

COMBAT
Cancer with
Hyperthermia

MAXBETSA

EXCELENCIA EN DISPOSITIVOS MÉDICOS

COMBAT
MEDICAL

PRS+
Agitation
Optimising HIPEC Delivery

Agitation
with CO₂
improves drug
and heat
distribution

COMBAT PRS⁺

Peritoneal Recirculation System + Agitation Optimising HIPEC Delivery

Agitation with CO₂ improves drug and heat distribution

HIPEC + Agitation

The **COMBAT PRS⁺** System utilises an innovative, patented agitation system to optimise HIPEC treatment. Compatible with all HIPEC techniques, giving the surgeon and healthcare professionals the flexibility to choose the most suitable HIPEC technique for the patient and the disease.

Developed in collaboration with surgeons to optimise the **Efficacy, Safety and Delivery** of the **HIPEC** technique.

+

EFFICACY - PRS is the only **HIPEC** System with automatic agitation to ensure homogenous drug and thermal distribution throughout the abdominal cavity and peritoneal surfaces to maximise safety and patient outcomes. Data presented in 2019 on 482 patients in a combined series showed disease free survival rates above 77% at 12 months.¹⁻⁴

SAFETY - Automatic agitation allows the chemotherapy to reach all peritoneal surfaces.³ This allows a closed **HIPEC** technique to give full distribution of the drug without the heat loss and chemotherapeutic exposure of the theatre staff associated with open procedures.¹ Complete, visually confirmed filling of the abdominal cavity is also achieved via passage of the fluid into the CO₂ chamber. Safety data on 482 patients was presented at ESSO 2019.⁴

DELIVERY - Continuously monitors and controls both pressure and temperature. Temperature probes in up to 8 locations ensure heat is accurately controlled and measured to optimise both safe delivery and hyperthermic cytotoxic benefit.⁺

Closed and laparoscopic HIPEC techniques using controlled intra-abdominal pressure, as performed with the PRS , have also been shown to improve drug penetration into the tumour and peritoneum.^{1,2}

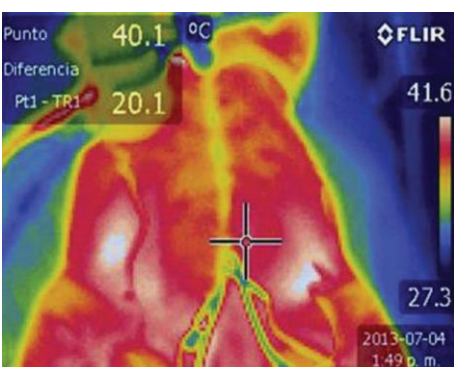
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The **PRS** patented heat exchanger and its flexible operating systems are compatible with all other open and closed **HIPEC** delivery techniques.

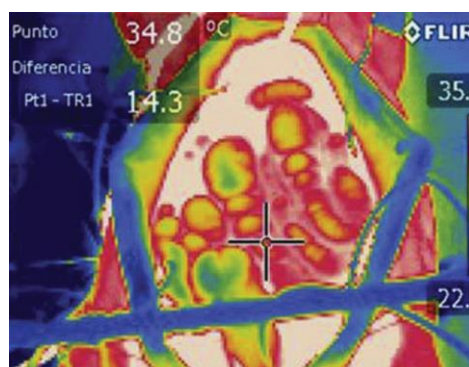
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Successful efficacy and tolerability outcomes have been reported using the **PRS Agitation** technique. Further results will continue to be presented.

Closed Technique + Agitation



Open Technique



Thermographic images from the closed CO₂ technique using the **COMBAT HIPEC + Agitation** technique in a porcine model. Image shows a more homogenous delivery of heated chemotherapy in comparison to the open technique.³

Oncological effectiveness of the technique is demonstrated by an increase in overall survival or progression free survival in the patients studied.¹

COMBAT Medical

The Combat group invests heavily in research & development and clinical trials to prove the **Safety, Efficacy** and **Delivery** of our technologies. We continue to work closely with clinicians on trials, evaluations and future developments to extend clinical use and optimise patient outcomes in an increasing number of disease areas.

Clinical Trials

We work collaboratively with clinicians to extend the use of **PRS+** to maximise the effectiveness of HIPEC. The **PRS** is currently being evaluated and trialled in the following areas:

Ovarian Cancer - NCT 02681432

A randomised, 72 patient, phase III clinical trial in women with epithelial primary ovarian cancer (Stage FIGO II, III and IV) or tumour recurrence. Estimated completion 2019. **Interim results from 72 patients presented in November 2017 show a 46% increase in mean survival and a 64% increase in disease free survival in the HIPEC group compared to the non HIPEC group.**⁵

Colo-Rectal - HIPECT4 - NCT02614534

Multicentre, randomised, 200 patient phase II trial across 15 multicentre, evaluating the safety and efficacy of HIPEC with Mitomycin C (MMC) for treating locally advanced colorectal carcinoma. Expected completion 2020.

