HFA-305

Date of Approval: NOV 18 2003

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-367

SYNOVEX T120; SYNOVEX T80; SYNOVEX T40
(trenbolone acetate and estradiol)

Cattle Hormone Implant

SYNOVEX T120 and SYNOVEX T80: For increased rate of weight gain and improved feed efficiency in feedlot steers.

SYNOVEX T40: For increased rate of weight gain in pasture cattle (slaughter, stocker, and feeder steers and heifers).

Sponsored by:

Fort Dodge Animal Health
Division of Wyeth

F015 1

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-367
b. Sponsor:	Fort Dodge Animal Health Division of Wyeth 500 Fifth Street NW Fort Dodge, IA 50501 Drug Labeler Code: 000856
c. Established Name:	Trenbolone acetate and estradiol
d. Proprietary Name:	SYNOVEX T120; SYNOVEX T80; SYNOVEX T40
e. Dosage Form:	Implant (pellets)
f. How Supplied:	Ten implants are provided in a cartridge for each product. One pouch contains ten 10-dose cartridges (100 implants).
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	Each SYNOVEX T120, SYNOVEX T80 and SYNOVEX T40 pellet contains 20 mg trenbolone acetate and 4 mg estradiol. One SYNOVEX 120 implant contains 6 pellets and delivers 120 mg trenbolone acetate and 24 mg estradiol. One SYNOVEX T80 implant contains 4 pellets and delivers 80 mg trenbolone acetate and 16 mg estradiol. One SYNOVEX T40 implant contains 2 pellets and delivers 40 mg trenbolone acetate and 8 mg estradiol.
i. Route of Administration:	Subcutaneous implant in the middle of the posterior aspect of the ear.
j. Species/Class:	SYNOVEX T120 and SYNOVEX T80: Steers fed in confinement for slaughter. SYNOVEX T40: Pasture cattle (slaughter, stocker, and feeder steers and heifers).

k. Recommended Dosage:	One SYNOVEX T120 implant containing 120 mg trenbolone acetate and 24 mg estradiol. One SYNOVEX T80 implant containing 80 mg trenbolone acetate and 16 mg estradiol. One SYNOVEX T40 implant containing 40 mg trenbolone acetate and 8 mg estradiol.
l. Pharmacological Category:	Hormone
m. Indications:	SYNOVEX T120 and SYNOVEX T80: For increased rate of weight gain and improved feed efficiency in feedlot steers. SYNOVEX T40: For increased rate of weight gain in pasture cattle (slaughter, stocker, and feeder steers and heifers).
n. Pioneer Product:	REVALOR-S, REVALOR-IS and REVALOR-G; trenbolone acetate and estradiol; NADA 140-897; Intervet, Inc.

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

The effectiveness of the pioneer products REVALOR-S, REVALOR-IS and REVALOR-G was established by data contained in approved NADA 140-897. The following clinical endpoint bioequivalence study established bioequivalence of Fort Dodge Animal Health's SYNOVEX T120 to Intervet Inc.'s REVALOR-S. A clinical endpoint bioequivalence study was determined to be the appropriate method of evaluation because blood level bioequivalence studies require evaluation of Cmax and the use of Cmax for the determination of rate is not appropriate for long-acting products.

Dr. Mary I. Wray, Wray and Associates, Inc., 13892 North 115th Street, Longmont, CO 80504 was the Study Director for the bioequivalence study. The purpose of the study was to demonstrate bioequivalence of SYNOVEX T120 to REVALOR-S through the comparison of clinical endpoint measurements in steers that were sham-implanted (negative controls) or implanted with SYNOVEX T120 or REVALOR-S.

Nine hundred (900) steers served as test animals, which included ten pens of steers containing 90 steers per pen. Steers were assigned to pens in weight blocks. Within each pen of 90 steers, 30 animals were randomly assigned to each of the three experimental treatments identified above.

Animals were assigned to weight blocks based on Day -1 body weights, then reweighed and treated on Day 0. The starting weight of each steer was defined as the mean of weights measured on Day -1 and Day 0. Blocks of steers were judged to have completed the study when live-animal evaluations resulted in the estimation that approximately 60% of animals within the block were likely to qualify for USDA Quality Grade scores of low Choice or higher. When animals were judged ready for slaughter, weights were measured on each animal within a block on two consecutive days, and then cattle were shipped for slaughter. The final weight of each animal was defined as the mean of the consecutive-day weights measured prior to slaughter. The average elapsed time between Day 0 and the day final weights were obtained on steers was 132 days.

The pivotal parameter that served as the basis for evaluating bioequivalence was average daily gain over the period from initial weights to final weights. Individual animals were the experimental units. Eight hundred seventy-five (875) animals successfully completed the study. Statistical evaluation of data and bioequivalence computations were conducted using procedures defined in the FDA/CVM Bioequivalence Guidance (10/10/00) relevant to clinical endpoint bioequivalence studies.

TABLE 1. Evaluation of Bioequivalence of SYNOVEX T120 and REVALOR-S

Treatment Means [a]			**SE of $X_T - X_R$**	**Lower 90% CL** [b]	**Upper 90% CL** [b]
Sham Control (X_C)	**SYNOVEX T120 (X_T)**	**REVALOR-S (X_R)**			
3.45 lb./day	4.10 lb./day	4.17 lb./day	.0437	-19.95	1.19

[a] Least squares means.
[b] L90, U90 = $([X_T - X_R] / [X_R - X_C] \pm t_{18, 0.05} * [SE_{XT-XR} / (X_R - X_C)] * 100$
where $t_{18, 0.05} = 1.734$

The 90% upper and lower confidence limits around the difference in ADG between animals treated with REVALOR-S and SYNOVEX T120, expressed as a percentage of the ADG difference between the negative controls and REVALOR-S, were -19.95% and 1.19%, respectively (Table 1). These limits lie within the bioequivalence criterion range of ±20% as established in the FDA/CVM Bioequivalence Guideline (10/10/00). Data obtained from this clinical endpoint bioequivalence study support the conclusion that SYNOVEX T120 and REVALOR-S implants are bioequivalent in finishing beef steers.

Approval of SYNOVEX T80 is granted based on data presented above demonstrating that SYNOVEX T120 and REVALOR-S are bioequivalent. SYNOVEX T80 is a reduced dose of SYNOVEX T120, with each pellet in SYNOVEX T80 (total of 4 pellets) containing 20 mg trenbolone acetate and 4 mg estradiol in the same formulation as each pellet in SYNOVEX T120 (total of 6 pellets). In the same way, the pioneer product, REVALOR-IS, is a reduced dose of REVALOR-S with each pellet in REVALOR-IS (total of 4 pellets) containing 20 mg trenbolone acetate and 4 mg estradiol in the same formulation as each pellet in REVALOR-S (total of 6 pellets). SYNOVEX T120 was shown to be bioequivalent to REVALOR-S in an adequate and well controlled clinical endpoint bioequivalence trial in steers fed in confinement for slaughter (see above). Because SYNOVEX T120 was shown to be bioequivalent to REVALOR-S in feedlot steers, improvements in performance by feedlot steers resulting from treatment with SYNOVEX T80 and REVALOR-IS will be equivalent.

Approval of SYNOVEX T40 is granted based on data presented above demonstrating that SYNOVEX T120 and REVALOR-S are bioequivalent. SYNOVEX T40 is a reduced dose of SYNOVEX T120, with each pellet in SYNOVEX T40 (total of 2 pellets) containing 20 mg trenbolone acetate and 4 mg estradiol in the same formulation as each pellet in SYNOVEX T120 (total of 6 pellets). In the same way, the pioneer product, REVALOR-G, is a reduced dose of REVALOR-S with each pellet in REVALOR-G (total of 2 pellets) containing 20 mg trenbolone acetate and 4 mg estradiol in the same formulation as each pellet in REVALOR-S (total of 6 pellets). SYNOVEX T120 was shown to be bioequivalent to REVALOR-S in an adequate and well controlled clinical endpoint bioequivalence trial in steers fed in confinement for slaughter (see above). Because SYNOVEX T120 was shown to be bioequivalent to REVALOR-S in feedlot steers, improvements in performance resulting from treatment of pasture cattle with SYNOVEX T40 and REVALOR-G will be equivalent. It is unreasonable to assume that the release (rate and extent) of trenbolone acetate and estradiol would be different in pasture cattle versus feedlot cattle.

3. *HUMAN SAFETY:*

- **Tolerance**
  The tolerance established for the pioneer product applies to the generic product. A tolerance for total trenbolone residues in uncooked edible tissues of cattle is not needed (21 CFR 556.739). The acceptable daily intake (ADI) for total residues of trenbolone is 0.4 micrograms per kilogram of body weight per day (21 CFR 556.739). The allowable incremental increases established for the pioneer product apply to the generic product. Estradiol is regulated under 21 CFR 556.240. No residues of estradiol, resulting from the use of estradiol or any of the related esters, are permitted in the uncooked edible tissues of heifers, steers, and calves in excess of the following increments above the concentrations of estradiol naturally present in untreated animals: 120 ppt for muscle, 480 ppt for fat, 360 ppt for kidney, and 240 ppt for liver.

- **Withdrawal Times**
  A withdrawal time is not required for SYNOVEX T120, SYNOVEX T80, and SYNOVEX T40 because one was not required for the pioneer products (21 CFR 522.2477).

- **Regulatory Method for Residues**
  A regulatory method is not required because one was not required for the pioneer products.

4. *AGENCY CONCLUSIONS:*

This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the Act and demonstrates that SYNOVEX T120, SYNOVEX T80, and SYNOVEX T40, when used under their proposed conditions of use, are safe and effective for their labeled indications.

5. *ATTACHMENTS:*

Facsimile generic labeling and currently approved pioneer labeling are attached as follows:

SYNOVEX T120 (Generic):
1. Foil pouch label front and back (reduced followed by enlarged)
2. Unfolded carton composite (reduced)
3. Outer Folding Carton Front, Back, and Sides (enlarged)
4. Carton Fold-Out Section Page 1 (enlarged)
5. Carton Fold-Out Section Page 2 (enlarged)

REVALOR-S (Pioneer):
1. Outer Folding Carton Front
2. Outer Folding Carton Back
3. Package Insert Front and Back

SYNOVEX T80 (Generic):
1. Foil pouch label front and back (reduced followed by enlarged)
2. Unfolded carton composite (reduced)
3. Outer Folding Carton Front, Back, and Sides (enlarged)
4. Carton Fold-Out Section Page 1 (enlarged)
5. Carton Fold-Out Section Page 2 (enlarged)

REVALOR-IS (Pioneer):
1. Outer Folding Carton Front
2. Outer Folding Carton Back
3. Package Insert Front and Back

SYNOVEX T40 (Generic):
1. Foil pouch label front and back (reduced followed by enlarged)
2. Unfolded carton composite (reduced)
3. Outer Folding Carton Front, Back, and Sides (enlarged)
4. Carton Fold-Out Section Page 1 (enlarged)
5. Carton Fold-Out Section Page 2 (enlarged)

REVALOR-G (Pioneer):
1. Outer Folding Carton Front
2. Outer Folding Carton Back
3. Package Insert Front and Back

50
Generic:
1. Foil Pouch

IMPLANTS FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

SYNOVEX® T120
(trenbolone acetate and estradiol)

ANADA 200-XXX
Approved by FDA

NDC 0856-6081-01

Synovex T120 (trenbolone acetate and estradiol) is an implant containing 120 mg trenbolone acetate and 24 mg estradiol. Each implant consists of 6 small yellow pellets. Ten implants are provided in a cartridge.

INDICATIONS FOR USE: Increases rate of weight gain and improves feed efficiency in a slow-release delivery system.

NOTE: Studies have demonstrated that the administration of Synovex® T120 can result in decreased marbling scores when compared to non-implanted steers.

