Step by Step for AVNeo Procedure

- Tricuspid and Bicuspid cases -

Edited by Prof. Shigeyuki Ozaki

Ver. 3.1, July 2017

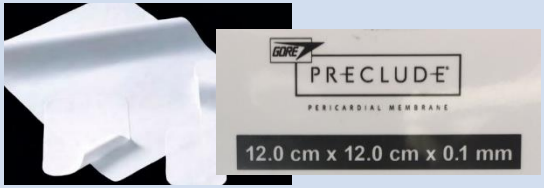
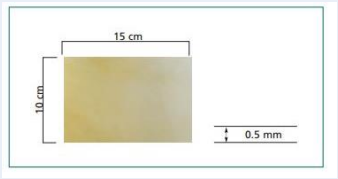
Table of contents

Instruments and sutures for AVNeo

Instruments for AVNeo (1/6)

Image	Description	Purpose
	ESTECH Universal Stabilizer Arm Hercules https://www.terumo-cvs.com/products/ProductDetail.aspx?groupId=79&familyID=870&country=1	To expose the aortic valve Qty: 2pcs
	Aortic Valve Assistant 11mm in width, frequently customized by doctors to **8mm** in width https://www.atricure.com/rakes-and-valve-assistants	To expose the aortic valve Qty: 2pcs
	SCANLAN® JACOBSON MICRO NEEDLE HOLDERS Model 3003-540 Straight jaws Streamline box lock With ratchet http://www.scanlaninternational.com/products/3003-540/ 3003-368 is the original model Prof. Ozaki uses at his hospital	For suturing valve cusp
	CUSA (Cavitron Ultrasonic Surgical Aspirator, SonoSurg, Olympus, Tokyo, Japan) https://www.olympus-europa.com/medical/en/medical_systems/products_services/product_details/product_details_10121.jsp	To remove calcification around the annulus

Instruments for AVNeo (2/6)

Image	Description	Purpose
	Harmonic scalpel (hook type) http://www.ethicon.com/healthcare-professionals/products/advanced-energy	To remove the surrounding tissues and expose the pericardium
	Felt pledget 5mm x 10mm, 2mm x 3mm Felt strip 5mm x 150 mm	To make the commissure 5x10mm for regular case 5x150、2x3mm for bicuspid valve or aortic dilatation
	GORE TEX sheet (EPTFE patch) Two sizes: 12 × 12cm or 15 × 20cm http://technicare.com.br/wp-content/uploads/2013/12/preclude-catalogo.pdf	To cover the defect of pericardium The one with the appropriate size will be used.
	Edwards bovine pericardium patch http://www.edwards.com/eu/Products/HeartValves/Pages/patch.aspx	As a backup when the pericardium is not available.
	0.6% Glutaraldehyde solution 100ml Document required to make the solution is provided by JOMDD	Used for fixation of the pericardium

Instruments for AVNeo (3/6)

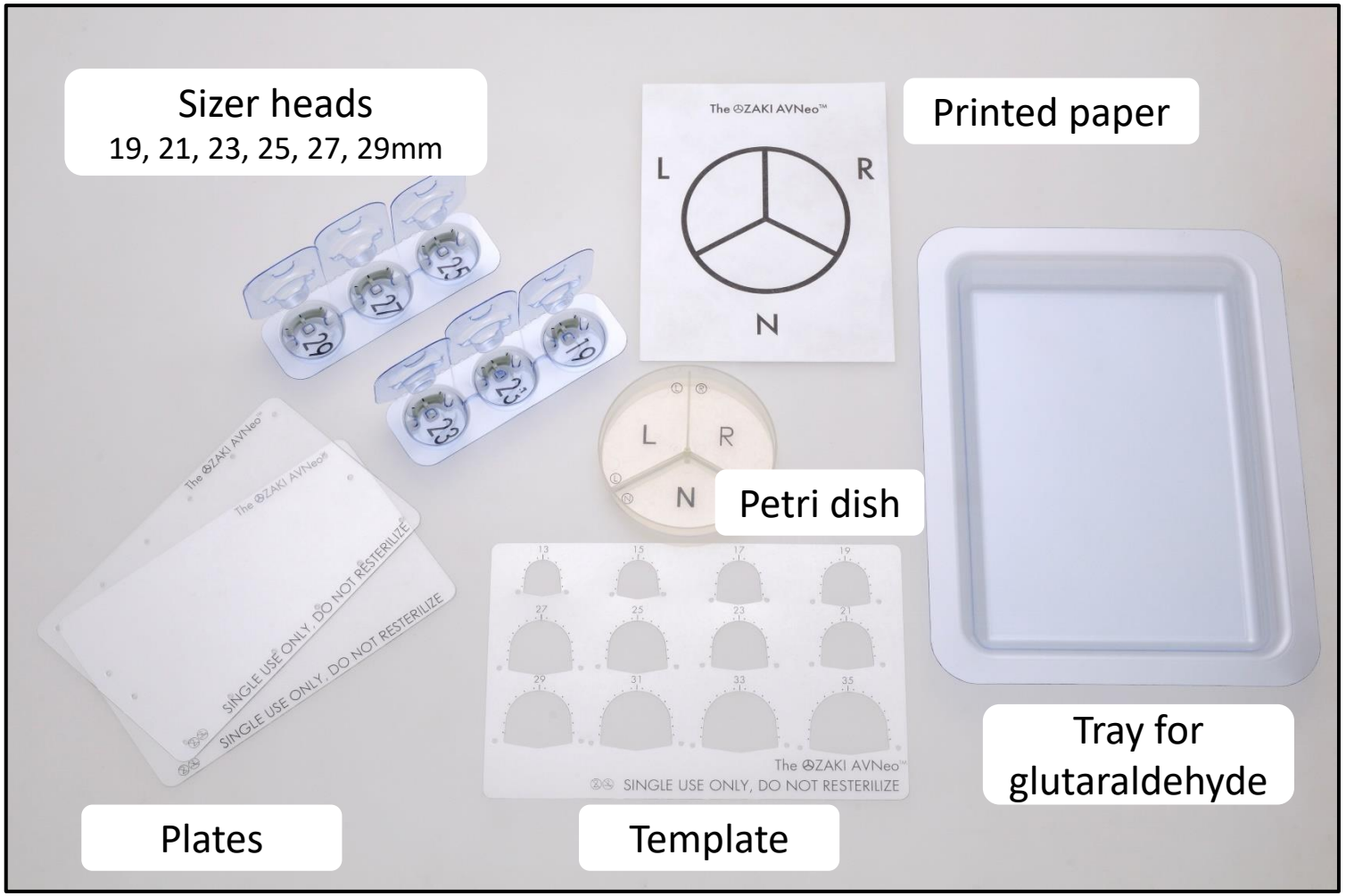
Image	Description	Purpose
	Medtronic Octobase x1 (28701 base) (28705 standard） (28706 deep） http://www.medtronic.com/us-en/healthcare-professionals/products/cardiovascular/revascularization-surgical/octobase-retractor-system.html	Chest opener compatible with Estech
	Medtronic Suture holder x1 （for Octobase 28707）	Used with Octobase
	Symmetry skin marker x 1 to 3 http://www.symmetrysurgical.com/Welcome/Default.aspx?scenarioID=301&StockCode=43-1030&ViewProduct=true	To draw on the treated pericardium
	NESCO Dermarker x1 to 3 LINK to the PDF	Used to mark dots on the annulus.

Instruments for AVNeo (4/6) -Sutures-

Image	Description	Purpose
	ETHICON 4-0 prolene, monofilament, blue, 36“（90cm） Needle name “TF”, taper, 13mm, 1/2 circle, double armed (brand code: D4295) Qty.3	To suture the cusp
	ETHICON 4-0 prolene (polyester), monofilament, blue, 36"（90cm） Needle name “RB-1”, taper, 17mm, 1/2 circle, double armed (brand code: 8557H) Qty.3	To make the commissures
	ETHICON 6-0 prolene (polyester), monofilament, blue, 18"（45cm） Needle name “C-1”, taper, 13mm, 3/8 circle, double armed (brand code: 8718) (Qty.6 For bicuspid)	To make the commissures, especially used for pledget reinforcement with autologous pericardium (for bicuspid)
	ETHICON 4-0 Prolene (polyester), monofilament, blue, 36"（90cm） Needle name “SH-1”, taper, 22mm, 1/2 circle, double armed (brand code: D7768)	To lift up aortic wall and adipose tissue around the aorta
	ETHICON 2-0 silk, braided, black, 18“(45cm) Needle name”SH”, taper 26mm, 1/2 circle, single armed (brand code: C012D)	To lift up the pericardium to the retractor
	ETHICON 3-0 silk, braided, black, 18“(45cm) Needle name”SH”, taper 26mm, 1/2 circle, single armed (brand code: C013D)	For fixation of the pericardium onto the plate

Instruments for AVNeo (5/6)

<AVNeo Single Use Common Kit>



Note that you cannot perform AVNeo without this certified kit.

Instruments for AVNeo (6/6)

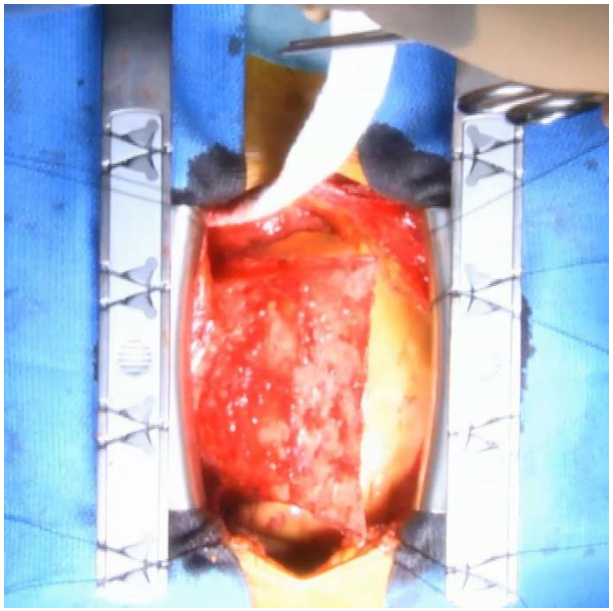
<AVNeo Single Use Accessories>

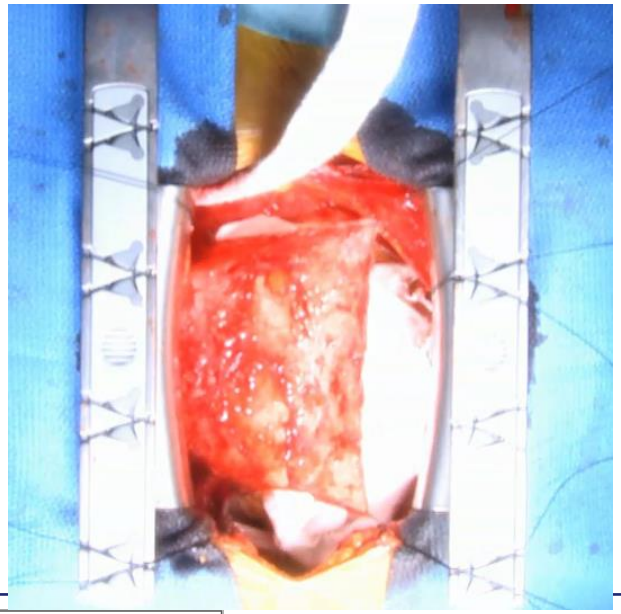
- Smaller sizer kit
  13,15,17

- Larger sizer kit
  31,33,35

Step by Step AVNeo
for tricuspid cases (Basic)

