

Spinal Simplicity Minuteman G6 MIS Fusion Plate

IMPORTANT INFORMATION ON THE SPINAL SIMPLICITY MINUTEMAN G6 MIS FUSION PLATE



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ENGLISH IMPORTANT INFORMATION ON THE SPINAL SIMPLICITY MINUTEMAN G6 MIS FUSION PLATE

Purpose:

The Spinal Simplicity Minuteman G6 MIS Fusion Plate is a posterior, non-pedicle fusion device, intended for use at a single interspace in the non-cervical spine (L1-S1). When using the lateral transverse technique at levels of L3 or above, a preoperative CT is recommended to ensure a safe trajectory to the spine.

Description:

The Minuteman G6 MIS Fusion Plate consists of spinous process plates and surgical instruments. Implants are made of Titanium alloy Ti-6AL-4V ELI per ASTM F136 standards and feature a hydroxyapatite coating per ASTM F1185.

MRI Safety Information:

MR Conditional: A patient with the Spinal Simplicity Minuteman G6 MIS Fusion Plate may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

- Nominal value(s) of Static Magnetic Field [T]: 1.5 T or 3 T
- Maximum Spatial Field Gradient [T/m and gauss/cm]: 30 T/m (3,000 gauss/cm)
- RF Excitation: Circularly Polarized (CP)
- RF Transmit Coil Type: Whole body transmit coil, Head RF transmit-receive coil (no restrictions on local transmit-receive coils that the device is not within)
- RF Receive Coil Type: Any receive coil
- Maximum Whole Body SAR [W/Kg]: 1.0 W/Kg (Normal operating mode)
- Limits on Scan Duration: 1.0 W/Kg whole body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
- MR Image Artifact: The presence of this implant may produce an image artifact of 47 mm

Note: If information about a specific parameter is not included, there are no conditions associated with that parameter.

Indications for Use:

The Spinal Simplicity Minuteman G6 MIS Fusion Plate is a posterior, non-pedicle fusion device, intended for use at a single interspace in the non-cervical spine (L1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving instrumented posterior arthrodesis (i.e., fusion) in the following conditions:

- Lumbar spinal stenosis;
- degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); and/or
- spondylolisthesis.

The Minuteman G6 MIS Fusion Plate is intended for use with bone graft material. The device may be implanted via a lateral transverse approach (L1-S1).

Contraindications:

The Minuteman G6 MIS Fusion Plate 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
- Incomplete 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 G6 MIS Fusion Plate 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

Warnings:

The Minuteman G6 MIS Fusion Plate 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 results.

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 G6 MIS Fusion Plate 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 contraindications 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.

General Conditions of Use:

The information contained in this package insert is necessary but not sufficient for the use of this device. This information is not intended as a substitute for the professional judgment, skill and experience of the surgeon in: careful patient selection; preoperative planning; device selection; knowledge of the anatomy and biomechanics of the spine; understanding of the material and the mechanical characteristics of the implants used; training and skill in both spinal surgery and use of associated instruments for implantation; securing the patient's cooperation in following an appropriately defined postoperative management program, and conducting postoperative follow-up examinations.

Preoperative:

- As part of the preoperative examination, the surgeon must check that no factors, especially biological and biomechanical, will affect the correct performance of the implant during the operation and postoperative period.
- Only patients that meet the criteria described in the Indications for Use should be selected.
- Patient conditions and/or pre-dispositions such as those addressed in the aforementioned contraindications should not be selected.
- Care should be used in the handling and storage of the Minuteman G6 MIS Fusion Plate components. Implants and instruments should be protected during storage, especially from corrosive environments.
- The type of construct to be assembled for the case should be determined prior to beginning the surgery. Based on the fatigue testing results, the surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may have an impact on the performance of the Minuteman G6 MIS Fusion Plate. An adequate inventory of implant sizes should be available at the time of surgery, including an excess of implant sizes expected to be used and implant sizes larger and smaller than those expected to fit in the patient.
- Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble each device to be used to verify that all parts and necessary instruments are present before the surgery begins. Damaged or defective instruments should not be used. Contact the manufacturer for repair or replacement instructions.
- All components should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

Intraoperative:

- At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves may result in loss of neurological functions.
- Breakage, slippage or misuse of instruments or implant components may cause injury to the patient or operative personnel.
- The correct selection of the type and size of implant appropriate to the patient, and positioning of the implant, are extremely important to allow maximum chances for a successful surgical result.

Postoperative:

- The physician's postoperative directions and warnings to the corresponding patient are important to allow maximum chances for a successful surgical result. Detailed instructions on the use and limitations of the device should be given to the patient. If excessive or early weight-bearing, or excessive muscular activity is discouraged during the early postoperative rehabilitation period, the patient must be warned that bending, loosening or breakage of the components are complications which can occur as a result of this activity. The risks of bending, loosening or breakage of the components are complications which can occur as a result of this activity, or if the patient is debilitated, demented, or using weight supporting devices. The patient should be warned to avoid falls or sudden jolts to lessen the possibility for bending, loosening or breakage of the internal fixation device.
- To allow maximum chances for a successful surgical result, the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility, and instructed to limit physical activities, especially lifting, twisting and any type of sport participation. The patient should be advised not to smoke, utilize nicotine products or consume alcohol or nonsteroidal anti-inflammatory drugs such as aspirin during the bone graft healing process.
- The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
- If a nonunion develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed nonunion of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device(s).
- The patient should be fully instructed in the appropriate postoperative care. The patient's ability and willingness to follow, as well as comprehension of the importance of following instructions are one of the most important aspects of successful postoperative healing.
- Explanted surgical implants must never be reused.
- As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures), prophylactic antibiotics should be considered, especially for patients with increased risk for infection.