DOSAGE: One implant containing 120 mg trenbolone acetate and 24 mg estradiol is administered to each animal. The 6 pellets that make up the dosage of Synovex T120 are contained in one division of the multiple dose cartridge. The ten-dose cartridge of Synovex T120 is designed to be used exclusively with a Synovex implanting device.

WARNING: Not to be used in animals intended for subsequent breeding or in dairy animals. For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted site for human or animal food.

ROUTE OF ADMINISTRATION: The implant is placed under the skin on the posterior aspect of the ear by means of an implanting device available from Fort Dodge Animal Health.

NOTE: Never sacrifice careful, clean technique for speed of implantation.

STORAGE: Store unopened product at room temperature. Avoid excessive heat and humidity. Use product before the expiration date on the label.

Once the pouch is opened, unused product may be stored in the end-folded pouch (away from light) for up to six months under refrigerated conditions (2-8 C/36-47 F) or at room temperature (15-30 C/ 59-86 F) for up to one month.

Manufactured By A Non-Sterilizing Process

Keep this and all drugs out of the reach of children.

Restricted Drug (California)—Use Only As Directed

See top of pouch for lot and expiration date.

FORT DODGE®

Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

03252 6082A

NET CONTENTS:
One pouch contains ten 10-dose cartridges (100 implants)

IMPLANTS FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

SYNOVEX® T120
(trenbolone acetate and estradiol)

ANADA 200-XXX
Approved by FDA

NDC 0856-6081-01

Synovex T120 (trenbolone acetate and estradiol) is an implant containing 120 mg trenbolone acetate and 24 mg estradiol. Each implant consists of 6 small yellow pellets. Ten implants are provided in a cartridge.

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ROUTE OF ADMINISTRATION: The implant is placed under the skin on the posterior aspect of the ear by means of an implanting device available from Fort Dodge Animal Health.

NOTE: Never sacrifice careful, clean technique for speed of implantation.

STORAGE: Store unopened product at room temperature. Avoid excessive heat and humidity. Use product before the expiration date on the label.

Once the pouch is opened, unused product may be stored in the end-folded pouch (away from light) for up to six months under refrigerated conditions (2-8 C/36-47 F) or at room temperature (15-30 C/ 59-86 F) for up to one month.

Manufactured By A Non-Sterilizing Process

Keep this and all drugs out of the reach of children.

Restricted Drug (California)—Use Only As Directed

See top of pouch for lot and expiration date.

FORT DODGE®

Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

03252 6082A

NET CONTENTS:
One pouch contains ten 10-dose cartridges (100 implants)

Generic:
1. Foil Pouch - Front

IMPLANTS FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

SYNOVEX® T120
(trenbolone acetate and estradiol)

ANADA 200-XXX
Approved by FDA

NDC 0856-6081-01

Synovex T120 (trenbolone acetate and estradiol) is an implant containing 120 mg trenbolone acetate and 24 mg estradiol. Each implant consists of 6 small yellow pellets. Ten implants are provided in a cartridge.

INDICATIONS FOR USE: Increases rate of weight gain and improves feed efficiency in a slow-release delivery syetem.

NOTE: Studies have demonstrated that the administration of Synovex® T120 can result in decreased marbling scores when compared to non-implanted steers.

DOSAGE: One implant containing 120 mg trenbolone acetate and 24 mg estradiol is administered to each animal. The 6 pellets that make up the dosage of Synovex T120 are contained in one division of the multiple dose cartridge. The ten-dose cartridge of Synovex T120 is designed to be used exclusively with a Synovex implanting device.

WARNING: Not to be used in animals intended for subsequent breeding or in dairy animals. For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted site for human or animal food.

ROUTE OF ADMINISTRATION: The implant is placed under the skin on the posterior aspect of the ear by means of an implanting device available from Fort Dodge Animal Health.

NOTE: Never sacrifice careful, clean technique for speed of implantation.

STORAGE: Store unopened product at room temperature. Avoid excessive heat and humidity. Use product before the expiration date on the label.

Once the pouch is opened, unused product may be stored in the end-folded pouch (away from light) for up to six months under refrigerated conditions (2-8°C/36-47°F) or at room temperature (15-30°C/ 59-86°F) for up to one month.

Manufactured By A Non-Sterilizing Process

Keep this and all drugs out of the reach of children.

Restricted Drug (California)—Use Only As Directed.

See top of pouch for lot and expiration date.

FORT DODGE®

Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

03252 6082A

NET CONTENTS:
One pouch contains ten 10-dose cartridges (100 implants)

IMPLANTS FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

SYNOVEX® T120

(trenbolone acetate and estradiol)

ANADA 200-XXX
Approved by FDA

NDC 0856-6081-01

Synovex T120 (trenbolone acetate and estradiol) is an implant containing 120 mg trenbolone acetate and 24 mg estradiol. Each implant consists of 6 small yellow pellets. Ten implants are provided in a cartridge.

INDICATIONS FOR USE: Increases rate of weight gain and improves feed efficiency in a slow-release delivery syetem.

NOTE: Studies have demonstrated that the administration of Synovex® T120 can result in decreased marbling scores when compared to non-implanted steers.

DOSAGE: One implant containing 120 mg trenbolone acetate and 24 mg estradiol is administered to each animal. The 6 pellets that make up the dosage of Synovex T120 are contained in one division of the multiple dose cartridge. The ten-dose cartridge of Synovex T120 is designed to be used exclusively with a Synovex implanting device.

WARNING: Not to be used in animals intended for subsequent breeding or in dairy animals. For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted site for human or animal food.

ROUTE OF ADMINISTRATION: The implant is placed under the skin on the posterior aspect of the ear by means of an implanting device available from Fort Dodge Animal Health.

NOTE: Never sacrifice careful, clean technique for speed of implantation.

STORAGE: Store unopened product at room temperature. Avoid excessive heat and humidity. Use product before the expiration date on the label.

Once the pouch is opened, unused product may be stored in the end-folded pouch (away from light) for up to six months under refrigerated conditions (2-8°C/36-47°F) or at room temperature (15-30°C/ 59-86°F) for up to one month.

Manufactured By A Non-Sterilizing Process

Keep this and all drugs out of the reach of children.

Restricted Drug (California)—Use Only As Directed.

See top of pouch for lot and expiration date.

FORT DODGE®

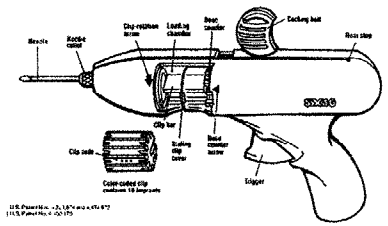
Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

03252 6082A

NET CONTENTS:
One pouch contains ten 10-dose cartridges (100 implants)

Generic:
1. Foil Pouch - Back

SYNOVEX® SX10® Gun*



U.S. Patent No. 4,313,475
U.S. Patent No. 4,551,975

HOW TO IMPLANT SYNOVEX® T120 IMPLANTS

For Use With Any Synovex Gun

Study the following instructions carefully then proceed step by step, until the technique becomes routine. Many head can be implanted per hour by an experienced team. one member of which should be assigned to do nothing but the implantation. Care should be taken to insure the hands of the person administering the implant are clean and only sanitary instruments are used.

SYNOVEX® T120 Implants

Synovex T120 is recommended for steers fed in confinement for slaughter. When properly administered, Synovex T120 implants monitor rate of weight gain and improve feed efficiency, in steers as a slow release delivery system.

STORAGE

Store unopened product at room temperature. Avoid excessive heat and humidity.

Use product before the expiration date printed on the label.

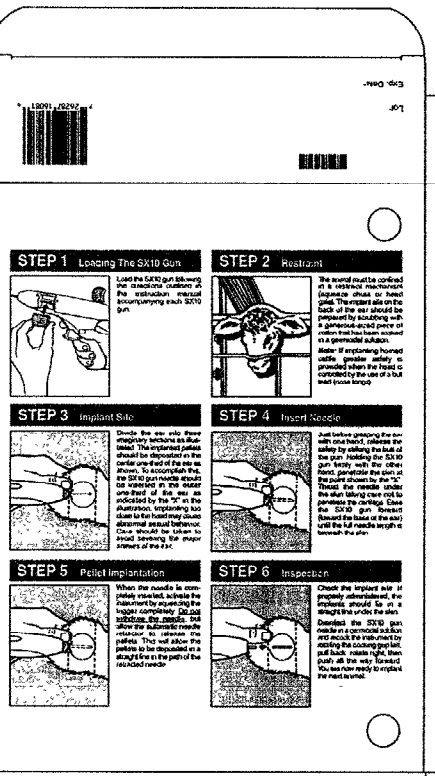
Once the pouch is opened, unused product may be stored in the end-folded pouch (away from light) for up to six months under refrigerated conditions (2-8°C/36-47°F) or at room temperature (15-30°C/59-86°F) for up to one month.

WARNING

Not to be used or sold or intended for subsequent breeding or dairy animals. For Animal Treatment Only. Not for Use in Humans. To prevent pellets in ear only. Any other location is a violation of Federal law. Do not attempt salvage of implanted site for human or animal food.

Keep this and all drugs out of the reach of children.

Restricted Drug (California) — Use Only as Directed



IMPLANTS FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

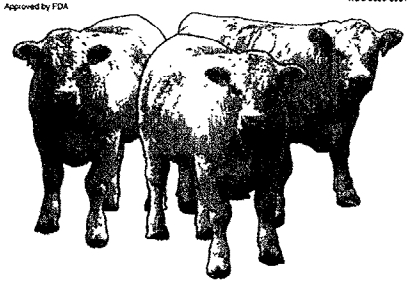
SYNOVEX® T120
(trenbolone acetate and estradiol)

IMPLANTS FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

SYNOVEX® T120
(trenbolone acetate and estradiol)

ANADA 200-XXX
Approved by FDA

NDC 0856-6081-01



FOR ANIMAL USE ONLY
NOT FOR USE IN HUMANS

INDICATIONS FOR USE:

NET CONTENTS: One pouch containing ten (10) cartridges (60 implants)

Manufactured By A Non-Sterilizing Process

Keep this and all drugs out of the reach of children.

Restricted Drug (California) — Use Only As Directed

FORT DODGE

NET CONTENTS: 10 CARTRIDGES
Each Cartridge Contains 10 Rows of 6 Pellets

IMPLANTS FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

SYNOVEX® T120
(trenbolone acetate and estradiol)

IMPLANTS FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

SYNOVEX® T120
(trenbolone acetate and estradiol)

Synovex T120 (trenbolone acetate and estradiol) is an implant containing 120 mg trenbolone acetate and 24 mg estradiol. Each implant contains 10 mg of total pellets. Ten implants are provided in a cartridge.

NOTE: Studies have demonstrated that trenbolone acetate (Synovex T120) can result in overbearing and mounting among well conditioned and crossbred steers.

DOSAGE: One implant containing 120 mg trenbolone acetate and 24 mg estradiol is administered to steers. The 10 pellets that make up the dosage of Synovex T120 are contained in one dose of one multi-dose cartridge. The ten-dose cartridge of Synovex T120 is designed to be used exclusively with a Synovex implanting device.

WARNING: Not to be used or sold or intended for subsequent breeding or dairy animals. For Animal Treatment Only. Not for Use in Humans. To prevent pellets in ear only. Any other location is a violation of Federal Law. Do not attempt salvage of implanted site for human or animal food.

ROUTE OF ADMINISTRATION: The implant is placed under the skin on the posterior side of the ear by means of an implanting device available from Fort Dodge Animal Health.

NOTE: Never sacrifice careful aseptic technique for speed of implantation.

STORAGE: Store product at room temperature. Avoid excessive heat and humidity. Use product by date on the expiration date on the label.

