Introduction and Methodology

This value analysis brief presents information on the design features and potential procedural benefits of using the DePuy Synthes Mitek Sports Medicine VAPR ARCTIC® Suction Electrode with COOLPULSE® Technology in patients requiring arthroscopic surgery of the hip. This device is intended for the resection, ablation, and excision of soft tissue as well as the coagulation and hemostasis of blood vessels during the arthroscopic procedure. The VAPR ARCTIC Suction Electrode is the first articulating bipolar suction electrode on the market and provides a rigid yet low-profile electrode for strength and maneuverability in the confined hip joint. Potential procedural benefits include:

- Excellent control and operating room convenience due to flexible design
- Fast and efficient tissue ablation
- Enhanced coagulation performance
- Reduced operating room time, leading to the potential for less procedural complications and cost savings

The referenced data for this value brief were obtained through a search of MEDLINE for current trends in arthroscopic hip surgery and biomechanical studies of radiofrequency electrode systems published in the last 5 years.

Note: The VAPR ARCTIC Suction Electrode is unique to DePuy Synthes Mitek Sports Medicine. Thus all studies referenced herein pertain directly to this technology.

Background

Hip arthroscopy is one of the most rapidly growing fields in orthopedic surgery. The number of hip arthroscopic procedures performed in the last decade has more than tripled.1,2 Advances in both surgical technique and instrumentation have allowed the evolution of hip surgery from an open procedure to an arthroscopic procedure, and have increased the complexity of conditions that can be treated in the central and peripheral compartments as well as the peritrochanteric space.

The use of radiofrequency energy probes in hip arthroscopy has gained popularity in recent years because of their ability to precisely remove (ablate) soft tissue as well as to simultaneously cut and coagulate vascular tissue.3,4 Radiofrequency devices work by generating a high frequency alternating electromagnetic current at the tip of the probe. The current flows into adjacent tissue and agitates intracellular and extracellular ions, thereby causing frictional heating of the tissue.4 Monopolar radiofrequency energy devices pass current from the active electrode in the probe to the return electrode, via a grounding pad on the patient. The current passes through the path of least resistance, heating mostly the tissue immediately below the active electrode probe.4 Bipolar radiofrequency energy devices pass current through two electrodes at the end of the probe and heating occurs at the tissue adjacent to the probe.4

Radiofrequency energy is indicated in hip arthroscopy for labral debridement and shaping, thermal capsulorraphy, thermal chondroplasty, synovectomy, and shrinkage of hypertrophic ligamentum teres.4 Although the use of radiofrequency energy probes in hip arthroscopy has been demonstrated to be safe and effective, radiofrequency devices can cause elevation of the fluid temperature both in and out of the joint, depending on a number of variables including the volume of fluid in the joint, the duration of use, and the flow rates of irrigation through the joint.3 If these variables are not properly controlled during the arthroscopic procedure, the heated irrigation fluid can lead to a variety of complications such as nerve injury, capsular tissue damage, dermal burn, and possibly, chondrolysis.3,5,6,7

There are a number of important factors to consider when evaluating radiofrequency energy probes for hip arthroscopy procedures. These factors include:

- Efficiency and rate of targeted tissue removal (ablation)
- Ability to precisely coagulate vascular tissue
- Risk of accidental damage to healthy tissue
- Access to hard-to-reach places in hip anatomy
- Ability to remove bubbles, debris, and heated saline
- Strength and maneuverability in the confined hip joint
The VAPR ARCTIC Suction Electrode addresses the clinical needs of today’s hip arthroscopic surgeons due to its:

- Long articulation length and large articulation range
- 3.4 mm shaft diameter
- Bipolar radiofrequency (with COOLPULSE Technology)
- Integrated suction
- Ergonomic handle and articulation lever design

These design elements translate into a number of potential procedural benefits to various stakeholders.

Potential Procedural Benefits

Flexible design offers excellent control and operating room convenience

As a result of the physical constraints of the hip joint, radiofrequency energy probes must be long and flexible to access many areas of the joint that are inaccessible with conventional instruments. The VAPR ARCTIC Suction Electrode is the first articulating bipolar suction electrode on the market and offers a variety of design features for operating room convenience (Figure 1).

