

Participant Information Sheet

Interview study to find out what men think about surgery for urine leakage after prostate surgery



Invitation

You have agreed to take part in a research study called the MASTER trial which compares the AUS with the male sling for urinary incontinence following prostate surgery. This is a further invitation to take part in a separate interview study running alongside the MASTER trial.

Before you decide we would like you to understand why this research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish and please ask us if there is anything that is not clear.

The first part of this information sheet tells you the purpose of the study and what will happen. If you are interested, you can read the more detailed information provided in the second section.

WHAT IS THE STUDY ALL ABOUT?

The purpose of the study is to find out what is most important to men with urine leakage after prostate surgery. Different treatments have different outcomes and not all men hope for the same thing. We are looking to speak to about eighty men to get their point-of-view.

Why have I been invited?

You have been invited because you have urine leakage following prostate surgery and have agreed to take part in the MASTER trial. We aim to gather opinions at different stages of the main MASTER trial to answer questions about:

1. expectations of the different operations available,
2. considerations when deciding to be included in the trial, and,
3. opinions about the operation.

We would ask you to be interviewed on one or more occasions about only one of these aspects of the whole experience,

Do I have to take part in an interview?

No, it's entirely up to you. Your decision will not affect the standard of your care and, if you change your mind, you can withdraw from the interview at any time. If you withdraw from the study during or after the interview, we will ask you if we can use any information collected up to your withdrawal for our research. If you do not want us to use your information it will not be used and will be erased from our records.

OK, so what happens next?

If you agree to be interviewed, a researcher from Bristol Urological Institute will contact you first by phone. They will answer any questions you have and arrange a time and place for the interview. The interview can be done at Southmead hospital, Bristol or if a face-to-face interview is not practical, we will do the interview by phone.

What happens in the interview?

The interview will take around thirty minutes to one hour and will be recorded. You will be asked about either your expectations from the two operations offered, your feelings about randomisation or your reflections about the surgery, depending on the time when you are interviewed. It is important that you realise there are no correct answers and we are not trying to change your mind - we just want to hear what you think. At the end of the interview you will be asked if you are happy to be interviewed again and for the current conversation to be included in the study.

How will the interview be used?

The conversation will be written out and used by the researchers to better understand the findings from the MASTER trial. Your name and any personal details will be removed from the written version so that everything you have said is anonymous. We hope to publish the results of the study in scientific journals, which may include anonymised quotations.

Expenses and payments

If you are to be interviewed over the phone, we will phone you so that you don't have to pay for the phone call. If you need to travel to the interview, we will pay for transport or arrange it so that it coincides with your routine hospital outpatient appointment. You will not be left out of pocket.

What are the benefits of taking part?

You will be helping us improve the treatment of men with urine leakage after prostate surgery. The findings will also help the doctors working on the main MASTER trial by showing them what is important to patients undergoing these operations. There will be no direct benefits for you.

What are the disadvantages of taking part?

The interview will take between 30 minutes and an hour of your time.

What happens after the interview?

Your health care will be completely unaffected. If you are taking part in the main MASTER trial you will be followed up in the way described in the other information sheet you were given for that trial.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

This completes the overview of the interview study, if you are interested in taking part please read the additional information below before making a decision.

FURTHER DETAILS OF THE STUDY

What will happen if I don't want to carry on with the interview study?

You can withdraw from this study at any time without giving a reason. If you withdraw from the study during or after the interview we will ask you if we can use any information collected up to your withdrawal for our research. If you do not want us to use your information it will not be used and will be erased from our records.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the lead researcher for the interview study, [NAMExxx] first who will do their best to answer your questions (their contact number is [NUMBERxxx] and email [EMAILxxx]). If you remain unhappy and wish to complain formally, you can do this through the National Health Service complaints procedure. Details can be obtained from the Patient Advice and Liaison Service (PALS <http://www.pals.nhs.uk/>) at your local hospital. Their contact number is [LOCAL PALS CONTACT].

Because this interview study does not involve any tests or treatment it is highly unlikely that you will be harmed during the research. If something does go wrong and this is due to someone's negligence then you may have grounds for legal action for compensation against the NHS Trust that treated you or the trial's sponsor organisation North Bristol NHS Trust. You may have to pay your legal costs. The normal NHS complaints mechanisms will always be available to you.

Will my taking part in the study be kept confidential?

Yes. If you agree to take part in this study, the records obtained while you are in this study as well as related health records will remain strictly confidential. Audio-recordings and interview transcripts (the anonymous written version of the interview) will be held at the Bristol Urological Institute. Recordings and transcripts will be labelled with a trial number (not with your name) to hide your identity. The recordings and anonymised interview transcripts will be securely stored by the research team. At the end of the study the recordings will be destroyed. The anonymised interview transcripts will be securely stored for up to a maximum of 15 years afterwards, and then they will be destroyed. Only the researchers and those employed on the study will have access to the recordings and anonymised interview transcripts.

Your records will be available to people authorised to work on the trial but may also need to be made available to people authorised by North Bristol NHS Trust, which is the Sponsor organisation responsible for ensuring that the study is carried out correctly. By signing the consent form you agree to this access for the current study and any further research that may be conducted in relation to it.

What will happen to the results of the research study?

The study results will be presented at research meetings, and published on the National Institute for Health Research Health Technology Assessment programme website and in scientific journals. We will also make the results widely available to the public. You will not be identified in any report or publication.

Who is organising and funding the research?

The MASTER trial interview study is being led by [NAMExxx] who is a Research Fellow based at Bristol Urological Institute. It is sponsored within the NHS by the North Bristol NHS Trust and funded by the National Institute for Health Research Health Technology Assessment programme with Trial Management being provided by the University of Aberdeen.

Who has approved the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your interests. This study has been reviewed and given favourable opinion by the Frenchay Research Ethics Committee.

What do I do now?

You will be contacted by a member of the research team. Please let them know whether you would like to take part.

Further information and contact details

If you have any further questions concerning this study please contact:

Lead Researcher

[NAMExx]

Address [ADDRESSxxx]

Phone: [NUMBERxxx] 4147933

Email: [EMAILxxx]xxx

Qualitative Researcher

[NAMExxx]

Address [ADDRESSxxx]

Phone: [NUMBERxxx]

Email:[EMAILxxx]

Thank you for thinking about taking part in our research.

Professor Paul Abrams

Chief Investigator

MASTER Trial

Bristol Urological Institute

Southmead Hospital

Westbury-on-Trym

Bristol

BS10 5NB

Phone: [NUMBERxxx]

Funded by the National Institute for Health Research Health Technology Assessment
(NIHR HTA) Programme 11/106/01

Consent Form for Patient Interview

MASTER: Male synthetic sling versus Artificial urinary Sphincter Trial:
Evaluation by Randomised controlled trial.



Interview study to find out what men think about surgery for urine leakage after prostate surgery

Participant Study Number -

Name of Chief Investigator Professor Paul Abrams

Name of Lead Researcher, Interview Study [NAMExxx]xxx

[NAMExxx].....

Name of Local Principal Investigator

By initialing each box and signing this form:

1. I confirm that I have read and understand the information sheet dated [DATExxx] v[VERSION NUMBERxxx] for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from regulatory authorities, from University of Aberdeen, or from the NHS Boards or Trusts, where it is relevant to my taking part in this research. I give permission for these individuals to access my records. ☐
4. I understand that I will not be personally named in any report and that anything I say will be treated in confidence (unless something I say indicates that either myself or someone else is at risk of harm and this would be discussed with me prior to telling anyone else). ☐
5. I agree to the interview being audio-recorded. ☐
6. I agree to take part in the above interview study.

Name of Patient

Date

Signature

Name of Person taking consent

Date

Signature

When completed: 1 original for researcher; 1 copy for patient; 1 copy for trial office.



MASTER patient advice sheet

Using the Internet for researching treatment options for clinical trials

The internet can be a very informative and helpful source of information. A quick search using Google or another search engine will return a wealth of information from multiple different sources from all over the world. This information may be well-researched and from reputable sources. However, there are some important points to keep in mind when you are deciding on your treatment options.

What is the source?

It is important to consider who is supplying the information as there may be a conflict of interest behind the way information is presented. For instance,

- A company may have a vested interest in selling their product, such as a drug company or health supplier.
- Private hospitals may also present information in a pro-treatment way, as they have a financial incentive to you having your medical treatment in their clinic.
- Articles about 'new' treatments from the media may be sensationalised, inaccurate or biased in their presentation of the facts.

Even articles that appear to be from trusted sources and are well-researched may often be misleading.

- The information is no longer up-to-date.
- There may be limited or no evidence for the facts and figures that are presented.
- There may be conflicting reports from multiple studies.

Which sources can I trust?

The information provided by the trial health professionals, NHS medical resources and organisations such as NICE (National Institute for Health and Care Excellence) has been based on up-to-date scientific evidence and has been carefully worded to be free of bias. If you are still unsure about your source of information then ask your doctor and they will be able to help you reach an informed decision.

BLADDER DIARY

YOUR MASTER STUDY NUMBER: _____

Please complete this **3 day** bladder diary. Enter the following in each column against the time. You can change the specified times if you need to. In the time column, please write **BED** when you went to bed and **WOKE** when you woke up.

IF YOU USE A SHEATH APPLIANCE INSTEAD OF PADS, PLEASE COMPLETE THIS AT THE SAME TIME AS YOU DO YOUR 24 HOUR PAD TEST

Drinks Write the amount you had to drink and the type of drink.

Urine output Enter the amount of urine you passed in millilitres (mls) in the urine output column, day and night. Any measuring jug will do. If you passed urine but couldn't measure it, put a tick in this column. If you leaked urine at any time write **LEAK** here.

Bladder sensation Write a description of how your bladder felt when you went to the toilet using these codes

0 - If you had no sensation of needing to pass urine, but passed urine for "social reasons", for example, just before going out, or unsure where the next toilet is.

1 - If you had a normal desire to pass urine and no urgency. "Urgency" is different from normal bladder feelings and is the sudden compelling desire to pass urine which is difficult to defer, or a sudden feeling that you need to pass urine and if you don't you will have an accident.

2 - If you had urgency but it had passed away before you went to the toilet.

3 - If you had urgency but managed to get to the toilet, still with urgency, but did not leak urine.

4 - If you had urgency and could not get to the toilet in time so you leaked urine.

Pads If you change a pad put a tick in the pads column.

Here is an example of how to complete the diary:

Time	Drinks		Urine output	Bladder sensation	Pads
	Amount	Type			
6am WOKE			350ml	2	
7am	300ml	tea			
8am			✓	2	
9am					
10am	cup	water	Leak	3	✓

DAY 1 DATE: ____ / ____ / ____

Time	Drinks		Urine output (mls)	Bladder sensation	Pads
	Amount	Type			
6am					
7am					
8am					
9am					
10am					
11am					
Midday					
1pm					
2pm					
3pm					
4pm					
5pm					
6pm					
7pm					
8pm					
9pm					
10pm					
11pm					
Midnight					
1am					
2am					
3am					
4am					
5am					



BLADDER DIARY

YOUR MASTER STUDY NUMBER: _____

DAY 2 DATE: ____/____/____

Time	Drinks		Urine output (mls)	Bladder sensation	Pads
	Amount	Type			
6am					
7am					
8am					
9am					
10am					
11am					
Midday					
1pm					
2pm					
3pm					
4pm					
5pm					
6pm					
7pm					
8pm					
9pm					
10pm					
11pm					
Midnight					
1am					
2am					
3am					
4am					
5am					

DAY 3 DATE: ____/____/____

Time	Drinks		Urine output (mls)	Bladder sensation	Pads
	Amount	Type			
6am					
7am					
8am					
9am					
10am					
11am					
Midday					
1pm					
2pm					
3pm					
4pm					
5pm					
6pm					
7pm					
8pm					
9pm					
10pm					
11pm					
Midnight					
1am					
2am					
3am					
4am					
5am					

Bladder sensation codes

0 - No sensation of needing to pass urine, but passed urine for "social reasons"

1 - Normal desire to pass urine and no urgency

2 - Urgency but it had passed away before you went to the toilet

3 - Urgency but managed to get to the toilet, still with urgency, but did not leak urine

4 - Urgency and could not get to the toilet in time so you leaked urine



24 HOUR PAD TEST FOR URINE LEAKAGE

In the MASTER Study, one of the ways we will see how much leakage you have is to ask you to do a pad test. This involves collecting the pads you usually use, to protect yourself from leakage, over a 24 hour period, in order to weigh them. We will ask you to do this before your operation and again 12 months after surgery. The second test is to see what effect the operation has had on your leakage. We think it is easiest for you if you do the first test the day before you come to the hospital for your first study visit.

Please drink normal fluids and conduct your normal physical activity whilst doing the pad test.

If you usually wear pads to protect yourself from leakage, please use your normal pads for this test.

If you do not usually use pads but protect yourself by using another means, such as a sheath appliance (Conveen), we would still like you to do the 24 hour pad test by wearing pads instead of your normal method of protection so we can measure your leakage exactly. Let us know if you want us to supply pads.

- Put a new pad on as soon as you get up in the morning and note the time.
- Whenever you need to change your pad, take off the old one and put it into a sealed airtight plastic bag. You can use one bag for all the pads or several bags.
- If you usually wear a pad at night, change your pad before you go to bed and put that into the bag.
- If you had to change a pad in the night also put this into the bag.
- Next morning please change your pad **AT THE SAME TIME AS ON THE FIRST MORNING**, and put your overnight pad into the bag.

Please remember to bring all your pads, to the hospital so that we can weigh them.

Also, please bring an unused pad, so that we can weigh that too.