Once the pouch is opened, unused product may be stored in the end-folded pouch (away from light) for up to six months under refrigerated conditions (2-8°C/36-47°F) or at room temperature (15-30°C/59-86°F) for up to one month.

Keep this and all drugs out of the reach of children.

Restricted Drug (California) — Use Only As Directed

Manufactured By A Non-Sterilizing Process

FORT DODGE

Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

Open here for implanting directions.

NET CONTENTS: 10 CARTRIDGES
Each Cartridge Contains 10 Rows of 6 Pellets

IMPLANTS FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

SYNOVEX® T120
(trenbolone acetate and estradiol)

53
Generic
2. Unfolded Carton
Composite

IMPLANTS FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

SYNOVEX® T120

(trenbolone acetate and estradiol)

IMPLANTS FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

SYNOVEX® T120

(trenbolone acetate and estradiol)

9923
03182
6061A

54

Generic.
2. Carton sizes.

Generic:
2. Carton-Front

IMPLANTS FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

SYNOVEX® T120
(trenbolone acetate and estradiol)

ANADA 200-XXX
Approved by FDA

NDC 0856-6081-01

FOR ANIMAL USE ONLY.
NOT FOR USE IN HUMANS.

INDICATIONS FOR USE:
Increases rate of weight gain and improves feed efficiency in a slow-release delivery system.

NET CONTENTS: One pouch contains ten 10-dose cartridges (100 implants).

Manufactured By A Non-Sterilizing Process

Keep this and all drugs out of the reach of children.

Restricted Drug (California)—Use Only As Directed.

FORT DODGE®

NET CONTENTS: 10 CARTRIDGES
Each Cartridge Contains 10 Rows of 6 Pellets

IMPLANTS FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

SYNOVEX® T120
(trenbolone acetate and estradiol)

Generic.

2. Carton - Back

IMPLANTS FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

SYNOVEX® T120

(trenbolone acetate and estradiol)

Synovex T120 (trenbolone acetate and estradiol) is an implant containing 120 mg trenbolone acetate and 24 mg estradiol. Each implant consists of 6 small yellow pellets. Ten implants are provided in a cartridge.

NOTE: Studies have demonstrated that the administration of Synovex® T120 can result in decreased marbling scores when compared to non-implanted steers.

DOSAGE: One implant containing 120 mg trenbolone acetate and 24 mg estradiol is administered to each animal. The 6 pellets that make up the dosage of Synovex T120 are contained in one division of the multiple dose cartridge. The ten-dose cartridge of Synovex T120 is designed to be used exclusively with a Synovex implanting device.

WARNING: Not to be used in animals intended for subsequent breeding or in dairy animals. For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted site for human or animal food.

ROUTE OF ADMINISTRATION: The implant is placed under the skin on the posterior aspect of the ear by means of an implanting device available from Fort Dodge Animal Health.

NOTE: Never sacrifice careful, clean technique for speed of implantation.

STORAGE: Store unopened product at room temperature. Avoid excessive heat and humidity. Use product before the expiration date on the label.

Once the pouch is opened, unused product may be stored in the end-folded pouch (away from light) for up to six months under refrigerated conditions (2-8°C/36-47°F) or at room temperature (15-30°C/ 59-86°F) for up to one month.

Manufactured By A Non-Sterilizing Process

Keep this and all drugs out of the reach of children.

Restricted Drug (California)—Use Only As Directed.

FORT DODGE®

Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

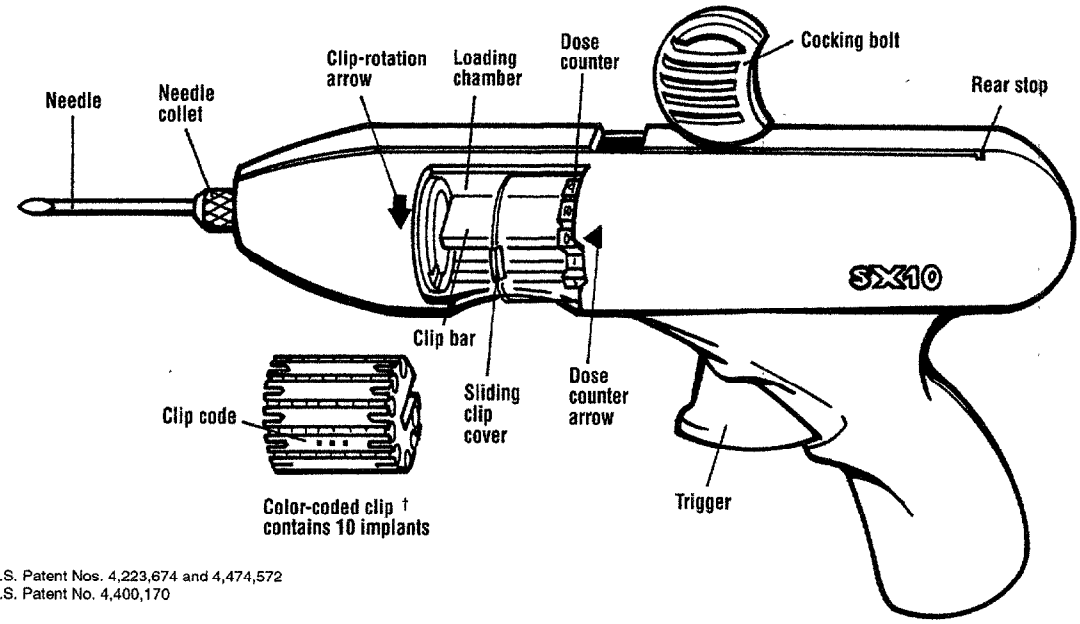
▶ Open here for implanting directions ▶

NET CONTENTS: 10 CARTRIDGES

Each Cartridge Contains 10 Rows of 6 Pellets

Generic:
4. Carton Fold-out Page 1

SYNOVEX® SX10® Gun*



* U.S. Patent Nos. 4,223,674 and 4,474,572
† U.S. Patent No. 4,400,170

HOW TO IMPLANT SYNOVEX® T120 IMPLANTS

For Use With Any Synovex Gun.

Study the following instructions carefully, then proceed step by step, until the technique becomes routine. Many head can be implanted per hour by an experienced team, one member of which should be assigned to do nothing but the implantation. Care should be taken to insure the hands of the person administering the implant are clean and only sanitary instruments are used.

SYNOVEX® T120 Implants

Synovex T120 is recommended for steers fed in confinement for slaughter. When properly administered, Synovex T120 implants increase rate of weight gain and improve feed efficiency in steers in a slow release delivery system.

STORAGE

Store unopened product at room temperature. Avoid excessive heat and humidity.

Use product before the expiration date printed on the label.

Once the pouch is opened, unused product may be stored in the end-folded pouch (away from light) for up to six months under refrigerated conditions (2–8°C/36–47°F) or at room temperature (15–30°C/59–86°F) for up to one month.

WARNING

Not to be used in animals intended for subsequent breeding or in dairy animals. For Animal Treatment Only. Not for Use in Humans. Implant pellets in ear only. Any other location is a violation of Federal law. Do not attempt salvage of implanted site for human or animal food.

Keep this and all drugs out of the reach of children.

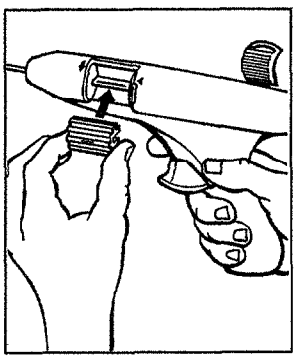
Restricted Drug (California)—
Use Only as Directed.

Generic
5. Carton Fold-out Page 2

Exp. Date:

Lot:

STEP 1 Loading The SX10 Gun



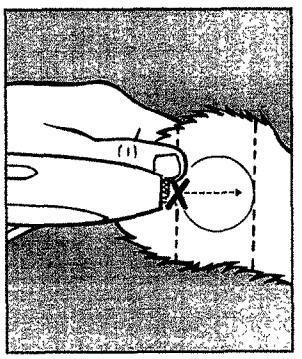
Load the SX10 gun following the directions outlined in the instruction manual accompanying each SX10 gun.

STEP 2 Restraint

The animal must be confined in a restraint mechanism (squeeze chute or head gate). The implant site on the back of the ear should be prepared by scrubbing with a generous-sized piece of cotton that has been soaked in a germicidal solution.

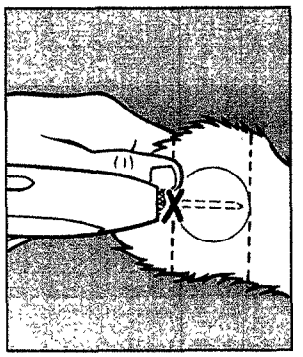
Note: If implanting horned cattle, greater safety is provided when the head is controlled by the use of a bull lead (nose tongs).

STEP 3 Implant Site



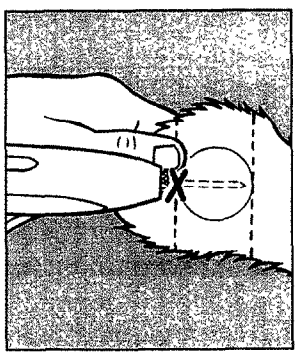
Divide the ear into three imaginary sections as illustrated. The implanted pellets should be deposited in the center one-third of the ear as shown. To accomplish this, the SX10 gun needle should be inserted in the **outer** one-third of the ear as indicated by the "X" in the illustration. Implanting too close to the head may cause abnormal sexual behavior. Care should be taken to avoid severing the major arteries of the ear.

STEP 4 Insert Needle



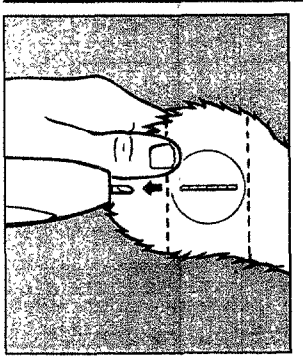
Just before grasping the ear with one hand, release the safety by striking the butt of the gun. Holding the SX10 gun firmly with the other hand, penetrate the skin at the point shown by the "X". Thrust the needle under the skin taking care not to penetrate the cartilage. Ease the SX10 gun forward (toward the base of the ear) until the full needle length is beneath the skin.

STEP 5 Pellet Implantation



When the needle is completely inserted, activate the instrument by squeezing the trigger completely. Do not withdraw the needle, but allow the automatic needle retractor to release the pellets. This will allow the pellets to be deposited in a straight line in the path of the retracted needle.

STEP 6 Inspection



Check the implant site. If properly administered, the implants should lie in a straight line under the skin.

Disinfect the SX10 gun needle in a germicidal solution and recock the instrument by rotating the cocking grip left, pull back, rotate right, then push all the way forward. You are now ready to implant the next animal.

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REVALOR – S 100 DS
011 EXP 06/03

Revalor®-S

(trenbolone acetate and estradiol)

PACKAGE QUANTITIES:
Box of 10 x 10 implants
Contains 100 doses in ten cartridges with ten implants per cartridge. Each dose contains 6 small yellow pellets. Each pellet contains 20 mg of trenbolone acetate and 4 mg estradiol

STORAGE CONDITIONS:
Store in a refrigerator (2-8°C; 36-47°F) and protect from sunlight. Use before the expiration date printed on the box and on the cartridge

INDICATIONS:
Increases rate of weight gain and improves feed efficiency in a slow-release delivery system.

NOTE:
Studies have demonstrated that the administration of Revalor®-S can result in decreased marbling scores when compared to non-implanted steers.

480907-B

FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER
Box of 10 x 10 Cartridge Implants

Manufactured by a non-sterilizing process

intervet

140x75x75
512 CV,
L47
FM x=30, y=40

1. Pouch: Carton - Front

2. Primary Container Label

Revalor®-S

(trenbolone acetate and estradiol)

FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

Box of 10 x 10 Cartridge Implants

Manufactured by a non-sterilizing process

intervet

Expiration Date: JUN. 2003

Lot Number: 02W025

USE DIRECTIONS:

See enclosed package insert.

