Product Lineup

ED COIL Electro Detach Coil Type R

ED COIL 10 Soft

Pusher Length 187cm

Catalogue Number	Primary Coil Diameter (inch)	Secondary Coil Diameter (mm)	Primary Coil Length (cm)
352-1610R	0.010	16	10
352-1620R			20
352-1630R			30

ED COIL 10 ExtraSoft

Pusher Length 187cm

Catalogue Number	Primary Coil Diameter (inch)	Secondary Coil Diameter (mm)	Primary Coil Length (cm)
353-1610R	0.010	16	10
353-1615R			15

ED COIL 14 Standard Spiral

Pusher Length 187cm

Catalogue Number	Primary Coil Diameter (inch)	Secondary Coil Diameter (mm)	Primary Coil Length (cm)
350-0209R	0.014	2	9
350-0312R		3	12
350-0412R		4	12
350-0515R		5	15
350-0620R		6	20
350-0720R		7	20
350-0730R			30
350-0820R		8	20
350-0830R			30
350-0930R		9	30
350-1030R		10	30
350-1230R		12	30

Do not re-use

STERILE EO Sterilized using ethylene oxide

Consult instructions for use

Manufacturer

KANEKA CORPORATION

3-18, 2-Chome, Nakanoshima, Kita-ku, Osaka-city, OSAKA, 530-8288 JAPAN

Tel.No. : (+81)-(0)6-6226-5256 CONTACT Tel.No. : (+81)-(0)3-5574-8136

EC-Representative

KANEKA PHARMA EUROPE N.V.

Nijverheidsstraat 16, 2260 Westerlo-Oevel, Belgium

Tel.No. : (+32)-(0)14-256-297 Fax No. : (+32)-(0)14-256-298

CE 0086

Apr. 2016

ED COIL10 ExtraSoft Xpiral

Pusher Length 187cm

Catalogue Number	Primary Coil Diameter (inch)	Secondary Coil Diameter (mm)	Primary Coil Length (cm)
353-01H1R	0.010	1.5	1
353-01H2R			2
353-01H3R			3
353-0202R		2	2
353-0203R			3
353-0204R			4
353-0206R			6
353-0208R			8
353-02H3R		2.5	3
353-02H4R			4
353-02H6R			6
353-0303R		3	3
353-0304R			4
353-0306R			6
353-03H6R		3.5	6
353-03H8R			8
353-0406R		4	6
353-0408R			8

ELECTRO DETACH GENERATOR v4

Catalogue Number
347-404

KANEKA MEDICAL PRODUCTS

– INSTRUCTION MANUAL –

CE 0086

ELECTRO DETACH GENERATOR v4

Do not re-use

STERILE EO

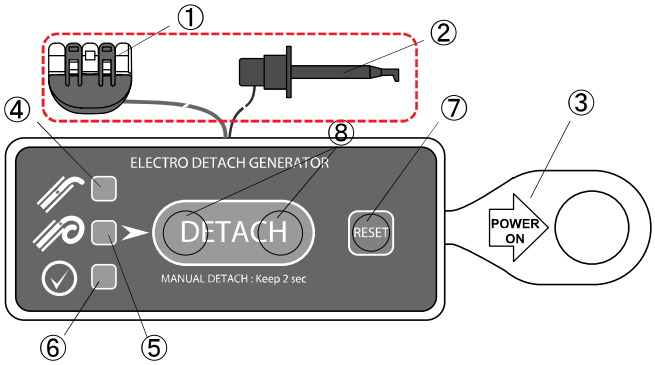
Sterilized using ethylene oxide

[Device Description]

ELECTRO DETACH GENERATOR v4 (hereinafter referred to as "EDG v4") is used to detach the platinum embolization coil from the delivery catheter (the pusher) of ED COIL manufactured by Kaneka Corporation.

[Names and Functions of Each Part]

In the box with red dashed line : Type BF applied part



Dimensions: 55 (H) × 125 (W) × 25 (D) mm

① ED clip (white/orange, output lead)

To be connected to the end of the pusher of the ED COIL.

② Patient-side clip (black, ground lead)

To be connected to the hypodermic needle placed in the patient.

