POWERGRIP 3.0 BIPOLAR COAGULATION LAPAROSCOPIC BIPOLAR FORCEPS

Assembly, Cleaning, & Sterilization Instructions

For Models No. 53020-322/53029-302/53020-320/53029-300

IMPORTANT:
These Instruments Are For Minimal Invasive Surgery. They Are Shipped Non-Sterile And Must Be Sterilized Before Use. Elmed, As The Manufacturer And Seller Of The Product, Accepts No Liability For Indirect Damage Or Preparation, Sterilization Or Maintenance. Instruments Are Only To Be Used As Designated In Their Specialized Fields By The Respective, Trained And Qualified Personnel. They Are Not Intended To Be Used On The Central Circulatory Or Central Nervous System.

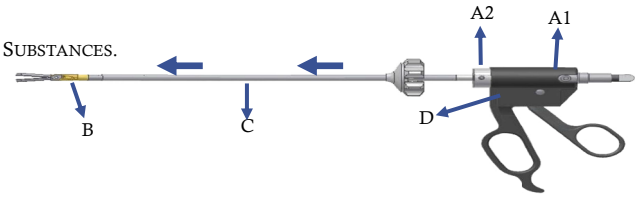
INTENDED USE:
The Elmed POWERGRIP Instrument Is Intended For Use In Minimally Invasive And Specially Laparoscopic Surgical Procedures. The Device Is To Be Passed Through A 5.5mm Laparoscopic Cannula. Coagulation Is Achieved Using Electrosurgical Energy Under Laparoscopic Supervision.
This Device Is Intended To Be Used With The Outputs Of Compatible Electrosurgical Generators Such As Elmed, Erbe, Valleylab And Comparable Generators.

CAUTION: Bipolar Coagulation Instruments Should Be Used Only By Individuals Who Are Trained And Licensed To Use Such Devices.
The POWERGRIP Bipolar Instrument Is Designed To Manipulate, Grasp Or Cut Selected Tissue. It Must Be Connected To The Bipolar Output Of An Electrosurgical Generator. As Indicated Bipolar Coagulation Current May Be Selectively Applied To The Tissue. The Maximum Output Voltage Of The Generator Must Not Exceed 500 V.

CAUTION: In Particular When Using The Scissors, Parenchymal Tissue May Deflagrate.

USE AND SAFETY INSTRUCTIONS:

- All Instruments Have To Be Completely Cleaned, Disinfected And Sterilized Before Initial Use And Any Subsequent Use.
- It Is Very Important To Check Each Surgical Instrument For Visible Damage And Wear Such As Cracks, Breaks Or Insulation Defects Before Each Use. In Particular, Areas Such As Blades, Tips, Notches, Locking And Blocking Devices As Well As All Mobile Parts, Insulated And Ceramic Elements Have To Checked Carefully.
- Never Use Damaged Instruments.
- Never Use The Instruments In The Presence Of Flammable Or Explosive Substances.
- The Instrument Must Never Be Laid Down On The Patient.



DISASSEMBLY
Step 1
On Handle "D" Press Button "A1" And " A2" To Release "B" Inner Tong And "C" Shaft Assembly And Withdraw In Direction Of Arrow.
Step 2
Remove "B" Threaded Insert By Turning Counter-Clockwise From Shaft "C".

REASSEMBLY
Reverse The Above Procedure

MAINTENANCE AND CARE:
Every Instrument Must Be Cleaned And Sterilized Before Being Used For The Time And After Every Subsequent Use. Appropriate Cleaning, Inspection And Maintenance Help To Ensure the Serviceability Of The Surgical Instrument And prolong Its service Life.
Clean, Inspect And Test All Instruments Thoroughly And Sterilize Before Use.
Cleaning And Rinsing Should Be Done Promptly After Every Use. Otherwise Tissue Particles Or Dried Secretions May Adhere To It, Which May Make Subsequent Cleaning And Sterilization Difficult, If Not Impossible. Instruments Must Be Entirely Free Of Any Foreign Bodies.

HANDLING STORAGE AND STERILIZATION:
Extreme Care Must Be Exercised While Using, Transporting, Cleaning, Sterilizing And Storing. Damage To The Function And Safety Of The Instrument May Occur If The Instrument Is Handled Roughly Or Improperly, Or Used For Something Other Than Its Intended Purpose.

