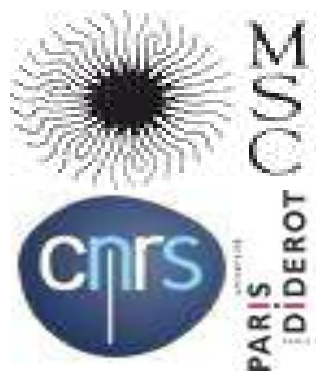


PREVENTION AND TREATMENT OF LUMEN OCCLUSION

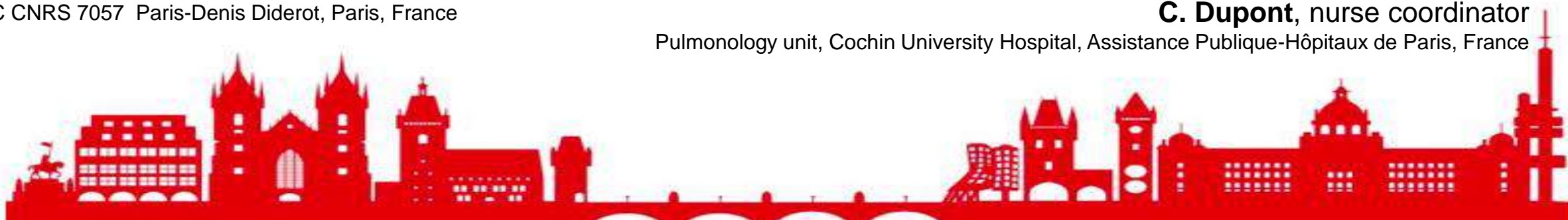


Thanks to Yamaoka Ippei (山岡 一平)
Medical Foods Research Institute, Otsuka, Japan



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Disclosure

BD, B-Braun, Vygon, Teleflex, 3M, ...

INTRODUCTION

- Dialysis catheter
- ICU, Neonatology, Pediatric units

- Pinch-off, tip malpositions
- Kinking, loop, fibroblastic sleeve, stenosis, thrombosis
- Integrated valve dysfunction
- Non coring needle malposition
- Occlusion caused by drug precipitates or contrast media
- Catheter breakage

**No personal
experience**

**No time today for
Extraluminal
causes
of
loss of patency**

INTRODUCTION

So I will speak about *the catheter that doesn't work anymore.*

What does it mean?

HOW TO DEFINE « OCCLUSION »?

- **Loss of patency:**
- Difficult injection/ Flow rate by gravity does not meet our need
- Difficult aspiration that does not allow blood sampling
- **Occlusion:** No injection and no blood sampling anymore
- **Blockage:** No injection and no blood sampling forever



C. Dupont

CONTEXTS OF OCCLUSIONS

- The catheter is in use and suddenly the occlusion appears
- The catheter is not in use and it's occluded when you begin to use it.



- SPC- Midline, PICC, CIC
- Implanted Port

Tubes and a cylinder connected to a tube

HOW TO DEFINE AN OCCLUSION?

- CINAS Card

CINAS CLASSIFICATION		INJECTION ABILITY (IN)			
		EASY ≥ 1 mL IN1	DIFFICULT ≥ 1 mL IN2	IMPOSSIBLE < 1 mL IN3	UNKNOWN INx
ASPIRATION ABILITY (AS)	EASY AS1 ≥ 3 mL	IN1AS1	IN2AS1	IN3AS1	INxAS1
	DIFFICULT AS2 ≥ 3 mL	IN1AS2	IN2AS2	IN3AS2	INxAS2
	IMPOSSIBLE AS3 < 3 mL	IN1AS3	IN2AS3	IN3AS3	INxAS3
	UNKNOWN ASx	IN1ASx	IN2ASx	IN3ASx	INxASx

Support Care Cancer
DOI 10.1007/s00520-015-2839-x

ORIGINAL ARTICLE

Diagnostic accuracy of the Catheter Injection and Aspiration (CINAS) classification for assessing the function of totally implantable venous access devices

G. A. Goossens^{1,2} · Y. De Waele³ · M. Jérôme¹ · S. Fieuwis⁴ · C. Janssens¹ · M. Stas⁵ · P. Moons^{2,6,7}

Can we trust our thumb?

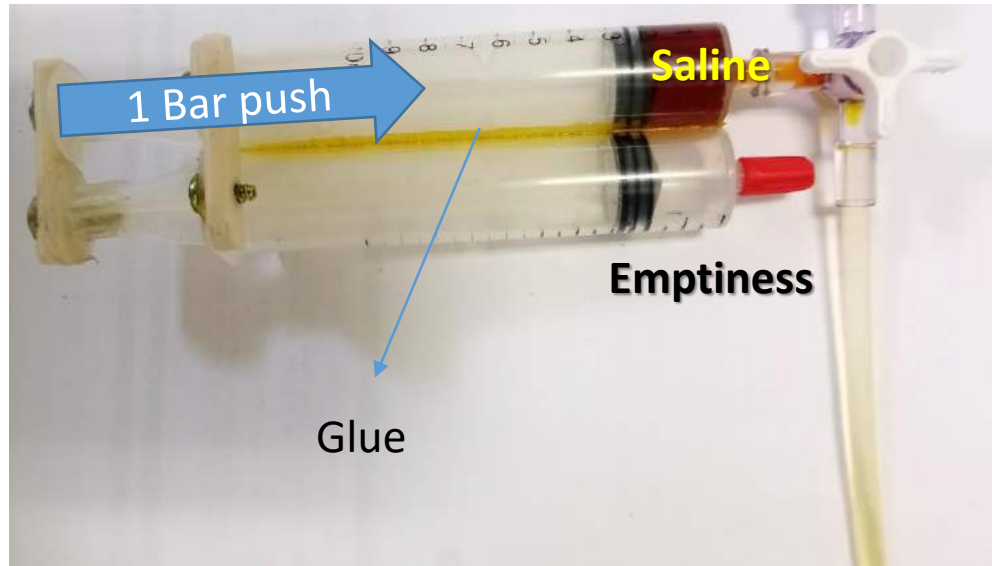


HOW TO DEFINE AN OCCLUSION?

- 4 Fr PICC line inserted for 14 days.
- PICC filled with blood.
- Removed and let 48 hrs in water.
- Try to inject saline with a 10 mL syringe -> Impossible. It's blocked

- Connection to a 10 mL syringe with an infusion device using an operating pressure of 1 Bar to inject saline

HOW TO DEFINE AN OCCLUSION?



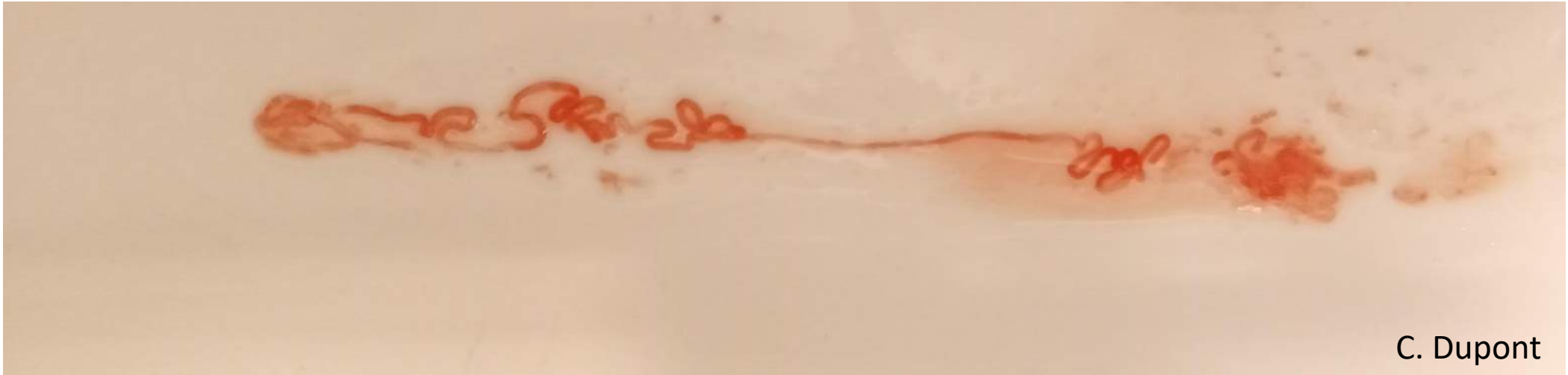
C. Dupont

Date	Hour	MI of Saline contained in the syringe
06/02/23	11.53	6
06/02	13.58	4
07/02	08.29	2

90 cm

HOW TO DEFINE AN OCCLUSION?

07/02 : Try to inject saline with 10 mL syringe using high force -> A clot is coming out



C. Dupont

Conclusion:

- The feelings are limited to understand the situation. It's not blocked, it's occluded.
- Too many catheters are removed meanwhile their lumen clearance could be restored.
- It works with a tube but does it work with a cylinder connected to a tube?

MECHANICAL TREATMENTS



- **Guidewire:**

Not recommended (The GAVECeLT manual of PICC and Midline, 2016).

- **Injection under « over-pressure »:**

GAVECELT 2016: “if the catheter is of silicone or PUR material, but is not power injectable, 10 ml syringes must be used to unblock it hydraulically to avoid excess pressure in the system. **If the PICC is power injectable, 5 ml or 2 ml can be used**, as they apply greater pressure: such pressure will, in any event, not exceed 325 psi (which is the pressure resistance limit for power injectable catheter)



What about the clot in blood circulation?



