

# Mustang™

## PTA Balloon Dilatation Catheter



Mustang Balloon Catheter: Excellence on every dimension

With superior cross and track, powerful dilatation, longer lengths, Mustang is designed to facilitate and speed up the procedure and covers a wide set of indications including hemodialysis access management

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### Product Details

#### Low Profile & Excellent Sheath Compatibility

- 0,040" (1,01 mm) lesion entry profile is only 15% larger than the wire
- 7 mm x 200 mm through a 5F\* sheath
- 10 mm x 80 mm through a 6F\* sheath

#### Powerful Dilatation

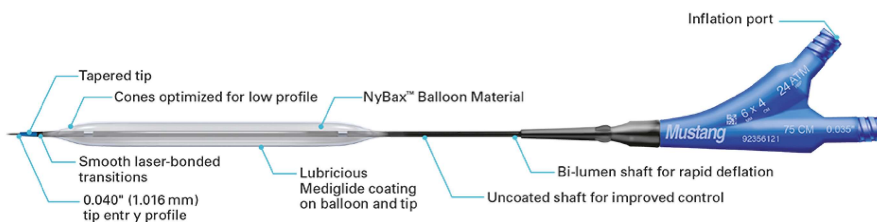
- NyBax™ Balloon Material combines the strength of Nylon with the flexibility of Pebax allowing for up to 24 atm (2431 kPa) rated burst pressure
- Excellent balloon rewinding allows for ease of introduction and withdraw all through the sheath

#### Superior Deliverability

- Combining excellent trackability and pushability with low lesion entry and crossing profiles, Mustang defines a new level in 0,035" (0,89 mm) deliverability



#### Schematic Overview



- Mustang is a larger treatment device used through smaller holes (with smaller sheath sizes : sheath compatibility from 5F to 7F)

Balloon length	Sheath compatibility*
3-7 mm	5F
8 -10 mm	6F
12 mm	7F

\*5F = 1,7mm, 6F = 2,00mm, 7F = 2,33mm

- Mustang benefits from a **low entry profile**.
- The tip is only 15% larger than the wire and is **coated with Mediglide silicone** to facilitate sheath insertion in the patient.





### Balloon Material

NyBax™ balloon material eliminates tradeoff between pressure and deliverability

- Proprietary co-extrusion of Nylon and Pebax™
- Nylon provides flexibility
- Pebax™ provides strength for lower profile and high rated burst pressure

The balloon is wrapped on either 3 wing (3-5mm balloon length) or 5 wing (6mm and plus balloon length) format which helps to improve trackability of the device.

- 3 wings on 3-5 mm
- 5 wings on 6 mm and plus

Mediglide hydrophilic coating to facilitate advancement through complex lesions



**Laser bonding** is performed at both the distal and proximal ends of the balloon. It is engineered to provide smooth transitions and enhanced flexibility.

The use of Pebax in the construction of the shaft enhances pushability and helps prevent kinking while the device is advances through tortuous anatomy.

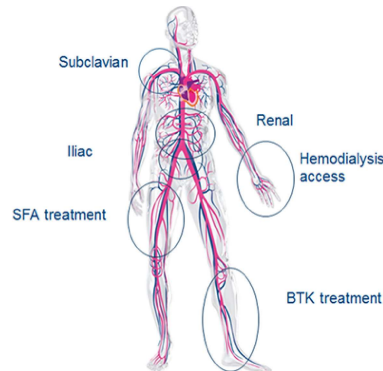
The balloon lumen is large which provides quick inflate and deflate time.

- Highly visible: Mustang has two highly visible swaged 1.5 mm wide Platinum Iridium RO markers and the dilatation zone is defined by the outside edge of the marker bands.

### Covers all your needs

#### One balloon for multiple indications

The Mustang Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including **iliac, femoral, popliteal, tibial, peroneal, subclavian, and renal arteries** and for the treatment of obstructive lesions of native or synthetic **arteriovenous dialysis fistulae**.



The Mustang Balloon Dilatation Catheter is also indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.



