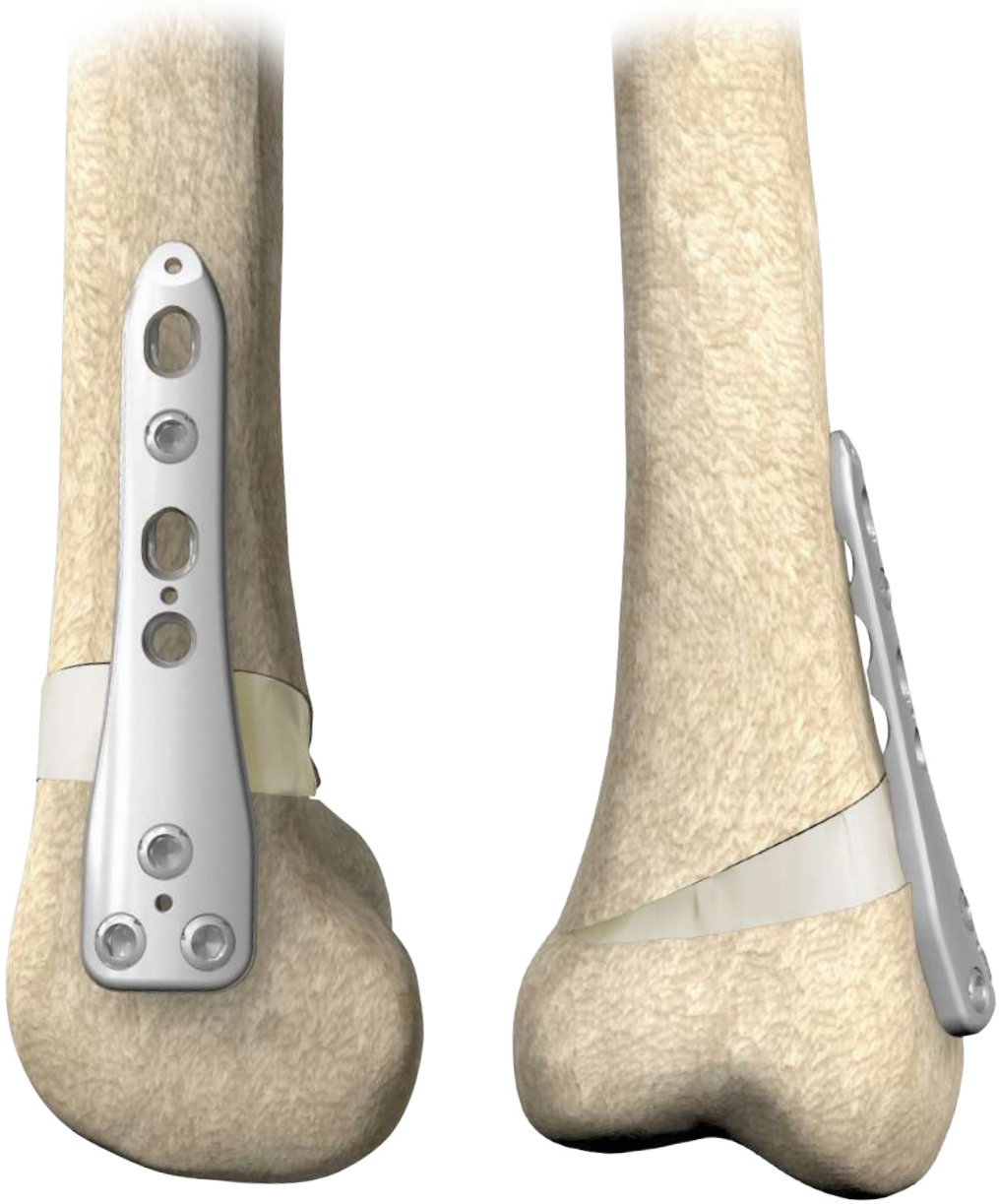
Distal Femoral Osteotomy System

OPENING WEDGE OSTEOTOMY INSTRUMENTATION

SURGICAL TECHNIQUE



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SYSTEM OVERVIEW

LOCATE AND CREATE OSTEOTOMY

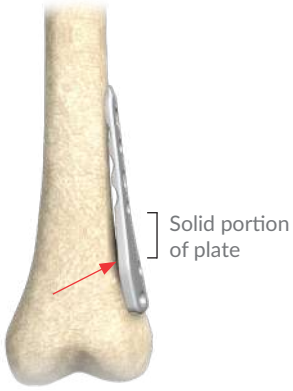

FIGURE 1: Locate start of oblique osteotomy

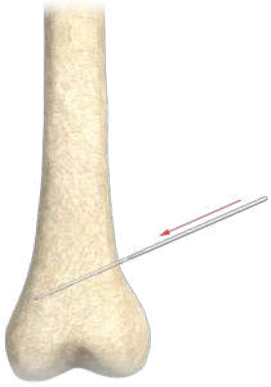

FIGURE 2: Insert initial guide wire

Place the desired plate on the lateral aspect of the distal femur to locate the start point of the osteotomy. The start point of the osteotomy should be located near the distal end of the solid portion of the plate (see Figure 1).

PRECAUTION: Consideration should be taken for the start point of the osteotomy, to ensure enough real-estate in the distal fragment for the three-hole cluster of screws. Starting the cut at the distal end of the solid portion of the plate will allow the osteotomy to be placed in as much metaphyseal bone as possible, and ensure that the holes in the plate surround the osteotomy.

Insert an initial 2.0mm guide wire at the start point of the osteotomy, located centrally about the metaphysis/diaphysis on the lateral femur. Using fluoroscopy, advance the guide wire towards the medial epicondyle, keeping the tip of the guide wire at least 1 cm away from the medial cortex (see Figure 2).

