



Product Information

Shark Screw[®] Allograft

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surge**bright** GmbH - Tissue Bank



Shark Screw®

Screw features & Biomechanics

Shark Screws® are screws made from allogeneic bone that are widely used in orthopedics and trauma surgery.

The gentle manufacturing process ensures that the natural bone structures are preserved, which in turn form the basis for a natural bone remodeling process. After being inserted into the bone, the Shark Screw® graft screws are colonized by the body's own cells, grown over and gradually converted into the body's own bone in the course of the bone remodeling process.

This intelligent biological process creates bone structures that are able to constantly adapt to mechanical requirements.

That means that patients do not have to have a second operation to remove metal and do not have the associated risks.

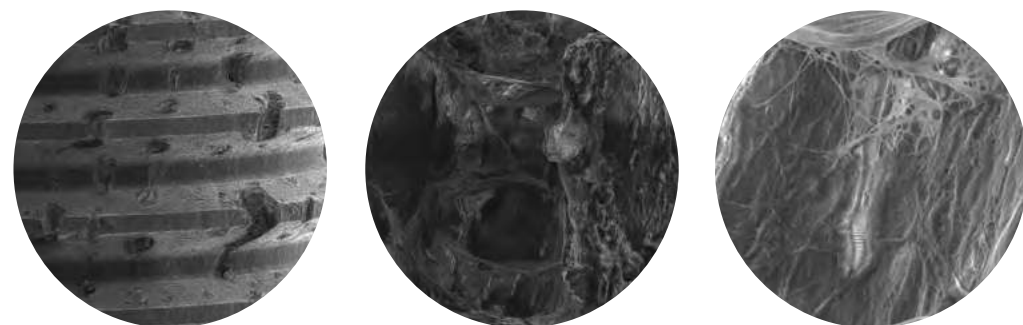
The Shark Screw® gives you, the surgeon, the opportunity to provide your patients with the best possible and natural care. Details on the respective areas of application and indications can be found beginning on page 10.

When developing the innovative Shark Screw®, surgebright worked together with the Institute for Biomechanics and the Institute for Electron Microscopy and Fine Structure Research at the Graz University of Technology. An important goal there was the development of a unique design to achieve maximum resilience and the highest level of patient safety.

Greater strength due to swelling in the recipient bone

After being inserted into the recipient bone, Shark Screws® swell by an average of 2% and thus ensure an even more rotationally stable bony connection.¹

¹ Holzapfel G. & Sommer G.: „Einfluss des Gewindedetailradius auf die biomechanischen Eigenschaften von Osteosyntheseschrauben aus humaner Corticalis“ – Experimental- und FEM-Studie, 2012, Technische Universität Graz



