IMPLANTEX®

Product information

Instruments for removing screws

Königsee
Implantate

DO YOU HAVE THE RIGHT EQUIPMENT TO HAND IN EMERGENCY SITUATIONS?

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Preface

Königsee Implantate GmbH is synonymous with intensive research and development work in the field of traumatology, orthopaedics and spinal column surgery. By working together with experienced doctors and examining clinical studies, we develop high-quality implants which are used around the world to treat bone fractures.

Our corporate philosophy combines quality, efficiency, and precision in the production process, as well as first-class customer support and excellent value for money, with our focus on customer requirements. Successful patient treatment is the yardstick by which we measure all of our developments.

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THE SOLUTION: IMPLANTEX®

IMPLANTEX® was developed to remove undamaged, damaged, over-tightened or broken-off screws. It can be used for:

- Angle-stable screws
- Cortical screws
- Cancellous screws
- Set screws
- Cannulated screws
- Locking screws
- Locking bolts

INTRODUCTION

One set of instruments for all cases

IMPLANTEX® is used to remove both undamaged and damaged bone screws made of titanium, titanium alloys or steel. This selection of instruments allows individual solutions to be developed for different emergency situations which require a screw removal.

Below, you will find information on how to correctly handle the instruments and recommendations as to which instruments you should choose for common emergency situations.

IMPLANTEX® allows you to remove a multitude of different screw types – be they mini, small or large fragments (with diameters measuring from 1.5 mm to 7.0 mm). The set also includes important instruments for bone surgery, handles with quick coupling and interchangeable inserts.

IMPLANTEX® is organised by screw diameter and offers the sizes you will need for mini, small and large fragments. All the screwdriver inserts conform to the valid standard dimensions and are at least compatible with the screws listed in the specifications ASTM F543, ISO 5835, ISO 10664:2005 and ISO 9268.

The instruments with quick coupling connection are used in a modular fashion together with the handles featuring jaw chucks, so they can be changed both quickly and safely. You must ensure that you choose the right size for the screw head.

The handles allow for safe and ergonomic handling while driving into and removing the screw, such that high torques can be transferred to the screw.

Other instruments for exposing the screw are available as an option.

IMPORTANT:

In addition to reading the present information, we expressly advise receiving instruction on handling these instruments from an experienced operator!

GENERAL USAGE INFORMATION

USE
GENERAL INFORMATION

Please read our General Operating Manual for Instruments and Implants in addition to this information. You can read the manual on our website at www.koenigsee-implantate.de or request to receive it as a document.

This manual provides a description of the instruments and information on how to handle them. In any case, we advise that you receive instruction from an experienced operator!

All of the instruments are coordinated to one another and are allocated to the standard classifications – namely mini, small and large fragment. We advise that the operator familiarises himself with the implant type, implant material, screw dimension, manufacturer, etc., before removing any screws so as to prepare a suitable set of instruments. Other instrument sizes which also allow users to remove screws with larger diameters are available as an option.

Should you require further information about handling and/or assembling the instruments, our field service staff and employees in our Product Training department will be more than happy to assist you.

STERILITY
NON-STERILE DELIVERY

Our instruments and implants are delivered in a non-sterile state. Please refer to our General Operating Manual for recommendations on cleaning and sterilisation. Please check that all of the products supplied are in full working order and not damaged before using them!

WARNINGS
DAMAGES

Königsee Implantate GmbH accepts no responsibility for damages and/or injuries caused by improper use or failure to comply with the manual. All of the warning notices and precautionary measures listed must be observed!

In principle, IMPLANTEX® can be used to remove:

- Undamaged screws
- Screws with a damaged drive
- Head locking screws blocked in the plate
- Broken screws
- Screw fragments remaining in bones

SAMPLE CASES

EMERGENCY SITUATION 1

A suitable screwdriver is required

IMPLANTEX® contains screwdrivers in a variety of shapes and sizes which cover most of the screw head geometries available on the market.

• To begin with, if necessary completely release the screw head from the tissue residue using a sharp hook!

• Before inserting the screwdriver, ensure that both the screw head and the screwdriver are intact!

