

# KIM BLUE

## INSTRUCTIONS FOR USE



### MANUFACTURER

Desarrollo e Investigación Médica Aragonesa S.L.  
Polígono Industrial Mediavega, Parcela 2.8  
50300 Calatayud (Zaragoza)  
Spain  
Ph.: +34-976-884065; Fax: +34-976-891872  
E-mail: [dimasl@dimasl.com](mailto:dimasl@dimasl.com)  
[www.dimasl.com](http://www.dimasl.com)



### DISTRIBUTOR

Productos Especiales de Neomedic International S.L.  
C/ Maestrat, nº 41-43 1º  
08225 Terrassa (Barcelona)  
Spain  
Ph.: +34-93-7804505; Fax: +34-93-7806105  
E-mail: [info@neomedic.com](mailto:info@neomedic.com)  
[www.neomedic.com](http://www.neomedic.com)



**CAUTION:** Federal law restricts use of this device to physicians trained in performing procedures and techniques for implanting suburethral slings for treating stress urinary incontinence and managing complications from gynecological use of surgical mesh.

Read all information contained in this document carefully, including, Indications, Contraindications, Warnings, Precautions, Adverse Reactions, Surgical Technique, etc., prior to using this product. Failure to follow instructions may cause malfunction and/or cause patient injury.

These instructions for use are not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence).

## IMPORTANT

This document aims to explain the instructions for use of the KIM BLUE. These instructions for use are not a substitute for training to correct SUI (Stress Urinary Incontinence). KIM BLUE should only be used by doctors instructed in the treatment of this kind of pathology and more specifically in the use of this device.

These instructions for use explain the common steps for implanting the KIM BLUE. Considering that each individual patient may present special anatomical conditions, it is imperative that the surgeon understands and plans for the safe and effective placement of the device. As with any surgical intervention, special circumstances may be also presented during the surgery; in such cases the medical specialist will be responsible for deviating from the instructions as necessary to ensure patient safety and health.

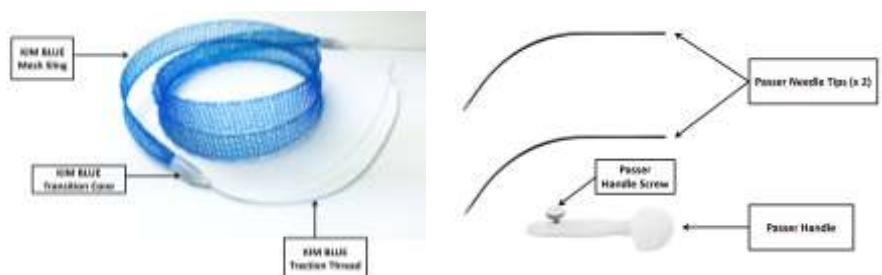
## INDICATIONS FOR USE

KIM BLUE is a device intended to be used as a surgical mesh system for treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

## DESCRIPTION OF THE DEVICE AND DEVICE ELEMENTS

All components of this device have been designed for single use only. System components:

- Sling.
- Retropubic Passers used for Sling placement. The Passer Needle Tips are curved and have small grooves at each end to connect the Sling Traction Threads.



## CONTRAINDICATIONS

Do not implant the device:

- in patients with pre-existing infections or other conditions that pose an unacceptable surgical risk as determined by the Physician, including comorbidities that may compromise tissue healing.
- in patients who suffer urinary tract infections or obstructions.
- in pregnant women or women who are considering future pregnancies.
- in patients who are still growing or less than 18 years of age.
- in sub-urethral or peri-urethral areas with signs of tissue necrosis, compromised/infected tissue or connective tissue disorders.
- in patients with known sensitivity or allergy to device materials.
- in patients undergoing concomitant bowel surgery.
- in direct contact with bowel or visceral organs, including the urinary bladder.
- for treatment of vaginal vault or pelvic organ prolapse.
- in contaminated wounds as subsequent infection may require removal of mesh.
- in patients with any pathology which would compromise implant placement.

