Synergy^{RF}™ System

HCP Value Analysis Brief

Arthrex®

Introduction

The Synergy*RF*™ system and Apollo*RF*® probes were designed to address the needs of patients, surgeons, and health care providers worldwide. The system uses a clinically proven radiofrequency with an improved, proprietary waveform to effectively ablate tissue during arthroscopic procedures. The Synergy*RF* system can be integrated with the rest of the Synergy arthroscopy system to provide a streamlined operating suite for surgeons and staff.

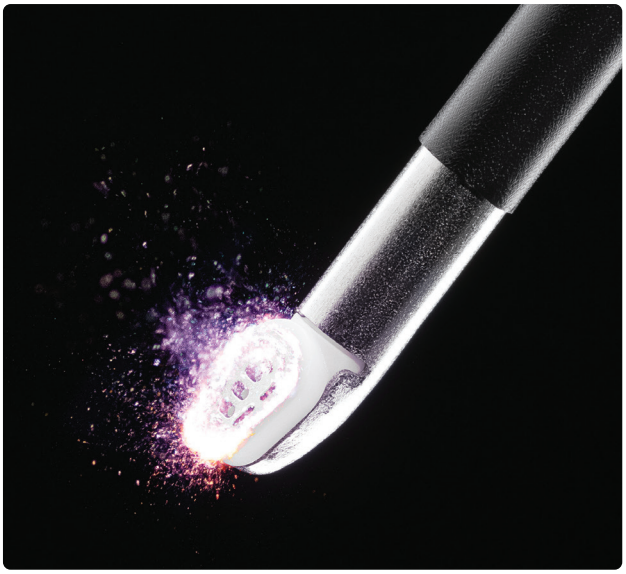
Synergy*RF*™ System

Benefits

- Effective radiofrequency for bipolar ablation
- Relatively low temperatures compared to traditional RF devices (eg, Bovie electrocautery)[1]
- Proprietary waveform for improved ablation performance
- Precise plasma layer limits effects on adjacent tissue[2]
- The only bipolar RF system to integrate with an arthroscopic imaging suite (including heads-up display)
- Minimizes blood loss during procedures with the coagulate function[3]
- Durable, 1-piece electrode design
- Probes designed for specific anatomy and procedures
- Optimized ablation settings for specific tissues
- No grounding pad required for use

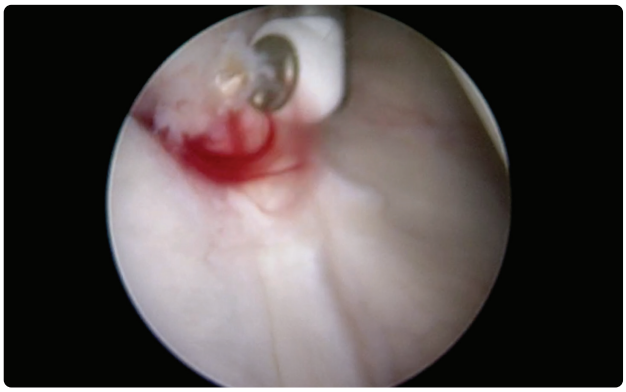
Tissue Ablation

Ablation technology is designed to resect soft tissues in arthroscopic procedures. Bipolar radiofrequency (RF) devices use active and return electrodes in the tip of the probe to localize the energy produced. Since the return electrode is contained within the probe tip, a grounding pad is not necessary for the operation of this device. The console initiates an electrical current to excite the ions and electrons in the conductive fluid (saline or Ringer's lactate), producing a gas plasma layer at the active electrode. The plasma layer contains excited particles capable of breaking down organic molecular bonds. This plasma layer is very thin, typically 100 to 200 µm in depth.[2] This lends itself to precise tissue vaporization in arthroscopic procedures.

