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MASTERING IMPLANT REMOVAL

Be in control of any situation of implant removal. OPERACE. Flexible, safe and efficient.

100% Made in Switzerland

This publication is not intended for distribution in the USA.

SURGICAL TECHNIQUE

PB SWISS TOOLS

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INNOVATION AND SWISS QUALITY

The new OPERACE instrument set is used to remove implant screws made of titanium, titanium alloys and stainless steel – particularly damaged screws.

OPERACE is the result of the combined innovative power of PB Swiss Tools, the Swiss manufacturer of high-quality tools, and leading manufacturers of orthopedic implants and instruments.

The practical instrument set was developed in close cooperation with doctors and specialists. It offers a fast solution for the extraction of implant screws. The intelligent combination of durable handles and a range of single-use inserts allows for precise, safe and fast extractions of any type of screw.

OPERACE comes in three practical sizes:
- Instrument set MINI for mini fragment
- Instrument set SMALL for small fragment
- Instrument set LARGE for large fragment

A detailed product overview can be found on page 7 of this Surgical Technique.

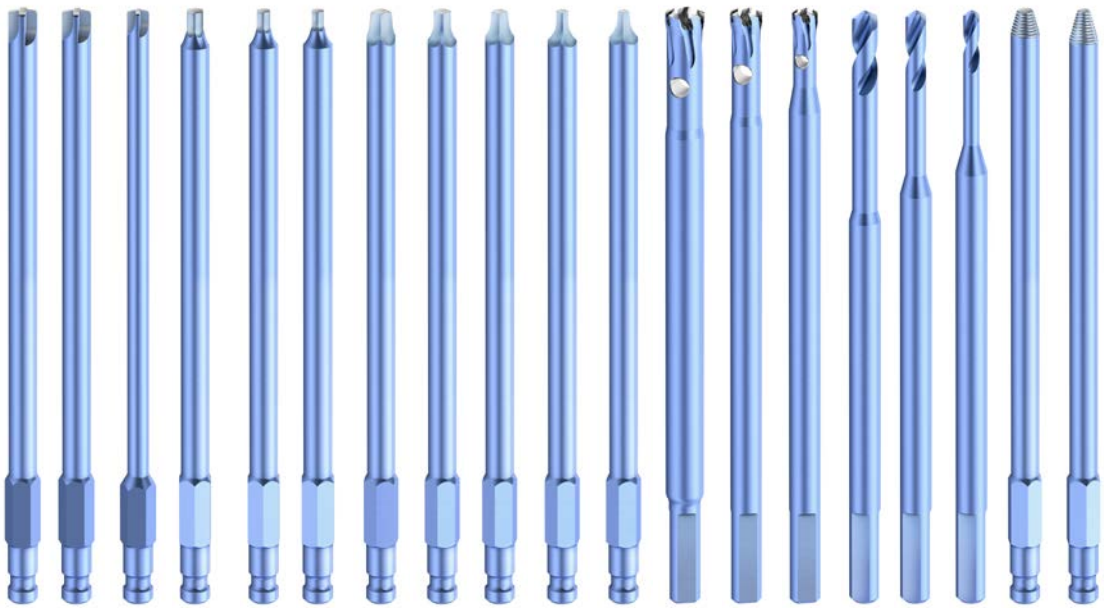
FIRST CHOICE FOR SURGEONS

- **Convenience** With OPERACE you are equipped to remove standard implant screws from various manufacturers. Clearly structured, flexible and user-friendly through the intelligent color-coding of the three set sizes for implant screws with mini, small and large fragment.
- **Safety** Sterile single-use inserts guarantee precision and direct power transmission with every use.
- **Efficiency** The ergonomic PB Swiss Tools handles fit the hand conveniently and allow for direct power transmission.
- **Economic** Time-consuming and expensive resterilization of instruments that are not required is a thing of the past. Resulting in an efficient surgical procedure and clear cost transparency.

Dr. Andreas Rindlisbacher Dep. Head of Surgical Clinic/Head of Trauma Surgery, Zug Cantonal Hospital, assisted with the development of the OPERACE instrument set.

«OPERACE provides users with the correct screwdriver inserts at any time, irrespective of the implant manufacturer. For defective screws, an insert with left-hand thread, a special drill or an extraction reamer can also be chosen.

As a surgeon, I particularly appreciate the sterile individual packaging of the inserts, which means that OPERACE is ready for use at any time, without any long sterilization times. The single-use technology guarantees the same high level of instrument precision at all times.»



OPERACE
Instrument set SMALL
for small fragment

APPLICATIONS

For the removal of undamaged and damaged or broken screws, in particular
- Angular stable screws
- Cortex screws
- Cancellous bone screws
- Shaft screws
- Cannulated Screws
- Locking screws
- Locking bolts

made of titanium, titanium alloys and stainless steel with the following standard drives[1)]:

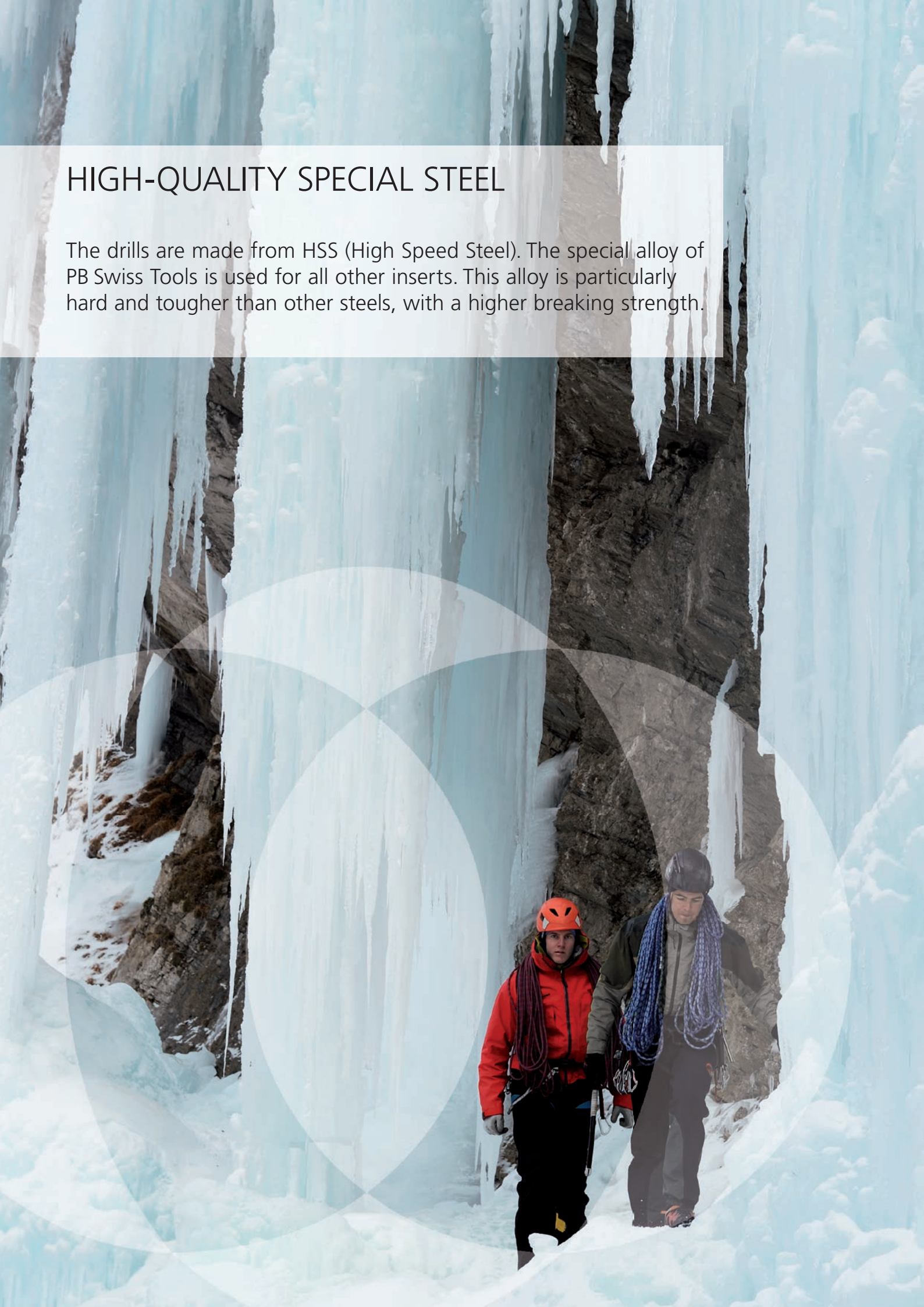
Hex	**Torx®/ Stardrive®**	**Square/ Robertson**	**Cruciform**	**Slotted**	**Phillips**
Screw head	Screw head	Screw head	Screw head	Screw head	Screw head
HEX	T	SQR	CR	SL	PH
Nominal tool size	Nominal tool size	Nominal tool size	Nominal tool size	Nominal tool size	Nominal tool size
1.3 mm, 1.5 mm, 1.8 mm, 2.0 mm, 2.5 mm, 3.0 mm, 3.5 mm, 4.0 mm, 5.0 mm	T4, T5, T6, T7, T8, T9, T15, T20, T25, T30, T40	0.7 mm, 1.0 mm, 1.2 mm, 1.5 mm, 1.8 mm, 2.2 mm, 2.3 mm	0.3 mm, 0.4 mm, 0.5 mm, 0.6 mm, 0.8 mm, 1.0 mm	0.3 mm, 0.4 mm, 0.5 mm, 0.6 mm, 0.8 mm, 1.0 mm	PH1

The system is organized into three color-coded sets based on screw diameter:
- Instrument set MINI for mini fragment, usually for screw diameters 0.9–2.0, yellow color-coding
- Instrument set SMALL for small fragment, usually for screw diameters 2.3–4.0, blue color-coding
- Instrument set LARGE for large fragment, usually for screw diameters 4.2–8.0, green color-coding

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

HIGH-QUALITY SPECIAL STEEL

The drills are made from HSS (High Speed Steel). The special alloy of PB Swiss Tools is used for all other inserts. This alloy is particularly hard and tougher than other steels, with a higher breaking strength.



STERILE SINGLE-USE INSERTS

Every OPERACE instrument set contains single use inserts which can be used with OPERACE handles, cross-handles and extensions or power tools with adapters.

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

OPERACE screwdriver inserts
Removal of intact screws with the following drives:
- Hexagonal socket (Hex)
- Torx®/Stardrive®
- Square socket (Robertson)
- Cruciform
- Slotted
- Phillips

OPERACE extraction screws
With left-hand thread, and available in a range of sizes, for the removal of screws with a damaged hexagonal socket, Torx®/ Stardrive® or square socket drive.