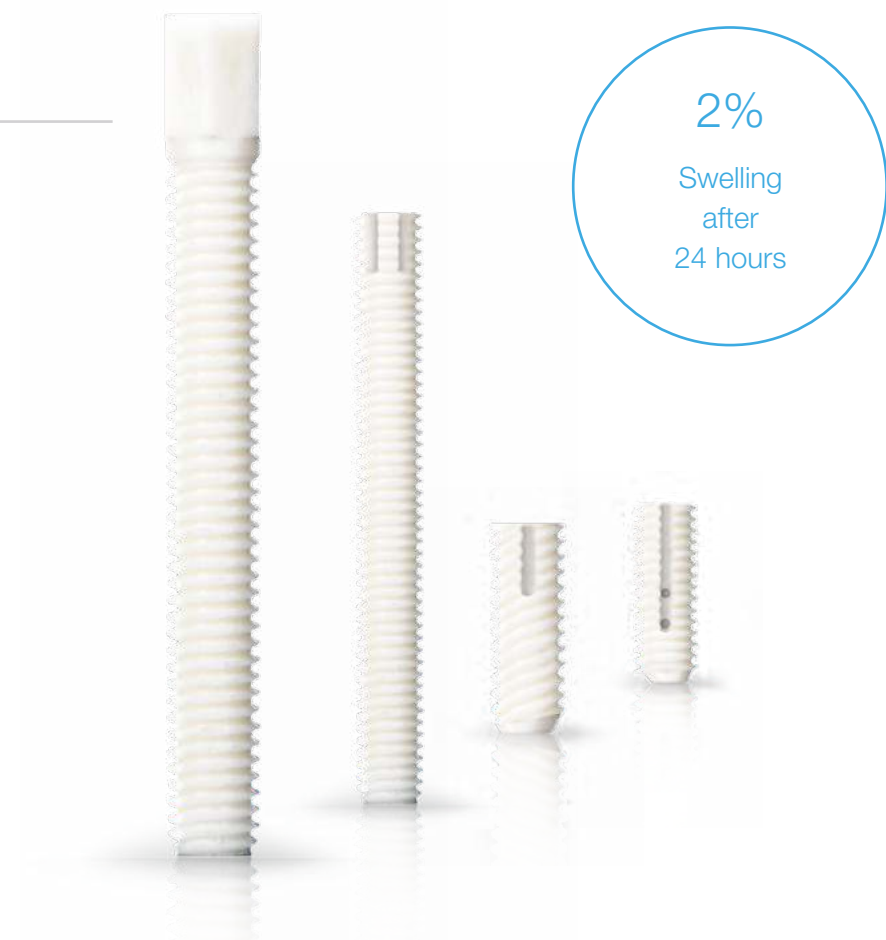
mag 25 x

mag 400 x

mag 3000 x

Intact Havers channels and Volkmann channels for the body's own cells

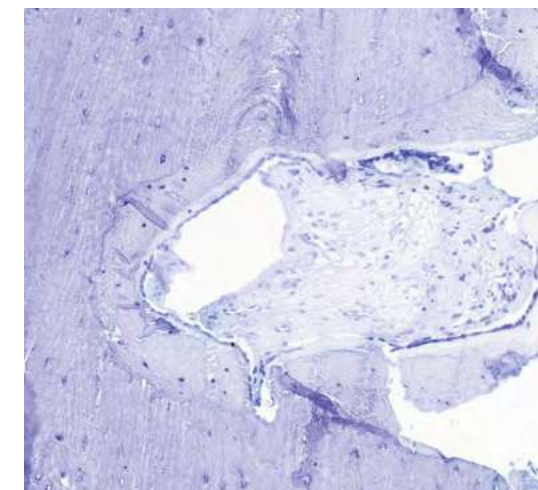
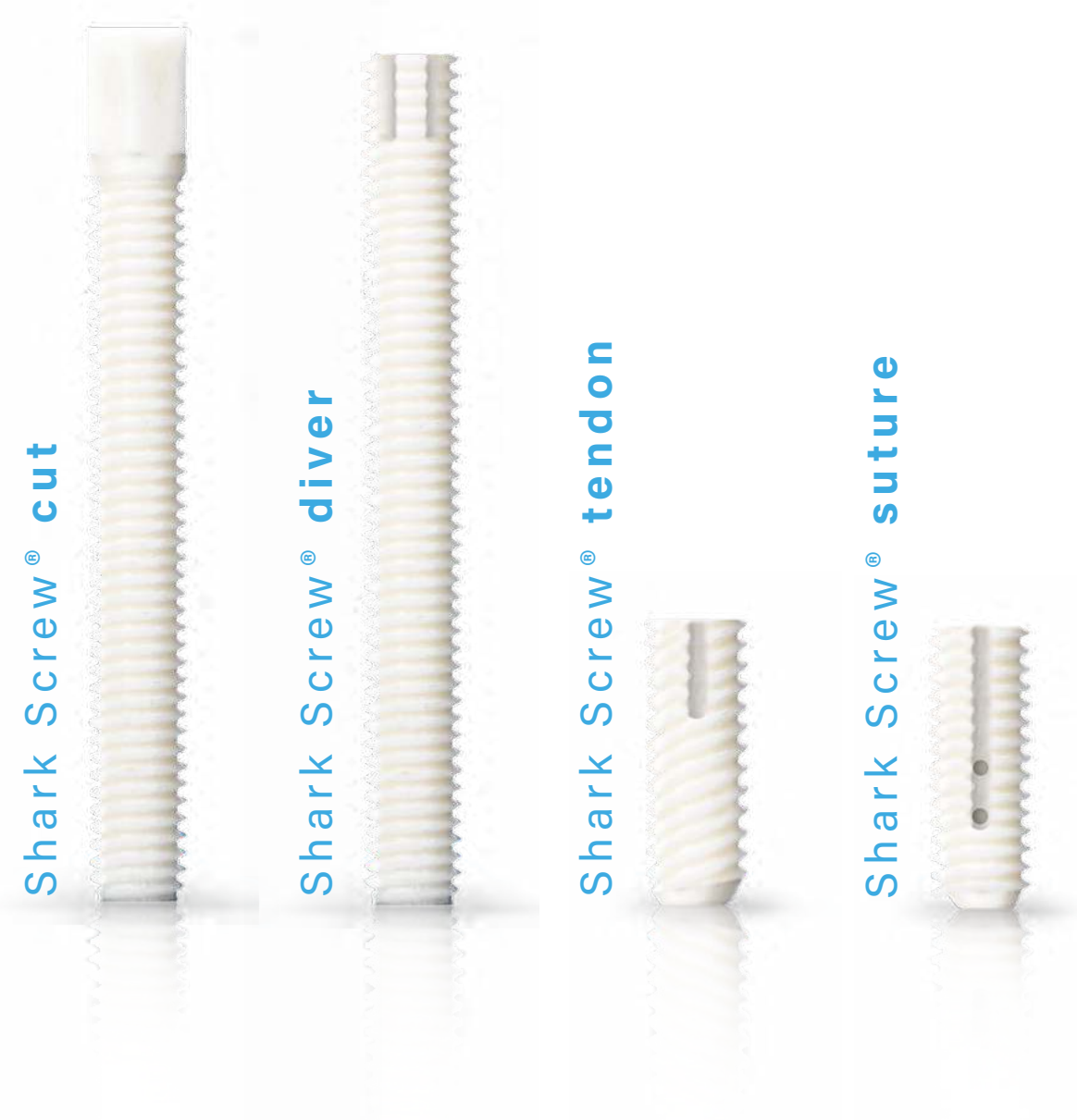
Intact Havers channels and Volkmann channels shape the structure of each individual Shark Screw®. The natural architecture of the Shark Screw® with its channel and cavity system provides a system for the direction of cells and cell fluids. The thread cut in the recipient bone creates a large active bone surface. This surface and the structure of the screw offer cells, messenger substances and hormones space to colonize the Shark Screw® and thus the possibility of quick integration of the screw through appropriate remodeling. (TU Graz FELMI Prof. DI. Dr. Plank)



