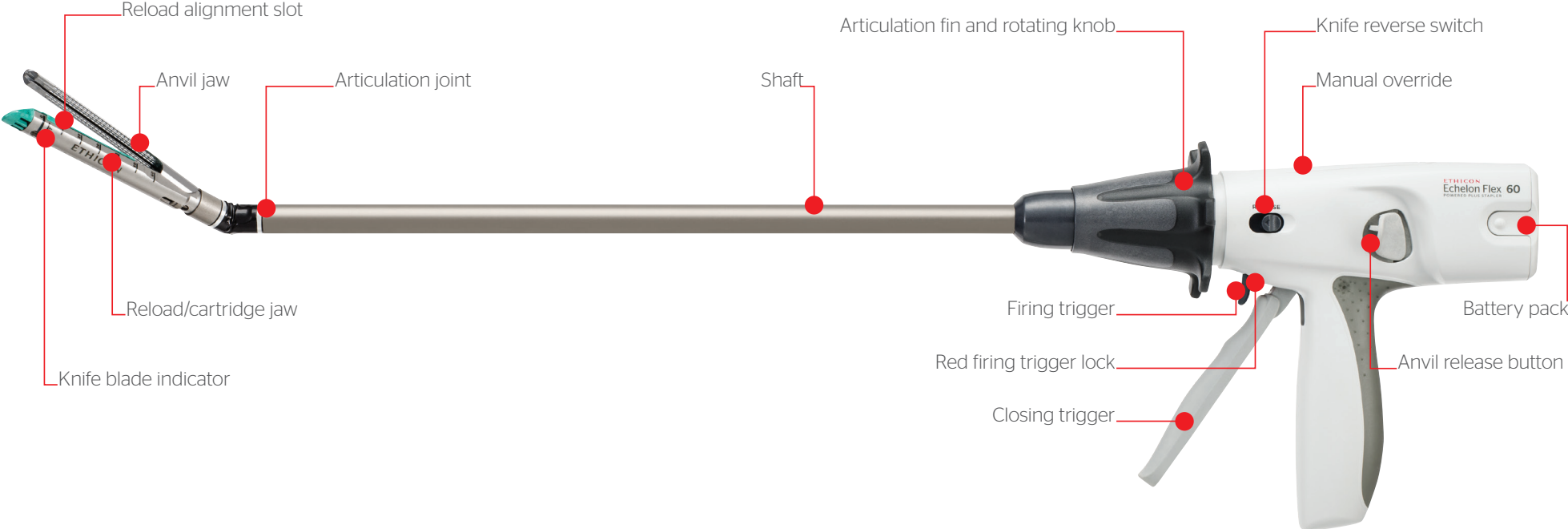


In-Servicing Guide

ECHELON FLEX™ Powered and Powered Plus Staplers



Nomenclature

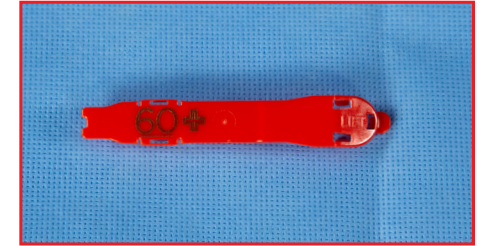
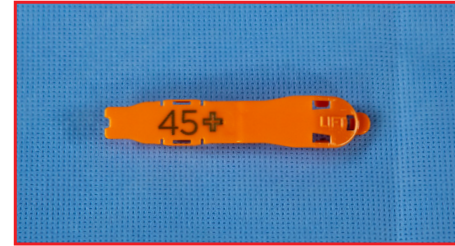


Loading the device

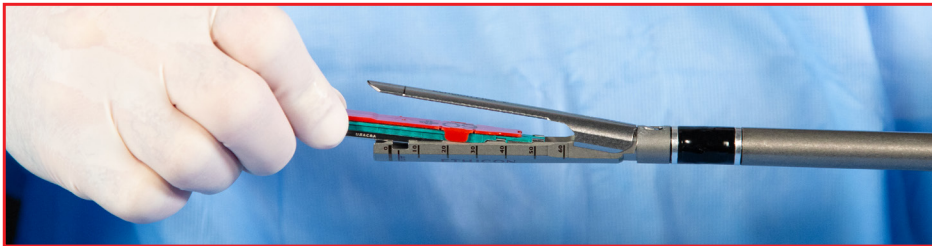


1. Install the battery pack. An audible click will be heard when the battery pack is fully inserted. It can be inserted in either orientation; there is no up or down.

Note: Tissue thickness should be carefully evaluated prior to using the instrument. Refer to the Reload Product Codes Chart for proper reload selection.



