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INSTRUCTION FOR USE

MADASILK

Black Braided Silk
Non-Absorbable Surgical Suture USP
Sterile Surgical Needled Suture

MADASILK is a sterile, non-absorbable surgical suture composed of braided silk and supplied with an attached surgical needle.

The suture is black in colour to enhance visibility during surgical procedures. The braided construction provides handling characteristics suitable for tissue approximation and ligation where the use of a non-absorbable surgical suture is clinically indicated.

MADASILK is available in different USP sizes with 75 cm suture length and 3/8 circle reverse-cutting needles in various needle lengths.

COMPOSITION

1. Braided natural silk
2. Black colourant/dye suitable for surgical suture use
3. Attached surgical-grade stainless-steel needle

INTENDED USE

MADASILK is intended for use in general soft-tissue approximation and/or ligation, including use in dental and oral surgical procedures, where the use of a non-absorbable braided surgical suture is appropriate.

INDICATIONS

MADASILK may be used for soft-tissue approximation and/or ligation in procedures including:

- Dental and oral surgical procedures.
- Closure of extraction and surgical sites.
- Periodontal surgical procedures.
- Oral soft-tissue approximation.
- Other surgical procedures where a non-absorbable silk suture is clinically indicated.

The selection of suture size, needle size, and suturing technique should be determined by the healthcare professional according to the tissue characteristics, wound condition, surgical procedure, and clinical requirements.

INSTRUCTIONS FOR USE

- Select the appropriate MADASILK suture size and needle configuration for the intended procedure.
- Inspect the sterile package before use. Do not use if the package is opened, damaged, wet, or otherwise compromised.
- Open the sterile package using an appropriate aseptic technique.
- Remove the suture carefully from the package, avoiding damage, kinking, crushing, or unnecessary handling.
- When handling the needle, grasp it with an appropriate needle holder. Avoid grasping the needle near the point or attachment area.

- Approximate the tissue using an appropriate surgical suturing technique.
- Apply sufficient tension to achieve secure tissue approximation without excessive tightening, strangulation, or damage to the tissue.
- Secure the suture using an appropriate surgical knot technique.
- Trim the suture ends as clinically appropriate.
- After completion of the procedure, dispose of the needle immediately in an approved sharps container.
- Monitor the surgical site according to standard clinical practice.
- Where removal is clinically required, remove the suture at an appropriate time based on the surgical site, tissue healing, and clinical assessment.

Important Application Information

- Sterile – Single Use Only.
- Do not reuse.
- Do not resterilize.
- Do not use if the sterile barrier system is damaged or compromised.
- Do not use after the expiry date.
- Discard any unused suture from an opened package.
- Selection and application of the suture should be performed by a qualified healthcare professional.

WARNINGS

- MADASILK should be used only by qualified healthcare professionals trained in surgical suturing techniques.
- Do not reuse or resterilize. Reuse may result in contamination, infection, loss of performance, or other patient risks.
- Do not use if the sterile package has been opened or damaged.
- Care should be taken to avoid excessive tension during suturing, as this may cause tissue damage, ischemia, or wound complications.
- Surgical needles may cause accidental needlestick injuries. Handle and dispose of needles using appropriate sharps precautions.
- Avoid crushing, bending, or damaging the suture with surgical instruments.
- Avoid unnecessary damage or deformation of the surgical needle during handling.
- As silk is a braided natural fibre, prolonged contact with body fluids may result in gradual loss of tensile strength over time.
- Appropriate surgical technique should be used to minimize the risk of wound infection and other postoperative complications.

PRECAUTIONS

- Use appropriate aseptic surgical technique.
- Select the appropriate suture diameter and needle size for the tissue and procedure.
- Avoid crushing or flattening the suture with forceps or needle holders.

