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## PART 1: GENERAL INFORMATION AND PRECAUTIONS

### 1.1 INTRODUCTION

These instructions contain the reprocessing methods recommended by PROCEPT BioRobotics for the AQUABEAM Scope (“The Scope”). These instructions contain essential information on reprocessing this Scope safely and effectively.

Before reprocessing, thoroughly review the manuals of the reprocessing chemicals and all equipment which will be used. Reprocess the Scope as instructed below.

For technical support, please contact PROCEPT BioRobotics.

### 1.2 IMPORTANCE OF REPROCESSING

The medical literature reports incidents of cross contamination resulting from improper reprocessing. It is strongly recommended that all individuals engaged in reprocessing the Scope closely observe all instructions given here and in the manuals of all ancillary equipment, and have a thorough understanding of the following items:

- Professional health and safety criteria of your hospital
- Individual facility’s cleaning and sterilization protocols
- Structure and proper handling of cystoscopic equipment
- Proper handling of pertinent chemicals
- Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings (US CDC).

Staff should wear appropriate personal protective equipment during reprocessing, as needed, and observe Universal Precautions for the Prevention of Transmission of Bloodborne Pathogens in the Healthcare Setting.

### 1.3 GENERAL PRECAUTIONS

#### 1.3.1 WARNING:

- **This device is supplied non-sterile. Before initial use and after each procedure, the Scope and its ancillary equipment must undergo thorough cleaning followed by sterilization as described in these instructions. Failure to properly clean, sterilize, or store the Scope according to the instructions given in this document initially and after each procedure may compromise device performance; cause damage to the Scope; or present an infection control risk.**

- If the Scope is not cleaned properly, effective sterilization may not be possible. Clean the Scope thoroughly before sterilization to remove microorganisms or organic material that could reduce the efficacy of sterilization. If the Scope is not immediately cleaned after each procedure, residual organic debris will begin to solidify, and it may be difficult to effectively reprocess the Scope.
- Patient debris and reprocessing chemicals are hazardous. Wear personal protective equipment to guard against dangerous chemicals. Always remove contaminated personal protective equipment before leaving the reprocessing area.
- Thoroughly rinse off the cleaning agents. Rinse the external surface of the Scope and the cleaning equipment thoroughly with water to remove any cleaning agent residue.
- The sterilization room must be adequately ventilated. Adequate ventilation protects against the buildup of toxic chemical fumes.
- Store alcohol in an air-tight container. Alcohol stored in an open container is a fire hazard and will result in a loss of efficacy due to evaporation.
- Handle the Scope carefully. Tightly gripping or sharply bending the Scope section can stretch or damage the Scope. Prior to each procedure, confirm that the Scope has undergone proper reprocessing. If it is determined that the Scope has not been properly reprocessed, do not use, and reprocess it again following the Scope Reprocessing instructions given here. Confirm that there is no abnormality before use and use under responsibility of a physician. Do not use if any abnormality is found.
- Unless the STERRAD® 100NX Standard Cycle or STERRAD® NX Advanced cycle is utilized, prions, which are considered to be the pathogenic substance of the Creutzfeldt-Jakob disease (CJD), cannot be destroyed or inactivated with any other reprocessing methods stated in these instructions. When using this Scope on a patient with CJD or variant Creutzfeldt-Jakob disease (vCJD), be sure to use this Scope for such patient only and/or immediately dispose of this Scope after use in an appropriate manner. For methods to handle CJD, please follow the respective guidelines in your country.
- If cleaning methods other than those stated in this document are performed (such as the respective methods stated in the guidelines of each country for destroying or inactivating prions), PROCEPT BioRobotics cannot guarantee the effectiveness, safety, and durability of this Scope.

#### 1.3.2 CAUTION:

- The Scope is not compatible with steam sterilization, which may cause damage to the Scope.


