Mega Fix®

Bioabsorbable and composite interference screws
The MEGA FIX® product family
MEGA FIX® interference screws

MEGA FIX® B and MEGA FIX® P bioabsorbable interference screws

**Fig. 1**

MEGA FIX® B
*The bioabsorbable interference screw (Fig. 1)*

**Fig. 2**

MEGA FIX® P
*The perforated bioabsorbable interference screw (Fig. 2)*

MEGA FIX® C and MEGA FIX® CP composite interference screws

**Fig. 3**

MEGA FIX® C
*The bioabsorbable composite interference screw (Fig. 3)*

MEGA FIX® CP
*The perforated bioabsorbable composite interference screw (Fig. 3)*
MEGA FIX® interference screws

Advantages

- Three-dimensional bone ingrowth in perforated MEGA FIX® screws (MEGA FIX® P)
- Firm connection between the MEGA FIX® screw and screwdriver (CROSSDRIVE®)
- Torsional stability
- Minimized risk of graft damage thanks to screw thread design
- High fixation strength
- Wide range of indications
- Complete absorption
- Osseous replacement following absorption

Wide range of indications

The bioabsorbable MEGA FIX® screws have a vast range of indications in reconstructive ligament surgery:

- Fixation of bone block grafts (patellar tendon, quadriceps tendon) in ACL and/or PCL reconstruction with autologous and/or homologous grafts
- Fixation of soft-tissue grafts (hamstring tendon, patellar tendon, quadriceps tendon) in ACL and/or PCL reconstruction with autologous and/or homologous grafts
- Patellofemoral reconstruction (MPFL replacement) with semitendinosus and/or gracilis tendon using autologous and/or homologous grafts
- Lateral and/or posterolateral ligament reconstruction with autologous or homologous (allograft) soft tissue and/or bone block grafts
- Medial and/or dorsolateral ligament reconstruction with autologous or homologous (allograft) soft tissue and/or bone block grafts
- Extra-articular lateral stabilization procedures (such as Lemaire anterolateral reconstruction)
- Hybrid fixation: additional periarticular graft fixation of soft tissue and/or bone block grafts (hamstring tendons, patellar tendon, quadriceps tendon) in ACL and/or PCL reconstruction using autologous and/or homologous grafts
Bioabsorbable base material and mechanical properties
MEGA FIX® B and MEGA FIX® P

All interference screws of the MEGA FIX® B and P product families consist of the amorphous stereocopolymer Poly(L-lactide-co-D, L-lactide), abbreviated as PLDLLA. Numerous studies have shown that the bioabsorbable material of the MEGA FIX® B and P screws features good degradation and absorption behavior as well as good biocompatibility (Figs. 4, 5).

Fig. 4
Animal study on the MEGA FIX® screw in the proximal tibia (sheep). The very thin implant-tissue interface proves the excellent tissue compatibility of the bioabsorbable base material Poly(L-lactide-co-D, L-lactide).

Fig. 5
Special screw design and appropriate drive

CROSSDRIVE® drive

Unlike other bioabsorbable screws, MEGA FIX® screws feature a special, patented thread configuration with a combination of sharp threads at the screw tip and blunt threads at the screw body (Fig. 6).

![Fig. 6](image)

The special screw design allows secure starting of the screw and simultaneously protects the graft during screw insertion.

Advantages

- **Sharp threads** at the screw tip for starting the MEGA FIX® screw easily and safely
- **Rounded threads** at the screw body for controlled insertion while protecting the graft

All screws of the MEGA FIX® family are inserted using the special, highly torsion-resistant CROSSDRIVE® drive (Fig. 7). This ensures high drive torque for every screw size and type, as confirmed by experiments on torsional strength (Fig. 8).

![Fig. 7](image)

With its special, cross-shaped drive, the CROSSDRIVE® ensures high force transmission between the screwdriver and the screw.

Advantages

- **High torsional stability**
- **Precise control of the screw’s insertion depth** through length marks on the screwdriver
MEGA FIX® P

The perforated bioabsorbable screw

In “normal” bioabsorbable screws, bony ingrowth in the screw body is only possible through the central cannula or drive. The MEGA FIX® P (Fig. 8) exhibits numerous perforations across the entire body of the screw (quantity depends on screw size).

Advantages

- Three-dimensional bone ingrowth in the screw body (Figs. 9, 10) (Achtnich et al. 2014)
- Reduced implant volume
- Enlarged bone-implant interface
- Complete degradation of the MEGA FIX® P screw in human bone (Fig. 11)

Fig. 8


Fig. 9


Fig. 10

In the non-perforated screw, in contrast, the center of the screw only exhibits soft, non-structured connective tissue (from Strobel, Zantop [2010] Vorderes Kreuzband, Anatomie, Diagnostik und Operationstechnik. Endo-Press, Tuttlingen).

