

Electronic

INSTRUCTIONS FOR USE

OPERACE

- Implant screw extraction system
- Screw Recess Trial
- Instruments for multiple use

Manuals are subject to change; the most current version of each manual is always available online.



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Electronic Instructions for Use



Please read this instruction for use and all corresponding documents carefully before use. Ensure that you are familiar with the appropriate surgical technique.

Intended use

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 screw
recess



Torx®/Star-
drive® screw
recess



Square /
Robertson
screw recess



Cruciform
screw recess



Slotted screw
recess

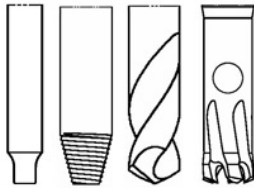


Phillips
screw recess



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 SINGLE-USE INSERTS



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



Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use, if the package is damaged. Single-use device.

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.

Screwdriver insert



- 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.

Extraction screw



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

Extraction drill bit



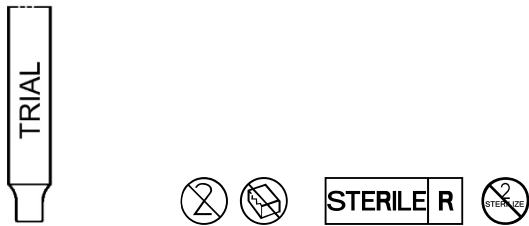
- Turn to the right, clockwise.
- Apply the drill bit while it is already rotating, not while it is stationary.
- Apply very little pressure initially, only using the weight of the power tool, and start with a slow speed.
- Cool the bit and aspirate drill chips during the procedure. In order to avoid 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.

Extraction reamer



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

SCREW RECESS TRIAL



The screw recess trials are delivered in sterile pouches and are only intended for single use.

Determine the correct size and shape of the screw recess by sight and by touch. Determine the correct screwdriver insert according to the reference printed on the trial.



Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use, if the package is damaged.

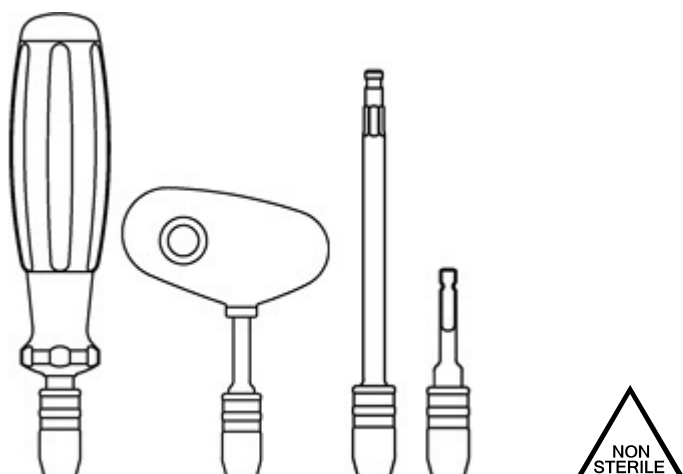
The trials must be snapped out of the bundle above the operating table and not close to the wound. Particles can be released when snapping out the trials.

The screw recess trials must not be used for removing the screws. The trials can break if subjected to excess loads.

For single use only. The products cannot be reconditioned. The trials will deform when sterilised with steam.

After the trials have been used, all trials (including unused ones) and remaining bundles must be disposed of.

INSTRUMENTS FOR MULTIPLE USE



- ⚠ The OPERACE handles, cross-handles, extensions and AO adapters are supplied in non-sterile condition. They must be cleaned and steam sterilized prior to surgical use. See detailed instructions in the document:





































CLEANING AND STERILIZATION INSTRUCTIONS FOR REUSABLE INSTRUMENTS

- ⚠ Blows and bending loads should be avoided since they can lead to instrument damage or breakage.

Side effects

- ⚠ As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include: Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, neurological impairments, etc.), thrombosis, embolism, infection.
- Nerve or injury of other critical structures including blood vessels, damage to soft tissues. Soft tissue injuries by slipping or breaking an instrument. Burns, necrosis due to high heating due to high speed, high pressure, insufficient cooling when drilling or milling. Abnormal scar formation, pain, discomfort, allergy or hypersensitivity reactions.

INTERPRETATION OF SYMBOLS

	Catalogue number
	Lot No./Batch code
	Serial number
	Manufacturer
	Date of manufacture
	Expiry date
	Non-sterile
	Read electronic documents
	Sterilized by radiation
	Authorised Representative
	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
	Screw driver insert
	Screw Recess Trial
	Extraction screw
	Extraction drill bit
	Extraction reamer
	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