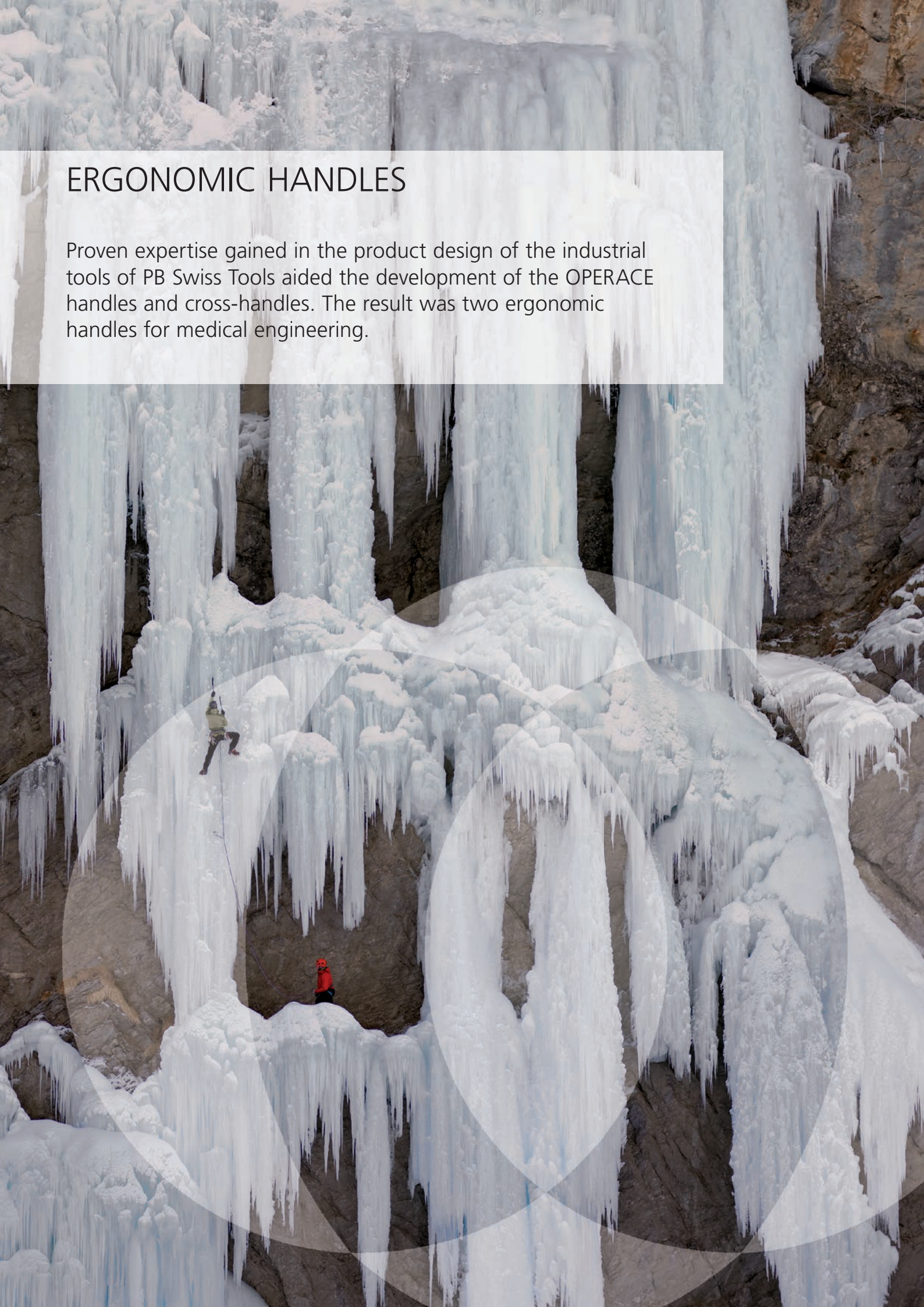
OPERACE extraction drill bit
Removal of stuck locking-head screws. The screw head is separated from the screw shaft by drilling, enabling the plate to be removed with the separated screw head.

OPERACE extraction reamer
Left-turning, removal of drilled or broken screws.
Three operations in one: reaming, gripping, extracting. Various sizes matched to their thread diameter.

Notes
- **Sterile-packed, for single use. Inserts may not be reprocessed.**
- **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.**
- **Unused components may not be resterilized.**

ERGONOMIC HANDLES

Proven expertise gained in the product design of the industrial tools of PB Swiss Tools aided the development of the OPERACE handles and cross-handles. The result was two ergonomic handles for medical engineering.



INSTRUMENTS FOR MULTIPLE USE

The OPERACE handles, cross-handles, extensions and AO adapters are supplied in **non-sterile** form. They are intended for multiple use (reprocessing).

OPERACE handle
- For fast rotation and universal use
- The ergonomic groove shape rests comfortably in the hand and allows high torques to be transmitted
- The large rounded end of the handle enables considerable axial pressure to be applied

OPERACE cross-handle
- For the safe application of extremely high torques
- Optimally adjusted to fit the hand perfectly
- Thanks to the slant angle, the wrist remains straight and is protected when using the screwdriver with high force

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

Important
- **The handles, extensions and couplings are intended for the loosening and unscrewing of implant screws.**
- **Blows and bending loads should be avoided since they can lead to instrument damage or breakage.**
- **The reprocessing must be carried out as described in the section on reprocessing.**

OPERACE INSTRUMENT SET

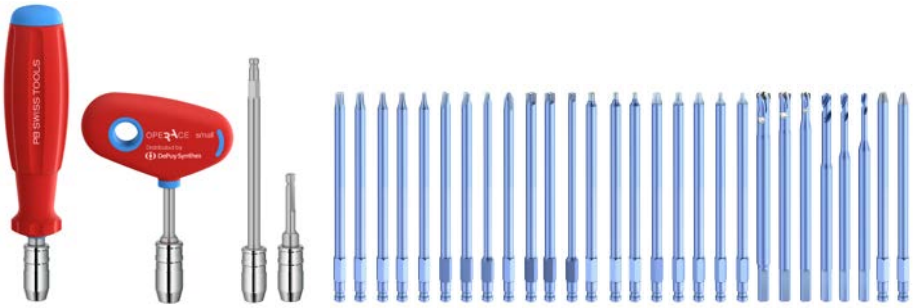
Three set sizes with practical color-coding

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

The purpose of the size specific handles for the screwdriver inserts i.e. the sizes MINI, SMALL and LARGE, is to ensure that the achievable manual torque of the handle is matched to the torque appropriate to the screw size.

