TECHNICAL BULLETIN
13 Aug 2018

Surgical Technique Pearls

for all Minuteman ISP Implants

(P/N 10-0004-008_016; 10-00017-008_016; 10-0018_22-000)

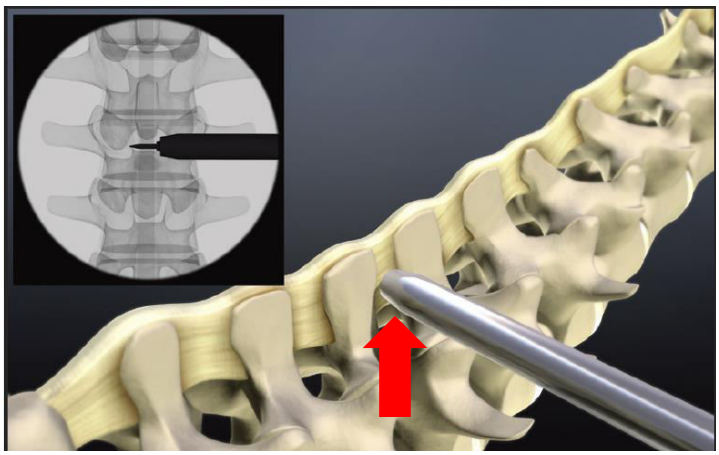
MIS LATERAL PROCEDURE

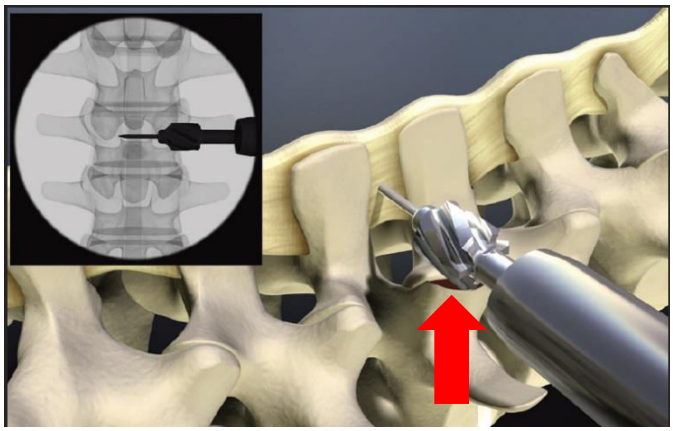
1. Sleeves & Dilators must be docked against the spinous processes.

If the Sleeves & Dilators cannot be docked against the spinous processes, there is an increased risk that the Spike Plate also cannot dock, resulting in the contra-lateral implant Wings being blocked by bone and prevented from opening. The MIS Lateral Surgical Technique describes the use of progressively sized Dilators and Sleeves to spread the muscle and open access for the Spike Plate to dock against the spinous processes. It has been noted that the L4-L5 level may be more difficult due to the shape of the lamina and spinous processes. As such, it may be necessary to angle the Insertion Instrument to enter superior to the iliac crest.

SOLUTIONS:

a. Ensure each of the Sleeves & Dilators dock against the interspinous ligament and/or spinous processes when dilating the tissue. This may require shifting the Dilators/Sleeves more posteriorly.





b. In cases where the facets are hypertrophied sufficiently to block the Dilator and/or Sleeve from docking against the spinous processes, rasping of the facets is required in order to properly advance the Dilator or Sleeve to the spinous processes. Leaving the Guide Wire in place, the successive Dilators are brought to the facet, up to the 20mm Sleeve. The gray Dilators are then removed, leaving the 20mm Sleeve in place, and the Bone Rasp is used to reduce the facet. Then, the smaller Dilators are again used to dock against the spinous processes as instructed in the

Surgical Technique.

2. The Implant Wings cannot be deployed at all.

If the Wings do not open and the Plunger Knob is difficult to turn, **DO NOT attempt to deploy the Wings with brute force as this will likely damage the implant or instrument**. It is very likely that the Wings are blocked by bone (lamina, spinous processes, or facets). This may be more likely at L4-L5 due to the shape of the lamina and spinous processes and the increased curvature of the spine at this level. The G3-R graft windows are optimized for each implant size, meaning that the Wings on larger sizes are typically slightly wider than the Wings on the comparable G3 device. It may be necessary to position the G3-R device slightly more posteriorly to compensate for the wider graft window.

