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Abstract

The MitraClip device has been in US trials since 2003 and in clinical use internationally since 2008. A great deal has been learned about how to perform the procedure since its inception. This chapter details the technique of percutaneous mitral leaflet repair. The mechanics of the procedure and the associated echocardiographic and anatomic imaging necessary to understand the procedure are reviewed in a step-by-step guide. The chapter is of interest to anyone wishing to learn how to perform this novel therapy or for operators who wish to learn more. Cardiologists, cardiac catheterization lab nurses and technicians, and echocardiographic technicians will also find the chapter informative.

Keywords

Mitral regurgitation • MitraClip • Procedure • Technique

Device Description and Procedural Overview

Over the last decade, as significant advances have been made in developing minimally invasive surgical repair of valvular heart disease, several percutaneous catheter-based technologies have been tested for the repair of severe mitral regurgitation (MR). In a surgical technique that was initially described by Dr. Ottavio Alfieri and his group in 1991, the placement of one or more sutures, approximating the edges of the mitral leaflets at the origin of the MR jet, led to the creation of a so-called bow-tie or double orifice with a significant reduction in the MR jet and has immediate and long-term sustainable results. Adapted from this technique, the MitraClip (Abbott Laboratories, Menlo Park, CA) has rapidly evolved as the only percutaneous method to gain wide clinical application for mitral valve repair (MVR) for selected patients. The procedure requires a dedicated team of physicians and is performed under general anesthesia using fluoroscopy and primarily transesophageal echocardiographic (TEE) guidance in the cardiac catheterization laboratory. The main procedure elements are well developed with a significant

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learning curve. It is critical that the interventional operator and the echocardiographer have a common vocabulary for the basic procedural TEE views so that clear communication can be maintained during the procedure. The US-based randomized Endovascular Valve Edge-to-Edge Repair Study (EVEREST) clinical trials showed both the safety and

efficacy of this therapy. The device is already CE approved and is being used increasingly for the percutaneous repair of both high surgical risk degenerative as well as functional MR patients in Europe, Asia, and Australia. In the USA as of this printing, its use is still under investigation and is not yet FDA approved.

MitraClip Device



Fig. 2.1 Double-orifice surgical MVR with a suture. Surgical repair of anterior leaflet prolapse using an edge-to-edge technique by opposing the middle scallops of the anterior and posterior leaflets with stitches creating a so-called dual-orifice or double-orifice mitral valve is shown [1–3]. The clinical success and simplicity of this technique prompted interest in development of a catheter-based MitraClip technology that would enable the interventional cardiologist to perform a percutaneous, endovascular valve repair in the cardiac catheterization laboratory

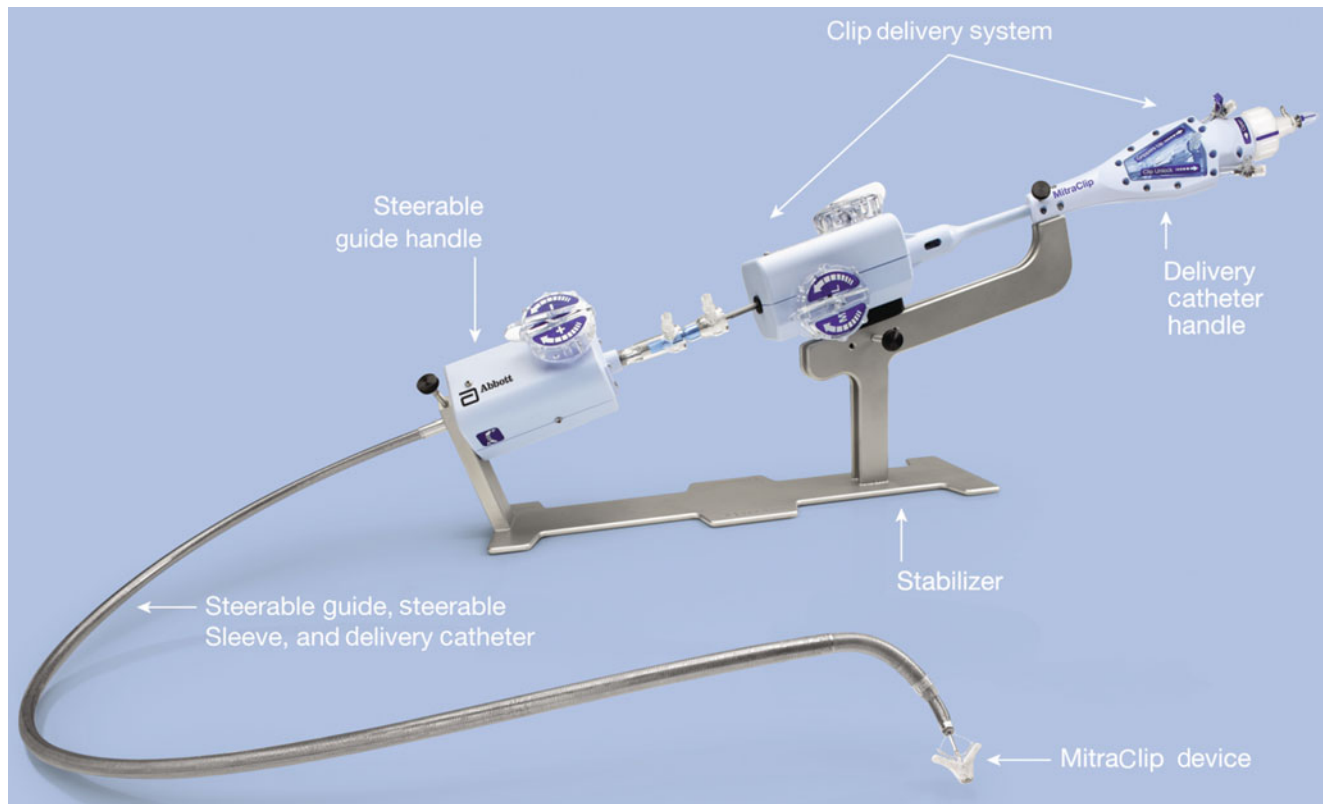
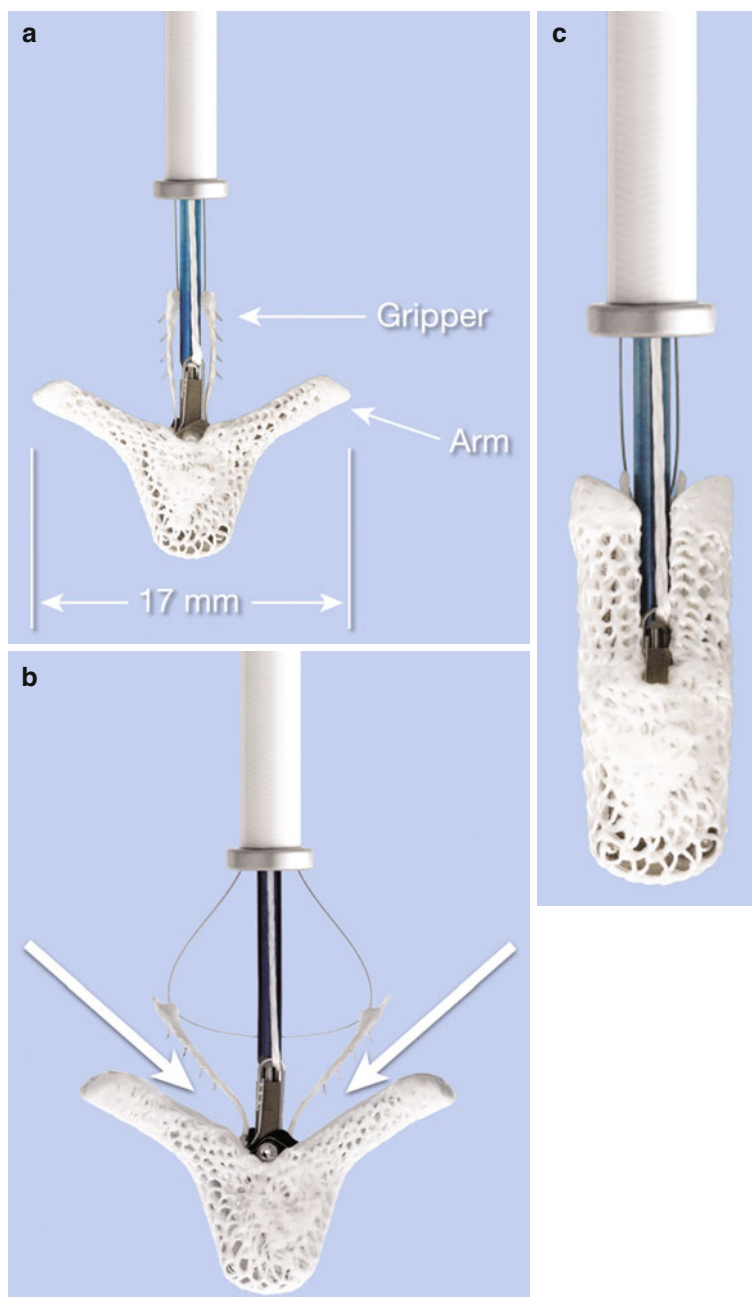


