ENGINE
Medical Equipment Manufacturing

V-EC08-10 Rev. A.5

Scalpel of Ultrasonic Surgical System
Instruction for use

Date issued: 2021.3.16

CE 0197

EC REP Prolinx GmbH
Brehmstr.56,40239 Duesseldorf,Germany

Engine Medical Equipment Manufacturing (Shanghai) Corporation
Adress:No.1199, Xinsiping Road , 201413, Shanghai, P.R. China
Contact us:86-21-57125335

PLEASE READ THROUGH THE POLLWING CONTENTS CAREFULLY BEFORE USING THE PRODUCT.

Important announcement

The operation manual provides ONLY the instruction for the use of scalpel of Ultrasonic Surgical System. The scalpel of Ultrasonic Surgical System is hereinafter referred to as the scalpel. This operation manual is NOT a technical reference for surgery. All users must read this manual carefully before using this product. This manual tells users the follow information: users must pay attention to operating procedures, operation that may lead to abnormity, and other dangerous operation which may cause damage to the product or even the risk of operator. Our company does not in charge of safety, reliability and performance if abnormal operation occurred which mentioned in this manual that must be avoided! And our company will not give free maintenance to this kind of malfunction.

Model of the scalpel: EG US36D, EG US23D, EG US14D, EG US36R, EG US23R, EG US14R, EG US36DN, EG US23DN, EG US14DN, EG US36RN, EG US23RN, EG US14RN,EG US45E, EG US36E, EG US23E, EG US14E, EG US45ES, EG US36ES, EG US23ES, EG US14ES

Chapter 1 Product Overview

Product Overview

- The scalpel consists of an end-effector, a shaft, and a handle, etc.
- The scalpel is designed to have multiple functions. The scalpel can be used for bleeding control, the blunt blade to obtain optimized homeostasis effect as well as tissue cutting, and the sharp blade for fast cutting and tissue dissection.
- Mechanical motion is transferred from the transducer to the scalpel, at the same time transmit ultrasonic energy to stop bleeding or cut the tissue. Note that mechanical vibration generated by the transducer still cannot be perceived or see, although it has been magnified by the ultrasonic horn. So operators must avoid the scalpel acting on unintended targets during usage.
- The scalpel has already be sterilized by EO before leaving the factory, and the period of validity is 4 years, it should be destroyed or scrapped if it out of validity or package damage.
- The scalpel is disposable, do not sterilize and use it repeatedly.

Working principle

The generator provides energy for the transducer and the scalpels. The foot switch and the manual control device on the scalpels are used to control the output energy of the generator.

Intended use

The Ultrasonic Surgical System is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired.

Suitable crowd

The Ultrasonic surgical system is indicated for patients who need to bleed control and minimal thermal injury of soft tissue for incision.

Contact site and contact time

The scalpel contacts the tissue, and the contact time is less than 24 hours.

Disposable/repeatability

The scalpel of Ultrasonic Surgical System is disposable. The generator, transducer and footswitch are reused.

Whether it is an implant product

The Ultrasonic Surgical System is a non-implantable product.

Contraindications

The scalpel not indicated for incising bone,contraceptive tubal occlusion, neurosurgery operation, sealing vessel that diameter over 3mm.

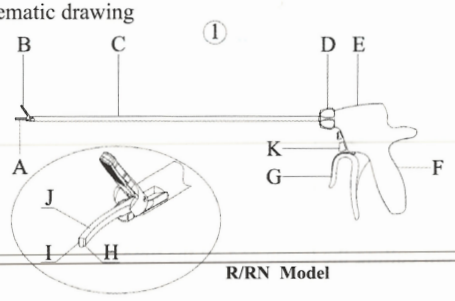
Parts list:

EG US14D/ EG US23D/EG US36D:a scalpel, an operation manual;
EG US14R/EG US23R/EG US36R:a scalpel, an operation manual;
EG US14DN/EG US23DN/EG US36DN: a scalpel, an operation manual;
EG US14RN/EG US23RN/EG US36RN: a scalpel, an operation manual;
EG US45E/EG US36E/EG US23E/EG US14E: a scalpel,an operation manual;
EG US45ES/EG US36ES/EG US23ES/EG US14ES: a scalpel, an operation manual;