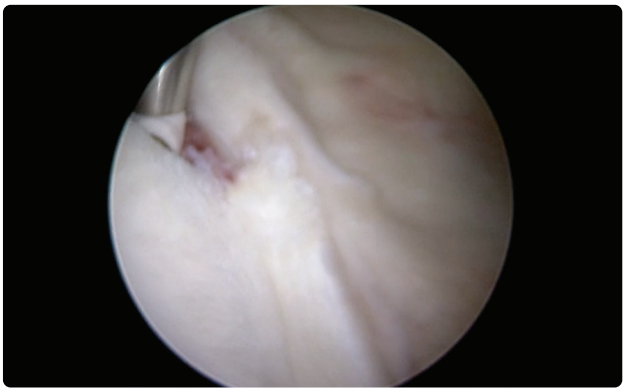


Coagulation

Bleeding in the Shoulder



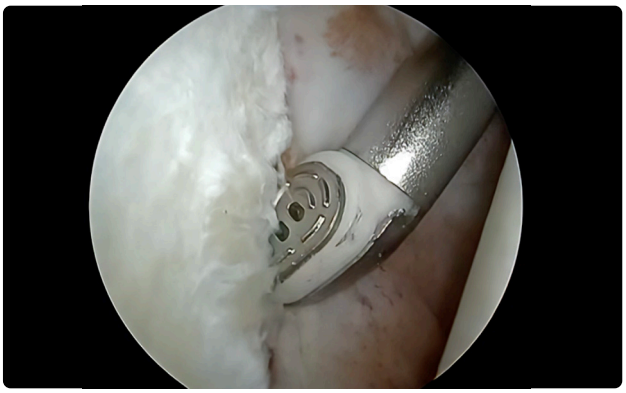
After Coagulation



In addition to ablation, the Apollo$^{RF®}$ probes have a coagulation function to seal bleeding vessels during procedures. Coagulation uses lower voltages to create a localized thermal effect. This thermal effect can shrink the vessel's fibers while coagulating the proteins in the blood.

- Reduce blood loss during procedures[3]
- Minimize dependency on fluid pressures to prevent intra-articular bleeds, reducing the risk of joint extravasation
- Lower temperature transmission than traditional radiofrequency devices[1]

Positive Outcomes



Bipolar RF ablation technology has been used for decades and is clinically proven:

- Bipolar RF debrides and resects tissue effectively and has shown excellent outcomes[4-6]
- Bipolar RF can potentially reduce operative time, which could reduce the risk of surgical site infections and provide cost savings[7,8]
- Clinical studies indicate certain procedures may benefit from bipolar RF ablation over standard mechanical burrs and shavers[4,6,9]

Fluid Temperatures

Arthrex adheres to proactive fluid management principles to avoid increased fluid temperature profiles. A clinical study in the journal *Arthroscopy* stated that “Clinical guidelines for using the RF ablation include: meticulous technique, intermittent use, good inflow and outflow, and pulsed lavage at frequent intervals.”[10] As part of the Imaging and Resection portfolio, Arthrex offers the DualWave™ arthroscopy pump to provide fluid inflow and remove tissue particulate and warm fluid via outflow tubing. The DualWave arthroscopy pump can be used in conjunction with the Apollo$^{RF®}$ probes to enhance the procedural experience for both surgeons and patients.

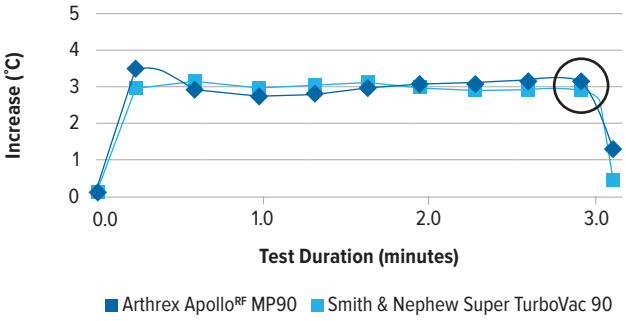
- Fluid temperature management demonstration video available at Arthrex.com[1]
- Thermal imaging shows that proactive fluid management nearly eliminates fluid temperature spikes during bipolar RF use
- DualWave pump and Apollo^{RF} MP90 probe used for demonstration

