



CLINICAL

PIPAC – How I Do It

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Disclosures

- I do not have any relevant disclosures.

This presentation and/or comments will provide a balanced, non-promotional, and evidence-based approach to all diagnostic, therapeutic and/or research related content.

The off-label or investigational use of Mitomycin C, Abraxane (Nab-Paclitaxel), Oxaliplatin, 5-FU, Cisplatin, and Doxorubicin will be discussed.

Cultural Linguistic Competency (CLC) & Implicit Bias (IB)

STATE LAW:

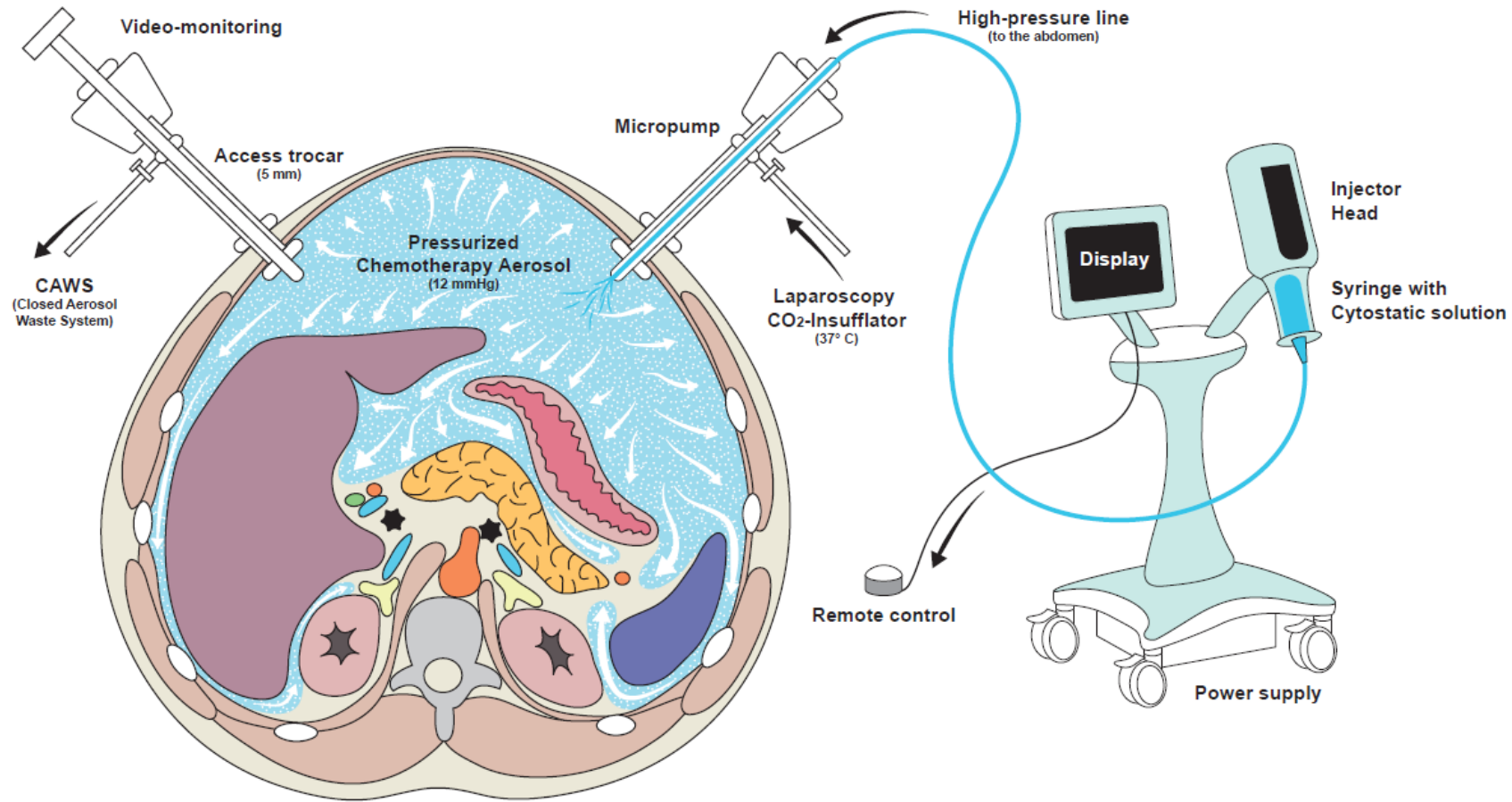
The California legislature has passed Assembly Bill (AB) 1195, which states that as of July 1, 2006, all Category 1 CME activities that relate to patient care must include a cultural diversity/linguistics component. It has also passed AB 241, which states that as of January 1, 2022, all continuing education courses for a physician and surgeon **must** contain curriculum that includes specified instruction in the understanding of implicit bias in medical treatment.

The cultural and linguistic competency (CLC) and implicit bias (IB) definitions reiterate how patients' diverse backgrounds may impact their access to care.

The following CLC & IB components will be addressed in this presentation:

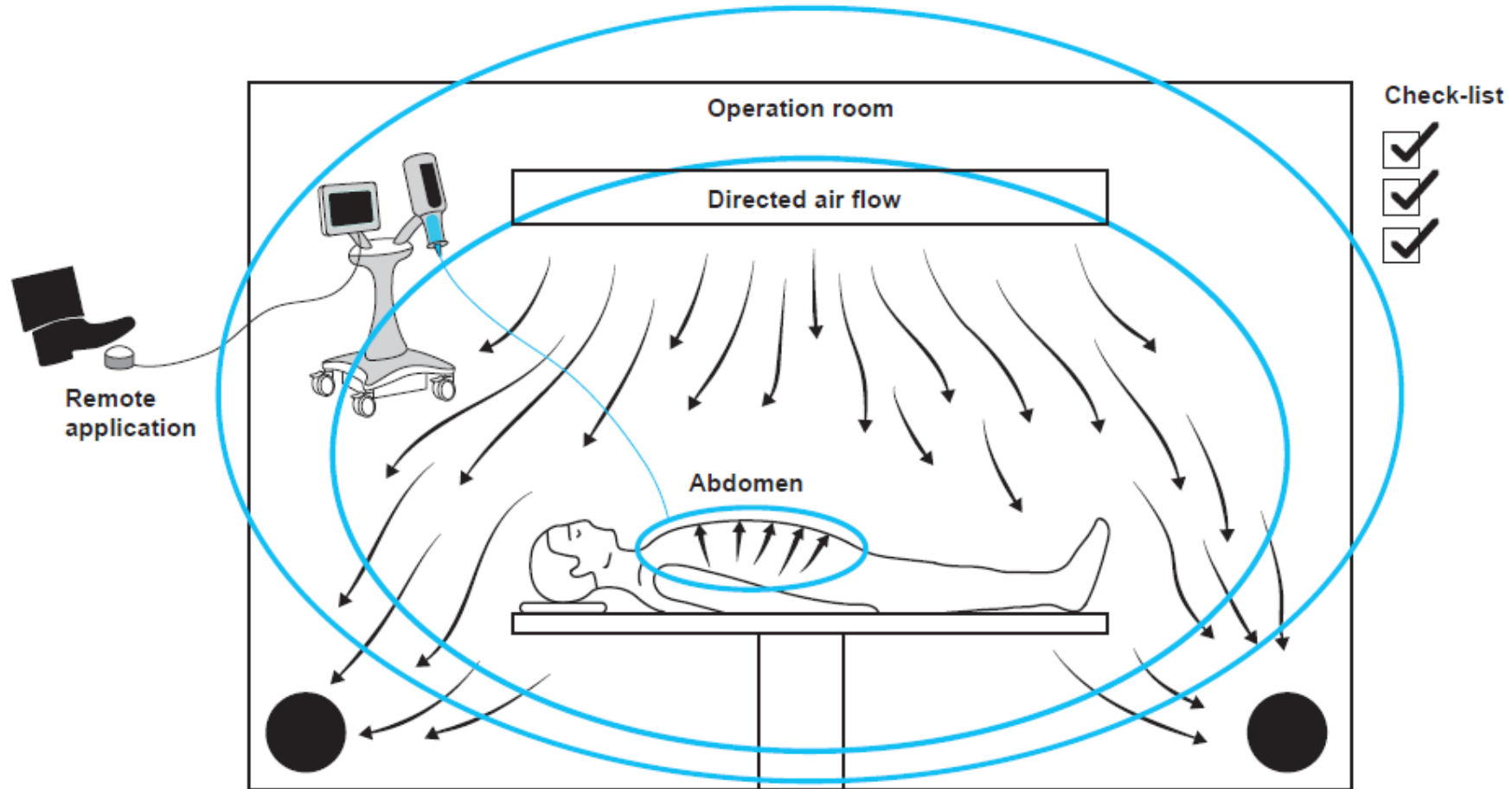
- Inclusion of patients in PIPAC trial should ensure racial and ethnic representation.
- Patients with peritoneal metastases are often considered end-stage with prognosis. There is an implicit bias against treatment that points to nihilism.

PIPAC: Set-Up



Picture: © CHUV Lausanne

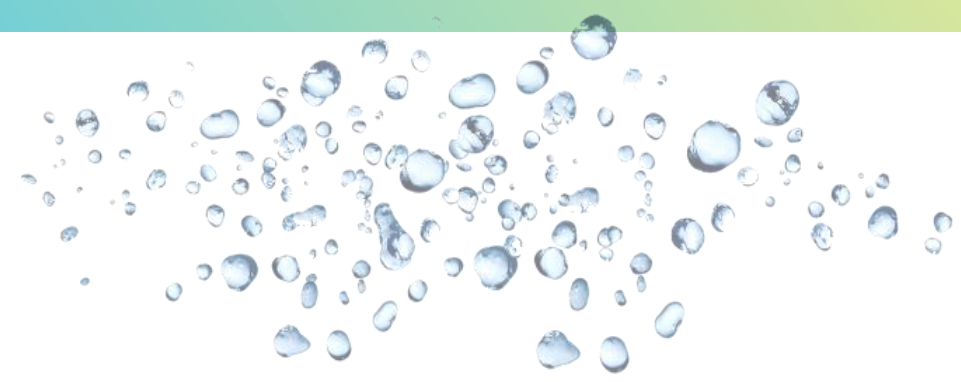
PIPAC: Safety First



Solass Ann Surg Oncol 2013,
Hübner EJSO 2017

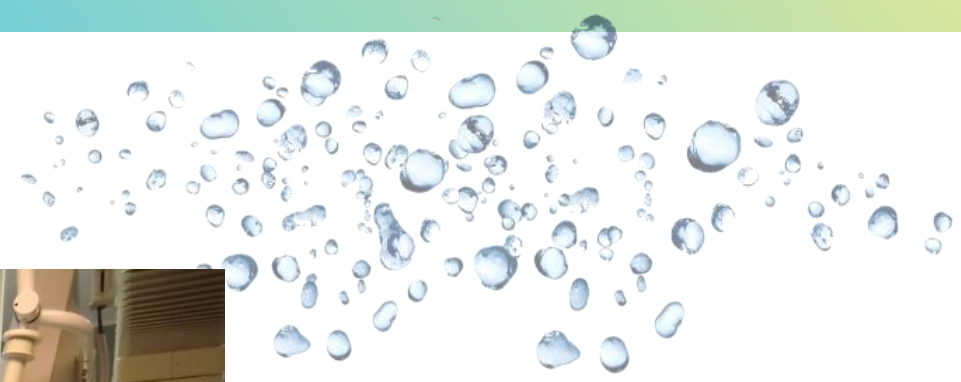
PIPAC: Procedure Steps

- Preparation and installation
- Access to the abdomen
- Staging laparoscopy
- Preparing chemotherapy administration
- Safety checklist
- Remote chemotherapy application
- Evacuation capnoperitoneum
- Closing the abdomen, finishing the procedure



