- INSTRUCTIONS FOR USE –

i-ED COIL

(Detachable coil)

[Device Description]

The i-ED COIL is used for vascular embolization with a platinum coil at the target lesion in the patient's blood vessel.

<Structure of the i-ED COIL; Name of Each Part>

The i-ED COIL consists of a platinum coil (hereinafter referred to as "coil"), the pusher, and a PVA rod (detachable part). (Figure1)

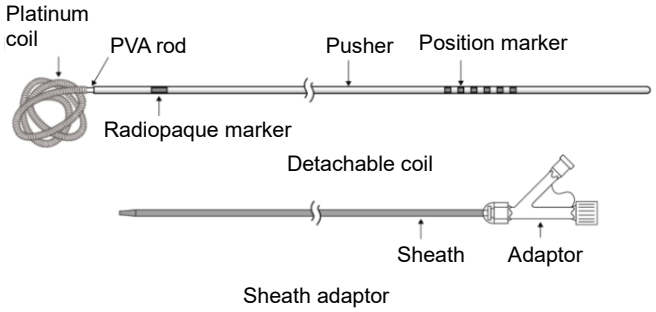

Figure 1. Schematic drawing of the i-ED COIL

Materials	
Platinum coil:	Platinum-tungsten alloy
Pusher:	Stainless steel wire coated with fluoro-resin and polyimide
PVA rod:	Polyvinyl alcohol

The position marker is intended and designed to use the i-ED COIL with a microcatheter which effective length is 150 cm.
The position marker is to indicate that the coil has not yet protruded out of the microcatheter when the position marker has reached the Rotating Hemostatic Valve (RHV) (as shown in Figure 2), while advancing the i-ED COIL into a microcatheter with 150 cm of the effective length.

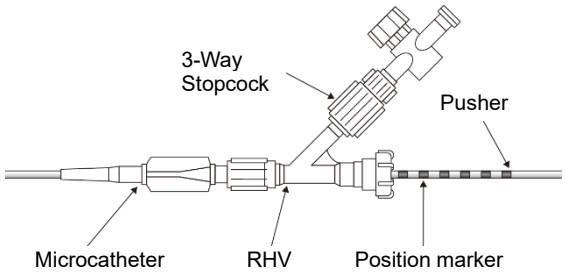

Figure 2. The position marker reached the RHV

<Working Mechanisms>

The i-ED COIL is used in combination solely with the ELECTRO DETACH GENERATOR v4 (hereinafter referred to as "EDG v4") manufactured by Kaneka Co., Osaka, JAPAN. The EDG v4 generates and delivers high-frequency current to the electrode at the distal edge (head) of the pusher of the i-ED COIL, and the electrode generates Joule heat to melt down the PVA rod to detach the coil.

[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 i-ED COIL must not be used in:

1. Patients with serious thrombocytopenia or abnormal disability in blood coagulation, for whom uncontrollable bleedings resulting in life-threatening consequences may occur during the procedures to place the coil.
2. Patients with a medical history of hypersensitivity to platinum and/or tungsten.
3. 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.
4. 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.
5. Embolization of a dissecting aortic aneurysm. In the event that a major bleeding occurs, it may result in the patient's death.

[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. Do not use the i-ED COIL if the device itself or its packaging is found damaged or to have any abnormality. (A damaged i-ED COIL may cause vascular injury or unexpected movement of the distal end of the coil during its placement. It also may affect stability during insertion or after placement and may cause migration or unraveling of the coil.)
3. Do not use the product after the "Use-by" date specified on the product label.
4. The i-ED COIL was designed and tested for use with the EDG v4. Do not use other detachment devices with the i-ED COIL as this may pose risks to patient safety.

[Precautions]

