



SINGLE-USE BIPOLAR FORCEPS

DE GEBRAUCHSANWEISUNG

EN INSTRUCTIONS FOR USE

US INSTRUCTIONS FOR USE

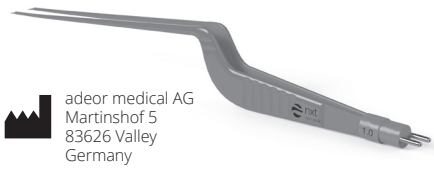
PT INSTRUÇÕES DE USO

DEUTSCH

GEBRAUCHSANWEISUNG Single-Use BIPOLAR PINZETTEN

Artikelbezeichnung: BIPAAABBSU

AAA wird je nach Modell durch eine 3-stellige Zahl ersetzt. BB wird entweder durch EU oder US ersetzt. EU steht für den europäischen und US für den amerikanischen Anschluss. SU steht für Single-Use.



adeor medical AG Martinshof 5 83626 Valley Germany

Achtung: Die Single-Use Instrumente werden steril geliefert.

Warnung:

Gesetzliche Bestimmungen schreiben vor, dass die Single-Use Instrumente nur von oder im Auftrag eines Arztes erworben werden dürfen.

Warnung:

Bitte lesen Sie die Informationen in diesem Faltpfalt aufmerksam durch. Unsachgemäße Handhabung und Pflege, sowie zweck-entfremdeter Gebrauch können zu vor-zeitigem Verschleiß oder zu Risiken für Patienten und Anwender führen.

Zweckbestimmung:

Die Single-Use Bipolar Pinzetten der adeor medical AG finden in allen Bereichen der offenen Chirurgie Anwendung. Sie dienen dem Fassen, Manipulieren und Koagulieren von Gewebe. Sie müssen mittels eines geeigneten bipolaren Kabels mit dem bipolaren Ausgang eines HF-Generators verbunden werden und dürfen nur mit bipolarem Koagulationsstrom eingesetzt werden. Mit folgenden Parametern sind die Single-Use Bipolar Pinzetten zu betreiben: Frequenzbereich zwischen 300 kHz und 1.000 kHz, max. Betriebsspannung des Generators 600 Vp.

Die Art der Behandlung muss in jedem Einzelfall vom Operateur in Zusammenarbeit mit dem Internisten und dem Narkosearzt bestimmt werden. Typische Eingriffe mit HF-Chirurgie sind:

- Dermatologie: Epilation, Warzenentfernung
- HNO: Polypentfernung, bipolare Blutstillung
- Gynäkologie: Elektro-Konisation der Portio, Sterilisation durch bipolare Koagulation des Eileiters
- Urologie: Transurethrale Resektion der Prostata, von Harnblasenkarzinomen und Blasenwandpapylomen, Schneiden und Koagulieren bei transabdominalen Eingriffen
- Laproskopie und Cystoskopie: Abtragen von Polypen
- Allg. Chirurgie: Primärschnitte, Durchtrennen von Gewebe, plastische Chirurgie, Blutstillung, Koagulationen
- Neurochirurgie: Bipolare Koagulationen

Kontraindikationen:

Nicht eingesetzt werden sollten die Single-Use Bipolar Pin-

zetten, wenn der Arzt entscheidet, dass die Risiken für den Patienten den Nutzen des Einsatzes übersteigen. Die Single-Use Bipolar Pinzetten der adeor medical AG sollen nicht für die Tubensterilisation oder Tubenkoagulation zur Sterilisation eingesetzt werden.

Nicht bei Patienten mit Herzschrittmachern oder anderen aktiven Implantaten anwenden.

Achtung:

Single-Use Instrumente für die Elektro-chirurgie dürfen nur von Personen eingesetzt werden, die speziell dafür ausgebildet oder eingewiesen sind.

Sicherheitshinweise:

- Prüfung, Gebrauch und Handhabung der Instrumente für die Elektrochirurgie liegt in der Verantwortung des Anwenders.
- Vor jedem Gebrauch muss das Single-Use Instrument unbedingt auf Verschleiß und sichtbare Schäden, wie Risse, Brüche oder Schäden an der Isolation geprüft werden, insbesondere Bereiche wie Schneide, Spitze, Nut, Stecker und Sperre sowie bewegliche Teile. Isolierungen müssen gründlich geprüft werden.
- Schadhafte Single-Use Instrumente nicht verwenden.
- Die Single-Use Instrumente nicht in Gegenwart von brennbaren oder explosiven Stoffen verwenden.
- Das Single-Use Instrument nicht auf dem Patienten ablegen.
- Nur koagulieren, wenn sich die Kontaktflächen im Sichtbereich befinden. Dabei keine anderen metallischen Instrumente berühren.

