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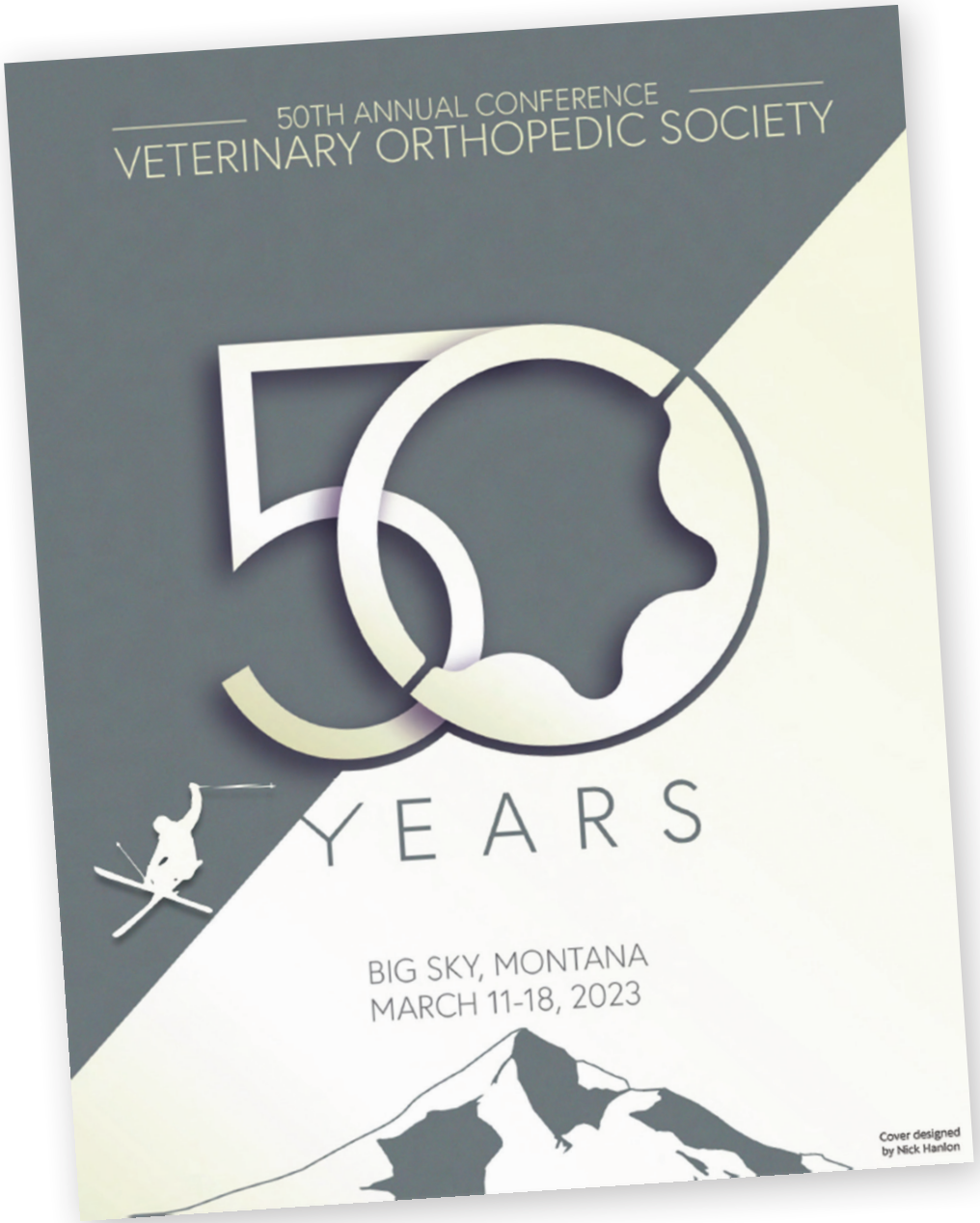
with OsteoCushion™ Technology

Efficacy report:

Kleeman E, Stewart SD. Evaluating the benefit and tolerability of an intra-articular injection of a collagen-elastin biomaterial into the stifle joint of dogs with suspected cruciate ligament rupture. *Proc Vet Orthopedic Soc* 2023; abstract 27. 50th annual conference, March 11-18, Big Sky, MT.



PODIUM ABSTRACTS

(27) Evaluating the Benefit and Tolerability of an Intra-Articular Injection of a Collagen-Elastin Biomaterial Into the Stifle Joint of Dogs with Suspected Cruciate Ligament Rupture

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INTRODUCTION: Cranial cruciate disease (CCD) in dogs often requires surgical intervention, which can be associated with significant expense and potential complications. An intraarticular device consisting of a collagen-elastin matrix functions to replace synovial fluid, provide a scaffold for the intraarticular space, and remains within the joint for a prolonged period of time. Its inert nature could allow it to be used to provide comfort to patients not suitable for surgical intervention.

