Yasargil Titanium and Phynox Aneurysm Clips

MRI SAFETY INFORMATION



The Yasargil Titanium and Phynox Aneurysm Clips are MR Conditional.

Non-clinical testing demonstrated that the Yasargil Aneurysm Clip is MR Conditional. A patient with this device can be safely scanned immediately after implantation in an MR system meeting the following conditions:

- Static magnetic field of 3-Tesla or less
- **Titanium** clip Maximum spatial gradient magnetic field of 3000 Gauss/cm (30.0 T/m) or less
- **Phynox** clip Maximum spatial gradient magnetic field of 1,500-Gauss/cm (15.0 T/m) or less
- Maximum MR system reported, whole body averaged SAR of4-W/kg (First Level Controlled Operating Mode)
- Do not take the aneurysm clip applier into the MR environment. It is MR Unsafe.

Under the scan conditions defined above, the Yasargil **Titanium** Aneurysm Clip is expected to produce a maximum temperature rise of +1.8°C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately 5 mm from the Yasargil Titanium Aneurysm Clip when imaged with a gradient echo pulse sequence and a 3-Tesla MR system.

Under the scan conditions defined above, the Yasargil **Phynox** Aneurysm Clip is expected to produce a maximum temperature rise of $+2.2^{\circ}$ C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately 20mm from the Yasargil Phynox Aneurysm Clip when imaged with a gradient echo pulse sequence and a 3-Tesla MR system.

For MRI Safety Information, including artifact information, Warnings and Precautions see product IFU SOP-AIC-5000566 (TA011251-US).

NOTE: Aesculap currently markets two lines of aneurysm clips; one from a cobalt alloy that we refer to as "Phynox" and one from a a titanium alloy. Phynox clips have been available since 1983 and have catalog numbers that begin with "FE". Titanium clips have been available since 1995 and have catalog numbers that begin with "FT".

Prior to 1985, Aesculap distributed various models of aneurysm clips manufactured from stainless steel. These aneurysm clips were identified with the letters "FD" and have not been proven safe for exposure to MRI. For this reason, Aesculap does not recommend the use of MRI on a patient implanted with a YASARGIL aneurysm clip identified with the letters "FD".

Phynox Reinforcing Clips

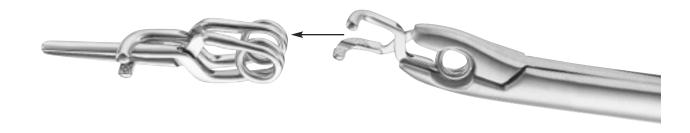
The Phynox Reinforcing Clip increases the closing force of Phynox Standard Aneurysm Clips by up to 40%.

PERMANENT

Item No.







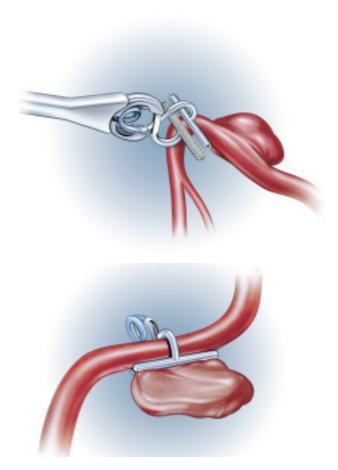
Phynox Extra Short Fenestrated Clips

Item No.		Fenestration Diameter (mm)	Jaw Length L1/L2 (mm)	Angle	Max. Opening (mm)	Closing Force N g (+/- 10%)	
FE942K		5.0 mm	3.0/8.1	50°	6.0 mm	1.47	150
FE944K		5.0 mm	3.0/6.4	90°	5.5 mm	1.47	150

Phynox T-Bar Clips

The clip you trust, now in a unique new design

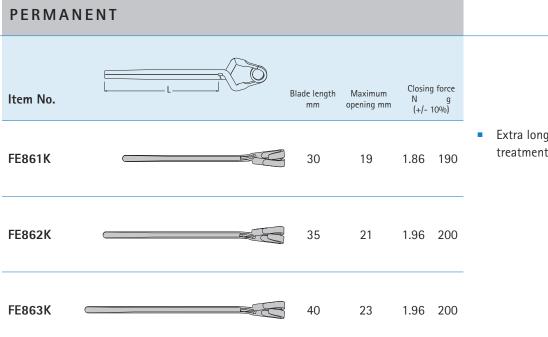
- T-Bar clip blades are oriented at a 45 or 90 degree angle to the axis of the spring plane, resulting in an innovative "T" shape
- T-Bar clip springs are identical to the springs of Yasargil standard aneurysm clips—no special applier needed
- Unique, patented design can eliminate the need for multiple stacked fenestrated clips when treating complicated aneurysms
 - Using fewer clips can lower the risk of perioperative aneurysm rupture
 - Using fewer clips can optimize your view of the aneurysm under the surgical microscope