If you have any questions please call us on...[insert local details].....



***National Institute for
Health Research***

Are you considering having surgery for urine leakage after your prostate operation?

If you would consider having an operation for your leakage you may be able to take part in a research study called the **MASTER** trial.

The **MASTER** trial is comparing two operations for urine leakage after prostate surgery in men, to see which is most effective and has fewer complications.

To take part you will need:

- to be male
- to have bothersome urine leakage after a prostate operation
- to have had simple treatments including pelvic floor exercises
- to have persistent symptoms nevertheless

If you would like to find out more, please ask your urologist or nurse about the **MASTER** trial.

For further information and advice about taking part, contact:

(Name) Research Nurse

Phone:

Email:

(Name) Local PI

Phone:

Email:

<< Date >>

<<Title>> <<Name>> << Surname>>

MASTER STUDY No. <<.....>>

<<Address 1>>

<<Address 2>>

<<Address 3>>

<<Address 4>>

<<Postcode>>

Dear <<Title>> <<Surname>

**The MASTER Study - Male synthetic sling versus Artificial urinary Sphincter
Trial: Evaluation by Randomised controlled trial**

You are being invited to take part in a research study because you will be having surgery for urine leakage after prostate surgery. We want to give you some information about the study now, to give you plenty time to think about it before your operation. We have enclosed a Participant Information Leaflet, a baseline questionnaire, an bladder diary, instructions about performing a 24 hour pad test and a consent form, as well as a Surgical Information Sheet with information about the surgery itself.

Thank you for taking the trouble to read this information. We hope that it will be helpful in enabling you to decide whether or not you would like to participate in the MASTER study. You will be approached about this when you go to hospital.

If after reading this information you think you would like to take part in this study, please complete the baseline questionnaire and the bladder diary and bring both along with you to hospital when you come in for your pre-assessment or your operation. Your urologist or local research nurse will be happy to give you more information before you decide whether you want to take part.

Please feel free to discuss this with your family, friends or GP if you wish. You may also wish to speak with your own urologist or research nurse, or the staff at the MASTER Study Office who will also be happy to answer any questions.

Thank you for considering taking part in MASTER study.

Yours sincerely,

[Local Urologist]

Enclosures MASTER Participant Information Leaflet
MASTER Surgical Information Sheet (Sling or Sphincter)
MASTER Baseline Questionnaire
MASTER Bladder Diary
MASTER 24 hour pad test instructions
MASTER Consent Form



<< Date >>

<<Title>> <<Name>> << Surname>>

MASTER STUDY No. <<.....>>

<<Address 1>>

<<Address 2>>

<<Address 3>>

<<Address 4>>

<<Postcode>>

Dear <<Title>> <<Surname>>

**The MASTER Study - Male synthetic sling versus Artificial urinary Sphincter
Trial: Evaluation by Randomised controlled**

Thank you very much for taking part in the MASTER Study to date.

We sent you a 6 month review questionnaire a few weeks ago. We are keen to find out how you have been getting on during the last six months. Unfortunately we have not yet received your answers.

We appreciate how busy you must be, but your answers to the questionnaire are very important to us. If you cannot answer all the questions don't worry. Please send it to us when you have answered as much as you can, using the envelope provided (no stamp required).

If you have any worries or problems in completing the questionnaire, a friend or relative may be able to help you. If still in doubt, do please contact the MASTER Study on 01224 438096. Please note that ALL the information you give will be treated with the strictest confidence. If your reply is already in the post, I would like to thank you for your help and apologise for this reminder.

We would like to thank you very much for taking part in the MASTER Study and in completing the questionnaire as your views and information about your recovery are very important to improving the management of men having leakage surgery in the future.

Yours sincerely,

<<Electronic signature>>

<<Name>>

Trial Manager

Enclosures 6 month MASTER Questionnaire.
Reply-paid Envelope.

<< Date >>

<<Title>> <<Name>> << Surname>>

MASTER STUDY No. <<.....>>

<<Address 1>>

<<Address 2>>

<<Address 3>>

<<Address 4>>

<<Postcode>>

Dear <<Title>> <<Surname>>

**The MASTER Study - Male synthetic sling versus Artificial urinary Sphincter
Trial: Evaluation by Randomised controlled**

Thank you very much for taking part in the MASTER Study to date.

We sent you the enclosed 6 month review questionnaire a few weeks ago. We are keen to find out how you have been getting on. Unfortunately we have not yet received your answers.

We appreciate how busy you must be, but believe this to be an important study for men's health. Your reply is very important to us. If your reply is already in the post, I would like to thank you for your help and apologise for this reminder.

Therefore we have enclosed another copy, and would be most grateful if you could take a few minutes of your time to complete it, and return it in the envelope provided (no stamp required). Please note that ALL the information you give will be treated with the strictest confidence.

Although some of the questions may not seem relevant we would like you to complete the questionnaire fully. However, you are not obliged to answer every question if you do not want to. If you have any worries or problems in completing the questionnaire, a friend or relative may be able to help you. If still in doubt, do please contact the MASTER Study Office on 01224 438096.

We would like to thank you very much for taking part in the MASTER Study and in completing the questionnaire as your views and information about your recovery are very important to improving the management of men having leakage surgery in the future.

Yours Sincerely,

<<Electronic signature>>

<<Name>>

Trial Manager

Enclosures 6 month MASTER questionnaire.
Reply-paid envelope.



<< Date >>

<<Title>> <<Name>> << Surname>>

MASTER STUDY No. <<.....>>

<<Address 1>>

<<Address 2>>

<<Address 3>>

<<Address 4>>

<<Postcode>>

Dear <<Title>> <<Surname>>

**The MASTER Study - Male synthetic sling versus Artificial urinary Sphincter
Trial: Evaluation by Randomised controlled**

Thank you very much for taking part in the MASTER Study.

We have enclosed your 6 month review questionnaire and bladder diary. We are keen to find out how you have been getting on during the last six months.

Although some of the questions in the questionnaire may not seem relevant we would like you to complete the questionnaire fully. However, you are not obliged to answer every question if you do not want to. If you have any worries or problems in completing the questionnaire, a friend or relative may be able to help you. If still in doubt, do please contact the MASTER Study Office on 01224 438096.

We would like to thank you very much for taking part in the MASTER Study and for completing the questionnaire and urinary diary as your views and information about your recovery are very important to improving the management of men having leakage surgery in the future.

Please return the questionnaire in the reply-paid envelope provided (no stamp is required).

Yours sincerely,

<<Electronic Signature>>

<<Name>>

Trial Manager

Enclosures 6 month MASTER questionnaire.
 3 day bladder diary
 Reply-paid envelope.



<< Date >>

<<Title>> <<Name>> << Surname>>

MASTER STUDY No. <<.....>>

<<Address 1>>

<<Address 2>>

<<Address 3>>

<<Address 4>>

<<Postcode>>

Dear <<Title>> <<Surname>>

**The MASTER Study - Male synthetic sling versus Artificial urinary Sphincter
Trial: Evaluation by Randomised controlled**

Thank you very much for taking part in the MASTER Study to date.

We sent you a two year review questionnaire a few weeks ago. We are keen to find out how you have been getting on. Unfortunately we have not yet received your answers.

We appreciate how busy you must be, but your answers to the questionnaire are very important to us. If you cannot answer all the questions don't worry. Please send it to us when you have answered as much as you can, using the envelope provided (no stamp required). If your reply is already in the post, we would like to thank you for your help and apologise for this reminder.

Please note that ALL the information you give will be treated with the strictest confidence. If you have any worries or problems in completing the questionnaire, a friend or relative may be able to help you. If still in doubt, do please contact the MASTER Study Office on 01224 438096.

We would like to thank you very much for taking part in the MASTER Study and in completing the questionnaire as your views and information about your recovery are very important to improving the management of men having surgery in the future.

Yours sincerely,

<<Electronic signature>>

<<Name>>

Trial Manager

Enclosures 2 year MASTER questionnaire.
Reply-paid envelope.



<< Date >>

<<Title>> <<Name>> << Surname>>
<<Address 1>>
<<Address 2>>
<<Address 3>>
<<Address 4>>
<<Postcode>>

MASTER STUDY No. <<.....>>

Dear <<Title>> <<Surname>>

**The MASTER Study - Male synthetic sling versus Artificial urinary Sphincter
Trial: Evaluation by Randomised controlled**

Thank you very much for taking part in the MASTER Study.

We sent you a two year review questionnaire a few weeks ago. We are keen to find out how you have been getting on. Unfortunately we have not yet received your reply.

We appreciate how busy you must be, but we believe this to be an important study for men. Your reply is very important to us.

Therefore we enclose a second copy of the questionnaire, and would be most grateful if you could give us a little of your time to complete it, and return it in the envelope provided (no stamp required). Please note that ALL the information you give will be treated with the strictest confidence. If your reply is already in the post, we would like to thank you for your help and apologise for this reminder.

Although some of the questions may not seem relevant we would like you to complete the questionnaire fully. However, you are not obliged to answer every question if you do not want to. If you have any worries or problems in completing the questionnaire, a friend or relative may be able to help you. If still in doubt, do please contact the MASTER Study Office on 01224 438096.

We would like to thank you very much for taking part in the MASTER Study and for completing the questionnaire. Your views and information about your recovery are very important to improving the management of men having an operation for urine leakage after prostate surgery in the future.

Yours sincerely,

<<Electronic signature>>
<<Name>>
Trial Manager

Enclosures 2 year MASTER questionnaire.
 Reply-paid envelope.



<< Date >>

<<Title>> <<Name>> << Surname>>
<<Address 1>>
<<Address 2>>
<<Address 3>>
<<Address 4>>
<<Postcode>>

MASTER STUDY No. <<.....>>

Dear <<Title>> <<Surname>>

**The MASTER Study - Male synthetic sling versus Artificial urinary Sphincter
Trial: Evaluation by Randomised controlled trial**

Thank you very much for taking part in the MASTER Study – you very kindly agreed to help this research project when you had your operation for urine leakage after prostate surgery.

We are keen to find out how you have been getting on. We have enclosed a review questionnaire and a bladder diary, and would be very grateful if you could fill both in.

Although some of the questions in the questionnaire may not seem relevant, we would like you to complete the questionnaire fully. However, you are not obliged to answer every question if you do not want to. If you have any worries or problems in completing the questionnaire, a friend or relative may be able to help you. If still in doubt, do please contact the MASTER Study Office on 01224 438096.

We would like to thank you very much for taking part in the MASTER Study and for completing the questionnaire, as your views and information about your recovery are very important to improving the management of men having leakage surgery in the future.

Please return the questionnaire and bladder diary in the reply-paid envelope provided (no stamp is required).

Yours sincerely,

<<Electronic signature>>
<<Name>>
Trial Manager

Enclosures 2 year MASTER questionnaire.
 3 day bladder diary.
 Reply-paid envelope.



<< Date >>

<<Title>> <<Name>> << Surname>>

MASTER STUDY No. <<.....>>

<<Address 1>>

<<Address 2>>

<<Address 3>>

<<Address 4>>

<<Postcode>>

Dear <<Title>> <<Surname>>

**The MASTER Study - Male synthetic sling versus Artificial urinary Sphincter
Trial: Evaluation by Randomised controlled trial**

Thank you very much for taking part in the MASTER Study to date.

We sent you a one year review questionnaire a few weeks ago. We are keen to find out how you have been getting on. Unfortunately we have not yet received your answers.

We appreciate how busy you must be, but your answers to the questionnaire are very important to us. If you cannot answer all the questions don't worry. Please send it to us when you have answered as much as you can, using the envelope provided (no stamp required). If your reply is already in the post, we would like to thank you for your help and apologise for this reminder.

Please note that ALL the information you give will be treated with the strictest confidence. If you have any worries or problems in completing the questionnaire, a friend or relative may be able to help you. If still in doubt, do please contact the MASTER Study Office on 01224 438096.

We would like to thank you very much for taking part in the MASTER Study and in completing the questionnaire as your views and information about your recovery are very important to improving the management of men having surgery in the future.

Yours sincerely,

<<<Electronic signature>>

<<Name>> Trial Manager

Enclosures 1 year MASTER questionnaire.
Reply-paid envelope.



<< Date >>

<<Title>> <<Name>> << Surname>> MASTER STUDY No. <<.....>>
<<Address 1>>
<<Address 2>>
<<Address 3>>
<<Address 4>>
<<Postcode>>

Dear <<Title>> <<Surname>>

**The MASTER Study - Male synthetic sling versus Artificial urinary Sphincter
Trial: Evaluation by Randomised controlled trial**

Thank you very much for taking part in the MASTER Study.

We sent you a one year review questionnaire a few weeks ago. We are keen to find out how you have been getting on. Unfortunately we have not yet received your reply.

We appreciate how busy you must be, but we believe this to be an important study for men. Your reply is very important to us.

We therefore enclose a second copy of the questionnaire, and would be most grateful if you could give us a little of your time to complete it, and return it in the envelope provided (no stamp required). Please note that ALL the information you give will be treated with the strictest confidence. If your reply is already in the post, we would like to thank you for your help and apologise for this reminder.

Although some of the questions may not seem relevant we would like you to complete the questionnaire fully. However, you are not obliged to answer every question if you do not want to. If you have any worries or problems in completing the questionnaire, a friend or relative may be able to help you. If still in doubt, do please contact the MASTER Study Office on 01224 438096.

We would like to thank you very much for taking part in the MASTER Study and for completing the questionnaire. Your views and information about your recovery are very important to improving the management of men having an operation for urine leakage after prostate surgery in the future.

