Instructions for Use of Microvascular Anastomotic Coupler

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Instructions for Use of Microvascular Anastomotic Coupler

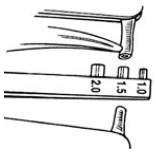
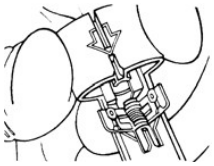


Figure 1


Figure 2


Figure 3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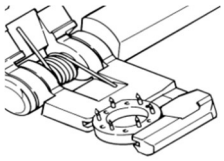
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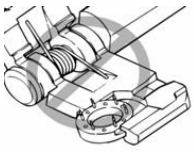
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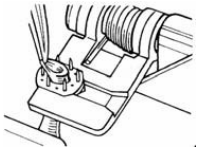
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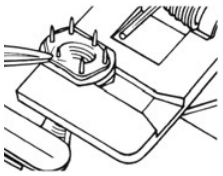
Figure 7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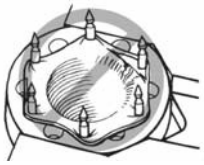
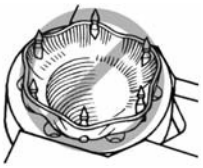

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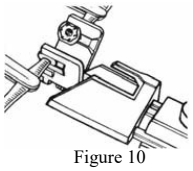
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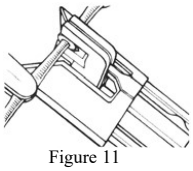
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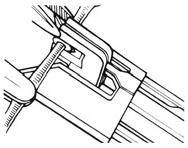
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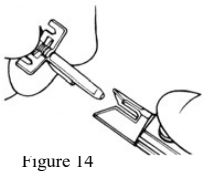
Figure 13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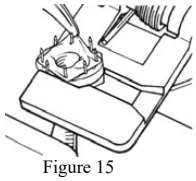
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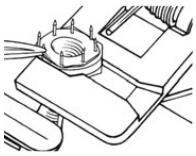
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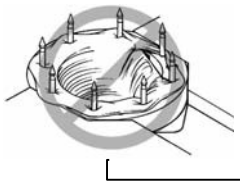
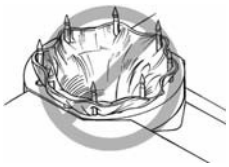

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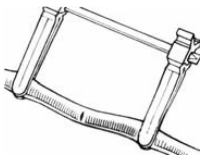
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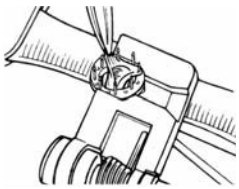
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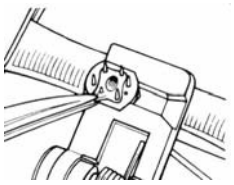
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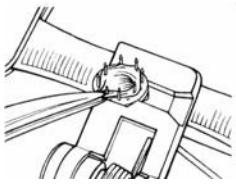
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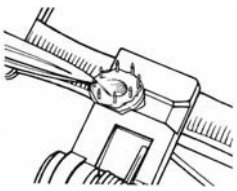
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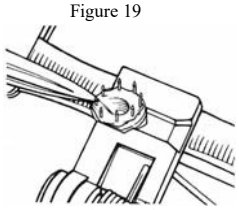
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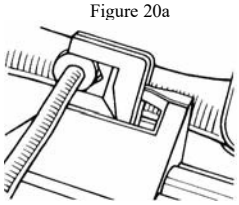
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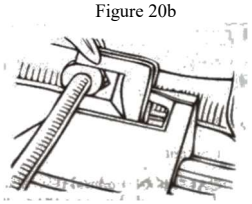


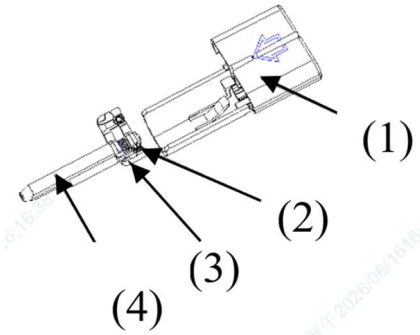
Figure 23

Instructions for Use of Microvascular Anastomotic Coupler

[Product Name] Microvascular Anastomotic Coupler

[Main Components]

The Microvascular Anastomotic Coupler consists of a protector, a pair of rings, a pair of bases, and one strutting piece.



