



RTMPLUG, RTMTAPE and RTMFOAM
Absorbable Dental Wound Dressings

INSTRUCTIONS FOR USE

Description:

CYTOPLAST® RTMPLUG, RTMTAPE and RTMFOAM are absorbent porous collagen matrices engineered from purified collagen derived from bovine dermis tissue. CYTOPLAST® RTMPLUG, RTMTAPE and RTMFOAM are applied directly to the wound and protect the wound bed and delicate new tissue. CYTOPLAST® RTMPLUG, RTMTAPE and RTMFOAM can be removed, replaced or left *in situ*. If left *in situ* the dressings will be essentially resorbed in 30 days.

CYTOPLAST® RTMPLUG, RTMTAPE and RTMFOAM are available in tape, foam and plug form, and are supplied sterile, non-pyrogenic and for single use only.

Indications and Usage

CYTOPLAST® RTMPLUG, RTMTAPE and RTMFOAM are indicated for the management of oral wounds and sores, including:

- Denture sores
- Oral ulcers (non-infected or viral)
- Periodontal surgical wounds
- Suture sites
- Burns
- Extraction sites
- Surgical wounds
- Traumatic wounds

Contraindications

This product is not indicated for patients with a known allergy to bovine-derived collagen materials.

Large tissue defects should not be filled with several layers of CYTOPLAST® RTMPLUG, RTMTAPE and RTMFOAM.

Warning

CYTOPLAST® RTMPLUG, RTMTAPE and RTMFOAM are not intended for use as a bone void filler or bone grafting material.

Product Application

The wound should be rinsed and excess fluid removed. CYTOPLAST® RTMPLUG, RTMTAPE and RTMFOAM should be applied over the wound and held in place until adherence has been achieved. At the end of the procedure, CYTOPLAST® RTMPLUG, RTMTAPE and RTMFOAM can be removed, replaced or left *in situ*.

Precautions

CYTOPLAST® RTMPLUG, RTMTAPE and RTMFOAM should not be used on infected or contaminated wounds.

Discontinue the use of CYTOPLAST® RTMPLUG, RTMTAPE and RTMFOAM and notify your doctor if excessive redness, pain, swelling or blistering occurs.

CYTOPLAST® RTMPLUG, RTMTAPE and RTMFOAM may be replaced if it falls off the wound prematurely. Replacement after premature removal of the CYTOPLAST® RTMPLUG, RTMTAPE and RTMFOAM is at the clinician's discretion.

CYTOPLAST® RTMPLUG, RTMTAPE and RTMFOAM have not been evaluated in pregnant women or children.

CYTOPLAST® RTMPLUG, RTMTAPE and RTMFOAM cannot be

re-sterilized or re-used. Open, unused CYTOPLAST® RTMPLUG, RTMTAPE and RTMFOAM must be discarded. *In vivo* stability may be adversely affected if re-sterilized. Cross-contamination and infection may occur if re-used.

Do not use if the product sterilization barrier or its packaging is compromised.

Adverse Reactions:

Hypersensitivity reactions have been noted with the use of other products containing collagen.

Storage:

The product should be stored at room temperature (15°C/59°F to 30°C/86°F). Avoid excessive heat and humidity.

How Supplied:

The dressings are supplied sterile and for single use only. They are available in a variety of shapes and sizes.

Individually packaged, ten (10) units per box:

Catalog Number	Size
RTMPLUG10	1 cm x 2 cm
RTMTAPE10	2.5 cm x 7.5 cm
RTMFOAM10	2 cm x 4 cm

Caution:

Federal (USA) law restricts this device to sale by or on the order of a physician or dentist.

Labeling Symbols:

Symbols may be used on some international package labeling for easy identification.



Caution, see instructions for use



Use by



Do not reuse



Lot number



Sterilized using irradiation



Temperature Limit



Catalog Number



Federal (USA) law restricts this device to sale by or on the order of a physician or dentist



Manufacturer



Do not use if the product sterilization barrier or its packaging is compromised.



Quantity

Manufacturer:

Collagen Matrix, Inc.
15 Thornton Road
Oakland, New Jersey 07436 USA

Distributed by:

Osteogenics Biomedical Inc.
4620 71st Street, Bldg 78-79
Lubbock, TX 79424 USA
www.osteogenics.com
Phone 888-796-1923