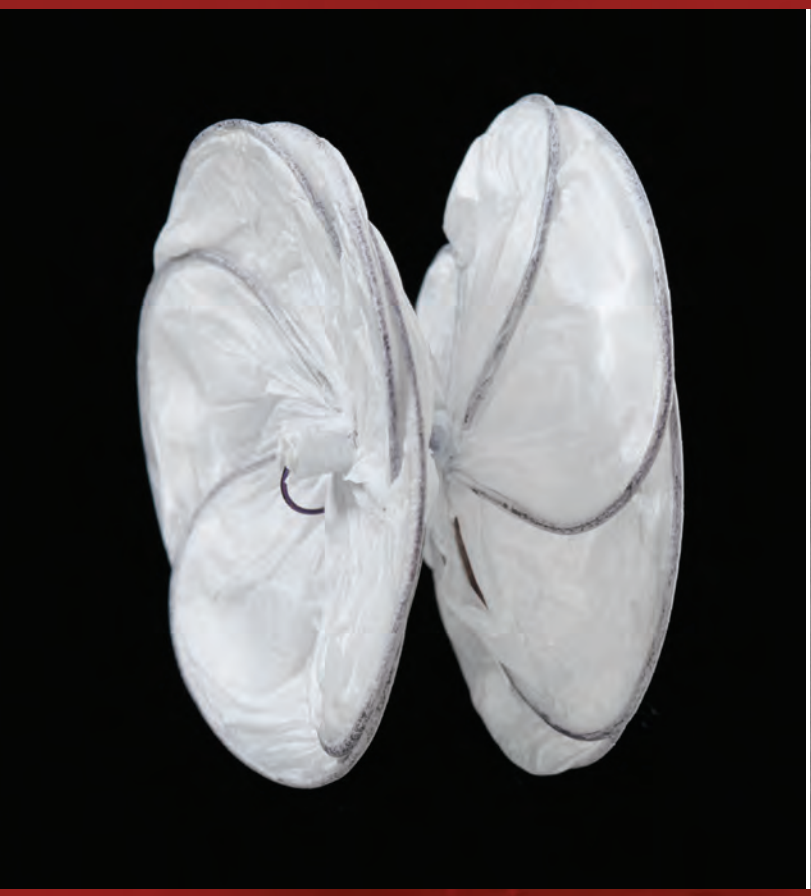
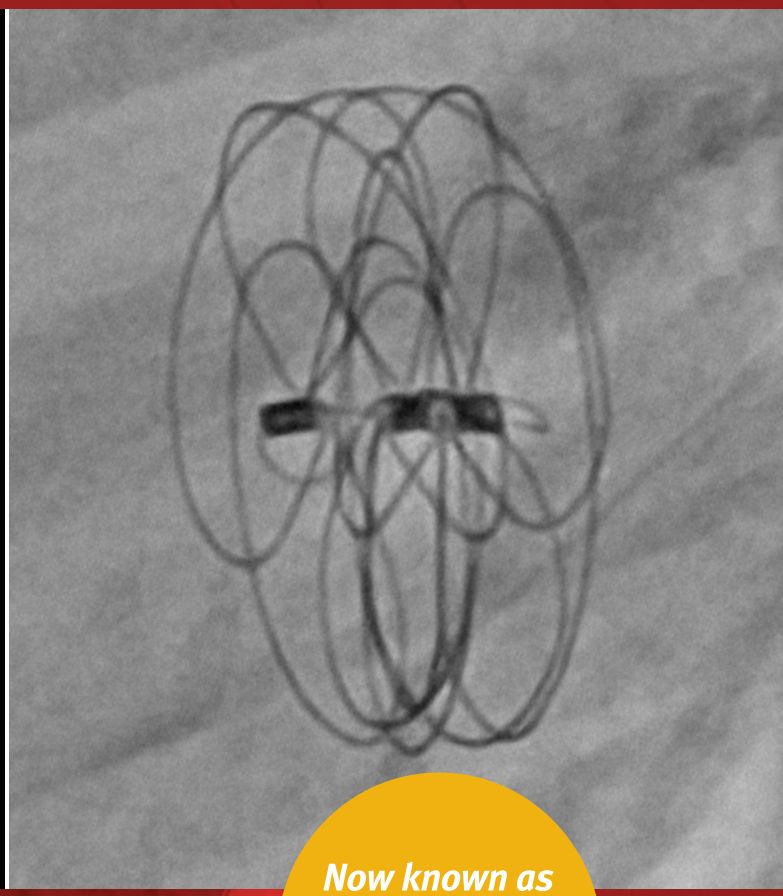
Case Study





