TITAN STAPLER INSTRUCTIONS FOR USE

TITAN Standard Gastric Stapler Instructions for Use
PRODUCT CODE: SGS23R, SGS23Rb

Please read all information carefully

Failure to properly follow instructions may lead to serious surgical consequences such as leakage or disruption.

Important: This package insert is designed to provide instructions for use for the Titan Stapler. It is not a reference to surgical techniques.

INTENDED USE
Intended for transection and resection of gastric tissue.

INDICATIONS FOR USE
The Titan SGS® linear cutter is intended for longitudinal transection and resection of gastric tissue for sleeve gastrectomy pouch creation.

CONTRAINDICATIONS
- Do not use the Titan Stapler on tissues that are necrotic, friable, or have scar tissue or alerted integrity, e.g. ischemic or edematous tissue.
- Do not use the Titan Stapler on patients that have had prior gastric surgery in the area where the stapler will be utilized.
- Evaluate tissue thickness carefully before firing any stapler. Refer to the table below for tissue compression requirements (closed staple height). Do not use Titan Stapler on tissues outside of the indicated tissue thickness range.
- This instrument is not intended for use when surgical stapling is contraindicated.

WARNINGS
- Do not use the Titan Stapler if damaged or if packaging is open or damaged.
- Do not resterilize/reuse the Titan Stapler. Reuse can lead to infection or transmission of bloodborne pathogens to patients and users.
- Use the Titan Stapler in accordance with these instructions for use. Improper use may cause serious injury.
- The Titan SGS® is indicated for use in gastric tissue, and is not intended to cross, divide, and seal major blood vessels. Do not use Titan SGS® on major blood vessels as hemostasis cannot be assured.
- Read all sections of this insert prior to use.
- Use caution when using Titan SGS® in patients with elevated risk for bleeding, such as those undergoing systemic anticoagulation or use of antiplatelet agents, as use of the device in this patient population has not been studied.
- Prior to firing, visually inspect for inclusion of unintended anatomic structures within the staple line.
- When positioning the stapler on the application site, ensure there are no intralumenal objects, such as bougies, tubes or probes within the jaws of the device. Firing over an obstruction may result in incomplete cutting or improperly formed staples.

WARNINGS CONTINUED
- Do not attempt to use on a resection line longer than 22cm.
- If a stapler malfunction occurs while applying the staples across a blood vessel, the user should clamp or ligate the vessel before releasing the stapler while the stapler is still closed on the tissue.

PRECAUTIONS
- Do not modify this equipment without authorization from the manufacturer.
- Inspect the package for shipping damage. Do not use an instrument that has shipping damage.
- Before using, remove the red-colored staple retaining cap and observe the surface of the cartridge. If any yellow- or orange-colored drivers are visible, DO NOT USE as staples may be missing.
- When placing the instrument through the trocar or incision, avoid inadvertently activating the trigger. The instrument may partially open and will provide an audible error.
- During insertion into and removal from the peritoneal cavity, the Titan Stapler must be fully closed. Open jaws will cause difficult insertion or withdrawal of the instrument and may result in damage to the instrument or patient injury.
- Use caution when closing the Titan Stapler jaws on tissue.
- Ensure there is no tissue in the “NO TISSUE ZONE” of the stapler (i.e. the proximal end of the stapler jaws). Closing on tissue in the “NO TISSUE ZONE” may result in tissue damage. Stapling tissue in this area of the device may result in tissue being transected without staples.
- Ensure that the tissue is flat and positioned properly between the jaws prior to closure. “Bunching” of tissue along the length of the jaws may lead to an incomplete staple line.
- The device jaws will not close on tissue too thick for stapling. If the jaws do not close, do not use the Titan Stapler.
- When stapling any tissue, careful consideration should be given to existing pathologic conditions as well as any pre-surgical treatment such as radiotherapy that the patient may have undergone.
- Do not partially fire the instrument. Incomplete firing can result in malformed staples, incomplete cut line, bleeding, and leakage from staple line and/or difficulty removing instrument.
- If the clamping mechanism becomes inoperative, and the jaws do not clamp on tissue, do not fire the instrument. Remove and do not continue to use the instrument.
- If the firing mechanism becomes inoperative, do not continue to use the instrument.
- If the device becomes inoperative during use the device can be manually operated by removing the motor unit and using the bailout chuck.
- Before removing the instrument, be sure tissue is cleared from the jaws and then close the jaws.

