Case Report: Chocolate® PTCA Balloon Catheter for pre-dilatation of an occluded right coronary artery.

A case-based discussion of the use of Chocolate PTCA Balloon Catheter in complex cases
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Incomplete stent expansion and malapposed stent struts are a predictor of subacute and late stent thrombosis.

Appropriate lesion preparation prior to stent implantation is necessary to assure complete stent expansion and stent strut apposition. This is of particular importance in challenging lesions, in particular those with calcific plaque.

The goal of the pre-dilatation is to obtain optimal luminal diameter prior to stenting without causing any significant dissections. There are few devices available that are specifically designed to facilitate predictable dilatation while minimizing the risk of flow-limiting dissection.

Patient and Disease State
- 60 year old male with two de novo lesions in RCA.
- History of stable angina and previous PCI.
- RCA showed moderate tortuosity. Both lesions were severely calcified (Type B) (Figure 1).

Procedural Steps
- Vascular access through femoral artery using 6F sheath and guide catheter. Hockey Stick (Merit Medical) and 0.014” BMW guidewire (Abbott Vascular) used to access RCA.
- Treatment strategy: implant a long DES that would cover both lesions.
- Due to severe calcification and to achieve optimal lesion preparation prior to stenting, a 2.5mm x 20mm Chocolate PTCA Balloon Catheter was used to predilate both lesions in two separate dilatations.
  - First inflation on proximal lesion at 16 ATM for 20 seconds.
  - Second inflation on distal lesion at 16 ATM for 20 seconds (Figure 2).
- No accessories were required to facilitate the use of the Chocolate PTCA balloon catheter.
- Following predilatation with Chocolate PTCA (Figure 3), a Xience drug eluting stent (Abbott Vascular), was deployed to cover both lesions.
- The 2.75mm x 38mm Xience stent was inflated to 16 ATM for 15 seconds.
Results

- The final angiographic result demonstrated satisfactory restoration of the artery flow without any dissection.

**Results**

Chocolate offers predictable luminal gain while minimizing the risk of flow-limiting dissection*. Chocolate balloon inflation is uniquely:

- Predictable
- Controlled
- Uniform

Unique nitinol constraining structure offers key benefits:

- Constraining structure
  - Protects the vessel from shear stress caused by balloon inflation
- Dilatation pillows
  - Vessel dilatation without cutting or scoring
- Plaque channeling grooves
  - Stress relief zones

Chocolate is the ideal balloon for vessel preparation because it offers predictable luminal gain even in calcified lesions. The pillows and grooves on Chocolate produce an atraumatic inflation to help prevent flow-limiting dissection.

**Manish Parikh, MD**

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Indications for Use: The Chocolate® PTCA Balloon Dilatation Catheter is indicated for balloon dilatation of the stenotic portion of coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. Contraindications: The Chocolate® PTCA Balloon Dilatation Catheter is contraindicated for use in unprotected left main artery, coronary spasm, crossing through stent struts. Warnings: Do not use in the presence of a freshly deployed stent. STERILE product.

One time use only. Re-sterilizing or re-using may compromise the structural integrity of the device and may create a risk of contamination which, in turn, may result in health risks to patients. The inflated diameter of the balloon should correspond to the diameter of the vessel for treatment. See IFU for more detail.

*Data on file at TriReme Medical. Based on MOA for the Chocolate and FEA analysis. Clinical data not available at this time.

**Physician statement.