- INSTRUCTIONS FOR USE –

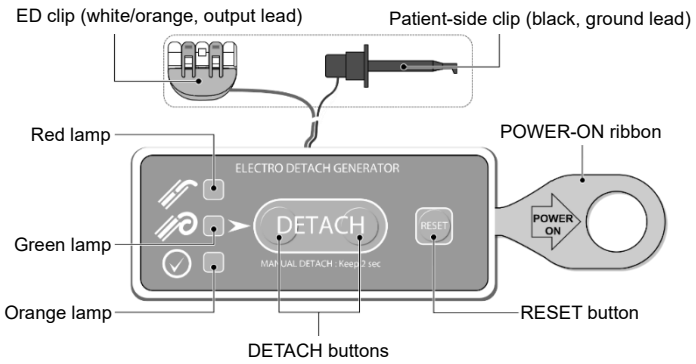
ELECTRO DETACH GENERATOR v4

(Detachment system)

[Device Description]

ELECTRO DETACH GENERATOR v4 (Model: “EDG v4”) is used to detach the platinum coil from the pusher of i-ED COIL manufactured by Kaneka Corporation.

<Names and Functions of Each Part>



In the box with dashed line: Type BF applied part

Figure.1 Schematic drawing of the EDG v4

ED clip	To be connected to the end of the pusher of the i-ED COIL.
Patient-side clip	To be connected to the hypodermic needle placed in the patient.
POWER-ON ribbon	Pull off the ribbon to turn on the EDG v4
Red lamp	The red lamp is lit when the detachable part of the i-ED COIL stays within the microcatheter. **[Precautions]** The red lamp blinks if there is a break in the lead-wire while the ED clip is connected.
Green lamp	The green lamp is lit when the detachable part of the i-ED COIL has just protruded out of the distal end of the microcatheter, and is in an appropriate position for detachment. **[Precautions]** The green lamp blinks at a certain interval when nothing is connected with the clip after the device is turned on.
Orange lamp	The orange lamp is lit when the electrode at the detachable part of the i-ED COIL is contacting the platinum coil and a short circuit occurs. **[Precautions]** The orange lamp blinks if a short circuit occurs when the ED clip is connected.
RESET button	Press the RESET button to restart detecting the detachable part, if the green lamp is lit while the detaching part is still within the microcatheter.
DETACH buttons	Press both two (the left and the right) buttons simultaneously while the green lamp is lit, and detaching output is generated for 5 seconds. **[Precautions]** (MANUAL DETACH) When it becomes necessary to detach the i-ED COIL while the red lamp is lit, press and hold the DETACH buttons for longer than 2 seconds to generate detaching output for 5 seconds.

<Operation signals (information and counter measure)>

While connecting the ED clip:	
Red lamp blinking;	indicates a possibility of a bad wire connection. Check the wire connections.
Orange lamp blinking;	indicates a possibility of a short circuit. Check the wire connections.
All the lamps (Red, Green and Orange) blinking	simultaneously; indicates a low battery status. Stop using this device and prepare for use a new one.
While manipulating the coil:	
Orange lamp lit;	indicates a possibility that the electrode at the detachable part of the i-ED COIL is contacting the platinum coil and a short circuit occurs. Pull back the i-ED COIL slightly until the green lamp comes on.
While detaching the coil:	
Red, Green the next, and then Orange lamps lighting up in this order repeatedly with the buzzer beeping intermittently (RETRY sign);	indicates a possibility that a sufficient detaching output could not be generated. Adjust the position of the detachable part of the i-ED COIL, and try again the coil-detachment (press both DETACH buttons simultaneously) while the green lamp is lit. **[Precautions]** The RETRY sign indicates that it is highly likely that the i-ED COIL has not been detached due to insufficient detaching output, however it is not an indication of whether or not the coil has been successfully detached.

<Operating Mechanisms>

The EDG v4 generates and delivers high-frequency current through the connected pusher of the i-ED COIL to generate Joule heat in the electrode at the distal edge of the pusher. The detachable part (made of a PVA rod) connecting the platinum coil and the pusher will melt down by the Joule heat, and the platinum coil will be detached and placed at the target site in the patient’s aneurysm or blood vessel.

