

IMPORTANT INFORMATION

OPERACE

Screws Extraction System

INSTRUCTION FOR USE

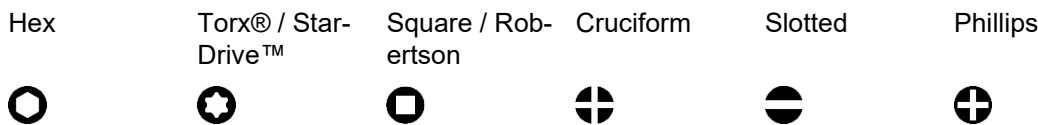
Read these instructions for use and all associated documents thoroughly before use. Make sure that you are familiar with the appropriate surgical technique for OPERACE. These instructions for use alone are not sufficient for using the system. Instruction in the use of this system by an experienced surgeon is recommended.

INTENDED USE

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

OPERACE can be used to remove intact screws made of titanium, titanium alloys and stainless steel with the following standard drives¹:



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

The OPERACE Screw Extraction System is not intended for inserting implant screws.

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.

Critical prolongation or termination of surgery due to inadequate preparation, having not all instruments ready, and not including possible alternatives.

The instructions for use are subject to change without notice. The latest version of the instructions for use is always available at www.pbswisstools.com/ifu

These instructions are for PB Swiss Tools Medical Devices sold in the United States.

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.

STERILE EXTRACTION INSERTS & SCREW RECESS TRIALS FOR SINGLE USE

DEVICE DESCRIPTION

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 screw recess trials are sterile-packed in a pouch, for single use only.

STERILITY

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.

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.

PRECAUTIONS

The screwdriver inserts can be used to remove several screws in one operation. The extraction screws, reamers and drills are subject to wear during use. If the cutting performance decreases, a new insert must be used.

INSTRUMENTS FOR REUSE

DEVICE DESCRIPTION

The OPERACE handles, cross handles, extensions and AO adapters are supplied non-sterile.

PRECAUTIONS

Before use in surgery, they must be reprocessed and steam sterilized. See also the detailed instructions in the document: REF 80462: 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.

MATERIALS OPERACE SCREW EXTRACTION SYSTEM

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

WARNING

Medical devices containing stainless steel may elicit an allergic reaction in patients with hypersensitivity to nickel. Ensure prior to use that the patient does not suffer from this allergy.



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































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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.

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
	Caution/Warning
	For single use
	Do not resterilize
	Do not use if sterile packaging is damaged
	Distributor
	Prescription only
	Hexagon/Hex screw recess
	Torx®/Stardrive™ screw recess
	Square/Robertson screw recess
	Phillips screw recess
	Slotted screw recess
	Phillips screw recess
	Screw diameter
	Screwdriver Insert
	Screw Recess Trial
	Extraction Screw
	Extraction Drill Bit
	Extraction Reamer
	Apply pressure
	Very little pressure
	Rotate clockwise
	Rotate counterclockwise
	Only in manual mode
	Cooling
	Low speed