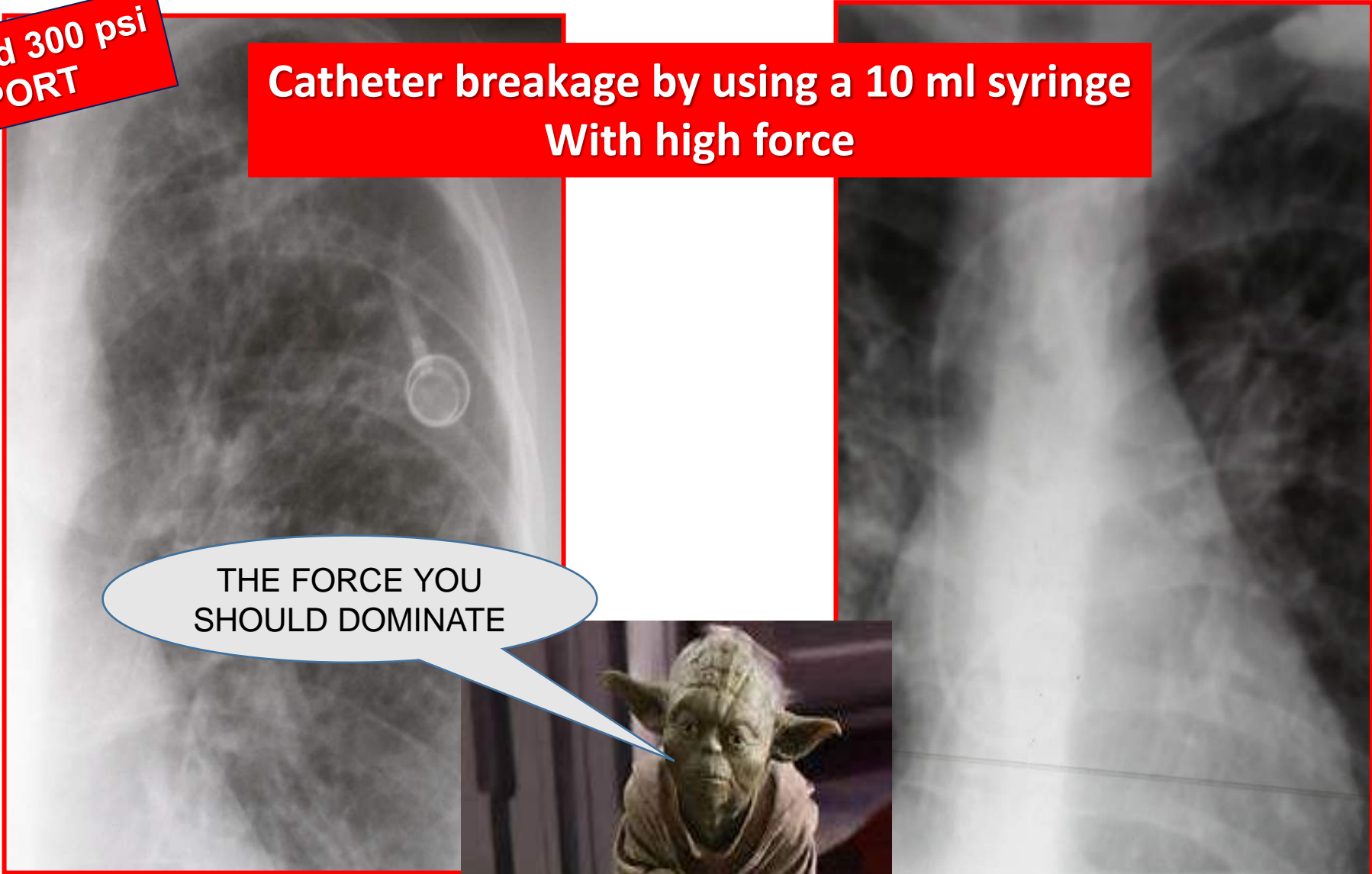
Usually, the procedure involves repeated infusion of few millimeters of saline solution under pressure, preceded by pumping or small, rapid movements of aspiration/infusion, in order to mobilize the agregates that obstruct the lumen.”

Infusion Nurse Society 2024, Sf2h 2012, 2013: « **Use a syringe no smaller than 10 mL for administration of a thrombolytic or catheter clarence agent.** »

AND risk of not being gentle anymore -> Misuse

Never exceed 300 psi
with a PORT

Catheter breakage by using a 10 ml syringe
With high force



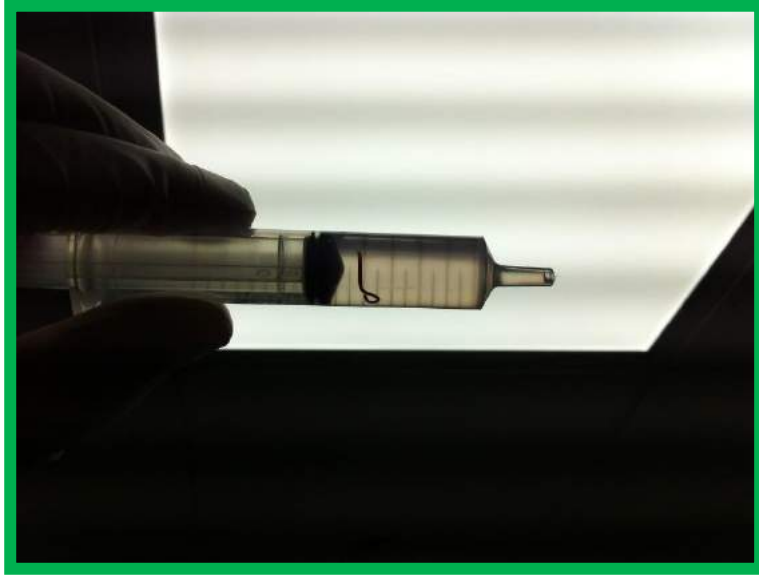
THE FORCE YOU
SHOULD DOMINATE



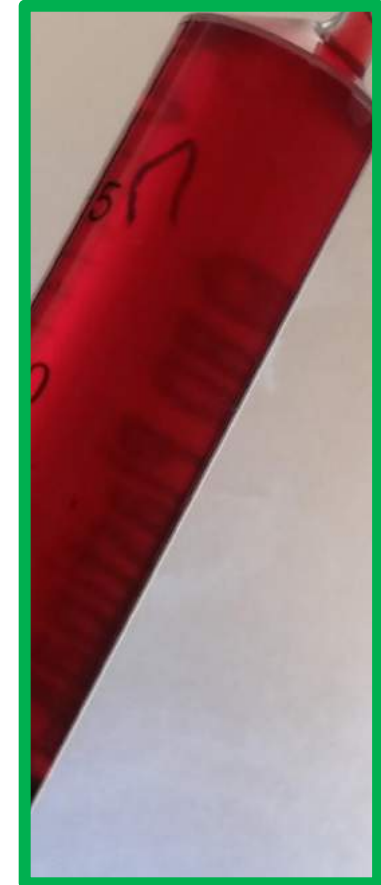
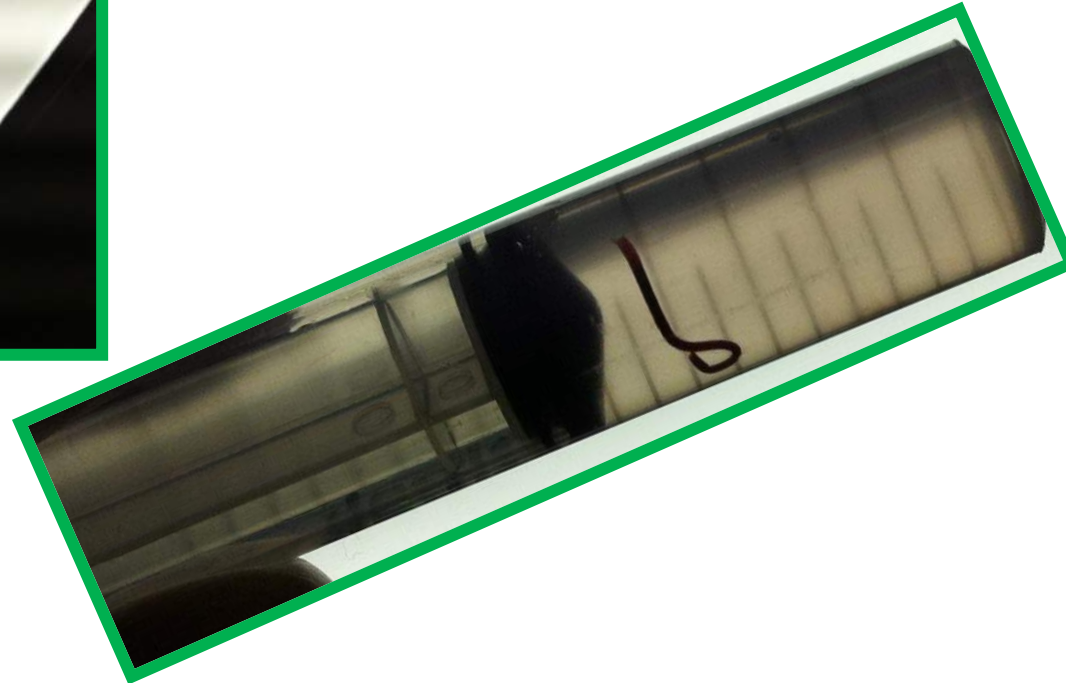
MECHANICAL TREATMENTS

Lasting injection under « over-pressure » not recommended with implanted port.

- POP-Technique procedure efficient and **safe** using.



Better results with « tubes »



C. Dupont

MECHANICAL TREATMENT: POP procedure

1 - Connect a 10cc syringe containing 1-2 mL normal saline to the catheter hub

2 – Hold the syringe vertically throughout the process

3 – Aspirate about 4-5 mL
Pause and hold (~ 2 seconds)

4 – Release the plunger ==> to initial position
Pause (~ 2 seconds)

5 – Repeat the process from step 3
Do not ever actively apply pressure on the piston

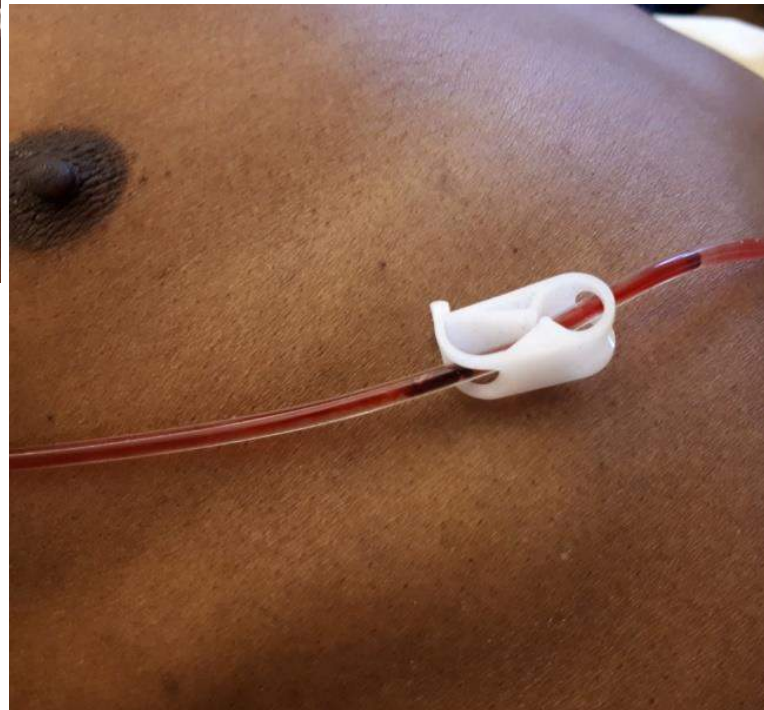
- POP technique works but doesn't clean the lumen efficiently. A fibrinolytic treatment is necessary.



MECHANICAL (AND CHEMICAL) TREATMENTS

- When is it necessary to remove the non coring needle and to insert a new one?

Remove it if it's **full of blood or clots** or it's a **22 gauge needle** (prefer larger diameter to clear the device).



BUT SOMETIMES THE POP DOESN'T WORK



CHEMICAL TREATMENTS

CHEMICAL TREATMENTS: WHICH PRODUCTS HAVE BEEN TESTED AND RECOMMENDED?

Obstruction with blood clot	<p>Urokinase (Gavecelt 2017 , Muller 2010, Leuven 2017)</p> <p>Rtpa (CVAA 2013, Gavecelt 2017)</p> <p>tPA, alteplase, Urokinase, retaplaste, tenectaplaste, and alfineprase (INS 2024)</p> <p>No Heparin</p>
------------------------------------	--



CHEMICAL TREATMENTS: WHICH PRODUCTS HAVE BEEN TESTED AND RECOMMENDED?

UROKINASE 10 000 UI/mL (Gavecelt 2017) , **10 000 UI / ML (Muller 2010)**. Urokinase lock over 24-48 Hrs is efficient

Rtpa 2 mg/mL (CVAA 2019, Gavecelt 2017) -> 2 inj max

RtPA, alteplase 2 mg/2 mL, which is allowed to remain in CVAD lumen for 30 minutes to 2 hours and repeated 1 time if necessary, is recommended as safe and effective in restoring catheter patency in neonatal, pediatric, and adult patients.

