

Urogynecology Treatment for “Unspoken” Pelvic Floor Disorders – Incontinence & Prolapse

Patrick Culligan, MD

Bilal Chughtai, MD

Tanaka Dune, MD

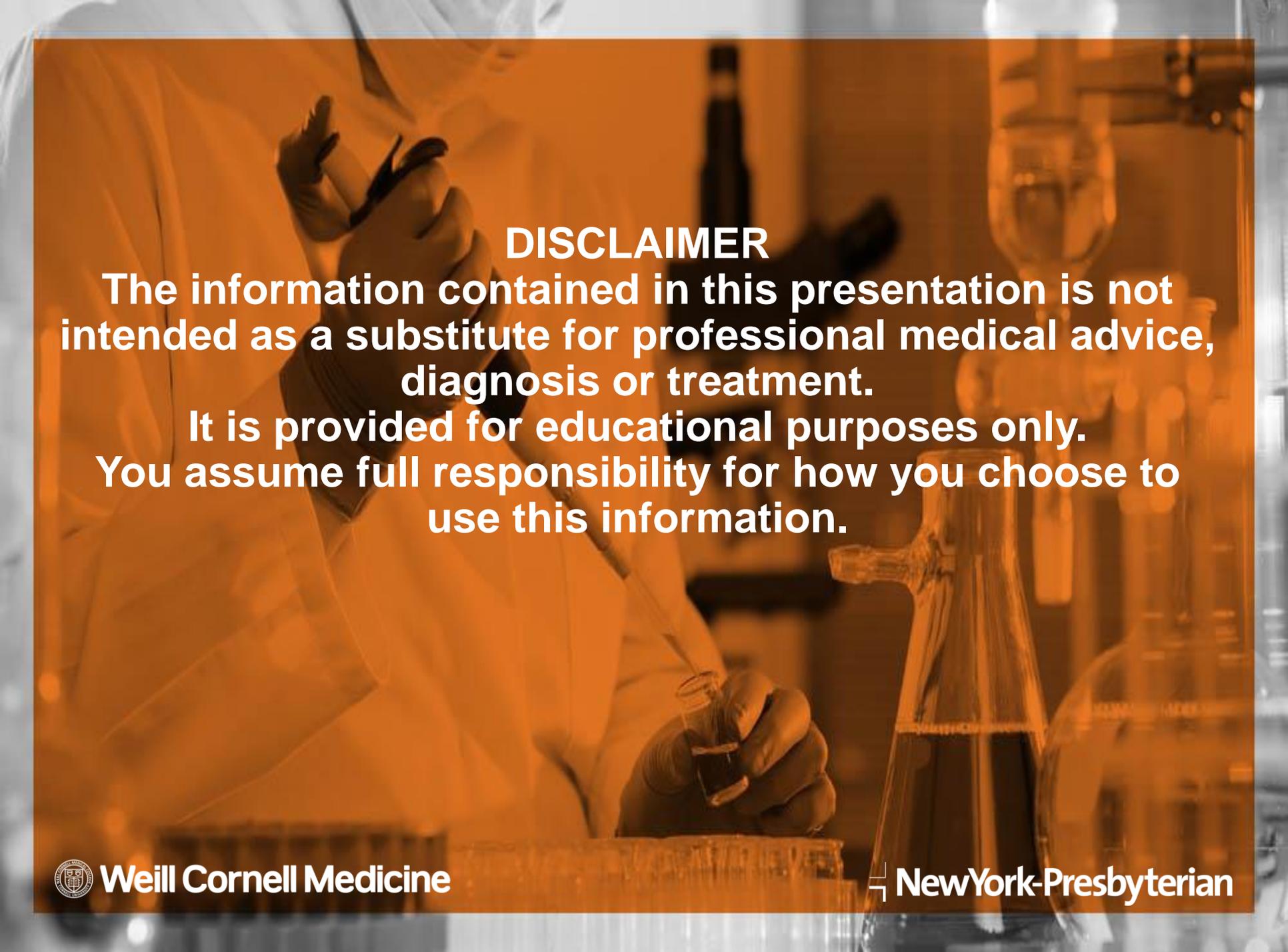
Department of Urology
Weill Cornell Medical College
New York-Presbyterian Hospital
New York, NY



Weill Cornell Medicine



New York-Presbyterian



DISCLAIMER

The information contained in this presentation is not intended as a substitute for professional medical advice, diagnosis or treatment.

**It is provided for educational purposes only.
You assume full responsibility for how you choose to use this information.**



Pelvic Organ Prolapse

Patrick Culligan, M.D., FACOG, FACS

Director of Urogynecology & The Center for Female Pelvic Health

Professor of Ob-Gyn & Urology
Department of Urology
Weill Cornell Medical College
New York-Presbyterian Hospital
New York, NY



Weill Cornell Medicine

New York-Presbyterian

What is Urogynecology?

Urology

Gynecology

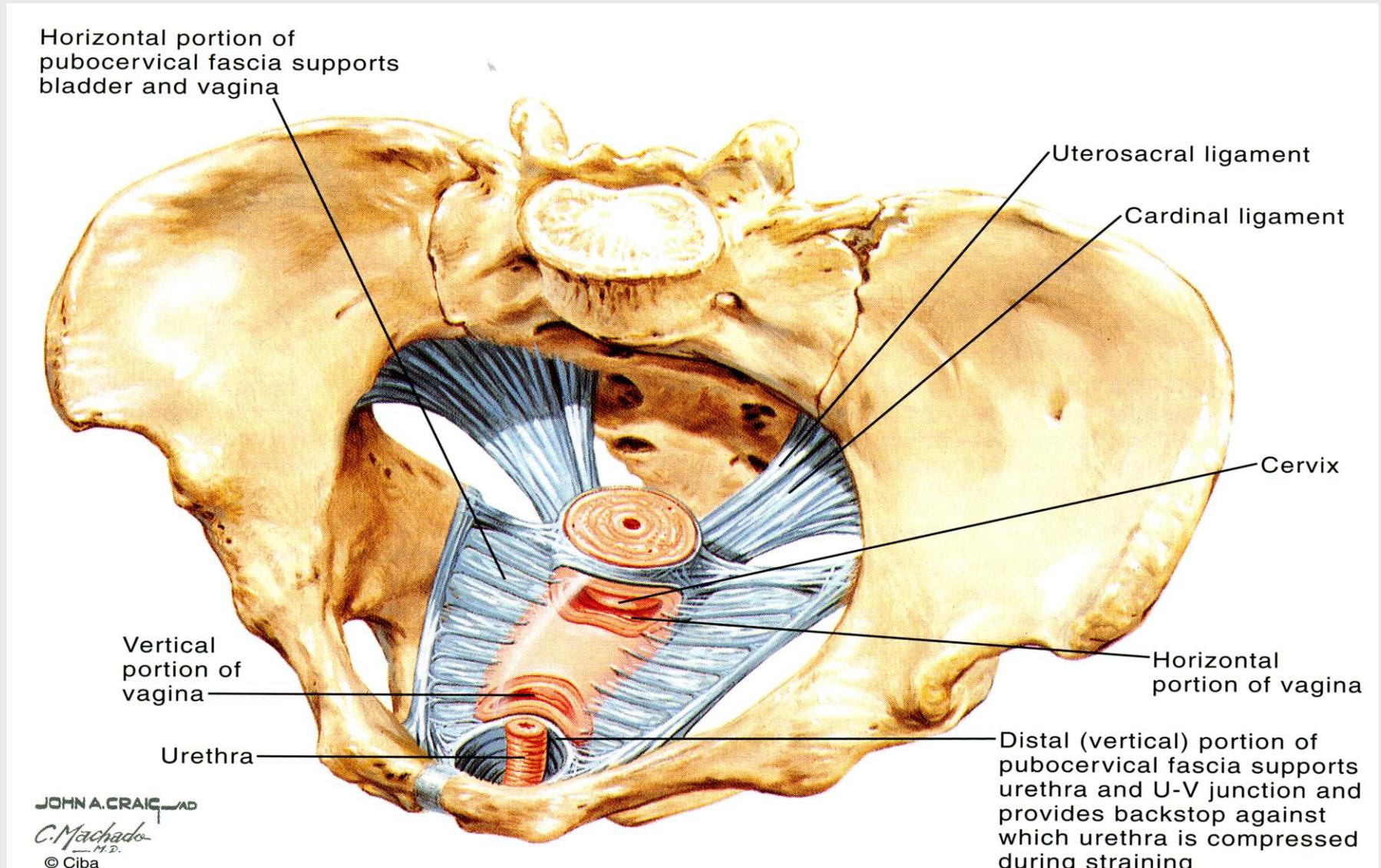
Urogynecology

Comprehensive evaluation and treatment for female pelvic floor disorders

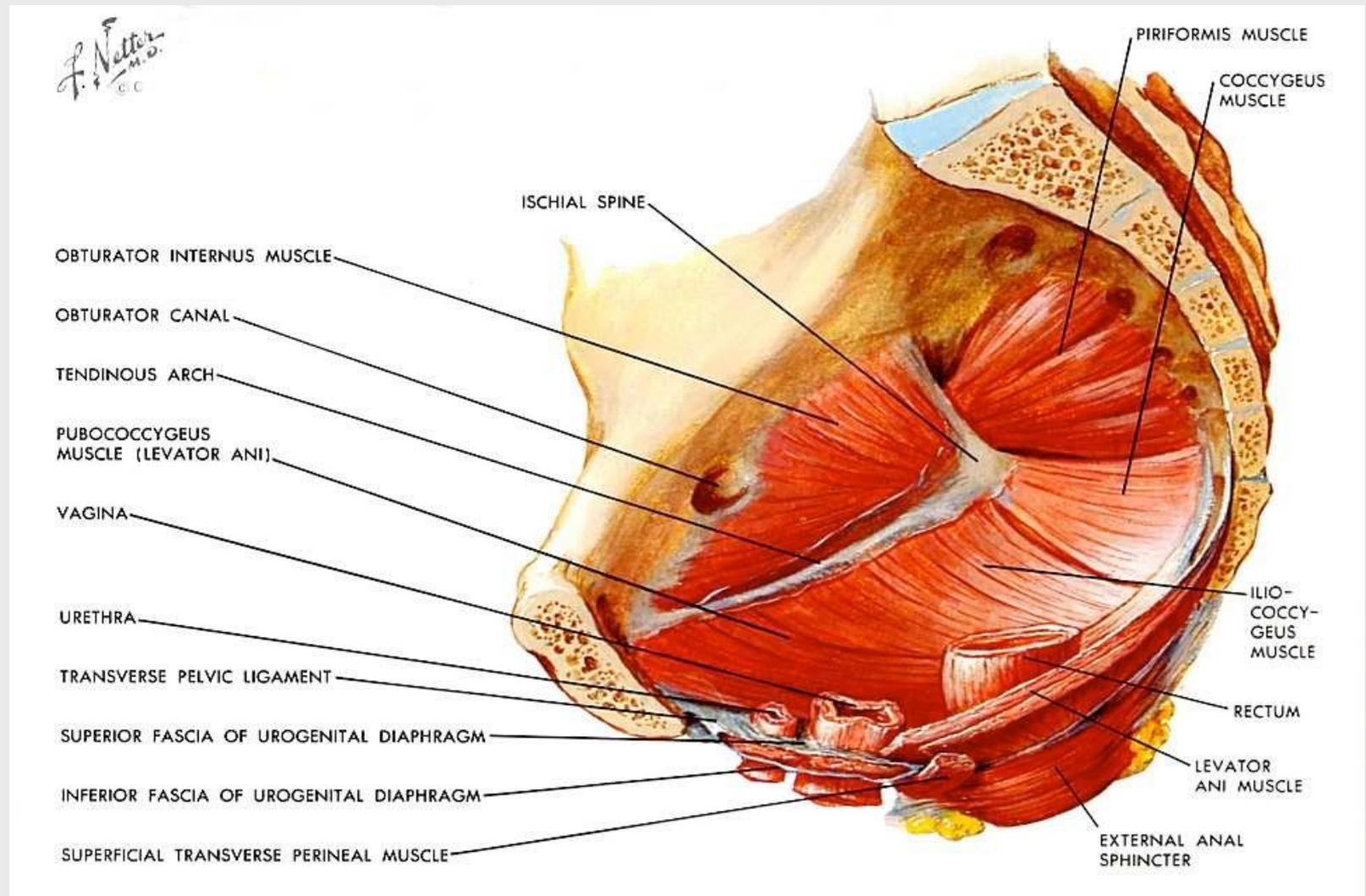
- Pelvic organ prolapse
- Urinary Incontinence, Frequency, Urgency etc...
 - Interstitial Cystitis
 - Fecal Incontinence
 - Constipation
- Defecation Disorders

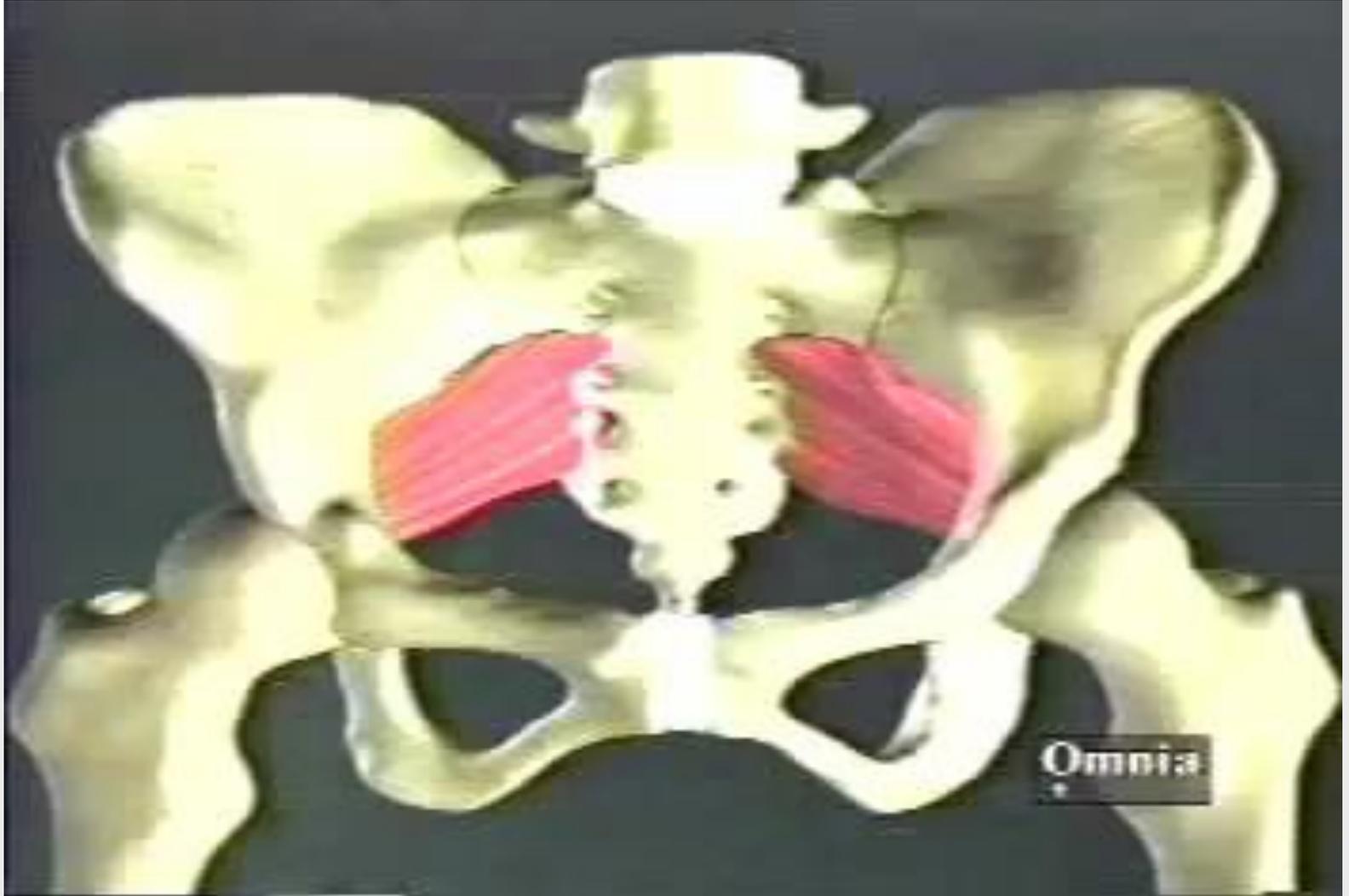


Normal Pelvic Support



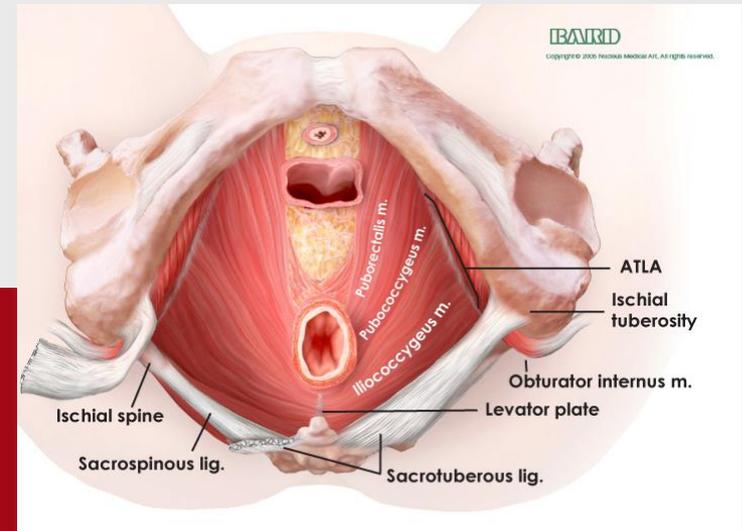
Pelvic Floor Muscles



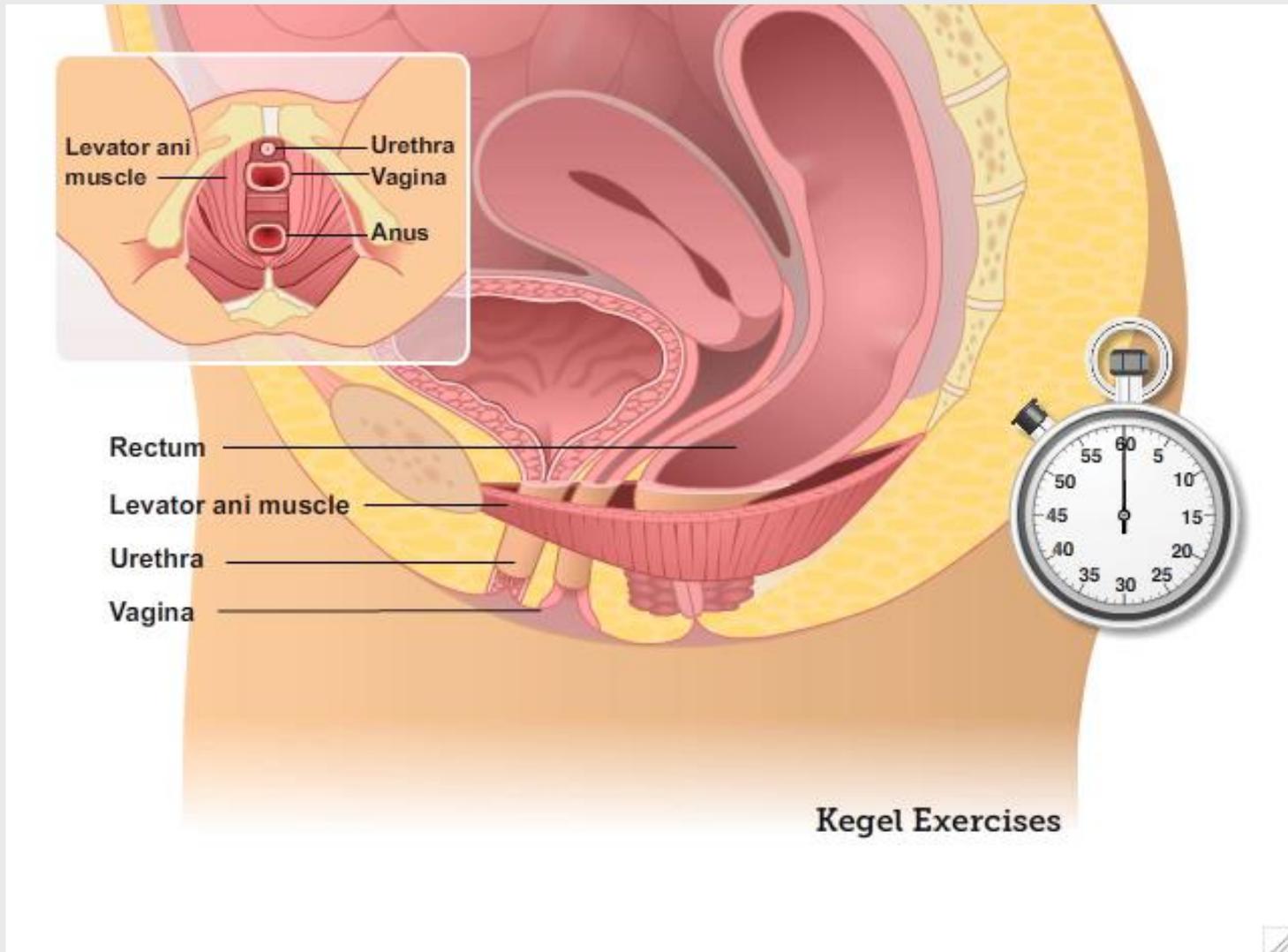


Rating Scale for Kegel Muscle Strength

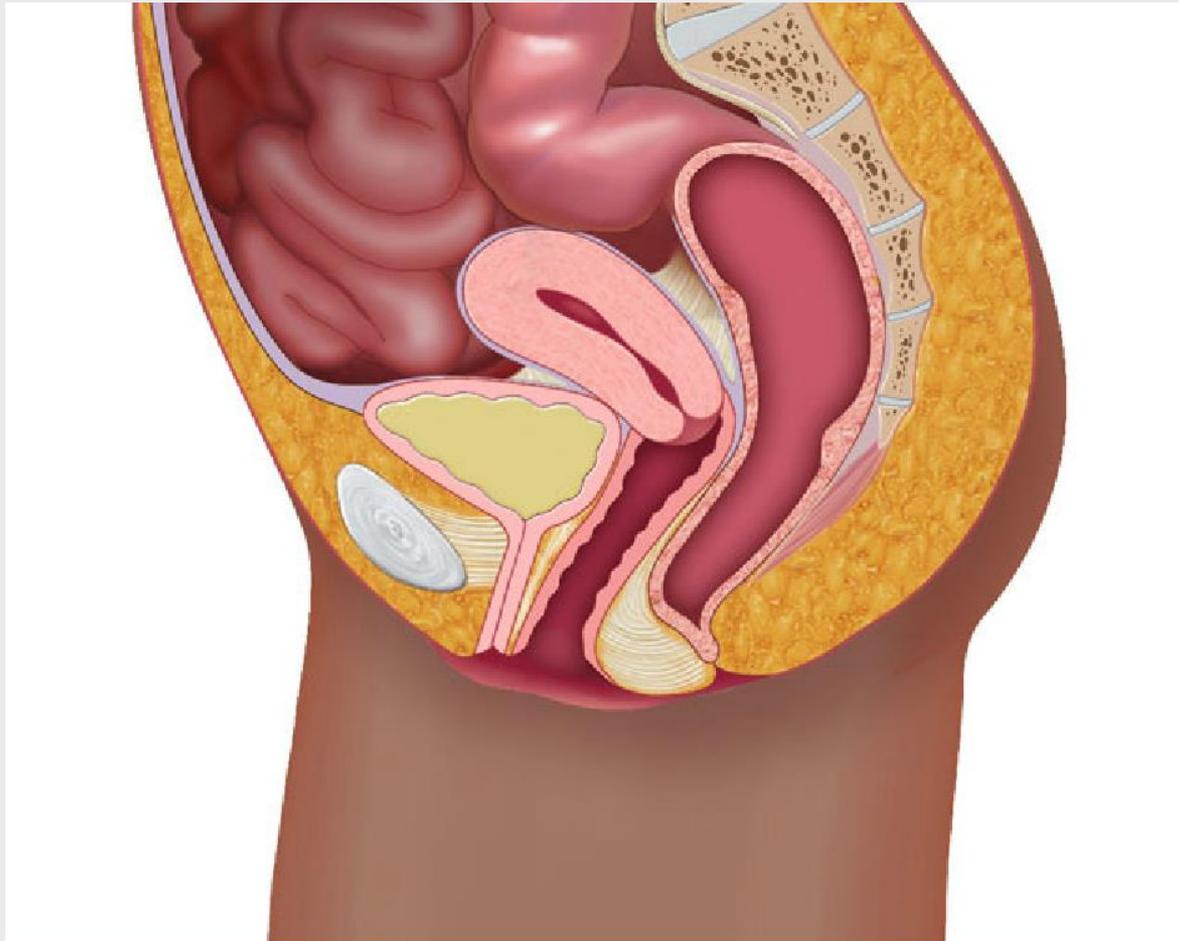
- 0 = No Contraction
- 1 = Flicker
- 2 = Weak squeeze with 2-second hold (no obvious lift)
- 3 = Fair squeeze with definite lift
- 4 = Good squeeze and hold
- 5 = Strong squeeze and hold -
 - good lift easily held for 5 - 10 seconds



