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LipogemsVet for Canine Orthopedics

This set of instructions covers the clinical use of the Lipogems adipose processing system for use in therapy of orthopedic conditions in the dog. The instructions are divided into four parts:

Part I Lipogems Setup Instructions

Part II Lipogems Lipoaspiration Instructions

Part III Lipogems Processing Instructions

Part IV Lipogems Treatment Instructions

WARNING: Lipogems cannot be used in any manner in the intravascular space (intra-arterial, intravenous, regional perfusion) due to major risk of fat embolism.

Pre-Collection Activities:

- 1. Inform Owner on the entire procedure
- 2. Complete "Animal & Contact Information" and "Injury Information" sections of the **Dog LipogemsVet Form**

Part I – LipogemsVet Setup Instructions

This section describes the set up to conduct a liposuction procedure and Lipogems processing for the dog.

- 1. Create a sterile field near the patient on which to lay out the sterile components and to be able to conduct the adipose processing. Ideally it is convenient to have a space at least 100cm long x 70cm wide.
- 2. Open the Lipogems Kit.
- 3. Inside the kit are the following components to be placed into sterile field:
 - a. Sterile Lipogems Processing System with chamber, tubes and waste bag.
 - b. Infiltration cannula
 - c. Lipoaspiration cannula
 - d. Supplied Convenience Kit of disposables:

60 ml luer lock syringe 2
10 ml luer lock syringe 4
10 ml luer VakLoc syringe 1
Adapters – male-to-male luer 2

e. Supplies Not Provided:

2 x 18G hypodermic needles Sterile infiltration solution bowl 250 ml 0.9% normal saline 500 ml 0.9% normal saline Adrenaline 1mg IV pole or equivalent

- f. Infiltration Solution
 - i. Make up the following:
 - 1. 250 ml 0.9% normal saline
 - 2. 1mg Adrenaline

Both in the sterile bowl

Part II - LipogemsVet Lipoaspiration Instructions

This section describes how to obtain an adipose sample from the dog by lipoaspiration. These instructions are specific for the collection of lipoaspirate from the flanks of a dog and specifically for use in the Lipogems processing system.

Goal: One flank will generally yield 30-60 ml lipoaspirate
30 ml of high quality white lipoaspirate will ideally yield 10ml of suitable
Lipogems material for intra-articular injection (4-5 doses)

1. Preparation of the liposuction site

- a. Clip the lumbar region above the flanks (15cm long x 10cm wide).
- b. Anesthetize the dog and place him in sternal recumbency.
- c. Scrub the site as in standard surgical procedure.
- d. Cover the site by surgical drapes. 8cm long x 6cm wide uncovered surgical site should be left.



e. Adipose tissue thickness must be at least 1cm to allow suitable collection.

2. Entrance Port

Pull up the skin and make an entrance hole (as in picture) in the center of the clipped area with 18G hypodermic needle, taking care to keep the needle angled towards the fat deposit and to penetrate into the subcutaneous area. The key to success of this step is to keep the hole small enough to avoid loss of suction during aspiration of adipose tissue but large enough to not have the skin dragged excessively on the harvesting cannula during insertion and retraction.



3. Infiltration

- a. Load 4 10 ml luer lock syringes with the prepared Infiltration Solution from the Setup Steps. If a technician is available, he can reload the 10 mL syringes with infiltration solution to speed the loading of Infiltration Solution while the veterinarian is infusing.
- b. The infiltration technique is critical to success. Slowly advance and retract the Infiltration Cannula into the adipose tissue in order to make tunnels in the area where fat will be collected (a triangle shape 10:00 to 2:00 on the clock face). Do NOT pull the cannula all the way out. Once the tunneling is done, slowly advance the cannula into the fat and deposit the Infiltration Solution while slowly retracting the cannula— DO NOT STOP MOVING WHILE INFUSING OR YOU WILL POOL THE INFILTRATION SOLUTION IN POCKETS. You can feel the cannula movement manually with finger placed over the area of infiltration.



- c. After each syringe full of Infiltration Solution has been delivered, disconnect the cannula leaving the cannula in the fat, and reload with another 10 ml until 100 ml of Infiltration Solution is used in each flank of the dog.
- d. **Critical:** Wait a minimum of 10 minutes and a maximum of 20 minutes to allow the solution to diffuse. This time allotment is needed for vasoconstriction (hemostasis) and soaking of the adipose tissue allowing an easier liposuction.

