SAT01 Transducer

en: Instructions for Use

REF SAT01 Transducer

Compatible with:

SAG01 Generator (SW V1 and above)

SAF01 Footswitch

SAS45, SanAgile™ Dissector, 5.5mm, 45cm, Curved.

SAS36, SanAgile™ Dissector, 5.5mm, 36cm, Curved.

SAS23, SanAgile™ Dissector, 5.5mm, 23cm, Curved.

SAS14, SanAgile™ Dissector, 5.5mm, 14cm, Curved.

SA10 Portable Controller (SW V1 and above)

SAA01 Connector (SW V1 and above)

Please read, understand, and follow the accompanying instructions carefully.

This Instructions for Use is designed to provide instructions for the use of SAT01 Transducer. It is not a reference to surgical techniques. Please visit www.snssurgical.com.cn/en/support for the latest version of this manual.

To understand and complete a task in a safe and thorough manner throughout this manual, please pay attention to those instructions provided in the form of a Warning, a Precaution, or a Note Statement.

SanAgile™ is the trademark owned by Shanghai Saints Sages Surgical Co., Ltd.

Customer Service

The service and repair of the transducer shall be conducted by the service engineers/technicians on behalf of or authorized by Shanghai Saints Sages Surgical Co., Ltd. Refer to Section 7 for the details of service and warranty.

Electric Shock

- Untrained service engineer and technician are not allowed to open the transducer.
- Ensure that the transducer is connected correctly to the compatible instruments and that no metal is exposed at any connection points.
- Connect the transducer and accessories to the compatible instruments only when the energy is off. Failure to do so may result in an injury or electric shock to the patient or operating room personnel.
- Use only CO_2 extinguisher in case of a fire. Spraying with water or other liquid extinguisher can induce the serious personal injury. Power off the compatible instrument before extinguishing to avoid electric shock.
- When receiving the product and before each use, the user shall confirm its functions and integrity to prevent personal injury to the operator or patient.

SAT01 Transducer is not made with natural rubber latex.

Rx
ONLY

This Instructions for Use is for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed. It is intended as a guide for using SAT01 Transducer.

Table of Content

1. Overview

1.1. Product Characteristics

SAT01 Transducer is designed to use with the compatible instruments to transect, dissect and coagulate tissue.

Figure 1: SAT01 Transducer

1.2. Devices and Components

The device covered in this Instructions for Use is SAT01 Transducer.

Please refer to the compatible instruments: SAG01 Generator User Manual, SanAgile™ Dissectors Instruction for Use, SA10 Portable Controller User Manual and SAA01 connector Instruction for Use respectively for the details on the compatibility.

1.3. Intended Purpose

The transducer, when used in conjunction with SanAngile™ Dissector, is intended to seal and cut vessels and/or to dissect, coagulate and cut soft tissue via ultrasonic oscillation.

1.4. Indications for Use

The transducer, when used in conjunction with SanAngile™ Dissector, is indicated for vessel sealing and soft tissue incision when bleeding control and minimal thermal injury are desired.

1.5. Contraindication

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

1.6. General Warning

- Do not use in patients who have electronic implants such as cardia pacemakers without first consulting a qualified professional (e.g., cardiologist). A possible hazard exists

because interference with the action of the electronic implant may occur, or the implant may be damaged.

- Do not use in the presence of flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen or in close proximity to volatile solvents such as ether or alcohol, as explosion may occur.
- Portable and mobile RF communications equipment in the proximity may affect the performance of the equipment. Refer to the EMC information provided in the User Manual for the compatible instruments.
- Visually inspect the transducer for breaks, cracks, nicks, or other damage. Do not use damaged components. Use of damaged components may result in injury to the patient or operator.
- Avoid accidental activation when attaching dissector and transducer to the compatible instruments. Accidental activation of the dissector can cause serious injury to the patient or surgical team.
- Do not activate the dissector when not in contact with target tissue, as this may cause injuries.
- As with all energy sources (Electrosurgery, Lasers, 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.
- When no using the transducer, place it in a clean, dry, highly visible area not in contact with the patient. Inadvertent contact with the patient may result in injury.

Infection hazard:

- Non-sterile transducer will contaminate the sterile field and place the patient at risk for infection.
- Transducer is provided non-sterile and must be cleaned and sterilized prior to first use and each re-use. Refer to Section 5 for the parameters in reprocessing the Cleaning and Disinfection.

1.7. General Precaution

- Use only SAT01 transducer with the compatible instruments. Devices and components from other manufacturers are not compatible with the transducer and may cause injury

to the patient and user.

