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Prophylactic negative pressure wound closure for high SSI risk laparotomy wounds.

Hungarian RCT

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ciNPWT = primary NPWT = preventive NPWT

Definition: NPWT used on high SSI risk, sutured, closed wounds to prevent SSI.

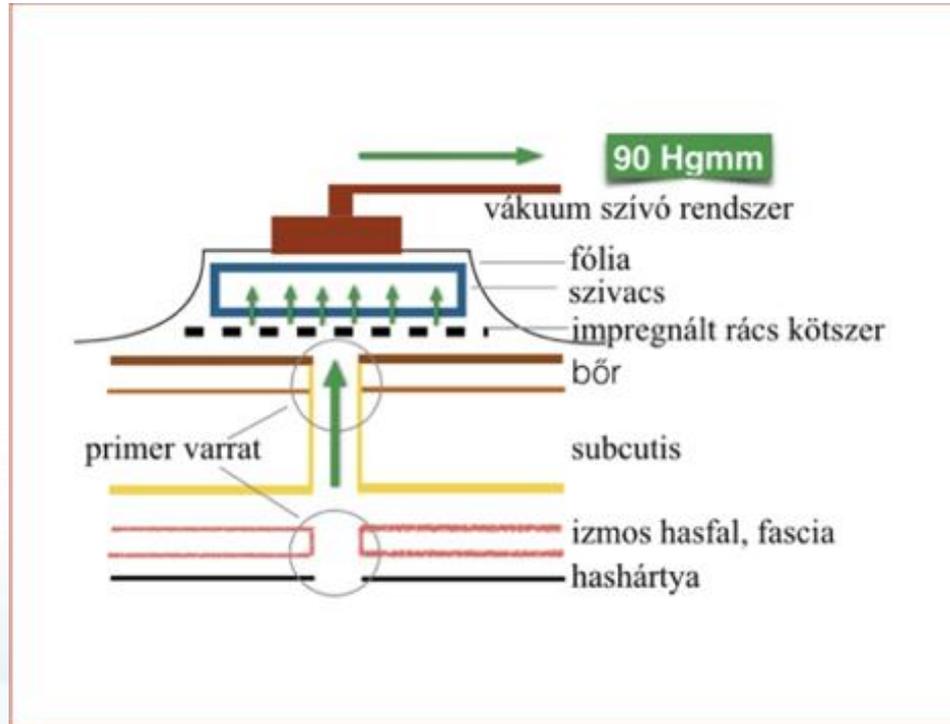
Technique: 4-5 days of NPWT on closed, sutured operative wound

Aim: to prevent SSI by

- direct drainage of incisional exudate,
- improving local microcirculation,
- increasing local ABx concentration in wound site,
- enhancing sterile wound healing process,
- stimulating local immune system at wound site.



ciNPWT = primary NPWT = preventive NPWT



NPWT effect

- Removal of exudate from wound cavity
- Improving capillary microcirculation, decreasing edema
- Locally increased ABx concentration
- Growth factors / angiogenesis / regeneration factors / cytokines locally concentrated.



[Negative Pressure Wound Therapy on Closed Surgical Wounds With Dead Space: Animal Study Using a Swine Model.](#)
Suh H, Lee AY, Park EJ, Hong JP.
Ann Plast Surg. 2016 Jun;76(6):717-22. doi: 10.1097/SAP.0000000000000231.

J Orthop Trauma. 2008 Nov-Dec;22(10 Suppl):S135-7. doi: 10.1097/BOT.0b013e31818956ce.
Current thought regarding the mechanism of action of negative pressure wound therapy with reticulated open cell foam.
[Webb LX1](#), [Pape HC](#).
"stimulatory effect of microstrain on cellular mitogenesis, angiogenesis, and elaboration of growth factors"
"lowering of the heightened capillary afterload and a qualitative dilution of contained microcontaminants, bacteria, and proinflammatory cytokines"

