



Shark Screw® Product information

surgebright's aim is to support you in providing your patients with the best possible care!

Surgebright only offers high-quality human donor tissue processed to US standards. That's our commitment. We provide no synthetic products.

Who is surgebright to you?

- » Your allograft provider for extremity surgeries
- » Your biologic screw manufacturer
- » Your helping hand to get through VAC committees
- » Your sparring partner for scientific endeavours
- » Your colleagues and people to have a good time with

An interesting fact:

the probability of winning the Euromillions lottery game is 1 in 140 million. The probability of getting an infection from a sterile allograft is 1 in 10 million billion, i.e. 1:10,000,000,000,000,000.⁷

⁷ J. Brune Update: Allogene Gewebetransplantate in Deutschland AFOR Expertengremium Pontresina 2019 | Association for Orthopedic Research

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SHARK SCREW®

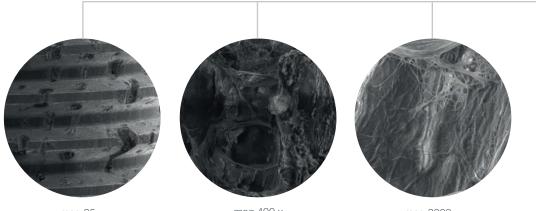
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Shark Screw[®] Material properties

Shark Screw[®] is an allograft screw for orthopedic and trauma surgery. The gentle manufacturing process ensures preservation of the natural bone structures, which in turn form the basis for a natural bone remodeling process. After insertion into the bone, the Shark Screw[®] allograft is colonized by the body's own cells and gradually transformed into the patient's own bone as part of the remodeling process.

This natural process creates bone structures that have the ability to constantly adapt to mechanical demands. This eliminates the need for a second surgery to remove metal implants, along with the associated risks for patients.

Shark Screw[®] allows you, the surgeon, to provide your patients with a reliable and natural treatment. Details about the areas of use and indications for each product can be found from page 10 onwards.



mag 25 x

mag 400 x

mag 3000 x

Intact Haversian and Volkmann's canals for colonization of the body's own cells

Intact Haversian canals and Volkmann's canals characterize the structure of every single Shark Screw[®]. It is the osteoconductive properties of the Shark Screw[®] allogeneic bone material that allow bone to grow on its surface. The threaded incision in the recipient bone creates a large active bone surface. The Haversian canals are colonized by cells specific to bone metabolism and filled with new vessels. The osteoblasts and osteoclasts present in the recipient bone slowly convert the allograft into the body's own material in a process known as "creeping substitution".¹

¹ I. Brcic, K. Pastl, H. Plank, J. Igrec, J. E. Schanda, E. Pastl, M. Werner. Incorporation of an Allogenic Cortical Bone Graft Following Arthrodesis of the First Metatarsophalangeal Joint in a Patient with Hallux Rigidus Life (2021)

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Screw characteristics and biomechanics

During the development of the Shark Screw[®], surgebright worked closely with the Institute of Biomechanics, the Institute of Electron Microscopy and Fine Structure Research at Graz University of Technology and the Institute of Biomedical Mechatronics at Johannes Kepler University Linz to achieve the maximum load-bearing capacity thanks to the unique design – and thus maximum patient safety.

Greater stability due to swelling in the recipient bone

After being inserted in the recipient bone, Shark Screw[®] allografts swell by an average of 2% and thus ensure an even more rotationally stable osseous connection.² ² Holzapfel G. & Sommer G.: "Einfluss des Gewindetalradius auf die biomechanischen Eigenschaften von Osteosyntheseschrauben aus humaner Corticalis" – Experimental and FEM Study, 2012, Graz University of Technology





Shark Screw[®] cut

Shark Screw[®] diver

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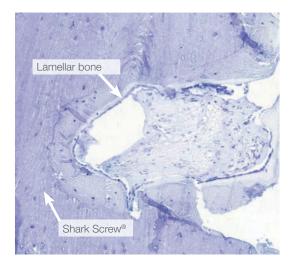
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NO!

