Hybrid fixation with MEGASHIM™
for femoral fixation in ACL reconstruction
Evolution

In recent years, the use of bioresorbable interference screws has become increasingly common in cruciate ligament surgery, primarily as a result of improved biocompatibility and good degradation properties. However, clinical experience shows that problems can arise in case of uncontrolled screw application between the graft and the tunnel (graft lesions, graft twisting, etc.). In revision procedures, the use of screws is problematic if the new femoral tunnel must be placed near the old tunnel. If the screw may slip into the old tunnel, adequate periarticular fixation is often forgone.

Innovative design

The novel MEGASHIM™ design reflects its function. Its oval profile allows the easy, quick, and safe placement of the MEGASHIM™ into a predilated gap between the graft and tunnel wall. The ridges of the MEGASHIM™ prevent backward slippage after application. Like many bioresorbable interference screws from the MEGAFIX® family, the MEGASHIM™ features perforations to promote osseous integration.

The new MEGASHIM™ is the logical advancement and addition to femoral fixation implants in cruciate ligament surgery. Our goal was to eliminate or reduce the limitations of interference screws in cases with minimal graft volumes.
**Optimal bioresorbable material**

The right material is essential to ensure that an implant is actually resorbed. In the past – and unfortunately to this day – implants were often made of “simple” poly-L-lactic acid (PLLA) material. However, numerous studies and extensive clinical experience show that even years later, such implants are almost completely intact and must be removed. This can present a particular problem and obstacle in case of revisions, complications, or repeat cruciate ligament tears.

Like all bioresorbable implants from KARL STORZ, the MEGASHIM™ is made of an amorphous stereocopolymer (poly-L-co-D, L-lactide). Numerous animal experiments and clinical studies have shown that this bioresorbable material (PLDLLA) features the best degradation behavior and complete biocompatibility.

Experimental studies comparing the fixation strengths of MEGASHIM™ and bioresorbable interference screws of the same diameter have shown that a MEGASHIM™ with a 30% smaller cross-sectional area has a fixation strength equal to a screw (Table 1).

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**Comparative study on the fixation strength of various implants**

![Graph showing fixation strength comparison](image)

<table>
<thead>
<tr>
<th>Shim and Screw Size</th>
<th>MEGASHIM™ stand alone</th>
<th>MEGASHIM™ &amp; FLIPPTACK® combined</th>
<th>Interference Screw stand alone</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 mm</td>
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<td></td>
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<tr>
<td>7 mm</td>
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<tr>
<td>9 mm</td>
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</table>

MEGASHIM™ advantages

The MEGASHIM™ optimally combines

- Reduced implant volume
- High implant stability
- High fixation strength
- Complete degradation
- Easy application
- Graft protection during application
- Support of oval femoral graft insertion
- Easy periarticular fixation in revision procedures
MEGASHIM™ instruments

The MEGASHIM™ is placed using special instruments. They include the following components:

1. **Dilator.** The dilator serves to dilate the implant bed – the gap between the graft and the tunnel. Alternatively, the bone-wedge technique can be used. During predilation, the implant size is also verified.
   Dilators are available in 2 sizes. The small dilator (4 mm diameter) is used with the 6 mm and 7 mm MEGASHIM™ (6 x 20 and 7 x 20 mm).
   The large dilator (5 mm diameter) is designed to prepare the implant bed for the 8 mm and 9 mm MEGASHIM™ (8 x 20 and 9 x 20 mm).

2. **Applicator.** The MEGASHIM™ is placed on the applicator’s two “guide pins”.
   The small applicator used to place the 6 mm and 7 mm MEGASHIM™. The larger MEGASHIM™ versions (size 8 mm and 9 mm) require the larger applicator, which is also centrally cannulated.
   This allows insertion of the 8 mm and 9 mm MEGASHIM™ using a nitinol wire.

![MEGASHIM™ instruments](image-url)
3. **Pusher.** If the MEGASHIM™ is not placed deep enough, e.g., in case of adverse viewing conditions, the pusher can be used to later drive it about 2-3 mm below the cortex level.