Figure 1. VAPR ARCTIC Suction Electrode

- Long articulation length and large articulation range (110°) allows surgeons access to hard-to-reach spaces in the hip anatomy that are not readily available with fixed-angle electrodes
- 3.4 mm shaft diameter provides a rigid yet low-profile electrode for strength and maneuverability in the confined hip joint
- Bipolar radiofrequency eliminates need to purchase a separate patient grounding pad.
- Integrated suction removes bubbles, debris and heated saline to promote a clear and sustained field of view
- Ergonomic handle and articulation lever design provides comfort and multiple grip positions

Overall, these design features of the VAPR ARCTIC Suction Electrode provide the surgeon with the efficiency, clarity, and comfort of a fixed-angle electrode.

Fast and efficient tissue ablation

Tissue removal rate in arthroscopic procedures is an important factor in determining surgical efficiency and procedure duration. A recent study was undertaken by DePuy Synthes Mitek Sports Medicine to evaluate the in vitro ablation performance of the VAPR ARCTIC Suction Electrode and the Smith & Nephew Dyonics® EFLEX® Ablator® Probe.

The Eflex® Probe is an articulating radiofrequency monopolar electrode without integrated suction. Bovine ligament tissue was used to measure tissue removal rate. Ligaments were weighed before and after ablation to determine the amount of tissue removed during a 60 second period. The ablation sample size was 15 repetitions for each electrode type. The results of this study showed that the VAPR ARCTIC Suction Electrode ablated over three times more ligament per minute than the Eflex® Probe (p<0.05) (Figure 2).

Figure 2. In Vitro Ablation Performance of the VAPR ARCTIC Suction Electrode and Eflex® Probe

The mean ablation rates for the VAPR ARCTIC Suction Electrode and the Eflex® Probe were 0.38 grams per minute (SD = 0.09) and 0.12 grams per minute (SD = 0.07), respectively. Overall, the results of this study demonstrate that the VAPR ARCTIC Suction Electrode displays improved ablation performance versus the Eflex® Probe in the in vitro setting. Further research should aim to validate these findings in the clinical setting since issue removal rate may have a substantial impact on procedure duration.
Enhanced coagulation performance

Today’s arthroscopic procedures are increasingly complex. Manipulation of devices and surgical instruments in a confined joint space requires skill and a clear surgical field. Orthopedic surgeons have been quick to recognize that visualization is key to a successful arthroscopic procedure. In addition to ablation, radiofrequency energy probes can also be used to simultaneously cut and coagulate vascular tissue. Enhanced coagulation performance allows for faster hemostasis of small blood vessels, which can “red out” or obscure the arthroscopic field.

A recent study was undertaken by DePuy Synthes Mitek Sports Medicine to evaluate the in vitro coagulation performance of the VAPR ARCTIC Suction Electrode, the Efлекс® Probe, and the ArthroCare® HipVac® 50 Probe. The HipVac® 50 Probe is a fixed angle radiofrequency bipolar electrode. Porcine kidney tissue was used to measure the coagulation efficiency by area of the thermal margin of a lesion. The ratio of the areas of each paired test was recorded to remove effects of tissue variation. A larger area of thermal margin is indicative of enhanced coagulation efficiency. The results of this study showed that the VAPR ARCTIC Suction Electrode displays enhanced coagulation performance versus both the EFLEX Probe and HipVac 50 Probe (Figure 3).

Figure 3. In Vitro Coagulation Performance of the VAPR ARCTIC Suction Electrode, Efлекс® Probe, and HipVac® 50 Probe

<table>
<thead>
<tr>
<th>Electrode Comparison</th>
<th>Area of Thermal Margin</th>
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<tbody>
<tr>
<td>VAPR ARCTIC Electrode vs. Efлекс® Probe (1 Second)</td>
<td>9.5</td>
</tr>
<tr>
<td>VAPR ARCTIC Electrode vs. HipVac® 50 Probe (1 Second)</td>
<td>7.2</td>
</tr>
<tr>
<td>VAPR ARCTIC Electrode vs. Efлекс® Probe (3 Seconds)</td>
<td>1.7</td>
</tr>
<tr>
<td>VAPR ARCTIC Electrode vs. HipVac® 50 Probe (3 Seconds)</td>
<td>0.73</td>
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Note: A larger area of thermal margin is indicative of enhanced coagulation efficiency