1. If the contrast media was infused from the microcatheter, ensure to flush out the contrast media with heparinized physiological saline solution (hereinafter referred to as “heparinized saline”) with at least 2-fold of the dead space volume of the lumen of the microcatheter. The residual contrast media, if any, inside the microcatheter lumen may delay swelling of the PVA rod.
2. Do not use this product that is once took out and put into the sheath again. Doing so may cause damage on the cover of the pusher and lead to insertion failure.
3. If any resistance is felt while advancing the pusher in the sheath or in the microcatheter, do not advance it forcibly. Identify the cause of resistance and remove the i-ED COIL together with the microcatheter, if necessary, out of the patient.
4. All procedures must be performed under aseptic conditions.
5. The i-ED COIL should only be used by physicians experienced in intravascular catheterization techniques and have received a prior explanation about the usage of this device, and in medical facilities where appropriate emergency measures will be available.
6. The size and number of coils to be placed should be carefully determined based on the experience of the physician.
7. The insertion and withdrawal of the i-ED COIL should be conducted gently with care so that damage to the patient’s blood vessel wall or the device itself may be prevented.
8. Keep the proximal end of the pusher away from wet drapes. If it occurs, conduction between the device and the patient’s body may occur and a detachment of the coil will become difficult or the green lamp of the EDG v4 may be lit even when the detachable part is still within the microcatheter.
9. If the i-ED COIL, even its part, is once inserted into and then pulled out from a microcatheter, do not insert that i-ED COIL into the microcatheter again.
10. For the delivery of the i-ED COIL into the patient, do not use a microcatheter that is used with embolization materials other than a coil. (The i-ED COIL may become stuck in the microcatheter, or foreign matters may be pushed out into the patient’s blood vessel.)
11. If the microcatheter kicks back from the position when performing embolization with a coil, do not attempt repositioning the microcatheter. If a repositioning is absolutely necessary, do it with a special care. Re-manipulation may cause migration of any placed coil into the peripheral blood vessel.
12. Immediately use the i-ED COIL after opening the sterilized package. Dispose of the device as medical waste after use.
13. 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.
14. Take all necessary actions to limit X-ray radiation doses to patients and users by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors whenever possible.

[Use for Pregnant Women, Parturient Women or Children]

As this product is used under fluoroscopy, use it only when it is judged that the clinical benefit outweighs the risk for pregnant women or patients who may be pregnant.

[Operation Methods]

<Devices Used Together>

The following devices are required to use this product.

- EDG v4
- Hypodermic needle
  (made of stainless steel without resin coating, 20–22 gauge)
- Rotating Hemostatic Valve (RHV)
- Microcatheter

<Recommended Size of Microcatheter>

Table.1 shows the recommended size of microcatheter.

The microcatheter should have 2 radiopaque markers; one is at the distal edge and the other (the second marker) at 30 mm from the distal edge.

Table.1

Platinum Coil	Recommended size of Microcatheter	
Primary coil OD	ID (required)	OD (suggested)
0.010 inch (0.25 mm)	0.013 ~ 0.019 inch (0.33 ~ 0.48 mm)	2.3 ~ 2.7 Fr (0.8 ~ 0.9 mm)
0.012 ~ 0.014 inch (0.30 ~ 0.36 mm)	0.0165 ~ 0.019 inch (0.42 ~ 0.48 mm)	2.3 ~ 2.7 Fr (0.8 ~ 0.9 mm)
0.017 inch (0.43 mm)	0.019 ~ 0.021 inch (0.48 ~ 0.53 mm)	2.3 ~ 3.2 Fr (0.8 ~ 1.1 mm)

“OD”: Outer Diameter

“ID”: Inner Diameter

“Fr”: French size (3Fr = 1 mm)

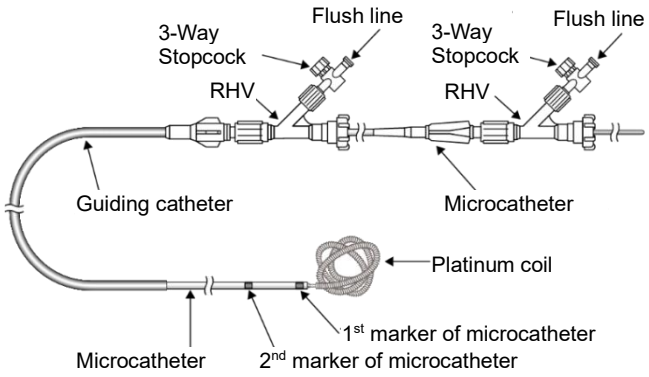

Figure 3. Connection diagram

Warnings

1. Do not use the position marker as a guide to advance the coil when used with a microcatheter of which its effective length is less than 150 cm, and if so, carefully advance the pusher with observing the location of the coil in the microcatheter under X-ray fluoroscopy.

