NEW TECHNOLOGY FOR PHYSICIAN-CONTROLLED PERIPHERAL THERAPY

PRESSANA
PRECISION DELIVERY SYSTEM

INDICATION

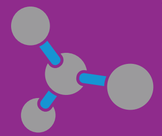
PRESSANA(r) OPC is indicated for localized infusion or irrigation of various diagnostic and therapeutic agents into the peripheral vasculature. PRESSANA(r) OPC may be repositioned for multiple treatments within the same patient. It is not indicated for use within the neurovasculature.

CONTRAINDICATIONS

Do not use this device for percutaneous transluminal angioplasty or stent deployment.

DISCLAIMER

- PRESSANA(r) OPC is cleared as a universal drug delivery device for the localized infusion or irrigation of various diagnostic and therapeutic agents into the peripheral vasculature. PRESSANA OPC has not been cleared for use with any specific drug, or to treat any specific disease state or condition.
- Physicians should decide which drugs to use with PRESSANA(r) OPC based upon their good judgment and logical medical extrapolation, and should consider the literature as it relates to drugs used in the peripheral vasculature to inform and guide their use of drugs with PRESSANA(r) OPC.



ADVANCED CATHETER THERAPIES, INC. (ACT) is committed to developing and delivering new therapies to patients. We are dedicated to the generation of clinical evidence to help drive advancement in the treatment of peripheral disease. If you are interested in trying the PRESSANA OPC or discussing Investigator Initiated Research, please contact ACT at 1-423-321-8964 or at info@acatheter.com

PRESSANA(R) OPC is a trade name for the Occlusion Perfusion Catheter (OPC), distributed by Advanced Catheter Therapies Inc. (ACT) Chattanooga, TN USA. PRESSANA OPC includes components developed by ACT and OpSens Medical. PRESSANA OPC has been cleared for use in the U.S. under FDA 510(k) K130525, K151554 and K153488. For a list of patents please go to: www:acatheter.com/patents

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Advanced Catheter Therapies, Inc.
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423.321.8964

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TARGETED LIQUID DRUG DELIVERY

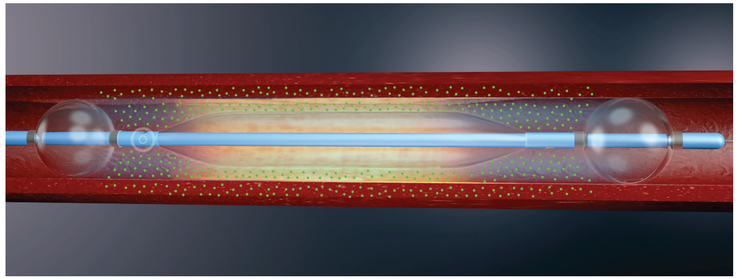
INTRODUCING

PRESSANA™
PRECISION DELIVERY SYSTEM

Occlusion **P**erfusion **C**atheter Platform Technology

PHYSICIAN-PRESCRIBED AGENTS.
PRECISION TECHNOLOGY.
PHYSICIAN-CONTROLLED PERIPHERAL THERPAY.

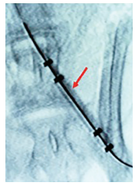
WELCOME TO PRESSANA(R) OPC



PRESSANA(R) OPC Precision Delivery System advanced technology provides new options for peripheral vascular procedures

- Isolated perfusion chamber created by conforming distal and proximal occlusion balloons
- Enhanced distribution and reduced agent volume provided by a center occupying balloon which is not intended to make contact with the arterial wall
- Controlled flushing, filling, circulation and evacuation of the treatment chamber through the inflow and outflow lumen
- Real-time monitoring of inter-arterial pressure within the perfusion chamber via fiberoptic sensor
- Targeted delivery aided by radiopaque markers (x4)

ADVANCING PERIPHERAL THERAPY



PHYSICIAN-PRESCRIBED AGENTS

PRESSANA(R) OPC enables direct endovascular delivery & infusion of various physician-prescribed therapeutic and diagnostic agents such as anticoagulants, antifibrins, antithrombins, anti-proliferatives, anti-inflammatories, antineoplastics and limus drugs, or other agents used to treat occlusions, stenosis, thrombolysis and restenosis in the peripheral vasculature.

PRECISION TECHNOLOGY

PRESSANA(R) OPC is designed to enhance efficient penetration of agents into the arterial wall and may reduce the potential for vascular trauma.

