PROXIMATE® TX
Reloadable Linear Stapler

Steps to Use

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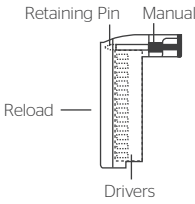
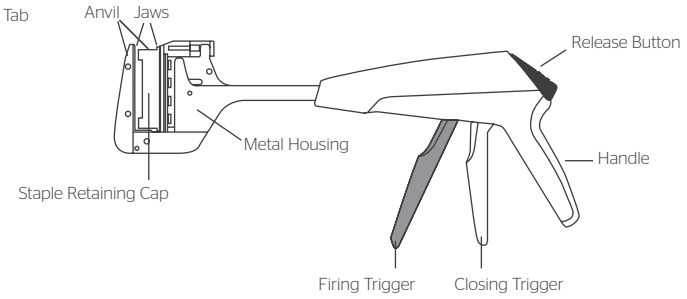
Steps to Use

Models available:
TX30V, TX30B, TX30G, TX60B, TX60G

Reloads available:
XR30V, XR30B, XR30G, XR60B, XR60G



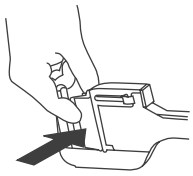


Verify compatibility of all instruments and accessories prior to using the instrument (see Instructions for Use).

1

Using sterile technique, remove the instrument from the package. To avoid damage, do not flip the instrument into the sterile field.

2



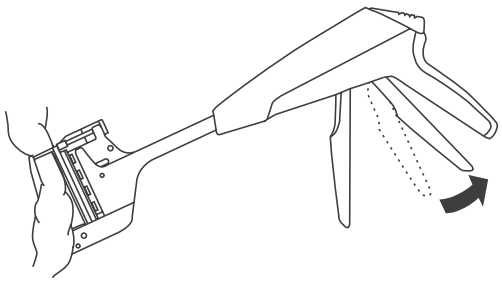
Remove the staple retaining cap from the instrument. Discard the staple retaining cap.

3

Position tissue to be stapled within the jaws of the instrument.

Note: Any tissue covering the hole in the anvil will be pierced by the retaining pin.

4

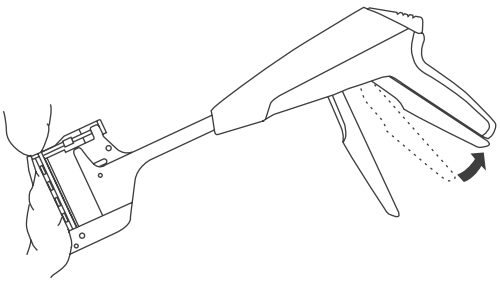


Squeeze the closing trigger until a click is heard. The instrument is in an intermediate position, the pin is fully seated in the anvil capturing the tissue and the jaws are partially open. Reposition tissue within the instrument if desired.

Note: The retaining pin automatically seats into the anvil when operating the closing trigger. If desired, the retaining pin may be manually seated while the jaws remain fully open. Push the manual pin tab toward the anvil after positioning the tissue to be stapled within the jaws of the instrument.

Note: Inspect for the unwanted presence of clips, instruments or other hard objects between the surfaces of the anvil and the staple cartridge (reload). Closing or firing over these items can damage the instrument and result in poor staple formation.

5



Squeeze the closing trigger and the handle fully together until a second click is heard. The closing trigger is now latched to the handle and the jaws are clamped onto the tissue, which is ready to be stapled. The firing trigger will simultaneously move down to the ready-to-fire position.

Note: Continue to grasp and manipulate the instrument using the closing trigger until ready to fire the instrument. Do not grasp the firing trigger before the instrument is to be fired.

Note: If the tissue needs to be repositioned within the instrument before stapling, open the jaws by pushing the release button and slowly releasing the grasp of the closing trigger. The closing trigger will return to the fully open position and the jaws will release the tissue. Tissue can now be repositioned.

Note: Attempting to force the trigger to complete the closing stroke with too much tissue or thickened tissue may result in poor staple formation with the loss of staple line integrity and subsequent leakage, disruption or poor healing. In addition, instrument damage or failure may result.

Caution: Unusually high closure force is a warning to open the instrument and inspect for tissue anomalies and hard objects or consider replacing the instrument.

