



A'TOMIC™

NITINOL FIXATION SYSTEM



Surgical Technique Overview

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Description

Implants of the A'TOMIC™ Nitinol Fixation System are intended for use as fixation and compression devices to support several surgical techniques (e.g., fracture, osteotomy, joint arthrodesis, and fixation of bone fragments). The implants are made of biocompatible Nitinol and are designed to exhibit superelastic properties at room temperature. The implants are provided sterile packed on retention blocks pre-loaded for insertion.

Indications

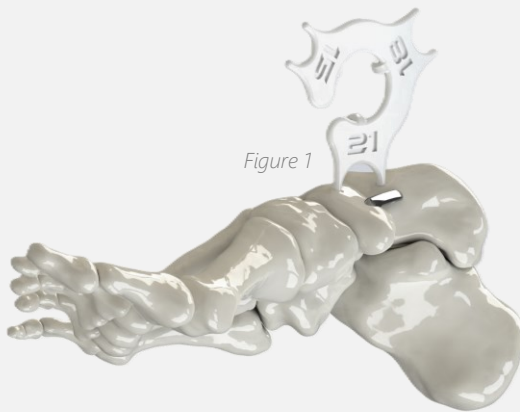
- The A'TOMIC™ Nitinol Fixation System is indicated for use in fracture, osteotomy fixation and joint arthrodesis as well as fixation of bone fragments (i.e., small fragments of bone which are not comminuted to the extent that precludes staple placement). The device is intended for use in short, long, or flat bones. The A'TOMIC™ Nitinol Fixation System is intended for single use only.

Contraindications

- Infection
- Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
- Patient conditions including blood supply limitations, obesity, and insufficient quantity or quality of bone that would impair the ability to securely fix the implant.
- Comminuted bone surface that would hinder staple placement.
- Foreign body sensitivity to metals. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.

Surgical Technique

1. Expose and prepare surgical site per standard procedure.
2. Reduce or re-approximate fracture, osteotomy, or joint. Apply temporary reduction and fixation.
3. Place the Sizing Guide in the desired position across the fracture, osteotomy, or joint to determine the desired implant bridge length and position. (Fig. 1)



4. If desired, attach the provided Tamp/Drill Guide Handle to the appropriate Drill Guide. (Figs. 2-3) Note that the Tamp/Handle can be placed with a downward or upward angle.



Figure 3

5. To create the first hole, drive the Drill through the Drill Guide into the bone to the far cortex. (Fig. 4)
6. Insert a Pull Pin through the Drill Guide and into the bone. (Fig. 5)

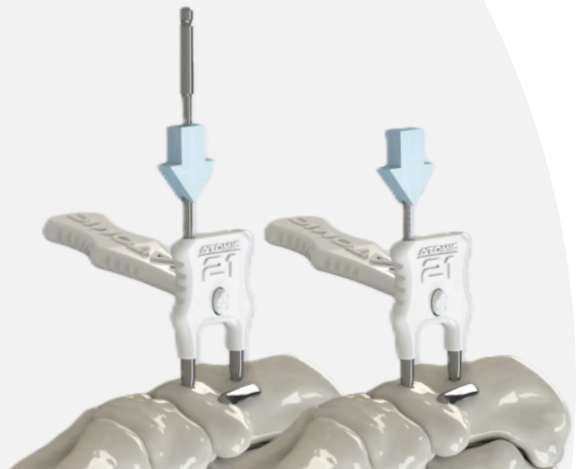
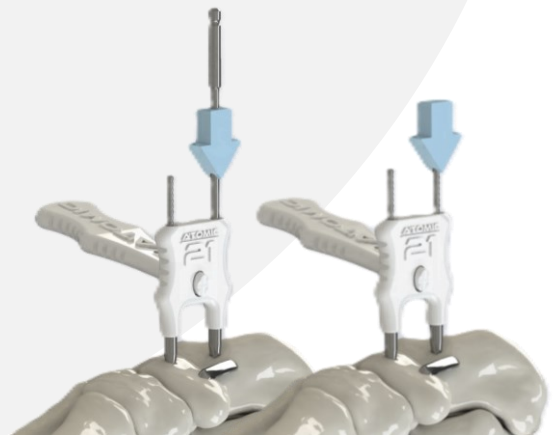


Figure 5

7. Repeat Step 5 and 6 to create the remaining hole(s). (Fig. 6)
8. Remove Drill, Pull Pins and Drill Guide. Pins may be left in place temporarily to mark the position of the drill holes.



