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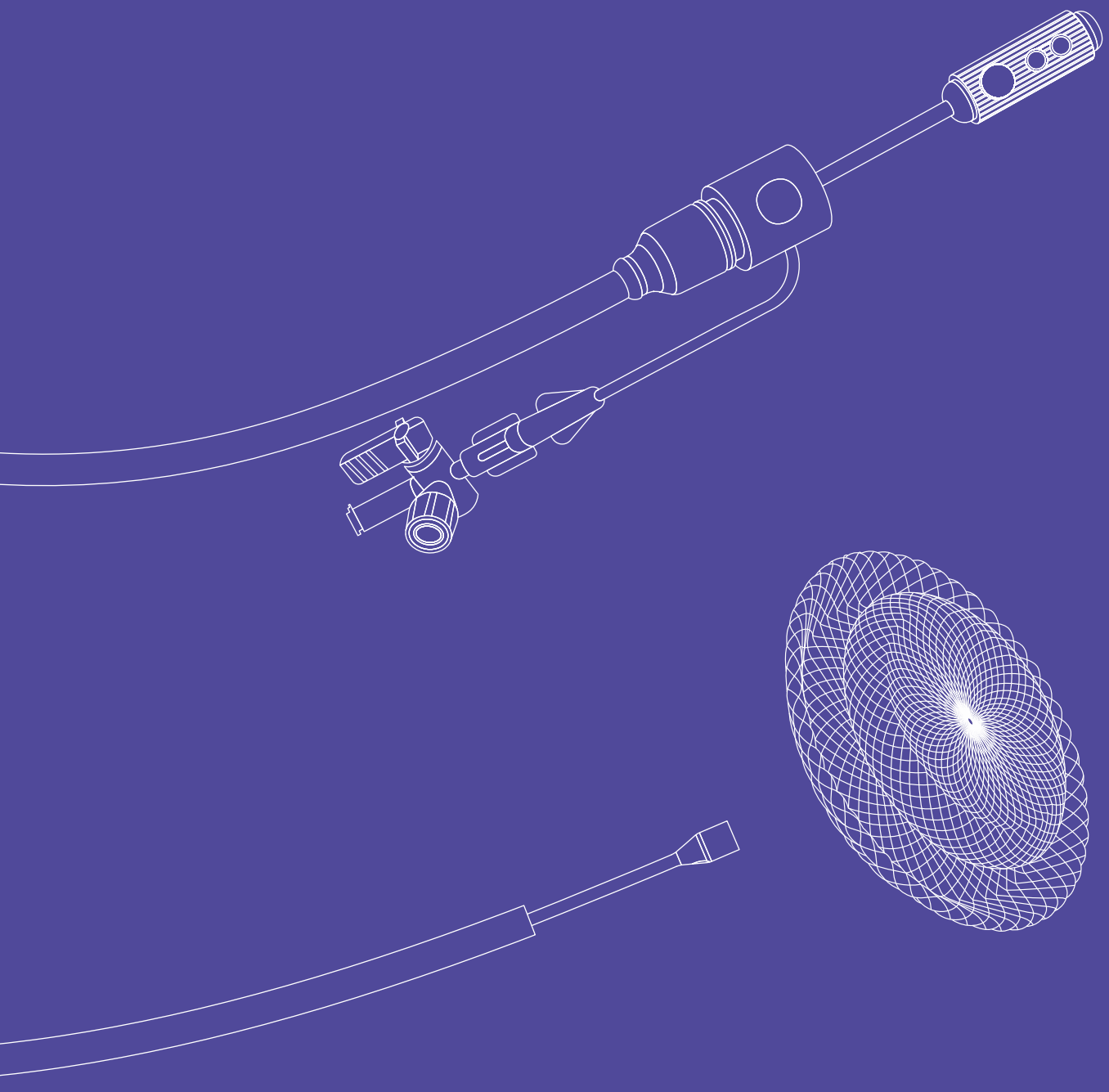
Biodegradable Patent Foramen Ovale Occluder



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* Please refer to the instructions for detailed taboos or precautions.

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Multiple closure to reduce shunting

Concave double buckles stabilize the closure of septum. The disk surface forms an effective closure.

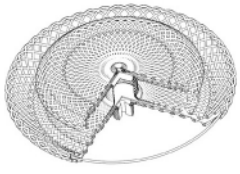
45° double-disk concave form with reinforced support clips the primum and secundum to form an effective closure.

Three-layer flow choking instantly prevents blood flow and creates an effective waist occlusion.

Waist flow barrier membrane is added to fill the interior of the PFO defect and reduce the risk of residual shunting.

