BLIS™

Bausch + Lomb Injector System Handpiece

en

For Injection of One-Piece Foldable Intraocular Lenses

DESCRIPTION

The Bausch + Lomb Injector System (BLIS) is used for folding and delivering into the eye Bausch + Lomb enVista® intraocular lenses as indicated in the table below. BLIS™ consists of two devices, a handpiece and a cartridge.

- The BLIS Handpiece, model **BLIS-R1**
  The handpiece is an autoclavable, reusable handpiece with titanium and stainless steel components (**Fig. 1**). The handpiece is composed of a body (**Fig. 2-A**) and a plunger (**Fig. 2-B**) and is provided non-sterile and must be cleaned and sterilized before use. The BLIS Handpiece is designed for use with the BLIS Cartridge only.
- The BLIS Cartridge, model **BLIS-X1** and model **BLIS-X0**
  The cartridge is a single-use only cartridge that is provided sterile (**Fig. 4**) and designated for use as follows:

enVista Model	Dioptric Power (D)	BLIS Cartridge Model
MX60	+0.0 to +34.0 D	BLIS-X0
	+10.0 to +34.0 D	BLIS-X1
MX60T	+6.0 to +9.5 D	BLIS-X0
	+10.0 to +30.0 D	BLIS-X1
MX60E	+0.0 to +34.0 D	BLIS-X1

INDICATIONS FOR USE

BLIS is indicated for the folding and injection of Bausch + Lomb intraocular lenses identifying BLIS in their approved labeling.

⚠ **CAUTION:**

Do not use the handpiece if the plunger tip appears damaged in any way.

INSTRUCTIONS FOR USE

Handpiece Preparation

1. Inspect the handpiece to ensure that it is not damaged. In the event the handpiece appears damaged or incapable of proper use, do not use and contact your Bausch + Lomb customer service representative or affiliate.
2. Clean and sterilize the handpiece before use in accordance with the methods specified in the **Instructions for Reprocessing**. Sterility assurance is the responsibility of the user.
3. Assemble the plunger to the body by pushing the key on the barrel into the slot (**Fig. 3-A**) on the body (**Fig. 3-1**). With the key in the slot, rotate the coupler (**Fig. 2-C**) clockwise (**Fig. 3-2**) until the body and plunger are securely connected.
4. Push the knob (**Fig. 2-E**) forward until the threads contact the barrel (**Fig. 2-D**). Turn the knob clockwise to ensure the plunger can be advanced smoothly and completely.

Loading the Lens into the Cartridge

Note: Folding and compression of the lens should be initiated just prior to insertion and delivery into the eye. Avoid excess dwell (>3 minutes) time between loading and lens insertion to minimize the potential for delivery complications including lens damage.

1. Inspect the cartridge tray before use. If the tray is damaged or seal is open, do not use the cartridge. Open the cartridge tray and transfer the sterile cartridge into the sterile field. If the cartridge is damaged, deformed, or has visible particulates, do not use.
2. Apply Bausch + Lomb viscoelastic into the cartridge from the proximal end (**Fig. 5**).
3. Hold the cartridge with lens diagram (**Fig. 4-A**) facing up.
4. Using forceps, grasp the lens by the optic edge with the anterior side up (**Fig. 6**). Engage the leading haptic with the notch to initiate tucking of the haptic over the lens optic (**Fig. 7**).
5. Slowly advance the lens into the cartridge such that the optic is a little more than halfway inside the cartridge (**Fig. 8**).
6. Push the optic down onto the base of the cartridge. Fold the trailing haptic over the top of the optic (**Fig. 8**) and into the cartridge.
7. Push the lens past the line (**Fig. 9-A**) so that the lens is held in the folded position. Once the lens is past the line, ensure that the lens and haptics remain in place after retracting the forceps until it is ready to be delivered. The cartridge is now ready to be installed into the handpiece.

Installing the Loaded Cartridge into the Handpiece

1. Fully retract the handpiece plunger.
2. Hold the cartridge with lens image facing up (**Fig. 4-A**).
3. Slide the loaded cartridge into the handpiece.
4. Push the cartridge forward into the hooks (**Fig. 10-1**) and then press the proximal end of the cartridge down to seat it fully (**Fig. 10-2**). The cartridge will snap into place when it is fully seated. If it does not snap, repeat this step until you feel it snap.
5. Advance the handpiece plunger until the threads engage. BLIS is now ready for lens insertion.

Lens Delivery

1. Insert the cartridge tip bevel down into the incision.
2. Rotate the handpiece knob clockwise to advance the plunger. Ensure that the plunger tip engages the lens and remains behind the lens throughout the entire delivery until the lens is fully released into the eye.

Note: If the plunger goes over or under the lens, retract the plunger and remove the cartridge. Using a new lens, repeat steps under **Loading the Lens into the Cartridge** and **Installing the Loaded Cartridge into the Handpiece**.

3. After the lens is fully delivered, withdraw the injector from the incision.

Removal of Cartridge from the Handpiece

1. Rotate the knob counterclockwise to withdraw the plunger completely from the cartridge.
2. Remove the cartridge from the handpiece.
3. Dispose of the cartridge in accordance with applicable regulations regarding the disposal of biohazardous materials.
4. Advance the plunger and wipe clean immediately after each use.
5. Clean and sterilize the handpiece in accordance with the methods specified in the **Instructions for Reprocessing**.

INSTRUCTIONS FOR HANDPIECE REPROCESSING

First Use

The BLIS handpiece is supplied non-sterile and must be cleaned and sterilized before the first use and with each additional use. Both a manual cleaning procedure and an automated washer cleaning procedure are presented for the user to select.

General Instructions

The following instructions have been validated by Bausch + Lomb as being **capable** of preparing the handpiece for reuse. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel in the facility to achieve the desired results. This requires routine verification and monitoring of the processes. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences. Please refer to nationally recognized standards, such as AAMI[1,2,3] standards, or to your facility's standard procedures.

Note: If required, a program for thermal disinfection (at least 1 minute at 90°C) may be used.

1. All cleaning and sterilization processes require validation at the point of use. Their effectiveness will depend on many factors and it is only possible to provide general guidance on proper device cleaning and sterilization.
2. Clean the handpiece immediately before first use and after each subsequent use.
3. The plunger barrel must be free of the threaded knob for effective cleaning and sterilization.
4. Due to the potential for the accumulation of particulate and bioburden residue in the automated cleaner and sterilizer washer water reservoirs, it is the surgical facility's responsibility to properly maintain the equipment and their associated filters to ensure the introduction of contaminant-free solutions onto the handpiece.
5. Do not clean the handpiece with non-ophthalmic products.
6. Use only demineralized, distilled, reverse osmosis, deionized or purified water for rinsing and cleaning. Do not use saline or balanced salt solution for rinsing or cleaning.
7. Proper wrapping or pouching of surgical instruments will reduce the exposure of instruments to process residues and contact with other instruments which may result in discoloration of the instruments when titanium and stainless steel instruments are sterilized together.
8. Due to the potential for Toxic Anterior Segment Syndrome (TASS), Bausch + Lomb does not recommend the use of enzymatic cleaners and detergents. If, however, local jurisdictions mandate their use relative to ophthalmic instruments, the materials of construction are compatible with both, up to a pH of 11.3.

Assembled Handpiece Disassembly

1. While holding the coupler (**Fig. 2-C**), rotate the plunger barrel (**Fig. 2-D**) counterclockwise to disengage the plunger from the main body (**Fig. 11-1**).
2. Pull the plunger completely out of the main body (**Fig. 11-2**).
3. With the two parts disassembled and the barrel (**Fig. 2-D**) free of the threaded knob (**Fig. 2-E**), the handpiece is now ready for cleaning and sterilization.

