GORE® CARDIOFORM ASD OCCLUDER DIDACTIC TRAINING

Together, improving life

Indication/Intended use

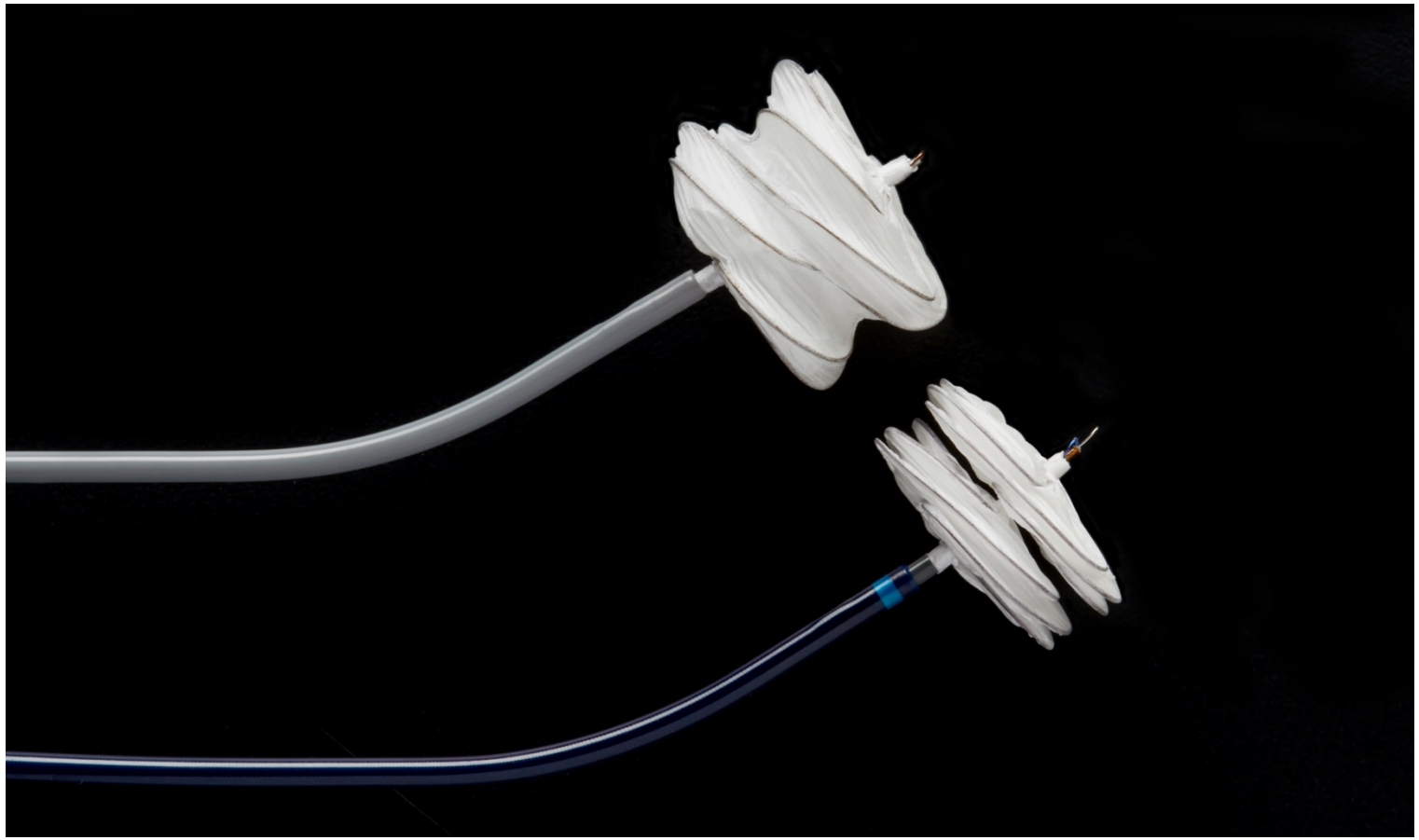
The GORE® CARDIOFORM ASD Occluder

The GORE® CARDIOFORM ASD Occluder is a permanently implanted device indicated for the percutaneous, transcatheter closure of ostium secundum atrial septal defects (ASDs)

Animation

GORE® CARDIOFORM Occluders

Soft, conformable design for implant success



Eight catalogue numbers cover ASDs up to 35 mm*

- GORE® CARDIOFORM ASD Occluder: Anatomically adaptable waist fills and conforms to the defect for ASDs from 8 to 35 mm[1]
- GORE® CARDIOFORM Septal Occluder: Two independent soft and conformable discs that span and cover the defect for ASDs and PFOs† less then or equal to 17 mm

* The GORE® CARDIOFORM ASD Occluder is only indicated for the percutaneous, transcatheter closure of ostium secundum atrial septal defects (ASDs).

† Refer to *Instructions for Use* for complete indication.

THE GORE ASSURED CLINICAL STUDY DATA HIGHLIGHTS: CLOSURE OF OSTIUM SECUNDUM ATRIAL SEPTAL DEFECTS

Pivotal study — Clinical results

Six-month data

Co-primary endpoints	
Closure success rate*,[2]	100% (112 / 112)
Composite clinical success†	90% (108 / 120)

Secondary endpoints	N = 125
Technical success‡	96% (120 / 125)
30-day serious adverse events (SAEs)[1]	4.8% (6 / 125)
Clinically significant new arrhythmia§,[2]	4.8% (6 / 125)
Device eventsII,[2]	2.4% (3 / 125)

* Defined as a clinical residual defect status of occluded or clinically insignificant as determined by the Echo Core Lab at the six-month.
† Composite clinical success as defined by satisfying achievement of technical success, safety success, and closure success.
‡ Successful deployment and retention (at conclusion of index procedure) of a GORE® CARDIOFORM ASD Occluder.
§ In subjects without prior history of arrhythmia, any new arrhythmia (documented on ECG) requiring hospitalization, initiation of new long-term medical therapy (persisting > 45 days), or any post-index procedure cardioversion or intervention (pacemaker, ablation, etc.).
II Defined as post-procedure embolization, device removal, or other device reintervention from completion of the implant procedure through six months (180 days) post-procedure.

OCCLUDER DESIGN

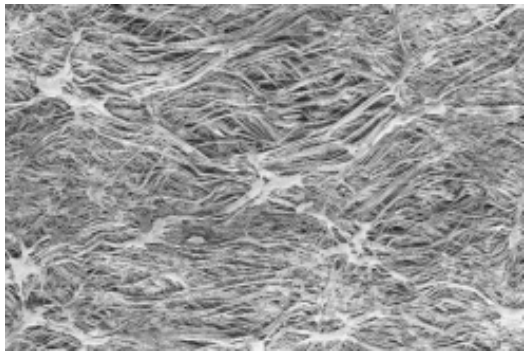
Material properties

Proprietary ePTFE*

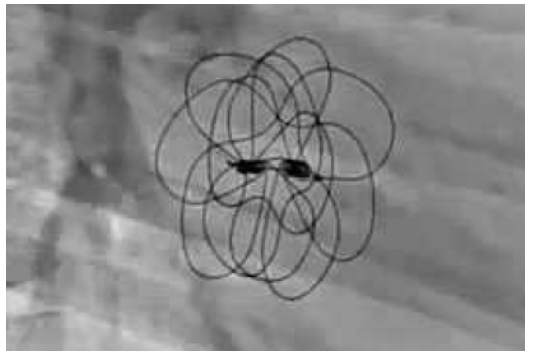
- Low thrombogenicity[3,4]
- Minimal inflammatory response
- Rapid endothelialization