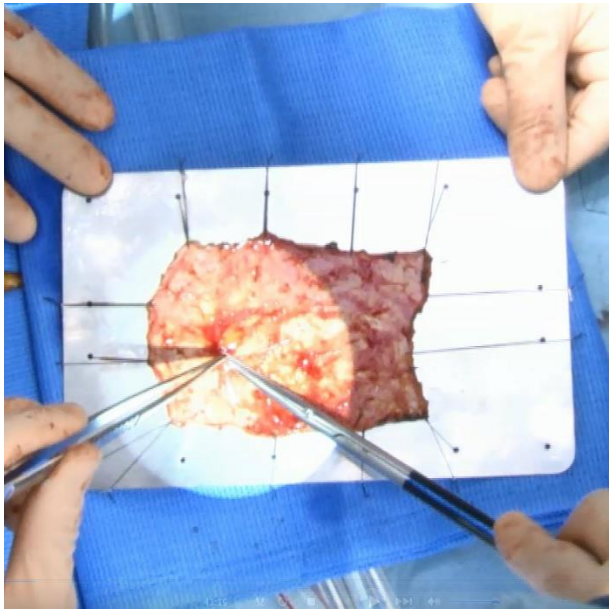
Harvesting Pericardium

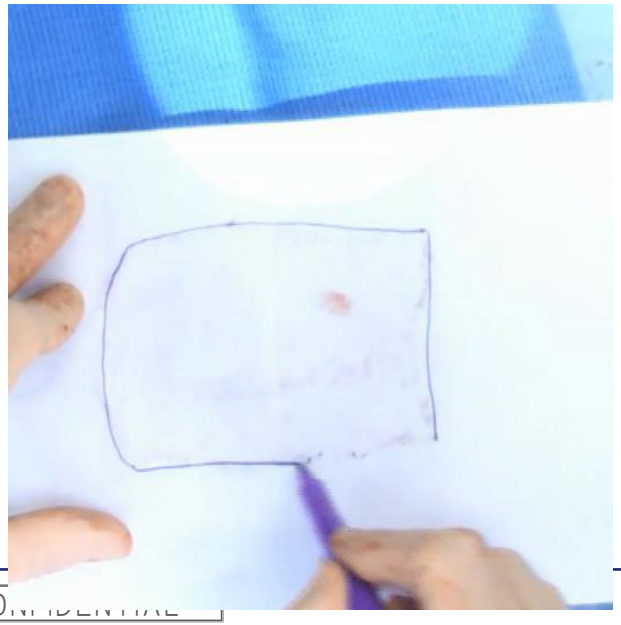




- **At least 7cm x 8cm pericardium** should be harvested.
- Before harvesting pericardium, adipose tissue is removed properly. Harmonic can be used.
- When cutting, gauze is placed between pericardium and cardiac muscle to prevent damage.

Fixation on plate

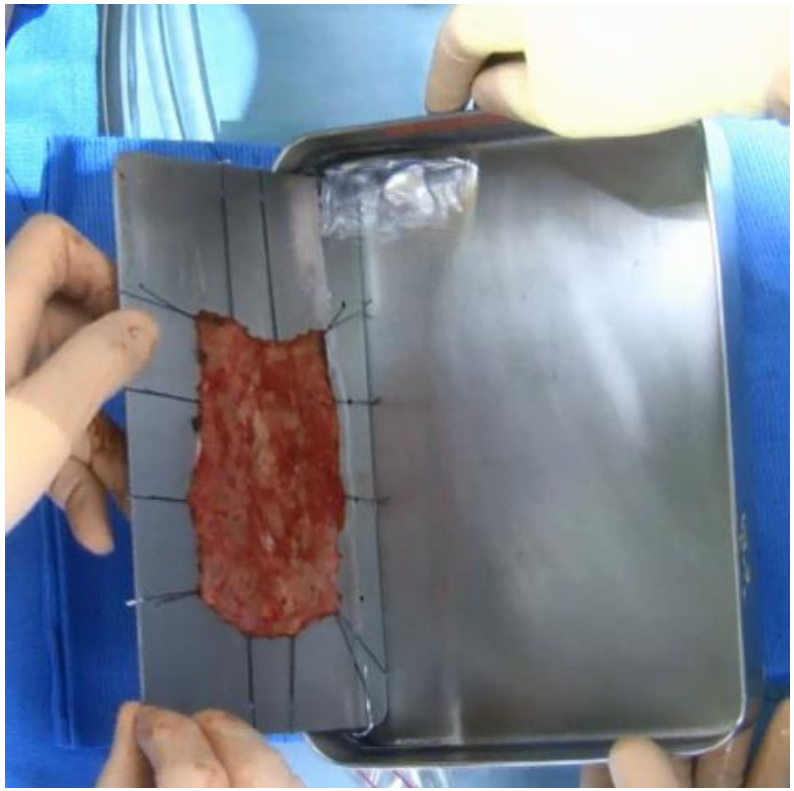




- Pericardium is attached to the plate (provided in the kit) with sutures to prevent shrinkage during fixation.
- **Rough (sternal) surface upward**
- **Remove redundant fat tissue with forceps, moistening surface with saline during dissection may be helpful.**

- Draw the shape of pericardium on a paper. This paper is later used to cut Pericardial Membrane sheet to close the pericardium defect.

Pericardium treatment

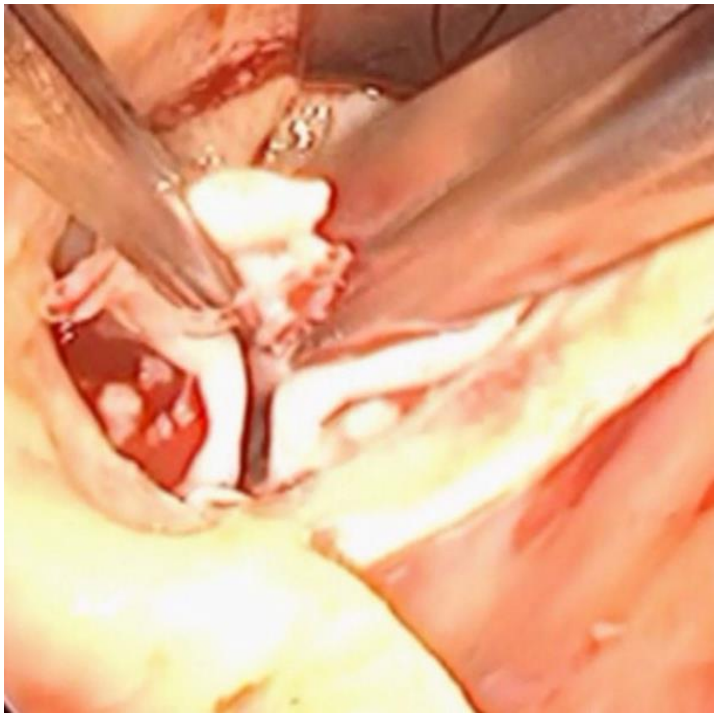


- Pericardium is soaked in 0.6% Glutaraldehyde solution for **10 minutes**
- **100 ml per case**

Rinsing

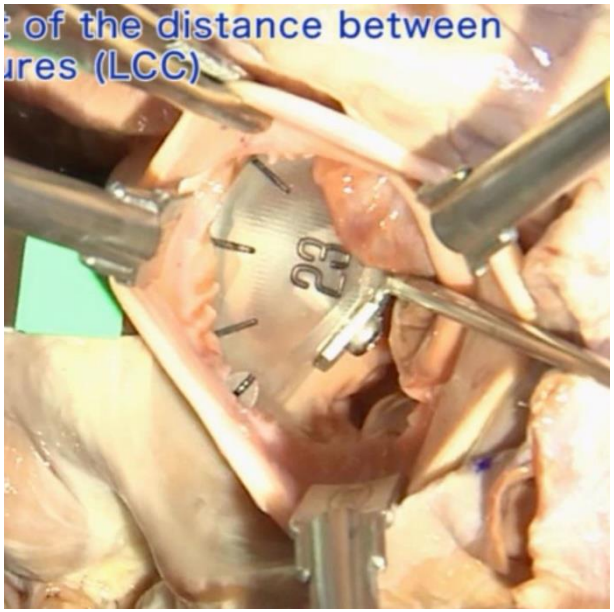
- After treatment in glutaraldehyde, pericardium is rinsed with normal saline for **6 minutes.**
- **Repeat 3 times. (=18 minutes)**
- Store pericardium in fresh normal saline until used.

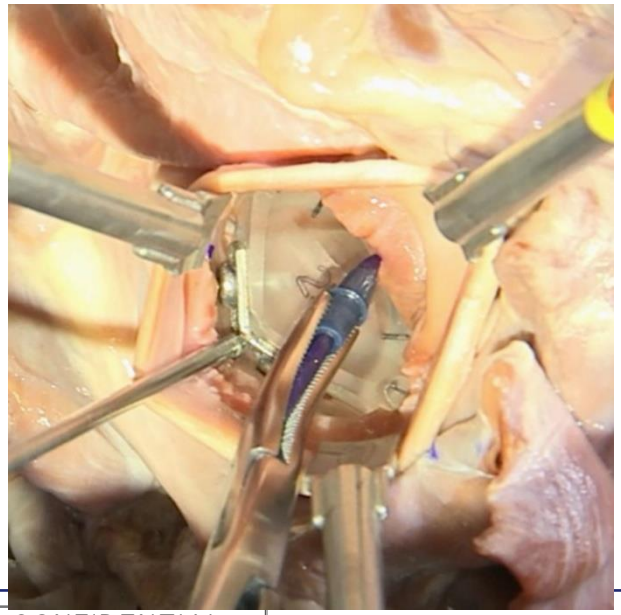
Removing diseased cusps



- Diseased cusps and surrounding calcification are removed as completely as possible.
- When calcification is severe, CUSA is useful (refer to the instrument section).

Sizing (1/3)





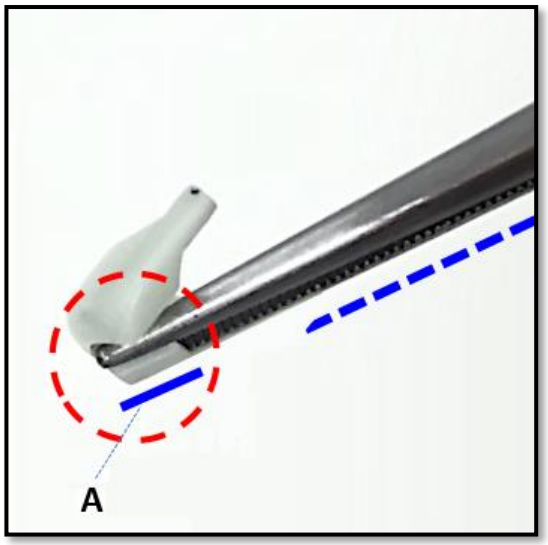
- Measure the distances between the commissures. The sizers are used to determine the circumferential length between the commissure at the level of commissure. The length of annulus is NOT measured.
- **First attach one side of a sizer to a commissure firmly, then check if the other side of the sizer fits to the other side of the commissure.**
- Repeat this until appropriate size is measured.
- If the size falls between two sizes, use the larger size.
- **Putting a mark on the mid point of each annulus.**

* The old model of sizer was used in the photos

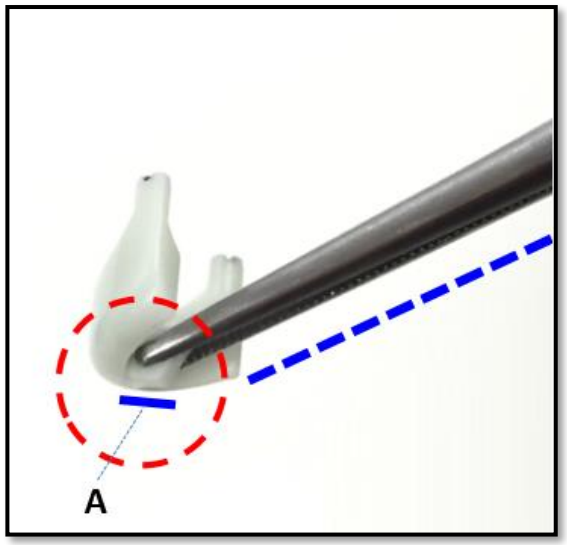
Sizing (2/3) Tips on using the single use sizers

<IMPORTANT>

Hold the sizer with straight forceps at the correct angle



Correct:
Line A and the forceps are parallel.

