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Clinical Data Analysis: Noncompliant, High-Pressure Balloon and Calcified, Undilatable Coronary Lesions

Mahmoud Radwan, Amin Bahloul, MD, Hela Sarray, MD, Yassmine Kammoun, MD, Tarek Ellouz, MD, Mourad Hentati, MD, PhD, Leila Abid, MD, PhD, Samir Kammoun, MD, PhD,

Cardiology Department,

Hedi Chaker Hospital, Sfax, Tunisia

Abstract

Optimal stent deployment can become a challenge for the interventional cardiologist, especially when it involves calcified, undilatable lesions. Various technologies have been developed to tackle this scenario and the super high-pressure balloon seems to be a promising adjunct in treating undilatable lesions. Herein, we present our initial experience with a new noncompliant, super high pressure balloon.

The **Apollo Balloon Dilatation Catheter**, developed by **Brosmed Medical Co., Ltd**, has undergone a comprehensive clinical review in alignment with the European Medical Device Regulation (MDR) and the MDCG guidance for clinical evaluation. This review forms part of the ongoing clinical data collection requirements under MDR, ensuring that the device meets stringent standards of clinical performance, safety, and benefit for patients. The clinical overview focused on demonstrating the Apollo Balloon's effectiveness in supporting optimal stent deployment, especially in cases involving challenging calcified or undilatable lesions. For interventional cardiologists, these lesions present a unique challenge, and the Apollo Balloon's noncompliant, super high-pressure design has shown promise as an adjunct technology in treating such complex cases.

Through extensive clinical data collection and evaluation, compliance with the General Safety and Performance Requirements (GSPR) was verified, confirming the Apollo Balloon Dilatation Catheter's adherence to regulatory standards. The catheter's high-pressure capacity facilitates precise stent deployment and improves treatment outcomes, offering a valuable tool in interventional cardiology for managing difficult lesions. This clinical review underscores the catheter's clinical benefits and reinforces its role in supporting advanced treatment options for patients.

Keywords: calcified, undilatable lesions, GSPR, Apollo Balloon Dilatation Catheter

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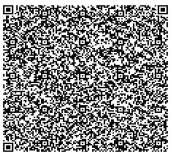	Website: www.ijcrims.com
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