

RFITT Bipolar Radiofrequency Induced Thermotherapy.

**A minimally invasive procedure
for daily practice in ENT.**

CELON AG, A MEMBER OF THE OLYMPUS MEDICAL SYSTEMS GROUP, DEVELOPS AND MANUFACTURES INNOVATIVE PRODUCTS IN THE FIELD OF MINIMALLY INVASIVE MEDICINE. OUR AIM IS TO OPEN UP NEW OPPORTUNITIES FOR DOCTORS AND PATIENTS THROUGH APPLICATION OF INTELLIGENT TECHNOLOGY.

CELON'S BASIC INNOVATION, BIPOLAR RADIOFREQUENCY INDUCED THERMOTHERAPY (RFITT), COMPLEMENTS THE APPLICATION AREAS OF OLYMPUS ENDOSCOPES WITH SEVERAL NEW THERAPEUTIC ALTERNATIVES.



New challenges for ENT medicine

Changes in health care

Innovative methods of treatment offer enormous potential for the ENT specialist. He is able to widen the range of services he provides and, using modern and tissue-preserving forms of treatment, he is able to offer paying patients added comfort and quality.

Results of conventional operating procedures in the ENT area

Today, many operating procedures in the delicate head-neck area are still performed for the most part in the hospital environment. These procedures include treatment of hyperplasia of the tonsils and nasal concha and treatment of sleep-related breathing disorders (habitual snoring, obstructive sleep apnoea). These procedures often cause the patient considerable pain during and after the operation. They also seriously restrict the patient's quality of life in the days and weeks following treatment.

New approaches: innovative, minimally invasive outpatient treatment

Bipolar radiofrequency induced thermotherapy (RFITT), developed by Celon and patented worldwide, allows ENT specialists to perform a number of conventional clinical procedures in a minimally invasive manner and on an outpatient basis.

Extending the range of ENT services

From the financial standpoint, the Celon method represents an attractive private service provision, and, in view of its effectiveness, it promises to become quickly accepted by patients. The Celon method allows the ENT specialist to broaden the range of treatments offered by him and to provide a forward-looking and economically advantageous outpatient procedure. Against the background of the increasing demands made by patients for tissue-friendly forms of treatment involving the least possible pain, the Celon method offers an opportunity to gain entry into a growing market segment.

Innovative, patient-friendly, economic: the Celon method

Safe and user-friendly

The innovative Celon method is already used worldwide in many ENT practices and hospitals. It is an effective, safe and particularly user-friendly procedure which takes very little time and which the ENT specialist can perform after just a brief training period.

Many applications in the ENT sector

The Celon method has proven effective in the treatment of snoring, hyperplasia of the nasal concha and tonsils, and mild obstructive sleep apnoea, for example. As a minimally invasive outpatient procedure, it is not only particularly gentle on the patient but also highly efficient: a hospital stay is not generally required.

Used successfully in other specialist areas of medicine

In surgery, interventional radiology and urology, positive treatment results also underline the strengths of the Celon method. For example, it permits precise thermal destruction of liver tumours and metastases and offers highly effective and low-risk treatment of benign prostatic hyperplasia (BPH).

The principle behind the Celon method: bipolar thermotherapy

In bipolar radiofrequency induced thermotherapy (RFITT), the bipolar RFITT applicator is introduced into the tissue area to be treated. A neutral electrode does not have to be applied to the surface of the patient's skin. A radio-frequency current is generated between the two electrodes integrated in the applicator tip. Because of its electrical resistance, the tissue in the area of the applicator tip is gently heated and is coagulated in a precise manner. The size of the resulting lesion is determined by the

power applied. Automatic dosimetry control ensures an optimal, reproducible soft coagulation. The 3D impedance feedback control permanently monitors the status of the treatment. After completion of the treatment, the body gradually breaks down the coagulated, necrosed tissue, resulting in volume reduction, scarring and tightening of the treated tissue area.

CelonENT for use in the ENT sector

The CelonENT system has been specially developed for treatment in the delicate head-neck area. It consists of the intelligent power control unit CelonLab ENT and fine bipolar RFITT applicators, whose shape and handling are tailored to the application area in question. With the innovative CelonENT system, the ENT specialist is able, for the first time, to produce defined and reproducible sizes of lesions in the tissue.

