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The Heart Team Approach

TAVI procedures with Artis zeego in the Cardiovascular Center (HKZ)
Rotenburg an der Fulda, Germany

Illustrated workflows in hybrid operating rooms, No. 9

Cardiovascular Center Rotenburg an der Fulda, Clinic for Cardiovascular Surgery

The Cardiovascular Center (HKZ) Rotenburg an der Fulda was founded in 1974. It is an integrated center for diagnostics, therapy and rehabilitation of cardiovascular diseases with about 570 beds and about 900 employees. Rotenburg is associated with the Johann Wolfgang Goethe University Frankfurt as an academic training institution. It accommodates several medical disciplines such as cardiovascular surgery, cardiology, neurology and orthopedics.

The Clinic for Cardiovascular Surgery complemented the center in 1989. It offers modern surgical therapies such as minimally invasive and catheter-based procedures of the heart. In particular, it focuses on the minimally invasive treatment of heart valve and coronary artery disease.

The institution provides four operating rooms, including a modern hybrid operating room (OR). This hybrid OR is managed by a joint team of cardiac surgeons and cardiologists.

It is utilized, e.g. for transapical and transfemoral replacement of the aortic valve and aortic stent implantation. Physicians and patients benefit from precise intra-operative imaging and guidance accomplished by the multi-axis Siemens Artis zeego imaging system.

Dr. Ardawan Rastan has headed the Clinic for Cardiovascular Surgery in Rotenburg since 2012. He is an internationally well-known cardiac surgeon who worked as a consultant in the Heart Center Leipzig before he took over the position in Rotenburg. He specialized in minimally invasive valve and coronary bypass surgery.

In the Rotenburg heart team, cardiac surgeons work with interventional cardiologists, anesthesiologists, and prosthetic valve specialists.