Yours sincerely,

<<Electronic signature>>
<<Name>> Trial Manager

Enclosures 1 year MASTER questionnaire.
Reply-paid envelope.



<< Date >>

<<Title>> <<Name>> << Surname>>

MASTER STUDY No. <<.....>>

<<Address 1>>

<<Address 2>>

<<Address 3>>

<<Address 4>>

<<Postcode>>

Dear <<Title>> <<Surname>>

**The MASTER Study - Male synthetic sling versus Artificial urinary Sphincter
Trial: Evaluation by Randomised controlled trial**

Thank you very much for taking part in the MASTER Study – you very kindly agreed to help this research project when you had your operation for urine leakage after prostate surgery.

We are keen to find out how you are getting on. We have enclosed a review questionnaire and a bladder diary, and would be very grateful if you could fill both in.

Although some of the questions in the questionnaire may not seem relevant we would like you to complete the questionnaire fully. However, you are not obliged to answer every question if you do not want to. If you have any worries or problems in completing the questionnaire, a friend or relative may be able to help you. If still in doubt, do please contact the MASTER Study Office on 01224 438096.

We would like to thank you very much for taking part in the MASTER Study and for completing the questionnaire and bladder diary, as your views and information about your recovery are very important to improving the management of men having leakage surgery in the future.

Please return the questionnaire and the bladder diary in the reply-paid envelope provided (no stamp is required).

Yours sincerely,

<<Electronic signature>>

<<Name>> Trial Manager

Enclosures 1 year MASTER questionnaire.
 3 day bladder diary
 Reply-paid envelope.

MASTER Study Number:

--	--	--	--	--

CONFIDENTIAL



MASTER STUDY

**Male synthetic sling versus Artificial urinary Sphincter Trial: Evaluation by
Randomised controlled trial**

BASELINE QUESTIONNAIRE

Thank you for helping with our research into treatment for men who leak urine after prostate surgery. We would be very grateful if you could complete this questionnaire and return in person or by post, to your Urology Dept.

After you have answered the questions, we can allocate you to a treatment group.

If you would like any further information or have any queries about the study, please contact:

**MASTER Study Office
Tel: 01224 438096
E-mail: master@abdn.ac.uk**

Thank you for taking the time to help us with our research.

HOW TO FILL IN THIS QUESTIONNAIRE

Most questions can be answered by putting numbers or a tick in the appropriate box or boxes. Please print your answers carefully within the boxes like this:

2	7
---	---

OR

M	I	K	E
---	---	---	---

OR

✓

If you make a mistake, shade out the wrong box completely and tick the correct one like this:

e.g. If you ticked often but meant to answer sometimes:

OFTEN
SOMETIMES
NEVER

✓
✓

Please try to complete the whole questionnaire.

There are no right or wrong answers.

Sometimes the box you tick tells you to skip forward so that you miss out questions which do not apply to you.

In some questions we would like you to think about different time periods, such as during the last week or during the last 4 weeks.
Please check the time periods carefully.

Some of the questions ask for answers in your own words, please write these in the boxes provided.

You do not have to answer any question if you do not want to.

Thank you for your help.

Please answer the following questions in relation to the protection you have used for your incontinence in the past and currently.

What protection have you used in the past to protect yourself from urine leakage?

Rolled up toilet paper ☐

Pantiliners ☐

Incontinence pads ☐

Coveen sheath ☐

Catheter ☐

Other (please state in box below)

What protection do you currently use to protect yourself from urine leakage?

Rolled up toilet paper ☐

Pantiliners ☐

Incontinence pads ☐

Coveen sheath ☐

Catheter ☐

Other (please state in box below)

SECTION A – URINE SYMPTOMS

When you answer these questions, please think about how you have been in the **LAST 4 WEEKS**.

If you wear protection such as a sheath or have a catheter fitted please answer the following questions as if you not protected by these methods.

A1. How often do you leak urine? (*Tick **ONE** box only*)

- Never ☐
- About once a week or less often ☐
- Two or three times a week ☐
- About once a day ☐
- Several times a day ☐
- All of the time ☐

A2. We would like to know how much urine you think leaks.

How much urine do you usually leak (whether you wear protection or not)? (*Tick **ONE** box only*)

- A small amount ☐
- A moderate amount ☐
- A large amount ☐
- None ☐

A3. Does urine leak when you are physically active, exert yourself, cough or sneeze? (*Tick **ONE** box only*)

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A4. Do you have a sudden need to rush to the toilet to urinate? (*Tick **ONE** box only*)

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A5. Does urine leak before you can get to the toilet? (Tick **ONE** box only)

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A6. How often have you had a slight wetting of your pants a few minutes after you have finished urinating and had dressed yourself? (Tick **ONE** box only)

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A7. Do you ever leak for no obvious reason and without feeling that you want to go? (Tick **ONE** box only)

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A8. Do you leak urine when you are asleep? (Tick **ONE** box only)

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A9. Overall, how much does leaking urine interfere with your everyday life?

Please choose a number between **0 (not at all)** and **10 (a great deal)**. (Tick **ONE** box only)

<u>Not at</u> <u>all</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<u>A great</u> <u>deal</u>
	0	1	2	3	4	5	6	7	8	9	10	

A10. How often do you usually pass urine during the daytime?

Enter number of times

A11. How often do you usually have to get up at night to pass urine?

Enter number of times

A12. Is there a delay before you can start to urinate? (Tick **ONE box only)**

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A13. Do you have to strain to continue urinating? (Tick **ONE box only)**

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A14. Would you say that the strength of your urinary stream is: (Tick **ONE box only)**

- Normal ☐
- Occasionally reduced ☐
- Sometimes reduced ☐
- Reduced most of the time ☐
- Reduced all of the time ☐

A15. Do you stop and start more than once while you urinate? (Tick **ONE box only)**

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A16. How often do you feel that your bladder has not emptied properly after you have urinated? (Tick **ONE box only)**

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

SECTION B – TREATMENT FOR URINE SYMPTOMS / CARE YOU HAVE RECEIVED

When you answer these questions, please think about how you have been in the **LAST 4 WEEKS**.

B1. Do you wear a pad or other protection (e.g. pantliners) because of leaking urine? (Tick **ONE box only)**

Yes ☐ Go to **B1a** No ☐ Go to **B2**



B1a. If Yes, how many pads/pantliners do you wear in an average day (24hours)?

Enter **TOTAL** number of pads/pantliners you wear in 24 hours

B1b. Of these pads, how many do you pay for yourself?

If you do not pay for them, please enter zero (0) in the boxes

Enter number of pads **YOU PAY FOR** yourself

B2. Do you use pads or protectors on your chair or bed in case you leak urine?

Yes ☐ Go to **B2a** No ☐ Go to **B3**



B2a. If Yes, how many chair or bed pads do you use in an average day (24 hours)?

Enter **TOTAL** number of chair and bed pads you use in 24 hours

B2b. Of these chair or bed pads, how many do you pay for yourself?

If you do not pay for them, please enter zero (0) in the boxes

Enter number of chair and bed pads **YOU PAY FOR** yourself

B3. Are you using a permanent catheter (inside your bladder) to collect your urine?

Yes ☐ No ☐

B4. Do you ever use an external (sheath) catheter to collect your urine?

Yes ☐ No ☐

B5. Have you seen your family doctor (GP) in the last 4 weeks?

Yes ☐ Go to **B5a** No ☐ Go to **B6**



B5a. If Yes, approximately how often have you seen your family doctor (GP) in the last 4 weeks?

Enter number of times seen GP **for leaking urine**

Enter number of times seen GP **for any other reason related to MASTER surgery or urine symptoms**

B6. Have you seen a nurse (from your doctor's practice) in the last 4 weeks?

Yes ☐ Go to **B6a** No ☐ Go to **B7**



B6a. If Yes, approximately how many times have you seen a nurse from your doctor's practice in the last 4 weeks?

Enter number of times seen nurse **for leaking urine**

Enter number of times seen nurse **for any other reason related to MASTER surgery or urine symptoms**

B7. In the last 4 weeks, have you seen NHS HOSPITAL staff for leaking urine?

I have seen a hospital doctor **about leaking urine**

If yes, enter number of visits

Yes ☐ → Number of visits No ☐

I have seen a hospital nurse **about leaking urine**

If yes, enter number of visits

Yes ☐ → Number of visits No ☐

I have seen a hospital physiotherapist **about leaking urine**

If yes, enter number of visits

Yes ☐ → Number of visits No ☐

B8. In the last 4 weeks, have you received any PRIVATE TREATMENT (for which you had to pay yourself) for leaking urine?

I have seen a private doctor **about leaking urine**

If yes, enter number of visits

Yes ☐ → Number of visits No ☐

I have seen a private nurse **about leaking urine**

If yes, enter number of visits

Yes ☐ → Number of visits

No ☐

I have seen a private physiotherapist **about leaking urine**

If yes, enter number of visits

Yes ☐ → Number of visits

No ☐

B9. In the last 4 weeks, have you been admitted to hospital because of leaking urine?

Yes ☐ Go to **B9a**

No ☐

Go to **B10**



B9a. If you were admitted in the last 4 weeks, how many nights did you stay in hospital? If this was a day case, please enter 0

Enter number of nights in hospital

B9b. In the last 4 weeks, have you had a new operation for leaking urine?

Yes ☐ Go to **B9c**

No ☐

Go to **B10**



B9c. If Yes, please give the name or type of operation and the date:

B10. In the last 4 weeks, have you taken any medications (from a doctor, or direct from the chemist's) for leaking urine?

Yes ☐ Go to **B10a**

No ☐

Go to **B11**



B10a. If Yes, please give details of medication received in the last 4 weeks for leaking urine. Please give drug names (e.g. detrusitol, duloxetine):

B11. Have you had any other treatment or advice for leaking urine in the last 4 weeks (other than the operation you named in B9c or the drugs you listed in B10a)?

Yes ☐ Go to **B11a**

No ☐

Go to **B12**



B11a. If Yes, please give details of other treatment or advice for leaking urine received in the last 4 weeks:

B12. Are you in paid employment?

Yes ☐

Go to **B12a**

No ☐

Go to **C1**



B12a. If Yes, approximately how many days off sick have you had for any reason since your prostate operation in the last 4 weeks?

days

SECTION C - ABOUT SEXUAL MATTERS

C1. Do you get erections? (Tick *ONE* box only)

Yes, with normal rigidity ☐

Yes, with reduced rigidity ☐

Yes, with severely reduced rigidity ☐

No, erection not possible ☐

C2. Do you have an ejaculation of semen? (Tick *ONE* box only)

Yes, normal quantity ☐

Yes, reduced quantity ☐

Yes, significantly reduced quantity ☐

Yes, but no semen comes out ☐

No ejaculation ☐

C3. Do you have pain or discomfort during ejaculation? (Tick *ONE* box only)

No ☐

Yes, slight pain / discomfort ☐

Yes, moderate pain / discomfort ☐

Yes, severe pain / discomfort ☐

C4. To what extent do you feel that your sex life has been spoilt by your urinary

symptoms? (Tick **ONE** box only)

Not at all ☐

A little ☐

Somewhat ☐

A lot ☐

C5. Have you used any of these treatments for sexual problems? (Tick **ALL** relevant boxes)

Physiotherapy (e.g. pelvic floor exercises) ☐

Medication or drugs (e.g. Viagra) ☐

Vacuum device ☐

Mechanical device (e.g. a ring) ☐

Surgery (e.g. an implant) ☐

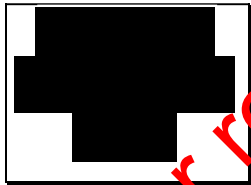
Other ☐

If other please give details:

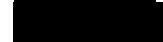
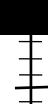
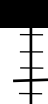
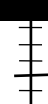
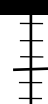
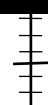
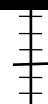
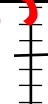
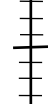
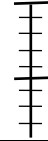
SECTION D – DESCRIBING YOUR OWN HEALTH TODAY (EQ-5D™)

[illegible]

1990 EuroQol Group EQ-5D™ is a trade mark of the EuroQol Group



Redacted for reasons of copyright



SECTION E – GENERAL HEALTH SF12©

[Redacted text]

[Redacted text]

[Redacted text]

[Redacted text]

[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]

[Redacted text]

[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]

[Redacted text]

[Redacted text]

SF-12v2™ Health Survey © 1992-2002 by Health Assessment Lab, Medical Outcomes Trust and QualityMetric Incorporated. All rights reserved. SF-12® is a registered trademark of Medical Outcomes Trust. (IQOLA SF-12v2 Standard, English (United Kingdom) 8/02)

[Redacted text]

[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]

[Redacted text]

[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]

[Redacted text]

Finally:

Date you filled in this questionnaire

D	D	/	M	M	/	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---	---

Your date of birth

D	D	/	M	M	/	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---	---

THANK YOU

VERY MUCH FOR YOUR TIME AND PATIENCE IN FILLING IN THIS QUESTIONNAIRE

The information you have given us will be extremely useful in helping us carry out research into treatment for men who leak urine after prostate surgery.

It will be treated with the strictest confidence and kept securely.

Please return the questionnaire to the hospital Dept. which is treating your urinary symptoms.

Please could you confirm your phone number:

If you would like any further information or have any queries about the study, please contact

The MASTER Trial Office in Aberdeen (Tel: 01224 438096)

This study is taking place in centres across the UK but the questionnaires are being processed in Aberdeen at the Centre for Healthcare Randomised Trials (CHaRT), Foresterhill, ABERDEEN, AB25 2ZD.

