

may form a caramel-coloured or off-white gel. Do not remove this gel by debridement. This caramelisation contains extracellular matrix (ECM), which continues to replace deficient and missing ECM in the wound.

- b) As healing occurs, sections of CholeDerm® may gradually peel. Carefully remove any remaining loose products around the edge as needed.
- c) Gently cleanse the wound surface with sterile saline; leave the ECM gel intact.
- d) Carefully reassess the wound and record healing progression, including wound dimensions, depth, type, and other relevant information.

#### VI. Reapplication of CholeDerm® and Dressing Changes

- a) Change secondary dressings as needed (see step IV).
- b) If the wound is free of infection and necrosis but not fully epithelialised, reapply newly prepared CholeDerm® over previously absorbed application (See steps II and III).
- c) Reapply CholeDerm® every seven days or as needed by repeating previous application steps.

**NOTE: If excess exudate collects under the sheet, small openings can be cut to allow the exudate to drain.**

#### SYMBOLS


















	Manufacturer		Double sterile barrier system
	Date of manufacture		Keep dry
	Use by/Expiration date		Do not reuse
	Lot number		Consult instructions for use
	Catalog number		Contains biological material of animal origin
	Model Number		Medical device
	Sterilized using ethylene oxide		Upper limit of temperature
	Do not resterilize		Unique Device Identifier
	Do not use if packaging is damaged		

Table 1: CholeDerm® Available Sizes and Packaging Options

S No:	Model No:	Size (LxB) cm	Pack Size
1	CD-P7646-5S	7.6x4.6	5 Sheets
2	CD-P7452-5S	7.4x5.2	5 Sheets
3	CD-P6646-5S	6.6x4.6	5 Sheets
4	CD-P5640-5S	5.6x4.0	5 Sheets
5	CD-P5237-5S	5.2x3.7	5 Sheets
6	CD-P4636-5S	4.6x3.6	5 Sheets
7	CD-P3630-5S	3.6x3.0	5 Sheets
8	CD-P7646-1S	7.6x4.6	1 Sheet
9	CD-P7452-1S	7.4x5.2	1 Sheet
10	CD-P6646-1S	6.6x4.6	1 Sheet
11	CD-P5640-1S	5.6x4.0	1 Sheet
12	CD-P5237-1S	5.2x3.7	1 Sheet
13	CD-P4636-1S	4.6x3.6	1 Sheet
14	CD-P3630-1S	3.6x3.0	1 Sheet

#### Reference:

- Thapasimuthu V. Anilkumar et al. Biomaterial properties of cholecyst-derived scaffold recovered by a non-detergent/enzymatic method. Journal of Biomedical Materials Research Part B: Applied Biomaterials. 2014. DOI: 10.1002/jbm.b.33131.
- Deepa Revi et al. Porcine cholecyst-derived scaffold promotes full-thickness wound healing in rabbit. Journal of Tissue Engineering. 2013. DOI: 10.1177/2041731413518060.
- Jaseer Muhamed et al. Comparative local immunogenic potential of scaffolds prepared from porcine cholecyst, jejunum, and urinary bladder in rat subcutaneous model. Journal of Biomedical Materials Research Part B: Applied Biomaterials. 2014. DOI: 10.1002/jbm.b.33296.
- Jaseer Muhamed et al. Comparative profiling of extractable proteins in extracellular matrices of porcine cholecyst and jejunum intended for preparation of tissue engineering scaffolds. Journal of Biomedical Materials Research Part B: Applied Biomaterials. 2015. DOI: 10.1002/jbm.b.33567.

**Mfg.Lic.No:** MFG/MD/2023/000551

**Loan.Lic.No:** MFG/MD/2024/000646

Microtrol Sterilisation Services Private Limited

#### Indian Patent:

Patent No. 413604.

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Ref. No: CD-P-IFU-003-140225

**Alicorn**  
Medical Private Limited

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**Alicorn**  
Medical Private Limited

**CholeDerm®**  
**Extracellular Matrix**

**Instructions For Use**

## PRODUCT DESCRIPTION:

The ChitraDesign® CholeDerm® is a sterile, lyophilised dry sheet composed of native, intact extracellular matrix (ECM) derived from the porcine gall bladder tissue, utilising the patented PrisTINE™ technology to preserve its innate biological structure and associated macromolecules, including collagen, elastin, glycosaminoglycans, and growth factors. When rehydrated with sterile saline or wound exudate, CholeDerm® becomes a pliable sheet that integrates into the wound bed. It is packaged in a double sterile barrier system and is available in different sizes. It is terminally sterilised using ethylene oxide.

