

HFA-305 Div. of  
Dockets Mgt.

Approval Date: OCT 28 2004

**FREEDOM OF INFORMATION SUMMARY**  
**SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION**

**NADA 110-315**

**COMPONENT E-C and COMPONENT E-S**  
**(Progesterone and Estradiol Benzoate)**

**COMPONENT E-C with TYLAN and COMPONENT E-S with TYLAN**  
**(Progesterone and Estradiol Benzoate with Tylosin)**

**This supplement provides for addition to the labeling of the statements "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal." to the warning section and "Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established." immediately following the indications.**

**Sponsored by:**

**Ivy Laboratories**  
**Division of Ivy Animal Health, Inc.**  
**8857 Bond Street**  
**Overland Park, KS 66214**

2004-110-315

F0151

**FREEDOM OF INFORMATION SUMMARY**

COMPONENT E-C and COMPONENT E-C with TYLAN  
Ear Implant for Suckling Beef Calves

COMPONENT E-S and COMPONENT E-S with TYLAN  
Ear Implant for Steers Weighing 400 lbs or More

**1. GENERAL INFORMATION:**

- a. File Number: NADA 110-315
- b. Sponsor: Ivy Laboratories  
Division of Ivy Animal Health, Inc.  
8857 Bond Street  
Overland Park, KS 66214  
Drug Labeler Code: 021641
- c. Established Names: Progesterone and Estradiol Benzoate  
Progesterone and Estradiol Benzoate with Tylosin
- d. Propriety Names: COMPONENT E-C, COMPONENT E-S,  
COMPONENT E-C with TYLAN, and  
COMPONENT E-S with TYLAN
- e. Dosage Form: Implantation (ear implant) as per 21 CFR 522.1940

- f. How Supplied:
- COMPONENT E-C: Each box contains 5 foil pouches each containing 1 cartridge belt with 20 cells. Each cartridge cell contains 1 implant dose. Each dose consists of progesterone USP 100 mg and estradiol benzoate 10 mg.
- COMPONENT E-C with TYLAN: Each box contains 5 foil pouches each containing 1 cartridge belt with 20 cells. Each cartridge cell contains 1 implant dose. Each dose consists of progesterone USP 100 mg and estradiol benzoate 10 mg with 29 mg tylosin tartrate as a local antibacterial.
- COMPONENT E-S: Each box contains 5 foil pouches each containing 1 cartridge belt with 20 cells. Each cartridge cell contains 1 implant dose. Each dose consists of progesterone USP 200 mg and estradiol benzoate 20 mg.
- COMPONENT E-S with TYLAN: Each box contains 5 foil pouches each containing 1 cartridge belt with 20 cells. Each cartridge cell contains 1 implant dose. Each dose consists of progesterone USP 200 mg and estradiol benzoate 20 mg with 29 mg tylosin tartrate as a local antibacterial.
- g. How Dispensed: OTC
- h. Amount of Active Ingredients:
- COMPONENT E-C:  
100 mg progesterone.  
10 mg estradiol benzoate.
- COMPONENT E-C with TYLAN:  
100 mg progesterone.  
10 mg estradiol benzoate.  
29 mg tylosin tartrate.
- COMPONENT E-S:  
200 mg progesterone.  
20 mg estradiol benzoate.
- COMPONENT E-S with TYLAN:  
200 mg progesterone.  
20 mg estradiol benzoate.  
29 mg tylosin tartrate.

- i. Route of Administration: Subcutaneous implantation on the posterior aspect of the middle one-third of the ear by means of an implant gun.
- j. Species/Class: Suckling beef calves and steers weighing 400 lbs or more
- k. Recommended Dosage: COMPONENT E-C: One implant containing 100 mg progesterone and 10 mg estradiol benzoate.  
COMPONENT E-C with TYLAN: One implant containing 100 mg progesterone and 10 mg estradiol benzoate with 29 mg tylosin tartrate.  
COMPONENT E-S: One implant containing 200 mg progesterone and 20 mg estradiol benzoate.  
COMPONENT E-S with TYLAN: One implant containing 200 mg progesterone and 20 mg estradiol benzoate with 29 mg tylosin tartrate.
- l. Pharmacological Category: Steroid hormones, anti-bacterial
- m. Indications: COMPONENT E-C and COMPONENT E-C with TYLAN: For increased rate of weight gain in suckling beef calves (at least 45 days of age) up to approximately 400 pounds of body weight.  
COMPONENT E-S AND COMPONENT E-S with TYLAN: For use in steers weighing 400 lbs or more for increased rate of weight gain and improved feed efficiency.
- n. Effect of Supplement: This supplement provides for addition to the labeling of the statements "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal." to the warning section and "Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established." immediately following the label indications.

**2. DRUG EFFECTIVENESS:**

No new effectiveness data are required for the approval of this supplement. The products' effectiveness has been established in the Freedom of Information (FOI) Summaries for the parent new animal drug applications for COMPONENT E-C, COMPONENT E-C with TYLAN, COMPONENT E-S, and COMPONENT E-S with TYLAN (NADA 110315).

**3. TARGET ANIMAL SAFETY:**

No new target animal safety data are required for the approval of this supplement. The products' target animal safety has been established in the Freedom of Information (FOI) Summaries for the parent new animal drug applications for COMPONENT E-C, COMPONENT E-C with TYLAN, COMPONENT E-S, and COMPONENT E-S with TYLAN (NADA 110315).

**4. HUMAN SAFETY:**

No new human food safety data are required for the approval of this supplement. The products' human food safety has been established in the Freedom of Information (FOI) Summaries for the parent new animal drug applications for COMPONENT E-C, COMPONENT E-C with TYLAN, COMPONENT E-S, and COMPONENT E-S with TYLAN (NADA 110315).

**5. AGENCY CONCLUSIONS:**

The information submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations providing for the addition to the labeling of the statements "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal." to the warning section and "Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established." immediately following the indications. The labeling is modified to conform to agency policy (69 FR 135 pages 42443-42444 dated July 15, 2004, and 69 FR 68 page 18594 dated April 8, 2004.)

