

NeuroOne

NeuroOne® Medical Technologies Corporation

# Stereoelectroencephalographic Radiofrequency Ablation of Brain and Nervous Tissue

ICD-10 Coordination and Maintenance Committee Meeting
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# Temperature-controlled stereoelectroencephalography (sEEG) radiofrequency ablation is an effective technique to create thermocoagulative lesions in an awake patient for the treatment of drug-resistant epilepsy

- Resection and destruction of the epileptogenic zone (EZ), the region indispensable for seizure onset, is the gold standard for the surgical treatment of drug-resistant epilepsy
- **Problem:** Certain surgical approaches can limit patient access to treatments and have limited effectiveness
  - Currently available RFA devices cannot control temperature and perform stereoelectroencephalographic (sEEG) recordings
  - Other techniques require magnetic resonance (MR) imaging guidance, which presents challenges for performing procedures in **awake** patients, and may require multiple hospital admissions, implantations, and removals of neuroelectrodes

As a therapeutic option for patients, describing temperature-controlled sEEG radiofrequency ablation in the ICD-10-PCS code set is important

# When the NeuroOne OneRF™ Ablation System is Used

- **The patient is admitted to the Epilepsy Monitoring Unit (EMU) for sEEG monitoring; the combination Evo(R) sEEG-RF Probes are implanted, which are intended for <u>both</u> diagnostic and when appropriate, for ablation use**
- **Based on sEEG monitoring results, the OneRF™ Ablation System delivers RF through the already implanted combination Evo® sEEG-RF probes**
- **Key benefits of this approach:**
  - Does not require MR guidance
  - Enables treatment at bedside/operating room in an awake patient
  - Allows for temperature controlled ablative procedures
  - Effectiveness of the intervention can be measured through same electrodes after the ablation
  - Patient may experience reduced seizure burden or freedom from seizures; reduction in seizures may be predictive of effectiveness of future procedures
  - May delay or avoid the need for further surgery

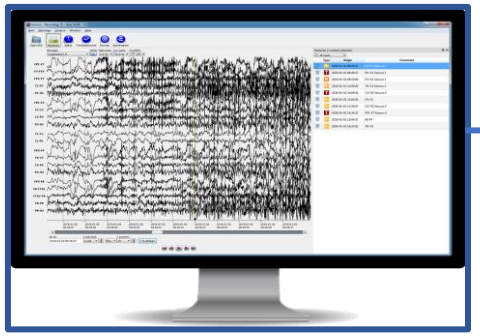
**Patient population**

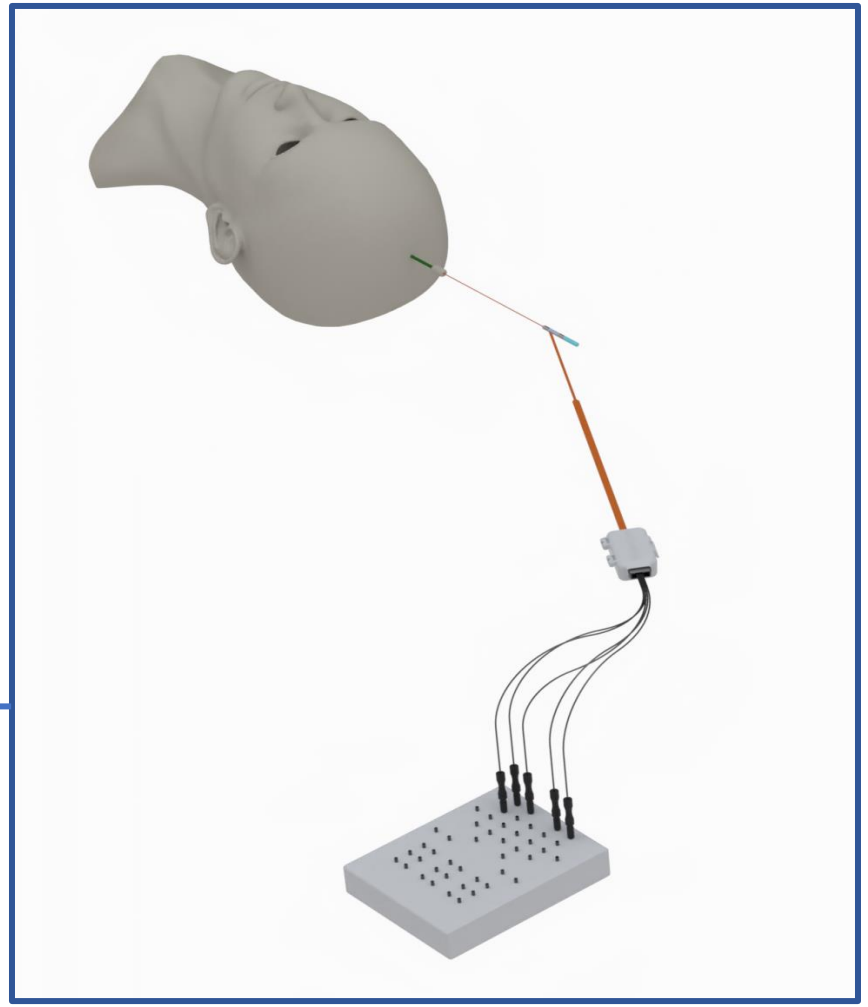
Patients with documented focal epilepsy experiencing multiple seizures not well-controlled on more than one anti-seizure medication

