Summary of Safety and Clinical Performance

Product	Microvascular Anastomotic Coupler
Product Models	KC1000/KC1500/KC2000/KC2500/KC3000/KC3500/KC4000
Manufacturer	Hua Rong Ke Chuang Biotechnology (Tian Jin) CO.,Ltd

Process	Person	Department	Signature	Date
Composing	Zhang Min	RA	Zhu Lei	2026-08-10
Review	Deng Heying	RA	Deng Heying	2026-08-10
	Pan Binhui	R&D	Pan Binhui	2026-08-10
Approval	Zhang zhongying	R&D	zhang zhong ying	2026-08-10

Content

1. Information for the professional user

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the Microvascular anastomotic coupler（MAC）.

The SSCP is prepared in accordance with the Medical Device Regulation (EU) 2017/745 (MDR) and the document MDCG 2019-9 of the Medical Device Coordination Group.

The SSCP is not intended to replace the instructions for use (IFU) as the main document to ensure the safe use of the Microvascular anastomotic coupler（MAC）, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

1.1 Device identification and general information

Device name(s)	Microvascular anastomotic coupler
	Model
	KC1000/KC1500/KC2000/KC2500/KC3000/KC3500/KC4000
Manufacturer's name and address	Hua Rong Ke Chuang Biotechnology (Tianjin) Co.,Ltd 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
Manufacturer's single registration number (SRN)	CN-MF-000037375
Basic UDI-DI	6971503873A201510UT
Medical device nomenclature	EMDN Code: C90010303 Haemostasis, Suture Or Clip Systems
Class of device	The product is classified as a Class IIb per Rule 8 of Annex VIII of the MDR (EU) 2017/745 of the European Parliament and the Council.
Year of first CE certificate	This device has no prior CE certificate. The issuance year will be [YYYY] (pending final approval).
Authorized representative	NOVAMEDICAL GmbH Address: Haslacher Weg, 12b 51063 Köln, Germany Single Registration Number (SRN): DE-AR-000036566
Notified body	BSI Group The Netherlands B.V.Notified Body number : 2797

1.2 Intended use of the device

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.
Indication(s)	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.
Targeted population(s)	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 and/or limitations	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.

1.3 Device description

1.3.1 Description of the Microvascular anastomotic coupler

Microvascular anastomotic coupler consists of a protector, a pair of rings, a pair of bases, and one strutting piece (see Figure 1).

The rings are permanent implants and hold 6 to 8 stainless steel pins on each.

The device is designed for end-to-end anastomosis and end-to-side anastomosis of microvessels. By closing the two rings to establish a tight friction fit, the device can connect the two damaged vessel ends attached on the stainless-steel pins.

The device is provided sterile and is intended for single use only.

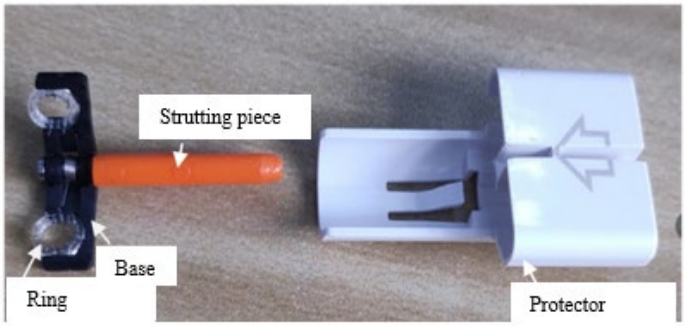


Figure 1 Photo of Microvascular anastomotic coupler

Principle of Operation

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 0.8 mm and not larger than 4.3 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.

During the procedure, after identifying the outer diameter of each vessel, the surgeon selects the appropriate size of Microvascular anastomotic coupler and inserts the device onto the matching Anastomotic Handle, as shown in Figure **2b**. Then the Device is removed from the protector by pulling it firmly away from the Anastomotic Handle, see Figure **2c**. The Anastomotic Handle is placed perpendicular to the vessel(s), with the base assembly near the two vessel ends, see Figure **2d**. Pull one vessel end through one of the rings using microforceps. Take a bite of approximately one to two pin diameters of the vessel wall and intimal lining, evert 90 degrees and impale onto one pin, as shown in Figure **2e**. Continue to impale the vessel firmly upon the remaining pin according to the technique of end-to-end anastomosis and end-to-side anastomosis. Ensure that both the vessel wall and the intimal layer are fully impaled upon each pin to reduce the risk of thrombosis, see Figure **2f**. After completing the impale of vessel onto one ring, impale the other vessel end upon the second ring. 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 base and the pins are not bent. Bring the rings together by turning the Anastomotic Handle knob clockwise, as shown in Figure **2g**. Prior to ejecting the rings, gently squeeze the end of the apposed base with a small hemostat to ensure ring approximation and a tight friction fit. Turn the Anastomotic Handle knob further clockwise to eject the joined rings. At the end, remove the base assembly from the Anastomotic Handle.

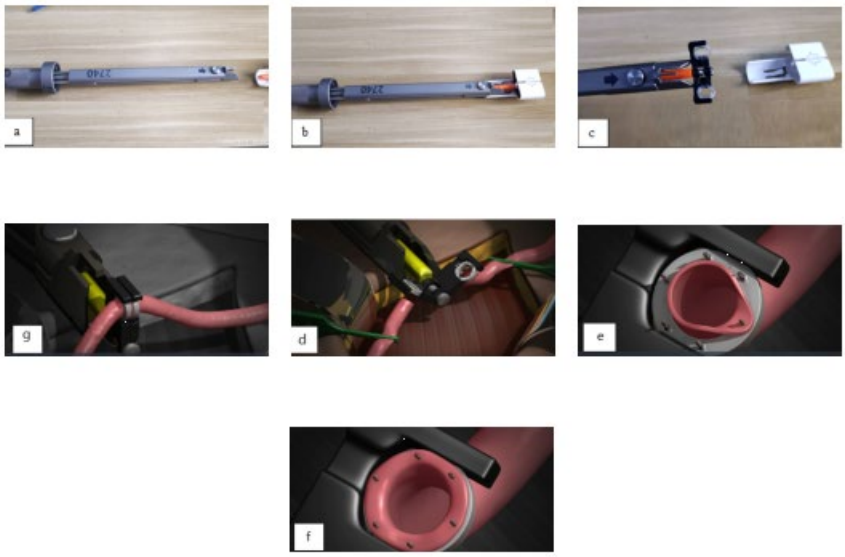


Figure 2 Overview of the use of Microvascular anastomotic coupler

1.3.2 Previous generations

Not applicable

1.3.3 Accessories

The product does not contain accessories, but requires and uses the rest of the tools.

