**SMB manufactures** non-absorbable surgical sutures meeting all the requirements for strength, quality and purity established by the United States Pharmacopoeia. They are manufactured in controlled environmental conditions to assure several fundamental characteristics like:

- Sterility
- Uniform diameter and size
- Pliability for ease of handling and knot security
- Uniform tensile strength by suture type and size
- Freedom from irritants or impurities that would elicit tissue reaction

A **suture material** is said to be ideal if it has the following characteristics:

- Sterile
- Non-electrolytic, non-capillary, non-allergenic and non-carcinogenic
- Easy to handle
- Minimally reactive in tissue and not predisposed to bacterial growth
  - Capable of holding tissue layers throughout the critical wound healing period securely when knotted without fraying or cutting
- Resistant to shrinking in tissues.
Polypropylene Monofilament

International quality polypropylene monofilament sutures for the most delicate speciality procedures.

VIRTUES
The strong, smooth, pliable SMB polypropylene suture provides superior handling, accurate knot placement and knot security with less throws.

* SMB Polypropylene a Versatile Monofilament, the suture of choice -
  * Uniform diameter with high tensile strength resists breakage
  * Soft, supple material reduces memory and improves handling
  * Passes through tissue easily
  * Highly visible in the wound
  * Increased suppleness and pliability
  * High degree of smoothness
  * Reasonable Elasticity
  * Strength plus suppleness results in greater knot security with fewer throws, less dispensing memory and improved handling characteristics.
  * Completely inert and non-capillary with minimal tissue reaction.

MATERIAL
Synthetic, Polypropylene Monofilament Suture is a Non-absorbable Surgical Suture. Blue colored for easy identification during Surgery.

Polypropylene Monofilament surgical suture meets all the requirements established by the United States Pharmacopoeia (U.S.P.) for diameter, knot pull strength and needle detachment strength.
SMB Polypropylene Monofilament show 50% more knot pull strength and needle detachment strength than limits specified for Class I sutures in current USP. A comparative analysis is placed below.

<table>
<thead>
<tr>
<th>Sr.No.</th>
<th>USP size</th>
<th>USP Avg. Needle Detachment strength (Kg)</th>
<th>SMB Avg. Needle Detachment strength (Kg)</th>
<th>USP Avg. knot pull strength (Kg)</th>
<th>SMB Avg. knot pull strength (Kg)</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>1.80</td>
<td>3.00</td>
<td>2.72</td>
<td>3.50</td>
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<td>0</td>
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<td>2.68</td>
<td>2.16</td>
<td>3.10</td>
</tr>
<tr>
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<td>2.23</td>
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<td>2.33</td>
</tr>
<tr>
<td>4</td>
<td>3/0</td>
<td>0.68</td>
<td>1.10</td>
<td>0.96</td>
<td>1.30</td>
</tr>
<tr>
<td>5</td>
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<tr>
<td>6</td>
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</tr>
<tr>
<td>7</td>
<td>6/0</td>
<td>0.17</td>
<td>0.28</td>
<td>0.20</td>
<td>0.30</td>
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<tr>
<td>8</td>
<td>7/0</td>
<td>0.080</td>
<td>0.16</td>
<td>0.11</td>
<td>0.20</td>
</tr>
<tr>
<td>9</td>
<td>8/0</td>
<td>0.050</td>
<td>0.070</td>
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<td>0.075</td>
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</table>

**TISSUE REACTION**
Minimal tissue reaction. Does not support any infection. As a monofilament, it has no interstices to support bacterial growth. It is unwetted by blood, unweakened by tissue enzymes, offers prolonged tensile strength even in infected areas.

**APPLICATIONS**
Polypropylene Monofilament is indicated for use in Cardiovascular, Ophthalmic, General Closure, Orthopedics, Plastic and Microsurgeries, soft tissue approximation and / or ligation. The suture is highly visible in the wound. The lack of adherence to tissues has facilitated the use of SMB Polypropylene suture as a pull out suture.

**CHOICE**
Polypropylene Monofilament suture is available in sizes USP 8/0 through 1 supplied sterile with various types of atraumatic eyeless needles in one dozen boxes. They are packed in strength configuration Tyvek Pouches for minimal memory.

**CAUTION**
Avoid damage to the surface of suture, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments, such as forceps or needle holders. Adequate knot security requires the accepted surgical techniques of flat, square ties, with additional throws as warranted by surgical circumstances and the experience of the surgeon.

