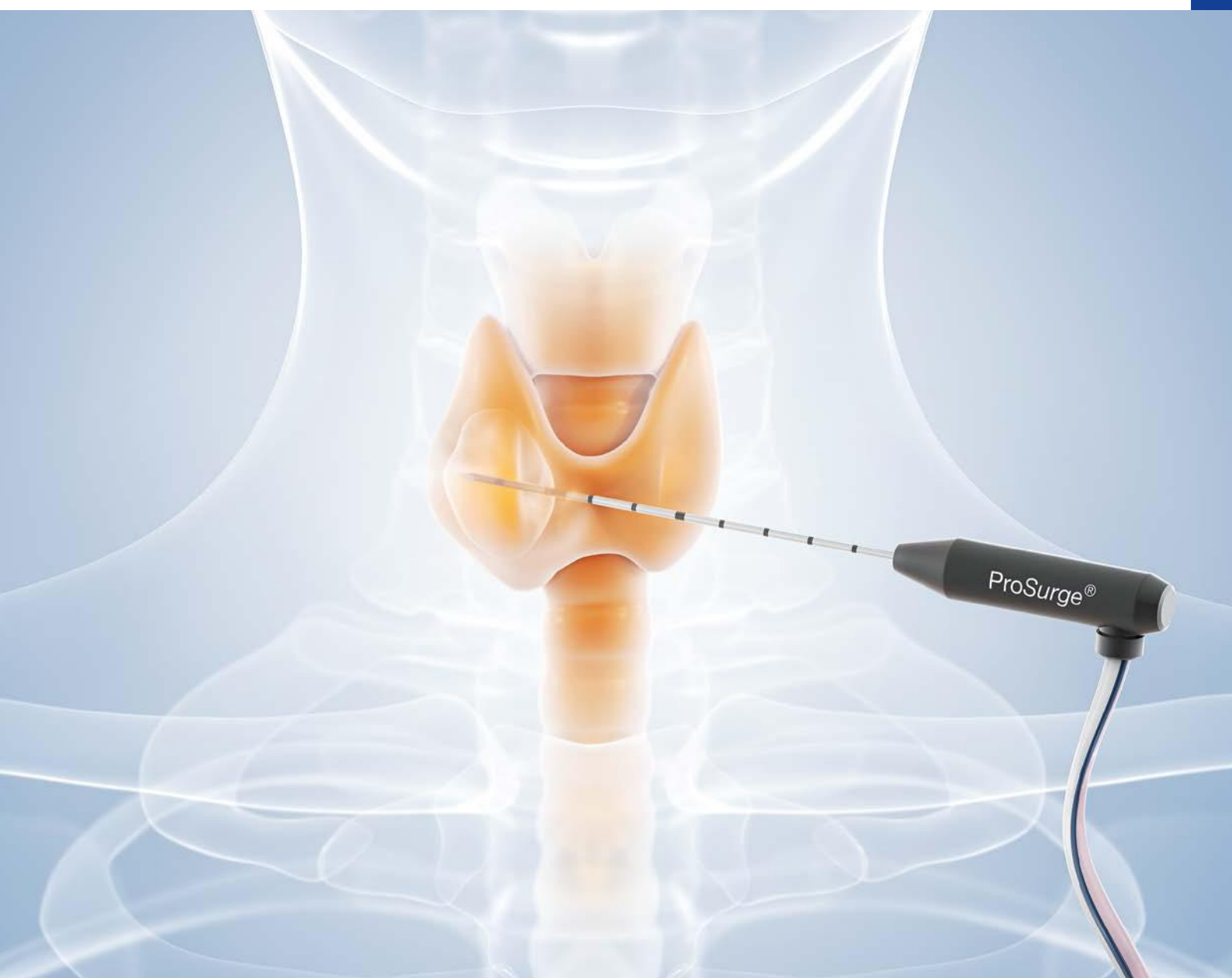


RADIOFREQUENCY ABLATION OF THYROID NODULES

Procedure Guide



DISCLAIMER

The surgical technique herein is presented to demonstrate the method utilized by Prof. Dr. Dr. Hüdayi Korkusuz. 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.

