



PROCEDURE GUIDE

For Better Clinical Outcomes in CELON ENT Procedures



DISCLAIMER

The surgical technique herein is presented to demonstrate the method utilized by Dr. F. Yildiz. The information on the products and procedures contained in this brochure does not represent and does not constitute medical advice or recommendations and should not be relied upon as such.

This information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case. Each patient must be examined and advised individually, and this brochure does not replace the need for such examination and/or advice in whole or in part.

This brochure should not be considered as a substitute for carefully reading all applicable labeling, including the instructions for use (IFU) supplied with the devices. Before using any product, please thoroughly review the relevant user manual(s) for instructions, including, but not limited to, contraindications, warnings, precautions, and adverse effects. Please note: It is the clinicians' responsibility to decide which instrument mode and settings they use in each clinical situation.

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The CELON system is a procedure-oriented, safe, and efficient solution for ENT specialists. Thanks to the innovative and minimally invasive CELON method, a variety of indications can be gently treated.

In this guide, we will escort you through the different steps of the Celon ENT procedures.

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VOLUME REDUCTION OF HYPERTROPHIC TURBINATES

In the following chapter, it is demonstrated how to use bipolar radiofrequency-induced thermotherapy (RFITT) to reduce the volume of the hypertrophic inferior turbinates.

01 Anesthesia and Medications

- · The turbinates can be treated with RFITT using local anesthesia.
- · For topical anesthesia, cotton swabs soaked in a two to four percent lidocaine solution are recommended.
- · Place the swabs around the inferior turbinate for three to five minutes.
- To make sure your patient has no pain during the procedure, it is recommended to inject 2 to 3 ml of a two percent adrenalin-free lidocaine solution into the whole treatment area of the inferior nasal concha [Figure 01a/b].





Figure 01a

Figure 01h

- The injection of lidocaine also increases the volume of the turbinate during the treatment, which reduces the risk of damage to the mucous membrane.
- · Therefore, do not administer vasoconstrictive substances prior to the procedure, as these would cause a temporary reduction in the volume of the turbinate.

02 | Treatment of the Nasal Turbinates (with RFITT)

Power settings: A power setting of 15 watts (mode: FineRFITT or PureRFITT) is recommended. You can use a higher setting of up to 20 watts to treat smaller turbinates, for instance when you are treating children. The power setting on the control unit determines the extent of coagulation induction. The lower the power setting, the longer the application time and the greater the extent of coagulation. The higher the power setting, the smaller the area of coagulation.

- · Use the CelonProBreath applicator to treat the hypertrophic turbinate.
- · Insert the applicator into the anterior end of the inferior turbinate. In case of a bulky head of the turbinate, the first coagulation should be done in the upper part [Figure 02].

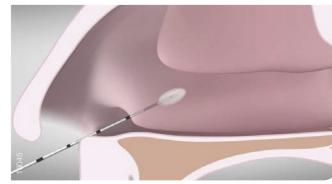


Figure 02

- · After positioning the applicator, activate the power supply by pressing the foot switch. You can monitor the status of coagulation via the acoustic signal. The power supply is reduced automatically to prevent overdose effects.
- · Now reposition the applicator by pulling it out slightly without removing it all the way [Figure 03a]. Insert it posteriorly beneath the mucous membrane [Figure 03b].

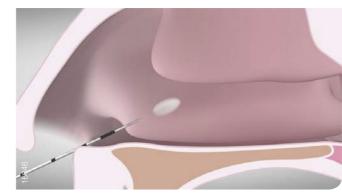
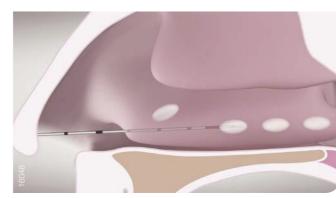




Figure 03a

Figure 03b

- · Place the electrode as closely as possible to midway between the bone and mucous membrane.
- Depending on the patients' anatomy, for example if they have a deviated septum, it may be necessary to use additional insertion points near the middle or the posterior end of the turbinate.
- To achieve coagulation along the entire length of turbinate, withdraw the needle repeatedly at around 1.5 cm and reactivate the power control unit [Figure 04 a/b]. You can use the 1 cm markings on the shaft of the applicator as a positioning gauge.