- No modification of the instruments is allowed.
- Modification or opening of the transducer invalidates the warranty and could create hazardous conditions.

2. Performance Characteristics

2.1. Technical Specification

• Input Electrical Power	60W ± 10%
• Drive Frequency	55.5kHz ± 2% (both Max and Min)
• Weight	< 400g
• Dimensions	Φ25*132 ± 5mm

2.2. Transducer cable length

3m

2.3. Storage and transportation conditions

• Ambient temperature	-20°C～55°C
• Relative humidity	20%～80%, no condensing
• Atmospheric pressure	700hPa～1060hPa

3. Operation Instruction

3.1. Transducer Parts

The transducer is intended to be connected to dissector, whereby it is designed to convert high frequency electrical current into an ultrasonic oscillation, to fragment soft tissue for cutting and/or coagulating tissue during surgery. One end is to connect to SanAgile™ dissector, and the other end is to connect to the compatible instruments.

Figure 2: Transducer Parts Diagram

1	Contact Ring	Used to connect to SanAgile™ Dissector
2	Transducer Cable	Cable connecting transducer plug and contact ring
3	Transducer Plug	Used to connect to the receptacle

3.2. Assembly Instruction

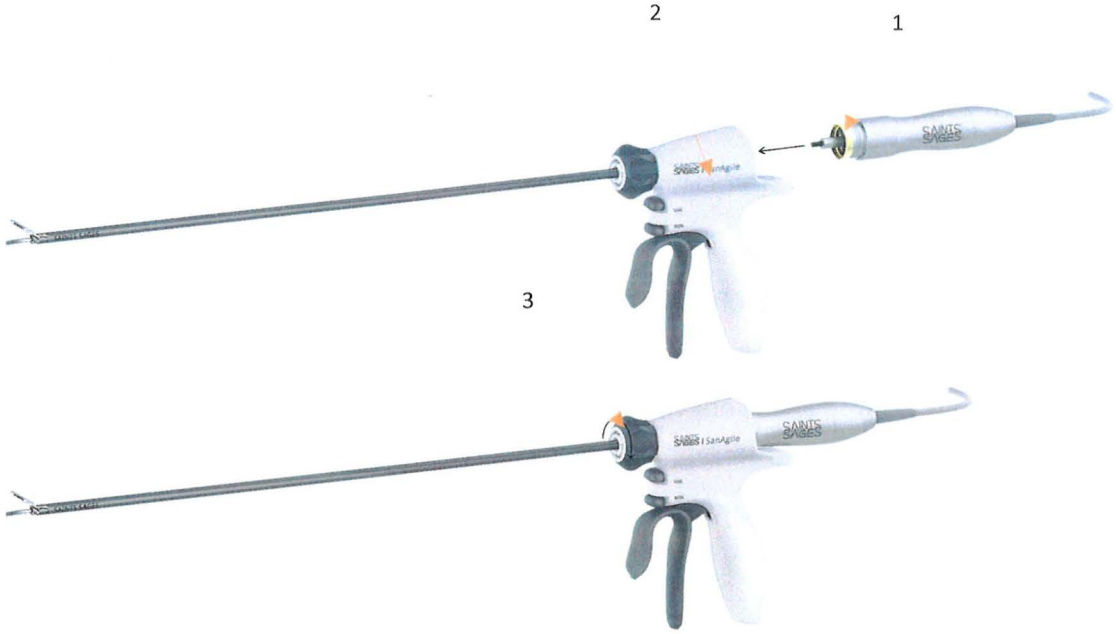
Warning:

- The transducer is intended for use with the compatible instrument. The use of any incompatible instruments may not result in the desired clinical effect. Please do not use the incompatible instruments with this transducer.

3.2.1 Examine the transducer for damage before connecting to the compatible instruments. Do not use the damaged devices.

3.2.2 Hold the dissector in one hand, push the Contact Ring (1) of transducer into the Grip Housing (2). Then hold the transducer in one hand and turn the Rotation Wheel (3) clockwise until it reaches a hard stop, and two clicks are heard.

Figure 3： Transducer and Dissector Assembly Diagram



3.2.3 Connect the Transducer Plug into the receptacle. The compatible instruments refer to the instruction of compatible instruments for the connection.