The Center for Veterinary Medicine has concluded that, for these products, adequate directions for use by the layperson have been provided and the products will have over-the-counter (OTC) status. Label directions are accompanied by pictorial diagrams and detailed instruction in plain language. The drugs are not controlled substances. The products' status remains OTC. The labeling is adequate for the intended use and has sufficient warnings/statements to prevent illegal use in veal calves.

This approval does not qualify for marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act.

Under the Center's supplemental approval policy (21 CFR 514.106(b)(2)), this is a Category II change. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. Accordingly, this approval did not require a reevaluation of the safety and effectiveness data in the parent application.

COMPONENT E-C with TYLAN and COMPONENT E-S with TYLAN are under the following US patent number:

<u>U.S. Patent Number</u>	<u>Date of Expiration</u>
5,874,098	May 28, 2017

**6. ATTACHMENTS:**

Facsimile Labeling is attached as indicated below:

COMPONENT E-C Carton Label  
COMPONENT E-C Foil Pouch (Front)  
COMPONENT E-C Foil Pouch (Back)  
COMPONENT E-C Package Insert  
COMPONENT E-C with TYLAN Carton Label  
COMPONENT E-C with TYLAN Foil Pouch (Front)  
COMPONENT E-C with TYLAN Foil Pouch (Back)  
COMPONENT E-C with TYLAN Package Insert  
COMPONENT E-S Carton Label  
COMPONENT E-S Foil Pouch (Front)  
COMPONENT E-S Foil Pouch (Back)  
COMPONENT E-S Package Insert  
COMPONENT E-S with TYLAN Carton Label  
COMPONENT E-S with TYLAN Foil Pouch (Front)  
COMPONENT E-S with TYLAN Foil Pouch (Back)  
COMPONENT E-S with TYLAN Package Insert

Progesterone and estradiol benzoate are naturally occurring hormones found in all cattle. COMPONENT® E-C Implant pellets are made by combining the two chemically pure steroid hormones - progesterone USP 100 mg and estradiol benzoate 10 mg - into one single dose consisting of 4 individual pellets contained within a multi-dose cartridge belt. The formulation has been designed to furnish complementary quantities of each of the two hormones as a means of achieving maximum weight gain. **DO NOT USE IN BULL CALVES INTENDED FOR REPRODUCTION OR IN CALVES LESS THAN 45 DAYS OLD.** Store at controlled room temperature - 15°-30°C (59°-86°F). DO NOT refrigerate - avoid excessive heat and humidity.

**COMPONENT®**  
BRAND IMPLANTS

**E-C**

progesterone USP 100 mg  
and estradiol benzoate 10 mg  
CALF IMPLANTS



Indicated for increased rate of weight gain in suckling beef calves up to approximately 450 lbs. of body weight.  
Contents: 100 multi-dose cartridge containing four pellets with 40 mg progesterone and 10 mg estradiol benzoate.  
Dosage: Administer 1 implant per animal. See dosage insert for detailed instructions. Do not use in veal calves.  
© Royalty, L., Animal Health, Inc. NADA 141-113, New York, NY, USA

100 IMPLANTS



6 13562 03203 9



**WARNING: Not to be used in animals intended for subsequent breeding, or in dairy animals. Implant one dose — 4 pellets (entire contents of one cartridge cell) — in the ear subcutaneously. Any other site of implantation is in violation of Federal Law. DO NOT attempt to salvage implantation site for animal feed or human food.**

**A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.**

**RESTRICTED DRUG — USE ONLY AS DIRECTED (CALIFORNIA) — FOR USE IN ANIMALS ONLY — NOT FOR HUMAN USE — KEEP OUT OF REACH OF CHILDREN**

**Caution:** Bulling, rectal prolapse, ventral edema and elevated tail-heads have occasionally been reported in animals implanted with progesterone and estradiol benzoate.

**Important:** Read the enclosed instruction brochure. Use as illustrated with a CAREFUL CLEAN TECHNIQUE. Never take short cuts at the expense of CLEANLINESS.

**Manufactured by a non-sterilizing process.**

COMPONENT® E-C implants are safe when used fully in accordance with directions.  
COMPONENT is a registered trademark of Ivy Animal Health, Inc.  
Manufactured for VetLife by Ivy Laboratories - Overland Park, KS 66214, USA  
VetLife and Ivy Laboratories are divisions of Ivy Animal Health, Inc.

01 03 03 04

CALF IMPLANTS  
progesterone USP 100 mg  
and estradiol benzoate 10 mg  
**COMPONENT®**  
BRAND IMPLANTS

3.125"



1/4" Seal Area

9.5"

**COMPONENT**  
BRAND IMPLANTS

**E-C**

progesterone USP 100 mg and  
estradiol benzoate 10 mg

**CALF IMPLANTS**



Indicated for increased rate of weight gain in suckling beef calves up to approximately 400 lbs. of body weight.

Contains: One cartridge belt\* of 20 implants sealed in a sanitary foil pouch.

Dosage: Administer 1 implant per animal. See package insert for detailed instructions. Do not use in veal calves.

Manufactured by a non-sterilizing process.  
\*Approved by the Animal Health Division, FDA

NADA 110-315. Approved by FDA  
One 20-Dose Cartridge Belt

18.073

9.375"

**WARNING: Not to be used in animals intended for subsequent breeding, or in dairy animals.** Implant one dose — 4 pellets (entire contents of one cartridge cell) — in the ear subcutaneously. Any other site of implantation is in violation of Federal Law. DO NOT attempt to salvage implantation site for animal feed or human food.  
**A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.**

**RESTRICTED DRUG — USE ONLY AS DIRECTED (CALIFORNIA) — FOR USE IN ANIMALS ONLY —  
NOT FOR HUMAN USE — KEEP OUT OF REACH OF CHILDREN**

**Caution:** Bulling, rectal prolapse, ventral edema and elevated tail heads have occasionally been reported in calves implanted with progesterone and estradiol benzoate.  
**DO NOT USE IN BULL CALVES INTENDED FOR REPRODUCTION OR IN CALVES LESS THAN 45 DAYS OLD.**

Subcutaneous ear implants for **SUCKLING BEEF CALVES ONLY**  
**Important:** See enclosed instruction brochure for complete directions and use as illustrated with a **CAREFUL CLEAN TECHNIQUE**.  
Never take short cuts at the expense of **CLEANLINESS**.

