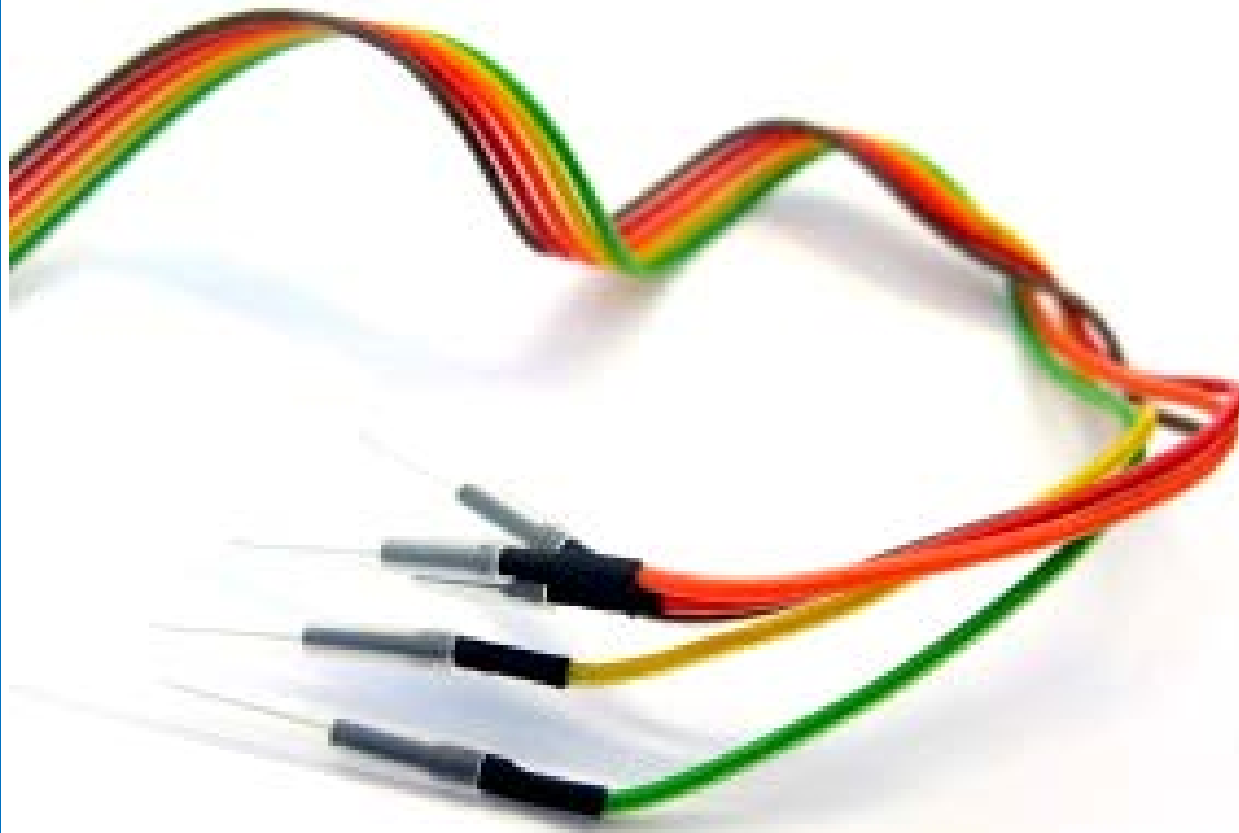


DISPOSABLE SUBDERMAL NEEDLE ELECTRODES



BIONEN S.A.S.

Via P. Petrocchi, 42/1
50127 Firenze – Italia
www.bionen.it

BIONEN
medical devices

DISPOSABLE SUBDERMAL NEEDLE ELECTRODES

GENERAL INFORMATION

Intended use: Electromyography (EMG) – Electroencephalography (EEG)

Instructions for use:

1. Check expiration date on package before use.
2. Make sure the disposable needle electrode you choose is suitable in length and diameter for the study.
3. Introduce the needle into a patient to a maximum depth of 3 mm from the hub.
4. If the needle cannula bend before, during or after insertion, DO NOT straighten or reinsert it. Bent needles should be discarded and replaced by new ones.