Hinweis:

Die angegebenen Artikel dieser Gebrauchsanweisung sind **nur zum einmaligen Gebrauch** vorgesehen. Sie dürfen nicht re-sterilisiert werden. Eine Re-Sterilisation führt potentiell zum Ausfall einer Produkt-komponente, wodurch die Produktfunktion beeinträchtigt werden könnte. Bei Schäden, besonders an der Isolierung und am Stecker, sind die Single-Use Pinzetten zu entsorgen.

Single-Use (Non-Stick) Bipolar Pinzetten:

Die polierten Spitzen sind aus Edelstahl (Silber) gefertigt und können anlaufen; dadurch wird die Funktion der Single-Use Instrumente **nicht** beeinträchtigt.

Funktionsprüfung:

Die Single-Use Instrumente müssen vor Gebrauch auf ihre Funktionsfähigkeit überprüft werden. Eine optische Be-gutachtung der Instrumente auf Sauberkeit und ein Funktions-test sind durchzuführen.

Bei Schäden an der Oberfläche (bspw. Kratzer, Risse, Schar-ten, Kerben sowie verbogene Teile) dürfen die Instrumente nicht verwendet werden.

Warnhinweis:

Funktionsfehler, Versagen des Instruments, beschädigte Isolierung

Maßnahme durch Anwender: Sichtkontrolle / Funktionsprüfung durch-führen. Einsatz ge-mäß Zweckbestimmung, Einsatz liegt in der Verantwortung des Anwenders.

Warnhinweis:

Elektrische Belastbarkeit der Elektroden ist überschritten.

Maßnahme durch Anwender: Herstellerangaben zu elektrischer Belast-barkeit beachten, siehe Zweckbestimmung.

Handhabung:

Alle chirurgischen Instrumente sollten stets mit größter Sorgfalt behandelt werden.

Dies gilt insbesondere für feine Spitzen und sonstige empfindliche Bereiche.

Anschluss an Generatoren:

Die Single-Use Pinzetten der adeor medical AG sind für den Einsatz mit folgenden Generatoren zugelassen:

ERBE Elektromedizin GmbH		
TYPE	ARTIKEL-NR.	MAX. BIP. COAG-LEISTUNG
VIO 300 D	10140-100	≤ 200 Watt
VIO 200 D	10140-200	≤ 120 Watt
VIO 300 S	10140-300	≤ 200 Watt
VIO 200 S	10140-400	≤ 120 Watt
VIO 100 C	10140-500	≤ 80 Watt

VIO 50 C	10140-550	≤ 50 Watt
ICC 350	ICC 350	≤ 150 Watt
ICC 300	ICC 300	≤ 150 Watt
ICC 200	ICC 200	≤ 150 Watt
ICC 80	ICC 80	≤ 50 Watt
ICC 50	ICC 50	≤ 50 Watt
ACC 451	ICC 451	≤ 120 Watt
ACC 450	ICC 450	≤ 120 Watt
ACC 430	ICC 43	≤ 120 Watt

SUTTER Medizintechnik GmbH		
TYPE	ARTIKEL-NR.	MAX. BIP. COAG-LEISTUNG
BM-780 II	360080-01	≤ 70 Watt

KARL STORZ GmbH & Co. KG		
TYPE	ARTIKEL-NR.	MAX. BIP. COAG-LEISTUNG
AUTOCON® II 200	205322 20	≤ 120 Watt
AUTOCON® II 400	205352 20	≤ 120 Watt

COVIDIEN		
TYPE	ARTIKEL-NR.	MAX. BIP. COAG-LEISTUNG
Force FX™	Force FX™	≤ 70 Watt
ForceTriad™	ForceTriad™	≤ 95 Watt
Force EZ™	Force EZ™	≤ 70 Watt
SurgiStat™	SurgiStat™	≤ 30 Watt

BOWA-electronic GmbH & Co. KG		
TYPE	ARTIKEL-NR.	MAX. BIP. COAG-LEISTUNG
ARC 400	900-400	≤ 350 Watt
ARC 350	900-351	≤ 350 Watt
ARC 303	900-303	≤ 120 Watt
ARC 250	900-250	≤ 120 Watt
ARC 100	900-100	≤ 100 Watt

Olympus Surgical Technologies Europe		
TYPE	ARTIKEL-NR.	MAX. BIP. COAG-LEISTUNG
ESG-100, 220-240 V	WB991036	≤ 120 Watt
ESG-100, 100-120 V	WB991046	≤ 120 Watt
ESG-400	WB91051W	≤ 320 Watt

Söring GmbH		
TYPE	ARTIKEL-NR.	MAX. BIP. COAG-LEISTUNG
MBC 600	MBC 600	≤ 100 Watt
MBC 601	MBC 601	≤ 100 Watt
MBC 601	MBC 601	≤ 100 Watt
UAM	UAM	
MBC 200	MBC 200	≤ 140 Watt
BCC 140	BCC 140	≤ 140 Watt

