

## INFORMED VOLUNTARY CONSENT FORM

You are invited to participate in a research study entitled “**The Effect of Vibration and Cold on Pain and Anxiety Associated with Chest Tube Removal After Coronary Artery Bypass Graft Surgery**”, conducted by XXXXXXXX under the supervision of XXXXXXXX.

The aim of this study is to determine and evaluate the effect of vibration and cold application on pain and anxiety related to chest tube removal after coronary artery bypass graft surgery.

The study will be carried out between September 2024 and June 2025 with 93 patients who have undergone bypass surgery and have a chest tube in place. Participation in this research is entirely **voluntary**. In order to achieve the purpose of the study, you are expected to answer the questions sincerely and freely, without any pressure or suggestion from anyone. Reading and signing this form means that you agree to participate in the study. However, you have the right not to participate or to withdraw from the study at any time after participation.

All information obtained in this study will be used solely for research purposes and your personal information will be kept confidential; however, your data may be used for publication purposes. The ethics committee, the institution, and other relevant health authorities may access your medical records. By signing this form, you will be deemed to have given permission for such access. Your contact information may be transferred to a “shared participant pool” only with your permission so that other researchers may contact you. Your confidentiality will be protected at all stages of the research. The study does not contain any questions revealing your identity. Your information will not be disclosed to the public and your identity will remain confidential even if the results are published. Completed forms will be stored by the researchers for a maximum of **2 years** after publication and then destroyed by paper shredding and deletion of digital data.

If you need further information about the study now or later, you may ask the researcher or contact them via XXXXXXX, or XXXXXX. If you would like to receive the general and/or personal results after completion of the study, please inform the researcher.

The research application and evaluation will take approximately 25–35 minutes. The data collection tools used in the study are the “*Data Form*” and the “*State–Trait Anxiety Inventory*.” You will be randomly assigned to one of the study groups.

- *Cold + vibration group*: Before removal of your chest tube, 10 minutes of cold application and 10 minutes of simultaneous cold and vibration application will be performed.
- *Vibration group*: Before removal of your chest tube, vibration will be applied for 10 minutes.

Your anxiety level will be assessed before and after the application. Your pain level will be assessed before the procedure, immediately before chest tube removal, immediately after removal, and at the 5th, 10th, and 15th minutes after removal. Your vital signs will also be recorded.

- *Control group*: No application will be performed.

At the same time intervals, your pain and anxiety levels will be assessed and your vital signs

recorded.

Your routine treatment and care will continue throughout the study. Participation in the study poses no life-threatening risk. Your decision to withdraw will not affect the healthcare you receive. There is no financial burden associated with participation. Neither you nor your relatives will be charged any fee, and no payment will be made to you or your relatives. Although participation does not involve significant risk, the sensation of cold or vibration may cause discomfort. If you do not wish to continue, you may withdraw at any time. The potential benefit of being in the intervention groups is a reduction in pain associated with chest tube removal. No alternative intervention will be provided within this study; you may also obtain necessary information from your physician. If new information that may affect your willingness to continue participation becomes available, you will be informed promptly. You will not have access to the research device after the study.

I have read all the explanations above and understood the scope and purpose of the research I am invited to participate in, as well as my responsibilities as a volunteer. Written and verbal information regarding the study has been provided to me by the researcher named below. I am aware of the possible risks and benefits. I trust that my personal information will be carefully protected. I understand that I participate voluntarily and may withdraw at any time with or without justification.

Under these conditions, I voluntarily agree to participate in this research of my own free will, without any pressure or coercion.

**Participant:**

Name-Surname:.....

Date: \_\_\_\_\_ Signature: \_\_\_\_\_

I consent / do not consent (please mark the appropriate option) to my contact information being transferred to the “shared participant pool” so that other researchers may contact me.

☐ I consent      ☐ I do not consent

**Researcher:**

Name-Surname:.....

Date: \_\_\_\_\_ Signature: \_\_\_\_\_