

Electronic

INSTRUCTIONS FOR USE

OPERACE

- Implant screws extraction system
- Screw recess trial
- Instruments for multiple use

The instructions for use are subject to change without notice. The latest version of the instructions for use is always available online.



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Instructions for use

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. These instructions for use alone are not sufficient for using the system. Instruction in the use of this system by an experienced surgeon is recommended.

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

INTENDED PURPOSE

OPERACE Screw Extraction System is intended for the removal of screws made of titanium, titanium alloys and stainless steel, in particular:

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

INDICATION FOR USE

OPERACE Screw Extraction System is used for the removal of metals, placed for osteosynthetic reasons in all patients.

CONTRAINDICATION

For the OPERACE Screw Extraction System no contraindication is given as long as the intended purpose is considered.

USER GROUPS AND USE ENVIRONMENT

Screws are removed invasively by experienced surgeons and medical professionals in a sterile operating environment or a suitably equipped outpatient treatment environment.

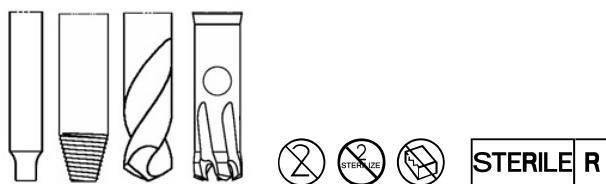
SIDE EFFECTS / RESIDUAL RISKS

As with all major surgical procedures, risks, side effects and adverse events can occur. While a variety of different reactions are possible, the most common are: problems due to anesthesia and patient positioning (e.g., nausea, vomiting, neurological impairment, etc.), thrombosis, embolism, infection.

Injury to nerves and other critical structures such as blood vessels and soft tissue due to slipping or breakage of the instrument. Burns, necrosis due to high heat generation caused by high speeds, high pressure and/or insufficient cooling during drilling or milling. Abnormal scarring, pain, discomfort, allergic or hypersensitivity reactions. Augmented risk of refracture after surgery due to weakened bone structure.

Critical prolongation or termination of surgery due to inadequate preparation, having not all instruments ready, and not including possible alternatives. Important tools include different pliers, irrigation equipment and carbide drills.

STERILE INSERTS FOR SINGLE USE



Precautions

The Screwdriver Inserts, Extraction Screws, Extraction Drill Bits and Extraction Reamers are supplied sterile in a double blister pack and are intended for single use only.

Components that are opened and are not used must not be resterilized.

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.

- Before use, check the expiration date of the product and the integrity of the sterile packaging. The product must not be used if the packaging is damaged, torn or unintentionally opened.
- The Screwdriver Inserts can be used to remove several screws in one operation. The Extraction Screws, Extraction Reamers and Drill Bits are subject to wear during use. One to several screws can be removed with them during one operation. If the cutting performance decreases, a new insert must be used.

OPERACE Screwdriver Inserts



OPERACE Screwdriver Inserts are used to remove implant screws in all patients.



Precautions

Ensure that the screwdriver insert is fully inserted into the screw recess, otherwise the insert may spin in the recess.

Use Slotted Screwdriver Inserts manually only.

Do not use a power tool for loosening screws.

In case of instrument breakage do not proceed with using the Screwdriver Inserts, instead follow up with Extraction Screws or Extraction Drill Bits.

OPERACE Screwdriver Inserts are compatible with the following standard screw recesses¹:

Screw Recess	Hexagonal socket 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	T4, T5, T6, T7, T8, T9, T10, T15, T20, T25, T30, T40
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	0.3 mm, 0.4 mm, 0.5 mm, 0.6 mm, 0.8 mm, 1.0 mm
Screw recess size	0.3 mm, 0.4 mm, 0.5 mm, 0.6 mm, 0.8 mm, 1.0 mm
Screw recess	PH1

HEX 

Screw Recess Hexalobular drive Torx® / StarDrive™

T 

Screw Recess Square / Robertson

SQR 

Screw Recess Cruciform

CR 

Screw Recess Slotted

SL 

Screw Recess Phillips

PH 

¹ The screwdriver inserts in OPERACE correspond to standard medical screwdriver inserts and are compatible with screws according to ASTM F 543, ISO 5835, ISO 10664 and ISO 9268 specifications.