**DO NOT refrigerate** — avoid excessive heat and humidity.  
**Store at controlled room temperature** — 15°-30°C (59°-86°F).

COMPONENT is a registered trademark of Ivy Animal Health, Inc.

Manufactured for **VetLife** by Ivy Laboratories • Overland Park, KS 66214, USA  
VetLife and Ivy Laboratories are divisions of Ivy Animal Health, Inc.  
01 03 02 03



EXP

LOT

TEAR HERE

CAUTION: KEEP OUT OF REACH OF CHILDREN

**COMPONENT**<sup>®</sup>  
BRAND IMPLANTS

**VetLife**

CALF IMPLANTS

**E-C**

progesterone USP 100 mg and estradiol benzoate 10 mg  
**20 dose CARTRIDGE BELT\***

For use with the COMPONENT One Gun<sup>SM</sup>  
**For Use In Animals Only**

Each CARTRIDGE BELT holds 20 doses of COMPONENT<sup>®</sup> E-C Implants. Each dose of 4 pellets contains a total of 100 mg progesterone USP and 10 mg estradiol benzoate. COMPONENT<sup>®</sup> E-C Implants are indicated for increased rate of weight gain in suckling beef calves up to approximately 400 lbs of body weight.

Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established.

**DOSAGE:**

Administer 1 implant per animal according to the following instructions.

**GENERAL INSTRUCTIONS:**

Study the instructions which should be followed carefully at all times, avoiding short cuts. Skin infection can be avoided by properly preparing implant site and implanter. During fly season use fly repellent on implant site.

One designated team member should always do the implanting. Cleanliness of hands and instruments is important at all times.

**DO NOT USE IN BULL CALVES INTENDED FOR REPRODUCTION, OR IN CALVES LESS THAN 45 DAYS OLD.**

**WARNING**

Not to be used in animals intended for subsequent breeding, or in dairy animals. Implant one dose — 4 pellets (entire contents of one cartridge cell) — in the ear subcutaneously. Any other site of implantation is in violation of Federal Law. DO NOT attempt to salvage implantation site for animal feed or human food.

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

**RESTRICTED DRUG — USE ONLY AS DIRECTED (CALIFORNIA) —  
FOR USE IN ANIMALS ONLY — NOT FOR HUMAN USE —  
KEEP OUT OF REACH OF CHILDREN**

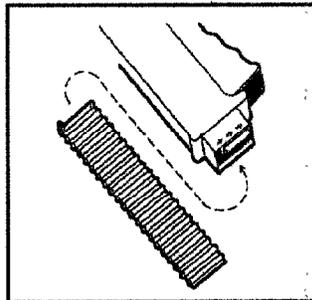
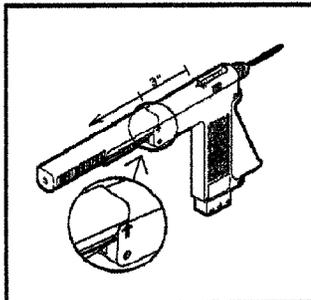
**CAUTION:**

Bulling, rectal prolapse, ventral edema and elevated tail-heads have occasionally been reported in animals implanted with progesterone and estradiol benzoate.

**IMPLANTING INSTRUCTIONS:**

**Loading the Implanter**

Load the implanter following the instructions supplied with each implanter.



**Restrain the Animal**

Speed of implantation as well as safety of handlers is best achieved by restraining animal in a squeeze chute using head restraint.

**Prepare the Implant Site**

Scrub the back side of the ear (implant site) with a piece of clean absorbent cotton which has been soaked with topical germicidal solution. Follow manufacturer's directions on germicide for correct strength and preparation of solution. Avoid getting disinfectant in animal's eyes.

**Where to Implant**

The full contents of one cartridge cell should be implanted beneath the skin on the back side of the middle one-third of the ear as illustrated in the drawing. The implant must not be closer to the head than the edge of the auricular cartilage ring farthest from the head. The location for 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. Avoid injuring the large arteries, veins and cartilage of the ear.

**Insert the Needle**

With one hand firmly grasp the ear. With the other hand insert needle point through the skin and ease forward on a lateral plane until the entire length of the needle is under the skin.

**Implant the Pellets**

After inserting the needle fully in the correct implant position, squeeze the trigger fully. As the needle is withdrawn from the ear, the controlled-pressure plunger action properly deposits the implant in the needle track. This procedure should prevent breakage or crushing of pellets if otherwise forced into contact with tough fibrous-tissue underlying the skin. The length and total contact area of a single dose are designed to permit absorption of the hormones after implantation to stimulate good weight gain. Broken or crushed pellets may interfere with rates of gain and may lead to undesirable side effects.

**Clean the Needle**

Clean the implanter needle with alcohol or a properly diluted germicidal solution prior to implanting the next animal.

**Storage Conditions**

Store at controlled room temperature 15° to 30° C (59° to 86° F)  
DO NOT refrigerate – avoid excessive heat and humidity.

NADA 110-315, Approved by FDA

**Manufactured by a non-sterilizing process.**

\*U.S. Patent No. 4,531,938

\*\*U.S. Patent Nos. 4,762,515 & 5,522,797 – Ivy Animal Health, Inc.

COMPONENT and COMPONENT One Gun are registered trademarks of Ivy Animal Health, Inc.

Manufactured for VetLife by Ivy Laboratories.

Overland Park, KS 66214, USA

VetLife and Ivy Laboratories are divisions of Ivy Animal Health, Inc.

