

The Power of Paclitaxel

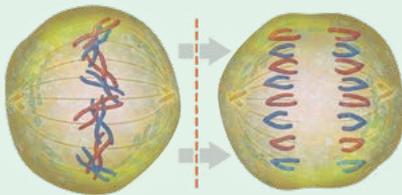
Localized delivery of a proven antiproliferative drug

UROLOGY & UROGYNECOLOGY

What is paclitaxel?

Paclitaxel is a proven antiproliferative drug that has been used in chemotherapy since the early 1990s. As a mitotic inhibitor, paclitaxel's mechanism of action (MoA) works by stabilizing microtubules to prevent the metaphase/anaphase transition, preventing cell division and migration, inhibiting new tissue growth and the fibrotic scarring that leads to stricture recurrence.

Optilume® is a drug coated balloon that dilates the urethral lumen and delivers paclitaxel directly to the site of an anterior urethral stricture to reduce recurrence.¹



How is it delivered?

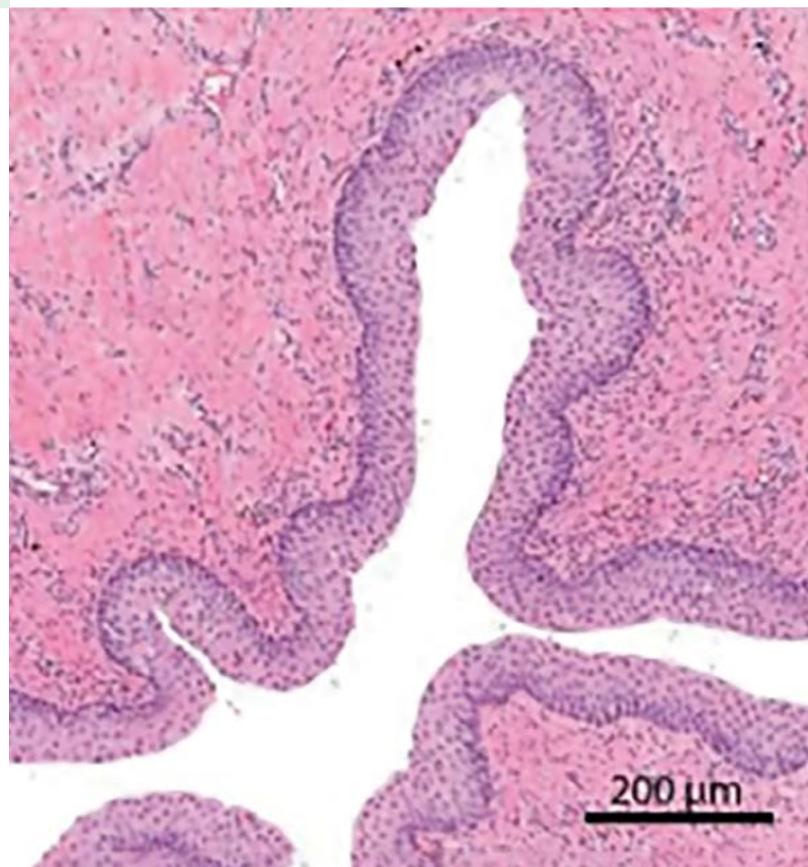
- Paclitaxel is suspended in a coating with an excipient that is uniformly applied to the Optilume® urethral drug coated balloon
- The balloon is inflated in the urethra, simultaneously dilating the stricture and creating microfissures that enhance the uptake of paclitaxel
- The excipient molecularly binds the paclitaxel to the balloon, until the inflated balloon comes in contact with the tissue for rapid drug release



Why it works.²

Along with paclitaxel's proven MoA, this molecule is particularly well-suited for localized delivery in targeted tissues due to its unique properties:

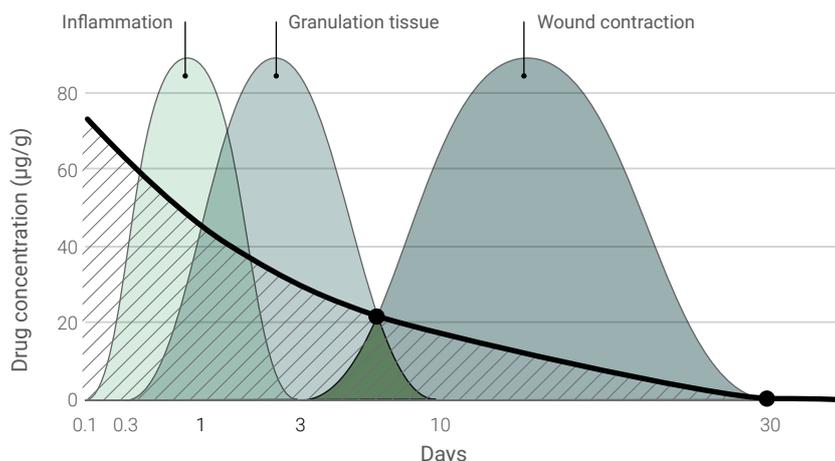
- Lipophilic and hydrophobic structure enables more rapid and complete uptake by urothelial cells and prevents paclitaxel from being washed out to promote more sustained residency³
- Localized delivery and absorption does not require prolonged exposure or sophisticated drug carriers²
- Cytostatic effect with low-dose administration, between 2 and 6 milligrams, maintains safety and integrity of surrounding tissue⁴



Sustained localized effects²

- Approximately 11 days half-life in the urothelium provides continued suppression through post-procedure inflammatory response
- Demonstrated tissue residency through 28 days inhibits hyperplastic tissue response and sustains efficacy, providing long-term symptomatic relief

Stages of healing



Safe, therapeutic drug levels in tissue to 28 days²

Paclitaxel used as a coating for device in millions of patients

In addition to being the best-selling cancer therapeutic ever manufactured,⁵ local, circumferentially delivered paclitaxel has been used to prevent neointimal growth in endovascular applications for over 15 years⁷

OVER
10 MILLION

paclitaxel-eluting stents used in interventional coronary and peripheral vascular procedures⁷

HUNDREDS OF
THOUSANDS

drug coated balloon procedures since in 2014⁶

TENS OF
THOUSANDS

of patients studied⁷

References

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- 2 Data on File: TR1041
- 3 Schorn I, Malinoff H, Anderson S, et al. The Lutonix® drug-coated balloon: a novel drug delivery technology for the treatment of vascular disease. *Adv Drug Deliv Rev* 2017;112:78-87.
- 4 Kamath KR, Barry JJ, Miller KM. The Taxus™ drug-eluting stent: a new paradigm in controlled drug delivery. *Adv Drug Deliv Rev* 2006;58:412-36.
- 5 Zasadil LM, Andersen KA, Yeum D, et al. Cytotoxicity of paclitaxel in breast cancer is due to chromosome missegregation on multipolar spindles. *Sci Transl Med* 2014;6(229):229ra43
- 6 Rosenfield K, Jaff MR, White CJ, et al. Trial of Paclitaxel-Coated Balloon for Femoropopliteal Artery Disease. *NEJM* 2015;372(2):145-53
- 7 <https://www.bostonscientific.com/en-EU/products/stents-vascular/eluvia-drug-eluting-stent-system/sustained-drug-release.html>

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Optilume® urethral drug coated balloon

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