- **Cleaning agents with chlorine or chloride as the active ingredient are corrosive to stainless-steel and must not be used.**
- **For transport and temporary storage, do not coil the Scope flexible (black) section with a diameter of less than 10cm (4in). The Scope can be damaged if coiled too tightly. The stainless-steel section of the Scope is not flexible. Do not coil the stainless-steel section.**
- **It is the responsibility of the reprocessor to ensure that reprocessing is performed using the appropriate equipment and materials, and that personnel in the reprocessing facility have been adequately trained in order to achieve the desired result. Any deviation by the reprocessor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.**

**2.2.3 Automated Disinfection:** use a disinfectant based on glutaraldehyde (for example neodisher endo SEPT GA (Dr. Weigert GmbH & Co. KG), 1% in tap water at 55°C) or peracetic acid (for example thermosept PAA base and additive (Schülke & Mayr GmbH), 1% in tap water at 35°C) according to the instructions for use of the manufacturer.

## PART 2: COMPATIBLE CLEANING CHEMICAL AGENTS/SOLUTIONS AND STERILIZATION METHODS

### 2.1 COMPATIBILITY SUMMARY

The Scope's compatibility has only been tested with the cleaning chemical agents/solutions and sterilization methods listed in Table 1.

 Any cleaning chemical/solutions or sterilization methods that are not listed in Table 1 can cause Scope damage.

**Table 1 Compatible Cleaning Chemical Agents/Solutions and Sterilization Methods**

Enzol® Solution or equivalent enzymatic detergent (as described in section 2.2.1 of this document)
0.5% solution of neodisher® MediClean (Dr. Weigert GmbH & Co. KG) or equivalent (as described in section 2.2.2 of this document)
70% isopropyl alcohol
Cidex® OPA (ASP®)
1% neodisher endo® SEPT GA (Dr. Weigert GmbH & Co. KG)
1% thermosept® PAA base and additive (Schülke & Mayr GmbH)
STERIS® System 1E® (Standard cycle)
STERRAD® (H <sub>2</sub> O <sub>2</sub> ) <ul style="list-style-type: none"> <li>• 100NX® (Standard Cycle)</li> <li>• NX® (Standard or Advanced Cycle)</li> <li>• 100S (Standard Cycle)</li> </ul>
STERIS (H <sub>2</sub> O <sub>2</sub> , Non-Lumen Cycle) <ul style="list-style-type: none"> <li>• V-Pro® 1 Plus</li> <li>• V-Pro® maX 2</li> </ul>
Geringe GSS67F Low Temperature Steam and Formaldehyde
Ethylene Oxide (EtO)



**Use the chemicals listed in this table in accordance with section 3. Cleaning and disinfection agents should only be used as a precursor to sterilization. (See section 3.7).**

### 2.2 DETERGENT SOLUTION

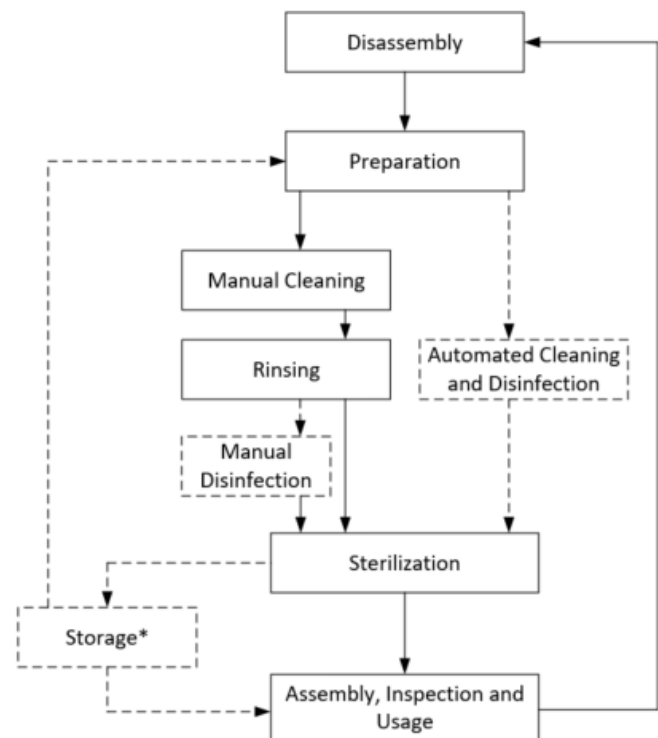
**2.2.1 Manual Cleaning:** Use a medical-grade, low-foaming, neutral pH detergent or enzymatic detergent such as Enzol® Solution and follow the manufacturer's dilution and temperature recommendations. Do not reuse detergent solutions

