

MUSTANG[™] 0.035" Balloon Dilatation Catheter

EXCELLENCE ON EVERY DIMENSION



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

Deliverable High Pressure

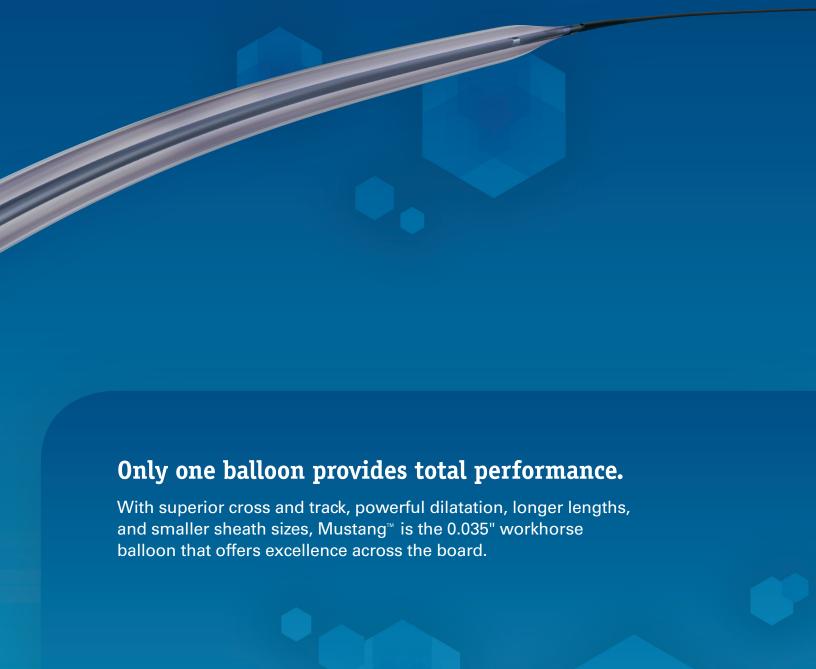
- + 24 atmosphere rated burst with a low profile
- + NyBax™ balloon material enables great trackability and high pressure in the same balloon

Broadest Size Matrix

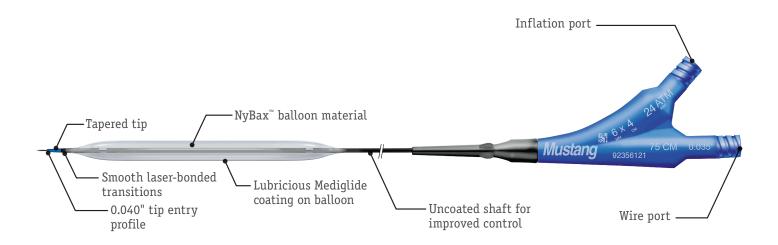
- + Balloon lengths 20-200 mm
- + Diameters 3-12 mm
- + Shafts 40 cm, 75 cm, 135 cm

Low Profile

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



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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