Unofficial Ottawa Guide to EVAR and TEVAR

U of Ottawa

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Unofficial Ottawa Guide to EVAR, Anton Sharapov, MD, U of Ottawa

This is a result of putting together 4 years worth of OR notes to self re: aortic stent grafting. This is not an exhaustive authoritative guide but a rough guideline& introduction into this deal. The movers and shakers of U of O endovascular (namely, Drs. Nagpal, Jetty & Hill) are primarily responsible for drilling the basics through my thick skull but they don't know what I carried away after the case and remembered or forgot to put into these notes...:) i.e. I could have gotten it all wrong but nevertheless this is a work in progress and we shall see how it will pan out... Please let me know what needs to be added or struck out... This is not a replacement for FYI and device manuals.

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Preliminary general notes:

There is no such thing as a "GO TO GRAFT" all the time... While some swear by Gore, and others stick by Cook, there are definite advantages and disadvantages to all grafts. The reality is - for run of the mill, regular AAA, any graft would do. Problems begin when you run out of simple AAA and get into tapered short angled necks, small external iliacs etc...

Ask for nickel allergy, as nitinol stents have nickel in them...

Before starting OR, make sure that the table is positioned - with supporting base pillar under pt's feet, so that one can image the chest easily. Left arm is tucked to allow unimpeded chest imaging. Put control box on the right side of the bed.

Always close knobs on side ports of sheath toward the patient - unneeded blood loss otherwise.

You can do this procedure under spinal or local but if the patient can't lie back flat for more than 2 hours, has sleep apnea then you may end up sedating him, that will naturally progress to GA on the fly with difficult airway and doped up pt flailing his limbs... So consider GA and intubation.

Warn anesthesia to top up heparin (given after 6 Fr sheath is placed) and estimate ACT when you occlude aorta with the balloon.

Always bring the imager as close to the body as possible. All DSA are off pulse, ask anesthesia to hold respiration just before you ask for DSA, clearly state when you want injection, **ask to resume respiration.**

Abdominal aortic EVAR Summary in 5 steps:

- 1. Access and preliminary aortogram:
- bensons up
- 6Fr sheeths, (CL place 8 Fr), heparin
- Pig on CL, exchange for Lunderquist in Ipsilateral groin
- Angio to check distance to bifurcation and renal location

- 2. Main body deployment:
- Mag/center on renals
- Orient main body, track over ipsi wire
- Angio, mark renals, form diamond (for cook)
- Angio to check, deploy 2 more stents
- For Cook Remove prox tie (BLACK in old models), release suprarenal fixation
- Unfurl CL origin
- 3. CL limb deployment:
- Pull Benson/Pig to CL origin
- C2/KMP/glide to cannulate CL
- Pig intomain body over CL twirl and test placement
- Angle/center/Angio via CL 6 French (8 french CL), mark CL iliac
- count markers to ID distance to CL iliac
- confirm CL extension length
- Deploy CL extension
- repeat angio to ID ipsi iliac
- plug CL sheath with Coda
- 4. Ipsilateral limb deployment:
- Complete deployment of ipsi limb
- For Cook remove distal tie White in old models
- load up sheath with dye, shoot to mark ipsi iliac
- pig up & count markers to ID distance to CL iliac
- confirm ipsi extensions' length
- Deploy ipsi extensions
- repeat angio to ID ipsi iliac
- 5. Ballooning and troubleshooting:
- Coda balloon to CL then main
- Completion angio
- Trouble shoot

Cook Abdominal graft:

Basic construction:

- 1. outside dark blue sheath with the valve at the proximal close to operator end.
- 2. inside the sheath sits the Grey Positioner Shaft with a channel running through it.

- 3. In the very center of the grey positioned shaft, runs the stiff wire with the pink hub on proximal end. Distally it is attached to the nosecone.
- 4. Nosecone sticks out of the sheath. Scalloped portion of the Grey Positioner Shaft is proximal to it: that's where the collapsed graft sits.
- 5. Nosecone is hallow and hides the outside fixation rods for the abdominal graft. Nosecone is separate from the Grey Shaft in Abdominal stents, sitting on the central stiff wire with the pink hub but it is screwed to the grey shaft with a small nut (need to release it before manipulating it).
- 6. within the scalloped portion of the Grey Positioner sits the collapsed graft, the bare proximal barbs are housed in the nosecone.

To prepare main body - remove metal pin (black head) from the pink end, remove black breakaway cover between the body and the sheath (slide out), inject end (pink) port and side catheter in the middle of the graft. Tip goes up to allow filling of the transparent camera of the side catheter.

Graft Deployment Mechanism:

- Graft is deployed by steadying the Grey Positioner Shaft with Right hand and Sliding out the dark blue sheath with Left exposing the graft nestled in the scalloped portion of the Grey shaft thus allowing graft to spring open. Indecent male anatomy images come to mind.
- First 2 stents of the graft spring open in the diamond shape. It is diamond, because the end is not fully expanded as it is tethered by the 1) holding proximal trip wire (used to be BLACK KNOB on old models), and 2) nose cone housing the suprarenal fixation spikes.
- In abdo stent, once first several stents are deployed and you are ready for suprarenal hooks, **RELEASE proximal trip** wire then turn the knob releasing the pink wire and slide the pink knob proximally with right hand inside the grey shaft: it will move the cone up and uncover the proximal fixation spikes.
 - O Black knob on the main body releases a tie that holds proximal end of the main body to the delivery system. You need to release this to allow deployment of the barbed suprarenal fixation housed in the nosecone. White knob corresponds to the distal fixation tie that is released after the distal end of the main body is deployed. **NOTE: new main body does not have black and white colors.**
- White knob holds DISTAL trip wire release it after you deployed the iliac end of the main graft.
- Finally, remove the grey positioned and nose cone but leave the sheath in place. However, after the proximal barbs are released, in order to avoid potential snagging of the barbs by the edge of the nosecone being pulled down, it is important to move UP the grey positioned shaft first to dock the cap, and then to pull out the grey delivery device (leaving the sheath in place). To do this, unscrew the tightening pin on the pink hubbed wire, ask you assistants to hold pink hub wire steady, and, while holding the sheath in place slide the grey positioned forward until it docks with the cap. Tighten the pin screw and now pull out the grey positioned and then nose cone leaving the sheath in place.

Size and length considerations:

Go to https://ifu.cookmedical.com/ifuPub/lookupIfu.jsf to look up IFU, Enter: G48464

Sheath size is VERY important and OFTEN companies – for marketing reasons – present ONLY INNER diameter of the sheath – which is not the most relevant factor. Outer diameter is what counts. I don't understand why companies insist on stating inner diameter only unless they hope to slide the graft bareback (only medtonics Talent and Endurant are designed for no sheath introduction).

For Cook Main body

22, 24, 26 mm – 18 ID, **21** (OD)

28, 30.32 mm – 20 ID, **23** (OD)

36 mm – 22 Fr, **24 Fr** (OD)

For AUI Converter:

24 mm 18 Fr OD 28, 32, 36 mm 20Fr OD

French Gauge	Diameter (mm)	Diameter (inches)
3	(<i>mm</i>)	0.039
4	1.35	0.053
5	1.67	0.055
6	2	0.000
7	2.3	0.079
8	2.3	0.092
9	3	0.118
10	3.3	0.131
11	3.7	0.144
12	4	0.158
13	4.3	0.170
14	4.7	0.184
15	5	0.197
16	5.3	0.210
17	5.7	0.223
18	6	0.236
19	6.3	0.249
20	6.7	0.263
22	7.3	0.288
24	8	0.315
26	8.7	0.341

The main body of the graft has longer ipsilateral limb and shorter conralateral one. There are several pre-defined length. Each graft is coded by 2 numbers. E.g. 30-82 - means that the proximal diameter is 30 mm and the length of **CONTRALATERAL** limb is 82 mm. This latter measurement is important as the CL limb length should not be longer than the distance to the aortic bifurcation. Also, if the calculation sheet suggest you use the main body of, say size 111, but the renal – bifurcation distance is 120, you know that you ONLY have 9 mm between CL iliac and the limb to cannulate – so you CAN'T afford to slip your main body during deployment at all. To be on a safe side, chose a shorter main body and – say 96 mm and leave yourself some room for cannulation.

The ipsilateral limb length is always 51 mm (3 stents) and contralateral -21 (mm) - i.e. 30 mm shorter. The main body itself varies in size. This may be of advantage - if you have long main body and require revision procedures, you may be able to accommodate a bifurcated revision device and avoid AUI. Other grafts have a predefined main body length.

Another important fact, is that distal end diameter of both ipsi and conralateral end of Cook graft is always 12.

On the contralateral limb, one can overlap up to 1.5 stents, i.e. 22 mm. For same side, the ipsilateral lenght is two stents longer compared to Contralateral. Hence, a 28 mm overlap – i.e. 2 stents - plus an extra 1 stent to the bifurcation - to a max 3 stent overlaps on ipsilateral side is allowed. If you exceed the overlap, you'll go post graft crotch and the this is not kosher according to the rep...