*****NOTE*** The Wings will always deploy using comfortable hand force. Re-positioning may be necessary to avoid blockage by the anatomy.**

SOLUTIONS (in the order to be used)**:**

a. Angle the Insertion Instrument and implant away from the lamina, angling the nose of the implant posteriorly. Attempt to advance the Plunger, but do not try to excessively force it (excessive force can cause the Insertion Instrument to detach from the back of the implant; should the implant become disengaged, it is possible to safely re-engage the Insertion Instrument to the implant in the body, as the spring force to compress the Insertion Adaptor is less than the strength of the spinous process).

b. Ensure the Wings are parallel to the lamina. This may not be directly cranial-caudal due to the lordosis curve of the spine. Rotate the implant to properly align with the anatomy (e.g., instead of cranial-caudal, it may be necessary to position the Wings slightly rotated).

c. Considering tissue adhesion on the contra-lateral side of the spine, rock the device slightly back and forth and edge the implant slightly posteriorly. Try again to advance the Plunger, but do not try to excessively force it. This can be repeated in small steps, if needed. Once the Wings deploy after a posterior shift, you can then shift the fully-deployed implant back to the original anterior position.

d. If the Wings remain stowed and there is concern that they are bound by the graft material, it is acceptable to remove the device from the patient and immediately re-insert without re-setting the implant. **Do not rotate the Plunger Knob counterclockwise to withdraw the implant if the Wings are stowed**. Rotating the Plunger Knob counterclockwise always initiates the disengagement of the Insertion Instrument from the implanted portion of the Minuteman. Once removed, the Wings can be checked for freedom of motion. Moving the implant & Insertion Instrument combination retrograde without turning the Plunger Knob does not affect the security of the implant on the Insertion Instrument.

3. Wings open less than 30 degrees.

(G3 & HA-G3 implants)

If the Wings partially deploy (less than 30 degrees), it is likely still due to catching on bone and the techniques listed in Section 2 remain valid. The implant may be withdrawn from the patient, the Plunger Knob may be turned counterclockwise until it stops against the Plunger Stop, and then the Wings may be squeezed closed.

(G3-R ONLY)
If the Wings partially deploy (less than 30 degrees), it is likely still due to catching on bone and the techniques listed in Section 2 remain valid. However, it **is not** recommended to withdraw and immediately re-insert the device with partially-deployed Wings, as the body halves may come apart. Implants withdrawn with partially deployed Wings should be replaced with a new implant, due to the Plunger position within the implant.

If the Wings open approximately 30 degrees each, the techniques listed in Section 2 should be used to assist them in opening to the full 90 degree position. **The user should only advance the Locking Hex Nut *after* the Wings have been fully deployed. Advancing the Locking Hex Nut before the Wings are fully deployed or alternating between rotating the Insertion Instrument Plunger Knob and the Insertion Instrument Spike Plate Knob to simultaneously deploy the Wings and advance the Locking Hex Nut can result in premature disengagement of the Removable Body and should not be attempted.** Upon successful Wing deployment to the full 90 degrees and subsequent Locking Hex Nut advancement, it is important to ensure that the Plunger is fully advanced to allow the Removable Body of the implant to be removed properly at the end of the procedure.

*****NOTE*** If the Wings partially deploy, it is critical that the Insertion Instrument Plunger Knob not be rotated counterclockwise as this can lead to disengagement of the implant halves.**

4. Difficulty tightening the Locking Hex Nut.

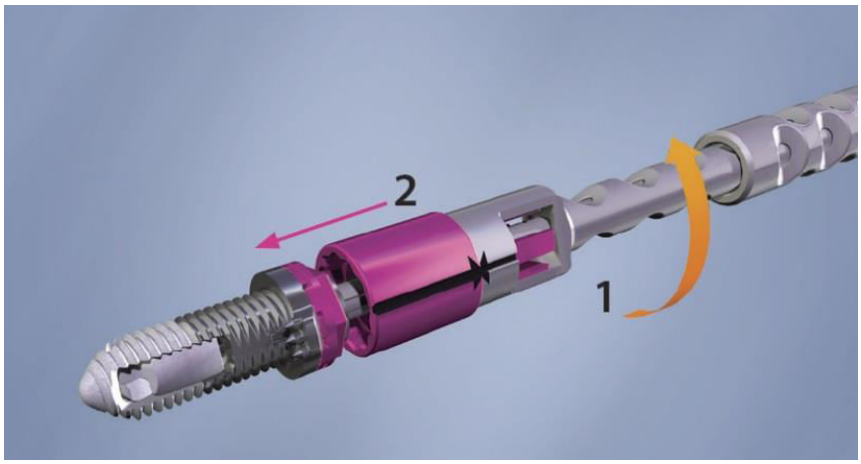
When rotating the Insertion Instrument Spike Plate Knob, the Locking Hex Nut draws the implant body back through the interspinous process space until the bone is clamped between the opened Wings and the Spike Plate. The plates must be drawn together until the spikes from both plates are engaged in either side of the spinous processes, and there is good mechanical torque on the Locking Hex Nut. "Three-fingers tight" is the rule-of-thumb that we instruct our users to employ. If the plates cannot be drawn together, there is either an anatomical obstruction preventing the movement or the Insertion Adapter has not been advanced against the implant during loading of the implant on the instrument.

