

# The Melody<sup>®</sup> TPV Implantation Step-by-Step: A Proctor's Guide

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The guideline below describes the consensus and the agreement reached by the group of European Melody<sup>®</sup> Transcatheter Pulmonary Valve (TPV) proctors on procedural steps for percutaneous pulmonary valve implantation with Melody<sup>®</sup> TPV and the Ensemble<sup>®</sup> Delivery System (DS). However, they are not meant to replace good medical judgement which may apply on a case by case basis, or to influence the current practice of proctors at their own institutions.

The proctors agreed to adhere to the recommendations and procedural steps summarized in this document, during their teaching and proctoring activities. These guidelines will be revised and discussed on a regular basis to adapt to the evolution of practice and available clinical data.

An appendix containing a table with products typically used for Melody<sup>®</sup> TPV implantations is attached.

These guidelines and appendix have been prepared by:

**Dr. Maarten Witsenburg, Erasmus Rotterdam, Rotterdam, The Netherlands**  
**Prof. Marc Gewillig, UZ Leuven, Leuven, Belgium**  
**Dr. Mark Turner, Universities Hospitals Bristol, Bristol, UK**  
**Prof. Ingo Dähnert, Herzzentrum Leipzig, Leipzig, Germany**

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## Patient Selection

- Assess symptoms, RV function, PS, PR, bifurcation.
- Confirm the indication to intervene: is the patient a candidate for Melody?
  - Candidates for Melody must be free of active infection, and have a conduit or an anatomical stenosis in the RVOT or main pulmonary artery - the presence of a complete ring of prosthetic material is advisable during early experience
  - A full understanding of the anatomy, size and precise surgical history of the RVOT is essential
- Is there a need for stenting peripheral pulmonary stenosis?
- Is there a bifurcation stenosis?
- Are coronary issues to be expected?
- Check MR, CT, angiography, surgical notes
- Treat all possible sources of endocarditis (dental check)

## Cath Lab Set-Up

- General anaesthesia preferred.
- Biplane catheterization laboratory preferred.
- Patient position: to improve image quality, keep patient's arms out of lateral view
  - Option 1: arms lifted up, behind patient's neck
  - Option 2: cushion under shoulders, chin upwards and back, arms alongside patient

Advantage of option 2:

- more cranial tilt possible for RVOT imaging
- Conversion to jugular access easier
- Reduced risk of overstretching leading to plexus lesion

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## Imaging Planes

### Lateral:

- Ideal to visualise anterior chest and landing zone for Melody
- Ideal for proximal end of pre-stent
- Best view during positioning of stents

### AP:

- With cranial tilt ideal to visualize bifurcation and distal end of stent
- AP cranial +/- LAO angulation to document relation to bifurcation

## Heparinization and Antibiotics

- Full Heparinization and Antibiotics according to local practice

## Initial access site preparation:

- Prepare both sides for vascular access to allow quick change in case of problems
- Use a maximum of 10Fr sheath for initial venous access:
  - suitable for insertion of sizing balloons without need to replace the introducer
  - suitable for wire and 6Fr Multitrack catheter
- Use 5Fr sheath for arterial access
- continuous direct arterial pressure monitoring throughout procedure

## Catheterization and Haemodynamic evaluation

- Angiography as needed depending on previous catheterisation and cross sectional imaging data
- Establish stiff wire position:
  - The fewer curves the better
  - Endeavour to maintain the tip of the wire at level diaphragm, or as distal as possible
  - Ensure wire does not interfere with Tricuspid valve chordae
    - Check with Multitrack  
and/or
    - Use balloon tipped or Pigtail catheter.
- Pre-bending of the wire may be indicated depending on individual anatomy

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## Pure Pulmonary Stenosis or Combined Pulmonary Stenosis / Regurgitation