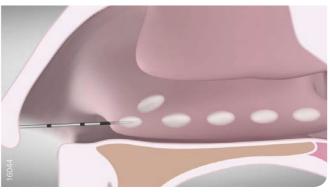


Figure 04a

Figure 04b

- \cdot Leaving healthy areas between the lesions will reduce the risk of crusting and improve healing.
- \cdot Repeat this procedure until the hypertrophic areas of the turbinates have been fully treated.

Note: If the mucous membrane turns white, interrupt the power output immediately by releasing the foot switch and reposition the applicator. This will avoid injuring the mucous membrane and prevent unnecessary crusting.

03 | Therapeutic Effect

- The coagulation achieves a local denaturation of the treated tissue area. Reduction sets in after a few days as a result of scarring and breakdown of the coagulated tissue.
- · After three weeks, you can expect a visible reduction in volume as a result of scarring and the body's resorption of the coagulated tissue [Figure 05].



Figure 05

04 | Postoperative Care

- · Your patients may experience temporary difficulties breathing through their nose until the swelling goes down.
- · It is recommended to use saline solution and mild nasal ointments postoperatively.
- · Nasal packing is usually not necessary, since there is normally no bleeding.
- · Schedule a follow-up visit with your patient the following day in order to check the results and to remove any fibrin formation, which might block the nose.
- · If your patient's breathing has not improved after three or four days, it might be necessary to have a second postoperative checkup and cleaning. However, additional CELON treatments of the turbinates are usually unnecessary.

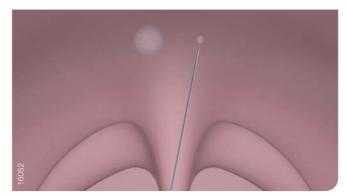
See also the CELON training video: www.olympus.eu/celon

TREATMENT OF HABITUAL SNORING – STIFFENING OF SOFT PALATE

Habitual snoring is frequently caused by vibrations in the soft palate, the uvula, or the tissue in the area of the palatine arches. It is recommended to properly diagnose a sleep-related breathing disorder before you start the procedure: If the patient has other conditions such as obstructive sleep apnea, additional treatments might be necessary. In the following chapter, it is demonstrated how to use bipolar radiofrequency-induced thermotherapy (RFITT) to treat habitual snoring caused by the soft palate.

01 | Anesthesia and Medications

- · The soft palate can be treated with RFITT using local anesthesia.
- · Apply a topical anesthetic like lidocaine gel or spray (ten percent) to the palate and uvula of your patient to counteract their gag reflex and reduce the pain of the injections.
- · For local anesthesia, the injection of 0.5 ml of a two percent lidocaine solution with adrenaline is recommended at two points paramedially below the border between the hard and soft palates [Figure 01a/b].



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Figure 01a

Figure 02a

Figure 01b

- These injections also enlarge the volume of the palatine tissue during the procedure and reduce the risk of damage to the mucous membrane.
- · After three to five minutes, additional four injections are necessary in the lower part of the soft palate (0.5 ml on each side) [Figure 02a/b].

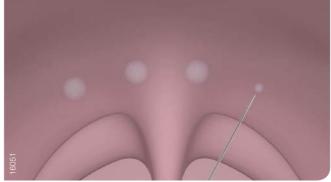






Figure 02b

02 | Treatment of the Soft Palate (with RFITT)

Power settings: A power setting of 12 watts (mode: PureRFITT) is recommended for treating the soft palate. The power setting on your control unit determines the extent of coagulation. The lower the power setting, the longer the application time and the greater the extent of coagulation. The higher the power setting, the smaller the area of the coagulation.

- · Use the CelonProSleep plus applicator to treat the soft palate.
- · Insert the tip of the applicator into the palatal muscle until the applicator's insulation tube touches the tissue [Figure 03a/b].

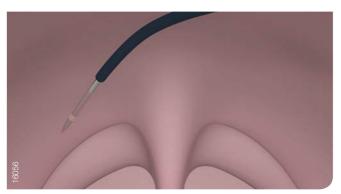




Figure 03a Figure 03b

- · After positioning the applicator, activate the power supply by pressing the foot switch. You can monitor the status of coagulation via the acoustic signal.
- · Make sure that the tip of the applicator is located as precisely as possible in the middle of the tissue (soft palate muscle). To avoid damage to the mucous membrane, do not place the coagulations too laterally or inferiorly. Furthermore, to prevent unnecessary swelling, do not insert the needle tip up into the uvula.
- The power supply is reduced automatically to prevent overdose effects. If your patient has a wide and very thick soft palate, you can increase the number of coagulations. One insertion with three coagulations on each side at regular intervals is recommended [Figure 04a/b].





