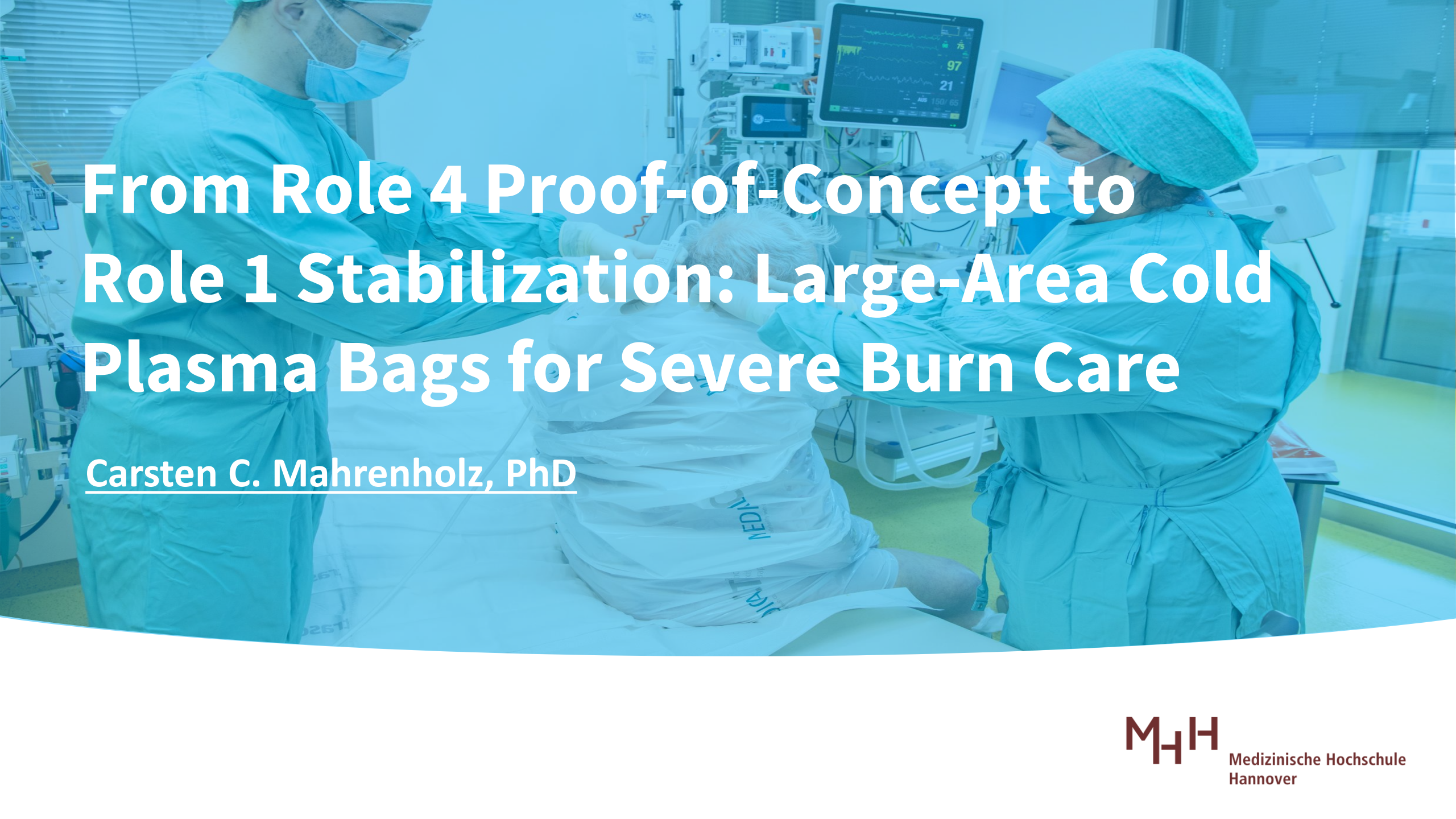


A photograph of two medical professionals in an intensive care unit (ICU) setting, wearing blue scrubs and masks, attending to a patient lying on a gurney. The patient is covered with a white sheet. In the background, there are medical monitors displaying vital signs and various medical equipment. The entire image has a blue tint.

From Role 4 Proof-of-Concept to Role 1 Stabilization: Large-Area Cold Plasma Bags for Severe Burn Care

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VINCENT MÄRZ, MD

THORBEN DIECK, MD

PETER M. VOGT, MD



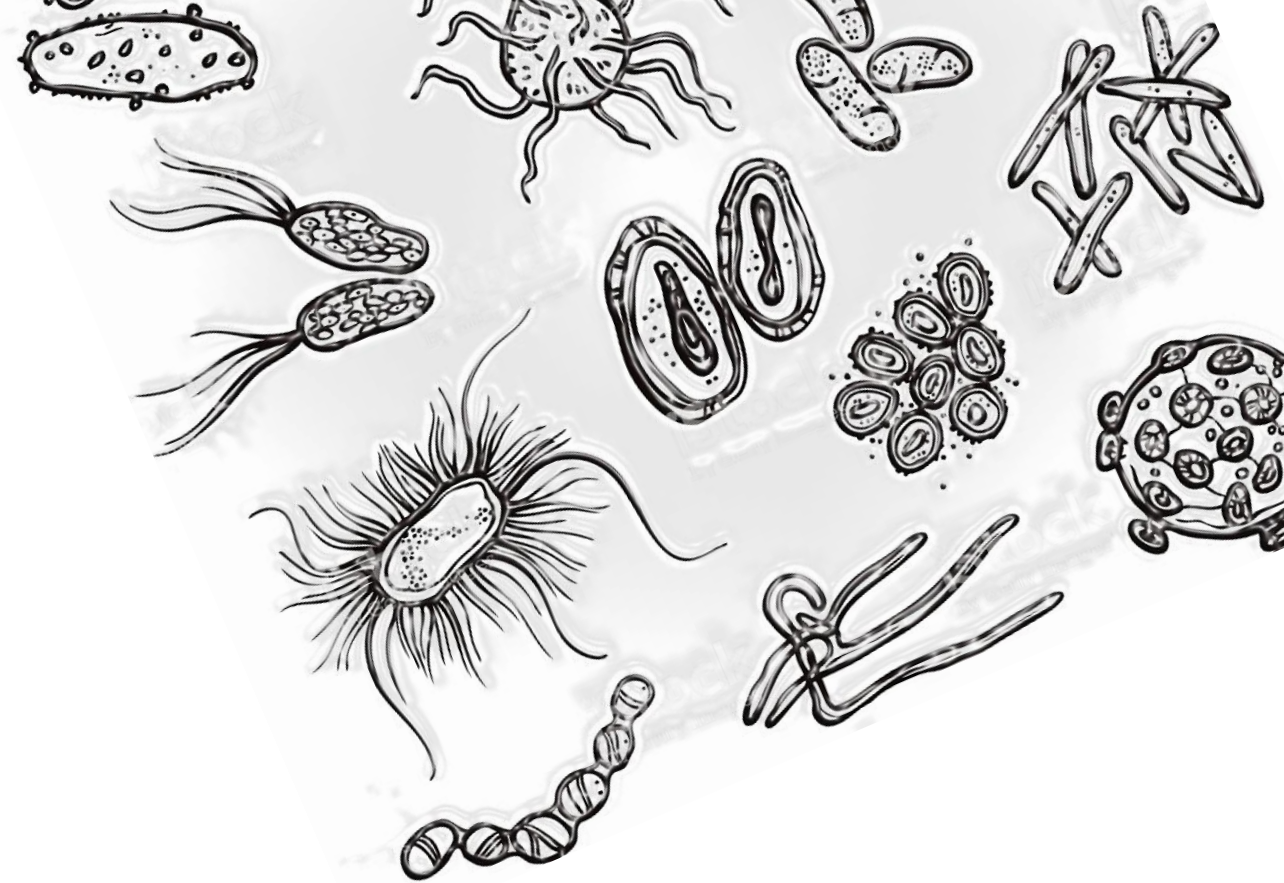
DISCLOSURE

*THIS PRESENTATION INCLUDES INFORMATION ABOUT THE **CPTCUBE** AND **CPTPATCH**, INNOVATIVE MEDICAL DEVICES DESIGNED FOR THE TREATMENT OF CHRONIC WOUNDS AND BURNS. THESE DEVICES ARE **CE MARKED** IN ACCORDANCE WITH EUROPEAN REGULATIONS, SIGNIFYING COMPLIANCE WITH THE APPLICABLE EU MEDICAL DEVICE REGULATION (MDR).*

