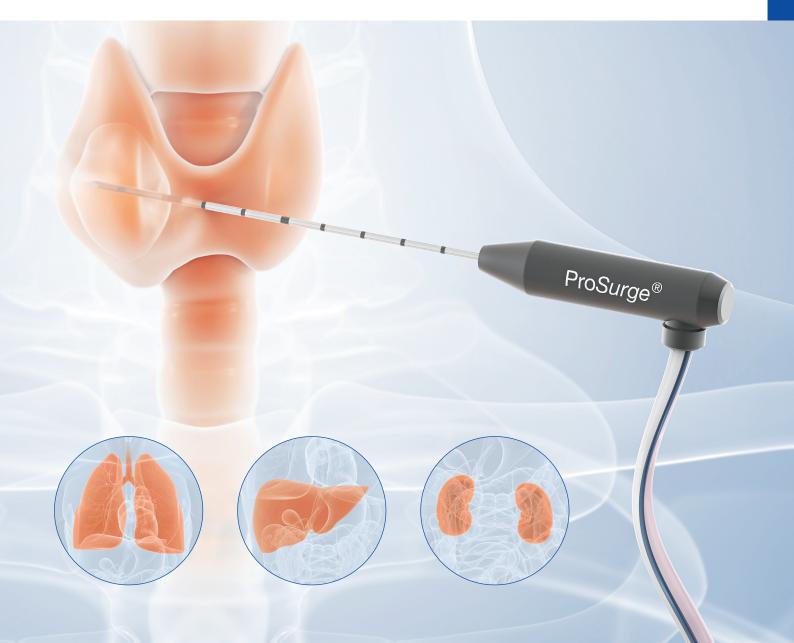


CELON POWER SYSTEM FOR TUMOR ABLATION

Bipolar and Multipolar RFA



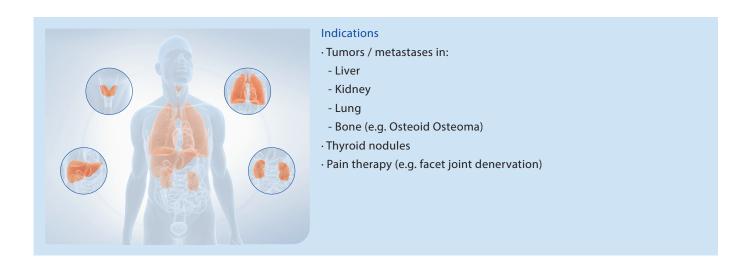
SAFE, EFFECTIVE AND UNIQUE

Bipolar and multipolar radiofrequency ablation (RFA) with the CELON Power System allows an effective treatment of tumors, metastases and other pathological tissues.

Being used in laparoscopic, percutaneous and open surgical procedures, this method complements e.g. chemotherapy or surgical procedures. It provides a safe alternative to monopolar radiofrequency ablation, microwave ablation or cryoablation.

Principle

The method is based on the principle of local thermal deactivation of the target tissue by depositing radiofrequency energy. The affected tissue is heated above 60°C and coagulated. The coagulated volume is resorbed by the body within a few weeks to months.



CT-guided bipolar and multipolar RF ablation of RCC has a high rate of clinical success and low complication rates. At short-term follow-up, clinical efficacy is high without deterioration of the renal function.

Sommer CM, Lemm G., Hohenstein E., et al. CT-guided bipolar and multipolar radiofrequency ablation (RF ablation) of renal cell carcinoma: specific technical aspects and clinical results. Cardiovasv Intervent Radiol. 2013 Jun;36(3):731-7.

CELON POWER SYSTEM

Clinical Benefits

- \cdot Predictable ablation: Bipolar RF current flow limited to target region
- \cdot Multipolar technology allows intratumoral and extratumoral (No-Touch Technique) placement of applicators
- · Large range of ablation diameters due to versatile applicator portfolio: from less than 5 mm up to 90 mm
- \cdot Lower rate of local tumor recurrence compared to monopolar RFA
- \cdot High clinical success and low complication rates
- \cdot Mode for track ablation to avoid puncture channel bleedings and tumor cell seeding
- · Optimized treatment by RCAP (resistance controlled automatic power)
- \cdot Percutaneous, laparoscopic and open surgical access



SAFE ABLATION OF THYROID NODULES

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.

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.

Ablation of Thyroid Nodules

Benign thyroid nodules can efficiently be treated with bipolar radiofrequency ablation. This minimally invasive method allows predictable and safe ablation of hot and cold nodules. After a few months a reduction of the initial nodule volume can be achieved.