4. Adipose Harvest

- a. Using sterile technique, attach the harvesting cannula to one of the 10ml VacLok syringes, introduce it into the entrance hole and insert at angle towards the fat pad at least 3 cm past the collection cannula hole, so that suction can be created/maintained. If the cannula does not fit through the hole, enlarge it with the 16 gauge needle.
- b. PRE-TUNNELING This is a critical step. Following the same pattern as the infiltration cannula, you will use the Harvest Cannula WITHOUT SUCTION to pre-tunnel into the fat. You are loosening up the fat particles



so that you will be able to easily remove the adipose tissue once suction is applied. Follow the 10:00 to 2:00 pattern with insertion of the Harvest Cannula and then move back, WITHOUT FULLY WITHDRAWING, and then move forward again. Repeat through entire field of collection.

- c. HARVEST With the cannula properly inserted into the fat pad, apply plunger suction and lock by withdrawing plunger and then turning to lock in place.
- d. HOLD THE CANNULA AT THE WHITE PLASTIC HUB TO AVOID BENDING/BREAKING. With continuous suction and a smooth continuous and gentle motion, partially withdraw and re- direct the cannula multiple times through the 10:00 to 2:00 field and multiple times over each segment. As you withdraw, turn the cannula to assist with cutting small pieces of fat and drawing them into the syringe. The aspirated fat tissue should flow easily. If suction is lost, remove VacLok syringe, unlock and depress plunger to remove air, reattach and lock plunger back in vacuum position.
- e. As the cannula is withdrawn and re-directed, no more than ¾ total length of the cannula should be xposed to avoid loss of suction. Even

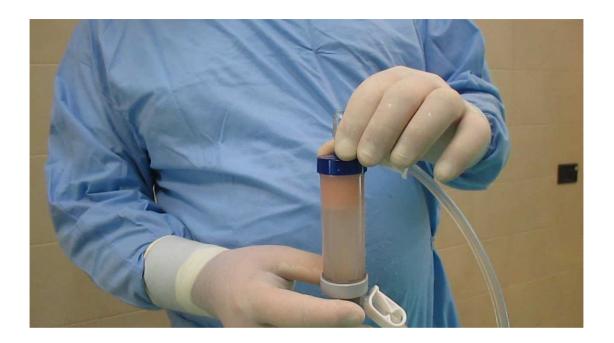
- and slow movement is most efficient, **as in playing a violin**, and twisting the cannula as you withdraw helps cut fat, as it is suctioned.
- f. Once the fat tissue has nearly filled the syringe, disconnect the syringe from the cannula, **leaving the cannula in the fat**. Connect the 10 ml harvest syringe to the 60 ml syringe with the sterile male-to-male adapter and push the lipoaspirate into the 60 ml syringe.
- g. Attach 10 ml VacLok syringe to the cannula and repeat the aspiration procedure as above.



- h. If the harvested material becomes red, it is time to stop on that side. Redirecting the cannula to be in the center of the fat pad may be an option.
- i. The object is to collect 30-60 ml of lipoaspirate from each flank of the dog.
- j. Once completed, proceed to the Lipogems Processing Instructions. If a technician is doing the processing, the collector could proceed to do the other flank, if orthopedical needs dictate collecting both sides.

5. What to look for in a liposuction collection:

The collection should look like the fat in the image below. Pinky harvested material (presence of low amount of blood) is acceptable and it is possible to continue the procedure.



- 6. **Skin Closure:** Leave the portal in the skin open to allow for drainage.
- 7. Antibiotics: Usage of antibiotics is recommended.
- 8. **Sterilization and Cleaning:** All materials are single-use disposables and not designed for re-use.
- 9. **Record** the total volume of lipoaspirate in the Dog LipogemsVet Form.

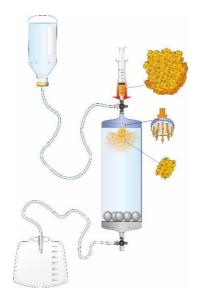
Part III - LipogemsVet Processing Instructions

Once lipoaspiration collection is complete:

- 1. Verify device connection is tight with the collection bag
- 2. Ensure the discard bag is well below device (place on floor)
- 3. Hang saline bag higher than the device (IV pole or equivalent)
- 4. All tube clamps closed except for the one closest to discard bag
- 5. Pierce the saline bag's entry port and fill the IV drip flow chamber ½ full
- 6. Turn the processing chamber GREY end up
- 7. Fill the processing chamber completely with saline by:
 - a. Open the clamps one by one starting at the one below the IV dripflow chamber until all are open
 - b. Allow the process chamber to fill completely with saline
 - c. Ensure all air bubbles are absent (gently shake if necessary)