Figure 04a Figure 04b

Note: • Should the mucous membrane becomes pale or white during the application, the power output must be stopped immediately. The applicator must be repositioned, as necrosis of the mucous membrane can occur otherwise, and, in the worst case, ulceration.

· In case of a very thin soft palate, a slightly higher power output setting may be helpful to create smaller lesions.

03 | Therapeutic Effect

The coagulation results in a local denaturation of the treated tissue area. Within approximately four weeks, you can expect a visible reduction in volume accompanied by a tightening of the palatine tissue as a result of the body's resorption process, and the formation of scar tissue [Figure 05].

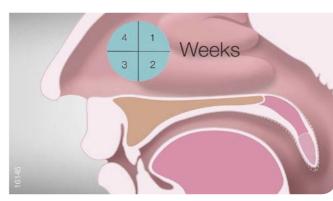


Figure 05

04 | Postoperative Care

To ensure that swelling is reduced more swiftly and to avoid pain, ibuprofen or diclofenac are recommended. A follow-up visit can be scheduled two to three days after the procedure to rule out any infections.

Note: • Clinical experience indicates that an additional coagulation treatment of the soft palate is usually necessary to achieve optimal results. When conducting additional treatments, the CELON applicator should be placed between the scarred areas of the tissue.

 \cdot It is recommended to wait at least four weeks before conducting a follow-up intervention.

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TREATMENT OF HABITUAL SNORING – SHORTENING OF UVULA/WEBBING

Additionally, if you find pronounced webbing and significant hypertrophy of the uvula [Figure 06a/b], this may indicate that a reduction of the uvula and the soft palate mucous membrane is necessary. In the following chapter, it is demonstrated how to use the CelonProCut technology to perform uvula palatoplasty during the same treatment session with no additional risks.





Figure 06a

Figure 06b

05 | Treatment of the Uvula and Webbing

Power settings: For this procedure, a power setting of 20 to 25 watts (mode: PureCut) is recommended. The positioning of a neutral electrode on the patient is not required.

- · Use the CelonProCut accessories to shorten the uvula and webbing.
- · Firstly, take hold of the uvula with the CelonProCut gripping forceps, which also serve as a return electrode. Secondly, activate the foot switch. Then, the incision can start to be made with the CelonProCut electrode [Figure 07a/b].

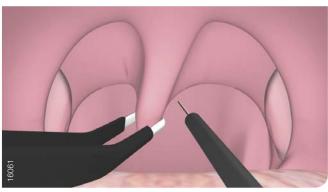




Figure 07a

Figure 07b

· It is recommended that the resection of excessive mucous membrane is performed as a rounded shape on both sides of the uvula. Make sure to leave at least 2 mm of mucous membrane in order to avoid damaging the muscle. An excess of mucous membrane also accelerates the wound healing and reduces postoperative pain.

· The next step is the resection of the tip of the uvula by using the CelonProCut accessories [Figure 08a/b].

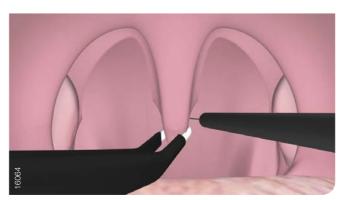




Figure 08a

Figure 08b

• The uvula musculature should be left in place. It is recommended that the reduction of the uvula and the soft-palate mucous membrane is carried out to the extent shown in this illustration [Figure 09a/b].

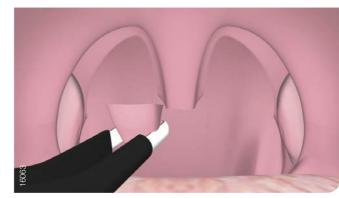




Figure 09a

Figure 09b

06 | Therapeutic Effect

Uvula and webbing will shorten further during the healing process in the weeks after the procedure.



Figure 10

07 | Postoperative Care

- To treat postoperative pain and swelling, ibuprofen or diclofenac is recommended, along with a proton pump inhibitor (such as pantozol) for longer-term analgesic issue.
- · The pain may last eight to ten days. A repetition of this procedure is normally not necessary.
- \cdot Schedule a follow-up visit three days after the procedure and then again after three weeks.

