remOVE
DC IMPULSE

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Instructions for use
English

Ref. No. 400.01

remOVE DC IMPULSE

remOVE DC Impulse
Instructions for use
Revision 06
Date 2017-06-19

For remOVE DC Impulse
Version 1.XX
Ref No.: 400.01

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Contents

1 About this document

These instructions for use refer to the following product:

Product	Manufacturer
remOVE DC Impulse Ref. No. 400.01 Version 1.XX	Ovesco Endoscopy AG Dorfackerstr. 26 72074 Tuebingen Germany

The instructions for use are part of the product.

When using the instructions for use, please observe the following:

1. Read the instructions for use carefully before first use of the product. Before first use, users should fully understand how the product works, how to handle the product and which possible risks are connected to use of the product.

2. Store the instructions for use in a place accessible to medical staff.

3. Pass on the instructions for use to every subsequent owner or user of the product.

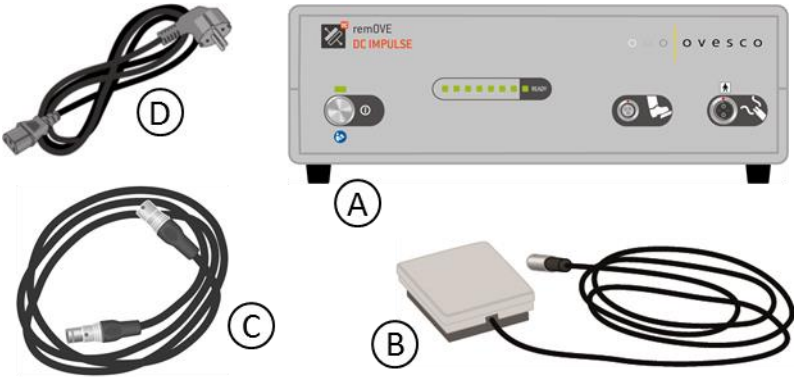
4. Update the instructions for use according to all amendments and revisions issued by the manufacturer.

The manufacturer assesses the right to alter the contents of these instructions for use without prior notice. Due to continuous further development of the product, it is possible that technical specifications and figures in this document are not up-to-date.

Maintenance and repair may only be performed by the manufacturer or by any person or persons authorized by the manufacturer. Unauthorized opening or performance of services by any non-authorized person or persons voids the warranty and the manufacturer's liability with regards to operational safety.

The manufacturer's warranty does not cover primary or secondary damage and defects resulting from improper or unreasonable use or maintenance, especially resulting from failure to follow the instructions for use.

2 Components



A remOVE DC Impulse
B Foot-activated switch with connector cable
C DC cord
D Power cord
Test instrument for electrical tests

Figure 1: Components of the remOVE DC Impulse (Ref. No. 400.01)

3 Accessories / replacement parts

Please only use original parts or parts certified by the manufacturer as compatible with the remOVE DC Impulse as accessories or replacement parts. Otherwise safety and functionality cannot be guaranteed.

The following accessories / replacement parts for the remOVE DC Impulse may be ordered separately:

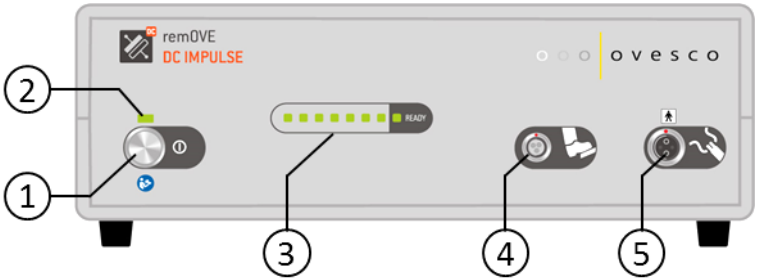
Accessory / replacement part	Max. length	Ref. no.
Foot-activated switch with connector cable	2 m	400.03
DC cord	2 m	400.04
Power cord*	2.5 m	400.10.XX
Test instrument for electrical tests**	2.2 m	810101

* When ordering the power cord, please note the country of use.
** The test instrument must be only used during electrical testing. – Non-sterile. – Not suitable for patient cases.