Osteogenesis and bone healing

Histology and integration of the Shark Screw® into the recipient bone

The following images show the revascularization, cell colonization and remodeling process of the Shark Screw[®]. Reworking was carried out using 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 initial operation.

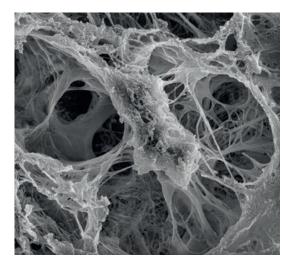


The a

(1)

The Shark Screw[®] thread and patient's bone

Highly-structured lamellar bone fits the thread contour exactly without a layer of connective tissue. This leads to primary bone healing without any inflammation or rejection. ¹





Mesenchymal stem cells and osteoprogenitor cells

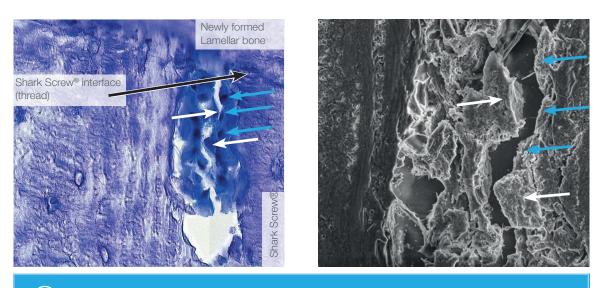
Progenitor cells migrate into the Shark Screw[®] allograft where they find the ideal conditions to differentiate into osteoblasts, which the body needs for bone formation.¹

I. Brcic, K. Pastl, H. Plank, J. Igrec, J. E. Schanda, E. Pastl, M. Werner. Incorporation of an Allogenic Cortical Bone Graft Following Arthrodesis of the First Metatarsophalangeal Joint in a Patient with Hallux Rigidus Life (2021)



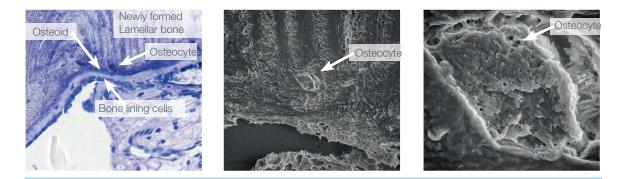


Primary bone healing with Shark Screw[®]



3 Osteoblasts

Osteoblasts (white arrows) form the basic bone substance (osteoid) and are primarily responsible for the organic matrix of bone tissue. Countless biochemical substances such as growth factors, hormones, messengers and proteins regulate bone healing. Bone lining cells (blue arrows) are also metabolically active and make a significant contribution to the formation of new bone.^{1, 3}



(4) Osteocytes

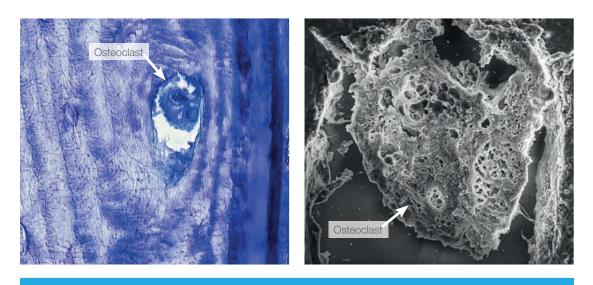
At around 42 billion, osteocytes are the most abundant cells in our bones. They are completely embedded in the bone and develop from osteoblasts. Their network of processes, with which they are connected to each other via canaliculi, is impressive. They secrete messengers that regulate bone metabolism.^{1, 4}

¹ I. Brcic, K. Pastl, H. Plank, J. Igrec, J. E. Schanda, E. Pastl, M. Werner. Incorporation of an Allogenic Cortical Bone Graft Following Arthrodesis of the First Metatarsophalangeal Joint in a Patient with Hallux Rigidus Life (2021)

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

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(5) Osteoclasts

Osteoclasts, seen here in a Haversian canal of the Shark Screw[®], break down the Shark Screw[®] bone material. By secreting cytokines, osteoclasts can promote or inhibit the local recruitment, differentiation and activity of osteoblasts. These special scavenger cells are in constant dialogue with osteocytes and osteoblasts and can significantly influence them.⁵ This constant crosstalk between the bone cells enables the allograft to be remodeled in the patient's bone.