Sterilization: Gamma Ray sterilized. DISPOSABLE device supplied in a STERILE pouch. DO NOT REUSE. Sterile packaging is guaranteed for 5 years. Do not use if packaging is damaged, opened or without the traceability data (code – batch number – expiry date). Do not use after expiry date.

If one of the previous situation occurs, needles will be substitute.

Lifetime: DISPOSABLE device. Do not use after 5 years from the sterilization date.

Materials: stainless steel AISI 304

Packaging: Sealed Medical Paper pouch.

Transport and Waste disposal: Any particular transport condition is expected. Always discard used or unshielded disposable needle electrodes in approved biohazard sharps containers. To avoid injuries, throw it away without applying the needle's cover again.

Regulation: class IIa device.

Comply with the MDD 93/42/CEE and its revised version and has been manufactured according to the procedures of BIONEN Quality System certified ISO 13485.

FDA 510 (K) CLEARANCE NR. K092973

DISPOSABLE SUBDERMAL NEEDLE ELECTRODES

AVAILABLE CONFIGURATION:

REF.	UM	N°	L NEEDLE	Ø NEEDLE		MATERIAL	SAFETY CONNECTOR	CABLE	INSULATION
-				MM	GAUGE				
0021.011	NR	1	10mm	0,35mm	28	INOX AISI 304	MCH D=2mm	100cm	NO INSULATION
0021.012	NR	1	15mm	0,35mm	28	INOX AISI 304	MCH D=2mm	100cm	NO INSULATION
0021.013	NR	1	25mm	0,35mm	28	INOX AISI 304	MCH D=2mm	100cm	NO INSULATION
0021.014	NR	1	35mm	0,35mm	28	INOX AISI 304	MCH D=2mm	100cm	NO INSULATION
0021.015	NR	1	45mm	0,35mm	28	INOX AISI 304	MCH D=2mm	100cm	NO INSULATION
0021.016	NR	1	HOOK	0,35mm	28	INOX AISI 304	MCH D=2mm	100cm	NO INSULATION
0021.021	NR	1	10mm	0,35mm	28	INOX AISI 304	FMM D=1,5mm	100cm	NO INSULATION
0021.022	NR	1	15mm	0,35mm	28	INOX AISI 304	FMM D=1,5mm	100cm	NO INSULATION
0021.023	NR	1	25mm	0,35mm	28	INOX AISI 304	FMM D=1,5mm	100cm	NO INSULATION
0021.024	NR	1	35mm	0,35mm	28	INOX AISI 304	FMM D=1,5mm	100cm	NO INSULATION
0021.025	NR	1	45mm	0,35mm	28	INOX AISI 304	FMM D=1,5mm	100cm	NO INSULATION
0021.026	NR	1	HOOK	0,35mm	28	INOX AISI 304	FMM D=1,5mm	100cm	NO INSULATION
0021.027	NR	1	15mm	0,35mm	28	INOX AISI 304	FMM D=2mm	60cm	NO INSULATION
0021.050	NR	1	12mm	0,35mm	28	INOX AISI 304	FMM D=1,5mm	TWISTATO 100cm	NO INSULATION
0021.051	NR	1	18mm	0,35mm	28	INOX AISI 304	FMM D=1,5mm	TWISTATO 100cm	NO INSULATION
0021.052	NR	1	12mm	0,35mm	28	INOX AISI 304	FMM D=1,5mm	TWISTATO 150cm	NO INSULATION
0021.053	NR	1	18mm	0,35mm	28	INOX AISI 304	FMM D=1,5mm	TWISTATO 150cm	NO INSULATION
0021.054	NR	1	12mm	0,35mm	28	INOX AISI 304	FMM D=1,5mm	TWISTATO 200cm	NO INSULATION
0021.055	NR	1	18mm	0,35mm	28	INOX AISI 304	FMM D=1,5mm	TWISTATO 200cm	NO INSULATION
0021.056	NR	1	HOOK	0,35mm	28	INOX AISI 304	FMM D=1,5mm	TWISTATO 200cm	NO INSULATION
0021.201	NR	1	10mm	0,35mm	28	INOX AISI 304	FMM D=1,5mm	5 POLI 150 cm	NO INSULATION
0021.202	NR	1	15mm	0,35mm	28	INOX AISI 304	FMM D=1,5mm	5 POLI 150 cm	NO INSULATION
0021.206	NR	1	HOOK	0,35mm	28	INOX AISI 304	FMM D=1,5mm	5 POLI 150 cm	NO INSULATION
0021.211	NR	1	10mm	0,35mm	28	INOX AISI 304	MCH D=2mm	5 POLI 100 cm	NO INSULATION
0021.212	NR	1	15mm	0,35mm	28	INOX AISI 304	MCH D=2mm	5 POLI 100 cm	NO INSULATION
0021.216	NR	1	HOOK	0,35mm	28	INOX AISI 304	MCH D=2mm	5 POLI 100 cm	NO INSULATION
0024.001	CF	5	10mm	0,35mm	28	INOX AISI 304	MCH D=1mm	SCONNETTIBILE	NO INSULATION
0024.002	CF	5	15mm	0,35mm	28	INOX AISI 304	MCH D=1mm	SCONNETTIBILE	NO INSULATION
0024.003	CF	5	25mm	0,35mm	28	INOX AISI 304	MCH D=1mm	SCONNETTIBILE	NO INSULATION
0024.004	CF	5	HOOK	0,35mm	28	INOX AISI 304	MCH D=1mm	SCONNETTIBILE	NO INSULATION

