



INSTRUCTIONS FOR USE & CARE – OPHTHALMIC REUSABLE PENCILS

This product is reusable and is supplied nonsterile. Process the pencil through cleaning and sterilization prior to initial use, following guidance as outlined below.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

INDICATIONS: The ophthalmic reusable pencil is an electrosurgical device designed to be used in soft tissue surgical procedures.

MAXIMIZING PENCIL LIFE

The reusable pencil has been designed to provide a minimum of 20 uses with normal care. However, the number of uses obtained from a pencil depends upon the sterilization method, the degree of care taken in processing and handling, and the surgical procedures and techniques in which the pencil is used. To achieve maximum life, we recommend the following:

- ◆ Not allowing gross organic contaminants to dry on the pencil (i.e., blood, mucous, and tissue), by initiating pencil decontamination immediately after completion of the surgical procedure.
- ◆ Completely drying the pencil before storage.
- ◆ Protecting the pencil from inadvertent damage while in storage, by wrapping it (especially tip), and avoiding extremes in temperature and humidity.

NOTE: SPOTTING OR DISCOLORATION MAY RESULT FROM INADEQUATE CLEANING PRIOR TO STERILIZATION OR MAY BE DUE TO MINERAL DEPOSITS IN WATER USED TO AUTOCLAVE.

INSPECTION OF PENCIL

Establish a procedural review, by which the pencil is inspected frequently (before and after each use) for damage such as:

- ◆ Tip (distal end) configuration altered.
- ◆ Tip damage, i.e. burrs or discoloration.
- ◆ Cracks or nicks in the molded handle of the instrument.

Such a review should establish criteria by which a pencil showing such damage or wear is discarded and replaced.

CAUTION: USING A PENCIL WHICH IS DAMAGED OR WORN CAN BE HAZARDOUS TO BOTH THE PATIENT AND OPERATING ROOM PERSONNEL.

REPROCESSING (i.e., cleaning & sterilization)

Institutional device reprocessing should occur in facilities that are adequately designed, equipped, monitored, and staffed by trained personnel. Clean and sterilize per your institution's validated procedures and cycle parameters. The following parameters for cleaning and for two of the most commonly utilized methods of sterilization are recommended as guidelines for validation.

NOTE: REPROCESSING THIS DEVICE DICTATES THAT IT UNDERGO A THOROUGH CLEANING PRIOR TO STERILIZATION.

CLEANING

- ◆ Rinse pencil thoroughly with sterile, purified water to remove any accumulated debris.
- ◆ Hand wash the surface of the pencil (paying particular attention to the tip) using a soft bristled cleaning brush, and enzyme cleaner e.g., Terg-a-zyme solution (Alconox, Inc.) or equivalent, to remove visible residual debris.

CAUTION: AVOID USE OF ABRASIVE CLEANERS OR SOLVENTS.

- ◆ After hand washing, the surface is to be thoroughly flushed with sterile, purified water until no visible detergent residual remains.
- ◆ Once the pencil is free of cleaning solution and debris, thoroughly dry using a sterile wipe.

STERILIZATION

- ◆ **STEAM /GRAVITY DISPLACEMENT:** Double wrap pencil in muslin i.e., CSR blue hospital wrap, and place (single layer) in a production type, steam sterilization vessel. Process at 132 °C (270 °F) for a 30 minute cycle.
- ◆ **STEAM /PRE-VACUUM:** Double wrap pencil in muslin i.e., CSR blue hospital wrap, and place (single layer) in production type, steam sterilization vessel. Process at 132 °C (270 °F) using pre-vacuum conditions for a 4 minute cycle.

SETUP and USE

WARNING: CONNECT BIPOLAR ACCESSORIES TO THE BIPOLAR RECEPTACLE ONLY. IMPROPER CONNECTION OF ACCESSORIES MAY RESULT IN INADVERTENT ACCESSORY ACTIVATION OR OTHER POTENTIALLY HAZARDOUS CONDITIONS.

Connect the sterile pencil and sterile cable to the generator only while it is in the "OFF or STANDBY" mode. Failure to do so may result in injury or electrical shock to the patient or operating room personnel.

While attaching the sterile pencil to the sterile cable, ensure that the pencil pins are fully seated in the cable receptacles.

CAUTION: BECAUSE OF THE VARIABILITY OF OUTPUT VOLTAGES AND MODES FROM GENERATOR TO GENERATOR, DO NOT USE THE PENCIL WITH GENERATORS HAVING BIPOLAR OUTPUT VOLTAGES THAT EXCEED 500 Vpk. REFER TO THE APPROPRIATE ELECTROSURGICAL GENERATOR MANUAL FOR INDICATIONS AND INSTRUCTIONS ON BIPOLAR OUTPUT CHARACTERISTICS TO ENSURE THAT ALL SAFETY PRECAUTIONS ARE FOLLOWED.

Begin procedures at the lowest possible power setting, slowly increasing power to achieve desired coagulation. If the generator fails to activate, check the pencil connection with the cable, and the cable with the generator. If activation is still not achieved, check the switching mechanism (footswitch or handswitch).

Manufactured for: Ambler Surgical
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SEE
INSTRUCTIONS
FOR USE



DATE OF
MANUFACTURE

REF

CATALOG
NUMBER

Rx Only

LOT

BATCH
CODE

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