

## NexoBrid® (anacaulase-bcdb)

# ESCHAR REMOVAL GUIDELINES

PRE-TREATMENT

TREATMENT WITH NEXOBRID

VISUAL ASSESSMENT

POST-TREATMENT

### INDICATION

NexoBrid® (*anacaulase-bcdb*) is indicated for eschar removal in adults and pediatric patients with deep partial thickness (DPT) and/or full thickness (FT) thermal burns.

#### Limitations of Use

The safety and effectiveness of NEXOBRID have not been established for treatment of:

- Chemical or electrical burns
- Burns on the face, perineum, or genitalia
- Burns on the feet of patients with diabetes mellitus or on the feet of patients with occlusive vascular disease
- Circumferential burns
- Burns in patients with significant cardiopulmonary disease, including inhalation injury

NexoBrid is not recommended for:

- Wounds contaminated with radioactive and other hazardous substances to avoid unforeseeable reactions with the product and an increased risk of spreading the noxious substance
- Treatment of burn wounds where medical devices (e.g., implants, pacemakers, shunts) or vital structures (e.g., large vessels) could become exposed during eschar removal

### IMPORTANT SAFETY INFORMATION

#### CONTRAINDICATIONS

NEXOBRID is contraindicated in patients with: known hypersensitivity to anacaulase-bcdb, bromelain, pineapples, or to any other components; known hypersensitivity to papayas or papain because of the risk of cross-sensitivity.

**Please see additional IMPORTANT SAFETY INFORMATION throughout and Full Prescribing Information.**

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The NexoBrid<sup>®</sup> Eschar Removal Guidelines provide detailed steps for the preparation, application, and removal of NexoBrid.

Please see [Full Prescribing Information](#) for additional guidance on preparation and application.

NexoBrid is available by prescription and should only be administered by a healthcare provider.

## NexoBrid Dosage & Administration Overview

### PRE-TREATMENT

#### Preparation of Patient and Burn Wound Treatment Area

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- NexoBrid Preparation
- Wound Preparation, Cleansing, and Soaking
- NexoBrid Mixing
- Wound Preparation

### TREATMENT WITH NEXOBRID

#### NexoBrid Treatment

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- Monitoring
- NexoBrid Removal
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**This piece is not intended to provide medical advice or direction. Healthcare professionals should assess each situation and consider their own procedures, including treatment and pain management, for their patients as each patient's situation and results will vary.**

Connect with your Vericel Representative for NexoBrid training and use support.

Please see additional [IMPORTANT SAFETY INFORMATION](#) throughout and [Full Prescribing Information](#).

### VISUAL ASSESSMENT

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- Use in Special Populations
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#### References



## NEXOBRID® OVERVIEW<sup>1</sup>

NexoBrid is a first-line enzymatic agent indicated for eschar removal in adults and pediatric patients with deep partial thickness and/or full thickness thermal burns.<sup>1</sup>

- **Applied as a 4-hour application within hours of patient presentation** for earlier and more informed medical planning for healing and care<sup>1-3</sup>
  - Remove NexoBrid after 4 hours



Product illustration

### DOSAGE AND ADMINISTRATION<sup>1</sup>

- NexoBrid is only to be administered by a healthcare provider
- Take precautions to avoid exposure to NexoBrid during preparation and handling (e.g., use gloves, surgical masks, other protective coverings, as needed)
  - In the event of inadvertent skin exposure, rinse NexoBrid off with water to reduce the likelihood of skin sensitization
- NexoBrid lyophilized powder and gel vehicle must be mixed no more than 15 minutes prior to administration
  - Discard NexoBrid if not used within 15 minutes of preparation, as the enzymatic activity of the product decreases progressively following mixing
- Each vial of lyophilized powder, jar of gel vehicle, and the mixed NexoBrid are for use for only one patient and for one application

### NEXOBRID IS AVAILABLE AS:

**5 g lyophilized powder (containing 4.85 grams of anacaulase-bcdb) mixed in 50 g gel vehicle for treatment of up to 450 cm<sup>2</sup> of burn area after mixing.<sup>1</sup>**

- For topical use only

AGE	NEXOBRID DOSING <sup>1</sup>	UNIT ORDERS*
Adults	<ul style="list-style-type: none"> <li>• Up to 15% body surface area (BSA) in one application</li> <li>• A second application may be applied 24 hours later—total treatment area must not exceed 20% BSA</li> </ul>	6 units = ~15% BSA
Pediatric Patients 6–17 Years of Age	<ul style="list-style-type: none"> <li>• Up to 15% BSA in one application</li> <li>• A second application is not recommended</li> </ul>	6 units = ~15% BSA
Pediatric Patients under 6 Years of Age	<ul style="list-style-type: none"> <li>• Up to 10% BSA in one application</li> <li>• A second application is not recommended</li> </ul>	4 units = ~10% BSA

\*Please consider that adults and pediatric patients have different body proportions and this may affect how surface area is calculated across the body.

