Clinically proven stent for the treatment of iliac disease

Pull-back delivery system for simple stent deployment

5.2F proximal shaft for contrast injection with device in sheath

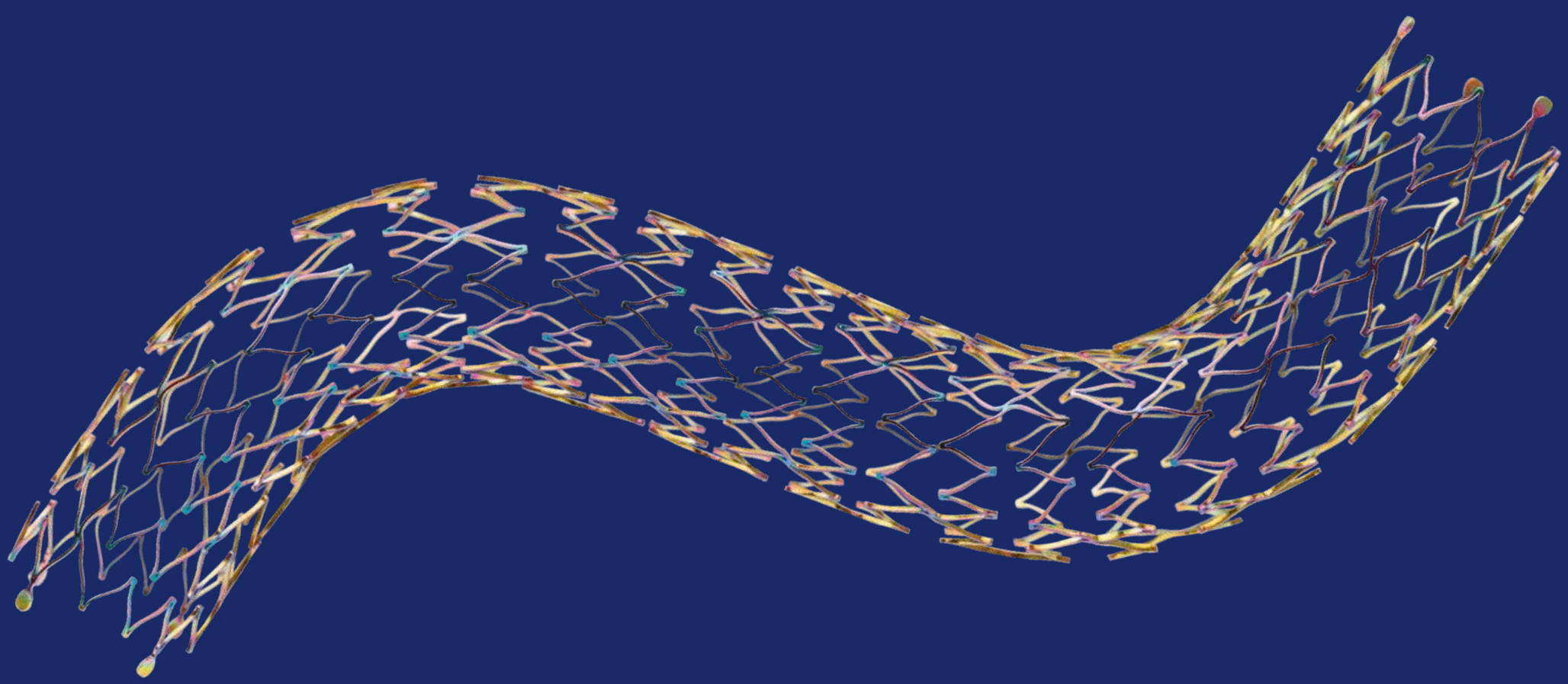
Technical data/ ordering info

Teleflex™

Empowering the future of healthcare

Astron™

Peripheral Self-Expanding Nitinol Stent System



Astron™ Peripheral Self-Expanding Nitinol Stent System

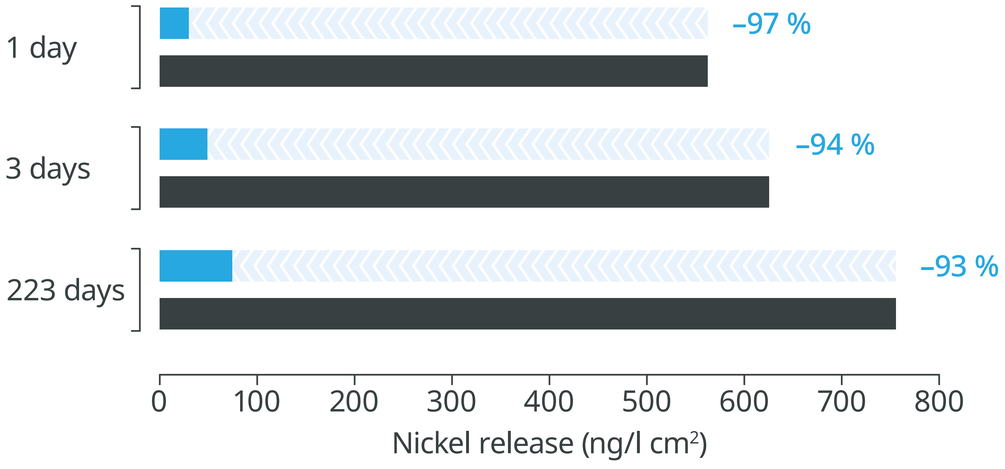
Clinically proven, with pull-back delivery system and 5.2F proximal shaft.

