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Preface

With the advent of interbody fusion techniques, load sharing and stability has been shifted away from the posterior spine, making large pedicle screw/rod constructs less needed and the morbidity associated with the classic posterior open procedure less acceptable. Reducing morbidity and size of posterior implants is a worthwhile and now, achievable goal; yet accomplishing this, while maintaining a rigid construct to promote fusion, still remains all important.

The Amedica®/US Spine® Facet Fixation System was developed to deliver, via minimal incision techniques, a small implant capable of rigid locking fixation over single or multiple levels. The Locking FacetBolt®, placed across the facet joint, secures a fixation point in close proximity to the center of rotation, allowing the implant to be very small in size and yet deliver very strong stabilization.

The FacetGun® Max was developed to deliver the FacetBolt® using a minimal number of steps, with a device that’s surgeon and team friendly. It is ergonomically efficient, color coded and utilizes an “all-in-one” tool concept, thus reducing hassles, trays and multiple tools.

Facet fixation, which predates pedicle screw stabilization, has now come full circle in its development and interest. With the advancement of interbody implants and approaches, the development of minimally invasive techniques and the addition of a locking mechanism, we believe you will find the Locking Facet Fixation System to be a very welcome addition to your stabilization techniques.

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Surgical Technique

NOTES:
- A Power Drill and standard Jacob’s Chuck are required.
- This surgical technique is for a L4-L5 operative site.

Pre-operative Steps: (Performed by scrub team)

Assemble the FacetGun® Max
- Close the hinged handle.
- Install both of the aluminum or plastic nuts securely. The larger nut fits on the back of the FacetGun® Max handpiece.
- Use the Crimper to crimp the distal end of washer tube 3-4 times, while simultaneously rotating instrument to ensure a secure fit with the proximal washer.
- Slide the outer tube over the barrel and tighten.

Load a cassette onto the FacetGun® Max
- Remove cassette from packaging and ensure both washers are properly positioned.
  NOTE: Depending on patient anatomy, the proximal washer can be flipped 180° to fit lamina.
- Rotate the barrel so it is in the unlocked position. Hold the cassette in the left hand and the FacetGun® Max hand-piece in the right hand.
- With the notches on the gun barrel in line with the arrows on the bridge, slide the bridge over the end of the hand-piece and rotate the hand-piece clockwise. Tighten the barrel to secure the bridge.
- With the roll control lever in the vertical position, squeeze the hand-piece trigger to lock the proximal washer into the end of the barrel. When secure, open the door of the plastic cartridge and release the trigger (this will disengage the washer from the plastic).
- Remove the plastic cartridge from the assembled bridge and discard.

Power
- Connect the Drill bit to a power drill with a Jacob’s chuck.
- Tighten the chuck with a key to ensure a confident grip.
Step 1: Patient Preparation & Exposure

- Position the patient in prone position on a fluoroscopy compatible table. Take a lateral fluoroscopy view centered over L4/5 with an 18g spinal needle aimed at the L4/5 disc in a straight vertical position.

- Prep/drape/ mark entry point of needle. Position incision (4-8cm) in midline such that the needle mark is at the halfway point of the overall incision.

- Utilize a single cerebellar retractor to facilitate soft tissue dissection down along the L4 spinous process and lamina to just beyond the L4/5 facet joints bilaterally. Repeat fluoroscopy images as necessary.

Step 2: Decompression

- Decompress the L4/5 interval preserving as much of the lamina as possible. Utilizing a Spinouspreader can facilitate this step, as described below.

- Remove the L4/5 interspinous ligament. Distract between the L4 and L5 spinous processes with the Spinouspreader. Identify and remove the ligamentum flavum and a portion of the lamina/arthritis as necessary, exposing the exiting L5 nerve root (NR). Cauterize epidural vessels as necessary. Work opposite the Spinouspreader and then switch sides to complete a bilateral decompression.
Step 3: Posterior Interbody Fusion Device/Cage Insertion (optional)

- Place the Spinouspreader on the side opposite the one you wish to place a cage. Utilize a lateral fluoroscopy image to facilitate placement. Distract with Spinouspreader.
- Retract the L5 nerve root with a scoville retractor and expose the L4/5 disc space.
- Remove more lamina as necessary to achieve a straight trajectory into disc space.
- Utilize the Amedica/US Spine PLIF or TLIF instruments and interbody fusion devices.
  Reference the appropriate IFU and Surgical Technique for complete information.

