SanAgile™

Ultrasonic Surgery Advanced Dissector

en: Instructions for Use

REF SASD45, SanAgile™ Advanced Dissector, 5.5mm, 45cm, Curved

SASD36, SanAgile™ Advanced Dissector, 5.5mm, 36cm, Curved

SASD23, SanAgile™ Advanced Dissector, 5.5mm, 23cm, Curved

SASD14, SanAgile™ Advanced Dissector, 5.5mm, 14cm, Curved

Compatible with:

SA10 Portable Controller (SW V1 and above)

Please read all information carefully.

This Instructions for Use is designed to provide instructions to use SanAgile™ Ultrasonic Surgery Advanced Dissector. 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™ Advanced Dissectors may contain substances that can be carcinogenic, mutagenic, reprotoxic (CMR), or substances with endocrine disrupting properties.

SanAgile™ Advanced 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™ Advanced Dissector is a sterile, single patient use instrument used with SA10 Portable Controller to transect, dissect and coagulate tissue in general, urologic, thoracic, gynecologic, thyroid and breast, plastic, exposure to orthopedic structures (such as spine and joint space), sealing and transection of lymphatic vessels, and other open or laparoscopic procedures. When assembled, the dissector can be used for tip coagulation, blunt hemostasis, sharp transection and tissue dissection.

SanAgile™ Advanced Dissector is designed to cut and coagulate the tissue through two different activation buttons. The MAX button is designed for dissection and the MIN button 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 buttons.

Figure 1：SanAgile™ Advanced Dissector

1.2 Devices and Components

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

Please refer to SA10 Portable Controller User Manual for the details on the compatibility.

1.3 Intended Purpose

SanAgile™ Ultrasonic Surgery Advanced 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

SanAgile™ Ultrasonic Surgery Advanced Dissectors are 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, exposure to orthopedic structures (such as spine and joint space), sealing and transection of lymphatic vessels, and other open or laparoscopic procedures.

The dissectors can be used to coagulate isolated vessels up to and including 7 mm in diameter, using the MIN button.

1.5 Contraindications

- SanAgile™ Advanced Dissector is not indicated for incising bone.
- SanAgile™ Advanced 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. Dissectors that are 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 SA10 Portable Controller.
- 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 Controller is powered on, contacting the clamping jaws of the dissector is prohibited.
- Avoid accidental activation by attaching dissector to the Controller. Accidental activation of the Advanced Dissector can cause serious injury to the patient or surgical team.

- Do not activate the Advanced 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 in order 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™ Advanced Dissectors with SA10 Portable Controller. Devices and components from other manufacturers are not compatible with SanAgile™ Advanced 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 instruments is allowed.

2 Operation Instruction

2.1 Advanced Dissector Overview

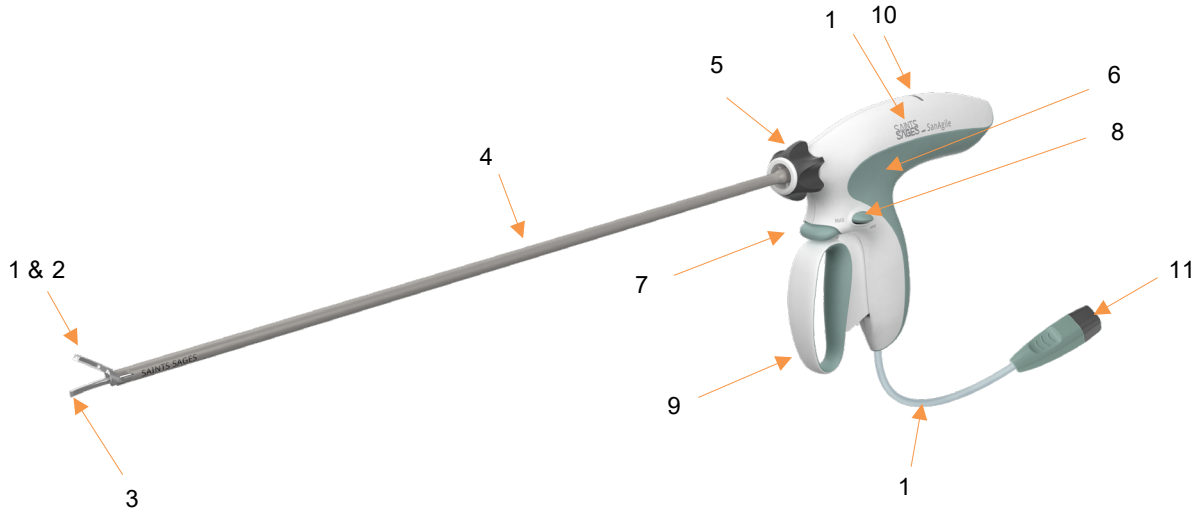


Figure 2: Advanced Dissector Illustration

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 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 (front)	Activates maximum power of the Controller when pressed.
8	MIN Button (right and left)	Activates minimum power of the Controller when pressed.
9	Clamp Jaw Lever	Controls the opening and closing of the jaw.
10	Dissector Status LED	Displays the dissector status and turns into different colors to indicate different usage status when dissector is connected.
11	Dissector Plug	Used to connect to the Controller.
12	Speaker	Emits tones signifying the dissector status.
13	Dissector Cable	The Dissector Cable is between the Dissector Plug and Grip Housing.

