Health Technology Review	
Technology Ref.:	HTA23067
Technology Name:	Chocolate Touch Paclitaxel-Coated PTA Balloon Catheter
Approvals by International Bodies:	**FDA approved and CE marked.**
Company name:	**G Vascular USA, LLC**
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Short Description of the Technology:	The Chocolate Touch® (Paclitaxel-Coated PTA Balloon Catheter) consists of the Chocolate® PTA Balloon Catheter coated with an anti-proliferative comprised of paclitaxel with an inactive excipient over the surface of the balloon. The nominal dose of paclitaxel is 2.95µg/mm2. The Chocolate Touch is an over-the-wire (OTW) angioplasty balloon catheter with a dilatation component that consists of a semi-compliant, nylon balloon restrained by a nitinol constraining structure (CS). Two radiopaque markers are added to define the working length of the Chocolate Touch to allow for positioning of the device within the vasculature. The proximal end of the catheter is comprised of a hub used to inflate the balloon and can be connected to a standard inflation device. In the deflated form of the Chocolate Touch, the CS is mounted over the balloon with both the balloon and CS coated with the paclitaxel formulation. After positioning at the intended deployment site and upon inflation, the CS expands with the balloon to a certain diameter; then the balloon expansion surpasses the CS. The inflated balloon provides a surface upon which the paclitaxel coating is directly exposed to the wall of the vessel, with transfer occurring during the mechanical inflation period within the vessel. Upon deflation, the CS is removed from the vessel along with the balloon catheter; no part of the device remains in the vessel after treatment. The drug formulation including the active pharmaceutical ingredient, paclitaxel, remains in the vessel wall for a limited amount of time. The Chocolate Touch is available with eighteen (18) total balloon sizes in an OTW catheter configuration compatible with two (2) guide wire sizes (0.014" or 0.018"). The catheter length is 120cm or 135cm and compatible with 5F to 7F introducer sheaths.

Health Technology Assessment Team Recommendation:	**Approved**

Summary of Review:

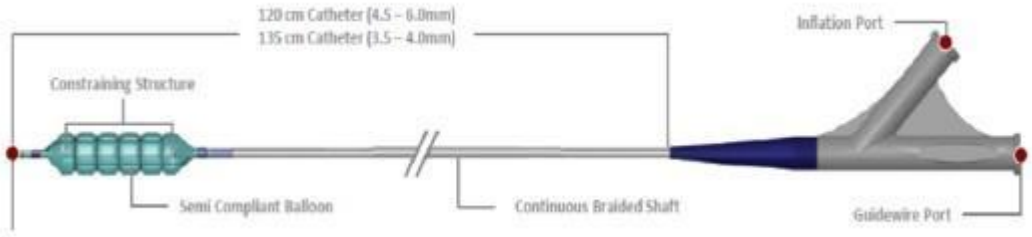
The technology is a peripheral angioplasty catheter having an anti- proliferative coating. The drug coating covers the distal assembly portion of the catheter. It is comprised of the active pharmaceutical ingredient, paclitaxel, and an excipient, propyl gallate. The intended use to to re-open blocked or narrowed arteries in the thigh and knee due to peripheral artery disease (PAD).

Advantages	Disadvantages
FDA Approved and CE Marked	It is important to consider that it is intended for use by trained healthcare professionals ONLY in interventional cardiology and vascular surgery operation theatres
There have been numerous clinical trials demonstrating the safety and efficacy of drug-eluting balloons in the treatment of coronary artery disease and lower extremity artery disease, and they are expected to be used in larger vessel and peripheral vascular diseases.	the current studies on drug-eluting balloons are characterized by small sample size and short observation time, and the technical shortcomings in the clinical use of drug-eluting balloons may lead to adverse conditions such as particulate matter and vessel dissection, therefore, more studies on the safety of drug-eluting balloons are needed
Drug-coated balloons (DCBs) have been increasingly used because of their potential to combine balloon angioplasty and antiproliferative drug elution without leaving a permanent metal implant that may distort and constrain the coronary vessel, limit vasomotion and adaptive remodelling, and promote chronic inflammation.	

We recommend an **approval of using this technology** with the following conditions:

1. Approval on the use of Chocolate Touch Paclitaxel-Coated PTA Balloon Catheter Model TUAA-BBB-XXYYY OTW (AA- guidewire, BB- catheter length, XX balloon diameter, YYY – balloon length)
2. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
3. Provision of regular updates and reports about the product to DOH upon request.
4. Any other documents or information requested regarding the product and cost to finalize the approval process.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image


Population, setting and intended user for Technology "Chocolate Touch Paclitaxel-Coated PTA Balloon Catheter".

- **Population/ Intended User**.
  - The Chocolate Touch DCB is used when arteries in the thigh and knee are narrowed or blocked because of peripheral artery disease/ is indicated for percutaneous transluminal angioplasty of de novo or restenosis lesions in length in native femoral or popliteal arteries.
- **To be performed by**:
  - By trained healthcare professionals ONLY in interventional cardiology and vascular surgery operation theatres
- **Clinical Setting:**
  - Hospitals, special surgery canters.
- **Condition of use:**
  - As per Manufacturer directions.
- **Exclusion criteria:**

  The Chocolate Touch DCB should not be used in:
  - Arteries that carry blood to the heart (coronary), kidneys (renal), brain (cerebrovascular), or branch off from the largest artery (supra-aortic).
  - Patients with a known hypersensitivity (allergy) to paclitaxel or drugs with similar characteristics as paclitaxel.
  - Patients who cannot take recommended medicines that thin the blood and prevent blood clots.
  - Women who are breastfeeding, pregnant, or intend to become pregnant; or men intending to father children.
  - If a doctor decides that a patient's narrowing, or blockage will prevent proper placement of the delivery system.