- 8. Turn the processing chamber so that the BLUE side is up again and then:
 - a. Close clamp on saline input line next to the BLUE end



- 9. Insert lipoaspirate into the processing chamber by:
 - a. Removing air from the 60 ml syringe with lipoaspirate (photo a)
 - b. Attaching the 60 ml syringe to the processing chamber at the BLUE end (photo b)
 - c. Instilling approximately 30ml into the device (photo c)



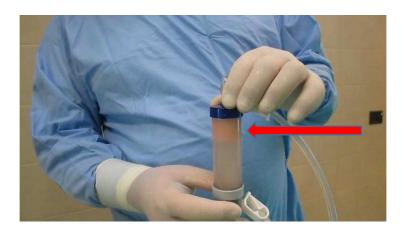




- 10. While keeping the Blue end up, open the input line clamp near the BLUE end and allow saline to flow through processing chamber for approximately 20 seconds. The saline with some lipid, red cells, and debris will flow into the waste bag on the floor.
- 11. Clamp off lines at the top and bottom of the processing chamber
- 12. Process the lipoaspirate by:
 - a. Shaking the processing chamber for approximately 2 minutes to emulsify the fat
 - i. Hold the processing chamber firmly in your hand
 - ii. The motion should be quite aggressive and in both directions side to side and up and down



- b. Open clamps at top and bottom of the processing chamber and allow saline to flow until you can nearly see someone looking through the mixture in the processing chamber approximately 20-30 seconds
- c. Clamp off both lines at the top and bottom of the processing chamber
- d. Tissue should appear light yellow or slightly red and compact, floating on transparent liquid



13. Turn the processing chamber so that the GREY end is up

- 14. Connect a 10ml syringe to each end of the processing chamber by:
 - a. Ensuring no air gap in either syringe
 - b. Then attaching the syringes, one to each end of the processing chamber (photo a)
- 15. Aspirate 10 ml saline from the BLUE end by:
 - a. Opening clamp on input line near the BLUE end to allow saline to flow
 - b. Aspirate 10ml saline into syringe (photo b)

16. Clamp closed the input line near the BLUE end







- 17. Inject the saline into the processing chamber by:
 - a. Injecting the saline firmly into the BLUE end
 - b. The syringe at the GREY end should fill with Lipogems mixture (photo c)
 - c. Remove syringe with Lipogems mixture and place in upright position to allow separation of Lipogems material from excess saline
- 18. If a significant amount of floating processed tissue is left at the top of the processing chamber, attach a new 10 ml syringe to the GREY end and repeat steps 15, 16 & 17 to collect another Lipogems syringe.
- 19. If more lipoaspirate is available to process then:
 - a. Remove saline syringe from BLUE end
 - b. Repeat all steps starting at step 8
- 20. Let the syringes with Lipogems settle with tip of syringe facing down for 5-10 minutes. Lipogems are adipose and will float.
- 21. Once the Lipogems have clearly separated from saline, discard the excess waste saline being careful to retain all the Lipogems in the syringe for injection. See Lipogems Treatment Instructions.
- 22. Discard entire intact processing apparatus in an appropriate manner.

PART IV – LipogemsVet Trearment Instructions

Treatment instructions are very specific to patient and injuries to be treated as well as the amount of Lipogems that can be obtained from a particular lipoaspiration collection. The guidelines are:

- 1. Use 1-5 ml of Lipogems per injury location to be treated.
 - a. The dose range of Lipogems is 1-5 ml.
 - b. Use the higher end if adequate Lipogems are collected and lesion allows.
 - c. Use the lower end if a lower volume of Lipogems is collected.
 - d. Try to keep minimum of 1 mL to send to the laboratory for storage for future culturing needs.
- 2. To make dosing easier, you can put all the Lipogems from the various syringes into one syringe, using the provided male-to-male adapter.
- Record the total volume of Lipogems in the Dog LipogemsVet Form and then
 determine your treatment plan as to volume per site. Record the volume per
 treatment site also.

4. Treatment

- a. The Lipogems product should easily flow through a 20 gauge needle.
- b. Place needle into treatment site using appropriate landmarks.
- c. Inject Lipogems into the treatment site without overfilling the lesion.