WARNING:

Not to be used in animals for subsequent breeding or in dairy animals. For Animal Treatment Only. Not for use in Humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted site for human or animal food.

intervet

NADA # 140-897, Approved by FDA

Made in Austria by
Intervet GesmbH
Distributed by
Intervet Inc.
Millsboro, DE 19966

3. Pioneer. Insert - Front

WARNING

Not to be used in animals intended for subsequent breeding, or in dairy animals. For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted site for human or animal food.

STORAGE CONDITIONS

Store in a refrigerator (2-8° C: 36-47° F) and protect from sunlight. Use before the expiration date printed on the box and on the cartridge.

PACKAGE QUANTITIES

Box of 10 x 10 cartridge implants.

Made in Austria by:
Intervet GesmbH

Distributed by:
Intervet Inc.
Millsboro, DE 19966

780900-B

intervet

NADA # 140-897, Approved by FDA

Revalor®-S

(trenbolone acetate and estradiol)

FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

DESCRIPTION

Revalor®-S (trenbolone acetate and estradiol) is an implant containing 120 mg of trenbolone acetate and 24 mg estradiol. Each implant consists of 6 small yellow pellets. Ten implants are provided in a cartridge.

Manufactured by a non-sterilizing process.

INDICATIONS

Increases rate of weight gain and improves feed efficiency in a slow-release delivery system.

NOTE

Studies have demonstrated that the administration of Revalor®-S can result in decreased marbling scores when compared to non-implanted steers.

DOSAGE

Dosage Form:

One implant containing 120 mg trenbolone acetate and 24 mg estradiol is administered to each animal. The 6 pellets which make up the dosage of Revalor®-S are contained in one division of the multiple dose cartridge. Ten doses are in each cartridge. The cartridge is designed to be used with a special implant gun.

Route of Administration:

The implant is placed under the skin on the posterior aspect of the ear by means of a special implanter available from Intervet Inc.

509019 GWUS 010

Pioneer · Insert · Back

With the animal suitably restrained, the skin on the outer surface of the ear should be cleaned. The implant is then administered by the method shown in the diagram below.

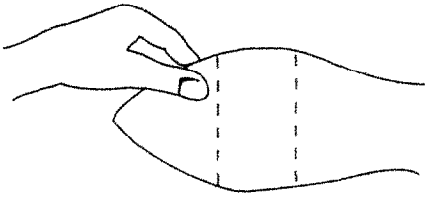


Fig. 1 - Ear of Bovine Ready for Implantation

SITE OF IMPLANTATION

After appropriately restraining the animal to allow access to the ear, cleanse the skin at the implant needle puncture site. It is subcutaneous between the skin and cartilage on the back side of the ear and below the midline of the ear. The implant must not be placed closer to the head than the edge of the cartilage ring farthest from the head. The location of insertion of the needle is a point toward the tip of the ear and at least a needle length away from the intended deposition site. Care should be taken to avoid injuring the major blood vessels or cartilage of the ear.

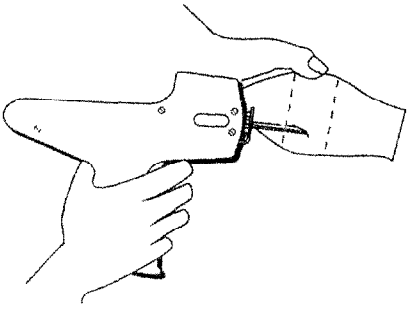
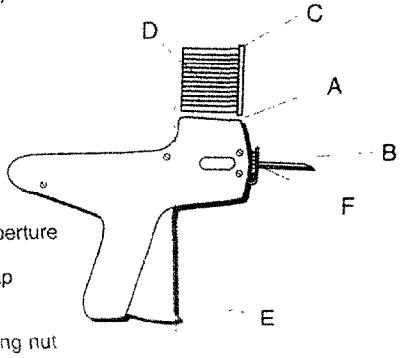


Fig. 2 - Rear View of the Bovine Ear Showing the Site for Insertion of the Implanter Needle.

METHOD OF USE

1. Do not remove the cap of the cartridge containing the implants.
2. Place the cartridge (D) with the capped end to the front into slot at the top of the implanter magazine marked (A) on the diagram.
3. Gently push the cartridge into the slot until it clicks into place.
4. The implanter is then ready for use.
5. Take the ear of the animal firmly with the free hand in the manner shown in Fig. 1. Then insert the needle into the subcutaneous tissue at the point indicated in Fig. 2.
6. After inserting the needle to its full extent, squeeze the trigger (E) gradually. Allow the pellets of the implant to be deposited in a single row.
7. Withdraw the implanter. This will advance the cartridge one groove in the magazine and the next implant is now ready for use.
8. When all the implants have been administered, the cartridge will discharge out the bottom of the magazine and may be replaced by a new one.
9. To change the needle, loosen the needle locking nut labeled (F) in Fig. 3 and replace the needle. Tighten the nut finger tight and the implanter is ready for use.



A - Magazine aperture
B - Needle
C - Cartridge cap
D - Cartridge
E - Trigger
F - Needle locking nut

Fig. 3 - Diagram of the Implanter and Cartridge

Generic
1. Foil Pouch

IMPLANTS FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

SYNOVEX® T80

(trenbolone acetate and estradiol)

ANADA 200-XXX
Approved by FDA

NDC 0856-6091-01

Synovex T80 (trenbolone acetate and estradiol) is an implant containing 80 mg trenbolone acetate and 16 mg estradiol. Each implant consists of 4 small yellow pellets. Ten implants are provided in a cartridge.

INDICATIONS FOR USE: Increases rate of weight gain and improves feed efficiency in a slow-release delivery system.

DOSAGE: One implant containing 80 mg trenbolone acetate and 16 mg estradiol is administered to each animal. The 4 pellets that make up the dosage of Synovex T80 are contained in one division of the multiple dose cartridge. The ten-dose cartridge of Synovex T80 is designed to be used exclusively with a Synovex implanting device.

WARNING: Not to be used in animals intended for subsequent breeding or in dairy animals. For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted site for human or animal food.

ROUTE OF ADMINISTRATION: The implant is placed under the skin on the posterior aspect of the ear by means of an implanting device available from Fort Dodge Animal Health.

NOTE: Never sacrifice careful, clean technique for speed of implantation.

STORAGE: Store unopened product at room temperature. Avoid excessive heat and humidity. Use product before the expiration date on the label.

Once the pouch is opened, unused product may be stored in the end-folded pouch (away from light) for up to six months under refrigerated conditions (2-8°C/36-47°F) or at room temperature (15-30°C/59-86°F) for up to one month.

Manufactured By A Non-Sterilizing Process

Keep this and all drugs out of the reach of children.

Restricted Drug (California)—Use Only As Directed

See top of pouch for lot and expiration date.

FORT DODGE®

Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

03252 6092A

NET CONTENTS:
One pouch contains ten 10-dose cartridges (100 implants)

IMPLANTS FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

SYNOVEX® T80

(trenbolone acetate and estradiol)

ANADA 200-XXX
Approved by FDA

NDC 0856-6091-01

Synovex T80 (trenbolone acetate and estradiol) is an implant containing 80 mg trenbolone acetate and 16 mg estradiol. Each implant consists of 4 small yellow pellets. Ten implants are provided in a cartridge.

INDICATIONS FOR USE: Increases rate of weight gain and improves feed efficiency in a slow-release delivery system.

DOSAGE: One implant containing 80 mg trenbolone acetate and 16 mg estradiol is administered to each animal. The 4 pellets that make up the dosage of Synovex T80 are contained in one division of the multiple dose cartridge. The ten-dose cartridge of Synovex T80 is designed to be used exclusively with a Synovex implanting device.

WARNING: Not to be used in animals intended for subsequent breeding or in dairy animals. For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted site for human or animal food.

ROUTE OF ADMINISTRATION: The implant is placed under the skin on the posterior aspect of the ear by means of an implanting device available from Fort Dodge Animal Health.

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STORAGE: Store unopened product at room temperature. Avoid excessive heat and humidity. Use product before the expiration date on the label.

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Manufactured By A Non-Sterilizing Process

Keep this and all drugs out of the reach of children.

Restricted Drug (California)—Use Only As Directed

See top of pouch for lot and expiration date.

FORT DODGE®

Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

03252 6092A

NET CONTENTS:
One pouch contains ten 10-dose cartridges (100 implants)

Generic:
1. Foil Pouch - Front

IMPLANTS FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

SYNOVEX® T80
(trenbolone acetate and estradiol)

ANADA 200-XXX
Approved by FDA

NDC 0856-6091-01

Synovex T80 (trenbolone acetate and estradiol) is an implant containing 80 mg trenbolone acetate and 16 mg estradiol. Each implant consists of 4 small yellow pellets. Ten implants are provided in a cartridge.

INDICATIONS FOR USE: Increases rate of weight gain and improves feed efficiency in a slow-release delivery system.

DOSAGE: One implant containing 80 mg trenbolone acetate and 16 mg estradiol is administered to each animal. The 4 pellets that make up the dosage of Synovex T80 are contained in one division of the multiple dose cartridge. The ten-dose cartridge of Synovex T80 is designed to be used exclusively with a Synovex implanting device.

WARNING: Not to be used in animals intended for subsequent breeding or in dairy animals. For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted site for human or animal food.

ROUTE OF ADMINISTRATION: The implant is placed under the skin on the posterior aspect of the ear by means of an implanting device available from Fort Dodge Animal Health.

NOTE: Never sacrifice careful, clean technique for speed of implantation.

STORAGE: Store unopened product at room temperature. Avoid excessive heat and humidity. Use product before the expiration date on the label.

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Manufactured By A Non-Sterilizing Process

Keep this and all drugs out of the reach of children.

Restricted Drug (California)—Use Only As Directed.

See top of pouch for lot and expiration date.

FORT DODGE®

Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

03252 6092A

NET CONTENTS:
One pouch contains ten 10-dose cartridges (100 implants)

IMPLANTS FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

SYNOVEX® T80

(trenbolone acetate and estradiol)

ANADA 200-XXX
Approved by FDA

NDC 0856-6091-01

Synovex T80 (trenbolone acetate and estradiol) is an implant containing 80 mg trenbolone acetate and 16 mg estradiol. Each implant consists of 4 small yellow pellets. Ten implants are provided in a cartridge.

INDICATIONS FOR USE: Increases rate of weight gain and improves feed efficiency in a slow-release delivery system.

DOSAGE: One implant containing 80 mg trenbolone acetate and 16 mg estradiol is administered to each animal. The 4 pellets that make up the dosage of Synovex T80 are contained in one division of the multiple dose cartridge. The ten-dose cartridge of Synovex T80 is designed to be used exclusively with a Synovex implanting device.

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ROUTE OF ADMINISTRATION: The implant is placed under the skin on the posterior aspect of the ear by means of an implanting device available from Fort Dodge Animal Health.

NOTE: Never sacrifice careful, clean technique for speed of implantation.

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Manufactured By A Non-Sterilizing Process

Keep this and all drugs out of the reach of children.

Restricted Drug (California)—Use Only As Directed.

See top of pouch for lot and expiration date.

FORT DODGE®

Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

03252 6092A

NET CONTENTS:
One pouch contains ten 10-dose cartridges (100 implants).

Generic:
2 Unfolded Cartons

Generic:
3. Cantoni - Sidan

9945
03192
6091A

IMPLANTS FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

SYNOVEX® T80
(trenbolone acetate and estradiol)

IMPLANTS FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

SYNOVEX® T80
(trenbolone acetate and estradiol)

Generic.
3. Carton - Front

IMPLANTS FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

SYNOVEX® T80

(trenbolone acetate and estradiol)

ANADA 200-XXX
Approved by FDA

NDC 0856-6091-01

FOR ANIMAL USE ONLY.
NOT FOR USE IN HUMANS.