Internal jugular vein

Vagus nerve (next to interna carotid artery)

Common carotid artery

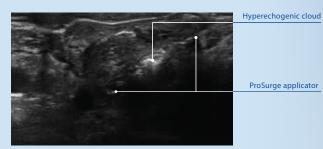
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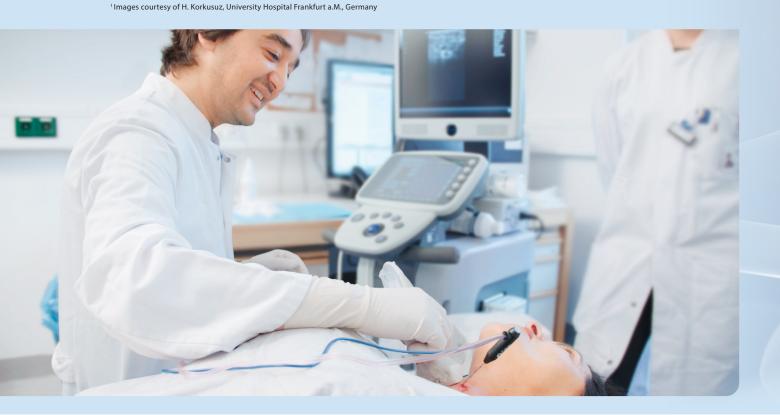
Illustration of vulnerable structures alongside a thyroid

nodule being visible under ultrasound

Danger Triangle incl. recurrent laryngeal nerve

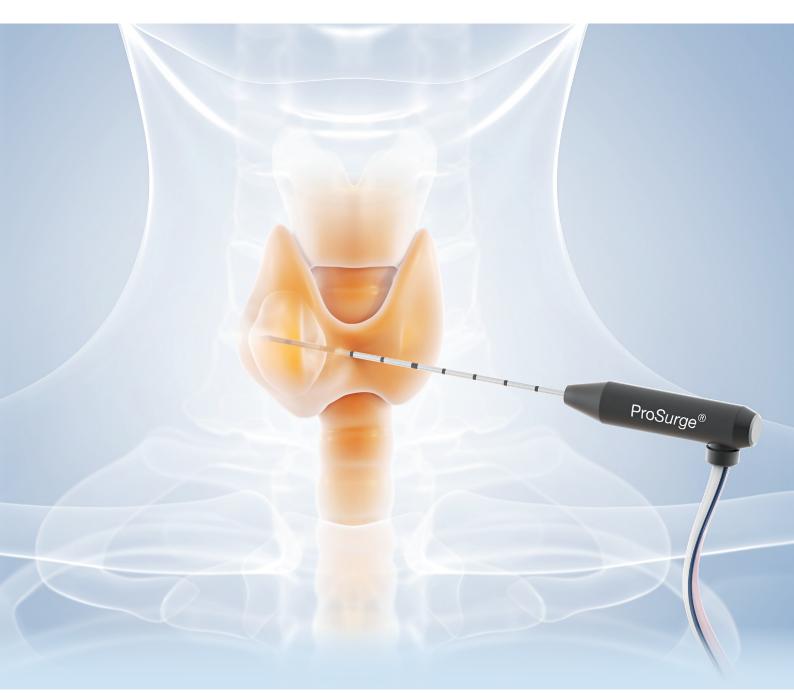


Sonographic image of a CELON ProSurge applicator positioned in a thyroid nodule



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.

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;89(1059):20150858



EFFECTIVE TREATMENT OF TUMORS AND METASTASES

Multipolar RFA is clinically successful for treating SRMs. Using preoperatively calculated energy settings, tailored size tumor lesions could be created.

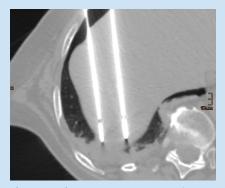
Kroeze S G C, Agenant M, Jonges G N, et al. Clinical efficacy of bipolar radiofrequency ablation of small renal masses. World J Urol. 2015 Oct;33(10):1535-1540.

Ablation of Liver Metastases

With bipolar and multipolar radiofrequency ablation liver tumors and metastases can be coagulated. In the present case an intratumoral placement of applicators was chosen.