The Bone Story - Osteogenesis

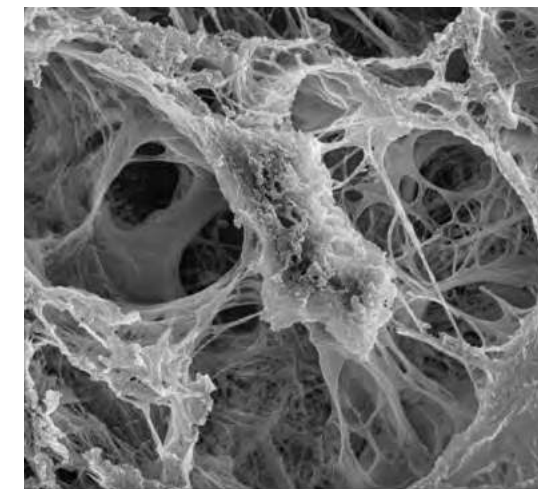
Histology & integration of the Shark Screw® in the recipient bone

The following pictures show the revascularization, cell colonization and remodeling process of the Shark Screw®. The processing was carried out by means of light microscopy (PD Dr. Mathias Werner Vivantes Berlin) and scanning electron microscopy (SEM) (Prof. Dipl.-Ing. Dr. Harald Plank FELMI Graz) on an explant 10 weeks after the first operation.



1 Shark Screw® thread & patient bones

The highly structured lamellar bone attaches itself to the thread contour without a layer of connective tissue. There are no inflammatory or rejection reactions. The patient's bones and graft form a stable Bone Healing Unit.²

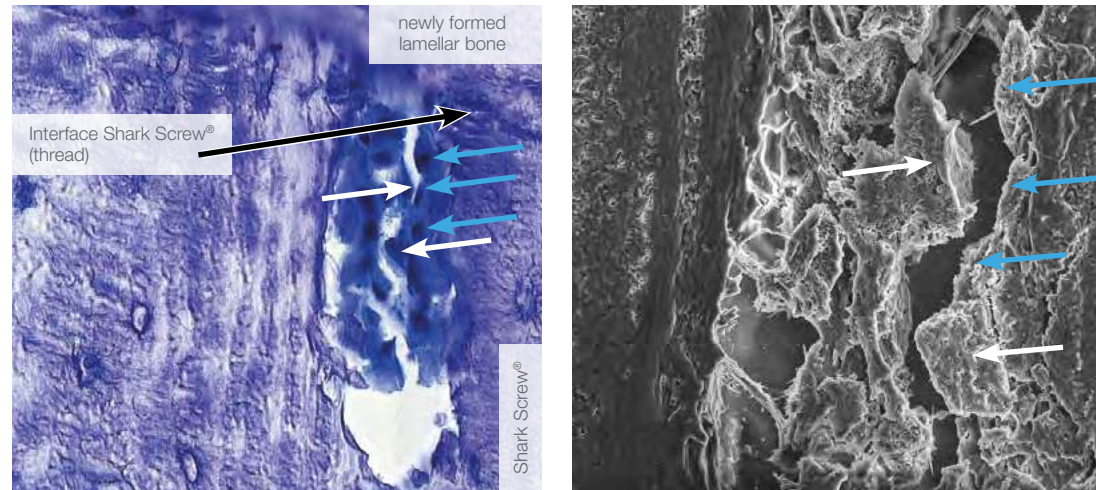


2 Mesenchymal stem cells and osteoprogenitor cells

These migrate into the Shark Screw® graft. There they find ideal conditions to differentiate into the cells that the body needs for bone healing. Osteoblasts to build up bones and chondrocytes to build up cartilage.