Platinum-filled nitinol

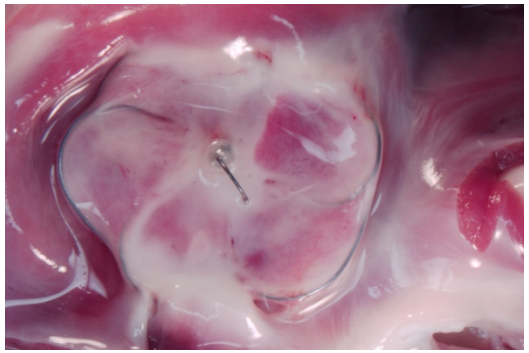
- Engineered for enhanced fluoroscopic visibility



ePTFE 250x magnification



GORE® CARDIOFORM ASD Occluder final implant

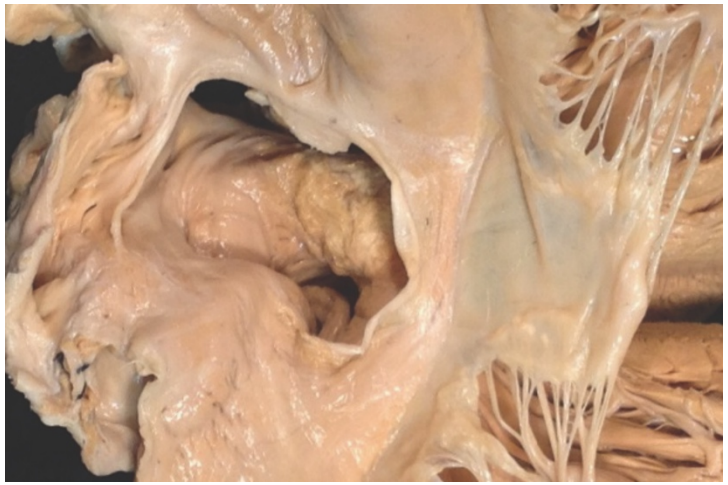


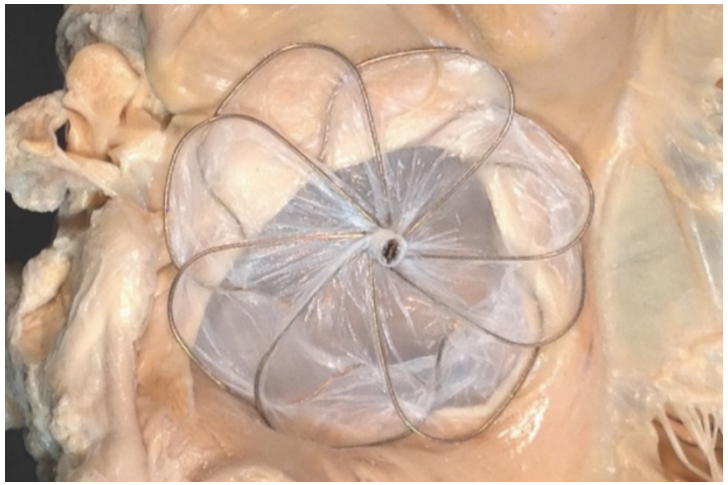
GORE® CARDIOFORM ASD Occluder after 90 days canine model

* ePTFE – expanded polytetrafluoroethylene.

Design features — Anatomically adaptable

Anatomically adaptable waist fills and conforms to the defect for ASDs from 8 to 35 mm[1]



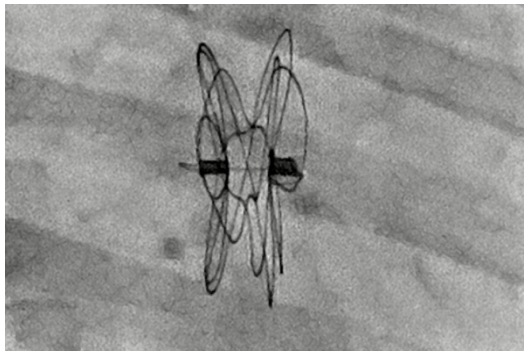


Cadaveric heart with ASD (left) and with 48 mm GORE® CARDIOFORM ASD Occluder (right)

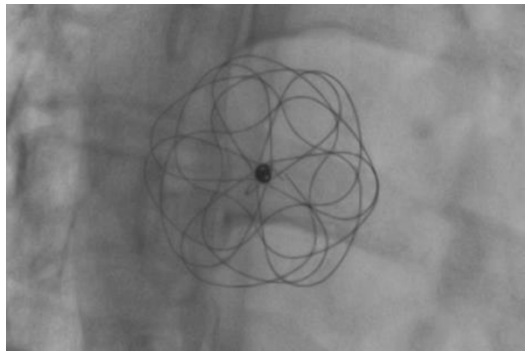
Occluder benefits — Soft, conformable design for short and long-term performance

Device design and material properties combine to optimize septal conformability and tissue ingrowth for short and long-term performance

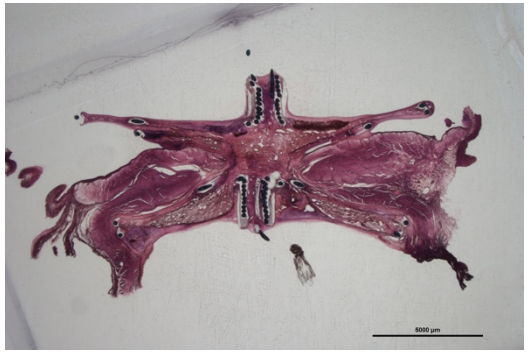
- Rapid occlusion*
- Conforms to the defect
- Optimal apposition
- Minimal inflammatory response
- Low thrombogenicity[3,4]
- Rapid endothelialization



GORE® CARDIOFORM ASD Occluder fluoro image taken at time of clinical implant



GORE® CARDIOFORM ASD Occluder fluoro

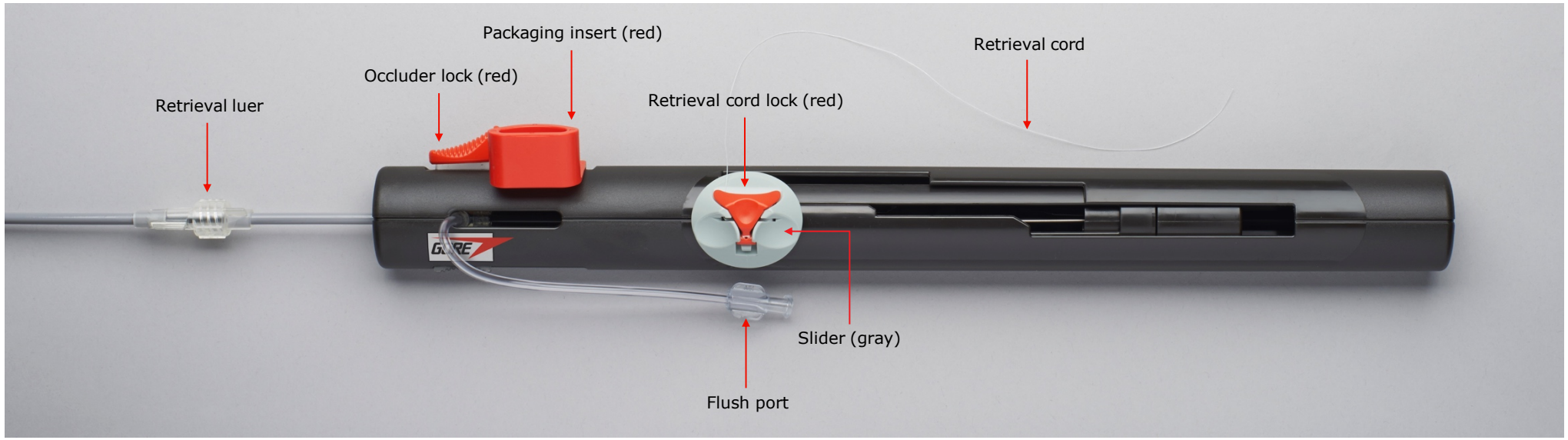


GORE® CARDIOFORM ASD Occluder after 90 days canine model

* Rapid occlusion defined as Technical Success with completely occluded defect or residual shunt ≤ 2 mm at the completion of the implant procedure.