Please see [Full Prescribing Information](#) for guidance on preparation and application.

### IMPORTANT SAFETY INFORMATION

#### WARNINGS AND PRECAUTIONS—CONTINUED

##### Coagulopathy

Avoid use of NEXOBRID in patients with uncontrolled disorders of coagulation. Use with caution in patients on anticoagulant therapy or other drugs affecting coagulation, and in patients with low platelet counts and increased risk of bleeding from other causes. Monitor patients for possible signs of coagulation abnormalities and signs of bleeding.

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### IMPORTANT SAFETY INFORMATION

#### WARNINGS AND PRECAUTIONS

##### Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylaxis, have been reported with postmarketing use of anacaulase-bcdb. If a hypersensitivity reaction occurs, remove NEXOBRID (if applicable) and initiate appropriate therapy.

Healthcare personnel should take appropriate precautions to avoid exposure when preparing and handling NEXOBRID (e.g., gloves, surgical masks, other protective coverings, as needed).

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## PREPARATION OF PATIENT AND BURN WOUND TREATMENT AREA<sup>1</sup>

### PAIN MANAGEMENT PLANNING<sup>1</sup>

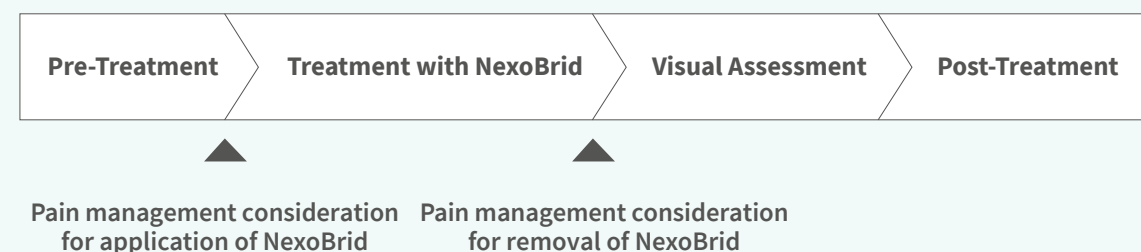
Eschar removal with NexoBrid® and treatment-related burn wound procedures are painful and require adequate analgesia and/or anesthesia.

- Pain management should be appropriate for an extensive dressing change of burn wounds

**At least 15 minutes prior to NexoBrid application, ensure adequate pain control measures are in place to address NexoBrid-related pain.**

**Pain management for NexoBrid should be adapted to the patient and burn center protocols.**

**Pain management should be considered during application and removal of NexoBrid.**



### NEXOBRID PREPARATION<sup>1</sup>

**Gather the following sterile supplies prior to NexoBrid preparation and application.**

- Instrument for mixing (e.g., spatula or tongue depressor)
- Tongue depressor for NexoBrid application
- 0.9% Sodium Chloride Irrigation
- Occlusive film dressing
- Loose, thick, fluffy dressing and bandage



*Image is a medical illustration. Individual results may vary.*

### IMPORTANT SAFETY INFORMATION

#### ADVERSE REACTIONS

The most common adverse reactions (>5%) in adults were pruritus, pyrexia, wound complication, anemia, vomiting and insomnia. The most common adverse reactions (>5%) in pediatric patients were pruritus, pyrexia and vomiting.

**Please see additional IMPORTANT SAFETY INFORMATION throughout and Full Prescribing Information.**

### IMPORTANT SAFETY INFORMATION

#### USE IN SPECIAL POPULATIONS

##### Geriatric Use

Clinical studies of NEXOBRID did not include sufficient numbers of subjects 65 years of age and older to determine whether they respond differently from younger adult subjects.

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## WOUND PREPARATION, CLEANSING, AND SOAKING<sup>1</sup>

Use pain management as practiced for an extensive dressing change of burn wounds 15 minutes prior to and throughout all NexoBrid<sup>®</sup>-related procedures.

**Thoroughly clean the wound and remove any charred tissue, blisters, and any topical products.<sup>1</sup>**

- Keratin isolates the eschar from direct contact with NexoBrid and prevents eschar removal<sup>3</sup>
- Eschar saturated with topical medicinal products and their remains (e.g., silver-based products or povidone iodine) can interfere with the activity of NexoBrid and decrease its efficacy<sup>3</sup>



*Image is a medical illustration. Individual results may vary.*

Apply a dressing soaked with an antibacterial solution to the treatment area for at least 2 hours.<sup>1</sup>

**Ensure the wound bed is clear of any remnants of topical agents (e.g., silver sulfadiazine, povidone iodine).**

- The dressing must remain wet until it is removed prior to application of NexoBrid. Soaks should be renewed every 2–4 hours, as necessary, as NexoBrid works best on a moist wound bed<sup>3</sup>
- A few days old or dry eschar may be less responsive to enzymatic debridement. Thorough soaking before NexoBrid application may improve this<sup>3</sup>



*Image is a medical illustration. Individual results may vary.*

## IMPORTANT SAFETY INFORMATION

### CONTRAINDICATIONS

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#### Hypersensitivity Reactions

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Healthcare personnel should take appropriate precautions to avoid exposure when preparing and handling NEXOBRID (e.g., gloves, surgical masks, other protective coverings, as needed).