2. Verify that the reload size matches the instrument size to be used (e.g., use 60mm reload with 60mm stapler).



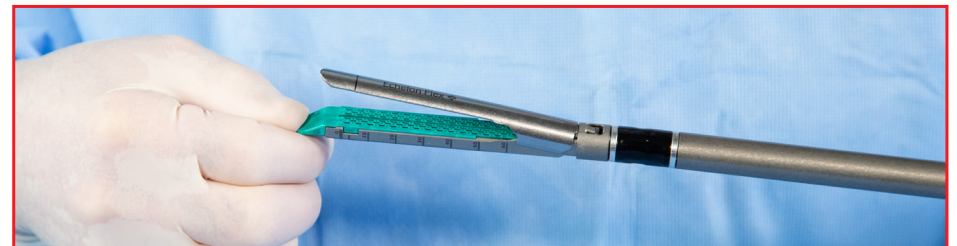
3. Ensure that the staple retaining cap is present. Insert the reload by sliding it against the bottom of the reload jaw until the stapler alignment tab stops in the reload alignment slot of the jaw.



4. Snap the reload securely in place.

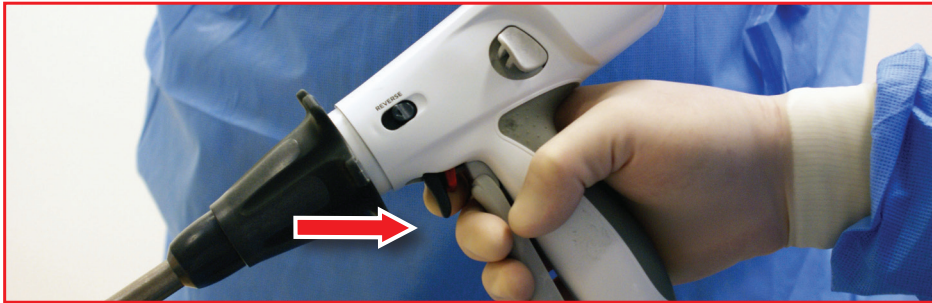


5. Remove the staple-retaining cap by lifting it straight up and discard.



6. Observe the surface of the new reload to ensure no colored drivers are visible and that the reload lies flat in the jaw channel.

Opening and closing the jaws



1. Close the jaws of the instrument by squeezing the closing trigger until a click is heard. The audible click indicates that the closing trigger and the jaws are locked.



2. To open the jaws, squeeze the closing trigger, and then simultaneously push the anvil release button on the side of the device. Maintain pressure on the anvil release button and slowly release the closing trigger.

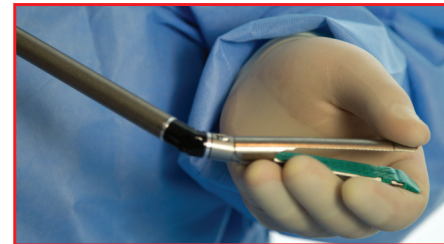
Articulation



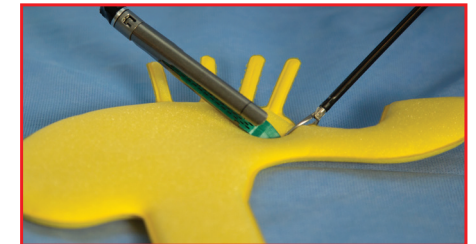
Ensure that the jaws are in the open position.

1. Pull back and hold the articulation fin to activate the articulation joint.
2. Apply lateral pressure to the jaws to articulate the device.
3. Release articulation fin to lock jaws into articulated position.
4. Clamp, staple, cut, return, release.

