OPERACE

Screw Extraction System

Surgical Technique

OPERACE
by PB Swiss Tools

Swiss Made

PB SWISS TOOLS

Johnson&Johnson
MedTech

AO approved by AO Technical Commission

MRI Information

The OPERACE Screw Extraction System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artifact in the MR environment. The safety of the Screw Extraction System in the MR environment is unknown.

3 Applications

4–8 Product Overview

9–16 Surgical Technique

Note

Precaution

OPERACE Screw Extraction System

Streamlined, color-coded system

The color-coding at the end of the handles corresponds to the color-coded size classification of the inserts (MINI, SMALL or LARGE).

Instrument MINI for mini fragment

Yellow color-coding

Screw diameters ∅ 0.9 – 2.0 mm

Instrument SMALL for small fragment

Blue color-coding

Screw diameters ∅ 2.3 – 4.0 mm

Instrument LARGE for large fragment

Green color-coding

Screw diameters ∅ 4.2 – 8.0 mm

Storage container

The storage container provides space for the sterile inserts and screw recess trials. The containers can be optionally labeled MINI (yellow), SMALL (blue) or LARGE (green). The container is not intended for sterilization.

OPERACE Screw Extraction System

OPERACE Screw Extraction System is intended for the removal of intact or damaged screws, in particular:

- Angular stable screws
- Cortex screws
- Cancellous bone screws
- Shaft screws
- Cannulated Screws
- Locking screws
- End cap screws

The OPERACE Screw Extraction System is not intended for the removal of screws implanted in the craniomaxillofacial anatomy using power-driven instruments.

OPERACE can be used to remove intact screws made of titanium, titanium alloys and stainless steel with the following standard drives[1]:

Screw Recess Hex	**HEX**
Screw recess size	1.3 mm, 1.5 mm, 1.8 mm, 2.0 mm, 2.5 mm, 3.0 mm, 3.5 mm, 4.0 mm, 3/16" (4.7 mm), 5.0 mm

Screw Recess Torx®/ StarDrive™	**T**
Screw recess size	T4, T5, T6, T7, T8, T9, T10, T15, T20, T25, T30, T40

Screw Recess Square / Robertson	**SQR**
Screw recess size	0.7 mm, 1.0 mm, 1.2 mm, 1.5 mm, 1.8 mm, 2.2 mm, 2.3 mm

Screw Recess Cruciform	**CR**
Screw recess size	0.3 mm, 0.4 mm, 0.5 mm, 0.6 mm, 0.8 mm, 1.0 mm

Screw Recess Slotted	**SL**
Screw recess size	0.3 mm, 0.4 mm, 0.5 mm, 0.6 mm, 0.8 mm, 1.0 mm

Screw Recess Phillips	**PH**
Screw recess size	PH1

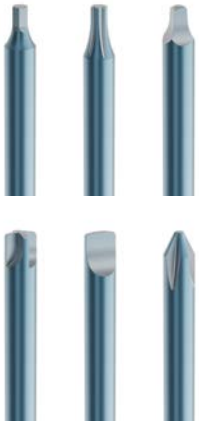
Note:

- 1. The screwdriver inserts in OPERACE correspond to standard orthopedic screwdriver inserts and are at least compatible with screws that satisfy the following specifications: ASTM F 543, ISO 5835, ISO 10664 and ISO 9268.

OPERACE Screw Extraction Inserts

The screwdriver inserts, extraction screws, extraction drill bits and extraction reamers are supplied in sterile form in a double blister packaging and are intended for single use only.

The OPERACE Screw Extraction Inserts are made of stainless steel. The Extraction Drill bit are made of high-speed steel. All Inserts have a silicium carbid coating.



OPERACE
Screwdriver inserts
Procedure 1

For the removal of intact screws with the following recess types:

- Hexagonal (Hex)
- Torx®/StarDrive™
- Square (Robertson)
- Cruciform
- Slotted
- Phillips

OPERACE
Extraction Screws
Procedure 2

For the removal of screws with a damaged hexagonal Torx ®/ StarDrive™ or square recesses.

OPERACE
Extraction Drill Bit
Procedure 3

For the removal of stuck locking-head screws. In this procedure, the screw head is separated from the screw shaft by drilling, enabling the plate to be removed with the separated screw head.

OPERACE
Extraction Reamer
Procedure 4a & 4b

For the removal of screws with seperated screw head after procedure 3 or broken screws.

Notes:

- Sterile-packed, single-use only inserts. Inserts must not be reprocessed after use.
- After determining the correct insert size, remove the sterile insert from the packaging using aseptic surgical techniques.
- Do not resterilize and do not reuse if the packaging is damaged or torn.
- Components that are opened and are not used must not be resterilized.

OPERACE Screw Extraction Handles

The OPERACE handles, cross-handles, extensions and AO adapters are supplied non-sterile. They are intended for reuse.

The OPERACE Screw Extraction Handles are made of stainless steel, PP and TPV plastics.

OPERACE

Handles with Quick Coupling

The handles and cross-handles with quick coupling are designed to accept all OPERACE screwdriver inserts, extraction screws and extensions.

OPERACE

Extensions with Quick Coupling

If required, the extensions can be inserted between the handle and the insert to facilitate the removal of deeper implanted screws.

OPERACE

Couplings with AO Adapter

Couplings with an AO adapter can be used as a link between power tools, AO handles and all OPERACE screwdriver inserts, extraction screws and extensions.

Notes:

- Avoid blowing and bending loads as they can lead to instrument damage or breakage.
- Reprocessing must be carried out as described in the section: Important Instructions.

OPERACE Screw Recess Trial

Sterile single-use trials that can be used to determine the correct size of the sterile Hex and Torx®/ StarDrive™ screwdriver insert.