**NeuroOne OneRF™ Ablation System was granted FDA Clearance in December 2023*

# Workflow:
# Standard of Care sEEG Diagnostics are Performed

- **Patient is monitored post sEEG electrode implant in the EMU**
- **Seizure location is identified**
- **Patient is identified as a candidate for RF ablation**

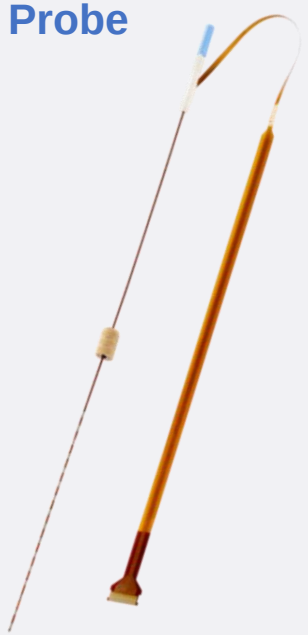




# OneRF™ Ablation System – Key Components

| sEEG<br>*(Already Implanted for Diagnostics)* | RF Procedure Single-Use | RF Generator |
|---|---|---|

**Evo® sEEG-RF Probe**



**Temperature Accessory Kit**

**Radiofrequency Connection Box (RFCB)**

**Temperature Accessory (TA)**



**Spacer Tubes**

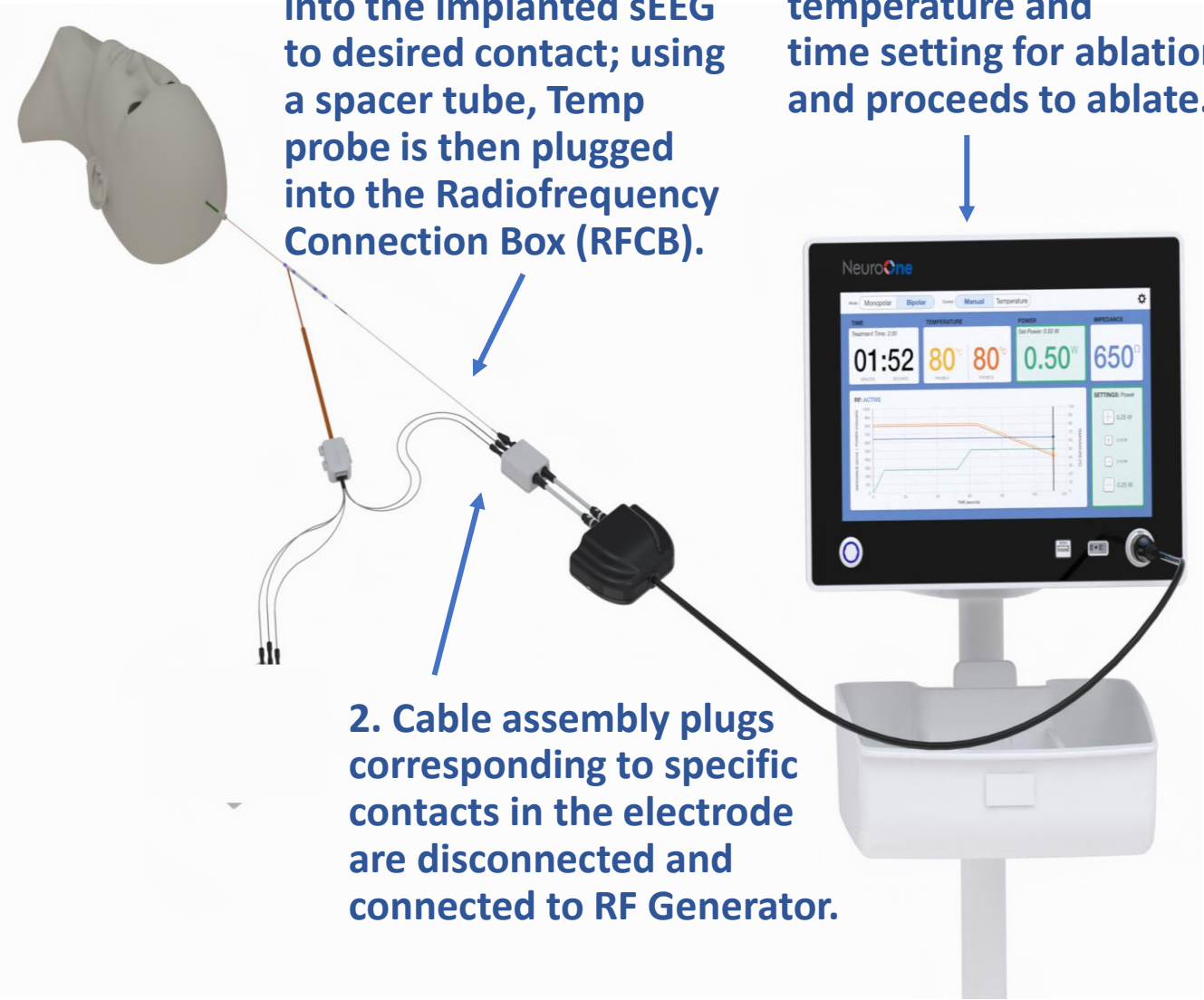
**NeuroOne Radiofrequency Generator, Generator Interface Cable (GIC), Foot Pedal (optional), and Cart**



# Workflow: RF Ablation with OneRF™ Ablation System

1.Temp probe is inserted into the implanted sEEG to desired contact; using a spacer tube, Temp probe is then plugged into the Radiofrequency Connection Box (RFCB).

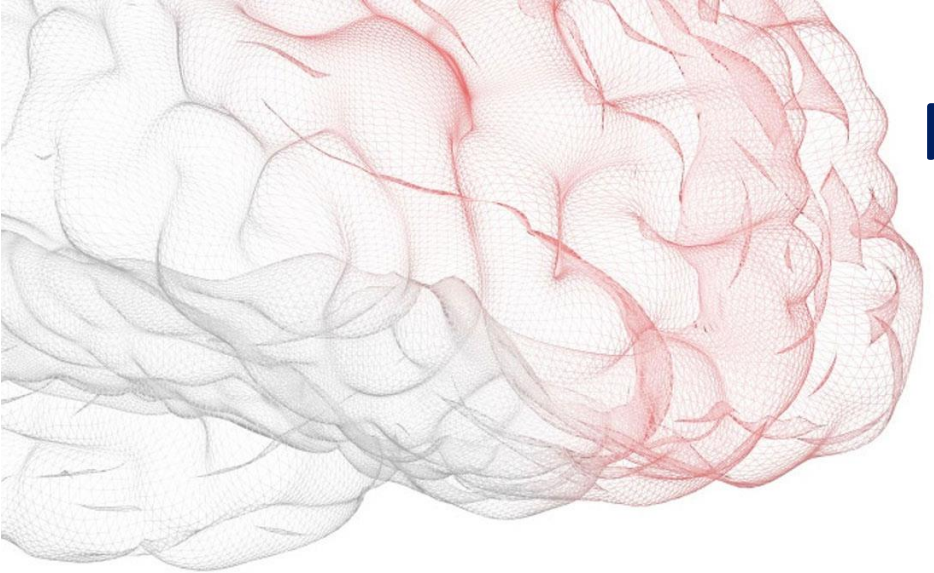
3. Surgeon sets the temperature and time setting for ablation and proceeds to ablate.




