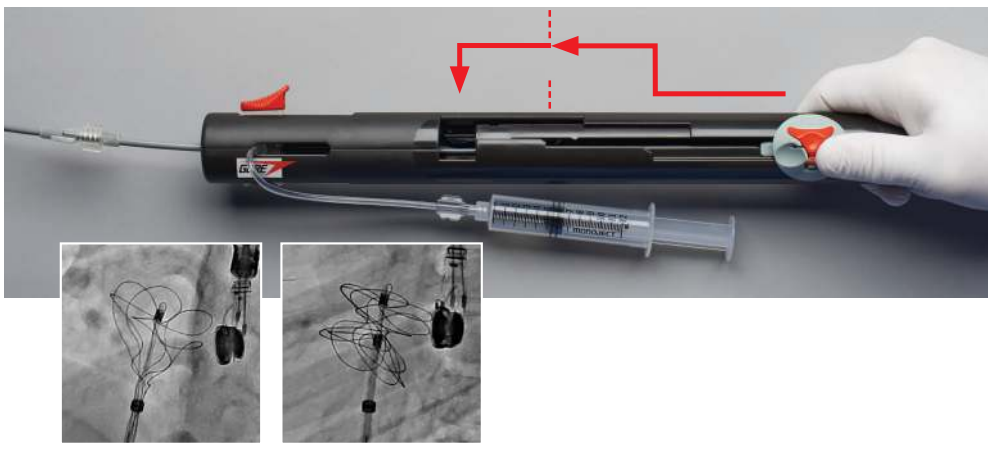
PROCEDURAL STEPS

Device size (Disc diameter)	Treatment range measured with stop flow balloon sizing	Catheter size
27 mm	8–15 mm	10 Fr
32 mm	13–20 mm	10 Fr
37 mm	18–25 mm	11 Fr
44 mm	23–30 mm	12 Fr
48 mm	28–35 mm	14 Fr

Preparation

- Remove from the package and visually inspect the device.
- Ensure that the retrieval luer is tight.
- Remove the packaging insert.
- Submerge the device and catheter tip in a heparinized saline bath.
- Flush the device prior to and after Occluder loading.
- To load the device, move the slider up and then to the right until it stops. Continue pushing down and then right until slider stops.
- If a 0.035" guidewire is used it is recommended to increase the introducer sheath size by 2 Fr.
- While flushing the device, load the delivery catheter into the appropriately sized introducer sheath.



Deployment

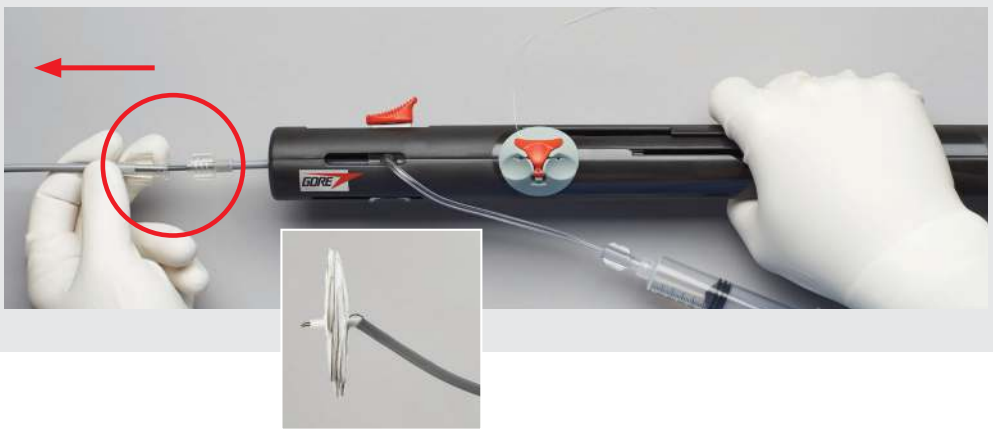
- Advance the delivery catheter across the atrial septum until the tip is positioned within the left atrium.
- If a guidewire was utilized, remove the guidewire before attempting to deploy the device.
- Begin deploying the left disc by pushing the slider to the left until it stops. This step may be performed while simultaneously retracting the delivery catheter to minimize advancement of the device within the left atrium.
- To form the left disc, push the slider up and to the left until the tactile cue is encountered. The device 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.
- To form the right disc, move the slider to the left until it stops, then move the slider down. Confirm that the slider has moved completely to the left and down position. Failure to do so may prevent locking of the device.
- Confirm that both left and right discs appear planar and apposed to the septum with septal tissue between the discs.

Locking

- Maintain handle in a fixed position to prevent applying tension on the occluder.
- Ensure the slider is completely to the left and down.
- Squeeze Occluder lock and then slide decisively and with a consistent amount of force to the right.
- Occluder remains tethered to the delivery system by retrieval cord.

Release

- Hold the handle in a fixed position.
- Flip up, twist and gently pull the until the retrieval cord has been completely removed from the handle.
- The Occluder is now released from the delivery system and the delivery system can be removed.



Retrieval

- Unscrew the retrieval luer and advance the delivery catheter to the right eyelet of the Occluder.
- It is preferred to leave the Occluder in a locked state.
- Simultaneously advance the delivery catheter while retracting the handle, collapsing the Occluder within the delivery catheter.

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 applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

Products listed may not be available in all markets.

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