Temperature data was collected on 72 patients from each treatment group.

CONTRAINDICATIONS

Drug interactions or a desiccant packet.

There were two deaths in the study. One control patient died during the study due to cardiopulmonary arrest. The other death was in the control group. The patient died of a cerebrovascular accident. There has not been a history of adverse events associated with COSEAL.

The Powder Component Pouch consists of a syringe containing liquid, a desiccant packet, and a luer cap.

INSTRUCTIONS FOR USE

POWDER COMPONENT POUCH:

The Powder Component Pouch consists of a syringe containing two PEG powders in a powder syringe and a luer cap.

APPLICATION GUIDELINES:

COSEAL is intended for use in vascular reconstructions to achieve adjunctive hemostasis by mechanically sealing areas of leakage. COSEAL is supplied as a sterile single use only unit. Do not re-sterilize any components. Discard unused material.

APPLICATION POUCH:

Each applicator pouch contains a syringe, a luer cap, and a transfer port.

ADVERSE EVENTS

CONTRAINDICATIONS

There are no known contraindications for this device.

ADVANCED TREATMENT

In a prospective, randomized, controlled multicenter trial, 148 patients were treated with COSEAL or the control

COSEAL is not to be applied over a site, replace the applicator tip.

Following application wait at least 60 seconds before restoring circulation, applying irrigation, blotting with gauze, or placing in contact with tissue or with gel.

To prevent clogging, airflow should always precede and follow product application.

For assembly, follow the Instructions for Use provided with the COSEAL Spray Set.

2. COSEAL Spray Set (sold as an accessory)

To prevent clogging, airflow should always precede and follow product application.

4. Glue the syringe clip to the end of the syringe housing (COSEAL) is then ready to use.

If the treated site fails to seal, blot the surface dry. Reclamping the vessel may be required to dry the field for reapplication of COSEAL. Reclamp the vessel and apply additional sealant. Do not reopen (or properly licensed practitioner). [Rx ONLY]

3. Snap the applicator onto the end of the syringe housing. COSEAL is now ready to use.

INSTRUCTIONS FOR USE

For assembly, follow the instructions for use provided with the COSEAL Spray Set.

To prevent any compressive effects in compression-sensitive cavities or in patients with an increased risk of tissue rupture, or gas entrapment with compression, that may be life threatening.

Additional applicators may be purchased separately.

Table 3: Patient Accountability

Number Patients Treated

Table 7: Cumulative Number of Patients with Complete Sealing at 10 Minutes by Surgical Group

Table 6: Sites Achieving Immediate Sealing by Degree of Pressure Blending, All Treated Sites

COSEAL: 72 (100%)

COSEAL Control

Non-Healing Wound**

It is concluded that there was not an unexpected adverse event finding, either by event type or number, attributed more than the total difference between treatment groups.

Several analyses were conducted to evaluate the effectiveness data by treatment site and by patient. These

Table 2: Adverse Events

All treated and control patients for the 10 most commonly reported events. The results are similar between the two

Patient Achieving Complete Sealing

The Powder Component Pouch consists of two PEG powders in a powder syringe and a luer cap.

Table 4: Patient Achieving Immediate Sealing by Degree of Pressure Blending, All Treated Sites

Table 5: Sites Achieving Immediate Sealing by Degree of Pressure Blending, All Treated Sites

POWDER COMPONENT POUCH:

The Powder Component Pouch consists of a syringe containing two PEG powders in a powder syringe and a luer cap.

APPLICATION GUIDELINES:

APPLICATION POUCH:

Each applicator pouch contains a syringe, a luer cap, and a transfer port.

ADVERSE EVENTS

CONTRAINDICATIONS

There are no known contraindications for this device.

ADVANCED TREATMENT

In a prospective, randomized, controlled multicenter trial, 148 patients were treated with COSEAL or the control

COSEAL is indicated for use in vascular reconstructions to achieve adjunctive hemostasis by mechanically sealing areas of leakage.

DOSAGE AND ADMINISTRATION

The Powder Component Pouch consists of a syringe containing two PEG powders in a powder syringe and a luer cap.

APPLICATION POUCH:

Each applicator pouch contains a syringe, a luer cap, and a transfer port.

ADVERSE EVENTS

CONTRAINDICATIONS

There are no known contraindications for this device.

ADVANCED TREATMENT

In a prospective, randomized, controlled multicenter trial, 148 patients were treated with COSEAL or the control

COSEAL is indicated for use in vascular reconstructions to achieve adjunctive hemostasis by mechanically sealing areas of leakage.

DOSAGE AND ADMINISTRATION

The Powder Component Pouch consists of a syringe containing two PEG powders in a powder syringe and a luer cap.

APPLICATION POUCH:

Each applicator pouch contains a syringe, a luer cap, and a transfer port.

ADVERSE EVENTS

CONTRAINDICATIONS

There are no known contraindications for this device.

ADVANCED TREATMENT

In a prospective, randomized, controlled multicenter trial, 148 patients were treated with COSEAL or the control

COSEAL is indicated for use in vascular reconstructions to achieve adjunctive hemostasis by mechanically sealing areas of leakage.

DOSAGE AND ADMINISTRATION

The Powder Component Pouch consists of a syringe containing two PEG powders in a powder syringe and a luer cap.

APPLICATION POUCH:

Each applicator pouch contains a syringe, a luer cap, and a transfer port.

ADVERSE EVENTS

CONTRAINDICATIONS

There are no known contraindications for this device.

ADVANCED TREATMENT

In a prospective, randomized, controlled multicenter trial, 148 patients were treated with COSEAL or the control

COSEAL is indicated for use in vascular reconstructions to achieve adjunctive hemostasis by mechanically sealing areas of leakage.

DOSAGE AND ADMINISTRATION

The Powder Component Pouch consists of a syringe containing two PEG powders in a powder syringe and a luer cap.

APPLICATION POUCH:

Each applicator pouch contains a syringe, a luer cap, and a transfer port.

ADVERSE EVENTS

CONTRAINDICATIONS

There are no known contraindications for this device.

ADVANCED TREATMENT

In a prospective, randomized, controlled multicenter trial, 148 patients were treated with COSEAL or the control

COSEAL is indicated for use in vascular reconstructions to achieve adjunctive hemostasis by mechanically sealing areas of leakage.

DOSAGE AND ADMINISTRATION

The Powder Component Pouch consists of a syringe containing two PEG powders in a powder syringe and a luer cap.

APPLICATION POUCH:

Each applicator pouch contains a syringe, a luer cap, and a transfer port.

ADVERSE EVENTS

CONTRAINDICATIONS

There are no known contraindications for this device.

ADVANCED TREATMENT

In a prospective, randomized, controlled multicenter trial, 148 patients were treated with COSEAL or the control