Pelvic floor muscle exercise (Kegels)

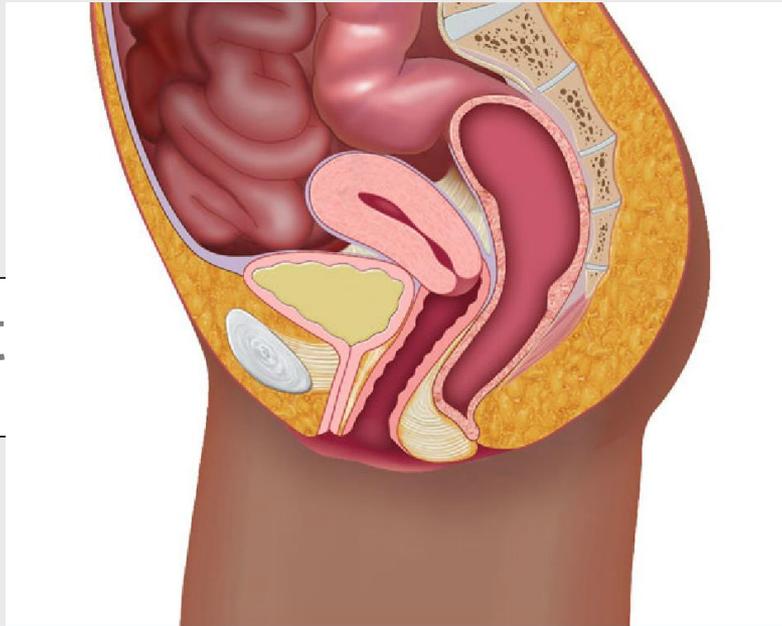


Normal Support

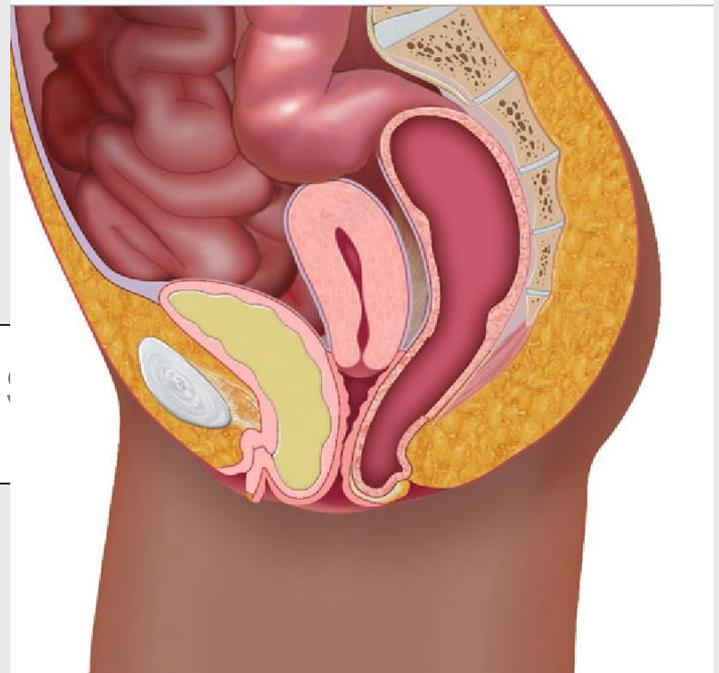


Important rule before treating prolapse.....

• If it

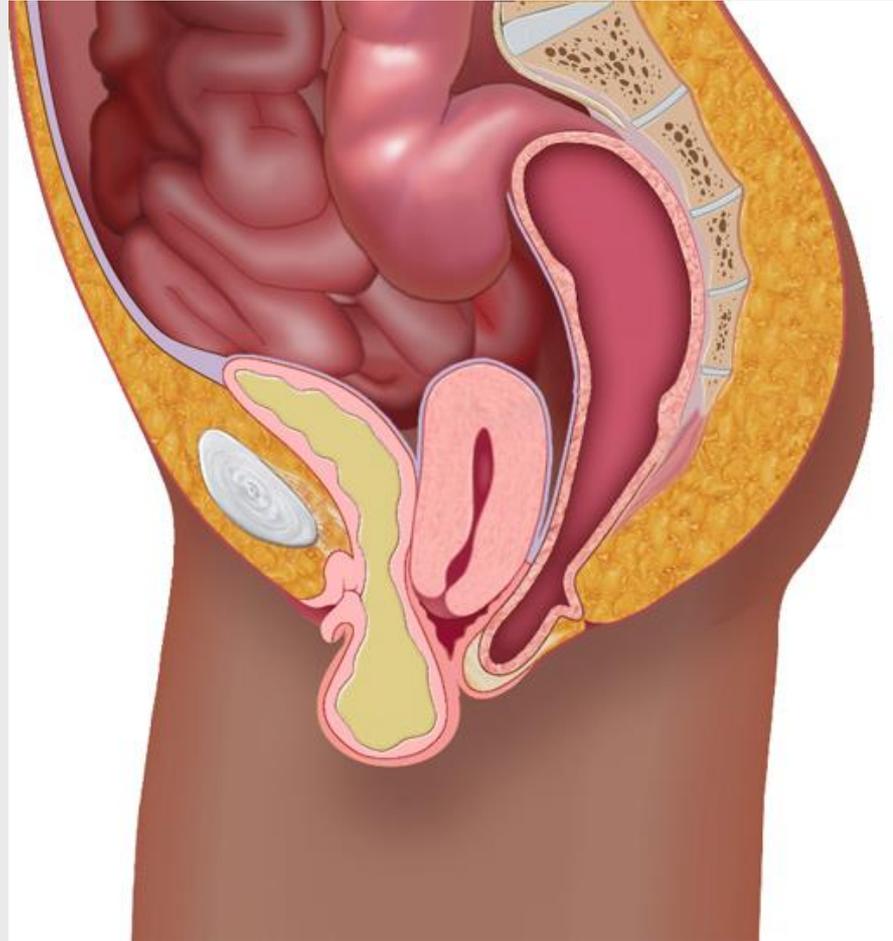


you s

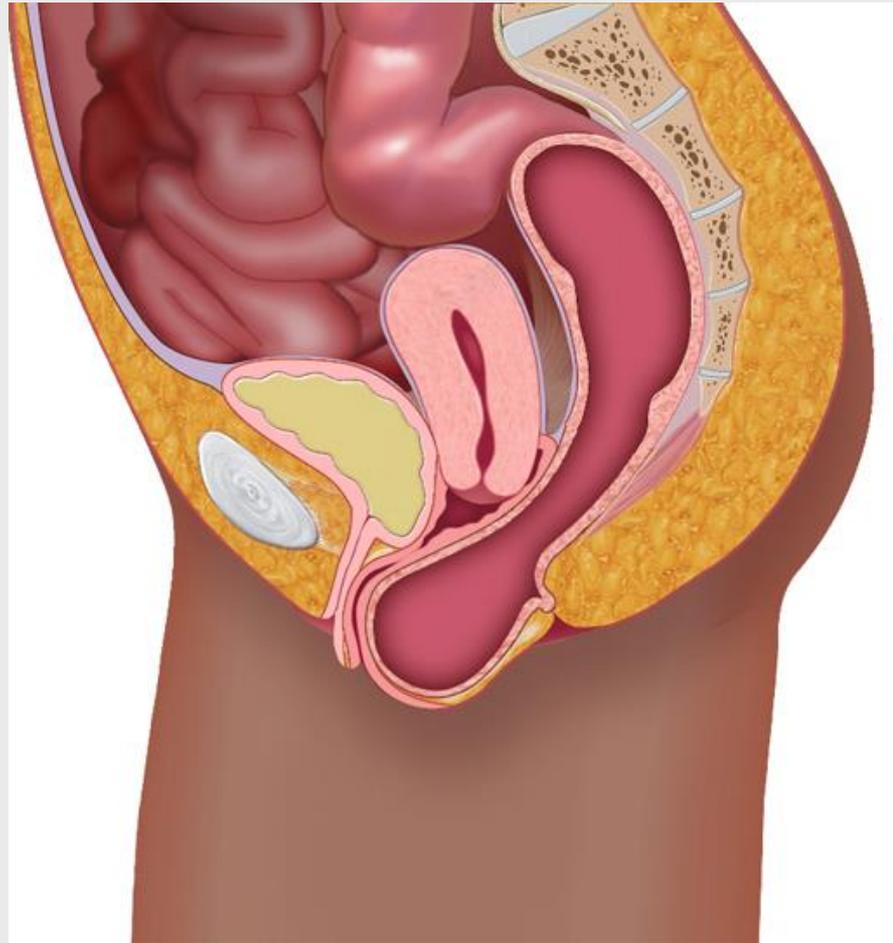


Don't fix it just because it's there

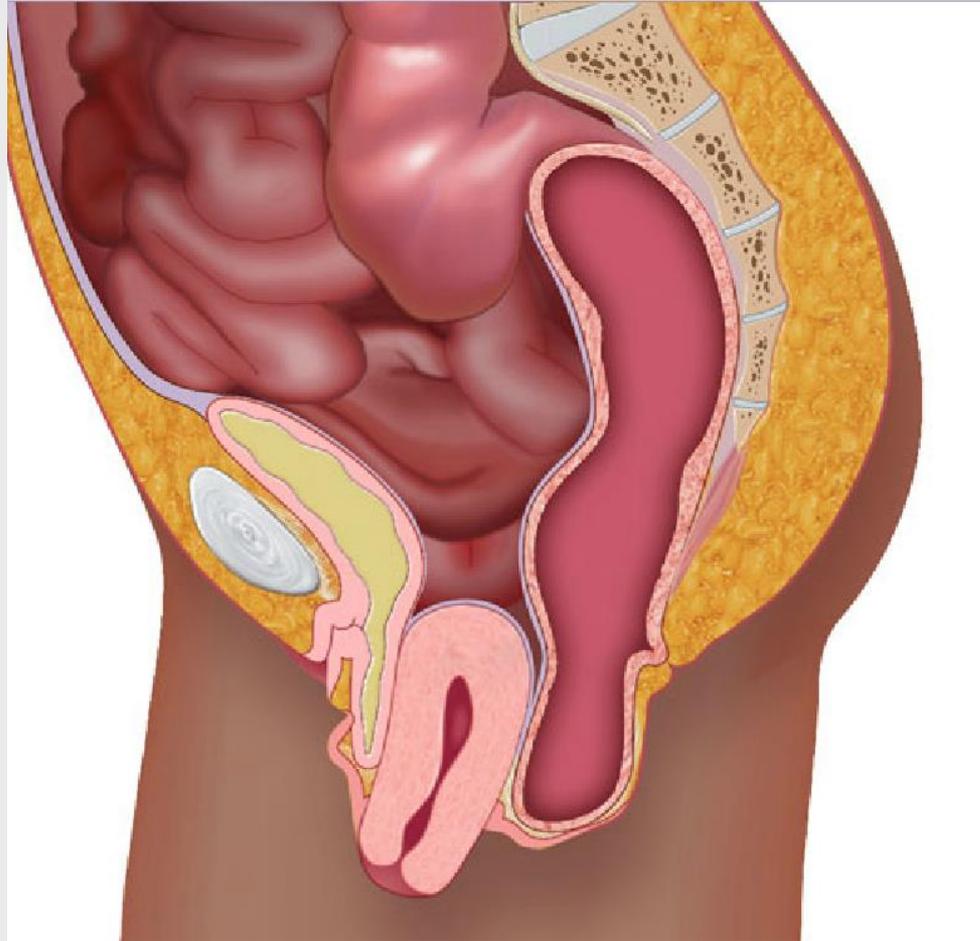
Cystocele



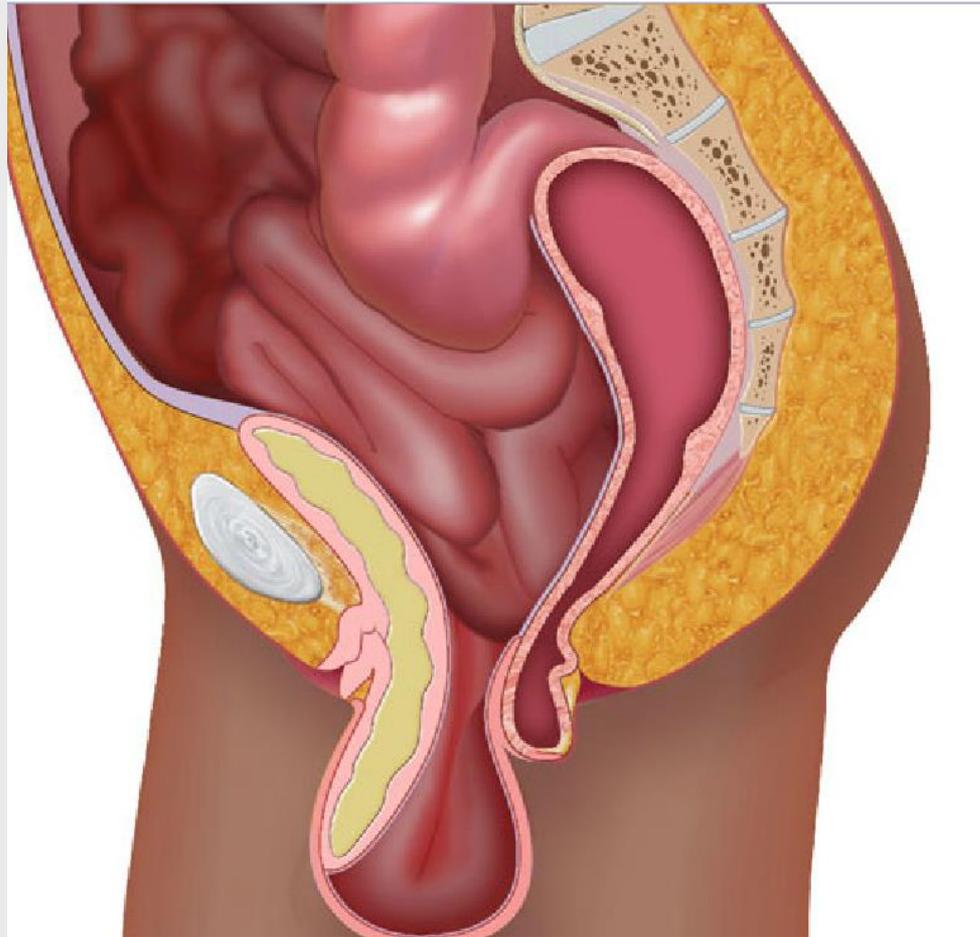
Rectocele



Uterine Prolapse



Enterocele



Symptoms of Prolapse

- Inability to retain a tampon
- Pressure / Bulging sensation (usually described as “heavy”)
- Need to “splint” vagina with fingers to urinate or defecate

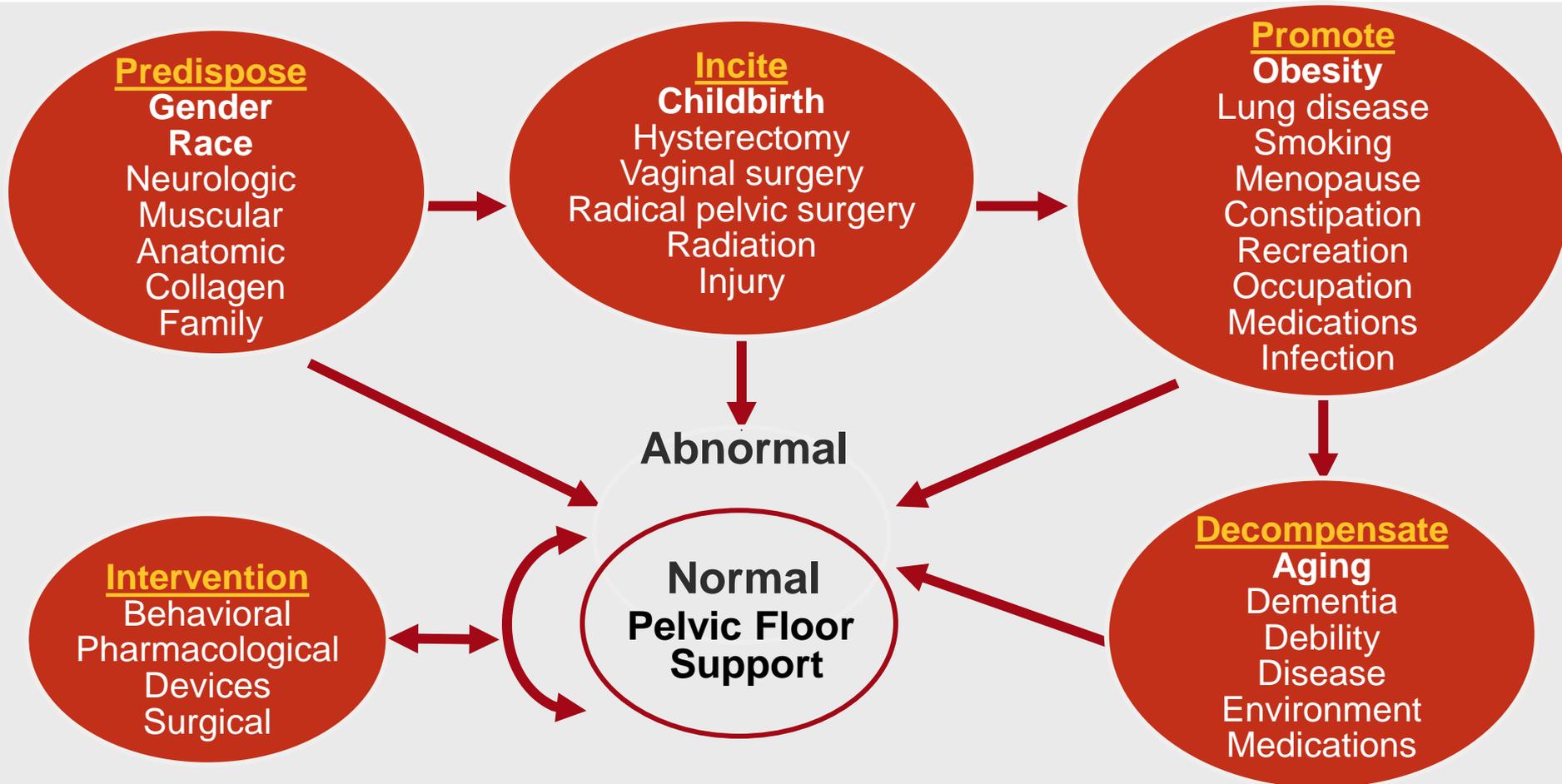
Pressure type

- “Pain”



- Dyspareunia
- Back Pain
- Fecal Urgency

Risk Factors for Pelvic Organ Prolapse



Bump RC, Norton PA. *Obstet Gynecol Clin North Am.* 1998;25(4):723-746.