On the contralateral limb, one can overlap up to 1.5 stents, i.e. 22 mm. For same side, the ipsilateral length is two stents longer compared to Contralateral. Hence, a 28 mm overlap – i.e. 2 stents - plus an extra 1 stent to the bifurcation - to a max 3 stent overlaps on ipsilateral side is allowed. If you exceed the overlap, you'll go post graft crotch and the this is not kosher according to the rep...

Choosing sizes:

In elective situation, you can just order the right length - Just follow the point by point protocol... You'll need to know the proximal aortic diameter, neck length, divergence, angle of the neck, distance to aortic bifurcation, distance to each CIA bifurcation – get a 2-3 mm scan, note station numbers, adjust for angles (i.e. for iliacs lengths use squared right angle triangle rules - Pythagorean theorem.)

In emergency situation you have limited supply so you end up with the main body (called TFFB) that is either too short or too long. So here is what I do.

You have to make sure that contralateral does not reach to the bifurcation as it will be difficult to cannullate it with an iliac extension. You'll need to evaluate the body of AAA length and make sure it is not too short...

As mentioned before, the size of main body is usually given as composite of 2 numbers - say TFFB 28 – 96 signifies proximal diameter is 28, and conralateral limb is 96 mm. Ipsilateral length is not given but it is always 30 mm longer than contralateral one... i.e. for 96 it will be 116... for 82 it will be 112. Give yourself LOTS of room on the CL side to cannulate.

The lengths of iliac extensions (noted as TFLE) are given as such: TFLE 14 - 54, i.e. the distal diameter is 14 (remember, proximal diameter is always 12) and working length (after overlap is taken care of) is 54 mm. Please note, 54 and 71 mm lengths are most common...

Note, that unlike Talent stents where distal diameter (of, say, 14 mm) is the actual diameter of the entire extension, the Cook graft have a bell bottom construction with only distal stent having the target distal size, then next stent is transition, and the remainder of the proximal length is 12 mm.

Remember, that the diameter of the each main body limb end is 12 mm. So you'll have to choose one long extension that has proximal 12 mm diameter and distal extension with the diameter of the target common iliac artery size. This is difficult when you are trying to mix & match and cobble up a bifurcated graft, as you'll never have enough extension to match the size.

Alternatively, you can choose an short interposition graft of 12 mm prox/12 mm distal size and then add to it your short 12 mm Prox/distal target size for the final extension. That way you can telescope extensions into each other and get the right length.

In Cook, the length of extension is pure extension distance, stent overlap already is taken care of. You need 1 stent, at most 1.5 for contralateral limb (if more, then it will protrude in the main body). For Extension on the main body side, you can telescope stent more, i.e. up to total of 3 stent overlaps..

It follows, then, for emergency supply you'd rather have a bunch of short to mid size main bodies, a bunch of long and short (12->12) links and a bunch of short (12->target size) extension finishers.

Diameter: Important when considering iliac vessels... Generally, Cook delivery system has 20 Fr (6.7 mm) inner diameter, and 21.5 Fr (7.7mm) outer diameter. i.e. you WON'T squeeze through the 6 mm iliacs...

Iliac limbs are smaller: they are all different depending on limb diameter - i.e.

- for 16 mm end, it is 4.7 mm(14 Fr) inner, 5.3. mm outer diameter.
- for 18 mm end, it is 5.3 mm inner, 6 mm outer...

I.e. it means, you need to have at least 7 mm one iliac(ipsi) and at least 6 mm the other (CL).

http://www.cookmedical.com/ai/dataSheet.do?id=4867

UPDATE: Cook came up with NEW iliac extensions. They are extremely conformable and maintain lumen diameter in most tortuous vessels. Very neat.

Pre-deployment notes:

3 off the wall statements that I keep reminding myself for no particular reason whatsoever...

- 1. Place at least 8 Fr sheath in CL groin, because you have to shoot angio through 8 Fr sheath with Pig in it to mark CL iliac origin... You can't do this very well with 6 Fr, dye won't go through.
- 2. For Cook graft, from the outset select 100 cm pig tail when you have deployed the iliac limbs and the deployment sheaths for Cook graft are partially out, they are sticking out far enough out of the groin to make usual 65 cm Pig not long enough to reach the renal arteries. For Medtronic Talent, you'll replace the deployment device with short 14 Fr Sheaths, so you can get away with shorter pigs...
- 3. When imaging renals, always take note of bony landmarks and mark these on the screen... If the imager is too low on the chest, when the pt takes a breath, the chest will rise and move the imager and you'll mark renal wrong/deploy too low...

 Breathing does not affect the location orifice of the renals, just the organs overlying it as well as the mask on DSA... But gas in the guts screws the mask in abdomen anyway...

Summary on main body deployment steps:

- hold grey positioner, slide out sheath, from diamond, confirm with angio, complete release until CL limb unfurls
- release proximal (black) trip wire
- slide forward top cap: release pin, hold grey positioner and slide pink wire forward.
- cannulate C/L, reposition pig, iliac CL limb deployment
- complete main body release by sliding sheath over positioner
- slide positioner forward over the pink wire to dock the cap, tighten pink pin grip
- hold sheath (ensure its' end is in External iliac) and remove grey positioner.

Detailed Deployment technique:

B/l groin dissection - transverse along ilioinguinal lig.

Small incision below the main incision to create a tunnel to allow more comfortable lie of the graft.

- guide needle through this incision and puncture with normal size needle
- may use mosquitoes to guide the needle

Benson wires up bilaterally

6 Fr Sheaths ipsilateral, 8 Fr contralateral

• Suture them as they WILL fall out

Exchange for Stiff wire on R (main body) over KMP catheter

- advance into arch
- Mark the position of the stiff wire end on the drape don't want it to move

Advance pig tail (100 cm, graduated) on L to T12-L1 level through CL groin

- Connect pig to power pump injector to the right of the monitor
- Don't forget to flush air out (bump up and aspirate once connected)
- Get two or three extension tubes to get the distance between the table and the pump (source of contamination).

First injection:

- get approximate renal artery location and bifurcation in the same screen.
- Need to visualize and confirm the distance to bifurcation and see if you calculated the main body size right.
- Use pig tail (calibrated).

Second injection: Mag up on renals.

- Center over renals. Shoot angio and ID renals.
- Ask tech to come in front of the monitor and mark them on screen.
- if aorta goes anteriorly, may want to tilt projector cephalad... Or sideways depending on the orientation of the renals.
- Usually need R lateral-anterior-oblique 10 degrees and cranio-caudal 10 degrees.
- Use 12 cc for total of 24 or 15 for 30 if AAA is large and no thrombus. Can get away with 12/20.
- Ask them to come off pulse first, then arrest breathing and shoot angio.

Position main body on skin surface and ID J position on CL limb

- should see straight profile on the opposite (L) side
- When J is seen, the CL limb is anterolateral,
- if it is seen in reverse, it is posterolateral,
- if it is seen as an "I" i.e. straight line, CL limb is lateral...
- FYI from Cook they recommend deploying the the marker pointing anteriorly, but some like it laterally. Antero-lateral projection makes sense as the direction of the ilacs point anteriorly as they come from the pelvis...

Remove R 6 fr sheath and Place Main body over R stiff wire, advance to just below renals.

Position 4 small gold dots 2 mm below renal takeoff and orient J

- Fabric is 2 mm above the markers...
- Orient J appropriately

Hold GREY POSITIONER tube with R hand and slide out proximal dark sheath keeping edge of the graft below renals. May use floppy rubber holder to secure your grip (available on newer devices). Deploy 2 stents, stop.

- Graft with open forming a diamond.
- May shoot another angio when diamond is out to check renal artery orifice and gold dots

NOTE: Cook manual suggest you cannulate contralateral limb at this point, but I was trained to complete proximal deployment first so that you won't move the proximal edge of the graft deploy too low or two high...

If happy, remove the proximal tie and deploy the suprarenal fixation:

- Remove distal black nub and pull out wire.
 - o This will allow to advance the tip of the main body of the devise to slide up.
- Loosen screw around thin metal pin 3/4 turn and then slowly advance this pin into the grey positiner tube while watching the struts with spurs unfurl and engage.

Slide out dark sheath until contralateral limb unfurls and stop.

Place benson into pig and pull the pig tail (presently sandwiched between aortic wall and the main body) out to the outside of the contralaral limb of the main body.

Exchange for pig for KMP cath or C2 cath plus glide wire and canulate contralateral limb.

- You may do entire thing with pig tail and benson but this is hard...
- You may try MPA but it is too long and is not as angulated as KMP.
- Would change for angled Glidewire right away
- if KMP does not work, would try C2...
- May try Vanchi 5 thing... (catheter that will hook at the edge of the CL limb)
- to improve control and add another angle, may put Raabe 6 Fr Sheath (curve tip with thumb/index first) or 8Fr cath with a curved tip then use your KMP or C2 and you'll have an extra degree of rotational freedom
- alternative up and over from ipsi and either fish out wire in CL limb or use snare
- It is tough.

Once canulated, exchange KMP or C2 for pigtail and advance it into the main body.