1.3.4 Combination with other devices

The product does not contain accessories, but requires and uses the rest of the tools.

In clinical use, Microvascular anastomotic coupler needs to be used with the corresponding tools. Microvascular measuring gauge, anastomotic handle and microforceps play their respective functions as medical devices during the use of the product.

Table 1 Accessories not included but necessary for use

REF	Tools name	Function	Basic UDI-DI
QA003	microvascular measuring gauge	The microvascular measuring gauge is applied to measure the outer diameter of blood vessel.	6971503871A00320210279
KC-A001	anastomotic	The anastomotic handle	6971503871A00120180

	handle	is applied for anastomosis of the vessels' two ends.	77D
KC-A002	microforceps	The microforceps is applied to clamp blood vessels and surrounding tissues	6971503871A0022018067U

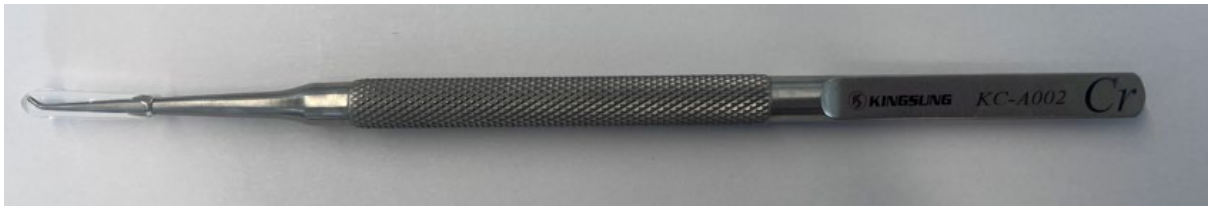
Microvascular anastomosis device kit is a necessary auxiliary tool for microvascular anastomotic coupler. The sterilizable tool box can be loaded with a anastomotic handle, two microforceps and a microvascular measuring gauge.

Anastomotic handle：

Intended use：Used to assist in the anastomotic procedure by mechanically bringing the Coupler rings together to join the vessels.

Anastomotic handle

Intended use：The microforceps is intended to be used to evert blood vessel tissue onto the stainless steel pins of the microvascular anastomotic coupler.



Microforceps

Microvascular measuring gauge：

Intended use：The microvascular measuring gauge is used to estimate the outer diameter of a blood vessel for the purposes of choosing the appropriate size Microvascular Anastomotic coupler for an anastomotic procedure.

Microvascular measuring gauge

1.4 Risks and warnings injuries

1.4.1 Residual risks and undesirable effects

1) Infection (superficial wound infection and deep surgical site infection). Infection can lead to wound breakdown, fistula formation, and secondary vascular spasm or thrombosis of the anastomosis, which may necessitate surgical debridement and systemic antibiotic therapy. On rare occasions, severe refractory infection may require removal of the microvascular anastomotic coupler and revision of the vascular anastomosis.

2) Thrombosis. If thrombus occurs during surgery, it is necessary to change the microvascular anastomotic coupler with appropriate specification for re-anastomosis, or change it to hand-sewn anastomosis; if thrombus occurs after surgery, urgent surgical exploration is required to save the free flap.

3) Vessel tear / rupture, including intimal tears, avulsion, or anastomotic disruption.

4) Anastomotic leak/perforation; occurring due to improper vessel eversion, inadequate pin engagement, or vessel wall trauma, which may require intraoperative correction or conversion to hand-sewn anastomosis.

5) Foreign body reaction: device palpability or subcutaneous induration may occur at superficial anatomical locations.

6) Vascular stenosis: routine periodic vascular imaging examination is vital to prevent serious flap-related complications.

7) Flap loss / partial necrosis (complete free flap failure or partial tissue necrosis of the transferred flap). This adverse event mainly results from persistent anastomotic thrombosis, vascular occlusion, arterial insufficiency, venous reflux disorder, surgical site infection, or hematoma compression; partial flap necrosis may necessitate minor debridement and revision, while complete flap loss usually requires secondary free tissue transfer for reconstruction.

8) Vascular crisis; or microvascular compromise manifesting as ischemia or congestion, requiring urgent surgical re-exploration to assess for thrombosis or compression.

9) Hematoma; formation at the surgical site which may cause external compression on the anastomosis or require surgical evacuation to prevent vascular compromise.

Rate below indicate expected occurrence rate

Adverse event	Rate from SOTA	Rate from Clinical data
Infection	0.17% for literature	Not happen
Thrombosis	6.4% for literature	Not happen
Vessel Tear / Rupture	0.16% for literature	Not happen
Anastomotic leak	0.21% for literature	Not happen
Foreign body reaction	0.02% for literature	Not happen
Graft stenosis	0.07% for literature	Not happen
Flap loss / partial necrosis	2.39% for literature	0.76%for clinical investigation
Vascular crisis	2.36% for literature	0.76%for investigation
Hematoma	0.21% for literature	Not happen

1.4.2 Warnings and precautions

-Warning

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.

• It is the physician's responsibility to inform the patient that the Microvascular Anastomotic Coupler ring is a permanent implant containing metal components.

• Carefully follow disinfection procedures during surgery.

• Failure to squeeze the bases with a hemostat or similar instrument prior to ejection of the joined rings may result in an inadequate friction fit and possible ring separation. Inspect the anastomotic site to ensure that the anastomosis has been satisfactorily completed.

• The Microvascular Anastomotic Coupler is supplied sterile and is for single use only. Do not resterilize or reuse the Microvascular Anastomotic Coupler. After use, the product should be disposed of in accordance with the regulations related to medical device waste.

• Do not use the Microvascular Anastomotic Coupler if the package has been opened or appears to be damaged or compromised.

• 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 children or adolescents has not been established. Not intended for fetal use.

• Security of an anastomosis utilizing a Microvascular Anastomotic Coupler that have been approximated, reopened, and then reapproximated has not been demonstrated. When re-approximation of the anastomosis is desired, the vessel should be removed from each ring and a new Microvascular Anastomotic Coupler utilized.

• 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.

-precautions

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.

◆ The Microvascular Anastomotic Coupler shall be stored in a cool, dry and light-free control room.

◆ Do not use the Microvascular Anastomotic Coupler if it is damaged.