INDICATIONS FOR USE:
Increases rate of weight gain and improves feed efficiency in a slow-release delivery system.

NET CONTENTS: One pouch contains ten 10-dose cartridges (100 implants).

Manufactured By A Non-Sterilizing Process

Keep this and all drugs out of the reach of children.

Restricted Drug (California)—Use Only As Directed.

FORT DODGE®

NET CONTENTS: 10 CARTRIDGES
Each Cartridge Contains 10 Rows of 4 Pellets

IMPLANTS FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

SYNOVEX® T80

(trenbolone acetate and estradiol)

Generic:
3. Carton - Back

IMPLANTS FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

SYNOVEX® T80

(trenbolone acetate and estradiol)

Synovex T80 (trenbolone acetate and estradiol) is an implant containing 80 mg trenbolone acetate and 16 mg estradiol. Each implant consists of 4 small yellow pellets. Ten implants are provided in a cartridge.

DOSAGE: One implant containing 80 mg trenbolone acetate and 16 mg estradiol is administered to each animal. The 4 pellets that make up the dosage of Synovex T80 are contained in one division of the multiple dose cartridge. The ten-dose cartridge of Synovex T80 is designed to be used exclusively with a Synovex implanting device.

WARNING: Not to be used in animals intended for subsequent breeding or in dairy animals. For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted site for human or animal food.

ROUTE OF ADMINISTRATION: The implant is placed under the skin on the posterior aspect of the ear by means of an implanting device available from Fort Dodge Animal Health.

NOTE: Never sacrifice careful, clean technique for speed of implantation.

STORAGE: Store unopened product at room temperature. Avoid excessive heat and humidity. Use product before the expiration date on the label.

Once the pouch is opened, unused product may be stored in the end-folded pouch (away from light) for up to six months under refrigerated conditions (2-8°C/36-47°F) or at room temperature (15-30°C/ 59-86°F) for up to one month.

Manufactured By A Non-Sterilizing Process

Keep this and all drugs out of the reach of children.

Restricted Drug (California)—Use Only As Directed.

FORT DODGE®

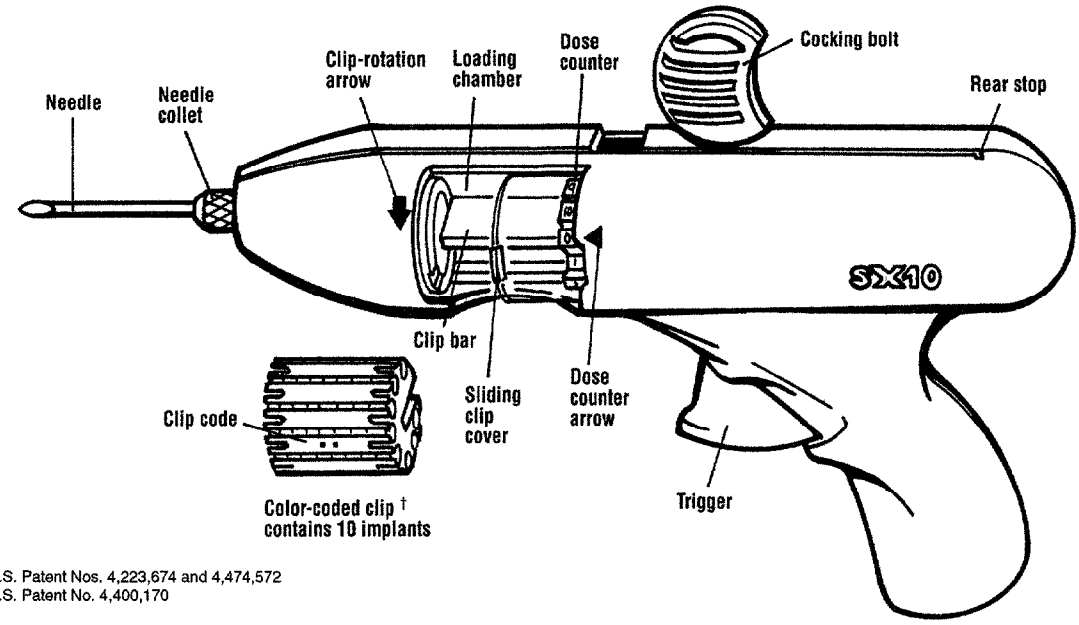
Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

▶ Open here for implanting directions ▶

NET CONTENTS: 10 CARTRIDGES
Each Cartridge Contains 10 Rows of 4 Pellets

Generic:
4 Carton Fold-out Page 1

SYNOVEX® SX10® Gun*



* U.S. Patent Nos. 4,223,674 and 4,474,572
† U.S. Patent No. 4,400,170

HOW TO IMPLANT SYNOVEX® T80 IMPLANTS

For Use With Any Synovex Gun.

Study the following instructions carefully, then proceed step by step, until the technique becomes routine. Many head can be implanted per hour by an experienced team, one member of which should be assigned to do nothing but the implantation. Care should be taken to insure the hands of the person administering the implant are clean and only sanitary instruments are used.

SYNOVEX® T80 Implants

Synovex T80 is recommended for steers fed in confinement for slaughter. When properly administered, Synovex T80 implants increase rate of weight gain and improve feed efficiency in steers in a slow release delivery system.

STORAGE

Store unopened product at room temperature. Avoid excessive heat and humidity.

Use product before the expiration date printed on the label.

Once the pouch is opened, unused product may be stored in the end-folded pouch (away from light) for up to six months under refrigerated conditions (2–8°C/36–47°F) or at room temperature (15–30°C/59–86°F) for up to one month.

WARNING

Not to be used in animals intended for subsequent breeding or in dairy animals. For Animal Treatment Only. Not for Use in Humans. Implant pellets in ear only. Any other location is a violation of Federal law. Do not attempt salvage of implanted site for human or animal food.

Keep this and all drugs out of the reach of children.

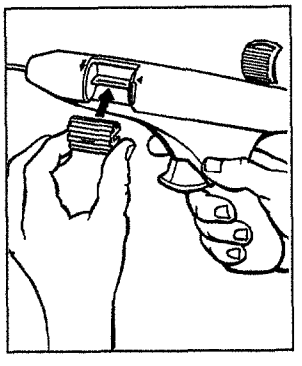
Restricted Drug (California)—
Use Only as Directed.

Generic:
5. Carton Fold-out Page 2

Exp. Date:

Lot:

STEP 1 Loading The SX10 Gun



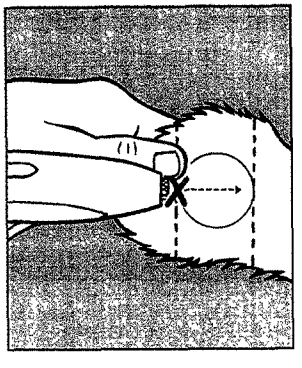
Load the SX10 gun following the directions outlined in the instruction manual accompanying each SX10 gun.

STEP 2 Restraint

The animal must be confined in a restraint mechanism (squeeze chute or head gate). The implant site on the back of the ear should be prepared by scrubbing with a generous-sized piece of cotton that has been soaked in a germicidal solution.

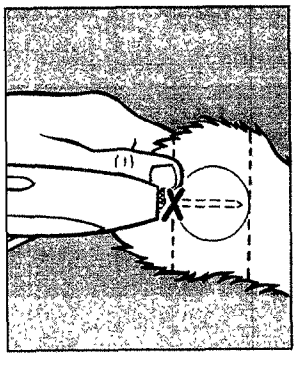
Note: If implanting horned cattle, greater safety is provided when the head is controlled by the use of a bull lead (nose tongs).

STEP 3 Implant Site



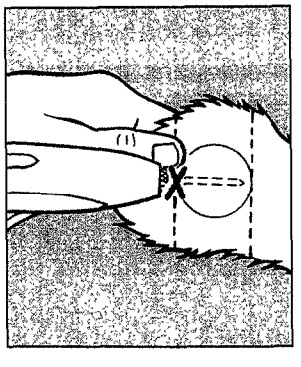
Divide the ear into three imaginary sections as illustrated. The implanted pellets should be deposited in the center one-third of the ear as shown. To accomplish this, the SX10 gun needle should be inserted in the **outer** one-third of the ear as indicated by the "X" in the illustration. Implanting too close to the head may cause abnormal sexual behavior. Care should be taken to avoid severing the major arteries of the ear.

STEP 4 Insert Needle



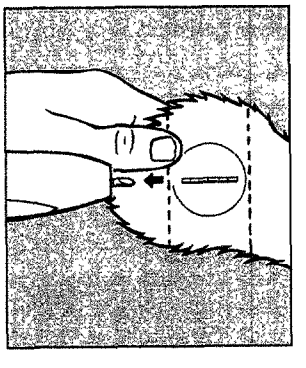
Just before grasping the ear with one hand, release the safety by striking the butt of the gun. Holding the SX10 gun firmly with the other hand, penetrate the skin at the point shown by the "X". Thrust the needle under the skin taking care not to penetrate the cartilage. Ease the SX10 gun forward (toward the base of the ear) until the full needle length is beneath the skin.

STEP 5 Pellet Implantation



When the needle is completely inserted, activate the instrument by squeezing the trigger completely. Do not withdraw the needle, but allow the automatic needle retractor to release the pellets. This will allow the pellets to be deposited in a straight line in the path of the retracted needle.

STEP 6 Inspection



Check the implant site. If properly administered, the implants should lie in a straight line under the skin.

Disinfect the SX10 gun needle in a germicidal solution and recock the instrument by rotating the cocking grip left, pull back, rotate right, then push all the way forward. You are now ready to implant the next animal.

Pioneer!
1. Carton - Front

Revalor®-IS

(trenbolone acetate and estradiol)

FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

Box of 10 x 10 Cartridge Implants

Manufactured by a non-sterilizing process

intervet

509016 FWUS
010

00021784813006

PACKAGE QUANTITIES:
Box of 10 x 10 implants
Contains 100 doses in ten cartridges with ten implants per cartridge
Each dose contains 4 small yellow pellets Each pellet contains 20 mg of trenbolone acetate and 4 mg estradiol.

STORAGE CONDITIONS:
Store in a refrigerator (2-8°C; 36-47°F) and protect from sunlight Use before the expiration date printed on the box and on the cartridge.

INDICATIONS:
Increases rate of weight gain and improves feed efficiency in a slow-release delivery system

481400-B

140x75x75
Pantone Orange 21 CV
L43
FM x=26; y=36

Pioneer 1
2. Cartoon Back

25

Revalor®-IS

(trenbolone acetate and estradiol)

Expiration Date: OCT. 2003

Lot Number 01W035

FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

Box of 10 x 10 Cartridge Implants

Manufactured by a non-sterilizing process

intervet

USE DIRECTIONS:

See enclosed package insert.

WARNING:

Not to be used in animals for subsequent breeding or in dairy animals. For Animal Treatment Only. Not for use in Humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted site for human or animal food.

intervet

NADA # 140-897, Approved by FDA

Made in Austria by
Intervet GesmbH
Distributed by:
Intervet Inc.
Millsboro, DE 19966

Pioneer:
3. Insert - Front

WARNING

Not to be used in animals intended for subsquent breeding, or in dairy animals. For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted site for human or animal food.

STORAGE CONDITIONS

Store in a refrigerator (2-8° C: 36-47° F) and protect from sunlight. Use before the expiration date printed on the box and on the cartridge.

PACKAGE QUANTITIES

Box of 10 x 10 cartridge implants.