4. **HALF PIPE®.** The HALF PIPE® is an insertion aid used to facilitate insertion of the applicator plus MEGASHIM™ and prevent “catching” in the anterior knee region (e.g., at the Hoffa fat pad) or at the medial instrument access.
Application – MEGASHIM™

1. Placing the graft and fixing it in place cortically

First pull the ACL graft into the femoral tunnel and fix it cortically using a FLIPPNTACK® (Fig. 1)

2. Dilating and determining the MEGASHIM™ size

Before applying the MEGASHIM™, dilate the gap between the graft and the tunnel wall. Introduce the dilator through the medial instrument access, and flex the knee at the same degree in which the femoral tunnel has been placed. In the medial portal technique for placing a femoral tunnel, the knee is flexed 120° to 125°. This places the dilator parallel to the graft (Fig. 2).

In femoral tunnels that are smaller than 8.5 mm, the small dilator is initially used. At a graft diameter above 9 mm, the larger dilator is recommended. The size of the required MEGASHIM™ is determined together with the dilator size. If the smaller dilator can be easily advanced between the graft and the tunnel wall, a 7 mm MEGASHIM™ is recommended.

Note: If it is difficult to advance or must be driven in using the mallet, a 6 mm MEGASHIM™ is sufficient.

The same applies to the larger dilator. If it is easy to advance, a 9 mm MEGASHIM™ should be considered. If it is difficult to advance, an 8 mm MEGASHIM™ is sufficient.
While the dilator is advanced, the graft must be kept under maximum tension. Otherwise, graft fibers may be pushed into the tunnel.

Advance the dilator between the graft and tunnel wall (Fig. 3); the length markings show the current dilation depth.

**Note:** The gap between the graft and tunnel wall must be dilated to a depth of about 30 mm to allow sufficiently deep insertion of the MEGASHIM™. If necessary, carefully drive the dilator to the desired depth using a mallet.

When reaching 30 mm, retract the dilator.

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**3. Inserting the HALF PIPE®**

To ensure the unimpeded passage of the MEGASHIM™ through the medial instrument access, advance the HALF PIPE® through the medial instrument access after the dilator is removed (Fig. 4).
4. Advancing the applicator plus MEGASHIM™

Insert the MEGASHIM™, attached to the applicator, through the HALF PIPE®, and place it in front of the dilated gap (Fig. 5). Then retract the HALF PIPE®.

Fig. 5

5. Applying the MEGASHIM™

Apply maximum tension to the graft and advance the MEGASHIM™ into the dilated gap between the graft and tunnel wall. Avoid rotation of the applicator plus MEGASHIM™.

**Note:** Apply maximum manual tension to the graft throughout the entire application procedure. Otherwise, graft tissue may be drawn in when advancing or tapping in the MEGASHIM™.

Drive the MEGASHIM™ into the predilated gap using controlled, firm taps with the mallet (Fig. 6).

**Note:** If more than half of the length of the MEGASHIM™ can be inserted into the dilated gap without resistance, it is probably too small. If in doubt, retract it and replace it by a 1 mm larger MEGASHIM™.

Fig. 6
Sink the MEGASHIM™ 2 mm to 3 mm below the cortex. The depth can be read off on the applicator (Fig. 7).

6. Removing the applicator

When the desired depth has been reached, retract the applicator (Fig. 8). Do not “rotate” or “lever” it. To remove the applicator from the implant, carefully tap the mallet onto the strike plate.

**Note:** Check the MEGASHIM™ for a firm fit. If it can be moved, it fits too loosely. In that case, grasp it using the grasping forceps, remove it, and replace it by a 1 mm larger MEGASHIM™.
7. Countersinking the MEGASHIM™

After removing the applicator, check the depth of the MEGASHIM™. If it is insufficient, insert the pusher. It is designed like the applicator, except without guide pins. Apply the pusher to the MEGASHIM™ and sink the latter to the desired depth using the mallet (Fig. 9).

8. Final inspection and palpation

Check the final placement once more (Fig. 10) using the palpation hook. There should no longer be a gap between the graft and the tunnel wall. Also check the stable fit of the MEGASHIM™ by palpation.