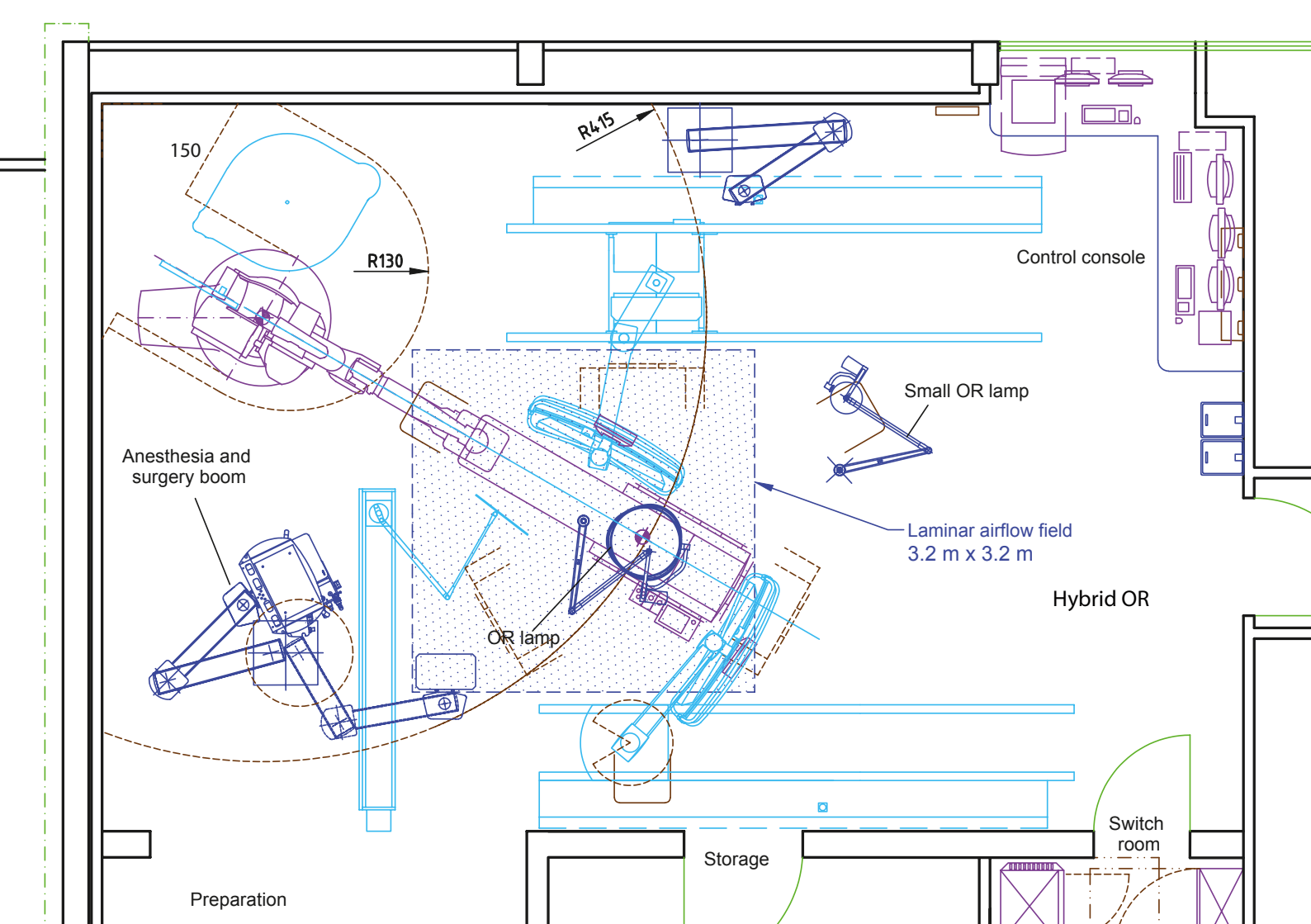


Hybrid operating room layout

The hybrid operating room (OR) in the Cardio-vascular Center Rotenburg is equipped with the robotic imaging system from Siemens, Artis zeego. The system is installed in-line with the free-floating Artis OR table, which is called the zero degree installation.

The room size is about 73 m² (786 ft²) excluding the control room. The room accommodates two Siemens Large Displays, a cardiovascular ultrasound system, a Dräger anesthesia boom, a Stöcker heart-lung machine and a range of storage shelves. A 3.2 m x 3.2 m laminar airflow field is installed above the operating table.









The heart team approach

Transcatheter aortic valve implantation (TAVI) is a minimally invasive, catheter-based procedure to replace the aortic valve without removing the non-functional native valve. TAVI is a fairly new method. However, the number of procedures has grown at double-digit rates over the last years. The procedure is indicated for patients with severe aortic stenosis who are considered high-risk candidates for open surgery. The American College of Cardiology (ACC) and the Society of Thoracic Surgeons (STS) recommend the utilization of a hybrid OR for TAVI.

During the procedure a biological valve prosthesis is crimped and introduced into the aortic annulus via a catheter, either through the apex of the heart (transapical approach) or the femoral artery (transfemoral approach). In the landing zone the valve is deployed within the native aortic leaflets. The main criteria for a successful delivery are: no aortic valve regurgi-

tation, low pressure gradient over the valve, no heart rhythm block and no interference with coronary perfusion.

In Rotenburg the TAVI procedure is performed in a heart team approach to ensure optimal patient treatment and favorable clinical outcomes. Before the procedure the cardiac surgeon and the interventional cardiologist jointly decide whether the transapical or transfemoral approach is the best access route for the individual patient. The anesthesiologist ensures hemodynamic stability and safety of the patient before, during and after the procedure. In many cases a prosthetic valve specialist performs the preparation and the crimping of the new valve into the delivery catheter.

