English

Instructions for Reprocessing (cleaning, disinfection, and sterilization) and Inspection of Skeletal Dynamics Products

Failure to follow instructions may lead to patient injury.

This insert, "Instructions for Cleaning, Disinfection, Sterilization, and Inspection of Skeletal Dynamics Products" contains information about:

- The reprocessing (cleaning, disinfection and sterilization) of Skeletal Dynamics products
- The proper care to prevent damages related to wear, tear, and/or loss of usability.

Additional information about the products is provided in the systems' "Instructions for Use", individual package inserts and surgical techniques. Additionally, all relevant information can be found on Skeletal Dynamics' website (skeletaldynamics.com/resources).

The reprocessing of the products (cleaning, disinfection, and sterilization) was tested and validated by Skeletal Dynamics. The term "products" covers implants, instruments, and trays.

All components that are delivered "non-sterile" must be sterilized in the user's facility.

Basics for Cleaning, Disinfection, and Sterilization

The pretreatment for cleaning/disinfection must be carried out for both methods. It is the end user's responsibility to ensure that the components are completely sterile when used and that:

- Only validated procedures are used for cleaning/disinfection and sterilization.
- The devices used (washer, disinfector, sterilizer) are serviced and inspected on a regular basis.
- The validated parameters and/or the manufacturer's recommended parameters are respected for each cycle.

A manual and an automatic method are described for the cleaning/disinfection of the Skeletal Dynamics products.

Materials used to reprocess (clean, disinfect, and sterilize) Skeletal Dynamics' products.

- Utility water (tap water)
- Critical water (water that has gone through some type of filtration system such as RO/DI, DI water, Purified water (PW), sterile water or germ-free water)
- Enzol enzymatic soap or similar soap with similar chemical characteristics
- Use clean, lint-free cloths and/or soft brushes. For reprocessing cannulated devices and/or products with a lumen you need materials and accessories such as cleaning stylets, pipettes, bottle brushes and/or syringes.
- DO NOT USE metal brushes or steel wool to clean Skeletal Dynamics instruments.

Table 1. Detergents not recommended with Skeletal Dynamics' products

Material	Not recommended
Aluminum	• Alkaline greater than 10.9. • Ingredients containing iodine or salts of heavy metals. • Poor water quality, alkaline cleaning agents, acidic neutralizers
Color coding	• All oxidating agents (e.g. nitric acid, acid sulfur, oxalic acid), hydrogen peroxide • Excessive concentrations of cleaning and disinfection agents
Stainless steel	• Elevated chlorine concentrations • Oxalic acid • Hydrogen peroxide
Titanium	• All oxidating agents (e.g. nitric acid, acid sulfur, oxalic acid), hydrogen peroxide

Detergents, Disinfectants, and Equipment

Consider the following aspects when choosing a detergent, disinfectant, and/or equipment for the reprocessing steps.

- These must be suitable for the intended use (e.g. cleaning, disinfecting, or ultrasonic cleaning)
- The detergent and disinfectant must be aldehyde-free.
- The detergents and disinfectants must be suitable and compatible with the products (refer to table above)
- The manufacturer's instructions must be followed, such as concentration, exposure time, and temperature[1].

Note[1]: Skeletal Dynamics recommends the use of new solution detergents and disinfectants.

1. Pre-treatment and Pre-Cleaning (Step 1)

1.1. Wipe as much visible soil as possible at point of use before transporting instruments to the reprocessing area.

1.2. Remove instruments from the tray.

1.3. Disassemble, as needed, and open instruments as much as possible (e, g., remove drills from drivers or any attached parts)