LAMIDEY NOURY MEDICAL		
TYPE	ARTIKEL-NR.	MAX. BIP. COAG-LEISTUNG
Optima 4	Optima 4	≤ 370 Watt
Optima 3	Optima 3	≤ 370 Watt
Optima 2	Optima 2	≤ 200 Watt
MC 2	MC 2	≤ 70 Watt
MC 3	MC 3	≤ 100 Watt
MC 4	MC 4	≤ 100 Watt

Integra LifeSciences Corporation		
TYPE	ARTIKEL-NR.	MAX. BIP. COAG-LEISTUNG
Elektrotrom® 621	Elektrotrom® 621	≤ 95 Watt
Elektrotrom® 630	Elektrotrom® 630	≤ 95 Watt

Gebrüder Martin GmbH & Co. KG		
TYPE	ARTIKEL-NR.	MAX. BIP. COAG-LEISTUNG
Minicutter	80-008-03-04	≤ 70 Watt
ME 102	80-010-02-04	≤ 80 Watt
maxium®, m-Version	80-042-00-04	≤ 320 Watt

maxium®, i-Version	80-042-02-04	≤ 320 Watt
maxium®, e-Version	80-042-04-04	≤ 320 Watt
ME MB 3, m-Version, 220-240 V	80-040-11-04	≤ 100 Watt

ME MB 3, m-Version, 100-127 V	80-040-11-10	≤ 100 Watt
ME MB 3, i-Version, 100-127 V	80-040-12-04	≤ 100 Watt
ME MB 3, i-Version, 100-127 V	80-040-12-10	≤ 100 Watt

ME MB 3, i-Version, 100-127 V	80-041-01	≤ 80 Watt
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Aesculap AG / B. Braun Melsungen AG		
TYPE	ARTIKEL-NR.	MAX. BIP. COAG-LEISTUNG
GN300	GN 300	≤ 80 Watt
GN640	GN640	≤ 100 Watt
GN060	GN060	≤ 50 Watt

Geeignete Anschlusskabel:

Die Single-Use Bipolar Pinzetten sind für den Einsatz mit folgenden bipolaren Anschlusskabeln für die oben genannten Generatoren zugelassen:

Kabelanschluss generatorseitig		
ERBE Elektromedizin GmbH, KARL STORZ GmbH & Co. KG	ERBE Elektromedizin GmbH – ICC-Serie, International	
Aesculap AG / B. Braun Melsungen AG, Gebrüder Martin GmbH & Co. KG, Sutter Medizintechnik GmbH	COVIDIEN, LAMIDEY NOURY MEDICAL, BOWA-electronic GmbH & Co. KG, ERBE Elektromedizin GmbH – VIO-Serie, Olympus Surgical Technologies Europe, Söring GmbH	

Kabelanschluss pinzettenseitig		
Europäischer Flachstecker		
2-Pin-Stecker(US-Stiftstecker)		

Diese Kabel sind an den bipolaren Ausgang von Elektro-chirurgiegeräten an-zuschließen. Vor dem Einsatz der Single-Use Bipolar Pinzetten die Bedienungsanleitung des Generators beachten, wie diese Kabel anzuschließen sind. Mit HF-Generatoren sind verschiedene Gefahren verbun-den, wie Fehlbedienung, ungewollte Hochfrequenzverbrennungen, Entzündungen brennbarer Flüssigkeiten und Gase (Explosionsgefahr).

Verpackung / Lagerung: Die Single-Use Instrumente sind zum Teil sehr empfindlich. Die Single-Use Instrumente sollten in einer trockenen, sauberen und staubfreien Umgebung bei moderaten Temperaturen von 5° C bis 40° C gelagert werden.

Gewährleistung:

adeor medical AG liefert ausschließlich geprüfte und fehler-freie Produkte an ihre Kunden aus. Alle unsere Produkte sind so ausgelegt und gefertigt, dass sie den höchsten Qua-litätsansprüchen genügen. Sollten dennoch Fehler auftren-nen, wenden Sie sich an unseren Service. Eine Haftung für Produkte, die gegenüber dem Original modifiziert, zweckentfremdet oder unsachgemäß behandelt oder ein-gesetzt wurden, wird ausgeschlossen. Die adeor medical AG übernimmt keine Haftung für zufäl-lige oder sich ergebende Schäden. Bei Reparaturen durch Firmen, die nicht von der adeor medical AG zur Reparatur autorisiert sind, entfällt die Gewährleistung.