NOTE: Either the 2.0mm X 150mm guide wire (01-0907-0022) or 2.0mm X 230mm guide wire (01-0907-0021) can be used for the initial guide wire. The use of a smaller diameter wire may result in the wire falling through the in-line cannulation of the cut guide.

NOTE: Proper placement of the initial guide wire is essential, as it will set the trajectory of the osteotomy.

PRECAUTION: Care should be taken to prevent the guide wire from entering the joint space.

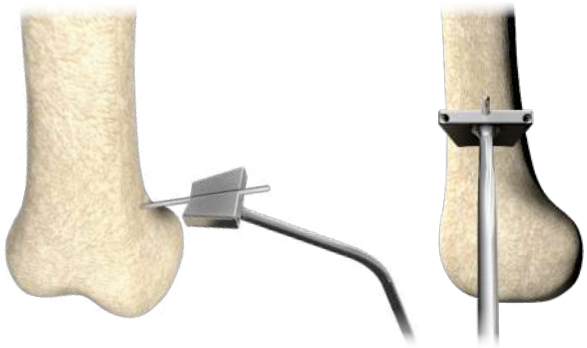

FIGURE 3: Place Opening Wedge Cut Guide

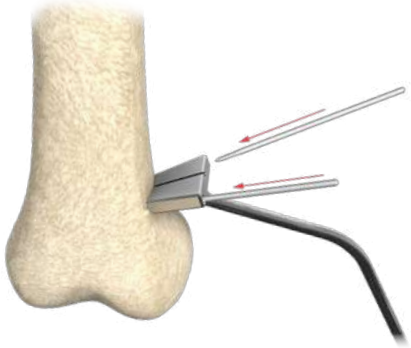

FIGURE 4: Insert two guide wires

Place the Opening Wedge Cut Guide over the initial 2.0mm guide wire, through the central 'in-line' cannulation (see Figure 3). Ensure the handle of the cut guide is parallel with the diaphysis of the femur to prevent unwanted flexion or extension in the osteotomy.

NOTE: The end of the cut guide that seats down on the bone is curved for proper fit.

Insert two 2.0mm guide wires in the peripheral holes of the cut guide, and then remove the initial central guide wire (see Figure 4).

NOTE: The 2.0mm X 75mm guide wires (01-1050-1760) should be used in the peripheral holes of the cut guide, as the shorter length will prevent interference with the sagittal saw.

Utilizing a sagittal saw, start the osteotomy through the lateral cortex. Osteotomes can be used to complete the osteotomy to the appropriate depth—to minimize the risk of fracturing the hinge, approximately 1 cm of medial bone should be preserved.