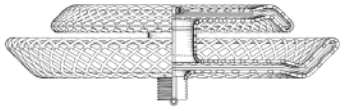
Dual patents guarantee the stable shaping

Patented edge locking design with shield-shaped disk buckle for stable support.



Disk surface edge locking enhances the mechanical support of the disk surface, without affecting the septum flap movement, to ensure the closure effect.

Patented riveting design ensures effective clipping and ensures good attachment.(*Patent No. 2020203199179)



Forming lock design ensures that the occluder is structurally stable after release, compliant to the structural movement of heart, without detachment.

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No remains after degradation, No obstruction for puncture

The occluder degrades safely in about one year, and guides bioremediation of autologous tissues.

3D Simulation of Degradation Process Tissue Interior

1M after operation

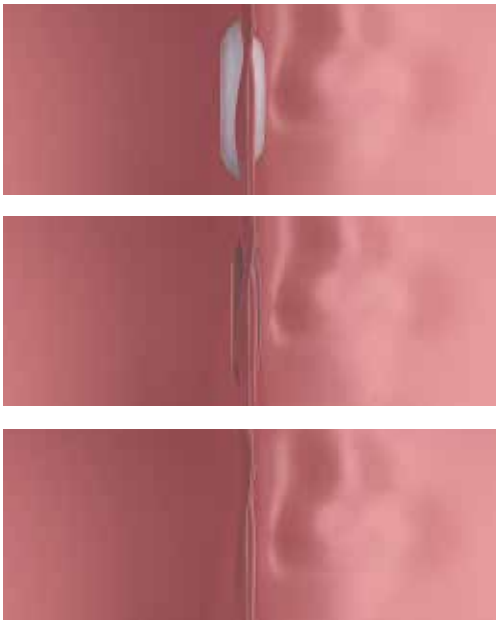
3M after operation

6M after operation

12M after operation

◉ Its degradation rate matches the tissue repair cycle and it gradually degrades after endothelialization is stabilized, achieving effective closure and autologous tissue repair.

Reshaping the structure of the fossa ovalis in the atrial septum and preserving access to interventional therapies.



◉ Atrial septal reconstruction is complete after degradation, preserving tissue elasticity and not interfering with the transatrial septal intervention path.

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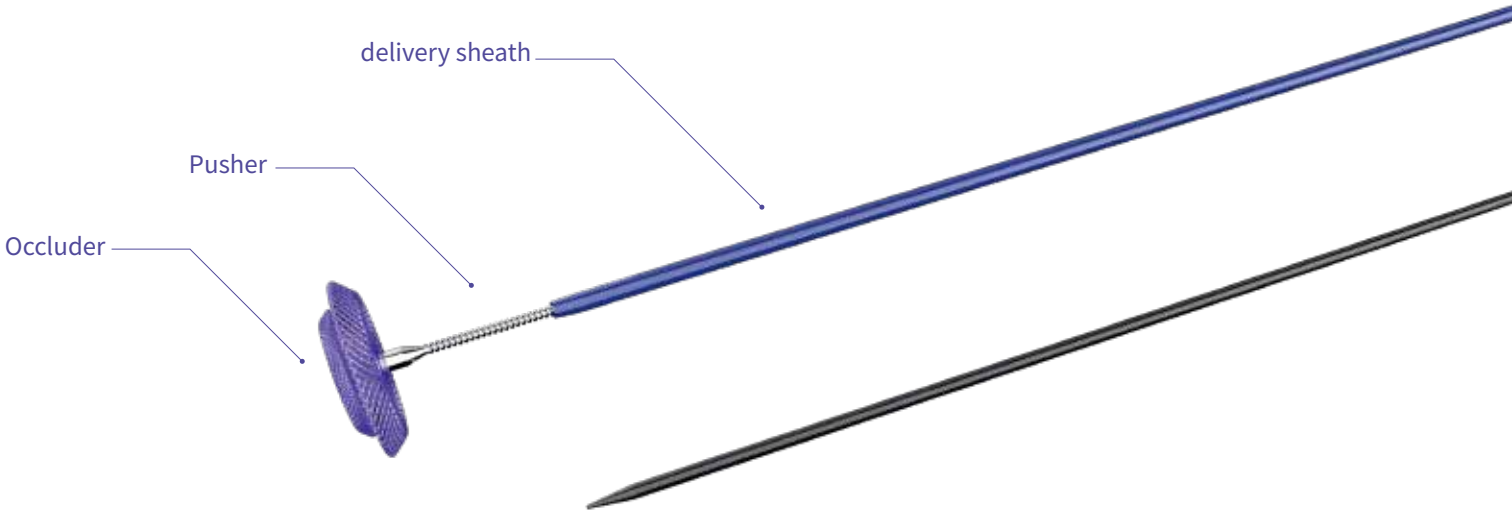
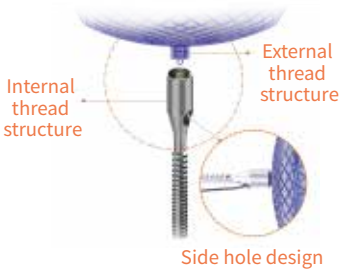