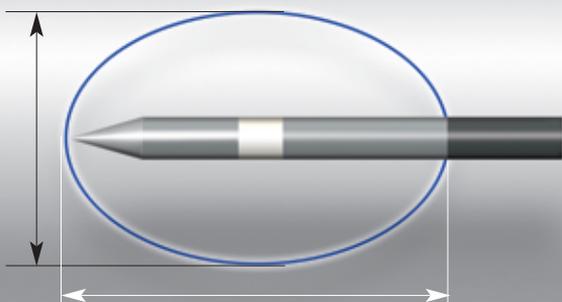
Rapid and tissue-preserving procedure

Outpatient treatment by the Celon method is distinguished by low level of pain exposure during and after the procedure, requires only local anaesthesia and generally takes only a few minutes. The Celon method is not only gentle on the patient, it is also efficient. The patient can immediately leave the treatment centre and return to work for example. No stay in hospital is needed.

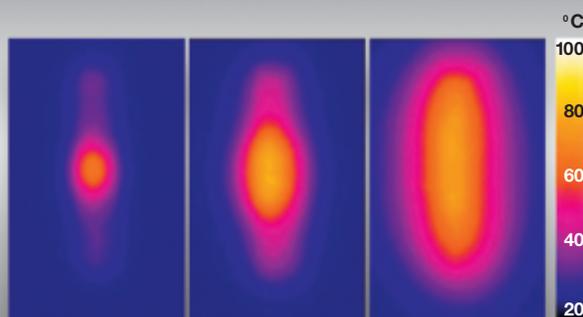
Advantages of the Celon method

The **bipolar** electrode configuration of the RFITT applicator enables the treatment area to be precisely defined, as the radiofrequency current flows exclusively between the two poles of the applicator tip.

Current around the tip of the bipolar RFITT applicator

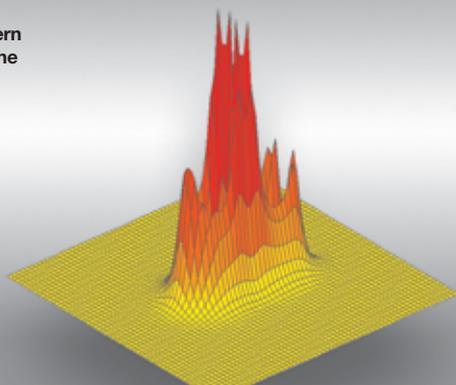


Thermographic image showing tissue heating



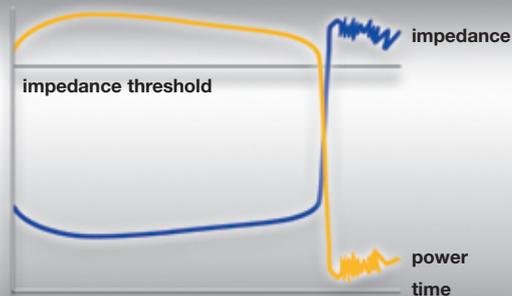
The precisely defined tissue area is heated to approx. 80° Celsius by the radiofrequency current and is therefore thermally denatured in a tissue-sparing and controlled way. This **soft coagulation** is generally achieved after just a few seconds.

Electric field pattern in the region of the applicator tip



The **3D impedance feedback** (3D impedance control) of CelonLab *ENT* controls the whole coagulation process and ensures controlled power output (automatic dosimetry control). An acoustic feedback signal informs the doctor of the treatment status at all times. As the degree of coagulation advances, the resistance in the tissue changes, and this resistance is measured directly at the bipolar RFITT applicator tip and is continuously recorded and evaluated by CelonLab *ENT* power control unit.

Representation of the auto-stop function on reaching of the required lesion size



When the defined impedance threshold is reached in the tissue, the coagulation is automatically ended (**auto-stop function**) and an acoustic feedback signal is emitted. The effects of excessive power application, such as carbonisation, are thereby avoided.

The Celon method: a tool for routine use in ENT practice

Occasional or habitual snoring

Habitual snoring is mostly caused by vibration of the relaxed soft palate muscle. In one or two treatment sessions, the ENT specialist uses the bipolar RFITT applicator to puncture the tissue at precise positions and in this way coagulates the excess submucosal tissue of the soft palate. The patient's body breaks down the necrosed tissue within a few weeks. The soft palate muscle contracts and scars in the treated area. This local scarring causes additional stiffening and tightening of the tissue. Result: it is possible to greatly reduce vibration of the soft palate, thereby largely eliminating the main cause of habitual snoring.

Hyperplasia of the nasal concha

To treat hyperplasia of the nasal concha, submucosal thermal necrosis is generated along the entire length of the concha within the tissue. In this way, the Celon method does not damage the ciliated epithelium and mucous membrane – important for preserving nasal function. Marked volume reduction of the nasal concha occurs seven to ten days after treatment. Result: it is possible to increase the pathway available for breathing, and thereby facilitate nasal respiration.