**WARNINGS AND PRECAUTIONS**

## Pre-operative:

- As with all surgical procedures, certain risk factors are known to impact patient outcomes in the pelvic floor which include, but are not limited to, impaired vascularity (e.g. diabetes, smoking status, estrogen status, pelvic floor radiation exposure, etc.), age, pelvic floor myalgia, impaired wound healing (e.g. diabetes, steroid usage, etc.), or active infection in or near the surgical site. The above pathophysiologic conditions must be considered when determining whether the patient is an appropriate candidate for mesh implantation.
- The patient should be counseled that there are alternatives to incontinence mesh surgeries, and the reason for choosing a mesh sling should be explained. Such alternatives include but are not limited to: Biofeedback, pelvic floor exercises (Kegel exercises), behavioral modification, pessary/vaginal tampons, transurethral bulking agents, medication, electrical stimulation and/or pads. The patient may also be offered non-mesh surgical options (e.g.: fascial sling, stitches).
- Conservative, non-invasive treatments should be recommended before choosing a suburethral sling implant.
- Obtain patient consent of surgery with an understanding of the postoperative risks and potential complications of mesh surgery.
- Patient counseling should include a discussion that the device to be implanted is a permanent implant, and that some complications associated with the implanted mesh may require additional surgery that may or may not correct the complication. A multi-disciplinary team of physicians is recommended for patient counseling.
- The patient should be counseled that future pregnancies may negate the effects of surgical procedure and the patient may again become incontinent.
- The physician must determine the risks that should be included in the patient informed consent.
- Users should be familiar with the surgical technique for bladder neck suspensions and should be adequately trained in the placement of KIM BLUE implantation procedure before employing the device. Ensure that the implant is placed with minimal tension under the mid-urethra. As with other incontinence procedures, de novo detrusor instability may occur following a pubo-urethral procedure utilizing the KIM BLUE. To minimize this risk, make sure to place the implant tension-free in the mid-urethral position.
- Surgical risks not associated directly with the use of the device, its function, or method of implantation require understanding and consideration by a qualified surgeon who is knowledgeable of anatomy, medical treatments and procedures for conditions appropriately treated with this device.
- The user must be qualified to manage any complications or adverse events associated to the device and the surgical procedure.
- As the anatomy of individual patients may vary greatly, for each procedure it is important that the intended plans for device advancement and the intended location for mesh placement are planned and known for each individual patient. Employment of imaging methods before and after mesh placement may aid in proper mesh placement and confirm absence of injury to non-target anatomical structures.
- Patients undergoing anticoagulant treatment therapy are at an increased risk of perioperative bleeding. Careful preoperative assessment and appropriate management of anticoagulation are essential. Anticoagulation therapy does not constitute a contraindication, but requires individual risk assessment and planning.
- Patients with renal insufficiency require careful preoperative assessment and monitoring due to increased risks associated with anesthesia and medication metabolism; monitor closely during and after the procedure.
- Caution is advised when performing the surgery on patients with immune diseases, as they may have an increased risk of infection and impaired healing.
- Patients with urethral stricture or urethral mobility issues may have an increased risk of impaired tissue healing or mesh complications. Careful assessment and close monitoring are recommended for these patients.
- The risks and benefits of performing the KIM BLUE procedure in patients with the following conditions should be carefully considered by the team of physicians:
  - Obese patients; The Sling and Passers have been designed to accommodate patients of all sizes, however in extreme conditions careful preoperative assessment is required;
  - Younger / premenopausal women;
  - Previous surgical history, especially vaginal surgeries for pelvic floor repair and including patients that already have a system implanted for prolapse or urinary incontinence.
  - Overweight patients;
  - Concomitant pelvic floor surgery; the performance of any additional, simultaneous procedures should be determined by the surgical team based on individual patient factors and clinical judgement. Potential risks and complications must be carefully evaluated to ensure that any concomitant intervention is appropriate and justified.
  - Patients with conditions that would compromise tissue healing (in patients who suffer cancers of the vagina, cervix, or uterus or in patients who have received radiation in the area of treatment, etc.) also including but not limited to patients with diabetes mellitus, smoking and ongoing steroid treatment. These factors should be considered during patient selection and perioperative management.
  - Patients with mild to light SUI.
  - Patients while on anticoagulants, non-steroidal anti-inflammatory agents, or in those with bleeding disorders.
- KIM BLUE is not recommended for women in the first two years after their last pregnancy.