PRECAUTIONS CONTINUED

- After removing the instrument, examine staple line for pneumostasis/hemostasis and proper staple closure. Minor bleeding can be controlled with manual sutures or other appropriate techniques.
- Certain conditions or preoperative treatments may cause changes in tissue thickness that would exceed the indicated range of tissue thicknesses for the Titan Stapler.
- Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.
- When using other technologies (e.g. electrocautery) in the procedure, observe precautions of the original equipment manufacturer to avoid the hazards associated with their use.
- Minimally invasive instruments may vary in diameter 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.
- Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.
- Dispose of all opened instruments whether used or unused. This device is packaged and sterilized for single use only.

DEVICE DESCRIPTION

The Titan stapler is a sterile, single patient use instrument used for resecting and stapling the stomach during laparoscopic and open surgical procedures. The Titan Stapler is provided preloaded with staples, fires once, and cannot be reloaded. The staple and cut lines are approximately 23cm long. The Titan Stapler does not articulate. The average pneumatic burst pressure on stomach was measured to be 163 mmHg.

Staple Rows	Closed Staple Height	Staple Line Length	Number of Staples
6	1.2-2.2mm	23cm	342

Illustration of closed staple heights along device is depicted below[1].

MR CONDITIONAL

Non-clinical testing has demonstrated the implantable staples made of titanium in the Titan Stapler are MR Conditional. A patient with this device can safely be scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T and 3 T
- Spatial gradient magnetic field of 4,000 gauss/cm (40 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4W/kg (First Level Controlled Operating Mode)

Under the scan conditions defined above, the device is expected to produce a maximum temperature rise of less than 3 ºC after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 5 mm from the device when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

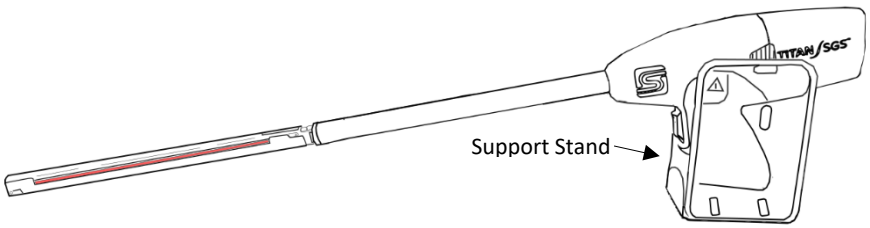
DIRECTIONS FOR USE

1. The Titan Stapler should be used on tissue easily compressible to 1.2mm as evaluated at the distal end of the device and 2.2mm at the proximal end of the device.

2. Examine the packaging of the device to ensure the sterility of the product has not been breached. Do not use the Titan Stapler if damaged or if packaging is open or damaged.

3. Remove the Titan Stapler from its package using sterile technique by grasping the device handle or the device shaft. Do not grasp the jaws of the device.

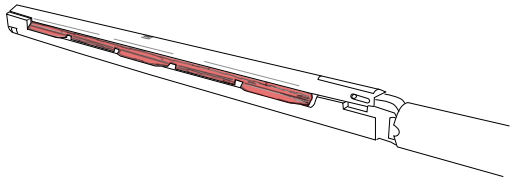
4. An optional device stand is included with the Titan Stapler. The device stand may be used to rest or prepare the stapler on a table but must be removed prior to use (see Step 10).



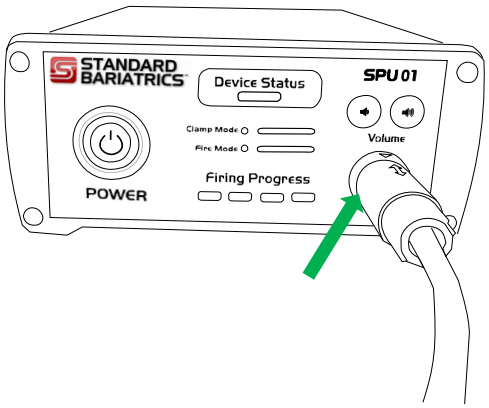
[1]Illustration of closed staple heights along device. Use on tissues easily compressible to the labeled closed staple heights.

