SanAgile™ Dissector

en: Instructions for Use

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

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

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

Compatible with:

SAG01 Generator (SW V1 and above)

SAF01 Footswitch

SAT01 Transducer

SA10 Portable Controller (SW V1 and above)

SAA01 Connector (SW V1 and above)

Please read all information carefully.

This Instructions for Use is designed to provide instructions to use SanAgile™ Dissectors. 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. Failure to properly follow the instructions may lead to serious surgical consequences.

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

SanAgile™ Dissectors do not contain substances that can be carcinogenic, mutagenic, reprotoxic (CMR), or substances with endocrine disrupting properties.

SanAgile™ Dissectors are not made with natural rubber latex.

Rx ONLY Precaution: Federal (USA) law restricts this device to sale by or on the order of a physician.

This Instructions for Use is for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed.

Table of Content

1 Overview

1.1 Product Characteristics

SanAgile™ Dissector is designed to use with the compatible instruments to transect, dissect and coagulate tissue. When assembled, the dissector can be used for tip coagulation, blunt hemostasis, sharp transection, and tissue dissection.

The dissector is designed to cut and coagulate the tissue through different output power settings. The MAX setting is designed for dissection and the MIN setting is for coagulation. The clinical intended use is achieved by the surgeon when pressure is applied to tissue placed between the Clamp Jaw and the exposed portion of the Tissue Blade while ultrasonic energy is activated through the use of two output power settings.

Figure 1：SanAgile™ Dissector

1.2 Devices and Components

The devices covered in this Instructions for Use is SanAgile™ Dissectors.

Please refer to the compatible instructions: SAG01 Ultrasonic Surgical Generator User Manual, SAT01 Transducer Instruction, SA10 Control User Manual and SAA01 connector instruction for Use respectively for the details on the compatibility.

1.3 Intended Purpose

SanAgile™ Dissectors are intended to seal and cut vessels and/or to dissect, coagulate and cut soft tissue via ultrasonic oscillation.

1.4 Indications for Use

Compatible with SAG01:

SanAgile™ Dissector is indicated for vessel sealing and tissue incisions when bleeding control and minimal thermal injury are desired in general, plastic, gynecologic, urologic, thoracic surgeries, and other open or endoscopic procedures. The dissector can be used to coagulate isolated vessels up to and including 5 mm in diameter.

Compatible with SA10:

SanAgile™ Dissector is indicated for vessel sealing and soft tissue incisions when bleeding control and minimal thermal injury are desired in general, urologic, thoracic, gynecologic, thyroid and breast, plastic, pediatric, exposure to orthopedic structures (such as spine and joint space), sealing and transection of lymphatic vessels, and other open or laparoscopic procedures. The dissector can be used to coagulate isolated vessels up to and including 7 mm in diameter, using the MIN button.

1.5 Contraindication

- SanAgile™ Dissector is not indicated for incising bone.
- SanAgile™ Dissector 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.
- Do no place the dissector near or in contact with flammable materials such as gauze or surgical drapes. Dissector that is activated or hot from use may cause a fire.
- 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 dissectors and cables 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.

- After the compatible instrument is powered on, contacting the clamping jaws of the dissector is prohibited.
- Avoid accidental activation by attaching dissector and transducer to the compatible instrument.
- 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.

Infection hazard:

- Dissectors are provided in a sterile package. Do not use the dissector if the package is damaged or unintentionally opened.
- This product cannot be adequately cleaned and/or sterilized by the user to facilitate safe reuse and is therefore intended for single use. Attempts to clean or sterilize these devices without appropriate regulatory authorization may result in bio-incompatibility, infection, or product failure risks to the patient.

