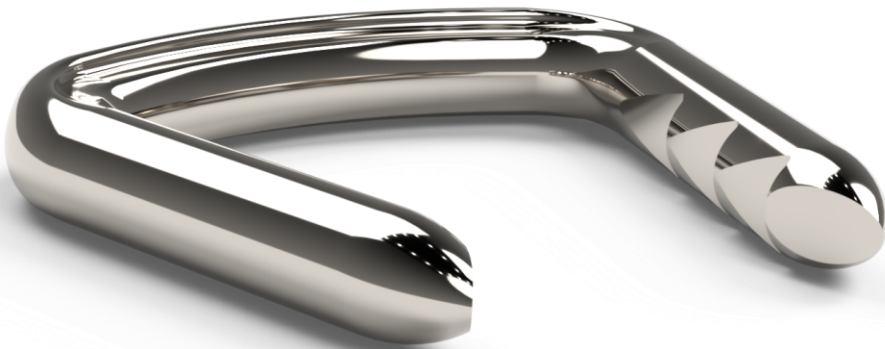




# **ATOMIC PULSE™**

VERSATILE MINI-FRAGMENT FIXATION



Surgical Technique Overview

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## Description

The A'TOMIC PULSE™ Nitinol Fixation System, which consists of the A'TOMIC PULSE™ implants and associated instruments, is intended for use for fixation and compression and supports several surgical techniques (e.g., fracture, osteotomy, joint arthrodesis, and fixation of bone fragments). The staples are made of implant-grade Nitinol and are designed to exhibit superelastic properties at room temperature. This allows for continued compression to be applied across bone segments, thus enhancing long-term stability and promoting fusion. Each staple is pre-loaded on an inserter for implantation and sterile packed. The staples are available in multiple sizes, varying by bridge length and leg length, to accommodate individual patient anatomy. Disposable Instrumentation is provided to assist in the surgical placement of the A'TOMIC PULSE™ implants.

## Indications

- The A'TOMIC PULSE™ 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 preclude staple placement). The device is intended for use in short, long, or flat bones. The A'TOMIC PULSE™ Nitinol Fixation System is intended for single use only.