Manual Handpiece Cleaning Procedure for Neutral Detergents

1. Completely detach the plunger from the body for cleaning per the **Handpiece Disassembly** instructions.
2. Rinse the plunger and body under running warm water (22° - 43°C) for a minimum of 1 minute. Remove viscoelastic and cellular debris using a soft-bristled brush or a clean, soft, lint-free cloth.
3. Prepare a neutral pH detergent cleaning solution using a neutral pH detergent (such as Alconox Luminox) per the manufacturer's instructions.
4. Fully immerse the plunger and body in the fresh, newly prepared neutral pH detergent cleaning solution for 2 to 10 minutes.
5. While immersed, manually clean the body and plunger using soft-bristled brushes for a minimum of 1 minute. Ensure that the brush accesses the inner lumens and threaded areas. Submerge the components under the surface of the solution while cleaning to prevent aerosolization of contaminants.
6. Remove the plunger and body from the cleaning solution and thoroughly rinse with running lukewarm water (22° - 43°C) for a minimum of 1 minute.
7. Dry with a clean, soft, lint-free cloth.
8. Visually inspect that the handpiece is thoroughly clean. If required, repeat the relevant previous cleaning steps as necessary.

Automated Handpiece Cleaning Procedure for Neutral Detergents

Note:
- This automated washing procedure provides a method per ISO 17664[4] for effectively processing the handpiece.
- The temperatures and cycle parameters below will not cause damage to the product.
- Use a neutral pH detergent (such as Alconox Luminox) per the manufacturer's instructions.

1. Completely detach the plunger from the body for cleaning per the **Handpiece Disassembly** instructions.
2. Rinse the plunger and body under running lukewarm water (22° - 43°C) for a minimum of 1 minute. Remove viscoelastic and cellular debris using a soft-bristled brush or a clean, soft, lint-free cloth.
3. Prepare a neutral pH detergent cleaning solution using a neutral pH detergent (such as Alconox Luminox) per the manufacturer's instructions.
4. Fully immerse the plunger and body in the fresh, newly prepared neutral pH detergent cleaning solution for 2 to 10 minutes.
5. While immersed, manually clean the body and plunger using soft-bristled brushes for a minimum of 1 minute. Ensure that the brush accesses the inner lumens and threaded areas. Submerge the components under the surface of the solution while cleaning to prevent aerosolization of contaminants.
6. Thoroughly rinse the body and plunger device with lukewarm (22° - 43°C), running tap water for a minimum of 30 seconds.
7. It is recommended to manually clean the handpiece immediately after the surgical procedure in accordance with the methods specified in the **Manual Handpiece Cleaning Procedure for Neutral Detergents** before using an automated washer.
8. Completely detach the plunger from the body and ensure that the plunger barrel is free of the threaded knob prior to cleaning.
9. Place devices in the automated washer in a suitable carrier that ensures both the protection of the instrument and access to surfaces for cleaning.
10. Prepare the washer per equipment Operator's Manual.
11. Set detergent dispensers as recommended by detergent and washer manufacturers.
12. Program washer to have the following automated cycle:
    a. Prewash with cold water (15°C or less) for 2 minutes (no detergent).
    b. Wash cycle with heated water (66°C) for 2 minutes.
    c. Wash cycle with heated water (66°C) and Alconox Luminox detergent for 2 minutes.
    d. Rinse with heated (66°C) deionized or high purity water for 15 seconds.
    e. Dry at 115.5°C for 7 minutes.
13. Visually inspect that the handpiece is thoroughly clean. If required, repeat the relevant previous cleaning steps as necessary.

Manual Handpiece Cleaning Procedure for Alkaline and Acidic Detergents

1. Completely detach the plunger from the body for cleaning per the **Handpiece Disassembly** instructions.
2. Rinse the plunger and body under running lukewarm water (22° - 43°C) for a minimum of 1 minute. Remove viscoelastic and cellular debris using a soft-bristled brush or a clean, soft, lint-free cloth.
3. Prepare an alkaline detergent cleaning solution, such as **neodisher MediClean forte**, per the manufacturer's instructions.
4. Fully immerse the plunger and body in the fresh, newly prepared alkaline detergent cleaning solution for 10 to 30 minutes.
5. While immersed, manually clean the body and plunger using soft-bristled brushes for a minimum of 1 minute. Ensure that the brushes access the inner lumens and threaded areas. Clean the components under solution to prevent aerosolization of contaminants.
6. Remove the plunger and body from the alkaline cleaning solution and thoroughly rinse with deionized or high purity lukewarm water (22° - 43°C) for a minimum of 30 seconds.
7. Dry with a clean, soft, lint-free cloth.
8. Visually inspect that the handpiece is thoroughly clean. If required, repeat the relevant previous cleaning steps as necessary.

Automated Handpiece Cleaning Procedure for Alkaline and Acidic Detergents

Note:
- This automated washing procedure provides a method per ISO 17664[4] for effectively processing the handpiece.
- The temperatures and cycle parameters below will not cause damage to the product.
- Use an alkaline detergent, such as **neodisher MediClean forte**, per the manufacturer's instructions.
- Use an acidic detergent, such as **neodisher Z**, per the manufacturer's instructions.

1. Completely detach the plunger from the body for cleaning per the **Handpiece Disassembly** instructions.
2. Rinse the plunger and body under running lukewarm water (22° - 43°C) for a minimum of 1 minute. Remove viscoelastic and cellular debris using a soft-bristled brush or a clean, soft, lint-free cloth.
3. Prepare an alkaline detergent cleaning solution, such as **neodisher MediClean forte**, per the manufacturer's instructions.
4. Fully immerse the plunger and body in the fresh, newly prepared alkaline detergent cleaning solution for 10 to 30 minutes.
5. While immersed, manually clean the body and plunger using soft-bristled brushes for a minimum of 1 minute. Ensure that the brushes access the inner lumens and threaded areas. Clean the components under solution to prevent aerosolization of contaminants.
6. Remove the plunger and body from the alkaline cleaning solution and thoroughly rinse with deionized or high purity lukewarm water (22° - 43°C) for a minimum of 30 seconds.
7. It is recommended to manually clean the handpiece immediately after the surgical procedure in accordance with the methods specified in the **Manual Handpiece Cleaning Procedure for Alkaline and Acidic Detergents** before using an automated washer.
8. Completely detach the plunger from the body per the **Handpiece Disassembly** instructions.
9. Place devices in the automated washer in a suitable carrier that ensures both the protection of the instrument and access to surfaces for cleaning.
10. Prepare the washer per equipment Operator's Manual.
11. Set detergent and neutralizer dispensers as recommended by detergent and washer manufacturers.
12. Program washer to have the following automated cycle:
    a. Prewash with lukewarm water (22° - 43°C) for 3 minutes (no detergent).
    b. Wash Cycle-1 with heated water (50° - 60°C) and **neodisher MediClean forte** alkaline detergent per manufacturer's instructions for 10 minutes.
    c. Wash Cycle-2 with heated water (40° - 60°C) and **neodisher Z** acidic detergent per manufacturer's instructions for neutralization for 90 seconds.
    d. Rinse with heated water (40° - 60°C) for 5 minutes.
    e. Rinse with lukewarm (22° - 43°C) deionized or high purity water for 10 seconds.
    f. Dry at 115.5°C for 7 minutes.
13. Visually inspect that the handpiece is thoroughly clean. If required, repeat the cleaning process as necessary.

Handpiece Sterilization

Sterilize the handpiece using a steam sterilization cycle. The sterilization instructions provided in Table 1 have been validated by Bausch + Lomb as being **capable** of sterilizing the handpiece for reuse.

Table 1: Sterilizer Cycle Settings

Sterilizer Type	Pulses	Sample Configuration	Set Temperature	Minimum Exposure Time (Minutes)	Minimum Drying Time (Minutes)
Pulsing Pre-vacuum*	3	Wrapped	132°C (270°F)	4.0	20
Pulsing Pre-vacuum*	3	Wrapped	134°C (273°F)**	3.0	20

* Also known as dynamic air removal sterilizers.

