MORCE POWER PLUS

RICHARD WOLF
spirit of excellence

Information sheet on Morce Power Plus

Richard Wolf GmbH's Mission Statement commits us to manufacturing products and providing services designed to reliably diagnose health status, to intervene minimally invasively and to improve the quality of life. We are therefore obliged to inform our customers about an FDA safety communication.

On December 30, 2020 the American FDA issued safety-relevant customer information relating to laparoscopic electric uterus morcellation during hysterectomy and myomectomy. This safety-relevant FDA communication informs that:

WARNING: 'Uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer, and decrease the long-term survival of patients. This information should be shared with patients when considering surgery with the use of these devices."

⚠ **CONTRAINDICATION:**
Laparoscopic power morcellators are contraindicated in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy !

⚠ **CONTRAINDICATION:**
Laparoscopic power morcellators are contraindicated for removal of uterine tissue containing suspected fibroids in patients who are:
· post-menopausal or over 50 years of age, or
· candidates for en bloc tissue removal through the vagina or via a mini-laparotomy incision.

⚠ **WARNING:**
Uncontained power morcellation has been associated with the spread of benign uterine tissue, i.e., parasitic myomas and disseminated peritoneal leiomyomatosis, potentially requiring additional surgeries.

⚠ **WARNING:**
The risk of occult cancer, including uterine sarcoma, increases with age, particularly in women over 50 years of age. This information should be shared with patients when considering surgery with the use of these devices

⚠ ***WARNING:***
Laparoscopic power morcellators should only be used with a containment system. The containment system should be compatible with the laparoscopic power morcellator.

The issue is known in the relevant medical literature and has been described repeatedly. We have also duly evaluated the facts. For this reason, since the products were launched for the first time, our manual GA-A 245 contains a corresponding warning note.

For the safety-relevant information issued by the FDA on December 30, 2020, please refer to the FDA website

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/product-labeling-laparoscopic-power-morcellators

Please contact our gynecology product marketing if you have questions.

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