oneyonis®

WHERE HEALING BEGINS AT THE INCISION

All-in-one device:

- contactless cutting dissecting
- below 50°C
- airplasma® technology

ELECTROSURGERY

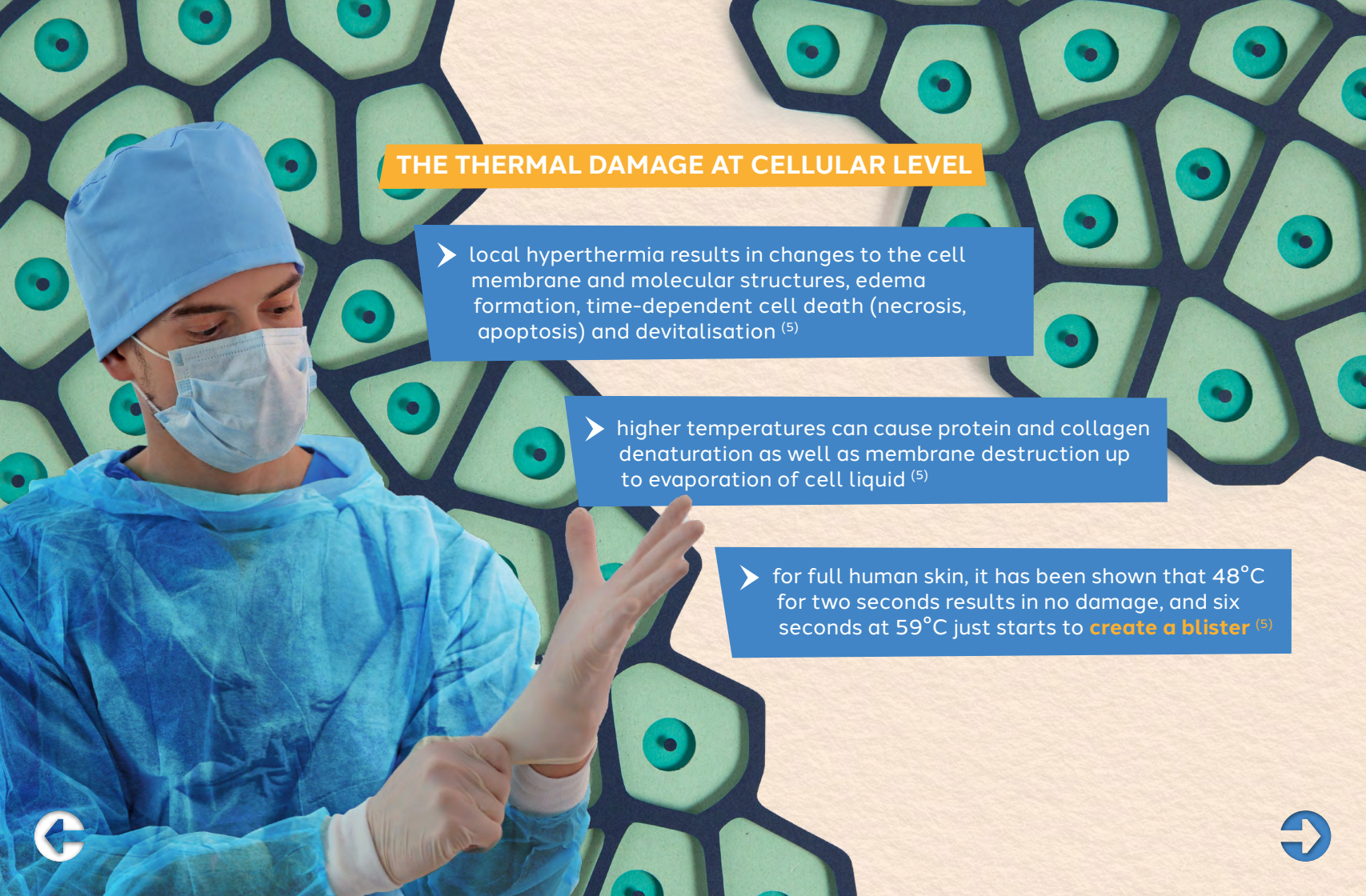
The damage of thermal energy

The benefits of electrosurgery have been acknowledged since the early 1920s, and nowadays more than 80% of surgical procedures involve devices that apply energy to tissues [1]

[...] however, a substantial amount of heat created by electrosurgical devices has been shown to spread throughout the tissue, leading to unintended thermal damage and impairment of a patient's postoperative quality of life. Due to this, special attention must be given by surgeons to minimize unneeded thermal damage [2]

