Mamba Suture Passer and Needle
Instructions for Use

ATTENTION OPERATING SURGEON

DESCRIPTION
The Biomet Sports Medicine Mamba instruments are utilized to aid in passing suture through soft tissue. The Mamba Needle (Figure B) is designed for use with the Mamba Suture Passer (Figure A). The needles are sterile, disposable, and for single-patient use only.

MATERIALS
- Nitinol
- Acrylonitrile butadiene styrene (ABS)
- Stainless Steel
- Silicone
- Polytetrafluoroethylene (PTFE)

INSTRUCTIONS FOR USE

NOTE: Carefully read the following instructions prior to surgical use.

Load Mamba Needle into the instrument:
1. Locate the cannulated shaft on the proximal end of the Mamba Suture Passer handle (Figure A1). Insert the needle forward until the button is aligned with the round notch of the needle actuator (Figure A2). Press button in place until fully seated in the Needle Actuator.

Load Suture:
2. Locate the distal tip of your passing suture. Slide the suture into the lower jaw suture slot with the free end downwards (Figure C). Keep tension on both ends of the suture. Apply light palm pressure to the needle actuator (Figure A2) to slightly advance the needle (Figure C1) until the suture loads into the needle eyelet (Figure C2). The suture must be secured by the needle eyelet to function properly.

NOTE: Advancing the needle too far may prevent the suture from properly loading into the needle eyelet.

Introduction and Passing of Suture:
3. A 5mm diameter or larger cannula may be used during arthroscopic approach. The forward lever on the Mamba Suture Passer is used to close the jaw. Position the jaw for appropriate bite of tissue and fully close the jaw when ready to pass suture.

NOTE: Top jaw must remain fully closed to ensure proper suture passing. Failure to ensure jaw remains fully closed may result in device malfunction.

4. With the top jaw fully closed, advance the needle actuator with light palm pressure to advance the needle forward, passing suture through tissue.

5. Retract the needle by removing palm pressure from the needle actuator.

6. Black Mamba Suture Passer: The suture is captured by the “trap door” to reduce extra suture retrieval steps. Release the forward lever to open jaw while pulling suture through an opening in the tissue and out of the shoulder.

A. Once the Black Mamba Suture Passer is removed from the shoulder, pull on one end of suture towards the handle to release from the “trap door”.

Figure A. Mamba Suture Passer.

Figure B. Mamba Needle.

Figure C. Mamba Suture Passer Jaw.
WARNINGS
1. The Surgeon is to be familiar with the equipment, instruments and surgical procedure prior to performing surgery.
2. The Mamba Needles are for single-patient use only. Do not reuse. Do not attempt to clean or re-sterilize this product. After use, this product may be a potential biohazard.
3. Do not use Mamba Needles that have been, even momentarily, placed in a different patient.
4. Users should exercise caution when handling surgical needles. Discard used needles in “sharps” container.
5. DO NOT USE opened or damaged instruments, and use only instruments that are packaged in unopened or undamaged containers.
6. Do not over-stuff the jaw with tissue.
7. Do not apply excessive force to the Needle Actuator.
8. Do not use if there is a loss of sterility of the instrument.
9. Correct handling of instruments is extremely important. Most instruments are not intended to be modified, notched, bent, etc. as notches, scratches or other damage and/or wear in the instrument occurring during surgery may contribute to breakage or affect the performance of the instrument. The nitinol wire is meant to be pliable during use.

PRECAUTIONS
Instruments are available to aid in the accurate implantation of internal fixation devices. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments that have experienced extensive use or excessive force are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Biomet Sports Medicine recommends that all instruments be regularly inspected for wear and disfigurement prior to surgery.

- The Mamba Suture Passer and Needle were designed for use with MaxBraid Suture. Use of Mamba instruments with suture from other manufacturers may compromise the integrity of the instrument and/or suture.
- All trial, packaging, and instrument components must be removed prior to closing the surgical site. Do not implant.
- The patient is to be warned by his/her physician of all surgical risks.

RESPONSIBILITIES OF THE USER

CLEANING AND DECONTAMINATION
1. Removal of Visible Contamination- The effectiveness of subsequent decontamination processes depends on prior removal of visible soil. Thoroughly clean instruments until visibly clean, repeating as necessary, prior to initial sterilization and as soon as possible after use. Do not allow soil to dry on the instruments. If cleaning must be delayed, place groups of instruments in a covered container with appropriate detergent or enzymatic solution to delay drying. Wash all instruments whether or not they were used or inadvertently came into contact with blood or saline solution. Visible soil should be removed under running water using a mechanical aid, such as a brush with rigid nylon bristles or pipe cleaner. Care should be taken to reduce splashing and generating aerosols by holding instruments below the surface of the water in a sink into which water is running and continuously draining. Instruments should not be held under a running tap, as this is likely to result in splashing.
2. Disassembly - The Mamba Suture Passer has been constructed in such a way that the device should be disassembled into their individual part components prior to decontamination as described in the DISASSEMBLY INSTRUCTIONS. Particular attention should be taken to remove all debris from all cannulations, crevices, serrations, and obscure holes in the instruments.

DISASSEMBLY INSTRUCTIONS
NOTE: Remove the Mamba Needle from the instrument prior to disassembly.

1. Locate the arrow on the top of the instrument (Figure D1) where the shaft meets the handle.
2. Compress the shaft and handle by pushing them together where the arrow is pointing to the lock symbol on the handle (Figure D2).

NOTE: The trigger must be pushed all the way forward for disassembly (Figure D3).

3. While shaft and handle are compressed, rotate the shaft until the arrow is pointing to the unlock symbol on the side of the handle (Figure E1).
4. Remove the shaft from the handle (Figure E2).
5. Separate spring from the main shaft, exposing cannulation (Figure F).