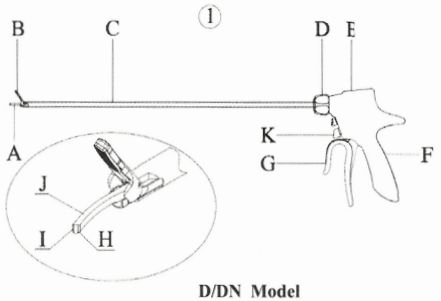
Chapter 2 Instructions

Adapter Device Model: Use device only with Engine Medical Generator EG GN15 and transducer EG TR100.

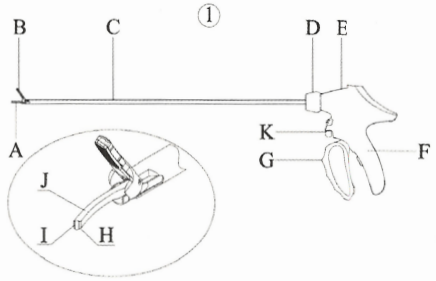
① Schematic drawing



R/RN Model



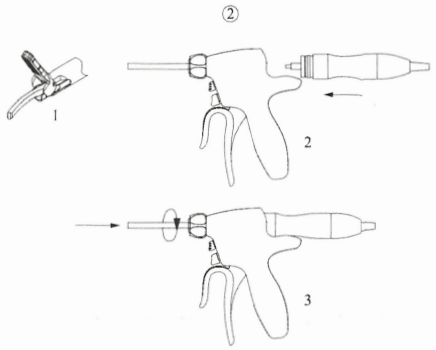
D/DN Model



E/ES Model

A)End-effector	E)Handle	I)Tip of the rod
B)Clamp	F)Grip	J)Blunt blade
C)Shaft	G)Trigger	K)Button
D)Rotation knob	H)Sharp blade	

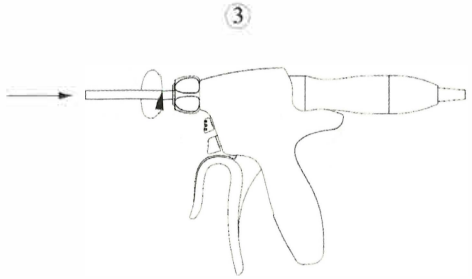
② **Assembly**



The clamp is in the open position when packaged. You can close it before assemble the transducer;

Align the thread end of the transducer with the screw hole of the handle of the scalpel as shown in figure 2.With the transducer in one hand and the handle in the other, and then rotate the rotation knob clockwise until a snap sound heard (twice);

③ **Disassembly**



Rotate the rotation knobanti-clockwise with the transducer in one hand and the scalpel in the other, then remove the transducer from the scalpel.

④ **Steps to use**

Note:Close the clamp with the clamping trigger before inserting the device into the trocar.

1.Insert the scalpel into atrocar of an appropriate diameter, or a large trocar with an adapter;

2.Open the clamp only after it is fully inside the cavity.

Note:DO NOT apply force on the clamping trigger.

3.The shaft can rotate by 360°. Adjust the end-effector to the optimal position with the rotation knob.

4.Place the tissue that need to be cut between the clamp and the end-effector. Make surethere is nothing else in the jaw. The cutting length shall not exceed the length of end-effector. More cutting can be conducted through multiple steps.

5.Apply the trigger to close the clamp containing tissue needed to be cut until the tissue is cut off. Do not apply excessive force on the trigger, otherwise the generator will generate an alarm and stop the output of ultrasonic energy.

6.After the cutting is completed, stop driving, open the clamp and remove the scalpel carefully. Verify the cutting and coagulation. If it is bleeding, suture it if needed.

7.Remove scalpel from the body cavity. Refer to the user manuals of the generator and transducer for more information.

