



TopClosure™ 3S System technical details

Component and adhesive structure:

TopClosure™ 3S System components (attachment plates and approximation strap) are composed of Polypropylene. There is no use of mold release agent or pigment in the manufacturing process.

Polypropylene's non toxic nature makes it suitable for medical applications, among which are medical devices, drug-delivery systems, and drugs packaging. Examples for products made of polypropylene include wound dressings, infant feeding tubes, syringes, spine support boards and blood oxygenator membranes. The chemical inertness of polypropylene enables long shelf-life, which is another important feature in the medical industry.

It is estimated that over 150 million pounds of polypropylene is used yearly in medical devices.

TopClosure™ 3S System attachment plate was designed to adhere to the skin in its non-invasive application by double-sided adhesive tape.

The Double-Sided Medical Tape is a hypoallergenic pressure sensitive adhesive. The tape is translucent, does not contain natural rubber latex, and is flexible and printable. The double-sided medical tape used for the adherence of the attachment plates to the skin has been already approved for medical use by the FDA and CE. It is fluid-repellent, allowing cleansing the wound surrounding without the fear of separation, maintaining its high adherence capability.

According to its product clinical data summary, the medical tape has been tested in accordance with the ISO 10993 Part-1 "Biological Evaluation of Medical Devices", as put forth by the FDA. The adhesive used in the tape has satisfied the requirements for devices in contact with intact skin for short term application (up to 29 days). All laboratory testing was conducted in accordance with the FDA Good Laboratory Practices Regulation of 1978.

The medical adhesive tape is compatible with ETO and Gamma sterilization.

Package content:

The package of the TopClosure™ 3S System contains 3 sets (each set is comprised of two attachment plates and an approximation strap). An additional approximation strap is provided in the package, for extending the approximation strap if needed. Two additional attachment plates are also provided.

3S System product line consists of three size options: 4mm, 6mm, 8mm.

