

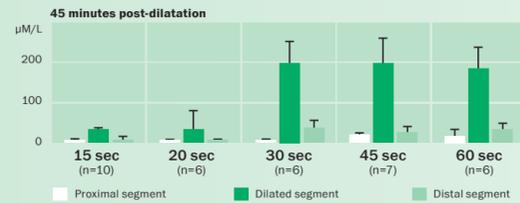
# Evidence-driven medicine

Anti-restenosis treatment

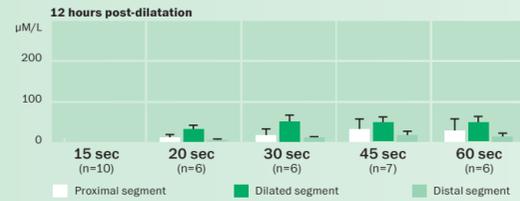
## Optimization for safety and efficacy

In a time-related study conducted in 29 porcine arteries treated with BioStream™, paclitaxel optimal arterial tissue concentration was achieved with a balloon inflation time of 45 seconds<sup>1</sup>.

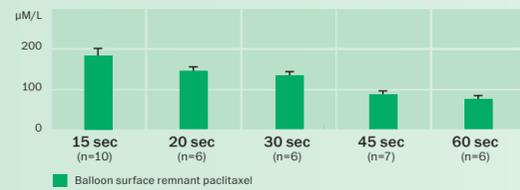
### Inflation time-dependent tissue and balloon surface paclitaxel concentrations



Coronary artery tissue paclitaxel concentrations of dilated segments, proximal as well as distal reference segments 45 minutes after 15, 20, 30, 45 and 60 second balloon inflations.



Coronary artery tissue paclitaxel concentrations of dilated segments, proximal as well as distal reference segments 12 hours after 15, 20, 30, 45 and 60 second balloon inflations.



Remnant paclitaxel amount on the balloon surface, after 15, 20, 30, 45 and 60 second balloon inflations.

## Proven efficacy in in-stent restenosis

Spanish registry<sup>3</sup>: LLL = 0.31±0.28 mm

In-stent restenosis	Sample size	TLR (%) at 6 months	TLR (%) at 12 months	Definite ST (%) at 12 months
BMS	65	9.2	9.2	0.0
DES	61	11.5	14.8	1.5
<b>Total</b>	<b>126</b>	<b>10.3</b>	<b>11.9</b>	<b>0.8</b>

Valentines I trial<sup>4</sup>

In-stent restenosis	Sample size	Definite stent thrombosis (%)	TLR (%) at 8 months
BMS	157	0.6	5.1
DES	83	1.2	10.8
Non-diabetic	166	1.2	5.4
Diabetic	78	0	11.5
Total number of patients*	250	0.8	7.4

\*Valentines I trial evaluated the drug-eluting balloon catheter in patients with ISR

### Ordering Information

Balloon diameter (mm)	Balloon length (mm)			
	15	20	25	30
<b>2.00</b>	BSTR-2015	BSTR-2020	BSTR-2025	BSTR-2030
<b>2.25</b>	BSTR-2215	BSTR-2220	BSTR-2225	BSTR-2230
<b>2.50</b>	BSTR-2515	BSTR-2520	BSTR-2525	BSTR-2530
<b>2.75</b>	BSTR-2715	BSTR-2720	BSTR-2725	BSTR-2730
<b>3.00</b>	BSTR-3015	BSTR-3020	BSTR-3025	BSTR-3030
<b>3.50</b>	BSTR-3515	BSTR-3520	BSTR-3525	BSTR-3530
<b>4.00</b>	BSTR-4015	BSTR-4020	BSTR-4025	BSTR-4030

1. A. Posa et al. Catheterization and Cardiovascular Interventions 76:395-403 (2010).
2. Axel D.L. et al. Circulation 1997; 96:636-45).
3. Vaquerizo B. et al. Insights from Spanish Multicenter Registry, Journal of Interventional Cardiology 2011, 24(6): 518-528
4. Stella P.R. et al. The Valentines Trial, EuroIntervention 2011; 7: 705-710

BioStream™ paclitaxel-eluting balloon catheter is CE Mark approved.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

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**BIOSTREAM™**  
PACLITAXEL ELUTING PTCA BALLOON CATHETER

Latest generation paclitaxel-eluting balloon for coronary interventions

the right choice



# The right choice

## The treatment process

With balloon dilatation, the injuries to the arterial wall initiate an inflammatory reaction with an excretion of growth factors which trigger the onset of cell division and smooth muscle cell migration. Paclitaxel prevents restenosis by stabilizing microtubular formation and thus prevents the cells going through the phases of replication, resulting in the inhibition of cell division. Paclitaxel reduces the excretion of the platelet-derived growth factor (PDGF) that mediates vascular smooth muscle cell migration to the intima<sup>2</sup>.

