3M[™] Precise[™] Vista Disposable Skin Staplers 3995, 3996, 3997, 3998 1 3M[™] Precise[™] Disposable Skin Staplers DS-5, DS-15, DS-25 3M[™] Precise[™] Disposable Skin Staplers PGX-15W, PGX-35W 3M[™] Precise[™] Disposable Skin Staple Removers SR-1, SR-3

Product Description

The 3M[™] Precise[™] Vista Disposable Skin Stapler is a lever action skin stapler with excellent staple visibility and is available in 15 and 35 staple counts, in regular and wide staple widths.

The $3M^m$ Precise m DS Disposable Skin Stapler is a forceps style skin stapler that is small, has an arcuate-shaped staple that offers tissue gather similar to that of a percutaneous suture, and is available in 5, 15, and 25 staple counts.

The 3M[™] Precise[™] PGX Skin Stapler is a lightweight pistol (gun) style skin stapler and is available in 15 and 35 staple counts, in wide staple widths.

The 3M[™] Precise [™] Disposable Skin Staple Remover SR-1 is a standard style metal skin staple remover constructed of stainless steel.

The 3M™ Precise™ Disposable Skin Staple Remover SR-3 is a scissors style skin staple remover constructed of plastic handles with stainless steel arms and iaws.

Intended Use

3M Precise disposable skin staplers can be used for skin closure in a wide variety of wounds and surgical incisions and are intended for external use only. 3M Precise disposable skin staple removers are universal in design and are used to remove any brand of staple. For professional use only.

Contraindications

- When it is not possible to maintain at least 5mm distance from the stapled skin to underlying structures, the use of staplers for skin closure is contraindicated.
- 2. The use of this skin stapler is contraindicated in patients with known sensitivities or allergies to the metals contained in 316L stainless steel, i.e., chromium, nickel, copper, cobalt, and iron.
- 3. Not to be used for internal tissue closure.
- 4. This product is not designed, sold, or intended for use except as indicated.

Warnings

- 1. Single patient use only.
- 2. Do not reprocess or resterilize. This may compromise the functional integrity of the product.
- Users should be familiar with surgical procedures and techniques involving the use of skin staplers before employing the 3M Precise disposable skin staplers for wound closure.
- 4. Any foreign material in the presence of bacterial contamination may enhance bacterial infectivity. Acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.
- 5. This device has not been tested for use during Magnetic Resonance Imaging (MRI) procedures. If this procedure is ordered by a physician, 316L stainless steel is only slightly affected by magnetism. When exposed to MRI, the staples may cause voids in the output (sometimes referred to as "blooming").
- 6. Do Not Reuse. Reuse may result in compromising product integrity, lead to device failure, or may create risk of wound contamination, patient infection or cross infection which may lead to injury, illness or death of the patient.

Cautions

- U.S.A. Federal law restricts this device to sale by or on the order of a physician.
- Adverse effects associated with the use of this device include: wound dehiscence; allergic response in patients with
 known sensitivities to metals contained in 316L stainless steel, (i.e., chromium, nickel, copper, cobalt, and iron);
 enhanced bacterial infectivity; minimal acute inflammatory tissue reaction; and pain, edema, and erythema at the
 wound site
- Precise skin staplers are made of 316L medical grade stainless steel wire, and are not absorbed. Cytotoxicity and intramuscular implant testing show no tissue toxicity.

Directions for Use

Instructions for Use – 3995, 3996, 3997, 3998 3M™ Precise™ Vista Disposable Skin Staplers:

- Approximate and slightly evert the skin edges. For best preview of the staple before placement, advance the staple by squeezing the trigger to the first stop position.
- Holding the stapler at a slight angle, lightly place the stapler over the everted skin edges. Excessive downward pressure on the instrument may make staple removal difficult and may contribute to a poor cosmetic result.
- 3. To form the staple, squeeze the handle completely until it stops.
- 4. Release the handle completely.
- 5. Lift the stapler away from the skin. Always check staple placement and replace improperly implanted staples.

CE 0086

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Instructions for Use - DS-5, DS-15, DS-25

3M™ Precise™ Multi-Shot DS Disposable Skin Stapler:

- Approximate and slightly evert skin edges. Hold stapler upright (90°). Place on skin with gentle downward pressure. Increased pressure results in a more deeply embedded staple.
- 2. To form staple, press trigger firmly and completely. Excessive downward pressure on the instrument may make the staple hang up on the anvil and staple ejection difficult. Excessive downward pressure will make staple removal difficult and may contribute to a poor cosmetic result.
- 3. To release device from staple, relax thumb pressure fully.
- 4. Back the instrument off the staple and lift the stapler away from skin. Always check staple placement and replace improperly implanted staples.

Instructions for Use - PGX-15W, PGX-35W

3M™ Precise™ PGX Disposable Skin Staplers:

- Approximate and slightly evert skin edges. Hold stapler upright (60-90°). A 90° angle results in a more deeply embedded staple. Place on skin with gentle downward pressure. Excessive downward pressure on the instrument may make staple removal difficult and may contribute to a poor cosmetic result.
- To form staple, squeeze the handle completely until it stops. Failure to squeeze the handle completely may result in incomplete staple formation, which may not adequately hold the tissue together.
- 3. Release handle completely.
- 4. Lift the stapler away from the skin. Always check staple placement and replace improperly implanted staples.

Instructions for Use - SR-1, SR-3

3M™ Precise™ Disposable Skin Staple Removers:

- 1. Staples should be inspected to assure they have not rotated. Any rotated staples should be righted before removal.
- 2. Make sure remover is in the correct position with the lower jaw on the bottom.
- 3. Insert both tips of the lower jaw of the remover under the staple.
- 4. Reposition any angled staples so they are perpendicular to the plane of the skin.
- 5. Lift slightly so that the staple remains perpendicular to the plane of the skin.
- 6. Continue slight lifting while gently squeezing the handles together to reform the staple.
- 7. Lift the reformed staple straight up from the tissue and discard according to your state or local requirements.

Storage/ Shelf Life/Disposal

Shelf life: 5 years

How supplied

3M Precise skin staplers and removers are supplied sterile. Sterility is guaranteed unless the package is damaged or open.

Explanation of Symbols



Do not use if package is damaged or open



Use by date



Caution, see instructions for use



LOT Batch code





Manufacturer

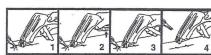
STERILE | R | Sterilized using irradiation



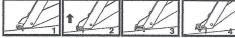
3M™ Precise™ Vista Disposable Skin Staplers, 3995, 3996, 3997, 3998



3M™ Precise™ Multi-Shot DS Disposable Skin Stapler System, DS-5, DS-15, DS-25



3M™ Precise™ PGX Disposable Skin Staplers PGX-15W, PGX-35W



3M[™] Precise[™] Disposable Skin Staple Removers SR-1, SR-3