OLYMPUS

INSTRUCTIONS FOR USE

BIPOLAR APPLICATOR

CELON ProCurve V

CELON

CE 0197

WB990207

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1 General information

1.1 User instructions

- Before use, thoroughly read these instructions for use and the instructions for use of all other products that will be used during the procedure.
- If the required instructions for use are missing, immediately contact a sales representative.
- Keep the instructions for use in a safe, accessible location.

1.2 Signal words

The following signal words are used throughout this document.

WARNING
Indicates a potentially hazardous situation which, if not avoided, can result in death or serious injury.

CAUTION
Indicates a potentially hazardous situation which, if not avoided, can result in minor or moderate injury.

1.3 Conventions throughout this document

This is the safety alert symbol. It is used to alert the user to potential physical injury hazards. Observe all safety messages that follow this symbol to avoid possible injury.

This symbol indicates additional helpful information.

1. A numeration indicates a sequence of actions.
2. ...

- Bullet points indicate individual actions or different options for action.

- Dashes indicate the listing of data, options or objects.

1) Numbers with right parenthesis name elements in illustrations.

[example]
Bracketed terms refer to elements in the graphical user interface or keys.
Elements in the graphical user interface can be:
- buttons
- menu items
- dialog elements

1.4 Manufacturer

Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg
Germany

2 Safety information

2.1 Intended use

2.1.1 General intended use

Bipolar applicator for ablation and coagulation of soft tissue to be used in combination with a compatible electrosurgical generator.

2.1.2 Specific intended use

The bipolar applicator, in combination with the compatible electrosurgical generator, is indicated for ablation and coagulation of soft tissue, as well as for shrinking vessels and lumens.

This method of treatment is called bipolar radiofrequency induced thermotherapy (RFITT).

2.2 Contraindications

Electrosurgical interventions are contraindicated if, in the judgment of the physician, tissue coagulation can have a negative effect on the state of the patient. Radiofrequency induced tissue coagulation may be contraindicated for patients with a weakened immune system, phlebitis, thrombophlebitis and coagulation disorders like coagulopathy.

Potential complications associated with the use of the bipolar applicator in general are the same as those associated with percutaneous, endoscopic or open surgical interventions using high frequency applicators for tissue coagulation. They include, but are not limited to:

- Bleeding
- Haematomata
- Infections

- Oedemata
- Mechanical and thermal damage to neighboring tissues/ structures such as nerves, vessels, lymph ducts and the skin.

In addition, the endoluminal or endovenous application of the bipolar applicator presents the risk of thrombosis or an embolism.

A vein diameter greater than 25 mm in a patient with a body mass index (BMI) greater than 40 is at the discretion of the treating physician.

2.3 User qualification

Medical use
This product is only intended to be used by a trained physician.

These instructions for use do not explain or discuss clinical procedures.

2.4 Environment of use

Medical use
This product is only intended to be used in an operating room or in a physician's office.

2.5 General dangers, warnings and cautions

The following warnings and cautions apply to the general handling of the product. This information is to be supplemented by the dangers, warnings and cautions given in each chapter in this document or in the instructions for use of any product being used with this product.

WARNING
Severe complications
If the bipolar applicator is used without appropriate training, then this can result in severe complications and injury to the patient.
- Only use the bipolar applicator as a physician who is trained in the use of bipolar electrosurgical equipment, the treatment of varicose veins and the targeted puncture of veins.

WARNING
Thrombosis or pulmonary embolism
Blood clots that build up at the tip of the bipolar applicator can come loose and can cause complications like thrombosis or pulmonary embolism. If such complications remain untreated, then they can result in serious harm or death of the patient.
- Only use the bipolar applicator if you are prepared to treat complications like thrombosis or pulmonary embolism.

WARNING
Pulmonary embolism
If the bipolar applicator is activated while the tip is positioned in the iliac vein, then this can cause pulmonary embolism.
- When performing a procedure near the saphenofemoral junction, take care that there is adequate clearance to the iliac vein.
- Before applying HF current near the saphenofemoral junction, check the correct position of the tip by ultrasound monitoring.