OPERACE Screw Recess Trials are made of ABS plastics.

Screw Recess Trial

To determine the correct size according to the following table

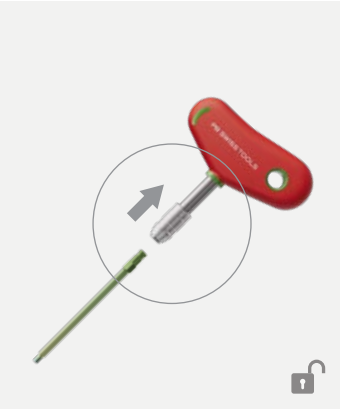
Screw Recess Hex	**HEX**
Screw recess size	1.3 mm, 1.5 mm, 1.8 mm, 2.0 mm, 2.5 mm, 3.0 mm, 3.5 mm, 4.0 mm, 3/16" (4.7 mm), 5.0 mm
Screw Recess Torx®/ StarDrive™	**T**
Screw recess size	T4, T5, T6, T7, T8, T9, T10, T15, T20, T25, T30

Notes:

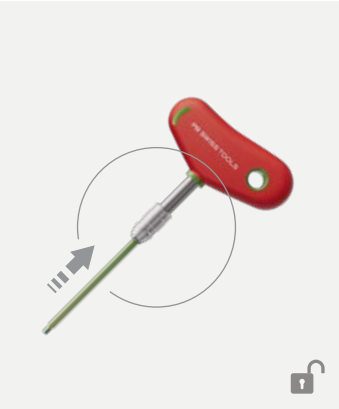
- Sterile-packed, for single use only. Inserts must not be reprocessed after use.
- Do not re-sterilize and do not reuse if the packaging is damaged or torn.
- Do not re-sterilize unused components.

OPERACE Screw Recess Trial

Insert insertion / removal



Pull back quick coupling to unlock



Insert the insert

Release quick coupling to lock in place

Pull back quick coupling to unlock and remove insert

Notes:

- The interface between Screwdriver Inserts and Handles/Cross-Handles is a hex coupling. Alignment of hex with coupling indicates the correct position of the Screwdriver Insert.
- Check that screwdriver insert is locked in place by pulling on the screwdriver insert.

Precaution:

- The color code of the handles and extensions must match the color code and size class (MINI, SMALL or LARGE) of the inserts.

Preoperative Planning and Preparation

To ensure that the appropriate screw removal instruments are obtained, the surgeon should have the following information before implant removal:

- Implant manufacturer
- Implant type
- Time of implantation
- Material
- Recess geometry and dimension of the screws (eg, Hex, Cruciform)
- Screw diameter
- Any visible damage to the implant (eg, broken screw shaft)

The range of extraction products can be used for the following four procedures:

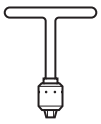
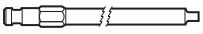
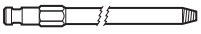
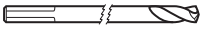
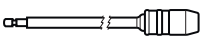
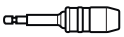
1. Removal of intact screws.
2. Removal of screws with a damaged screw recess.
3. Removal of locking head screws stuck in the plate.
4. Removal of broken screws and of screws processed according to procedure 3.

⚠ Precaution:

- The correct instrument sizes to remove screws must be carefully chosen to facilitate screw extraction and to reduce the risk of further screw damage during the procedure.

■ Note:

- Read these instructions for use and all associated documents thoroughly before use. Make sure that you are familiar with the appropriate surgical technique for OPERACE.

Combination matrix	OPERACE System						
	 Handle	 Cross-Handle	 Extension	 Coupling with AO Adapter	 Small Universal Chuck with T-Handle	 Power Tool	 AO Handle
 Screwdriver insert	●	●	●	●			
 Extraction Screw	●	●	●	●			
 Extraction Drill Bit						●	
 Extraction reamer					●	●	
 Extension	●	●		●			
 Coupling with AO Adapter						●	●

● intended

Screw Size Estimation

Identify Size of Sterile Screwdriver Inserts

Instruments used

- Sterile single-use trials for Hex and Torx®/StarDrive™

Sterile single-use trials

Procedure

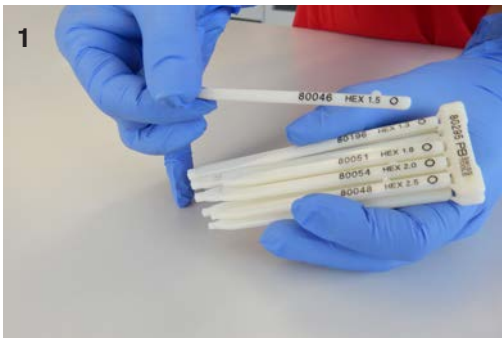
1. Estimate the possible trial size from the bundle in accordance with the screw recess size and snap it out.
2. Check the size by inserting the trial and turning it slightly. If too small, choose a larger one. If the trial is too large, choose a smaller one from the bundle.
3. The trial must fit in the screw recess properly.
4. Determine the correct sterile screwdriver insert using the corresponding reference.

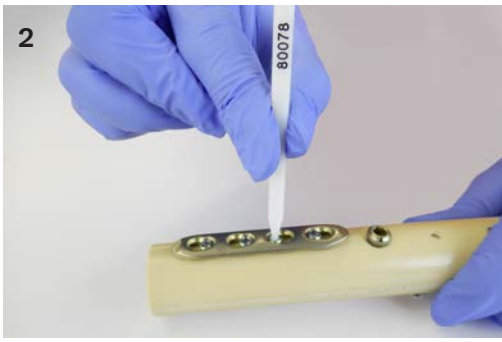
Note:

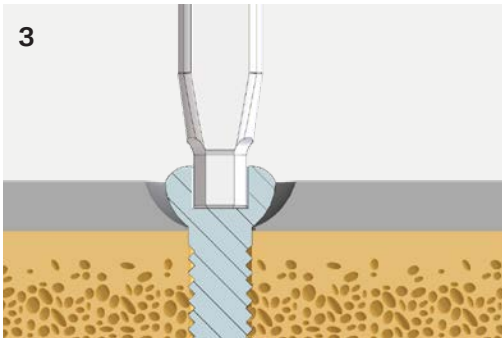
- Screw recess trials are intended to determine the correct size of the sterile screwdriver insert and should be used with sterile screwdriver inserts.