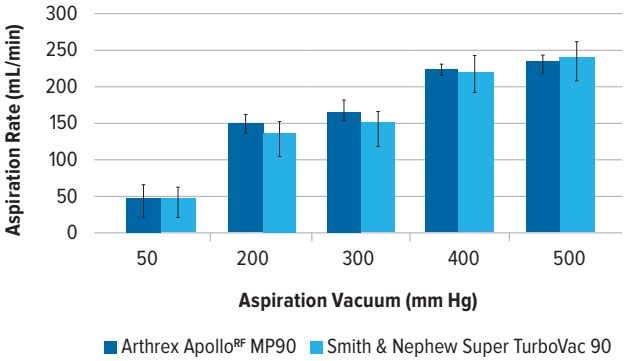
Arthrex, VID1-01141-EN, 2018

Arthrex Apollo^{RF} MP90 Probe Versus Smith & Nephew Super TurboVac 90 Wand

The Apollo^{RF} MP90 probe was compared to the market-leading 90° wand (Smith & Nephew Super TurboVac 90) in a white paper study designed to compare fluid temperatures during bipolar RF device use.[11]

- The study featured multiple ablation and suction vacuum settings. Each device was tested for 3 minutes of continuous ablation with temperatures being recorded every 20 seconds.
- Over a wide range of ablation and suction settings, the Apollo^{RF} MP90 probe and Super TurboVac 90 exhibited similar temperature profiles.
- The FDA cleared the Synergy$^{RF™}$ system[12] and determined that it is substantially equivalent to the ArthroCare Quantum 2 console and wands.

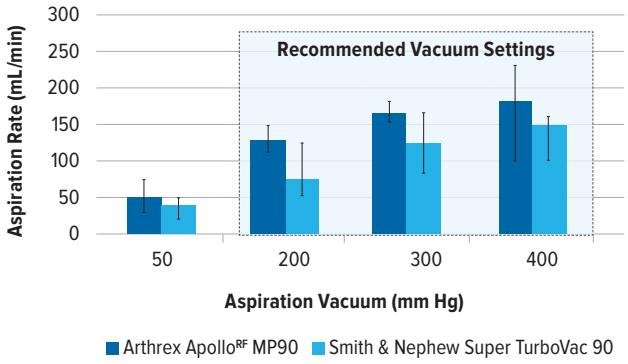


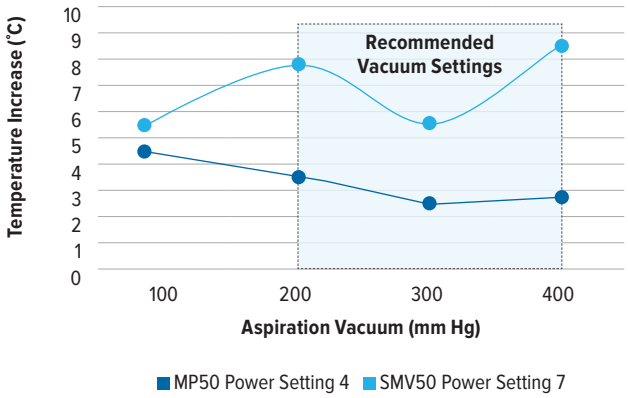


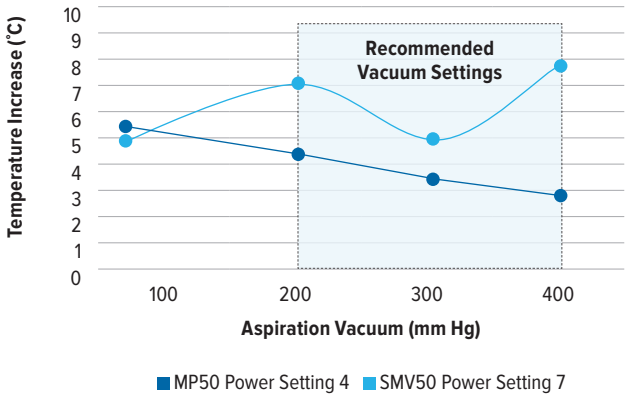
Arthrex Apollo[RF®] MP50 Probe Versus Smith & Nephew Super MultiVac 50 Wand