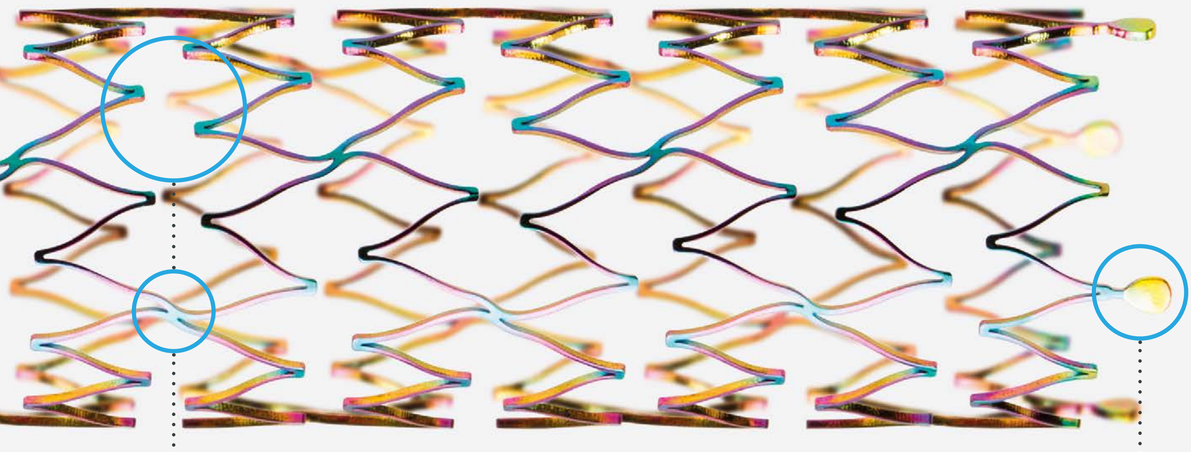
Clinically proven Stent for the treatment of iliac disease

– Segmented stent design and strut thickness to provide sufficient chronic outward force in the iliac territory.
– Peak-to-valley design and S-articulating connecting bars provide multi-directional flexibility and avoid fish-scaling in tortuous arteries.

proBIO™ Silicon Carbide Coating reduces nickel ion release[1]

proBIO™ Coating acts as an effective and reliable barrier to nickel ion diffusion.