*HOWEVER, **THESE DEVICES ARE NOT FDA-CLEARED OR FDA-APPROVED** AND ARE NOT CURRENTLY AUTHORIZED FOR SALE OR USE IN THE UNITED STATES. THE INFORMATION PRESENTED IS INTENDED SOLELY FOR EDUCATIONAL AND INFORMATIONAL PURPOSES AND SHOULD NOT BE CONSTRUED AS A SOLICITATION OR PROMOTION OF THE DEVICES FOR USE IN THE U.S. MARKET.*

DISCLOSURE: THE PRESENTER IS THE CEO OF COLDPLASMATECH GMBH, THE MANUFACTURER OF THE CPT® DEVICES DISCUSSED IN THIS PRESENTATION. THE COMPANY DID NOT FUND THE TREATMENTS PRESENTED, HAD NO INFLUENCE ON DATA COLLECTION, ANALYSIS, OR INTERPRETATION, AND THE DEVICES USED WERE COMMERCIALY PURCHASED BY THE RESPECTIVE INSTITUTIONS.

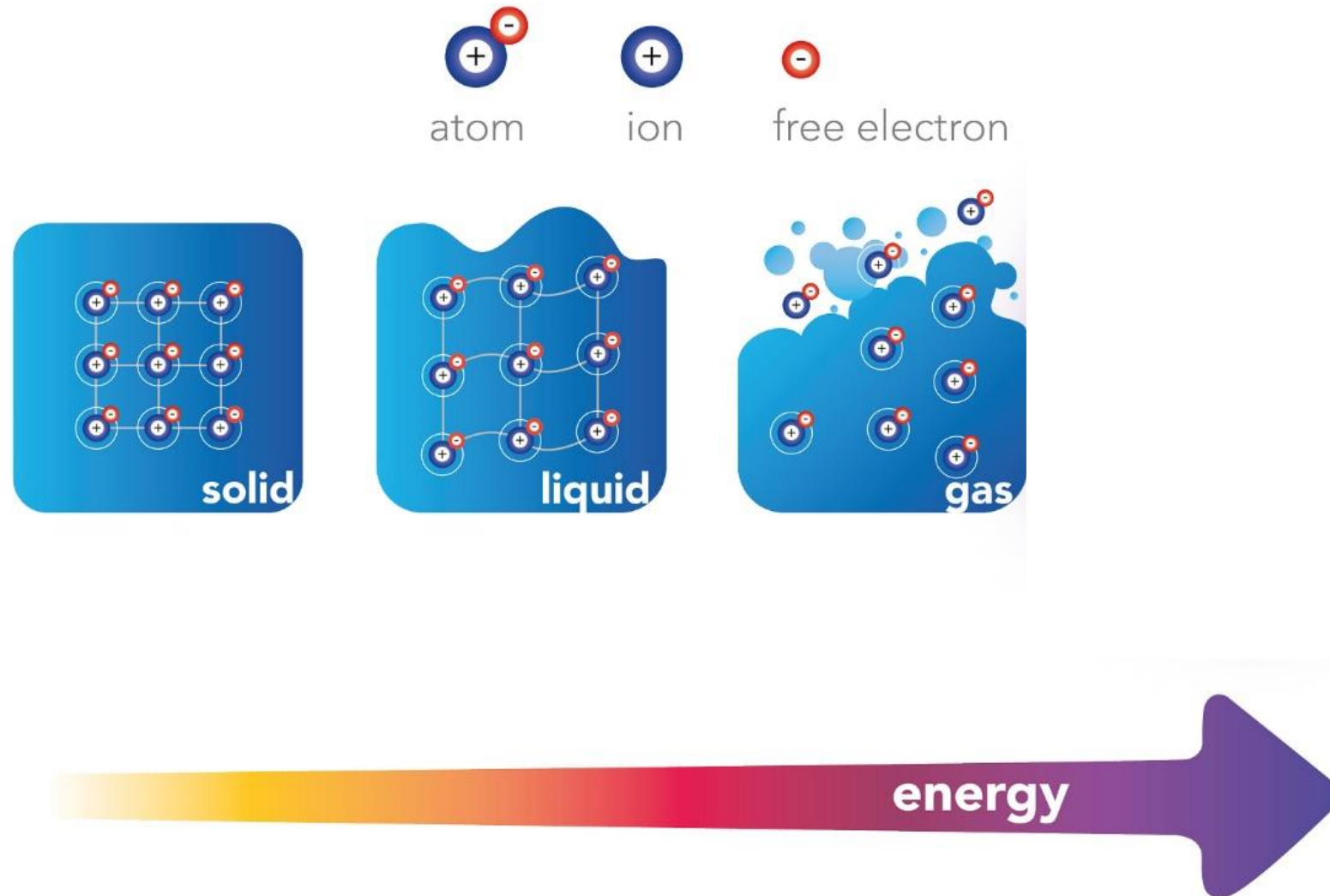
ANTIMICROBIAL RESISTANCE AND
WOUND INFECTIONS LEAD TO AN
INCREASING NUMBER OF
COMPLICATIONS



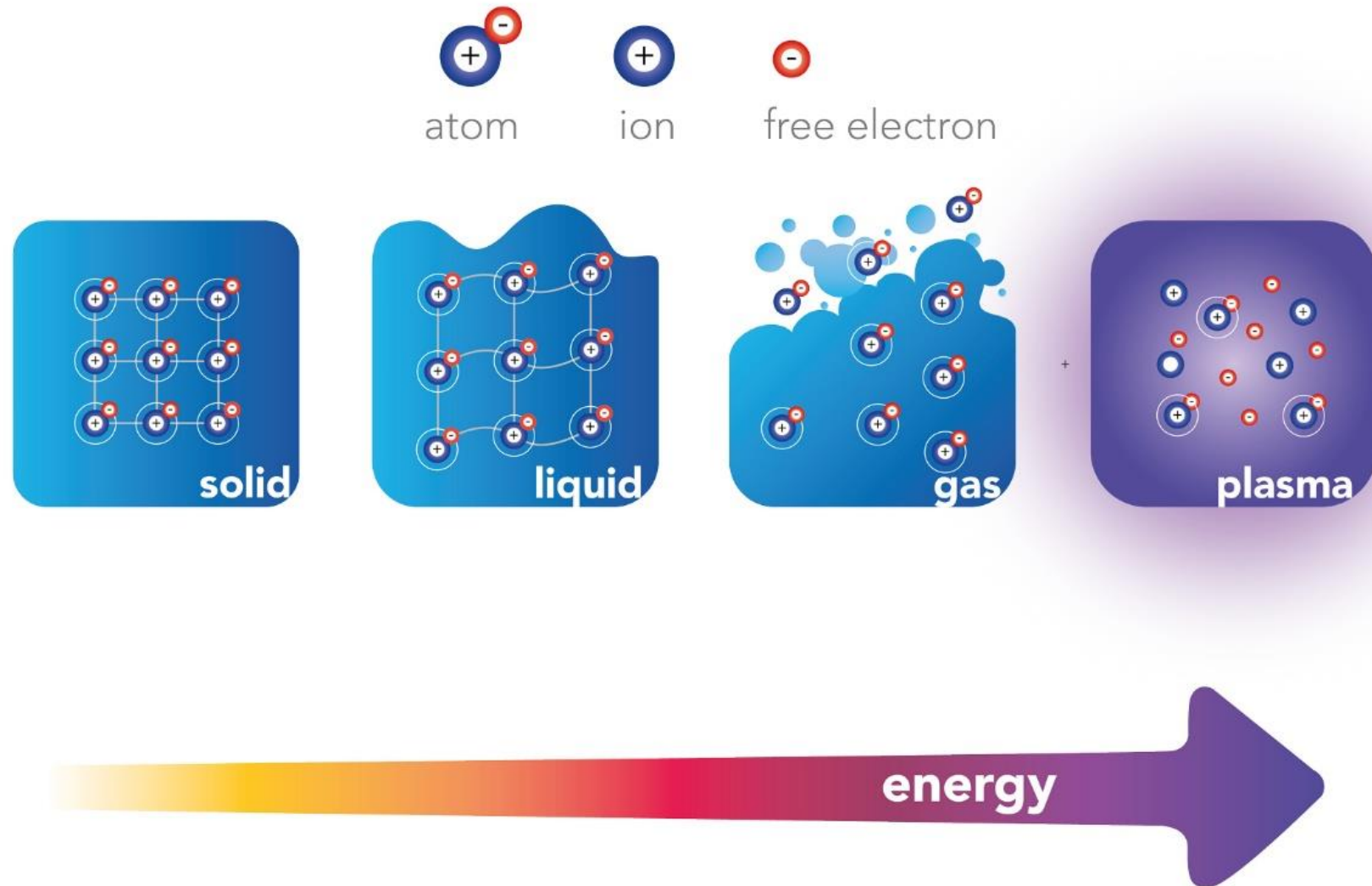
ANTIMICROBIAL-RESISTANT **BURN WOUND
INFECTION AFTER DELAYED EVACUATION**
THREATENS SURVIVAL, GRAFTING, AND
TRANSPORT IN LARGE-SCALE COMBAT
OPERATIONS.