MATERIALS AND METHODS: Eligible dogs were older than 6 months and diagnosed with a suspected CCR by a Board-certified surgeon. Using a Simon's two-stage design, an initial cohort of 22 dogs was enrolled. The biomaterial was injected into the affected stifle joint and dogs were followed over 84-days with serial evaluations using the visual lameness score, modified Glasgow Composite Pain Score (mGCPS), and the Liverpool Osteoarthritis in Dogs (LOAD) questionnaire.

RESULTS: Fourteen of 22 dogs (64%) experienced a >25% improvement in their mGCPS. Fifteen dogs (68%) showed an improvement in their visual lameness scores (median improvement 36%). 16 dogs (73%) had an improvement in their LOAD scores (median improvement 43%). There have been no serious adverse events reported.

DISCUSSION/CONCLUSION: Over half of injected patients were reported to have a positive response in the first stage of the study. This suggests a significant benefit to the device and allows for accrual into stage two of the study (18 additional dogs). The lack of adverse events reported supports the device as being a minimally invasive management option for canine CCD.

ACKNOWLEDGEMENTS: Funding for this study has been provided by the company that produces the collagen-elastin biomaterial being investigated.

spryng™

with OsteoCushion™ Technology

The relieving **OsteoCushion™ Technology** with a *naturally* derived particulate matrix for intra-articular injection to avoid issues associated with lameness, joint pain, and osteoarthritis.

PRODUCT DESCRIPTION

- Composed of a protein-carbohydrate matrix made from purified, natural materials.
- Micro-cushion self-assembles to form a sterile, insoluble, and pliable matrix using a proprietary, patented process.
- Naturally forms a strong, sterile, hydrated biomaterial that mimics natural cartilage.
- Offers moderation of joint pain without pharmacologic, chemical, or metabolic action.
- Available only through veterinarians, for veterinary administration.

INTENDED USE

- Aid in the management of joint pain from loss of cartilage or tissue-bone mechanical malfunction caused by joint dysfunction not associated with infection.

FABRICATION

- Precisely sized micronized particles composed of 2 purified, naturally derived animal proteins (collagen, elastin) and 1 animal carbohydrate (heparin).
- Micro-particles (~1 million/cc) form an insoluble and pliable matrix.
- Patented, proprietary product.

FDA STATUS

- Veterinary medical device.
- Not a drug; does not rely on chemical or metabolic action in the animal's body to achieve intended effects.

ADMINISTRATION

- Administer using a sterile needle inserted into synovial space of affected joint, applying even pressure on the plunger of the syringe.
- Use clinical judgement pertaining to volume needed.

DURATION

- Particles do not readily dissolve, are resistant to interstitial proteases, and are too large to pass through the pores of the synovium.
- A single treatment provides long-duration joint protection.

SAFETY

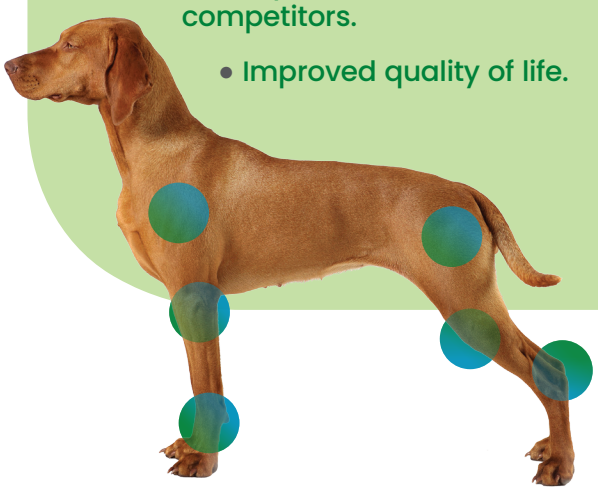
- Naturally derived, has been demonstrated to be safe.
- Used safely in humans for dermatological procedures.

PACKAGING, STORAGE

- Supplied in sterilized, aseptically filled syringes (absent needle).
- Syringe contains 2 cc Spryng; 1 syringe/box.
- Store at room temperature (approx. 40° to 90°F). Use within 26 months of the manufacture date on package.

KEY FEATURES

- Injected cushion that mimics natural cartilage in arthritic or damaged joints.
- Provides immediate joint protection.
- Naturally derived, inert, precisely sized particulate matrix readily integrates with joint fluid and conforms to synovial space.
- Spongy, cushioning action absorbs and releases synovial fluid in response to mechanical forces.
- Structural scaffold to help joint tissue.
- Helps protect the joint from further injury, unlike other products that only treat symptoms (NSAIDs, corticosteroids, monoclonal antibodies, radiation, etc.).
- Long-term joint reinforcement.
- Easy intra-articular injection.
- A medical device, not a drug.
- Positive benefits for less client cost.
- Innovative product with no direct competitors.
- Improved quality of life.