Progesterone and estradiol benzoate are naturally occurring hormones found in all cattle. COMPONENT® E-C Implant pellets are made by combining the two chemically pure steroid hormones - progesterone USP 100 mg and estradiol benzoate 10 mg - into one single dose consisting of 4 individual pellets contained within a multi-dose cartridge belt. The formulation has been designed to furnish complementary quantities of each of the two hormones as a means of achieving weight gain. DO NOT USE IN BULL CALVES INTENDED FOR REPRODUCTION OR IN CALVES LESS THAN 45 DAYS OLD. Store at controlled room temperature - 15°-30°C (59°-86°F). DO NOT refrigerate - avoid excessive heat and humidity.

**COMPONENT®**  
BRAND IMPLANTS

**E-C**  
CALF IMPLANTS

with Tylan

progesterone USP 100 mg and estradiol benzoate 10 mg  
with 29 mg tylosin tartrate as a local antibacterial



Indicated for increased rate of weight gain in suckling beef calves up to approximately 400 lbs. of body weight.  
Contents: 5 pellets (entire contents of one cartridge cell) with 29 mg Tylosin Tartrate as a local antibacterial, 100 mg progesterone USP 100 mg and estradiol benzoate 10 mg with 29 mg tylosin tartrate as a local antibacterial.  
Dosage: Administer 1 implant per animal. See package insert for detailed instructions. Do not use in adult calves.  
© Registered by Ivy Animal Health, Inc. NADA 141-315. Approved by FDA.

100 IMPLANTS



Use With Gray  
Component  
One Gun Only

**WARNING: Not to be used in animals intended for subsequent breeding, or in dairy animals. Implant one dose — 5 pellets (entire contents of one cartridge cell) — in the ear subcutaneously. Any other site of implantation is in violation of Federal Law. DO NOT attempt to salvage implantation site for animal feed or human food.**

**A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.**

**RESTRICTED DRUG — USE ONLY AS DIRECTED (CALIFORNIA) — FOR USE IN ANIMALS ONLY — NOT FOR HUMAN USE — KEEP OUT OF REACH OF CHILDREN**

**Caution:** Bulling, rectal prolapse, ventral edema and elevated tail-heads have occasionally been reported in animals implanted with progesterone and estradiol benzoate.

**Important:** Read the enclosed instruction brochure. Use as illustrated with a CAREFUL CLEAN TECHNIQUE. Never take short cuts at the expense of CLEANLINESS.

**Manufactured by a non-sterilizing process.**

COMPONENT E-C with Tylan is covered by U.S. Patent No. 5,874,088  
COMPONENT® E-C implants are safe when used fully in accordance with directions  
COMPONENT is a registered trademark of Ivy Animal Health, Inc.  
Tylan is a registered trademark of Eli Lilly and Company.  
Manufactured for VetLife by Ivy Laboratories • Overland Park, KS 66214, USA  
VetLife and Ivy Laboratories are divisions of Ivy Animal Health, Inc.

01 23 03 02

**COMPONENT®**  
CALF IMPLANTS  
progesterone USP 100 mg  
and estradiol benzoate 10 mg  
with 29 mg tylosin tartrate as a  
local antibacterial

3.125"

181

9.5"

# COMPONENT<sup>®</sup> E-C

BRAND IMPLANTS CALF IMPLANTS

progesterone USP 100 mg and estradiol benzoate 10 mg  
with 29 mg tylosin tartrate as a local antibacterial



**VetLife** TEAR H

Indicated for increased rate of weight gain in suckling beef calves up to approximately 400 lbs. of body weight.

**Contains:** One Cartridge Belt<sup>®</sup> of 20 implants each sealed in a sanitary foil pouch. Each implant contains 3 pellets with a total content of progesterone USP 100 mg and estradiol benzoate 10 mg with 29 mg tylosin tartrate as local antibacterial.

**Dosage:** Administer 1 implant per animal. See package insert for detailed instructions. Do not use in veal calves.

Manufactured by a non-sterilizing process.

\*Patented by Ivy Animal Health, Inc. NADA 110-315, Approved by FDA.



One 20-Dose Cartridge Belt

1/4" Seal Area

18.673

9.375

**WARNING: Not to be used in animals intended for subsequent breeding, or in dairy animals.** Implant one dose — 5 pellets (entire contents of one cartridge cell) — in the ear subcutaneously. Any other site of implantation is in violation of Federal Law. **DO NOT** attempt to salvage implantation site for animal feed or human food.

**A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.**

**RESTRICTED DRUG — USE ONLY AS DIRECTED (CALIFORNIA) — FOR USE IN ANIMALS ONLY —  
NOT FOR HUMAN USE — KEEP OUT OF REACH OF CHILDREN**

**Caution:** Bulling, rectal prolapse, ventral edema and elevated tail-heads have occasionally been reported in animals implanted with progesterone and estradiol benzoate.  
**DO NOT USE IN BULL CALVES INTENDED FOR REPRODUCTION OR IN CALVES LESS THAN 45 DAYS OLD.**

**Store at controlled room temperature** — 15°-30°C (59°-86°F).  
**DO NOT refrigerate** — avoid excessive heat and humidity.

**Important:** Read the enclosed instruction brochure. Use as illustrated with a **CAREFUL CLEAN TECHNIQUE.** Never take short cuts at the expense of **CLEANLINESS.**

**COMPONENT® E-C implants are safe when used fully in accordance with directions.**  
**COMPONENT** is a registered trademark of Ivy Animal Health, Inc.