1.4. Remove visible contaminants with a soft brush.

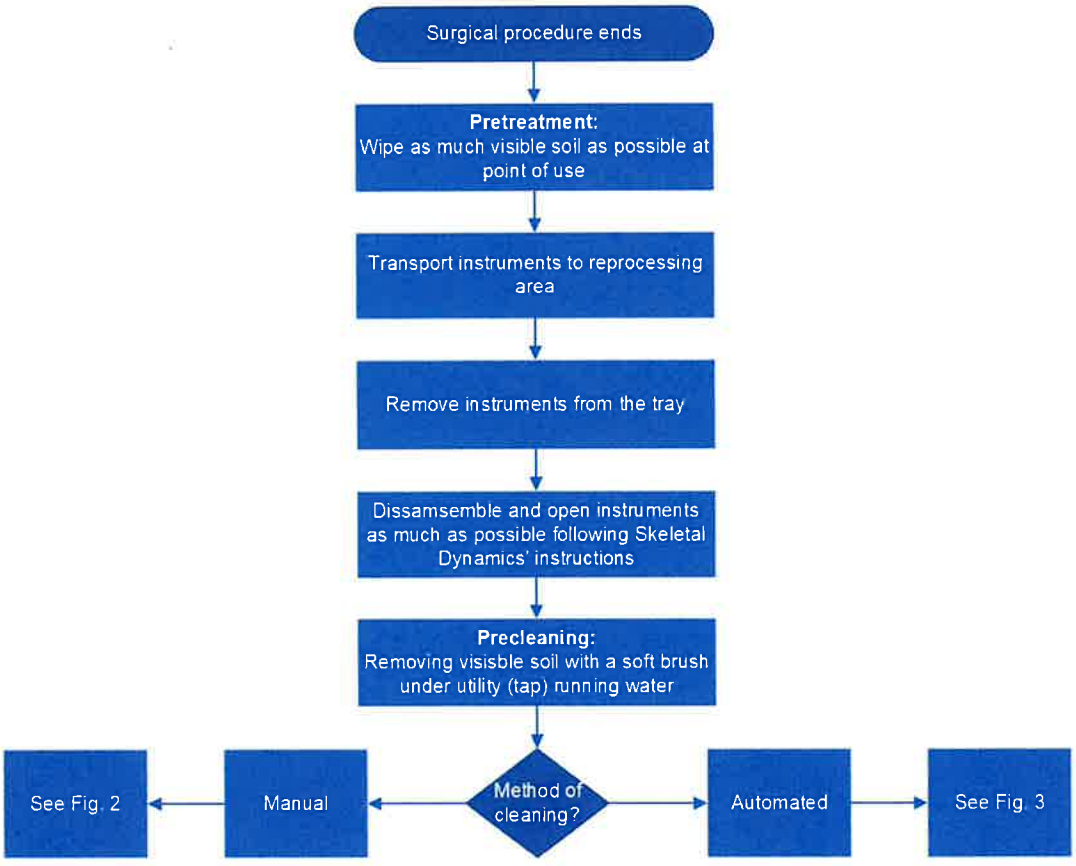
1.5. Shift movable parts under running water back and forth multiple times and rinse them thoroughly with utility (tap) water.

1.6. Clean large lumens and/or cannulated devices using a syringe and cannula (or needle) with running utility (tap) water through the lumens.

1.7. After rinsing, visually inspect all the products, and if necessary, repeat the previous precleaning procedure until contamination is no longer visible.

1.8. Choose method of cleaning according to the flowchart below (Fig. 1 Pre-treatment / Pre-cleaning flowchart)

Fig 1. Pre-treatment / Pre-cleaning flowchart



Preparing for Cleaning and Disinfection

After selecting the method of cleaning, gather products to be cleaned[2].

Note[2]: When gathering dirty products, the following aspects must be considered: instruments can be damaged (e.g. deformation, breakage, etc.) by improper usage. Therefore, it is important to consider handling these carefully and properly, and that trays are not overloaded.

2. Cleaning and Disinfection (Step 2)

Manual Cleaning

2.1. Prepare a new solution of detergent to be used. Skeletal Dynamics recommends a neutral enzymatic detergent with a pH range from (7-10.9).