ALTEPLASE : INCOMPATIBILITES

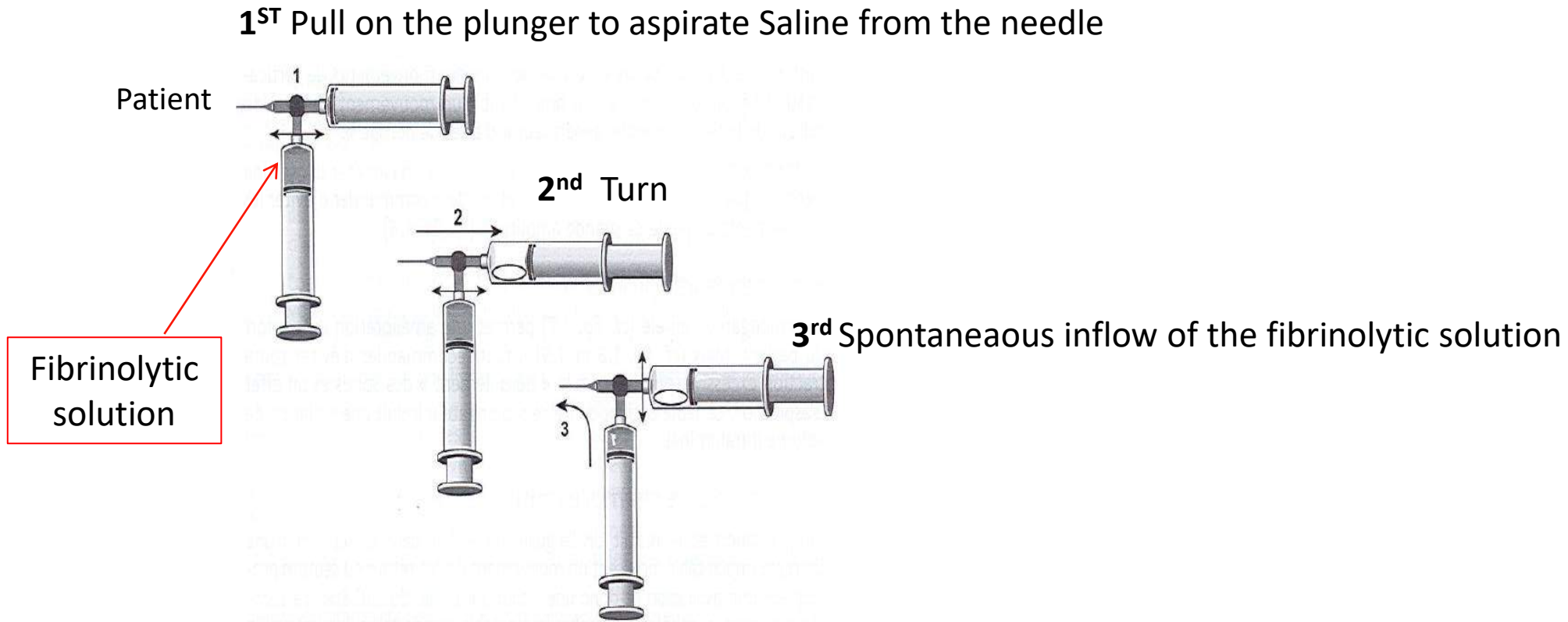
Propofol
Furosemid
G5%

Pharmacie clinique – <https://pharmacie.hug.ch/>

- Use of Hydrochloric acid, Sodium bicar 8,5%, 50 to 70% Ethanol alcohol; **what do we no exactly about that?**
- **In any case of occlusion**, infuse first **Fibrinolytic solution as Urokinase** and **2nd other product** (it depends on the composition of the clot). (Leuven 2017)

CHEMICAL TREATMENTS

- An if I want to inject fibrinolytic solution using the inserted and primed needle?



PREFER 3 WAY-TAP METHOD TO INJECT THE THROMBOLYTIC SOLUTION or CHANGE THE NEEDLE TO SAVE TIME



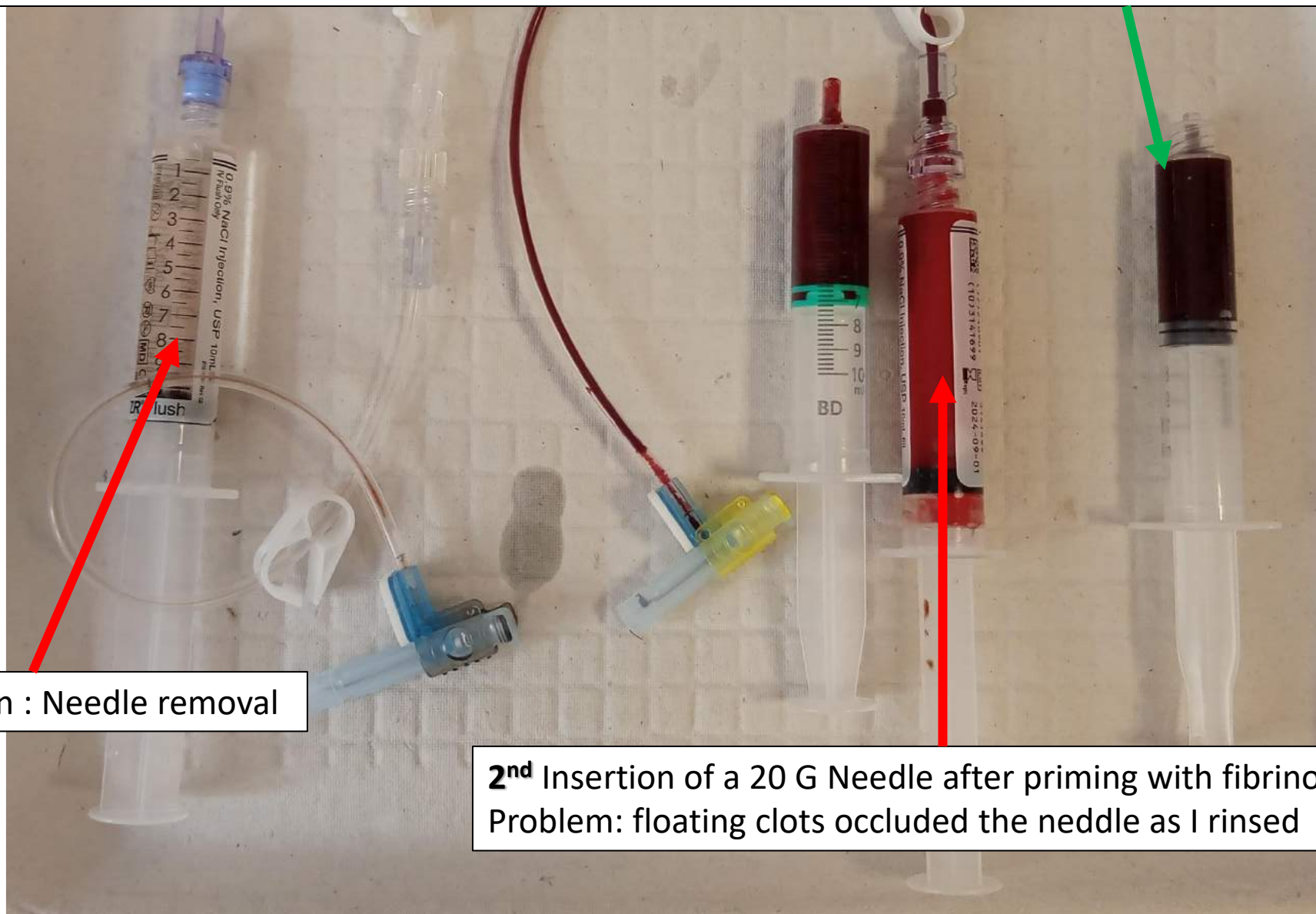
**BUT FIRST:
THE FORCE
YOU SHOULD
DOMINATE**



Brief Over Presssure Injections technique

3rd : Insertion of a 3rd needle after priming with fibrinolytic solution.

1Hr 15 « making BOPI» - > 0.75 mL of fibrinolytic injected - Wait for 2 Hrs (or more) until the complete clots dissolution



1st Port occlusion : Needle removal

2nd Insertion of a 20 G Needle after priming with fibrinolytic
Problem: floating clots occluded the needle as I rinsed

TREATMENTS OF OCCLUSIONS

THE BEST TREATMENT IS

THE PREVENTION



HOW TO DECREASE POLLUTION?

- **A device with a simple internal design is easy to clean**

Ex. : Prefer an opaque NFC with a straight flow pathway to a transparent one with a complicated inner design

- **To prevent blood reflux as line disconnection:** know how using the NFC ; do not insert 19 G in the septum of a large septum
- **To prevent risks with infusion per gravity:** use specific valves



OCCLUSION PREVENTION

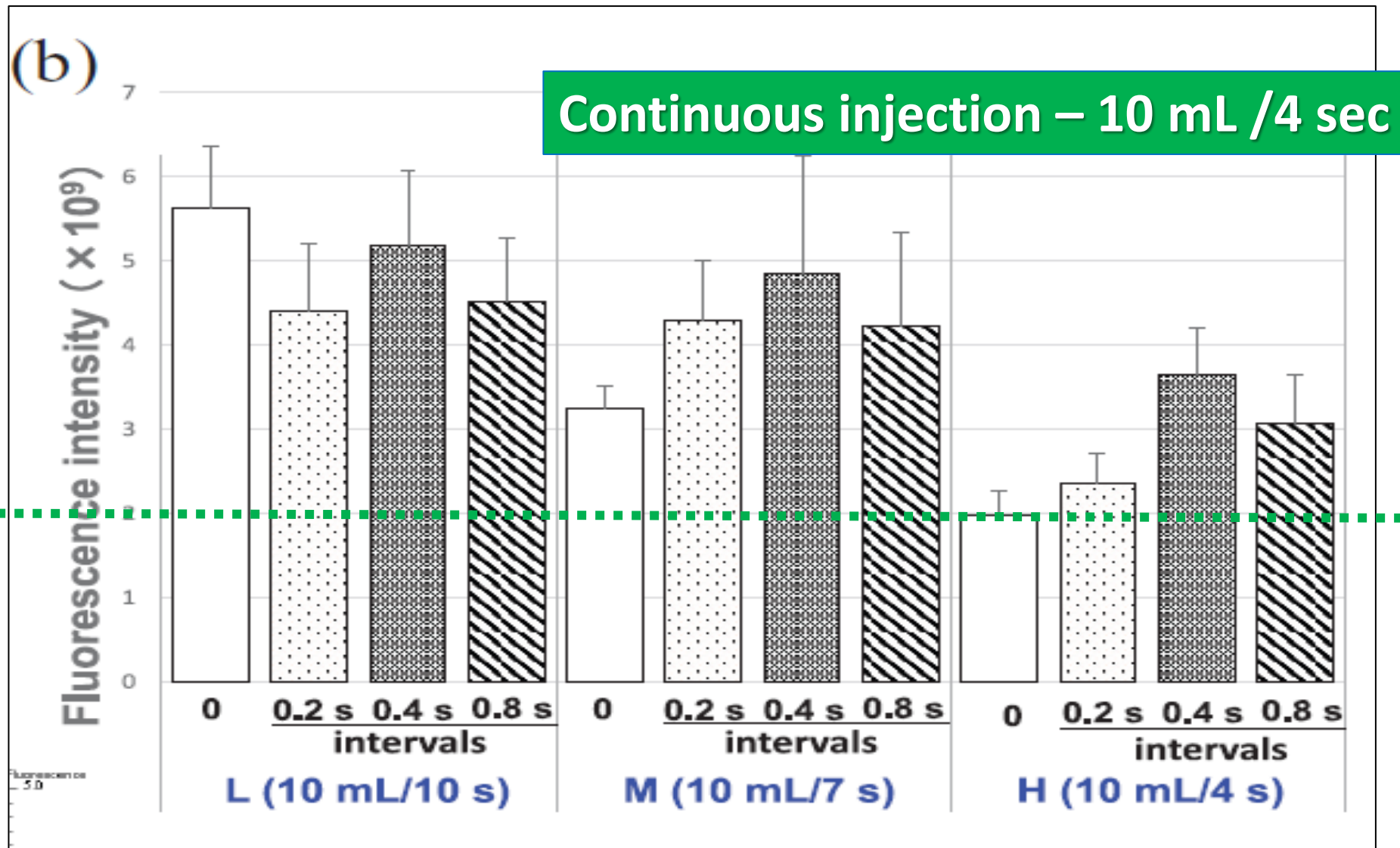
- **Rinsing**: Injecting a fluid to eliminate a drug product or biological content in a medical device (md)
- **Flushing**: Injecting a fluid in order to remove fixed but removable drugs and proteins on the wall of a md
- **Locking**: Close the md hoping to find it next time your catheter is usable as you let it

HOW TO RINSE EFFICIENTLY A TUBE?

