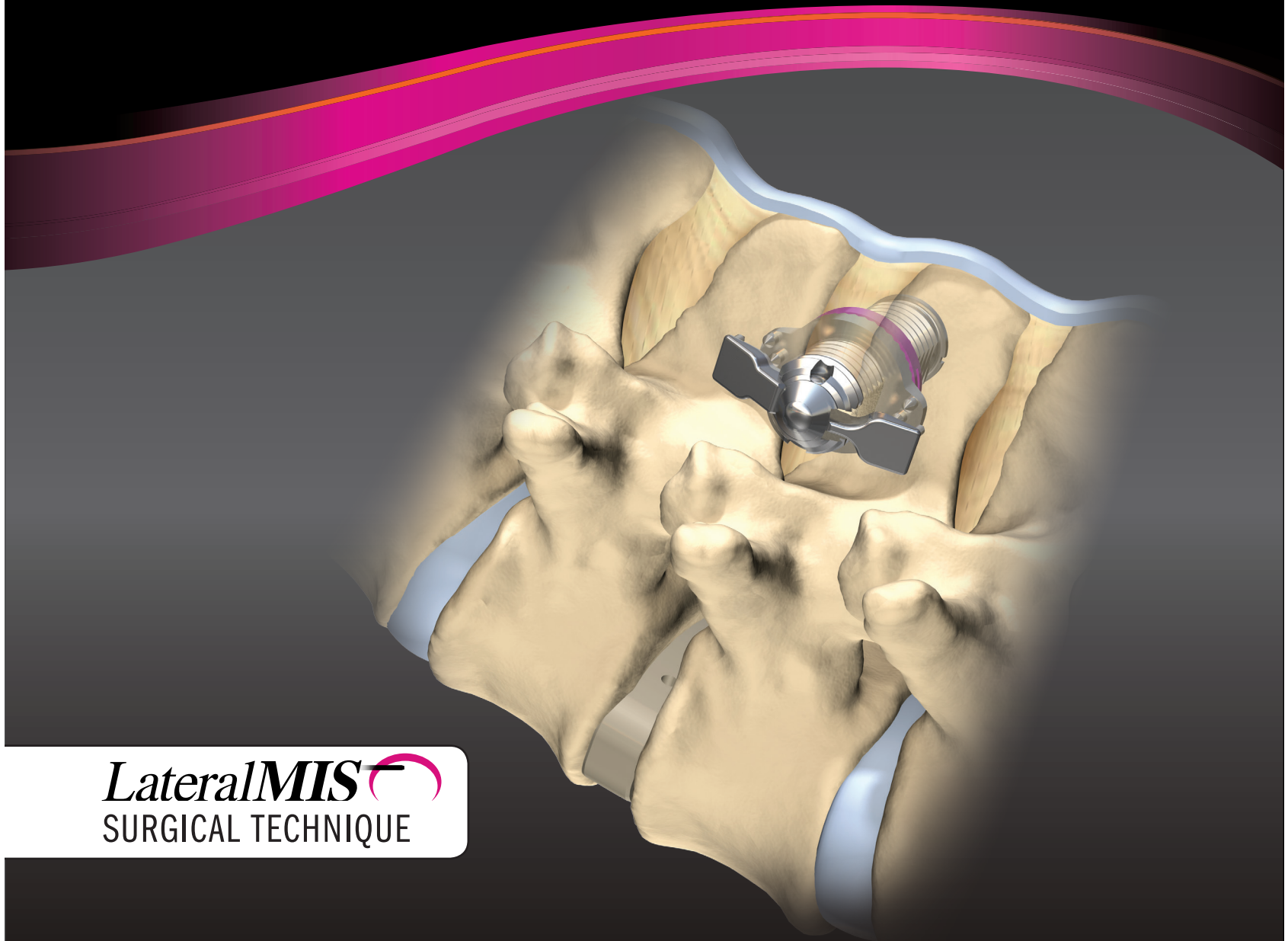


# Minuteman<sup>®</sup>G<sub>3</sub>

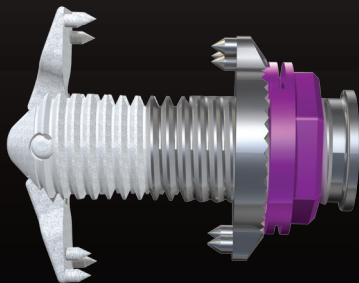
MIS FUSION PLATE



*LateralMIS*   
SURGICAL TECHNIQUE

## Spinal fusion...simplified

STANDARD AND HA-COATED MINUTEMAN<sup>G3</sup>

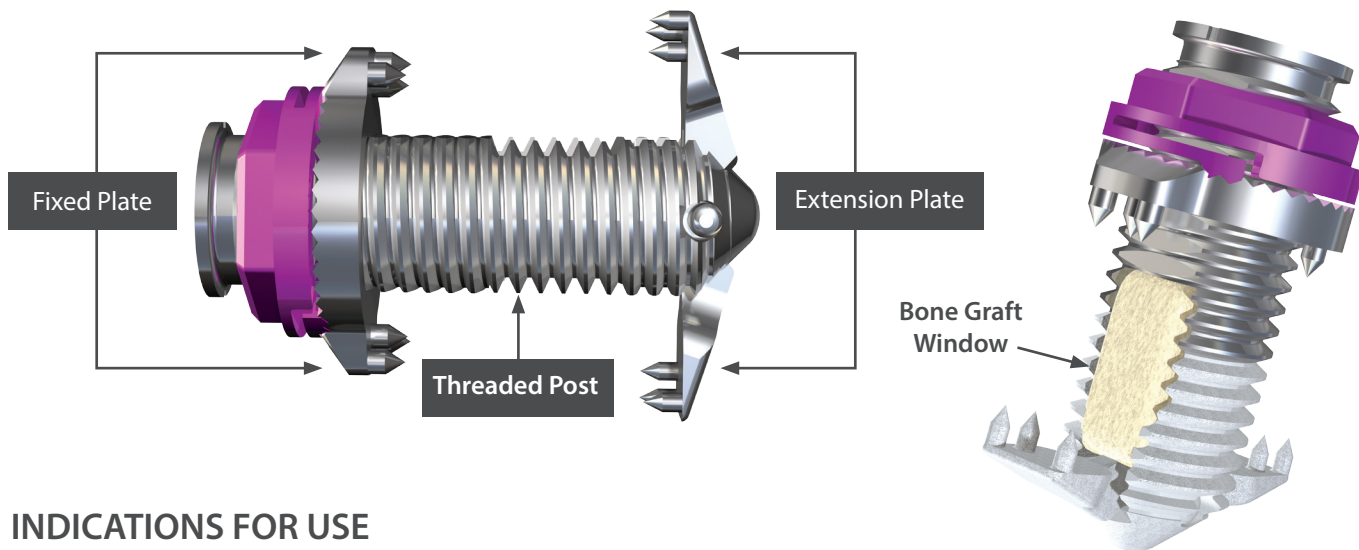


Spinal  Simplicity  
Innovative simple solutions

# THE MINUTEMAN<sub>G3</sub> DESIGN RATIONALE

The Minuteman<sub>G3</sub> is a minimally invasive, interspinous-interlaminar fusion device intended for the temporary fixation of the thoracic, lumbar and sacral spine while awaiting bony fusion to occur. It is designed for attachment to the posterior non-cervical spine at the spinous processes through its bilateral locking plates, and is intended for use with bone graft material placed within the device and on the outside of the threads to prevent unwanted spike plate movement.

The Minuteman<sub>G3</sub> provides immobilization and stabilization of the spinal segments while used as an adjunct to interbody fusion. The core threaded post provides controlled distraction, while a wide range of sizes allows for enhanced anatomical fit. The Minuteman<sub>G3</sub> can easily be placed under fluoroscopy through a lateral MIS or posterior MIS approach. The Minuteman<sub>G3</sub> is delivered sterile and individually packed.



## INDICATIONS FOR USE

The Spinal Simplicity Minuteman<sub>G3</sub> MIS Fusion Plate / HA Minuteman<sub>G3</sub> MIS Fusion Plate is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions:

- Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Trauma (i.e., fracture or dislocation); and/or
- Tumor

The Minuteman<sub>G3</sub> / HA Minuteman<sub>G3</sub> is intended for use with bone graft material and is not intended for stand-alone use. The device may be implanted via a minimally invasive posterior approach (T1-S1) or a minimally invasive lateral approach (L1-S1).

## WARNINGS

The Minuteman<sub>G3</sub> components are not to be connected to the components of devices from another manufacturer. Titanium implants should not be mixed with stainless steel implants in the same construct. A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery, where many extenuating circumstances may compromise the result. The Minuteman<sub>G3</sub> has not been evaluated for safety and compatibility in the MR environment. The Minuteman<sub>G3</sub> has not been tested for heating or migration in the MR environment.