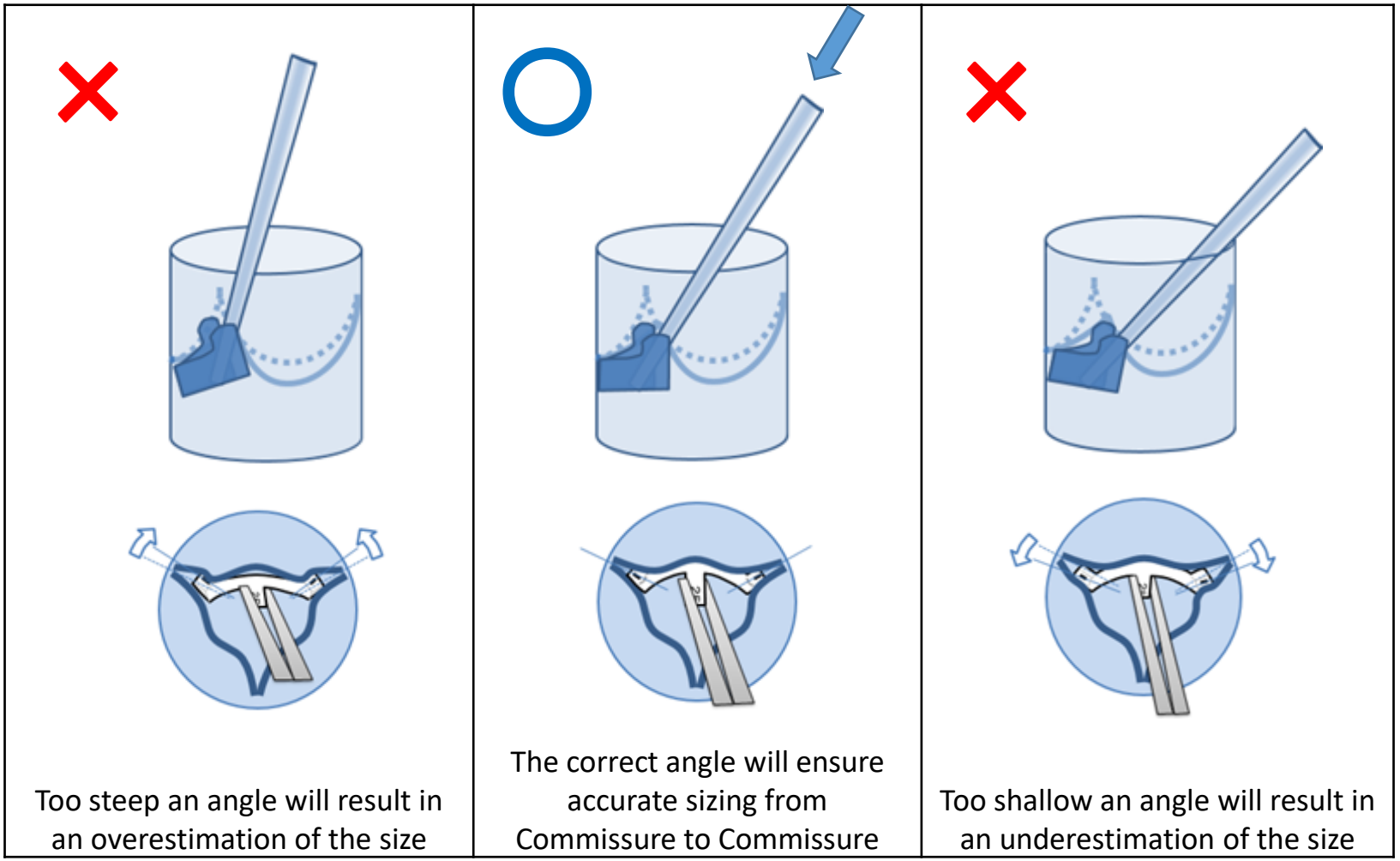


Incorrect:
Line A and the forceps are not in parallel.

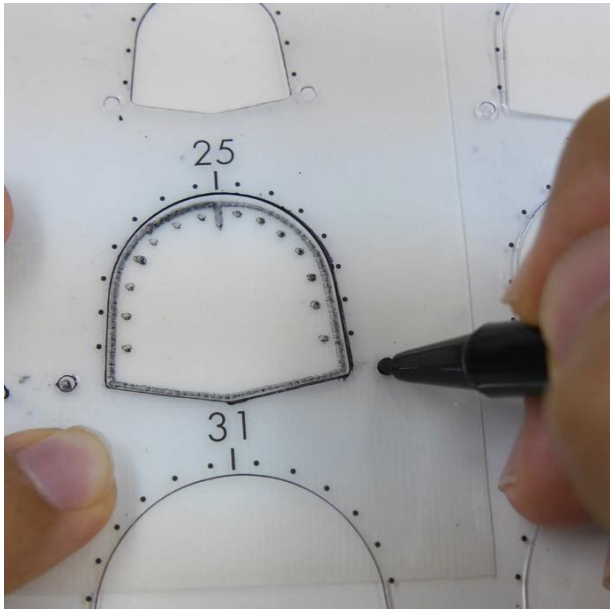
***Please count and confirm the number of sizer heads before and after the operation.**

Sizing (3/3) Tips on using the single use sizers

<IMPORTANT>
Apply the sizers with the correct angle

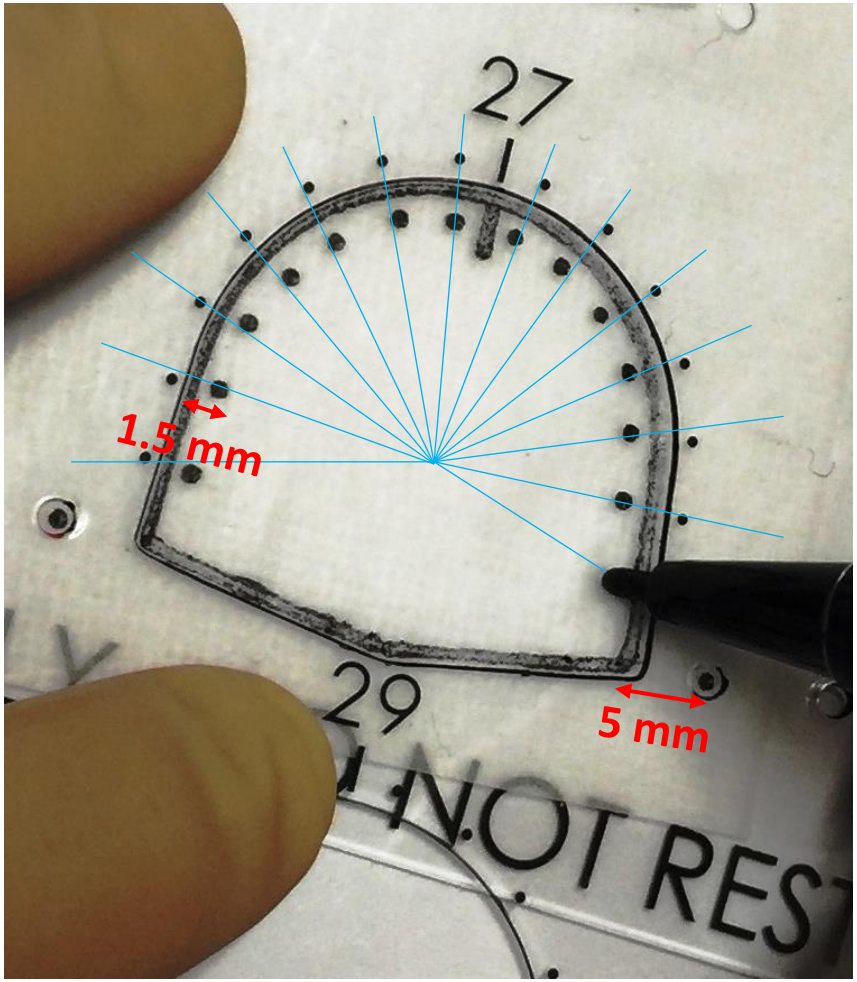


Marking Out The Pericardium (1/2)



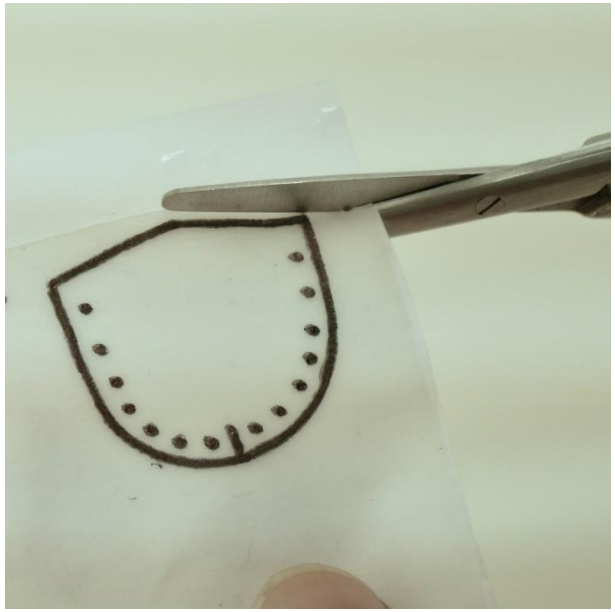
- Dry both the pericardium and the plate with gauze.
- The pericardium is placed on the plate with **the SMOOTH SURFACE upward**.
- Larger cusps should be made from the thicker diaphragm side of the pericardium.
- Draw the cusps according to the corresponding window on the template with the surgical marker.
- Place dots in the hole at both corners of the window to form the “wing extensions”
- **Draw a longer line at the center of the window.**

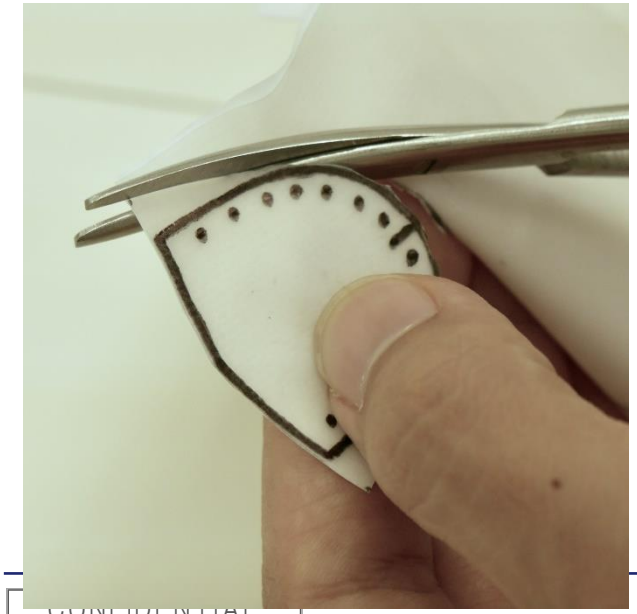
Marking Out The Pericardium (2/2)