WARNING
Cross contamination, nosocomial or general infection
The product is for single use only. The product is delivered in a sterile condition. Reuse, cleaning, reprocessing, resterilization and improper storing conditions can lead to injury of the patient and the user and malfunction of the product.
- Do not use the product if the packaging has been opened, if the packaging is damaged or if there are other signs of nonsterility.
- Do not use the product after its use by date.
- Open the packaging only immediately before use.
- After unpacking, do not wrap the product.
- Do not attempt to clean, reprocess or resterilize the product.

WARNING
Risk of fire and explosion
The igniting of flammable gases like anesthetics or gases within the intestines of the patient can cause fire or explosion when applying HF current. This can result in serious injuries to the patient, the user and the medical personnel.
- Do not use flammable anesthetics, e.g. nitrous oxide or oxygen.
- Take precautionary measures to keep away flammable gases from the site of intervention.
- Before the procedure, replace intestine gases by air or by other non-flammable gases.

WARNING
Malfunction of pacemakers and defibrillators
Using HF equipment on patients with implanted electronic devices, e.g. cardiac pacemakers or cardioverter defibrillators, can cause failure of the implanted electronic device. Failure of the implanted electronic device will affect the heart and can result in cardiac arrest.
- Before the procedure, confirm its safety with a cardiologist or the manufacturer of the implanted electronic device.
- Do not apply the HF instrument in close proximity to the implanted electronic device.

WARNING
Use of a damaged product
The use of a damaged product or of a product with improper functioning can cause an electric shock, mechanical injury, infection and thermal injury.
- Before each use, inspect the product according to the instructions in the section “Preparing a matching introducer” on page 18.
- Do not use a damaged product or a product with improper functioning.
- Replace a damaged product or a product with improper functioning.

WARNING
Unauthorized repair and product modification
There is a risk of injury to the patient and the user caused by unauthorized repairs and product modification.
- Do not attempt to repair or modify the product.

CAUTION
Incompatible electrosurgical generators
Incompatible electrosurgical generators can deliver an inappropriate and uncontrolled amount of HF current. This can result in severe thermal damage of the target tissue and of non-target tissue or in incomplete therapy. Furthermore, other complications like strong sticking to the vein wall or excessive blood clotting can occur.
- Only use a compatible electrosurgical generator as listed in the chapter “Compatible equipment” on page 27.
- Observe the maximum permitted power and voltage for the bipolar applicator as stated in the chapter “Storage and technical data” on page 28.

CAUTION
Using physiological monitoring equipment
Current can flow to the monitoring electrodes and can cause thermal injury where the monitoring electrodes are attached to the patient. Especially, the use of needle electrodes can result in burns to the patient.
- Place the monitoring electrodes as far away as possible from the electrodes of the HF instrument.
- Do not use needle monitoring electrodes.
- Use physiological monitoring equipment with HF current limiting measures.

CAUTION
Harm by accelerated metal parts
Strong magnetic fields as known from MRI (magnetic resonance imaging) can accelerate metal parts of the product. Such accelerated parts can harm the patient, the user and the medical personnel.
- Do not use the bipolar applicator under strong magnetic fields.

CAUTION

The electrosurgical generator can disturb other equipment

During activation, HF noise is generated by the electrosurgical generator which can disturb neighboring electrical equipment. Malfunction of the devices can occur, e.g. the monitor of endoscopic imaging equipment might freeze or black out, which can result in injury to the patient.

- Make sure that the electrosurgical generator is not used next to or stacked with equipment that is not part of the electrosurgical generator or of the system.
- Before use, thoroughly confirm the compatibility of all equipment.
- Do not use the electrosurgical generator in conjunction with:
  - Electrical equipment for which the safety against leakage current is not confirmed.
  - Electrosurgical equipment for which the safety in combined use is not confirmed.
- Do not loop cables.
- Do not bundle cables together with cables belonging to other medical equipment.

3 Product description

3.1 Scope of delivery

- Before use, check that all items listed below are available.
- Contact a sales representative or an authorized service center if any items are missing or damaged.