WARNING & PRECAUTIONS:

- Check For proper Grounding Of Instrument And Patient Prior To Use. Visual Inspection Alone may Not Be Sufficient To Ensure That The Insulation Is Intact. Usen An Endo Test to Assure The Instruments Insulation.
- Lap Procedures Should Be Performed Only By Physicians Having Adequate Training & Familiarity With Lap Techniques
- A Thorough Understanding Of The Principles & Techniques Of Electrosurgery Is Necessary To Avoid Shock And Burn Hazard To The Patient, Operator, and Operating room Personnel
- DO NOT USE In Patients Who Have Electronic Implants Such As Cardiac Pacemakers Without First Consulting A Qualified Professional.
- DO NOT USE In The Presence Of Flammable Anesthetics Or Oxidizing Gases 9Such As Nitrous Oxide (N2O) & Oxygen) Or In Close Proximity To Volatile Solvents (Such As Ether Alcohol), As Explosion May Occur
- DO NOT Place Instruments Near Or In Contact With Flammable Materials 9Such A Gauze Or Surgical Drapes). Instruments That Are Activated Or Hot From Use May Cause A Fire.
- When Not Using Instruments, Place Them In A Clean, Dry, highly Visible Area Not In Contact With The Patient. Inadvertent Contact With The patient May Result In Burns.
- INSPECT Instruments And Cables For Damage Prior To Each Use, Especially The Insulation Of Laparoscopic/Endoscopic Instruments. This May Be Done Visually Under Magnification Or With A High Voltage Insulation Testing Device. Insulation Failures May Result In Burns Or Other Injuries To The Patient Or Operator.
- The Surface Of The Active Electrode May Remain Hot Enough To cause Burns After The RF Current Is Deactivated
- Due To Concerns About Carcinogenic And Infectious Of Electrosurgical ByProducts, protective Eyewear, Filtration Mask and Effective Smoke Evacuation Should Be Used During The Procedures
- Connect Adapters And Accessories To The Electrosurgical Unit Only When The Energy Is Off
- DO NOT Activate The Instrument When Not In Contact With Target Tissue, As This May Cause Injuries Due To Capacitive Coupling With Other Surgical Equipment.

CAUTIONS: The Intensity Should Be Set As Low As Is Necessary To Achieve The Desired Effect. Keep The Electrodes Clean. Buil-up Of Eschar ay Reduce The Instrument's Effectiveness. Do Not Activate The Instrument While Cleaning. Injury To Operating Room Personnel May Result.

CLEANING AND HANDLING
IMPORTANT: *OBSERVE FOR ALL CLEANING METHODS*
Be Sure To Always Check The Forceps Tips. The Tips Should Be Free From Any Tissue Or Any Other Material That May hAve Adhered To It During Coagulation. Unless These Tips Are Completely Clean, The Forceps Will Not Coagulate Properly. The Inner Tong Should Be Tested For Proper Conductivity Prior To Sterilization. Immediately After Each Surgical Procedure, Clean All Instruments Thoroughly As Follows:

DISINFECTION: Machine Operated Thermal Disinfection Must Be Carried Out In Consideration Of The National Requirements With Regard To The A0 Value (See ISO15883).

DRYING: Dry The Outside Of The Instruments By Carrying Out A Drying Cycle Of The Cleaning/ Disinfection Machine. If Necessary, Manual Drying May Additionally Be Carried Out Using A lint Free Cloth. Dry Cavities By Blowing With Sterile Compressed Air.

AUTOMATIC WASHERS: Follow Manufacturer Instructions

ULTRASONIC PRE-CLEANING:

1. The Instrument Must Be Inserted In An Ultrasonic Bath With 0.5% Enzymatic Cleaning Detergent. Ultrasound Must Be Applied For 15 Minutes At 40° C / 104° F.
2. Remove The Instrument And Rinse Completely With Cold Water To Remove The Cleaning Detergent.

MANUAL CLEANING:

Prepare A Cleaning Bath According To The Manufacturer's Instructions.

1. Rinse Products With Cold Tap Water (< 40° C) Until All Visible Accumulations Of Dirt Have Been Removed. Remove Stuck Dirt By Using A Soft Brush.
2. Place Products In The Prepared Cleaning Bath So That They Are Completely Submersed. Observe Residence Time According To The Manufacturer's Instructions.
3. Clean The Instrument In The Bath Manually Using A Soft Brush. Brush All Surfaces Several Times.
4. The Following Step Only Applies To Channels And The Inside Of Tubes: Push The Brush In And Out Of The Tubes At Least Six Time. Rinse The Tubes With DI Water. Repeat The Procedure.
5. Rinse The Products Thoroughly With DI Water To Remove The Cleaning Agents Without Residue.