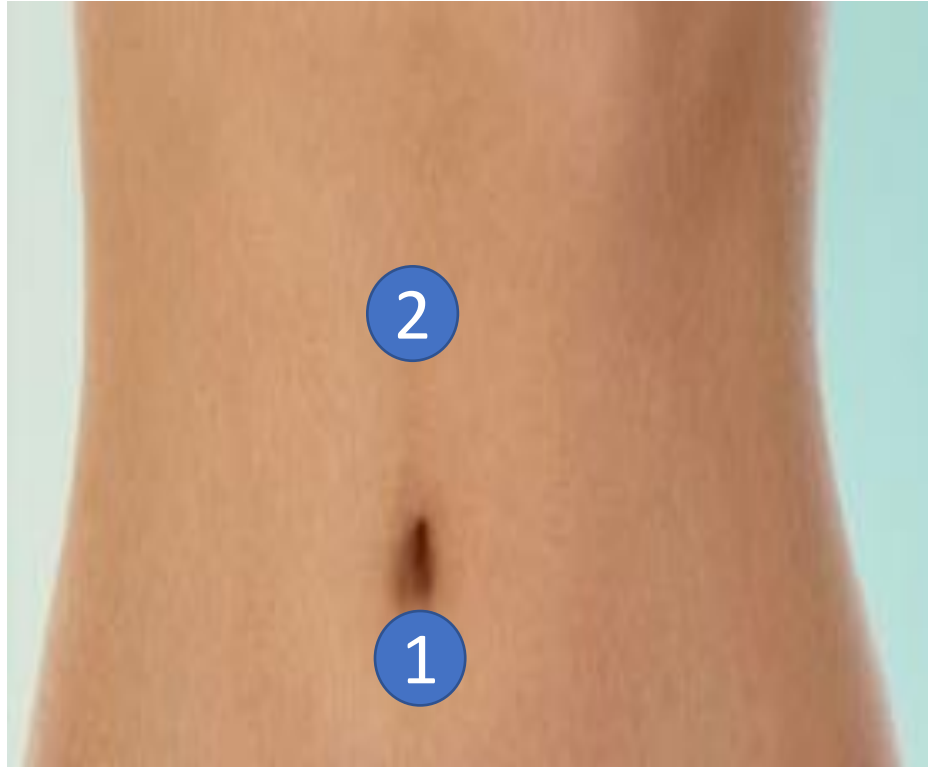
Hübner EJSO 2017

Preparation and Installation



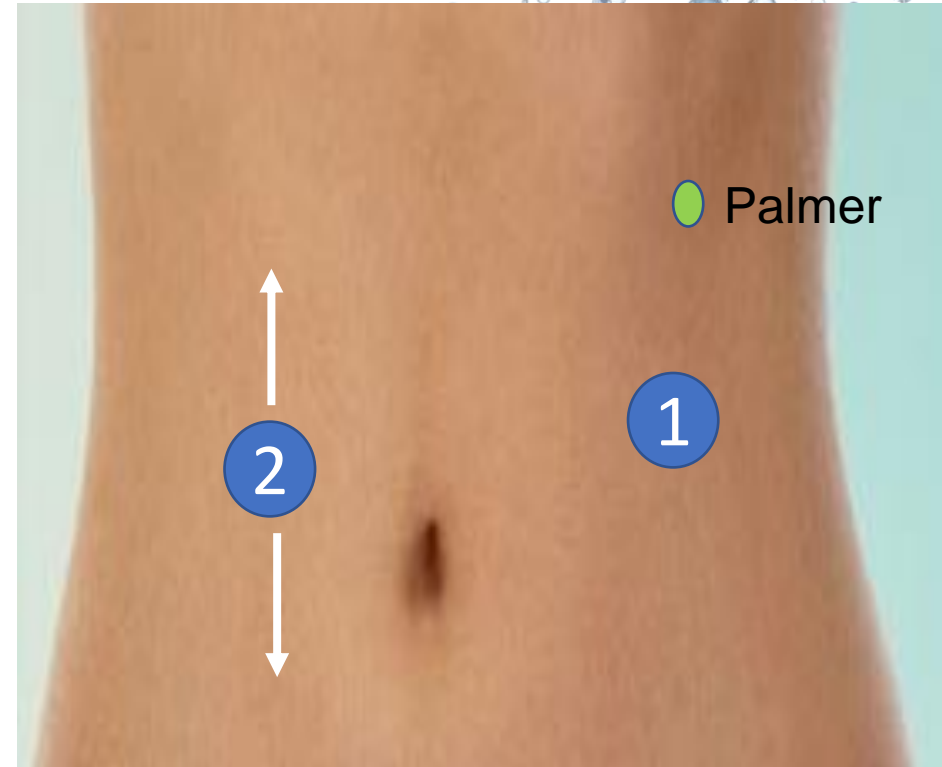
Patient in supine position

Abdominal Access



French technique (open access)

First access point depending on scars: midline preferred ...
Second trocar inserted under video control



Alternative technique (closed access)

Verres needle at the Palmer point (optional).
Possibly ultrasound can help.

Trocar Type

- Double-balloon trocars recommended
 - To ensure abdominal tightness
 - For example: Kii®, Applied Medical
- Alternative: single-port access in the midline ^{1,2}
 - Reduce the abdominal non-access rate ?
 - For example: QuadPort+ (Olympus Medical)¹

1 Vaira et al , Pleura Peritoneum 2016

2 Seitenfus R et al 2017 Rev Col Bras Chir 2018



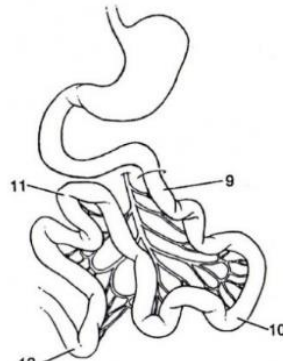
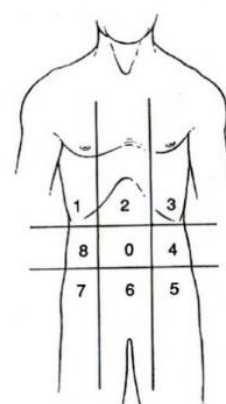
Staging Laparoscopy

Documentation of ascites volume and of the Peritoneal Cancer Index (PCI)

Peritoneal Cancer Index

| <u>Regions</u> | <u>Lesion Size</u> | <u>Lesion Size Score</u> |
|------------------|--------------------|--------------------------|
| 0 Central | _____ | LS 0 No tumor seen |
| 1 Right Upper | _____ | LS 1 Tumor up to 0.5 cm |
| 2 Epigastrium | _____ | LS 2 Tumor up to 5.0 cm |
| 3 Left Upper | _____ | LS 3 Tumor > 5.0 cm |
| 4 Left Flank | _____ | or confluence |
| 5 Left Lower | _____ | |
| 6 Pelvis | _____ | |
| 7 Right Lower | _____ | |
| 8 Right Flank | _____ | |
| 9 Upper Jejunum | _____ | |
| 10 Lower Jejunum | _____ | |
| 11 Upper Ileum | _____ | |
| 12 Lower Ileum | _____ | |

PCI



No routine adhesiolysis

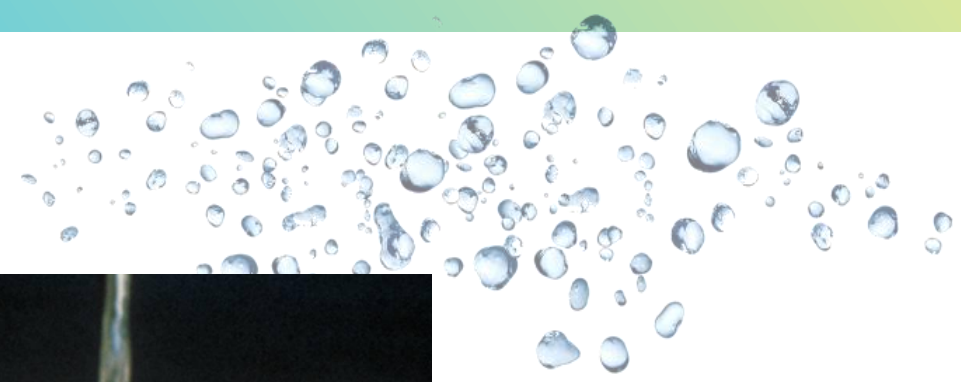
Biopsies + Cytology

- Ascites drainage / washing : cytology
- 4 parietal peritoneum biopsies
 - No deep biopsy (respect the fascia)
 - Be careful with diaphragmatic surface biopsy
 - Optional: clip marking of the biopsy site
- Local peritonectomy (non-diseased)