A comparison of the effects of pulsatile and bolus methods on lipid emulsion residues that lead to bacterial growth in intravenous catheters.

N. Okamura, I. Yamaoka. JVA. Dec 2023

IN VITRO TEST



A comparison of the effects of pulsatile and bolus methods on lipid emulsion residues that lead to bacterial growth in intravenous catheters.

N. Okamura, I. Yamaoka. JVA. Dec 2023

Polybutadiene/ 16 cm/ 0,1 cm + Straight or looped Nexiva (0,32 cm, 18 G – 0,11 cm) + Bionector

Lipid mixed TPN + Fluorescence agent that can visualize and quantify the amount of residue. No stay at 37°C

Filled catheter with pollution

High-performance syringe pump.

Rinsing/flushing with saline solution then 1/ Optical imaging system; 2/ Culture (Pseudomonas Aeruginosa)

5 times

- 10 mL with and without PP technique /4 sec
- 10 mL with and without PP technique /7 sec
- 10 mL with and without PP technique /10 sec

Pause between 1 mL bolus 0,2 - 0,4 - 0,8

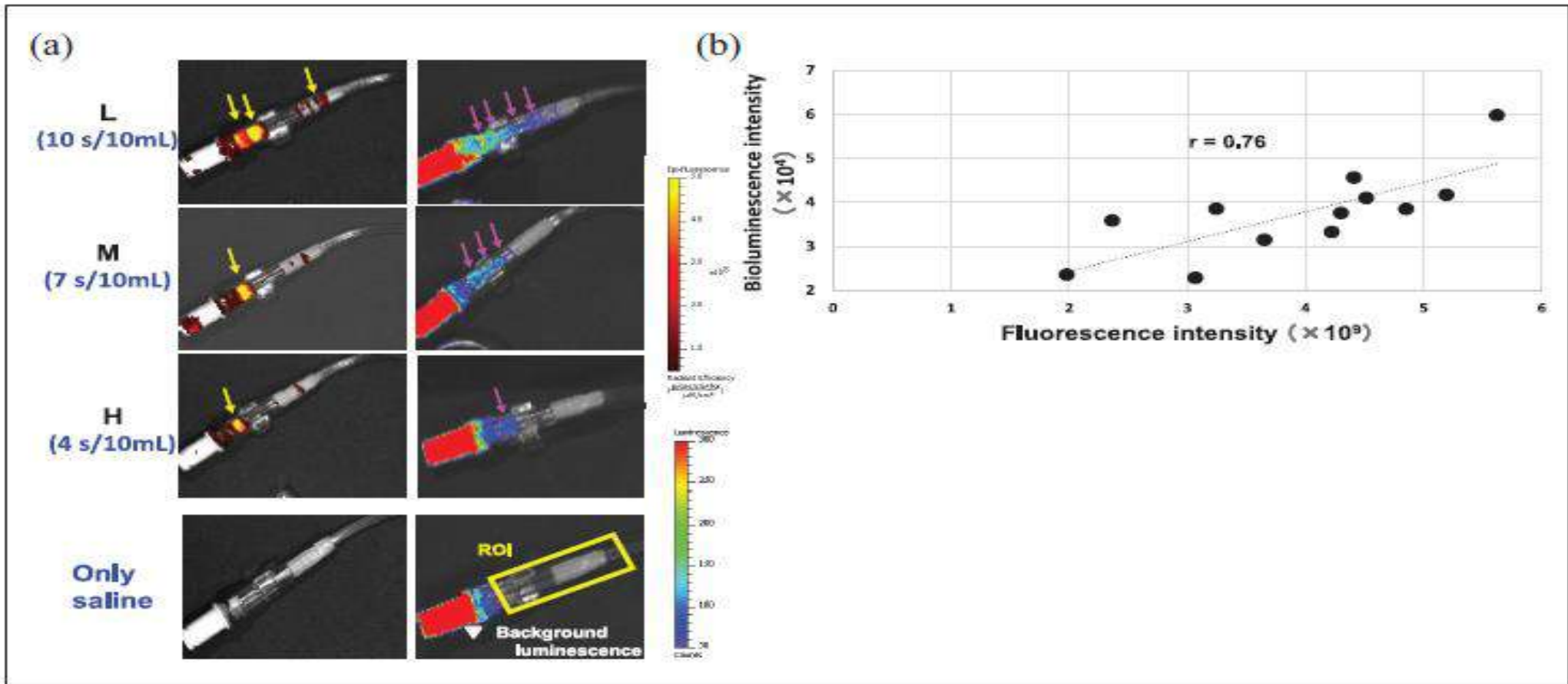


Figure 2. Representative fluorescence and bioluminescence images of a flushed central venous (CV) model (a). Left: Residual nutrients remain (indicated by yellow arrows) even after flushing at various speeds without intervals. Right: Bioluminescence images after flushing with *Pseudomonas aeruginosa* Xen 05 at each flushing speed without intervals show bacterial growth (indicated by pink arrows). Correlation between the average of fluorescence and bioluminescence intensities in the catheter after all respective flushing treatments in the present study (b).

TPN RESIDUE IMPACTS ON INFECTION RISK

A comparison of the effects of pulsatile and bolus methods on lipid emulsion residues that lead to bacterial growth in intravenous catheters.

N. Okamura, I. Yamaoka. JVA. Dec 2023

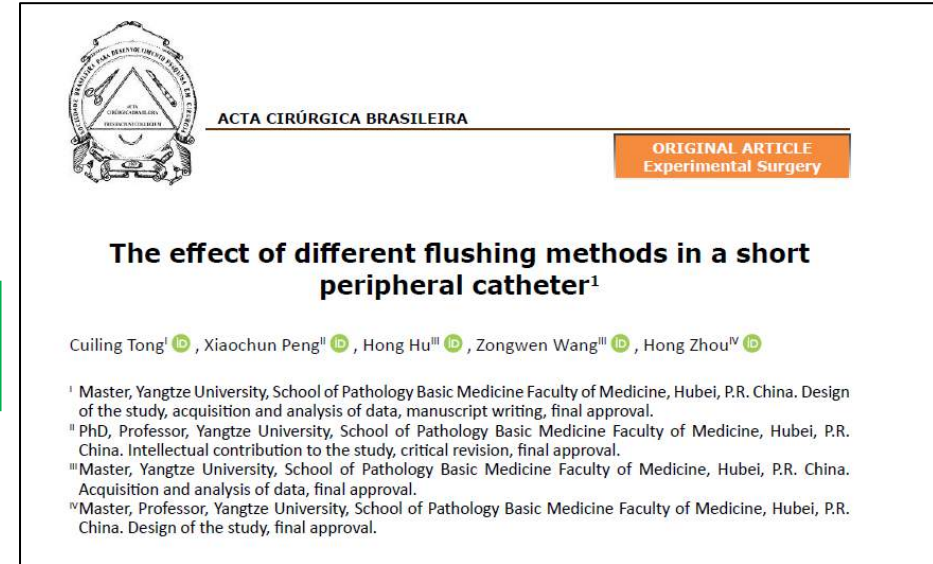
DO NOT FORGET THE VEIN!

Group A: Used pulsed flush. The method consisted of 5 successive boluses, 1 mL flushed in 0.5 s each. The reference time of “flush-pause” sequence was 0.5 s flush, then 0.4 s pause (90 mL/min, flushing time is 9 s), until the end of the bolus₅.

Group B: Used uniform flush. The method was a single 5 mL bolus (10 mL/min, flushing time is 30 s), until the end of the bolus.

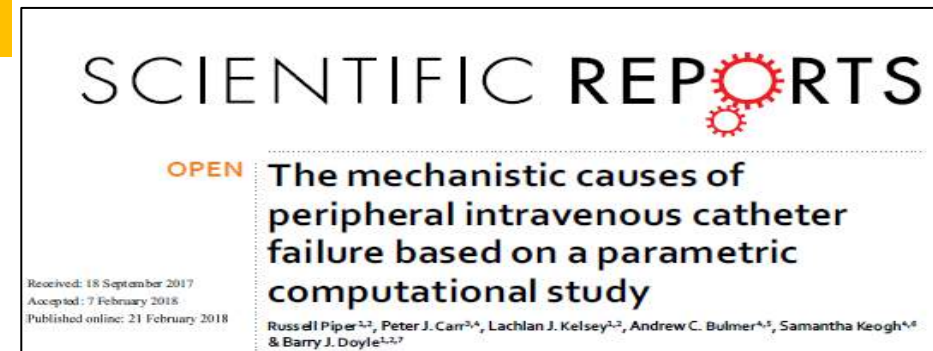
Group C: Without treatment/control group.

IN VIVO TEST (2019)



- Flush at 1 ml/sec or less to prevent peripheral vessel wall (2018)

NUMERICAL TEST



HOW TO RINSE EFFICIENTLY A CYLINDRICAL PORT CHAMBER?

Evaluation of the amount of residual lipid emulsion in chambers of flushed totally implantable venous access devices using fluorescence imaging.