2.6 cm metastasis in segment 8 of the liver under the dome of the diaphragm.² ² Images courtesy of T. Albrecht, Vivantes Klinikum Berlin-Neukölln, Germany



After creation of a temporary iatrogenic pneumothorax four CelonProSurge 200-T40 applicators were placed in the periphery of the metastasis choosing a transthoracic approach.²

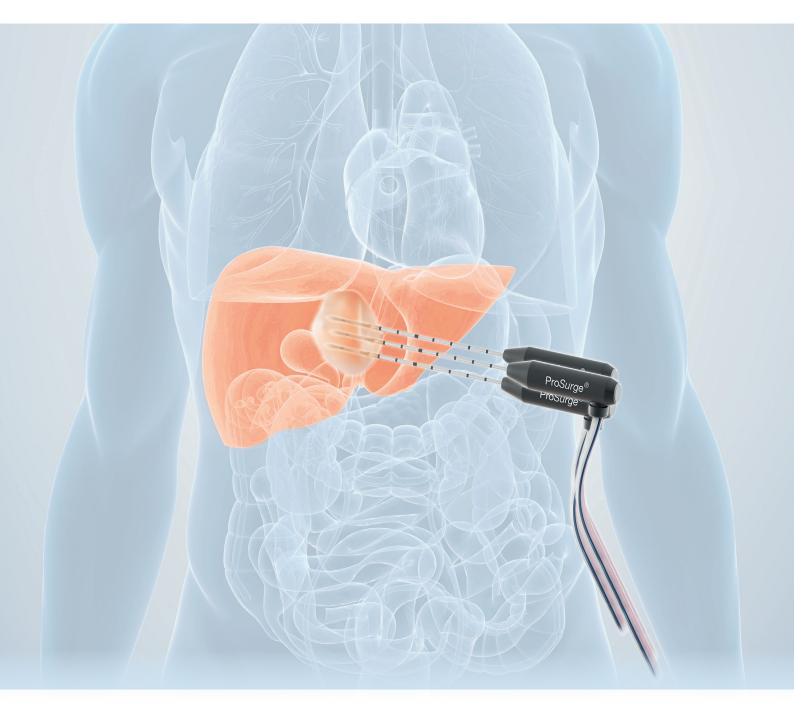


Fusion of CT images before and after ablation (160 W, 14 min): ablation zone of 7 x 5.5 x 4 cm covering the metastasis with a surrounding safety margin of > 1 cm.²



Compared to monopolar radiofrequency, multipolar radiofrequency improves tumor ablation with a subsequent lower rate of local tumor recurrence.

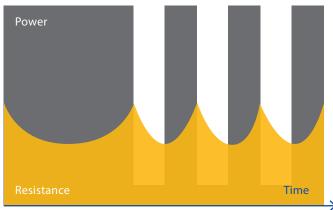
Cartier V, Boursier J, Lebigot J, et al. Radiofrequency ablation of hepatocellular carcinoma: Mono or multipolar? J Gastroenterol Hepatol. 2016 Mar;31(3):654-60.



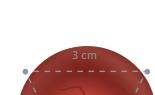
UNIQUE TECHNOLOGY

The CELON Power System offers a unique combination of proven technical features for an optimized treatment.

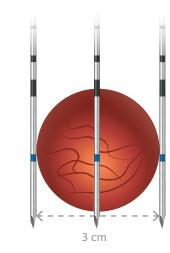
RCAP (Resistance Controlled Automatic Power)



The CELON Power generator provides an algorithm for optimized energy deposition and minimized treatment time. The integrated automatic power control RCAP automatically modulates the power output. Therefore, the tissue resistance is continuously measured. RCAP prevents the tissue from dehydration in order to avoid an interruption of the RF current flow. Manual control of the power level is not necessary during the treatment.

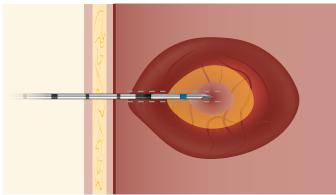


No-Touch technique



For multipolar radiofrequency ablation the CELON ProSurge applicators can be placed inside or around the tumor. By insertion of the applicators just beyond the tumor margins the target tissue is coagulated from the outside to the inside. The predictability of the ablation volume is even more precise due to this ablation approach. Also, the possibility to cause seeding of tumor cells when positioning the applicators decreases by this means. Studies show that the complete necrosis rate can be improved as well as the rate of tumor recurrence.

Track ablation



For completing the ablation procedure the puncture channel can be coagulated during applicator removal. Puncture channel bleedings or tumor cell seeding can be avoided. An acoustic impedance feedback and an Auto Stop function guide the user through this track ablation.

Ablation of small HCCs with multipolar RF ablation based on the no-touch concept improves the rate of complete necrosis during pathologic examination compared with monopolar techniques.

