Synergy*RF*™ System with Apollo[RF]® Probes

What is the basis for the introduction of your product into the US market?

The Food and Drug Administration (FDA) cleared the Synergy*RF* system with Apollo[RF] probes[1] and determined that the system is substantially equivalent to the Quantum 2 Controller (ArthroCare 12000 System) as listed below.

Summary of Performance Testing

The performance testing of the Synergy*RF* system has been shown to be substantially equivalent to the predicate ArthroCare 12000 system by evaluation of coagulation/ablation zone measurements, visual similarity of coagulation/ablation of tissue samples, and with respect to the measured temperatures of adjacent tissue, in vitro.[2]

Substantial Equivalence Summary

Synergy*RF* system is substantially equivalent to the predicate device ArthroCare 12000 system based on the same indications, FDA product code, CFR regulation number, classification and indications for use. Any differences between the Synergy*RF* system and the predicate are considered minor and do not raise questions concerning safety and effectiveness. The proposed device is substantially equivalent to the predicate device in regards to its intended use, design, energy source and function.

The Synergy*RF* bipolar system with Apollo[RF] probes is based on a proactive approach to managing fluid temperature. A recent journal article that supports this approach provides clinical guidance on using RF in arthroscopic procedures: “Clinical guidelines for using the RF ablation include: meticulous technique, intermittent use, good inflow and outflow, and pulsed lavage at frequent intervals.”[3]

We tested our product extensively and compared it to the leading competitive product, using suction values (200 mmHg to 400 mmHg) as outlined in our Directions For Use (DFU) and documented in a white paper that supports this proactive approach. The results and conclusion are listed below.

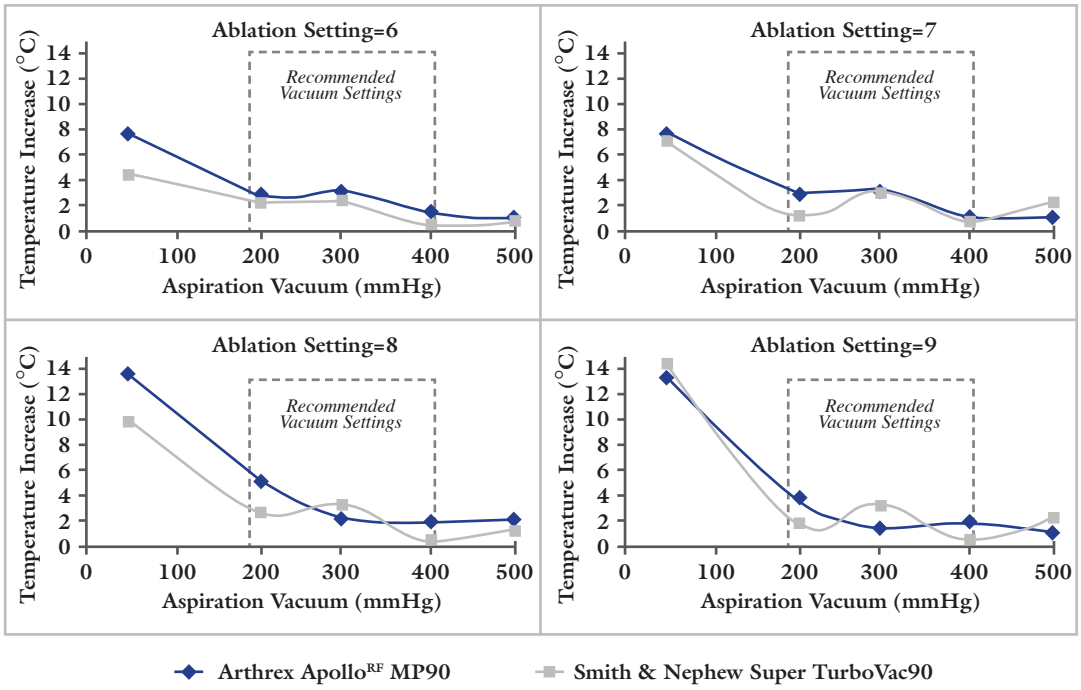
Apollo[RF] MP90 Probe

Apollo[RF] XL90 Probe

Apollo[RF] Hook Probe

Apollo[RF] MP50 Probe

Thermal Response of the Arthrex Apollo^RF MP90 and Smith & Nephew Super TurboVac90 Bipolar Ablation Probes in a Simulated Joint Space[4]



Conclusion

Temperatures measured for the Arthrex Apollo^RF MP90 and Smith & Nephew Super TurboVac90 were similar over all of the conditions tested. At recommended vacuum settings (200-400 mmHg), temperature increase over baseline at the probe tip was less than 5°C for both probes.

While this study only used a set inflow of irrigation fluid to replace what was aspirated by the probe, additional fluid outflow through the joint is clinically possible when outflow tubing is used to further moderate temperature increase. This can be easily accomplished with the Arthrex DualWave™ arthroscopy pump with outflow tubing.

References

1. FDA 510(k) K161581. September 9, 2016.
2. Data on file. Thermal Response of the Arthrex® ApolloRF® MP90 and Smith & Nephew Super TurboVac90 Bipolar Ablation Probes in a Simulated Joint Space, Arthrex, LA1-00047-EN_A, 2016
3. McCormick F, Alpaugh K, Nwachukwu BU, Xu S, Martin SD. Effect of radiofrequency use on hip arthroscopy irrigation fluid temperature. Arthroscopy. 2013;29(2):336-342. doi:10.1016/j.arthro.2012.10.001.
4. Arthrex, Inc. LA1-00047-EN_A. Naples, FL; 2017.

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