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**Patient information**

 **NEURIMPULSE**



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## WHAT IS NEUROSTIMULATION?

Neurostimulation is a pain control therapy which has been approved and recommended by doctors and can be useful in improving the quality of life of patients suffering from chronic pain. Neurostimulation can be central (spinal cord stimulation) or peripheral.

The neurostimulation of the peripheral system involves targeted action in the area in which pain is felt, using less invasive methods and systems compared to central stimulation.

The Neurimpulse system for peripheral stimulation has been approved by the Istituto Superiore della Sanità [ Italian Institute of Health ] as a treatment for chronic pain.

Patients suffering from chronic pain in the peripheral system should know that there are several treatment options.

One possibility is drug therapy. If drug therapy is not effective, there are other options including physiotherapy or psychotherapy, surgery, nerve blocks or medical devices such as neurostimulators and infusion systems.

The implantation of a neurostimulator may lead to:

- a 50% decrease in pain
- a reduction in or elimination of the use of drugs
- an overall improvement in quality of life.

Neurostimulation does not however cure the causes of pain. It is a therapy, the purpose of which is to mask pain, blocking the transmission of pain signals to the brain.

If you wish to know whether neurostimulation therapy is right for you, please contact a pain specialist.

### Leonardo's story (27 years old)

In 2007, Leonardo was required to undergo surgery in order to remove a chondroma at the level of the eighth rib on the right side, a benign tumour that affects the bone tissue.

Approximately two months after surgery however, Leonardo began to experience very severe pain in the abdominal area.

His quality of life worsened as he endured pain for a long period, which limited his physical abilities.

Leonardo's family doctor tried different treatments to control the pain.

Oral medications were not very effective and had many drawbacks.

After one year, Leonardo's doctor referred him to a pain management specialist who diagnosed him with intercostal neuritis.

The specialist suggested that Leonardo try Neurimpulse neurostimulation therapy.

Leonardo underwent a trial period in order to determine whether he was an ideal candidate for the therapy.

The patient reported that he felt significant relief from the pain in the affected area due to stimulation during the test period. As a result, in May 2011, Leonardo had the neurostimulator implanted.

After the neurostimulator was implanted, Leonardo reported a 90% decrease in pain, with almost complete coverage of the affected area. In addition, he stopped taking medication entirely. Leonardo has gone back to work and can even play football with friends.





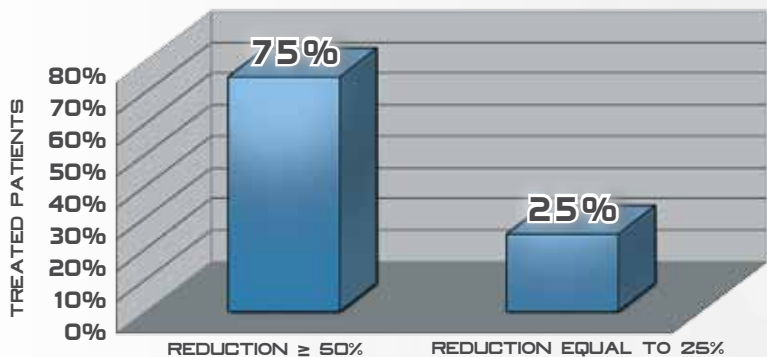
## **NEUROSTIMULATION: AN EFFECTIVE THERAPY**

In recent years many clinical studies have been carried out in order to determine the effectiveness of this therapy.

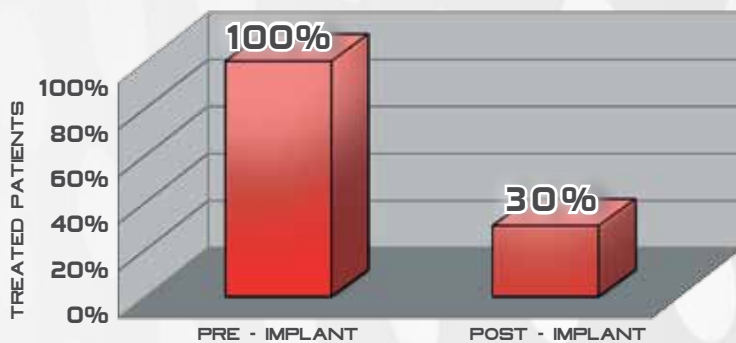
The purpose of these studies has been to evaluate certain parameters such as, for example, the reduction in pain, improvement in the quality of life and the level of daily activity.

The diagrams below show the data obtained from some of these studies.