Precautions:

- Break trials out of the bundle above the operating table.
- Do not use trials to remove the screws. Overload may lead to trial breakage.
- Dispose of all samples and the rest of the bundle after use.







Procedure 1

Removal of Intact Screws

Instruments used

- Screwdriver insert of the appropriate size and shape according to Table 1 on the following page.
- Handle and cross-handle of the appropriate size.

Option

- Extensions for the removal of deeply inserted screws.

Notes:

- Start with the handle.
- If the screw cannot be rotated using the handle, use the cross-handle.
- Ensure that the screwdriver insert is fully inserted into the screw recess. Otherwise, the insert may spin in the recess.

Procedure

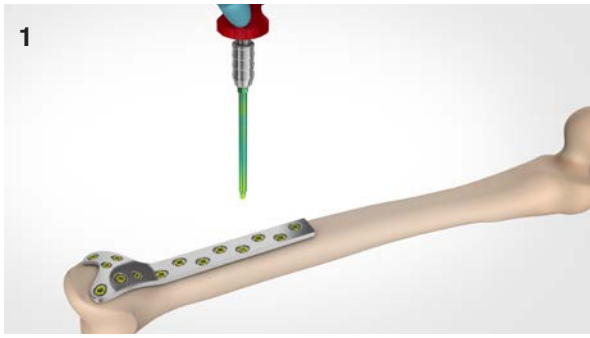
1. Carefully clean screw recess. Engage screwdriver insert in the handle coupling.
2. Insert the screwdriver insert into the screw recess.
3. Loosen screw manually by turning counter-clockwise.

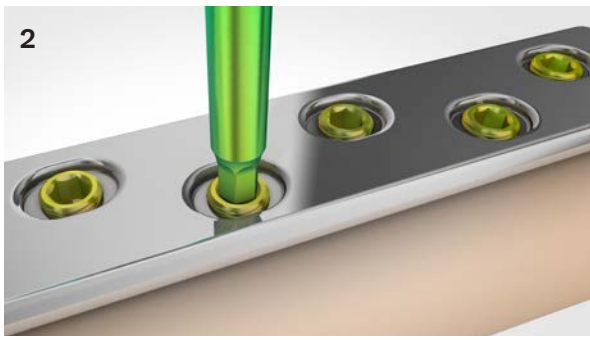
Option

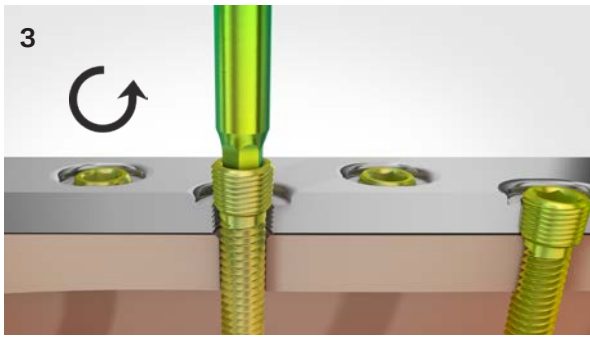
- After it is loosened, remove the screw with the coupling with AO adapter and power tool at low speed.

Precautions:

- Use Slotted screwdriver inserts manually only.
- Irrigate and apply suction for removal of debris potentially generated during implant removal.