MASTER Study Number:

--	--	--	--	--

CONFIDENTIAL



MASTER STUDY

**Male synthetic sling versus Artificial urinary Sphincter Trial: Evaluation by
Randomised controlled trial**

24 MONTH QUESTIONNAIRE

**We would be very grateful if you could complete and return this questionnaire in the
pre-paid envelope enclosed**

If you would like any further information or have any queries about the study, please contact:

**MASTER Study Office
Tel: 01224 438096
E-mail: master@abdn.ac.uk**

Thank you for taking the time to help us with our research.

HOW TO FILL IN THIS QUESTIONNAIRE

Most questions can be answered by putting numbers or a tick in the appropriate box or boxes. Please print your answers carefully within the boxes like this:

2	7
---	---

OR

M	I	K	E
---	---	---	---

OR

✓

If you make a mistake, shade out the wrong box completely and tick the correct one like this:

e.g. If you ticked often but meant to answer sometimes:

OFTEN
SOMETIMES
NEVER

✓
✓

Please try to complete the whole questionnaire.

There are no right or wrong answers.

Sometimes the box you tick tells you to skip forward so that you miss out questions which do not apply to you.

In some questions we would like you to think about different time periods, such as during the last week or during the last 4 weeks.
Please check the time periods carefully.

Some of the questions ask for answers in your own words, please write these in the boxes provided.

You do not have to answer any question if you do not want to.

Thank you for your help.

SECTION A – URINE SYMPTOMS

When you answer these questions, please think about how you have been in the **LAST 12 MONTHS**.

If you wear protection such as a sheath or have a catheter fitted please answer the following questions as if you not protected by these methods.

A1. How often do you leak urine? (*Tick **ONE** box only*)

- Never ☐
- About once a week or less often ☐
- Two or three times a week ☐
- About once a day ☐
- Several times a day ☐
- All of the time ☐

A2. We would like to know how much urine you think leaks.

How much urine do you usually leak (whether you wear protection or not)? (*Tick **ONE** box only*)

- A small amount ☐
- A moderate amount ☐
- A large amount ☐
- None ☐

A3. Does urine leak when you are physically active, exert yourself, cough or sneeze? (*Tick **ONE** box only*)

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A4. Do you have a sudden need to rush to the toilet to urinate? (*Tick **ONE** box only*)

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A5. Does urine leak before you can get to the toilet? (Tick *ONE* box only)

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A6. How often have you had a slight wetting of your pants a few minutes after you have finished urinating and had dressed yourself? (Tick *ONE* box only)

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A7. Do you ever leak for no obvious reason and without feeling that you want to go? (Tick *ONE* box only)

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A8. Do you leak urine when you are asleep? (Tick *ONE* box only)

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A9. Overall, how much does leaking urine interfere with your everyday life?

*Please choose a number between 0 (not at all) and 10 (a great deal). (Tick *ONE* box only)*

<u>Not at</u> <u>all</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<u>A great</u> <u>deal</u>
	0	1	2	3	4	5	6	7	8	9	10	

A10. How often do you usually pass urine during the daytime?

Enter number of times

A11. How often do you usually have to get up at night to pass urine?

Enter number of times

A12. Is there a delay before you can start to urinate? (Tick **ONE box only)**

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A13. Do you have to strain to continue urinating? (Tick **ONE box only)**

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A14. Would you say that the strength of your urinary stream is: (Tick **ONE box only)**

- Normal ☐
- Occasionally reduced ☐
- Sometimes reduced ☐
- Reduced most of the time ☐
- Reduced all of the time ☐

A15. Do you stop and start more than once while you urinate? (Tick **ONE box only)**

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A16. How often do you feel that your bladder has not emptied properly after you have urinated? (Tick **ONE box only)**

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

SECTION B – TREATMENT FOR URINE SYMPTOMS / CARE YOU HAVE RECEIVED

When you answer these questions, please think about how you have been in the **LAST 12 MONTHS**.

B1. Do you wear a pad or other protection (e.g. pantliners) because of leaking urine? (Tick **ONE box only)**

Yes ☐ Go to **B1a** No ☐ Go to **B2**



B1a. If Yes, how many pads/pantliners do you wear in an average day (24hours)?

Enter **TOTAL** number of pads/pantliners you wear in 24 hours

B1b. Of these pads, how many do you pay for yourself?

If you do not pay for them, please enter zero (0) in the boxes

Enter number of pads **YOU PAY FOR** yourself

B2. Do you use pads or protectors on your chair or bed in case you leak urine?

Yes ☐ Go to **B2a** No ☐ Go to **B3**



B2a. If Yes, how many chair or bed pads do you use in an average day (24 hours)?

Enter **TOTAL** number of chair and bed pads you use in 24 hours

B2b. Of these chair or bed pads, how many do you pay for yourself?

If you do not pay for them, please enter zero (0) in the boxes

Enter number of chair and bed pads **YOU PAY FOR** yourself

B3. Are you using a permanent catheter (inside your bladder) to collect your urine?

Yes ☐ No ☐

B4. Do you ever use an external (sheath) catheter to collect your urine?

Yes ☐ No ☐

B5. Have you seen your family doctor (GP) in the last 12 months?

Yes ☐

Go to **B5a**

No ☐

Go to **B6**



B5a. If Yes, approximately how often have you seen your family doctor (GP) in the last 12 months?

Enter number of times seen GP **for leaking urine**

Enter number of times seen GP **for any other reason related to MASTER surgery or urine symptoms**

B6. Have you seen a nurse (from your doctor's practice) in the last 12 months?

Yes ☐

Go to **B6a**

No ☐

Go to **B7**



B6a. If Yes, approximately how many times have you seen a nurse from your doctor's practice in the last 12 months?

Enter number of times seen nurse **for leaking urine**

Enter number of times seen nurse **for any other reason related to MASTER surgery or urine symptoms**

B7. In the last 12 months, have you seen NHS HOSPITAL staff for leaking urine?

I have seen a hospital doctor **about leaking urine**

If yes, enter number of visits

Yes ☐ → Number of visits

No ☐

I have seen a hospital nurse **about leaking urine**

If yes, enter number of visits

Yes ☐ → Number of visits

No ☐

I have seen a hospital physiotherapist **about leaking urine**

If yes, enter number of visits

Yes ☐ → Number of visits

No ☐

B8. In the last 12 months, have you received any PRIVATE TREATMENT (for which you had to pay yourself) for leaking urine?

I have seen a private doctor **about leaking urine**

If yes, enter number of visits

Yes ☐ → Number of visits

No ☐

I have seen a private nurse **about leaking urine**

If yes, enter number of visits

Yes ☐ → Number of visits

No ☐

I have seen a private physiotherapist **about leaking urine**

If yes, enter number of visits

Yes ☐ → Number of visits

No ☐

B9. In the last 12 months, have you been admitted to hospital because of leaking urine?

Yes ☐

Go to **B9a**

No ☐

Go to **B10**



B9a. If you were admitted in the last 12 months, how many nights did you stay in hospital? If this was a day case, please enter 0

Enter number of nights in hospital

B9b. In the last 12 months, have you had a new operation for leaking urine?

Yes ☐

Go to **B9c**

No ☐

Go to **B10**



B9c. If Yes, please give the name or type of operation and the date:

B10. In the last 12 months, have you taken any medications (from a doctor, or direct from the chemist's) for leaking urine?

Yes ☐

Go to **B10a**

No ☐

Go to **B11**



B10a. If Yes, please give details of medication received in the last 12 months for leaking urine. Please give drug names (e.g. detrusitol, duloxetine):

B11. Have you had any other treatment or advice for leaking urine in the last 12 months (other than the operation you named in B9c or the drugs you listed in B10a)?

Yes ☐

Go to **B11a**

No ☐

Go to **B12**



B11a. If Yes, please give details of other treatment or advice for leaking urine received in the last 12 months:

B12. Please tell us about any costs (direct expenses to you) as a result of your incontinence surgery and any resulting problems in the last 12 months?

	No (✓)	Yes (✓)		If yes, approximately how much did you spend?
Over the counter medications			£	
Private health care			£	
Any other health care expenses you paid for			£	
Please provide information about the type of other health care expenses you pay for.				

B13. Since your incontinence surgery have you experienced any of the following problems that relate to your incontinence surgery (please tick all that apply) and have you received further treatment for the problem?

Problem	No (✓)	Yes (✓)	Treatment received (surgery, drugs or details)
Bowel obstruction			
Constipation			
New bladder/urinary symptoms (give details)			
Urinary tract infection			
Other infection such as sepsis, septicaemia or abscess			
Problems with the device (give details)			
New sexual problem (give details)			
Wound breakdown			
Pain at site of surgery or elsewhere (give details)			

B13a. If you have had further surgery to treat any of these problems what was the date of the surgery?

□□ / □□

Tick here if you are currently on waiting list

☐

B14. Are you in paid employment?

Yes ☐

Go to **B14a**

No ☐

Go to **C1**



B14a. If Yes, approximately how many days off sick have you had for any reason in the last 12 months?

□□□ days

SECTION C - ABOUT SEXUAL MATTERS

C1. Do you get erections? (Tick **ONE** box only)

- | | | | |
|-------------------------------------|--------------------------|----------------------------|--------------------------|
| Yes, with normal rigidity | <input type="checkbox"/> | Yes, with reduced rigidity | <input type="checkbox"/> |
| Yes, with severely reduced rigidity | <input type="checkbox"/> | No, erection not possible | <input type="checkbox"/> |

C2. Do you have an ejaculation of semen? (Tick **ONE** box only)

- | | | | |
|-------------------------------------|--------------------------|-----------------------------|--------------------------|
| Yes, normal quantity | <input type="checkbox"/> | Yes, reduced quantity | <input type="checkbox"/> |
| Yes, significantly reduced quantity | <input type="checkbox"/> | Yes, but no semen comes out | <input type="checkbox"/> |
| No ejaculation | <input type="checkbox"/> | | |

C3. Do you have pain or discomfort during ejaculation? (Tick **ONE** box only)

- | | | | |
|---------------------------------|--------------------------|-------------------------------|--------------------------|
| No | <input type="checkbox"/> | Yes, slight pain / discomfort | <input type="checkbox"/> |
| Yes, moderate pain / discomfort | <input type="checkbox"/> | Yes, severe pain / discomfort | <input type="checkbox"/> |

C4. To what extent do you feel that your sex life has been spoilt by your urinary symptoms? (Tick **ONE** box only)

- | | | | |
|------------|--------------------------|----------|--------------------------|
| Not at all | <input type="checkbox"/> | A little | <input type="checkbox"/> |
| Somewhat | <input type="checkbox"/> | A lot | <input type="checkbox"/> |

C5. Have you used any of these treatments for sexual problems? (Tick **ALL** relevant boxes)

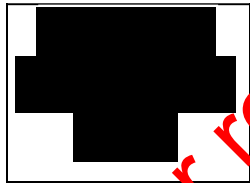
- | | | | |
|---|--------------------------|---------------------------|--------------------------|
| Physiotherapy (e.g. pelvic floor exercises) | <input type="checkbox"/> | Surgery (e.g. an implant) | <input type="checkbox"/> |
| Medication or drugs (e.g. Viagra) | <input type="checkbox"/> | Vacuum device | <input type="checkbox"/> |
| Mechanical device (e.g. a ring) | <input type="checkbox"/> | Other | <input type="checkbox"/> |

If other please give details:

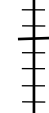
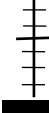
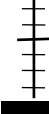
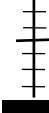
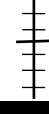
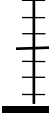
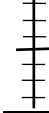
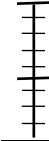
SECTION D – DESCRIBING YOUR OWN HEALTH TODAY (EQ-5D™)

Redacted for reasons of copyright

1990 EuroQol Group EQ-5D™ is a trade mark of the EuroQol Group



Redacted for reasons of copyright



[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

Redacted for reasons of copyright

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Finally:

Date you filled in this questionnaire

D	D	/	M	M	/	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---	---

Your date of birth

D	D	/	M	M	/	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---	---

THANK YOU

VERY MUCH FOR YOUR TIME AND PATIENCE IN FILLING IN THIS QUESTIONNAIRE

The information you have given us will be extremely useful in helping us carry out research into treatment for men who leak urine after prostate surgery.

It will be treated with the strictest confidence and kept securely.

Please send the questionnaire back to us in Aberdeen in the stamped addressed envelope provided.

Please could you confirm your phone number:

If you would like any further information or have any queries about the study, please contact

The MASTER Trial Office in Aberdeen (Tel: 01224 438096)

This study is taking place in centres across the UK but the questionnaires are being processed in Aberdeen at the Centre for Healthcare Randomised Trials (CHaRT), Foresterhill, ABERDEEN, AB25 2ZD.

MASTER Study Number:

--	--	--	--	--

CONFIDENTIAL



MASTER STUDY

**Male synthetic sling versus Artificial urinary Sphincter Trial: Evaluation by
Randomised controlled trial**

12 MONTH QUESTIONNAIRE

**We would be very grateful if you could complete and return this
questionnaire in the pre-paid envelope enclosed**

If you would like any further information or have any queries about the study, please contact:

**MASTER Study Office
Tel: 01224 438096
E-mail: master@abdn.ac.uk**

Thank you for taking the time to help us with our research.

HOW TO FILL IN THIS QUESTIONNAIRE

Most questions can be answered by putting numbers or a tick in the appropriate box or boxes. Please print your answers carefully within the boxes like this:

2	7
---	---

OR

M	I	K	E
---	---	---	---

OR

✓

If you make a mistake, shade out the wrong box completely and tick the correct one like this:

e.g. If you ticked often but meant to answer sometimes:

OFTEN
SOMETIMES
NEVER

✓
✓

Please try to complete the whole questionnaire.

