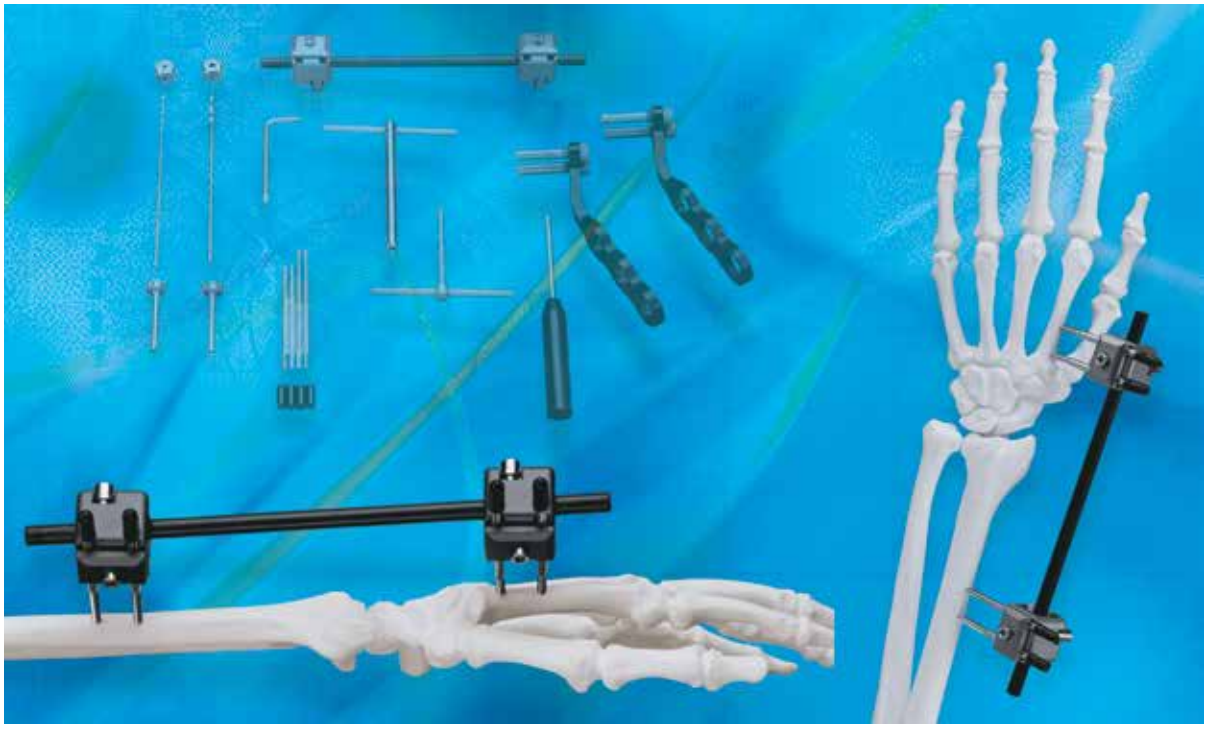
BIOMET TRAUMA

WristFix™
Distal Radius Fixator

Surgical Technique



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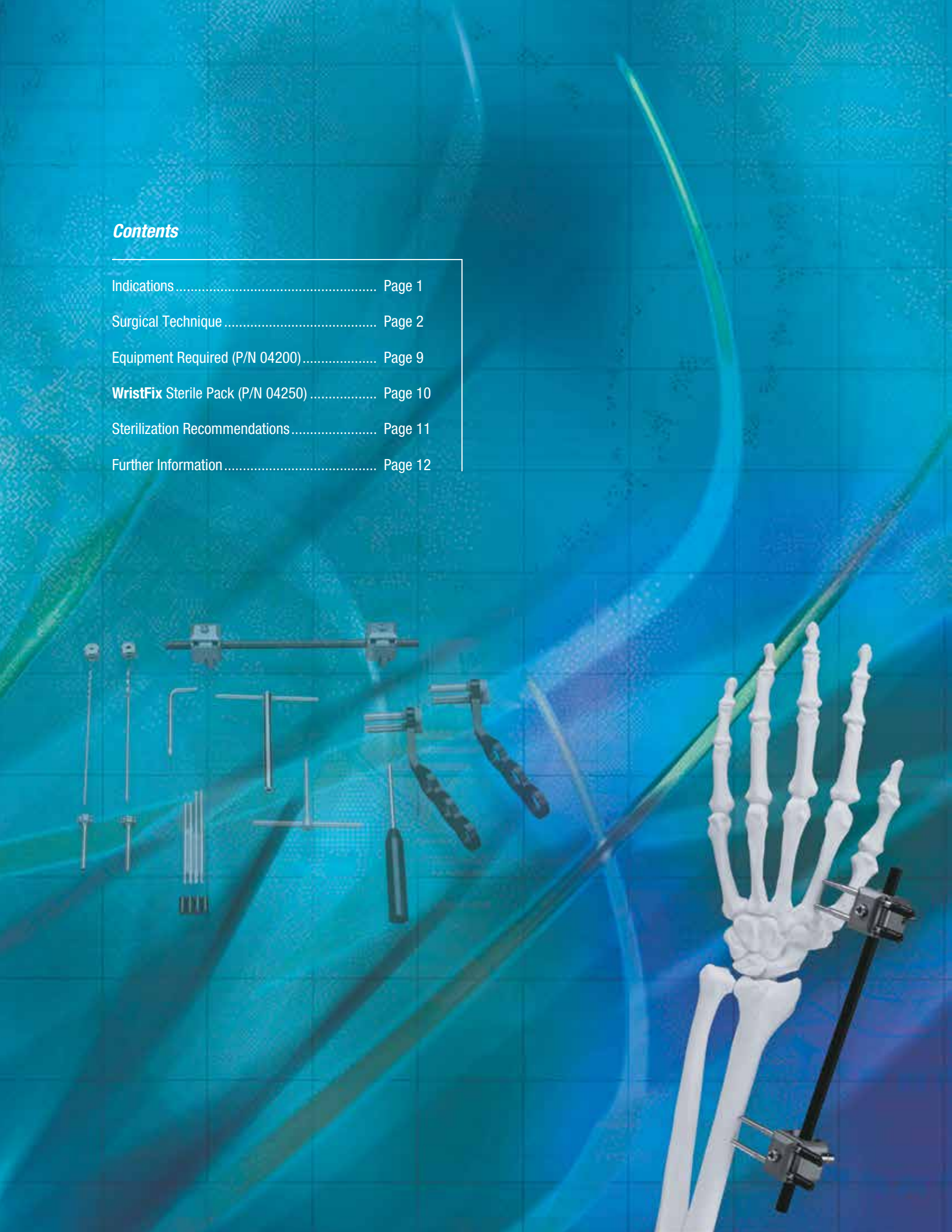


Indications

The **WristFix** Distal Radius Fixator is intended for use in upper extremity applications for the reduction, alignment and stabilization of intra-articular and extra-articular fractures, corrective osteotomies and soft tissue deformities.

Contraindications

Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.

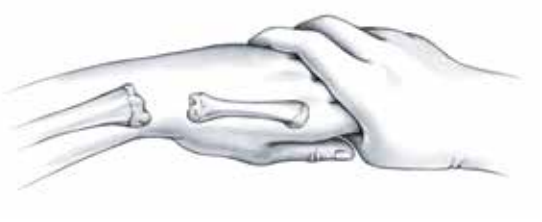
Surgical Technique

1. As with all surgical intervention, pre/operative planning is required prior to the application of the device. A hand table is utilized and gross reduction is performed. The wrist should be positioned to facilitate a frontal/radial surgical approach.

   Prior to the introduction of the distal bone screws, the soft tissues should be manipulated and gentle pressure applied in the region of the anatomical snuff box to allow for edema dissipation and to identify the radial sensory branch, metacarpal extensor tendon, and flare of the second metacarpal.

SURGICAL NOTE: In order to avoid extensor tendon impingement/ entrapment, a percutaneous pin is placed through a tendon to the level of the bone. Care should be taken to avoid insertion of this pin into the bone, rather the pin should be placed through a tendon. Motion will occur with flexion or extension of the digit giving clues to possible tendon or nerve perforation or penetration. In sequential order, the first and second metacarpals are then flexed and extended.[*1]

