Transducer of Ultrasonic Surgical System Generators of Operation Manual

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Content

Please read all information carefully.

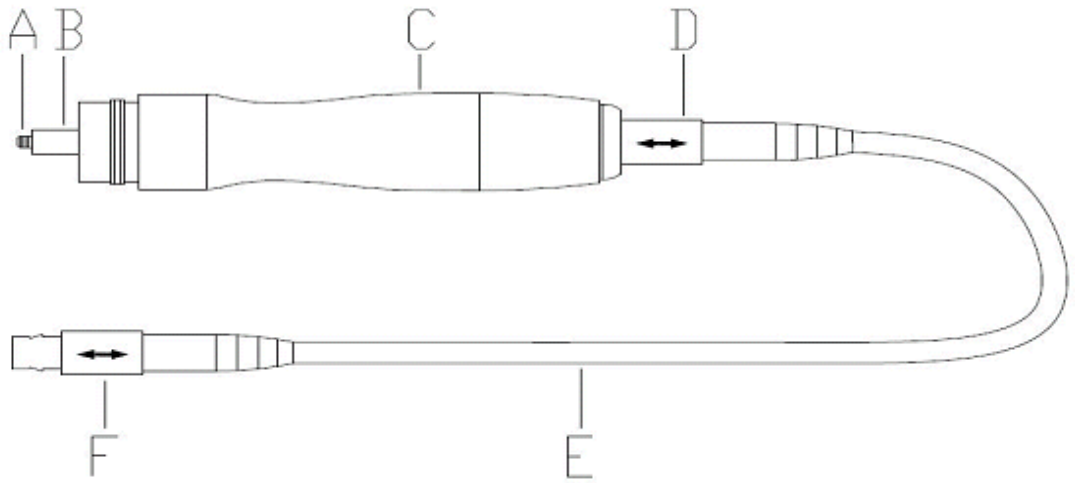
Failure to properly follow these instructions may lead to serious consequences.

Important: This package insert is designed to provide instruction for use of **Transducer of Ultrasonic Surgical System Generators**
It is not a reference to surgical techniques.

Chapter1 Product Overview

The transducer consists of a connecting screw (A), a Blade Mount Surface (B), a shell (C) and a cable (E) with two connectors (D and F).

Operation instructions



Schematic drawing

A) Connecting Screw
B) Blade Mount Surface
C) Shell
D) Connector to the Transducer
E) Cable

F) Connector to the Generator

Indications

The transducer, when used in conjunction with the Instruments, is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The Instruments can be used as an adjunct to or substitute for electrosurgery, lasers and steel scalpels.

Contraindications

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

Device Description

The Transducer is designed to convert electrical energy from a compatible Generator to mechanical motion for the instrument blades. This Transducer is intended for use with a compatible Generator.
The Transducer is attached to a cord which connects to the front of the Generator.
The Transducer is re-usable instrument with a limited service life.

Chapter2 Cleaning and Disinfection

Verify compatibility of all instruments and accessories prior to using the instrument.
Prior to use, remove and discard the protective cover over the Blade Mount Surface.

Transducer Cleaning and Sterilization
The user must ensure that cleaning and sterilization are conducted in accordance with the appropriate guidelines, standards, or national health authorities' requirements.
The Transducer must be cleaned and sterilized prior to each use. This instrument has been designed to allow for thorough cleaning and safe sterilization.

Transducer Cleaning

Remove the adaptor and instrument from the Transducer before cleaning. Remove and process the adaptor and instrument according to the instructions included with the adaptor and instrument.

Pre cleaning

All surgical instruments are subjected to a degree of wear and tear as a result of normal use. A regular and precise visual check of the instrument should be made before each use.
The Transducer is immersible and may be soaked in a pH neutral detergent or pH neutral enzymatic detergent for a period of up to one hour prior to cleaning.
Note: The use of ultrasonic cleaners is not recommended for the Transducer.

Cleaning

The Transducer may be cleaned manually or by machine pH neutral detergents or pH neutral enzymatic detergents should be used. In addition, Neodisher Mediclean Forte can be used. Purified or deionized water should be used throughout the Transducer cleaning process when using Neodisher Mediclean Forte.

