EN INSTRUCTIONS FOR USE | PG03 RETRACTING INSTRUMENTS

This instruction manual applies exclusively to **PRODUCT GROUP PG03**, retracting instruments.

Reference number	Description	Intended Purpose
22.00.00 - 22.99.99	Wound retractors	A reusable surgical instrument for holding back and retracting tissue and soft tissue to expose the desired anatomical region in the surgical field.
24.00.00 - 24.99.99	Wound hooks, bone levers	A reusable surgical instrument for holding back and retracting tissue, muscle and soft tissue to expose the desired anatomical region in the surgical field.
24.51.100	Lever extension	Accessory: exclusively for use with all Subtilis bone levers and wound hooks with two-hole handle.

Please read this manual and the included reprocessing instructions carefully before each use, and keep it easily accessible for the user or the corresponding medical staff.

⚠ Carefully read the warning and safety instructions marked with this symbol. Improper use of the instruments can lead to serious injury to the patient, the user, or third parties.

Indications

The instruments are intended for retracting and holding back tissue and soft tissue in order to expose the desired anatomical region within the surgical field and to enable precise, atraumatic, and tissue-conserving surgical procedures.

Contraindications

⚠ The instruments must not be used if the attending physician determines, in a specific case, that the individual risks for the patient outweigh the potential benefits of using the instrument.
These instruments are not intended for direct application to the heart or central nervous system.

Meaning of the symbols on labels and instructions

	Consult instructions for use
	Product is supplied non-sterile
	Caution, observe warnings
	Manufacturer
	Date of manufacture
CE 0483	European conformity, Notified Body number
CE	CE marking without Notified Body number
EU REP	European Authorized Representative
REF	Reference/Article number
LOT	Batch/Lot number
QTY	Quantity
MD	Medical device
UDI	Unique Device Identifier
Rx only	For prescription use only in the United States

Intended Use

The instrument must be used exclusively for its intended medical purpose by adequately trained and qualified personnel, such as surgeons or physicians in related specialties.

The user or attending physician is responsible for:

- Selecting appropriate instruments for specific applications or surgical procedures
- Ensuring proper training and information
- Possessing sufficient experience to handle the instruments correctly

Application Environment

The instruments are intended for use in controlled clinical environments such as hospitals, clinics, outpatient facilities, private practices, or similar healthcare institutions.

Storage and Transport

Store instruments clean, cool, and dry. Protect them from mechanical damage. Always store and transport them in secure containers or packaging. Handle instruments with care—do not throw or drop them.

Safety Instructions

⚠ The instruments are supplied non-sterile and must be thoroughly cleaned, disinfected, and sterilized prior to first and every subsequent use. Accuratus AG recommends washing the instruments separately three times prior to first use to support the formation of a passive protective layer.

⚠ Before each use, instruments must be inspected for wear and visible damage such as cracks, deformations, nicks on sharp edges, or fractures. In addition, a functional test must be performed to ensure safe use.

⚠ These surgical instruments are designed solely for surgical purposes and must not be used for any other application. Improper handling, care, or misuse can lead to premature wear or failure of the instruments.

⚠ Incorrect or negligent handling (e.g., surface damage) and exposure to chemical, electrochemical, or physical influences may impair corrosion resistance and result in instrument failure.

⚠ Surgical instruments are subject to corrosion and functional impairment if exposed to aggressive substances. It is therefore essential to strictly follow the cleaning and sterilization instructions provided.

⚠ To ensure the safe operation of surgical instruments, proper maintenance and care of the products is imperative. Please refer to the corresponding sections of this Instructions for Use.

⚠ For patients with Creutzfeldt-Jakob Disease (CJD), suspected CJD or variants thereof, or for patients with HIV infection, the respective national regulations on reprocessing must be followed. In such cases, we decline any responsibility for reuse of the instrument.

⚠ Please note that successful reprocessing of these instruments can only be guaranteed following prior validation of the reprocessing procedure. Responsibility for this validation lies with the operator or reprocessing facility.

⚠ Any serious incidents or adverse events related to the use of this product must be reported without delay to the manufacturer and the competent authority of the member state where the user is established.

VALIDATED REPROCESSING PROCEDURE

1. General Principles and Safety Instructions

This document contains general instructions for the reprocessing of surgical instruments from ACCURATUS.

Please read this reprocessing instruction carefully and completely before the first reprocessing cycle.

Only perform reprocessing if you have fully understood these instructions. Always follow them precisely.

Keep these instructions readily available.

The surgical instruments covered by this reprocessing instruction are delivered by Accuratus AG in a non-sterile condition and must be reprocessed prior to first and each subsequent use as described herein.

The cleaning, disinfection, and sterilization procedures described in this document have been validated by Accuratus AG. Accuratus AG assumes no liability for improper or non-compliant reprocessing or any resulting consequences. If an alternative method is used, the user is responsible for proving its suitability.

The medical device operator is responsible for ensuring that the actual reprocessing procedure used (based on the available equipment, materials, and qualified personnel within the reprocessing facility) achieves the desired outcome. Routine validation of the mechanical reprocessing procedure is required. Reprocessing may only be carried out by sufficiently qualified and experienced personnel.