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## NEXOBRID<sup>®</sup> MIXING<sup>1</sup>

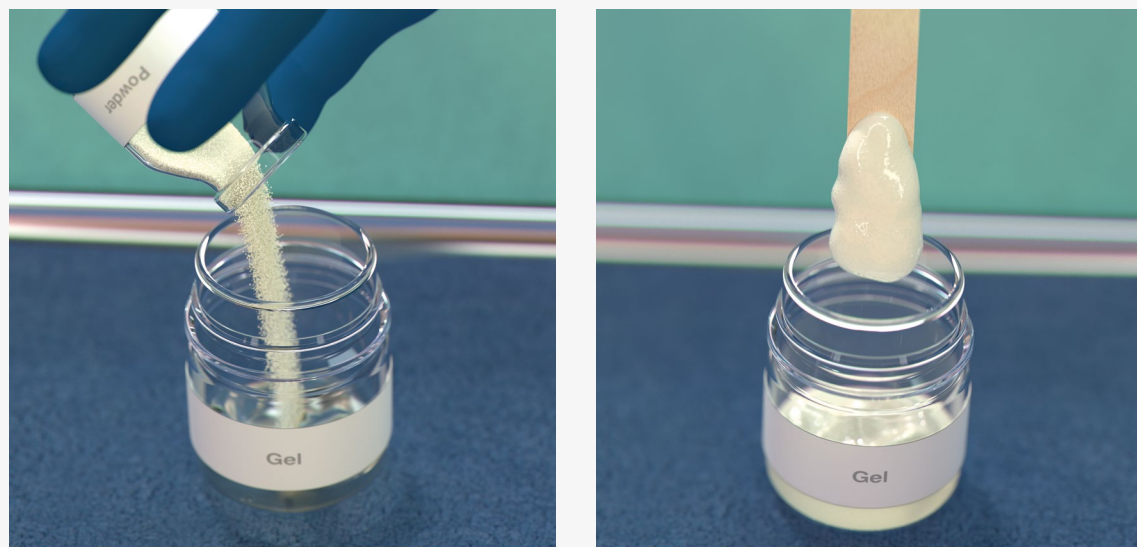
**Prepare NexoBrid at the patient's bedside within 15 minutes of the intended application.**

Using aseptic technique, mix NexoBrid lyophilized powder and gel vehicle as follows:

- Pour the NexoBrid lyophilized powder into the gel vehicle jar
- Thoroughly mix the NexoBrid lyophilized powder and gel vehicle using a sterile instrument (e.g., tongue depressor or spatula) until the mixture is uniform

The mixed lyophilized powder and gel vehicle produce NexoBrid in a final concentration of 8.8%.

- Discard NexoBrid if not used within 15 minutes of preparation, as the enzymatic activity of NexoBrid decreases progressively following mixing



*Image is a medical illustration. Individual results may vary.*

## WOUND PREPARATION<sup>1</sup>

Apply an ointment skin protectant (e.g., petrolatum) 2 to 3 cm outside of the treatment area to create an ointment barrier.

Protect any open wounds (e.g., laceration, abraded skin, and escharotomy incision) with skin protectant ointments or ointment gauze to prevent possible exposure to NexoBrid.

- Avoid applying the ointment to the treatment area itself, as this would impede direct contact of NexoBrid with the eschar



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## IMPORTANT SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS—CONTINUED

#### Coagulopathy

Avoid use of NEXOBRID in patients with uncontrolled disorders of coagulation. Use with caution in patients on anticoagulant therapy or other drugs affecting coagulation, and in patients with low platelet counts and increased risk of bleeding from other causes. Monitor patients for possible signs of coagulation abnormalities and signs of bleeding.

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## IMPORTANT SAFETY INFORMATION

### ADVERSE REACTIONS

The most common adverse reactions (>5%) in adults were pruritus, pyrexia, wound complication, anemia, vomiting and insomnia. The most common adverse reactions (>5%) in pediatric patients were pruritus, pyrexia and vomiting.

