MEDLINE UNITE® SNAP-OFF SCREWS
INSTRUCTIONS FOR USE
Attention Operating Surgeon

Device Description

The Medline UNITE®Snap-Off Screws are manufactured from Titanium Alloy. The screws are offered in various diameters and lengths.

Indications

The Medline UNITE® Snap-Off Screws are indicated for use in bone reconstruction, osteotomies, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device. Screws are intended for single use only.

Information for Use

The surgeon must select the type and size implant that best meets the patient's surgical needs.

Contraindications

1. Any previous or active infection or blood supply limitations.
2. Insufficient quality of bone or soft tissue.
3. Patients who are unwilling or incapable of following postoperative care instructions.
4. Material sensitivity. If suspected, tests should be conducted prior to implantation.
5. This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Adverse Effects

1. Fracture of implant due to excessive activity, prolonged loading upon the device, incomplete healing, or excessive force exerted on the implant during insertion.
2. Implant migration and/or loosening.
3. Metal sensitivity or histological or allergic reaction resulting from implantation of foreign material.
4. Pain, discomfort, or abnormal sensations due to the presence of an implant.
5. Nerve damage resulting from surgical trauma.
6. Necrosis of the bone or bone resorption.
7. Necrosis of the tissue or inadequate healing.

Warnings

1. For safe and effective use, the surgeon must be thoroughly familiar with this type of implant, the method of application, instrumentation, and the recommended surgical technique for this type of device. Improper insertion of the device during implantation can increase the possibility of loosening or migration.
2. The Medline UNITE® Snap-Off Screws are not designed to withstand the stress of weight bearing, load bearing, or excess activity. Device breakage or damage can occur when the implant is subjected to increased loading associated with delayed union, nonunion, or incomplete healing. The postoperative care instructions provided by the surgeon should be strictly followed to avoid adverse stresses applied to the device. The patient must be warned, preferably in writing, that failure to follow postoperative care instructions can cause implant and/or treatment failure.
3. The Medline UNITE® Snap-Off Screws have not been evaluated for safety in the MR environment. The Medline UNITE® Snap-Off Screws have not been tested for heating, migration, or image artifact in the MR environment. The safety of the Medline UNITE® Snap-Off Screws in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
4. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure. Device removal should be followed by adequate postoperative care.

Precautions

1. An implant shall never be reused. Previous stresses may have created imperfections, which can lead to a device failure. Protect implants from scratching and nicking as such stress concentrations can lead to failure.
2. Instruments, particularly drills, countersinks, and drivers shall be inspected for wear or damage prior to use.
3. The Medline UNITE® Snap-Off Screws are designed specifically for use with Medline instrumentation. The use of other instrumentation is not recommended.

Cleaning & Sterilization

All implants and instruments are provided non-sterile in trays or individually packaged and must be adequately cleaned and sterilized prior to use or re-use. Both manual and automated cleaning methods are provided and have been developed and tested consistent with TIR 30 (manual) and ISO15883/TIR30 (automated) respectively. The provided sterilization recommendations have been developed and tested consistent with ANSI/AAMI ST79.

An implant should never be re-sterilized after contact with human body tissues or fluids. Devices labeled for single use only should never be reused. Re-use of these devices may result in, but are not limited to: decreased performance of the product, cross-infection, and contamination.

Trays should be thoroughly cleaned and inspected prior to use. Visually inspect the tray for cleanliness. Repeat cleaning process, as necessary, until tray is visually clean.

Manual Cleaning

Do not allow excessive debris and soft tissue to dry after use. Begin cleaning process as soon after use as possible. Additional scrubbing may be required if debris and soft tissue dry.

1. **Rinse** under cool running tap water to remove visual soil.
2. **Prepare** enzymatic detergent per manufacturer's recommendation using lukewarm tap water.
3. **Allow the device to soak in the prepared enzymatic detergent for 1 minute.**
4. **Using** a soft bristled brush, thoroughly brush the device to remove soil.
5. **Run** a stylet through lumens a minimum of 3 times to remove soil.
6. **Using** a syringe, aggressively flush the lumens with the enzymatic detergent.
7. **Remove** the device from the detergent and rinse under cool running tap water to remove detergent residuals.
8. **Using** a syringe, aggressively flush the lumens.
9. **Prepare** neutral detergent per manufacturer's recommendation using warm tap water.
10. **Allow** the device to soak in the prepared neutral detergent for 3 minutes**.**
11. **Using** a soft bristled brush to remove soil.
12. **Run** a stylet through lumens a minimum of 3 times to remove soil.
13. **Using** a syringe, aggressively flush lumens with the prepared neutral detergent.
14. **Remove** the device from the detergent and rinse in (RO/DI) water to remove detergent residuals.
15. **Prepare** enzymatic detergent per manufacturer's recommendation in a sonication unit.
16. Allow the device to sonicate for 10 minutes.
17. **Remove** the device from the sonicator and thoroughly rinse under running RO/DI water.
18. **Using** a syringe, aggressively flush the lumens..
19. **Dry** the device with a disposable, lint-free cloth.
20. **Visually inspect** the device for cleanliness.

Instruments should be inspected for any damage or wear prior to use. Instruments that have corrosion, pitting, and/or discoloration should not be used.

Sterilization

Sterilization should be performed in the provided tray double-wrapped in FDA cleared wrap using the following method:

Cycle Type	Parameter	Minimum Set Point
Prevacuum	Exposure Temperature	270°F (132°C)
	Exposure Time	4 minutes
	Dry Time	40 minutes

Do not stack tray during sterilization

Ensure that the implants and instruments are at room temperature prior to use.

Storage

Store all devices in a clean and dry environment. The devices are manufactured from non-degradable materials. When stored under the recommend conditions, the shelf life of this product is not limited.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

For additional product information, please visit www.medline.com or contact customer service at 1-800-MEDLINE.

Manufactured for and distributed by:
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