OCCLUDER DEVICES APPROVED IN THE UNITED STATES

Company Name	Product Name	Indicated Use	Recommended Size of Introducer (F)	Recommended Diameter of Defect for Device (mm)
AGA Medical Corporation	Amplatzer Septal Occluder	Transcatheter atrial septal defect closure	6–12-F TorqVue Delivery Systems (device size determines delivery sheath selection)	Ability to close 4- to 38-mm defects; 40 mm not available in the US
	Amplatzer Cribriform Septal Occluder	Transcatheter multifenestrated atrial septal defect closure	8–10-F TorqVue Delivery Systems (device size determines delivery sheath selection)	Shortest distance from defect to aortic root or distance from defect to superior vena cava orifice: 35-mm device up to 17.5 mm; 25-mm device if defect is between 12.5 and 17.4 mm; 18-mm device is between 9 and 12.4 mm; do not implant if defect is ≤ 9 mm; 40 mm not available in the US
	Amplatzer Duct Occluder	Transcatheter occlusion of patent ductus arteriosus	5–7-F TorqVue Delivery Systems (device size determines delivery sheath selection)	Ability to close 2.5- to > 5-mm defects
	Amplatzer Muscular VSD Occluder	Transcatheter muscular septal defect closure	6–9-F TorqVue Delivery Systems (device size determines delivery sheath selection)	Ability to close 4- to 18-mm defects
NMT Medical Inc.	The CardioSeal Septal Repair Implant and StarFlex Septal Repair Implant	The CardioSeal septal repair implant is indicated for use in the nonsurgical treatment of intracardiac defects	10	CardioSeal and StarFlex sizes should be based on both the diameter and shape of the defect; the area containing the target defect must be large enough to allow the implant to fully deploy, and the surrounding structures should be fully examined in multiple planes to assure no interference by the device; the CardioSeal or StarFlex implant should be at least 1.7:1 times the stretched diameter of the defect; the CardioSeal and StarFlex should fit within the anatomy without interfering with other intracardiac structures and with all arms in contact with the septum; the defect should have adequate rim around the circumference to provide a stable platform
Nobles Medical Technology	SuperStitch EL	Vascular stitching in general surgery, including endoscopic procedures not intended for blind vascular closure	12	N/A
W. L. Gore & Associates, Inc.	Gore Helex Septal Occluder	Ostium secundum, ASD (CE Mark, US), PFO (CE Mark)	10	Device diameter should be twice that of the defect diameter

ASD, atrial septal defect; MRI, magnetic resonance imaging; PDA, patent ductus arteriosus; PFO, patent foramen ovale; VSD, ventricular septal defect.

Device Size (mm)	Delivery Device Length (cm)	Regulatory Status (US and CE Mark)	Comments
4–38 (waist diameter ASD) (40-mm device not available in the US)	60 or 80	US and CE	Low-profile, nitinol and polyester construction; device waist fills defect for optimal fit and occlusion; endothelialization process promotes low thrombogenicity; low risk of erosion
18, 25, 30, 35 (40-mm device not available in the US)			Nitinol and polyester construction; thin waist offers optimal fit and occlusion of the multifenestrated ASD
5/4, 6/4, 8/6, 10/8, 12/10; 14/12 and 16/14 not available in the US (device diameter at descending aorta/device diameter at pulmonary artery)	60 (5–7 F) 80 (6–7 F)		Nitinol and polyester construction of the Duct Occluder allows its use on varied PDA shapes and sizes
4–18 (waist diameter VSD)	60 (6–8 F) 80 (6–9 F)		Nitinol and polyester fabric in the device waist and discs provide for rapid occlusion properties
CardioSeal: 17, 23, 28, 33, 40; StarFlex: 23, 28, 38	N/A	CardioSeal has VSD in US; CE Mark and HPB for the transcatheter closure of atrial-level defects; StarFlex has VSD in the US and CE Mark for atrial-level repair	The CardioSeal and StarFlex septal repair implants have the longest clinical use history of all currently available septal occluders; the double-umbrella implant provides a highly conformable design with very low septal profile and low metal surface area; the polyester tissue scaffold is proven to promote endothelialization; the CardioSeal and the StarFlex have a framework that is made of MP35N, a cobalt-based alloy known for its excellent corrosion resistance and MRI safety; as MP35N is not a shape memory material, it does not distort cardiac anatomy; StarFlex has a nitinol spring that enables the implant to self-center within the defect
12	85	US and CE	The SuperStitch EL allows physicians to place sutures in remote locations to close arteriotomies, venotomies, or approximate tissue planes in the vascular system including cardiovascular
15, 20, 25, 30, 35	75	US and CE	Single, circumferential nitinol wire frame; ePTFE membrane with low thrombogenicity; soft, conformable design with low risk of erosion/perforation; fully retrievable even after lock release