The inserted MEGASHIM™ is easier to visualize when the arthroscope and instrument access are switched and the arthroscope is inserted through the medial access. The MEGASHIM™ position can be easily visualized when the knee is flexed to 120°. With greater extension, the ACL graft covers the MEGASHIM™.
Alternative technique: Bone-wedge technique

1. Placing the graft and fixing it in place cortically
   (see Fig. 1 page 8).

2. Preparing the bone wedge
   In 120-125° flexion, use a bone wedge chisel to mobilize a bone wedge about 2 mm to 3 mm proximally to the femoral tunnel to a depth of about 20 mm.

3. Dilating and determining size
   Then proceed as you would for conventional MEGASHIM™ placement (see previous pages). First, prepare the gap using the appropriate dilator (dilation depth 30 mm), and determine the implant size.

4. Applying the MEGASHIM™
   After inserting the HALF PIPE®, advance the applicator plus MEGASHIM™, and drive it in after retracting the HALF PIPE®. After removing the applicator, assess the position of the MEGASHIM™.

5. Countersinking the MEGASHIM™
   If necessary, use the pusher to countersink the MEGASHIM™ 2-3 mm below the cortex (Fig. 11).

It is recommended to check the suitability of the product for the intended procedure prior to use.
Implants and Instrumentation

The sizes of MEGASHIM™ implants are indicated as follows:

<table>
<thead>
<tr>
<th>Product No.</th>
<th>Size (width x length)</th>
<th>Height</th>
<th>Instrumentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>2870620 MSP</td>
<td>6 x 20 mm</td>
<td>4 mm</td>
<td>Dilator 28728 DS</td>
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<td></td>
<td>Applicator 28767 E</td>
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<td>Pusher 28767 C</td>
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<td></td>
<td></td>
<td></td>
<td>HALF PIPE® 28728 SH</td>
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<td>2870720 MSP</td>
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<td>Dilator 28728 DL</td>
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<td>Applicator 28789 E</td>
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<td>HALF PIPE® 28728 SH</td>
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<tr>
<td>2870820 MSP</td>
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<td>Pusher 28789 C</td>
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<td></td>
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<td>HALF PIPE® 28728 SH</td>
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</tbody>
</table>

Implants

2870620 MSP  MEGASHIM™, bioresorbable oval wedge, perforated, 6 x 20 mm, sterile

2870720 MSP  MEGASHIM™, bioresorbable oval wedge, perforated, 7 x 20 mm, sterile

2870820 MSP  MEGASHIM™, bioresorbable oval wedge, perforated, 8 x 20 mm, sterile

2870920 MSP  MEGASHIM™, bioresorbable oval wedge, perforated, 9 x 20 mm, sterile
**Instruments**

28728 DS  **Dilator**, graduated, diameter 4 mm, working length 15 cm, for use with MEGASHIM™ 6 x 20 (2870620 MSP) and MEGASHIM™ 7 x 20 (2870720 MSP)

28728 DL  **Dilator**, graduated, diameter 5 mm, working length 15 cm, for use with MEGASHIM™ 8 x 20 (2870820 MSP) and MEGASHIM™ 9 x 20 (2870920 MSP)

28767 E  **Applicator**, distal marking at 2 and 4 mm, with strike plate, working length 15 cm, for use with MEGASHIM™ 6 x 20 (2870620 MSP) and MEGASHIM™ 7 x 20 (2870720 MSP)

28789 EK  **Applicator**, cannulated, distal marking at 2 and 4 mm, with strike plate, working length 15 cm, for use with MEGASHIM™ 8 x 20 (2870820 MSP) and MEGASHIM™ 9 x 20 (2870920 MSP)

28767 C  **Pusher**, distal marked at 2 and 4 mm, working length 15 cm, for use with MEGASHIM™ 6 x 20 (2870620 MSP) and MEGASHIM™ 7 x 20 (2870720 MSP)

28789 C  **Pusher**, distal marked at 2 and 4 mm, working length 15 cm, for use with MEGASHIM™ 8 x 20 (2870820 MSP) and MEGASHIM™ 9 x 20 (2870920 MSP)

28728 SH  **HALF PIPE®**, without handle, short, working length 85 mm