** This cycle is not for use in the United States.

Note: The 134°C (273°F)/18 minutes sterilization cycle is not considered by the United States Food and Drug Administration (US FDA) to be a standard sterilization cycle. User should only use sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators and sterilization containers) that have been cleared by the US FDA for the selected sterilization cycle specifications 134°C (273°F)/18 minutes.

Handpiece Storage

After handpiece sterilization, the instrument may be stored in a clean area free of temperature and humidity extremes in accordance with your institution's policies.

References

1. ANSI/AAMI ST79: Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
2. AAMI TIR12: Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for device manufacturers.
3. AAMI TIR30: A Compendium of processes, materials, test methods and acceptance criteria for cleaning reusable medical devices.
4. ISO 17664: Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices.

PRECAUTIONS AND WARNINGS

1. U.S. Federal law restricts the handpiece and cartridge to sale by or on the order of a physician.
2. Failure to follow the **Instructions For Use** may result in patient injury.
3. Inspect the handpiece to ensure that it is not damaged. Instruments which exhibit visible corrosion, pitting, flaking, excessive wear, bent shafts, or failure to operate smoothly should not be used. In the event the handpiece appears damaged or incapable of proper use, do not use and contact your Bausch + Lomb customer service representative or affiliate.
4. The BLIS Handpiece is designed for use with the BLIS Cartridge only. The cartridge is intended for single use only. Reuse and/or resterilization of the cartridge may compromise device performance, which could cause serious harm to the patient's health and safety.
5. The handpiece is non-sterile and must be cleaned and sterilized prior to each use per the **Instructions for Reprocessing**.
6. The plunger barrel must be free of the threaded knob for effective cleaning and sterilization.
7. For colored instruments, mixing titanium and stainless steel instruments during sterilization may result in discoloration of the instruments.
8. If, in the opinion of the physician, a patient with a prion-related disease undergoes a high risk procedure, the handpiece should be destroyed or be processed according to applicable regulations.
9. Loading of the lens should be done just prior to insertion and delivery.
10. The BLIS Cartridge is validated for use with Bausch + Lomb viscoelastics only.
11. The use of viscoelastics is required when loading the lens into the BLIS Cartridge. Do not use balanced salt solution.
12. Do not store the BLIS Cartridge at temperatures over 25°C (77°F).

SURGICAL PROCEDURE

The appropriate surgical techniques are the responsibility of the individual surgeon. Surgeons must determine the suitability of any particular procedure based on their medical training and experience.

WARRANTY AND LIMITATIONS OF LIABILITY

Manufacturer's liability is restricted to the performance of repairs resulting from product defects, which are clearly not the result of incorrect handling.

Handpiece Warranty

The BLIS Handpiece is warranted for a lifetime against defects in material and workmanship when used for its intended surgical purpose. Bausch + Lomb will repair or replace, at its option, any BLIS Handpiece found to be defective in materials or workmanship.

Handpiece Repair Warranty

Repairs performed by Bausch + Lomb for other than defective materials or workmanship are warranted for a period of 30 days from date of the repair invoice.

BAUSCH & LOMB INCORPORATED EXCLUDES ALL WARRANTIES, WHETHER EXPRESSED, IMPLIED OR BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS. BAUSCH & LOMB INCORPORATED SHALL NOT BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL OR EXEMPLARY LOSS, DAMAGE OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM THE USE OF THE BLIS BAUSCH + LOMB INJECTOR SYSTEM EVEN IF BAUSCH & LOMB INCORPORATED HAS BEEN ADVISED OR THE POSSIBILITY OF SUCH LOSS, DAMAGE OR EXPENSE. BAUSCH & LOMB INCORPORATED IS NOT RESPONSIBLE FOR ANY DAMAGE TO THE PRODUCT DUE TO IMPROPER STERILIZATION, CARE AND HANDLING, OR MISUSE.

RETURN GOODS POLICY

All products returned to Bausch & Lomb Incorporated must be accompanied by a Return Authorization number. Call 1-800-338-2020 for a return authorization and full policy information. Outside the USA, contact your customer service affiliate.

SYMBOLS USED ON HANDPIECE LABELING

Symbol	Description	Symbol	Description
⚠	Caution	NON STERILE	Non-Sterile
(umbrella)	Keep Dry	(green dot)	Meets EU Packaging Directive
(damaged package)	Do Not Use if Package is Damaged	℞ ONLY	Prescription Only (USA)
SN	Serial Number	REF	Catalogue Number
(factory)	Manufacturer	EC REP	Authorized Representative in the European Community
(factory outline)	Date of Manufacture		

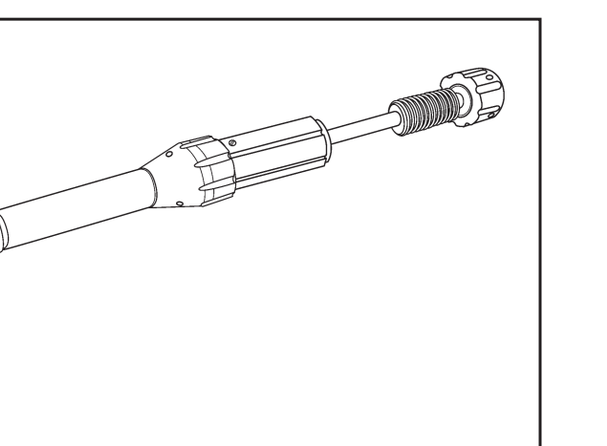
Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14609 USA

EC REP Bausch & Lomb GmbH
Brunsbütteler Damm 165-173
13581 Berlin, Germany

Manufactured By: Bausch & Lomb Incorporated, 3365 Tree Court Industrial Blvd., St. Louis, MO 63122 USA

®/™ are trademarks of Bausch & Lomb Incorporated or its affiliates. All other brand/product names and/or logos are trademarks of their respective owners.
© Bausch & Lomb Incorporated

