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en Disposable Ultrasonic Scalpels Instructions

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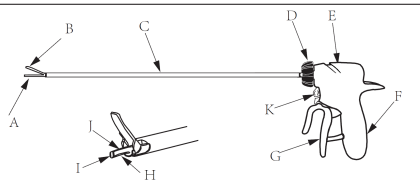
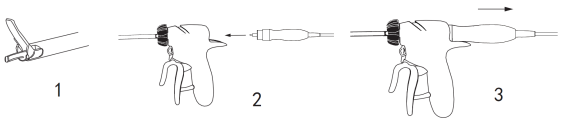
Illustrations

01
Schematic



02
Assembly and Unloading



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Disposable Ultrasonic Scalpels Instructions for Use

Please read all information carefully.
Failure to properly follow these instructions may lead to serious consequences.
Important: This package insert is designed to provide the instruction for use of Disposable Ultrasonic Scalpels.
Models include: CH45PD, CH36PD, CH23PD and CH14PD.
It is not a reference for surgical techniques.

Chapter 1 Product Overview

The operation manual is intended to assist in using the Disposable Ultrasonic Scalpels (hereinafter referred to as the 'scalpel'). It is not a reference for surgical techniques. The product is designed, inspected and manufactured for use ina single surgical operation. The instruments are EO sterile, single patient use for dissection, grasping, coagulation, and cutting between the blade and clamp. If repeatedly used or reworked, the product may lose its functions, or may simultaneously cause patient's injury or cross contamination. Please never repeatedly use or rework the product.

Intended Use

This instrument is used to dissect soft-tissue for cutting and/or coagulating tissues.

Indications

This instrument is designed to be attached to an ultrasound surgical equipment and contact with a patient during vibration at high frequency in order to dissect soft-tissue for cutting and/or coagulating tissue in open surgeries or endoscopic surgeries. In general, pediatric, gynecologic, urologic, thoracic, and sealing and transection of lymphatic vessels.

Intended User

This instrument is intended for use by healthcare professionals for surgical applications.

Intended Use Environment

This instrument is intended to be used in a hospital.

Intended patient population:

Patients aged 3 and older who need surgery in which soft tissue incisions with bleeding control and minimal thermal injury are required.

Clinical benefit:

•Shorter operative time;
•Less intraoperative bleeding;
•Less thermal injury.

Contraindications

* The instruments are not indicated for incising bone.
* The instruments are not intended for contraceptive tubal occlusion.

Chapter 2 Operation instructions

Scalpel consists of end-effecter, rod and handle. The scalpel has multiple functions: its head can be used for spot homeostasis, its blunt side on one side can implement the best homeostasis function, simultaneously with tissue incision function, while the other sharp side functions rapid tissue incision and separation.

The scalpel is a single-use product.

How to Use

Schematic drawing

A) Blade	B) Clamp
C) Shaft	D) Rotation Knob
E) Handle Top	F) Handle
G) Trigger	H) Sharp Side
I) Tip	J) Blunt Side
K) Buttons	

Assembly and Unloading

1. The clamp is designed in its open position in the package; do not try to close it; do not apply too much force on the trigger.
2. Align the screwed end of transducer with threaded hole in the handle along the direction shown in Fig. 2, hold transducer with one hand and hold the rotation knob with the other hand, and turn clockwise till you hear the click sound.
3. Hold the transducer with one hand while holding the rotation knob with the other hand, and turn anti-clockwise to disassemble the transducer.

Procedure for Use

Caution: Before the scalpel is inserted into the puncture outfit, the clamp must be closed, which can be implemented through the trigger.
1. Insert the ultrasonic scalpel into a proper puncture outfit, or into a larger puncture outfit through an adapter. The maximum diameter of the scalpel shaft is 5.6mm and the maximum working length is 45cm.
2. After the ultrasonic scalpel is fully entered into coelom, open the clamp;
Caution: Do not apply force on the trigger arbitrarily.
It is not requried to be inserted into the puncture outfit in the open surgeries.
3. The shaft can be turned by 360°. By rotation knob, adjust the scalpel end-effecter to optimum position;
4. Place tissue into clamp and scalpel end-effecter, and make sure that there are no other obstacles in the clamp. The tissue length to be cut should not exceed exposed scalpel end-effecter length. Longer tissue to be cut may be incised several times;
5. Hold on trigger tightly, so as to close clamp arm, in which the tissue to be incised is contained.
6. After incision is completed, stop driving, open the clamp, and remove the scalpel carefully. Check haemorrhage at operative site. If there is any haemorrhage, manually suture and legate for haeomostasis.
7. Close the clamp arm and take the scalpel out of coelom. More system usage information can be referred to the operation manual of Ultrasound Surgical Equipment or Transducer.