  NOTE: Cages may be placed obliquely if one implant is used or bilaterally if two implants are used. Switch sides and instruments and repeat steps to place the 2nd interbody fusion device.

Step 4: Preparation for FacetBolt® Placement

NOTE: You will be placing the FacetBolt® on the side opposite where you are standing. After placing one FacetBolt®, switch sides with your assistant and place the other FacetBolt®.

Prepare Facet joint:

- Have assistant use a handheld Meyerding retractor to retract the tissue just beyond the L4/5 facet joint to facilitate further exposure. Strip capsule, soft tissue and excess arthritic overgrowth from the facet joint.
- Remove soft tissue down to the transverse process of L5. Full exposure of the transverse process is not needed. Optional: Remove facet cartilage and replace with an osteoconductive product.
  Use caution to not weaken bone architecture.
- Remove a portion of the caudal aspect of the L4 spinous process to facilitate the FacetGun® trajectory. Preserve the more cephalad portion and the L3/4 interspinous ligament.
- Use the Trial Gun to initially assess the trajectory and proper location for the FacetGun® Max and FacetBolt®.

  NOTE: The goal is to place the FacetBolt® so it grips firmly across the facet joint. To achieve this, the distal-locking washer must be below the horizon of the facet joint and the proximal washer must engage a fairly flat surface of the lamina. Typically a small amount of burring down of the “spine” of the lamina is needed to create a flat landing pad for the proximal washer. Feel the Trial Gun distal washer hit the transverse process and walk it up from there and deep under the superior facet outer surface. Observe how the proximal washer mates with the lamina surface and trim the surface flat as necessary. Once achieved, switch to the FacetGun® Max.
Surgical Approach

- With the FacetGun® Max and a properly-loaded cassette, determine the proper trajectory over the desired facet joint. NOTE: Be sure that you are able to visualize the lateral portion of the superior facet.

- Aim the bridge towards the transverse process, feel the distal-locking washer touch the transverse process, walk the distal-locking washer up and deep along the superior facet outer surface. Note: Do not dislodge the distal-locking washer.

- Once the bridge is placed over the joint, pull back slightly to secure the distal-locking washer teeth onto the outer surface of the superior facet. This will provide proper grip of the implant into the bone.

- The roll controller at the top of the handpiece can be used to manipulate the washer-angle for proper seating of the proximal washer on the lamina surface.

- Position the proximal washer along the flat surface of the lamina, across the thickest portion of bone.

- While holding the handpiece steady, compress the trigger with one smooth controlled movement. This will compress the joint and lock both of the washers onto the facet joint surfaces. NOTE: The FacetGun® Max, once engaged, is a long lever arm. DO NOT MOVE or TORQUE. We recommend positioning the forearm of your non-dominant hand on the patient and using the non-dominant hand to firmly, continuously grip the Facet Gun® Max housing until the FacetBolt® is placed.

- With the FacetGun® Max handpiece clamped into position on the facet joint, determine the proper FacetBolt® length on the color-coded FacetBolt® measurement grid located at the top of the handpiece. The laser etched marking will align with the color and/or number that correspond to the appropriate FacetBolt® length. NOTE: If the indicator is in-between sizes, select the shorter length.
Pre-Awl/Pre-Drill

- Slide hand awl down the FacetGun® Max shaft and create a small indentation into the lamina surface for the drill.
- (Prepared ahead of time) Connect the Drill bit to a power drill with a Jacob’s chuck. Tighten the chuck with a key to ensure a confident grip.
- Insert the drill GENTLY into the back of the FacetGun® Max handpiece and drill forward and backward slowly to create a channel for the FacetBolt®. Then remove the drill while maintaining speed with the drill motor.

