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APYX MEDICAL DISCLOSURES

FINANCIAL DISCLOSURES (at time of publication)

This poster by S. Gueli Alletti, A. Rosati, V.A. Capozzi, B. Constantini, G. Vizzielle, A. Fagotti, F. Fanfani, C. Fedele, S. Cianci, G. Scambia was not supported by Apyx Medical, Inc. The opinions contained herein are those of the authors(s) and do not necessarily represent the official position or policies of Apyx Medical, Inc. The authors have no financial connection with Apyx Medical, Inc. other than as a purchaser/user of the technology.

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RISKS: Risks associated with the use of J-Plasma may include: Helium embolism due to insufflation of gas into the surgical site or due to inadvertent introduction into the venous or arterial blood supply system; ineffective hemostasis; infection of the treatment site post-treatment; unintended injury (burn, scarring, increased healing time) due to excessive treatment; pneumothorax, hematoma, pain, erythema, edema, or bleeding. As with all energy devices there are inherent risks associated with its use, refer to the IFU for further information.

INTENDED USE DISCLOSURE: The Renuvion®/J-Plasma® Precise Open Handpiece is intended to be used with compatible J-Plasma electrosurgical generators for the delivery of radiofrequency energy and/or helium plasma for cutting, coagulation and ablation of soft tissue during open surgical procedures. The Renuvion®/J-Plasma® Precise & Precise Open® Handpieces are compatible with electrosurgical Generators BVX-200H, and BVX-200P. Refer to the Instructions for Use for the currently approved or cleared indications.

Preliminary experience in the use of J-Plasma device in gynecological malignancies

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Introduction / Background: The present study investigated the role of this novel plasma energy device in gynecological malignancies in the context of a modern personalized approach delivered by a tertiary care referral center. The indication was the resection/ablation of peritoneal and/or serosal carcinomatosis, either in laparotomy or in laparoscopy.

Methodology: From January 2019 to April 2019 six patients, referring to the Division of Gynecologic Oncology, Fondazione Policlinico Universitario A. Gemelli IRCCS in Rome, were selected for a feasibility study on the use of J-Plasma in advanced gynecological cancer conditions. The setting of the device used was Coagulation 45, Cut 45, Bipolar Macro 1, J-Plasma Power 40%, Gas Flow 4.0 l/min, Pulsing 80.

Results: All patients showed peritoneal/serosal carcinomatosis with an indication of regional peritonectomy and/or ablation respectively. Three patients underwent laparoscopic cytoreduction (Group 1= for interval debulking surgery (n=2) and stage IV endometrial cancer (n=1). Three patients underwent laparotomic primary debulking surgery for advanced ovarian cancer (Group 2). All patients achieved optimal residual tumor at the end of surgery. The device was used for parietal, diaphragmatic, and mesenteric peritonectomy and to ablate nodules on the bowel serosa.
The median OT and median EBL were 195 min and 100 ml for Group 1, and 420 min and 500 ml for Group 2. The median hospital stay was 4 days for Group 1 and 13 days Group 2 respectively. No intra- and post-operative complications were registered within 60 days after surgery

Conclusion: The use of J-PLASMA in the laparoscopic or laparotomic cytoreductive surgery could enhance the removal of peritoneal and serosal carcinomatosis. This kind of energy seems to be safe in performing peritoneal stripping and serosal ablation without increasing the morbidity. Further experience and a longer follow-up period are required to establish the use of the J-PLASMA in cytoreductive surgery for gynecological cancer.

Table 1. Patients baseline characteristics

	LPS	LPT
Number of patients (N)	3	3
Median Age (years)	67	58
Median BMI (N)	24	30
Indication for surgery		
PDS in AEOC	-	3
IDS in AEOC	2	-
Stage IV endometrial cancer	1	-

Table 2. Perioperative variables

	LPS	LPT
Median operative time (min)	195	420
Median EBL (ml)	100	500
Residual tumor (mm)	0	0
Median hospital stay	4	13
Surgical procedures with J-Plasma		
Parietal/Pelvic Peritonectomy	3	2
Diaphragmatic Peritonectomy	1	3
Mesenteric Peritonectomy	1	1
Bowel serosal ablation	-	1