### A huge size matrix: 75 balloon sizes, 203 codes

Balloon Diameter	Balloon Length									
	20 mm	30 mm	40 mm	60 mm	80 mm	100 mm	120 mm	150 mm	180 mm	200 mm
3.0 mm	40, 75, 135 cm shaft						75, 135 cm shaft			
4.0 mm	40, 75, 135 cm shaft						75, 135 cm shaft			
5.0 mm	40, 75, 135 cm shaft						75, 135 cm shaft			
6.0 mm	40, 75, 135 cm shaft						75, 135 cm shaft			
7.0 mm	40, 75, 135 cm shaft						75, 135 cm shaft			
8.0 mm	40, 75, 135 cm shaft						75, 135 cm shaft			
9.0 mm	40, 75, 135 cm shaft						75, 135 cm shaft			
10.0 mm	40, 75, 135 cm shaft						75, 135 cm shaft			
12.0 mm	40, 75, 135 cm shaft						75, 135 cm shaft			

- Full size matrix to treat spectrum of 0.035" (0,889 mm) lesions with a single product line
- Up to 200 mm lengths to treat long SFA disease with a single inflation

### Ability to dilate even the most resistant stenosis

Mustang is a high pressure balloon and a non compliant balloon which provides the ability of the balloon to treat very calcified lesions especially for hemodialysis access management. It allows for a single device to be used across a variety of indications.

### Up to 24 ATM (2431 kPa) rated burst pressure

**MUSTANG™** 0.035" Balloon Dilatation Catheter

# EXCELLENCE ON EVERY DIMENSION



*Non-Compliant*



*24 ATM*



*7x200 thru 5 F*



# Powerful dilatation combined with superior deliverability and a complete size matrix.

## Deliverable High Pressure

- + 24 atmosphere rated burst with a low profile
- + NyBax™ balloon material enables great trackability and high pressure in the same balloon

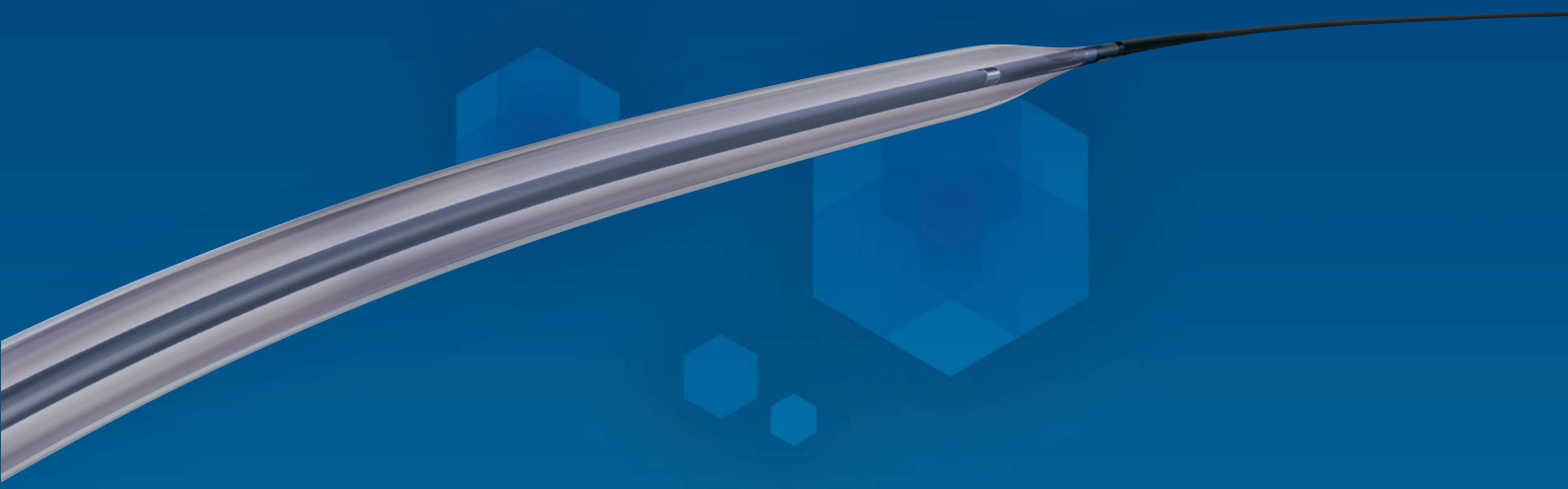
## Broadest Size Matrix

- + Balloon lengths 20–200 mm
- + Diameters 3–12 mm
- + Shafts 40 cm, 75 cm, 135 cm

