ADVERSE EFFECTS

The surgeon should carefully consider the following when selecting a patient for surgery:

PRE-OPERATIVE PRECAUTIONS

• Instruments, particularly drills, reamers, and drivers shall be inspected for wear or damage.
• An implant shall never be reused. Previous stresses may have created imperfections, which
  may cause implant and/or treatment failure. Periodic follow-up, including x-rays for comparison
  of the damage caused by the stresses, may be prevented, an implant should not be used.

INTRA-OPERATIVE PRECAUTIONS

• Instrument sensitivity. If suspected, tests should be conducted prior to implantation.
• This device is not intended for screw attachment or fixation to the posterior elements
  (pedicles) of the cervical, thoracic, or lumbar spine.

ADVERSE EFFECTS

• Fracture of implant due to excessive activity, prolonged loading upon the device, incomplete
  or inadequate healing, or excessive force exerted on the implant during insertion.
• Implant migration and/or loosening requiring revision surgery.
• Bone resorption and/or over-production.
• Metal sensitivity or histological or allergic reaction resulting from implant material
  or tissues.
• Infection or painful, swollen or inflamed implant site.
• Migration of particle wear debris possibly resulting in bodily response.
• Embolism.
• Pain, discomfort, or abnormal sensations due to the presence of an implant.
• Necrosis of the bone.
• Necrosis of the tissue.
• Nerve damage resulting from surgical trauma.

CONTRAINDICATIONS

• Any previous or active infection or blood supply limitations.
• Insufficient quality of bone or soft tissue.
• Patients who are unwilling or incapable of following postoperative care instructions.
• Material sensitivity. If suspected, tests should be conducted prior to implantation.

INFORMATION FOR USE

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

PRE-OPERATIVE PRECAUTIONS

• Instruments should be inspected for any damage or wear prior to use. Instruments that have
  been damaged or show wear should not be used.

• More conservative treatment options
• Patient’s weight, occupation, and activity level
• Patient’s expectations of the device
• Patient’s willingness to follow post-operative instructions
• Patient conditions that may limit their ability to recognize limitations of the device that may
  lead to device failure, such as senility, mental illness, or alcoholism
• Known or suspect material allergies
• Comorbidities, eg. diabetes, smoking

The patient should be warned of surgical risks and be made aware of possible adverse effects. 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 and indications for this type of device. Improper implantation of the device can increase the possibility of loosening or migration. No metal implants can be expected to withstand loads at the same level as healthy bone. Medline UNITE® Snap-Off Screws have not been designed to withstand the stress of weight bearing, load bearing, or excess activity. Fracture of the implant or damage can occur when the implant is subjected to increased loading associated with delayed union, nonunion, or incomplete healing. If excessive loading cannot be prevented, an implant should not be used.

INTRA-OPERATIVE PRECAUTIONS

• The surgeon must select the type and size implant that best meets the patient’s surgical needs.
• Inspect all implants for scratching and nicking prior to use as such stress concentrations can
  lead to failure. Avoid flaking the implant surface during insertion to minimize the potential
  for failure.
• An implant shall never be reused. Previous stresses may have created imperfections, which
  can lead to a device failure.
• Instruments, particularly drills, reamers, and drivers shall be inspected for wear or damage
  prior to use.
• Medline Snap-Off Screws are designed specifically for use with Medline instrumentation.

POST-OPERATIVE PRECAUTIONS

• The patient should be warned of the limitations of surgery and the need to protect the
  implant from all weight bearing until adequate fixation and healing have occurred. The
  postoperative care instructions provided by the surgeon should be strictly followed to avoid
  adverse stresses applied to the device. Failure to follow postoperative care instructions
  can cause implant and/or treatment failure. Periodic follow-up, including x-rays for comparison
  to early post-op conditions, is recommended to monitor the position and state of the implant,
  the condition of the bone, and any signs of implant migration, loosening, bending, or cracking.

RECOMMENDATIONS REGARDING DEVICE FRAGMENTS

1. In the event of implant fracture, carefully consider and discuss with the patient, if possible,
   the risk/benefit of removing the hardware versus leaving the fragment in place. Things to consider and discuss with the patient include: the material composition of the
   fragment (if known), the size and location of the fragment, and the potential mechanisms
   of injury if the fragment is not removed, including MRI exams.
2. Any decision to remove the device should take into consideration the potential risk to
   the patient of a second surgical procedure.
3. If removal is determined to be the best course of action, inspect the device immediately after
   removal from patient for signs of damage. If the device is damaged, retain the device to
   assist the manufacturer’s investigation of the event. Device removal should be followed by
   adequate postoperative care.

CONCERNING MAGNETIC RESONANCE ENVIRONMENT

Medline UNITE® Snap-Off Screws have not been evaluated for safety and compatibility in the
MR environment. It has 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.

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. A manual cleaning method
is provided and has been developed and tested consistent with TIR 30 (manual). The provided
sterilization recommendations have been developed and tested consistent with ANSI/AAMI
ST79. An implant shall never be re-sterilized after contact with human body tissues or
fluids. Devices labeled for single use only should never be reused. Reuse 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.

All instruments, where applicable, must be disassembled prior to cleaning.

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 the lumens a minimum of 3 times to remove soil.
6. Using a syringe, aggressively flush the lumens with the prepared 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, thoroughly brush the device to remove soil.
12. Run a stylet through the lumens a minimum of 3 times to remove soil.
13. Using a syringe, aggressively flush the lumens with the prepared neutral detergent.
14. Remove the device from the detergent and rinse in running RO/DI water to remove deter-
gent 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.

Sterilization

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

<table>
<thead>
<tr>
<th>Cycle Type</th>
<th>Parameter</th>
<th>Minimum Set Point</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevacuum</td>
<td>Exposure Temperature</td>
<td>270° F (132° C)</td>
</tr>
<tr>
<td></td>
<td>Exposure Time</td>
<td>4 Minutes</td>
</tr>
<tr>
<td></td>
<td>Dry Time</td>
<td>40 Minutes</td>
</tr>
</tbody>
</table>

Do not stack trays 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 recommended 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.

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