

F3[®]

**Flexible Fragment
Fixation**

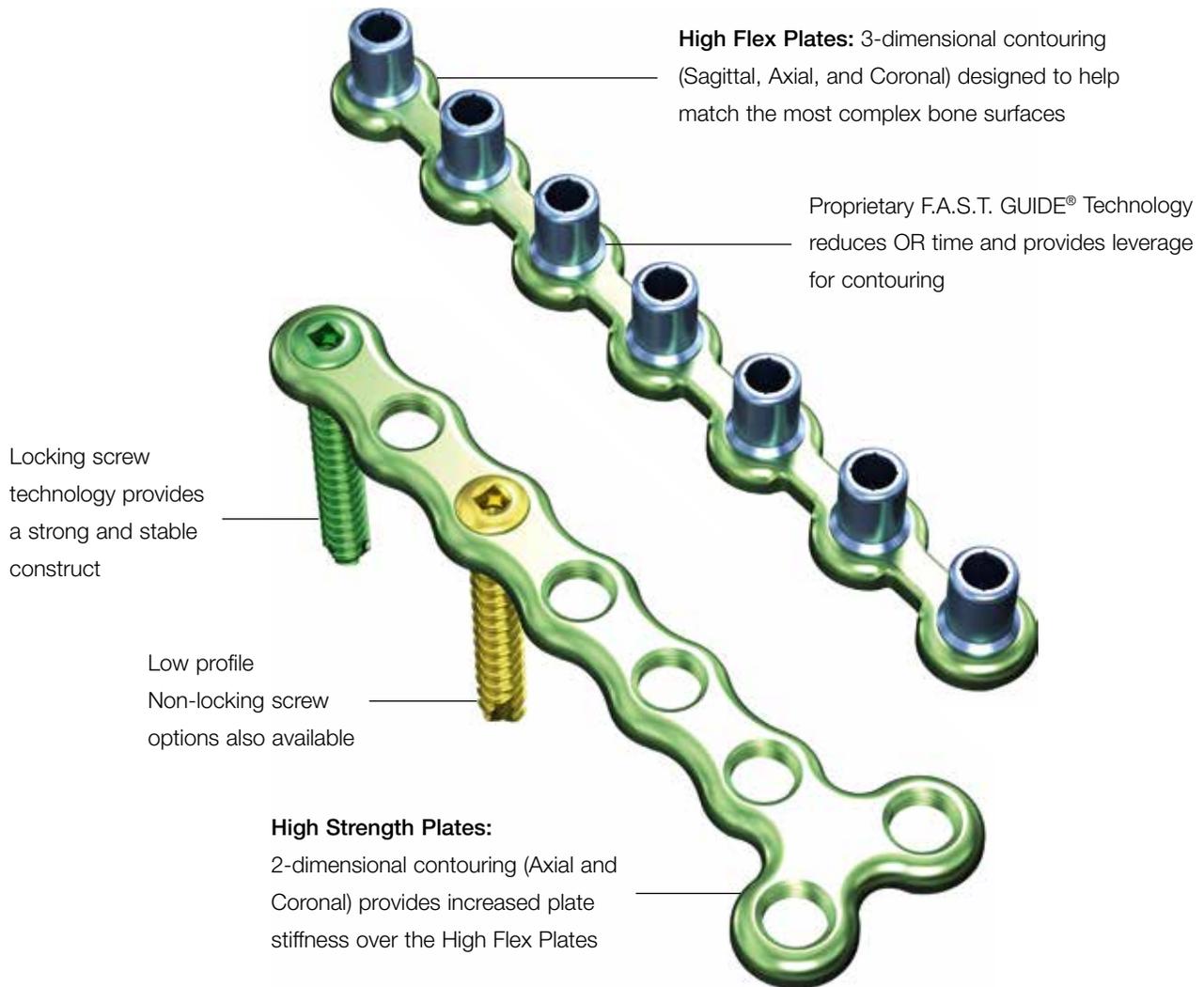
Surgical Technique

BIOMET[®]



F³® Flexible Fragment Fixation

The F³® Fragment Plating System offers low profile, yet strong fixation in a locked plating construct that can be contoured directly to the bone.