The remOVE DC Cutter Set 12 / 14 (Ref. no. 400.02.01 / 400.02.02) is not included with the remOVE DC Impulse and has to be ordered separately:

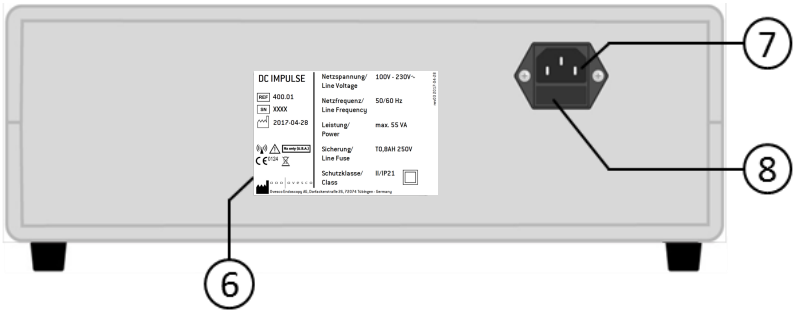
Product	Ref. no.
remOVE DC Cutter Set 12 / 14 (remOVE DC Cutter, remOVE SecureCap 12 / 14, remOVE Grasper, remOVE Shield)	400.02.01 / 400.02.02

4 Description



1 ON/OFF switch
2 ON/OFF display
3 Status display: charge of battery / ready for use / error
4 Connection foot-activated switch
5 Connection DC cord

Figure 2: Front view of the remOVE DC Impulse



6 Name plate
7 Connection to power supply
8 Fuse

Figure 3: Back side view of the remOVE DC Impulse

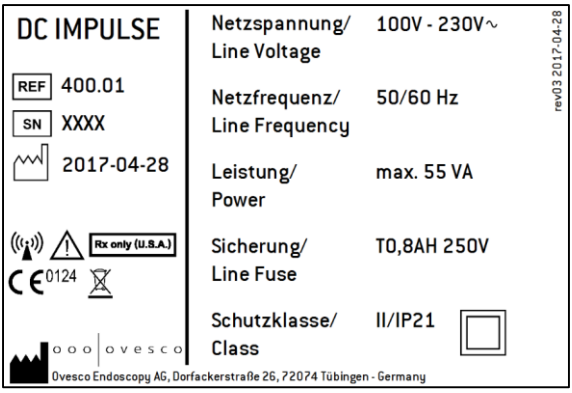


Figure 4: Name plate of remOVE DC Impulse

5 Intended use / indication

The remOVE DC Impulse is a medical electrical device for fragmentation of OTSC® and FTRD® clips made by Ovesco Endoscopy AG for the digestive tract.

Clips produced by Ovesco Endoscopy AG are:

Product	**Ref. No.**
OTSC® System Set	100.03, 100.04, 100.05, 100.06, 100.07, 100.08, 100.09, 100.10, 100.11, 100.12, 100.13, 100.14, 100.27, 100.28, 100.29, 100.30, 100.31
OTSC® Reloader	200.37, 200.38, 200.39, 200.40, 200.41, 200.42, 200.43
FTRD® System Set	200.70
OTSC® Proctology	200.60

It is not permitted to use the remOVE DC Impulse outside of its intended use as specified above. Using the remOVE DC Impulse for fragmentation of objects other than the products specified above may lead to defects and damages to the remOVE DC Impulse, destruction of the remOVE DC Cutter and permanent bonding of remOVE DC Cutter to the object.

6 Contraindications

The remOVE DC Impulse must not be used if flexible endoscopic procedures and/or the fragmentation and removal of an OTSC or FTRD clip manufactured by Ovesco are contraindicated. Fragmentation and removal of a clip are also contraindicated as long as the clinical effect of the clip is still required.

7 Complications / warnings / precautions

The complications listed below are possible when using the product for its intended purpose.

Damage to the tissue in the digestive tract, particularly:

- Thermal damage to the wall of the respective digestive organ
- Haemorrhages resulting from damage
- Perforations; these may also become apparent after medical intervention

According to the official definition in the current standard, the following passage can generally be applied to all medical electrical equipment: “Even the lowest current presents the risk of triggering ventricular fibrillation” (IEC 60601-1, section 8.7.3, A.14).

Please check whether the components are complete and/or have any defects before use. Any incomplete or defective components must be replaced. Defective or missing components can lead to malfunctioning of the remOVE System. For example, defective insulation on power lines can cause an electric shock to the patient and/or user.

Ignition and/or explosion of flammable gases e.g. due to high oxygen concentration in or outside of the digestive tract are possible during use due to sparking. Before use, ensure that no flammable gases/materials are in reach of the device and/or application point.

Electrical conductive cables/parts must not be close or touch the remOVE DC Cutter. Defective lines can cause an electric shock to patient/user.

All clip fragments must be removed from the patient's body. If sharp-edged clip fragments are left behind, they could cause damage to the organs in the digestive tract or other abdominal organs. This damage may also become apparent after medical intervention.

Partially cut and/or truncated clips may no longer fulfil their intended purpose if left in the patient's body. These clips can also break apart, resulting in sharp-edged clip fragments which could cause damage to the organs of the digestive tract or other abdominal organs. This damage may also become apparent after medical intervention.