◆ Do not use if the package is open, damaged or broken.

◆ Please use before the "Use by date".

◆ Please follow the instructions carefully.

◆ This Microvascular Anastomotic Coupler is advised for use with the Anastomotic Handle manufactured （KC-A001）. It is recommended that operators refrain from using it with any other anastomotic instruments due to the potential risk of device failure. In such cases, any resulting issues are not within our responsibility.

◆ Microvascular Anastomotic Coupler in combination with any implantable device may present potential risks, such as infection, perforation, or vascular rupture, erosion, implant rejection, or device loss/movement.

◆ When the ring is closed, carefully examine the anastomosis site.

◆ Check the device before use to make sure it is the right size and condition for the specific procedure.

◆ After opening the internal resistance package, place the device in a sterile area.

1.4.3 Other relevant aspects of safety

Sales Data:

The product of microvascular anastomotic coupler was approved by the NMPA in June 2023 and is only sold in China. As of June 25, 2025, the sales details are as follows:

Product name	Model	Number
Microvascular Anastomotic coupler	KC1000	56
	KC1500	378
	KC2000	1277
	KC2500	1646
	KC3000	1123
	KC3500	482

	KC4000	249

Adverse Event:

Since its launch in China, a total of two adverse events have been received. The primary issue described in both cases is that product was skewed, resulting in poor alignment of the product. There were no death, no serious adverse events during sale period in China. And there were no reports of death across the public vigilance databases searched of the Microvascular Anastomotic Coupler.

The Quality Department conducted a root cause analysis, and the cause was identified as improper operation during the process of opening the package or during use.

Action taken: 1)providing training to the company's sales team and surgeons to strictly follow the operation guidelines in the IFU, the pass rate of the assessment is 100%, please see the record of training for sales and doctors

2）add relevant content in risk management. In the PFMEA, measures such as 100% alignment inspection were taken in the installation process of No.100 (page 2 in PFMEA) and No. 270 (page 6 in PFMEA) to ensure that the coupler ring is not misaligned during the production process, and measures were taken to reduce the risk of the stapling needle's deflection during transportation in the transportation verification of No. 390 (page 8 in PFMEA); in UFEMA, No. 60 (page 2 in UFMEA), No. 280 (page 6 in UFMEA) and No. 320 (page 7 in UFMEA), all of which take measures to identify whether the product is deflected before and during use, so as to prevent the product with deflected product from being used for human body.

The implementation of the above measures effectively prevented the deflected product from being used, and no complaints on similar adverse events was received after the implementation of the measures, indicating that the measures were effective.

1.5 Summary of clinical evaluation and relevant information on post-market clinical follow-up (PMCF)

1.5.1 Summary of clinical data related to equivalent devices

There will be no claim of equivalence to other device.

The GEM Microvascular Anastomotic COUPLER Device, which has been marketed in the European Union and China, was selected as similar device, also as the control product in the clinical trial, so the clinical data of the similar product was detailed in the clinical investigation report.

1.5.2 Summary of clinical data from conducted investigations of the device before CE-marking

Clinical data from proprietary investigations before CE-marking are available in Part G section 6.6.7 Clinical investigation report. The summary of clinical investigation was listed in below table which was conducted in China.

Identity of the investigation	TJHRKC0.3-R (conducted in China)
Identity of the device	KC1000, KC1500, KC2000, KC2500, KC3000, KC3500, and KC4000
Intended use	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 0.8 mm and not larger than 4.3 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.
Objectives of the study	This clinical investigation was conducted to evaluate the effectiveness and safety of the microvascular anastomotic coupler (indicated with "Hua Rong Ke Chuang" below) manufactured by Hua Rong Ke Chuang Biotechnology (Tianjin) Co., Ltd. versus the GEM Microvascular Anastomotic COUPLER Device (indicated with the trade name "GEM Coupler" below, registration No.: GXZJ20163461834) manufactured by Synovis Micro Companies Alliance, Inc for vascular anastomosis and reconstruction after acute vascular injury or free flap reconstruction.
Study design	Randomized controlled trial,
Primary and secondary endpoint(s)	**Primary Endpoint** To evaluate that the immediate vascular patency rate of microvascular anastomotic coupler (Hua Rong Ke Chuang)

	was not inferior to that of GEM Microvascular Anastomotic Coupler Device (GEM Coupler) for vascular anastomosis and reconstruction after acute vascular injury or free flap reconstruction. **Secondary Endpoints** 1)To evaluate that there were no differences in secondary effectiveness endpoints, such as postoperative vascular patency rate, effective flap survival, distal tissue survival, distal tissue warm ischemia time, anastomosis time, and performance evaluation, between microvascular anastomotic coupler (Hua Rong Ke Chuang) and GEM Microvascular Anastomotic Coupler Device (GEM Coupler) for vascular anastomosis and reconstruction after acute vascular injury or free flap reconstruction. 2)To evaluate that there were no differences in safety endpoints, such as incidence of vascular crisis, arterial/venous thrombosis, intraoperative complications, AEs, SAEs and device deficiency, and laboratory test results, between microvascular anastomotic coupler (Hua Rong Ke Chuang) and GEM Microvascular Anastomotic Coupler Device (GEM Coupler) for vascular anastomosis and reconstruction after acute vascular injury or free flap reconstruction.
Inclusion/exclusion criteria for subject selection	**Inclusion criteria** 1)18 to 65 years old (both inclusive), male or female; 2)Patients who require vascular anastomosis after acute vascular injury or during free flap reconstruction*; 3)Patients with acute vascular injury who are expected to have distal tissue warm ischemia for no more than 6 h#; 4)The blood vessel to be anastomosed has an outside diameter of 0.8–4.3 mm and a wall thickness of 0.5 mm or less; 5)The subject or his/her legal representative could understand the objective of the investigation, shows sufficient compliance with the investigation plan, and sign the ICF. *Tissue flaps include simple flap, fasciocutaneous flap, and composite skin flap (myocutaneous flap, osteocutaneous flap, etc.). #Warm ischemia time is defined as the time interval from the onset of vascular injury symptoms to the completion of anastomosis of blood vessels in the distal tissues. **Exclusion criteria**