Epidemiology Challenges

- The aging population make the incidence and prevalence of pelvic floor disorders a moving target.
- By 2050, 33% of the U.S. population will be post-menopausal women (currently 23%)
 - *U.S. Census Data (www.census.gov)*



Pelvic Organ Prolapse: Non-Surgical Management



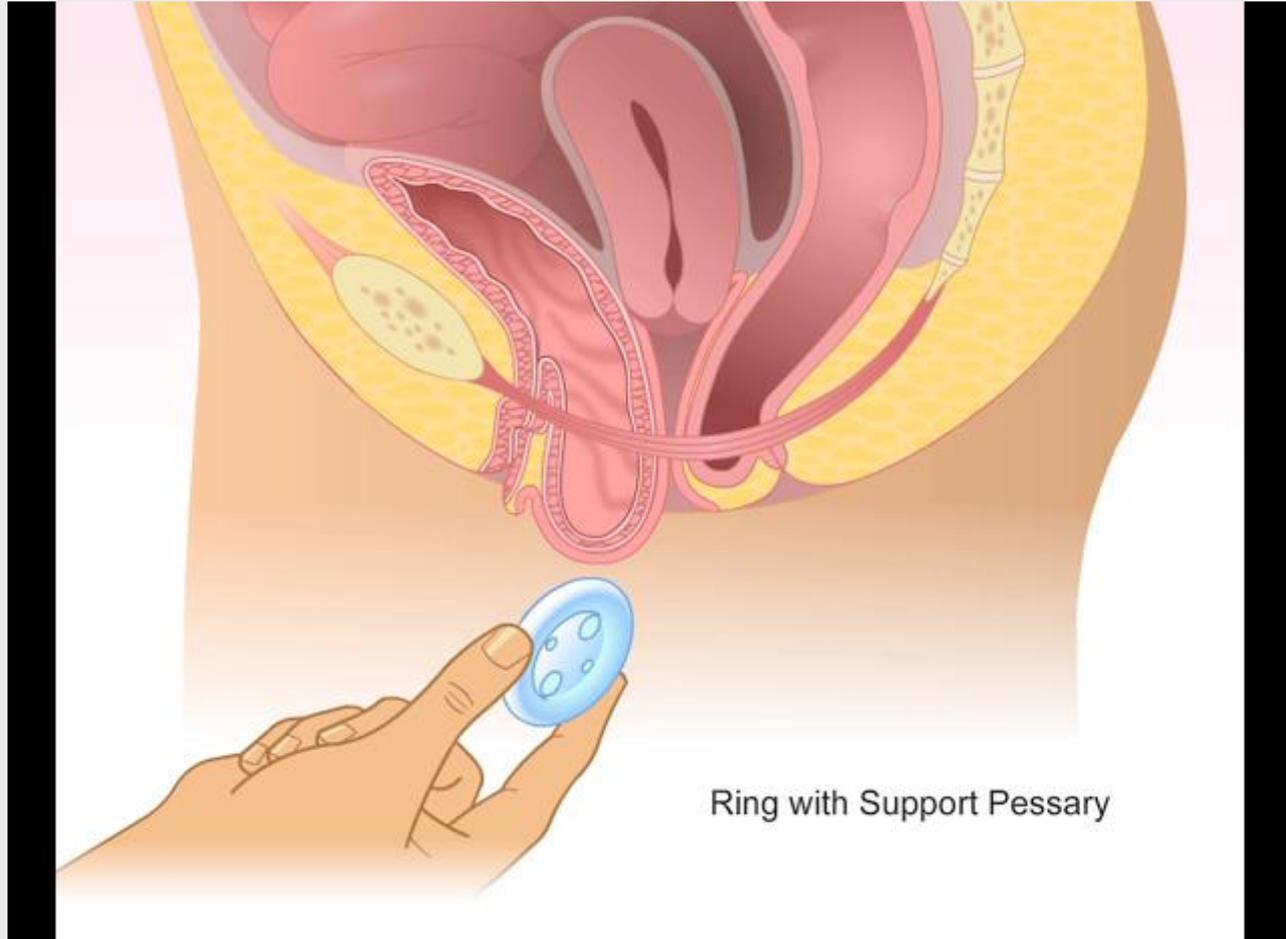
Weill Cornell Medicine



New York-Presbyterian

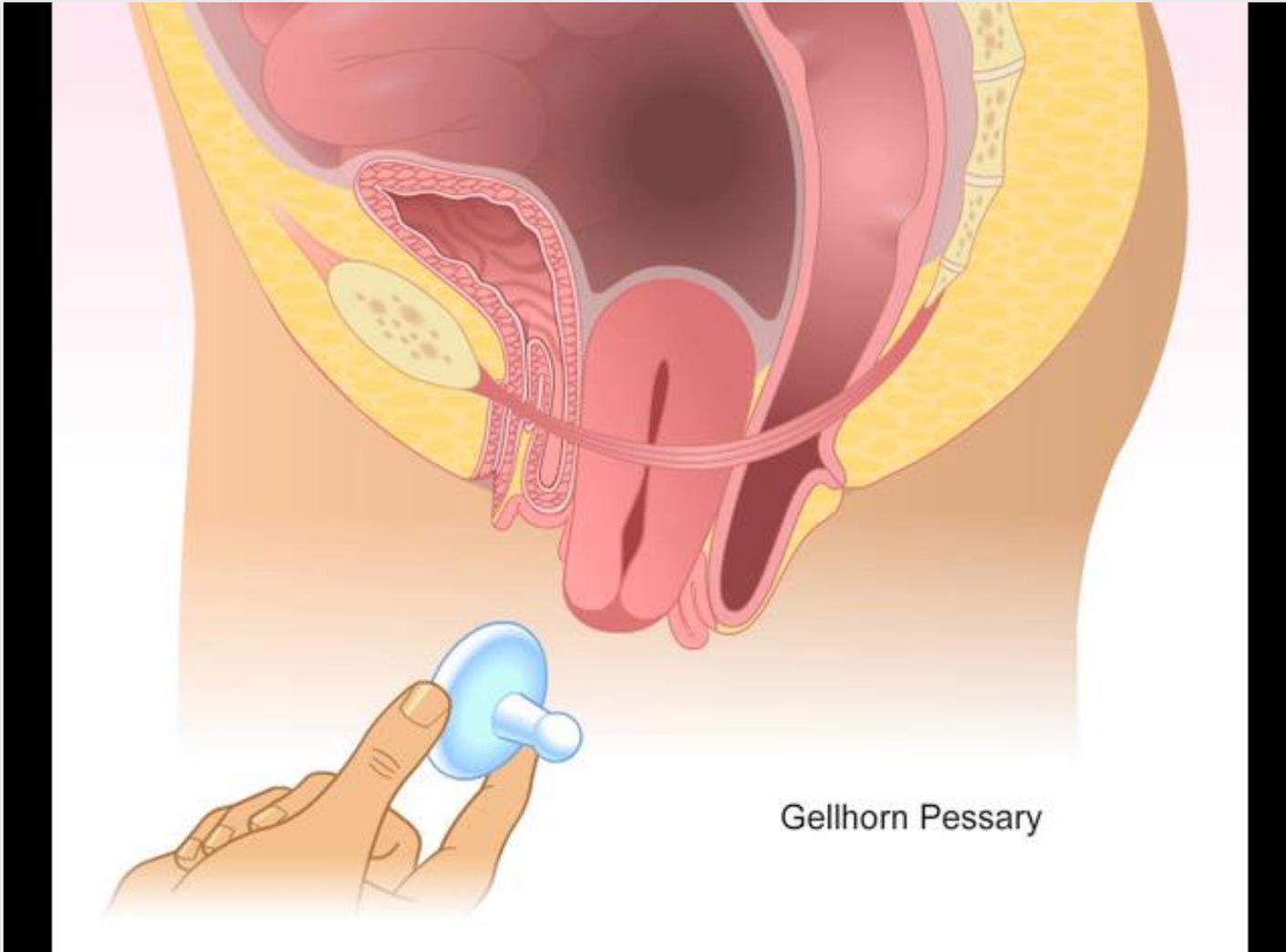
NON-SURGICAL MANAGEMENT

Pessary



NON-SURGICAL MANAGEMENT

Pessary





Pelvic Organ Prolapse Surgical Management

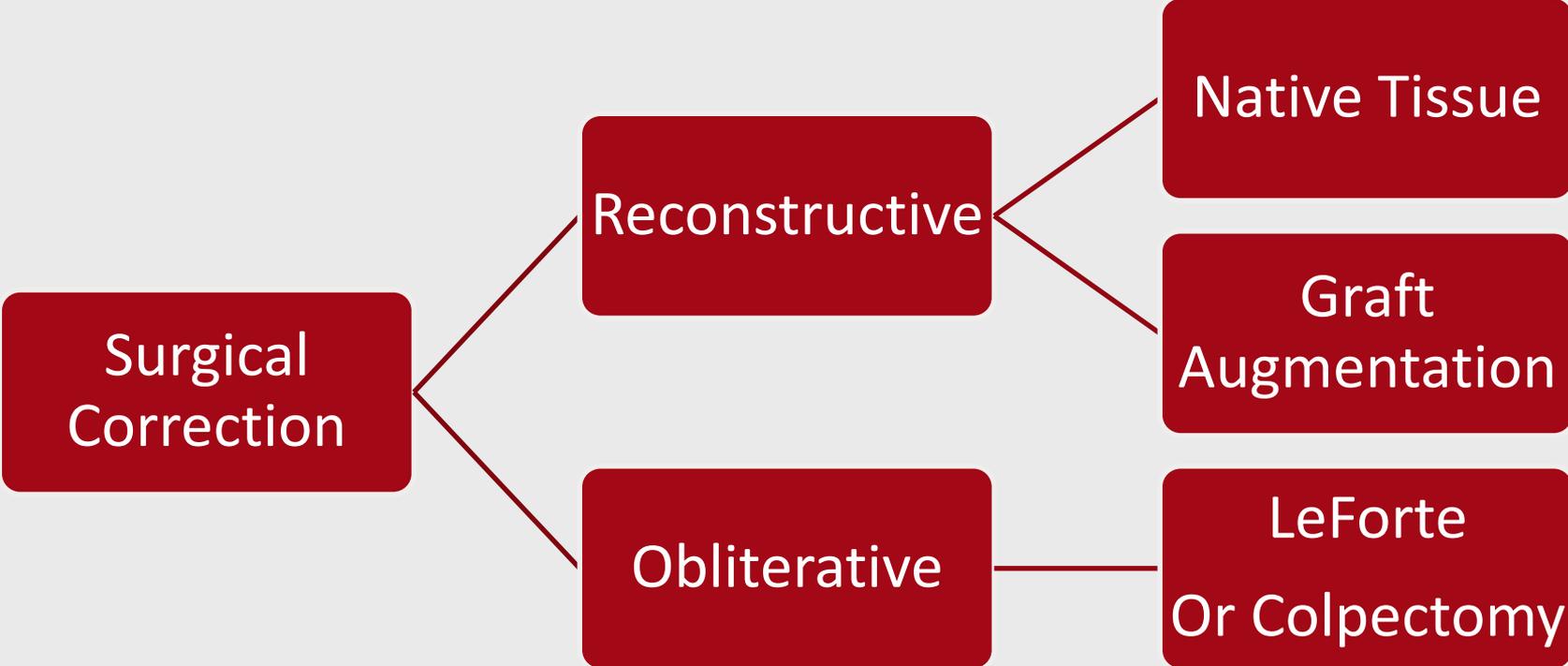


Weill Cornell Medicine

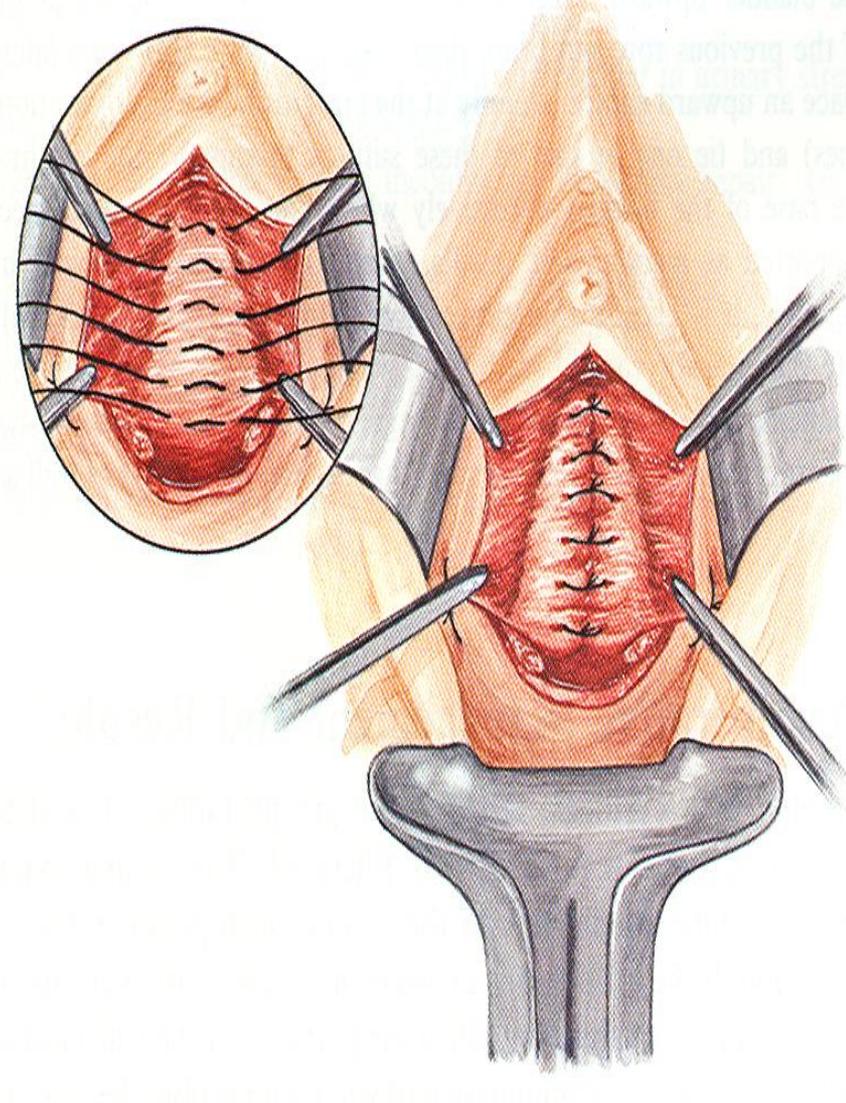
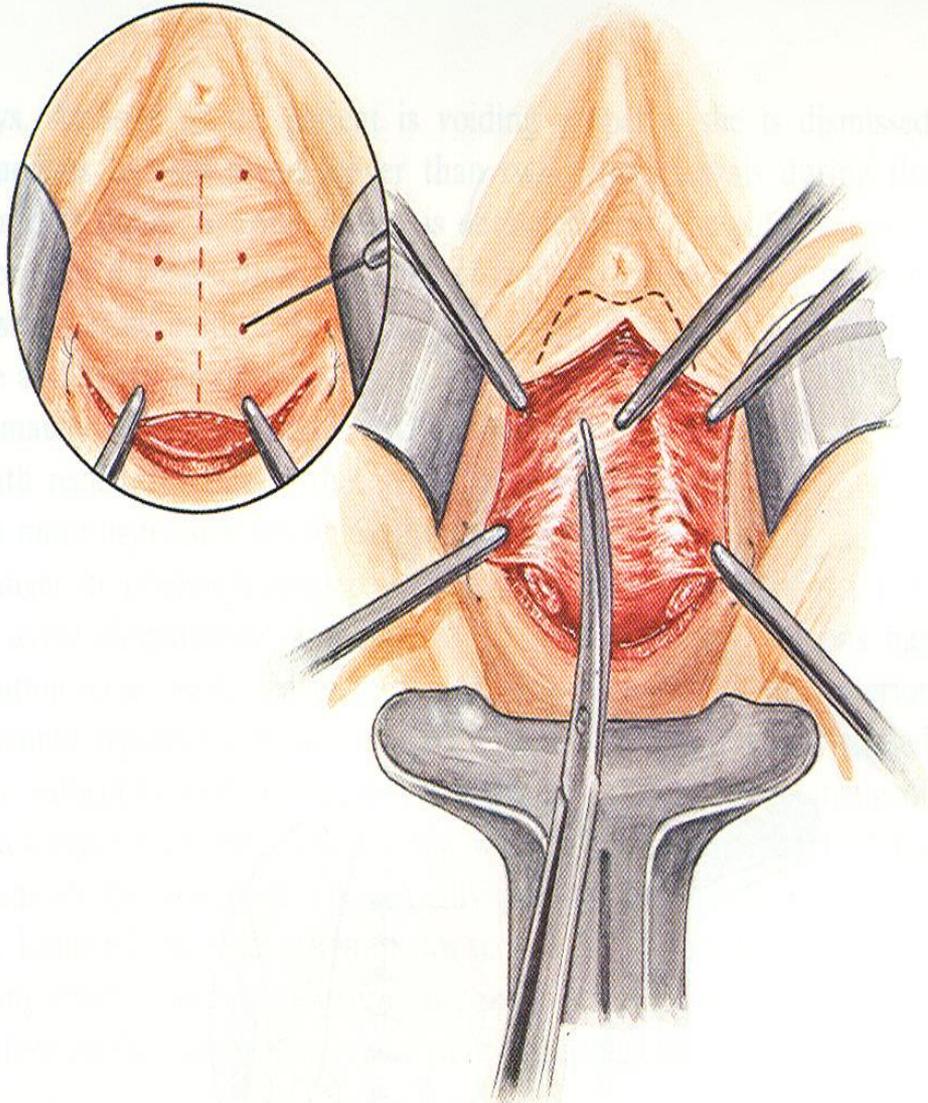


New York-Presbyterian

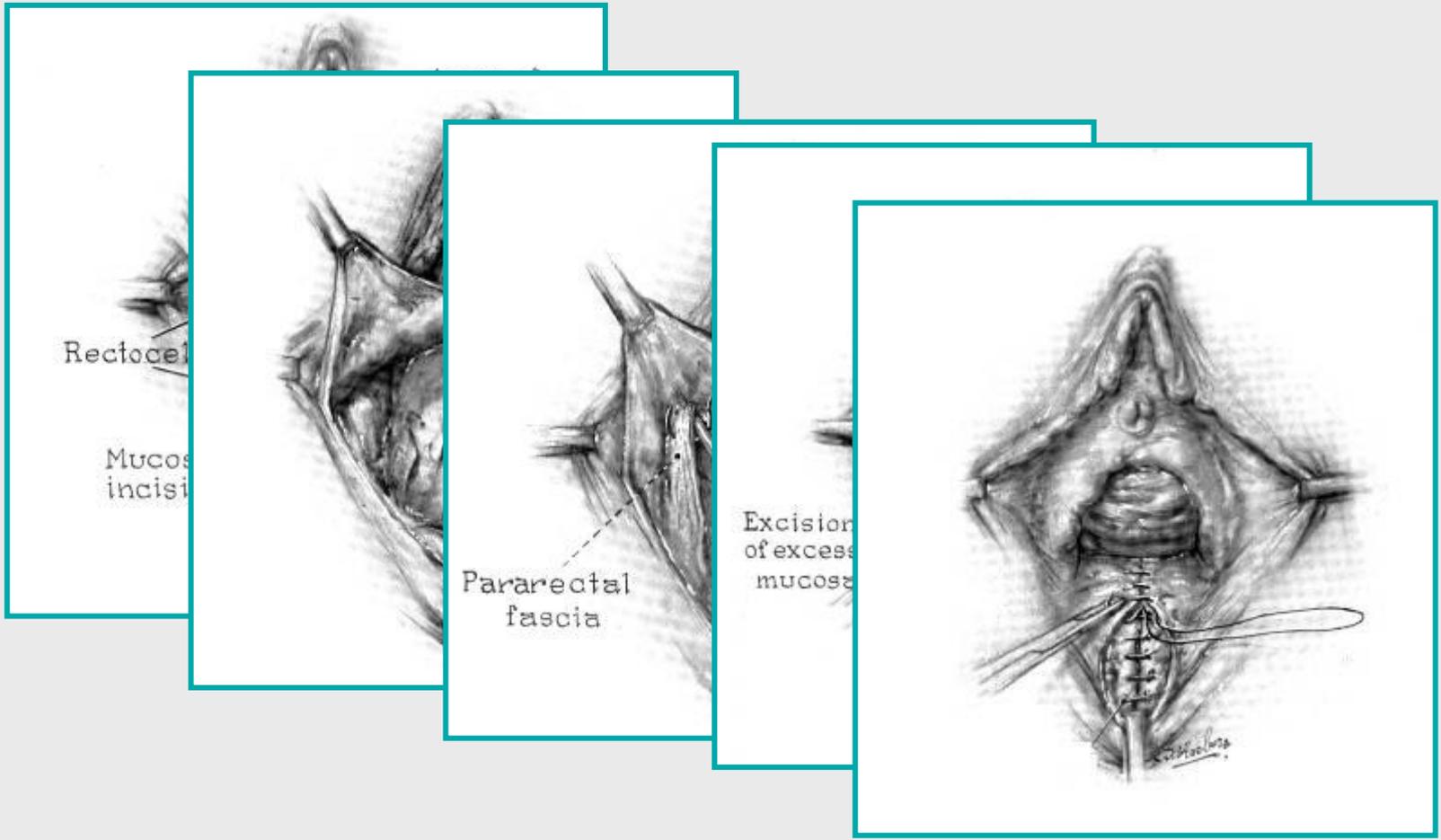
Prolapse Surgery Decision Tree



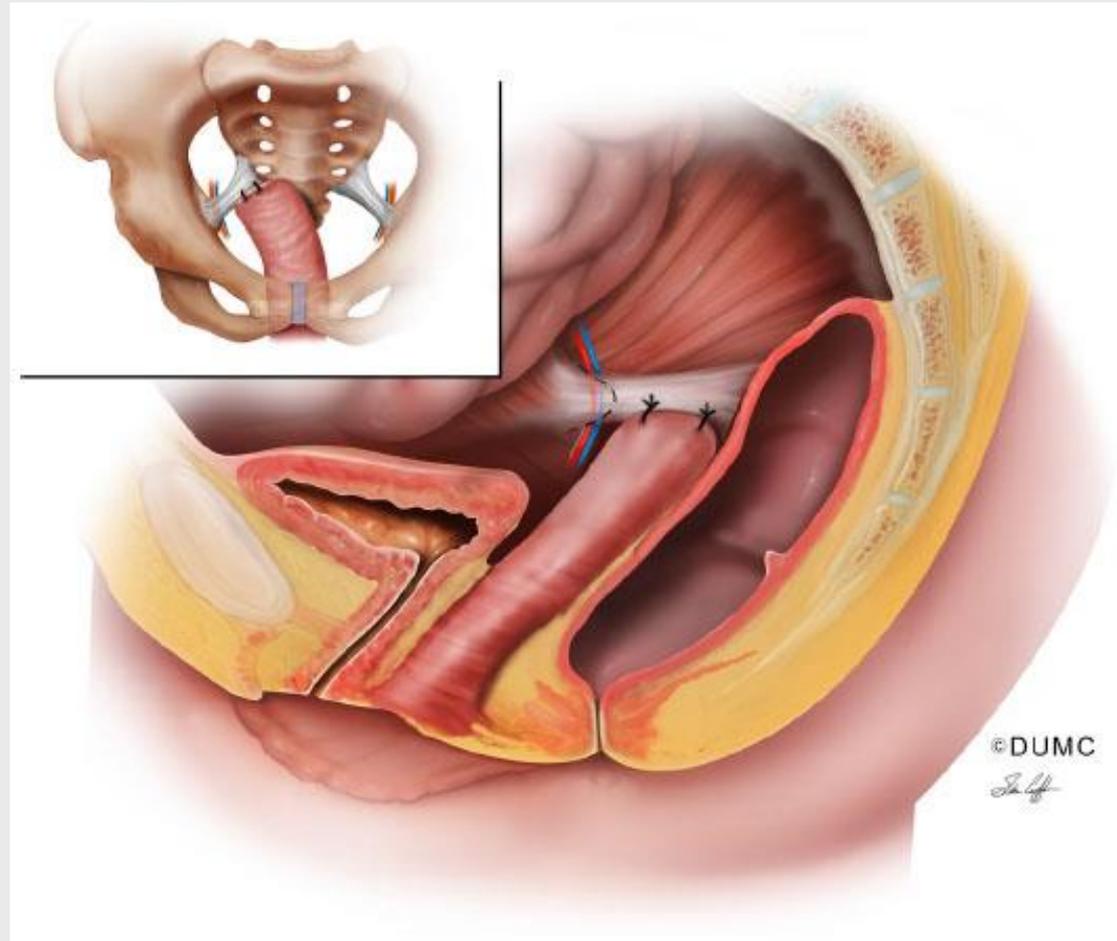
Anterior Colporrhaphy (i.e. “Anterior Repair”)