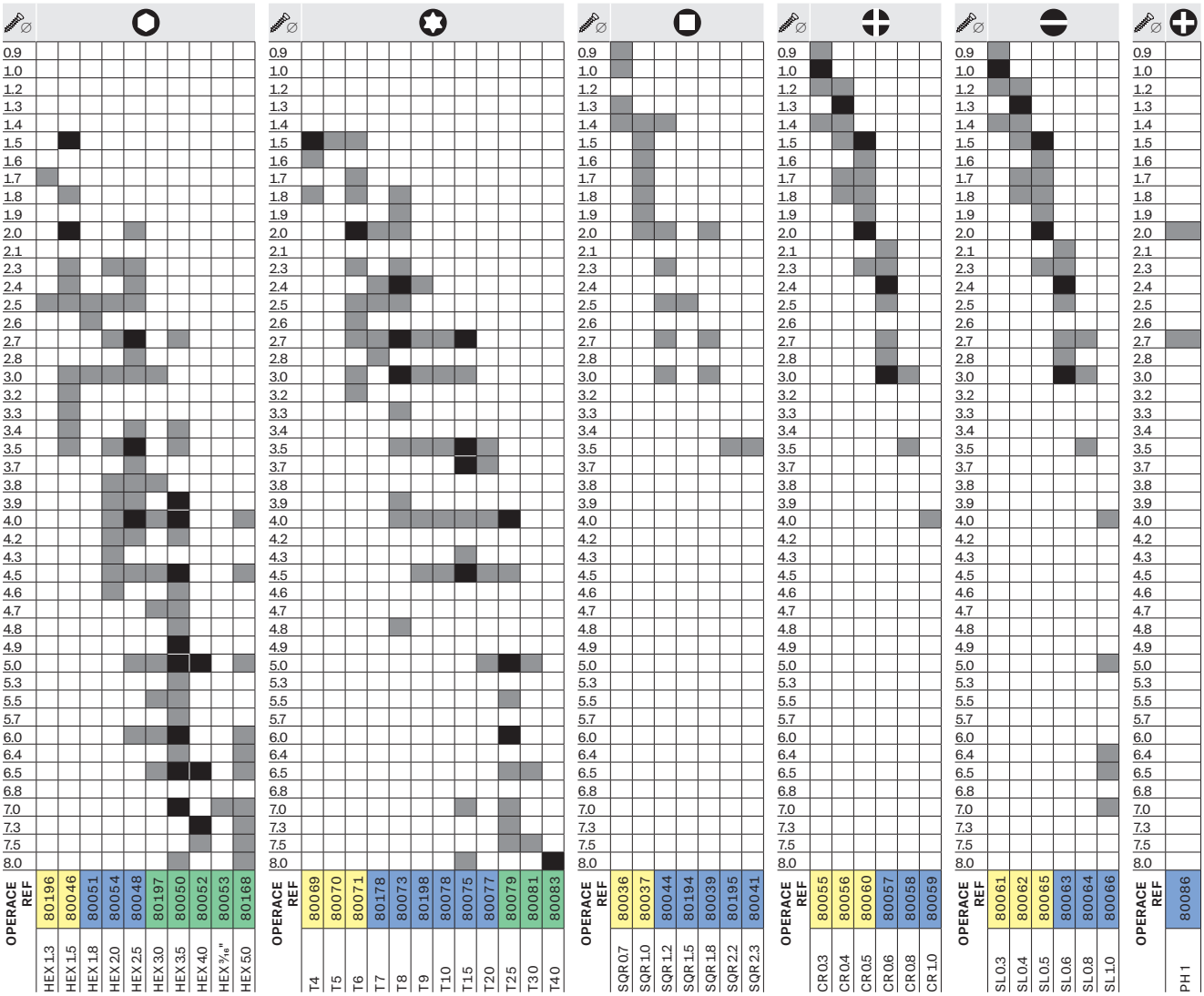




Turn counterclockwise

Compatibility Matrix

Table 1: Compatibility matrix based on screw diameter



■ Most commonly used screw recess
■ Other possible screw recesses

The table provides an overview of the screw recesses used for the respective screw diameters. Cells highlighted in black denote the most often used screw recesses and corresponding screwdriver inserts.

Other screw recesses are used depending on the manufacturer in each case. These and the corresponding screwdriver inserts are highlighted in gray.

⬡	HEX 1.3, HEX 1.5, HEX 1.8, HEX 2.0, HEX 2.5, HEX 3.0, HEX 3.5, HEX 4.0, HEX 3/16" (4.7), HEX 5.0
✪	T4, T5, T6, T7, T8, T9, T10, T15, T20, T25, T30, T40
▢	SQR 0.7, SQR 1.0, SQR 1.2, SQR 1.5, SQR 1.8, SQR 2.2, SQR 2.3
✚	CR 0.3, CR 0.4, CR 0.5, CR 0.6, CR 0.8, CR 1.0
⬭	SL 0.3, SL 0.4, SL 0.5, SL 0.6, SL 0.8, SL 1.0
⊕	PH1

Note:

- Recommendation for the selection of screwdriver inserts, with no guarantee of correctness or completeness.

Electronical Matrix Screw Recess Finder

www.pbswisstools.com/srf/en-us

Procedure 2

Removal of Screws with Damaged Recess

Instruments used

- Extraction screw of the appropriate size according to Table 2.
- Handle or cross-handle of the appropriate size.

Procedure

1. Insert extraction screw in the handle coupling. Start turning the extraction screw counterclockwise, in the same axis as the screw to be removed.
2. Continue turning, applying constant pressure, until the conical left-handed thread is securely seated in the damaged recess and until sufficient torque is applied to loosen the screw.
3. Then unscrew turning counterclockwise.

⚠ Precautions:

- Turn counterclockwise.
- Use extraction screws only for removing screws with a damaged drive recess.
- Use extraction screws manually only.

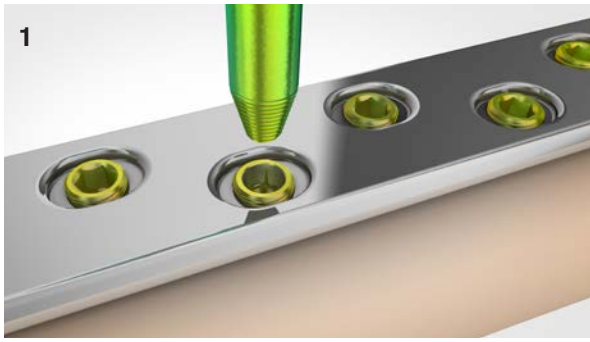
■ Notes:

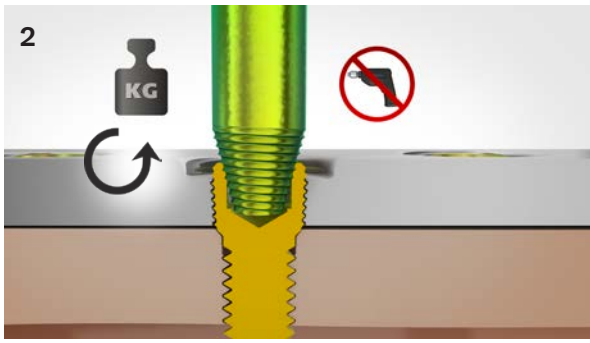
- For HEX 5.0 mm, T30 and T40 screw recess, a slightly deeper hole can be drilled in the screw recess with extraction drill bit 4.0.
- If the extraction screw spins in the screw recess, an attempt can be made to drill the screw recess with an extraction drillw bit according procedure 3 and Table 3 (on the following page) to anchor the extraction screw more deeply.

