I have been asked to participate in the above mentioned device study (clinical trial). received a written information leaflet and oral information about this study. I understand the information about the study. I have had enough time to think about my participation. Information given by: . I have been able to ask questions about this study and have received satisfactory answers. I can ask more questions later.

I have been told how my personal data is collected and used for this study. The information is contained in Appendix: *"15-17-year-old - Information leaflet on the Processing of Personal Data: Appendix to the Informed Consent Form".* I have been informed about that in writing on .

I have been told that in Finland the supervisory authority for medicines and medical devices (Finnish Medicines Agency Fimea) has the right to ensure that the research has been carried out in an appropriate manner. Foreign authorities for medicines or medical devices and representatives of the study (clinical trial) sponsor/organization conducting the study can also review the study information. To ensure the accuracy of the study data, my information is compared, for example, with my original patient records*. In this case, the information is processed under the supervision and responsibility of the study physician or other research personnel. My information can also be disclosed to an authority for medicines or medical devices for applying for a marketing authorization or safety review. In all cases, my information is kept confidential.

I understand that my participation in this study is voluntary. If I want to withdraw from the study or withdraw my consent, I will tell the study doctor or nurse. If the doctor decides to withdraw me from the study, they will explain why. In that case, my information and the samples collected so far can be used as part of the study material. This is necessary to ensure the safety of the research results and people participating in the study. I have been told that withdrawing from the study does not in any way affect the treatment I need and that I will receive the best possible care.

☐ My guardian(s) have been informed about this study other means Form: "*Notification to the Guardian of a 15-17-year-old child Participating in a Clinical Trial*". According to law, a 15-17-year-old child can decide themselves if they want to participate in a drug or device trial, but their legal guardian(s) must be informed of the decision. Date of notification:

[Add if applicable:] A voluntary gene sample is examined in this study to get information about my genes. I consent to the collection of my gene sample and analysis of the samples for genetic studies described in the trial information sheet. I also consent to the storage of the samples until the end of the genetic studies, but not exceeding [xx] years, before they are destroyed. I may request that my samples are destroyed earlier, during year [xx].

I consent to this part of the study as well: Yes ☐ No ☐

***** Patient record: A document that includes information about the patient's illness, conducted examinations and administered treatment. In hospitals, patient records are usually stored electronically in patient information systems.

I consent to my participation in this study:

_____		
Signature	*Date of birth or Social security number*	*Date*
Name in block letters	*Home address*	

Confirmation of the person obtaining the consent;

- The person who have been asked to participate in the study have been told about this study and they have received a written study information leaflet.
- The person who have been asked to participate in this study have been given the opportunity to ask questions which have been answered.
- The person who have been asked to participate in this study have been given enough time to consider and decide on the participation.

I have told the person who have been asked to participate about this study in line with the Trial Information Sheet and receive this consent (filled in by a doctor/nurse)**:**

_____	
Signature of person giving the study information and receiving consent	*Place and date*
Name in block letters	

This consent form is prepared in two copies, one for the subject and the other is archived in a study file.