

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



MEGA FIX® B

The bioabsorbable interference screw (Fig. 1)

Fig. 1



MEGA FIX® P

*The **perforated** bioabsorbable interference screw (Fig. 2)*

Fig. 2

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



MEGA FIX® C

The bioabsorbable composite interference screw (Fig. 3)

MEGA FIX® CP

The perforated bioabsorbable composite interference screw (Fig. 3)

Fig. 3

MEGA FIX® interference screws

Advantages

- Three-dimensional bone ingrowth in perforated MEGA FIX® screws (MEGA FIX® P)
- Optimal connection between the MEGA FIX® screw and screwdriver (CROSSDRIVE®)
- Torsional stability
- Minimized risk of graft damage thanks to optimal 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 optimal degradation and absorption behavior as well as good biocompatibility (Figs. 4, 5).

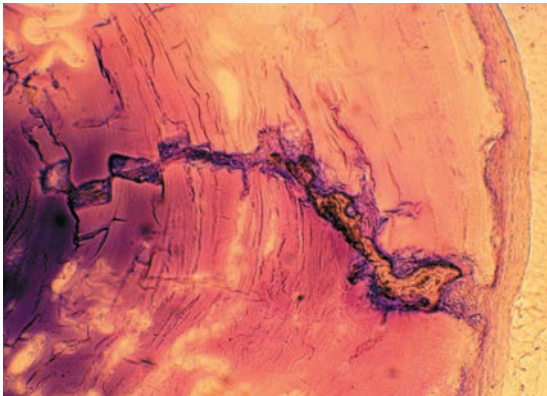


Fig. 4

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).

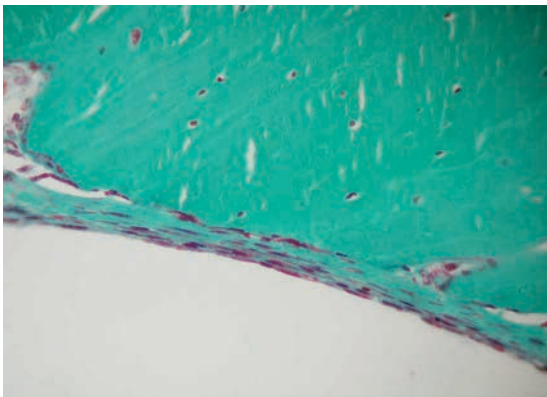


Fig. 5

Poly(L-lactide-co-D, L-lactide) implant 15 months after implantation in the animal model. The implant fragments and simultaneously exhibits ingrowth of trabecular bone. (Courtesy of Saunders WB (2000) Arthroscopy 16:305.321).

Optimal screw design and optimal 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).



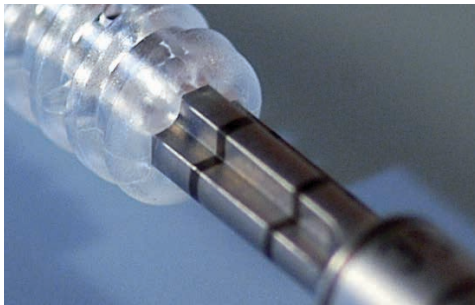
Advantages

- **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

Fig. 6

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

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



Advantages

- Uniform distribution of driving forces across the entire screw body
- Higher torsional stability
- Avoidance of local stress peaks at specific areas of the screw
- Precise control of the screw's insertion depth through length marks at the screwdriver

Fig. 7

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

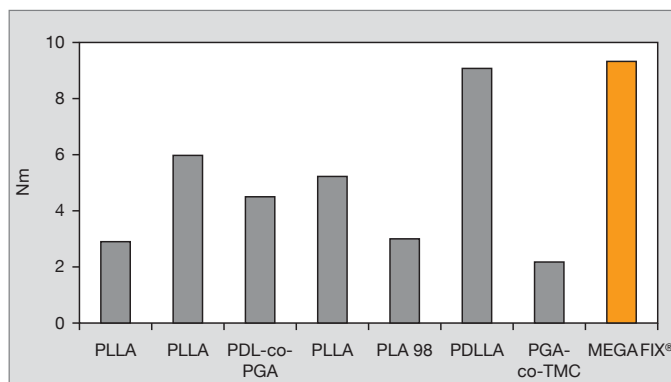


Fig. 8

Comparative study on the torsional stability (Nm) of different bioabsorbable screws. The CROSSDRIVE® drive of the MEGA FIX® screw exhibits the highest torsional stability.

MEGA FIX® P

The first and only perforated bioabsorbable screw

In “normal” bioabsorbable screws, bony ingrowth in the screw body is only possible through the central cannula or drive. As the first and only bioabsorbable screw, MEGA FIX® P (Fig. 9) exhibits numerous perforations across the entire body of the screw (quantity depends on screw size).