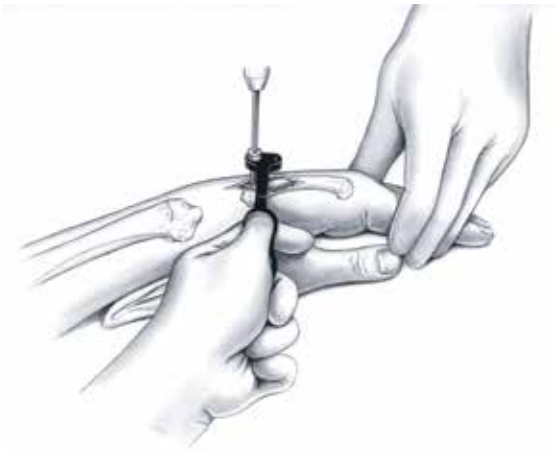
Obtain pre/operative reduction



Position for frontal/radial approach

2. An open technique is used, a 1cm longitudinal incision should be used to provide exposure and, protection of the terminal radial nerve sensory branches and interosseous muscles. The distal pin sites can also be approached through a percutaneous longitudinal incision, made at the flair of the base of the second metacarpal, extending distally along the shaft. Only the skin is incised to avoid damage to the cutaneous nerves and any dilated veins. The soft tissue is spread in line with the metacarpal bone using a hemostat introduced perpendicular to the long axis of the bone. Care should be taken to identify and move the branch of the radial sensory nerve away from the introduction of the drill guide and drill bit.

3. Using the bone screw template (P/N 05025), the distal bone screws are prepared for introduction. The bone screw template is introduced, and a hemostat is used to prevent soft tissues from being trapped under the template. Placement of the bone screw template should be confirmed visually to insure that the drilling process occurs in the center of the bone. Once the bone screw template position has been determined, insert the appropriate drill guide.



Establish first screw position and orientation

Insert appropriate drill guide into bone screw template

Surgical Technique (Continued)

4. The appropriate drill bit is introduced into the drill guide. The bone is pre-drilled perpendicular to the long axis of the bone at 30° to 45° dorsal to the radial plane. The near and far cortices are drilled without over penetration of the far cortex, avoiding soft tissue injury.

5. The drill guide is then removed. The appropriate bone screw is selected and manually inserted through the bone screw template. The bone screw T-wrench (P/N 05005) is then used to turn the bone screw clockwise until bicortical penetration is achieved.

   To obtain optimal purchase and to reduce complications of metacarpal fracture or bone screw loosening, all screws must be bicortical with two to three threads protruding beyond the far cortex. Image intensification is utilized to confirm depth of penetration.

SURGICAL NOTE: Once bicortical penetration is confirmed, the drill bit is left in place to secure the bone screw template and insure that the second hole will be drilled in the appropriate location.*[2]

SURGICAL NOTE: When inserting screws, care must be taken to avoid over penetration. Due to the tapered thread design, screws must not be backed out or they will lose purchase.

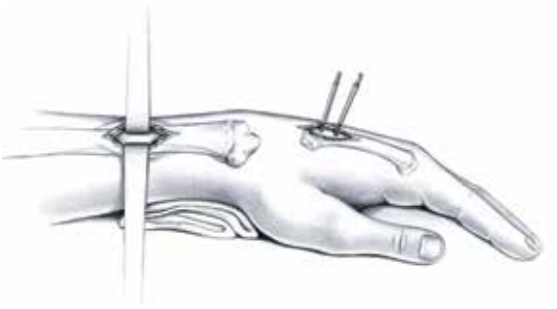
Commence drilling with appropriate drill bit. Use of drill stop will prevent over-penetration

Using bone screw T-wrench insert appropriate bone screw. Confirm bi-cortical purchase with image identification

6. In preparation for pre-drilling the second hole for the distal screw cluster, insert the appropriate drill guide into the bone screw template. The drill bit is then inserted into the drill guide and is used to achieve bicortical penetration. Repeat step five for application of bone screw.

7. In preparation for the insertion of the proximal bone screw cluster, a 2cm longitudinal incision is made along the dorsoradial aspect of the radial shaft, proximal to the fracture site. This allows for identification and protection of the radial sensory nerve and provides access to the radial shaft through the safe interval between the extensor radialis longis and brevis tendons. The most distal screw of the proximal screw cluster should be placed no closer than 2cm to the fracture site and 4cm proximal to the radial styloid. With the proximal screw in place, insert the threaded screw guide into the remaining fitting of the bone screw template. Repeat steps 2 through 5. Remove bone screw template.

