Upper limit of temperature is 40℃

Do not re-use

Do not use if package is damaged

Attention, see Instruction for Use

Keep away from sunlight and keep dry

Sterilized by ethylene oxide

Beijing Taijieweiye Technology Co., Ltd.
No.1 Plant, Maohua Industrial, Nancai Industrial Park, Shunyi, Beijing, P.R.China
Tel.: +86-010-89471461 Fax: +86-010-89471460

EC REP Lepu Medical (Europe) Cooperatief U.A.
Abe Lenstra Boulevard 36, 8448 JB, Heerenveen, the Netherlands
Tel: +31-515-573399 Fax: +31-515-760020

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TJWY MEDICAL

CE 2292

Embolic Coil System

Instructions for Use

Beijing Taijieweiye Technology Co., Ltd.

MR Conditional

No secondary sterilization

Table 1.The specifications of ECS

Spec	Loop Dia.（mm）	Length（cm）	Type
TJCST1.502-2D	1.5	2	Helical
TJCST1.503-2D	1.5	3	Helical
TJCST1.504-2D	1.5	4	Helical
TJCST0201-2D	2	1	Helical
TJCST0202-2D	2	2	Helical
TJCST0203-2D	2	3	Helical
TJCST0204-2D	2	4	Helical
TJCST0206-2D	2	6	Helical
TJCST0208-2D	2	8	Helical
TJCST2.502-2D	2.5	2	Helical
TJCST2.504-2D	2.5	4	Helical
TJCST2.506-2D	2.5	6	Helical
TJCST2.508-2D	2.5	8	Helical
TJCST0304-2D	3	4	Helical
TJCST0306-2D	3	6	Helical
TJCST0308-2D	3	8	Helical
TJCST0310-2D	3	10	Helical
TJCST0312-2D	3	12	Helical
TJCST3.506-2D	3.5	6	Helical
TJCST3.508-2D	3.5	8	Helical
TJCST3.510-2D	3.5	10	Helical
TJCST3.512-2D	3.5	12	Helical
TJCST0404-2D	4	4	Helical
TJCST0406-2D	4	6	Helical
TJCST0408-2D	4	8	Helical
TJCST0410-2D	4	10	Helical
TJCST4.506-2D	4.5	6	Helical
TJCST4.508-2D	4.5	8	Helical
TJCST4.510-2D	4.5	10	Helical
TJCST4.512-2D	4.5	12	Helical
TJCST4.515-2D	4.5	15	Helical
TJCST0509-2D	5	9	Helical
TJCST0510-2D	5	10	Helical
TJCST0515-2D	5	15	Helical
TJCST0520-2D	5	20	Helical
TJCST0610-2D	6	10	Helical
TJCST0611-2D	6	11	Helical
TJCST0615-2D	6	15	Helical
TJCST0620-2D	6	20	Helical
TJCST0715-2D	7	15	Helical
TJCST0720-2D	7	20	Helical
TJCST0730-2D	7	30	Helical
TJCST0815-2D	8	15	Helical
TJCST0820-2D	8	20	Helical
TJCST0830-2D	8	30	Helical
TJCST0920-2D	9	20	Helical
TJCST0930-2D	9	30	Helical
TJCST1020-2D	10	20	Helical
TJCST1030-2D	10	30	Helical
TJCST1130-2D	11	30	Helical
TJCST1230-2D	12	30	Helical
TJCST1330-2D	13	30	Helical

