VALUE ANALYSIS BRIEF

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® TRIPOLAR 90 Suction Electrode with COOLPULSE® Technology in patients requiring arthroscopic surgery. 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 TRIPOLAR 90 Suction Electrode is the first hand-controlled tripolar suction electrode on the market. The proprietary tripolar tip design maintains an ideally positioned return to optimize the ablation energy field and another ideally positioned return to optimize the coagulation energy field. Potential procedural benefits include:

- Excellent control and operating room convenience
- Fast and efficient tissue ablation
- Enhanced coagulation performance
- Lower saline outflow temperature, which may reduce risk of damage to healthy tissue
- Reduced operating room time, leading to the potential for cost savings

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

Note: The VAPR TRIPOLAR 90 Suction Electrode is unique to DePuy Synthes Mitek Sports Medicine. Thus all studies referenced herein pertain directly to this technology.

Background

The use of radiofrequency energy probes in 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.\(^1\)\(^2\) 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.\(^2\) 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.\(^2\) 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.\(^2\) In the design of bipolar radiofrequency electrodes, compromises in geometry were required to accommodate both the ablation and coagulation functions. The innovative and new tripolar design independently optimizes ablation and coagulation through the use of one active and two return components, all in a single 90-degree fixed angle radiofrequency energy device.

There are a number of important factors to consider when evaluating radiofrequency energy probes for 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
- Ability to remove bubbles, debris, and heated saline
- Control and visualization in the confined joint

The VAPR TRIPOLAR 90 Suction Electrode addresses the clinical needs of today’s arthroscopic surgeons due to its:

- Proprietary tripolar tip design
- Independently optimized ablation and coagulation
- Integrated suction
- Integrated flow control
- 360° sets of hand controls

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

**Tripolar design offers excellent control and operating room efficiency**

The VAPR TRIPOLAR 90 Suction Electrode is the first hand-controlled tri-polar suction electrode on the market and offers a variety of design features for operating room efficiency and convenience (Figure 1).

**Optimization:** Proprietary tripolar tip design with 3 poles and 2 dedicated returns maintains an ideally positioned return to optimize the ablation energy field and another ideally positioned return to optimize the coagulation energy field.

**Efficiency:** Independently optimized ablation and coagulation means no performance trade-off, regardless of setting.

**Clarity:** Integrated suction allows for the removal of bubbles, debris and heated saline directly from the joint space while the integrated flow control can better assess bleeders and improve visualization.

**Comfort:** 360° sets of hand controls for comfortable operation in any orientation.

Overall, these design features of the VAPR TRIPOLAR 90 Suction Electrode provide the surgeon with the efficiency, comfort, and clarity needed for arthroscopic procedures in the confined joint space.

**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 its VAPR TRIPOLAR 90 Suction Electrode with COOLPULSE Technology versus the ArthroCare® Ambient® Super TurboVac® 90 Electrode with Coblation® Technology.  

The Ambient® Super TurboVac® 90 Electrode is a 90-degree fixed angle radiofrequency electrode with integrated suction and ablation/coagulation hand controls. 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 36 repetitions for each electrode type. The results of this study showed that the VAPR TRIPOLAR 90 Suction Electrode ablated 22% more ligament tissue per minute than the Ambient® Super TurboVac® 90 Electrode (Figure 2).

![Figure 2. In Vitro Ablation Performance of the VAPR TRIPOLAR 90 Suction Electrode and Ambient® Super TurboVac® 90 Electrode](https://example.com/image-url)
The mean ablation rates for the VAPR TRIPOLAR 90 Suction Electrode and the Ambient® Super TurboVac® 90 Electrode were 1.30 grams per minute (SD = 0.16, n=35) and 1.04 grams per minute (SD=0.16, n=36), respectively. Overall, the results of this study demonstrate that the VAPR TRIPOLAR 90 Suction Electrode displays improved ablation performance versus the Ambient® Super TurboVac® 90 Electrode in the in vitro setting. Further research should aim to validate these findings in the clinical setting since tissue 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 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 TRIPOLAR 90 Suction Electrode and the Ambient® Super TurboVac® 90 Electrode. Porcine kidney tissue was used to measure the coagulation efficiency by area of the thermal margin of a lesion. Pairs of lesions were produced by each electrode side by side on the same sample tissue. 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 sample size for the coagulation test was 20 repetitions for each electrode. The results of this study showed that the VAPR TRIPOLAR 90 Suction Electrode displays enhanced coagulation performance versus Ambient® Super TurboVac® 90 Electrode (Figure 3). In the one-second coagulation test, the VAPR TRIPOLAR 90 Suction Electrode produced a 5.4 times greater area of thermal margin than the Ambient® Super TurboVac® 90 Electrode (SD=1.3; p<0.05), while this ratio was reduced to 1.09 for a longer three-second test (SD=0.17; p<0.05). Overall, the results of this study demonstrate that the VAPR TRIPOLAR 90 Suction Electrode displays enhanced coagulation performance versus the Ambient® Super TurboVac® 90 Electrode in the in vitro setting.