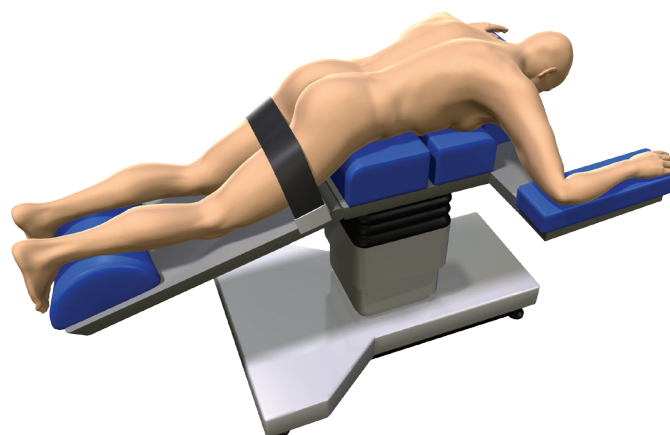
# Surgical Technique - PREPARATION, POSITIONING & LATERAL MIS APPROACH

## 1. Preoperative Planning

Routine preoperative studies include AP and lateral x-rays (flexion and extension views are also recommended), MRI, or CT myelography. It is important to rule out gross instability, spondylolisthesis > grade I, significant scoliosis, severe osteoporosis, and ankylosed spinal segment. If the lateral MIS approach is required at L3-L4 or above, a preoperative CT is recommended to ensure safe trajectory to the spine. The lateral MIS approach may not be performed for levels above L1.

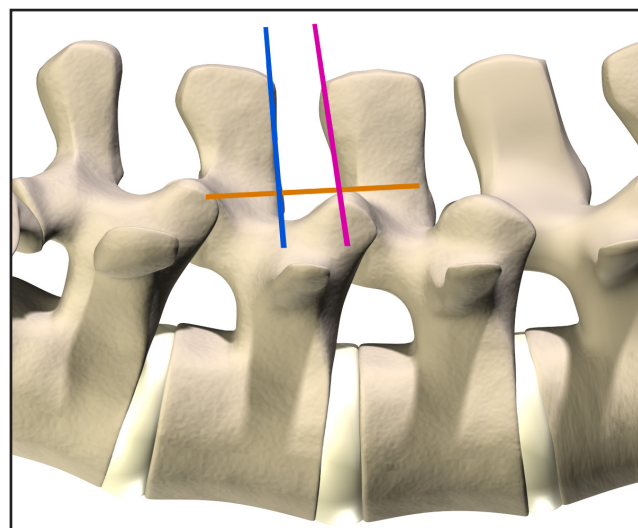
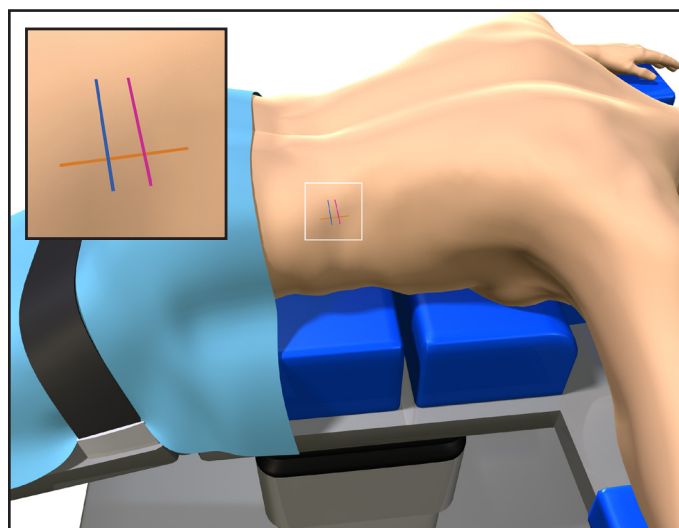
## 2. Patient Positioning

The patient should be placed in a prone position on a frame that decreases the lordosis of the spine and allows for the abdomen to not be compressed. It is advisable to tilt the pelvis by inclining the table at the level of the pelvis. This will allow for a natural distraction of the spinous processes. The frame and operating table need to be radiolucent in both an AP and a lateral plane.

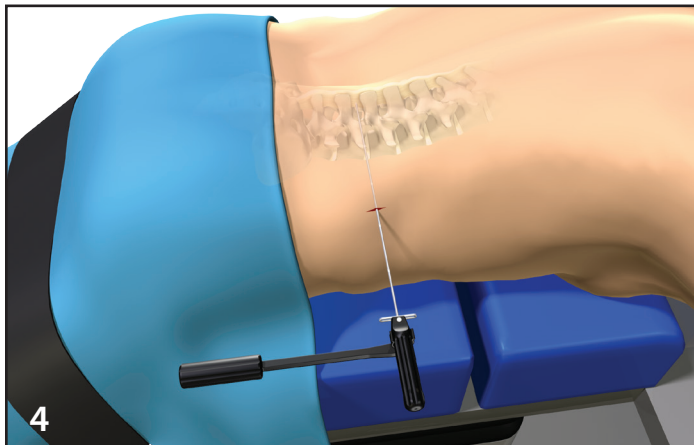


## 3. LATERAL MIS APPROACH - Targeting the Access Point

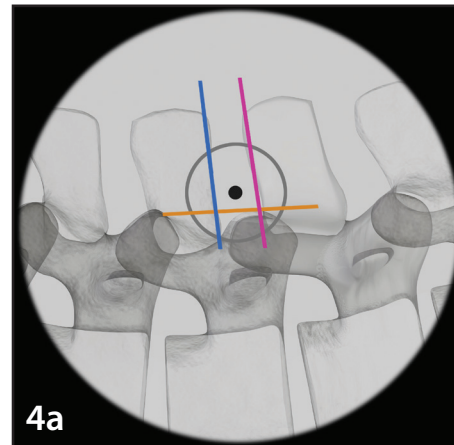
Using manual palpation and AP fluoroscopy, identify the midline of the spinous processes at the level to be instrumented and insert a spinal needle. Under lateral fluoroscopy, define the anatomical landmarks and project them onto the skin. A skin mark (shown in Blue) is made corresponding to the superior edge of the inferior spinous process. A second skin mark (shown in Magenta) is made corresponding to the inferior edge of the superior spinous process. A third skin mark (shown in Orange) is made corresponding to the posterior limit of the facet joint. Make a longitudinal incision of approximately 2.5 cm along the Orange line and between the Blue and Magenta lines.



# Surgical Technique - GUIDE WIRE INSERTION



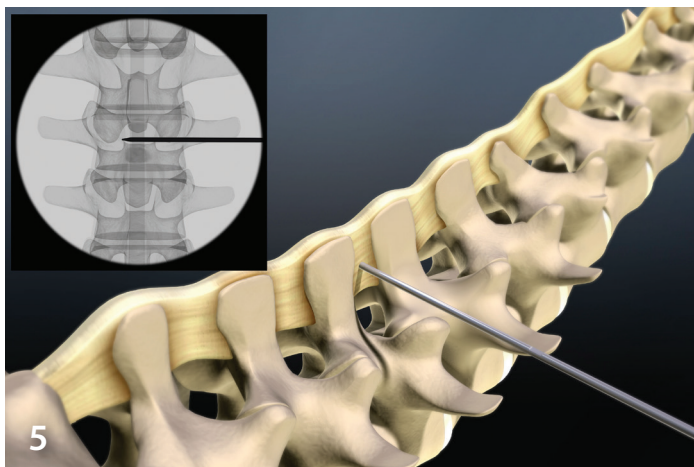
Introduce the Guide Wire into the Aiming Device until it reaches the first Stop. The Guide Wire is inserted through the incision. Depress the Aiming Device Knob to increase the Guide Wire length. Under lateral fluoroscopy, carefully advance the Guide Wire between the spinous processes and pierce the interspinous ligament.



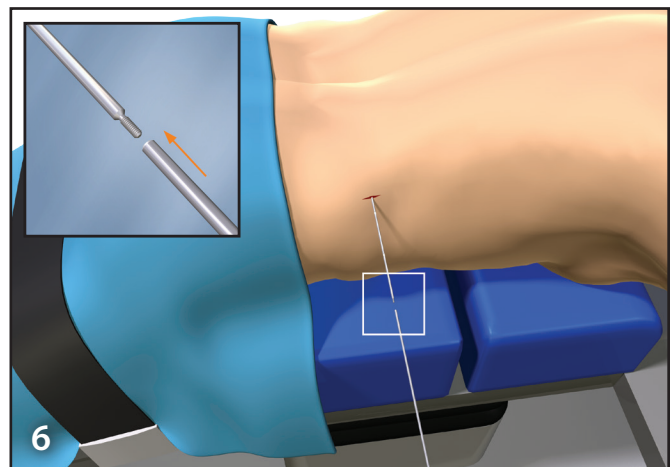
For optimal placement of the Minuteman<sub>G3</sub>, the Guide Wire must be placed as far anterior as possible.

It is important to keep the Guide Wire parallel with the coronal plane. Attach the Aiming Device Holder to the Aiming Device when using fluoroscopy.

