Instructions for Use of Microvascular Anastomotic Coupler

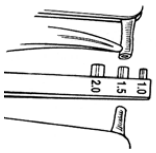


Figure 1


Figure 2


Figure 3

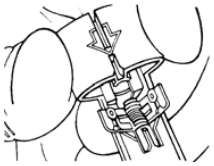


Figure 4

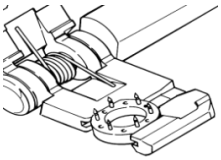


Figure 5a

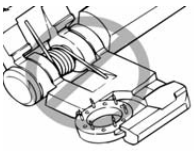


Figure 5b

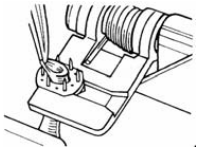


Figure 6


Figure 7

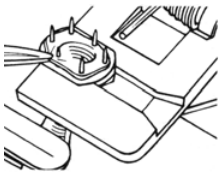


Figure 8

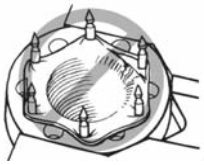
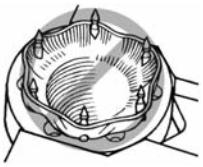



Figure 9

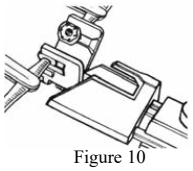


Figure 10

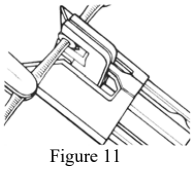


Figure 11

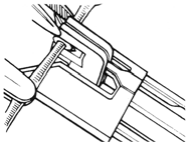


Figure 12


Figure 13

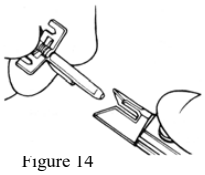


Figure 14

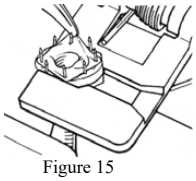


Figure 15

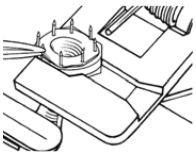


Figure 16

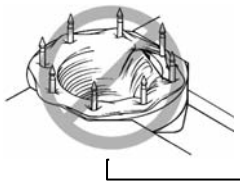
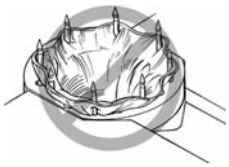



Figure 17

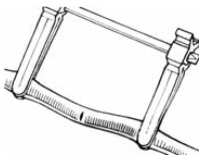


Figure 18

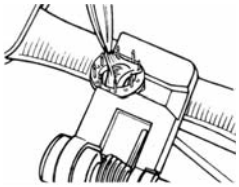


Figure 19

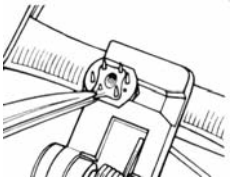


Figure 20a

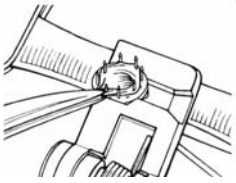


Figure 20b

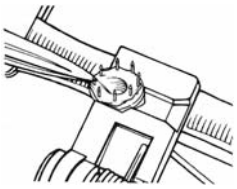


Figure 21a

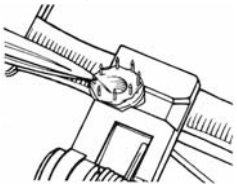


Figure 21b

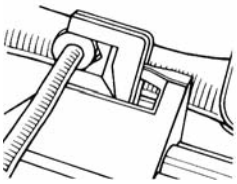


Figure 22

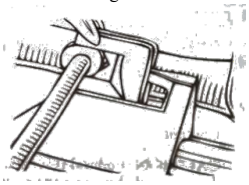


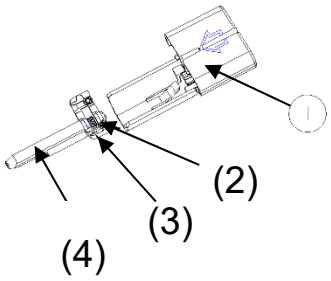
Figure 23

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
1	Protector	ABS（Acrylonitrile Butadiene Styrene）
2	Rings	Thermoplastic polyurethane (TPU)
3	Bases	Polyaramide
4	Strutting piece	Polycarbonate

[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	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	1.0 mm	1.0 ± 0.20	Gray	6
KC1500	1.5 mm	1.5 ± 0.20	Blue	6
KC2000	2.0 mm	2.0 ± 0.20	Green	6
KC2500	2.5 mm	2.5 ± 0.20	Red	6
KC3000	3.0 mm	3.0 ± 0.20	Yellow	6
KC3500	3.5 mm	3.5 ± 0.24	Violet	8
KC4000	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:

KC—XXXX

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. The bases should be closed smoothly without jamming.