N. Okamura, T. Yamato, I. Yamaoka. European Journal of Clinical Nutrition (2019) 73:1084-1087

IN VITRO TEST

22 G NCN + Bionector + cylindrical port

Lipid mixed TPN

Fluorescence optical imaging system

Mechanical syringe pump. Rinsed then Optical imaging system then bacteriological test

3 tests

Flushing bolus with 5, 10, 20, 40 or 70 mL saline

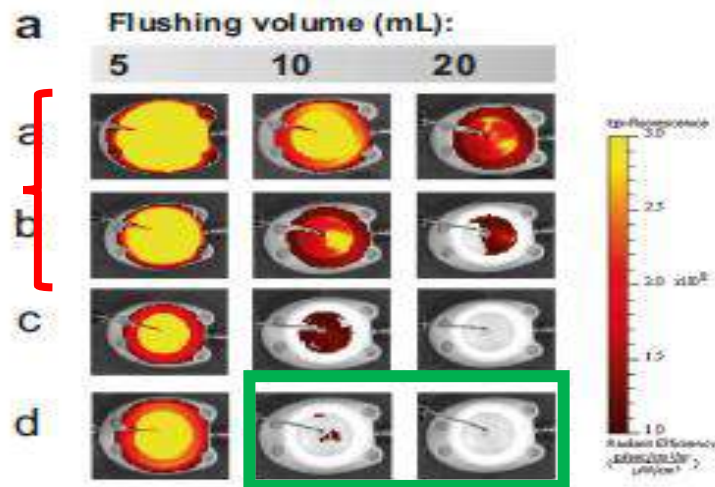
- **Bolus** at a speed of 15, 30, 40, 50, 60 mL/min
- **Pulsatile flushing** 10 ml of saline at a speed of 30 or 60 mL/min by 1 or 3 holdings

Exit at 0°, 90° and 120°

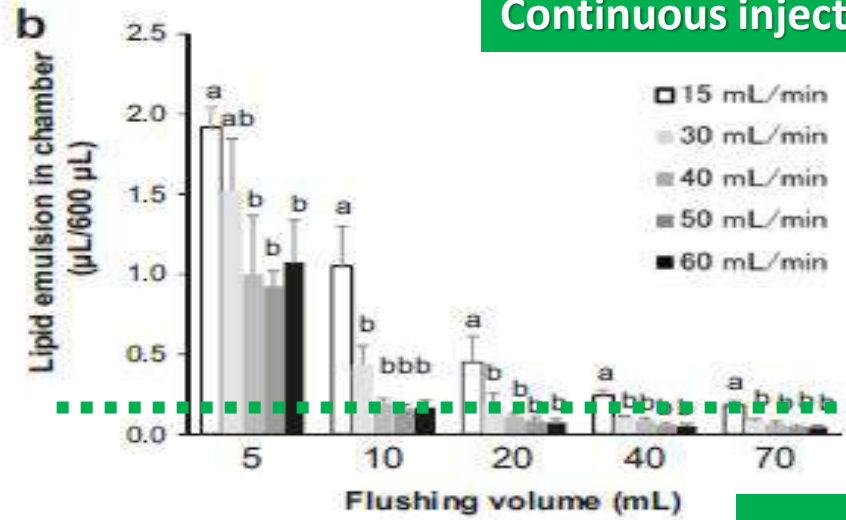
<30 mL/min

40 mL/min

60 mL/min



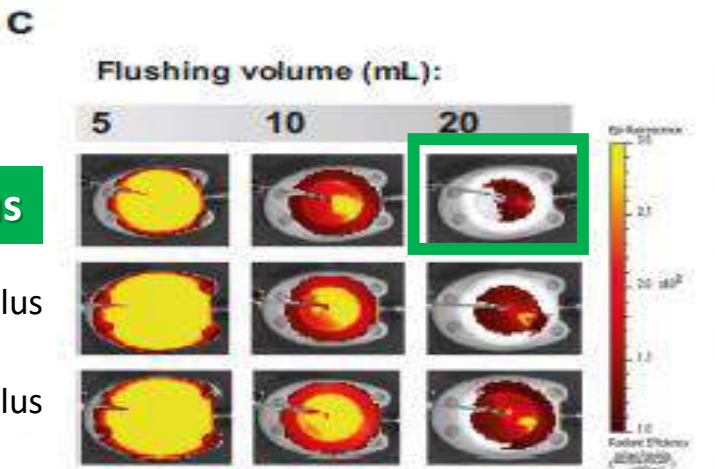
Continuous injection > PP technique injection



Continuous

1 sec between bolus

3 sec between bolus



Higher flow rate > Prefer flow rate > 40 mL/min

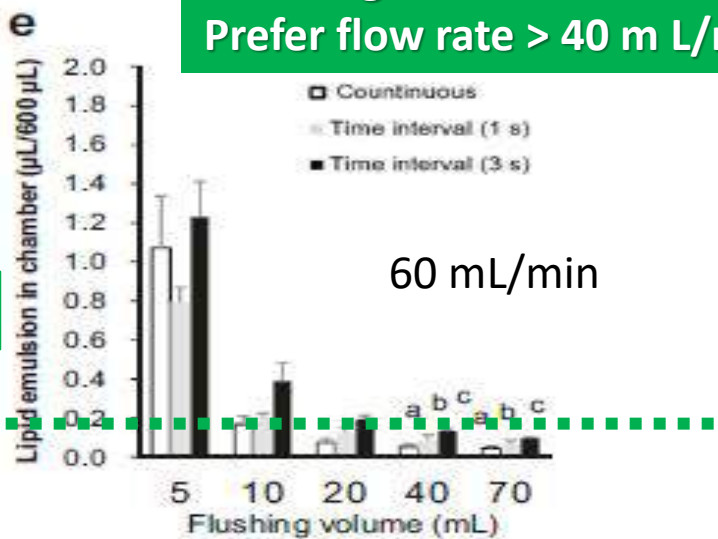
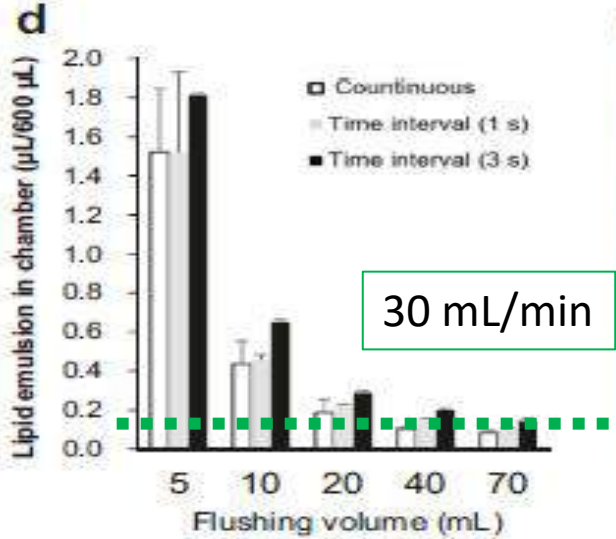
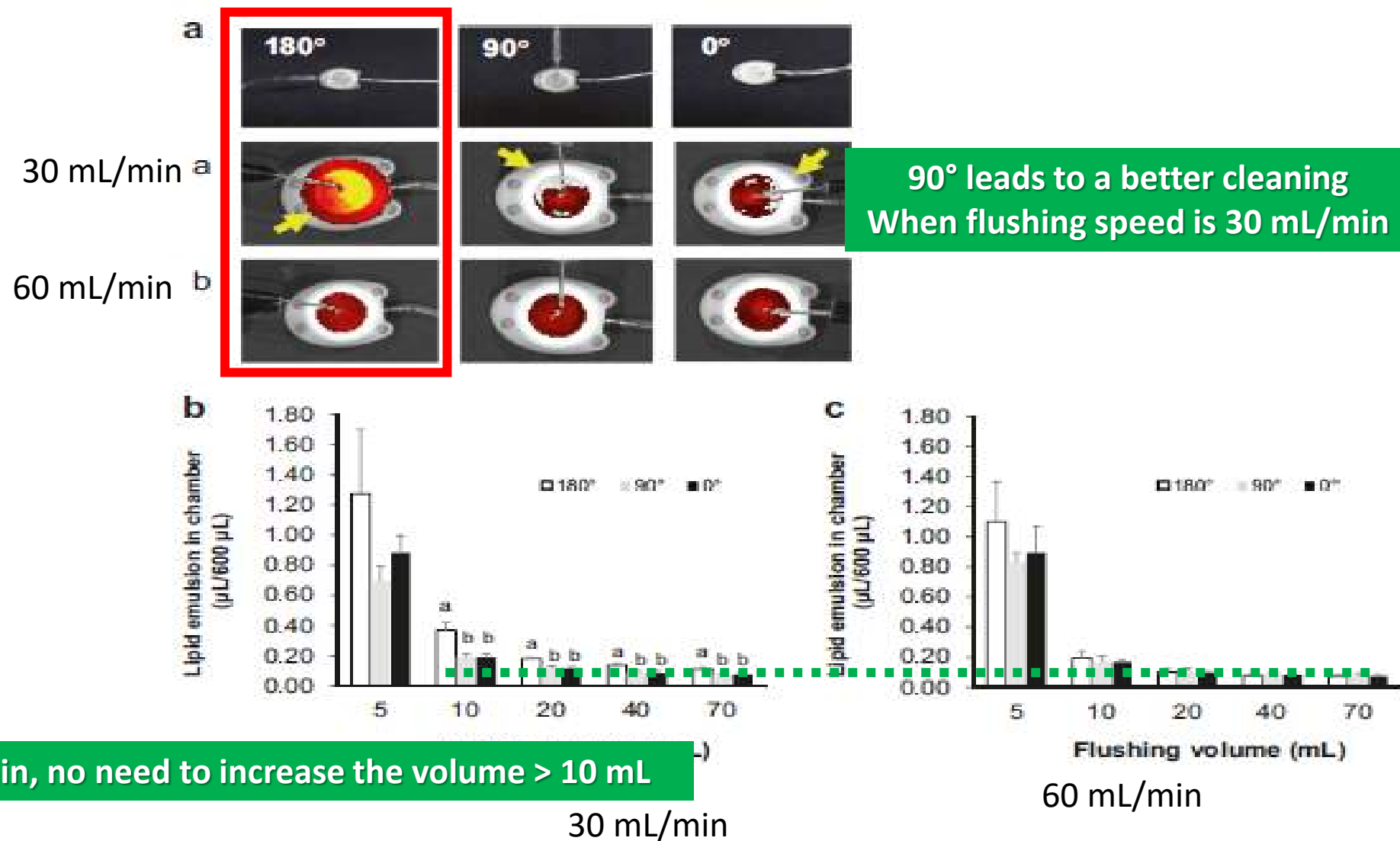


Fig. 1 Representative fluorescence images of residual lipid emulsion after continuous flushing at 15 (a), 30 (b), 40 (c), or 60 (d) mL/min until reaching flushing volume (in a), and with or without (a) a time interval of 1 s (b) or 3 s (c) between boluses at 30 mL/min (in c). The residual amounts at various speeds (15–60 mL/min) until reaching

flushing volume (in b) and between continuous and pulse intermittent flushing at 30 mL/min (in d) and 60 mL/min (in e). Values are expressed as mean ± standard deviation (n = 3). Different small letters indicate significant differences between groups (p < 0.05)

Fig. 2 Representative bright-field and fluorescence images of chambers continuously flushed with 20 mL at 30 (a) or 60 (b) mL/min at various insertion angles (in a). The residual amounts among various insertion angles after continuous flushing at 30 (in b) or 60 (in c) mL/min in each volume with 5–70 mL. Values are expressed as mean \pm standard deviation ($n = 3$). Different small letters indicate significant differences between groups ($p < 0.05$)



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RINSING IN A FEW WORDS

- Rinse asap from the injection port;
- The continuous injection is more efficient than the push-pause injection;
- For **port chamber**: - When flow rate > 30 mL/min, no need to increase the volume > 10 mL
-When the NCN's hole is oriented at 90° a flushing speed at 30 mL/min is enough
- With short peripheral cannula rinse with 1 mL /sec or less to prevent thrombosis;
- The hole of the NCN shouldn't face the exit of the port chamber;
- **And that's all**

HOW TO FLUSH EFFICIENTLY A TUBE?

The fouling and cleaning of venous catheters: A possible optimization of the process using intermittent flushing.