Fig. 11

8 months after ACL reconstruction. Transplant ruptured during sports. After removing the screw component, columnar osseous formations (arrows) are found next to the thread impressions; they result from bone ingrowth through the screw perforations (from Strobel, Zantop [2014] Arthroskopische Chirurgie, Part 1, Volume 3. Springer Verlag Berlin Heidelberg).
Bioabsorbable composite base material and mechanical properties

MEGA FIX® C and MEGA FIX® CP

For composite screws, the ceramic base material β-tricalcium phosphate (β-TCP) is an appropriate option.

Advantages of β-tricalcium phosphate (β-TCP):
- Very similar to the mineral component of bone
- Active promotion of bone metabolism
- Osseous remodeling

The β-tricalcium phosphate (β-TCP) is a suitable ceramic base component for producing composite screws.
The mixing ratio of base material Poly(L-lactide-co-D, L-lactide) (PLDLLA) to ceramic material (β-TCP) is 80:20.

Rate of absorption
- 14-18 months for MEGA FIX® composite screws (Fig. 12)
- Elimination of excessively rapid absorption (3-4 months)
- Enlarged bone-implant interface (MEGA FIX® CP)

Fig. 12
MEGA Fix® composite interference screw in the femoral bone of sheep. Again, only a thin layer of tissue is found between the bone and the implant as a sign of good tissue compatibility.
Special screw design and appropriate drive
MEGA FIX® C and MEGA FIX® CP

Like all screws of the MEGA FIX® family, the composite screws (Fig. 13) feature a special screw design and the CROSSDRIVE® drive (see p. 5).

**Fig. 13**
Composite screw (MEGA FIX® C)

**MEGA FIX® CP**

The perforated composite screw

Bony ingrowth in “normal” composite screws is only possible through the central cannula or through the drive. Considering the essential advantages of bioabsorbable screws, it made sense to develop a composite screw with perforations (Fig. 14).

**Advantages**
- Perforations in the body of the screw
- Reduced implant volume
- Enlarged bone-implant interface
- Three-dimensional bone ingrowth in the screw body
- Improved osteoconductivity with high mechanical stability

**Fig. 14**
Perforated composite screw
(MEGA FIX® CP)
References


MEGA FIX® interference screws

MEGA FIX® B – The bioabsorbable interference screw

Material: Amorphous stereocopolymer Poly(L-lactide-co-D,L-lactide (PLDLLA))

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Note: The last 4 digits indicate the screw size. The letter B denotes the bioabsorbable screws (not perforated).

MEGA FIX® P – The perforated bioabsorbable interference screw

Material: Amorphous stereocopolymer Poly(L-lactide-co-D,L-lactide (PLDLLA))

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Note: The last 4 digits indicate the screw size. The letter P denotes the perforated bioabsorbable screws.
MEGA FIX® interference screws

MEGA FIX® C – The bioabsorbable composite interference screw

Material: Composite from an amorphous stereocopolymer Poly(L-lactide-co-D,L-lactide (PLDLLA) and the ceramic material β-tricalcium phosphate (80:20)

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Note: The last 4 digits indicate the screw size. The letter C denotes the composite screws (not perforated).

MEGA FIX® CP – The perforated bioabsorbable interference screw

Material: Composite from an amorphous stereocopolymer Poly(L-lactide-co-D,L-lactide (PLDLLA) and the ceramic material β-tricalcium phosphate (80:20)

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Note: The last 4 digits indicate the screw size. The letters CP denote the perforated composite screws.
# MEGA FIX® interference screws

## Available sizes and combination possibilities

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</table>
For tightening MEGA FIX® screws

28789SK CROSSDRIVE® Screwdriver, cannulated, sizes 8-11, color code: blue

28770SK CROSSDRIVE® Screwdriver, cannulated size 7, color code: red

28760SK CROSSDRIVE® Screwdriver, cannulated, size 6, color code: green

28789GW-6 Nitinol Guide Wire, diameter 1.1 mm, length 38.5 cm

28789KW-6 Nitinol Guide Wire, short, diameter 1.1 mm, length 25.5 cm

Notching the bone makes it easier to start MEGA FIX® screws

28729N Notcher, working length 15 cm

28729NN Bone Wedge Chisel, for creating a bone wedge in cruciate ligament surgery, with wide handle, working length 13 cm
Dilator with fin predefines direction of insertion
Prevents screw slippage during insertion

28729DFM  Dilator with Fin, for dilating the femoral drill channel to diameter 4 mm and simultaneous placement of a notch 17 mm in length

28729DFO  Dilator with Fin, cannulated, for dilating the femoral drill channel to diameter 6 mm and simultaneous placement of a notch 25 mm in length

28729DFP  Same, for dilating the femoral drill channel to diameter 6.5 mm

28729DFQ  Same, for dilating the femoral drill channel to diameter 7 mm

28729DFR  Same, for dilating the femoral drill channel to diameter 7.5 mm

28729DFS  Same, for dilating the femoral drill channel to diameter 8 mm

28729DFT  Same, for dilating the femoral drill channel to diameter 8.5 mm

28729DFU  Same, for dilating the femoral drill channel to diameter 9 mm
Notes

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

Please note that the described products in this medium may not be available yet in all countries due to different regulatory requirements.
More than 75 Years

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