Informed Consent for Clinical Trial

1. Invitation to Participate

We invite you to take part in a clinical study conducted by researchers who follow ethical principles outlined in the Helsinki Declaration and comply with relevant regulations. This study, meant for research purposes, is experimental and unverified. Feel free to reach out at any time if you have questions about the study or this consent form. Your participation is entirely your choice, and you can decide whether or not to join. Take your time, consider consulting your family or friends, and remember that your decision won't disadvantage you.

2. Purpose of the Clinical Study

This clinical study focuses on research. It aims to address the need for better methods of treating tracheal defects by using bioprinting technology. The goal is to develop effective and safe ways to regenerate organ tissue using 3D printing. By participating, you're contributing to advancements in medical research and technology.

3. Clinical Procedures

Throughout the study, you'll undergo various procedures. Initially, a doctor will explain the study's purpose and give you time to decide. If you decide to join, you'll sign an agreement and possibly undergo a physical examination and blood tests (around one spoonful of blood). Women will also take a pregnancy test. Subsequent visits involve health checks, questions about your health, and tests like endoscopy or CT scans.

4. Your Role

If you experience unusual reactions during the study, inform the research staff promptly. During the study, avoid other clinical trials or medications that might affect the study. Let the research team know if you're taking any other drugs aside from the implant bioprinting organ or material.

5. Experimental Aspects

This study aims to ensure the safety and new effectiveness of bioprinted organ transplants. While

the implant is made in a sterile environment, the final identification of bacteria and viruses happens later. Antibiotics may be used based on identification results. Please note that benefits and side effects can't be fully predicted.

6. Risks and Discomforts

Possible risks include bleeding, subcutaneous emphysema, and uncommon complications during surgery. Recurrence of thyroid cancer is also possible. Unexpected side effects may arise. Your doctor will discuss these with you. If you experience side effects, inform your doctor for treatment. Severe reactions could lead to discontinuation of the study.

7. Benefits

While improvement is possible, participation doesn't guarantee it. The study's findings will help future patients.

8. Treatment Options

You can choose not to participate and receive standard treatment instead. Various surgical methods exist for tracheal defects. Your doctor will discuss these options and their risks and benefits with you.

9. Duration and Participants

Participation lasts for 96 weeks (2 years). Thyroid cancer patients will have follow-up for up to 5 years. You'll be one of the participants contributing to this research.

If you have any questions or concerns at any point, don't hesitate to ask the research team. Your participation plays a crucial role in advancing medical knowledge and improving treatments for others in the future. Your well-being is our priority throughout this study.

12. Compensation and Damage
If any physical harm occurs due to the research procedures during this study, Professor Bae Ja-sung from Seoul St. Mary's Hospital, the responsible researcher, will provide compensation as outlined in the "Compensation Rules for Victims." Signing this agreement won't waive your legal rights. If you face any incident related to this study, contact your clinical research physician

immediately for information and treatment.

13. Financial Compensation and Costs

All medical and examination costs arising from your participation will be covered by the researcher. Transportation costs between the hospital and your home (50,000 to 100,000 won per visit) will be reimbursed after the screening visit. All research-related expenses are borne by the research director.

14. Participation Restrictions

You may be unable to continue participating if:

You pass away or become pregnant

You withdraw your consent

You require discontinuation of organ/material transplantation

Serious adverse reactions occur

You violate selection/exclusion criteria

Other serious diseases arise

You use medications affecting evaluation

Follow-up fails

Research personnel decide to stop the study

Your safety will be ensured during tests if participation is interrupted. Researchers may also halt the entire study for safety reasons.

15. New Information

Your participation is voluntary. We'll notify you or your representative of new information that might influence your willingness to continue. After the study ends, we'll contact you yearly for five years to check for unexpected issues.

16. Your Rights and Withdrawal

Participation is voluntary, and you can withdraw at any time without a reason. Withdrawal won't impact your future medical care. If you withdraw, data collected before your decision may still be used for the study.

17. Questions and Concerns

For any unresolved questions, concerns, or complaints, contact the Clinical Research Review Committee of Seoul St. Mary's Hospital through the Research Ethics Secretariat of the Catholic Medical Center. If you need further assistance or have questions about your rights, reach out to the Clinical Research Review Board.

Catholic Medical Center Research Ethics Office/ Subject Protection Team: (02) 2258–8202-8206

Seoul St. Mary's Hospital Clinical Research Review Committee/Research subjects Helpdesk: (02) 2258–8196-8201