2.2. Place the products in a neutral enzymatic cleaner for a minimum of ten (10) minutes. Please be aware that components must be fully immersed in the cleaner and positioned properly to avoid any damage.

2.3. Thoroughly rinse all components with utility (tap) water. While rinsing, use a soft bristle brush, pipettes, or syringes to clean lumens, holes, and other challenging features.

2.4. In an ultrasonic bath unit, prepare a fresh solution of enzymatic cleaner and sonicate the products for a minimum of five (5) minutes. **If an ultrasonic bath unit is not available refer to the Manual Disinfecting section.**

2.5. Ensure all features, such as lumens, holes, hinged components, mating surfaces, and crevices are thoroughly scrubbed. Actuate all movable features and expose all areas to cleaner and to the brush, pipette, or syringe.

2.6. Remove the products from the ultrasonic unit and thoroughly rinse all components with critical (treated) water, using pipettes, syringes, or water jets to clean out lumens, holes, and other difficult features. Actuate all movable features to fully irrigate all areas.

2.7. Visually inspect all components for soil. Repeat the cleaning procedure until no visible soil remains on the components. Repeat as necessary until no soil is visible.

2.8. Perform a final rinse using critical (treated) water.

2.9. Dry the clean components using compressed air or a soft, lint free, clean cloth.

2.10. Transfer products to tray and transport to sterilization.

Manual Disinfecting

2.11. Prepare a new solution of disinfectant to be used. Skeletal Dynamics recommends neutral enzymatic detergent with a pH range from (7-10.9).

2.12. Place the products in a neutral enzymatic disinfectant for a minimum of ten (10) minutes.

2.13. Please be aware that components must be fully immersed in the cleaner and positioned properly to avoid any damage.

2.14. Actuate all movable features at least ten (10) times to fully irrigate all areas during disinfection. Ensure that lumens, holes, and all components are fully submerged in disinfectant solution.

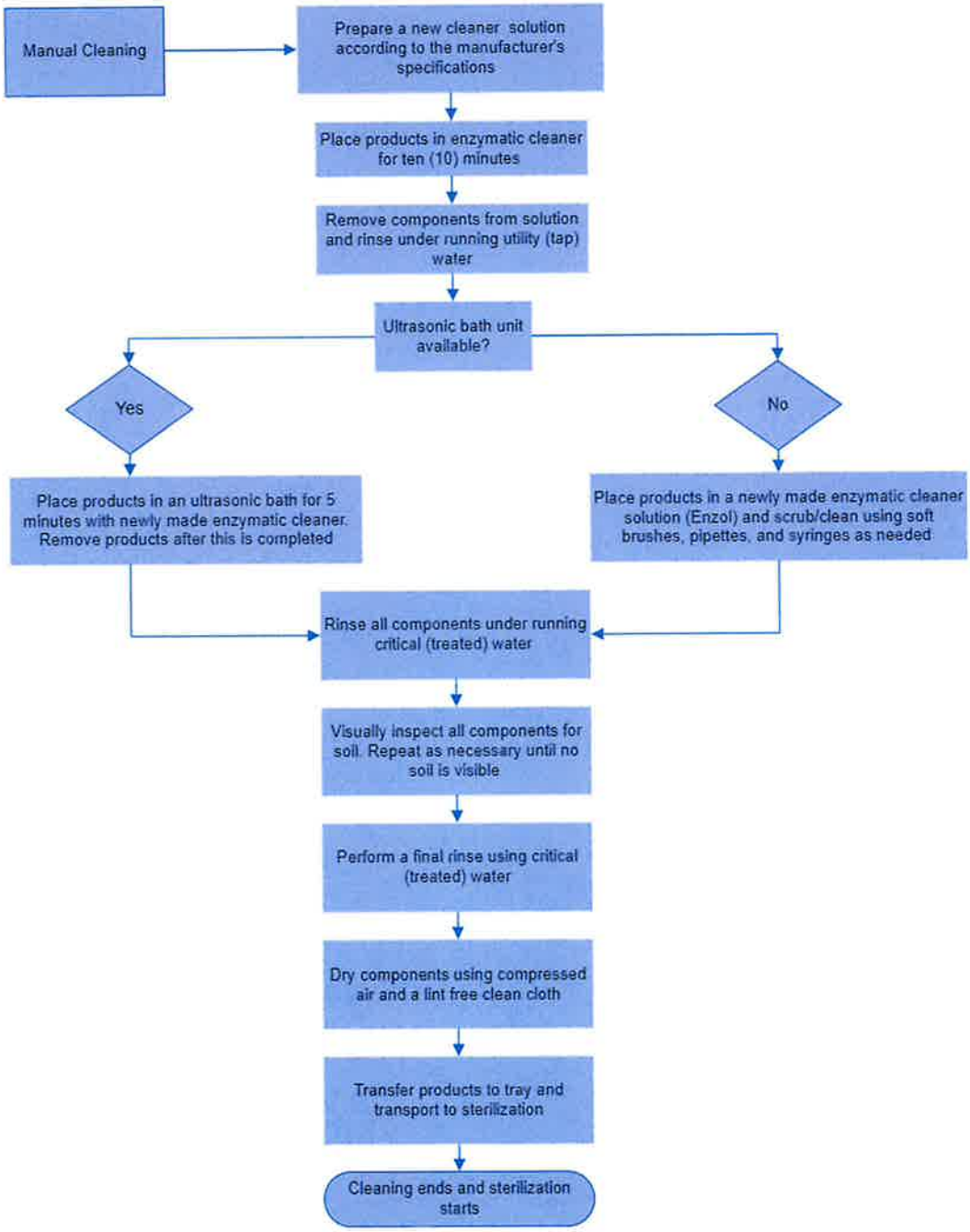
2.15. Remove the products from the disinfection bath and thoroughly rinse all components until all leftovers are removed. Actuate all movable features to fully irrigate all areas.