A separate test was conducted to demonstrate the effectiveness of the Apollo[RF] MP50 probe, which was created specifically for use in the knee. To reduce the risk of damaging sensitive tissues, it was designed with a lower energy default setting. The Apollo[RF] MP50 probe was compared to the market-leading 50° wand (Smith & Nephew Super MultiVac 50) in a white paper study of the same design.[13] Identical controls and variables were used, including aspiration settings, thermocouple placement, and simulated joint space.

- Over identical suction vacuum settings, the Apollo[RF] MP50 probe demonstrated statistically significant higher aspiration values than the Super MultiVac 50. Each device has the same recommended suction vacuum settings (200 to 400 mm Hg).
- The first test staged each device at its default setting (Apollo[RF] MP50: setting 4; Super MultiVac 50: setting 7). According to the Smith and Nephew (ArthroCare) instructions for use: “the default set point 7 should be maintained at all times during use. Use of an ablation set point below the default setting has not been validated” and “could result in thermal injury to the user or patient.”[14] The Apollo[RF] MP50 probe demonstrated a statistically significant lower average temperature increase than the Super MultiVac 50.
- The second test compared set point 7 for both devices. The Apollo[RF] MP50 probe demonstrated an average lower temperature increase compared to the Super MultiVac 50 across the recommended suction ranges of both devices.
- The higher aspiration rate of the Apollo[RF] MP50 probe effectively removes warm fluid and demonstrates how proactive fluid management is essential to ensure low fluid temperatures during arthroscopic procedures.







OR Efficiency

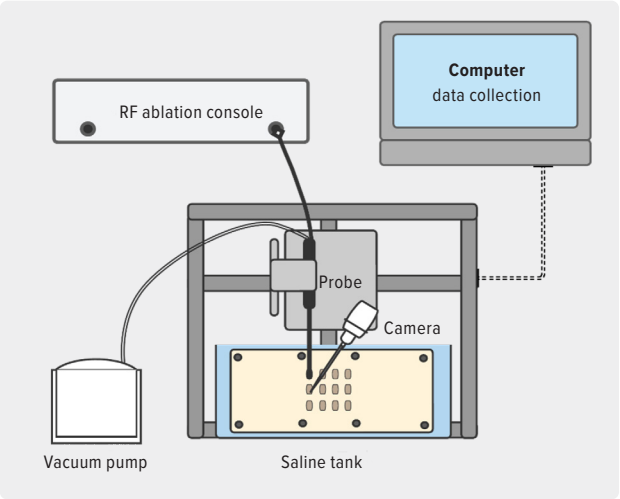
The performance of an ablation probe can be defined by its capacity to effectively ablate tissue, which directly impacts removal rate. A high removal rate is not only critical for efficiency, but it reduces time in the joint space.[15] Decreased shoulder arthroscopy procedure time is associated with fewer adverse short-term outcomes.[16] At default settings, the Apollo[RF] i90 probe has the greatest average tissue removal rate when compared to the leading market competitors.[17]

Arthrex Apollo[RF®] i90 Versus Smith & Nephew Flow 90, Smith & Nephew Super TURBOVAC 90, Stryker 90-S Cruise, Depuy Synthes CoolPulse 90, and DePuy Synthes VAPR TRIPOLAR 90

The Apollo[RF] i90 probe was compared to market-leading 90° probes (Smith & Nephew Flow 90, Smith & Nephew Super TURBOVAC 90, Stryker 90-S Cruise, Depuy Synthes CoolPulse 90, and DePuy Synthes VAPR TRIPOLAR 90) in a white paper study designed to compare the volume of tissue removed.