How to check intraluminal placement for CL wire:

- twirl the pig
- coda balloon
 - o put coda balloon (needs 9Fr sheath at least) over the wire that you think is in the CL limb
 - o advance it to overlap the bifurcation, then inflate the balloon and see if it gets dented by the bifurcation as it spills over.
 - o If no denting, then you have not canulated the CL limb...

Place stiff glide wire in CL limb.

Tilt angio 30 degrees obliquely (RLO for L iliac) and Shoot retrograde angio via contalateral 8 Fr sheath to ID L internal iliac take off

- pull down pig tail with graduations to measure true distance between contralateral end of the limb and internal iliac.
- To better visualize internal ilia (if it is pointing posteriorly), may have to do extreme caudal tilt of the C-arm.

Select extension size. May have to mag up.

In Cook, the length of extension is pure extension distance, stent overlap already is taken care of. You need 1stent, at most 1.5 for contralateral limb (if more, then it will protrude in the main body). For Extention on the main body side, you can telescope stent more, i.e. up to total of 3 overlaps..

If you placed an extension and the end of it looks crimped in and narrow, you may have miscalculated and landed it more distally (i.e. into the External iliac).

If you feel it is going to happen and you maxed out on the in-graft stent overlap, try to slide up the delivery device in between stents popping out as you deploy the extension

• thus "accordioning" the floppy fabric between the stent and gaining extra 2 mm per stent interface.

Remove pigtail and place extension into the contralateral limb. Slide sheath down over grey tube and this will unfurl the graft. There are no nubs to pull here, just loosen the nut 3/4 turn over metal pin and (unlike with proximal main body deployment) pull pin out and dock with the sheath).

IMPORTANT: on most Cook extension sheaths you DON'T see the tip of the sheath clearly – the radio-opaque band is too thin... So beware of pushing the sheath blindly - not only will you snow plough the endothelium/dissect, you'll may push the iliac extension back and displace it. It has been done before, so don't go there... I was told that a remedy is being worked on.

Remove grey delivery device from CL limb, leave sheath in place and place Coda balloon into the sheath of the extension

• to close off large hole around the wire and prevent bleeding.

Complete deployment of the ipsi limb. Once limb is unfurled, recapture the nose cone:

- Steady metal wire with pink knob and the blue sheath, and slide grey tube proximally under direct vision and dock the tip of grey tube into nose cone.
- Do not forget to REMOVE WHITE tie that holds the graft to the delivery shaft.

Steady blue sheath, and pull on the pink knob/steel wire and remove the device leaving blue sheath in place.

Main body sheath has nice valve, but extension sheath does not... Tighten valve on main sheath.

- After deployment of the device, diaphragm in the main body sheath is too loose to allow hemostatic seal around the device, so it will leak all the time..
- So either use fogarty clamp to clamp the sheath, or put pig or coda balloon or 14 Fr sheath through the diaphragm of the Cook sheath to stop leaks...

Ipsilateral extension:

- Pull sheath on ipsilataral side to below R internal iliac artery (may need to do angio)
- Place pig tail to measure distance between R internal iliac and edge of the R limb of the main body.
- Advance grey tube proximally and dock with the edge of the cone at the tip, then withdraw completely leaving large sheath in place and tighten valve.

Keep you hands on the sheaths and prevent them from coming back, particularly in thin patients. If you pull them out on accident, you'll lose half a unit in 3 sec and you'll need grey introducer to advance them if they come out (or else they'll snow plow the endothelium).

Place R extension through main body sheath and deploy - when in place, slide extension sheath out, watch graft unfurl, then loosen cap, pull pin down to dock with extension sheath, pull out.

Balloon every junction. Feel the resistance manually.

- Don't overdistend.
- Stay INSIDE fabric all the time, particularly in iliacs
- Keep it inflated for 15 sec.
- Take pictures for every balloon.
- Balloon may rupture fabric...
- If bifurcation is too tight, you may want to do kissing balloon dilation of the graft at the bifurcation to prevent inadvertent reduction in diameter of the limbs.
- Confirm with angio shots centered on bifurcation with pig in the main body.

Place pig tail over CL wire past renals, and do completion angio and look for:

- 1. renals and iliac open (you did not harm the pt)
- 2. endoleaks? type 1 vs 2 vs 3?
- 3. aneurysm is excluded(you made him better)

Trouble shooting:

If proximal leak - re-balloon, consider palmatz. If persists, you can put prox extension. If type 3 - may need to reline with AUI...

• If AUI is placed initially, rapid filling of CL iliac is indicative that something fishy is on the go.

• Pull pig into graft, occlude aorta proximally, and shoot dye.

Summary:

- 1. Access and preliminary aortogram:
- Bensons up
- 6Fr sheeths, (CL place 8 Fr), heparin
- Pig on CL, exchage for Lunderquist in Ipsi
- Angio to check distance to bifur and renal location
- 2. Main body deployment:
- Mag/center on renals
- Orient main body, track over ipsi wire
- Angio, mark renals, diamond (for cook)
- Angio to check, 2 more stents
- Remove prox tie, release suprarenal fix (for cook)
- Unfurl CL origin
- 3. CL limb deployment:
- Pull Benson/Pig to CL origin
- C2/KMP/glide to canulate CL
- Pig into main body over CL
- Angle/center/Angio via CL 6 French (8 french CL), mark CL iliac
- count markers to ID distance to CL iliac
- confirm CL extension length
- Deploy CL extension
- repeat angio to ID ipsi iliac
- plug CL sheath with Coda
- 4. Ipsilateral limb deployment:
- Complete deployment of ipsi limb
- load up sheath with dye, shoot to mark ipsi iliac
- pig up & count markers to ID distance to CL iliac
- confirm ipsi extensions' length
- Deploy ipsi extensions
- repeat angio to ID ipsi iliac
- 5. Ballooning and troubleshooting:
- Coda balloon to CL then main
- Completion angio
- Trouble shoot

Sherbrooke variation (Dr. Benko)

They do it slightly differently.

They use 2-3 frames/sec (not 15, like in Ottawa) to reduce radiation dose.

On CL side, they put 5 Fr cath followed by lunderquist for CL limb.

Above 5 Fr puncture, they put pig tail bareback. Pig is kept there until the main body is deployed, then pulled into aneurysm from where it is used to image CL iliac to measure and deploy the CL iliac limb. It is then pulled between main body and CL iliac limb extentension and is re-canulated in the fully deployed CL limb and placed in the lower part of the main body to perform injections for the ipsilateral iliac measurement. I.e. thus there is no need for back injections through the sheaths to id iliacs.

If there are internal iliacs, they don't pull back on sheaths to allow flow into external iliacs...

on ipsi side, they don't use sheaths, just KMP cath with lunderquist. Limbs are oriented in lateral orientation (i.e. check mark is a straight line).

Summary on abdominal bifurcated Cook device:

- 1. Reliable device with somewhat involved deployment protocol. However, able to deliver the device with great precision
- 2. Excellent columnar strength and radial strength.
- 3. True suprarenal fixation with barbs and 12 stainless steel wire hoops may be an advantage for short tapered necks
- 4. Main body can be long so if revision procedure required, can still use bifurcated relining
- 5. Has "Renu" device available converts bifurcated into Aorto-Uni-Iliac configuration. Very helpful for slipped/migrated grafts revisions. Very precise delivery
- 6. Has stiffer body then other grafts but company is working on creating lower profile
- 7. Treats proximal diameter necks of up to 36 mm
- 8. The most advanced platform to-date used for fenestrated grafts. No other company has reliable working fenestrated program with track record of Cook.

Final notes on Cook:

What gives the graft its' columnar strength? In abdominal grafts it is the bar that runs on the medial side of the extensions, the stiffness of the body plus, most importantly - the fact that graft rests on the distal landing zones. If there is no bar, then the graft migration will be determined by how strong proximal fixation it has. Cook has the best proximal fixation with hooks. Anaconda has very limited columnar strength so it may need palmaz stent to reinforce proximal fixation zone.

Off label applications:

Cookakonda - body Cook, iliac anaconda - for tortuous iliacs...

Thoracic stent for infrarenal aorta - for perforated ulcers/small aneurysms with distal aorta intact... Cook thoracic stent has proximal barbs but not as agressive as abdominal version. Minimal length is 70 mm. It also has the bar to help with columnar strength. you can't really use talent thoracic graft in abdomen - has no bar. Anaconda iliac limbs- max diamter of iliac limb is 18 mm.

Medtronic products:

Currently, there are three products being offered and one being phased out. Talent is on the way out. AneuRx AAAadvantage (older system), Aortouniiliac system, and Endurant (newcomer) are here to stay.

Talent graft: abdominal bifurcated - PHASED OUT. NOW replaced by Endurant (see below).

 $\underline{\text{http://manuals.medtronic.com/wcm/groups/mdtcom_sg/@emanuals/@era/@cardio/documents/documents/m707213b001_cont_20080415.pdf}$

Graft description:

Nitinol based stent. Easy deployment. The only stent FDA approved for 10 mm necks and 60 degrees angulated necks.

