A NEW TREATMENT FOR INTRACTABLE CHRONIC CLUSTER HEADACHE PATIENTS
Occipital Nerve Stimulation (ONS) with AnkerStim™ may offer proactive control for intractable chronic cluster headache (iCCH) patients.

Cluster headache (CH) is a severe headache condition characterized by extreme unilateral pain in the orbital, supraorbital or temporal area, lasting 15 to 180 minutes and occurring up to 8 times per day. CH is associated with other signs or symptoms (e.g., conjunctival injection, eyelid oedema, and/or restlessness or agitation). CH is considered chronic when these attacks last for more than 1 year or with remission lasting less than 1 month. Refractory, or intractable Chronic Cluster Headache (iCCH) includes those suffering at least 3 severe CH attacks per week despite at least 3 consecutive trials of adequate preventative treatments.

For those with iCCH, there is a new treatment option available: Occipital Nerve Stimulation (ONS) using the AnkerStim™ lead. ONS is a promising treatment option for patients with iCCH and may reduce attack frequency and intensity, as well as medication use.

Of patients receiving ONS therapy for iCCH:

- 55.8% experienced a ≥50% reduction in CH frequency
- 63.5% experienced a ≥30% reduction in frequency
- 34.6% experienced a ≥30% reduction in pain intensity during attacks
- 48.1% were able to reduce CH medication
- 80.8% said they would recommend the procedure to others

Despite these encouraging results, historical use of ONS lead placement has experienced a number of complications. In an internal analysis pooling safety data from 8 prospective studies reporting on 322 patients, the most commonly reported adverse events occurring in patients were lead migration (14.9%), and persistent pain at the device site (13.4%).

The New AnkerStim™ Lead is designed to reduce complications.

An innovative lead designed for ONS

The AnkerStim™ lead is designed to resist migration and improve comfort.

- Lead tip features a dual-prong tine for lead fixation in the subcutaneous layer. Two additional single-prong tines provide extra fixation between the two proximal electrodes. These tines are designed to resist migration and avoid the use of anchors in the occipital area that were a source of discomfort at the implant site.
- Flexible spring-coil electrodes adjust to the shape of the skull and are designed to improve comfort at the device site and lower the risk of skin erosion.
- 14G curved introducer needle adjusts to the curvature of the skull to help facilitate lead implant.
- 60 cm lead length allows for 2 strain relief loops along the lead trajectory intended to further resist lead dislodgement.

How does it work?

- AnkerStim™ lead is implanted subcutaneously near the occipital nerves at the base of the head.
- Leads are connected to an implanted neurostimulator via an extension.
- Electrical stimulation targets occipital nerves and may evoke the sensation of paresthesia.
- Stimulation is thought to work by interfering with pain signals and possibly restoring balance with non-functioning nerves.
- An external hand-held programmer allows physicians to set and adjust patient stimulation parameters in clinic.
- Patients can adjust stimulation settings and turn their system on and off using their MyStim wireless device.
"Intractable Chronic Cluster Headache is a terrible disease with patients often having no options to help manage the incredibly painful symptoms. It is important for Neurologists, Headache Specialists, and Pain Specialists to know about important advances in treatments such as the AnkerStim™ lead and ONS procedural standardization."

– Professor Denys Fontaine, Neurosurgeon and Dr. Lanteri-Minet, Neurologist, Nice, France

"The AnkerStim™ lead is a truly innovative product that aims to improve safety and efficacy of ONS for iCCH. Our experience with this product in treating these patients has been very positive."

– Professor Jean-Pierre Van Buyten and Dr. Iris Smet, Anesthesiologists & Pain Specialists, Sint-Niklaas, Belgium

ONS and the AnkerStim™ lead are available to a limited number of centers. Contact your local Medtronic Sales Representative for more information and to assess your ability to offer this treatment option to your patients.

See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. The AnkerStim™ is not MRI compatible. If using an MRI SureScan® neurostimulator in combination with AnkerStim™, the system is not MRI compatible and MRI shall not be performed. For further information, contact your local Medtronic representative and/or consult the Medtronic website at www.medtronic.com.


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