- **To ensure correct alignment the dots are marked radially with reference to the center of the cusp and with a distance of 1.5mm from the edge of window.**
- **It is very important to mark the dots exactly as instructed here. If the dots are too close to the edge then the attachment of the cusps might become unstable which might lead to a tearing of the cusps. If the dots are too far from the edge then the size of the cusps may be suboptimal.**

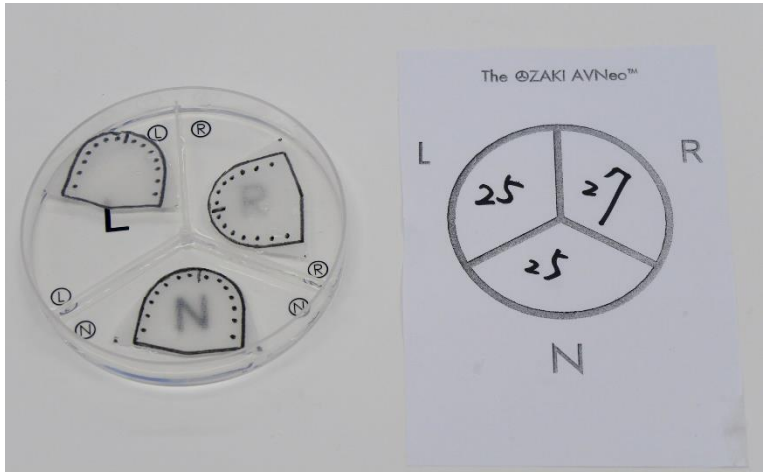
Trimming pericardium





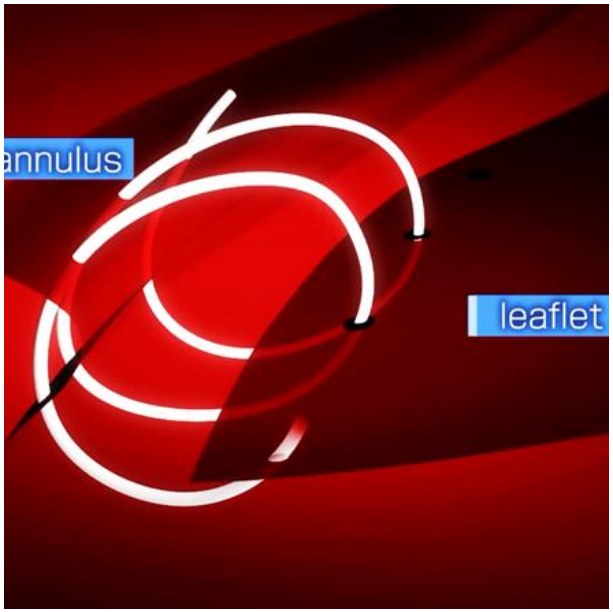
- Attaching pericardium on a wet solid paper makes it easier to trim.
- **Cusps are trimmed with scissors along the outside edge of the lines.**
- **Straight scissors should be used for the free edge of the cusps, curved scissors should be used for the remaining edge.**
- 5mm of “wing extensions” are made on both sides of the cusps.

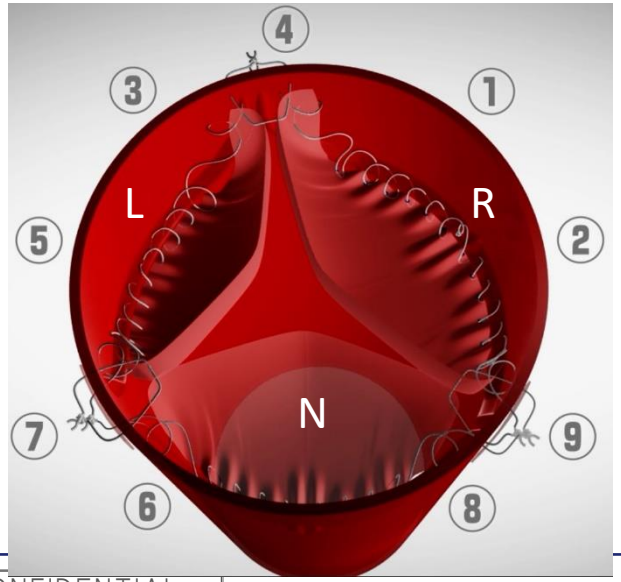
Trimmed cusps



- Petri dish is filled with normal saline, and cusps are placed in it until used.

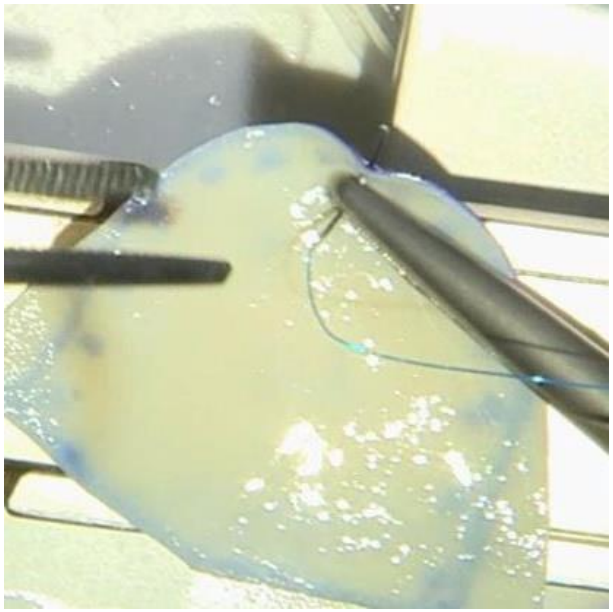
Suturing (1/6)

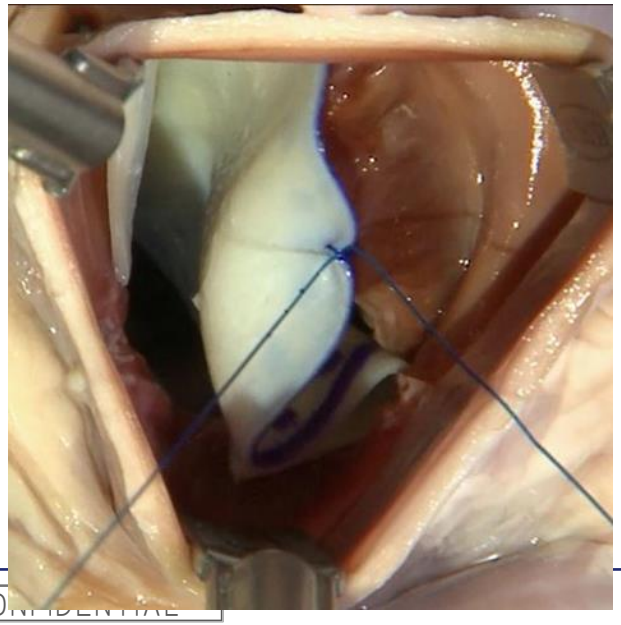




- **Cusps are sutured on annulus from the center of the annulus.**
- Sutures always run from upside to downside on cusps, and downside to upside on annulus.
- Cusps are sutured in the order described in the image. **RCC is the most difficult area and should be sutured first.**

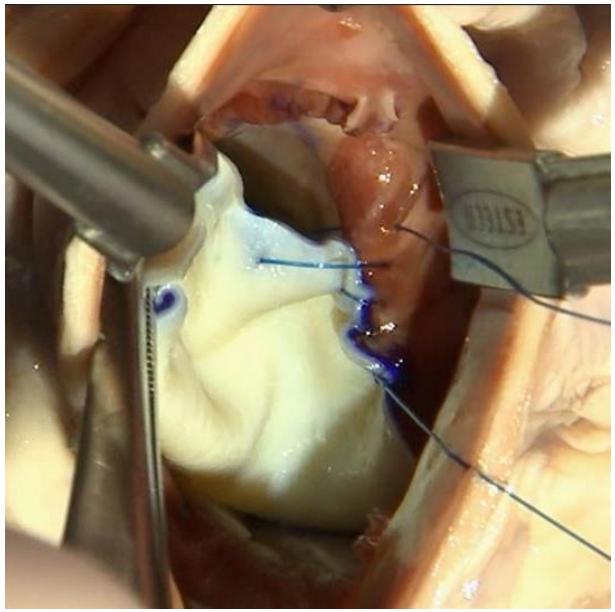
Suturing (2/6)

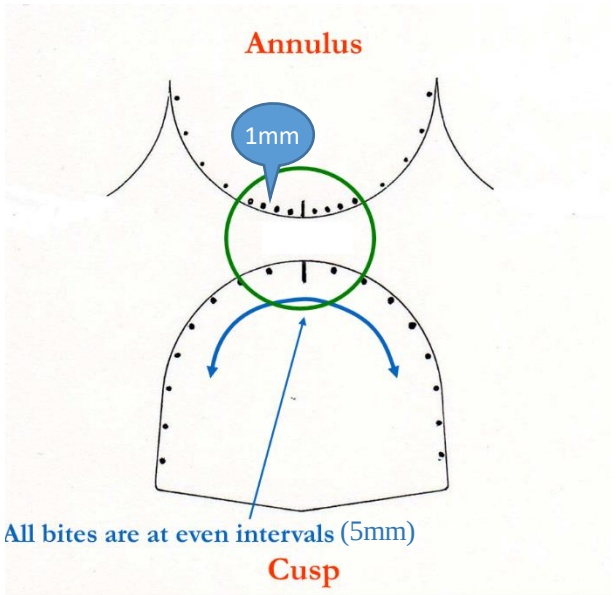




- **Cusps are sutured using 4-0 prolene TF needle (13mm, 90cm).**
- **Smooth surface of the cusp faces left ventricular side. This means that dots and lines face left ventricular side.**
- First, suture runs from the midpoint of a cusp to the midpoint of corresponding annulus, and then the cusp is dropped into left ventricle.
- The suture is **tied with three knots**.

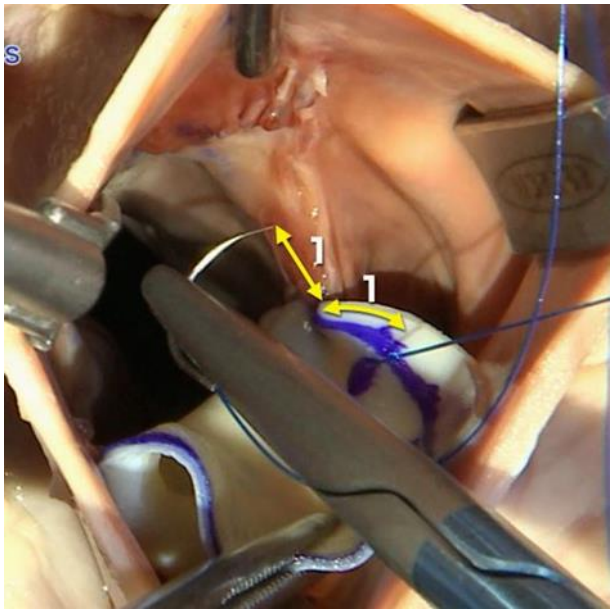
Suturing (3/6)

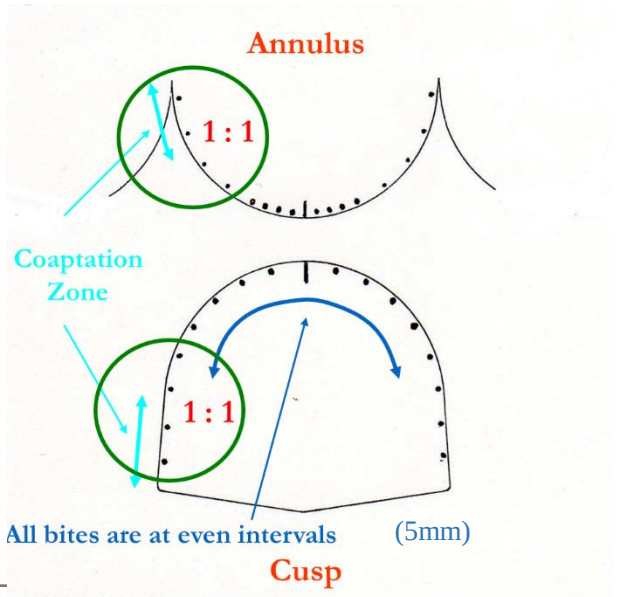




- The suture runs are as shown in the image.
- The needle should pass exactly through the dots marked on the pericardium.
- On the annulus side, in the beginning the ‘bites’ are made **with 1mm intervals along the annulus.**
- The cusp is pushed down into the left ventricular outflow tract as the thread is tightened, so that the cusp is sutured in a sub-annular manner, not in a supra-annular manner.

