EN Change-A-Tip™ Handle Battery Replacement and Changing Tip and/or Sheath

low-temp handles & high-temp handles

ES Change-A-Tip™ Reemplazo de las Pilas y la Punta Cauterizadora Punta y el Manto Stéril

maneja a alta temperatura y baja temperatura se encarga

PT Change-A-Tip™ Cautério com Ponta & Pilhas Substituíveis / Estéril Bainha

lida com temperatura alta e baixa temperatura lida

FI Change-A-Tip™ Vaihdettava Paristo- ja Kärkikauteri / Steriiliä Kuoren

korkean lämpötilan kahvat ja matalan lämpötilan kahvat

DE Change-A-Tip™ Auswechselbare Batterie und Kauterisationsspitze und Scheide

hochtemperatur-griffen und niedriger temperatur verarbeitet

DA Change-A-Tip™ Udskifteligt Batteri og Udskiftelig Cauteriumsspids / Sterilt Skede

høj temperatur håndtag og lav temperatur håndtag

SV Change-A-Tip™ Utbytbart Batteri och Kauterspets / Sterila Slida

hög temperatur handtag och låg temperatur handtag1

IT Change-A-Tip™ Batteria e Punta di Cauterizzazione Sostituibili / Guaina

maniglie ad alta temperatura e bassa temperatura maniglie

FR Change-A-Tip™ Cautère à Piles et Embout Remplaçables et / ou Gaine Stérile

poignées à haute température et à basse température des poignées

NL Change-A-Tip™ Vervangbare Batterij & Cauterisatiepunt en/of Schacht

hoge temperatuur verwerkt en lage temperatuur verwerkt

EL Αλλαγή μπαταρίας λαβής και αλλαγή άκρου ή/ και θηκαριού

Λαβές χαμηλής θερμοκρασίας & λαβές υψηλής θερμοκρασίας

CN 手柄电池更换及更换烧灼头和/或护套

低温手柄和 高温手柄

JA ハンドルのバッテリー交換および チップおよび／またはシースの交換

低温ハンドル & 高温ハンドル

PL Rękojeść Change-A-Tip™ – Wymiana baterii oraz wymienna końcówka i/lub osłona

Rękojeści o niskich temperaturach i rękojeści o wysokich temperaturach

RO Înlocuirea bateriei din mânerul Change-A-Tip™ şi înlocuirea vârfului şi/sau tecii

mânere pentru temperaturi scăzute şi mânere pentru temperaturi ridicate

SK Výmena batérie rukoväte Change-A-Tip™ a výmena hrotu a/alebo puzdra

rukoväte pre nízke teploty a rukoväte pre vysoké teploty

TR Change-A-Tip™ Kol Pili Değiştirme ve Ucu ve/veya Kılıfı Değiştirme

düşük sıcaklıktaki kollar ve yüksek sıcaklıktaki kollar

HANDLES

℞ ONLY






STERILE TIPS AND SHEATHS

(OPTIONAL AND SOLD SEPARATELY)

℞ ONLY







STERILE | EO

EN - Not Made With Natural Rubber Latex
ES - No está fabricado con látex de caucho natural
PT - Não fabricado com látex de borracha natural
FI - Valmistuksessa ei ole käytetty luonnonkumilateksia
DE - Ohne Naturkautschuklatex hergestellt
DA - Ikke fremstillet med naturlig gummilatex
SV - Ej tillverkad med naturgummi
IT - Non realizzato con lattice di gomma naturale
FR - Exempt de latex de caoutchouc naturel
NL - Niet vervaardigd uit latex van natuurlijk rubber
EL - Δεν είναι κατασκευασμένο από φυσικό καουτσούκ λάτεξ
CN - 非天然橡膠乳膠製成
JA - 天然ゴムラテックスで作られていません
PL - Nie zawiera naturalnej gumy lateksowej
RO - Nu se face cu latex din cauciuc natural
SK - Nie je vyrobený z prírodného latexu
TR - Doğal kauçuk lateksten yapılmamıştır

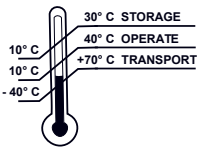
NON-STERILE / SINGLE USE TIPS

℞ ONLY





CAUTERY





STORAGE
10 to 75 % non-condensing
OPERATE
30 to 75 % non-condensing
TRANSPORT
10 to 100 % including condensation

EN Change-A-Tip™ Handle Battery Replacement and Changing Tip and/or Sheath

low-temp handles & high-temp handles

NOTE: Sterile tips and sheaths may be optional and are sold separately.

WARNINGS: ***(APPLIES TO SINGLE USE TIPS AND STERILE SHEATH)***

THIS MEDICAL DEVICE CANNOT BE EFFECTIVELY CLEANED AND/OR STERILIZED BY THE USER AND THEREFORE CANNOT BE SAFELY REUSED. IT IS INTENDED FOR SINGLE USE ONLY. ANY ATTEMPT BY THE USER TO CLEAN AND RESTERILIZE THIS DEVICE MAY RESULT IN BIOINCOMPATIBILITY, INFECTION, OR OTHER RISKS OF DEVICE FAILURE TO THE PATIENT. DO NOT USE IN THE PRESENCE OF FLAMMABLE GASES / MATERIALS OR OXYGEN RICH ENVIRONMENTS. FIRE COULD RESULT.

DEL0, DEL1 - ALWAYS REMOVE THE TIP WHEN THE DEVICE IS IN STORAGE OR NOT IN USE. FAILURE TO FOLLOW THESE INSTRUCTIONS COULD RESULT IN FIRE.

