INFORMATION FOR PROJECT PARTICIPANTS
AND INFORMED CONSENT FORM FOR PARTICIPATION IN THE PROJECT
"The Effect of Using an Automated Circumcision Device on Visual Outcomes and Sexual Function in Patients Diagnosed with Phimosis."

PROJECT DESCRIPTION AND OBJECTIVE

You are invited to participate in the project "The Effect of Automatic Circumcision on Visual Outcomes and Sexual Function in Patients Diagnosed with Phimosis." The aim of the project is to compare the aesthetic outcomes and sexual function after circumcision performed using the conventional method and using an automatic circumcision device.

The aim of this study is to demonstrate that the use of an automatic circumcision device allows for the circumcision procedure to be performed in a shorter time with comparable visual outcomes and sexual function.

This randomized study will involve a group of 100 men diagnosed with phimosis undergoing circumcision, divided into two groups: 50 men who underwent surgical circumcision and 50 men who underwent circumcision using an automatic circumcision device.

Study Design:

1. Qualification for circumcision based on clinically diagnosed phimosis.

2. Completion of the VAS 0-10 questionnaires (itching, burning, pain at rest, pain during intercourse, cold sensation, heat sensation, vibration sensation), IIEF 15 (International Erectile Dysfunction Index), MGSIS-7 (self-assessment of the male genitalia) before the procedure.

3. Penile sensation testing before the procedure (biothesiometer).

4. Performing the circumcision procedure (classical/automatic circumcision device).

5. Completion of the VAS 0-10 questionnaires (itching, burning, pain at rest, pain during intercourse, cold sensation, heat sensation, vibration sensation), IIEF 15 (International Erectile Dysfunction Index), MGSIS-7 (self-assessment of the male genitalia) 3 months after the procedure.

6. Penile sensation testing 3 months after the procedure (biothesiometer). During the Project, your biological material (foreskin during a routine surgical circumcision) will also be collected. This material will be used for histopathological examination to rule out cancer in the removed foreskin.

IS PARTICIPATION IN THE PROJECT MANDATORY?

Participation in the Project is completely voluntary. If you declare your willingness to participate in the Project, you will be asked to sign two copies of the informed consent forms. One set of documents will be provided to you, and the other will be included in the Project documentation.

You have the right to refuse consent to participate in the Project and to withdraw your consent at any time, without providing a reason and without negative legal consequences in the form of any discrimination, including in terms of your right to healthcare. Withdrawal of consent must be submitted in writing to: Clinic of Urology, University Clinical Center in Gdańsk, ul. Smoluchowskiego 17, 80-402 Gdańsk or email: gondekkuba@wp.pl

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WHAT WILL PARTICIPATION IN THE PROJECT INVOLVE?

After obtaining your written consent to participate in the Project, the following procedures will be performed:

• Medical interview, including gathering information about your health, lifestyle, and contact information – 25 minutes

• Review of your medical records to provide additional information, such as the course of your illness, current treatments, and comorbidities

• Physical examination and qualification for circumcision, including determining the extent of the procedure – 10 minutes

• Completion of VAS 0-10 (pain, itching, burning), IEEF 15 (International Erectile Function Index), and MGSIS-7 (self-assessment of male genitalia) questionnaires prior to the procedure – 15 minutes

• Performing the circumcision procedure using a surgical method or an automated circumcision device – 60 minutes

• Sending the removed foreskin for histopathological examination.

WHAT ARE THE RISKS ASSOCIATED WITH PARTICIPATION IN THE PROJECT?

A physical examination will be performed by qualified medical personnel. You may experience some discomfort during the examination.

Circumcision – the procedure is performed under local anesthesia. During anesthesia, you may experience mild discomfort related to the local anesthetic injections. Bleeding may occur during the procedure, which is immediately treated using electrocautery. After the procedure, a circumcised dressing will be placed on the penis. You will receive detailed postoperative instructions. Elevation of the penis, daily dressing changes, lubrication of the suture lines with fusidic acid, and avoidance of long baths for approximately one week will be necessary.

If you experience any concerning symptoms related to the treatment, please immediately contact the research project leader directly at the provided telephone number (+48798741669) for further instructions.

If you have any questions or concerns regarding the procedure, our staff will endeavor to answer them honestly. If you still have any doubts about the procedure or if any adverse events occur, the procedure will be postponed.

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WHAT ARE THE POTENTIAL BENEFITS OF THE PROJECT?

Participation in this Project will likely not directly impact your therapeutic decisions. The primary motivation for participating in the Project is to help researchers and healthcare professionals better understand the causes and progression of diseases so they can develop new methods for preventing, detecting, and treating them. The knowledge gained during the Project may benefit others in the future. You should not expect any personal gain from participating in this Project.

You will not receive financial or other compensation for your participation in the Project. It is possible that some of the research conducted using your biological samples will lead to the development of new diagnostic tests or other commercial products. In such a case, you will not share in the profits from such products. If new diagnostic methods or medicinal products are developed, any profits and property rights will belong to the University and the researchers. You will not incur any costs for participating in this Project. Due to the University's cooperation with numerous research entities in Poland and abroad, it is possible that your samples/medical data may be made available to researchers/entities outside of MUG conducting research, including foreign entities, both public and private.

WILL YOU HAVE ACCESS TO INFORMATION RELEVANT TO YOUR HEALTH AND THE GENERAL RESULTS OF THE PROJECT?

