

Detach Point Detection System

The Electro Detach Generator v4 detects and indicates by sound and light signals the best Detach Point even when the position of the second marker of a microcatheter is not detectable under a X-ray fluoroscopy, Easy to use, disposable, sterilized, detachment of the coil can be done in single step operation by pressing 2 buttons simultaneously.

Red lamp
The red lamp is lit while the detaching part of the ED COIL stays within the microcatheter.

Green lamp
The green lamp is lit when the detaching part of the ED COIL has come out of the microcatheter.

Orange lamp
The orange lamp is lit when a current leak or other trouble occurs.

DETACH button
Detaching output is generated when the left and right buttons are pressed simultaneously while the green lamp is lit.

Manual Detachment
When it is necessary to detach the ED COIL while the red lamp is lit, press and hold the left and right buttons simultaneously for longer than 2 seconds, and a detaching output is generated.

RESET button
If the green lamp is lit while the detaching part is still within the microcatheter, press the reset button to restart detecting the detach point.

POWER ON ribbon
Pull off the POWER ON ribbon and the Electro Detach Generator v4 is powered on.

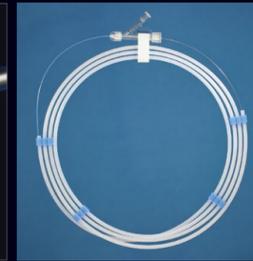
The red lamp is lit when the ED clip is connected to the pusher.

The green lamp is lit when the detaching part of the ED COIL has come out of the microcatheter. Subsequently, detachment of the coil can be done by pressing 2 buttons simultaneously.

Patient-side clip to be used with Hypodermic Needle made of stainless-steel without resin-coating (20G to 22G)

NAME

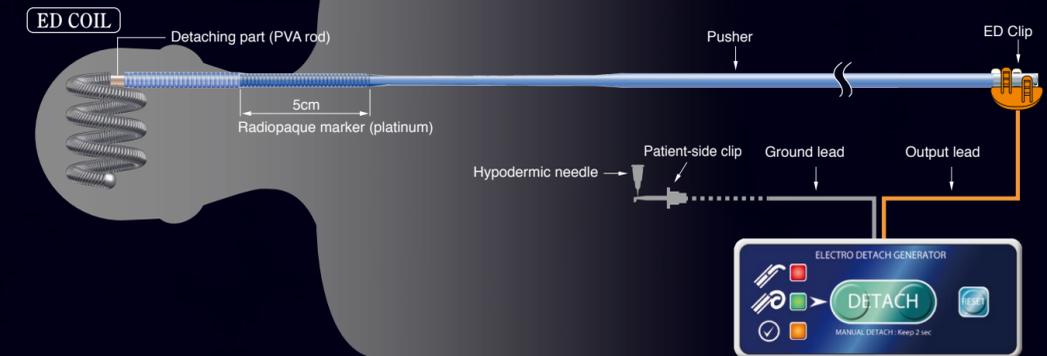
ED COIL



ELECTRO DETACH GENERATOR v4



SET UP



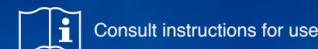
HOW TO USE

* See Instructions For Use

- Preparation**
Pull off the POWER ON ribbon to power on the Electro Detach Generator v4 with making sure that neither the ED clip nor the Patient-side clip is connected to any device and without touching any button of the Electro Detach Generator v4. The self-check function is activated immediately with all the lamps on with a beep sound for around one second, and then, all the lamps and the beep sound turn off to become the stand-by mode. Connect the Patient-side clip to the patient's hypodermic needle which shall be inserted at least 10 mm deep into the patient.
- Swelling the Detaching part (the PVA rod)**
Before taking out the ED COIL from the carrier tube, infuse about 1 mL of heparinized saline into the sheath of the ED COIL from the adaptor by using a 1 mL-syringe and wait for at least 2 minutes for Detaching Part (PVA rod) to be swollen.
- Detecting the Detach point**
Insert the ED COIL into the microcatheter placed in the patient's vessel. Confirm by using a X-ray fluoroscopy that the detaching part of the ED COIL passes the second marker of the microcatheter, and then, connect the ED clip to the end of the pusher. Confirm that the red lamp is on and the beeping is on. While checking the radiopaque marker, advance the ED COIL. When the radiopaque marker end of the ED COIL reaches the second marker of the microcatheter, the detaching part comes out of the microcatheter, then, the red lamp turns off, the green lamp is lit, and the beeping stops.
- Detaching the ED COIL**
Press the DETACH button, the left and the right buttons simultaneously, while the green lamp is on, then a detaching output is generated for 5 seconds and the coil will be detached immediately. Slowly pull back the pusher with checking if the detachment of the ED COIL is completed properly, and then pull out the pusher from the patient.



STERILEEO Sterilized using ethylene oxide



Manufacturer

KANEKA CORPORATION

CONTACT TEL. +81-3-5574-8136

3-18, 2-Chome, Nakanoshima, Kita-ku, Osaka-city, OSAKA, 530-8288 Japan
TEL. +81-6-6226-5256

EC-Representative

KANEKA PHARMA EUROPE N.V.