COLD PLASMA IS A STATE OF MATTER

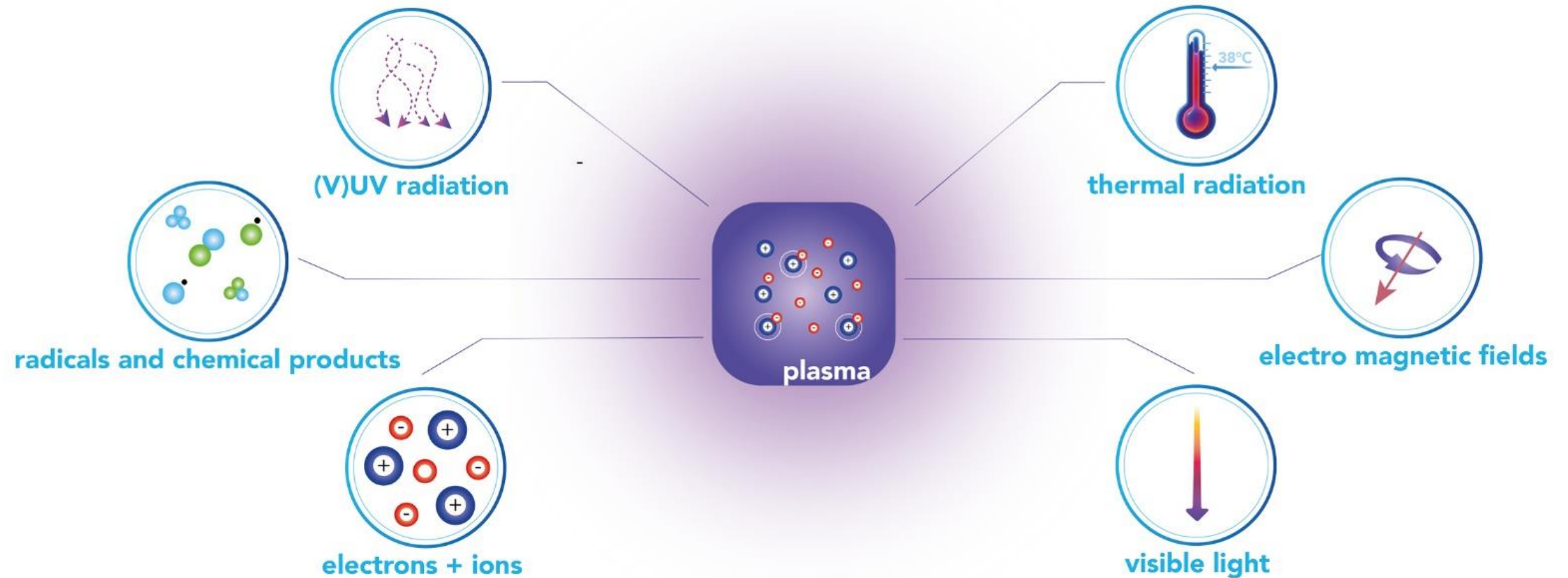
COLD PLASMA IS A STATE OF MATTER



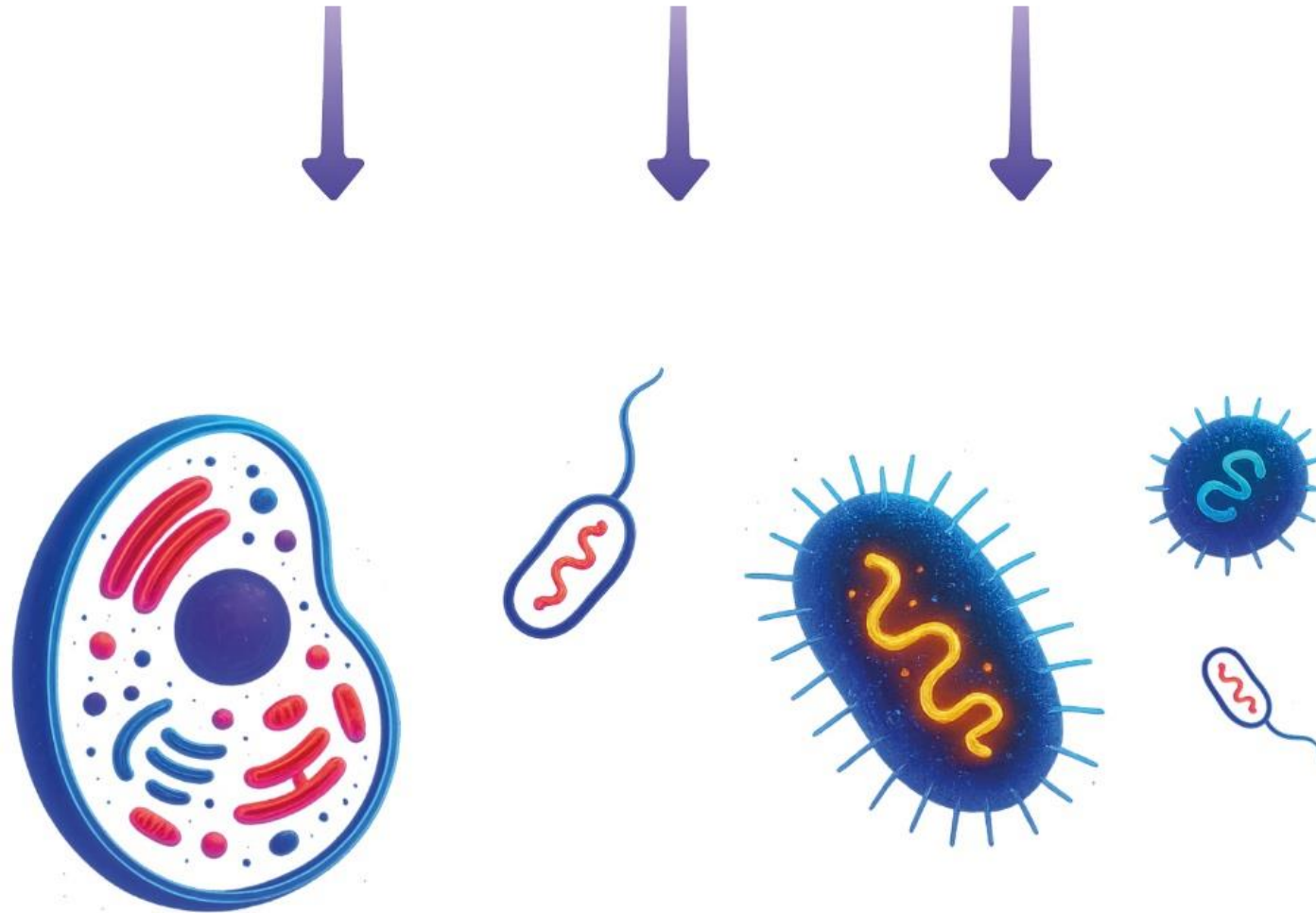
COLD PLASMA IS A STATE OF MATTER



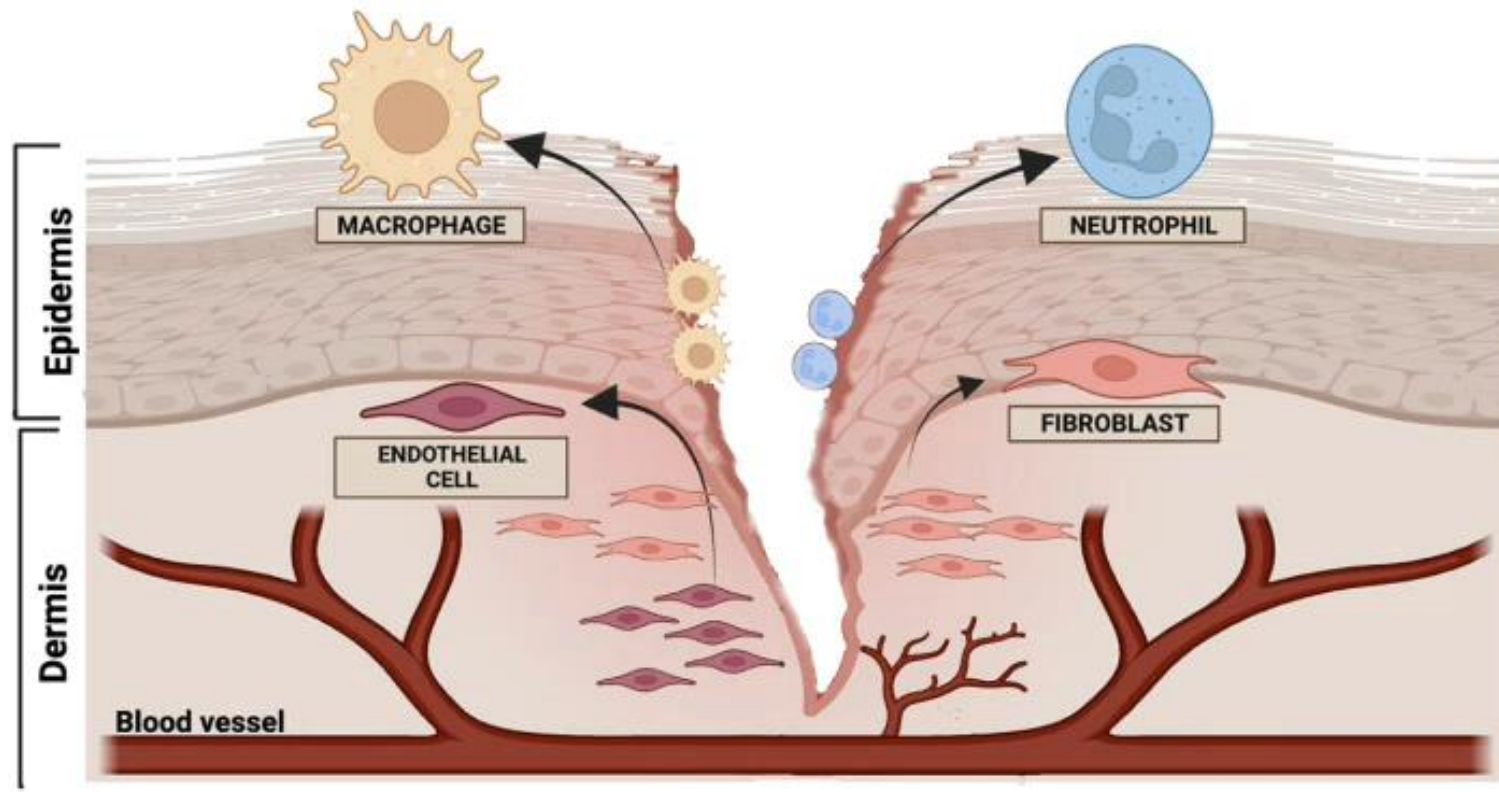
COLD PLASMA IS A STATE OF MATTER AND UNDER SPECIFIC CIRCUMSTANCES BIOACTIVE



COLD PLASMA IS A STATE OF MATTER AND UNDER SPECIFIC CIRCUMSTANCES BIOACTIVE – APPLICATION IS PAIN FREE, FAST AND INDUCES SECRETION OF A VARIETY OF MESSENGERS TO **ACTIVATE CELLS AND KILL BACTERIA**



MECHANISM OF ACTION OF THE OCCLUSIVE THERAPY



COLD PLASMA TREATMENT PLATFORM - BASE COMPONENTS



PLATFORM - MODULES



Large



Medium



Small

**Foil- and
Bag-Systems**



Adhesive frame

PLATFORM - MODULES



Large



Medium



Small

**Foil- and
Bag-Systems**



C²PE system (in development)



