

📍 Europe



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Paclitaxel safety IN.PACT™ Admiral™ Paclitaxel-coated PTA Balloon Catheter

DEDICATED TO TRANSPARENCY

There have been concerns surrounding the safety of paclitaxel in therapies to treat peripheral artery disease (PAD). Medtronic is dedicated to data transparency and confident in the safety and effectiveness of our IN.PACT™ Admiral™ Paclitaxel-coated PTA Balloon Catheter.

PACLITAXEL SAFETY IN THE PERIPHERY: A REVIEW OF CURRENT LITERATURE AND GUIDELINES

This CME-accredited discussion covers the main topics and questions that the physician community has been asking:

- **Informed patient consent** regarding paclitaxel safety.
- Patients at **high risk of restenosis** and the **IN.PACT™ Admiral™ Paclitaxel-coated PTA Balloon Catheter data for these patients.**

- **Implications of big data** (CMS, Medicare) and how to interpret these data sets.
- **Analysis of the FDA letter from August 2019**, and implications for daily practice.

FACULTY

Peter Schneider, M.D. (Moderator)

Professor of Surgery

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Daniel Clair, M.D.

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Assistant Professor of Medicine

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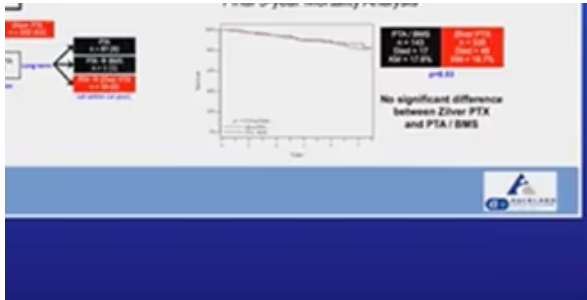
Dr. Dan Clair: An Update On The FDA Panel And The Impact On Practice



Panel Discussion

Does drug dose impact mortality following PAD treatment with Paclitaxel-eluting or Coated Devices?

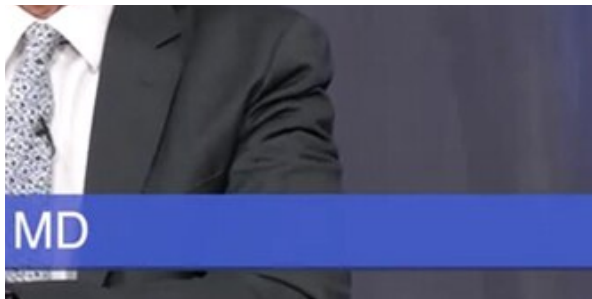
A panel discussion: Andrew Holden, M.D.; Michael R. Jaff, D.O.; Peter A. Schneider, M.D.



IN.PACT™ Patient-level Meta-analysis

DCBs over the long-term: are they safe for our PAD Patients?

Insights from the IN.PACT™ DCB program: Peter A. Schneider, M.D.



To confirm the safety of our IIN.PACT™ Admiral™ Paclitaxel-coated PTA Balloon Catheter, an independent, patient-level analysis was conducted by the Baim Institute for Clinical Research, formerly HCRI, on all subjects from all of our studies treated with IN.PACT™ Admiral™ Paclitaxel-coated PTA Balloon Catheter. This analysis included 1,980 patients who were enrolled across our IN.PACT™ Admiral™ Paclitaxel-coated PTA Balloon Catheter clinical programs.

The results from the independent, patient-level analysis found **NO correlation between paclitaxel dose and mortality.**¹

There was NO difference in total mean dose of paclitaxel between DCB patients who survived vs. those who died.¹

[VIEW NOMINAL DOSE DATA \(OPENS NEW WINDOW\) \(/CONTENT/DAM/MEDTRONIC-COM/PRODUCTS/CARDIOVASCULAR/DRUG-COATED-BALLOONS/INPACT-ADMIRAL/DOCUMENTS/SCHNEIDER-PTX-SAFETY-SPEAKER-READY.PDF#PAGE=11\)](#)

There was no correlation between survival status of patients stratified by paclitaxel dose.¹

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Paclitaxel was not identified as a predictor for mortality in a multivariable analysis.¹

[VIEW MULTIVARIABLE ANALYSIS \(OPENS NEW WINDOW\) \(/CONTENT/DAM/MEDTRONIC-COM/PRODUCTS/CARDIOVASCULAR/DRUG-COATED-BALLOONS/INPACT-ADMIRAL/DOCUMENTS/SCHNEIDER-PTX-SAFETY-SPEAKER-READY.PDF#PAGE=14\)](#)

[IN.PACT™ Admiral™ Paclitaxel-coated PTA Balloon Catheter Patient-level Safety Data](#)**(opens new window)**
[\(/content/dam/medtronic-com/products/cardiovascular/drug-coated-balloons/inpact-admiral/documents/schneider-ptx-safety-speaker-ready.pdf\)](#)

Presented at Charing Cross by Dr. Schneider.

[JACC Manuscript \(opens new window\) \(http://www.onlinejacc.org/content/73/20/2550?rss=1\)](#)

Mortality Not Correlated With Paclitaxel Exposure

An Independent Patient-level Meta-analysis Of A Drug-coated Balloon

Peter A. Schneider, John R. Laird, Gheorghe Doros, Qi Gao, Gary Ansel, Marianne Brodmann, Antonio Micari, Mehdi H. Shishehbor, Gunnar Tepe, and Thomas Zeller

Related Pages

- [IN.PACT™ Admiral™ Paclitaxel-coated PTA Balloon Catheter \(/xd-en/healthcare-professionals/products/cardiovascular/drug-coated-balloons/inpact-drug-coated-balloon.html\)](/xd-en/healthcare-professionals/products/cardiovascular/drug-coated-balloons/inpact-drug-coated-balloon.html)
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Reference

1

Schneider P. DCBs Over The Long-Term: Are They Safe For Our PAD Patients? Insights From The IN.PACT DCB Program. Presented at Charing Cross 2019; San Francisco, CA.

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