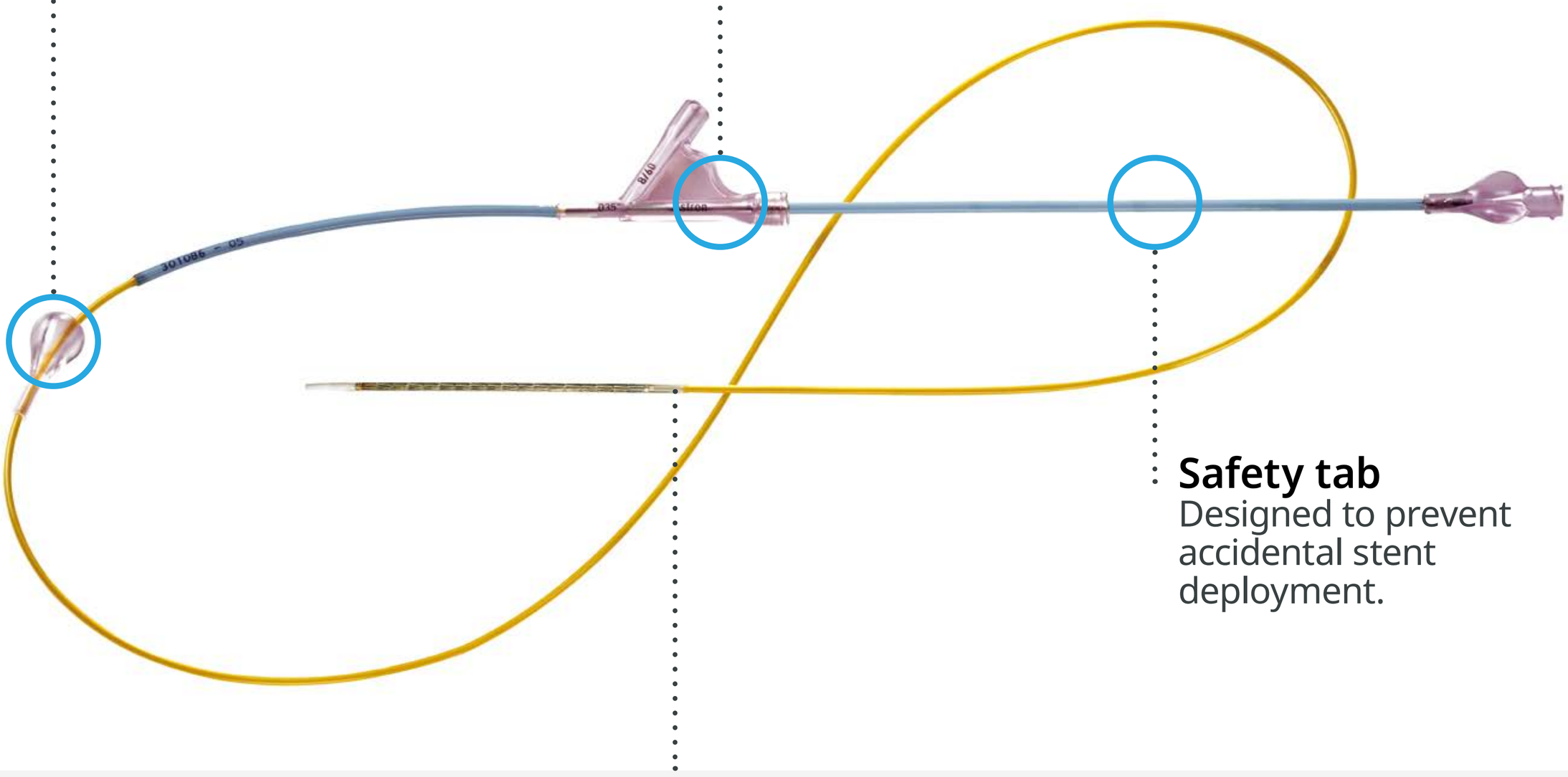
Peak-to-valley design and S-articulating connecting bars

Enhanced visibility
4 gold markers at each end provide enhanced radiopacity

Pull-back delivery system for simple stent deployment[2]

Pull-back delivery system
Enables simple stent deployment.

Easy release
Relieves friction of introducer valve on the retractable shaft during stent deployment, providing a smoother action.



Safety tab
Designed to prevent accidental stent deployment.

6F Distal shaft

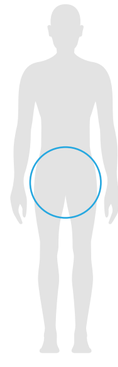
5.2F Proximal shaft

5.2F proximal shaft for contrast injection with device in sheath

6F distal shaft with a 5.2F proximal shaft allows contrast injection while the device is positioned inside the introducer and across the lesion.

Astron™ Peripheral Self-Expanding Nitinol Stent System

Vascular Intervention
Peripheral



Indicated for improving luminal diameter in patients with iliac atherosclerotic lesions in vessel reference diameters between 4.3mm and 9.5mm and lesion lengths up to 105 mm.

Technical data

STENT	
Catheter type	OTW
Recommended guide wire	0.035"
Stent material	Nitinol
Strut thickness	225 µm (10 mm = 230 µm)
Stent coating	**proBIO™ Coating** (Amorphous Silicon Carbide)
Stent markers	4 gold markers each end
Sizes	7–10 mm; L: 30–80 mm
Proximal shaft	5.2F, hydrophobic coating
Usable length	72 and 130 cm

Ordering Information

	STENT	CATHETER LENGTH 72 CM; STENT LENGTH			
		30 mm	**40 mm**	**60 mm**	**80 mm**
6F	**7.0 mm**	364645	364646	364647	364648
	8.0 mm	364649	364650	364651	364652
	9.00 mm	364653	364654	364655	364656
	10.0 mm	–	364657	364658	364659

	STENT	CATHETER LENGTH 130 CM; STENT LENGTH			
		30 mm	**40 mm**	**60 mm**	**80 mm**
6F	**7.0 mm**	364660	364661	364662	364663
	8.0 mm	364664	364665	364666	364667
	9.0 mm	364668	364669	364670	364671

INDICATIONS:
The Astron stent system is indicated for improving luminal diameter in patients with iliac atherosclerotic lesions in vessel reference diameters between 4.3mm and 9.5mm and lesion lengths up to 105 mm.

CONTRAINDICATIONS:
There are no known contraindications.