2.16. Visually inspect all components and repeat the cleaning and disinfection procedure as needed until visible contamination is no longer visible.

2.17. Dry the clean components using compressed air or a soft, lint free, clean cloth.

2.18. Transfer products to tray and transport to sterilization.

Fig 2. Cleaning
Manual Cleaning Flowchart



Automated Cleaning and Disinfection

2.1. Prepare a new solution of detergent (Table 2) to be used in the washer.

2.2. Place products in an ultrasonic bath unit with the newly prepared detergent and sonicate the products for a minimum of five (5) minutes.

Please be aware that components must be fully immersed for the entire time in the cleaner and positioned properly to avoid any damage.

2.3. Remove products from ultrasonic bath unit and thoroughly rinse with utility (tap) water. Then, transfer products to the automated washer unit and distribute evenly inside the washer.

2.4. Follow the washer instructions to select the cycle. Ensure that the cycle has the phases displayed in Table 2.

Table 2. Cycles to be performed by automated washer.

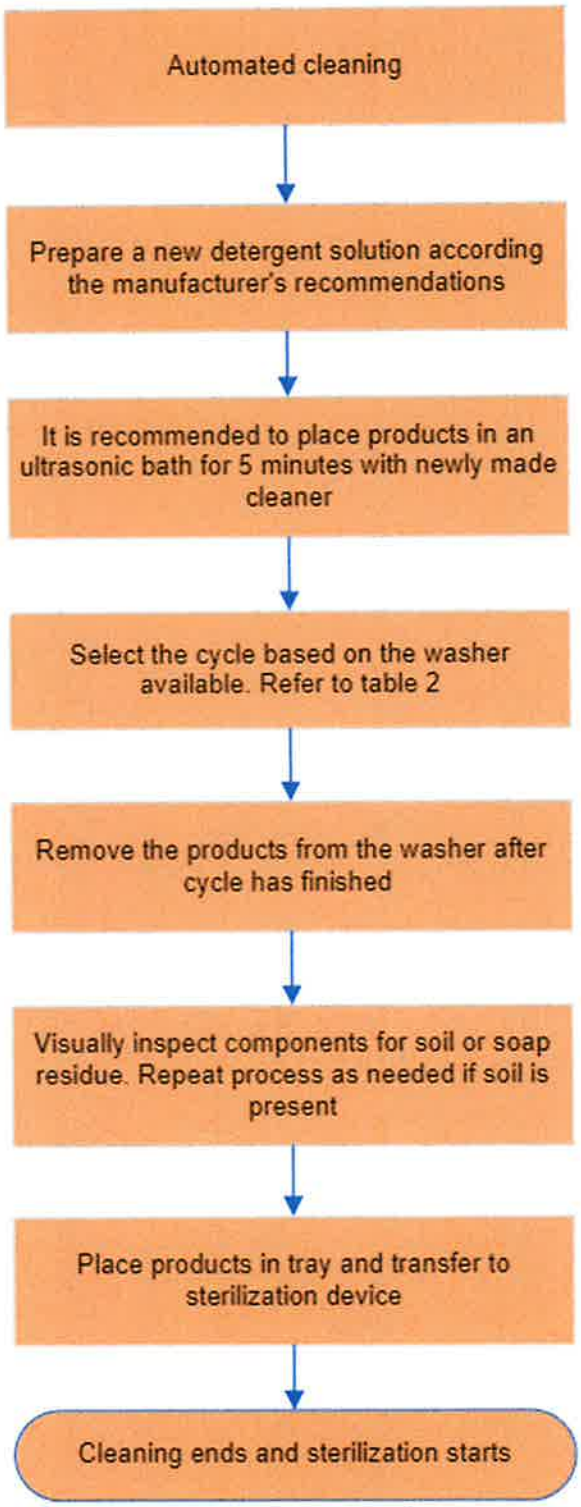
Phase	Temperature	Duration	Action
Cleaning	55°C ± 2°C (131°F ± 3.6°F)	10 minutes	Adding detergent. **Note:** Neutral enzymatic and alkaline (pH ≤ 10.9) detergents are recommended for cleaning reusable devices. **Note:** Neutral enzymatic pH range from (7-10.9).
Neutralization	Cold (< 40°C / 104°F)	2 minutes	Neutralizing with cold water
Rinsing	Cold (< 40°C / 104°F)	1 minute	Rinse with cold water
Thermal disinfection (A value > 3000)	≥ 90°C (194°F)	5 minutes	With critical water, **do not** add detergent
Dry	Device specific (< 141°C / 286°F)	Device-specific	Drying process

Note[3]: The information provided above is based on the use of "Neodisher MediClean forte" for this validation. If a different detergent is used, exposure times, concentrations and temperatures may vary; please refer to detergent's manufacturer's instructions.

2.5. Once the washer has finished the cycle visually inspect all components for soil. Repeat the cleaning procedure until no visible soil remains on the components.

2.6. Place products inside the tray and prepare for sterilization.

Fig 3. Automated Cleaning Flowchart



3. Sterilization (Step 3)

Note 4: Immediate-Use Steam Sterilization (IUSS) not recommended.

