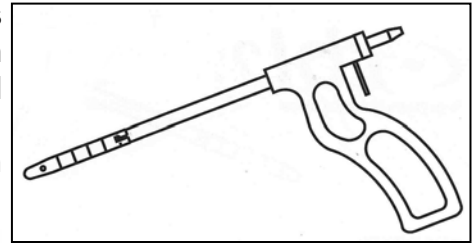


# INSTRUCTIONS FOR USE

## Introduction

These instructions refer to the rbi2 manufactured by Aus systems Pty Ltd. 18 Kinkaid Avenue, North Plympton, South Australia. Compliance with all requirements and special information contained in these instructions is essential; otherwise the product must not be introduced or employed in clinical applications.



The product refers to:

- ♦ Gamma sterilized assembled capsule, blade, seal + suction and tube/syringe adaptor.
- ♦ Re-useable trigger assembly handpiece. Handpiece must be sterilized before use. (Refer to HP1000 Instructions)\*

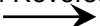
(Refer to package insert supplied with each product for complete instructions, warnings and precautions.)

## Device Purpose:

To achieve a controlled, consistent suction rectal biopsy specimen of mucosa and submucosa for pathological examination for the diagnosis of Hirschsprung's disease.

## Design:

The rbi2 consists of a gamma sterilized single use polystyrene closed end cylinder shaped capsule with a small hole at the closed end which contains a stainless steel cutting blade and a polyethylene seal. The capsule connects to a re-useable handpiece (HP1000) via a quick twist and lock systems and suits both left and right handed operators. The HP1000 has an inner piston which automatically locates in the internal seal when the capsule is connected. This creates an airtight loop to the attached syringe via the suction tube/syringe adaptor. The inner piston is pushed forward when the thumb trigger is activated pushing the blade forward past the capsule hole cutting the specimen.

Procedure Continued on Reverse 



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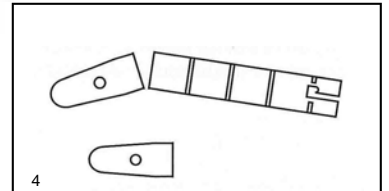
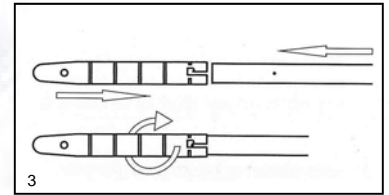
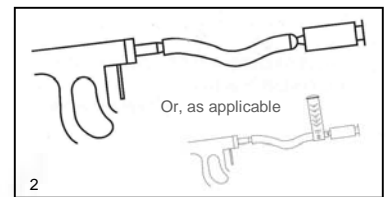
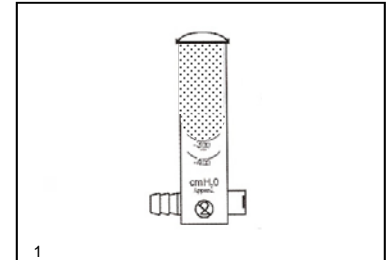
M211B 01/10

# INSTRUCTIONS FOR USE, CONT'D

## The Procedure:

Normally 3 biopsies are taken. It is recommended that **all biopsies are taken posteriorly**. Usually 2 specimens are placed in Formalin for routine H & E sections and the other sent "fresh" for histochemical assessment.

1. Calibration of manometer (if applicable, manometer is not required to use system) - **Do not remove RED cap until after initial calibration.** Place syringe onto manometer & pull back syringe plunger until blue diaphragm reads -300 cmH<sub>2</sub>O. Release syringe plunger to neutral position & remove red cap. Place manometer onto tubing. **Calibration is required before the first use only.** (Reference sketch 1)
2. Connect suction tube to handpiece and syringe before loading capsule (6ml or 10ml syringe recommended). (Reference sketch 2)
3. Place capsule onto handpiece (twist & lock). Ensure hole faces to the left for right handed and right for left handed use. (Reference sketch 3)
4. Lubricate outside surface of capsule with KY gel or similar.
5. Insert capsule 2-3 cms into rectum.
6. Withdraw syringe to **3ml-5ml** (or until manometer diaphragm reaches -150cmH<sub>2</sub>O) for suction pressure (refer to Warnings and Precautions). If using the manometer and the diaphragm does not move, the biopsy hole is not covered by tissue.
7. Push thumb trigger forward until fully "engaged".
8. Release syringe suction to neutral pressure before removing from patient.
9. Remove capsule from patient.
10. Remove capsule from handpiece.
11. Break capsule at first measurement marker to view if specimen is present. (If no specimen is present, flush inner tube with saline). (Reference sketch 4)
12. Flush capsule with saline onto gauze swab via capsule hole to remove specimen. Transfer specimen with needle, mucosa side up onto absorbent paper.



Repeat steps 2-11 for each biopsy.

Additional Equipment Required: 3 specimen pots, Formalin, 1 x 5ml, 1 x 6ml syringe, absorbent paper, needle, gauze, saline, KY Gel or similar lubricant.

\*Cleaning (applies to handpiece – HP1000 only): The handpiece should be flushed with normal saline immediately after use to avoid body fluids drying in or on the handpiece. Refer to HP1000 Instructions for Cleaning/Sterilization.

**Warnings and Precautions:** Care needs to be taken not to deliberately force the instrument but gently approximate the instrument to the mucosa. It is recommended that all biopsies be taken posteriorly. Suction required may vary depending on user technique and patient age. **Excessive suction** may cause bowel perforation. Some bleeding is to be expected post biopsy and further rectal procedures are prohibited for 24 hours. 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, its intended use, any additional instrumentation and any available surgical techniques.



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