REFINE Study: Scar Prevention and the Clinical Effectiveness of using a Novel Mechanomodulating Polymer

NEODYNE BIOSCIENCES

We are an evidence based company developing and commercializing innovative tissue repair devices to minimize scar formation, restoring both function and aesthetic appearance. Utilizing patented technology, we believe that effective scar minimization will become a reality for many of those undergoing surgical procedures.

Our strategy is to establish our technology as a global standard of care for the prevention of scarring – initially entering the market with aesthetic and reconstructive plastic surgery solutions, and then expanding beyond plastic surgery to address various injury and non-discretionary surgical incisional wounds.

Neodyne was founded in 2007 at Stanford University. In 2008, the Company licensed the technology from Stanford and is led by an experienced team of medical device industry executives. Neodyne is located in the heart of Silicon Valley with access to a wealth of expertise in medical technology research and development and venture capital.

neodyne Bioscience

The Neodyne technology consists of a load bearing biopolymer that is stretched by means of an applicator and then applied to the skin with a goal of optimizing a regenerative wound environment for minimal scar formation.

The objective is to complete clinical trial(s) utilizing a market-ready device to provide expanded data for de novo surgical incisions as well as explore the potential to improve scar appearance after a scar revision procedure.

Ultimately, this data will be used to support the commercial launch of the product, and to make the technology available to both military and civilian patients.

- Study Objectives: Evaluate the Neodyne Dressing when utilized for post-surgical incision care
- Study Design: Prospective, open label, randomized (subject as their own control), multi-center study of up to 100 subjects
- Primary Endpoints: Scar formation in incision area covered by Neodyne Dressing as compared to control incision area
- Additional Outcome Measurements:
  - Ease of use – application and Removal
  - Pain amelioration, comfort and scar smoothness
  - Infection rate (treated versus untreated)
- Subject Study Duration: 6 months (with optional follow-up at 12 months)
- Subjects/Sites: 100 subjects at up to 20 sites
- Study Population: Subjects who have scheduled an elective abdominoplasty

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