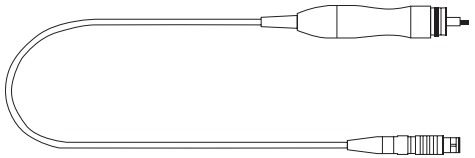
REACH SURGICAL | SOUND REACH

SOUND REACH TRA6 Transducer



en Transducer of Ultrasound Surgical Equipment
(Instructions)

Rev.A.0

CE 0197

Reach Surgical, Inc.
120 Xinxing Road, West Zone, TEDA, 300462 Tianjin, China

EC REP **MDSS GmbH**
Schiffgraben 41, 30175 Hannover, Germany

Issue date: 2024-08-12

Fig.1 Schematic Drawing

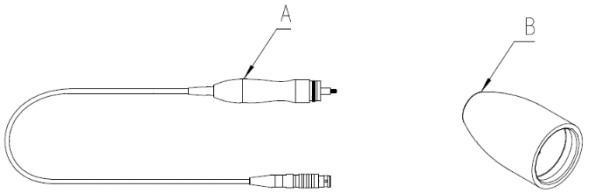
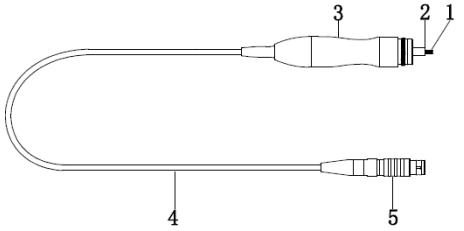


Fig.2 Transducer Structural Composition



en

Transducer of Ultrasound Surgical Equipment (Instructions)

Fig.1 Schematic Drawing
A. Transducer
B. Sheath

Fig.2 Transducer Structural Composition
1. Connecting Screw
2. Scalpel Mount Surface
3. Shell
4. Cable
5. Connector

Transducer of Ultrasound Surgical Equipment

(hereinafter referred to as the Transducer)
Caution: This booklet is designed to assist in using the product and is not a reference to surgical technique. Before using this product, please read the following information:
How Supplied: Non-sterile
Model: TRA6
The Transducer is permanently attached to a cable which connects to the front of the Generator of Ultrasound Surgical Equipment (hereinafter referred to as the Generator).

Nomenclature and Illustration

Each Transducer is provided with a Sheath, please refer to Fig.1.

Structural Composition

Please refer to Fig.2.

Device Description

The Transducer is used with the Disposable Ultrasonic Scalpel (hereinafter referred to as the Scalpel) as a cutting and coagulation device. The Transducer is designed to convert electrical energy from the Generator to mechanical motion of the Scalpel. When the Transducer is used in conjunction with the Ultrasound Surgical Equipment, the Transducer provides ultrasonic vibration, which enables the Scalpel's cutting and coagulation ability.
The Transducer is a reusable instrument with one year service life. The Transducer is programmed with a counter to limit the service life to 100 procedures with the Transducer software V01. The number of remaining procedures is indicated on the display of the Generator during the power on, if the number of remaining procedures is not more than 10 times. The Generator will give a notice (Transducer has 0 use remaining, replace the Transducer) after 100 procedures are completed. The number of activations during a procedure is not limited. When the Transducer is connected to the Generator and the Generator is turned on, the counter will record only one procedure at most.

Intended Use

This device, when used in conjunction with the Ultrasound Surgical Equipment is intended for soft tissue incisions when bleeding control and minimal thermal injury are desired.

Indications

This device, when used in conjunction with the Ultrasound Surgical Equipment, is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. This device can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels 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 device is intended for healthcare professionals who use this device for surgical purposes.

Intended Use Environment

This device 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 instrument is not indicated for incising bone.
- The instrument is not intended for contraceptive tubal occlusion.

Instructions for Use

Step 1: Transducer Cleaning and Sterilization
The Transducer is supplied non-sterile. The Transducer must be thoroughly cleaned and sterilized prior to each use.

Preparation before cleaning:
Remove the Sheath over the Scalpel Mount Surface before cleaning. A regular and precise visual check of the Transducer should be made before each use, to make sure the Transducer has no tear, deep scratches, discoloration, corrosion in the cable insulation, or obvious damage to the threads or Scalpel Mount Surface.

Cleaning:
Thoroughly clean Transducer according to the following steps:
- Rinse the Transducer with the screw side up and clean with a soft bristle brush with purified water until there are no smudges on the surface;
- The Transducer is soaked in a pH neutral enzymatic detergent (main ingredients: protease, lipase, amylase, cellulase, pectinase and other biological enzymes, environmentally friendly surfactant, rust prevention factor and stabilizer) for a period of up to 10 minutes at an appropriate temperature 15°C~65°C. The ratio of detergent and purified water is 1:400.
- Rinse the Transducer with the screw side up with purified water for 2 minutes;
- Clean the Connecting Screw, Scalpel Mount Surface and Connector with an alcohol wipe.
- Soak the Transducer in 75% medical alcohol and hold and shake it for 30 times;
- Rinse the Transducer with the screw side up with purified water for 2 minutes.

Note: The use of ultrasonic cleaners is not recommended for the Transducer.

Drying:
Drying temperature: 50~70°C, drying time: 30min.

Transducer Sterilization:
Following the cleaning and drying steps above, the Transducer must be sterilized by one of the methods listed below.
Steam Sterilization (121°C)
- Sheath should be installed before sterilization. Transducer should be wrapped during sterilization. Put the Transducer into a high-temperature steam sterilization pot for sterilization, with a temperature of 121°C and a duration of 30min.
- Drying temperature: 50~70°C, drying time: 30min.