Hübner M et al, Eur J Surg Oncol 2017

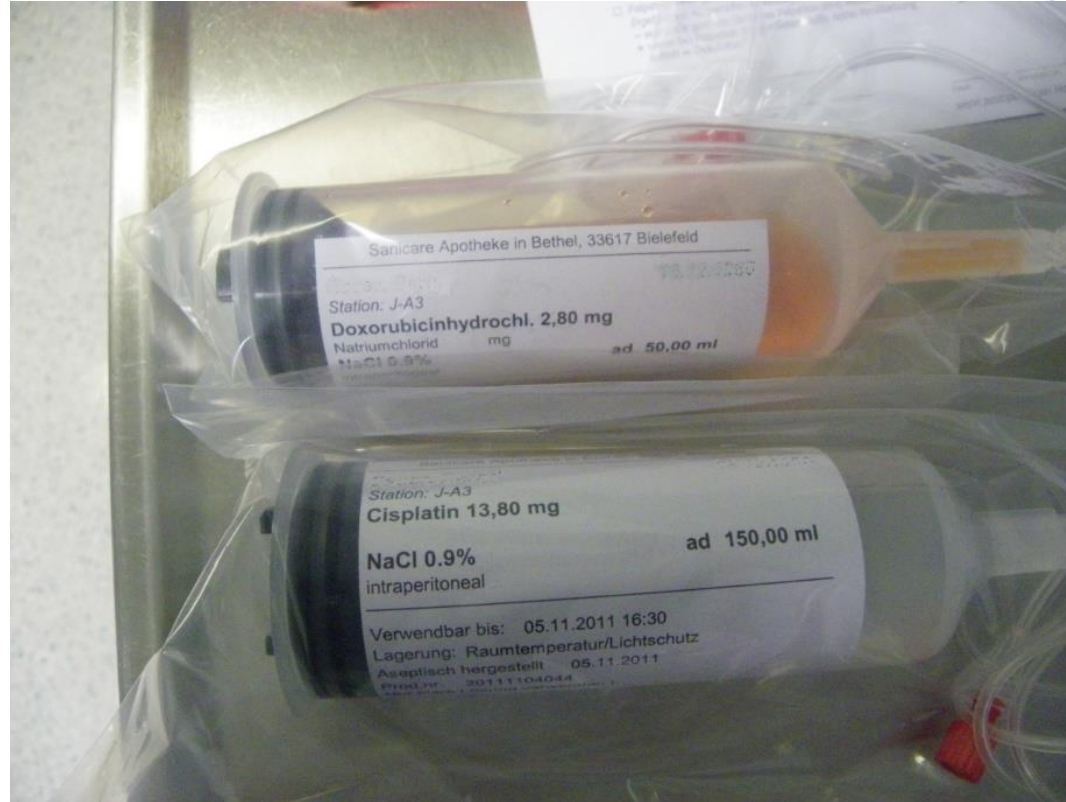
Chemotherapy: 4-Eyes Principle



For your eyes only

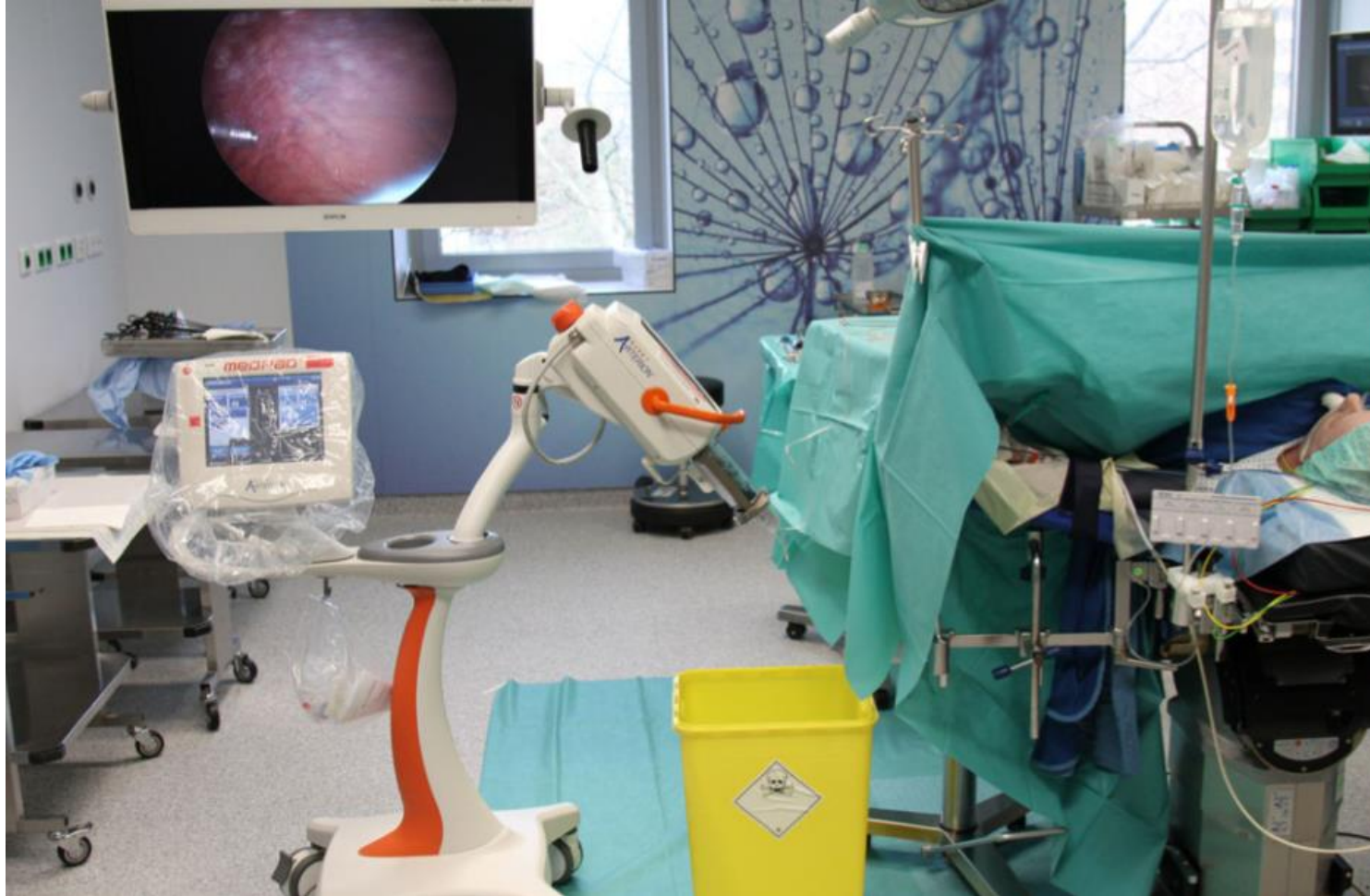


Chemotherapy: 4-Eyes Principle



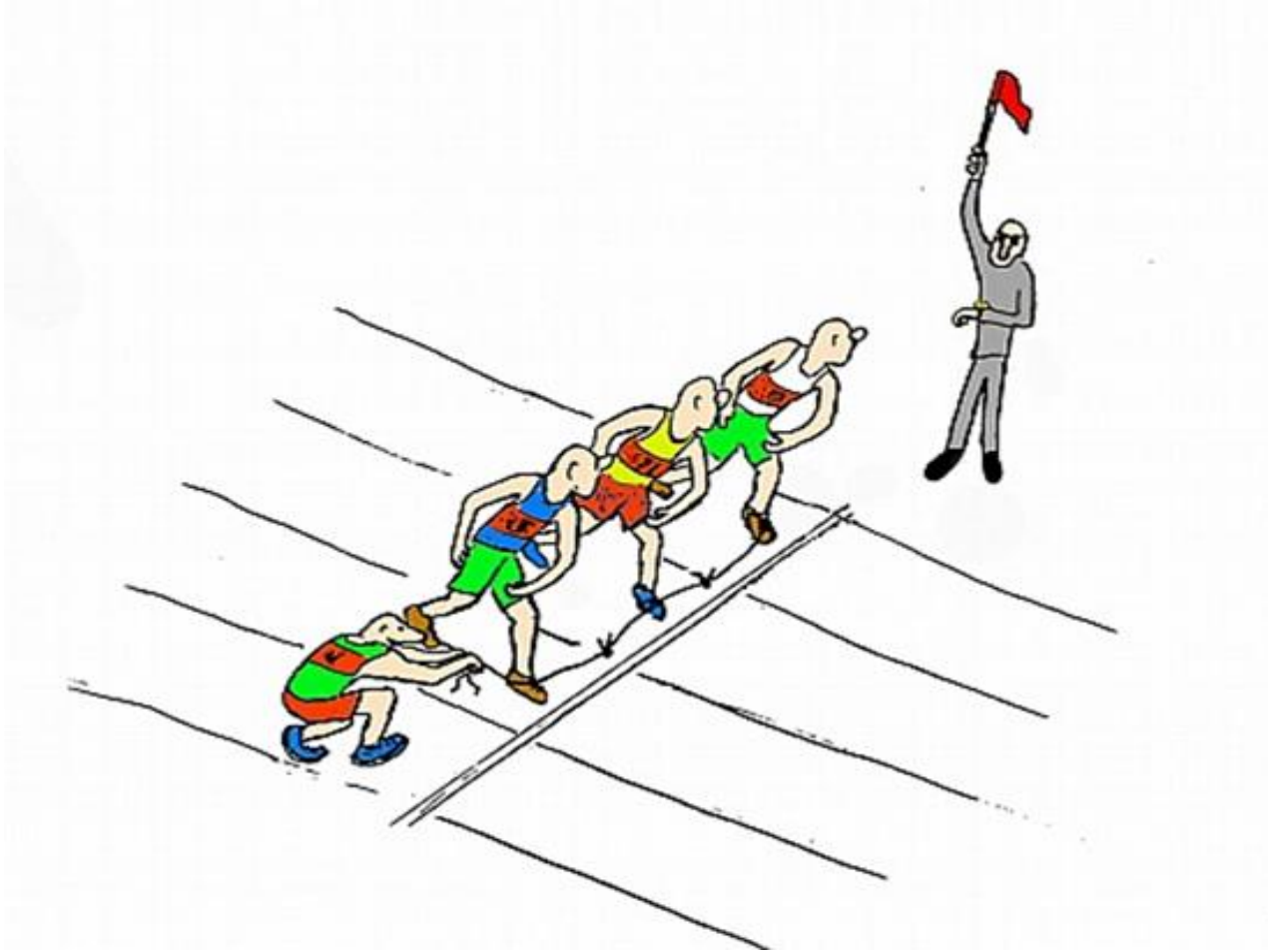
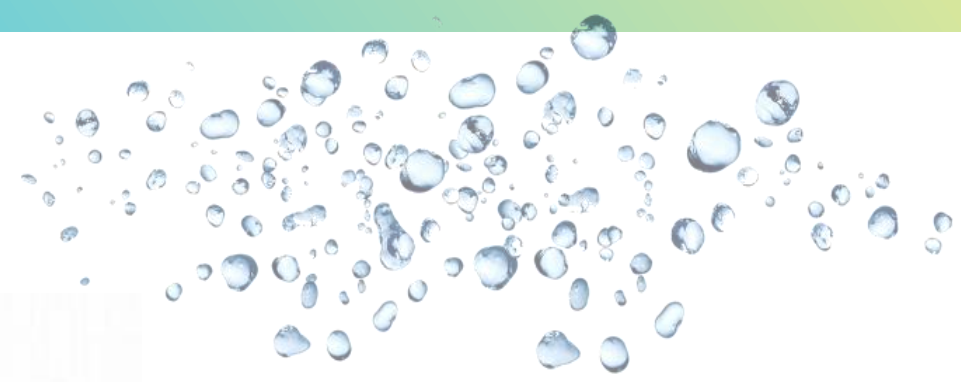
Name of patient, drug and dose need to be controlled by
2 physicians
(standard operating procedure in oncology !)

Prepare for Chemotherapy Administration



Giger-Pabst U et al. J Gastroint Surg 2018

Ready to Go?



NO !!!

Courtesy by M Hübner

Check List is Mandatory (4-Eyes Principle)

OPERATIONAL SECURITY CHECK-LIST

PIPAC : Pressurized IntraPeritoneal Aerosol Chemotherapy

1. Before starting the procedure = Team time-out :

- ☐ Patient's name OK ?
- ☐ Planned procedure OK ?
- ☐ Chemotherapy drugs available in the operating room ? Check for the label : patient, drug and dosage ?
- ☐ Safety material available ?
- ☐ All team members wearing glasses, gloves and protecting clothes as needed ?
- ☐ Special waste containers present in OR ?
- ☐ Protective sheet on the floor under the injector ?
- ☐ Laminar air flow activated in the operating room (OR) ?

