

CLINIPORATOR

LEADING CLINICAL ELECTROPORATION



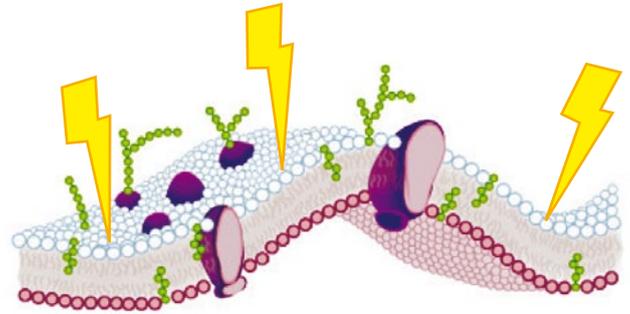
A simple solution
for challenging
situations

IGEA[®]
CLINICAL BIOPHYSICS

PHYSICS AND CHEMISTRY TOGETHER IN THE FIGHT AGAINST TUMOURS

PHYSICS

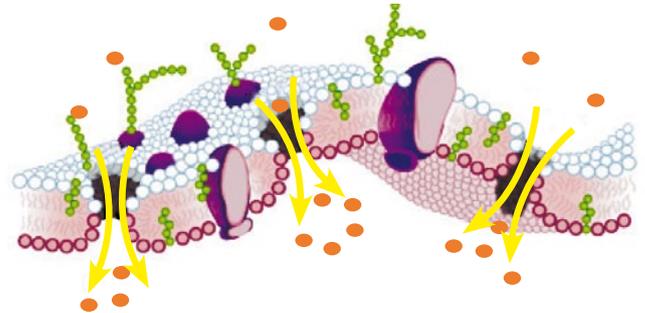
The application of electric pulses to the tumour tissue induces the formation of pores across the plasma membrane: electroporation.



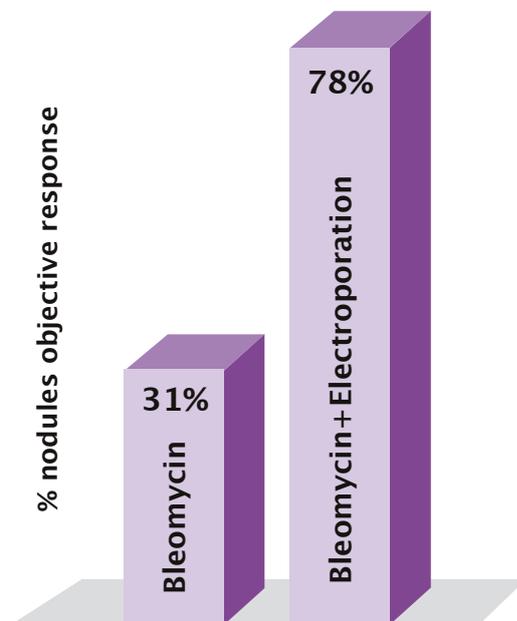
Cell membrane

CHEMISTRY

The pores allow the diffusion into the cell of poorly permeant drugs, significantly increasing the drug intracellular concentration and thus its cytotoxicity.



Electroporated cell membrane



Bleomycin i.t. vs Bleomycin i.t. + Electroporation in metastatic melanoma [Byrne CM, 2006].

ELECTROCHEMOTHERAPY IN CLINICAL PRACTICE

The combination of physics and chemistry is the foundation for electrochemotherapy and its efficacy, which is independent of the tumour histology.

The efficacy of bleomycin in the treatment of melanoma is increased by over 100% when associated with electroporation.

ELECTROCHEMOTHERAPY: FAST AND EFFECTIVE

THE COMBINATION OF HIGH POWER ELECTRONICS AND MICROELECTRONICS

The easy to use CLINIPORATOR system completes electroporation of tumour cells in just a few minutes, minimising operating room usage. The short treatment time allows multiple lesions to be treated in a single session.

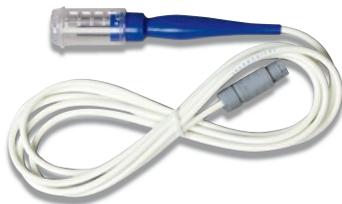


The **TOUCH SCREEN** facilitates the CLINIPORATOR use through a simple and clear graphic interface.



The **REAL-TIME MEASUREMENT** of the electric current passing through the tumour tissue provides an indication of effective electroporation.

Electroporation is obtained using **DEDICATED ELECTRODES** designed for cutaneous lesions, mucosa and subcutaneous tumour tissue up to a depth of 3 cm. Large tumour nodules can be treated with repeated applications of electric pulses.