Insert threaded screw guide into remaining fitting of bone screw template and repeat steps 2 through 5

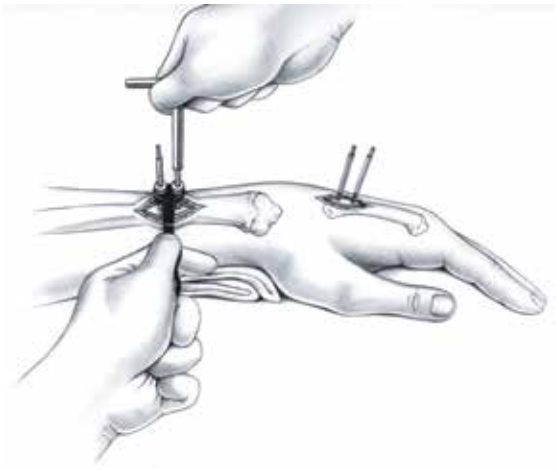


Identify and expose location of proximal screw cluster

8. The procedure described for insertion of the metacarpal screws should be repeated for the two radial screws. Image intensification is used to confirm screw position and depth of penetration.

SURGICAL NOTE: When inserting screws, care must be taken to avoid over penetration. Due to the tapered thread design, screws must not be backed out or they will lose purchase.

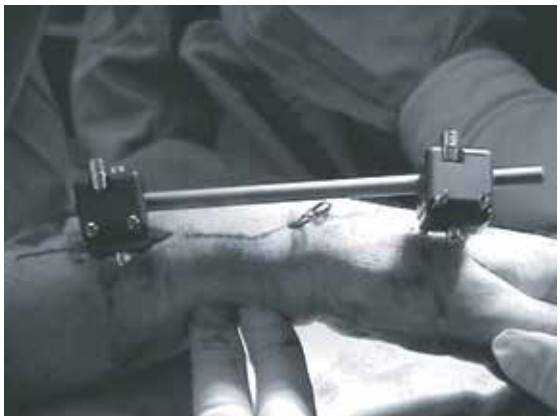
9. Prior to applying the fixator to the bone screws, the clamp cover screws and the rod locking screws on both sides of each clamp should all be loose. The clamp cover screws and the rod locking screws can be loosened by utilizing a 3mm T-wrench (P/N 05045) and turning each screw counterclockwise. Once the fixator has been made flexible by loosening the various locking mechanisms it is ready to be applied.



Repeat steps 2 through 5. Confirm screw depth and position with image intensification

10. With the clamp covers loose enough for the bone screw shanks to slide through the fixator clamps, apply the fixator to the bone screws. It is important to make sure that the fixator is far enough away from the patient's skin to allow for potential swelling and pin site hygiene. Two to three centimeters is an average distance the fixator should remain from the skin.

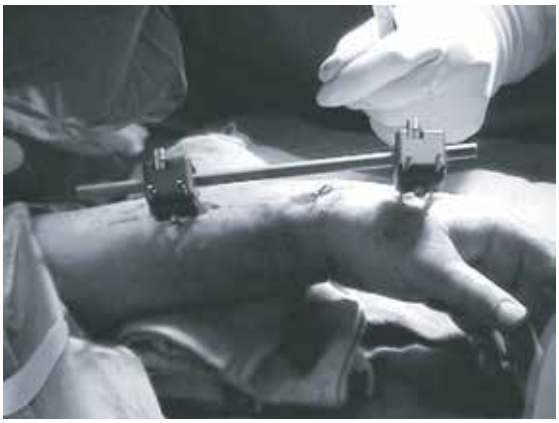
11. Once the frame is properly positioned, the clamp covers should be definitively locked. The fracture can now be addressed using the fixator as a reduction tool. The fixator can be manipulated to allow for radial/ulnar and dorsal/volar translation. The fracture reduction can be accomplished using the principles of ligamentotaxis. Most unstable fracture patterns are amenable to closed manipulation and direct ligamentotaxis. This primary ligamentotaxis may be achieved by loosening the proximal bone screw clamp and distracting across the fracture site. Once length has been established, the bone screw clamp should be locked to maintain position.



Surgical Technique (Continued)

12a. Once the fracture has been reduced and radiographically assessed, the proximal and distal bone screw clamps are definitively locked using a 3mm T-wrench. If fine-tuning of the fracture reduction is necessary, the distal and/or proximal rod locking screw should be loosened and tightened independently until a satisfactory reduction is achieved.

12b. At the conclusion of the fixator application and fracture reduction, wounds are closed and dressed. Dry sterile gauze is wrapped around the shanks of the bone screws to prevent pistoning of the soft tissue on the bone screws. Surgeons should maintain routine pin site care protocol. Screw sites should be monitored during subsequent clinic visits. All fixator fittings should be evaluated for tightness during subsequent clinic visits.