Adhesive frame

PLATFORM - COMBINATION



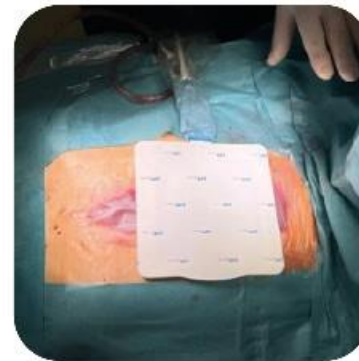
**Artificial
transplants**



Skin transplant



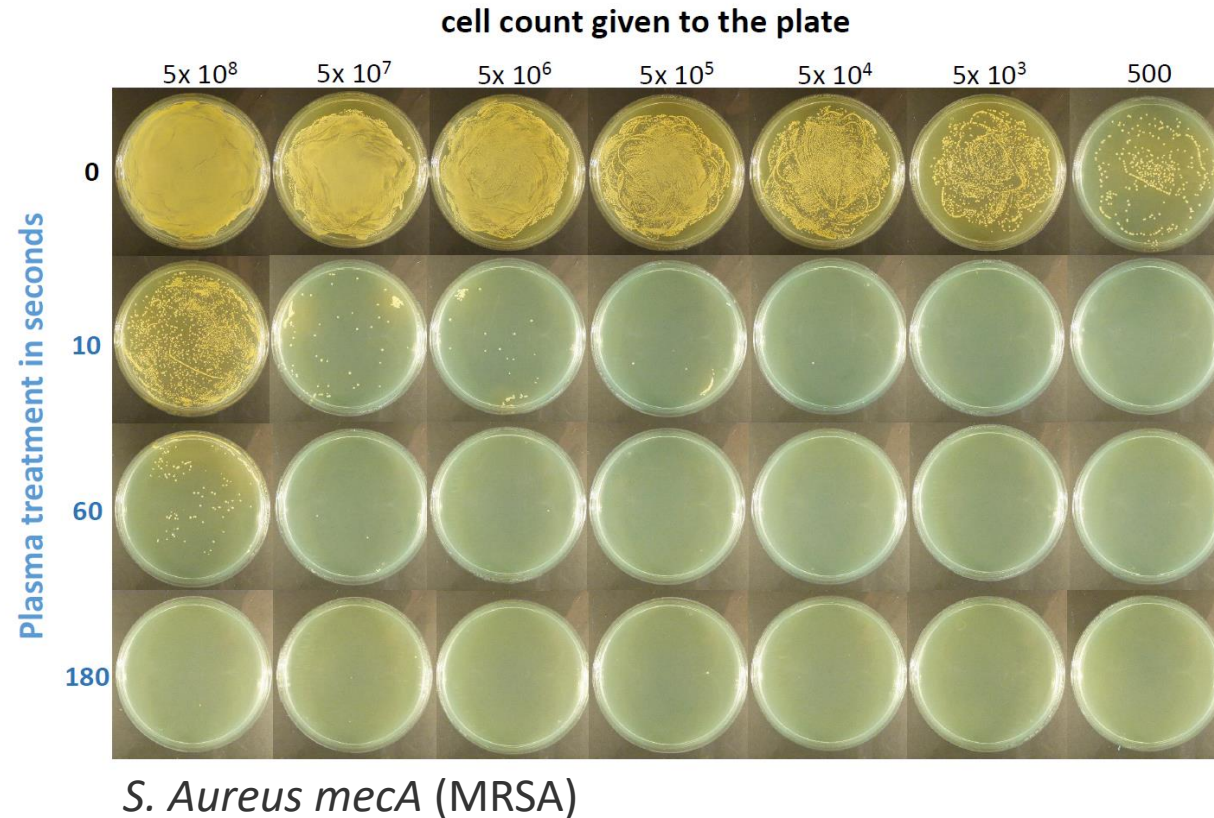
Incorporated



Add-On

NPWT

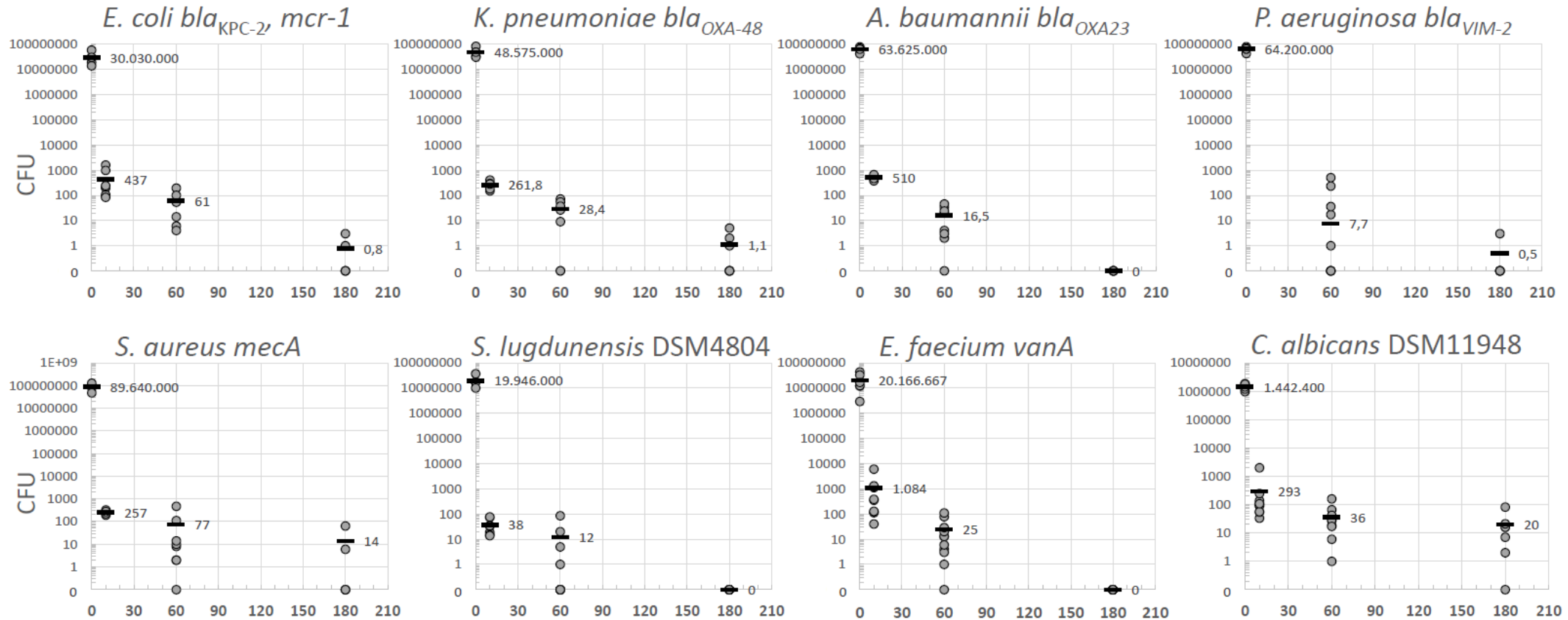
MICROBIOLOGY – *IN VITRO* MINIMAL INHIBITION TESTS SHOW DESINFECTION IN SECONDS WHILE KEEPING CELLS INTACT



German National Reference Center
for multi-resistant bacteria



PLASMA KILLS HIGH AMOUNTS OF GRAM⁺, GRAM⁻ AND FUNGAL PATHOGENS IN SECONDS



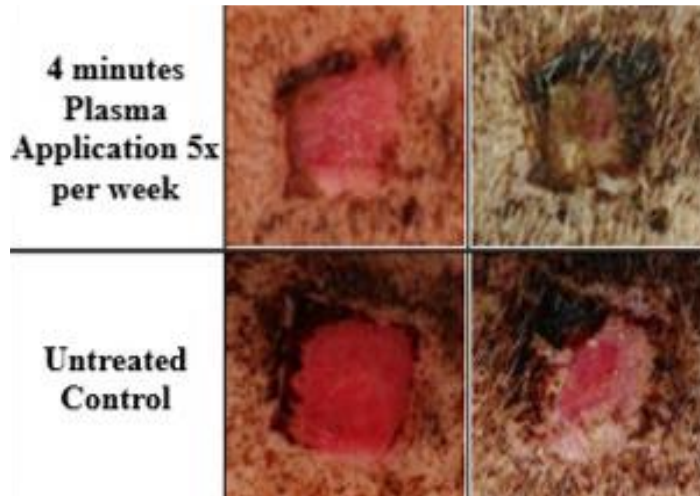
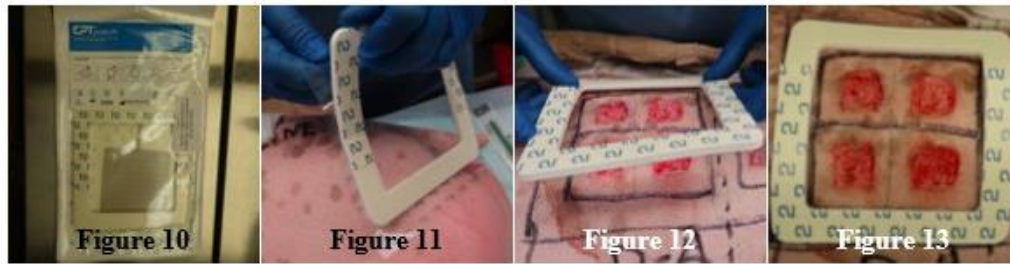
Plates were inoculated using 100 μ l of a cell suspension $OD_{600} = 1,0$ and exposed to cold plasma for 0, 10, 60 or 180 seconds. Remaining cfu were counted (points) and mean values (bars) were calculated.

