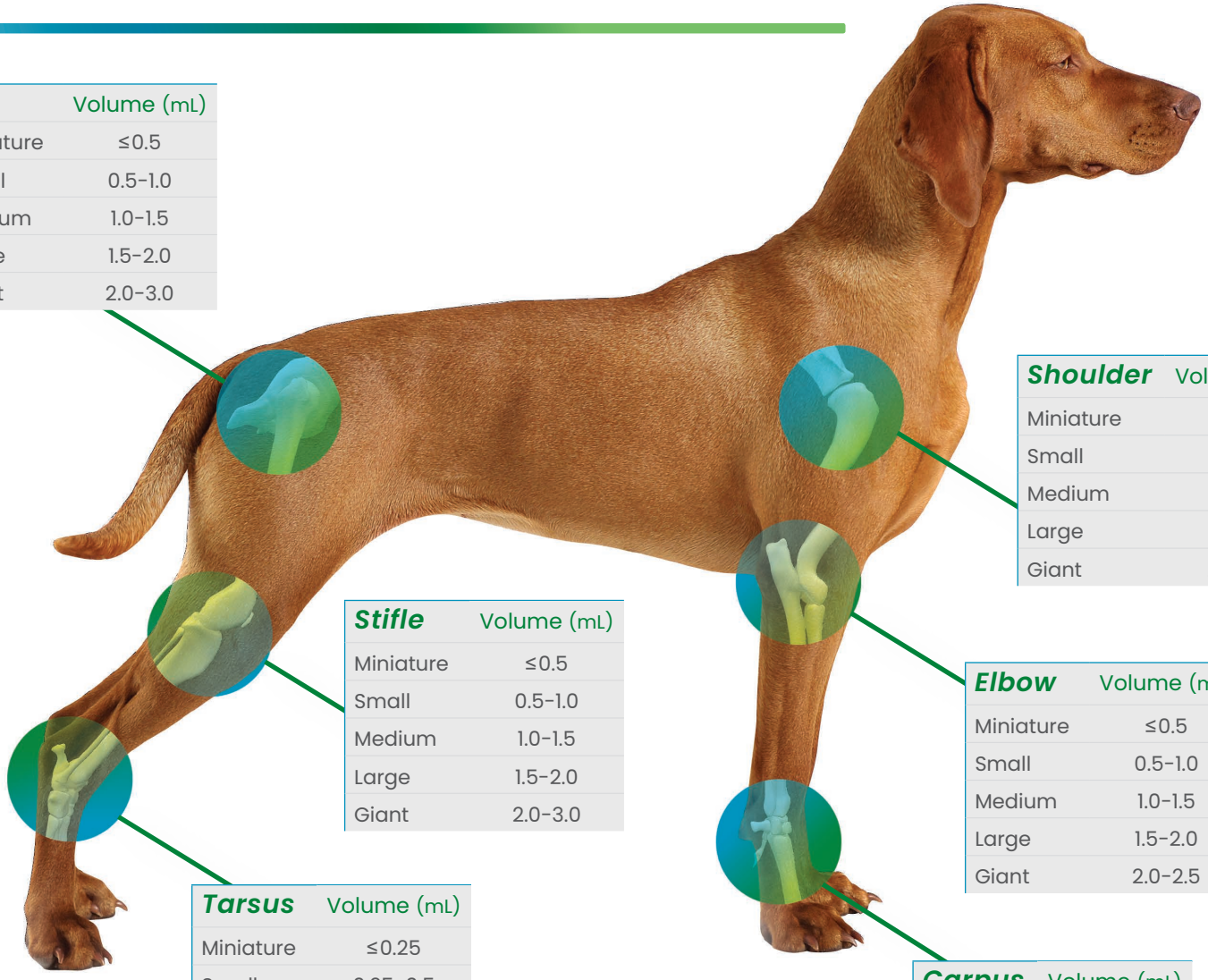
Spryng™ Intra-Articular Injection Volume Guidelines

spryng™
with OsteoCushion™ Technology

The volume of Spryng™ to administer will vary based on body size, breed, and disease status of the specific joint. The suggested volumes in this document are approximate guidelines. In dogs, it is common to use a needle size ranging between 19-25 g. The volume and needle size are at the attending veterinarian's discretion and may vary from case to case.

Category	Weight (lb)*
Miniature	<10
Small	10-25
Medium	25-50
Large	50-100
Giant	>100

*lean body weight



Hip	Volume (mL)
Miniature	≤0.5
Small	0.5-1.0
Medium	1.0-1.5
Large	1.5-2.0
Giant	2.0-3.0

Shoulder	Volume (mL)
Miniature	≤0.5
Small	0.5-1.0
Medium	1.0-1.5
Large	1.5-2.0
Giant	2.0-3.0

Stifle	Volume (mL)
Miniature	≤0.5
Small	0.5-1.0
Medium	1.0-1.5
Large	1.5-2.0
Giant	2.0-3.0

Elbow	Volume (mL)
Miniature	≤0.5
Small	0.5-1.0
Medium	1.0-1.5
Large	1.5-2.0
Giant	2.0-2.5

Tarsus	Volume (mL)
Miniature	≤0.25
Small	0.25-0.5
Medium	0.25-1.0
Large	0.75 - 1.0
Giant	≤1.0

Carpus	Volume (mL)
Miniature	≤0.25
Small	0.25-0.5
Medium	0.25-1.0
Large	0.75 - 1.0
Giant	≤1.0

These values represent actual volumes of Spryng™ administered under clinical conditions by surveyed practitioners.