Precautions

1. Use the i-ED COIL with a microcatheter having 2 radiopaque markers; one is at the distal edge and the other (the second marker) at 30 mm from the distal edge. Especially, for the use in the lesion other than in the head and the neck, use a microcatheter having metal braid-reinforcement over the entire length (with a microcatheter having no metal braid reinforcement, detecting the position of the detachable part by the EDG v4 may become difficult).
2. Do not excessively reshape the distal end portion of the microcatheter. (The metal mesh-reinforcement mounted in the microcatheter wall may become exposed in the microcatheter lumen. If it occurs, a short circuit between the i-ED COIL and the exposed metal mesh may occur, and consequently, the green lamp of the EDG v4 will be lit even in the situation where the coil has not been appropriately placed in the target lesion, and may result in unintended detachment of the coil.)

<Wire Connections in the Use of the i-ED COIL >

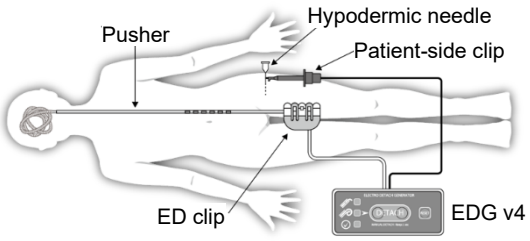

Figure 4. Wire connections amongst the i-ED COIL, the EDG v4, and a hypodermic needle placed in the patient

<Usage>

1. Preoperative Preparation

(1) Place the hypodermic needle (made of stainless steel without resin-coating, 20 - 22 gauge) 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) Connect a RHV (not included in the package of the i-ED COIL) to the hub of the microcatheter. Continuously perfuse heparinized saline from a pressurized solution bag via the side port of the RHV.

(3) Insert the microcatheter into the target blood vessel and deliver it to the target position.

(4) Pull off the POWER ON ribbon of the EDG v4 to switch on the EDG v4.

(5) Connect the Patient-side clip (black) of the EDG v4 with the hypodermic needle placed in the patient.

(6) Select the coil size that is adequate to the lesion referring to the angiogram.

(7) As shown in Figure 5, infuse about 1 ml of heparinized saline into the sheath from the adaptor to swell the PVA rod of the i-ED COIL.

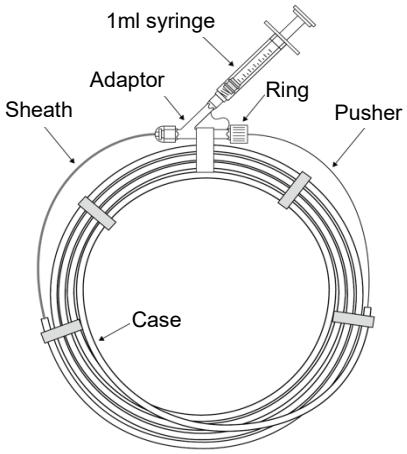

Figure 5. How to swell the PVA rod

Precautions

1. If a coil stiffer than the one placed for framing is used for filling or finishing, the frame may be damaged or the framing coil may pushed out into the parent artery.
2. In an embolization of aneurysm with the i-ED COIL, ensure to achieve a sufficient volume embolization ratio (VER). Insufficient VER may cause coil compaction.
3. When placing a coil for finishing, carefully confirm the conditions of embolization and placement. If the size of the coil chosen is much smaller than the residual space-volume or the coil is not properly deployed in the basket that has been produced, the coil may migrate into the peripheral blood vessel when retrieving the microcatheter.

2. Delivery of the i-ED COIL to the target lesion of the patient

(1) Pull out the whole length of the sheath from the case, without pulling out the proximal part of the pusher from the case.

(2) Before introducing the sheath into the microcatheter, carefully observe the detachable part through the sheath-wall (semitransparent) and confirm that the pusher is not directly touching the coil (the PVA rod should stay in between the edge of the pusher and the coil.)

Precautions

1. If the coil comes into contact with the pusher, the green lamp of the EDG v4 is lit even if the coil is not properly positioned in the target site, and it may result in unintended detachment of the coil. Replace this i-ED COIL with a new one.

(3) Loosen the ring of the adaptor so that the insertion of the i-ED COIL through the sheath becomes possible.

(4) Introduce the end of the sheath into the hub of the microcatheter. Make sure that the end of the sheath is securely contacting the orifice of the microcatheter, and slowly insert the coil into the microcatheter so that any deformation of the coil may not occur.