Instrument set MINI for mini fragment
Yellow color-coding
Screw diameters ∅ 0.9–2.0 mm
Quick coupling with one ring

Instrument set SMALL for small fragment
Blue color-coding
Screw diameters ∅ 2.3–4.0 mm
Quick coupling with two rings



Instrument set LARGE for large fragment
Green color-coding
Screw diameters ∅ 4.2–8.0 mm
Quick coupling with three rings

Insert insertion/removal

Pull back quick coupling

Insert or remove insert

Release quick coupling
to lock in place

Note

- **Check for correct engagement by pulling on the screwdriver insert**

Storage container

The handy storage container provides space for the sterile inserts and processed (sterile) handles of one set. The containers can be optionally labeled MINI (yellow), SMALL (blue) or LARGE (green).

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SURGICAL TECHNIQUE

USING OPERACE CORRECTLY

Extracting screws requires experience and expertise. The OPERACE instrument set may be used only by trained operators.

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.

Animation

Important

- **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.**
- **Supplementing the information in this manual, instruction in the surgical use of these instruments by a surgeon experienced in their handling is strongly recommended.**

PROCEDURE 1

Removal of intact screws that can be loosened by hand

Handle | Cross-handle | Screwdriver insert

Instruments used
- Handle or cross-handle of the appropriate size.
- Screwdriver insert, sterile-packed, single-use.

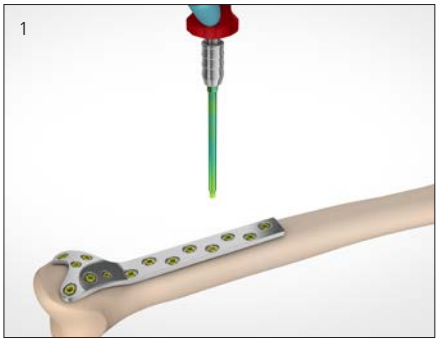
Option
- **Extensions for the removal of deeply inserted screws**
- **Adapter with AO coupling for the use of instruments with power tools.**

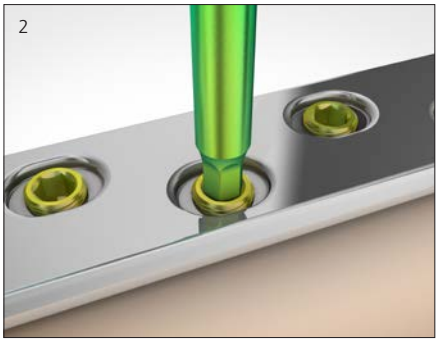
Note
- **Start with the handle.**
  If the screw cannot be rotated, use the cross-handle.

Procedure
1. Select screwdriver insert of the appropriate size and shape according to table 1.
2. Carefully clean screw recess.
3. Lock screwdriver insert in the handle coupling.
4. Insert the screwdriver insert into the screw recess.
5. **Loosen screw manually** by turning counterclockwise.

Option
- **After it is loosened, remove the screw with the adapter with AO coupling and power tool**

Important
- **Use slot screwdriver inserts manually only**
- **Ensure that the screwdriver insert is fully inserted into the screw recess, otherwise the insert may spin in the recess.**





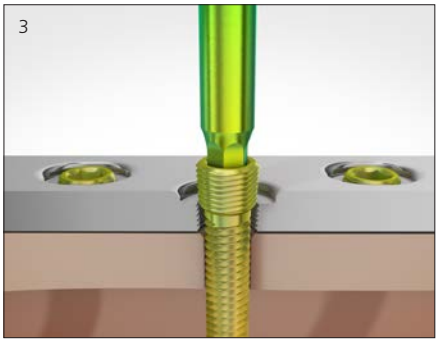


Table 1 — **Compatibility matrix based on screw diameter**

Screw diameter in mm

	OPERACE REF	0.9	1.0	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1	2.3	2.4	2.5	2.6	2.7	2.8	3.0	3.2	3.3	3.4	3.5	3.7	3.8	3.9	4.0	4.2	4.3	4.5	4.7	4.8	4.9	5.0	5.3	5.5	5.7	6.0	6.4	6.5	6.8	7.0	7.3	7.5	8.0
Hex 1.3	80196								■							■																															
Hex 1.5	80046						■			■		■		■	■	■				■	■	■	■	■																							
Hex 1.8	80051															■				■																											
Hex 2.0	80054													■				■		■				■				■	■	■	■															
Hex 2.5	80048											■		■	■	■		■	■	■				■	■	■	■	■			■				■										
Hex 3.0	80197																			■						■					■														
Hex 3.5	80050																	■					■	■			■	■	■		■	■	■	■	■	■	■	■	■	■			■	■
Hex 4.0	80052																																								■		■	
Hex 5.0	80168																											■			■												■		■	■

	OPERACE REF	0.9	1.0	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1	2.3	2.4	2.5	2.6	2.7	2.8	3.0	3.2	3.3	3.4	3.5	3.7	3.8	3.9	4.0	4.2	4.3	4.5	4.7	4.8	4.9	5.0	5.3	5.5	5.7	6.0	6.4	6.5	6.8	7.0	7.3	7.5	8.0
T4	80069						■	■		■																																				
T5	80070						■																																								
T6	80071									■		■		■		■	■	■		■	■																									
T7	80178											■				■	■		■																											
T8	80073									■		■		■		■		■		■				■				■						■										
T9	80198															■		■		■				■				■			■														
T15	80075																	■		■				■				■			■														■
T20	80077																							■	■	■		■			■				■									
T25	80079																											■			■				■									
T30	80081																																											
T40	80083																																											■