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. Bone reports, 3, 481.the activities of bone formation and resorption: a multitude of signals within the basic multicellular unit. BoneKEy reports, 3, 481.

nteresting studies on allografts and Shark Screw

- » Holzapfel G. & Sommer G.: "Einfluss des Gewindetalradius auf die biomechanischen Eigenschaften von Osteosyntheseschrauben aus humaner Corticalis" Experimental and FEM Study, 2012, Graz University of Technology
- Sims, N. A., & Martin, T. J. 2014 Reports, 3, 481. the activities of bone formation and resorption: a multitude of signals within the basic multicellular unit. Bone
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- » I. Brcic, K. Pastl, H. Plank, J. Igrec, J. E. Schanda, E. Pastl, M. Werner. Incorporation of an Allogenic Cortical Bone Graft Following Arthrodesis of the First Metatarsophalangeal Joint in a Patient with Hallux Rigidus Life (2021)
- » Anika Grüneboom, Ibrahim Hawwari, Daniela Weidner, Stephan Culemann. A network of trans-cortical capillaries as mainstay for blood circulation in long bones | Nature Metabolism | VOL 236 1 | FEBRUARY 2019 | 236–250 |
- » Axel Pruss, Arne Hansen, Moujahed Kao, Lutz Gürtler, Georg Pauli, Frank Benedix. Comparison of the efficacy of virus inactivation methods in allogeneic avital bone tissue transplants | Cell and Tissue Banking 2:201–215, 2001.
- » Klaus Pastl, Wolfgang Schimetta. The application of an allogeneic bone screw for osteosynthesis in hand and foot surgery: a case series | Archives of Orthopedic and Trauma Surgery (2021)
- » E. Walter, K. Schalle, and M. Voit, "Cost-Effectiveness of A Bone Transplant Fixation "Shark Screw" Transplant Compared To Metal Devices In Osteosynthesis In Austria", Value in Health, ed. 19, no. 7, p. A539, 2016, doi: 10.1016/j.jval.2016.09.1115.
- » T. Huber, S. G. Hofstätter, R. Fiala, F. Hartenbach, R. Breuer, and B. Rath, "The Application of an Allogenic Bone Screw for Stabilization of a Modified Chevron Osteotomy: A Prospective Analysis", Journal of Clinical Medicine, ed. 11, no. 5, p. 1384, 2022, doi: 10.3390/jcm11051384.
- » S. Sailer et al., "Treatment of scaphoid fractures and pseudarthroses with the human allogeneic cortical bone screw. A multicentric retrospective study", J Orthop Traumatol, ed. 24, no. 1, p. 6, Feb. 2023, doi: 10.1186/s10195-023-00686-7.

Shark Screw® cut

As Shark Screw[®] cut is available in four different diameters and can also be processed intraoperatively in length, it is used for over 60 different indications. With uses in hand & wrist and foot & ankle surgery, it is the standard allograft for percutaneous screw fixation of the scaphoid bone and bunion deformities, as well as the allograft of choice for complex revisions and non-unions.



Examples: Bunion 8 weeks post op. and a

scaphoid non-union 6 months postop.





• Special features:

- » Forms a natural bone bridge
- Areas of use:

Hand & wrist, foot & ankle, shoulder, knee and pediatric surgery

• Recommended for:

Arthrodesis, refixation of bone fragments, fractures, osteotomies, osteochondral defects, nonunion and revision operations

• Available diameters:

•

3.5 mm / 4.0 mm / 4.5 mm / 5.0 mm Always select the largest possible diameter for Shark Screw[®] cut.

Available lengths:
 35 mm / 45 mm (only available for 4.5 mm)

Shelf life:

5 years from date of manufacture

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Shark Screw[®] diver

Shark Screw[®] diver enables surgeons to treat fractures and osteotomies in a completely new way. The head can be lowered far below the bone level, making it possible to splint fractures, osteotomies and arthrodesis intramedullary. Shark Screw[®] diver serves as a lead structure in the bone for colonizing cells.