4108005 Rev. 2018-07


FIG. 1

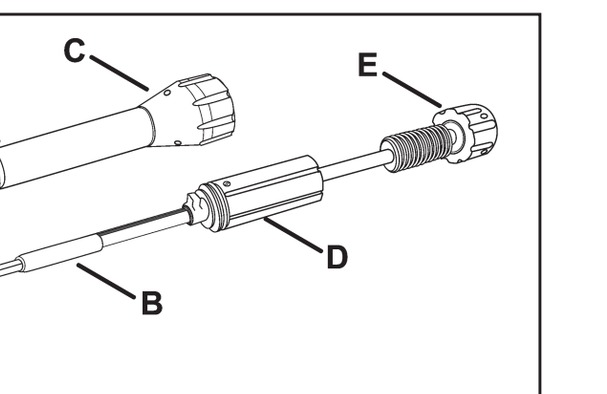


FIG. 2

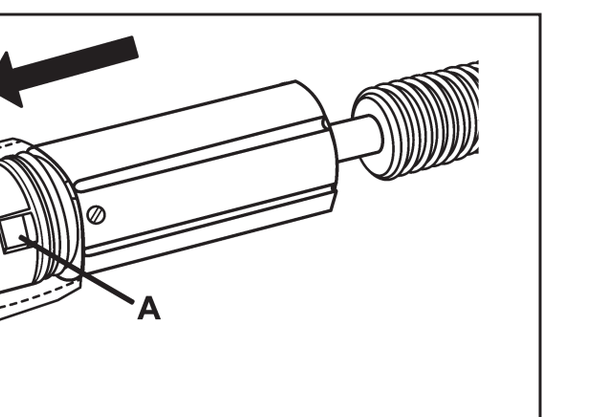


FIG. 3

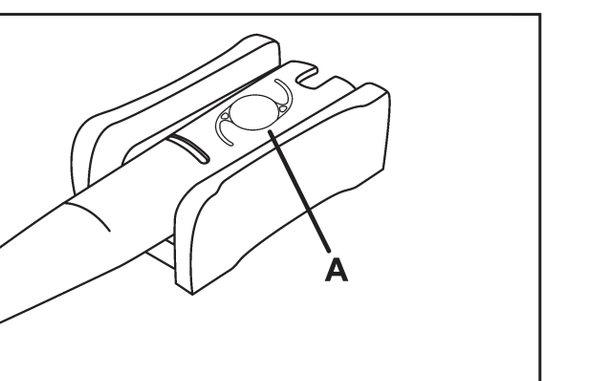
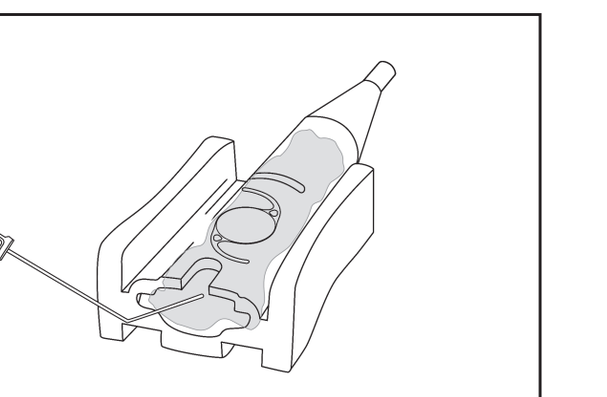
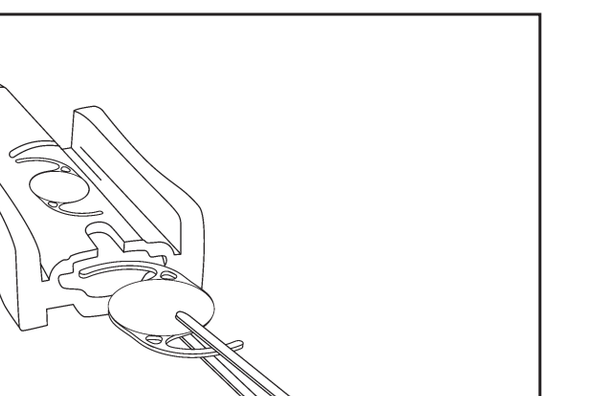
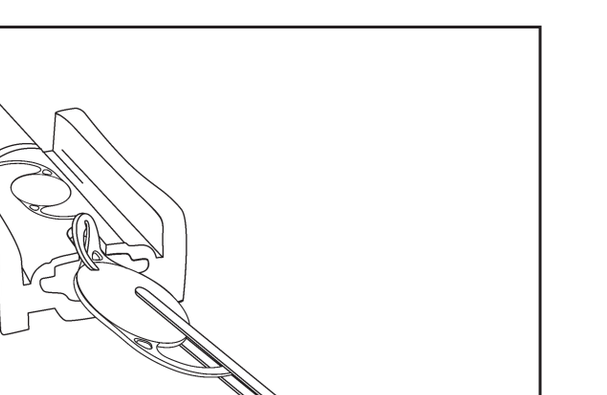
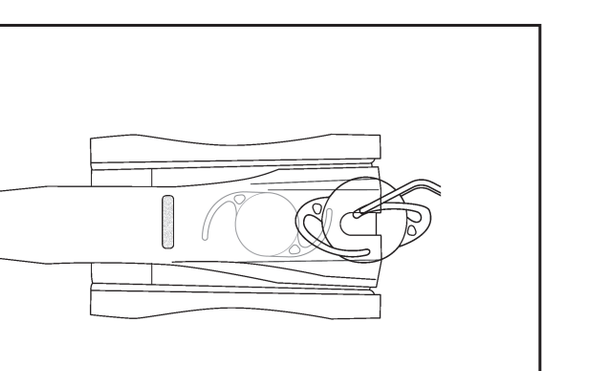