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- Avoid excessive manipulation of the suture.
- Grasp the needle appropriately with a needle holder to minimize bending or breakage.
- Exercise particular care when using the suture in contaminated or infected wounds.
- Monitor the wound for signs of infection, inflammation, dehiscence, or other adverse reactions.
- Remove the suture when clinically indicated.

CONTRAINDICATIONS

- MADASILK should not be used:
- In patients with a known allergy or hypersensitivity to silk or any component of the product.
- In clinical situations where long-term permanent retention of tensile strength is required.
- Where the use of a braided non-absorbable suture is considered clinically inappropriate.
- In tissues or procedures for which another type of suture material is specifically required.

POSSIBLE ADVERSE EFFECTS

- Local tissue irritation or inflammation.
- Transient inflammatory tissue reaction.
- Infection.
- Wound dehiscence.
- Granuloma or foreign-body reaction.
- Suture sinus formation.
- Hypersensitivity or allergic reaction.
- Tissue injury caused by excessive suture tension.
- Needle-related injury.

Appropriate clinical management should be provided if an adverse reaction occurs.

STERILITY

- MADASILK is supplied sterile in an individual sterile barrier system.
- STERILE – SINGLE USE ONLY
- Do not reuse. Do not resterilize.
- Do not use the product if the sterile barrier system is damaged, opened, or otherwise compromised.

STORAGE

- Store in a clean, cool, and dry place.
- Protect from moisture and direct sunlight.
- Protect from excessive heat.
- Keep in the original packaging until immediately before use.
- Do not use after the expiry date indicated on the packaging.

SHELF LIFE

Refer to the expiry date indicated on the product packaging.

PRESENTATION

MADASILK – Black Braided Silk, Non-Absorbable Surgical Suture USP
Common specifications: Suture length 75 cm | Needle 3/8 Circle, Reverse Cutting | 12 sterile sutures/pack

REF	USP	Metric	Needle
5D75CX19	1-0	4	19 mm
5D75CX24	1-0	4	24 mm
5E75CX16	2-0	3	16 mm
5E75CX19	2-0	3	19 mm

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5E75CX24	2-0	3	24 mm
5F75CX19	3-0	2	19 mm
5F75CX24	3-0	2	24 mm
5G75CX19	4-0	1.5	19 mm
5G75CX24	4-0	1.5	24 mm
5H75CX19	5-0	1	19 mm
5H75CX24	5-0	1	24 mm
5I75CX19	6-0	0.7	19 mm
5I75CX24	6-0	0.7	24 mm

Pack: 12 individually packed sterile surgical needled sutures.

DISPOSAL

Immediately dispose of used surgical needles in an approved sharps container.
Dispose in accordance with applicable healthcare waste regulations and local requirements in the country of use.

CONTACT

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This material is intended solely for professional dental use. Application must be carried out strictly according to the instructions for use. The manufacturer accepts no liability for damages resulting from failure to follow the provided instructions or for use beyond the stipulated applications. The user is responsible for assessing the material's suitability for any purpose not explicitly stated in this instruction sheet. The descriptions and data provided do not constitute a warranty of attributes and are not legally binding.

This product is specially formulated for use in dentistry and to be used by qualified dental personnel

Symbol for "TEMPERATURE LIMITATION"
Symbol for "KEEP OUT OF THE REACH OF CHILDREN"
Symbol for "DO NOT USE IF PACKAGE IS DAMAGE"
Symbol for "KEEP AWAY FROM SUNLIGHT"
Symbol for "MANUFACTURER NAME & ADDRESS"
Symbol for "CONSULT INSTRUCTION FOR USE"
REF Symbol for "CATALOGUE NUMBER"
MD Symbol for "MEDICAL DEVICE"
Symbol for "KEEP DRY"
Symbol for "DO NOT RESTERILE"
LOT Symbol for "BATCH CODE"
Symbol for "CAUTION"
STERILE EO Symbol for "STERILIZED USING ETHYLENE OXIDE"
Symbol for "USE BY"

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