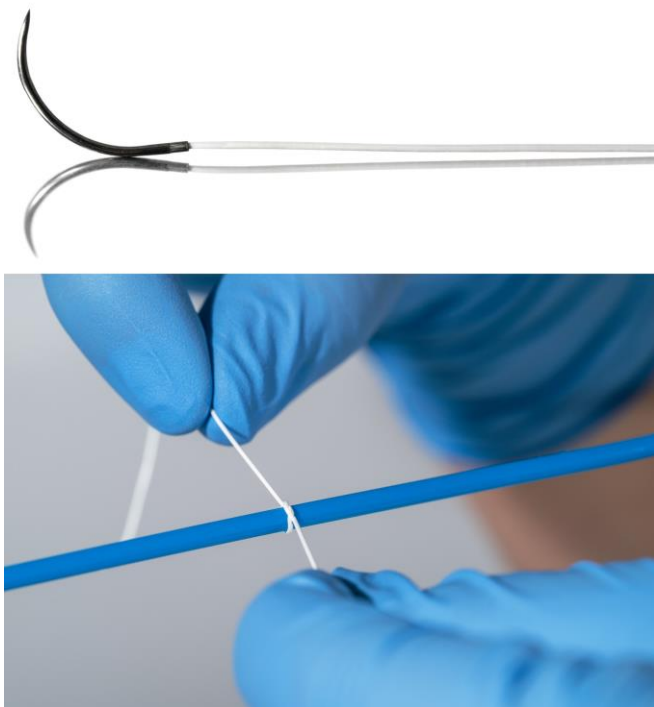


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SUTURES AND AEOS® ePTFE MONOFILAMENT



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INTRODUCTION AND HISTORICAL PERSPECTIVE

Sutures are fibers, filaments, or thread-like materials used to hold tissue or a wound together. In surgical terms, sutures are used for apposition – that is, the placing (of tissue) side by side to allow healing. Sutures provide tensile support for wounds until the healing tissue has regained sufficient strength to exist without the sutures. As ligatures, sutures are also used to tie off vessels to stop bleeding. Today we take these tools for granted as they have become ubiquitous, and it is difficult to imagine performing any kind of surgery without them.

Sutures, in fact, have been with us since before recorded memory and well before the earliest days of civilization. At least as far back as 30,000 B.C.E., eyed needles for sutures were used in Europe, and by 20,000 B.C.E. bone needles remained state-of-the-art until the 14th century. East Africans were known to have used tendons as ligatures to tie off blood vessels as well as acacia thorns with strips of vegetation as sutures. By 2000 B.C.E., sutures were being made from plant fibers such as cotton, hemp, bark fiber, flax, and even hair; and by 1600 B.C.E., catgut (twisted or braided animal intestines), and later silk, had become primary suture materials.

Aside from the suture materials themselves, early physicians took notice of how these ancient devices performed. The Greek surgeon Galen (ca. 150 A.D.), for example, suggested that sutures be made of a material that would not “rot,” perhaps giving rise to the concept of a permanently implantable type of suture. Later and juxtaposed to this idea, the 11th century Persian physician Avicenna observed that sutures made of certain natural fibers tended to break down rapidly when used on infected wounds. (To overcome this problem, Avicenna used pig bristles thus inventing the first monofilament suture). Avicenna’s realization that sutures could decompose hinted at the possibility for a deliberate dissolvable suture.

Despite their long-standing presence in medicine, by the turn of the 18th century sutures were still not universally preferred. Many highly regarded physicians still clung to methods such as cauterization for wound closure and hemostasis. Furthermore, certain adhesive bandages were known to dissolve when contacted with the drainage from wounds. American born and Scottish trained physician Philip Syng Physick quickly realized that ligatures which behaved in this way could be of significant value and a much less painful alternative to cauterization. Physick’s experimental – and absorbable – buckskin ligature was indeed successful. Carrying this idea forward, Joseph Lister (1827-1912), founder of aseptic technique, pioneered sterile sutures treated with his specialized carbolic acid solution. Lister’s carbolized absorbable catgut ligature was soon in use nearly everywhere.

