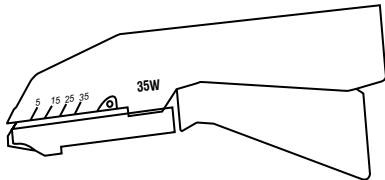


Instructions For Use

Disposable Skin Stapler

Manufactured by Mais India Medical Devices Pvt. Ltd.



General Device Description:

The Disposable Skin Stapler is a sterile, single-use medical device intended for the temporary approximation and closure of skin incisions and lacerations following surgical procedures or traumatic wounds.

Product Name: Disposable Skin Stapler

Brand Names: Maiskin Stapler

Variants: 35W

Intended Use:

The device is intended to apply uniform metal staples to hold the edges of the skin together, thereby facilitating proper wound healing until staple removal.

Material of construction:

Stainless Steel + ABS.

Indications for use:

- General surgery.
- Emergency and trauma wound closure.

Contra-indications:

The Disposable Skin Stapler is contraindicated in the following situations:

- When it is not possible to maintain a minimum distance of 5 mm.
- For internal tissue closure.
- In patients with known hypersensitivity or allergic reactions to stainless steel.
- In areas with very thin, fragile, or delicate skin.

Intended Patient Population:

All Patient Population.

Intended User:

Healthcare Professionals.

Use environment:

Proper Healthcare Setup.

Instruction for use:

- Check the sterile package for integrity. Do not use if the package is damaged or the expiry date has passed.
- Prepare the wound according to standard surgical practice.
- Control bleeding and ensure that deeper tissue layers, if required, are properly closed prior to skin closure.
- Maintain adequate eversion of the skin edges to ensure proper staple formation.
- Ensure that a minimum distance of 5 mm is maintained between the skin surface and underlying structures.
- Hold the stapler at an angle of approximately 35° to the skin surface, unless clinical judgment indicates otherwise.
- Slowly depress the handle and fully compress the trigger until resistance is felt and the staple is formed.
- Ensure the handle is fully released before removing the stapler.
- Repeat the above steps until the wound is closed.
- Dispose of the set after single use as per hospital protocol.

Intended Clinical Benefits to the patients:

- Enables faster skin closure compared to conventional suturing techniques, contributing to reduced operating or procedure time.
- Staples provide temporary fixation and can be removed once healing is sufficient, avoiding permanent implantation.
- Standardized staple delivery and formation support uniform wound closure, independent of operator suturing variability.
- Minimizes manual manipulation of tissue compared to suturing, which may reduce additional tissue trauma during closure.
- Facilitates reliable approximation of skin edges, supporting primary wound healing following surgical procedures or traumatic injury.

Clinical Safety:

- Device Design and Material Safety.
- Biocompatible products.
- Our device is a single use device.
- Our product is non-toxic, sterile & non-pyrogenic.

Performance characteristics:

- Delivers one preloaded staple per cycle through a manual, mechanically actuated mechanism
- Forms staples into a predefined closed configuration to ensure reliable approximation of skin edges
- Provides sufficient holding strength to maintain skin closure during the healing period until staple removal
- Supplied sterile and intended for single use, eliminating risks associated with cross-contamination or device degradation due to reuse.

Accessories which can be used with the device:

Standard Surgical Supplies.

Warnings:

- The product should not be reprocessed.
 - Improper transport and handling may cause structural and/or functional damage to device or packaging.
 - Do not clean or resterilize.
 - Do not expose to heat or direct sunlight.
 - The product should be used immediately after opening the packaging.
- MAIS INDIA disclaims any responsibility for possible consequences resulting from improper use.*

Cautions:

- Do not use if package is damaged.
- Discard after single use.

Limitations:

The device is intended only for external skin closure and must not be used for internal tissues, including subcutaneous, fascial, muscular, or organ tissue.

Potential Side Effects:

- Pain or discomfort at the staple site during implantation or removal.
- Redness, swelling, or mild irritation at the wound site.
- Minor bleeding at the staple site during placement or removal.

Disposable instructions:

Used Devices may be contaminated with infectious and/or other hazardous materials. Unused expired devices should be disposed of as per local regulations.

Duration of use:

Short-term duration (Normally intended for up-to 7days).

Storage Conditions:

Store in Cool & Dry Place. Keep away from direct sunlight.

Shelf life:

3 Years.

Type of Sterilization:

This device is sterilized by ethylene oxide gas. Do not re-sterilize, and do not reuse. Do not use it if the package is opened or damaged. Discard opened unused devices.

Notice to Users and/ or Patients:

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Explanation of symbols used:

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Sterilized using ethylene oxide (Indicates a medical device that has been sterilized using ethylene oxide)		Use-by date (Indicates the date after which the medical device is not to be used)
	Do not re-sterilize (Indicates a medical device that is not to be re-sterilized)		Batch Number (Indicates the manufacturer's batch number so that the batch or lot can be identified)
	Do not re-use (Indicates a medical device that is intended for one single use only)		PVC free (Indicates product that does not contain the polyvinyl chloride (PVC)).
	Non-pyrogenic (Indicates a medical device that is non-pyrogenic)		Keep away from sunlight (Indicates a medical device that needs protection from light sources)
	Do not use if packaging is damaged and consult instructions for use. (Indicates a medical device that should not be used if its packaging has been damaged or opened, and that the user should consult the instructions for use for additional information)		Caution (To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.)
	Keep dry (Indicates a medical device that needs to be protected from moisture)		Manufacturer (Indicates the medical device manufacturer) Manufacturing Unit: 525P, Sector-37, Pace City II, Gurgaon, Haryana-122001, India. Contact Details.: +91 8527589990 Fax No.: 0124 404 7533 Email ID: info@maisindia.com Website:www.maisindia.com
	Single sterile barrier system (Indicates a single sterile barrier system)		Country of manufacture (To identify the country of manufacture of products)
	Unique Device Identifier (Indicates a carrier that contains Unique Device Identifier information)		Medical device (Indicates the item is a medical device)
	Reference number (Indicates the manufacturer's catalogue number so that the medical device can be identified)		Latex free (Indicates a medical device that is Latex free)
	This way up		Fragile, handle with care (Indicates a medical device that can be broken or damaged if not handled carefully)

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Consult instructions for use (Indicates the need for the user to consult the instructions for use)		Latex free (Indicates a medical device that is Latex free)
	Phthalate Free (Indicates product that does contain the phthalate plasticizers DEHP.		Date of manufacture (Indicates the date when the medical device was manufactured)

 **Manufactured by:**
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