Neuromuscular irritation is highly unlikely during application due to the physical mechanism of action and the technical design of the remOVE System, however it cannot be completely ruled out as a matter of principle. When application takes place in the esophagus there is always a residual risk of neuromuscular irritation, particularly of the heart muscle. Likewise, interference with active cardiac implants cannot be completely ruled out. Please note the following before use in the esophagus:

- Clinically relevant disturbances of the electrolyte balance, particularly hypokalemia, should be compensated for. A cardiologist should be consulted if necessary.
- For patients with an implantable cardioverter defibrillator (ICD) a cardiologist must be consulted and it must be considered to disconnect the ICD with monitoring the patient for the duration of the procedure.

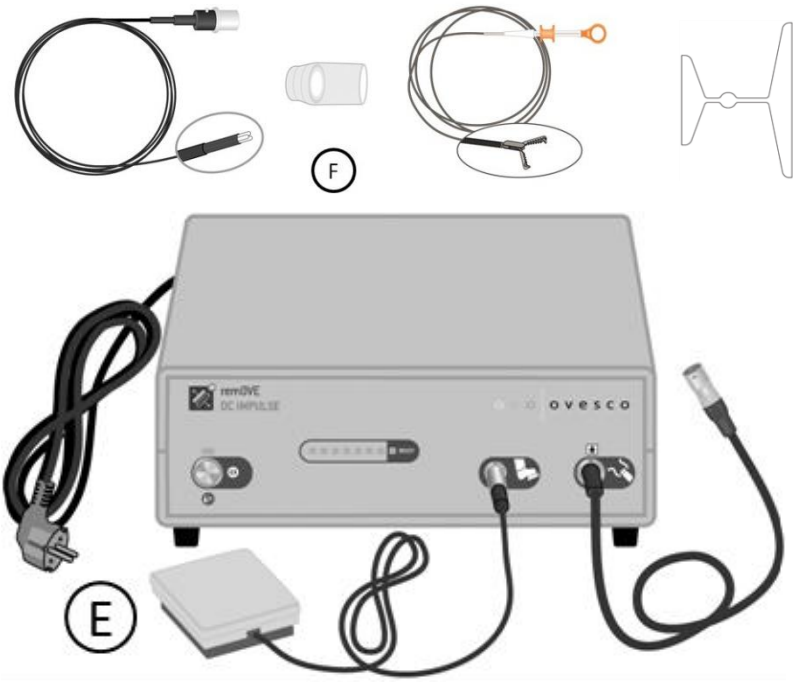
Applied parts and generator are not protected against defibrillation. Remove instrument before using a defibrillator on the patient.

The emission characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

8 Components and products required for use

The remOVE DC Impulse may only be used in conjunction with manufacturer-approved accessories and products as detailed in the instructions for use.

The use of accessories, cables and transducers, other than those the remOVE DC Impulse was designed for, can significantly increase emissions and reduce immunity of the remOVE DC Impulse against interference.



E	remOVE DC Impulse incl. accessories	Ref. No. 400.01
F	remOVE DC Cutter Set 12 / 14 (remOVE DC Cutter, remOVE SecureCap 12 / 14, remOVE Grasper, remOVE Shield)	Ref. No. 400.02.01/ 400.02.02

Figure 5: Products required for use

9 Preparation

Additional devices to be connected to medical electric devices have to be in compliance with IEC or ISO norms. Additionally, all configurations have to be in compliance with normative requirements for medical systems (see IEC 60601-1-1

or Section 16 of the third revision of IEC 60601-1, respectively). The person or persons who connect additional devices to medical electric devices are system configurators and are thus responsible for ensuring that the system is in compliance with the normative requirements for systems. Be advised that local law takes precedence over the normative requirements detailed above.

When setting up the remOVE DC Impulse please make sure that the user has clear, unobstructed line of sight to the status display.

When setting up the remOVE DC Impulse please make sure that environmental factors do not impair the user's perception of acoustic signals generated by the remOVE DC Impulse.

Do not connect the remOVE DC Impulse to the power supply unless a protective earthing conductor is present in order to avoid electrocution.

Before use of product please follow the steps detailed below:

1. Place the device on a stable surface in sufficient distance to the wall, ensuring that the device can immediately be disconnected from power supply if necessary.

2. Connect the power cord to the remOVE DC Impulse and connect the power cord to the power supply.

3. Connect the foot-activated switch and the DC cord to the remOVE DC Impulse.

4. Connect the remOVE DC Cutter to the DC cord.

   In order to connect the remOVE DC Cutter with the DC cord, align the two markings (red and white dot) on both devices in such a way that the white dot on the plug of the remOVE DC Cutter and the red dot on the plug of the DC cord are opposite to each other, see figure below.

Figure 6: left: remOVE DC Cutter; right: DC cord

5. Activate the remOVE DC Impulse by pressing the ON/OFF switch. The ON/OFF switch lights up to indicate that the device is activated.

The status display indicates the charge of the remOVE DC Impulse through green flashing LEDs.

