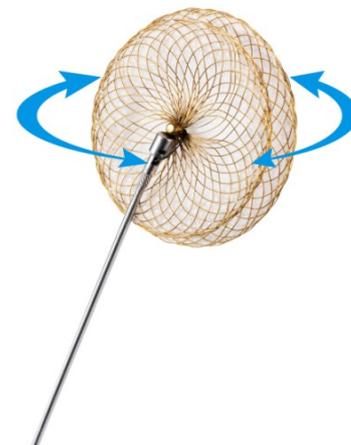


## CeraFlex™ Closure System Evaluation Report

# CeraFlex™ Closure System Product Evaluation



## Summary

### DEVICE INTRODUCTION

The CeraFlex™ closure system is a percutaneous, transcatheter pre-loaded device developed by Lifetech Scientific for the interventional closure of ASD, MF-ASD, PDA, and PFO. The new, innovative CeraFlex™ pre-loaded occluder device is easy and convenient to use. With a maximum range of Pivot 360 degrees, the CeraFlex™ occluder allows for accurate positioning during the procedure. The new CeraFlex™ occluder removed left disc distal hub, it designed to minimize thrombotic complications.

The new CeraFlex™ closure system series includes CeraFlex™ ASD, MF-ASD, PFO, or PDA occluders as well as the SteerEase™ delivery device, and is

now more convenient and more user-friendly.

The state-of-the-art design and proprietary Titanium nitride coating technology accelerates endothelialization, and prevents 93% of nickel release when compared with traditional uncoated occluders. All Nitinol structures are plated with titanium nitride (TiN) to improve the biocompatibility.

The CeraFlex™ occluders must be used in conjunction with the SteerEase™ delivery system. The delivery system contains a coil-reinforced sheath, a dilator, and a haemostatic valve. And the CeraFlex delivery system occluder system includes an occluder, a loader, a haemostatic valve, a cable, and a cable handle.

### FEEDBACKS FROM PHYSICIANS

*"Advantage for residual shunt detection, better positioning."* -

Ahmet Celebi

*"The new CeraFlex™ is so usable!"* - Murat Muhtar Yilmazer

*"Positioning of device visible before procedure."* - Kemal Nisli

*"More user-friendly and safe!"* - Ramazan Akdemir

*"The new device is very comfortable."* - Hasan Ali

Gumrukcuoglu



product  
design award

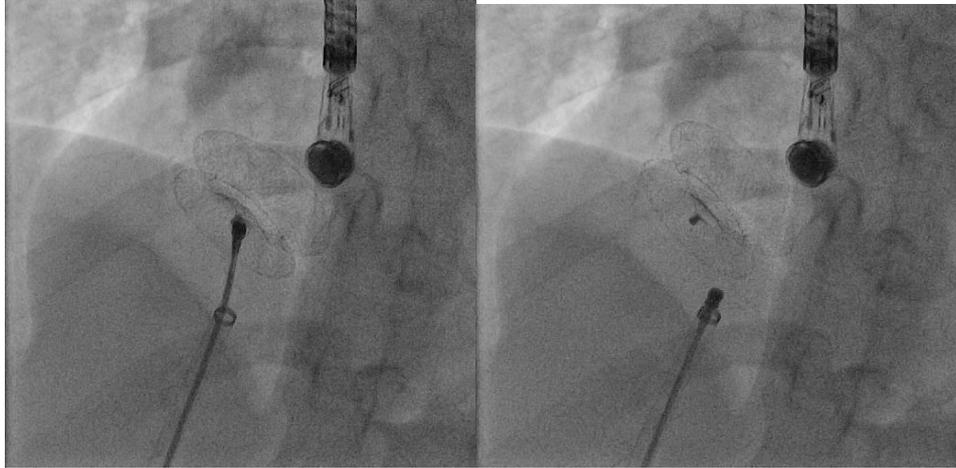
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**FLUORO - PICTURES & ANGIOGRAPHY (before and after release)**

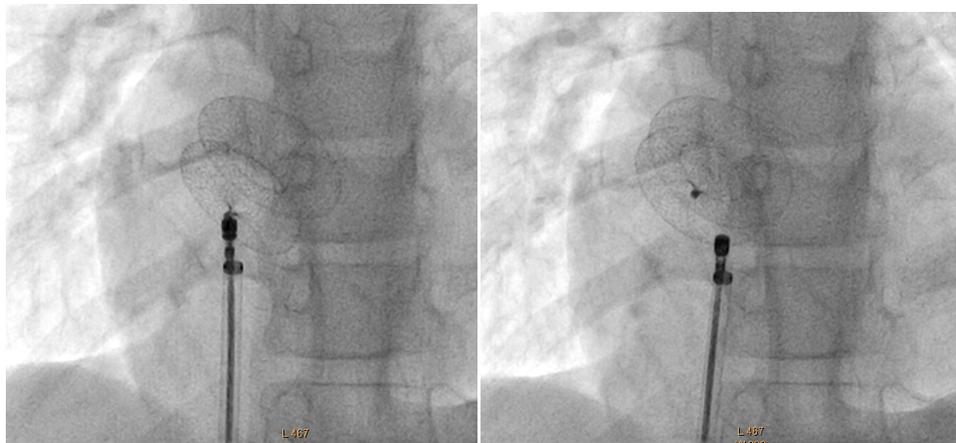
Case 1: ASD, 16.5mm, implanted with CeraFlex™ ASD occluder size 22.



