

# Open, Multicentric, Clinical Evaluation of the Technical Efficacy, Reliability, Safety, and Clinical Tolerance of the Plasma Surgical PlasmaJet™ System for Intra-operative Coagulation in Open and Laparoscopic General Surgery

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## Introduction

The objective of this clinical evaluation is to verify the efficacy, precision and ease of use of the PlasmaJet™ (neutral plasma coagulation system manufactured by Plasma Surgical Limited) in the coagulation of large surfaces, both in open and laparoscopic surgery, and to measure the system's advantages and/or disadvantages vs. the existing techniques of electrosurgery.

## Patients and methods

The non-controlled, pilot study took place between February 17, 2004 and November 24, 2005, in 4 French clinical centers. It included 89 patients undergoing liver surgery (74.16%), abdominoplasty (17.98%) or other types of surgery (7.86%) for a total of 79 open and 10 laparoscopic surgeries. Overall 54 open surgery handpieces and 35 laparoscopic handpieces have been evaluated.

## Results

The PlasmaJet™ allowed for a quick, precise, homogeneous and complete hemostasis in 87 to 100% of the cases. It reduced blood loss in 78% of the cases, and offered a specific efficacy in more than 85% of these procedures. It was considered superior to other coagulation methods in more than 80% of the surgeries. Overall the PlasmaJet™ was found safe and reliable during its use with 88 to 100% positive answers. More specifically, the centers that trialed the PlasmaJet™ laparoscopically recorded that the system presents no drawbacks for this surgical approach (no heating or overpressure).

The technical evaluation of the console and its accessories showed an excellent rating (86 to 100% positive answers) in regard to ease of set up, ease of use and ease of cleaning. Overall, the handpieces were found satisfactory, easy to use, ergonomic (rating from 70 to 98%). The PlasmaJet™ did not incur any complication during its use. Post-operatively, 14 adverse events (6 serious and 8 non serious) occurred but none were directly related to the tested device.

## Conclusion

The PlasmaJet™ is efficient for intra-operative coagulation in open and laparoscopic general surgery, particularly on large surfaces. The study results allow to conclude that the PlasmaJet™ offers an excellent clinical tolerance. The device might offer an interesting alternative to conventional haemostatic methods, especially in liver surgery. Additional studies were started in 2005 to confirm the advantages of the PlasmaJet™ system.

*Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.*

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