Sterility:

Gamma irradiation is indicated by the "Sterile-R" symbol on the Minuteman G6 MIS Fusion Plate implant labeling. These devices remain sterile as long as the package integrity has not been violated.

Packaging:

Packages for each of the Minuteman G6 MIS Fusion Plate components should be intact upon receipt. Inspect each package prior to use and do not use the component if any seal or cavity is damaged or breached or if the expiration date has been exceeded. Once opened, the component must be used, discarded, or returned to the manufacturer. If a loaner or consignment instrument system is used, all sets should be carefully checked for completeness to ensure there is no damage prior to use. Damaged packages or products should never be used and should be returned to the manufacturer.

Handling and storage:

The Minuteman G6 MIS Fusion Plate implants and instruments must be stored with care. Before use, inspect all instrumentation for proper function, possible damage, wear or non-function. Damaged or defective instruments should not be used. Note: At some point in time, instruments wear out and should be replaced. Contact the manufacturer for repair or replacement instructions.

Recommendations for Care and Cleaning of Minuteman G6 MIS Fusion Plate Surgical Instrument System (Instruments, Cases, and Trays):

After completion of the procedure, it is recommended to immediately remove gross soil using either single-use, non-shedding wipes soaked in cleaning solution or transfer of the medical devices into a water bath to prevent drying of soil and contaminants in and on the instrumentation

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 cannales, lumens, crevices, grooves and hard to reach areas. Repeatedly operate/bend/articulate all movable components while cleaning. Allow instruments to soak in detergent prepared bath for manufacturer's recommended soaking time.

Final cleaning and disinfecting should be performed by sonication or an automated washer/disinfecter cycle. See below recommendations for each:

Sonication:

1. Remove the instruments from bath and rinse in utility water (per ANSI/AAMI ST108) 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 critical water (ANSI/AAMI ST108) for at least 3 minutes.
4. Visually inspect to determine if all visible soil has been removed from the surfaces, lumen, cannales, 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 cannales). Be sure to completely dry the instruments immediately after rinse to inhibit corrosion.

Automated Washer:

1. Remove instruments from bath and rinse in critical 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/disinfecter basket and process through a standard washer/disinfecter cleaning cycle. The following minimum parameters are essential for thorough cleaning and disinfecting.
 - a. 2 minute prewash with cold utility water
 - b. 20 second enzyme spray with hot utility water
 - c. 1 minute enzyme soak

- d. 15 second cold utility water rinse
- e. 2 minute detergent wash with hot utility water (64-66°C/146-150°F)
- f. 15 second hot utility water rinse
- g. 2 minute thermal rinse (80-93°C/176-200°F)
- h. 10 second critical water rinse (64-66°C/146-150°F)
- i. 7 to 30 minute hot air dry (116°C/240°F)

NOTE: The washer/disinfectant 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.

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.

Recommendations for Sterilization of Minuteman G6 MIS Fusion Plate Surgical Instrument System (Instruments, Cases, and Trays):

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.

Product Complaints:

Communicate suspected deficiencies in product quality, identity, durability, reliability, safety, effectiveness and/or performance directly to Spinal Simplicity, LLC. When filing a complaint provide component name(s), part number(s), lot number(s), your name and address, the nature of the complaint and patient case number. Sterilize and return all component(s) to Spinal Simplicity, LLC. Notify Spinal Simplicity, LLC immediately of any complaints and any incidents resulting in patient death or serious injury.

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

Symbols Glossary

Symbol	Symbol Title	Explanatory Text	Standard Text	Standard Reference
	Manufacturer	Indicates the Medical Device Manufacturer	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 15223-1 Reference #5.1.1
	Date of Manufacture	Indicates the date when the medical device was manufactured	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 15223-1 Reference #5.1.3
	Use-By-Date	Indicates the date after which the medical device is not to be used	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 15223-1 Reference #5.1.4
	Lot Code	Indicates the manufacturer's batch code so that the batch or lot can be identified	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 15223-1 Reference #5.1.5
	Catalogue Number	Indicates the manufacturer's Catalogue number so that the medical device can be identified	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 15223-1 Reference #5.1.6
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 15223-1 Reference #5.2.4
	Do not use if packaged is damaged	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 15223-1 Reference #5.2.8
	Do not re-use	Indicates a medical device that is intended for one single use only	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 15223-1 Reference #5.4.2
	Do not re-sterilize	Indicates a medical device is not to be re-sterilized	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 15223-1 Reference #5.4.6

	Consult instruction for use	Indicates the need for the user to consult the instructions for use	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 15223-1 Reference #5.4.3
	Keep Dry	Indicates a medical device that needs to be protected from moisture	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 15223-1 Reference #5.3.4
	Prescription Only	Caution: Federal law restricts this device to sale by or on the order of a physician	US FDA Code of Federal Regulations	21 CFR 801.15(c)(1)(i)F
	MR Conditional	A medical device with demonstrated safety in the MR environment within defined conditions including conditions for the static magnetic field, the time-varying gradient magnetic fields, and the radiofrequency fields	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.	ASTM F2503
	Quantity	Custom symbol denotes Quantity per box	NA	NA
	Size	Custom symbol indicates size	NA	NA