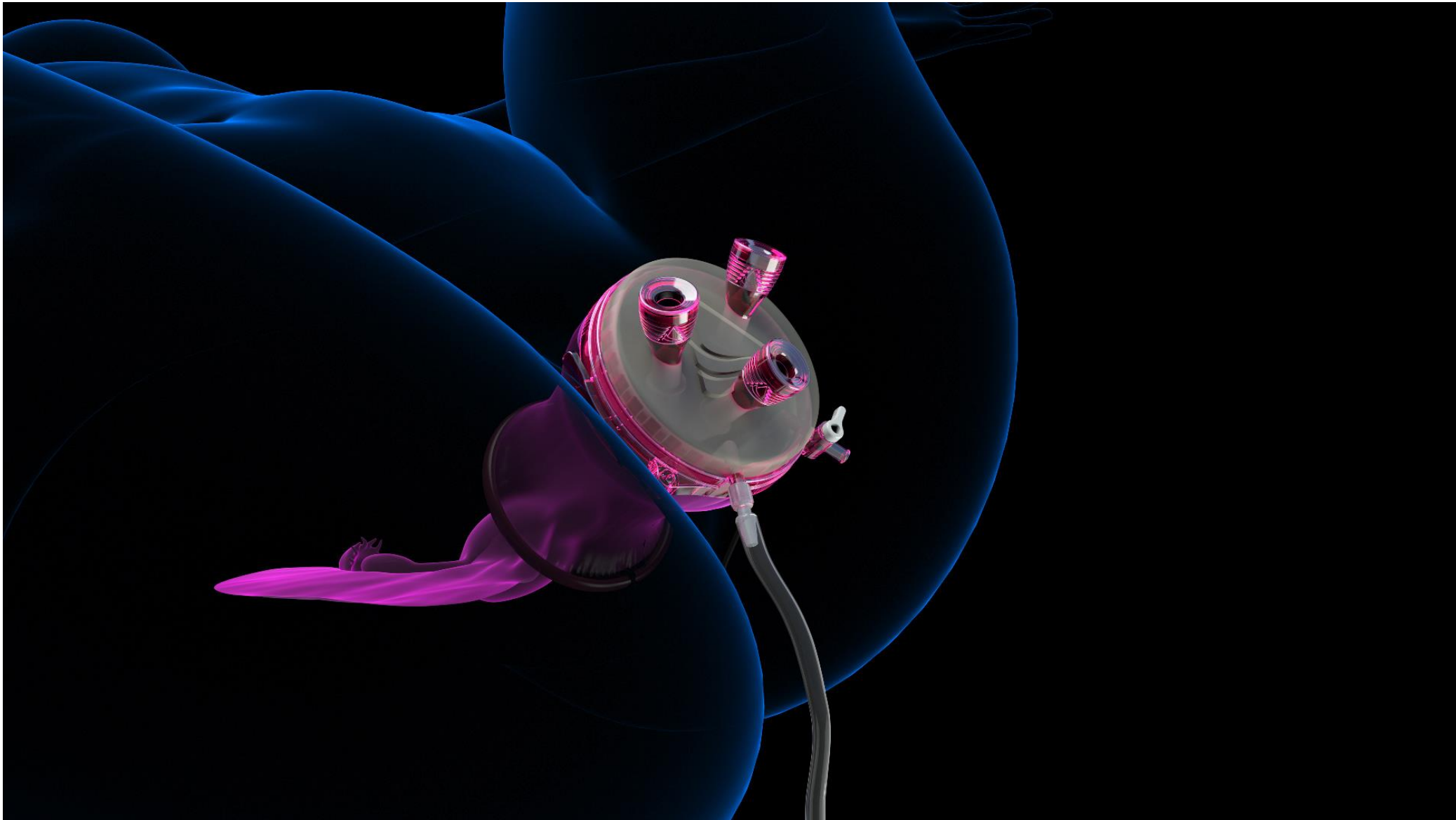


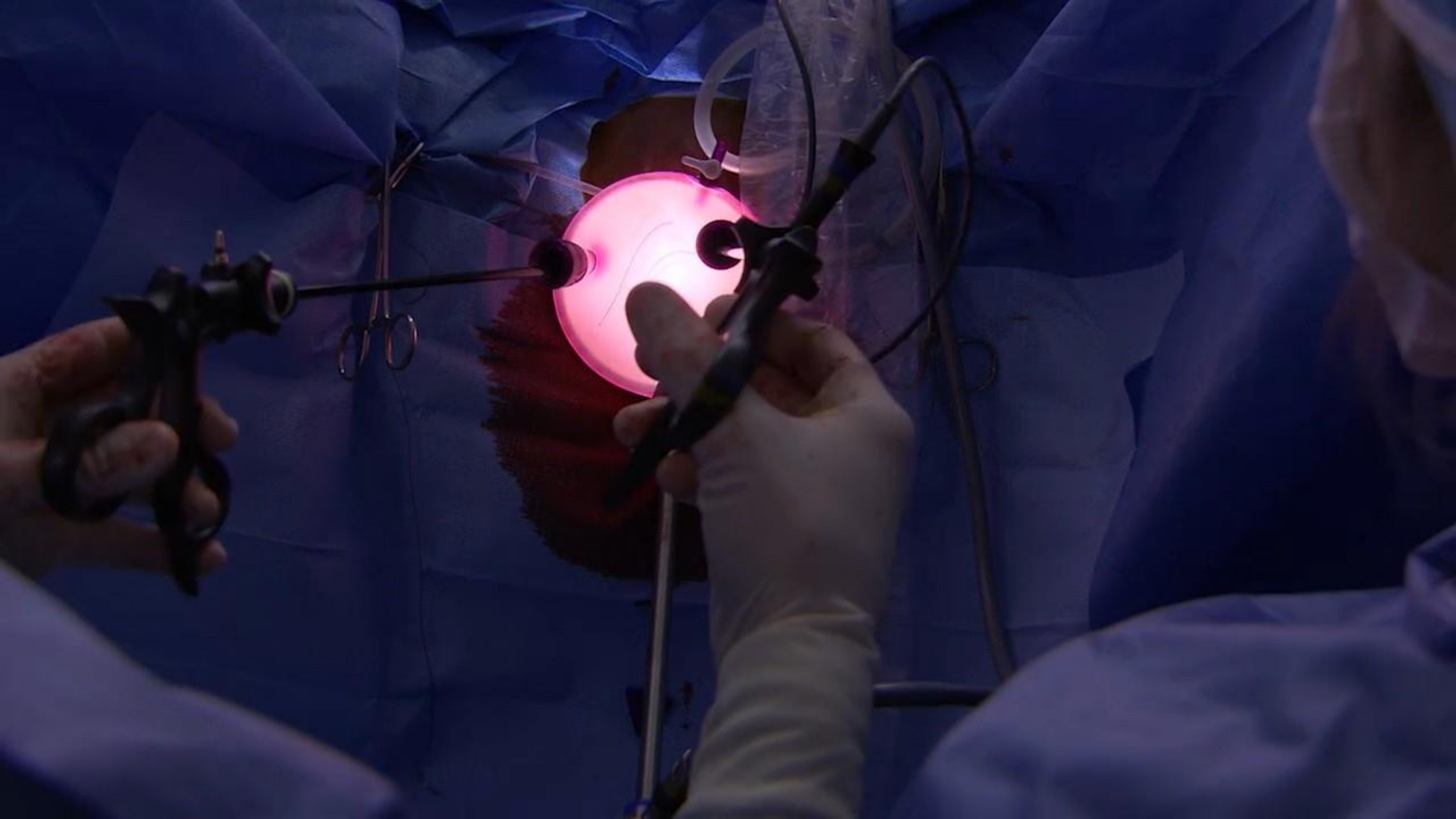
Våga Välja Vaginalt- Vaginalkirurgi 2.0

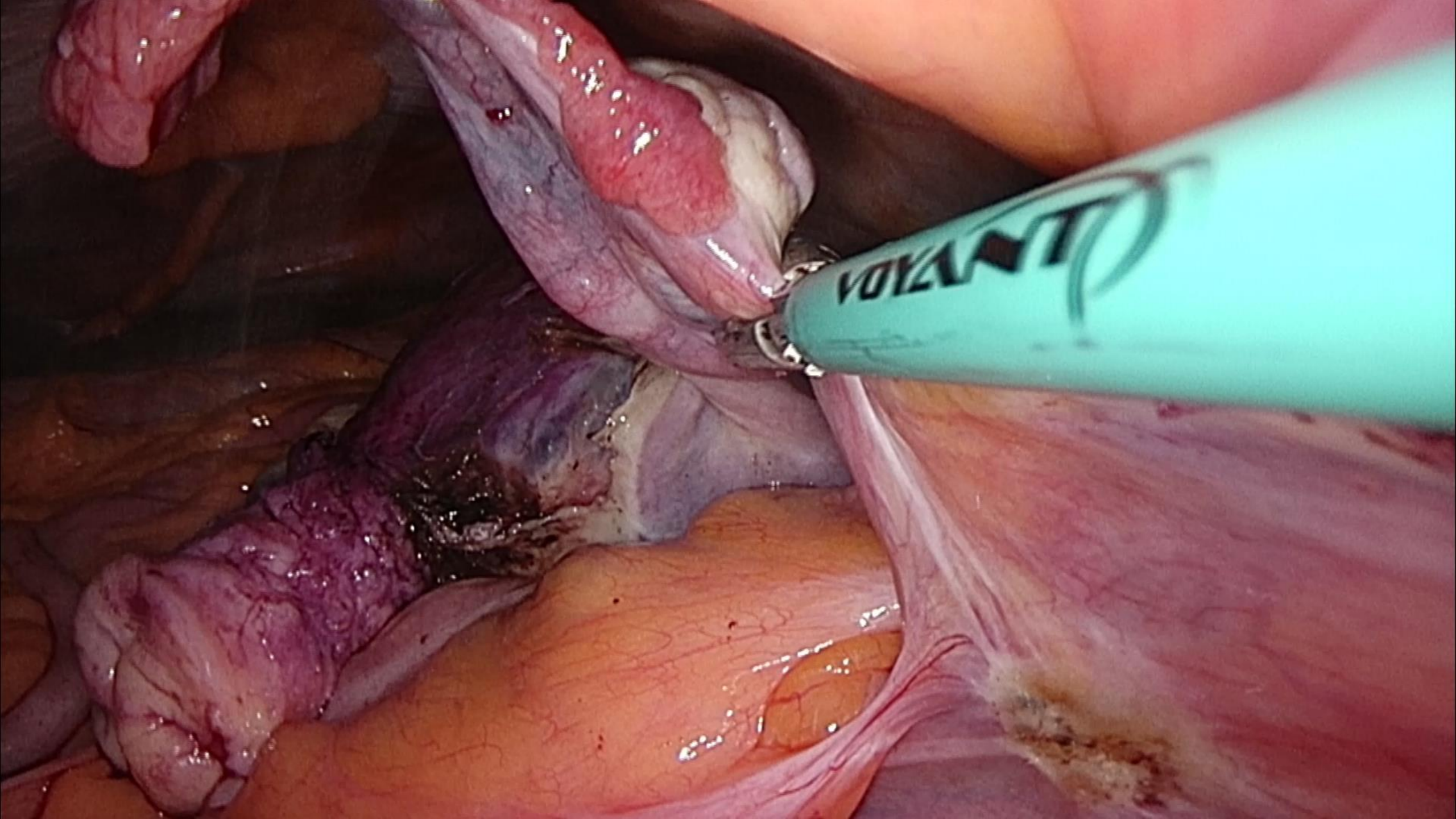
- vNOTES - Vaginal natural orifice transluminal endoscopic surgery
Operationen är en kombination av vaginal och endoskopisk hysterektomi.
- Etablerades ca 2012 av Dr. Jan Baekelandt vid Imelda Sjukhus, Bonheiden, Belgien.

vNOTES

- Fossa Douglassi och fossa vesikouterina öppnas så som vid en vaginal hysterektomi. Den endoskopiska delen sker via en gelplatta som sätts vid introitus.
- Patienten får inga ärr på buken.







Fördelar

- Färre bukväggsbråck
- Färre bukväggsinfektioner
- Inga troakarrelaterade komplikationer
- Snabbare postoperativ återhämtning
- Mindre postoperativ smärta
- Ergonomi
- Fler patienter i dagkirurgi (därmed lägre kostnader)
- Möjlighet att operera adnexa/opportunistisk salpingektomi
- Möjlighet att undvika laparotomi - kan ta uterus upp till 3 kg
- Fördel vid tidigare bukkirurgi

HALON: a randomized controlled trial

Hysterectomy by trans-Abdominal Laparoscopy Or transvaginal NOTES

Objective:

To compare transvaginal Natural Orifice Transluminal Endoscopic Surgery (vNOTES) Hysterectomy and Total Laparoscopic Hysterectomy (TLH) for the successful removal of the uterus for benign gynecological pathology.

Design:

Randomized controlled, single center, blinded, parallel-group, non-inferiority, efficacy study.

ClinicalTrials.gov: NCT02631837

Setting:

Gynecology department of non-university teaching hospital in Belgium.