Dedicated system features and software for TAVI and cardiac surgery

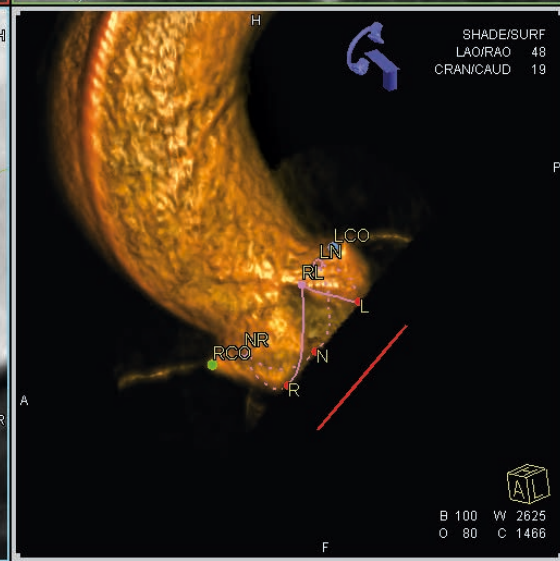
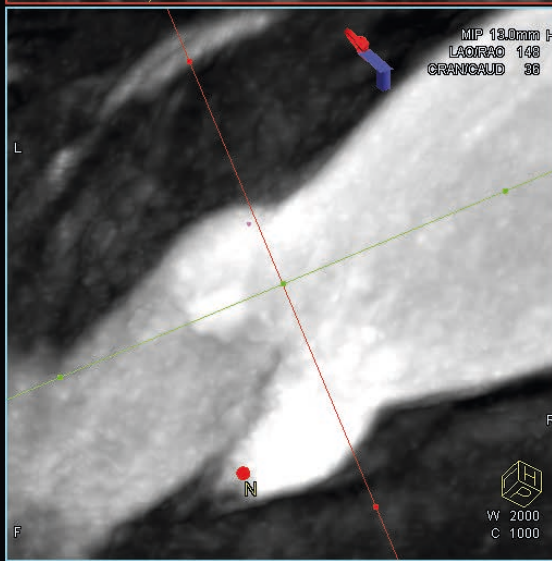
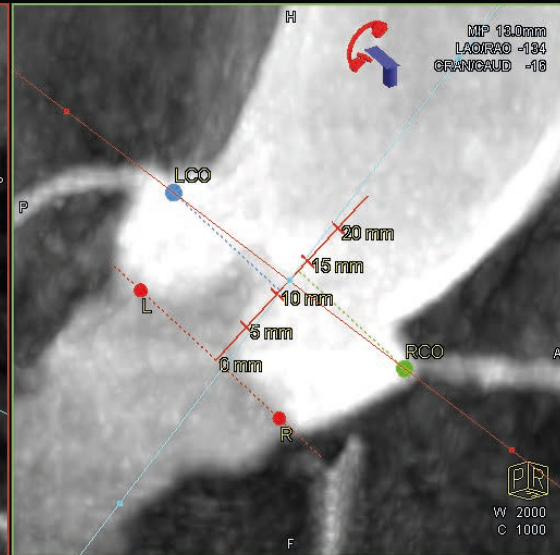
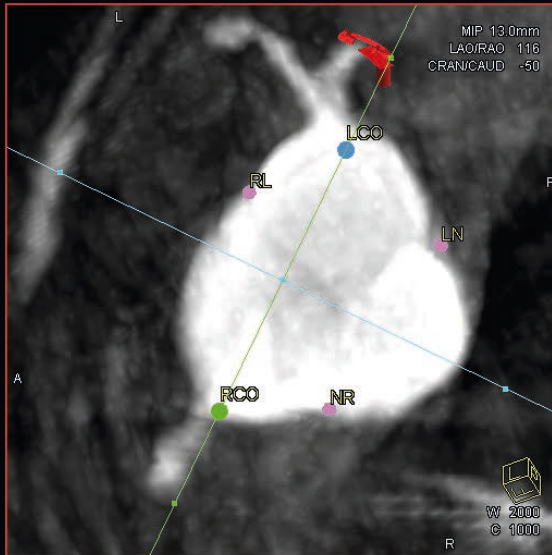
The Clinic for Cardiovascular Surgery in Rotenburg uses the dedicated features of the Artis zeego and software applications to support the surgical procedure.