Adjustable Electrodes (Hexagonal)



Adjustable Electrodes (Linear)

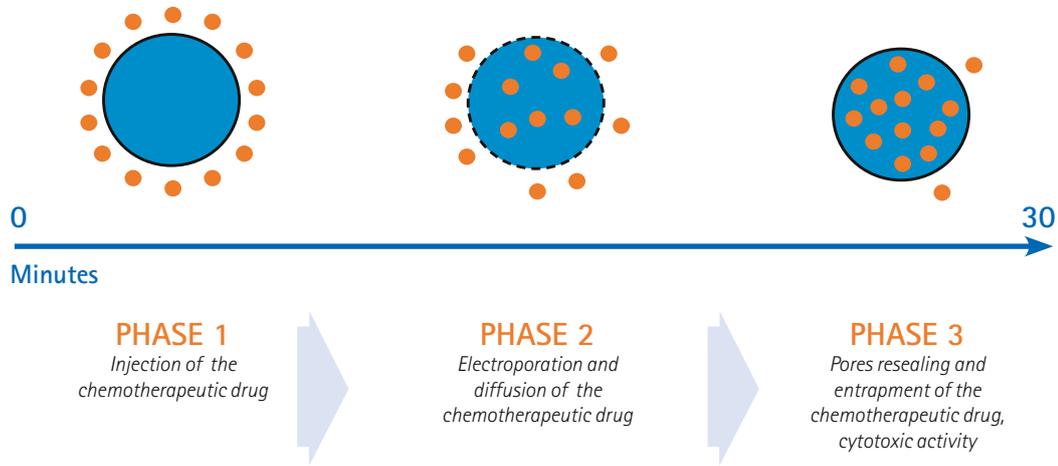


Finger electrode for the treatment of nodules in body cavities



Needle electrodes

ELECTROCHEMOTHERAPY STANDARD OPERATING PROCEDURES



The **STANDARD OPERATING PROCEDURES**, prepared and validated in the ESOPE study (European Standard Operating Procedures for Electrochemotherapy), describe precisely the drug dosing, the electric field amplitude applied and the treatment schedule to obtain reproducible positive results on all tumour types [Mir LM, 2006].

INDICATIONS FOR USE

Electrochemotherapy is indicated in the local treatment of cutaneous and subcutaneous metastatic lesions regardless of tumour histology and ongoing or previous treatments.

Demonstrated effectiveness, complete response and long term tumour control, justifies its use in the early treatment of cutaneous metastases.



ADVANTAGES



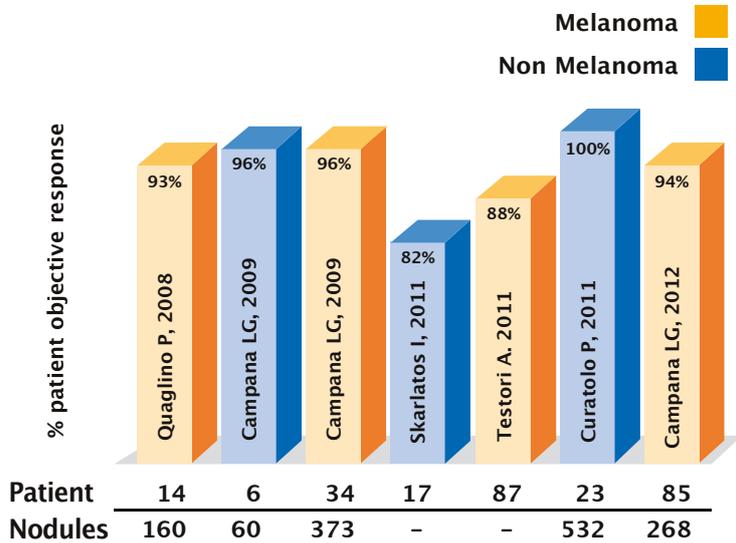
- Thirty minutes treatment time
- Out-patient procedure
- Repeatability
- Does not preclude other treatments
- Minimal side effects