**WARNINGS**
As with any foreign body, prolonged contact of this or any other suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation. Users should be familiar with surgical procedures and techniques involving non absorbable sutures before employing Polypropylene Monofilament surgical suture for wound closure as risk of wound dehiscence may vary with the site of application and the suture material used. Acceptable surgical practice should be followed with respect to drainage and closure of contaminated or infected wounds.

**ABSTRACT**
Polypropylene Monofilament suture has evolved as the standard suture for the majority of cardiovascular procedures. This suture is known for low tissue drag, easy handling and good strength.

**STERILIZATION**
By Ethylene Oxide Gas Sterilization.
**Strong, Long Lasting Polyester Braided Sutures with PTFE Coating.**

International quality strong, long lasting braided polyester sutures with PTFE coating.

**VIRTUES**

SMB Polyester braided suture with PTFE coating offers utmost lubricity
- Heavy PTFE coating and tight weave provide minimum friction, allowing the suture to pass easily through the most friable tissue
- Heavy coating also eliminates dead space
- Knots slide smoothly and offers best knot security
- It is strong inert and compatible with body tissue
- Easy to handle and provokes less tissue reaction
- Smoother and stronger than Silk
- Provides high tensile strength and long lasting support, which is critical in cardiovascular and orthopedic applications.

**MATERIAL**

The unique PTFE coating and impregnation process helps to reduce “dead space” in the braid, rendering the suture material virtually inert and reducing the risk of wicking and tissue reactivity, while providing superior lubricity. Polyester Braided Suture with PTFE Coating is available in White and Green color. The product meets all the requirements established by the United States Pharmacopoeia (U.S.P.) for diameter, knot pull strength and needle detachment strength. SMB Polyester Sutures with PTFE coating show 50% more knot pull strength and needle detachment strength than limits specified for Class I sutures in current USP.
Polyester Braided Suture
Silicon Coated

International quality braided polyester suture silicon coated.

VIRTUES
- The fine braiding of Polyester gives this material an excellent smoothness
- Easy to handle, its uniform surface minimizes the trauma.
- Its higher tensile strength and good knot security provide long-term wound support.
- Monofilament like structure allows easy passage through tissue.
  Strong, secure and is ideal for use where extended approximation of tissue under stress is required.

MATERIAL
Silicon coated Polyester Suture is biologically inert, non-absorbable suture. SMB polyester is coated with specially developed silicon for extra smooth surface and non capillary action. The product meets all the requirements established by the United States Pharmacopoeia (U.S.P.) for diameter, knot pull strength and needle detachment strength. SMB Polyester Suture show 50% more knot pull strength and needle detachment strength than limits specified for Class I sutures in current USP.

A comparative analysis is placed below.

<table>
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<th>Sr.No.</th>
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<tr>
<td>1</td>
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<td>1.80</td>
<td>2.7</td>
<td>2.72</td>
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<td>2.25</td>
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<tr>
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<td>1.47</td>
<td>0.96</td>
<td>1.69</td>
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<tr>
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<td>7</td>
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<td>0.17</td>
<td>0.30</td>
<td>0.20</td>
<td>0.41</td>
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</table>

TISSUE REACTION
Polyester Surgical Suture elicits a minimal acute inflammatory reaction in tissue, which is followed by gradual encapsulation of the suture by fibrous connective tissue. Polyester Surgical Suture is not absorbed, nor is any significant change in tensile strength retention known to occur in vivo.

APPLICATIONS
Polyester Suture is indicated for use in Cardiovascular, Ophthalmic, neurological procedures and also used in general soft tissue approximation and! or ligation.

CHOICE
Polyester Suture available in USP sizes 6/0 through 1 supplied Green / White sterile in precut lengths both non needled and affixed to various types of atraumatic needles in one dozen boxes.

CAUTION
Avoid damage to the surface of suture, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments, such as forceps or needle holders. Adequate knot security requires the accepted surgical techniques of flat, square ties, with additional throws as warranted by surgical circumstances and the experience of the surgeon.

STERILIZATION
Polyester Suture Silicon coated is sterilized by Gamma Sterilization whereas Polyester Suture with PTFE coating is sterilized by Ethylene Oxide Gas Sterilization.
Silk Braided Suture  
Silicon Coated

International Quality Black Braided Silicon coated Silk Suture

VIRTUES
- The finest quality braided natural silk for the ultimate in handling and knot security.
- Silk is degummed to the highest level to eliminate all toxic elements for the maximum safety and reliability.
- Silk is dyed with non-irritant and non-toxic colors. It is colored black for higher visibility during surgery and has least memory. Its modern braiding techniques provide a uniform, smooth and a greater tensile strength than the prescribed USP limits.