Population:

All women 18-70 in need of hysterectomy for benign indication for TLH.

Exclusion:

History of rectal surgery
Suspected rectovaginal endometriosis
Suspected malignancy
History of PID
Active lower genital tract infection
Virginity
Pregnancy
Failure to provide consent

Interventions:

Intervention group: 35VNH
Control group: 35 TLH

Blinding: Sham incisions in vNOTES group
Standardized pre-peri-postoperative protocols

Stratification:

uterus <10; 10-16; >16 weeks

Outcome Measures:

Primary Outcome:

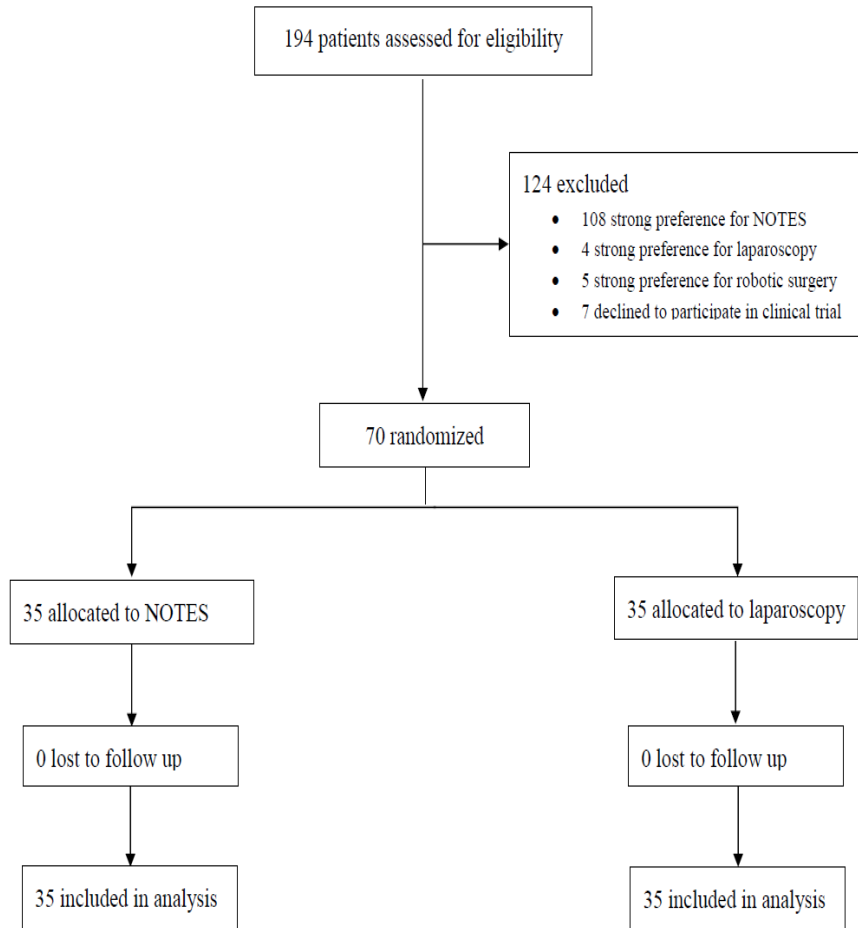
Successful removal of uterus with intended approach without conversion.

Secondary Outcomes:

Proportion of women discharged on same day
Postoperative pain scores and analgesics used
Postoperative infection
Peri- and postoperative complications
Hospital readmission
Duration of procedure
Incidence of dyspareunia
Sexual wellbeing
Cost up to 6 weeks

HALON: a randomized controlled trial

Hysterectomy by trans-Abdominal Laparoscopy Or transvaginal NOTES



HALON: a randomized controlled trial

Table 1. Baseline Characteristics of the Trial Participants.*

	TLH group (N=35)	vNOTES group (N=35)	Non-randomized group (N=124)
Age (y) (mean \pm SD)	49 (8.9)	46 (8.1)	49 (8.5)
Body Mass Index (kg/m ²) (mean \pm SD)	26 (4.5)	27 (6.3)	26 (4.9)
N vaginal births (mean \pm SD)	1.3 (0.9)	1.4 (1.1)	1.5 (1.1)
Prior surgery (n, %)	16 (46 %)	20 (57 %)	50 (40 %)
Prior Caesarean section (n, %)	5 (14 %)	8 (23 %)	12 (10 %)
Uterine weight (g) [†] (mean \pm SD)	177 (150)	206 (178)	206 (338)
Pain vagina (n, %)	6 (17%)	15 (43%)	NA
VAS pain vagina (median \pm IQR)	0 (0 - 0)	0 (0 - 4)	NA
Pain pelvis (n, %)	8 (23%)	12 (34%)	NA
VAS pain pelvis (median \pm IQR)	0 (0 - 0)	0 (0 - 4)	NA
Quality of life (mean \pm SD)	77 (18)	75 (18)	NA

HALON: a randomized controlled trial

Table 2. HALON Trial Secondary Outcomes.