TRIOMFLAAN 173, 1160 BRUSSELS, BELGIUM



Ref No.107-48f Date Jan. 2015 2000 MJ

ED COIL
Electro Detach Coil



ED COIL—*Electro Detach Coil*—

“Reliable Coil Embolization” achieved by
 “Accurate Coil Placement and Tight Packing”



ED COIL
 Electro Detach Coil

Instant Detachment

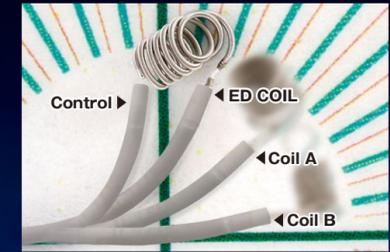
A platinum coil is connected to the pusher with a short poly vinyl alcohol (PVA) rod. The PVA rod is thermally melt down (at around 70°C) by high-frequency current generated by the Electro Detach Generator v4, and the coil is instantly detached.

Detach Point Detection

The Electro Detach Generator v4 detects and indicates by sound and light signals the best Detach Point even when the position of a microcatheter is not detectable under a X-ray fluoroscopy.

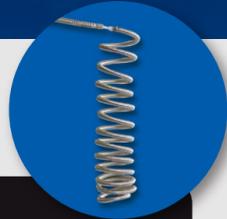
Soft Tip Pusher

The tip (through 30 mm from the distal end) is very flexible, therefore, it prevents kick-back of the microcatheter while deploying the coil in the aneurysm.



Comparison of Tip Softness

ED COIL10 ExtraSoft



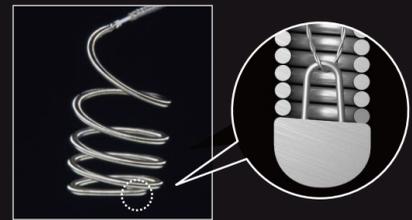
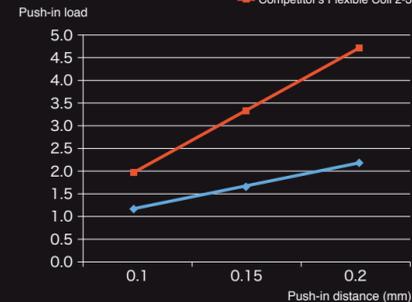
Soft and flexible coil for finishing

Feature • Extremely flexible coil that facilitates tight packing



2-4ES (φ2mm x 4cm) tightly packed in a 2 mm aneurysmal model.

Flexibility of ExtraSoft — ED COIL ES 2-3 (blue line), Competitor's Flexible Coil 2-3 (orange line)



The stretch resistant wire provides flexible and anti-stretching characteristics.

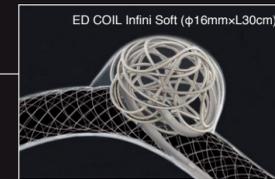
ED COIL10 [Infini]



A unique large diameter coil provides flexible filling regardless of the size and shape of an aneurysm.

Feature

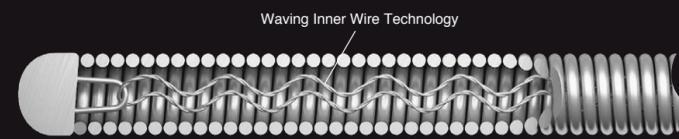
- Conforming outward to reduce compartment space
- Compactly folding and entering into even a gap space
- Conforms in accordance with the shape of an aneurysm even with irregular shape
- Provides a tight embolization with a small number of coils for a vessel occlusion



ED COIL Infini Soft (φ16mm x L30cm)
 Infini Soft's large coil-diameter reduces the risk of coil-protrusion through a stent strut into the parent artery, and it enables its use for both framing and filling.



ED COIL Infini Soft (φ16mm x L30mm)
 Infini Soft conforms outward to the aneurysm wall, thereby contributing to uniform packing even in an aneurysm with irregular shape.



Waving Inner Wire Technology enables coil-folding in smaller size despite its large primary coil-diameter.

ED COIL14 Standard

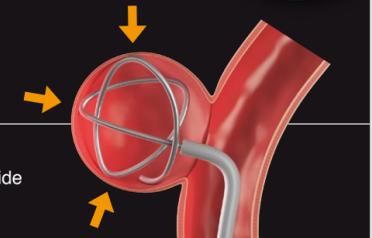


Helical coil spreading randomly

Feature

- The coil with 0.014 inch primary coil-diameter may provide sufficient coil embolization with a small number of coils
- The unique aSpiral coil structure provides random coil movement by deflection according to the aneurysm wall
- Strong framing by the unique aSpiral structure
- Suitable for both framing and filling

≤ 6 mm (small pitch): suitable for filling
 ≥ 7 mm (large pitch): suitable for both framing and filling



The random coil spreading with the aSpiral structure enables to change direction of the coil expanding in accordance with the shape of the wall of the aneurysm.



aSpiral (φ10mm x L30cm) in a model of a 10 mm aneurysm



The unique aSpiral shape, designed to form a strong frame with random loops by having 1:1 ratio between coil diameter and pitch (≥ 7 mm coil)