**Safety Disclosure**

This notification serves as a safety disclosure for the [Device Name], a medical device intended exclusively for research purposes. The [Manufacturer Name] acknowledges that, as of [Date], the device has not undergone review and clearance or approval by the U.S. Food and Drug Administration (FDA) for commercial distribution and use.

**Important Safety Information:**

**Research-Only Purpose:** The devices discussed on this site are exclusively intended for research purposes and are not cleared or approved by the FDA for clinical use or commercial distribution. It is solely available to researchers and research institutions.

**Lack of FDA Review:** The safety and effectiveness of these devices have not been established through the FDA's formal review process. Researchers should be aware that the device has not undergone the regulatory scrutiny required for general medical use.

**Risk Awareness:** The potential risks associated with these devices are not fully known. Researchers and research institutions are advised to exercise caution and fully inform all involved parties about the investigational nature of the device and the uncertainties surrounding its safety and efficacy.

**Informed Consent:** Researchers using these devices are responsible for obtaining informed consent from participants, clearly communicating the experimental nature of the device and any potential risks associated with its use.

**Monitoring and Reporting:** Researchers are urged to closely monitor the use of these devices during research activities and promptly report any adverse events or unexpected side effects to Openwater [**safety@openwater.cc**](mailto:safety@openwater.cc)**.** This information is crucial for ongoing evaluation and refinement of these devices.

**Restricted Use:** These devices should be confined to research settings and not used in clinical practice or commercial applications. Their use should be limited to researchers and research institutions with the expertise to manage and monitor the investigational nature of the device.

For inquiries or additional information, please contact [info@openwater.cc](mailto:info@openwater.cc)