NOTE: Handle with care as the shaft may be more vulnerable to damage in this position.

Figure D, Disassembly Steps 1 & 2.

Figure E, Disassembly Steps 3 & 4.

Figure F, Disassembly Step 5.

3. Washing/Disinfecting - It is recommended that the instruments are disassembled as described in the DISASSEMBLY INSTRUCTIONS and decontaminated using an automatic washer-disinfection unit.
utilizing thermal disinfection. This should preferably be of the ultrasonic or continuous tunnel process type. The cabinet type is an acceptable alternative if a continuous process machine is not available. Compatible detergents and rinse aids may be used as recommended by the manufacturer of the washer-disinfection unit. These detergents and/or rinse aids, however, should be of neutral or near neutral pH. Excessively acidic or alkaline solutions may corrode aluminum instruments. The following table provides a validated method for cleaning instruments.

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<th>Time (Minutes)</th>
<th>Temperature &amp; Water Quality</th>
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<td>Detergent Wash</td>
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<td>Enzol per manufacturer instruction</td>
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**PREPARATION AND ASSEMBLY FOR STERILIZATION**

After cleaning/disinfecting, the disassembled instruments should be reassembled and should be sterilized in a separate container or pouch.

**Sterility.** The health care facility is responsible for ensuring that any packaging method or material, including a reusable rigid container system, is suitable for use in sterilization processing and sterility maintenance in a particular health care facility. ANSI/AAMI ST79 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health care Facilities and ISO 17665-1 Annex D Sterilization of health care products Moist heat Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices provides guidelines for preparation and assembly, sterilization cycle, quality assurance, sterile storage, transport, and aseptic use.

**CARE AND HANDLING**

Surgical instruments are susceptible to damage for a variety of reasons including prolonged use, misuse, rough or improper handling. Care must be taken to not compromise their exacting performance. To minimize damage and risk of injury, the following should be done:

- Inspect the instruments for damage upon receipt and after each use and cleaning. Instruments in need of repair should be set aside for repair service or returned to Biomet. Instruments returned to Biomet or its distributors should be cleaned and sterilized prior to shipment. ANSI/AAMI ST35 Safe Handling and Biological Decontamination of Reusable Medical Devices in Health Care Facilities and in Nonclinical Settings provide guidelines for return, or contact Biomet or your distributor for further instruction.
- When handling sharp instruments use extreme caution. Consult with an infection control practitioner to develop and verify safety procedures appropriate for all levels of direct instrument contact.

**STERILITY**

**Mamba Needles**

The Mamba Needles are supplied sterile by Ethylene Oxide Gas (ETO). Single Use Only. Do Not Reuse. Do not use any instrument from an opened or damaged package. Do not resterilize. Do not use past expiration date.

**Mamba Passers**

Unless otherwise indicated, instruments are NOT STERILE and must be thoroughly cleaned and sterilized prior to use.

Instruments should NOT be flash-autoclaved. Flash-autoclaving of individual instruments should be avoided. Biomet Mamba Passers can be steam autoclaved and repeat autoclaving will not adversely affect them, unless otherwise indicated in the labeling. If you have any problems when using Biomet Mamba Instrumentation please bring this to Biomet’s or its distributor’s attention when you return them. Instruments returned to Biomet or its distributors should be cleaned and sterilized prior to shipment.

**ANSI/AAMI ST79 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities** provides guidelines for return or contact Biomet or your distributor for further information.

Set forth below is a recommended minimum cycle for steam sterilization that has been validated by Biomet under laboratory conditions.

Use of ANSI/AAMI ST79 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities is recommended. When used in the U.S., sterilization wraps and rigid containers used during the steam sterilization process are to be FDA cleared.

Individual instruments should be sterilized within a Tyvek pouch of suitable size or placed in an empty mesh tray that can be wrapped or placed inside a rigid container.

The following cycle parameters are for individual instrument or individual instruments in a rigid container up to 22.5 lbs (10kgs).

**U.S. PARAMETERS**

**DYNAMIC-AIR-REMOVAL STEAM STERILIZER**

270°F (132°C)– Wrapped per manufacturer’s instructions

4 minutes exposure time – 30 minutes drying time (allow for cooling)

**INTERNATIONAL PARAMETERS**

**DYNAMIC-AIR-REMOVAL STEAM STERILIZER**

134°–137°C (274°–278°F) – Wrapped per manufacturer’s instructions

3 minutes exposure time – 30 minutes drying time (allow for cooling)

**STORAGE AND SHELF LIFE**

Individual instruments that have been processed and wrapped to maintain sterility should be stored in a manner to avoid extremes in temperature and moisture. Care must be exercised in handling of individual instruments to prevent damage to the sterile barrier. The health care facility should establish a shelf life for sterilized instrumentation based upon the type of sterile wrap or rigid container used and the recommendations of the sterile wrap or rigid container manufacturer. The user must be aware that maintenance of sterility is event-related and that the probability of occurrence of a contaminating event increases over time, with handling, and whether woven or non-woven materials, pouches, or container systems are used as the packaging method.

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

Comments regarding Biomet Sports Medicine products can be directed to Attn: Regulatory Dept., Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, Fax: 574-372-3968.

**CE Mark on the package insert (IFU) is not valid unless there is a CE Mark on the product (description) label.**

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Enzol is a registered trademark of Johnson & Johnson Co. Renu-Klenz is a trademark of Steris Corporation.

Tyvek is a trademark of E.I. DuPont de Nemours and Company

Authorized Representative: Biomet U.K., Ltd.

Waterton Industrial Estate

Bridgend

CF31 3XA UK
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