Precision Prophylaxis: A New Standard in Surgery

Targeted Product Profile: Clindamycin Phosphate for Intradermal Injection

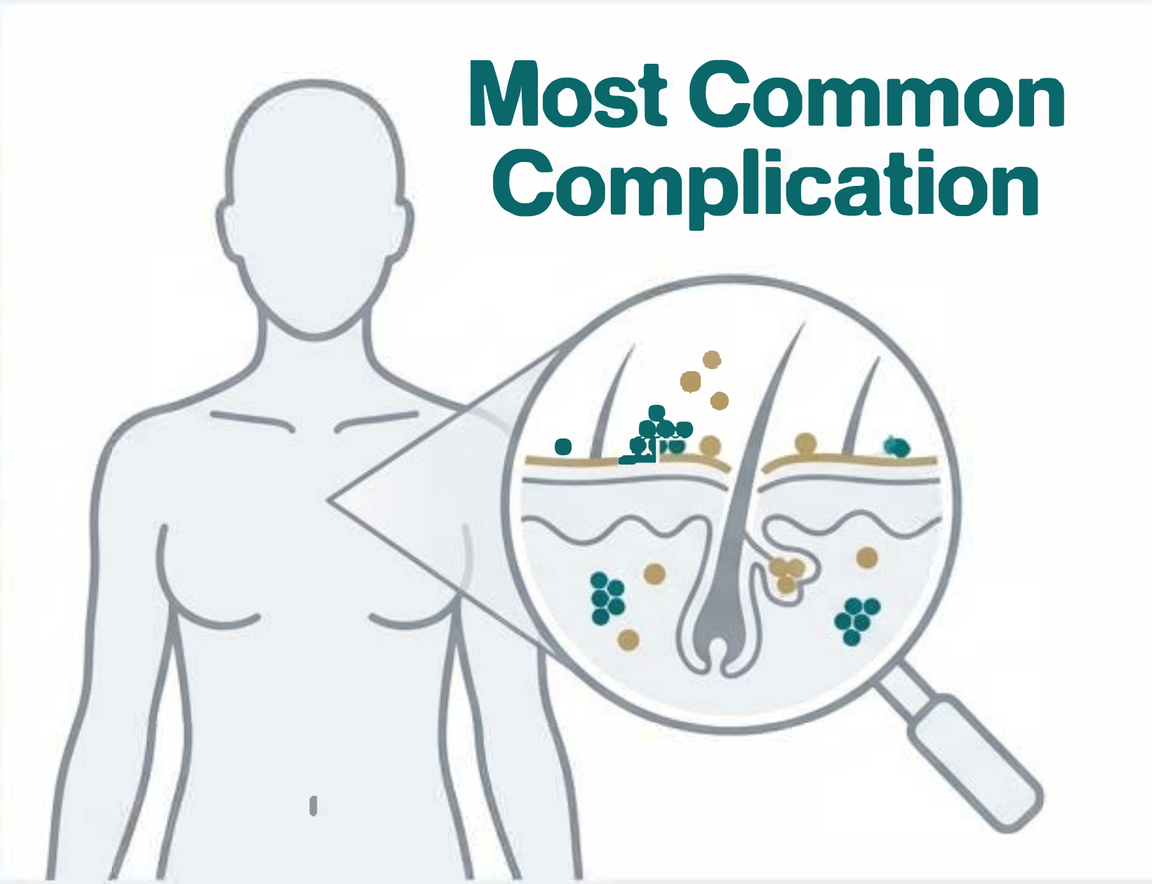
The Global Imperative: Confronting Antimicrobial Resistance (AMR)

The overuse and misuse of systemic antibiotics are compromising the foundations of modern medicine, particularly the safety of surgical procedures.

WHO's first global report on antibiotic resistance reveals serious, worldwide threat to public health

"Resistant organisms in health-care and community settings pose a threat to survival rates from serious infections... and limit the potential health benefits from surgeries..."

