What can I expect after surgery?

In the recovery room, the device will be programmed to help you find the greatest amount of comfort and relief. It may take days, weeks, or even months, to know if the therapy may work for you. Things you will learn:

- How to use the handheld programmer
- How to care for the surgical incisions until they heal
- What activities and movements to avoid during the healing period after implant

You might experience some discomfort in the area where the system was implanted. This is temporary and should resolve in the hours and days following the procedure. You may also experience some changes in stimulation intensity with certain activities.

What are the risks of ONS therapy?

Some patients do experience problems. You cannot have an MRI if you have the device implanted. As with any surgical procedure, there are risks associated with the surgical implant procedure and anesthesia. Reported problems following implant include undesired movement of the lead, broken components of the implanted system, pain at the site of implant, and undesirable change in stimulation. Some complications may require additional surgery. While the AnkerStim[™] lead is designed to reduce some of these risks, all risks cannot be avoided. Speak to your doctor to understand all the risks.

Will the device completely eliminate my cluster headaches?

Many people experience significant reduction in the frequency of cluster headaches with ONS, in addition to reduction in pain intensity during attacks, reduction in the use of medications, and high satisfaction with the treatment.⁴⁻⁸ However, the therapy does not work for everyone. It is possible that ONS will provide no benefit to you.

ONS may help you get back to doing the everyday things you love most.

ONS is intended to reduce the number of cluster headache attacks before they start and has shown promise as a therapy for iCCH – being able to reduce the frequency and intensity of attacks and medication use in some patients.⁴⁻⁸

SPEAK TO YOUR DOCTOR TO LEARN MORE ABOUT OCCIPITAL NERVE STIMULATION AND MEDTRONIC'S ANKERSTIM^{TT} LEAD AND SYSTEM

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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Medtronic

Europe

Medtronic International Trading Sàrl. Route du Molliau 31 Case postale CH-1131 Tolochenaz Tel. +41 (0)21 802 70 00 Fax +41 (0)21 802 79 00

United Kingdom/Ireland

Medtronic Limited Building 9 Croxley Park Hatters Lane Watford Herts WD18 8WW www.medtronic.co.uk Tel: +44 (0)1923 212013 Fax: +44 (0)1923 241004

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A NEW TREATMENT FOR INTRACTABLE CHRONIC CLUSTER HEADACHE PATIENTS (iCCH)

Medtronic

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INTRODUCING OCCIPITAL NERVE STIMULATION FOR INTRACTABLE CHRONIC CLUSTER HEADACHE (iCCH)

Cluster headache is a severe headache condition that is different from migraine and tension-type headaches. It affects about 1 in 1,000 individuals.¹

Cluster headaches are characterized by extreme pain attacks on one side of the face, typically around the eye, lasting 15 to 180 minutes and occurring once every other day, up to 8 times per day.² Other symptoms associated with the attacks may include.²

- Redness or tearing of the eye
- Constriction of the pupil
- Drooping and/or eyelid swelling
- Nasal congestion or runny nose
- Forehead and facial sweating
- Restlessness or agitation

When these attacks last for more than 1 year or you have periods without headaches that last less than 1 month, the condition is considered chronic.²

Treatments for chronic cluster headache (CCH) include preventative medications and abortive treatments (to stop the headache after it starts). For those who are unable to obtain relief from multiple treatments, the condition is considered refractory or intractable (iCCH).

If you have been diagnosed with CCH and are not getting satisfactory relief despite trying multiple treatments, you may qualify for a new medical implant intended to reduce the frequency of attacks before they start.

FREQUENTLY ASKED QUESTIONS

What is Occipital Nerve Stimulation?

Occipital Nerve Stimulation (ONS) therapy consists of applying mild electrical stimulation to the nerves via wires implanted just under the skin, near the occipital nerves at the base of the head. The wires are connected to an implanted battery that generates the stimulation, which interferes with pain signals and may evoke the sensation of tingling or paresthesia.

The AnkerStim[™] lead is a new product that is CE mark approved for ONS for iCCH. It is specially designed for better performance and comfort, compared to previous devices.

What will be implanted in my body?

If you and your doctor decide that ONS is right for you, the system will be implanted during a surgical procedure. Your doctor will discuss what to expect for your specific procedure.

AnkerStim™ Lead

One or two leads (thin, flexible wires) are implanted just under the skin at the base of the head. You may have leads implanted on both sides of your head, or on only one side; your doctor will decide which is best for you. The wires are

placed under your skin using an extension wire and connected to an implanted neurostimulator (battery) that generates the stimulation. The battery is commonly implanted in the abdomen or upper buttocks area. There are two types of batteries: Rechargeable and Recharge-free.



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The stimulation interferes with pain signals and possibly restores balance with non-functioning nerves.³

Implanted system



Can I control the stimulation?

Your doctor will program the settings based on your needs and preferences, but you can adjust the level of stimulation using your handheld programmer, which works like a remote control. This handheld programmer allows you to turn your device on or off, and adjust the intensity of the stimulation.

