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THN Sleep Therapy™ System Site FAQ

1. Is there a chance something could go wrong with the device and hurt the patient?
   The safety and wellbeing of our recipients is of utmost importance to ImThera Medical. The aura6000, Remote Control Charger and Charging Antenna have undergone rigorous testing to ensure the highest possible quality and reliability. In the event that a malfunction does occur, ImThera Medical will replace the device/components or assist with troubleshooting.
2. How big is the scar?
   There are two small incisions made to implant the aura6000 device. The first incision, located in the upper chest, is typically less than 5 cm long and the second incision, located on the neck is typically less than 6 cm in length.
3. Can recipients feel the implant working?
   THN therapy is typically set at the lowest level possible to provide tone to the muscles of the tongue while sleeping. The intent of the therapy is to minimize disruption to sleep. If a patient reports stimulation related discomfort, the device can be adjusted to address this complaint.
4. What does it feel like?
   Most recipients report a mild tingling sensation and movement at the back of the tongue when stimulation is on. If a patient reports stimulation related discomfort, the device can be adjusted to address this complaint.
5. Can others see the cable?
   The cable connecting the implant body and electrode is not intended to be visible to others. However, individual outcomes will depend on patient anatomy and how the cable is placed by the surgeon.
6. How long will the implant last?
   The THN Sleep Therapy™ system is designed to last up to 15-years before battery replacement is required.
7. What happens if a recipient forgets to turn the implant off in the morning?
   The implant is programmed, based on each patient's nightly routine and preferences, to turn-off automatically at the conclusion of therapy.
8. Can the implant be set to start stimulation/treatment after the subject falls asleep?
   Yes, the implant is programmed to turn on and off based on the recipient's nightly routine and preferences.
9. How does the implant charge?
   To charge the implant, the Remote Control & Charger (RCC) is set to charge mode and the charging antenna (CA) is placed over the implant.
10. Can recipients exercise with the implant?
    Yes, recipients may exercise as usual after the healing period recommended by their surgeon.

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11. Is swimming allowed after receiving the implant?
    Yes, recipients can swim after the healing period recommended by their surgeon.
12. Are there any activities recipients should avoid after implantation?
    All strenuous activities and lifting should be avoided during the post-implant healing period of approximately 1-month. Once medically cleared, normal activities can be resumed. It is important to note, however, that ImThera advises against sports or activities that could result in significant impact to the implant site and/or the electrode site.
13. Will the implant improve or stop snoring?
    The THN Sleep Therapy™ system is designed to treat Obstructive Sleep Apnea, not snoring. However, many recipients report a reduction or elimination of tongue-based snoring when therapy is used.
14. What other surgeries are available for OSA?
    There are a variety of medical treatments available for OSA. CPAP is the most common treatment; however, there are a variety of other surgical and non-surgical options. The most common alternatives are described in the Informed Consent Form which should be reviewed with the subject prior to enrollment.
15. How long does the surgery take?
    The surgery to implant the THN Sleep Therapy™ system usually lasts 45 – 90 minutes and is done as an outpatient procedure.
16. If the implant stimulates muscles in the tongue, will it affect speech?
    Therapy is typically applied only while the patient is sleeping, therefore speech is not a factor. However, if the patient awakens during therapy, or if therapy is started during waking hours, speech will most likely be affected (e.g. slurred).
17. Will sleeping sitting-up prevent OSA from occurring?
    OSA occurs independent of sleep position; however, the severity may change depending on the position of sleep.
18. Are there other FDA approved implants for OSA?
    Yes, the Inspire Upper Airway Stimulation™ (UAS) system is commercially available in the US. However, it does not yet have broad-based insurance coverage.
19. How is the Inspire UAS system different from ImThera's THN Sleep Therapy™ system?
    The primary differences between the Inspire system and THN Sleep Therapy are:
    - THN therapy is designed to treat the cause of OSA – poor muscle tone in the tongue during sleep. In contrast, the Inspire system is designed to open the airway by protruding the tongue forward.
    - The Inspire system uses a sensing lead to trigger stimulation during inspiration. This is done to avoid the muscle fatigue associated with chronic stimulation of a single muscle group. THN therapy uses a 6-contact electrode array to stimulate multiple muscles of the tongue continuously throughout the night. This implementation results in a less

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complex, shorter surgery with fewer incisions and a shorter recover period for the patient.

- The ImThera implant is less than half the volume of the Inspire implant, allowing more superficial placement of the ImThera IPG and potentially less visibility after implantation.
- THN therapy is designed for battery replacement every 12 - 15 years whereas Inspire therapy requires battery replacement every 10-12 years.

20. How long does the THN3 study last?
    The study lasts for 5-years. Visit schedules are dependent on subject randomization. Details are outlined in the Informed Consent document.
21. How many people are implanted?
    141 people will be implanted in the THN3 study, of which more than 80 subjects are already implanted. The total implanted population worldwide, from ImThera's previous studies and commercial sales, is ~200 implants.
22. Does the implant have a 100% success rate? If not, what is the success rate?
    The success rate of the therapy is unknown and will be established as part of the THN3 Study. However, information learned as a result of two previous THN feasibility studies was used to define the inclusion and exclusion criteria for the study, with the expectation that the majority of candidates meeting these criteria will benefit from therapy.
23. How do we know it will work?
    It is impossible to guarantee the efficacy of any OSA-related surgery. However, two previous THN feasibility studies lead to the development of the THN3 inclusion/exclusion criteria in order to maximize potential to provide therapeutic benefit to the majority of subjects.
24. Are there other implants that use electric stimulation?
    Yes, the Inspire Upper Airway Stimulation system also uses electric stimulation.
25. Will the Hypoglossal nerve stop responding to electrical stimulation over time?
    No, there is no evidence that a nerve will stop responding to electrical stimulation over time.
26. How big is the remote control?
    Physical dimensions: 203mm X 95mm X 38 mm
    Weight: 225 grams
27. What if an implant battery lasts less than 12 – 15 years?
    If at any point the implant battery requires replacement, it can be surgically replaced in an outpatient procedure.
28. Can electrical stimulation damage the nerve?
    There are well-established scientific safety limits that must be obeyed when applying electrical stimulation to a nerve. After decades of use in other applications, there is no evidence of nerve damage when stimulation is applied within these limits.

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29. What are the risks?
    The surgical risks associated with implantation of the THN Sleep Therapy™ system are similar to any other implant procedure. A detailed summary of all risks is included in the informed consent document that should be provided, and reviewed, with subjects prior to consenting for participation.
30. What happens if the implant fails after the study is over, who will replace it?
    Subjects that require a replacement implant or system components will be provided these items free of charge for the duration of the study.
31. Do subjects get paid to participate in the study?
    All costs associated with participation in the study, including the device, surgery, doctors' fees and sleep tests are paid by the study Sponsor. Additionally, subjects will receive a small stipend to cover out-of-pocket costs associated with travel to and from appointments. The total amount of the stipend is stated in the informed consent document.
32. What are the benefits of participating in the study?

    A comprehensive list of benefits is provided in the informed consent document, including:
    - Subjects are able to work with a sleep doctor and team of healthcare professionals that have experience with OSA
    - Subjects will contribute to the understanding of Hypoglossal nerve stimulation for OSA
    - Subjects' OSA may improve with treatment
    - Subject may help themselves and others by increasing the medical community's knowledge about OSA
    - Subjects will receive the device and all study related care at no cost

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