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





• Special features:

- » Forms a natural bone bridge
- » Can be sunk deep into the bone intramedullary
- Areas of use:

Hand & wrist, foot & ankle, shoulder and pediatric surgery

• Recommended for:

Arthrodesis, fractures, osteotomies, non-union and revision operations

- Available diameters: 5.0 mm
- Available lengths:

35 mm / 45 mm

Shark Screw[®] diver has a continuous thread, enabling the head to be sunk deep into the bone.

• Shelf life:

5 years from date of manufacture





Field of use Hand & Wrist

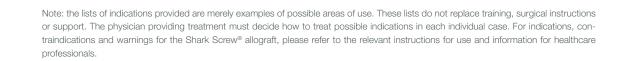
- » Fractures on fingers and metacarpus
- » Carpus fractures (e.g. scaphoid fracture)
- » Treatment of non-union
- » CP, polyarthrosis, Heberden's nodes, Bouchard's nodes, arthrodesis of DIP and PIP finger joints
- » Arthrodesis of the thumb IP joint
- » Partial arthrodesis of the carpus (e.g. STT arthrodesis)
- » 4-corner fusion of SNAC and SLAC wrists

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Field of use Shoulder & Elbow

- » Treatment of non-unions
- » Radius and ulna osteotomies (displaced ulna, sagittal ulna rupture)
- » Refixation of dissecates on the humerus and radius
- » Latarjet, Bankart lesions





Field of use Foot & Ankle

- » Fractures of the toes, metatarsus, tarsus and hindfoot
- » Arthrodesis of the tarsus/metatarsus
- » Metatarsal osteotomy (e.g. Weil osteotomy)
- » For bunion:

Subcapital metatarsal osteotomy using Austin procedure

- » For hallux rigidus:
 Metatarsophalangeal 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 non-unions
- » Distal fibula fracture
- » Malleolus osteotomies
- » Calcaneal osteotomy
- » Calcaneus fracture



Field of use Knee



- » Refixation of dissecates (osteochondritis dissecans)
- » Antegrade screw fixation of cartilage bone injuries

Note: the lists of indications provided are merely examples of possible areas of use. These lists do not replace training, surgical instructions or support. The physician providing treatment must decide how to treat possible indications in each individual case. For indications, contraindications and warnings for the Shark Screw[®] allograft, please refer to the relevant instructions for use and information for healthcare professionals.



Clinical case documentation

The body's own vessels and bone cells can colonize and spread into the fine bone channels and structures of the Shark Screw[®] allograft. This process is a prerequisite for the remodeling processes in the body and the bone healing and remodeling of the Shark Screw[®]. The following images show the integration process of the Shark Screw[®] based on a number of examples.

Bunion using the Austin procedure



X-ray preop. bunion, right.



8 weeks postop. Good build up of the osteotomy and good hold of the allograft.



6 months postop. Good integration and remodeling of the bone screw – the allograft is only rudimentarily visible now.

Scaphoid fracture



X-ray preop. Scaphoid fracture in the middle third.



Postoperative after suture removal, no signs of screw loosening.



X-ray check-up after 3 months Patient has no problems, wrist moves easily.

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TMT II/III arthrodesis



CT preop. Shows clear arthrosis in the TMT joint.



X-ray of preoperative treatment of arthrosis with Shark Screw[®] allografts 5.0 mm.



X-ray image 6 weeks postop. Optimum position of allografts, initial development of arthrodesis.



X-ray image 3 months postop. Stable position of the Shark Screw® allografts, no osteolysis.



X-ray image 6 months postop. The allografts have successively converted into the patient's own bones.



X-ray image 1 year postop. Complete non-reactive arthrodesis of TMT joints II and III. Allografts barely visible.

IP arthrodesis



X-ray preop. Distinct arthrosis can be seen in the IP joint.



Postoperative x-ray Good bridging of the arthrodesis gap with Shark Screw[®] diver.