3.1. Place all components inside the sterilization tray.

3.2. Visually inspect proper placement of products inside the tray according to Skeletal Dynamics' specifications.

3.3. Wrap tray in polypropylene wrap[6]

3.4. Place one (1) tray inside sterilizer device.

3.5. Select the cycle and temperature according to the sterilizer available. Refer to table 3.

3.6. Allow the tray to dry after the cycle is completed.

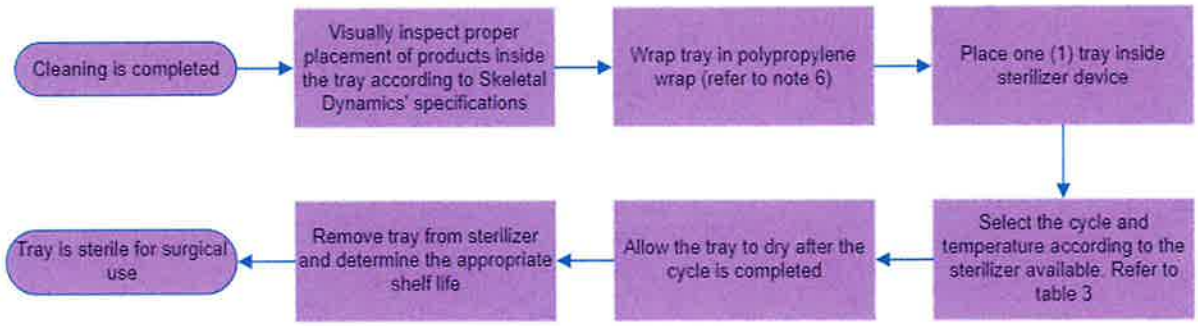
3.7. Remove tray from sterilizer and determine the appropriate shelf life.

Table 3. Sterilization cycle parameters[5]

Temperature	Exposure time	Drying time
132°C (269°F)	≥ 3 minutes	≥ 45 minutes
134°C (273°F)	≥ 3 minutes	≥ 45 minutes

Note[5]: The cycle selected depends on the sterilizer available.

Fig 4. Sterilization Flowchart



Note[6]: Use an FDA approved wrap (if in US), outside of US use any wrap approved by an applicable regulatory body. The current validation was performed with an approved polypropylene FDA wrap.

All non-sterile products must be sterilized in an autoclave. These must be in accordance with EN285 and EN13060 regarding validation, servicing, maintenance, and controlling.

For both initial and subsequent sterilization, Skeletal Dynamics has validated the following parameters in accordance with the current sterilization standards, EN ISO 17665 and ANSI/AAMI ST79.

Outside the USA: The sterilization time may be extended to 18 minutes to meet recommendations established by the WHO and the Robert Koch Institute (RKI).

Storage: After the tray has been properly sterilized, it must be stored in a dry and dust-free environment. Avoid temperature variations to prevent corrosion damage. The user should define a maximum shelf life for sterile products until usage, as products that are not used during this time will have to be reprocessed.

Inspection and Maintenance

Instrument Inspection

Instruments are visually inspected after sterilization. Check all products after cleaning and disinfection for damage and function. Check for damages related to

- Corrosion
- Damaged surfaces
- Fissures
- Other abrasion
- Functionality

During inspection consider the following aspects:

- Inspect critical parts such as handles, cavities, cannulated products, articulated instruments, etc.
- Products with lumens and cannulas must be checked for free passage without obstructions.
- Cutting instruments (e.g. drills) must be checked for sharpness and damage.
- Rotating instruments (e.g. drills) must be checked for bending. This can be easily done by rolling it down on a flat surface.

Tray Inspection

Check all trays after cleaning and disinfection for damage and functions. Check for damages related to

- Corrosion
- Damaged surfaces
- Fissures
- Chipping
- Contamination
- Functionality

Packaging

Skeletal Dynamics recommends sterilizing the products in the instrument trays. In addition, single sterilization wrapping (single or double wrapping) and/or other sterilization containers can be used[6].

Please ensure that the following requirements are met. (Review language)

- Accord with EN ISO 11607/EN 868-3 to 10 (ANSI/AAMI/ISO 11607)
- Regular maintenance of the trays provided by Skeletal Dynamics
- Usage of an approved wrap[6]

Warnings & Precautions

- Do not use metal brushes or abrasive detergents during reprocessing.
- Do not apply excessive force while disassembling products.
- Take caution while handling devices. Dropping, tossing, or bumping devices may cause unforeseen damage.
- Any instrument contaminated with blood, tissue, and/or bodily fluids/matter should be processed according to healthcare facility protocol.
- Users should wear appropriate personal protective equipment (PPE).
- Users should be qualified personnel with documented evidence of training and competency.

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