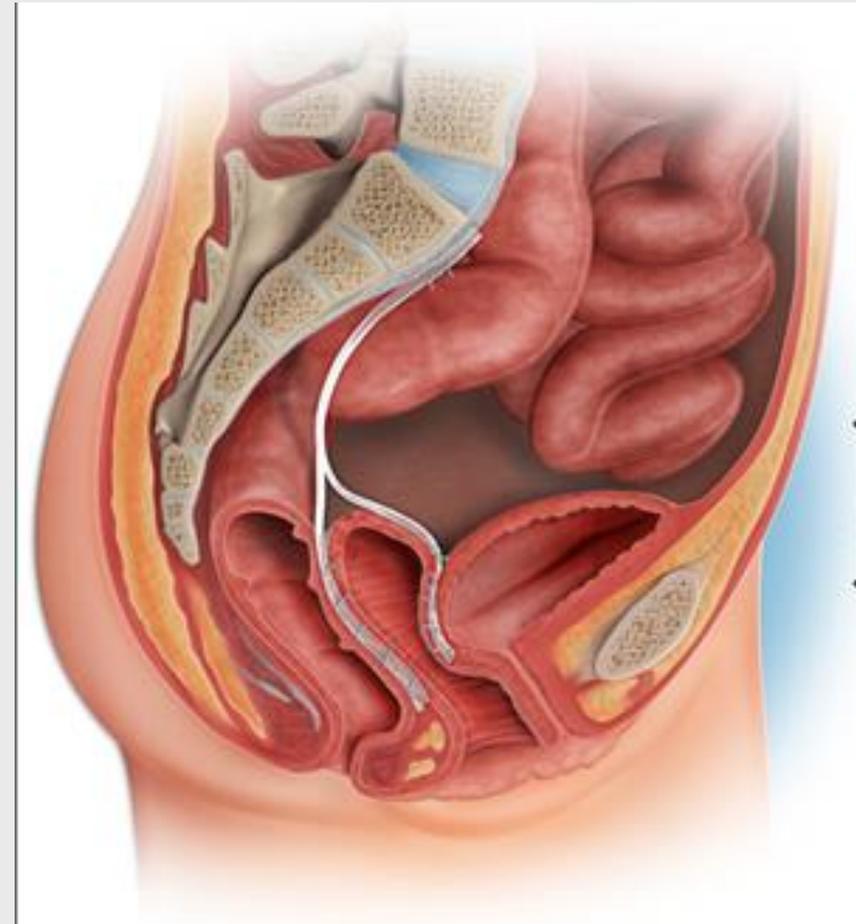
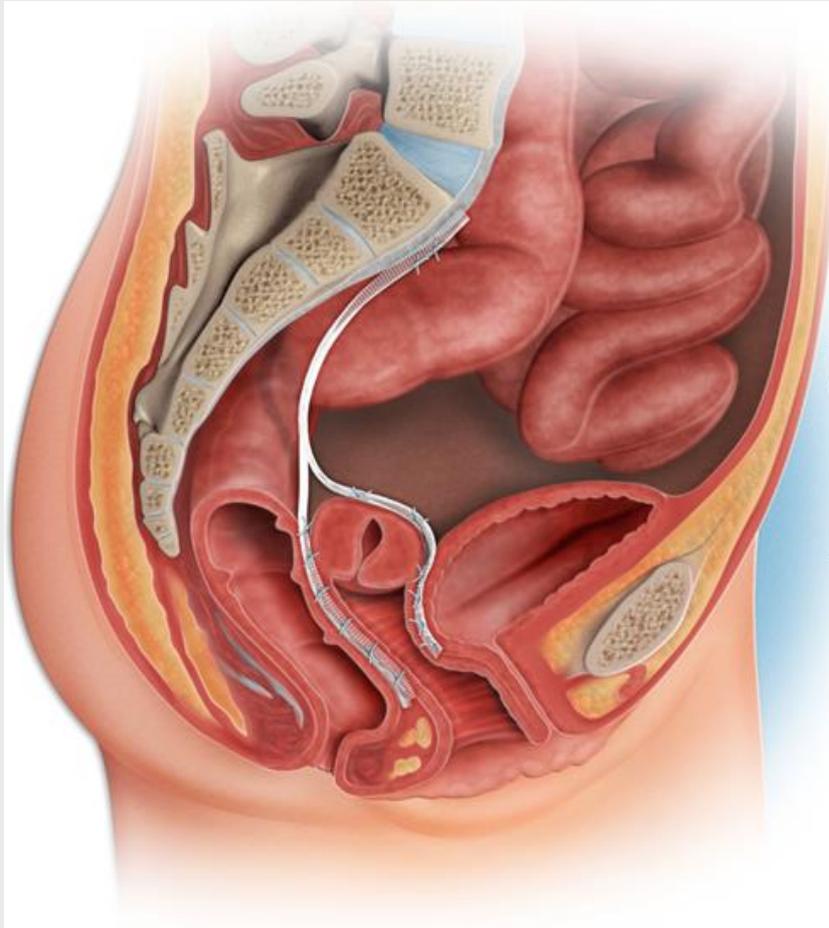
Posterior Colporrhaphy (i.e. "Posterior Repair")



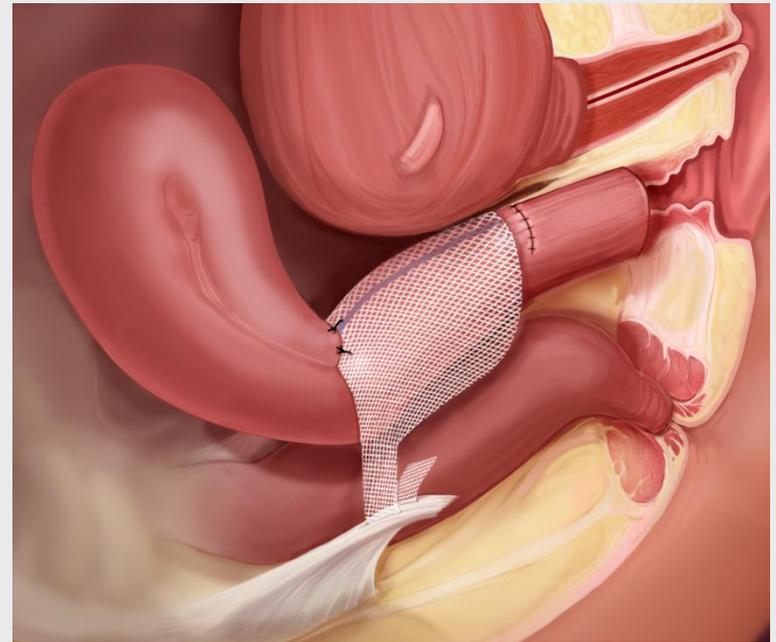
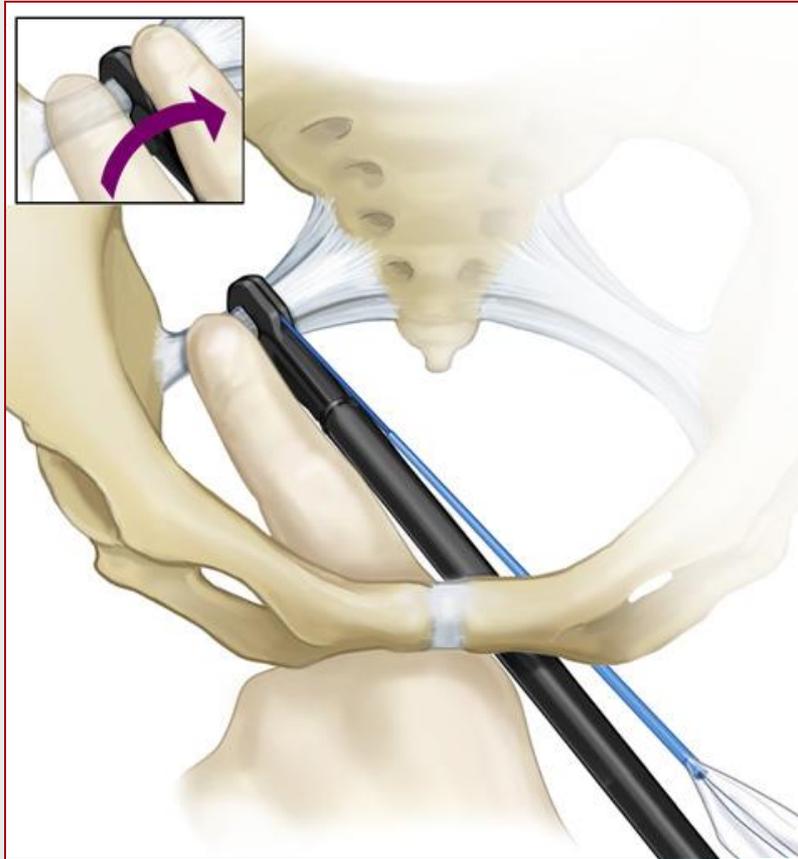
Native Tissue Repair



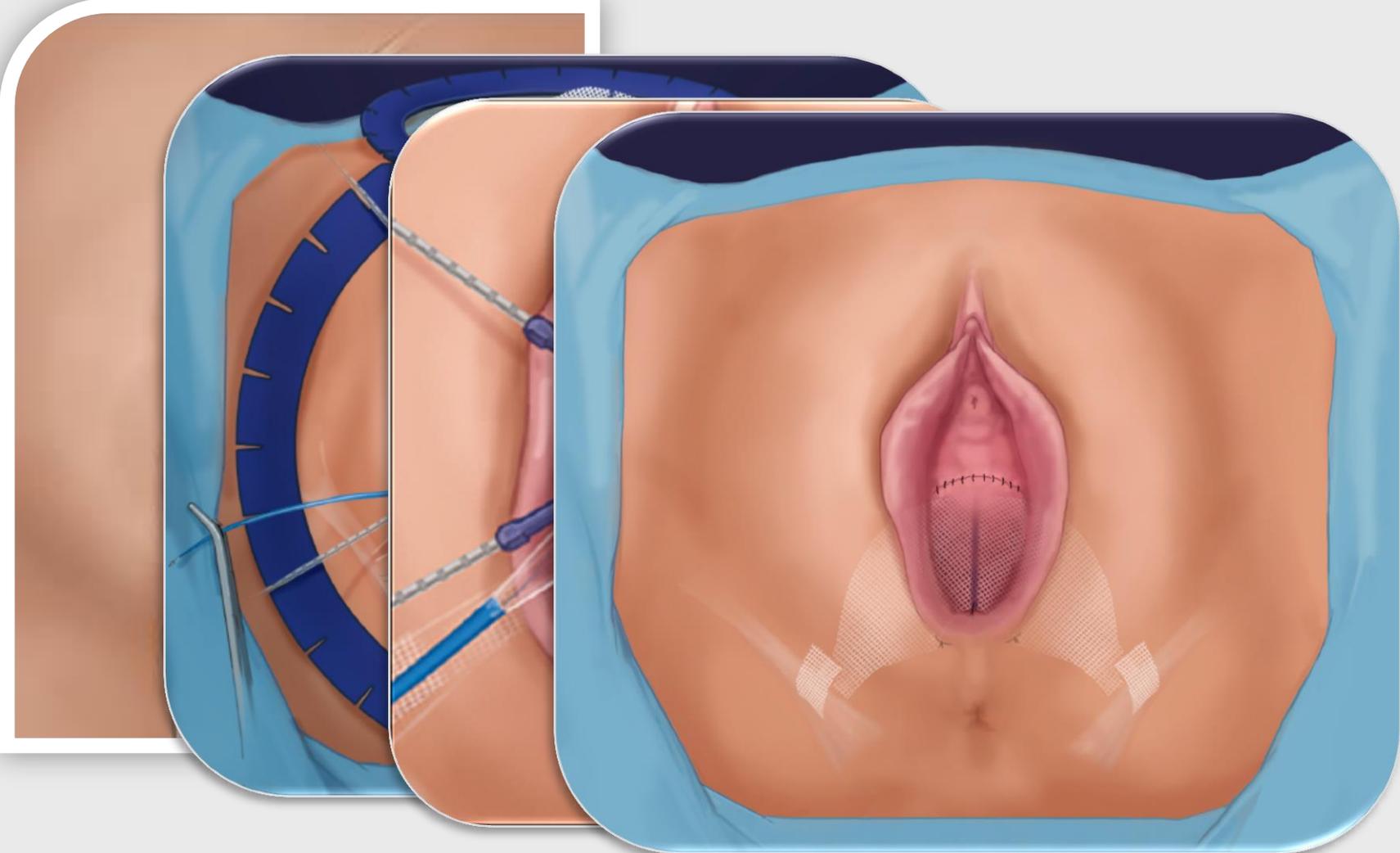
Sacrocolpopexy



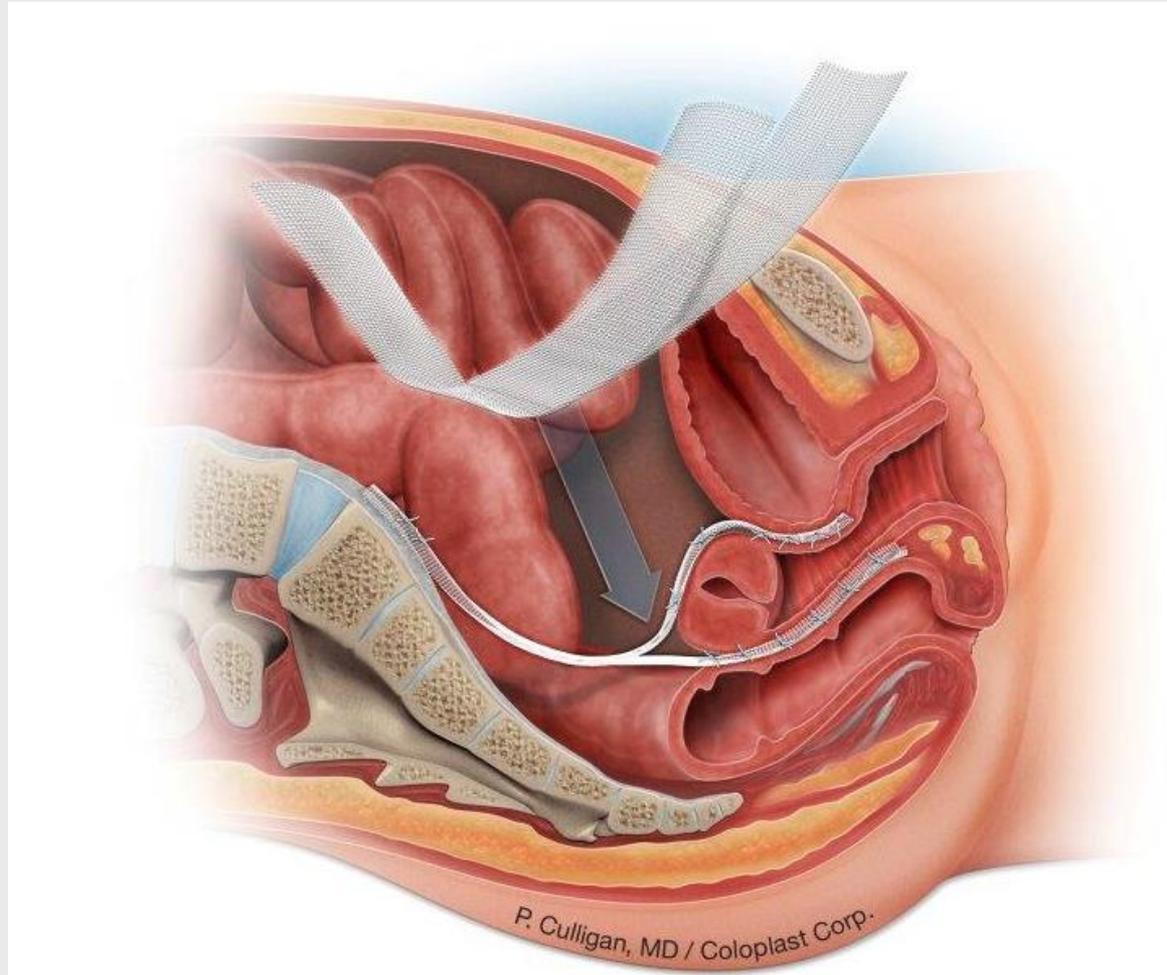
Vaginal Mesh



Vaginal Mesh



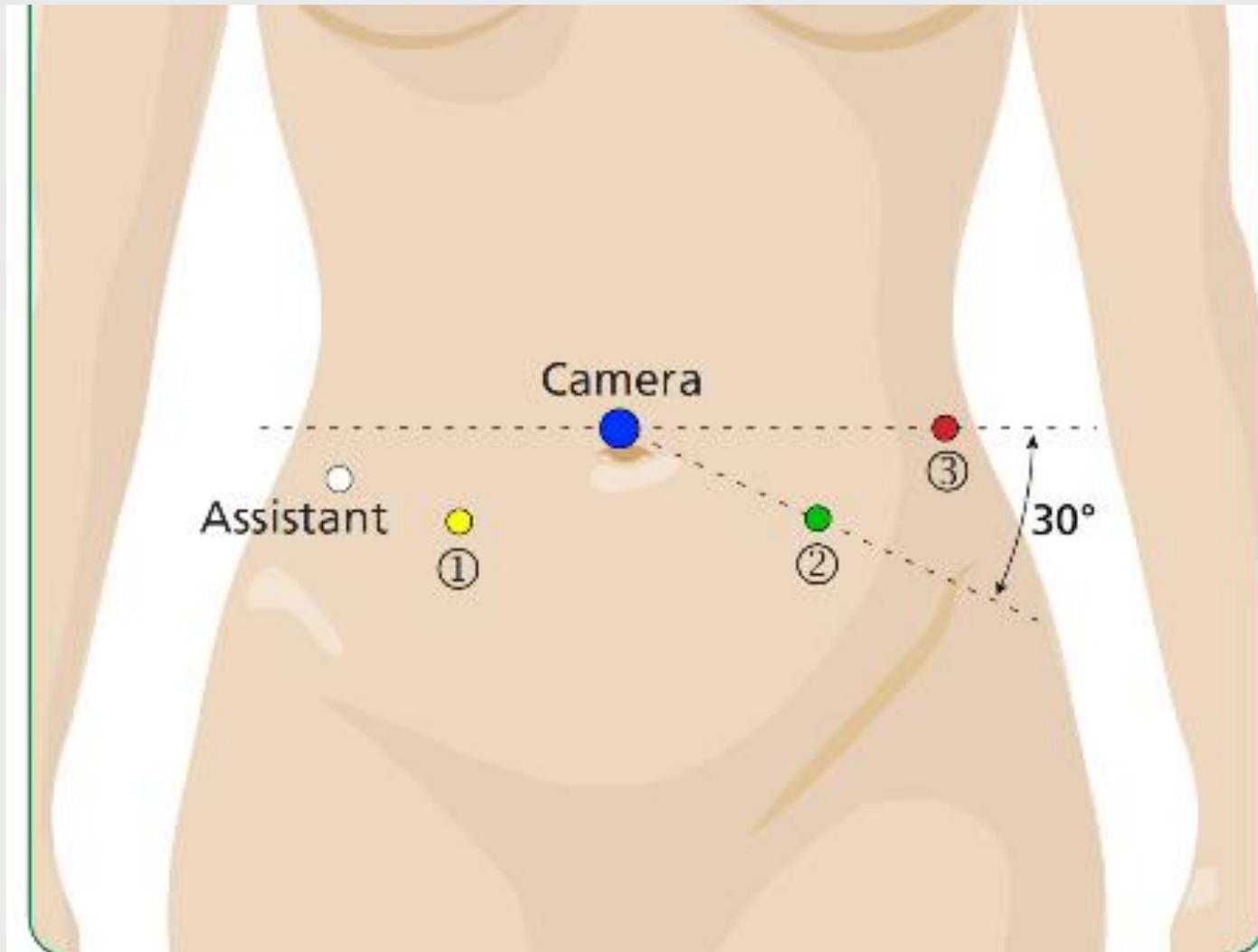
Sacrocolpopexy – NOT “Vaginal Mesh”