## BioStream™: The right choice

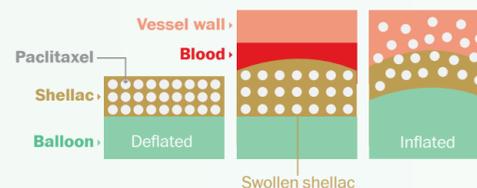
- > BioStream offers excellent pushability, trackability and crossability due to its low balloon profile, low tip entry profile and the hydrophilic coating on the distal shaft of the catheter.
- > BioStream with the shellac and paclitaxel coating and its 3-fold balloon design, enables delivery of the drug without worry of dissolution in transit, to where it matters most - across the lesion<sup>3</sup>.
- > For in-stent restenosis BioStream delivers the designated dose of paclitaxel and leaves nothing behind.
- > BioStream offers a significant reduction in the incidence of recurrent in-stent restenosis<sup>3,4</sup>.

## The BioStream balloon coating

- ▶ The BioStream balloon coating consists of a 1:1 mixture of paclitaxel (3 µg/mm<sup>2</sup>) and shellac, a natural resin approved by the FDA (GRAS), and by Europe (E904) as a food additive.
- ▶ BioStream delivers the designated concentration of paclitaxel locally to the arterial tissue.
- ▶ The properties of shellac, and the 3-fold balloon design, protect the paclitaxel during transition and placement<sup>3</sup>.

## Delivering the drug

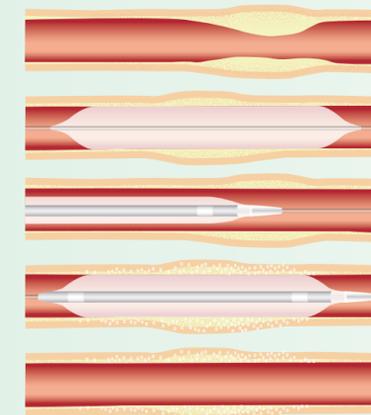
Once in contact with blood, the shellac and paclitaxel coating swells and begins to open, facilitating the pressure-induced transfer of the paclitaxel.



## Delivering the paclitaxel drug

Immediately after the controlled PTCA, injury to the vessel wall key pathways contribute to the formation of neointimal hyperplasia. Injury from cracking plaque can lead to narrowing of the lumen. The paclitaxel dose will act over the short term to inhibit cell re-growth.

- 1 Pre-dilatation prepares the way for the delivery of paclitaxel from the BioStream balloon surface.
- 2 BioStream is advanced to the lesion site.
- 3 Once the operator is satisfied with the position of BioStream across the lesion, an inflation at 8 bar for at least 30 seconds will deliver the paclitaxel through the cracked plaque and onto the vessel wall.
- 4 BioStream is then withdrawn. The shellac carrier remains on the balloon surface.



## Designed for in-stent restenosis



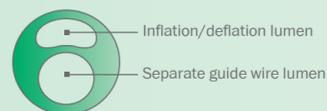
The use of the BioStream PTCA catheter is indicated for patients with discrete lesions of the coronary arteries with a reference vessel diameter of 1.50 to 4.00 mm for the purpose of improving the coronary lumen diameter.

The BioStream PTCA catheter is indicated for the dilatation of the affected segments of a coronary artery or a coronary bypass in order to enhance myocardial perfusion.

The BioStream paclitaxel eluting coronary balloon catheter is especially indicated for the treatment of coronary in-stent restenosis.

HypoTube shaft

## Rapid Exchange (Rx) Coronary Catheter

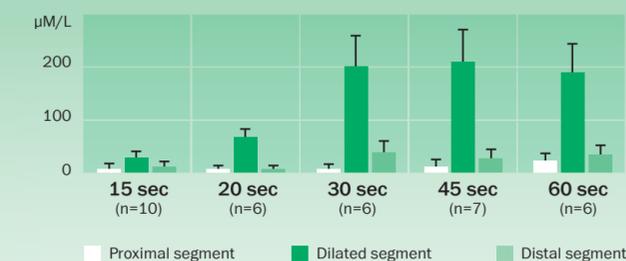


Tip profile 0.016"



For illustration purpose only - not to scale.

## Tissue concentrations of paclitaxel are inflation time dependent. Optimal use of DEB in coronary arteries<sup>1</sup>



## A choice of balloon length and diameter

Available balloon diameters	2.0, 2.25, 2.5, 2.75, 3.0, 3.5 and 4.0 mm
Balloon lengths	15, 20, 25 and 30 mm
Usable catheter length	140 cm
Recommended guide wire	0.014"

BIOSTREAM™