MATERIAL
Silk Surgical Suture is coated with specially developed silicon for extra smooth surface like monofilament, which allows easy passage through the tissue and non capillary action. Silk Surgical Suture meets all the requirements established by the United States Pharmacopeia (U.S.P.) for diameter, knot pull strength and needle detachment strength. SMB Silk Surgical Suture show 50% more knot pull strength and needle detachment strength than limits specified for Class I sutures in current USP.

A comparative analysis is placed below.

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<tr>
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<td>0.17</td>
<td>0.34</td>
<td>0.20</td>
<td>0.40</td>
</tr>
</tbody>
</table>

TISSUE REACTION
Silk surgical suture elicits minimal acute inflammatory reactions in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissue. While Silk suture is not absorbed, progressive degradation of the proteinaceous silk fiber in vivo may result in gradual loss of the suture’s tensile strength over time.

CAUTIONS
The use of this suture is contraindicated in patients with known sensitivities or allergies to silk. Due to the gradual loss of tensile strength, which may occur over prolonged periods in vivo, Silk suture should not be used where permanent retention of tensile strength is required.

APPLICATION
Indicated for use in Cardiovascular, ophthalmic and neurological procedures and also in general, soft tissue approximation and / or ligation.

CHOICE
Silk Surgical Suture is available in USP sizes 6/0 through 2 supplied Sterile in precut lengths non needed and affixed to various types of atraumatic needles in one dozen boxes, also non sterile on spools of 25mtrs in container of 6 spools.

WARNING
In case of Non Sterile Spools repeated and prolonged sterilization should be avoided for superior performance.

STERILIZATION
Silk Surgical Suture is sterilized by Gamma Radiation or by Ethylene Oxide Gas Sterilization.
Polyamide Monofilament Surgical Suture

VIRTUES
- The uniform and smooth surface allows tissue penetration with minimum trauma, extremely well tolerated
- Being a monofilament it has no interstices to support bacterial growth
- Polyamide Monofilament Suture is a suture of choice for Microsurgery
- SMB Polyamide is as inert as steel and has high in vivo strength and easy removal with no tissue adherence
- It will not support bacterial growth and has the further advantage of minimal tissue irritation
- It is remarkably smooth and easy for the surgeon to handle.

MATERIAL
Polyamide Monofilament suture dyed blue or black colored for easy identification during surgery. Polyamide Monofilament meets all the requirements established by the United States Pharmacopoeia (U.S.P.) for diameter, knot pull strength and needle detachment strength. SMB Polyamide Monofilament show 50% more knot pull strength and needle detachment strength than limits specified for Class I sutures in current USP

A comparative analysis is placed below.

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<tr>
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<tr>
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<tr>
<td>9</td>
<td>7/0</td>
<td>0.080</td>
<td>0.16</td>
<td>0.11</td>
<td>0.20</td>
</tr>
</tbody>
</table>

TISSUE REACTION
Polyamide Monofilament Suture elicits a minimal acute inflammatory reaction in tissues.

CHOICE
Polyamide Monofilament Suture available in USP sizes 7/0 through 2 supplied Sterile in precut lengths non needled and affixed to various types of atraumatic needles in one dozen boxes, also non sterile Hanks in bundle of 1000/100 strands.

WARNING
In case of Non Sterile Spools repeated and prolonged sterilization should be avoided for superior performance.

STERILIZATION
Polyamide Monofilament Surgical Suture is sterilized by Ethylene Oxide Gas sterilization.
SMB Atraumatic suture needles are manufactured from superior quality Martensitic grade of stainless steel conforming to German specification Werkstoff nr. 1.4031, equivalent to BS: EN 56D, JIS : SUS 420 J2 or AISI : 420. Needles are hardened and tempered to a controlled hardness of VPN 525-625 which ensure adequate stiffness to withstand the pressure encountered in the suturing procedure while eliminating brittleness.

