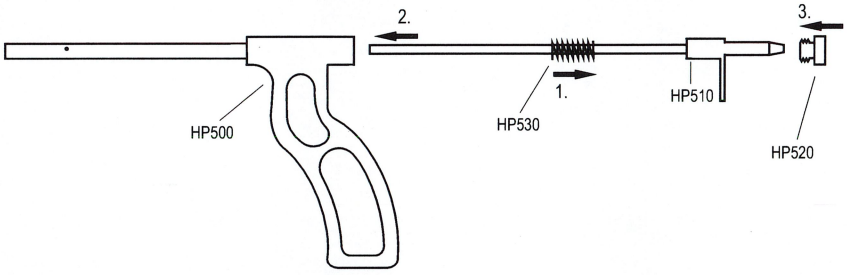
rbi2

CLEANING & STERILIZATION INSTRUCTIONS FOR REUSABLE rbi2 HANDPIECE AND TRAY

English Instructions for Use (Refer CP1200 instructions before using)	**Español** Instrucciones de uso (Consultar las instrucciones de CP1200 antes de utilizar)	**Dansk** Brugsvejledning (Se brugsvejledningen til CP1200 før ibrugtagning)
Nederlands Gebruiksaanwijzing (Raadpleeg de CP1200 instructies vóór gebruik)	**Deutsch** Gebrauchsanweisung (Vor Gebrauch s. Gebrauchsanweisung CP1200)	**Italiano** Istruzioni d'uso (Fare riferimento alle istruzioni d'uso CP1200 prima dell'uso)
Français Notice d'utilisation (Pour CP1200 Instructions avant utilisation)	**Svenska** Bruksanvisning (Se instruktioner för CP1200 före användning)	**Português** Instruções de utilização (Consulte as instruções CP1200 antes da utilização)



English Assembly 1. Slide HP530 onto HP510. 2. Slide HP510 into HP500 . 3. Slide HP520 onto HP510 and screw into HP500. Reverse for Disassembly	**Español** Montaje 1. Deslice el HP530 en el HP510 2. Deslice el HP510 en el HP500 3. Deslice el HP520 en el HP510 y fíjelo en el HP500 Invierta el orden para desmontar	**Dansk** Samling: 1. Før HP530 på HP510. 2. Før HP510 ind i HP500. 3. Sæt HP520 på HP510 og skru på HP500. Omvendt rækkefølge for adskillelse.
Nederlands Montage 1. Schuif HP530 op HP510. 2. Schuif HP510 in HP500. 3. Schuif HP520 op HP510 en schroef vervolgens in HP500 Voor demontage in omgekeerde volgorde uitvoeren.	**Deutsch** Zusammenbau: 1. Schieben Sie HP530 auf HP510. 2. Schieben Sie HP510 in HP500 hinein. 3. Schieben Sie HP520 auf HP510 und verschrauben Sie es in HP500 hinein. Für das Zerlegen gilt die umgekehrte Reihenfolge.	**Italiano** Assemblaggio 1. Far scivolare l'HP530 sul HP510 2. Far scivolare l'HP510 sul HP500 3. Far scivolare l'HP520 sul HP510 e avviatrlo sull'HP500 Fare la procedura inversa per disassemblare
Français Montage 1. Glisser HP530 sur HP510. 2. Glisser HP510 dans HP500. 3. Glisser HP520 sur HP510 et visser dans HP500 Pour le démontage, procéder dans l'ordre inverse	**Svenska** Sammansättning 1. Trä på HP530 på HP510. 2. För in HP510 i HP500. 3. Trä på HP520 på HP510 och skruva in i HP500 Gör i omvänd ordning för att demontera	**Português** Montagem 1. Deslizar HP530 sobre HP510. 2. Deslizar HP510 para HP500. 3. Deslizar HP520 sobre HP510 e aparafusar em HP500. Para desmontar proceder em ordem contrária

The rbi2 handpiece (HP1000) is designed to be used with the rbi2 capsule (CP1200) to achieve a controlled, consistent suction biopsy specimen of mucosa and submucosa for pathological examination for the diagnosis of Hirschsprung's disease in neonates, children, adolescents, and adults. Rbi2 is recommended to be used in a hospital environment or physician consulting room.

