

# freedom-8A

# freedom-4A

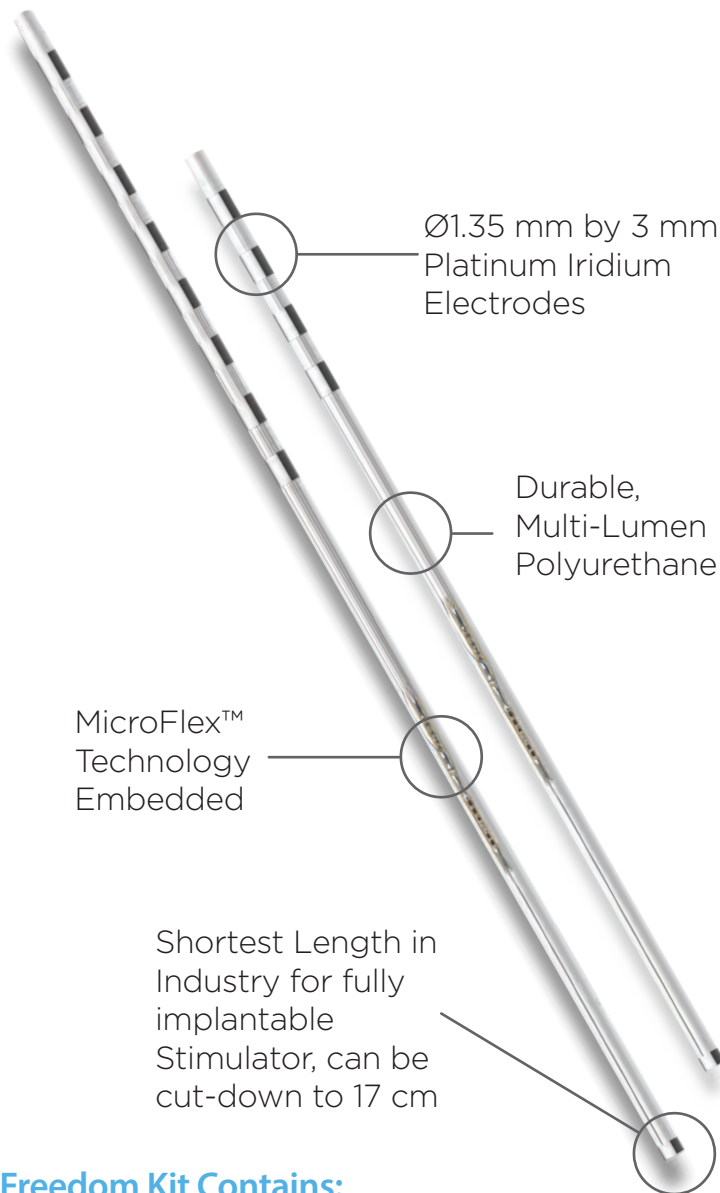
Introducing the **Freedom-8A** and **Freedom-4A**, the world's first passive, electrode-selectable, wireless, microsize stimulator platform for pain management. The device is placed through a 14G needle, leveraging nanotechnology and advancements in high frequency energy transmission. This approach brings the complexity outside the body, eliminating wires, tunneling, and large pockets. The implanted device is 95% smaller than alternative Spinal Cord Stimulators, making Freedom SCS System the **least invasive SCS product available!**

## Technical Specifications:

Diameter	1.35 mm
Electrode/Spacing	3 mm / 4 mm
Total Length/Cut Length	45 cm / 17 cm
Total Pulse Current	0 - 24 mA
Pulse Width	10 - 1,000 $\mu$ s
Pulse Rate	5 - 10,000 Hz
MR Conditionality	1.5T & 3T Full Body

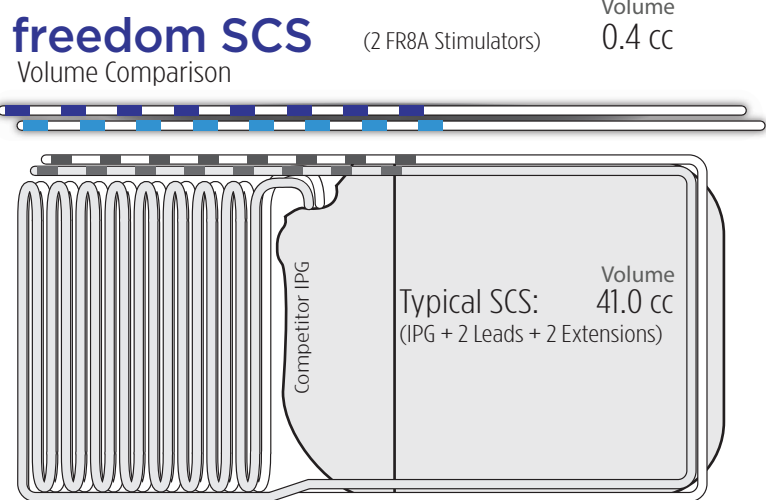
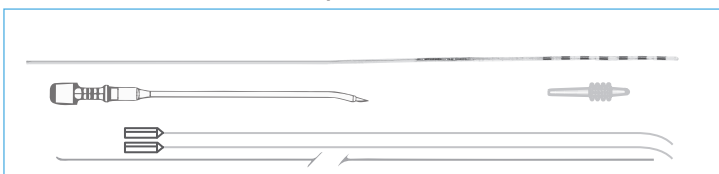
## Freedom Stimulator Features:

- Quick Epidural SCS Placement and Anchoring
- DRG Placement with Transforaminal Entry
- Minimally Invasive Implantable with Simple Anchoring
- Visualize with Fluoroscopy, Ultrasound, or Endoscope
- No Implanted Batteries
- Wireless Power Transmission



## Freedom Kit Contains:

- One Receiver Stimulator
- One 14 G Needle-Introducer
- Two Stylets
- One Guide Wire
- One Suture Sleeve Cap (Anchor)



Distributed by:  
Freedom Neuro BV  
J.J. Viottastraat 52  
1071 JT Amsterdam  
The Netherlands



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www.stimwave.co.uk





# freedom

## Spinal Cord Stimulators™



The Most Versatile System:

-  Low-Frequency
-  High-Frequency
-  Spike Waveforms
-  DRG Transforaminal Placement
-  IPG-Free Percutaneous Procedure
-  1.5T & 3T MRI Full Body Conditional

**wireless pain relief®**



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# TREAT YOUR SHOULDER PAIN

With the Freedom Stimulator System  
Less Pain and More Living™



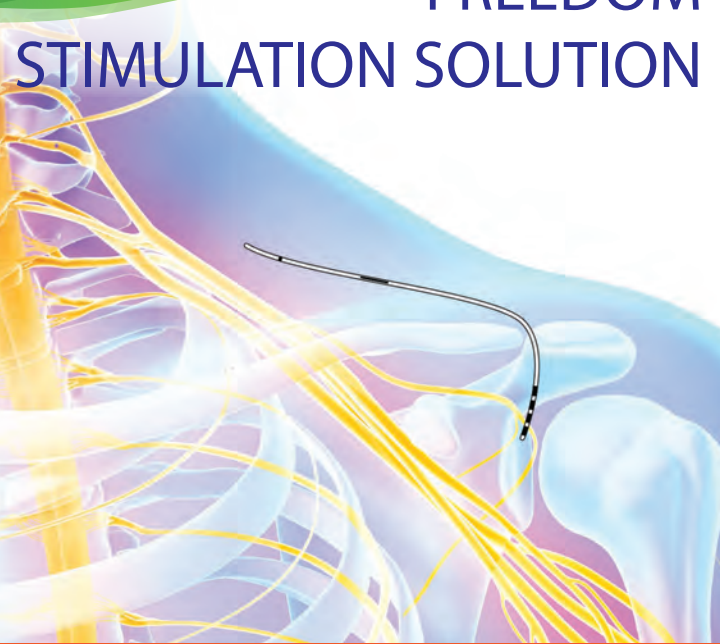
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## SUPRASCAPULAR & BRACHIAL PLEXUS PAIN

Arthroscopic shoulder surgery has a 45% incidence of leading to severe postoperative long-term pain. Many patients suffer from chronic shoulder & scapula pain and occasional numbness of the entire joint making it impossible to have normal mobility in their arm. Many patients report ongoing recurrence of pain radiating to the scapula and down the arm or into the upper back. **The suprascapular nerve supplies 70% of the sensory nerve supply to the shoulder joint.** You may have tried various treatments, such as muscle relaxants, physical therapy, non-steroidal anti-inflammatories, opioids or radiofrequency ablation/lesioning to help treat your pain. You may have had suprascapular nerve blocks to help relieve your post-operative or chronic shoulder pain, **however there is a limit to how many of these type of injections you can have** due to concerns with systemic toxicity. Suprascapular nerve stimulation for pain relief due to arthroscopic shoulder surgery is an effective and safe method for long-term relief of postoperative pain. The Freedom Stimulator is placed with a minimally invasive procedure through only a small incision over the suprascapular nerve in the shoulder. The ability to restore mobility and freedom with less shoulder pain, for more living, puts you back in control of your life.

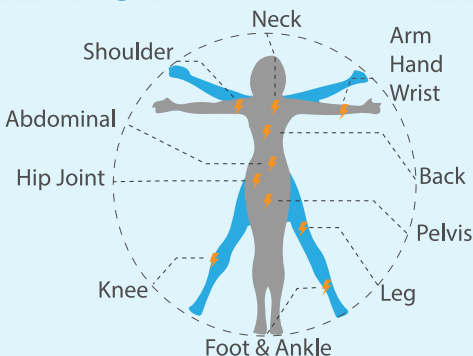
# FREEDOM STIMULATION SOLUTION



## Why Stimulation?

Stimulation uses electrical signals to interrupt pain signals to the brain. A stimulator, the size of a very small wire with electrodes on it, is placed near the painful nerve to deliver electrical pulses. The intensity and frequency of the electrical current are able to alleviate your pain and help you get back to a normal life! You control the therapy as the Freedom System integrates Wireless Pain Relief® into your clothes and daily activity, so you can have less pain and more living!