### 1. Pre-Dilatation

- Decide about final target diameter to be achieved with Melody<sup>®</sup> TPV for optimal hemodynamic outcome: 18 – 20 – 22 mm.
- Consider the maximal outside diameter of the Melody<sup>®</sup> TPV with fully inflated balloon to be 24mm, 22.4mm or 20mm respectively (for Ensemble sizes 22, 20 or 18mm)
- Delineate landing zone, if doubt interrogate with balloon:
  - Low pressure/ sizing balloon: delineate anchoring zone
  - High pressure balloon: is conduit / RVOT dilatable?  
**NOTE:** If high risk for conduit tear is present, do not perform aggressive high pressure dilation - proceed to coronary investigation and immediate covered CP stent implantation
- Combined aortic root angiogram and balloon dilation to delineate coronary anatomy and exclude risk of coronary ostium/ coronary compression:
  - If coronary arteries are distant, low pressure will suffice
  - If coronary arteries are close, full inflation indicated (if fear for tear: see below)
- If in doubt about coronary compression: perform selective coronary angiogram with high pressure balloon 18-22 mm and full opening of balloon. In addition, consider additional views (i.e. "barrel view" with maximum caudal/LAO angulation)
- If still in doubt: repeat last step with a balloon + 2 mm in size:
  - Consider, that the Melody<sup>®</sup> TPV stent dilated with a 22mm Ensemble will reach a maximum outside diameter of 24mm
  - Consider to compensate for thickness of Melody<sup>®</sup> TPV and any pre-stent(s)
- Control RVOT angiography for possible extravasation:
  - If fear of tear **or** proven extravasation and rupture:
    - Deploy covered CP stent with length coverage from  $\geq 1$  zig below to  $\geq 1$  zig beyond conduit  
**NOTE:** Long covered CP stents need to be available on the shelf (available with CE mark up to length of 45mm).
    - Initially no need to fully open stent (especially if danger of coronary compression): appose stent to wall and flare ends against wall to seal tear
    - If danger of coronary compression: abort procedure
    - If no danger of coronary compression: proceed

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## 2. Pre-Stenting

Consider using 18Fr venous sheath for easy exchange of balloons and long sheaths for pre-stenting and successive pre-dilatation of vessel to accommodate 22Fr Ensemble<sup>®</sup> DS

- Stent choice for first stent:
  - *Bare stent if*
    - No extravasation
    - Full balloon expansion achieved by pre-dilatation
    - No later need for further expansion to accommodate for patient growth
  - *Covered stent in case of*
    - Extravasation
    - Anticipated conduit tear or fracture
    - A late possible tear following Melody<sup>®</sup> TPV implantation, when accommodating for expected patient growth - a tear may require bail-out stenting with a covered stent which will render the first Melody<sup>®</sup> TPV non-functional
- Stent length & technique
  - *General:*
    - Consider Melody stent length to be 23mm, 24.2mm or 26.2mm after delivery on Ensemble 22mm, 20mm or 18mm, respectively.
    - Aim to cover the entire length of the Melody<sup>®</sup> TPV
  - *Bare stent:*
    - Length: sufficient to cover stenotic area and entire length of the Melody<sup>®</sup> TPV
    - No need for flaring stent
    - If in bifurcation and PA is jailed: dilate cells with Atlas ultra-high pressure balloons > 20 atm to re-open stent to PA
  - *Covered stent*
    - Length: aim for coverage from  $\geq 1$  zig below to  $\geq 1$  zig beyond conduit
    - Beware of PA jailing
    - Flare ends to get maximal apposition of stent against wall to seal expected tear
    - If inadequate sealing is expected at that point, allow ingrowth for two months
- Continue with bare pre-stents until no recoil/ compression/ unwanted motion
  - To control this, record balloon in- and deflation
  - If in doubt, repeat coronary angiogram before further dilation
  - Dilate stent until desired internal diameter  $\leq 23$  mm is achieved
- Re-evaluate RV and PA pressure / gradient
- Repeat RVOT angiogram for extravasation
  - If none, proceed with Melody<sup>®</sup> TPV
  - If yes, place additional covered stent

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## 3. Melody<sup>®</sup> TPV Insertion and Implantation