Artis zeego

Intra-operative 3D imaging and guidance is the main benefit of a hybrid OR and the most important feature of the Artis zeego. The multi-axis robotic system provides unmatched flexibility in different positions of the patient and the team. This allows for minimal disturbance of the workflows including anesthesia. The robotic arm can be parked away from the table to free up space at tableside. Artis zeego can adapt to the height and angulation of the OR table. The surgeon can work ergonomically even during imaging. Because of the floor-mounted design, interference of the C-arm with laminar airflow is minimized. High hygienic standards are promoted by the floor-mounted design.

syngo DynaCT

Planning and guiding complex procedures can be improved with intra-procedural 3D images that show the actual state of the aorta. *syngo DynaCT* utilizes data acquired from a rotational angiography run to create 3D images. It enables the surgeon to examine pathologies from angles unavailable in open surgery. *syngo DynaCT* is the basis for advanced 3D applications like *syngo iPilot* and *syngo Aortic Valve Guide*.



Dedicated system features and software for TAVI and cardiac surgery

***syngo* iPilot**

Based on 3D images acquired with *syngo* DynaCT *syngo* iPilot provides the ability to overlay the segmented 3D volume on top of the live fluoroscopic image. The software is the key to 3D image guidance during surgery: It dynamically overlays the registered 3D volume, either as a volume-rendered or a contour outline, correcting for every change in the C-arm angulation, table position, zoom and source-image distance (SID) and provides 3D orientation during fluoroscopy.

***syngo* Aortic Valve Guide**

For 3D image guidance during TAVI with minimal user interaction, *syngo* Aortic Valve Guide (AVG) offers automatic segmentation of the aortic root and the coronary arteries after 3D acquisition. The software then automatically detects anatomical landmarks and displays other guidance features such as the measurement scales, centerline, and commissures. Most importantly, it suggests the ideal perpendicular projection plane.

After contrast injection into the aorta and a five-second image acquisition, *syngo* Aortic Valve Guide automatically reconstructs and segments the aorta and the coronary arteries. The software detects the commissures and the lowest points of the aortic cusps. Together, these three points define the annulus plane. One centimeter below and parallel to this plane, *syngo* Aortic Valve Guide calculates an imaginary circle, which can be rotated virtually

until only a line is visible (red line below aorta in screenshot). This is the optimal view of the aortic annulus for valve implantation.

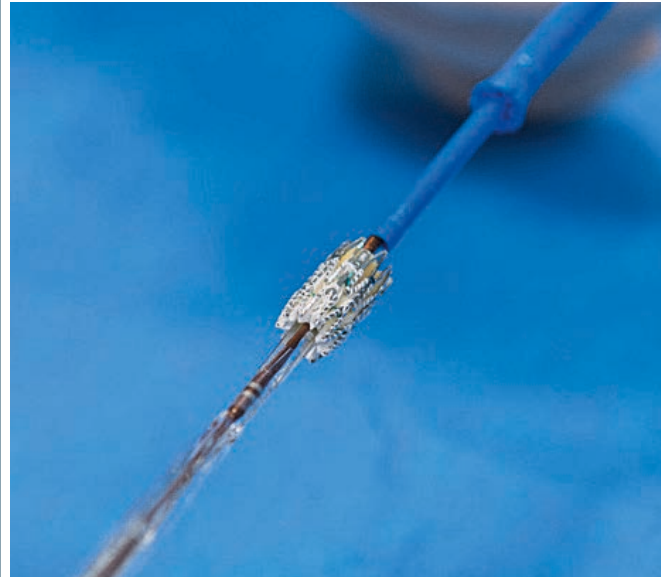
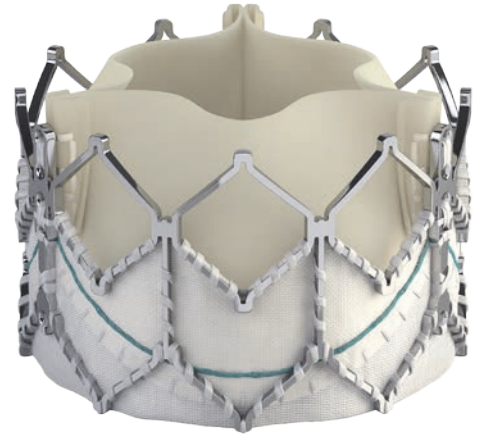
The entire AVG workflow takes less than 25 seconds. Once the optimal angulation is found, the C-arm can be moved automatically to that position perpendicular to the annulus plane. Automation and straightforward guidance reduce total fluoroscopy time [Poon et al., EuroIntervention, 2012].