FIG. 4


FIG. 5


FIG. 6


FIG. 7


FIG. 8

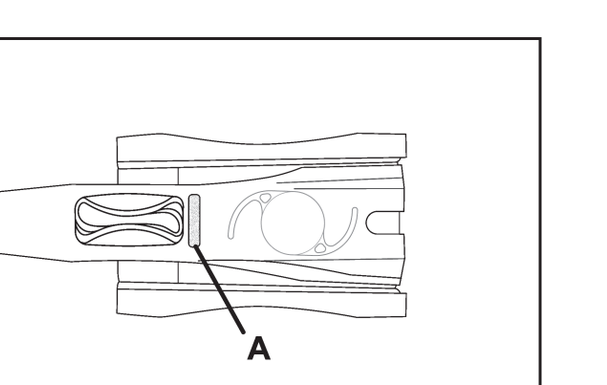


FIG. 9

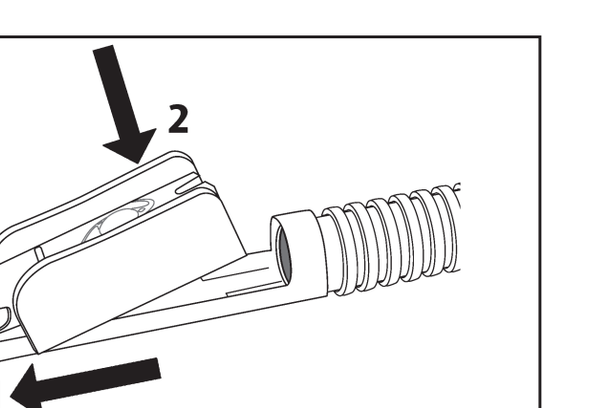


FIG. 10

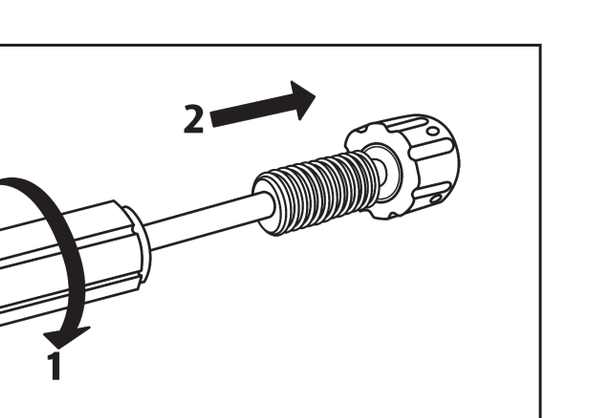


FIG. 11

Регистрация МИ в Росздравнадзоре
www.nevacert.ru | info@nevacert.ru

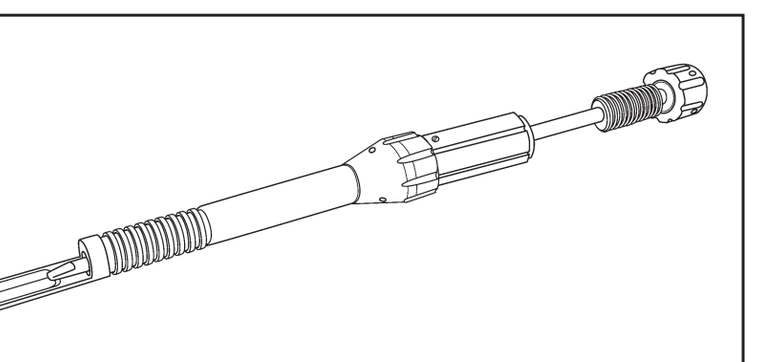


FIG. 1

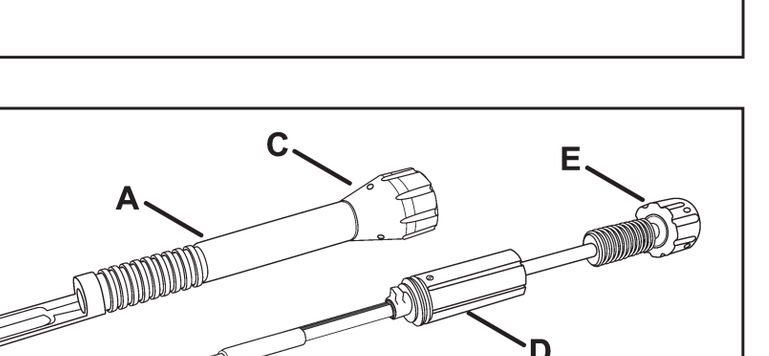


FIG. 2

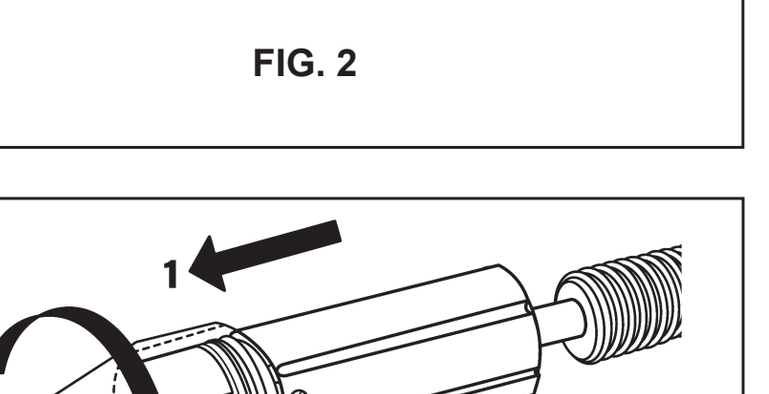


FIG. 3

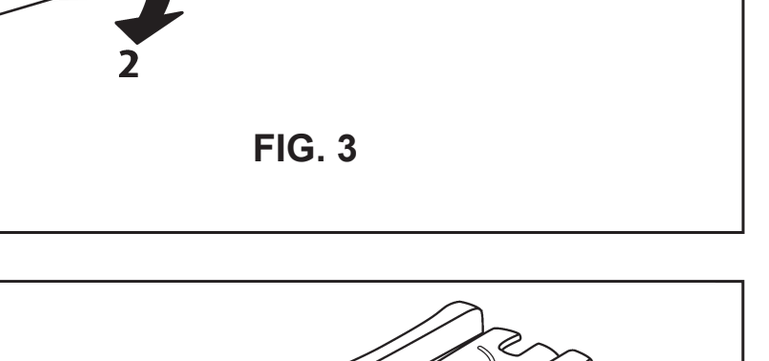


FIG. 4

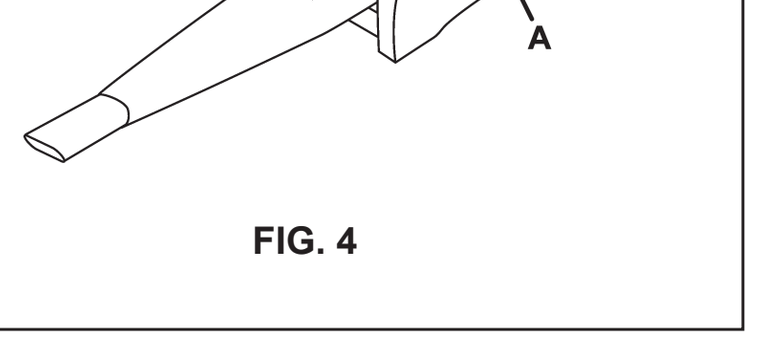


FIG. 5