 $\frac{http://www.medtronic.com/wcm/groups/mdtcom_sg/@mdt/@endov/documents/documents/talentabdominalbrochure.pdf?bcsi_scan_17DEB92708C82C35=1$

Graft preparation:

- 1. inject proximal port, see it squirt distally.
- 2. Check that transparent button is fully engaged (the one that you release later on to allow docking of the cap after graft deployment)

Calculating sizes:

For elective cases, you have work sheet and you can order custom made bifurcated graft. For emergency situations, you are stuck with AUI.... Note, the notations:

Main body AUI: AUF 3016 (proximal 30 mm distal 16 mm), C125 (length is 125 mm). Iliac extensions: IXW 1814 (proximal 18 mm distal 14 mm) C75 (length 75 mm)

Note, that distal main bifurcated body limb diameter is always 14 mm (for AUI it could be any number)... Iliac extensions, (unlike in Cook - prox always 12, distal varies) - have variable collection of proximal and distal sizes, so that makes it difficult to have a stock of iliac extensions for ER cases...

Oversize proximal diameter by 20% - that way you'll be able avoid troublesome type 1 leak. Cook (stainless steel) is oversized proximally by 10%. Also, Nickel content in Talent graft is higher than in Anaconda, so it will expand much more then you'd expect in Anaconda. Iliac extensions are oversized by 2 mm, max 3 mm...

Main body is always 50 mm, CL stub is always 30 mm long. That means - contralateral limb/extension overlap can never be more than 3 cm... If more, then extension will protrude into the main body, the rep will get bent out of shape saying that it will cause emboli etc.. I asked if they worry about the in-folding of the extension and covering the main lumen? They tell me that's not the issue... I don't see why not, though as you'd just move bifurcation up...

Distal diameter of each limb of the MAIN bifurcated body is always 14 mm.

For contralateral limb, figure of 8 radio-opaque marker is about *1.5 cm ABOVE* the actual orifice of the CL limb, so don't aim at the marker when trying to canulate it..

Instruction manual states that bifurcation should be at least 28 mm (each limb is 14 mm wide), so if it is smaller, then go with smaller profile system (Gore, Anaconda, Cook) or AUI.

Extensions have three markers, one each at the prox and distal edge and one at the proximal end signifying minimal (2 stent) overlap....) When adding extensions, subtract 15 mm from length for overlap to calculated useful length. Ideally, achieve 2 stents overlap..., i.e. the entire length of the CL stub... Then, predictably, CL extension useful length will be 30 mm shorter...

Wires above proximal edge extend 14 mm above..

On review of CT estimate Aorta is travelling - if anteriorly, then do Cranio-Caudal incline of C arm to get true AP aortic diameter, if to the left, may do oblique... Usually need R lateral-oblique 10 degrees and cranio-caudal 10 degrees.

Technique:

Assume R side main body L:

- 1. b/l groin dissection transverse along ilioinguinal lig. Needle puncture, benson wire up under fluoro.
- 2. 6Fr sheath up on the ipsilateral and 8FR ON THE CONTRALATERAL (when you need to back inject to see CL internal iliac, you won't be able to inject through 6 french with pigtail in place...) DON'T drive in sheaths all the way to the hilt you will dilate the arteriotomy to size greater than 6 and this will leak...
- 3. glide cath or KMP up to help navigate wires up into descending aorta. Exchange for lunderquist wire on R over glide cath (or KMP), place pig tail over benson wire on L
- 4. Shoot angio with power injector (12 ml for total of 24 ml, i.e 2 sec) you do this angio to ID position of renals and aortic bifurcation. Count out on pig the distance and see if your main body is longer than that (i.e. ipsi limb will end up in the ipsi iliac). Don't forget to ask pt to stop breathing and then resume it. Ask to put up landmarks, note where renals are wrt L1 and L2, position pig appropriately, center the screen so that renals would be in the middle of the screen. MAG UP. Tilt fluoro appropriately.
- 5. Fluoro graft before insertion and confirm correspondence of dot on the deployment mechanism and figure of 8 on the contralateral limb visually. Place main body on R position edge around L1-L2, keep dot pointing medially to ensure that CL limb is positioned contralaterally...
- 6. shoot another angio, this time only 12 for 15. ID renals and mark them. Place markers below renals and deploy graft by rotation the lever. Graft will tend to move up... So start high and pull it down.. You can't push graft up once deployed but you can pull it down... (see note for AUI below) Need to keep constant down ward pressure until the graft is fully deployed. If magged up for the first portion, then you have to come off magnification to see where the distal part lands.
- 7. half way through deployment shoot angio to see if renals are ok. Warn tech to be ready to shoot half way through. Top up the dye supply preemptively.
- 8. when contralateral limb is out, rapid deploy (Left hand over proximal, L thumb against the rapid deployment part, R hand depresses release and pulls out distal part.
- 9. go as far as the sheath on R and then with R hand press transparent button on the end of the graft and pull out the end of an inner shaft until the conical top of the graft delivery system docks onto sheath while L hand holds the graft. This allows to capture the nose cone into the sheath prior to pulling the delivery out...
- 10. CL limb place Benson wire to straighten pig tail and pull it out to the entrance of CL limb. May attempt to place wire into CL lumen now or use Venschi5 (shepherds hook)

cath. May need to use C2 catheter, or KMP. May need to rotate R lateral oblique or L lateral oblique while shooting fluoro. to see where you are at... Note: figure of 8 marker is about *1.5 cm ABOVE* the actual orifice of the CL limb, so don't aim at it... May need to mag up. May need to change for LAO and PA.

- 11. Advance pigtail into main body and rotate several full turns. Or else, Coda balloon trick. See cook graft for details. Switch L benson for lunderquist over pigtail.
- 12. Bring up L CL limb extentions. It has figure of 8 right **on the edge**. So you need to park 8 vs 8 marker for 1 stent overalap. Deploy extension. May go more if necessary maximum 2 stents overall i.e. 3 cm. Don't annoy reps.
- 13. Remove delivery devises and exchange them for 12 Fr sheaths. NOTE: this is not necessary for Cook graft as their own deployment sheaths can be used for angio. Tilt LAO and do hand injection to ID iliacs. If don't care re: internal iliac (if occluded) then don't need angio, just go straight for another extension, then 12 Fr sheath then balloon... place pig tail (graduated) to ID length of extension needed.
- 14. Place extension by switching 12 Fr sheath for extension body delivery system, deploy.
- 15. Do ballooning of all junctions via 12 Fr sheeth. IMPORTANT: ipsilateral main body limb does not have a supported stent portion close the bifurcation don't over-distend the balloon there, may rupture...
- 16. Complete angio with pigtail while aspirating on 12 Fr cath with 60 cc balloons to create suction and allow dye to circulate...

So... Summary in 5 steps...:

bensons up
 Fr sheeths, heparin
 Pig on CL, exchage for Lunderquist in Ipsi
 Angio to check distance to bifur and renal location

2. Mag/center on renals
Orient main body, track over ipsi wire
Angio, mark renals, diamond
Angio to check, 2 more stents
Remove prox tie, release suprarenal fix
Unfurl CL origin

3. Pull Benson/Pig to CL origin C2/KMP/glide to canulate CL Pig into main body over CL Angle/center/Angio via CL 6 French, mark CL iliac count markers to ID distance to CL iliac confirm CL extensions
Deploy CL extension
repeat angio to ID ipsi iliac
plug CL sheeth with Coda

4. Complete deployement ipsi limb load up sheeth with dye, shoot to mark ipsi iliac pig up count markers to ID distance to CL iliac confirm ipsi extensions
Deploy ipsi extensions
repeat angio to ID ipsi iliac

5. Coda balloon to CL then main Completion angio Trouble shoot

Talent Graft AUI:

French size is:

- 1. Use *longitudinal* cuts, double loop and stab skin to allow traction on loops.
- 2. Know your lengths... So you may want put a graduated pig tail over the main stiff wire to get you exact measurement of you length, because you may only need one main body length... The other pig goes over the contralateral iliac and is curled above renals to allow flushing...
- 3. Please note, that even though the graft may be deployed proximally and then pulled down, unlike bifurcated, *you don't have an ability to pull it down once proximal 2 stents are deployed...* So, partially deploy the graft (say 1 stent), do angio, then correct if necessary, then with constant downward gentle pull on the graft (maintaining the figure of 8 marker at the marked renal) complete deployment of the graft.
 - Ok, say you are too high and the graft is sliding out of the delivery tube. You may attempt the following pull down nosecone until it jams in the delivery sheath for this you'll need to release transparent button on the end of the delivery device. This will trap the partially deployed stent and you can now pull it down.
- 4. If the graft is deployed too low proximally, then you'll have three choices:
 - proximal extension (low precision of deployement, can't pull down half way through...)