TODAY'S SUTURES

Today's sutures are diverse and made in multiple forms and from a broad scope of materials. Absorbable and non-absorbable sutures are in common use and readers of this article have likely had them both during the course of their lives. Absorbable sutures have reached new levels of sophistication and specialization and can be customized to remain in the body for specified lengths of time. Non-absorbable sutures resist the body's attempts to dissolve them and have been improved to support tissue growth. Non-absorbable sutures may be removed or they may be left in the body as a permanent implant. Absorbable and non-absorbable sutures have their particular applications while providing a significantly expanded surgical portfolio.

As earlier physicians discovered, suture materials factor significantly into a suture's application. Today, sutures are made from both natural and synthetic materials. Silk, linen, and catgut are but a few of the natural materials used, while synthetic materials include polyglycolic acid, poly(*p*-dioxanone), and nylons. Polyesters, steel, nylons, and silk represent some of the common non-absorbable suture types, while catgut and glycolides fall into the absorbable category. Suture location, such as outside of the body or internal, and the ease and necessity of suture removal influence the decision on whether to use absorbable or non-absorbable sutures.

Equally important in governing how the suture will be used is suture form: monofilament or multifilament. Monofilament sutures consist of a single thread or fiber. Multifilament sutures consist of multiple strands or fibers that may be twisted or braided together to form a larger filament. Monofilament sutures have low surface drag and pass through tissue more easily than twisted or braided multifilament sutures; they sutures generally carry lower risk of infection. Multifilament sutures, on the other hand, are easier to knot and possess greater knot strength.

In addition to suture form, the mechanical properties of the suture figure prominently into its performance and application. Tensile strength, knot strength, and elasticity are all critical attributes that result from suture form, material, and size. Knot strength, for example, can be as low as 50% of the tensile strength of the straight unknotted suture. As another example, stiffness (sometimes referred to as memory) affects the ease of handling and tying of the suture. Sutures with high memory are stiff and resistant to mechanical deformation; this could mean that they untie easily or are difficult to manipulate during stitching. Collectively, suture mechanical properties help guide the surgeon's selection of suture materials for specific surgeries.

Lastly, there is the consideration of how the body reacts towards the sutures. As a foreign presence in the body, sutures can trigger an immune response. Additionally, damaged tissue resulting from the suture implantation will create concomitant inflammation. Immune reaction and inflammation can occur with absorbable and non-absorbable sutures. Typically visible as redness and swelling (and pain) at the suture

site, inflammation can be significant resulting in fever, reduced blood pressure, anaphylaxis, loss of function of the affected area, and further tissue damage. On occasion absorbable sutures are even rejected by the body instead of being absorbed. The degree to which sutures elicit immune and inflammatory responses plays a significant role in determining the extent to which the wound site is restored to its former state.

BIOCOMPATIBLE PLASTICS AND SUTURES

In light of the many of considerations for implantable sutures, it was a natural transition towards synthetic sutures whose properties could be tailored to improve outcomes. Typically made of polymer plastics, materials such as PTFE (polytetrafluoroethylene), PVDF (polyvinylidene difluoride), PVC (polyvinyl chloride), PP (polypropylene), PE (polyethylene), PC (polycarbonate), and PEEK (polyether ether ketone) have opened up many new applications for plastics in the medical device industry. Biocompatible plastics in their unadulterated form have inherent properties particularly suited to medical use. With minimal to no chemical reactivity within the body, many of these durable plastics are ideal as permanent or removable implants and show little to no toxic side effects.

PTFE, for example, has an extensive and successful history of use in medical applications. This highly unreactive fluoropolymer has been used for implantable device components such as vascular stent coverings and anastomosis for more than 20 years. A modified variant of PTFE known as expanded PTFE (ePTFE) has also found favor in the medical device industry. Created by mechanically expanding PTFE following extrusion under controlled conditions, ePTFE is a material with unique mechanical and microporous properties. ePTFE has been used in such diverse applications ranging from gasket material to membranes to sealer for flange joints. For biomedical applications, ePTFE was used as far back as 1979 as an artery tube. Today, ePTFE medical applications include ligament and tendon repair, surgical meshes, and vascular stent grafts.

ePTFE SUTURES

ePTFE sutures represent a continued evolution of this highly successful biocompatible material. Extruded as a monofilament, these non-absorbable sutures have been in use for nearly three decades. ePTFE monofilament has grown in popularity in the medical device industry because it has several advantages over other non-absorbable sutures. ePTFE has an extremely low coefficient of friction allowing sutures made from this material to pull through tissue easily. The compressible nature of the expanded polymer

material likewise results in a knot that does not loosen or slip. Compared to braided and absorbable sutures, ePTFE monofilament does not absorb saliva, bacteria, or blood thus promoting healing. Lastly, and perhaps most importantly, ePTFE sutures on whole do not cause irritation.

