

# Minimally-invasive surgical explantation of a partially detached Cardioband device

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## Abstract

Transcatheter repair systems are becoming increasingly popular as a potential solution for high-risk and inoperable patients with mitral regurgitation. The Cardioband (Edwards Lifesciences, Irvine, California) is a transcatheter direct annuloplasty device, based on the concept of an undersized ring annuloplasty. We report a case of minimally invasive surgical explantation of a failed Cardioband device 21 months after its implantation. Intraoperatively, it was found that 3 anchors of the Cardioband device were detached from the posterior annulus at P2. In this report, a “cut and unscrew” technique with some tips and tricks is presented for the removal of the device.

## Introduction

Functional mitral regurgitation (FMR) is characterized by mitral annular dilatation, inadequate leaflet coaptation and tethering of the mitral valve leaflets resulting from left ventricular dysfunction and remodeling [1].

The increased risk of surgical annuloplasty in the setting of FMR, and the unclear benefits of this procedure [2] has encouraged the search for alternative, innovative catheter-based and minimally invasive solutions such as indirect annuloplasty, direct annuloplasty and transcatheter mitral valve repair (TMVR).

The Cardioband (Edwards Lifesciences, Irvine, California) is a transcatheter direct annuloplasty device, which is based on the surgical concept of an undersized ring annuloplasty. Since its clinical use started in 2014, several procedural complications have been reported, such as complete atrioventricular block and device dehiscence during or immediately after the intervention [3,4]. In this report, a “cut and unscrew” technique is presented for surgical explantation of a dehiscence Cardioband device 21 months after the implantation.

## Case Presentation

A 75-year-old female, with systemic hypertension, atrial fibrillation, renal failure and ischemic cardiomyopathy, presented with progressive dyspnoea (New York Heart Association functional class III) 21 months after a TMVR with the Cardioband for FMR at another institution.

During the cinching phase of the device implantation, a detachment of an anchor had been visualised at the P2 level. Periprocedural transesophageal echocardiography (TEE) revealed a residual mild MR at the end of the procedure. The patient had remained symptom-free with mild to moderate MR documented at outpatient follow-up visits until the 21st month post-implantation.

On admission, TEE showed left ventricular systolic dysfunction (ejection fraction 45%), dehiscence of the Cardioband at P2 and severe MR with two jets originating from the anterior and posterior aspect of dehiscence

part of the device (Figures 1A and 1B). After multidisciplinary heart team discussion, the patient was scheduled for a minimally invasive mitral valve replacement, with a STS-PROM score of 6.08%.

A minimally invasive approach through a right anterolateral minithoracotomy was performed and the mitral valve was visualized using a three-dimensional (3D) endoscope. An endocardial ablation procedure was performed using AtriCure Cryo Module (AtriCure, Inc., West Chester, OH). Intraoperatively, it was found that 3 anchors of the Cardioband were detached from the posterior annulus at P2 and the remaining part was highly endothelialized (Figure 2A). The highly-endothelialized part of the Cardioband was dissected from the surrounding annular tissue via scalpel and electrocautery (Figure 2B). Care was taken to avoid injuries of the adjacent structures such as the coronary sinus and the circumflex coronary artery; every effort was made to maintain the annular structure to avoid atrioventricular groove disruption. The time consuming part of the procedure was the removal of the Cardioband by applying a “cut and unscrew” technique. To facilitate the removal, the Cardioband was cut between the anchors and the anchors were then unscrewed by counter-clockwise rotation (Figures 2C and 2D). These manoeuvres were performed repeatedly until the last anchor was removed. Since the likelihood of successful mitral repair was considered low, due to the valvular morphology, a St. Jude Medical Epic bioprosthetic mitral heart valve (St Jude Medical, Inc, St Paul, Minn) was implanted and fixed using Cor Knots (LSI SOLUTIONS, Victor, New York, USA).

The pre-discharge transthoracic echocardiography revealed a normal function of the mitral valve with a low gradient and absence of paravalvular leakage. The patient was discharged after an uneventful post-operative course.

## Discussion

TMVR systems are becoming increasingly popular as they represent a potential solution for high-risk and inoperable patients with MR. Percutaneous mitral leaflet repair with the Mitraclip (Abbot Vascular, Santa Rosa, CA) has revolutionized TMVR, but it is far from providing a stand-alone solution to FMR with mitral annular dilatation as the leading pathology. It has been advocated that the absence of a concomitant annuloplasty long term may result in an inadequate reduction or recurrence of regurgitation in patients with FMR. The Cardioband is a transcatheter direct annuloplasty device implanted transvenously, transseptally in patients with FMR in case surgical and medical treatment options are limited.

Since the first-in-man implantation of the Cardioband, a few studies have reported safety, efficacy and the short-term results of the technique [5, 6]. In a multicenter study, Zeitoun et al. reported 1 year outcomes of the system with a technical success rate of 97%. Partial device dehiscence due to anchor disengagement was reported in 16.6% of patients immediately after implantation [5]. Eschenbach et al. has also reported an anecdotal explantation of the Cardioband three days after the intervention [4].

In the presented patient, although a detachment of one of the anchors was found already during the procedure, two more dehiscent anchors were confirmed during the operation. This may have resulted from “unscrewing” of the anchors over time under high tension during cardiac contractions, especially at the P2 segment where annular displacement has the highest amplitude. This challenging problem may be overcome with procedural modifications such as increasing the number of implanted anchors at this segment.

The Cardioband is a promising device for TMVR in patients at high surgical risk. However, the lack of long-term results and the limited short-term reports with several complications might discourage surgeons and interventionalists from wide adoption. Mitral surgery after Cardioband implantation is technically demanding as anchor removal from the mitral annulus is not easily accomplished. A longer interval between the implantation and explantation of the device makes surgical explantation more challenging due to the risk of a potential complication during removal of the highly-endothelialized device. In these cases, care must also be taken to prevent damage to adjacent structures. We believe that the suggested “cut and unscrew” technique may reduce the risk of procedure related complications..

## Conclusion

In summary we report a “cut and unscrew” technique for the removal of a failed Cardioband device 21

months after implantation. This report demonstrates that the cut and unscrew technique may be performed safely during removal, even for highly-endothelialized device, while preserving the mitral annular integrity.

## References

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**Figure 1:** 3D transesophageal echocardiographic image shows a partially detached device at P2 (A). Severe mitral regurgitation with two jets originating from the anterior and posterior aspect of dehiscent device (B).

**Figure 2:** Intraoperative findings: A detachment of the 3 anchors of the Cardioband at P2 (A). The highly-endothelialized part of the device was dissected from the surrounding annular tissue via scalpel (B). The Cardioband was cut between the anchors and the anchors were unscrewed by counter-clockwise rotation (C, D).