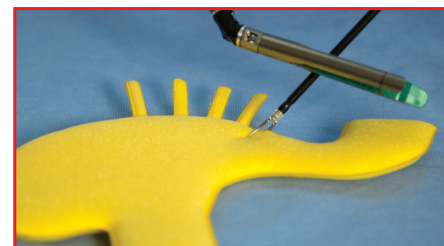
Four ways to articulate



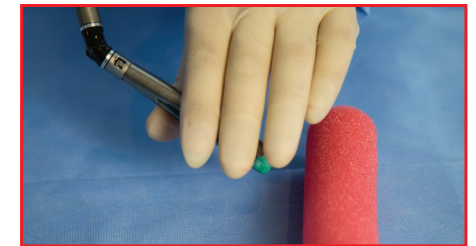
1. Against the body wall



2. Against tissue in the body

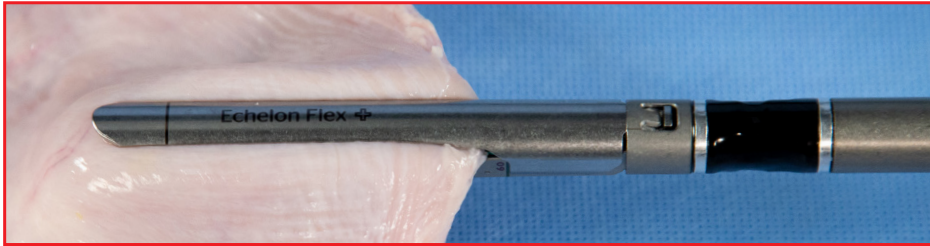


3. Against a grasper



4. Hand assisted

Firing the device



1. Ensure that the tissue lies flat and is positioned properly between the jaws and that no obstructions (e.g., clips, stents) are within the jaws. Any "bunching" of tissue along the reload may result in an incomplete staple line.



2. Fully close the closing trigger until it clicks (audible click will occur).

Note: Holding the jaws in place for 15 seconds after closing and prior to firing may result in better compression and staple formation.



3. Pull back the red firing trigger lock.

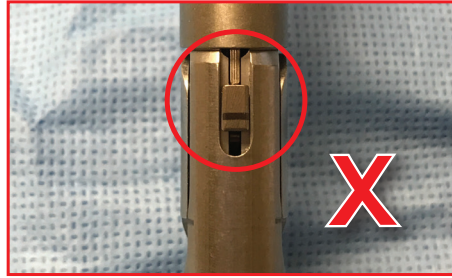
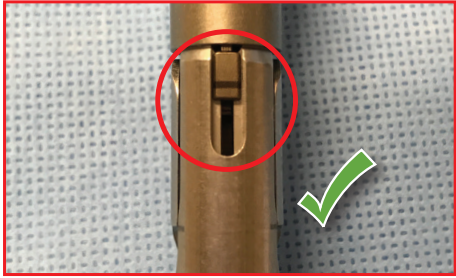


4. Pull the exposed trigger to fire (motor will be audible).

Note: Alternatively, for enhanced tissue compression when using the ECHELON FLEX™ Powered Plus Stapler, the user may pulse the firing trigger throughout the firing cycle until the transection is completed. Similarly, if the firing sequence is interrupted, the user may pulse the firing trigger to continue the transection. It is recommended that the pulsing technique not be initiated until after the knife blade indicator has moved into the closed bottom channel and is no longer visible to minimize potential of inadvertent lockout.

5. When the motor stops, release the firing trigger to automatically return the knife to the home position.

Opening the jaws



1. Ensure the knife is in the home position by doing a visual check on the underside of the reload jaw. The jaws will not open if the knife is not in the home position.



2. Squeeze the closing trigger, and then simultaneously push the anvil release button on the side of the device. Maintain pressure on the anvil release button and slowly release the closing trigger.

Reloading the device

1. Push upward (toward the anvil) to unsnap the reload from the reload jaw.



2. Prior to reloading the stapler, hold the instrument in a vertical position with anvil and cartridge jaw completely submerged in sterile solution. Swish vigorously to remove any loose formed staples.



3. Wipe the inside and outside surfaces of the anvil and cartridge jaws to clean any unused staples from the instrument.

4. Follow the same steps outlined earlier in the **Loading the device** section.

Stapler lockout

Under certain circumstances, the stapler will lock out. These include instances when no cartridge or an incorrect or used cartridge is present. At any time, if the knife reverse switch does not return the knife to the home position and the jaws will not open:



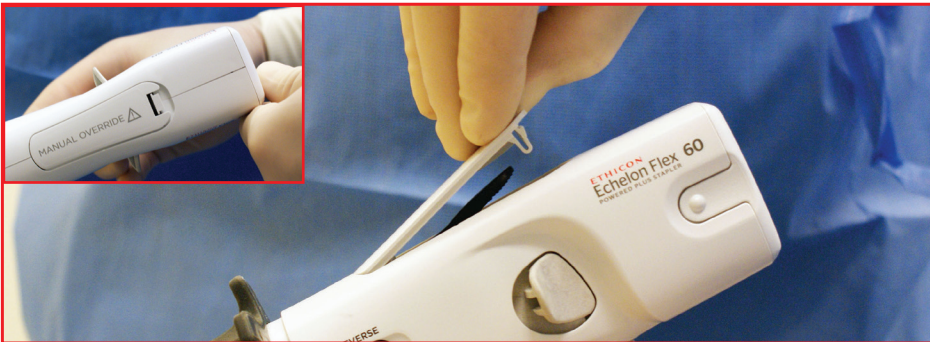
1. Reverse: Slide the knife reverse switch forward.



2. Battery: Remove and re-install the battery to check that it is securely installed and that the device has power.



3. Reverse: See Step 1.



4. Override: If the knife does not return, use the manual override (remove the access panel labeled "Manual Override" on the top of the handle).

