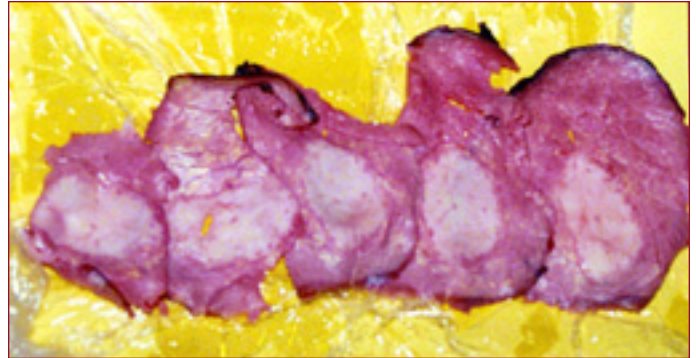


**SECTION III. RECOMMENDED BEST MANAGEMENT PRACTICES (BMPs) TO MEET QUALITY CHALLENGES****III-A. Pharmaceutical Use & Administration*****Reducing the Economic Impact of Injection Site Blemishes/Lesions***

Based on the **2000 National Beef Quality Audit**, injection site blemishes (or lesions) cost the beef industry \$188 million annually. This means producers lose an average \$7.05 per head per year in the value of the fed cattle marketed.

In 1991, 21.6% of fed cattle marketed had injection site lesions with 14.2% of these lesions being fluid-filled. By 1998, this defect was down to 5.6% with 0.3% being fluid-filled.

Fluid-filled injection site lesions indicate more recent occurrence, such as during the animal's time in the feedlot. However, improper injections given to calves result in non-fluid-filled injection site lesions, which are later found in the muscle meat of cattle as yearlings and adults.



- (Above) These slices of roast beef came from an airport cafe, where they were about to be served to a customer. These lesions were not discovered until the fully cooked roast was sliced down by a foodservice employee.



On the other hand, the results of the first **Market Cow and Bull Quality Audit** in 1994 showed the percentage of injection site lesions found in meat from culled beef and dairy cattle was 28.9 (7.5% fluid-filled). In the second Market Cow and Bull Quality Audit (1999), **the percentage of injection site lesions INCREASED to 40.9.**

Contrary to popular belief, not all beef from market cows is sold as ground beef. For example, ribeye rolls and rounds from market cows and bulls are used as whole muscle cuts in popular consumer products such as Philly Steak and roast beef sandwiches as well as marinated and tenderized steak products.

**Research sponsored by NCBA uncovered a negative relationship between meat tenderness and injection sites, including those injection sites that had no visible lesion.**

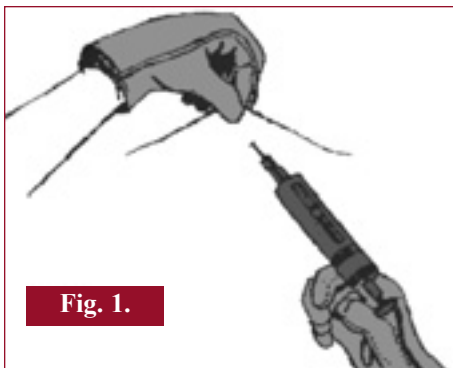
Findings concluded that all intramuscular (IM) injections, including sterile water, create permanent damage -- regardless of the age of the animal at the time the product was given. At the very least, tenderness is reduced in a 3-inch area surrounding the injection site.

## Injections -- Site and Techniques

**Moving the injection site area TO THE NECK stops costly damage to economically important cuts of beef.** It also makes it easier for packers to identify lesions at the plant level, so they do not end up inadvertently on a consumer’s plate. To lessen injection site defects, the preferred site for all injections **has now been reduced to the smaller injection area of the neck region** compared with the larger area introduced as the preferred site in the 1990s (Fig. 2). This is particularly important when administering intramuscular (IM) products. The reason for this is, even the shoulder chuck primal contains value-added cuts in today’s beef trade. The food industry has introduced a number of new, “value added” beef cuts utilizing this area of the carcass. Furthermore, the food industry has moved to a modified atmosphere (MA) packaging process for case-ready meats. This process contains 80% oxygen and 20% carbon dioxide mixture, which can cause green discoloration of the meat close to an injection site, *even when no blemish or lesion has occurred.*

