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Contact Person: I. Kaufman Arenberg, MD
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Trade Name: Round Window μ Cath™ (RWμC)
Common Name: Middle Ear Catheter
Classification Name: Class II

Equivalence: The RWμC is substantially equivalent to the combination of the middle ear catheter and the tympanostomy tube. Both the RWμC and the middle ear catheter are catheters with a fenestrated reservoir tip on the distal end; both are designed to be attached to a syringe at the proximal end; and both are intended to be used to irrigate the middle ear. Both the RWμC and the vent tube allow air to pass between the middle ear and ear canal. This air passage serves to aerate the middle ear, thereby reducing the risk of middle ear infection. The RWμC and the vent tube are also similar in that they are intended to be left in place for longer periods of time than the middle ear catheter (the vent tube for up to a year, and the for up to 14 days).

Description: The RWμC consists of a double lumen (two parallel and attached Tecoflex 80A (polyurethane) extruded tubes) opening into a common fenestrated reservoir tip on the distal end. The soft, flexible reservoir tip of the RWμC will be available in three sizes: 2mm, 3mm, and 4mm diameters. It is intended that the surgeon will choose an appropriate sized tip to fit the anatomy of the patient (for background information about the anatomy in the Round Window Niche See Appendix 7). The double lumen is bent at approximately a 60-75 degree angle slightly proximal to the reservoir tip. One lumen is intended to serve as an in-flow and the other an out-flow. The outflow lumen is intended to (1) relieve or avoid a build up of air and/or fluid pressure in the device; and (2) facilitate the removal of fluid from the device. A silicone, paparella-type vent tube will be placed around the RWμC during manufacturing.

Intended use: The Round Window μ Cath™ (RWμC) is intended to be used by any board certified otolaryngologist or otologist to irrigate the entire middle ear or the round window area of the middle ear. During the course of the irrigation treatment, it is intended that the vent tube through which the RWμC's dual lumen passes, will aerate the middle ear. The treating physician will choose, based on what he/she feels will be most beneficial for his/her patient, the following: (1) the exact fluids to be delivered through the RWμC; (2) the proper quantities; and (3) the duration and interval of treatment (up to 14 days). It is intended that the physician load the RWμC with the initial fluid to be delivered prior to placement. The RWμC is intended to remain in place for up to 14 days. Neuro-Biometrix, Inc. recommends the physician use only fluids indicated for this use. The physician should refer to the fluid labelling prior to use with the RWμC.

Principles of Operation: The distal end of the RWμC is a soft, flexible, fenestrated-reservoir tip which is designed to allow the surgeon to irrigate various locations in the middle ear. For example, the surgeon can (1) irrigate the middle ear generally by placing the tip in the middle ear space and applying the fluid with a syringe; (2) irrigate the round window area specifically by placing the appropriately sized tip in the round window niche; or (3) place the tip anywhere else in the middle ear he/she feels is appropriate. The RWμC's double lumen runs from the reservoir tip back through a ventilation tube in the ear drum and into the external ear canal where the proximal end will be accessible to the treating physician.

Technological Characteristics: The RWμC and the predicate devices, the Microtek Irrigation System and the tympanostomy tube are constructed of class VI biocompatible materials (even though the materials are different). Each has been subjected to biocompatibility testing.

Performance Testing: A bench test protocol was developed to assess the performance of the RWμC in terms of pressure vs. flow, distal tip bond strength, tensile strength of the catheter body, and proximal hub bond strength. All tests will be conducted on final sterile product. Sufficient samples will be used for each test. Each sample will also be visually inspected for workmanship and dimensional compliance.