Bioresorbable bone pin from polylactide.

PolyPIN®

IMPLANT. Metal implants are normally removed in a second operation, once the bone has healed. This not only means additional expense, but is also stressful for the patient. What is more, a second stay in hospital is necessary to remove the metal, involving absence from work and increased risk of complications. The ideal osteosynthesis implant should, therefore, simply dissolve after it has fulfilled its stabilising or fixing task, without subjecting the body to an additional burden in doing so. The PolyPIN is such an implant. It is a pin made of a polylactide copolymer Poly(L-lactide-co-D, L-lactide) 70/30. Thanks to the material it is made of and the way it is designed, it offers significant advantages.

MATERIAL. The PolyPIN is made of polylactide, a bioresorbable biomaterial which has proved its worth as a material for biological implants, as shown by extensive in vitro and in vivo testing and in clinical use over several years. The special copolymer Poly(L-lactide-co-D,L-lactide) 70/30 has good absorption properties: its flexural strength remains constant for 24 weeks, which is a sufficient time for the fracture to heal, and then drops at a constant rate.

DEGRADATION. Biological degradation takes place mainly due to hydrolysis, into lactic acid, which is a natural product of metabolism, and is subsequently metabolised into CO_2 and H_2O. Within 15 months the PolyPIN is completely degraded from a mechanical point of view, although it can still be detected in the form of a cylindrical fragment of the original pin. After 18 to 21 month only fibrous cords are recognisable and after another three months the place of implant is filled with bony substance. Studies have shown that the same results are achieved both by the PolyPIN and a metal implant, but in the case of the PolyPIN no implantdependent complications arise.

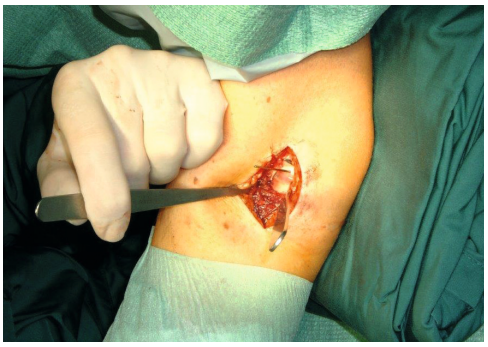
DESIGN

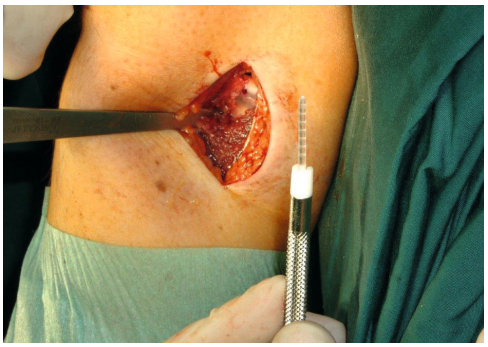
The PolyPIN special design is its distinguishing feature and improves its performance:

- The head exerts a slight compression on the facture fragments.
- The circular ribs prevent the PolyPIN from slipping.

The PolyPIN is available in three different diameters:

- PolyPIN 1.5, length: 8 - 25 mm
- PolyPIN 2.0, length: 10 - 35 mm
- PolyPIN 2.7, length: 12 - 60 mm





INDICATIONS

Fractures subject to low load stresses:

PolyPIN 1.5

- Bone or osteochondral fragment fixation
- Arthrodeses of fingers and toes
- Stabilisation of certain finger fractures
- Osteochondral fractures or dissecans

PolyPIN 2.0

- Apical fragements
- Osteochondral fractures or dissecans
- Spongiosa or lightly load-bearing fragments

PolyPIN 2.7

- Large osteochondral fragments

APPLICATION

Drilling

After reducing the fragments, drill a hole of the same diameter as the PolyPIN

- diameter 1,5 mm for the PolyPIN 1.5
- diameter 2,0 mm for the PolyPIN 2.0
- diameter 2,7 mm for the PolyPIN 2.7

perpendicular to the surface of the fracture. If more than one PolyPIN is used, the drilled holes should not run parallel, but converge, to ensure secure fixation of the fragment.

Length measurement

After loosening the locking screw, insert the measuring tip of the appropriate depth gauge as far as possible to the end of the drilled hole. The depth of the drilled channel can then be determined. Tighten the locking screw. In this way, the measured length is transferred directly to the cutting guide secured at the rear. The PolyPIN is then sheared to about 1 mm less than the measured drilling depth.

Shortening the PolyPIN

Push the PolyPIN head first as far as the stopper in the mounting at the rear end of the measuring device. Secure by means of the locking screw. Position the shearing head so that the arrow marked on it is visible.

