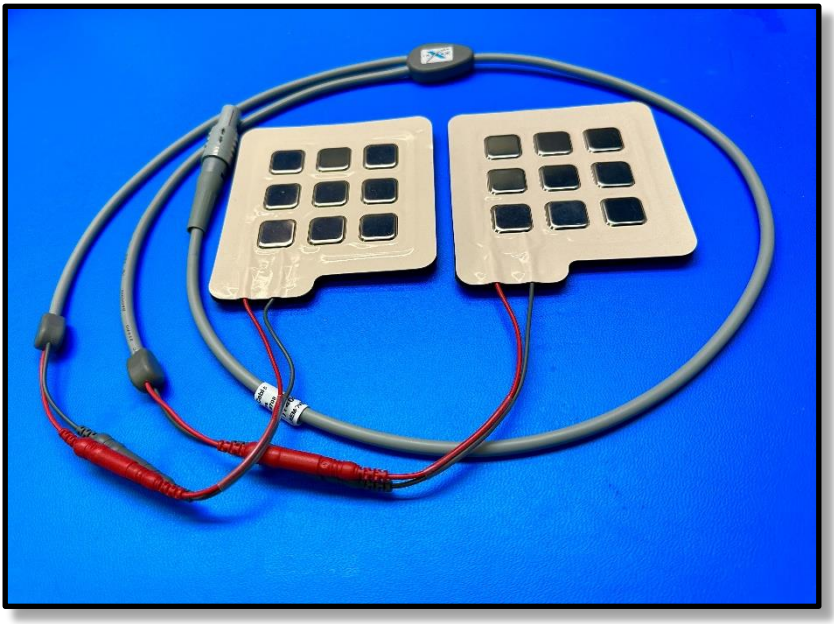
INTERX® COMFORT FLEX III ARRAY™

Instruction Manual



US Patent No. 9,630,003 B2 and Patents Pending

INDICATIONS FOR USE

The Comfort Flex III Array™ is FDA cleared and indicated for symptomatic relief and management of chronic intractable pain, and adjunctive treatment in the management of post-surgical and post-traumatic pain.

InterX® Technologies is an ISO 13485 Registered Company.

The Comfort Flex III Array™ is a Class II medical device and requires a prescription or an NPI number of a medical professional for purchase.

INTRODUCTION

This manual provides information regarding the controls and functions of the InterX® Comfort Flex III Array™. This array™ must be used strictly in accordance with these instructions. Read this manual completely prior to using the Comfort Flex III Array™.

The Comfort Flex III Array™ is a non-sterile product and should not be applied in a sterile field.

The Comfort Flex III Array™ can be safely and effectively used for chronic or acute injuries and for pain after surgery, even for patients with metal implants.

The Comfort Flex III Array™ is not user serviceable.

The Comfort Flex III Array™ is designed for use with the InterX® 5002 Professional Device and the InterX® 1000 Personal Device. Please refer to the Operations Manual for these devices for additional information.

The Comfort Flex III Array™ features and benefits:

- **More malleable** than the 3x3 or 4x4 Flexible Array™ so that it can form to the arm, wrist, foot, ankle, knee, and lower leg more comfortably.
- **Thicker** than the Personal Flexible Array™ so it can form to the neck and spine when lying on the pad and the placement will be more perceptible.
- Delivers stimulation at **all the settings** that are provided by the InterX® 1000 Personal and the InterX® 5002 Pro devices. You will be able to use setting 5 on the 1000 device with the Comfort Flex III Array™. **Use setting 5 with caution, no more than 10 minutes.** Device will shut off in 10 minutes in setting 5.
- Delivers a **numeric reading indicative of skin impedance** when connected to the InterX® 5002 Pro device showing where the stimulation is most effective; with the InterX® 1000 Personal device the patient will determine by sensation the optimal location to treat.

CONTRAINDICATIONS

- Electrode placement over malignant tumors
- Do not use with current or recent history of blood clots
- Transcerebral and/or carotid sinus electrode placement
- Use over mucous membranes
- Undiagnosed pain (until etiology is established)
- Patients who are prone to siezures (e.g. patients with epilepsy)
- Use over pharyngeal or laryngeal muscles. The electrical impulses generated may cause muscle spasm resulting in difficulty in breathing
- Patients that have a **demand-type cardiac pacemaker**
- Electrode placement over or near the **pacemaker that is NOT demand type** - treat away from the pacemaker, never directly over or near it.