Chapter 3 Warnings and Precautions

1. The products can only be used for haemostasis of blood vessel of 5mm or smaller;
2. If you fail to observe haemostasis situation at operative site, do not use the product;
3. The product is a single-use sterile apparatus. Discard it after use. Do not sterilize and use it repeatedly.
4. The product uses 5mm puncture outfit. Before scalpel is inserted into or taken out of sleeve of puncture outfit, its clamp mouth should be kept closed;
5. During and after incision, haemostasis should be checked; slight haemorrhage may, if any, be manually stitched for haemostasis.
6. Tissue placed beyond exposed length of ultrasonic scalpel end-effecter or too much force applied may cause apparatus failure and abnormal incision;
7. Place tissue to be cut between clamp arm, and be sure that there are no other obstacles in the clamp mouth;
8. After incision is finished, the generator should stop driving at the same time, and the scalpel end-effecter should avoid contacting other tissues as possible;
9. Blunt side of the scalpel is used for hemostasis at power lever 3 or lower, or incision at power lever 4 or higher. Sharp side of the scalpel is intented for incision at all power levels. Top of the scalpel is intented for spot hemostasis.
10. To use the MIN level, press the MIN button of the scalpel or step on the VAR pedal of footswitch, with gentle tone, generator MIN level light flashing and low energy output; to use the MAX level, press the MAX button of the scalpel or step on the FULL pedal of footswitch, with urgent tone, generator MAX level light flashing and high energy output;
11. During the separation of the gallbladder and liver tissue, the liver and gallbladder should be reliably protected, to avoid the tip of the scalpel mistakenly in contact with the tissue and avoid bleeding and other injuries.
12. Minimally invasive surgery can only be performed by doctors with rich experience and familiarity with minimally invasive surgery. Before surgical operation, doctors should consult related literatures so as to understand surgical technology, complication and risks.
13. This product is supplied sterile, EO sterilized. If sterile package is damaged, DO NOT use.
14. Used products should be placed in a specified recycle bin or refuse container. Do not litter to

avoid environmental pollution. At the end of the service life, the scalpel should not be discarded at will. It should be disposed of by professionals in a timely manner in strict accordance with the state and local regulations on the disposal of medical waste, so as to avoid infection and environmental pollution.
15. This product is applicable for the general population. The device has universal applicability.
16. Vibration of, mechanical force on and heating of the tip of device are generated during cutting and hemostasis. One to two mm thermal damage may occur around the surgical site. The heat may accumulate near the tip of the outer tube. Therefore, contact with and clamping of normal tissues should be minimized.
17. When the generator alarms, the scalpel stops vibration, and it is required to check whether the scalpel touches foreign objects and other abnormal use, and to find the abnormal situation of connected equipment based on the system tips.
18. Before each use, it is important to check that the inner parts of the endoscope and endoscope attachments inserted into the body have no safety hazards on rough surfaces, sharp edges, or protrusions.
19. When a high-frequency noise is made by the scalpel or transducer, it indicates that the scalpel or transducer does not function properly, that the scalpel is not properly connected or that the transducer is out of service life, which may cause the scalpel temperature to abnormally rise to the extent that it can cause harm to the doctor and the patient.
20. In case of system failure, it is required to ensure that suitable spare equipment is prepared and run immediately.
21. If devices and accessories other than this system are used in a single operation, the compatibility between the products should be confirmed and insulation and grounding shall be checked for good condition.
22. Please use the product before its expiration date, and expired products are prohibited to be used.
23. A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to Reach Surgical, Inc. through Reachquality@reachsurgical.com. and the competent authority of the Member State in which the user and/or patient is established.
24.Scalpel of the Ultrasound Surgical Equipment must be stored in a room with ambient humidity not more than 80%, temperature -10°C ~ +55°C, atmospheric pressure 860hPa~1060hPa, no acid or alkali or corrosive gas, good ventilation, no strong mechanical vibration or strong magnetic field or sunlight irradiation. After sterilization, the period of validity counted from sterilization is set to 5 years by following rules for storage.

TIPS FOR SCALPEL USE

1. Clean the blade in time during operation.
When the Scalpel is free, it is necessary to gently wipe off the residual tissue frequently from the back to front with wet gauze, because the residual tissues which are attached on the blade or Scalpel End-Effectors may lead to overload.
2. Do not hold the trigger too tight when the blood vessels are closed.
When you close the jaws with tissue and hear a 'click' from Scalpel handle, it means the jaws have acted uniform pressure on tissue. DO NOT strongly hold the handle and trigger, and try to give more tension to tissue to increase the cutting speed.
3. Use the front 2/3 of the blade.
In the surgery, use the front 2/3 of the Scalpel End-Effectors to grasp the tissue. Holding the tissue with back 1/3 may lead to overload.
4. Try to avoid cutting with too much tissue.
Holding too much tissue will lead to overload due to the complexity of the tissue.
5. Try to avoid cutting without tissue in the jaw
In the tissue cutting, if the jaw is closed without tissue, it will easily burn the tissue pad, cause scalpel failure and even blade broken.
6. Firing time for each spot should not be too long.
Try to avoid over 6-7 seconds for one spot. If it is hard to cut down, try to adjust the position of the cutting.

EO Batch	**EN** Sterilization batch
	EN Peel Here
02 PE-HD	**EN** HDPE recyclable
	EN Recyclable

	en Electrical and Electronic equipment, separate collection
	EN Refer to instruction manual
EC REP	**EN** Authorized Representative in the European Community
	EN Do not use if package is damaged.
STERILIZE	**EN** Do not resterilize
	EN Manufacturer
	EN Date of manufacture
SN	**EN** Serial number
LOT	**EN** Batch code
	EN Use-by date
	EN Fragile, handle with care
	EN Keep dry
	EN Keep away from sunlight
	EN Up
	EN Do not re-use
	EN Caution

REF	**EN** Catalogue number
	EN Storage temperature limit
	EN Storage humidity limitation
	EN Storage atmospheric pressure limitation
	EN Single sterile barrier system
CN	**EN** Country of manufacture
MD	**EN** Medical device
UDI	**EN** Unique device identifier
STERILE EO	**EN** Sterilized by Ethylene Oxide.
www.int.reachsurgical.com/support	**EN** Consult instructions for use or consult electronic instructions for use