

*Better
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Patient information

Clinical Evaluation Of The NeXtra Pump Shaver System

Trauma and Orthopaedics

We have been asked to evaluate a new piece of equipment that we would like to use during your operation. This information sheet provides you with all details of what we would like to do and how it affects you. Please read the pages and feel free to ask any questions.

Background

You are going to undergo an operation on your shoulder which is being performed using keyhole surgery (arthroscopy). During the operation a number of small holes, usually less than one centimetre cm ($\frac{1}{2}$ inch) long will be made; the number varies from usually two to about five or six.

One or more small plastic tubes called cannulae may be passed through the incisions into the joint to allow the passage of instruments and various small devices used to perform the repair that you need on your shoulder. We also use the plastic tubes to pass fluid through the joint. The fluid is used to keep the space in the joint open and to wash out any blood or other debris.

The fluid is delivered to the joint by using a mechanical device called an arthroscopic pump-shaver. These are commercially developed and CE marked devices designed specifically for the purpose of managing fluid and driving a device called a shaver used during arthroscopic procedures.

There are a variety of devices available. The one that we have used in the Broadgreen Orthopaedic Operating Theatres for sometime is called an FMS pump-shaver and is marketed by a company called Depuy Mitek which is a division of Johnson and Johnson. The pump allows us to adjust how much fluid is passed through the joint (flow) and at what pressure.

The shaver part is linked to the pump. The shaver allows us to trim soft tissue and bone; there is a tube attached to the pump which sucks debris out of the joint.

The reason why the shaver is linked to the pump is to ensure that the space is kept open by increasing the flow when the shaver is actively sucking the fluid and debris out.

Aims of the evaluation

We have been asked by Depuy Mitek to test (evaluate) a new pump that they are going to sell in the UK and Europe.

The pump has a CE mark showing that it is considered safe and suitable to be used for the purpose of fluid management during keyhole surgery.

We will be seeing if the flow and pressure settings that are set in the machine are really suitable for surgery and we will be setting-up a series of “default” settings that other surgeons can simply access when they are starting out.

Why is a new pump-shaver system needed?

There are several reasons why the new machine is being introduced. Overall the idea is to ensure that surgeons have the best available equipment based on up-to-date technology to undertake technically demanding surgery.

The device that we have been using has been available for probably ten years without modification. We have been using the system in Broadgreen for that period of time.

We know the system works. However the pressure is measured at the machine and so we do not know the exact pressure in the joint. The actual operation of the machine uses switches rather than computer driven touch screens.

The pedal used to operate the machine is cumbersome and the actual shaver hand-pieces are heavy and not well designed for the surgeon to hold comfortably.

Finally, the setting up of the system by the theatre staff is not particularly user friendly. We would emphasize that none of these problems affect the working of the machine or pose any danger to you, the patient.

Therefore, the new machine has a number of features that deal with the problems. First, the system is run by a modern computer with a touch screen which allows alterations to the settings to be done quickly and easily. The read out of flow and pressure is clear and been made easy to understand.

In order to more effectively measure the pressure within the joint a pressure sensor is positioned in the tubing that goes from the pump to the plastic cannulae very near to your joint. This will make measuring the pressure much more sensitive allowing the system to adjust for changes more quickly.

For the theatre staff the set up procedure is much easier and quicker. The theatre staff simply have to plug a cassette into the machine which has all the tubing going through it.

How does this involve you?

As we have said you are having keyhole surgery to your shoulder and that we routinely use a pump in all types of arthroscopic shoulder surgery. We are asking you to allow us to evaluate the pump during your surgery.

In reality what will happen to you is almost identical to what has happened to thousands of patients in our unit over the last 14 years. The only change we will make is that we will change the flow and pressure delivered by the pump in order to ascertain which settings give us the best view at different stages in the operation.

Sometimes representatives of the company that is selling the machine may attend the operating theatres to observe how the machine is working and how it affects the surgery.

All the representatives are fully trained in and familiar with being in and around operating theatres during surgery. They are also totally committed to complete patient confidentiality. We will ask your permission for the company representatives to be present.

Are there any benefits to you?

There are no direct benefits to you. The surgery you are undergoing will be performed in exactly the same way as it would be with the “old” pump. There will be benefit for other patients in the future as we will be able to recommend particular settings for particular types of surgery which will ensure that a clear view is maintained easily.

Are there any risks to you?

We undertook an initial small evaluation (approved by the New Devices and Techniques Committee of the hospital) in October 2008.

This small test reassured us that the machine works, as far as the patient is concerned, in a similar way to our present machine.

We do not believe that there are any potential dangers to you but if we feel that anything is not functioning correctly we will immediately disconnect the new machine and go back to using our present system.

What information will be recorded and what will happen to that?

During the operation we will record the type of operation and any changes in the settings that we make during the surgery. We will also make some observations about how we think the pump and shaver worked.

The items we record will be given to Depuy Mitek. Theoretically, because the type of surgery and the date of operation will be recorded you can be identified.

However as only the medical staff have access linking the operation name and date to you it is almost impossible for anyone outside of the hospital to identify you. We will endeavour to ensure that you are not identified.

What happens if something goes wrong?

In the unlikely situation that something goes wrong and you are harmed in any way the incident will be investigated through normal channels

If you have any questions or concerns please contact a member of your medical team or you can contact the following persons directly:

Further Information

**Professor S P Frostick
Professor of Orthopaedics
Tel: 0151 706 2000 Ext 3544**

**Mr P Brownson
Consultant Orthopaedic Surgeon
Tel: 0151 706 2000 Ext 6441**

Thank you for reading this leaflet.

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