Handle

Cross-Handle

Extraction Screw





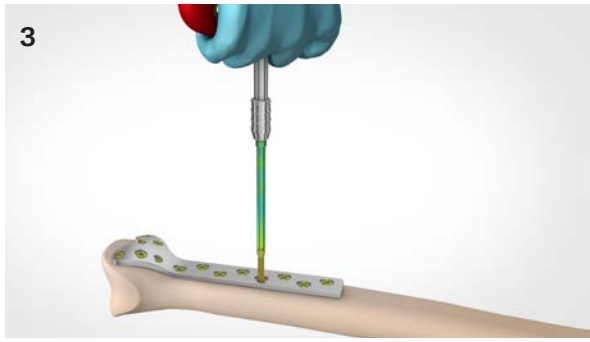


Table 2

	Screw recess size				
∅mm	⬡	✪	▢	OPERACE REF	
1.5 – 3.2	Hex 1.5	T6, T7	SQR 1.0, 1.2, 1.5	80018	Extraction screw 1.6
2.0 – 4.3	Hex 1.8, 2.0	T8, T9	SQR 1.8	80170	Extraction screw 2.0
2.3 – 6.0	Hex 2.5, 3.0	T10, T15	SQR 1.8, 2.2	80020	Extraction screw 2.6
3.5 – 8.0	Hex 3.5, 4.0	T20, T25	SQR 2.3	80022	Extraction screw 3.5

Applying pressure

Turn counterclockwise

Use manually only

Procedure 3

Removal of Locking Screws Stuck in Plate

Instruments used

- Extraction drill bit of the appropriate size according to Table 3.
- Power tool with a drill chuck.

Procedure

1. Position the drill bit alredy rotating clockwise in the screw recess.
2. Applying very little pressure in the same axis as the screw to be removed.
3. Drill until the far side of the plate is reached . The screw head will be loosened from the shaft and weakened to cause it to break off when the plate is lifted.
4. Remove the plate. Continue to Procedure 4 to remove embedded screw shafts.

Precautions:

- Turn clockwise.
- Apply the drill bit while it is already rotating, not while it is stationary.
- Apply very little pressure initially, using approximately the weight of the power tool, and start with a slow speed.
- Cool the drill bit and vacuum drill chips during the procedure. In order to avoid overheating, relieve the pressure on the drill from time to time.
- The OPERACE system is not intended for the removal of screws implanted in the craniomaxillofacial anatomy using power-driven instruments.

Notes:

- When the drill bit has reached the base of the recess, increase the pressure on the screw to achieve continuous ribbon chip formation.
- Do not use the drill bit to drill in bone or drill out broken screwdriver tips.
- Irrigate and apply suction for removal of debris potentially generated during implant removal.

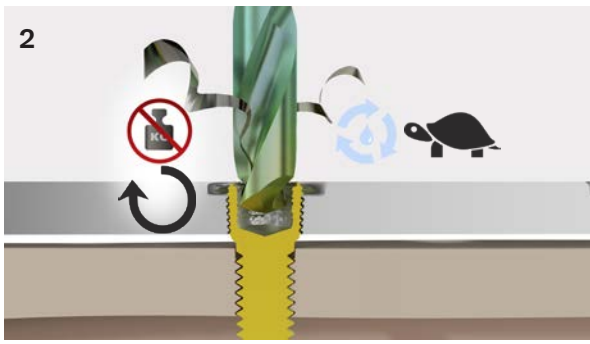
Table 3

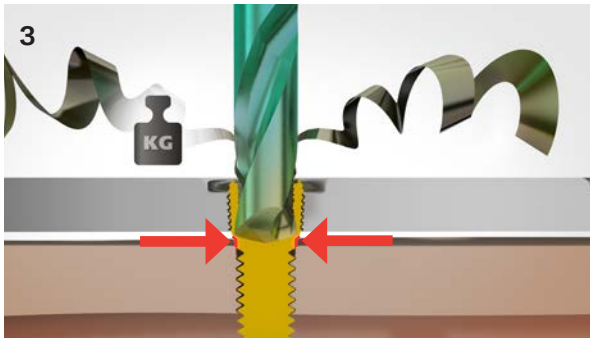
Screw diameter in mm

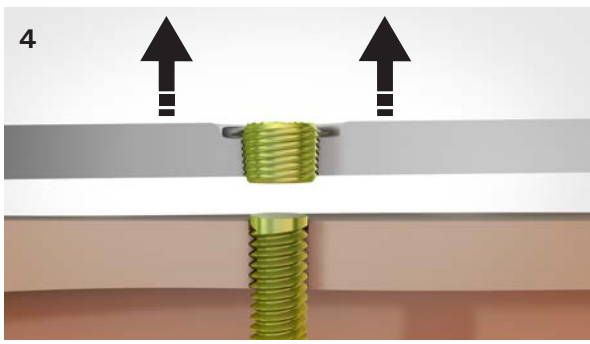
∅	OPERACE REF	
1.0 – 1.5	80023	Extraction drill bit 1.5
1.6 – 2.0	80123	Extraction drill bit 2.0
2.1 – 2.5	80024	Extraction drill bit 2.5
2.6 – 3.2	80025	Extraction drill bit 3.2
3.3 – 4.0	80019	Extraction drill bit 4.0
4.1 – 5.0	80026	Extraction drill bit 5.0
5.1 – 6.5	80027	Extraction drill bit 6.5
6.6 – 7.5	80021	Extraction drill bit 7.5

Power Tool

Extraction Drill Bit







Applying pressure
Very little pressure
Turn clockwise
Cooling
Slow speed

Procedure 4a

Removal of Broken Screws

Instruments used

- Extraction reamer of the appropriate size according to Table 4.
- Small Universal Chuck with T-Handle or Power Tool with a drill chuck.