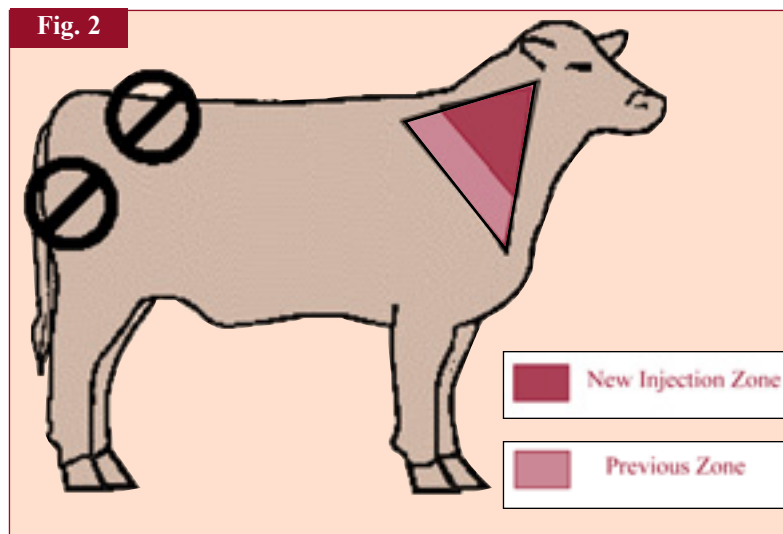
Several animal health products are now approved to be injected into the ear of cattle. This location is excellent from a BQA perspective as ears are removed at harvest and do not enter the food chain. Certain antibiotics and implants are approved for the ear injection site. The exact location on the ear depends on the product. For example, liquid growth implants are given in the middle third of the ear; whereas some antibiotics are administered in the outer third of the ear. **The ear must be very clean, and producers should take care to avoid blood vessels.** Read product labels carefully. An example of the ear injection technique can be found on the internet at: [http://www.excede.com/docs/ERA\\_TechBull.PDF](http://www.excede.com/docs/ERA_TechBull.PDF).

Whenever possible, choose products formulated and labeled for injection under the skin (subcutaneous/SQ) rather than intramuscular (IM). Figures 1 and 2 illustrate proper injection site and techniques.



**Fig 1. “TENT” TECHNIQUE FOR SQ INJECTION**

Calf necropsy demonstrations prove that when SQ products are given with one hand sliding the needle under the skin, some of the product and needle penetrate the muscle. The “tent” technique ensures that the product is truly being administered in the subcutaneous region.



**Fig. 2. NEW INJECTION ZONE**

To lessen injection site defects the preferred injection site has been reduced to the smaller (dark red) injection area shown above -- particularly with IM products. This has become necessary to ensure the quality of new value-added products from the chuck. Even in the absence of blemishes, case-ready packaging processes can cause discoloration of meat near an injection site.

## Needle Selection

Primary considerations in needle selection include: route of administration, size of the animal, and location or site of the injection.

Secondary considerations include: viscosity of the fluid (how thick and tenacious the fluid is) and volume injected.

ROUTE OF ADMINISTRATION									
Injectable Viscosity	SQ (1/2 - 3/4 inch needle)			IV (1 1/2 inch needle)			IM (1 inch needle)		
	Cattle Weight			Cattle Weight			Cattle Weight		
	<300	300-700	>700	<300	300-700	>700	<300	300-700	>700
<b>Thin</b> Ex: Saline	18	18-16	16	18-16	16	16-14	20-18	18-16	18-16
<b>Thick</b> Ex: Oxytetracycline	18-16	18-16	16	16	16-14	16-14	18	16	16

**SELECT THE NEEDLE GAUGE TO FIT THE CATTLE SIZE  
(THE SMALLEST PRACTICAL SIZE WITHOUT BENDING)**

## Proper Sanitation is Essential

Some basic steps to good sanitation include:

- ▶ Keep the contents of the bottle sterile.
- ▶ Clean transfer needles regularly to avoid contamination.
- ▶ Do not go back into the vaccine bottle with a needle once it has been used for anything else.
- ▶ Change needles frequently, at least every 10 animals, or every syringe of vaccine.
- ▶ When using killed vaccines, keep a saucer or sponge of alcohol or disinfectant nearby, and wipe off the needle after each use. However, do not disinfect needles between injections when using a modified live vaccine, as the disinfectant can destroy the vaccine.
- ▶ Make sure the injection site is clean. Injecting into a wet or muddy site increases the risk for spreading disease, and it increases the incidence of injection site lesions.