Proximal End of Device Distal End of Device

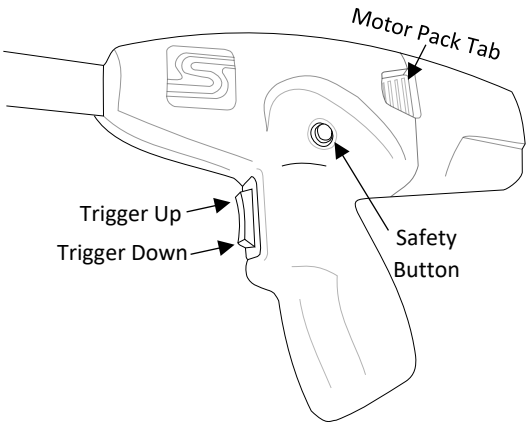
5. Examine the stapler for the presence of the red- colored staple retaining cap. If the retaining cap is not in place, discard the stapler.



6. [Reference the TITAN Standard Power Unit SPU01 Manual for setup and operation instructions] Connect the Titan Stapler plug connector to the power source by aligning the arrow on the SPU with the arrow on the connector housing, using a sterile technique. Listen for an audible click, or observe that a click can be felt, to ensure the Titan Stapler is fully connected to the SPU. If the click is not heard or felt, the Titan Stapler may not be fully connected to the SPU. Speaker will say “System Ready. Closure System Mode”



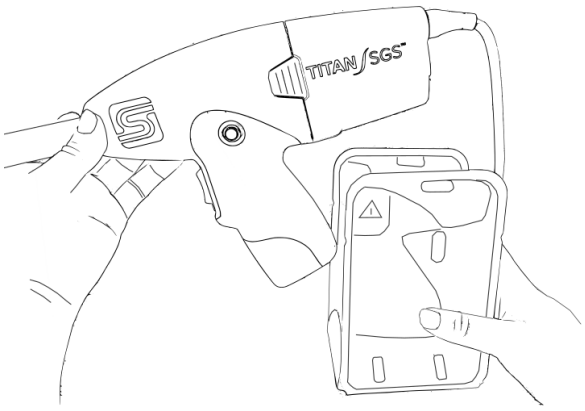
7. Open the jaws of the Titan stapler by holding the Trigger Up button. When the jaws are completely open, the speaker will say “Device open.”



8. Remove the red retaining cap. Examine the surface of the stapler cartridge. If any yellow- or orange-colored drivers are visible, do not use, as staples may be missing.

9. Close the jaws of the Titan Stapler by holding the Trigger Down button. When the jaws are completely closed, the speaker will say “Device closed.”

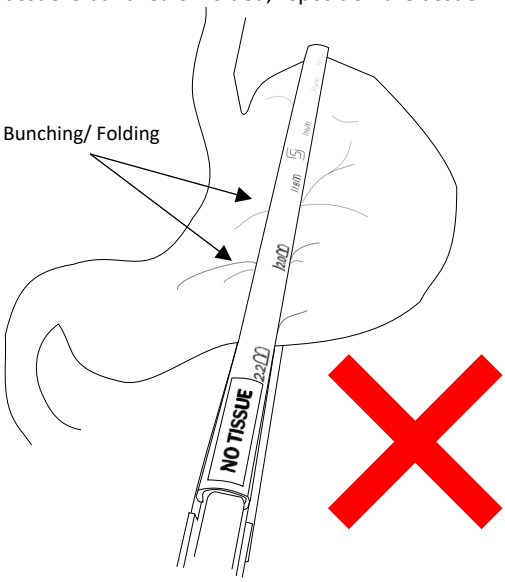
10. Carefully remove the Titan Stapler from its device stand.