Warnings

1. Do not rotate the pusher while inserting the coil. (Doing so may unravel or fracture the coil.)

Precautions

1. In the case that any abnormality in the coil such as unraveling, deformation, or damage occurs, remove carefully the i-ED COIL out of the patient, and prepare to use a new i-ED COIL.
2. If any resistance is felt during placement of the coil, retrieve the coil into the microcatheter, and remove the i-ED COIL together with the microcatheter while monitoring the behavior of the device.

(5) Advance the pusher into the sheath to its rear end, then, hold it, and remove the sheath through the rear end of the pusher.

(6) Confirm if the position marker exists and is visible on the proximal end of the pusher.

(7) Carefully advance the pusher till the position marker has reached at the proximal end of the RHV connected with the microcatheter (see Figure 2).

(8) Advance further the pusher to deliver the coil to the distal end of the microcatheter. Confirm, using X-ray fluoroscopy, that the detachable part has advanced exceeding the second marker (proximal side) of the microcatheter.

(9) Connect the ED clip to the end of the i-ED COIL pusher. Confirm that the red lamp of the EDG v4 is lit and the buzzer is beeping. (If the ED clip is connected before the detachable part has crossed over the second marker of the microcatheter, the EDG v4 may not be activated to detect the detachable part. If this occurs, disconnect the ED clip, advance the detachable part to cross over the second marker of the microcatheter, and then, reconnect the ED clip to the pusher.)

3. Detachment of the coil

(1) Slowly advance further the pusher to deliver the coil with constantly confirming using X-ray fluoroscopy that the edge of the microcatheter is in an appropriate position.

(2) Stop pushing the pusher when the proximal edge of the radiopaque marker of the pusher reaches the second marker of the microcatheter. Confirm that the red lamp of the EDG v4 turns off, the green lamp is lit and the buzzer beep has stopped.

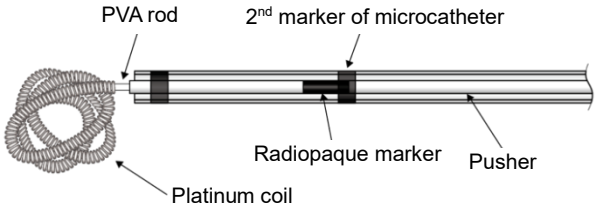

Figure 6. Alignment of the position marker

Precautions

1. If the red lamp will not turn off and the green lamp will not become lit on the EDG v4 even though the proximal end of the radiopaque marker of the pusher reaches the second marker (proximal side) of the microcatheter, under X-ray fluoroscopy, check each connection shown in Figure 4. If no abnormalities are noted in any of the connections, replace this i-ED COIL with a new one.
2. If the orange lamp of the EDG v4 is lit, pull back the pusher slightly and confirm that the orange lamp turns off and the green lamp is lit. If the green lamp is not lit, replace this i-ED COIL with a new one.

(3) Press DETACH buttons (both the right and the left buttons simultaneously) of the EDG v4 while the green lamp of the EDG v4 is lit, and then, the detaching output will be generated for 5 seconds to detach the coil. While the detaching output is generated, the green lamp blinks and the buzzer beeps intermittently.

(4) If the EDG v4 could not generate sufficient detaching output, the RETRY sign appears. If the RETRY sign appears, reduce the power to push the pusher and 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 on.

(5) Slowly and carefully pull back the pusher to confirm if the coil detachment was completed using X-ray fluoroscopy.

(6) If the coil did not detach, press the RESET button and repeat the above procedure 4) after checking the position of the detachable part again.