- Special care should be taken in patients with conditions that may be aggravated by their placement in modified dorsal lithotomy position.
- Special care should be taken in patients with anterior prolapse because of anatomical distortion of the pelvic floor.
- This product is provided sterile and must be sterile before its use. Before opening the product, the package must be inspected to ensure it is not damaged and that the sterility is not compromised.
- Do not reuse or reesterilize this device. No component of the KIM BLUE system is reusable. Reuse of the device could lead to potentially serious consequences for the patient that may lead to medical intervention, permanent injury or death. Reject and do not use any unpackaged system.
- The KIM BLUE sling is designed for, and should be used only with DIMA passers specifically indicated for use with the KIM BLUE sling.
- The date of the last revision of this document is included in these Instructions For Use. If more than 24 months have passed since the last revision date, please contact the manufacturer or distributor to receive the updated Instructions For Use.

**Intra-operative:**

- This product is an implant that must be implanted in an operating theatre. Use strict aseptic and antibiotic coverage measures during the surgical procedure. Prophylactic antibiotics can be administered according to the physician's usual practice.
- KIM BLUE Sling should not be placed in contact with bowel or visceral organs, including the urinary bladder.
- Cystoscopy should be performed after the passers passage to confirm bladder integrity and to recognize any inadvertent bladder or urethral injury or perforation.
- Avoid excess tensioning of the mesh to minimize urinary retention, obstruction or the possibility of damage to tissues or internal organs.
- Intra-operative bleeding may occur.
- Take special care during surgical intervention to avoid perforation of bladder, bowel, urethra, vaginal wall, intestine and other internal pelvic structures as well as damage of nerves, blood vessels, pubic bone, or mechanical disruption of the tissue. Attention to local anatomy and proper passage of needles will minimize risks.
- Do not contact any part of KIM BLUE with any staples, clips, or clamps as mechanical damage to the mesh may occur.
- No data is available on the use of KIM BLUE with tissue adhesives and is not recommended.
- The Transition Cones, the Traction Threads and the Passers are not permanent implants.
- To avoid device breakage or patient injury upon implantation, if high level of resistance is encountered, withdraw sling and reattempt placement.
- The Passers, discarded Transition Cones and Traction Thread, as well as any excess Sling Mesh may be a potential biohazard. The Passers have sharp tips, which could potentially protrude when not in use. Handle and dispose of the Passers, as well as the discarded components in accordance with any local and federal laws regarding medical waste and disposal requirements for sharp devices, to prevent unnecessary injury or harm.
- Omitting the vaginal and skin incisions to insert the Passers may result in excessive force and could cause injury to the patient.
- A digital rectal exam should be performed to detect or avoid possible rectal perforation.
- The implanted mesh sling must always be separated from the abdominal cavity by peritoneum.