The Focused Challenge: Surgical Site Infections in Dermatologic Surgery



- Surgical Site Infections (SSIs) are the most common complication of dermatologic surgery, with rates ranging from 0.4% to 2.5%.
- The vast majority of SSIs are caused by the patient's own skin flora, with *Staphylococcus aureus* being a primary pathogen.
- This points to a need for a targeted, local solution that neutralizes pathogens at the incision site, rather than relying on systemic antibiotic bombardment.

A Paradigm Shift in Prophylaxis: A Prefilled, Single-Use System

The Drug:
An optimized, low-dose clindamycin formulation.

The Device:
A precision-engineered syringe for safety and ease of use.

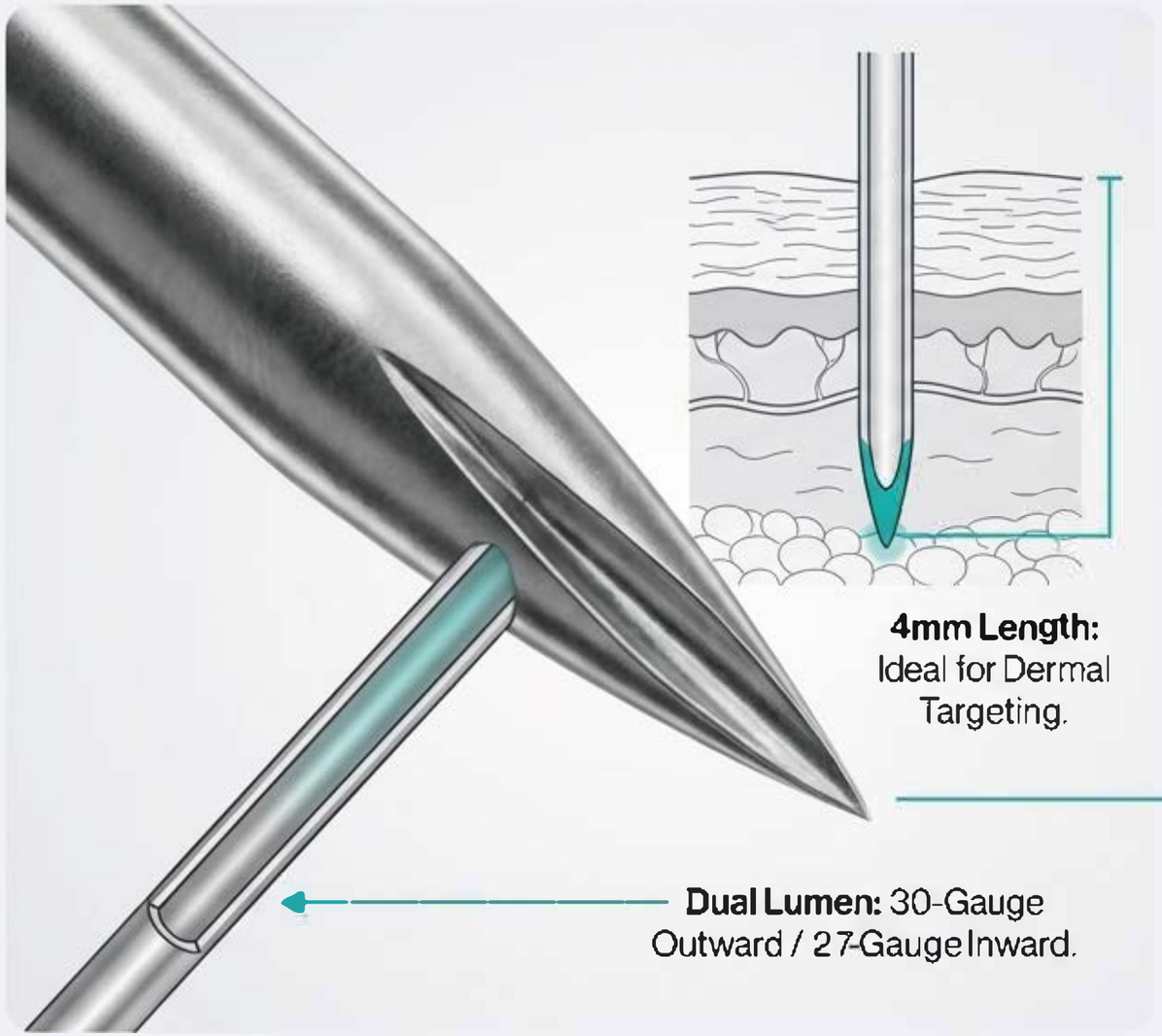
The Delivery: A specialized nanoneedle for targeted intradermal administration.

