Peripheral Nerve Stimulation for Intractable Chronic Migraine
Fact Sheet

Peripheral nerve stimulation for intractable chronic migraine is the use of a type of neurostimulation therapy to manage the pain and disability associated with this devastating condition. Intractable chronic migraine is defined as headache lasting at least four hours per day for 15 or more days per month, causing at least moderate disability, and not responding to three or more preventive drugs.

Other frequently used neurostimulation therapies include spinal cord stimulation for the management of chronic pain and deep brain stimulation for the symptomatic treatment of Parkinson’s disease and other movement disorders.

WHAT IS PERIPHERAL NERVE STIMULATION?
Peripheral nerve stimulation (PNS) is a therapy that uses mild electrical pulses to stimulate the nerves of the peripheral nervous system. The peripheral nerves make up a network of nerves outside of the central nervous system. For example, the ulnar nerve in the arms and the sciatic nerve in the legs are part of the peripheral nervous system.

The St. Jude Medical systems currently approved for PNS in select markets look and operate much like a cardiac pacemaker. However, instead of sending pulses to the heart, the pulses are carried to the occipital nerves, located in the back of the head.

FAST FACT
Intractable chronic migraine is defined as headache lasting at least four hours per day for 15 or more days per month, causing at least moderate disability, and not responding to three or more preventive drugs.4

APPLYING PERIPHERAL NERVE STIMULATION TO THE OCCIPITAL NERVES
Stimulation of the occipital nerves has been reported to be effective at managing pain and disability associated with chronic migraine.1 In a St. Jude Medical study, 65 percent of patients reported excellent or good headache pain relief at one year, and 88 percent said they would recommend the procedure to someone else. Additionally, study results showed that 67 percent of patients expressed that their quality of life had improved one year after implant.2

Researchers believe that by delivering electrical pulses to these specific peripheral nerve fibers, PNS may influence the way the nerves communicate with the brain and provide an alternative to long-term drug therapy for the relief of chronic migraine.
unlike pharmaceutical treatments, neurostimulation therapies are targeted to the source of the problem, rather than delivered systemically throughout the body.

HOW DOES A NEUROSTIMULATION SYSTEM WORK?

A neurostimulation system has four parts:

- **Neurostimulator** (or pulse generator) — a stopwatch-sized metal case containing the battery and electronics that create the pulses which stimulate the nerves
- **Leads** — thin wires with several electrodes or contacts that carry mild electrical pulses from the neurostimulator to specific nerves
- **Controller** — a remote control device that enables a patient to turn the neurostimulation system on and off, adjust power levels, and select from preset programs
- **Programmer** — a remote control device that enables a medical professional to adjust and fine-tune the stimulation programs

To receive a neurostimulation system for chronic migraine, the patient undergoes a minor surgical procedure in which one or more leads are placed just under the skin near the occipital nerves to be stimulated. The leads are then connected to the neurostimulator which comprises the power source and the system electronics. The system is activated and the neurostimulator is individually programmed to best control the person’s migraine symptoms.

Patients routinely undergo a temporary evaluation or trial so that they are able to understand what the stimulation feels like before they commit to the surgical implant of the system. Neurostimulation therapies like peripheral nerve stimulation are reversible. Physicians can immediately cease treatment by turning off or removing the stimulator.

The St. Jude Medical Genesis™ neurostimulator was the first and only fully implantable neurostimulation system approved in Europe and Australia for PNS of the occipital nerves for the management of the pain and disability for patients diagnosed with intractable chronic migraine. Recently, additional approvals were granted in Europe for the Eon™, Eon Mini™, and the EonC™ rechargeable neurostimulators for this condition. Use of a neurostimulation for the treatment of chronic migraine in the U.S. is not approved by the U.S. Food and Drug Administration.

WHAT IS MIGRAINE?

Migraine is a neurological disorder characterized by a number of specific symptoms that can last for hours or days at a time. The severity of each migraine attack can vary widely, with typical symptoms ranging from sensitivity to light, noise and motion, to nausea and vomiting in addition to headache. In general, people suffering from chronic migraine have progressed to the level where they have migraine or migraine-like symptoms on more days than they are migraine free. Intractable chronic migraine is defined as headache lasting at least four hours per day for 15 or more days per month, causing at least moderate disability, and not responding to three or more preventive drugs. Estimates by the World Health Organization (WHO) indicate that 10 percent of adults worldwide suffer from migraine, and 1.7 to 4 percent of adults have headaches on 15 or more days per month. In fact, migraine ranks as one of the top 20 most disabling conditions in the world, according to WHO.

REFERENCES