③ POWER-ON ribbon

Pull off the ribbon to turn on the EDG v4.

④ Red lamp

The red lamp is lit when the detachable part of the ED COIL stays within the microcatheter.

※ The red lamp blinks if there is a break in the lead-wire while the ED clip (①) is connected.

⑤ Green lamp

The green lamp is lit when the detachable part of the ED COIL has just protruded out of the distal end of the microcatheter, and is in an appropriate position for detachment.

⑥ Orange lamp

The orange lamp is lit when the electrode at the detachable part of the ED COIL is contacting the platinum coil and a short circuit occurs.

※ The orange lamp blinks if a short circuit occurs when the ED clip (①) is connected.

⑦ 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.

⑧ DETACH buttons

Press both two (the left and the right) buttons simultaneously while the green lamp (⑤) is lit, and detaching output is generated for 5 seconds.

※ (MANUAL DETACH) When it becomes necessary to detach the ED COIL while the red lamp (④) is lit, press and hold the DETACH buttons for longer than 2 seconds to generate detaching output for 5 seconds.

[Operating Mechanism]

The EDG v4 generates and delivers high-frequency current through the connected pusher of the 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.

[Product Specifications]

Rating output: 1.37 W
Output frequency: 333 kHz ± 5 kHz
Electric safety: IEC 60601-1: compliant
Electromagnetic compatibility: IEC 60601-1-2: compliant

[Device Classification]

Type of protection against electric shock:
devices with internal power source
Level of protection against electric shock:
Type BF applied part

[Intended Use, Indications]

The EDG v4 is intended for use solely to detach a platinum coil from the delivery catheter (the pusher) of the ED COIL

[Contraindications]

The EDG v4 must not be used in:

1. patients with an implanted medical device having electrodes in the head or the neck (e.g., artificial cochlear system, brain/spinal stimulation device) and
2. patients for whom the use of the 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 crossinfection, 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. EDGv4 should not be used with other medical devices than the ED COIL

[Precautions For Use]

1. Do not touch connection cables while the detaching is generated.
2. Do not connect the ED clip to any other electrical devices.
3. Do not connect the hypodermic needle placed in the patient to other medical devices.
4. When placing a hypodermic needle in the patient, insert it at least 10 mm deep in the thigh or the groin of the patient with a special care not to injure the patient's blood vessels or nurves.
5. Do not use the EDG v4 near a defibrillator or electrical device that generates high voltage or electromagnetic waves.
6. Do not drop the EDG v4 or expose it to water.

7. It may be difficult to obtain accurate information about the position of the detachable part of the ED COIL using only the lamps or buzzer of the EDG v4. Be sure to use X-ray fluoroscopic guidance.
8. Be sure to operate the DETACH button while the green lamp is lit. For Manual Detach, see 3, “MANUAL DETACH” procedure in [Handling Methods].
9. Do not operate the ED COIL while the detaching output is generated.
10. The RETRY sign indicates that it is highly likely that the 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.
11. When the battery level is low, stop using the EDG v4 as soon as possible and replace it with a new one.
12. Operating the ED COIL with wet hands or a wet drape may result in failure to detect the detachable part of the ED COIL.
13. The EDG v4 must not be used in:
    patients for whom the use of the ED COIL is contraindicated, and patients for whom the use of the EDG v4 is contraindicated, i.e., patients with an implanted medical device having electrodes in the head or the neck (e.g., artificial cochlear system, brain/spinal stimulation device).

[Important, Basic Precautions]

1. 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
2. Be sure to avoid shocks to the product during storage, use, and transfer.
3. Constantly monitor the product and the patient to ensure that there are no abnormalities with them.
4. If there are any abnormalities detected in the product or the patient, take appropriate measures in a manner that is safe for the patient.
5. Do not allow the product to come into contact with water or alcohol.
6. Do not disassemble or modify the product. Do not replace the battery.
7. Be sure to refer to the instructions for use of medical devices to be used together with the product.
8. For any treatment, another EDG v4 must be prepared as backup.

[Other Precautions]

1. Do not use the product if it or its packaging is found to be damaged or to have abnormalities.
2. 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.
3. Immediately use the product after tearing open the sterilized package. Dispose of the product as medical waste after use.
4. Avoid the use of the product under air/flammable anesthesia gas or oxygen/nitrogen monoxide flammable anesthesia gas.

