

## ***Patient information leaflet***

### **Transvaginal Treatment of Anterior and Apical Genital Prolapses Using an Ultra Lightweight Mesh: Restorelle® Direct Fix™: a Retrospective Study on Feasibility and Morbidity**

Principal Investigator:.....  
Mailing address:.....

Madam,

You have suffered from organ descent or genital prolapse. Prolapse occurs when one of the organs in the woman's pelvis (bladder, uterus, rectum) is no longer held by the muscles and/or ligaments that make up the pelvic floor. These organs, whose attachments have lost their effectiveness, eventually descend and externalize into the vagina. On the advice of your doctor, you have decided to treat your prolapse with a surgical procedure consisting of repositioning the organ(s) by the low or natural route. This repositioning is accompanied by a reinforcement of the organs' support means by the use of a synthetic reinforcing fabric compatible with the human body (Restorelle Direct Fix prosthetic implant). The reinforcing tissue is positioned between the vagina and bladder (for bladder prolapse), between the vagina and rectum (for rectal prolapse).

We would like to evaluate the effectiveness and safety of the vaginal reinforcement prosthesis. To this end, if you agree, we will collect information on the management of your prolapse. This study does not influence the management of your condition or the care provided by the surgeon during your hospitalization or during the follow-up over a longer period of time. In addition, your participation does not generate any individual benefit or risk. The data will be derived from your medical file and the information collected by your doctor during consultations related to the following points:

- Your medical history and tests related to your genital prolapse.
- Medical data collected during your hospitalization and during post-operative visits (surgical information, post-operative events, examinations and treatments).

Your participation is optional. If you refuse or wish to interrupt your participation, this will not affect your support within the service. The information collected will be kept unless you object.

Your personal data will be processed in order to analyse the results in the light of the research objective presented to you. To this end, medical data concerning you and data relating to your lifestyle, as well as data relating to your sexual life, will be transmitted to the person in charge of

research in France. These data will be identified by a code number. They may, under conditions ensuring their confidentiality, be transmitted to the French or foreign health authorities and to other entities of the institution responsible for the research. The publication of the study results will not include any individual results

In accordance with the provisions of the law relating to data processing, files and freedoms, you have a right of access and rectification. You also have the right to object to the transmission of data covered by professional secrecy that may be used in the context of this research and processed. These rights of access and rectification of data apply until the destruction of the correspondence. You can also access all your medical data directly or through a doctor of your choice in accordance with the provisions of Article L1111-7 of the Public Health Code. These rights are exercised with the doctor who is following you in the research and who knows your identity.

In accordance with article L 1122-1 of the Public Health Code (March 2002 law on patients' rights), the overall results of the study may be communicated to you if you so wish.

This study received a positive opinion from the Advisory Committee on the Processing of Health Research Information on 1<sup>st</sup> March 2017.

After reading this information document, feel free to ask your doctor any questions you may have.

Thanking you in advance for the trust you have placed in us.

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« Name of the principal investigator »