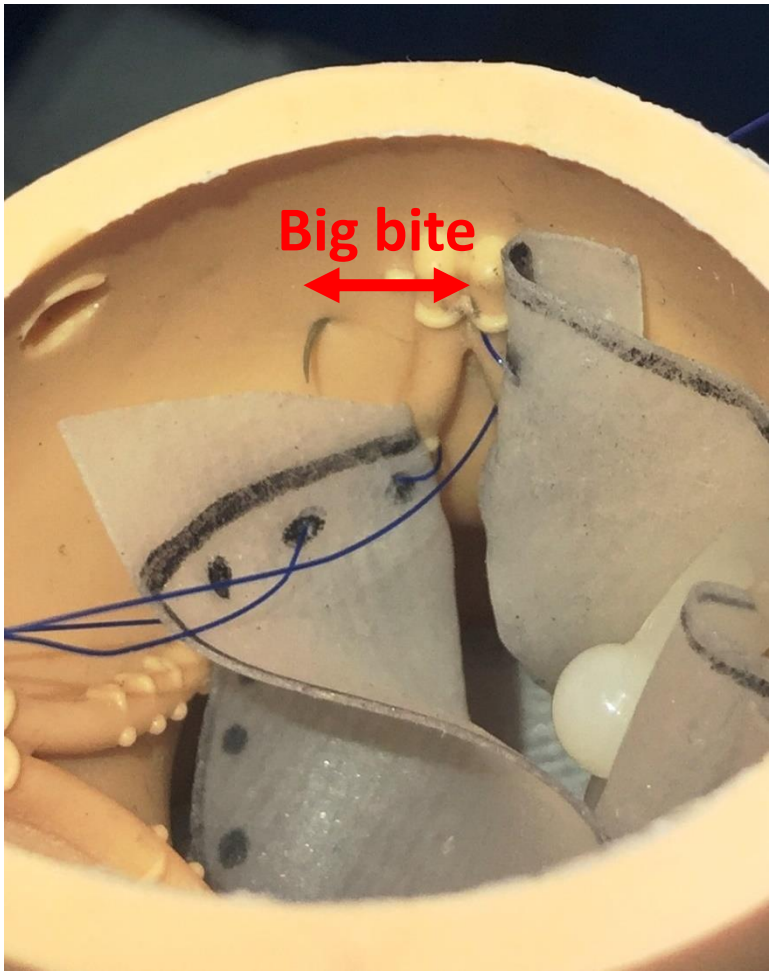
Suturing (4/6)





- After several stitches, check the remaining length of the cusp. This will determine when to increase the suture spacing on the annulus.
- **After the point where the remaining length of the cusp is similar to, or slightly longer than, the remaining length of annulus, the travel between 'bites' on the annulus should become equal to the travel between 'bites' on the cusp (Two or three dots remaining on the cusp is the usual point of the conversion to 1:1 spacing of sutures)**

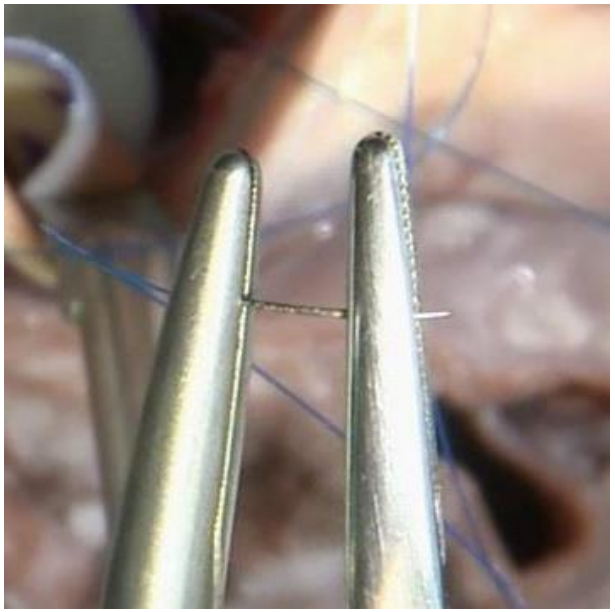
Suturing (5/6)

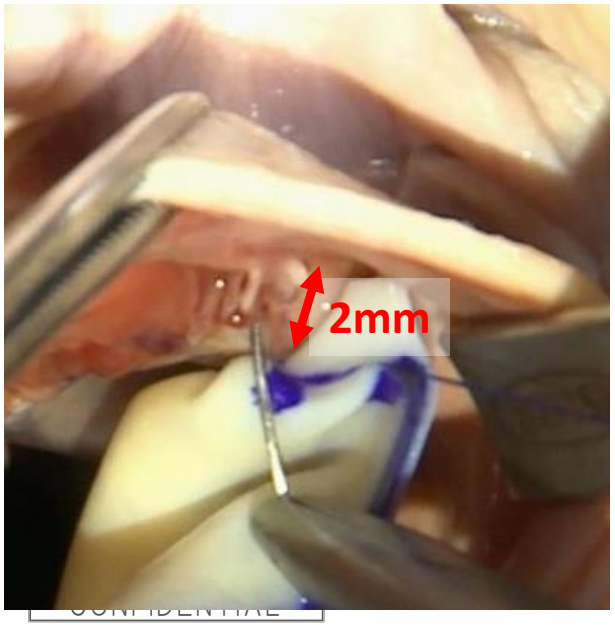


(5mm)

- **The second to the last ‘bite’ is always a large ‘bite’. This will increase stress tolerance of the cusps attachment near the commisure, and flattens the wing extension of the neo leaflet onto the aortic wall.**
- **Ensure that the sutured zone of the cusp is attached below the annulus. However, please note that the area of the ”wing extension” is located above the annulus.**
- **The last suture on the cusp is always 5mm from its free edge.**

Suturing (6/6)

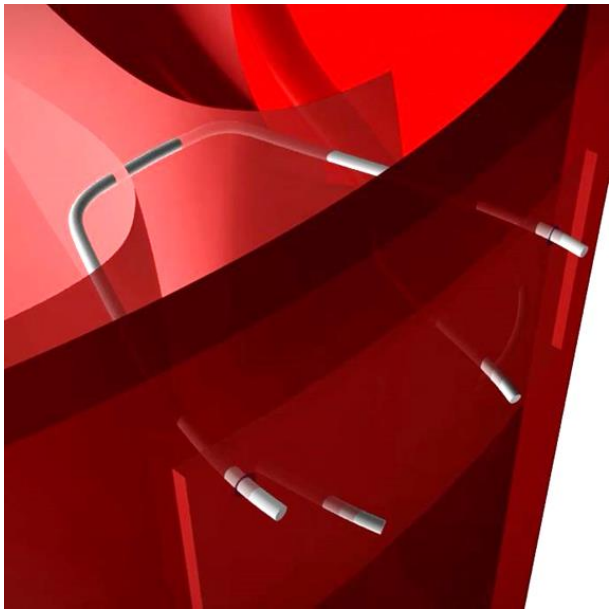


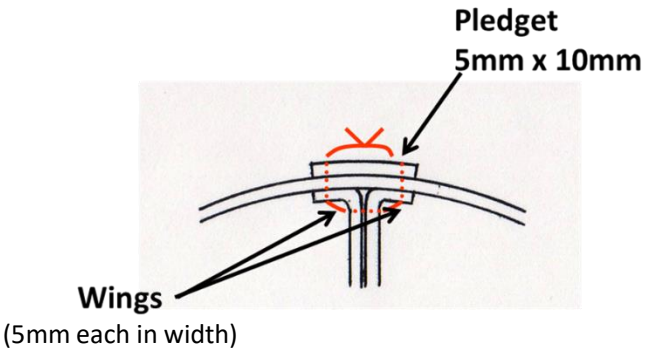


- After suturing the last marker dot, which is 5mm from the edge, the needle is then straightened using a needle holder. This affords the small full curved needle adequate length to pass perpendicular through the aortic wall.

