HYPODERMIC NEEDLE ELECTRODE FOR BOTULINUM TOXIN INJECTION

BIONEN
medical devices

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GENERAL INFORMATION

Intended use: The use of electromyographic (EMG) recording during the application of Botox® is particularly useful to pinpoint the exact point of nerve disorder. The electrode with an open lumen is designed for simultaneous recording of spontaneous activity and delivery of Botox® in patients affected by sustained involuntary contractions of muscles. The specific Botox® type to be injected must be chosen by the physician.

Instruction of 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.

Specifications

1. Sterile hypodermic needle for single use (ISO 7864)
2. AISI 304 stainless steel, insulated coating up to the tip.
3. Recording surface limited to the area of the exposed bevels and inner cannula face.
4. Needle hub with a secure Luer-Lock fitting to which the injection syringe is connected.

Wire with touch-proof connector which provides for electrical connection to a stimulating or recording device.

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: 5 years from the sterilization date.

Packaging: Sealed Medical Paper pouch.

Storage: Any particular precautions for storing are not necessary.

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 (D.L. 46/97) and its revised versions and has been manufactured according to the procedures of BIONEN Quality System certified ISO 13485.

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AVAILABLE CONFIGURATIONS:

REF.	L NEEDLE	EXTERNAL ⌀ NEEDLE		CANNULA MATERIAL	CONNETTOR COLOR	NEEDLE CONNETTOR	L CBLE	CONNECTOR CABLE
		MM	GAUGE					
0028.511	20mm	0,51	25	INOX AISI 304 INSULATED	BLACK	LUER LOCK	100cm	FMM D=1,5mm
0028.512	30mm	0,51	25	INOX AISI 304 INSULATED	GREEN	LUER LOCK	100cm	FMM D=1,5mm
0028.513	40mm	0,51	25	INOX AISI 304 INSULATED	RED	LUER LOCK	100cm	FMM D=1,5mm
0028.514	50mm	0,51	25	INOX AISI 304 INSULATED	GREY	LUER LOCK	100cm	FMM D=1,5mm
0028.515	60mm	0,51	25	INOX AISI 304 INSULATED	YELLOW	LUER LOCK	100cm	FMM D=1,5mm
0028.516	75mm	0,51	25	INOX AISI 304 INSULATED	BLUE	LUER LOCK	100cm	FMM D=1,5mm
0028.521	25mm	0,31	30	INOX AISI 304 INSULATED	ORANGE	LUER LOCK	100cm	FMM D=1,5mm
0028.522	25mm	0,41	27	INOX AISI 304 INSULATED	GREEN	LUER LOCK	100cm	FMM D=1,5mm
0028.523	37mm	0,41	27	INOX AISI 304 INSULATED	BLUE	LUER LOCK	100cm	FMM D=1,5mm
0028.524	37mm	0,46	26	INOX AISI 304 INSULATED	BLACK	LUER LOCK	100cm	FMM D=1,5mm
0028.525	50mm	0,46	26	INOX AISI 304 INSULATED	RED	LUER LOCK	100cm	FMM D=1,5mm
0028.526	75mm	0,64	23	INOX AISI 304 INSULATED	GREY	LUER LOCK	100cm	FMM D=1,5mm
0028.527	33mm	0,35	28	INOX AISI 304 INSULATED	YELLOW	LUER LOCK	100cm	FMM D=1,5mm
0028.528	45mm	0,35	28	INOX AISI 304 INSULATED	WHITE	LUER LOCK	100cm	FMM D=1,5mm