Br J Surg. 2014 Dec;101(13):1627-36. doi: 10.1002/bjs.9636. Epub 2014 Oct 8.
Systematic review of molecular mechanism of action of negative-pressure wound therapy.
[Glass GE1](#), [Murphy GF](#), [Esmaili A](#), [Lai LM](#), [Nanchahal J](#).
"Tumour necrosis factor expression was reduced in acute and chronic wounds, whereas expression of interleukin (IL) 1 β was reduced in acute wounds only. Systemic IL-10 and local IL-8 expression were increased by NPWT. Expression of vascular endothelial growth factor, fibroblast growth factor 2, transforming growth factor β and platelet-derived growth factor was increased, consistent with mechanoreceptor and chemoreceptor transduction in response to stress and hypoxia. Matrix metalloproteinase-1, -2, -9 and -13 expression was reduced but there was no effect on their enzymatic inhibitor, tissue inhibitor of metalloproteinase 1."



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Who will benefit?

SSI risk factors

Surgery-related	Patient-related	Health condition related
Wound class	ASA-3 +,	Emergency,
Outpatient or inpatient	BMI 25 kg/m ² ,	Metastatic cancer
More than 1 procedures	depth of sc. tissue;	sepsis
GA	regular steroid treatment	blood loss
Length of OP (240 min),	hypalbuminaemia	Low Hb
	smoking	
	PAD,	
	DM, HT	
	Chr. kidney disease	
	IBD	
	XIII. factor def., Fibrinogen	
	def, Hemophylia B	



SSI risk calculators

The screenshot shows the ACS NSQIP Surgical Risk Calculator interface. At the top, it features the ACS NSQIP logo and the American College of Surgeons logo. The main heading is "Surgical Risk Calculator". Below this, there are navigation links: "Risk Calculator Home Page", "About", "FAQ", "ACS Website", and "ACS NSQIP Website". The primary section is titled "Enter Patient and Surgical Information". It includes a "Procedure" dropdown menu with a "Clear" button. Below the procedure field, there is a "Reset All Selections" button. A section titled "Are there other potential appropriate treatment options?" includes radio buttons for "Other Surgical Options", "Other Non-operative options", and "None". A note below this section states: "Please enter as much of the following information as you can to receive the best risk estimates. A high estimate will still be generated if you cannot provide all of the information below." The form is divided into two columns of input fields, each with a help icon. The left column includes: "Age Group" (Under 40 years), "Sex" (Female), "Functional Status" (Independent), "Emergency Case" (No), "ASA Class" (Healthy patient), "Steroid use for chronic condition" (No), "Aspirin within 30 days prior to surgery" (No), "Systemic Sepsis within 60 hours prior to surgery" (None), and "Ventilator Dependent". The right column includes: "Diabetes" (No), "Hypertension requiring medication", "Competitive Heart Failure in 30 days prior to surgery" (No), "Dyspnea" (No), "Current Smoker within 1 Year" (No), "History of Severe COPD" (No), "Dialysis" (No), and "Acute Renal Failure" (No). At the bottom right of the form, there is a "BMI Calculation" button.

The image shows the title page of a research paper. At the top left, it says "OPEN ACCESS Freely available online". At the top right, it features the PLOS ONE logo. The main title is "The Surgical Site Infection Risk Score (SSIRS): A Model to Predict the Risk of Surgical Site Infections". Below the title, the authors are listed: "Carl van Walraven^{1,2,4*}, Reilly Musselman³". The footnotes indicate: ¹ Department of Medicine, University of Ottawa, Ottawa, Canada, ² Department of Surgery, University of Ottawa, Ottawa, Canada, ³ Ottawa Hospital Research Institute, Ottawa, Canada, ⁴ Institute for Clinical Evaluative Sciences, Toronto, Canada. The asterisk on the first author's name indicates they are the corresponding author.

The screenshot shows the SSIRX calculator interface. The title is "SSI Risk Index". It is divided into three main sections: "A - PATIENT DEMOGRAPHICS AND BASELINE", "B - PAST MEDICAL HISTORY", and "C - SURGICAL INFORMATION". Section A includes: "Smoker" (Yes/No), "Patient weight (in pounds)" (pounds), and "Patient height (in inches)" (inches). Section B includes: "Peripheral vascular disease" (Yes/No), "Metastatic Cancer" (Yes/No), "Steroid in last month for at least 10 days" (Yes/No), and "SIRS/Sepsis in last 2 days" (Yes/No). Section C includes: "Location, urgency" (Out Patient, In Patient - non-emergent, In Patient - emergent), "Wound Type" (Clean, Clean / Contaminated, Contaminated / Dirty / Infected), "ASA Physical Status Classification" (1-5), "General Anesthesia" (Yes/No), "Additional procedures by same surgical team" (Yes/No), and "Total Operation time in hours" (hours). At the bottom, there is a "CPT Code" dropdown menu and a "Calculate Estimated probability of SSI" button.