**Lower saline outflow temperature may reduce the risk of damage to healthy tissue**

Although the use of radiofrequency energy probes in 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. If these variables are not properly controlled during the procedure, the heated irrigation fluid can lead to a variety of complications such as nerve injury, capsular tissue damage, dermal burn, and possibly, chondrolysis.

A recent study was undertaken by DePuy Synthes Mitek Sports Medicine to evaluate the in vitro saline outflow temperature of the VAPR TRIPOLAR 90 Suction Electrode and the Ambient® Super TurboVac® 90 Electrode. During the ablation phase, the saline outflow temperature from the electrodes was measured using a Luxtron Fluoroptic™ temperature probe. The results of the study showed that the mean outflow temperature rise for the Ambient® Super TurboVac® 90 Electrode was significantly greater (40°) than for the VAPR TRIPOLAR 90 Suction Electrode (28°) (p<0.05). If these results were applied to the clinical setting, then a lower saline outflow temperature for the VAPR TRIPOLAR 90 Suction Electrode may potentially reduce the risk of damage to healthy tissue compared to competitor radiofrequency energy probes.

**Reduced operating room time, leading to the potential for cost savings**

The rate and efficiency of tissue removal as well as enhanced coagulation during arthroscopic procedures may have a significant impact on overall procedure duration. Potential benefits of shorter procedure time may include less operative complications for the patient, increased patient throughput for the surgeon, and cost savings for the provider from less operating room time. A recent study by Diab and colleagues sought to evaluate the time savings in arthroscopic subacromial decompression using bipolar versus monopolar radiofrequency energy probes. The study prospectively randomized 40 patients into two groups; one group was treated with a bipolar device (n=20) and the other group was treated with a monopolar device (n=20). The results of this
study demonstrated that the average procedure time in the bipolar group was 13 minutes (range 5-25 minutes) compared with 21 minutes (range 10-35 minutes) in the monopolar group. In the in vitro setting, the VAPR TRIPOLAR 90 Suction Electrode ablated 22% more ligament per minute than a competitor probe. If these in vitro results for the VAPR TRIPOLAR 90 Suction Electrode were applied to the average procedure time of the bipolar and monopolar radiofrequency probes in the clinical setting (from the study by Diab and colleagues), then a resulting operating time savings of about 3 minutes per procedure would be achieved compared to bipolar probes and 4.6 minutes per procedure compared to monopolar probes. 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 either 3 minutes or 4.6 minutes would be about $162 or $248 per procedure, respectively.

Conclusions

Overall, the VAPR TRIPOLAR 90 Suction Electrode addresses the clinical needs of today’s arthroscopic surgeons with its ability to precisely remove soft tissue, simultaneous cut and coagulate vascular tissue, remove bubbles, debris, and heated saline, and provide control and clarity in the confined joint space. It is the first hand-controlled tripolar suction electrode on the market with independently optimized ablation and coagulation. The fast ablation rate, lower saline outflow temperature, and enhanced coagulation performance observed in the in vitro setting may lead to a reduction in operating room time, potential cost savings, and less risk of damage to healthy tissue. 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® TRIPOLAR 90 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. Please refer to the package insert for a complete list of indications, contraindications, precautions and warnings. Customer discussions/inquiries regarding use in other applications should be directed to the Mitek Sports Medicine Strategic Medical Affairs team at MitekScientific@its.jnj.com OR 866-533-5354. For further information on DePuy Synthes products, please contact your local DePuy Synthes representative.