(1) Protector; (2) Ring; (3) Base; (4) strutting piece

[Main Components and Materials]

Serial number	Component/part		Materials
Implantable component (w/w%)			
1	Rings	Frame	Thermoplastic polyurethane (TPU) /High Density Polyethylene (HDPE) （52.6～74.6%）
		Pins	316L Stainless Steel （25.4～47.4%）
Non-implantable components			
2	Bases		Polyaramide
3	Strutting piece		Polycarbonate
4	Protector		ABS（Acrylonitrile Butadiene Styrene）

[Model, Type, and Description of Classification]

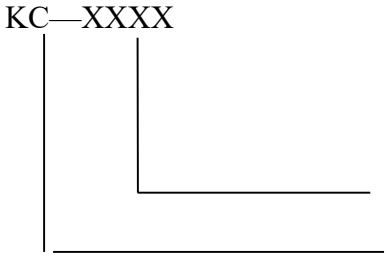
1. See the following table for product models and types:

Table 1. Models and types of Microvascular Anastomotic Coupler

REF	Materials of Ring	Outer Diameter of Vessels to Use	Inner Diameter of the pair of rings(mm)	Color of the strutting piece	Number of pins on the rings
KC1000	TPU	1.0 mm	1.0 ± 0.20	Gray	6
KC1500	TPU	1.5 mm	1.5 ± 0.20	Blue	6
KC2000	TPU	2.0 mm	2.0 ± 0.20	Green	6
KC2500	TPU	2.5 mm	2.5 ± 0.20	Red	6
KC3000	TPU	3.0 mm	3.0 ± 0.20	Yellow	6
KC3500	TPU	3.5 mm	3.5 ± 0.24	Violet	8
KC4000	TPU	4.0 mm	3.8 ± 0.24	Orange	8
KC1000A	HDPE	1.0 mm	1.0 ± 0.20	Gray	6
KC1500A	HDPE	1.5 mm	1.5 ± 0.20	Blue	6
KC2000A	HDPE	2.0 mm	2.0 ± 0.20	Green	6
KC2500A	HDPE	2.5 mm	2.5 ± 0.20	Red	6
KC3000A	HDPE	3.0 mm	3.0 ± 0.20	Yellow	6
KC3500A	HDPE	3.5 mm	3.5 ± 0.24	Violet	8
KC4000A	HDPE	4.0 mm	3.8 ± 0.24	Orange	8

2. Model and description of classification:

The product label is composed of brand code (KC) and type code (XXXX), as shown below:



Type code, such as "1000" for size 1.0 mm.

Brand code: The brand code is the initials of "Ke Chuang" (Chinese Pinyin).

[Product Performance]

1. Separating force of the rings: After anastomosis with the product, the separating force is determined to be no less than 3.5 N.

2. Product sterility: The product should have been sterilized according to the validated sterilization process and should be sterile.

[Intended Purpose]

The Microvascular anastomotic coupler is intended to be used in the anastomosis of veins and arteries (excluding coronary arteries) normally encountered in microsurgical procedures only in the peripheral vascular system. The Microvascular anastomotic coupler is intended for use with veins and arteries having an outside diameter not smaller than 1.0 mm and not larger than 4.0 mm and a wall thickness equal to or less than 0.5 mm, so as to achieve the effect of maintaining unobstructed local blood flow.

[Indications]

The Microvascular anastomotic coupler is suitable for surgeries involving acute vascular injuries of the peripheral vascular system that require vascular anastomosis or repairs using free tissue flaps.

[Patient Populations]

The Microvascular anastomotic coupler is applicable to patients who need vascular anastomosis in the peripheral vascular system due to acute vascular injury or the need to perform free tissue flap repair surgery.

The Microvascular anastomotic coupler is not suitable for patients with diseases where microsurgical repair using suturing techniques cannot be performed, including but not limited to:

- Patients with or suspected of having peripheral vascular disease;
- Patients undergoing radiotherapy in the area of acute vascular injury, flap donor site, or flap recipient site;
- Patients with clinical infection in the area of acute vascular injury, flap donor site, or flap recipient site;
- Patients with expected infection caused by severe contamination in the area of acute vascular injury, flap donor site, or flap recipient site;
- Patients with fragile vascular tissues due to sclerotic diseases;
- Patients with comorbid diabetes;
- Patients receiving concurrent corticosteroid therapy.

[Intended user]

The Microvascular anastomotic coupler is intended to be used by trained physicians who have technical knowledge, professional training, experience, and education on microsurgical procedures.

[Contraindications]

Not recommended for use outside of the peripheral vascular system.

The Microvascular Anastomotic Coupler is not intended for use in patients presenting conditions that would normally preclude microvascular repair with suture technique. Examples of such conditions include, but are not limited to:

• Pre-existing or suspected peripheral vascular disease;

• Ongoing irradiation of the area of reconstruction;

• Clinical infection of the area of reconstruction;

• Anticipated infection due to significant contamination of the area of reconstruction;

• Friability of the vascular tissue due to sclerotic conditions;

• Concurrent diabetes mellitus;

• Concurrent corticosteroid therapy.