German National Reference Center
for multi-resistant bacteria

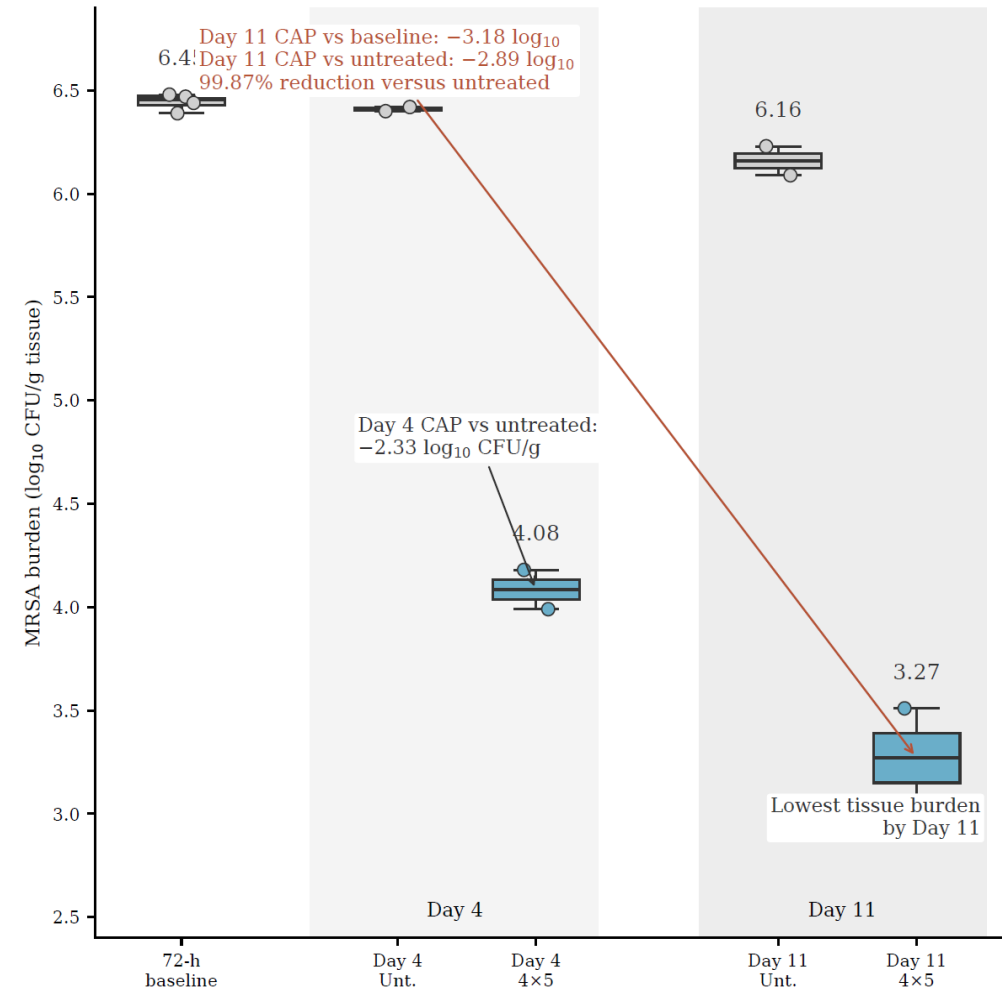


Jeffery, S.; Wakaf, A.; Marlinghaus, L.; Gatermann, S.; Meyer, T.; Gil, J.; Jovic, I.; Davis, S. C. Cold Atmospheric Plasma Disrupts Wound Bioburden: In Vitro, Porcine, and Clinical Fluorescence Evidence from Bench to Bedside. *Biomedicines*.

PIG STUDY DATA SHOWS 3.18-LOG MRSA300 REDUCTION IN 72H BIOFILM MODEL WITH INCREASING TISSUE REPAIR AND NO SIGNS OF TOXICITY



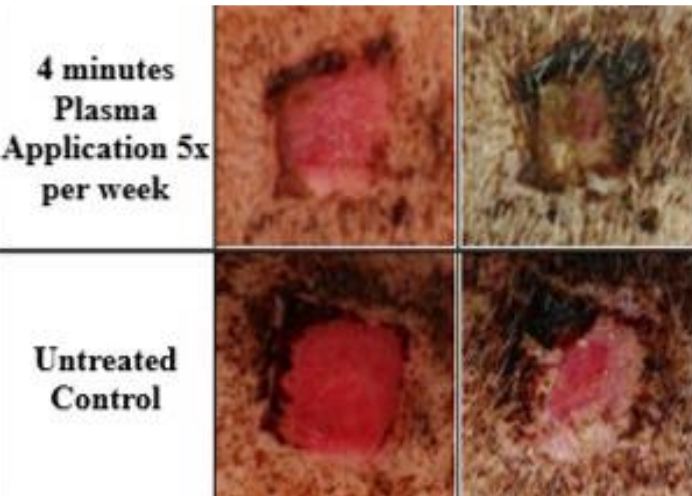
A. 72-h MRSA biofilm: 4 min × 5/week only



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of MEDICINE

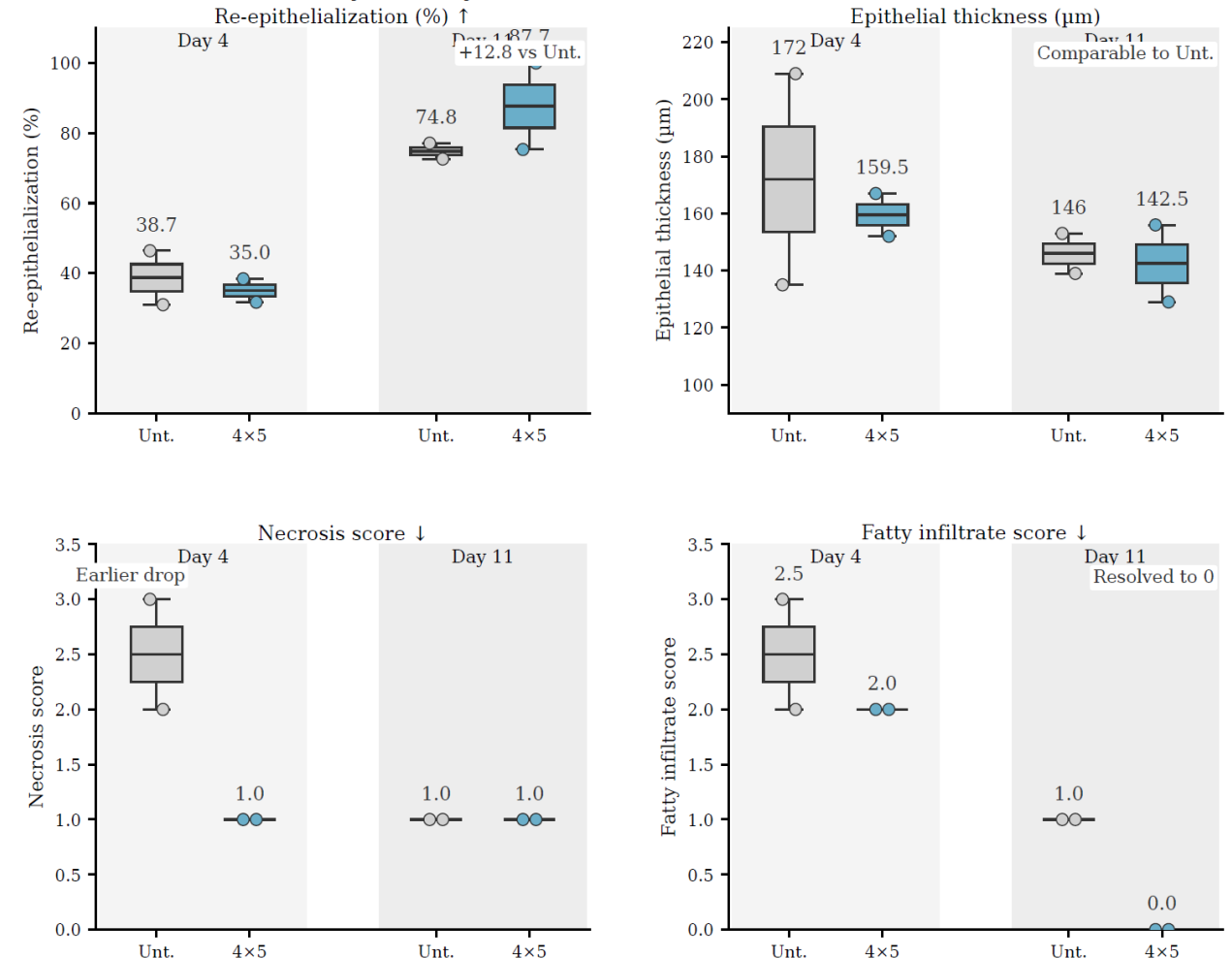
Jeffery, S.; Wakaf, A.; Marlinghaus, L.; Gattermann, S.; Meyer, T.; Gil, J.; Jovic, I.; Davis, S. C. Cold Atmospheric Plasma Disrupts Wound Bioburden: In Vitro, Porcine, and Clinical Fluorescence Evidence from Bench to Bedside. *Biomedicines*.

