

CeraFlex

3rd generation occluder devices

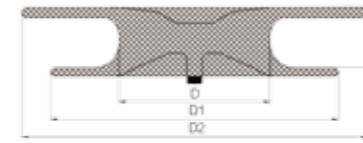
Designed for Deliverability and Ease of Use

Innovative Titanium Nitride Coating Technology

Conforms to Fit Each Patient's Anatomy

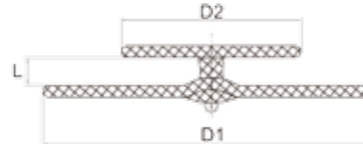
Order Information

CeraFlex™ ASD Occluder Product Specification



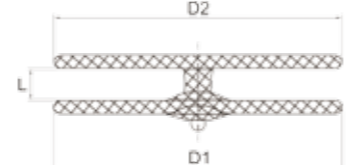
Code	D Waist Diameter (mm)	D1 Right Disc Diameter (mm)	D2 Left Disc Diameter (mm)	L Waist Length (mm)	Minimum Sheath Size (Fr)
LT-ASDF-06	6	14	18	4	8Fr
LT-ASDF-08	8	16	20	4	8Fr
LT-ASDF-10	10	18	22	4	8Fr
LT-ASDF-12	12	22	26	4	9Fr
LT-ASDF-14	14	24	28	4	10Fr
LT-ASDF-16	16	26	30	4	10Fr
LT-ASDF-18	18	28	32	4	10Fr
LT-ASDF-20	20	30	34	4	12Fr
LT-ASDF-22	22	32	36	4	12Fr
LT-ASDF-24	24	34	38	4	12Fr
LT-ASDF-26	26	36	40	4	12Fr
LT-ASDF-28	28	38	42	4	12Fr
LT-ASDF-30	30	40	44	4	14Fr
LT-ASDF-32	32	42	46	4	14Fr

CeraFlex™ PFO Occluder Product Specification



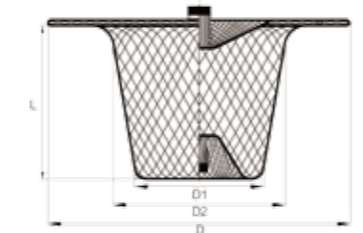
Code	D1 Right Disc Diameter (mm)	D2 Left Disc Diameter (mm)	L Waist Length (mm)	Minimum Sheath Size (Fr)
LT-PFOF-1818	18	18	3	9Fr
LT-PFOF-2518	25	18	3	10Fr
LT-PFOF-2525	25	25	3	10Fr
LT-PFOF-3025	30	25	3	12Fr
LT-PFOF-3030	30	30	3	12Fr
LT-PFOF-3525	35	25	3	14Fr

CeraFlex™ MF-ASD Occluder Product Specification



Code	D1 Right Disc Diameter (mm)	D2 Left Disc Diameter (mm)	L Waist Length (mm)	Minimum Sheath Size (Fr)
LT-ASDF-MF-1818	18	18	3	9Fr
LT-ASDF-MF-2525	25	25	3	10Fr
LT-ASDF-MF-3030	30	30	3	12Fr
LT-ASDF-MF-3535	35	35	3	14Fr
LT-ASDF-MF-4040	40	40	3	14Fr

CeraFlex™ PDA Occluder Product Specification



Code	D Retention Skirt (mm)	D1 Proximal Diameter (mm)	D2 Distal Diameter (mm)	L Waist Length (mm)	Minimum Sheath Size (Fr)
LT-PDAF-0406	10	4	6	7	6Fr
LT-PDAF-0608	12	6	8	7	7Fr
LT-PDAF-0810	14	8	10	7	7Fr
LT-PDAF-1012	16	10	12	7	8Fr
LT-PDAF-1214	20	12	14	7	9Fr
LT-PDAF-1416	22	14	16	8	9Fr
LT-PDAF-1618	24	16	18	8	10Fr
LT-PDAF-1820	26	18	20	9	12Fr
LT-PDAF-2022	28	20	22	9	12Fr
LT-PDAF-2224	30	22	24	10	14Fr

