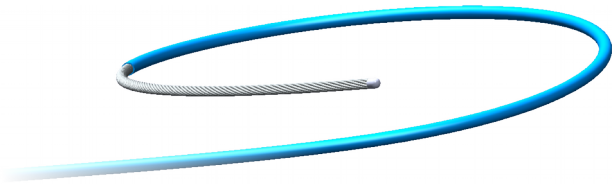
DATA SHEET

P-Lead



REF ACEL-05P
ACEL-10P
ACEL-15P

CE 0476

Product codes:	ACEL-05P ACEL-10P ACEL-15P
CND classification:	Z12101185
CE class:	IIa

National repertory numbers:

ACEL-05P	1432464
ACEL-10P	1432465
ACEL-15P	1432466

ELECTRODE FOR PERIPHERAL ELECTRICAL NEUROSTIMULATION

INDICATIONS

Occipital and Supraorbital Neuralgia, Neuropathic Abdominal Pain, Myofascial Pain, Post-Herpetic Pain, Post-Mastectomy Pain, Cicatricial and Post-operative Pain, Allodynia Pain, CRPS, "Phantom Limb" Syndromes, Peripheral SCS Trial.

DESCRIPTION

The P-LEAD device is a thin flexible and disposable electrode specifically designed for the electrical neurostimulation therapies in subcutaneous area, in the treatment of chronic pain, and it is used in conjunction to the ACCUSTIM-P stimulators.

Use of the P-LEAD electrode is allowed ONLY with external neurostimulators ACCUSTIM-P of Bioampere Research Srl.

The P-LEAD electrode is available in different lengths of its active part in order to better approach to different condition of the particular clinical indication being treated.

The P-LEAD electrode, combined with the ACCUSTIM neurostimulator can be used both in the OR environment (if needed use of tools presents in the operating room), and in the ambulatory environment.

The typical patients profile submitted to peripheral neuro-stimulation treatments is generally characterized by patients over 40 age, but could be cases of younger patients with the same pathologies caused by particular events (eg trauma or congenital disorders).

Functioning

Through a percutaneous access performed with the Tuohy needle included in the package, the P-LEAD electrode is inserted subcutaneously in the pain area to be treated; once positioned in a right area suitable for the treatment, the electrode will be connected to the external stimulator ACCUSTIM-P and it will act as a vector of the electrical stimulus supplied by the neurostimulator.

The electrode will be inserted subcutaneously for the exact portion to be used for stimulation: the stimulation current, in fact, will go ONLY in the subcutaneous inserted electrode portion, NOT in the rest of electrode outside the access hole. This part of the electrode is folded and secured with the sterile strip and fixing patches included in the package. There are three standard sizes of electrodes: 50mm, 100mm and 150mm. The 200mm electrode is available upon request.

The treatment will end in a maximum of 30 days, in which the device can be turned off for rest breaks, or it can be adjusted according to the physician's instructions or the patient's needs without removing the implant. The very thin size of electrodes (0.4 mm diameter - 27Ga) and its particular flexibility, are such as not to cause particular annoying to patients, whom can, therefore, easily tolerate treatments for several days/weeks.

Configurations

The clinical picture of the patient, the type of subcutaneous nerve structure to be treated and the access area of the patient, can induce the physician to use the electrode in one of the following two configurations:

- MONOPOLAR configuration: In this configuration the stimulation system consists of the ACCUSTIM-P stimulator, a P-LEAD electrode and a dispersion plate. The stimulation current will go through the electrode to the dispersion plate placed close to the pain area.

- BIPOLAR configuration: in this configuration the stimulation system includes the ACCUSTIM stimulator and TWO P-LEAD electrodes. The stimulation current will go through from one electrode to the other one. Both electrodes are subcutaneously inserted in the pain area to be treated, generally in such a way to enclose nervous structures to treat.

TECHNICAL FEATURES

Length of the electrode	32cm / 37cm / 42cm
Length of the active part	5cm / 10cm / 15cm
Electrode size	0,40mm (27Ga)
Packaging	Single pouch
Sterilization	Ethylene Oxide (ETO)
Environmental conditions of use	temp.: 10°C ÷ 40°C / Rel. Humidity: 20% ÷ 80%
Shelf life	5 years
Class of protection	IP20
Classification Applied Part	BF

RAW MATERIALS

Raw materials of P-LEAD device are:

- Medical Stainless steel 1.4404 (AISI 316L)
- Medical PE

BOX CONTENTS

Box for MONOPOLAR treatments

- n.1 P-Lead electrode sterile pouch;
- n.1 Tuohy 20Ga introducer to perform percutaneous access;
- n.4 Ground-plates to connect to the stimulator;
- n.1 Sterile fixing for percutaneous accesses;
- n.1 Auxiliary fixing to secure fix P-Lead connector;
- n.1 Instruction for use.

Box for BIPOLAR treatments

- n.2 P-Lead electrode sterile pouches;
- n.2 Tuohy 20Ga introducers to perform percutaneous access;
- n.1 Sterile fixing for percutaneous accesses;
- n.1 Auxiliary fixing to secure fix P-Lead connector;
- n.1 Instruction for use.

Use of the P-LEAD electrode is allowed ONLY with external neurostimulators ACCUSTIM-P of Bioampere Research Srl.

NOTE FOR THE STORAGE AND TRANSPORT

Environmental conditions for storage and transport:

- Temperature: 10°C ÷ 40°C
- Relative Humidity: 30% ÷ 60%
- Pressure: 0,5bar ÷ 2bar

Store in a dry area and away from direct heat. Do not use after the expiration date. Keep out of children's reach.

NOTE FOR DISPOSAL

The crossed bin symbol on its packaging indicates that once used, the device must NOT be disposed of as household waste but must be made for it a different collection from other waste. Therefor the user must bestow the product to the appropriate differentiated collection centers for electronic and electro-technical waste, or return to Bioampere Research Srl, which will carry out the collection and proper disposal procedure. Appropriate separate collection or follow the above mentioned factors, helps to avoid possible negative effects on the environment and on health and promotes the reuse and/or recycling of the making up materials the equipment.

Illegal disposal of the product by the user entails the application of administrative sanctions provided by law.

MANUFACTURER

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