## FULL BODY PAIN RELIEF™



# freedom

## Stimulators™



Programmer



Wearable Antenna  
Assembly



Freedom-8A/-4A  
Receiver



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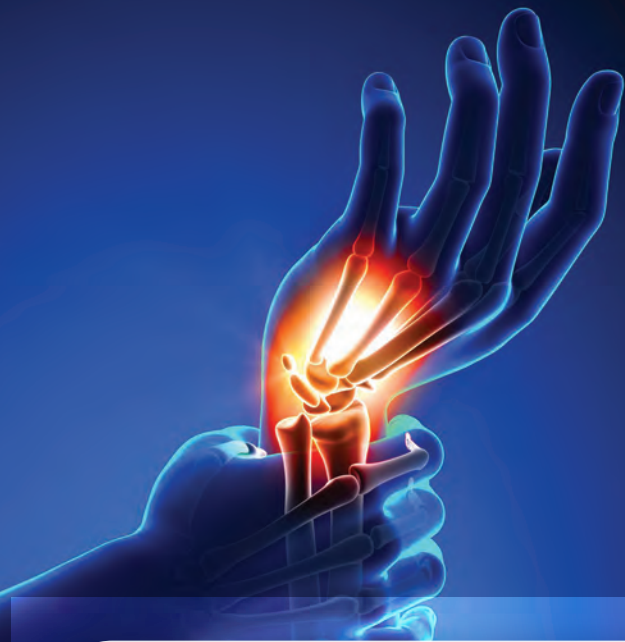
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# TREAT YOUR ARM & WRIST PAIN

With the Freedom Stimulator System  
Less Pain and More Living™



**wireless pain relief®**



## ULNAR & RADIAL PAIN

The ulnar nerve runs from the shoulder to the hand and is responsible for carrying nerve signals between the hand and the brain, enabling motion and feeling in the hand and forearm. Ulnar neuropathy is an inflammation or compression of the ulnar nerve, resulting in numbness, tingling, and pain. Estimates are that **40% of Americans experience some form of this neuropathy at some point in their lives.** Ulnar neuropathy can be caused by compressive injury, by leaning or resting on the elbows or a blow to the elbow or ulnar nerve entrapment. Symptoms include:

- Weakness/ Tenderness in Hand
- Sensitivity to Cold
- Tingling in Palm & 4th/5th Fingers
- Elbow Tenderness
- Burning Feeling in Hand, Arm or Fingers

You may have tried occupational therapy, non-steroidal anti-inflammatories, splints, steroid injections, or even non-entrapment surgery to restore function and alleviate pain. You may have tried a multitude of these treatment options that provided some short-term relief, only to find that the pain has returned. If none of these options have really provided long-term relief, peripheral nerve stimulation with the Freedom Stimulator System may be a viable option to let you start living again with less pain!



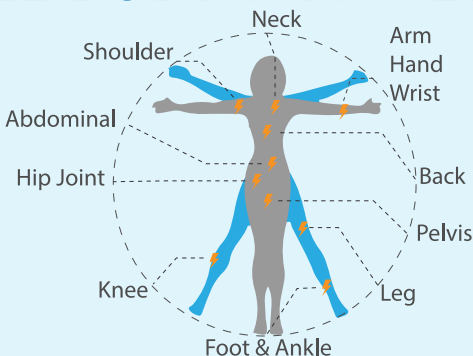
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# freedom

## Stimulators™



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Receiver



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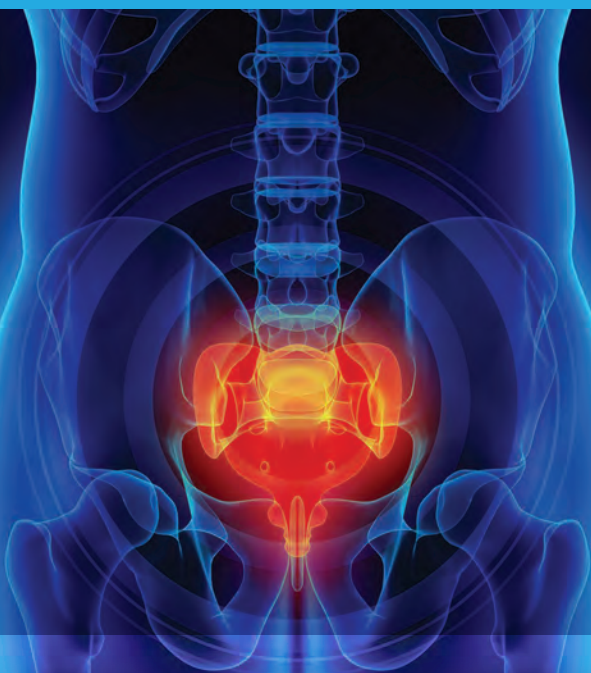
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# TREAT YOUR S.I. JOINT PAIN

With the Freedom Stimulator System  
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# SACROILIAC JOINT PAIN

Studies show that up to 62% of chronic low back pain is sacroiliac joint in origin<sup>1</sup>. Pain from sacroiliac joint disorders can be felt anywhere from the lower back, buttocks, or in the legs. Chronic SI joint pain can make it difficult to perform common daily tasks, and affect every aspect of a patient's life. Chief complaints include:

- low back pain
- numbness
- tingling
- weakness
- pelvis/buttock pain
- hip/groin pain
- leg instability
- disturbed sleep
- inability to sit long

You may have tried physical therapy, massage therapy, chiropractic care, anti-inflammatories, steroid injections, nerve blocks, radiofrequency ablation, or even fusion to help alleviate the pain. Many of these treatments can only provide temporary relief, and your long-term chronic pain may persist. Sacroiliac Joint Chronic Pain can be effectively treated with peripheral nerve stimulation<sup>2</sup>.