Fig. 9

Advantages

- Three-dimensional bone ingrowth in the screw body (Figs. 10, 11) (Achtnich et al. 2014)
- Reduced implant volume
- Enlarged bone-implant interface
- Complete degradation of the MEGA FIX® P screw in human bone (Fig. 12)

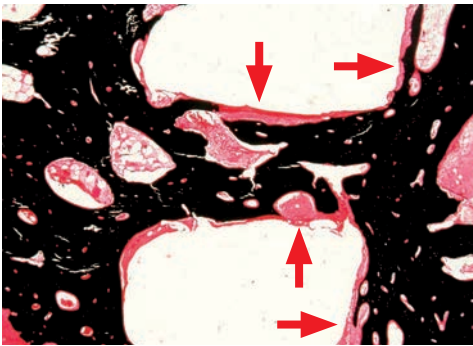


Fig. 10

Complete bone ingrowth in the area of the perforations and in the center of the screw (from Strobel, Zantop [2010] Vorderes Kreuzband, Anatomie, Diagnostik und Operationstechnik. Endo-Press, Tuttlingen).

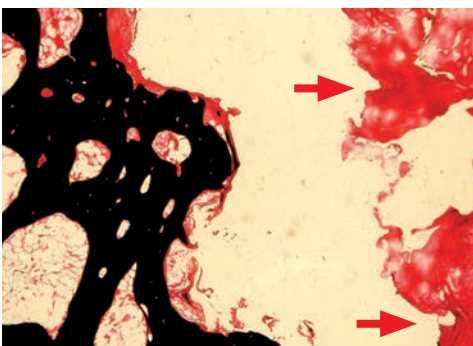


Fig. 11

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).

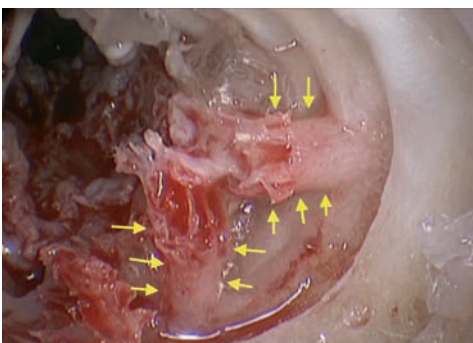


Fig. 12

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

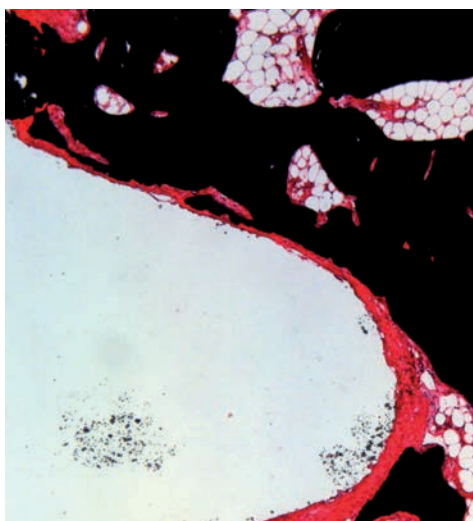
For composite screws, the ceramic base material β -tricalcium phosphate (β -TCP) is an excellent option.

Advantages of β -tricalcium phosphate (β -TCP):

- Very similar to the mineral component of bone
- Active promotion of bone metabolism
- Osseous remodeling

This makes β -tricalcium phosphate (β -TCP) the perfect 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. This ensures an optimal balance between the buffering/neutralization of acidic substances and the preservation of ideal mechanical properties.



Rate of absorption

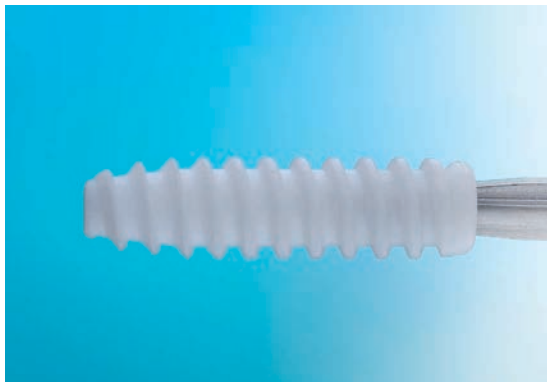
- 14-18 months for MEGA FIX® composite screws (Fig. 13)
- Elimination of excessively rapid absorption (3-4 months)
- Enlarged bone-implant interface (MEGA FIX® CP)
- Reduced risk of foreign-body reactions and cyst formation in the implant bed

Fig. 13

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.