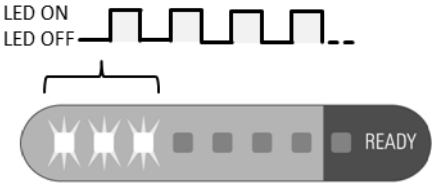


Figure 7: Status display indicates charge during charging phase by flashing green LEDs corresponding to the charge level

If the remOVE DC Impulse has not been in use for more than two days, the internal energy storage is fully charged over a time period of about 10 minutes. If the remOVE DC Impulse has been in use in the past two days, the device might charge faster.

Successful completion of charging cycle is indicated through three short acoustic signals in quick succession. The status display indicates operational readiness through emitting constant green light from all eight LEDs.

Figure 8: Status display indicates operational readiness through emitting constant green light from all eight LEDs

6. As soon as all eight green LEDs are constantly on, the remOVE DC Impulse is ready for use.

10 Use of product

The user has to make sure that set-up, assembly and use of the remOVE DC Impulse, all accessories and endoscopic instruments are carried out in accordance with the respective instructions for use.

Always use a DC cord to connect the remOVE DC Cutter to the remOVE DC Impulse. Proper operational characteristics of the product are no longer guaranteed if making a direct connection without a DC cord or a connection using several DC cords. This may also lead to damage of the remOVE DC Impulse.

Make sure the clip can be removed. If the clip is deeply embedded superficial tissue removal may be necessary to bare the clip.

When retrieving the clip fragments, ensure that the clip fragment is completely inside the remOVE SecureCap. The protruding sharp-edged parts of a clip fragment can result in damage to the organs in the digestive tract. Perforations can also arise subsequently after intervention.

When inserting and removing the remOVE DC Cutter, check that neither the endoscope nor the remOVE DC Cutter have been damaged, e.g. through kinking the instrument hose.

Winding the remOVE DC Cutter too tightly can lead to bending of instrument tip. Bending can make positioning/contacting the clip difficult during use.

Check that the remOVE Shield is affixed to the lens before the cutting process and keep a minimum distance of 30-40 mm between the endoscope tip and the clip during the cutting process. The endoscope tip can be damaged by sparking during the cutting process. Affixing the remOVE Shield to the lens and maintaining the maximum possible distance between the endoscope tip and instrument tip reduce the risk of damage.

Note that the instrument tip of the remOVE DC Cutter can heat up to 130 °C during the cutting process. Moving the instrument tip immediately after use can lead to superficial burns to the skin.

Use of the remOVE DC Cutter in a CO_2 atmosphere may reduce the effectiveness of the clip fragmentation.

Even if the product is used as intended, secondary effects may occur. For this reason, Ovesco products should only be used by persons who are qualified and trained to use the product for its intended purpose.

Make sure that the foot-activated switch is not permanently pressed. A single DC pulse is only triggered when the foot-activated switch is pressed during an acoustic contact signal. Permanent activation of the foot-activated switch may cause unintended triggering of a DC pulse.

When removing material residue from the instrument tip through a DC pulse, the instrument tip must be shielded from patient, user and any third parties because sparks might occur.

If user suffers from red-green color blindness, make sure that the user understands the status display.

For use of the product, the following steps have to be observed:

1. Guide the endoscope to the clip to be removed.

2. Insert the remOVE DC Cutter through the working channel and establish contact with the clip. A continuous audible signal indicates sufficient electrical contact with the clip.

3. When a continuous audible signal appears, trigger the cutting process by pressing one time on the foot switch. The audible signal stops and the status display flashes green for about six seconds when the cutting process is complete. Afterwards, the audible signal sounds three times and the status display shows that it is ready for use.

   To make clip removal easier, the clip should ideally be cut at two spots on opposite sides of the row of teeth.

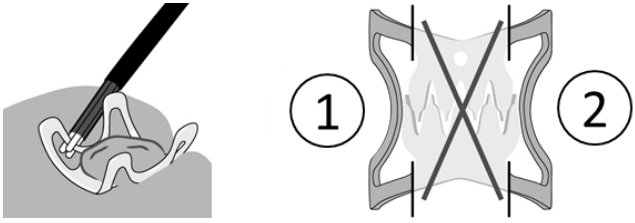


Figure 9: Spots on the clip for fragmentation: Make first cut at (1), and second cut on the opposite side (2)

After the cutting process, residues of the clip material can get caught at the instrument tip of the remOVE DC Cutter and create a permanent connection between the electrodes. This is indicated by a constant audible signal without clip contact. The remains can be removed by applying a new DC pulse. It is recommended to withdraw the remOVE DC Cutter from the endoscope first and remove the remains by pressing on the foot switch to trigger a DC pulse. As this can lead to sparking, patients, users or third parties must be shielded from the instrument tip.