## Cleaning Syringes and Needles

The use of disposable equipment is recommended and preferred. However, if used, reusable syringes, needles, and other injection equipment should be heat-sterilized by boiling. If any disinfectants are used -- including alcohol -- they must be thoroughly rinsed from equipment because they neutralize vaccine and chemically react with some antibiotics. If disinfectant is used, syringes should be thoroughly rinsed with sterile water before use. Sterile water can be purchased. Distilled water is not sterile water. Consult your veterinarian before sterilizing equipment to ensure proper techniques. Improper sterilization can reduce the effectiveness of future injections and result in infection at the injection site. Do not contaminate modified live virus products with disinfectants as effectiveness will be decreased or even eliminated.

## Needle Quality Control and Safety

For BQA purposes, single-use needles are preferred; they also help prevent the spread of blood-borne diseases like Leukosis. This virus is a leading cause of carcass condemnation in slaughter facilities. At the very least, **be sure to change needles at a maximum of every 10 head** to prevent using a dull needle, which can develop a burr on the end.

Change needles immediately if the needle bends. Do not straighten it or use it again. Obtain a new needle if the needle in use becomes contaminated with feces or an irritating chemical. Your veterinarian must determine how animals will be handled should a needle break in the neck muscle. A broken needle is an emergency, and time is of the essence. Broken needles migrate in tissue. If not immediately handled, they will be impossible to find -- requiring the animal to be destroyed. **Under no circumstances should animals with broken needles be sold or sent to a packer.**

**Needle Storage/Disposal** Store unused needles in a protected area using these disposal guidelines:

- ▶ Place in container with secure lid.
- ▶ Place container in rigid container lined with plastic.
- ▶ Dispose of as solid waste.

**Drug Storage** Animal health products usually have specific storage requirements. Some require refrigeration. All should be stored in a clean place where they cannot become dirty or contaminated. Observe and obey the manufacturer's recommended storage instructions for each product. Where refrigeration is needed, be sure it is kept clean and located in a safe place -- not likely to be overheated or contaminated by dirt or manure. Animal health products should be stored away from feed ingredient or mixing areas unless regularly mixed feed additives. Storage of partially used medication or vaccine bottles is discouraged because they may become contaminated and could cause infections or tissue reactions, if re-used.

### **Vaccine Handling Precautions**

#### **SAFETY FIRST...**

- ▶ **Always read and follow label instructions** and supply them in Spanish if needed.
- ▶ **Post the local poison control center number** by all phones.
- ▶ **Use proper restraints** when injecting cattle.
- ▶ **With medication known to be toxic to humans, use extra precautions** -- particularly when using the two-handed SQ tent technique. **Do not** use automatic-powered syringes for these medications.



#### **ENSURE EFFECTIVENESS...**

- ▶ **Never use an outdated drug or vaccine.** Purchase fresh vaccines and store them in the refrigerator.
- ▶ **Purchase vaccines in containers holding the number of doses appropriate for the task at hand.** Storing partially used containers may lead to infections at injection sites and result in ineffectiveness of the vaccine.
- ▶ **Use transfer needles to reconstitute vaccines.** Place one end of needle into the sterile liquid and the other into the bottle containing the freeze-dried cake of vaccine. There should be a vacuum that immediately pulls the liquid down. If not, discard the vaccine, as it may not be effective.
- ▶ **Mix vaccines thoroughly, and do not mix too much at one time.** Modified live vaccine (MLV) begins to degrade after about an hour. Direct sunlight also degrades these products; so keep vaccines and syringes in a cooler while working cattle. Gently shake mixed vaccine bottles from time to time.
- ▶ **Do not use the same syringes to inject modified live and killed products.** A trace of killed product can harm the effectiveness of the modified live product.
- ▶ **Clean the top of the vaccine bottle** before inserting needles, and keep the equipment clean. Depending on what product is being injected, be careful how you clean.
  - ◆ **MLV:** clean by using only hot water. Disinfectants leave residues, which destroy MLV vaccines.
  - ◆ **BACTERIN:** clean with hot water or mild disinfectant.
- ▶ **Don't put the needle you are injecting with back into the bottle** to avoid contaminating the vaccine.
- ▶ **Change needles at a maximum of every 10 uses.** Discard any bent needles.
- ▶ **Use only approved combinations.** Mixing unlike products can destroy effectiveness.
- ▶ **Do not store veterinary products (or pesticides) in the feed room,** to avoid accidental mixing in ration.
- ▶ **Make sure veterinary and chemical products are clearly labeled in storage.**