Optimal screw design and optimal drive

MEGA FIX® C and MEGA FIX® CP



Like all screws of the MEGA FIX® family, the composite screws (Fig. 14) feature a special screw design and the CROSSDRIVE® drive (see p. 5).

Fig. 14
Composite screw (MEGA FIX® C)

MEGA FIX® CP

The first and only 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. 15).



Fig. 15
Perforated composite screw
(MEGA FIX® CP)

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

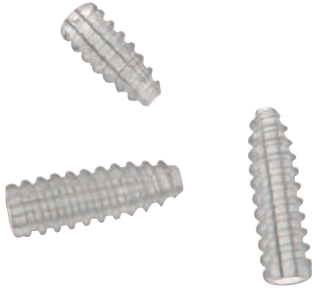
References

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MEGA FIX® interference screws

MEGA FIX® B – The bioresorbable interference screw

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



Diameter	Length	Order No.
6 mm	19 mm	2870619 B
	23 mm	2870623 B
7 mm	19 mm	2870719 B
	23 mm	2870723 B
	28 mm	2870728 B
8 mm	19 mm	2870819 B
	23 mm	2870823 B
	28 mm	2870828 B
9 mm	23 mm	2870923 B
	28 mm	2870928 B

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

MEGA FIX® P – The perforated bioresorbable interference screw

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



Diameter	Length	Order No.
8 mm	23 mm	2870823 P
	28 mm	2870828 P
9 mm	23 mm	2870923 P
	28 mm	2870928 P
	35 mm	2870935 P
10 mm	28 mm	2871028 P
	35 mm	2871035 P
11 mm	35 mm	2871135 P

Note: The last 4 digits indicate the screw size.
The letter P denotes the perforated bioresorbable screws.

MEGA FIX® interference screws

MEGA FIX® C – The bioresorbable 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)

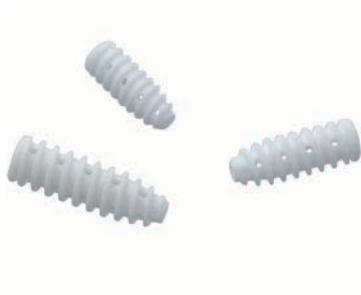


Diameter	Length	Order No.
6 mm	19 mm 23 mm	2870619 C 2870623 C
7 mm	19 mm 23 mm 28 mm	2870719 C 2870723 C 2870728 C
8 mm	19 mm 23 mm 28 mm	2870819 C 2870823 C 2870828 C
9 mm	23 mm 28 mm	2870923 C 2870928 C

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

MEGA FIX® CP – The perforated bioresorbable 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)



Diameter	Length	Order No.
8 mm	23 mm 28 mm	2870823 CP 2870828 CP
9 mm	23 mm 28 mm 35 mm	2870923 CP 2870928 CP 2870935 CP
10 mm	28 mm 35 mm	2871028 CP 2871035 CP
11 mm	35 mm	2871135 CP

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

Diameter	Length				Suitable screwdriver (cannulated)
	19 mm	23 mm	28 mm	35 mm	
6 mm	MEGA FIX® B MEGA FIX® C	MEGA FIX® B MEGA FIX® C			CROSSDRIVE® (size 6) color code: green
7 mm	MEGA FIX® B MEGA FIX® C	MEGA FIX® B MEGA FIX® C	MEGA FIX® B MEGA FIX® C		CROSSDRIVE® (size 7) color code: red
8 mm	MEGA FIX® B MEGA FIX® C	MEGA FIX® B MEGA FIX® P MEGA FIX® C MEGA FIX® CP	MEGA FIX® B MEGA FIX® P MEGA FIX® C MEGA FIX® CP		CROSSDRIVE® (size 8-11) color code: blue
9 mm		MEGA FIX® B MEGA FIX® P MEGA FIX® C MEGA FIX® CP	MEGA FIX® B MEGA FIX® P MEGA FIX® C MEGA FIX® CP	MEGA FIX® P MEGA FIX® CP	
10 mm			MEGA FIX® P MEGA FIX® CP	MEGA FIX® P MEGA FIX® CP	
11 mm				MEGA FIX® P MEGA FIX® CP	

For tightening MEGA FIX® screws



- 28789 SK **CROSSDRIVE® Screwdriver**, cannulated, sizes 8-11, color code: blue
- 28770 SK **CROSSDRIVE® Screwdriver**, cannulated size 7, color code: red
- 28760 SK **CROSSDRIVE® Screwdriver**, cannulated, size 6, color code: green
- 28789 GW **Nitinol Guide Wire**, diameter 1.1 mm, length 38.5 cm
- 28789 KW **Nitinol Guide Wire**, short, diameter 1.1 mm, length 25.5 cm

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



- 28729 N **Notcher**, working length 15 cm



- 28729 NN **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



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

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

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

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

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

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

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

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

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