

# TheraForm™

## PRODUCT INSERT



Regrow®

• STANDARD

• SHEET

• BILAYER

• DENTAL

To order please contact: **1800-209-0309**

# TheraForm™ Standard / Sheet

## Absorbable Collagen Membrane



### Description

TheraForm™ Standard / Sheet Absorbable Collagen Membrane is a sterile, pliable surgical porous wound dressing made of highly purified collagen derived from porcine skin. TheraForm™ Standard / Sheet are completely absorbable and highly biocompatible.

#### 1) TheraForm™ Standard

- Square shaped porous collagen sponge (thick)

#### 2) TheraForm™ Sheet

- Square shaped porous collagen sponge (thin)

### Indications

TheraForm™ Standard / Sheet is intended for the management of wounds including:

- Partial and full-thickness wounds
- Pressure ulcers
- Venous ulcers
- Diabetic ulcers
- Chronic ulcers
- Surgical wounds (donor sites / grafts, post-laser surgery, podiatric, wound dehiscence)
- Trauma wounds (abrasions, lacerations, second-degree burns, and skin tears)
- Draining wounds

### How to use

TheraForm™ Standard / Sheet is packaged in a sterile blister tray. The general principles of sterile handling and basic surgical procedures should be followed when using TheraForm™ Standard/Sheet.

- Treat infection area and debride the wound before application of TheraForm™ Standard / Sheet.
- Trim TheraForm™ Standard / Sheet by scissors according to the exposed defect.
- Place TheraForm™ Standard / Sheet in either dry or wet state. If the wet collagen membrane is prepared, hydrate TheraForm™ Standard / Sheet in room temperature with sterile water or saline prior to placement, apply pressure with gloved fingers to facilitate wetting and keep it in the sterile water/ saline until application.
- Apply non-adhesive dressing as a primary dressing on the TheraForm™ Standard / Sheet.
- If necessary, split-thickness skin graft transplantation should be done

#### Packaging: 1 each/ 1 box

PRODUCTS	SIZE (mm)		REMARK
	DEPTH	WIDE	
Theraform™ Standard	40	30	Allowable dimension: ±10%
	70	50	
	100	100	
Theraform™ Sheet	40	30	
	70	50	
	100	100	

### Post operative care

- Change the outer dressing as needed. It will depend upon volume of exudate and type of dressing and clinician's choice.
- Observe hematoma or excess exudates when changing the dressing and keep the site clean by clinician

### Contraindications

- TheraForm™ Standard / Sheet should not use in patients who have hypersensitive or allergic reactions to porcine collagen.
- TheraForm™ Standard / Sheet should not be placed where active infection or contaminated wound.

### Warning

- If the following abnormal symptoms occur, patients should be instructed to the clinician immediately, and the TheraForm™ Standard / Sheet should be removed by the clinician. ; Infection, severe pain, inflammation, severe hemorrhage and allergic reactions.

### Precautions

- Do not re-sterilize. Discard all opened and unused TheraForm™ Standard / Sheet.
- Do not use if the package or product is damaged.
- The safety and effectiveness of TheraForm™ Standard / Sheet have not been assessed in pregnant women or children.
- Like any other surgical procedures, cautions should be taken closely to the patients who are receiving long-term steroid or anti-coagulant therapy.
- Do not use until excessive exudate, acute swelling, and infection is controlled.
- Hot/warm saline damages collagen. If hydration in warm/hot saline is suspected, do not use it.

### Adverse Reactions

Although TheraForm™ Standard / Sheet is made of Atelocollagen™, allergic reactions may not be completely excluded. However, the following side effects may be caused due to the surgical procedures; dehiscence, hematoma, redness, inflammation, increased sensitivity and pain.

