

For the diagnosis of
Hirschsprung's Disease

rbi2

Suction Rectal Biopsy System

Suitable for use with:
Neonates - Adolescents - Adults



**World's
#1
System**

Patent No US 7,479,117 B2

Controlled Consistent Rectal Biopsies

The rbi2 is the world's #1 suction rectal biopsy system used to obtain controlled consistent biopsies of mucosa and sub mucosa for pathological examination for the diagnosis of Hirschsprung's Disease.

Eliminating problems associated with older suction rectal biopsy equipment, the rbi2 is a hybrid system made up of a sterile, single-use capsule, a re-useable handpiece and a negative pressure manometer.

The capsule houses an ultra-sharp blade for a clean cut, provides an airtight seal for precise suction and features a unique snap system to break the capsule for easy retrieval and viewing of the biopsy specimen.

Self-calibrating between biopsies and with highly visible indication markers, the negative pressure, single patient use manometer assists the operator to achieve neutral capsule pressure against the mucosa and provides repeatable readings.

rbi2 Features

- ✓ suitable for use with neonates, adolescents, adults
- ✓ a clean, precise cut
- ✓ consistent suction
- ✓ uniform specimens
- ✓ easy specimen access
- ✓ totally enclosed scalpel sharp blade
- ✓ measuring indicators
- ✓ suitable for left & right handed operators



Best Performance

To get the best performance from your rbi2 suction rectal system, it's important to understand the unique characteristics and essential techniques associated with using the device.

Take your time...

There is no need to quickly fire the trigger once the suction is achieved. Because this system is airtight, there will be no loss of suction whilst taking the biopsy – so take your time!

Minimal suction required with this airtight system...

The unique design of the rbi2 capsule features an internal seal that fits tightly around the inner tube of the handpiece. This provides an airtight pathway from the front of the capsule all the way to the syringe. As a result, additional suction to account for suction loss, which is a technique used with older systems is not necessary.

Make sure the specimen has been released into the capsule tip...



Prior to firing the trigger, the mucosa is drawn into the hole in front of the blade.



When the trigger is fired the blade cuts the specimen and becomes lodged in the cutting block.



When the blade is fully advanced into the cutting block the specimen is released into the capsule tip for retrieval.

After withdrawing the instrument from the patient, and prior to breaking the capsule open for specimen retrieval, check that the hole in the blade aligns with the hole in the capsule – you should see no silver blade.

If you can still see blade, simply fire the trigger to push the blade fully forward.

Failure to do this may make specimen removal difficult as it is possible the specimen will remain trapped between the blade and the cutting block.

Fig. 1



Understanding the critical combination of negative suction pressure and gentle approximation of the capsule against the mucosa...

The single patient use manometer measures the amount of negative suction pressure and is used as a guide to let the operator know if the capsule is *not* placed against the mucosa.

A successful biopsy will be achieved when the capsule hole is covered by the mucosa, with the capsule itself gently approximated in the neutral position against the mucosa.

The blue diaphragm of the manometer will only react if the hole is covered - see Fig 1. The manometer will not indicate if too much pressure is being applied against the mucosa so it is critical not to push the capsule against the mucosa to avoid inadequate specimens.

Fig. 2

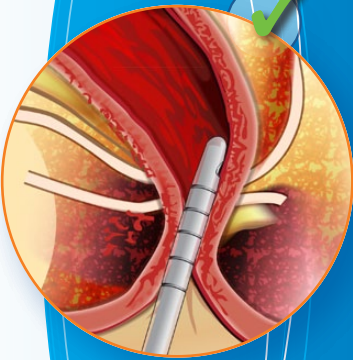


Fig. 3



Do not deliberately force the capsule against the mucosa...

Gently approximate the capsule tip in the neutral position to the mucosa - see Fig 2.

Do not push or force the capsule against the mucosa. The mucosa will stretch and tighten, making it more difficult to withdraw the tissue into the capsule hole - see Fig 3. or prevent tissue from entering the hole altogether.

(please refer to the package insert for full instructions for use)

Product Details

Order Code: **CP1200**

Procedure Packs

(10 single use procedure packs)

- 3 capsules per pack
- supplied sterile (gamma)
- scalpel sharp blade
- blade totally enclosed - no accidental sharps injuries
- internal seal - consistent suction control
- consistent, accurate aspiration
- consistent specimen
- no instrument servicing or blade sharpening required
- 5 x 10mm depth measuring indicators
- no internal blade lubrication required
- disposable capsule, blade, seal, tubing & adaptor - infection reduction
- quick twist and lock system suits left and right handed operation
- quick snap for easy access to specimen
- specimen captured in front section of capsule
- instructions for use with each procedure pack



Order Code: **MR100**

Negative Pressure Manometer

(10 single use units per box)

- supplied sterile (gamma)
- highly visible identification markers
- self calibrating between biopsies
- allows neutral capsule pressure against mucosa
- repeatable readings



Order Code: **HP1000**

Handpiece

- re-useable, easy to clean & heat sterilisable (autoclavable)
- easy to use thumb trigger
- light comfortable handle for steady placement
- easy assembly and disassembly



Order Code: **SS1000**

Sterilisation/Storage Container

- individual component pockets
- re-useable & heat sterilisable (autoclavable)
- marked with assembly & disassembly instructions
- clear top for easy identification



'Manufactured in Australia'

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.

This device should be used only by physicians familiar with the device, it's intended use, any additional instrumentation and any available surgical techniques. Responsibility for correct patient selection, adequate training and experience in performing suction rectal biopsies rests with the physician.



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