Department of Musculoskeletal Oncology
Glasgow Royal Infirmary
Glasgow, G4 0SF

**Negative pressure dressing versus non-negative pressure dressing for soft tissue sarcoma excision**

**Information Sheet**

Your surgeon would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it will involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information.

**Who is conducting the research?**

The research is being carried out by Mr David Shields, Mr Oliver Bailey, Sister Emma Sharp, Mr Sanjay Gupta and Mr Ashish Mahendra, from the Department of Musculoskeletal Oncology in Glasgow Royal Infirmary.

**What is the purpose of the study?**

This study is being performed in order to investigate the best way to cover wounds after removal of a cancer such as yours. At present, there are a wide range of acceptable techniques each with their own advantages and disadvantages. We wish to compare two different methods of providing post-operative wound coverage to see which provides the best results in terms of wound healing.

**Why have I been invited?**

You have been invited to take part in this study as you have been scheduled to undergo removal of a sarcoma (soft tissue cancer). This operation is performed at our hospital by a musculoskeletal oncological surgeon. The researchers propose to compare two different wound dressings to be used on the wound after closure with stitches. Both of these

techniques are currently being used in surgical practice and the results so far show that patients who are at high risk of wound problems may benefit from a new dressing technique. However, the two techniques have not been compared before in this group of patients. The research team hope that by comparing these two techniques directly, it will be established whether one is better than the other for patients undergoing cancer removal operations.

**Do I have to take part?**

No, it is up to you to decide. The surgical team will describe the study and go through this information sheet, which we will then be given to you. You will be asked to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive or your future treatment.

**What does taking part involve?**

You will be seen by your surgeon at the pre-operative assessment clinic as normal. At this visit, a member of staff involved in the performance of this study will give you some information about what participation in the study involves. Any risks and benefits will be discussed with you at this visit. You will be seen again before your operation at which point any further questions you have will be answered. If you decide that you would like to take part in the study, you will be asked to sign a consent form and will be allocated at random into one of two groups by computer generated random numbers.

In no way will this study interfere with the primary aim of your treatment which is to remove your soft tissue cancer, this will be removed as planned by the musculoskeletal surgeon and as described to you at the pre-operative assessment clinic.

After surgery your wound will be closed by a standard technique of stitching and only then will an envelop be opened which describes which wound dressing group you have been allocated to. The type of dressing will differ slightly in each group so that the two different types of wound dressing can be compared

Patients in Group 1 Will have their wound closed in a standard fashion with a waterproof absorbent dressing

Patients in Group 2 Will have their wound closed in the same fashion, but their wound covered with a waterproof dressing attached to a vacuum pump (negative pressure

dressing).

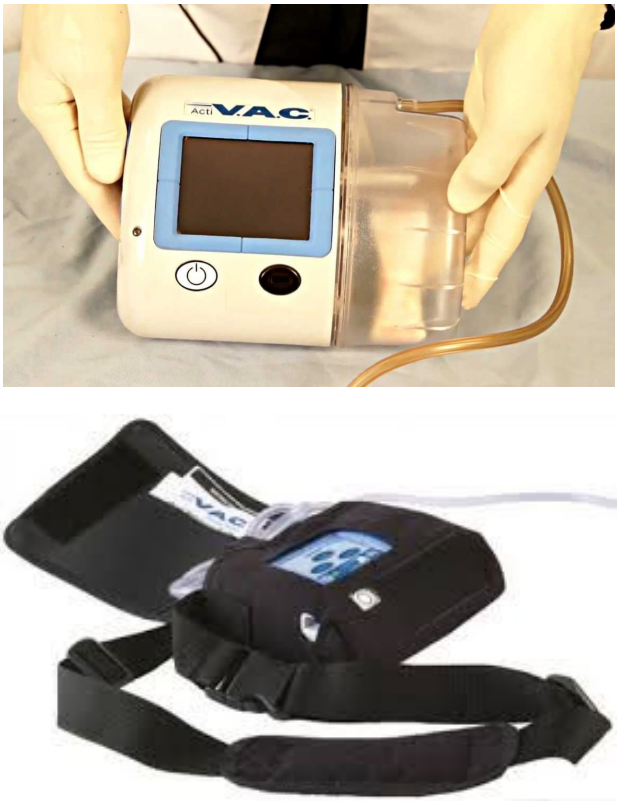


**Figure 1**: The 'Activac' pressure pump. The pump is approximately the size and weight of a hardback novel (8x6 inches) and comes in the above shown carry case.

The techniques described will be performed by an experienced orthopaedic surgeon trained in use of these dressings in theatre at the end of the operation.

After the operation, both groups of patients will receive routine post-operative care. This will consist of regular nursing observations, regular pain killers, and oxygen if required. This care can take place both on the regular orthopaedic ward or the high dependency ward. The physiotherapy team will do exercises with you which will be guided by your surgeon. This is standard care after this type of surgery.

The surgeon may find at the end of your operation your wound may not be suitable for application of the dressing (such as shape of the wound), and so may remove you from the study at that point. We would then apply the most suitable dressing and continue your care as we normally would as if you were not involved in the study.

After the operation your surgical wound will be monitored on a regular basis as it would be normally. The researchers may take written assessment of your wound to compare to other wounds.

**What happens to the information?**

Your identity and personal information will be completely confidential and known only to the researchers. The information obtained will remain confidential and stored within a locked filing cabinet for a period of 5 years. The data are held in accordance with the Data Protection Act, which means that we keep it safely and cannot reveal it to other people, without your permission.

**What are the possible benefits of taking part?**

It is hoped that by taking part in this research, you will be providing valuable information regarding the best wound dressing after soft tissue cancer removal. We hope that we can help to identify the best wound dressing for this type of procedure.

**Are there any risks?**

As with all type of surgery there are risks, which will be discussed in detail with you during consent for your operation by your surgeon and your anaesthetist. However it is not believed there is any additional risk inferred by the use of these dressings.

**Who has reviewed the study?**

This study has been reviewed and approved by the board Research and Development department and the West of Scotland Research Ethics Committee.

**If you have any further questions?**

If you would like more information about the study and wish to speak to someone **not** closely linked to the study, please contact**; Sister Helen Findlay or Sister Catriona Graham Oncology Nurse Specialists, 0141 2114443**

**Contacts:**

Ashish Mahendra, Consultant Musculoskeletal Oncology Surgeon

Sanjay Gupta, Consultant Musculoskeletal Oncology Surgeon

David Shields, Orthopaedic Registrar, Glasgow Royal Infirmary; telephone (via switchboard) 0141 2114000

**If you have a complaint about any aspect of the study?**

If you are unhappy about any aspect of the study and wish to make a complaint, please contact: Margaret Smith, The Complaints Manager, Glasgow Royal Infirmary, telephone 0141 2115112. ***Thank you for your time and cooperation***