9. Select appropriate implant and remove pre-loaded implant from the packaging.

Squeeze the wings of the retention block to release the keystone and remove the implant from the retention block. (Figs. 7-9)



Figure 7

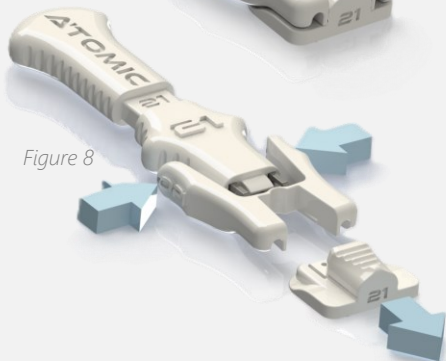


Figure 8

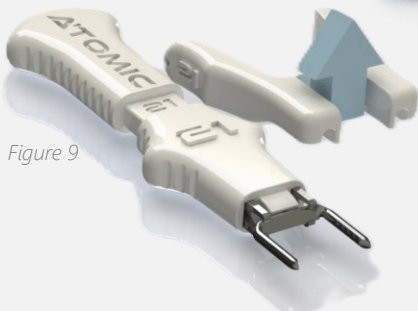


Figure 9

10. Insert the implant into the pre-drilled holes and pull the slider of the Inserter upwards towards the handle to release the implant. (Figs 10-12)
11. As necessary, lightly tamp the implant with the provided Tamp/Drill Guide Handle to fully seat the implant. (Fig. 13)



Figure 10

Figure 11

Figure 12

Figure 13

12. Confirm final position using fluoroscopy and proceed with standard closure.



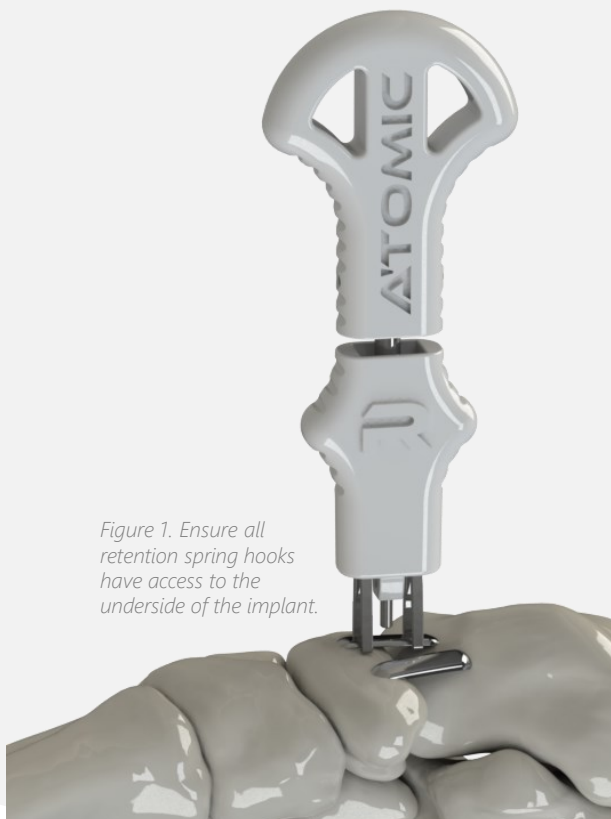
Explant Information

Without Removal Tool

Use a small osteotome or curette to lift the implant. If necessary, use a clamp to remove the implant from the bone. The implant bridge may be cut with a pin cutter to release the compression of the implant and allow for ease of implant leg removal if needed.