[Cautions]

Use a microvascular measuring gauge to approximate the diameter of the vessel for selection of an appropriate Microvascular Anastomotic Coupler size. In an end-to-end anastomosis, the two vessel ends should be approximately the same size as the inside diameter of the rings of the Microvascular Anastomotic Coupler being used. In an end-to-side anastomosis, the opening made to the side vessel should be approximately the same size as the inside diameter of the rings of the Microvascular Anastomotic Coupler being used. If the end vessel size is outside of the specified range, do not use the Microvascular Anastomotic Coupler to mate the vessels.

◆ Please use before the "Use by date".

[Warnings]

• Use the product prior to the sterilization expiration date clearly indicated on the label, and the sterility and performance of the product cannot be guaranteed beyond the expiration date.

• Failure to use the microvascular measuring gauge to approximate the vessel size could result in using a Microvascular Anastomotic Coupler of an inappropriate size. Using a ring too large for the vessel may result in stressing or tearing of the vessel wall and a compromised anastomosis. Using a ring too small for the vessel may unduly constrict the vessel and lead to thrombosis or ring separation.

• The Microvascular Anastomotic Coupler should only be used within the indications.

• Failure to use a hemostat or similar instrument to clamp the rings prior to dislodging the rings from the bases may result in insufficient rings closure and subsequent rings separation. Prior to dislodging the rings from the bases, inspect the anastomotic sites to ensure secure closure of both rings sides.

• The Microvascular Anastomotic Coupler is supplied sterile and is for single use only. Do not resterilize or reuse the Microvascular Anastomotic Coupler. Failure to comply with this warning may result in failure of

vascular anastomosis.

• Prior to use, carefully examine that the product and labels are intact and do not use if any deformities, cracks, or missing items are observed.

• Do not use the Microvascular Anastomotic Coupler if the package has been opened or appears to be damaged or compromised. Sterility could be compromised which could result in patient infection.

• Safe use of the Microvascular Anastomotic Coupler for the anastomosis of tubular structures other than veins and arteries has not been established.

• Security of the Microvascular Anastomotic Coupler for the anastomosis of growing vessels in minors has not been established.

• The Microvascular Anastomotic Coupler rings cannot be opened and reused after closure, and a new Microvascular Anastomotic Coupler should be used when re-stapling is required.

• The anastomotic handle, microvascular measuring gauge, microforceps, and sterilization tray (such as tool box) must be sterilized prior to use.

• The anastomotic handle, microvascular measuring gauge, microforceps, and sterilization tray (such as tool box) should be thoroughly inspected before use. Instruments that are damaged and/or in need of repair should not be used.

• When performing an end-to-side anastomosis, the lumen of the "side" vessel is narrowed slightly. For this reason, the diameter of the "side" vessel should be larger than that of the "end" vessel when completing such a procedure. The opening made to the side vessel should be approximately the same size as the inside diameter of the Microvascular Anastomotic Coupler being used.

• Adequate intraoperative hemostasis should be maintained to prevent local compression due to hematoma.

• The suture tension should be controlled at a level not to reduce vascular patency.

• Adequate postoperative analgesic and antispasmodic therapy should be provided to prevent vasospasm and reduce vascular crises.

•Attention should be paid to the patient's hemodynamic changes after the surgery to guard against deep vein thrombosis and pulmonary embolism.

In case of any Serious Adverse Event, please contact your local distributor immediately, inform your European Authorized Representative, report the Competent Authorities, and inform the Notified Body and Hua Rong Ke Chuang Biotechnology (Tianjin) Co., Ltd.

[Potential Risks]

• Use of the Microvascular Anastomotic Coupler involves potential risks normally associated with any implanted device, e.g., infection, thrombosis, vessel tear / rupture, anastomotic leak, foreign body reaction, graft stenosis, flap loss / partial necrosis, vascular crisis, hematoma.

[MRI Compatibility]

It is the responsibility of the clinician to inform the patient that he/she is the recipient of the permanent implants which contain metallic components (implant-grade stainless steel pins). In non-clinical testing, Microvascular Anastomotic Coupler has been shown to be MR Conditional.