The composition of this grade of stainless steel is as follows:

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<tbody>
<tr>
<td>C</td>
<td>0.32-0.40%</td>
</tr>
<tr>
<td>Si</td>
<td>1.00%max.</td>
</tr>
<tr>
<td>Mn</td>
<td>1.00%max.</td>
</tr>
<tr>
<td>P</td>
<td>0.04%max.</td>
</tr>
<tr>
<td>S</td>
<td>0.03%max.</td>
</tr>
<tr>
<td>Ni</td>
<td>0.60%max.</td>
</tr>
<tr>
<td>Cr</td>
<td>12.5-14.0%</td>
</tr>
</tbody>
</table>

All needle points are honed to ensure the highest standards of sharpness. The needles are polished to remove micro-asperities on the surface by a series of mechanical operations followed by electro-polishing. This reduces tissue drag to a minimum during the suturing operation. Needles are also offered with a 'ribbed' body to increase the stiffness of the needle body and to improve the stability in the needle holder when used by the surgeon.

**Drilled-end type needles:**

These needles are made from non-free cutting grade of the stainless steel, which has ductility and corrosion resistance superior to the free cutting grade which most manufacturers use. This type of needles is said to cause the least trauma.

The drilled end of our needle is not annealed as done by other manufacturers resulting in the following advantages:

- The corrosion resistance of the needle is unimpaired.
- There is no potential loss of stiffness of the needle due to imprecise annealing.
- The grip on the suture obtained after swaging is better. Though this requires a higher swaging force, the attaching strength obtained is higher than with annealed end needles.

**Cardiovascular Needles:**

SMB Cardiovascular needles are made from special maraging steel conforming to ‘Custom 455’, & Custom 470 duly age-hardened to around VPN 580 to 650 so as to give optimum strength & ductility after heat treatment. This grade of steel offers much greater strength and resistance to bending as compared with austenitic or martensitic grades of steel.
The cardiovascular needles are designed with a lower needle-to-suture diameter ratio to reduce risk of leakage at the needle tract during anastomosis. The cardiovascular needles have a long taper ratio point, with superior penetration characteristics and reduced tissue drag.

All cardiovascular needles are siliconised using Dow Corning silicone grade MDX 4-4159, duly cured. The silicone coating considerably reduces tissue drag and enhances point durability.

**Micro Suture Needles:**

Micro Needles meet the highest standards of modern micro surgery. Micro needles are made from special quality maraging steel conforming to, ‘Custom 455, Custom 465 & Custom470’, duly age hardened to around VPN 570 to 600 so as to give optimum strength & ductility after heat-treatment.

Micro needles are available in several variations e.g.
- Square-flattened needles with spatulated or taper point
- Triangular needles with reverse cutting point
- Slim blade micro-needles with cutting edge point

**Channel Type Needles:**

In this type of needles, the channels are cold forged to close tolerances to ensure that final dimensions of the channel correspond to the suture diameter. Furthermore, the needles manufactured are uniformly heat-treated. Most manufacturers anneal the channel end to avoid cracking during crimping. The metallurgy of needles permits a hardened channel to be crimped satisfactorily without any problems; this results in uniform metallurgy of the needle and thereby improved corrosion resistance as well as resistance to bending.

The needles conform to the general requirements for suture needles as specified in IS:9165-1992 and also conform to the corrosion resistance requirements as per IS:7531-1990.

A strict Quality Control protocol is followed at each stage of manufacture. The tests include point sharpness, stiffness of the needles, corrosion resistance, ductility and hardness measurement.
Since its introduction to the industry more than 30 years ago, DuPont™ Tyvek® brand protective material has been recognized as a standard of excellence for medical packaging. Tyvek® earned this distinction because it provides a higher degree of protection for medical devices and supplies than any other porous material used for sterile packaging applications.

The unique structure of Tyvek® gives it inherent advantages over other materials. Specifically, Tyvek® offers:

**Superior Tear Strength And Puncture Resistance**

The tough, continuous fibers of Tyvek® protect package integrity from both product breakthrough inside and rough handling outside. Tyvek® is so tough, it resists punctures - even from the irregular or sharp edges of many surgical devices.

**Excellent Barrier To Microbial Penetration**

The number-one priority in selecting packaging materials for medical devices is the ability of the package to maintain sterility from the point of sterilization until it is opened for the product to be used.

Even under the most rigorous conditions in highly contaminated environments, Tyvek® is highly resistant to penetration by bacteria spores and other contaminating microorganisms. Bacteriological tests clearly demonstrate that Tyvek® outperforms other commercially available porous packaging materials, including medical-grade papers. Comprehensive shelf-life studies have shown that Tyvek® can maintain sterility for at least five years if package integrity is not compromised.