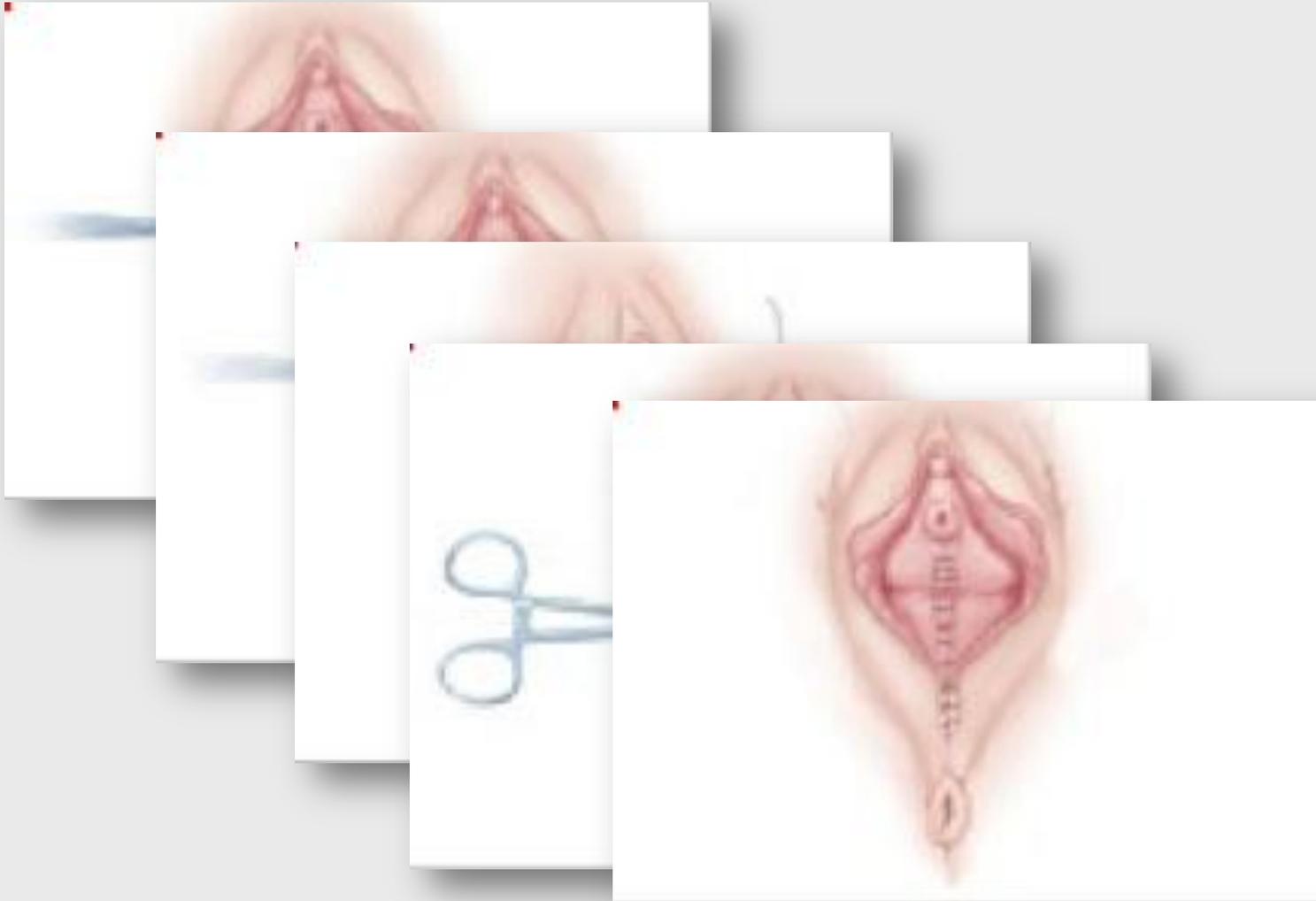
The daVinci Robot



Trocar Placement



LeForte Colpocleisis (i.e. Closing the vagina)



Health and Wellness Seminar on Urogynecology:

Treatment for "Unspoken" Pelvic Floor Disorders, Incontinence and Prolapse

Bilal Chughtai, MD

Assistant Professor of Urology

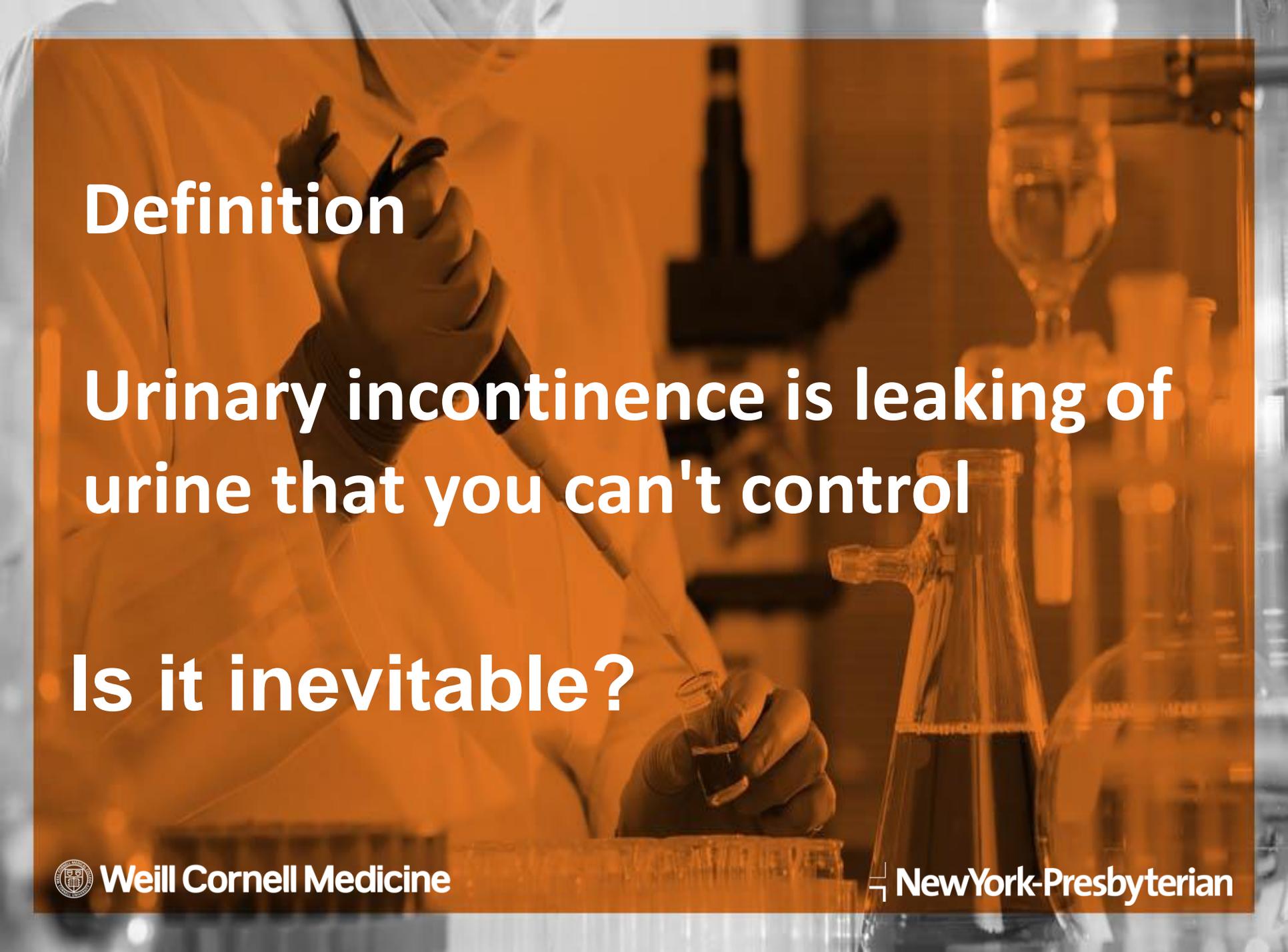
Assistant Professor of Obstetrics and Gynecology

Weill Cornell Medical College



Weill Cornell Medicine

 **New York-Presbyterian**



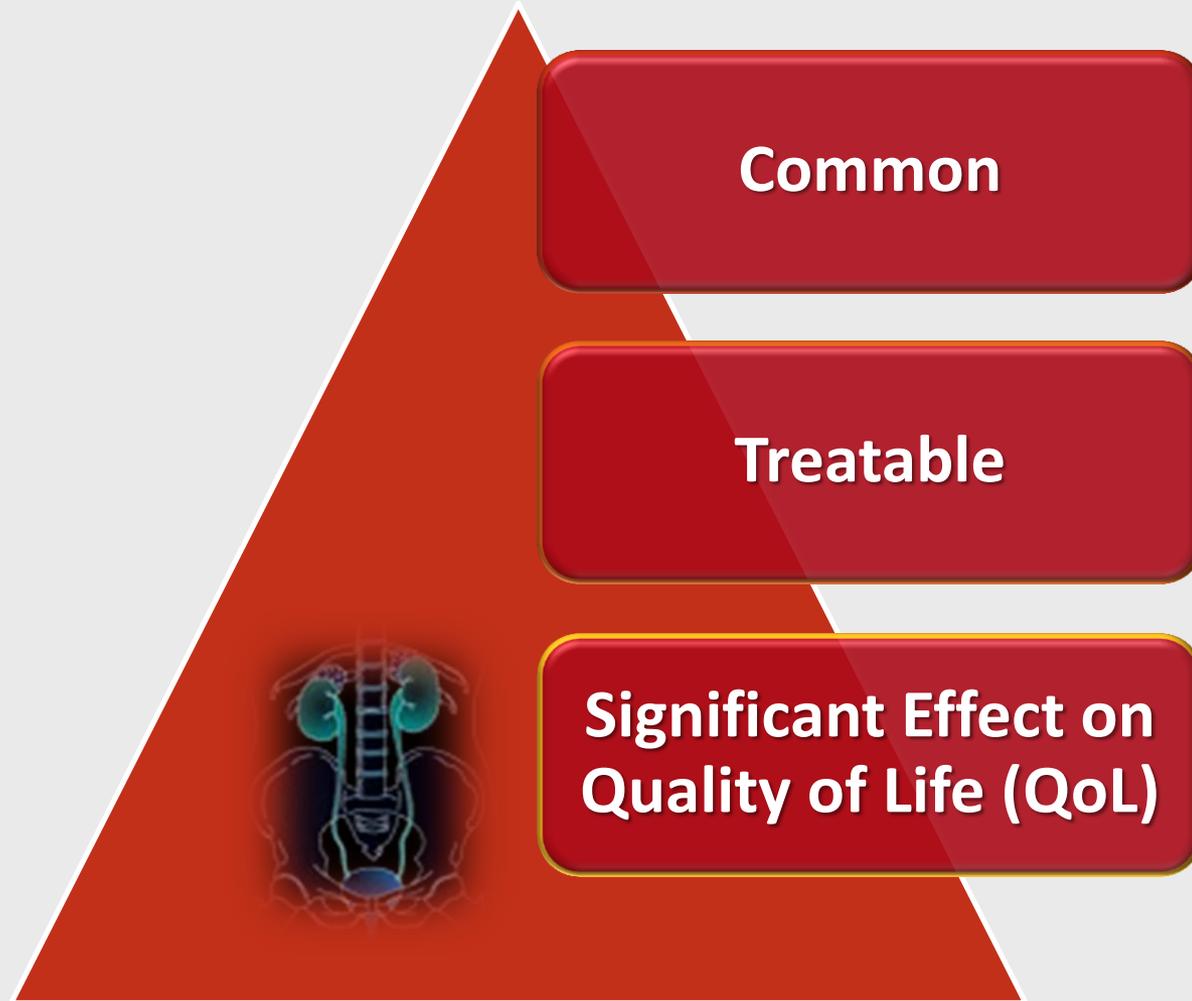
Definition

Urinary incontinence is leaking of urine that you can't control

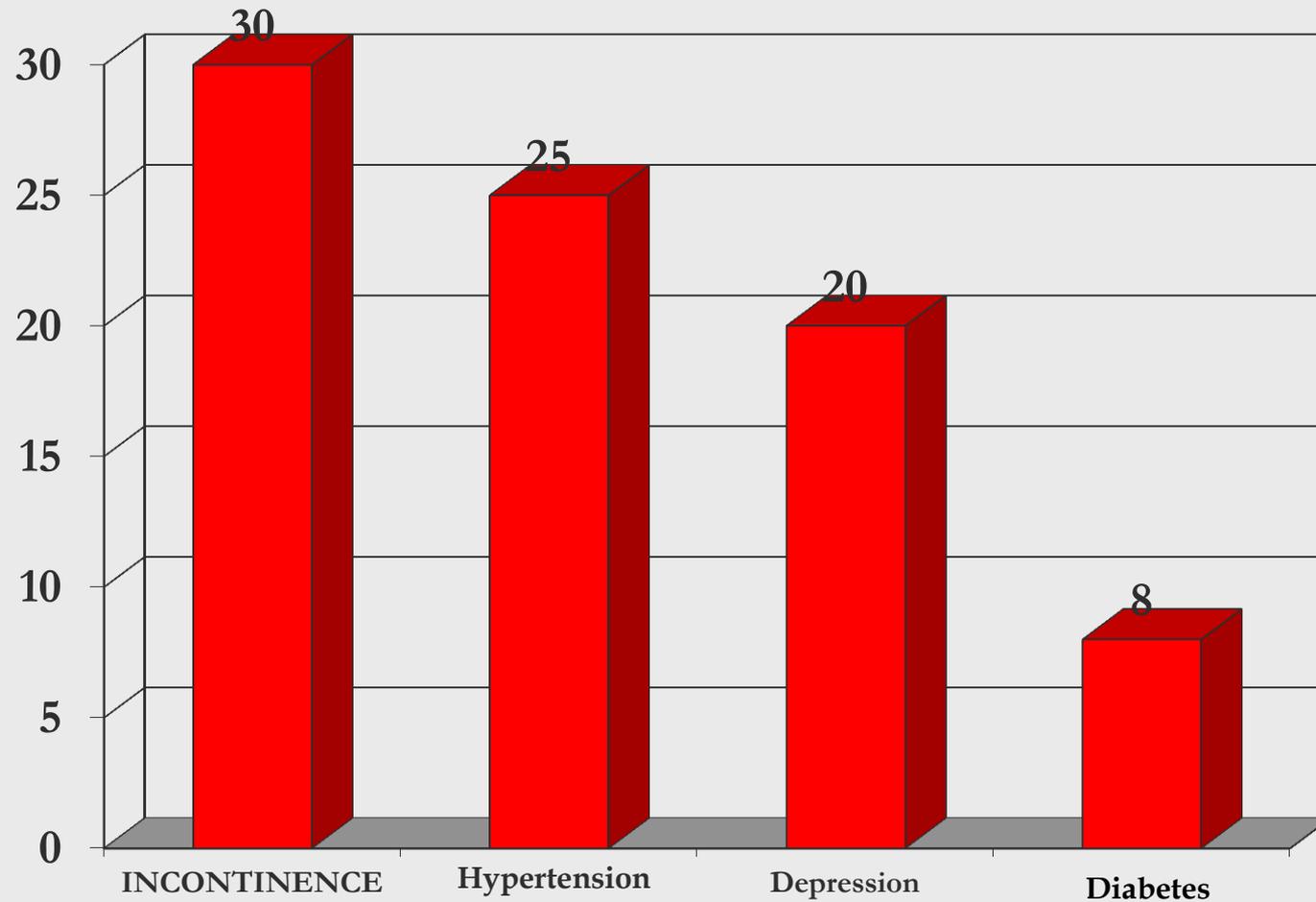
Is it inevitable?



URINARY INCONTINENCE



Prevalence of disease in women



Aging Changes

- Decreased bladder capacity
- Reduced voiding volume
- Reduced flow rates
- Increased urine production at night

* Nordling, J *Experimental Gerontology*, 2002, 37:991



Impact on Quality of Life

- Embarrassment
- Reduced Self esteem
- Impaired emotional & psychological well-being
- Poorer sexual relationships
- Impaired social activities and relationships

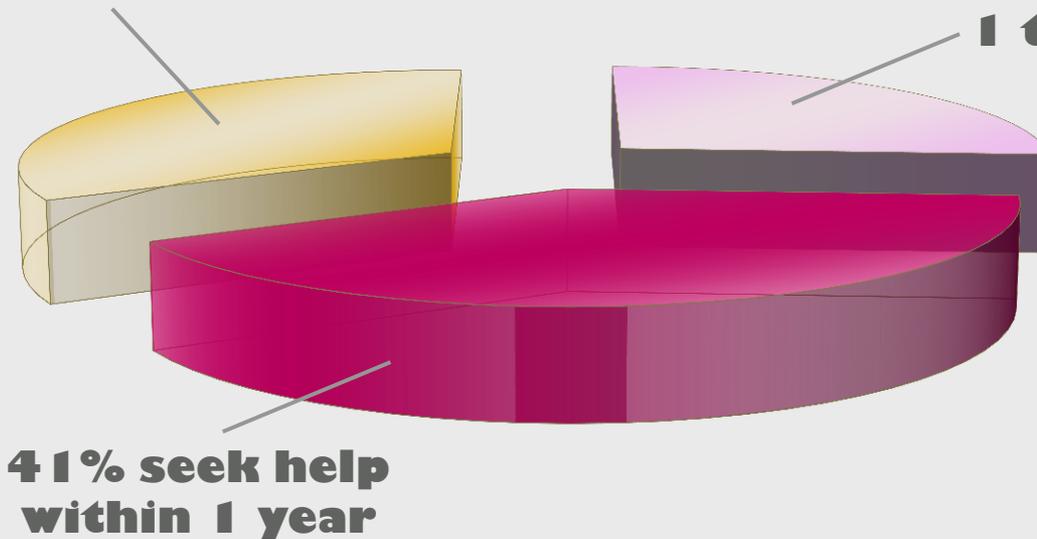


Bladder Control

Don't Wait to Talk with Your Doctor

**26% of women
wait over 5 years
to seek help**

**33% wait
1 to 5 years**



**41% seek help
within 1 year**

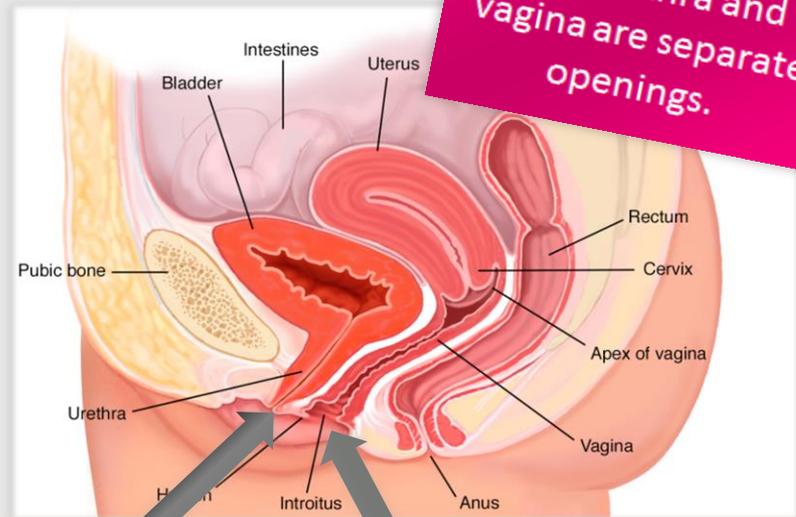
- Norton, P A et al. Distress and Delay Associated With Urinary Incontinence. BMJ, 297(5), November 1988.



Bladder Control

How the Bladder Works

- Your body stores water (urine) in the bladder.
- The bladder connects to a tube called the urethra. Muscles and nerves help control the bladder and urethra.
- When you go, these muscles and nerves signal urine to leave the body through the urethra.



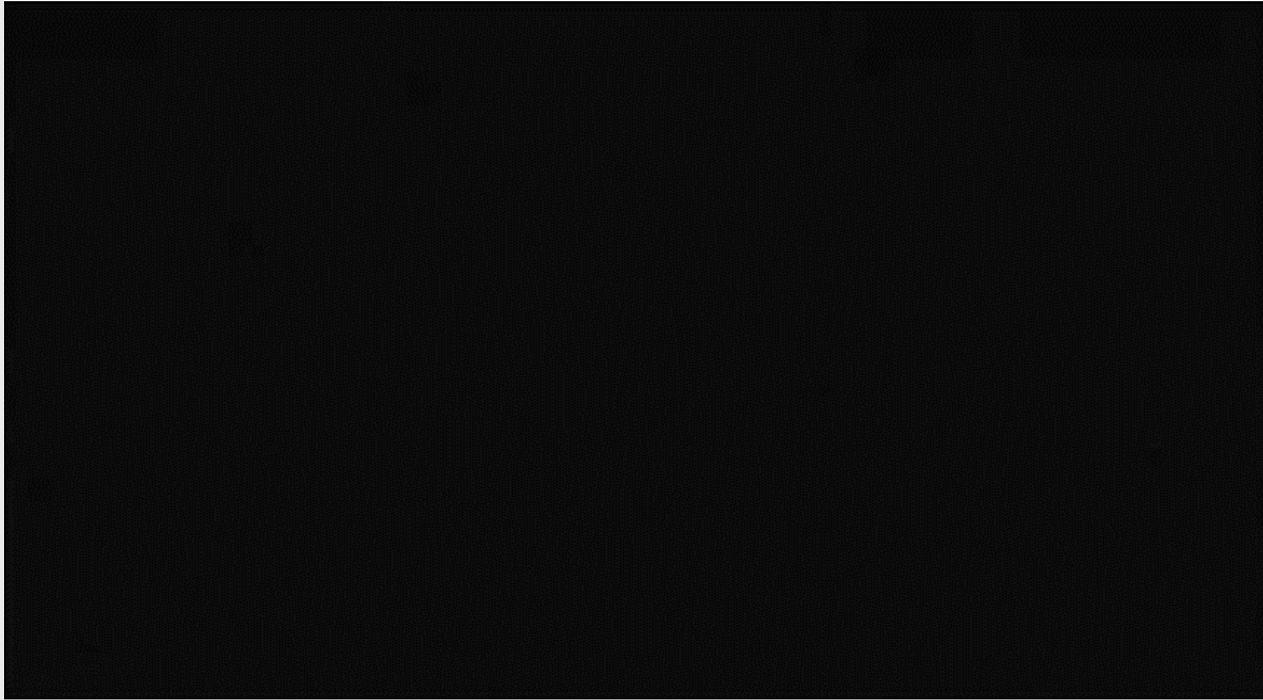
Did you know?
The urethra and vagina are separate openings.

