

sysorb[®]

Bioresorbable
Interference Screw

Technique Guide



sysorb[®]



swiss made

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Note

Before using an implant distributed by Degradable Solutions AG, it is important to familiarise yourself with the correct usage of the instruments, the product-specific surgical technique, as well as the warnings, safety notes and recommendations provided in the information leaflet. Please utilise the user training courses offered by Degradable Solutions AG and apply the recommended surgical technique.

1. Introduction



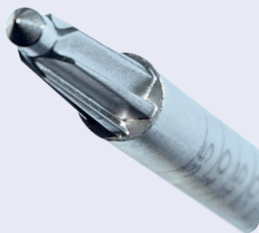
The sysorb bioresorbable interference screw is suitable for juxtaarticular femoral and tibial graft fixation in cruciate ligament surgery. The special shape of the bioresorbable screw makes it possible to securely anchor either pure soft-tissue transplants (semitendinosus/gracilis multiple bundles or proximal end of the quadriceps tendon) or bone plugs (bone-patellar tendon-bone) in the bone.

The sysorb screw has been successfully tried and tested in cruciate ligament surgery since 1995. The rate of graft-related complications is less than 0.03 %. The purpose of this brochure is to provide the surgeon with a few useful suggestions.

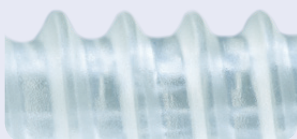
**Easy to screw in,
bioresorbable and
very well tolerated**



**Turbine-like drive,
minimized risk
of screw breakage**



**No injury to tendon
graft thanks to blunt,
atraumatic thread**



Product characteristics

- Turbine-like screw drive (high torque, ideal force transmission)
- Material-adapted design prevents screw breakage
- Anchoring strength equivalent to metal screws
- No injury to tendon graft thanks to blunt, atraumatic thread
- Excellent tissue compatibility of the amorphous polymer poly (D,L-) lactide
- Complete degradation within about 1.5 years
- No artefacts in MRI or CT
- Excellent clinical documentation (see bibliographical references)

Surgical technique

With the present surgical technique, the sysorb bioresorbable interference screws are used to fixate hamstring tendons directly to the original insertion points of the anterior cruciate ligament (ACL). This surgical technique accelerates the engraftment process and results in an insertion of the tendon that corresponds histologically to the normal ACL.

The surgical technique described below is limited to the fixation of the graft with the sysorb bioresorbable interference screw and provides important advice to achieve secure placement. General aspects such as patient positioning, surgical approaches and graft harvesting are not covered.

2. Indication/Contraindications

Indication

This product is used as an interference screw for the tibial and femoral fixation (primary anchorage) of autologous tendon grafts (or allograft) as used in the reconstruction of the cruciate ligaments of the human knee.

Contraindications

- Missing bone substance or poor bone quality, which make stable anchoring of the interference screw in the bone impossible
- Poor blood supply
- Previous infection or risk of infection
- Patients who have not reached skeletal maturity
- Severe muscular, neurological or vascular deficiencies affecting the extremity concerned

3. Surgical technique

Preparation for secure fixation

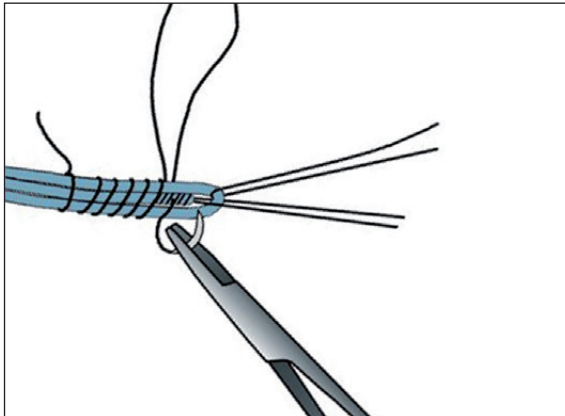


Fig. 1 Suturing of the graft

The soft-tissue graft should be tightly sutured with absorbable suture and baseball stitching along the entire length of its future contact with the sysorb interference screw in the bone tunnel (Fig. 1).