Made in Austria by:
Intervet GesmbH

Distributed by:
Intervet Inc.
Millsboro, DE 19966

482020-B

intervet

NADA # 140-897 Approved by FDA

Revalor®-IS

(trenbolone acetate and estradiol)

FOR STEERS FED IN CONFINEMENT FOR SLAUGHTER

DESCRIPTION

Revalor®-IS (trenbolone acetate and estradiol) is an implant containing 80 mg of trenbolone acetate and 16 mg estradiol. Each implant consists of 4 small yellow pellets. Ten implants are provided in a cartridge.

Manufactured by a non-sterilizing process.

INDICATIONS

Increases rate of weight gain and improves feed efficiency in a slow-release delivery system.

DOSAGE

Dosage Form:
One implant containing 80 mg trenbolone acetate and 16 mg estradiol is administered to each animal. The 4 pellets which make up the dosage of Revalor®-IS are contained in one division of the multiple dose cartridge. Ten doses are in each cartridge. The cartridge is designed to be used with a special implant gun.

Route of Administration:
The implant is placed under the skin on the posterior aspect of the ear by means of a special implanter available from Intervet Inc.

509015 GWUS 010

Pioneer
3. Insert - back

With the animal suitably restrained, the skin on the outer surface of the ear should be cleaned. The implant is then administered by the method shown in the diagram below.

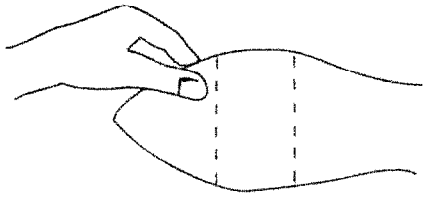


Fig. 1 - Ear of Bovine Ready for Implantation

SITE OF IMPLANTATION

After appropriately restraining the animal to allow access to the ear, cleanse the skin at the implant needle puncture site. It is subcutaneous between the skin and cartilage on the back side of the ear and below the midline of the ear. The implant must not be placed closer to the head than the edge of the cartilage ring farthest from the head. The location of insertion of the needle is a point toward the tip of the ear and at least a needle length away from the intended deposition site. Care should be taken to avoid injuring the major blood vessels or cartilage of the ear.

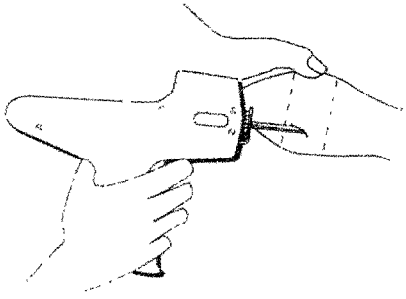
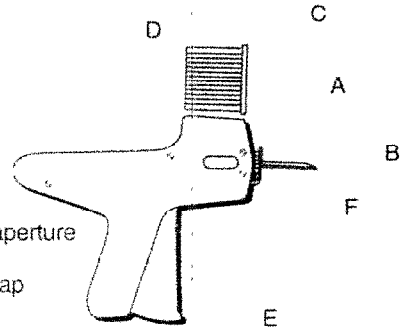


Fig. 2 - Rear View of the Bovine Ear Showing the Site for Insertion of the Implanter Needle.

METHOD OF USE

1. Do not remove the cap of the cartridge containing the implants.
2. Place the cartridge (D) with the capped end to the front into slot at the top of the implanter magazine marked (A) on the diagram.
3. Gently push the cartridge into the slot until it clicks into place.
4. The implanter is then ready for use.
5. Take the ear of the animal firmly with the free hand in the manner shown in Fig. 1. Then insert the needle into the subcutaneous tissue at the point indicated in Fig. 2.
6. After inserting the needle to its full extent, squeeze the trigger (E) gradually. Allow the pellets of the implant to be deposited in a single row.
7. Withdraw the implanter. This will advance the cartridge one groove in the magazine and the next implant is now ready for use.
8. When all the implants have been administered, the cartridge will discharge out the bottom of the magazine and may be replaced by a new one.
9. To change the needle, loosen the needle locking nut labeled (F) in Fig. 3 and replace the needle. Tighten the nut finger tight and the implanter is ready for use.



A - Magazine aperture
B - Needle
C - Cartridge cap
D - Cartridge
E - Trigger
F - Needle locking nut

Fig. 3 - Diagram of the Implanter and Cartridge

Generic:
c. 1. Foil Pouch

IMPLANTS FOR PASTURE CATTLE
(SLAUGHTER, STOCKER AND FEEDER STEERS AND HEIFERS)

SYNOVEX® T40
(trenbolone acetate and estradiol)

ANADA 200-XXX
Approved by FDA

NDC 0856-6131-01

Synovex T40 (trenbolone acetate and estradiol) is an implant containing 40 mg trenbolone acetate and 8 mg estradiol. Each implant consists of 2 small yellow pellets. Ten implants are provided in a cartridge.

INDICATIONS FOR USE: Increases rate of weight gain in pasture cattle (slaughter, stocker and feeder steers and heifers) in a slow-release delivery system.

DOSAGE: One implant containing 40 mg trenbolone acetate and 8 mg estradiol is administered to each animal. The 2 pellets that make up the dosage of Synovex T40 are contained in one division of the multiple dose cartridge. The ten-dose cartridge of Synovex T40 is designed to be used exclusively with a Synovex implanting device.

WARNING: Not to be used in animals intended for subsequent breeding or in dairy animals. For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted site for human or animal food.

ROUTE OF ADMINISTRATION: The implant is placed under the skin on the posterior aspect of the ear by means of an implanting device available from Fort Dodge Animal Health.

NOTE: Never sacrifice careful, clean technique for speed of implantation.

STORAGE: Store unopened product at room temperature. Avoid excessive heat and humidity. Use product before the expiration date on the label.

Once the pouch is opened, unused product may be stored in the end-folded pouch (away from light) for up to six months under refrigerated conditions (2-8°C/36-47°F) or at room temperature (15-30°C/ 59-86°F) for up to one month.

Manufactured By A Non-Sterilizing Process

Keep this and all drugs out of the reach of children.

Restricted Drug (California)—Use Only As Directed.

See top of pouch for lot and expiration date.

FORT DODGE®

Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

03362 6132A

NET CONTENTS:
One pouch contains ten 10-dose cartridges (100 implants)

NOTE: Leave 0.4375" white space on bottom of front and back.

IMPLANTS FOR PASTURE CATTLE
(SLAUGHTER, STOCKER AND FEEDER STEERS AND HEIFERS)

SYNOVEX® T40
(trenbolone acetate and estradiol)

ANADA 200-XXX
Approved by FDA

NDC 0856-6131-01

Synovex T40 (trenbolone acetate and estradiol) is an implant containing 40 mg trenbolone acetate and 8 mg estradiol. Each implant consists of 2 small yellow pellets. Ten implants are provided in a cartridge.

INDICATIONS FOR USE: Increases rate of weight gain in pasture cattle (slaughter, stocker and feeder steers and heifers) in a slow-release delivery system.

DOSAGE: One implant containing 40 mg trenbolone acetate and 8 mg estradiol is administered to each animal. The 2 pellets that make up the dosage of Synovex T40 are contained in one division of the multiple dose cartridge. The ten-dose cartridge of Synovex T40 is designed to be used exclusively with a Synovex implanting device.

WARNING: Not to be used in animals intended for subsequent breeding or in dairy animals. For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted site for human or animal food.

ROUTE OF ADMINISTRATION: The implant is placed under the skin on the posterior aspect of the ear by means of an implanting device available from Fort Dodge Animal Health.

NOTE: Never sacrifice careful, clean technique for speed of implantation.

STORAGE: Store unopened product at room temperature. Avoid excessive heat and humidity. Use product before the expiration date on the label.

Once the pouch is opened, unused product may be stored in the end-folded pouch (away from light) for up to six months under refrigerated conditions (2-8°C/36-47°F) or at room temperature (15-30°C/ 59-86°F) for up to one month.

Manufactured By A Non-Sterilizing Process

Keep this and all drugs out of the reach of children.

Restricted Drug (California)—Use Only As Directed.

See top of pouch for lot and expiration date.

FORT DODGE®

Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

03362 6132A

NET CONTENTS:
One pouch contains ten 10-dose cartridges (100 implants)

.25" 8.875" .375" .375" 9" .25" .25" 6.75" .25"

Generic:
1. Foil Pouch - Front

IMPLANTS FOR PASTURE CATTLE
(SLAUGHTER, STOCKER AND FEEDER STEERS AND HEIFERS)

SYNOVEX® T40
(trenbolone acetate and estradiol)

ANADA 200-XXX
Approved by FDA

NDC 0856-6131-01

Synovex T40 (trenbolone acetate and estradiol) is an implant containing 40 mg trenbolone acetate and 8 mg estradiol. Each implant consists of 2 small yellow pellets. Ten implants are provided in a cartridge.

INDICATIONS FOR USE: Increases rate of weight gain in pasture cattle (slaughter, stocker and feeder steers and heifers) in a slow-release delivery system.

DOSAGE: One implant containing 40 mg trenbolone acetate and 8 mg estradiol is administered to each animal. The 2 pellets that make up the dosage of Synovex T40 are contained in one division of the multiple dose cartridge. The ten-dose cartridge of Synovex T40 is designed to be used exclusively with a Synovex implanting device.

WARNING: Not to be used in animals intended for subsequent breeding or in dairy animals. For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted site for human or animal food.

ROUTE OF ADMINISTRATION: The implant is placed under the skin on the posterior aspect of the ear by means of an implanting device available from Fort Dodge Animal Health.

NOTE: Never sacrifice careful, clean technique for speed of implantation.

STORAGE: Store unopened product at room temperature. Avoid excessive heat and humidity. Use product before the expiration date on the label.

Once the pouch is opened, unused product may be stored in the end-folded pouch (away from light) for up to six months under refrigerated conditions (2-8°C/36-47°F) or at room temperature (15-30°C/ 59-86°F) for up to one month.

Manufactured By A Non-Sterilizing Process

Keep this and all drugs out of the reach of children.

Restricted Drug (California)—Use Only As Directed.

See top of pouch for lot and expiration date.

FORT DODGE®

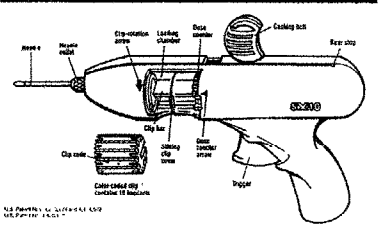
Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

03362 6132A

NET CONTENTS:
One pouch contains ten 10-dose cartridges (100 implants)

Generic:
2. Unfolded carton

SYNOVEX® SX10® Gun*



*U.S. PATENT NO. 5,078,143 5,078,144 5,078,145

HOW TO IMPLANT SYNOVEX® T40 IMPLANTS

For Use With Any Synovex Gun

Study the following instructions carefully then proceed step by step until the technique becomes routine. Many head can be implanted per hour by an experienced team one member of which should be assigned to do nothing but the implantation. Care should be taken to insure the hands of the person administering the implant are clean and only sanitary instruments are used

SYNOVEX® T40 Implants

Synovex T40 is recommended for pasture cattle (slaughter, stocker and feeder steers and heifers). When properly administered Synovex T40 implants increase rate of weight gain and improve feed efficiency.

STORAGE

Store unopened product at room temperature. Avoid excessive heat and humidity.

Use product before the expiration date printed on the box.

Once the pouch is opened unused product may be stored in the enclosed pouch (away from light) for up to six months under refrigerated conditions (2°-8°C/36°-47°F) or at room temperature (15°-30°C/59°-86°F) for up to one month.

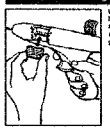
WARNING

Not to be used in animals intended for subsequent breeding or in dairy animals. For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear only. Any other location is in violation of federal law. Do not attempt salvage of implanted site for human or animal food.

Keep this and all drugs out of the reach of children.

