# Breath Biopsy® Sample Collection Toolkit

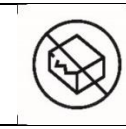
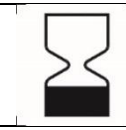
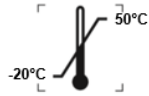
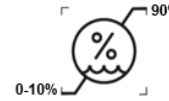
# User Guide

**For use with part numbers:**

**01-0967**
**00-0167**

Issue 3

## Symbol Key

| Description | Symbol | Description | Symbol |
|---|---|---|---|
| Caution, Consult Accompanying Documents |  | Manufacturer |  |
| Catalogue or Reference Number |   | Date of Manufacture |  |
| Serial Number |   | Do Not Reuse |  |
| Lot Number |   | Do not use if packaging is damaged |  |
| Consult instructions for use |  | This mark indicates approval for use in the European Union countries |  |
| Fragile, handle with care |  | Use-by date |  |
| Storage Temperature Limit |   | Humidity Limit |   |
| This mark indicates approval for use in the United Kingdom |   | DO NOT dispose of in household waste (WEEE Directive) |  |

# Contents

# 1 General Information

## 1.1 Introduction

This user guide explains how to use the Breath Biopsy Sample Collection Toolkit to assemble, disassemble and maintain the parts of the Breath Biopsy Cartridge required for use with the ReCIVA® Breath Sampler. The Toolkit is supplied on a professional business-to-business basis for the purpose of research and development.

Breath Biopsy Cartridges should only be used with ReCIVA. If you wish to use an alternative, please ensure you carry out your own risk assessment to prevent potential harm to the study subject.

It is essential that this instruction manual be read and understood before commencing any work with the Breath Biopsy Sample Collection Toolkit.

Read and understand the various precautionary notes and symbols contained inside this manual pertaining to the safe use and operation of this product before using it.

## 1.2 Safety

Safety instructions for the use of ReCIVA are provided in the ReCIVA User Manual. It is essential that these safety instructions are read and understood before commencing any work with the Breath Biopsy Sample Collection Toolkit.

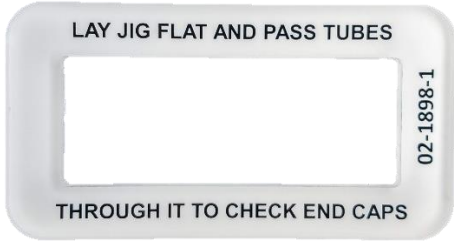
**Always observe the following standard safety precautions:**

- Wear clean nitrile examination gloves when handling the Breath Biopsy Cartridge as chemicals from your hands can affect the results and may lead to cross contamination.
- Wash your hands with soap and water – do not use alcohol-based gels (e.g. Cutan foam) as these leave volatile chemicals behind which may affect the breath collection.
- Do not use the Breath Biopsy Cartridge if it is dropped or damaged prior to the breath collection commencing.
- If you encounter any problems with the equipment or this procedure, please contact Owlstone Medical Ltd immediately using the contact details in this guide.

# 2 Introduction

## 2.1 Parts included in the Breath Biopsy Sample Collection Toolkit

The Breath Biopsy Sample Collection Toolkit contains the following items:

| Title | Part No | Qty | Picture |
|---|---|---|---|
| CapLok Tool | 74-0035 | 1 |  |
| Wera 1/4 in Hex Torque Driver, Set to 0.25Nm | 74-0056 | 1 |  |
| Hexagon Bit, 2 mm | 74-0058 | 1 |  |
| O-ring Removal Tool | 74-0052 | 1 |  |
| O-ring Insertion Tool | 74-0053 | 1 |  |
| Sorbent Tube End Cap Jig | 02-1898 | 1 |   |

| | | | |
|---|---|---|---|
| O-ring,<br>6.35 x 1.78mm<br>Viton<br>60 Shore,<br>Black<br>Baked clean | 50-1283 | 18 |  |
| Cable tie,<br>Blue, Nylon,<br>270 x 4.6 mm | 50-1550 | 10 |  |
| Stainless Steel diffusion-locking ('DiffLok') caps (gold) | 50-1950 | 2 |  |
| Inert diffusion-locking ('DiffLok') caps (silver) | 50-1951 | 2 | |

## 2.2 Parts included in other Breath Biopsy Kits and Packs

The following items are required to assemble a Breath Biopsy Cartridge. These items are supplied as part of other Breath Biopsy Kits or Packs.

| Title | Part No | Qty | Picture |
|---|---|---|---|
| Sorbent Tube (See note) | Various | 4 |  |
| Brass Storage Caps | 01-1057 | 8 | |
| Tube Clamp Assembly (Tube Holder) | 01-0622 | 1 |  |
| Travel End Cap | 01-0603 | 2 |  |

NOTE: There are different types of Sorbent Tube but this User Guide is applicable to all of them.