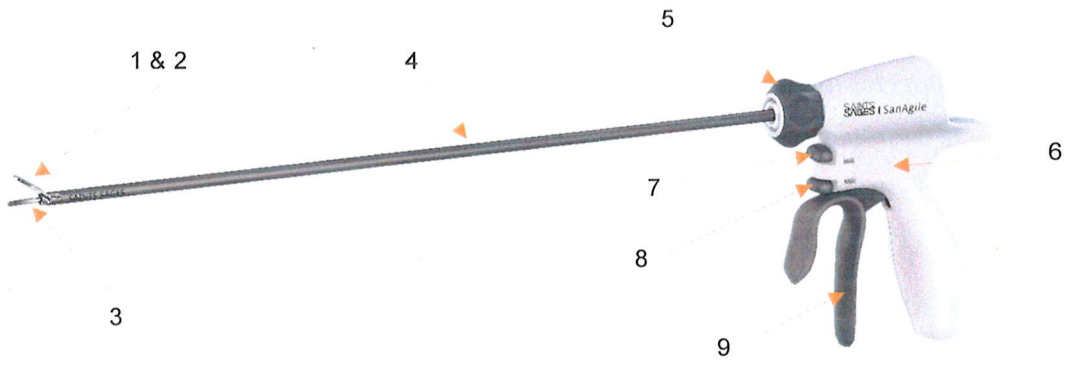
1.7 General Precaution

- Use only SanAgile™ Dissectors with the compatible instruments. Devices and components from other manufacturers are not compatible with the dissector and may cause injury to the patient and user.
- Keep the dissector jaws clean. Build-up of eschar or tissue may reduce the effectives of the dissector.
- No modification of the instrument is allowed.

2 Operation Instruction

2.1 Dissector Overview

Figure 2: Dissector Illustration



1	Clamp Jaw	Clamps or grasps tissue together with the tissue blade.
2	Tissue Pad	Attached to clamp jaw to grasp tissue.
3	Tissue Blade	Delivers energy to cut and coagulate tissue.
4	Shaft	Holds the tissue blade with the appropriate diameter to access target tissue.
5	Rotation Wheel	Used to lock the transducer and rotate the clamp jaw.
6	Grip Housing	Used to fix shaft, rotation wheel and clamp jaw lever. Provides a handle with buttons to activate the dissector.
7	MAX Button (above)	Activates maximum power when pressed.
8	MIN Button (below)	Activates minimum power when pressed.
9	Clamp Jaw Lever	Controls the opening and closing of the jaw.

2.2 Assembly Instruction

Warning:

- SanAgile™ Dissector is intended for use with the compatible Instruments. The use of any incompatible instrument may not result in the desired clinical effect. Please do not use the incompatible instruments with these dissectors.

Precaution

- The dissector jaws may remain open when in the package. Do not try to close the jaws

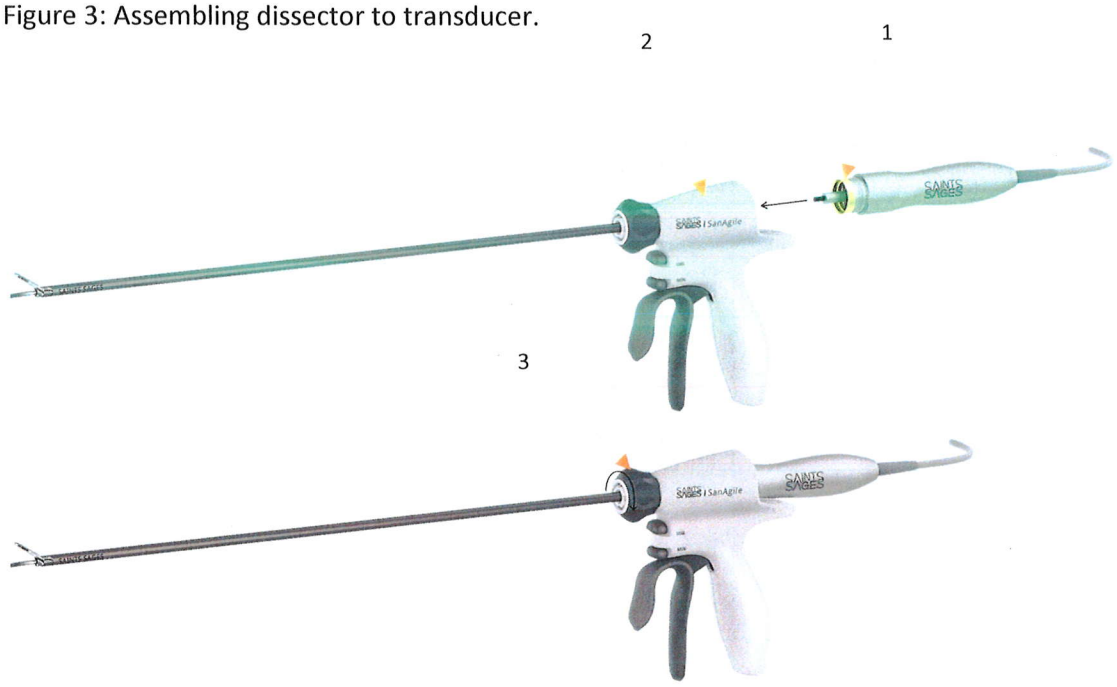
during the assembly.

