Surgical Technique

Removal of icotec Carbon/PEEK pedicle screws using trephines (BAAT Medical)

INTENDED USE

The trephines are intended for the removal of icotec Carbon/PEEK pedicle screws which are stuck or broken and cannot be extracted with standard instrumentation.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

USE INFORMATION

The trephines can only be used by surgeons who are fully familiar with the underlying surgical technique. The operating surgeon must take care not to use the instruments to exert inappropriate stress on the patient or the implants and must scrupulously comply with any operating procedure described in the surgical technique provided. For example, the forces exerted when repositioning an instrument in-situ must not be excessive as this is likely to cause injury to the patient.

To reduce the risks of breakage, it is not allowed to impact the instrument. Extreme care must be taken when the devices are used near vital organs, nerves or vessels.

The trephines are made of stainless steel (1.4028) and are equipped with a standard AO coupling and may only be connected to a compatible power tool. The trephines are designed for use only in counterclockwise rotation! They are not offered sterile and must therefore be cleaned and sterilized prior to use. Disinfection and sterilization specifications can be found in the BAAT Medical IFU (18019BR190710_IFU_rev2 (2020)).

CLINICAL BENEFIT

In case of a screw breakage the remaining screw part could be removed and therefore another screw could be placed in the same position to enable revision of the icotec pedicle system.

WARNINGS

- The trephines are not offered sterile and must therefore be cleaned and sterilized prior to use. Disinfection and sterilization specifications can be found in the BAAT Medical IFU (18019BR190710_IFU_rev2 (2020)).

- The surgeon should strictly follow the recommendations in the surgical technique. All staff involved should be familiar with the surgical procedures associated with using the Trephines to avoid adversely affecting device performance or surgical outcome.

- The Trephines are provided as single use instruments only, and are not to be reused for multiple procedures as this might adversely affect device performance (sharpness). If the Trephine was used during a procedure it cannot be used for another procedure because it cannot be guaranteed that the Trephine is clean and sterile after reprocessing when it is used. The Trephines can be used for removal of multiple pedicle screws during the same procedure. The Trephines can be reprocessed in case the Trephine was not used during the procedure.

- The Trephine is available in different sizes. Correct size selection is critical to the surgical outcome. Use of a wrong size trephine can lead to injury. See Catalogue

- Make sure that the Trephine is aligned with the screw. Use a K-wire for the alignment of the trephine in case of cannulated screws. The correct size K-wire (Length: maximum 150 mm diameter: 1.6 mm) needs to be used.

- To avoid heating induced damage of the surrounding tissue the Trephine should only be used at low RPM. During the Procedure the Trephine needs to be cooled with Ringer solution.

- The trephine is designed for counterclockwise rotation only. Incorrect direction of rotation can result in anterior migration of the pedicle screw which may cause injury.

- Apply minimal pressure on the trephine during drilling to avoid anterior migration of the pedicle screw. If the screw migrates anteriorly, immediately stop the procedure. Anterior migration of the pedicle screw may cause injury.

- The particles generated during overdrilling of the Trephine need to be flushed and aspirated.

- Potential risks identified with the use of the Trephines may require additional surgery include: Device fracture, fracture of the vertebra, neurological injury, vascular or visceral injury.

- The use of Trephine may cause injury to the patient.

- Don’t use the trephine in situations where the screw has not been placed correctly within the pedicle and has contact to the dura or nerve root.

DISPOSAL

Used single-use Trephines must be disposed of in accordance with the regulations applicable at the location of use.

RETURN

The Trephines may be returned only after consulting the distributor. All returned products must be decontaminated or sealed in the unopened original packaging.