Equipment Required (P/N 04200)

Appropriate Size Bone Screws

3.3/3.0mm Diameter, Tapered
- 70mm Long/20mm Thread - (P/N A33-07020)
- 80mm Long/20mm Thread - (P/N A33-08020)
- 80mm Long/35mm Thread - (P/N A33-08035)
  (2.7mm Drill Bit and Guide Required)

3.0/2.5mm Diameter, Tapered
- 70mm Long/20mm Thread - (P/N A30-07020)
- 80mm Long/20mm Thread - (P/N A30-08020)
  (2.0mm Drill Bit and Guide Required)

SURGICAL NOTE:

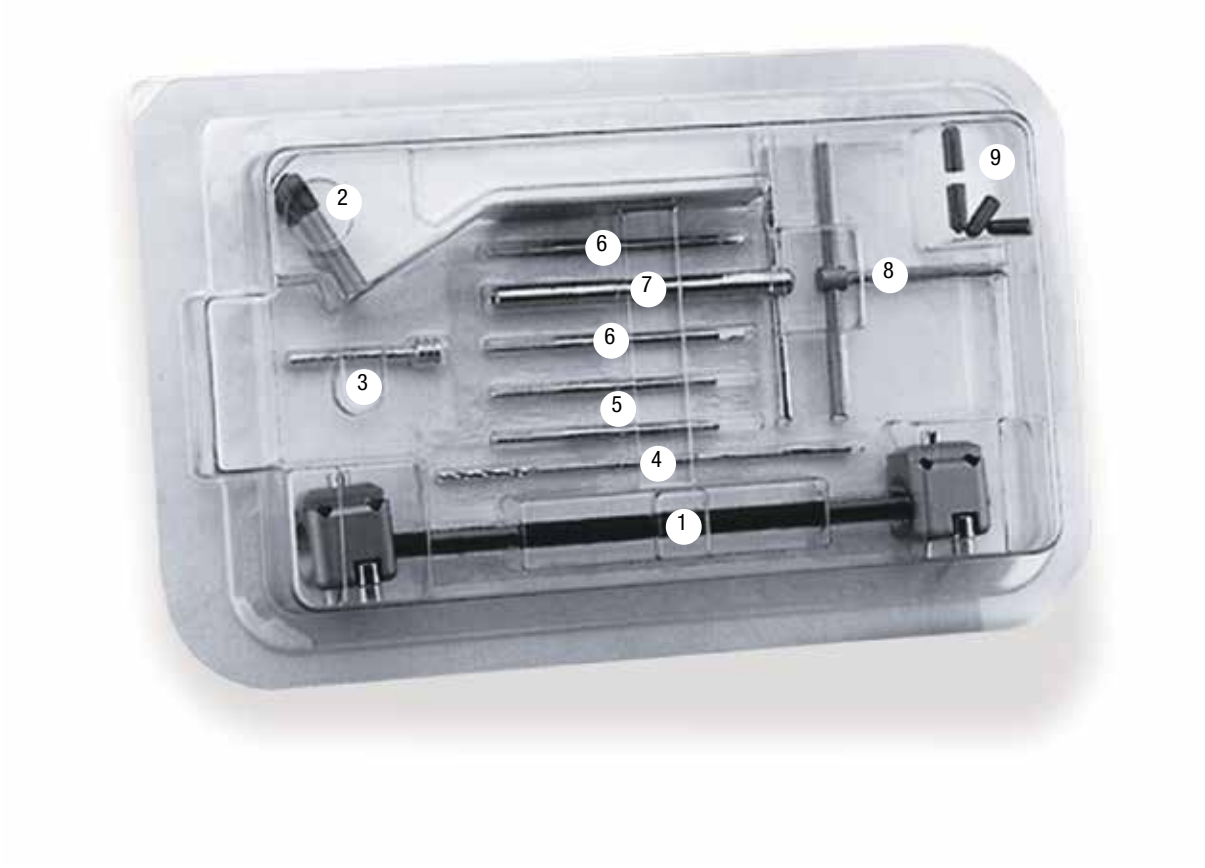
- Bone Screw Diameter should not exceed 1/3 the diameter of the bone
- Due to the tapered thread design, screws must not be backed out or they will lose purchase