2. Cable assembly plugs corresponding to specific contacts in the electrode are disconnected and connected to RF Generator.

**Protocol:**

- Disconnect sEEG contact pins corresponding to contacts chosen to be ablated
- Choose the appropriate spacer tube corresponding to the contact(s) to be ablated and position it onto the sEEG RF probe
- Insert TA into sEEG
- Insert sEEG chosen contact pins into RFCB, connect TA to RFCB
- Connect RFCB to GIC/Generator
- In Generator choose treatment mode, desired temperature, time and power and then initiate ablation
- Monitor ablation in real time using graphic display
- Lesioning duration is up to 10 minutes per lesion
- At the end of the ablation disconnect all the accessories
- Pre-and post ablation sEEG recording can be attained




# Medical Record Documentation and Key Terms

- **Medical record documentation may reference stereoelectroencephalography (sEEG) radiofrequency ablation in the**
  - **Patient admission records**
  - **Progress notes**
  - **Operative or surgical notes**
  - **Discharge summary notes**
- **Key terms include:**
  - **Radiofrequency ablation (RFA)**
  - **Radiofrequency thermocoagulation**
  - **sEEG radiofrequency ablation**
  - **Temperature-controlled sEEG radiofrequency ablation**
  - **Temperature-controlled sEEG radiofrequency thermocoagulation**
  - **Tissue temperature RFA, stereotactic RFA**
- **Use of a radiofrequency generator, voltage increases and decreases may be referenced**

# Stereoelectroencephalography-guided radiofrequency ablation of the epileptogenic zone as a treatment and predictor of future success of further surgical intervention. Shields JA, Greven ACM, Shivamurthy VKN, Dickey AS, Matthews RE, Laxpati NG, Alwaki A, Drane DL, Isbaine F, Willie JT, Bullinger KL, Gross RE. Epilepsia. 2023 Aug;64(8):2081-2093. doi: 10.1111/epi.17673. Epub 2023 Jun 29. PMID: 37300533.

**Objectives**

1. examine the single-center outcomes of RFA;
2. determine whether, when seizures persist, RFA response could be useful in predicting the outcome of subsequent procedures,
3. present the way in which the two procedures can be used in conjunction, as needed, for a patient-specific surgical treatment approach.

**Methods**

1. Single-center retrospective study; review of clinical records of RFA procedures performed 2014-2021
2. 57 patients (44 f; age 36.7 ±12.3; age at epilepsy onset 16.2 ±12.1) with refractory focal epilepsy who underwent SEEG-guided RFA procedures as the initial destructive therapy and had at least 6 months follow-up
3. Ablation contacts: sEEG electrodes in the epileptogenic zone (EZ)
4. Ablation parameters: monopolar and bipolar; the power was increased to between 1 and 2 W over ~15 s and then held there for 60 s, up to 8W.
5. Intracranial EEG (iEEG) recordings monitored throughout the entire procedure, (except during RFA) and used for: (1) Confirmation of the presence or absence of epileptiform discharges after each ablation; (2) Performing further ablation if discharges persisted, and an additional lesion could be made (i.e., power was sustainable).
6. Outcomes: at >6 months
   - "Success": Engel classification of I or II
   - "Failure": Engel III or IV

**Results**

**1. Clinical outcomes**

✓ RFA alone outcomes:17/57 patients
- Seizure-free (Engel class I): 12/17 patients
- Engel III: 2/17 patients; no further surgical intervention;
- Success 70%, Failure 25%.