WB990207
- Bipolar applicator CELON ProCurve V
- Instructions for use

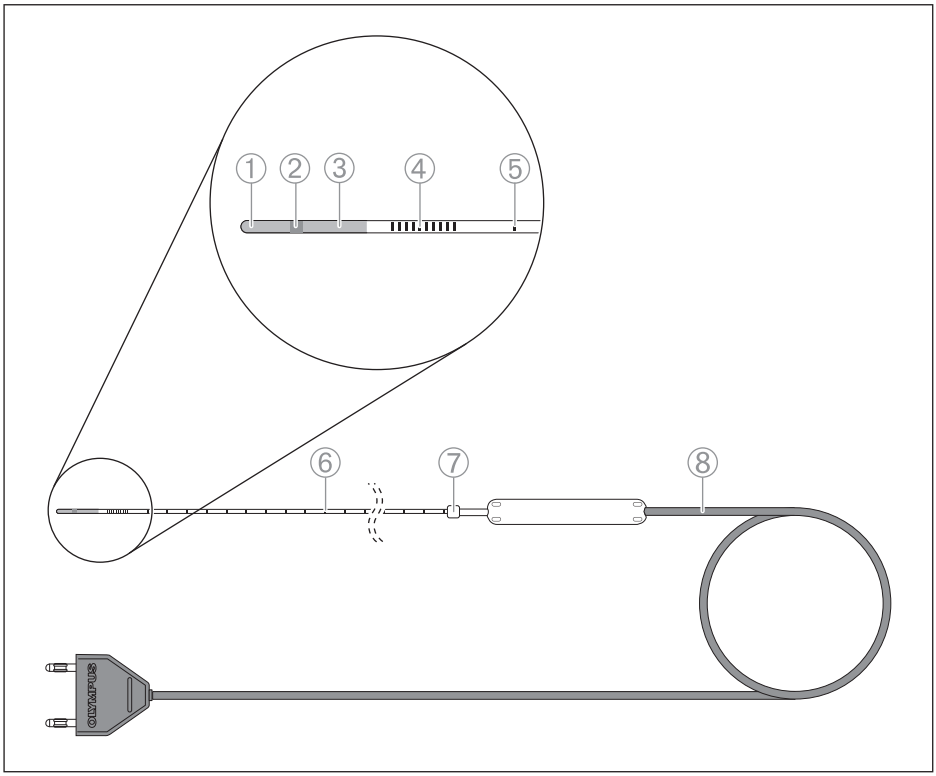
3.2 Symbols

This section gives an explanation for each symbol used on the product and on the packaging of the product.

Symbol	Explanation	Symbol	Explanation
	Catalog number		Keep away from rain. Keep dry
	Batch code		Sterilized using irradiation
	Quantity of content		Do not reuse
	Manufacturer		Do not resterilize
	Follow instructions for use		Storage conditions
	Do not use if package is damaged		Transport conditions
	Use by date		Indicates the temperature limits to which the medical device can be safely exposed

Symbol	Explanation	Symbol	Explanation
Rx only	Federal (USA) law restricts this device to sale by or on the order of a physician		Indicates the range of humidity to which the medical device can be safely exposed
CE 0197	CE certification mark – symbol for the compliance with the Medical Device Directive 93/42/EEC		Indicates a recovery/recyclable package or package material
	Green Dot-symbol for dual recycling system	---	---

3.3 Parts and names



1) Distal electrode with spherical tip
2) Insulator
3) Proximal electrode
4) Stop markers
5) 1 cm marker
6) Flexible catheter with 1 cm markers
7) Shiftable rubber ring
8) HF cable with plug

3.4 Functionality

The CELON ProCurve V is a bipolar applicator that uses RFITT (radiofrequency induced thermotherapy) technology. The spherical tip of the catheter is inserted into the insufficient vein. While the operator slowly and steadily withdraws the CELON ProCurve V from the vein, resistance controlled HF current is applied by the compatible electrosurgical generator. The application of HF current heats the tissue, which causes the vein to shrink and occlude. The obliterated vein remains in the body.

Refer to the instructions for use of the compatible electrosurgical generator for the functionality of the bipolar RFITT coagulation modes.

