INFORMED CONSENT FORM – ATRILASH TRIAL

Principal Investigator: <<Insert Name>>
Study Title: Left Atrial Appendage Closure During Cardiac Surgery in Atrial Fibrillation Patients With Seralene
Version: 1.0 (1-10-2025)
Date: <<Insert Date>>

Participant ID: ☐/☐☐☐☐

---

1. VOLUNTARY PARTICIPATION

I confirm that I have read and understood the Patient Information Sheet (Version 1.0) for the above study. I have had the opportunity to ask questions and have received satisfactory answers.

---

2. AGREEMENT TO PARTICIPATE

I understand the nature of the procedures and assessments described in the information leaflet and that they are related to evaluating the safety and efficacy of the AtriLash procedure (left atrial appendage closure with the Seralene Binder). All foreseeable risks have been explained.

---

3. WITHDRAWAL

I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason, and without any impact on my medical care or legal rights. I understand that data collected up until my withdrawal may still be used for research analysis unless I request otherwise.

---

4. ACCESS TO MEDICAL RECORDS

I understand that authorized personnel from the research team, ethics committee, regulatory authorities, or the sponsor may review relevant sections of my medical records for study purposes. All personal information will remain confidential.

---

5. DATA PROTECTION

I understand that the information collected during the study will be stored securely and kept confidential. My identity will not be disclosed in any publication or report. I understand that data will be pseudonymized and may be securely transferred to central data analysis centers within the EU.

---

6. DATA SHARING

I agree that anonymized or pseudonymized data may be shared with academic collaborators and used for ethically approved future research. All shared data will be de-identified.

---

7. FOLLOW-UP AND DATA LINKAGE

I agree that the research team may access national health records and hospital databases, where available, to collect additional information about my health status for up to 10 years.

---

8. FAMILY CONTACT IN CASE OF INCAPACITY

I agree that a family member or legally authorized representative may be contacted to provide information if I become incapacitated or too ill to respond personally.

---

9. FUTURE CONTACT

I agree to be contacted about potential future studies related to this research.

---

10. NOTIFICATION OF GP

I agree that my general practitioner (GP) may be informed of my participation in this study.

---

11. STUDY RESULTS

☐ Yes, I would like to receive a summary of the study results in a language I understand.
☐ No, I do not wish to receive the study results.

---

12. FINAL CONSENT

I voluntarily agree to participate in the AtriLash Clinical Study.

Participant's Name: _____
Signature: _____
Date (DD/MM/YYYY): _____

Name of Person Obtaining Consent: _____
Signature: _____
Date (DD/MM/YYYY):: _____

Initial here to confirm each statement:
☐ I have read and understood each section
☐ I had the opportunity to ask questions
☐ I voluntarily agree to participate