Sorbent Tubes are supplied preconditioned by the tube manufacturer. Before first use, the user should confirm that the tubes have been conditioned appropriately for the intended application.

# 3 Breath Biopsy Cartridge Assembly

Ensure that the Breath Biopsy Cartridge is correctly assembled before use

Always wear clean nitrile examination gloves when handling the Breath Biopsy Cartridge

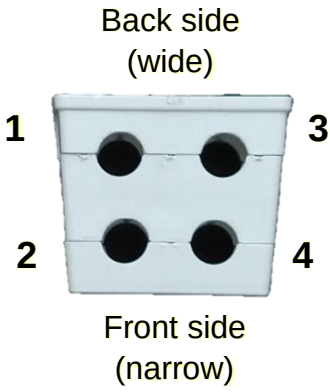
The assembly of the Sorbent Tubes into the Tube Clamp Assembly is a time-critical process, which should not be started unless there is time for completion.

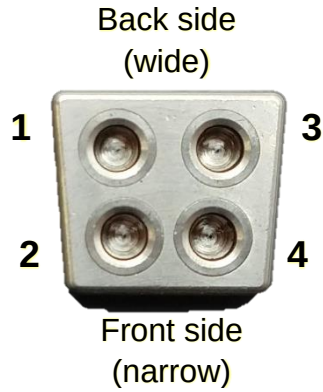
There is a risk of contamination to the tubes if uncapped tubes are exposed to air for too long.

Before use, the user should confirm that the Sorbent Tubes have been conditioned appropriately for the intended application.

Each tube has its own location within the Tube Clamp Assembly. The standard hole position numbering and part orientation description used within OML is shown below.

NOTE: The front side of the Tube Clamp Assembly is slightly narrower than the back side.




Prepare all the material required for this task. Ensure the worksurface is clean and free from dust or liquids and is low in volatile organic compounds (VOCs).

Place one Travel End Cap flat on the surface with the holes facing up.

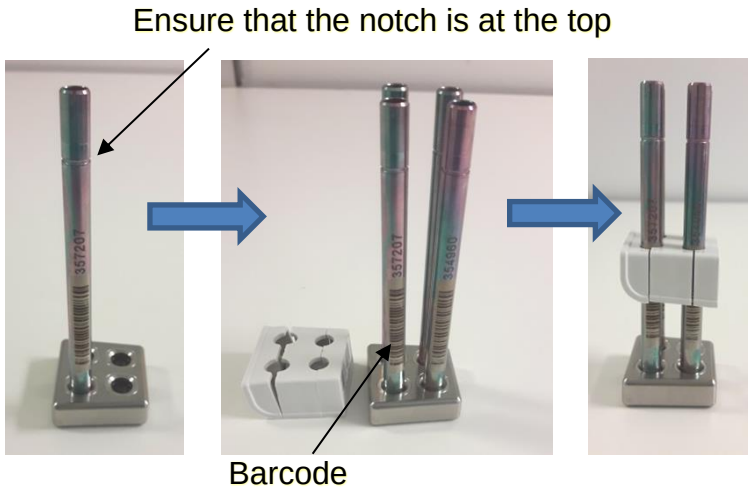
Remove the brass storage caps from each of the tubes in turn using the supplied CapLok tool.

Once the storage caps are removed, the tubes can be loaded into the Travel End Cap. Ensure that the arrow marked on the side of each tube is pointing downwards and that the notch is at the top of tube as shown below.

The tubes should be loaded in the same order each time and a record made of their position using the barcode marked on the side of each tube.

Load the tubes such that the barcode and the numbers are facing the outside side of the tube holder so that they are accessible after assembly, if required.

Once all tubes have been loaded the Tube Clamp Assembly (Tube Holder) can be fitted.




The screw may need to be loosened if the holder is too tight to fit to slide onto the tubes.

The Tube Clamp Assembly (Tube Holder) should be positioned about midway along (covering) the bar codes.

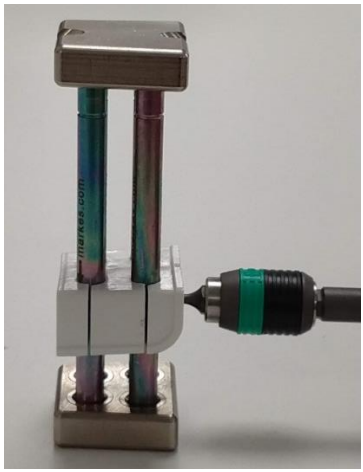
Fit the second Travel End Cap on the top of four tubes ensuring the cap is orientated the correct way.