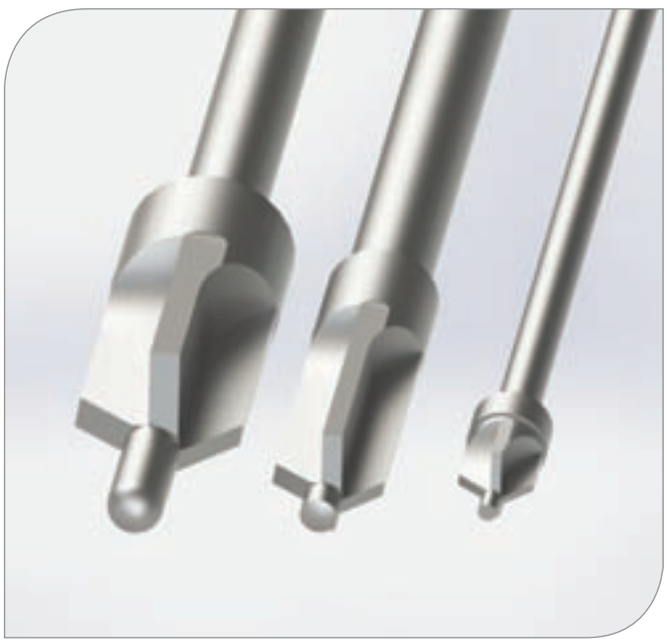
• Select the right screwdriver for the screw head. Guide the screwdriver as deep into the screw head as possible in one axis with the screw shaft.

• Under certain circumstances, the screwdri-ver's position in the screw head can be optimised by tapping the handle gently with a hammer.

• Then, applying slight counterpressure, the screwdriver is turned by hand in an anti-clockwise direction.

• If removal is not possible in this way, you can choose from a multitude of instruments to remove damaged screws.

THE RIGHT INSTRUMENT



Countersinks

Countersinks are required to reach screw fragments located in bone. A conical channel to the fragment is created using the cutter.

Our headspace cutters are available in lengths of 57 mm, 72 mm and 115 mm for screws with diameters of 1.5 mm to 6.5 mm.

Screwdrivers for extraction

Screwdrivers for extraction of screws with a left-hand thread are used to quickly and safely remove over-tightened screw heads. The hardened material in a slim, conical shape has a cutting left-hand twist.

Our removal instruments with quick coupling are to be used for screws featuring a width across flats of 1.5 mm to 3.5 mm.

For removing intact screws

Cross-head screwdriver with plastic handle
- In the sizes 1.5 / 2.5 / 3.5

Screwdriver with plastic handle for six-lobe
- In the sizes 6 / 8 / 15 / 25

Hexagon screwdriver with handle
- For screws with a diameter of 1.5 to 2.0 mm; AF 1.5; length 215 mm; conical
- For screws with a diameter of 2.7 to 4.0 mm; AF 2.5; length 215 mm; conical
- For screws with a diameter of 4.5 to 7.0 mm; AF 3.5; length 215 mm

Screwdriver insert for quick coupling for hexalobular socket 10

FOR ALL CASES

Screw shaft extractor

Screwdriver for extraction from shank of screws are used to remove screw residue in bone. The tool, which features a conically milled inner profile, is coordinated to the most commonly used screw diameters.

Our screw shaft extractors with quick coupling are to be used for screws with a diameter of 1.5 mm to 7.0 mm.

Hollow cutter

Hollow cutters are required when the screw shaft needs to be over-milled to extract the screw. A cylindrical channel is thereby created around the screw shaft.

Our hollow cutters, which are coordinated to the screw diameters for quick coupling, are available for screws with a diameter of 1.5 mm to 7.0 mm.

Optional instruments

Holding forceps
- For screws in mini, small and large fragment

Metal hammer; 300 g

T-handle piece with quick coupling;
- Length 93.5 mm

Coupling element
- For dental coupling on quick coupling

Chisel with PPSU handle
- Blade width 7 mm, total length 180 mm

SAMPLE CASES

EMERGENCY SITUATION 2

Screwdriver has no grip in the over-tightened screw head

Ensure that you always turn in an anti-clockwise direction and only apply a slight amount of pressure.
Only use the handles with quick coupling. Do not use any active drilling machines! If the extractor can not be driven in deep enough, the screw head can be drilled open slightly with a drill.
Screw heads with a cross-tip can not be removed using the removal instruments with left-hand thread due to their geometry!