Symbols

	Manufacturer		Refer to instruction manual/booklet
	Date of manufacture	LOT	Batch code
EC REP	Authorized representative in the European Communtity		Keep dry
	Humidity limitation		Atmospheric pressure limitation
	Tempenture limitation		Keep away from sunlight

	Caution		Separate collection of EEE
	Use-by date	CE 0197	Indicate the device compliance with the Medical Devices Directive 93/42/EEC 0197 is Notified Body NO.
	Do not resterilize		Do not re-use
STERILE EO	Sterilized using ethylene oxide		Biological risks
	Do not use if package is damaged		Fragile,handle with care
	Consult instructions for use		

Warning:

1.The product is only applicable to blood vessels with diameter less than 3 mm.

2.It is not applicable to the tissues such as liver or spleen as the device compresses the tissue after clamping, which may cause tissue damage.

3.DO NOT use the product if the hemostasis cannot be achieved or observed.

4.The product is a disposable medical device and should be disposed it immediately after use. DO NOT sterilize it for reuse.

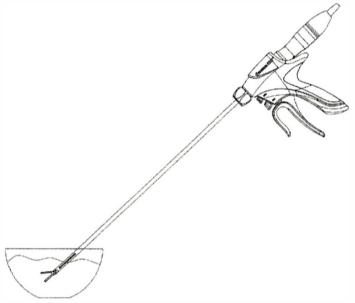
5.Use the front parts of Blade (two thirds of the front parts of blade which will be perfect) for tissue cutting.

6.To avoid tissue sticking, clean the end-effector of blade, clamp arm, and distal end of the tube throughout the procedure by activating the scalpel tip in saline. It is recommended to clean thescalpel at least 5 minutes.

Note: Do not touch the instrument to metal while activated.

Note: It can be wiped with a moist gauze sponge to remove tissue, if necessary.

If tissue is still visible in the clamp arm, use hemostats to remove residue, taking care not to actuate the scalpel . If desired, the instrument may be unplugged.



7.The shears should not be cut empty. After cutting the tissue, loosen the trigger immediately to prevent the end - effector of the shear from cutting the tissue pad all the time .

Cautions:

1.Close the clamp before end-effector insertion and pulling out from the trocar.

2.Verify there is no bleeding during and after cutting. If there is small amount of bleeding, suture by hand to stop it.

3.Placement of tissue exceeding the length of end-effector, or applying excessive force on the trigger may cause device malfunction and affect normal cutting.

4.Place the tissue needed to be cut into the jaw and make sure there is no other object.

5.After each cutting, release the foot pedal, and avoid the contact between the end-effector and other tissue.

6.Use the scalpel to stop bleeding with the power level under 3; use the scalpel to cut with the power level above 3(including 3); use the scalpel tip of the end-effector for point bleeding control.

7.Endoscopic operation shall be executed only by a trained physician familiar with endoscopic techniques. The doctor shall refers to relevant books to look into its techniques, complications and hazards.

8.If the devices and accessories from different manufactures are used in one operation, verifies the products compatibility, insulation and grounding.

9.The product is in a sterile package that is sterilized by EO and is only for one time use. Dispose it after use, and DO NOT sterilize and reuse it.

10.After use, dispose the product into specific collection box for medical waste to avoid environment pollution.

11.Please use it within the validity period printed on the package. Use after expiration date is forbidden.

12.The scalpel of the Ultrasonic Surgical System shall be stored in an environment where the humidity is no more than 90%, temperature between -35°C and 55°C,atmosphere pressure between 700hPa and 1060hPa,and no corrosive gas present. No mechanical shock, intense magnetic field or exposure to sun is allowed in storage.Validity Period is 4 years after sterilization when it is stored under these required conditions.

Batch Code\Date of manufacture\Use-by date:On the package.

Status of document change control

Revision no.	Issued date	Description of Document Change
A.0	2017.9.22	First Release
A.1	2018.9.26	Add European Authorised Representative information and issued date
A.2	2019.4.18	Refine the detailed rules for cleaning the scalpel and attention
A.3	2019.5.13	Add matching Generator and transducer model
A.4	2020.11.19	The validity period is changed to 4 years
A.5	2021.03.16	Add model of the scalpel and adjust address

Engine Medical Equipment Manufacturing (Shanghai)Corporation