There are no right or wrong answers.

Sometimes the box you tick tells you to skip forward so that you miss out questions which do not apply to you.

In some questions we would like you to think about different time periods, such as during the last week or during the last 4 weeks.
Please check the time periods carefully.

Some of the questions ask for answers in your own words, please write these in the boxes provided.

You do not have to answer any question if you do not want to.

Thank you for your help.

SECTION A – URINE SYMPTOMS

When you answer these questions, please think about how you have been in the **LAST 6 MONTHS**.

If you wear protection such as a sheath or have a catheter fitted please answer the following questions as if you not protected by these methods.

A1. How often do you leak urine? (*Tick **ONE** box only*)

- Never ☐
- About once a week or less often ☐
- Two or three times a week ☐
- About once a day ☐
- Several times a day ☐
- All of the time ☐

A2. We would like to know how much urine you think leaks.

How much urine do you usually leak (whether you wear protection or not)? (*Tick **ONE** box only*)

- A small amount ☐
- A moderate amount ☐
- A large amount ☐
- None ☐

A3. Does urine leak when you are physically active, exert yourself, cough or sneeze? (*Tick **ONE** box only*)

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A4. Do you have a sudden need to rush to the toilet to urinate? (*Tick **ONE** box only*)

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A5. Does urine leak before you can get to the toilet? (Tick **ONE** box only)

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A6. How often have you had a slight wetting of your pants a few minutes after you have finished urinating and had dressed yourself? (Tick **ONE** box only)

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A7. Do you ever leak for no obvious reason and without feeling that you want to go? (Tick **ONE** box only)

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A8. Do you leak urine when you are asleep? (Tick **ONE** box only)

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A9. Overall, how much does leaking urine interfere with your everyday life?

Please choose a number between **0 (not at all)** and **10 (a great deal)**. (Tick **ONE** box only)

- | | | | | | | | | | | | |
|-------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|---------------------|
| <u>Not at all</u> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <u>A great deal</u> |
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

A10. How often do you usually pass urine during the daytime?

Enter number of times

A11. How often do you usually have to get up at night to pass urine?

Enter number of times

A12. Is there a delay before you can start to urinate? (Tick **ONE box only)**

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A13. Do you have to strain to continue urinating? (Tick **ONE box only)**

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A14. Would you say that the strength of your urinary stream is: (Tick **ONE box only)**

- Normal ☐
- Occasionally reduced ☐
- Sometimes reduced ☐
- Reduced most of the time ☐
- Reduced all of the time ☐

A15. Do you stop and start more than once while you urinate? (Tick **ONE box only)**

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A16. How often do you feel that your bladder has not emptied properly after you have urinated? (Tick **ONE box only)**

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

SECTION B – TREATMENT FOR URINE SYMPTOMS / CARE YOU HAVE RECEIVED

When you answer these questions, please think about how you have been in the **LAST 6 MONTHS**.

B1. Do you wear a pad or other protection (e.g. pantliners) because of leaking urine? (Tick **ONE box only)**

Yes ☐ Go to **B1a** No ☐ Go to **B2**



B1a. If Yes, how many pads/pantliners do you wear in an average day (24hours)?

Enter **TOTAL** number of pads/pantliners you wear in 24 hours

B1b. Of these pads, how many do you pay for yourself?

If you do not pay for them, please enter zero (0) in the boxes

Enter number of pads **YOU PAY FOR** yourself

B2. Do you use pads or protectors on your chair or bed in case you leak urine?

Yes ☐ Go to **B2a** No ☐ Go to **B3**



B2a. If Yes, how many chair or bed pads do you use in an average day (24 hours)?

Enter **TOTAL** number of chair and bed pads you use in 24 hours

B2b. Of these chair or bed pads, how many do you pay for yourself?

If you do not pay for them, please enter zero (0) in the boxes

Enter number of chair and bed pads **YOU PAY FOR** yourself

B3. Are you using a permanent catheter (inside your bladder) to collect your urine?

Yes ☐ No ☐

B4. Do you ever use an external (sheath) catheter to collect your urine?

Yes ☐ No ☐

B5. Have you seen your family doctor (GP) in the last 6 months?

Yes ☐ Go to **B5a** No ☐ Go to **B6**



B5a. If Yes, approximately how often have you seen your family doctor (GP) in the last 6 months?

Enter number of times seen GP **for leaking urine**

Enter number of times seen GP **for any other reason related to MASTER surgery or urine symptoms**

B6. Have you seen a nurse (from your doctor's practice) in the last 6 months?

Yes ☐ Go to **B6a** No ☐ Go to **B7**



B6a. If Yes, approximately how many times have you seen a nurse from your doctor's practice in the last 6 months?

Enter number of times seen nurse **for leaking urine**

Enter number of times seen nurse **for any other reason related to MASTER surgery or urine symptoms**

B7. In the last 6 months, have you seen NHS HOSPITAL staff for leaking urine?

I have seen a hospital doctor **about leaking urine**

If yes, enter number of visits

Yes ☐ → Number of visits No ☐

I have seen a hospital nurse **about leaking urine**

If yes, enter number of visits

Yes ☐ → Number of visits No ☐

I have seen a hospital physiotherapist **about leaking urine**

If yes, enter number of visits

Yes ☐ → Number of visits No ☐

B8. In the last 6 months, have you received any PRIVATE TREATMENT (for which you had to pay yourself) for leaking urine?

I have seen a private doctor **about leaking urine**

If yes, enter number of visits

Yes ☐ → Number of visits No ☐

I have seen a private nurse **about leaking urine**

If yes, enter number of visits

Yes ☐ → Number of visits

No ☐

I have seen a private physiotherapist **about leaking urine**

If yes, enter number of visits

Yes ☐ → Number of visits

No ☐

B9. In the last 6 months, have you been admitted to hospital because of leaking urine?

Yes ☐ Go to **B9a**

No ☐ Go to **B10**



B9a. If you were admitted in the last 6 months, how many nights did you stay in hospital? If this was a day case, please enter 0

Enter number of nights in hospital

B9b. In the last 6 months, have you had a new operation for leaking urine?

Yes ☐ Go to **B9c**

No ☐ Go to **B10**



B9c. If Yes, please give the name or type of operation and the date:

B10. In the last 6 months, have you taken any medications (from a doctor, or direct from the chemist's) for leaking urine?

Yes ☐ Go to **B10a**

No ☐ Go to **B11**



B10a. If Yes, please give details of medication received in the last 6 months for leaking urine. Please give drug names (e.g. detrusitol, duloxitene):

B11. Have you had any other treatment or advice for leaking urine in the last 6 months (other than the operation you named in B9c or the drugs you listed in B10a)?

Yes ☐ Go to **B11a** No ☐ Go to **B12**



B11a. If Yes, please give details of other treatment or advice for leaking urine received in the last 6 months:

B12. Please tell us about any costs (direct expenses to you) as a result of your incontinence surgery and any resulting problems in the last 6 months?

	No (✓)	Yes (✓)		If yes, approximately how much did you spend?
Over the counter medications			£	
Private health care			£	
Any other health care expenses you paid for			£	
Please provide information about the type of other health care expenses you pay for.				

B13. Since your incontinence surgery have you experienced any of the following problems that relate to your incontinence surgery (please tick all that apply) and have you received further treatment for the problem?

Problem	No (✓)	Yes (✓)	Treatment received (surgery, drugs or details)
Bowel obstruction			
Constipation			
New bladder/urinary symptoms (give details)			
Urinary tract infection			
Other infection such as sepsis, septicaemia or abscess			
Problems with the device (give details)			
New sexual problem (give details)			
Wound breakdown			
Pain at site of surgery or elsewhere (give details)			

B13a. If you have had further surgery to treat any of these problems what was the date of the surgery?

□□ / □□

Tick here if you are currently on waiting list ☐

B14. Are you in paid employment?

Yes ☐ Go to **B14a** No ☐ Go to **C1**



B14a. If Yes, approximately how many days off sick have you had for any reason in the last 6 months?

□□□ days

SECTION C - ABOUT SEXUAL MATTERS

C1. Do you get erections? (*Tick **ONE** box only*)

- Yes, with normal rigidity ☐
- Yes, with reduced rigidity ☐
- Yes, with severely reduced rigidity ☐
- No, erection not possible ☐

C2. Do you have an ejaculation of semen? (*Tick **ONE** box only*)

- Yes, normal quantity ☐
- Yes, reduced quantity ☐
- Yes, significantly reduced quantity ☐
- Yes, but no semen comes out ☐
- No ejaculation ☐

C3. Do you have pain or discomfort during ejaculation? (*Tick **ONE** box only*)

- No ☐
- Yes, slight pain / discomfort ☐
- Yes, moderate pain / discomfort ☐
- Yes, severe pain / discomfort ☐

C4. To what extent do you feel that your sex life has been spoilt by your urinary symptoms? (*Tick **ONE** box only*)

- Not at all ☐
- A little ☐
- Somewhat ☐
- A lot ☐

C5. Have you used any of these treatments for sexual problems? (Tick *ALL* relevant boxes)

Physiotherapy (e.g. pelvic floor exercises) ☐

Medication or drugs (e.g. Viagra) ☐

Vacuum device ☐

Mechanical device (e.g. a ring) ☐

Surgery (e.g. an implant) ☐

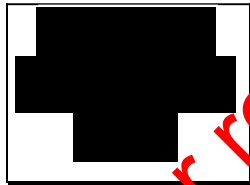
Other ☐

If other please give details:

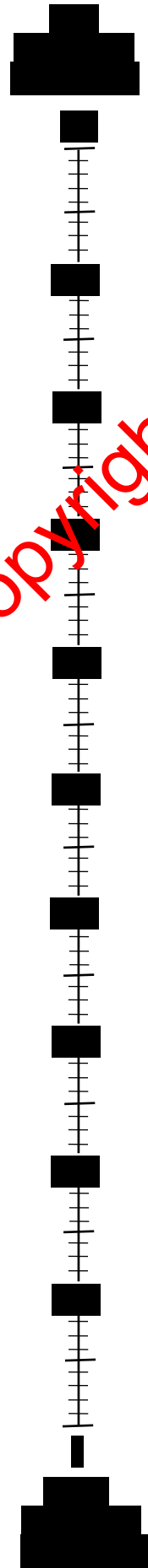
SECTION D – DESCRIBING YOUR OWN HEALTH TODAY (EQ-5D™)

[illegible]

1990 EuroQol Group EQ-5D™ is a trade mark of the EuroQol Group



Redacted for reasons of copyright



SECTION E – GENERAL HEALTH SF12©

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

SF-12v2™ Health Survey © 1992-2002 by Health Assessment Lab, Medical Outcomes Trust and QualityMetric Incorporated. All rights reserved. SF-12® is a registered trademark of Medical Outcomes Trust. (IQOLA SF-12v2 Standard, English (United Kingdom) 8/02)

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

SECTION F - GENERAL INFORMATION

F1. After your surgery for urine leakage a year ago, how long was it before you were able to get back to your normal daily activities?

Enter number of months

F2. Please describe how your urine leakage is now, compared with how it was before you had surgery one year ago:

- Very much better ☐
- Much better ☐
- A little better ☐
- No change ☐
- A little worse ☐
- Much worse ☐
- Very much worse ☐

F3. Overall how satisfied are you with the results of your surgery for urine leakage?

- Completely satisfied ☐
- Fairly satisfied ☐
- Fairly dissatisfied ☐
- Very dissatisfied ☐
- Not sure ☐

F4. Would you recommend this surgery to a friend?

Yes ☐ No ☐

Finally:

Date you filled in this questionnaire

D	D	/	M	M	/	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---	---

Your date of birth

D	D	/	M	M	/	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---	---

THANK YOU

VERY MUCH FOR YOUR TIME AND PATIENCE IN FILLING IN THIS QUESTIONNAIRE

The information you have given us will be extremely useful in helping us carry out research into treatment for men who leak urine after prostate surgery.

It will be treated with the strictest confidence and kept securely.

Please send the questionnaire back to us in Aberdeen in the stamped addressed envelope provided.

Please could you confirm your phone number:

If you would like any further information or have any queries about the study, please contact

The MASTER Trial Office in Aberdeen (Tel: 01224 438096)

This study is taking place in centres across the UK but the questionnaires are being processed in Aberdeen at the Centre for Healthcare Randomised Trials (CHaRT), Foresterhill, ABERDEEN, AB25 2ZD.

MASTER Study Number:

--	--	--	--	--

CONFIDENTIAL



MASTER STUDY

**Male synthetic sling versus Artificial urinary Sphincter Trial: Evaluation by
Randomised controlled trial**

6 MONTH QUESTIONNAIRE

We would be very grateful if you could complete and return this questionnaire in the pre-paid envelope enclosed

If you would like any further information or have any queries about the study, please contact:

**MASTER Study Office
Tel: 01224 438096
E-mail: master@abdn.ac.uk**

Thank you for taking the time to help us with our research.

HOW TO FILL IN THIS QUESTIONNAIRE

Most questions can be answered by putting numbers or a tick in the appropriate box or boxes. Please print your answers carefully within the boxes like this:

2	7
---	---

OR

M	I	K	E
---	---	---	---

OR

✓

If you make a mistake, shade out the wrong box completely and tick the correct one like this:

e.g. If you ticked often but meant to answer sometimes:

OFTEN
SOMETIMES
NEVER

✓
✓

Please try to complete the whole questionnaire.

There are no right or wrong answers.

