

Manufactured by Surgebright, Inc.
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Frequently asked questions about Shark Screw[®] grafts

Disclaimer: This document aims at educating sales representatives in a basic manner. These FAQs serve as a teaching aid for clinical support in the use of Shark Screw[®] grafts. The teaching material alone is not a substitute for hands-on training. This document does not replace the instructions for use provided. The use of the grafts, the surgical procedure as well as the postoperative treatment depend on the patient and must be decided individually by the treating physician for each case of application. In doing so, the physician must act after careful examination of the relevant medical literature, according to his/her training, experience and the general health condition of the patient(s).

General questions

1. Shelf Life and storage conditions

5 years at ambient temperature (no temperature monitoring is necessary)

2. What are the advantages/disadvantages of metal implants?

Advantages: high strength, partly cheaper

Disadvantages: Metal abrasion, soft tissue damage, rejection reactions, loosening of implant, reoperations, MRI artefacts, metal removal (2nd surgery in 9-60% of cases) = pain, cost and additional problem (holes), stress shielding (can happen as pressure from metal screw hits bone does not fit together bone can recede, resorption hem), cannot bond with own bone material, length cannot be adjusted, when area of surgery gets infected postop. a biofilm emerges surrounding the implant -> leading to the necessity of removing it

3. What is an osteotomy?

Surgical cutting of bones This procedure is used, for example, to correct the malposition of a joint.

4. What is an arthrodesis?

Therapeutic bony stiffening of a joint.

5. What is a pseudoarthrosis?

So-called "false joint", or nonunion, incorrect healing after fracture, grows together incorrectly or not at all. Shark Screw can treat pseudoarthrosis very well

General information about Shark Screw®

6. What are the general advantages of Shark Screw?

Allogeneic/human bone graft, no need for a hardware removal surgery, savings in the health care system, easy to use, problem solver, remodeling into patient's bone

7. What bone is the Shark Screw graft made from?

Human cortical bone

8. Is Shark Screw made from bovine bone?

No

9. Is Shark Screw a bioresorbable screw?

No (screws does not contain any synthetic materials)

10. What instruments are available to insert the Shark Screw graft?

See product brochure

11. What consequences does the use of the Shark Screw graft have for the hospital from an economic point of view?

Since no metal is implanted during the operation, the hospital does not have to pay for metal removal. This can lead to massive cost savings for the hospital and the health care system.

Less sick leaves, less medication, no refractures after hardware removal

The elimination of the metal removal frees up OR capacities. This shortens the waiting time for patients and the operating times can be scheduled even more effectively.

The small size of the trays reduces storage sizes in hospitals. + sterilization costs are higher with larger instrument sets / one tray for all products of Shark Screw® line

Doctor saves time: screw can be cutted intraoperatively and length can therefore also be adjusted. Doctor does not have to search for the right screw length. (normally: different OR's: different screws).

12. Is the Shark Screw graft a medical device?

No, as it is not a medical device. It is a HCT/P (biologic product)

13. What does the red dot (red is exposed) on inner pouch mean?



Don't worry. It is just an indicator for our sterilization process. If dot is red, Shark Screw was successfully sterilized (low dose gamma sterilization)

14. Does the Shark Screw graft need to be rehydrated before use?

No, it should not be hydrated

15. Are there any studies on the Shark Screw?

Yes, several. Find a maintained list here: [Publications - Shark Screw® \(surgebright.com\)](https://www.surgebright.com/publications-shark-screw)

16. Why are the instruments color coded?

It helps the surgeon and assistance to pick the correct and matching drills and taps. Screw outer package also contain a color dot (blue, yellow, red, black)

17. Actual length of Shark Screw cut?

Shark Screw cut comes in 4 different diameters (3.5, 4.0, 4.5 and 5.0) and a standard length of 35 mm. Length of the thread is 30 mm.

18. Will be longer screws available?

Yes, surgebright is working on introducing Shark Screw divers on the US market. Longest one will be 45 mm. Divers will be headless screws and can be countersunk (e.g. for calc slide etc)

Timeline and go to market dates will be shared with you.

Biomechanical properties

19. What loads can Shark Screw withstand?

See the biomechanical study and the overview. Shark Screw is not designed for weight bearing directly after the surgery. Post operative Management depends on the patient and indication.

20. Why is Shark Screw not a compression screw?

Compression is necessary when using metal screws and plates in order to create an area where the bone fragments connect directly so the fragments can „grow“ together. When using Shark Screw -> the Screw itself creates a large and stable bone bridge gaping the fragments. Still surgeons need to be advised to keep the gap as small as possible.

21. How does Shark Screw compare in biomechanics to metal, PLL and magnesium?

Shark Screw swells after insertion and is transformed/integrated into the patient's own bone. Metal, PLL and magnesium either dissolve, are not biological material (risk of rejection), create osteolysis, often loose stability. This means that Shark Screw increases in strength whereas bioresorbable implants get weaker over time.

22. What is the difference between a compression screw and a set screw (like Shark Screw)?

Compression screw can create compression

A set screw keeps the given compression, which is given by the surgeon, and which is temporarily held by a k-wire

23. Why is Shark Screw not cannulated?

This would weaken the screw and have a negative effect on biomechanical properties

24. Is the Shark Screw a self-tapping screw?

No, you need a separate tap, which is used first. Only then can the screw be inserted.