Of particular note with respect to ePTFE sutures is needle size. Earlier generations of sutures such as polypropylene typically only allowed needles to be swaged (*crimped* or *pressed*) onto them that were of slightly larger diameter than the suture fiber or filament. The result was a suture that created a hole in the tissue larger than the suture fiber resulting in increased bleeding. ePTFE monofilament, however, is highly compressible. Thus, when swaged onto needles, the diameter of the unswaged portion of the filament remains nearly equal to that of the swage itself. The result is a suture with a fiber or filament that more completely fills the hole in the tissue created by the needle thus reducing bleeding. Another benefit of ePTFE sutures is that they move through tissue more smoothly causing much less trauma to tissue when transitioning from needle to filament.

ZEUS AEOS® ePTFE SUTURE MONOFILAMENT

For many years, versions of ePTFE sutures have been available. However, and with occasional exceptions, these sutures were only available commercially as branded and complete products with needles swaged onto the suture fibers. Considering this status of the market, Zeus Industrial Products, Inc. (headquartered in Orangeburg, SC), has created a unique line of ePTFE suture monofilament: Zeus' Aeos® ePTFE monofilament non-absorbable suture (**Fig. 1**). This suture is intended for permanent implantation within the body. These sutures are available unbranded and in bulk (without needles) for users who wish to create their own suture lines. Offering this suture material unbranded addresses a key market preference and allows secondary vendors such as packaging and swaging companies to elevate their brand awareness.