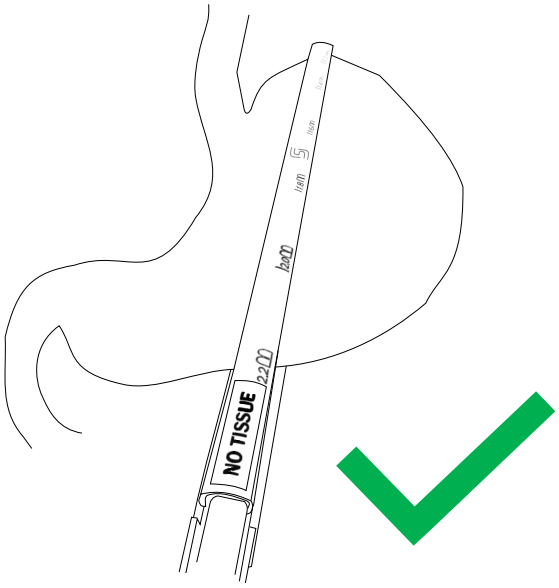


11. Insert the end effector of the Titan Stapler into a 19mm trocar. Ensure the red band around the shaft of the Titan Stapler has cleared the trocar cannula (and is visible) prior to opening the jaws of the Titan Stapler. Do not attempt to open the jaws of the Titan stapler before the jaws are completely through the trocar. Opening the jaws within the trocar will cause difficultly completing insertion and may result in damage to the instrument or patient injury.

12. Fully open jaws by holding the Trigger Up button until the speaker says “Device open.”

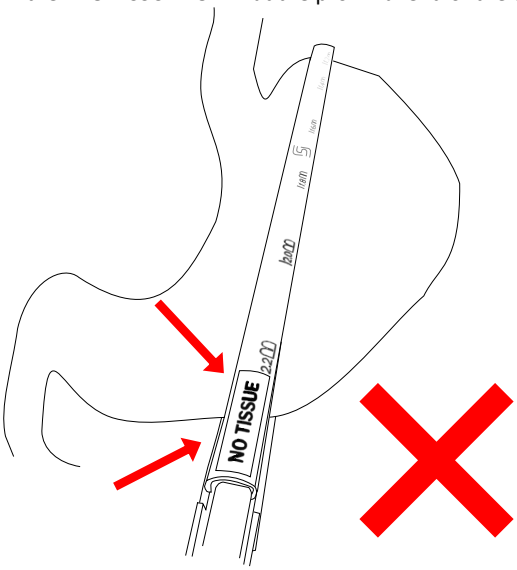
13. Advance the Titan Stapler to the target tissue and place the Titan Stapler jaws in the desired location ensuring tissue is flat and evenly distributed between the jaws and that no folds of tissue are created prior to closing the device. If tissue is bunched or folded, reposition the tissue.





14. Ensure that the jaws of the Titan Stapler are unobstructed and only tissue intended for resection is between the device jaws.

15. Prior to closure, ensure no tissue is inadvertently captured in the “NO TISSUE ZONE" at the proximal end of the device.



16. If tissue is in the “NO TISSUE ZONE”, open and reposition the jaws of the device such that there is no tissue in the “NO TISSUE ZONE”.

17. If the planned resection is longer than the Titan Stapler, do not use.

18. Close the jaws of the Titan Stapler by holding the Trigger Down button. To pause closing, let go of Trigger Down button. When the jaws are completely closed, the speaker will say “Device closed” and the Safety Buttons will blink.

19. Continue to Firing System Timeout by pressing one of the blinking Safety Buttons. Speaker will say “Timeout. Check jaws to ensure there are no tissue folds, no tissue is present in the no tissue zone and no unintended objects are clamped in the jaws. Press Safety button to acknowledge and enter firing mode.” and Safety Button will blink. If tissue and stapler are positioned to satisfaction, advance to Step 23.

20. If repositioning is necessary, re-enter Closure System Mode be pressing the Trigger Up button.

21. To open the jaws and readjust tissue sample, hold the Trigger Up button until jaws are open to a satisfactory level. To pause opening, let go of Trigger Up button. Ensure the jaws of the Titan Stapler device are visible and unobstructed prior to opening.

22. When tissue has been readjusted, close the jaws of the Titan Stapler by holding the Trigger Down button. When the jaws are completely closed speaker will say “Device closed.” and the Safety Buttons will blink. Return to Step 19.