**2.2.2 Automated Cleaning:** Use a low foaming, slightly alkaline (with pH 10.5) detergent with alkalinity donors, enzymes, and surfactants such as 0.5% solution of neodisher® MediClean (Dr. Weigert GmbH & Co. KG) and follow the manufacturer's recommendations.

## PART 3: REPROCESSING PROCEDURES

### 3.1 REPROCESSING PROCEDURES

Reprocess the Scope according to the procedure described in Figure 1 below. The Scope must undergo cleaning prior to sterilization. Options and alternative procedural steps are represented by dashes in Figure 1 below. Disinfection may be applied per hospital practice to further prepare the Scope prior to sterilization but shall not replace sterilization. The Scope must be sterilized prior to each use.



**Figure 1 Reprocessing Overview**

\*Refer to individual facility protocols for the specific sterilization method used in order to determine the appropriate period of storage allowable before use. Follow the general storage recommendations in part 4 of this document. Repeat these reprocessing instructions in full if appropriate storage has not been maintained, or if for any other reason the sterility of the Scope may have been compromised.

### 3.2 DISASSEMBLY AND PREPARATION

Disassemble and wipe down the exterior of the Scope immediately after each procedure by following the instructions below. Then, immediately prepare the Scope by thoroughly brushing and rinsing per the steps below.

#### 3.2.1 SCOPE DISASSEMBLY

Remove the light adapter from the Scope. The light adapter is to be reprocessed in the same manner as the Scope.

### 3.2.2 SCOPE PREPARATION

Wipe down the external surfaces of the Scope with a damp cloth to remove excess debris. Keep the Scope moist and do not allow the Scope and debris to dry completely prior to cleaning.

### 3.3 MANUAL CLEANING

**3.3.1** Prepare a basin of detergent solution (Enzol® Solution or equivalent medical grade enzymatic detergent as described in section 2.2.1) at the temperature and concentration recommended by the detergent manufacturer. The basin must be deep enough to allow the Scope to be completely immersed.

**3.3.2** Prepare a second basin of clean water. The basin must be deep enough to allow the Scope to be completely immersed.

**3.3.3** Completely submerge the Scope in the detergent solution basin. Allow Scope to soak for a minimum of 10 minutes.

**3.3.4** With the Scope immersed, use a soft-bristled brush, such as Olympus® Cleaning Brush MH-507, or equivalent, to thoroughly brush or wipe all external surfaces of the Scope. Pay particular attention to crevices, mated surfaces and other hard-to-clean areas until all visible soil has been removed. The detergent solution should be changed if it becomes bloody, turbid, or otherwise contaminated.

**3.3.5** Remove the Scope from the detergent solution and rinse in clean water for a minimum of 1 minute. Continue rinsing until there is no sign of blood or soil in the rinse stream. Thoroughly flush difficult to reach areas.

**3.3.6** Dry the Scope with a clean, soft, lint-free cloth or disposable, absorbent, non-shedding wipe.

**3.3.7** Filtered, pressurized air (not to exceed 48kPa (7psi)) may be used to assist drying.

**3.3.8** Inspect the Scope for residual debris. Should debris remain, repeat the manual cleaning procedure.

### 3.4 RINSING AFTER MANUAL CLEANING

Once removed from cleaning solution, the Scope must be thoroughly rinsed with sterile water to remove any cleaning residue. If sterile water is not available, clean potable tap water or water which has been processed (e.g., filtered) to improve its microbiological quality may be used.

When non-sterile water is used after cleaning, wipe the Scope with 70% isopropyl alcohol, then air-dry to inhibit the growth of residual bacteria. Do not reuse rinsing water.