Restricted Drug (California)—Use Only As Directed

STEP 1 Loading The SX10 Gun



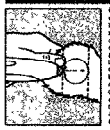
Load the SX10 gun following the directions outlined in the instruction manual accompanying your SX10 gun.

STEP 2 Restraint

The animal must be restrained in a restraint mechanism (squeeze chute or head gate). The implant site on the back of the ear should be prepared by scrubbing with a generous alcohol pulse of cotton that has been soaked in a germicidal solution.

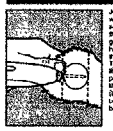
Note: If implanting horned cattle, greater Safety is provided when the head is controlled by the use of a bull horn crowe tongs.

STEP 3 Implant Site



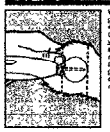
Grasp the ear only where cartilage sections are illustrated. The implanted pellets should be deposited in the center third of the ear as shown. To accomplish this, the SX10 gun needle should be inserted in the outer one third of the ear as indicated by the "A" in the illustration. Implanting too close to the head may cause abnormal sexual behavior. Care should be taken to avoid severing the major arteries of the ear.

STEP 4 Insert Needle



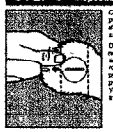
Just before grasping the ear with one hand, release the safety by cocking the bolt of the gun. Holding the SX10 gun firmly with the other hand, penetrate the skin at the point shown by the "A". Thrust the needle under the skin taking care not to penetrate the cartilage. Ease the SX10 gun forward (toward the base of the ear) until the full needle length is beneath the skin.

STEP 5 Pellet Implantation



When the needle is completely inserted, activate the mechanism by squeezing the trigger completely. Do not pull trigger a second time. Do not allow the automatic needle retraction to release the pellets. This will allow the pellets to be deposited in a straight line in the part of the vascularized needle.

STEP 6 Inspection



Check the implant site. If properly administered, the implants should lie in a straight line under the skin.

Disinfect the SX10 gun needle in a germicidal solution and recock the instrument by rotating the cocking grip left, pull back, release sight, then push all the way forward. You are now ready to implant the next animal.

Open here for implanting directions

IMPLANTS FOR PASTURE CATTLE
(SLAUGHTER, STOCKER AND FEEDER STEERS AND HEIFERS)

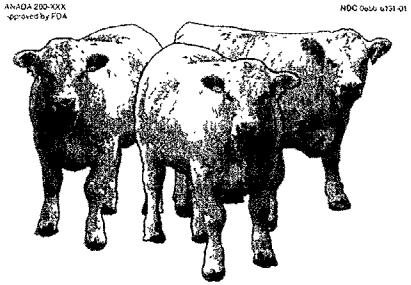
SYNOVEX® (trenbolone acetate and estradiol) T40

IMPLANTS FOR PASTURE CATTLE
(SLAUGHTER, STOCKER AND FEEDER STEERS AND HEIFERS)

SYNOVEX® (trenbolone acetate and estradiol) T40

AMADA-200-XXX
approved by FDA

NDC 0856 6791-01



FOR ANIMAL USE ONLY
NOT FOR USE IN HUMANS.

INDICATIONS FOR USE: Increases rate of weight gain in pasture cattle (slaughter, stocker and feeder steers and heifers) in a sustained-release delivery system.

NET CONTENTS: One pouch containing 10 dose cartridges (100 implants).

Manufactured By A Non-Sterilizing Process

Keep this and all drugs out of the reach of children.

Restricted Drug (California)—Use Only As Directed.

FORT DODGE®

NET CONTENTS: 10 CARTRIDGES
Each Cartridge Contains 10 Rows of 2 Pellets

IMPLANTS FOR PASTURE CATTLE
(SLAUGHTER, STOCKER AND FEEDER STEERS AND HEIFERS)

SYNOVEX® (trenbolone acetate and estradiol) T40

IMPLANTS FOR PASTURE CATTLE
(SLAUGHTER, STOCKER AND FEEDER STEERS AND HEIFERS)

SYNOVEX® (trenbolone acetate and estradiol) T40

Synovex T40 (trenbolone acetate and estradiol) is an implant containing 40 mg trenbolone acetate and 8 mg estradiol. Each implant consists of 2 small yellow pellets. Ten implants are provided in a cartridge.

DOSAGE: One implant containing 40 mg trenbolone acetate and 8 mg estradiol is administered to each animal. The 2 pellets that make up the dosage of Synovex T40 are contained in one division of the multiple dose cartridge. The two-dose cartridge of Synovex T40 is designed to be used exclusively with a Synovex implanting device.

WARNING: Not to be used in animals intended for subsequent breeding or in dairy animals. For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear only. Any other location is in violation of federal law. Do not attempt salvage of implanted site for human or animal food.

ROUTE OF ADMINISTRATION: The implant is placed under the skin on the posterior aspect of the ear by means of an implanting device available from Fort Dodge Animal Health.

NOTE: Never sacrifice careful, clean technique for speed of implantation.

STORAGE: Store unopened product at room temperature. Avoid excessive heat and humidity. Use product before the expiration date on the box.

Once the pouch is opened, unused product may be stored in the enclosed pouch (away from light) for up to six months under refrigerated conditions (2°-8°C/36°-47°F) or at room temperature (15°-30°C/59°-86°F) for up to one month.

Manufactured By A Non-Sterilizing Process.

Keep this and all drugs out of the reach of children.

Restricted Drug (California)—Use Only As Directed.

FORT DODGE®

Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

NET CONTENTS: 10 CARTRIDGES
Each Cartridge Contains 10 Rows of 2 Pellets

IMPLANTS FOR PASTURE CATTLE
(SLAUGHTER, STOCKER AND FEEDER STEERS AND HEIFERS)

SYNOVEX® (trenbolone acetate and estradiol) T40

Lot

Exp Date

Generic:
3, Canton - Sidon

9946
03362
6131A

9946
6131A

IMPLANTS FOR PASTURE CATTLE
(SLAUGHTER, STOCKER AND FEEDER STEERS AND HEIFERS)

SYNOVEX® T40
(trenbolone acetate and estradiol)

IMPLANTS FOR PASTURE CATTLE
(SLAUGHTER, STOCKER AND FEEDER STEERS AND HEIFERS)

SYNOVEX® T40
(trenbolone acetate and estradiol)

Generic:
3. Carton-Front

IMPLANTS FOR PASTURE CATTLE
(SLAUGHTER, STOCKER AND FEEDER STEERS AND HEIFERS)

SYNOVEX® T40
(trenbolone acetate and estradiol)

ANADA 200-XXX
Approved by FDA

NDC 0856-6131-01

FOR ANIMAL USE ONLY.
NOT FOR USE IN HUMANS.

INDICATIONS FOR USE:
Increases rate of weight gain in pasture cattle (slaughter, stocker and feeder steers and heifers) in a slow-release delivery system.

NET CONTENTS: One pouch contains ten 10-dose cartridges (100 implants).

Manufactured By A Non-Sterilizing Process

Keep this and all drugs out of the reach of children.

Restricted Drug (California)—Use Only As Directed.

FORT DODGE®

NET CONTENTS: 10 CARTRIDGES
Each Cartridge Contains 10 Rows of 2 Pellets

IMPLANTS FOR PASTURE CATTLE
(SLAUGHTER, STOCKER AND FEEDER STEERS AND HEIFERS)

SYNOVEX® T40
(trenbolone acetate and estradiol)

Generic
3. Carton - Back

IMPLANTS FOR PASTURE CATTLE
(SLAUGHTER, STOCKER AND FEEDER STEERS AND HEIFERS)

SYNOVEX® T40
(trenbolone acetate and estradiol)

Synovex T40 (trenbolone acetate and estradiol) is an implant containing 40 mg trenbolone acetate and 8 mg estradiol. Each implant consists of 2 small yellow pellets. Ten implants are provided in a cartridge.

DOSAGE: One implant containing 40 mg trenbolone acetate and 8 mg estradiol is administered to each animal. The 2 pellets that make up the dosage of Synovex T40 are contained in one division of the multiple dose cartridge. The ten-dose cartridge of Synovex T40 is designed to be used exclusively with a Synovex implanting device.

WARNING: Not to be used in animals intended for subsequent breeding or in dairy animals. For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted site for human or animal food.

ROUTE OF ADMINISTRATION: The implant is placed under the skin on the posterior aspect of the ear by means of an implanting device available from Fort Dodge Animal Health.

NOTE: Never sacrifice careful, clean technique for speed of implantation.

STORAGE: Store unopened product at room temperature. Avoid excessive heat and humidity. Use product before the expiration date on the label.

Once the pouch is opened, unused product may be stored in the end-folded pouch (away from light) for up to six months under refrigerated conditions (2-8°C/36-47°F) or at room temperature (15-30°C/ 59-86°F) for up to one month.

Manufactured By A Non-Sterilizing Process

Keep this and all drugs out of the reach of children.

Restricted Drug (California)—Use Only As Directed.

FORT DODGE®

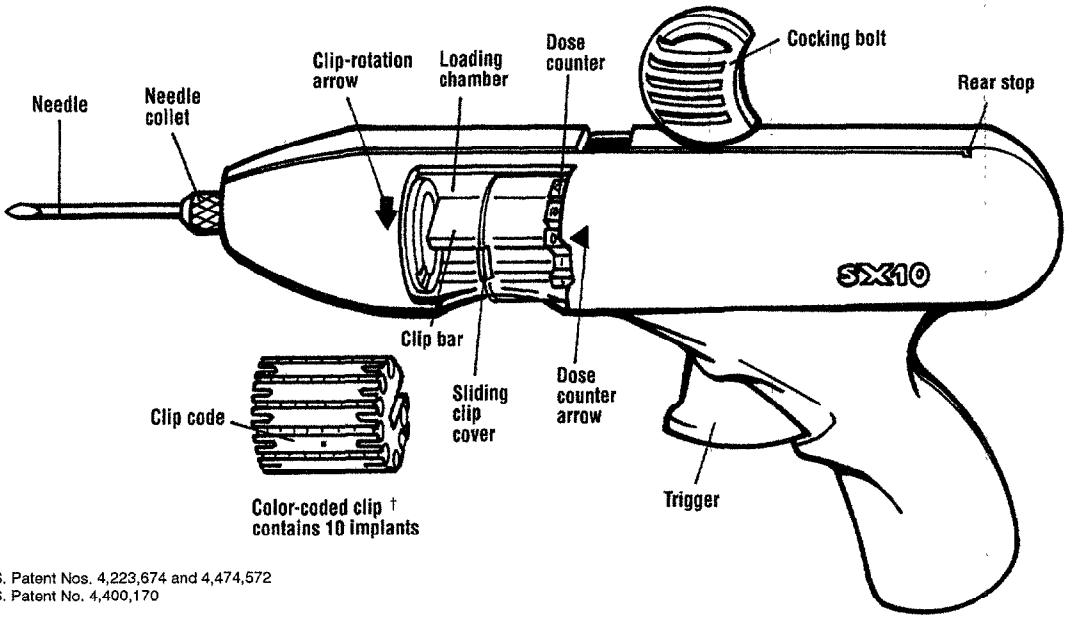
Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

▶ Open here for implanting directions ▶

NET CONTENTS: 10 CARTRIDGES
Each Cartridge Contains 10 Rows of 2 Pellets

Generic :
4. Carton Fold-out Page

SYNOVEX® SX10® Gun*



* U S. Patent Nos. 4,223,674 and 4,474,572
† U S. Patent No. 4,400,170

HOW TO IMPLANT SYNOVEX® T40 IMPLANTS

For Use With Any Synovex Gun.

Study the following instructions carefully, then proceed step by step, until the technique becomes routine. Many head can be implanted per hour by an experienced team, one member of which should be assigned to do nothing but the implantation. Care should be taken to insure the hands of the person administering the implant are clean and only sanitary instruments are used.