Tylan is a registered trademark of Eli Lilly and Company.  
Manufactured for **VetLife** by Ivy Laboratories • Overland Park, KS 66214, USA  
VetLife and Ivy Laboratories are divisions of Ivy Animal Health, Inc.  
01 23 02 02

**PURCHASE SEAL 20 IMPLANTS**



EXP

LOT

TEAR HERE

CAUTION: KEEP OUT OF REACH OF CHILDREN

**COMPONENT**  
BRAND IMPLANTS

**VetLife**

**E-C WITH Tylan.**

CALF IMPLANTS

progesterone USP 100 mg and estradiol benzoate 10 mg with 29 mg tylosin tartrate as a local antibacterial

### 20 dose CARTRIDGE BELT\*

For use with COMPONENT One Gun\*\*  
For Use In Animals Only

Each CARTRIDGE BELT holds 20 doses of COMPONENT® E-C with Tylan Implants. Each dose of 5 pellets consists of 4 pellets containing a total of 100 mg progesterone USP and 10 mg estradiol benzoate plus 1 pellet containing 29 mg tylosin tartrate as a local antibacterial. COMPONENT® E-C Implants are indicated for increased rate of weight gain in suckling beef calves up to approximately 400 lbs of body weight.

Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established.

#### DOSAGE:

Administer 1 Implant per animal according to the following instructions.

#### GENERAL INSTRUCTIONS:

Study the instructions which should be followed carefully at all times, avoiding short cuts. Skin infection can be avoided by properly preparing implant site and implanter. During fly season use fly repellent on implant site.

One designated team member should always do the implanting. Cleanliness of hands and instruments is important at all times.

**DO NOT USE IN BULL CALVES INTENDED FOR REPRODUCTION, OR IN CALVES LESS THAN 45 DAYS OLD.**

#### CAUTION:

Bulling, rectal prolapse, ventral edema and elevated tail-heads have occasionally been reported in animals implanted with progesterone and estradiol benzoate.

#### WARNING

Not to be used in animals intended for subsequent breeding, or in dairy animals. Implant one dose — 5 pellets (entire contents of one cartridge cell) — in the ear subcutaneously. Any other site of implantation is in violation of Federal Law. DO NOT attempt to salvage implantation site for animal feed or human food.

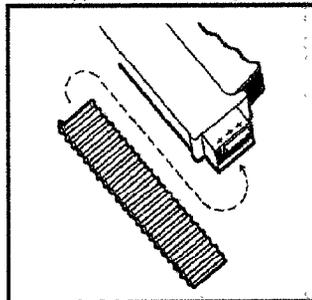
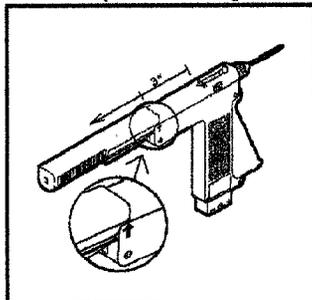
A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

**RESTRICTED DRUG — USE ONLY AS DIRECTED (CALIFORNIA) —  
FOR USE IN ANIMALS ONLY — NOT FOR HUMAN USE —  
KEEP OUT OF REACH OF CHILDREN**

#### IMPLANTING INSTRUCTIONS:

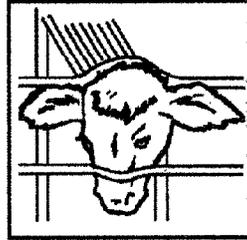
##### Loading the Implanter

Load the implanter following the instructions supplied with each implanter

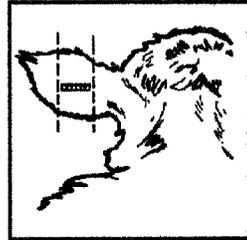


**Restrain the Animal**

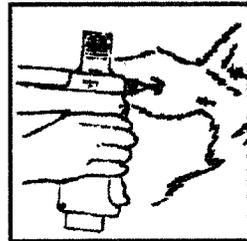
Speed of implantation as well as safety of handlers is best achieved by restraining animal in a squeeze chute using head restraint.

**Prepare the Implant Site**

Scrub the back side of the ear (implant site) with a piece of clean absorbent cotton which has been soaked with topical germicidal solution. Follow manufacturer's directions on germicide for correct strength and preparation of solution. Avoid getting disinfectant in animal's eyes.

**Where to Implant**

The full contents of one cartridge cell should be implanted beneath the skin on the back side of the middle one-third of the ear as illustrated in the drawing. The implant must not be closer to the head than the edge of the auricular cartilage ring farthest from the head. The location for 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. Avoid injuring the large arteries, veins and cartilage of the ear.

**Insert the Needle**

With one hand firmly grasp the ear. With the other hand insert needle point through the skin and ease forward on a lateral plane until the entire length of the needle is under the skin.

**Implant the Pellets**

After inserting the needle fully in the correct implant position, squeeze the trigger fully. As the needle is withdrawn from the ear, the controlled-pressure plunger action properly deposits the implant in the needle track. This procedure should prevent breakage or crushing of pellets if otherwise forced into contact with tough fibrous-tissue underlying the skin. The length and total contact area of a single dose are designed to permit absorption of the hormones after implantation to stimulate good weight gain. Broken or crushed pellets may interfere with rates of gain and may lead to undesirable side effects such as noted in the CAUTION.

**Clean the Needle**

Clean the implanter needle with alcohol or a properly diluted germicidal solution prior to implanting the next animal.

**Storage Conditions**

Store at controlled room temperature 15° to 30° C (59° to 86° F)  
DO NOT refrigerate – avoid excessive heat and humidity.

NADA 110-315, Approved by FDA

**Manufactured by a non-sterilizing process.**

\*U.S. Patent No. 4,531,938

\*\*U.S. Patent Nos. 4,762,515 & 5,522,797 – Ivy Animal Health, Inc.

COMPONENT E-C with Tylan is covered by U.S. Patent No. 5,874,098

COMPONENT and COMPONENT One Gun are registered trademarks of Ivy Animal Health, Inc.

Tylan is a registered trademark of Eli Lilly and Company.

Manufactured for VetLife by Ivy Laboratories.

Overland Park, KS 66214, USA

VetLife and Ivy Laboratories are divisions of Ivy Animal Health, Inc.