Sometimes the box you tick tells you to skip forward so that you miss out questions which do not apply to you.

In some questions we would like you to think about different time periods, such as during the last week or during the last 4 weeks.
Please check the time periods carefully.

Some of the questions ask for answers in your own words, please write these in the boxes provided.

You do not have to answer any question if you do not want to.

Thank you for your help.

SECTION A – URINE SYMPTOMS

When you answer these questions, please think about how you have been in the **LAST 4 WEEKS**.

If you wear protection such as a sheath or have a catheter fitted please answer the following questions as if you not protected by these methods.

A1. How often do you leak urine? (*Tick **ONE** box only*)

- Never ☐
- About once a week or less often ☐
- Two or three times a week ☐
- About once a day ☐
- Several times a day ☐
- All of the time ☐

A2. We would like to know how much urine you think leaks.

How much urine do you usually leak (whether you wear protection or not)? (*Tick **ONE** box only*)

- A small amount ☐
- A moderate amount ☐
- A large amount ☐
- None ☐

A3. Does urine leak when you are physically active, exert yourself, cough or sneeze? (*Tick **ONE** box only*)

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A4. Do you have a sudden need to rush to the toilet to urinate? (*Tick **ONE** box only*)

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A5. Does urine leak before you can get to the toilet? (Tick **ONE** box only)

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A6. How often have you had a slight wetting of your pants a few minutes after you have finished urinating and had dressed yourself? (Tick **ONE** box only)

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A7. Do you ever leak for no obvious reason and without feeling that you want to go? (Tick **ONE** box only)

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A8. Do you leak urine when you are asleep? (Tick **ONE** box only)

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A9. Overall, how much does leaking urine interfere with your everyday life?

Please choose a number between **0 (not at all)** and **10 (a great deal)**. (Tick **ONE** box only)

- | | | | | | | | | | | | | |
|-----------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|-------------------------------|
| <u>Not at</u>
<u>all</u> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <u>A great</u>
<u>deal</u> |
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | |

A10. How often do you usually pass urine during the daytime?

Enter number of times

A11. How often do you usually have to get up at night to pass urine?

Enter number of times

A12. Is there a delay before you can start to urinate? (Tick **ONE box only)**

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A13. Do you have to strain to continue urinating? (Tick **ONE box only)**

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A14. Would you say that the strength of your urinary stream is: (Tick **ONE box only)**

- Normal ☐
- Occasionally reduced ☐
- Sometimes reduced ☐
- Reduced most of the time ☐
- Reduced all of the time ☐

A15. Do you stop and start more than once while you urinate? (Tick **ONE box only)**

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A16. How often do you feel that your bladder has not emptied properly after you have urinated? (Tick **ONE box only)**

- Never ☐
- Occasionally ☐
- Sometimes ☐
- Most of the time ☐
- All of the time ☐

A17. Thinking about your incontinence surgery 6 months ago, how much pain did you suffer in the FIRST 2 WEEKS? (Tick **ONE box only)**

- None ☐
- A little ☐
- A lot ☐
- Severe Pain ☐

SECTION B – TREATMENT FOR URINE SYMPTOMS / CARE YOU HAVE RECEIVED

When you answer these questions, please think about how you have been in the **LAST 4 WEEKS**.

B1. Do you wear a pad or other protection (e.g. pantliners) because of leaking urine? (Tick **ONE box only)**

Yes ☐ Go to **B1a** No ☐ Go to **B2**



B1a. If Yes, how many pads/pantliners do you wear in an average day (24hours)?

Enter **TOTAL** number of pads/pantliners you wear in 24 hours

B1b. Of these pads, how many do you pay for yourself?

If you do not pay for them, please enter zero (0) in the boxes

Enter number of pads **YOU PAY FOR** yourself

B2. Do you use pads or protectors on your chair or bed in case you leak urine?

Yes ☐ Go to **B2a** No ☐ Go to **B3**



B2a. If Yes, how many chair or bed pads do you use in an average day (24 hours)?

Enter **TOTAL** number of chair and bed pads you use in 24 hours

B2b. Of these chair or bed pads, how many do you pay for yourself?

If you do not pay for them, please enter zero (0) in the boxes

Enter number of chair and bed pads **YOU PAY FOR** yourself

B3. Are you using a permanent catheter (inside your bladder) to collect your urine?

Yes ☐

No ☐

B4. Do you ever use an external (sheath) catheter to collect your urine?

Yes ☐

No ☐

When you answer these questions, please think about the care you received **SINCE YOUR INCONTINENCE SURGERY 6 MONTHS AGO.**

B5. Have you seen your family doctor (GP) since your incontinence surgery?

Yes ☐

Go to **B5a**

No ☐

Go to **B6**



B5a. If Yes, approximately how often have you seen your family doctor (GP) since your incontinence surgery?

Enter number of times seen GP for leaking urine

Enter number of times seen GP for any other reason related to MASTER surgery or urine symptoms

B6. Have you seen a nurse (from your doctor's practice) since your incontinence surgery?

Yes ☐

Go to **B6a**

No ☐

Go to **B7**



B6a. If Yes, approximately how many times have you seen a nurse from your doctor's practice since your incontinence surgery?

Enter number of times seen nurse for leaking urine

Enter number of times seen nurse for any other reason related to MASTER surgery or urine symptoms

B7. Since your incontinence surgery, have you seen NHS HOSPITAL staff for leaking urine?

I have seen a hospital doctor **about leaking urine**

If yes, enter number of visits

Yes ☐ → Number of visits

No ☐

I have seen a hospital nurse **about leaking urine**

If yes, enter number of visits

Yes ☐ → Number of visits

No ☐

I have seen a hospital physiotherapist **about leaking urine**

If yes, enter number of visits

Yes ☐ → Number of visits

No ☐

B8. Since your incontinence surgery, have you received any PRIVATE TREATMENT (for which you had to pay yourself) for leaking urine?

I have seen a private doctor **about leaking urine**

If yes, enter number of visits

Yes ☐ → Number of visits

No ☐

I have seen a private nurse **about leaking urine**

If yes, enter number of visits

Yes ☐ → Number of visits

No ☐

I have seen a private physiotherapist **about leaking urine**

If yes, enter number of visits

Yes ☐ → Number of visits

No ☐

B9. Since your incontinence surgery, have you been admitted to hospital because of leaking urine?

Yes ☐ Go to **B9a**

No ☐

Go to **B10**



B9a. If you were admitted since your incontinence surgery, how many nights did you stay in hospital? If this was a day case, please enter 0

Enter number of nights in hospital

B9b. Since your incontinence surgery, have you had a new operation for leaking urine?

Yes ☐ Go to **B9c**

No ☐

Go to **B10**



B9c. If Yes, please give the name or type of operation and the date:

B10. Since your incontinence surgery, have you taken any medications (from a doctor, or direct from the chemist's) for leaking urine?

Yes ☐ Go to **B10a** No ☐ Go to **B11**



B10a. If Yes, please give details of medication for bladder/ urinary problems received since your incontinence surgery, for leaking urine. Please give drug names (e.g. detrusitol, duloxetine):

B11. Have you had any other treatment or advice for leaking urine since your incontinence surgery, (other than the operation you named in B9c or the drugs you listed in B10a)?

Yes ☐ Go to **B11a** No ☐ Go to **B12**



B11a. If Yes, please give details of other treatment or advice for leaking urine received since your incontinence surgery:

B12. Please tell us about any costs (direct expenses to you) as a result of your incontinence surgery and any resulting problems in the last 6 months?

	No (✓)	Yes (✓)		If yes, approximately how much did you spend?
Over the counter medications			£	
Private health care			£	
Any other health care expenses you paid for			£	
Please provide information about the type of other health care expenses you pay for.				

B13. Since your incontinence surgery have you experienced any of the following problems that relate to your incontinence surgery (please tick all that apply) and have you received further treatment for the problem?

Problem	No (✓)	Yes (✓)	Treatment received (surgery, drugs or details)
Bowel obstruction			
Constipation			
New bladder/urinary symptoms (give details)			
Urinary tract infection			
Other infection such as sepsis, septicaemia or abscess			
Problems with the device (give details)			
New sexual problem (give details)			
Wound breakdown			
Pain at site of surgery or elsewhere (give details)			

B13a. If you have had further surgery to treat any of these problems what was the date of the surgery?

□□ / □□

Tick here if you are currently on waiting list ☐

B14. Are you in paid employment?

Yes ☐

Go to **B14a**

No ☐

Go to **C1**



B14a. If Yes, approximately how many days off sick have you had for any reason since your incontinence surgery?

□□□ days

SECTION C - ABOUT SEXUAL MATTERS

C1. Do you get erections? (Tick **ONE** box only)

- | | | | |
|-------------------------------------|--------------------------|----------------------------|--------------------------|
| Yes, with normal rigidity | <input type="checkbox"/> | Yes, with reduced rigidity | <input type="checkbox"/> |
| Yes, with severely reduced rigidity | <input type="checkbox"/> | No, erection not possible | <input type="checkbox"/> |

C2. Do you have an ejaculation of semen? (Tick **ONE** box only)

- | | | | |
|-------------------------------------|--------------------------|-----------------------------|--------------------------|
| Yes, normal quantity | <input type="checkbox"/> | Yes, reduced quantity | <input type="checkbox"/> |
| Yes, significantly reduced quantity | <input type="checkbox"/> | Yes, but no semen comes out | <input type="checkbox"/> |
| No ejaculation | <input type="checkbox"/> | | |

C3. Do you have pain or discomfort during ejaculation? (Tick **ONE** box only)

- | | | | |
|---------------------------------|--------------------------|-------------------------------|--------------------------|
| No | <input type="checkbox"/> | Yes, slight pain / discomfort | <input type="checkbox"/> |
| Yes, moderate pain / discomfort | <input type="checkbox"/> | Yes, severe pain / discomfort | <input type="checkbox"/> |

C4. To what extent do you feel that your sex life has been spoilt by your urinary symptoms? (Tick **ONE** box only)

- | | | | |
|------------|--------------------------|----------|--------------------------|
| Not at all | <input type="checkbox"/> | A little | <input type="checkbox"/> |
| Somewhat | <input type="checkbox"/> | A lot | <input type="checkbox"/> |

C5. Have you used any of these treatments for sexual problems? (Tick **ALL** relevant boxes)

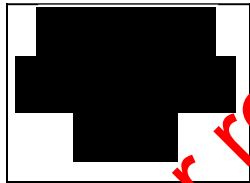
- | | | | |
|---|--------------------------|---------------------------|--------------------------|
| Physiotherapy (e.g. pelvic floor exercises) | <input type="checkbox"/> | Vacuum device | <input type="checkbox"/> |
| Medication or drugs (e.g. Viagra) | <input type="checkbox"/> | Surgery (e.g. an implant) | <input type="checkbox"/> |
| Mechanical device (e.g. a ring) | <input type="checkbox"/> | Other | <input type="checkbox"/> |

If other please give details:

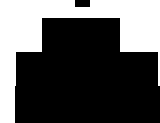
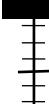
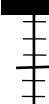
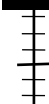
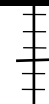
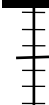
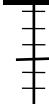
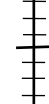
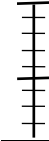
SECTION D – DESCRIBING YOUR OWN HEALTH TODAY (EQ-5D™)

Redacted for reasons of copyright

1990 EuroQol Group EQ-5D™ is a trade mark of the EuroQol Group



Redacted for reasons of copyright



SECTION E – GENERAL HEALTH SF12©

[Redacted text]

[Redacted text]

[Redacted text]

[Redacted text]

[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]

[Redacted text]

[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]

[Redacted text]

[Redacted text]

SF-12v2™ Health Survey © 1992-2002 by Health Assessment Lab, Medical Outcomes Trust and QualityMetric Incorporated. All rights reserved. SF-12® is a registered trademark of Medical Outcomes Trust. (IQOLA SF-12v2 Standard, English (United Kingdom) 8/02)

[Redacted text]

[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]

[Redacted text]

[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]

[Redacted text]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

Finally:

Date you filled in this questionnaire

D	D	/	M	M	/	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---	---

Your date of birth

D	D	/	M	M	/	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---	---

THANK YOU

VERY MUCH FOR YOUR TIME AND PATIENCE IN FILLING IN THIS QUESTIONNAIRE

The information you have given us will be extremely useful in helping us carry out research into treatment for men who leak urine after prostate surgery.

It will be treated with the strictest confidence and kept securely.

Please send the questionnaire back to us in Aberdeen in the stamped addressed envelope provided.

Please could you confirm your phone number:

If you would like any further information or have any queries about the study, please contact

The MASTER Trial Office in Aberdeen (Tel: 01224 438096)

This study is taking place in centres across the UK but the questionnaires are being processed in Aberdeen at the Centre for Healthcare Randomised Trials (CHaRT), Foresterhill, ABERDEEN, AB25 2ZD.

SURGICAL INFORMATION SHEET



Male synthetic sling versus Artificial urinary Sphincter Trial for men with urodynamic stress incontinence after prostate surgery: Evaluation by Randomised controlled trial

Surgical Information Sheet for men having surgery for urine leakage after prostate surgery

1. Proposed operations:

The aim of the MASTER trial is to compare the Artificial Urinary Sphincter (AUS) with the Male Sling in men having surgery for urine leakage after prostate surgery. Put simply, we want to compare a more complex operation with good results, with a less complex operation that has slightly less successful results.

2. Why am I having this operation?

You and your urologist have agreed that you need an operation to cure or improve your urine leakage.