WARNINGS AND CAUTIONS

- (USA only) Federal law restricts this device to sale by, or on the order of, a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.
- The user must keep this electrode out of reach of children.
- The safety of the use of InterX® has not been established during pregnancy or childbirth.
- Do not use on patients that are undergoing dialysis or are being treated in an MRI, X-ray, or with other diagnostic equipment that may be impacted by the electrical impulses.
- If you have known metal allergies, use caution when using InterX® devices or accessory electrodes and perform a skin test first to check for reaction.
- This electrode contains high voltages when connected to the electro-stimulation device. Do not use in the vicinity of an exposed live source of electricity and do not operate close to exposed hazardous voltages.
- Spinal cord stimulators should be turned off when using InterX® device and electrodes.
- The Comfort Flex III Array™ electrodes should not be used in the vicinity of equipment or appliances with moving or rotating parts.
- Use caution in applying the InterX® over areas which are swollen, infected, or inflamed as it may result in a worsening of the symptoms. Use above the involved area to stimulate the nerves.
- Do not make contact with the InterX® electrodes on wet skin. Natural bodily fluids, including sweat, are acceptable.
- Avoid placing the Comfort Flex III Array™ on the skin when first turning the InterX® device ON.

WARNINGS AND CAUTIONS

- The Comfort Flex III Array™ electrodes **should not be used in a fixed location for more than 20 minutes continuously**. Wait a minimum of one hour before re-treating the same location again with the array. Inspect your skin between uses for skin sensitivity or redness.
- Skin irritation, bruising, electrode burns, dizziness, nausea, and headaches are potential adverse reactions. Caution should be taken when using high levels of stimulation on sensitive areas, especially thin skin or bony protrusions.
- Built-in device electrodes and external electrodes should not be used in combination trans-cerebrally.
- The InterX® should not be used while driving or operating machinery.
- Do NOT allow individual electrodes to come in contact with one another.
- Do NOT allow individual pads to overlap one another.

NOTE: Both pads of the Comfort Flex III Array™ are active during stimulation and should be in contact with the skin during treatment. If only one pad is required, the other pad should either be disconnected or covered with the provided sock.

DEFINITIONS AND SYMBOLS

DO NOT use this device without adequate training in its function and purpose. Refer to InterX® manuals for additional information.

The symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.

This MD symbol signifies that this product is a medical device.

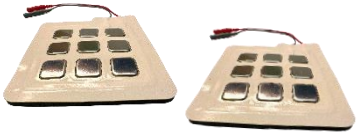
This stimulator is internally powered only. This symbol indicates the device was manufactured according to the degree of protection against electrical shock for this type BF protection class equipment.

This symbol indicates the medical device manufacturer.

The Comfort Flex III Array™ is compatible with both the InterX® 1000 Personal Device and the InterX® 5002 Professional Device. Read the entire device user manual prior to using the Comfort Flex III Array™.

Instructions for Use

Before first use, remove protective film from the square electrode surfaces and assemble the Comfort Flex III Array™. Each Comfort Flex III Array™ includes two Electrodes and one Y-Cable.

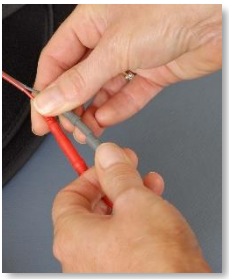


Electrodes

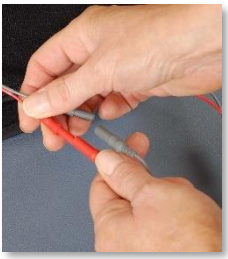
Y-Cable

1. Attach Comfort Flex III Array™ Electrodes to Y Cable

The Y-Cable has two pairs of red and gray connectors which should be connected to the red and gray connectors of each electrode array in the Comfort Flex III Array™ Electrodes. Connect the red connector to red and the gray connector to gray as pictured. The Y-Cable should be connected when there is no active stimulation. NOTE: If electing to use only one electrode array (e.g. to treat a hand), then ensure that only one electrode array is connected.