1-Shushovan Chakraborty, et. al. "Intractable sacroiliac joint pain treated with peripheral nerve field stimulation" *Journal of Anaesthesiology Clinical Pharmacology*. 2016;32:392-394.

2-Guentchev, Marin, et. al. "Technical Note: Treatment of Sacroiliac Joint Pain with Peripheral Nerve Stimulation." *Neuromodulation*. Volume 18, Issue 5. July 2015. 392-396.

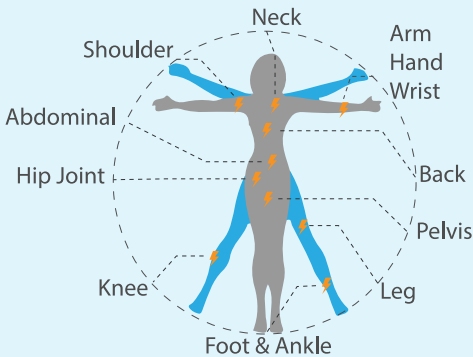
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# TREAT YOUR BACK PAIN

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## CLUNEAL NERVE PAIN

Neuropathic chronic low back and hip pain is the largest proportion of direct medical costs in the US. According to the Bureau of Labor Statistics, **approximately 2% of the work force are compensated for back injuries each year.** The cluneal nerves are formed from the lumbar and sacral spine nerve roots. The cluneal nerves are the primary sensory nerve supply to the iliac crests, hips, buttocks, and thighs. When the pain is located in the focal area across the top of the hips, it is usually carried to the brain by the superior cluneal nerves. Spinal surgery can result in scarring and fibrosis, alterations in muscle tension criss-crossing layers of tissue, and surgical trauma to the nerve branches if bone is harvested from the iliac crest. These various pressure stresses on the cluneal nerves in the low back can result in:

- Neural entrapment
- Neural tethering (stretching)
- Chronic, indolent neuralgia
- Altered biomechanics of adjacent fascial planes

The Freedom Stimulator is placed with a minimally invasive procedure through only a small incision over the cluneal nerve in the lower back. Peripheral Nerve Stimulation for Cluneal Nerve is a treatment for your long-term neuropathic and mechanical low back pain effectively without drugs!



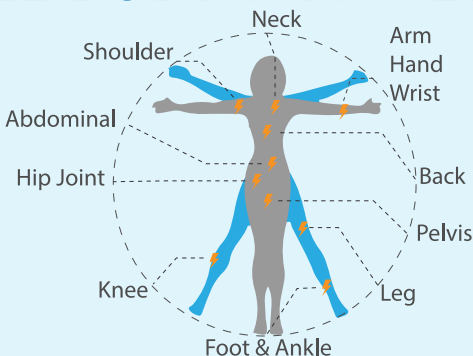
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## FULL BODY PAIN RELIEF®



# freedom

## Stimulators™



Programmer



Wearable Antenna  
Assembly



Freedom-8A/-4A  
Receiver



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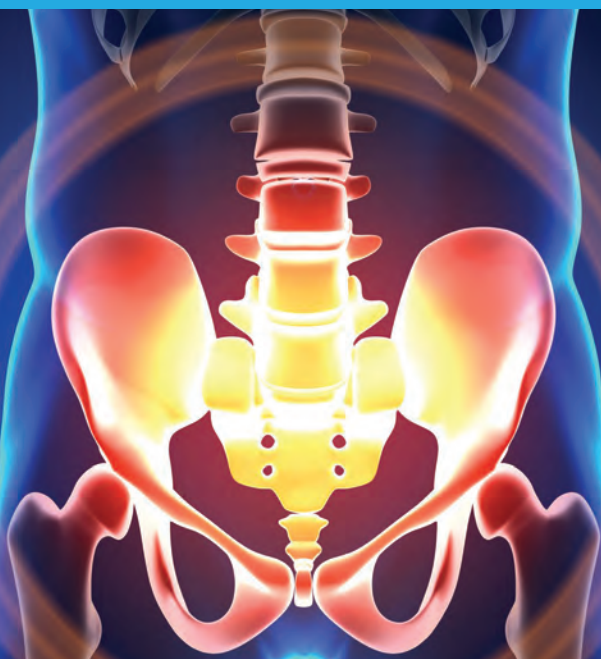
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# TREAT YOUR PELVIC PAIN