Entsorgung:

Sofern die Single-Use Bipolar Pinzetten durch Beschädigun-gen nicht mehr eingesetzt werden können, sind diese fach-gerecht zu entsorgen.

Bedeutung der Symbole:

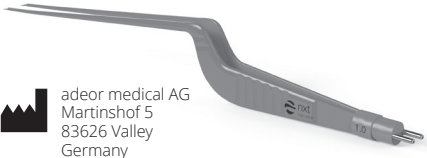
	Gebrauchsanweisung beachten
	Produkt vor Nässe, Kondenswasser schützen
	Produkt vor Sonneneinstrahlung schützen
	Sterilisiert durch Bestrahlung
	Achtung, Hinweise beachten
	Hersteller / Herstelldatum
	Bestellnummer
	Single-Use / Einmal-Produkt
	Lot- bzw. Chargencode
	Verwendbar bis
	CE-Kennzeichnung inklusive Kennziffer der Benannten Stelle

ENGLISH

INSTRUCTIONS FOR USE SINGLE-USE BIPOLAR FORCEPS

REF	Product group: Single-Use HF Forceps
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Reference: BIPAAABBSU
AAA will be replaced by a 3-digit number.
BB will be replaced by EU or US.
EU represents the Euro-pean and US the American connector type.
SU means Single-Use.



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Attention: The single-use instruments are supplied sterile.

Rx Only Warning: Legal regulations stipulate that the single-use instruments may only be acquired by or on behalf of a physician.

Warning:

Please read the information in this leaflet carefully. Improper use and care or use for unintended purposes can lead to premature wear or risks for patients and users.

Intended use:

Single-use bipolar forceps made by adeor medical AG are intended for use in all areas of open surgery. They are de-signed to grasp, manipulate and coagulate tissue. They are connected through a suitable bipolar cable with the bipolar output of a HF generator and may be used only with bipolar coagulation current. adeor bipolar forceps must be opera-ted with the following parameters:
Frequency range between 300 kHz and 1,000 kHz; maxi-mum generator operating voltage 600 Vp.
The surgeon must determine the appropriate type of treat-ment for each individual case in cooperation with the internist and the anaesthetist. Typical HF surgical interventions include

- Dermatology: hair and wart removal
- ENT: polyp removal, bipolar hemostasis
- Gynecology: electro-conization of the portio, sterilization by bipolar coagulation of the fallopian tube
- Urology: transurethral resection of the prostate, bladder tumour or bladder wall papillomas; cutting and coagulation in transabdominal surgery
- Laparoscopy and cystoscopy: Removal of polyps
- General surgery: primary sections, separating tissue, plastic surgery, hemostasis, coagulation
- Neurosurgery: Bipolar coagulations

Contraindications:

The single-use bipolar forceps should not be used if the physician determines that the risk to the patient outweighs the benefits.

Single-Use bipolar forceps made by adeor medical AG should not be used for tubal sterilization or tube coagulation for sterilization.

Do not use on patients with cardiac pacemakers or other active implants.

Attention:

Single-use instruments for electrosurgery may only be used by persons who are specially trained or instructed.

Safety instructions:

- Checking, using and handling electrosurgical instruments is the responsibility of the user.
- Before each use, the single-use instrument must be inspected for wear and visible damage, such as cracks, fractures or damage to the insulation, in particular areas such as the blade, tip, groove, connector, lock and moving parts. Check the insulation thoroughly.
- Do not use damaged single-use instruments.
- Do not use the single-use instruments in the presence of flammable or explosive substances.

- Do not place the single-use instrument on top of the patient.
- Perform coagulation only if the contact surfaces are in the visible area. Do not touch any other metal instru-ments during the procedure.

Warning:

The parts mentioned in this instruction for use are **single-use only**. They cannot be resterilized.

Resterilization causes malfunction to parts of the product which infects the function.

If the single-use forceps are damaged, especially at the insulation or the connector, dispose the product.

Single-Use (Non-stick) Bipolar forceps: The polished tips are made of stainless steel (silver) and may tarnish which **does not** affect the function of the single-use instruments.

Functional testing:

Single-use instruments must be checked for functionality before each use. Visually inspect the instruments for clean-liness and carry out a function test. If necessary, repeat the reprocessing process until the instrument looks clean. Surface damage, such as scratches, cracks, nicks, notches etc., or bent parts mean that the instruments may not be used.

Warning:

Malfunction, instrument failure, damaged insulation

Action required by user: Perform a visual inspection/functional testing. It is the re-sponsibility of the user to ensure that the instruments are used in line with the intended purpose.

Warning:

Electrical loading capacity of the electrodes exceeded

Action required by user: Follow manufacturer's instructions for electrical loading; see "Intended use".

Handling:

Surgical instruments should always be treated with the utmost care. This is particular pointed on tips and other sensitive areas.