3.125"



9.5"

**COMPONENT**  
BRAND IMPLANTS

**E-S**  
progesterone USP 200 mg and  
estradiol benzoate 20 mg  
STEER IMPLANTS



TEAR HERE

COMPONENT E-S Implants are for use in steers weighing 400 lbs. or more. Daily weight gains of up to 3 lbs per animal can be expected in steers implanted with COMPONENT E-S when fed a balanced high energy finishing ration. Maximum benefits of accelerated weight gains and improved feed efficiency will be obtained when implanting high quality animals free of feedlot diseases and parasitism.

**Contains:** One Cartridge Bolt of 20 implants sealed in a sanitary foil pouch.

**Dosage:** Administer 1 implant per animal. See package insert for detailed instructions. Do not use in veal calves.

**Manufactured by a non-sterilizing process**

\*Patented by Ivy Animal Health, Inc.

NADA 115-316, Approved by FDA.

One 20-Dose Cartridge Bolt

1/4" Seal Area

18.8/5"

9.375"

TEAR HERE

**WARNING: Not to be used in animals intended for subsequent breeding, or in dairy animals. Implant one dose — 8 pellets (entire contents of one cartridge cell) — in the ear subcutaneously. Any other site of implantation is in violation of Federal Law. DO NOT attempt to salvage implantation site for animal feed or human food.**

**A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.**

**RESTRICTED DRUG — USE ONLY AS DIRECTED (CALIFORNIA) — FOR USE IN ANIMALS ONLY —  
NOT FOR HUMAN USE — KEEP OUT OF REACH OF CHILDREN**

**CAUTION:** Bulling, rectal prolapse, ventral edema and elevated tail-heads have occasionally been reported in animals implanted with progesterone and estradiol benzoate.

**Important:** Read the enclosed instruction brochure. Use as illustrated with a CAREFUL CLEAN TECHNIQUE. Never take short cuts at the expense of CLEANLINESS.

**Storage Conditions:** Store in a refrigerator (2°-8°C; 36°-46°F) and protect from sunlight. Use before the expiration date.

COMPONENT is a registered trademark of Ivy Animal Health, Inc.

Manufactured for **VetLife** by Ivy Laboratories • Overland Park, KS 66214, USA  
 VetLife and Ivy Laboratories are divisions of Ivy Animal Health, Inc.  
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EXP

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**COMPONENT**<sup>®</sup>  
GRAND IMPLANTS

**VetLife**<sup>®</sup>  
STEER IMPLANTS

**E-S**

progesterone USP 200 mg and  
estradiol benzoate 20 mg

**20 dose CARTRIDGE BELT\***

For use with the COMPONENT One Gun<sup>®\*\*</sup>  
For Use In Animals Only

Each CARTRIDGE BELT holds 20 doses of COMPONENT<sup>®</sup> E-S Implants. Each dose of 8 pellets contains a total of 200 mg progesterone USP and 20 mg estradiol benzoate. COMPONENT<sup>®</sup> E-S Implants are recommended for use in steers weighing 400 lbs or more for INCREASED RATE OF WEIGHT GAIN AND IMPROVED FEED EFFICIENCY.

Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established.

**DOSAGE:** Administer 1 implant per animal according to the following instructions.

**GENERAL INSTRUCTIONS:** Study the instructions which should be followed carefully at all times, avoiding short cuts. Skin infection can be avoided by properly preparing implant site and implanter. During fly season use fly repellent on implant site. One designated team member should always do the implanting. Cleanliness of hands and instruments is important at all times.

**WARNING**

Not to be used in animals intended for subsequent breeding, or in dairy animals. Implant one dose — 8 pellets (entire contents of one cartridge cell) — in the ear subcutaneously. Any other site of implantation is in violation of Federal Law. DO NOT attempt to salvage implantation site for animal feed or human food.

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

**RESTRICTED DRUG — USE ONLY AS DIRECTED (CALIFORNIA) —  
FOR USE IN ANIMALS ONLY — NOT FOR HUMAN USE —  
KEEP OUT OF REACH OF CHILDREN**

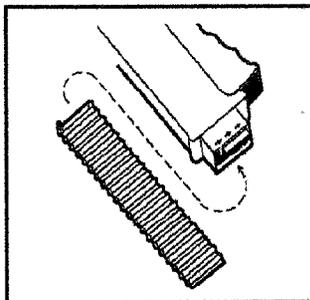
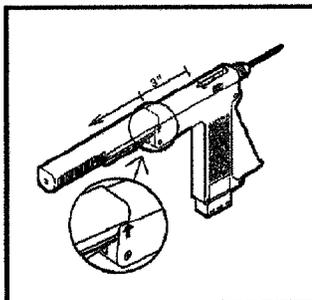
**CAUTION:**

Bulling, rectal prolapse, ventral edema and elevated tail-heads have occasionally been reported in animals implanted with progesterone and estradiol benzoate.

**IMPLANTING INSTRUCTIONS:**

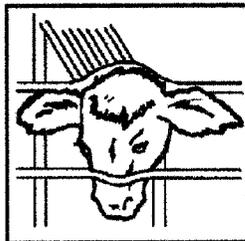
**Loading the Implanter**

Load the implanter following the instructions supplied with each implanter.



#### Restrain the Animal

Speed of implantation as well as safety of handlers is best achieved by restraining animal in a squeeze chute using head restraint. When implanting horned cattle, better control is obtained with additional use of nose tongs.



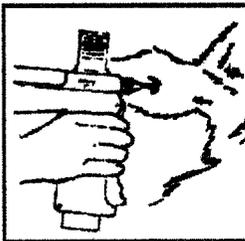
#### Prepare the Implant Site

Scrub the back side of the ear (implant site) with a piece of clean absorbent cotton which has been soaked with topical germicidal solution. Follow manufacturer's directions on germicide for correct strength and preparation of solution. Avoid getting disinfectant in animal's eyes.



#### Where to Implant

The full contents of one cartridge cell should be implanted beneath the skin on the back side of the middle one-third of the ear as illustrated in the drawing. The implant must not be closer to the head than the edge of the auricular cartilage ring farthest from the head. The location for 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. Avoid injuring the large arteries, veins and cartilage of the ear.



