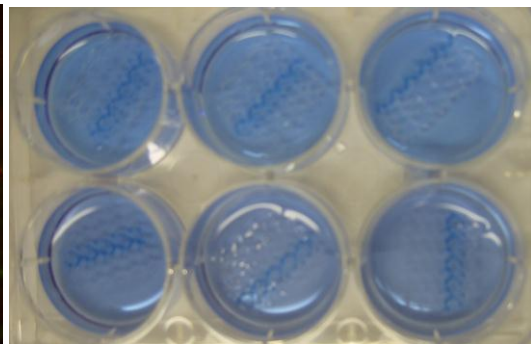
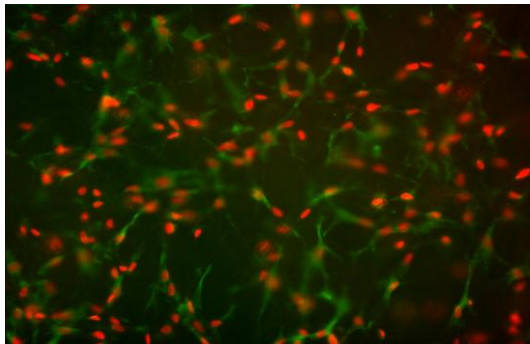


Appendix 2



The
University
Of
Sheffield.

PATIENT INFORMATION LEAFLET



Title of Project:

Development of tissue engineered constructs for use in urological applications

Donation of Surplus Tissue for Research

Prof. Christopher Chapple
Royal Hallamshire Hospital
Glossop Road
Sheffield S10 2JF
Tel: 0114-271-3048

As part of the urethroplasty surgery you are about to undergo a small amount of surplus tissue is often removed. Normally, this would be discarded. You are being invited to donate this tissue for use in a research project; being undertaken by scientists and research doctors to improve the future treatment options for patients. No extra tissue will be removed and you will not be required to have any additional tests or procedures.

Before you decide whether or not you wish to donate your tissue, it is important for you to understand why the research is being done and what it will involve. Please take time to read this information leaflet carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

This study has been reviewed and approved by the Sheffield Local Research Ethics Committee. This committee consists of health professionals and members of the general public. Your participation is entirely voluntary and all samples will remain completely anonymous i.e. it will not be possible to trace the waste tissue that you donate back to you.

Thank you for reading this leaflet.

What is the purpose of the study?

By isolating the cells from your donated tissue we are able to re-construct new tissues in the laboratory and grow them for a few weeks (this is called tissue engineering). By treating the engineered tissue in different ways we can replicate and study approaches to treating various urological diseases in the laboratory. This enables us to develop new treatments in the laboratory before testing them in patients and will help to reduce or eliminate the need for animal testing.

Why have I been chosen?

You have been identified as a potential tissue donor because your surgeon has told us that surplus tissue is often removed during the procedure you are having performed.

What tissue will be taken?

Only waste tissue that would normally be disposed of is collected during the procedure. No extra tissue will be taken. We ask that instead of disposing of this waste material you allow it to be collected and used for research purposes.

What will happen to the tissue?

Once you have donated the tissue, it will be given an anonymous reference number. The tissue will then be collected and recorded as an anonymous tissue donation for a Human Tissue Authority authorised Research Tissue Bank within the University of Sheffield, KROTO Research Institute. Here it will be used in research experiments over the next few weeks or months. Once the experiments have been completed any remaining tissue will be safely disposed of. We will not do any tests on the tissue that have any relevance to your current or future health.

What will happen to the tissue after the research is finished?

Very small samples of the tissue will be stored (with an anonymous reference number) as part of the record of the project, but the majority of the tissue will be safely disposed of after the research is finished.

Who is involved in the project?

The study is being organised by researchers at the University of Sheffield (see contact details on last page) and the waste tissue is being collected by doctors at the Sheffield Teaching Hospitals NHS Trust.

Who can I talk to if I have any questions or concerns about the study?

If you have any questions regarding this research, or would like more information, please contact the investigator Prof. Christopher Chapple or his team on 0114-271-3048 who will be happy to speak to you and answer any questions you may have.

Thank you for considering donating tissue to this research. If you decide to do so, you will be given a copy of this leaflet to keep and you will be asked to sign a consent form to give permission for the removed tissue to be used for research.

Please note that you can change your mind about whether you wish to donate tissue for research or not, at any time prior to surgery. However, after surgery has taken place, this is not possible as all tissue for research is handled on an anonymous basis to protect your identity. We would therefore be unable to trace your donated tissue.