L. Royon, G. Guiffant et al. Chemical Engineering Research and design. 90 (2012) 803-807

IN VITRO TEST

10 ml bolus / 5 sec (120 mL/min) -> 1,65 mg (62,5%)

10 ml bolus / 2,5 sec (240 mL/min) -> 1,85 mg (79%)

500 ml/24Hrs (21 ml/min) -> 77%

10 mL with PP technique with 0,4 sec pauses between each 1 mL injection
-> (90% +/-3%)

10 mL with PP technique with 0,1 sec pauses -> (64%)

10 mL with PP technique with 0,8 sec pauses -> (69%)

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PUR/ 16 cm/ 0,1 cm/ Vol. int. 0,52 mL

Fibronectin + Albumin solution for 24 Hrs at 37°C

Polluted and emptied catheter

Syringe pump/manual.

Dosage of albumine in the rinsing/flushing saline solution

12 times

- 10 mL bolus /2,5 (240)- 5 (120)-10 (60)-20 sec (30 mL/min)
- 500 mL/24Hrs (21 mL/Hrs)

Pause between 1 mL 0,1- 0,2 - 0,4 - 0,5 - 0,6 - 0,8

HOW TO FLUSH EFFICIENTLY A CYLINDRICAL PORT CHAMBER?

Flushing ports of totally implantable venous access devices, and impact of the Huber point needle bevel orientation: experimental tests and numerical computation.

G. Guiffant, P. Flaud et J. Merckx. Medical Devices: Evidence and Research. 12 april 2012

IN VITRO & NUMERICAL TESTS

19 and 22 G NCN + cylindrical ports of 3 different series (0,15 – 0,3 – 0,4 mL)

Filled with fibronectin solution and kept 48 Hrs at 37°C + Flushing with 30 mL of pure water + Removal of nonadherent fibronectin by air injection + Filling with a saline solution of bovine serum albumin + 24 Hrs incubation à 37°C + Air flushing + Ports were flushed. / Computer

Albumin was titrated using an ultraviolet spectrophometer (%age of extracted albumin) / Computer

Autopulsed syringe

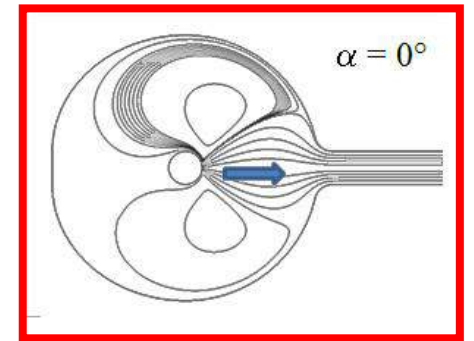
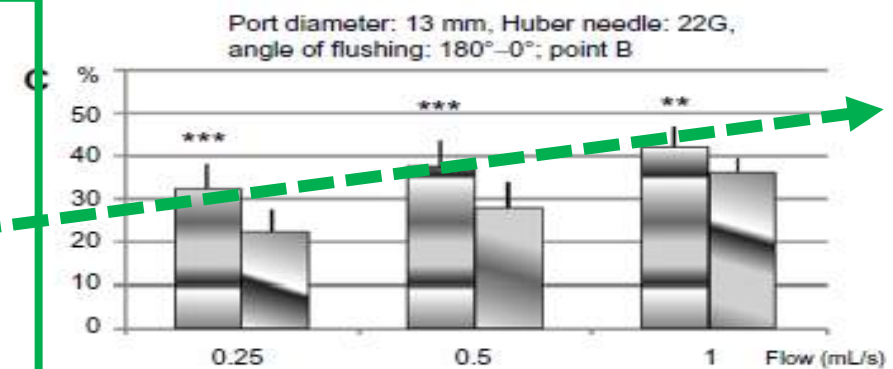
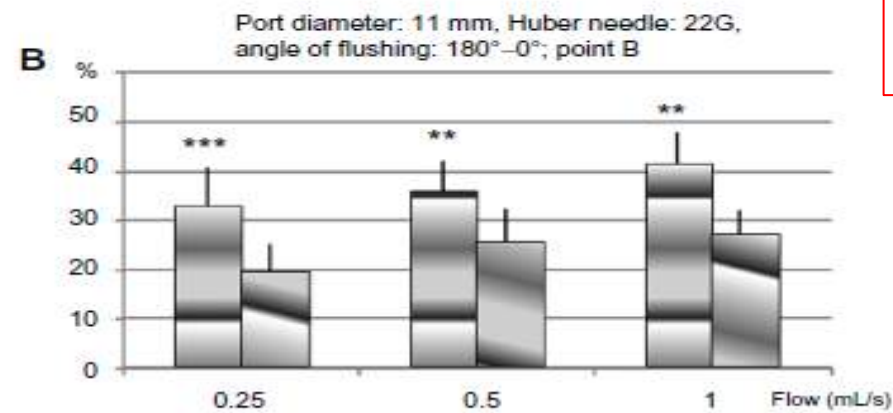
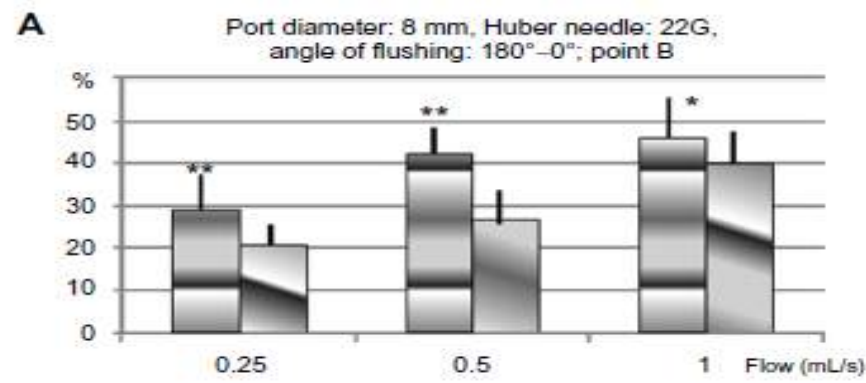
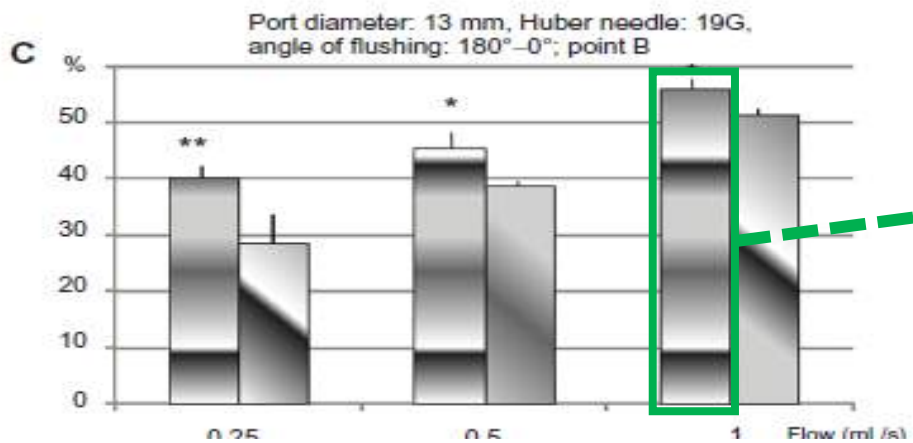
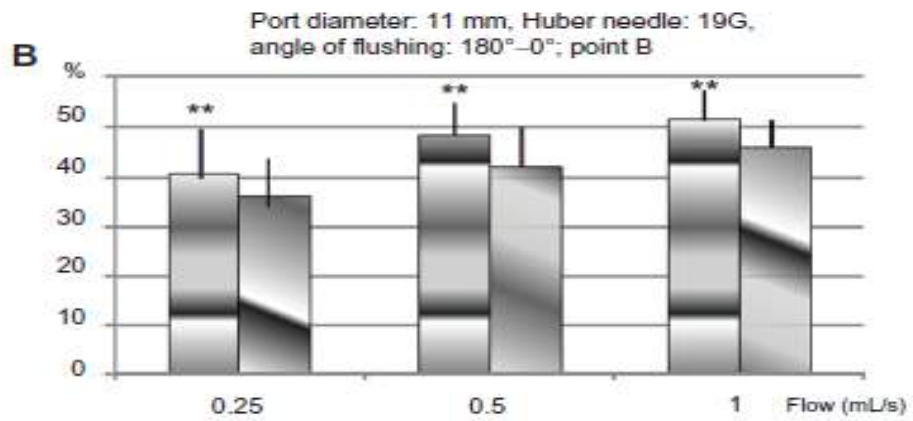
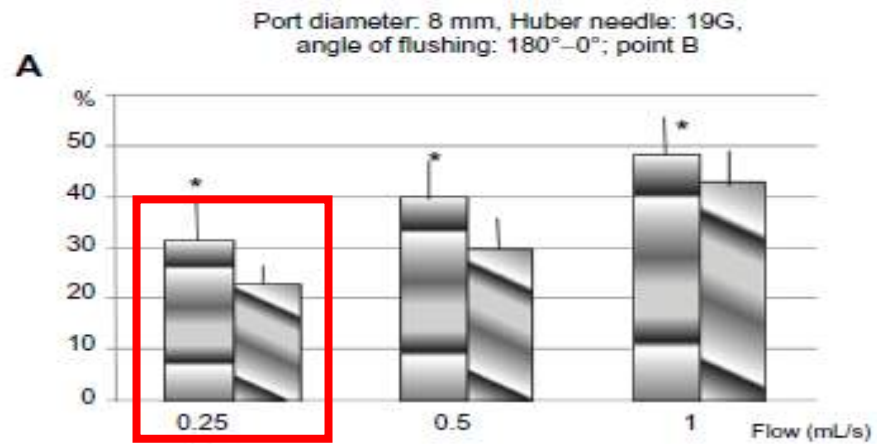
6 tests for each of the 36 combinations

Flushing bolus with 10 ml saline

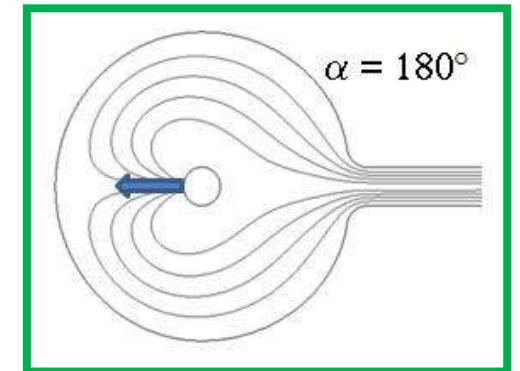
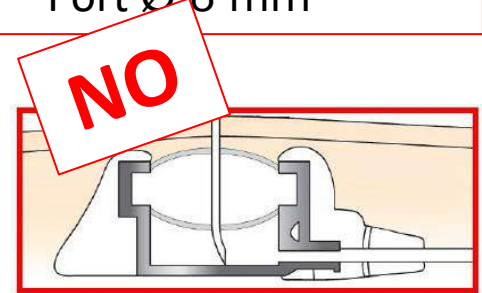
10 mL of saline at 0,25-0,5-1 mL /sec

- **Bolus** flushing

Exit at 0°, at 180° and at axis perpendicular to the central site. **Then computer analysis** of the impact of the NCN orientation on the shears.