	OPERACE REF	0.9	1.0	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1	2.3	2.4	2.5	2.6	2.7	2.8	3.0	3.2	3.3	3.4	3.5	3.7	3.8	3.9	4.0	4.2	4.3	4.5	4.7	4.8	4.9	5.0	5.3	5.5	5.7	6.0	6.4	6.5	6.8	7.0	7.3	7.5	8.0
SQR 0.7	80036		■	■		■	■																																					
SQR 1.0	80037						■	■	■	■	■	■																																	
SQR 1.2	80044						■		■			■		■		■		■		■																									
SQR 1.5	80194															■																													
SQR 1.8	80039											■						■		■																									
SQR 2.2	80195																							■																					
SQR 2.3	80041																							■																					

	OPERACE REF	0.9	1.0	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1	2.3	2.4	2.5	2.6	2.7	2.8	3.0	3.2	3.3	3.4	3.5	3.7	3.8	3.9	4.0	4.2	4.3	4.5	4.7	4.8	4.9	5.0	5.3	5.5	5.7	6.0	6.4	6.5	6.8	7.0	7.3	7.5	8.0
CR 0.3	80055		■	■		■	■					■		■																														
CR 0.4	80056				■	■	■		■	■																																			
CR 0.5	80060					■	■	■	■	■	■	■		■				■																											
CR 0.6	80057											■	■	■	■	■		■	■	■																									
CR 0.8	80058																			■				■																					
CR 1.0	80059																			■																									

	OPERACE REF	0.9	1.0	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1	2.3	2.4	2.5	2.6	2.7	2.8	3.0	3.2	3.3	3.4	3.5	3.7	3.8	3.9	4.0	4.2	4.3	4.5	4.7	4.8	4.9	5.0	5.3	5.5	5.7	6.0	6.4	6.5	6.8	7.0	7.3	7.5	8.0
SL 0.3	80061		■	■		■	■					■		■																														
SL 0.4	80062				■	■																																						
SL 0.5	80065						■	■	■	■	■	■		■				■																											
SL 0.6	80063											■	■	■	■	■		■	■	■																									
SL 0.8	80064																			■				■																					
SL 1.0	80066																			■															■										

	OPERACE REF	0.9	1.0	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1	2.3	2.4	2.5	2.6	2.7	2.8	3.0	3.2	3.3	3.4	3.5	3.7	3.8	3.9	4.0	4.2	4.3	4.5	4.7	4.8	4.9	5.0	5.3	5.5	5.7	6.0	6.4	6.5	6.8	7.0	7.3	7.5	8.0
PH 1	80086											■						■																										

■ most commonly used screw drive for the respective diameter
■ other possible screw drives for the respective diameter

The table provides an overview of the screw recesses used for the respective screw diameters.
Cells highlighted in black denote the screw recesses most commonly used in medicine with the correspondingly recommended screwdriver inserts.
Other screw recesses are used depending on the manufacturer in each case.
These and the correspondingly recommended screwdriver inserts are highlighted in gray.

Note

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

PROCEDURE 2

Removal of screws with a damaged screw recess

Handle Cross-handle Extraction screw

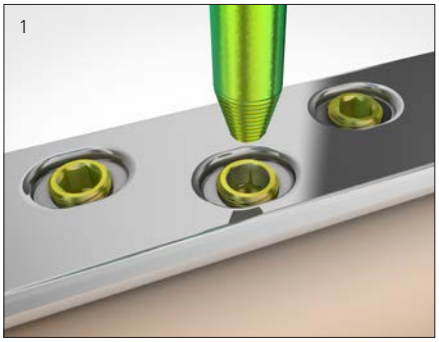
Instruments used
- Handle or cross-handle of the appropriate size.
- Extraction screw of the appropriate size, sterile-packed, single-use.

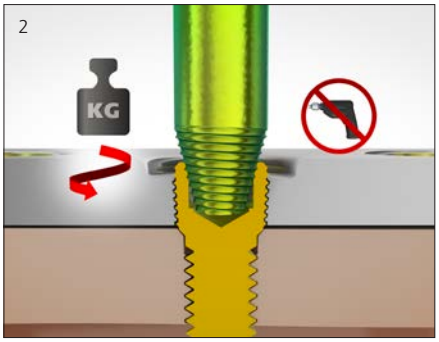
Procedure
1. Select extraction screw of the appropriate size matched to the screw recess size according to table 2.
2. Lock extraction screw in the handle coupling.
3. Start turning the extraction screw **to the left, counterclockwise,** in the same axis as the screw to be removed.
4. Continue turning, applying constant pressure, until the conical left-handed thread is securely seated in the damaged recess and until sufficient torque is applied to unscrew the screw.
5. Then unscrew the screw, turning to the left.