## Residue Avoidance

Drug residue in livestock products is an important issue confronting the industry. Consumers are concerned about the drugs used in dairy and livestock production, and how they affect the food they eat. The industry can address these concerns by assuring consumers that the necessary steps are taken to prevent drug residues. Consumers expect zero tolerance.

Classes of Cattle	Violative Residues of Antibiotics (%)			
	2000	2001	2002	2003
<b>Bulls</b>	0.05	0.11	0.08	0.06
<b>Beef Cows</b>	0.10	0.03	0.12	0.04
<b>Dairy Cows</b>	0.24	0.17	0.42	0.40
<b>Fed Heifers</b>	0.03	0.07	0.00	0.05
<b>Fed Steers</b>	0.06	0.00	0.00	0.05
<b>Dairy Bob Calves</b>	0.56	0.77	0.81	1.40
<b>Formula-Fed Veal</b>	0.19	0.19	0.97	0.94

*(Adapted from USDA/FSIS Domestic Residue Data Books)*

Residue violations and condemnations can be avoided by implementing and following control systems that incorporate the following segments:



- ▶ **Maintain proper individual animal identification.**
- ▶ **Maintain complete medical records.**
- ▶ **Properly store, label and account for all medication.**
- ▶ **Obtain and use animal health products only as they are labeled.**
- ▶ **Maintain a valid “Veterinary/Client/Patient Relationship.”** *(sample VCPR form can be found in the Manual Appendix).*
- ▶ **Educate all employees and family members about your control systems.**

Penicillin accounts for more than 20% of all antibiotic residue violations in beef. It is the most commonly-used drug and is routinely purchased over the counter. Gentamicin and streptomycin run a close second in the number of residue violations attributed to these antibiotics.

## Common Mistakes

The following are some common mistakes made when label directions on medication are not carefully followed:

- ▶ **Treating a condition that is not indicated on the label.**
- ▶ **Treating a type of animal not indicated on the medication label.**
- ▶ **Using more than the dosage indicated on the label.**
- ▶ **Not following the proper withdrawal time of the medication.**
- ▶ **Failing to clean out water and feed systems when medications are used.**
- ▶ **Improper administration of a drug.**
- ▶ **Improper storage of drugs.**

Open and consistent communication between dairy/livestock producers and a veterinarian is needed to assure: quality control, animal welfare, and preventing drug and chemical residues. Using animal health products exactly as they are labeled or prescribed by a veterinarian, with whom the producer has a valid Veterinary/Client/Patient Relationship (VCPR), is required for a BQA program.



*Guidelines 1-13 adapted by NCBA, from AVMA, AABP and AVC Appropriate Veterinary Antibiotic Use Guidelines.*

# Producer’s Guide for Judicious Use of Antimicrobials in cattle...

1. **PREVENT PROBLEMS:** Emphasize appropriate husbandry and hygiene, routine health examinations and vaccinations.
2. **SELECT AND USE ANTIBIOTICS CAREFULLY:** Consult with your veterinarian on the selection and use of antibiotics. Have a valid reason to use an antibiotic. Therapeutic alternatives should be considered prior to using antimicrobial therapy.
3. **AVOID USING ANTIBIOTICS IMPORTANT IN HUMAN MEDICINE AS FIRST LINE THERAPY:** Avoid using as the first antibiotic, those medications that are important for treating strategic human or animal infections.
4. **USE THE LABORATORY TO HELP YOU SELECT ANTIBIOTICS:** Cultures and susceptibility test results should be used to aid in the selection of antimicrobials, whenever possible.
5. **AVOID USING BROAD SPECTRUM:** Use narrow spectrum antimicrobials, whenever possible. Combination antibiotic therapy is discouraged.
6. **AVOID INAPPROPRIATE ANTIBIOTIC USE:** Confine therapeutic antimicrobial use to proven clinical indications, avoiding inappropriate uses such as for viral infections without bacterial complication.
7. **TREATMENT PROGRAMS SHOULD REFLECT BEST USE PRINCIPLES:** Regimens for therapeutic antimicrobial use should be optimized using current pharmacological information and principles.

