WITTENSTEIN | intens

Orthopedic Medical Devices

Instructions
for Cleaning,
Sterilization and
Maintenance

6022-D005014

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1 Purpose

These instructions mean to regulate the handling procedures (reprocessing and maintenance) of the reprocessed medical products made by WITTENSTEIN intens of stainless steel, aluminum and silicone. The instructions are necessary because the respective instruments and their functionality depend on correct treatment and maintenance.

WITTENSTEIN intens has validated the processes contained in these instructions in order to ensure their principal efficacy.

The instructions for use refer to all instruments and screws listed in the *FITBONE® Instrument Set/Instrumentarium* (6091-D001701) and *Check List FITBONE® Instrument Set* (6091-D001700), as well as to the FITBONE® SAA sliding sleeves, bolts and intramedullary nails.

This document is to be observed and applied by the surgery personnel and all employees working in Central Sterilization at our partner clinics.

2 Warning

	**Due to their continuous utilization, the instrument set is subject to natural wear and use-related damages which determine the end of the product life. Signs for damages and wear are, without any claim to completeness, corrosion (i.e., rust, pitting), discoloration, deep scratches, peeling, abrasions and cracks. Instruments that do not function correctly, which are defective or excessively worn, or instruments whose markings can no longer be read or identified, or whose part numbers are missing or no longer visible (abraded) may not be used any longer and must be discarded or replaced.**
	**The user as well as the equipment, cleaning agents and procedures contribute to the reprocessing efficacy. The clinical facility is to ensure that the reprocessing steps selected are safe and efficient.**
	**Alternative reprocessing methods not contained in this document may be suitable for reprocessing but must be validated and given evidence of by the end user, i.e. the partner clinics.**
	**Appropriate protective equipment must be used when handling contaminated or potentially contaminated materials, instruments and products.**
	**Irrespective of whether cleaning is done manually or automatically, always check with utmost care which cleaning agent is and may be used with what technique. The provisions governing dilution and application must absolutely be adhered to. We recommend cleaning agents with a pH value of < 12.**

	**Corrosion is a form of destruction and wear which can be caused by chemical reactions such as:** – **Damaged surface structures** – **Human body fluids if in prolonged contact with the instruments** – **Excessive exposure to certain solutions: saline and iodine solutions, chloride or strong acids, alkaline solutions as well as incorrectly used disinfectants** – **Water of inferior quality used for cleaning, disinfection, steam sterilization or rinsing of instruments, e.g. due to rusty water pipes, contamination of steam sterilizers by rust, metal or dirt particles etc.** – **Insufficient instrument maintenance: rust may form and infest other instruments. Avoid contact to not endanger sterilization!** – **Non-adherence to the guidelines issued by the disinfectant manufacturer governing concentrations and temperatures: if the indicated concentrations and temperatures are significantly exceeded, some materials may change color and/ or corrode. This can also be the case if the instruments are not sufficiently rinsed after cleaning and disinfection.**

	**Used screws, bolts, sliding sleeves and intramedullary nails must <u>not</u> be reprocessed and reused.**

	**Sterile container and nop mat must <u>not</u> be used for the reprocessing process because they exclusively serve for the protection of the instruments during transport.**

3 Reprocessing Instructions

3.1 Preparation at the Place of Use

- Remove body fluids, bonemeal and tissue with cloths from the instruments during surgery; after use, put the instruments back in their specific places.
- Rinse perforated instruments during or immediately after surgery in order to prevent any drying of blood and bonemeal in the inner lumen.
- Rinse with sterile distilled water for instrument cleaning. Saline solution does not suffice the purpose. Do not soak the instruments in the solution.
- For optimum results, preclean and dry the instruments within 30 minutes after use in order to keep particles from drying on and thus avoid irreparable damages before the instruments can be subjected to thorough cleaning.
- <u>Never</u> use cleaning agents and disinfectants containing <u>strongly</u> acid or alkaline additives such as soda, caustic soda or acids.
- All instruments used during surgery are classified as contaminated.
- The instruments are to be placed into the appropriate mesh racks and holder systems.

3.2 Transport

Used instruments must be transported for cleaning in closed or covered containers in order to prevent any unnecessary contamination hazard and injury to personnel or environment.
We strongly recommend cleaning the instruments not later than six hours after use.

3.3 Preparation for Cleaning

- Instruments with detachable parts must be taken apart; all screws, nuts, bolts and other small parts are to be clearly arranged and kept in the same storage place. The person in charge of assembly and dismantling needs to be trained accordingly.
  The following product is to be dismantled: 60000408 - depth gauge for sleeves
- For reprocessing of the cannulated medullary reamers, material-specific brushes are to be used for inner diameter cleaning.
- Soak and rinse strongly contaminated instruments (e.g. instruments with hollow spaces, holes and cavities) before placing them in the cleaning device.
- Preclean all pointed and sensitive instruments by hand.

Ultrasonic Cleaning

- Threads or instruments with deep grooves, for example, should be precleaned in ultrasonic baths.
- Remove all body fluids on the instrument before placing it in the ultrasonic bath. Remove by wiping the instruments with absorbent, lint-free paper towel.

Ultrasonic cleaning must be followed by automatic cleaning and disinfection!

3.4 Automatic Cleaning and Disinfection

We strongly recommend cleaning in a correctly installed, qualified, regularly services and validated **washer-disinfector**.

- Always observe the instructions for use provided by the manufacturer of the cleaning devices and agents.
- Clean instruments with threads in open condition.
- Connect the cannulations on the washer-disinfector rinse connections.
- Do not overload the trays, place heavy instruments on the tray bottom.
- Avoid any contact between the instruments during washing.