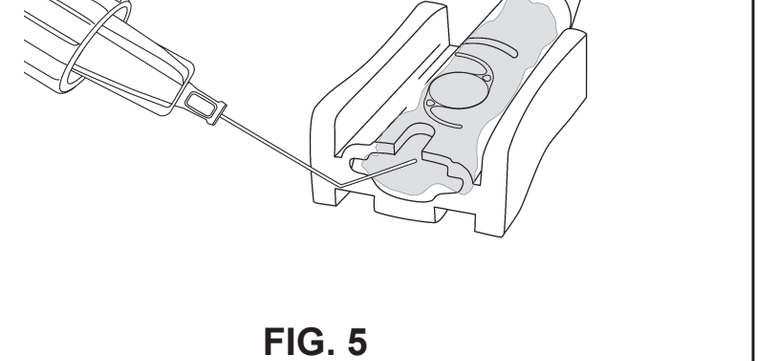


FIG. 6

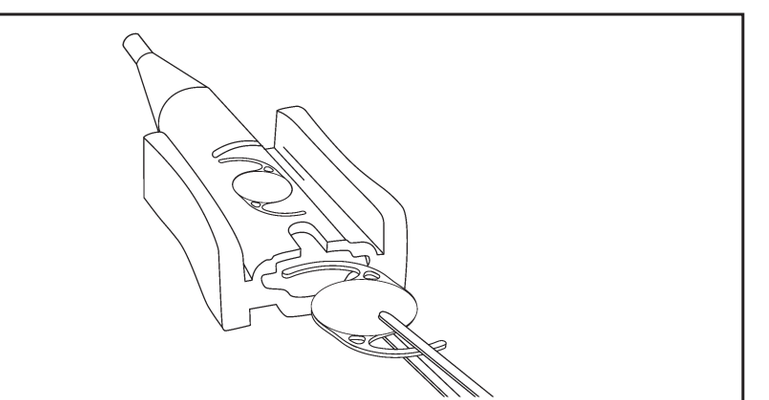


FIG. 7

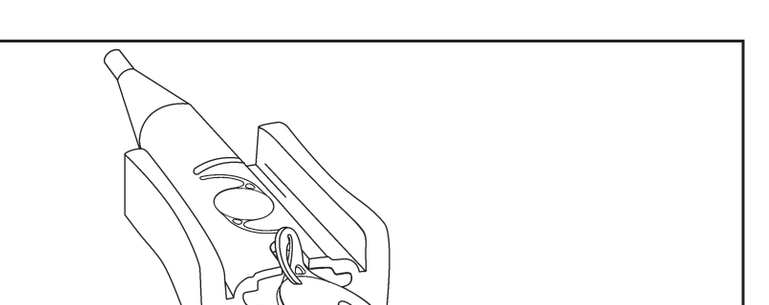


FIG. 8

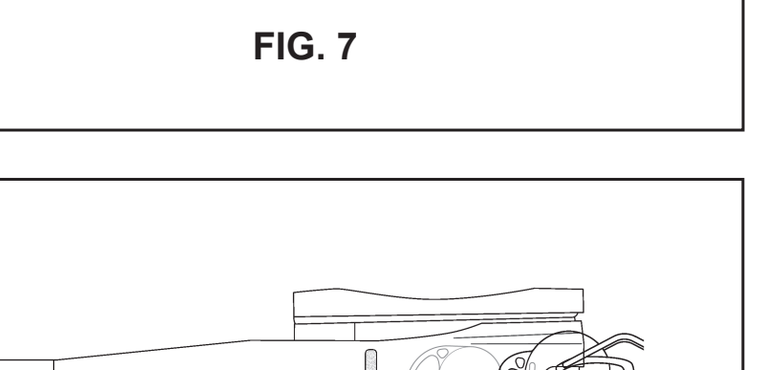


FIG. 9

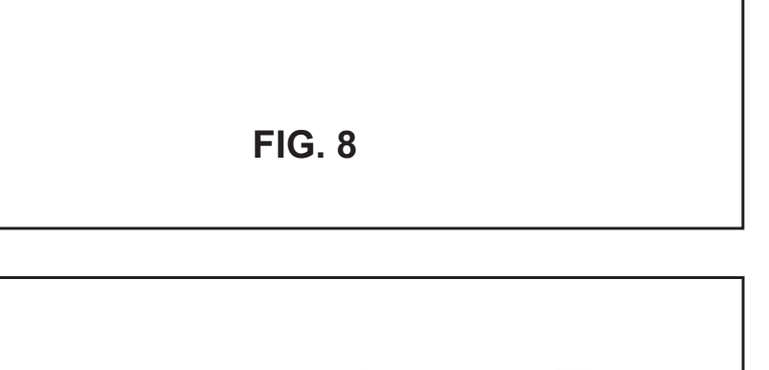


FIG. 10

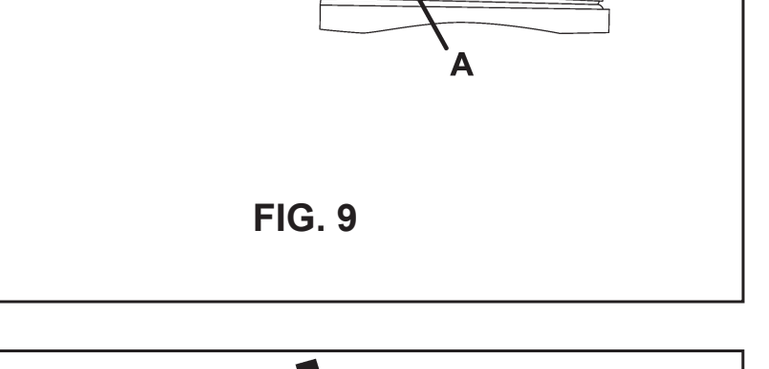


FIG. 11

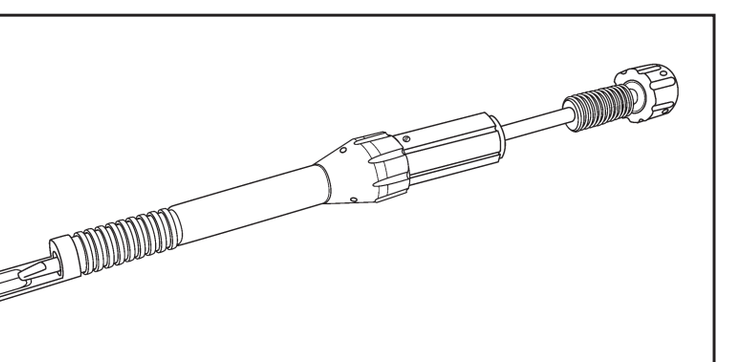


FIG. 1

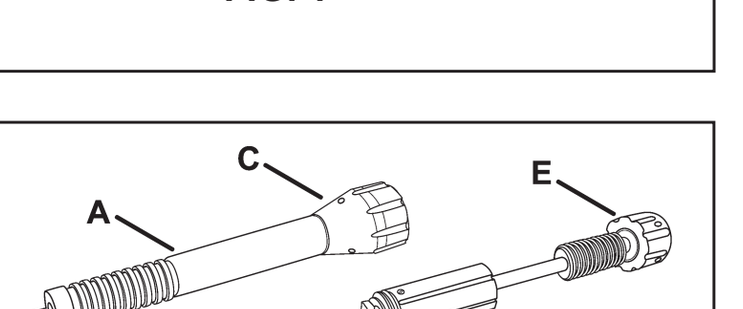


FIG. 2

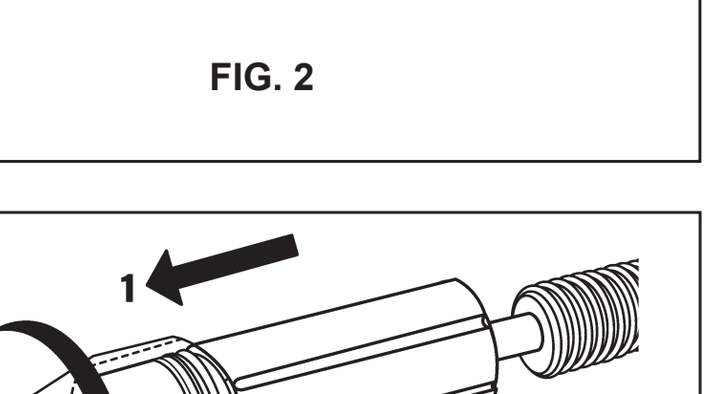


FIG. 3

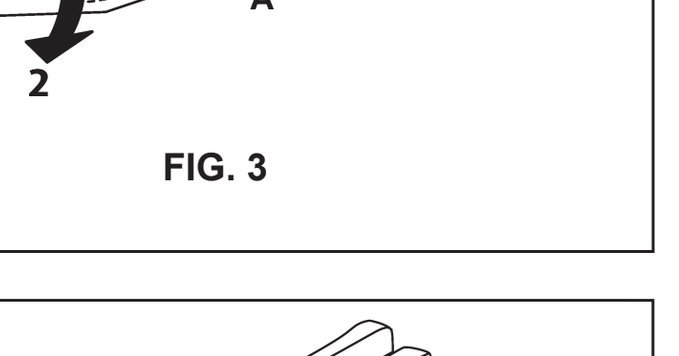


FIG. 4