ISOLATED PERFUSION +

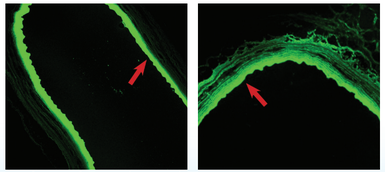
- Targets delivery and dwell time
- Reduces volume of agent needed within the occluded perfusion chamber

CONTROLLED FLUID DYNAMICS +

- Reduces mixing of agent and blood
- Limits systemic agent exposure

MONITORED PRESSURE

- Directs integral agent delivery within the occluded perfusion chamber – including to arterial surfaces that are uneven or asymmetrical



Confocal images (fluoroscopy) from pre-clinical studies demonstrate penetration of agent (with excipient) into medial layer of the arterial wall.

Porcine model; Dr. Saami Yazdani, University of South Alabama

VERSATILE PERFORMANCE

PRESSANA(R) OPC offers multiple sizes, including low-profile, to help facilitate access to challenging anatomies. The compliant occlusion balloons increase tolerance for catheter to vessel sizing. OPC can be used multiple times within a vessel to treat long lesions or multiple lesions using a single catheter — this may provide cost savings.

PERIPHERAL PROCEDURAL OVERVIEW

VESSEL PREPARATION + **LIQUID INFUSION** + **OPTIONAL MULTI-USE**

Vessel preparation using standard crossing and de-bulking approaches

PRESSANA™ catheter insertion, positioning, pressurized delivery, and agent removal

Multiple placements of the PRESSANA™ catheter in single patient vessel

PRESSANA™
PRECISION DELIVERY SYSTEM

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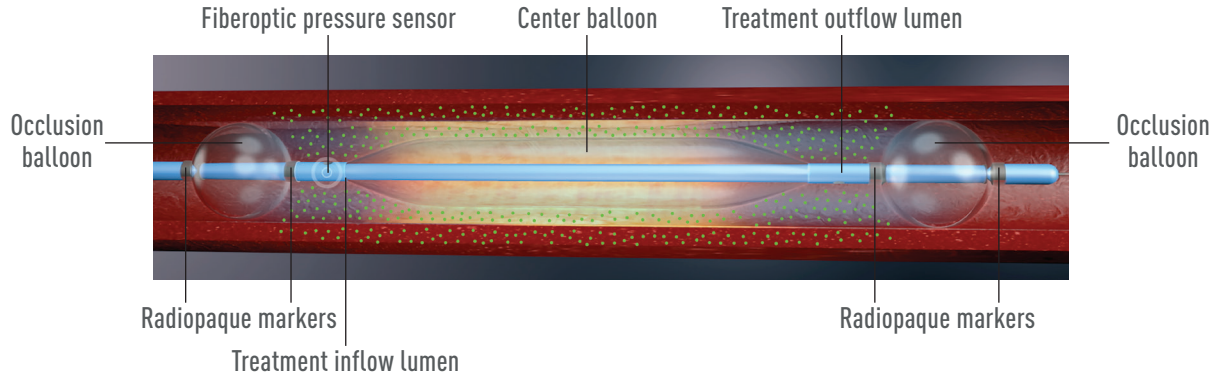
INFORMATION AND SPECIFICATIONS



DESCRIPTION

PRESSANA(R) OPC is a universal targeted liquid drug delivery catheter for localized delivery of therapeutic agents to the peripheral vasculature with little to no systemic release. The catheter has a 5 Fr. shaft with three balloons; two occlusion balloons which define the treatment chamber and a center space-occupying balloon. The catheter is .014" guidewire compatible, and the catheter shaft contains an Occlusion Balloon inflation lumen, Center Balloon inflation lumen, Treatment inflow lumen, Treatment Outflow lumen and the guidewire lumen for a total of five (5) lumens. Occlusion balloon sizes can range from 3mm up to 10mm in diameter with treatment chamber lengths from 3cm up to 15cm.

PERIPHERAL PROCEDURAL OVERVIEW

STEP 1: OCCLUSION BALLOONS DEPLOYED IN TARGET LESION

The occlusion balloons are positioned and deployed at the lesion. Blood flow is subsequently stopped.

STEP 2: BLOOD FLUSHED FROM TREATMENT CHAMBER

Saline is flushed through the inflow port and exits through the outflow port. This ensures blood does not interact with the drug solution and the delivery process.

STEP 3: DRUG DELIVERED TO CHAMBER AND INTO THE ARTERIAL WALL

The drug is delivered through the inflow port until the chamber is filled. At this stage, the outflow port is closed and pressure is applied to deliver drug into the medial wall.

STEP 4: REMAINING DRUG FLUSHED FROM TREATMENT CHAMBER WITH SALINE

Following delivery and dwell time, the remaining drug in the chamber is flushed with saline to reduce/eliminate systemic drug circulation.