8. **TREAT THE FEWEST NUMBER OF ANIMALS POSSIBLE:** Limit antibiotic use to sick or at-risk animals.
9. **TREAT FOR THE RECOMMENDED TIME PERIOD:** This will minimize the potential for bacteria to become resistant to antimicrobials.
10. **AVOID ENVIRONMENTAL CONTAMINATION WITH ANTIBIOTICS:** Steps should be taken to minimize antimicrobials reaching the environment through spillage, contaminated ground run-off, or aerosolization.
11. **KEEP RECORDS OF ANTIBIOTIC USE:** Accurate records of treatment and outcome should be used to evaluate therapeutic regimens. Always follow proper withdrawal times.
12. **FOLLOW LABEL DIRECTIONS:** Follow label instructions, and never use antibiotics other than as labeled without a valid veterinary prescription.
13. **EXTRA-LABEL ANTIBIOTIC USE MUST FOLLOW FDA REGULATIONS:** Prescriptions, including extra-label use of medications must meet the Animal Medicinal Drug Use Clarification Act (AMDUCA) amendments to the Food, Drug, and Cosmetic Act and its regulations. This includes having a valid Veterinary/Client/Patient Relationship.
14. **SUBTHERAPEUTIC ANTIBIOTIC USE IS DISCOURAGED:** Antibiotic use should be limited to prevent or control disease and should not be used if the principle intent is to improve performance.

## Drug / Vaccine Labeling and Classification

The FDA has the responsibility for determining the market status of animal drugs, based in part upon whether or not it is possible to prepare “adequate directions for use” under which a layperson can use the drugs safely and effectively. The two basic classes of drugs available to livestock producers are over-the-counter (OTC) and prescription (Rx) drugs. A drug that has significant potential for toxicity in humans or animals (or other harmful effects), which may have a unique method of use, or which requires other special considerations for its use, is usually labeled as a prescription drug. Such products can be used or dispensed only by or on the order of a licensed veterinarian, and the label must contain the legend: **“CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.”** Please refer to the *Compendium of Veterinary Products* in the Manual Appendix.

## Extra-Label Use of Drugs

OTC drugs can be purchased from multiple sources and must be used as directed on the label. For example, most procaine penicillin G products are labeled for use at 1 cc/cwt and are given intramuscularly (IM). So, a 600-pound calf would get 6 cc IM. Producers are not allowed to change the dose or give it by any other route, such as subcutaneously (SQ). **OTC products must be used exactly as labeled.**

“Extra-label use” is defined as the “actual or intended use of a drug in a manner that is not in accordance with the label.” Under the provisions of the Animal Medicinal Drug Use Clarification Act of 1994, the FDA recognized the professional judgment of veterinarians and allows the extra-label use of drugs (either OTC or Rx) by veterinarians under certain conditions. Extra-label use is limited to situations where the health of an animal is threatened or suffering and death may result from failure to treat and only by or under the supervision of a veterinarian.

**Veterinarians may only consider using drugs (OTC or Rx) in an extra-label manner when the following conditions apply:**

- ▶ 1. There is no approved drug that is labeled for such use and that contains the same active ingredient in the required dosage form and concentration, or a currently approved and labeled drug is clinically ineffective for its intended use (for example: drug resistant bacterial infections)
- ▶ 2. Prior to using or dispensing a drug in an extra-label manner, the veterinarian must use the following criteria:

### **EXTRA-LABEL Rx CRITERIA**

- Make a **careful diagnosis** and evaluation of the conditions for which the drug is to be used;
- Establish a **substantially extended withdrawal period** prior to marketing of milk, meat, eggs, or other edible products;
- Institute procedures to assure that the **identity of the treated animal(s)** is carefully maintained; and
- Take appropriate measures to **assure that the assigned withdrawal times are met** and that no illegal drug residues occur in any food-producing animal subjected to extra-label treatment.