<table>
<tr><td></td><td>1)Pre-existing or suspected severe soft tissue contusion or other vascular diseases at the acute vascular injury site, donor site, or recipient site;
2)Severe soft tissue contusion or vascular bed destruction at the acute vascular injury site, donor site, or recipient site;
3)Severe contamination or pre-existing severe infection at the acute vascular injury site, donor site, or recipient site;
4)Ongoing irradiation at the acute vascular injury site, donor site, or recipient site;
5)High avulsion of the blood vessels at the acute vascular injury site or recipient site;
6)Simple epidermal and/or dermal vascular injury;
7)Concurrent diabetes mellitus;
8)Concurrent glucocorticoid therapy;
9)Platelet count (PLT) < 60 × 109/L or international normalized ratio (INR) > 1.5;
10)Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) > 3× upper limit of normal (ULN);
11)Serum creatinine (Cr) level > 2 mg/dL (177 umol/L);
12)A past medical history of unstable coronary heart disease or myocardial infarction within 1 year;
13)A past medical history of organ failure and serious illnesses related to the heart, lung, liver, and kidney;
14)Pregnant or breastfeeding females;
15)Patients who have participated in or are participating in other clinical studies of drugs or devices within 1 month before the investigation;
16)Patients who could not comply with follow-ups;
17)Other situations not suitable for enrollment in the opinion of the investigator.</td></tr>
<tr><td>Number of enrolled subjects</td><td>75 subjects from the investigational device group and 76 subjects from the control group</td></tr>
<tr><td>Study population</td><td><table>
<tr><td></td><td>Gender (male-to-female ratio)</td><td>Age</td></tr>
<tr><td>Investigational device group</td><td>60/15</td><td>42.29±13.57</td></tr>
<tr><td>Control group</td><td>59/17</td><td>41.64±13.79</td></tr>
</table></td></tr>
<tr><td>Summary of study methods</td><td>The clinical investigation adopted a prospective, multicenter, stratified randomized, single-blind, parallel positive-controlled, non-inferiority design.</td></tr>
<tr><td>Summary of results</td><td>From Jul. 17, 2018 to Mar. 31, 2021, A total of 151 subjects (75 in the investigational device group and 76 in the control group) were included in the full analysis set (FAS),149</td></tr>
</table>

	subjects (74 in the investigational device group and 75 in the control group) in the per-protocol set (PPS), and 151 subjects (75 in the investigational device group and 76 in the control group) in the safety set (SS). The primary effectiveness endpoint immediate vascular patency rate was analyzed in both FAS and PPS. In FAS, the immediate vascular patency rates in the investigational device group and the control group were both 100.00%. The difference (95% confidence interval (CI)) in immediate vascular patency rate between the two groups calculated by the Newcombe method was 0.00% (-4.87%, 4.81%). The lower limit of the 95% CI of the difference was -4.87%, which was greater than the non-inferiority margin of -10%, so the non-inferiority conclusion is valid. In PPS, the immediate vascular patency rates in the investigational device group and the control group were both 100.00%. The difference (95% CI) in immediate vascular patency rate between the two groups calculated by the Newcombe method was 0.00% (-4.93%, 4.87%). The lower limit of the 95% CI of the difference was -4.93%, which was greater than the non-inferiority margin of -10%, so the non-inferiority conclusion is valid. The PPS conclusion is consistent with the FAS conclusion. The primary effectiveness endpoint was stratified and analyzed with investigation sites, surgical methods (vascular anastomosis and reconstruction after acute vascular injury and free flap reconstruction), and types of anastomotic vessels (arteries and veins) as stratification factors. The immediate vascular patency rate by different investigation sites, surgical methods, and types of anastomotic vessels in the investigational device group and the control group was 100.00% in both FAS and PPS. The secondary effectiveness endpoints were analyzed in both FAS and PPS. In FAS, no statistically significant differences were observed in vascular patency rate on D14±3 after surgery (investigational device group: 95.59%, control group: 95.65%, P=1.000), vascular patency rate on D90±14 after surgery (investigational device group: 98.55%, control group: 98.48%, P=1.000), distal tissue warm ischemia time (investigational device group: 8.18±2.88 h, control group: 8.77±6.32 h, P=0.614), anastomosis time (investigational device group: 8.42±7.24 min, control group: 6.47±4.58 min, P=0.142), and

	performance evaluation (proportion falling into good (acceptable operation and hand feeling) and excellent (easy operation and good hand feeling) categories) (investigational device group: 100.00%, control group: 100.00%, P=0.719) between the investigational device group and the control group (P>0.05). Effective flap survival on D14±3 and D90±14 after surgery and distal tissue survival on D14±3 and D90±14 after surgery in the investigational device group and the control group were the same, at 100.00%. In PPS, no significant differences were observed in vascular patency rate on D14±3 after surgery (investigational device group: 95.52%, control group: 95.59%, P=1.000), vascular patency rate on D90±14 after surgery (investigational device group: 98.53%, control group: 98.46%, P=1.000), distal tissue warm ischemia time (investigational device group: 8.41±2.73 h, control group: 8.77±6.32 h, P=0.430), anastomosis time (investigational device group: 8.44±7.29 min, control group: 6.36±4.50 min, P=0.115), and performance evaluation (proportion falling into good (acceptable operation and hand feeling) and excellent (easy operation and good hand feeling) categories) (investigational device group: 100.00%, control group: 100.00%, P=0.719) between the investigational device group and the control group (P>0.05). Effective flap survival on D14±3 and D90±14 after surgery and distal tissue survival on D14±3 and D90±14 after surgery in the investigational device group and the control group were the same, at 100.00%. Safety endpoints were analyzed in SS. On D14±3 and D90±14 after surgery, no arterial/venous thrombosis occurred in the two groups (P=1.000); no statistically significant differences were observed in the incidence of AEs (investigational device group: 32.00%, control group: 38.16%, P=0.496) and SAEs (investigational device group: 5.33%, control group: 7.89%, P=0.745) between the investigational device group and the control group (P>0.05). No vascular crisis on D14±3 and D90±14 after surgery, intraoperative complication, or device deficiency occurred in the investigational device group and the control group. The proportions of laboratory tests (hematology, coagulation test, urinalysis, blood biochemistry, fasting

	blood glucose (FBG) or glycosylated hemoglobin, and pregnancy test) and ECG values that were normal before surgery but abnormal and clinically significant after surgery were similar between the investigational device group and the control group.
Any limitations of the study	The limitations of this study are currently unknown.
Any device deficiency and any device replacements related to safety and/or performance during the study	No device deficiency occurred in the investigational device group and the control group.

1.5.3 Summary of clinical data from other sources

1.5.3.1 Clinical data in the literature

There is no clinical literature on this product.