Instrument recognition and automatic default settings
The CELON ProCurve V is equipped with a memory chip that stores the following default settings:

Default mode:.....Pulse RFITT
Default output power: .....18 W
Minimum output power: .....5 W
Maximum output power: .....25 W

As soon as the CELON ProCurve V is connected, the electrosurgical generator recognizes the instrument. If the current settings of the electrosurgical generator are outside of the restricted range, then the default mode and default output power are set automatically.

Limited usage span
The CELON ProCurve V is delivered sterile and is intended for single use only.

To protect the patient from a worn-out instrument the integrated memory chip also records the usage. When the permitted usage span is nearly reached, the electrosurgical generator alerts the user by emitting an alarm tone and displaying a message box. At this stage and as soon as the treatment situation allows, the bipolar applicator needs to be replaced. When the permitted usage span is exceeded, it becomes impossible to activate the bipolar applicator.

Automatic end-of-procedure detection – Autostop
As soon as the resistance of the treated tissue exceeds a limited value the electrosurgical generator automatically reduces the HF current which stops the coagulation process, i.e. Autostop.

Autostop is indicated by continuous short beeps of the electrosurgical generator.

3.5 Warranty

Any warranty claims towards Olympus are forfeited if the user or unauthorized persons attempt repair or modification of the product. No warranty is provided for any damage due to misuse of the product.

4 Preparation and connection

4.1 Safety information for preparation

CAUTION
Unintended current flow and HF leakage current
Unintended current flow and HF leakage current can cause thermal injury to the patient. The patient must be insulated against all electrically conductive parts.

- Ground the operating table.
- Make sure that the patient does not come in contact with metal parts, e.g. the operating table.
- Place the patient on a dry, electrically insulating surface.
- Make sure that the patient's clothes are dry.
- Prevent any contact between different skin surfaces (arms, legs) of the patient. Place dry gauze between the body and arms and between the legs to prevent such contact.
- Prevent any skin contact between the patient and the user.
- Remove any metallic items from the patient, e.g. wristwatches, jewelry.
- Route all connecting cables so that they are not in direct contact with the patient.
- Route all connecting cables so that they are not in contact with other cables.

4.2 Preparing for ultrasound monitoring

Olympus recommends to observe the treatment process under ultrasound monitoring.

4.3 Preparing a matching introducer

- When selecting a matching introducer observe the flexible catheter's outer diameter of 1.8 mm.

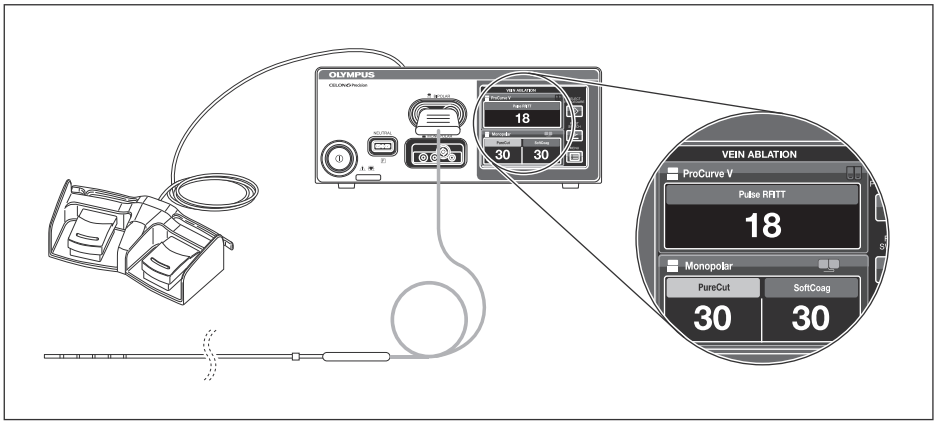
4.4 Preparing the electrosurgical generator

- For installation, setup and use of the compatible electrosurgical generator refer to the respective instructions for use.
- Inspect the electrosurgical generator for damage. Do not use a damaged electrosurgical generator.

4.5 Preparing the bipolar applicator

1. Inspect the packaging of the bipolar applicator for integrity of sterility.
   Do not use the bipolar applicator if there is any damage to the packaging.
2. Inspect the use by date on the label.
   Do not use the bipolar applicator beyond the use by date.
3. Remove the bipolar applicator from the packaging.
4. Remove the protective cover from the tip of the bipolar applicator.
5. Inspect the bipolar applicator, its HF cable and the plug for damage.
   Do not use a damaged bipolar applicator.