✓ Delayed secondary surgery following RFA: 32/57 patients in whom seizures persisted or recurred following RFA underwent a delayed procedure (N=26 LITT; n=5 open resection, n=1 RNS; in a separate admission )
- Engel I: 16; Engel II: 9, Engel III: 4, Engel IV:3.
- Success 78%, Failure 22%.

✓ Immediate secondary surgery following RFA: 8/57 patients underwent a secondary procedure (LITT) immediately after RFA during the same admission.
- Engel I:2, Engel II:2, Engel III/IV:4.
- Success 50%, Failure 50%.

✓ Overall: 25% seizure free

**2. Predictive value of RFA results for outcome of subsequent procedures:**

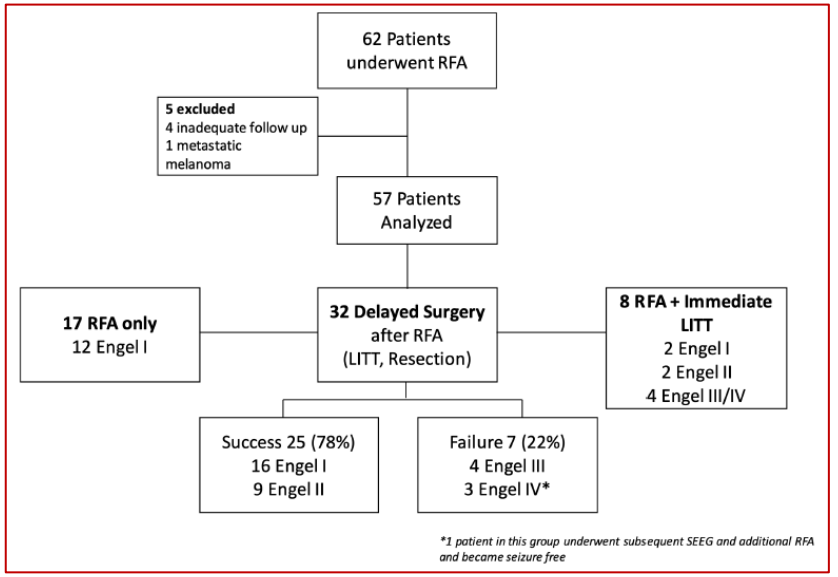
- Transient time of seizure freedom (time from RFA to 1st seizure reoccurrence), was significantly longer for patients achieving "Success" versus "Failure" (4 ± 2.65 vs 0.75 ± 1.17 months)

**3. Clinical outcome relationship with radiological findings**

- Gliosis, hippocampal sclerosis, PVNH, encephalocele, FCD, others
- More lesional findings on preoperative imaging in the "success" vs "failure" group

**4. Safety outcomes**

- **All procedures:** Post-operative complications: 7/ 57 (12%); most complications were transient and expected based on the treatment location and functional mapping. One patient (2%) experienced a permanent mild motor deficit with >50% improvement after physical therapy at long-term follow-up.
- **RFA related:** 2/17 patients that had RFA alone with no other follow-up procedure, experienced temporary postoperative complications, lasting <3 months and consisting of weakness (n=2) and intracerebral hemorrhage (n=1). These complications were expected based on the functional mapping. 1/32 patient that underwent RFA followed by LITT experienced an unexpected temporary complication after RFA, lasting for 2 months and consisting of hand weakness. 1/32 patient that underwent RFA followed by LITT experienced temporary (1 month) facial droop and sensory disturbance attributed to both RFA and LITT procedures.




## Conclusions

- RFA targeting the EZ has transient or prolonged effects on seizure outcomes, with a seizure free rate of ~25%
- Time interval between RFA and 1st seizure occurrence, correlates with clinical outcomes from subsequent surgical procedures: longer time, better outcomes
- RFA provides the surgeon with real time clinical data underlying ablated tissue.
- The procedure is safe, with a low rate of post operative complications, most predicted and transient
- RFA is safe and can result in long-term seizure freedom

*Thank you.*

*Clinical Questions?*