Seror O., N'Kontchou G., Van Nhieu JT, et al. Histopathologic comparison of monopolar versus no-touch multipolar radiofrequency ablation to treat hepatocellular carcinoma within Milan criteria. J Vasc Interv Radiol. 2014 Apr;25(4):599-607.

Bipolar RFA

A CELON ProSurge applicator provides two electrodes at the tip being separated by an insulator. The current flows between those two electrodes only. No neutral electrode is needed. This improves the treatment's level of safety.

Multipolar RFA

The CELON Power System allows the user to connect more than one applicator at the same time. In multipolar mode the RF current flows between all possible electrode combinations. Hereby, a large and homogenous ablation zone around the applicators and especially in their center can be achieved.

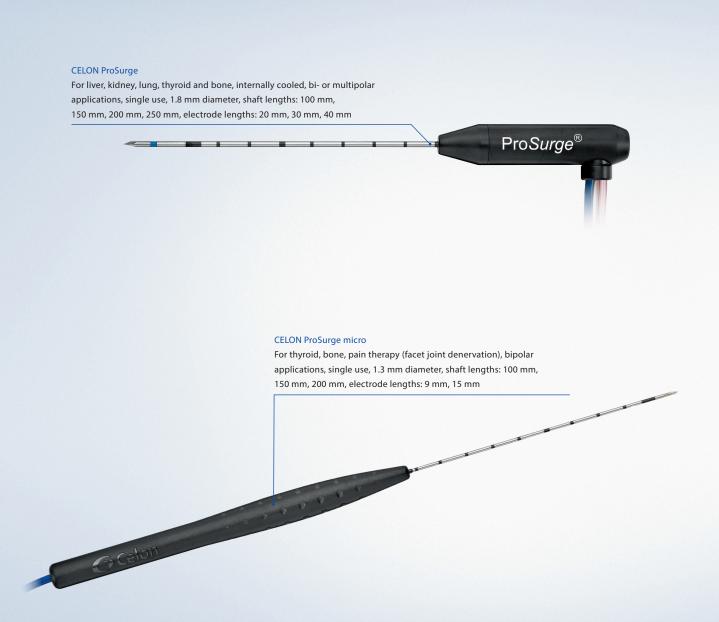
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ProSura

ProSurge

VERSATILE APPLICATOR PORTFOLIO

Being optimized for different fields of application, the bipolar CELON ProSurge applicators are available in various diameters, shaft and electrode lengths. Shaft markings enable the user to estimate the penetration depth. High flexural rigidity and sharp trocar tips allow precise placement of the applicators and easy puncturing of tissue. By means of the peristaltic pump CELON Aquaflow most of the applicators are internally cooled in order to improve the coagulation efficiency.



SMART SYSTEM

The CELON Power System consists of the CELON Power generator, the peristaltic pump CELON Aquaflow and the system trolley CELON Mobile with infusion stand. The provided foot switch allows hands-free starting of energy deposition. A clear design of the control elements and user-friendly functionalities simplify the use of CELON Power. Up to three simultaneous CELON ProSurge connections are possible for performing multipolar ablations. By using CELON Connect BU adapters even the connection of up to six applicators at the same time can be realized.



CELON POWER SYSTEM FOR TUMOR ABLATION

Ordering Information

CELON Power System

WB992001 CELON Power System

Consisting of generator CelonLab POWER (WB991029), peristaltic pump CelonAquaflow III (WB950059) and system trolley CelonMobile (WB950067)

WB990188

CELON ProSurge

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. Diameter: 1.8 mm, three-sided tip, sterile, for single use.

| 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 |

"CelonProSurge 250-T40"

CELON ProSurge micro

Bipolar RF applicator for precise thermal ablation of tissue. Diameter: 1.3 mm, three-sided tip, sterile, for single use.

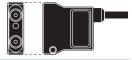
| WB990072 | "CelonProSurge micro 100-T09" | 100 mm / 9 mm |
|----------|-------------------------------|----------------|
| WB990104 | "CelonProSurge micro 100-T15" | 100 mm / 15 mm |
| WB990091 | "CelonProSurge micro 150-T09" | 150 mm / 9 mm |

| 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 |

CelonConnect BU Adapter

By means of CELON Connect BU adapters up to six CELON ProSurge applicators can be connected to the CELON Power generator. Per socket two applicators can be connected using CELON Connect BU.

WB950145 Adapter "CelonConnect BU"



ProSurge[®]

250 mm / 40 mm

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