- reline the graft with another AUI... you'll have to put an extension on it as well and add 10,000 to the cost of the procedure...
- 5. Connecting bar should be long the longest curve of the aorta.
- 6. Occluder:
- 7. CL limb: pull pig (over benson) into CL iliac. Get benson wire exchanged for stiff in the contralateral (to be occluded) limb over glidecath. (external iliac may accordion over the stiff wire if it is redundant giving an impression of stenosis, ignore this). Get contralateral lateral oblique projection, no need to arrest respirations. Manually inject through sheath to ID internal IA. Mark it on screen.

the occluder works as follows:

Old type: looks like a prizm wrapped in ptfe..:

- A. 14 Fr. Gauge sheath (radiolucent) with ring marker at the distal part you park that marker past internal iliac into CIA.
- B. introducer core radioopaque. remove it once sheet is in place and don't move the sheath (it will snow plough and damage endothelium with the sharp edge)
- C. Once positioned, attach a piston tube (that contains the occluder stent) on the end of the sheeth, use push rod to push the stent into the proximal sheeth. Remove the housing piston tube, and then push the stent through the sheeth with push rod until the sten is past the radioopaque ring mark.
- D. by convention, keep pressure on the occulder, and pull the sheath onto the occluder (again, indecent male anatomy images) thus gradually exposing the occluder to the artery. Note the ringed marker on the sheath but look at the occluder outline itself. Don't spring board i.e. push the occluder out of the sheath (less control, can snow plow, can push against the iliac and rupture, etc). But some say this can be done at times.

IMPORTANT: when putting the sheath up with the rod inside, watch the tip of the rod - it may perf the main body of the graft. Has been done before. Also, watch that ring on the sheath does not move distally during deployment past marked internal iliac as it may get deployed across the internal.

New type:

A. comes with the deployment wire. Can be taken out of the metal casing and reloaded... Fine mesh soft balloon flanked by two mesh donuts on both sides... very flexible. about 22 mm long.

- B. Occlude is preloaded on a metal sheath. Attach it to the 8Fr sheath appropriately positioned, then use the wire attached to the occluder to advance it into the 8Fr sheath. Do not turn the wire counterclockwise (will detach the wire from the occluder).
- C. Advance where you need it, withdraw sheath, make sure you don't occlude internal iliac, then twist wire COUNTERCLOCKWISE and you'll detach it from the occluder... done.

Talent abdominal graft:

- 1. Very reliable easy precise deployment
- 2. Have 34 and 36 mm device (Cook only 32 and 36, Endologix only up to 34)
- 3. Has the only AUI device excellent for ruptures
- 4. I am not sure suprarenal fixation 6 loops does much of anything. It does not have much radial strength and don't do much other then orient the graft. In fact, next edition of Medtronics graft is going to feature barbs (Endurant)... That may make some difference. Cook wanna be?

Endurant graft:

http://www.medtronicendovascular.com/system/files/EndurantIFU.pdf

Like Talent, it is Nitinol wire based, has suprarenal fixation, and features the same delivery system and no sheath deployment. UNLIKE Talent, it has active suprarenal barb fixation, highly conformable fabric edge at proximal end to accommodate to 20-30% oversizing without pleating, smaller profile than Talent, Iliac limbs have LESS radial strength.

Treats necks 19-32, and iliacs 8-25. The only graft approved for necks = 10 mm long in US (less in Europe).

Outer diameter delivery device size:

http://www.medtronicendovascular.com/product/abdominal/endurant?quicktabs_7=1#quicktabs_7

proximal size true outer diameter

23,25 18Fr (6 mm)

28,32,36 20Fr (6.7 mm)

The ONLY difference as far as deployment is concerned compared to Talent, is the treatment of suprarenal fixation.

Once you imaged renals, deploy first 2 stents. Fabric edge is 0.5 -1 mm above the markers. Proximal hoops will be constrained by cone. Cone is moved up and releases the hoops with barbs on them. This is done by dialing a knob at the base of the devise as indicated – i.e. clockwise. This can be done prior or after deployment of Ipsi limb.

From limited personal use in our group we found deployment straitforward and precise. Extension limbs at times require reinforcement stenting as they don't have enough radial strength in calcified arteries. We had limbs thrombose but all were rescued with balloon expandable stents. It is a more expensive graft.

Preliminary Conclusions on Endurant:

While Medtronics designed this graft to be deployed in short necks, I am not sure it has advantage over Cook in precision of deployment. Theoretically, Cook has more aggressive barb profile and more hoops and, hence, may offer advantage in truly compromised (short, divergent) necks as it may offer more suprarenal hold. This is a personal impression only. Delivery profile is smaller than Cook for Large Diameter grafts – it only second to Endologix in delivery size (with 19 Fr sheath delivery up to 32 mm devise). I am concerned about weak radial strength of iliac limbs requiring reinforcement in small calcific iliacs.

AneuRx AAAadvantage:

Older graft that my partner have been using extensively. Nitinol based with polyester fabric. Highest radial strength on the market and low delivery profile for iliac limbs makes it a very attractive graft for small calcified iliacs. There were concerns regarding migration of this graft but, according to my partners who used it extensively, with ballerina crossed limbs they have not have an issue with it. This is done by orienting CL limb marker (dot) to 10 pm. When deployed in ballerina configuration, you'll see a space between limbs that literally looks like a dancer. Space indicates there are no contrast (i.e. endoleaks) in the sac. It is very important to post dilate stent with compliant ballon ABOVE the markers to the level of the fabric. Failure to fully expand the graft at the rim can result in infolding of the edges when balloon is inflated below the edge. This may predispose to type 1 leak.

http://www.medtronicendovascular.com/system/files/AneuRx IFU.pdf

http://www.medtronicendovascular.com/product/abdominal/aneurx

Main body comes as 20, 22, 24,26, 28 mm device in 21 Fr outer diameter profile.

Extensions 12-16 mm – 16 Fr, 18, 20 – 19 Fr.

Graft is deployed similar to talent. Pleas note that markers are about 4 mm below the edge of fabric. Crossing of the limbs is recommended to increase columnar strength of the graft and prevent migration.

Upsides: lower profile, highest radial strength. Downside: some reported migration, treats up to 26 mm aortic neck only.

Gore abdominal graft:

NEW C3 graft version is available. Description pending. No personal experience.

http://www.goremedical.com/resources/dam/assets/AN0210ML1.EN.US.pdf?bcsi_scan_17DEB 92708C82C35=y3QuqyvRmcw3/hMjXJAMnQIAAABEndQA&bcsi_scan_filename=AN0210M L1.EN.US.pdf

This graft is nitinol based PTFE.

It came in 4 basic diameters - 23, 26, 28.5, 31 mm. NOTE that this is INTIMA to INTIMA measurement, UNLIKE other grafts, so actual equivalent size wise is 2-3 mm wider.

Cool advantages of this graft are several:

- 1. delivery sheath i.e. 18 Fr (20 Fr for 31 mm) for main body and 12 Fr for iliac extension (more if bell bottom large diameter) way smaller than Cook and Talent. Company recommends bifurcation/distal aorta diameter at least 18 mm. Note that Cook is putting out a new low profile system next year and Engologix deployment system is 18 Fr (20 for large diameter) but CL side needs only 9 Fr
- 2. has 3 mm scallops on top can "endowedge" these in renal artery orifice (protected by balloon) to gain extra 3 mm of seal.
- 3. PTFE is fused to the wires hence small chance of deterioration and tears from the endoskeleton with time.
- 4. Active infrarenal fixation: has INFRARENAL 7 double needles pointing downward at the proximal end for migration prevention. Has very low migration rates but overall they are same across the board for all grafts (except, may be, Talent)... Migration rate is neck dependent. If <15 mm, could be as high as 10 % endoleak I, vs 3% for > 15 mm.

5. Very flexible delivery BUT sheath is stiff and NON-slippery with no diaphragm at the end – so it leaks and may not slide by tight 7 mm vessels as it supposed to...

Main body has 3 gold marker on edge, windsock cuff to prevent type 1 leak. Main body is 4 cm long (5 for 31 mm) and together with body of the ipsilateral limb it is 12-18 cm (increments of 2 cm). Subtract 3 cm for overlap if extension is needed. CL stump is 3 cm (i.e. minimum overlap).

Iliac extension come in two shapes – tapered down (to 10, 12, or 14.5 mm) or bell bottom (Cook style) – 16, 18, 20 mm. Length is 9.5 to 13.5 cm.

CL side has long marker, ipsi has short marker.

Recommended neck is 15 mm, angle < 60, minimal length from renals to:

- aortic bifurcation is 70 mm
- CL side 140 mm
- Ipsilateral side 120 mm

For placement, you'll need 18 and 12 Fr sheath.

Placement outline:

- 1. Wires up BL, measuring catheters up, place Prostar closure device now if going percutaneous
- 2. 18 Fr sheath up to the HILT in ipsilateral - i.e. past your neck you need this as the body delivery device is basically a long catheter with the graft constrained by the thin strip of goretex. There is a step up at the tip of the graft and you won't be able to track the delivery devise without catching and snow-ploughing the intima. Place 12 Fr sheat in CL limb.
- 3. ID where CL gate is (may want to cross limbs for ease of cannulation)
- 4. Do angios, line up 3 edge markers, position graft appropriately (just like Cook)
- 5. Place main graft in 18 Fr sheath, withdraw sheath back to the second white mark on the main device delivery mechanism there are two white marks one at the bottom of the constrained graft and the other one 35 cm proximally. If you position the hilt of the sheath at the 2nd (35 cm) line, you will fully unsheathe the graft now.
- 6. Confirm position of renals, then deploy graft with 2 person technique. One surgeon holds the delivery catheter as it enters the sheath, the other unscrews the lateral deployment side knob and pulls it out quickly. Company recommends keeping MAP low during this.