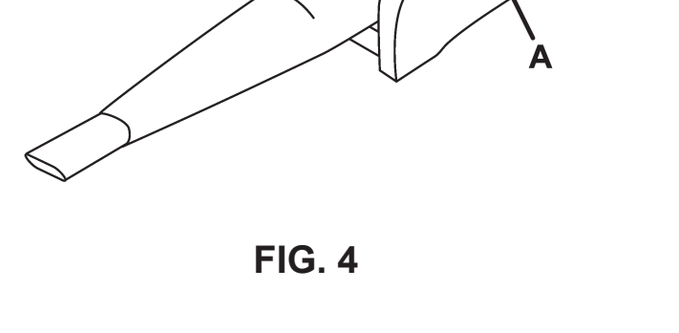


FIG. 5

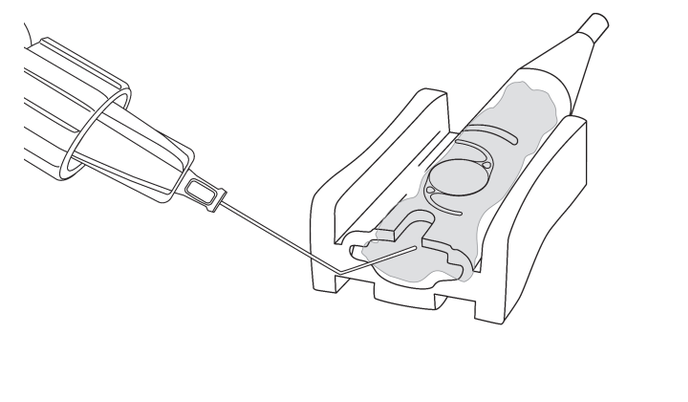


FIG. 6

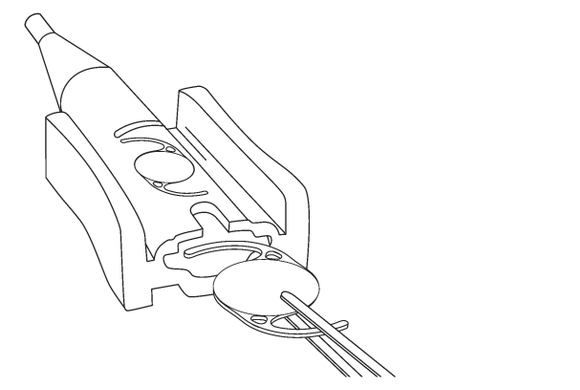


FIG. 7

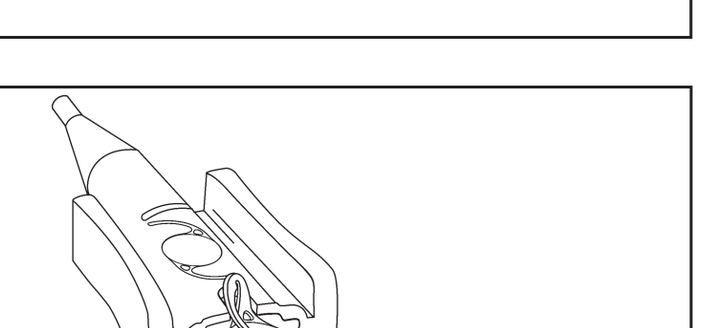


FIG. 8

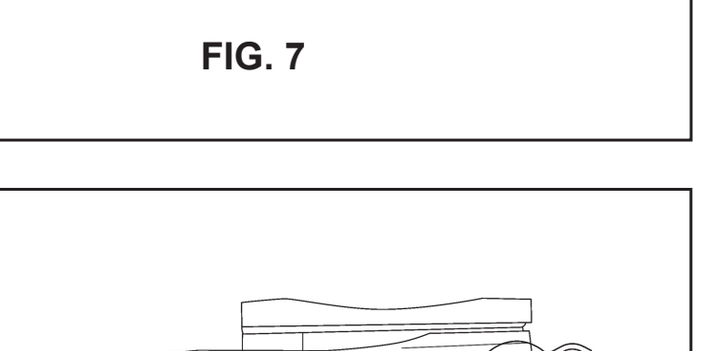


FIG. 9

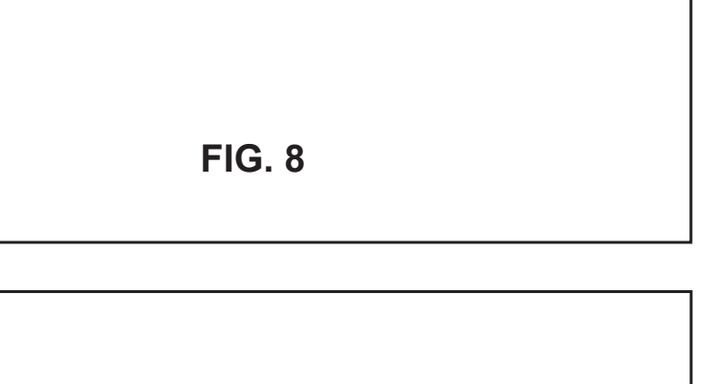


FIG. 10

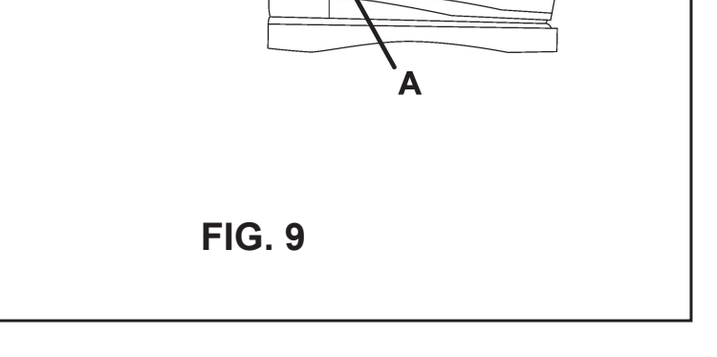


FIG. 11

Регистрация МИ в Росздравнадзоре
www.nevacert.ru | info@nevacert.ru

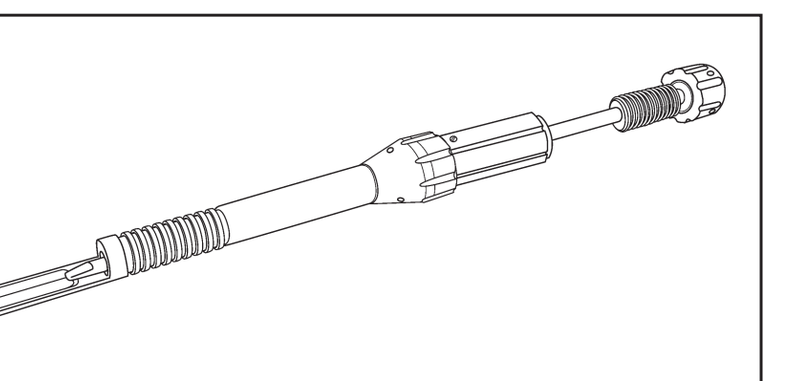


FIG. 1

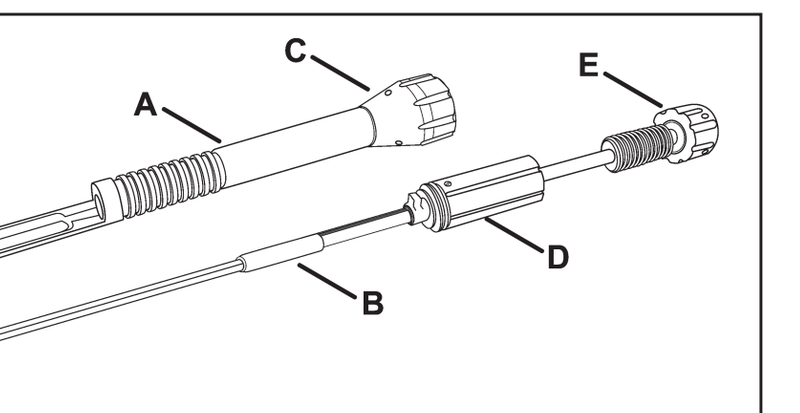


FIG. 2