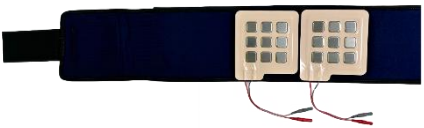


When disconnecting, gently pull the red and grey connectors apart holding the ribbed section of the connector. Do NOT pull the wires to separate the connectors as this may cause damage.



2. Attach the Comfort Flex III Array™ Electrodes to Strap

The Comfort Flex III Array™ Electrodes can be attached to Velcro® straps and can easily be moved further apart or closer together as necessary.



3. Connect the Y Cable to the Device

To connect, plug the connector into the accessory port located at the end of the device. Use care when you plug in the connector, noting the alignment guide for proper connection.

When connecting and disconnecting the Y-Cable from the InterX® device, do not attempt to twist the connector as this may cause damage. Do not pull on the cable. Ensure that the InterX® device is switched off prior to connecting or disconnecting.

4. Place the Comfort Flex III Array™ Electrodes on Skin

Any skin lotions, makeup or oils can make the stimulation sting and can corrode the pads more quickly. Clean the skin prior to treatment.

Place the arrays firmly onto clean skin with the stainless steel electrodes touching the skin. The strap should be wrapped firmly around the area to be treated with both electrode arrays having good contact with the skin.

NOTE: The Comfort Flex III Array™ Electrode placement is determined by multiple factors, including patient complaint, practitioner experience, and skin response. When in doubt, it is safest to treat above or below an injury or on the opposite limb at the same location for the first treatment to determine response. The same nerve root treats both sides so you can get a good effect treating the opposite limb. Eventually move closer to the injured area with successive treatment, and complete treatment with movement with the pads on the injured area when it is safe to move the injured body part.



If using the 5002 device, electrode placement can be determined by looking at the numerical readings on the device when the pads are placed on the skin. Move the pads around the injured area to find the highest reading and also check the opposite limb readings. Treat where the numbers are the highest. When using the 1000 device, treat where you feel the stimulation the strongest using the same pattern.

Ensure that all electrode surfaces have good contact with the skin for maximum effect. Since the Comfort Flex III Array™ can bend around bony prominences, joints, fingers, and toes, take caution to keep the intensity lower as the skin is thin in these areas and the potential for skin irritation is higher over thin skin or bony areas

NOTE: Excessive bending of the personal arrays over time will decrease the life of the pads. Do NOT allow individual electrodes to come in contact with one another. Do NOT allow individual pads to overlap one another.

The sensation from stimulation should never be painful, it should be a strong comfortable sensation.

When treating the back or neck area, you may find it easier to lie on the pads, taking care to ensure that good electrode contact is felt through both electrode arrays.

STEP 5. SET STIMULATION INTENSITY

NOTE: The intensity level should be started at a minimum level and gradually increased until you feel a comfortable tingling sensation. The treatment intensity level will vary from patient to patient and location based upon individual sensitivity to the electric impulse and skin impedance.

Stimulation may feel different at each electrode. Ensure that the most sensitive area receives a comfortable tingling sensation.

The sensation from stimulation should never be painful.

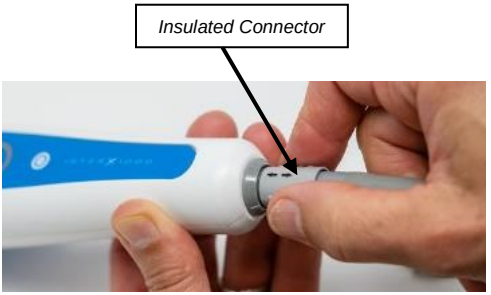
The InterX® Professional Device is designed to allow for no more than 10 minutes of continuous stimulation. The device will pause if the time-on-skin clock reaches 10 continuous minutes without a break. At this time you may continue treating the area with the device electrode or move the Comfort Flex III Array™ electrodes to another treatment area or perform dynamic treatment using movement for up to 5 minutes according to the instruction manual of your device.

The InterX® Personal Device will stimulate for 20 continuous minutes on settings 1 – 4 and 10 continuous minutes on setting 5.

