

MonoMax®

Description

MonoMax® is a sterile long term absorbable monofilament surgical suture made from poly(4-hydroxybutyrate) (C₄H₆O₂)_n polymer. MonoMax® is dyed using D&C violet No. 2 (color index number 60725), a dyestuff approved for monofilament sutures by the FDA, but it's also available undyed in the natural beige colour. MonoMax® complies with all requirements of the European Pharmacopoeia as well as the United States Pharmacopoeia for sterile synthetic absorbable monofilament sutures, except for a minor oversize in diameter.

Maximum Suture Oversize in Diameter (mm) From USP

USP suture size designation	Maximum oversize (mm)
5-0	0,029
4-0	0,029
3-0	0,090
2-0	0,060
0	0,100
1	0,071
2	0,039

Indications

MonoMax® absorbable sutures are indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.

Mode of application

Sutures should be selected depending on the tissue to be sutured, the specific duration of wound support needed from the suture material, the size of the wound, the patient's condition and the specific suturing technique.

Mode of action

Consecutively to its implantation, MonoMax® is degraded by hydrolysis and via enzymatic pathways. The final degradation product of the fiber, 4-hydroxybutyric acid, is a natural metabolite of the human body that is primarily converted to carbon dioxide and water. The degradation process leads to a successive decrease of the material's tensile strength and finally to a complete mass absorption of the fiber. Subcutaneous implantation studies in rabbits and rats revealed the following degradation profile (Weeks post-implantation - Approximate breaking strength retention):

Time	USP 5/0 - 4/0	USP 3/0 - 2/0	USP 0 - 1 - 2
4 weeks	~60 %	~ 90 %	~90 %
12 weeks	~20 %	~60 %	~70 %
26 weeks	N / A	< 25 %	~60 %
Complete Absortion	12 - 18 months		22 - 28 months

In consequence to the implantation and absorption process, MonoMax® elicits a mild inflammatory reaction at the implantation site, which is characteristic for an endogenous reaction to a foreign body.

Contra-indications

The usage of MonoMax® is contra-indicated for tissues that require a permanent wound support, the approximation of tissues under tension or for the suturing of synthetic implants like vascular grafts and cardiac valves. MonoMax® sutures should not be used for persons with a known intolerance towards the poly(4-hydroxybutyrate) raw material.

Warning notes / precautionary measures

- Users should be familiar with the surgical suturing techniques of absorbable monofilament sutures before applying MonoMax®.
- The user must take into consideration that the risk of wound dehiscence may vary depending on the implantation site and the type of suture material used.
- As with any other suture materials, prolonged contact with salt solutions, such as urine and bile, can lead to calculus formation.
- The implantation of MonoMax® in low vascularized tissue can lead to a delayed absorption. Usage of MonoMax® may not be advised for patients suffering from diseases or conditions in which a delayed wound healing process is known or evident.
- As MonoMax® is an absorbable suture material, the surgeon should consider the use of supplemental non-absorbable sutures in the closure of wounds which may undergo expansion, stretching or distension, or which may require additional support.
- Contaminated or infected wounds should be treated following the appropriate surgical practice. MonoMax® should be used applying the standard surgical suturing and knotting techniques, taking into account the surgeon's experience with the respective surgical procedure. Care should be taken that the knots are positioned properly and adequate knot security is given. At least a minimum of 4 correctly placed square and flat knots should be done.
- When working with MonoMax® suture material, great care should be taken to avoid any crushing or crimping damage of the monofilament by instruments such as forceps or needle holders. In certain applications (e.g. in orthopaedics) immobilization by external support may be employed besides the surgical use of MonoMax®.
- Care should be taken to avoid damaging the needle when using the suture material. Always grasp the needle in a section 1/3 to 1/2 of the distance from the fiber attachment end to the needle point, never at the end where the fiber is attached or the needle point. Grasping the needle at the area of its point could impair the penetration performance and cause a fracture of the needle. Grasping the needle close to the fiber attachment end could cause bending or breakage. Reshaping needles should be avoided and may result in a loss of their strength and resistance towards bending and breaking. Care must also be taken to avoid needle stick injuries when handling with surgical needles. Discard the needles after use in specially intended containers.
- The polymer absorbable sutures have not been tested in neural tissue or in adult cardiovascular tissue, nor have they been evaluated for ophthalmic or neural surgery.
- Device manufacture involves exposure to tetracycline hydrochloride and kanamycin sulphate. The safety and product use for patients with hypersensitivities to these antibiotics are unknown.

Side effects

As for every other absorbable suture material, the usage of MonoMax® can be accompanied by transient local irritations of the wound site and a transient inflammatory foreign body reaction. Hardening of tissues may not always be avoided during absorption of subcuticular sutures and existing infections may occasionally be enhanced.

Sterilization

MonoMax® is sterilized by ethylene oxide gas. Do not resterilize the sutures. In case that the individual suture container has been damaged or opened before the actual use, discard the affected suture.

Storage

Store at room temperature. Avoid exposure to extreme temperatures over a long period of time. Do not use after the expiry date.

How supplied

MonoMax® sutures are available undyed (clear) and dyed with violet colour, sutures in sizes 5/0 through 2 (metric sizes 1,5 – 6) in a variety of lengths with or without needles attached.

For more detailed information on the suture range and the needle types, please see B. Braun Aesculap's catalogue "Sutures and Surgical Specialities".

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

CUSTOMER SERVICE

For further information regarding Monomax® Suture please contact Tissue Seal, LLC's Customer Service at 1-877-754-6458 or customerservice@tissue seal.com

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