Manual Cleaning

1 Manually clean the Transducer using a pH neutral detergent or pH neutral enzymatic detergent prepared according to the manufacturer's recommendation. Clean with a soft bristle brush or equivalent. Do not use abrasive materials.

2 Thoroughly rinse the Transducer with purified water.

3 Visually inspect the instrument for cleanliness.

4 Clean the Blade Mount Surface with an alcohol wipe.

Manual Chemical Disinfection

The following chemical disinfectants, concentrations and contact times are approved for use with the Transducer disinfectants should be prepared according to the manufacturer's recommendations. A thorough, purified water rinse must follow the chemical disinfection process.

Disinfectant	Recommended Concentration	Minimum Contact Time
Cidex OPA	100%-No preparation	12 minutes
Deconex 53 Plus	1.5% solution	30 minutes
Glgasept	10%solution	30 minutes
Glgasept FF	6% solution	15 minutes
Kohrolin	3%solution	60 minutes
Aseptisol	4% solution	30 minutes

Disinfectants should be prepared and used according to the manufacturer's recommendations for use, concentration and contact time.

Use of other disinfectants. The use of disinfectants, other than those specified in this IFU, should be assessed for equivalency before use. Technical data sheets are typically available through the manufacturer's we pages assist in this assessment. Any disinfection process, including tools and solutions, may influence the wear and tear on a device or equipment. In some instances, changing to another disinfectant may be required.

Within the applied decontamination process, ensure that detergent and disinfectant residuals are sufficiently removed. Purified or deionized water should be used during final sensing processed, where applicable (multiple rinses may be required). Refer to the manufacturer's recommendations for the removal of disinfectant residuals.

Automated Washer/disinfector (Thermal and/or Chemical Disinfection Option)

1. The Transducer may be cleaned in a washer/disinfector using a typical non-lubrication cycle such as a utensil, rubber goods or glassware cycle. The instrument cycle can be used to clean the Transducer as well in a washer/disinfector provided that the lubrication step can by by-passed.

Note: Do not expose the Transducer to a lubrication cycle.

2. A pH neutral detergent and pH neutral enzymatic detergent can be sued. Additionally, Neodisher Mediclean Forte can be used during the wash cycles. Purified or deionized water should be used throughout the Transducer cleaning process when using the Neodisher Mediclean Forte.

3. A thermal disinfection cycle not to exceed 199.4F (93℃) for a maximum of ten (10) minutes is allowable.

4. Chemical disinfection using one of the following disinfectants is allowable in lieu of the thermal disinfection phase for those machines that do not support a thermal phase option: Cidex OPA, Deconex 53 Plus, Gigasept, Gigasept FF, Kohrolin or Aseptisol

5. Purified or deionized water should be used as the final rinse after cleaning and disinfection.
6. Drying can be achieved using temperatures less than 273F (134℃) for a maximum time of 30 minutes.
7. Wipe the Blade Mount Surface of the Transducer with an alcohol wipe upon removal from the automated washer/disinfector.
8. Clean the Upper and lower contact rings by wetting cotton swabs with Isopropyl alcohol and moving the cotton swab around the entire inside contact surface. Continue cleaning contact rings until little or no residue is visible on the cotton swabs.

Chapter3 Transducer Sterilization

Following the cleaning and disinfection steps above, the Transducer must be sterilized by one of the methods listed below. Drying times post-sterilization of 273F (134℃) or less for a maximum of 30 minutes is allowable. Handing of the Transducer should follow hospital protocol throughout the cleaning and sterilization process.

Steam

The following steam sterilization cycle parameters are approved for use.

Sterilizer Type	**Method**	**Cycle Time (at temperature)**	**Temperature Set Points**	**Preconditioning Pulses**
Pre vacuum	Wrapped	3-18 minutes	270F/273F	3
Pre vacuum	Unwrapped	3-5 minutes	270F/273F	3
Pre vacuum	Wrapped	20 minutes	250F (121℃)	3
Gravity	Unwrapped	10minutes	270F/273F	Not applicable
Gravity	Wrapped OR Unwrapped	30 minutes	250F	Not
applicable Gravity	Wrapped	15 minutes	270F/273F	Not applicable

Minimum dry time for each method above is 0 minutes.

