

Avalon Medical

Innovative Veterinary Surgical Products

ReGain™ Injectable Collagen

ReGain™ Injectable Collagen is a purified, bovine-derived, Type I insoluble crosslinked collagen in physiological saline intended for the treatment of urinary incontinence. The *ReGain* kit is intended for use in cystoscopic procedures. The kit is supplied with a sterile 22 gauge needle.

Indications for Use

- *ReGain™* is intended for use in the treatment of urinary incontinence. When injected into the submucosal tissue *ReGain™* creates increased bulk, resulting in improvement of the coaptation of the urethral lumen. Subsequent fibrosis of the tissue at the injection site creates a long-term effect resulting in improvements of the incontinent condition.
- *ReGain™* is intended for veterinary use only in the canine and feline species. NOT FOR HUMAN USE.

Product Description

ReGain™ Injectable Collagen is comprised of 6.3% (w/w) sterile, aldehyde crosslinked, bovine, insoluble collagen fractions and polyethylene glycol dispersed in physiological saline. The collagen fraction consists primarily of Type I insoluble collagen.

Cautions

- For veterinary use only. *ReGain™* is not intended for human use.
- All components are sterile and should be assembled using aseptic technique.
- Store refrigerated at 32-45° F. Do not freeze.

Warnings

- ***ReGain™* is intended for single use only. Opened syringes should not be stored for future use.**
- *ReGain™* contains a bovine-derived component.
- As with the use of any implantable medical device, serious complications may lead to injury or death.

Contraindications

ReGain™ should not be implanted into any patient with:

- Known sensitivity to bovine derived products.
- Known sensitivity to aldehyde products.
- Auto immune deficiencies.
- Infections of any type.
- Severe allergies.
- Severe arthritis.
- Urethritis.

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Patients exhibiting these conditions may have increased sensitivity to injectable tissue products, thus demonstrating a propensity towards accelerated reduction of the injected collagen resulting in decreased long term efficacy. *ReGain™* should not be implanted directly into the vasculature. *ReGain™* contains collagen, a known initiator of platelet aggregation and the resultant coagulation responses.

Shelf Life & Storage

ReGain™ should be stored under refrigerated conditions. *ReGain™* should not be frozen. The product has a shelf life of one year. Unused material should be disposed of properly.

Instructions for Use

ReGain™ should only be used by clinicians who are familiar with cystoscopic techniques associated to the injection of collagen bulking agents. *ReGain™* is supplied sterile in a single use, 2.5ml syringe containing 6.3 % collagen. Once opened, the contents of the syringe cannot be re-sterilized. Discard any unused material.

ReGain™ must be warmed to room temperature before use. Immediately prior to use, the syringe must be shaken vigorously for 30 seconds to assure that the contents of the package have been thoroughly dispersed within the syringe.

- Using standard aseptic procedures prepare the patient for cystoscopy.
- Flush needle with sterile saline prior to use with *ReGain™*.
- Advance needle through the perineum to the desired location for injection.
- Once the needle has been properly positioned, shake the syringe containing the *ReGain™* vigorously and attach to the needle.
- Slowly inject a small portion of the contents of the syringe into the desired submucosal space until bulking is observed and the tissue is clearly demonstrating occlusion of the urethral lumen.
- Should the needle become clogged with the *ReGain™* material, use the other needle supplied with the packaging (after flushing with sterile saline).
- Reposition the needle opposite the original injection site and repeat the process again, observing for tissue bulking.
- Continue until satisfied that the proper bulking density has been achieved.
- Withdraw needle and endoscope.
- Discard any unused material.

Distributed By

Veterinary distributors or contact Avalon Medical at (888) 289-1890 or at www.avalonmed.com.

Presentation

ReGain™ Injectable Collagen includes a single use, 2.5ml syringe and includes a 22 gauge peri-urethral needle. *ReGain™* is available in a single pack (Model 22-01).

Successful use of this product is dependent upon the use of aseptic technique, proper material preparation and good surgical practices. Avalon Medical guarantees that reasonable care was taken in the preparation and processing of this *ReGain™* Injectable Collagen. No other warranty, expressed or implied, applies to the sale or use of *ReGain™*.