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## NEXOBRID<sup>®</sup> TREATMENT

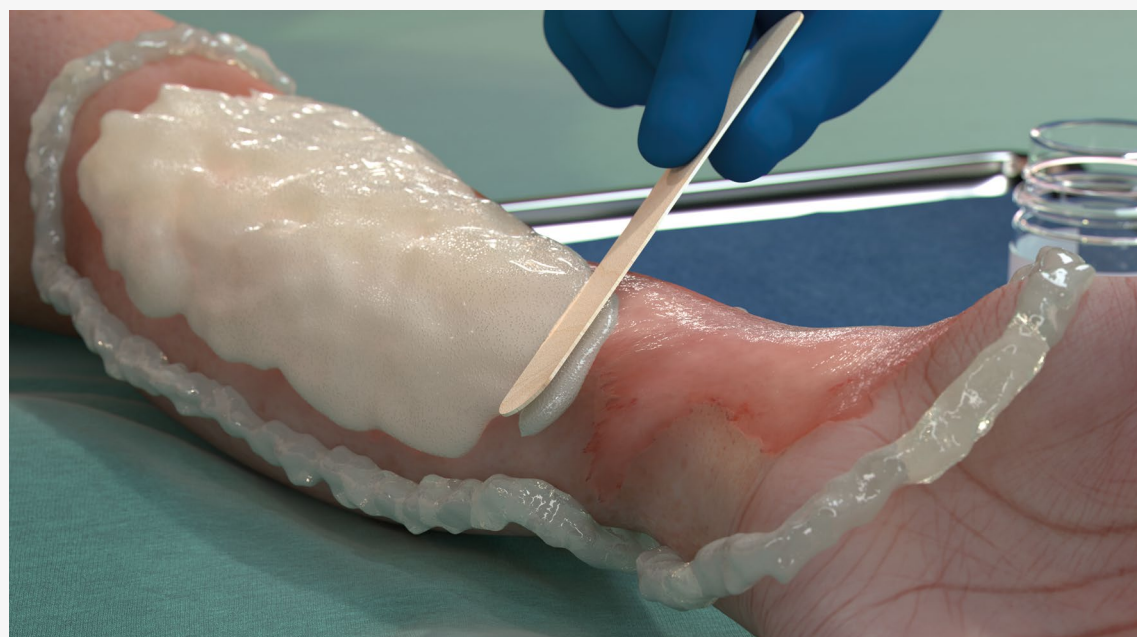
### NEXOBRID APPLICATION<sup>1</sup>

**Ensure adequate pain control measures are in place throughout the entire procedure.**

Apply NexoBrid within 15 minutes of preparation as follows:

Moisten the treatment area by sprinkling sterile 0.9% Sodium Chloride Irrigation onto the burn wound.

Using a sterile tongue depressor, completely cover the moistened burn wound treatment area with the mixed NexoBrid in a 3 mm thick layer (approximate thickness of a tongue depressor). Ensure NexoBrid covers the entire target treatment area.



*Image is a medical illustration. Individual results may vary.*

Cover the treated wound with a sterile occlusive film dressing.

Gently press the occlusive film dressing at the area of contact with the ointment barrier.

- Ensure adherence between the occlusive film dressing and the ointment barrier
- Achieve complete containment of NexoBrid on the treatment area
- There should be no visible air under the occlusive film dressing

Position patient to minimize movement and avoid pressure on the treatment area during treatment time.<sup>4</sup>

- NexoBrid will liquify as enzymatic process begins
- Care should be taken to keep gel vehicle in place
- Monitor throughout application for continuous coverage



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### IMPORTANT SAFETY INFORMATION

#### USE IN SPECIAL POPULATIONS

##### Geriatric Use

Clinical studies of NEXOBRID did not include sufficient numbers of subjects 65 years of age and older to determine whether they respond differently from younger adult subjects.

**Please see additional IMPORTANT SAFETY INFORMATION throughout and Full Prescribing Information.**

### IMPORTANT SAFETY INFORMATION

#### CONTRAINDICATIONS

NEXOBRID is contraindicated in patients with: known hypersensitivity to anacaulase-bcdb, bromelain, pineapples, or to any other components; known hypersensitivity to papayas or papain because of the risk of cross-sensitivity.

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## NEXOBRID<sup>®</sup> APPLICATION<sup>1</sup>—CONTINUED

Cover the occlusive film dressing with a sterile loose, thick, fluffy dressing and secure with a sterile bandage.

Discard any unused portions of NexoBrid.



*Image is a medical illustration. Individual results may vary.*

## MONITORING<sup>1</sup>

**Monitor patients for signs of local or systemic allergic reactions. If a hypersensitivity reaction occurs, remove NexoBrid (if applicable) from the treatment area and initiate appropriate therapy.**

## IMPORTANT SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS

#### Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylaxis, have been reported with postmarketing use of anacaulase-bcdb. If a hypersensitivity reaction occurs, remove NEXOBRID (if applicable) and initiate appropriate therapy.

Healthcare personnel should take appropriate precautions to avoid exposure when preparing and handling NEXOBRID (e.g., gloves, surgical masks, other protective coverings, as needed).

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## NEXOBRID REMOVAL

**Ensure adequate pain control measures are in place throughout the entire procedure.**

### Remove NexoBrid after 4 hours.

Gather the following sterile supplies prior to NexoBrid removal:

- Blunt-edged instruments (e.g., tongue depressor)
- Large dry gauze
- Gauze soaked with 0.9% Sodium Chloride Irrigation
- Dressing soaked with an antibacterial solution

Remove the occlusive film dressing using aseptic technique.