The screwdriver used has no grip in the screw due to a damaged or over-tightened screw head geometry (Fig. 1).

IMPLANTEX® includes removal instruments with lefthand thread (Fig. 3, item no. 2.948. xx), which cut into the screw head and enable removal in an anti-clockwise direction (see Fig. 2).

• Select the right removal instrument for the screw diameter and clamp it into the T-handle such that the insert audibly snaps into place.

• Insert the removal instrument as deep into the screw to be removed as possible.

• Now, applying constant pressure, the screw is turned in an anti-clockwise direction in the same axis as the screw until the left-hand thread is firmly fixed in the damaged screw head. If sufficient torque is transferred, the screw can be removed.

Figure 1

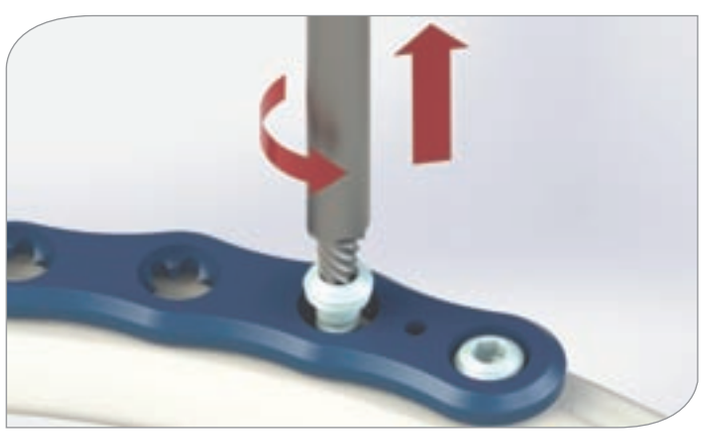


Figure 2

Depending on the size of the screw to be removed, we advise using the following instruments:

Mini fragment:
Removal instrument with left-hand thread for AF 1.5
Item no. 2.948.15A

Small fragment:
Removal instrument with left-hand thread for AF 2.5
Item no. 2.948.25A

Large fragment:
Removal instrument with left-hand thread for AF 3.5
Item no. 2.948.35A

Figure 3

Königsee Implantate

EMERGENCY SITUATION 3

Screw head blocked in the plate
Instruments have no grip

Figure 4

Figure 5

If the screw cannot be removed from the bones and plate using the screwdriver or the extractor, the screw can be drilled open to loosen the plate from the bone (Fig. 4).

To this end, we have provided coated drills in a variety of sizes (Item no. 2.9042.xx) which can be used to drill open the damaged screw head as far as the shaft.

• The drill is clamped in the drilling machine using a suitable (Jacobs or three-jaw) collet chuck. It should be used when rotating and in one axis with the screw head.

• If the drill has reached the base of the screw head, it should be drilled against the screw with in creased pressure so as to achieve good chip formation.

• Pre-drilling takes place as far as the underside of the plate until the screw head loosens from the shaft when the plate is lifted (Fig. 5).

• Ensure that the drill is sufficiently cooled and that the metal swarf produced is extracted! The drill pressure should occasionally be relieved to prevent excessive heating.

Opening up of screw heads always causes wear on the drill's cutting element. We therefore advise replacing the drill with a new one after single use to guarantee optimum performance.

Depending on the size of the screw to be removed, we advise using the following instruments:

Mini fragment:
• Drilling with a DLC drill Ø 2.5 mm
Item no. 2.9042.025

Small fragment:
• Pre-drilling with a DLC drill Ø2.5 mm
Item. no. 2.9042.025
• Drilling with a DLC drill Ø4.0 mm
Item no. 2.9042.040

Large fragment:
• Pre-drilling with a DLC drill Ø 3.0 mm
Item no. 2.9042.030
• Drilling with a DLC drill Ø 5.0 mm
Item no. 2.9042.050

DLC-COATED DRILLS

Our special metal drills are equipped with a bio-compatible, wear-proof and corrosion-resistant DLC coating.