*Alternatively, the Disposable Guide Wire may be used in steps 4-10 as a single piece replacement for the Guide Wire and Guide Wire Extension.*



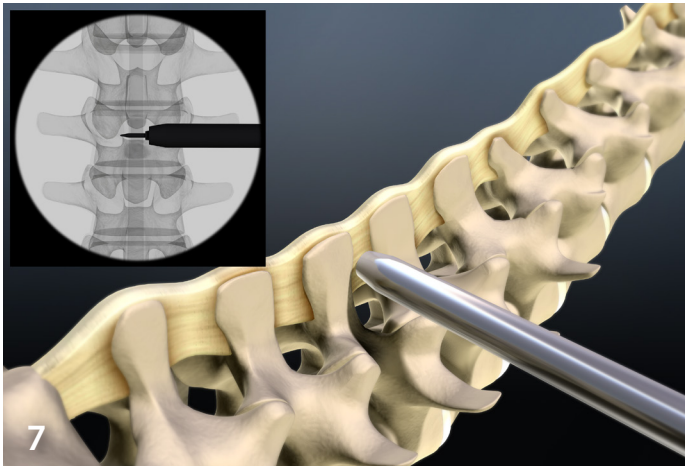
Under AP fluoroscopy, advance the Guide Wire approximately 2 cm across the midline of the spine. Verify position of the Guide Wire with AP and lateral views.



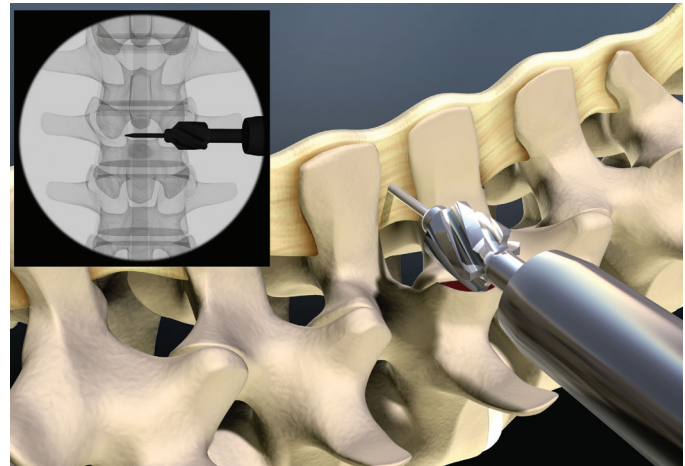
Depress the Aiming Device Knob and carefully remove the Aiming Device from the Guide Wire. It is important to maintain Guide Wire position. The Guide Wire Extension is threaded onto the Guide Wire. The Guide Wire Extension helps maintain correct Guide Wire placement while inserting Dilators, Sleeves and other instruments.



## Surgical Technique - IMPLANT SITE PREPARATION

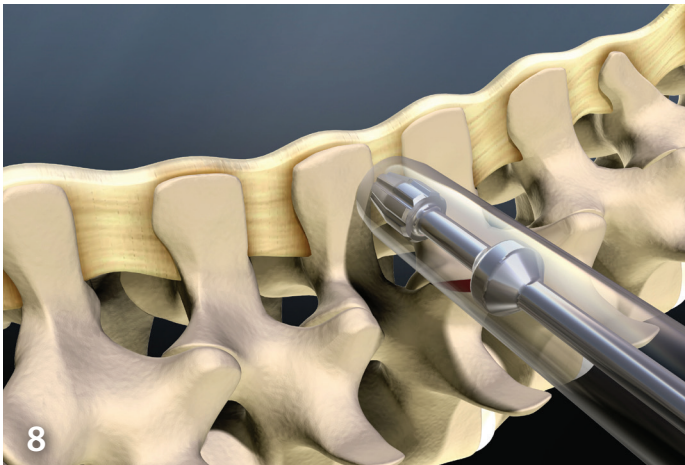


Slide the 3 mm Soft Tissue Dilator over the Guide Wire. Under AP fluoroscopy, the 3 mm Dilator is inserted through the skin incision while holding the Guide Wire in place. Insert the 3 mm Dilator until it is adjacent to the spinous processes. Repeat this technique for the 8 mm Dilator, 14 mm Dilator and the 20 mm Sleeve.

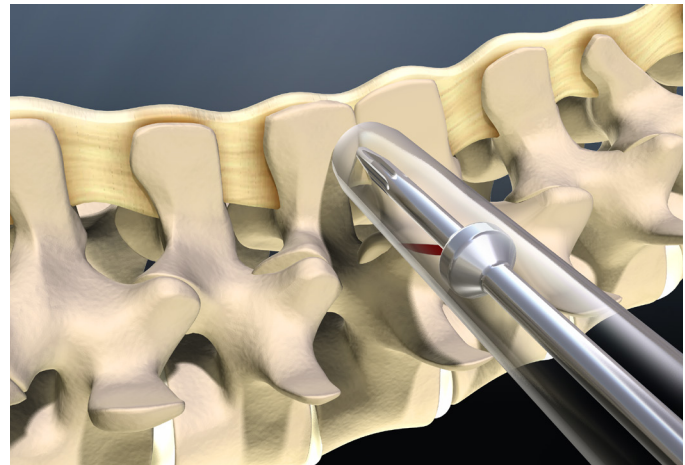


Optional: If facet hypertrophy does not allow the Sleeve to dock against the spinous processes, the Bone Rasp is inserted over the Guide Wire and rotated clockwise to gradually reduce the mass of the facets. Remove the Bone Rasp and leave the Guide Wire in place.

While inserting instruments over the Guide Wire, it is important to ensure that the Guide Wire does not further advance.



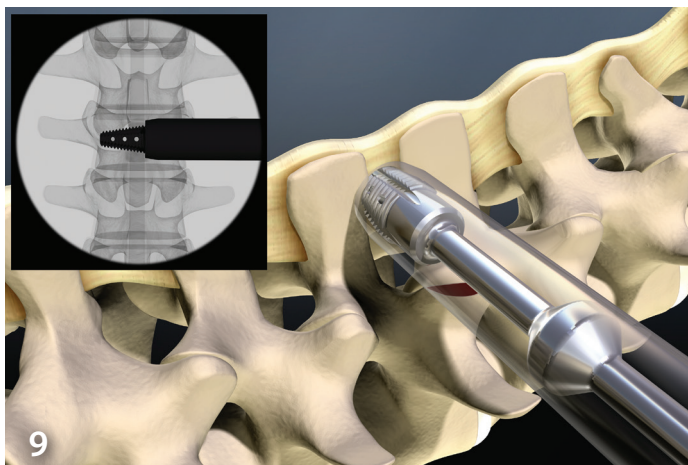
The Soft Tissue Rasp is inserted over the Guide Wire and into the interspinous process space. The Rasp is rotated clockwise to partially remove the interspinous ligament and to partially decorticate the spinous processes. The Rasp is then removed and the Guide Wire is left in place.



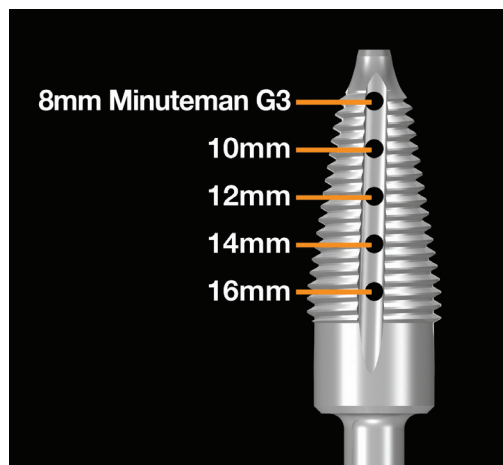
Optional: If the Soft Tissue Rasp does not advance between the spinous processes due to touching spinous processes, the Starter Rasp is inserted over the Guide Wire and rotated clockwise to gradually distract the spinous processes.

A snug fit should be obtained during use of the Soft Tissue Rasp and Graduated Tap, but do not over-distract the interspinous process space as this may fracture the spinous processes.

## Surgical Technique - IMPLANT SIZING



The Graduated Tap is inserted over the Extended Guide Wire. Under AP fluoroscopy, the Tap is threaded clockwise into the interspinous process space. Apply gentle force to engage the threads of the Tap with the spinous processes. As the Tap is advanced, the Tap gradually distracts the spinous processes. Once adequate distraction is obtained, the degree of distraction can be determined by viewing which Tap sizing hole is positioned between the spinous processes. This degree of distraction determines the appropriate implant size.



To determine the Minuteman<sub>G3</sub> size, the Tap has sizing holes that correspond with the degree of distraction, and these holes can be visualized on AP fluoroscopy.