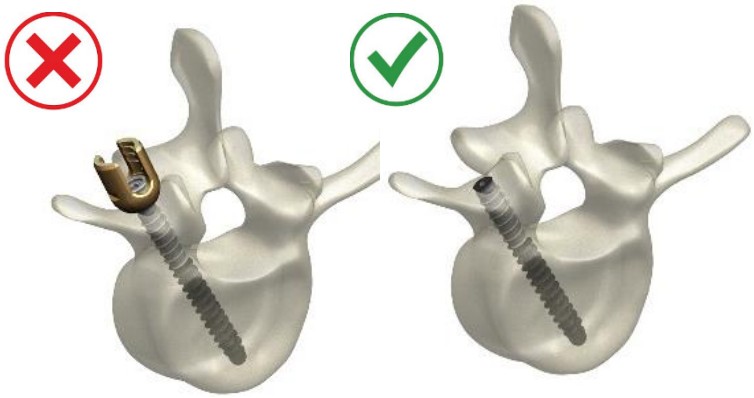
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the State in which the user and/or patient is established.

DISCLAIMER

The recommendations for storage, care, maintenance, reprocessing and sterilization have been carefully checked, conform to international standard ISO 17664 and are considered to be appropriate. The person who actually reprocesses the instruments is responsible for achieving the desired results with the provided equipment, materials and personnel in the reprocessing facility. The user is responsible for complications or other negative consequences which may result from reasons such as an incorrect indication or surgical technique, inappropriate material selection, inappropriate application or handling of the instruments, or any kind of application that is not described in the intended uses and any incorrect use, and cannot be blamed on the manufacturer, importer or supplier. No liability is accepted in the event of failure to observe the instructions in this Surgical Technique.

SURGICAL STEPS

Perform preoperative imaging (CT or MRI) to rule out that the screw has breached the medial wall of the pedicle and has contact to the dura or a nerve root. Overdrilling such malpositioned screw position may cause dura mater and nerve root damage.

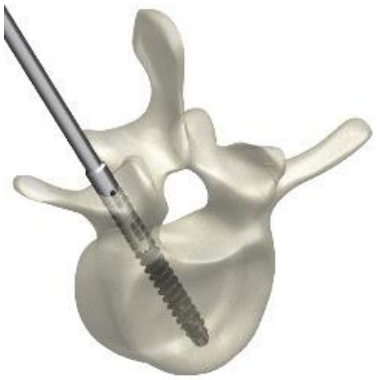


The tullip must be removed before the trephine can be used. This is done with a standard surgical instrument (e.g., pliers).

Depending on the implanted screw diameter the corresponding size of the trephine is to be chosen. The size of the screw is engraved on the tullip of the screw.

For the successful application of the trephine, a good centration to the screw is essential. This can be conducted through a K-wire (maximum length of 150 mm, diameter of 1.6 mm) in case of cannulated screws.

The trephine is drilled counterclockwise over the shaft of the screw. For drilling, a standard powered tool with an AO coupling is used.



The counterclockwise rotation is important as it prevents the screw from being driven further into the bone.

Flushing and aspirating during and after the use of the trephine is required to reduce the particles amount remaining in the patient.
The generated heat, caused by the friction shall be reduced by using Ringer's solution.

During overdrilling of the titanium-coated section of the screw, the adhering bone is separated and the screw automatically extracted as a result of the counterclockwise rotation and the friction between the core and the trephine.

The outer diameter of the Trephine can differ from the screw size. An overview of the outer diameters of the Trephine is shown below. The diameter of the pedicle screw tip is smaller. Therefore if the tip of the screw is broken a Trephine one sizes smaller should be used.

In case multiple screws are removed with the Trephine in the same surgery, check complete removal of the screw and possible bone parts from the Trephine and check its sharpness.

CATALOGUE

Reference	Product name	Screw size (broken head)	Screw size (broken tip)
42-440-45	Trephine for Revision, Ø 4.5 mm Screw	∅ 4.5 mm	∅ 5.5 mm
42-440-55	Trephine for Revision, Ø 5.5 mm Screw	∅ 5.5 mm	∅ 6.5 mm
42-440-65	Trephine for Revision, Ø 6.5 mm Screw	∅ 6.5 mm	n.a
42-440-75	Trephine for Revision, Ø 7.5 mm Screw	∅ 7.5 mm	n.a