See also the CELON training video:
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VOLUME REDUCTION OF THE TONGUE BASE

In the following chapter, it is demonstrated how to use bipolar radiofrequency-induced thermotherapy (RFITT) at the base of the tongue to treat snoring and mild obstructive sleep apnea. Before you use this method, make sure that a proper diagnosis of the type and severity of the sleep-related breathing disorder has been made.

01 | Anesthesia and Medications

- · The tongue base can be treated with RFITT using local anesthesia.
- · It may be advisable to use general anesthesia for patients with a strong gag reflex, and for those requiring multilevel treatment, depending on your judgement.
- · Firstly, disinfect the tongue base, for example with hexetidine. It is also recommended to disinfect the oropharynx to avoid postoperative infections (abcess) at the tongue base.
- · Secondly, extend the tongue and apply a topical anesthetic like lidocaine gel to the rear of the tongue.
- After that, it is suggested to use a long curved cannula to inject 6 to 9 ml of a two percent lidocaine solution in each of about three points in the circumvallate papillae area [Figure 01]. Make sure to stay in midline and wait for about five minutes before you start with the RFITT treatment.



Figure 01

02 | Treatment of the Tongue Base (with RFITT)

Power settings: A power setting of 7 watts (mode: PureRFITT) is recommended for treating the tongue. The power setting on the control unit determines the extent of coagulation induction. The lower the power setting, the longer the application time and the greater the extent of coagulation. The higher the power setting, the smaller the area of the coagulation.

- \cdot Use the CelonProSleep plus applicator to treat the base of the tongue.
- · Insert the tip of the applicator into the tongue muscle until the insulation tube touches the tissue [Figure 02 a/b].

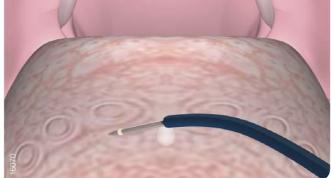






Figure 02b

- Be aware that the surface is difficult to penetrate. Therefore, it is suggested that, after each puncture, you try to make more than one coagulation by partially removing and repositioning the applicator [Figure 03a].
- · After positioning the applicator, activate the power supply by pressing the foot switch. You can monitor the status of coagulation via the acoustic signal. The power supply is reduced automatically to prevent overdose effects.
- · The application takes less than ten seconds for each lesion.
- · It is recommended that the individual coagulation zones are along the midline and approximately 1 cm apart to maintain a seam of untreated tissue between them.
- · Depending on the size of the tongue base, approximately nine coagulations in the circumvallate papillae area are recommended [Figure 03b].



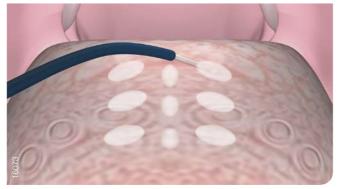


Figure 03a

Figure 03b

Note: To avoid damage to the hypoglossal nerve, do not coagulate too laterally.

03 | Therapeutic Effect

The coagulation results in a local denaturation of the treated tissue area. You can expect a visible reduction in volume accompanied by a tightening of the tissue within the next four to six weeks as a result of scarring and the body's resorption process [Figure 04].

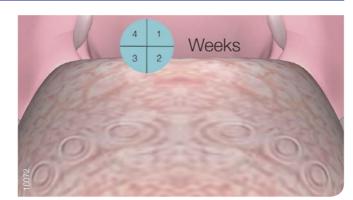


Figure 04

04 | Postoperative Care

- · Because swelling at the tongue base may occur, it is recommended to observe your patient for a couple of hours following the treatment.
- · A follow-up visit is usually not necessary, only in very rare cases of complications.
- · To prevent postoperative pain and swelling treatment, if necessary, ibuprofen or diclofenac is generally suitable.
- · Postoperative antibiotic prophylaxis is highly recommended using cephalosporin or clindamycin orally, for example to avoid abscess formation.

Note: · Clinical experience indicates that an additional coagulation treatment of the base of tongue is usually necessary to achieve optimal results. When conducting additional treatments, the CELON applicator should be placed between the scarred areas of the tissue.

· It is recommended to wait at least four weeks before conducting a follow-up intervention.

See also the CELON training video: Nwww.olympus.eu/celon

VOLUME REDUCTION OF HYPERTROPHIC TONSILS

In the following chapter, it is demonstrated how to use bipolar radiofrequency-induced thermotherapy (RFITT) to reduce the volume of hypertrophic tonsils in children.