If the graft is NOT moved, it will deploy exactly where you placed it... It deploys from top to bottom. See slow deployment next page for angulated necks...

7. Place extensions as per COOK techniquq: measure distance to iliac bifurcations, balloon etc..

Overall, this is a very easy convenient graft for small iliacs and tight bifurcation.

There is no AUI type – you'll need to deploy a second main body device turned 180 degrees. Each device costs about 10,000. BUT cheap alternative is to deploy a 16 mm iliac limb about 3.5 cm from the renal arteries first, then place main body through the iliac limb thus compressing the the CL limb.

Endologix graft:

Basic construction:

This graft underwent major revamp and now features improved low profile delivery sheath. Sheath size is MISLEADING. <u>It is widely portrayed as 17 Fr but this is INNER diameter of this devise. TRUE OUTSIDE diameter is 19 French.</u> While Cook, Gore and Medtronics have smaller sheaths for small necks, Endologix requires 19 Fr sheath (outside) for ALL sizes. It does NOT have 36 devise. Sizes available:

22, 25, 28 mm

Ilia limbs – 3 and 4 cm long, 13, 16, 20, 25 mm diameter.

Proximal extensions – 55, 75, 80, 95, 100 mm long, different for different diameters.

Single wire cobalt-chromium alloy, twisted to create a flexible endoskeleton. On the outside lined with high density PTFE. PTFE is attached at proximal and distal ends only, allowing the graft to flare out with heart beats and minimizing its' contact with skeleton.

Main body is bifurcated and both limbs are equally long — either 3 or 4 cm . Angle of bifurcation is less acute compared to other grafts, thus making potentially easier to go up and over after placement if needed. CL limb has a wire preinstalled in it. The wire is doubled over and brought out through the top of the device between the cone and the hub. This wire has a channel in it to accommodate 0.014 wire. Since it is a precanulated CL limb, the wire is call Sure Pass Wire.

Principles of deployment:

Deploy distal bifurcated unit first and firmly sit it over the bifurcation – hence the term anatomic fixation. Then add proximal cuffs to go the renals. Proximal seal is supported by the columnar support of the graft resting on the aortic bifurcation.

Sizes: aortic diameter 25, 28, 34, iliac 16, 20, 25 mm. 16 mm will contour to 8 mm iliac without pleating – graft material is outside the skeleton.

Perks: smallest delivery profile in business for large necks (see notes below on sheath sizing), anatomic fixation, can treat large tortous necks, precanulated CL limb.

Downsides: We've used this graft extensively in our group. Proximal extensions do not always conform to neck and can slip down with ballooning. Prox extensions and main body CAN separate as aneurysm remodels. See final notes below.

Brief outline of deployment:

- 1. Angio to measure renal/bifurcation and iliac length. Some use endovascular US and save about 40 cc of dye here.
- 2. Position one wire from groin to groin across bifurcation, the other (stiff) into thoracic
- 3. Advance/deploy distal bifurcated platform
- 4. Angio renals on magnification. Place proximal extension
- 5. Iliac extension optional.

Detailed deployement: NEW graft

Bilateral cutdowns (or contralateral puncture)

Place sheaths: 12.5 Fr ipsi side, 9 Fr conta side – do percutaneus puncture or open.

1. First advance 19 Fr sheath up on ipsi side = if it goes smoothly, main device will go as

well. If it does not, you haven't opened main device yet, so nothing is lost. Consdier AUI Medtronic...

- 2. Advance sheath tip up to bifurcation. Advance snare through the CL sheath. Advance CL limb wire from graft along side the stiff wire in the sheath. Snare CL wire at bifurcation and bring it to the CL side limb.
- 3. Advance the device into the sheath. Devise itself is short and, after its' base docks/clicks with the handle of the sheath, continue advancing pushing the delivery rod (black) inside the sheath until devise is fully inside the sheath.
- 4. Now advance entire unit up until the bottom of the constrained graft is above bifurcation. Feed CL wire up and rotate graft to ensure CL wire is not tangled vs delivery assembly.
- 5. Hold the core and withdraw the sheath thus unfurling the main body (still mostly constrained) until the CL limb is opened up. Apply gentle pull on CL wire as it becomes lose.
- 6. Now direct limbs into each iliac and pull down with entire devise form ipsi groin and pull on the CL wire to sit the devise over bifurcation.
- 7. Place 0.014 wire through SPW into the chest through cl limb. SPW has a channel in it to accommodate the wire.
- 8. Break tab off on the main device, and pull it the thread slowly: this will deploy main body from the bottom up. Stop half way, and readjust/reseat the device over the bifurcation. Device will never truly seat on the bifurcation, sitting up 3-5 mm up from it, thus shortening the iliac limbs.
- 9. Complete deployment of the main body by pulling out core. You still have CL iliac limb undeployed.
- 10. Pull SPW out, pushing 0.014 wire forward. This will complete deployment of cl limb and pull out the wrap of the main body. As you pull SPW, this will pull down a transparent plastic cylinder that constrains the CL limb. This will deploy CL limb. You will see red cover (used to cover main body) and transparent sheath come out together with the SPW. Keep you eye on the 0.014 wire and make sure you don't pull it out with the SPW.
- 11. Now you can place obturator into ipsi sheath (you don't need to jam it all the way in, when it sticks out 4 finger breadths on the outside of the 19 Fr sheath, it is far enough).

Advance obturator and the tip of the 19 Fr sheath above renal arteries. Ipsi iliac limb

may not be completely opened up and, hence, present a resistance to the obturator. To avoid catching the edge of the graft and, hence pushing it up, balloon distal landing ipsi zone OR/AND place inflated balloon in CL ipsi limb and pull it down gently while advancing the obturator. This will ensure you won't move the graft up.

- 12. Place proximal cuff delivery device load onto stiff wire, click into place, now delivery sheath for the proximal extensor is fused with the 19 Fr sheath as one. Advance core of the proximal extension forward all the way. Stabilize the core, and pull down the sheath opening up first 2 stents. STOP.
- 13. Orient image intensifier to see the tips of the proximal stent in one single line, I.e. perpendicular to the aortic lumen. Note, that you want to orient the spine of the proximal cuff along the longest curve of the neck spine corresponds to the side port on the delivery device. This is important since if you have angled neck, the proximal stent can be made to line up with the contour of the aortic wall, achieving a better seal. Judge the contour of the aorta from preop CT and angio.

Note that size 34 mm proximal extension has delivery device that will not fit into 19 Fr sheath. Hence, it has a special delivery modification called Express. It has short cartridge that fits onto the opening of the 19 Fr sheath. Within the cartrige sits free but constrained proximal cuff. As you push mandrel behind the sheath forward, it will transfer the free floating proximal cuff from the cartridge into 19 fr of the main sheath. Prior to doing this, you need to line up side arms of the 22 Fr and 19 Fr sheath to correspond for the sheaths main and proximal extension. This delivery is similar to deployment of the embolization coils. Continue pushing mandrel forward until edge of the proximal stent margin is above renal artery.

- 14. Pull back on the sheath, deploy proximal 2 stents, shoot angio after you adjusted for the angle and re-orient the cuff to allow cuff to line the long curve of the angulated neck, complete deployment. Consider palmaz for short necks.
- 15. Coda Balloon. Some use kissing balloons for bifurcation.

Detailed deployement: OLD GRAFT

Bilateral cutdowns (or contralateral puncture)

Place sheaths: 12.5 Fr ipsi side, 9 Fr conta side

- 1. Wire up contralateral side, snare from ipsilateral side, bring wire through ipsilateral sheath across bifurcation
- 2. Double lumen catheter (DLC) from contralateral to ipsilateral across bifurcation (note, some do not use this step. DLC constructed thus: has one lumen from hub to tip. This is the lumen through which up and over wire will go. Second lumen starts through skive opening about 10 cm proximal to the tip and leads to another skive opening about 25 cm proximal to the first one It corresponds to the bifurcation on the aorta. This is the channel that will direct the stiff wire into thoracic aorta.

The only purpose of DLC is to allow to pass one wire to the contralateral groin, and the other one to the aorta to keep these from tangling. However, if wires do get tangled, they can be easily detangle at a later step. Hence, some forgo DLC altogether.

- 3. Through ipsi side, place stiff wire through skive hole of DLC, keep end of DLC medially, and watch it exit second skive hole that is parked in proximal ipsi iliac artery. Advance tip to chest.
- 4. Thread Sure Pass Wire (SPW) from the tip of the device into the end of the tip of DLC, place stiff wire end into the tip of the device, track the device over two wires close to the 12.5 Fr peel away sheath. Keep SPW medially.
- 5. Advance Sure Pass Wire (SPW) to the contralateral sheath, thus body flossing the bifurcation from R to L groin. Remove DLC from CL side.

