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Bulkamid® Hydrogel

CE 0123

Instructions for use - Australian specific

PRODUCT DESCRIPTION

Bulkamid® Hydrogel is a non-resorbable, injectable transparent, hydrophilic gel for urethral bulking. Bulkamid® Hydrogel consists of approximately 2.5% cross-linked polyacrylamide and 97.5% non-pyrogenic water. It is biocompatible and non-biodegradable. Bulkamid® Hydrogel is supplied in a pre-filled, sterile, 1 mL syringe, sealed with a Luer lock fitting. It is intended to be injected with the sterile 23Gx 12cm needle. A 3-part label with the LOT number accompanies each syringe. Attach one of them to the patient's record in order to ensure product traceability. Bulkamid® Hydrogel is intended to be used with the Bulkamid Rotatable Sheath.

MODE OF ACTION

Bulkamid® Hydrogel is injected into the submucosal tissue of the proximal half of the urethra. Bulkamid® Hydrogel is intended to improve urethral coaptation.

INDICATION

Bulkamid® Hydrogel is intended to be used as a urethral bulking agent for the treatment of female urinary incontinence where the stress component is significant.

CONTRAINDICATIONS

Bulkamid® Hydrogel must not be used in patients suffering from acute cystitis and urethritis. Do not inject patients who have active Herpes Genitalis.

WARNINGS/PRECAUTIONS

During the bulking procedure, the blood vessels must always remain visible at the site of injection in order to avoid the risk of necrosis and potential leakage of the hydrogel. Do not inject Bulkamid® Hydrogel intravascularly. It is possible that accidental vascular injection will cause embolization. Do not inject Bulkamid® into sites previously injected with other bulking agents or vice versa. Evaluate the condition of the tissue (e.g. hardness, oedema, haematoma, atrophy) at the site of injection prior to treatment. Do not inject if the tissue is damaged. A change to the device insertion technique can lead to implant complications. The efficacy of the device may diminish over time.

Bulkamid® Hydrogel is intended for female patients, above the age of 18 years that have failed conservative treatments. The effect of Bulkamid® Hydrogel has not been evaluated in women during pregnancy, delivery or lactation. Patients receiving treatment interfering with blood coagulation have an increased risk of haematoma or urethral bleeding. If the patient has undergone major dental work or surgery, Bulkamid® should not be injected until the patient is fully recovered. If the patient needs surgery or major dental work post Bulkamid® injection, antibiotic treatment to reduce risk of infection should be considered by physician. Patients with acute or chronic infection in other sites of the body must be treated with caution. Only patients with well-controlled diabetes should be considered for Bulkamid® Hydrogel injection. Do not inject Bulkamid® Hydrogel into other sites of the body. The procedure may cause urinary tract infections and scratches in urethra and bladder. Prophylactic antibiotic is recommended. It is possible that inflammatory changes seen at the site of implant may be misinterpreted at a later time for other pathology. Bulkamid® Hydrogel is only to be administered by a qualified physician, e.g. gynaecologist, urologist, or urogynaecologist. Do not mix Bulkamid® Hydrogel with any other substances. Bulkamid® Hydrogel is sterile when supplied. Only use the Bulkamid® Hydrogel and other components of the Bulkamid® Urethral Bulking System if the packaging and products are intact and undamaged. Do not re-sterilize Bulkamid® Hydrogel. Discard any unused material/ product per local protocol/procedure. Bulkamid® should be used with caution in patients on immunosuppressive therapy. Safety has not been established for patients with autoimmune diseases. All components of the Bulkamid® Urethral Bulking System are only intended for single patient use and single use. Do not re-use. Reuse increases the risk of contamination and hereby increases the risk of infection. Do not use any other component of the Bulkamid® Urethral Bulking System components after the expiry date printed on the packaging. Safety and effectiveness of Bulkamid® Hydrogel have not been established in patients under 18 years.

ADVERSE EVENTS

Postoperatively, transient symptoms such as dysuria, haematuria, oedema, urinary tract infection and acute retention and pain during voiding may occur. Long-term adverse events such as non- acute retention, abscess formation, fibrosis (tissue hardening), migration and necrosis are possible but rare.

