point implanted. Whole blood sirolimus PK parameters for this study are been tested extensively. The following is a summary of data available. See

- CONTRAINDICATIONS
  - Contraindications may include the presence of a foreign body, an infection, or any condition that would contraindicate the use of this stent. The stent must not be implanted if the patient has a known allergy to sirolimus or any component of the stent.
  - The stent should not be implanted in patients with a known history of hypersensitivity to any component of the stent.
  - The stent should not be implanted in patients with a known history of severe allergic reactions to medications containing sirolimus.

- PRECAUTIONS
  - Precautions should include careful evaluation of the patient’s cardiac anatomy and physiology before implantation. The stent should be implanted with care to avoid any damage to the surrounding tissue.
  - Precautions should also include careful evaluation of the patient’s response to previous stent placements, as well as any other potential risks associated with stent implantation.

- INDICATIONS
  - Indications for stent implantation include the treatment of coronary artery lesions, including lesions that are refractory to balloon angioplasty.
  - Indications for stent implantation also include the treatment of bifurcation lesions, as well as lesions that are not amenable to balloon angioplasty.

- PATIENT MONITORING
  - Patient monitoring should include regular monitoring of the patient’s vital signs, as well as monitoring of any potential complications or adverse effects.
  - Patient monitoring should also include regular monitoring of the stent’s position and patency.

- USE OF THE COMBO STENT
  - Use of the stent should be made by trained and experienced personnel.
  - Use of the stent should be made in accordance with the instructions for use provided by the manufacturer.

- MANUFACTURER:
  - OrbusNeich Medical, Inc.
  - www.OrbusNeich.com

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**DEVELOPMENT SYSTEM DESCRIPTION**

The stent is a biocompatible, biodegradable polymer containing sirolimus (also known as rapamycin). Carcinogenicity studies were conducted in mice and rats. In an 18-month carcinogenicity study in male rats, testicular tubular degeneration was also seen in a 4-week intravenous study of mice. An increased length of hospital stay relative to length of stay for coronary artery bypass grafting (CABG) was associated with the use of sirolimus-eluting stents. No significant findings were noted in the study conducted in mice. The stent is not designed for use in conjunction with any other drug-eluting stent or any other type of stent.

**DELIVERY SYSTEM DESCRIPTION**

The stent is delivered through a transluminal coronary stent delivery catheter with a working length of approximately 20 cm. The catheter is designed to provide precise control of the stent delivery and to minimize the risk of dislodgement or embolization. The catheter is composed of materials that are biocompatible and biodegradable, and it is designed to be used in conjunction with the stent.

**PRODUCT DESCRIPTION**

The Combo stent is a bio-engineered sirolimus eluting stent designed for use in coronary arteries. The stent is composed of a biocompatible, biodegradable polymer containing sirolimus. The stent is designed for use in conjunction with the delivery system described in this manual.

**APPLICATIONS**

The Combo stent is designed for use in patients with coronary artery disease who require stent implantation. The stent is intended for use in the treatment of coronary artery lesions, including lesions that are refractory to balloon angioplasty.

**CONTRAINDICATIONS**

The stent is contraindicated for use in a group of selected patients eligible for coronary artery bypass surgery (CABG) and/or who are not candidates for either percutaneous coronary intervention (PCI) or CABG.

**PRECAUTIONS**

Precautions should include careful evaluation of the patient’s cardiac anatomy and physiology before implantation. The stent should be implanted with care to avoid any damage to the surrounding tissue.

**INDICATIONS**

Indications for stent implantation include the treatment of coronary artery lesions, including lesions that are refractory to balloon angioplasty. Indications for stent implantation also include the treatment of bifurcation lesions, as well as lesions that are not amenable to balloon angioplasty.

**PATIENT MONITORING**

Patient monitoring should include regular monitoring of the patient’s vital signs, as well as monitoring of any potential complications or adverse effects. Patient monitoring should also include regular monitoring of the stent’s position and patency.

**USE OF THE COMBO STENT**

Use of the stent should be made by trained and experienced personnel. Use of the stent should be made in accordance with the instructions for use provided by the manufacturer. The stent is not designed for use in conjunction with any other drug-eluting stent or any other type of stent.