Some keep bentson wire in the DLC and push out as the SPW is advanced. This gives DLC stiffness and allows SPW to traversed steep angle of the bifurcation. Controlled pull on the DLC from the contralateral groin will also allow to get across bifurcation.

If you did not use DLC at this point, use any straight cath to exchange bentson for the SPW.

6. Remove DLC through the CL sheath. This will rip the ipsilateral side of the SPW vs. stiff

wire as you pull it out.

- Start pulling out 12.5 FR peel away sheath as close to the arteriotomy as possible, then
 peel it away, track the device over 2 wires to the bifurcation, control bleeding from the
 arteriotomy.
- 8. Advance device further until the tip of the delivery sheath is at the bifurcation, stop. Verify that SPW is medial. Device is now inside and sitting in the ipsilateral 19 Fr sheath that will remain there until the end of the procedure. Advance device further to above level of renal arteries.
- 9. Untwist valve ¼ turn, and holding the inner core, pull sheath back. This will expose the collapsed graft and unfurls the cl limb with SPW in it (it was doubled over and brought through the tip of the device between the core cone and the sheath). You may need to carefully rotate inner core to untangle the sure pass wire if it is wrapped around the device. Pull down SPW to pick up slack and then pull the device down and sit it over bifurcation. Do not be afraid to pull at SPW (unless you pull with a LOT of force) as SPW won't get dislodged unless the main body is deployed.
- 10. Place 0.014 wire through SPW into the chest through cl limb. SPW has a channel in it to accommodate the wire.
- 11. Break tab off on the main device, and pull it the thread slowly: this will deploy main body from the bottom up. Stop half way, and readjust/reseat the device over the bifurcation. Device will never truly seat on the bifurcation, sitting up 3-5 mm up from it, thus shortening the iliac limbs.
- 12. Complete deployment of the main body. You still have both iliacs undeployed.
- 13. Pull SPW out, pushing 0.014 wire forward. This will complete deployment of cl limb and pull out the wrap of the main body. As you pull SPW, this will pull down a transparent plastic cylinder that constrains the CL limb. This will deploy CL limb. You will see red cover (used to cover main body) and transparent sheath come out together with the SPW. Keep you eye on the 0.014 wire and make sure you don't pull it out with the SPW.
- 14. Hold ipsi sheath in place, pull inner core down until it docks with sheath (parked at the ipsi proximal iliac). This will pull the clear plastic wrap off the ipsi iliac limb and deploy it

inside the sheath. Pull sheath down to external iliac thus liberating ipsi limb into the common iliac.

15. Now you can place obturator into ipsi sheath (you don't need to jam it all the way in, when it sticks out 4 finger breadths on the outside of the 19 Fr sheath, it is far enough).

Advance obturator and the tip of the 19 Fr sheath above renal arteries. Ipsi iliac limb may not be completely opened up and, hence, present a resistance to the obturator. To avoid catching the edge of the graft and, hence pushing it up, balloon distal landing ipsi zone OR/AND place inflated balloon in CL ipsi limb and pull it down gently while advancing the obturator. This will ensure you won't move the graft up.

- 16. Place proximal cuff delivery device load onto stiff wire, click into place, now delivery sheath for the proximal extensor is fused with the 19 Fr sheath as one. Advance core of the proximal extension forward all the way. Stabilize the core, and pull down the sheath opening up first 2 stents. STOP.
- 17. Orient image intensifier to see the tips of the proximal stent in one single line, I.e. perpendicular to the aortic lumen. Note, that you want to orient the spine of the proximal cuff along the longest curve of the neck spine corresponds to the side port on the delivery device. This is important since if you have angled neck, the proximal stent can be made to line up with the contour of the aortic wall, achieving a better seal. Judge the contour of the aorta from preop CT and angio.

Note that size 34 mm proximal extension has delivery device that will not fit into 19 Fr sheath. Hence, it has a special delivery modification called Express. It has short cartridge that fits onto the opening of the 19 Fr sheath. Within the cartrige sits free but constrained proximal cuff. As you push mandrel behind the sheath forward, it will transfer the free floating proximal cuff from the cartridge into 19 fr of the main sheath. Prior to doing this, you need to line up side arms of the 22 Fr and 19 Fr sheath to correspond for the sheaths main and proximal extension. This delivery is similar to deployment of the embolization coils. Continue pushing mandrel forward until edge of the proximal stent margin is above renal artery.

18. Pull back on the sheath, deploy proximal 2 stents, shoot angio after you adjusted for the angle and re-orient the cuff to allow cuff to line the long curve of the angulated neck, complete deployment. Consider palmaz for short necks.

19. Coda Balloon. Some use kissing balloons for bifurcation.

Advantages of Endologix graft:

- Anatomical fixation rests on the bifurcation, no need to hang onto short neck to keep graft in place. No other graft has this. You don't need to rely on the radial strength of the graft and barbs/hooks to keep the graft from sliding down as it hangs on the proximal fixation zone. Cook graft has great columnar strength, but it is also inflexible and cannot take as much of the angle as Endologix.
- 2. Lowest delivery profile of all aortic endografts for a given aortic size. Most grafts go through 19 Fr ipsi and 9 Fr contra sheath.
- 3. Sheath is very flexible and has the BEST hemostatic valve in business you blood loss will be lower.
- 4. Grafts is fused to the skeleton only proximally and distally, reducing the tear & wear between the rigid skeleton and the graft. This improves long term longevity of the graft. Also, for reversed tapered necks, the fabric will expand and seal the entire neck zone with every heart beat. This you can't have with other grafts with fabric fused to the skeleton.
- 5. Build device bottom up: if you know the iliac length (I.e. it has to be 4 cm or longer) and renal to bifurcation distance is more than 80 cm, you can deploy the bottom platform prior to any contrast injection. Then you need to inject a series of short burst (15 cc/sec) to ID renal. You saving on contrast injection. You deploy proximal graft last and do not stress the proximal seal during manipulation unlike other grafts.
- 6. Precanulated cl limb saves time and effort in very small aortas and very large aneurysms. Make it feasible to deploy this graft as bifurcated unit in aortoiliac occlusive disease reconstruction.
- 7. Controlled deployment, slow and precise.
- 8. Proximal cuff can be ordered with suprarenal hoops. Granted, there are only 6 of them (like in Talent and unlike in Cook there are 12 of them with Barbs). Also, with anatomic fixation advantage, these are probably redundant.
- 9. Versatile: May construct AUI device out of iliac extensions and main body cuffs.

10. I saw this graft deployed over very small iliacs and very tight aortic bifurcation, making it ideal for AIOD.

Disadvantages of Endologix graft:

- 1. Can't use in short iliacs (less than 3.5 cm) without the risk of internal iliac coverage.
- 2. If aortic bifurcation angle is very sharp and calcified, one can crack this open trying to sit the graft. Has seen this before...
- 3. Graft has an ENDOskelton... i.e. if you need to re-cannulate it, wire may go between the fabric and the skeleton, not intraluminally.. You will need to get a pig tail catheter to get into the lumen:
 - a. Jam the tip of the wire between the fabric and skeleton
 - b. advance pig tip to sit between the fabric and the skelton
 - c. pull back the wire and push pig up it will kink and hopefully will make a hunched curve that will stay intraluminally. Puch pig up....
- 4. Proximal stents are fairly bulky and long. They are not as compliant and flexible as Gore graft so it may not conform to the tortuous aortic neck. So if you deployed one stent 1 cm too low in an angulated neck and the side is beaking, you'll have hard time smoothing out the beaking edge.
- 5. Ideally, would like to have more diversity of iliac diameter sizes and an option of having a main body iliac limbs less than 4 cm. Also, having shorter proximal cuffs length with shorter individual stents would make it an ideal cuff for rescue type one leaks with other EVAR systems.

Conclusion on Endologix graft:

Essentially can be thought of as a variation of gore device (ptfe, rip deployment) except it is precannulated, smaller delivery profile, has very well controlled delivery and - the biggest plus - it has anatomic fixation. Has been shown to be very effective in short angulated necks.

Angled necks:

Graft always follows the wire. In angled necks, wire will tend to go from one end of the vessel to the other and not stay in center, thus making you deploy the device in a way that is not complying with the aortic wall. There are two ways to correct this. Since deployment is perpendicular to the wire axis so if you can conform the hard wire to go parallel to the aortic wall

- and make the graft conform to the aortic bend by either bending the wire at the spot that is positioned in the aortic neck (works very well for extensions, but not the main bodies); or withdraw the hard wire partially leaving a floppy end in the undeployed proximal graft (thus allowing graft to bend with the wall of aorta and not the stiff wire); finally – bow the wire but that requires a human floss with brachial puncture and push from above.

For Gore graft one can use slow deployment - one "rip"/click per second – deploy a few cm first, stop. Start lower and push up – hooks won't let you pull graft down. Proximal fixation zone on the CL side of the limb (long marker) will flower out first AND will bend down about 3-4 mm – this is used to your advantage in angled necks with one renal artery above the other... Protect lowest renal artery with balloon, place graft with ipsilateral side on the side of the highest renal artery, then slow deploy, orient graft to make sure that lowest artery is not impinged upon, wedge the valley of the CL side into the underside of the balloon, compete deployment. Can gain another 3 mm of seal...