1.5.3.2 Clinical data obtained by clinical trials or PMCF-measures

GEM Microvascular Anastomotic COUPLER Device, which has been marketed in the European Union and China, was selected as the control product in the clinical trial, so the clinical data of this product was reflected in the clinical trial report.

GEM Microvascular Anastomotic COUPLER Device, which has been marketed in the European Union and China, was selected as the control product in the clinical trial, so the clinical data of this product was reflected in the clinical trial report.

75 patient data of our products were recorded in clinical trial reports.

1.5.3.3 Clinical data in medical device databases

The medical device is only marked in China, The medical device registries “Adverse Events Surveillance System” maintained by NMPA were searched for clinical data on the product during the preparation of the CER. The recent search was conducted on December 31, 2024 and the searched time period in the database encompassed October 01, 2023 to December 31, 2024.

No data related to this product was found.

1.5.4 An overall summary of the clinical performance and safety

[lifetime] the lifetime of device is considered as 90 days

This can be determined through the following information.： The clinical effect of this product can be simply described as connecting the blood vessels and achieving smooth blood flow. Due to the alignment of the inner membranes of the blood vessels after the anastomosis, the self-repair cycle of the blood vessels takes place within 3 months. After 3 months, the vascular function of the human body has recovered, and

the microvascular anastomosis device no longer performs its clinical function. However, due to the limitations of the fixation method, it cannot be removed. It needs to remain as an implant in the human body for a long time. Considering all these factors, defining the clinical lifetime period as 90 days is sufficient. Of course, the safety of its long-term presence in the body is also something we need to consider. We mainly take into account two aspects of factors:

(1) Whether the product can maintain a stable closed state for a long time, and the two rings will not separate after long-term implantation.

This factor is verified through the "In Vitro Fatigue test" to ensure that there is no risk of the anastomosis rings separating for at least ten years.

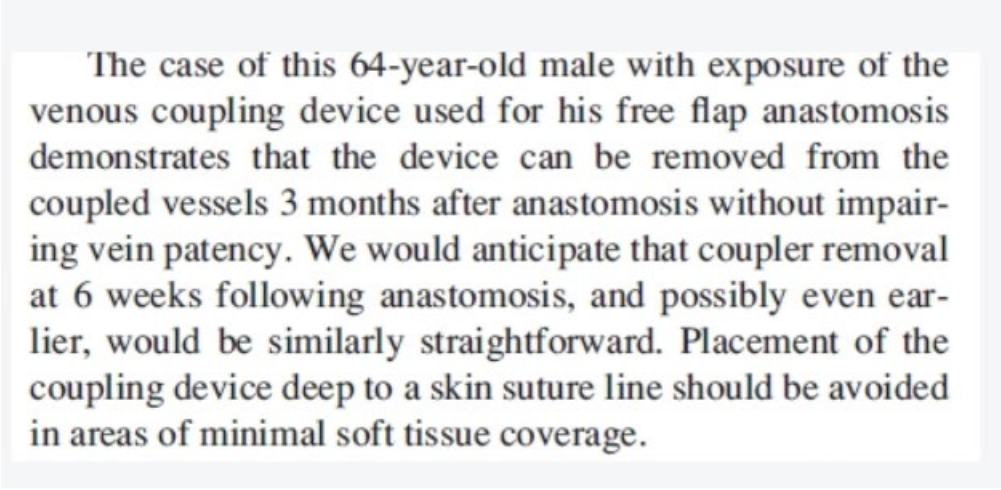
(2) The biocompatibility of the material of the implanted part.

We conducted biological tests such as implant experiments on the implant materials to confirm that the materials are medical materials that can be implanted for a long time.

Supported by clinical data

The follow-up period of the clinical experiment conducted in China is 90 days. This report has been confirmed and discussed with clinical experts, and the clinical doctors believe that a follow-up period of 90 days meets the requirements.

By reviewing the clinical literature of the already marketed GEM Microvascular Anastomotic COUPLER Device, it was found that most of the documents did not specify the follow-up period. However, some documents indicated that after performing the vascular anastomosis, the product was removed 3 months after the operation, and the venous vessels were unobstructed. It also stated that the vascular healing had been completed 6 weeks after the operation.



The case of this 64-year-old male with exposure of the venous coupling device used for his free flap anastomosis demonstrates that the device can be removed from the coupled vessels 3 months after anastomosis without impairing vein patency. We would anticipate that coupler removal at 6 weeks following anastomosis, and possibly even earlier, would be similarly straightforward. Placement of the coupling device deep to a skin suture line should be avoided in areas of minimal soft tissue coverage.

[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.

All parameters meet or exceed the acceptance criteria of existing best practices, which can provide reliable support for surgical effectiveness, safety, and operational convenience in clinical applications, ultimately helping to improve patients'

postoperative prognosis.
The clinical benefits are based on the results of prospective, multi-center clinical trials and clinical references, with the core benefits as follows:
Surgical Success Rate: The intraoperative immediate success rate (for both arteries and veins) reaches 100%, and the success rate at 90±14 days postoperatively is 98.55%. Both meet the acceptance criteria for success rate in clinical literature (>94%), enabling rapid restoration of blood flow to tissues/organs and reducing the risk of ischemic necrosis.
Tissue Survival: The effective flap survival rate and distal tissue survival rate at 14±3 days and 90±14 days postoperatively all reach 100%, which meets the acceptance criteria for flap failure rate in clinical literature (<4.36%). This ensures the complete preservation of the function of repaired tissues/organs.
Anastomotic Time: The average intraoperative anastomotic time is 8.42±7.24 minutes, which falls within the safe and effective range recommended in clinical literature (3-29.5 minutes). The operational process is compatible with routine clinical surgical scenarios, helping to improve surgical efficiency.
Thrombosis Risk: The incidence of postoperative arterial and venous thrombosis is 0%, which meets the acceptance criteria for arterial thrombosis (<3.6%) and venous thrombosis (<3%) in clinical literature. This reduces complications such as limb ischemia and organ dysfunction caused by thrombosis.
Safety Profile: There are no relevant serious complications, and the incidence of adverse events is controlled within the acceptance criteria for coupler-related complications in clinical literature (<5%). This reduces the burden of postoperative infections, secondary interventions, and other issues for patients.