<Wire Connections in the use of the EDG v4>

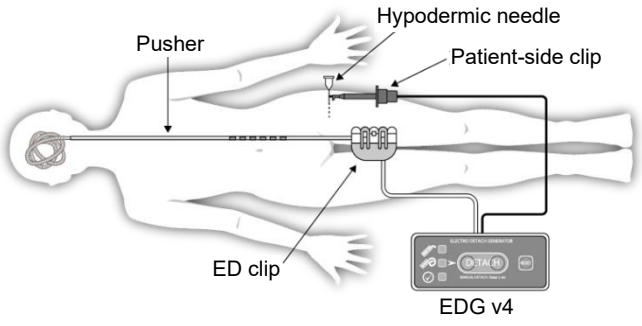


Figure 2. Wire connections amongst the i-ED COIL, the EDG v4 and a hypodermic needle placed in the patient

[Indications For Use]

The i-ED COIL System (i-ED COIL and EDG v4) is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae.

The i-ED COIL System is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolizations in the peripheral vasculature.

[Contraindications]

The EDG v4 must not be used in:

1. Patients with a pacemaker because electrical noises generated during the use of the i-ED COIL may cause malfunctions of the pacemaker resulting in life-threatening consequences.
2. Patients with an implantable cardioverter defibrillator (ICD), because electrical noises generated during the use of the i-ED COIL may cause malfunctions of the ICD resulting in life threatening consequences.
3. Patients for whom the use of the i-ED COIL is contraindicated.

[Warnings]

1. For single use only. Do not re-use. Do not resterilize. Re-use, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Re-use, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
2. EDG v4 should not be used with other medical devices than the i-ED COIL.
3. Do not use the EDG v4 near a defibrillator or electrical device that generates high voltage or electromagnetic waves. Additionally, use of the EDG v4 adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the EDG v4 and the other equipment should be observed to verify that they are operating normally.
4. Do not use the product after the “Use by” date.

[Precautions]

1. Do not drop the EDG v4 or expose it to water.
2. It may be difficult to obtain accurate information about the position of the detachable part of the i-ED COIL using only the lamps or buzzer of the EDG v4. Be sure to use X-ray fluoroscopic guidance.
3. When the battery level is low, stop using the EDG v4 as soon as possible and replace it with a new one.
4. Operating the i-ED COIL with wet hands or a wet drape may result in failure to detect the detachable part of the i-ED COIL.
5. This product should only be used by physicians experienced in intravascular catheterization and who have received a prior explanation on how to operate and use the product. Its use should also be limited to medical institutions able to provide appropriate emergency treatment.
6. Be sure to avoid shocks to the product during storage, use, and transfer.
7. Constantly monitor the product and the patient to ensure that there are no abnormalities with them.
8. If there are any abnormalities detected in the product or the patient, take appropriate measures in a manner that is safe for the patient.
9. Do not allow the product to come into contact with water or alcohol.
10. Do not disassemble or modify the product. Do not replace the battery.
11. Be sure to refer to the instructions for use of medical devices to be used together with the product.
12. For any treatment, another EDG v4 must be prepared as backup.
13. Do not use the product if it or its packaging is found to be damaged or to have abnormalities.
14. Immediately use the product after tearing open the sterilized package. Dispose of the product as medical waste after use.
15. Avoid the use of the product under air/flammable anesthesia gas or oxygen/nitrogen monoxide flammable anesthesia gas.
16. Use this device carefully for patients with an implantable medical device having electrodes in the head and neck (e.g., artificial cochlear system, brain/spinal stimulation device). High frequency from this device may affect to the implantable devices.

[Operation Methods]

1. Preparation

Pull off the POWER-ON ribbon to power on the EDG v4 with making sure that neither the ED clip or the Patient-side clip is connected to anything and any button of the EDG v4 is not touched. (Figure 3.)

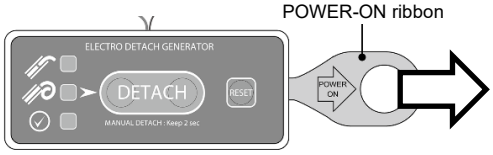


Figure 3. Turn on the power

The self-check function will be activated immediately with all the lamps (red, green and orange) on and a buzzer-beep for around one second. Then, all the lamps and the buzzer-beep will turn off automatically to enter the stand-by mode.