Fig. 2.2 Components of the MitraClip system. The MitraClip system consists of a 24-Fr steerable guide catheter and a clip delivery system (CDS), which includes the detachable clip itself. The guide catheter

tapers down to 22 Fr at the point where it crosses the atrial septum. A steering knob on the proximal end of the guide catheter marked as “±” allows for flexion and movement of the distal tip [4–12]

Fig. 2.3 The MitraClip. (a) The clip itself is a polyester-covered mechanical device with two arms that are opened and closed by control mechanisms on the CDS. The two arms have a span of approximately 2 cm when opened in the grasping position. On the inner portion of the clip are U-shaped “grippers,” as indicated by the *arrows* which appose and stabilize the leaflets from the atrial aspect as they are captured during closure of the clip arms. When closed, the clip has an outside diameter of 15 Fr. It is designed to hold up to 8 mm of leaflet height (*vertically*) and 4 mm of width (*horizontally*). (b) Leaflet tissue is secured between the arms and each side of the gripper, and (c) the clip is then closed and locked to effect and maintain coaptation of the two leaflets



Procedural Technique

A 6-Fr arterial and an 8-Fr venous sheath are placed in the left femoral artery (LFA) and femoral vein (FV), respectively. Alternatively, radial artery and internal jugular venous access can be obtained to minimize groin access sites. A 14-Fr sheath is placed in the right FV for transseptal access

and guide catheter delivery. Using the left femoral access, a 7-Fr balloon-tipped pulmonary artery catheter and a 6-Fr pigtail left ventricular (LV) catheter are placed. Cardiac output, baseline pulmonary capillary wedge, and LV and pulmonary artery pressures are measured. An activated clotting time (ACT) of 250–300 s is maintained throughout the procedure, with ACT measurements taken every 30 min.

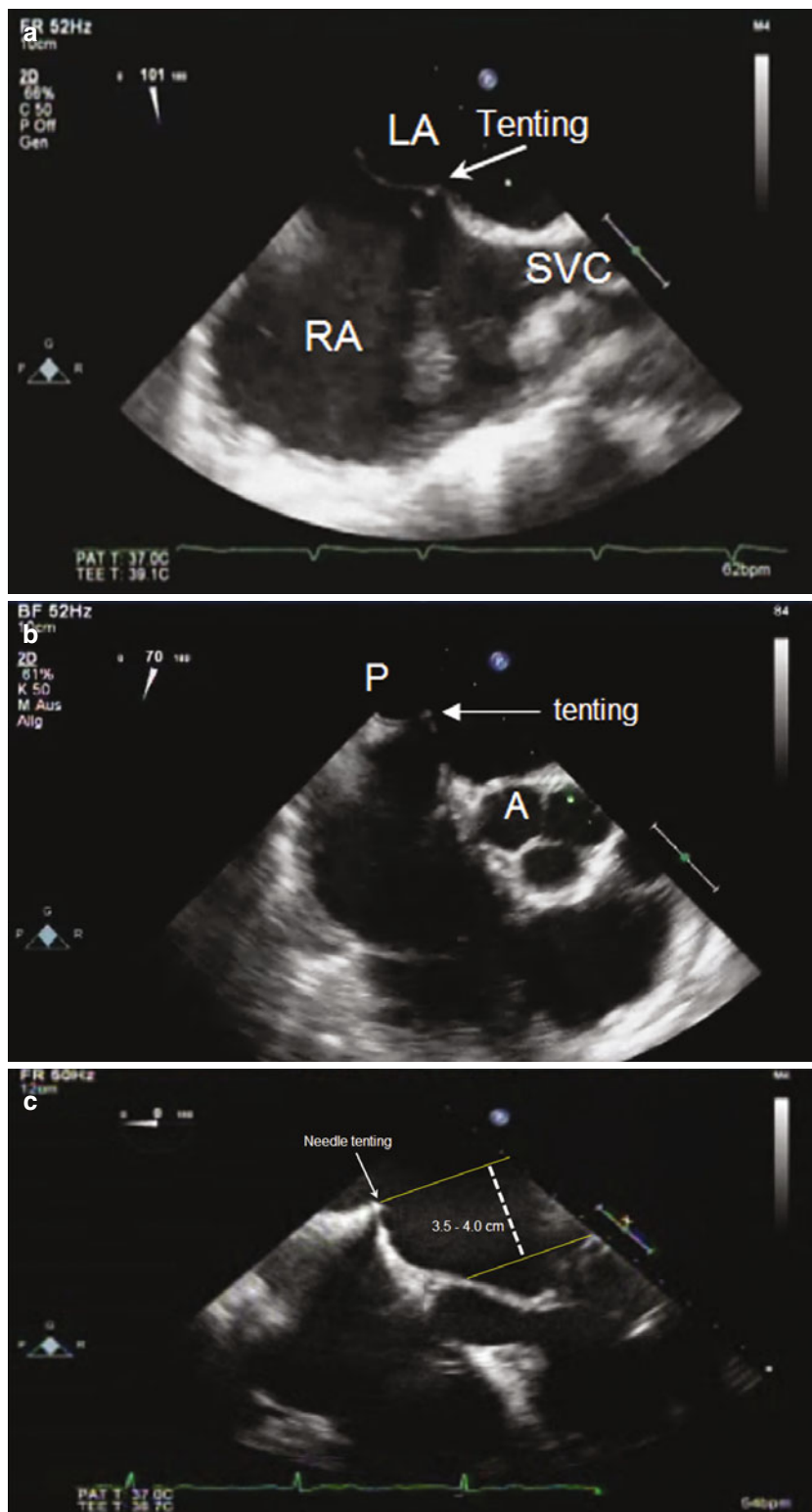


Fig. 2.4 TEE-guided transseptal puncture. Initially, an 8-Fr Mullins sheath and then a transseptal needle are advanced into the right atrium (RA). A TEE-guided transseptal puncture is performed in a location, ideally in the superior and posterior part of the interatrial septum with the aim of obtaining adequate working space and distance above the mitral annulus (the ideal height from the annulus should be 3.5–4.0 cm). Using TEE bicaval (a) and short-axis views at the base of the heart (b) the position of the puncture site is evaluated, and the “tenting” of the atrial septum can be seen as the transseptal needle is pushed against it. In the short-axis view (b) the tenting should be close to the posterior edge, and in the bicaval view (a) it should be at the junction of the muscular and membranous septum. Afterward, using a long-axis four-chamber view (c) the catheter tip should be moved to as “high” a position as possible while remaining in the fossa ovalis. A transseptal puncture should be only performed if such tenting is clearly seen in both of these views (a, b)

Fig. 2.5 Advancement of Mullins sheath into the LA and placement of guide wire. **(a)** After the appropriate transseptal puncture is achieved, an 8-Fr Mullins sheath is advanced into the LA, and LA–LV pressure is measured at the baseline. **(b)** A 260-cm (0.035-in.), extra-stiff J-tipped Amplatz guide wire is then placed, ideally in the left superior pulmonary vein or alternatively looped in the LA. Intravenous heparin is given (50–70 units/kg) to achieve ACT greater than or equal to 250 s

