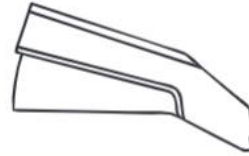




## Reflex® One and Reflex® TL Single-Use Skin Stapler

### Instructions for Use



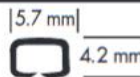
**Read and understand instructions prior to use and follow all warnings and precautions.**

#### Description

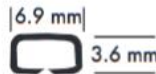
Reflex® One and Reflex® TL Staplers are hand-held, disposable, sterile devices used to approximate open skin by deploying staples. Staplers contain a minimum of 35, 25, or 15 staples in wide and regular widths. Staples are comprised of 316L stainless steel and designed to hold skin in place until sufficient wound healing to allow for staple removal. A finger trigger is the staple deployment mechanism. Reflex® One ejects the staple and as the trigger is released the next staple is loaded into position. Reflex® TL continues to hold onto the staple at the end of the trigger stroke. The staple is not ejected until the trigger is released at which point the next staple is loaded. All product versions of the Reflex® Staplers include a visible counter and provide audible and tactile feedback to confirm end of trigger stroke.

#### Formed Staple Dimensions

Regular staples 0.51 mm diameter wire.



Wide staples 0.56 mm diameter wire.



#### Indications

The Reflex® One and Reflex® TL Skin Staplers are used for closure of skin in a wide variety of surgical procedures.

#### Contraindications

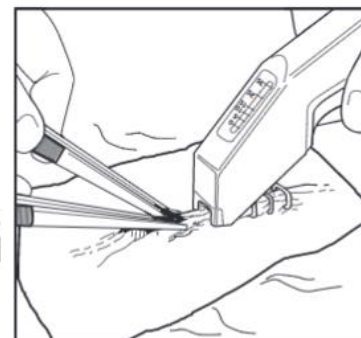
1. When it is not possible to maintain at least 5mm distance from the stapled skin to underlying bones, vessels, and internal organs, the use of staples for skin closure is contraindicated.

#### Instructions for Use

1. Evert and approximate skin tissue.
2. Position stapler lightly on everted skin tissue. Touching the skin lightly will allow the stapler to float above the incision, resulting in better cosmetic closure and easier removal.

Reflex® One:

- 3a. Squeeze trigger fully and then release trigger fully. The staple will release automatically from the anvil with trigger release. The stapler can be removed from the incision in any direction.



Reflex® TL:

- 3b. Squeeze trigger fully and then release trigger fully. Back the instrument off the staple to remove the anvil out from under the staple.
4. Verify staple placement.
5. Move stapler to next desired position and repeat procedure.
6. Quantity of staples remaining is shown on the counter window.

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## Warnings

1. Reflex® One and Reflex® TL Skin Staplers should be used only by personnel with adequate training and knowledge of skin closure procedures.
2. The Reflex® One and Reflex® TL are intended for use in skin closure procedures and are not to be used on internal tissue closure as placement and proximity to bones, vessels, and internal organs are not verifiable.
3. Prior to inserting staple, confirm staple will be positioned free of other staples or obstructions. Firing a staple over another staple may result in tissue compression and risk of compromised healing or scarring.
4. Reflex® One and Reflex® TL stainless steel skin staples are not to be used on patients with nickel and/or metal (e.g. chromium, copper, cobalt, iron) hypersensitivity to prevent related adverse reactions.

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## Precautions

1. This device is provided sterile for single-use only. Do not use if package is opened or damaged. Do not re-sterilize. Discard after use.
2. Always ensure trigger is fully closed and released to properly feed the next staple into position.
3. The ability to effectively clean and re-sterilize this single-use device has not been established and subsequent re-use may adversely affect the performance, safety and/or sterility of the device.

U.S. Patent Number 4,558,810



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