- Dissectors are supplied in sterile. Follow the Unseal symbol to open the sterile package. Only assemble the dissector in the sterile area before the procedure. To avoid damage, do not flip the dissector into the sterile area.

2.2.1 Using sterile technique to remove the dissector from the package. Examine the dissector for damage. Do not use the damaged dissector. If the package of dissector is damaged or unintentionally opened, please replace with a new dissector.

2.2.2 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: Assembling dissector to transducer.



2.2.3 Connect the Transducer Plug into the receptacle on the compatible instruments refer to the compatible instruments' instruction for the connection.

2.3 Operation

Precaution

- Verify the connection between the compatible instruments, transducer and dissector are secured and ready for use.
- Do not insert or extract the dissector with the jaws open through a trocar sleeve as this may damage the dissector.

2.3.1 Press MAX and MIN Buttons of the dissector respectively to check the audio tone and adjust the volume if required.
If compatible with SAG01 generator, repeat with the footswitch by pressing the Right and Left Pedals for the same purpose, until the audio tone can be heard clearly.

2.3.2 Close the jaws by pressing the Clamp Jaw Lever if the jaws remain open, and push the dissector shaft into a trocar of the diameter > 5 mm.

2.3.3 Open the jaws until the dissector shaft is fully inserted.

2.3.4 The dissector shaft can be rotated 360° using the Rotation Wheel to facilitate visualization and access to the target tissue.

2.3.5 Position the tissue within the jaws at the desired location and check no other metal or hard objects within the jaws before activation.

Warning

- Avoid contact with any or all metal or hard objects when the compatible instrument is activated. Contact with staples, clips or other instruments while the compatible instrument is activated and energy is delivered may result in scratches on the blade, cracked or broken blades and premature blade failure.

2.3.6 Press the Clamp Jaw Lever from the dissector to clamp the targeted tissue between jaws and press the dissector button to activate the energy until the tissue is divided. An audible tone can be heard until the end of the activation.

2.3.7 Release the dissector button after a complete sealing and division are achieved, open the jaws and carefully remove from the targeted tissue. Check if the tissue is coagulated and vessel is sealed. If bleeding is observed, regrasp and create a second seal adjacent to the first seal or use appropriate techniques to maintain hemostasis.

2.3.8 If compatible with SAG01 generator, the footswitch pedal is alternative for 2.3.6 and 2.3.7.

Warning

- If activation is unintentionally stopped while sealing, maintain jaws closure and reactivate it. Releasing the Clamp Jaw Lever while sealing may result in lack of hemostasis.

Note

- Through the study, the dissector has been verified for a quick tissue dissection using the MAX setting, and the coagulation of vessels using the MIN setting. The complete study data is available upon request.

2.4 Disassembly Instruction

2.4.1 Close the jaws by pressing Clamp Jaw Lever and remove the shaft from trocar.

2.4.2 Unplug the Transducer Plug from the compatible instrument.

2.4.3 Power off the compatible instrument according to the compatible instruments User Manual.

2.4.4 Hold the transducer in one hand, turn the Rotation Wheel (1) counterclockwise by the other hand. 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: Disassembly Diagram

2.4.5 Discard the dissector in an appropriate container and dispose it according to the applicable local regulation. Transducer can be cleaned and sterilized for the next use. Please refer to the Instructions of Use of the transducer for the details.

Note

- Refer to the compatible instruments User Manual for LED indicator color definition and audio feedback.

3 Patient and Operation Room Safety

3.1 Before a Procedure

Precaution

- Use only SanAgile™ Dissector with the compatible instruments. Devices from other manufacturers are not compatible with the dissector and may cause injury to the patient and the operator.

3.1.1 Visually inspect the dissector and the compatible devices 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.

3.1.2 Dissector is supplied sterile for single use. Do not use the dissector if the sterile package is unintentionally opened, damaged, or has exceeded the expiration date.

3.1.3 The dissector is intended to be used with a 5mm trocar when used laparoscopically.

Verify proper trocar size and compatibility prior to using the device in a procedure.

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

3.2 During a Procedure

3.2.1 Tissue Pad damage may occur if the dissector is activated without tissue in the closed jaws. Activation without tissue between the jaws will cause tissue pad degradation.

3.2.2 Close the dissector jaws before inserting or extracting from a trocar to prevent damage to the jaws and trocar.

3.2.3 Do not overfill the jaws of the dissector with tissue as this may reduce device performance.

3.2.4 The surgeon may inspect the seal after cutting the vessel or tissue. If there is bleeding, the surgeon should create a second seal adjacent to the first seal or use appropriate techniques to maintain hemostasis. Failure to inspect the vessel may cause serious injury to the patient.