25. What to do if fixation isn't that stable (e.g. bad patient bone quality)

Don't worry. Screws underwent a freeze-drying process. Screws will soak surrounding fluids. Studies showed that screws swelled by 2 % in outer diameter after only 72 hours. First effects can be seen after 1-4 hours. This property will increase stability of fixation.

26. Are Shark Screw grafts rotationally stable?

Yes! Due to very dense thread (small thread pitch) of screws, they hold compression and also show very good rotational stability even when using one single screw.

Surgery related questions about Shark Screw

27. Can Shark Screw be used like a pin?

No, it cannot be used as a pin or nail.

28. What can be done if the screw breaks during the operation?

Generally, screws do not break because instrumentation is perfectly matched. If the thread is not rinsed carefully - because of bone residues, it might be possible. When inserting in the screw, at some point the end of the drillhole is reached – if the surgeon tries to go further than that, the screw head will break. → Use Fluoroscopy + marking desired inserting depth directly on screw.

If the surgeon wants to remove this screw, it can be pinned with a K-wire and then it can be drilled over in order to remove it.

If a screw is used and the head breaks off, the screw can be screwed in further with flat-nose pliers.

If the osteotomy is stable and the screw head breaks off – the screw can be left in situ.

29. Hint for drilling with k-wire

When using a 1.2 / 1.1 mm k-wire, it is possible that the k-wire gets bent while insertion, which makes drilling difficult – and may lead to drilling onto the k-wire. To avoid that the surgeon can use a stiffer 1.6mm k-wire first – remove it and then use and replace the 1.2 / 1.1 mm. (Attention: instruments are cannulated with 1.3 mm)

30. How can you tell if the k-wire is blocking the drill?

If there is resistance, do not drill against it with force. The drill is sharp and it should be progressing smoothly – if it stops going deeper, the k-wire might be in its way. So better have a look and change the k-wire

31. Can the surgeon continue working with a yellow tap after pre-drilling with a red drill?

No, the colors must always match.

32. Can Shark Screw be „re sterilized” after opening the packaging and not using it?

No! Screws must be discarded

33. Is the thread cut by machine or by hand?

Depending on the indication, by hand or machine. Depending on the thickness of the existing bone. The advantage of thread cutting by machine is, that you can guide in the axial direction, where you want to go.

34. What should I pay attention to when cutting the thread?

Depending on the indication, color marking, even cutting, do not overtighten the thread, cut the thread carefully slowly and calmly without pressure. Stop when end of drilled hole is reached, otherwise you will overcut thread (problems when inserting Screw → no matching between screw thread and cut thread).

Pay attention to rotational directions when cutting thread!!

Clockwise → going in

Counterclockwise → going out

35. What should I pay attention to when checking the image converter after each surgical step?

Depending on the indication, check the position of the wires, correct reduction of fragments, correct positioning of the wire for the Shark Screw, sufficient bone bridge from the operated bone (so that no fragment breaks off).

36. Which surgery can be performed with Shark Screw?

General: Arthrodesis, pseudoarthrosis, fractures, osteochondral defects. An overview can be found in surgical guidance documentation.

37. What happens if I forget to rinse the drilled and tapped channel?

Shark Screw can become interlocked and difficult to insert; possibly head can break off.

38. Can the surgeon cut off the head of the screw?

Yes, in any case it is necessary to cut it off, and not to leave it, because it would destroy the nearby soft tissue. The head has only the function to insert the screw but does not work like a head of a metal screw (“bite”).

39. Is it possible to fix a metal plate as metal with the screw?

No, you can't fix metal plates with the shark screw.

40. Is it possible to use Shark Screw and create compression?

The screw holds the given compression, which is created by the surgeon, this needs to be transfixed with k-wires or compression clamps.

41. What instruments are used to cut the screw?

Oscillating saw, luer rongeurs, burrs etc.

42. What happens if small parts of the screw are protruding into soft tissue?

Nothing to worry about, these screw parts will be remodeled by the patient's metabolism within some months.

Questions related to instruments

43. Are instruments shipped sterile?

No, the instruments must be sterilized according to the supplied instructions before the first use

44. Are all instruments reusable?

Yes, all instruments provided are reusable. Instruments must be sterilized according to the supplied instructions before reuse

45. What should be done with broken Instruments?

Broken instruments should be reported to surgebright. This report may should include: Ref. Nr. of instrument, LOT Nr., known reason for failure, harmed patients
After that the instruments can be disposed.

46. Can the claw coupling (Shark Screw® coupling) be used in conjunction with an active insertion instrument?

No, due to regulatory reasons the Shark Screw® coupling is not intended to be combined with active insertion instruments. surgebright assumes no liability when this combination is used.

47. What can be done if the Shark Screw® coupling breaks during application?

Generally, the instrument is designed in such a way that the claws do not break during the insertion process. Fractures of the claws are based in most cases on an application error. To avoid fractures of Shark Screw® coupling:

- Ensure that rinsing has been performed after thread cutting
- Ensure axial screwing in
- Screwing in should be done in one go
- Screws in situ should not be repositioned (Shark Screw swells after insertion!)
- Note the depth marking while screwing in
- Avoid screwing further in, while the end of the drillhole is reached

If a claw has fractured, the fragment should be removed from the surgical field e.g. with suction. The screw may can be inserted further using the second Shark Screw® coupling provided.

48. How to remove a k-wire from the instruments?

Use a 1,6 k-wire and try to push out the stuck 1,2 mm k-wire or use a flat-nose pliers to pull out the stuck k-wire.

Keep also in mind that the instruments are not designed for 1,6 mm k-wires.