3. What do the operations involve?

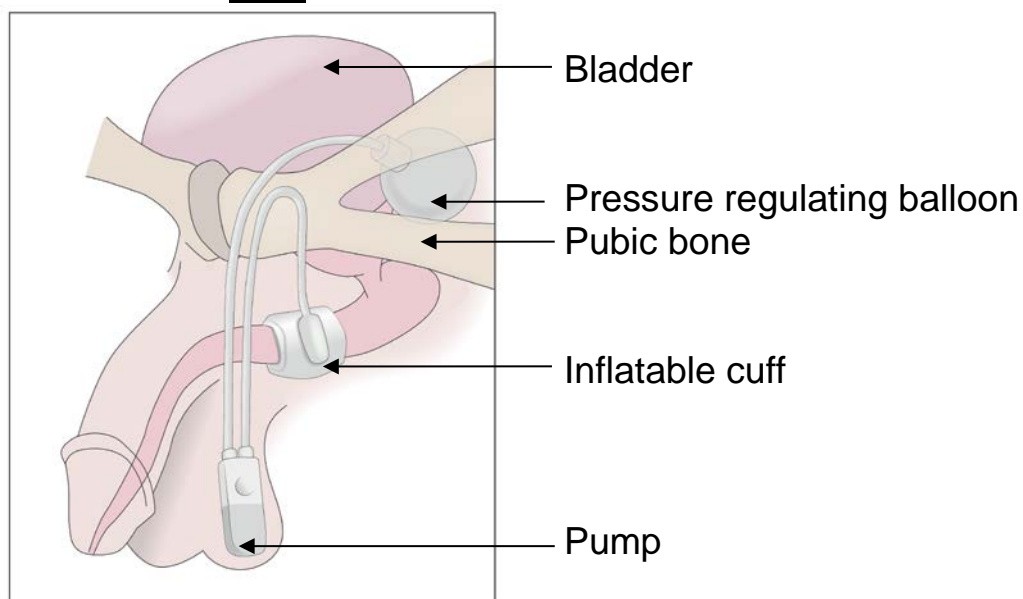
Both operations involve a surgical procedure to implant a plastic (prosthetic) device designed to stop or reduce your urine leakage. Your operation will be done by a specialist urological surgeon who is expert at doing these operations. We have used the AUS for almost 40 years, during which time the device has been updated to make use of new materials and to improve both its effectiveness and its safety. The male sling has been used for the last 3 to 5 years, and we want to see how it compares with the AUS. We now describe the established method of the AUS and the newer sling.

SURGICAL INFORMATION SHEET

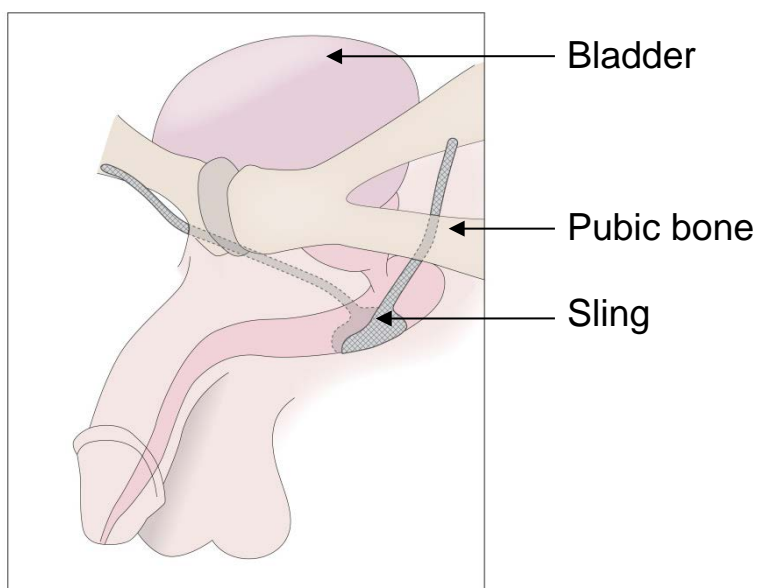
With both operations you will need to stay in hospital for one or two days. You will also have a catheter draining your bladder at first. Once you can pass urine yourself, you should be able to go home.

Here are illustrations of how both devices will look when they are fitted. We will also show you samples of both devices and show you how they work.

AUS



Male sling



SURGICAL INFORMATION SHEET

ARTIFICIAL SPHINCTER

The AUS has three parts connected to each other. There is a circular **inflatable cuff** placed around the waterpipe (urethra), a **pressure regulating balloon** to keep the cuff inflated, and a small **pump**, placed in the scrotum, that you squeeze when you want to void, which means to empty your bladder. The aim is to close the urethra so that you are dry except when you are ready to void.

The balloon and the pump are put in through incisions in your groin and scrotum. The balloon is placed in the space under the muscles of your abdominal (tummy) wall and the pump is placed in the scrotum where you will easily be able to feel it, but not see it. The cuff is placed around the urethra through a cut in the skin behind the scrotal sac but in front of the back passage.

After surgery, the cuff is left deflated, meaning that it does not work at once. This is to allow any swelling from the operation to settle down. Three to six weeks after surgery you will come back so we can set the AUS working. This is easily done in the outpatient department by squeezing the pump.

Before you go home we will check that you are happy working your AUS. This requires three squeezes of the control pump in the scrotum to deflate the cuff and allow you to void. The cuff then automatically refills over 2-3 minutes from the balloon reservoir to stop you leaking again.

If the AUS is not successful enough, you will still be able to use pads or catheters, or pelvic floor exercises. It is also possible to adjust the cuff. If it fails some years later, it is possible to replace it with a new AUS, or, more rarely, to use a male sling.

MALE SLING

The male sling supports the urethra and puts it in a more natural position to allow the sphincter muscles to function more normally to control urine leakage.

The male sling is a strip of permanent plastic mesh that is placed under the urethra through a small cut in the skin behind the scrotal sac but in front of the back passage. The two ends of the sling are passed under the urethra and out through the pelvic area into the upper thigh on each side. It is then tightened just enough to lift and partially compress the waterpipe. The sling can work right away although it may take a few weeks to reach its best. The sling has a passive mode of action,

SURGICAL INFORMATION SHEET

meaning that you will be able to pass urine normally when you are ready to void.

If the sling is not successful enough, you will still be able to use pads or catheters, or pelvic floor exercises. If that is not enough it is possible to fit an AUS later (see information above about AUS).

Both types of surgery are classed as major operations and you should be just as careful as after an operation through your abdomen. For example, you should not do any heavy lifting or strenuous exercise for three months.

4. What type of anaesthetic will I have?

A general anaesthetic (being asleep) or a spinal or epidural anaesthetic (to numb the lower half of your body) can be used. Your anaesthetist will discuss these with you, and which one you would prefer, provided this is appropriate for your operation.

5. What extra procedures may become necessary during the operation?

All surgery may have complications such as bleeding, damage to other organs, or infection. You should be reassured, however, that most men do not suffer any serious problems during or after this type of surgery.

6. What adverse effects or problems may occur after the operation?

Sometimes problems occur but are **not usually serious** and are expected, and can normally be easily treated. These include:

- Urinary retention (being unable to pass urine after the catheter is removed)
- Bleeding
- Infections in the wound
- Infections in the urine or urinary passages
- Passing urine more frequently or urgently than normal, or stinging when you pass urine
- Later pain or infection at the operation site.

Some more serious problems can occur more rarely after surgery, are treated as and when they arise, and include:

- Damage to blood vessels or excessive bleeding requiring return to theatre or blood transfusion
- Bleeding leading to an internal collection of blood (haematoma)
- Damage to bladder or urinary passages

SURGICAL INFORMATION SHEET

- Damage to bowel
- Blood clots in the legs or lungs (venous thrombosis and embolism)
- Serious infections or pelvic abscess
- Serious device problems such as infection or exposure through the skin or into the urethra.

7. What may I expect in the long term?

Your surgery is designed to cure or very much improve your urine leakage. However, your urine leakage may come back at a lesser level that does not need another operation.

You may, however, have problems that trouble you, such as:

- Leakage of urine getting worse over time
- Having to pass urine frequently or urgently, or having to get up often at night
- Pain, which may be felt, for example, where the incisions have been made to put in the device.
- The need to remove the device and replace it if possible with another one

Your urologist or GP will help you treat any symptoms that trouble you.

8. What other treatments are available for urine leakage?

You may practise pelvic floor muscle exercises, use absorbent pads, have drug treatment or a catheter or a sheath. These treatments may also be used after incontinence surgery by men who still have symptoms.



**Male synthetic sling versus Artificial urinary Sphincter Trial for men with
urodynamic stress incontinence after prostate surgery:
Evaluation by Randomised controlled trial**

MASTER TRIAL

PATIENT INFORMATION LEAFLET

The purpose of the MASTER research study is to compare two different types of surgery for men with urine leakage (urinary incontinence) after prostate surgery, in order to identify the most effective operation. This will be done by dividing men who suffer from urinary incontinence between two different types of surgery that are used to treat this problem. The improvement in urinary incontinence will be used to compare the success of the surgeries. The results from this study will show which operation is the most effective operation in treating urinary incontinence and will help men who suffer from the problem in the future.

Please take time to read this information leaflet and discuss it with your family, friends or GP if you wish.

Do not hesitate to contact us if there is anything you do not understand or if you would like more information.

master@abdn.ac.uk

or

01224 438096

1. Description of Study

There are two main types of operation used to treat urine leakage (incontinence) resulting from prostate surgery. There is not enough evidence from previous research to let us know which operation should be used. This study is comparing these two operations, which use different devices. The Surgical Information Sheet, which you have also received, gives the details of the differences between the two operations, the male sling and the artificial urinary sphincter (AUS). The AUS has been used for 40 years, but the male sling is newer. Because of this, NICE, the National Institute for Health and Clinical Excellence, does not recommend the male sling unless it is in a research study. This is why we are doing this research and the male sling will not normally be available outside this study.

2. Why have I been invited to take part?

You are being invited to take part in the MASTER study because you will be having an operation for your urine leakage. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully.

3. Background

One in fifty men will need an operation for urine leakage after prostate surgery. Both types of surgery that you might undergo in this study are in use in the NHS. You will find more information about these in the Surgical Information Sheet, and your urologist will also discuss these with you. We would like to be able to compare the results of these two different operations, particularly in the long term. Your participation in the study will help us do so.

You will not have to undergo any tests or procedures that are not part of routine care for this type of surgery.

There may be no direct benefit to you if you do take part, but you will be helping with research to enable doctors to assess which operation is best and most effective for future patients.

4. What is the purpose of the study?

The aim of the study is to find out which of the operations gives the best results and is most effective. Therefore, when the study is finished, doctors in the future will be able to choose the surgery that has the best results with the fewest problems. This may include better health and quality of life for men, less need for further operations and better use of NHS facilities.

5. Do I have to take part?

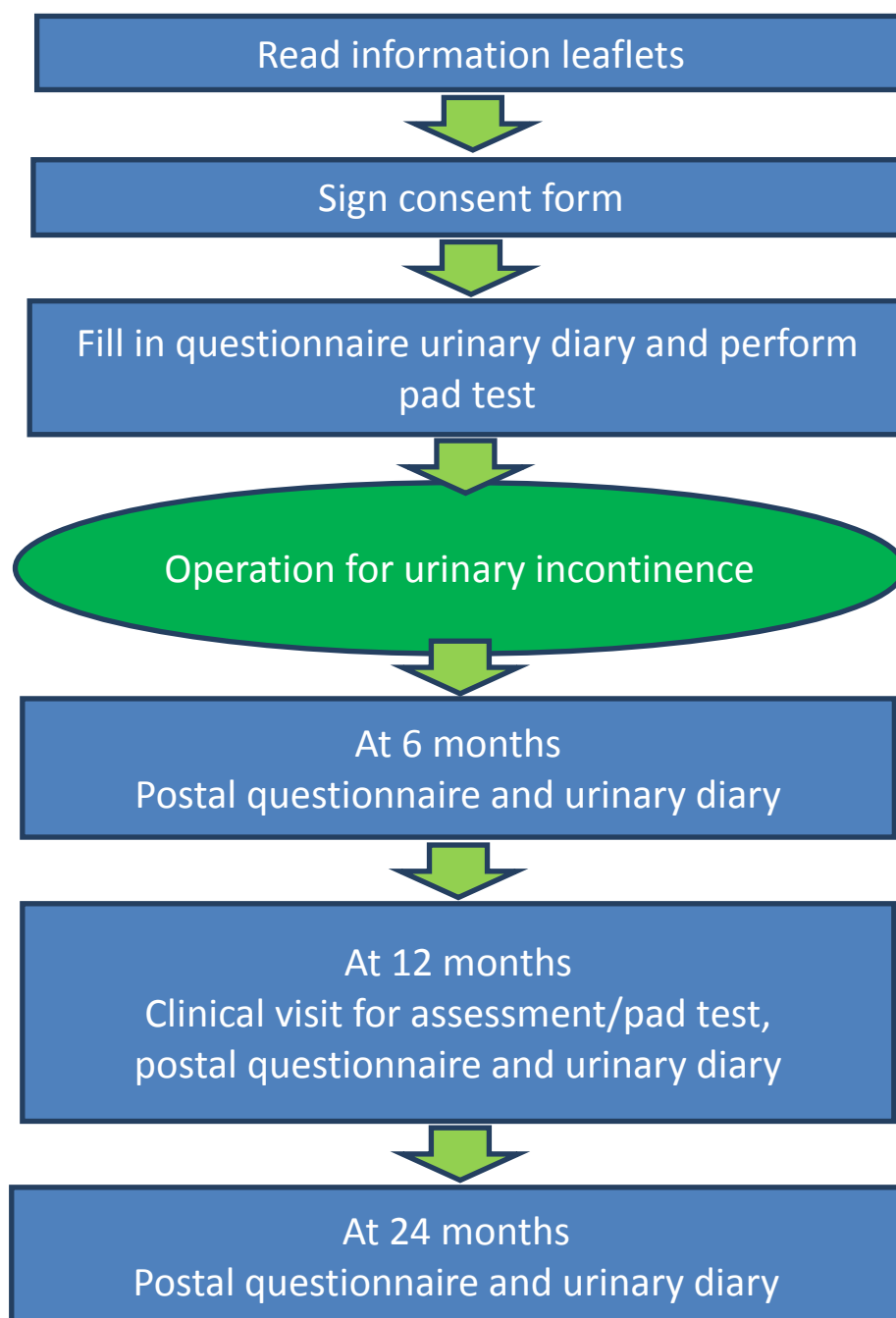
No, it is up to you whether you decide to take part. If you do take part you would be free to withdraw at any time without giving any reason. This will not affect your current or future medical treatment. Before you decide, your urologist or the MASTER research nurses will provide you with more information and will be happy to discuss any questions you may have. If you agree to take part, you will be asked to sign a consent form for this research study. Your urologist will make you aware of all

relevant issues surrounding the surgery itself, and you will sign a separate NHS information and consent form for your operation.