Unique design, safe to push



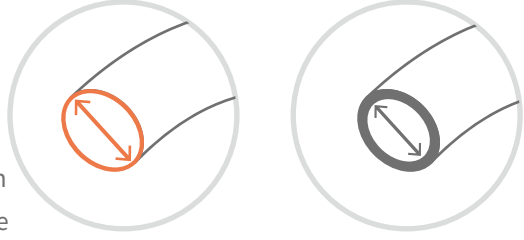
◉ The internal thread at the head end of the push device is an encircling screw design, which firmly connects the occluder and facilitates delivery and withdrawal.

◉ The flexible section of the spring at the distal end is designed to adapt to tortuous pathways, while the proximal end is designed with multiple strands of hardening to provide good support.

Large cavity with thin walls, visible in and out

◉ The inner diameter of the sheath is larger, the tube wall is thinner, the delivery performance is better, and it can be adapted to more specifications and models of occluders.

◉ A metal developing mesh is added to the tube body to visualize the transportation process, and a platinum ring is developed at the head end to facilitate intraoperative positioning.



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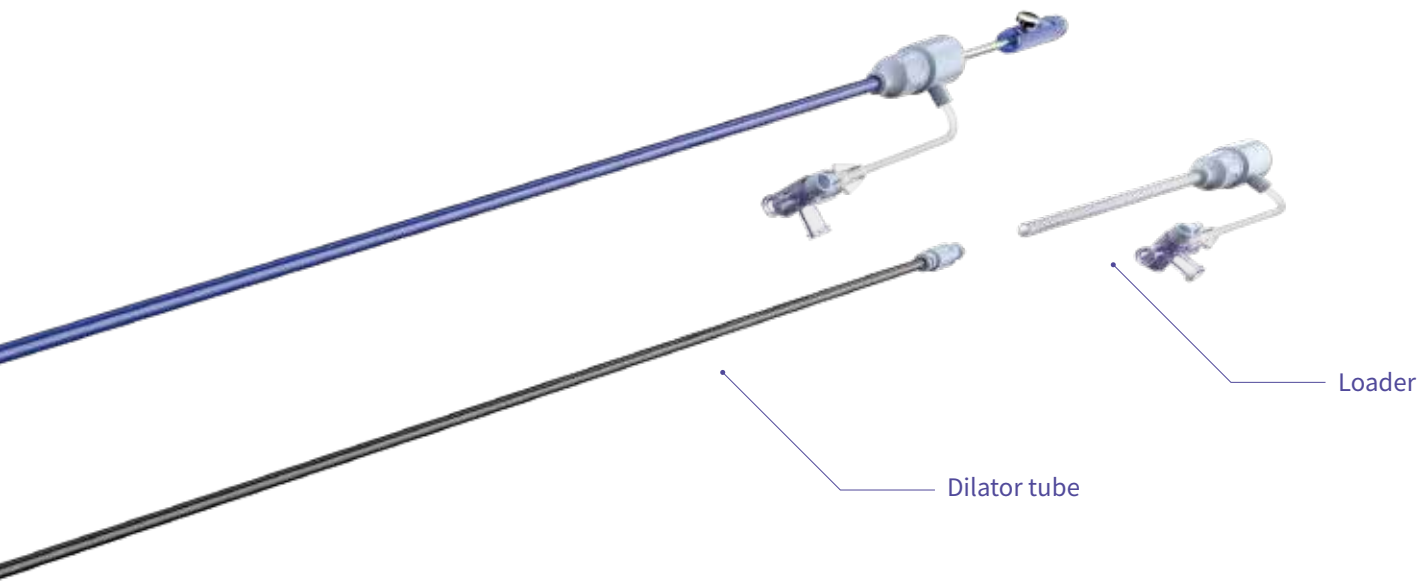
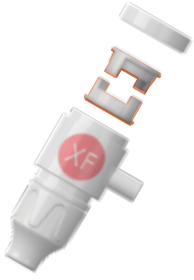
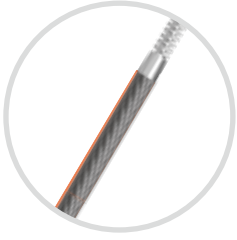


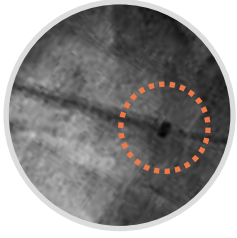
Multiple seals, worry-free transportation





◉ The double-layer hemostatic valve design provides stronger sealing and reduces intraoperative blood leakage.