OPEN OSTEOTOMY, CREATE & INSERT GRAFT

FIGURE 5: Insert Tap n' Jack

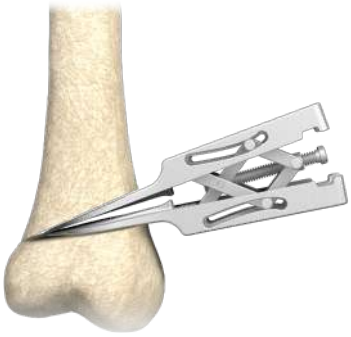

FIGURE 6: Open jack to targeted correction angle

FIGURE 7: Open jack to targeted correction angle

Insert the Tap n' Jack into the osteotomy, and use a T20 Hexalobe Driver to open the jack to the targeted correction angle (see Figures 5, 6 & 7). This step should be performed slowly to reduce the risk of medial cortex fracture. Fluoroscopy should be used to check limb alignment and confirm that the desired correction angle has been achieved.

NOTE: To reduce the risk of bending or fracturing the Tap n' Jack, ensure the osteotomy is complete through the anterior, posterior, and lateral cortices prior to opening the device.

NOTE: The use of any other driver besides a T20 Hexalobe Driver may result in stripping of the drive feature on the Tap n' Jack. The device will not open or close unless the bolt is turned.

NOTE: The maximum amount of lateral cortex opening, in millimeters, is dependent on how far the Tap n' Jack is inserted into the osteotomy. With the Tap n' Jack inserted its full length, at max opening approximately 25mm of lateral cortex opening can be achieved.

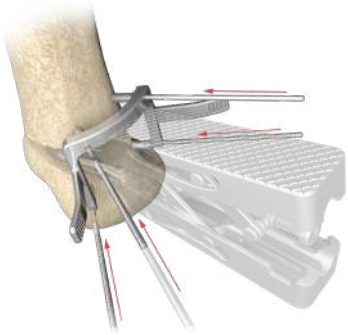

FIGURE 9: Insert four guide wires

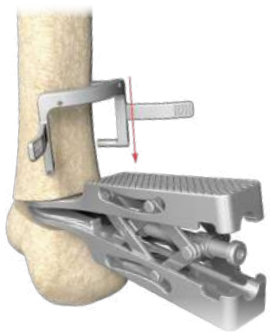

FIGURE 8: Place Bridge over Tap n' Jack

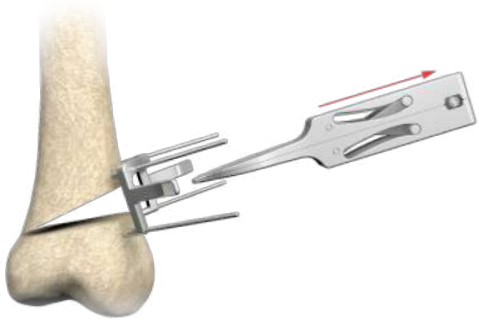

FIGURE 10: Collapse and remove Tap n' Jack

Place the Bridge over the Tap n' Jack, with the opened end of the device oriented over the distal femur (see Figure 8). The proximal end of the Bridge is marked for visual clarity.

Insert four 2.0mm guide wires into the cannulations of the Bridge (see Figure 9).

After confirming desired correction angle, collapse the Tap n' Jack using a T20 Hexalobe driver and remove (see Figure 10).

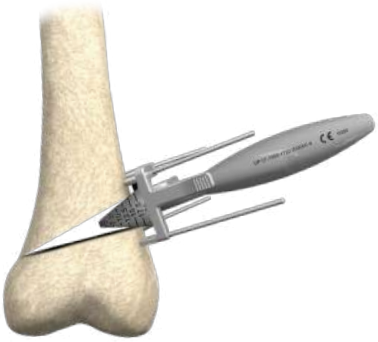

FIGURE 11: Insert Measurement Handle

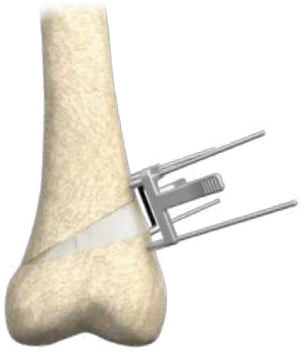

FIGURE 12: Insert graft

Insert the Measurement Handle into the osteotomy and read the amount of opening in millimeters at the lateral cortex (see Figure 11).

NOTE: The graft measurement handle has numeric calibrations along all four sides for visual clarity.

Prepare the graft and insert it into the osteotomy (see Figure 12).