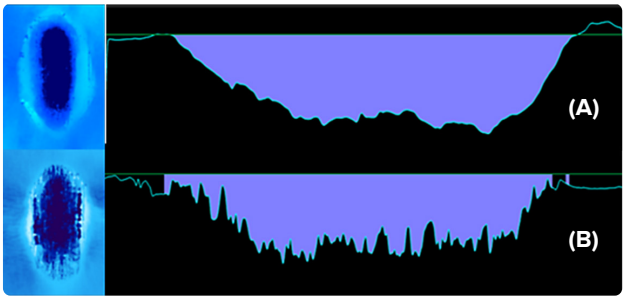
› Each probe was secured in a fixture, so the electrode was parallel to the rawhide, which was used to ensure a flat, reliable ablation surface. Each probe was connected to its respective console at default settings and ran in a 3 × 4 grid, where each strike consisted of dragging in tissue for 9 seconds at a speed of 2.3 in/min on the rawhide.

Figure 1. Volumetric Ablation Test Setup



› After testing was complete, each zone was evaluated by the Keyence VR-3200, which uses a top-down optical 3D scan to determine the total volume of the indentation. During the evaluation, each zone was considered an independent measurement. A one-way ANOVA was performed using Minitab to check for statistically significant differences between the groups.

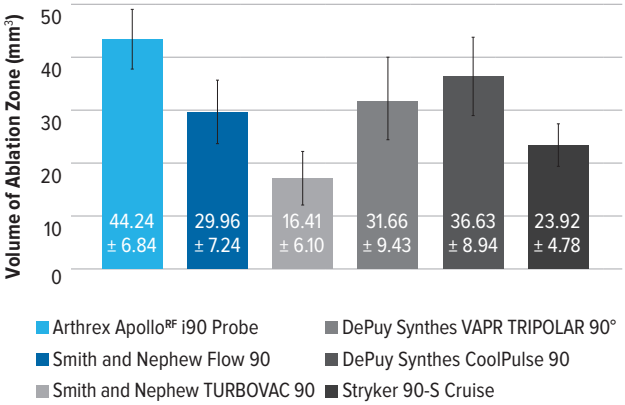
Figure 2. Example Topographical Scan (Left) and Sectioned View (Right) of Indentation Volume via Keyence VR-3200



(A) Arthrex Apollo[RF] i90 aspirating ablator **(B)** Smith and Nephew Super TURBOVAC 90

› The results of this testing indicate that the Apollo[RF] i90 probe has the greatest average tissue removal rate compared to the leading market competitor probes ($P < .001$)[17]

Figure 3. Comparison of Average Ablated Volume Between Arthrex Apollo[RF] i90 Probe, Smith and Nephew Super TURBOVAC 90, DePuy Synthes CoolPulse 90, Smith & Nephew Flow 90, DePuy Synthes VAPR TRIPOLAR 90, and Stryker 90-S Cruise



Hospital Efficiencies

The Synergy$^{RF™}$ system with Apollo$^{RF®}$ probes comprises a part of the Synergy arthroscopy platform. The platform integrates imaging, fluid management, and resection devices (shavers, burrs, RF probes, etc) to provide a heads-up display for all connected devices. The heads-up display places relevant information about fluid flow rates, pressure, device selection, and power settings on the 4K monitor, allowing the surgeon to quickly visualize device settings without shifting focus away from the surgical field.

- Improved visibility of device settings during procedures
- Simple preoperative setup
- Synergy Matrix™ network can enhance the OR functionality by integrating with EHR, PACS, and worklists to enhance facility workflow
- Standardization of consumables reduces volume and simplifies the ordering process

A Full Arthroscopy Portfolio

Synergy OR Integration Suite is equipped with the latest in 4K imaging, integration, and resection technology. This state-of-the-art technology can increase efficiency, lower the cost of ownership, and positively impact the patient experience.

Product Listing

Synergy*RF*™ Console

Minimally invasive bipolar RF ablation system that effectively ablates and coagulates tissue in arthroscopic procedures.