- Prepare Melody<sup>®</sup> TPV on Ensemble<sup>®</sup> DS
  - After covering the valve, de-air and further crimp the Melody<sup>®</sup> TPV as this will facilitate uncovering
- Pre-dilate groin with 22Fr dilator
  - This is not required if sheath 18Fr is used, as outer diameter ≈ 22Fr
- Insert Ensemble<sup>®</sup> DS in groin and push haemostatic sleeve valve in groin/ access site
- Advance Melody<sup>®</sup> TPV to preferred landing zone:
  - RA, landing zone and distal tip of wire must be seen at all times
  - If wire position is lost any time during Melody<sup>®</sup> TPV positioning:
    - Do not push the stiff wire forward as risk for peripheral vascular rupture is high
    - Melody<sup>®</sup> TPV can be safely removed and repositioned as long as the valve is at least partially covered
    - Re-establish stable wire position with use of catheter
  - Co-ordination between first and second operator is necessary to safely advance the system into position
    - Pushing the Ensemble<sup>®</sup> DS at the groin will only move the system forward or backward (turning not possible)
    - Driving the wire will determine how carrot moves:
      - Keep wire “fixed”: if lucky carrot may take nicely all turns
      - If carrot encroaches at entry into the RVOT:
        - Push on Ensemble<sup>®</sup> DS on fixed wire will make tip wire come backward!
        - Push on Ensemble<sup>®</sup> DS and little pull on wire may make carrot come loose from wall and allow advancement
      - **NOTE:** be aware of wire coming back; if too much, wire needs to be repositioned as distal as possible
      - Push on Ensemble<sup>®</sup> DS and push on wire to establish a loop in RA: once against wall in RA, fix wire which will allow more push on carrot at a different angle in RVOT
    - Once carrot has passed landing zone, straighten the wire in RA - the loop keeps Tricuspid Valve open - then proceed with implantation of Melody<sup>®</sup> TPV
  - If placement remains difficult, consider
    - Changing of present wire position in LPA or RPA
      - Wire in LPA: carrot will push anterior on RVOT
      - Wire in RPA: carrot will push left lateral on RVOT
      - Loop wire in RA or with jugular access: carrot will enter RVOT more centrally
    - Change to stiffer or less stiff wire
    - Change to jugular access: carrot will enter RVOT more centrally

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- Uncover Melody<sup>®</sup> TPV by pulling the sheath back to the double marker on the Ensemble<sup>®</sup> DS
- Before uncovering, tension should be removed from wire and Ensemble<sup>®</sup> DS
  - To uncover the valve the shaft of the Ensemble<sup>®</sup> DS should be held in a fixed position with right hand and then the cover (not the seal-valve) should slowly be withdrawn with the left hand, towards the right  
**NOTE:** Forward movement of the valve may occur during this manoeuvre
  - In cases where it is difficult to advance the valve, the (partial) uncovering manoeuvre may allow the valve to be advanced the final few millimeters into position. In cases where this is needed, the outer cover can be fixed with the left hand and the shaft of the Ensemble<sup>®</sup> DS may be advanced with the right hand.  
**NOTE:** This should only be performed by an experienced implanter
  - Ensemble<sup>®</sup> DS may also move forward when the inner balloon is inflated
  - Avoid falling backward into the RVOT, as you may not be able to regain landing zone forward - falling forward into PA is less problematic (see below)
  - If too much friction and/ or unable to uncover:
    - Straighten the Melody<sup>®</sup> TPV in the distal PA
    - Start uncovering
    - Then reposition Melody<sup>®</sup> TPV in the landing zone  
**NOTE:** this manoeuvre may be difficult/ impossible when open-cell or hybrid-cell stents are used for pre-stenting
  - Complete uncovering must be confirmed prior to any balloon inflation, by checking markers on balloon shaft
    - Further confirmation can also be demonstrated by a contrast injection into the side arm of the Ensemble<sup>®</sup> DS
    - If the Ensemble<sup>®</sup> DS has moved significantly after uncovering, reconfirmation of uncovering should be undertaken just prior to balloon inflation
- Deploy Melody<sup>®</sup> TPV by inflating the inner balloon first and then - after confirmation of position, if needed - inflate outer balloon until satisfactory deployment is achieved such that the Melody is well apposed to the pre-stent to ensure stability
- The inner balloon is usually deflated first followed by deflation of the outer balloon - recording the deflation can be helpful
- Care must be taken when removing the Ensemble<sup>®</sup> DS through the Melody<sup>®</sup> TPV to avoid leaflet damage
  - The balloon should be carefully and slowly withdrawn by maintaining the wire position in the center of the valve.
- The Ensemble<sup>®</sup> DS with deflated balloon should be carefully removed in order to avoid damage to the valve leaflets
  - Closing of the sheath should not be attempted before having retracted the Ensemble<sup>®</sup> DS into the IVC - the carrot has a flush-flow design so closing of the Ensemble<sup>®</sup> DS before removal at the groin is not necessary

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- Post dilation with appropriately sized (ultra-) high pressure balloon (maximum balloon size is 24mm) is indicated, if there is a gradient of >20mm Hg or if any angiographic stenosis is present.
  - NOTE: Verify before, whether the gradient is caused by the valve diameter or another sub- or supra- valvular structure
- RV pressure and RV-PA gradient should be measured
- Angiography should be performed
  - RVOT angiography can demonstrate if any extravasation of contrast has occurred and should be performed in case of any hemodynamic instability
  - Main PA angiography may be performed to demonstrate competence of the valve.
    - For patients with renal insufficiency TTE may be used to demonstrate valve competence.