22 G 0,25 ml/sec (15 ml/min)
Port \varnothing 8 mm



19 G - 1 ml/sec
Port \varnothing 13 mm

Figure 3 Percentage of proteins removed in TIVADs of diameters 8 mm (A), 11 mm (B), and 13 mm (C), with a Huber point needle of 22G, for two orientations

Port diameter: 13 mm, Huber needle 22G,
direction of flushing: *i, j*, point C

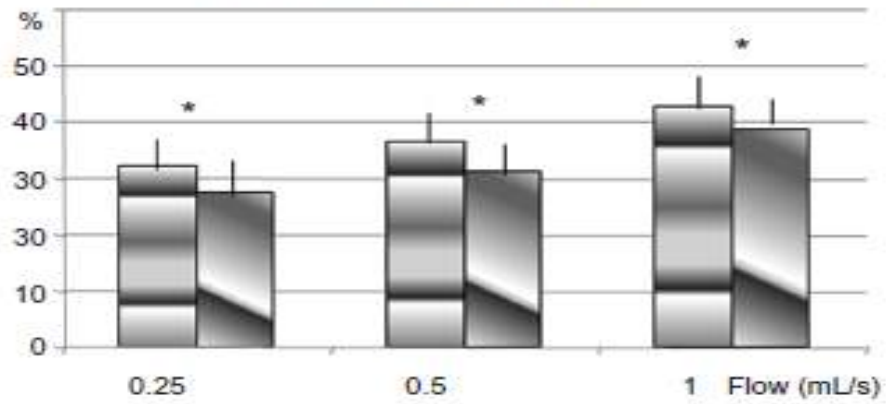


Figure 4 Percentage of proteins removed in TIVAD of 13 mm (c), with an HPN of 22G, for two orientations of the flow from the point C: *i* towards the bottom of the cavity, *j* towards the exit channel.
Abbreviations: G. gauge; HPN, Huber point needle; TIVAD, totally implantable venous access devices.

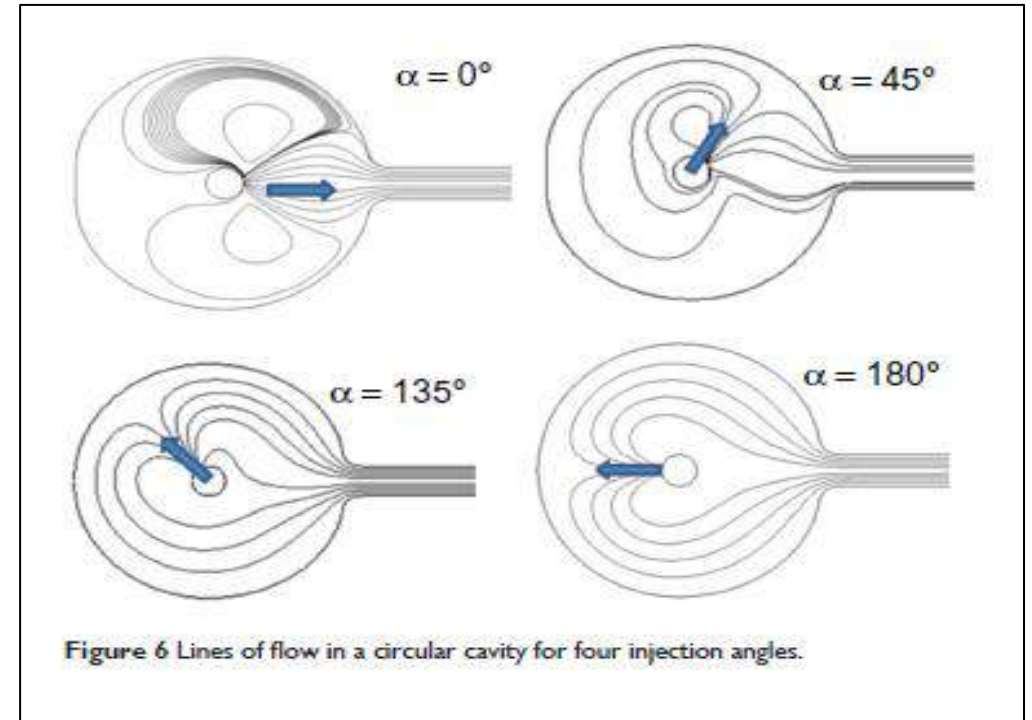
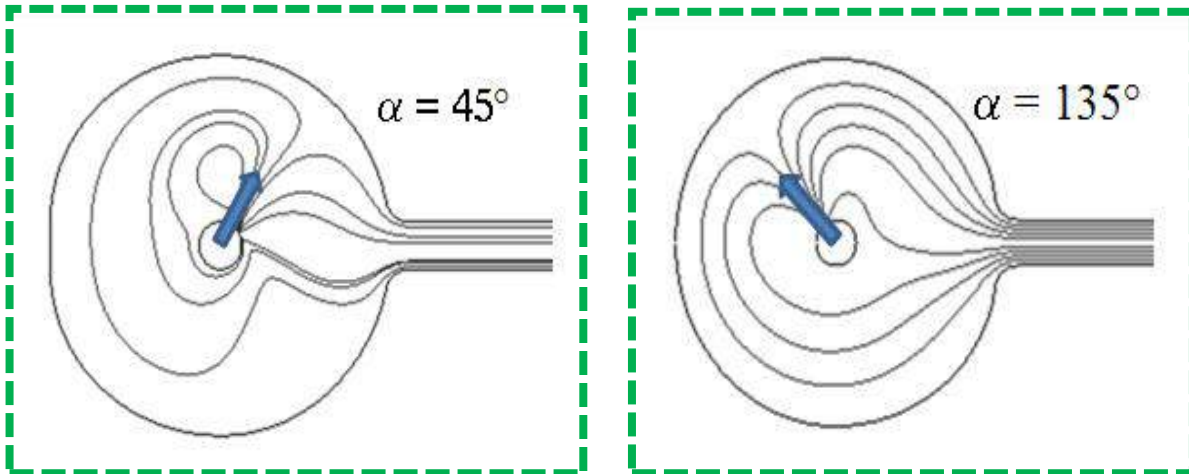


Figure 6 Lines of flow in a circular cavity for four injection angles.



NUMERICAL COMPUTATION.



IN VIVO TEST



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L. Royon, G. Guiffant et al. Chemical Engineering Research and design. 90 (2012) 803-807

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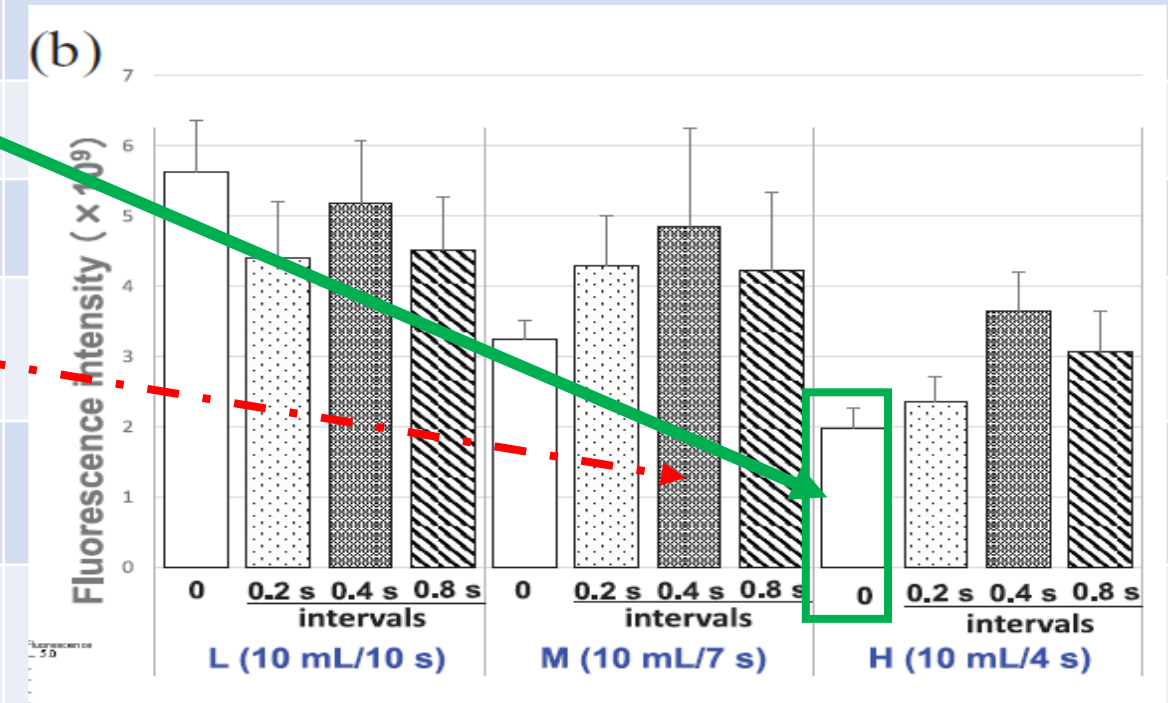
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Polluted and emptied catheter

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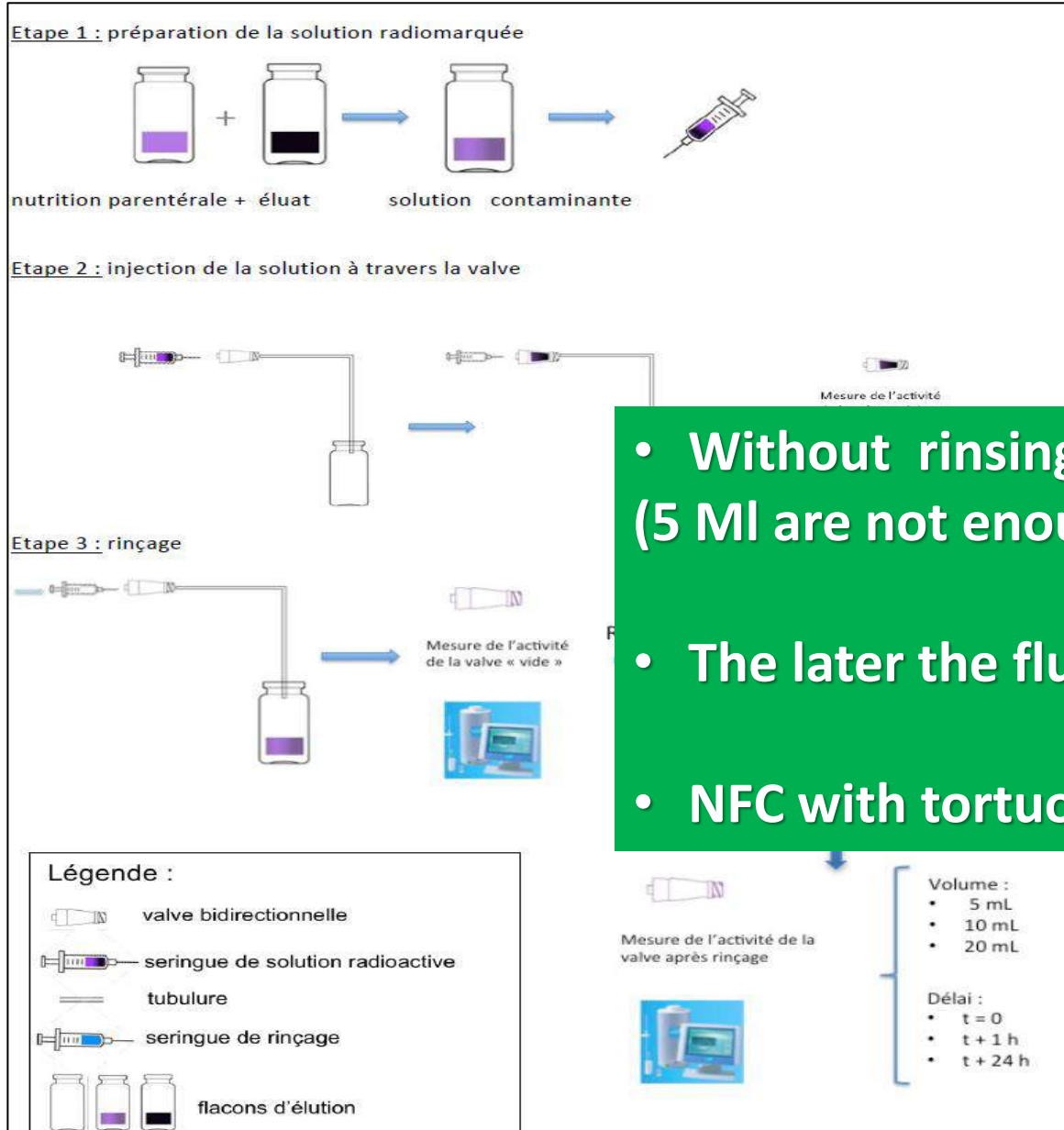
Evaluation of the amount of residual lipid emulsion in chambers of flushed totally implantable venous access devices using fluorescence imaging.