- ▶ 3. Drugs prescribed or dispensed to producers for extra-label use must have additional labeling, including at least the following information:

**ADDITIONAL LABELING**

- The name and address of the prescribing veterinarian;
- The name of the active ingredient(s);
- Directions for use including identity of the animal being treated, dosage, frequency and duration of treatment, and route of administration;
- Any cautionary statements specified by the veterinarian; and
- The veterinarian’s specified withdrawal time.

- ▶ 4. Extra-label use of drugs may only take place within the scope of a valid Veterinarian/Client/Patient Relationship (VCPR). A valid VCPR exists when:

**CRITERIA FOR VALID VCPR**

- The veterinarian has assumed the responsibility for making clinical judgements regarding the health of the animal(s) and the need for medical treatment, and the client has agreed to follow the veterinarian’s instructions.
- The veterinarian has sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). This means that the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of an examination of the animal(s), or by medically appropriate and timely visits to the premises where the animal(s) are kept.
- The veterinarian is readily available, or has arranged for emergency coverage, for follow-up evaluation in the event of adverse reactions or failure of the treatment regimen.

**Limitations to the Extra-Label Use Privilege**

**The privilege of extra-label use of drugs is not permitted for extra-label use of drugs in or on animal feeds.** A veterinarian cannot use or prescribe drugs for use in feed in any manner except for the approved use and at the approved dosage. Extra-label use of drugs in treating food-producing animals for improving rate of weight gain, feed efficiency, or other production purposes is also prohibited. Some specific drugs are completely prohibited for extra-label use in food-producing animals, including: chloramphenicol, clenbuterol, diethylstilbestrol, dimetridazole, ipronidazole, other nitroimidazoles, furazolidone, nitrofurazone, fluoroquinolones, and glycopeptides.

## Drug Withdrawal Times

A withdrawal time (WD) may be indicated on the label of certain medications. This is the period of time that must pass between the last treatment and the time the animal will be slaughtered. For example, if a medication with a 14-day withdrawal period was last given on August 1st, the withdrawal would be completed on August 15th, and that would be the earliest the animal could be harvested for human consumption. Often there are separate WDs for milk and meat, and meat withdrawals are always longer.

It is important that you follow withdrawal time directions as given by the label or as prescribed by your veterinarian. From the day you acquire your animals until the day they leave your care, you should maintain feed and treatment records. This is important for the day-to-day care of your animal and for whomever may later purchase your animal.

Observe label instructions and withdrawal times carefully. When using drugs by “extra-label,” work closely with the veterinarian on dosages and withdrawal times. Never use an approved veterinary drug in an extra-label manner without consulting the veterinarian. Doing this without direction by a licensed veterinarian is an illegal act.

Unacceptable levels of drug residues detected in edible tissues collected at slaughter may result in traceback, quarantine, and potential fines or jail time. Substantial economic losses may result for the individual producer as well as negative publicity for the entire beef industry.

**Producers are responsible for residue problems, and should follow these three rules:**

- **Do not market animals for food until the withdrawal time listed on the label, or as prescribed by the veterinarian, has elapsed.**
- **Use only medications approved for cattle and exactly as the label directs or as prescribed by your veterinarian.**
- **If ever in doubt, rely on the Veterinarian/Client/Patient Relationship you have established with your veterinarian. Consult your veterinarian with all questions and concerns.**

All federally approved drugs will include the required withdrawal time for that drug on the product label or package insert. These withdrawal times can range from 0 to as many as 60 days or more. The current *Compendium of Veterinary Products* is provided in the BQA Manual Appendix. The *Compendium*, published by the North American Compendiums, Inc., gives a comprehensive list of drugs approved for use in beef animals as well as a description of each drug. In addition, the *Compendium* includes a chart of the withdrawal times for meat and also includes time of milk withholding. **The drug label, itself, always supersedes the *Compendium* if there is a discrepancy.** It is your responsibility to be aware of the withdrawal times of any drugs that you use on your cattle. More information is available at these websites: <http://www.fda.gov/> or <http://www.farad.org/>.

