



MultICath Guidelines

FOR MEN

WELCOME TO THE MULTICATH STUDY

Thank you for agreeing to take part in this research. By doing so, you are helping to answer some important questions about intermittent catheterisation.

In the study, you will be using your own catheters as well as reusable catheters. We will give you the reusable catheters and any items you need for using them.

Using a reusable catheter involves some simple processes which we hope you will find straightforward. The reusable catheters are called Cliny catheters. This booklet will tell you all about Cliny catheters and how to use them.

We have developed this guide together with intermittent catheter users who have been using Cliny catheters in preparation for this study.

The information in this booklet is based on instructions provided by the catheter manufacturer but has lots of additional information—**please** follow the guidance as set out in this booklet.

There is also a short video which you can view at the Multicath website www.soton.ac.uk/multicath. If you do not have access to the internet and would prefer a DVD, please ask your research nurse.

If you have any questions, please contact your research nurse:

Name:

Email:

Telephone number:

ABOUT CLINY CATHETERS

- → Cliny catheters are used for clean, intermittent self-catheterisation (IC) or clean catheterisation by a sole (personal) carer if you need one.
- → Most IC catheters are thrown away after one use. Cliny catheters are licensed (CE marked) for reuse for up to 28 days when cleaned between uses as shown in this booklet.
- \rightarrow After 28 days use, Cliny catheters should be thrown away.
- $\rightarrow\,$ Cliny catheters come in a kit with a storage tube and carrying pouch please see Figure 1.



FIGURE 1. The Cliny intermittent catheterisation kit

PREPARING TO USE CLINY CATHETERS

Check the packaging - Cliny catheters are provided in sealed packets. Before using each Cliny catheter for the first time, check that the packaging is intact. If the packaging is damaged do not use the catheter but keep it and contact your research nurse.

Clean before use - New Cliny catheters are supplied clean but not sterile. Therefore each new Cliny catheter should be cleaned before being used for the first time, using the cleaning instructions in this booklet.

GETTING USED TO CLINY CATHETERS AND LUBRICATION

- → Cliny catheters are made from silicone and, like some other IC catheters, are uncoated. This means that you will have to add a lubricant before insertion.
- → Catheterising with a Cliny catheter may feel quite different from catheterising with your usual catheter. This is especially likely if you are used to a pre-lubricated catheter or one which requires water to make it slippery.
- → You should apply lots of lubricant at least to start with. After washing your hands, apply this with your fingers or some paper towel. Alternatively, squirt some gel into a ziplock bag, then place the catheter in the bag to apply lubricant.
- → Pass the Cliny catheter as you would your usual catheter using the same technique and at your usual times of use.
- → Cliny catheters can be used repeatedly as often as you like for up to 28 days.
- → Regardless of how often they have been reused, throw them away after 28 days.

Some people take longer to learn to use this type of catheter than others — that is fine!

Your research nurse will support you through this process.

O CLEANING CLINY CATHETERS USING MILTON

- → Cliny catheters are cleaned using soapy water and Milton (Sodium Hypochlorite).
- → Milton is commonly used for cleaning babies' bottles and purifying drinking water so is a very safe product. However, it is important that you use it in the correct concentration – see PREPARING THE MILTON SOLUTION
- → Please note: Milton can bleach fabrics so avoid spills see WHAT TO DO IF YOU SPILL MILTON.
- → Always wash your hands with soap and water before and after using Milton and dealing with the catheter.

PREPARING THE MILTON SOLUTION

- \rightarrow Fill the Milton Solo Travel container with cold tap water to the mark on the side of the container (this is 1.25 litres).
- → Add one Milton tablet. When the tablet has dissolved fully, the Milton solution is ready for use.
- \rightarrow Every 24 hours empty the container, wash with soapy water and fill with fresh Milton solution. Do not use the same Milton for more than 24 hours.

CLEANING CLINY CATHETERS IS A SIMPLE TWO-STEP PROCESS:

Step 1 Wash the Cliny catheter in soapy water — any type of soap will do. Clean along the length of the catheter and around the eyeholes. Rinse under running tap water.

Step 2 Using the blue syringe, flush the catheter with Milton and then immerse in the Milton, and screw on the lid of the container.

After 15 minutes the catheter will be ready for use.

After removal from the Milton, it is not necessary to rinse the Cliny catheter with tap water before use but some people prefer to do this.

