

English

Introduction

These instructions refer to the rbi2 and manometer manufactured by Aus systems Pty Ltd, 3 Charles Street, Allenby Gardens, 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 sterilised assembled capsule, blade, seal, suction tube and manometer.
- Re-useable Handpiece. To be sterilised before use. (Refer HP1000/SS1000 Instructions)

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 in neonates, children, adolescents, and adults. The rbi2 is recommended to be used in a hospital environment or physician consulting room.

Design

The rbi2 consists of a gamma sterilised 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 system 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 manometer. The inner piston is pushed forward when the thumb trigger is activated pushing the blade forward past the capsule hole cutting the specimen.

Warnings and Precautions

Handpiece HP1000 is to be sterilised before use. Refer HP1000 instructions for use.

Care needs to be taken not to deliberately force the instrument but gently approximate the instrument to the mucosa or biopsy tissue. Suction required may vary depending on user technique and patient age. Excessive suction may cause bowel perforation and/or persistent bleeding. 1st biopsy should be taken with negative pressure as per instruction No.6. To obtain a larger specimen size, increase pressure by -50cmH₂O increments. Some bleeding is to be expected post biopsy and further rectal procedures are prohibited for 24 hours. *Read all instructions and warnings before use, and do not use if the packaging is damaged. Any serious incident should be reported to the manufacturer and the competent authority.

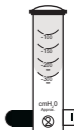
Contraindications - None known

Caution: For use on or by the order of a physician only.

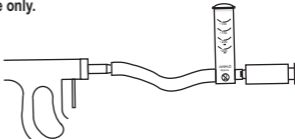
Caution: (U.S.) Law restricts these devices for sale by or on the order of a physician only. These devices should be used only by physicians familiar with the device, its intended use any additional instrumentation and any available surgical techniques

The Procedure

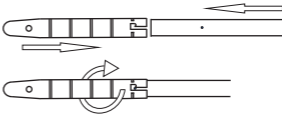
1. Calibration of manometer. - **Do not remove RED cap until after initial calibration.**
Place syringe onto manometer & pull back syringe plunger until blue diaphragm reads -300 cmH₂O. A number of syringe pull backs may be required.
Release syringe plunger to neutral position & remove red cap.
Place manometer onto tubing.
Calibration is required before the first use only.



2. Connect suction tube to handpiece **before** loading capsule.
(10ml syringe recommended)



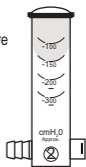
3. Place capsule onto handpiece (twist & lock).
Ensure hole faces to the left for right handed use and right for left handed use.



4. Lubricate outside surface of capsule with KY gel or similar.

5. Insert capsule 2-3 cms into rectum. **DO NOT** push capsule hard against mucosa tissue. Place capsule against biopsy site gently. Failure to do this may stop tissue from entering capsule hole.

6. Withdraw syringe until manometer diaphragm reaches -150 cmH₂O suction pressure (refer Warnings and Precautions). If diaphragm does not move, the biopsy hole is not covered by tissue. Ensure capsule is placed on handpiece correctly.

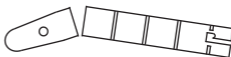


7. Push thumb trigger forward until **fully** stopped. Do not stop at first resistance.

8. Release syringe plunger for suction to return to a neutral pressure **before** removing from patient.

9. Remove capsule from handpiece.

10. Break capsule at first measurement marker to view if specimen is present. (If no specimen is present, flush inner tube with saline).



11. Flush capsule with saline through capsule biopsy hole onto gauze swab via capsule hole to remove specimen.



Note: If specimen appears trapped between blade and internal plastic cutting board, slide a pair of forceps along blade until you reach the cutting board. Push and snap the board to release the specimen. Repeat no.11

Repeat steps 3-11 for each biopsy.

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: HP1000 Instructions for cleaning / Sterilisation.

Sterilisation (Handpiece HP1000 only)

Refer: HP1000 Instructions for Cleaning / Sterilisation.



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DO NOT RE-USE



(Rx only)
PRESCRIPTION ONLY