Procedure

1. Use the T-handle.
2. Remove the screw shaft remaining in the bone.
3. Apply slight pressure initially, counterclockwise. As soon as the reamer grips the screw shaft, continue reaming with increased pressure until the conical thread is securely seated on the screw shaft.
4. When unscrewing the screw do not relieve the pressure, but maintain the constant axial pressure and direction of rotation.

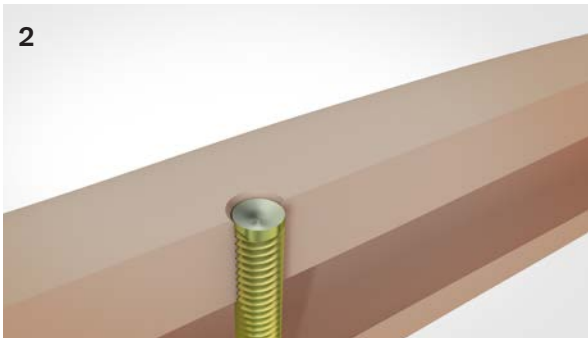
Note:

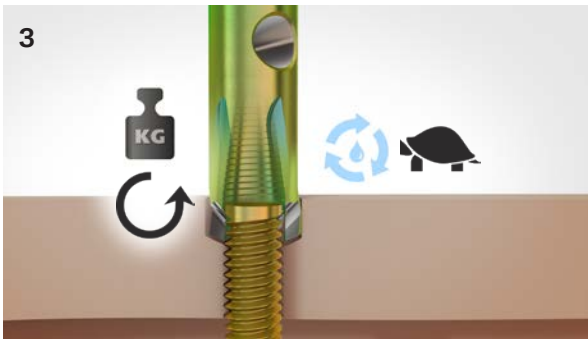
- A manual procedure with a Small Universal Chuck with T-Handle is preferred.

Precautions:

- Turn counterclockwise.
- If a power tool is used, it should be kept at a very low speed. Otherwise too much frictional heat will be generated and the reamer will not grip the screw shaft.
- Cool the reamer and vacuum ribbon chips during the procedure.
- The OPERACE system is not intended for the removal of screws implanted in the craniomaxillofacial anatomy using power-driven instruments.

T-Handle Power Tool Extraction Reamer





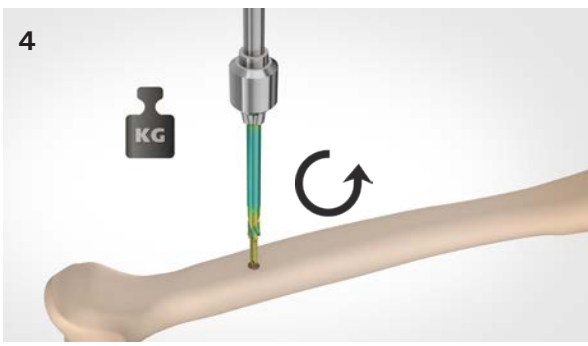


Table 4

Screw diameter in mm

∅	OPERACE REF	
1.4 – 2.0	80009	Extraction reamer 2.0
2.1 – 2.5	80028	Extraction reamer 2.5
2.6 – 3.2	80029	Extraction reamer 3.2
3.3 – 4.0	80030	Extraction reamer 4.0
4.1 – 4.5	80033	Extraction reamer 4.5
4.6 – 5.8	80035	Extraction reamer 5.8
5.9 – 7.5	80015	Extraction reamer 7.5

Applying pressure
Turn counterclockwise
Cooling
Slow speed

Procedure 4b

Removal of Buried Broken Screw Shafts

Instruments used

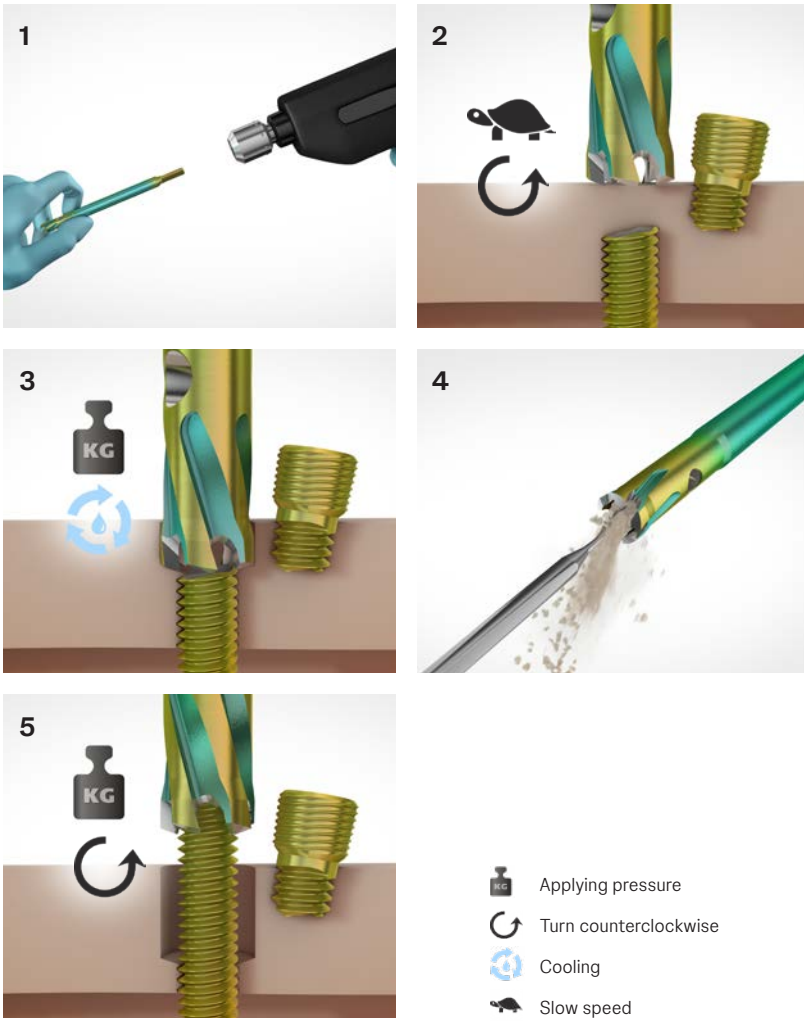
- Extraction reamer of the appropriate size according to Table 4 (on the previous page).
- Small Universal Chuck with T-Handle or Power Tool with a Drill Chuck.