See Section CLINY CATHETERS

- → Remove the catheter from the Milton and drain any excess liquid from it. Sometimes a little liquid remains inside the tip – this is usual and not something to worry about.
- $\rightarrow\,$ Dry with a paper towel or allow the catheter to air dry hanging from the wall-mounted catheter holder.
- $\rightarrow\,$ Cliny catheters can remain in the Milton until needed in which case drying is not necessary.

STORING CLINY CATHETERS

You can store Cliny catheters in the following ways to suit you:

- ightarrow In Milton in the Solo container or in the tube.
- ightarrow In the empty tube.
- \rightarrow If you are using the tube for storing the catheter, keep it unhooked in a straight position whenever convenient.
- → Store catheters away from direct sunlight, high temperatures and humidity and low temperatures below 10 °C.

\Lambda WHAT TO DO IF YOU SPILL MILTON

- \rightarrow If you get Milton on a garment, wash it as soon as possible.
- → If you get Milton in your eyes, wash the affected area with lots of running water.
- → If stinging occurs or persists or you have any concerns, please contact your family doctor.

Additional precautionary measures (on undiluted tablets): Causes serious eye irritation. May cause respiratory irritation. Toxic to aquatic life with long-lasting effects. Read label before use. Keep out of reach of children. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: get medical advice/ attention. If medical advice is needed, have product container at hand. Use only outdoors or in a well-ventilated area. Store locked up. Store in a dry place. Avoid release to the environment. Dispose of contents/container in accordance with local regulation. Contacts with acids liberates toxic gas. Warning! Do not use together with other products. May release dangerous gases (chlorine).

TAKING PART IN THE MULTICATH STUDY

Before you begin the study, there is a 14 day **LEARNING PERIOD** to allow you time to get used to the Cliny catheters. This is followed by the 12 month **TRIAL**. Please read the whole booklet, then follow the instructions below:

THE LEARNING PERIOD

Day 1 For <u>one</u> of your catheterisations, use the Cliny catheter from the kit then throw it away, retaining the tube. Use lots of lubricant at least until you get used to the Cliny catheter.

Day 2 Repeat Day 1 but practise cleaning the catheter after use. Then throw it away.

Day 3–7 Start using Cliny catheters instead of your single use catheters as often as you feel able to. Clean the Cliny catheters between uses as instructed in this booklet.

Day 7 Your research nurse will contact you to arrange sending out more of the items you need for the Trial.

Day 8-14 Carry on using the Cliny catheters whenever you can.

Day 14 Your research nurse will contact you to ensure you have all the items you need for starting the Trial.

THE TRIAL

During the Trial, your research nurse will contact you each month to find out how you are getting on, if you have had a urinary tract infection (UTI), how often you are using Cliny catheters and any events that have happened e.g. hospital visits. To help with this, in your folder you have:

A Monthly questionnaire: This is for reference only so you know what questions you will be asked over the telephone—do not fill it in.

Catheter diary sheets: For you to record how many of each catheter type (Cliny and your usual catheter) you use for the week before the monthly call. Your research nurse will remind you in advance to do this.

Event diary sheets: For you to record any events during the preceding month e.g. hospital visits.

UTI questionnaires: For you to complete if you think you have a UTI –please follow the instructions on page 10.

Urine sample shipment forms: For sending urine samples.

USING CLINY TUBES

The Cliny tubes can be used for storing and carrying Cliny catheters. They can also be used for cleaning Cliny catheters as they are designed to hold Milton solution.

Cleaning Cliny catheters using Cliny tubes

- → Wash the catheter with soapy water, rinse under running tap water and place the blue cap in the funnel end.
- → Using the blue syringe, fill the catheter tube with Milton solution to the mark on the tube. This varies according to catheter size. Your research nurse will show you the correct level for your catheter.
- ightarrow Pass the catheter into the tube.
- \rightarrow Push the cap firmly into the tube and twist to close securely.
- \rightarrow Dry the outside of the tube with a paper towel.
- → Check that the Milton does not leak.

After 15 minutes the catheter will be ready for use.

The tube and cap can be cleaned with soapy water and Milton. A small bottle brush or old toothbrush can be used to aid cleaning.

When using a Cliny tube for cleaning, you are unlikely to be able to flush the inside of the catheter. Therefore once a day clean your catheters in the Solo Travel container flushing through with Milton using the blue syringe.