Generator connections:

Single-use forceps made by adeor medical AG are appro-ved for use with the following generators:

ERBE Elektromedizin GmbH		
TYPE	ITEM NO.	MAX. BIPOLAR COAG. POWER
VIO 300 D	10140-100	≤ 200 Watt
VIO 200 D	10140-200	≤ 120 Watt
VIO 300 S	10140-300	≤ 200 Watt
VIO 200 S	10140-400	≤ 120 Watt
VIO 100 C	10140-500	≤ 80 Watt
VIO 50 C	10140-550	≤ 50 Watt
ICC 350	ICC 350	≤ 150 Watt
ICC 300	ICC 300	≤ 150 Watt
ICC 200	ICC 200	≤ 150 Watt
ICC 80	ICC 80	≤ 50 Watt
ICC 50	ICC 50	≤ 50 Watt
ACC 451	ICC 451	≤ 120 Watt
ACC 450	ICC 450	≤ 120 Watt
ACC 430	ICC 43	≤ 120 Watt

SUTTER Medizintechnik GmbH		
TYPE	ITEM NO.	MAX. BIPOLAR COAG. POWER
BM-780 II	360080-01	≤ 70 Watt

KARL STORZ GmbH & Co. KG		
TYPE	ITEM NO.	MAX. BIPOLAR COAG. POWER
AUTOCON® II 200	205322 20	≤ 120 Watt
AUTOCON® II 400	205352 20	≤ 120 Watt

COVIDIEN		
TYPE	ITEM NO.	MAX. BIPOLAR COAG. POWER
Force FX™	Force FX™	≤ 70 Watt
ForceTriad™	ForceTriad™	≤ 95 Watt
Force EZ™	Force EZ™	≤ 70 Watt
SurgiStat™	SurgiStat™	≤ 30 Watt

BOWA-electronic GmbH & Co. KG		
TYPE	ITEM NO.	MAX. BIPOLAR COAG. POWER
ARC 400	900-400	≤ 350 Watt
ARC 350	900-351	≤ 350 Watt
ARC 303	900-303	≤ 120 Watt
ARC 250	900-250	≤ 120 Watt
ARC 100	900-100	≤ 100 Watt


US

INSTRUCTIONS FOR USE
SINGLE-USE BIPOLAR FORCEPS

REF	Product group: Single-Use HF Forceps
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Reference: BIPAAABBSU
AAA will be replaced by a 3-digit number.
BB will be replaced by EU or US.
EU represents the European and US the American connector type.
SU means Single-Use.



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Germany

Attention:

The single-use instruments are supplied sterile.

Warning:

Legal regulations stipulate that the single-use instruments may only be acquired by or on behalf of a physician.

Warning:

Please read the information in this leaflet carefully. Improper use and care or use for unintended purposes can lead to premature wear or risks for patients and users.

Intended use:

The adeor medical Single-Use Non-stick Bipolar Forceps are intended for use by a physician familiar with electro-surgery in bipolar coagulation for general open surgery where coagulation of soft tissue is needed.
adeor bipolar forceps must be operated with the following parameters:
Frequency range between 300 kHz and 1,000 kHz;
maximum generator operating voltage 600 Vp.
The adeor medical Single-Use Non-stick Bipolar Forceps have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.

The types of surgery intended include:

- ENT
- Gynecology (except for use in female sterilization)
- Urology
- General surgery
- Neurosurgery
- Laryngeal Surgery
- Orthopedic Surgery
- Thoracic Surgery

Contraindications:

The single-use bipolar forceps should not be used if the physician determines that the risk to the patient outweighs the benefits.
Single-Use bipolar forceps made by adeor medical AG should not be used for tubal sterilization or tube coagulation for sterilization.

Do not use on patients with cardiac pacemakers or other active implants.

Attention:

Single-use instruments for electrosurgery may only be used by persons who are specially trained or instructed.

Safety instructions:

- Checking, using and handling electrosurgical instruments is the responsibility of the user.
- Before each use, the single-use instrument must be inspected for wear and visible damage, such as cracks, fractures or damage to the insulation, in particular areas such as the blade, tip, groove, connector, lock and moving parts. Check the insulation thoroughly.
- Do not use damaged single-use instruments.
- Do not use the single-use instruments in the presence of flammable or explosive substances.
- Do not place the single-use instrument on top of the patient.
- Perform coagulation only if the contact surfaces are in the visible area. Do not touch any other metal instruments during the procedure.

Warning:

The parts mentioned in this instruction for use are single-use only. They cannot be resterilized.

Resterilization causes malfunction to parts of the product which infects the function.

If the single-use forceps are damaged, especially at the insulation or the connector, dispose the product.

