

# INSTRUCTIONS FOR USE

## Ambu® Neuroline Monopolar Needle Electrode (with or without lead wire)

Single-use

### 1. Important information – Read before use

The Ambu Neuroline Monopolar Needle Electrode is sterile, single-use product which penetrate patient skin and muscle. It is indicated for use with the Ambu Neuroline Stimulator connected to an electrostimulation system.

There is no warranty on the Ambu Neuroline Monopolar Needle Electrode.

### 1. Intended use

The Ambu Neuroline Monopolar Needle Electrode is made for muscle activity recording for Electromyography (EMG) applications. It is not intended for any other use.

### 1.2. Indications for use

The Ambu Neuroline Monopolar Needle Electrodes are indicated for examination of the electrical activity in skeletal muscles.

### 1.3. Intended patient population

The Ambu Neuroline Monopolar Needle Electrodes can be used for infants, children, adolescents and adults (from 29 days up and over).

### 1.4. Intended user

The Ambu Neuroline Monopolar Needle Electrodes are designed for use by healthcare professionals trained in Electromyography (EMG) procedures.

### 1.5. Contra Indications

Do not use the product for stimulation or for any other purpose.

### 1.6. Clinical benefits

Single-use application minimizes the risk of cross-contamination of the patient.

### 1.7. Warnings and cautions

Warnings and cautions: Do not use the needle electrode if the individual pouch is damaged or has been opened for longer than 12 hours after manufacture. Do not use the needle electrode for electrical stimulation as this may lead to tissue infection.

### 1.8. Potential adverse events

Do not use if patient is allergic to latex, mild tenderness and/or bruising.

### 1.9. General notes

This product is a medical device or as a result of its use. A breach incident has occurred, please refer to the manufacturer and your national authority.

### 1.10. Packaging and storage

Keep in the original packaging until use. Store at 10 to 25 °C (50 to 77 °F). Do not use if the product shows signs of damage.

### 1.11. Disposal

Do not reuse the product. Dispose of the product in accordance with local regulations.

### 1.12. Manufacturer information

AMBU AB, S-141 86 Huddinge, Sweden.

### 1.13. Contact information

For further information, please contact your local distributor.

### 1.14. Trademark

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### 1.16. Version

Version 1.0, 2015.

### 1.17. Revision

Revisions: 1.0 to 1.15.

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## 2. Device description

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## 3. PRECAUTIONS

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## 4. OBSERVAZIONI

Attenzione: Non utilizzare l'elettrodo se il contenitore individuale è danneggiato o se è stato aperto per un periodo superiore a 12 ore dalla data di produzione.

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## 5. Účel

Účel: Používatelný pro záznam svalové aktivity. Určen pouze pro jednorázovou aplikaci. Vždy používejte nové jednorázové elektrody. Pokud je poškozen obal nebo je obal otevřen déle než 12 hodin od data výroby, nepoužívejte elektrodu. Nepoužívejte elektrodu pro elektrickou stimulaci, protože může vést k infekci tkáně.

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### 1.3. Intended patient population