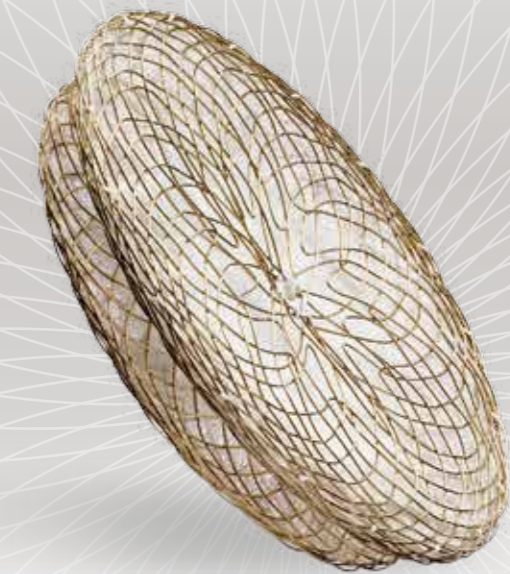
References

- Zhi xiong Zhang, Bu fang Fu, De yuan Zhang, et al. Safety and efficacy of nano lamellar TiN coatings on nitinol atrial septal defect occluders in vivo. Materials Science and Engineering C33; 2013:1355-60.
- Ahang Zui, Zhang De-yuan, He Ling-lr, Qi Feng-jun. Effects of nano-structured Ti/TiN coatings on the biocompatibility of nitinol. Progress in Modern Biomedicine 2009; Vol.9 No.13:2465-68.
- Deyuan Zhang, Zhiwei Zhang, Zhenjun Zi, Yanhong Zhang, Weijun Zeng, Paul K. Chu. Fabrication of graded TiN coatings on nitinol occluders and effects on in vivo nickel release. Bio-Medical Materials and Engineering 18 (2008):387-93.

For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use. For further inquiries, please contact your local sales representative.

Not available for sale in the US.

CeraFlex™
3rd GENERATION OCCLUDER DEVICES



Designed for Controlled Release and Conformability



CE 0344

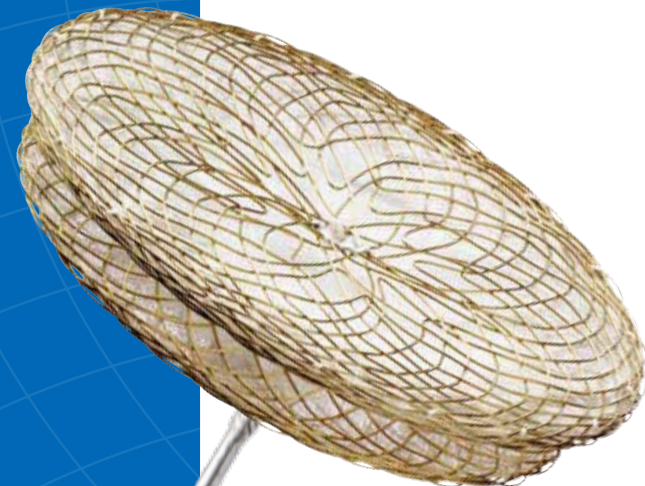
Version No.: 2016-EN-B-1.0

Ceraflex™



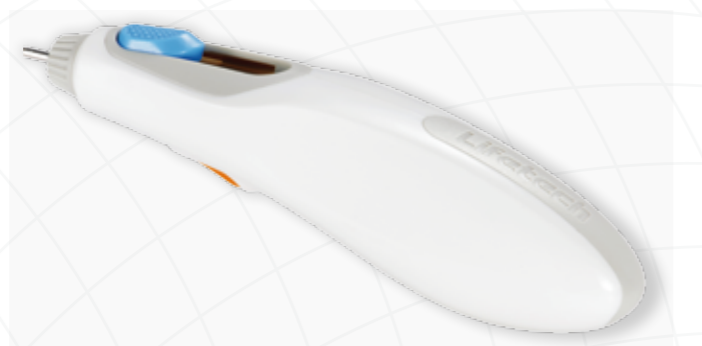
3rd Generation Occluders Designed to Optimize Performance

- Proprietary TiN coating attributes to a softer occluder for *maximum flexibility and conformability* to septal tissue
- *Flat profile with no left disk hub* reduces metal in the left atrium



Pre-mounted Delivery System Designed for Accuracy and Ease of Use

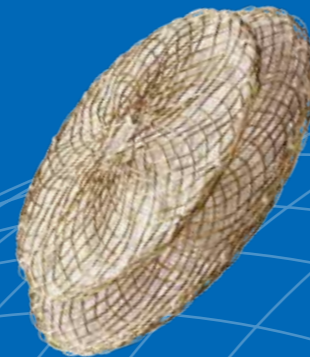
- 360° rotation for accurate occluder visualization and placement prior to *controlled release*
- Streamlined delivery handle for *quick and accurate deployment*