Remove the ointment barrier using a sterile blunt-edged instrument.

Remove the dissolved eschar from the wound by scraping it away with a sterile blunt-edged instrument.



*Image is a medical illustration. Individual results may vary.*

## IMPORTANT SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS—CONTINUED

#### Coagulopathy

Avoid use of NEXOBRID in patients with uncontrolled disorders of coagulation. Use with caution in patients on anticoagulant therapy or other drugs affecting coagulation, and in patients with low platelet counts and increased risk of bleeding from other causes. Monitor patients for possible signs of coagulation abnormalities and signs of bleeding.

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## NEXOBRID<sup>®</sup> REMOVAL<sup>1</sup>—CONTINUED

Wipe the wound thoroughly with a large sterile dry gauze.

- Then wipe with a sterile gauze that has been soaked with sterile 0.9% Sodium Chloride Irrigation
- Rub the treated area until the appearance of a clean dermis or subcutaneous tissues with pinpoint bleeding

To remove remnants of dissolved eschar, apply a dressing soaked with an antibacterial solution for at least 2 hours.

- The appearance of the resulting wound bed should improve following the removal of the soaking dressing<sup>3</sup>
- Such soaking and dressing removal (“wet to dry”) can be repeated as necessary<sup>3</sup>



*Image is a medical illustration. Individual results may vary.*

## SECOND APPLICATION OF NEXOBRID—FOR ADULT PATIENTS ONLY<sup>1</sup>

**ADULTS ONLY: A second application of NexoBrid may be applied 24 hours following the first application to either the same area previously treated with NexoBrid or to a new area.**

The total treatment area must not exceed 20% BSA across two treatment sessions.

**In pediatric patients, a second application is not recommended.**

## IMPORTANT SAFETY INFORMATION

### ADVERSE REACTIONS

The most common adverse reactions (>5%) in adults were pruritus, pyrexia, wound complication, anemia, vomiting and insomnia. The most common adverse reactions (>5%) in pediatric patients were pruritus, pyrexia and vomiting.

**Please see additional IMPORTANT SAFETY INFORMATION throughout and Full Prescribing Information.**

## IMPORTANT SAFETY INFORMATION

### USE IN SPECIAL POPULATIONS

#### Geriatric Use

Clinical studies of NEXOBRID did not include sufficient numbers of subjects 65 years of age and older to determine whether they respond differently from younger adult subjects.

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## ASSESSMENT OF WOUND BED AFTER NEXOBRID®

### VISUAL WOUND BED ASSESSMENT

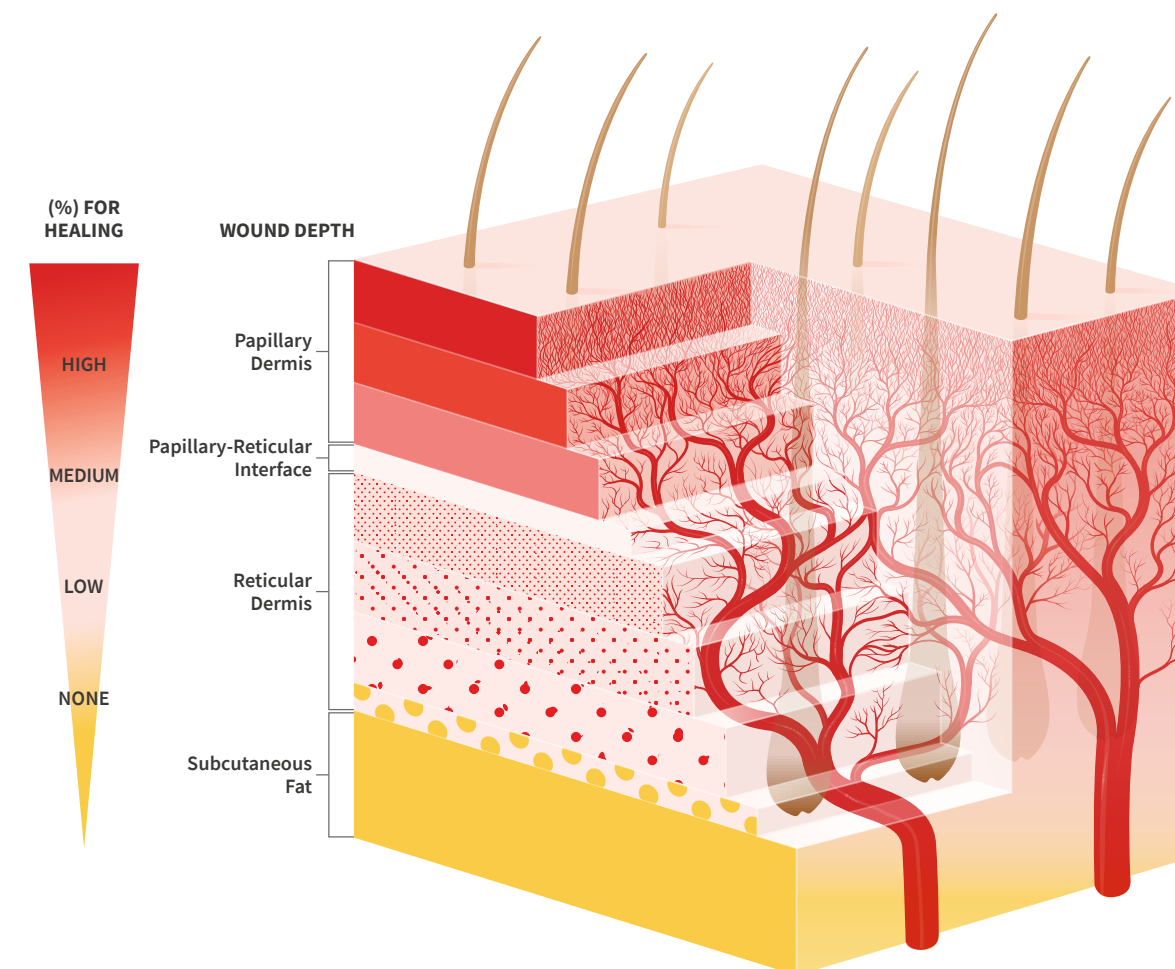
Following the removal of NexoBrid from a burn wound, a comprehensive assessment of the post-treatment tissue should be performed. Providers determine the success of the procedure and an appropriate treatment of the burn wound following eschar removal.