““ Bipolar RFA is a safe and effective treatment option for symptomatic benign thyroid nodules.(1) ””

““ Ultrasound-guided percutaneous BRFA seems to be an effective and safe method for the treatment of benign thyroid nodules. It may gain a wide use in clinical practice.(2) ””

““ The use of bipolar RFA is an effective, safe and suitable thermoablative technique to treat benign thyroid nodules. Combined with the multiple overlapping shot technique it allows sufficient ablation.(3) ””

PREPARATION AND ANESTHESIA

Radiofrequency ablation of the thyroid nodule

In this application guide the treatment of benign thyroid nodules with the aid of bipolar radiofrequency ablation is demonstrated. Before you use this method, make sure that a proper diagnosis of the type of the nodule has been made and that malignancy has been excluded e.g. by fine needle aspiration.

1



The patient shall lie down comfortably on a treatment table with the neck extended slightly.

2

Before starting the procedure, the location of the thyroid nodule is confirmed with the aid of sonographic imaging.

3

The dimensions of the nodule are measured in transisthmic view in order to choose a suitable applicator for the treatment.

Example:

Nodule diameter: 32 mm

Chosen applicator: CELON ProSurge 100-T20 (20 mm electrode length)

Preparation and Anesthesia

4

After choosing an appropriate applicator, the generator can be started and the CELON ProSurge applicator is connected. More information about how to prepare the system can be found in our "Olympus CELON Power System Set-Up Guide".



5



It is important to provide an extensive amount of disinfection to the patient's skin in order to avoid infections.

6



Under ultrasound guidance, local anesthesia is superficially injected in the skin. Anesthesia of the thyroid or the thyroid nodule is generally not necessary. In some cases, it might be advisable to administer an analgesic to your patient.

7

You can use a scalpel to make a 2 mm incision in the skin to ease the insertion of the CELON ProSurge applicator.

8

For the insertion of the applicator, sterile conditions are mandatory.

TREATMENT OF THE THYROID

9



Under ultrasound guidance, the applicator is now inserted from the contralateral side through the isthmus of the thyroid into the nodule.

10

By applying the transisthmic approach, vulnerable structures can be displayed and avoided.



Treatment of the Thyroid

11

A safety margin next to the so called danger triangle containing the recurrent laryngeal nerve between trachea and thyroid should be created.

You should also provide a safety margin to vulnerable structures like the carotid artery, the jugular vein and the vagus nerve.

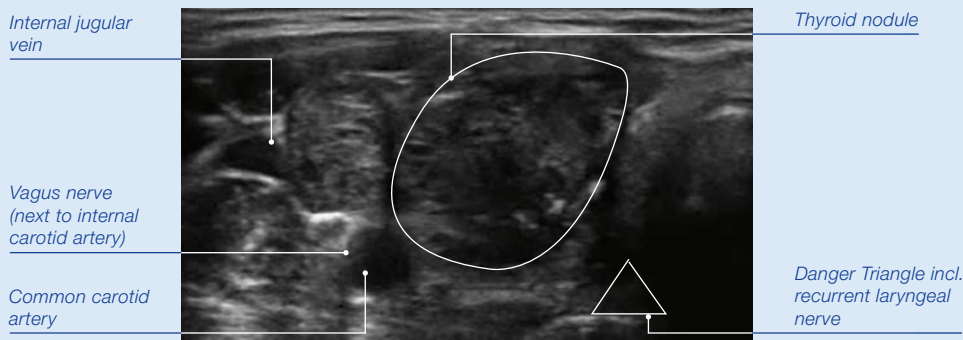


Illustration of vulnerable structures alongside a thyroid nodule being visible under ultrasound

