Preparing bone holes for the MULTIFIX S Anchor

Step A
Align the slit of the insertion guide in the direction of the stitch in the tissue. Assess the patient’s bone quality prior to use. If, in the physician’s opinion, the bone is hard, use the Tapered Punch to create a bone hole. A bone hole is also required if the implant is to be placed at an angle other than perpendicular to the bone surface.

Step B
Using the Tapered Punch, advance the instrument to the 25 mm mark on the instrument shaft. Care must be taken to avoid creation of a shallow bone hole.

Step C
Remove the punch from the bone.

Deploying the implant

Step 1
Suture soft tissue utilizing #2 MAGNUMWIRE™ Suture. Load suture legs through the snare loop ensuring about 3 cm of each extends past the snare. The device is intended to be used with 2-4 suture strands or two strands of suture and two strands of ULTRATAPE™ Suture.

Step 2
To snare the sutures through the anchor, pull the suture loader cross bar away from the shaft and toward the handle at 45°. Discard the suture loader after the sutures have been passed through the anchor.

Step 3
Holding the free ends of the sutures, advance the loaded anchor to the surface of the bone. Advance until sutures can be clearly seen between the tissue and the pound-in tip. Confirm that the sutures are not wrapped around the inserter. If wrapped, pull the device out and repeat this step.

Step 4
Place the pound-in tip at the desired location lateral to where the tendon is to be secured. Ensure the eyelet of the pound-in tip orients the sutures toward the tissue. Do not split the sutures with the anchor. Establish axial alignment of the inserter shaft perpendicular to the bone. If a bone hole was created, establish axial alignment of the inserter handle with the bone hole.

Step 5
Remove desired slack in the sutures by pulling on the suture tails.

Step 6
Mallet the proximal end of the inserter handle to drive the pound-in tip into the bone. Advance until the leading thread on the screw is subcortical. CAUTION: If the pound-in tip does not penetrate the bone on the first strike, create a bone hole according to steps B and C. Use a new anchor in the bone hole. NOTE: Properly align the implant and inserter handle with the bone hole during pound-in. Incomplete insertion or poor bone quality may result in the anchor pulling out.

Step 7
Tension will be applied to the tissue during advancement of the pound-in tip. If additional tension is required, individually pull the free suture tails in line with the axis of the inserter, while maintaining downward pressure on the inserter handle. Suture may be placed in the suture cleats for suture management if desired.

Please refer to the Instructions for Use (IFU) packaged with the product for a complete list of Warnings, Precautions and Contraindications.
CAUTION: Individually tensioning the sutures may cause the device to back out of the bone hole. If this occurs, advance the pound-in tip until the laser mark on the leading edge of the screw is subcortical before applying tension to the next suture.
CAUTION: Do not over-tension the sutures as breakage or tissue pull through may occur. In addition, over-tension may result in incomplete insertion or anchor pull out.

Step 8
While maintaining downward pressure on the inserter handle, deploy the screw by turning the deployment knob clockwise until the screw is flush or below the surface of the bone and the deployment knob has come to a hard stop. Disengage the anchored anchor from the inserter handle by turning the end cap counterclockwise a minimum of six turns.
NOTE: If the screw threads do not bite, mallet the threads further into the bone. Then, continue turning the deployment knob until the screw is flush or below the surface of the bone and the deployment knob has come to a hard stop.

Step 9
Disengage sutures from the cleats if needed prior to retracting the inserter handle. Trim remaining loose suture ends at the bone hole.
NOTE: If placing more than one anchor, ensure bone holes are at least 7 mm apart.

Ordering information

<table>
<thead>
<tr>
<th>Reference #</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>OM-2300</td>
<td>MULTIFIX® S 5.5 mm - Anchor</td>
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<tr>
<td>OM-2365</td>
<td>MULTIFIX® S 6.5 mm - Anchor</td>
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<tr>
<td>OM-9220</td>
<td>Tapered Punch</td>
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<tr>
<td>OM-9615</td>
<td>Insertion Guide with Obturator Set</td>
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<tr>
<td>22-4038</td>
<td>FIRSTPASS® ST Suture Passer, self capture</td>
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<tr>
<td>22-4039</td>
<td>FIRSTPASS® ST Suture Passer, Standard</td>
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</tbody>
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