September 15, 2025

RE: Scientific Information on Unapproved Uses Communication to Healthcare Providers Regarding the Off-Label Use of the Orca Foam® Absorbable Gelatin Sponge Hemostat, U.S.P., an FDA-Cleared Product

Dear User of Orca Foam® Absorbable Gelatin Sponge Hemostat, U.S.P.:

This Scientific Information on Unapproved Uses (SIUU) communication is consistent with the recommendations in FDA's Guidance *Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products; Questions and Answers* issued in January 2025, and is for the purpose of providing healthcare providers (HCPs) with scientific information about known off-label uses of Orca Foam® Absorbable Gelatin Sponge Hemostat, U.S.P. (ORCA FOAM).

Recent observations and reports have indicated an increased interest in the use of ORCA FOAM outside its original cleared intended use[1], prompting further evaluation and discussion within the clinical community.

The current intended use of ORCA FOAM is "to control minimal bleeding by tamponade effect, blood absorption and platelet aggregation following [Otolaryngology] ENT surgery" and is indicated for use "during and after ENT procedures in intra cranial, middle ear, intra oral, intra nasal, laryngeal, and head & neck soft tissue procedures to achieve hemostasis by tamponade effect."

Any other uses of ORCA FOAM have not been cleared or approved by FDA.

ORCA FOAM is contraindicated for those who have known allergies to porcine products and should not be used to in closures of skin incisions, as it may interfere with healing.

ORCA FOAM should not be used:

- if the package has been opened or damaged;
- with antibiotics in infected wounds
- embedded in a contaminated wound without drainage;
- for controlling postpartum bleeding or menorrhagia;

[1] ORCA Foam IFU.pdf

- in bleeding from large arteries to avoid embolization.

Anticoagulants may extend time to hemostasis and ORCA FAOM should not be re-sterilized since it is intended for single use only.

This communication is not intended to endorse or promote the use of ORCA FOAM outside of its cleared Intended Use, but in alignment with FDA, Orca Products, LLC, recognizes the importance of disseminating accurate and scientifically sound information to HCPs so they can better exercise comprehensive clinical judgment. While the safety and effectiveness of ORCA FOAM for uncleared uses has not been established, Orca Products, LLC, offers real world data (RWD) and real-world evidence (RWE) supporting its safety and effectiveness for off-label uses in surgeries outside of ENT procedures.

RWD are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources, and RWE is the clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD.[2, 3]

Orca Products, LLC remains committed to transparency and patient safety; an extensive literature search including FDA's Manufacturer and User Facility Device Experience (MAUDE) database and other available databases, no adverse events (AEs) have been reported related to the use of ORCA FOAM on- or off-label since its clearance in 2006.

We would like to take the opportunity to provide HCPs with truthful and non-misleading scientific and medical information to assist in making more informed decisions on whether to use or prescribe ORCA FOAM for an uncleared use based on your medical judgment. We believe that sharing well-substantiated information regarding potential uncleared uses may be valuable for advancing medical knowledge and improving outcomes. It is in this spirit of collaboration and commitment to real world evidence (RWE)-based practice that we provide the following information for your consideration.

Again, this communication and the attached Appendices are not intended to influence clinical practice decisions on conclusions about the safety or efficacy of ORCA FOAM uses

[2] Real-World Evidence | FDA
[3] Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices | FDA

outside of ENT surgeries but rather to inform you on the RWD and RWE that can inform your decisions, and we hope you find it helpful to that end.

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Appendix A

Publications/Published Scientific or Medical Journal Articles (Reprints)

Esposito F, Cappabianca P, Angileri FF, et al. Gelatin-thrombin hemostatic matrix in neurosurgical procedures: hemostatic effectiveness and economic value of clinical and surgical procedure-related benefits. *J Neurosurg Sci*. 2020;64(2):158-164. doi:10.23736/S0390-5616.16.03771-1PMID: 27456032 DOI: 10.23736/S0390-5616.16.03771-1

U.S. Food and Drug Administration (FDA) Executive Summary Prepared for the May 31, 2019 Meeting of the General and Plastic Surgery Devices Panel Reclassification of Absorbable Collagen-Based Hemostatic Devices; GPSDP-05.31.19-FDA-Executive-Summary Reclassification of Absorbable Sponges.pdf

Irfan NI, Mohd Zubir AZ, Suwandi A, Haris MS, Jaswir I, Lestari W. Gelatin-based hemostatic agents for medical and dental application at a glance: A narrative literature review. *Saudi Dent J*. 2022 Dec;34(8):699-707. doi: 10.1016/j.sdentj.2022.11.007.

Kobatake K, Mita K, Kato M. Effect on hemostasis of an absorbable hemostatic gelatin sponge after transrectal prostate needle biopsy. *Int Braz J Urol*. 2015 Mar-Apr;41(2):337-43. doi: 10.1590/S1677-5538.IBJU.2015.02.22

MacDonald MH, Zhang G, Tasse L, Wang D, De Leon H, Kocharian R. Hemostatic efficacy of two topical adjunctive hemostats in a porcine spleen biopsy punch model of moderate bleeding. *J Mater Sci Mater Med*. 2021 Sep 30;32(10):127. doi: 10.1007/s10856-021-06586-8.