23. Enter into Firing System Mode by pressing one of the blinking Safety Buttons. Speaker will say “Device Ready to Fire” and Safety Buttons will be illuminated green.

24. Once in firing mode, to fire the stapler ‘manually’, hold the Trigger Down button. When firing is complete, speaker will say “Firing Complete” and Safety Buttons will be off. To pause firing as needed, let go of the Trigger Down button. Speaker will say “Firing Paused”. To resume firing, hold Trigger Down button. If an obstruction is encountered during firing, the stapler will stop automatically, and the speaker will give an error message. Follow the instructions per the error message [see MANUAL BAILOUT DIRECTIONS as necessary].

25. Once in firing mode, to fire the stapler ‘automatically’, hold the Trigger Down button to begin firing and simultaneously depress one of the Safety Buttons. Release the Safety Button and the Trigger Down button. Speaker will say “Auto firing mode enabled”. The stapler will continue to fire, unless any button is depressed, until it reaches the end or an obstruction is hit. While device is firing automatically, depressing any button (Trigger Up, Trigger Down or Safety Buttons) will pause firing. Speaker will say “Firing Paused”. If an obstruction is encountered during firing, the stapler will stop automatically, and the speaker will give an error message. Follow the instructions per the error message [see MANUAL BAILOUT DIRECTIONS as necessary]. To resume firing, hold Trigger Down button (‘manual’) or hold the Trigger Down button and simultaneously depress one of the Safety Buttons to reenter ‘automatic’ mode.

26. Before opening the Titan Stapler jaws, ensure that the jaws are unobstructed. To open the Titan Stapler, hold the Trigger Up button. Speaker will say “Device open”. To pause opening, let go of the Trigger Up button. With the jaws open, ensure all tissue is disengaged from the Stapler. Close the jaws fully to ensure that the device may be removed from the trocar. Confirm the jaws are not closed on tissue prior to removal.

27. After removing the stapler, examine the staple lines for pneumostasis/ hemostasis and proper staple closure. Minor bleeding can be controlled with manual sutures or other appropriate techniques.

28. The Titan Stapler cannot be fired more than once.

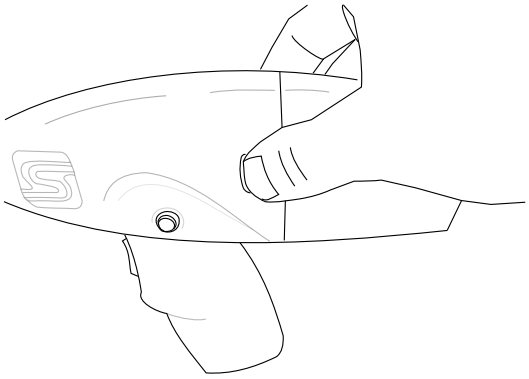
29. Dispose of the Titan Stapler per local ordinances.

MANUAL BAILOUT DIRECTIONS

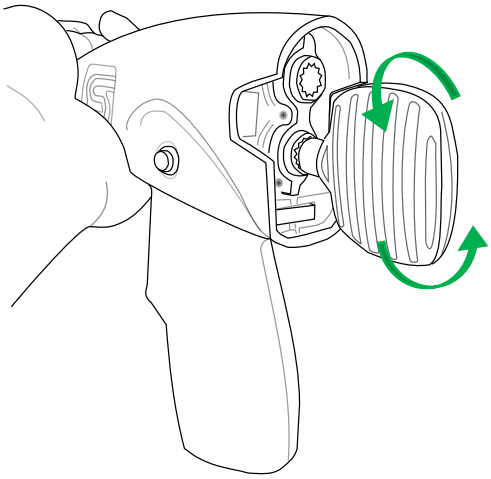
The manual bailout feature may be used in the rare event where an excessive force is experienced, due to a power loss or device malfunction with an audible prompt (power source Device Status indicator will illuminate red). Manual bailout should only be used if the device opening/ closing or firing modes are inoperable.