Single-Use (Non-stick) Bipolar forceps:

The polished tips are made of stainless steel (silver) and may tarnish which does not affect the function of the single-use instruments.

Functional testing:

Single-use instruments must be checked for functionality before each use. Visually inspect the instruments for cleanliness and carry out a function test. If necessary, repeat the reprocessing process until the instrument looks clean.

Surface damage, such as scratches, cracks, nicks, notches etc., or bent parts mean that the instruments may not be used.

Warning:

Malfunction, instrument failure, damaged insulation

Action required by user:

Perform a visual inspection/functional testing. It is the responsibility of the user to ensure that the instruments are used in line with the intended purpose.

Warning:

Electrical loading capacity of the electrodes exceeded

Action required by user:

Follow manufacturer's instructions for electrical loading; see "Intended use".

Handling:

Surgical instruments should always be treated with the utmost care. This is particular pointed on tips and other sensitive areas.

Suitable connection cables:

adeor single-use bipolar forceps can be used with bipolar connection cables that are suitable for use with generators that meet the required operating parameters.

Cable connection, forceps

European flat plug

2-pin plug (US male connector)

These cables may be connected only to the bipolar output of electrosurgical devices. Please follow the generator instructions on connecting these cables before using the single-use bipolar forceps.

HF generators pose a number of risks, such as incorrect operation, unintended high-frequency burns, ignition of flammable liquids and gases (risk of explosion).

Packing/Storage:

Some parts of these single-use instruments can be easily damaged. The sterilized single-use instruments should be stored in a dry, clean and dust-free environment at moderate temperatures of 5°C to 40°C.

Warranty:

adeor medical AG provides customers with tested, fault-free products. All our products are designed and manufactured to meet highest quality standards. However, should problems occur, please contact our customer service team. Liability is excluded for products that were modified from the original product, used for other than the intended purposes, handled or used improperly.




adeor medical AG does not accept liability for incidental or consequential damages. This warranty is voided if repairs are carried out by companies that are not authorized for repair by adeor medical AG.

Proper disposal of bipolar forceps:


If the single-use bipolar forceps can no longer be used, e.g., because of damage, they must be disposed properly.


(This section is a translation of the German text. It may not be accurate.)

Symbols and their meaning:

	Follow operating instructions
	Protect the product against moisture and condensation
	Protect the product against direct sunlight


	Sterilized by radiation
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	Caution: Please follow instructions
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	Manufacturer / Date of manufacture
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
	Order No.
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	Do not reuse/Single-use only
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	Lot number
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	Use by – symbol is accompanied by a date
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	Prescription device only (USA)
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	CE including Notified Body code
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PORTUGUÊS

INSTRUÇÕES DE USO
PINÇA BIPOLAR DE USO ÚNICO

REF	Grupo de produtos: Pinça HF de uso único
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Referência: BIPAAABBSU
AAA será substituído por um número de 3 dígitos.
O BB será substituído pela UE ou pelos EUA.
EU representa o europeu e os EUA tipo de conector americano.
SU significa Uso Único.



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Atenção:

Os instrumentos de uso único são fornecidos estéril.

Atenção:

Por favor, leia as informações neste folheto cuidadosamente. Uso e cuidados inadequados ou uso para fins não intencionais podem levar a prematuro desgaste ou riscos para pacientes e usuários.

Uso pretendido:

Pinça bipolar de uso único feita por adeor A medical AG destina-se ao uso em todas as áreas de cirurgia aberta. Elas são projetadas para segurar, manipular e coagular tecido. Elas estão conectadas através de um cabo bipolar adequado, com a saída de frequência de um gerador HF e pode ser usado apenas com corrente bipolar de coagulação.
Pinça bipolar adeor deve ser operado com os seguintes parâmetros:
Faixa de frequência entre 300 kHz e 1.000 kHz;
funcionamento máximo do gerador tensão 600 Vp.

O tipo de tratamento deve ser determinado em cada caso individual pelo cirurgião em cooperação com o especialista de medicina interna e o anestesista. Os procedimentos típicos com cirurgia de AF são:

- Dermatologia: epilação, remoção de verrugas
- ORL: remoção, hemostasia bipolar
- Ginecologia: conização elétrica do cérvix, esterilização através de coagulação bipolar da trompa de Falópio
- Urologia: ressecção transuretral da próstata, de carcinomas da bexiga e papilomas da parede da bexiga, corte e coagulação em procedimentos transabdominais
- Laparoscopia e cistoscopia: extirpação de pólipos
- Cirurgia geral: corte primário, separação de tecidos, cirurgia plástica, hemostasia, coagulações
- Neurocirurgia: coagulações bipolares

Contraindicações:

A pinça bipolar de uso único não deve ser usada se o médico determinar que o risco para o paciente supera os benefícios.
Pinça bipolar descartável feita por adeor medical AG não deve ser usado para esterilização tubária ou coagulação do tubo para esterilização.