Clinical case

The 79-year-old female patient presents with significant aortic stenosis and a calcified aortic valve. Because of the patient's frailty and serious comorbidities, the TAVI procedure is chosen instead of open surgery. Her femoral arteries are calcified and too small for transfemoral access to the heart. Therefore, the heart team decides on a transapical path to the aortic valve. In this case the Edwards SAPIEN XT valve is used for implantation.

With 3D guidance based on syngo Aortic Valve Guide the second and third generation of TAVI valves (e.g., Medtronic Engager, JenaValve, Symetis Acurate) can also be rotated and positioned according to the anatomy of the patient and the geometry of the valve.

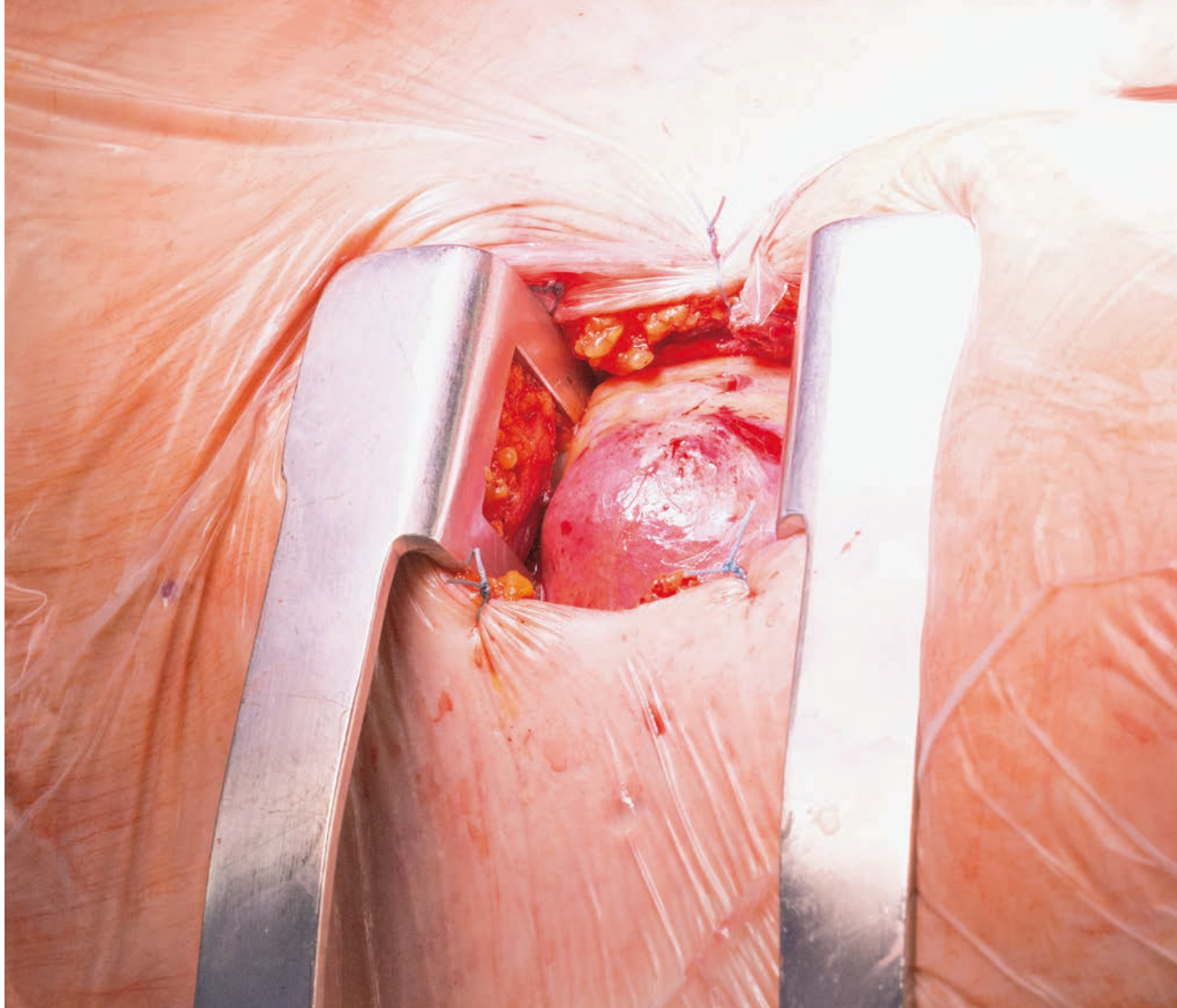




Transapical access to the heart

In this particular case the transapical access path is optimal for the implantation of the new valve. The patient is in the supine position and covered with sterile drapes. The surgeon exposes the patient's heart by lateral thoracotomy through the sixth intercostal space. In this position the apex of the heart is easily accessible and allows a straight trajectory to the aortic valve. As part of the preparation the ribs are spread and the pericardium is incised near the left ventricular apex. After exposure of the cardiac apex, purse string sutures are placed around the access puncture at the tip of the left ventricle.





3D image acquisition with *syngo* DynaCT