MELANOMA AND OTHER SKIN TUMOURS

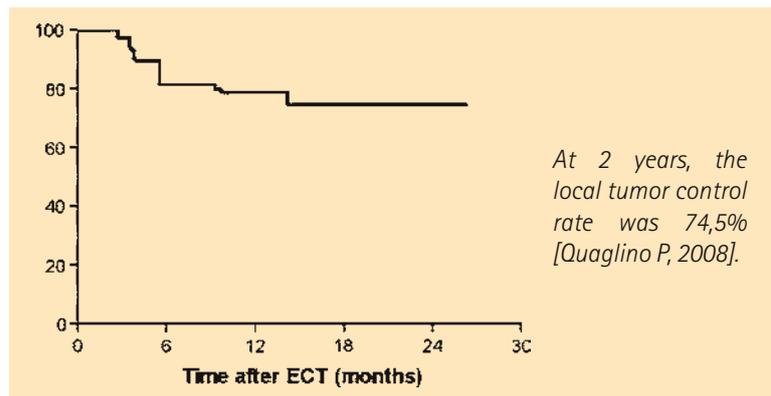
ELECTROCHEMOTHERAPY IS INDICATED IN PATIENTS WITH STAGE IIIB/C AND STAGE IV M1 MELANOMA AND CAN BE CONSIDERED AN ELECTIVE TREATMENT FOR METASTASES LOCATED ON THE TRUNK.

Several independent clinical studies (validated by a systematic review and meta analysis - Mali et al EJSO 2012) have demonstrated that more than 80% of metastases from melanoma respond to treatment using the CLINIPORATOR system. The palliation of bleeding and painful lesions occurs within a few days of the therapy. Treatment response can be assessed by two weeks post procedure.

LOCAL RECURRENCES FOLLOWING ELECTROCHEMOTHERAPY ARE RARE. Complete response is confirmed by the absence of tumour cells, as shown by histological analysis [Quaglino P, 2008].



Patient	14	6	34	17	87	23	85
Nodules	160	60	373	-	-	532	268



ADVANTAGES



- Objective response rate > 80%
- Repeatability
- Tissue sparing and preservation of organ function
- Long term local control

OTHER SKIN TUMOURS

Electrochemotherapy is successfully used for the treatment of:

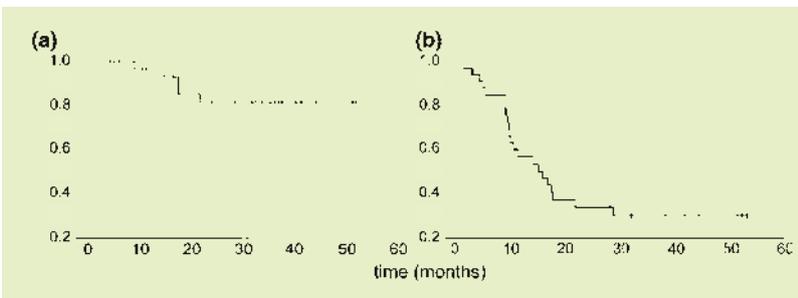
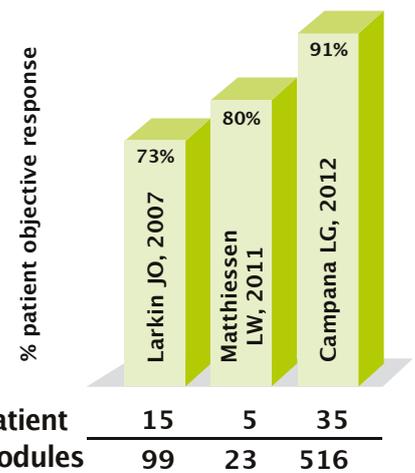
- Basal cell carcinoma
- Squamous cell carcinoma
- Kaposi's Sarcoma
- Gorlin-Goltz syndrome
- Merkel cell carcinoma

LOCAL RECURRENCES AND CUTANEOUS METASTASES FROM BREAST CANCER

THE IMPORTANCE OF LOCAL TUMOUR CONTROL

A meta-analysis conducted by Clarke M [Lancet, 2005] demonstrates that the association of systemic and local control in breast cancer treatment improves by 4.9% the overall survival at 15 years. Clinical evidence from multiple independent reports demonstrates that electrochemotherapy is an effective treatment for local recurrences and skin metastases from breast cancer, with an objective response rate of 85%.

	PRIMARY BREAST CANCER	DISEASE RELAPSE recurrence or skin metastases
Systemic	CHEMOTHERAPY BIOLOGICAL THERAPIES HORMONE THERAPY	CHEMOTHERAPY BIOLOGICAL THERAPIES HORMONE THERAPY
Local	SURGERY: - quadrantectomy - mastectomy RADIOTHERAPY	SURGERY (if feasible) RADIOTHERAPY (if feasible) BRACHYTHERAPY ELECTROCHEMOTHERAPY



Local tumor control in 35 BC patients treated with ECT for refractory chest wall recurrence.
(a) Local progression-free survival (LPFS) on the electroporated metastases.
(b) New lesion-free survival (NLFS) (e.g., freedom from new skin lesions on the chest wall in non-electroporated areas).
 [Campana LG, 2012].