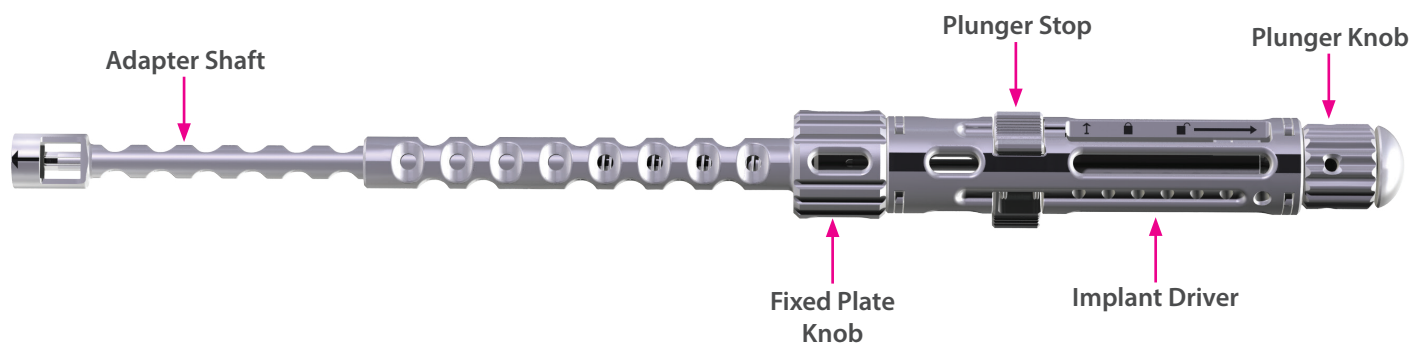
A snug fit should be obtained during use of the Graduated Tap, but do not over-distract the interspinous process space as this may fracture the spinous processes. If the interspinous process space measures in-between sizes, it is recommended to choose the smaller size implant.



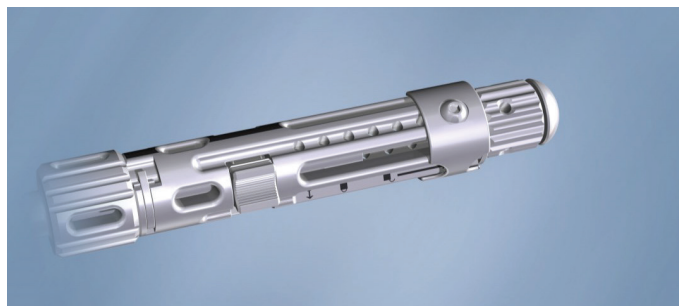
Slide the 23 mm Sleeve over the 20 mm Sleeve. Insert the 23 mm Sleeve until it is adjacent to the spinous processes. Repeat this step for the 26 mm Sleeve. Remove the 20 mm and 23 mm Sleeves, leaving the 26 mm Sleeve in place.

It is important to keep the Sleeve docked against the spinous processes to maintain a clear pathway to the implant delivery site. For implant delivery, the 26 mm Sleeve is required. The Minuteman G3 will not pass through the 20 mm or 23 mm Sleeve.

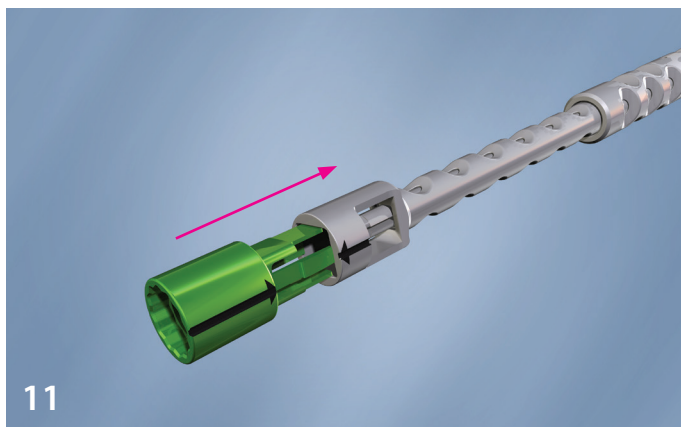
# Surgical Technique - ALL-IN-ONE G2-INSERTER



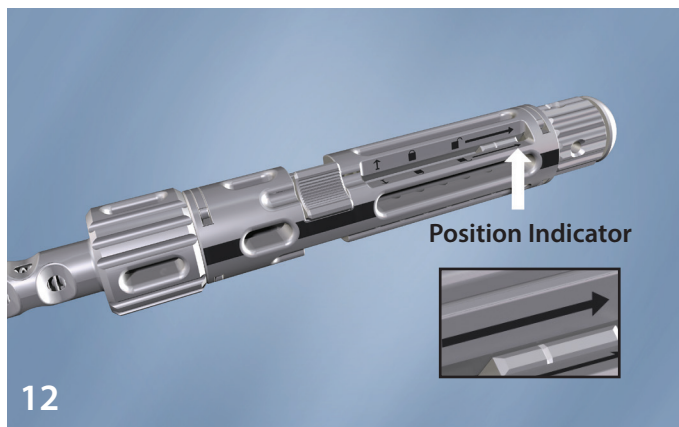
Optional: The Insertion Instrument Collar Kit may be used to further secure the locking tabs during the procedure. Slide the Collar over the proximal end of the Insertion Instrument until the screw holes on the Collar are aligned with the threaded holes on the Insertion Instrument.



Hand tighten the two screws into the threaded holes on the Insertion Instrument.



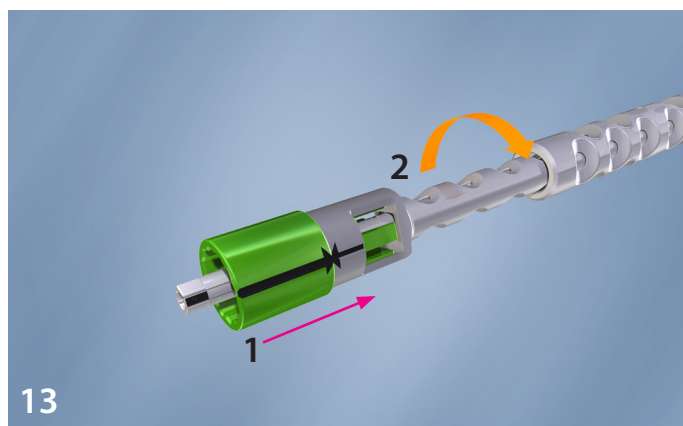
Remove the Guide Wire while leaving the Sleeve in place against the lateral surface of the spinous processes. After determining the appropriate Minuteman<sub>G3</sub> size, attach the corresponding size Insertion Adaptor to the distal end of the G2-Inserters. The color of the Insertion Adaptor will match the color of the appropriate size Minuteman<sub>G3</sub> Hex Nut



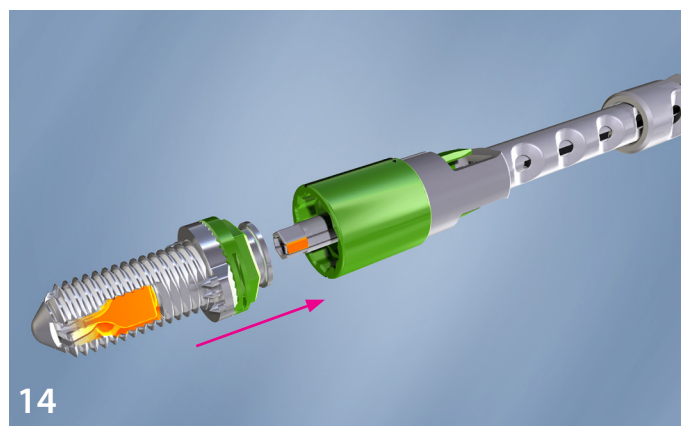
Verify the G2-Inserters is in the unlocked position in order to attach the Minuteman<sub>G3</sub>. The Position Indicator will be aligned with the arrowhead as shown above.



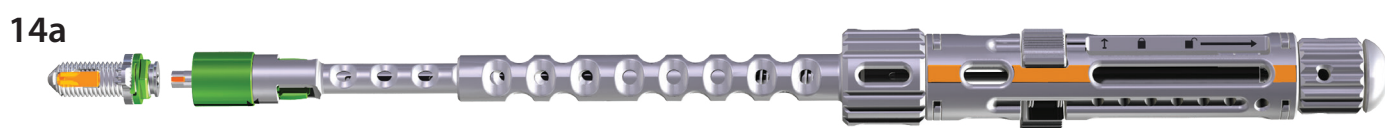
# Surgical Technique - MINUTEMAN<sub>G3</sub> ATTACHMENT TO THE G2-INSERTER



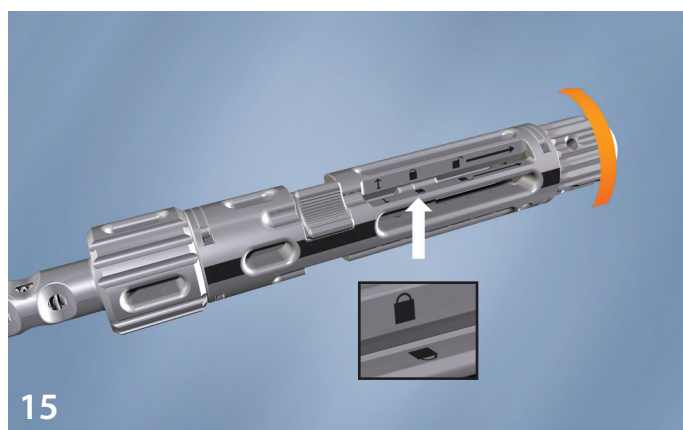
13  
The spring loaded Adaptor Shaft is (1) compressed towards the Fixed Plate Knob until the Adaptor Shaft bottoms out and then (2) rotated counterclockwise approximately 1/8 turn.



