Minuteman® G3
Percutaneous Interlaminar Fusion Device

PercLIF™
Surgical Technique

Spinal Simplicity
Innovative simple solutions

Spinal Fusion ...simplified
INDICATIONS FOR USE

The Minuteman G3 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 G3 is intended for use with bone graft material and is not intended for stand-alone use.

The device may be implanted via an open (T1-S1) or percutaneous (L1-S1) approach.

WARNINGS

The Minuteman G3 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 G3 has not been evaluated for safety and compatibility in the MR environment. The Minuteman G3 has not been tested for heating or migration in the MR environment.
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 percutaneous approach is taken L3-L4 or above, a preoperative CT is recommended to ensure safe trajectory to the spine. The lateral percutaneous 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 PERCUTANEOUS 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.
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.

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.

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.

For optimal placement of the Minuteman G3, the Guide Wire must be placed as far anterior as possible.
Surgical Technique - IMPLANT SITE PREPARATION

Slide the 3 mm Soft Tissue Dilator over the Extended 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.

If facet hypertrophy does not allow for perpendicular docking of the Sleeve against the spinous processes, the Bone Rasp is inserted over the Extended Guide Wire and rotated clockwise to gradually reduce the mass of the facets. The Bone Rasp is brought close to the spinous processes, but is not inserted into the interspinous process space. Remove the Bone Rasp and leave the Guide Wire in place.

Under AP fluoroscopy, the Soft Tissue Rasp is inserted over the Extended 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.

While inserting the Soft Tissue Rasp, Graduated Tap and Sleeves, it is important to ensure that the Guide Wire does not further advance. 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.
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 G3 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.

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.

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

5 KEY FUNCTIONS OF THE ALL-IN-ONE G2-INSERTER
1. Attach and lock the Minuteman G3 to the G2-Inserter
2. Thread the Minuteman G3 into the interspinous process space
3. Deploy the Extension Plate of the Minuteman G3
4. Fixate the Plates to the spinous processes
5. Unlock and detach the Minuteman G3 from the G2-Inserter

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

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

To lock the Minuteman G3 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 G3 to the G2-Inserter.

Align the Extension Plate of the Minuteman G3 in the same orientation as the Plunger Slots and snap the implant into place. Proper placement allows the Extension Plate to be aligned with the Plate Reference Lines.

Alignment of the Extension Plate with the Plunger Slots allows the surgeon to utilize the Plate Reference Lines on the G2-Inserter to ensure accurate plate orientation during the procedure.

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 G3 Hex Nut. If the Insertion Adaptor does not properly engage the Minuteman G3 Hex Nut, slowly rotate the Adaptor Shaft until the Insertion Adaptor slides into place.
Bone graft material is placed within the threaded body of the Minuteman G3.

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

<table>
<thead>
<tr>
<th>Minuteman G3</th>
<th>8mm</th>
<th>10mm</th>
<th>12mm</th>
<th>14mm</th>
<th>16mm</th>
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</thead>
<tbody>
<tr>
<td>Graft Volume</td>
<td>1.2cc</td>
<td>1.45cc</td>
<td>1.8cc</td>
<td>2.0cc</td>
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The G2-Inserter with the attached Minuteman G3 is inserted into the Sleeve and advanced to the interspinous process space aiming as far anterior as possible. Rotate the G2-Inserter clockwise to engage the threads of the Minuteman G3. Under fluoroscopy, the Minuteman G3 is advanced into the interspinous space, until the Fixed Plate is adjacent to the spinous processes.

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.

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 G3 is now ready for fixation to the spinous processes.
To fixate the implant to the spinous processes, hold the G2-Inserter 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.

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.

(24) The G2-Inserter 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. (25) Slide and hold the Plunger Stop back to the left and continue to rotate the Plunger Knob counterclockwise until it stops. The G2-Inserter is now detached from the implant.

The G2-Inserter 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 G3 Open Instrument Set. A percutaneous attempt to remove the Minuteman G3 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 G3 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 accidently deployed during attachment of the Minuteman G3 to the G2-Inserter, the Plate Reset Instrument is utilized. First detach the Minuteman G3 from the G2-Inserter. The Plate Reset Instrument is inserted into the caudal end of the Minuteman G3 and threaded clockwise (only 2-3 rotations) to engage the inner mechanism of the Minuteman G3. Gentle retraction of the inner mechanism of the Minuteman G3 is performed with the Plate Reset Instrument to unlock the Extension Plate of the Minuteman G3. The Plate Reset Instrument is then rotated counterclockwise to disengage it from the Minuteman G3, 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 G3. 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 G3® 5 ANATOMICAL SIZES & COLOR CODED

<table>
<thead>
<tr>
<th>Color Code</th>
<th>Size</th>
<th>Product Number</th>
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Spinal Simplicity is in constant pursuit of innovative, simple solutions. The Minuteman G3 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 G3 away from the neural elements through a percutaneous lateral approach.

The patent-pending G2-Inserter is the first and only all-in-one inserter that provides delivery, deployment and fixation of the Minuteman G3, streamlining spinal fusion procedures.

**TOP TRAY**
1. Dilators (3mm, 8mm, 14mm)
2. Bone Chip Plunger
3. Guide Wire Extension
4. Guide Wire
5. Modular Handle
6. Aiming Device

**BASE TRAY**
1. G2-Inserter x 2
2. Bone Rasp
3. Soft Tissue Rasp
4. Graduated Tap
5. Direct Drive T-Handle
6. Dilator/Sleeve Handle
7. Plate Reset Instrument
8. Sleeves (20mm, 23mm, 26mm)
9. Insertion Adaptors (8mm, 10mm, 12mm, 14mm, 16mm)
## Ordering Information

### Minuteman G3 Implants and disposables:

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<th>Size</th>
<th>Code</th>
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<tbody>
<tr>
<td>8 mm Minuteman G3</td>
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<td>Guide Wire - Long</td>
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### Minuteman G3 Percutaneous Instruments:

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<td>Plate Reset Instrument</td>
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<tr>
<td>Direct Drive T-Handle</td>
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<td>Dilator/Sleeve Handle</td>
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<td>Bone Chip Plunger</td>
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<td>G2-Insertor</td>
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<td>Aiming Device Holder</td>
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<tr>
<td>Percutaneous Case/Tray</td>
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</tbody>
</table>
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).
(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 G3 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
- Infection
- Blood vessel damage/bleeding
- Deep vein thrombosis
- Hematoma
- Pneumonia
- Neurological system compromise
- Stroke
- Nerve injury or spinal cord damage
- Paralysis
- Thrombus formation
- Graft donor site complications, including pain, fracture or wound healing complications
- Dural tear
- Wound dehiscence or delayed healing
- Pain/discomfort at the operative site
- Death
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 G3 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.
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 G3 system.

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

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