3.3. Operation

Note:

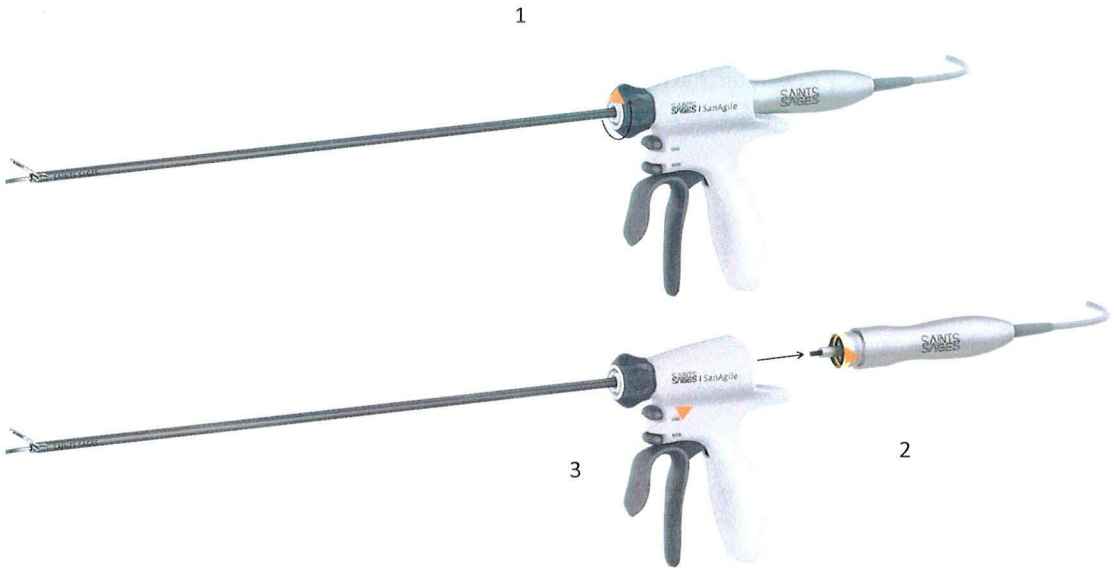
- After startup, the compatible instrument enters the power-on self-test, the Status LED illuminates in different colors to indicate the status. Please refer to the compatible instruments User Manual for the LED guide and operation in details.

3.4. Disassembly Instruction

3.4.1. Unplug the Transducer Plug from the compatible instrument according to the compatible instruments User Manual

3.4.2. Hold the transducer in one hand, turn the Rotation Wheel (1) counterclockwise. Then hold the dissector in one hand and pull the Contact Ring (2) of transducer from the Grip Housing (3) until it disconnects from the dissector.

Figure 4: Transducer and Dissector Disassembly Diagram



4. Patient and Operation Room Safety

4.1. Before a Procedure

Precaution

- Use only SAT01 Transducer with the compatible instruments. Devices from other manufactures are not compatible with the transducer and may cause injury to the patient and the operator.
- Please remove the black cover from the transducer before assembly.

4.1.1. Visually inspect the transducer, the compatible instruments for breaks, cracks, nicks, or other damage. Do not use damaged components. Use of damaged components may result in injury to the patient or user.

4.1.2. Visually check the assembly and connection are secured and ensure the compatible instruments self-test is completed before the procedure.

4.1.3. The transducer is provided non-sterile and must be cleaned and sterilized before use, according to the procedures specified in section 5 **Cleaning and Sterilization**.

4.1.4. Ensure the availability of backup dissector and transducer in case of the device failure.

4.2. During a Procedure

4.2.1. The transducer may get hot if a buzzing is heard during the procedure. The dissector or transducer may not work properly due to the inappropriate manipulation. Stop the operation immediately, inspect the dissector or transducer to confirm if they are in the correct status and assembled correctly.

4.2.2. The transducer is verified for compliance with IEC 60601-1 and can be manipulated by the operator. To prevent the inadvertent activation, avoid transducer contacting with the patient tissue.

4.2.3. Do not knock the transducer and avoid dropping during the manipulation.

4.3. After a Procedure

Precaution

- Before cleaning, please disassemble the transducer from the compatible instruments and the dissector according to the procedures specified in section 3.4 **Disassembly Instruction**.

4.3.1. Clean and sterilize the transducer according to the instructions provided in Section 5

Cleaning and Sterilization in this Instructions for Use.

4.3.2. When not using the transducer, place it in a clean, dry, highly visible area not in contact with the patient. Inadvertent contact with the patient may result in injury.

4.3.3. Transducer contains Lead. Disposal should be performed according to local requirements and regulations.

5. Cleaning and Sterilization

5.1. Cleaning

Warning

- Local rules and regulations must be followed to clean and sterilize the transducer.
- Transducer is designed for multiple patient multiple use with the limitation on reuse and reprocessing (100 times). Prior to each use, transducer must be cleaned and sterilized.
- The transducer was not verified for cleaning using ultrasonic cleaning machine or any other auto washer-disinfectors. Do not clean the transducer in this way.