This instrument HP1000 & Container SS1000 are to be sterilised before use.

Caution: For use on or by the order of a physician only.
Caution: (US) Law restricts these devices to sale by or on the order of a physician only.
These devices should be used only by physicians familiar with the device and its intended use.

Aus systems pty ltd

Manufacturer:
Aus systems Pty Ltd
3 Charles Street, Allenby Gardens
South Australia 5009, Australia
Ph: +61 8 8346 6400
Fx: +61 8 8346 6411
rbi2@aussystems.com.au
www.aussystems.com.au

CE 0805

EC REP
EUROPEAN REPRESENTATIVE
Advena Limited
Tower Business Centre,
2nd Floor Tower Street
Swatar, BKR 4013, Malta

2021-05 V7

English

rbi2

CLEANING & STERILIZATION INSTRUCTIONS FOR REUSABLE "rbi2" HANDPIECE AND TRAY

These instructions provide recommended information for cleaning and sterilization for the rbi2 reusable Handpiece and Sterilization/storage tray manufactured by Aus systems Pty Ltd. Part Numbers: HP1000 & SS1000.

Cleaning and sterilization equipment varies in performance characteristics and must be validated accordingly. The reprocessing facility is responsible for the routine validation and monitoring of all equipment, materials and personnel used in their facility to ensure the desired results are achieved. These instructions have been validated as being capable of preparing rbi2 reusable handpiece and sterilization/storage tray prior to initial use and for ongoing reuse. Any deviations from these procedures must be evaluated for efficacy by the reprocessing facility.

LIMITATIONS ON REPROCESSING

Repeated reprocessing according to these instructions has a minimal effect on instrument and tray life. The useful life is normally determined by a visual and/or functional evaluation prior to use. Any limitations to reprocessing cycles will be noted in this instruction sheet.

CONTRAINDICATIONS

Refer to specific product instructions for use (CP1200 IFU) for any usage contraindications.

WARNINGS

These instructions have not been proven effective for sterilizing instruments contaminated with unconventional transmissible agents (prions) such as the causative agents of Creutzfeldt-Jakob Disease (CJD) and Bovine Spongiform Encephalopathy (BSE). It should not be assumed that the methods described are effective against such agents.

Personal protective equipment should be worn, per individual hospital protocol when handling and working with contaminated or potentially contaminated instruments and trays.

Cleaning is an essential pre-requisite to ensure effective sterilization. Lumens, blind holes, cavities, serrations and joints require particular attention during cleaning. Failure to completely remove organic debris and/or cleaning residues may lead to inadequate sterilization and result in an increased probability of infection.

Failure to thoroughly remove cleaning agents may lead to sensitivity and/or allergic reactions.

Saline and cleaning/disinfection agents containing aldehyde, chloride, active chlorine, bromine, bromide or iodide are corrosive and should not be used as these may shorten instrument life. Exposure to temperatures above 137 °C (278.6°F) may accelerate instrument degradation.
Water impurities, such as alkali metal, metal and chloride ions may discolour or corrode instruments.

All non-sterile handpieces and trays must be thoroughly cleaned and sterilized prior to use. rbi2 products labeled for "single use only" must not be reprocessed.
Always clean and sterilize surgical instruments before returning them to Aus systems.

Use only soft bristled brushes when cleaning handpiece and trays. At no time should you use metal or abrasive brushes / pads.

INSTRUCTIONS

POINT OF USE / PRE CLEANING

1. Disassemble, loosen, or unlock handpiece where possible.
2. Rinse/flush handpiece and tray under cool or lukewarm running water.
3. Remove excess soil while rinsing using non abrasive brush/cloth.

Clean as soon as reasonably practical or within 30 minutes following use.