Now known as
GORE® CARDIOFORM Septal Occluder

Use of the GORE® Septal Occluder for Percutaneous Closure of an Iatrogenic Atrial Septal Defect after Percutaneous MITRACLIP® Clip Delivery System Implantation

GORE CARDIOFORM SEPTAL OCCLUDER

PERFORMANCE by design

CASE STUDY

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A 68-year-old male was admitted to the hospital due to recurrent cardiac decompensations with severe pulmonary and peripheral edema. The patient complained about New York Heart Association Class III-IV dyspnea. Concomitant diseases were hypertensive heart disease with a left ventricular ejection fraction of approximately 10%, status post-implantation of a three-chamber Cardiac Resynchronization Therapy (CRT) system (left bundle branch block was previously diagnosed), status post-mechanical aortic valve replacement, permanent atrial fibrillation, chronic renal failure, iron deficiency anemia, and obstructive sleep apnea syndrome with nasal continuous positive airway pressure ventilation therapy. Cardiovascular risk factors besides hypertension were diabetes Type 2, hyperlipidemia, and obesity. Cardiac catheterization showed only coronary arteriosclerosis. Transthoracic and further transesophageal echocardiography revealed severe mitral valve regurgitation *(Figure 1)*. After interdisciplinary discussion, the patient was recommended to undergo percutaneous mitral valve repair with the MITRACLIP® Clip Delivery System.

After venous access and transseptal puncture, the MITRACLIP® Device was advanced via a special 24 Fr delivery system into the left ventricle under transesophogeal echocardiography (TEE) and fluoroscopic guidance *(Figure 2)*. The device was positioned over the mitral orifice and perpendicular to the mitral valve leaflets. While pulling back, the MITRACLIP® Device grasped the leaflets and was tightened to ensure permanent leaflet approximation and to reduce the mitral valve regurgitation *(Figure 3)*. In this particular case of severe functional Mitral Valve Regurgitation (MR) due to significantly reduced left ventricular function, a total of four clips were implanted

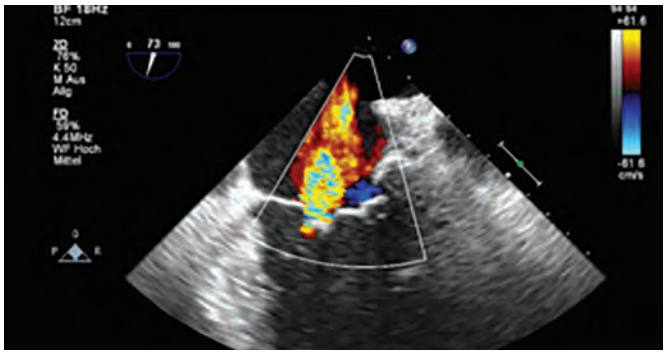


Figure 1. *The severity and morphology of the MR is demonstrated under use of the intercommisural projection.*

using a so called “zipping technique” *(Figure 4)*. Post-interventional echocardiography confirmed a reduction of the MR from severe to mild.