**Post-operative:**

- The sling tension should not be adjusted post-operatively.
- Patient could suffer post-operational pain. Excessive or chronic pain should be reported to the Physician.
- Instruct the patient to report dysuria, bleeding, hematuria, pain, paresthesia, cystoliths, vaginal discharge, signs of infection or other problems or abnormal symptoms to the surgeon as soon as possible.
- Post-operative retropubic bleeding may occur. Observe any signs or symptoms before the patient is released from the hospital. The patient must be instructed to contact the surgeon immediately if any hemorrhaging occurs.
- Patient should report incontinence, voiding dysfunction or problems defecating to the surgeon as soon as possible.
- It is recommended that patients do not overly exert themselves physically (i.e.: heavy lifting) or partake in any moderate to strenuous sporting activity (e.g.: biking, jogging, etc.) for at least a minimum of two months following surgery. It is also recommended to avoid sexual intercourse during the first two months after surgery.
- The device is provided with multiple, product ("hospital") labels of which must be included in the patient medical file as well as administered to the patient for easy identification of the implant.
- Taking into account the condition of each individual patient, the surgeon will plan for post-operative follow-up. Follow-up is recommended at short/mid-term and long-term if possible (follow-up periods are subjective and depend on the follow-up plan established by the surgical team).

**POTENTIAL ADVERSE REACTIONS**

Known risks of surgical procedures for the treatment of urinary incontinence with a mid-urethral sling include but are not limited to the following:

- Temporary surrounding tissue irritation, allergic reaction or adverse reactions to foreign bodies may occur.
- Inflammation/swelling (acute or chronic), adhesion formation, fistulas, abscess (acute or delayed), seromas, edema, hypersensitivity or other immune reaction and/or hardening of the mesh caused by fibrosis.
- Bleeding (hemorrhage, perforation of vessels, hematuria, edema, erythema, hematoma).
- Perforation of bladder, bowel, vaginal wall, urethra, ureter, intestine and other pelvic structures, and that may require open surgical repair.
- As a foreign body, KIM BLUE could stimulate a pre-existing infection, or suffer rejection.
- Extrusion, exposure, and/or migration of the mesh from the desired location. The device may also produce erosion through the vagina, urethra, bladder or other surrounding tissues or structures. Mesh contraction (shrinkage) is associated with vaginal tightening, vaginal shortening and vaginal pain.
- Urinary problems such as voiding symptoms, de novo or worsened incontinence in the form of urgency/overactive bladder (OAB), frequency or nocturia may appear after the intervention.
- Failure of the procedure resulting in recurrence (continued or worsening urinary incontinence).
- Altered bladder and/or bowel function such as temporary or permanent urinary retention/obstruction or problems defecating. Bowel obstruction. Signs and symptoms of bowel obstruction include but are not limited to constipation, abdominal pain, vomiting and bloating.
- Infection, wound infection, urinary infection, fever.
- Acute and/or chronic pain in the groin, thigh, buttox, leg, pelvic and/or abdominal area. Dysuria. Other pains. Discomfort.
- Nerve damage, neuromuscular problems.
- Vaginal spotting, bleeding, abnormal discharge or scarring. Redness, itching or dryness of the vagina.
- Dyspareunia and loss of sexual function (apareunia), which may be ongoing and may not resolve in some patients. Sexual partners may experience discomfort, irritation and/or pain during sexual activity.
- Palpable mesh during pelvic examination, foreign body sensation, or, discomfort.
- Excess tension on the mesh may produce temporary or permanent urinary obstruction and retention. Over-correction, i.e., too much tension applied to the implant, may cause temporary or permanent lower urinary tract obstruction. If this occurs, this can lead to the need for prolonged foley catheter use and/or additional surgery to release the sling.

As with all surgical interventions, the patient is at risk of:

- Wound site complications (i.e.: excess granulation formation, necrosis, wound dehiscence or infection).
- Scarring.
- Physical deformity.
- Emotional problems.
- Post-op nausea and/ or vomiting.
- Slight discomfort when returning to normal activities.
- Other complications such as embolic events or death.

The occurrence of adverse reactions may require revision surgery and/or specific additional treatments, including, but not limited to, antibiotics, blood transfusions, intravenous (IV) therapy, drainage, reconstructive surgery, and partial or complete removal of the mesh. If partial or complete removal of the mesh is required, significant dissection may be necessary.

