Lateral bone stock.

1 Why do the pins enter through the medial femoral cortex and not the lateral cortex like the predicate RIGIDFIX System?

a. Femoral tunnels drilled through the anteromedial (AM) portal technique are typically more oblique or lower on the clock face than ones drilled through the TT portal. Cross-pin placement on the lateral side with these low AM tunnels poses a risk of damaging the surrounding neurovascular structures, such as, the peroneal nerve laterally, the lateral collateral ligament, iliotibial band, popliteal tendon, cartilage on the lateral femoral condyle and lateral meniscus. To avoid potential complications associated with these structures, RIGIDFIX CURVE cross-pins enter on the medial side.

b. With tunnels more oblique, sleeves positioned on the lateral side would be loose since there would not be sufficient bone stock to hold the sleeves in proper position.

c. The IT band can potentially bend the sleeves out of position when placed on the lateral side.

d. There is a risk of the proximal portion of the pin (the blunt end) protruding through the lateral cortex.

2 Does the knee have to be flexed at 120° to drill the tunnel?

Yes. This helps to ensure that that the guide pin exit point is above the lateral midline of the femoral shaft; thus, creating an optimal tunnel trajectory which maximizes lateral bone stock and reduces the risk of pin protrusion. It also reduces the potential for backwall blow out.

3 What is lateral bone stock?

This is the distance between the tip of the implant when in the final implanted position, and lateral femoral cortex.

4 What is the purpose of the prescribed anteromedial (AM) portal?

This portal placement allows a surgeon to target the center of the native ACL footprint while maximizing lateral bone stock. Placement of the AM portal is approximately 5 mm–10 mm medial to the medial edge of the patellar tendon, distal to the inferior pole of the patella and superior to the medial meniscus.
5 What is the purpose of drilling in the 1” 2 1” location?

The bone in this area has fewer contours which minimizes the risk of trocar divergence and inaccurate drilling. Also, drilling in this target location will help to ensure:

a. The entry point of the sleeves and trocar are away from critical structures.

b. Accuracy of pin placement in the center of the tunnel.

c. Maximizes lateral bone stock

6 What is the purpose of the Arc Attachment?

The Arc Attachment is a tool used to predict and ensure that sufficient lateral bone stock is available prior to drilling the position of the sleeves and trocar for cross-pin placement.

7 What is the pull-out strength?

Approximately 704N with two pins. Tested in cadaveric bone, cycled, with PLA pins. Strength with a single pin is approximately 425N.²

8 Do I need to drill a 30 mm femoral socket?

Yes. The system is designed to ensure 30 mm of graft in tunnel. If the tunnel is shorter than 30 mm the most distal pin (one closest to the aperture) may protrude into the joint space.

9 Does the trocar drill across the tunnel?

No. By design the trocar does not drill across the tunnel into the other side. This allows for a compression fit between the pins and bone to ensure rigid fixation. You can check pin accuracy post drilling using a 2.4 mm guide pin or the bone gauge pin.

10 What is the diameter of the trocar?

The RIGIDFIX CURVE trocar is smaller at the distal working end to ensure a compression fit between the pins and bone. The diameter is 2.4 mm at the working end.

11 Do the sleeves cross the tunnel?

No. By design the sleeves do not cross the tunnel. The sleeves cannot enter the tunnel as this would prohibit removal of the femoral rod and instrumentation post drilling.

12 What is the distance from the pins to the aperture, 30 mm mark on the femoral rod?

Reference Table B.
13 What are the measurements of the pins within the socket?

Reference Table B.

14 What is the amount of pin engagement on the lateral side of the tunnel?

The amount of pin engagement varies depending on the tunnel size and angulation. Reference Table A for some measurements taken when the block is in the -25°, 0° and +20° positions.

15 What happens if you drill a femoral tunnel and it is less than 30 mm?

A 30 mm tunnel depth is recommended for use with the RIGIDFIX CURVE system. Table B shows the distance from the 30 mm position on the femoral rod to the most distal implant for a range of tunnel sizes and block settings. As each patient’s anatomy is different, the surgeon must use discretion with tunnels less than 30 mm to ensure that the implant will not protrude into the joint space or notch. A tunnel depth greater than 30 mm is not an issue for RIGIDFIX CURVE System.