Makhija D, Rock M, Xiong Y, Epstein JD, Arnold MR, Lattouf OM, Calcaterra D. Cost-consequence analysis of different active flowable hemostatic matrices in cardiac surgical procedures. *J Med Econ*. 2017 Jun;20(6):565-573. doi: 10.1080/13696998.2017.1284079.

Özer A, Köstü B. Use of Gelatin Sponge Affects Postoperative Morbidity In Cesarean Section Patients. *Med Sci Monit*. 2017 Mar 4;23:1141-1145. doi: 10.12659/msm.899860.

Ramirez MG, Niu X, Epstein J, Yang D. Cost-consequence analysis of a hemostatic matrix alone or in combination for spine surgery patients. *J Med Econ*. 2018 Oct;21(10):1041-1046. doi: 10.1080/13696998.2018.1513261.

Saif R, Jacob M, Robinson S, Amer A, Kei-Hui D, Sen G, Manas D, White S. Use of fibrin-based sealants and gelatin-matrix hemostats in laparoscopic liver surgery. *Surg Laparosc Endosc Percutan Tech*. 2011 Jun;21(3):131-41. doi: 10.1097/SLE.0b013e31821db688.

Samudrala S. Topical hemostatic agents in surgery: a surgeon's perspective. *AORN J*. 2008 Sep;88(3):S2-11. doi: 10.1016/S0001-2092(08)00586-3.

Schonauer C, Tessitore E, Barbagallo G, Albanese V, Moraci A. The use of local agents: bone wax, gelatin, collagen, oxidized cellulose. *Eur Spine J*. 2004;13 Suppl 1(Suppl 1):S89-S96. doi:10.1007/s00586-004-0727-z

Slezak P, Heher P, Monforte X, Keibl C, Redl H, Spazierer D, Gulle H. Efficacy of Topical Hemostatic Agents: A Comparative Evaluation of Two Gelatin/Thrombin-Based Hemostatic Matrices in a Porcine Kidney Surgical Model. *J Invest Surg*. 2019 Nov;32(7):646-653. doi: 10.1080/08941939.2018.1447619.

Tsai KM, Kiu KT, Yen MH, Yen YC, Tam KW, Chang TC. Comparison the effect of gelatin sponge and epinephrine-soaked gauze for hemostasis and pain control after hemorrhoidal surgery. *Sci Rep*. 2023 Oct 21;13(1):18010. doi: 10.1038/s41598-023-45380-0.

Vyas KS, Saha SP. Comparison of hemostatic agents used in vascular surgery. *Expert Opin Biol Ther*. 2013 Dec;13(12):1663-72. doi:10.1517/14712598.2013.848193.

Wang X, Sheng Y, Wang Z, Wang W, Xia F, Zhao M, Han X. Comparison of different embolic particles for superior rectal arterial embolization of chronic hemorrhoidal bleeding: gelfoam versus microparticle. *BMC Gastroenterol*. 2021 Dec 14;21(1):465. doi: 10.1186/s12876-021-02046-3.

Appendix B

Published Clinical Reference Resources

Deopujari CE, Ambekar S, Yetukuri BR, Diyora B, Ghosh A, Krishnan P, Panigrahi M, Ranjan R, Raman C, Tyagi S, Vaishya S, Venkataramana N, Sinha VD, Paniker D, Das S. Expert panel recommendations for topical hemostatic agent use in varied bleeding sites and situations during neuro-spine surgeries. *J Clin Neurosci*. 2024 Feb;120:30-35. doi: 10.1016/j.jocn.2023.12.007. Epub 2024 Jan 3. PMID: 38176112.

Frantz, V. K. New Absorbable Hemostatic Agents, Bull. New York Acad. Med. 22:102-110, 1946. PMID: 21011158

Appendix C

Other Studies

Córdoba-Fernández A, Lobo-Martín A. Hemostatic Efficacy of Absorbable Gelatin Sponges for Surgical Nail Matrixectomy after Phenolization-A Blinded Randomized Controlled Trial. *J Clin Med*. 2022 Apr 26;11(9):2420. doi: 10.3390/jcm11092420.

Mathiasen RA, Cruz RM. Prospective, randomized, controlled clinical trial of a novel matrix hemostatic sealant in children undergoing adenoidectomy. *Otolaryngol Head Neck Surg*. 2004 Nov;131(5):601-5. doi: 10.1016/j.otohns.2004.05.025.

Xu D, Ren Z, Chen X, Zhuang Q, Sheng L, Li S. A randomized controlled trial on effects of different hemostatic sponges in posterior spinal fusion surgeries. *BMC Surg*. 2016 Dec 12;16(1):80. doi: 10.1186/s12893-016-0197-3.