HOW THE THERMAL DAMAGE IS CREATED

- Adjacent to the active electrode, tissue resistance to the passage of alternating current converts electrical energy to heat, resulting in thermal tissue damage [3]
- Because there is more available energy to heat tissue, thermal damage is predictably deeper and more widespread during contact electrosurgical phenomena [4]



THE THERMAL DAMAGE AT CELLULAR LEVEL

- local hyperthermia results in changes to the cell membrane and molecular structures, edema formation, time-dependent cell death (necrosis, apoptosis) and devitalisation [5]

- higher temperatures can cause protein and collagen denaturation as well as membrane destruction up to evaporation of cell liquid [5]

- for full human skin, it has been shown that 48°C for two seconds results in no damage, and six seconds at 59°C just starts to **create a blister** [5]


INSPIRED BY NATURE,
A NEW SURGICAL
TECHNOLOGY IS BORN

PLASMA IS THE FOURTH STATE OF MATTER

PLASMA

- plasma, in physics, is an electrically conducting medium in which there are roughly equal numbers of positively and negatively charged particles, produced when the atoms in a gas become ionised [6]
- supply of energy to a gas, strong electric fields results in a partial or complete ionisation of gas atoms or molecules, respectively.
  Because of the resulting motile electrons and ions, plasmas are conductive. [10]

PLASMA TEMPERATURE

- a plasma may be produced in the laboratory by heating a gas to an extremely high temperature [6]
- low temperature plasma is a partially ionised gas containing a variety of ions, electrons, active molecules, electric fields and ultraviolet radiation [7]

PLASMA MEDICINE

- a new field of medical research at the interface between plasma physics and life sciences [8]
- the topic and aim of plasma medicine is the use of physical plasmas for medical applications [8]

COLD PLASMA IN ACTION

COLD PLASMA

- CAPP = Cold Atmospheric Pressure Plasma
- This is a kind of plasma produced at a normal temperature and atmospheric pressure that respects the tissues and does not cause carbonisation [9]

VARIOUS CLINICAL ADVANTAGES [11]

- Reduction of post-operative pain level
- Reduced wound healing period of wound healing
- Functional-aesthetic improvement of scars
- Reduction of bacterial load in pre-operative and post-operative setting

OTHER ADVANTAGES OF COLD PLASMA

- Non-thermal plasma enhances endothelial cell proliferation due to reactive oxygen species mediated **FGF2 (Fibrin Growth Factor 2)** [14]
- Recent studies have shown that Plasma-Activated Medium (PAM) (culture medium irradiated by non-thermal plasma) selectively induces **apoptotic death of cancer cells** but not normal cells. [12]
- Several authors have reported the **effectiveness against cancer** in different cell lines and animal models [13]

airplasma® technology

a new technology that generates plasma directly from the air without external inert gas sources

Air is naturally neutral and an electric insulant but, with airplasma® technology, it becomes an ideal conductor of electrical energy, due to the application of high voltage pulses.

In a maximum gap of 3 mm, between the tip of the electrode and the tissue, the air becomes ionised and therefore conductive.

Plasma from the air in the gap is visible in the form of a glow. Plasma's electrons and the ions transfer their energy to the biological tissues, inducing **"tissue vaporisation".**

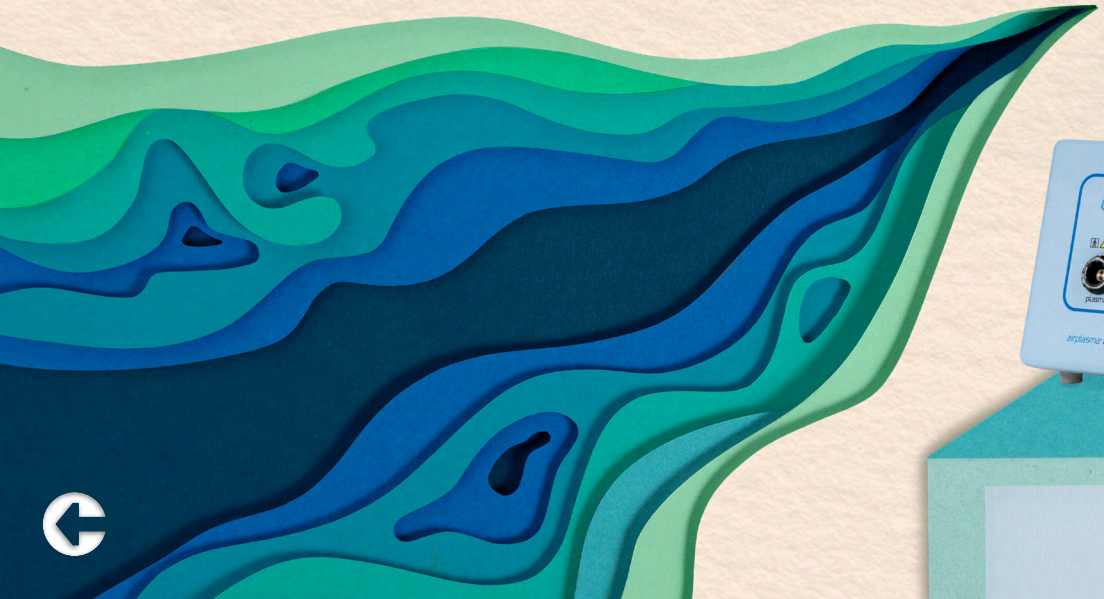
THE MAXIMUM WORKING TEMPERATURE ON THE TISSUE IS 50°C (122°F).