KIM BLUE mesh is intended to be a permanent implant. One or more surgical procedures may be required to remove the implant, in whole or in part, or to manage mesh-related complications. Such procedures may be difficult and may require significant dissection. Partial or complete removal of the implant will not necessarily alleviate the patient's symptoms and may result in further scarring, tissue damage, severe chronic pain that may not be satisfactorily treated, recurrence of stress urinary incontinence (SUI), or other adverse outcomes. Removal of eroded mesh will not necessarily prevent further erosion or other adverse events.

## SURGICAL TECHNIQUE

Before using KIM BLUE, the doctor must read and understand the instructions for use.

### *Anaesthetics and antibiotic therapy:*

The surgical procedure to implant KIM BLUE can be performed under regional or general anesthesia. It is advisable to use the hospital antibiotic protocol for implants.

### *KIM BLUE placement (Retropubic Technique):*

1.- Vaginal incision: With the patient in modified dorsal lithotomy position, prepare the surgical field with a vaginal valve. Start by making a longitudinal incision in the anterior vaginal wall, preparing the submucosal space to present the best possible view of the urethral tract. Make two suprapubic skin incisions at the needle exit points of the abdominal site, approximately 1cm above the symphysis.

2.- Insertion of the Passers through the Retzius space: Blunt or sharp paraurethral dissection is performed to allow the Passers to pass through the Space of Retzius. Insert the Passers into the para-urethral spaces, through the Retzius space, from the vaginal incision, until the tip can be clearly seen at the abdominal exit points, continuously maintaining the tip of the Passer Needles distanced from the urethra and in continuous contact with the posterior wall of the pubis. Avoid going too lateral to the pelvic side wall to avoid injury of the pelvic vessels and be sure to stay away from the peritoneal wall. Bladder mobilization techniques may also be used to avoid bladder perforation. Remove the handles and leave the Passers in place.

3.- Cystoscopy: Perform a cystoscopy to determine the bladder integrity, and ensure that the bladder is not perforated. If perforated, repair as necessary, withdraw the Passers and repeat step 2.

4.- Placement of the KIM BLUE sling: After removing the device from the sterile container, place the Traction Threads through the grooves in the proximal tips of the Passer Needles Tips and move the Passers forward by pushing them through the Retzius space towards the abdominal site incisions or pulling them from the abdominal side until the Traction Threads appear at the abdominal incision. Ensure the sling is not twisted with placement and lies completely flat under the urethra. Position the KIM BLUE Sling at the mid-urethra with no tension. Remove the Passer from the Traction Thread. When ideal urethral support is achieved, cut the excess Sling protruding from the suprapubic abdominal incisions, including the Traction Threads and Transition Cones. Close vaginal and abdominal incisions.

### Connection of the Passer Needle Tip to the Passer Handle:

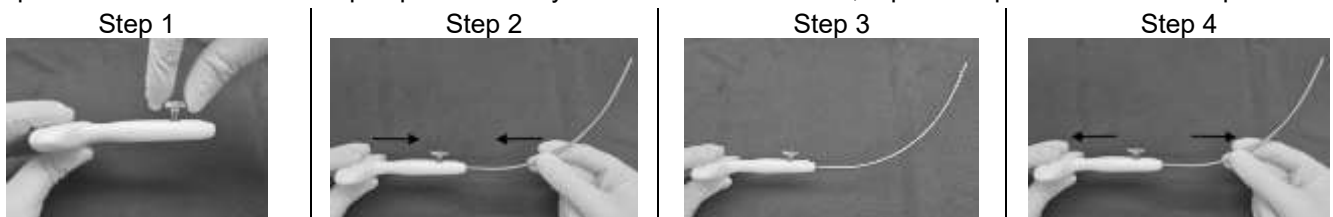
Step 1.- Hold the Passer Handle and verify that the Passer Handle Screw is sufficiently loosened. Avoid fully unscrewing or removing the Passer Handle Screw to prevent it from falling or being lost.

