1. Regulatory Information

1.1 Requirement Designator

The DuraSeal® dural sealant system is a class III medical device according to Rule 8 Annex IX of the European council Directive 93/42/ECC and its relatives. The Notified Body is TÜV Product Service (0123).

A copy of the current certificates and declarations of conformity relative to the DuraSeal® dural sealant system and to its application accessories (Extended Tip Applicator, MicroMyst® Applicator and Flow Regulator) are included in the Appendix.
Please note that regulatory documents for DuraSeal® dural sealant system might be updated. A copy of these updated documents will be provided when available.

1.2 Indications

The DuraSeal® dural sealant system is intended for use as an adjunct to standard methods of dural repair, such as sutures, to provide watertight closure.
The Extended Tip Applicator is intended for use in the simultaneous delivery of two non-homogenous solutions onto a surgical site.
The MicroMyst® Applicator is intended for use in the delivery of two non-homogenous solutions onto a surgical site.
The Flow Regulator is intended to provide pressurized gas (air or nitrogen) to gas-assisted applicators.

1.3 Contraindications

Do not apply the DuraSeal® Dural Sealant in abdominopelvic surgical procedures for use as a sealant or adhesion barrier.
Do not use Extended Tip Applicator, MicroMyst® Applicator and Flow Regulator for other indications than ones provided in the instructions for use.

2. Description and Presentation

2.1 Description

The DuraSeal® dural sealant system consists of components for preparation and delivery of a synthetic absorbable surgical sealant.
The surgical sealant is composed of two solutions: a polyethylene glycol (PEG) ester solution and a trilysine amine solution (referred to as the blue and the clear precursors, respectively).
When mixed together, the precursors link to form the surgical sealant. The mixing of the precursors is accomplished as the materials exit the tip of the applicator. DuraSeal® dural sealant system should be used within 1 hour of preparing the blue precursor.
The DuraSeal® dural sealant system is absorbed in a timeframe of 4 to 8 weeks, sufficient to allow for normal wound healing, is fully synthetic and has no human or animal derived products. All components are provided sterile.

2.2 Presentation

Powder Vial

Blue Precursor Syringe

Clear Precursor Syringe

3 Spray Tips

Dual Liquid Applicator

Syringe Holder

Plunger Cap