TJCST1430-2D	14	30	Helical
TJCST1530-2D	15	30	Helical
TJCST1630-2D	16	30	Helical
TJCST1830-2D	18	30	Helical
TJCST2030-2D	20	30	Helical
TJCST1.502-3D	1.5	2	Complex
TJCST1.503-3D	1.5	3	Complex
TJCST1.504-3D	1.5	4	Complex
TJCST0201-3D	2	1	Complex
TJCST0202-3D	2	2	Complex
TJCST0203-3D	2	3	Complex
TJCST0204-3D	2	4	Complex
TJCST0206-3D	2	6	Complex
TJCST0208-3D	2	8	Complex
TJCST2.502-3D	2.5	2	Complex
TJCST2.504-3D	2.5	4	Complex
TJCST2.506-3D	2.5	6	Complex
TJCST2.508-3D	2.5	8	Complex
TJCST0304-3D	3	4	Complex
TJCST0306-3D	3	6	Complex
TJCST0308-3D	3	8	Complex
TJCST0310-3D	3	10	Complex
TJCST0312-3D	3	12	Complex
TJCST3.506-3D	3.5	6	Complex
TJCST3.508-3D	3.5	8	Complex
TJCST3.510-3D	3.5	10	Complex
TJCST3.512-3D	3.5	12	Complex
TJCST0404-3D	4	4	Complex
TJCST0406-3D	4	6	Complex
TJCST0408-3D	4	8	Complex
TJCST0410-3D	4	10	Complex
TJCST4.506-3D	4.5	6	Complex
TJCST4.508-3D	4.5	8	Complex
TJCST4.510-3D	4.5	10	Complex
TJCST4.512-3D	4.5	12	Complex
TJCST4.515-3D	4.5	15	Complex
TJCST0509-3D	5	9	Complex
TJCST0510-3D	5	10	Complex
TJCST0515-3D	5	15	Complex
TJCST0520-3D	5	20	Complex
TJCST0610-3D	6	10	Complex
TJCST0611-3D	6	11	Complex
TJCST0615-3D	6	15	Complex
TJCST0620-3D	6	20	Complex
TJCST0715-3D	7	15	Complex
TJCST0720-3D	7	20	Complex
TJCST0730-3D	7	30	Complex
TJCST0815-3D	8	15	Complex
TJCST0820-3D	8	20	Complex
TJCST0830-3D	8	30	Complex
TJCST0920-3D	9	20	Complex
TJCST0930-3D	9	30	Complex
TJCST1020-3D	10	20	Complex
TJCST1030-3D	10	30	Complex
TJCST1130-3D	11	30	Complex
TJCST1230-3D	12	30	Complex
TJCST1330-3D	13	30	Complex
TJCST1430-3D	14	30	Complex
TJCST1530-3D	15	30	Complex
TJCST1630-3D	16	30	Complex
TJCST1830-3D	18	30	Complex
TJCST2030-3D	20	30	Complex

(18) After the coil is outside the microcatheter, pull the entire delivery system out of the microcatheter.
(19)Verify the position of the coil angiographically through the guide catheter.
(20)Prior to removing the microcatheter from the treatment site, place an appropriately sized guidewire completely through the microcatheter lumen to ensure that no part of the coil remains within the microcatheter.
The physician has the discretion to modify the coil deployment technique to accommodate the complexity and variation in embolization procedures. Any technique modifications must be consistent with the previously described procedures, warnings, precautions and patient safety information,

8. STORAGE

The Embolic Coil System should be stored in a cool, dry, clean and well ventilated place with the relative humidity no more than 80%, temperature below 40 ℃, no toxic and corrosive gas.

9. STERILIZATION VALID PERIOD

The Embolic Coil System is aseptic and pyrogen-free, and the sterilization validity is three years.

10. APPROPRITE SIZE SELECTION

The specification of ECS should be chosen by physician in accordance with the shape, diameter and residual space of the aneurysm shown in the drawings under DSA.

1. DEVICE DESCRIPTION

The Embolic Coil System (ECS) consists of the Implant coil and the delivery system. The ECS coils are platinum-tungsten alloy coils. The coil has a three-dimensional anti-unwinding structure, including three-dimensional helical and three-dimensional complex coils. Its good flexibility， conformability and unique design can prevent unwinding caused by overstretching during the treatment.
A variety of standard models are available (see Table1), according to the different diameter of the secondary loop and length of the implant coil. Each Coil type must be delivered only through a wire- reinforced microcatheter with the minimum Inner diameter specified. Recommended minimum inner diameter of microcatheter is 0.0165 ".

Other components required:

• Guide catheter compatible with the microcatheter;
• Wire-reinforced microcatheter with 2 tip RO markers, appropriately sized;
• Steerable guide wire compatible with microcatheter;
• 2 rotating hemostatic Y valves (RHV);
• 1 three-way stopcock;
• 1 one-way stopcock;
•Coil Detachment Controller (Beijing Taijieweiye) or V-Grip detachment controller (MicroVention Inc.), for only one patient;
• Sterile saline and / or lactated Ringer's Injection;
• Pressurized sterile saline drip.

2. INDICATIONS FOR USE

It is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The Embolic 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.

