INFORMATION FOR CLINICAL RESEARCH PATIENTS

The **General Data Protection Regulation** (GDPR) is a regulation in EU law on data protection and privacy for all individuals within the European Union and became enforceable on 25 May 2018.

As a medical device company, AventaMed may from time-to-time carry out clinical research on its products to monitor their performance and safety or collect marketing information.

Clinical research data is considered a "special" data category whereby processing is necessary for scientific or research purposes.

When undertaking clinical research on their products, AventaMed follow all the necessary rules and regulations. This means that where applicable, AventaMed will ask for your explicit consent for the collection of your clinical data. When you sign a clinical research Informed Consent Form it will clearly state what data is being collected and why.

If you provide your informed consent to participate in an AventaMed clinical research study, your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate.

If you withdraw from an AventaMed clinical research study, we will keep the information about you that we have already obtained.

To safeguard your rights, we will use the minimum personally-identifiable information possible, and only use your data in the ways needed to conduct and analyse the clinical research study. AventaMed take responsibility for looking after your information and using it properly.

It is important to remember that AventaMed may not be able to directly link clinical research data to you as it may be coded or not contain any identifiable information. If you wish to make an enquiry or complain about how we have handled your clinical data, you should first talk to the doctor who treated you as part of the clinical research study. They can contact us at clinical@aventamed.com on your behalf, identifying you by your study code only. You can also contact us at clinical@aventamed.com if you wish to talk to us directly.

If you are not satisfied with the response or believe your clinical data is being processed in an unlawful way you can complain to the Information Commissioner's Office.

A summary of your rights under GDPR can be found below.

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Your Rights under the General Data Protection Regulation

1. **The Right to be Informed**: this encompasses our obligation to provide fair processing information, which we do through a Privacy Policy.

2. **The Right of Access:** this is your right to obtain confirmation that we process your data and to access it.

   To obtain confirmation that we process your data and/or to access the personal clinical research data held on you, please inform your study doctor or treating hospital who will get in contact with us at clinical@aventamed.com. You can also contact us directly at clinical@aventamed.com.

3. **The Right of Rectification:** this is your right to have your personal data rectified if it is inaccurate or incomplete. If you believe that the information recorded about you is incorrect, you will need to tell us or your study doctor so that we are able to contact the person who entered the information. We will correct factual mistakes and provide you with a copy of the corrected information. Wherever possible, we will also tell you the names of any third parties that we have disclosed this data to.

   If you are not happy with an opinion or comment that has been recorded, we will add your own comments to the record so they can be viewed alongside any information you believe to be incorrect.

4. **The Right to Erasure:** this is also known as your 'right to be forgotten', where there is no compelling reason to continue processing your data in relation to the purpose for which it was originally collected or processed.

   Your information is retained in accordance with regulatory guidance, and because of our legal and regulatory obligation to keep records, it is extremely rare that we destroy or delete records earlier than the recommended retention period. However, if you believe you have compelling grounds for having all or part of your information erased you should contact us or your study doctor.

The doctor in charge of your care and AventaMed will decide whether your request can be accommodated. If you provide your informed consent to participate in an AventaMed clinical research study, your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate.

If you withdraw from an AventaMed clinical research study, we will keep the information about you that we have already obtained.

If you are unhappy with our decision you may wish to register a complaint to the Information Commissioner.

5. **The Right to Restrict Processing**: this is your right to block or suppress the processing of your personal data. If you raise an issue relating to the clinical research data gathered on you, AventaMed will put an alert on their system to flag that your concerns are being investigated.

6. **The Right to Data Portability**: this is your right to obtain and re-use any information you have provided to us as part of an automated process. At present we do not process any clinical research study data that meets this requirement.

7. **The Right to Object:** this is your right to object to AventaMed processing your clinical data because of your particular situation. Because of our legal and regulatory obligation to keep records it is extremely rare that we would stop processing your data if you wish to continue in an AventaMed clinical research study. If you believe you have compelling grounds for AventaMed to stop processing your data, you should contact your study doctor or AventaMed.

   The doctor in charge of your care and AventaMed will decide whether your request can be accommodated. If you provide your informed consent to participate in an AventaMed clinical research study, your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate.

   If you withdraw from an AventaMed clinical research study, we will keep the information about you that we have already obtained.

   If you are unhappy with our decision you may wish to register a complaint to the Information Commissioner.

8. **Rights in Relation to Automated Decision Making and Profiling** – GDPR provides safeguards for individuals against the risk that a potentially damaging decision is taken without human intervention. At present, AventaMed do not process any such systems.

USEFUL CONTACTS

AventaMed

Post: Rubicon Centre
Rossa Avenue
Bishopstown
Cork, T12 Y275
Ireland

Tel: +353 21 492 8980

E-Mail: clinical@aventamed.com

Information Commissioner

If after exhausting our internal processes you believe that we have not complied with the data protection legislation you may wish to seek advice from the Information Commissioner.