Important
- **Turn to the left, counterclockwise.**
- **Use extraction screws only for removing screws with a damaged drive recess.**
- **Use extraction screws manually only.**

Note
- **If the extraction screw spins in the screw recess, an attempt can be made to drill the screw recess with the corresponding extraction drill bit to anchor the extraction screw more deeply.**

Note
- **For HEX 5.0 mm, T30 and T40 screw drives, a slightly deeper hole can be drilled in the recess with extraction drill bit 4.0.**





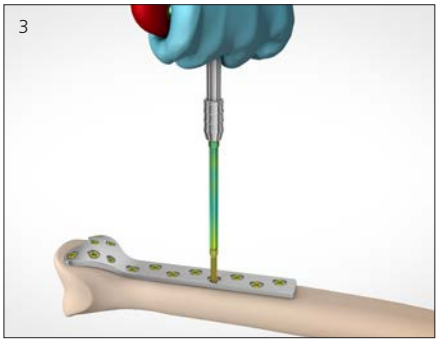


Table 2
Screw recess size

						OPERACE REF	
⬡	Hex 1.5	✪	T6, T7	▢	SQR 1.0, 1.2, 1.5	80018	Extraction screw # 1.6
	Hex 1.8, 2.0		T8, T9		SQR 1.8	80170	Extraction screw # 2.0
	Hex 2.5, 3.0		T15		SQR 1.8, 2.2	80020	Extraction screw # 2.6
	Hex 3.5, 4.0		T20, T25		SQR 2.3	80022	Extraction screw # 3.5

PROCEDURE 3

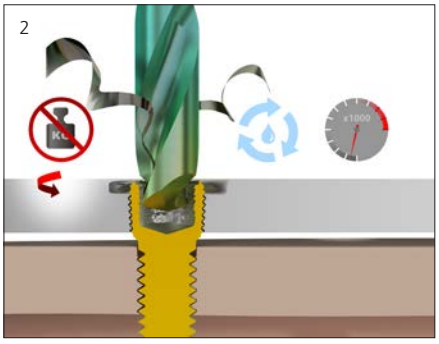
Removal of locking head screws stuck in the plate which cannot be removed by any of the above procedures

Instruments used
- Power tool with Jacobs chuck.
- Extraction drill bit of the appropriate size, sterile-packed, single-use.

Procedure
1. Select extraction drill bit of the appropriate size according to table 3.
2. Position the drill bit in the screw recess and start turning the drill bit matching the screw diameter **to the right, clockwise,** in the same axis as the screw to be removed and applying **very little pressure.**
3. Only drill down until the underside of the implant plate is reached. This either loosens the screw head from the shaft or else weakens it sufficiently to cause it to break off when the plate is lifted.
4. Remove the plate.
5. Remove the screws according to procedure 4.

Important
- **Turn to the right, clockwise.**
- **Apply the drill bit while it is already rotating, not while it is stationary.**
- **Apply very little pressure initially, only using the weight of the power tool, and start with a slow speed.**
- **Cool the bit and aspirate drill chips during the procedure. In order to avoid overheating, relieve the pressure on the drill from time to time.**
- **When the bit has reached the base of the recess, increase the pressure on the screw in order to obtain good chip formation.**
- **Do not use the bit to drill in bone or drill out broken screwdriver tips.**

Power tool Extraction drill bit



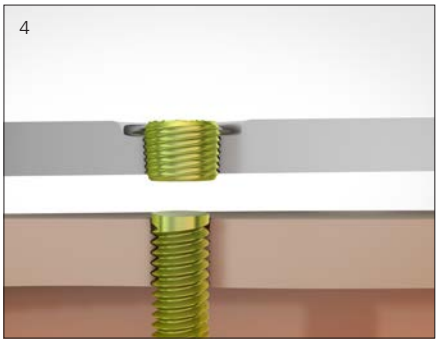


Table 3
Screw diameter in mm

∅	OPERACE REF	
1.0–1.5	80023	Extraction drill bit 1.5
1.5–2.0	80123	Extraction drill bit 2.0
2.3–2.5	80024	Extraction drill bit 2.5
2.6–3.2	80025	Extraction drill bit 3.2
3.4–4.0	80019	Extraction drill bit 4.0
4.2–5.0	80026	Extraction drill bit 5.0
5.3–6.5	80027	Extraction drill bit 6.5
7.0–7.5	80021	Extraction drill bit 7.5

PROCEDURE 4A

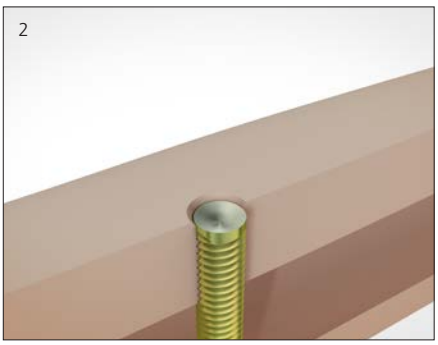
Removal of broken, projecting screws or screws processed according to procedure 3

Instruments used
- Standard T-handle with Jacobs chuck or
- Power tool with Jacobs chuck.
- Extraction reamer of the appropriate size, sterile-packed, single-use.

T-handle Power tool Extraction reamer

Procedure
1. Select extraction reamer of the appropriate size matched to the screw recess according to table 4.
2. Locate the stationary extraction reamer and turn in the direction of the screw axis to ream over the screw shaft remaining in the bone. Apply **slight pressure** initially, **turning to the left, counterclockwise.**
3. As soon as the reamer grips the screw shaft, continue reaming with increased pressure until the conical left-handed thread is securely seated on the screw shaft.
4. **When unscrewing the reamer do not relieve the pressure, but maintain the constant axial pressure and direction of rotation.**

Note
- **A manual procedure with a T-handle and Jacobs chuck is preferred.**



Important
- **Turn to the left, counterclockwise. When unscrewing the reamer do not relieve the pressure, but maintain the constant axial pressure and direction of rotation.**
- **If a power tool is used, it should be kept at a very low speed.**
- **Cool the reamer and aspirate the drill chips during the procedure.**