Parameter Category	Specific Conditions
MRI Safety Status	MR Conditional
Static Magnetic Field Strength	3.0 T only
Static Magnetic Field Orientation	Horizontal closed-bore MRI system
Maximum Spatial Field Gradient	|∇B|_{max} ≤ 7.109 T/m
Maximum |B||∇B|	≤ 17.243 T^2/m
Maximum Gradient Slew Rate	≤ 220 T/m/s
Maximum Single-Axis Gradient Field Strength	≤ 42 mT/m
RF Transmit Coil Type	Body coil only (whole-body transmit); local transmit coils prohibited
RF Operating Mode	Normal Operating Mode or Level I Controlled Operating Mode
Maximum Whole-Body SAR	≤ 2.23 W/kg
Maximum Continuous Scan Duration	≤ 15 minutes
Allowed Pulse Sequences	Conventional clinical sequences including SE, Turbo SE, GRE; other sequences require individual evaluation
Magnetically Induced Displacement Force Safety	Maximum deflection angle 18° (<45°); displacement force < gravity
Magnetically Induced Torque Safety	Maximum torque < 1.46×10^{-7} N·m; no alignment or rotation observed
RF Heating (at 3T)	Maximum temperature rise 1.41 ℃ (at whole-body SAR 2.23 W/kg, 15 min)

Image Artifact	Maximum artifact width 7.98 mm (length direction); 7.46 mm (diameter direction)
Exceptions / Prohibitions	• Do not scan at field strength >3.0 T • Do not exceed SAR or scan duration limits above • Multiple implants or adjacent untested devices require separate evaluation

[Instructions for Use]

These Instructions for Use are designed for proper use of this device. They are not intended to serve as a reference to surgical technique, to supersede institutional protocols or professional clinical judgment regarding patient care.

3.0 mm Microvascular Anastomotic Coupler Size or Smaller:

End-to-end anastomosis Using conventional microsurgical techniques, mobilize a minimum of 1 cm of each vessel end. Use micro forceps to grasp the vessel wall and flush the opening of the vessel.

1. After gentle dilation, estimate the outside diameter of each vessel using the microvascular measuring gauge. The circular guides on the gauge should not be placed inside the vessel lumen (See Figure 1). If there is a size discrepancy between the two vessels, use the measurement of the smaller vessel to choose the appropriate Microvascular Anastomotic Coupler.

2. The degree of vessel spasm and the elasticity of the vessel should be considered when choosing the size of the Microvascular Anastomotic Coupler to be used. Both vessel ends should be approximately the same size as the inside diameter of the Microvascular Anastomotic Coupler being selected.

3. The Microvascular Anastomotic Coupler is packaged in double boxes. Take the inner box out from the outer box and put it in a sterile area after being opened. Inspect the inner box. Do not use the product if the inner box is damaged or if the seals are not intact.

4. Turn the anastomotic handle fully counterclockwise, and insert the Microvascular Anastomotic Coupler onto the anastomotic handle. The matching indicator arrows on the Microvascular Anastomotic Coupler and the anastomotic handle should be pointing toward each other when loading (See Figures 2 & 3). Ensure that an audible click is heard for proper loading.

5. Remove the protector by pulling it firmly away from the anastomotic handle (See Figure 4).

6. If the pins are bent, do not attempt to straighten them. Instead, use a new Microvascular Anastomotic Coupler. Visually inspect to see that both rings are seated at the bottom of the U portion of the bases and the pins are not bent (See Figures 5a & 5b).

7. Perpendicularly pull the vessel ends through the rings. Pull one vessel end through one of the Coupler rings using microforceps (See Figure 6).

8. Evert the vessel wall and intimal layer 90° with micros forceps and pierce it on the needle nearest to the opening of the base (open end of the U-shaped portion of the base). Proceeding in a triangular fashion, impale the vessel firmly upon every other pin, completing three pins (See Figure 7). Complete vessel placement on the ring by impaling the vessel upon the remaining three intermediate pins (See Figure 8). Ensure that both the vessel wall and the intimal lining are fully impaled onto each pin to reduce the risk of thrombosis. Should the vessel wall tear during impalement, remove the vessel, trim the end, and repeat the procedure. For examples of improper impalement of the vessel, see Figure 9.

9. Repeat Steps 7 and 8 to impale the other vessel end upon the second Coupler ring.

10. When both vessel ends have been suitably impaled, visually inspect to ensure that both rings are seated at the bottom of the U portion of the bases and the pins are not bent (See Figures 5a and 5b). Bring the rings together (See Figures 10 & 11) by turning the anastomotic handle clockwise. Turn the anastomotic handle only until the ejector rod has just started to move the now joined rings.

11. Prior to ejecting the joined rings, gently squeeze the end of the apposed bases with a hemostat (See Figure 12) to ensure ring approximation and a tight friction fit. Turn the anastomotic handle further clockwise to eject the joined rings.