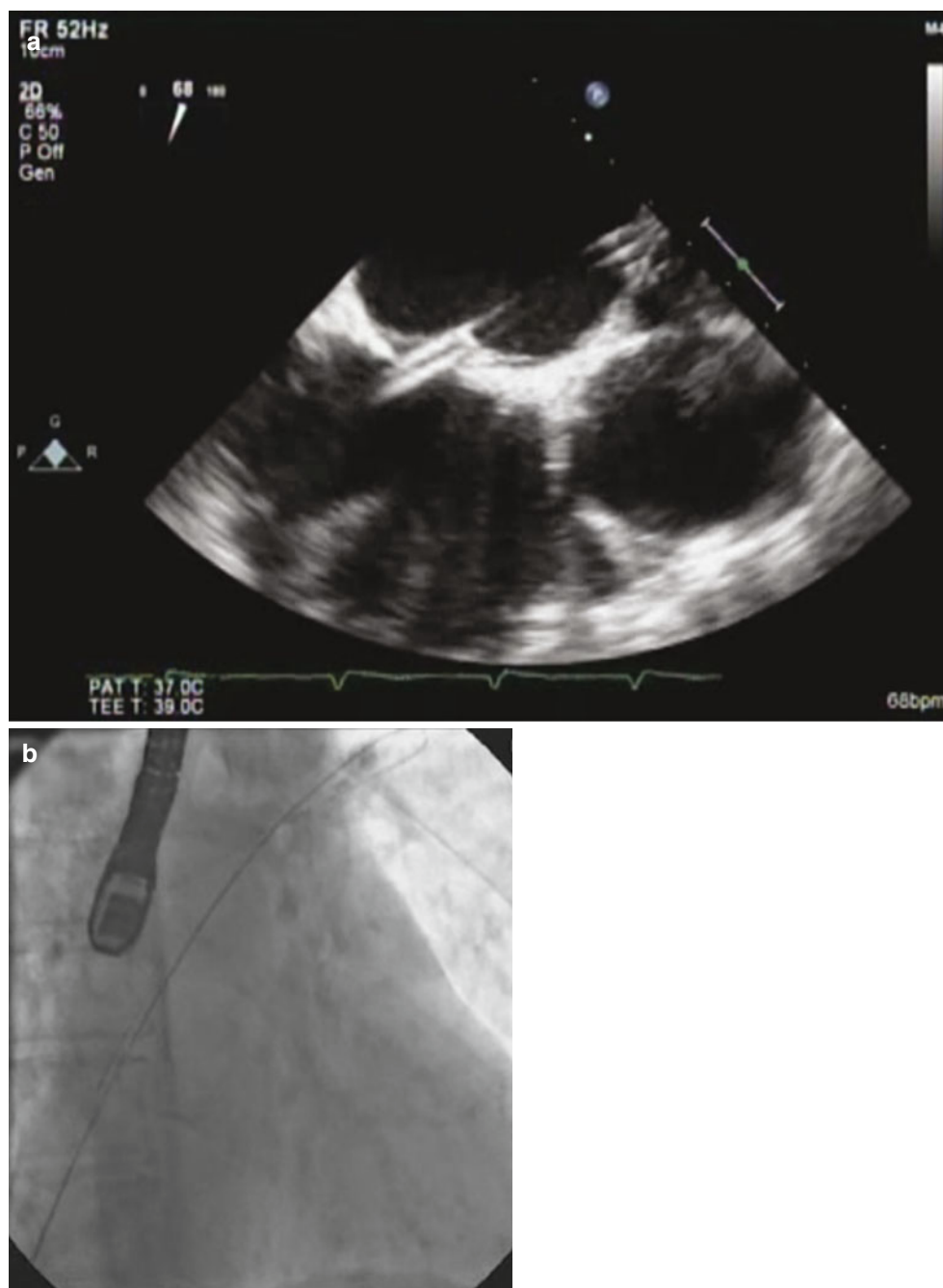
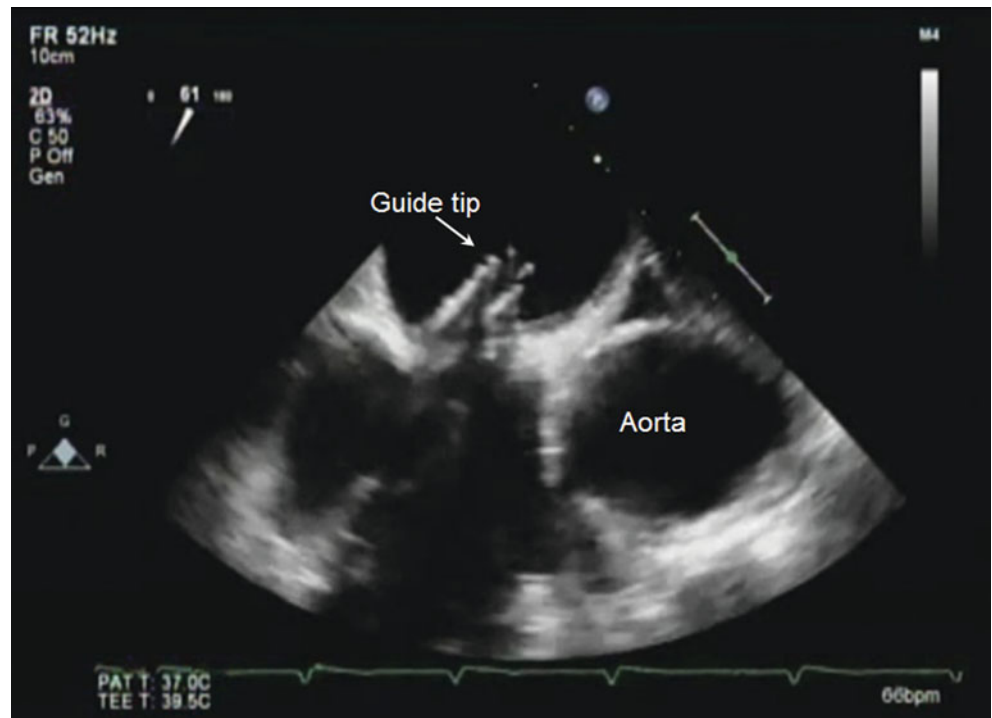


Fig. 2.6 Dilation of the interatrial septum. After removing the Mullin's sheath, the puncture site is dilated to accommodate a 22-Fr guide catheter by gentle and forward movement of the dilator tip, which can be visualized by TEE due to echogenic coils. When the dilator tip is halfway to three-quarters across the septum, waiting a few seconds is often useful to allow the atrial septum to stretch



Fig. 2.7 Advancement of the guide catheter into the LA. It is very important not to place the guide catheter tip too far into the LA to avoid contact with LA walls, but rather to aim for a position of its tip about 1 or 2 cm across the atrial septum in the center of the LA in the short-axis view at the base. It is critical to carefully de-air the guide catheter upon removal of the dilator and guide wire assembly once the guide catheter tip is 1–2 cm across the atrial septum prior to advancement of CDS