Procedure

1. Use the T-handle or power tool.
2. Ream the buried screw shaft free. Position the stationary extraction reamer perpendicular to the bone so that the teeth evenly against the surface.
3. Apply slight pressure initially, turning counterclockwise. As soon as the reamer grips, ream in the direction of the screw axis under image intensifier control until it has been guided through the screw shaft.
4. Remove reamer at regular intervals and free it of accumulated bone material.
5. Continue reaming with increased pressure until the thread is securely seated on the screw shaft. When extracting the screw do not relieve the pressure. Maintain constant axial pressure and direction of rotation.

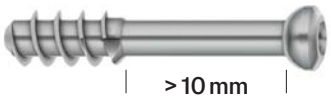
⚠ Precautions:

- Turn counterclockwise.
- If a power tool is used, it should be kept at a very low speed. Otherwise too much frictional heat will be generated and the reamer will not grip the screw shaft.
- Cool the reamer and vaccum the drill chips during the procedure.
- Irrigate and apply suction for removal of debris potentially generated during implant removal.



Notes:

- Since the external diameter of short-threaded cancellous bone screws is smaller in the shaft than in the thread, smaller extraction reamers can be used if a break occurs in the shaft area. At least about 10 mm of shaft without thread must be present.
- After implant removal is complete, discard any fragments in an approved sharps container.



OPERACE Instrument MINI

80001

80006

Reprocessable instruments		
	80001	Handle MINI
	80006	Extension MINI, for screwdriver inserts
Sterile single-use inserts		
	80196	Screwdriver insert for hexagonal socket screws, Hex 1.3
	80046	Screwdriver insert for hexagonal socket screws, Hex 1.5
	80069	Screwdriver insert for screws Torx® and StarDrive™, T4
	80070	Screwdriver insert for screws Torx® and StarDrive™, T5
	80071	Screwdriver insert for screws Torx® and StarDrive™, T6
	80055	Screwdriver insert for cruciform recess screws, Cr 0.3
	80056	Screwdriver insert for cruciform recess screws, Cr 0.4
	80060	Screwdriver insert for cruciform recess screws, Cr 0.5
	80036	Screwdriver insert for square socket screws, Sqr 0.7
	80037	Screwdriver insert for square socket screws, Sqr 1.0
	80061	Screwdriver insert for slotted screws, Sl 0.3
	80062	Screwdriver insert for slotted screws, Sl 0.4
	80065	Screwdriver insert for slotted screws, Sl 0.5
	80018	Extraction screw, 1.6
	80023	Extraction drill bit, 1.5 f / screws ∅1.0 – 1.5
	80123	Extraction drill bit, 2.0 f / screws ∅1.6 – 2.0
	80009	Extraction reamer, 2.0 f / screws ∅1.4 – 2.0

OPERACE Instrument SMALL

80002 80004 80007 80010

Reprocessable instruments

80002	Handle SMALL
80004	Cross handle SMALL
80007	Extension SMALL, for screwdriver inserts
80010	Coupling, SMALL, with AO adapter

Sterile single-use inserts

80051	Screwdriver insert for hexagonal socket screws, Hex 1.8
80054	Screwdriver insert for hexagonal socket screws, Hex 2.0
80048	Screwdriver insert for hexagonal socket screws, Hex 2.5
80178	Screwdriver insert for screws Torx® and StarDrive™, T7
80073	Screwdriver insert for screws Torx® and StarDrive™, T8
80198	Screwdriver insert for screws Torx® and StarDrive™, T9
80078	Screwdriver insert for screws Torx® and StarDrive™, T10
80075	Screwdriver insert for screws Torx® and StarDrive™, T15
80077	Screwdriver insert for screws Torx® and StarDrive™, T20
80057	Screwdriver insert for cruciform recess screws, Cr 0.6
80058	Screwdriver insert for cruciform recess screws, Cr 0.8
80059	Screwdriver insert for cruciform recess screws, Cr 1.0
80086	Screwdriver insert for Phillips screw, Ph 1
80044	Screwdriver insert for square socket screws, Sqr 1.2
80194	Screwdriver insert for square socket screws, Sqr 1.5
80039	Screwdriver insert for square socket screws, Sqr 1.8
80195	Screwdriver insert for square socket screws, Sqr 2.2
80041	Screwdriver insert for square socket screws, Sqr 2.3
80063	Screwdriver insert for slotted screws, Sl 0.6
80064	Screwdriver insert for slotted screws, Sl 0.8
80066	Screwdriver insert for slotted screws, Sl 1.0
80170	Extraction screw, 2.0
80020	Extraction screw, 2.6
80024	Extraction drill bit, 2.5 f/ screws ∅2.1–2.5
80025	Extraction drill bit, 3.2 f/ screws ∅2.6–3.2
80019	Extraction drill bit, 4.0 f/ screws ∅3.3–4.0
80028	Extraction reamer, 2.5 f/ screws ∅2.1–2.5
80029	Extraction reamer, 3.2 f/ screws ∅2.6–3.2
80030	Extraction reamer, 4.0 f/ screws ∅3.3–4.0