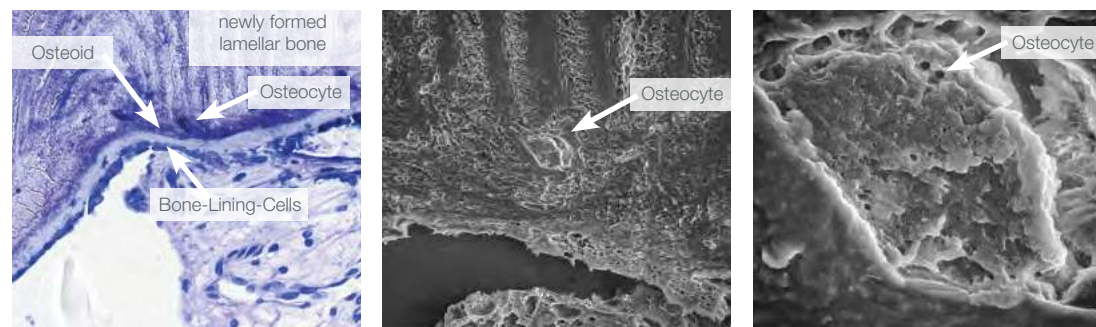
² Elliott DS, Newman KJ, Forward DP, et al. A unified theory of bone healing and nonunion: BHN theory. Bone Joint J. 2016;98-B(7):884-891.





3 Osteoblasts

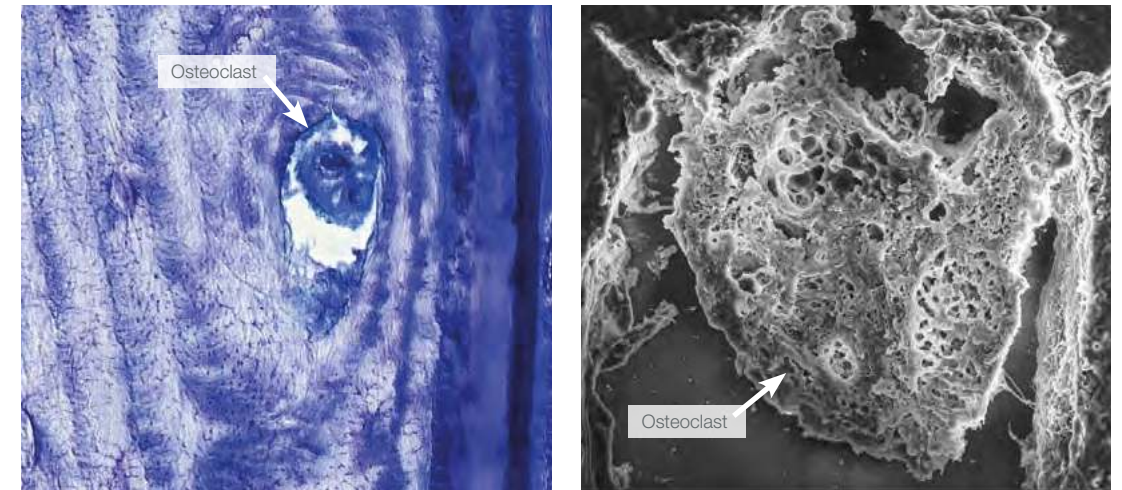
Osteoblasts (white arrows) form the basic bone substance and are primarily responsible for the organic matrix of the bone tissue. Countless biochemical substances such as growth factors, hormones, messenger substances and proteins regulate bone healing inside the Shark Screw®. Bone-lining cells (blue arrows) are also metabolically active and make a significant contribution to new bone formation.³



4 Osteocytes

At about 42 billion, osteocytes are the most numerous cells in our bones. They are completely embedded in the bone. They develop from the osteoblasts. They have an impressive network of appendages, with which they are connected by canaliculi. They secrete messenger substances that promote both bone formation and bone resorption.⁴

³ Matic, I. et al. (2016). Quiescent Bone Lining Cells Are a Major Source of Osteoblasts During Adulthood Stem cells (Dayton, Ohio), 34(12), 2930–2942.
⁴ Kurth A. & Lange U., Fachwissen Osteologie 2018



5 Osteoclasts

In a Haversian Shark Screw® system here, these break down the bone material of the Shark Screw®. By secreting cytokines, osteoclasts can promote or inhibit the local recruitment, differentiation, and activity of osteoblasts. These special phagocytes are in constant exchange with osteocytes and osteoblasts and can significantly influence them.⁵ This constant crosstalk among the bone cells enables the graft to be remodeled in the patient's bones.