STEP 5: OCCLUSION BALLOONS DEFLATED AND CATHETER REMOVED

Occlusion balloons are deflated and blood flow is resumed. The catheter can then be removed or deployed to another site for multiple usage in the same patient.

Refer to Pressana OPC Instructions For Use for further detail.

INDICATION FOR USE

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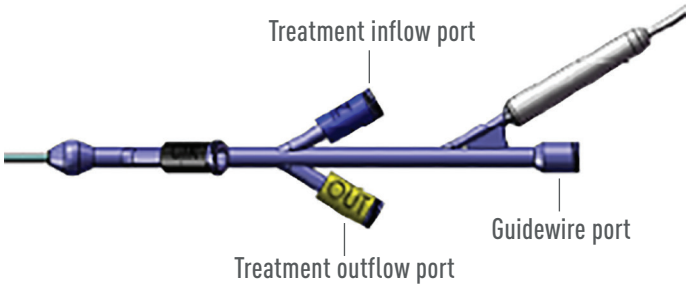
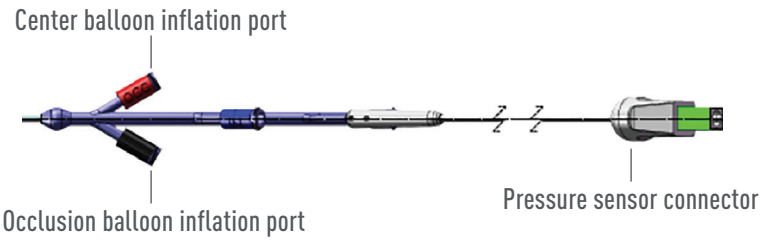
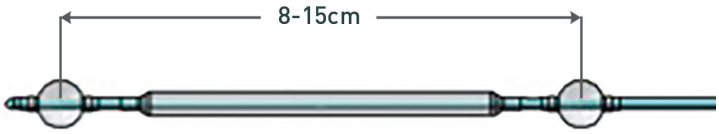
CATHETER HUB PORT DETAILS





NOMINAL TREATMENT CHAMBER LENGTHS

3mm Pressana™



7mm Pressana™

Pressana(R) Size	Nominal Occlusion Balloon Diameter	Nominal Treatment Chamber Length	Recommended Sheath Size	Reference Number
3x8	3mm	8cm	6Fr	OPC0009
3x15	3mm	15cm	6Fr	OPC0002
7x8	7mm	8cm	7Fr	OPC0010

Working length for all catheters is 135cm

For More Information Contact:
Advanced Catheter Therapies Inc.

423-321-8964

E-mail: info@acatheter.com

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

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Precision technology.
Physician-controlled peripheral therapy.

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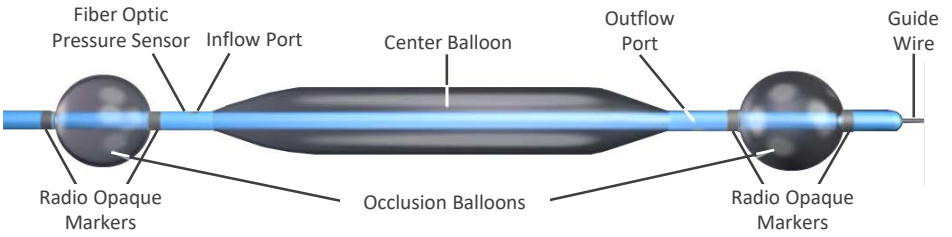

FEATURE	SPECIFICATION
Nominal Balloon Diameter, mm [1]	Ø 3 mm – Ø 10 mm
Vessel Size Range, mm	Ø 2 mm – Ø 11 mm
Treatment Chamber Length, cm [1]	3cm – 15cm
Inflow Lumen Area and Diameter Equivalent [2]	0.52 mm^2 / Ø 0.814 mm Equivalent
Outflow Lumen Area and Diameter Equivalent [2]	0.32 mm^2 / Ø 0.638 mm Equivalent
Catheter Working Length, cm	135 cm
Catheter Shaft Size, Fr.	5Fr.
Guidewire Compatibility	Standard Ø.014”
Sheath Compatibility, Fr.	Standard 6Fr. or 7Fr.
Maximum Balloon Inflation Pressure, ATM	4ATM
Recommended Agent Infusion Pressure, ATM	0.1 – 2 ATM, as monitored with internal fiber optic sensor and external monitoring system.

[1] Sizes currently in production are 3mm x 8 cm, 3mm x 15cm & 7mm x 8cm.
[2] Minimum internal diameter at Luer hub connection is Ø 0.312mm