Right Drug. Right Place. Right Time.

The Device: Engineered for Precision and Compatibility

- **3-mL Syringe Barrel:** Chosen for optimal handling and control during delicate intradermal injections.
- **Luer Lock:** Ensures a secure, leak-proof connection between the syringe and needle.
- **Advanced Materials:** Syringe components (barrel, plunger) are specifically selected for compatibility with clindamycin phosphate solution.
- **Safety-Tested:** Rigorously tested for leachables and extractables to ensure product purity and patient safety.

The Nanoneedle: Optimizing Delivery, Enhancing Experience



- **4mm Length:** The ideal length for precise intradermal delivery, ensuring the antibiotic is deposited directly into the target tissue layer.
- **30-Gauge Outward / 27-Gauge Inward Lumen:** This thinner-wall needle technology enhances fluid flow.
- **Benefit:** This design reduces the required injection force, improving the user experience for the clinician and potentially reducing patient discomfort.

The Formulation: Optimized for Local Efficacy and Stability

Drug & Concentration

Clindamycin Phosphate at 500 µg/mL. This 'micro-dose' is optimized for potent local effect without the risks of systemic administration.

Physiologic pH

Formulated to a pH of 6.8 - 7.0 for improved patient comfort upon injection.

Shelf Life

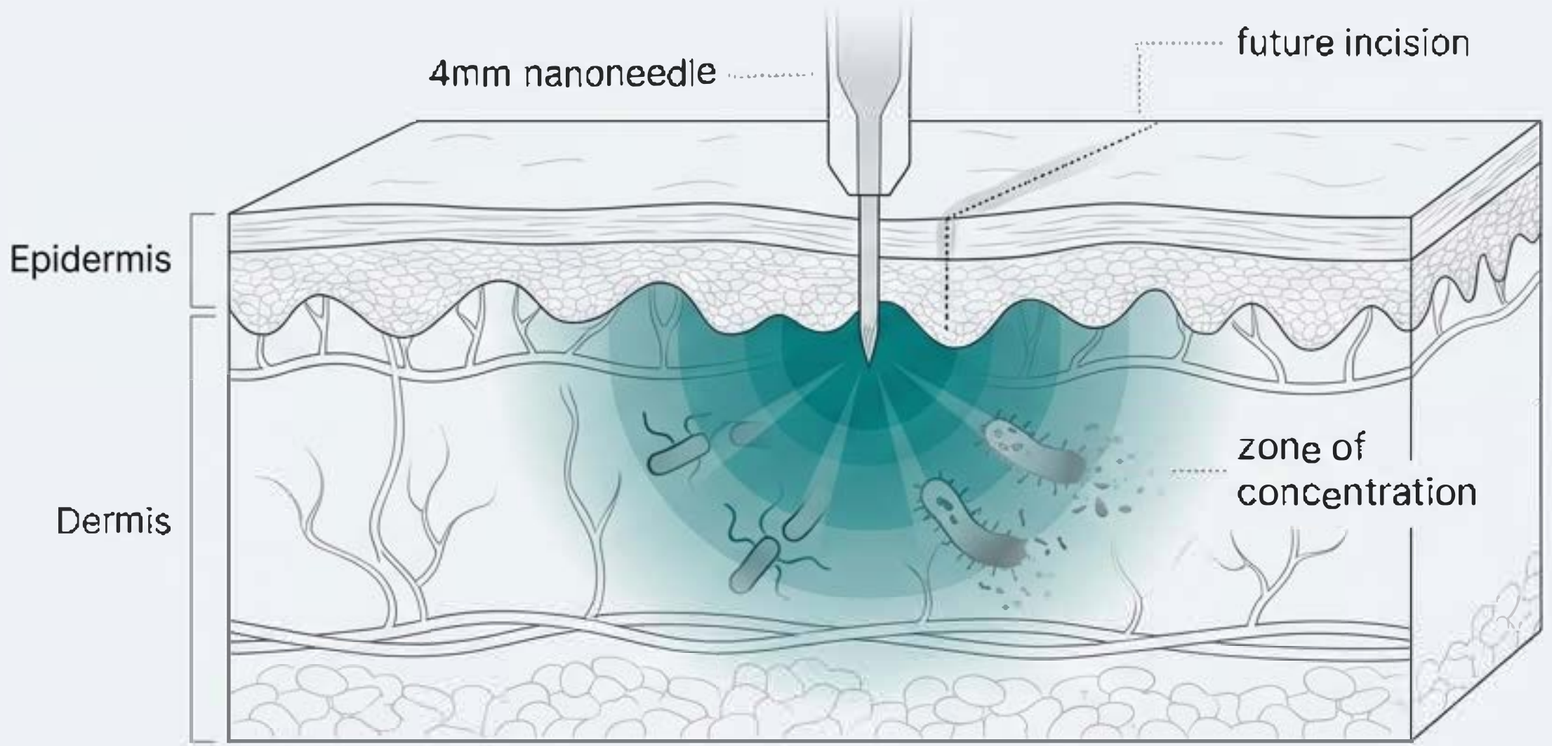
Proven 24-month stability at room temperature, ensuring reliability and simplifying storage.

Ready-to-Use

Aseptically prefilled and single-use, eliminating the risk of dosing errors, contamination, and admixing variability.