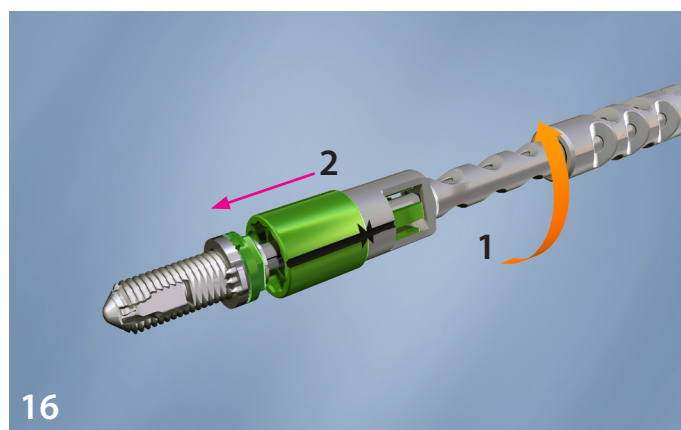
14  
Align the Extension Plate of the Minuteman<sub>G3</sub> in the same orientation as the laser etching and snap the implant into place. Proper placement allows the Extension Plate to be aligned with the Plate Reference Lines.



14a  
Alignment of the Extension Plate with the laser etching allows the surgeon to utilize the Plate Reference Lines on the G2-Inserter to ensure accurate plate orientation during the procedure.



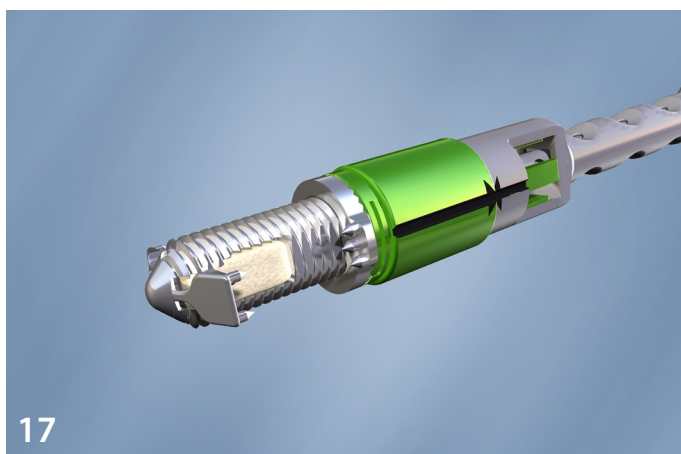
15  
To lock the Minuteman<sub>G3</sub> to the G2-Inserter, rotate the Plunger Knob clockwise until the Position Indicator is in the locked position. The Plunger Stop automatically clicks to the right, locking the Minuteman<sub>G3</sub> to the G2-Inserter.



16  
Hold the Fixed Plate Knob and (1) rotate the Adaptor Shaft clockwise, approximately 1/8 turn and (2) allow the Adaptor Shaft to gently spring forward. The Insertion Adaptor will engage the Minuteman<sub>G3</sub> Hex Nut. If the Insertion Adaptor does not properly engage the Minuteman<sub>G3</sub> Hex Nut, slowly rotate the Adaptor Shaft until the Insertion Adaptor slides into place.



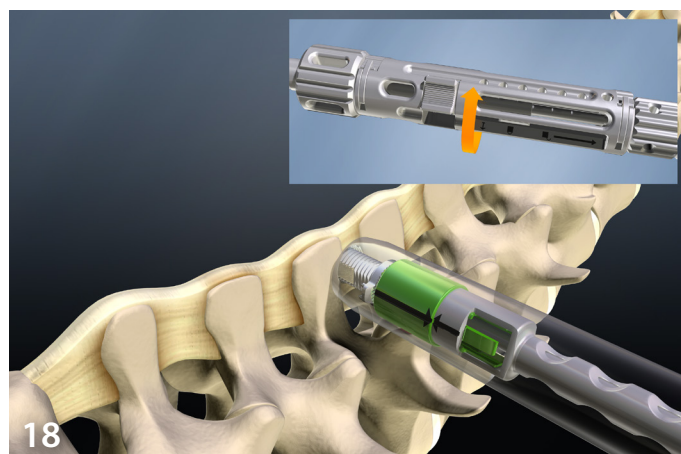
## Surgical Technique - INSERTING THE MINUTEMAN G3



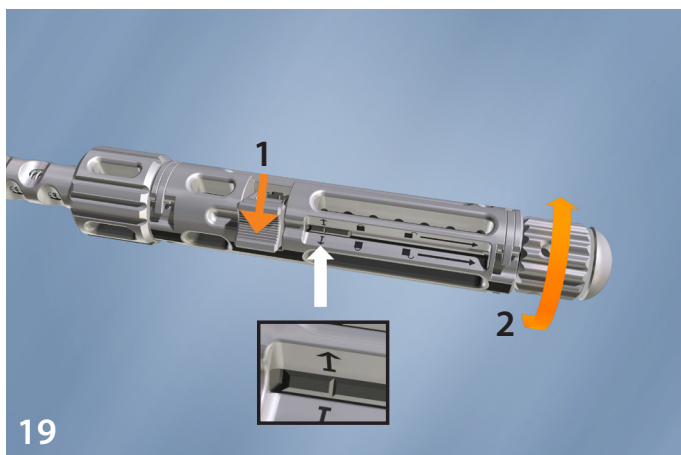
17  
Bone graft material is placed within the threaded body and around the exterior threads of the Minuteman<sub>G3</sub>.

The bone graft material must be viscous in nature to allow the inner mechanism to properly function.

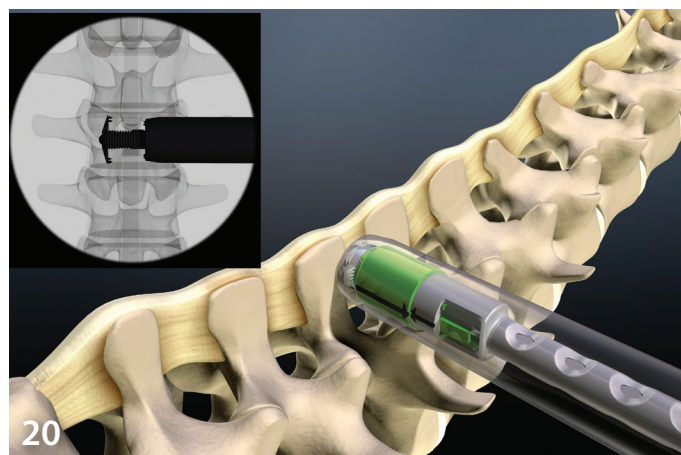
Minuteman <sub>G3</sub>	8mm	10mm	12mm	14mm	16mm
Graft Volume	1.2cc	1.45cc	1.8cc	2.0cc	2.5cc



18  
The G2-Insertor with the attached Minuteman<sub>G3</sub> is inserted into the Sleeve and advanced to the interspinous process space aiming as far anterior as possible. Rotate the G2-Insertor clockwise to engage the threads of the Minuteman<sub>G3</sub>. Under fluoroscopy, the Minuteman<sub>G3</sub> is advanced into the interspinous space, until the Fixed Plate is adjacent to the spinous processes.



19  
To deploy the Extension Plate, (1) slide and hold the Plunger Stop to the left and (2) rotate the Plunger Knob clockwise until the Plunger Knob stops. The Position Indicator will be aligned close to the Plate Deployment Symbol.

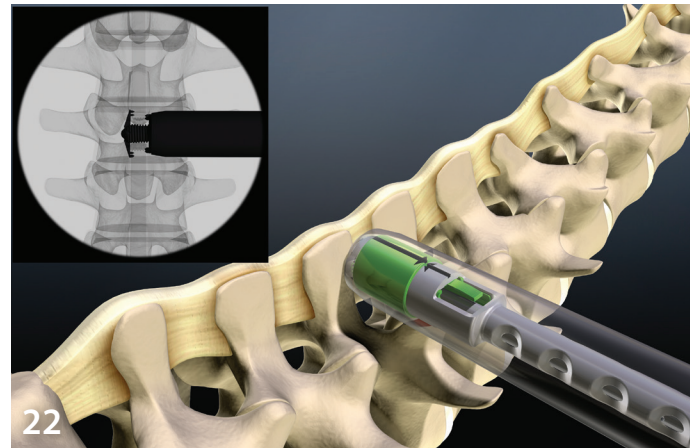


20  
Verify under fluoroscopy that the Extension Plate has been deployed and will engage the spinous processes as far anterior as possible during fixation. The Minuteman<sub>G3</sub> is now ready for fixation to the spinous processes.