With Removal Tool

1. Place the retention springs of the Removal Tool centered on the bridge of the implant. If necessary, use an osteotome to lift the implant 1-2mm from the bone so that the hooks of the retention springs can capture the underside of the implant bridge. (Fig. 1)

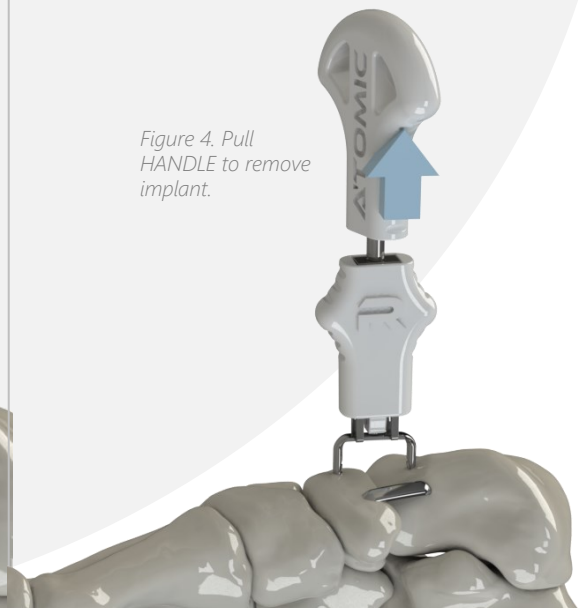


2. Move slider towards the implant and turn the handle clockwise until the implant can be removed. (Figs. 2-4)

Figure 3. Turn HANDLE clockwise to advance center pin.



Figure 4. Pull HANDLE to remove implant.



Catalog Numbers/SKU

The system is comprised of various sizes to accommodate individual patient anatomy, varying by leg diameter, bridge length, leg length and number of legs. Leg diameters may be 2.0mm, 2.7mm or 3.2mm. Catalog numbers are descriptive such that 07.27.2118.21A describes an RMR Ortho implant (07) with 2.7mm diameter legs, 21mm bridge, and two 18mm legs.

| SKU | DESCRIPTION |
|--|---|
| A'TOMIC 2.0 | |
| 07.20.1010.21A | A'TOMIC 2.0MM NITI IMPLANT KIT 10X10MM 2-LEG, STERILE |
| A'TOMIC 2.7 | |
| 07.27.1515.21A | A'TOMIC 2.7MM NITI IMPLANT KIT 15X15MM 2-LEG, STERILE |
| 07.27.1818.21A | A'TOMIC 2.7MM NITI IMPLANT KIT 18X18MM 2-LEG, STERILE |
| 07.27.2118.21A | A'TOMIC 2.7MM NITI IMPLANT KIT 21X18MM 2-LEG, STERILE |
| 07.27.2518.41A | A'TOMIC 2.7MM NITI IMPLANT KIT 25X18MM 4-LEG, STERILE |
| A'TOMIC 3.2 | |
| 07.32.1820.21A | A'TOMIC 3.2MM NITI IMPLANT KIT 18X20MM 2-LEG, STERILE |
| 07.32.2120.21A | A'TOMIC 3.2MM NITI IMPLANT KIT 21X20MM 2-LEG, STERILE |
| 07.32.2520.41A | A'TOMIC 3.2MM NITI IMPLANT KIT 25X20MM 4-LEG, STERILE |
| OPTIONAL* ANCILLARY INSTRUMENTS | |
| 07.20.QDS | A'TOMIC 2.0MM QUICK DISCONNECT DRILL, STERILE |
| 07.27.QDS | A'TOMIC 2.7MM QUICK DISCONNECT DRILL, STERILE |
| 07.32.QDS | A'TOMIC 3.2MM QUICK DISCONNECT DRILL, STERILE |
| 07.27.SG1 | A'TOMIC SIZING GUIDE, STERILE |
| 07.27.RT1S | A'TOMIC REMOVAL TOOL, STERILE |

**Sterile kits are provided without drills. Facilities may request a corresponding drill from RMR Ortho or use an appropriately-sized drill bit: 2.0 implants require a 2.0mm drill bit; 2.7 implants require a 2.7 or 2.8mm drill bit; 3.2 implants require a 3.2mm drill bit. These drill bits must have a minimum length of 125mm.*

Reusable instruments and additional Implant sizes are subject to availability. Please contact your local RMR Ortho representative for more information.

For more information or placement of orders, contact your local RMR Ortho distributor or call our support staff at the number below.

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