The Indication: Prophylaxis for Surgical Procedures

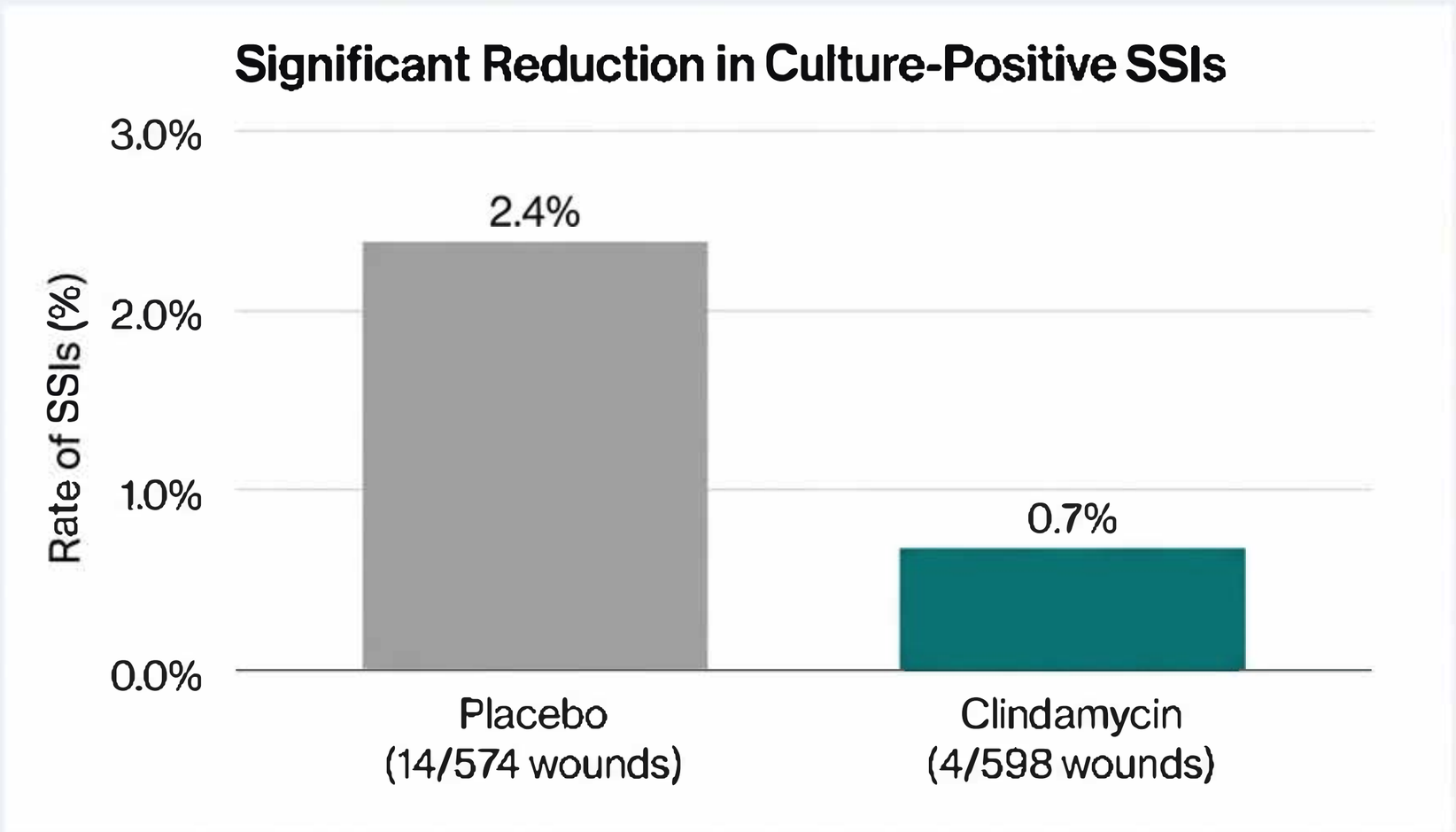
For use as surgical antibiotic prophylaxis immediately before surgical procedures.



Delivers a targeted, high concentration of clindamycin directly to the surgical site, eradicating key pathogens *before* the first incision.

Clinical Precedent: Evidence for Incisional Clindamycin Prophylaxis

Prospective, randomized, placebo-controlled trial by Huether et al.



A statistically significant reduction in SSIs.
(P=.02, Fisher exact test)

The Clinical Strategy: The DERM_SSIP Pivotal Trial

Protocol DERM_SSIP

(Dermatology Surgical Site Infection Prevention)

A pivotal trial designed to provide definitive evidence of efficacy for regulatory submission.

Trial Design

The protocol is designed to mimic the successful and highly credible **Picasso trial** (Goh et al., JAMA Surgery).

Focus

Evaluating the effect of micro-doses of **incisional clindamycin** on SSI rates in cutaneous surgery.