The safety and efficacy of this product have been proven through premarket clinical trials in China.
By complying with all warnings and precautions, the product provides an acceptable benefit-risk profile and meets the requirements for an acceptable side effect and an acceptable benefit-risk profile.
The regular PMS data show very low complaint rates.
Clinically relevant marketing claims for the safety and performance of the product can be fully justified by the technical characteristics of the device, product testing, and PMS data.
In summary, the product can be demonstrated to comply with the General Safety and Performance requirements (GSPRs) stipulated in the Medical Device Regulation (MDR) EU 2017/745, and the safety and performance of the product can be confirmed

1.5.5 Ongoing or planned post-market clinical follow-up

PMCF is a continuous process that reviews and updates the clinical evaluation during the post-market phase. According to PMCF confirming the safety and performance, including the clinical benefit of the device throughout its expected lifetime.
It is necessary to have a PMCF plan and report for Microvascular anastomotic coupler,

among the PMCF activities, general activities include the scientific literature data on the subject device and similar device, post-market data collection, specific activities that listed in below:

The key points that the product focuses on in the PMCF include:

1) The safety and efficacy of KC1000 after its launch - based on the clinical investigation sample, there were only 12 cases. Therefore, for the KC1000 model, all the sales data for the first year in the European Union will be tracked.

2) Through the specific clinical follow-up after the listing, further verification will be conducted to confirm the consistency of the results with those obtained in the pre-market investigation in the EU population.

3) To ensure the safety of the product as a long-term implant, our tracking period exceeds the Clinical lifetime. We will foc us on adverse events occurring between 90 days and 1 year after implantation.

We will updated the PMCF report at least once a year throughout the life cycle of device, to ensures compliance with general safety and performance requirements after CE marking, generates necessary real-world evidence, and continuously maintains the acceptability of the product's benefit-risk ratio.

1.6 Possible diagnostic or therapeutic alternatives

1.6.1 Hand-sewn

Hand-sewn anastomoses are routinely performed in modern microsurgical practice and considered as gold standard for more than 40 years. Anastomosis completed by hand-sewn technique use 8–0 or 9–0 nylon. this technique is time-consuming and may cause other problems, resulting in complications and even flap loss. The success rate of the HS anastomoses is reported 95% [1]. It has been reported that hand suturing anastomosis is between 10 and 55 min. This is in contrast with the coupling device anastomosis time, which ranges between 2 and 36 min[6]. In the literature the incidence of thrombosis in hand-sewn venous anastomosis is as high as 10%, especially in lower limb trauma reconstruction, and less than 3% in breast reconstruction. Hand suturing anastomosis is not only time-consuming and technically challenging but also potentially introduces many problems for the anastomosis: exposing suture material into the lumen of the vessel or poor vessel edge eversion, inadequate eversion of the edges, lumen narrowing due to intimal flaps, vessel distortion due to size mismatches or uneven sutures. The hand-sewn anastomoses have an accepted failure rate of 2–5% .

1.6.2 Adhesive

The use of adhesives in surgery has gathered more interest in recent times. Currently available surgical adhesives can be broken into two groups—cyanoacrylates and the so-called ‘‘fibrin glues.’’ Cyanoacrylates have long been used by emergency departments and general practitioners to close minor wounds, particularly in pediatric populations. Various other uses have been reported in the literature including roles in

microvascular reconstructive surgery. Thrombin-based fibrin glues such as Tisseel and Tissucol continue to generate interest in terms of novel surgical applications. In theory, these substances could be used for sutureless anastomoses and also for stabilizing anastomoses and plugging minor leaks after conventional anastomoses. Certainly the use of these products in anastomosing other structures such as vas deferens, nerves, and hollow viscus is well reported in the literature.

However, concerns regarding the inherent thrombogenicity of these products and the potential for triggering intraluminial thrombosis exist.Although promising animal studies have been published, few clinical series exist. At least one large series of free tissue transfers in breast reconstruction (n=5 349) reports use of thrombin-based glues with no apparent increase in anastomotic failure. A cohort study in 2009 compared sutured anastomoses with or without fibrin glue. It was found that the fibrin glue group had faster anastomotic times and used reduced number of sutures. Outcomes were similar although the two groups were small. In addition, a series of 36 digital replants using reduced sutures and fibrin sealant was reported by Isogai et al. This series used a reduced number of sutures and fibrin sealant was applied to the anastomoses. An overall failure rate of 11% was reported, consistent with other studies. A small series reporting the use of fibrin glues to stabilize pedicles and prevent kinking showed no increased rate of thrombotic anastomotic complications.

Various potential uses of cyanoacrylate adhesives have been reported in animal studies ranging from completely sutureless anastomoses with glue only or glue with absorbable biostents to reduced suture anastomoses with adhesive and hemostasis. Although these studies have gone some way to demonstrate safety and increased speed and reliability of anastomoses, some studies have shown significant histological foreign body reactions in vessels walls. One report in the literature advocates use of a coating of cyanoacrylate to give collapsed veins added rigidity thereby reducing the risks of suturing the back wall and at least one report of using cyanoacrylates as haemostatic agent in anastomoses in humans exists. Although some of these reports are letters referring to human surgical practices, there are no published series supporting the benefits or safety of cyanoacrylates in microvascular reconstructive surgery.

1.6.3 Laser and photochemical-assisted anastomoses

Interest began to develop in the use of lasers in microsurgical anastomoses in the early 1980s. Since then many studies investigating various lasers (e.g., carbon dioxide, argon, thulium–holmium–chromium) for thermal bonding of microvascular anastomoses have been reported, although descriptions of use in clinical practice remain limited. Most recently, interests in Excimer1 laser-assisted nonocclusive anastomoses in neurosurgery and the use of the KTP-532 laser for microsurgical anastomoses96 have emerged. Laser-assisted thermal bonding for neural reconstruction and the use of photochemical bonding using visible spectrum light and photoactive dyes have been described.

A solitary clinical paper by Lecle`re et al. reports perhaps the first use of laser microanastomoses in clinicaluse in reconstructive surgery. In this series, 27 patients

underwent 58 anastomosis with the use of a 1.9 micron diode laser to perform welded reduced suture anastomoses. Generally, four sutures were still applied to achieve apposed edges. This study included arteries and veins and both end-to-end and end-to-side anstomoses. A single case of anastomosis failure was reported (1.7%) in which an arterial anastomosis ‘‘ruptured,’’ possibly due to the anastomosis being in irradiated tissue. Anastomotic time was not measured but was considered anecdotally to be reduced. There was no control arm in this study.

