

## Atos Medical Products and Hyperbaric Oxygen Suitability Statement

Atos Medical & Tracoe products are manufactured using nonflammable materials, including hospital-grade silicone and fluoroplastic. Most Atos Medical voice prostheses and accessories do not contain metallic components; however, certain products such as the Provox ActiValve do incorporate magnets as part of their design.

Atos Medical has not conducted safety and efficacy testing of its products in hyperbaric oxygen (HBO) environments, as this is not a regulatory, compliance, or quality requirement for these devices. Because our products have not been evaluated under hyperbaric conditions, Atos Medical cannot provide guidance or recommendations regarding their use during HBO therapy.

If questions arise regarding the suitability of any Atos Medical or Tracoe product for use in a hyperbaric chamber, we advise that the treating physician and/or the Hyperbaric Safety Officer review the product Instructions for Use (IFU) and make a clinical determination based on the individual patient situation and the specific requirements of the HBO treatment.

Instructions for Use for all Atos Medical products are available at:

<https://www.atosmedical.us/ifu-instructions-for-use/>

Technical Data for all Atos Medical products are available at: [Atos Medical | Regulatory Information - Atos Medical](#)

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