# CATRIX® WOUND DRESSING
# CARTILAGE POWDER

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## Description

CATRIX® Wound Dressing cartilage powder is a collagen based product containing approximately 73% protein, 18% carbohydrates, and 9% other cartilage components. The particles are composed of collagen macro-molecules arranged naturally in a three-dimensional network of macro-molecular chains of cross-linked collagen, which is large enough to allow substances with a molecular weight of less than 1,000 to freely enter. Substances with a molecular weight of 1,000 to 5,000 enter the particles less freely, while those substances with larger molecular weights remain in the interspaces between the particles.

CATRIX® Wound Dressing is produced to have an average particle size of approximately 35 microns.

## Indications for Use

CATRIX® Wound Dressing cartilage powder is a collagen based powder intended for use in the management of decubitus ulcers (stages I - IV), stasis ulcers, 1st and 2nd degree burns, diabetic ulcers, foot ulcers, post surgical incisions, radiation dermatitis, cuts, lesions with partial loss of substance and abrasions, irritations of the skin, partial thickness wounds and skin conditions associated with peristomal care.

CATRIX® Wound Dressing has also been shown to be useful for wound exudate absorption.

## Precautions

- This wound dressing should not be used on patients with a documented adverse reaction to bovine products.

- Consult a physician, if the treated condition worsens or does not improve within 10-14 days.

- Treatment of any underlying condition (venous or arterial flow, pressure, diabetes, post surgical care, etc.) should proceed concurrently with the use of CATRIX® Wound Dressing.

- Keep this and all similar products out of the reach of children.
- For external use only.
- Avoid contact with eyes.

**Instructions for Use**

- Debride and clean the lesion in the usual manner.
- Treat with medication, if needed.
- Apply CATRIX® Wound Dressing in an even manner to a thickness of at least 1/8 inch.
- Apply an appropriate dressing (gauze, hydrocolloid, etc.) in order to maintain a moist wound environment.
- Can be applied daily and no less than three times per week and/or with each change of dressing.
- For reapplication, clean the wound in the usual manner, debride if needed, reapply CATRIX® Wound Dressing as directed above.
- Discontinue application when complete wound closure is achieved.

**Instructions for use for hard to reach areas**

Prepare a mixture of CATRIX® Wound Dressing with glycerin (2 - 5 cc) or normal saline (4 - 10 cc) to achieve desired consistency. Apply paste directly to wound to a layer of 1/8" thick paste or apply paste-covered dressing directly to wound. Wounds may also be packed with paste as needed.

**Adverse Reactions**

Sensitivity to CATRIX® Wound Dressing is infrequent. If a reaction is observed, discontinue use and consult a physician.

**How Supplied**

- CATRIX® Wound Dressing is supplied in sterile foil pouches containing 1 gram.
- CATRIX® Wound Dressing is supplied in shelf boxes of 3, 7, or 14 pouches each.
- For external use only.
- Avoid contact with eyes.
- Store in a dry place below 85° F.

## Characteristics

Each gram of wound dressing powder can absorb approximately 3-4 ml of fluid, due to its hydrophilic characteristics. Its other wound healing properties are derived from an average 35 micron particle size, combined with the material's biocompatibility and biodegradation characteristics.

1. Particle Size

The average 35 micron particle size is based upon the tensile strength study of healing wounds by Prudden (1964). In a search for the best cartilage preparation for stimulating repair of wounds, Prudden evaluated the wound tensile strength following a single 2 mg/cm$^2$ topical application of cartilage powder from different animal species, animal age (fetal, calf, and adult) and particle sizes (20 microns, 50 microns and 70 microns). The results showed that after seven days of healing, calf bovine cartilage powder caused greater increases in mean tensile strength as compared to adult bovine cartilage powder. The investigator also showed that calf bovine cartilage powder with a particle size of 20 microns resulted in greater tensile strength as compared to calf bovine cartilage powder with a particle size of 70 microns (Table 1).

**Table 1**
**Wound Healing Produced by Cartilage Preparations. (Prudden, 1964)**

| | |
|---|---|
| **Type of Cartilage Tested**: | calf tracheal cartilage; fetal cartilage; adult bovine cartilage |
| **Species**: | albino Sherman strain rat, female |
| **Route**: | topical at the wound |
| **Dosing Frequency**: | single atomized application 2 mg/cm$^2$ at wound closure |
| **Treatment**: | paired animals of treatment with control |
| **Parameters Evaluated**: | wound tensile strength measured in mm Hg at the seventh post-operative day |

**Results**:

| Treatment Groups (size) (n = pairs) | % ↑ over control | Tensile Strength (p value)** |
|---|---|---|
| calf cartilage (70 micron) vs. control (48) | 30 | << 0.001* |
| fetal cartilage (70 micron) vs. control (36) | 19.7 | < 0.001* |
| adult bovine cartilage (50 micron) vs. control (30) | 22.2 | < 0.001* |
| calf cartilage (20 micron) vs. control (20) | 52.5 | <<< 0.001* |

* statistically different from the control
** as compared to standard treatment with 70 micron adult bovine cartilage preparation

**Comments**:

- Combining the favorable qualities of small particle size (less than 45 micron and an average diameter of approximately 20 micron) with those of a young animal source, we have been able to achieve a better than 50% increase in tensile strength at the seventh post-operative day.

- It is possible to potentiate the effect of cartilage powder by variation of the donor animal's nature and/or age or by a change in the physical status of the powder itself.

## 2. Biodegradation Characteristics

The biodegradation characteristics of cartilage powder were obtained from the results of a study performed by Food and Drug Research Labs, Ltd. in 1970. The results from this study are summarized below (Table 2).

A 20% suspension of cartilage powder was prepared in sterile saline and implanted into skeletal muscle on the ventral side of New Zealand albino rabbits. A histologic examination of the muscle specimens was performed at different time intervals during the two month study. The biodegradation of the cartilage preparation was demonstrated by its rapid disappearance from the tissue site within one week of the application.

Histologically, cartilage can be identified as islands of basophilic material in which there are orifices. This material is associated with a few adjacent degenerating muscle fibers, a moderate infiltration by mononuclear cells, including many macrophages, and the initiation of a mild proliferation of fibroblasts.

**Table 2**

Biodegradation of Cartilage Implanted into the Skeletal Muscle of Rabbits.

(Food & Drug Research Laboratories, 1970)

**Test Material**: egg shells with attendant membranes; calcium citrate powder; calf cartilage powder: a 20% suspension of each material was prepared in sterile saline

**Route**: three trochar implants through the fascia into the spinalis and longissimus muscles on either side of a ventral midline incision

**Dosing Frequency**: single application

**Treatment**: six implants of test material were made per animal (10 per group) & control animals received the vehicle by itself, sterile saline

**Parameters Evaluated**: gross pathology and histopathology at weeks 1, 2, 3, 4, & 8

**Results**: (treatment group of calf cartilage only)

| Parameter Evaluated | Results |
|---|---|
| gross pathology | •Implants were not visible at the end of 1 week. |
| histopathology | •Readily identified as islands of basophilic material in which there are orifices.<br><br>•Associated with few adjacent degenerating muscle fibers, a moderate infiltration by mononuclear cells, including many macrophages, and the initiation of a mild proliferation of fibroblasts.<br><br>•Identified by its irregular calcareous outlines and this initiates localized limited degenerative changes in muscle with mild mononuclear cell infiltration and slight fibrosis. |

**Comments**:

- Biodegradation of the test material, cartilage, is clearly demonstrated.
- The rate of biodegradation cannot be precisely compared because of wide range of particle size initially implanted and variation in distribution of injection sites on microscopic slides examined.

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