Australia (English)

Bulkamid Important Safety Information ISI for Physicians

INDICATION AND PATEINT TARGET GROUP

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. Bulkamid® Hydrogel is intended for female patients, above the age of 18 years that have failed conservative treatments.

INTENDED USERS

Bulkamid® Urethral Bulking System is intended for use by qualified physicians, e.g., gynaecologist, urologist, or urogynaecologist.

CONTRAINDICATIONS

Bulkamid® Urethral Bulking System is contraindicated in:

- Patients suffering from acute cystitis or urethritis.
- Patients who have active Herpes Genitalis.
- Patients with damaged tissue in the urethra.

WARNINGS

- Do not inject Bulkamid® Hydrogel intravascularly. It is possible that accidental vascular injection will cause embolism.
- A change to the device insertion technique can lead to implant complications.
- During the bulking procedure, the blood vessels must always remain visible at the site of injection to avoid the risk of necrosis and subsequent potential leakage of the hydrogel.
- Evaluate the condition of the tissue (e.g. hardness, oedema, haematoma, atrophy) at the site of injection prior to treatment.
- Patients receiving treatment interfering with blood coagulation have an increased risk of haematoma or urethral bleeding.

PRECAUTIONS

- Do not inject Bulkamid® Hydrogel into sites previously injected with other bulking agents or vice versa.
- If the patient has undergone major dental work or surgery, Bulkamid® Hydrogel should not be injected until the patient is fully recovered.
- If the patient needs surgery or major dental work post Bulkamid® Hydrogel 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 prior to the procedure is recommended.
- It is possible that inflammatory changes seen at the site of implant may later be misinterpreted for other pathology.
- Do not mix Bulkamid® Hydrogel with any other substances.
- Discard any unused material/product per local protocol/procedure.
- Bulkamid® Hydrogel should be used with caution in patients on immunosuppressive therapy. Safety has not been established for patients with autoimmune diseases.
- Do not introduce Bulkamid® Rotatable Sheath into other body cavities.
- 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 re-sterilize Bulkamid® Hydrogel, Bulkamid® Needle or Bulkamid® Rotatable Sheath.
- Do not use any component of the Bulkamid® Urethral Bulking System after the expiry date printed on the packaging.
- The effect of Bulkamid® Hydrogel has not been evaluated in women during pregnancy, delivery, or lactation.
- The efficacy of the device may diminish over time.

Safety and effectiveness of Bulkamid® Hydrogel has not been established in patients with any of the following conditions:

- Under 18 years
- Fragile urethral mucosal lining.
- Urethral hypermobility.
- Detrusor overactivity.
- Known polyuria.
- Unevaluated haematuria.
- Prolapse stage greater than Stage II.
- BMI >35 kg/m^2.
- Neurogenic bladder.

SIDE EFFECTS

General side effects normally associated with any surgical implantation procedure or local anaesthesia also apply to the placement of Bulkamid® Hydrogel.Specifically, the following side effects may be associated with the use of the device system:

- Postoperatively, transient symptoms such as dysuria, stranguria, haematuria, urinary tract infection, and acute retention may occur.
- Scratching of the urethra mucosa may occur during the procedure.
- Long-term side effects such as non-acute retention, abscess formation, fibrosis (tissue hardening), de novo urgency, and necrosis are possible, but rare.