2. Work Steps Immediately After Use

Immediately after use, gross contamination must be removed by soaking the instrument in cold water (<30°C / <86°F), brushing manually, and if applicable, rinsing internal channels.

⚠ Do not use metal brushes or steel wool as they may damage the surface of the instruments.

⚠ Do not use fixatives or hot water (>40°C / >104°F) as this may cause fixation of residues and compromise cleaning efficiency.

⚠ Do not place instruments in physiological saline solution, as prolonged exposure may lead to pitting corrosion and rust formation.

⚠ Improper placement and stacking can cause damage to the instruments (e.g., carbide tips on scissors may break, or small clamps may bend).

⚠ Avoid long waiting times before reprocessing (e.g., overnight or over the weekend).
Maximum allowable delay before reprocessing: 1 hour.

3. Reprocessing

⚠ The products are delivered non-sterile and must be cleaned, disinfected, and sterilized before the first and each subsequent use according to this instruction manual.

⚠ Defective products must undergo the entire reprocessing procedure prior to return for repair, due to potential infection risks.

⚠ For cases involving:

- Creutzfeldt-Jakob Disease (CJD)
- Bovine Spongiform Encephalopathy (BSE)
- Transmissible Spongiform Encephalopathy (TSE)

the instruments must be processed after use according to applicable national infection control guidelines.

3.1 General Notes

⚠ Always use freshly prepared cleaning solutions.
Extended use of a single solution can cause:

- Risk of corrosion due to contamination.
- Risk of corrosion due to increased concentration (e.g., from evaporation)
- Reduced disinfection efficacy due to contamination

3.2. Water Quality

The quality of water used for cleaning and sterilization must be tested and monitored. It is recommended to use freshly prepared, at least fully demineralized or deionized water, particularly from the final rinse step onward throughout all following stages.

3.3. Automated Cleaning

The following procedures have been validated by Accuratus AG. For effective reprocessing, all steps (manual pre-cleaning, automated cleaning, and sterilization) must be completed.

⚠ These instruments are designed for automated cleaning. Manual cleaning is not permitted due to its lower effectiveness and reliability.

Disassemble all reprocessable instruments completely before cleaning and begin with pre-cleaning.

3.4 Pre-Cleaning

- Soak instruments in cold tap water (<30°C / <86°F) for at least 10 minutes.
- Brush the entire instrument under running cold tap water (<30°C / <86°F) until no visible residues remain.
- Rinse thoroughly under running water.
- Use a water spray gun (minimum 3.7 bar static pressure) to flush joints, cavities, bores, and threads for at least 20 seconds
- Place instruments in an ultrasonic bath at 40°C (104°F) for at least 20 minutes with a 0.5% enzymatic cleaner (e.g., Neodisher Medizym – Dr. Weigert GmbH & Co. KG) and sonicate.
- Remove the instrument and rinse for at least 20 seconds with a water pressure gun (static pressure min. 3.7 bar).
- Finally, rinse with cold tap water (<30°C / <86°F).

3.5. Alkaline Cleaning Process (Miele PG 8535)

⚠ Do not overload the trays to ensure proper exposure of all instruments. Avoid instrument contact with each other.
The cleaning process was validated based on the specified detergents and equipment. If different detergents or equipment are used, it is the responsibility of the user to validate the alternative process.

⚠ Only use washer-disinfectors (WDs) compliant wit DIN EN ISO 15883-1 and ensure they are properly maintained. Ensure the following when selecting WDs:

- Use of a validated program with thermal disinfection (A_0 value > 3000) is recommended,
- Final rinsing must be done with fully demineralized/deionized water (max. conductivity 15 µS/cm),
- WDs must be regularly serviced and checked.

After cleaning and disinfection, critical evaluation of the instrument's cleanliness is required:

- Dry instrument cavities with filtered compressed air (oil- and germ-free, low particulate)
- If necessary, use lint-free cloths for manual drying.
- Contaminated instruments must be subjected to the full cleaning process again.

⚠ Adequate cleanliness is a prerequisite for successful sterilization.

⚠ Improper reprocessing or insufficient care may significantly reduce product lifespan.

⚠ Accuratus AG assumes no responsibility or liability for any damage or malfunction of instruments resulting from improper use, inadequate reprocessing, or insufficient maintenance and care.

Validated Cleaning Process:

Step	Description	Medium	Concentration [%]	Temp. [°C]	Duration [Min.]
1	Pre-rinse	Cold tap water	-	< 30	1
2	Drain	-	-	-	-
3	Pre-rinse	Cold tap water	-	< 30	3
4	Drain	-	-	-	-
5	Cleaning	• Neodisher Mediclean Forte (Dr. Weigert GmbH & Co. KG)	0.5	55	10
6	Drain	-	-	-	-
7	Neutralization	• Cold DI water + Neodisher Mediclean Forte (Dr. Weigert GmbH & Co. KG)	0.1	< 30	2
8	Drain	-	-	-	-
9	Final Rinse	Cold DI water	-	< 30	2
10	Drain	-	-	-	-

3.6. Disinfection

Automated disinfection – thermal process.