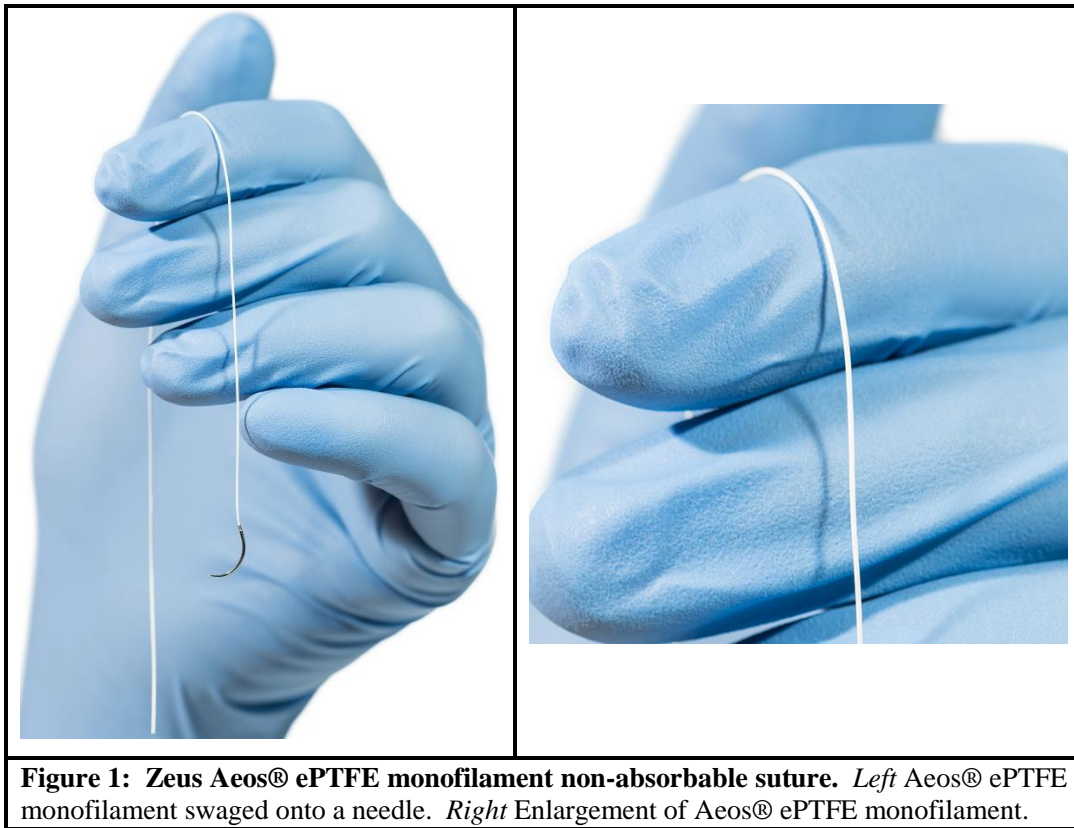
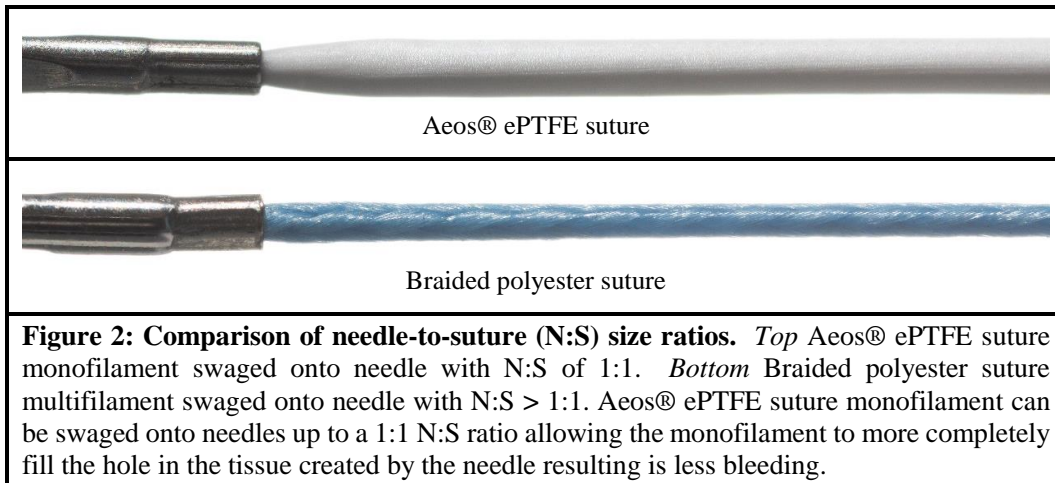
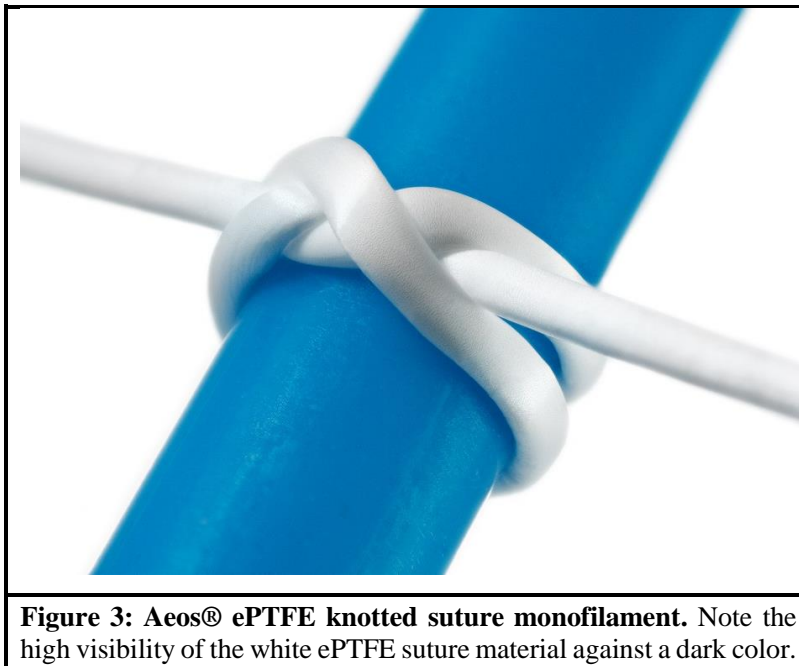


Figure 1: Zeus Aeos® ePTFE monofilament non-absorbable suture. *Left* Aeos® ePTFE monofilament swaged onto a needle. *Right* Enlargement of Aeos® ePTFE monofilament.