◉ The steel cable coating design reduces the possibility of air locks and ensures transportation safety.



8 models
and specifications

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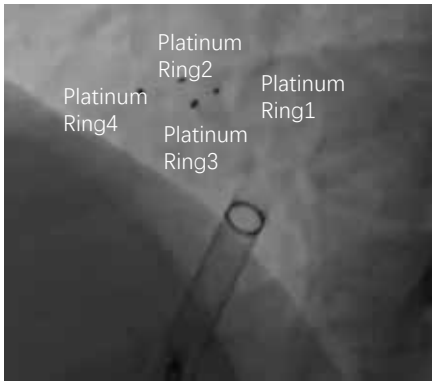
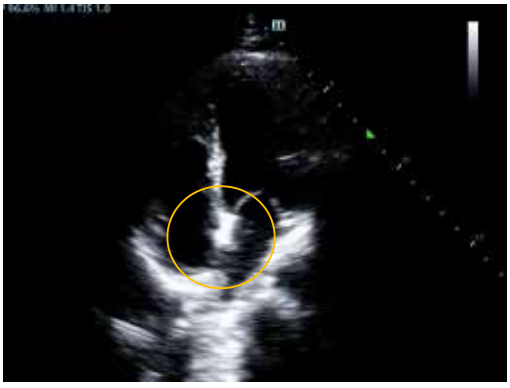
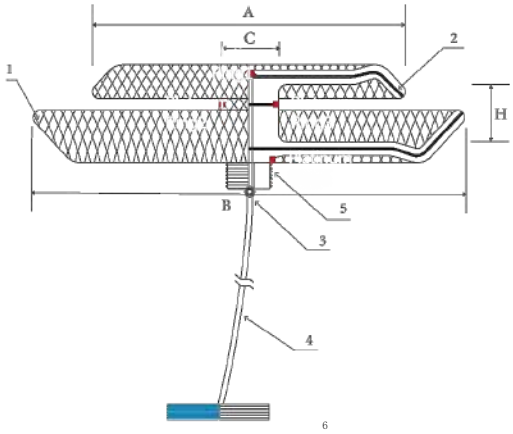
Marker design + ultrasound guidance: solving visual operation problems

- There are 4 Makers visible under DSA to assist in judging the launch status of the occluder disk.
- The complete shape of the occluder can be seen under ultrasound, and the position of the occluder can be determined through comprehensive evaluation.

Platinum Ring1	Platinum Ring2	Platinum Ring3	Platinum Ring4
Center of left disk	Left side of waist of occluder	Right side of waist of occluder	Center right of the right diskRight side of tail weld ball







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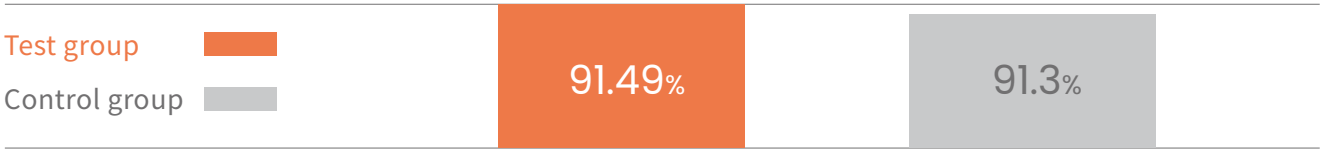
Clinical trial results

◉ Effective sealing, the sealing effect is not inferior to that of metal sealing devices.

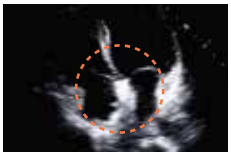
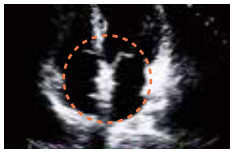
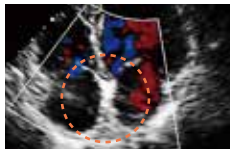
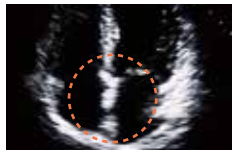
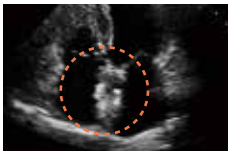
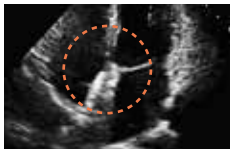
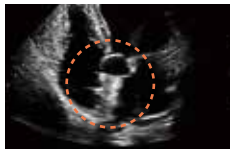
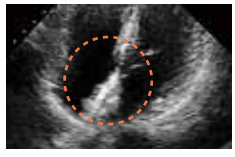
Biodegradable PFO occluder (test group)
Metal occluders already on the market (control group)
Occlusion success rate（6 months after surgery）