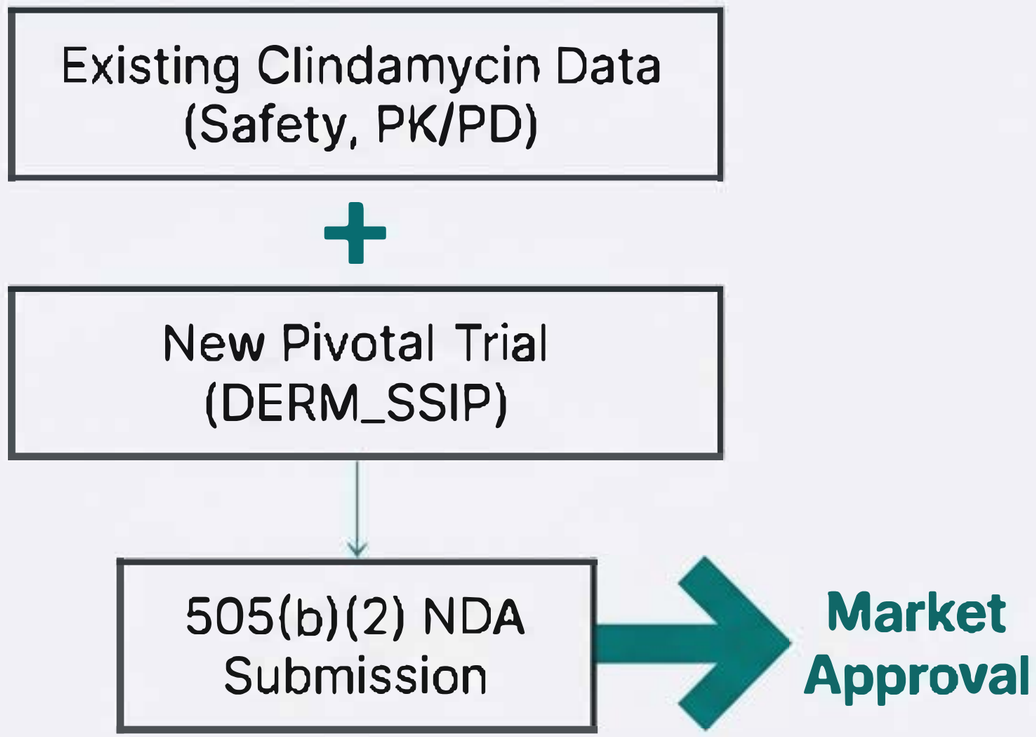
This approach leverages a proven, efficient trial design to generate the required clinical data for approval.

The Regulatory Pathway: A De-Risked 505(b)(2) Approach

Pathway: We will pursue a 505(b)(2) New Drug Application (NDA).

Advantage: This pathway is highly efficient as it allows us to reference the FDA's prior findings of safety and effectiveness for clindamycin.

Requirement: While this pathway leverages existing data, it requires a new clinical trial to establish efficacy for the proposed indication and delivery method.



The Roadmap to Launch

Activities: Finalize device engineering, complete CMC stability testing, manufacture investigational product batches.

Key Deliverable: ~1000 syringes for clinical trial use.

Activities: Site initiation, patient enrollment, and completion of the DERM_SSIP trial.

Key Deliverable: Top-line clinical trial data.

Activities: NDA submission and review, scale-up of commercial production of aseptically prefilled syringes.

Key Deliverable: Product Launch.

Redefining the Standard of Care in Dermatologic Surgery

THE PROBLEM

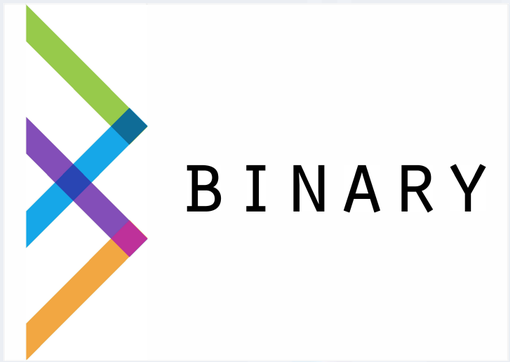
Widespread SSI risk and growing antimicrobial resistance demand a smarter, more targeted approach than systemic antibiotics.

OUR SOLUTION

First in class drug product. A precise, ready-to-use, prefilled drug-device combination designed specifically to prevent SSIs at the source.

THE PLAN

Supported by strong clinical precedent, with a clear and efficient clinical (DERM_SSIP) and regulatory (505(b)(2)) path to market.



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