2. Check-list before application :

- ☐ Trocars tightly fixed to the abdominal wall
- ☐ Sealed pneumoperitoneum with 12 mm Hg CO₂ and no leak ?
- ☐ Closed Aerosol Waste System (CAWS) connected to the camera trocar. Closed clamp? Port valve closed ? Microparticle filter installed ? Connected to wall outlet ?
- ☐ Video camera inserted in trocar, fixed to the Octopus stand ?
- ☐ CO₂ tube adapted to 12 mm trocar (insufflation port open) ?
- ☐ Peritoneal Carcinosis Index (PCI) documented ?
- ☐ Ascites volume documented ? Cytology ?
- ☐ Diagnostic peritoneal biopsies sampled in different areas ?
- ☐ Local peritonectomy performed ?
- ☐ Samples for research and studies obtained ? documented and labeled ?
- No, not planned ☐
- ☐ Micropump inserted in the 12 mm trocar port ? Free-floating and no contact with bowel loops?
- ☐ Cover sheet fixed to the micropump ? System flushed ?
- ☐ Syringe(s) with chemotherapy placed into the high-pressure injector ?
- ☐ Remaining air (dead space) removed from the syringe(s) ?



2



- ☐ High pressure line connected to the syringe(s) and fixed to the cover sheet ?
- ☐ Set up the injector : Syringe(s) volume, pressure max. 20 bars, flow 30 ml/min ?
- ☐ ePIPAC ? If yes :
 - ☐ Electrode positioned correctly ? Within the camera field (visible) ?
 - ☐ Generator **not** activated yet ?!!
- ☐ Screens and devices checked-up for remote monitoring ?
- ☐ All team members leave the operating room !
- ☐ Remote-controlled application of chemotherapy product.
- ☐ ePIPAC : please activate the generator at the end of administration of cytostatics !
- ☐ Wait 30 minutes after end of chemotherapy administration ?

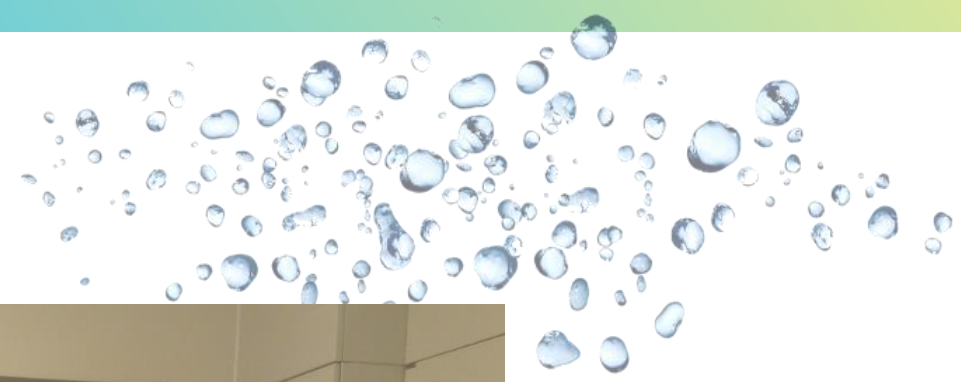
3. Uninstalling and ending the procedure:

- ☐ Max 2 people in the OR: High filtration mask and sterile reinforced protective gown.
- ☐ ePIPAC : remove electrode !
- ☐ Stop CO₂ insufflator. Close trocar port and disconnect tubing.
- ☐ Video camera oriented laterally in order to avoid bowel suction into the trocar port.
- ☐ Activate CAWS system (open port and valve), proceed to closed exsufflation of the toxic aerosol in closed circuit.
- ☐ Do not use standard suction devices !
- ☐ Close trocar port in order to avoid bowel suction into it (active suction !)
- ☐ Removal of all trocars with « en bloc » technique, thrown away in labeled waste container.
- ☐ All disposable material eliminated into labeled chemotherapy waste container.
- ☐ Prospective documentation in a dedicated database ?
- ☐ For study patients, make the Case Report Forms (CRFs) complete.