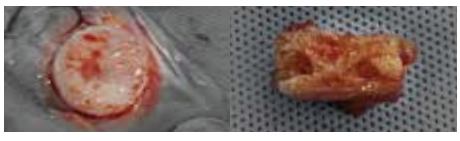
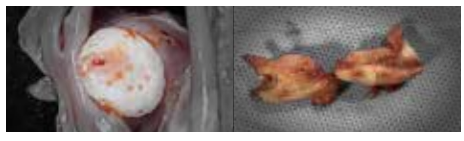


Successful sealing: The contrast-enhanced ultrasound results 6 months after the operation show that there is no RLS or only a small amount of RLS, that is, the RLS grade is 0 or 1 (otherwise the sealing fails).

◉ Safe degradation, gradual degradation after endothelialization and stabilization

Biodegradable PFO occluder (test group)
Metal occluders already on the market (control group)
Occlusion success rate（6 months after surgery）

	1M after surgery	3M after surgery	6M after surgery	12M after surgery
Ultrasound observation-Test group Biodegradable PFO occluder				
Ultrasound observation-Control group Metal occluders already on the market				

	1M after surgery	3M after surgery
Postoperative endothelialization-Test group Metal occluders already on the market		
Postoperative endothelialization-Control group Metal occluders already on the market		

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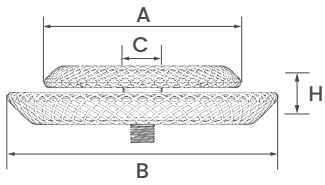
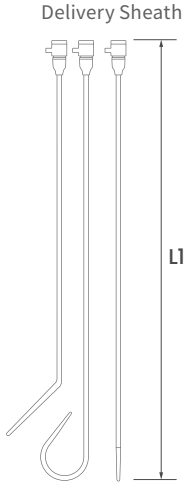
Biodegradable PFO occluder model specifications (mm)

Model	A/Diameter of upper disk	B/Diameter of lower disk	C/Waist diameter	H/Waist height	Smallest Recommended Sheath Size
BDPFO -I 1218	12	18	4	3	I-9F/10F
BDPFO -I 1818	18	18	4	3	I-9F/10F
BDPFO -I 1824	18	24	4	4	I-12F
BDPFO -I 2424	24	24	4	4	I-12F
BDPFO -I 2228	22	28	4.5	4	I-14F
BDPFO -I 2828	28	28	4.5	4	I-14F
BDPFO -I 2534	25	34	5	5	I-14F
BDPFO -I 3434	34	34	5	5	I-14F



Model specifications of interventional delivery system for biodegradable occluders (mm)

Model	F/Sheath inner diameter	Top bend angle	L1/Effective length of delivery sheath	Match pusher specifications	L1/Effective length of pusher
I-6F	6F	45°	820	TSQ16L	1200
I-7F	7F	45°	820	TSQ20L	1200
I-8F	8F	45°	820	TSQ25L	1200
I-9F	9F	45°	820	TSQ25L	1200
I-10F	10F	45°	820	TSQ30L	1200
I-12F	12F	45°	820	TSQ35L	1200
I-14F	14F	45°	820	TSQ35L	1200
I-16F	16F	45°	820	TSQ35L	1200
II-6F	6F	180°	820	TSQ16L	1200
II-7F	7F	180°	820	TSQ20L	1200
II-8F	8F	180°	820	TSQ25L	1200
II-9F	9F	180°	820	TSQ25L	1200
II-10F	10F	180°	820	TSQ30L	1200
II-12F	12F	180°	820	TSQ35L	1200
II-14F	14F	180°	820	TSQ35L	1200
II-16F	16F	180°	820	TSQ35L	1200
III-6F	6F	0°	140	TSQ16S	600
III-7F	7F	0°	140	TSQ20S	600
III-8F	8F	0°	140	TSQ25S	600
III-9F	9F	0°	140	TSQ25S	600
III-10F	10F	0°	140	TSQ30S	600
III-12F	12F	0°	167	TSQ35S	600
III-14F	14F	0°	167	TSQ35S	600
III-16F	16F	0°	167	TSQ35S	600



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