ASD



PDA

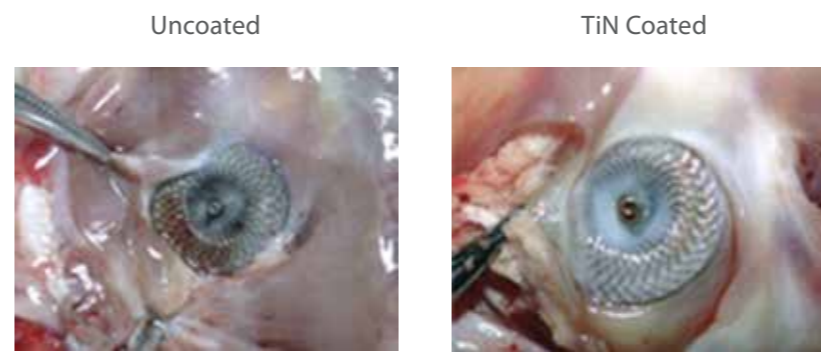


PFO

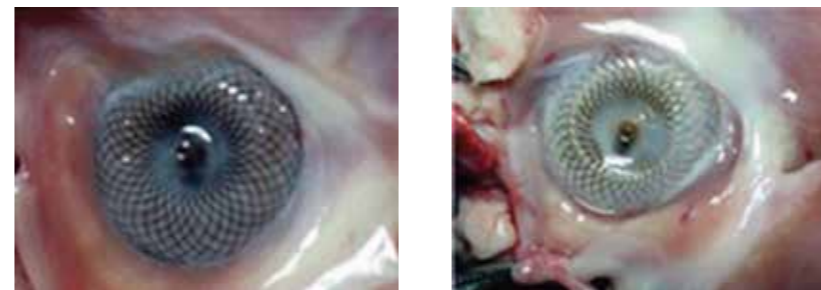
Innovative Titanium Nitride (TiN) Coating Technology

Accelerated Endothelialization¹

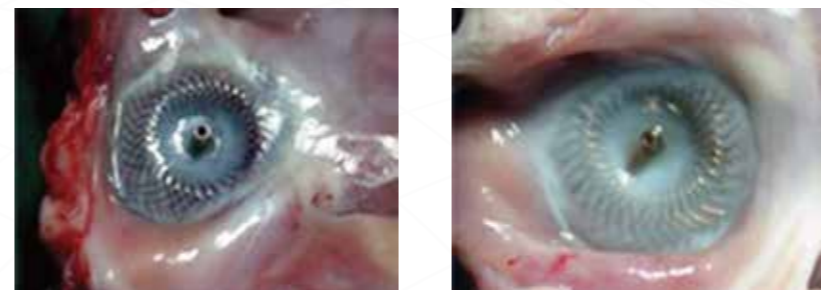
TiN coating allows for faster growth of endothelial cells reducing the risk of thrombus formation



2 Months



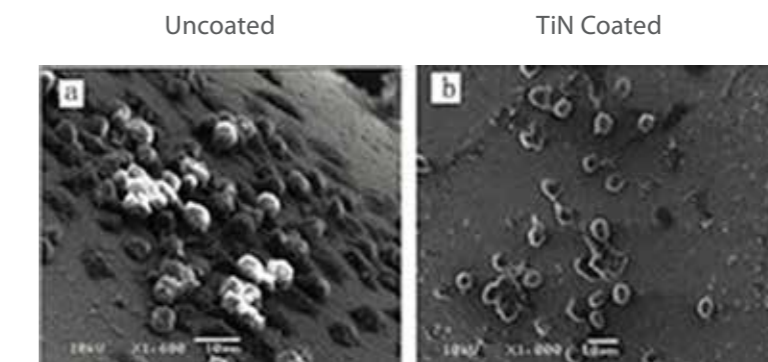
4 Months



6 Months

Improved Thrombotic Resistance²

Less thrombus formation on TiN coated occluder



Minimal Nickel Release³

The uniquely braided TiN coated occluder offers excellent adaptability to the septal tissue and reduces nickel release