⁵ Sims, N. A., & Martin, T. J. (2014). Coupling the activities of bone formation and resorption: a multitude of signals within the basic multicellular unit. BoneKEY reports, 3, 481. the activities of bone formation and resorption: a multitude of signals within the basic multicellular unit. BoneKEY reports, 3, 481.



Shark Screw® cut

Since the Shark Screw® cut is available in four different diameters and the length can be machined during surgery, it is used for over 60 different indications. With applications from the hand to the foot, it is regarded as the standard graft for percutaneous screwing of scaphoid and hallux valgus deformities, among other things, and as the tool of choice for complex revisions and pseudarthroses.

Shark Screw® cut



- **Special features:**
 - Natural bone bridge
- **Application areas:**
Hand, foot, shoulder, knee and pediatric surgery
- **Recommended for:**
Arthrodesis, refixation of bone fragments, fractures, osteotomies, osteochondral defects, pseudarthroses and revision operations
- **Available diameters:**
3.5 mm / 4.0 mm / 4.5 mm / 5.0 mm
Always choose the largest possible diameter for the Shark Screw® cut.
- **Available lengths:**
35 mm
- **Durability:**
5 years from the date of manufacture

Shark Screw® diver

The Shark Screw® diver gives the surgeon the opportunity to treat fractures and osteotomies in a completely new way. The head, which can be sunk well below the bone level, makes it possible to splint fractures, osteotomies and arthrodesis intramedullary. The Shark Screw® diver functions as a structure in the bone to direct cells that settle there.



Figures:
IP arthrodesis of the big toe and calcaneus osteotomy with Shark Screw® diver.

Shark Screw® diver



- **Special features:**
 - forms a natural bone bridge
 - can be sunk deep into the bone intramedullary
- **Application areas:**
Hand, foot, shoulder and pediatric surgery
- **Recommended for:**
Arthrodesis, fractures, osteotomies, pseudarthroses and revision operations
- **Available diameters:**
5.0 mm
- **Available lengths:**
35 mm / 45 mm
The Shark Screw® diver has a continuous thread. The head can therefore be sunk deep into the bone.
- **Durability:**
5 years from the date of manufacture

Shark Screw® tendon

The special design of the Shark Screw® tendon allows complete, arthroscopic sinking of this tendon anchor into the recipient bone. Stress tests on the femoral head show excellent hold and make the Shark Screw® tendon a safe allogeneic anchor for fixation of tendons and ligaments.⁶

Shark Screw® tendon



- **Special features:**
 - forms a natural bone bridge
 - firm interlocking of the screw in the cancellous bone and tendon
- **Application areas:**
Hand, foot, shoulder, elbow, knee and pediatric surgery
- **Recommended for:**
Tenodesis, tendon fixation
- **Available diameters:**
5.0 mm
- **Available lengths:**
15 mm
- **Durability:**
5 years from the date of manufacture

⁶ Holzapfel G. & Sommer G.: „Gesamtbericht zu den mechanischen Ausreißtests des allogenen Fadenankerprototyps in humanen Spenderknochen im Vergleich zu zwei handelsüblichen Fadenankersystemen“, 2019, Technische Universität Graz

Shark Screw® suture

The Shark Screw® suture is a suture anchor whose special design enables complete, arthroscopic countersinking in the recipient bone. Stress tests on the humeral head show excellent hold and make the Shark Screw® suture a safe allogeneic anchor for fixation of tendons and ligaments. When biomechanical stress tests were carried out, the suture anchors reached a max. pull-out force of up to F_{\max} 422 N.⁷

Shark Screw® suture



- **Special features:**
 - forms a natural bone bridge
 - thread material can be selected freely
 - Revision security
 - Allograft augmentation for osteoporotic bone
- **Application areas:**
Hand, foot, shoulder, elbow, knee and pediatric surgery
- **Recommended for:**
Osteoporotic bone, fixation of tendons and ligaments
- **Available diameters:**
5.0 mm
- **Available lengths:**
15 mm
- **Durability:**
5 years from the date of manufacture

⁷ Holzapfel G. & Sommer G.: „Gesamtbericht zu den mechanischen Ausreißtests des allogenen Fadenankerprototyps in humanen Spenderknochen im Vergleich zu zwei handelsüblichen Fadenankersystemen“, 2019, Technische Universität Graz

Application fields

Shoulder & Elbow

The Shark Screw® is unique as well as versatile so it can be used in hand, elbow, knee and foot surgery. As a human-biological bone screw graft, it offers surgeons the opportunity to treat bones after bone fractures and diseases without inorganic implants.