Note:

1. The above table includes the minimum temperature and time validated to assure sterility.
2. Based on steam autoclave tolerance, the actual autoclave temperature can exceed the set point temperature by a maximum of +5F (+3℃).
3. **Health authorities in some regulated regions do not accept unwrapped sterilization methods. Please review the appropriate guidelines, standards and national Health Authorities' guidelines when determining acceptable steam sterilization process parameters for use in each respective country.**

EO

Packaging
EO breathable pouch, sterilization trays wrapped in CSR wrap, or enclosed in an EO breathable pouch.
EO Concentration
600 mg/liter minimum
Preconditioning Time
Sufficient to allow temperature and relative humidity to rise to specified targets.
Sterilizer Set Temperature

130F (54℃)
EO Dwell Period
2 Hours
Relative Humidity
50%
Aeration
12 Hours minimum
EO Residuals Dissipation
24 Hours minimum

STERRAD

1 Clean and dry the Transducer following the steps listed in the Transducer Cleaning section.
2 Carefully place the Transducer within the appropriately seized packaging and wrap the tray according to hospital procedure.
3 Sterilize the Transducer within the STERRAD Sterilizer according to the instructions provided in the STERAD Operator's Manual.

Transducer Attachment
Refer to a compatible Generator User Manual for Transducer attachment and system operation instructions.

Environmental Conditions for Transport and Storage

Temperature: -10°C- +55°C

Humidity:≤80%

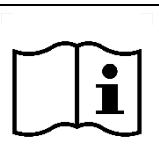
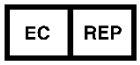
Disposal

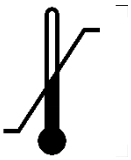
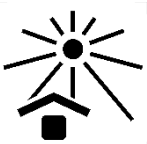
Some internal components of the Transducer contain lead. Disposal should be performed according to local requirements and regulations.

How Supplied

The transducer is supplied non-sterile. Sterilize prior to use.

Chapter 4 - Symbols

	Manufacturer		Refer to instructions manual
	Authorized representative In the European Community		Keep dry
	Date of manufacture		Fragile, handle with care

SN	Serial number		Up
	Proper disposal of Equipment according local Regulations		Temperature limit
	Biological risk		Keep away from sunlight
	Do not use if package is Damaged.		
CE 0197	Indicating the device compliance with the Medical Devices Directive 93/42/EEC. CE0197 is Notified Body No.		

Chapter5 Warning 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 employed 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: Audible high-pitched tones are abnormal condition and an indicator that blade or Transducer is not operating properly. The tones may be an indicator that the Transducer is beyond its useful life or that the blade has not been attached properly, which may result in abnormally high temperatures and user or patient injury.

WARNING: Do not use the Transducer without proper adaptor. Failure to use the proper adaptor may result in user or patient burn injury.

WARNING: To prevent burn injury, discontinue use if the Transducer temperature becomes uncomfortable to hold.

WARNING: As with all every source (Electro surgery, Laser, or Ultrasound), there are concerns about the carcinogenic and infectious potential of the by-products, such as tissue smoke plume and aerosols.

Appropriate measures such as protective eyewear, filtration masks, 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 instrument blades should not be in contact with patient, drapes or flammable materials while not in us.

WARNING: During and following activation in tissue, the instrument blades may become hot. Avoid unintended blade contact with tissue, draped, 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 and adaptor 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 Panther Healthcare, 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 this Transducer only with a compatible Panther Healthcare's Generator to avoid potential electric shock hazard.

WARNING: After removing the excessive instruments, examine the tissue for hemostasis. If hemostasis is not present, appropriate techniques should be used to achieve hemostasis

WARNING: In case of system failure, ensure the availability of the appropriate back up equipment relevant to the specific procedure.

EC REP

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