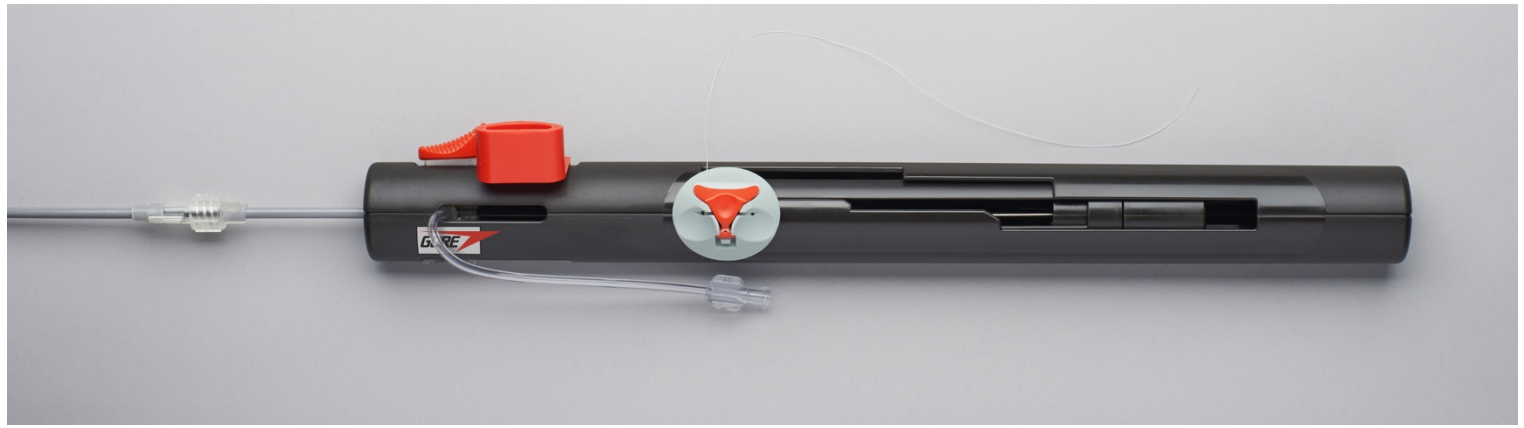
HANDLE DESIGN

Handle design



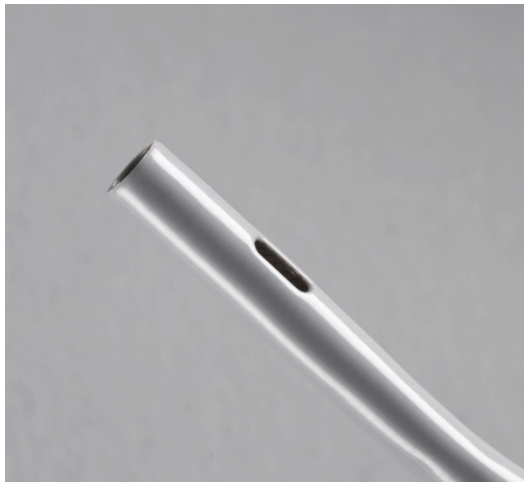
Delivery catheter design

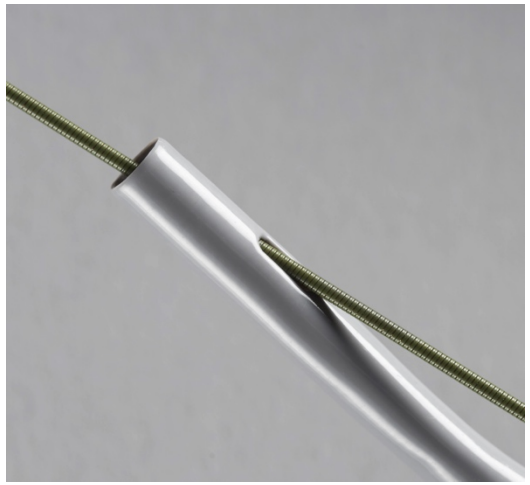
- Designed for optimized control and implant precision
- Designed for easy and fast Occluder loading, deployment and release
- Allows for complete device retrieval after locking, if necessary



Delivery catheter design

- Outer diameter varies by Occluder size (10 Fr to 14 Fr)
- Allows delivery over 0.035" guide wire, or smaller (2 Fr larger introducer required)
- Pre-curved, 80 cm working length
- Radiopaque distal marker band
- Braided delivery catheter for excellent torque response





PREPARATION AND DELIVERY STEPS

Optimal size selection

- The defect and atrial chamber size should be evaluated by transesophageal (TEE) or intracardiac echo (ICE) to confirm that there is adequate space to accommodate the selected occluder size without impinging on adjacent cardiac structures
- There must be adequate room in the atrial chambers to allow the right and left atrial discs to lie flat against the septum with disc spacing equal to the septal thickness
- To assure that there is adequate space to accommodate the discs within the atrial chambers, the selected GORE® CARDIOFORM ASD Occluder maximum outer disc diameter should be less than 90% of the measured septal length
- The septal tissue margins surrounding the defect must be of sufficient size and integrity to prevent disc prolapse through the defect and GORE® CARDIOFORM ASD Occluder embolization

Sizing chart

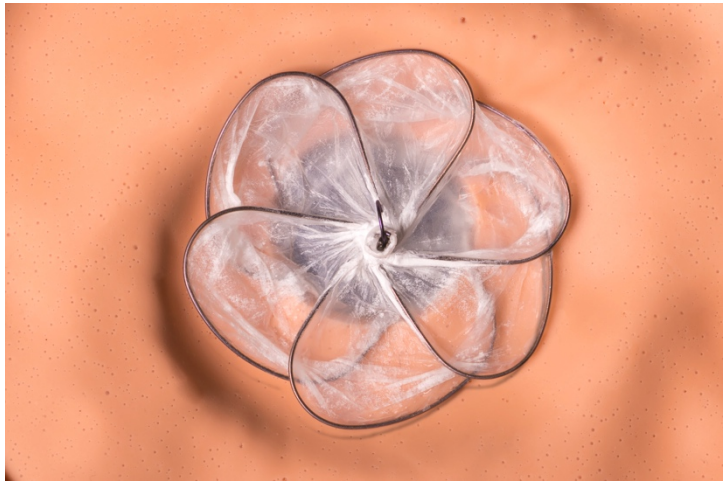
GORE® CARDIOFORM ASD Occluder

Catalogue number	Device size (disc diameter)	Treatment range measured with stop flow balloon sizing	Catheter size*
ASD27A	27 mm	8–15 mm	10 Fr
ASD32A	32 mm	13–20 mm	10 Fr
ASD37A	37 mm	18–25 mm	11 Fr
ASD44A	44 mm	23–30 mm	12 Fr
ASD48A	48 mm	28–35 mm	14 Fr

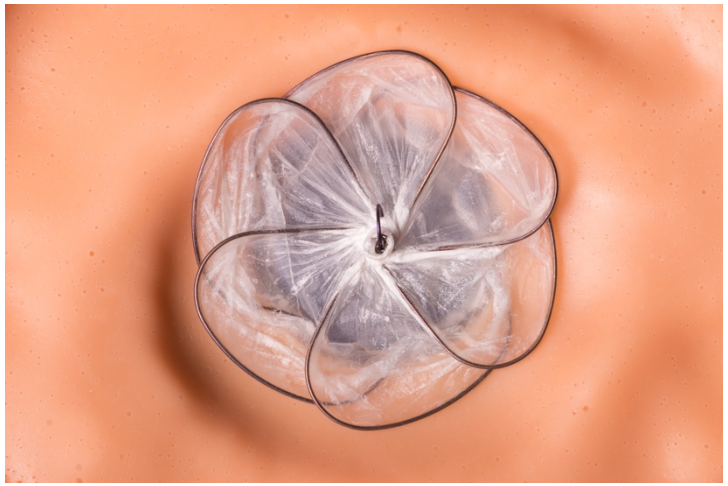
* If a 0.035" guidewire is used it is recommended to increase the introducer sheath size by 2 Fr.