SpryngHealth.com youtube.com/@spryngheath

Spryng™ with OsteoCushion™ Technology is a veterinary medical device by **PetVivo, Inc.**
Veterinary use only - federal law restricts this device to use by or on the order of a licensed veterinarian.
See reverse side for more complete product information.

spryng™
with OsteoCushion™ Technology

Instructions for use

Veterinary medical device for use in dogs.

Veterinary Use Only
Federal law restricts this device to use by or on the order of a licensed veterinarian.

1. Product Description
Spryng is an intra-articular injection that is designed to prevent the occurrence and re-occurrence of joint pain from loss of cartilage or tissue-bone mechanical malfunction by augmenting and reinforcing cartilage to assist in the normalization of joint function. The Spryng gel-particles act as a micro-cushion mass of material that integrate into the synovial fluid and surrounding space to provide a soft, lubricous, elastic cushion. The synovial fluid is absorbed by and passes through the gel-particles, which are insoluble and will slowly absorb into the surrounding tissues within the joint.

Spryng is composed of a protein-carbohydrate matrix made from purified, natural materials. Each Spryng micro-cushion is a purified composition of two proteins (collagen, elastin) and a carbohydrate (heparin glycan) that self-assemble to form a sterile, insoluble, and pliable matrix using a proprietary, patented process. This process naturally forms a strong, sterile hydrated biomaterial that mimics natural cartilage.

1.1 How Supplied
Spryng material is sterile and supplied in aseptically filled, luer lock syringes. Syringes contain 2 cc of Spryng. Each package contains one (1) syringe of Spryng (needle not included).

Figure 1.

1.2 Storage
Spryng particles are recommended to be kept at approximately 40°–90°F. Use of Spryng particles is recommended within 26 months of the manufacture date on the package.

2. Intended Use and Indications for Use
Spryng particles for intra-articular injection are intended for cartilage reinforcement and/or augmentation. It is indicated to aid in the management of joint pain from loss of cartilage or tissue-bone mechanical malfunction caused by joint dysfunction not associated with infection (e.g., lameness, osteoarthritis, degenerative joint disease). Spryng matrices restore proper joint mechanics by adding natural, viscosolid matrices to the joint's synovial fluid.

For use in dogs to maintain and/or improve articulation.

3. Contraindications
Spryng is contraindicated in the following conditions:

- If there is an infection.
- If significant inflammation is present in the joint (i.e. swollen, tenderness, erythema).

Note: Spryng particles can be injected if there is no or mild inflammation in the joint or if the inflammation has been effectively treated with an anti-inflammatory agent. If inflammation exists, prior effective treatment with anti-inflammatory agents is recommended.

4. Warnings
Spryng particles must not be injected into blood vessels. Injection of Spryng particles into blood vessels can interfere with local circulation, resulting in vessel laceration, occlusion, infarction, embolic phenomena, and/or abscess at injection site.

Not for use in humans. Keep this device out of the reach of children.

5. Precautions
Using drugs that reduce coagulation (e.g., NSAIDs) may cause increased bruising or bleeding at the injection site. Injection should be performed only by a licensed veterinarian skilled in the delivery of intra-articular (IA) injections.

6. Directions for Use
Spryng material is sterilized and aseptically filled in syringes containing 2 cc of material. It is intended for single-use, intra-articular injection (Figure 1). Use clinical judgement pertaining to volume needed. The amount of Spryng particles injected should represent an appropriate volume as determined by the veterinarian.

Preparation for use

- The injection site should be thoroughly disinfected.
- Follow aseptic techniques.
- Animal restraint and sedation is recommended.
- The injection technique, location, amount of synovial fluid removal, depth of injection, needle type, and the administered quantity of Spryng, may vary based on veterinarian clinical judgment and the joint selected.
- Spryng particles should be administered using a sterile needle (e.g., 18-23G). The needle should be inserted based on the veterinarian's assessment of the needle tip location.
- Settling of Spryng particles in the buffer solution during storage is normal; injection in the settled state will not impact its efficacy. Shaking to disperse particles may be performed.
- Inject Spryng particles by applying even pressure on the plunger rod.
- Route of administration is via intra-articular injection. Multiple joints may be injected as a part of the same treatment.
- Spryng is recommended for repeat administration depending on the veterinarian's assessment, animal activity levels, and age of the animal. In case studies, Spryng particles provided beneficial effect for greater than one year.
- There is no maximum annual administration frequency.
- Each syringe is for a single use only. Do not use if the package is open or the syringe is damaged.

Disposal
The syringe and any unused material must be discarded after a single treatment visit. Follow national, local, or institutional guidelines for use and disposal of medical sharp devices.

7. Potential Adverse Reactions
Mild, short-term injection-site swelling has been observed. Adverse events should be reported to PetVivo at 844-PET-VIVO (738-8486) or info1@petvivo.com

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