PTA Balloon Catheters

REEF HP®
PTA Balloon Catheter
OTW 0.035”

Admiral Xtreme™
PTA Balloon Catheter
OTW 0.035”

Pacific® Plus
PTA Catheter
OTW 0.018”

Pacific® Xtreme
PTA Balloon Catheter
OTW 0.018”

Amphirion® Plus
PTA Catheter
OTW 0.014”

Amphirion® Deep
PTA Balloon Catheter
OTW 0.014”

Innovating for life.
A PTA PLATFORM THAT PROVIDES LESION SPECIFIC SOLUTIONS

As pioneers of long balloon technology, portfolio highlights include a BTK dedicated tapered 210mm balloon and balloon lengths up to 300mm.

**Reef HP®**
- **PTA Balloon Catheter OTW 0.035”**

**Pacific®**
- **Xtreme**
- **PTA Balloon Catheter 0.018”**

**Amphirion®**
- **Plus**
- **PTA Balloon Catheter OTW 0.014”**
- **Deep**
- **PTA Balloon Catheter OTW 0.014”**

**Control Under Pressure**

Flexitec™ XF utilizes advanced balloon polymer technology to deliver up to 22 atm for controlled high pressure procedures.

- High pressure strength, with controlled low-compliance, enables dilatation of resistive lesions

**Low Profile Tip and Balloon Design Enable Controlled Crossability†**
- 5F compatible allows small access site (up to 6mm diameter)
- 6-folding balloon technology provides consistent low profile crossability and re-wrap†† for balloon lengths 20 and 40mm

**5F Dual Lumen Shaft for Controlled Pushability and Kink Resistance†**

Wide range of balloon lengths (20-80mm) and diameters (4.0-8.0mm); shaft lengths of 80 and 120cm up to 22 atm RBP through a 5F-7F sheath.

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† For balloon diameters 4.0-6.0mm
†† 6-folding construction available only for balloon diameter from 5 to 8mm. 3-folding design available for 4.00mm balloon diameter
THE FIRST 300mm 0.035” PTA BALLOON

LONG PTA BALLOONS, UP TO 300mm, MAY REDUCE DILATATIONS AND SHORTEN PROCEDURE AND FLUOROSCOPY TIMES*

FLEXITEC® XTREME ADVANCED BALLOON TECHNOLOGY**
- Provides low compliance while maintaining flexibility, strength and durability

HYDROPHILIC COATING IMPROVES CROSSABILITY**
- On shaft and balloons of lengths 60 – 300mm
- Bikini coating on shaft and balloon shoulders†

SHAFT MATERIAL AND DUAL LUMEN DESIGN**
- Pushability and kink resistance combined with flexibility
- Large inflation lumen for rapid inflation/deflation

VERSATILITY FOR EVERYDAY AND BEYOND

90, 130, 180CM SHAFT LENGTHS WITH 0.014” AND 0.018” COMPATIBILITY ALLOW FOR MORE ACCESS OPTIONS

FAST DEFLATION MAY CONTRIBUTE TO SHORTER PROCEDURE TIMES

IMPROVED REWRAP TECHNOLOGY ENABLES MULTIPLE INFLATIONS AND LOW COMPLIANT BALLOON MATERIAL ADDRESSES VARIOUS LESIONS

EXCELLENT CROSSABILITY TO IMPROVE LESION CROSSING
- Hydrophilic coating on shaft contributes to crossability
- Low profile enables high crossability

WIDE RANGE OF BALLOON LENGTHS (20-150mm) AND DIAMETERS (2.0-7.0); SHAFT LENGTHS OF 90, 130, AND 180cm UP TO 22atm RBP THROUGH A 4F-5F SHEATH.

** In vitro testing data.
† of balloon lengths 20 and 40mm.

Bench test data is on file with Medtronic, Inc. Test data not indicative of clinical performance.
DEFINING PERFORMANCE IN LOWER LIMB INTERVENTIONS

LONG PTA BALLOONS, FROM 150-300mm, MAY REDUCE THE NUMBER OF DILATATIONS AND SHORTEN YOUR PROCEDURAL AND FLUOROSCOPY TIMES*

SHAFT MATERIAL ENABLES STRONG PUSHLABILITY AND KINK RESISTANCE, COMBINED WITH EXCELLENT FLEXIBILITY

- Tapered tip profile for successful lesion crossing
- Balanced deliverability
- Trackability for reaching distal lesions

LOW PROFILE INTRODUCER SHEATH COMPATIBILITY FOR LESS POSSIBLE PUNCTURE TRAUMA**

FLEXITEC® XTREME BALLOON MATERIAL PROVIDES IMPROVED FLEXIBILITY

WIDE RANGE OF BALLOON LENGTHS (150-300mm) AND DIAMETERS (4.0-7.0mm); SHAF T LENGTHS OF 90 AND 130cm UP TO 14atm RBP THROUGH A 4F-5F SHEATH.

TAKE A STEP FORWARD

AMPHIRION PLUS
- Delivers crossability and pushability to address various lesion profiles
- Quick deflation time may contribute to shorter procedure times
- Low compliant balloon design enables wide range of inflation pressures (up to 20atm)

AMPHIRION DEEP
- Reaches, access and treats challenging vasculature
- Designed for below-the-knee, offering a broad size range including 210mm long tapered diameter
- Proprietary Flexitec™ Ultra semi-compliant balloon polymer delivers flexibility and conformability for challenging anatomy

ABOVE THE ANKLE

Amphirion Plus
- Relatively straight vessels
- Highly calcified vessels
- Workhorse BTK cases

LENGTHS: 14-120MM
DIAMETERS: 2.0-4.0MM
SHAFT LENGTHS: 100 AND 150CM
20ATM RBP THROUGH A 4F SHEATH

BELOW THE ANKLE

Amphirion Deep
- Tortuous anatomy
- Small diameter and low vessel wall thickness
- Key for Angiosome concept

LENGTHS: 20-210MM
DIAMETERS: 1.5-4.0MM
SHAFT LENGTHS: 120 AND 150CM
14ATM RBP THROUGH A 4F SHEATH

* See Dr. Nelson Bernardo “The Next Frontier in Below-the-Knee Interventions” Endovascular Today, November 2010, p.34
** 4F/5F depending on diameter and length
INDICATIONS FOR USE

The Admiral Xtreme™ PTA Balloon Dilatation Catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

The Amphirion® Deep PTA Balloon Dilatation Catheter up to 120mm balloon length is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The Amphirion Deep™ PTA Balloon Dilatation Catheter in 150mm and 210mm balloon lengths is intended to dilate stenoses in the femoral, popliteal, and infra-popliteal arteries.

The Amphirion® Plus PTA Catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

The Pacific® Xtreme PTA Balloon Dilatation Catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

The Pacific® Plus PTA Catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Warning: Prior to use, refer to the Instructions for Use supplied with these devices for indications, contraindications, side effects, suggested procedure, warnings and precautions.

Warning: Do not exceed the rated burst pressure.

Caution: Larger models of the Pacific® Plus PTA catheter may exhibit slower deflation times, particularly on long catheter shafts. Potential Adverse Events: Possible adverse events associated with use of the Pacific® Plus PTA Catheter include, but are not limited to, complications related to puncture such as, but not limited to, local hematoma, infection and hemorrhage; dilatation related complications including, but not limited to, dissection, perforation and restenosis; angiography related complications such as, but not limited to, hypotension, drug allergic reactions and death.

Caution: Federal (USA) law restricts this product for sale by or on the order of a physician. Test data is on file at Medtronic Inc. Bench test results may not be indicative of clinical performance.

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