SOLUTIONS (in the order to be used)**:**

a. Use the techniques described in Section 2a through 2c to eliminate any anatomical restriction impeding the implant tightening.

b. In the case where you are using the Minuteman G3 or HA G3 implant and the Insertion Instrument Adapter Shaft has not been returned to contact the Locking Hex Nut, as described in the Surgical Technique, the Locking Hex Nut will stop advancing within a few rotations as it advances beyond the reach of the compressed spring. The Insertion Instrument Plunger Knob can be turned counterclockwise to disengage the Insertion Instrument from the implant. The Insertion Instrument is then withdrawn, leaving the implant in the body, and the Insertion Instrument spring can be uncompressed by turning the Insertion Instrument Adapter Shaft a quarter turn to release the spring.

The Insertion Instrument would then be reinserted back into the Sleeve and re-attached to the implant by compressing the spring while pushing the Insertion Instrument onto the implant and rotating the handle until the hex shaft re-engages the implant. The Plunger Knob would then be turned clockwise to lock on to the implant, and the procedure would be completed as described in the Surgical Technique.



c. In the case where the Minuteman G3-R is being implanted and the Insertion Instrument Adapter Shaft has not been returned to contact the Locking Hex Nut, as described in the Surgical Technique, the Locking Hex Nut will stop advancing within a few rotations as it advances beyond the reach of the compressed spring.

The Insertion Instrument Plunger Knob SHALL NOT be rotated counterclockwise, as this will release the Removable Body from the Main Body of the implant. An incision must be made posteriorly to the implantation site, and the Insertion Instrument Adapter Shaft must be prevented from rotating (forceps or similar instrument may be used). Once the Insertion Adapter is secure, rotate the Spike Plate Knob on the Insertion Instrument counterclockwise to release the spring lock. The spring will release and compress against the implant, and the procedure would be completed as described in the Surgical Technique.

5. Detaching the G3-R Removable Body.

After full fixation of the device, it only takes 1 full counter-clockwise rotation of the Insertion Instrument Plunger Knob to disengage the Removable Body. It is not necessary to reverse the Insertion Instrument Plunger Knob until the Plunger Stop clicks over before attempting to disengage the Removable Body. The user should attempt to disengage the Removable Body after 1 full counter-clockwise rotation of the Insertion Instrument Plunger Knob by pulling gently on the Insertion Instrument. If the Removable Body does not detach, rotate the Insertion Instrument Plunger Knob approximately another half-turn in the counter-clockwise direction and pull gently on the Insertion Instrument. Repeat this process until the Removable Body can be pulled free, and withdraw the Insertion Instrument/Removable Body assembly from the patient.

*****NOTE*** Continuing counterclockwise rotation after the Plunger Stop clicks over may cause the Insertion Instrument to disengage from the Removable Body, requiring you to re-attach the Insertion Instrument to the Removable Body, lock on, and pull off the Removable Body.** A grasper may also be used to remove the Removable Body.

6. G3-R Removable Body does not release from implant.

Should the Removable Body not release from the implant by the time Plunger Stop clicks over, the surgeon should once again advance the Insertion Instrument Plunger. This is done by turning the Insertion Instrument Plunger Knob clockwise until the position indicator on the Insertion Instrument shows it has reached the Plate Deployment symbol. **If the Plunger does not travel the full distance, then the Removable Body will remain locked on the implant.** Once the Plunger has traveled the full distance, rotating the Plunger Knob one full revolution counter-clockwise will release the Removable Body.

MINUTEMAN GRAFT MATERIAL SELECTION

The Interspinous Interlaminar Minuteman implant device is to be implanted with bone graft material filling the graft window to create a boney fusion between the adjacent spinous processes. The surgical technique instructs the user to insert graft material as follows:

> *"Bone graft material is added by holding one Wing open and one Wing closed and injecting bone graft material into the threaded body. Bone graft material is also applied around the exterior threads of the Minuteman..."*

Additionally, there is a descriptive comment regarding the nature of the graft material:

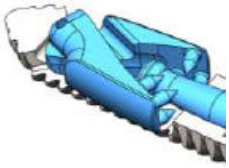
> *"The bone graft material must be viscous in nature to allow the inner mechanism to properly function."*

The graft material is delivered in the space in and around the pivoting wings and the plunger which opens these wings. The graft material must not interfere with the wing and plunger movement. Graft material shall not contain bone chips, fibers, or be rigid or semi-cured in nature as this would interfere with proper operation of the pivoting wings. Bone chips are considered to be interspersed elements greater than 0.5mm in dimension and are not uniformly ground bone less than 0.5mm in dimension. The result of using graft material with bone chips may be the inability to open the wings on the contra-lateral side of the spinous processes when using the defined MIS lateral surgical technique.