### Storage

Store at room temperature and avoid excessive heat and humidity

Symbols used on labeling			
	Do not reuse		See instructions for use
	Catalogue number		Lot number
	Expiration date		Method of sterilization – Gamma radiation
	Date of Manufacture		EC Representative
	Federal (USA) law restricts this device to sale by or on the order of a physician.		Manufacturer

# TheraForm™ Bilayer

## Absorbable Collagen Membrane



### Description

TheraForm™ Bilayer Absorbable Collagen Membrane is a sterile, pliable surgical porous scaffold agent made of highly purified collagen derived from porcine skin. TheraForm™ Bilayer is completely absorbable (with the exclusion of silicone layer) and highly biocompatible. The silicone layer helps maintaining moist environment; increases tear strength and provide a flexible adherent covering for the wound surface.

- Square shaped porous collagen sponge with silicone layer

### Indications

TheraForm™ Bilayer is intended for the management of wounds including:

- Partial and full-thickness wounds
- Pressure ulcers
- Venous ulcers
- Diabetic ulcers
- Chronic ulcers
- Surgical wounds (donor sites / grafts, post-laser surgery, podiatric, wound dehiscence)
- Trauma wounds (abrasions, lacerations, second-degree burns, and skin tears)
- Draining wounds

### How to use

TheraForm™ Bilayer is packaged in a sterile blister tray. The general principles of sterile handling and basic surgical procedures should be followed when using TheraForm™ Bilayer.

#### Application

1. Debride the wound before application of TheraForm™ Bilayer.
2. Trim TheraForm™ Bilayer with scissors according to the exposed defect.
3. Place TheraForm™ Bilayer in either a dry or wet state.
4. If a wet atelocollagen membrane is needed, hydrate TheraForm™ Bilayer at room temperature in sterile water or saline and keep the Theraform™ Bilayer in the sterile water/saline until it is applied.
5. Slightly squeeze the hydrated TheraForm™ Bilayer with gloved fingers before applying it.
6. Apply the Theraform™ Bilayer directly to the wound and be sure there is contact between the atelocollagen layer and the prepared wound and place the silicon layer to the outside.
7. Apply a non-adhesive dressing as an outer dressing over the TheraForm™.
8. TheraForm™ Bilayer should not be removed as it will eventually be completely absorbed.

#### Removal and Post-Application

- If edges are loose before full healing has occurred, the silicone can be trimmed away from the loose areas until entire wound has healed.
- Remove the silicone layer of the TheraForm™ Bilayer when the tissue underneath is healed, typically 7 to 14 days.
- Remove by starting at one corner and pull gently. The silicone layer will peel off healed tissue relatively easily.

- If bleeding occurs, or if patient complains of excessive pain, stop and wait 1 to 2 additional days. Forced removal may result in wound reinjury.

### Post operative care

- Change the outer dressing as needed. This will depend on the volume of exudates, the type of wound dressing, and the clinician's choice.
- The clinician should properly treat a hematoma or excess exudates when changing the dressing and should keep the site clean.
- If necessary, split-thickness skin graft transplantation should be performed.

### Contraindications

- TheraForm™ Bilayer should not be used in patients who are hypersensitive to or who may have allergic reactions to porcine collagen.
- TheraForm™ Bilayer should not be placed where there is active infection or in a contaminated wound.

### Warning

- If the following abnormal symptoms occur, patients should be instructed to immediately contact the clinician and the TheraForm™ Bilayer should be removed by the clinician. These symptoms include infection, severe pain, inflammation, severe hemorrhage, rash, hives or any allergic reaction.
- Do not touch the material.

### Precautions

- Do not resterilize. Discard any opened or unused TheraForm™ Bilayer.
- Do not use if the package or product is damaged.
- The safety and effectiveness of the TheraForm™ Bilayer have not been assessed in pregnant women or in children.
- As with any other surgical procedure, caution should be taken when using in patients who are receiving long-term steroid or anti-coagulant therapy.
- Do not use until excessive exudate, acute swelling, and infection are controlled. If hematoma or exudate is collected beneath the silicon layer, make drainage holes in the TheraForm™ Bilayer type.
- Hot/warm saline damages collagen. If hydration in warm/hot saline is suspected, do not use the TheraForm.