Load the Fast Driver

- Select the appropriate FacetBolt® length previously determined by the FacetBolt® measurement grid. NOTE: If the indicator is in-between sizes, select the shorter FacetBolt® length.
- (Performed by scrub team while the surgeon preps and drills) To load the FacetBolt®, grasp the FacetBolt® and with the hex assembly facing down, seat the hex end of the FacetBolt® flush into the Fast Driver assembly shaft. When the FacetBolt® is seated flush with the shaft, turn the retainer clockwise to engage the threaded portion of the retainer rod into the hex end of the FacetBolt®. Provisionally finger-tighten to avoid stripping the FacetBolt®. NOTE: Do not overtighten.
- GENTLY slide the screw-end of the Fast Driver assembly into the open proximal end of the handpiece and apply moderate forward pressure. Rotation of the Fast Driver can help advance it through the facet joint to a fully-seated position. The fully-seated position is indicated when the black color band fills the window located posterior to the roll controller. NOTE: (optional) Connect the ratchet handle to the back of the Fast Driver. The direction selector on the Ratchet Handle should be rotated to the left for clockwise advancement.
Deploy the FacetBolt®

- When the Fast Driver is in the fully-seated position, turn the Fast Driver to advance the FacetBolt® into the distal-locking washer. Gentle but firm pressure forward for the first one or two turns engages the FacetBolt® and the threaded shaft of the driver. From there, just turn clockwise with two or three fingers. NOTE: The driver shaft is threaded and will move forward without pressure.

- As the FacetBolt® is tightened, observe (surgeon/assistant) the “window” colors transitioning from black to gray to yellow. When the window is completely yellow, you will feel a positive stop. NOTE: Do not over-tighten.

- Approximately two millimeters of the FacetBolt® will be protruding through the distal-locking washer to ensure proper engagement of the locking mechanism.

- Confirm with fluoroscopy prior to removal of the FacetGun® Max.
Remove the FacetGun® Max from the operative site

- To remove the FacetGun® Max handpiece, first disengage the FacetBolt® from the Fast Driver by rotating the retainer counter-clockwise until it spins freely.

- Release the clamp by depressing the clamp release. NOTE: If for some reason the proximal washer does not disengage from the washer tube, pull back slightly on the roll controller.

- Place two fingers on the underside of the barrel where the barrel meets the housing while gently rolling the FacetGun® Max handpiece side-to-side, lift the gun in a plane towards your assistant. NOTE: Do not angle or lever the FacetGun® Max off the distal-locking washer. Do not lift the FacetGun® Max toward the ceiling.

- Remove the FacetGun® Max from the wound site. Remove bridge and reload FacetGun® Max with a new cassette assembly.

- Repeat steps to place a second FacetBolt® on the opposite side.

- Once both FacetBolts® are in position, use the Distal Locking Retainer and the Bolt Tightener for final tightening. NOTE: Do not over-tighten. Tighten with two or three finger tightness, feeling and listening for 2-4 clicks (max) as the proximal washer locks with the inner teeth of the FacetBolt® head.

Confirm Implant Placement

- Confirm the implant position and fixation via fluoroscopy AP/LAT views.

Closure

- If a TLIF or PLIF was preformed, it is recommended to use a drain and to remove after day 1-2.
INDICATIONS: CAUTION: USA Law restricts this device to sale by or on the order of physician. The Facet Fixation System is indicated for the posterior surgical treatment of any or all of the following at the C2 to S1 (inclusive) spinal levels: 1) Trauma, including spinal fractures and/or dislocations; 2) Spondylolisthesis; 3) Spondylolysis; 4) Pseudoarthrosis or failed previous fusions which are symptomatic or which may cause secondary instability or deformity; 5) Degenerative diseases which include: (a) degenerative disc disease (ddd) as defined by neck and/or back pain of discogenic origin as confirmed by patient history with degeneration of the disc as confirmed by radiographic studies and/or (b) degenerative disease of the facets with instability. When properly used, facet screws will provide temporary stabilization as an adjunct to spinal bone grafting processes.

Key Instruments

- FacetGun® Max Hand Piece
- Trial Gun
- Spinouspreader (Optional)
- Crimper
- Fast Driver
- Drill
- Bolt Tightener
- Retainer – Distal Washer
- Ratchet Handle