#### Insert the Needle

With one hand firmly grasp the ear. With the other hand insert needle point through the skin and ease forward on a lateral plane until the entire length of the needle is under the skin.

#### Implant the Pellets

After inserting the needle fully in the correct implant position squeeze the trigger fully. As the needle is withdrawn from the ear, the controlled-pressure plunger action properly deposits the implant in the needle track. This procedure should prevent breakage or crushing of pellets if otherwise forced into contact with tough fibrous-tissue underlying the skin. The length and total contact area of a single dose are designed to permit absorption of the hormones after implantation to stimulate good weight gain. Broken or crushed pellets may interfere with rates of gain and may lead to undesirable side effects such as noted in the CAUTION.

#### Clean the Needle

Clean the implanter needle with alcohol or a properly diluted germicidal solution prior to implanting the next animal.

#### Storage Conditions

Store in a refrigerator (2°-8°C; 36° to 46° F) and protect from sunlight. Use before the expiration date printed on foil pouch.

Store at controlled room temperature 15° to 30° C (59° to 86° F)

**DO NOT refrigerate** – avoid excessive heat and humidity.

NADA 110-315, Approved by FDA

**Manufactured by a non-sterilizing process.**

\*U.S. Patent No. 4,531,998

\*\*U.S. Patent Nos. 4,762,515 & 5,522,797 – Ivy Animal Health, Inc.

COMPONENT and COMPONENT One Gun are registered trademarks of Ivy Animal Health, Inc.

Manufactured for VetLife by Ivy Laboratories.

Overland Park, KS 66214, USA

VetLife and Ivy Laboratories are divisions of Ivy Animal Health, Inc.

**Important:** Read enclosed instruction brochure and follow directions.

Store at controlled room temperature – 15°-30°C (59°-86°F). **DO NOT refrigerate** – avoid excessive heat and humidity.

# COMPONENT® E-S

BRAND IMPLANTS      STEER IMPLANTS



progesterone USP 200 mg and estradiol benzoate 20 mg  
with 29 mg tylosin tartrate as a local antibacterial



COMPONENT E-S with Tylan is used to control estrus in the female beef cow. Each cartridge contains 9 pellets (entire contents of one cartridge cell) of the implant. Each cartridge contains 9 pellets (entire contents of one cartridge cell) of the implant. Each cartridge contains 9 pellets (entire contents of one cartridge cell) of the implant.

**Contents:** 9 pellets (entire contents of one cartridge cell) with 20 mg progesterone USP 200 mg and estradiol benzoate 20 mg and 29 mg tylosin tartrate as a local antibacterial.

**Dosage:** Administer 1 implant per animal. See package insert for detailed instructions. Do not use in veal calves.

\* Approved by U.S. Animal Health, Inc. NADA 141-316 Approved by FDA

100 IMPLANTS



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Use With Gray  
Component  
One Gun® Only

STEER IMPLANTS

progesterone USP 200 mg  
and estradiol benzoate 20 mg  
with 29 mg tylosin tartrate as a  
local antibacterial

COMPONENT® E-S

**WARNING: Not to be used in animals intended for subsequent breeding, or in dairy animals. Implant one dose — 9 pellets (entire contents of one cartridge cell) — in the ear subcutaneously. Any other site of implantation is in violation of Federal Law. DO NOT attempt to salvage implantation site for animal feed or human food.**

**A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.**

**RESTRICTED DRUG — USE ONLY AS DIRECTED (CALIFORNIA) — FOR USE IN ANIMALS ONLY — NOT FOR HUMAN USE — KEEP OUT OF REACH OF CHILDREN**

**Caution:** Bulling, rectal prolapse, ventral edema and elevated tail-heads have occasionally been reported in animals implanted with progesterone and estradiol benzoate.

**Important:** Read the enclosed instruction brochure. Use as illustrated with a CAREFUL CLEAN TECHNIQUE. Never take short cuts at the expense of CLEANLINESS.

**Manufactured by a non-sterilizing process.**

COMPONENT E-S with Tylan is covered by U.S. Patent No. 5,874,068.  
COMPONENT is a registered trademark of Ivy Animal Health, Inc.  
Tylan is a registered trademark of F. I. Lilly and Company  
Manufactured for VetLife by Ivy Laboratories • Overland Park, KS 66214, USA  
VetLife and Ivy Laboratories are divisions of Ivy Animal Health, Inc.

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3.125"



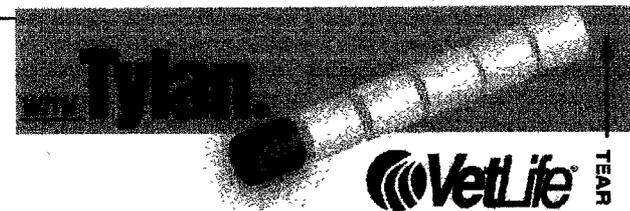
1/4" Seal Area

9.5"

# COMPONENT® E-S

BRAND IMPLANTS STEER IMPLANTS

progesterone USP 200 mg and estradiol benzoate 20 mg  
with 29 mg tylosin tartrate as a local antibacterial



COMPONENT® E-S implants are for use in steers weighing 400 lbs. or more. Daily weight gains of up to 3 lbs. per animal can be expected in steers implanted with COMPONENT® E-S when fed a balanced high energy finishing ration. Maximum benefits of accelerated weight gains and improved feed efficiency will be obtained when implanting high quality animals free of teardrop diseases and parasitism.

Contains: One Cartridge Belt of 20 implants each sealed in a sanitary foil pouch. Each dose contains of progesterone USP 200 mg and estradiol benzoate 20 mg with 29 mg tylosin tartrate as a local antibacterial.

Dosage: Administer 1 implant per animal. See package insert for detailed instructions. Do not use in veal calves.

Manufactured by a non-sterilizing process.

Patented by Ivy Animal Health, Inc. NADA 110-315. Approved by FDA.