4. Verify that the clip is successfully fragmented at two spots by checking the endoscopic image.

5. Remove the endoscope and place the remOVE SecureCap on the endoscope tip. Guide the endoscope with the fitted remOVE SecureCap to the clip fragments.

6. Use the remOVE Grasper to pull the clip fragment into the remOVE SecureCap and retrieve it from the body. Hold the clip fragment firmly with the forceps when withdrawing the endoscope (Fig. 10). Repeat this procedure for the second clip fragment or, if necessary, for further clip fragments.

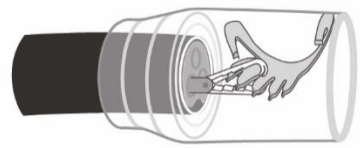


Figure 10: Clip fragment with remOVE Grasper in the remOVE SecureCap

7. Turn off the remOVE DC Impulse by pressing the ON/OFF switch.

11 Mode of operation

The remOVE DC Impulse is designed to send an electrical direct current pulse of typically I_S = 155 A for the duration of 60 ms through the bipolar, endoscopic instrument remOVE DC Cutter.

This DC pulse flows through the clip segment the remOVE DC Cutter is establishing contact with, resulting in localized melting of the clip material.

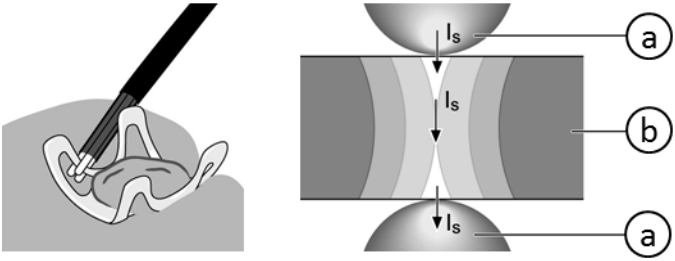


Figure 11: Left: Establishment of contact between clip segment and remOVE DC Cutter. Right: Cross-section of clip segment to be cut (b) and marking of current path I_S between electrodes (a)

The remOVE DC Impulse is equipped with internal energy storage, allowing the device to generate a DC pulse without additional load on the power supply. This internal energy storage is charged before the remOVE DC Impulse generates the DC pulse.

The remOVE DC Impulse is designed to ensure that a direct current pulse can only be generated when sufficient contact with a segment of the clip is established. Sufficient contact is indicated through an acoustic signal.

Should contact break off between the remOVE DC Cutter and the clip during the application of a DC pulse, the output of the remOVE DC Impulse will be deactivated within less than 500 µs. Breaking-off of contact might occur, for example, if one or both electrodes lose contact with the clip due to successful clip fragmentation.

During a DC pulse, the voltage drop between the electrodes of the remOVE DC Cutter is between 1.3 V and 2.0 V. During loss of contact, short-term (max. 500 µs) voltage spikes max. 22 V may occur. These spikes might be transferred into the tissue if both electrodes of the remOVE DC Cutter are in contact with tissue.

12 Error message

The remOVE DC Impulse is equipped with a failure detection system. Technical failures are indicated via the status display. Failure detection is implemented to ensure user/patient safety.

If a failure message occurs, the device casing may not be opened. Life-threatening electrocution could occur.

If a failure message occurs, the device may no longer be used in order to ensure the safety of users and/or patients. If a failure occurs, all eight LEDs of the status display are flashing orange, see figure below.

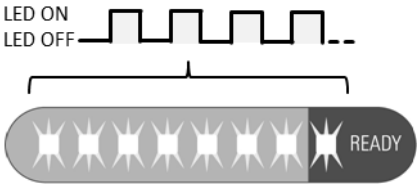


Figure 12: Status display flashes orange during failure message.

If a failure message is displayed by the remOVE DC Impulse, acoustic contact detection between instrument and clip is deactivated. A DC pulse can no longer be generated, and the internal energy storage of the remOVE DC Impulse can no longer be recharged.

In the case of failure message or malfunctioning of the device, please contact manufacturer.

13 Cleaning and disinfection

As part of your responsibility to ensure hygiene and cleanliness of all product components during use, please make sure that only suitable devices and procedures validated specifically for this product are used for cleaning and disinfection of the product. Please follow the respective local and/or national legislation as well as hygiene regulations pertaining to medical practices or hospitals.

13.1 Wipe disinfection

For cleaning surfaces of the device, please use approved cleaning/disinfection supplies and only in accordance with instructions by the respective manufacturer. Observe specifications regarding concentration, temperature and exposure time.

Apply alcohol-based cleaning/disinfection agent. Do not use benzyl-alcohol-based and/or any other agents because it can cause damages to the remOVE DC Impulse materials.