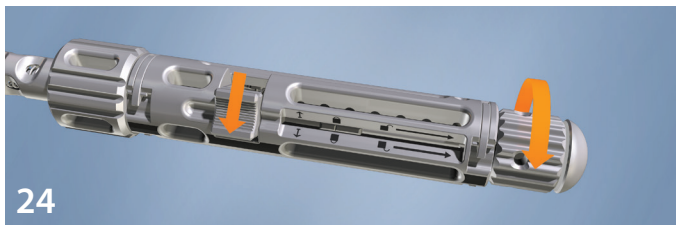
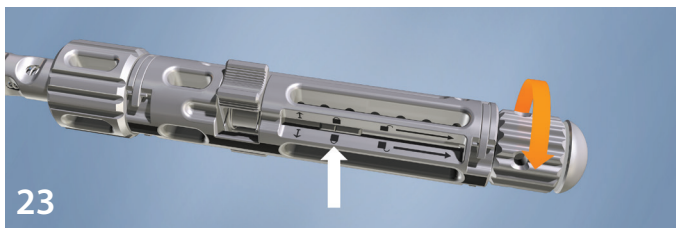
## Surgical Technique - IMPLANT FIXATION TO THE SPINOUS PROCESSES



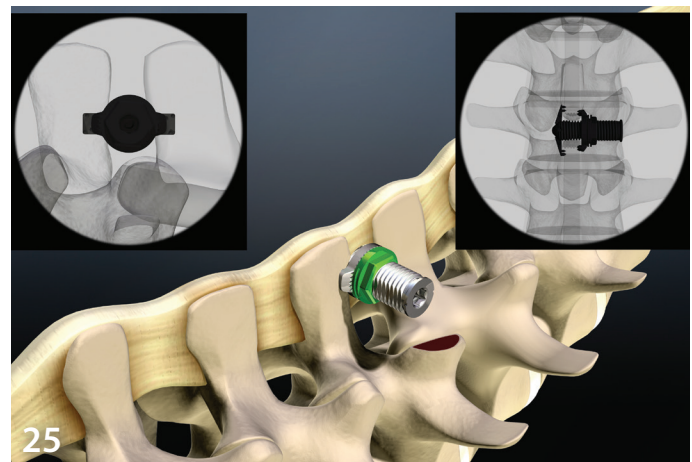
21  
To fixate the implant to the spinous processes, hold the G2-Insertor to stabilize the implant's position and rotate the Fixed Plate Knob clockwise to advance the Fixed Plate. As the Fixed Plate is tightened, the Extension Plate will be brought to engage the distal lateral surface of the spinous processes.



22  
A ratcheting sensation will be felt which represents the locking mechanism of the implant. The degree of applied torque should correspond to the bone quality and age of the patient.



(23) The G2-Insertor is detached from the implant by rotating the Plunger Knob counterclockwise until the Position Indicator reaches the lock position. The Plunger Stop automatically clicks to the right. (24) Slide and hold the Plunger Stop back to the left and continue to rotate the Plunger Knob counterclockwise until it stops. The G2-Insertor is now detached from the implant.



25  
The G2-Insertor and Sleeve are removed. Sutures or steristrips are then applied.

# Surgical Technique - IMPLANT REMOVAL & EXTENSION PLATE RESET

## Implant Removal

The implant can be removed through a conventional posterior open surgical approach using the Minuteman<sub>G3</sub> Open Instrument Set. A lateral MIS attempt to remove the Minuteman<sub>G3</sub> is not recommended.

1. Insert the Insertion Hex into the back of the implant for stabilization.
2. Attach appropriate size Wrench to the Hex Nut and loosen the Hex Nut completely.
3. Insert the Plate Reset Instrument into the caudal end of the Minuteman<sub>G3</sub> and thread clockwise to engage the inner mechanism.
4. Gentle lateral retraction of the inner mechanism unlocks the Extension Plate allowing the Extension Plate to fully collapse.
5. With the Extension Plate collapsed, gently guide the implant out of the interspinous process space and remove from the incision.

## EXTENSION PLATE RESET

If the Extension Plate is accidentally deployed during attachment of the Minuteman<sub>G3</sub> to the G2-Inserter, the Plate Reset Instrument is utilized. First detach the Minuteman<sub>G3</sub> from the G2-Inserter. The Plate Reset Instrument is inserted into the caudal end of the Minuteman<sub>G3</sub> and threaded clockwise (only 2-3 rotations) to engage the inner mechanism of the Minuteman<sub>G3</sub>. Gentle retraction of the inner mechanism of the Minuteman<sub>G3</sub> is performed with the Plate Reset Instrument to unlock the Extension Plate of the Minuteman<sub>G3</sub>. The Plate Reset Instrument is then rotated counterclockwise to disengage it from the Minuteman<sub>G3</sub>, and it is then removed.

When threading the Plate Reset Instrument into the inner mechanism, only 2-3 rotations is necessary. It is important to not fully remove the inner mechanism from the Minuteman<sub>G3</sub>. As the inner mechanism is retracted, a détente from the inner mechanism will be felt. This is the limit of retraction for the inner mechanism



# Minuteman<sub>G3</sub> LATERAL MIS INSTRUMENT SET

Spinal Simplicity is in constant pursuit of innovative, simple solutions. The Minuteman<sub>G3</sub> Instrument Set is the result of this pursuit. Precision manufactured to the highest quality standards and thoughtfully designed, the set enables a surgeon to implant and fixate the Minuteman<sub>G3</sub> away from the neural elements through a lateral MIS approach. The patent-pending G2-Insertor is the first and only all-in-one inserter that provides delivery, deployment and fixation of the Minuteman<sub>G3</sub>, streamlining spinal fusion procedures.

## Lateral MIS Instruments

Guide Wire	20-0001-000
Guide Wire Extension	20-0002-000
Dilator, 3 mm	20-0003-003
Dilator, 8 mm	20-0003-008
Dilator, 14 mm	20-0003-014
Sleeve, 20 mm	20-0004-020
Sleeve, 23 mm	20-0004-023
Sleeve, 26 mm	20-0004-026
Bone Rasp	20-0005-000
Soft Tissue Rasp	20-0006-000
Aiming Device	20-0007-000
Graduated Tap	20-0009-000
Plate Reset Instrument	20-0012-000
Direct Drive T-Handle	20-0013-000
Dilator/Sleeve Handle	20-0014-000
Modular Handle	20-0024-000
Bone Chip Plunger	20-0025-000
G2-Insertor	20-0026-000
Aiming Device Holder	20-0049-000
Insertion Adaptor, 8 mm	20-0092-008
Insertion Adaptor, 10 mm	20-0092-010
Insertion Adaptor, 12 mm	20-0092-012
Insertion Adaptor, 14 mm	20-0092-014
Insertion Adaptor, 16 mm	20-0092-016
Insertion Instrument Collar Kit	20-0093-000
Starter Rasp	20-0099-000
Minuteman MIS Case/Tray	30-0006-000

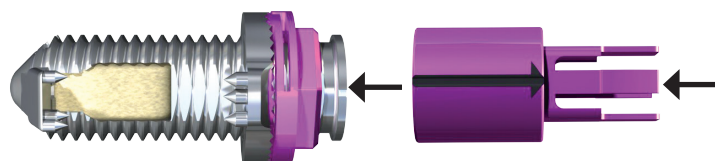
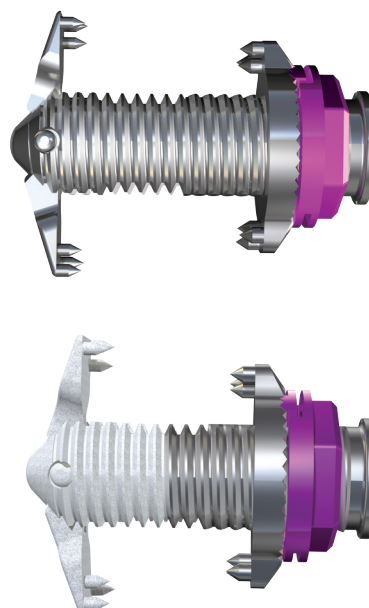
The Minuteman<sub>G3</sub> implants are packaged in rigid custom thermoformed PETG trays. The trays consist of an inner and outer tray that are sealed with a Tyvek lid providing a double sterile barrier. The custom thermoformed tray packaging allows for easy introduction of the implants to the surgical field. The surgeon can quickly and easily access the implant via custom finger pockets in the tray. The sealed trays are housed in a custom Spinal Simplicity thin cardboard unit carton box affixed with tamper seals.

The implant outer packaging is labeled in two locations for easy identification and includes a gamma sterilization indicator label. Additional peel-and-stick labels are provided within the package for inclusion into the patient's medical record.

The diameter color code on the packaging corresponds with the Hex Nut and Insertion Adapter color to easily verify the correct implant size.