One 20-Dose Cartridge Belt

9.375

TEAR HERE

**WARNING: Not to be used in animals intended for subsequent breeding, or in dairy animals.** Implant one dose — 9 pellets (entire contents of one cartridge cell) — in the ear subcutaneously. Any other site of implantation is in violation of Federal Law. DO NOT attempt to salvage implantation site for animal feed or human food.

**A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.**

**RESTRICTED DRUG — USE ONLY AS DIRECTED (CALIFORNIA) — FOR USE IN ANIMALS ONLY —  
NOT FOR HUMAN USE — KEEP OUT OF REACH OF CHILDREN**

**Caution:** Bulling, rectal prolapse, ventral edema and elevated tail-heads have occasionally been reported in animals implanted with progesterone and estradiol benzoate.

**Important:** Read the enclosed Instruction brochure. Use as illustrated with a CAREFUL CLEAN TECHNIQUE. Never take short cuts at the expense of CLEANLINESS.

**Store at controlled room temperature — 15°-30°C (59°-86°F).  
DO NOT refrigerate — avoid excessive heat and humidity.**

COMPONENT is a registered trademark of Ivy Animal Health, Inc.  
Manufactured for VetLife by Ivy Laboratories • Overland Park, KS 66214, USA  
VetLife and Ivy Laboratories are divisions of Ivy Animal Health, Inc.  
01 21 02 02

PURCHASE SEAL 20 IMPLANTS



EXP

LOT

CAUTION: KEEP OUT OF REACH OF CHILDREN

**COMPONENT**  
BRAND IMPLANTS

**VetLife**

# E-S WITH Tylan.

STEER IMPLANTS



progesterone USP 200 mg and  
estradiol benzoate 20 mg with 29 mg tylosin  
tartrate as a local antibacterial

## 20 dose CARTRIDGE BELT

For use with the COMPONENT ONE GUN\*\*  
For Use In Animals Only

Each CARTRIDGE BELT holds 20 doses of COMPONENT® E-S implants. Each dose of 9 pellets consists of 8 pellets containing a total of 200 mg progesterone USP and 20 mg estradiol benzoate plus 1 pellet containing 29 mg tylosin tartrate as a local antibacterial. COMPONENT® E-S Implants are recommended for use in steers weighing 400 lbs or more for INCREASED RATE OF WEIGHT GAIN AND IMPROVED FEED EFFICIENCY.

Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established.

**DOSAGE:** Administer 1 implant per animal according to the following instructions.

**GENERAL INSTRUCTIONS:** Study the instructions which should be followed carefully at all times, avoiding short cuts. Skin infection can be avoided by properly preparing implant site and implanter. During fly season use fly repellent on implant site. One designated team member should always do the implanting. Cleanliness of hands and instruments is important at all times.

### WARNING

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A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

**RESTRICTED DRUG — USE ONLY AS DIRECTED (CALIFORNIA) —  
FOR USE IN ANIMALS ONLY — NOT FOR HUMAN USE —  
KEEP OUT OF REACH OF CHILDREN**

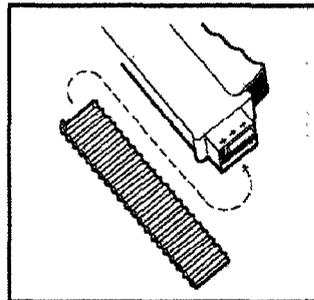
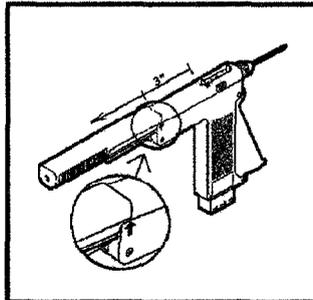
### CAUTION:

Bulling, rectal prolapse, ventral edema and elevated tail-heads have occasionally been reported in animals implanted with progesterone and estradiol benzoate.

### IMPLANTING INSTRUCTIONS:

#### Loading the Implanter

Load the implanter following the instructions supplied with each implanter.



#### Restrain the Animal

Speed of implantation as well as safety of handlers is best achieved by restraining animal in a squeeze chute using head restraint. When implanting horned cattle, better control is obtained with additional use of nose tongs.



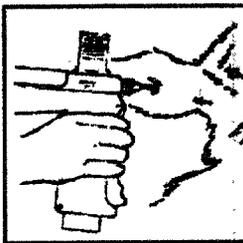
#### Prepare the Implant Site

Scrub the back side of the ear (implant site) with a piece of clean absorbent cotton which has been soaked with topical germicidal solution. Follow manufacturer's directions on germicide for correct strength and preparation of solution. Avoid getting disinfectant in animal's eyes.



#### Where to Implant

The full contents of one cartridge cell should be implanted beneath the skin on the back side of the middle one-third of the ear as illustrated in the drawing. The implant must not be closer to the head than the edge of the auricular cartilage ring farthest from the head. The location for 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. Avoid injuring the large arteries, veins and cartilage of the ear.



#### Insert the Needle

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#### Implant the Pellets

After inserting the needle fully in the correct implant position squeeze the trigger fully. As the needle is withdrawn from the ear, the controlled-pressure plunger action properly deposits the implant in the needle track. This procedure should prevent breakage or crushing of pellets if otherwise forced into contact with tough fibrous-tissue underlying the skin. The length and total contact area of a single dose are designed to permit absorption of the hormones after implantation to stimulate good weight gain. Broken or crushed pellets may interfere with rates of gain and may lead to undesirable side effects such as noted in the CAUTION.

#### Clean the Needle

Clean the implanter needle with alcohol or a properly diluted germicidal solution prior to implanting the next animal.

#### Storage Conditions

Store at controlled room temperature 15° to 30° C (59° to 86° F)  
**DO NOT refrigerate** – avoid excessive heat and humidity.

NADA 110-315, Approved by FDA

**Manufactured by a non-sterilizing process.**

\*U.S. Patent No. 4,531,938

\*\*U.S. Patent Nos. 4,762,515 & 5,522,797 – Ivy Animal Health, Inc.

COMPONENT E-S with Tylan is covered by U.S. Patent No. 5,874,098

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