13.2 Instructions

1. Prepare the cleaning/disinfectant agent per the manufacturer's guidelines.

2. Wipe down the equipment using a cloth with surface disinfectant. Clean gross contamination first and then uniformly treat all the surfaces.

3. Wipe the surfaces ensuring that they are uniformly treated. Comply with the action time of the disinfectant specified by the manufacturer.

4. Wet a sponge or cloth in clean water and wipe off the cleaning/disinfection agent.

5. Dry the device using a clean, lint-free cloth.

6. Check by visual inspection all surfaces of the equipment. If soil remains visible, repeat the entire cleaning/disinfection procedure.

13.3 Safety Instructions

Before cleaning the remOVE DC Impulse, disconnect the device from the power supply.

Do not use flammable or explosive cleaning or disinfecting solutions. Make sure no fluids enter the device casing. Non-compliance may result in burning hazard and/or electrocution.

Only clean and disinfect the product manually. Do not sterilize the product under any circumstances.

14 Transport and shipping / storage

14.1 Transport and shipping

Perform surface disinfection and properly package device for shipping. Add another form of packaging, to avoid bacterial contamination and infections once you leave the hospital.

Be advised to transport / ship the remOVE DC Impulse in its original, undamaged packaging.

Make sure the packaging is not damaged and/or wet. Otherwise, the device might get damaged during transport / shipping, which may lead to malfunction during the next use. This, in turn, may endanger the user/patient.

When transporting / shipping the device, make sure to follow the respective terms of transport.

14.2 Storage

If the remOVE DC Impulse is not stored properly, customer claims may not be considered. Improper storage may also lead to malfunction, which may endanger the user/patient.

It is recommended to store the remOVE DC Impulse in its undamaged original packaging.

It is recommended to thoroughly clean the remOVE DC Impulse before storing it.

Do not expose the remOVE DC Impulse to direct or indirect sunlight or other types of UV radiation.

Do not store the remOVE DC Impulse in the vicinity of chemicals, disinfectants and/or sources of radioactive radiation.

Do not place heavy objects on top of the remOVE DC Impulse or its packaging.

Make sure to store the remOVE DC Impulse in a dry and clean space, ensuring appropriate storage conditions.

14.3 Transport and storage conditions

When transporting or storing the remOVE DC Impulse, please make sure that the following environmental requirements are met:

Environmental factors	Storage	Transportation
Temperature	0 °C to +50 °C	-20 °C to +50 °C
Relative humidity	0 % to 90 %, RH non-condensing	0 % to 90 %, RH non-condensing
Air pressure	500 to 1060 hPa	500 to 1060 hPa

15 Maintenance / repair

15.1 In general

After every use of the remOVE DC Impulse and its accessories, please check for damages or defects. Pay special attention to intact isolation of all cords and cables.

Never use a damaged remOVE DC Impulse or damaged accessories. Immediately replace defective accessories.

Make sure that a safety inspection of the remOVE DC Impulse is performed annually.

15.2 Safety inspection

Safety inspections have to be performed annually.

Consider that national regulations might call for more frequent safety inspections and make sure to have the inspections performed accordingly. When performing a safety inspection, please make sure all national requirements and rules are met.

Safety inspections of the device and its accessories may only be performed by qualified personnel with all required knowledge and experience, who are authorized to perform safety inspections without supervision.

The inspector documents all testing results and measurements according to the printable inspection record (see appendix of the instructions for use).

If considerable deviations or abnormalities are recorded, please contact the manufacturer.

15.3 Repair

If repairs are needed, please contact the manufacturer. Do not attempt to repair the device yourself under any circumstances.

Ovesco accepts liability with regards to safety, reliability and functionality of the device under the following circumstances:

- All instructions with regards to installation and intended use given in this document have been followed properly.
- Modifications, repairs, etc. were only performed by personnel authorized for these tasks by Ovesco.

- Electrical installations in the space concerned are in accordance with local and national rules and regulations.

In your repair request, please include the following information. Correct and complete information ensures quick and successful repair work.

- Complete address
- Order number of remOVE DC Impulse
- Serial number of remOVE DC Impulse
- Describe the problem, the act of use when the problem occurred and all accessories used.

16 Disposal

When disposing or recycling the product or its components, please make sure to follow national rules and regulations.

Symbol	Description
	Products with this symbol have to be delivered to a separate collection for electrical and electronic equipment. Inside the European Union, the manufacturer will dispose of the product free of charge.

17 Operating conditions

When using the remOVE DC Impulse, please make sure the following operating conditions are met:

Environmental factors	Value
Temperature	+10 °C to +40 °C
Relative humidity	25 % to 75 %, RH non-condensing
Air pressure	700 to 1060 hPa
Operation level	≤ 4000 m

If the remOVE DC Impulse has been stored or transported at a temperature of less than + 10 °C, it must be acclimated to room temperature for at least 3 hours.

