

Aquamantys Bipolar Sealer

May 2024

Device Overview

Aquamantys bipolar sealers by Medtronic, are electro-surgical products that use radio frequency (RF) energy and saline instillation technology to seal soft tissue and control bleeding.[1] These sealers function at 100 degrees Celsius, which is a lower temperature than other electro-surgical devices.[1] These sealers are used in combination with a pump generator.[1] They are advertised for use in orthopedic, spine, surgical oncology, cardiac, neurosurgery, and thoracic specialties.[1]

FDA Approval

The Aquamantys Bipolar Sealer was approved by the FDA in 2022 (Linked [here](#)).[3] Indications for use include: “used in conjunction with the Aquamantys Pump Generator for delivery of RIF energy and saline for hemostatic sealing and coagulation of soft tissue and bone at the operative site.”[3]

Actions for Consideration



PARTNER

ENGAGE SUBJECT MATTER EXPERTS

Assess current utilization of device and engage key physician specialties including surgeons (ortho, CV, & ENT), nurses, value analysis leaders

CONSIDER GUIDELINES FOR USE

Develop ‘criteria for use’ guidelines sharing pricing & reimbursement information

UNDERSTAND CONCERNS

Continue conversations with key specialties, leverage physician peer to peer conversations to understand decision making



CONNECT

SEEK CLINICAL IMPACT

Review data & physician utilization by procedure to support improved quality of care and patient outcomes

CONDUCT ANALYSIS

Compare cost of device vs standard bipolar, include reimbursement and outcomes information to inform decision making

DETERMINE POPULATION

Work with key stakeholders to determine appropriate patient & procedures for utilization



COMMUNICATE

EDUCATE AND TRAIN

Provide information on available training & encourage hands on demonstrations (leveraging supplier support) to gain familiarity with the product

PLAN AHEAD

Share ‘criteria for use’ guidelines as well as data to support decision making with key stakeholders

FOLLOW-UP FOR FEEDBACK

Create on-going feedback loop for challenges, ideas, recognition of wins, & further opportunities for success

Clinical Insights: HealthTrust Physician Advisors

A panel of orthopedic, spine, gynecologic oncology, otolaryngology, and neurosurgeons within our HealthTrust Physician Advisor Network offered the following insight with regard to the use of Aquamantys bipolar sealers. [4]

Physician Advisor Insights



Cardiothoracic surgery

- Can be used in mammary takedown.
- More cumbersome and expensive than traditional electro-surgical devices.

Gynecologic oncology

- Has potential use in debulking procedures, especially if a liver resection is required.
- In this specialty, traditional devices are technologically superior.

Neurosurgery

- Can be used in lumbar or thoracic fusion.
- Use is determined by type of procedure and if patient is oozing during surgery.
- Works better with muscle.

Orthopedic surgery/Orthopedic spine

- Can be used in total Hip and lumbar spine surgery, total joints, microdiscectomy, revision surgeries.
- Cost can be prohibitive and most procedures can be done with traditional electro-surgical devices.
- Device selection is based on procedure.
- Used inside the spinal canal and avoids bipolar cautery.
- Advantages noted: less soft tissue damage, less chance for dural tear, also decreased dysphasia in anterior cervical discectomy and fusion, no heat transmitted to adjacent dura, efficiency in coagulation to speed up surgery in more complex cases, and smokeless.

Clinical Insights: HealthTrust Physician Advisors, *cont'd*

Physician Advisor Insights



Otolaryngology

- Used in parotidectomy, neck dissection, thyroidectomy.
- Assists in avoiding thermal injury to neighboring structures in procedures where nerve dissection is required, making bipolar useful.
- Aquamantys is beneficial as it uses saline irrigation to cool and protect neighboring tissue.

Overall

- Achieves hemostasis at a lower energy level with less smoke being generated.
- Not very practical for all surgical procedures and is limited to certain surgical specialties.
- Concern regarding cost versus revenue due to the added expense of Aquamantys.
- Expensive compared to traditional devices with equal efficacy and achieve similar outcomes.
- Cooling ability for tissues that heat with use of bipolar. It reduces tissue sticking on the tips of the bipolar, reducing the need to clean the tips throughout the surgery.
- There are a variety of handheld tip sizes.
- Aquamantys has set bipolar tips to optimize pretreating the tissue prior to incising it.
- Choice of use may be related to physician's personal preference.