OPERACE Extraction Screws



OPERACE Extraction Screws are used for removal of implant screws with damaged hexagonal -, hexalobular drive or square recess.



Precautions

Turn counterclockwise.

Use Extraction Screws manually only.

- Use Extraction Screws only for removing screws with damaged recess.
- Separate an implant screw from the Extraction Screw by turning clockwise

Ø mm	Screw Recess Size			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

OPERACE Extraction Drill Bit



OPERACE Extraction Drill Bits are used for the removal of damaged or stuck screws.



Precautions

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 by irrigation and apply suction for removal of debris potentially generated during implant removal.

If a broken screwdriver tip is in the screw, first attempt to remove the broken part with a sharp hook and/or pliers. If this attempt fails, use a carbide drill bit.

- Turn clockwise.
- Do not use the drill for drilling into bone or drill out broken screwdriver tips.

Screw diameter in mm

Ø	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

OPERACE Extraction Reamer



OPERACE Extraction Reamer are used to remove broken screws or screws with their head drilled off.



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 by irrigation and apply suction for removal of debris potentially generated during implant removal.

- A manual procedure with a Small Universal Chuck with T-Handle is preferred.
- When unscrewing the screw, do not relieve the pressure, but maintain a constant axial pressure and direction of rotation.
- Separate an implant screw from the Extraction Reamer by turning clockwise.

Screw diameter in mm

Ø	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

SCREW RECESS TRIALS



STERILE R

Screw Recess Trial

Screw Recess Trials are used to determine the size of undamaged screw recesses.

Screw Recess Hexagonal socket 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 Hexalobular drive Torx® / StarDrive™

T 

Screw recess size T4, T5, T6, T7, T8, T9, T10, T15, T20,
T25, T30



Precautions

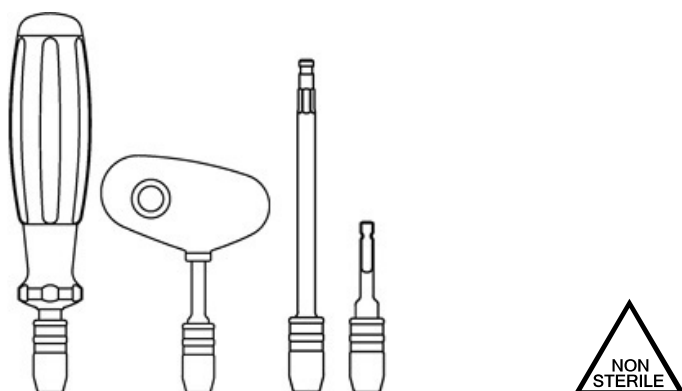
Do not break Screw Recess Trials out of the bundle over the patient. Particles could be generated during break-out.

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.

- The Screw Recess Trials are supplied sterile in pouch packaging and are intended for single use only.
- Screw Recess Trials are used to determine the size of undamaged screw recesses in trauma surgery and are always used together with sterile screwdriver inserts.
- Determine the correct size and shape of the screw recess by visual inspection and tactile probing. Determine the correct screw insert using the printed reference on the trial.
- Before use, check the expiration date of the product and the integrity of the sterile packaging. The product must not be used if the packaging is damaged, torn or unintentionally opened.
- For single use only. The products cannot be reprocessed. The trials will deform when sterilized with steam.