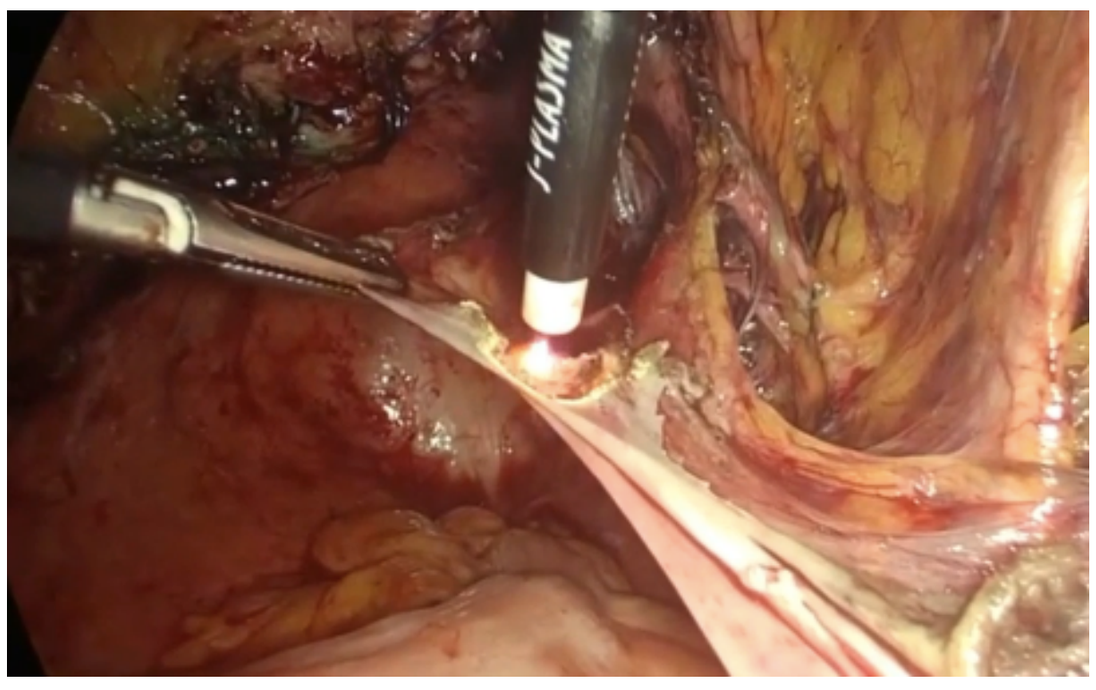

Fig 1. J-Plasma laparoscopic pelvic peritonectomy

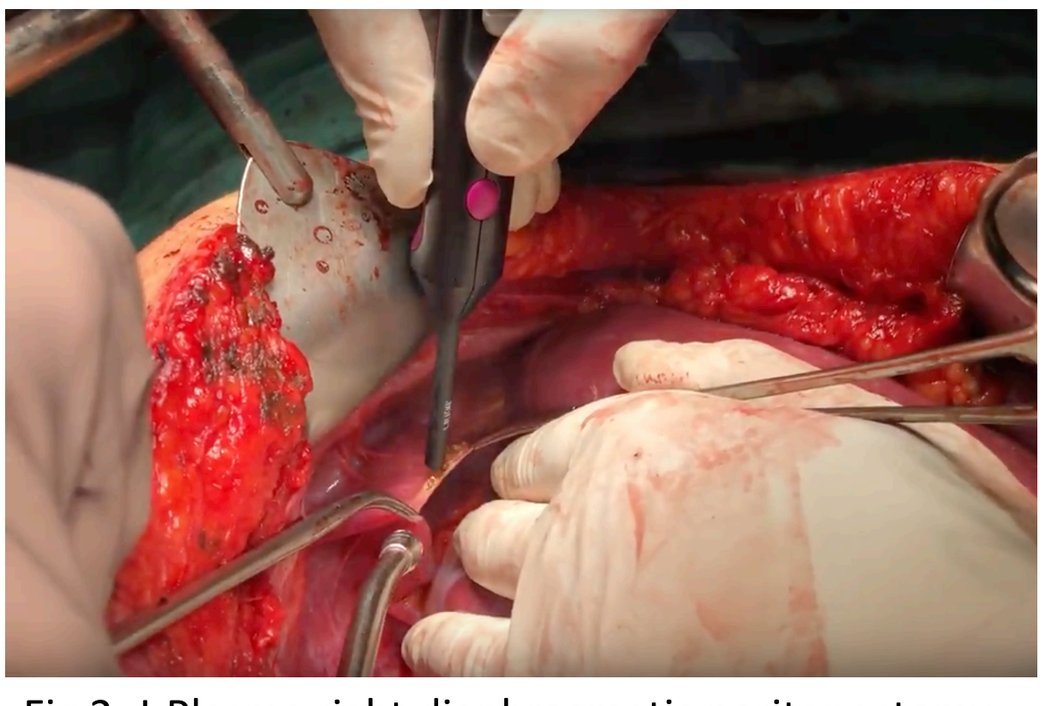

Fig 2. J-Plasma right diaphragmatic peritonectomy

ESGO European Society of Gynaecological Oncology

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