In the one-second coagulation test, the VAPR ARCTIC Electrode produced a 9.5 times greater area of thermal margin than the Efлекс® Probe, while this ratio was reduced to 1.7 for the longer three-second test. Similarly, the VAPR ARCTIC Electrode produced a 7.2 times greater area of thermal margin than the HipVac® 50 probe for the one-second test, while this ratio was reduced to 0.73 for the longer three-second test. Overall, the results of this study demonstrate that the VAPR ARCTIC Suction Electrode displays enhanced coagulation performance versus both the Efлекс® Probe and HipVac® 50 probe in the in vitro setting.

Reduced operating room time, leading to the potential for less procedural complications and cost savings

Arthroscopic treatment for hip pathologies remains one of the most challenging aspects of sports medicine. Access to the hip is much more difficult than access to other joints because of the highly constrained nature of the joint. Surgeons typically use a system similar to a standard traction fracture table in order to distract the hip and give access to the central compartment. Attention to traction time is imperative to allow for the sufficient management of the hip pathology. Traction-related injuries account for the majority of hip arthroscopy complications reported in the literature, and most of these are nerve injuries from prolonged traction time. Other complications reported from prolonged traction include scrotal necrosis, vaginal laceration, and erectile dysfunction. Minimizing these traction-related complications involves using the least magnitude of traction force required for adequate distraction as well as limiting the total time under traction (to less than two continuous hours). Thus, employing strategies that reduce the total time under traction may help reduce the rate of hip arthroscopy complications.

A recent survey of orthopedic surgeons was undertaken by Mitek Sports Medicine to estimate the total usage time (operating room time) for the VAPR ARCTIC Suction Electrode in patients requiring arthroscopic surgery of the hip. This product evaluation survey was completed by 14 surgeons and accounted for 65 cases between September and December 2014. The results of the survey showed that the average utilization time for the VAPR ARCTIC Suction Electrode during hip arthroscopy was 9.8 minutes (range 7.4 to 60 minutes). If it assumed that the ablation time for hip procedures may sometimes take up to 30 minutes, then applying the survey results to the clinical setting could potentially achieve an operating room time savings of about 20 minutes per procedure (calculation: 30 minutes minus 9.8 minutes). The validity of this assumption is supported by the results from the in vitro setting where the VAPR ARCTIC Suction Electrode ablated over three times more ligament per minute than a competitor probe. Consequently, a reduction in total patient time under traction time from a faster ablation probe may lead to a lower rate of hip arthroscopy complications.

The potential reduction in operating time from using the VAPR ARCTIC Suction Electrode instead of other radiofrequency electrodes may have economic implications as well. Assuming the cost of operating time is about $54 per minute for orthopedic procedures, then the estimated cost savings from a reduction in procedure time by 20 minutes would be about $1,080 per procedure. Additional cost savings also may be achieved if there was a reduction in the rate of procedural complications due to less traction time.
Conclusions

Overall, the VAPR ARCTIC Suction Electrode addresses the clinical needs of today’s hip arthroscopic surgeons with its ability to precisely remove soft tissue, simultaneous cut and coagulate vascular tissue, access hard-to-reach places in the hip anatomy, remove bubbles, debris, and heated saline, and provide strength and maneuverability in the confined hip joint. It is the first articulating bipolar suction electrode on the market yet provides the efficiency, clarity, and comfort of a fixed angle electrode. The fast ablation rate and enhanced coagulation performance observed in the in vitro setting may lead to a reduction in operating room time and potential cost savings. Further research should aim to validate these findings in the clinical setting.

Citations

**Mitek Sports Medicine:**

Limited Warranty and Disclaimer: DePuy Mitek, Inc. products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: USA Law restricts these devices to sale by or on the order of a physician.


Not all products are currently available in all markets.

**Indication for Use:** The VAPR ARCTIC® Suction Electrode for use with the VAPR VUE® Radiofrequency Electrode System is intended for resection, ablation and excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissue in patients requiring arthroscopic surgery of the hip. Please refer to the package insert for a complete list of indications, contraindications, precautions and warnings. For further information on DePuy Synthes products, please contact your local DePuy Synthes representative.