## **Pure Pulmonary Regurgitation**

- Angiography: landing zone retention  $\leq 2$  mm, length of landing zone sufficient?
- Delineate landing zone with low pressure or sizing balloon of 25mm - no need for high pressure balloon:
  - Check for residual waists
  - Check distensibility of conduit or tissue
  - Do not apply maximum pressure to preserve landing zone
- Exclude danger of coronary compression
- Pre-stent landing zone with bare stent on BiB with maximum diameter of 24 mm
  - Open-cell or hybrid-cell bare stents are preferred due to their improved anchoring facilities.
  - Use the longest available stent for pre-stenting to achieve stable landing zone and be sure to have adequately sized balloons available
- In case of pre-stenting with balloons >24mm allow for ingrowth and shaping of the stent contour for 6-8 weeks - re-assess and consider an additional pre-stent for stability
- If doubt about stability: allow ingrowth of stent for  $\geq 8$  weeks
  - If stent re-entered with wire after 8 weeks,
    - Avoid side hole of stent by use of a J- tipped wire or balloon tipped catheter
    - Ensure wire does not interfere with Tricuspid valve chordae
- Continue implantation as described above in section 3.

## **Appendix: Products typically required for Melody<sup>®</sup> TPV implantation**

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### Products typically required for Melody<sup>®</sup> TPV implantation

Product	Manufacturer
<b>Sheaths / Introducers</b>	
18F sheath (30cm)	Cook / SJM
12F Mullins long sheath Check-Flo Performer Introducer	Cook
14F Mullins long sheath Check-Flo Performer Introducer	Cook
<b>Balloons</b>	
Sizing balloons up to 30mm diameter	various
High pressure balloons (5-7 atm burst pressure) in sizes up to 26mm	various
Mullins-X Ultra High pressure dilation catheter 18mm X 4 cm	NuMed
Mullins-X Ultra High pressure dilation catheter 20mm X 4 cm	NuMed
Mullins-X Ultra High pressure dilation catheter 22mm X 4 cm	NuMed
Mullins-X Ultra High pressure dilation catheter 25mm X 4 cm	NuMed
Atlas PTA Balloon Dilatation catheter 18 mm X 2 cm X 125 cm	BARD
Atlas PTA Balloon Dilatation catheter 20 mm X 2 cm X 125 cm	BARD
Atlas PTA Balloon Dilatation catheter 22 mm X 2 cm X 75 cm	BARD
Atlas PTA Balloon Dilatation catheter 24 mm X 2 cm X 75 cm	BARD
BIB dilation catheter 18mm x 4.5 cm*	NuMed
BIB dilation catheter 20mm x 4.5 cm*	NuMed
BIB dilation catheter 22mm x 4.5 cm*	NuMed
BIB dilation catheter 24mm x 5 cm * **	NuMed
* balloon length should reflect length of chosen stent	
** advanced users	

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Product	Manufacturer
<b>Guidewires*</b>	
Amplatz Ultra Stiff guide wire 0.035 in x 260cm	Cook
E-wire 0.035 in x 300cm*	Jotec
Archer 0.035 x 260 cm Single J or Double J*	Medtronic
Lunderquist 0.035 in x 260cm*	Cook
Back-up Meier guidewire 0.035in x 300cm*	Boston Scie.
* one wire in addition to Amplatz Ultrastiff per user preference	
<b>Stents*</b>	
CP stent 34mm / 39mm /45mm	NuMed
Intrastent Max LD 36mm	ev3
Andra stent XXL 39/43/48/57mm	Andra Med
* per Operator preference; open cell stents preferred for dilatable conduits	
<b>Covered CP stent</b>	
CCP 34 mm	NuMed
CCP 39mm	NuMed
CCP 45mm	NuMed
<b>Dilator</b>	
22 Fr vessel dilator	Cook
<b>Products required for valve preparation:</b>	
2 bowls filled with a minimum of 500 ml isotonic saline	
1 empty smaller bowl	
Scalpel	
Forceps	
2/ 2.5 ml syringe	