The detector unit and the tube of the Artis zeego are packed in sterile draping to provide sterility when the C-arm is rotating over the surgical field. For a *syngo* DynaCT run Artis zeego comes from a stand-by position and approaches the patient from the right cranio-lateral direction. Before the acquisition run a slower test rotation is performed to ensure collision-free movement of the C-arm. Therefore the heart team cleans up wires, tubes and drapes that could interfere with the C-arm. A fluoroscopic shot of the aorta without contrast medium is done so that the system can calculate appropriate tube parameters.

Then a five-second *syngo* DynaCT is performed to acquire 3D image data. Typically 25 cc contrast dye diluted with 50 cc saline are injected. *syngo* Aortic Valve Guide reconstructs and segments the aorta and the coronary arteries automatically after the 3D run has been performed. It marks the nadir points of the aortic cusps, the commissures and the centerline of the

aorta on the screen. The nadir points define a plane in three-dimensional space. The software calculates an imaginary circle one centimeter below and parallel to this plane. It rotates the circle virtually until it transforms into a line (see red line in screenshot). This perpendicular view on the aortic annulus is optimal for the implantation of the prosthetic valve. With a push of a button the C-arm can be moved to this projection plane.





Surgical preparation

Under fluoroscopic control a guidewire and a sheath (short hollow tube) are introduced via the apex of the heart into the left ventricle. *syngo* Aortic Valve Guide is used to display an overlay of the 3D volume and the fluoroscopic image. The overlay view helps the surgeon to find the optimal position for the balloon catheter.