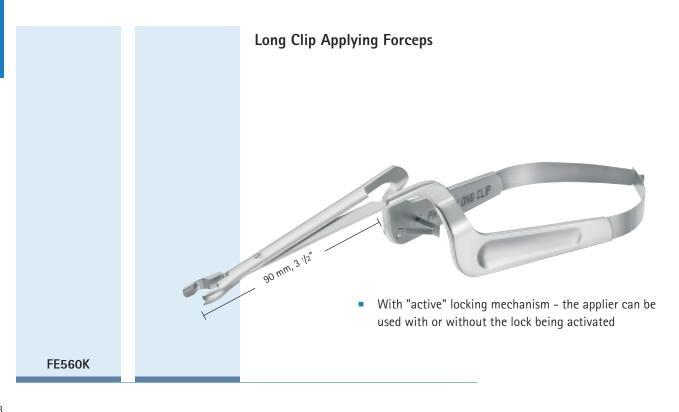
PERMANENT								
		Diam	1 5 mr	5 mm				
Item No.		Blade length mm	Angle	Maximum opening mm	Closing N (+/- 1	g		
FE852K		5.0	45°	5.5	1.47	150		
FE853K		9.0	45°	5.5	1.47	150		
FE854K		5.0	90°	5.5	1.47	150		
FE855K		9.0	90°	5.5	1.47	150		
FE856K		13.0	90°	5.5	1.77	180		
FE857K		9.0	90°	5.5	1.47	150		
FE858K		9.0	90°	5.5	1.47	150		
FE859K		13.0	60°	5.5	1.77	180		
FE860K		13.0	60°	5.5	1.77	180		
FE864K		9.0	90°	5.5	1.47	150		
FE865K		13.0	90°	5.5	1.77	180		

Developed in cooperation with Dr. Thomas A. Kopitnik, M.D. Central Wyoming Neurosurgery Casper, Wyoming, USA

Phynox Long Clips and Applying Forceps



Extra long clips for the treatment of giant aneurysms



Phynox Mini Clips

TEMPORARY						PERMANENT					
Item No.		Blade length mm	Maximum opening mm	Closing N (+/- 10	q	Item No.		Blade length mm	Maximum opening mm	Closing N (+/- 10	
FE681K	~518	3.0	3.3	0.49	50	FE680K	<518	3.0	3.3	1.08	110
FE691K		5.0	4.0	0.49	50	FE690K		5.0	4.0	1.08	110
FE683K	/ETS	2.8	3.2	0.49	50	FE700K	C 575	3.0	3.3	1.08	110
FE693K		4.7	3.8	0.49	50	FE710K		5.0	4.0	1.08	110
FE721K		7.0	4.6	0.69	70	FE720K		7.0	4.6	1.08	110
FE723K		6.6	4.4	0.69	70	FE682K	/518	2.8	3.2	1.08	110
FE725K		5.0	4.0	0.69	70	FE692K		4.7	3.8	1.08	110
						FE694K		4.0	3.6	1.08	110
						FE711K		4.0	3.6	1.08	110
						FE712K		4.7	3.8	1.08	110
						FE713K		4.0	3.6	1.08	110
						FE726K		5.2	4.0	1.08	110
						FE722K		6.6	4.4	1.08	110
						FE714K		3.9	3.5	1.08	110
						FE724K		5.0	4.0	1.08	110

Phynox Mini Clips

PERMANENT								
Item No.		Blade length mm	Maximum opening mm	Closing force N g (+/- 10%)				
FE716K		5.0	3.5	1.28	130			
FE807K		4.7	4.0	1.08	110			
FE717K		6.3	6.0	1.28	130			
FE727K		4.0	7.0	1.28	130			
FE728K		7.0	5.7	1.28	130			
FE806K		7.0	4.5	1.28	130			