Precautions

1. Pull off the POWER-ON ribbon immediately before use. Once the POWER-ON ribbon is pulled off, the product consumes the battery, and may eventually become unusable.
2. The green lamp blinks at a certain interval when nothing is connected with the clip after the device is turned on.
3. If there is any abnormality with the EDG v4, all the lamps blink and the buzzer beeps intermittently. If it occurs, do not use this EDG v4 and prepare with a new one.

2. Usage Methods

(1) Connect the Patient-side clip to a hypodermic needle (made of stainless steel without resin-coating, 20–22 gauge) placed in the patient. (Figure 4.)

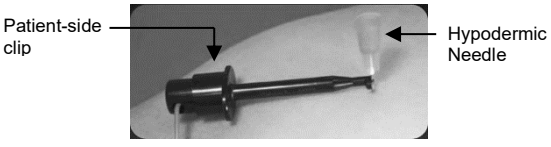


Figure 4. Patient-side clip with a hypodermic connected to the patient

Precautions

1. Do not connect the hypodermic needle placed in the patient to other medical devices.
2. Place the hypodermic needle at a depth of at least 10 mm vertically to the skin of the thigh or groin, with a special care not to injure the patient's blood vessels or nerves.

(2) In accordance with the instructions for use of the i-ED COIL, insert the i-ED COIL into the microcatheter placed in the blood vessel of the patient.

(3) Advance the i-ED COIL to the end of the microcatheter. Confirm, using X-ray fluoroscopy, that the detachable part of the i-ED COIL has advanced exceeding the second marker (proximal side) of the microcatheter.
Connect the ED clip to the proximal end of the i-ED COIL pusher and confirm that the red lamp is lit and the buzzer is beeping. (Figure 5.)

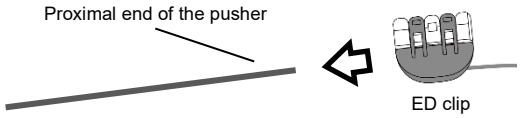


Figure 5. ED clip connecting to the pusher

Precautions
1. Do not connect the ED clip to any other electrical devices.
2. If no buzzer beeps while the ED clip is connected, do not use this EDG v4 and prepare with a new one.
3. If there is any abnormality in the wire connections, either the red lamp or the orange lamp blinks and the buzzer beeps intermittently. When it occurs, check and make sure that the wire connection is properly made.
4. If the ED clip is connected after the detachable part of the i-ED COIL has come out of the microcatheter, the EDG v4 cannot detect the location of the detachable part. Be sure to connect the ED clip before the detachable part of the i-ED COIL has come out of the distal end of the microcatheter.

(4) With checking the location of the radiopaque marker using X-ray fluoroscopy, move the i-ED COIL forward.
When the proximal end of the radiopaque marker of the i-ED COIL pusher reaches the second marker (proximal side) of the microcatheter, confirm that the red lamp is off, the green lamp is lit, and the buzzer beeping has stopped.

(5) Press both DETACH buttons simultaneously while the green lamp is lit, and the detaching output is generated for 5 seconds. (Figure 6.)
While the detaching output is generated, the green lamp blinks and the buzzer beeps intermittently.
For Manual Detach, see 3, “MANUAL DETACH” procedure in [Operation Methods].

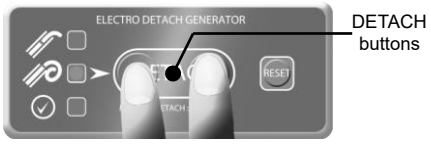


Figure 6. How to generate the detaching output

Precautions
1. Do not touch connection cables while the detaching is generated.
2. Be sure to operate the DETACH button while the green lamp is lit.
3. Do not operate the i-ED COIL while the detaching output is generated.
4. If the EDG v4 could not generate sufficient detaching output, the RETRY sign appears, i.e., the lamps (Red, Green the next, and then Orange) light up in this order repeatedly with the buzzer beeping intermittently (RETRY sign). If the RETRY sign appears, adjust the position of the detachable part of the i-ED COIL, and try again the COIL-detachment (press both DETACH buttons simultaneously) while the green lamp is lit.