4.6 Connecting the bipolar applicator



1. Insert the plug into the BIPOLAR socket of the electrosurgical generator.
   - The electrosurgical generator automatically recognizes the CELON ProCurve V.
   - If the current settings are not within the restricted range, then the CELON ProCurve V automatically presets the electrosurgical generator to the default mode and the default output power.
   - [ProCurve V] is displayed next to the bipolar socket indicator of the electrosurgical generator's touchscreen.
2. Do not use the bipolar applicator if it is not recognized correctly by the electrosurgical generator.
3. Make sure that the foot switch is assigned to the BIPOLAR socket.

5 Use

5.1 Safety information for use

WARNING
Infection of the user and the medical personnel
When the flexible catheter is withdrawn from the patient, there is the risk that the already withdrawn part wobbles and moves uncontrollably. Tissue debris and blood can spatter which can result in an infection of the user and the medical personnel.
- While withdrawing the product from the patient, make sure that the flexible catheter maintains under control and is coiled up immediately.

CAUTION
Thermal damage to adjacent tissue
Applying excessive HF energy to the target tissue can affect surrounding tissue. Both, a low power level with a long application time as well a high power level with a short application time can lead to an excessive dosage of HF energy. This can cause severe thermal damage to adjacent tissue.
- Adapt the dosage of HF energy by withdrawal speed. The acoustic resistance feedback indicates the coagulation status.
- If there is uncertainty, check the coagulation process under ultrasound monitoring.
- Carefully observe the instructions in the chapter “Application” on page 22.

CAUTION
Damage to the product
Bending and twisting the tip of the bipolar applicator can damage the joints, which results in unnoticed destruction or malfunction. The use of a damaged product can cause injury to the patient.
- If it is necessary to clean the tip or the flexible catheter from coagulated blood clots, then carefully wipe the affected areas with gauze that has been moistened with sterile water.
- Do not bend or twist any part of the product.

CAUTION
Failure of automatic instrument recognition
If the automatic instrument recognition fails when connecting the bipolar applicator to the electrosurgical generator, then this indicates that the bipolar applicator is damaged. The use of a damaged product can cause injury to the patient.
- Do not use the bipolar applicator if the instrument recognition failed.

CAUTION
Unintended tissue contact
Unintended contact between tissue and the active part of the HF instrument can cause burns to the patient, the user and the medical personnel.
- Store temporarily unused HF instruments in an electrically insulated container.
- Do not place unused HF instruments on the patient.

5.2 Setting the power level

Within the restricted range, the default settings can be adapted according to the physician's assessment of the clinical findings.

5.3 Application

5.3.1 General instructions for application

Tumescent anesthesia for saphenous veins
Before activating the bipolar applicator for the treatment of a saphenous vein, Olympus recommends to apply a generous amount of tumescent anesthesia when the bipolar applicator is located approximately 1 cm distal of the saphenous-femoral junction. This is to avoid nerve irritation.

Stop markers
To avoid coagulating the epidermis, stop coagulating as soon as the stop markers become visible when withdrawing the bipolar applicator.

Avoiding Autostop
Olympus recommends to withdraw the activated bipolar applicator slowly and steadily from the vein and to avoid Autostop. If Autostop occurs more frequently, then coagulum builds up a the tip of the bipolar applicator. Thus, the procedure needs to be interrupted to clean the bipolar applicator.

- Refer to the section “Cleaning the bipolar applicator during use” on page 24.

Ultrasound monitoring
Olympus recommends to observe the treatment process under ultrasound monitoring.

5.3.2 Step-by-step instructions for application

1. Insert the bipolar applicator into the proximal direction.
2. Start coagulating by depressing the blue coagulation pedal of the foot switch.
3. While coagulating, slowly and steadily withdraw the bipolar applicator from proximal to distal.
4. Observe the audible resistance feedback and the display of the electrosurgical generator.
5. To stop coagulating release the foot switch pedal.
6. At the end of the treatment, completely remove the bipolar applicator from the patient.
7. Check the result of the treatment by ultrasound imaging.