[Handling 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. 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.

※ 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.
2) In accordance with the instructions for use of the ED COIL, insert the ED COIL into the microcatheter placed in the blood vessel of the patient.
3) Advance the ED COIL to the end of the microcatheter. Confirm, using X-ray fluoroscopy, that the detachable part of the ED COIL has advanced exceeding the second marker (proximal side) of the microcatheter. Connect the ED clip to the proximal end of the ED COIL pusher and confirm that the red lamp is lit and the buzzer is beeping.
   ※ If no buzzer beeps while the ED clip is connected, do not use this EDG v4 and prepare with a new one.
   ※ If there is any abnormality in the wire connections, either the red lamp or the green lamp blinks and the buzzer beeps intermittently. When it occurs, check and make sure that the wire connection is properly made.
   ※ If the ED clip is connected after the detachable part of the 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 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 ED COIL forward. When the proximal end of the radiopaque marker of the 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. While the detaching output is generated, the green lamp blinks and the buzzer beeps intermittently.
   ※ 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 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 ED COIL pusher and confirm that the coil detachment is properly completed under X-ray fluoroscopy, and then carefully pull out the ED COIL pusher from the patient.

7) Disconnect the ED clip from the 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 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 (④) is lit, press and hold the DETACH buttons for longer than 2 seconds to generate detaching output for 5 seconds.

※ 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.

4. 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 ED coil is contacting the platinum coil and a short circuit occurs. Pull back the 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 ED COIL, and try again the coil-detachment (press both DETACH buttons simultaneously) while the green lamp is lit.

[Storage Method and Expiration Period]

1. Store in a clean and cool place avoiding getting wet and direct sunlight, extreme temperature, or high humidity.
2. The expiration date is indicated on the individual box. Do not use after the expiration date.

[Environment in storage and transportation]

Temperature: -10 ~ +60°C, and
Humidity: 30 ~ 85% RH
Atmospheric Pressure: 70 ~ 106kPa

[Environment in use]

Temperature: 10 ~ 30°C, and
Humidity: 30 ~ 85% RH

[Package]

1 piece / box

[Name and Address of Manufacturer, Manufacturing Site and EC Representative]

[Manufacturer]

Name: KANEKA CORPORATION
Address: 3-18, 2-Chome, Nakanoshima, Kita-ku, Osaka-city, OSAKA, 530-8288 JAPAN
Tel: (+81)-(0)6-6226-5256
Fax: (+81)-(0)6-6226-5143

[Manufacturing Site]

Name: KANEKA MEDIX CORPORATION KANAGAWA PLANT
Address: 225-1, Aza Deguchi, Yamakita, Yamakita-machi, Ashigara-Kami-gun, KANAGAWA, 258-0113 JAPAN

[EC Representative]

Name: KANEKA PHARMA EUROPE N.V.
Address: Triomflaan 173, B-1160 Brussels, Belgium
Tel: (+32)-(0)2-663-0340
Fax: (+32)-(0)2-663-0361

[Description of Symbols for Use]

Symbol	Description
	Caution,consult accompanying documents
	Consult instructions for use
	Type BF applied part
	Do not use if package is damaged
	Do not re-use
	Do not resterilize
	Sterilized using ethylene oxide
	Keep away from sunlight
	Keep away from rain

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 : 2007.

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	±6 kV contact ±8 kV air	±6 kV contact ±8 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	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Not applicable
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>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 sec	Not applicable	Not applicable
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

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
			Portable and mobile RF communications equipment should be used no closer to any part of the ELECTRO DETACH GENERATOR v4, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1,2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (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 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 ELECTRO DETACH GENERATOR v4 is used exceeds the applicable RF compliance level above, the ELECTRO DETACH GENERATOR v4 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ELECTRO DETACH GENERATOR v4.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the ELECTRO DETACH GENERATOR v4

The ELECTRO DETACH GENERATOR v4 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ELECTRO DETACH GENERATOR v4 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ELECTRO DETACH GENERATOR v4 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 $d = 1,2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1,2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.