COOLINGBiS®

Powerful coagulation in surgical oncology

vecmedical

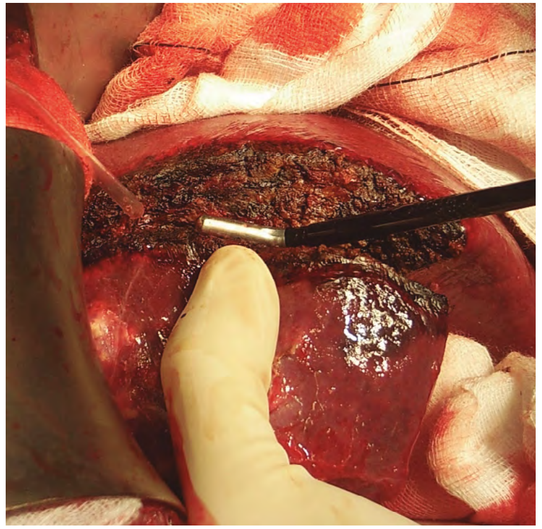
01

COOLINGBIS®
Features

COOLINGBIS® is a monopolar electrosurgical electrode intended for haemostatic sealing, coagulation and cut (models with blade) of soft tissues.

COOLINGBIS® uses radiofrequency (RF) energy and an **internally cooled electrode** to facilitate surgical sealing, increasing safety and drastically reducing intraoperative bleeding.

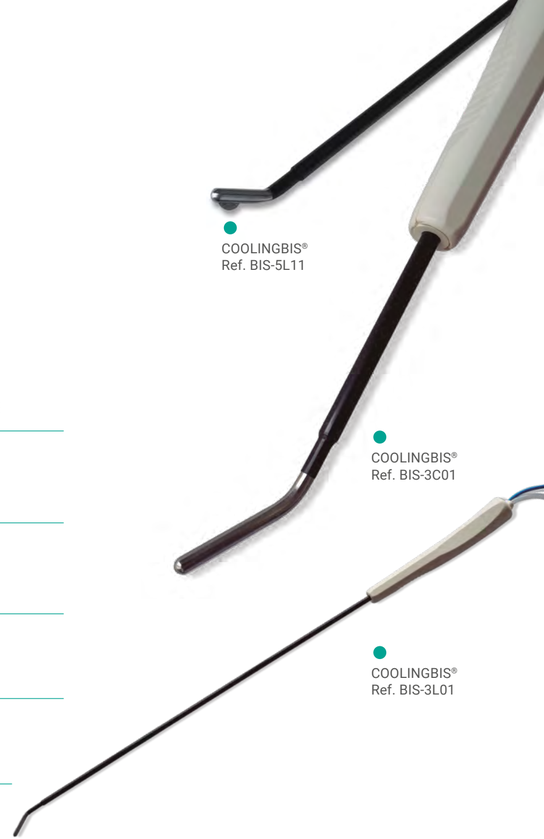
COOLINGBIS® is one of the most efficient coagulation devices on the market.



02

COOLINGBIS®
Models and References

WORKING MODE	MODEL	REFERENCE
Coagulation and cut in laparotomy (DUAL)	Short electrode of 3 mm with blade	BIS-3C11
	Short electrode of 5 mm with blade	BIS-5C11
	Short electrode of 8 mm with blade	BIS-8C11
Coagulation in laparotomy (COAG)	Short electrode of 3 mm without blade	BIS-3C01
	Short electrode of 5 mm without blade	BIS-5C01
	Short electrode of 8 mm without blade	BIS-8C01
Coagulation and cut in laparoscopy (DUAL)	Long electrode of 3 mm with blade	BIS-3L11
	Long electrode of 5 mm with blade	BIS-5L11
Coagulation in laparoscopy (COAG)	Long electrode of 3 mm without blade	BIS-3L01
	Long electrode of 5 mm without blade	BIS-5L01



03

COOLINGBIS®
Benefits

DUAL working mode

The DUAL working mode incorporates a blade to coagulate and cut the tissue, avoiding the need of using other dissecting devices.