ADVANTAGES

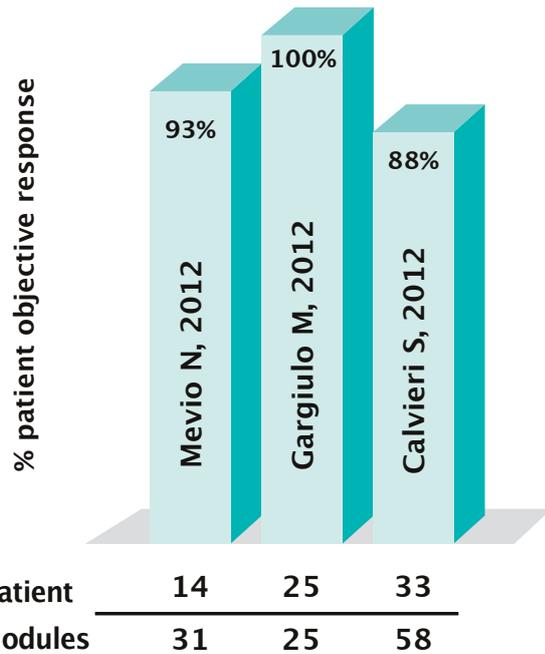


- Objective response rate > 85%
- Efficacy in areas previously treated with radiation therapy
- Palliation of painful, ulcerated or bleeding lesions
- Improved quality of life and cosmetic results
- Concomitant use with other therapies

Breast Cancer



HEAD AND NECK CANCERS



Head and neck cancers are most often associated with squamous cell carcinoma and are characterised by locally aggressive lesions and high risk of relapse. This disease is usually controlled with **LOCAL TREATMENTS**.

Electrochemotherapy is indicated for head and neck cancers due to the treatment efficacy and the **MINIMAL EFFECT ON NORMAL TISSUE AND ON ORGAN FUNCTION**.

Electrochemotherapy in Head and Neck cancers is an effective tool for radical local disease control and as a neoadjuvant treatment. For locally advanced challenging Head and Neck cancers it can be a first line treatment [Gargiulo M, 2010].

ADVANTAGES

- Objective response rate >88%
- Cytoreduction as adjuvant to surgery
- Preservation of normal tissue and organ function
- Palliation of painful, ulcerated or bleeding lesions
- Efficacy in previously irradiated areas
- Repeatability



Courtesy of Fondazione IRCCS Policlinico San Matteo - University Pavia

PRODUCT	CODE	DESCRIPTION
CLINIPORATOR ECT	IG0020B	Electroporator for electrochemotherapy (EPS02 – B)
CLINIPORATOR ECT + EGT	IG0020F	Electroporator for electrochemotherapy and gene transfer (EPS02 – F)
GREEN LEAD	IG0M915	Lead for electrodes (H266CC99) for CLINIPORATOR mod. EPS02
ELECTRODES	IG0E100	Box of 5 electrodes N-10-HG Hexagonal 10mm
	IG0E102	Box of 5 electrodes N-20-HG Hexagonal 20mm
	IG0E104	Box of 5 electrodes N-30-HG Hexagonal 30mm
	IG0E106	Box of 5 electrodes I-40-HG Hexagonal 40mm D. 0,7 Insulated
BLUE LEAD	IG0M910	Lead for electrodes (H20066CC) for CLINIPORATOR mod. EPS02
ELECTRODES	IG0E150	Box of 5 electrodes N-10-4B Linear 10mm
	IG0E152	Box of 5 electrodes N-20-4B Linear 20mm
	IG0E154	Box of 5 electrodes N-30-4B Linear 30mm
FINGER ELECTRODES	IG0E350	Finger Electrode F-05-LG 5mm/longitudinal
	IG0E351	Finger Electrode F-05-OR 5mm/ortogonal
	IG0E360	Finger Electrode F-10-LG 10mm/longitudinal
	IG0E361	Finger Electrode F-10-OR 10mm/ortogonal
ADJUSTABLE ELECTRODES	IG0E070	Adjustable electrode, linear configuration 30 mm (30), Standard
	IG0E080	Adjustable electrode, linear configuration 40 mm (40), Insulated
	IG0E050	Adjustable electrode, hexagonal configuration 30 mm (30), Standard
	IG0E060	Adjustable electrode, hexagonal configuration 40 mm (40), Insulated

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