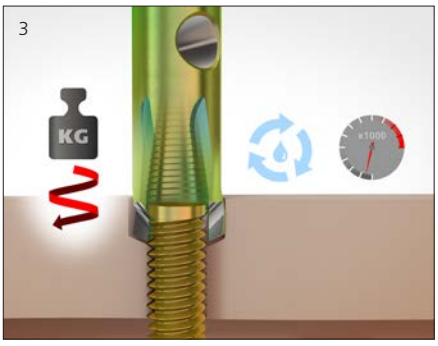
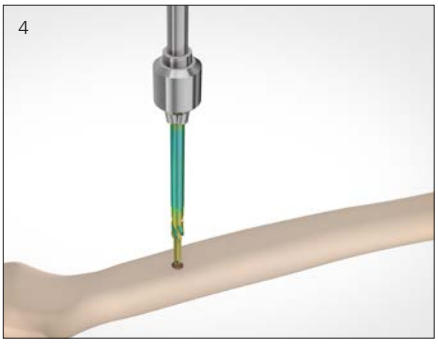


Table 4
Screw diameter in mm

∅	OPERACE REF	
1.5–2.0	80009	Extraction reamer 2.0
2.3–2.5	80028	Extraction reamer 2.5
2.6–3.2	80029	Extraction reamer 3.2
3.4–4.0	80030	Extraction reamer 4.0
4.2–4.5	80033	Extraction reamer 4.5
4.7–5.8	80035	Extraction reamer 5.8
6.0–7.5	80015	Extraction reamer 7.5



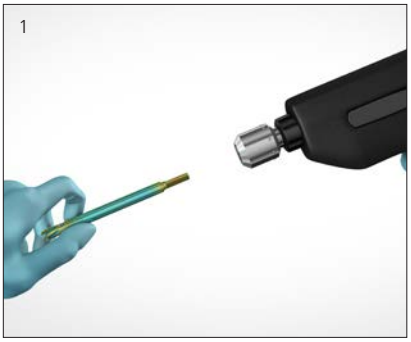
PROCEDURE 4B

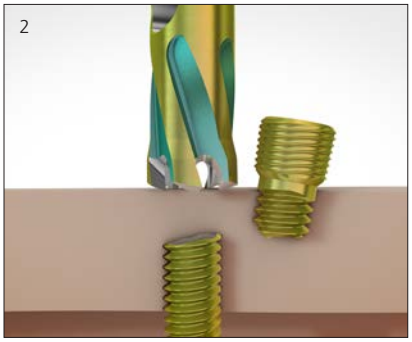
Removal of buried broken screw shafts

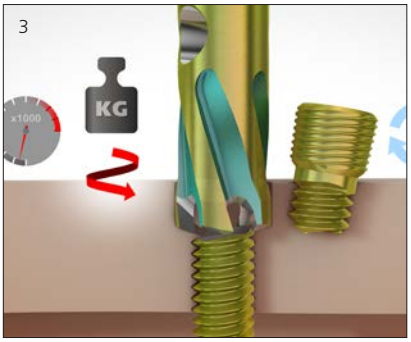
Instruments used
- Standard T-handle with Jacobs chuck or
- Power tool with Jacobs chuck.
- Extraction reamer of the appropriate size, sterile-packed, single-use.

T-handle Power tool Extraction reamer

Procedure
1. Select extraction reamer of the appropriate size matched to the screw recess according to table 4.
2. Locate the stationary extraction reamer perpendicular to the bone so that the teeth rest on the bone as evenly as possible. Apply **slight pressure** initially, **turning to the left, counterclockwise.**
3. 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 the reamer from the bone at regular intervals and free it of accumulated bone material.**
5. Continue reaming with increased pressure until the conical left-handed thread is securely seated on the screw shaft.
6. **When unscrewing the reamer do not relieve the pressure, but maintain the constant axial pressure and direction of rotation.**



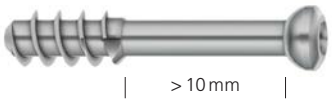




Important
- **Turn to the left, counterclockwise.**
- **When unscrewing the reamer do not relieve the pressure, but maintain the constant axial pressure and direction of rotation.**
- **If a power tool is used, it should be kept at a very low speed. If the screw grips, a manual procedure with a T-handle and Jacobs chuck is preferred.**

Note

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. Although a reamer diameter smaller than that shown in the table 4 is used for this purpose, at least 10 mm of shaft without thread must be present.



OPERACE INSTRUMENT SET MINI

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 ∅ 1.5–2.0
	80009	Extraction reamer, 2.0 f/screws ∅ 1.4–2.0
Storage		
	81000	Storage container, empty

OPERACE INSTRUMENT SET SMALL

Reprocessable instruments		
	80002	Handle SMALL
	80004	Cross handle SMALL
	80007	Extension SMALL, for screwdriver inserts
	80010	Pick-up coupling, SMALL, with AO/Synthes 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
	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 ∅2.3–2.5
	80025	Extraction drill bit, 3.2 f/ screws ∅2.6–3.2
	80019	Extraction drill bit, 4.0 f/ screws ∅3.4–4.0
	80028	Extraction reamer, 2.5 f/ screws ∅2.3–2.5
	80029	Extraction reamer, 3.2 f/ screws ∅2.6–3.2
	80030	Extraction reamer, 4.0 f/ screws ∅3.4–4.0
Storage		
	81000	Storage container, empty

OPERACE INSTRUMENT SET LARGE

Reprocessable instruments		
	80003	Handle LARGE
	80005	Cross handle LARGE
	80008	Extension LARGE, for screwdriver inserts
	80011	Pick-up coupling, LARGE, with AO/Synthes 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
	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 ∅4.2–5.0
	80027	Extraction drill bit, 6.5 f/ screws ∅5.3–6.5
	80021	Extraction drill bit, 7.5 f/ screws ∅7.0–7.5
	80033	Extraction reamer, 4.5 f/ screws ∅4.2–4.5
	80035	Extraction reamer, 5.8 f/ screws ∅4.7–5.8
	80015	Extraction reamer, 7.5 f/ screws ∅6.0–7.5
Storage		
	81000	Storage container, empty

IMPORTANT INSTRUCTIONS

GENERAL INSTRUCTIONS

Disposal
Used single-use inserts must be disposed of correctly.