Shoulder and elbow

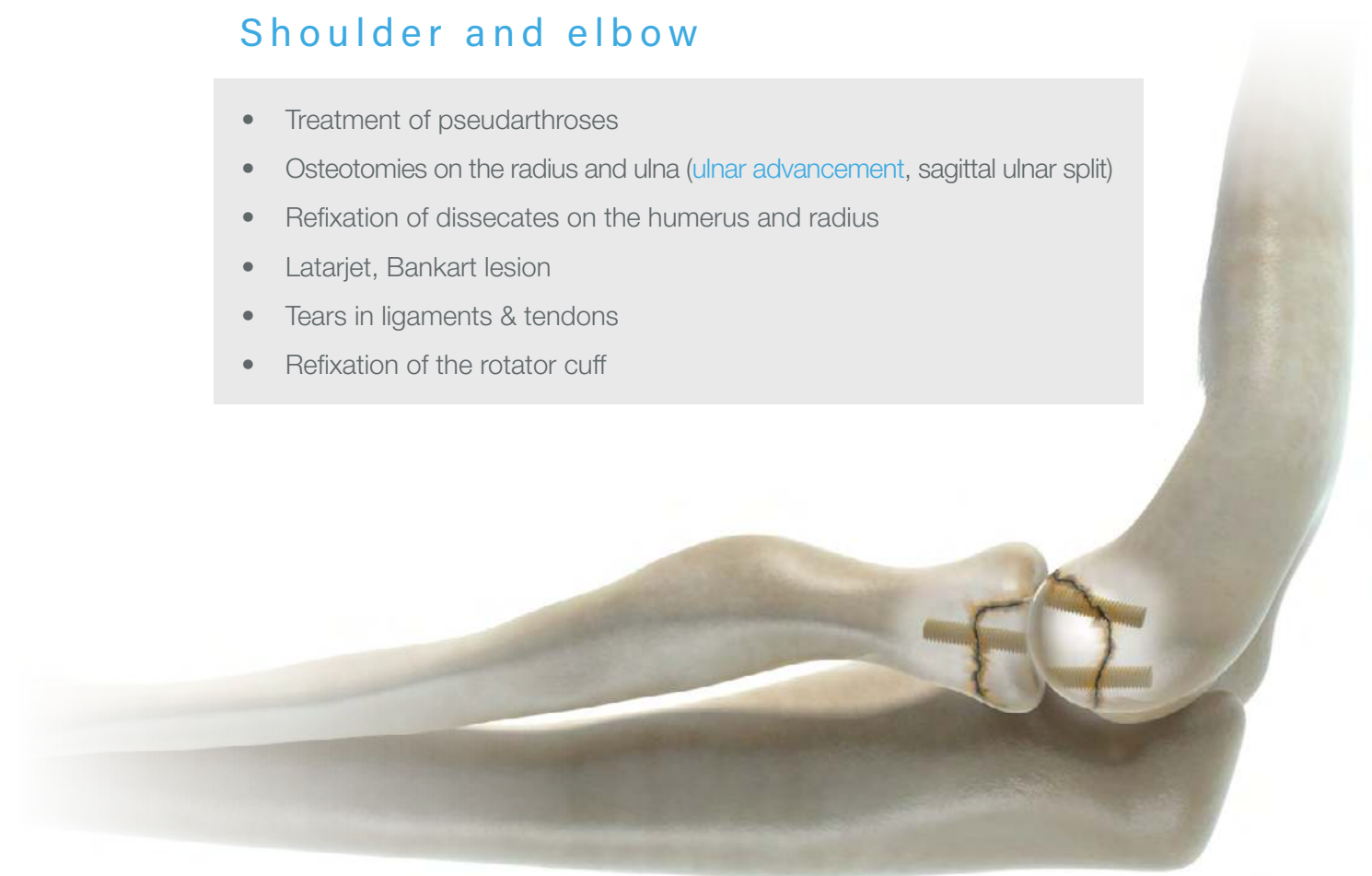
- Treatment of pseudarthroses
- Osteotomies on the radius and ulna ([ulnar advancement](#), sagittal ulnar split)
- Refixation of dissecates on the humerus and radius
- Latarjet, Bankart lesion
- Tears in ligaments & tendons
- Refixation of the rotator cuff