- **The needle should penetrate at about 2mm below the top of commissure.**

Commissure illustrated

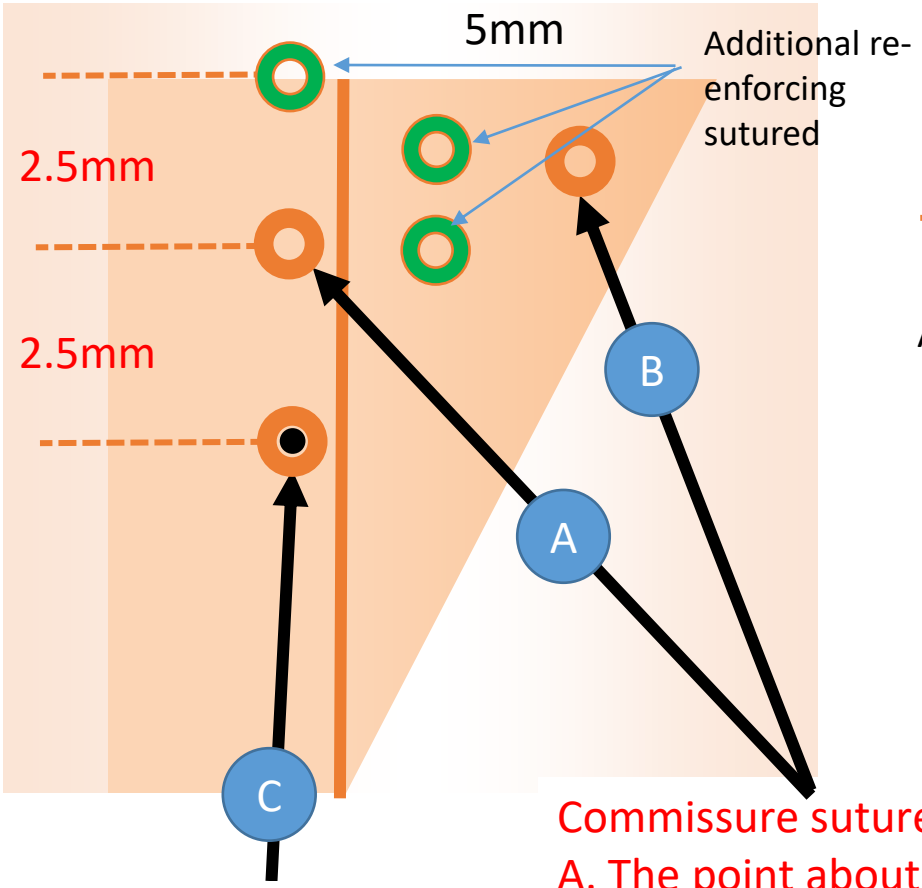




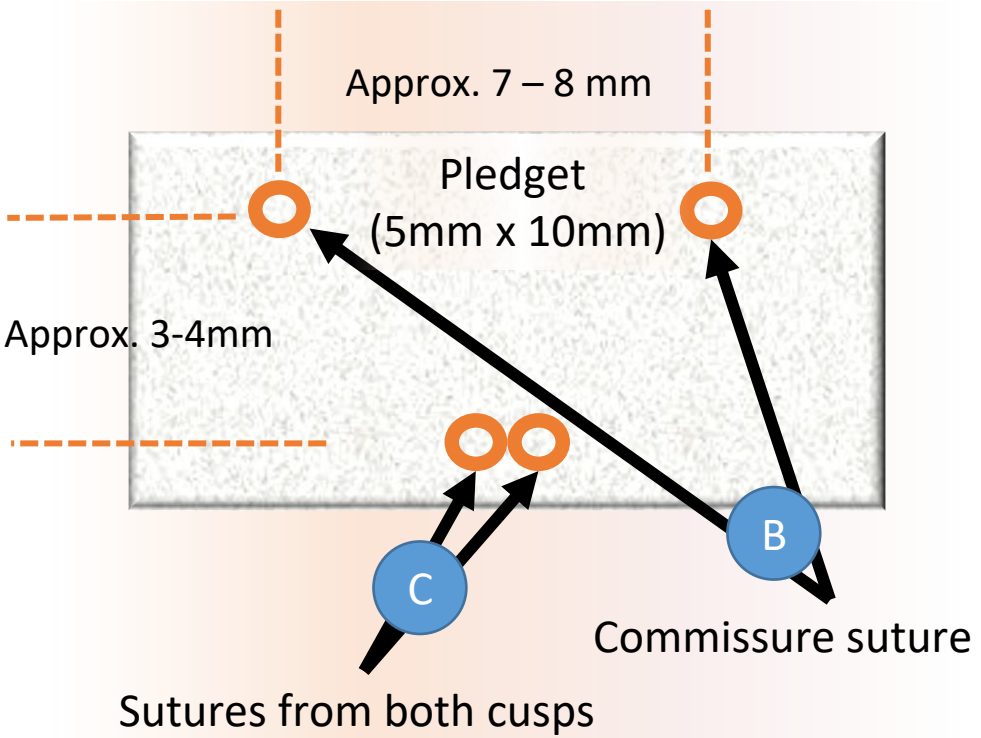
- **A 4-0 proline RB-1 (17mm, 90cm) is used to make commissure.**
- The suture runs as described in the images. It is placed at midpoint between the free edge and the previous stitch (approx. 2.5mm from edge).
- It then penetrates the wing extensions.
- Finally, the suture penetrates the aorta, leaving 4 sutures outside of the aortic wall.
- **A 5mm x 10mm PTFE pledget is sutured on the aortic wall with the 4 sutures.**

Map of the commissure

View from inside of the aorta



View from outside of the aorta



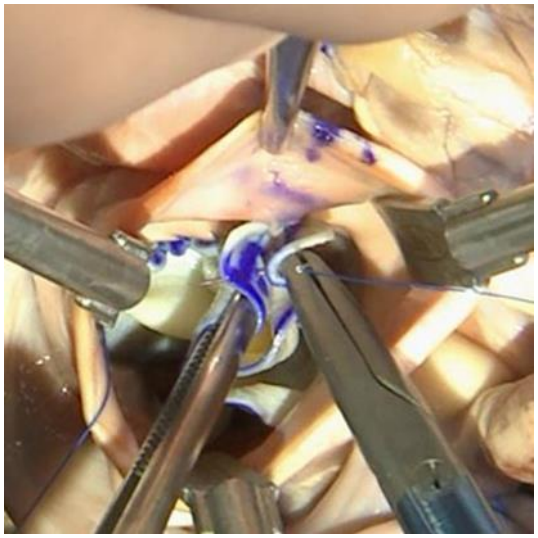
Last annular suture (=**last dot**)on cusp located at 5mm from edge

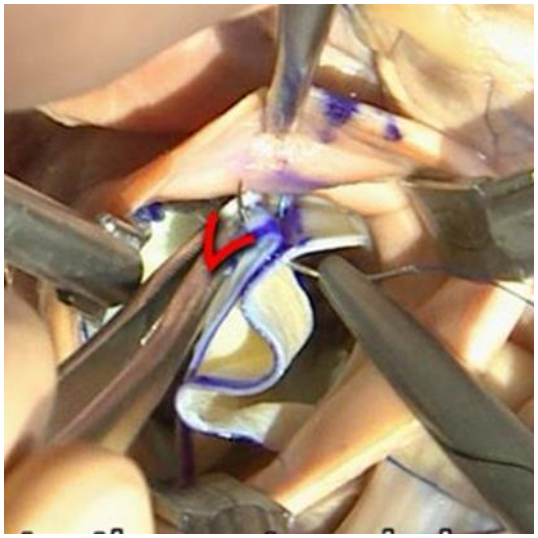
Commissure suture

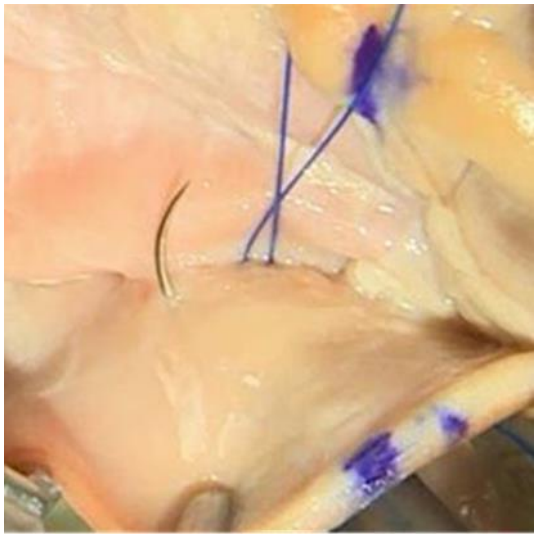
A. The point about 2.5mm from edge should be sutured.
This is almost the same height as native commissure.

B. The sutured point at the corner of the wing extension is located slightly higher than point 'A'

Commissure suturing (1/3)

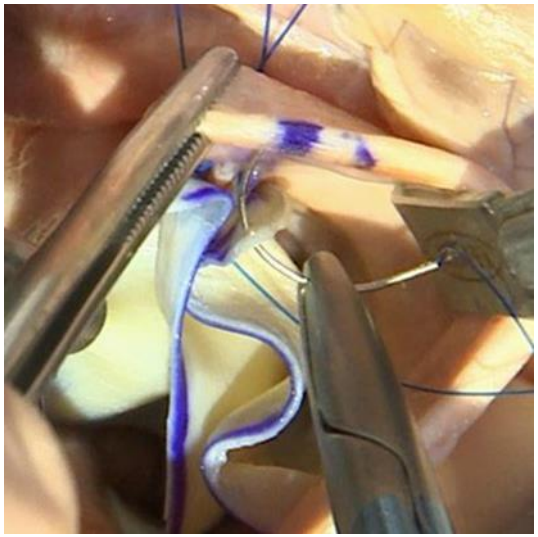


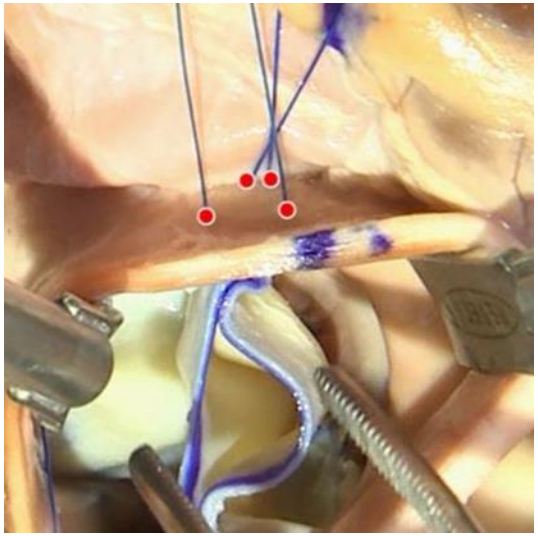




- 4-0 proline RB-1 (17mm, 90cm) is used to make the commissure.
- **First, penetrate the two cusps by passing the needle at the point 2.5mm from the edge (as described before in point A).**
- **Secondly, penetrate the top corner of wing extension.**
- **Then, penetrate the aortic wall at point B. Please make sure that point B is located laterally and superiorly from point A.**
- This needle does not need to be straightened.

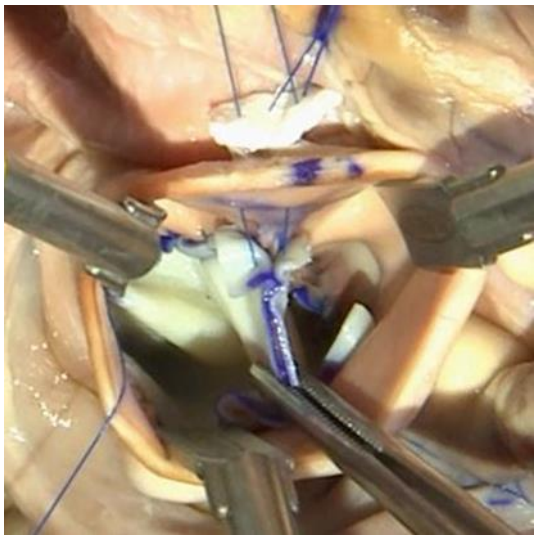
Commissure suturing (2/3)





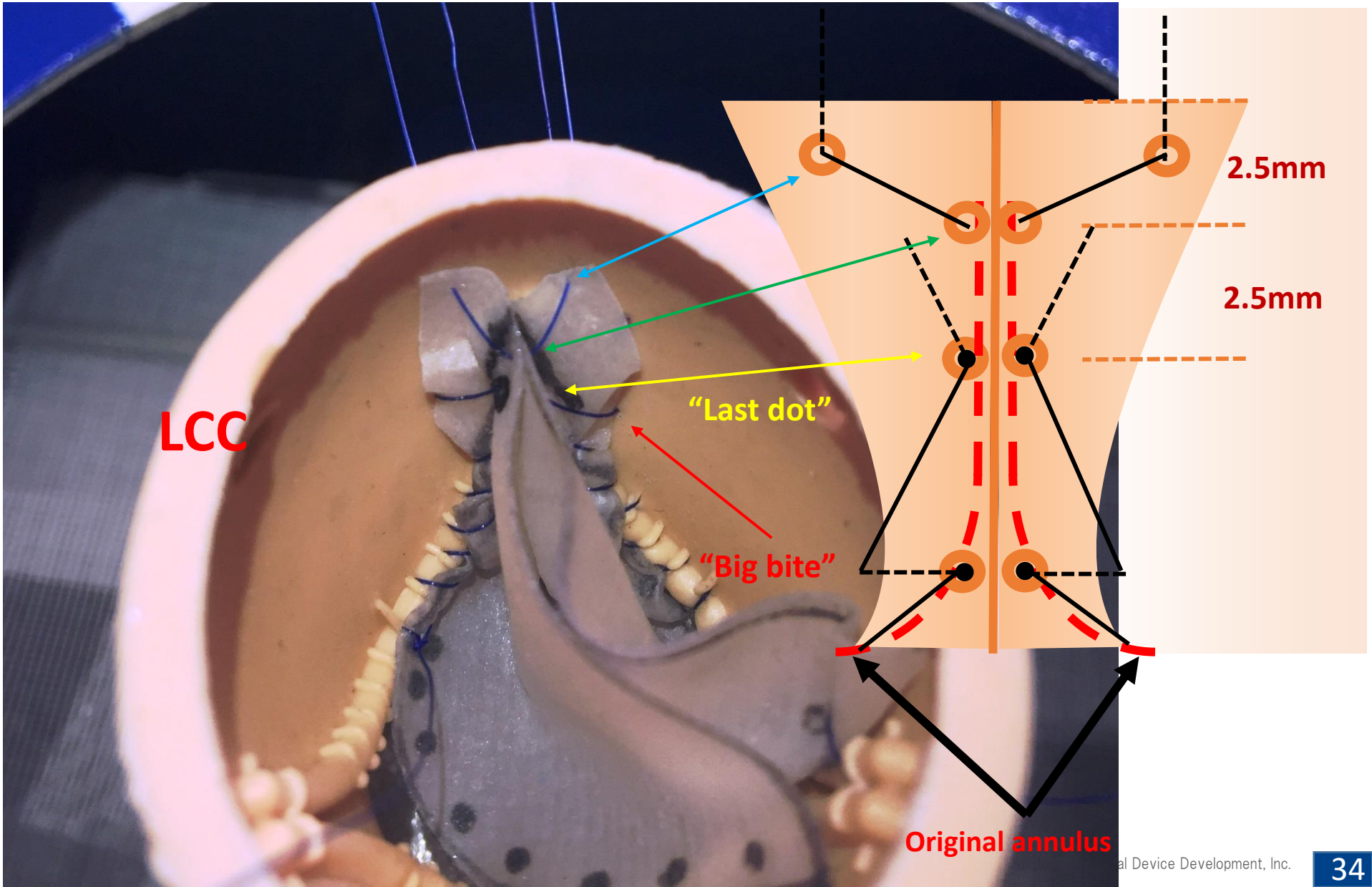
- Penetrate the top corner of the other cusp with the other needle and pass through the aortic wall.
- Then, four sutures can be seen from outside of the aorta.
- Pass the four sutures through a 5mm x 10mm PTFE pledget, (note the two higher threads are more widely separated than the lower two threads.