12

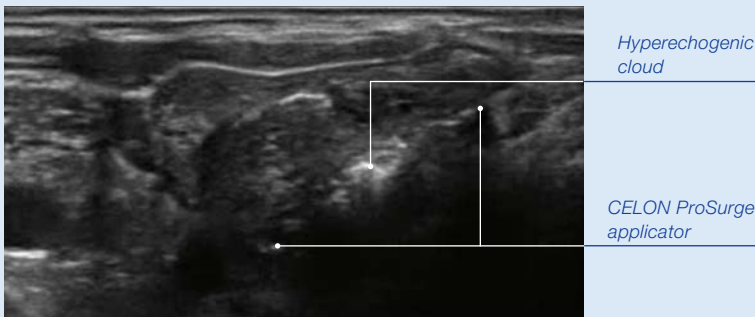
By inserting the applicator in the transisthmic approach, the entire length of the electrode can be visualized via ultrasound.

The insulator between the two electrodes at the tip is clearly visible.

TREATMENT OF THE THYROID

13 After positioning the applicator, activate the RF power by pressing the foot switch. You can monitor the status of coagulation via sonographic imaging.

14 On the ultrasound display, an upcoming hyperechogenic cloud becomes visible around the insulator. It can be identified as an indicator for vaporizing.



Ultrasound image of a CELON ProSurge applicator inside a thyroid nodule.

15 The ablation of the first part of the thyroid nodule is finished when the power output slightly decreases.

The generator power display switches from set power to applied power after pressing the foot switch.

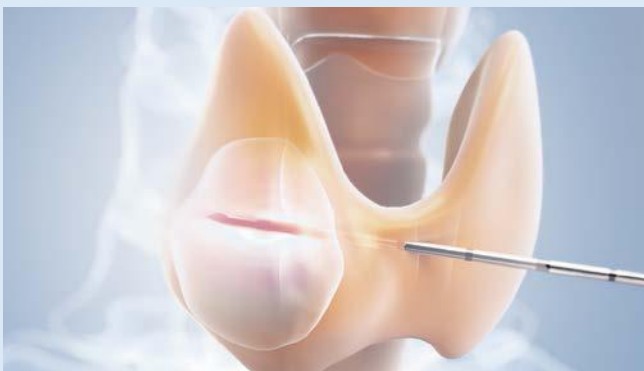
| Electrode | Set power | Target power |
|-----------|-----------|--------------|
| T20 | 25W | 15W |
| T30 | 35W | 25W |
| T40 | 45W | 35W |

16 It is recommended to animate the patient to a conversation during the ablation to recognize a possible damage of the nerves in an early stage.

Treatment of the Thyroid

17 In the following step, the position of the applicator is slightly changed and the ablation is started again.

By repositioning the applicator next to the prior ablation area, you can create overlapping ablation volumes. With only a few repositionings, most of the nodule volume is treated. This approach is called Multiple Overlapping Shot Technique (MOST).



18 This step is repeated until the required ablation volume is achieved. An indicator for complete treatment is total coverage of the targeted nodule volume by the hyperechogenic cloud.

19 After the ablation procedure is completed, the applicator can be easily removed by pulling it out gently.

20 The insertion site just needs to be cleaned with a swab.

THERAPEUTIC EFFECT

21



The coagulation achieves a local denaturation of the treated area.

Therapeutic Effect

22

After several weeks, your patient can expect a visible reduction in volume as a result of the body's resorption of the coagulated tissue.

23

The therapeutic effect can also be measured with the help of different imaging modalities like echogenicity and elasticity measurements, contrast-enhanced ultrasound, Doppler blood flow and (MIBI) scintigraphy.



POSTOPERATIVE CARE

24



Immediately after the treatment, the patient will hardly notice any differences. The puncture site only needs to be covered with a band-aid.

Postoperative Care

25

Following the procedure, the patient should help protect the wound. Advise your patient not to take showers over the next couple of days. Furthermore, overstretching of the neck as well as heavy physical work should be avoided.