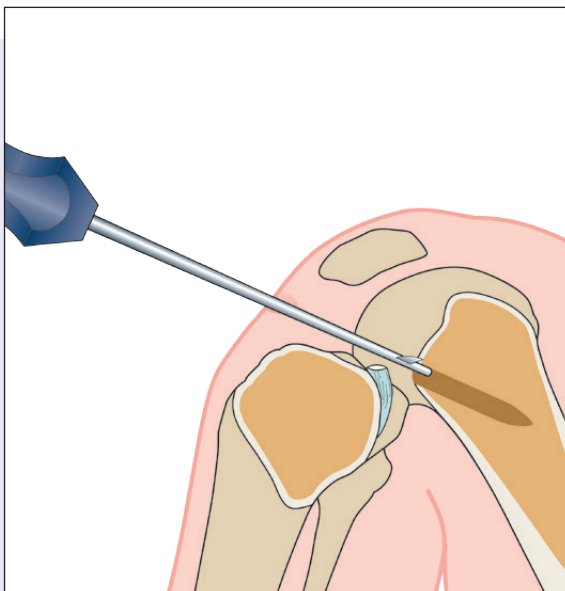


Fig. 2 Notch placement

Additionally, a notch should be placed at the tunnel entrance where the femoral sysorb interference screw is to be inserted. For this purpose, it is recommended to use a special instrument, the “notcher” (Fig. 2).

3. Surgical technique

Fixation of the graft in the femoral semi-tunnel

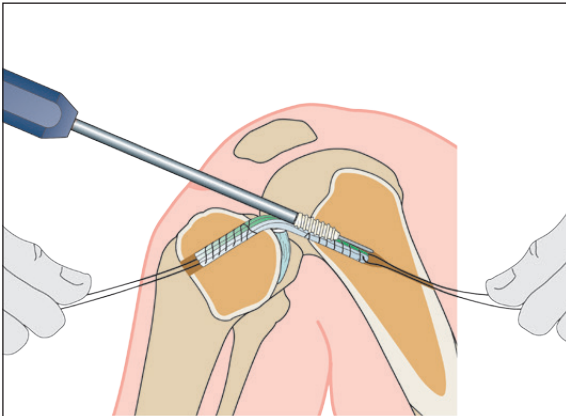


Fig. 3 Insertion of the sysorb bioresorbable interference screw into the femoral tunnel

Before the sysorb screw is inserted, it is recommended to use a 4 mm diameter dilatator to widen the space into which the screw will be inserted. Insertion is accomplished through the anteromedial arthroscopic access to the femoral tunnel at the position of the notch (see Fig. 2).

To insert the femoral sysorb interference screw, the knee joint is fully flexed and the graft is held at both ends with the holding threads.

It is recommended to first tap in the sysorb bioresorbable interference screw by a few millimetres with soft hammer strokes. The sysorb screw is then rotated counter-clockwise by one full turn while it is pushed into the femoral tunnel. This procedure enables the sysorb screw to engage between the graft and the bone. Next, the sysorb screw is turned in clockwise while making sure that it is firmly seated on the screwdriver. The sysorb screw is turned in until it is just below the articular surface (Fig. 3).

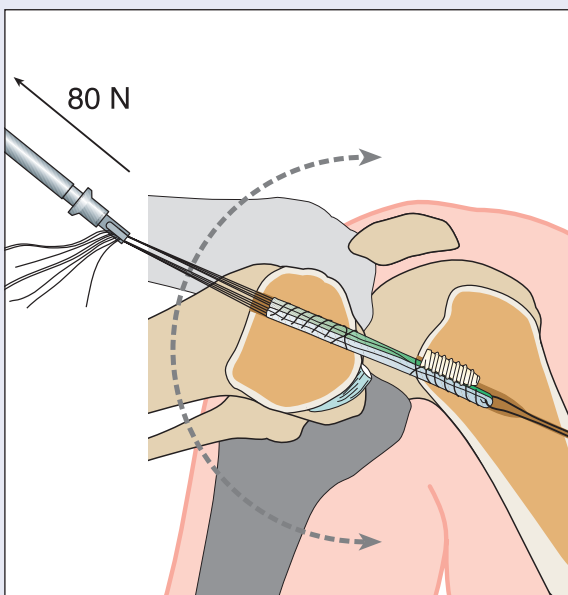


Fig. 4 Pretensioning of the graft

The tensiometer is attached to the tibial holding threads of the graft, and the graft is pretensioned with 80–90 N. Under this pretension, the knee joint is cyclically moved several times through its full range of motion (Fig. 4).