Commissure suturing (3/3)

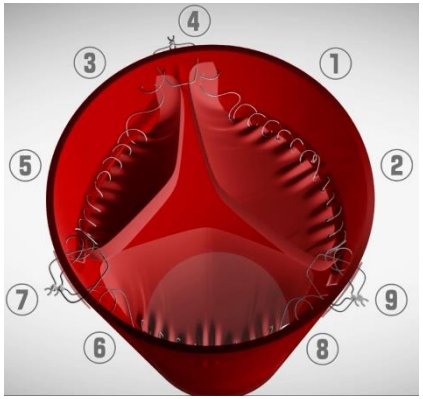


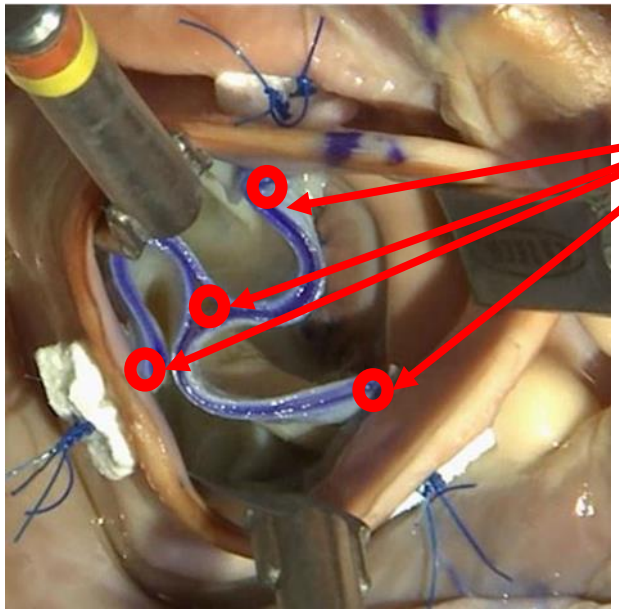
- **Before tying knots, make sure that (1) the cusp at the area of the commissure is oriented inward and (2) the wing extensions are applied neatly against the aortic wall.**
- **After confirming (1) and (2), tie the upper (wider) pair of sutures first then tie the lower (narrower) pair of sutures.**
- Each pair of sutures are tied with eight knots.

Completion of the commissure



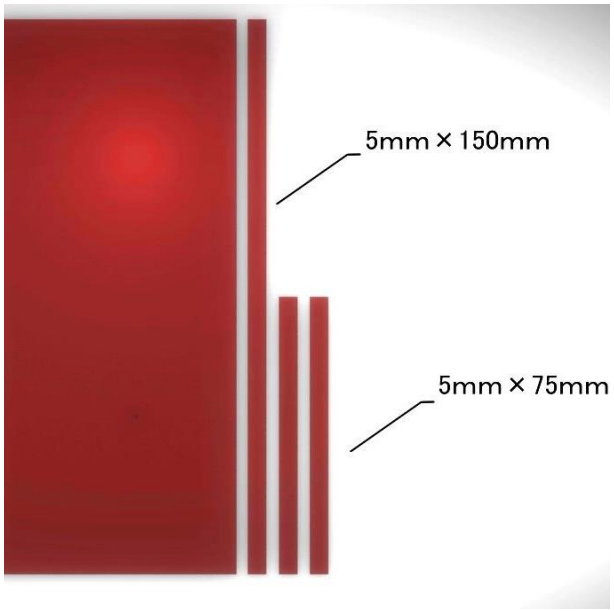
Completion of AVNeo

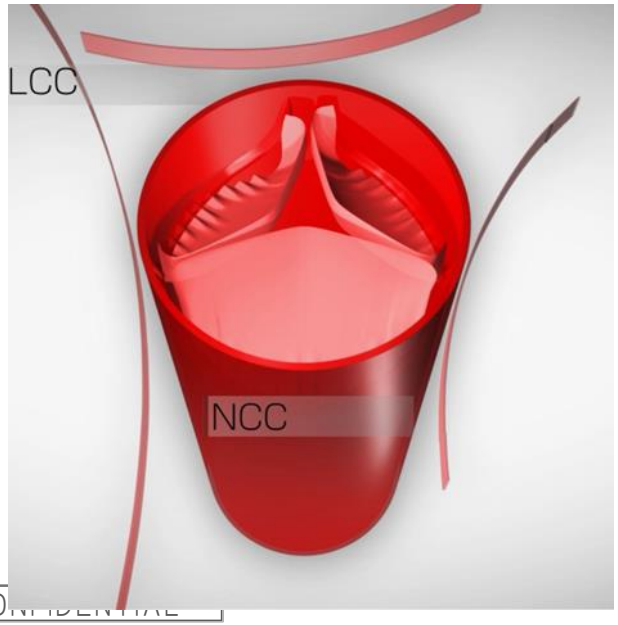




- Create three commissures in the order shown left.
- Before closing the aorta, make sure that:
  i. The three cusps form the typical “pinwheel”.
  ii. The three commissures and the contact point of those commissures are on the same plane.
  iii. A good optimal and large coaptation zone is formed.

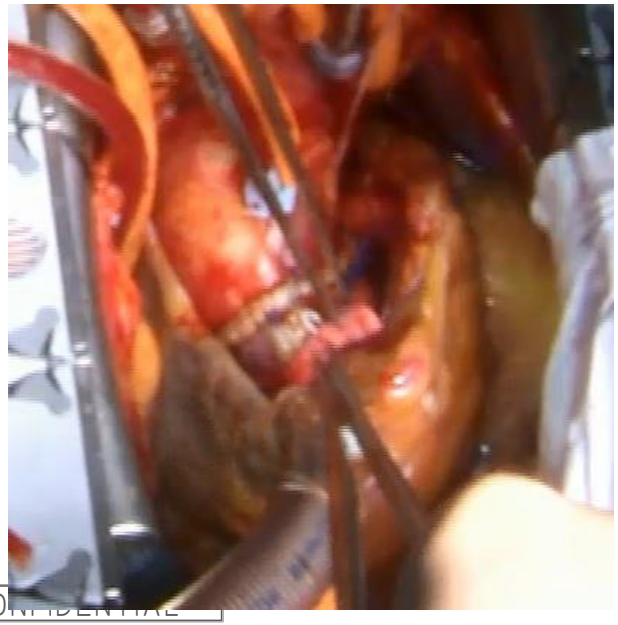
Reinforcement with pledgets - 1





- There is a chance of remote aortic dilatation in the cases of aortic regurgitation, bicuspid aortic valve, and unicuspid aortic valve.
- In cases with normal AVNeo, felts with the size of 5x10 mm are used to make commissures, but in cases with risk of aortic dilatation, three longer felt strips are used.
- The longest felt strip with 150mm in length is used between LCC and NCC.

Reinforcement with pledgets - 2



- After raising the pressure of the ascending aorta by de-clamping, then start suturing the felt strip onto the aorta from of the both the end.
- In cases where there is an anomalous origin of LCA (higher than usual), the felt strip can cause obstruction of the ostium. In these cases, regular felt pledgets should be used.

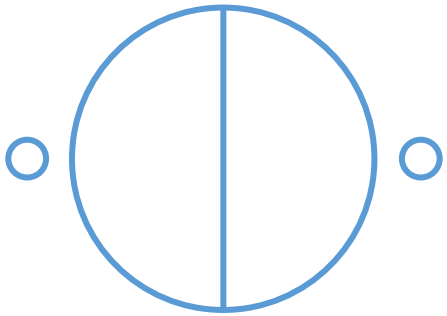
Additional instructions for bicuspid cases (Advanced)

Important steps for bicuspid cases

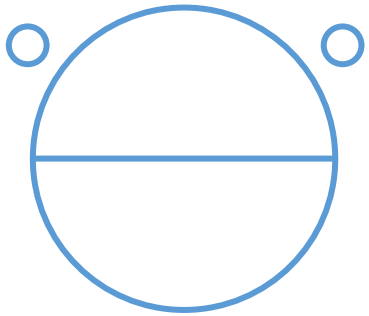
- Identify the types of bicuspid valves
- Decide the reference point
- Decide the size of the cusps
- Draw new annulus and commissure
- Reinforcement of the new commissure
- Pledget reinforcement

Other than this, follow the same technique as described in the tricuspid section (page 23-35).