http://www.ohri.ca/SSI_risk_index/Default.aspx



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<https://riskcalculator.facs.org/RiskCalculator/>



Case

78y ♀

Rectal cancer perf., feculant peritonitis

Primary resection, proximal biluminal colostomy

3/7 ITU

LOS 10 days

Oncotherapy started in 4w.



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Outcome of ciNPWT

Successful:

Primary wound healing after 5/7 ciNPWT

Unsuccessful:

Open wound care needed due to SSI within 30 days in spite of ciNPWT

Ineffectual:

Deep, abdominal cavity septic complication (e.g. leak) within 5/7 leading to concomitant SSI

ciNPWT indications

Indications: any (I-IV.) class, high SSI risk wound.

Main territories:

- faeculent or purulent peritonitis
- intraabdominal organ perforation (DU, Hy3-4. diverticulitis, colonic tumor perforation)
- GI bleeding with exploration - hypoproteinaemia, peritonitis
- stoma closure site
- Reoperation for anastomotic leak
- sinus pilonidalis
- etc.



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NO FIRM GUIDANCE AVAILABLE SO FAR!

Areas of successful attempts

Colorectal and general surgery

C. Section (in obese)

Inguinal LN dissection

Hip fracture

Red. Mammoplasty

Split thickness skin grafts

Inguinal vascular intervention

...

High risk colo-rectal anastomosis

JAMA Surg. 2018 Sep 26:e183467. doi: 10.1001/jamasurg.2018.3467.

Colorectal Dis. 2018 Jul 26. doi: 10.1111/codi.14350.

Am J Obstet Gynecol. 2018 Feb;218(2):200-210.e1

BJOG. 2018 Aug 1. doi: 10.1111/1471-0528.15413.

Trials. 2018 Oct 19;19(1):570.

BMJ Open. 2018 Apr 12;8(4):e020632.

Injury. 2017 Jul;48(7):1518-1521.

Plast Reconstr Surg Glob Open. 2018 Mar 23;6(2):e1720

Wound Repair Regen. 2018 Jan;26(1):77-86.

J Reconstr Microsurg. 2018 Mar;34(3):200-205.

Surg Infect (Larchmt). 2014 Apr 1; 15(2): 123–130.



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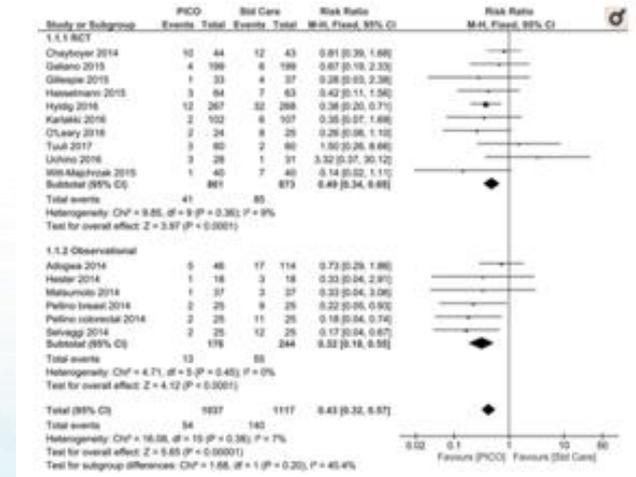
Be suspicious with literature!

Surg Infect (Larchmt). 2017 Oct;18(7):810-819. doi: 10.1089/sur.2017.156. Epub 2017 Sep 8.

Meta-Analysis of Comparative Trials Evaluating a Prophylactic Single-Use Negative Pressure Wound Therapy System for the Prevention of Surgical Site Complications.