12. Check the anastomosis under the operating microscope before opening the vascular clamps. Remove the clamps and inspect the anastomotic site to ensure that the anastomosis has been satisfactorily completed (patent vessel without leakage).

13. To completely separate the bases, turn the anastomotic handle fully counterclockwise (See Figure 13). Press the release button located near the arrow on the anastomotic handle, and remove the accessories (See Figure 14).

14. Rinse the anastomosis tools (microvascular measuring gauge, anastomotic handle, microforceps) with water after use.

3.5 mm Microvascular Anastomotic Coupler Size or Larger:

End-to-end anastomosis:

1. Follow the same directions as for 3.0 mm Microvascular Anastomotic Coupler size or smaller (Steps 1 through 7).

8. Evert the vessel wall and intimal layer 90° with micros forceps and pierce it on the needle nearest to the opening of the base (open end of the U-shaped portion of the base). Impale the opposite side of the vessel opening to the pin directly across from the initial pin. Next, impale the vessel onto the pins located near the sides of the ring, keeping the vessel as evenly spaced as possible between the four pins (See Figure 15). Continue vessel placement on the ring by impaling the vessel onto the two remaining pins near the open end of the base. Complete vessel placement by impaling the vessel onto the last two pins near the bottom of the base (bottom of the U portion of the base); this final step prevents the rings from sliding out of the base

prematurely (See Figure 16). Ensure that both the vessel wall and the intimal lining are fully impaled upon each pin to reduce the risk of thrombosis. Should the vessel wall tear during impalement, remove the vessel, trim the end, and repeat the procedure. For examples of improper impalement of the vessel, see Figure 17.

9. to 14. Follow the same directions as for 3.0 mm Microvascular Anastomotic Coupler size or smaller (Steps 9 through 14).

All Microvascular Anastomotic Coupler Sizes:

End-to-side anastomosis: Using conventional microsurgical techniques, with a minimum of 1 cm for free end branch vessels and 2 cm for free side branch vessels. Use micro forceps to grasp the vessel wall and flush the opening of the vessel.

1. When performing an end-to-side anastomosis with the device, the lumen of the "side" vessel is narrowed slightly. For this reason, the diameter of the "side" vessel should be larger than that of the "end" vessel when completing such a procedure.

2. Estimate the outside diameter of the "end" vessel using the microvascular measuring gauge. The circular guides on the gauge should not be placed inside the vessel lumen (See Figure 1).

3.The degree of vessel spasm and the elasticity of the vessel should be considered when choosing the size of the Microvascular Anastomotic Coupler to be used.

4. The Microvascular Anastomotic Coupler is packaged in a tray-in-tray design. Take the inner tray out from the outer tray and put it in a sterile area after being opened. Inspect the inner tray Do not use the product if the inner tray is damaged or if the seals are not intact.

5. Turn the anastomotic handle fully counterclockwise, and insert the Microvascular Anastomotic Coupler onto the anastomotic handle. The matching indicator arrows on the protector of the Microvascular Anastomotic Coupler and the anastomotic handle should be pointing toward each other after loading (See Figures 2 & 3). Ensure that an audible click is heard for proper loading.

6. Remove the protector by pulling it firmly away from the anastomotic handle (See Figure 4).

7. Visually inspect to see that both rings are seated at the bottom of the U portion of the bases and the pins are not bent (See Figures 5a and 5b). If the pins are bent, do not attempt to straighten them. Instead, use a new Microvascular Anastomotic Coupler.

8. Place the anastomotic handle perpendicular to the direction of the "end" vessel. Place the "end" vessel upon one ring as described in Steps 7 and 8 for end-to-end anastomosis directions of the appropriate Microvascular Anastomotic Coupler size.

9.Provisionally clamp amenorrhoea the isolated side branch vessel with a vascular clamp, create an incision at the appropriate location of the side branch vessel (See Figure 18), trim the incision and ensure the incision diameter does not exceed the inner diameter of the selected microvascular stapling device. Flush the lumen of the side branch vessel through the incision.

10. Using microforceps, grasp the vessel wall and intimal lining near one end of the transverse incision and pull them through the remaining ring. Evert the vessel wall and intimal lining 180 degrees and impale the vessel first upon the pins situated nearest the incision end (See Figure 19).

11. Proceed in a similar manner at the opposite end of the incision to impale the vessel wall and intimal lining upon the pins situated nearest the incision end (See Figure 20a for Coupler sizes 3.0 mm and smaller; See Figure 20b for Coupler sizes 3.5 mm and larger). Complete the pinning procedure by everting the vessel upon the remaining pins (See Figure 21a for Coupler sizes 3.0 mm and smaller; See Figure 21b for Coupler sizes 3.5 mm and larger). Ensure that both the vessel wall and the intimal lining are fully impaled upon each pin.