CLEANING

MANUAL CLEANING

1. Disassemble the articles prior to cleaning.
2. Rinse excess soil from each article. Use a soft bristled brush and lumen brush to aid in removing excess soil from inner and outer shafts while rinsing.
3. Prepare Enzol® enzymatic detergent per manufacturers recommendation, 1oz per gallon (or 31mL per 4 litres) of warm tap water.
4. Immerse the articles into the prepared detergent solution and flush each article with 60mL of the detergent solutions.
5. Allow articles to soak for a minimum of 1 minute.
6. Using a soft-bristled brush and lumen brush, thoroughly clean each article for a minimum of 1 minute. Ensure full depth of the cannula is reached while brushing.
7. Visually examine each article. If visible soil is noticed repeat the cleaning steps starting from step 2.
8. Remove the articles from the detergent solution and rinse the articles under lukewarm running tap water for a minimum of 1 minute each.
9. Prepare ValSure neutral detergent per manufacturer's recommendation at ¼oz per gallon (or 8mL per 4 litres) of warm water in a sonicator.
10. Immerse the articles into prepared detergent solution and flush each article with 60mL of detergent solution.
11. Allow articles to sonicate for 10 minutes.
12. Remove the articles from the sonicator and rinse each article under lukewarm running tap water for a minimum of 1 minute each.
13. Using disposable lint free cloths thoroughly dry the articles. Filtered pressurized air may be used to aid in drying.
14. Visually inspect each article for visible soil. Repeat from step 2 as necessary.

AUTOMATED CLEANING

1. Disassemble the articles prior to cleaning
2. Rinse excess soil from each article. Use a soft bristled brush and lumen brush to aid in removing excess soil from inner and outer shafts while rinsing.
3. Transfer the articles into the washer for processing positioning article for maximum surface exposure.
4. Run washer at recommended manufacturer's instructions.
5. Remove articles from washer and dry using disposable lint free cloths thoroughly dry the articles. Filtered pressurized air may be used to aid in drying.
6. Visually inspect each article for visible soil. Repeat from step 2 as necessary.

Automated Cycle Used in Validation

Phase	Time (Min.)	Temperature	Detergent/Concentration
Pre-wash 1	2:00	Cold tap water	Not applicable
Enzyme wash	4:00	Hot tap water	Enzol enzymatic 1oz/gallon or 31mL/4 litres
Wash 1	2:00	65.5°C (149.9°F)	ValSure neutral ¼oz/gallon or 8mL/4 litres
Rinse 1	00:15	Hot tap water	Not applicable
Drying	6:00	98.8°C (209.84°F)	Not applicable

CLEANING INSPECTION

Carefully inspect articles to ensure all visible contamination has been removed. Reassemble handpiece as necessary to test function.

STEAM STERILIZATION

1. Disassemble applicators for sterilization and place in identified position in tray.
2. Double wrap tray or individual applicator components in 2 layers of 1-ply polypropylene wrap using sequential wrapping techniques
3. Place wrapped tray/applicators in prevacuum steam sterilizer, following validated sterilization parameters.

Steam Sterilization Parameters Validated

Sterilizer Type	Pre-vacuum
Preconditioning Pulses	3
Temperature	132°C (269.6°F)
Half Cycle Exposure Time	02:00 minutes
Dry Time	30:00 minutes

Sterilizer Type	Pre-vacuum
Preconditioning Pulses	3
Temperature	134°C (273.2°F)
Half Cycle Exposure Time	1:30 minutes
Dry Time	30:00 minutes

Validation wrap: Individually wrapped in two applications of 1-ply polypropylene wrap (Kimgaurd KC600).

STORAGE AND USE

Store and transport sterile instruments in such a way as to maintain sterility and functional integrity.
Store sterile packaged instruments in a limited access area that is well ventilated, protected from contaminants and dry.
If package integrity is compromised or suspect, repeat processing prior to use.
Carefully examine sterile instrument packaging prior to use, ensuring package integrity is maintained.