SYNOVEX® T40 Implants

Synovex T40 is recommended for pasture cattle (slaughter, stocker and feeder steers and heifers). When properly administered, Synovex T40 implants increase rate of weight gain in a slow release delivery system.

STORAGE

Store unopened product at room temperature. Avoid excessive heat and humidity.

Use product before the expiration date printed on the label.

Once the pouch is opened, unused product may be stored in the end-folded pouch (away from light) for up to six months under refrigerated conditions (2–8°C/36–47°F) or at room temperature (15–30°C/59–86°F) for up to one month.

WARNING

Not to be used in animals intended for subsequent breeding or in dairy animals. For Animal Treatment Only. Not for Use in Humans. Implant pellets in ear only. Any other location is a violation of Federal law. Do not attempt salvage of implanted site for human or animal food.

Keep this and all drugs out of the reach of children.

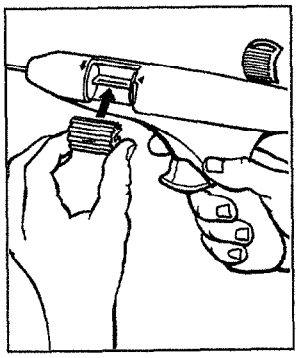
Restricted Drug (California)—
Use Only as Directed.

Generic!
5. Carton Fold-out Page # 2

Exp. Date:

Lot:

STEP 1 Loading The SX10 Gun



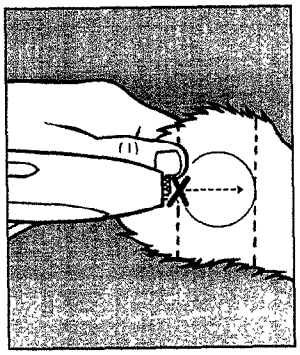
Load the SX10 gun following the directions outlined in the instruction manual accompanying each SX10 gun.

STEP 2 Restraint

The animal must be confined in a restraint mechanism (squeeze chute or head gate). The implant site on the back of the ear should be prepared by scrubbing with a generous-sized piece of cotton that has been soaked in a germicidal solution.

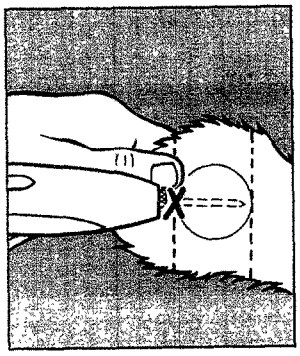
Note: If implanting horned cattle, greater safety is provided when the head is controlled by the use of a bull lead (nose tongs).

STEP 3 Implant Site



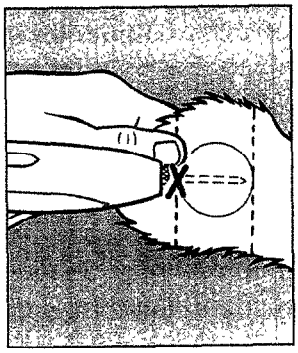
Divide the ear into three imaginary sections as illustrated. The implanted pellets should be deposited in the center one-third of the ear as shown. To accomplish this, the SX10 gun needle should be inserted in the **outer** one-third of the ear as indicated by the "X" in the illustration. Implanting too close to the head may cause abnormal sexual behavior. Care should be taken to avoid severing the major arteries of the ear.

STEP 4 Insert Needle



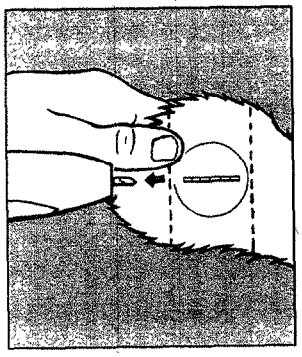
Just before grasping the ear with one hand, release the safety by striking the butt of the gun. Holding the SX10 gun firmly with the other hand, penetrate the skin at the point shown by the "X". Thrust the needle under the skin taking care not to penetrate the cartilage. Ease the SX10 gun forward (toward the base of the ear) until the full needle length is beneath the skin.

STEP 5 Pellet Implantation



When the needle is completely inserted, activate the instrument by squeezing the trigger completely. Do not withdraw the needle, but allow the automatic needle retractor to release the pellets. This will allow the pellets to be deposited in a straight line in the path of the retracted needle.

STEP 6 Inspection



Check the implant site. If properly administered, the implants should lie in a straight line under the skin.

Disinfect the SX10 gun needle in a germicidal solution and recock the instrument by rotating the cocking grip left, pull back, rotate right, then push all the way forward. You are now ready to implant the next animal.

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Pioneer:
1. Carton - Front

Revalor®-G

(trenbolone acetate and estradiol)

FOR PASTURE CATTLE
(SLAUGHTER, STOCKER AND FEEDER STEERS AND HEIFERS)

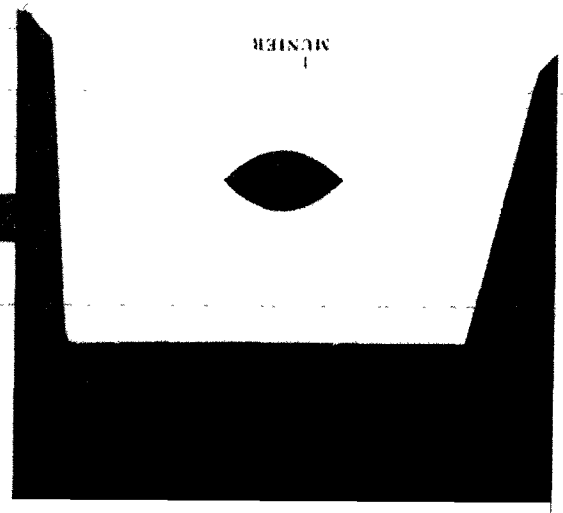
Box of 10 x 10 Cartridge Implants

Manufactured by a non-sterilizing process
The name and logo Hoechst are registered trademarks of Hoechst AG.

Hoechst Roussel Vet

Revalor®-G is a registered trademark of Hoechst Roussel Vet, S.A

MUNIER



Expiration Date JUN 2002 Lot Number: 310

USE DIRECTIONS:
See enclosed package insert.

WARNING:
Not to be used in animals for subsequent breeding or in dairy animals. For Animal Treatment Only. Not for use in Humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted site for human or animal food.

Hoechst
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Made in France by:
Hoechst Roussel Vet, S.A.
Distributed by:
Hoechst Roussel Vet
Clinton, NJ 08809

Pioneer:
2. Carton - Back

30

V 81 227 0

2 17848 11002 4

PACKAGE QUANTITIES:
Box of 10 x 10 implants
Contains 100 doses in ten cartridges with ten implants per cartridge
Each dose contains 2 small yellow pellets. Each pellet contains 20 mg of trenbolone acetate and 4 mg estradiol

STORAGE CONDITIONS:
Store in a refrigerator (2-8°C; 36-47°F) and protect from sunlight. Use before the expiration date printed on the box and on the cartridge.

INDICATIONS:
Increases rate of weight gain in a slow-release delivery system.

481200-A

Revalor®-G

(trenbolone acetate and estradiol)

FOR PASTURE CATTLE
(SLAUGHTER, STOCKER AND FEEDER STEERS AND HEIFERS)

Box of 10 x 10 Cartridge Implants

Manufactured by a non-sterilizing process
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Hoechst Roussel Vet

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Pioneer :
2. Insert Front

WARNING

Not to be used in animals intended for subsequent breeding, or in dairy animals. For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted site for human or animal food.

STORAGE CONDITIONS

Store in a refrigerator (2-8° C; 36-47° F) and protect from sunlight. Use before the expiration date printed on the box and on the cartridge.

PACKAGE QUANTITIES

Box of 10 x 10 cartridge implants.

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781200-A

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V 71 210 0

Revalor®-G

(trenbolone acetate and estradiol)

FOR PASTURE CATTLE (SLAUGHTER, STOCKER AND FEEDER STEERS AND HEIFERS)

DESCRIPTION

Revalor®-G is an implant containing 40 mg of trenbolone acetate and 8 mg estradiol. Each implant consists of 2 small yellow pellets. Ten implants are provided in a cartridge.

INDICATIONS

Increases rate of weight gain in pasture cattle (slaughter, stocker and feeder steers and heifers) in a slow-release delivery system.

DOSAGE

Dosage Form:

One implant containing 40 mg trenbolone acetate and 8 mg estradiol is administered to each animal. The 2 pellets which make up the dosage of Revalor®-G are contained in one division of the multiple dose cartridge. Ten doses are in each cartridge. The cartridge is designed to be used with a special implant gun.

Route of Administration:

The implant is placed under the skin on the posterior aspect of the ear by means of a special implanter available from Hoechst Roussel Vet.

Pioneer:
3. Insert - Back

With the animal suitably restrained, the skin on the outer surface of the ear should be cleaned. The implant is then administered by the method shown in the diagram below.

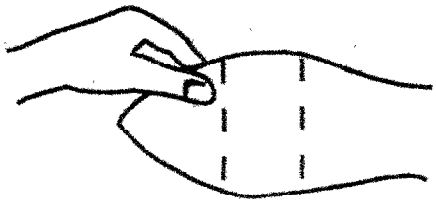


Fig. 1 - Ear of Bovine Ready for Implantation

SITE OF IMPLANTATION

After appropriately restraining the animal to allow access to the ear, cleanse the skin at the implant needle puncture site. It is subcutaneous between the skin and cartilage on the back side of the ear and below the midline of the ear. The implant must not be placed closer to the head than the edge of the cartilage ring farthest from the head The location of insertion of the needle is a point toward the tip of the ear and at least a needle length away from the intended deposition site. Care should be taken to avoid injuring the major blood vessels or cartilage of the ear.

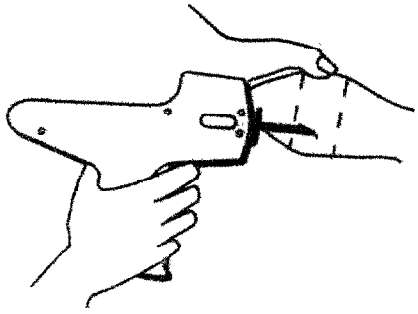
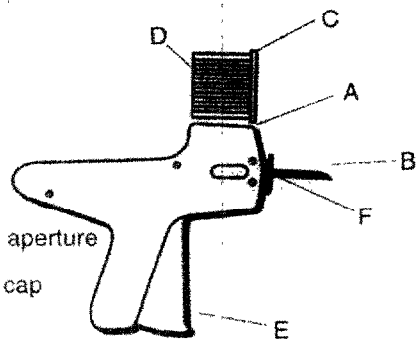


Fig 2 - Rear View of the Bovine Ear Showing the Site for Insertion of the Implanter Needle.

METHOD OF USE

1. Do not remove the cap of the cartridge containing the implants.
2. Place the cartridge (D) with the capped end to the front into slot at the top of the implanter magazine marked (A) on the diagram.
3. Gently push the cartridge into the slot until it clicks into place.
4. The implanter is then ready for use.
5. Take the ear of the animal firmly with the free hand in the manner shown in Fig. 1. Then insert the needle into the subcutaneous tissue at the point indicated in Fig. 2.
6. After inserting the needle to its full extent, squeeze the trigger (E) gradually. Allow the pellets of the implant to be deposited in a single row.
7. Withdraw the implanter. This will advance the cartridge one groove in the magazine and the next implant is now ready for use.
8. When all the implants have been administered, the cartridge will discharge out the bottom of the magazine and may be replaced by a new one.
9. To change the needle, loosen the needle locking nut labeled (F) in Fig. 3 and replace the needle. Tighten the nut finger tight and the implanter is ready for use.



A - Magazine aperture
B - Needle
C - Cartridge cap
D - Cartridge
E - Trigger
F - Needle locking nut

Fig. 3 - Diagram of the Implanter and Cartridge