

Instructions for Use of Disposable Vascular Fixation Clamp

[Product Name]

Disposable Vascular Fixation Clamp

[Intended Use]

Disposable vascular fixation clamps are used in microsurgical procedures to occlude blood vessels during anastomosis. The visible background spacer is used to isolate blood vessels, lymphatic vessels, nerves, or tendons from the surrounding tissues during the procedure, and is removed immediately after procedure. The product is supplied sterile and for single use.

[Indications]

Disposable vascular fixation clamps are instruments which are used for all microsurgical procedures. They are used to occlude vessels during anastomosis, which is necessary as a result of vessel damage or thrombosis.

[Contraindications]

No obvious contraindications.

[Target Population]

Patients who require temporary occlusion of blood vessels during surgical procedures.

[Intended Users]

Qualified and well-trained surgeons.

[Models/Types and Description of Classification]

1. Product models/types are shown in the following table

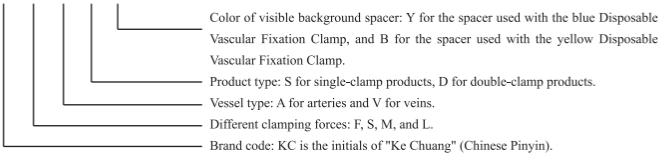
Table 1. Models/types of the disposable vascular fixation clamp

Model	Type			
Single clamp for artery	KCSASB	KCMASB	KCLASB	—
Double clamp for artery	KCSADB	KCMADB	KCLADB	—
Single clamp for vein	KCSVSY	KCMVSY	KCLVSY	KCFVSY
Double clamp for vein	KCSVDY	KCMVDY	KCLVDY	KCFVDY

2. Type/Model and Description of Classification

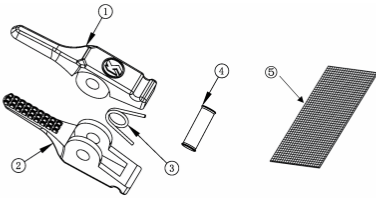
- 1) Classified according to the strength of clamping force: F for tiny, S for small, M for moderate, and L for large.
- 2) Classified according to vessel type (artery or vein) to be used on: V for clamps for veins and A for clamps for arteries.
- 3) Classified according to product model: S for single clamps, and D for double clamps.
- 4) Classified according to the color of the matching visible background spacer: Y for the spacer used with the blue Disposable Vascular Fixation Clamp, and B for the spacer used with the yellow Disposable Vascular Fixation Clamp.

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[Main Components]

1. The disposable vascular fixation clamp consists of an upper clip, a lower clip, a spring, a stainless casing (or dowel pin), and a visible background spacer.



1) Upper clip; 2) Lower clip; 3) Spring; 4) Stainless casing (or dowel pin); 5) Visible background spacer

Component/part	Material
Upper clip	Polycarbonate (PC)
Lower clip	
Spring	SUS304
Stainless casing	SUS304
Visible background spacer	Medical silicone material

[Performance Indicators]

1. Appearance

- 1.1 The upper and lower clips of the Disposable Vascular Fixation Clamp should be straight and have uniform thickness, and there is no obvious gap or misalignment at the closure of the two clips.
- 1.2 The tips should be smooth, the internal and external surfaces should be polished, and there should be no burrs, sharp edges, cracks, scars, or other defects.
- 1.3 The raised zigzag pattern should be clear and complete, without missing or broken teeth.
- 1.4 The colors of the Clamps: Blue and yellow, where yellow is for arteries and blue is for veins.
- 1.5 The front side of the visible background spacer should be non-reflective and the back side should be flat.
- 1.6 Visually, the Disposable Vascular Fixation Clamp should be free of damage, sink marks, flashes, burrs, and other defects.
- 1.7 The visible background spacer has a raised 1 mm grid pattern on the front, and the pattern should be clear and complete.
- 1.8 The visible background spacer is available in the following colors: Blue and yellow.

2. Operational Performance

- 2.1 Elasticity and firmness: The Clamp should be free from deformation and breakage.
- 2.2 Tip misalignment: The offset between the tips of the upper and lower clips should not exceed 0.5 mm.
- 2.3 Different types of disposable vascular fixation clamps have different clamping forces. See Table 2 for specific clamping forces.
- 2.4 Sterility: The product is supplied sterile and for single use.