3. POTENTIAL COMPLICATIONS

The complications irrelevant with the device may occur during or after the procedure:

Complications related with Puncture

- Hematoma at the puncture site
- Hemorrhage at the puncture site
- Local or distal thromboembolism
- Thrombosis
- Arteriovenous fistula
- Pseudoaneurysm
- Puncture site infection

Complications related with Operation

- Artery dissection
- Vessel wall perforation or aneurysm rupture
- Long time vasospasm
- Acute occlusion required for surgical intervention

Complications related with Device

The anticipated adverse reactions related with the device are minimal (pyrogen reaction, infection, etc.), but it can't completely exclude the possibility of occurrence of adverse reactions.

4. CONTRAINDICATION

No special contraindications are known with the device, and its clinical contraindications are the same with the general endovascular interventional operation.

(1) Do not use with patients in whom anticoagulant and antiplatelet therapy is contraindicated.
(2) Do not use in vessels with excessive tortuosity and serious calcification.
(3) Do not use in patients with renal impairment, who are allergic to contrast medium.

5. WARNINGS

(1) Confirm whether the patients have allergic reaction to contrast agent before operation.

be activated when connected to the proximal of delivery system. It is not necessary to push the detachment button on the side of the controller to activate it.

(13)Verify that the RHV is firmly locked around the delivery system and the position of the implant coil was fixed before connect the detachment controller with the delivery system.

(14)Insert the proximal of the delivery system into the detachment controller, and the light will turn green to signal that it is ready to detach the coil. If the detachment button is not pushed within 30 seconds, the solid green lights indicate that the device is ready to detach. If the green light does not appear, check to ensure that the connection has been made. If the connection is correct and no green light appears, replace the detachment controller.

(15) Verify the position of the implant coil before press the detachment button.

(16) Press the detachment button. At the end of the detachment cycle, audible tones will sound and the light will flash yellow three times. Verify detachment of the coil by first loosening the RHV valve, then pulling back slowly on the delivery system and verifying that there is no coil movement, if the implant coil did not detach, do not attempt to detach it more than two additional times, If it does not detach after the third attempt, remove the delivery system.

Note: When the indicator light turns red, you should replace it with a new detachment controller.

(17) After detachment has been confirmed, slowly advance the delivery system until the proximal end of the coil is outside the microcatheter.

Note: Advancing the delivery system beyond the microcatheter tip once the coil has been detached involves risk of aneurysm or vessel rupture.

RHV. Close the RHV around the delivery system. Slide the inner tube completely off of the delivery system. Use care not to kink the delivery system.

Note: The ECS cannot be re-sheathed after introduction into the microcatheter.

(7) Visually verify that the flushing solution is infusing normally. Once confirmed, loosen the RHV enough to advance the delivery system, but not to influence the continuous flushing.

(8) Under fluoroscopic guidance, slowly advance the ECS coil out the tip of the microcatheter. Continue to advance the ECS coil into the lesion until optimal deployment is achieved. Reposition if necessary. **If the coil size is not suitable, remove and replace with another device.**

(9) Advance the coil into the desired site until the radiopaque proximal marker on the delivery system is adjacent to the proximal marker on the microcatheter. The proximal end of the coil is inside the microcatheter (see Fig.2).

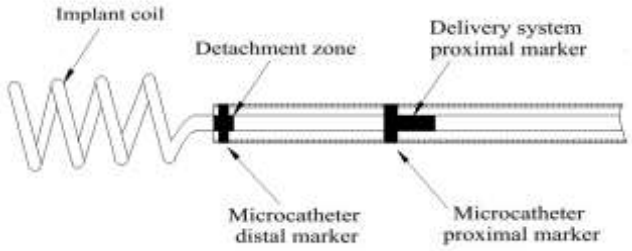

Fig.2 Position of Marker Bands for Detachment

(10) Tighten the RHV to prevent movement of the coil.

(11) Verify repeatedly that the distal shaft of the delivery system is not under stress before coil detachment. Axial compression or tension could cause the tip of the microcatheter to move during coil delivery. Catheter tip movement could cause the aneurysm or vessel to rupture.

(12) The detachment controller is pre-loaded with batteries and it will

(2) Only the experienced physicians should use the product.

(3) The coil is sterile and make sure the package is intact before use.

(4) The product with open or damaged packaging is forbidden to be used.

(5) Before the treatment, please check the coil system to verify its functionality, size and shape to meet the surgical requirements.

(6) Consistently follow the general technical requirements of the use of the Microcatheter, including the systematic heparinization, and flushing all the microcatheters which need to be inserted into blood vessel with aseptic heparinized saline solution or similar isotonic solution.

(7) The applications of the embolic coil system and technical methods must be based on the patient's condition and the operator's experience.