PLACE & ATTACH IMPLANT

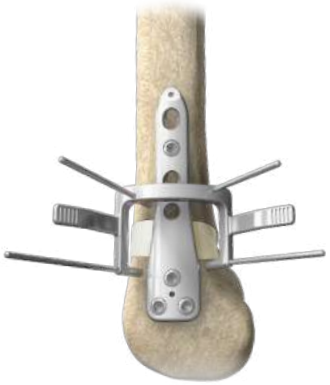

FIGURE 13: Place implant under Bridge and insert screws

FIGURE 14: Remove guide wires and Bridge

Place the desired implant under the Bridge, starting distally to proximally. Insert the implant screws per the Distal Femoral Osteotomy System Surgical Technique, ST-1050-07-01 (see Figure 13).

Remove all four 2.0mm guide wires and the Bridge (see Figure 14).

PRODUCT INFORMATION

INSTRUMENTS

Item Number	Description
01-1050-1700	DFOS Tap n' Jack
01-1050-1710	DFOS Bridge
01-1050-1720	DFOS Measurement Handle
01-1050-1730	DFOS Opening Wedge Cut Guide
01-1050-1760	2.0 x 75mm Threaded Guide Wire Cobalt Chrome
01-9473-5017	2.0 x 75mm Threaded Guide Wire Stainless Steel

NOTE: The stainless steel guide wire options listed may not be available in all countries.

IMPLANTS

5° FLARE PLATES, NO OFFSET

Item Number	Description	Holes
00-1050-5004	3.5mm 90° DFOS Plate, 5° Flare, No Offset	4
00-1050-5006	3.5mm 90° DFOS Plate, 5° Flare, No Offset	6
00-1050-6004	4.5mm 90° DFOS Plate, 5° Flare, No Offset	4
00-1050-6006	4.5mm 90° DFOS Plate, 5° Flare, No Offset	6
00-1050-7004	3.5mm 80° DFOS Plate, 5° Flare, No Offset	4
00-1050-7006	3.5mm 80° DFOS Plate, 5° Flare, No Offset	6
00-1050-8004	4.5mm 80° DFOS Plate, 5° Flare, No Offset	4
00-1050-8006	4.5mm 80° DFOS Plate, 5° Flare, No Offset	6

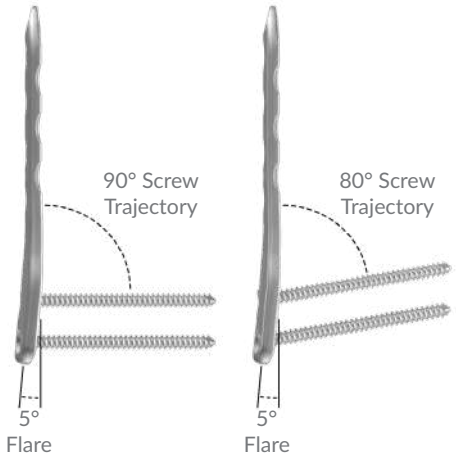

FIGURE 15: Side profile of plates, showing distal flare and screw trajectory

Figure 16 shows the distance between the centers of the most proximal of the distal screw holes and the most distal of the proximal screw holes. This value is the same for all 3.5mm plates and 4.5mm plates, respectively.

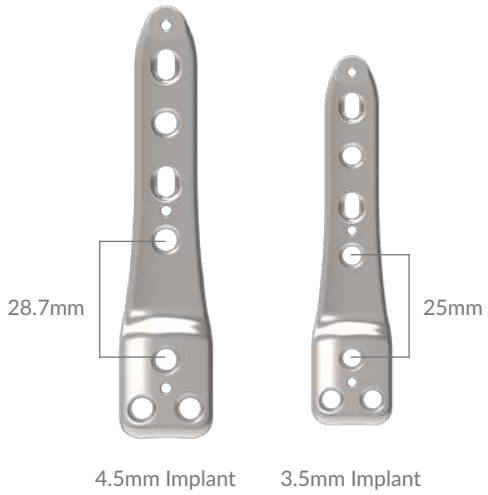

FIGURE 16: Distance between implant screw holes

CAUTION: Federal law restricts this device to sale by or the order of a Physician.

CAUTION: Devices are supplied Non-Sterile. Clean and sterilize before use according to instructions.

CAUTION: Implants components are single-use. Do not reuse.

CAUTION: The device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine

CAUTION: Only those instruments and implants contained within this system are recommended for use with this technique. Other instruments or implants used in combination or in place of those contained within this system is not recommended.

NOTE: This technique has been provided by one of our medical advisors only as guidance and it is not intended to limit the methods used by trained and experienced surgeons.

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2850 Frontier Drive | Warsaw, IN 46582
ph: 574.268.6379 or 877.268.6339 | **fax:** 574.268.6302
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