AFTER TREATMENT:

DISCONNECTING INTERX® 1000 FROM THE Y-CABLE

When disconnecting the Y-Cable from the InterX® 1000, gently pull on the insulated connector. Do not attempt to twist the connector as this may cause damage. **Do not pull on the cable** or any other part of the connector.



STORAGE AND CLEANING

Always remove the Comfort Flex III Array™ Electrodes from straps or wrap and detach from device before attempting to clean.

Comfort Flex III Array™ Electrodes - Do not expose to chemical solvents or harsh cleaning fluids. Do not sterilize or immerse in any fluid. Between treatments, thoroughly clean electrodes with 70% isopropyl alcohol wipes. Use of other cleaning solutions may damage the housing. Never spray cleaners directly on the electrodes. Ensure that all leads and connections are disconnected when storing for more than one month. Always transport the Comfort Flex III Array™ with care. When not in use, store safely in dry conditions. **Do not wrap the lead wires around the pads for storage. Excessive bending of the wires will shorten the life time of use.**

Wrap or Strap - Sponge clean or gently hand wash in warm soapy water and hang dry. Do not attempt to dry using a drying machine.

NOTE:

- Safe use of the InterX® Comfort Flex III Array™ is the primary responsibility of the user. The user is responsible for the monitoring of the product.
- Do not use cleaning products on any part of the InterX® System that contain ethyl alcohol and/or ammonium chloride. These chemicals may cause cracking or corrosion of the product's components. The only approved cleaning agent is isopropyl alcohol that is less than or equal to 80% by volume.
- Using unapproved cleaning agents will void the manufacturer's warranty.
- The InterX® Comfort Flex III Array™ is designed for a maximum of 30 days use. If used without extreme bending or pulling on the wires or pads, the arrays will last much longer.
- Contact clinical / technical support if this InterX® product and/or any part of this InterX® Comfort Flex III Array™ appears to be operating incorrectly. Do not use if any part of the InterX® Comfort Flex III Array™ is damaged.
- Do not attempt to sterilize the InterX® Comfort Flex III Array™.

InterX® Comfort Flex III Array™ Warranty

To obtain service, contact InterX® Technologies Customer Service at 972-665-1810, for a Return Authorization (RA) number. Send the entire unit, with all accessories (if applicable), packed in the original carrying case, freight and insurance prepaid to the address provided to you by InterX® Technologies. Include in the package a copy of your original invoice and a note describing the problem. Be sure to include your return address, phone number, fax number and/or an email address, if available. The serial number must still be attached to have the warranty be valid.

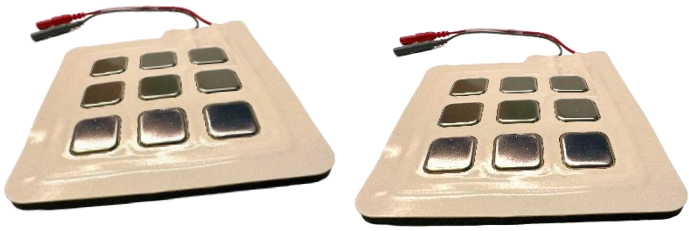
InterX® Technologies will not be responsible for damage due to improper packaging or shipment.

InterX® Technologies warrants to the original purchaser that each new InterX® Comfort Flex III Array™ is free of defects in workmanship and materials under normal use for a period of 30 days from original purchase date.

During the warranty period, our sole obligation shall be, at InterX® Technologies' option, to repair or replace the InterX® Comfort Flex III Array™ without charge. If the InterX® Comfort Flex III Array™ is outside the warranty coverage period any requested repairs or replacement charges will be invoiced to the customer. If InterX® Technologies determines there is a defect covered by this warranty, the repaired or replaced product will be shipped back, freight and insurance prepaid.

InterX® Comfort Flex III Array™ Electrodes and Y-Cable Limited Warranty

There is a 90 day warranty on the Y-Cable and a 30 day warranty covering materials and workmanship for the InterX® Comfort Flex III Array™.



INTERX® Technologies

www.interx.com

Manufactured by:
InterX Technologies
3465 Technology Dr, Suite A
Plano, TX 75074 USA
Tel: +1 (972) 665-1810 Fax: +1 (972) 665-1814