1.7 Suggested profile and training for users

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

1.8 Reference to any harmonized standards and CS applied

The harmonized standards applicable to microvascular anastomotic coupler products can be available in Part A HRKC-ZC-A-005-CE Regulatory Assessment. And there is no common specifications applied to the device.

By adhering to the reference harmonized standards and general technical specifications, this medical device has achieved effective guarantees in terms of technical performance, safety performance and quality control, providing users with reliable and safe medical device products.

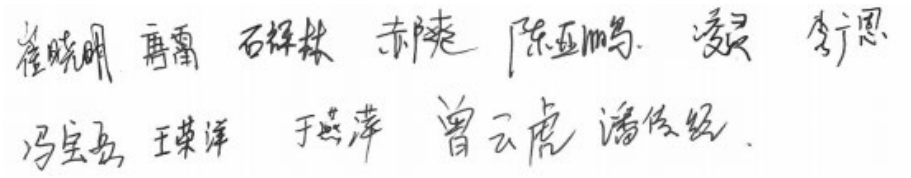
1.9 Revision history

Revision	Date	Summary of revision	Revision validated by the Notified Body
B.0	2025-04-03	New version release	☐Yes Validation language: ☐No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
B.1	2025-06-28	The document version has been upgraded due to adjustments to information such as the intended use of some referenced documents.	☐Yes Validation language: ☐ No
B.2	2025-11-21	Revised in accordance with the first-round review opinions of BSI	☐Yes Validation language: ☐ No
B.3	2026-08-10	Revised section 1.4.1.	

Appendix Record of training for sales and doctor

Hua Rong Ke Chuang Biotechnology (Tian Jin) Co., Ltd

	Training Record Form	Record Number	HRKC-JL-6.2-04
		Version No.	B.2

Training Topic	Key points of microvascular anastomosis coupler operation				
Date	2025.02.26	Training Location	Meeting room		
Number of Trained	**12**	Training Format	Training offline	trainning hour	1 h
Trainee					

Content of Training Abstract:

Operating contents of training instructions and simulation of practical operation

Lecturer:Jia **Zheng**  Date: 2025.02.26

Evaluation method	(See the attached page for the evaluation results)
Training Effectiveness	(For the trainee to be clear and have the training knowledge or operate as required): The trainees are clear about and have mastered the training content. Signature of examiner:**Jia** **Zheng**  Date: 2025.02.26
Remark	How to check the product status before implantation

Notes: 1. For the above inapplicable items during external training, please fill in with single horizontal bar; 2. The relevant supporting data for assessment can be attached;

Hua Rong Ke Chuang Biotechnology (Tian Jin) Co., Ltd

	Training Record Form	Record Number	HRKC-JL-6.2-04
		Version No.	B.2

Overview of Assessment Results Attached:

Assessment Record				
Name	Job Position	Assessment form	Assessment Result	Operational qualification
Cui Xiaoming	Sales	□practice □oral ☑exam	□pass □fail	□qualified □not qualified
Tang Xiao	Distributor	□practice □oral □exam	□pass □fail	□qualified □not qualified
Shi Xiang lin	Distributor	□practice □oral □exam	□pass □fail	□qualified □not qualified
Hao Shuang	director	□practice □oral □exam	□pass □fail	□qualified □not qualified
Chen Yapeng	Sales	□practice □oral □exam	□pass □fail	□qualified □not qualified
Ling ling	Distributor	□practice □oral □exam	□pass □fail	□qualified □not qualified
Li Guangen	director	□practice □oral □exam	□pass □fail	□qualified □not qualified
Feng Baoyue	Distributor	□practice □oral □exam	□pass □fail	□qualified □not qualified
Wang Rongyang	director	□practice □oral □exam	□pass □fail	□qualified □not qualified
Yu Yanping	director	□practice □oral □exam	□pass □fail	□qualified □not qualified
Zeng Yunhu	director	□practice □oral □exam	□pass □fail	□qualified □not qualified
Pan Chuanjing	director	□practice □oral □exam	□pass □fail	□qualified □not qualified
		□practice □oral □exam	□pass □fail	□qualified □not qualified
		□practice □oral □exam	□pass □fail	□qualified □not qualified
		□practice □oral □exam	□pass □fail	□qualified □not qualified
		□practice □oral □exam	□pass □fail	□qualified □not qualified
		□practice □oral □exam	□pass □fail	□qualified □not qualified
		□practice □oral □exam	□pass □fail	□qualified □not qualified
		□practice □oral □exam	□pass □fail	□qualified □not qualified

Assessor/Date: 2025.02.26

Summary of Safety and Clinical Performance for patient

Patient-version

Product	Microvascular Anastomotic Coupler
Product Models	KC1000 KC1500 KC2000 KC2500 KC3000 KC3500 KC4000
Manufacturer	Hua Rong Ke Chuang Biotechnology (Tian Jin) CO.,Ltd

Process	Person	Department	Signature	Date
Composing	Zhu Lei	RA	Zhu Lei	2026-08-09
Review	Deng Heying	RA	Deng Heying	2026-08-09
	Pan Binhui	R&D	Pan Binhui	2026-08-09
Approval	Zhang zhongying	R&D	zhang zhong ying	2026-08-09

Revision records:

Revision	Date	Summary of revision
B.0	2025-07-28	New version release
B.1	2025-11-28	Make revisions according to the review opinion of BSI
B.3	2026-08-09	Revise some descriptions

The SSCP is not intended to give general advice on the treatment of a medical condition. If you have questions about your medical condition or how to use the device,please contact your healthcare professional. This SSCP is not intended to replace an Implant card or the Instructions For Use to provide information on the safe use of the device.

SSCP 并非旨在就某种医疗状况的治疗提供一般性建议。如果您对自身病情或该设备在您所处情况下的使用有疑问，请联系您的医疗专业人员。此 SSCP 并非旨在取代植入卡或使用说明来提供有关该设备安全使用的信息。

1. Device identification and general information (产品的基本信息)

Device name 器械名称	Microvascular anastomotic coupler（微血管吻合装置）
Model 型号	KC1000, KC1500, KC2000, KC2500, KC3000, KC3500, KC4000
Manufacturer's name and address 制造商名称及地址	Hua Rong Ke Chuang Biotechnology (Tian Jin) Co., Ltd. （华融科创生物科技（天津）有限公司） 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 Single Registration Number (SRN): CN-MF-000037375
Basic UDI-DI	6971503873A201510UT
Class of device 设备分类	The product is classified as a Class IIb per Rule 8 of Annex VIII of the MDR (EU) 2017/745 of the European Parliament and the Council. （根据 MDR (EU) 2017/745 附件 VIII 规则 8，该产品被归类为 IIb 类。）
Authorized Representative 欧代信息	NOVAMEDICAL GmbH Address: Haslacher Weg, 12b 51063 Köln, Germany Single Registration Number (SRN): DE-AR-000036566

2. Intended Use of the device

Intended purpose:

After using this product, the damaged blood vessels (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) or tissues can achieve the effect of normal blood circulation.