18 Specifications

Isolation / Classification	
EMC	IEC 60601-1-2:2007
Type of protection, through casing	IP 21
Type of protection, through foot-activated switch	IPX8
Type of protection according to EN 60601-1	II with functional earth
Type of applied part according to 60601-1	BF
Compliance with standards	IEC 60601-1: 2005+Cor.: 2006 + Cor.: 2007 + A1 2012 IEC 60601-1-2: 2007 IEC 60601-1-6:2010 ISO 14971: 2007 ISO 13485: 2003 + AC 2009
Classification according to 93/42/EEC	IIb

Power input	**100V – 230 V**	
Power supply voltage	**220V - 230 V**	**100 V – 120 V**
Power consumption in standby mode once fully charged	6 W / 17 VA	6 W / 10 VA
Power consumption in standby mode	60 mA	90 mA
Max. power consumption	50 W / 55 VA	50 W / 50 VA
Mains fuse	T 0.8 A H 250 V	T 0.8 A H 250 V
Line frequency	50 / 60 Hz	50 / 60 Hz

Measurements and weight	
Measurements of product	340 x 340 x 110 mm
Net weight	5.0 kg
Type of packaging / measurements	Carton 400 x 400 x 300 mm
Gross weight	7.5 kg

Operating conditions	
State of charge	Indicated by green flashing LEDs on status display.
Ready for use initial	Indicated by three short acoustic signals in quick succession and continuous glowing of all LEDs on status display in green once operating voltage is reached. Initial charge when device energy storage is completely discharged takes ca. 10 minutes.
Ready for use signal	Indicated by three short acoustic signals in quick succession once operating voltage is reached or 6 seconds after DC pulse.
Ready for use visual	Indicated by all LEDs on the status display being lit in green.
On/Off signal	Yes. Green LED display above on/off switch.
Overheating protection	Yes.
Error message	Yes. All LEDs are flashing orange on status display.

Documentation	
Log and record of number of uses	Yes. Readout by qualified personnel only.

Specifications	
Instrument type remOVE DC Cutter	Bipolar / direct current
One-time duration of impulse during activation	≤ 65ms
Output current remOVE DC Cutter	≤ 165 A
Output voltage remOVE DC Cutter	1.3 – 2.0 V
Interval between activations	≥6 s

Compatibility	
remOVE DC Cutter Set 12 / 14	Art.-Nr. 400.02.01 / 400.02.02
Foot-activated switch	Art.-Nr. 400.03
DC cord	Art.-Nr. 400.04
Power cord	Art.-Nr. 400.10.XX

Environmental conditions for operation, transport and storage	Operation	Storage	Transportation
Temperature	+10°C to +40°C	0 °C to +50 °C	-20 °C to +50 °C
Relative humidity	25 % to 75%, RH non-condensing	0 % to 90 %, RH non-condensing	0 % to 90 %, RH non-condensing
Air pressure	700 to 1060 hPa	500 to 1060 hPa	500 to 1060 hPa
Operation level	≤ 4000 m	-	-

19 Electromagnetic compatibility (EMC)

Make sure no electronic devices which could be compromised by electromagnetic fields are present in the vicinity of the remOVE DC Impulse. A compromised device could lead to malfunction and/or failure of respective device and thus may endanger user and/or patient.

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents.

Guidance and manufacturer's declaration - electromagnetic emissions (IEC 60601-1-2, Table 1)		
The remOVE DC Impulse is intended for use in the electromagnetic environment specified below. The customer or the user of the remOVE DC Impulse should assure that it is used in such an environment.		
Measurements of electromagnetic emissions	**Compliance**	**Electromagnetic environment- guidance**
RF emissions CISPR11	Group 1	The remOVE DC Impulse uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class A	The remOVE DC Impulse is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	complies	

Guidance and manufacturer's declaration
- electromagnetic immunity (IEC 60601-1-2, Table 2)

The remOVE DC Impulse intended for use in the electromagnetic environment specified below. The customer or the user of the remOVE DC Impulse should assure that it is used in such an environment.

Immunity testing	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact	± 6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
	± 8 kV air	± 8 kV air	
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	± 1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.
	± 2 kV line(s) to earth	± 2 kV line(s) to earth	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % $_{UT}$ (> 95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T for 5 s	< 5 % $_{UT}$ (> 95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the remOVE DC Impulse requires continued operation during power mains interruptions, it is recommended that the remOVE DC Impulse be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration
- electromagnetic immunity (IEC 60601-1-2, Table 4)

The remOVE DC Impulse is intended for use in the electromagnetic environment specified below. The customer or the user of the remOVE DC Impulse should assure that it is used in such an environment.