The images below demonstrate the mechanism fit within the graft window. The graft material must not interfere with this action:

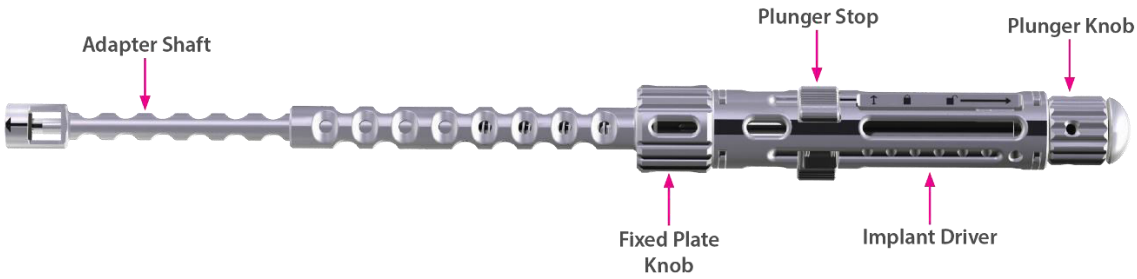
Initial position

Implanted position



INSTRUMENTATION

1. Insertion Instrument (Part Number 20-0026-000)



The Minuteman Insertion Instrument is a critical instrument in the implantation of the Minuteman ISP fusion device. The five key functions of the Insertion Instrument are:

- Attach and lock the Minuteman onto the Insertion Instrument
- Thread the Minuteman through the interspinous process space
- Deploy the extension plates of the Minuteman
- Rotate the fixed plate nut to tighten the Minuteman onto the Spinous Processes
- Unlock and detach from the Minuteman implant

As of 2/11/2016, Spinal Simplicity ships an updated revision of the Insertion Instrument. Our customers and distributors should be aware of the update to the hex driver feature, from the previous design, and how the surgical technique has been updated to reflect the changes.

ITEM #1

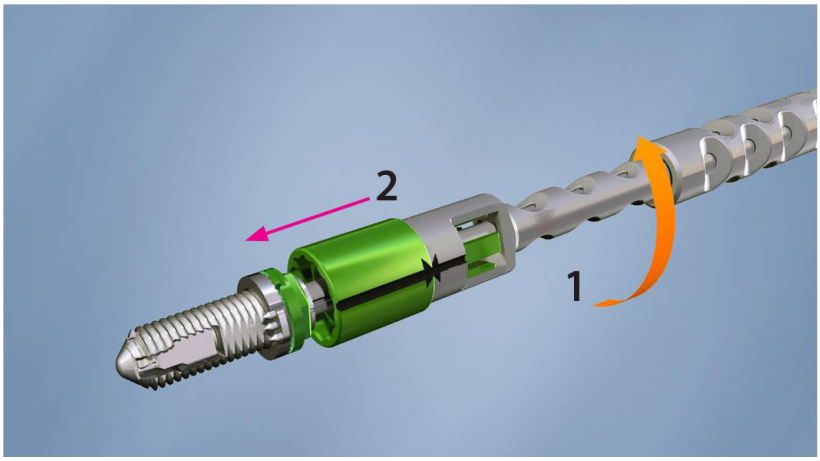
The hex was modified such that the hex driver no longer has a "split tip" design, but has a robust full hex shape, with embedded flex fingers. These flex fingers have been laser etched (highlighted in orange below) to indicate their unique positions. In the Surgical Technique Guide, the user is instructed to "align the Extension Plate of the Minuteman in the same orientation as the laser etching". This allows the surgeon to utilize the Plate Reference Lines (highlighted in orange below) on the Insertion Instrument; ensuring accurate Extension Plate (highlighted in orange below) orientation of the Minuteman during the procedure. Reference the Surgical Technique Guide for full update.

If the Extension Plates are not properly aligned with the Plate Reference Lines, the Insertion Instrument may bind, become difficult to turn, or prevent full deployment of the Extension Plates during surgery. Extra care must be taken to ensure correct attachment and orientation of the Minuteman implant to the Insertion Instrument. Prior to insertion of Minuteman implant into the body, the orientation should be confirmed.

ITEM #2

The Minuteman Surgical Technique Guide instructs the user to allow the Adaptor Shaft to gently spring forward to engage the Insertion adaptor onto the Hex Nut of an Implant. Care must be taken to ease the Insertion Adaptor onto the Minuteman Hex Nut.

*****CAUTION*****Allowing the Adaptor Shaft to surge forward onto a Minuteman Implant with any appreciable spring force may result in difficultly with deployment of the Extension Plate when the plunger knob is rotated.



CONTACT

For questions or clarifications on this Technical Bulletin, please contact info@spinalsimplicity.com