3.2.5 Avoid grasping any objects other than vessels and tissue. The jaws may be damaged during the activation if any other objects are in the jaws of the dissector.

3.2.6 Avoid contact with the dissector jaws when the generator is activated. Do not contact with any or all metal or hard objects, or bone during the activation.

3.2.7 Place the vessel or tissue in the center of the jaws when using SanAgile™ dissector to assure optimal hemostatic effect. Do not place the vessel and/or tissue in the jaw hinge. Do not drag the tissue.

3.2.8 Keep the external surface of the dissector jaws away from the adjacent tissue while activating the dissector or unintended injury may occur.

3.2.9 Stop the activation immediately after vessel sealing and cutting are complete.

3.2.10 Keep the jaws clean during use. Buildup of eschar and tissue may reduce the effectiveness of the dissection and coagulation functions and cause abnormally high temperatures at the distal end of the dissector. Carefully wipe the Clamp Jaw, Tissue Pad and Tissue Blade with a wet gauze, or submerse the distal end in a sterile saline batch and activate as needed. Keep the jaws away from the metal objects.

3.2.11 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.

3.3 After a Procedure

3.3.1 Discard the dissector after use and dispose it according to the local requirements and regulations.

Warning

- SanAgile™ dissector cannot be adequately cleaned or sterilized for safe reuse and is , therefore intended for single use. Attempts to clean and sterilize the dissector for reuse may result in infection or product-failure risks to the patient and operator.

3.4 Undesirable Side Effects/Residual Risks

Undesirable side effects and risks associated with SanAgile™ dissector include but not limited to:

- Potential for bleeding such as poor coagulation and post-hemorrhage
- Soft tissue injury via thermal damage
- Inflammatory or unintended tissue reaction at the incision
- Introduction of non-sterile surfaces or pathogen transfer
- Unintended harm, extended surgery or altered surgical approach may result from issues related to unintentional device activation, damaged devices, etc.

3.5 Incident Reporting

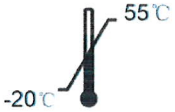
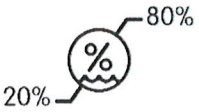
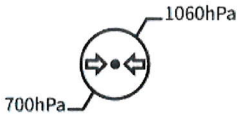
Any serious incident that has occurred in relation to this device should be reported to Saints Sages and the competent authority of the European Union member state in which the user and/or patient is established.

4 Specifications

Protection Against Electric Shock	Class I, CF Applied Part	
Output	Tip Vibration Frequency	55.5kHz±2%
Transport and Storage Conditions	Ambient Temperature	-20°C～55°C
	Relative Humidity	20%～80%, no condensing
	Atmosphere Pressure	700hPa～1060hPa

5 Symbols

No	Symbols	Meaning
1		Manufacturer
2		Importer
3		Type CF Applied Part
4		Do not re-use
5		Consult the User Manual or Instructions for Use
6		Batch Number
7		Use-by Date
8		Do not use if package is damaged and consult Instructions for Use
9		Country of Manufacture /Date of Manufacture
10		Medical Device

No	Symbols	Meaning
11		Temperature Limitation: -20℃～55℃
12		Humidity Limitation: 20%～80%
13		Atmospheric Pressure Limitation: 700hPa～1060hPa
14		Single sterile barrier system with protective packaging outside, and Sterilized using Ethylene Oxide
15		Single sterile barrier system, and Sterilized using Ethylene Oxide
16		Unseal the sterile package
17		Quantity: 6
18		Catalogue Number
19		Unique Device Identifier
20		For Prescription Use Only

No	Symbols	Meaning
21		Not Made with Natural Rubber Latex
22		Does not contain substances that can be carcinogenic, mutagenic, reprotoxic (CMR), or substances with endocrine disrupting properties

6 Environmental Safety

6.1 EU 2011/65/EU (RoHS)

The SAG01 Generator, SanAgile™ Dissectors, SA10 Portable Controller, SAA01 Connector and accessories have 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

6.2 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 SAG01 Generator, SanAgile™ Dissectors, SA10 Portable Controller, SAA01 Connector and accessories, can be found on the website: www.snssurgical.com.cn/en/support.

Rx
ONLY

MD

Shanghai Saints Sages Surgical Co., Ltd.
No.19, Lane 388, Shengrong Road, Pilot Free Trade Zone,
201210 Shanghai, People's Republic of China

Part Number: IFU-SA-002EN

Rev: Feb.2024

www.snssurgical.com.cn