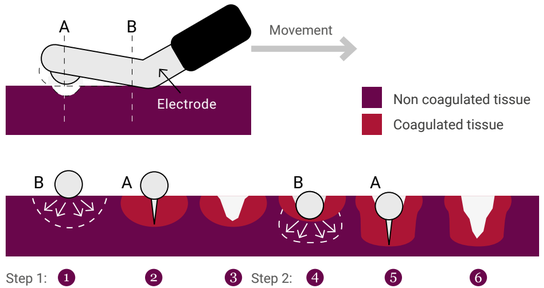
Internal cooling system

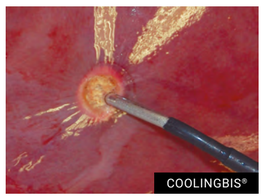
The cooled saline flows inside the electrode without touching the tissue, which allows:

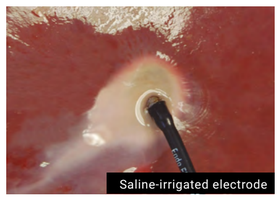
> Preventing carbonized tissue from sticking to the electrode, which increases the coagualtion capacity.

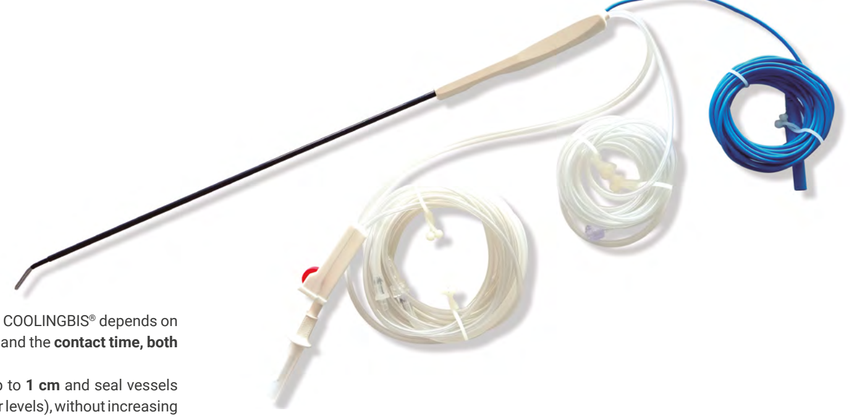
> Increasing the safety of the product. Some of the incidents caused by similar devices correspond to burns in the surgical area caused by heated irrigated saline.

> Generating a lesion circumscribed under the electrode surface.









Lesion depths

The range of lesion depths that can be achieved with COOLINGBIS® depends on the **power level**, the **contact type** (tip only vs. lateral) and the **contact time, both superficial and deep lesions can be produced.**
Internal cooling allows enhancing lesions depths up to **1 cm** and seal vessels **over 5 mm** diameter (depending on models and power levels), without increasing the risk of thermal lesion to nearby structures. This allows for the creation of an additional ablation margin, which can **prevent local hepatic recurrence compared to conventional technologies, specially when the resection margin of healthy tissue that the surgeon left is limited** [1,2].

Combinable

COOLINGBIS® allows the possibility of combining RF-assisted coagulation and cut with other devices (e.g. with an ultrasonic dissector).

Faster

The design allows the rapid creation of coagulation lines by placing the whole electrode on the tissue. The electrode tip allows for easy sealing of blood vessels.

User-friendly

The curved shape of the electrode eases the movement and displacement along the working area, allowing easy access to areas that need to be coagulated and to the points of possible bleeding.

Coagulation efficiency

Without a doubt, COOLINGBIS® is currently **one of the most efficient coagulation devices on the market.** The high coagulation power drastically reduces blood loss and should therefore reduce the need for transfusion. Its high coagulation power is particularly useful in laparoscopic approaches where resources for effective and rapid haemostasis are more limited.