## Implants and Disposables

Minuteman <sub>G3</sub> , 8 mm	10-0004-008
Minuteman <sub>G3</sub> , 10 mm	10-0004-010
Minuteman <sub>G3</sub> , 12 mm	10-0004-012
Minuteman <sub>G3</sub> , 14 mm	10-0004-014
Minuteman <sub>G3</sub> , 16 mm	10-0004-016
HA-Coated Minuteman <sub>G3</sub> , 8 mm	10-0017-008
HA-Coated Minuteman <sub>G3</sub> , 10 mm	10-0017-010
HA-Coated Minuteman <sub>G3</sub> , 12 mm	10-0017-012
HA-Coated Minuteman <sub>G3</sub> , 14 mm	10-0017-014
HA-Coated Minuteman <sub>G3</sub> , 16 mm	10-0017-016
Disposable Guide Wire	20-0001-001

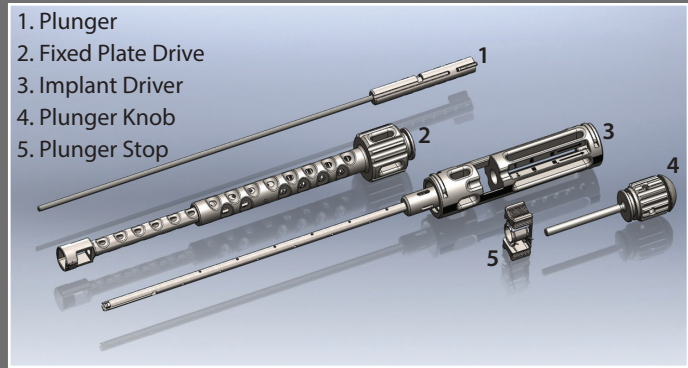


Diameter Color Code	Implant Size
Yellow	8mm
Orange	10mm
Green	12mm
Blue	14mm
Dark Blue	16mm

# G2-INSERTER DISASSEMBLY GUIDE

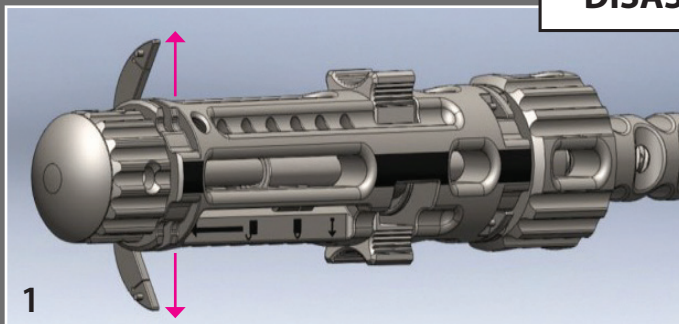


ASSEMBLED

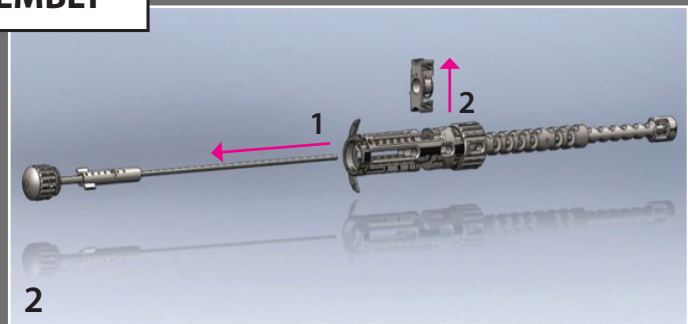


DISASSEMBLED

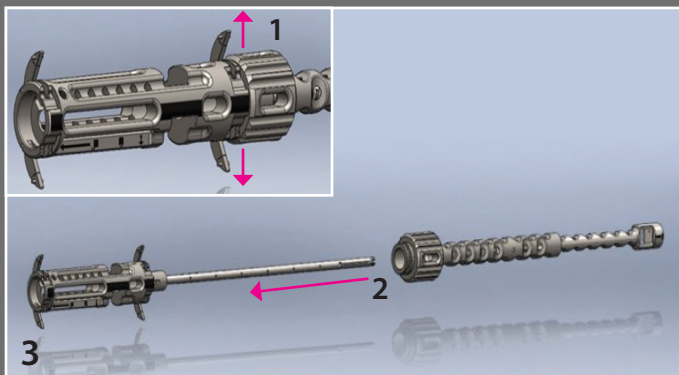
## DISASSEMBLY



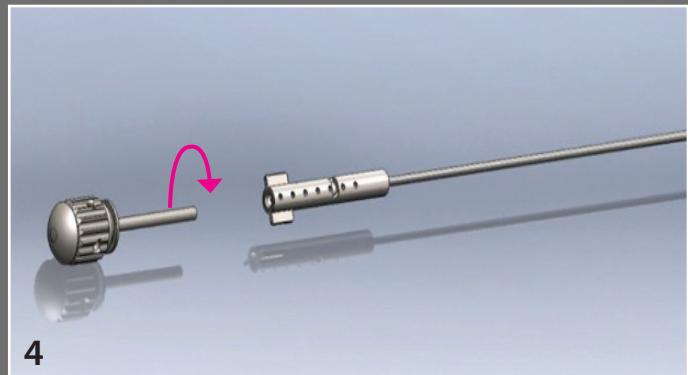
Use the Modular Handle to pry open and unlock the underside of the Plunger Locking Tabs.



(1) Pull Plunger Knob out of the Implant Driver. (2) The Plunger Stop will disengage allowing the Plunger Stop to be removed.



(1) Use the Modular Handle to pry open and unlock the underside of the Locking Tabs adjacent to the Fixed Plate Drive. (2) Remove the Implant Driver from the Fixed Plate Drive.

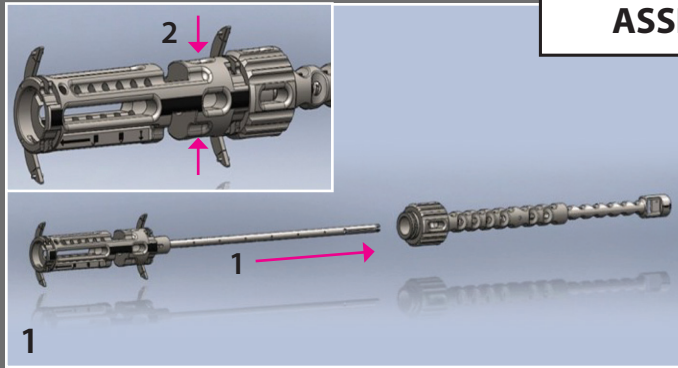


Unthread Plunger Knob from Plunger by rotating Plunger Knob clockwise. (reverse thread).

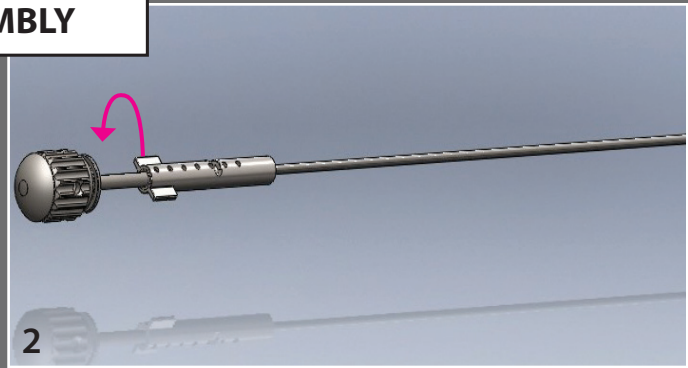


# G2-INSERTER ASSEMBLY GUIDE

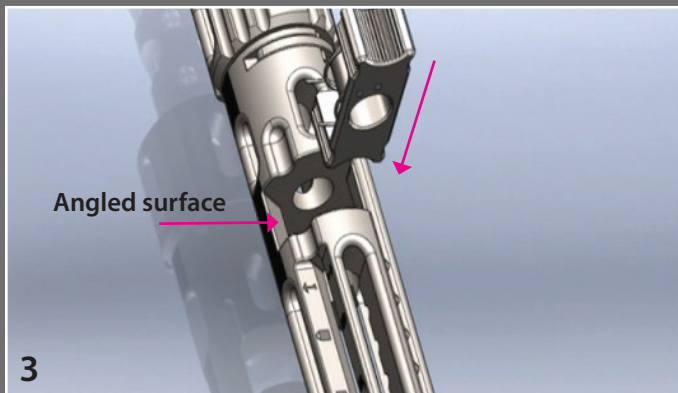
## ASSEMBLY



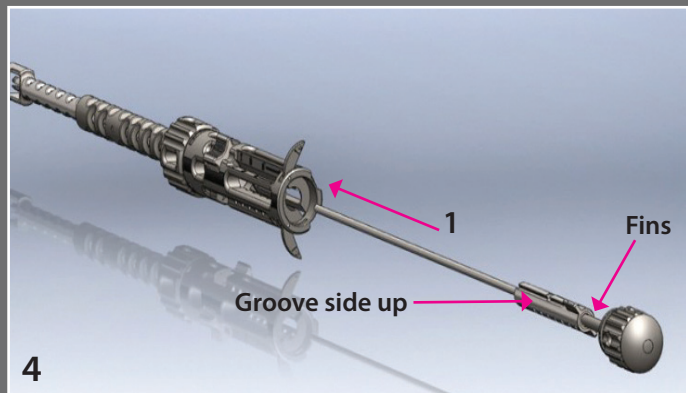
(1) Insert Implant Driver into Fixed Plate Drive. (2) Lock the Locking Tabs closest to the Fixed Plate Drive. An audible click will be heard when locked.