Screws

Screw

Available Lengths

Fully Threaded Pegs (Locking)



10, 12 14, 16, 18, 20, 22, 24, 26, 28 and 30

Fully Threaded Pegs (Non- Locking)



10, 12 14, 16, 18, 20, 22, 24, 26, 28 and 30

F³® Fragment Plating System

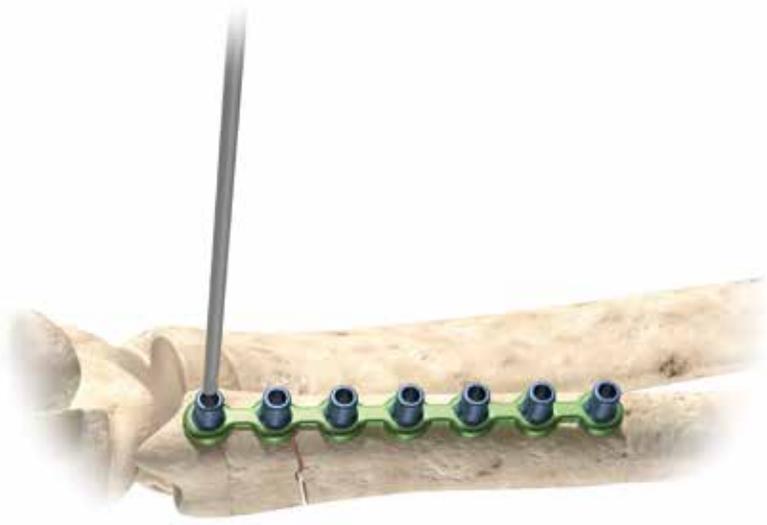


Figure 1



Figure 2

Surgical Technique

Prior to the surgery, the plate can be contoured to better fit the anatomy of the bone and nature of the fracture.

After making the incision and dissecting the surgical site, debride the fracture as needed. K-wires or reduction clamps can be used through the F.A.S.T. guide Inserts for temporary fixation of the fracture. Hold the plate firmly and drill through one of the holes using the 2.0 mm drill bit (DB20) (Figure 1).

Use the bone depth gauge (FBDG) to select the appropriate length screw. If measuring through a F.A.S.T. GUIDE Insert, use the rounded side of the depth gauge labeled "F.A.S.T. Guide." If measuring directly through the plate, read off the flat side of the depth gauge (FBDG) (Figure 2).

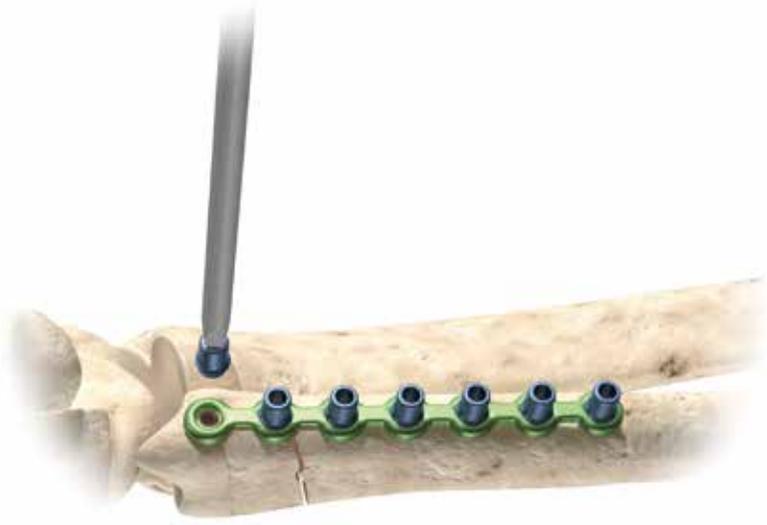


Figure 3

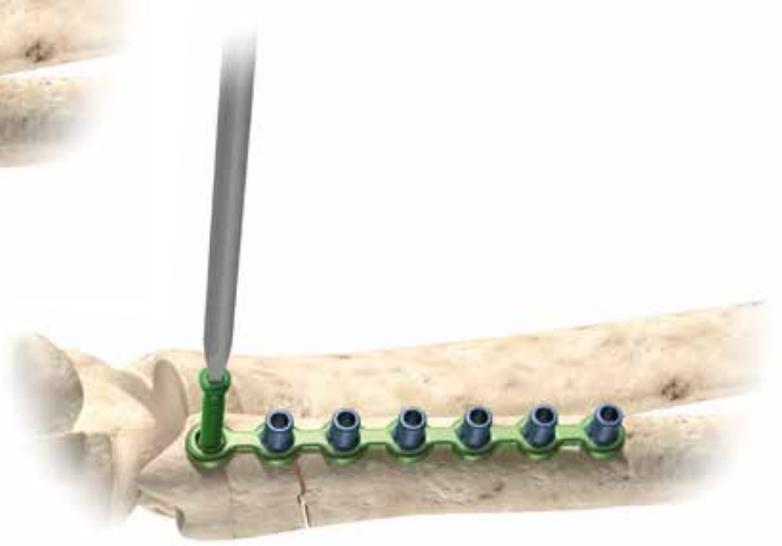


Figure 4

Remove the F.A.S.T. Guide Insert with the F.A.S.T. Peg Driver (FPD20) and discard (Figure 3).