Precaution

- Unplug the transducer from the compatible instruments, and thoroughly inspect the transducer for any signs of damage, cracks, or improper mechanical function. Do not use transducer if there are signs of damage.
- To prolong the life of the transducer, keep it from contacting other metal instruments during the cleaning and sterilization.

5.1.1 Prepare a neutral pH detergent or a neutral pH enzymatic detergent according to the manufacturer's directions. The following detergent is approved for use with the transducer:

CIDEZYME® XTRA, dispense 8 ml per liter of water as required.

5.1.2 Use a soft, clean cloth lightly moistened with the cleaning solution to manually clean the surfaces and the connectors for five (5) minutes. Do not soak the transducer during the cleaning process. Transducer must be thoroughly cleaned. Do not clean transducer with a scratch pad or other abrasives.

5.1.3 Thoroughly rinse the transducer under clean, warm, running tap water for three (3) minutes to remove the residual detergent and blood. Do not rinse the Transducer Plug.

5.1.4 Clean the Contact Ring using 75% alcohol pad.

5.1.5 If visible contaminants are present, repeat the cleaning process.

5.2. Sterilization

Warning

- The dissector must be removed from the transducer for effective sterilization.
- The transducer must be sterilized prior to each use.
- Handling of the transducer should follow hospital protocol throughout the cleaning and sterilization process.

Note

- Repeat autoclaving may tarnish the transducer surface.
- The table below includes the minimum temperature and time validated to assure sterility.
- Please review the appropriate guidelines, standards and national Health Authorities' guidelines when determining acceptable steam sterilization process parameters for use in each respective country.
- The following sterilization cycle was validated by Saints Sages with the instrument wrapped.

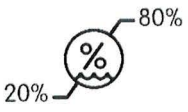
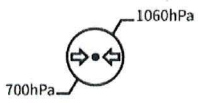
5.2.1 Steam Sterilization – Wrapped(A):

Method	**Type**	**Sterilize Time**	**Temperature**	**Dry Time**
Wrapped	Prevacuum	4 min.	132°C (270°F)	30 min.

5.2.2 Steam Sterilization – Wrapped(B):

Method	**Type**	**Sterilize Time**	**Temperature**	**Dry Time**
Wrapped	Prevacuum	5min-10min.	134°C (273.2°F)	30 min.

6. Symbols

No.	Symbols	Meaning
1		Manufacturer
2		Importer
3		Consult the User Manual or Instructions for Use
4		Serial Number
5		Batch Number
6		Country of Manufacture /Date of Manufacture
7		Medical Device
8		Temperature Limitation: -20℃～55℃
9		Humidity Limitation: 20%～80%
10		Atmospheric Pressure Limitation: 700hPa ~ 1060hPa
11		Catalogue Number

No.	Symbols	Meaning
12		Unique Device Identifier
13		For Prescription Use Only
14		Contain substances that can be carcinogenic, mutagenic, reprotoxic (CMR), or substances with endocrine disrupting properties
15		Not Made with Natural Rubber Latex
16		Environmental Protection Use Period
17		Non-Sterile
18		Quantity: 1
19		This way up
20		Fragile, handle with care
21		Keep dry

7. Service and Warranty

The transducer is designed to be used up to 100 times beyond the date of purchase, whichever comes first. It is not designed to use over the limit (100 times).

Incident Reporting

Any serious incident that has occurred in relation to this device should be reported to Saints Sages and the competent authority of the European Union member state in which the user and/or patient is established.

Technical Support

For additional information about the use of the devices hereof, contact Saints Sages at one of the following.

Service Hotline: +86-4006196507

Email: service@snssurgical.com.cn

www.snssurgical.com.cn

8. Environmental Safety

8.1. EU 2011/65/EU (RoHS)

The transducer has been assessed and/or tested in a typical configuration as described in this user manual in accordance with the Directive and standards listed below:

- EU Directive 2011/65/EU and amendments
- EN IEC 63000:2018

8.2. REACH

The EU REACH Regulation 1907/2006 requires to provide chemical content information for Substances of Very High Concern (SVHC), if they are present in the relevant article above a concentration of 0.1% weight by weight. Information on substances, contained in the SAT01 Transducer, can be found on the website: www.snssurgical.com.cn/en/support.

8.3. Disposing of SAT01 Transducer

The transducer must not be disposed in trash at the end of life with other waste. It may contain hazardous substances that can cause serious environment pollution. To recycle waste equipment, obtain instructions from Saints Sages Service Hotline (4006196507), contact your local sales representative, or dispose of this product according to local regulation.

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www.snssurgical.com.cn

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Rev: Feb.2024

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