1. **WristFix** Distal Radius Fixator (P/N 04200)
2. 2.0mm Drill Bit for 3.0/2.5mm Tapered Bone Screws (P/N 05010)
   2.7mm Drill Bit for 3.3/3.0mm Tapered Bone Screws (P/N 05015)
3. 2.0mm Drill Guide (P/N 05020)
   2.7mm Drill Guide (P/N 05021)
4. Bone Screws (See Above)
5. Bone Screw Cover (P/N 03310)
6. 3mm Allen Wrench (P/N 05045)
7. T-wrench for Bone Screws (P/N 05005)
8. 3mm T-wrench (P/N 05045)
9. Trocar (P/N 05030)
10. Bone Screw Templates (P/N 05025)

WristFix Sterile Pack (P/N 04250)

Contents Include:

1. **WristFix** Fixator with Carbon Fiber Rod (1)
2. Bone Screw Template with Soft Tissue Sleeve (1)
3. 2.7mm Drill Guide (1)
4. 2.7mm Drill Bit (1)
5. A33-07020 Cortical Bone Screws (2)
6. A33-08020 Cortical Bone Screws (2)
7. Bone Screw Wrench (1)
8. 3mm T-wrench with Allen Tip (1)
9. Bone Screw Covers (4)



Sterilization

STERILITY

The Biomet® DFS WristFix Distal Radius Fixator is provided nonsterile, and must be sterilized prior to use. All packaging materials must be removed prior to sterilization. All fixator components should be sterilized in a loosened state such that components may move freely.

The following steam sterilization parameters are recommended.

Cycle:	Vacuum steam
Temperature:	270°/(132ºC)
Time:	8 minutes
Drying Time	20 minutes

Individuals or hospitals not using the recommended method, temperature, and time are advised to validate any alternative methods or cycles using an approved method or standard.

The Biomet WristFix Sterile Pack P/N 04250 is provided sterile using minimum dosage of 2.5 MegaRad (25kGy) of gamma radiation. This product should not be resterilized.

See package insert for full prescribing information.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Biomet Trauma, as the manufacturer of this device, and their surgical consultants do not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and utilizing the appropriate techniques for implanting the device in each individual patient. Biomet and their surgical consultants are not responsible for selection of the appropriate surgical technique to be utilized for an individual patient.

Further Information

Surgical Notes are utilized by Jeffrey L. Visotsky, MD. Biomet Trauma, as the manufacturer of this device, and their surgical consultants do not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and utilizing the appropriate techniques for implanting the device in each patient. Biomet and their surgical consultants are not responsible for selection of the appropriate surgical technique to be utilized for an individual patient.

For further information, please contact the Customer Service Department at:

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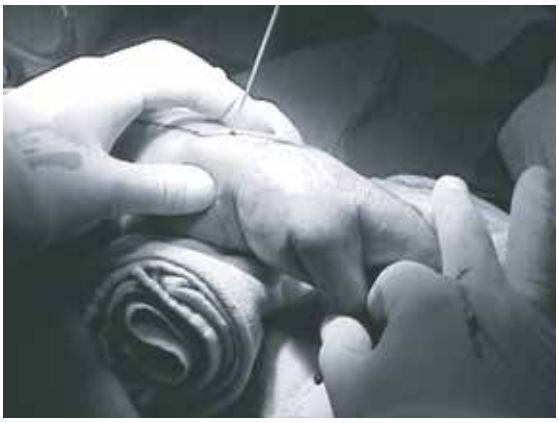
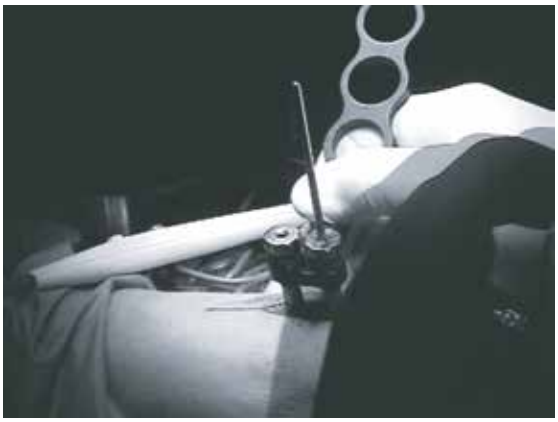


SURGICAL NOTE: In order to avoid extensor tendon impingement/ entrapment, a percutaneous pin is placed in the soft tissue to the level of the bone. Care should be taken to avoid insertion of this pin into the bone, rather the pin should only be placed into the soft tissues. In sequential order, the first and second metacarpals are then flexed and extended. The position of the pin is checked to make sure the percutaneous pin has not moved.



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BIOMET® TRAUMA

One Surgeon. One Patient.®

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