12. Bring the rings together by turning the anastomotic handle clockwise, only until the ejector rod has just started to move the now joined rings. Hold the anastomotic handle when bringing the rings together such that the jointed rings can be ejected from the bases successfully (See Figure 22).

13. Prior to ejecting the joined rings, squeeze the end of the apposed bases with a hemostat (See Figure 23) to ensure ring approximation and a tight friction fit. Turn the anastomotic handle further clockwise to eject the joined rings.

14. Check the anastomosis under the operating microscope before opening the vascular clamps. Remove the clamps and inspect the anastomotic site to ensure that the anastomosis has been satisfactorily completed (patent vessel without leakage).

15. To completely separate the bases, turn the anastomotic handle fully counterclockwise (See Figure 13). Press the release button located near the arrow on the anastomotic handle, and remove the accessories (See Figure 14).

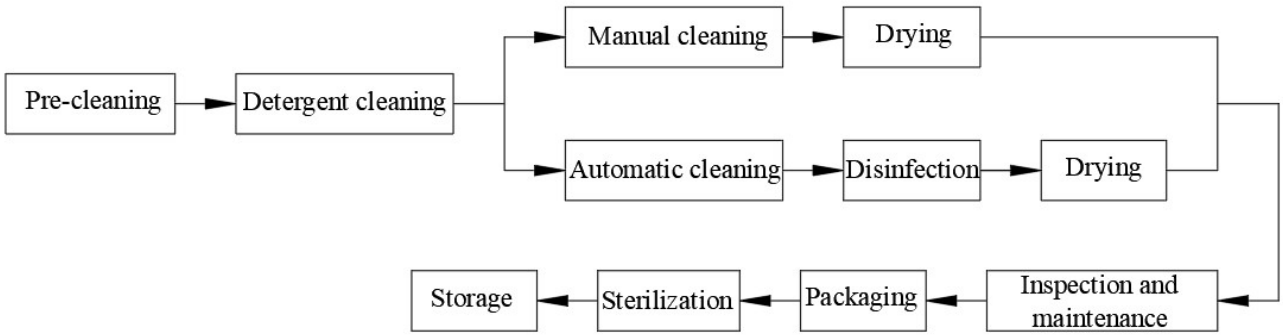
16. Rinse the anastomosis tools (microvascular measuring gauge, anastomotic handle, microforceps) with water after use.

[Special Instructions]

• This product is recommended to be used in combination with the devices (anastomotic handle, microvascular measuring gauge, microforceps) produced by Hua Rong Ke Chuang Biotechnology (Tianjin) Co., Ltd.. If there is a risk of product failure when using the product in combination with other devices, and the problems generated therefrom are unrelated to the company, the operator is advised to use it with caution. • The anastomotic handle, microvascular measuring gauge, microforceps must be sterilized prior to use. • Anastomotic handle, microvascular measuring gauge, microforceps Thoroughly inspect prior to use. Do not use a device that has been damaged or requires repair.
Limitations on reprocessing: No particular limitations

[Cleaning, Maintenance, and Sterilization]

The cleaning, maintenance, and sterilization process of microscopic instruments is provided below:



Cleaning and sterilization precautions: Due to their precision nature, microscopic instruments should be cleaned separately from other instruments to prevent damage. During the cleaning process, prioritizing self-protection is crucial to prevent accidental infections.

After use, microscopic instruments should be promptly placed in a sealed container or pre-cleaned without delay. Processed microscopic instruments should be transferred from the hospital to the CSSD Cleaning and Recycling Center for cleaning, maintenance, and sterilization.

The cleaning, maintenance, and sterilization procedures for microscopic instruments in the CSSD Cleaning and Recycling Center are as follows:

Step 1 Pre-cleaning

Soak the microscopic instruments in water for at least 5 min. Carefully brush the microscope instruments with a soft-bristled brush (to prevent scratching the surface) in tap water until removing all visible residue. Finally, rinse the instruments again under flowing water.

Step 2 Detergent cleaning

1. After pre-cleaning, prepare the washing solution according to the requirements of the detergent ratio, with a pH value of 7-10;
2. Brush the microscopic instruments with a soft-bristled brush to remove all residual blood and debris. Pay special attention to areas where debris may be concentrated.
3. Finally, rinse the instruments thoroughly with flowing purified water.

Note: Avoid using detergents with a pH higher than 10 or brushing tools that could potentially scratch the surface of the microscopic instruments. This precaution is necessary to prevent damage to the passivation layer on the instrument's surface and the anodized layer on the tool case's surface.