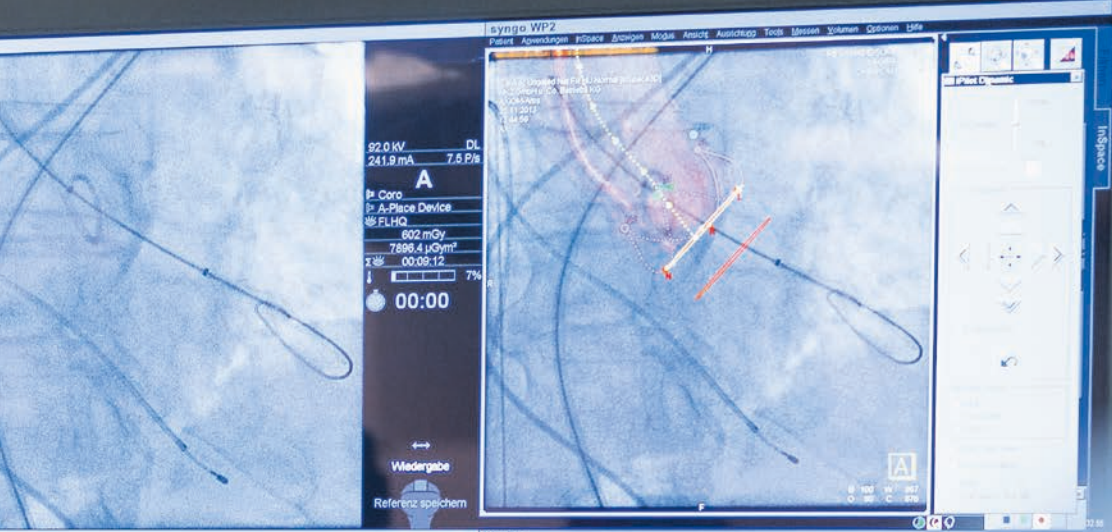




Balloon valvuloplasty

Balloon valvuloplasty facilitates the preparation of the stenotic valve for implantation of the new valve. Before the new valve can be placed, the native valve has to be opened. A balloon catheter is introduced into the aortic annulus via the left ventricle. It is inflated with a contrast-diluted fluid at about 2 atm to dilate the constricted valve. Balloon valvuloplasty is performed under rapid pacing. A ventricular pacemaker stimulates the heart to beat at about 180 bpm, which minimizes movement and blood flow.





Deployment of the new valve

In this case the Edwards SAPIEN XT valve is used. It is constructed of bovine pericardium on a metal stent. To get the valve through the catheter, it is crimped onto the delivery balloon. The surgeon ensures the correct orientation and position of the transcatheter valve according to the anatomy of the patient and the geometry of the valve. Artis zeego is used in fluoroscopic mode to advance the valve through the sheath into the aortic annulus within the native valve of the patient.

syngo Aortic Valve Guide is used to overlay the segmented 3D volume of the aorta on top of the fluoroscopic image. The software shows the surgeon the perpendicular projection plane on the aortic annulus. If necessary, contrast medium is injected to confirm the position of the Edwards prosthesis, ideally about 1/3 below the base of the aortic sinuses. In addition to fluoroscopy the heart team is uses transesophageal echocardiography to check pressure gradients and confirm regular valve functioning in order to avoid paravalvular leaks.



Surgical closure and debriefing of the heart team

Wires and introducer are removed at a systolic blood pressure of about 100 mmHg. To reduce pain after the procedure, the surgeon injects bupivacaine close to the intercostal nerve. A drainage tube stays in the left chest to remove liquids from the wound. The surgeon approximates the intercostal muscles and closes the skin of the patient.

After the procedure is finished the heart team meets to review the results of the procedure.





Configuration of the hybrid operating room

Cardiovascular Center Rotenburg an der Fulda, Germany

- Artis zeego multi-axis imaging system with Automap functionality
- Artis OR table
- Two Large Displays with AXIOM Sensis XP interface
- 30x40 cm² detector, 3D CARD acquisition
- syngo X Workplace with syngo DynaCT, syngo iPilot, syngo iGuide Toolbox, syngo Aortic Valve Guide and syngo Angio package
- Weiss Mediclean laminar airflow field 3.2x3.2 m²
- Dräger Polaris OR lamps, Movita booms, Agila ceiling supply unit
- Stöckert S5 heart-lung machine
- Heinen + Löwenstein Leon Plus anesthesia system
- Cardiac ultrasound system





The Benefits

- Intra-operative 3D guidance and increased procedural safety
- Speed and efficiency with automated workflow
- From rotational angiography to segmented 3D volume in less than 25 seconds
- Less overall fluoroscopy time [Poon et al., EuroIntervention, 2012]
- Hygienic design because no ceiling-mounted components disturb laminar airflow
- Unrestricted access to the patient and plenty of space for anesthesia



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