Step 2.- Insert the Passer Needle Tip into the Passer Handle, making sure that the needle tip is oriented in the direction shown in the figure.

Step 3.- Tighten the Passer Handle Screw firmly to secure the Passer Needle Tip to the Passer Handle.

Step 4.- Verify that the Passer Needle Tip is securely attached to the Passer Handle by attempting to pull the two components apart with both hands.

Step 5.- If the Passer Needle Tip separates easily from the Passer Handle, repeat the procedure from Step 1.



### Connection of the Traction Thread to the Passer Needle Tip:

Step 1.- The Sling has one Traction Thread at each end. Each Traction Thread should be connected to a different Passer Needle Tip. The Passer Needle Tips have a T-shaped slot at the tip to allow proper connection of the Traction Thread.

Step 2.- Position the Traction Thread over the T-shaped slot at the tip of the Passer Needle Tip.

Step 3.- Gently tension the Traction Thread until it engages within the slot.

Step 4.- Confirm that the Traction Thread is properly attached to the Passer Needle Tip before proceeding.



## MATERIALS USED IN MANUFACTURING

### Patient contacting materials:

Sling Mesh: Polypropylene monofilament (colorant: [Phthalocyaninato(2-)] copper CAS no. 147-14-8)

Sling Transition Cones: Polypropylene

Sling Traction Threads: Ultra-high molecular weight polyethylene (UHMWPE) multifilament

Passer (Needles): Stainless steel\*

No phthalates, latex or other hazardous materials are used in the manufacture of KIM BLUE.

\*Stainless steel components contain nickel.

## STERILIZATION

KIM BLUE is sterilized with Ethylene Oxide. This product is a single use device and must not be re-sterilized or re-used. Do not use if the packaging has been damaged.

## STORAGE

It is recommended to store the product in a clean and dry place at room temperature, away from heat and direct light.

Do not use after the expiration date detailed on the package.

## MAGNETIC RESONANCE (MR) SAFETY INFORMATION

MR Safe: The KIM BLUE poses no safety hazards in the MR environment and may be placed anywhere in the MR environment. Patients with MR Safe devices have no scanning restrictions.

## SINGLE USE PRODUCT DISCLAIMER

Device intended to be used once only for a single patient. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization of a single-use device may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, inadequate cleaning and disinfection, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient cross-contamination, infection or cross-infection, residuals from cleaning agents may lead to biological responses; impairment or failure of functional product use as the device may not function to its intended purpose; impairment or failure of product integrity as the device material may become fatigued and weakened including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. In addition, the reuse, reprocessing or resterilization of a single-use device can have ethical, legal and regulatory implications. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

## SYMBOLS USED ON PRODUCT LABELS

|                                                                                     |                          |                                                                                     |                                  |                                                                                       |                                 |
|-------------------------------------------------------------------------------------|--------------------------|-------------------------------------------------------------------------------------|----------------------------------|---------------------------------------------------------------------------------------|---------------------------------|
|  | MEDICAL DEVICE           |  | DO NOT REUSE                     |   | STERILIZED USING ETHYLENE OXIDE |
|  | CATALOGUE NUMBER         |  | DO NOT RESTERILIZE               |  | NON-PYROGENIC                   |
|  | SERIAL NUMBER            |  | DO NOT USE IF PACKAGE IS DAMAGED |  | SINGLE STERILE BARRIER SYSTEM   |
|  | UNIQUE DEVICE IDENTIFIER |  | CONSULT INSTRUCTIONS FOR USE     |  | KEEP AWAY FROM SUNLIGHT         |
|  | MANUFACTURER             |  | USE BY DATE                      |  | KEEP DRY                        |
|  | DATE OF MANUFACTURE      |  | PATIENT INFORMATION WEBSITE      |  | MR SAFE                         |
|  | DISTRIBUTOR              |                                                                                     |                                  |                                                                                       |                                 |