



# Shark Screw<sup>®</sup>

## Product Information





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## SHARK SCREW®

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# Shark Screw®

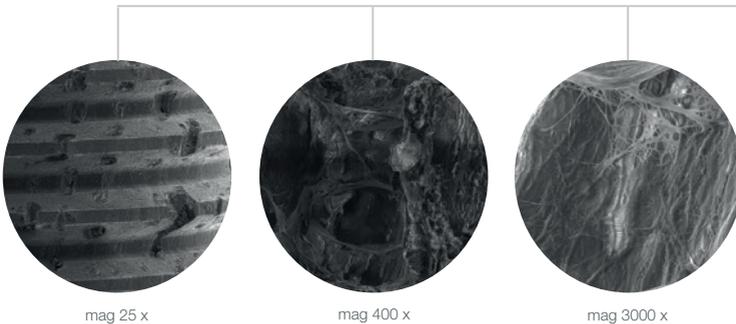
## Material properties

Shark Screw® allografts are screws made from allograft bone for orthopedics 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, Shark Screw® allografts are colonized by the body's own cells and gradually converted into the patient's own bone material during the course of the bone 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 the metal implant as well as the associated risks for patients.

Shark Screw® gives you, the surgeon, the opportunity to give your patients the best possible, natural care. Details about the areas of use and indications for each product can be found from page 10 onwards.



### 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® allograft 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".<sup>1</sup>

<sup>1</sup> 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)

# Screw characteristics and biomechanics

During the development of the Shark Screw<sup>®</sup>, 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<sup>®</sup> allografts swell by an average of 2% and thus ensure an even more rotationally stable osseous connection.<sup>2</sup>

<sup>2</sup> Holzapfel G. & Sommer G.: "Einfluss des Gewindetralradius auf die biomechanischen Eigenschaften von Osteosyntheseschrauben aus humaner Corticalis" – Experimental and FEM Study, 2012, Graz University of Technology



**Shark Screw® cut**



**Shark Screw® diver**



**Shark Screw® tendon**



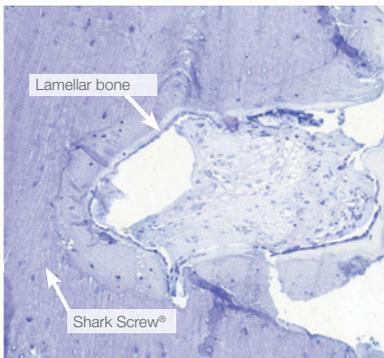
**Shark Screw® suture**



# Osteogenesis and bone healing

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

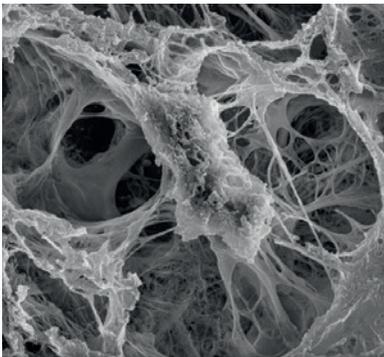
The following images show the revascularization, cell colonization and remodeling process of the Shark Screw®. Reworking was carried out using light microscopy (PD Dr Mathias Werner, Vivantes Berlin) and scanning electron microscopy (SEM) (Prof. Dipl.-Ing. Dr Harald Plank, FELMI Graz) on an explant 10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



1

### The Shark Screw® thread and patient bones

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.<sup>1</sup>



2

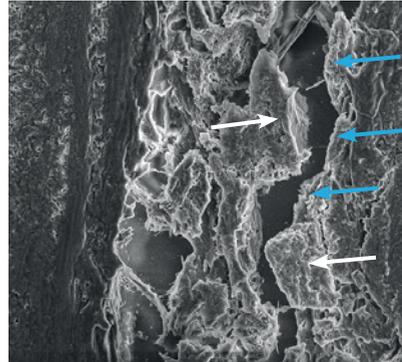
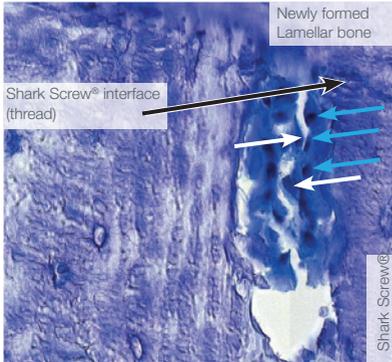
### Mesenchymal stem cells and osteoprogenitor cells