REPORTING OF ADVERSE EVENTS

All adverse events/complications must be reported to the local distributor or directly to Contura International A/S via e-mail to complaints@contura.com. Download Incident Report Form at www.bulkamid.com.

PATIENT INFORMATION

The patient should be informed about the intended use, expected results, contraindications, precautions, warnings and potential adverse events.

METHOD OF ADMINISTRATION:

PRE-OPERATIVELY

Test the patient's urine in order to exclude Urinary Tract Infection (UTI). Do not proceed if infection is present. Place the patient in lithotomy position. Disinfect according to local routine procedure. Place anaesthetic gel inside the urethra, and/or inject 5–10 mL Lidocaine (0.5–1%) with Adrenaline or similar bilaterally to the mucosa along the urethra (3 and 9 o'clock) 5–10 minutes prior to the procedure.

PERI-OPERATIVELY

Use the Bulkamid® Rotatable Sheath according to the Bulkamid® Rotatable Sheath Instruction For Use. Remove the protective tip cap from the Bulkamid® Hydrogel syringe; attach the 23G needle firmly into the Luer lock socket. Make sure the needle is correctly mounted. Assemble the Bulkamid® Urethroscope (with camera) and the Bulkamid® Rotatable Sheath by inserting the Bulkamid® Urethroscope, with the light connection aligned with the water tubes on the Bulkamid® Rotatable Sheath. Connect the Bulkamid® Rotatable Sheath to the infusion set using the Luer lock on the short water inflow tube. Place the long outflow tube in a container or drain for waste water. Introduce the assembled system into the urethra and bladder and open inflow and outflow for flushing and inspecting. Empty the bladder by separating the optic from the Bulkamid® Rotatable Sheath or by closing inflow and opening outflow. Introduce the needle mounted on the syringe into the working channels of the Bulkamid® Rotatable Sheath. The tip of the needle must not yet be visible on the screen. Open inflow, close outflow and place the tip of the Bulkamid® Rotatable Sheath at the bladder neck. Turn the rotatable tube part of the Bulkamid® Rotatable Sheath to the first injection position posteriorly, e.g. at a location between 5 to 7 o'clock. Retract the system to approximately 2 cm from the bladder neck. Push the needle forward so that the tip can be seen. Press the system parallel against the urethral wall in order to get the mucosa placed in front of the tip of the needle. Do not angle the system; angling could lead to either too deep or too superficial an injection. Insert the needle into the submucosal tissue until the 1 cm marking on the needle is aligned with the mucosal surface. At each injection site, inject Bulkamid® Hydrogel until reaching the midline of the urethral lumen, while making sure that the blood vessels remain visible in order to avoid necrosis. Perform the injections with water inflow to dilate the urethra, in order to have sufficient vision during the injections. Depending on the shape and position of the first deposit, repeat the procedure two or three times in order to get a regular filling around the circumference of the urethra. Limit the number of puncture holes to avoid increased risk of extravasation of the material. Make sure the needle is retracted before rotating or removing the Bulkamid® Rotatable Sheath. If necessary, change the syringe during the procedure, and repeat the injections, making sure not to re-inject the same site more than once, as the typical amount of Bulkamid® Hydrogel used is 1.5–2.0 mL. If necessary, open the outflow between injections to avoid urgency symptoms. Do this either by closing inflow and open outflow or by separating the optic from the Bulkamid® Rotatable Sheath. As the last step, empty the bladder by removing the optic from the Bulkamid® Rotatable Sheath.

POST-OPERATIVELY

Observe the patient until the first normal voiding where <100 mL residual urine can be measured either by catheter emptying or by a bladder scan. Use soft disposable Ch 10–12 catheter, if intermittent catheterization is necessary. If necessary, repeat the procedure after 4–6 weeks.

SYMBOLS USED ON PACKAGING:

Manufacturer

Consult Instructions for Use

For single use only. Do not re-use

Sterile. Sterilized by moist heat

Use before the date printed on the label

On needle: *non-Pyrogenic*

Batch code

Do not freeze

Do not re-sterilize

Keep away from sunlight

Do not use if package is damaged

contura
Contura International A/S
Sydmarken 23, DK-2860 Soeborg, Denmark