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REF.	UM	N°	L NEEDLE	Ø NEEDLE		MATERIAL	SAFETY CONNECTOR	CABLE	INSULATION
-			MM	GAUGE					
0024.005	CF	5	12mm	0,35mm	28	INOX AISI 304	MCH D=1mm	SCONNETTIBILE	NO INSULATION
0024.006	CF	5	10mm	0,35mm	28	INOX AISI 304	MCH D=1mm	SCONNETTIBILE 6cm	NO INSULATION
0024.007	CF	5	15mm	0,35mm	28	INOX AISI 304	MCH D=1mm	SCONNETTIBILE 6cm	NO INSULATION
0024.008	CF	5	25mm	0,35mm	28	INOX AISI 304	MCH D=1mm	SCONNETTIBILE 6cm	NO INSULATION
0024.009	CF	5	HOOK	0,35mm	28	INOX AISI 304	MCH D=1mm	SCONNETTIBILE 6cm	NO INSULATION
0024.00A	NR	1	10mm	0,35mm	28	INOX AISI 304	MCH D=0,7mm	SCONNETTIBILE 6cm	NO INSULATION
0024.00B	NR	1	5mm	0,35mm	28	INOX AISI 304	MCH D=0,7mm	SCONNETTIBILE 6cm	NO INSULATION
0024.00C	NR	1	25mm	0,35mm	28	INOX AISI 304	MCH D=0,7mm	SCONNETTIBILE 6cm	NO INSULATION
0024.00D	NR	1	HOOK	0,35mm	28	INOX AISI 304	MCH D=0,7mm	SCONNETTIBILE 6cm	NO INSULATION
0024.00E	NR	1	35mm	0,35mm	28	INOX AISI 304	MCH D=0,7mm	SCONNETTIBILE 6cm	INSULATION
0024.011	NR	1	20mm	0,35mm	28	INOX AISI 304	FMM D=1,5mm	SCONNETTIBILE 10cm	NO INSULATION
0024.012	NR	1	30mm	0,35mm	28	INOX AISI 304	FMM D=1,5mm	SCONNETTIBILE 10cm	NO INSULATION
0024.013	NR	1	40mm	0,35mm	28	INOX AISI 304	FMM D=1,5mm	SCONNETTIBILE 10cm	NO INSULATION
0026.011	NR	1	10mm	0,35mm	28	INOX AISI 304	MICROCONNECTOR	SCONNETTIBILE	NO INSULATION
0026.012	NR	1	15mm	0,35mm	28	INOX AISI 304	MICROCONNECTOR	SCONNETTIBILE	NO INSULATION
0026.013	NR	1	20mm	0,35mm	28	INOX AISI 304	MICROCONNECTOR	SCONNETTIBILE	NO INSULATION