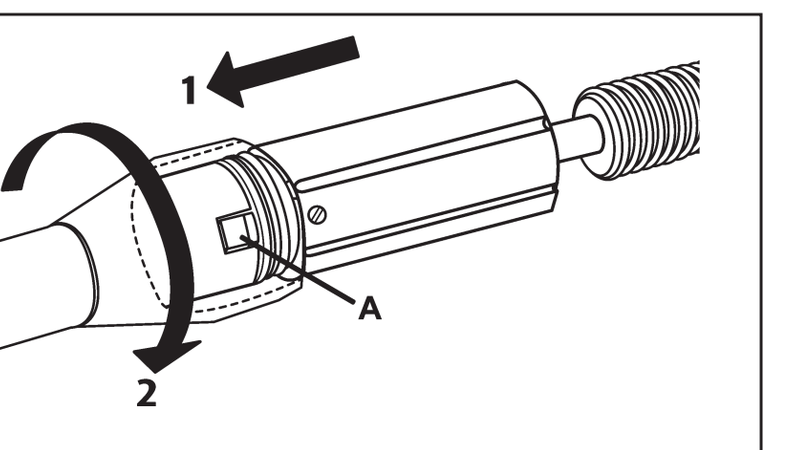


FIG. 3

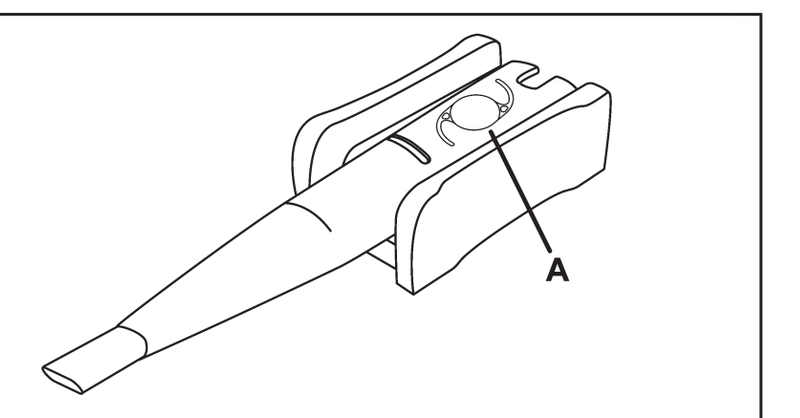


FIG. 4

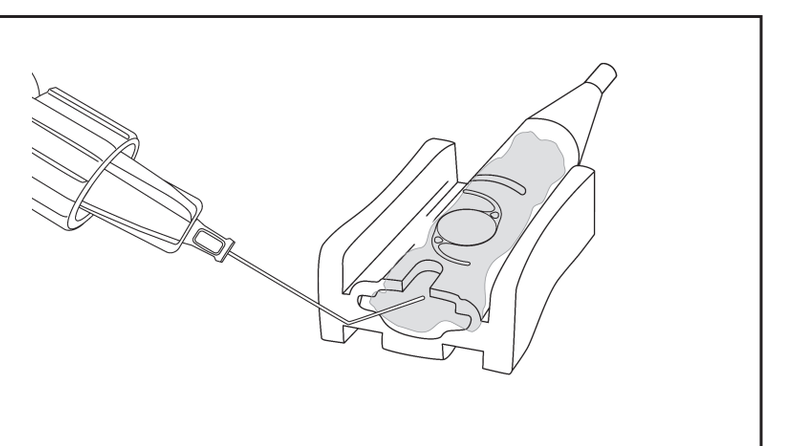


FIG. 5

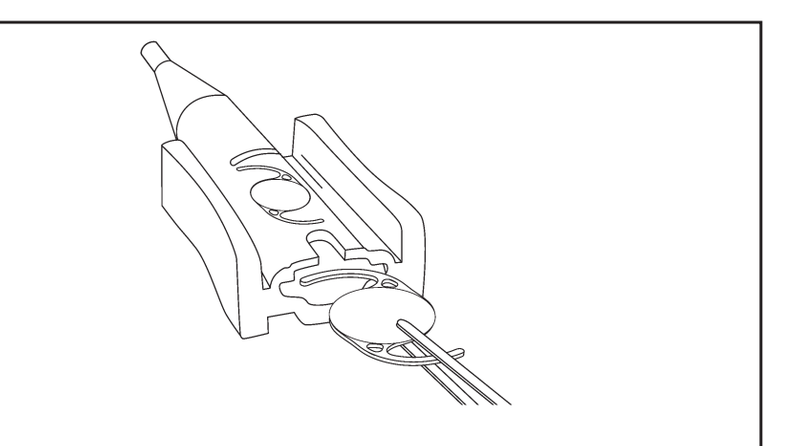


FIG. 6

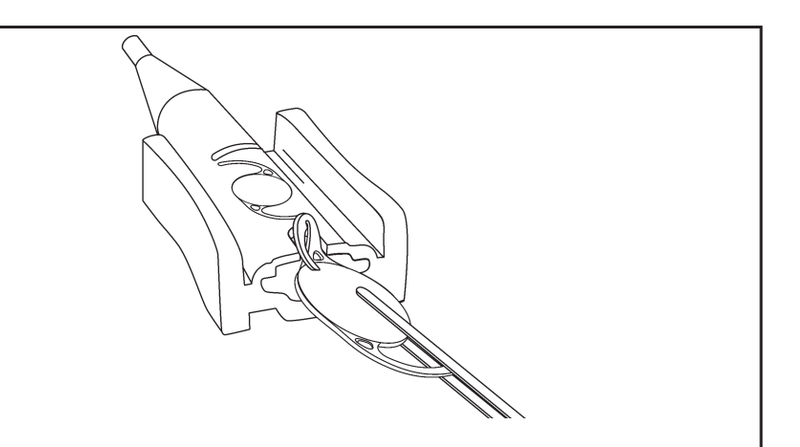


FIG. 7

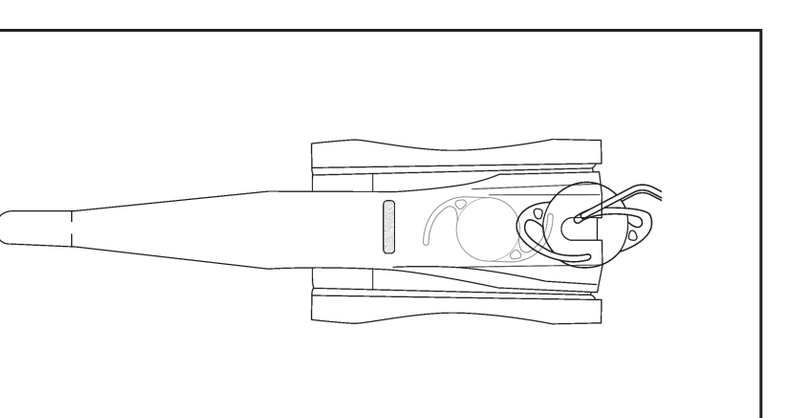


FIG. 8

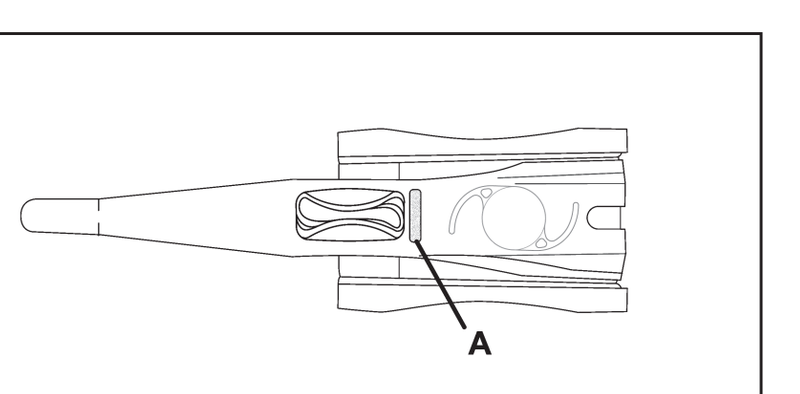


FIG. 9

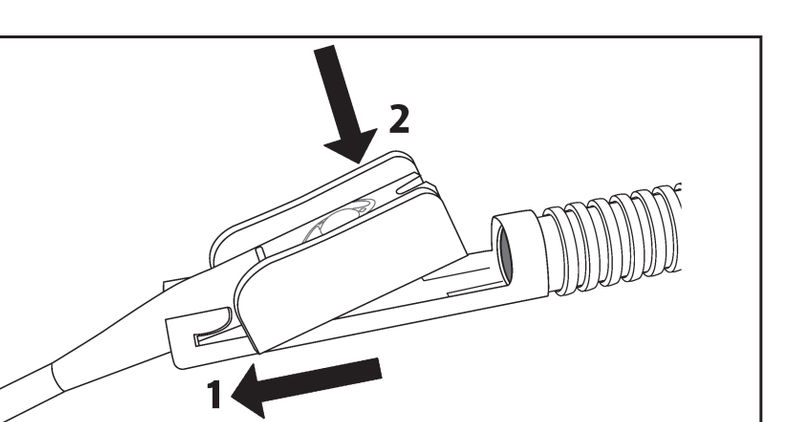


FIG. 10

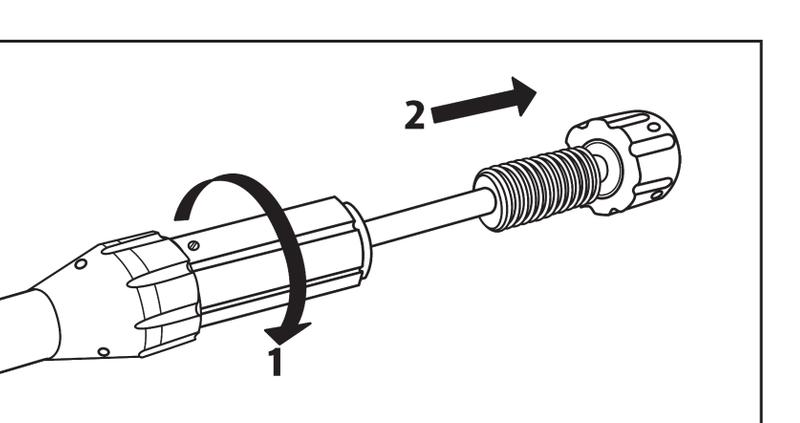


FIG. 11

Регистрация МИ в Росздравнадзоре
www.nevacert.ru | info@nevacert.ru