OPERACE Instrument LARGE

80003 80005 80008 80011

Reprocessable instruments		
	80003	Handle LARGE
	80005	Cross handle LARGE
	80008	Extension LARGE, for screwdriver inserts
	80011	Coupling, LARGE, with AO adapter

Sterile single-use inserts		
	80197	Screwdriver insert for hexagonal socket screws, Hex 3.0
	80050	Screwdriver insert for hexagonal socket screws, Hex 3.5
	80052	Screwdriver insert for hexagonal socket screws, Hex 4.0
	80053	Screwdriver insert for hexagonal socket screws, Hex 3/16'' (4.7)
	80168	Screwdriver insert for hexagonal socket screws, Hex 5.0
	80079	Screwdriver insert for screws Torx® and StarDrive™, T25
	80081	Screwdriver insert for screws Torx® and StarDrive™, T30
	80083	Screwdriver insert for screws Torx® and StarDrive™, T40
	80022	Extraction screw, 3.5
	80026	Extraction drill bit, 5.0 f / screws ∅4.1–5.0
	80027	Extraction drill bit, 6.5 f / screws ∅5.1–6.5
	80021	Extraction drill bit, 7.5 f / screws ∅6.6–7.5
	80033	Extraction reamer, 4.5 f / screws ∅4.1–4.5
	80035	Extraction reamer, 5.8 f / screws ∅4.6–5.8
	80015	Extraction reamer, 7.5 f / screws ∅5.9–7.5

OPERACE Screw Recess Trial and Storage Container

Sterile single-use trials

⬡		80295	Screw recess trial for hexagonal socket screws, Hex 1.3–5.0
✪		80296	Screw recess trial for screws Torx® and StarDrive™, T4–T30

Storage container

		81006	The storage container provides space for the for the sterile inserts and screw recess trials. The containers can be optionally labeled MINI (yellow), SMALL (blue) or LARGE (green).

Important Instructions

General Instructions

Disposal

Used single-use interchangeable inserts must be disposed of properly in accordance with national regulations and local requirements.

Return

Surgical instruments or sterile inserts may be returned only after consulting the distributor. All returned products must be decontaminated or sealed in the unopened original packaging. Unopened products with an exceeded expiry date may not be returned.

Disclaimer

The recommandations for storage, care, maintenance, reprocessing and sterilization are available as PDF files at www.pbswisstools.com/ifu

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 of PB Swiss Tools products. No liability is accepted in the event of failure to observe the instructions in this Surgical Technique. Please also note the described indications and contraindications as well as residual risks and a symbol glossary in the INSTRUCTIONS FOR USE: REF 80461. Available as PDF files at www.pbswisstools.com/ifu

Single-use products

Products intended for single use should never be reused. The reuse or reprocessing of single-use products can harm the product or jointly reprocessed products and/or lead to product failure. Furthermore, the reuse or reprocessing of single-use products increases the risk of contamination, potentially resulting in injury, illness or death of the patient or user.

Important Instructions

Instructions for single-use products

These instructions for use apply to all sterile inserts supplied by PB Swiss Tools AG and listed in this Surgical Technique.

- Screwdriver Inserts
- Extraction Screws
- Extraction Reamers
- Extraction Drill Bits

Sterile-packed, for single use

Inserts must not be reprocessed or resterilized.

After determining the correct insert size, remove the sterile insert from the packaging using aseptic surgical techniques. Do not resterilize and do not reuse if the packaging is damaged or torn.

Plasma coating

The color-coding of the inserts consists of a plasma coat-ing. Slight deviations in color or shading result from the manufacturing process and do not affect the quality of the inserts.

Instructions for resuable products

These instructions for use apply to all reprocessable surgical instruments supplied by PB Swiss Tools AG and listed in this Surgical Technique.

- Handles
- Cross-Handles
- Extensions
- Couplings with AO Adapter

The instruments are supplied in non-sterile form and must be reprocessed before every use. This also applies to the first use of reprocessable surgical instruments after delivery. Sterilization of the delivery packaging is not possible or permitted. Please note that only validated methods may be used for cleaning/disinfection and sterilization. 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 respective national and any applicable internal regulations must be observed. For detailed information on cleaning and sterilization please refer to CLEANING AND STERILIZATION INSTRUCTIONS FOR REUSABLE INSTRUMENTS: REF 80462, available as PDF files at www.pbswisstools.com/ifu

Glossary of Symbols

Glossary of Symbols

REF	Catalogue number
LOT	Lot-/Batch code
	Manufacturer
	Date of manufacture
	Use-by date
UDI	Unique Device Identifier
MD	Medical device
NON STERILE	Non-sterile
eIFU	Consult electronic instructions for use
STERILE R	Sterilized using irradiation
	Double sterile barrier system
	Single sterile barrier system
	Caution/Warning
	For single use
	Do not resterilize
	Do not use if sterile packaging is damaged
	Distributor
Rx only	Prescription only

	Hexagon/Hex screw recess
	Torx®/Stardrive™ screw recess
	Square/Robertson screw recess
	Cruciform screw recess
	Slotted screw recess
	Phillips screw recess
	Screw diameter
	Screwdriver Insert
TRIAL	Screw Recess Trial
	Extraction Screw
	Extraction Drill Bit
	Extraction Reamer
KG	Apply pressure
	Very little pressure
	Rotate clockwise
	Rotate counterclockwise
	Only in manual mode
	Cooling
	Low speed

CAUTION: Federal Law restricts these devices to sale by or on the order of a physician.

Not all products may currently be available in all markets.

Surgical techniques are available as PDF files at www.pbswisstools.com/ifu

PB SWISS TOOLS

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