Bladder Opening

Vaginal Opening

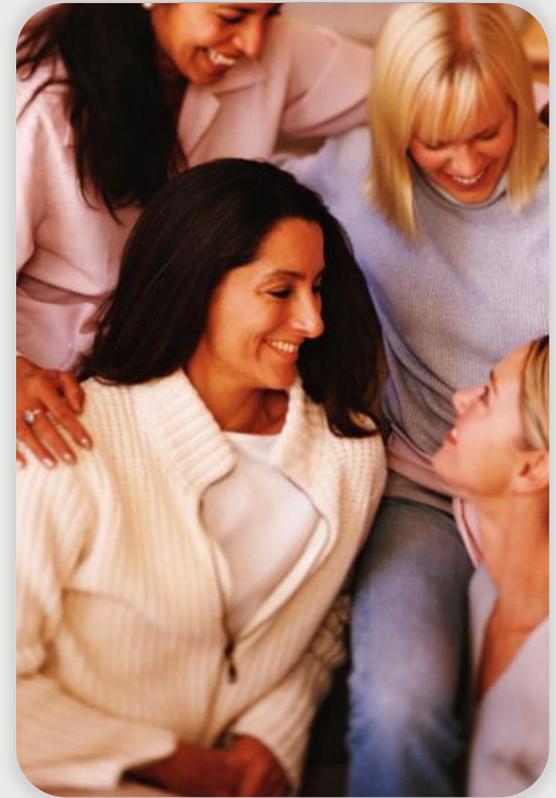
- National Institute of Diabetes and Digestive and Kidney Diseases. Urinary Incontinence in Women, [kidney.niddk.nih.gov/KUDiseases/pubs/uiwomen](https://www.kidney.niddk.nih.gov/KUDiseases/pubs/uiwomen).





Symptoms of Control Problems

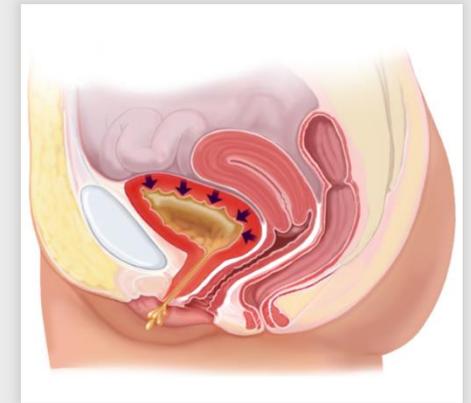
- Problems with muscles and nerves that help to hold or release urine:
 - **Loss of urine (urinary incontinence).**
 - **Difficulty emptying your bladder, for example, trouble starting the flow of urine.**
- Symptoms vary:
 - **Strong, sudden urge just before losing a large amount of urine.**
 - **Involuntary loss of both small and large amounts of urine with activities such as coughing or straining.**
 - **Slow or interrupted urine stream or sense of incomplete bladder emptying.**



▪ National Institute of Diabetes and Digestive and Kidney Diseases. Urinary Incontinence in Women, kidney.niddk.nih.gov/KUDiseases/pubs/uiwomen.

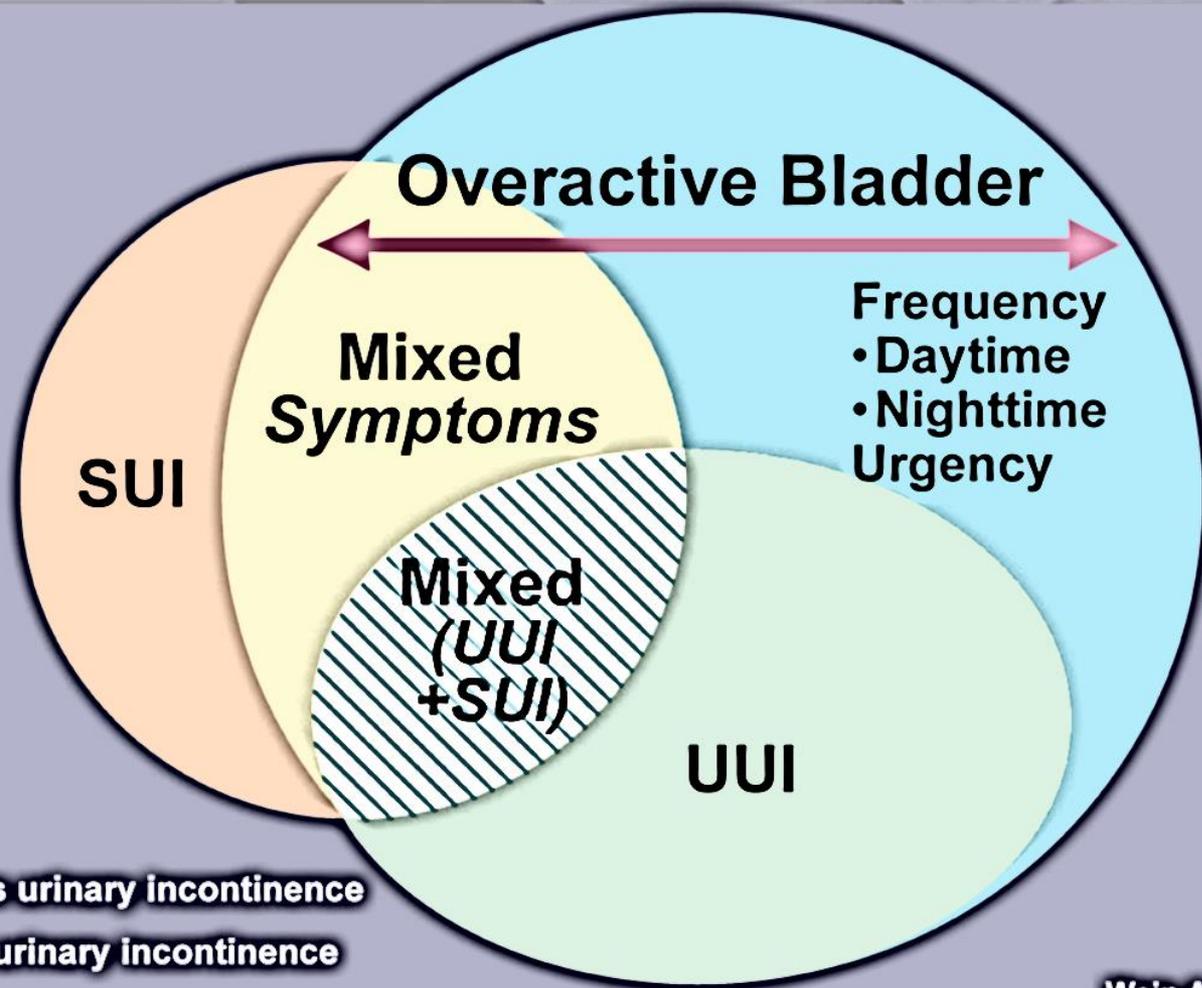
Bladder Control Types of Urinary Incontinence

- Stress incontinence:
 - Urine leaks with activities (coughing, sneezing, laughing, lifting, exercising).
- Urge incontinence/overactive bladder (OAB):
 - “Gotta go *now*” sensation (urgency).
 - “Gotta go *now*” with leakage (urge incontinence).
 - “Gotta go *often*” (frequency).
 - Going often during the night (nocturia).
- Other types:
 - Mixed incontinence (stress and urge).
 - Continuous (unpredictable) incontinence.



▪ National Institute of Diabetes and Digestive and Kidney Diseases. Urinary Incontinence in Women, kidney.niddk.nih.gov/KUDiseases/pubs/uiwomen.





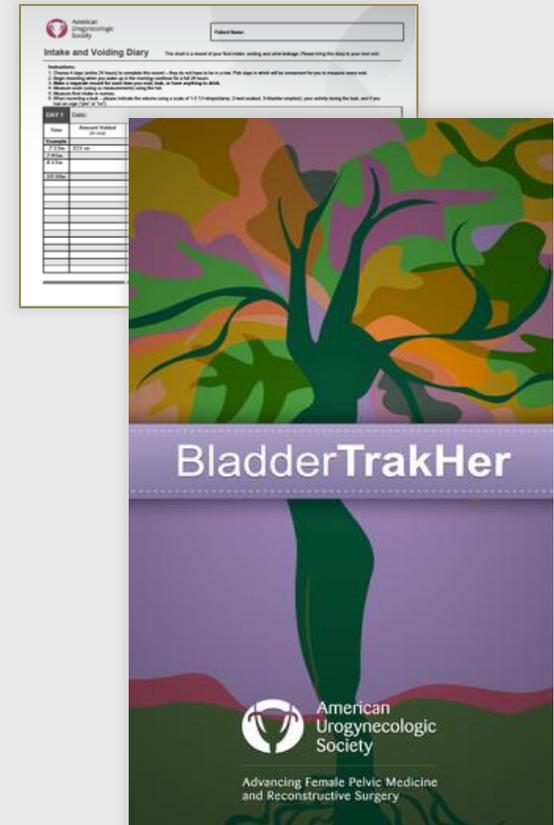
SUI = stress urinary incontinence
UUI = urge urinary incontinence

Wein A. 2004.

Bladder Control

Treatments—Urinary Incontinence

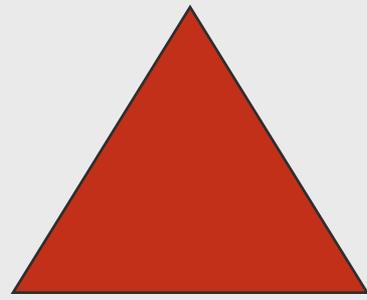
- Find out what treatment is best for YOU:
 - Ask your doctor about risks, potential complications, and follow-up care.
- Diet and exercise:
 - Lose weight (if overweight).
 - Limit alcohol and caffeine.
 - Keep pelvic muscles healthy and working well.
 - Do pelvic floor exercises (kegels).
- Bladder diary—app or paper:
 - Track how often you go.
 - Try to “schedule” bathroom trips.



Surgical Treatment



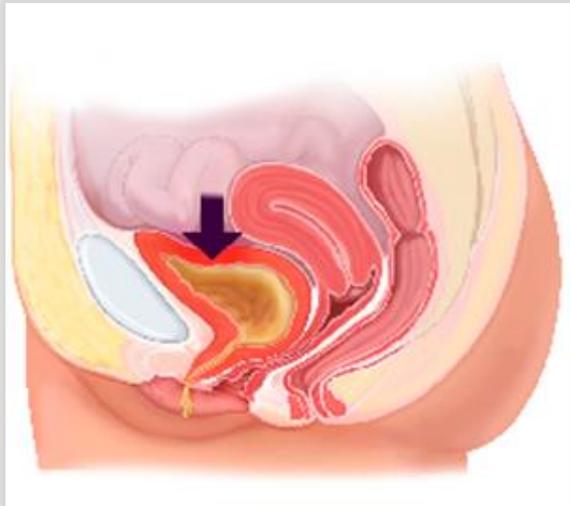
Best long
term result



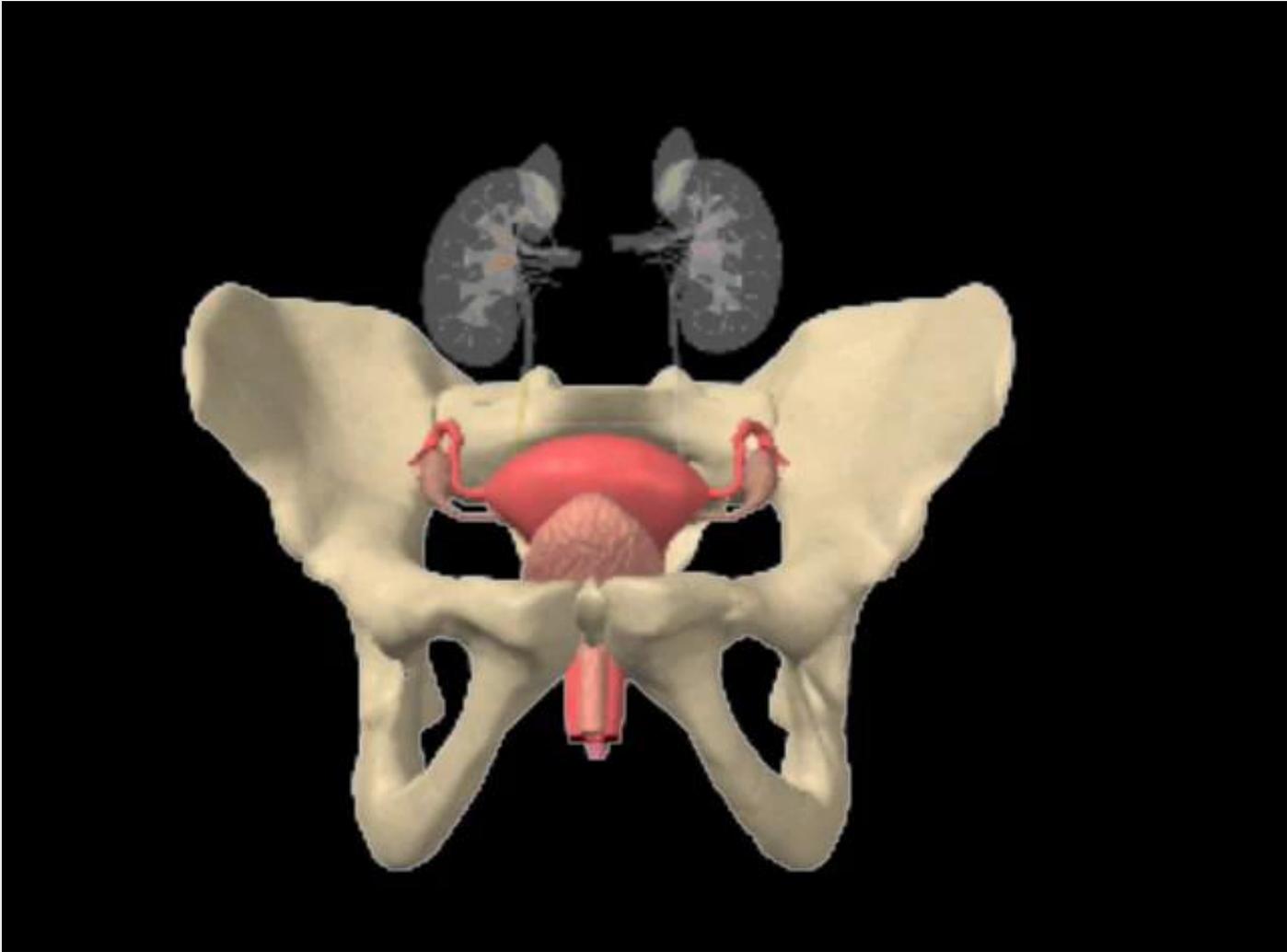
minimal
complication

Bladder Control

Treatments—Stress Incontinence



- Bulking therapy:
 - Outpatient or office based procedure.
 - Inject gel like material around the urethra just outside of the bladder.
 - Bulk up the area to close the lumen of the urethra and help block leaking.
 - Lower success rate than surgery.
 - Goal to improve quality of life.
- Surgery:
 - Helps to support urethra and bladder.
 - Aims to stop or reduce urine leakage.
 - Goal to improve quality of life.





U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

PUBLIC HEALTH NOTICES



**“Time heals all wounds,”
but money can help too.**

Have you been diagnosed with
severe injuries internally & have

Vaginal Mesh?

You may be entitled
to compensation

we can help!



Mesh Erosion Lawsuits

FDA ALERT: Recent studies show high failure rates and erosion with the use of Vaginal Mesh, aluat

VAGINAL MESH LAWSU



Have you or a loved one
mesh implant?

Contact Us For A Free Case Eva

**\$3.35 Million Verdict Against
Johnson & Johnson in First
Transvaginal Mesh Trial**

SH PATCH LAWSUIT CENTER

ur wife experiencing problems
her mesh implant?



es!

CLICK HERE
More Information

**OVER 160,000 CLIENTS
CAN'T BE WRONG**

Transvaginal Mesh

Are you the victim of Transvaginal Mesh Implant Failure?

**\$3.35 MILLION VERDICT
IN VAGINAL MESH LAWSUIT**

resbyterian

Is mesh safe?

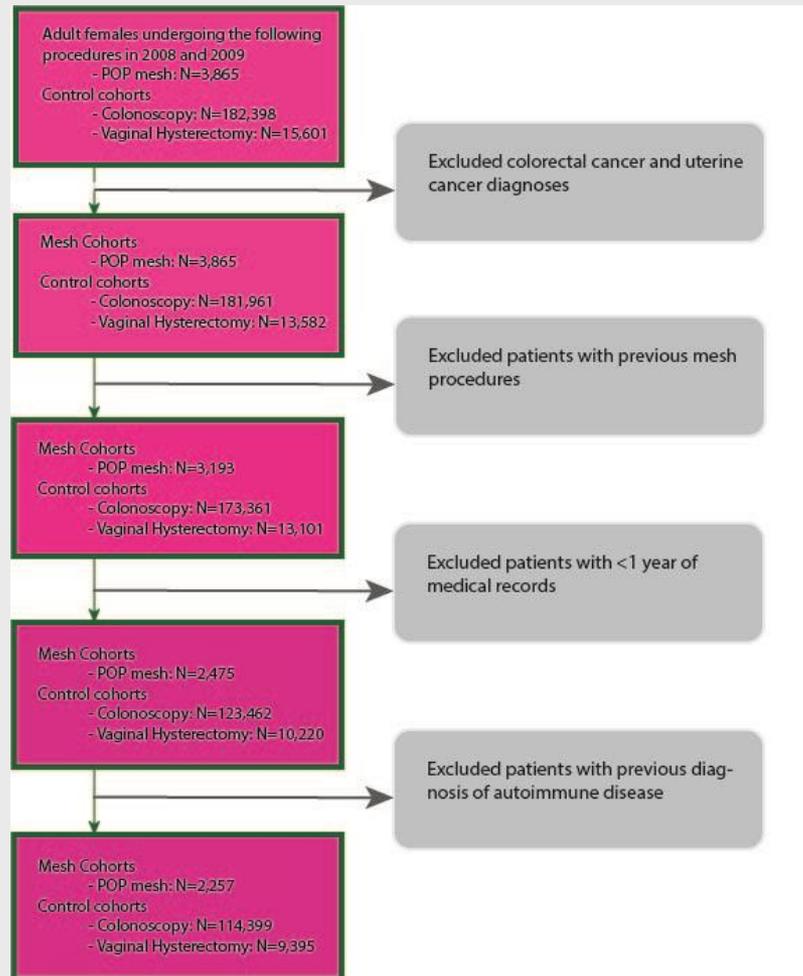


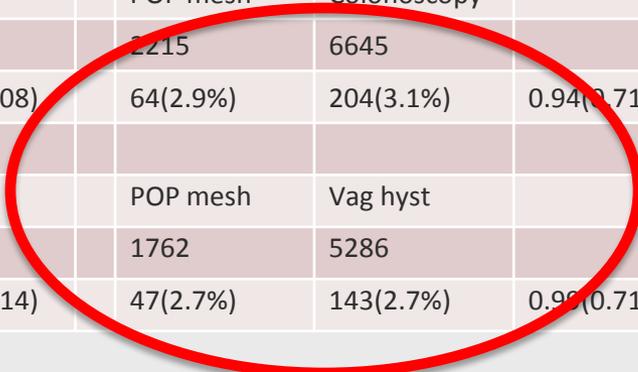
Table 2. Designated autoimmune disease

Disease	ICD-9 codes
Grave's Disease	242.0, 242.00, 242.01
Hashimoto's Thyroiditis	245.2
Pernicious Anemia	281.0
Autoimmune Hemolytic Anemia	283.0
Autoimmune Thrombocytopenic Purpura	287.31
Amyotrophic Lateral Sclerosis	335.20
Multiple Sclerosis	340
Guillain-Barre Syndrome	357.0
Myasthenia Gravis	358.0, 358.00, 358.01
Goodpasture's Syndrome	446.21
Vasculitis	447.6
Celiac Disease	579.0
Pemphigus Vulgaris	694.4
Systemic Lupus Erythematosus	710.0
Systemic Sclerosis	710.1
Sjogren's Syndrome	710.2
Dermatomyositis	710.3
Polymyositis	710.4
Rheumatoid Arthritis	714.x
Ankylosing Spondylitis	720.0
Fibromyalgia	729.1



Table 2. Follow-up of systemic autoimmune/ inflammatory disease in mesh and control cohorts.

	Unmatched			Matched		
	Mesh Cohort	Control Cohort	RR (95% CI)	Mesh Cohort	Control Cohort	RR (95% CI)
Cohort	POP mesh	Colonoscopy		POP mesh	Colonoscopy	
N	2257	114399		2215	6645	
SAID	66(2.9%)	3934(3.4%)	0.85(0.67-1.08)	64(2.9%)	204(3.1%)	0.94(0.71-1.24)
Cohort	POP mesh	Vag hyst		POP mesh	Vag hyst	
N	2257	9395		1762	5286	
SAID	66(2.9%)	312(3.3%)	0.88(0.68-1.14)	47(2.7%)	143(2.7%)	0.96(0.71-1.36)



Cancer Diagnoses

Number	Cancer Type	Prevalence
1	Breast	888,374
2	Colon and rectum	191,620
3	Corpus & Uterus	190,409
4	Thyroid	151,384
5	Melanoma of the skin	135,294
6	Lung and Bronchus	127,939
7	Non-Hodgkin Lymphoma	95,811
8	Ovary	61,283
9	Kidney	60,602
10	Leukemia	52,239



Mesh and Carcinogenesis

	POP mesh (N=1699)	Cholecystectomy (N=5097)	P value	RR (95% CI)
Demographics				
Age (Mean(std))	60.2(13.1)	60.2(13.1)	0.97	
Race/Ethnicity*			1	
White (Non-Hispanic)	1366(80.7%)	4098(80.7%)		
Black (Non-Hispanic)	93(5.5%)	279(5.5%)		
Hispanic	146(8.6%)	438(8.6%)		
Other	88(5.2%)	264(5.2%)		
Insurance			1	
Medicare	620(36.5%)	1860(36.5%)		
Medicaid	126(7.4%)	378(7.4%)		
Commercial	912(53.7%)	2736(53.7%)		
Other	41(2.4%)	123(2.4%)		
NY resident	1682(99.0%)	5046(99.0%)	1	
Comorbidities			0.58	
0	805(47.4%)	2360(46.3%)		
1	544(32.0%)	1629(32.0%)		
2+	350(20.6%)	1108(21.7%)		
Cancer during FU				
1-year	12(0.7%)	87(1.7%)	<0.01	0.41(0.23-0.75)
2-year	31(2.0%)	162(3.2%)	<0.01	0.57(0.39-0.84)
All FU	86(5.1%)	386(7.6%)	<0.01	0.67(0.53-0.84)

Abbreviations: FU=Follow-up, RR=Risk Ratio

*Race/ethnicity information missing in 0.9% patients.