Due to their unconfirmed clinical value, the research results will not be disclosed to you. The overall results of the Project will be published in the form of articles in scientific journals, maintaining the anonymity of the Project participants in a manner that does not allow for the identification of the Project participants.

HOW ARE YOUR BIOLOGICAL SAMPLES AND DATA STORED AND PROTECTED? WHO HAS ACCESS TO THEM?

Your privacy is protected by the obligation of confidentiality for all those involved in working with personal data and biological material. These individuals are obligated to comply with the provisions of the General Data Protection Regulation of April 27, 2016 (GDPR) and the Personal Data Protection Policy of the Medical University of Gdańsk (MUG).

After agreeing to participate in the Project, your medical data, including health data, and the collected biological material will be marked with a special, unique project code (pseudonymization).

The coded samples of your biological material will be stored at very low temperatures in a room accessible only to authorized persons. Only in this form will the biological material and related data be sent for analysis. Your biological material and related data may be sent for analysis to other research facilities, specialized service laboratories, or entities conducting scientific/medical activities in Poland and abroad. During the Project, an electronic scientific database will be created containing information about the Project participants, their health status, and the results of analyses of collected biological material. This scientific database will not contain any information identifying the Project participants, only a project code assigned to each participant. This scientific database will be used to perform comprehensive scientific analyses on data collected from all Project participants.

Your identifying data will be stored separately and independently from the scientific database in a password-protected electronic database with limited access. Data processing media (computers, disks, etc.) will be protected in accordance with data protection regulations. Paper documentation, including your signed consent to participate in the Project, will be stored in a secure cabinet in a room with limited access. No one else will have access to your identifying data except authorized personnel.

Your identifying data will be used to supplement and update information from your medical records, for future communication with you regarding the current Project, and for invitations to future research studies. Your identifying data will not be transferred to scientists conducting research on the collected biological material and related data, including foreign collaborators, nor will it be included in public databases or scientific publications.

INTENDED USE OF PROJECT RESULTS AND COLLECTED BIOLOGICAL MATERIAL

Anonymized research results, including DNA genetic analysis results, will be posted in public online scientific databases, published in scientific journals, and presented at scientific conferences and meetings. Publicly disseminated research results will never contain data identifying Project participants.

If the biological material collected in the Project is not fully utilized in the current Project, with your consent, it will be used, along with related data, in future scientific research (including genetic research) that has received a positive opinion from the relevant Bioethics Committee or equivalent body in the relevant country.

Your biological material and related data will be transferred for future scientific research only in anonymized form to researchers from the Medical University of Gdańsk and researchers from collaborating research institutions, specialized service laboratories, and private/private entities in Poland and abroad. It is currently impossible to predict all the possible uses for your biological material and data. These include research aimed at improving the prevention, diagnosis, and treatment of a wide range of diseases, as well as promoting health in society. We hope that this research will give future generations a better chance of living free from diseases that prevent normal functioning and/or have a high mortality rate.

Your biological material will be stored long-term (for the duration of the biobank project) until it is fully utilized. If the material is deemed no longer suitable for research or you withdraw your consent to its use, it will be destroyed in accordance with procedures in force at the Medical University of Gdańsk.

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RECONTACT

We request your consent to be contacted again by our medical or research staff to collect additional samples of biological material, provide additional health information, or invite you to further research in the future.

PROJECT INSURANCE

The project is insured under the terms of the Medical University of Gdańsk insurance policy.

PROJECT FINANCING SOURCES

Not applicable

ADDITIONAL INFORMATION

The project has received a positive opinion from the Independent Bioethics Committee for Scientific Research at the Medical University of Gdańsk.

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CONSENT TO PARTICIPATE IN THE PROJECT:

Project Participant Code .....

I voluntarily consent to participate in the Project: "The Effect of Using an Automatic Circumcision Device on Visual Outcomes and Sexual Function in Patients Diagnosed with Phimosis."

I confirm that I have read and understood the above information about the Project. I have obtained all necessary information about the proposed Project. I have had the opportunity to freely ask questions and have received satisfactory answers to these questions. I understand that my participation in the Project is voluntary and that I may withdraw my consent at any time without providing a reason. YES ☐ NO ☐

I consent to the collection, storage, and use of my foreskin for scientific research, including genetic research, for the purposes of carrying out the above Project. YES ☐ NO ☐

I consent to the long-term (multi-year) storage, in encrypted form, of my biological material (including genetics) and related data, and their reuse in future scientific research aimed at improving the prevention, diagnosis, and treatment of a wide range of diseases and promoting health in society. YES ☐ NO ☐

I consent to the sharing of samples/data with researchers/entities outside of the Medical University of Gdańsk, including foreign non-public/private entities. YES ☐ NO ☐

I consent to access to registers containing medical, demographic, and other information.

YES ☐ NO ☐

I am aware that I will not receive any financial benefits from participating in the research (e.g., if it leads to the development of a commercial product in the future). YES ☐ NO ☐

I consent to being contacted again in the future for the following purposes:

1. to complete and update my health information YES ☐ NO ☐

2. to be invited to subsequent projects YES ☐ NO ☐

* please mark the appropriate answer

_____	_____	_____
Name of Project Participant	Date	Signature

_____	_____	_____
Name of Person Obtaining Consent	Date	Signature