The MITRACLIP® Clip Delivery System has a diameter of 24 Fr. Thus, an iatrogenic ASD (iASD) is created and in some cases it will disappear over time. In patients such as the one treated here, with a highly limited left ventricular ejection fraction and with potential hemodynamic relevance of an ASD, percutaneous closure of the iASD in the same procedure as the MITRACLIP® Device implantation is prudent. A GORE® Septal Occluder was chosen for closure because of its soft material, optimal adaption to the septum, atraumatic and conformable disc design, as well as the low risk of thrombus formation due to the ePTFE covering. Balloon sizing showed a defect size of 8.5 mm and therefore a 20 mm GORE® Septal Occluder was selected. After verifying sufficient heparinization (activated clotting time > 200 seconds) the introducer sheath was placed at the femoral vein. Then the Occluder was loaded under heparinized saline into the delivery catheter and flushed abundantly in order to eliminate all air in the system and avoid air embolism. The Occluder was then advanced through the iASD into the left atrium with the correct position confirmed via fluoroscopy and TEE. First, the left atrial disc was positioned and then the right atrial disc was deployed to configure the device *(Figure 5)*. After confirming the correct position, the Occluder was locked and released. TEE confirmed complete closure and flat profile of the Occluder against the septum *(Figure 6)*.

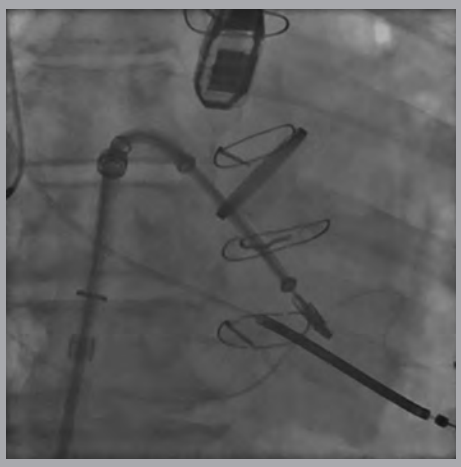


Figure 2. *The 24 Fr sheath is placed in the left ventricle with the first MITRACLIP® Device positioned in the mitral orifice.*

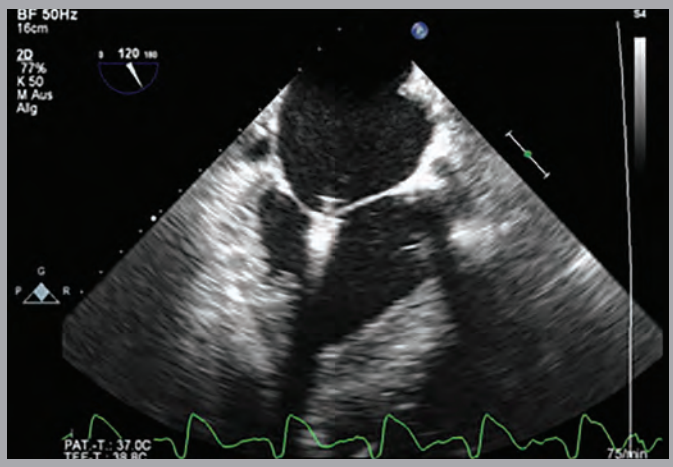


Figure 3. *Long-axis view demonstrating the first released MITRACLIP® Device in its correct place.*