Treatment range

The anatomically adaptable waist of the occluder fills and conforms to the defect to treat a range of defect sizes[1]



37 mm GORE® CARDIOFORM ASD Occluder in 18 mm defect



37 mm GORE® CARDIOFORM ASD Occluder in 25 mm defect

Equipment and accessories

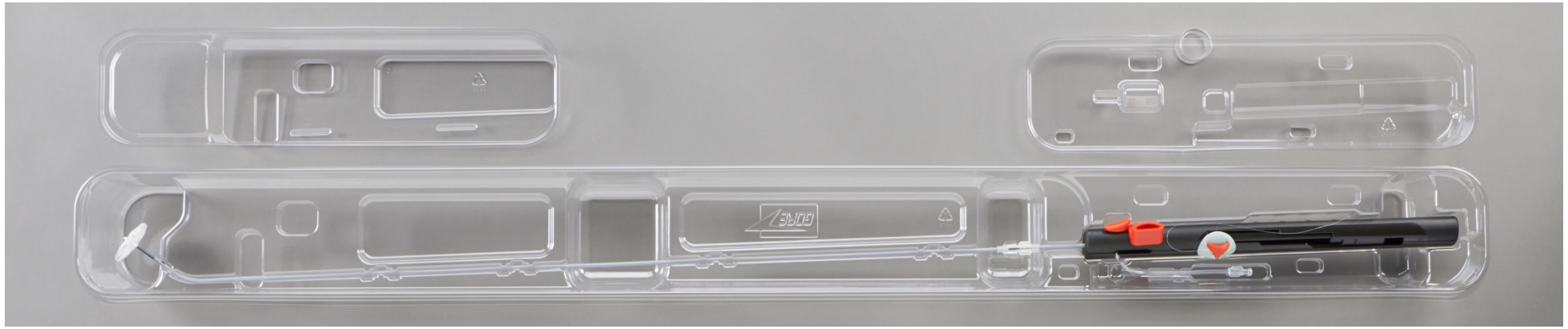
- High resolution fluoroscopy
- Transesophageal (TEE) or intracardiac echo (ICE) with color flow Doppler
- Required accessories
  - Introducer sheath (consult sizing chart for size recommendations)
  - Heparinized saline
  - Flushing syringe
  - Stopcock
  - Sizing balloon
  - Sterile bowl for flushing catheter
- Optional accessories
  - 0.035" guidewire or smaller
  - Introducer sheath that is 2 Fr larger than detailed in the sizing chart when a guidewire is utilized

How supplied

- The Occluder is supplied sterile in a protective tray and pouch. Provided that the integrity of the pouch is not compromised in any way, it will serve as an effective barrier until the “Use By” (expiration) date printed on the box.
- Check the “Use By” (expiration date) and the condition of the package
- Using aseptic technique, remove the sterile tray from the pouch

Package

- Device is pre-assembled and ready for use
- Handle color is black for GORE® CARDIOFORM ASD Occluder
- Remove the packaging tray lids
- Remove the device from the package and visually inspect the device for shipping damage

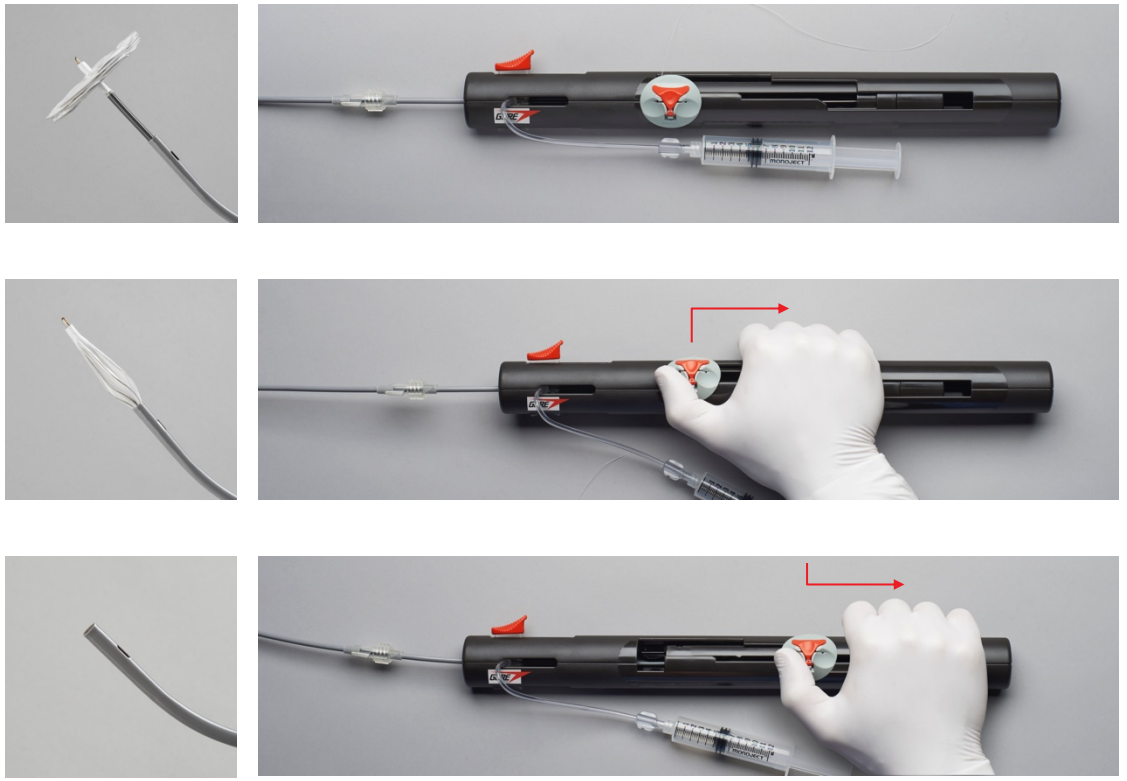


Device preparation

- Remove packaging insert
- Occluder lock should not be moved before or during device loading or deployment
- Ensure retrieval luer is tight

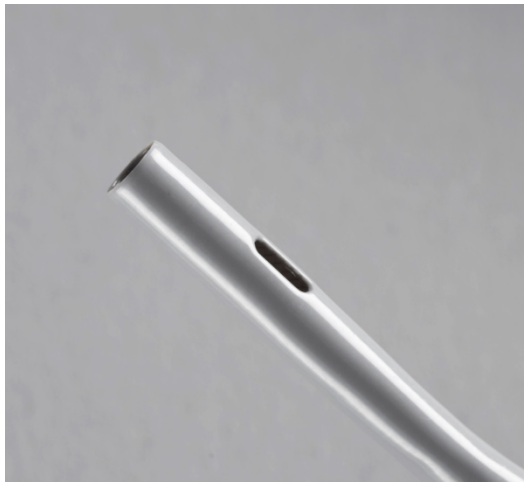
Occluder loading and flushing

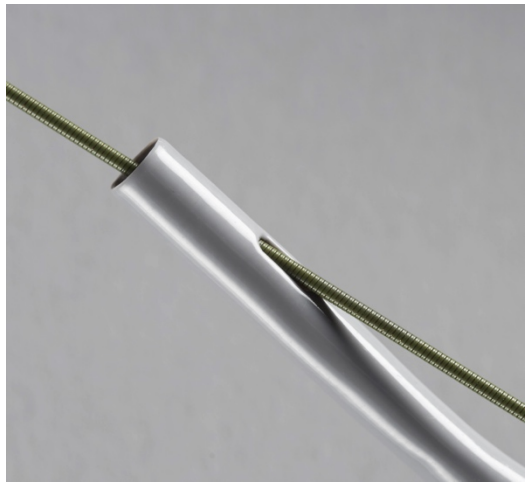
- Flush catheter prior to and after Occluder loading
- Submerge the GORE® CARDIOFORM ASD Occluder and catheter tip in a heparinized saline bath during flushing and loading
- Flush the device until air no longer exits the tip of the delivery catheter
- When the initial flushing is complete, begin loading
- To load the Occluder:
  - Submerge the Occluder
  - Push the slider up and then to the right until the slider stops
  - Continue by pushing slider down and then right until the slider stops
  - Flush the device again until air no longer exits the tip of the delivery catheter



Occluder delivery

- If applicable, load a 0.035" guidewire through the guidewire slot located at the distal end of the delivery catheter through the guidewire slot from the luminal surface out.
- While flushing the device, load the delivery catheter into the appropriately sized introducer sheath. Close the stopcock and remove the flushing syringe from the stopcock.
- Advance the delivery catheter across the atrial septum until the tip is positioned within the left atrium.
- If a guidewire was utilized, remove the guidewire before attempting to deploy the Occluder.