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.<sup>1</sup>

1. Broic, 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)

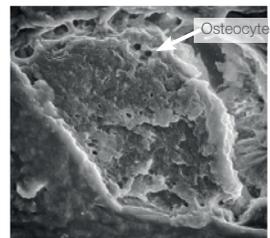
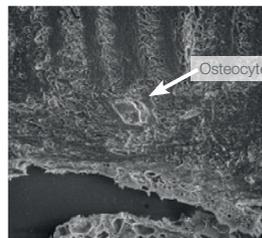
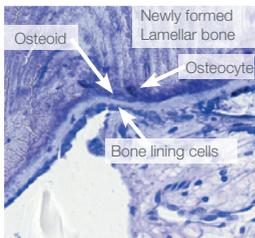


# Primary bone healing with Shark Screw®



## 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.<sup>1,3</sup>



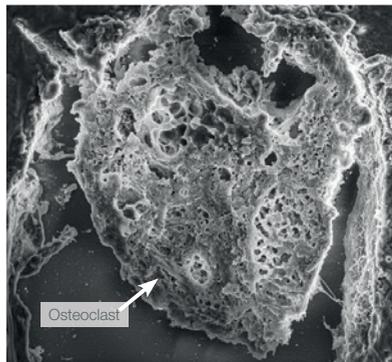
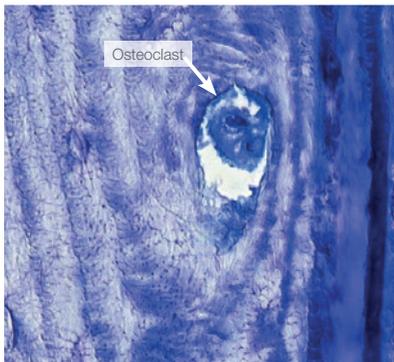
## 4 Osteocytes

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.<sup>1,4</sup>

<sup>1</sup> I. Bricic, 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)

<sup>3</sup> 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.

<sup>4</sup> Kurth A. & Lange U., Fachwissen Osteologie 2018



## 5 Osteoclasts

Osteoclasts, seen here in a Haversian canal of the Shark Screw<sup>®</sup>, break down the Shark Screw<sup>®</sup> 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.<sup>5</sup> This constant crosstalk between the bone cells enables the allograft to be remodeled in the patient's bone.

<sup>5</sup> 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.

## Interesting studies on allografts and Shark Screw<sup>®</sup>

- » Holzapfel G. & Sommer G.: "Einfluss des Gewindedetailradius 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 reports*, 3, 481. the activities of bone formation and resorption: a multitude of signals within the basic multicellular unit. *BoneKey reports*, 3, 481.
- » 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 pseudarthrosis.



**Examples:**

Bunion 8 weeks post op. and  
a scaphoid non-union 6  
months postop.

Shark Screw® cut



- **Special features:**
  - » Forms a natural bone bridge
- **Areas of use:**  
Hand & wrist, foot & ankle, shoulder, knee and pediatric surgery
- **Recommended for:**  
Arthrodesis, fixation 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 select the largest possible diameter for Shark Screw® cut.
- **Available lengths:**  
35 mm
- **Shelf life:**  
5 years from date of manufacture

# 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.

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, pseudarthroses 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



# Shark Screw® tendon

The special thread design of the Shark Screw® tendon allows this tendon anchor to be completely sunk into the recipient bone using arthroscopy. Its excellent hold makes Shark Screw® tendon a secure allogeneic anchor for fixing tendons and ligaments.



Examples:  
FDL transfer 6 weeks post-op.  
for a flat foot. Remodeling of  
the anchor already underway.

Shark Screw® tendon



- **Special features:**
  - » Forms a natural bone bridge
  - » Firm interlocking of the screw in cancellous bone and tendon
- **Areas of application:**  
Hand, foot, shoulder, elbow, knee, and pediatric surgery
- **Recommended for:**  
Tenodesis, fixation of tendons and ligaments
- **Available diameters:**  
5.0 mm
- **Available lengths:**  
15 mm
- **Shelf life:**  
5 years from date of manufacture

# Shark Screw® suture

Shark Screw® suture is a thread anchor whose special design allows complete arthroscopic sinking into the recipient bone. Load tests on the humeral head show excellent hold and make Shark Screw® suture a secure allogenic anchor for fixing tendons and ligaments.<sup>5</sup>



#### Examples:

Use of Shark Screw® suture  
for Achilles tendon tendinitis.  
6 weeks post-op.

Shark Screw® suture



- **Special features:**
  - » Forms a natural bone bridge
  - » Choice of suture material
  - » Revision-proof
  - » Allograft augmentation
  - » For osteoporotic bone
- **Areas of application:**  
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
- **Shelf life:**  
5 years from date of manufacture

<sup>5</sup> Holzapfel G. & Sommer G.: "Comprehensive report on mechanical pull-out tests of the allogenic thread anchor prototype in human donor bone compared to two commercially available thread anchor systems," 2019, Graz University of Technology



# Field of use

## Hand

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- » Fractures on fingers and metacarpus
- » Carpus fractures (e.g. [scaphoid fracture](#))

- » Treatment of pseudarthrosis
- » 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

# Field of use

## Shoulder & Elbow

- » Treatment of non-unions
- » Radius and ulna osteotomies (displaced ulna, sagittal ulna rupture)
- » Refixation of dissections on the humerus and radius
- » Latarjet, Bankart lesions
- » Tears in ligaments and tendons
- » Refixation of the rotator cuff



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.