Synergy*RF* console	AR-9800

Synergy*RF* Console Foot Pedal

- Separate ablation and coagulation pedals
- Central ablation level adjustment button
- Integrated carrying handle

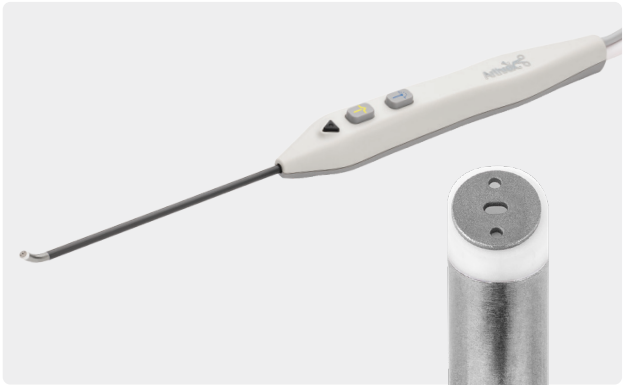
Synergy*RF* foot pedal	AR-9800-F

Apollo*RF*® i90 Probe

- Torpedo-shaped electrode designed for easy access into the joint and accurate removal of tissue
- Edge control for a defined plasma edge that enables greater precision and gentle ablation distally and on the sides of the electrode
- Optimized flow rate/flow path
- Shorter working length of 140 mm for increased control

Apollo*RF* i90 probe	AR-9831

Apollo[RF®] SJ50 Probe



- Reduced probe dimension of 110 mm working length and 3.3 mm diameter for ease of access in the ankle, elbow, and knee
- 360° edge control for precise ablation
- Anatomic 50° tip configured to reach and ablate tissue efficiently
- Low default ablation setting (4) for reduced energy delivery
- Optimized aspiration to remove tissue particulate and maintain optimal fluid temperatures

Apollo[RF] SJ50 probe	AR-9845

Apollo[RF] H50 Probe

- Extended working length of 185 mm
- Reinforced shaft for enhanced integrity
- High-strength materials for increased durability
- 360˚ edge control for precise ablation
- For use in hip procedures

Apollo[RF] H50 probe	AR-9835

Apollo[RF] MP50 Probe

Ergonomic, Anatomic, Precise:

- Smooth radius at tip designed to access confined anatomy
- 360˚ edge control for precise ablation
- Dual aspiration slots for effective suction
- Lower ablation default setting of 4 for use around sensitive tissue
- For use in knee and shoulder procedures

Apollo[RF] MP50 probe	AR-9815

Apollo[RF] XL90 Probe

- 25% longer electrode than Apollo[RF] MP90 probe to remove more tissue per pass
- Durable, 1-piece active electrode
- Easy-to-use, ergonomic hand controls
- Additional aspiration slot further improves visibility during use

Apollo[RF] XL90 probe	AR-9821

Apollo[RF®] MP90 Probe

- Uses controlled plasma-based bipolar RF technology
- 90° tip configured to access and ablate tissue rapidly
- Durable, 1-piece active electrode
- Easy-to-use, ergonomic hand controls
- Multiple ports for efficient bubble removal

Apollo[RF] MP90 probe	AR-9811

Apollo[RF] Hook Probe

- Generous 2 mm hook size for easy tissue capture and rapid tissue resection
- Provides a thin, precise, 0.75 mm resection plane
- Durable, 1-piece active electrode
- Easy-to-use, ergonomic hand controls
- Configured to access and reach tissue in various arthroscopic procedures

Apollo[RF] Hook probe	AR-9825

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This description of technique is provided as an educational tool and clinical aid to assist properly licensed medical professionals in the usage of specific Arthrex products. As part of this professional usage, the medical professional must use their professional judgment in making any final determinations in product usage and technique. In doing so, the medical professional should rely on their own training and experience, and should conduct a thorough review of pertinent medical literature and the product's directions for use. Postoperative management is patient-specific and dependent on the treating professional's assessment. Individual results will vary and not all patients will experience the same postoperative activity level or outcomes.

Arthrex manufacturer, authorized representative, and importer information (Arthrex eIFUs)

US patent information

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