Possible future solution for wire centering?

Ideally, there should be a technology that would center the wire in the lumen. I can see how one can device a flow permitting balloon – say, trilobed Gore balloon that is not flow limiting or Unballoon device – they won't limit the flow and won 't be pushed down during deployment - that is converted to MONORAIL combination. Such balloon is delivered over the main wire, inflated above renals. This will center the wire and allow more precise deployement. Eventually, they may even have a balloon on the tip of the nose cone as well. Downside – you'll need to manipulate suprarenal aorta with balloons…

Alternatively, if one can tie a loop prolene around existing trilobed balloon, Use large 22 Fr sheath that would accommodate centering balloon and the main ipsi wire. Place the balloon making sure the ipsi wire goes through the loop on the balloon first, so it stays close to the center with balloon is deployed... Just dreaming...

Internal Iliac artery embolization:

Jam RIM or Sauce into the orifice, confirm position, deploy.

To better visualize internal iliac may have that is pointing posteriorly, may have to do extreme caudal tilt of the C-arm. Embolization from Cook come in standard coils and in torent coils (forms round pyramid, has fuzzies). All coils are loaded in the steel tube in a straight shape. When pushed out, it reforms to assume the torrent shape or the coiled mess...

To deploy, select the size - they are sized by the final diameter of the coil. Choose the Fr for the catheter used to canulate the internal - 0.35 or 0.018 system. Attach the metal tube to the end of the cather, use metal rod to push coil into catheter, then use back end of the benson wire (or 0.018 wire, depends) to push wire out and into the internal iliac. Put a few.

don't put guidewire too far into internal, it will perforate and cause RP bleed! you can use water jet to push out the coil.

Ruptured and symptomatic AAA:

For ruptured, if EVAR is chosen it is wise to procede with AUI as it will give you faster exclusion time. That means Talent or Cook+converter. Proximal Balloon, while achieving immediate cross clamp, my make procedure difficult as it will be necessary to deflate and inflate it, remove it, etc letting blood pressure drop...

For LEAKING/Symptomatic AAA, bifurcated graft may be attempted. Proximal balloon may not be necessary.

First priority - proximal control...

Dissect groin for Contralateral (if bifurcated) or Occluder side (if AUI) - get benson up, then 14 Fr sheath - idealy 35 cm to give it some support, then coda balloon to thoracic aorta with stopcock to give you proximal clamp... Place balloon high, so that you'll be be able to position you main device with nosecone not pushing against the balloon. Be mindful that you'll be occluding SMA/Celiac/ Renals etc...

Allow anesthesia to catch up while you dissect ipsi groin and get benson up to balloon. Load catheter of your choice and park it below the balloon. You'll have let the occlusive ballon down to let the benson with catheter sneak by into proximal descending aorta. Then re-inflate the balloon re-gaining proximal control.

The problem is - how to shoot angio with contralateral groin taken by 14 Fr sheath plus coda balloon and ipsi occupied by main body? if you use 20 Fr cook sheaths, you can needle puncture outside portion of it and get 6 Fr sheath and introduce pig tail up to the level of balloon. For 14 Fr sheath, you can simply get pigtail along side of balloon through the main axis hole, it will fit...

Advance main body, hopefully you parked balloon high up to allow no contact between the balloon and the tip of the device. Shoot angio (with balloon, do hand injection, no need for power injection with proximal balloon), make note of BONY LANDMAKS and mark the screen.

Before you deploy device, you'll need to deflate the proximal balloon, pull it out and re-introduce it in ipsi limb (over 14 Fr sheath) after you promptly deployed the device. Advance the balloon into proximal thoracic aorta, inflate it. Then place pig over ipsi limb, shoot angio via sheath, measure distance to iliac, select iliac extension, mark it, again promptly remove sheath/balloon and deploy extension. Now aneurysm is almost excluded.

Then place occluder in contralateral limb, do fem-fem.

DO COMPLETION ANGIO – it is a separate code for billing...

Summary:

For AUI rupture:

- 1.14 french or large cook sheath in CL groin balloon chest via contralateral access
- 2. pig tail via contralateral via dotter or double puncture of sheath ipsi stiff wire and catheter advance temp balloon down >reinflate once wire in the chest
- 3. angio, bony marks remove balloon from CL groin-> temporary bleeding now!

 Deploy main body, reintroduce balloon via ipislateral groin, place it in chest, control regained.
- 4. graduated pig to ipsi, sheath angio, mark iliac, select iliac extension,
- 5. remove balloon -> temporary bleeding again!
 Deploy iliac extension control regained, aneurysm excluded.
- 6. Place occluder proximal to internal iliac and fem-fem.

Bifrucated? well, it takes time (particulaly may spend extra time wiht CL limb canulations) and this may necessitate placement of proximal balloons.

Thoracic grafts:

Summary of deployment:

- 1. dissect one groin (main), puncture 5 Fr the other, Lunderquist on main, pig tail the other (ensure Lunderquist is in the distal ascending aorta, may need to use pig to get it there)
- 2. position for proximal visualization, measure aortic length, note the take off of L subclavian, heparin.
- 3. deploy proximal stent

- 4. take lateral oblique shot of distal descending/prox abdo aorta, may need to canulate celiac to ensure distal graft does not encrouch upon it
- 5. take a view of distal end of proximal extension and the celiac take off, measure with pigtail (graduated markings), calculate what extension you need to get to distal landing zone or to celiac
- 6. distal extension deployment, 2 stent overlap, exchange Fr 12 sheath to main groin and reposition pigtail over benson into the lumen of graft
- 7. completion angio, balloon only if necessary.

IMPORTANT:

- A. in thoracic graft, once the graft is deployed (if close to the L CCA) at the arch, immediately withdraw the nosecone to sit at the end of the sheath (and out if necessary). Otherwise, nosecone can actually block the opening of the CCA and compromise flow. Ask anesthesia to verify the patency of CCA with transesophageal ECHO.
- B. Do not forget to ask **for pacing or hypotension** when deploying the graft. For thoracic grafts, it is connected to the delivery system until you pull the trip wires, so you can always slide it up...
- C. For thoracic graft, need at least 2 stents to allow for overlap. Use L Lateral oblique to expose the arch +/- craniocaudal. Always visualize celiac (lateral view) to get the measurement of the distance between the end of the graft and the celiac take off.
- D. For thoracic, need one groin dissection and the other side can be straight puncture (for size 6 sheeth and pigtail for measurements).

Cook:

Treats 24-38 mm aorta, 20 or 22 Fr delivery.

IFU- http://www.cookmedical.com/ai/content/mmedia/I-TX2-US-0806-352-01EN-080602.pdf

Particulars:

1. may not need 5Fr sheath in contralateral groin at all - just thread pigtail over benson....

- 2. Nosecone is fused with grey shaft in thoracic grafts. Thin wire with pink hub is connected to the nosecone. It is solid for thoracic graft as these do not have extra fixation proximal to the fabric covered stents.
- 3. In thoracic graft, forward movement of the pink wire is not necessary so it is used to slide it out to dock the nosecone with the empty sheath once the graft is deployed. When the graft is deployed, for the newer model of Cook graft the entire assembly pulled out but the older once (the extensions), need to have their nose cone brought down to dock (like in iliac extensions) and then the whole thing can be pulled out.
- 4. Proximal Cook extensions have no protruding wires with spikes but they do have spikes that point downward... that means, the graft can be partially deployed lower where you want it to go, then you can push it up... You don't want to deploy high and then pull it down spikes won't let you...
- 5. The graft is unfurled by sliding the black outside sheath out but the graft won't form the diamond it is almost completely deployed but is slightly crimped down and held to the delivery system with trip wires... There are 4 trip wires two hold proximal and distal end and the other two keep the graft slightly crimmped and away from the aortic wall.
- 6. After two proximal stents are deployed, you can still slide up the graft a bit.... Then when you are happy after an angio during prox deployment, you can release all 4 wires at once they are held down very tight so pulling the green knob off is harder than you think. For thoracic **distal extensions**, deployment mechanism is similar to proximal stent (no wire spikes hidden in the nosecone) but there are spikes present at the fabric edge and they point up to prevent upward migration... So you can deploy the **distal extension HIGH** and then pull it down...Distal Cook extension has only 3 trip wires these all sit on the single green metal hub.

Note: you don't need to have distal extensions - you can use only proximal ones and get away with it..

Talent:

Talent graft is different - it has looped wires extending proximally and no spikes... It also treats larger aortas – **22-46mm**, Delivery 22-25 Fr.

http://www.medscape.com/viewarticle/562772_6

http://www.talentstentgraft.com/thoracic/main.htm

IFU -

 $\frac{http://manuals.medtronic.com/wcm/groups/mdtcom_sg/@emanuals/@era/@cardio/documents/documents/m708499b001_cont_20090410.pdf$

Gore:

Treats necks 23-37 mm – newest addition can treat up to 42 mm neck, size 20-24 Fr IFU - http://www.goremedical.com/en/ifu/AM0171-ML1(EN).pdf http://www.goremedical.com/en/file/AK0314.pdf