The Travel End Cap may need to be applied with some force to ensure it is fitted all the way onto the tubes.

Tighten the Tube Clamp Assembly (Tube Holder) using the torque screwdriver

The Tube Holder should be tightened after securing the second end cap, as sealing both ends of the tube should be prioritized over other tasks

The torque screwdriver is pre-set to 0.25 Nm and will click once the screw has been sufficiently tightened. The screw cannot be overtightened as the torque driver will just continue to click without tightening further.

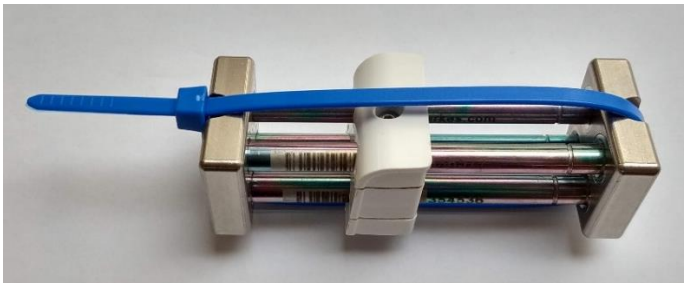


Once the Breath Biopsy Cartridge has been assembled, use the Sorbent Tube End Cap Jig to check if the set easily passes through it to ensure caps are correctly fitted.

If the Breath Biopsy Cartridge does not fit through, push the Travel End Caps together with your palms.

Handle the tubes with care; the inside is fragile and test performance can be affected if dropped or handled roughly


If the assembled cartridge needs to be transported prior to use, then fit a cable tie as shown and tighten it to avoid the end caps being removed during transport.



A bubble wrap bag is also recommended to protect the Cartridge Assembly during any handling.

# 4 Breath Biopsy Cartridge Disassembly

The disassembly process is essentially the reverse of the assembly process.

Cut the cable tie (if applied).

Remove one of the Travel End Caps.

Use the torque screwdriver to sufficiently release the screw in the Tube Clamp Assembly so that the tubes will slide out ready for the application of brass caps or DiffLok caps etc. as required.

If required, attach the supplied brass storage caps to each of the tubes in turn using the supplied CapLok tool.

Owlstone Medical recommend that the tubes are dry-purged using an inert gas before being placed into storage.

When using Tenax-Carbograph sorbent tubes, use the arrow marked on the side of each tube to ensure that the correct DiffLok caps are fitted prior to analysis. This is necessary to maintain sample integrity during thermal desorption.

- The arrow must point towards the Stainless Steel cap (which is gold in colour).
- The arrow must point away from the Inert cap (which is silver in colour).