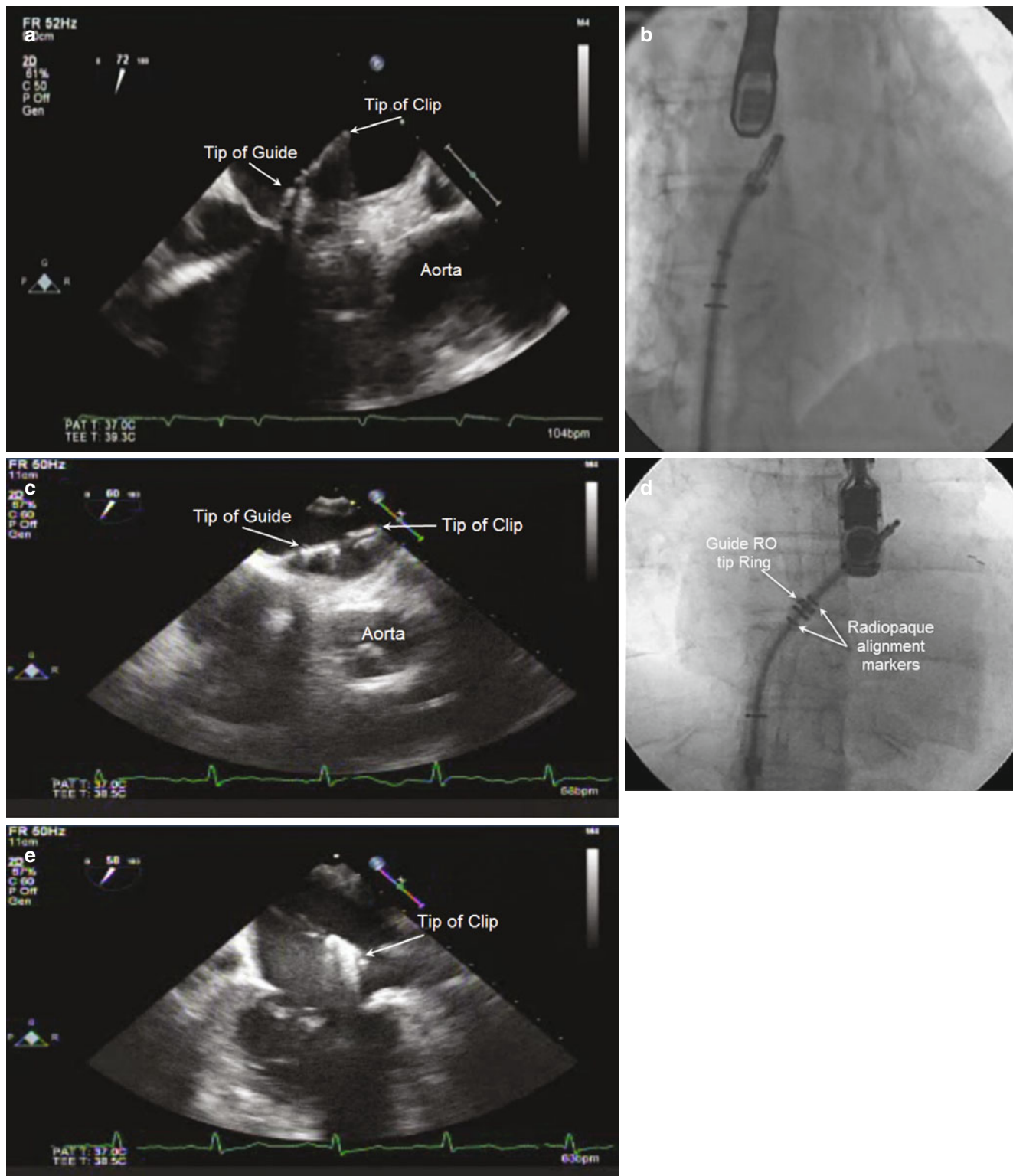
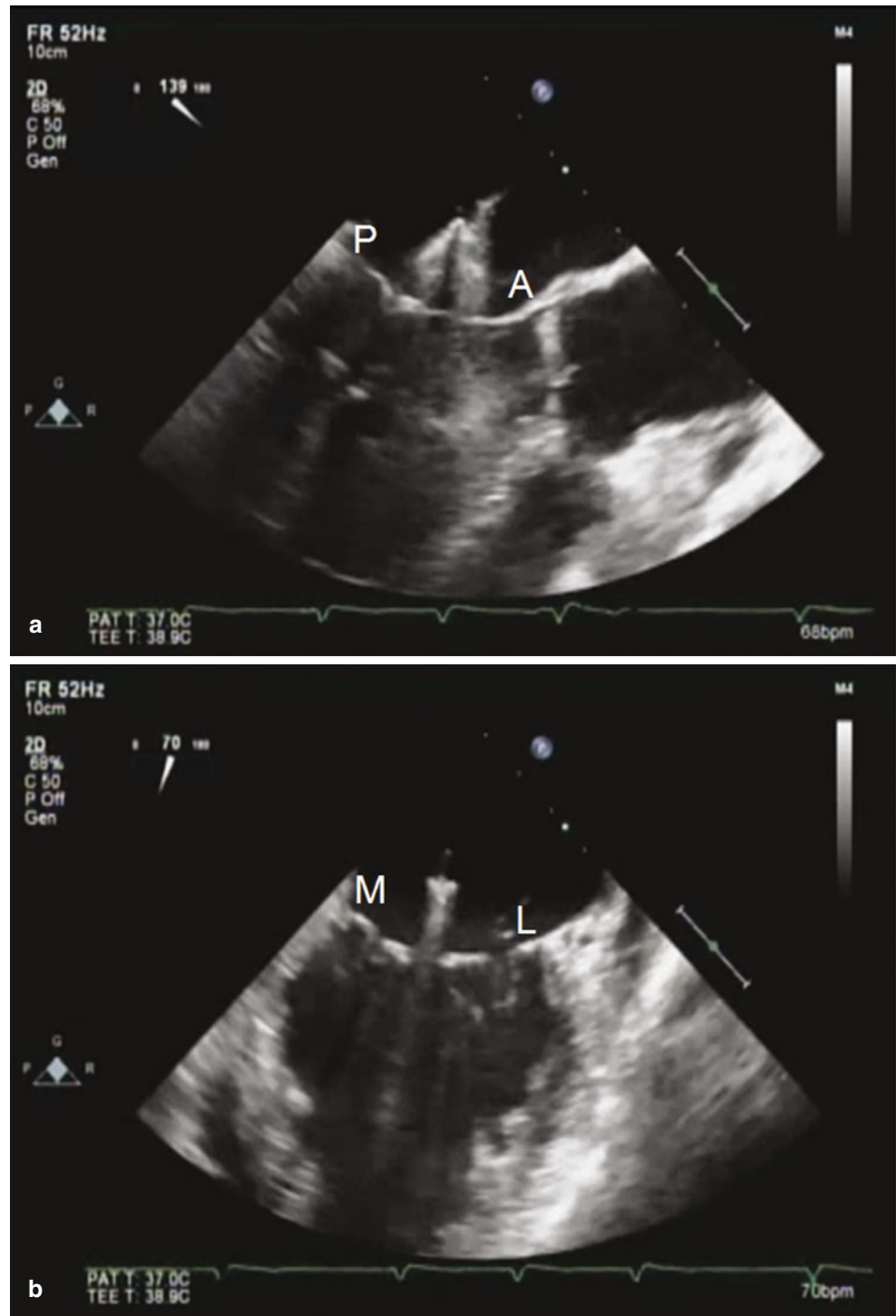


Fig. 2.8 Steering and positioning of the MitraClip CDS in the LA. Once introduced into the guide catheter, the CDS is advanced until its tip is even with the guide tip under fluoroscopic guidance. Then, the CDS is further advanced into the LA while observing the MitraClip device in the short axis at the base or two-chamber intercommissural

TEE views to avoid tissue contact (a, b). The CDS is further advanced until the guide radiopaque (RO) tip ring marker is centered between the sleeve alignment markers with confirmation on fluoroscopy (c, d). Afterward, the CDS is steered down toward the mitral valve (e)

Fig. 2.9 Steering the clip toward the mitral valve. The MitraClip device is then steered down until the trajectory is perpendicular to the line between the annular hinge points of the mitral valve in both the left ventricular outflow tract (LVOT) anteroposterior (*A-P*) alignment and two-chamber intercommisural mediolateral (*M-L*) alignment imaging planes (**a**, **b**). The clip is positioned over the MR jet origin to split the jet (**c**)



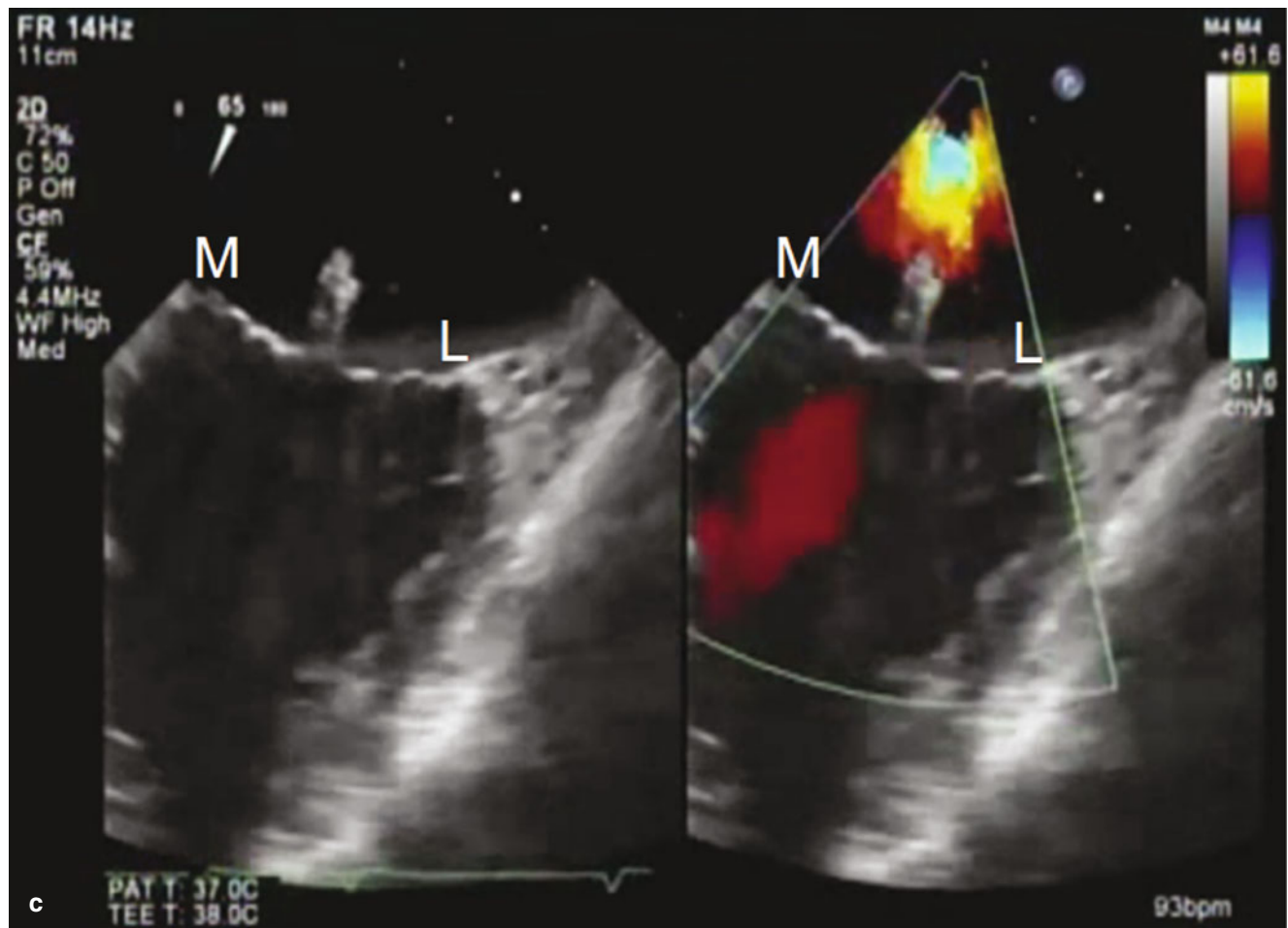


Fig. 2.9 (continued)