DLC = diamond-like carbon

SAMPLE CASES

EMERGENCY SITUATION 4

Removing drilled-out or broken-off screws – screw shaft visible


Figure 6

The screw has broken off in the bone or the head has been drilled out as described on page 9. In both cases the remaining screw shaft is still visible (Fig. 6).

If the screw shaft is protruding from the bone, it is grasped with a pair of holding forceps (Fig. 11) and removed by turning in an anti-clockwise direction. If the remaining screw shaft is slightly raised above the bone surface, the bone a few millimetres around the screw shaft can be removed with a hollow chisel (Fig. 12) to create a sufficient contact surface between the forceps and the shaft.

If the shaft has broken off such that it is flush with the bone surface but still visible, proceed as follows:

- The size of the hollow cutter must be chosen such that it is suitable for the screw diameter.
- The cutter is clamped into the T-handle (item no. 10.305.05) and placed in a central position above the remaining shaft on the bone in one axis with the screw.
- Applying constant pressure, turn the cutter in an anti-clock-wise direction such that a cylindrical channel is created around around the screw shaft (Fig. 7).
- Once the channel has been prepared, the suitable screw shaft extractor (item no. 2.9481.xx) is positioned above the exposed shaft and it is removed while applying constant pressure and turning in an anti-clockwise direction (Fig. 8).
- We advise using the T-handle. A drilling machine should only be used at very slow speeds.

Depending on the size of the screw to be removed, we advise using the following instruments:

Mini fragment:
Hollow cutter for screws with a diameter of 1.5 mm to 2.0 mm
Item no. 2.9101.15
Screw shaft extractor for screws with a diameter of 1.5 mm to 2.0 mm
Item no. 2.9481.15

Small fragment:
Hollow cutter for screws with a diameter of 2.7 mm to 4.0 mm
Item no. 2.9101.35
Screw shaft extractor for screws with a diameter of 2.7 mm to 4.0 mm
Item no. 2.9481.27

Large fragment:
Hollow cutter for screws with a diameter of 4.5 mm to 7.0 mm
Item no. 2.9101.45
Screw shaft extractor for screws with a diameter of 4.5 mm to 6.0 mm
Item no. 2.9481.45

