INTERX® FLEXIBLE ARRAY™ AND THE DUAL FLEXIBLE ARRAY™

US Patent No. 9.630.003 B2 and Patents Pending

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INDICATIONS FOR USE

- Symptomatic relief and management of chronic intractable pain
- Adjunctive treatment in the management of post-surgical and post-traumatic pain
- Relaxing muscle spasms
- Muscle re-education

Any serious incident that occurs in relation to the device should be reported immediately to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

DEFINITIONS AND SYMBOLS

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.

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

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.

GENERAL CARE INSTRUCTIONS

NOTE: *Before first use, remove protective film from the square electrode surfaces to ensure full contact for stimulation.*

Safe use of the accessory electrodes is the primary responsibility of the user. The user is responsible for the monitoring of the product. Contact clinical / technical support if the electrode appears to be operating incorrectly. Do not use any damaged electrodes. The Flexible Array™ and Dual Flexible Array™ are not user serviceable.

Do not expose to chemical solvents or harsh cleaning fluids. Do not sterilize or immerse in any fluid. Between treatments clean the electrodes and the surface area of the Flexible Array™ and the Dual Flexible Array™. With the main power OFF, gently wipe the surfaces with a damp cloth or with 70% isopropyl alcohol wipes.

The InterX® is a non-critical patient contact device indicated only for contact between the electrodes and intact skin. The Flexible Array™ and Dual Flexible Array™ are intended for contact with unbroken skin. These products are constructed of polished stainless steel electrodes and Urethane.

INSTRUCTIONS FOR USE

1. Electrode Attachment

Plug the Flexible Array™ into the accessory port located at the opposite end of the devices built in electrode. Use care when you plug in the connector noting the alignment guide for connection. To remove, hold the insulated connector and gently pull apart. Do not jerk or twist the cable upon removal as this may cause damage.

The electrode should be connected when there is no active stimulation. If an electrode is plugged in during active stim, you may have to re-establish the correct stimulation pattern and reset the stimulation intensity to continue treatment.

Do not attempt to plug the InterX® Flexible Array™ into other devices or accessories. Only manufacturer approved InterX® devices may be used. Use of the Flexible Array™ is consistent with instructions provided in the InterX® device manuals.

2. Establish Electrode Contact

Electrode placement is determined by multiple factors, including patient complaint, practitioner experience, and skin response. Identify the area of electrode placements as directed in InterX® training. *Never place electrodes transcerebrally.*

When beginning treatment with the Flexible Array™ electrodes, ensure that the device intensity is at the initial default setting of 2.0%. Using the attachment strap provided or alternative as appropriate, place the Flexible Array™ firmly on clean and dry skin.

Ensure that all electrode surfaces have good contact with the skin for maximum effect. If the shape of the area being treated causes poor electrode contact (eg. hands, ankles, elbow) then use an alternate accessory electrode or specialty attachment material.

NOTE: Damage to internal componants can occur if the Flexible Array™ electrodes are subjected to extreme bending.

Do NOT bend the Flexible Array™ electrodes diagonally.

Do NOT allow individual electrodes to come in contact with one another.

Do NOT allow individual pads to come in contact with one another.

3. Set Stimulation Intensity

NOTE: Intensity should be set to experience a comfortable tingling sensation. The treatment intensity level will vary from patient to patient and location based upon individual sensitivity to the electrical 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® Flexible Array™ is designed not to allow more than 10 minutes of continuous skin contact. 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 Flexible Array™ electrodes to another treatment area.

PRESET STIMULATION PATTERNS

The Flexible Array™ electrodes are designed to provide maximum effect to the treated area. Stimulation patterns most appropriate for up to 10 minutes of continous treatment are available when the Flexible Array™ electrodes are attached to your device. Other stimulation patterns are inactive.

Professional Products - The chart identifies where the preset stimulation pattern is available on the device menus.

Preset	Sport				5002		
							
15-60				✸		✸	✸
30-120			✸		✸	✸	✸
90-360*	✸	✸			✸		✸
Cyc1		✸					✸
Cyc2			✸				✸
Cyc3				✸			✸

Personal Products – Please refer to the relevant section of the Operations Manual and Training Guide.

CONTRAINDICATIONS

- Electrode placement over malignant tumors
- Transcerebral and/or carotid sinus electrode placement
- Use over mucous membranes
- Patients who are prone to seizures (i.e., 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

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 device 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.

The Flexible Array™ electrodes should not be used on more than one person at a time.

The Flexible 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.

Do not make contact with the InterX® electrodes on wet skin. Natural bodily fluids, including sweat, are acceptable.

WARNINGS AND CAUTIONS (CONTD..)

Avoid placing the Flexible Array™ on the skin when turning the InterX® ON or returning from PAUSE to avoid electrical signal.

The Flexible Array™ electrodes should not be used in a fixed location for more than 10 minutes continuously. Wait a minimum of one hour before re-treating the same location again with the Flexible Array™ or Dual Flexible Array™.

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.

Built-in device electrodes and external electrodes should not be used in combination transcerebrally.

The InterX® should not be used while driving or operating machinery.

The InterX® devices should never be used in the shower, immersed in water, or with visible condensation on the device.

NOTE: Both pads of the Dual Flexible Array™ are active during stimulation and should be in contact with the skin during treatment. If only one pad is required, then the other should be placed in the protective cover supplied.

SERVICE AND WARRANTY

To obtain service, first contact InterX® Technologies Customer Service at 972-665-1810, or your InterX® distributor for a Return Authorization (RA) number. Send the Flexible Array™, 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. Always be sure to include the RA number you were assigned with your returned device.

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® Flexible Array™ is free of defects in workmanship and materials under normal use for a period of 1 year from original purchase date.

During the warranty period, our sole obligation shall be, at InterX® Technologies' option, to repair or replace the InterX® Flexible Array™ without charge. If the InterX® Flexible 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® Technologies

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