2.2 Assembly Instruction

Warning:

- SanAgile™ Advanced Dissector is intended for use with SA10 Portable Controller. The use of any incompatible ultrasonic surgical generator may not result in the desired

clinical effect of SanAgile™ portfolio. Please do not use the incompatible generator 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.
- Prior to assembly, please follow SA10 Portable Controller User Manual to ensure the Controller completes self-testing and the Controller Status LED is on.

2.2.1 Using sterile technique to remove the dissector from the package. Examine the dissector for damage. Do no use the damaged devices. If the package of dissector is damaged or unintentionally opened, please replace with a new dissector.

2.2.2 Place the Portable Controller on a cart, if available, or any other suitable fixture in the appropriate position. The Controller can also be hung to the cantilever support of boom system or cart with strap or hook.

2.2.3 Hold the Controller in one hand, connect the power cord to the Power Cord Receptacle (AC IN Port) on the Controller and to a grounded electrical outlet. The power requirements for the Controller are listed in the Controller User Manual.

2.2.4 After the power cord is connected to the Controller, the Controller runs the self-test. The Controller Status LED illuminates green with breathing when the self-test succeeds.

2.2.5 Hold the controller in one hand, connect the Dissector Plug (1) into Instrument Receptacle (Dissector Port) (2) on the Controller.

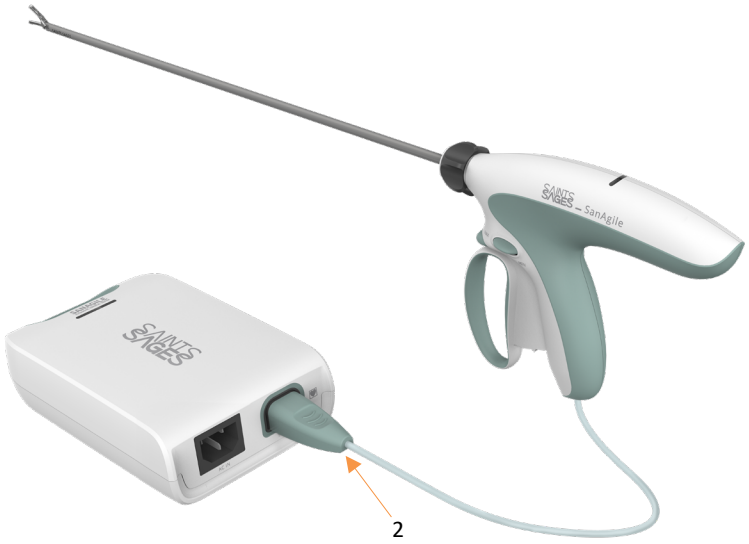


Figure 3: Connecting dissector to Portable Controller

2.2.6 When the dissector plugs in to the Controller, and the dissector will run the self-check. Once succeeds, the Dissector Status LED will illuminate green with an audio signal to beep three pulses.

Figure 4: Dissector Status LED Illuminates Green and Audio Tone Beeps

2.3 Operation

Precaution

- Verify the connection between the Controller 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 Prior to the surgery, keep the jaws open, press MAX and MIN buttons of the dissector respectively to check the audio tone and Dissector Status LED works.

2.3.2 When press MAX Button, the status LED illuminates cyan with flashing, at the same time, a high pulsating audio tone repeats quickly with short intervals from the dissector.

2.3.3 When press MIN Button, the status LED illuminates cyan with flashing, at the same time, a low pulsating audio tone repeats slowly with long intervals from the dissector.

Figure 5: Dissector Status LED Illuminates Cyan and Audio Tone Repeats

Note

- When the Dissector Status LED changes to yellow or red, please refer to Section 5, **Troubleshooting** for the resolution.
- When the dissector is being activated by either MAX button or MIN button, the Controller Status LED always keeps green with breathing, i.e., the Controller Status LED repeats from off to green.

2.3.4 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.

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

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

2.3.7 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 Controller is activated. Contact with staples, clips or other instruments while the Controller is activated and energy is delivered may result in scratches on the blade, cracked or broken blades and premature blade failure.

2.3.8 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 from the dissector can be heard until the end of the activation.

2.3.9 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.

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, SanAgile™ Advanced Dissector has been verified for a quick tissue dissection using the MAX setting, and the coagulation of vessels up to and including 7mm in diameter using the MIN setting, when connecting to SA10 Portable Controller. 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 Dissector Plug from the Controller.