## Low Profile

- + Lesion entry only 15% larger than the wire
- + 7x200 through 5 F
- + 10x80 through 6 F

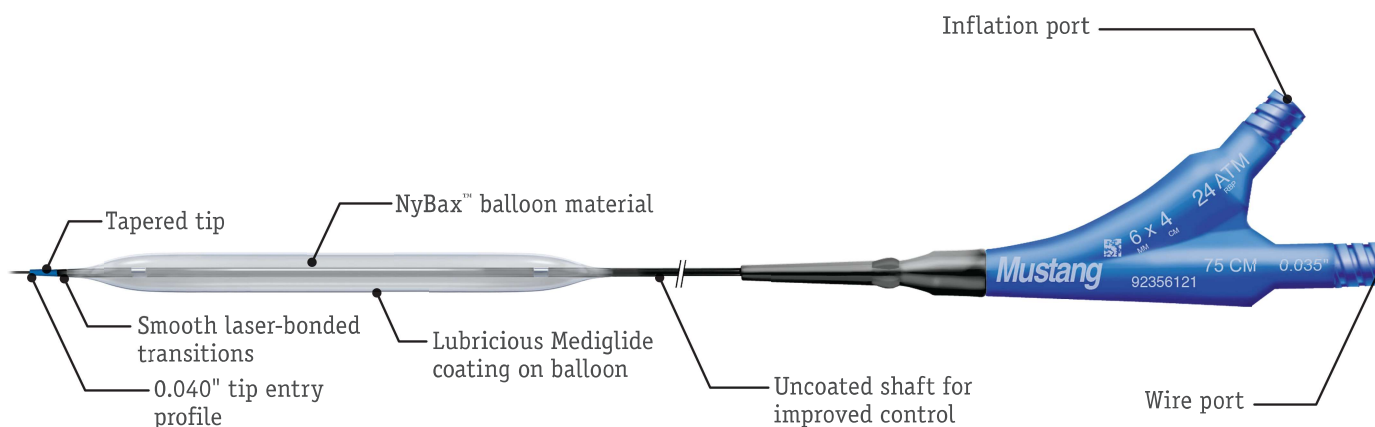




## **Only one balloon provides total performance.**

With superior cross and track, powerful dilatation, longer lengths, and smaller sheath sizes, Mustang™ is the 0.035" workhorse balloon that offers excellence across the board.

# Mustang™ Balloon Dilatation Catheter



Data on file PDM 90721880.

## MUSTANG™ BALLOON DILATATION CATHETER

**CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

**INDICATIONS FOR USE:** The Mustang Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, tibial, peroneal, subclavian, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The Mustang Balloon Dilatation Catheter is also indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature. Mustang Balloon Dilatation Catheters with balloons up to 120 mm in length are indicated for the treatment of biliary strictures.

**CONTRAINDICATIONS:** None Known.

**WARNINGS:** The Mustang PTA balloon catheter is not for use in the coronary arteries. Any use for procedures other than those indicated in these instructions is not recommended.

**PRECAUTIONS:** The Mustang PTA Balloon Dilatation Catheter shall only be used by physicians trained in the performance of percutaneous transluminal angioplasty. The Mustang PTA Balloon Dilatation Catheter should be used with caution for procedures involving calcified lesions or synthetic vascular grafts due to the abrasive nature of these inflation sites. The Mustang PTA Balloon Dilatation Catheters are not intended for injection of contrast medium. Precautions to prevent or reduce clotting should be taken when any catheter is used: • Consider systemic anticoagulation • Flush or rinse all products with sterile saline or a similar solution prior to use.

**ADVERSE EVENTS:** The complications that may result from a balloon dilatation procedure include, but are not limited to: • Allergic reaction (device, contrast medium and medications) • Arteriovenous fistula • Embolization (air, device, plaque, etc.) • Hematoma • Hemorrhage, including bleeding at puncture site • Pseudoaneurysm • Sepsis/infection • Thromboembolic episodes • Vessel injury, e.g. dissection, perforation, rupture • Vessel occlusion • Vessel spasm

Additionally, the following complications may result from a balloon dilatation procedure within the biliary system: • Cholangitis • Hemobilia • Pancreatitis • Duct injury, e.g. dissection, perforation, rupture • Duct occlusion • Duct spasm

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### Peripheral Interventions

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