pub



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B. Tissue tolerability & safety: 4 min × 5/week



Cold plasma for large areas

- Whole burned area enclosed in an airtight treatment bag – C²PE principle
- Foil inside the bag
- Necessary: small pocket of air between wound and bag
- 4-6 min treatment
- once a day
- off label use



OTHER COLLABORATORS:

Patient 23

European Burn Journal 5, no. 3: 271-282. <https://doi.org/10.3390/ebj5030025>

- 45 years, male, no preconditions
- **Ukrainian soldier**
- **nearby explosion in his trench (rocket hit)**
- amputation of the right foot in Kyiv
- 40% burned surface area

Microbiologic findings:

- *Acinetobacter baumannii* 4-MRGN
- Vancomycin resistant *Enterococcus faecium*
- *Pseudomonas aeruginosa* 4-MRGN



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OTHER COLLABORATORS:

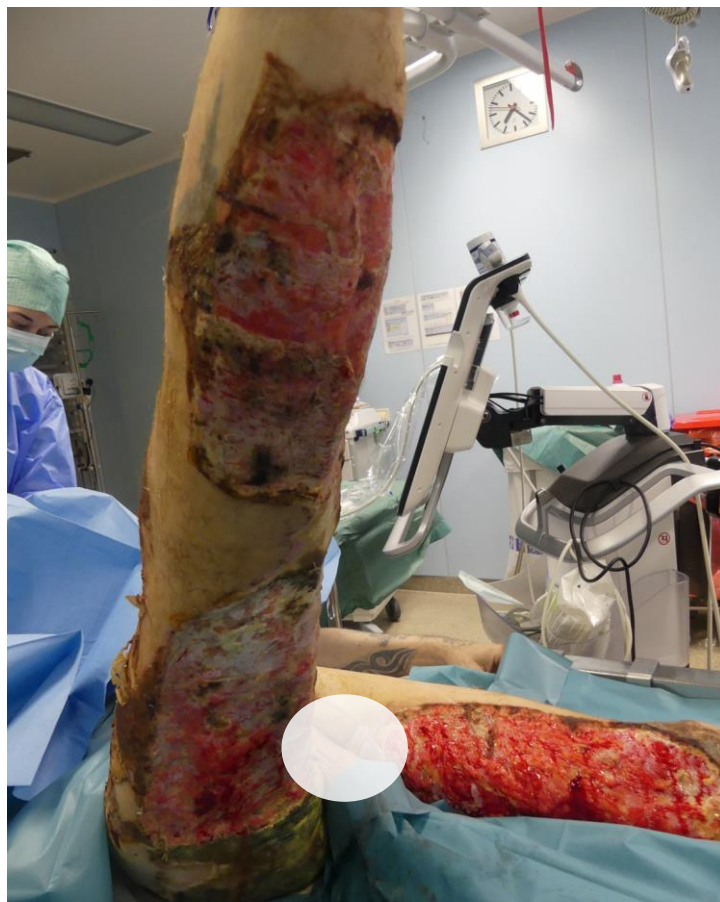


Patient 23 on admission

- Infected wounds
- Insufficient debridement
- Very high inflammation parameters



Patient 23 on admission



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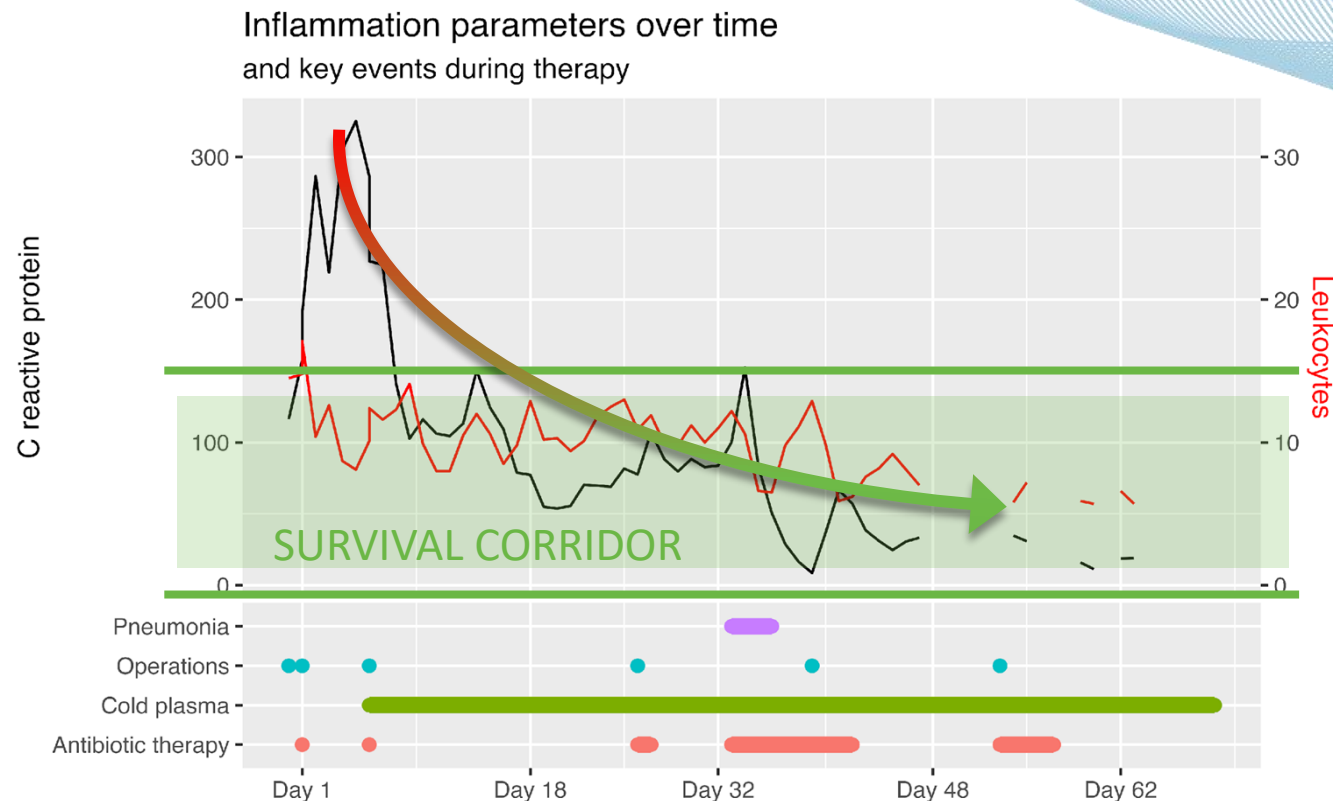


OTHER COLLABORATORS:



Patient 23

- Daily large area cold plasma
- Corridor of contained infection is preserved
- Only perioperative antibiotics and pneumonia treatment



OTHER COLLABORATORS:



Patient 23

- BTM applied on **day 5**
- Cold plasma treatment proceeded



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OTHER COLLABORATORS:



Patient 23

- after complete BTM take on **day 27**: Split thickness skin grafting using Meek's technique



Patient 23

Day 50:

- 90% wound coverage
- No wound associated sepsis
- High patient acceptance



Patient 12

- 27, male , no preconditions
- **Ukrainian soldier**
- **mine explosion**
- 60% burned surface area

Microbiologic findings:

- Acinetobacter baumannii 4-MRGN
- Escherichia coli 4-MRGN
- Klebsiella pneumoniae 4MRGN
- Pseudomonas aeruginosa 4-MRGN
- MRSA



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OTHER COLLABORATORS:



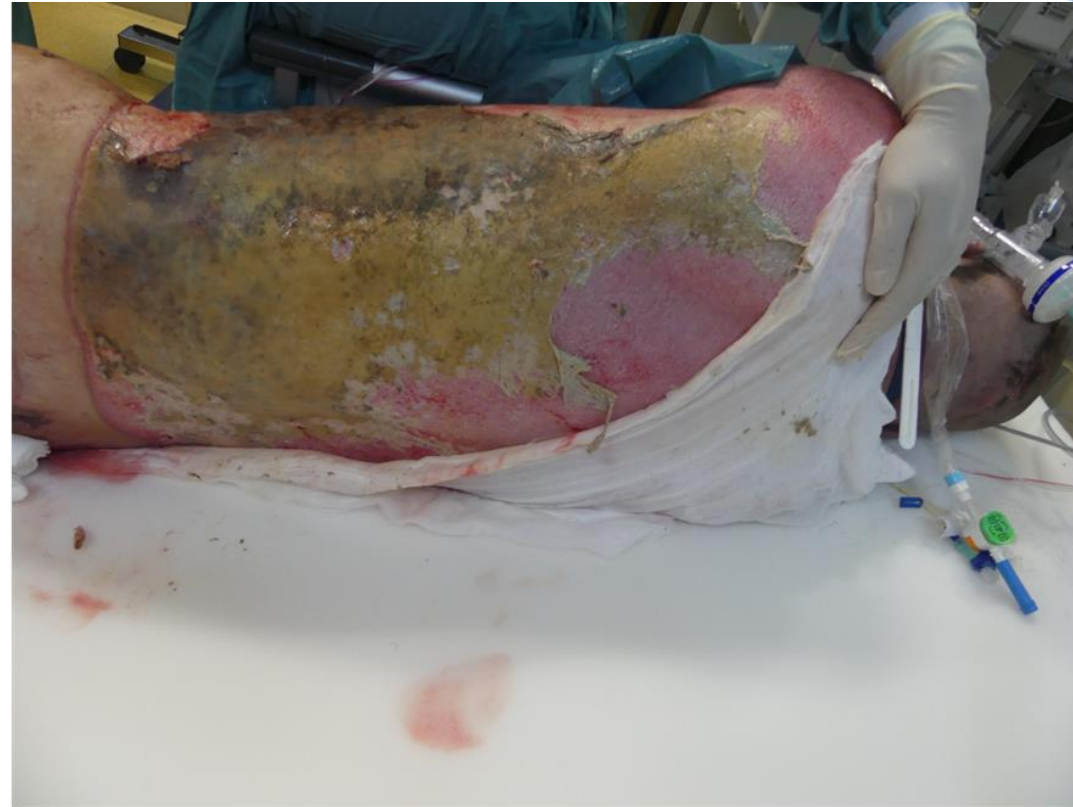
Patient 12 on admission

- Unstable patient
- Smeary wounds
- Adherent pseudo eschar on the back
- Escharotomy of the hands



Patient 12 on admission

- Unstable patient
- Smeary wounds
- Adherent pseudo eschar on the back
- Escharotomy of the hands



Patient 12 on admission

- Unstable patient
- Smeary wounds
- Adherent pseudo eschar on the back
- Escharotomy of the hands



Patient 12 on admission

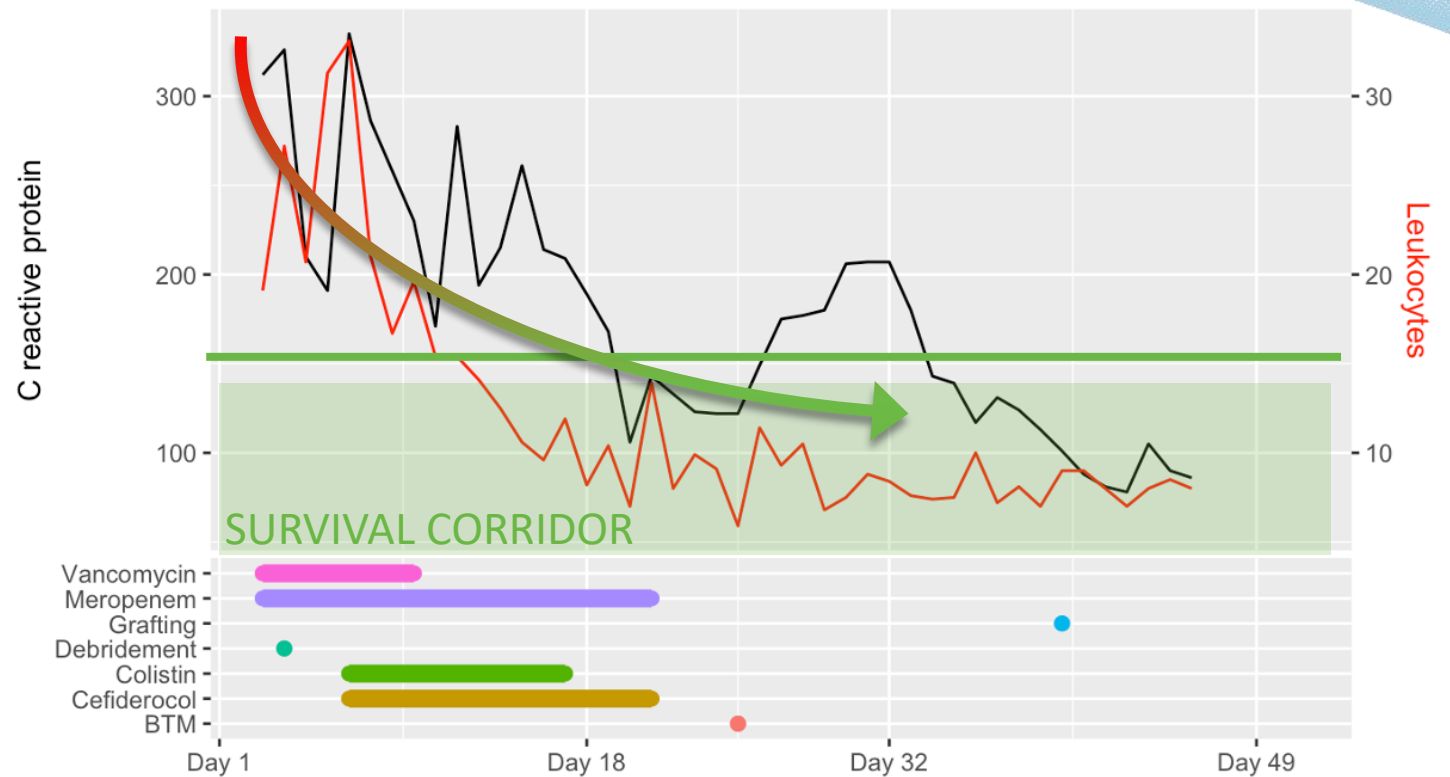
- Unstable patient
- Smeary wounds
- Adherent pseudo eschar on the back
- Escharotomy of the hands



Patient 12

- Daily large area cold plasma
- After entering the stable phase, no more antibiotics needed

Inflammation parameters over time
and key events during therapy



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OTHER COLLABORATORS:



Patient 12

- Debridement on **day 2**
- BTM on epifascially debrided areas
- Allogeneic skin on potentially regenerating skin



Patient 12

- Debridement on **day 2**
- BTM on epifascially debrided areas
- Allogeneic skin on potentially regenerating skin



Patient 12

- BTM properly integrated on **day 30**
- 90% of the back covered with Epidermis
- Split thickness skin grafting on BTM



Patient 12

- BTM properly integrated on **day 30**
- 90% of the back covered with Epidermis
- Split thickness skin grafting on BTM



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OTHER COLLABORATORS:



Patient 12

Day 40:

- 99% wound coverage
- Split thickness skin grafting with 100% take rate



Conclusion

Large area cold plasma bags after 50 patients (1 year):

- less wound associated **sepsis** —
- less smeary and **smelly wounds** —
- less treatment associated **pain** —
- higher split skin **take rate** +
- no complications or sideeffects ✓
- universally compatible ✓
- high patient acceptance ✓



ROLE 4 TO ROLE 1 TRANSITION

The clinical results suggest

- a contained plasma bag can **condition wounds**,
- help **control bioburden**,
- **preserve a survival corridor**,
- support **transport readiness**,
- and **reduce dependence on reserve antibiotics** when evacuation is delayed.

Goals for a portable plasma bag (C²PE-System)

- **extend time to definitive care,**
- **improve survivability** of extensive burns,
- bring **infection control,**
- **warming,**
- **and wound stabilization** to austere and mass-casualty settings.