Clinical Evidence

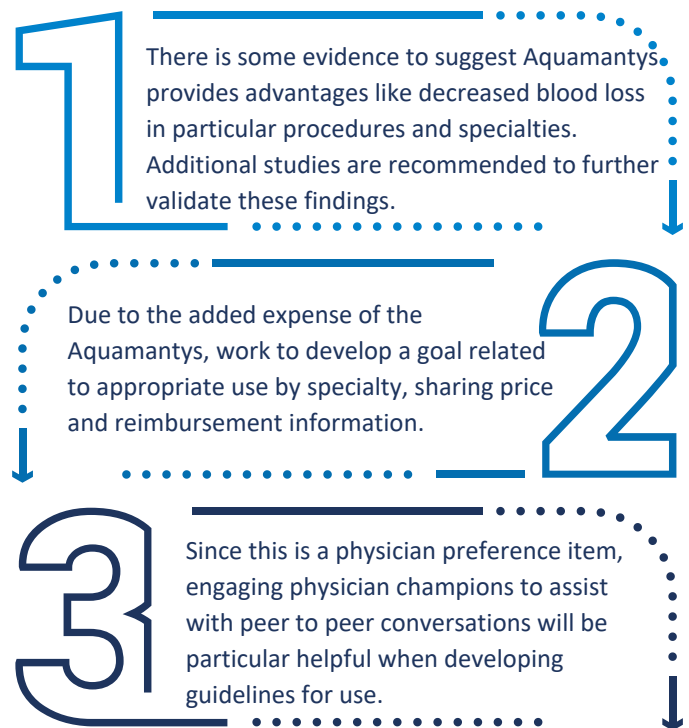
There are a few studies, greater than 5 years old, relating to the use of Aquamantys in specific procedures as well as comparison to traditional electro-surgical devices. A sampling of those studies is included below.

A 2016 meta-analysis of 6 randomized controlled trials (totaling 751 patients) studied effectiveness of bipolar sealers and the need for transfusion and amount of total blood loss in primary total hip surgery. Outcomes included the need for transfusion, blood loss (total, drainage, and intraoperative), and rates of infection. The analysis concluded that sealers were effective at decreasing the need for transfusion and the amount of total blood loss. However, there was no significant difference in intraoperative blood loss and blood loss in drainage.[5]

A 2017 retrospective study included 33 patients that were divided into two groups; one group that received surgery using the Aquamantys, and one group that did not. Results of the study found that the groups had similar operative times and no difference in mortality. However, the Aquamantys group required less transfusions ($P = 0.024$).[6]

A 2017 retrospective study of 43 patients was performed to determine the effectiveness of Aquamantys for interoperative hemostasis in surgery of skull base tumors.[7] This review found that the Aquamantys was effective at achieving hemostasis during this type of surgery. Additional studies comparing the use of the Aquamantys to other electro-surgical devices is recommended to further validate results.[7]

Summary



**See Reference section
for complete listing of
research sources.**

HealthTrust Clinical Resources

Allow us to connect you with the resources you need. Examples for this category include resources on value analysis and engaging physician champions.

ASK A QUESTION

PROVIDE YOUR FEEDBACK

SHARE YOUR VOICE

NETWORK WITH PEERS



PERSONALIZED REQUEST SERVICE & RESOURCE LIBRARY

www.hpginsights.com



PEER NETWORKING

www.huddle.healthtrustpg.com
App store: "HealthTrust Huddle"

References

1. Medtronic. Electrosurgical Products - Aquamantys Bipolar Sealers. Medtronic.com. Published 2014. <https://www.medtronic.com/us-en/healthcare-professionals/products/general-surgery/electrosurgical/aquamantys-bipolar-sealers.html>
2. Geller DA, Tsung A, Maheshwari V, Rutstein LA, Fung JJ, Marsh JW. Hepatic resection in 170 patients using saline-cooled radiofrequency coagulation. *HPB (Oxford)*. 2005;7(3):208-213
3. Food and Drug Administration. 510(k) Premarket Notification. www.accessdata.fda.gov. Accessed February 7, 2024. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K111732>
4. 2023 Physician Advisor Network: Aquamantys Bipolar Sealers Survey. Collected January 16th through January 31st 2024.
5. Min JK, Zhang QH, Li HD, Li H, Guo P. The Efficacy of Bipolar Sealer on Blood Loss in Primary Total Hip Arthroplasty: A Meta-Analysis. *Medicine (Baltimore)*. 2016;95(19):e3435. doi:10.1097/MD.0000000000003435
6. Caruana EJ, Kadlec J, Iyer S, Mani A, Solli P, Scarci M. The Aquamantys(®) system improves haemostasis and pneumostasis in open decortication for thoracic empyema. *J Thorac Dis*. 2016;8(7):1540-1545. doi:10.21037/jtd.2016.06.03
7. Bram R, Fiore S, McHugh D, Samara GJ, Davis RP. Hemostasis in endoscopic endonasal skull base surgery using the Aquamantys bipolar sealer: Technical note. *J Clin Neurosci*. 2017;41:81-85. doi:10.1016/j.jocn.2017.02.061