SYMBOLS USED ON THE LABEL			
Symbol	Description	Symbol	Description
	Do not reuse - Single use		Expiry date
	Lot number		Ethylene Oxide Sterilization
	Reference code		See instructions for use
	Do not use if the packaging is not intact		Manufacturer
	Do not resterilize		CE Certification according to MDD 93/42
	Non-pyrogenic		Date of manufacture

AMS Group S.r.l. s.u. accepts no responsibility for damage caused to the patient and/or staff if the system is used abnormally, improperly, or by unauthorized personnel.

Rev. 02 - 04/2021

Manufactured by:

amsgroup LIFE GETS BETTER

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i-PROBE

INSTRUCTIONS FOR USE

PENS Bipolar needle

The **i-PROBE** bipolar needle is used in PENS (Electrical Peripheral Nerve Stimulation) procedures in combination with the **i-STIM** pulse generator.
PENS therapy involves the positioning of the **i-PROBE** bipolar needle subcutaneously in the area causing pain and the consequent delivery of a low-voltage signal with the sole purpose of inhibiting the transmission of peripheral neuropathic pain. An analgesic effect is therefore reproduced.

This minimally invasive procedure is recommended for the following treatments:

- Treatment of chronic peripheral neuropathy;
- Treatment of nociceptive neuropathy resistant to conventional therapies;
- Chronic postsurgical pain;
- Cervicalgia;
- Headache;
- Muscle pain (myofascial) encountered both at rest and during movement;
- Occipital / supraorbital / intercostal neuralgia
- Postherpetic neuropathy;
- Phantom limb pain.

Warning: Patients with other pathologies, other than those listed, must be treated with responsibility and effectiveness that can be attributed to the operator.

CHARACTERISTICS OF THE i-PROBE BIPOLAR NEEDLE

- The needle is equipped with a flute tip to improve the contact of the device during treatment of the analgesic target.
- Absence of electrical dispersion and maximum electrical signal on the nerve to be treated, resulting in longer term therapeutic efficacy.
- Constant impedance read-outs in real time thanks to direct needle-generator communication.
- The needle is equipped with an integrated infusion route, thus allowing the infusion of drug and/or contrast liquid directly into the analgesic area.
- Dedicated generator with 7" touch screen, with the possibility of inputting personalized therapeutic programs, such as frequency, pulse amplitude, treatment duration, output signal adjustment and wash-out (rest time between one pulse cycle and another).
- The i-probe needle is echogenic in all available versions.

MEASURES

***i*-Probe**

Codice	Gauge	Length	Description
BPP-1835IL	18	35mm	Bipolar needle with infusion line
BPP-1870IL		70mm	

Codice	Gauge	Length	Description
BPP-2135IL	21	35mm	Bipolar needle with infusion line
BPP-2170IL		70mm	
BPP-21100IL		100mm	
BPP-21120IL		120mm	

Codice	Gauge	Length	Description
BPP-2235IL	22	35mm	Bipolar needle with infusion line
BPP-2270IL		70mm	
BPP-22100IL		100mm	
BPP-22120IL		120mm	
BPP-2235	22	35mm	Bipolar needle **without infusion line**
BPP-2270		70mm	
BPP-22100		100mm	
BPP-22120		120mm	
BPP-22200		200mm	

GENERAL INSTRUCTIONS

The **i-PROBE** bipolar needle must be used exclusively with the **i-STIM** impulse generator**,** which features the possibility of inputting personalized therapeutic programs in terms of frequency, pulse amplitude, treatment duration, output signal adjustment and wash-out (rest time between one pulse cycle and another).

TREATMENT DURATION AND THERAPEUTIC EFFECT

The PENS procedure is minimally invasive and has no side effects for the patient. The treatment can last from 15 to 30 minutes. The patient can experience therapeutic relief immediately and with a variable duration.

STIMULATION SPECIFICATIONS

Amplitude: 0.0 to 5.0 V adjustable in 0.05 V increments; accuracy ±5%
Stimulation frequency: 2 to 100 Hz adjustable in 0.1 Hz increments; accuracy ±5%
Pulse duration: 0.2 to 2 msec adjustable in 0.1 ms increments; accuracy ±5%
Treatment length: 0.2 to 2 msec adjustable in 0.1 ms increments; accuracy ±5%

CONTRAINDICATIONS

The use of the **i-PROBE** bipolar needle is contraindicated in the following cases:

- In patients with an implantable electronic device (e.g. cardiac pacemaker, defibrillator or neurostimulator).
- In patients with heart problems or epilepsy.
- In patients with a confirmed or presumed pregnancy.
- In patients with thrombotic problems or those undergoing anticoagulant therapy.
- In patients with infection at the site to be treated.
- **i-PROBE** is not intended for use in paediatric patients.

SIDE EFFECTS

No particular side effects were detected during clinical evaluation except for: infections, slight bleeding or bruising at the probe insertion site, temporary pain and functional nerve impairment in cases of incorrect electrode insertion.

STERILIZATION

The **i-PROBE** bipolar needle is a single-use device and comes in a sealed bag. It is not designed for reuse. Sterilization has been performed with Ethylene Oxide (EtO), valid for 5 years from the date of packaging.

STORAGE

i-PROBE electrodes must be stored in their original packaging, in a cool, dry place, away from direct heat sources, at a temperature below 40°C.

Warning: Do not use **i-PROBE** electrodes if the packaging is not intact.

PRESENCE OF LATEX - PHTHALATES

The **i-PROBE** bipolar needle is free from latex and from phthalates.

PACKAGING

Primary packaging: the device is enclosed in a plastic/tyvek laminated bag.
Secondary packaging: the device in its primary packaging is placed in a plastic/tyvek bag.

Warning: Do not use if the packaging is not intact. The device is supplied sterile and pyrogen-free. For single use.

DISPOSAL

After use, the **i-PROBE** bipolar needle must be disposed of in the appropriate container for contaminated or sharp waste, following the guidelines approved by the Healthcare facility.