(8) It is forbidden to make the product through catheter with inner diameter smaller than the minimum dimension.

(9) The product is intended for single use only, and it cannot be re-sterilized or reused, otherwise it may result in damage to the instrument performance and increases the re-disinfection improper and the risk of cross-infection.

(10)The treatment must be performed under X-ray monitoring.

(11) The coil position can only be changed by the delivery wire and it is forbidden to move the coil system in the process of conveying.

(12) If the resistance appears, determine the resistance causes before moving coil.

(13) Please use the product before the expiration date printed on the product label.

6. PREPARATION FOR USE

It is necessary to maintain continuous flushing with a suitable solution between the following devices, in order to ensure the good performance of the coil and minimize the risk of thrombus:

• Between the femoral artery sheath and guide catheter
• Between the dual-marker microcatheter and guide catheter
• Between the dual-marker microcatheter and guide wire; between the dual-marker microcatheter and coil delivery wire

(1) Attach a rotating hemostatic valve (RHV) to the hub of the guide catheter. Attach a 3-way stopcock to the side arm of the RHV and then connect a line for continuous infusion.
(2) Attach a second RHV to the hub of the microcatheter. Attach a 1-way stopcock to the side arm of the second RHV and connect the flush solution line to the stopcock. It is recommended to inject a solution from the pressure bag every 3-5 seconds.
(3) Check all devices during injection process to ensure no air into the guide catheter or micro-catheter.

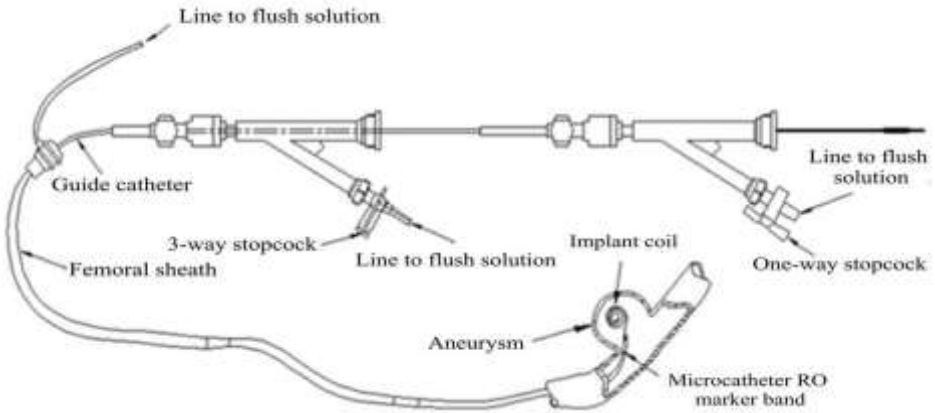

Fig.1 Continuous flushing connection diagram

7. APPLICATION TECHNIQUE

The input system comprises a guide catheter which can fully accommodate the dual-marker microcatheter, which allows the

contrast medium to cross through dual-marker microcatheter in order to be radiopaque. Select the appropriate coil spec by estimating the aneurysm size.
(1) Unlock the lock tube to make the delivery system with the implant coil can move freely in the inner tube.
(2)Check the whole system by pushing the delivery wire slowly. **If it is not smooth, replace it with a new one.**
(3)Push the implant coil out of the inner tube slowly and check it carefully in hand with disposable glove. **If the delivery system is abnormal, such as deformation or loop memory loss, replace it with a new one.**
(4) Dip the implant coil and detachment zone in sterile saline or lactated Ringer's Injection carefully. In order to ensure good shape memory of the implant coil, do not touch it as possible as you can. Retract all of the Implant coil back slowly into the inner tube and make sure the distal implant coil is about 1~2cm away from the distal end of the inner tube.
(5)Fix the lock tube and insert the inner tube of the ECS through the RHV. Seat the distal tip of the inner tube at the distal end of the microcatheter hub and close the RHV lightly around the inner tube to secure the RHV to the inner tube. **Do not over-tighten the RHV around the inner tube. Excessive tightening could damage the device.**
(6)Unlock the Lock tube and push the coil into the lumen of the microcatheter. Take caution to avoid catching the coil on the junction between the inner tube and the microcatheter hub. This step is best done by two people: one to maintain the stability of the RHV and the inner tube in the microcatheter hub, the other one to hold the inner tube and push the coil. Push the ECS through the microcatheter until the proximal end of the delivery system meets the proximal end of the inner tube. Loosen the RHV and retract the inner tube just out of the