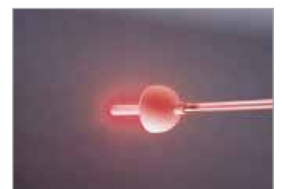
To guarantee an optimal illumination of the tumours at different application sites **biolitec** developed a wide range of different optical fibres. The Microlens diffuser is perfectly suitable for homogeneous light distribution during surface illumination, whereas the inflatable PDT – applicators and balloon diffusers are ideal for interstitial or intracavity use. Additionally the fibres contain integrated X-ray markers for radiological position control.

Surface illumination

- Microlens diffuser (frontal light distributor)
 - Optical fibre with small lens fixed at distal end
 - Clearly delineated circular spot
 - Uniform distribution of light
 - Ideal for surface illumination



Microlens diffuser for surface illumination

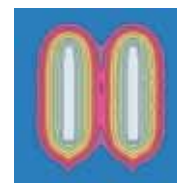


Cervix applicator for intracavity illumination

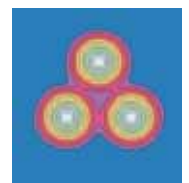
Interstitial illumination (solid tumours)

- Cylindrical diffuser (10-90mm active length)
- Bare fibrer
- Fiber application grids for precise positioning of catheter needles and homogeneous illumination

Light distribution of interstitial illumination



Side view with two fibres



Top view with three diffusers

Intracavity illumination (e.g. lung, oesophagus, cervix)

- Balloon diffuser (inflatable 20-40 mm active length)
- Cervix applicator

Further innovative and effective accessories:

- Applicator Sets
- Disposables
- Hand pieces

▶ PDT Lasers

For optimal treatments **biolitec** offers the latest diode technology for innovative and efficient PDT diode laser systems compatible for a wide range of photosensitizer. The maintenance free and portable laser systems contain adapted and versatile software features for different applications.

- 630, 633, 635, 652, 670, 689, 692, 732 nm
- Multiport systems with up to 6 ports
- Portable laser systems
- Internal calibration sphere enabling calibration of optical fibres and accurate dosing of the patient
- Maintenance free laser systems
- Fast set up and easy to use
- Operates from standard electrical socket
- Software language options for most European languages
- Hand & footswitch for control of laser energy
- Forced air cooling



Technical Specifications

Laser Type	GaAlAs Diode Laser
Wavelengths	630, 633, 635, 652, 670, 689, 692, 732 nm
Laser power	1-3 Watt (4 Watt on request)
Emmission modes	Time mode and Microlens mode
Length of treatment time	1 – 9999 seconds
Aiming beam	635 nm – 4 mW
Dimensions H x W x D	18 x 44 x 37 cm
Weight	16 kg
Power supply	220 V / 110 V, 50/60 Hz

▶ Multiport Laser

The treatment of big and voluminous cancers made it necessary to illuminate from different points to reach a consistent and sufficient light exposure. The **biolitec** multiport laser with up to 6 ports enables to simultaneously illuminate with several independently adjustable fibres or diffusers. This offers the possibility to treat complicated cancers faster and equally and therefore makes it a safe and easy procedure.

▶ Ceralas I AMD

For the treatment of wet age-related macular degeneration (wet AMD) **biolitec** developed a new generation of ophthalmic laser system. The PDT treatment in combination with the laser light in the visible red performs no heat and does not damage the healthy retina tissue surrounding the disease. Therefore patients can be treated earlier in the disease progression while preserving the maximum amount of vision.

The wide range of accessories enable clinicians to perform accurate treatments on the basis of therapeutic needs and makes it a versatile laser system.

Features of the laser system

- New generation AMD treatment software
- Wide range of contact glasses implemented (recallable from list)
- Spot sizes on retina 1-8 mm
- Navigation through the operation screen and setting of all parameters
- After setting spot size and contact lens magnification the laser spot is calculated automatically
- All parameters reflect actual values on the cornea
- Dye timer adjustable from 0s – 10000s
- Very easy set up and alignment of slit lamp adapters



AMD laser system



Special adapted software

Accessories for ophthalmology lasers

- Slit lamp adapters for a big variety of Haag Streit, Zeiss and similar type slitlamps
- Laser indirect ophthalmoscope (LIO)
- 20 Gauge endoprobes straight and curved
- 25 Gauge endoprobes straight and curved
- Cyclophotocoagulation-Probes



Slit lamp adapter

▶ LED Lamp (Light Emitting Diode)

Foscure is a specially developed light source unit for PDT in dermatology. The small and easy to handle LED units deliver the ideal intensity level for topical illuminations especially for large superficial lesions. The PDT therapy in dermatology showed high response rates with excellent healing of the treated site.