Nom

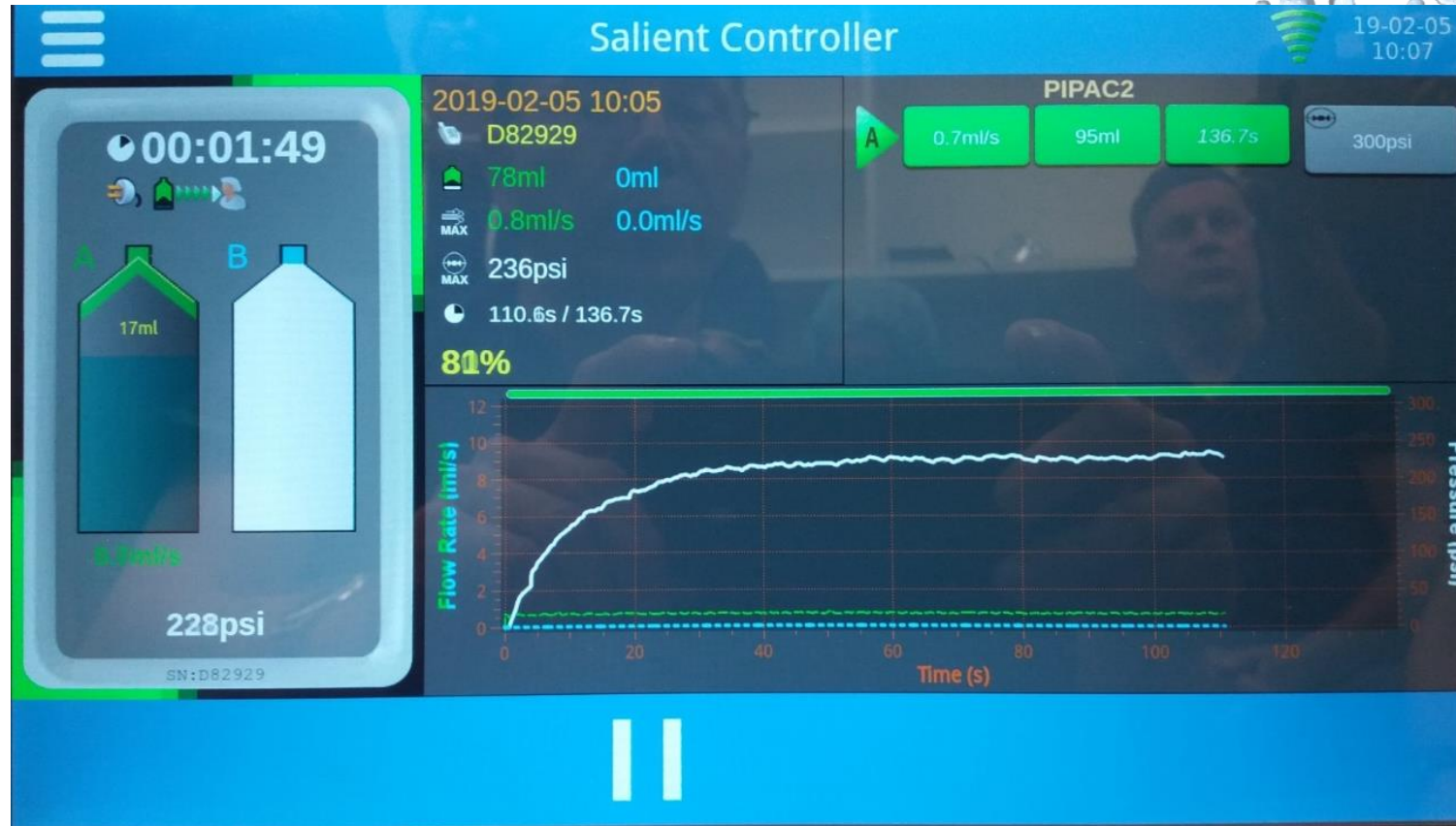
Signature

Remote Control



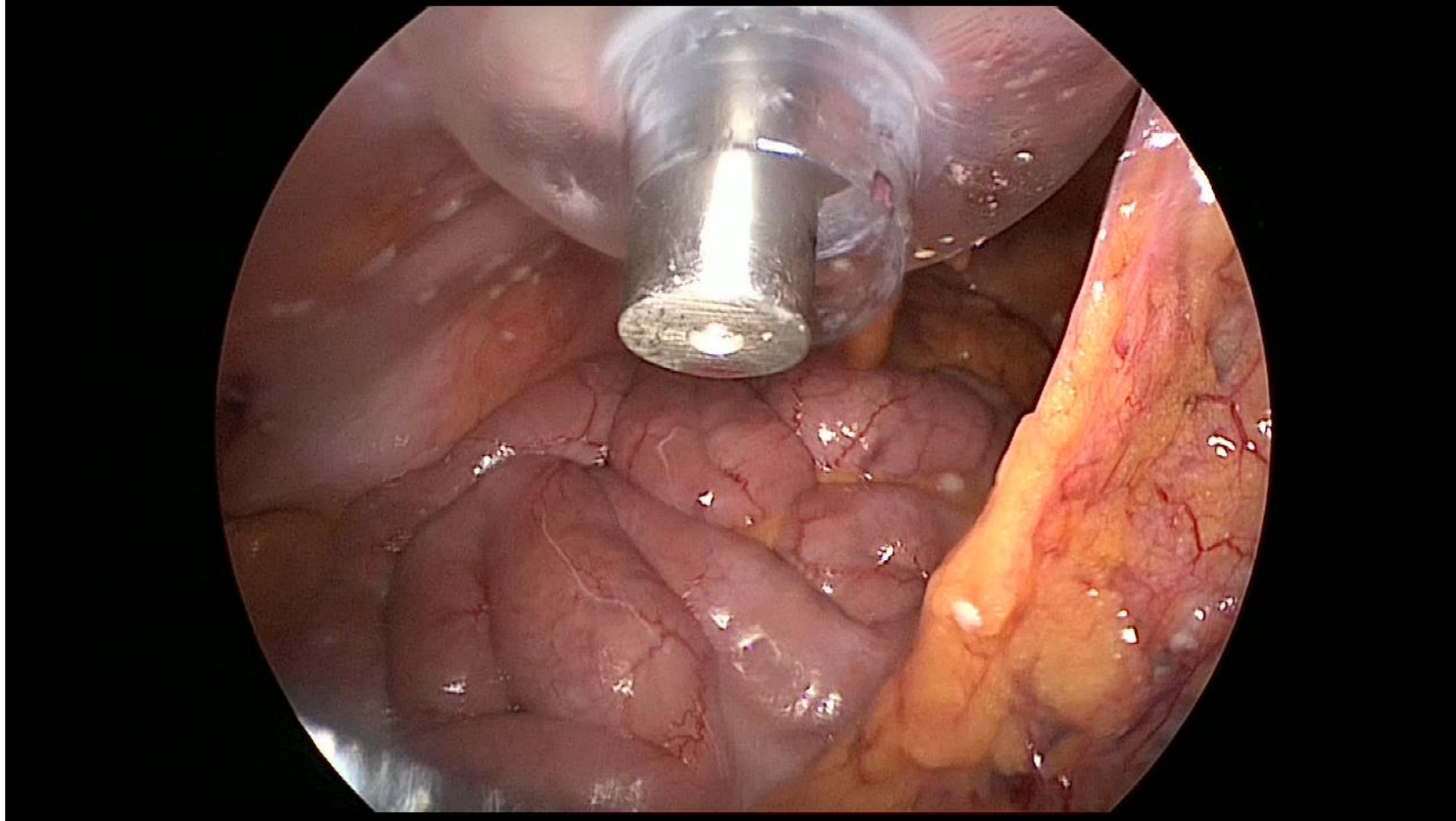
The procedure is remote-controlled; **nobody** is present in the operating room during nebulization.

Checking Upstream Pressure During Aerosolization



Pressure (angioinjector) should be in the range between 13 and 20 bar (= 200 to 300 psi)
→ set flow at 0.5-0.7ml/s