2.4.3 Unplug the power cord.

2.4.4 Discard the dissector in an appropriate container and dispose it according to the applicable local regulation.

3 Patient and Operation Room Safety

3.1 Before a Procedure

Precaution

- Use only SanAgile™ Advanced Dissector with SA10 Portable Controller. Devices from other manufacturers are not compatible with the Controller and may cause injury to the patient and the operator.

3.1.1 Visually inspect the dissectors 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 trocar of the diameter > 5 mm 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 Controller in case of the failure.

3.2 During a Procedure

3.2.1 Tissue Pad damage may occur if the Controller 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 Controller 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™ Advanced

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.

3.3 After a Procedure

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

Warning

- SanAgile™ Advanced 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 the ultrasonic surgery 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%
	Primary Tip Vibration Excursion	80μm±8 (MAX) 50μm±8 (MIN)
Transport and Storage Conditions	Ambient Temperature	-20℃～55℃
	Relative Humidity	20%～80%, no condensing
	Atmosphere Pressure	700hPa～1060hPa
Dissector Cable	3m	

5 Troubleshooting

Note

- When the dissector is being activated, the Controller Status LED always keeps green with breathing, i.e., the Controller Status LED repeats from off to green, even if Dissector LED is in yellow or red.

General troubleshooting and Status LED Indicator.

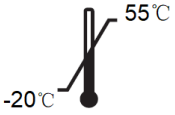
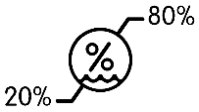
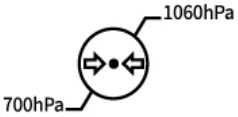
Dissector LED	Tone	Cause	Solution
LED is off 	N/A	The Dissector Plug is not connected to the Portable Controller.	Please check if the dissector is connected to the Portable Controller first, then connect the Dissector Plug into the Portable Controller.
	N/A	The dissector cable is damaged.	Please re-plug the dissector plug into the Portable Controller first. If LED keeps off, then exchange with a new dissector.
	N/A	The Controller Status LED is red.	Please re-plug the power cord into the Controller first. If the Controller Status LED keeps

Dissector LED	Tone	Cause	Solution
			red, then exchange with a new Controller.
	N/A	The Controller is not powered on (the power cord is disconnected).	Please check if the power cord is connected to the Portable Controller and wall outlet first, then plug the power cord into the Portable Controller and wall outlet.
	N/A	The Controller is damaged.	Please check Controller Status LED first. If not lit, then exchange with a new Controller.
Yellow Light 	Four Pulses	Dissector is activated over 20s.	Please release the dissector button immediately. The dissector can be re-activated immediately after release.
		Dissector jaws are over-closed.	Please release jaw lever. Do not apply excessive force to the jaw lever when grasping tissue.
		The dissector shaft is damaged.	If the Dissector Status LED keeps yellow when the dissector is activated each time, exchange with a new Dissector.
		Press the MAX and MIN buttons at the same time.	Please check if the MAX and MIN buttons were pressed at the same time first, then release the buttons and re-press the MAX or MIN button.
Red Light	Three Pulses	The dissector self-test fails.	Please re-plug the dissector plug into the Portable Controller first. If it still exists, then exchange with a new Dissector.

Dissector LED	Tone	Cause	Solution
		The dissector loses communication with the Controller or detects an error.	Please re-plug the dissector plug into the Portable Controller first. If it still exists, then exchange with a new Dissector.
		The dissector is damaged.	Please re-plug the dissector plug into the Portable Controller first. If it still exists, then exchange with a new Dissector.

6 Symbols

No	Symbols	Meaning
1		Manufacturer
2		Authorized Representative in the European Community/European Union
3		Importer
4		Type CF Applied Part
5		Do not re-use
6		Consult the User Manual or Instructions for Use

No	Symbols	Meaning
7		Batch Number
8		Use-by Date
9		Do not use if package is damaged and consult Instructions for Use
10		Country of Manufacture /Date of Manufacture
11		Medical Device
12		Temperature Limitation: -20℃～55℃
13		Humidity Limitation: 20%～80%
14		Atmospheric Pressure Limitation: 700hPa ~ 1060hPa
15		Single sterile barrier system with protective packaging outside, and sterilized using Ethylene Oxide
16		Single sterile barrier system, and sterilized using Ethylene Oxide

No	Symbols	Meaning
17		Unseal the sterile package
18		Quantity: 6
19		Catalogue Number
20		Unique Device Identifier
21		For Prescription Use Only
22		CE Mark with Notified Body Number
23		Contain substances that can be carcinogenic, mutagenic, reprotoxic (CMR), or substances with endocrine disrupting properties
24		Not Made with Natural Rubber Latex
25		This way up
26		Fragile, handle with care
27		Keep dry
28		INMETRO Seal with OCP number

7 Environmental Safety

7.1 EU 2011/65/EU (RoHS)

The dissectors have been assessed and/or tested in a typical configuration as described in this Instructions for Use in accordance with the Directive and standards listed below:

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

7.2 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 Controller and accessories, can be found on the website: www.snssurgical.com.cn/en/support.

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Rev. Feb./2025

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