### Adverse Reactions

Although TheraForm™ Bilayer is made of collagen; allergic reactions may not be completely excluded. However, the following side effects may be experienced due to the surgical procedures: dehiscence; hematoma; resorption of the applied root; redness; inflammation; increased sensitivity; and pain.

### Storage

- Store at room temperature and avoid excessive heat and humidity.
- Do not use after expiration date.

### Packaging

1 each / 1 box

Products	Size (mm)		
	Depth	Wide	Remark
TheraForm™ - Bilayer	40	30	Allowable dimension: ± 10%
	70	50	
	100	100	

#### Symbols used on labeling

	Do not reuse		See instructions for use
REF	Catalogue number	LOT	Lot number
	Expiration date	STERILE R	Method of sterilization - Gamma radiation
	Date of Manufacture	EC REP	EC Representative
	Federal (USA) law restricts this device to sale by or on the order of a physician.		Manufacturer

# TheraForm™ Plug

## Absorbable Collagen for Tissue-filling Augmentation



### Description

TheraForm™ Plug, tissue-filling augmentation material, is a sterile, pliable, surgical, porous scaffold agent made of highly purified collagen derived from porcine skin.

TheraForm™ Plug is completely absorbable, highly biocompatible and suitable for soft tissue augmentation.

### Indications

TheraForm™ Plug is a collagen-based bone-filling augmentation material used for filling tooth extraction sockets.

### Instructions for use

TheraForm™ Plug is packaged in a sterile blister tray. The general principles of sterile handling and basic surgical procedures should be followed when using the TheraForm™ Plug.

- Treat infection area and debride the tooth extraction sockets before applying the TheraForm™ Plug.
- Secure TheraForm™ Plug by suturing to prevent its dislodgement from the socket.
- TheraForm™ Plug should not be removed as it will be completely absorbed after approximately 4~8 weeks.

### Post-operative care

When the TheraForm™ Plug is applied, patients should rinse their mouths with an antimicrobial agent prescribed by their dentist, in order to minimize the risk of infection.

### Contraindications

- TheraForm™ Plug should not use in patients who are hypersensitive to or who may have allergic reactions to porcine collagen.
- TheraForm™ Plug should not be placed where there is active infection or in a contaminated wound.

### Warning

- Single-use only, do not re-sterilize or re-use
- Not intended for immediate load-bearing
- Do not overfill defects
- Do not leave defect open
- Do not compromise blood supply to the defect area
- The device should be secured in order to prevent motion and migration and used only in areas where a graft can be adequately contained
- Do not use if the package has been opened or is damaged or if the expiration date has been exceeded.

### Precautions

- Do not resterilize. Discard any opened or unused TheraForm™ Plug.
- Do not use if the package or product is damaged.
- The safety and effectiveness of the TheraForm™ Plug has not been assessed in pregnant women or in children.
- As with any other surgical procedure, caution should be taken when using in patients who are receiving long-term steroid or anti-coagulant therapy.
- Do not use until excessive exudate, acute swelling, and infection are controlled.
- Hot/warm saline damages collagen. If hydration in warm/hot saline is suspected, do not use the Plug.
- Maintain good oral hygiene during the application period. Do not place and fill with an excessive amount in the extracted tooth socket as this may cause tenderness and irritation.

### Adverse Reactions

Although TheraForm™ Plug is made of Atelocollagen allergic reactions may not be completely excluded. However, the following side effects may be experienced due to the surgical procedures: dehiscence; hematoma; resorption of the applied root; redness; inflammation; increased sensitivity; and pain.











### Storage

Store at room temperature and avoid excessive heat and humidity.

### Packaging

1 each / 1 box: 8 x 25 mm

#### Symbols used on labeling

	Do not reuse		See instructions for use
	Catalogue number		Lot number
	Expiration date		Method of sterilization – Gamma radiation
	Date of Manufacture		EC Representative
	Federal (USA) law restricts this device to sale by or on the order of a licensed dentist.		Manufacturer

To order please contact: **1800-209-0309**

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