Fig. 2.10 Opening of the clip arms. The clip arms are opened to 180° and aligned perpendicular to the line of coaptation in the LVOT view. In the LVOT view, the open arms should be visible and symmetric (a). Arm alignments are checked also in the two-chamber intercommissural and the transgastric short-axis or 3D En Face views (b, c).
L lateral, *M* medial

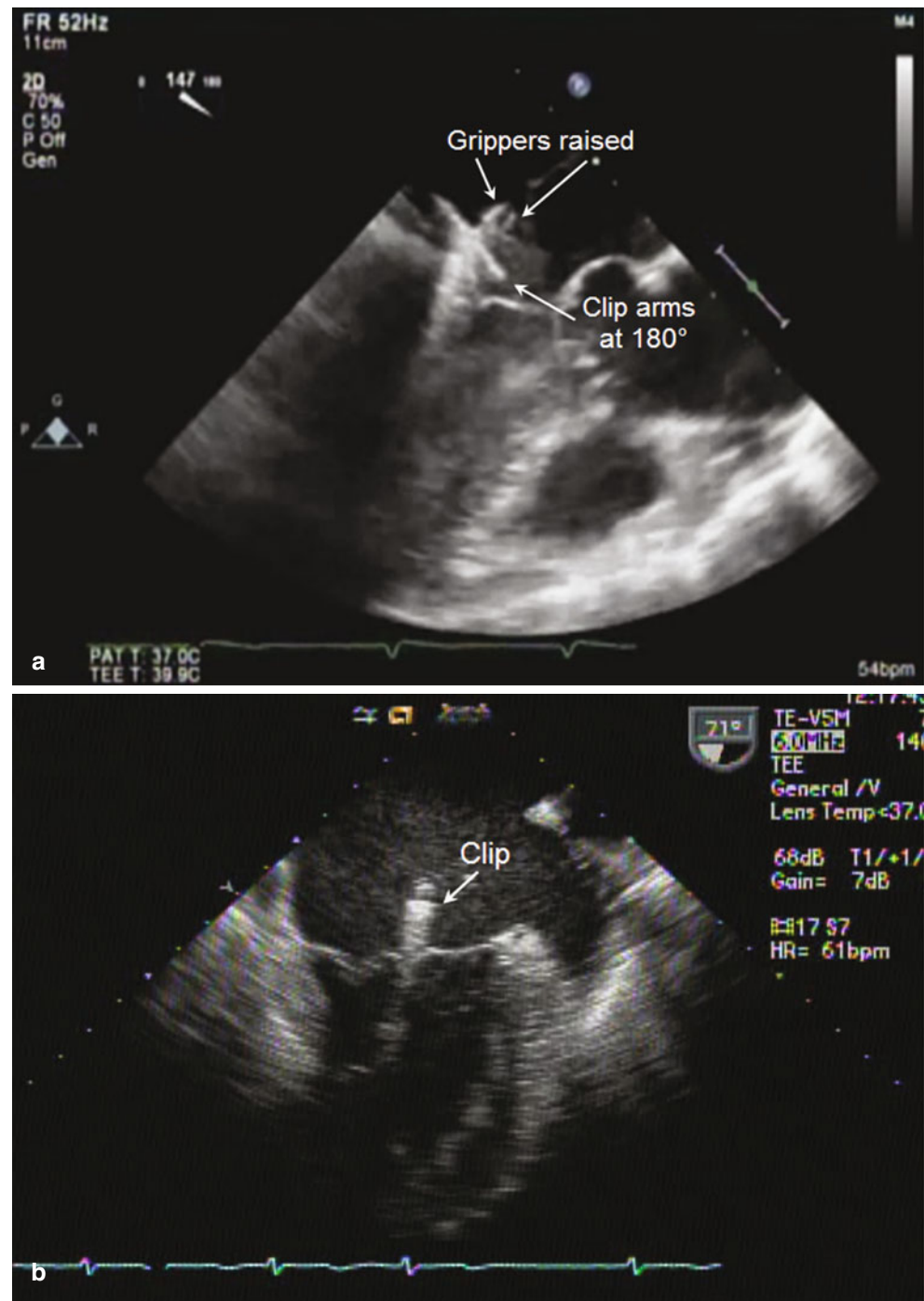


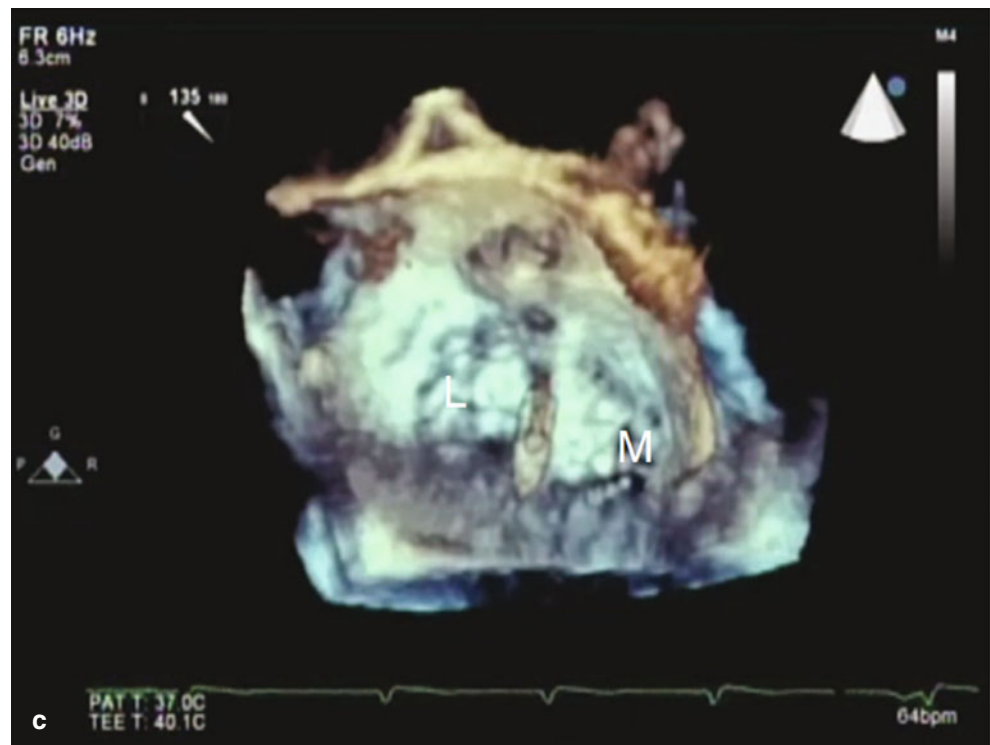
Fig. 2.10 (continued)

Fig. 2.11 Crossing the mitral valve with the clip. After the proper alignment is achieved, the clip is advanced into the LV so that the clip arms are under the free edges of the mitral leaflets (**a**). Free motion of the leaflet edges is important to note, and restriction of the leaflets by the clip arms means it is not far enough below the free edges to achieve a successful grasp. Using LVOT, two-chamber intercommissural, and short-axis views, a final check of the perpendicular orientation is done with the clip in the LV to be sure there is no deviation of clip orientation to the mitral leaflets (**b–d**)