DISINFECTION:

Prepare A Disinfectant Bath According To The Instructions Of The Disinfectant Manufacturer. Place The Instruments In The Disinfectant Bath And Observe The Specified Residence Time. Rinse The Products Thoroughly With Fully Demineralized Water To Remove The Disinfectant Without Residue.

DRYING:

Manual Drying Is Carried Out Using A Lint Free Cloth And In Particular, For Drying Cavities And Channels, Sterile Compressed Air.

FUNCTIONAL TEST AND PACKAGING:

Perform A Visual Inspection For Cleanliness. If Required, Perform An Assembly And Functional Test According To The Operating Instructions. If Necessary Repeat The Reprocessing Process Until The Instrument Is Optically Clean.

STERILIZATION

The Instruments Can Be Sterilized Fully Assembled (Recommended) Or It Can Be Sterilized Disassembled And Then Reassembled In A Sterile Field In The Operating Room.

STEAM AUTOCLAVING WITH PREVACUUM AND GRAVITY STERILIZERS

If A Wrapping Method Is used, Make Certain that The Instruments Are Individually Wrapped Or Sealed In A Sterile Pack. Other Metal Objects Should Never Come In Contact With The Insulating Material Of The Flexible Instruments, Or With RF-Connection Cables. Such Points Of Contact May Cause Melting Of The Insulation.

We Recommend The Following Values/Parameters, But We Also Suggest Following The Manufacturer's Instructions For Steam Sterilization:

Cycle	Sterilizing Temp.	Sterilizing Time	DRYING TIME* [3]
Pre vacuum/Wrapped	270° F (132° C)	4 Minutes	30 Minutes
Gravity/Wrapped	250° F (121° C)	30 Minutes	45 Minutes
Gravity/Wrapped	270° F (132° C)	15 Minutes	45 Minutes

STERIS V-PRO LOW TEMPERATURE STERILIZATION

Validated- Adhere To The Sterilizations Instructions Provided By The Manufacturer. (Steris Corporation)

ETO STERILIZATION

The Instrument May Be Sterilized By Ethylene Oxide, Following The instructions Recommended By The Manufacture of The Sterilization Equipment. Typical Conditions Are 500 mg/1 Ethylene Oxide, 30-70% Relative Humidity And 120-135°F Temperature. Temp. Should Not Exceed 68.3°C(155°F). Exposure Time Will Depend On the Type Of Equipment Used.

STERRAD STERILIZATION PROCESS INCLUDING STERRAD NX

The Sterilization Process Is A Multiple Sterilization Process That Utilizes A Combination Of Exposure To Hydrogen Peroxide Vapor And Plasma To Affect Sterilization. The Sterrad NX Sterilizer Can Sterilize Instruments Which Have Diffusion Restricted Spaces, Such As Hinged portions Of Forceps And Scissors.

Adhere To The Sterilization Instructions Provided by the Manufacturer. (Advanced Sterilization Products a Johnson & Johnson Company).

FLASH AUTOCLAVING (Fast Heating/Cooling Cycle)

Flash Sterilization: Minimum Exposure Time 4 minutes at 132°C. Average Drying Time 8 To 15 Minutes.

Important! Flash Autoclaving Will Reduce The Useful Life Of The Instrument Particularly When It Is Constructed Of Various Materials, Encompassing Different Expansion Rates.

CHEMICLAVING—Soaking: ***Not Recommended***

This Is The Most Destructive Method To The Insulating And Silicone Materials Of Electrosurgical Accessories And Can Cause Rapid Deterioration And Failure.

*[3] **IMPORTANT**: Adhere To Proper Drying Cycle To Make Sure That Instruments Are Completely Dry On The Inside.

WARRANTY:

- All Elmed Instruments Are Warranted Against Defects In Material & Workmanship For 1 Year.
- Routine Resharpening, Reinsulating, And Adjustments As Well As Repair Of Damaged Instruments Is Available For A Modest Charge. Any Servicing Of Elmed Instruments Performed By Any Source Other Than Elmed, Inc. *VOIDS* This Warranty.
- Elmed, Inc., As A Manufacturer And Seller Of The Product, Accepts No Liability For Indirect Damage Or Subsequent Damages That Result By Improper Usage, Improper Handling Or Through Improper Preparation, Sterilization Or Maintenance.
- Instruments Are Only To Be Used As Designated In Their Specialized Medical Fields By The Respective Trained And Qualified Personnel. They Are Not Intended To Be Used On The Central Circulatory Or Central Nervous System.

We Design, Manufacture, & Sell The Tools The Surgeons Use

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