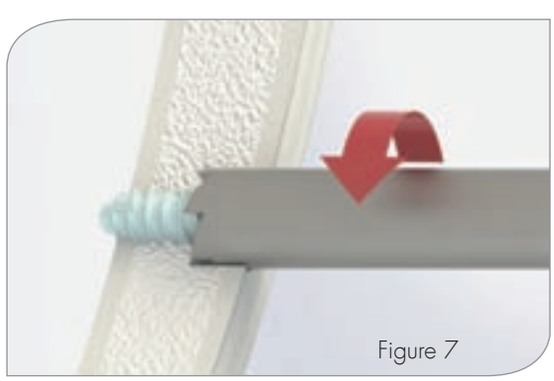


Figure 7

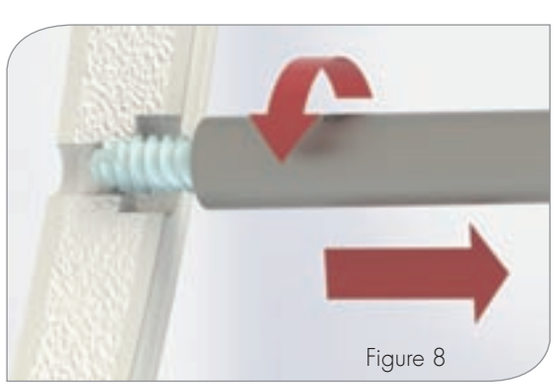


Figure 8

EMERGENCY SITUATION 5

Removing drilled-out or broken-off screws – screw shaft invisible

Figure 9

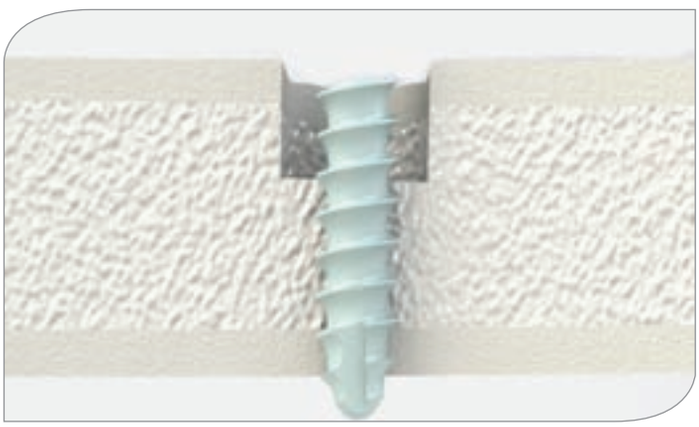


Figure 10

The screw has broken off in the bone or the head has been drilled out as described on page 9. In both cases, the remaining screw shaft is no longer visible (Fig. 9).

• The bone above the screw can be removed in a conical shape using a headspace cutter so as to expose the centre of the screw shaft. Alternatively, the hollow cutter must be placed in a central position above the screw shaft.

• The size of the hollow cutter must be chosen such that it is suitable for the screw diameter.

• The cutter is clamped into the T-handle (item no. 10.305.05) and placed in a central position above the remaining shaft on the bone in one axis with the screw.

• Applying constant pressure, turn the cutter in an anti-clock-wise direction such that a cylindrical channel is created around around the screw shaft (Fig. 7).

• Once the channel has been prepared, the suitable screw shaft extractor (item no. 2.9481.xx) is positioned above the exposed shaft and it is removed while applying constant pressure to the handle and turning in an anti-clock-wise direction (Fig. 8).

• We advise using the T-handle. A drilling machine should only be used at very slow speeds.

• When using a drilling machine, ensure that the drill is sufficiently cooled and that any metal swarf produced is extracted!

Depending on the size of the screw to be removed, we advise using the following instruments:

Mini fragment:
Hollow cutter for screws with a diameter of 1.5 to 2.0 mm – item no. 2.9101.15

Screw shaft extractor for screws with a diameter of 1.5 to 2.0 mm – Item no. 2.9481.15

Countersink with a diameter of 1.5 to 2.0 mm – item no. 10.505.15

Small fragment:
Hollow cutter for screws with a diameter of 2.7 to 4.0 mm – Item no. 2.9101.35

Screw shaft extractor for screws with a diameter of 2.7 to 4.0 mm – Item no. 2.9481.27

Countersink with a diameter of 2.7 to 4.0 mm – Item no. 10.515.40

Large fragment:
Hollow cutter for screws with a diameter of 4.5 to 7.0 mm - Item no. 2.9101.45

Screw shaft extractor for screws
With a diameter of 4.5 to 6.0 mm – Item no. 2.9481.45

Countersink with a diameter of 4.5 to 6.5 mm – Item no. 10.515.81

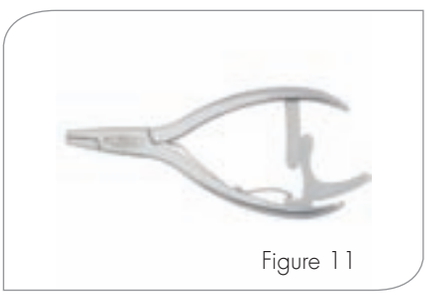


Figure 11

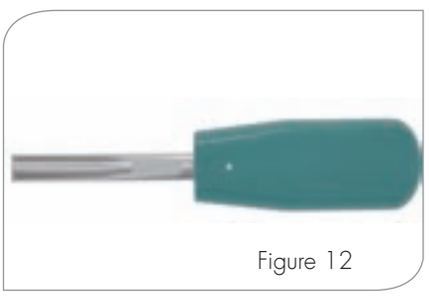
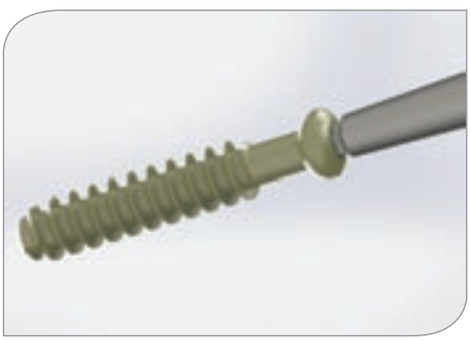