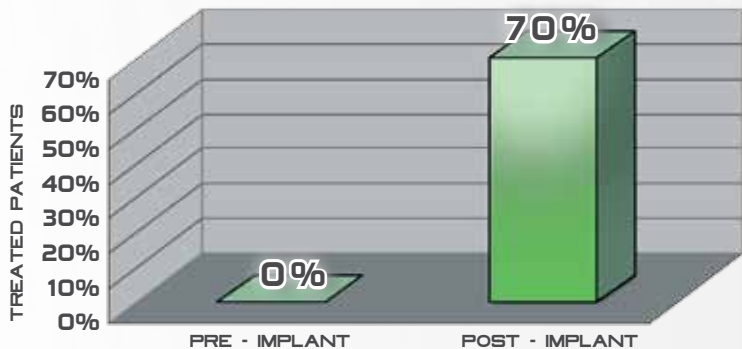
**PAIN REDUCTION**



**ADMINISTRATION OF NSAIDS-OPIOIDS**



**WORK ACTIVITY**

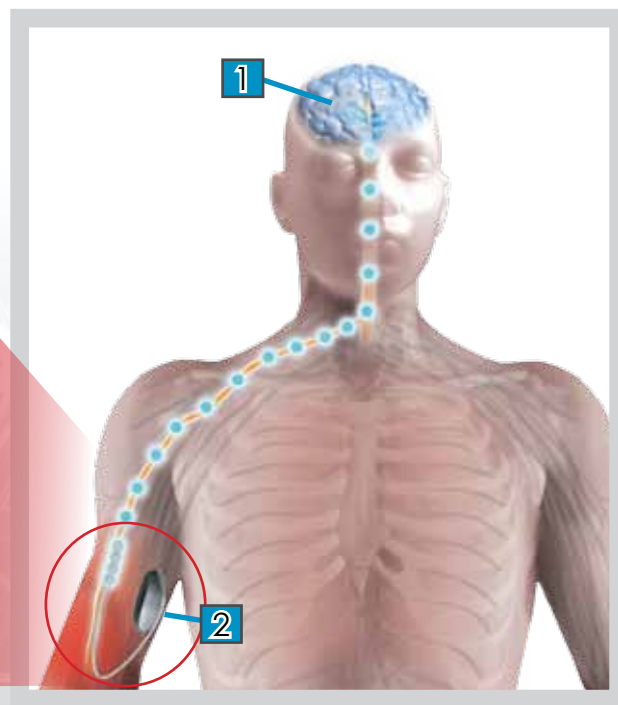


## HOW DOES NEUROSTIMULATION WORK?

Neurostimulation intercepts pain signals before they reach the brain. For this purpose, a small stimulator generating electrical signals is implanted under the skin. These signals run through the nerves, masking the feeling of pain and replacing pain with a pleasant feeling.

Patients sometimes report that it feels like a light massage and sometimes like a tingling sensation.

- 1** Pain signals reach the brain through the nervous system.
- 2** A generator sends electrical pulses through a lead (thin wire).
- 3** The lead sends pulses to the surrounding peripheral nerves.
- 4** The pulses are perceived as a pleasant sensation that replaces the painful sensation.





The intensity of the stimulation can be adjusted by the patient via a remote control handset. In addition, it is possible to set different levels of stimulation at different times of the day.

## THE COMPONENTS OF THE SYSTEM

The peripheral neurostimulation system consists of three components.

- Neurostimulator: this is a pulse generator equipped with a battery. It is normally implanted subcutaneously in a comfortable area for the patient (depending upon which area is to be treated).
- Lead: this is a thin wire which transmits power from the stimulator to the surrounding nerves through the catheter tip.
- Patient programmer: this is a remote control supplied to the patient which allows the patient to vary the intensity of the stimulation.



## WHO CAN BENEFIT FROM NEUROSTIMULATION?

It is advisable to consult a doctor who will assess whether or not the type of pain is suitable for treatment by neurostimulation.

The suitability of this type of treatment depends on various factors such as, for example, the intensity of the pain or the extent of the painful area.

The response to treatment will be assessed during a test phase which may last from 15 to 45 days.



## **AN INNOVATIVE SYSTEM**

The neurostimulation systems presently available in the market fall into two groups: systems for the stimulation of the peripheral nervous system and systems for spinal cord stimulation.

The choice of the most appropriate system depends mainly on the position and extent of the area affected by pain.

The Neurimpulse neurostimulation system is an innovative system that different from the systems already available in the market as it is specifically designed for peripheral neurostimulation.

In general, peripheral neurostimulation involves less risk than spinal cord stimulation.

This is mainly due to the less invasive technology used.

The benefits include:

- a lower risk of infection in the peripheral system which has no components within the epidural space
- full reversibility of implantation of the system: if necessary it can be easily removed without particular risks
- the small size of the system compared to those designed for spinal cord stimulation.

The treatment is not significantly invasive, which means that the risks are negligible.

However, as with any therapy, side effects may arise.

## ADVANTAGES OF THE SYSTEM

- Pleasant tingling sensation in the painful area
- Pain reduction of at least 50%
- Reduction or elimination of painkillers
- Improvement in quality of life (return to daily activities, work, etc.)
- Use of a minimally invasive neurostimulator for easy positioning
- Personal aesthetics unaffected thanks to the small size of the system.

## POSSIBLE CONSEQUENCES

- No stimulation, resulting in loss of pain relief, due to the dislodgement of the lead or to other system problems
- Not optimal stimulation in the painful points if the leads are dislodged from the right position
- Annoying stimulation
- Communication problems between the neurostimulator and the remote control.

In addition, it is good practice to consider the fact that the implantation of a neurostimulation system involves surgery and that there is a risk of infection with the consequent removal of the system.

Finally, any type of complication related to the system may require additional surgery to reposition or replace components.

## NOTE

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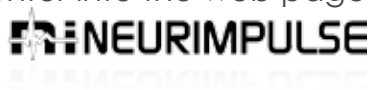
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