Case 2: PDA, 4mm, implanted with CeraFlex™ PDA occluder size 0608.

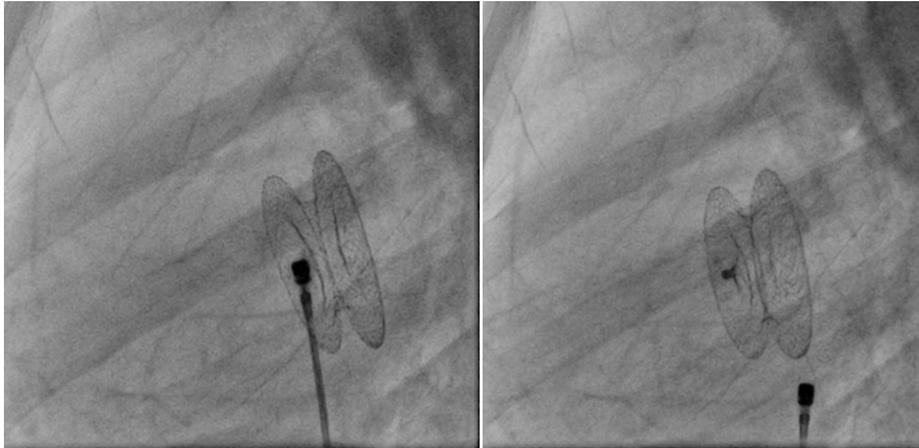


Case 3: ASD, 16mm, implanted with CeraFlex™ ASD occluder size 18.

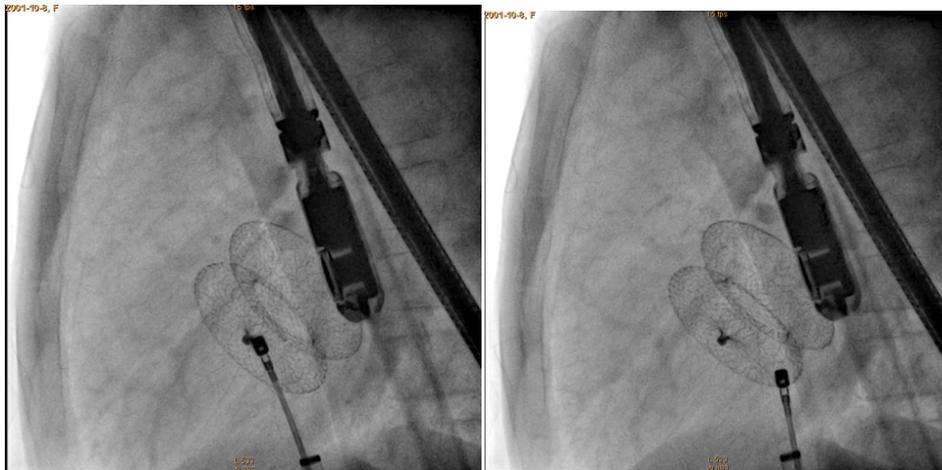


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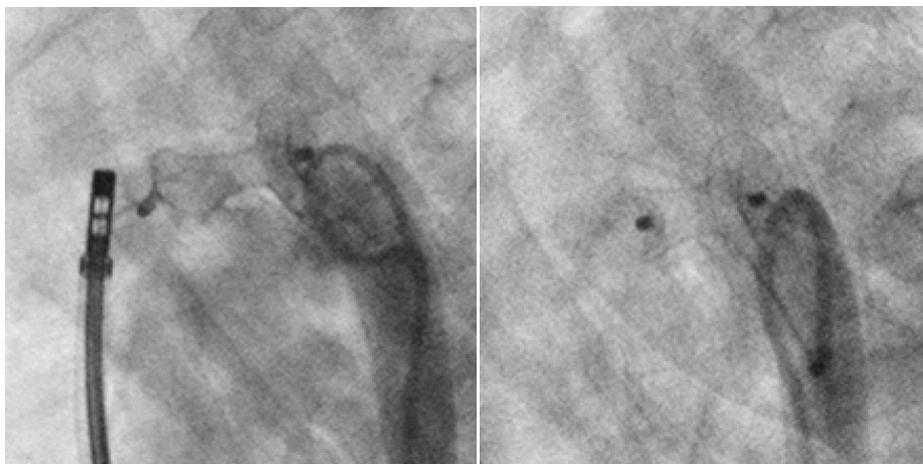
Case 4: ASD, 17mm, implanted with CeraFlex™ ASD occluder size 22.



Case 5: ASD, 20mm, implanted with CeraFlex™ ASD occluder size 26.



Case 6: PDA, implanted with CeraFlex™ ASD occluder size 0608.



## **DISCUSSION**

Closing ASD, PFO and PDA may be challenging for several reasons including deficient or floppy rims, abnormal anatomy of the defect, and so on. It's important for our physicians to visualize the presumed final position of the device. The CeraFlex delivery cable has a flexible Nitinol wire connecting

the CeraFlex occluder in a max of 360 degrees rotation without any significant tension and stress on the implant. This new wire connection system offers an accurate final positioning without any adverse tension or stress caused by the delivery cable, even in challenging cases!