WARNINGS:
• In patients with poor kidney function, contrast agents may precipitate kidney failure.
• Persons with known hypersensitivities to the following substances may suffer an allergic reaction to this implant:
  - nitinol and / or its components (e.g. nickel, titanium)
  - amorphous silicon carbide
• DO NOT use after the “use by” date specified on the label.
• Device is supplied STERILE and for single use only. DO NOT resterilize and/or reuse. Reuse of single use devices creates potential risks including infections. Contamination of the device may lead to serious injury or patient harm.
• Appropriate anticoagulation and antiplatelet therapy should be administered pre- and post-procedure in accordance with standard practices.
• If using to treat a previously stented lesion, long-term outcomes following repeat dilatation of endothelialized stents have not been studied.
• DO NOT use in patients after failed guide wire or balloon catheter access.
• DO NOT use in highly-calcified lesions resistant to Percutaneous Transluminal Angioplasty (PTA) or in lesions that prevent complete inflation of an appropriately sized angioplasty balloon.
• DO NOT use if the sterile package is opened or damaged or any information provided is obscured. DO NOT use if the device is damaged or if the stent is partially deployed.
• Advancement of the stent system without the guide wire extended beyond the tip may lead to vessel damage.
• DO NOT push the stainless steel tube. The stent will not be deployed at the target site if the tube is pushed.
• DO NOT advance a partially deployed stent proximally or distally. Dragging or repositioning the stent may cause injury to the patient.
• Once the stent is partially deployed it cannot be recaptured using the stent system.
• It is only recommended to place overlapping stents using two Astron stents. The risk of corrosion increases when stents of differing metals contact one another.
• If unusual resistance is experienced during the introduction of the delivery system or deployment, or if stent cannot be deployed, remove the entire stent system (a partially deployed stent may require surgical removal).

PRECAUTIONS:
• Only physicians thoroughly trained and educated in the performance of PTA and stent implantation should use this device.
• Stenting across a bifurcation or side branch could compromise future diagnostic or therapeutic procedures.
• The minimum introducer sheath size is indicated on the label. If the device is used in conjunction with long and/or braided introducer sheaths, a larger French size than indicated on the label may be necessary to reduce friction.
• Exercise care during handling to reduce the possibility of releasing the stent prematurely, accidental breakage, bending or kinking of the delivery system.
• Exposure of the stent system to organic solvents, e.g. alcohol, may cause damage to the stent system.
• The stent system is not designed for use with power injection systems.
• Always keep the device filled with sterile heparinized isotonic saline while it is in the vascular system.
• Verify that the distal end of the outer sheath is flush with the radiopaque tip. If a gap exists between the outer sheath and the tip, carefully advance the outer sheath over the inner catheter tubing until the outer sheath is flush with the proximal edge of the tip.
• To avoid premature stent release, secure the sliding T-connector to the safety tab and underlying stainless steel tube while manipulating the stent system.
• Limited data exists on use of two overlapping Astron stents. If multiple stents are required to treat a lesion, it is recommended to use the same type of stent and a maximum of two stents. Overlapping of more than two stents has not been investigated.
• If multiple stents are required to treat the lesion, it is recommended that the more distal stent should be placed first. Allow for sufficient overlap between the stents.
• Recrossing a stent with adjunct devices must be performed with caution.
• The use of mechanical atherectomy devices or laser catheter is not recommended within the stented area.

POTENTIAL ADVERSE EVENTS/COMPLICATIONS:
Possible complications include, but are not limited to:
• Allergic reactions to contrast media, antiplatelet aggregation or anticoagulant medications, amorphous silicon carbide and nitinol and/or its components (e.g. nickel, titanium)
• Bleeding events: Access site bleeding or hemorrhage, hemorrhage requiring transfusion or other treatment
• Death
• Embolization of air, thrombotic or atherosclerotic material
• Emergency surgery to correct vascular complications
• Infection and sepsis
• Stent system events: Failure to deliver stent to intended site, stent misplacement, stent deformation, stent embolization, stent thrombosis or occlusion, stent fracture, stent migration, inadequate apposition or compression of stent/s, withdrawal difficulties, embolization of catheter material
• Tissue necrosis and limb loss due to distal embolization
• Vascular events: Access site hematoma, hypotension/ hypertension, pseudoaneurysm, arteriovenous fistula formation, retroperitoneal hematoma, vessel dissection or perforation, restenosis, thrombosis or occlusion, vasospasm, peripheral ischemia, dissection, distal embolization (air, tissue debris, thrombus)

References:
1 Schmehl, J. M., Harder, C., Wendel, H. P., Claussen, C. D., & Tepe, G. (2008). Silicon carbide coating of nitinol stents to increase antithrombogenic properties and reduce nickel release. Cardiovascular Revascularization Medicine, 9(4), 255–262. https://doi.org/10.1016/j.carrev.2008.03.004
2 Data on file at Teleflex.

CAUTION: Federal (USA) law restricts this device to sale or use by or on the order of a physician.

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