Hand

- Broken bones in the fingers and metacarpal
- Broken bones at the wrist
(e.g. [scaphoid fracture](#))

- Treatment of pseudarthroses
- CP, [polyarthroses](#), Heberden arthrosis, Bouchard osteoarthritis, arthrodesis on DIP, PIP finger joints

- Arthrodesis on the IP joint of the thumb
- Partial arthrodesis on the wrist
(e.g. [STT arthrodesis](#))
- 4-corner fusion with SNAC and SLAC wrist



Note: The listed indications are only examples of possible areas of application. These lists are not a substitute for training, instruction or support during operations. Treatment of possible indications must be decided on individually by the attending physician for each application. The respective instructions for use are decisive for the indications, contraindications and warnings for the Shark Screw® graft.

Foot

- Broken bones on toes, metatarsus, tarsus and hindfoot
 - Arthrodesis of the tarsus/metatarsus
 - Metatarsal osteotomy (e.g. Weil osteotomy)
- For [hallux valgus](#):
Austin subcapital metatarsal osteotomy
 - For [hallux rigidus](#):
Big toe joint arthrodesis
 - Jones fracture
- Correction of the metatarsus primus varus using TMT-I arthrodesis, Lapidus arthrodesis, MT-I base corrective osteotomy
 - Arthrodesis of the toe joints
 - Treatment of pseudarthroses
 - Distal fibular fracture
 - Malleolus osteotomies
 - Achilles tendon rupture
 - FDL transfers



Knee



- Refixation of dissecates ([osteochondritis dissecans](#))
- Antegrade screwing of cartilage-bone injuries
- MPFL reconstruction

Note: The listed indications are only examples of possible areas of application. These lists are not a substitute for training, instruction or support during operations. Treatment of possible indications must be decided on individually by the attending physician for each application. The respective specialist and professional information is decisive for the indications, contraindications and warnings for the Shark Screw® graft.

Clinical case documentation

The body's own vessels and bone cells can settle and spread in the fine bone channels and structures of the Shark Screw® allografts. This process is a prerequisite for the remodeling processes in the body and for bone healing with the Shark Screw®. Clinical images show the integration process of the Shark Screw® for possible indications.

Hallux valgus according to Austin



X-ray image preoperative
Hallux valgus, right.

8 weeks postoperative
Good build-up of the osteotomy and good hold of the graft.

6 months postoperative
Good integration and remodeling of the bone screw – the graft is only rudimentarily visible.

Scaphoid fracture



X-ray image preoperative
Scaphoid fracture in the middle third.

Postoperative after sutures have been removed
As in the last picture, no signs of loosening the screw.

X-ray check after 3 months
Patient symptom-free, wrist easily movable.

TMT II/III arthrodesis



CT preoperative
Shows significant osteoarthritis in the TMT joint.

X-ray image preoperative
Care of osteoarthritis with Shark Screw® grafts 5.0 mm.

X-ray after 6 weeks
Optimal position of the grafts, arthrodesis begins to develop.



X-ray after 3 months
Stable situation of Shark Screw® grafts, no osteolysis.

X-ray after 6 months
Grafts are successively converted into the patient's own bones.

X-ray 1 year postoperative
Complete non-reactive arthrodesis of TMT joints II and III. Grafts barely visible.

IP-arthrodesis



X-ray image preoperative
Distinct osteoarthritis can be seen in the IP joint.

X-ray postoperative
Good bridging of the arthrodesis gap with Shark Screw® diver.

X-ray 1 year postoperative
Almost complete remodeling of the Shark Screw®.

Economic advantages

Use of Shark Screw® has positive economic benefits.

Cost reduction

- ✓ By using the Shark Screw®, the hospital can save an average of € 434 per avoided complication or re-op (negative ICER).¹
- ✓ Costs in the health system are reduced by eliminating the need for a second operation (cost benefit of € 141 per patient).³
- ✓ The small instrument set saves space and costs in sterilization. No need to sterilize grafts that are not used.
- ✓ Low storage costs due to minimal space requirements.

Long durability

- ✓ With unopened packaging, the Shark Screw® is stable for five years when stored below 25 °C from the date of manufacture, prepared and ready for immediate use.

¹ Evelyn Walter, Karin Schalle & Marco Voit. (2016). Cost-Effectiveness of a bone transplant fixation "SHARK SCREW" transplant compared to metal devices in osteosynthesis in Austria. ISPOR 19th Annual European Congress. Vienna: IPF Institute for Pharmacoeconomic Research

Training offer

Find out more about our extensive **SPECIALIST PROGRAM** and current dates online.

This advanced training program, which was developed with leading doctors, aims to provide doctors with the best possible support in caring for their patients. It includes digital training, interactive webinars and surgical workshops in addition to observation appointments and surgical support.