(6) After the detaching output has become off, pull back slowly the i-ED COIL pusher and confirm that the coil detachment is properly completed under X-ray fluoroscopy, and then carefully pull out the i-ED COIL pusher from the patient.

(7) Disconnect the ED clip from the i-ED COIL pusher, and all the lamps will light simultaneously with the buzzer beeping for 1 second. Then, all the lamps and the buzzer will turn off and the EDG v4 enters in the stand-by mode.

(8) To use this EDG v4 for another i-ED COIL in a single treatment, repeat the above procedures from 2) in this section.

(9) If the power of the battery is found too low, all the lamps will blink simultaneously with the buzzer beeping intermittently. In such a case, do not use this EDG v4 and prepare for use a new one.

3. “MANUAL DETACH” procedure

When it becomes necessary to detach the coil while the red lamp is lit, press and hold the DETACH buttons for longer than 2 seconds to generate detaching output for 5 seconds.

Precautions
1. A coil detachment may become more difficult in the manual detachment compared to the normal (automatic) detachment (while the green lamp is lit). It might be possible that the coil will not be detached by the manual detachment.

[Device Failures]

1. Power-On Failure
2. Failure of detecting the detachment point
3. Failure of detaching the platinum coil

[Product Specifications]

Dimensions:	55 (H) × 125 (W) × 25 (D) mm
Rating output:	1.37 W
Output frequency:	333 kHz ± 5 kHz
Electric safety:	IEC 60601-1: compliant
Electromagnetic compatibility:	IEC 60601-1-2: compliant
Type of protection against electric shock:	Devices with internal power source
Level of protection against electric hock:	Type BF applied part
Degree of protection provided against intrusion water:	IPX2 (Protected against vertically dripping water, when tilted 15 degrees)
Package	1 piece / box

[Storage Method and Expiration Period]

Store in a clean and cool place avoiding getting wet and direct sunlight, extreme temperature, or high humidity.
The “use-by” date is indicated on the product label.

[Environment in Storage and Transportation]

Temperature: -10 ~ +60°C
Humidity: 30 ~ 85% RH

[Environment in Use]

Temperature: 10 ~ 30°C
Humidity: 30 ~ 85% RH
Atmospheric Pressure: 70 ~ 106 kPa

Important EMC notices for use in the medical environments

- The ELECTRO DETACH GENERATOR v4 needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this important EMC notices.
- The portable and mobile RF communications equipment such as cellular phones can affect the ELECTRO DETACH GENERATOR v4.
- The below guidance and manufacturer's declarations conform to IEC60601-1-2: 2014.

Guidance and manufacturer's declaration – electromagnetic emissions

The ELECTRO DETACH GENERATOR v4 is intended for use in the electromagnetic environment specified below.
The customer or the user of the ELECTRO DETACH GENERATOR v4 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The ELECTRO DETACH GENERATOR v4 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 CISPR 11	Class B	The ELECTRO DETACH GENERATOR v4 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	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity

The ELECTRO DETACH GENERATOR v4 is intended for use in the electromagnetic environment specified below.
The customer or the user of the ELECTRO DETACH GENERATOR v4 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	Not applicable	Not applicable	Not applicable
Surge IEC 61000-4-5	Not applicable	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable	Not applicable	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 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

The ELECTRO DETACH GENERATOR v4 is intended for use in the electromagnetic environment specified below.
The customer or the user of the ELECTRO DETACH GENERATOR v4 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 V 150 kHz to 80 MHz 6 V in ISM bands between 150 kHz and 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the ELECTRO DETACH GENERATOR v4, including cables, than 30 cm.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	Interference may occur in the vicinity of equipment marked with the following symbol 
	27 V/m 380 to 390 MHz	27 V/m	
	28 V/m 430 to 470 MHz 800 to 960 MHz 1.7 to 1.99 GHz 2.4 to 2.57 GHz	28 V/m	
	9 V/m 704 to 787 MHz 5.1 to 5.8 GHz	9 V/m	

[Name and Address of Manufacturer, Manufacturing Site]

<Manufacturer >

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