Immunity testing	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF disturbances IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	10 V	Portable and mobile RF communications equipment can affect the remOVE DC Impulse and should be used no closer to any part of the remOVE DC Impulse, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF disturbances IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Recommended separation distance

$d = 0.35 \times \sqrt{P}$ for 150 kHz to 80 MHz
$d = 1.2 \times \sqrt{P}$ for 80 MHz to 800 MHz
$d = 2.3 \times \sqrt{P}$ for 800 to 2.5 GHz

Where P is the rated maximum output power of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol.

Note 1	At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
a	Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.
b	Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the remOVE DC Impulse (IEC 60601-1-2, Table 6)			
The remOVE DC Impulse is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the remOVE DC Impulse can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the remOVE DC Impulse as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz; d = 0.35 x √P	80 MHz to 800 MHz; d = 1.2 x √P	800 MHz to 2.5 GHz; d = 2.3 x √P
0.01	0.035	0.12	0.23
0.1	0.11	0.38	0.73
1	0.35	1.2	2.3
10	1.1	3.8	7.3
100	3.5	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1	At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.		
Note 2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

20 Warranty

Ovesco Endoscopy AG, the manufacturer, grants a 24 month warranty on material and construction of the remOVE DC Impulse, starting from date of purchase.

The warranty covers any faults occurring in the product due to the materials used in the manufacturing process or faulty installation by the manufacturer. Faults the manufacturer is notified of within the warranty period will be fixed free of charge.

The warranty is void if the buyer or non-authorized third parties have interfered with the device. The warranty does not cover defects due to incorrect handling, use, storage, transport, force majeure or other external forces.

All other warranty claims are excluded.

Faults corrected under the manufacturer's warranty will not engender any incidental expenses. Shipping costs inside the Federal Republic of Germany will be borne by the manufacturer or distributor.

21 Symbols

	CE-mark and identification number of Notified Body
	See instructions for use
	Caution: please observe
	Serial number
	Reference number
	Date of manufacture
	Manufacturer
	When operating this device, electric energy is used, resulting in electromagnetic radiation.
	Protection class II device with functional earth
	ON/OFF switch
	Ready for use
	Connection foot-activated switch
	DC cord connection
	Applied part type BF
	Do not use if packaging is damaged
	Air pressure limit
	Air humidity limitation
	Temperature limitation
	Marking of electrical and electronic equipment according to applicable guideline 2012/19/EU (WEEE), see disposal

Appendix 1

Inspection sheet

Annual technical safety control

Make sure the DC Cord is correctly plugged into the generator.

Do not press the foot-activated switch while testing the device.

Ensure that country-specific regulations and requirements, which include the generally accepted technical standards, as well as valid regulations for occupational safety and accident prevention, will be implemented and complied with during setup, operation and maintenance.

Device: **remOVE DC Impulse**	Safety classification: **II**
Article no.: **400.01**	Type of applied part: **BF**
Serial no.:	
Equipment: ☐ Foot-activated switch ☐ DC Cord ☐ Power cord ☐ Test Instrument for electrical tests	☐ Inspection before initial start-up (reference value) ☐ Repeated inspection ☐ Inspection after maintenance

1. Electrical tests (The tests must be executed when the device is fully charged)	Result
1.1 Are all cable insulations intact? → Insulation must be intact	☐ passed ☐ failed ☐ annex, where appropriate
1.2 Insulation resistance according to the standard EN 62353:2014 figure 4	☐ passed ☐ failed ☐ annex, where appropriate
1.3 Direct measurement for the device leakage current according to the standard EN 62353:2014 figure 7	☐ passed ☐ failed ☐ annex, where appropriate
1.4 Direct measurement of the leakage current of the applied part according to the standard EN 62353:2014 figure 10	☐ passed ☐ failed ☐ annex, where appropriate

2. Operational test	Result
2.1 Are all components available? → Components must be complete	☐ passed ☐ failed ☐ annex, where appropriate
2.2 Do all LEDs light up correctly? (On/Off display, status display) → All LEDs must light up according to the instructions for use.	☐ passed ☐ failed ☐ annex, where appropriate
2.3 Is the successful completion of the charging cycle indicated by three short acoustic signals? → Completion of charging cycle must be indicated by three short acoustic signals	☐ passed ☐ failed ☐ annex, where appropriate

Defects/Comments:_____

_____

_____

_____

Overall evaluation:

☐ No Safety or functional defects were detected.

☐ No direct risk, the detected defects can be fixed shortly.

☐ The device has to be withdrawn from use until the defects are corrected.

☐ The device does not meet the requirements – Modifications/Replacement of components/removal from service is recommended.

⚠ Contact the manufacturer if there is any deviation, abnormality and/or an indication of error.

The next inspection should be carried out after 12 months.

_____ _____

Name of the inspector Date / Signature

CE 0124

CE-marking according to
EC directive 93/42 EEC

ovesco
innovation in scope

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