# 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, larpus 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
- » MPFL reconstruction

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® allografts. 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.

## TMT II/III arthrodesis



CT preop.  
Shows clear arthrosis in the  
TMT joint.



X-ray of preoperative treat-  
ment of arthrosis with Shark  
Screw®  
allografts 5.0 mm.



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



X-ray image 3 months post-  
op.  
Stable position of the Shark  
Screw® allografts, no osteo-  
lysis.



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



X-ray image 1 year postop.  
Complete non-reactive ar-  
throdesis 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 arthrodes-  
is gap with Shark Screw®  
diver.



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



# Economic viability and sustainability

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By using Shark Screw®, you save human and financial resources in your clinic and for the entire healthcare system.

## You reduce costs in our healthcare system

For every metal removal avoided and Shark Screw used, you can save the health insurance company and the healthcare system many other costs such as physical therapy, rehabilitation, and sick leave. Your patients benefit from around 15-35 fewer sick days. This is the average number of days lost due to outpatient and inpatient metal removals.<sup>6</sup>

<sup>6</sup> Information from the Upper Austrian Regional Health Insurance Fund Outpatient surgery in Upper Austria in 2016

## You avoid surgical waste

As a Shark Screw® clinic, you reduce the amount of medical waste generated in the operating room! Simply by using the Shark Screw® instrument set. You can easily reprocess it. Your Shark Screw® allografts are also manufactured in such a way that product expiration is virtually impossible. You can store them for five years from the date of manufacture at 4°C to 30°C.

# Training offer

Find out online about the comprehensive SPECIALIST PROGRAM and the latest dates.

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
SC35351	Shark Screw® cut 3.5		35 mm x Ø 3,5 mm	
SC35401	Shark Screw® cut 4.0		35 mm x Ø 4,0 mm	
SC35451	Shark Screw® cut 4.5		35 mm x Ø 4,5 mm	
SC35501	Shark Screw® cut 5.0		35 mm x Ø 5,0 mm	



## Shark Screw® diver

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

Part number	Description	Color	Length	Diameter
SC3550d	Shark Screw® diver		35 mm x Ø 5,0 mm	
SC4550d	Shark Screw® diver long		45 mm x Ø 5,0 mm	



## Shark Screw® suture

Allogeneic thread anchor made from human donor bone / freeze-dried

Part number	Description	Color	Length	Diameter
SC1435s	Shark Screw® mini suture		14 mm x Ø 3,5 mm	
SC1550s	Shark Screw® suture		15 mm x Ø 5,0 mm	
SC2170	Shark Screw® ALC		21 mm x Ø 7,0 mm	
SC2180	Shark Screw® ALC		21 mm x Ø 8,0 mm	
SC2190	Shark Screw® ALC		21 mm x Ø 9,0 mm	



## Shark Screw® tendon

Allogeneic tendon anchor made from human donor bone / freeze-dried

Part number	Description	Color	Length	Diameter
SC1435h	Shark Screw® suture		14 mm x Ø 3,5 mm	
SC1550t	Shark Screw® tendon		15 mm x Ø 5,0 mm	



OP-Videos  
Shark Screw®



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## Shark Screw® instruments

All medical devices listed bear one of the following CE markings:

CE | CE<sub>0483</sub> | CE<sub>0123</sub>

Image	Description
	Shark Screw® handle
	Shark Screw® driver for Cut
	Shark Screw® coupling
 ●	Shark Screw® drill Ø 2.85 mm blue
 ●	Shark Screw® tap Ø 3.5 mm blue
 ●	Shark Screw® drill Ø 3.25 mm yellow
 ●	Shark Screw® tap Ø 4.0 mm yellow
 ●	Shark Screw® drill Ø 3.70 mm red
 ●	Shark Screw® tap Ø 4.5 mm red
 ✕ ●	Shark Screw® drill Ø 4.20 mm black
 ✕ ●	Shark Screw® tap Ø 5.0 mm black
	Shark Screw® knob
	

## 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 unified theory of bone healing and nonunion: BHN theory. *Bone Joint J.* 2016;98-B(7):884-891.

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## Swissmedic Notifikation Allobone®



**Neutromedics AG is ISO 13485 certified.**

**SWISS MEDTECH**  
**Member**

**Neutromedics AG is a member of Swiss Medtech.**