Figure 12

SAMPLE CASES

EMERGENCY SITUATION 6

Removing cannulated screws with a partial or full thread



A: Screws with an intact head, removal using the suitable screwdriver

• To begin with, if necessary completely release the screw head from the tissue residue using a sharp hook!

• Before inserting the screwdriver, ensure that both the screw head and the screwdriver are intact!

• Select the right screwdriver for the screw head. Guide the screwdriver as deep into the screw head as possible in one axis with the screw shaft.

• Under certain circumstances, the screwdriver's position in the screw head can be optimised by tapping the handle gently with a hammer.

• Then, applying slight counterpressure,the screwdriver is turned in an anti-clockwise direction.

• If removal is not possible in this way, you can choose from a multitude of instruments to remove damaged screws.

B: Inner thread in the screw head defective

Applying slight pressure, drive the removal instrument into the defective head in an anti-clockwise direction. If the screw does not loosen, drill the screw head open using the DLC twist drill and remove it.

Remove the remaining screw shaft as follows:

Partial thread screws:
• If the shaft is not entirely embedded in the bone, it is grasped and removed using a pair of alligator forceps.
• Expose the screw shaft using the hollow cutter
• If the thread is visible: Position the shaft extractor above the screw shaft and, applying slight pressure, turn in an anti-clockwise direction until the screw shaft can be removed
• Alternatively: Drive / cut the suitable removal instrument into the cannulation of
the remaining screw shaft in an anti-clockwise direction and remove it from the bone together with the shaft

Full thread screws:
• Expose the screw shaft using the hollow cutter
• Position the shaft extractor above the screw shaft and, applying slight pressure, turn in an anti-clockwise direction until the screw shaft can be removed
• Alternatively: Drive / cut the removal instrument into the cannulation of the remaining screw shaft in an anti-clockwise direction and remove it from the bone together with the shaft.

C: Screw head broken off, shaft still visible

• Expose the screw shaft until there is sufficient space around the screw shaft to grasp it with the alligator forceps and remove in an anti-clockwise direction.

D: Screw head broken off, shaft still visible

• Expose the screw shaft until there is sufficient space around the screw shaft to grasp it with the alligator forceps and remove in an anti-clockwise direction.