SSI of 58% from 12.5% to 5.2% with NPWT (RR 0.43 [95% CI 0.32-0.57] $p < 0.0001$)

significant reduction in dehiscence from 17.4% to 12.8% with NPWT (RR 0.71 [95% CI 0.54-0.92] $p < 0.01$)



Szent Borbála Hospital RCT 2018

Patients

2018.07.01 - 2018.07.01

30 cases; 1:1 randomization

intraoperative high SSI risk assessed (Type C-D)

Local ethical committee approval

Informed consent

Methods

Application: in the morning after emergency
intervention, ciNPWT

Continuous 90 Hgmm negative pressure suction

Canister system

5 days

Assessment: 30th day



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End points:

Primary: SSI requiring wound opening-up

Secondary: abdominal wall dehiscence requiring
reoperation

Exclusion:

Deep organ sepsis

Exit within 5/7



Szent Borbála Hospital RCT 2018

	ciNPWT	Control	p
n	15	15	
Age	64 +/- 16 év	58 +/- 17 év	p=0,328
Sex	4 nő : 11 ffi	8 nő : 7 ffi	p=0,101
ACS SSI Risk	10 +/- 7,9 %	8,4 +/- 4,3 %	p=0,29
Operation wound class	A - 0 B - 0 C - 3 D - 12	A - 0 B - 0 C - 2 D - 13	p=0,62
BMI	26,3 +/- 4,5	26 +/- 6,4	p=0,88
Diabetes	3	2	p=0,62



Szent Borbála Hospital RCT 2018

Results

	ciNPWT	Control	p
SSI	1 (6 %)	5 (30 %)	p=0,089
Dysruption	0	0	n.s.
LOS	11 nap	9 nap	nem értékelhető
ITU	4/15	4/15	n.s.

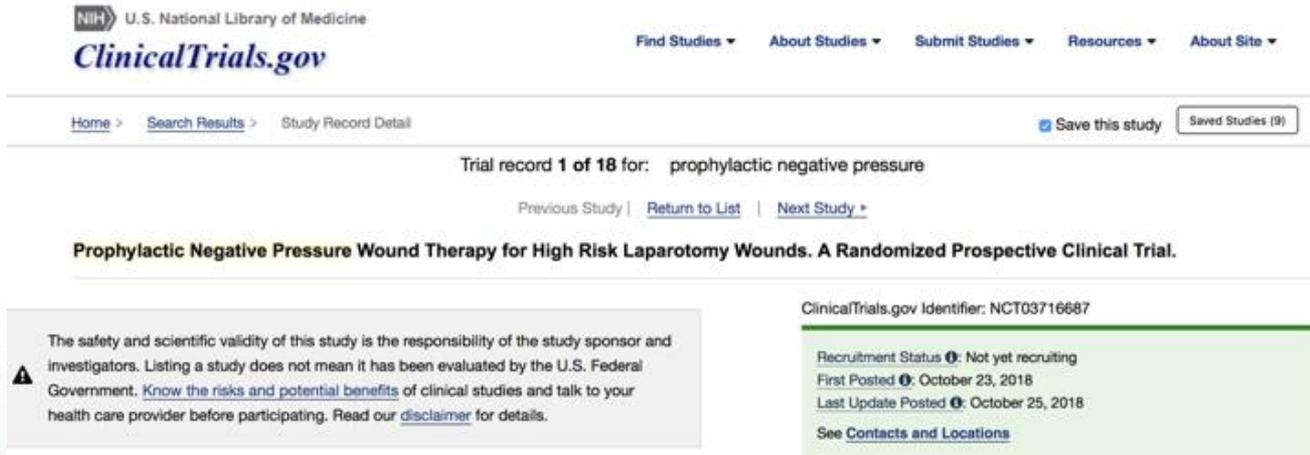
But! Small case Nr, heterogeneity in indication.

Unsuccessful ciNPWT was treated on with open NPWT.



Multicentric prospective RCT – HUNGARY 2019

(10 ciNPWT trials are running at the moment world wide)



NIH U.S. National Library of Medicine
ClinicalTrials.gov

Find Studies ▾ About Studies ▾ Submit Studies ▾ Resources ▾ About Site ▾

Home > Search Results > Study Record Detail Save this study Saved Studies (9)

Trial record 1 of 18 for: prophylactic negative pressure

[Previous Study](#) | [Return to List](#) | [Next Study >](#)

Prophylactic Negative Pressure Wound Therapy for High Risk Laparotomy Wounds. A Randomized Prospective Clinical Trial.