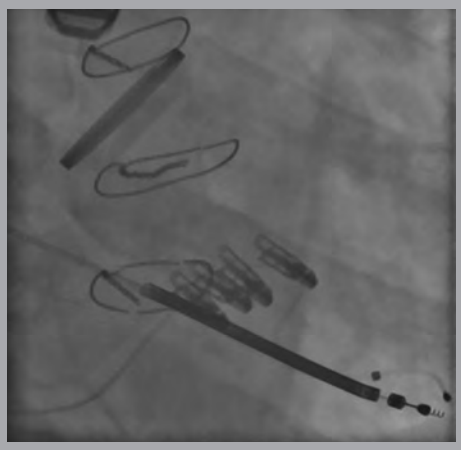


Figure 4. *A total of four MITRACLIP® Devices were implanted.*

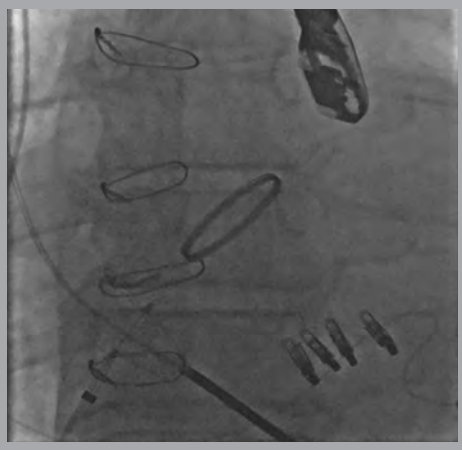
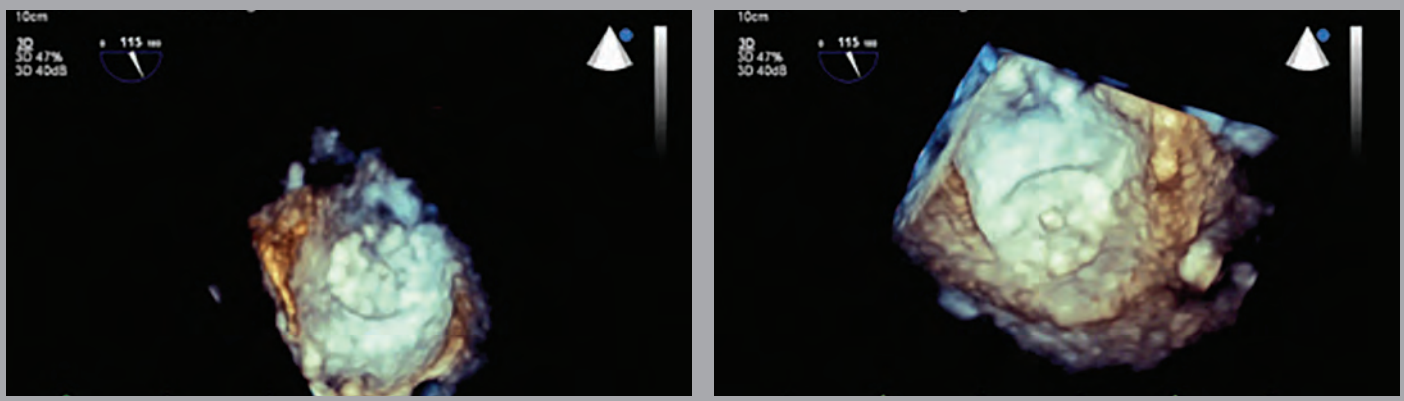


Figure 5. *Opening and positioning of the left atrial disc of the GORE® Septal Occluder. The MITRACLIP® Devices are apparent in the bottom right.*



Figures 6a and 6b. *Three dimensional echocardiography views showing the left atrial disc of the GORE® Septal Occluder in place with a flat profile against the septum.*

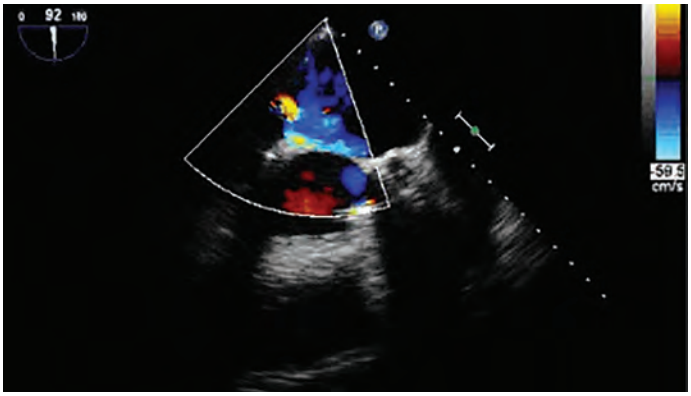


Figure 7. *Six-month follow-up TEE showing no evidence of a relevent residual shunt.*

In this case, the GORE® Septal Occluder was ideal for closure of an iASD in this highly compromised patient.

Post-procedural dual antiplatelet therapy was administered for one month, as the patient was on additional vitamin K antagonist due to his mechanical aortic valve.

Six months after the procedure, TEE confirmed a stable position of the Occluder and showed no evidence of residual leakage and the patient reported a significant improvement of his symptoms *(Figure 7)*.

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