N. Okamura, T. Yamato, I. Yamaoka. European Journal of Clinical Nutrition (**2019**) 73:1084-1087

SURFACE

LUMEN

What about needle free connectors?



- Without rinsing, 10 mL of saline are necessary to clean the NFC (5 mL are not enough and 20 are useless)
- The later the flushing is, the harder is the DM to clean
- NFC with tortuous design are hard to clean

IN VITRO TEST

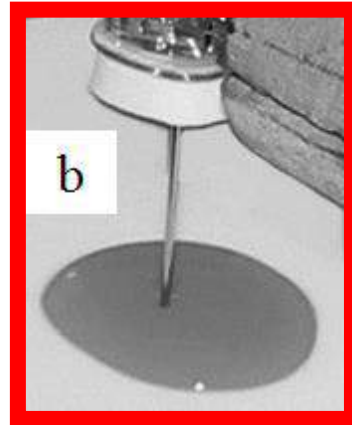
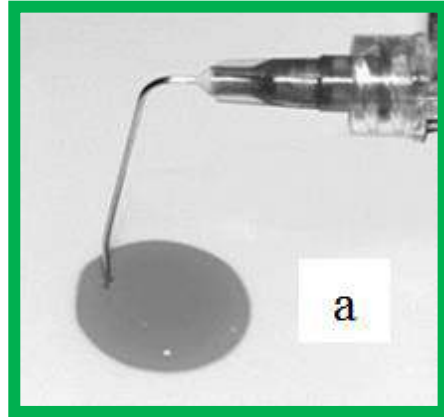
VALVES BIDIRECTIONNELLES ET RISQUE INFECTIEUX : DE LA THEORIE A LAPRATIQUE

Voahangy RASAMIJAO

CHU St Louis, Assistance Publique-Hôpitaux de Paris

2014

Don't forget the impact of the NCN bevel



THE BEVEL GUIDES THE FLUSHING FLOW

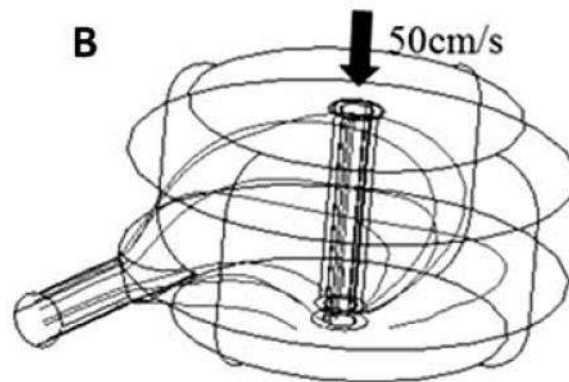
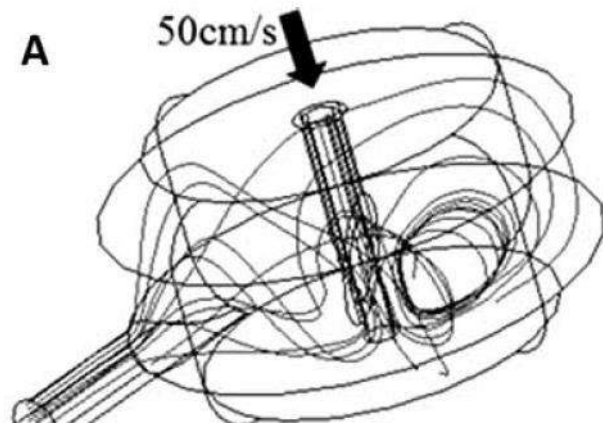
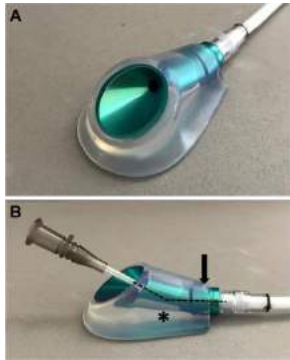


Fig. 4 - Representation of the streamlines in a curved side wall port: (A) with beveled non-coring needle (BNCN), (B) with BFC (L), (C) with BFC (H).

IN VITRO TEST

INTERNAL DESIGN OF THE CHAMBER IMPACT ON THE RINSING/FLUSHING



Spherical Port chambers are easier to flush

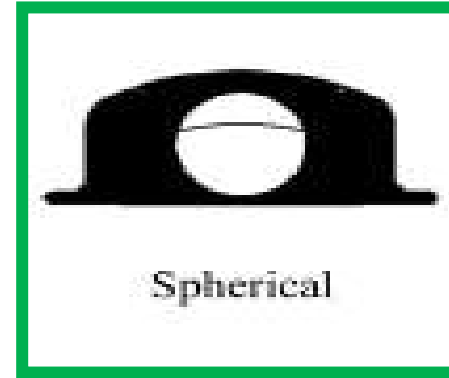
Importance of devices design when flushing



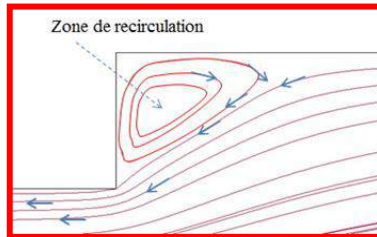
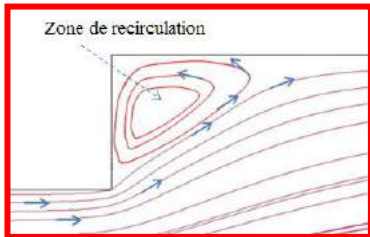
Cylindrical



Rounded



Spherical



The port clearance test was developed based on FDA guidance⁸ and is available on the FDA website (<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationand%20Guidance/GuidanceDocument/UCM081374.pdf>). The FDA

NUMERICAL TEST

IN VITRO TEST

The port clearance test: why is it important for clinicians. M. Dalton and al. JAVA, Vol 19 N°1. 2014

Flushing ports of totally implantable venous access devices, and impact of the Huber point needle bevel orientation: experimental tests and numerical computation. G. Guiffant et al. Med Devices (Auckl). 2012; 5: 31–37.

PUSHING WITH HIGH FORCE ON THE PLUNGER IS NOT NECESSARY TO FLUSH EFFICIENTLY

IN VIVO TESTS



FLUSHING IN A FEW WORDS

- Flush asap from the injection port and NFC;
- 5 mL of saline are not enough to clean a non rinsed NFC but 10 mL are;
- Pushing with high force on the plunger is not necessary;
- **10 mL of saline injected with PP technique with 0,4 sec pause between 2 one mL injections is sufficient to clean a 16 cm peripheral catheter**

The push-pause injection is more efficient than a bolus injection to flush a tube

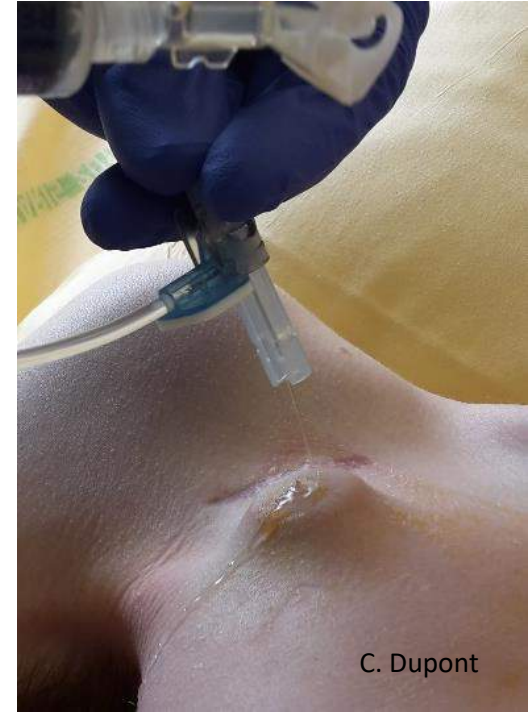
- Don't flush with PP technique a SPC inserted in a peripheral vein;
- **With implanted port**, the hole of the NCN shouldn't face the Port exit **and** a bolus of 10 m L of saline injected at **1 ml/sec in a Port Ø 13 mm** through a 19 G NCN has better results in the G. Guiffant's study
- **And that's all**
- We can ONLY SUPPOSE that **The push-pause injection is more efficient** than a bolus injection to flush an implanted port /

That **rinsing then flushing** would be the best way to clean the line and the catheter /

AND that changing the main line every 96 Hrs would be a correct recommandation;

HOW TO LOCK EFFICIENTLY?

- Saline is not less efficient than Heparin as a lock solution to prevent occlusion and it has no side effect (on the contrary, Heparin has some);
- Inject the saline as you lock the line and do the same as you remove the NCN;
- No consensus about lock renewal: **Peripheral cannulae** -> once a day - **1 lumen PICC** -> every week (or twice if 2 lumens) - **Thoracic central lines** -> every month - **Ports** -> every 4 months.
- **Implanted port:** Before injecting the new lock, take 5 to 10 mL of blood and discard it if the date of the last lock is unknown or is up to 13 weeks.
- **And what's all.**



C. Dupont

Comparing normal saline versus diluted heparin to lock non-valved totally implantable venous access devices in cancer patients: a randomised, non-inferiority, open trial. *Annals of Oncology*. Goossens G. A., Jérôme M., Janssens C., et al. 2013;24(7):1892–1899.

Totally implantable port management: impact of positive pressure during needle withdrawal on catheter tip occlusion (an experimental study). Lapalu L. et al *JVA* 2010; 11:46-51

Flushing and locking of venous catheters: available evidence and evidence deficit. Goossens GA. *Nurs Res Pract*. Epub ahead of print 14 May 2015.

Evidence-based criteria for the choice and the clinical use of the most appropriate lock solutions for central venous catheters (excluding dialysis catheters): a GAVeCeLT consensus. M. Pittiruti, S. Bertoglio et al *J Vasc Access* 2016

Safety of extending implanted vascular access device maintenance flush frequency. *Clinical Journal of nursing Oncology Nursing*. April 2023. Vol 27 N02M Mc Manus et al.

Incidence of the curvature of a catheter on the variations of the inner volume; Application to the peripherally central catheters. Merckx J. and Guiffant G. 2012



- Litterature **review**
- Multidisciplinarity
- Follow-up and practices audits
- R & D and new studies
- A.I.

This is too much for one team!



IT'S ABOUT TIME TO CREATE A « SUPERMARIO I.V. GROUP »

TO be at the TOP, let's create **an international network about catheter patency**

Super I.V. plumber

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WOCOVA

8th World Congress on Vascular Access