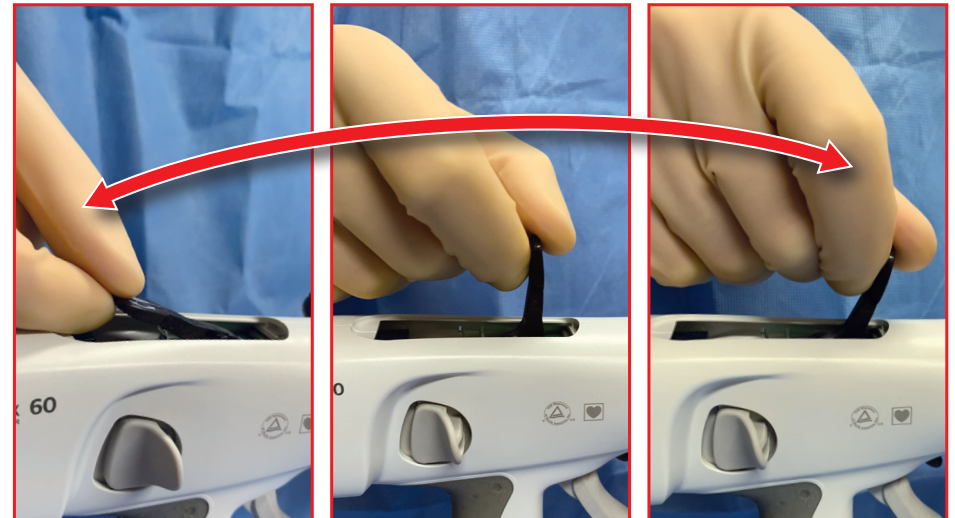
Note: After the manual override is used, the device becomes nonfunctional.

Manual override system

ONLY to be used if the reverse switch does not return the knife blade.



1. To use the manual override, remove the access panel labeled “Manual Override” on the top of the instrument handle. The manual override lever will be exposed.

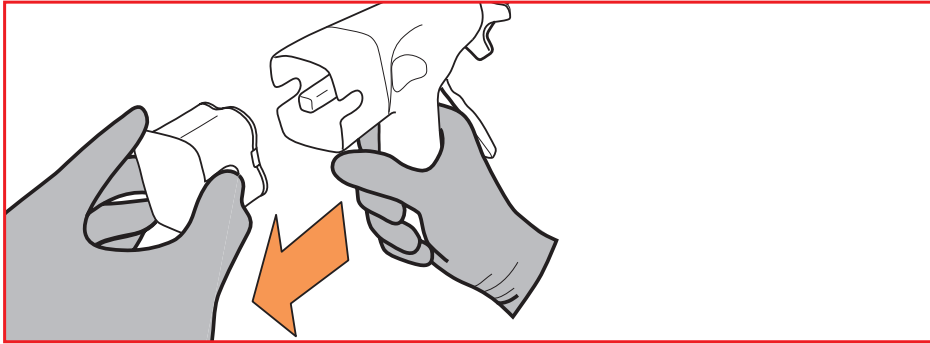


2. Move the lever **FORWARD AND BACKWARD** until it can no longer be moved. The forward and backward movement of the lever may require multiple cycles and should be completed until the knife blade is confirmed to be in the home position.

Note: After the manual override is used, the device becomes disabled for any subsequent firings.

Battery pack disposal

Because of the built-in battery drain, it is safe to discard the battery pack in the normal medical waste stream. If your local regulations require lithium batteries to be recycled, the battery pack must first be decontaminated according to the instructions below.



1. Disconnect the battery pack.

Note: In the event that the battery pack needs to be decontaminated before disposal, follow this process between Steps 1 and 2:

- Use a soft bristle brush to clean the battery pack surface with a neutral pH detergent or neutral pH enzymatic detergent (e.g., Simple Green D Pro 3,[†] 10% bleach, 70% isopropyl alcohol), prepared according to the manufacturer's instructions.
- Thoroughly scrub areas that contain crevices.
- Thoroughly wipe off detergent with lukewarm tap water (DO NOT SUBMERGE IN WATER OR DETERGENTS).
- Visually inspect to ensure the debris is removed. Repeat cleaning if necessary to obtain a visually clean battery pack.

IMPORTANT: Do NOT incinerate/autoclave battery pack in the hospital.

- Per the manufacturer, the batteries are not to be exposed to temperatures above 100 degrees Celsius.
- The batteries are not reusable and do not need to be sterilized.
- Do not use Ethylene Oxide (EtO) process for battery pack.



2. Discard pack in the normal medical waste stream.