	Laparoscopy (N=35)	vNOTES (N=35)	Effect size (95%CI)	P (<0.05)
Duration of surgery (minutes) (mean ±SD)	75 (27)	41 (22)	MD -34 (- 46 to - 22)	<0.001
Discharge day 0 (n, %)	15 (43%)	27 (77%)	RD + 0.34 (+ 0.13 to + 0.56)	=0.007
Length of hospital stay (days) (mean ±SD)	1.3 (1.2)	0.8 (0.77)	MD - 0.50 (- 0.98 to - 0.02)	=0.004
Total use analgesics (units) (mean ±SD)	14 (11)	8 (6.5)	MD -5.9 (- 10 to - 1.8)	=0.006
Complications:				
- Intra-operative (n, %)	0 (0 %)	1 (3 %)	RD + 0.03 (- 0.05 to + 0.10)	NSD
- Postoperative (n, %)	13 (37 %)	3 (9 %)	RD - 0.29 (- 0.47 to - 0.10)	=0.009
Postoperative infection (n, %)	2 (6 %)	1 (3 %)	RD - 0.03 (- 0.12 to + 0.07)	NSD
Readmission < 6 weeks (n, %)	6 (17 %)	1 (3 %)	RD - 0.14 (- 0.28 to 0.0)	NSD
Total hospital bill (USD) (mean ±SD)	4,103 (1,348)	3,599 (914)	MD -504 (-1,044 to + 36)	NSD

Primary Outcome:
 No Conversions
 vNOTES equally successful as TLH

HALON: a randomized controlled trial

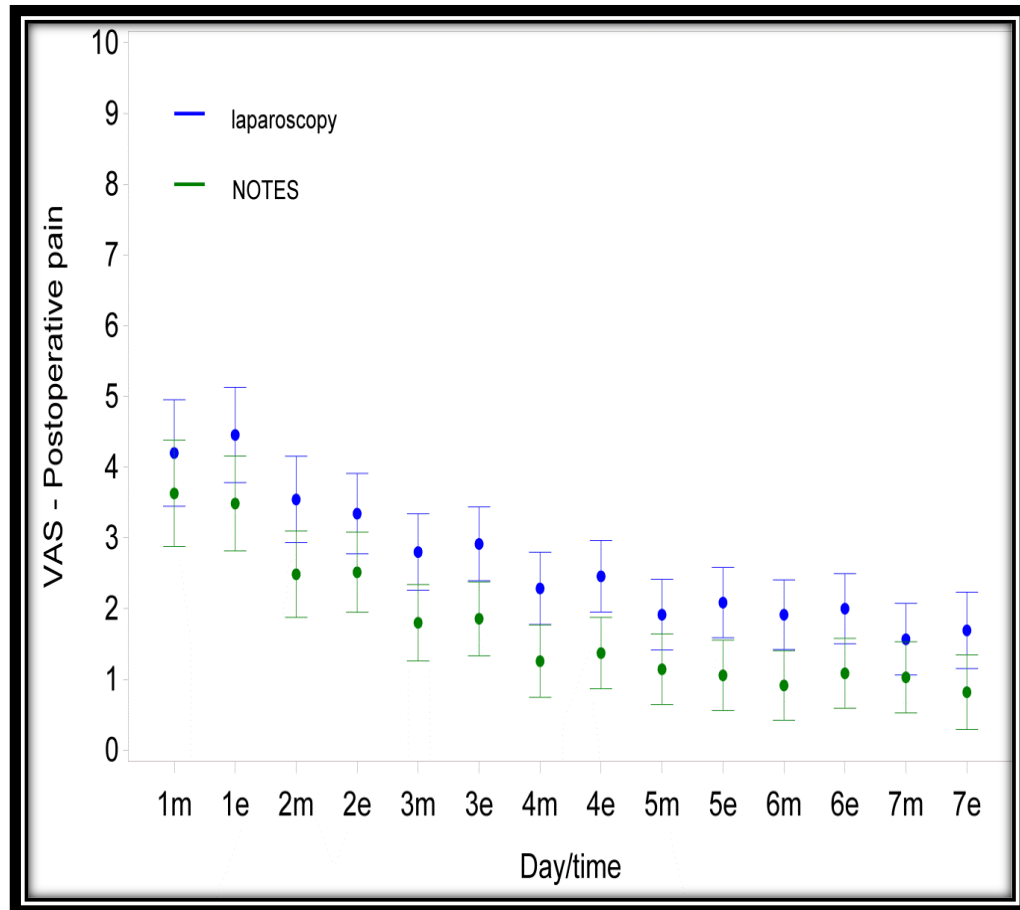
Table 3. HALON Trial Patient Reported Outcomes.*