Steam Sterilization (134°C)
- Sheath should be installed before sterilization. Transducer should be wrapped during sterilization. Put the Transducer into a high-temperature steam sterilization pot for sterilization, with a temperature of 134°C and a duration of 10min.
- Drying temperature: 50~70°C, drying time:30min.

Low Temperature Plasma Sterilization
- Sheath should be installed before sterilization. Carefully place the Transducer within the appropriately sized package and wrap the tray according to hospital procedure, and then put it into a low-temperature plasma sterilizer (Type: PS-100X; Manufacturer Name: Shinva Medical Instrument CO., LTD.) for sterilization.

Note: When using other sterilizers, make sure that they have the same sterilization effect.

Step 2: Assembly
a. Inspect Transducer for damage. The Transducer should be inspected for damage before each use. DO NOT USE the Transducer if damaged. Damage to the Transducer may result in device failure during use.
b. Assemble the Scalpel to the Transducer. Refer to the appropriate Disposable Ultrasonic Scalpel Operation Manual.
c. Connect the Transducer to the Generator. Refer to the appropriate Ultrasound Surgical

Equipment Operation Manual.

Step 3: Use of the Ultrasound Surgical Equipment
Refer to the Ultrasound Surgical Equipment Operation Manual and the Disposable Ultrasonic Scalpel Operation Manual.

WARNING	**If the Transducer is used in conjunction with instruments outside the Ultrasound Surgical Equipment, verify the compatibility of all instruments and accessories prior to use.**

Step 4: Disassembly
a. Unplug the connector of the Transducer from the Generator. When unplugging, make sure that the Generator does not move.
DO NOT activate the Generator with the Transducer disconnected. Reboot the Generator if a Generator error occurs. Call Customer Service if the Generator error persists.
b. Disassemble the Scalpel from the Transducer. Refer to the appropriate Disposable Ultrasonic Scalpel Operation Manual.

Operating conditions:
Working Temperature: 10°C-30°C
Relative humidity≤70%.
Air pressure: 860hPa-1060hPa

Environmental Conditions for Transport and Storage
Temperature: -40°C- +55°C
Humidity: ≤80%

IP classification
IP20

Disposal
Some internal components of the Transducer contain lead. Disposal should be performed according to local requirements and regulations.

Warnings and Precautions
WARNING: Minimally invasive procedures should be performed only by persons having adequate training and familiar with minimally invasive technique. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.
WARNING: Minimally invasive instruments may vary from manufacturer to manufacturer. When minimally invasive instruments and accessories from different manufacturers are used together in a procedure, verify compatibility prior to initiation of the procedure.
WARNING: A thorough understanding of the principles and techniques involved in laser, electrosurgical, and ultrasonic procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instrument. Ensure that electrical insulation or grounding is not compromised. Do not immerse electrosurgical instruments in liquid unless the instruments are designed and labeled to be immersed.
WARNING: To prevent burn injury, discontinue use if the Transducer temperature becomes uncomfortable to hold.
WARNING: As with every source (Electro Surgery, Laser, or Ultrasound), there are concerns about the carcinogenic and infectious potential of the by-products, such as tissue smoke plumes and aerosols. Appropriate measures such as protective eyewear, filtration mask, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures.
WARNING: To avoid user or patient injury, do not activate an electrosurgical device in close proximity to the instruments. The aerosols created by the activation of the instruments in fatty tissue are potentially flammable.
WARNING: To avoid user or patient injury in the event that accidental activation occurs, the scalpels should not be in contact with patient, drapes or flammable materials while not in use.
WARNING: During and following activation on tissue, the instrument scalpels may become hot. Avoid unintended scalpel contact with tissues, drapes, surgical gowns, or other unintended sites after activation.
WARNING: The Transducer meets the international safety standard EN60601-1 for user contact and is not intended for patient contact. To prevent burn injury, avoid direct tissue contact with the Transducer or take preventative measures to protect tissue that comes in contact with the transducer and adaptor.
WARNING: Handle the Transducer carefully, as damage may shift resonant frequency.
Do not bang or drop the Transducer.
Do not clean the Transducer electrical connector with alcohol.
WARNING: Verify compatibility with Generator prior to use.
WARNING: Products manufactured or distributed by companies not authorized by Reach Surgical, Inc. may not be compatible with the System. Use of such products may lead to unanticipated results and possible injury to the user or patient.
Use the Transducer only with a compatible Reach Surgical, Inc.'s Generator to avoid potential electric shock hazard.
WARNING: After removing the excessive instruments, examine the tissue for homeostasis. If homeostasis is not present, appropriate techniques should be used to achieve homeostasis.
WARNING: In case of system failure, ensure the availability of the appropriate spare equipment relevant to the specific procedure.
WARNING: 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.

EO Batch	**EN** Sterilization batch
	**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.
	**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** Caution

REF	**EN** Catalogue number
	**EN** Storage temperature limit
	**EN** Storage humidity limitation
	**EN** Storage atmospheric pressure limitation
CN	**EN** Country of manufacture
MD	**EN** Medical device
UDI	**EN** Unique device identifier
IPN$_1$N$_2$	**EN** N1 = 2 Protected against solid foreign objects of 12,5 mm Φ and greater; N2 = 0 Non-protected
 **www.int.reachsurgical.com/support** 	**EN** Consult instructions for use or consult electronic instructions for use