## Contraindications

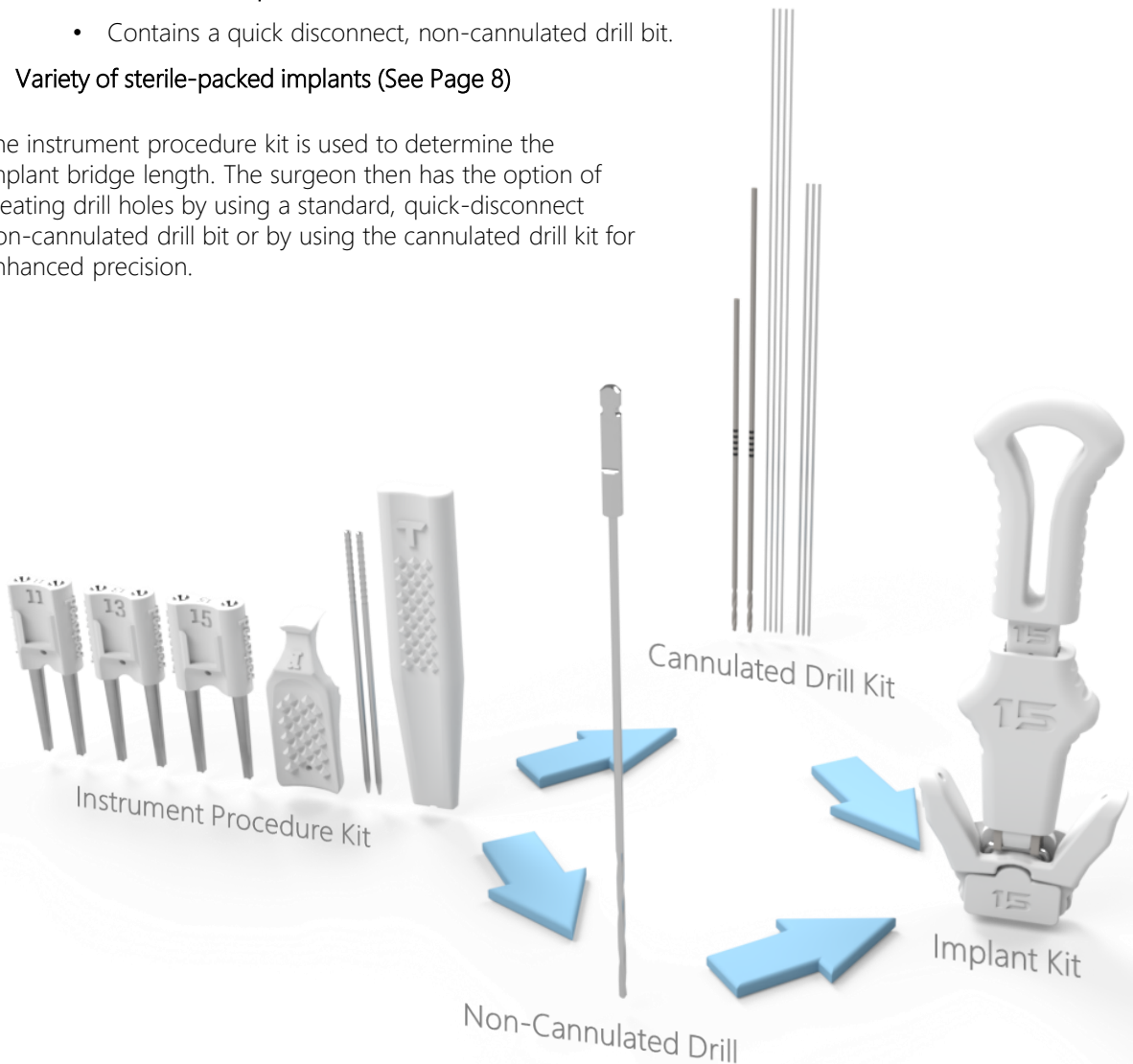
- Infection
- Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
- Patient conditions including blood supply limitations, obesity, and insufficient quantity or quality of bone that would impair the ability to securely fix the implant.
- 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.

## System Packaging

The A'TOMIC PULSE™ Nitinol Fixation System consists of the following pre-sterilized, disposable packages::

- **Instrument Procedure Kit (07.20.IPK):**
  - Contains drill guides, drill guide handle, pull pins, and tamp
- **Cannulated Drill Kit (07.20.CDK)**
  - Contains 1.1mm provisional fixation wires, 2.0mm pin-drive cannulated drill bits, 0.9mm guide wires
- **Non-cannulated drill option (07.20.QDS)**
  - Contains a quick disconnect, non-cannulated drill bit.
- **Variety of sterile-packed implants (See Page 8)**

The instrument procedure kit is used to determine the implant bridge length. The surgeon then has the option of creating drill holes by using a standard, quick-disconnect non-cannulated drill bit or by using the cannulated drill kit for enhanced precision.



## SURGICAL TECHNIQUE

1. Expose and prepare fusion surfaces using standard technique.

2. Reduce bone segments.

Use K-Wires as needed for temporary fixation. Temporary fixation should be placed in such a way as to prevent interference while drilling.

NOTE: If using the precision drilling option, the cannulated drill kit (07.20.IPK) contains 1.1mm K-wires that may be used for provisional fixation.

3. Determine the correct implant bridge length and shape using the drill guides.

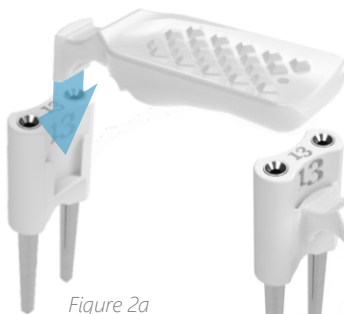
Place the drill guide across the fusion site to determine the desired implant bridge length (Fig. 1).

If necessary, place the drill bits into the drill guide and note the location and trajectory of the drill bits visually and/or using fluoroscopy.