Warnings

1. Make sure that there is no resistance felt at the distal end of the microcatheter before detaching the coil. (Pressure and tension in the axial direction loaded on the microcatheter during insertion of the coil may move the distal end of the microcatheter, and it may rupture the blood vessel wall.)
2. Confirm that the size of the platinum coil is appropriate using X-ray fluoroscopy before detaching the coil. If the size is not compatible, replace the coil with one of an appropriate size. (A coil of an incompatible size may migrate away from the aneurysm after detachment and cause vascular occlusion.)
3. Confirm that the coil does not protrude into the parent artery using X-ray fluoroscopy before detaching the coil.
4. Do not advance the pusher passing the distal end of the microcatheter after detaching the coil. (Doing so may perforate the blood vessel.)
5. In order to prevent delays in the procedure that may pose risks to the patient, be sure to perform coil detachment after more than 1 minute has passed to fully swell the PVA rod. If the coil detachment is unsuccessful due to insufficient swelling time (i.e., less than 1 minute) retry the detachment procedures above described in (3) of section “3. Detachment of the coil” after confirming that more than 1 minute for the swelling has passed.
6. If the coil is attempted to detach while pressure in the axial direction on the pusher still remains, the PVA rod may not be completely melt off due to adhesion of the coil end and the head of the pusher. Make sure to conduct the coil detachment after delivering the coil to the appropriate deployment position and release the pressure in the axial direction on the pusher. If the coil still does not detach despite redoing the detachment with reduced pressure on the pusher, replace this i-ED COIL with a new one.
7. If the RETRY sign, i.e., the lamps (Red, Green the next, and then Orange) light up in this order repeatedly with the buzzer beeping intermittently, appears repetitively on the EDG v4, slowly and carefully pull back the pusher with monitoring by X-ray fluoroscopy. If the coil is not detached, carefully remove the i-ED COIL out of the patient, and prepare to use a new i-ED COIL.

Precautions

1. Confirm that the ED clip of the EDG v4 is securely connected to the pusher before detaching the coil.
2. Be sure to manipulate the i-ED COIL with carefully monitoring under X-ray fluoroscopy. (The lamps and the buzzer signs of the EDG v4 may not provide accurate information about the position of the coil and if a coil detachment is successfully completed.)

4. Retrieval of the pusher

Remove the ED clip from the pusher, and withdraw the pusher from the microcatheter.

Precautions

1. Retrieve the pusher after confirming that the coil is successfully detached by checking the behavior of the coil. if you attempt to retrieve the pusher while the coil is not detached, PVA rod may break and unexpected detachment may occur.

5. Employment of another i-ED COIL(s)

Leave the microcatheter in situ, and use the next i-ED COIL following the procedures from 6) of 1. Preoperative Preparation.

[Device Failures, Adverse Events and Complications]

The following device failures, adverse events and complications may occur during the use of the i-ED COIL. However, device failures, adverse events and complications are not limited to those listed below. Immediately take appropriate measures in the event that any abnormality occurs.

1. Device Failures
   (1) Migration of the platinum coil
   (2) Breakage or unraveling of the platinum coil
   (3) Detach-failure of the platinum coil
   (4) Delivery failure of the platinum coil
2. Adverse Events
   (1) Death
   (2) Hematoma
   (3) Injury to blood vessels or tissues, vessel wall dissection, blood vessel perforation, blood vessel rupture
   (4) Embolization
   (5) Bleeding, ischemia
   (6) Angiospasm
   (7) Stroke, cerebral infarction
   (8) Nerve disorder
   (9) Infection
   (10) Shock
   (11) Allergic reaction
3. Complications related to X-ray fluoroscopy
   (12) Alopecia
   (13) Burns ranging in severity from skin reddening to ulcers
   (14) Cataracts
   (15) Delayed neoplasia

Adverse Event Reporting

Please notify your KANEKA CORPORATION’s representative immediately if a device malfunction or patient complication or injury is experienced or suspected. Please make every attempt to retain any suspect device, its associated components and their packaging for return to KANEKA CORPORATION.

[Interactions]

Magnetic Resonance Imaging (MRI) Safety Information:

The MRI compatibility of the platinum coil of the i-ED COIL has been confirmed in a nonclinical test conducted in accordance with the American Society for Testing and Materials (ASTM) standards under the following conditions.

- Static magnetic field of 1.5 T or 3.0 T
- Maximum spatial gradient magnetic field of 5,000 Gauss/cm (50 T/m)
- Maximum Head specific absorption rate (SAR) of 3.2 W/kg
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of MRI scanning

Under the scan conditions defined above, this product is expected to produce a maximum temperature rise of less than or equal to 1.7°C (1.5 Tesla) and 1.6°C (3.0 Tesla) after 15 minutes of continuous scanning.
The presence of this implant may produce an image artifact. Per ASTM F2119-07, an image artifact of approximately 8.3 mm was measured from the i-ED COIL when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.
The temperature test was not conducted with the models of peripheral vasculature, arteriovenous malformation and arteriovenous fistula.

[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.

[Package]

1 piece / box

[Name and Address of Manufacturer, Manufacturing Site]

<Manufacturer >

Name : KANEKA CORPORATION
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<Manufacturing Site >

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