Zero Defect Implanting* Critical Control Points

CRITICAL CONTROL POINT #1

Sanitation

Site of implantation

- · Classify ears as clean or dirty.
- Clean and dry ear: Cleaning optional; follow procedure below, if desired.
- Dirty ear: Using a brush in clean antiseptic solution, make two to three brush strokes in one direction at implantation site.

Implanting equipment

- Implanting gun should be cleaned prior to use. Wash the exterior of the gun and flush water through the front gun magazine. Allow the gun to dry thoroughly before use. Do not use disinfectant solution to clean the gun.
- Periodically check implant needle integrity. Replace needles that develop a blunt burr.
- Implants should be stored in a clean container.
- Place diluted disinfectant solution in a disinfecting tray with a clean sponge.
- Disinfect the needle between each animal by wiping across the sponge on each side of the needle to remove hair and contaminants.
- Operator should wear latex gloves.

Work area

• Work area should be kept clean, and supplies should be arranged in an orderly fashion.





CRITICAL CONTROL POINT #2

Operator training

- Operator must be trained on proper operation and techniques used with the various implanting devices.
- Implanting must be restricted to operators who have been given sufficient time to build skill level in the implanting procedure.
- Back-up implanting operator should be available.



CRITICAL CONTROL POINT #3

Implanting procedure

- Step 1: Clean and prepare implant site according to procedure outlined above.
- Step 2: Insert the needle at the outer third of ear.
- Step 3: Insert needle between the skin and cartilage. Avoid digging into cartilage.
- Step 4: Deposit implant in the middle third of the ear and withdraw needle.
- Step 5: Check implant by running thumb over site. Check implant site to ensure implant is in the correct position of the ear and that the pellets are in a straight line.



CRITICAL CONTROL POINT #4

Implant quality control verification

- Two to three weeks after processing, check ears for defects in a random sample.
- Conduct regular chute-side evaluations during implanting.
- Review results with implanting personnel.
- Implement an ongoing training program for new personnel.

See label for complete use guidelines, including all cautions and warnings. Always read, understand and

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

For more information about Elanco products, visit https://farmanimal.elanco.com/us/beef. *Critical control point implant training does not guarantee zero defects.

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follow the label and use directions.



(progesterone and estradiol benzoate and tylosin tartrate implants)

Each implant consists of 100 mg progesterone USP and 10 mg estradiol benzoate and 29 mg tylosin tartrate

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

IMPLANTS FOR BEEF CALVES 45 DAYS OF AGE AND OLDER AND WEIGHING UP TO 400 LBS

Use with a Component Implanter

DESCRIPTION: Each cartridge belt holds 20 doses of Component E-C with Tylan (progesterone and estradiol benzoate and tylosin tartrate implant) 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.

INDICATIONS FOR USE: For increased rate of weight gain in beef calves 45 days of age and older and weighing up to 400 lbs.

This implant is not approved for repeated implantation (reimplantation) with this or any other cattle ear implant as safety and effectiveness has not been evaluated.

Do not use in calves less than 45 days of age or veal calves because effectiveness and safety have not been evaluated.

Do not use in animals intended for subsequent breeding, or in dairy cows.

DIRECTIONS: Administer 1 implant - the entire contents of one cartridge cell (5 pellets) - subcutaneously in the back of the middle third of the ear. Study and carefully follow at all times the "IMPLANTING INSTRUCTIONS" presented below, 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.

Withdrawal Periods and Residue Warnings

No withdrawal period is required when used according to labeling.

Do not use in beef calves less than 45 days of age, dairy calves, and veal calves. Do not use in bull calves intended for reproduction. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. Implant pellets subcutaneously in ear only. Any other location is a violation of Federal law. Do not attempt salvage of implanted site for human or animal food.

USER SAFETY WARNINGS: Not for use in humans.

Keep out of reach of children.

Restricted Drug (California) - Use Only as Directed

ANIMAL SAFETY WARNINGS: Bulling has occasionally been reported in implanted steers and heifers. Vaginal and rectal prolapse, udder development, ventral edema and elevated tailheads have occasionally been reported in heifers administered Component E-C with Tylan Implants.

WARNINGS: This product is intended for use in cattle at high risk of developing ear abscesses. Not recommended for use in cattle at low risk of developing ear abscesses (e.g., dry, clean cattle).

The benefit of using a cattle ear implant containing a tylosin tartrate pellet when animals receive a concomitant antimicrobial product has not been evaluated.

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 or brush 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.

This 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 lead to undesirable side effects such as bulling, rectal and vaginal prolapse, etc., as noted in the WARNINGS.

STORAGE CONDITIONS: Store at controlled room temperature 15° to 30°C (59° to 86°F) DO NOT refrigerate – avoid excessive heat and humidity. Discard open foil pouches.

Approved by FDA under NADA # 110-315

Manufactured by a non-sterilizing process.