1. Disconnect the stapler from the power source.

2. Manually remove the motor pack from the back of the stapler by depressing the tabs on either side.



3. If the device is mid-fire, the knife can be manually reset (i.e. brought back to the starting position) by inserting the Bailout Key into the bottom (black) gear.



4. Rotate the Bailout Key counter-clockwise to retract the knife back to the start position (i.e. bring the knife back to the distal end of the jaws).

5. Stop rotating the Bailout Key when the knife has returned to the start position. Resistance will be encountered if attempting to continue rotating the Bailout Key once the knife has returned.

6. To manually open or close the device jaws, insert the Bailout Key into the top (metallic silver) gear. Rotate the Bailout Key clockwise to close the device jaws, and counter-clockwise to open the device jaws.

INSPECTION AND HANDLING

Titan Stapler devices are carefully inspected before shipment. Titan Stapler and packaging should be inspected upon receipt as packaging may become damaged in transit. All Titan Staplers must be inspected prior to use.
Instruments should be handled and operated by personnel completely familiar with their use. Handle the device with care at all times.

HOW SUPPLIED

The Titan Stapler is provided sterile and intended for single patient use. Ensure sterile packaging is intact prior to use. Dispose of device per local ordinances. Do not resterilize, reprocess or reuse.

PACKAGING AND STORAGE

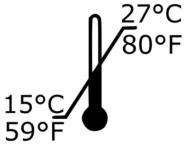
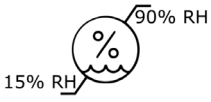
The Titan Stapler is provided in sterile packing and should be stored at room temperature. Avoid prolonged exposure to elevated temperatures. The Titan Stapler should always be handled with great care in transportation and storage.

QUESTIONS

For questions related to this product please contact Standard Bariatrics® customer service: 513-620-7751

SYMBOLS

Symbol	Definition	Reference Standard/ Requirement
	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician	21 CFR 801, Section 109
	Medical Device	ISO 15223-1, Reference # 5.7.7
	Refer to Instruction Manual	IEC 60601 Edition 3.1 2012-08, Table D.2, No. 10
	Consult Instructions for Use	ISO 15223-1, Reference # 5.4.3
	Caution, consult accompanying documents	ISO 15223-1, Reference # 5.4.4
	Manufacturer	ISO 15223-1, Reference # 5.1.1
	Distributor	ISO 15223-1, Reference # 5.1.9
	Catalogue Number	ISO 15223-1, Reference # 5.1.6 21 CFR 820.120
	Lot Number	ISO 15223-1, Reference # 5.1.5 21 CFR 820.65
	Do no resterilize	ISO 15223-1, Reference # 5.2.6
	Sterilized using gamma irradiation	ISO 15223-1, Reference # 5.2.4
	Do not re-use	ISO 15223-1, Reference # 5.4.2
	Not made with natural rubber latex	N/A
	Use by Date	ISO 15223-1, Reference # 5.1.4 21 CFR 801.18

Symbol	Definition	Reference Standard/ Requirement
	Date of Manufacture	ISO 15223-1, Reference # 5.1.3
	Applied Part Type B (TITAN SGS23R, Stapling End Effector and Shaft)	IEC 60601 Edition 3.1 2012-08, Table D.1, No. 19
	Magnetic Resonance (MR) Conditional	ASTM F2503-13
	Electrical and Electronic equipment. Return waste to a collection system or treatment and recycling facilities. Follow decontamination instructions before returning waste.	Article 11(2) of Directive 2002/96/EC
	Do not use if the package is damaged	ISO 15223-1, Reference # 5.2.8
	Keep Dry	ISO 15223-1, Reference # 5.3.4
	Storage Temperature Limitations: Upper Limit: 27°C (80°F) Lower Limit: 15°C (59°F)	ISO 15223-1, Reference # 5.3.7
	Storage Humidity Limitation: 15 – 90% Relative Humidity (RH)	ISO 15223-1, Reference # 5.3.8

Standards:
Code of Federal Regulations (CFR) Title 21, Part 801 – Labeling
Code of Federal Regulations (CFR) Title 21, Part 820 – Quality System Regulation
ISO 15223-1 Medical Devices – Symbols To Be Used with Medical Device Labels, Labeling, and Information to be Supplied

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