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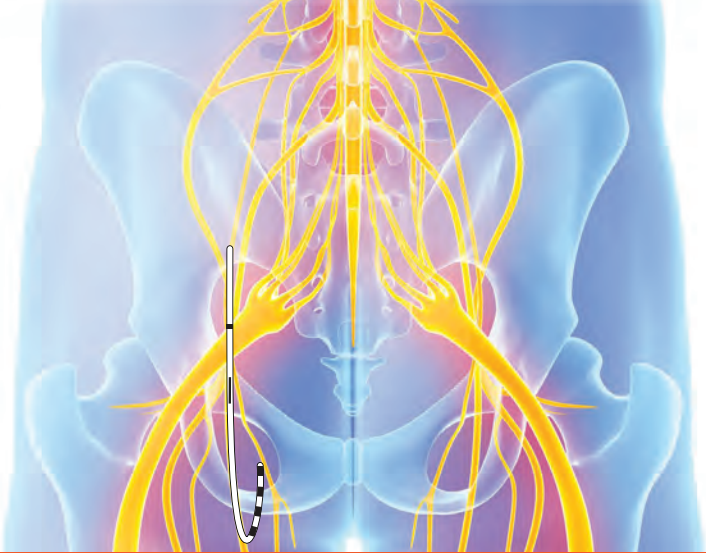


## PUDENDAL NERVE PAIN

Irritation, compression or injury to the pudendal nerve is a common cause of pelvic pain. The **pain can be felt in the bladder, pelvis, vagina, penis, scrotum and rectum and even refer to inner thighs and is a common cause of sexual pain.** The pain can be worse when sitting. A pudendal nerve block resulting in temporary relief of symptoms helps confirm the diagnosis. Risk factors may include pelvic trauma, bike riding, childbirth, pelvic surgery, peripheral neuropathy or pelvic mass. However, in most cases an exact cause cannot be identified. Pudendal nerve pain is often misdiagnosed as other pain disorders such as interstitial cystitis, chronic prostatitis and endometriosis. Common treatments include non-steroidal anti-inflammatories, cortical steroids, pelvic floor physical therapy, trigger point injections, pudendal nerve blocks, botulinum toxin injections of the pelvic floor, epidural steroid injections, surgical decompression and pulsed radiofrequency ablation of the pudendal nerve.

If you suffer from pudendal nerve pain and have tried other treatments that only provided temporary relief of symptoms, peripheral nerve stimulation with the Freedom Stimulator system may let you start living again with less pain!

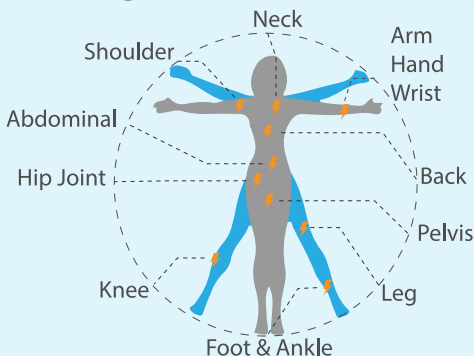
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# TREAT YOUR HERNIA PAIN

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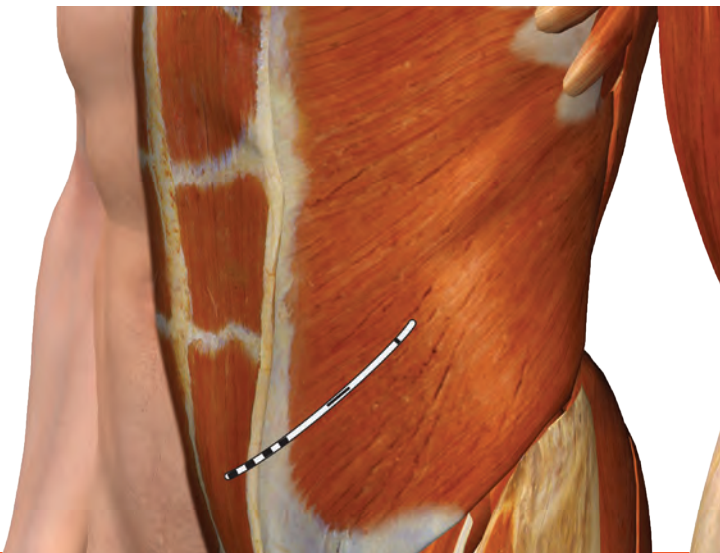


## ILIOINGUINAL PAIN

There are over **1,000,000 hernia repair surgeries in US annually** with over 80% estimated to repair an inguinal hernia which is one of the leading causes of abdominal and groin pain. Complications from these procedures can include recurrent surgery, infection, pain and adhesions. Pain present in the abdominal and/or groin area can be just subtle, to completely debilitating. This type of pain does not always respond well to pharmacologic treatment options. Nerve blocks are the most common treatment, however they are not usually a solution for long-term relief. The nerve fibers running through this area of the body are called the ilioinguinal nerves. **Peripheral nerve stimulation has been shown to provide pain relief for post surgical hernia pain.** Small wire-like devices are placed over the inflicted nerves around the hernia incision using a minimally invasive technique. The wires are activated from an external device that will energize the implant and block the nerve pain transmission signal to the brain. **The result?** The pain is reduced significantly, with some patients being completely pain free!