Step 3 Cleaning

Manual cleaning:

1. Put the microscopic instruments in the ultrasonic cleaner;
2. Inject the prepared detergent solution into the ultrasonic cleaning tank, ensuring it covers all instruments completely;
3. Set ultrasonic cleaning parameters, with a temperature of 40-45℃ and a duration of 15 min;
4. After cleaning, thoroughly rinse the microscopic instruments again with purified water.

Automatic cleaning:

1. Put the microscopic instruments in the automatic cleaning machine;
2. Inject the prepared detergent solution into the machine;
3. Set the cleaning procedure to initiate cleaning. Procedure: Pre-rinse with cold water for 1 min - Rinse with cold water for 3 min - Rinse with detergent solution at 45-55 ℃ for 10 min -Neutralize with 40℃ warm water for 3 min -Rinse with 40℃ warm water for 2 min

Note: 1. Instruments must not be stacked. 2. User can choose either manual cleaning or automatic cleaning. 3. The preparation concentration, temperature, and usage time of the detergent must comply with the instructions provided by the manufacturer. The detergent must be proven to be used for reusable general metal surgical instruments.

Step 4 Disinfection

(Optional) Use an automatic cleaning machine to heat disinfect the instruments at a temperature of 90-95℃ for at least 5 min.

Step 5 Drying

After manual cleaning, place the instruments into an electric hot air drying oven for drying, and set the drying temperature to 80℃ for 1 h.

After automatic cleaning, the automatic cleaning machine starts the drying cycle program to dry the instruments, with a drying temperature of 80℃ for 1 h.

Step 6 Inspection, maintenance, and packaging

Inspection: Verify that all visible debris is removed to maintain the instrument's high quality.

Maintenance: For instruments with moving components should be maintained. Failure to follow maintenance prompts may result in instrument failure.

Packaging: After inspection, the relevant microscopic instruments are placed in a tool case for packaging, which is then placed in a sterilizer. Packaging of instruments is conducted using the appropriate method according to the selected sterilization cycle.

Step 7 Sterilization

The gravity high-pressure sterilizer and pre-vacuum high-pressure sterilizer are used for sterilization. The sterilization parameters are shown in the table below.

Sterilization parameters of high-pressure sterilizer

<table>
<tr><th>Sterilization method</th><th>Instrument configuration</th><th>Temperature</th><th>Exposure duration (non-total cycle time)</th><th>Drying temperature and duration</th></tr>
<tr><td rowspan="3">Gravity high-pressure sterilizer</td><td>Packaged (unpackaged)</td><td>250°F (121°C)</td><td>15 min</td><td rowspan="5">1. Unpackaged 80°C/10 min
2. Packaged 80°C/30 min</td></tr>
<tr><td>Packaged</td><td rowspan="2">270°F (132°C)</td><td>10 min</td></tr>
<tr><td>Unpackaged</td><td>3 min</td></tr>
<tr><td rowspan="2">Pre-vacuum high-pressure sterilizer</td><td>Packaged</td><td rowspan="2">270°F-273°F
132°C-134°C</td><td>4-5 min</td></tr>
<tr><td>Unpackaged</td><td>3-5 min</td></tr>
</table>

Step 8 Storage

Instruments must be stored in a dry, clean, chemical-free, and dust-free environment. Instruments must be packaged and stored in closed sterile containers to maintain aseptic conditions. It is recommended to store instruments at room temperature.

Note: It is recommended that each institution determines the cleaning and sterilization effectiveness of their respective cleaning and sterilization procedures.

[Storage]

Recommended storage at a controlled temperature of 15°C–35°C.

[Transportation]

Avoid rain and rough handling during transportation.

[Model/Type] See the individual product label.

[Date of Manufacture] See the individual product label.

[Batch Number] See the individual product label.

[Use-by Date] The product is valid for 5 years from the date of manufacture.

[Sterilization] Sterilization using irradiation.

[Disposal] After use, dispose of the product according to local regulations.

[Manufacturer] Hua Rong Ke Chuang Biotechnology (Tianjin) Co., Ltd.

[Address] Building A, 1st Floor A Zone and 2nd Floor Building B, No. 69, Xin'An Road, Tianjin Economic-Technological Development Area West, Tianjin, 300462, China

[Phone] +86-22-65625051

[European Authorized Representative] NOVAMEDICAL GmbH

[Address] Haslacher Weg 12b, 51063 Köln, Germany

[SSCP] A summary of the safety and clinical performance for this device is available at https://ec.europa.eu/tools/eudamed. Search for the device using the Basic UDI-DI. The Basic UDI-DI is 6971503873A201510UT.