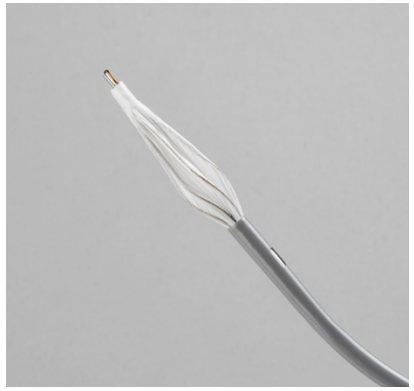




Occluder deployment

Left disc

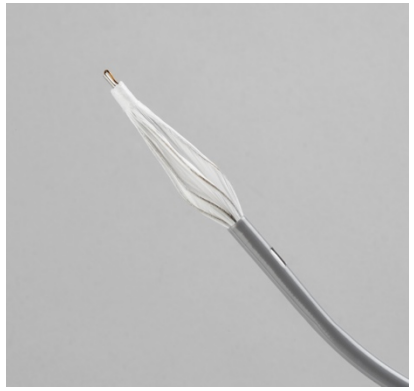
- Begin deploying the left disc by pushing the slider to the left until it stops
- This step may be performed while simultaneously retracting the delivery catheter to minimize advancement of the catheter tip within the left atrial chamber

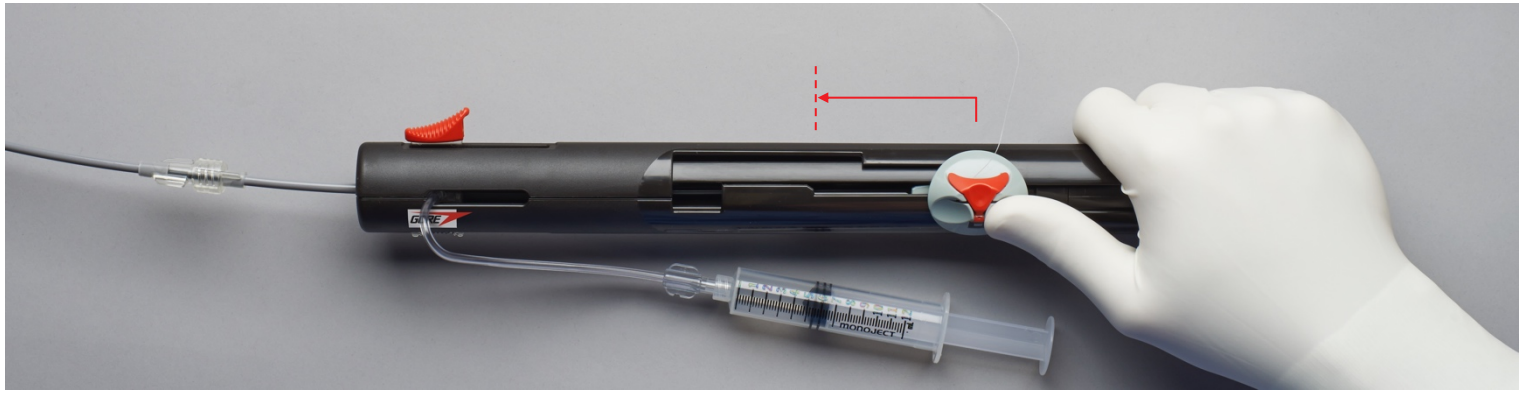


Occluder deployment

Left disc

- Complete left disc deployment by pushing the slider up and to the left until the tactile cue is encountered
- The Occluder will assume a funnel shape with a generally circular left disc
- Gently retract the handle to bring the left atrial disc onto the surface of the left atrial septum