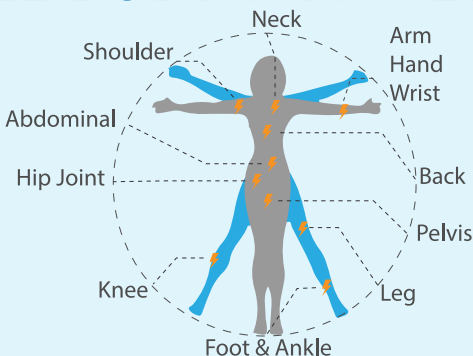
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# TREAT YOUR KNEE PAIN

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## CHRONIC KNEE PAIN

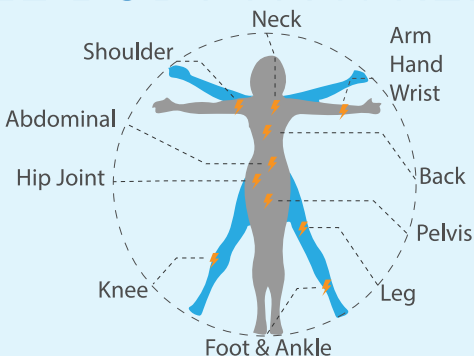
**Over 500,000 total knee replacements are done each year in the USA.** While most are successful, chronic postoperative pain occurs frequently. The pain is believed to be caused from peripheral nerve or soft tissue injury, or even neuroma formations, causing joint pain in more than 20% of patients over one year following the surgery. Treatment options include: **knee mobilizations, surgical revisions, nerve block injections, physical therapy, radio frequency ablation, or pain medication such as non-steroidal anti-inflammatory drugs (NSAIDs) or opioids.** You may have also tried physical therapy, anesthetic patches, and TENS. If you are one of these patients, you may have a significant disability and are dealing with ongoing rehabilitation at great expense and inconvenience. Although these treatments **may have provided some short-term relief, many times the pain returns...** Peripheral nerve stimulation with the Freedom Stimulator system may be a viable option to let you start living again with less pain for long-term relief! The Freedom Stimulator is placed with a minimally invasive procedure through only a small incision over the lateral and medial knee. The ability to restore mobility and freedom with less knee pain, for more living as quick as the same day, puts you back in control of your life!

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Indications for Use. The Freedom System is intended as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or lower limbs; all peripheral nerves excluding the cranial nerves. The Freedom System is contraindicated for patients who: are unable to operate the Freedom System, are poor surgical risks, are pregnant, have an occupational exposure to high non-ionizing radiation, are implanted with cardiac system, or diathermy. Refer to the Instructions for Use provided with the Freedom System or Stimwave.com for potential adverse effects, warnings, and precautions prior to using this product. Rx Only. Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician. Wireless Pain Relief® is a registered trademark of Stimwave. Stimwave LLC is a distributor of Stimwave Technologies Inc, and StimQ LLC.

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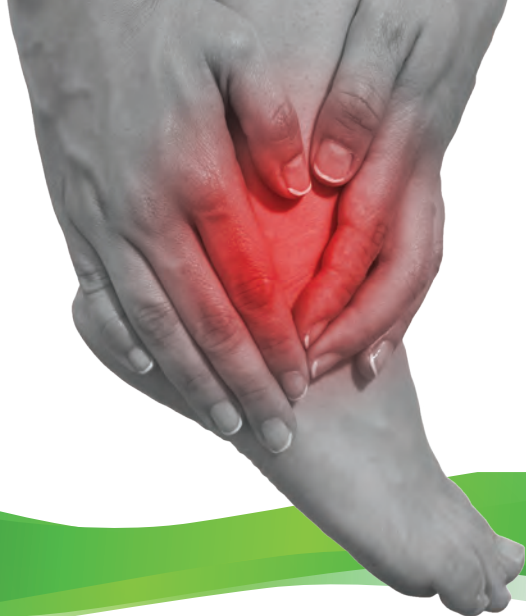


# TREAT YOUR LEG & FOOT PAIN

With the Freedom Stimulator System  
Less Pain and More Living™



**wireless pain relief®**



## TIBIAL AND SURAL NERVE STIMULATION

Lower leg and foot pain can be caused by peripheral neuropathy from diabetes, direct trauma, pressure on the nerve for a long period of time, and even nerve entrapment from scar tissue or pressure on ligaments around the ankle and foot. **You may be experiencing symptoms like: numbness, pain in the bottom of the foot and toes, weakness or deformation of foot muscles, toes or ankle. This may include prickling, tingling or the sensation of pins and needles with shocking, shooting or even a burning pain.** You may be experiencing pain from the lightest touch to the skin, from changes in weather, itching, or even radiating pain throughout the entire limb. Surgical removal of lesions that press on the nerve may benefit some people, but many are still left in pain. You may have tried various medications or even physical therapy, however it may be really hard and painful to exercise or even walk with the pain. You may have tried nerve blocks or radio frequency ablation that provided some short-term relief, only to find that the pain has returned. If none of these options have really provided long-term relief, peripheral nerve stimulation with the Freedom Stimulator System may be a viable option to let you start living again with less pain!