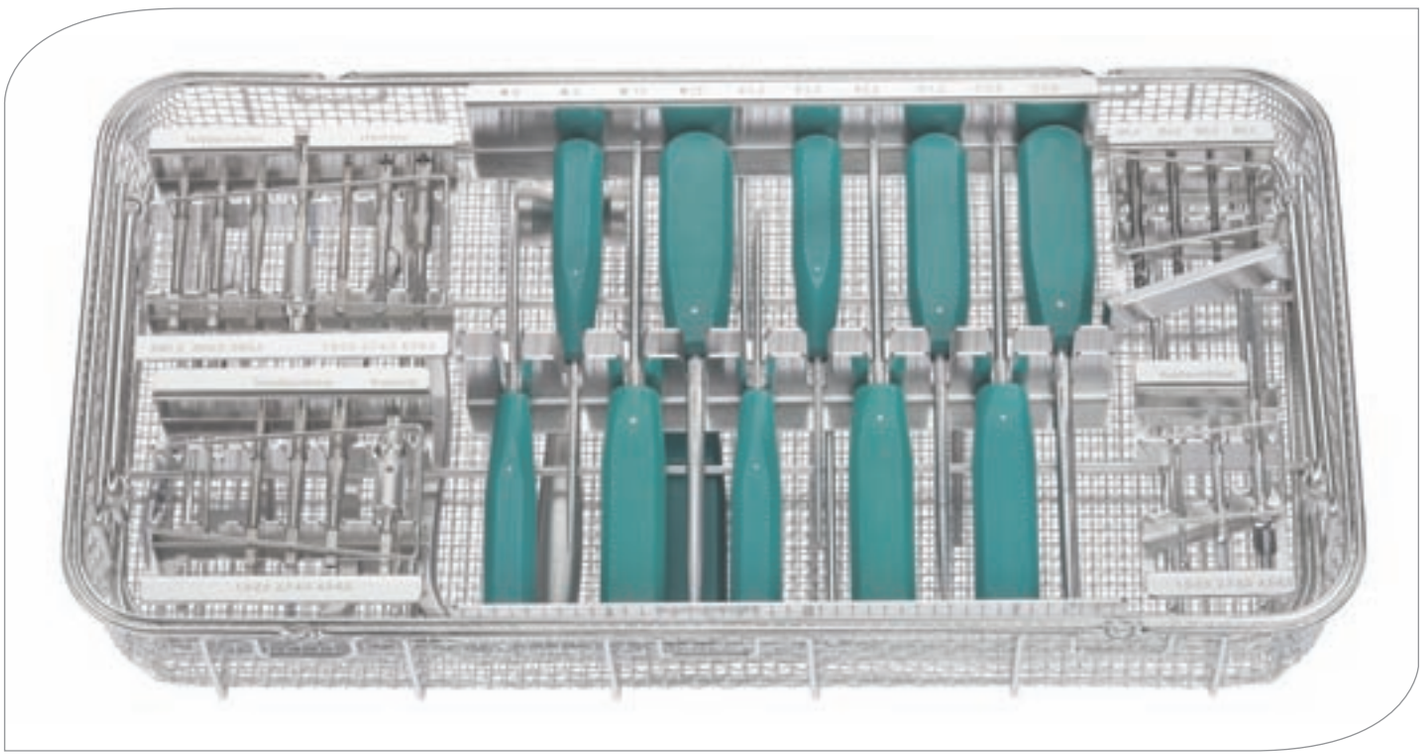
• Then the screw shaft is exposed using the hollow cutter.

• Position the shaft extractor above the screw head and, applying slight pressure, turn it in an anti-clockwise direction until the screw shaft is removed with it.

NOTE
FRACO SCREWS

IMPLANTEX® can also be used to remove our fracture compression screws (fraco screws).
Since the cannulated screws have a thin wall thickness, when performing removal work you should only apply a measured degree of force, because these screw can break faster than screws made of solid material!

OUR IMPLANTEX® OPERATION SET



The complete set for all areas of application!

The IMPLANTEX® complete operation set offers users all the important instruments they'll need to successfully remove metal.

With this set, operators are well-equipped in any situation, meaning they can respond to a multitude of situations and complications when removing implants.

Our developers have created a targeted selection of instruments in close collaboration with clinical users. You can thus choose from individual options for removing bone screws. Our instruments allow you to remove different screw types with a diameter of 1.5 mm to 7.0 mm (mini, small and large fragments).

The instruments are stored in our perforated baskets which are optimally suited to multiple sterilisation operations.

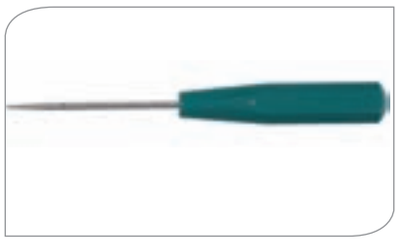
We also offer you a modular system and a version for veterinary activities as smaller variants.

INDIVIDUAL SOLUTIONS ARE OUR STRENGTH!

THE IMPLANTEX® operation set was specially designed for use in hospitals. We also offer you individual solutions for specialised medical fields in the form of the IMPLANTEX® modular and IMPLANTEX® vet sets.