	Laparoscopy (N=35)	vNOTES (N=35)	Effect size (95%CI)
Pain vagina at 3 months (n, %)	9 (26%)	8 (23%)	RD -0.03 (- 0.23 to + 0.17)
VAS pain vagina at 3 months (median ±IQR)	0 (0-1)	0 (0-1)	MD + 0.30 (- 0.88 to + 1.5)
Pain vagina at 6 months (n, %)	8 (23%)	5 (14%)	RD - 0.09 (- 0.27 to + 0.10)
VAS pain vagina at 6 months (median ±IQR)	0 (0-1)	0 (0-0)	MD - 0.10 (- 0.97 to + 0.77)
Pain pelvis at 3 months (n, %)	8 (23%)	6 (17%)	RD - 0.06 (- 0.24 to + 0.13)
VAS pain pelvis at 3 months (median ±IQR)	0 (0-0)	0 (0-0)	MD 0.0 (- 0.94 to + 0.94)
Pain pelvis at 6 months (n, %)	5 (14%)	4 (11%)	RD - 0.03 (- 0.19 to + 0.13)
VAS pain pelvis at 6 months (median ±IQR)	0 (0-0)	0 (0-0)	MD - 0.10 (- 0.88 to + 0.68)
Quality of life at 3 months (mean ±SD)	80 (18)	84 (14)	MD + 4.0 (- 3.5 to 12)
Quality of life at 6 months (mean ±SD)	87 (9)	88 (11)	MD + 1.0 (- 3.7 to + 5.7)

* There were **no significant differences** ($P < 0.05$) between the two groups in any of the analyses of Table 3.

HALON: a randomized controlled trial

Hysterectomy by trans-Abdominal Laparoscopy Or transvaginal NOTES



1-7 = days after surgery
Analogue Scale

m=morning

e=evening

VAS=Visual

Tid att uppnå VAS 0

- 80% i vNOTES-gruppen hade uppnått VAS 0 morgonen efter operation.
- I TLH-gruppen tog det 7 dagar innan 80% av patienterna hade uppnått VAS 0

HALON: a randomized controlled trial

Hysterectomy by trans-**A**bdominal **L**aparoscopy **O**r transvaginal
NOTES

Conclusions:

vNOTES and TLH are equally efficacious for benign hysterectomy

vNOTES **decreases operating time**
decreases hospitalization
allows more women to leave the
hospital on the day of surgery
reduces postoperative complications
reduces pain

no increased cost

Våra erfarenheter i Helsingborg

- Sista halvåret har vi gjort 50 vNOTES-ingrepp
- 40 hysterektomier och 10 adnex (SOEB, SOE, salpingektomi)
- ” Standardpatienten” = Operationstid för vNOTES hyst + SOEB + McCall ca 50 minuter för standardingrepp. Gjort uterus med vikt över 1 kg.

2 st Clavien-Dindo 3 komplikationer:

- Dränering av vaginaltoppshematom
- En pat som blödde kraftigt vaginalt 3 veckor postoperativt och laparoskopierades. McCall-suturen hade släppt vid toalettbesök.

Vill du lära dig mer om vNOTES?

Bra app med steg-för-steg-instruktioner + video

Google play: sök på OR APP

Apple: OR APP VNOTES



www.notesurgery.org

Mer information om Vnotes

- www.notesurgery.org

Kurser i vNOTES-kirurgi

- Applied Medical ordnar kurser
- Kurserna hålls av Dr. Jan Baekelandt i Bonheiden, Belgien. Antingen på plats eller i hemlandet. Då sänds live-kirurgin digitalt och de praktiska delarna (2 hysterektomier + adnexkirurgi i vNOTES-simulator) sker på plats i hemlandet.
- Intresserad av kurs?
- Kontakt Tom Bergman: tbergman@appliedmedical.com
- 0721- 660900