04

COOLINGBIS®
Applications

COOLINGBIS® is intended to be used in:

Liver

Kidney

Pancreas

Spleen

Since it allows coagulation and cut of the tissue, it is especially intended for partial or total resection of these organs, i.e. for radiofrequency-assisted surgical resection.

COOLINGBIS® is especially useful in clinical cases that involve:

Livers with poor hemostasis:

> Cirrhotic livers

> Livers that underwent a lot of chemotherapy

Difficult to control bleeding:

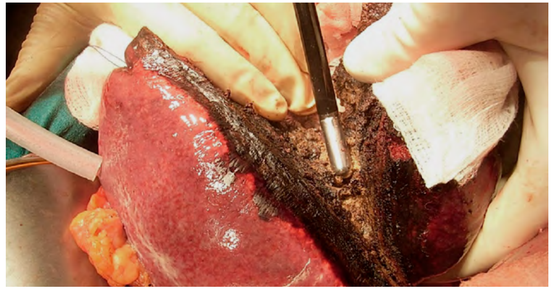
> Large vessels

Additional oncological ablation margins:

> Very useful for parenchymal-sparing liver surgery

Pancreas:

> To decrease pancreatic fistula in distal pancreas resections



05

COOLINGBIS®
Clinical Outcomes In Liver

❶ Reduction of complications:

COOLINGBIS® significantly reduces complications according to Clavien-Dindo classification[7].

The high hemostatic capacity of COOLINGBIS® reduces the need of clamping manoeuvers. Intraoperative time is reduced[3].

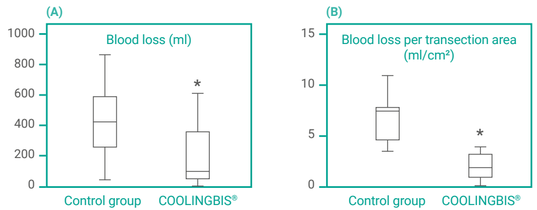
Plane of coagulative necrosis allows the optimum sealing of vessels and ducts and as a result may reduce the risk of biliary leakage[4,5].

❷ Less need of transfusion:

Great power of coagulation which drastically reduces blood loss:

Results of the randomised clinical trial to evaluate the impact of COOLINGBIS® on intraoperative blood loss during liver resection (AGEMED 312/08 EC).[6]

BLOOD LOSS



The box diagram shows blood loss during transection (A) and blood loss per transection area (B) in the control group, in which haemostasis is obtained using conventional techniques, and in the MRFC (monopolar radiofrequency coagulation) group, in which haemostasis is obtained using COOLINGBIS®. The box represents the interquartile range containing 50% of the values. The whiskers are lines that extend from the box to the larger and smaller values. The line in the box indicates the median. Both results are statistically significant (*p<.05).

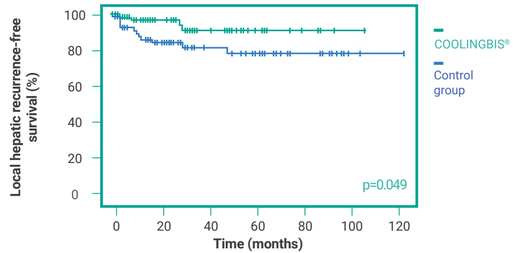
❸ Reduction of local recurrence:

On the basis of the argument that remaining malignant cells in the hepatic remnant are responsible for tumour relapse, M. Villamonte, F. Burdío, E. Pueyo et. al. aimed to demonstrate that additional coagulation of the hepatic surface with an efficient RF-based device (COOLINGBIS®) not only successfully achieved hemostasis but also had a favorable effect on local recurrence[7].

Of the 185 patients included in this study (84 in the control group and 101 in the COOLINGBIS® group), 83 patients from each of the two groups were selected for the assessment of local liver recurrence, after propensity score matching.
Figure shows the Kaplan-Meier curve of local hepatic recurrence-free survival in patients with liver tumors with distance from the tumour to resection margin <10 mm (Log-rank test p=0.049).