Image is a medical illustration. Individual results may vary.

### THE VISUAL DIAGNOSIS SCALE<sup>5,6</sup>

After NexoBrid, wound depth may be determined according to vascular patterns and colors.<sup>7</sup> The vascular patterns and colors coincide with relevant structures of the dermis and subcutaneous layers, including the blood vessels and hair follicles throughout various dermis depths.<sup>7</sup>



This Visual Diagnosis Scale is being provided for information purposes only. It is not used as part of the standard of care or as a validated scale. It was used to initiate a burn center into the DETECT and NEXT Clinical Trials, as well as for education during wound bed diagnosis after treatment with NexoBrid.

### IMPORTANT SAFETY INFORMATION

#### CONTRAINDICATIONS

NEXOBRID is contraindicated in patients with: known hypersensitivity to anacaulase-bcdb, bromelain, pineapples, or to any other components; known hypersensitivity to papayas or papain because of the risk of cross-sensitivity.

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### IMPORTANT SAFETY INFORMATION

#### WARNINGS AND PRECAUTIONS

##### Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylaxis, have been reported with postmarketing use of anacaulase-bcdb. If a hypersensitivity reaction occurs, remove NEXOBRID (if applicable) and initiate appropriate therapy.

Healthcare personnel should take appropriate precautions to avoid exposure when preparing and handling NEXOBRID (e.g., gloves, surgical masks, other protective coverings, as needed).

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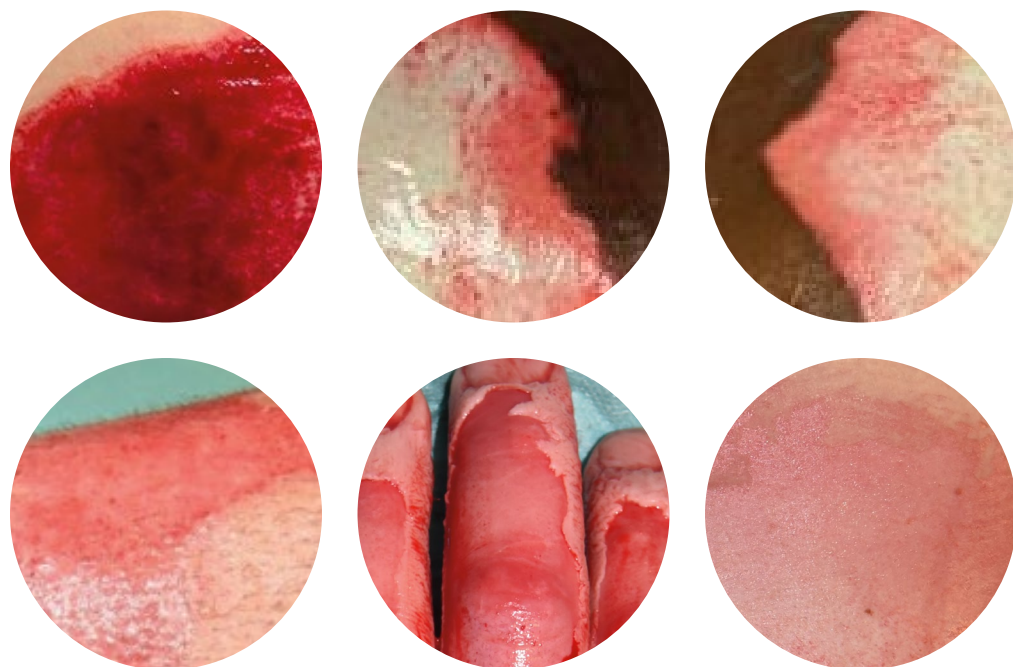
## BURN DEPTH DIAGNOSIS<sup>7,8</sup>

The post-NexoBrid<sup>®</sup> wound bed is different in appearance from wounds that have been surgically excised. The following clinical examples detail what has been seen after eschar removal with NexoBrid.<sup>7,8</sup>

### PAPILLARY DERMIS<sup>7,8</sup>

A uniform red color (with no visible circles) remains as a result of an abundance of capillaries.