Progetto PSC, Modena

Studies on the fumes generated during the procedure demonstrated that **no detectable carcinogenic compounds** are present.

"Technical Report" – Idrogeolab, Alessandria

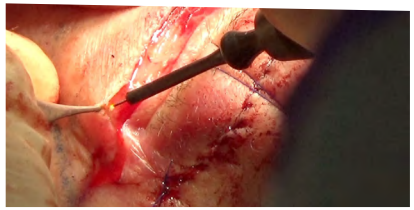
IMPROVED TISSUE HEALING DUE TO LESS THERMAL DAMAGE



oneyonis®

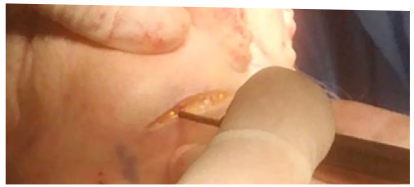
By operating at a temperature < 50°C we minimise the thermal damage to the tissue

HOW IT WORKS



NO-TOUCH AIRPLASMA® TECHNIQUE

Plasma is generated by simply approximating the tip of the handpiece (electrode) to the tissue. This enables **superficial treatment.**



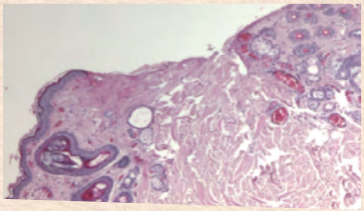
TOUCH AIRPLASMA® TECHNIQUE

Moving the electrode closer to touch the tissue allows to perform **cutting** and **dissection.**

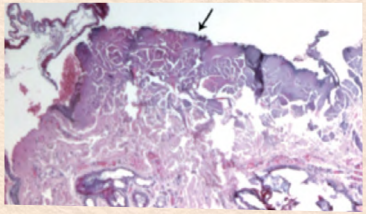
We demonstrated that the plasma scalpel provides efficient skin incision with a superior wound profile, comparable to that of the cold blade but with significantly less bleeding, and lower thermal damage compared to electrosurgery.
These results suggest that the plasma scalpel has an interesting potential in surgical fields where electrosurgery is not used extensively. [15]

The thickness of the area of coagulation necrosis is greater in the incisions made with the radiosurgical scalpel than in those made with the plasma device [16]

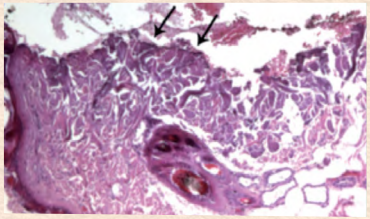
SCALPEL BLADE



AIRPLASMA® TECHNOLOGY



ELECTROCAUTERY



ABSENCE OF SIGNIFICANT LESIONS: HISTOLOGICAL FINDINGS [17]

0.5 cm sample Heat damage 250 microns	0.5 cm sample Heat damage 280 microns	0.7 cm sample Heat damage 200 microns	0.8 cm sample Heat damage 300 microns

oneyonis® AT A GLANCE

UNIQUE
Generates plasma directly from the air

INNOVATIVE
Operates at temperature < 50 °C

ALL-IN-ONE
Superficial external treatment, cutting and dissecting

ACCURATE
Micro-control of cold plasma in action

SAFE
No special protections are needed for the operator

PORTABLE
Easy-to-carry

ONEYONIS® - Device description

ONEYONIS® A 1000

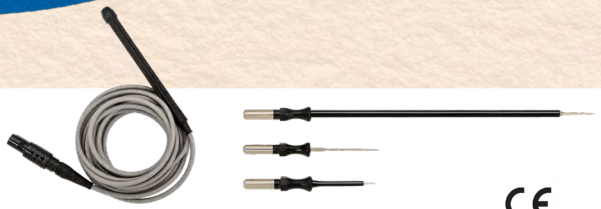
CE 1282

Oneyonis® A 1000 is a plasma-activated, radiofrequency-operated, surgically invasive medical device, of class IIb, that belongs to the category of electrosurgical devices and works with airplasma® technology. REF: A 1000