The estimated 1-, 3-, and 5-year local recurrence free survival of the control and COOLINGBIS® group patients were 93.5%, 86.0%, 81.0% and 98.8%, 97.2%, 91.9% respectively (p=0.049). The COOLINGBIS® Group was significantly associated with reduced local recurrence[7].

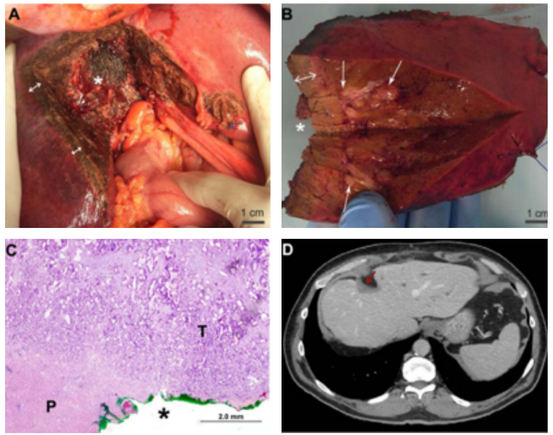
LOCAL HEPATIC RECURRENCE



Patients at risk (censored)							
COOLINGBIS®	83(0)	47(34)	25(54)	13(66)	5(74)	1(78)	0(79)
Control group	83(0)	50(23)	30(42)	26(45)	11(60)	3(68)	1(70)

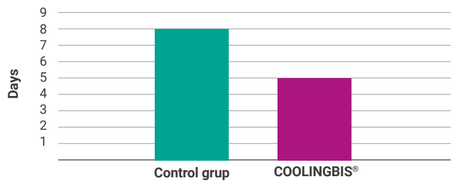
05

(A) The liver after removal of the sample; the coagulated tissue (<->) and the resection margin (*) can be seen. **(B)** The liver sample from the same patient; the resection margin and the thickness of the coagulated tissue (<->), which is in contact with the metastasis (->), can be seen. The * shows the correct position of the sample. **(C)** Histological section of the resection margins of the sample (use the asterisk for the correct position). The resection margin is marked with green ink. You can see the tumour (T) and the coagulated parenchyma (P) in contact with the margin. The coagulated tumour did not prevent the correct evaluation of the invasion of the margins. **(D)** CT scan of the same patient 56 months after liver resection, no signs of liver local recurrence are observed. The remaining ablated tissue at the margin can be noted (red arrow)[1].



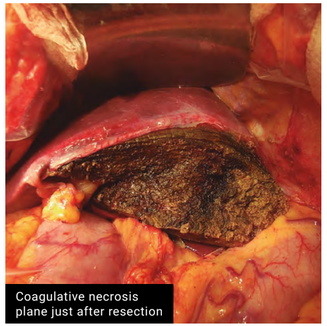
4 Shorter postoperative recovery:

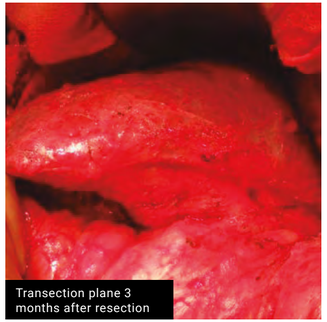
Significant reduction of **postoperative stay (days):**



Results of a retrospective analysis of 185 patients who underwent radical hepatic resection. After propensity score adjustment, 83 patients in the control group and 83 in the COOLINGBIS® group were analysed. In the control group haemostasis was achieved using conventional haemostatic devices. Hospital stay was significantly shorter in the COOLINGBIS® group than control group (median, 8 vs. 5 days, p = 0.015) [7].