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 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. Any deviation from the instructions in the reprocessing section on page 25 should be analyzed and assessed in respect of their new possible risks.

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.

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.

INSTRUCTIONS FOR SINGLE-USE PRODUCTS

These instructions for use apply to all sterile inserts supplied by PB Swiss Tools GmbH and listed in this Surgical Technique.
- Screwdriver inserts
- Extraction Screws
- Extraction reamers
- Extraction drill bits

Sterile-packed, for single use
Inserts may 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 coating. Slight deviations in color or shading result from the manufacturing process and do not affect the quality of the inserts.

INSTRUCTIONS FOR REPROCESSABLE PRODUCTS

These instructions for use apply to all reprocessable surgical instruments supplied by PB Swiss Tools GmbH and listed in this Surgical Technique.
- Handles
- Cross-handles
- Extensions
- AO/Synthes couplings

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 respective national and any applicable internal regulations must be observed. For further information on cleaning and sterilization see the reprocessing section on page 25.

INTERPRETATION OF SYMBOLS

REF	Catalogue number
LOT	Lot No./Batch code
SN	Serial number
	Manufacturer
	Date of manufacture
	Expiry date
	Non-sterile
STERILE R	Sterilized by radiation
	For single use
	Do not resterilize
	Do not use if the sterile packaging is damaged
	Caution, consult the instruction for use
	Hex screw recess
	Torx®/Stardrive® screw recess
	Square/Robertson screw recess
	Cruciform screw recess
	Slotted screw recess
	Phillips screw recess
⌀	Screw diameter
	Extraction screw
	Extraction drill bit
	Extraction reamer
CE 1250	CE mark with identification number of the recognized inspection body
	Applying pressure
	Very little pressure
	Turn clockwise
	Turn counterclockwise
	Use manually only
	Cooling
	Slow speed

REPROCESSING

CLEANING AND STERILIZATION INSTRUCTIONS FOR REPROCESSABLE INSTRUMENTS

Limitations associated with reprocessing
The life of the instruments is not unlimited. The maximum number of processing cycles cannot be determined in advance. The life of the instruments is determined by their correct use and by careful handling. The instruments should be meticulously examined before every use in order to ensure that they are fully functional.

Preparation for cleaning/disinfection
The handles, extensions and couplings should be cleaned and disinfected as soon as possible after use. Dried-on contaminants may impede cleaning.

Cleaning/disinfection, rinsing and drying
Since mechanical methods can be standardized and are much more effective, they should be given preference over manual methods.

Mechanical reprocessing
Use only validated washers and disinfectors (WDs) in accordance with ISO 15883. The operating instructions of the WD manufacturers must be observed. Detergents with a pH of 7–9.5 are recommended, subject to a maximum pH of 11. The handles and extensions must be loaded with the holes face down so that the detergent can drain properly.

Typical washer-disinfector program:
1. Prewash for 3 min, cold tap water
2. Add detergent/disinfectant
3. Wash for 10 min at 55 °C
4. Rinse for 1 min with tap water
5. Rinse for 1 min with demineralized water
6. Thermal disinfection (at least 5 min at >90 °C)
7. Dry (according to the drying cycle of the washer/disinfector. If necessary, continue drying cannulations with sterile-filtered compressed air).

Manual reprocessing
Manual cleaning should be done only if the option of mechanical reprocessing is not available. For manual cleaning, the components are placed in a solution of a combined detergent/disinfectant with a proven disinfectant action. The solutions must be prepared according to the manufacturer's instructions (concentration, temperature, contact time). Detergents and disinfectants with a pH of 7–9.5 are recommended, subject to a maximum pH of 11. Pay particular attention to the cleaning of cannulations (e.g. at the front of the coupling).

Typical manual method:
1. Place product in cold water for at least 5 min
2. Remove blood and other residues with a soft brush (do not use metal brushes or scourers)
3. Immerse product for at least 10 min in a bath with detergent/disinfectant at 45 °C or according to the manufacturer's instructions
4. After cleaning, thoroughly rinse the product with demineralized water. Cannulations must be filled and emptied several times
5. Dry the instruments

INSPECTION

Cleanliness
After every cleaning/disinfection process the products must be free of visible residues and other contaminants. The products, and particularly the cannulations on the couplings, should be carefully inspected for possible residues. If necessary, the reprocessing process should be repeated until the product is visually clean.

Function
Before each use the surgical instruments should be checked for fractures, cracks, distortions, corrosion and correct function. On couplings, it must be possible to move the slide ring gently back and forth.

Packing and labelling
Pack the products/instrument tray as soon as possible after reprocessing in a sterilization bag or sterilization container according to ISO 11607 and label the packaging accordingly.

Sterilisation
We recommend steam sterilization for the handles, extensions and couplings. The sterilization must be carried out in validated, properly maintained steam sterilizers according to ISO 17665.
- Steam sterilization in saturated superheated water steam
- Sterilization at 134°C, holding time 18 minutes

Drying time 20–60 minutes depending on the packing material or container and the performance features of the sterilizer. The operating instructions must be followed in all cases.

Storage
The instruments should be stored in a clean, dry environment, protected from direct sunlight, vermin, extreme temperatures and humidity.

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PB SWISS TOOLS

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