Post: 18 Lower Lesson Street
Dublin 2, D02 HE97
Ireland

Tel: +353 1 639 5689

E-Mail: info@oic.ie

INFORMATION FOR CLINICAL RESEARCH PATIENTS

Privacy Policy

AventaMed has a duty to comply with the General Data Protection Regulation (GDPR), which requires that processing of your personal data is **fair**, **lawful** and **transparent**. This means we must:

- keep sufficient information to provide services and fulfil our legal responsibilities
- keep your records secure and accurate
- only keep your information as long as necessary
- collect, store and use the information you provide in a manner that is compatible with the data protection legislation

Furthermore, we have a legal obligation to respect the common law duty of confidentiality.

Using your Information for Research

Research has a vital role to play in the development of new medical device products. As a medical device company, AventaMed is obligated to gather clinical data on the safety and performance of their products before and after they have been brought to market. AventaMed is proactive in their pursuit of this clinical data and often conduct or support clinical research studies using their products.

Clinical research must be approved before it can take place. This approval is given by organisations independent of AventaMed. If we wish to use your personal information and health data for research, we would only do so with your explicit consent and will provide information beforehand regarding how your data will be processed.

Clinical research data held by AventaMed will almost always be coded or not contain any identifiable information; AventaMed will rarely be able to directly link clinical research data to you.

How Clinical Research Data is Used

AventaMed use clinical research data to:

- confirm their products perform as intended
- confirm their products are safe and do not cause harm to patients
- support marketing claims about our products

Sharing of Clinical Research Data

As a medical device company, AventaMed is regularly inspected by organisations whose job involves ensuring we follow all the regulations to produce safe and effective products. These organisations may request to view clinical research data held by AventaMed as part of their inspection. AventaMed may also need to share clinical research data with the organisations who approve medical devices for the market, to show them our product is safe and effective and is ready to be put on the market.

Clinical research data shared by AventaMed with such organisations will, where appropriate, always be coded or not contain any identifiable information; these organisations will not be able to link clinical research data directly to you. Furthermore, these organisations have a legal obligation to respect the common law duty of confidentiality, and often their staff are contractually bound to this obligation through their terms and conditions of employment.

Use of Clinical Research Data for other Purposes

AventaMed will not disclose your clinical research data to any other third parties or commercial companies without your consent unless we are required to report information. In such instances, and where appropriate, AventaMed will always take the necessary steps to ensure your clinical research data cannot be traced back to you.

AventaMed may also use unidentifiable clinical research data to:

- receive funding
- manage and plan our products
- help investigate concerns or complaints that patients or healthcare workers may have

Storing Clinical Research Data

AventaMed, as a medical device company, is obligated to store and retain documents for a defined period of time. This policy may vary for clinical research data but will always be for at least 15 years.

Keeping Clinical Research Data Secure and Confidential

You have the right to confidentiality. This right is legally protected and everyone working in AventaMed has a legal duty to keep clinical research data confidential.

Clinical research data is held in secure systems in both paper and electronic format. Electronic files are held on password protected systems, with the files themselves password protected; both passwords are different. Paper files are held in locked cabinets. Only AventaMed

employees who need to have access to clinical research data to carry out their job will know these passwords or have access to these cabinets.

Transferring Clinical Research Data

Very occasionally clinical research data may be transferred outside of the Republic of Ireland and the EU. If this is necessary for regulatory purposes, the receiving organisation has a legal obligation to respect the common law duty of confidentiality, and often their staff are contractually bound to this obligation through their terms and conditions of employment.

If done for other purpose, it will be done so under contract, and a data processing agreement will stipulate the required protection required under data protection laws.

Clinical research data transferred by AventaMed will, where appropriate, be coded or not contain any identifiable information; the clinical research data will not be linked back to you.

Your Rights

GDPR affords participants of clinical research a number of rights in relation to the information held about them, with clinical research data considered a “special” data category. These rights are explained above.

Upon request we will inform you whether your personal data is processed by AventaMed and will send you a copy of that data. It is important to remember, however, that AventaMed may not be able to directly link clinical research data to you as it may be coded or not contain any identifiable information. It may be necessary to make a request for information through you study doctor.

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Magnetic Resonance Safety Information

If you have been treated with the AventaMed Solo+ Tympanostomy Tube Device (TTD) and you require Magnetic Resonance Imaging (MRI) while the tube(s) are still in your ear, the below MR Safety Information is important to share with your healthcare team. Your healthcare team will understand this information. You are not expected to understand this information.

MR Safety Information:

Non-clinical testing has demonstrated that the tympanostomy tube of the Solo+ TTD is **MR Conditional**. A patient implanted with the Solo+ TTD tympanostomy tube may be safely scanned under the conditions outlined below. Failure to follow these conditions may result in injury to the patient. If information about a specific parameter is not included, there are no conditions associated with that parameter.

Nominal value(s) of Static Magnetic Field	1.5 T or 3 T
Maximum Spatial Field Gradient:	7.2 T/m (720 gauss/cm)
RF Excitation	Circularly Polarized (CP)
Maximum Whole Body SAR	4.0 W/kg
Limits on Scan Duration	4.0 W/kg whole body average SAR for 1 hour of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artefact	The presence of this implant may product an image artefact of 12mm