As ePTFE material, Zeus Aeos® sutures carry all of the beneficial traits of PTFE. These sutures feature supreme biocompatibility, excellent durability, and are chemically inert inside the body. The extremely low coefficient of friction of PTFE allows these sutures to pull through tissue with minimal drag. These sutures can also be swaged onto needles up to a 1:1 needle-to-suture (N:S) ratio (**Fig. 2**). These latter two elements in particular reduce tissue trauma at the surgical site resulting in less bleeding and minimal associated inflammation. As a microporous material, Aeos® sutures are highly amenable to new tissue growth into the sutures with long-term implantation resulting in very high levels of tissue encapsulation. Aeos® ePTFE sutures also can be sterilized by autoclaving and ethylene oxide (ETO), and PTFE is USP Class VI compliant as a medical polymer plastic.



In a surgical setting, Zeus Aeos® ePTFE sutures are easily integrated into any scenario where ePTFE sutures are appropriate. Sutures made with Aeos® ePTFE monofilament display easy handling, excellent drape, and soft feel in the surgeon's hand. The stiffness or memory of Aeos® sutures gives them dependable knot strength, and their high surface smoothness allows surgeons to place knots precisely (**Fig. 3**). The white color of Aeos® sutures results in excellent visibility in an application setting. Once in the body, Aeos® ePTFE sutures maintain high tensile strength making them suited to stressful anatomical environments. Aeos® sutures are also radiologically lucent and thus do not interfere with procedures such as MRI, angiography, or x-ray.



AEOS® ePTFE SUTURE APPLICATIONS

Zeus Aeos® ePTFE suture monofilament is particularly well-suited to applications as a permanently implantable medical device component. For anastomosis, as an example, Aeos® ePTFE sutures can be used to join vessels to circumvent damage, clots, and other disruptions in circulation. Aeos® sutures can be used for hernia repair to close the abdominal wall directly or to suture mesh in place. For stent deployment, the extremely high lubricity of Aeos® sutures allows surgeons to smoothly pull these sutures through the delivery system releasing the stent for final placement. For covered stents or stent grafts, Aeos® sutures can be used to suture the graft material to the wire stent frame. Finally, and perhaps most importantly, ePTFE sutures have gained wide acceptance for mitral valve repair or replacement of *chordae tendineae* in the heart. These sutures can effectively treat mitral valve regurgitation, and sutures of this type have shown safe and reproducible long-term benefits. Indeed, the versatility and biocompatibility of Aeos® ePTFE monofilament has placed sutures made from this material in ever greater demand.

SUMMARY

The invention of sutures to treat wounds extends back thousands of years. Trial and error taught the earliest humans that suture materials behaved differently and that some materials dissolved while others did not. With the development of civilization and the advancement and spreading of human knowledge, early physicians realized that they might be able to direct the behavior of certain suture types depending upon the material and nature of the wound. While considerable improvements to sutures were initially slow, the 19th century saw the development of sterile dissolvable and non-dissolvable sutures. The invention of plastics and their application towards sutures was a significant step in suture evolution. Today, there are myriad suture types including synthetic, natural, absorbable, and non-absorbable materials.

One of the most successful synthetic materials with suture applications has been PTFE and its variant, expanded PTFE (ePTFE). The unique microporous properties of ePTFE give it advantages over other polymers used in medical devices with particular benefits as a suture. Typically available only from large branded companies, there has been growing demand in the medical device market for an ePTFE suture material that could be purchased generically. Aeos® ePTFE suture monofilament is a new offering from Zeus Industrial Products, Inc., created especially to fill this market void. With decades of proven durability, biocompatibility, and safety of ePTFE, applications for Aeos® sutures are significant. Anastomosis, hernia repair, stent placement, and heart *chordae tendineae* repair can all be accomplished using Aeos® ePTFE sutures with many other applications possible. Zeus Aeos® ePTFE suture monofilament provides all of the hallmarks for safe and effective surgical interventions while being readily obtainable for non-exclusive or unbranded use.

ABOUT ZEUS

Zeus is the world's leader in polymer extrusion technologies. For over 50 years, Zeus has been serving the medical, aerospace, energy exploration, automotive, and fiber optics industries. Headquartered in Orangeburg, South Carolina, Zeus employs approximately 1,250 people worldwide and operates multiple facilities in North America and internationally. You can find us at www.zeusinc.com.

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