- Perform thermal disinfection using a validated washer-disinfector (WD) that complies with DIN EN ISO 15883-1.
- Minimum holding time: 5 minutes at a minimum of 90°C (194°F).

Drying

- External drying of the instruments must be performed by the drying cycle of the washer-disinfector (WD).

Inspection

- Perform visual inspection and reassembly of instruments. If visible contamination or residue is still present, repeat the reprocessing cycle until the instrument is visibly clean.
- Repeated reprocessing has only a minimal impact on the product lifetime. The end of life is typically determined by wear and damage resulting from clinical use. Therefore, after each reprocessing cycle, the product must be carefully inspected for proper function, damage, and any signs of excessive wear, corrosion, surface deterioration, chipping, deformation, restricted mobility, and the presence of hairline cracks, particularly in joint areas.

⚠ If there is any doubt that reprocessing was performed correctly, the instrument must not be used.

⚠ Instruments showing signs of significant wear or damage must not be reused and must be returned to Accuratus AG for maintenance.

⚠ Defective instruments intended for return to Accuratus AG must undergo the entire reprocessing cycle before shipping.

⚠ Corroded instruments must be discarded, as they may cause corrosion of intact instruments through contamination.

4. Limitation of Reusability

The end of life of reusable medical devices is determined by wear and damage resulting from use and reprocessing.

Reusable medical devices are subject to wear and mechanical stress even under normal use, particularly when excessive force is applied.

The end of life must be identified through careful functional and visual inspection during each reprocessing cycle. For this reason, it is not possible to specify a general maximum number of reprocessing cycles. Detailed instructions for functional testing can be found in section 6.

Medical devices that do not function properly, have markings that are unreadable (either by human or machine), have missing or worn-off part numbers, or show signs of damage or excessive wear must not be used and must be repaired or disposed of.

5. Maintenance

Maintenance must always be carried out before functional testing.

⚠ Allow the instrument to cool to room temperature before maintenance.

- Lightly lubricate moving parts (e.g., joints and locks) using suitable maintenance oil (e.g., T3000 care oil, Ref. No. 265-950-40 or STERILIT, Ref. No. JG 598).
- Apply the lubricant manually to joints, threads, and sliding surfaces, and ensure even distribution by moving the joints/sliding parts.
- Remove excess lubricant from surfaces using a lint-free cloth.
- Instruments must be visually and tactilely checked for cleanliness and be free of visible residue.

⚠ Do not use silicone-based lubricants!

6. Functional Testing

Detailed functional testing instructions for individual instruments can be found at:
www.accuratus.ch/info-ifu

7. Packaging

Sterilization must be carried out in single-use sterilization packaging and/or sterilization containers. These must comply with the applicable standards (e.g., DIN EN ISO/ANSI AAMI ISO 11607 / EN 868), be suitable for the sterilization method used, and offer adequate protection against mechanical damage. If the packaging is damaged after sterilization or opened prior to use, the instrument must not be used and must undergo the entire reprocessing cycle again.

8. Sterilization

The recommended sterilization parameters are not intended nor suitable for the inactivation of prions. If the product has been in contact with infectious TSE tissue or if such contact is suspected, it must be disposed of in accordance with applicable national regulations on infection control.

- Sterilize products using a fractionated pre-vacuum process in accordance with DIN EN 13060 / ISO 17665, while also observing national requirements.
- Sterilization has been validated at 132°C (270°F) for 3 minutes. Therefore, a minimum sterilization time of 3 minutes must be maintained.

	Europa	Schweiz
Process	Fractionated pre-vacuum	Fractionated pre-vacuum
Temperature	134°C (273°F)	134°C (273°F)
Holding Time	5 minutes	18 minutes
Drying Time	Min. 10 minutes	Min. 10 minutes

	USA	
Process	Dynamic Air Removal (Wrapped cycle)	Dynamic Air Removal (Wrapped cycle)
Temperature	132°C (270°F)	135°C (275°F)
Holding Time	4 minutes	3 Minuten
Drying Time	Min. 16 minutes	Min. 20 minutes

9. Storage of Sterile Instruments

Sterile instruments must be stored in a dry, clean, and dust-free environment, protected from direct sunlight and maintained at moderate ambient temperatures.

10. Repair

Repairs must be carried out exclusively by Accuratus AG or by an organization authorized by Accuratus AG.

11. Disposal

Before disposal, instruments must be cleaned, disinfected, and sterilized. Disposal of the instruments, packaging materials, and any accessories must be performed in accordance with applicable national laws and regulations.

12. Warranty

Accuratus AG provides a 3-year warranty covering verifiable material or manufacturing defects or quality issues.

Any improper use, handling, modifications, or unauthorized third-party repairs will immediately void all warranty claims and invalidate the medical device's conformity.

The instructions for use are updated regularly. Please ensure that you are using the current version. The version date and version number of the respective edition can be found in the bottom right corner of the document. The currently valid document number and version are also published on our website.

For this and additional information, please visit:
www.accuratus.ch/info-ifu

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PG03_0016-IFU_Version_03/07072026