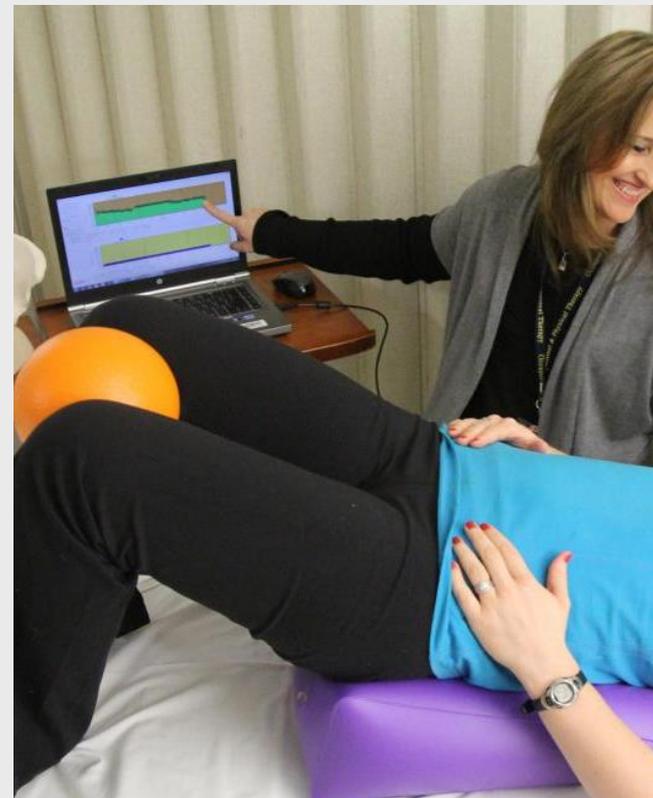
Vaginal surgery with implantation of mesh was not associated with the development of cancers

This data refutes claims against mesh as a cause of carcinogenesis

Bladder Control

Treatments—Urge Incontinence/OAB

- Lifestyle changes:
 - Retrain your bladder and learn ways to control when you go.
 - Exercise your pelvic floor muscles and make diet changes.
- Physical Therapy:
 - Biofeedback (pelvic muscle training).
- Medicines:
 - Bladder relaxant medicines.

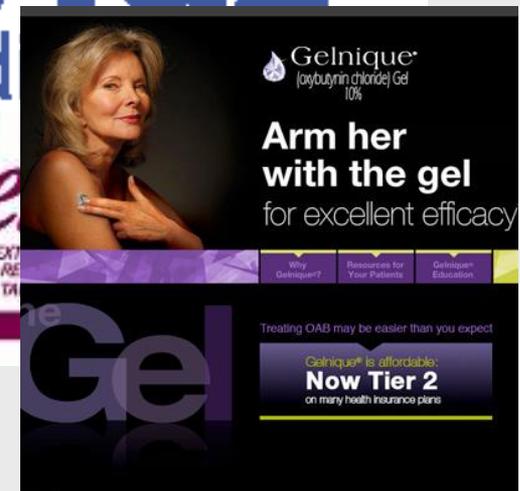


▪ National Institute of Diabetes and Digestive and Kidney Diseases. **Urinary Incontinence in Women**, kidney.niddk.nih.gov/KUDiseases/pubs/uiwomen.

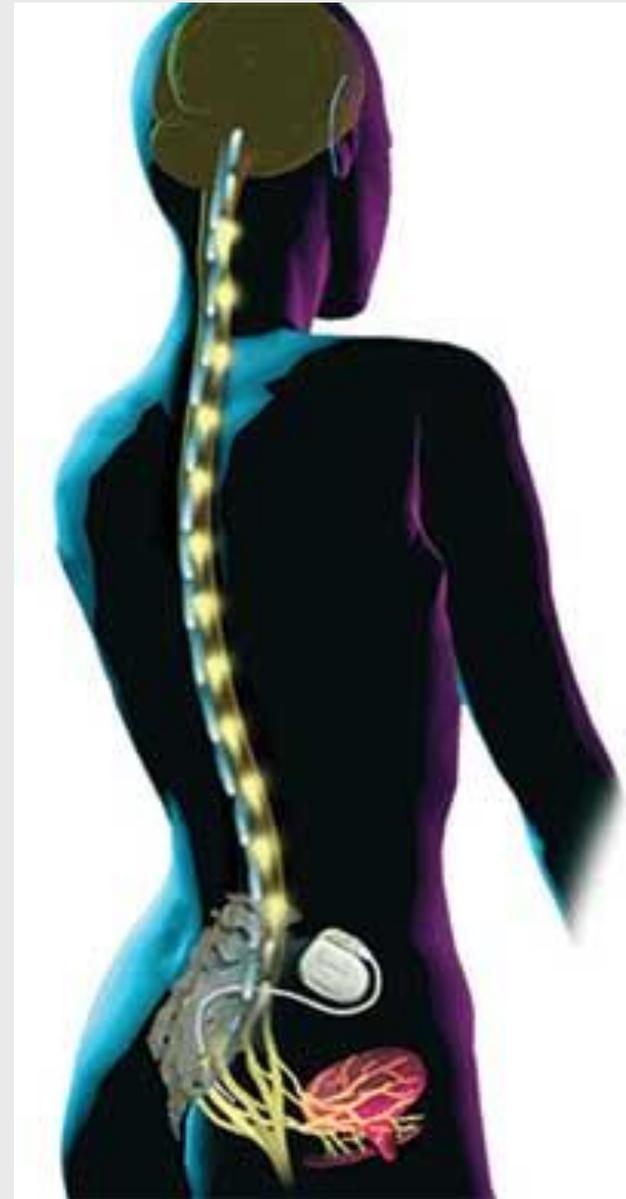
▪ Gormley EA, et al. American Urological Association (AUA) Guideline: Diagnosis and Treatment of Overactive Bladder (non-Neurogenic) in Adults: AUA/SUFU Guideline, May 2012.

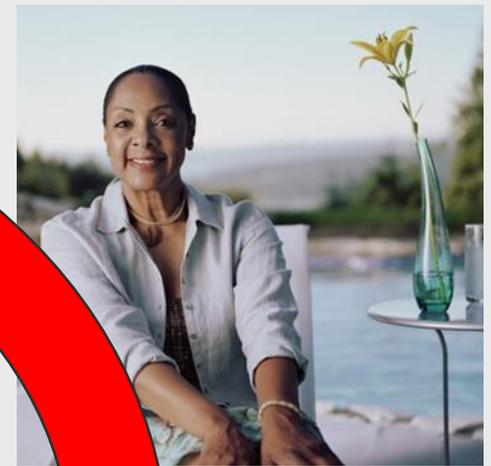


Medications



- Surgeries:
 - Botox™ Preparation bladder injections.
 - Bladder nerve stimulator (electrical stimulator or neuromodulator).
 - Tibial Nerve Stimulation.
- Combination of treatments.





Is bladder leakage inevitable?



LOWER URINARY TRACT & PELVIC FLOOR SYMPTOMS

Tanaka J. Dune

Assistant Professor of Urology

Assistant Professor of Obstetrics and Gynecology

Urogynecologist

Weill Cornell Medicine
Center for Female Pelvic Health

525 East 68th Street, F9 West

New York, NY 10065

T 212.746.4600

F 646-962-0715

urology.weillcornell.org



Weill Cornell Medicine

New York-Presbyterian

Contents

- **Urinary Tract Infection (UTI)**
- **Recurrent UTI**
- **Testing for UTI/Recurrent UTI**
- **Treating UTI/Recurrent UTI**
- **Is It Really a UTI?**



Urinary Tract Infection (UTI)

- **THE most common ambulatory bacterial infection in the U.S.**
- **8.6 million appointments (vast majority by women – 84%)**
- **By early 30's, ½ of all women would have had at least one UTI**



Hooten NEJM 2012

Urinary Tract Infection (UTI)

Uncomplicated

- Acute cystitis (quick onset bladder infection)

Or

- Acute pyelonephritis (quick onset kidney infection)

And

- In the setting of:
 - healthy non-pregnant pre-menopausal woman
 - no prior urological abnormalities

Complicated

- Everyone else

Used to guide:

-Choice and duration of antibiotics

-But we miss:

-diversity of UTI disorders

-what about the healthy pre-menopausal woman

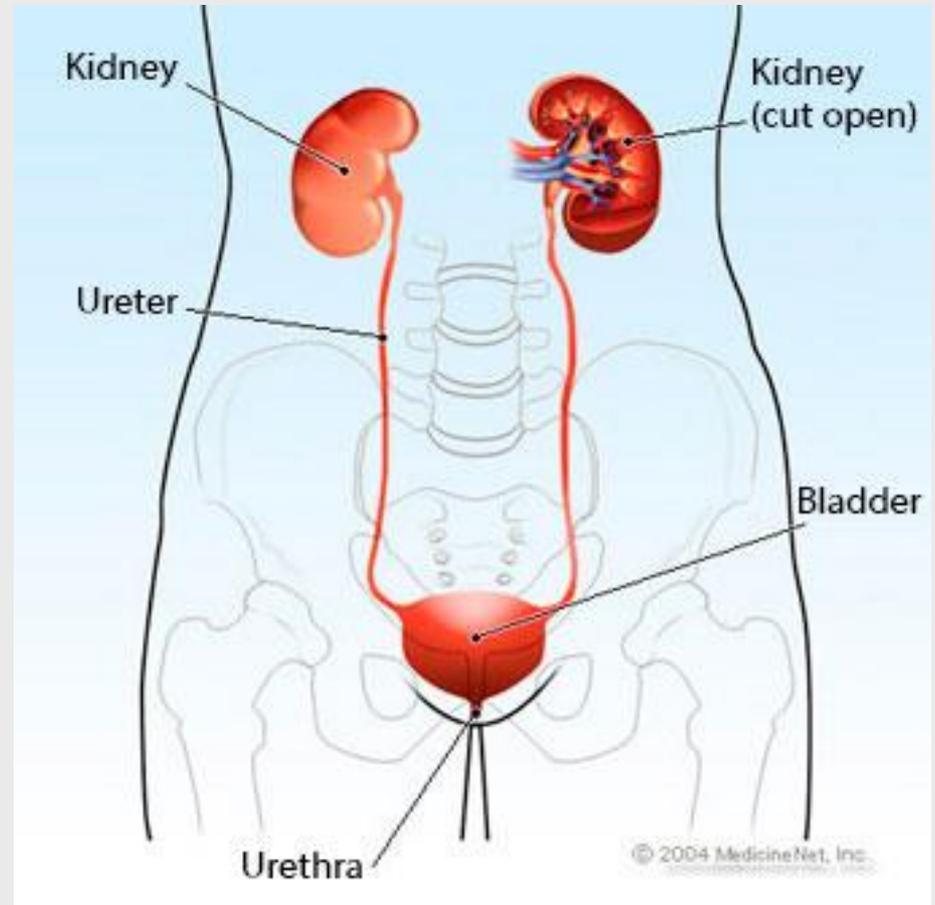
Hooten NEJM 2012



UTIs...Why & How Do They Happen?

- **Intricate**
- **Bacteria from bowel and vagina**
- **Infection by ascending bacteria into the:**

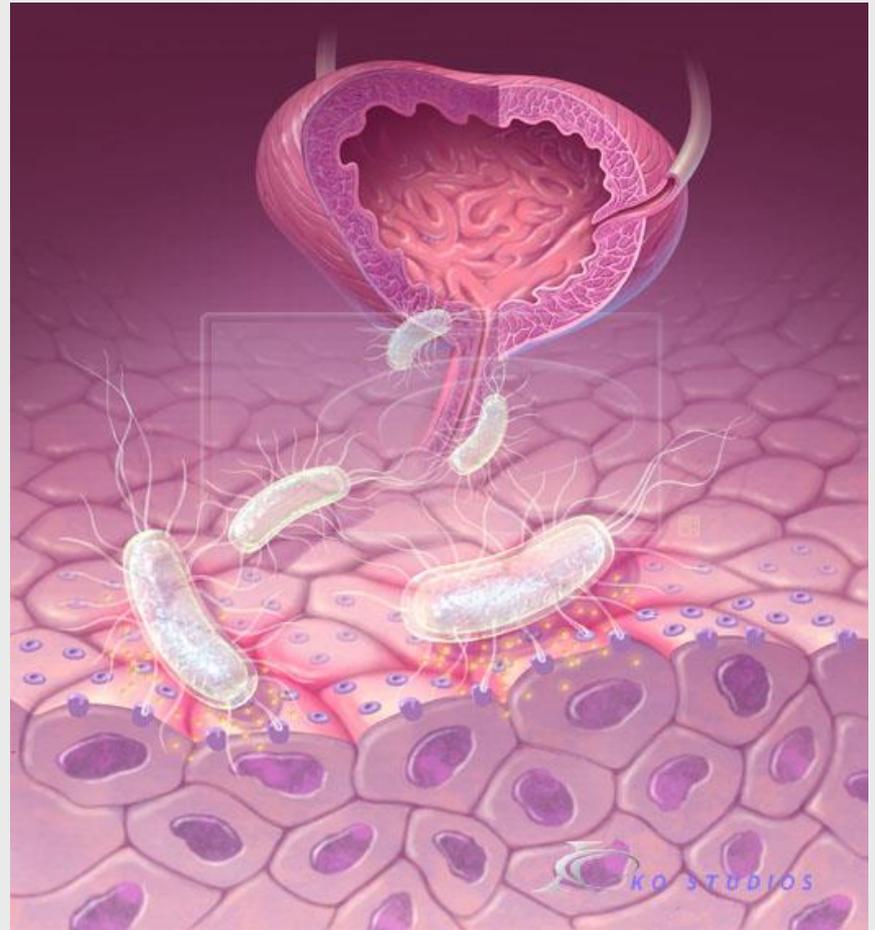
**urethra → bladder →
sometimes even higher**



Hooten NEJM 2012

UTIs...Why & How Do They Happen?

- ***Escherichia coli* (E. coli)** is a common bacteria (75-95% of episodes)
- Noxious inflammatory response
- Overcome our natural internal defense systems
- Pathogenesis for an uncomplicated UTI is the same for recurrent UTI



Hooten NEJM 2012



UTI Symptoms

Likely True Symptoms

- Frequency of urination
- Urgency of urination
- Dysuria or burning during urination
- Cannot empty bladder completely/passing small amounts of urine
- Pain or pressure in lower abdomen/pelvis
- Low back pain
- Blood in urine
- Even malodorous urine

Likely Not Symptoms

- Sore hands
- Sore feet
- Headache

Controversial in <65 & healthy

- Generalized fatigue
- Generalized malaise
- Generalized weakness

Hooten NEJM 2012

Contents

- **Urinary Tract Infection (UTI)**
- **Recurrent UTI**
- **Testing for UTI/Recurrent UTI**
- **Treating UTI/Recurrent UTI**
- **Is It Really a UTI?**

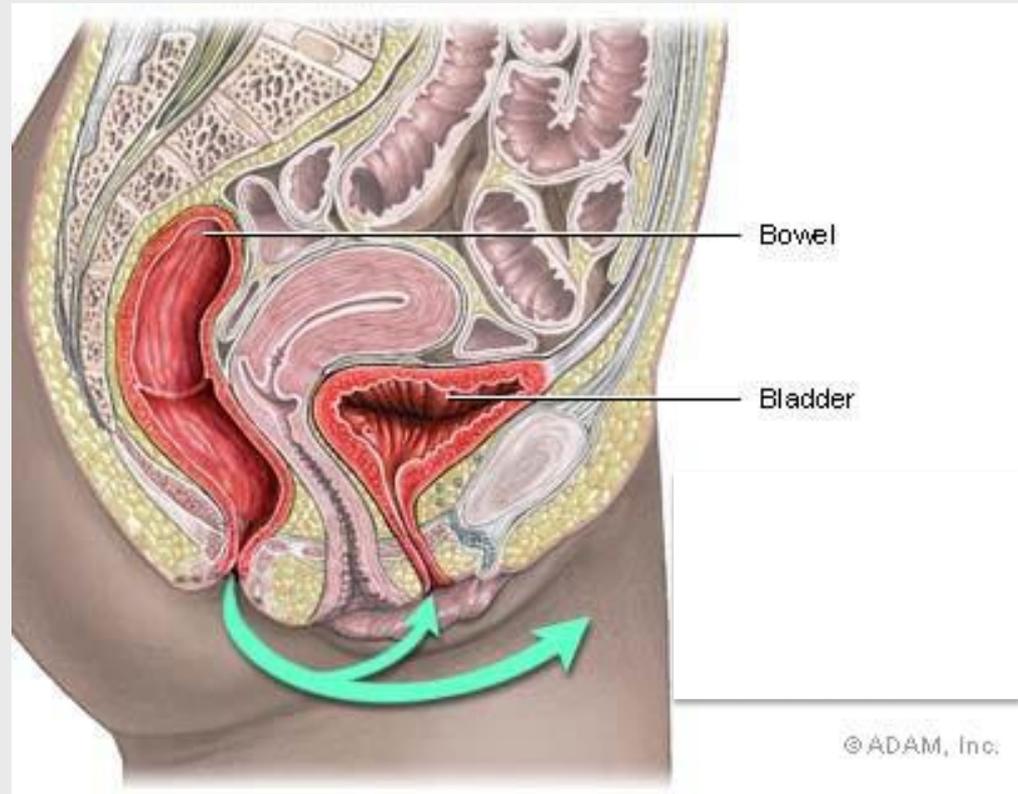


Recurrent UTI (Definition)

- **≥ 2 infections in 6 months or ≥ 3 infections in one year**
- **Reinfection**
 - **If an infection appears after two weeks of a prior infection, even if the organism is the same**
- **Relapse**
 - **Occurs if an infection re-appears within two weeks or less**
- **Most recurrences are re-infection, rarely relapse**

Recurrent UTI

- Majority of recurrences in healthy women (~67%) comprise the same bacteria
- Healthy young women:
 - 25% recurrence within 6 months of 1st episode
 - Recurrence rate increases with > 1 previous episode



Hooten NEJM 2012

Recurrent UTI

Risk Factors

- **Sexual intercourse**
- **Spermicides in younger women**
- **New sexual partner**
- **Women have short urethra's**
- **Prior UTI**
- **UTI in 1st degree relative**
- **Persistent bladder focus (i.e. stone)**
- **Pelvic anatomy – perineal body, cystocele**
- **PVR**
- **Incontinence**
- **ABH blood group non secretor**

Reasons

- **Uropathogenic bacteria can stay in the bowel for years even when eradicated from the bladder**
- **Risk of infection increases with recent antibiotic use**
- **Biofilm in the bladder**
- **Changed barrier (atrophy), post-menopausal status, lack of estrogen**

Hooten NEJM 2012



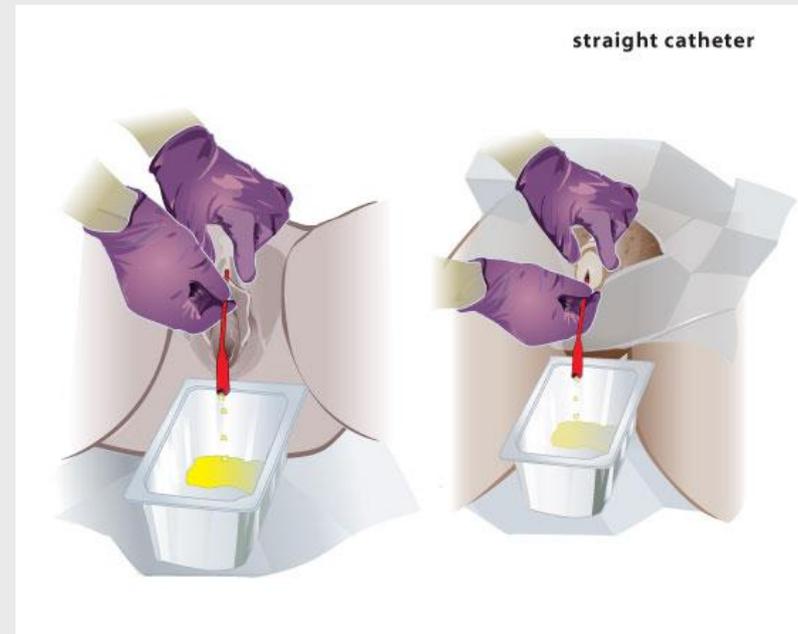
Contents

- **Urinary Tract Infection (UTI)**
- **Recurrent UTI**
- **Testing for UTI/Recurrent UTI**
- **Treating UTI/Recurrent UTI**
- **Is It Really a UTI?**

Testing for UTI/Recurrent UTI

- Voided urine specimen
- Urinalysis
- transurethral catheter urine specimen
- Urine culture

Steps involve Cleaning the Genital area voiding fore stream and collecting midstream



Contents

- **Urinary Tract Infection (UTI)**
- **Recurrent UTI**
- **Testing for UTI/Recurrent UTI**
- **Treating UTI/Recurrent UTI**
- **Is It Really a UTI?**

Treating UTI/Recurrent UTI

- Empiric antibiotics
- Wait for culture (especially in the setting of recurrent UTI)
- Treatment is becoming more intricate
 - increase in multidrug resistant bacterial strains
 - C-diff (flora concerns) “ecologic adverse effects”
 - multiple drug allergies
 - side effects of antibiotics



Treating UTI/Recurrent UTI...Colistin

Proactive Efforts by U.S. Federal Agencies Enable Early Detection of New Antibiotic Resistance

May 26, 2016 | By: [U.S. Department of Health and Human Services \(HHS\)](#)

- Pennsylvanian woman with a dreaded multidrug resistant *Escherichia coli* (mcr-1 *E.coli*, resistant even to the last resort antibiotic Colistin (typically only used when all other drugs fail) found in her lower urinary tract system
- This is the first time in the U.S. that an infectious bacterium has been discovered to be Colistin resistant, essentially, no cure or form of treatment



Treating UTI/Recurrent UTI

Antibiotic stewardship is KEY

Treating Recurring UTI

- Reassess symptoms
- Definitely obtain a urine culture
- Await urine culture results
- Consider broader spectrum antibiotics

Pyridium
Azo, Uristat
Flush with fluids

Hooten NEJM 2012

Treating Recurring UTI...Behavior?