Turn the shearing head in the direction of the arrow to shear the PolyPIN to the requiered length.

WARNING: Do not turn the shearing head in the opposite direction to the arrow. This could press the PolyPIN against the locking screw and cause deformations.

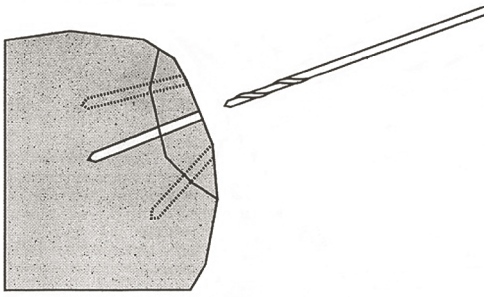


Figure 1: Drilling

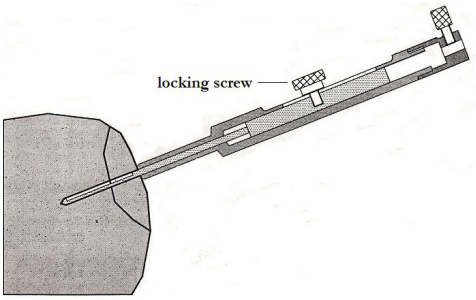


Figure 2: Length measurement

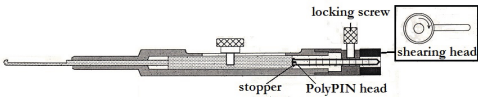


Figure 3: Shortening

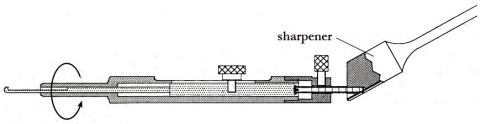


Figure 4: Adjusting the tip

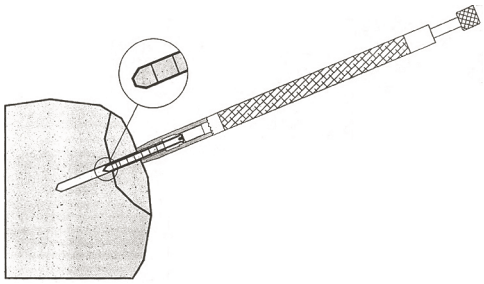
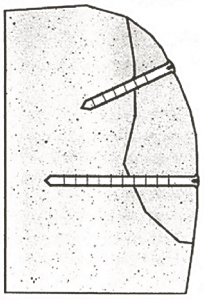


Figure 5: Impacting



Adjusting the tip of the PolyPIN

Adjust the pin using the sharpener to simplify insertion. Once the cut – off part has been removed, withdraw the pin sligthly from the depth gauge and then secure again by means of the locking screw. Then adjust sligthly using the sharpener as you would use a pencil sharpener.

Impacting the PolyPIN

The respective special impacting device and a hammer must be used to insert the PolyPIN. Remove the pin from the impactor and insert the PolyPIN tip first into the casing from the rear. Insert the pin again and push it forwards slowly until the tip of the PolyPIN into the drilled hole and place the impacting device over the hole, perpendicular to the fragment surface. Make sure that the PolyPIN does not become jammed while it is being hammered in. Then carefully hammer the PolyPIN into the drilled channel until the head is below the level of the surface of the fragment.

WARNING: Oblique positioning may cause the impacting device to slip resulting in the PolyPIN being broken and the white cap for the impacting device damaged.

Information for ordering:

PolyPIN	1.5	Resorbable Pin	PL 02.04308.015
PolyPIN	2.0	Resorbable Pin	PL 02.04311.020
PolyPIN	2.7	Resorbable Pin	PL 02.04318.027
PolyPIN		Impactor	I 10
PolyPIN	1.5	Cap for Impactor	I 10A
PolyPIN	2.0	Cap for Impactor	I 10B
PolyPIN	2.7	Cap for Impactor	I 10C
PolyPIN		Depth Gauge incl. Cutting Head	I 11
PolyPIN		Sharpener	I 12
PolyPIN		Tray	I 17

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BIOVISION specialises in the development and manufacturing of biomaterials. In particular in the processing of resorbable polymer products by means of injection moulding and the production of resorbable ceramic products. These technologies are used inter alia in our products for dental surgery/implantology and for orthopedics. The following products are also included in our portfolio:

Orthopedics:

BetaBASE bioresorbable bone replacement

BioBASE bioresorbable bone replacement

PolyPIN bioresorbable bone pin

Wound Care:

EpiGARD synthetic skin replacement

Dental Surgery:

BetaBASE MP bioresorbable bone replacement

BioBASE AP bioresorbable bone replacement

LeadFIX bioresorbable membrane pin

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