16 What happens if the femoral rod backs out after measuring lateral bone stock with the arc and gauge pin?

a. If the femoral rod is not fully seated in the socket at 30 mm and backs out there are a couple of concerns:

i. You will not have an accurate reading on the amount of available lateral bone stock. The measurement taken with the Arc Attachment and Bone Gauge Pin to determine the amount of lateral bone stock will be false. There’s a tendency for the femoral rod to slightly slip down the socket, so, remember to always check to ensure that the femoral rod/frame assembly is held firmly in place and the rod is fully seated in the socket at 30 mm.

ii. When the cross pins are placed into the tunnel, there’s a potential that the pins will miss the tunnel or potentially enter the joint at the aperture if the rod is not fully seated at 30 mm.

17 Why is the AM portal placement important with this system?

a. It maximizes lateral bone stock for cross pin insertion. Lateral bone stock is the distance between tip of implant when in the final implanted position, and lateral cortex (see question #3).

b. Placement of the AM portal within the prescribed area, approximately 5 mm–10 mm medial to the medial edge of the patellar tendon, distal to the inferior pole of the patella and superior to the medial meniscus, will allow for good access to the ACL femoral footprint and will help to achieve the desired tunnel placement.
18 The surgeon typically makes a far AM portal to target the anatomic ACL footprint and drills a very low, lateral tunnel. Will this tunnel placement work for the RIGIDFIX CURVE System?

No, it will not. We recommend avoiding a far medial portal (one that is further medial from the prescribed portal, and creates a guide pin exit point below the lateral midline). Creating a far medial portal will minimize the amount of lateral bone stock for cross pin insertion. Insufficient bone stock will result in pin protrusion. Far medial portals also increase likelihood of damaging the medial condyle and lead to a shorter (<30 mm) tunnel.

19 Why does the push rod have a laser line instead of a shoulder?

During internal usability studies it was observed that 70% of surgeons tended to overdrive the implants with a push rod which had a hard stop shoulder. Integrating a laser line forces the surgeon to focus on the laser line with increased diligence.

20 What happens if I overdrive the cross-pins?

Depending on available lateral bone stock, overdriving the pins may result in pin protrusion through the lateral cortex. The laser line on the Pin Pusher Rod is designed and calibrated to ensure accurate pin placement within the tunnel. Closely observe the laser line when advancing the pins into the sleeves and be sure to stop when the laser line is flush with the top of the sleeve.

21 Why is it important to have the drill pin exit above the lateral mid-line of the femur?

Targeting above the lateral mid-line ensures a good tunnel trajectory that will maximize lateral bone stock for cross pins and helps to create tunnels that are 30 mm or greater.

22 What is the diameter of the pin tip of the Bone Gauge Pin?

The diameter of the pin tip is 1.5 mm.
23 Do I need to remove the Bone Gauge Pin and Arc Attachment before drilling the Sleeves?

This is surgeon preference. With the Arc attached to the Guide Block the system is naturally balanced in the joint. The Bone Gauge pin helps to stabilize the system to ensure the correct entry point of the sleeves and trocars. However, if the entry point is properly marked, the components may be removed before drilling.

24 What if the laser line on the bone gauge pin is not visible when assessing the amount of lateral bone stock?

If the laser line is not visible on the Bone Gauge Pin, when held firmly against lateral bone, this would indicate that there is not enough lateral bone stock to proceed and pin protrusion will occur. To safely proceed, slightly adjust the Guide Block position and/or rotate the Guide Frame about the tunnel axis. **Ensure the Guide Block maintains a position anterior to the medial epicondyle.** Recheck bone stock with Bone Gauge Pin. The first adjustment should be with the guide block in the proximal direction.

25 What if I think the pins protruded through the lateral cortex?

The surgeon would need to palpate the area to determine risk to lateral structures and take necessary action.

26 Where should I put the Guide Block on the Guide Frame to ensure correct placement of the sleeves?

a. The correct position of the Guide Block is essential to ensuring accurate sleeve placement and ultimately pin placement within the tunnel. To find the target entry point for the sleeves:
1. Locate the medial epicondyle.
2. Go approximately 1” (2.5 cm) anterior to the coronal plane (i.e. perpendicular to the axis of the femur)
3. Go approximately 1” (2.5 cm) proximal, parallel to the femoral shaft.
4. Adjust the Guide Block on the frame to this target zone.
5. Tighten the screw on the block to secure it in this position.

**Note:** The Guide Block position should always be anterior to the medial epicondyle to eliminate the risk of cross pins diverging into the posterior aspect of the knee.
27 What will happen if I don’t tighten the screw on the block into position once I’ve found the target sleeve entry zone?

The sleeves will not rest securely in the guide block and this will increase the chance of missing the femoral tunnel. Also, to further ensure the pins accurately hit the femoral tunnel, do not put undue force or torque on the trocar drill when drilling.