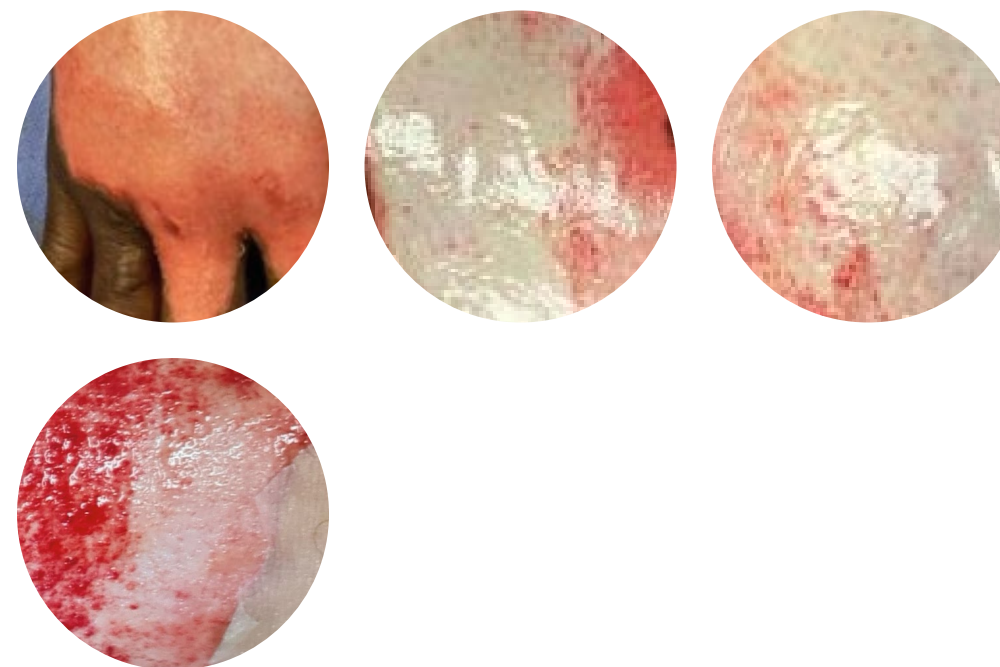
*Images are from real NexoBrid patients treated both inside and outside of the U.S. following standard application protocol. Individual results may vary.*



### PAPILLARY-RETICULAR INTERFACE<sup>7,8</sup>

White layer of the wound bed that is differentiated from burn eschar based on moisture content. Remaining eschar will be dry and not blanch.

*Images are from real NexoBrid patients treated both inside and outside of the U.S. following standard application protocol. Individual results may vary.*



## IMPORTANT SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS—CONTINUED

#### Coagulopathy

Avoid use of NEXOBRID in patients with uncontrolled disorders of coagulation. Use with caution in patients on anticoagulant therapy or other drugs affecting coagulation, and in patients with low platelet counts and increased risk of bleeding from other causes. Monitor patients for possible signs of coagulation abnormalities and signs of bleeding.

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## IMPORTANT SAFETY INFORMATION