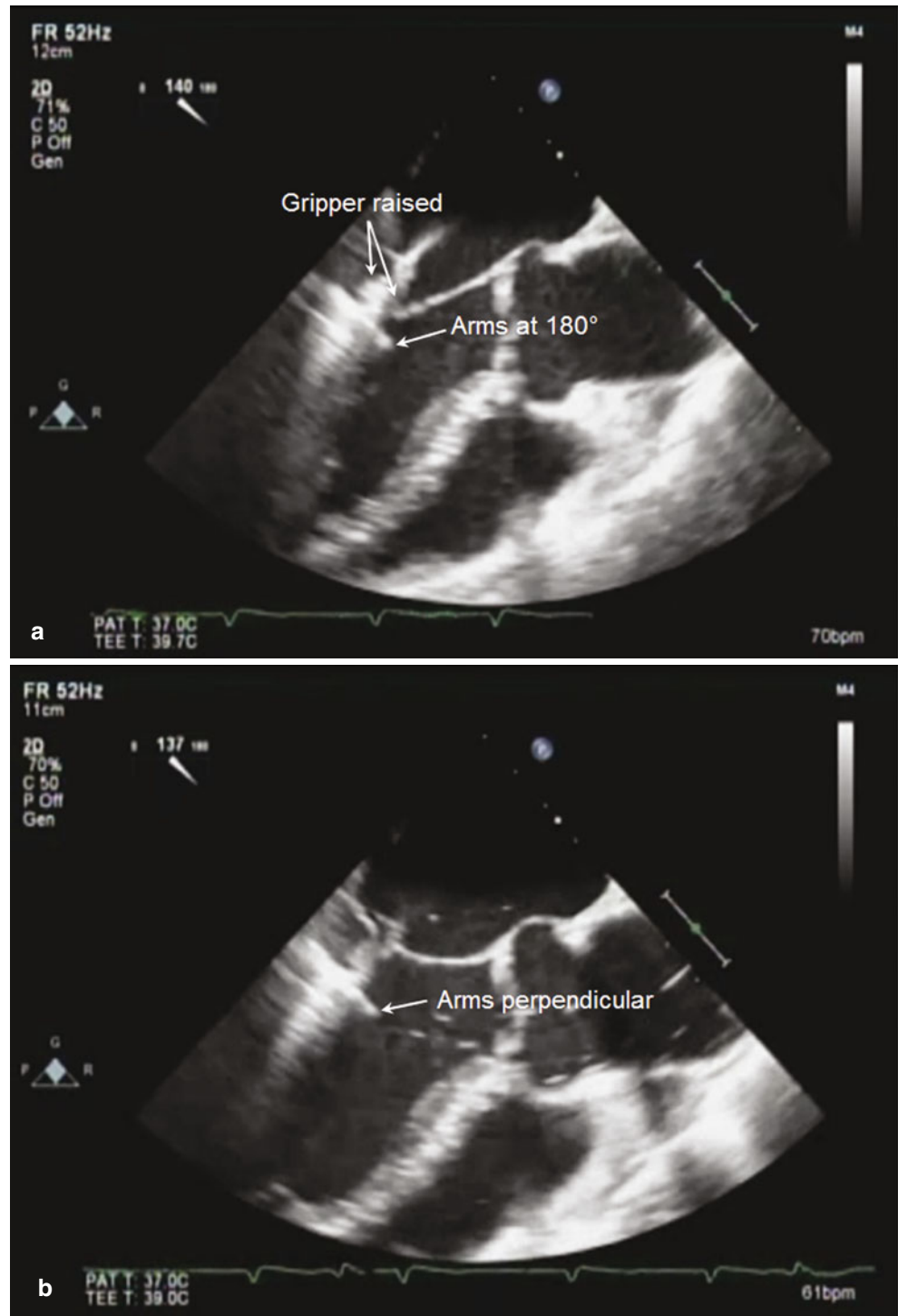


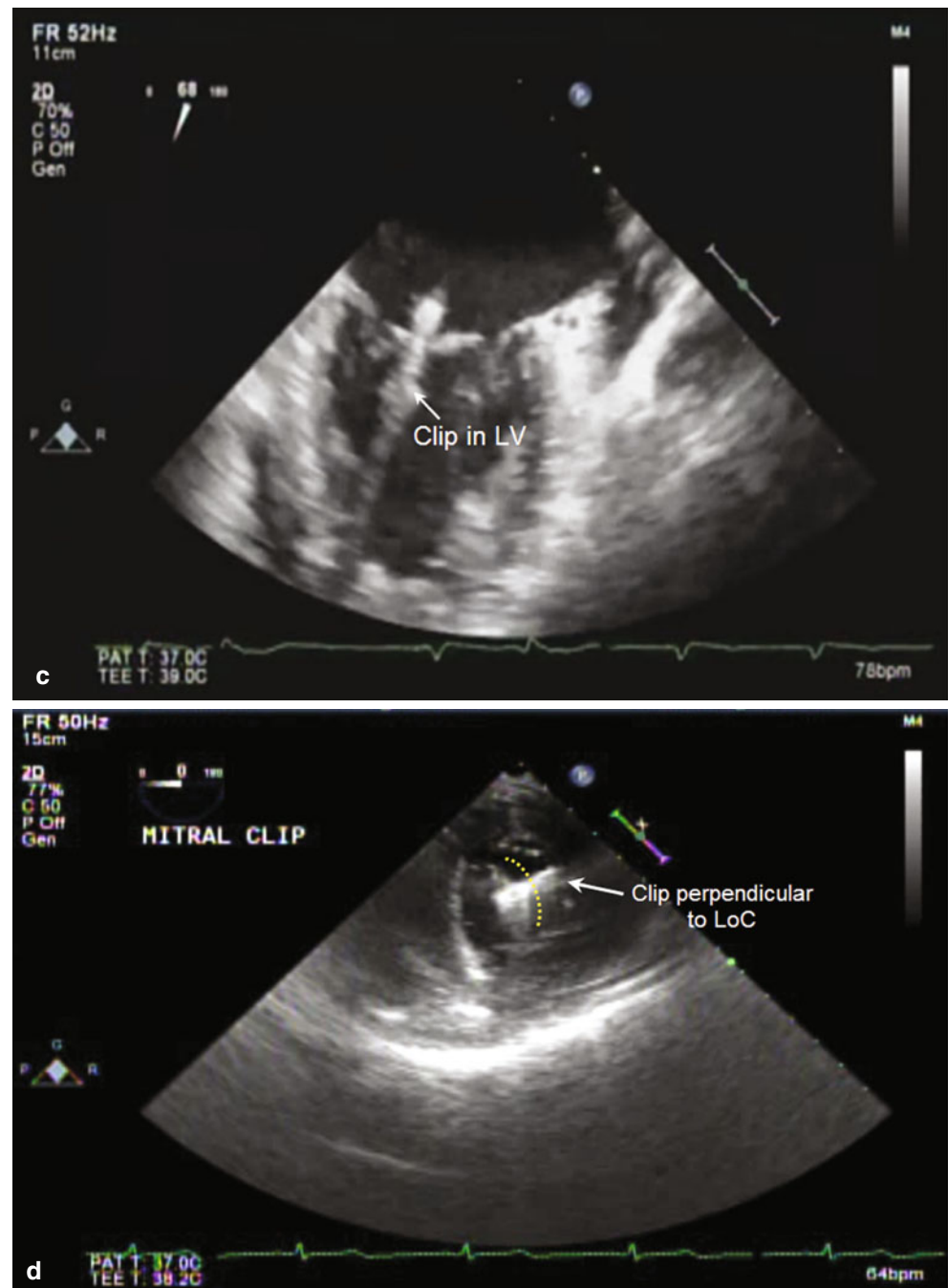
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Fig. 2.12 Grasping of leaflets.

The leaflets are grasped by retracting the delivery catheter slowly as the mitral leaflets are closing in systole in the LVOT view (a). If the leaflets are successfully stabilized by the open clip, then the grippers are quickly lowered, and the clip is closed to about 60° (b, c). When fully inserted, the leaflets should be stable and immobile at the clip entry point in the LVOT view (d). In the two-chamber intercommissural view, the leaflets should enter the center of the clip and be stable medial and lateral to the clip (e). This stability can also be confirmed in the four-chamber view (f). Finally, once more, the MitraClip device is assessed in the LV to confirm that the clip arms are perpendicular to the line of coaptation in the transgastric short-axis view. There should also be medial and lateral contact between the anterior and posterior leaflets during diastole adjacent to the MitraClip device (g–h). Once adequate leaflet insertion has been confirmed at 60°, continue slowing closing the clip just until the leaflets are coapted and MR is sufficiently reduced. Leaflet insertion assessment is repeated using LVOT, two-chamber intercommissural, and transgastric short-axis views