用途：使用该产品后，破损的血管(血管直径再 1.0-4.0mm，血管壁厚不超过 0.5mm 的动脉和静脉)或者组织达到实现血液正常流通的效果

Indications and Intended patient groups:

The Microvascular anastomotic coupler is suitable for vascular anastomosis (the specific situation will be confirmed by the healthcare professional.)

微血管吻合装置适用于血管吻合（具体情况需由医疗专业人员确认）。

Contraindications:禁忌证

The Microvascular anastomotic coupler should not be used in patients with conditions that prevent microvascular repair with suture technique. A healthcare professional will confirm the specific situation based on the instructions for use (IFU) and their technical knowledge.The healthcare professional will confirm the specific situation according to IFU and technical knowledge.

微血管吻合装置不适用于那些因自身病情通常无法采用缝合技术进行微血管修复的患者。具体情况需由医疗专业人员根据产品使用说明和专业知识进行确认。

3. Device description 产品描述

Device description and material/substances in contact with patient tissues

The Microvascular Anastomotic Coupler (MAC) made by Hua Rong Ke Chuang Biotechnology (Tian Jin) Co.,Ltd consists of a protector, a pair of rings, one base, and one strutting piece.The manufacturer provides the Microvascular Anastomotic Coupler sterile for single-use.

由华融科创生物科技（天津）有限公司生产的微血管吻合装置（MAC）由保护套、吻合环、一个基座和一个支撑件组成。该微血管吻合装置为一次性无菌包装。

The components of the implanted part-rings: 316 stainless steel and TPU

植入部分的成分吻合环：316 不锈钢和 TPU

Description of how the device is achieving its intended mode of action 该设备如何实现其预期作用方式的描述

The device is used for anastomosis of microvessels. By closing the two rings to establish a tight friction fit, the device can connect the two damaged vessel ends attached on the stainless-steel pins.

该设备专为血管吻合而设计。通过将两个环闭合以形成紧密的连接，该设备能够将附着在不锈钢针上的两个受损血管端连接起来。

4. Risks and warnings 风险和警告

If you think the device is causing side effects or if you have concerns about risks, talk to your healthcare professional.This document does not replace a consultation with your healthcare professional if needed.

如果您认为自己出现了与该设备或其使用相关的副作用，或者对其中的风险有所担忧，请联系您的医疗保健专业人员。本文件并非在必要时取代与您的医疗保健专业人员的咨询。

How potential risks have been controlled or managed 潜在风险是如何被控制的

We ensure our medical devices are safe and effective through strong quality controls and ongoing monitoring after a product is launched. The results for this product are positive. There have been no deaths or serious adverse events reported in China since its launch. Searches of global safety databases also confirm no reports of death are linked to this device.

我们公司建立了良好的质量管理控制和风险控制流程，生产的产品安全有效。产品上市后会进行持续的上市后监督和跟踪，持续验证已上市器械的安全性和性能。在中国销售期间没有出现死亡病例，也没有发生严重的不良事件。而且在搜索了本产品相关的公共监测数据库后，也未发现有死亡病例的报告。

Remaining risks and undesirable effects 剩余风险和不良反应

If you notice any of the following concerns, please contact your healthcare professional:

You think you are having side effects from the device.

The implanted area becomes red, swollen, or causes you concern.

You have any other worries about the risks of the device or its use.

如果您认为自己出现了与该设备或其使用相关的副作用，或者对其中的风险有所担忧，如植入部位红肿、发热等，请联系您的医疗保健专业人员。

Warnings and precautions 警告和注意事项

Please talk to your healthcare professional if you have any questions or concerns.

如果你有任何需要了解或者担心的问题，请直接联系你的医疗保健人员

5. Summary of clinical evaluation and post-market clinical follow-up

临床评估总结及上市后临床跟踪

Clinical background of the device and the clinical evidence for the CE-marking

产品的临床背景和 CE 注册的临床证据

This product has been a trusted tool in microsurgery since the 1960s. It uses a mechanical method to connect blood vessels, helping them stay open so blood can flow normally. Many medical studies show it works well in surgery.

该类型产品从 20 世纪 60 年代问世并应用于显微外科，借助机械原理使血管实现良好的吻合，达到血管正常流通的效果，许多医学研究都表明，该产品在手术中效果显著。

A clinical trial was conducted on 75 patients. The immediate post-operative patency rate was 100%, the blood circulation patency rate at 14 days post-operation was 95.6%, and the vascular patency rate at 90 days post-operation was 98.55%.

有效性：开展 75 例患者的临床试验，术后即可通畅率为 100%，术后 14 天的血环通畅率额为 95.6%，术后 90 天的血管通畅率为 98.55%

6. Possible diagnostic or therapeutic alternatives

可能的诊断或治疗替代方案

Talk to your healthcare professional to find the right treatment for you.

在考虑替代疗法时，建议联系您的医疗保健专业人员，

7. Suggested training for users 建议用户的培训

Only trained healthcare professionals with the necessary skills and experience may use this device. Patients should not be trained on or use this device.

For more information, please speak with your doctor or nurse, or visit our website: (https://kingsungmedical.com/en).

Questionnaire 问卷

Name 姓名		Gender 性别	Male(男) ☐ Female（女）☐	Date 日期	
by SSCP, whether can identify the equipment basic information? 通过 SSCP，是否可以识别器械的基本信息？				Yes (是) No (否)	
By SSCP, whether can understand what is the validity of the instrument? **通过 SSCP,是否就可以了解器械的有效性是什么？**				Yes (是) No (否)	
By SSCP, whether can understand known risks and security information? **通过 SSCP,是否就可以了解已知风险与安全信息？**				Yes (是) No (否)	
If an exception occurs, you understand what actions need to take? **如发生异常，您了解需要采取什么行动吗？**				Yes (是) No (否)	
Can you read the above information? **上述信息您是否可以读懂？**				Yes (是) No (否)	