01 | Anesthesia and Medications

- · This procedure is commonly performed on children aged three and over in an operating room. In children from year three to eight, it is recommended to use intubation anesthesia. In older children, however, a laryngeal mask can be used to administer anesthesia.
- · In adults, tonsils can be treated with bipolar radiofrequency-induced thermotherapy using local anesthesia. First, use, for example lidocaine pump spray for superficial anesthesia of the tongue and the pharynx. Then apply local anesthesia to the mucous membrane of the anterior and posterior palatine arches and the peritonsillar tissue with approximately 10 ml of one percent lidocaine solution with epinephrine 1 : 200,000.
- · Perioperative antibiotic prophylaxis, for example cephalosporin, is rarely necessary.

02 | Treatment of the Tonsils (with RFITT)

Power settings: A power setting of 7 watts (mode: PureRFITT) is recommended to make lesions in large palatine tonsils. The power setting on your control unit determines the extent of coagulation induction. The lower the power setting, the longer the application time and the greater the extent of coagulation. The higher the power setting, the smaller the area of the coagulation.

- · Use the CelonProSleep plus applicator to treat hypertrophic tonsils.
- · Insert the applicator into the tonsils until the insulating tube of the probe touches the tissue [Figure 01a/b].

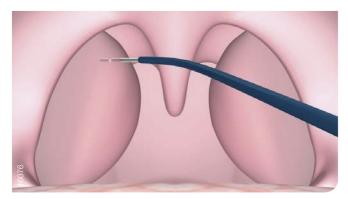




Figure 01a

- · After positioning the probe, activate the power supply by pressing the foot switch. You can monitor the status of coagulation via the acoustic signal. The power supply is reduced automatically to prevent overdose effects.
- · It is recommended to separate the points of insertion by approximately 1 cm. The number of insertions required depends on the size of the tonsils, but usually involves four to six punctures [Figure 02a/b].

Note: • Take care not to penetrate the underlying tonsil capsule.

• During the coagulation process, avoid the immediate area of the tonsil bed by pulling the tonsils away from the critical structures and towards the median plane [Figure 01b].

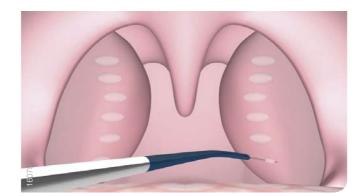




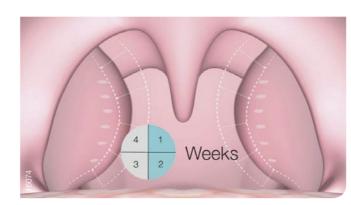
Figure 02a

Figure 02b

- · A little blanching may occur, which is normal and not a reason to stop the coagulation.
- Due to the soft lymphatic tissue of children, the application takes up to ten seconds for each lesion. It might be necessary to clean the tip between coagulations.
- · Bleeding is rare, and in most cases soon stops on its own.

03 | Therapeutic Treatment

The coagulated tissue is absorbed over the next three to four weeks by the body's own absorption process, leading to a volume reduction of 30 to 40 percent [Figure 03a/b].



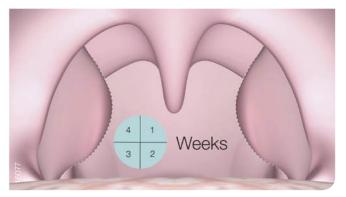


Figure 03a

Figure 03b

04 | Postoperative Care

- · Because of the risk of swelling, it is recommended to keep children under postoperative observation for at least a couple of hours after the procedure. Adults can go home straight after the procedure.
- · For postoperative pain treatment, ibuprofen or paracetamol are recommended for children, and diclofenac is recommended for adults. A follow-up visit should be scheduled for the next morning, then again after three weeks.
- · Treatment with the CELON method can be repeated without any problems six weeks later, if required.

 $\textbf{Note:} \, \cdot \, \text{This procedure should not be performed on children under three.}$

- · If your patient has chronically recurrent tonsillitis, thermo-therapeutic treatment is not recommended.
- · This procedure should also not be used to treat 'kissing tonsils' in small children due to the risk of postoperative swelling.

See also the CELON training video: **()** www.olympus.eu/celon

PARTIAL REMOVAL OF HYPERTROPHIC TONSILS

In the following chapter, it is demonstrated how to use the CelonProCut technology for the partial resection of the hypertrophic tonsils by keeping the capsule intact.