5.3.3 Cleaning the bipolar applicator during use

Coagulum that builds up at the tip of the bipolar applicator can affect the performance of the electrosurgical generator. If the performance of the electrosurgical generator drops remarkably, proceed as follows:

1. Stop coagulating by releasing the foot switch pedal.
2. Position the shiftable rubber ring to the insertion point.
3. Completely withdraw the bipolar applicator.
4. Carefully clean the tip with gauze that has been moistened with sterile water. Do not bend or twist any part of the product.
5. Reinsert the bipolar applicator up to the position of the shiftable rubber ring.
6. Continue with the procedure.

6 After use

6.1 Disconnecting the bipolar applicator

1. Switch off the electrosurgical generator.
2. Pull the plug of the bipolar applicator to disconnect it from the electrosurgical generator. Do not pull on the cable.

6.2 Disposal

When disposing of the product or any of its components, follow all applicable national and local laws and guidelines.

7 Repair and shipment

7.1 Repair

There is no repair service.
- Do not send the product to Olympus for repair.
- Do not attempt to repair or modify the product.

7.2 Shipment

When sending products to an authorized service center for warranty claims, note the following.

Used products represent a risk of infection for the servicing personnel. Service centers are entitled to refuse soiled or contaminated products for reasons of safety.
- Clean the product as thoroughly as possible.
- Include the original sterile packaging to provide traceability.
- Seal the product in an additional sterile packaging and mark it as “Infectious material”.
- Use the original cardboard packaging for the transport of the product.
- If this is not possible, wrap each component individually in sufficient paper or sheets of foamed material and place them in a cardboard box.

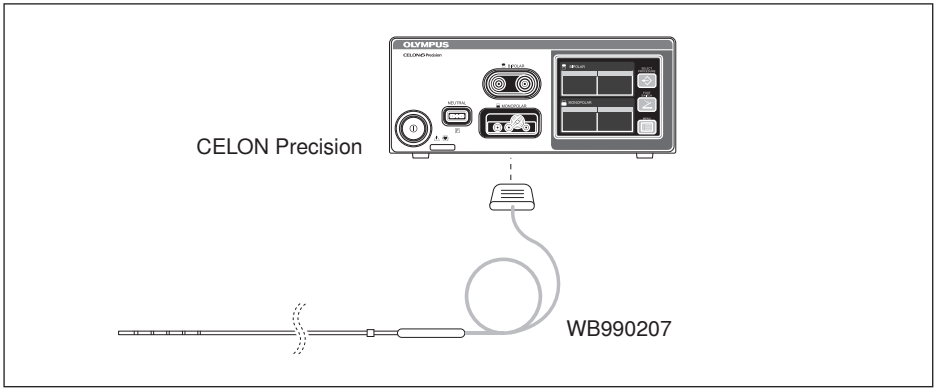
Service centers do not accept warranty claims for damage caused by inadequate packaging.

8 Compatible equipment

Olympus recommends the use of equipment as listed in this chapter. If combinations are used that are not listed in this chapter, the user takes the full responsibility.

Future equipment may also be compatible. For more information, contact a sales representative.

Some of the products listed in this chapter may not be available in all sales territories.



9 Storage and technical data

9.1 Storage

- Store the product between -20 to 50 °C (–4 to 122 °F).
- Store the product between 20 to 75% relative humidity, non-condensing.
- Keep away from moisture and direct heat.
- Do not use after use by date printed on the instrument label.

9.2 Specifications

Size

Outer diameter of flexible catheter ..... 1.8 ± 0.1 mm
Length of flexible catheter ..... 1200 ± 20 mm
Active/conductive length ..... 17 ± 1.5 mm
Cable length ..... 3000 ±15 mm

Power supply

Maximum permitted HF power output ..... 30 W
Maximum permitted HF peak voltage ..... 275 V_{peak}

9.3 Ambient conditions

Operating conditions

Ambient temperature ..... 10 to 40 °C (50 to 104 °F)
Relative humidity ..... 15 to 80%, non-condensing

Transport conditions

Temperature ..... –34 to 65 °C (–29 to 149 °F)
Relative humidity ..... 15 to 80%, non-condensing

OLYMPUS

Barcode

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