Application of Chemotherapy

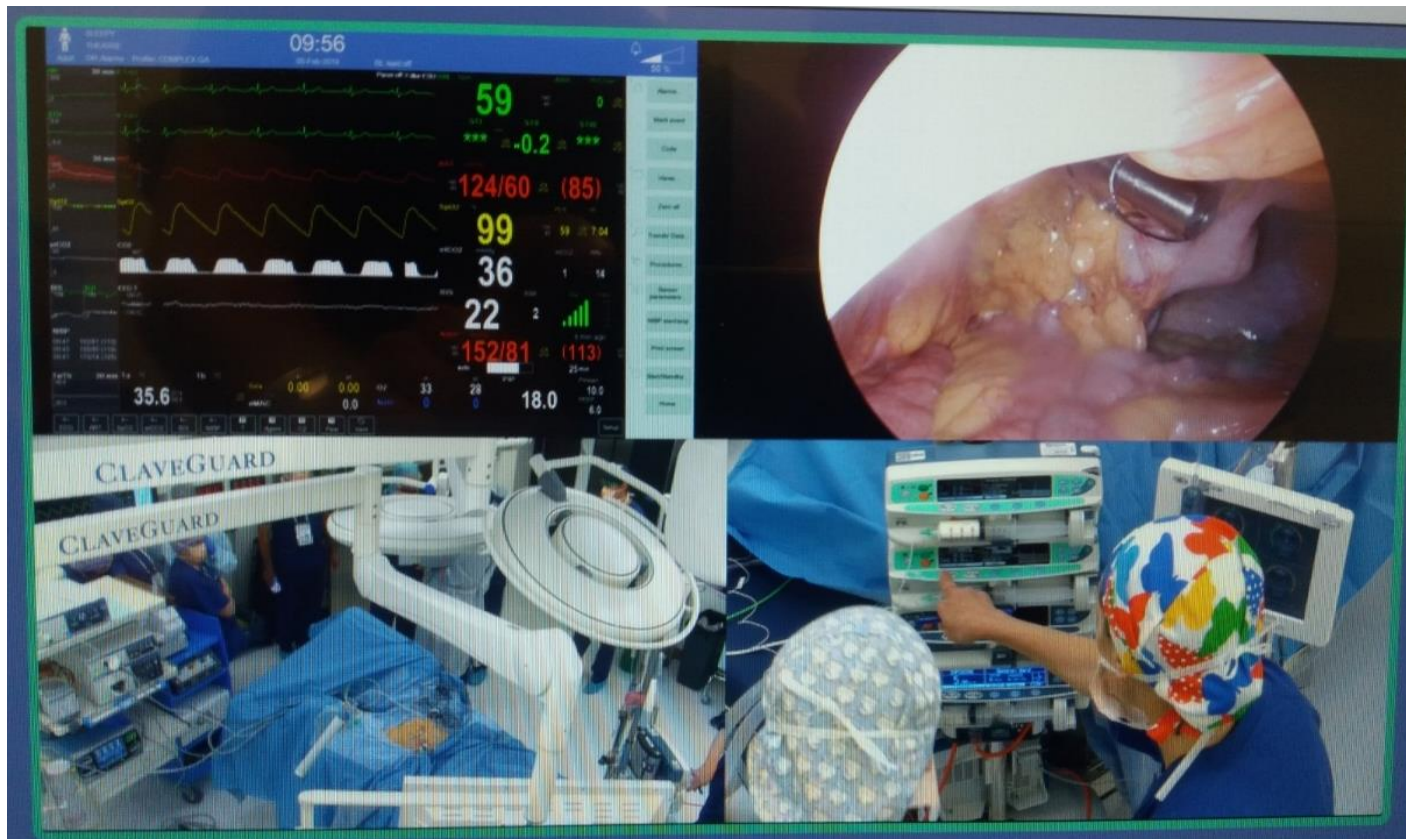


Courtesy by M Hübner

Remote Control of the Procedure

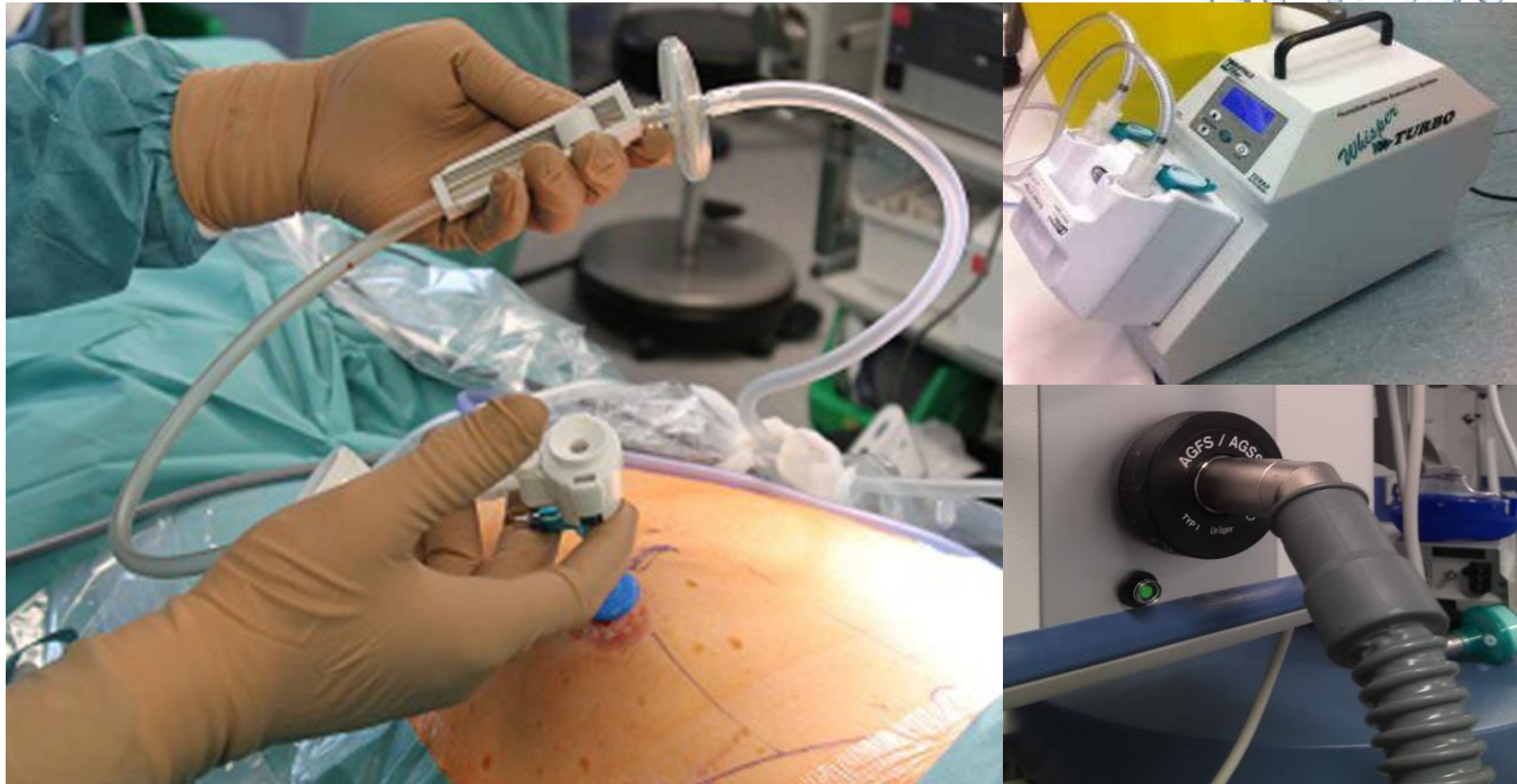


Advanced monitoring technology ... or looking through the window !



Picture: Peter Mc Callum Melbourne

Safe Elimination of the Toxic Aerosol



Giger-Pabst U et al J Gastroint Surg 2018

Ending the PIPAC Procedure



Prevent projection of liquids

Close the fascia for the 10-12 mm trocar incisions

Wipe the shaft of the Hopkins optics with a humid gauze

Dismiss the single-use material directly into the chemical waste bin

Clean up carefully the syringe head of the angio-injector

Hübner M et al. Eur J Surg Oncol 2017, Casauran JB et al. J Gastroint Surg 2017,
Giger-Pabst et al. J Gastroint Surg 2018