01 | Anesthesia and Medications

- · This procedure is commonly performed on children aged three and over in an operating room using intubation anesthesia.
- · It is not recommended to use a larynx mask because it obstructs the physician's view and does not protect the patient from aspiration.

02 | Treatment of Hypertrophic Tonsils

Power settings: A power setting of 20 to 25 watts (mode: PureCut) is recommended. It is not necessary to place a neutral electrode on the patient.

- · Use the CelonProCut accessoires to partially resect the tonsil.
- · Hold the tonsils with the gripping forceps, which also serve as the return electrode, and retract them slightly medially for better exposure. Avoid contact between the electrode tip and forceps.
- · After grasping the tonsil, activate the power supply by pressing the foot switch.
- · Next, start the incision with the cutting electrode. Start in the upper tonsil pole and continue parallel to the anterior palatine arch caudally [Figure 01a/b].

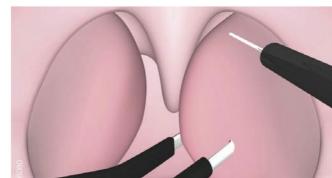






Figure 01b

18

Figure 01a

· Make sure to use the tip of the electrode to cut into the depth of the tonsil [Figure 02a/b].

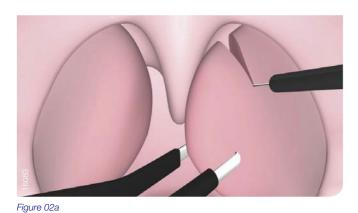




Figure 02b

· The portion of the tonsil that projects medially of the anterior and posterior palatine arch can be removed [Figure 03a/b].





Figure 03a

Figure 03b

- · Minor intraoperative bleeding can occur, which generally arises from smaller vessels and can be easily stopped by inserting an appropriate packing material.
- \cdot If necessary, you can also apply bipolar coagulation to the bleeding area [Figure 04a/b].

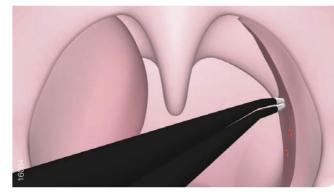




Figure 04a

Figure 04b

- · Postoperative bleeding is very rare.
- \cdot Be careful not to damage the underlying tonsil capsule, the palatine arch, or the tongue.
- \cdot The partial resection of both tonsils takes only a few minutes.

Note: If necessary, you can perform an adenoidectomy in the conventional manner using an adenoid curette during the same treatment session with no additional risks.

03 | Therapeutic Effect

You can expect to achieve the final result in approximately three weeks as a result of the body's resorption process and the formation of scar tissue [Figure 05].

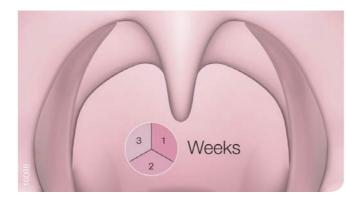


Figure 05

04 | Postoperative Care

- · Because bleeding may occur, it is recommended to keep children under postoperative inpatient observation for one to two days.
- \cdot For postoperative pain treatment, ibuprofen or paracetamol is generally suitable for children.
- · Perioperative antibiotic prophylaxis is rarely necessary.

See also the CELON training video: Nww.olympus.eu/celon

ORDERING INFORMATION

Power Control Un	uit en
Order No.	Description
WA90001A	CELON ELITE "Type E", monopolar output socket for international/Erbe plugs, (incl. double-pedal foot switch)
WA90002A	CELON ELITE "Type B", monopolar output socket for international/Bovie plugs, (incl. double-pedal foot switch)
WA95621A	Power cable, EU, 4.5 m w. angled plug, (many European countries, type E/F)
WA95622A	Power cable, US, 4.5 m w. angled plug, (USA, Canada, and other countries, type B)
WA95623A	Power cable, UK, 4.5 m w. angled plug, (United Kingdom and other countries, type G)
WB50402W	Double-pedal foot switch

RFITT Applicator	s
Order No.	Description
WB990007	CelonProBreath, (5 pcs/box)
WB990008	CelonProSleep plus, (5 pcs/box)

ProCut Accessories	
Order No.	Description
WB990278	CELON ELITE ProCut handpiece
WB990202	CelonProCut gripping forceps
WB990177	CelonProCut electrode, (5 pcs/box)

Other	
Order No.	Description
E0427213	MAJ-814 Neutral electrode cable (reusable)

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