



GENERAL DISCLAIMER

AQUAGOLD® is a medical device and not a drug or a biologic. We do not offer indications or treatment options based on skin conditions. We are not affiliated with any third party brand. We do not recommend or suggest pricing to medical providers. We are not responsible for any treatment outcomes. All questions and concerns should be directed to the medical professional administering the treatment. AQUAGOLD® does not come prefilled and/or with any kind of a solution, it comes as an empty vial and a micro-channel mechanism to be attached onto the vial. It is at the full discretion of the medical professional to fill the vial at their own risk and liability. Any questions as to the solutions must be addressed with the medical professionals.

In an effort to assist patients and medical professionals in identifying medical resources, certain third parties may be mentioned and may provide a link to those third party websites. AQUAVIT MAKES NO WARRANTIES OR REPRESENTATIONS, AND EXPRESSLY DISCLAIMS ANY RESPONSIBILITY FOR THE INFORMATION OR TREATMENT THAT YOU MAY RECEIVE FROM ANY HEALTHCARE PROVIDER.

APPROVED USES

Patients should consult their medical provider for more information.

Medical professionals should be aware that AQUAGOLD® fine touch™ is Medical Device Class I.

(a) Identification. A manual surgical instrument for general use is a nonpowered, hand-held, or hand-manipulated device, either reusable or disposable, intended to be used in various general surgical procedures. The device includes the

applicator, clip applier, biopsy brush, manual dermabrasion brush, scrub brush, cannula, ligature carrier, chisel, clamp, contractor, curette, cutter, dissector, elevator, skin graft expander, file, forceps, gouge, instrument guide, needle guide, hammer, hemostat, amputation hook, ligature passing and knot-tying instrument, knife, blood lancet, mallet, disposable or reusable aspiration and injection needle, disposable or reusable suturing needle, osteotome, pliers, rasp, retainer, retractor, saw, scalpel blade, scalpel handle, one-piece scalpel, snare, spatula, stapler, disposable or reusable stripper, stylet, suturing apparatus for the stomach and intestine, measuring tape, and calipers. A surgical instrument that has specialized uses in a specific medical specialty is classified in separate regulations in parts 868 through 892.

(b) Classification. Medical Device Class I (general controls). Subchapter H › Part 878 › Subpart E › Section 878.4800 Manual surgical instrument for general use. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 878.9.

AQUAGOLD