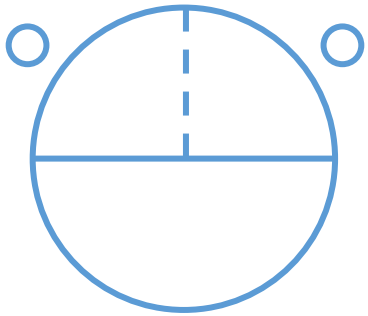
Types of bicuspid valves



Left-Right type



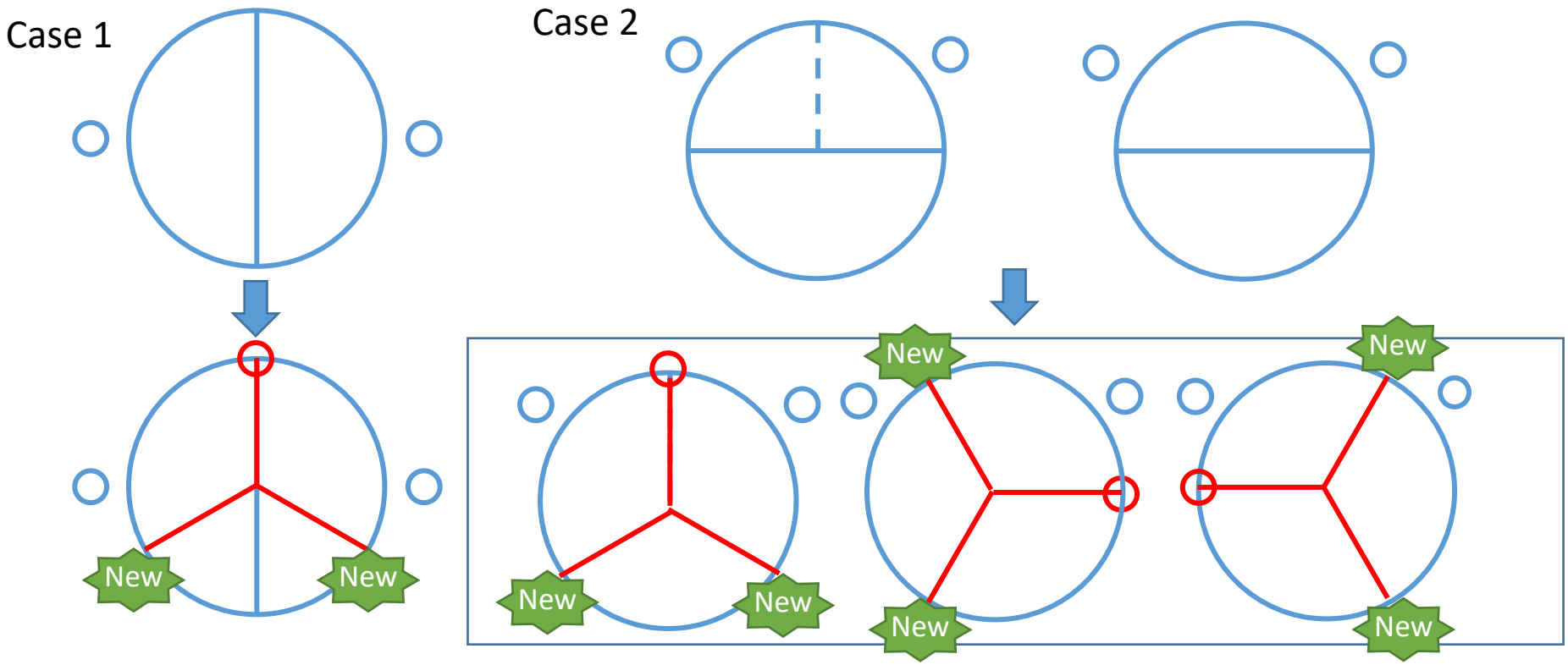
Ant-Post type (raphe -)



Ant-Post type (raphe +)

- First, identify the types of bicuspid valve is important.
- Please check the locations of coronary arteries, commissures and raphes if exist.

Deciding the reference

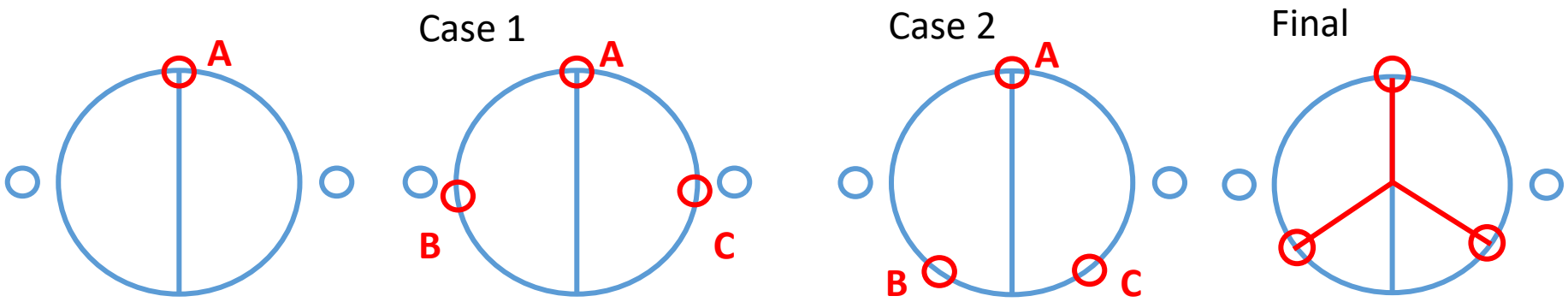


- Depending on the locations of coronary arteries and commissures, one of the commissures or raphe (or if no raphes, mid point of both coronary arteries) is used as “reference”
- Case 1: The reference should be either of the commissures.
- Case 2: The reference should be the raphe (or if no raphes, mid point of both coronary arteries) or the commissure.

Deciding the size (1/2)

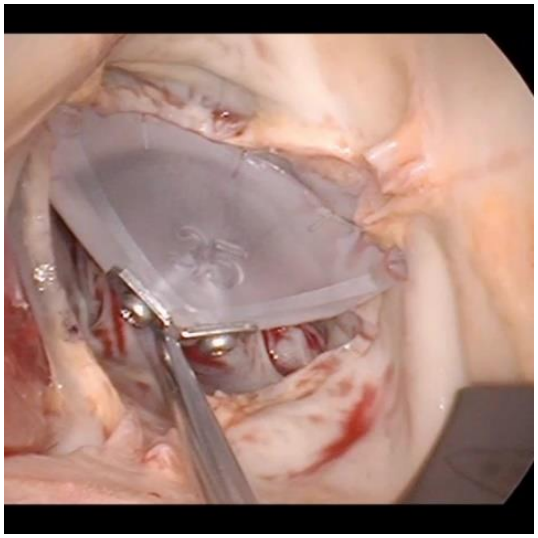
- Basically, the sizes of three cusps should be as equal as possible.
- If a cusp is far larger than the others, smaller cusps sometimes do not move naturally.
- Additionally, existing commissures, raphes and native cusp attachment line should be used as much as possible because of their increased tolerance for stress.
- Sizing the leaflets for bicuspid patients requires more sizer trials, adjustments, and retrials compared to tricuspid patients .

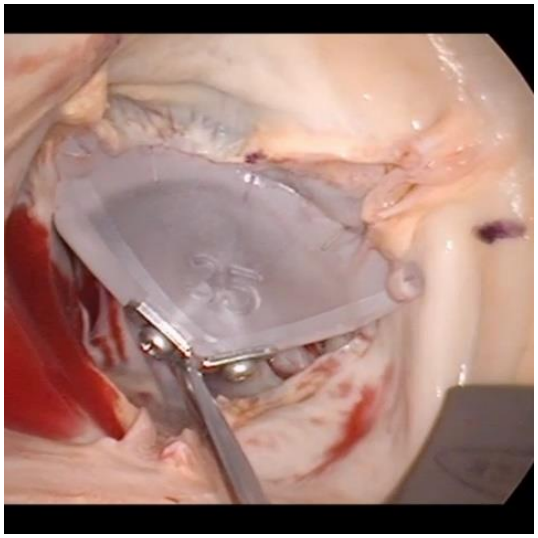
Deciding the size (2/2)

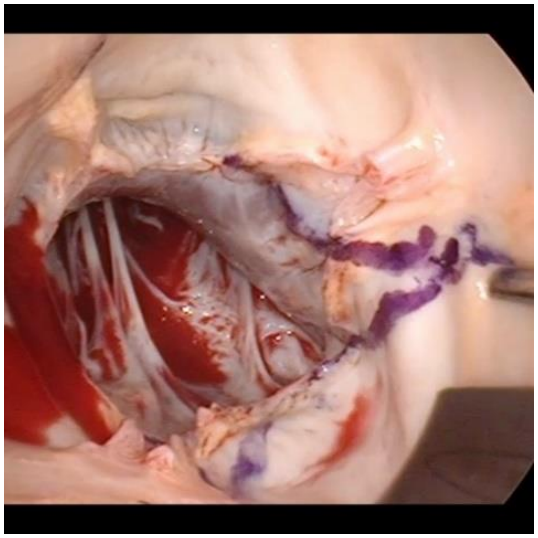


- First, attach one endpoint of the sizer to the reference(A) and check the locations of the other endpoint on both sides (B and C).
- If distance between B and C is far longer than the selected sizer, select a larger sizer and measure again (Case 1).
- If distance between B and C is far shorter than the selected sizer, select a smaller sizer and measure again (Case 2).
- Repeat this process until an appropriate size is found（Final).

Drawing new annulus and commissure

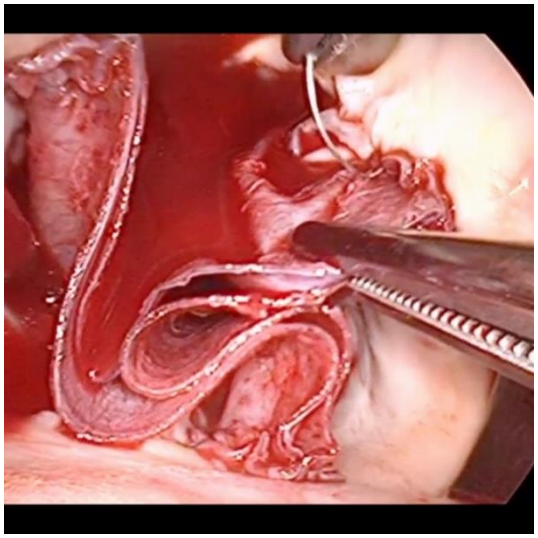
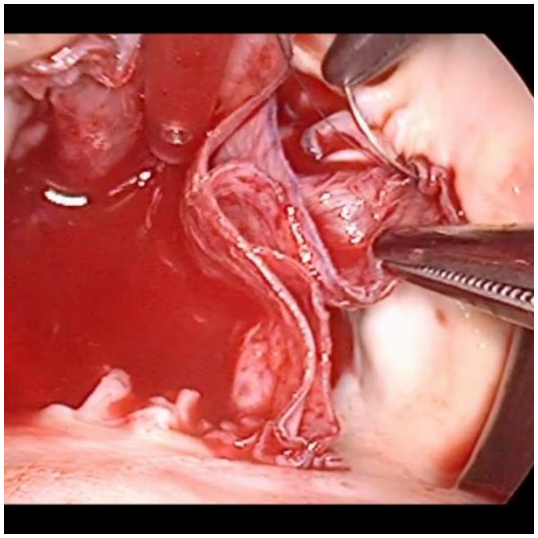
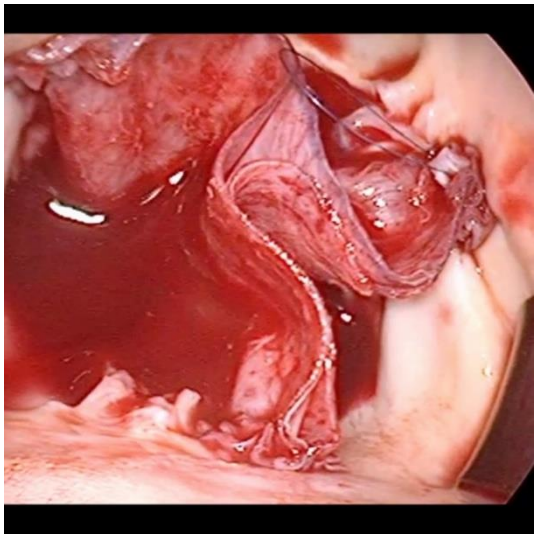






- Using the selected sizer, mark the location of the new commissure and the midpoint of new annulus.
- Height of the new commissure is the same height as the native commissure.
- Referring the new commissure and the midpoint of the new annulus, draw new annulus.

Reinforcement of new commissure

- Using residual pericardium, pericardial pledgets are trimmed (2 x 3mm).
- These pericardial pledgets are attached on the wing of the cusp to reinforce the new commissure.
- Wing and aortic wall are sandwiched with the pericardial pledget inside and the felt pledget (3 x 4 mm) outside.

Reinforcement of new commissure illustrated