Component E-C with Tylan (progesterone and estradiol benzoate and tylosin tartrate implants) is covered by U.S. Patent No. 5,874,098

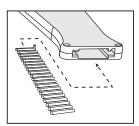
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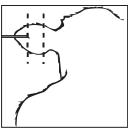
Tylosin: Product of United Kingdom

Revised: June 2023











FOR GROWING BEEF STEERS AND HEIFERS ON PASTURE (Stocker, Feeder, and Slaughter)

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

20 dose Cartridge Belt

Use with a Component Implanter DESCRIPTION:

Each cartridge belt holds 20 doses of Component TE-G with Tylan (trenbolone acetate and estradiol and tylosin tartrate implant) Implants. Each dose of 3 pellets consists of 2 pellets containing a total of 40 mg of trenbolone acetate and

8 mg estradiol plus 1 pellet containing 29 mg tylosin tartrate as a local antibacterial.

INDICATIONS FOR USE:

For increased rate of weight gain in growing beef steers and heifers on pasture (stocker, feeder, and slaughter).

Not approved for repeated implantation (re-implantation) with this or any other cattle ear implant in growing beef steers and heifers on pasture (stocker, feeder, and slaughter). Safety and effectiveness following re-implantation have not

been evaluated.

Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because effectiveness and safety have not been established. Do not use in animals intended for subsequent breeding, or in dairy cows.

WARNING:

This product is intended for use in cattle at high risk of developing ear abscesses. Not recommended for use in cattle at low risk of developing ear abscesses (e.g., dry, clean cattle).

The benefit of using a cattle ear implant containing a tylosin tartrate pellet when animals receive a concomitant antimicrobial product has not been evaluated.

Withdrawal Periods and Residue Warnings

No withdrawal period is required when used according to labeling.

Do not use in beef calves less than 2 months of age,
dairy calves, and veal calves. A withdrawal period has not
been established for this product in pre-ruminating calves.
Do not use in dairy cows or in animals intended for
subsequent breeding. Use in these cattle may cause drug
residues in milk and/or calves born to these cows.
Implant pellets subcutaneously in ear only. Any other location
is a violation of Federal law. Do not attempt salvage of
implanted site for human or animal food.

USER SAFETY WARNINGS:

Not for human use. Keep out of reach of children.

Restricted Drug (California) - use only as directed.

IMPLANTING INSTRUCTIONS: Loading the Implanter

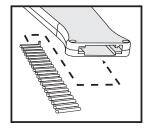
Load the implanter following the instructions supplied with each implanter.

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 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 position, squeeze the trigger

fully as the needle is withdrawn from the ear. This 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 the 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.

Storage Conditions

Store unopened product at or below 25°C (77°F). Avoid excessive heat and humidity.

Use before the expiration date printed on foil pouch. Discard open foil

Approved by FDA under ANADA # 200-221

Manufactured by a non-sterilizing process.

Component TE-G with Tylan is covered by U.S. Patent No. 5,874,098

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Tylosin: Product of the United Kingdom

QUESTIONS/COMMENTS? For a copy of the Safety Data Sheet or to report side effects, contact Elanco US, Inc. at 1-888-545-5973. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.







FOR GROWING BEEF HEIFERS FED IN **CONFINEMENT FOR SLAUGHTER**

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

20-dose Cartridge Belt

Use with a Component Implanter

DESCRIPTION: Each cartridge belt holds 20 doses of Component TE-IH with Tylan (trenbolone acetate and estradiol and tylosin tartrate implant) Implants. Each dose of 5 pellets consists of 4 pellets containing a total of 80 mg of trenbolone acetate and 8 mg estradiol plus 1 pellet containing 29 mg tylosin tartrate as a local antibacterial.

INDICATIONS FOR USE: For increased rate of weight gain and improved feed efficiency in growing beef heifers fed in confinement for slaughter.

Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant in growing beef heifers fed in confinement for slaughter. Safety and effectiveness following re-implantation have not been evaluated.

Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because effectiveness and safety have not been established.

Do not use in animals intended for subsequent breeding, or in dairy cows.

NOTE: Studies have demonstrated that administration of Component TE-IH can result in decreased marbling scores when compared to non-implanted heifers.

WARNING: This product is intended for use in cattle at high risk of developing ear abscesses. Not recommended for use in cattle at low risk of developing ear abscesses (e.g., dry, clean cattle).

The benefit of using a cattle ear implant containing a tylosin tartrate pellet when animals receive a concomitant antimicrobial product has not been evaluated.

Withdrawal Periods and Residue Warnings

No withdrawal period is required when used according to labeling. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.

Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or calves born to these cows. Implant pellets subcutaneously in ear only. Any other location is a violation of Federal law. Do not attempt salvage of implanted site for human or animal food.

USER SAFETY WARNINGS

Not for use in humans. Keep out of reach of children.

Restricted Drug (California) - use only as directed.

IMPLANTING INSTRUCTIONS: Loading the Implanter

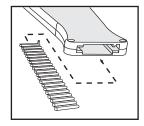
Load the implanter following the instructions supplied with each implanter.

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 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 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 position, squeeze the trigger fully as the needle

is withdrawn from the ear. This 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.

Storage Conditions

Store unopened product at or below 25°C (77°F).

Avoid excessive heat and humidity.

Use before the expiration date printed on the foil pouch.

Discard open foil pouches.