Não use em pacientes com insuficiência cardíaca, com marca-passos ou outros implantes ativos.

Atenção:

Instrumentos descartáveis para eletrocirurgia só podem ser usados por pessoas que são especialmente treinados ou instruídos.

Instruções de segurança:

- A verificação, uso e manuseio dos instrumentos eletro-cirúrgicos é o responsabilidade do usuário.
- Antes de cada uso, o instrumento de uso único deve ser inspecionado quanto a desgaste e danos visíveis, como rachaduras, fraturas ou falhas no isolamento, em áreas específicas, como a lâmina, ponta, ranhura, conector, bloqueio e movimento das partes. Verificar o isolamento completamente.
- Não use o instrumento de uso único se danificado.
- Não use o instrumento de uso único na presença de substâncias inflamáveis ou substâncias explosivas.
- Não coloque o instrumento de uso único em cima do paciente.
- Realize a coagulação somente se o contato superfícies estão na área visível. Não toque em qualquer outro instrumento de metal durante o procedimento.

Atenção:

As partes mencionadas nesta instrução para o uso é apenas de uso único. Elas não podem ser reesterilizadas.

A reesterilização causa mau funcionamento as partes do produto que pode afetar a sua função.

Se a pinça descartável estiver danificada, especialmente no isolamento ou no conector, descarte o produto.

Pinça bipolar de uso único (antiaderente):

As pontas polidas são feitas de aço inoxidável (prateadas) e podem manchar, o que não afeta a função dos instrumentos de uso único.

Teste funcional:

Instrumentos de uso único devem ser verificados quanto à funcionalidade antes de cada uso. Inspecione visualmente os instrumentos quanto à limpeza e realize um teste de funcionamento. Se necessário, repita o processo de reprocessamento até que o instrumento pareça limpo. Danos à superfície, como arranhões, rachaduras, entalhes, entalhes, etc., ou peças dobradas, significam que os instrumentos não podem ser usados.

Atenção:

Mau funcionamento, falha do instrumento, isolamento danificado.

Ação requerida pelo usuário:

Realizar uma inspeção visual / teste funcional. É de responsabilidade do usuário garantir que os instrumentos sejam usados de acordo com a finalidade pretendida.

Atenção:

Capacidade de carga elétrica dos eletrodos excedidos

Ação requerida pelo usuário:

Siga as instruções do fabricante para carregamento elétrico; consulte "Uso pretendido".

Manipulação:

Instrumentos cirúrgicos devem sempre ser tratados com o máximo cuidado. Isto é, particularmente observando pontas e outras áreas sensíveis.

Conexões do gerador:

Pinças de uso único feitos pela adeor medical AG são aprovados para uso com os seguintes geradores:

ERBE Elektromedizin GmbH		
TIPO	ITEM NÚMERO	PODER MAX. COAG BIPOLAR
VIO 300 D	10140-100	≤ 200 Watt
VIO 200 D	10140-200	≤ 120 Watt
VIO 300 S	10140-300	≤ 200 Watt
VIO 200 S	10140-400	≤ 120 Watt
VIO 100 C	10140-500	≤ 80 Watt
VIO 50 C	10140-550	≤ 50 Watt
ICC 350	ICC 350	≤ 150 Watt
ICC 300	ICC 300	≤ 150 Watt
ICC 200	ICC 200	≤ 150 Watt
ICC 80	ICC 80	≤ 50 Watt
ICC 50	ICC 50	≤ 50 Watt
ACC 451	ICC 451	≤ 120 Watt
ACC 450	ICC 450	≤ 120 Watt
ACC 430	ICC 43	≤ 120 Watt

SUTTER Medizintechnik GmbH		
TIPO	ITEM NÚMERO	PODER MAX. COAG BIPOLAR
BM-780 II	360080-01	≤ 70 Watt

KARL STORZ GmbH & Co. KG		
TIPO	ITEM NÚMERO	PODER MAX. COAG BIPOLAR
AUTOCON® II 200	205322 20	≤ 120 Watt
AUTOCON® II 400	205352 20	≤ 120 Watt

COVIDIEN		
TIPO	ITEM NÚMERO	PODER MAX. COAG BIPOLAR
Force FX™	Force FX™	≤ 70 Watt
ForceTriad™	ForceTriad™	≤ 95 Watt
Force EZ™	Force EZ™	≤ 70 Watt
SurgiStat™	SurgiStat™	≤ 30 Watt

BOWA-electronic GmbH & Co. KG		
TIPO	ITEM NÚMERO	PODER MAX. COAG BIPOLAR
ARC 400	900-400	≤ 350 Watt
ARC 350	900-351	≤ 350 Watt
ARC 303	900-303	≤ 120 Watt
ARC 250	900-250	≤ 120 Watt
ARC 100	900-100	≤ 100 Watt