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Instructions for use

Veterinary medical device for use in dogs and cats.

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 intended to aid in maintaining the mechanical homeostasis of tissues within and adjacent to the synovial lining of the joint. Spryng is composed of a protein-carbohydrate matrix made from purified, natural materials. Each viscoelastic micro-cushion of Spryng 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 durable, sterile, hydrated biomaterial that mimics natural cartilage properties. The synovial fluid is absorbed by and passes through the porous gel-particles (Figure 1), which are insoluble and will integrate with the synovial fluid before slowly adsorbing onto the synovial membrane and subsequently being integrated into the subsynovial tissue.

How Supplied
Spryng material is sterile and supplied in aseptically filled, luer-lock syringes (Figure 1). Each package consists of one (1) syringe, which contains no less than 2 mL of Spryng in a phosphate-buffered saline carrier solution (needle not included). It is intended for single-use, intra-articular injection.

Figure 1.

Storage
Spryng should be stored at room temperature with a range of 40°-90°F (5°-30°C). Use of Spryng particles is recommended within the expiration date stated on the package.

2. Intended Use and Indications for Use
Spryng microparticles promote restoration of proper joint mechanics by adding natural, viscosolid matrices to the joint's synovial fluid. Spryng is indicated to aid in the management of noninfectious sources of joint pain including, but not limited to, joint instability, abnormal joint biomechanics, degenerative joint disease, and osteoarthritis..

3. Contraindications
Spryng is contraindicated in the following conditions:

- If there is a suspected infection in the intended joint or adjacent soft tissue or skin.
- If significant joint inflammation is present. If inflammation exists, prior effective treatment with anti-inflammatory agents is recommended.

4. Warnings
Do not inject Spryng intravascularly, as blood vessels may become occluded, infarcted, or emboli may form leading to life-threatening complications.

The use of this product in combination with other intra-articular medications has not been evaluated.

Not for use in humans.

Spryng has not been evaluated when combined with other intra-articular medications in one syringe or co-administered during a single procedure.

5. Precautions
Use Spryng with precaution in animals with a previous history of hypersensitivity. 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 mL of material. It is intended for single-use, intra-articular injection (Figure 1). Use clinical judgement pertaining to volume needed. Some joints may require more or less than 2 mL of material. The amount of Spryng particles injected should represent an appropriate volume as determined by the veterinarian.

Preparation for Use

- Animal restraint and sedation is recommended.
- Perform a thorough surgical prep over the joint to be injected, following aseptic techniques in accordance with standard veterinary practices.
- Only the contents of the syringe are sterile. The exterior of the syringe is not sterile. Adjust technique accordingly.

Administration of Spryng

- Agitate the syringe to resuspend the particles homogeneously, ensuring ease of administration and accurate dosing.
- Administer intra-articularly using a sterile 19-25g needle.
- Apply even pressure on the plunger rod while injecting Spryng particles
- Do not over-distend joints.
- Volume injected may vary from 0.25 mL up to 3 mL, depending on breed, intended joint, and joint capsule elasticity.

Additional Administration Information

- 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 target joint.
- Multiple joints may be injected as a part of the same procedure.
- Repeat or additional administration of Spryng may be considered based on the veterinarian's assessment. Field experience suggests the benefits of Spryng are long lasting and may extend beyond one year.
- A maximum annual administration frequency has not been established.
- If a syringe is only partially used, discard the unused portion. 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. Counseling for Owners
Reasonable expectations should be discussed with the owner prior to administration of Spryng regarding time to onset, duration, and level of improvement. Owners should be informed about pre- and post-administration NSAIDs, activity restrictions, contraindications, precautions, and potential complications. They should be encouraged to contact their veterinarian if unexpected signs occur.

8. Potential Adverse Reactions
Adverse events should be reported to PetVivo at 844-PET-VIVO (738-8486) or info1@petvivo.com

Some animals experience discomfort within the first 48 hours after injection, similar to other intra-articular therapies. If not septic in origin, these events normally begin to resolve within 24 hours with symptomatic therapy. This may include rest, cold therapy, NSAIDs, systemic anti-inflammatories, antimicrobials, and cold laser, among other modalities. Veterinarians should use their clinical judgement to determine whether unexpected signs could be related to a potentially septic joint.

MADE IN THE USA
Manufactured, marketed, and distributed by PetVivo, Inc.
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