









## Start-to-finish drug eluting product development and manufacturing in an FDA compliant facility.

Trelleborg Sealing Solutions is a leading expert in the manufacture of drug eluting combination products using silicone and bioresorbable materials. Patented processes and expertise in areas such as GeoTrans® extrusion, micromolding, thin film membranes, and coating technologies are all immediately applicable to drug eluting combination products. A wealth of engineering experience and pharmaceutical licensing allow us to offer complete product development and manufacturing.

Our manufacturing and process development services deliver comprehensive support to innovators in both the pharmaceutical and medical device industries, spanning from design assistance, feasibility and prototyping to clinical builds and commercial products. In addition, our business model, quality system, and facility layout are all designed for maximum flexibility in meeting the myriad requirements of our various customers.

## **Application Examples**

- · Female Healthcare
- · Wound Care
- · Steroidal Collars
- · Pacemaker Leads
- · Ophthalmic Devices
- Antimicrobials

## **Drug Device Services**

- Collaboration with pharmaceutical companies to assist with the design and creation of new and innovative drug device components, products, and manufacturing processes
- Contract manufacturing from concept and raw materials to regulatory agency-compliant drug device components and products
- · Mixing of silicone and active pharmaceutical ingredients
- Mixing of bioresorbable materials with active pharmaceutical ingredients
- Complete packaging and assembly of drug device components and products
- Full quality rigorous control system that can support development and production of any device

## **Advantages of Drug Device Combination Products**

Combination products can offer several advantages when compared with drug delivery via oral, injection and infusion methods. All drug device combination products exhibit one or more of the following attributes.

- · Drug device components provide controlled release of the Active Pharmaceutical Ingredient (API) instead of bolus-type delivery. This allows API concentrations to be consistently maintained within an optimal therapeutic range.
- · Drug eluting devices, particularly implanted devices, provide targeted delivery of the API. This approach, when contrasted with systemic administration, permits higher therapeutic dosages to be delivered while minimizing adverse side effects.
- · Combination products have been shown to improve patient compliance. Most healthcare practitioners agree that within an aging population such as ours, compliance becomes less certain and therefore, more important.
- · An API added to a device can improve the device function and help to prevent local, as well as systemic infection.

