

# WALLACH®

## DISPOSABLE BALL ELECTRODES

LOOP – **REF** 909007, 909009, 909011, 909013, 909017, 909131, 909134

NEEDLE – **REF** 909005, 909135

BALL – **REF** 909003, 909038, 909136

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### INSTRUCTIONS FOR USE

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STERILE EO

CE0086



**READ ALL SAFETY INFORMATION AND INSTRUCTIONS BEFORE USING THIS PRODUCT!**

**WARNING: KEEP ACTIVE ACCESSORIES AWAY FROM THE PATIENT WHEN NOT IN USE. BEFORE INSERTING OR CHANGING AN ELECTRODE, BE SURE THE ACTIVE ACCESSORY IS NOT CONNECTED TO AN ELECTROSURGICAL GENERATOR OR THAT THE GENERATOR IS OFF OR IN THE WAIT MODE.**

- **CONTENTS SUPPLIED STERILE. DO NOT USE IF STERILE BARRIER IS DAMAGED.**
- **FOR SINGLE USE ONLY. DO NOT REUSE, REPROCESS OR RESTERILIZE. REUSE, REPROCESSING OR RESTERILIZATION MAY COMPROMISE THE STRUCTURAL INTEGRITY OF THE DEVICE AND/OR LEAD TO DEVICE FAILURE WHICH, IN TURN, MAY RESULT IN PATIENT INJURY, ILLNESS OR DEATH. REUSE, REPROCESSING OR RESTERILIZATION MAY ALSO CREATE A RISK OF CONTAMINATION OF THE DEVICE AND/OR CAUSE PATIENT INFECTION OR CROSS-INFECTION, INCLUDING, BUT NOT LIMITED TO, THE TRANSMISSION OF INFECTIOUS DISEASE(S) FROM ONE PATIENT TO ANOTHER. CONTAMINATION OF THE DEVICE MAY LEAD TO INJURY, ILLNESS OR DEATH OF THE PATIENT. DISPOSE OF IN ACCORDANCE WITH ALL APPLICABLE FEDERAL, STATE, AND LOCAL MEDICAL/HAZARDOUS WASTE PRACTICES.**

**CAUTION: U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.**

**STERILE: DO NOT USE ELECTRODE IF PACKAGING IS DAMAGED OR OPENED.**

**ELECTRODES MAY BE USED WITH ELECTROSURGICAL GENERATORS WITH A MAXIMUM HF VOLTAGE RATING OF 5000 VOLTS.**

**IMPROPER ELECTRODE INSTALLATION MAY RESULT IN INJURY TO THE PATIENT OR OPERATING ROOM PERSONNEL BY ARCING AT THE ELECTRODE/PENCIL CONNECTION.**

**ELECTRODES HAVE A STANDARD 3/32" (2.4 MM) DIAMETER SHAFT AND ARE DESIGNED TO FIT MOST ELECTROSURGICAL PENCILS.**

**BEFORE USING, INSPECT THE ELECTRODE INSULATION FOR CRACKS, NICKS, CUTS, DENTS, AND DEPRESSIONS, WHICH MAY DECREASE THE INSULATION EFFECTIVENESS.**

#### **INSTRUCTIONS FOR USE:**

1. Grasping the electrode by the insulating sleeve, insert the round shank into the electrosurgical accessory until the insulating sleeve is inserted approximately 1/8" (3.2 mm).
2. Prior to use, it is important to check the electrode connection to the accessory you are using to assure proper fit and compatibility. The shank and insulating sleeve should fit securely into the handle. If the shank and/or insulating sleeve does not fit, or if the insulation will not insert 1/8" (3.2 mm), use of this electrode/accessory combination is not recommended.
3. Refer to the generator instruction manual for the proper procedure for connecting the active accessory to the generator and the proper power settings.
4. Dispose of electrodes in accordance with Local Medical Hazardous Waste Regulations.

**Note:** Only ball electrodes are used for coagulation. It is not recommended to use the LOOP/Needle electrodes for coagulation.

## EXPLANATION OF SYMBOLS



Reorder number



Do not re-sterilize



Batch code



Type BF applied part



Use-by date



Shock Hazard



Caution



Sterilized using ethylene oxide



Consult instructions for use



Class II Equipment



Do not re-use

**R<sub>x</sub> Only**

Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician



Do not use if package is damaged



Authorized European Representative in the European Community



Not made with natural rubber latex



Manufacturer

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Made in the USA

# WALLACH®

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