28 What is the position of the pins within the femoral tunnel.

Reference Table C.

29 What is the most important point to know about the RIGIDFIX CURVE system?

Follow the prescribed surgical technique to maximize lateral bone stock which will reduce the risk of pin protrusion through the lateral cortex. Giving close attention to:
1. AM portal placement
2. Guide pin exit point above lateral midline of femur
3. Positioning sleeve in 1” × 1” area with respect to the medial epicondyle
4. Do not overdrive the pins.

References:
2 Reference DePuy Synthes Mitek Sports Medicine internal test data, DHF101870DFTR
CROSS PIN ENGAGEMENT IN BONE (TABLE A)

+20° Guide Block Angle (max proximal adjustment)

<table>
<thead>
<tr>
<th>Tunnel Size (mm)</th>
<th>Proximal Pin</th>
<th>Distal Pin</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Lateral (mm)</td>
<td>Medial (mm)</td>
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<tr>
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<tr>
<td>9</td>
<td>10.1</td>
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<td>22.4</td>
</tr>
<tr>
<td>11</td>
<td>8.9</td>
<td>22.1</td>
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0° Guide Block Angle (TransTibial)

<table>
<thead>
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<th>Tunnel Size (mm)</th>
<th>Proximal &amp; Distal Pin</th>
<th>Distal Pin</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lateral (mm)</td>
<td>Medial (mm)</td>
</tr>
<tr>
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<td>23.7</td>
</tr>
<tr>
<td>11</td>
<td>7.8</td>
<td>23.2</td>
</tr>
</tbody>
</table>

-25° Guide Block Angle (max distal adjustment)

<table>
<thead>
<tr>
<th>Tunnel Size (mm)</th>
<th>Proximal Pin</th>
<th>Distal Pin</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Lateral (mm)</td>
<td>Medial (mm)</td>
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<tr>
<td>7</td>
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<td>11</td>
<td>5.4</td>
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</tr>
</tbody>
</table>

Reference DePuy Synthes Mitek Sports Medicine internal test data, DHF101870DFTR
DISTANCE FROM PINS TO APERTURE, 30 MM MARK (TABLE B)

-25° Minimum Inferior setting

<table>
<thead>
<tr>
<th>Tunnel Diameter</th>
<th>7 mm</th>
<th>8 mm</th>
<th>9 mm</th>
<th>10 mm</th>
<th>11 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.1 mm (0.36&quot;)</td>
<td>8.9 mm (0.35&quot;)</td>
<td>8.6 mm (0.34&quot;)</td>
<td>8.4 mm (0.33&quot;)</td>
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</table>

0° Perpendicular setting

<table>
<thead>
<tr>
<th>Tunnel Diameter</th>
<th>7 mm</th>
<th>8 mm</th>
<th>9 mm</th>
<th>10 mm</th>
<th>11 mm</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>11.2 mm (0.44&quot;)</td>
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+20° Maximum Superior setting

<table>
<thead>
<tr>
<th>Tunnel Diameter</th>
<th>7 mm</th>
<th>8 mm</th>
<th>9 mm</th>
<th>10 mm</th>
<th>11 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.7 mm (0.38&quot;)</td>
<td>9.4 mm (0.37&quot;)</td>
<td>9.4 mm (0.37&quot;)</td>
<td>9.1 mm (0.36&quot;)</td>
<td>8.9 mm (0.35&quot;)</td>
<td></td>
</tr>
</tbody>
</table>

Note: A 30 mm tunnel depth is recommended for use with the RIGIDFIX CURVE system. The charts above show the distance from the 30 mm position on the femoral rod to the most distal implant for a range of tunnel sizes and block settings. As each patient’s anatomy is different, the surgeon must use discretion with tunnels less than 30 mm to ensure that the implant will not protrude into the joint space or notch. A tunnel depth greater than 30 mm is not an issue for RIGIDFIX CURVE.

Reference DePuy Synthes Mitek Sports Medicine internal test data, DHF101870DFTR
# IMPLANT LOCATION ALONG TUNNEL AXIS
## (TABLE C)

### Frame at 0° Perpendicular Setting

<table>
<thead>
<tr>
<th></th>
<th>Y1</th>
<th>Y2</th>
<th>Y3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>8.6 mm</td>
<td>8.1 mm</td>
<td>13.0 mm</td>
</tr>
<tr>
<td></td>
<td>(0.34&quot;)</td>
<td>(0.32&quot;)</td>
<td>(0.51&quot;)</td>
</tr>
</tbody>
</table>

Reference DePuy Synthes Mitek Sports Medicine internal test data, DHF101870DFTR
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