Using the F.A.S.T. Peg Driver, apply the appropriate length locking (FP series) or non-locking (SP series) screws to secure the plate to the bone. Reduce the fracture (Figure 4).

Once the plate is initially fastened to the bone, it can be further contoured intraoperatively using the benders.

Note: It is important that you do not drill through multiple F.A.S.T. GUIDE Inserts at the same time before putting any screws in the plate, but instead drill one hole and apply the appropriate screw before moving to the next hole. This will help guarantee that each screw locks or seats firmly in the plate.

F³® Fragment Plating System

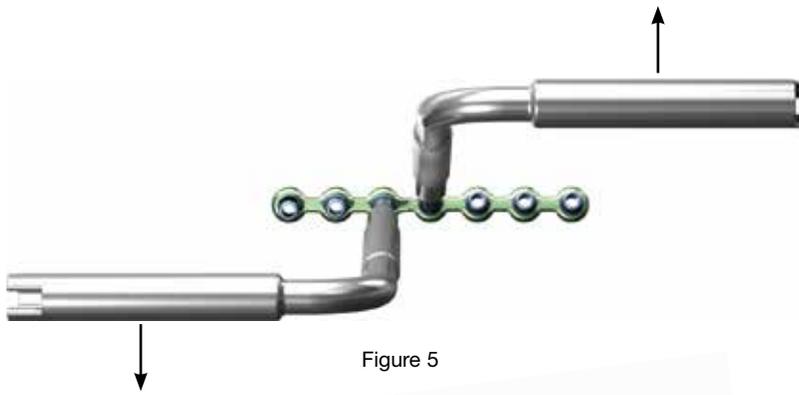


Figure 5

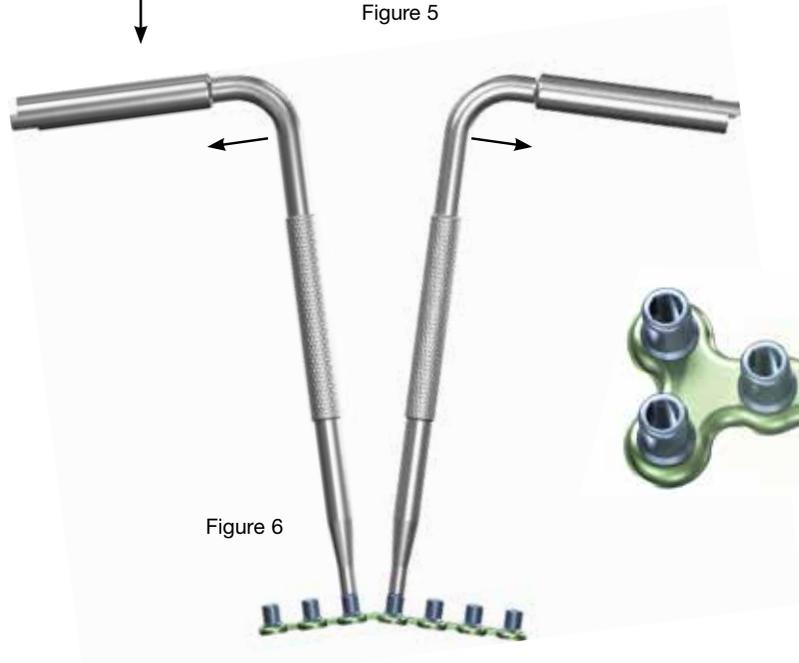


Figure 6

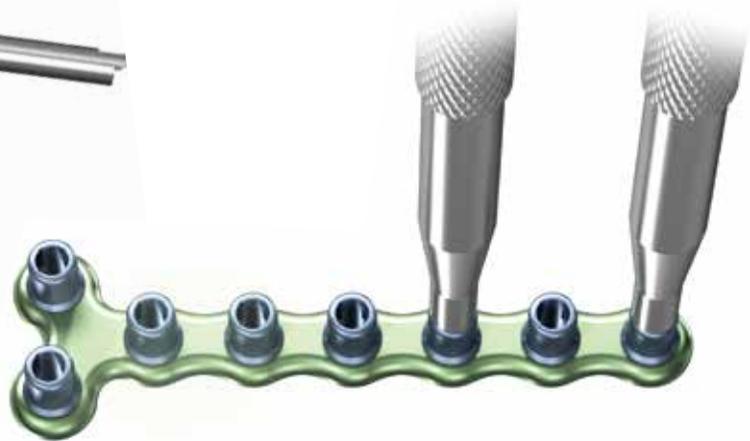


Figure 7

Plate Bending

Axial and Coronal Bends

Insert the pin end of each of the benders into the F.A.S.T. Guide Insert. Apply force to the benders in opposite directions (Figures 5 and 6). Care should be taken not to over-bend the plate.