Approved by FDA under ANADA # 200-346

Manufactured by a non-sterilizing process.

Component TE-IH with Tylan (trenbolone acetate and estradiol and tylosin tartrate implants) is covered by U.S. Patent No. 5,874,098

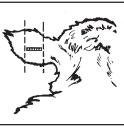
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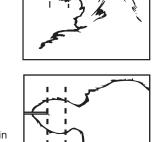
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Tylosin: Product of the United Kingdom

QUESTIONS/COMMENTS? For a copy of the Safety Data Sheet or to report side effects, contact Elanco US, Inc. at 1-888-545-5973. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.







FOR GROWING BEEF STEERS FED IN CONFINEMENT FOR SLAUGHTER

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

20-dose Cartridge Belt

Use with a Component Implanter

DESCRIPTION: Each cartridge belt holds 20 doses of Component TE-IS with Tylan (trenbolone acetate and estradiol and tylosin tartrate implant) Implants. Each dose of 5 pellets consists of 4 pellets containing a total of 80 mg of trenbolone acetate and 16 mg estradiol plus 1 pellet containing 29 mg tylosin tartrate as a local antibacterial.

INDICATIONS FOR USE: For increased rate of weight gain and improved feed efficiency in growing beef steers fed in confinement for slaughter.

Not approved for repeated implantation (re-implantation) with this or any other cattle ear implant in growing beef steers fed in confinement for slaughter.

Safety and effectiveness following re-implantation have not been evaluated.

Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because effectiveness and safety have not been established.

Do not use in animals intended for subsequent breeding, or in dairy cows.

WARNING:

This product is intended for use in cattle at high risk of developing ear abscesses. Not recommended for use in cattle at low risk of developing ear abscesses (e.g., dry, clean cattle).

The benefit of using a cattle ear implant containing a tylosin tartrate pellet when animals receive a concomitant antimicrobial product has not been evaluated.

Withdrawal Periods and Residue Warnings

No withdrawal period is required when used according to labeling.

Do not use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.

Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or calves born to these cows.

Implant pellets subcutaneously in ear only. Any other location is a violation of Federal law. Do not attempt salvage of implanted site for human or animal food.

USER SAFETY WARNINGS

Not for human use. Keep out of reach of children.

Restricted Drug (California) - use only as directed.

IMPLANTING INSTRUCTIONS:

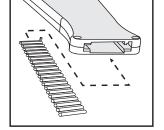
Loading the Implanter

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 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 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. This 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.



Store unopened product at or below 25°C (77°F). Avoid excessive heat and humidity.

Use before the expiration date printed on the foil pouch. Discard open foil pouches.

Approved by FDA under ANADA # 200-221

Manufactured by a non-sterilizing process.

Component TE-IS with Tylan is covered by U.S. Patent No. 5,874,098

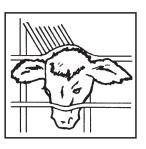
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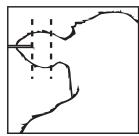
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Tylosin: Product of the United Kingdom

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FOR GROWING BEEF STEERS AND HEIFERS FED IN CONFINEMENT FOR SLAUGHTER

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

20 dose Cartridge Belt

Use with a Component Implanter

DESCRIPTION: Each cartridge belt holds 20 doses of Component TE-200 with Tylan (trenbolone acetate and estradiol and tylosin tartrate implant) Implants. Each dose of 11 pellets consists of 10 pellets containing a total of 200 mg of trenbolone acetate and 20 mg estradiol plus 1 pellet containing 29 mg tylosin tartrate as a local antibacterial.

INDICATIONS FOR USE: For increased rate of weight gain and improved feed efficiency in growing beef steers and heifers fed in confinement for slaughter.

Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant in growing beef steers and heifers fed in confinement for slaughter.

Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because effectiveness and safety have not been evaluated.

Do not use in animals intended for subsequent breeding, or in dairy cows.

WARNING: This product is intended for use in cattle at high risk of developing ear abscesses. Not recommended for use in cattle at low risk of developing ear abscesses (e.g., dry, clean cattle).

The benefit of using a cattle ear implant containing a tylosin tartrate pellet when animals receive a concomitant antimicrobial product has not been evaluated.

Withdrawal Periods and Residue Warnings

No withdrawal period is required when used according to labeling.

Do not use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.

Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or calves born to these cows.

Implant pellets subcutaneously in ear only. Any other location is a violation of Federal law. Do not attempt salvage of implanted site for human or animal food.

USER SAFETY WARNINGS

Not for human use. Keep out of reach of children.

Restricted Drug (California) - use only as directed.

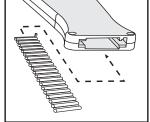
IMPLANTING INSTRUCTIONS:

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 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 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. This 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.



Store unopened product at or below 25°C (77°F). Avoid excessive heat and humidity.

Use before the expiration date printed on the foil pouch. Discard open foil pouches.

Approved by FDA under ANADA # 200-346

Manufactured by a non-sterilizing process.

Component TE-200 with Tylan (trenbolone acetate and estradiol and tylosin tartrate implants) is covered by U.S. Patent No. 5,874,098

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