Could your organization use calcium chloride? “Nuts and Bolts”

Getting involved in field testing of nonsurgical sterilants:
Lessons learned, and what organizations and veterinarians should consider when getting involved

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Overview

• How calcium chloride sterilization works
• How calcium chloride injection is made
• Could your organization use it? (regulatory)

How calcium chloride sterilization works

Testicular injection
Nerves in the scrotum of male

How calcium chloride injection is made

VIDEO 1

VIDEO 2

OR
How calcium chloride is made

**Ingredients:**
- 20% calcium chloride dihydrate USP
- Pure pharmaceutical-grade alcohol

mixed and sterile filled in vials

If a compounding pharmacy isn’t available...

How calcium chloride is made

2,500 dogs

ACC&D 5th International Symposium on Non-Surgical Contraceptive Methods of Pet Population Control
When might it be appropriate?

- Is Zeuterin®/Esterisol® available?
  - Yes: Explore regulations; obtain community support
  - No: Explore regulations; obtain community support

- Is behavior change needed?
  - Yes: Use Zeuterin®/Esterisol® (much simpler!)
  - No: Explore regulations; obtain community support

Could your organization use it?

Investigational New Animal Drug #______?

Regulatory Status

- Countries without strong veterinary regulatory structure
  - “It depends” for animal and community

- Countries with strong veterinary regulatory structure
  - I.e., Europe, Canada, Mexico, S. Africa, Brazil, Australia, Argentina, Indonesia

- United States

Is it “Complementary and Alternative Veterinary Medicine?”

... in which case you’re probably okay.
Or is it “Extralabel Drug Use,” in which case there are conditions to meet?

... But it can’t be, because there is no labeled drug on the market.

But isn’t compounding from bulk substances illegal according to the FDA?

...Yes, but the AVMA recognizes circumstances in which it may be medically necessary.

Current Status of Calcium Chloride

How brave are you?

In any case, follow best practices, including:
- read all peer-reviewed literature
- establish a patient relationship
- start slowly
- keep records
- follow up
- be prepared to treat or surgically castrate any animals that have problems
- until confident in technique and outcome, use only in animals that can be monitored (no TNR use)

And seek community support, including:
- thought leaders
- local animal lovers
- colleagues
- local officials
- local agitators
- regional veterinary society / veterinary board
- state or country-level regulators

...more detail at our table and on the USB flash drive.
Your Options

Try it out
• Read everything
• Start small
• Try first where there is no other option?
  - bleeding diatheses (not von Willebrand’s)
  - remote locations without surgical facilities
  - anesthesia risk due to age/condition

Wait it out
• Use Zeuterin™ if behavior change not necessary (dogs only)
• Encourage funders to take CaCl through the regulatory process

Shout it out
• Spread the word
• Join the effort on Facebook

Considering the first option?
Get the data at our table and on the USB flash drive.

Thank you to everyone involved!

These experts can answer questions:

Natalie Jones
Far and dog studies in India

Raffaella Leoci
Dog studies in Italy

Kevin Morris*
- FDA program liaison
- Community partners liaison

Linda Brent
Grants manager, calcium chloride research

Douglass Oeller
Douglass Oeller Consulting
Program manager, FDA submission

Your Options

Research & Field Expertise

Program Mgmt/Regulatory

Kuladip Jana
Cat and dog studies in India

* (pro bono to date)