6. What will happen if I take part?

As described in the Surgical Information Sheet, there are two different types of operation that you could have. If your urologist thinks that either of the operations would be equally suitable for you, with your agreement you will be put into one group by chance (randomly). All of the men in that group will be given the same operation. You will not be told which operation you are going to have before surgery. After the operation we will tell you whether you have had the Male Sling or the AUS.

The following diagram shows you what you will be asked to do:



Each questionnaire will take about 10-20 minutes of your time to complete. Your answers will help us measure how things have changed after the operation.

Although we would like you to complete the questionnaires fully, you are not obliged to answer every question if you don't want to.

You will also be asked to perform a urinary pad test which measures the amount of urine you lose in 24 hours. This will be done by wearing absorbent pads for 24 hours, and then these wet pads are taken with you when you attend the hospital to be weighed. We will also ask you to fill in a 3 day urinary diary. Together this gives the study team measurements of your urine leakage.

7. Further Research

A further part of the MASTER study will involve members of the study team approaching some of the men being studied to invite them to take part in additional research to talk about their expectations and point of view on urine leakage after prostate surgery. This will involve having a short interview which will either be in person or over the telephone. We may contact you in the future about this part of the study and will provide you with a participant information sheet and an additional consent form. It is up to you if you would like to take part in this additional part of the study and this will not affect any other part of the study.

With your permission, we would like to contact you again after the two year follow up to a) check on your long term health, for example by sending you other questionnaires to add information to what we already know about you, or by checking your medical NHS records; and b) to ask you to take part in other relevant studies. However, you will not have to reply to any questionnaires or take part in other studies unless you want to at that time.

8. *Will the information I provide be kept confidential?*

Yes, all information collected for the study at any time will be stored using a Study Identity Number for confidentiality and will be kept secure using passwords. This includes the questionnaires that may be sent to you in the longer term as mentioned above. The information will only be available to the research team and the NHS or University bodies responsible for maintaining research standards. Your own doctor (GP) will be informed of your participation in the study.

In order to increase the usefulness of the whole study, we plan to confidentially link your answers with electronic data from your medical NHS records related to your health after your surgery. We will ask you for specific consent to this, again this information will be kept secure and confidential.

Other researchers may wish to access data from this study in the future: this will not include names, addresses or dates of birth, and it will not be possible to identify participants in any way. If other researchers request to access the data, the consultant leading the study will ensure that the other researchers comply with legal, data protection and ethical guidelines.

9. *How will the information I provide be used?*

We hope that around 700 men will take part in this study during the next three years in centres across the UK. Urologists will be informed of the recommendations from the study, so that in future all men can receive the best and most effective operations. The results of the study will be published in scientific journals and a short

version will also be available to those men who took part in the study if they wish. Men will not be identifiable in any of the study reports.

10. *What will happen if I don't want to carry on with the study?*

You can withdraw from the study at any time, but you will continue to receive your standard NHS care after surgery, such as attending appointments with your consultant.

11. *What if there is a problem?*

Both of the operations are already being used in the NHS for incontinence surgery. Your participation in the study is therefore only to help us compare these procedures with each other and should not involve any additional risk to you.

Taking part in this study does not affect your normal legal rights. Whether or not you do take part, you will retain the same legal rights as any other patient in the NHS (which includes professional indemnity insurance for negligence). If you wish to complain about your health care or any aspects of this study, the normal NHS mechanisms will be available to you. Although we do not expect participation to affect private medical insurance, please check with your insurers before agreeing to take part in the study.

If you have a concern about any aspect of the study, you should ask to speak with the research team who will do their best to answer your questions (phone 01224 438096). If you remain unhappy and wish to complain formally, you can do this through the National Health Service complaints procedure. Details can be obtained from the Patient Advice and Liaison Service (PALS <http://www.pals.nhs.uk/>) at your local hospital.

If you became unable or unwilling to continue in MASTER, we would withdraw you from the study. We would retain, confidentially and with your consent, the relevant information that we had already collected about you, for the purposes of the study only.

12. *Who is doing this study?*

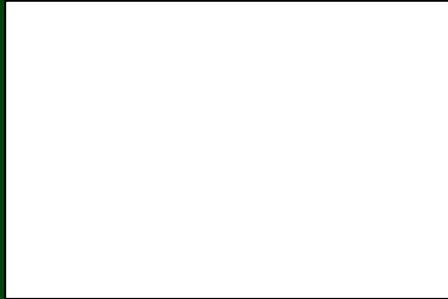
This study is being funded by the NHS National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre, Health Technology Assessment programme (NETSCC HTA). The research is being carried out by a group of experienced doctors and researchers from the Bristol Urological Institute and the Health Services Research Unit at the University of Aberdeen, in collaboration with the British Association of Urological Surgeons.

13. *Who has approved this study?*

Your local hospital, your urology consultant and Frenchay Research Ethics Committee in Bristol have given approval for this study to be carried out. An independent Trial Steering Committee and a Data Monitoring Committee monitor safety and ensure that the study is conducted in accordance with good research practice.

14. *How do I get in touch with the research team if I want any further information about the study?*

If you have any questions about the study, or any aspect of your treatment or health, please speak to your MASTER research nurse or your own urology consultant or GP. Alternatively you can contact the MASTER Study Office (details over).



You can contact the study team who are organising the research:

Trial Manager
MASTER STUDY OFFICE
Centre for Healthcare Randomised Trials (CHaRT)
Health Services Research Unit
University of Aberdeen
Health Sciences Building
Foresterhill Aberdeen AB25 2ZD
Tel. 01224 438096

or the Chief Investigator
Prof Paul Abrams
Bristol Urological Institute
Southmead Hospital, Bristol
BS10 5NB

Or you can email us at:

master@abdn.ac.uk

Thank you for reading this leaflet & considering taking part in MASTER.

Funded by the National Institute for Health Research Health Technology
Assessment (NIHR HTA) Programme 11/106/01



STUDY CONSENT FORM

MASTER: Male synthetic sling or Artificial
Urinary Sphincter Trial Evaluation by
Randomised controlled trial

MASTER Study No:

--	--	--	--	--

Please initial
ALL boxes



By signing this form and initialling each box I agree that I have:

- been given the Patient Information Leaflet about the study (Version ,D D / M M / Y Y)
- had the opportunity to discuss the study
- received satisfactory answers to questions
- been given enough information about the study.....

☐

I understand that:

- my participation is voluntary and taking part in the study may not benefit my own health
- I am free to withdraw from the study at any time without having to give a reason
- If I withdraw, this will not affect my medical care or legal rights
- I may be contacted in the future for long term follow-up.....

☐

I agree that relevant sections of my medical notes and data collected during the study may be looked at by individuals directly involved in the study, from the University of Aberdeen, from regulatory authorities or from the NHS Boards or Trusts, where it is relevant to my taking part in this research. I give permission for these individuals to have access to them

☐

I agree that information relevant to the MASTER study may be collected from my hospital and NHS records, including Office of National Statistics (ONS) and NHS central registers

☐

I agree that relevant data and my contact details will be held confidentially and securely by the study office in Aberdeen.....

☐

I am willing to be contacted by post, telephone or other means about matters connected with MASTER by research and NHS staff.....

☐

I agree that my family doctor (GP) may be told that I am taking part in this study.....

☐

I am willing to be asked in the future if I would be willing to take part in other relevant research

☐

I confirm that I have discussed the types of surgery suitable for me with my urologist,
and I agree to take part in the study

☐

I agree to be randomised.....

☐

Your signature (participant) _____

Your name in block capitals _____

Date: _____

To be completed by the local team member taking consent

I confirm that I have explained to the person named above, the nature and purpose of the MASTER study and the procedures involved

Signature: _____

Name in block capitals: _____

Date: _____

MASTER Study Office, Health Services Research Unit, University of Aberdeen, Scotland AB25 2ZD
Tel: 01224 438096; Fax: 01224 438165; Email: master@abdn.ac.uk

Copies: Copy sent to researchers in Aberdeen; copy to participant; copy to be filed with hospital notes; copy for research site file.

MASTER INFORMATION SHEET

Title of project

Male synthetic sling versus Artificial urinary Sphincter Trial for men with urodynamic stress incontinence after prostate surgery: Evaluation by Randomised controlled trial (MASTER)

Background

Around one in five men who undergo prostate surgery for cancer or benign disease need to use incontinence pads because of leakage of urine when they walk around, cough, or do any physical exertion. This ruins their quality of life, greatly lowers their self-esteem, stops them working, and damages their personal relationships.

At present the traditional surgical treatment is insertion of a plastic artificial urinary sphincter (AUS) device, which involves a major operation to place an inflatable cuff around the urine pipe close to the bladder, and inflating it to prevent leakage. The man then has to deflate the cuff by squeezing a pump (usually 2-3 times) placed in his scrotum, to allow him to pass urine when needed. Recently, a new male sling has been developed which, when inserted under the urine pipe, supports the outlet of the bladder but doesn't need a pump. It is less expensive for the NHS and easier to insert surgically, but some men may still need a subsequent operation to place an AUS if they feel their incontinence has not improved enough. It is also uncertain whether there are other advantages or disadvantages compared to the AUS, and whether men will be as satisfied with the results.

It is important for the NHS to decide whether the male sling or AUS is better because the number of men needing this type of surgery is likely to increase. This is because more men are requiring surgery for early prostate cancer with wider use of the PSA blood test. If our trial shows that the male sling is as good as the AUS and is preferred by men having this surgery, as well as being cheaper, it will help men, their doctors and the NHS planners to decide which treatments should be available.

Brief outline of the study

We will ask men who are considering having surgery for urine leakage to consent to treatment with either the male sling or AUS. The type of surgery will be decided at random by computer.

The success of surgery will be judged by the men's report of urine leakage, using postal questionnaires at 6, 12 and 24 months after operation. Other outcomes will include their satisfaction with treatment, sexual function, 24-hour pad tests, quality of life, adverse effects, costs, and use of health services. The men will also be followed up in the longer term to monitor clinical outcomes.

The Researchers

The research team includes surgeons who are experts in caring for men with incontinence and in clinical research, together with experts in the design, successful conduct, analysis and reporting of clinical trials in the NHS. We also have the benefit of a patient advisor to make sure that the trial addresses matters of most concern to men with incontinence.

The trial is being co-ordinated by the Centre for Healthcare Randomised Trials (CHaRT, a fully registered UK CRN clinical trials unit), at the Health Services Research Unit, University of Aberdeen. Urologists in your local hospital have agreed to allow their patients who are having incontinence surgery to be invited to enter the study. All urologists involved in this study will be experienced in the types of surgery to which their patients may be randomised.

References

1. Silva LA, Andriolo RB, Atallah ÁN, da Silva EMK. Surgery for stress urinary incontinence due to presumed sphincter deficiency after prostate surgery. Cochrane Database of Systematic Reviews 2011, Issue 4. Art. No.: CD008306. DOI: 10.1002/14651858.CD008306.pub2.

MASTER Study Office
Centre for Healthcare Randomised Trials (CHaRT)
3rd Floor, Health Sciences Building
University of Aberdeen
Foresterhill
Aberdeen
AB25 2ZD
Master@abdn.ac.uk

<< Date >>

<<Participant Title & Name>>
<<Address 1>>
<<Address 2>>
<<Address 3>>
<<Address 4>>
<<Postcode>>

Dear <<Participant Title & Name>>

**The MASTER Trial: Male synthetic sling versus Artificial urinary Sphincter Trial:
Evaluation by Randomised controlled trial.**

You were recently asked if you like to take part in a trial of two types of treatment that are available for urine leakage after prostate surgery. Whether or not you wanted to take part in the trial, we would be interested in hearing about your experience and how you made your choice.

This letter is an invitation to take part in an interview study looking at men receiving treatment for urinary leakage. The interview is entirely optional and will not affect your treatment. However, your participation could help to provide better care for men suffering from the same symptoms.

If you would be interesting in taking part, or would just like more information, you can either contact me directly or return the attached slip and consent form using a self-addressed envelope provided.

Yours sincerely,

Alan Uren
MASTER Trial Researcher

Bristol Urological Institute
Southmead Hospital
Westbury-on-Trym
Bristol
BS10 5NB

0117 3234543
alan.uren@bui.ac.uk