4. Attach handle to selected Drill Guide.

Slide the handle into the dovetail feature on the drill guide (Figs. 2a-b). The use of the handle is optional.

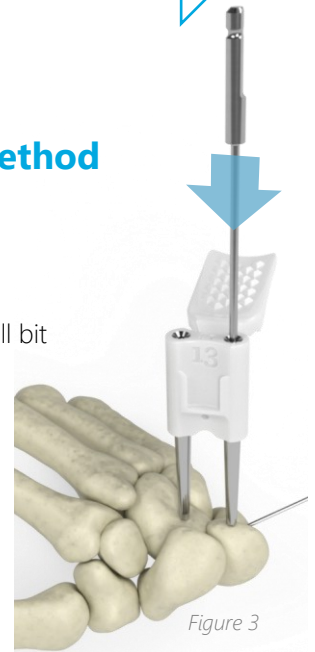


Proceed to STEP 7 if using the  
Cannulated Drilling Option

## Standard Drilling Method

5. Create first hole.

Create the first hole using a 2.0mm quick disconnect drill bit (Fig. 3).

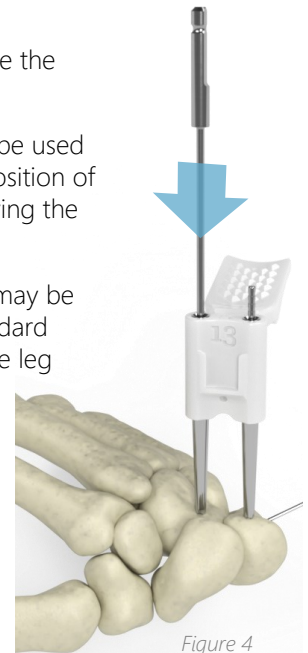


6. Create second hole.

Insert a pull pin and create the second hole (Fig. 4).

The second pull pin may be used to assist in locating the position of the drill holes after removing the drill guide.

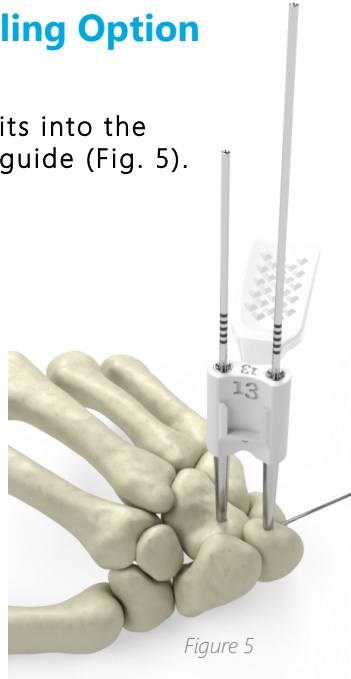
NOTE: Implant selection may be facilitated by using a standard depth gauge to determine leg length.



Proceed to  
Step 10

## Cannulated Drilling Option

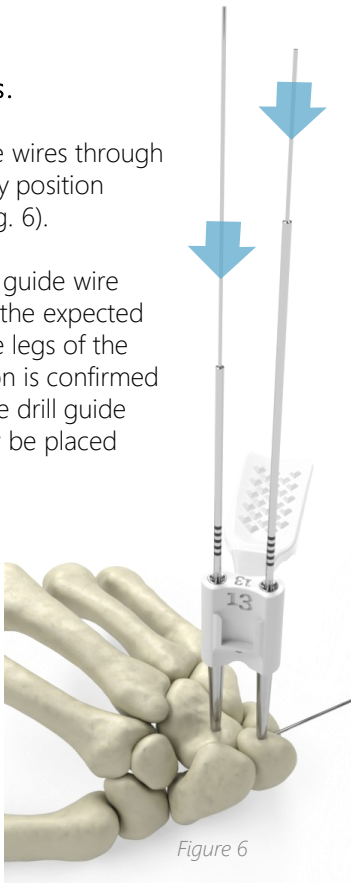
7. Place both drill bits into the tubes in the drill guide (Fig. 5).