**3.4.1** Fill a basin with USP grade sterile water. The basin must be deep enough to allow the Scope to be completely immersed.

**3.4.2** Immerse the Scope in the sterile water for a minimum of 1 minute.

**3.4.3** Discard the rinse water.

**3.4.4** Refill the basin with USP grade sterile water.

**3.4.5** Re-immers the Scope in sterile water for a minimum of 1 minute.

**3.4.6** Using a sterile, lint-free cloth, thoroughly dry all external surfaces.

**3.4.7** Wipe all external surfaces with 70% isopropyl alcohol (IPA).

**3.4.8** Using a sterile, lint-free cloth, thoroughly wipe and dry all external surfaces.

### 3.5 MANUAL DISINFECTION

At hospital's discretion, the manual disinfection process can be used following cleaning to further prepare the Scope for sterilization by one of the methods described in 3.7.

**3.5.1** According to manufacturer's instructions for Manual Processing, immerse the Scope in the Cidex® OPA solution for a minimum of twelve (12) minutes at 20°C.

**3.5.2** Following removal from Cidex® OPA solution, thoroughly rinse by immersing completely in a large volume of water (e.g., two gallons, or 7.5L). Keep the device totally immersed for a minimum of one (1) minute. Remove the Scope and discard the rinse water. Do not reuse the water for rinsing or any other purpose.

**3.5.3** Repeat the rinsing step two (2) additional times, for a total of three (3) rinses to remove Cidex OPA residues. Always use fresh volumes of water for each rinse.



**Three (3) separate, large-volume water immersion rinses are required.**

**3.5.4** Allow devices to air dry. Do not expose to direct sunlight while drying.

### 3.6 AUTOMATED CLEANING and DISINFECTION PROCESS

The automated cleaning and disinfection process below can be used as an alternative to the manual processes described in sections 3.3-3.5.

**3.6.1** Wipe the used Scope with a damp, lint-free cloth.

**3.6.2** Carefully place Scope on rack of the washer-disinfector. Make sure that all parts of the scope can be completely exposed to the fluid (such as two-level rack Miele E327) in Miele Washer-disinfector machine (Miele Professional G 7836 CD).

**3.6.3** Following the instructions for use of the washer-disinfector, and the manufacturers of the cleaning and disinfection agents, use an automated process with the following parameters:

- 2 minutes pre-cleaning with cold tap water
- Draining
- 5 minutes cleaning with a mildly alkaline cleaning solution (see section 2.2.2) at 40°C
- Draining
- 3 minutes rinsing with cold deionized water
- Draining
- 5 minutes disinfection (see section 2.2.3 for approved disinfectants and their corresponding temperature settings)
- Draining
- 2 minutes rinsing with deionized water
- Draining
- 3 minutes rinsing with deionized water
- Draining

- Drying in the washer-disinfector if available and compatible, at a temperature not to exceed 55°C.
- Alternatively, the scope can be dried with a clean, soft, lint-free cloth or disposable, absorbent, non-shedding wipe. Filtered, pressurized air (not to exceed 48kPa (7psi)) may be used to assist drying.

### 3.7 STERILIZATION



**Before sterilization, the Scope must be thoroughly cleaned and all visible organic material, blood and cleaning/disinfectant agents completely removed.**



**The approved sterilization parameters are only valid with sterilization equipment that is properly maintained and calibrated.**



**Any deviations from the recommended parameters for sterilization should be validated by the user.**

#### 3.7.1 EtO STERILIZATION

- Place the Scope in a sterilization tray.
- Wrap with two layers of EtO compatible polypropylene wrap or equivalent material, or seal in a Tyvek pouch intended for EtO sterilization.
- PROCEPT BioRobotics has validated Ethylene Oxide (EtO) sterilization using the following parameters:

##### Conditioning Parameters (In-Chamber)

Temperature (set point): 55°C (131°F)