TIPS FOR MANAGING YOUR

- → Take enough clean catheters to cover the time you plan to be away and bring them home for cleaning or take only one and clean using the Cliny tube containing Milton. See USING CLINY TUBES
- \rightarrow If you are going away overnight you might prefer to take the Solo travel container with you and make up a small kit which can be stored inside it.
- → Lubricant—if you only have a large tube of lubricant available, you may prefer to place the amount you need in a ziplock bag.
- → Use a small opaque plastic bag (e.g. nappy sac but any small bag would do), for storing used catheters.
- → If you think you won't be near running water take some wet wipes to clean your hands. Remember not to dispose of wet wipes in the toilet!
- \rightarrow You may prefer to use your usual single-use catheters at times when you think cleaning your catheters will be difficult.

WHAT TO DO WHEN SENDING A URINE SAMPLE OR IF YOU THINK YOU HAVE A UTI

- 1. Phone your research nurse and complete a UTI questionnaire.
- 2. Carry on using the Cliny and your own catheters as usual.
- 3. Send a urine specimen to the Trial lab.

For this you will need:

- → Blue "Safe Box" (see picture)
- ightarrow Red top urine sample container
- ightarrow Urine sample shipment and postage form



How to send a urine specimen to the lab:

- → Collect the urine sample in the red top urine container using one of your own sterile single use catheters. Wash hands before taking the specimen and afterwards.
- \rightarrow Leave the powder that is in the container.
- \rightarrow Make sure the pot is full—this is about 20ml of urine.
- → Write the sample date on the urine container and check that your unique study number and initials are on it.
- → Open the SafeBox and use the silver/white sheet to wrap the urine container.
- \rightarrow Put the wrapped urine container in the clear plastic side of the SafeBox.
- → Complete a 'URINE SAMPLE SHIPMENT AND POSTAGE FORM', ticking the appropriate box (e.g. 'At time of urinary tract infection' etc).
- \rightarrow Write the date and time of the sample on the bottom of the form.
- \rightarrow Put the form inside the SafeBox next to the clear plastic compartment.
- → Remove cardboard insert from the lid of the Safebox and place the lid on top of the box. Push down sharply until it clicks. It is now sealed and cannot be opened.
- → Peel the backing from the sticky address label, fold it over the top of the SafeBox and stick down firmly. The laboratory address in Newcastle should already be on the label.
- → Post the SafeBox as soon as possible to the Newcastle Laboratory in any Royal Mail post box or post office. Please try to post it before the last post of the day so that it arrives promptly at the laboratory.
- → If you think you have a UTI collect a separate specimen and send it to your GP following your usual practice. Please do not use a trial Safebox for this.

ADDITIONAL INSTRUCTIONS FROM THE MANUFACTURER

- → Only clean the Cliny catheter using the instructions provided in this information sheet.
- → Do not use boiling water to clean any items as this may cause damage and affect the function of the Cliny catheter.
- → Check the 'use before' date on the outer packaging.
- → Do not use out of date Cliny catheters.
- → Before use, check the Cliny catheter for any signs of damage.
- → Do not insert or remove the Cliny catheter forcibly. If you experience difficulty passing the catheter, contact your GP or nurse.
- \rightarrow Do not modify the Cliny catheter.

- → Do not expose the Cliny catheter to organic solvent e.g. white spirit, nail varnish remover, strong acid or alkali agents.
- → Do not handle the Cliny catheter with sharp implements e.g. forceps.
- → Only use the Cliny catheter for intermittent catheterisation and not for other procedures.
- → Dispose of the Cliny catheter in the same way as your usual catheter.
- → These instructions for use (IFU) are based on those provided with the device by Create Medic, the manufacturer and LinC Medical, the UK distributor.

IMPORTANT NOTE: These guidelines are only for use with the Cliny clean intermittent catheterisation kit when used in the Multicath trial. Do not use outside the Multicath testing.

FINALLY....

- → Most people who do intermittent catheterisation have bacteria in their urine even when using sterile, single-use catheters.
- → We have found the cleaning method in this booklet to be very effective at removing bacteria from catheters both in the laboratory and when used by men and women.
- → When using your single-use catheter, please continue to follow any instructions provided by the manufacturer.
- → These guidelines have been developed as part of the Multicath research study. They cannot be recommended for use outside the study at this time.
- → The guidelines are designed to be used with the Cliny catheters only. You should not attempt to re-use the single-use catheters you usually use.
- → If you experience any problems with catheterising with any of your catheters (e.g. bleeding, pain) please record it in your event diary and tell your Research Nurse.
- \rightarrow Please follow the safety advice on the Milton tablets.

We have worked together with men who do intermittent catheterisation to develop the cleaning, storage and lubrication guidelines described in this booklet.

We are very interested in your views about the information in the booklet. Please comment in writing overleaf or tell your research nurse what you think.

Thank you from the research team

Notes