STABILISER CABLE

CE 1282

The stabiliser cable recovers surface currents spread over the patient's body. The cleaning and disinfection procedure, explained in the user instructions, requires a container, lukewarm water, CIDEZIME® or ENZOL®, an ultrasonic bath and final rinsing and drying.
The stabiliser cable is expected to last for 25 cleaning and disinfection cycles, but this will depend on wear and damage incurred during use.
REF: STCA1



HANDPIECE WITH ELECTRODES*

CE 1282

The handpiece may be sterilised in an autoclave at 134°C for 5 ' in accordance with ISO 17665 (Sterilization of medical device in moist heat). The handpiece maintains its use and performance properties for up to 25 steam sterilisation cycles. REF: HBCC1

Cheaper and more environmentally sustainable compared with disposable handpieces.

(*) Distribution products

PEDAL

CE 1282

The pedal activates the airplasma® generator. REF: PED2


SAFE SURGERY,
HAPPIER PATIENTS

REFERENCES

1. Meeuwsen FC et al. The Art of Electrosurgery: Trainees and Experts. Surgical Innovation 2017; 24(4):373–378.
2. Dodde RE et al. Monopolar Electrosurgical Thermal Management for Minimizing Tissue Damage. IEEE Trans Biomed Eng 2012; 59(1):167-73.
3. Arash Taheri – Electrosurgery, Part I. Basics and Principles
4. Brill AI Electrosurgery: principles and practice to reduce risk and maximize efficacy Obstet Gynecol Clin North Am 2011; 38(4):687-702.
5. Wende K et al. Emission of thermal energy - Springer International Publishing AG, part of Springer Nature 2018 H. - R.Metelmann et al. (eds.), Comprehensive Clinical Plasma Medicine p.84
6. Kelley MC Plasma Encyclopedia Britannica 2020
7. Gao L et al. Applications and challenges of low temperature plasma in pharmaceutical field. Journal of Pharmaceutical Analysis 2021; 11:28-36.
8. von Woedtke T et al. Introduction to Plasma Medicine - Springer International Publishing AG, part of Springer Nature 2018 H. - R. Metelmann et al. (eds.), Comprehensive Clinical Plasma Medicine p.3
9. Podmelle F et al. Perspectives in Aesthetic Medicine - Springer International Publishing AG, part of Springer Nature 2018 H. - R. Metelmann et al. (eds.), Comprehensive Clinical Plasma Medicine p.355
10. von Woedtke T et al. Introduction to Plasma Medicine - Springer International Publishing AG, part of Springer Nature 2018 H. - R. Metelmann ed al. (eds.), Comprehensive Clinical Plasma Medicine p.3
11. Rutowsky R et al. Cold Atmospheric Plasma in Context of Surgical Site Infection - Springer International Publishing AG, part of Springer Nature 2018 H. - R.Metelmann et al. (eds.), Comprehensive Clinical Plasma Medicine p.159
12. Ikeda J et al. Plasma-activated medium (PAM) kills human cancer-initialing cells. Pathology International 2018; 68(1):23-30
13. Metelmann HR et al. Clinical experience with cold plasma in the treatment of locally advanced head and neck cancer. Clinical Plasma Medicine 2018; 9:6-13
14. Kalghatgi S et al. Endothelial cell proliferation is enhanced by low dose non-thermal plasma through fibroblast growth factor-2 release. Ann Biomed Eng 2010; 38(3):748-57
15. Lacitignola L et al. Comparative Morphological Effects of Cold-Blade, Electrosurgical, and Plasma Scalpels on Dog Skin. Vet Sci 2020; 7(1):8.
16. Vezzoni A et al. Clinical use of a new plasma device. Veterinaria 2016; 4:227-234.
17. University of Turin. Vet Clinic Roma Sud. Histological and Morphometric analysis of thermal shock alterations in tissue samples.

OTECH
INDUSTRY

info@otechindustry.it
www.otechindustry.it

Otech Industry Srl
Corso Felice Cavallotti, 60
15121 Alessandria (Italy)

CE
1282

Quality standard management according
to EN ISO 13485:2016

ID code eBRO EN.B.05.21