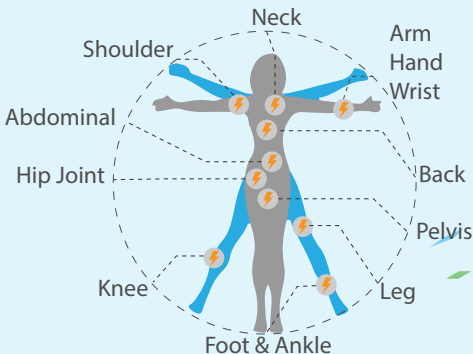


# FREEDOM STIMULATION SOLUTION



Stimulation uses electrical signals to interrupt pain signals to the brain. A stimulator, the size of a very small wire with electrodes on it, is placed near the painful nerve to deliver electrical pulses. The intensity and frequency of the electrical current are able to alleviate your pain and help you get back to a normal life! You control the therapy as the Freedom System integrates Wireless Pain Relief® into your clothes and daily activity, so you can have less pain and more living!

## FULL BODY PAIN RELIEF®



# freedom

## Stimulators™



Programmer



Wearable Antenna  
Assembly



Freedom-8A/-4A  
Receiver



Freedom System offers the same therapy as other systems... without an implanted battery, the system is only 5% the size, and is the Most Minimally Invasive.



Don't lose out on therapy options. Program for Low Frequency, High Frequency\*, Surge, DRG, or PNS.



Upgrade your externals to evolve with your lifestyle and cutting edge technology. No surgery needed for upgrades.

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# WIRELESS PAIN RELIEF<sup>®</sup>

With the NEW Freedom Stimulator,  
You'll have Less Pain, and More Living<sup>™</sup>



# freedom

Stimulators

2

Micro  
Stimulators



+



1

External  
Transmitter



# SMALLEST STIMULATORS AVAILABLE



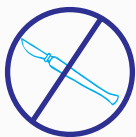
Freedom System offers the same therapy as other systems.... without an implanted battery, only 5% the size, and is the MOST **Minimally Invasive Option Available**



Don't stop your standard **treatment!** Freedom System allows for Full Body 1.5T & 3T MRI Scans.



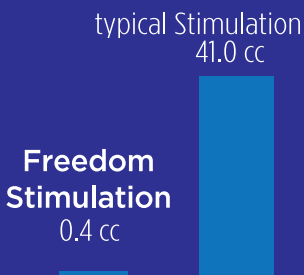
Don't lose out on Therapy Options. **Program** for High Frequency\*, Surge, DRG, or PNS.



**Upgrade** your externals to evolve with your lifestyle and cutting edge technology. No surgery needed for upgrades.

This revolutionary small implant reduces the risk of surgical complications and device related adverse events.

IMPLANT VOLUME



5% of the Size



No Batteries

# MANAGING PAIN WITH LESS DRUGS- USING STIMULATION YOU CONTROL

Understand your options  
for managing chronic pain

Chronic Pain debilitates and limits you  
from having a normal life.

**NOW**, there is a way to effectively treat  
your pain with dramatically less or  
absolutely no drugs through a short  
minimally invasive procedure, and begin  
living in FREEDOM again!



## CONSTANT PAIN —

The inability to consistently terminate or alleviate the painful areas of your body. Nerve pain such as burning, aching, pinching, numbness, and stabbing.

- **Why Stimulation?**

Electrical stimulation has been used for over 40 years to effectively reduce chronic pain.

## OPIOID OVERUSE —

Moderate to heavy dependency of prescribed pain relief medication 3-5x a day plus episodic usage as a relief for chronic pain.

- **Why Stimulation?**

It's a Drug-Free therapy. SCS and PNS therapy and additional tools your physician uses to control your chronic pain, thus reducing your need for long-term medication.

## LIMITED LIFESTYLE —

The inability to function in normal daily activity and routines due to your chronic pain. Walking, bending over, standing up, and exercise.

- **Why Stimulation?**

SCS and PNS therapies have historically improved people's quality of life by reducing pain and allowing you to get back to the everyday activities you enjoy.

# HOW FREEDOM WORKS

1

Stimulation Therapy begins with identifying your greatest pain areas.

2

Through a small cut, the Physician places one or more thin, flexible devices near your spinal column, positioned to provide stimulation to the targeted pain areas.

3

You control the intensity of the stimulation through an external unit that clips into your clothing. The Stimulation disrupts the pain signals to your brain. It feels like a gentle tingling sensation, which takes the place of the pain.

4

Your Stimwave Therapy Specialist is available to program your device to optimize pain relief.

5

As you enjoy your therapy, you may see remarkable pain relief, decreased drug usage, improved mobility, and an overall better of quality of life!





# THE FREEDOM PROCESS



Ask your physician about how a Freedom Stimulator can reduce your pain



Schedule a Freedom Stimulator Trial to test drive the therapy for up to 30 days



After the trial determine whether you are happy with the pain therapy.



Permanent Stimulator Receiver is Implanted either in the spinal column or peripherally.



Follow up for Reprogramming as needed



With an implanted Freedom System, you can begin to live with less pain and more control.

# THINGS TO CONSIDER

- **Is my movement limited after implant?**

After 14 days, you will be able to bend, twist, and operate as you normally would. The implant needs time to secure into your tissue.

- **Will the procedure create more pain?**

The implant procedure is minimally invasive so the risk for surgical damage is low. You will experience soreness for the first day or two from the needle.