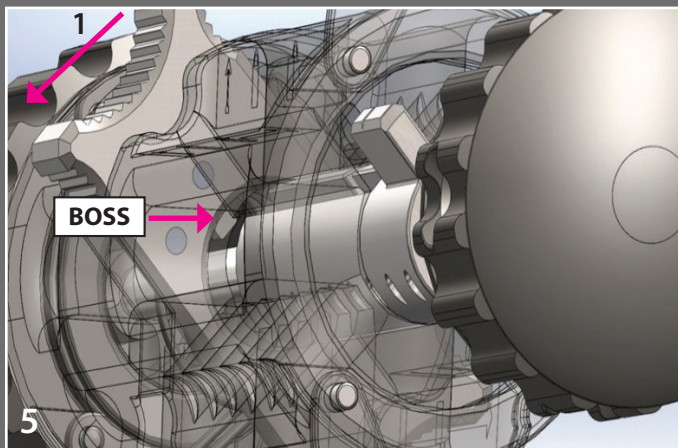
Thread Plunger Knob to the Plunger by rotating counterclockwise (reverse thread).



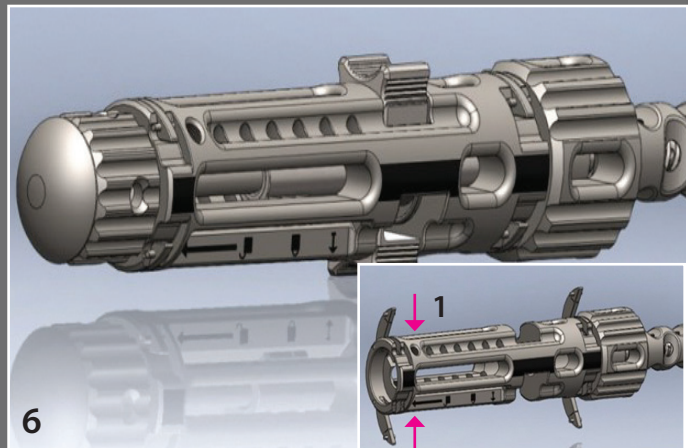
Insert Plunger Stop into Implant Driver (Legs of the spring must rest on angled surface and the #2 on the Plunger Stop will be visible) and hold in position.



Insert Plunger partially, groove side up, into the Implant Driver. As you continue to insert, it is important to align the two fins on Plunger with the two openings in the Implant Driver.



Continue to insert. Once resistance is felt, (1) rotate and hold the Plunger Stop to the far left to align Boss with the groove in Plunger. Continue to insert Plunger until fully seated.



(1) Lock the Plunger Knob Locking Tabs. An audible click will be heard when locked. G2-Inserter is now ready for use.

## CONTRAINDICATIONS

The Minuteman<sub>G3</sub> is contraindicated in patients with

- An allergy to titanium or titanium alloy
- Spinal anatomy or disease that would prevent implantation of the device, or cause the device to be unstable in situ such as
  - Significant instability of the lumbar spine;
  - An ankylosed segment at the affected level(s);
  - Acute fracture of the spinous process or pars interarticularis;
  - Significant scoliosis (Cobb angle greater than 25 degrees);
- Diagnosis of severe osteoporosis
- Active systemic infection or infection localized to the site of implantation
- Insufficient quality or quantity of bone, which would inhibit rigid device fixation
- Incompetent or missing posterior arch
- Pregnancy

## POSSIBLE ADVERSE EFFECTS

### Device related:

- Implant dislodgement/migration
- Implant not positioned correctly
- Fracture of the spinous process
- Additional surgery, including removal of the Minuteman G3 device
- Foreign body reaction
- Mechanical failure of the device
- Failure of the device/procedure to improve symptoms and/or function

### Surgery related:

- |                                      |   |
|--------------------------------------|---|
| • Myocardial infarction              | • Paralysis   |
| • Infection                          | • Thrombus formation  |
| • Blood vessel damage/bleeding       | • Graft donor site complications, including pain, fracture or wound healing complications |
| • Deep vein thrombosis               | • Dural tear  |
| • Hematoma                           | • Wound dehiscence or delayed healing   |
| • Pneumonia                          | • Pain/discomfort at the operative site   |
| • Neurological system compromise     | • Death   |
| • Stroke                             |   |
| • Nerve injury or spinal cord damage |   |

## PRECAUTIONS

Preoperative and operating procedures, including knowledge of surgical techniques and proper selection and placement of implants, are important considerations in the successful utilization of the Minuteman<sub>G3</sub> by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of the consequences. Obese, malnourished, and/or alcoholic patients are poor candidates for spinal fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spinal fusion.

The surgeon must be fully conversant with all aspects of the surgical technique and know the indicators and contraindicators of this type of implant. Before beginning the surgical procedure, the surgeon must be acquainted with the specific technique for insertion of the implant, which is available from the manufacturer. Never re-use any implant even if it appears unmarked or undamaged. Any implant implanted and then removed must be discarded. Use only new implants for each case. Implants are not to be re-sterilized.



## CLEANING INSTRUCTIONS

Both physical and chemical (detergent) processes are necessary to minimize the bioburden on all soiled items. Chemical (detergent) cleaners alone cannot remove all soil and debris, therefore a careful manual cleaning of each item is essential for maximum decontamination. Spinal Simplicity recommends the use of a mild enzymatic detergent with a near-neutral pH prepared following the manufacturer's instructions for preparation and use. Saline solution should NOT be used, as saline has a corrosive effect on stainless steel. Remove heavy or large debris using single-use, non-shedding wipes soaked in cleaning solution. Immerse instruments in prepared bath. Using a soft bristle brush (do not use steel brushes) brush all surfaces of the instruments while they are submerged in bath, ensuring that all visible soil is removed. Whenever applicable: use a pipe cleaner and syringe to clean all cannulae, lumens, crevices, grooves and hard to reach areas. Repeatedly operate/bend/articulate all moveable components while cleaning. Allow instruments to soak in detergent prepared bath for manufacturer's recommended soaking time. Final cleaning and disinfecting should be performed via sonication or an automated washer/disinfector cycle. See below recommendations for each:

### Sonication:

1. Remove the instruments from bath and rinse in tap water for a minimum of 3 minutes. Thoroughly and aggressively flush lumen, holes, and difficult-to-reach areas.
2. Place prepared cleaning agents in a sonication unit. Completely submerge instruments in cleaning solution and sonicate for 10 minutes at 45-50 kHz.
3. Rinse instruments in purified water for at least 3 minutes.
4. Visually inspect to determine if all visible soil has been removed from the surfaces, lumen, cannulae, crevices, serrations, threading, etc. If visible soil remains, repeat the cleaning/disinfecting procedure.
5. Dry the instruments with single-use, non-shedding absorbent wipes and/or medical compressed air (e.g. interiors and cannulae). Be sure to completely dry the instruments immediately after rinse to inhibit corrosion.

### Automated Washer:

1. Remove instruments from bath and rinse in purified water for a minimum of 1 minute. Thoroughly and aggressively flush lumen, holes, and difficult-to-reach areas.
2. Place instruments in a suitable washer/disinfector basket and process through a standard washer/disinfector cleaning cycle. The following minimum parameters are essential for thorough cleaning and disinfecting.
  - A. 2 minute prewash with cold tap water
  - B. 20 second enzyme spray with hot tap water
  - C. 1 minute enzyme soak
  - D. 15 second cold tap water rinse
  - E. 2 minute detergent wash with hot tap water (64-66°C/146-150°F)
  - F. 15 second hot tap water rinse
  - G. 2 minute thermal rinse (80-93°C/176-200°F)
  - H. 10 second purified water rinse (64-66°C/146-150°F)
  - I. 7 to 30 minute hot air dry (116°C/240°F)

NOTE: The washer/disinfector manufacturer's instructions should be strictly adhered to.

3. Visually inspect to determine if all visible soil has been removed from the surfaces, lumen, cannulae, crevices, serrations, threading, etc. If visible soil remains, repeat the cleaning/disinfecting procedure.

**Caution:** certain cleaning solutions such as those containing formalin, glutaraldehyde, mercury, active chlorine, chloride, bromine, bromide, iodine, iodide, and/or alkaline cleaners may damage some instruments. Such cleaning solutions should not be used.

## CLEANING INSTRUCTIONS CONTINUED

### Inspection:

Check all instruments for corrosion, damage to surfaces, chipping, pitting, discoloration, and contaminants. Remove and adequately dispose of any instruments that show signs of damage.

## STERILIZATION INSTRUCTIONS

For typical steam autoclave cycles, the following are recommended times and temperatures:

### 1. Prevacuum Sterilizer:

Wrapped cases, trays and instruments, or cases, trays and instruments should be exposed to 135° C (275° F) for at least 3 minutes. Dry for 30 minutes. A legally marketed, FDA-cleared sterilization barrier (e.g., wrap, pouch, or container) should be used to maintain sterility after processing.

**Caution:** Do not stack trays during sterilization.



# Spinal Simplicity

*Innovative simple solutions*

The surgical technique description depicted in this brochure is provided as an educational tool and clinical aid to assist properly licensed medical professionals. As part of this professional usage, the medical professional must use their professional judgment in making any final determination in product usage and technique. This procedure should only be performed with fluoroscopic guidance. Please refer to the Product Insert for a more complete description of indications, contraindications, warnings, cautions and other information about the Minuteman<sub>G3</sub> system.



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CAUTION: Federal law restricts this device to sale by or on the order of a physician.

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