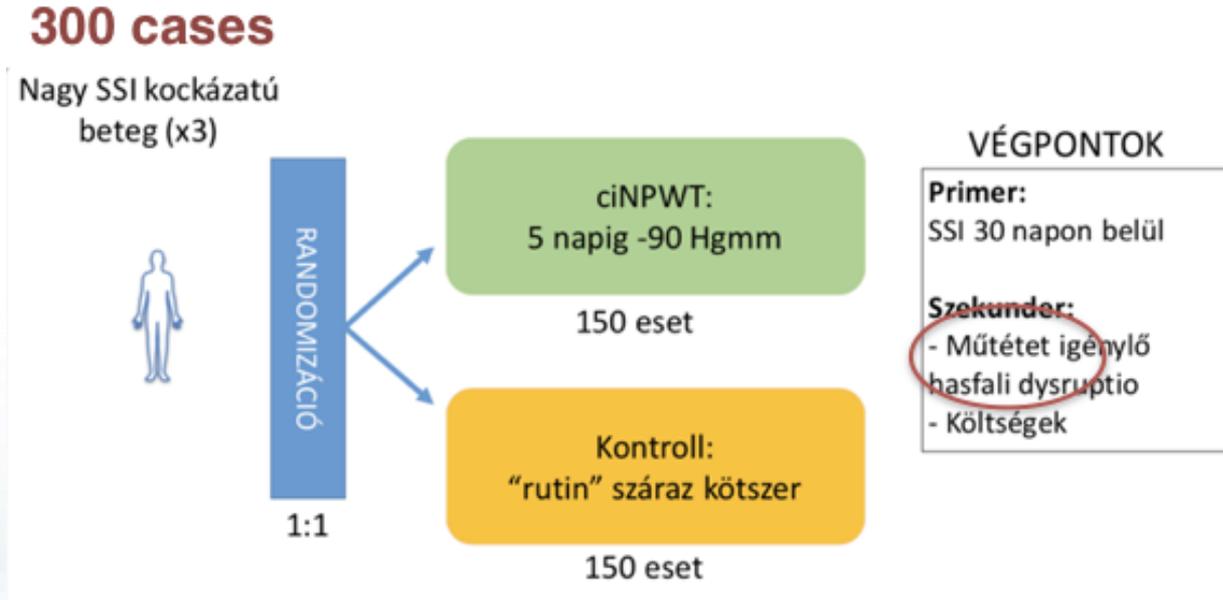
ClinicalTrials.gov Identifier: NCT03716687

⚠ The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. [Know the risks and potential benefits](#) of clinical studies and talk to your health care provider before participating. Read our [disclaimer](#) for details.

Recruitment Status **ⓘ**: Not yet recruiting
First Posted **ⓘ**: October 23, 2018
Last Update Posted **ⓘ**: October 25, 2018
[See Contacts and Locations](#)