- **Will it remove ALL of my pain?**

Stimulation does not heal your body, rather it masks the pain signal to your brain. It may not cover all of your pain. The trial run is a time to evaluate if Stimulation is of benefit to your condition.

- **How long does the external last?**

The external transmitter can last from 8 to 14 hours depending on the therapy settings. You are given two transmitters to allow one to be charging and one to be in use, simultaneously.

- **Can I shower with my external device?**

Your external device must be removed before showering to prevent water damage. During your trial period and during the first 2-3 days post-implant, a sponge bath is recommended.

- **Does insurance cover the implant cost?**

Most insurance companies and Medicare cover Stimulation procedures. Check with your provider to understand your financial responsibility.

## Included in Your Kit:

2 External Transmitters

1 Charger Plug

1 USB Cable

User Guide

Patient ID Card





# Freedom to get FULL BODY 1.5T or 3T MRI Scans†!

stim wave 	✓
1.5T Full Body MRI	✓
3T Full Body MRI	✓



IPG's

✓\*\*

\*\*MRI Conditions for IPG based SCS Systems are extremely limiting and come with long lists of limiting and circumstantial conditions.



MR  
1.5T/3T Full Body†



# How to Get Connected



Learn more about Stimwave, wireless pain relief, the procedure, the product, read patient stories and find answers about the Freedom System by visiting:

[WirelessPainRelief.com](http://WirelessPainRelief.com)

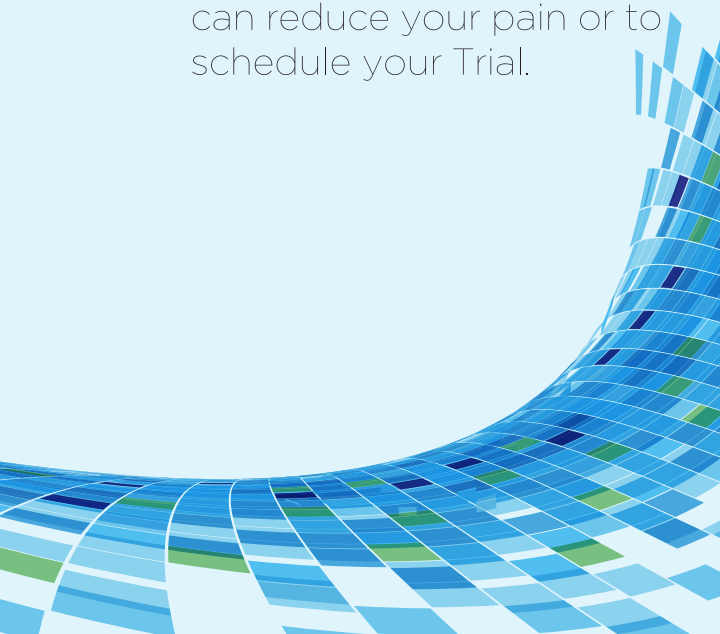


**wireless pain relief<sup>®</sup>**

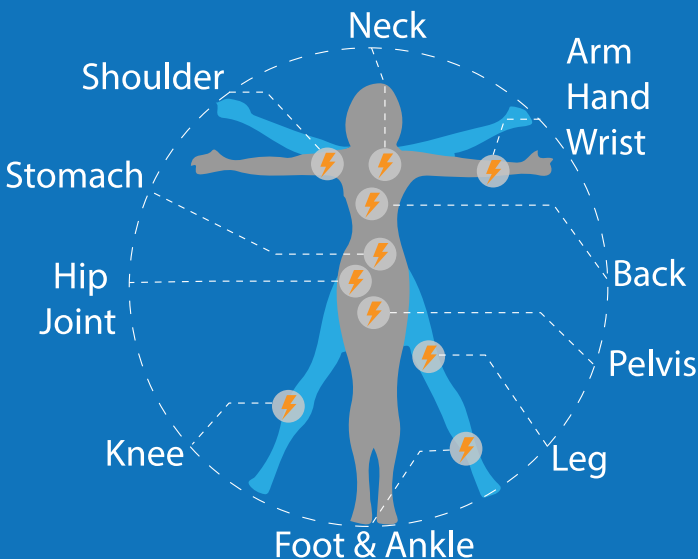




Please talk to your doctor if you are interested in finding out more about how Freedom Stimulators can reduce your pain or to schedule your Trial.



# FULL BODY PAIN RELIEF<sup>®</sup>



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\*Full Body MRI-Use under specific product and conditions for both 1.5T & 3T MRI scans. Refer to approved labeling for complete list of conditions. Indications for Use. The Freedom System is intended as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or lower limbs, including unilateral or bilateral pain. The Freedom System is contraindicated for patients who: are unable to operate the Freedom System, are poor surgical risks, are pregnant, have an occupational exposure to high non-ionizing radiation, are implanted with cardiac system, or diathermy. Refer to the Instructions for Use provided with the Freedom SCS System or Stimwave.com for potential adverse effects, warnings, and precautions prior to using this product. Rx Only. Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician. Wireless Pain Relief<sup>®</sup> is a registered trademark of Stimwave.



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