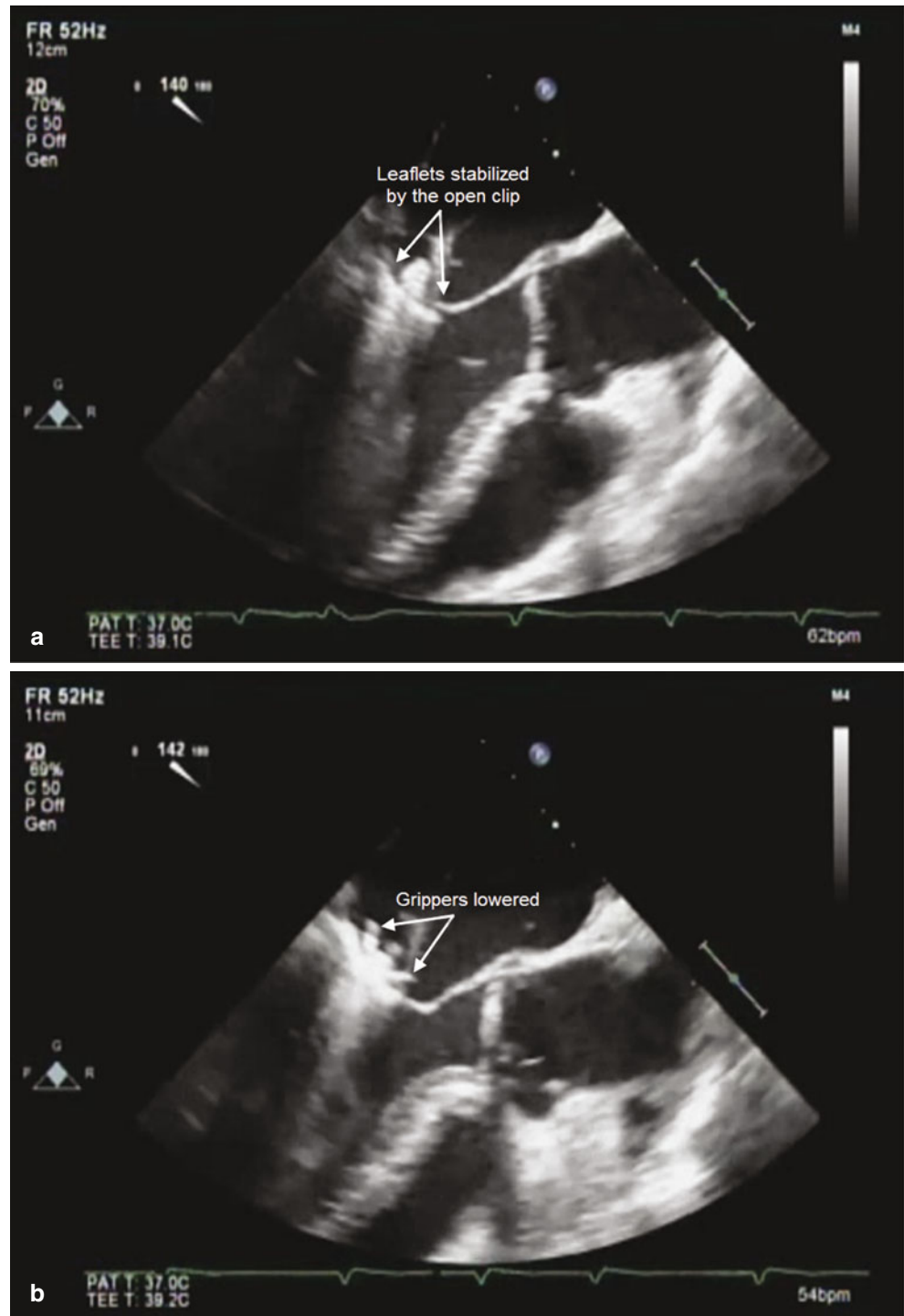


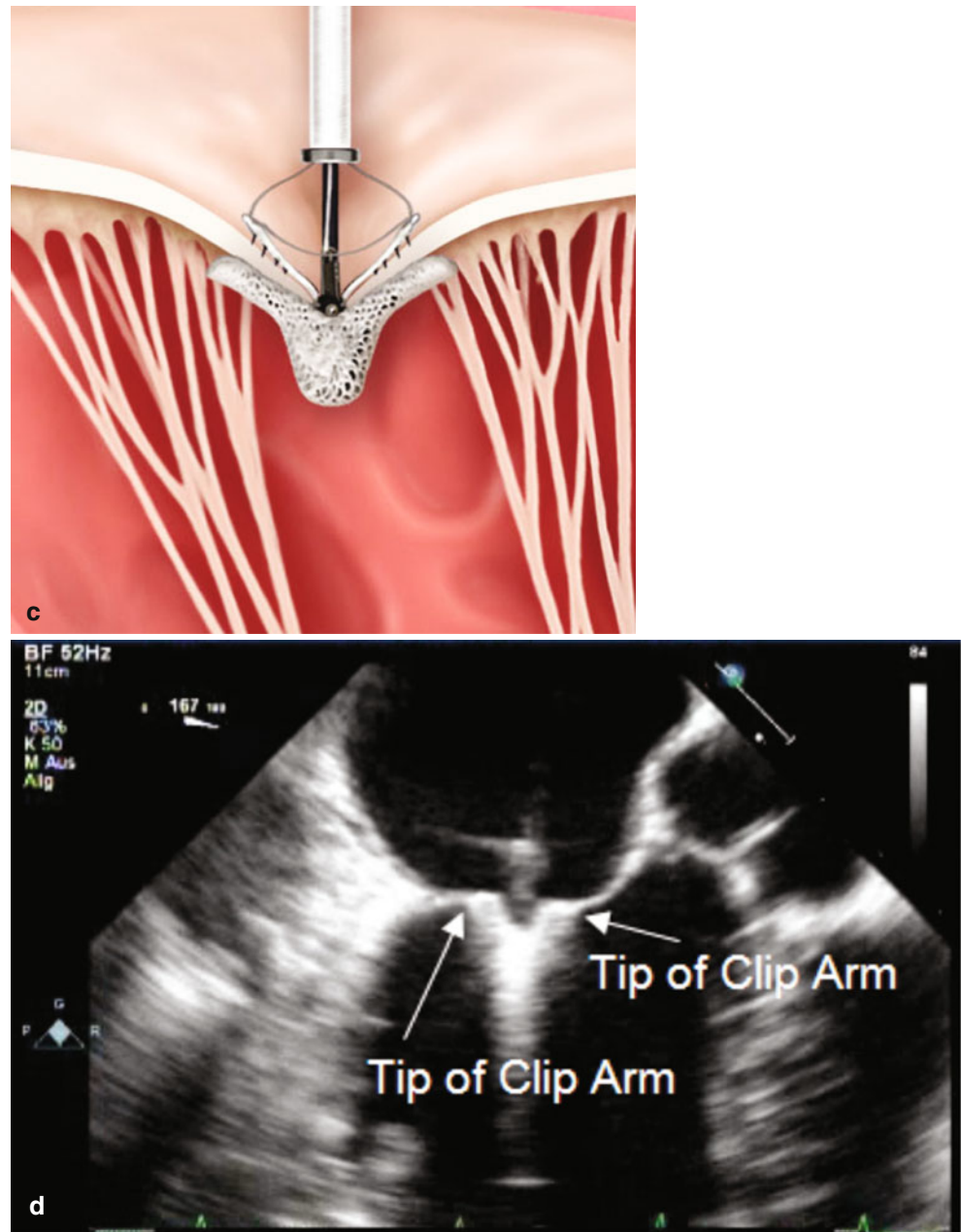
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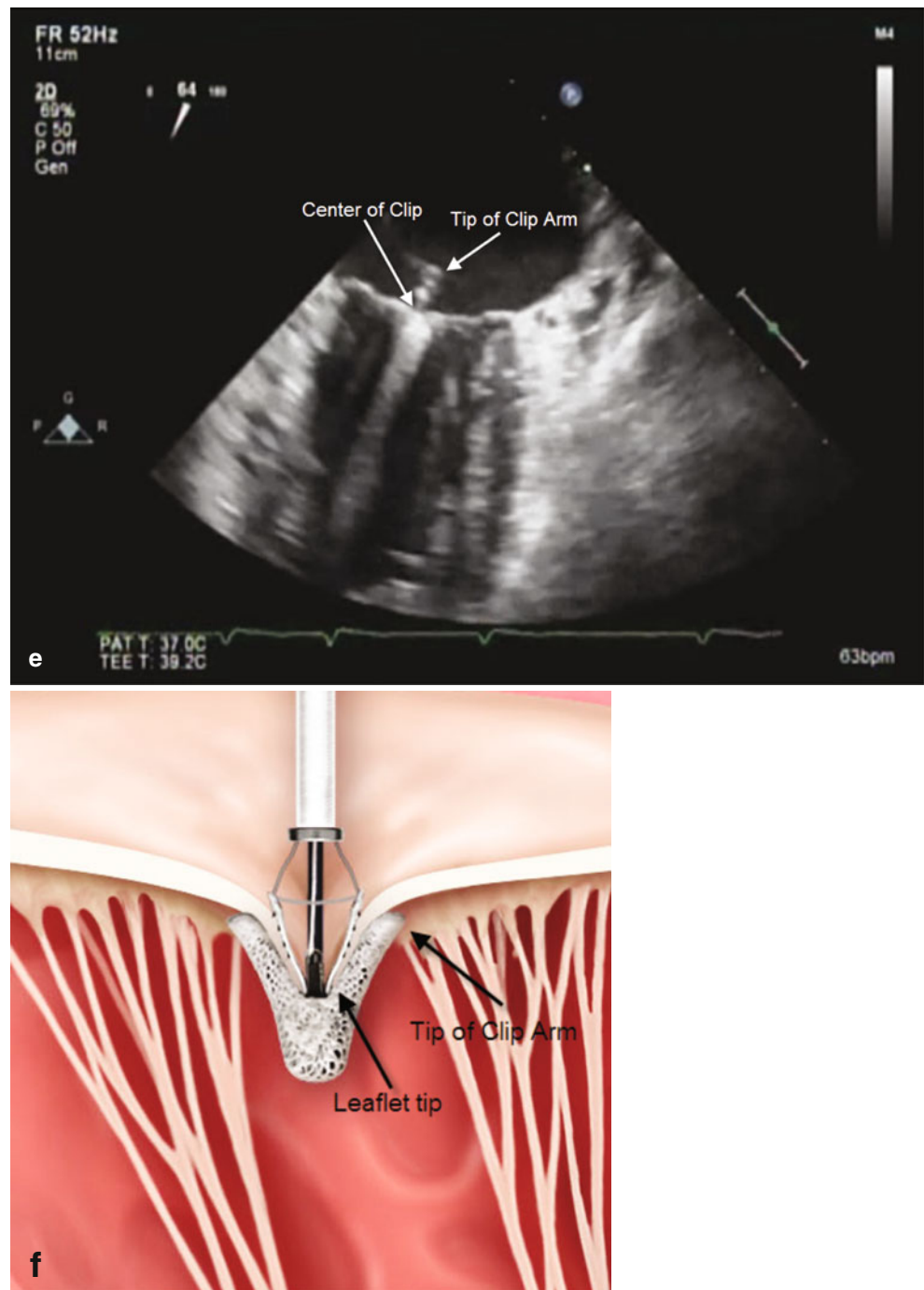
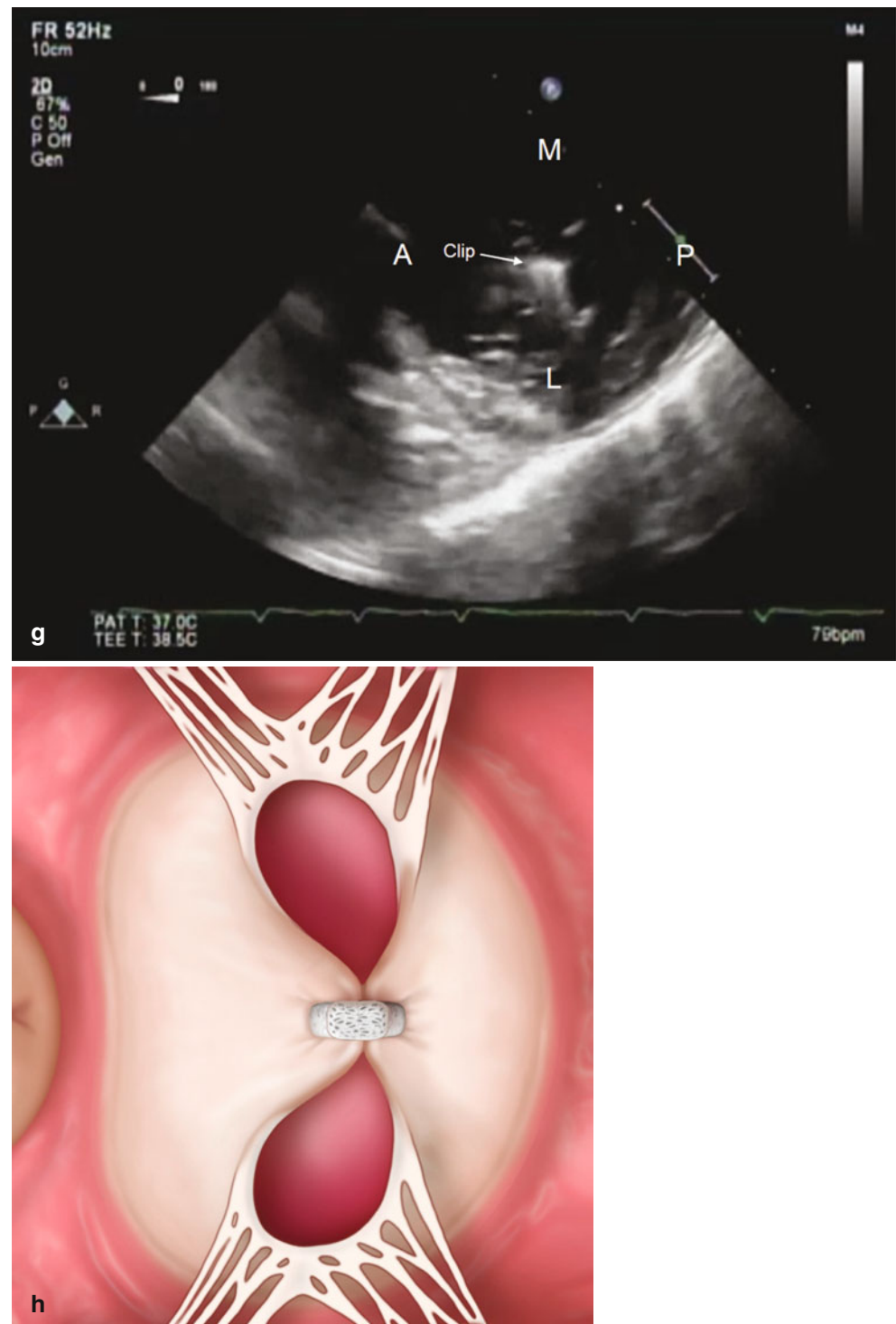
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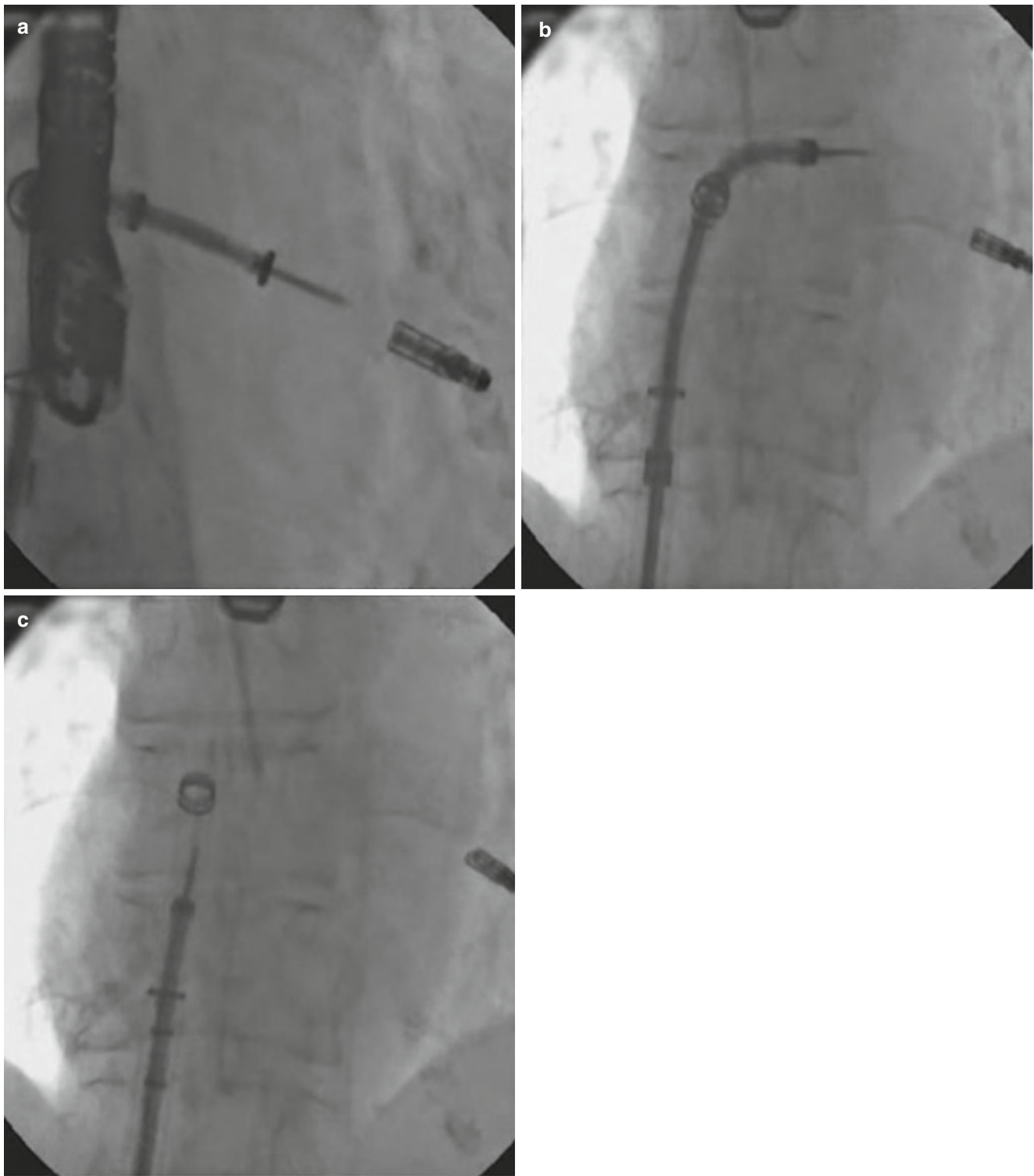


Fig. 2.13 MitraClip device deployment and system removal. Once the optimal reduction in MR jet is achieved, the clip is released using fluoroscopic guidance (**a**). A RAO-caudal or LAO-cranial view may be used for the side view of the clip after its deployment. It is critical that the tip of the delivery catheter is carefully retracted back into the guide catheter to avoid damage to the LA (**b**). Careful and reverse steering with slow retraction of the CDS back into the guide catheter is performed using TEE. Once the CDS is retracted, the guide catheter is

withdrawn into the RA and removed (**c**). Hemodynamic measurements, mainly simultaneous LV and PCWP, are repeated after the clip placement. There are several techniques to achieve femoral vein hemostasis which are described in a separate chapter. In one technique, the large-caliber venous access site can be closed using subcutaneous “figure-of-eight” sutures for immediate hemostasis, and they can be removed after several hours [13] (Adapted from Cilingiroglu et al. [14])

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