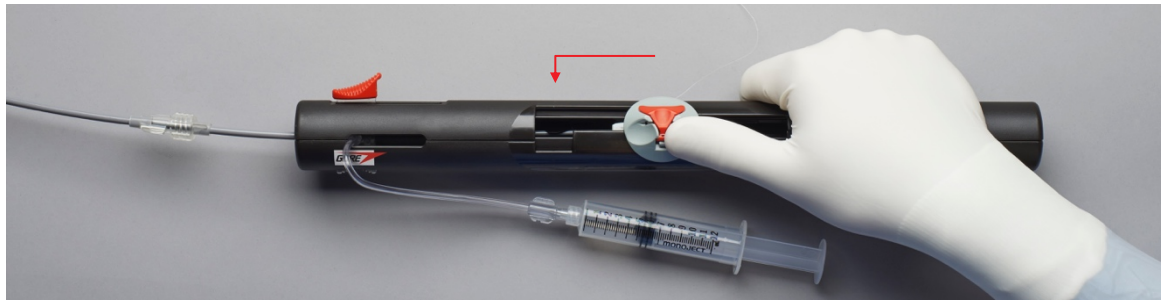


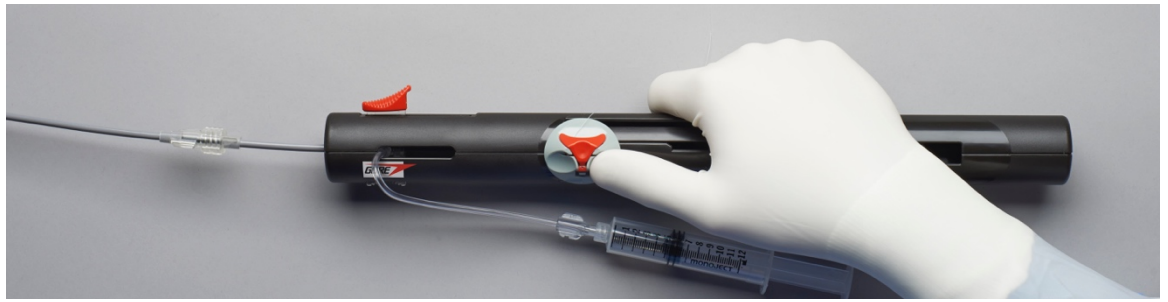


Occluder deployment

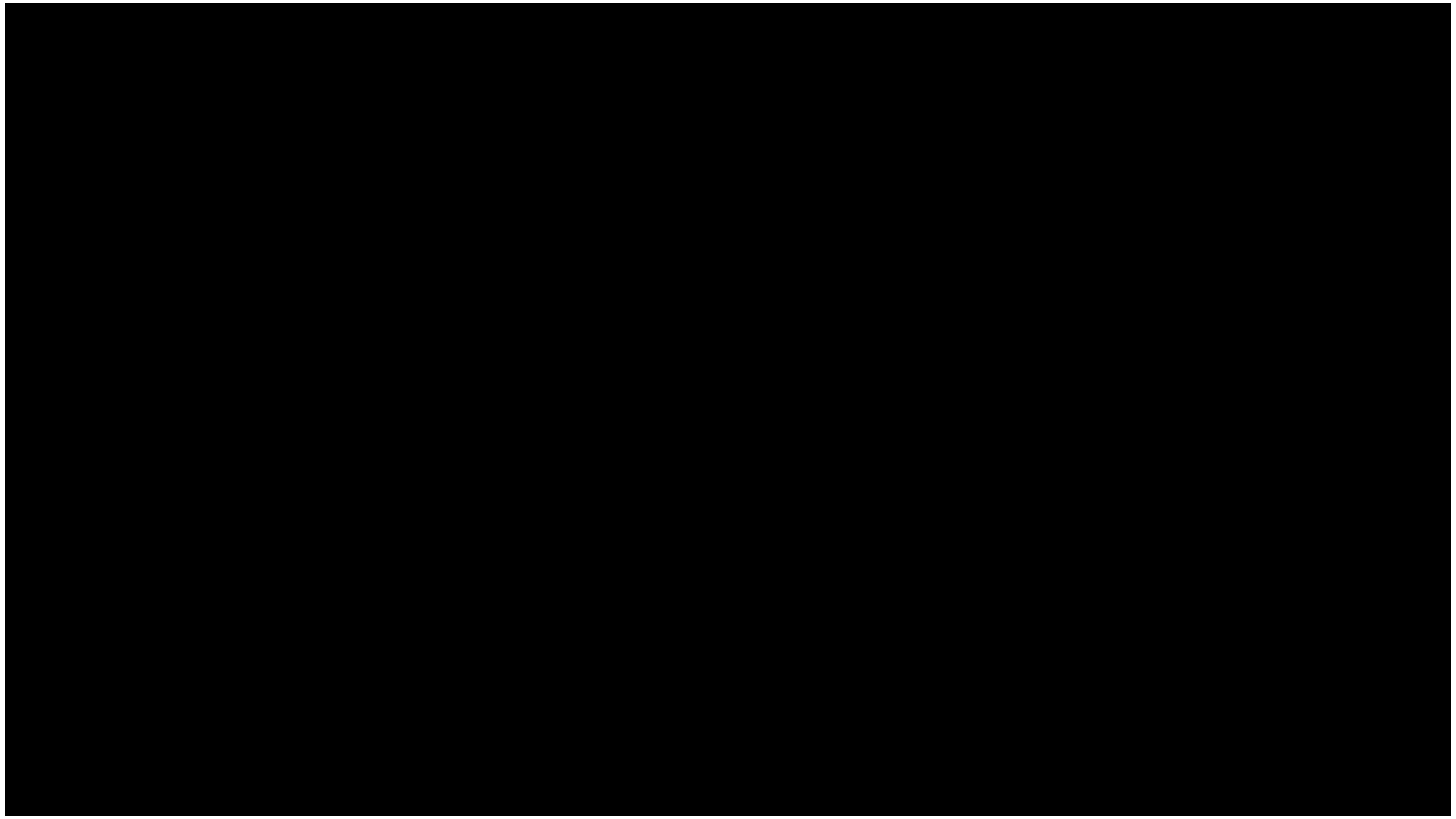
Right disc

- Deploy the right atrial disc by pushing the slider to the left until it stops and then push the slider down.
- Confirm that both left and right discs appear planar and apposed to the septum with septal tissue between the discs.



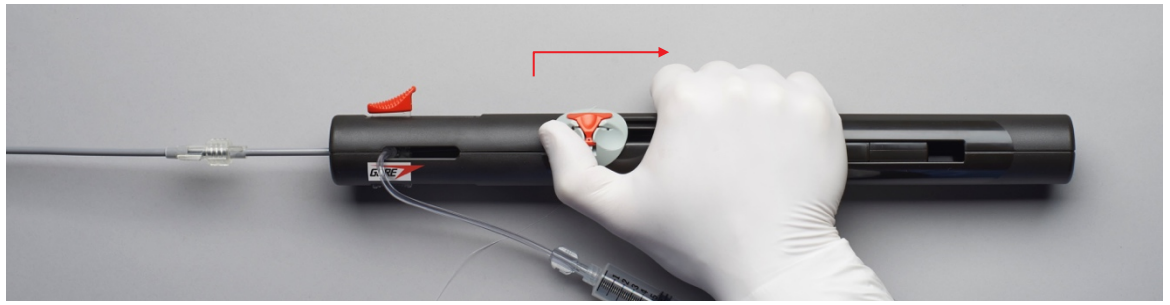


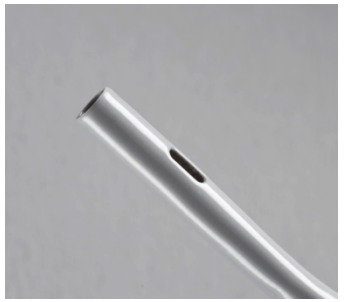
Occluder deployment



Repositioning

- It is preferable to reload only the right disc for device repositioning.
- Push the slider up and then to the right until the right disc is reloaded.
- If desired, complete Occluder reloading by pushing the slider down and then to the right until it stops. Ensure that the delivery catheter tip remains across the defect to maintain defect access.
- If successful deployment cannot be achieved after three attempts, an alternative device or treatment for septal defect closure is recommended.