2. The spring of the product should be sufficiently elastic to enable the bases to restore quickly.

3. Corrosion resistance of the pins: The corrosion resistance shall meet the requirements of Level a in 5.4 of ISO 13402:1995 (identical to YY/T 0149 in China).

4. Surface roughness of the pins: The surface roughness Ra of pins on the rings shall be not more than 0.8 μm.

5. Separating force of the rings: After anastomosis with the product, the separating force should not be less than 3.5 N.

6. Hardness of the pins: The hardness of the pins should not be less than 250 HV0.2.

7. Package seal strength: The seal strength of the inner and outer trays is not less than 1.5 N/15 mm. After peeling off, the two contact surfaces should be smooth, continuous, and uniform, without delamination or tearing.

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

[Indications for use]

The Microvascular Anastomotic Coupler is intended to be used in the anastomosis of veins and 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.

[Contraindications]

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.

◆ 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.

[Warnings]

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 reapproximation 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.

[Potential Risks]

• Use of the Microvascular Anastomotic Coupler involves potential risks normally associated with any implanted device, e.g., infection, perforation, or laceration of vessels, erosion, implant rejection, or device dislodgement/migration.

[MRI Compatibility]

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.

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). The Microvascular Anastomotic Coupler has been evaluated with a 3 Tesla magnetic field and no change in displacement was observed in each

of the three orthogonal planes. The pins in the Microvascular Anastomotic Coupler are nominally nonferromagnetic. However, the US Food and Drug Administration (FDA) has made recommendations for any medical device implanted which have metallic components to include:

• Documentation of the identity of the implant (manufacturer, model, batch and serial numbers) in the official medical record.

• Documentation of the technique and results of any magnetic testing performed on the implant or that no such testing was done.

• Patient education regarding the particular implant and recommendation for identifying medical alert card, bracelet, or necklace characterizing the implanted device.

[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 technique, mobilize a minimum of 1 cm of each vessel end. Using vascular clamps, clamp off the vessel(s) and irrigate the vessel openings. The Microvascular Anastomotic Coupler requires a greater amount of free vessel within the clamps than a conventional suture repair.

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. 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.

2. Select the Microvascular Anastomotic Coupler of an appropriate size. 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. 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. 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. Take a bite of one to two pin diameters of the vessel wall and intimal lining, evert 90 degrees, and impale onto the pin situated nearest to the open part of the base (open end of the U 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 technique, mobilize a minimum of 1 cm of the "end" vessel. Clamp the vessel and irrigate the vessel lumen. Mobilize a minimum of 2 cm of the "side" vessel and clamp 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. Select the Microvascular Anastomotic Coupler of an appropriate size.

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. Create a transverse incision in the "side" vessel of a length no greater than the inside diameter of the Microvascular Anastomotic Coupler selected. Slide the clamps together slightly to remove tension and to open the incision (See Figure 18). Irrigate the vessel lumen through the created opening.
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]

Anastomotic handle:

Before loading: Check the condition and operation of the anastomotic handle to ensure that the handle and release button can move flexibly. The use of anastomotic instruments that have not been properly cleaned or lubricated could cause device failure.

Cleaning of tools:

• Using a neutral (pH 7–10) detergent, wash each tool clean of all blood and debris after every use.
• Scrub each tool with a soft brush. Pay particular attention to areas where debris can accumulate.
• Avoid the use of any harsh material that can scratch or mar the surface of the instruments.

• Rinse the instruments thoroughly with running water. Apply a fine jet stream through the hole at the end of the handle and press the release button while rinsing to ensure that all surfaces of the instrument are cleaned.

• Dry the instruments after washing. Ensure that all visible debris is removed to assure the continued quality of the instruments.

• Lubricate the cleaned anastomotic tools with a water-soluble lubricant prior to sterilization. Failure to clean and lubricate the anastomotic tools as directed may result in device failure.

[Sterilization]

The anastomotic handle, microvascular measuring gauge, microforceps, and sterilization tray are supplied non-sterile and must be sterilized before use.

The gravity high-pressure sterilizer and pre-vacuum high-pressure sterilizer are used for sterilization. The sterilization parameters are shown in the table below. Following sterilization, an electric hot air drying oven is used for drying.

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>

Note: Sterilization must be carried out following relevant in-house specifications.

[Storage]

Recommended storage at a controlled room 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, the product should be centrally disposed of.

[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] Elisabeth-Selbert-Str. 5, D-40764 Langenfeld Germany

Do not use if package is damaged

Do not reuse

Consult instructions for use

Use-by date

Date of manufacture

STERILE

Sterile

STERILE R

Sterilized using irradiation

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