Nasal polyps

Depending on the indication, the ENT specialist can use the bipolar RFITT applicator to coagulate the vessels or tissue of nasal polyps. The polyp stem can be coagulated in order to cut the blood supply to the polyp. The polyp tissue can be vaporised with high power to reduce the volume of the polyp.

Hyperplasia of the tonsils

In patients with hyperplasia of the palatine tonsils, for example as a consequence of repeated tonsillitis, complete removal of the tonsils is not indicated in every case. The Celon method provides the ENT specialist with a tissue-friendly outpatient procedure which preserves the function of the palatine tonsils. Using the bipolar RFITT applicator, the lymphatic tissue within the tonsils is precisely coagulated. The treatment therefore involves minimal risk and minimal pain – important especially when treating children. Result: after the necrosed tissue heals, it is thereby possible to achieve a marked volume reduction of the tonsils.

Mild obstructive sleep apnoea (OSAS)

The Celon method is also used successfully in patients who, because of enlargement or slackening of the muscles of the pharynx and tongue, suffer from episodes of interrupted breathing combined with snoring symptoms. In these cases, the bipolar RFITT applicator is used to perform a combination treatment of the corresponding muscle areas of the root of the tongue and of the soft palate in order to achieve volume reduction. Treatment of the root of the tongue should only be performed with 24-hour inpatient monitoring.

Webbing and uvula

In patients with a large excess of mucous membrane, a condition called webbing, the Celon method can also be successfully used for minimally invasive resection, with little bleeding, of the tissue at the palatine arch and the enlarged uvula. In this way, the ENT specialist can, for example, effectively support the treatment of habitual snoring and optimise the treatment results.

Celon^{ENT}

Advantages of the Celon method

For the patient

- ▶ Outpatient treatment under local anaesthesia
- ▶ Short duration of treatment (only a few minutes per treatment)
- ▶ No current flow in the delicate head/neck area, because no neutral electrode is used
- ▶ Protection of the tissue areas not directly affected, e.g. the organ surfaces (mucosa, ciliated epithelium)
- ▶ Minimal pain during and after the procedure
- ▶ In general, no restriction on quality of life and daily routine in the days and weeks following treatment

For the ENT specialist

- ▶ Outpatient treatment completed in a short period of time
- ▶ Defined, reproducible results
- ▶ Repeatable procedures
- ▶ Useful addition to the range of treatments offered
- ▶ Possibility to individually address private patients and self-paying patients

Celon supports the ENT specialist with comprehensive **after-sales service**.

This includes, for example:

- ▶ Expert technical advice and initial training,
- ▶ Regular follow-up training events, at national and international level, on application technology, on accounting options and on patient marketing,
- ▶ Patient information sources referring patients to Celon user centres and physicians,
- ▶ Collaboration with national and international university hospitals, whose most recent findings are communicated directly to the ENT specialist.

OLYMPUS

Manufactured by
CELON AG MEDICAL INSTRUMENTS

Rheinstraße 8, 14513 Teltow, Germany

Distributed by
OLYMPUS WINTER & IBE GMBH
OLYMPUS EUROPA GMBH
OLYMPUS AMERICA INC.
KEYMED LTD
OLYMPUS SINGAPORE PTE LTD
OLYMPUS MOSCOW LIMITED LIABILITY COMPANY
OLYMPUS AUSTRALIA PTY. LTD
OLYMPUS LATIN AMERICA INC.
OLYMPUS (BEIJING) SALES & SERVICE, CO., LTD.
OLYMPUS MEDICAL SYSTEMS CORPORATION

Kuehnstraße 61, 22045 Hamburg, Germany
Wendenstraße 14-18, 20097 Hamburg, Germany
Two Corporate Center Drive, Melville, N.Y. 11747-3157, U.S.A.
KeyMed House, Stock Road, Southend-on-Sea, Essex SS2 5QH, United Kingdom
491B, River Valley Road #12-01/04, Valley Point Office Tower, Singapore 248373
117071, Moscow, Malaya Kaluzhskaya 19, bld. 1, fl.2, Russia
31 Gilby Road, Mount Waverley VIC 3149, Australia
6100 Blue Lagoon Drive, Suite 390 Miami, FL 33126-2087, U.S.A.
13F - 14F, East Tower, Gongyuan No. 6 Royal Palace, No. 6 Gonyuan Xijie, Jianguomennei, Dongcheng District, Beijing 100005, China
2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan

 **Celon AG**
medical instruments

A Member of the
Olympus Medical Systems Group