## INTENDED USE:

**CholeDerm®** is a single-use, porcine gall bladder-derived extracellular matrix designed for advanced wound care. It covers, protects, and maintains a moist environment conducive to optimal healing.

## Clinical Benefits of CholeDerm®:

- Modulates Wound Healing: Addresses chronic wound inflammation by regulating proteases for balanced healing.
- Supports Tissue Regeneration: Provides an extracellular matrix scaffold for the patient's cells to build granulation tissue and support epithelialisation.

## INDICATION FOR USE:

CholeDerm® is indicated for the management of wounds, including:

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

**CAUTION: This device is to be sold by or on the order of a licensed healthcare practitioner.**

## CONTRAINDICATIONS:

- CholeDerm® is derived from a porcine source and should not be used in patients with a known sensitivity to porcine material.
- It is not indicated for use in third-degree burns.

## PRECAUTIONS:

- **CholeDerm®** should not be applied until excessive exudate, bleeding, acute swelling, and infection are controlled.
- Do not re-use or re-sterilize.
- Do not use if the package seal is broken.
- Do not use after the printed expiration date.
- Dispose of any open & unused, damaged/contaminated, and used CholeDerm® according to hospital regulations and local waste disposal guidelines.

**POTENTIAL COMPLICATIONS:** The following complications are possible. If any of these conditions occur, the device should be removed.

- Infection
- Chronic inflammation (Initial application of wound dressings may be associated with transient, mild, localised inflammation.)
- Allergic reaction.
- Excessive redness, pain, swelling, or blistering.

Report any severe incident to Alicorn Medical via the local authorised representative and the applicable Member State competent authority or other regulatory authority, by regional requirements.

**STORAGE:** CholeDerm® should be stored at room temperature in a clean, dry location.

## SUGGESTED INSTRUCTIONS FOR USING CholeDerm®

**NOTE: Always handle CholeDerm® using an aseptic technique.**

*These steps are only suggestions for using the CholeDerm® Collagen Wound Matrix. They're not meant to replace the protocols your hospital or clinic has or the decisions made by your healthcare team.*

### I. Wound Bed Preparation

- a) Prepare the wound bed using standard methods to ensure it is free of exudate and devitalised tissue. An initial excision or debridement of the wound may be necessary to ensure the wound edges contain viable tissue.
- b) Wait for any bleeding to stop before applying CholeDerm®
- c) Cleanse the wound thoroughly with sterile saline.

### II. Selection and Preparation of CholeDerm®

- a) Measure the wound and select the sheet of dry CholeDerm® of the appropriate size. The product may be additionally fenestrated or meshed with a scalpel if necessary.
- b) Cut the sheet to a size and shape or use multiple sheets side by side that will cover the entire wound surface and extend slightly beyond the wound margins.

### III. Application of CholeDerm®

- a) For easy handling, apply CholeDerm® by placing it in a dry state over the wound.
- b) Position the dry CholeDerm® to completely contact the entire surface of the wound bed and extend slightly beyond all wound margins. If multiple sheets are necessary to cover the wound, slightly overlap the edges of the sheets.
- c) As required, securely anchor CholeDerm® with the physician's preferred fixation method (e.g., STERI-STRIP®, tissue sealant, bolsters, dissolvable clips, sutures, staples, or another appropriate fixation method) based on the type of wound, location of the wound, patient's mobility, and patient compliance.
- d) Thoroughly rehydrate CholeDerm® by applying sterile saline.
- e) To protect CholeDerm® from adhering to the secondary dressing, apply an appropriate nonadherent primary wound dressing over the CholeDerm®
- f) Apply an appropriate secondary dressing (multi-layer compression bandage system, total contact cast, or other appropriate dressing) to manage the wound exudate, keep the CholeDerm® moist, and keep all layers securely in place.

### IV. Dressing Changes

- a) To prevent damage to the newly incorporated CholeDerm®, change the primary dressing only as necessary, typically every seven days.
- b) Change the secondary dressing as appropriate.
- c) Avoid dislodging the CholeDerm® when the secondary dressing is changed.

### V. Wound Assessment and Wound Bed Preparation for Reapplication of CholeDerm®

- a) Change all dressings every 7 days or as necessary.

**NOTE:** If a gel forms on the wound surface, do not attempt to remove it forcibly. Successful absorption of CholeDerm®