[Methods of Operation]

1. Surgeons can distinguish between the types of disposable vascular fixation clamps (clamp for

arteries or veins) by the color of the clamp, which also helps prevent the clamp from being retained in the wound. A yellow clamp paired with a blue spacer indicates an arterial type, while a blue clamp paired with a yellow spacer indicates a venous type.

2. Prior to using any type of disposable vascular fixation clamps, surgeons need to identify the type of vessels (arteries or veins) and the diameter of the vessel (in mm) to ensure that the appropriate vascular clamp is selected, as shown in Table 2.

Table 2. Clamping force of the Clamp and applicable vessel type

Type	Model	Clamping force (g)	Applicable vessel diameter (mm)
Clamp for arteries	KCSASB	40±10	< 1
	KCSADB		
	KCMASB	60±10	1–2
	KCMADB		
	KCLASB	120±20	2–4
	KCLADB		
Clamp for veins	KCSVSY	30±5	1–2
	KCSVDY		
	KCMVSY	30±5	1–2
	KCMVDY		
	KCLVSY	40±10	2–4
	KCLVDY		
	KCFVSY	15±5	0.2–1
	KCFVDY		

3. The visible background spacer is used to isolate vessels, lymphatic vessels, nerves, and tendons from surrounding tissues and can be cut to the desired size. The 1 mm grid lines provide surgeons with precise measuring tools and are available in blue or yellow for optimal contrast. Non-reflective material eliminates glare from OR lighting.
4. Only well-packaged products can be used to ensure product sterility.
5. Check the shelf life on the package and ensure that the product is within this shelf life.
6. Disposable vascular fixation clamps are sterilized by radiation. Neither vascular clamps nor visible background spacers can be re-sterilized. The manufacturer does not assume any liability arising from the user's re-sterilization of the vascular clamps.
7. Check that all disposable vascular fixation clamps and accessory spacers have been removed prior to closure of the surgical site. Removal of the product should be kept as gentle as possible to avoid adhesion of the vascular clamps or visible background spacers to tissues such as vessels, nerves, and tendons, and to avoid tissue damage caused by the dowel pin.
8. After any surgical procedure, it should be noted that empty sterile bags should be counted to account for the exact number of disposable vascular fixation clamps and accessory spacers used.

[Supporting Instruments]

None.

[Precautions]

1. Never use disposable vascular fixation clamps that have been damaged or whose packaging has been torn.
2. The Disposable Vascular Fixation Clamp is for single use only and must not be reused.
3. After completing the procedure, do not leave any disposable vascular fixation clamps in the wound.
4. It is not recommended for use in the central circulation and central nervous system.
5. The Disposable Vascular Fixation Clamp is supplied sterile and must not be resterilized.
6. This product should be used by qualified and well-trained medical professionals who are familiar with the technical requirements for using this product.
7. This product should be used in a sterile environment.
8. After use, this product should be disposed of in accordance with local laws and regulations.
9. After the product package is opened, the label should be kept together with the patient's medical records.
10. Select the product model/type in strict accordance with blood vessel type and diameter to avoid clamping dysfunction or failure caused by use of incorrect model/type.
11. The product should be inspected for integrity prior to use. If visible creases or defects are present, the product must not be used.

[Transport Conditions]

Avoid rain and rough handling during transport.

[Storage Conditions]

The product should be stored at room temperature in a well-ventilated place with relative humidity not above 80%, and protected against corrosive gases.

[Type/Model] See the product label.

[Date of Manufacture] See the product label.

[Batch Number] See the product label.

[Shelf Life] The product is valid for 5 years from the date of manufacture.

[Sterilization Method] Radiation sterilization.

[Disposal] After use, the disposable vascular fixation clamp will be collected by the Equipment Department and placed in the designated area for centralized disposal.

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

[Manufacturer 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

[Contact Information of Registrant] +86-22-65625051

[EU REP] NOVAMEDICAL GmbH

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

[Symbols and Meanings]



Do not use if package is damaged



Do not reuse



Consult instructions for use



Date of manufacture



Manufacturer



Use-by date



Sterile



Sterilized using irradiation



Do not resterilize



Caution



Double sterile barrier system



Humidity limitation



CE marking



Medical device



Information of European Authorized Representative (EAR)



Quantity



Double sterile barrier system with protective packaging outside



Catalogue number



Batch code