There are also regular user meetings that are primarily focused on one thing: honest exchanges. Take part, have a discussion and share your experiences, pitfalls and successes with your colleagues.



Simply scan the QR code with your smartphone camera and you will immediately find all the latest information and dates under Specialist Program on our homepage www.surgebright.com.

Compact OP Videos (2 to 4 minutes)



Are you pressed for time between operations, but want to go through the surgical technique again?

Follow surgebright on YouTube and stream surgery videos from Shark Screw® experts on the indications that interest you. Simply scan the QR code with your smartphone camera and play the videos.

Product overview & Order information



Allogene Schraube aus humanem Spenderknochen / gefriergetrocknet
Allogenic screw made of human bone / freeze-dried

Artikelnummer Item number	Beschreibung Description	Produktfarbe Color	Länge Length	Durchmesser Diameter
SC35351	Shark Screw® cut 3.5	■	35mm	3.5mm
SC35401	Shark Screw® cut 4.0	■	35mm	4.0mm
SC35451	Shark Screw® cut 4.5	■	35mm	4.5mm
SC35501	Shark Screw® cut 5.0	■	35mm	5.0mm

Shark Screw® diver

Allogene Schraube aus humanem Spenderknochen / gefriergetrocknet, intramedullär verwendbar
Allogenic screw made of human bone / freeze-dried, can be used intramedullarily

Artikelnummer Item number	Beschreibung Description	Farbe Color	Länge Length	Durchmesser Diameter
SC3550d	Shark Screw® diver	✘	35mm	5.0mm
SC4550d	Shark Screw® diver long	✘	45mm	5.0mm

Shark Screw® suture

Allogener Fadenanker aus humanem Spenderknochen / gefriergetrocknet
Allogenic suture anchor made of human bone / freeze-dried

Artikelnummer Item number	Beschreibung Description	Farbe Color	Länge Length	Durchmesser Diameter
SC1550s	Shark Screw® suture	✘	15mm	5.0mm

Shark Screw® tendon

Allogener Sehnenanker aus humanem Spenderknochen / gefriergetrocknet
Allogenic tendon anchor made of human bone / freeze-dried

Artikelnummer Item number	Beschreibung Description	Farbe Color	Länge Length	Durchmesser Diameter
SC1550t	Shark Screw® tendon	✘	15mm	5.0mm

Instrumente Shark Screw® / Instruments Shark Screw®

Abbildung Figure	Art.-Nr. Item No.	Beschreibung Description
	R-PL.00	Shark Screw® suture tension knob reusable
	R-SC.00	Shark Screw® handhold with quick connect cannulated
	HN.ISW415.AO	hexagon screwdriver for Shark Screw® cut
	C-08.00	claw coupling for Shark Screw® diver, Shark Screw® tendon, Shark Screw® suture
	SPIBO-2.85-K	cannulated drill for Shark Screw® Ø 3,5 colour: blue length: 110mm
	G.SCHNEIDER.LH3.5K	cannulated thread die for Shark Screw® Ø 3,5 colour: blue length: 110mm
	SPIBO-3.25-K	cannulated drill for Shark Screw® Ø 4,0 colour: yellow length: 110mm
	G.SCHNEIDER.LH4.0K	cannulated thread die for Shark Screw® Ø 4,0 colour: yellow length: 110mm
	SPIBO-3.7-K	cannulated drill for Shark Screw® Ø 4,5 colour: red length: 145mm
	G.SCHNEIDER.LH4.5K	cannulated thread die for Shark Screw® Ø 4,5 colour: red length: 145mm
	SPIBO-4.2-K	cannulated drill for Shark Screw® Ø 5,0 colour: black length: 145mm
	G.SCHNEIDER.LH5.0K	cannulated thread die for Shark Screw® Ø 5,0 colour: black length: 145mm
	SCD E1.6	Shark Screw® K-wire for transfixation unilateral trocar tip Ø 1,6mm length: 150mm
	SCD B1.2	Shark Screw® K-wire to guide with trocar tip on both sides Ø 1,2mm length: 150mm
	SCD EG1.2	Shark Screw® K-wire to guide with thread unilateral trocar tip Ø 1,2mm length: 150mm
	CB-405-070	Shark Screw® sterilisation container (bottom)
	CL-400-040	Shark Screw® sterilisation container (cap)
	SM-850-000	Shark Screw® sterilisation container (silicon mat)



Distributed by:

Web www.surgebright.com
E-Mail info@surgebright.com
Tel (+43) 720 371 355
Gewerbezeile 7,
A-4040 Lichtenberg bei Linz

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