5 Transection plane is completely regenerated after procedure:


Coagulative necrosis plane just after resection


Transection plane 3 months after resection

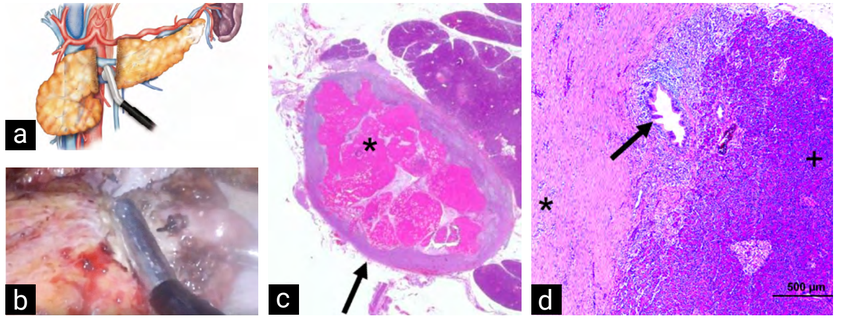
05

COOLINGBIS®
Clinical Outcomes In Pancreas

Reduction of pancreatic fistula in distal pancreas resections

Hyperthermic coagulative necrosis induced during the application of a radiofrequency-assisted device could prevent the occurrence of postoperative pancreatic fistula (POPF) by eliciting fibrosis and collagen contraction of the main and secondary pancreatic duct.

In a recent retrospective analysis of 89 patients, E. Pueyo-Périz et al. obtained notable reductions in the POPF rate of up to 10%-14% when a radiofrequency device is used (COOLINGBIS®) at the parenchymal transection plane compared to stapler closure[8]. Under this premise, in an ongoing multicenter randomized trial (NCT04402346), P. Sanchez-Velazquez et al. aim to evaluate the efficacy of radiofrequency-assisted transection (COOLINGBIS®) of the pancreas in terms of duct sealing compared to the classical method of transection (with stapler) to significantly reduce POPF rates in distal pancreatectomy[9].



Figures a and b show representative **(a)** and original **(b)** methods of pancreatic transection with COOLINGBIS®. Histopathological study of the transection margin of the pancreas in RF **(c,d).** Figure c shows a complete histological section (H/E) showing the area of coagulative necrosis **(asterisk)** surrounded by fibrosis. Figure d shows the main pancreatic duct **(arrow)** surrounded by fibrosis **(asterisk)** and normal pancreatic tissue **(cross)** (H/E).

06

COOLINGBIS®
References

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2. Burdío, F., Berjano, E.J., Navarro, A. et al. Research and development of a new RF-assisted device for bloodless rapid transection of the liver: Computational modeling and in vivo experiments. BioMed Eng OnLine 8, 6 (2009). https://doi.org/10.1186/1475-925X-8-6.

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6. Quesada, R. et al. Impact of monopolar radiofrequency coagulation on intraoperative blood loss during liver resection: a prospective randomised controlled trial. Int. J. Hyperth. 33, 135–141 (2017).

7. Villamonte, M. et al. The impact of additional margin coagulation with radiofrequency in liver resections with subcentimetric margin: can we improve the oncological results? A propensity score matching study. Eur. J. Surg. Oncol. 25–29 (2021).

8. Pueyo-Périz, E et al. Radiofrequency-assisted transection of the pancreas vs stapler in distal pancreatectomy: a propensity score matched cohort analysis. Sci. Rep. 12,7486 (2022).

9. Sánchez-Velázquez, P et al. Radiofrequency-assisted transection of the pancreas versus stapler in distal pancreatectomy: study protocol for a multicentric randomised clinical trial (TRANSPAIRE). BMJ open. 12 (11), e062873. (2022).

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Refer to product instructions for use for instructions, warnings, precautions and contraindications.

Web

COOLINGBIS®

vecmedical
Innovative solutions
for a healthier life

Vecmedical Spain S.L.
Pol. Ind. Can Milans, nave 9
Montcada i Reixac, Barcelona 08110

Tel. +34 93 572 50 15
vecmedical@vecmedical.com
www.vecmedical.com

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