For the High Strength Plates, it is recommended to leave one node free between bender locations (Figure 7).

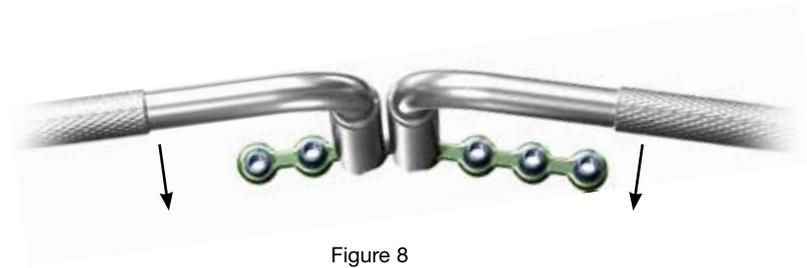


Figure 8



Figure 9

Sagittal/Planar Bends (High Flex Plates only)

For sagittal bends, place the cylindrical end of the benders over the F.A.S.T. Guide Insert ensuring the handles are pointed in opposite directions and are parallel with the plate. Pull the handles inward (Figure 8).

Drill through the F.A.S.T. Guide Insert, remove the F.A.S.T. Guide Insert and insert the appropriate length screw.

When bending the end node of plate, the End Bender must be placed over the F.A.S.T. Guide Insert in the end hole (Figure 9).

Use fluoroscopy to confirm reduction and placement. Close the wound with standard technique (Figure 10).

Trimming of Fragment Plates

High Strength Plates, a pair of cutters is necessary and should be used before implantation.

High Flex Plates, a pair of cutters may be used, however, the benders can be used to bend the node back and forth until it breaks.

The cut edges should be smoothed with a bone rasp to avoid soft tissue irritation.



Figure 10

F³® Fragment Plating System

Ordering Information

Hand Innovations Screws



Screws, Locking

Fully threaded to anchor fragments for added fixation

10 mm – 30 mm lengths (2 mm steps)



Screws, Non-locking

Fully threaded to aid in fracture reduction

10 mm – 30 mm lengths (2 mm steps)