Inert cap

Stainless Steel cap

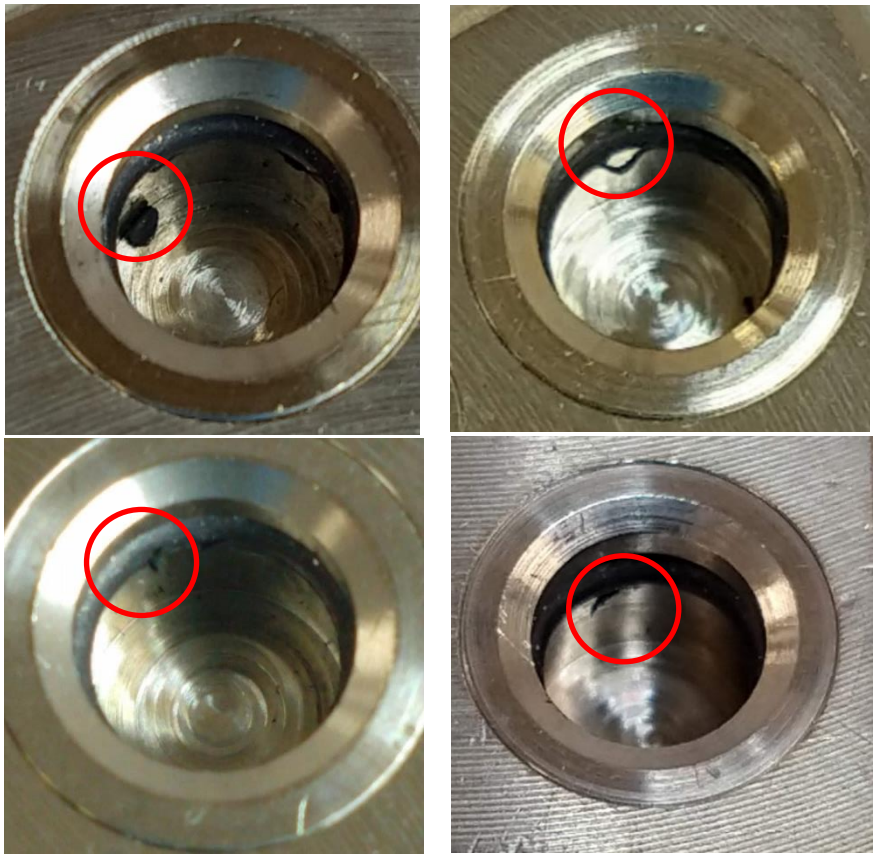
# 5 Maintenance instructions

Check for damage and wear after every use

The images below show some typical defects indicating that the o-rings in the Travel End Cap have become damaged and need to be replaced.

The o-rings should also be replaced, and the Travel End Cap cleaned, if there are silver particles on the surface of the o-ring and/or there is black debris visible in or around any of the holes in the cap.

Remove the o-rings before cleaning the Travel End Cap. Clean the metal cap using mechanical cleaning. It is recommended to replace the o-rings with new items after cleaning.

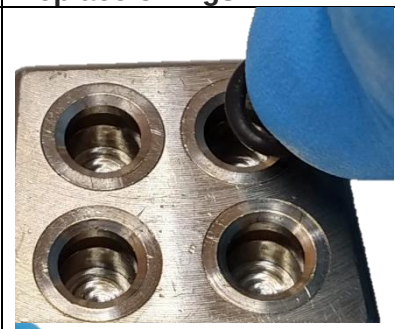
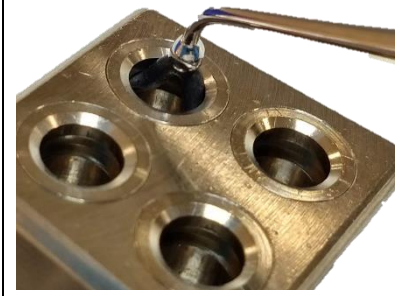


## 5.1 Removal of O-rings

The o-rings are removed by using the o-ring Removal Tool to carefully pierce the o-ring as shown below, left.

Do not push through into the metal surface as you could scratch this which can mean the seal is less effective.

Pull the o-ring forward and then upwards to remove.

| Remove o-rings | Replace o-rings |
| --- | --- |
|  |  |
|  |  |
|  |  |

## 5.2 Replacement of O-rings

The o-rings are replaced by slightly squeezing them between your fingers and forming a “banana” shape as shown above, right

This o-ring is then inserted as shown above, and finally pushed home into the inset groove using the o-ring Insertion Tool.

## 5.3 Baking O-rings

Note: o-rings must NEVER be greased or coated as this will add contaminants or could change the sealing properties of the o-ring.

Note: The o-rings supplied with this kit have been pre-baked.

Any o-rings *not* supplied by Owlstone Medical should also be baked to reduce the contaminants they hold.

This is done by arranging them on a clean, stainless steel try, slightly overlapping to decrease the area touching the tray.

Bake in a clean oven (preferably only used for this purpose) at 180C for 12-16 hours, preferably with carbon scrubbed or “zero air” flowing through the oven to remove the contaminants that evolve from the o-rings.

## 5.4 Cleaning the Travel End Caps

Travel End Caps should be cleaned after EVERY USE OR after changing the o-rings by baking in an oven

Use mechanical cleaning first to remove particles that may be stuck to the surface.

To do this, arrange the Travel End Caps in a clean, stainless steel tray, hole side up.

Bake in a clean oven at 180C for 12-16 hours preferably with carbon scrubbed or “zero air” flowing through the oven to remove the contaminants that evolve from the end caps and o-rings.

## 5.5 Maintaining the Brass Storage Caps

After each use, visually inspect the Brass Storage Caps for signs of wear or damage, paying particular attention to the PTFE ferrule contained within the cap. Replace any worn or damaged ferrules. Replacement caps and ferrules are available from Owlstone Medical.

# 6 Contacts and Support

The Owlstone Medical Ltd team is dedicated to providing excellent support. For all technical and safe use questions relating to this manual, contact us at:

Owlstone Medical Ltd.
183 Cambridge Science Park
Milton Road
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United Kingdom

Tel: +44 (0) 1223 428200

Or email support@owlstone.com