INSTRUMENTS FOR MULTIPLE USE



The OPERACE Handles, Cross-Handles, Extensions and AO Adapters are supplied non-sterile. Before use in surgery, they must be reprocessed and steam sterilized. See also the detailed instructions in the document: REF 80290 "Cleaning and sterilization instructions for reusable instruments". Available as PDF files at www.pbswisstools.com/ifu

The instructions contain information on the reprocessing (cleaning, disinfection and sterilization) of OPERACE products, the inspection and care of the instruments, the identification features regarding wear/tear and loss of usability.

The OPERACE Handles are accessories for the OPERACE Screwdriver Inserts and Extraction Screws. They are designed to fit with OPERACE Extensions if required. The OPERACE Extensions are connected to extend the OPERACE Handles to the OPERACE Inserts. The OPERACE AO Adapters are used to connect the OPERACE Inserts with an AO connection.

Shocks and bending loads on the instruments must be avoided, as they can damage the instrument or destroy it.

Precaution

The color code of the Handles and Extensions must match the color code and size class (MINI, SMALL or LARGE) of the inserts.

Prior to each procedure, reprocessing must be carried out as described in the document: REF 80290 "Cleaning and sterilization instructions for reusable instruments".

MATERIALS OPERACE SYSTEM

- Hardened spring steel
- Hardened stainless steel
- High-speed steel
- Stainless steel
- Plastics PP, TPV, ABS

LABELING OF HAZARDOUS SUBSTANCES

The number below the symbol indicates which hazardous substance is present in the medical device.



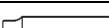
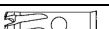
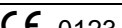
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- 1 This product contains cobalt, a substance present as CMR 1B at a mass concentration greater than 0.1%. Current biocompatibility assessment and scientific evidence demonstrate that this medical device does not pose an increased risk of cancer, genetic mutation or adverse effects on reproductive function.

DISPOSAL

Dispose OPERACE Inserts in accordance with national regulations and local requirements.

GLOSSARY OF SYMBOLS

	Catalogue number
	Lot- / Batch code
	Manufacturer
	Date of manufacture
	Use-by date
	Unique device identifier
	Medical device
	Non-sterile
	Consult electronic instructions for use
	Sterilized using irradiation
	Double sterile barrier system
	Single sterile barrier system
	Precaution
	For single use
	Do not resterilize
	Do not use if sterile packaging is damaged
	Contains hazardous substances
	Distributor
	Hexagonal socket / Hex screw recess
	Hexalobular drive Torx®/Stardrive™ screw recess
	Square/Robertson screw recess
	Cruciform screw recess
	Slotted screw recess
	Phillips screw recess
	Screw diameter
	Screwdriver Insert
	Screw Recess Trial
	Extraction Screw
	Extraction Drill Bit
	Extraction Reamer
	European Conformity with identification number of the notified body
	United Kingdom Conformity
	European Authorized Representatives
	Applying pressure
	Very little pressure
	Turn clockwise
	Turn counterclockwise
	Use manually only
	Cooling
	Slow speed

OPERACE Screw Extraction System

	CND	GMDN	REF
Screwdriver Inserts	P0913	58776	80036, 80037, 80039, 80041, 80044, 80046, 80048, 80050, 80051, 80052, 80053, 80054, 80055, 80056, 80057, 80058, 80059, 80060, 80061, 80062, 80063, 80064, 80065, 80066, 80069, 80070, 80071, 80073, 80075, 80077, 80078, 80079, 80081, 80083, 80086, 80168, 80178, 80194, 80195, 80196, 80197, 80198
Extraction Screws	P0913	61030	80018, 80020, 80022, 80170
Extraction Drill Bits	P0913	43390	80023, 80123, 80024, 80025, 80019, 80026, 80027, 80021
Extraction Reamers	P0913	61029	80009, 80015, 80028, 80029, 80030, 80033, 80035
Screw Recess Trials	V0912	64122	80295, 80296
Handles, Cross-Handles	L091001	47829	80001, 80002, 80003, 80004, 80005
Extensions and AO Adapters	L091001	47847	80006, 80007, 80008, 80010, 80011