The procedure validated by WITTENSTEIN intens provides the following cleaning program:

Pre-rinsing	with cold, softened town water ≥ 51.8 °F (≥ 11 °C) for 2 minutes
Cleaning	with 0.5 % MUCAPUR AF(*) at 131 °F (55 °C) for 5 minutes
Rinsing I	with cold DI water for 1 minute
Neutralization (**)	with 0.15 % MUCAPUR Z(*) with cold water mix (2/3 town water and 1/3 DI water) for 1 minute
Rinsing II	with cold DI water for 1 minute
Thermal disinfection	with DI water at 199.4 °F (93 °C) for 10 minutes or when reaching an A_O value of > 3000.
Drying	at 212 °F (100 °C) for 25 minutes

(*) Similar cleaning agents and procedures validated by the user may be used as well.
(**) Necessary only in case of strongly alkaline cleaning agents which need to have, however, a pH value of < 12

After program completion, unload the device and check the medical products (see 3.6). If the products are not absolutely clean, they must undergo a second cleaning cycle.

	- **By way of their design as well as material and functional features, RKI recommendations (see point 11 chapter 5) classify the medical products as belonging to the critical A & B risk class, which means that they need to be reprocessed in an automated process.** - **Instruments of anodized aluminum should not get in contact with certain disinfectant solutions or cleaning agents; for this reason, the solvents to be used should always be checked for applicability and compatibility with anodized aluminum prior to exposing the metal to a chemical reaction.**

3.5 Drying

- All instruments must be absolutely dry inside and outside in order to prevent malfunctions or the formation of rust.
- Compressed air may be used for drying instruments with lumen or hinges.
- Lint-free cloths may be used as well.

3.6 Check, Function Tests and Maintenance

- Prior to each sterilization and use, all instruments of the set are to be checked for cleanliness, intactness and proper functions.
- Visually inspect for contamination and corrosion. Ensure proper illumination and/or use a magnifying glass.
- Dismantled instruments need to be re-assembled by trained personnel.
- Damaged parts must not be reused; order replacement parts from and return the damaged ones to WITTENSTEIN intens.
- If instruments have moving parts, joints etc., oil them thoroughly after cleaning/disinfection. Use only oils which comply with ISO 10993 and have been physiologically cleared and can be steam-sterilized according to ISO 17665. Excessive oil must be removed prior to packing. Rinsing is not necessary.
- After check, function test and maintenance, the dry instruments are double-wrapped in fleece. For packing, use double AAMI fleece or similar.

3.7 Steam Sterilization

For sterilization a steam autoclave (moist heat) with fractionated pre-vacuum cycle (forced air removal) must be used. The autoclaves used for sterilization are to be conform with the requirements set forth in EN 285, ISO 17665 and ANSI/AAMI ST79, must be validated for the adherence to such standards and maintained accordingly.

Sterile container and nop mat must not be used during sterilization!

WITTENSTEIN intens validated the following minimum parameters for sterilization, which achieve an SAL value of 10^{-6}:

	USA	Outside of USA
Exposure temperature	269.6 °F (132 °C)	273.2 °F (134 °C)
Residence time	4 minutes	5 minutes
Drying time	20 minutes at 248 °F (120 °C)	20 minutes at 248 °F (120 °C)

Exceedance of these parameters may reduce instrument lifetime and lies within the responsibility of the hospital.

3.8 Storage

After sterilization, the products must be cooled before they can be put into storage.

For this purpose, keep the packed medical products in a specially assigned room with limited access. The room should be well-ventilated and provide sufficient protection against dust, humidity, insects, vermin and extreme temperatures.

Before opening sterile-packed medical products, carefully check their packaging for damages and expiry date.

4 The Hospital's Responsibilities towards Rental Sets

In general, orthopedic surgery instruments have a long life. Wrong handling or insufficient protection, however, can reduce their service time significantly. Instruments which - due to long use, wrong handling or bad maintenance - do no longer function as they should, should be returned to WITTENSTEIN intens for disposal. Please inform WITTENSTEIN intens on all problems regarding the instruments.

Rental sets should be decontaminated, cleaned, disinfected, inspected and sterilized before their return to WITTENSTEIN intens. The return package to WITTENSTEIN intens should also include the *Cleaning and sterilization evidence of instruments and instrument sets* (6097-D003375).

If instruments of the rental set are missing or damaged, please inform the person in charge of the operating theater so she or he can contact the WITTENSTEIN intens sales department. This is necessary in order to ensure that the next hospital receives a complete and functioning instrument set.

The instructions provided in this manual were lab-validated by WITTENSTEIN intens and are suitable for the preparation of orthopedic products for use. It lies within the responsibility of the hospital to guarantee that 1) reprocessing is done with the appropriate equipment and materials and 2) the reprocessing personnel has been trained accordingly. The desired results can be achieved only if the above prerequisites are fulfilled. Equipment and procedures should be validated and monitored at regular intervals. In order to exclude adverse effects, all deviations from the prescribed reprocessing process by the person in charge must be assessed for their efficacy.

5 References

1. 6091-D001701: FITBONE® Instrument Set/Instrumentarium
2. 6091-D001700: Check List FITBONE® Instrument Set
3. 6097-D003375: Cleaning and sterilization evidence of instruments and instrument sets
4. ISO 15883: Washer-disinfectors
5. ISO 17664: Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices
6. EN 285: Sterilization - Steam sterilizers - Large sterilizers
7. ISO 10993: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
8. ISO 17665: Sterilization of health care products - Moist heat
9. ANSI/AAMI ST79: Comprehensive guide to steam sterilization and sterility assurance in health care facilities
10. AAMI TIR12: Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
11. Recommendation from the Commission on Hospital Hygiene and Infection Protection at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on the "Hygiene requirements for the reprocessing of medical devices"

For all technical questions, please contact the manufacturer:

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