Plate Benders



2312-07-000 Bender 2.0

Designed to contour F³ Plates



2312-07-001 End Bender 2.0

Designed to contour F³ Plates from the end nodes

High Flex Plates

1312-17-100 High Flex Right

13.0 mm x 42.7 mm



1312-17-101 High Flex Left

13.0 mm x 42.7 mm



1312-17-102 High Flex Straight

5.6 mm x 50.1 mm



1312-17-103 High Flex Y

16.1 mm x 40.5 mm



High Strength Plates

1312-17-000 High Strength Right

11.7 mm x 45.3 mm



1312-17-001 High Strength Left

11.7 mm x 45.3 mm



1312-17-002 High Strength Straight

5.6 mm x 50.0 mm



1312-17-003 High Strength Y

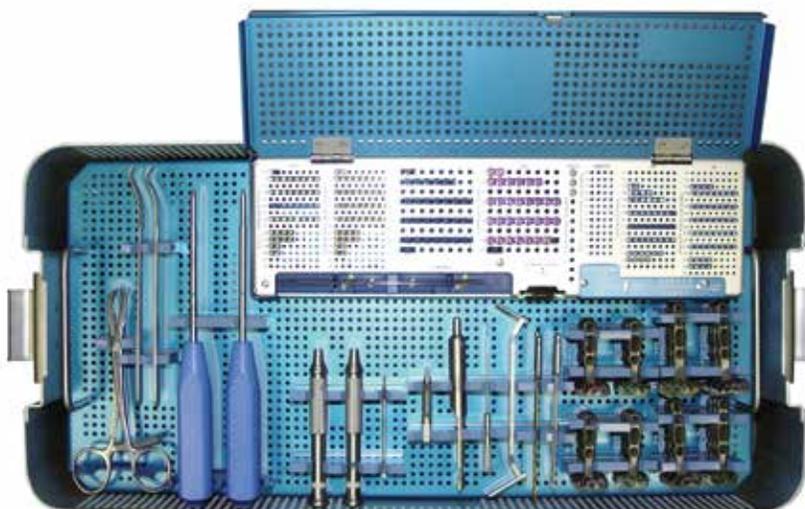
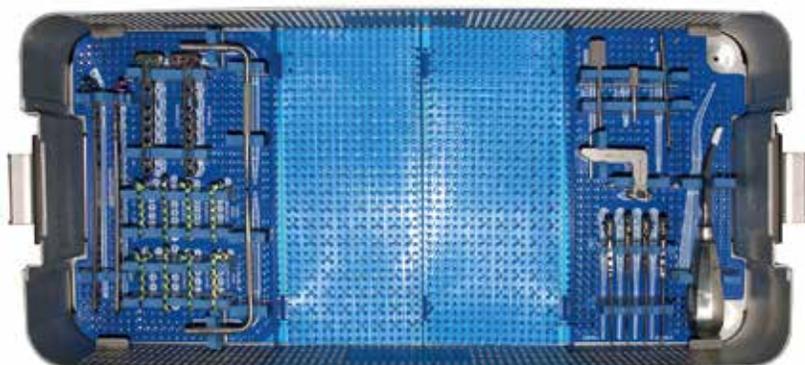
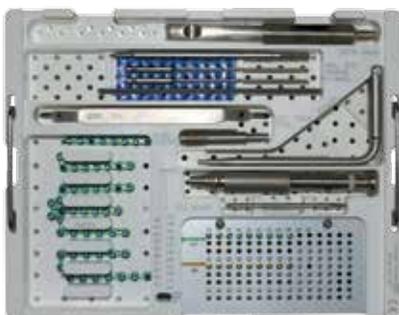
12.9 mm x 43.7 mm



DVR® Anatomic Plate Modular Tray

New fully modular tray system addresses multiple applications with the use of a single tray

- Reduced OR Instruments
- Improved Workflow



F³® Fragment Plating System

Important:

This Essential Product Information sheet does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

Indications:

The Fragment Plate System is intended for essentially non-load bearing stabilization and fixation of small bone fragments in fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, foot, wrist, ankle, humerus, scapula, finger, toe, pelvis and craniomaxillofacial skeleton.

Contraindications:

If any of the following are suspected, tests are to be performed prior to implantation. Active or latent infection. Sepsis. Insufficient quantity or quality of bone and/or soft tissue. Material sensitivity. Patients who are unwilling or incapable of following post operative care instructions.

Warnings and Precautions

- Although the surgeon is the learned intermediary between the company and the patient, the important information conveyed in this document should be conveyed to the patient. The patient must be cautioned about the use, limitations and possible adverse effects of these implants. The patient must be warned that failure to follow postoperative care instructions may cause the implant or treatment to fail.
- An implant must never be reused. Previous stresses may have created imperfections that can potentially lead to device failure. Protect implant appliances against scratching or nicking. Such stress concentration can lead to failure.
- Orthopaedic instrumentation do not have an indefinite functional life. All re-usable instruments are subjected to repeated stresses related to bone contact, impaction, routine cleaning and sterilization processes. Instruments should be carefully inspected before each use to ensure that they are fully functional. Scratches or dents can result in breakage. Dullness of cutting edges can result in poor

functionality. Damaged instruments should be replaced to prevent potential patient injury such as metal fragments into the surgical site. Care should be taken to remove any debris, tissue or bone fragments that may collect on the instrument. Most instrument systems include inserts/trays and a container(s). Many instruments are intended for use with a specific implant system. It is essential that the surgeon and operating theatre staff are fully conversant with the appropriate surgical technique for the instruments and associated implant, if any.

- Exercise care when bending the fragment plates to avoid weakening or fracture of the plates.
- Ensure removal of all F.A.S.T. GUIDE® Inserts after use.
- The fully threaded pegs (FP) and SP series screws are designed for use with the fragment plates.
- Do NOT use peg/screw lengths that will excessively protrude through the far cortex. Protrusion through the far cortex may result in soft tissue irritation.
- Do NOT permanently implant K-wires through the holes of the plate as they may back out and cause tissue damage. Use of the K-wires allows you to provisionally secure the plates to the anatomy.

Adverse Effects

The following are possible adverse effects of these implants: potential for these devices failing as a result of loose fixation and/or loosening, stress, excessive activity, load bearing particularly when the implants experience increased loads due to a delayed union, nonunion, or incomplete healing.

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For product information, including indications, contraindications, warnings, precautions and potential adverse effects, see the product labeling.



One Surgeon. One Patient.®

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