- Ideal for topical illumination of large superficial lesions
- Effective and safe treatment
- Small unit with self-explanatory handling
- Different wavelengths available (635, 652, 689 nm)
- Intensity levels up to 200mW/cm²
- Treatment area Ø 30mm
- Forced air cooling



Control unit



LED lamp

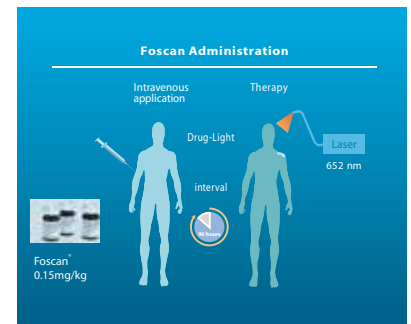
Foscan® in Photodynamic Therapy

Foscan® offers a novel treatment option using photodynamic therapy (PDT), and is an important tool in the management of advanced Head and Neck cancer. **Foscan®** is activated by the red light emitted by the 652nm **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."

Squamous cell carcinoma of the head and neck is an extremely aggressive disease and is associated with a poor prognosis. For patients with very advanced disease, who have already undergone treatment with surgery or radiotherapy, there is often no further treatment available.

The aims of treatment with **Foscan®-PDT** may include preservation of organ function, local tumour destruction, relief of symptoms and avoidance of disease-related complications.



Clinical studies have shown that Foscan®-PDT can offer significant improvements

Effective tumour destruction

- Complete tumour destruction was achieved in 50% of completely illuminated lesions irrespective of depth
- Complete tumour destruction was achieved in 68% of completely illuminated lesions

Preservation of organ function

- Functional and anatomical integrity were preserved allowing patients to eat, speak and to improve their social well-being

Survival improved in responders

- Survival rate at 1 year was observed to be twice as high in patients with complete tumour clearance compared with patients who did not achieve complete tumour clearance

Improvement in quality of life

- 57% of patients with completely illuminated lesions experienced symptom improvement

Favourable risk/benefit profile

- No systemic side effects were encountered other than photosensitivity, which is transient and manageable

Cost effective solution

- Foscan®-therapy is around 40 percent cheaper than standard therapies

Foscan® Solution for Injection

Presentation: Solution in vials containing 3.5ml (14mg temoporfin) or 5ml (20mg temoporfin), waterfree ethyl alcohol, propylene glykol.

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

Contraindications: Porphyrria 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 photosensitizing agent.

Adverse reactions: Pain (also during injection), haemorrhage, scar, ulceration or mouth necrosis, dysphagia, face oedema constipation, obstipation, anaemia, oedema, trismus, localised infection, fever, blisters, erythema, hyper pigmentation, photosensitivity reaction, sunburn, skin necrosis, giddiness.

Precautions: Single dose. Dispose remaining pharmaceutical. Ethical drug.

Date of preparation: Jan 2005

Registered in the EU with the EMEA by : biolitec pharma, Dublin, IRL

▶ 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 specialities. The **biolitec** group includes the CeramOptec brand of medical lasers and fibers and 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, fibers and photosensitisers.

▶ Training and After-Sales Support

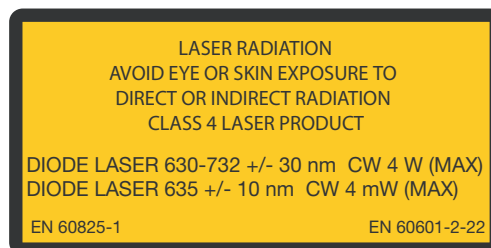
biolitec products are sold around the world through our network of local sales offices or by exclusive distributors. We have a strong commitment to provide clinician training in the safe and successful use of our products either in the form of user workshops or one to one training at a **biolitec** reference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

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 your laser system.

▶ Your biolitec point of contact

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