

Electronic

INSTRUCTIONS FOR 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

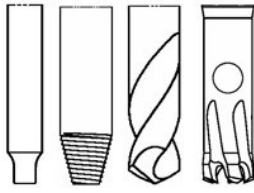
- Angular stable screws
- Cortex screws
- Cancellous bone screws
- Shaft screws
- Cannulated Screws
- Locking screws
- Locking bolts

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

Hex screw recess	Torx®/Stardrive® 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



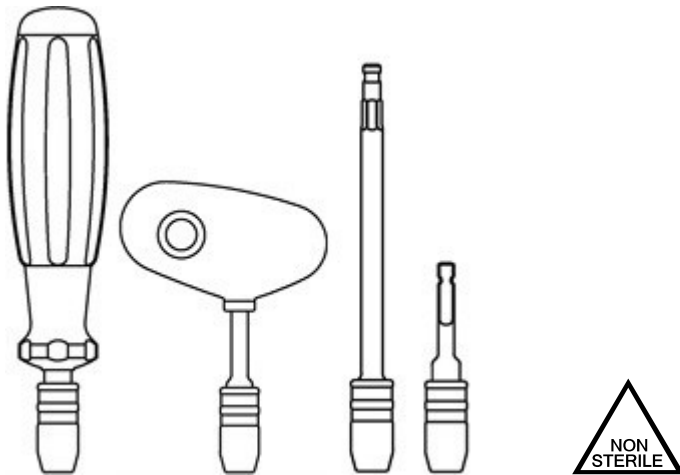
- Turn to the right, clockwise.
- Apply the drill bit while it is already rotating, not while it is stationary.
- Apply very little pressure initially, only using the weight of the power tool, and start with a slow speed.
- Cool the bit and aspirate drill chips during the procedure. In order to avoid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

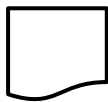


- Turn to the left, counterclockwise.
- When unscrewing the reamer do not relieve the pressure, but maintain the constant axial pressure and direction of rotation.
- If a power tool is used, it should be kept at a very low speed.
- Cool the reamer and aspirate the drill chips during the procedure.
-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

REUSABLE INSTRUMENTS



- ⚠ 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
 eIFU	Read electronic documents
	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
	Screw driver insert
	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