Pancreatic - Eurdract - 2016 - 004298-41

A 42 patient, single centre, controlled, randomised, phase II trial using HIPEC with Gemcitabine in peritoneal carcinomatosis of pancreatic origin. Trial commenced 2017, expected completion 2020.

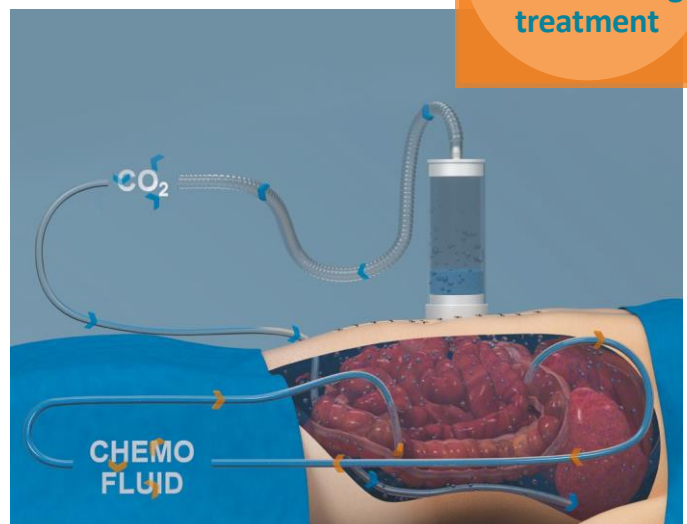
PRS Registry

A collaboration with clinicians from the PRS working group to develop an independent and secure platform to record and analyse real world data. Helping to optimise HIPEC treatments across a range of disease areas.

Please contact us for more information on our current clinical programme.



Safe and effective pressure control during treatment



Technical Specifications:

Equipment external dimensions:

Height 890mm Width 420mm Depth 350mm

Equipment weight:

PRS system 32.6kg plus stand

Safety alarms:

High temperature alarm

High pressure alarm

Auto safety cut off

Safety lock

Electrical risk classification:

Class I, Type B

Fluid ingress protection:

IPX2

Certification:

IEC/UL 60601 - 1; IEC 60601 - 1 - 2;

EN 60601 - 1 - 2; EN 60601 - 1

Function mode:

Continuous delivery at set temperature between 20°C to 43°C ± 1°C

References:

1. Sánchez-García, S., Villarejo-Campos, P., Padilla-Valverde, D., Amo-Salas, M. & Martín-Fernández, J. Intraperitoneal chemotherapy hyperthermia (HIPEC) for peritoneal carcinomatosis of ovarian cancer origin by fluid and CO2 recirculation using the closed abdomen technique (PRS -1.0 Combat): A clinical pilot study. *Int. J. Hyperth.* 32, 488–495(2016).
2. Sánchez-García, S., Padilla-Valverde, D., Villarejo-Campos, P., García-Santos, E. P. & Martín-Fernández, J. Hyperthermic chemotherapy intra-abdominal laparoscopic approach: development of a laparoscopic model using CO2 recirculation system and clinical translation in peritoneal carcinomatosis. *Int. J. Hyperth.* 33, 684–689 (2017).
3. Sánchez-García, S. et al. Experimental development of an intra-abdominal chemohyperthermia model using a closed abdomen technique and a PRS -1.0 Combat CO2 recirculation system. *Surg. (United States)* 155, 719–725 (2014).
4. A. Gutierrez, R.Gomez, F.Pereira et al, Analysis of the survival of patients undergoing CRS + closed HIPEC with CO2 (small 2) agitation system: a multicentre study. Presented GECOP 5-7th June and ESSO 2019, 9-11 October Rotterdam.
5. Sánchez-García, S., Villarejo-Campos, P., Padilla-Valverde, D., et al. Hyperthermic Intraperitoneal Chemotherapy with a closed technique and recirculation of CO2 with Paclitaxel in Advanced Ovarian Cancer. Preliminary results of clinical trial 10-008, EudraCT 2011-006319-69, NCT02681432. Oral Communication. Congreso SEOQ y Reunión GECOP, Palma de Mallorca, España, 8-10 noviembre 2017.

COMBAT Group continues to demonstrate:

- Innovative product development
- Investment and commitment to clinical trials and support
- Excellence in training, education and customer service
- Expansion of its clinical working advisory group throughout Europe

For more information on **HIPEC + Agitation** delivered by the **PRS+** including details of the current clinical programme please contact **COMBAT Medical** on:

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Manufactured by **BIO**surgical part of the **COMBAT** group



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