Olympus Surgical Technologies Europe		
TIPO	ITEM NÚMERO	PODER MAX. COAG BIPOLAR
ESG-100, 220-240 V	WB991036	≤ 120 Watt
ESG-100, 100-120 V	WB991046	≤ 120 Watt
ESG-400	WB91051W	≤ 320 Watt

Söring GmbH		
TIPO	ITEM NÚMERO	PODER MAX. COAG BIPOLAR
MBC 600	MBC 600	≤ 100 Watt
MBC 601	MBC 601	≤ 100 Watt
MBC 601 UAM	MBC 601 UAM	≤ 100 Watt
MBC 200	MBC 200	≤ 140 Watt
BCC 140	BCC 140	≤ 140 Watt

LAMIDEY NOURY MEDICAL		
TIPO	ITEM NÚMERO	PODER MAX. COAG BIPOLAR
Optima 4	Optima 4	≤ 370 Watt
Optima 3	Optima 3	≤ 370 Watt
Optima 2	Optima 2	≤ 200 Watt
MC 2	MC 2	≤ 70 Watt
MC 3	MC 3	≤ 100 Watt
MC 4	MC 4	≤ 100 Watt

Integra LifeSciences Corporation		
TIPO	ITEM NÚMERO	PODER MAX. COAG BIPOLAR
Elektrotom®	Elektrotom®	≤ 95 Watt
621	621	≤ 95 Watt
Elektrotom®	Elektrotom®	≤ 95 Watt
630	630	≤ 95 Watt

Gebrüder Martin GmbH & Co. KG		
TIPO	ITEM NÚMERO	PODER MAX. COAG BIPOLAR
Minicutter	80-008-03-04	≤ 70 Watt
ME 102	80-010-02-04	≤ 80 Watt
maxium®, m-Version	80-042-00-04	≤ 320 Watt
maxium®, i-Version	80-042-02-04	≤ 320 Watt
maxium®, e-Version	80-042-04-04	≤ 320 Watt
ME MB 3, m-Version, 220-240 V	80-040-11-04	≤ 100 Watt

ME MB 3,	80-040-11-10	≤ 100 Watt
m-Version, 100-127 V		
ME MB 3,	80-040-12-04	≤ 100 Watt
i-Version, 100-127 V		
ME MB 3,	80-040-12-10	≤ 100 Watt
i-Version, 100-127 V		
ME 411	80-041-01	≤ 80 Watt

Aesculap AG / B. Braun Melsungen AG		
TIPO	ITEM NÚMERO	PODER MAX. COAG BIPOLAR
GN300	GN 300	≤ 80 Watt
GN640	GN640	≤ 100 Watt
GN060	GN060	≤ 50 Watt

Cabos de conexão adequados:

Uma pinça bipolar de uso único foi aprovada para uso com o cabo bipolar.

Este cabo pode ser conectado apenas à saída bipolar de dispositivos eletrocirúrgicos. Por favor, siga as instruções do gerador para conectar esses cabos antes de usar a pinça bipolar de uso único.

Os geradores de alta frequência apresentam vários riscos, como operação incorreta, queimaduras de alta frequência não intencionais, ignição de líquidos e gases inflamáveis (risco de explosão).

Embalagem / Armazenamento:

Algumas partes desses instrumentos descartáveis podem ser facilmente danificadas. Os instrumentos descartáveis esterilizados devem ser armazenados em um ambiente seco, limpo e livre de poeira em temperaturas moderadas de 5 ° C a 40 ° C.

Garantia:


A adeor medical AG fornece aos clientes produtos testados e sem falhas. Todos os nossos produtos são projetados e fabricados para atender aos mais altos padrões de qualidade. No entanto, caso ocorram problemas, entre em contato com nossa equipe de atendimento ao cliente.

A responsabilidade é excluída para produtos que foram modificados a partir do produto original, usados para outros fins que não os pretendidos, manipulados ou utilizados indevidamente.


A adeor medical AG não aceita responsabilidade por danos incidentais ou consequenciais. Esta garantia é anulada se os reembolsos forem realizados por empresas que não estejam autorizadas para reparo pela adeor medical AG.


Descarte adequado da pinça bipolar:


Se a pinça bipolar descartável não puder mais ser usada se estiver danificada, ela deve ser descartada adequadamente.


	Siga as instruções de operação
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	Proteja o produto contra umidade e condensação
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	Proteja o produto contra a luz solar direta
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	Esterilizado por radiação
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	Atenção: por favor siga as instruções
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	Fabricante / Data de fabricação
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	Catálogo nº
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