

Werewolf Bipolar Sealer by Smith & Nephew

May 2024

Device Overview

The Werewolf Coblation System and Fastseal 6.0 wand by Smith & Nephew, includes a controller and a wand that incorporates both Radio Frequency (RF) energy and saline to achieve hemostasis. [1] The peak temperature of these sealers is 96 degrees Celsius (C) (+/-3C), which is approximately 200 degrees cooler temperature than other electrosurgical devices, limiting tissue damage according to the supplier.[1] These sealers are used in combination with a pump generator.[1] They are advertised for use in open orthopedic procedures.[1]

FDA Approval

The Werewolf Coblation System’s (controller and Fastseal wand) most recent FDA approval in 2021 (linked [here](#)) includes indications for use as: “hemostasis via coagulation of soft tissue and bone in orthopedic procedures.” This includes the coblation system, controller, and Fastseal 6.0 Hemostasis Wand. [2]

Actions for Consideration



PARTNER

ENGAGE SUBJECT MATTER EXPERTS

Assess current utilization in total hip/knee procedures and engage key physicians (orthopedic), nurses, & value analysis leaders

CONSIDER GUIDELINES FOR USE

Develop ‘criteria for use’ guidelines if considering changing or adopting this technology, share pricing & reimbursement information

UNDERSTAND CONCERNS

Discuss concerns, 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, available training & encourage hands on demonstrations to gain familiarity with the product

PLAN AHEAD

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

FOLLOW-UP FOR FEEDBACK

Create on-going feedback loop and monitor utilization, outcomes, and physician experiences, address as needed

Clinical Insights: HealthTrust Physician Advisors

A panel of orthopedic and spine surgeons within our HealthTrust Physician Advisor Network offered the following insight with regard to the use of the Werewolf bipolar sealers.[3]

Physician Advisor Insights



- Can be used in total hip and knee procedures
- Not approved for use in spine or anterior vasculature
- May be helpful for big hip revision cases but may not be necessary for primary joint arthroplasty
- Infected total knees and hips may benefit from this type of technology
- Cost can be prohibitive and most procedures can be done with traditional electro-surgical devices
- For hips and knees this product is comparable to its competitor
- Not a product used on every case

Clinical Evidence

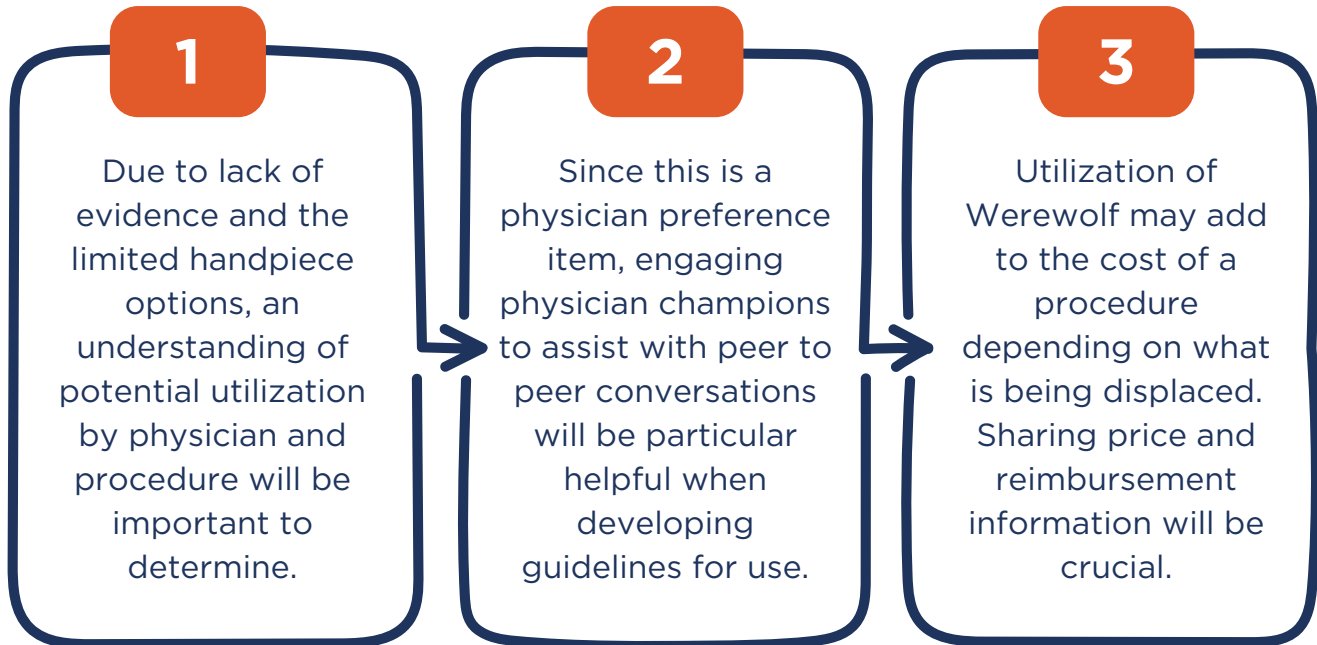
On the Clinical Trials.gov site, there is an clinical trial sponsored by Smith and Nephew that is active and not enrolling; therefore, results are not available or published at this time.[4] The purpose of the study is to show the effectiveness of the Werewolf Fastseal 6.0 Bipolar Sealer. [4]

A 2016 meta-analysis of 6 randomized controlled trials (totaling 751 patients) studied effectiveness of bipolar sealers and the need for transfusion including 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]



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

Summary



HealthTrust Clinical Resources

Allow us to connect you with the resources you need. Examples for this category include resources on value analysis and product trials. [6,7]

ASK A QUESTION

PROVIDE YOUR FEEDBACK

SHARE YOUR VOICE

NETWORK WITH PEERS



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References

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