Behavior Modifications

- Abstinence?
- Reduce sexual intercourse frequency?
- Urinate before and after intercourse
- Push Fluids
- Wipe front to back
- Loose underwear
- No douching

- Unfortunately no good evidence for any of these suggestions



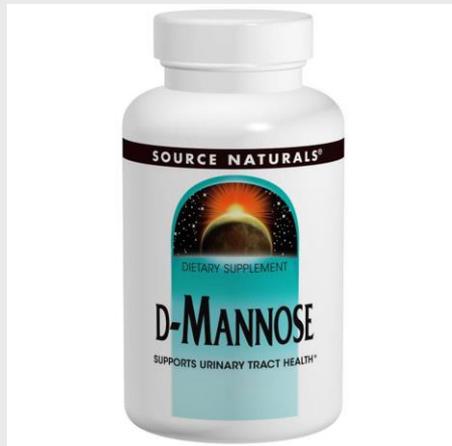
Hooten NEJM 2012

Treating Recurring UTI...

Non-antimicrobial alternatives?

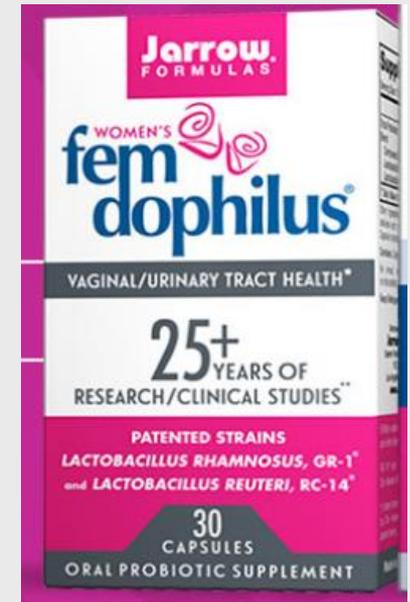
Non-antimicrobials

- Cranberry
- Vaginal estrogen
- D-mannose
- Methenamine & vitamin C
- Vaccines



Non-antimicrobials

- Oral immunostimulants (heat killed E.coli)
- E.coli (avirulent) bladder instillation
- Florastor
- Femdophilus



Treating Recurring UTI... Vaginal (Topical) Estrogen



Treating Recurring UTI...

Vaginal (Topical) Estrogen

- **Evidence it works to prevent UTI**
- **Takes about 6 weeks to start working**
- **Can be used in patients with a history of prior hormone receptor positive Br Ca**

Cranberry

The Cure for UTIs? It's Not Cranberries

By JAN HOFFMAN OCT. 27, 2016



Treating Recurring UTI

- **Daily antimicrobial prophylaxis for true recurrent UTI**
 - **When non antibiotic treatments have failed**
- **Post-coital prophylaxis**
- **Self-treatment (intermittent)**
- **Sometimes we wait and watch and do not treat**
 - **Urinary microbiome**

Hooten NEJM 2012



Treating Recurring UTI...GOAL

- Sustain an suitable standard of living and quality of life, but also reduce exposure to antibiotics



Hooten NEJM 2012

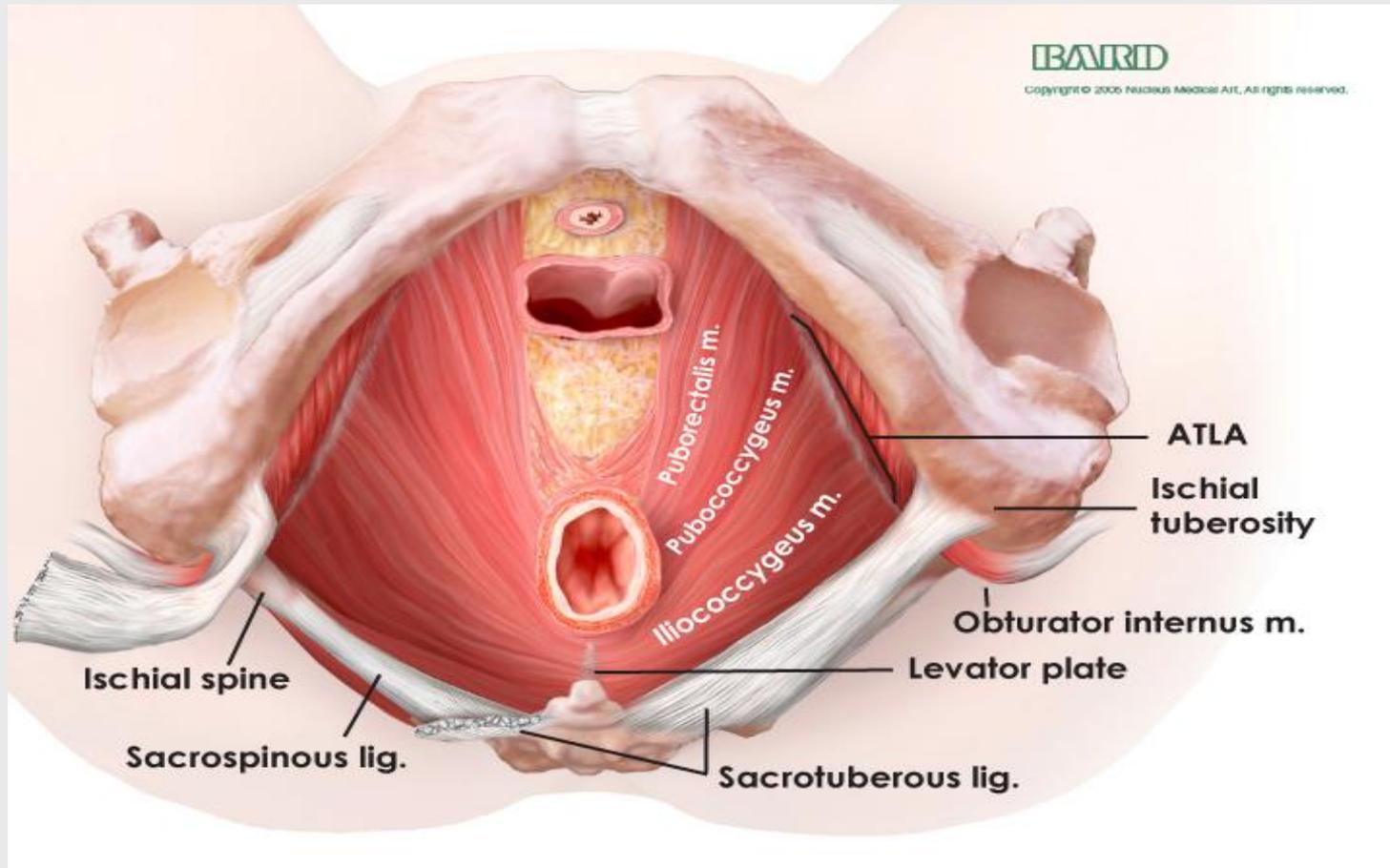


Contents

- **Urinary Tract Infection (UTI)**
- **Recurrent UTI**
- **Testing for UTI/Recurrent UTI**
- **Treating UTI/Recurrent UTI**
- **Is It Really a UTI?**

Is It Really a UTI?

- Let's not forget the pelvic floor
- Consider pelvic floor muscle pain



Is It Really a UTI?

- **Lower abdomen pain**
- **Lower back pain**
- **Pelvic & bladder pain**
 - **Burning**
 - **Sharp**
 - **Pressure**
 - **Ache**
- **Feeling of recurrent UTI**
- **Urgency and Frequency Syndrome**
- **External physical therapy**
- **Internal vaginal pelvic floor physical therapy**
- **Vaginal medications**
- **Nerve medications**
- **Acupuncture**
- **Low dose antidepressant**
- **Exercise**
- **Yoga**
- **Weight loss**
- **Abdominal support**
- **Women's health psychologist**



Is It Really a UTI?

Women's health Psychology & Pelvic Therapy

- Cognitive behavioral therapy
- Desensitization
- Relaxation before strengthening...more than Kegel's





END



Weill Cornell Medicine



New York-Presbyterian



Resources



Weill Cornell Medicine



New York-Presbyterian

Patient Advocacy and Resources

- American Urogynecologic Society
 - <http://www.augs.org/page/pop-q>



AUGS Advancing Female Pelvic Medicine and Reconstructive Surgery

Home About AUGS Education Resources Fellows Clinical Practice News Research Member Center

In this Section

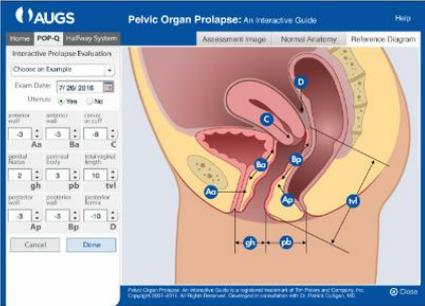
- » Awards & Scholarships
 - » Jack Robertson
 - » Raymond A. Lee
 - » Resident Scholars
 - » Robin Haff Research Award
- » Subspecialty Certification
- » Career Center
- » Information for Your Patients
- » FDA Mesh Announcements
- » Informed Consent
- » Guidelines and Position Statements
- » Patient Privacy

Pelvic Organ Prolapse: An Interactive Guide

The POP-Q Interactive Assessment Tool is a flexible application that will help you visually demonstrate pelvic floor exam results to your patients.

Through this interactive application you can enter POP-Q scores, visually demonstrate the captured measurements for patients, educate patients before and after surgery, and print out patient-specific results.

Access the tool.



anterior wall	anterior wall	central canal	posterior wall
3	3	3	3
Aa	Ba	C	Cc
2	3	10	
Gh	Gb	Hc	Hb
3	3	10	
Ap	Bp	Cc	Dc

© 2016 American Urogynecologic Society. All rights reserved.



American Urogynecologic Society
1100 Wayne Avenue, Suite 670
Silver Spring, MD 20910
P: 301-273-0570 | F: 301-273-0778
info@aug.org
Support the PFD Research Foundation

As the leader in Female Pelvic Medicine and Reconstructive Surgery, AUGS promotes the highest quality patient care through excellence in education, research and advocacy.

[Contact Us](#) | [Privacy Policy](#) | [HONcode Accredited](#)
© 2016 American Urogynecologic Society. All rights reserved.

Patient Advocacy and Resources

- American Urogynecologic Society
 - <http://www.augs.org/page/pop-q>



AUGS Advancing Female Pelvic Medicine and Reconstructive Surgery

Home About AUGS Education Resources Fellows Clinical Practice News Research Member Center

In this Section

- » Awards & Scholarships
 - » Jack Robertson
 - » Raymond A. Lee
 - » Resident Scholars
 - » Robin Haff Research Award
- » Subspecialty Certification
- » Career Center
- » Information for Your Patients
- » FDA Mesh Announcements
- » Informed Consent
- » Guidelines and Position Statements
- » Patient Privacy

FDA Mesh Announcements

On January 4, 2016 the FDA announced that transvaginal mesh implants for pelvic organ prolapse were being moved from Class II devices (generally moderate risk devices) to Class III devices (generally high risk devices) and that more rigorous clinical data would have to be provided for new products in this category. *This is not a new or unexpected announcement but may bring questions from your patients or referring physicians.*

Prior to Monday, transvaginal mesh received FDA approval through the 510(k) process which required only a predicate device for these new products to be released and used. This meant no actual patient clinical data had to be submitted on the new product (industry could utilize the data from the predicate device) and it could be on the market in as little as three months from the initial FDA submission. Transvaginal mesh implants for prolapse were able to use full-length midurethral slings as their predicate device. Again, this meant they did not have to submit actual clinical data on their new product. If sufficient complications arise from new medical devices under the 510(k) process, the FDA can require more detailed information be collected and submitted to them regarding the product. This process is known as Section 522 under the FDA Medical Devices and Radiation-Emitting Division and requires post-market surveillance of the particular product.

Helpful Links

- [January 4th FDA Press Release on Up Classification of Transvaginal Mesh Products](#)
- [FDA Surgical Urogynecologic Mesh Implants Fact Sheet](#)
- [AUGS Informed Consent Toolkit](#)
- [Archived Documents and Position Statements](#)

Useful Downloads

- [Up Classification Talking Points for Physicians](#)
- [FDA Recommendations for Patients Undergoing Treatment for Prolapse](#)

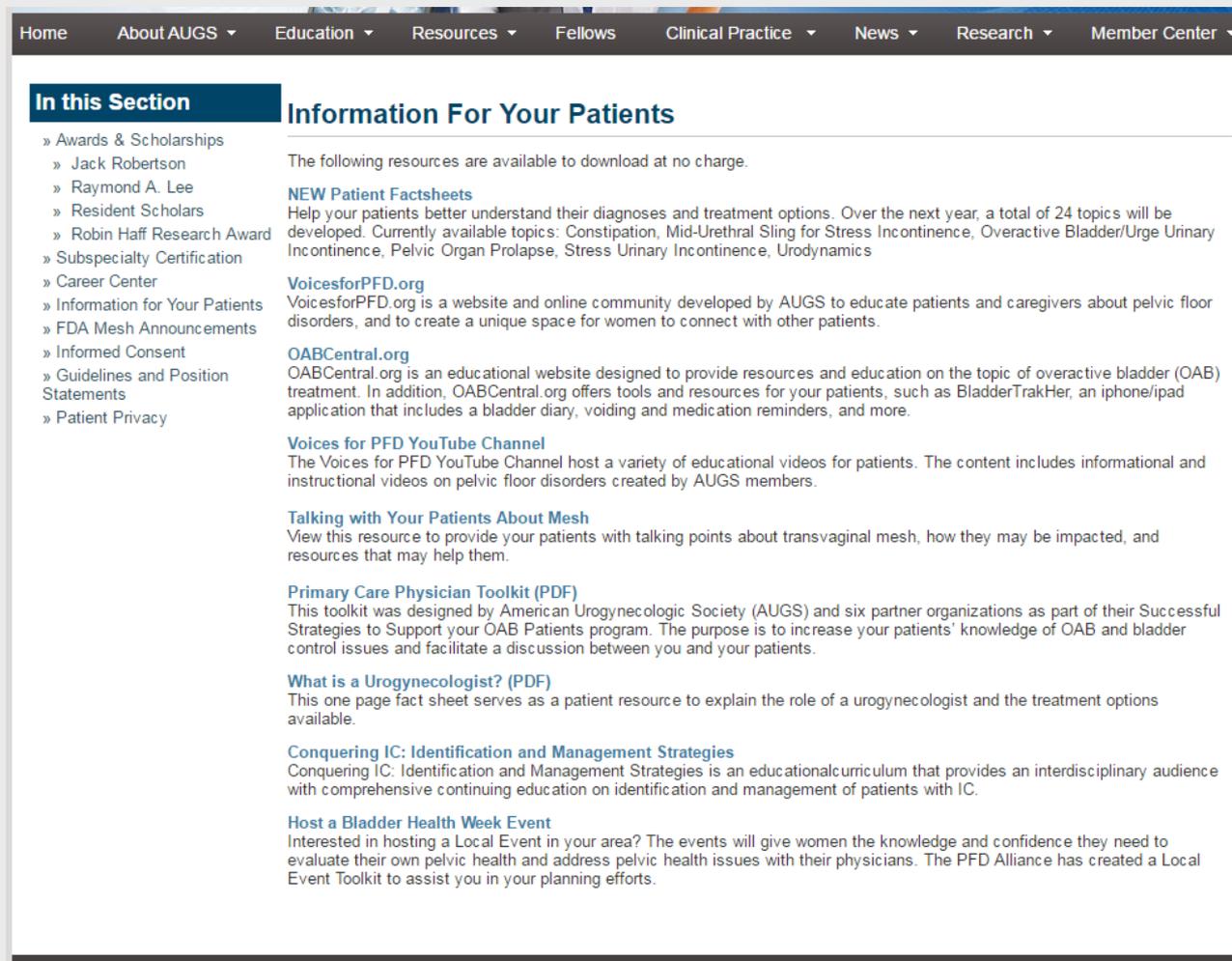
American Urogynecologic Society
1100 Wayne Avenue, Suite 670
Silver Spring, MD 20910
P: 301-273-0570 | F: 301-273-0778
info@aug.s.org
Support the PFD Research Foundation

As the leader in Female Pelvic Medicine and Reconstructive Surgery, AUGS promotes the highest quality patient care through excellence in education, research and advocacy.

Contact Us | Privacy Policy | HONcode Accredited
© 2016 American Urogynecologic Society. All rights reserved.

Patient Advocacy and Resources

- American Urogynecologic Society
 - <http://www.augs.org/page/pop-q>



The screenshot displays the AUGS website's navigation menu and a section titled "Information For Your Patients". The navigation menu includes: Home, About AUGS, Education, Resources, Fellows, Clinical Practice, News, Research, and Member Center. The "Information For Your Patients" section lists various resources available for download at no charge, including awards, career center, informed consent, and patient privacy. It also provides detailed information about new patient factsheets, the OABCentral.org website, the Voices for PFD YouTube Channel, a toolkit for primary care physicians, a fact sheet on urogynecologists, and strategies for conquering interstitial cystitis (IC).

In this Section

- » Awards & Scholarships
 - » Jack Robertson
 - » Raymond A. Lee
 - » Resident Scholars
 - » Robin Haff Research Award
 - » Subspecialty Certification
- » Career Center
- » Information for Your Patients
- » FDA Mesh Announcements
- » Informed Consent
- » Guidelines and Position Statements
- » Patient Privacy

Information For Your Patients

The following resources are available to download at no charge.

NEW Patient Factsheets
Help your patients better understand their diagnoses and treatment options. Over the next year, a total of 24 topics will be developed. Currently available topics: Constipation, Mid-Urethral Slings for Stress Incontinence, Overactive Bladder/Urge Urinary Incontinence, Pelvic Organ Prolapse, Stress Urinary Incontinence, Urodynamics

VoicesforPFD.org
VoicesforPFD.org is a website and online community developed by AUGS to educate patients and caregivers about pelvic floor disorders, and to create a unique space for women to connect with other patients.

OABCentral.org
OABCentral.org is an educational website designed to provide resources and education on the topic of overactive bladder (OAB) treatment. In addition, OABCentral.org offers tools and resources for your patients, such as BladderTrakHer, an iPhone/iPad application that includes a bladder diary, voiding and medication reminders, and more.

Voices for PFD YouTube Channel
The Voices for PFD YouTube Channel host a variety of educational videos for patients. The content includes informational and instructional videos on pelvic floor disorders created by AUGS members.

Talking with Your Patients About Mesh
View this resource to provide your patients with talking points about transvaginal mesh, how they may be impacted, and resources that may help them.

Primary Care Physician Toolkit (PDF)
This toolkit was designed by American Urogynecologic Society (AUGS) and six partner organizations as part of their Successful Strategies to Support your OAB Patients program. The purpose is to increase your patients' knowledge of OAB and bladder control issues and facilitate a discussion between you and your patients.

What is a Urogynecologist? (PDF)
This one page fact sheet serves as a patient resource to explain the role of a urogynecologist and the treatment options available.

Conquering IC: Identification and Management Strategies
Conquering IC: Identification and Management Strategies is an educational curriculum that provides an interdisciplinary audience with comprehensive continuing education on identification and management of patients with IC.

Host a Bladder Health Week Event
Interested in hosting a Local Event in your area? The events will give women the knowledge and confidence they need to evaluate their own pelvic health and address pelvic health issues with their physicians. The PFD Alliance has created a Local Event Toolkit to assist you in your planning efforts.

Patient Advocacy and Resources

- International Urogynecologic Association
 - <http://www.iuga.org/?patientinfo>



IUGA 
international urogynecological association

Home | Forums | Documents | Renew Now | Join IUGA

Membership Meetings Education Connect Affiliates Projects Resources Journal About Us

IUGA Search
Enter search criteria...
Search »

Sign In
Username
Password
 Remember Me
Sign In
Forgot your password?
Haven't registered yet?

Urogyn News More

10/7/2016
Surgical management of pelvic organ prolapse in women

9/27/2016
Incontinence affects QOL for survivors of gynecologic cancers

8/23/2016
Pessary and exercise relieve symptoms for women with pelvic floor prolapse

Calendar Dates More

10/20/2016 - 10/23/2016
38th Congress of the Société Internationale d'Urologie

10/26/2016 - 10/28/2016
43rd International Deves Forum - Update in Obstetrics, Gynecology and Reproductive Medicine

10/29/2016 - 10/31/2016
16th Biennial Meeting of the International Gynecologic Cancer Society (IGCS 2016)

Resources » Patient Information

Share |    



IUGA is dedicated to advances in knowledge of urogynecological diseases, urinary or fecal incontinence, and vaginal prolapse. Without accepting responsibility for the content, we provide a number of informational leaflets and other tools for patient reference.

+ Anatomy and Treatment Posters: 
Take a look at our posters, which are available for purchase in the IUGA online store. Click here for more info.

+ Continence and Pelvic Organ Prolapse Resource Directory: 
A listing of continence societies worldwide. Click here for more info.

+ Find A Urogynecologist Tool: 
Find a physician in your country who treats pelvic floor disorders. Click here for more info.

+ Patient Leaflets: 
IUGA is pleased to offer Patient Leaflets in pdf format for convenient download. Click here for more info.

+ Patient Videos 
A great resource for women seeking treatment or more information about pelvic floor problems.