8. Insert guide wires.

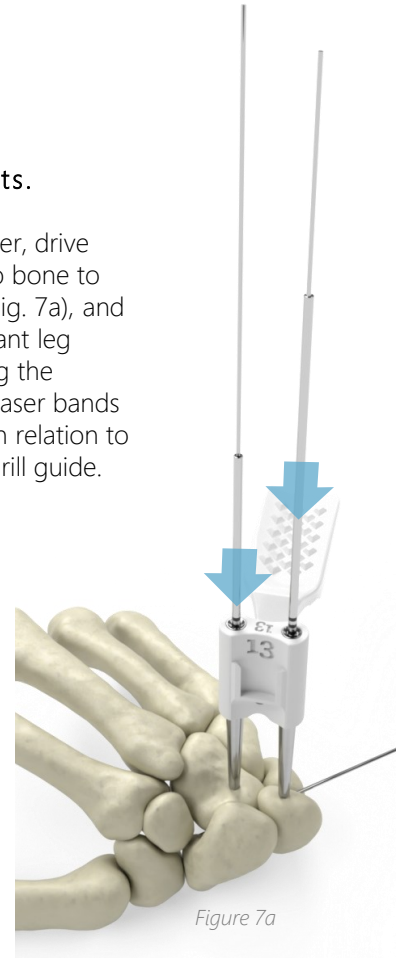
Drill the 0.9mm guide wires through the drill bits and verify position using fluoroscopy (Fig. 6).

Alternatively, the first guide wire may be inserted into the expected position of one of the legs of the implant. Once position is confirmed using fluoroscopy, the drill guide and long drill bit may be placed over the guide wire.



9. Insert drill bits.

Using a pin driver, drive the drill bits into bone to the far cortex (Fig. 7a), and determine implant leg length by noting the location of the laser bands on the drill bit in relation to the top of the drill guide.



The bands correspond to 8, 10, 12, 14 and 16mm, respectively (Fig. 7b).

Use the smallest measurement to determine the implant leg length.



## Implantation

### 10. Remove Inserter Assembly from Retention Block.

Lightly squeeze the wings of the retention block just enough to release the keystone (Fig. 8a-b).

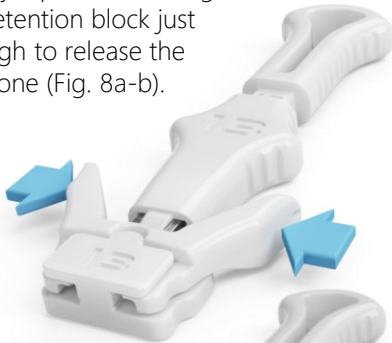


Figure 8a

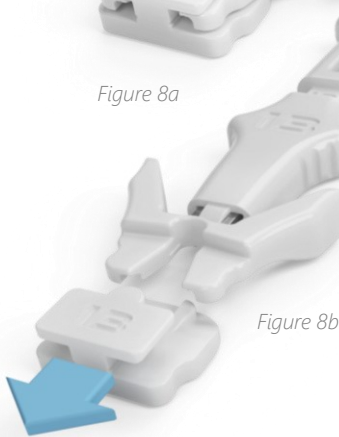


Figure 8b

Remove the implant from the retention block (Figs. 8c-d).



Figure 8c

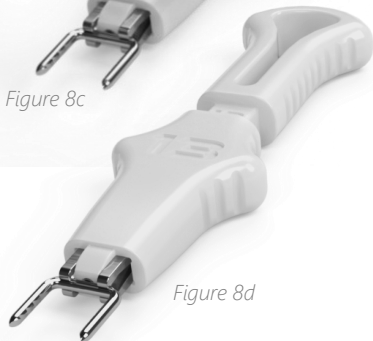


Figure 8d

### 11. Insert implant into pre-drilled holes.

Align the implant legs with the trajectory of the pre-drilled holes and insert the implant fully (Fig. 9a-b).