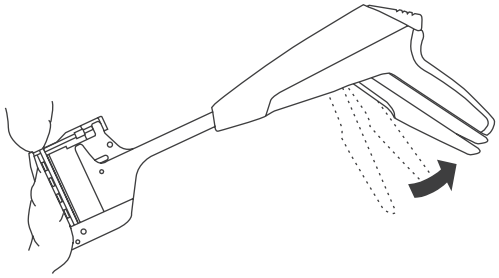
6

Before firing, check to ensure the retaining pin is seated in the anvil. If the pin is not properly positioned, staples may not form properly, which may result in leakage or disruption of the staple line.

Note: Make sure tissue to be stapled is properly positioned in the jaws before stapling. Bunching, stretching or uneven loading of tissue could result in leakage, lack of hemostasis or disruption of staple line.

Note: When dividing major vascular structures, it is mandatory to adhere to the basic surgical principle of proximal and distal control. Failure to fire the device, or incomplete firing of the device, and then proceeding to divide the vessel may lead to catastrophic bleeding. For this reason, inspect the staple line by releasing the device prior to dividing the vessel. An alternative approach is to place a vascular clamp across the vessel prior to dividing.

7



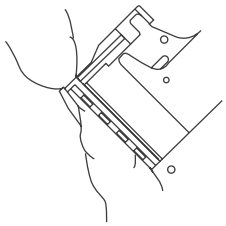
Fire the instrument by pulling the firing trigger back completely against the closing trigger until a click is heard, signifying the staples are fully formed.

Note: The firing stroke must be completed. Do not partially fire the instrument. Incomplete firing can result in malformed staples, incomplete cut line, bleeding and leakage from the staple line and/or difficulty removing the device.

Note: The instruments and reloads are designed with a lock-out feature, which prevents firing if a used reload or no reload is in the instrument. If the firing trigger does not pull back completely against the closing trigger, open the instrument as described in Step 9. Replace the reload with a new reload.

Note: Make sure that the release button is not pressed during firing, as proper formation of staples may be compromised.

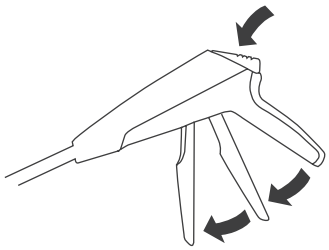
8



Prior to opening the instrument and releasing the tissue, the edge of the reload or the side of the anvil may be used as a guide to transect tissue (not vessels) or to excise tissue that is protruding through the jaws. This aids in cutting at a proper distance from the staple line.

Caution: For vascular applications, open the instrument and examine the integrity of the staple line before cutting.

9



Open the jaws by pushing the release button and releasing the grasp of the closing trigger. The trigger and jaws will fully open, releasing the tissue. Remove the instrument.

Caution: Examine the staple line for hemostasis/pneumostasis and proper staple formation. If hemostasis/pneumostasis is not present, appropriate techniques should be used to achieve hemostasis/pneumostasis.

Reloading the Linear Stapler

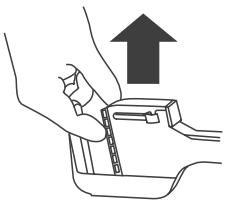
1

Using the sterile technique, remove the instrument from the package. To avoid damage, do not flip the instrument into the sterile field.

2

Depress the release button to ensure the instrument is in the open position and the retaining pin is fully retracted into the reload.

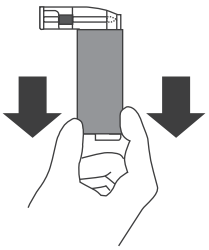
3



Remove the used reload from the instrument. Grasp the top of the reload and lift upward, unsnapping the reload from the jaws. Properly discard the used reload.

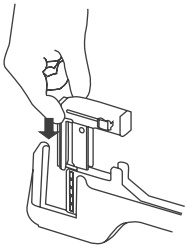
Caution: Inspect the instrument's anvil and jaw surfaces after rinsing in sterile solution and wiping away any unused staples or debris.

4



Examine the new reload for the presence of a staple retaining cap. Remove the staple retaining cap by sliding it off the reload. If the retaining cap is not in place, discard the reload.

5



Insert the new reload into the metal housing and snap into position. The tracks on each side of the reload should be used as guides to align the reload within the jaws of the instrument. When the reload is properly aligned, push the reload into the instrument until it is fully seated and a click is heard. Check that the reload is held firmly within the jaws.

6

After reloading, observe the surface of the new reload. If colored drivers protrude out of the reload, replace with another reload. The Linear Stapler is now reloaded and ready for use.

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For complete product information, including full steps for use, indications, contraindications, warnings and precautions, please see the Instructions for Use.