DO NOT USE IN THE PRESENCE OF FLAMMABLE GASES / MATERIALS OR OXYGEN RICH ENVIRONMENTS. FIRE COULD RESULT.

CAUTERY PRODUCES HEAT IN EXCESS OF 1000 DEGREES F, WHICH CAN CAUSE BURNS OR FIRE FROM MISUSE.

ACCIDENTAL EXPOSURE TO CAUTERY TIP MAY LEAD TO INADVERTENT BURNS TO PATIENT OR USER.

PROLONGED TISSUE EXPOSURE TO CAUTERY MAY LEAD TO DAMAGE OF ADJACENT TISSUE.

CAUTERY TIP WILL REMAIN HOT IMMEDIATELY AFTER DEACTIVATION AND MAY CAUSE INADVERTENT BURNS TO USER OR PATIENT.

HIT0, HIT1 - ALWAYS RETAIN THE COVER CAP AND REPLACE IT ON THE CAUTERY WHEN NOT IN USE.

WARNING: ***(APPLIES TO HANDLE)***

DEACTIVATE THE CAUTERY BEFORE DISCARDING THE DEVICE IN A BIOHAZARD OR "SHARPS" DISPOSAL CONTAINER. FIRST, REMOVE CAUTERY TIP. THEN, REMOVE BATTERIES BY TURNING THE REAR CAP. FAILURE TO FOLLOW THIS INSTRUCTION COULD RESULT IN UNINTENDED ACTIVATION OF THE CAUTERY AND MAY CAUSE A FIRE IN THE DISPOSAL CONTAINER.

CAUTIONS: ***(APPLIES TO HANDLE, TIP AND SHEATH)***

Do not autoclave the handle. Damage may occur.

The sheath is heat sensitive. Do not autoclave. Use the sterile sheath in accordance with these instructions.

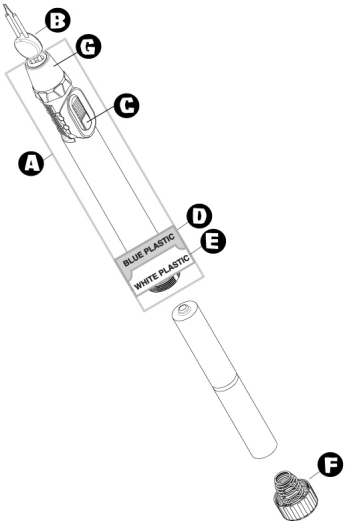
Do not use this device if the packaging is damaged or opened.

Excessive activation may cause handle to overheat.

Applying excessive force on the cautery during use may cause tip to bend or break.

To avoid an undesireable effect, select proper cautery model.

The recommended Duty Cycle is 2 Seconds on and 6 Seconds off for a continuous time of no longer than 15 minutes.



ILLUSTRATION

INSTRUCTIONS FOR HANDLE BATTERY REPLACEMENT:

1. REMOVE CAUTERY TIP Ⓑ before beginning battery replacement procedure.
2. To remove depleted batteries, turn the rear cap Ⓕ left (counter clockwise).
3. Tilt the handle so the batteries slide out. A gentle downward shake may be required in some instances.
4. Insert new AA alkaline batteries positive end first (never use carbon zinc batteries in this device.).
5. Replace rear cap, turn right (clockwise) to close cap.
6. Replace CAUTERY TIP Ⓑ.
7. Activate the unit by depressing the green power button Ⓒ.

INSTRUCTIONS FOR REPLACING STERILE SHEATH:

CAUTION: Use sterile technique when replacing tips and/or sheaths.

1. REMOVE CAUTERY TIP Ⓑ from handle.
2. Remove the sterile sheath Ⓐ from the peel pouch.
   NOTE: Sterile tips come packaged with a sterile sheath.
3. Holding the sheath with the blue stripe Ⓓ up, insert the handle BETWEEN THE WHITE PLASTIC Ⓔ AND WHITE PAPER TABS.
4. Slide the handle forward, until the nose Ⓖ, of the handle is at the end of the sterile sheath Ⓐ.

IMPORTANT - Visually inspect sheath for damage after application to the handpiece and prior to placing in sterile field.

5. Peel away the blue stripe Ⓓ section and the white paper backing. Discard pouch.

INSTRUCTIONS FOR REPLACING STERILE/NON-STERILE TIPS:

1. Handle the tip Ⓑ with care, avoiding the fragile wire. ALWAYS HOLD THE TIP BY THE PLASTIC GRIP TO AVOID DAMAGE.
2. Insert the sterile cautery tip Ⓑ through the sterile sheath Ⓐ. DO NOT FORCE, it should easily slide into place.

Your cautery unit is now ready for use.

3. Activate the unit by depressing the green power button Ⓒ.

After use, remove sheath and tip and dispose of properly.

MEDICAL PURPOSE / INDICATION:

Bovie® Cautery Devices are used for stopping small bleeders in hemostasis and other similar uses.

Operating Principle

This is a handheld battery powered device that delivers thermal energy through a heating element to the patient by use of an activation switch.

Patient Population

- No restriction

Site of Use and Site Conditions

- Site of use – No restrictions
- Site Condition – Aseptic

Intended User Profile

- Education
  - Trained medical professional
- Knowledge
  - Read and understand the supplied IFU
  - Understands hygiene
- Experience
  - Some training on techniques or training under surveillance/supervision
- Permissible Impairments
  - Mild reading/vision impairment or corrected vision to 20/20.

Bovie®

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