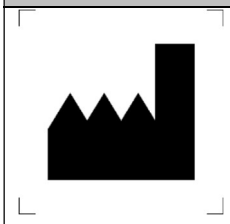
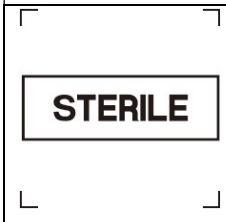
In accordance with the transition period requirements before the EUDAMED system becomes fully applicable, the Summary of Safety and Clinical Performance for this device is available on our company's official website: http://en.kingsungmedical.com/pro/d60.html

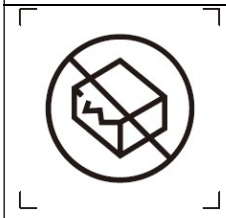
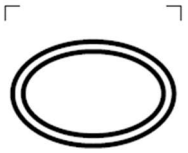
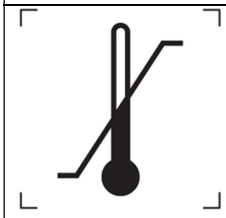
[eIFU] http://en.kingsungmedical.com/pro/d60.html

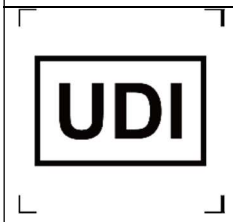
[Lifetime] 90 days

[Clinical benefits]

The Microvascular Anastomotic Couplers is used for the anastomosis of veins and arteries in microsurgical procedures. The expected clinical benefits of the product focus on three core dimensions: maintaining a high surgical success rate, ensuring operational efficiency, and reducing the risk of key complications.

Symbol	Standard and Symbol Number	Symbol Title	Symbol Description
	EN ISO 15223-1 5.1.1	Manufacturer	Indicates the medical device manufacturer
	ISO 15223-1 5.1.2 AMENDMENT 1 2025-03	Authorized representative in the European Community/ European Union	Indicates the authorized representative in the European Community/European Union
	EN ISO 15223-1 5.1.4	Use-by date	Indicates the date after which the medical device is not to be used
	EN ISO 15223-1 5.1.5	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified
	EN ISO 15223-1 5.1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified
	EN ISO 15223-1 5.1.3	Date of manufacture	Indicates the date when the medical device was manufactured
	EN ISO 15223-1 5.2.1	Sterile	Indicates a medical device that has been subjected to a sterilization process

Symbol	Standard and Symbol Number	Symbol Title	Symbol Description
	EN ISO 15223-1 5.2.4	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation
	EN ISO 15223-1 5.2.6	Do not resterilize	Indicates a medical device that is not to be resterilized
	EN ISO 15223-1 5.2.8	Do not use if package is damaged and consult instructions for use	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
	EN ISO 15223-1	Double sterile barrier systems with protective packaging outside	Indicates two sterile barrier systems with protective packaging outside
	EN ISO 15223-1 5.3.7	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed
	EN ISO 15223-1 5.4.2	Do not re-use	Indicates a medical device that is intended for one single use only
	EN ISO 15223-1 5.4.3	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use

Symbol	Standard and Symbol Number	Symbol Title	Symbol Description
	EN ISO 15223-1 5.4.4	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	EN ISO 15223-1 5.7.7	Medical device	Indicates the item is a medical device
	EN ISO 15223-1 5.7.10	Unique device identifier	Indicates a carrier that contains unique device identifier information
	ASTM F2503-23	MR Conditional	Indicates that the device is MR Conditional
	EN ISO 15223-1 5.3.1	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully
	EN ISO 15223-1 5.3.2	Keep away from sunlight	Indicates a medical device that needs protection from light sources

Symbol	Standard and Symbol Number	Symbol Title	Symbol Description
	EN ISO 15223-1 5.3.4	Keep dry	Indicates a medical device that needs to be protected from moisture
CE 2797		Notified Body code	

变更履历：

Revision history：

版本号 Rev	变更内容 Change Description	变更人 Reviser	变更日期 Date
B.0	Initial release	YangXian	2023/07/18
B.1	Change of address	YangXian	2024/09/24
B.2	The description related to the revised purpose has been updated to include clinical benefits.	Wang Gengwu	2025/06/27
B.3	Revise the overall content based on BSI audit observations	Wang Gengwu	2025/09/30
C.0	HDPE is added in the project for 7 models.	Wang Gengwu	2026/02/06
C.1	Updated the MRI and website information based on the competent authority's supplementary review comments.	Wang Gengwu	2026/06/08