26

Schedule a follow-up appointment with your patient after three months to control the effect of the bipolar radiofrequency ablation of the thyroid nodule.

RADIOFREQUENCY ABLATION OF THYROID NODULES

Ordering Information

CELON Power System

WB992001 Set "CelonPOWER System"
Consisting of generator CelonLab POWER (WB991029), peristaltic pump CelonAquaflow III (WB950059) and system trolley CelonMobile (WB950067)

CELON ProSurge Applicators

Internally cooled bipolar radiofrequency applicator for tumor ablation to be used individually or in multipolar combinations.

Included in delivery of each applicator: Applicator, tubing, puncture guide
1.8mm (15 Gauge), three-sided tip, sterile, for single use

| Order Number | Description | Shaft lengths/electrode lengths |
|-----------------|-----------------------|---------------------------------|
| WB990129 | CelonProSurge 100-T20 | 100 mm / 20 mm |
| WB990146 | CelonProSurge 100-T30 | 100 mm / 30 mm |
| WB990147 | CelonProSurge 100-T40 | 100 mm / 40 mm |
| WB990148 | CelonProSurge 150-T20 | 150 mm / 20 mm |
| WB990149 | CelonProSurge 150-T30 | 150 mm / 30 mm |
| WB990150 | CelonProSurge 150-T40 | 150 mm / 40 mm |
| WB990151 | CelonProSurge 200-T20 | 200 mm / 20 mm |
| WB990152 | CelonProSurge 200-T30 | 200 mm / 30 mm |
| WB990153 | CelonProSurge 200-T40 | 200 mm / 40 mm |
| WB990187 | CelonProSurge 250-T30 | 250 mm / 30 mm |
| WB990188 | CelonProSurge 250-T40 | 250 mm / 40 mm |

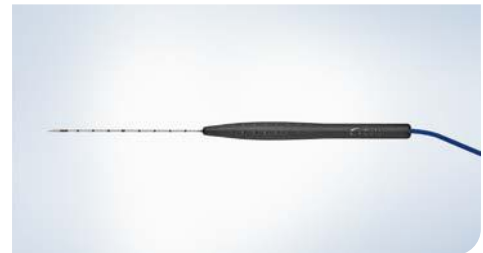


CELON ProSurge micro Applicators

Bipolar RF applicator for precise thermal ablation of tissue

1.3mm (18 Gauge), three-sided tip, sterile, for single use

| Order Number | Description | Shaft lengths/electrode lengths |
|-----------------|-----------------------------|---------------------------------|
| WB990072 | CelonProSurge micro 100-T09 | 100 mm / 9 mm |
| WB990104 | CelonProSurge micro 100-T15 | 100 mm / 15 mm |
| WB990091 | CelonProSurge micro 150-T09 | 150 mm / 9 mm |
| WB990105 | CelonProSurge micro 150-T15 | 150 mm / 15 mm |
| WB990092 | CelonProSurge micro 200-T09 | 200 mm / 9 mm |
| WB990106 | CelonProSurge micro 200-T15 | 200 mm / 15 mm |



References

- 1 Korkusuz Y, Erbeling C, Kohlhase K, et al. Bipolar Radiofrequency Ablation of Benign Symptomatic Thyroid Nodules: Initial experience with Bipolar Radiofrequency. Fortschr Röntgenstr 2016; 188: 671–675.
- 2 Li XL, Xu HX, Lu F, et al. Treatment efficacy and safety of ultrasound-guided percutaneous bipolar radiofrequency ablation for benign thyroid nodules; Br J Radiol. 2016 Mar; 89(1059):20150858.
- 3 Kohlhase KD, Korkusuz Y, Gröner D, et al. Bipolar radiofrequency ablation of benign thyroid nodules using a multiple overlapping shot technique in a 3-month follow-up. Int J Hyperthermia. 2016 Aug;32(5):511-6.