Informed Consent Form

Currently, we are conducting a prospective randomized controlled study on the modified local compression method and the traditional whole breast compression method in minimally invasive breast surgery. Given that you are about to undergo minimally invasive breast surgery, we invite you to participate in this study. Before you decide whether to participate in this study, please read the following content carefully. It will help you understand the content, purpose, procedures, and duration of this study, as well as the potential benefits, risks, and discomforts that may be brought to you by participating in the study, and all the rights you possess. If you wish, you can also discuss it with your relatives and friends, or ask your doctor for an explanation to help you make a decision.

1. Background and Purpose of this Study:

Due to the relatively large trauma to the breast caused by traditional general anesthesia surgery, long recovery time, high incidence of postoperative complications, and the fear of general anesthesia surgery among patients, the Mammotome minimally invasive rotational resection technique has emerged. The advantages of this minimally invasive breast surgery are quite prominent, mainly manifested as visualization, small incisions, and safety and reliability. Currently, the commonly used bandaging method after minimally invasive breast surgery in clinical practice is the whole breast compression bandaging method. One or two pieces of sterile loose gauze are kneaded into a gauze ball and pressed on the residual cavity. Then, 5 to 8 pieces of loose gauze are continuously used to stack gauze balls within a 5-cm diameter around the wound for bandaging. Finally, an elastic bra is used for compression bandaging for one day. The elastic bra is a special compression elastic bandage for breast surgery, aiming to achieve auxiliary therapeutic effects such as eliminating the cavity and protecting the surgical incision. However, in the process of clinical practice, it has been found that this bandaging method brings great discomfort to patients. It is not only reflected in varying degrees of skin itching on the covered skin, with a relatively high occurrence of local red rashes, but also affects the patients' breathing. The vast majority of patients complain of pain and discomfort due to the tightness on the chest and back, being restless while sitting or lying down. At night, they can only sleep in a semi-sitting position and are largely unable to enter deep sleep, seriously affecting the patients' daily activities and sleep. In order to improve the patients' experience and reduce their discomfort as much as possible, the medical and nursing joint team has explored and modified the compression bandaging method after minimally invasive surgery and found that the local compression bandaging method is more comfortable. That is, one or two pieces of loose gauze are kneaded into a gauze ball to replace multiple gauze balls and placed in the residual cavity. Then, elastic medical adhesive tape is

used for local compression and sticking. Finally, a pure cotton clean towel is placed inside the elastic bra and the elastic bra is worn for one day. In order to further compare the application effects of the whole breast compression bandaging method and the local compression bandaging method, our research team intends to conduct a controlled study of these two methods.

2. Research Content, Observation Procedures, and Duration:

You will randomly draw an envelope, in which there is a numbered label. If the number drawn is 1, it means that the whole breast compression bandaging method will be used as the control group. If the number drawn is 2, it means that the local compression bandaging method will be used as the experimental group. You will enter the corresponding group according to the label you draw.The surgeries for patients are all scheduled during the non-menstrual period. On the first day after the surgery, patients in both groups will fill in the questionnaire via the QR code. The content of the questionnaire QR code includes general information (such as name, age, underlying diseases, educational background, etc.), a pain rating scale, a comfort scale, whether there is a hematoma, and a patient satisfaction survey. Use breast color Doppler ultrasound to check the wound healing and hematoma status at 2 weeks and 3 months after the surgery respectively. The preoperative examinations and other procedures that the subjects undergo during the study are all routine clinical diagnosis and treatment procedures. The elastic bras and pure cotton clean towels involved for the patients in the above two groups are all purchased by the patients themselves. In addition, there is no need for the patients in both groups to bear additional expenses, and there are no untested new drugs or new treatment plans. There are no additional inspection items for the subjects due to their participation in the study.

3. Potential Benefits and Risks of Participating in the Study: It is uncertain whether the subjects can benefit from participating in this study. Patients in both groups may face risks such as subcutaneous hematoma, itching, pain, and poor breathing. If any damage related to the study occurs, it will be handled in accordance with relevant national laws and regulations.

4. Your Rights: Your participation in this study is completely free and voluntary. Refusing to participate will not cause any trouble, nor will it damage your rights and interests. You will continue to receive the wholehearted service from the doctor as before. If you decide to participate, you need to sign a written informed consent. However, during the study, you can withdraw at any time without giving any reason. Similarly, if the researcher believes that your continued participation in the study is not in your best interest, the researcher will also decide to let you withdraw. We promise that your withdrawal will never affect your relationship with the medical staff or your future diagnosis and treatment.

5. Confidentiality: Within the scope permitted by law, all information and examination results collected about you in this study will be kept strictly

confidential. They will not be provided to any other individuals or units other than the researchers. All your study records and test results are only accessible to the superior department in charge of scientific research in the hospital, members of the ethics committee, and research doctors for analysis, processing, and verification, and they will strictly keep your secrets.

Signing this document indicates that you have authorized the above-mentioned use of your medical records.

Contact Information for Obtaining More Information or Assistance

During the study, you can obtain relevant information at any time. If you have any questions about this study, please contact:

Researcher Contact： Phone Number ： Date of Signature:

Telephone number of the Medical Ethics Committee of Guangdong Provincial People's Hospital: 020-83525975