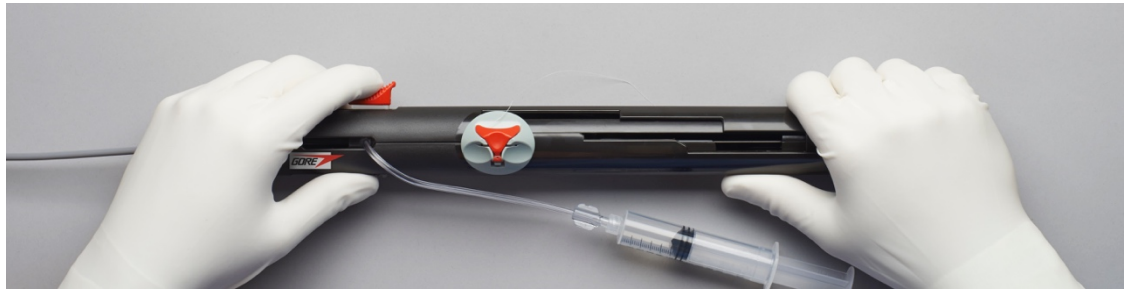




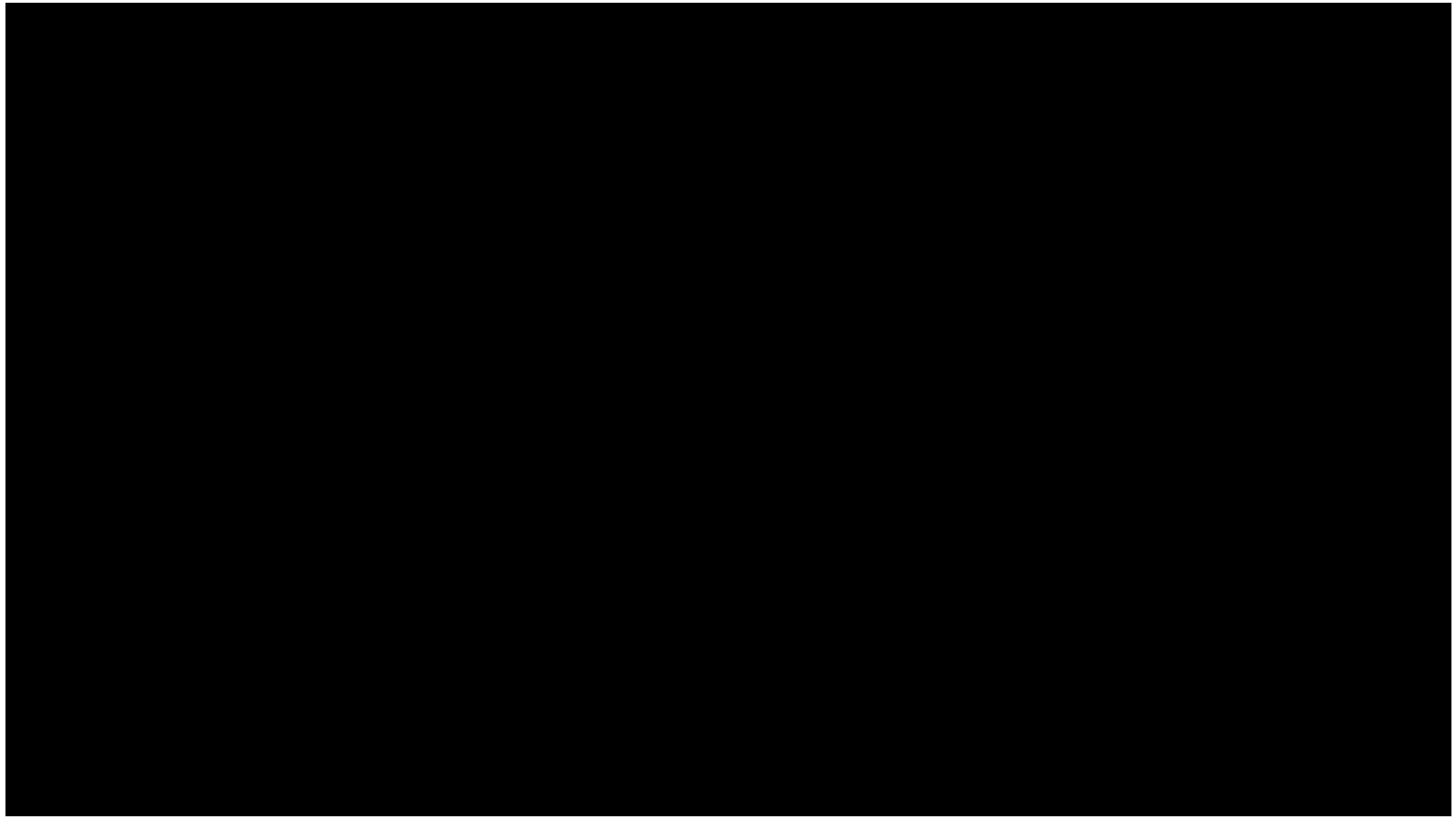
Repositioning

Locking

- Prior to Occluder locking, assess that the Occluder position and defect closure are acceptable and that the delivery system is not exerting tension on the septum and Occluder. Confirm adequate introducer sheath insertion prior to locking.
- Secure handle and hold it in a fixed position.
- Ensure the slider is completely to the left and down.
- Squeeze the Occluder lock then slide to the right with consistent force.

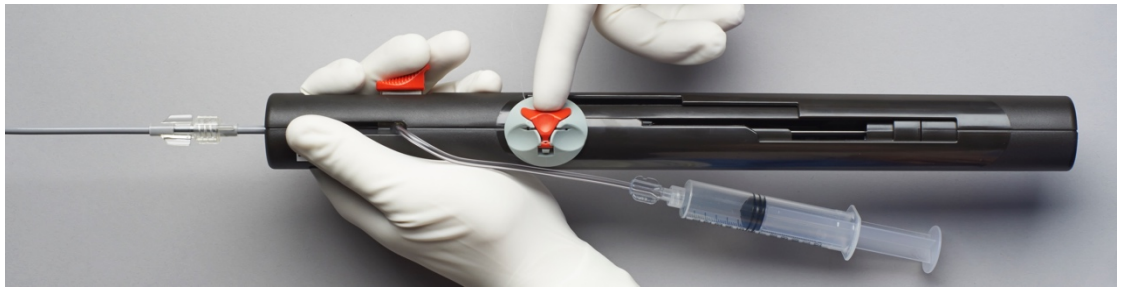


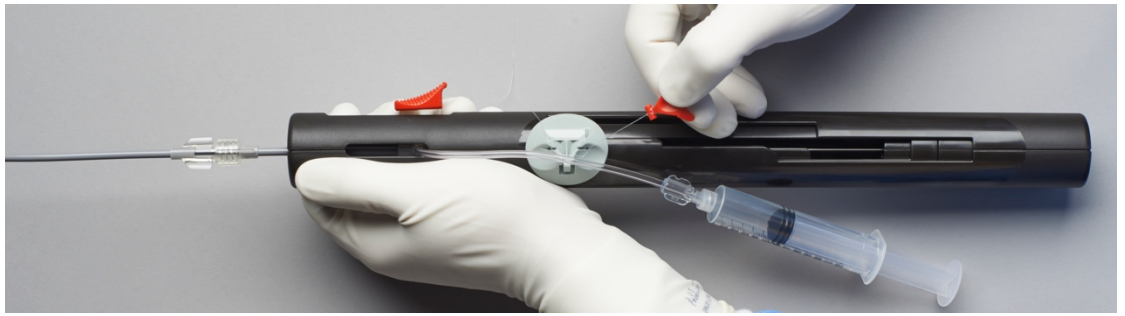
Locking



Occluder release

- Prior to releasing, assess the Occluder position to confirm it is acceptable
- Secure handle in a fixed position
- Flip up, twist and pull retrieval cord lock to disengage it from the slider
- Gently pull the retrieval cord lock until the retrieval cord has been completely removed from the handle

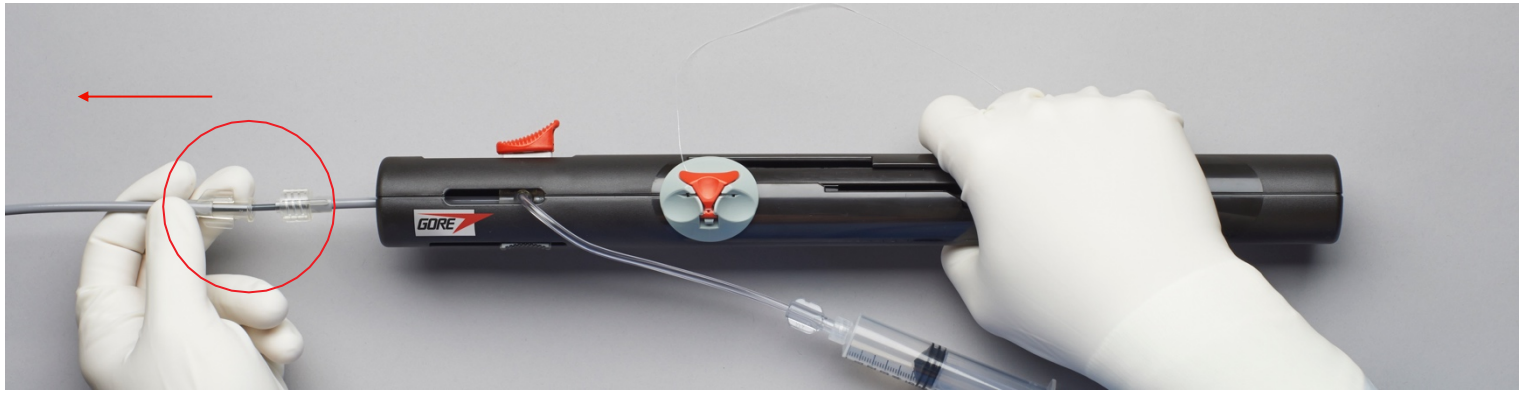




Occluder release

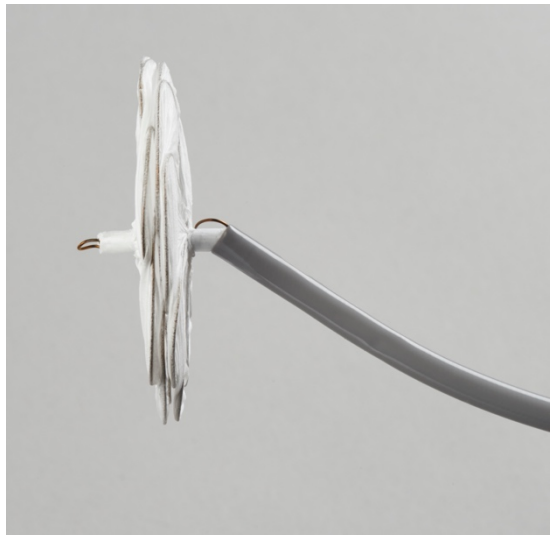
Occluder retrieval

- Unscrew and disconnect the retrieval luer
- Advance the loose delivery catheter to the right eyelet of the Occluder
- It is preferred to leave the Occluder in a locked state



Occluder retrieval

- Once the delivery catheter reaches the right eyelet and the locking loop, simultaneously advance the delivery catheter while retracting the handle, collapsing the Occluder within the delivery catheter*



* If high forces are encountered, discontinue retraction of the Occluder into the delivery catheter and withdraw the delivery system in its entirety down to the femoral venous access sheath and remove the Occluder and delivery system through the venous access sheath.

