

Patient Information on use of power morcellation for laparoscopic myomectomy or laparoscopic hysterectomy

Laparoscopic myomectomy is an operation carried out through keyhole surgery. For myomectomy, the fibroids are removed from the uterus (womb) in a similar manner to open surgery. However once removed from the womb they need to be removed from the abdominal cavity via the small holes. A morcellator is used for this process. The morcellator is an electrically driven coring device that cuts the fibroid into small pieces so that they can be removed. For laparoscopic hysterectomy with a large womb or subtotal hysterectomy (where the neck of the womb is left) a morcellator may also be required to remove the womb from the abdominal cavity.

There have been concerns raised in the USA by the FDA (food and drug administration) on the use of morcellators. The risk is that if the fibroid contains cancerous material then the cancer will have been spread around the body and the data suggests that this will reduce cure rates and survival.

The problem is that there is no way to accurately predict whether a growth has cancer before it has been looked at in the laboratory. However, if a malignancy (sarcoma) is suspected then removing fibroids (even intact) is the wrong operation and a hysterectomy through an open operation is the correct operation. In addition, if a sarcoma is suspected then a wait and see approach and not having any operation is incorrect as well. This includes other non-invasive treatments, medical treatments or uterine artery embolization.

The incidence of unsuspected sarcoma is rare, and the FDA has suggested a rate of 1 in 350. The Society of Gynaecological Oncology (SGO) gives a rate of 1 in 1000. Thus, the exact figure is unknown; this is because it is a rare tumour. The SGO also point out that the outcome is very poor even when the fibroid is removed intact.

A number of population-based studies have reported the incidence of unexpected leiomyosarcoma among surgery for uterine fibroids or hysterectomy for whatever cause.

In the largest published database, risk figures for premenopausal women of all ages (<50 years) range from 1 in 1250 (hysterectomy or myomectomy whatever cause) to 1 in 769 (women with uterine fibroids). The reference below (RCOG) expands on these risks further.

We do not recommend a laparoscopic myomectomy or use of the morcellator during hysterectomy where we are concerned that the fibroid contains a sarcoma. Your option is to have an open myomectomy or open hysterectomy if you are concerned but this does not guarantee long-term survival either. The alternative to use of the morcellator is to perform the operation via keyhole surgery and then to morcellate through the vagina (where appropriate) or by making a bikini line incision.

More recently morcellation bags have been introduced to reduce the risk of spillage and this may be recommended by your consultant. The advice is conflicting. The RCOG states that this may increase the risk of bowel injury whilst others feel that it may reduce the risk. The FDA only allows morcellation when a bag is used.

This is additional information and should be used in conjunction with the main Consent Form. Please ask your Consultant if you have any further questions. May 2021.

We are informing you of the potential risk due to the warnings given by the FDA. We are obliged to ask you to confirm that you have read this letter as part of your consent process but do please ask if you have any further questions.

The web address for the FDA is below. This site also has links to the other report referred to in this letter

<https://www.fda.gov/medical-devices/safety-communications/update-perform-only-contained-morcellation-when-laparoscopic-power-morcellation-appropriate-fda>

The Royal College of Obstetrics and Gynaecology also produces a patient information leaflet: <https://www.rcog.org.uk/en/patients/patient-leaflets/morcellation-myomectomy-hysterectomy/>

Please confirm that you have read this information leaflet.

Name (print)..... Date:

Signature.....