Figure 9a

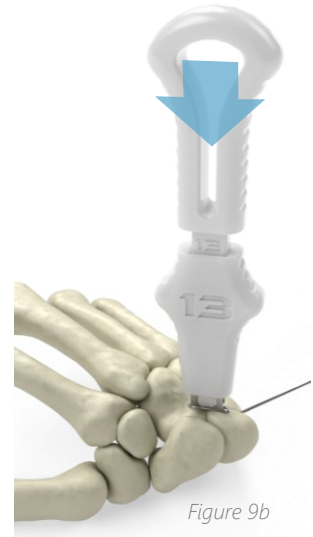


Figure 9b

### 12. Release the implant and tamp.

Pull the slider on the inserter assembly to release the implant. Use the tamp as necessary to fully seat the implant (Fig. 10a-c). Confirm final implant position using fluoroscopy.

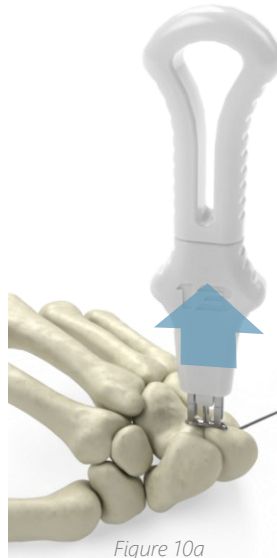


Figure 10a

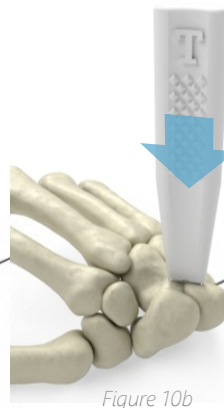


Figure 10b

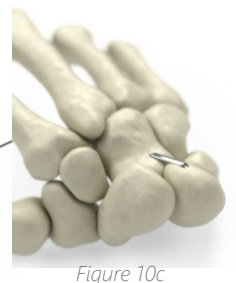


Figure 10c

## Explant Information

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

## Catalog Numbers/SKU

The system is comprised of various sizes to accommodate individual patient anatomy, varying by bridge length and leg length. All leg diameters are 2.0mm. Catalog numbers are descriptive such that 07.20.1110.21A describes an RMR Ortho implant (07) with 2.0mm diameter legs, 11mm bridge, and two 10mm legs. The implants are measured in the open position with legs parallel. The bridge width is measured from the center of one leg to the other leg. The leg length is measured from the underside of the bridge to the tip of the legs.

SKU	DESCRIPTION
<b>A'TOMIC PULSE™</b>	
07.20.1108.21A	A'TOMIC PULSE 2.0MM NITI IMPLANT KIT 11X08MM 2-LEG, STERILE
07.20.1110.21A	A'TOMIC PULSE 2.0MM NITI IMPLANT KIT 11X10MM 2-LEG, STERILE
07.20.1308.21A	A'TOMIC PULSE 2.0MM NITI IMPLANT KIT 13X08MM 2-LEG, STERILE
07.20.1310.21A	A'TOMIC PULSE 2.0MM NITI IMPLANT KIT 13X10MM 2-LEG, STERILE
07.20.1312.21A	A'TOMIC PULSE 2.0MM NITI IMPLANT KIT 13X12MM 2-LEG, STERILE
07.20.1510.21A	A'TOMIC PULSE 2.0MM NITI IMPLANT KIT 15X10MM 2-LEG, STERILE
07.20.1512.21A	A'TOMIC PULSE 2.0MM NITI IMPLANT KIT 15X12MM 2-LEG, STERILE
07.20.1514.21A	A'TOMIC PULSE 2.0MM NITI IMPLANT KIT 15X14MM 2-LEG, STERILE
07.20.1516.21A	A'TOMIC PULSE 2.0MM NITI IMPLANT KIT 15X16MM 2-LEG, STERILE
<b>ANCILLARY INSTRUMENTS</b>	
07.20.IPK	A'TOMIC 2.0MM INSTRUMENT PROCEDURE KIT, STERILE
07.20.CDK	A'TOMIC 2.0MM CANNULATED DRILL KIT, STERILE
07.20.QDS	A'TOMIC 2.0MM QUICK DISCONNECT DRILL, STERILE





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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