Occluder retrieval

Recapture / Snaring

- In the event that the GORE® CARDIOFORM ASD Occluder is malpositioned, embolized or otherwise requires removal, it may be recaptured
- Long sheath 2 Fr or larger than the delivery catheter is recommended
- Loop snares may be used
- Attempt to recapture the device by first snaring the left or right atrial eyelet
- Otherwise snare any portion of the Occluder

Contraindications

- The GORE® CARDIOFORM ASD Occluder is contraindicated for use in patients:
  - Unable to take anti-platelet or anticoagulant medications such as aspirin, heparin or warfarin
  - With anatomy where the GORE® CARDIOFORM ASD Occluder size or position would interfere with other intracardiac or intravascular structures, such as cardiac valves or pulmonary veins
  - With active endocarditis, or other infections producing bacteremia, or patients with known sepsis within one month of planned implantation, or any other infection that cannot be treated successfully prior to device placement
  - With known intracardiac thrombi

Warnings

- Read all *Instructions for Use* carefully. Failure to properly follow the instructions, warnings and precautions may lead to serious consequences or injury to the patient.
  - The GORE® CARDIOFORM ASD Occluder is not recommended for defects smaller than 8 mm and larger than 35 mm.
  - The GORE® CARDIOFORM ASD Occluder has not been studied in patients known to have multiple defects requiring placement of more than one device.
  - The GORE® CARDIOFORM ASD Occluder is not recommended for, and has not been studied in, patients with other anatomical types of ASDs that are eccentrically located on the septum (examples include sinus venosus ASD and ostium primum ASD), or fenestrated Fontan.
  - Embolized devices must be removed. An embolized device should not be withdrawn through intracardiac structures unless the occluder has been adequately collapsed within a sheath.

Warnings

- Read all *Instructions for Use* carefully. Failure to properly follow the instructions, warnings and precautions may lead to serious consequences or injury to the patient. Use of this product in applications other than those indicated, including but not limited to those listed below, has the potential for serious complications.
  - The GORE® CARDIOFORM ASD Occluder should be used only by physicians trained in its use, and in transcatheter defect closure techniques.
  - Patients allergic to nickel may suffer an allergic reaction to this device. Certain allergic reactions can be serious; patients should be instructed to notify their physicians immediately if they suspect they are experiencing an allergic reaction, such as difficulty breathing or inflammation of the face or throat. Some patients may also develop an allergy to nickel if this device is implanted.
  - Do not use if the package is opened or damaged, or it is suspected that the sterility of the device has been compromised, as infection and related serious potential patient harms could occur.
  - The device is designed for single use only. Reuse may result in infection and related serious potential patient harms.
- Do not disassemble the delivery catheter at the retrieval luer prior to device use. Loading the occluder attached to the delivery system back into the delivery catheter after disassembly (even if the delivery catheter is not fully removed), or into an alternative accessory device used as a delivery catheter, may lead to scraping the inner lumen of the catheter or accessory device. Embolism of foreign material may occur, potentially leading to stroke or other ischemic event and potentially necessitating reintervention or other treatment.

Warnings

Device sizing

- Regarding device sizing the following should be considered:
  - The defect and atrial chamber size should be evaluated by transesophageal (TEE) or intracardiac echo (ICE) to confirm that there is adequate space to accommodate the selected occluder size without impinging on adjacent cardiac structures (e.g. A-V valves, ostia of the pulmonary veins, coronary sinus or other critical features)
  - There must be adequate room in the atrial chambers to allow the right and left atrial discs to lie flat against the septum with disc spacing equal to the septal thickness, and without interference with critical cardiac structures or the free wall of the atria
  - Device removal and replacement should be considered if an occluder pulls through the defect after disc conformation
  - The device should not be larger than recommended for the defect size or the patient may have a higher risk of developing new arrhythmia or other complications

Precautions

General and before implant procedure

- The GORE® CARDIOFORM ASD Occluder is designed for single use only. An unlocked and removed GORE® CARDIOFORM ASD Occluder cannot be reused.
- Inspect the package before opening. If seal is broken, contents may not be sterile.
- Inspect the product prior to use in the patient. Do not use if the product has been damaged.
- Do not use after the labeled “Use By” (expiration) date.
- Do not resterilize.

Precautions

Procedure

- The GORE® CARDIOFORM ASD Occluder should only be used in patients whose vasculature is adequate to accommodate the introducer sheath
- An Activated Clotting Time (ACT) greater than 200 seconds should be maintained throughout the procedure
- The GORE® CARDIOFORM ASD Occluder should be used only in conjunction with appropriate imaging techniques to assess the septal anatomy and to visualize the wire frame
- Retrieval equipment such as large diameter sheaths, loop snares and retrieval forceps should be available for emergency or elective removal of the GORE® CARDIOFORM ASD Occluder
- If successful deployment cannot be achieved after three attempts, an alternative device or treatment for septal defect closure is recommended

Precautions

Procedure

- Removal of the GORE® CARDIOFORM ASD Occluder should be considered if:
  - The lock loop does not capture the right eyelet
  - The GORE® CARDIOFORM ASD Occluder will not come to rest in a planar position apposing the septal tissue
  - The selected GORE® CARDIOFORM ASD Occluder allows excessive shunting
  - There is impingement on adjacent cardiac structures

Precautions

After implant procedure

- Patients should take appropriate prophylactic antibiotic therapy consistent with the physician's routine procedures for 6 months following device implantation.
- Patients should be treated with antiplatelet therapy for six months post-implant. The decision to continue antiplatelet therapy beyond six months is at the discretion of the physician.
- In patients sensitive to antiplatelet therapy, alternative therapies, such as anticoagulants, should be considered.
- Patients should be advised to avoid strenuous physical activity for a period of at least two weeks after occluder placement.
- Patients should have transthoracic echocardiographic (TTE) exams prior to discharge, and at one, six and 12 months after GORE® CARDIOFORM ASD Occluder placement to assess defect closure and device stability. In instances where device stability is questionable, fluoroscopic examination without contrast is recommended in order to identify and assess wire frame fractures.

MRI information

- The GORE® CARDIOFORM ASD Occluder has been determined to be MR-conditional. Non-clinical testing demonstrated that the GORE® CARDIOFORM ASD Occluder is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:
  - Static magnetic field of 3-Tesla or 1.5 Tesla
  - Maximum spatial gradient magnetic field of 4,000-Gauss / cm (40 T / m) or less
  - Maximum MR system reported, whole body averaged specific absorption rate (SAR) of <2 W / kg (Normal Operating Mode)The effect of overlapping Occluders has not been studied and is not understood
  - Under the scan conditions defined above, the GORE® CARDIOFORM ASD Occluder is expected to produce a maximum temperature rise of 2 degrees Celsius after 15 minutes of continuous scanning
- In non-clinical testing, the image artifact caused by the device extends approximately 5 mm from the GORE® CARDIOFORM ASD Occluder when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system

References

1. GORE® CARDIOFORM ASD Occluder Imaging Training Tool. Flagstaff, AZ. W. L. Gore & Associates; 2017. [Digital training tool]. AW0214-EN1.

2. GORE® CARDIOFORM ASD Occluder [*Instructions for Use*]. Flagstaff, AZ: W. L. Gore & Associates, Inc; 2019.

3. Hamlin GW, Rajah SM, Crow MJ, Kester RC. Evaluation of the thrombogenic potential of three types of arterial graft studied in an artificial circulation. *British Journal of Surgery* 1978;65(4):272-276.

4. Köveker GB, Burkel WE, Graham LM, Wakefield TW, Stanley JC. Endothelial cell seeding of expanded polytetrafluoroethylene vena cava conduits: effects on luminal production of prostacyclin, platelet adherence, and fibrinogen accumulation. *Journal of Vascular Surgery* 1988;7(4):600-605.

Together, improving life

Consult Instructions for Use
eifu.goremedical.com

INDICATIONS / INTENDED USE: The GORE® CARDIOFORM ASD Occluder is a permanently implanted device indicated for the percutaneous, transcatheter closure of ostium secundum atrial septal defects (ASDs). **CONTRAINDICATIONS:** The GORE® CARDIOFORM ASD Occluder is contraindicated for use in patients: Unable to take anti-platelet or anticoagulant medications such as aspirin, heparin or warfarin; with anatomy where the GORE® CARDIOFORM ASD Occluder size or position would interfere with other intracardiac or intravascular structures, such as cardiac valves or pulmonary veins; with active endocarditis, or other infections producing bacteremia, or patients with known sepsis within one month of planned implantation, or any other infection that cannot be treated successfully prior to device placement; with known intracardiac thrombi. Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all warnings, precautions and adverse events. ℞ Only

Products listed may not be available in all markets.

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