## Managing Implants

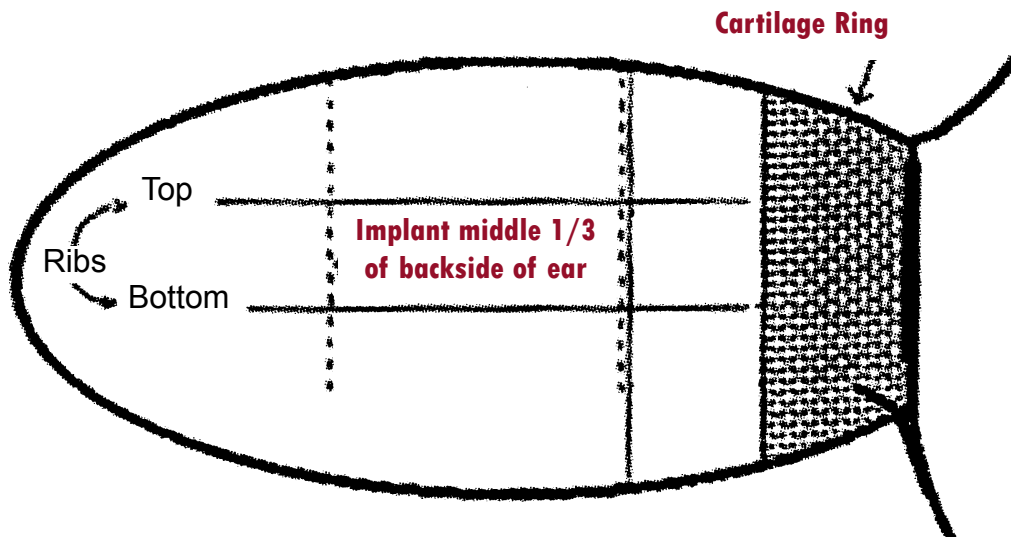
Implants may provide an economic advantage in the production of safe and wholesome beef. Beef from implanted cattle has proven to be leaner than beef from non-implanted cattle, with minute differences in hormone levels. Nevertheless, consumer concern remains high with regard to implanted beef. Administer implants properly and follow label directions, including proper sanitation and the use of antiseptic on the needle between every use. Proper sanitation results in fewer abscesses in the ear and allows for higher utilization of the implant.



Regulations governing the use of implants are set by the U.S. Food and Drug Administration (FDA). Always read and follow the manufacturer’s directions before implanting any cattle. The growth promotant implants approved for use in the U.S. are extremely safe for both producers and consumers of beef. There is **no required withdrawal time** for slaughter with FDA approved implants.

### **Figure 3. Approved Location for Implant Administration.**

*If the middle of the ear has been damaged, place implant on the top of the ear.  
If the tip of the ear is missing, place implant in the outer 1/2 of the remaining ear.*



The only approved location for implant administration is the middle third of the backside of the ear. All implants must be located subcutaneously within this area (Figure 3.) This should place the implant outside the cartilage ring at the base of the ear. **Implants should never be placed in locations other than the ear.**

Routine inspection of implant and vaccine sites should be done every time animals are handled through a chute. Document the results of the inspection for future reference in implant management decisions.

While there is no withdrawal period for implants, there are quality considerations in the timing. Aggressive implant strategies that maximize the response to the implant in growth and feed efficiency can compromise carcass grade. On the other hand, a conservative approach may not pay when the Choice and Select price spread is too narrow to offset the lost value in feed efficiency and gain, which implants provide. It is as much an economic decision as it is a quality decision. The objective is to know your options, then plan and keep records to evaluate your decisions.

## Using Implants Correctly

### Implanting Mistakes and Solutions

*(Compudose Technical Manual, 1982)*

<b><u>Problem</u></b>	<b><u>Cause</u></b>	<b><u>Solution</u></b>
Abscess at implant site	Lack of sanitation	Disinfect equipment, dry ears, improve restraint
Bunched pellets	Needle moved, poor restraint	Improve cattle restraint
Retrograde abscess	Infection after implanting	Pinch site after implanting; improve sanitation
In cartilage	Poor needle, too fast, Improper placement	New needle; slow down; Place properly
Crushed pellet	Needle not fully inserted	Fully insert needle
Missing implant	Not advancing cartridge through ear, abscess in	Check implant position, pinch site shut
Separated pellet	Rapid withdraw of needle, processing too fast	Slow down, withdraw needle slowly
Partial implant	Needle too short, too fast, poor restraint	Use needle provided, slow down, improve restraint
Pellet too close to the head	Inexperience	Implant only in middle one-third of the ear
Walled-off implant	Abscess	Improve sanitation