ITEMS INCLUDED IN THE SET

Cross-head screwdriver



2.9366.15	Cross-head screwdriver with plastic handle; size 1.5
2.9366.25	Cross-head screwdriver with plastic handle; size 2.5
2.9366.35	Cross-head screwdriver with plastic handle; size 3.5

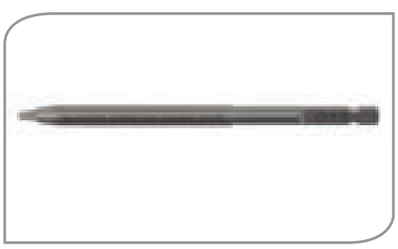
Screwdriver for six-lobe

2.9386.06	Screwdriver with plastic handle for six lobe 6
2.9386.08	Screwdriver with plastic handle for six lobe 8
2.9386.15	Screwdriver with plastic handle for six lobe 15
2.9386.25	Screwdriver with plastic handle for six lobe 25

Hexagon screwdriver with handle

2.9406.15	Hexagon screwdriver for screws with ∅ 1.5 to 2.0 mm; AF 1.5; con.
2.9406.25	Hexagon screwdriver for screws with ∅ 2.7 to 4.0 mm; AF 2.5; con.
2.9406.35	Hexagon screwdriver for screws with a diameter of 4.5 to 7.0 mm; AF 3.5

Screwdriver for extraction of screws



2.948.15A	Screwdriver for extraction of screws for quick coupling; AF 1.5
2.948.25A	Screwdriver for extraction of screws for quick coupling; AF 2.5
2.948.35A	Screwdriver for extraction of screwsfor quick coupling; AF 3.5

Drill bit, DLC-coated

2.9042.025	Drill bit; ∅ 2.5 mm x 46 mm; spiral length 14 mm; double spiral
2.9042.030	Drill bit; ∅ 3.0 mm x 50 mm; spiral length 17 mm; double spiral
2.9042.040	Drill bit; ∅ 4.0 mm x 54 mm; spiral length 22 mm; double spiral
2.9042.050	Drill bit; ∅ 5.0 mm x 62 mm; spiral length 26 mm; double spiral

Hollow cutter

2.9101.15	Hollow cutter with hexagon for screws with a diameter of 1.5 mm to 2.0 mm
2.9101.35	Hollow cutter with hexagon for screws with a diameter of 2.7 mm to 4.0 mm
2.9101.45	Hollow cutter with hexagon for screws with a diameter of 4.5 mm to 7.0 mm

Screw shaft extractor

2.9481.15	Screw shaft extractor for quick coupling for screws with a diameter of 1.5 mm to 2.0 mm
2.9481.27	Screw shaft extractor for quick coupling for screws with a diameter of 2.7 mm to 4.0 mm
2.9481.45	Screw shaft extractor for quick coupling for screws with a diameter of 4.5 mm to 6.0 mm

Countersink

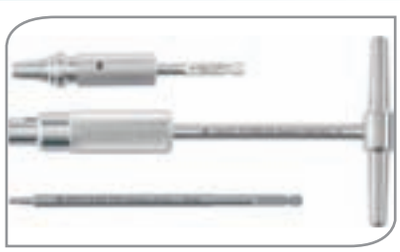
10.505.15	Countersink for dental coupling; length 57 mm; for screws with a diameter of 1.5 mm / 2.0 mm
10.505.40	Countersink for quick coupling; length 72 mm; for screws with a diameter of 2.7 mm / 3.5 mm / 4.0 mm
10.505.81	Countersink for quick coupling; length 115 mm; for screws with a diameter of 4.5 mm / 6.5 mm

Other instruments

2.975.03	Hammer made of metal; weight 300 g
10.2406.05	Hollow chisel with plastic handle
10.426.10	Screw holding forceps,mini fragment
10.426.20	Screw holding forceps,large fragment

Accessories

10.305.10	Coupling element for dental coupling on quick coupling
10.305.05	T-handle piece with quick coupling; length 93.5 mm
2.941.T10	Screwdriver insert for quick coupling for hexalobular socket 10
19.510.00	Perforated autoclavable container with inset for IMPLANTEX®



Item. no. for the complete operation set: 19.511.00

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Certified pursuant to
EC Directive 93/42/EEC
DIN EN ISO 13485

IMPLANTEX®
Product information