(The photomicrographs shown here illustrate how bacteria are trapped on the fiber surfaces of Tyvek®)

**Figure 1. Scanning electron micrographs (SEMs) of Tyvek.**
The unique structure of Tyvek, which creates a tortuous path with substantial lateral movement, results in superior microbial barrier properties.

**Figure 2. Microbial barrier test results.**
Per ASTM F1608. Microbial barrier is the measure of the ability of a porous substrate to prevent bacteria penetration. A completely impermeable control sample (microbial penetration is zero) is challenged with
one million or $10^6$ colony forming units (cfu). The number of cfu $10^6$ has a log value of 6. If a sample challenged in the same way as the control allows 10 cfu (log 10 = 1) to penetrate, then its log reduction value (LRV) is 5 (6-1=5). Therefore, the higher the LRV, the more resistant the packaging is to bacteria and microorganisms.

**Superior Tear Strength And Puncture Resistance**

The tough, continuous fibers of Tyvek® protect package integrity from product breakthrough and also from penetration by an object outside the packaging during rough handling. Compared to medical-grade papers, Tyvek® provides superior puncture resistance and tear strength, which means that Tyvek® does not puncture easily and tears do not readily propagate if a package is nicked.

Tyvek® is up to eight times stronger than medical-grade papers of equal or greater basis weight, so it resists punctures even from the irregular or sharp edges of many surgical devices. In contrast, one small tear in a package made of medical-grade paper can contaminate a sterilized device and compromise the entire sterile field.

**Figure 3. Elmendorf Tear (MD) test results.**
Per ASTM D1424 and DIN EN 21974. Elmendorf Tear measures the force required to propagate an initiated tear from a cut or a nick. MD signifies machine direction. The higher the value, the less likely a material will tear under force.

**Figure 4. Spencer puncture test results.**
Per ASTM D3420. (Probe ?16-fl. [14.3-mm] diameter). Spencer Puncture is the measure of the ability of a substrate to resist puncture by impact using a bullet-shaped probe. The higher the value, the less likely an object striking the package (from the inside or on the outside) will break through, compromising the package's sterility and/or damaging the medical device.
Clean peel
Unlike paper, which can release a significant number of particulates when a package is opened, Tyvek® is known for its clean peel and low-linting features. Particulate generation tests comparing Tyvek® to medical-grade papers provide conclusive evidence that Tyvek® generates far fewer airborne particulates that could contaminate the medical device or the wound site.

Outstanding water resistance
Tyvek® is highly resistant to penetration by water and other liquids. In fact, water in contact with Tyvek® does not "wet" its surface, which means that water does not spread but remains as droplets on the surface of Tyvek®. Even in the event of accidental laboratory or operating room spills, Tyvek protects the integrity and sterility of packaged medical devices. Unlike medical-grade papers, Tyvek® maintains its strength, both wet and dry. Because Tyvek® does not get wet by water, it will not absorb water and, therefore, contamination of the product by waterborne organisms is highly unlikely.

DET NORSKE VERITAS

MANAGEMENT SYSTEM CERTIFICATE

Certificate No. 26946-2008-AQ-IND-NA

This is to certify that the Management System of:

SMB Corporation of India

13, 33-36, Prem Industrial Estate, 400 060 MUMBAI, India

has been found to conform to the standard:


This Certificate is valid for the following product or service ranges:

Manufacturing and supply of intra-uterine contraceptive devices and non-absorbable sutures.

Initial Certification date:
13 April 2005

This Certificate is valid until:
13 April 2014

The audit has been performed under the supervision of
Atoma Dutta
Lead Auditor

Place and date:
Havik, 12 April 2011

for the Accredited Unit:
DET NORSKE VERITAS
CERTIFICATION AS, NORWAY

Eugenie Winger Husebye
Management Representative

Lack of fulfillment of conditions as set out in the Certification Agreement may render this Certificate invalid.

HEAD OFFICE, Det Norske Veritas AS, Vennelysten 1, 3221 EKEØ, Norway. Tel +47 55 31 9000 Fax +47 55 37 99 11 - www.dnv.com
SMB CORPORATION OF INDIA
(AN ISO 9001:2000 / CE CERTIFIED COMPANY)

PREM INDUSTRIAL ESTATE, SUBHASH ROAD,
JOGESHWARI (EAST), MUMBAI - 400 060, INDIA.
TEL: +91-22-3293 7949, +91-22-2834 5637
FAX: +91-22-2821 5157
E-mail: sales@smbcorpn.com
Website: www.smbcorpn.com