Humidity: ≥ 70% RH

Vacuum (set point): 1.3 psia

Conditioning Dwell Time: 30 minutes

##### Sterilization Parameters

Sterilant: 100% Ethylene Oxide

Temperature (set point): 55°C (131°F)

Humidity: ≥ 70% RH

Humidity Dwell Time: 30-45 minutes

EtO Gas Concentration: 725 ± 30 mg/L

EtO Gas Exposure Time: 120 minutes

##### Aeration Parameters

Time: 12 hours

Temperature (set point): 55°C (131°F)

Temperature range: 51° - 59°C (124° - 138°F)

#### 3.7.2 STERRAD 100S

- Use standard cycle for sterilization.
- Follow the manufacturer's instructions for using the STERRAD 100S system.

#### 3.7.3 STERRAD NX

- Use standard or advanced cycle for sterilization.
- Follow the manufacturer's instructions for using the STERRAD NX system.

#### 3.7.4 STERRAD 100NX

- Use standard cycle for sterilization.
- Follow the manufacturer's instructions for using the STERRAD 100NX system.

#### 3.7.5 STERIS V-Pro 1 Plus, V-Pro maX 2

- Use non-lumen cycle for sterilization

- Follow the manufacturer's instructions for using the STERIS V-Pro 1 Plus and V-Pro maX 2

#### 3.7.6 STERIS SYSTEM 1E LIQUID CHEMICAL STERILANT PROCESSING SYSTEM

- Use standard cycle for sterilization
- Follow the manufacturer's instructions for using the STERIS SYSTEM 1E Liquid Chemical Sterilant.

#### 3.7.7 Getinge GSS67F Low Temperature Steam and Formaldehyde

- Use 55°C cycle.
- Place Scope in a sterilization tray. Double wrap tray in sterilization sheets.
- Follow the manufacturer's instructions for using Low Temperature Steam and Formaldehyde.

### 3.8 INSPECTION & FUNCTION TESTING PRIOR TO USE

**3.8.1** Carefully inspect each Scope component to ensure that all visible blood and soil has been removed.

**3.8.2** Visually inspect for damage and/or wear.

**3.8.3** Install the appropriate light adapter to the Scope.

**3.8.4** Notify PROCEPT BioRobotics of any Scopes removed from service for further evaluation.

**3.8.5** Discontinue use of the Scope if any of the following occur:

- Any part appears cracked, slit or otherwise damaged along its length or joints of surfaces.
- Any of the distal stainless-steel sections of the Scope exhibit pitting, corrosion or other visual defects.
- Image quality degrades below acceptable limit as determined by the user (physician).

## PART 4: STORAGE AND DISPOSAL

### 4.1 STORAGE OF REUSABLE PARTS AND REPROCESSED SCOPE

Follow hospital protocol for the appropriate storage of cleaned or sterilized devices. General recommendations include the following:

- Reprocessed Scopes should be stored in a designated, limited access area that is well ventilated and provides protection from contaminated equipment, dust, moisture, insects, vermin, and temperature/humidity extremes.
- Do not store the Scope in direct sunlight, at high temperature, in high humidity or exposed to x-rays and ultraviolet rays. These could damage the Scope or pose an infection-control risk.
- Do not store the Scope in a cystoscope carrying case. Routinely storing the Scope in a humid, non-ventilated environment, such as the carrying case, may present an infection control risk. If such storage is required, ensure the Scope is properly reprocessed after removal from storage case and subsequent use.

### 4.2 DISPOSAL

Follow hospital disposal protocols. The Scope has a use life of 8 (eight) months (tested by PROCEPT BioRobotics to be the equivalent of 58 reprocessing cycles).

## DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY



















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## SYMBOLS GLOSSARY

	CE Mark		European Authorized Representative		Manufacturer
	Date of Manufacture		General Warning Sign		Caution
	Consult Instructions for Use		Temperature Limit		Humidity Limit
	Atmospheric pressure limitation		Do Not Use if Package is Damaged or Opened		Keep Dry
	Catalog Number		Batch Code		Serial Number
	WEEE		TUV Mark		Non-sterile