OGYÉI/15347-5/2018

ciNPWT MRCT for high SSI risk laparotomy wounds

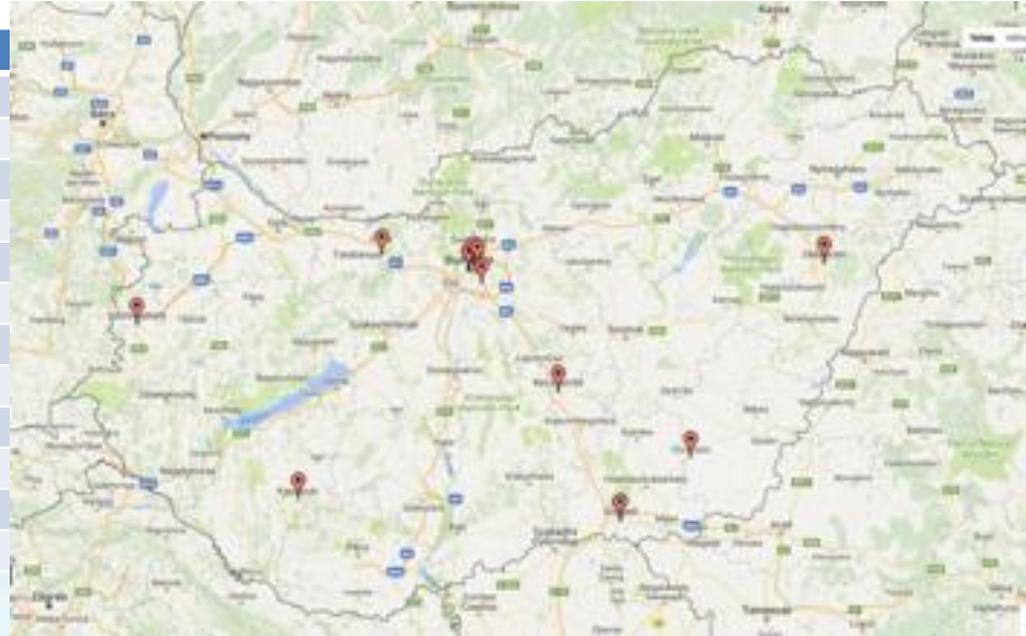


ciNPWT MRCT for high SSI risk laparotomy wounds

Collaborating centers

1. táblázat

Szent Borbála Kórház Sebészeti Osztály, Tatabánya
Semmelweis Egyetem I. sz. Sebészeti Klinika, Budapest
Jahn Ferenc Dél-Pesti Kórház, Sebészeti Osztály, Budapest
Jósa András Oktatókórház, Sebészeti Osztály, Nyíregyháza
Kaposi Mór Oktatókórház, Általános-Mellkas és Érsebészeti Osztály, Kaposvár
Orosházi Kórház, Invazív Mátrix Sebészeti Szakág, Orosháza
MH Egészségügyi Központ, I.sz. Sebészeti Osztály, Budapest
Egyesített Szent István és Szent László Kórház, Sebészeti Osztály
Debreceni Egyetem OEC Sebészeti Intézet
Kanizsai Dorottya Kórház, Általános Sebészeti Osztály, Nagykanizsa
Uzsoki Utcai Kórház, Sebészeti – Onkosebészeti Osztály, Budapest
Szegedi Tudományegyetem Sebészeti Klinika, Szeged
Markusovszky Egyetemi Oktatókórház, Sebészeti Osztály, Szombathely



Data collection



92 fields

- Patient-related data
- Procedure related data
- Follow-up data
- Cost-analysis data

Adding new Study ID 1

Study ID	1
Betegazonosító (helyi sorszám) <small>* must provide value</small>	<input type="text"/>
Centrum neve	<input type="text"/>
Koordinátor	<input type="text"/>
Belegyező információk	
Beválogatás dátuma <small>* must provide value</small>	<input type="text"/> Today Y-M-D YYYY-MM-DD
Belegyező nyilatkozat másolat feltöltése	Upload document
Vizsgálati csoport	<input type="radio"/> ciNPWT <input type="radio"/> Kontroll reset
Belegyezőt aláírta	<input type="radio"/> Yes <input type="radio"/> No reset
Vérminta levéve, szérum -20 °C-on	<input type="radio"/> Yes <input type="radio"/> No reset <small>Piros kupakos cső, szérumhoz</small>
Beteg	
Vezetéknév (családnév)	<input type="text"/>
Keresztnév	<input type="text"/>
TAJ szám	<input type="text"/>



ciNPWT MRCT for high SSI risk laparotomy wounds

State of the project

Interim analysis results:

- Nr of cases enrolled
- Nr of centres active
- Demographics
- Rate of SSI in interventional and control group



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Open questions

Indication:

- Who will benefit? ... RCT
- ciNPWT or open-abd NPWT

Length of care:

- 3 vs 5 days

Technical problems:

- Does suture technique matter?
- When to remove / open wound?
- Blockage of “white foam” ...
- When to suspect initial failure or deep organ sepsis?
- Negative pressure level - adjustable or not?
- Sealing problems - single use devices (?)

Financing:

- NNT (15-20 cases ???)
- 130-150 EUR/case
- Threshold problem

New fields:

- Plastic surgery
- Mastectomy with or without primary reconstruction
- Low rectal anastomosis