X-ray image 1 year postop. Almost complete remodeling of the Shark Screw^{®.}

Expert opinion



"Very few things in medicine make as much sense as the Shark Screw[®]. It's a device that really makes you wonder how no one developed this sooner." - Tom Fusco, DPM, Florida, USA



"The Shark Screw[®] provides a completely natural solution for osteosynthesis. The allograft screw ensures stable fixation of the fragment while the body gradually integrates it, allowing it to be remodeled into the patient's bone."

- Vytautas Ringus, M.D., Oklahoma, USA



"I trust Shark Screw[®] because it represents the cutting-edge technology and reliability that my patients need. Shark Screw[®] has consistently proven to be a reliable partner in achieving the best results for my patients, especially in complex reconstructive cases."

- Khoa D. Nguyen, DPM, Connecticut, USA

Training offer

Learn more about our comprehensive Specialist Program and the latest dates online.

This training program, developed with leading doctors, aims to provide surgeons with the best possible support for caring for their patients. In addition to work-shadowing appointments and surgical supervision, it also includes online training, interactive webinars and surgical workshops.





Simply scan the QR code with your smartphone camera to view all the latest information and dates for training and further training courses.

Short surgical videos (2 to 4 minutes)

Do you only have a short amount of time between two cases, but you want to have another look at the surgical technique?



Follow surgebright on YouTube and stream surgical videos of Shark Screw[®] experts talking about the indications that you are interested in. Simply scan the QR code with your smartphone camera and play the videos.



Shark Screw[®] cut

Allograft screw made from human donor bone / freeze-dried

Part number	Description	Product color	Length	Diameter
USC35351	Shark Screw [®] cut 3.5		35 mm	3.5 mm
USC35401	Shark Screw [®] cut 4.0		35 mm	4.0 mm
USC35451	Shark Screw [®] cut 4.5	•	35 mm	4.5 mm
USC35501	Shark Screw [®] cut 5.0	•	35 mm	5.0 mm
USC45451	Shark Screw [®] cut 4.5	•	45 mm	4.5 mm

Shark Screw[®] diver

Allograft screw made from human donor bone / freeze-dried For intramedullary use



Part numb	ber Dese	pription	Color	Length	Diameter
USC355	0d Sha	rk Screw [®] diver	×	35 mm	5.0 mm
USC455	0d Sha	rk Screw [®] diver long	×	45 mm	5.0 mm





Surgical videos Shark Screw®



Follow us on

Shark Screw[®] instruments



Interesting studies on allografts and Shark Screw®

- » P. Amann, K. Pastl, E. Neunteufel, and P. Bock, "Clinical and Radiologic Results of a Human Bone Graft Screw in Tarsometatarsal II/+III Arthrodesis", Foot Ankle Int., ed. 43, no. 7, p. 913–922, July 2022, doi: 10.1177/10711007221081533.
- » K. Pastl, E. Pastl, D. Flöry, G. H. Borchert, and M. Chraim, "Arthrodesis and Defect Bridging of the Upper Ankle Joint with Allograft Bone Chips and Allograft Cortical Bone Screws (Shark Screw®) after Removal of the Salto-Prosthesis in a Multimorbidity Patient: A Case Report", Life, ed. 12, no. 7, p. 1028, July 2022, doi: 10.3390/life12071028.
- » J. E. Schanda et al., "Biomechanical properties of a suture anchor system from human allogenic mineralized cortical bone matrix for rotator cuff repair", BMC Musculoskelet Disord, ed. 23, no. 1, p. 422, Dec. 2022, doi: 10.1186/s12891-022-05371-0.
- » B. Hanslik-Schnabel, D. Flöry, G. H. Breuer, and J. E. Schanda, "Clinical and Radiologic Outcome of First Metatarsophalangeal Joint Arthrodesis Using a Human Allogeneic Cortical Bone Screw", Foot Ankle Orthop, ed. 7, no. 3, p. 24730114221112944, July 2022, doi: 10.1177/24730114221112944.
- » Elliott DS, Newman KJ, Forward DP, et al, A unifi ed theory of bone healing and nonunion; BHN theory. Bone Joint J. 2016;98-B(7):884-891

What and how do your colleagues perform surgeries using Shark Screw[®]?

Click here to stream surgical videos



What's going on at surgebright?

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