3. Surgical technique

Fixation of the graft in the tibial tunnel

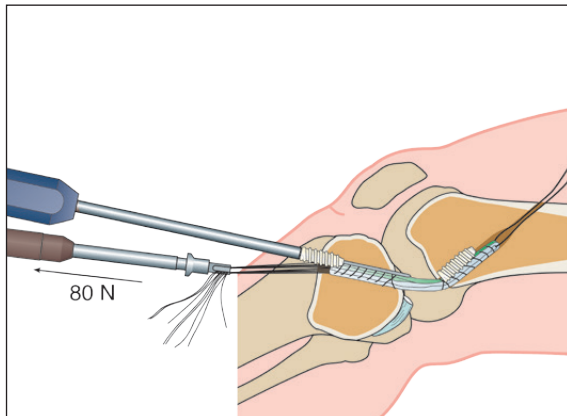


Fig. 5 Insertion of the sysorb bioresorbable interference screw into the tibial tunnel (keeping graft under constant tension)

The knee joint is extended to approx. 20°. A guide wire can now be inserted through the tibial tunnel into the knee joint. By adjusting the position of the guide wire under arthroscopic control, it is possible to correct the graft position in case the placement in the tunnel is not optimal (the position of the screw relative to the graft in the tunnel can be freely chosen). The tension of 80–90 N is maintained and the sysorb bioresorbable interference screw is turned in with the screwdriver parallel to the graft until its tip almost appears in the joint space (Fig. 5).

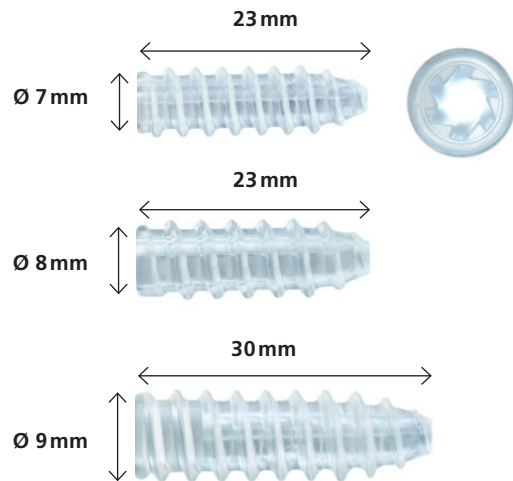
3. Surgical technique

Summary

The following precautions minimise the risk for the sysorb screw to turn around the graft during insertion or to damage the graft:

- Suture the soft-tissue graft with baseball stitches
- Use notcher to make a notch at the femoral tunnel entrance
- Use blunt dilatator (4 mm) to widen the screw hole
- Remove guide wire before turning in the screw (prevents kinking, jamming or breakage of the screwdriver tip)
- sysorb screw must seat firmly on the screwdriver
- Start: Tap in the screw with soft hammer strokes
- Rotate sysorb screw under axial pressure by one full counter-clockwise turn, then screw in clockwise
- Fully flex the knee joint during femoral screw insertion (especially in case of left knee)
- Always keep graft under tension while turning in the screw

4. Grafts and instruments



sysorb Bioresorbable Interference Screw

Item no.	Description/Size
B16-401	Ø 7 mm, Length 23 mm
B16-402	Ø 8 mm, Length 23 mm
B16-403	Ø 9 mm, Length 30 mm

Material: Amorphous polymer poly (D, L) Lactid



sysorb Screwdriver | Dilatator

Item no.	Description
81.34.0037	7 mm
81.34.0038	8/9 mm
81.34.0036	8/9 mm cannulated
81.34.0040	Dilatator 4 mm

Additional instruments used with the surgical technique described above:

- Notcher
- Tensiometer
- Nitinol Guide Wire

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