### ADVERSE REACTIONS

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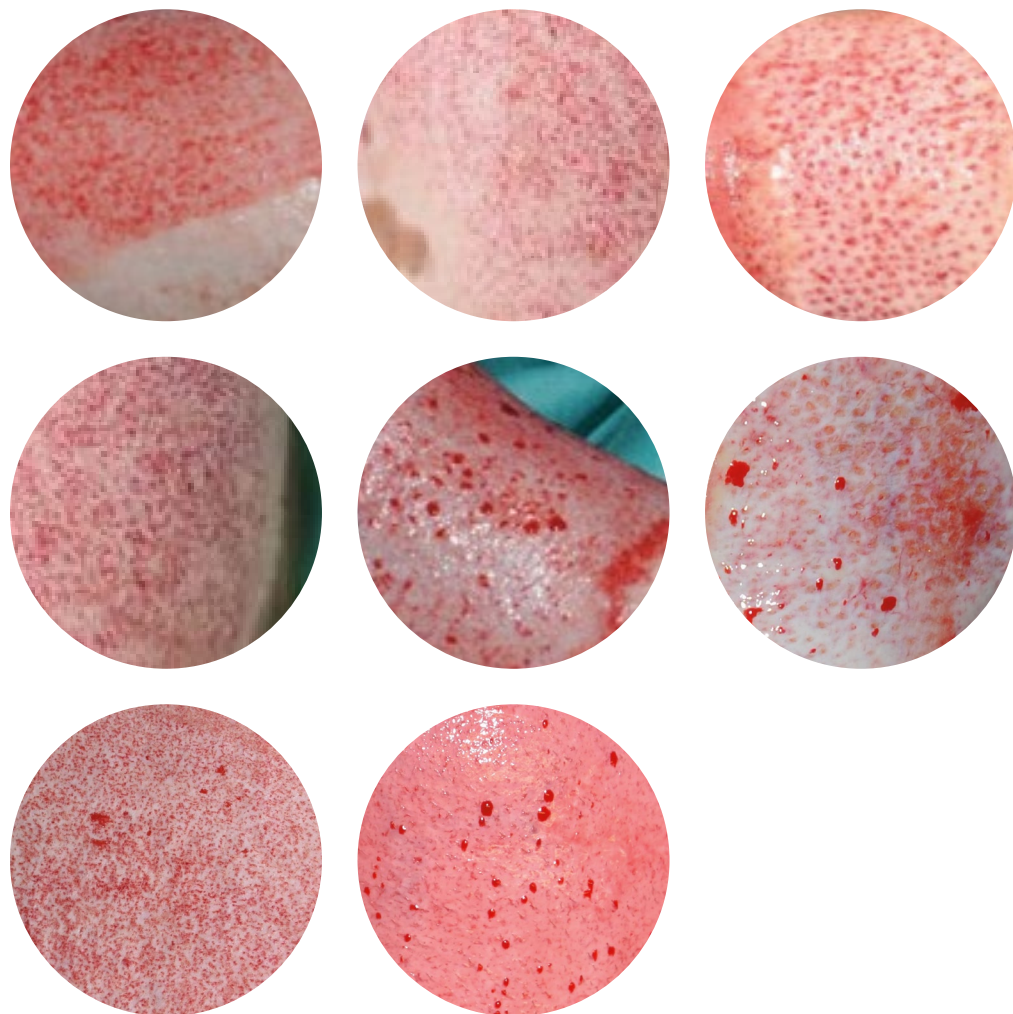
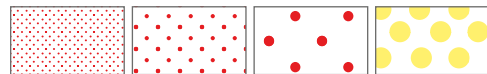
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## BURN DEPTH DIAGNOSIS—CONTINUED

### RETICULAR DERMIS<sup>7,8</sup>

A white color remains due to an abundance of collagen with small-to-medium pinpoint bleeding circles and some potential for translucent and visible fat.

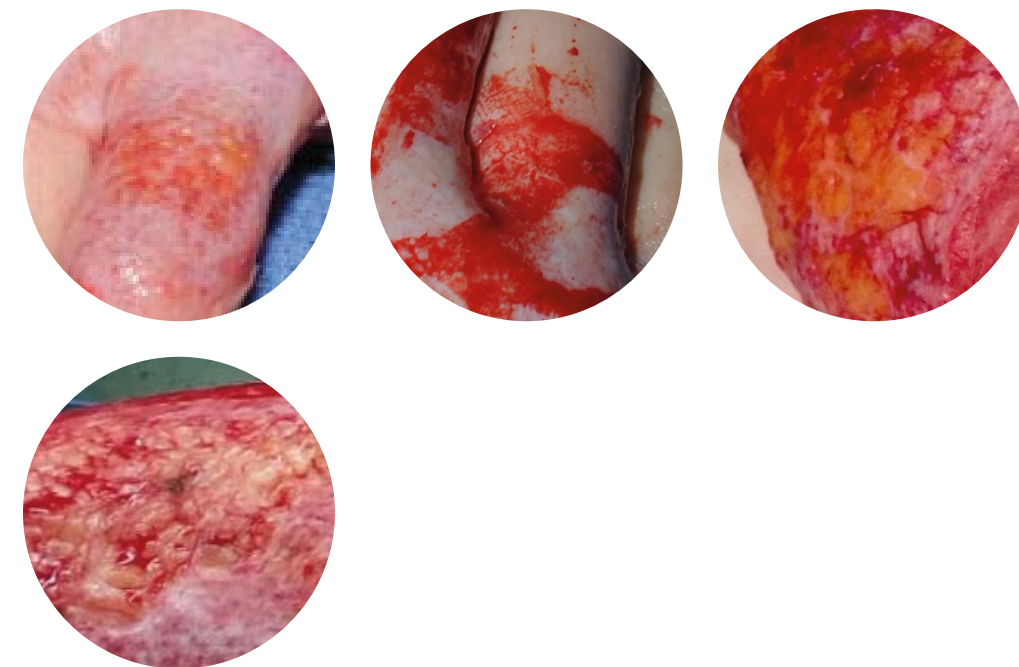
*Images are from real NexoBrid<sup>®</sup> patients treated both inside and outside of the U.S. following standard application protocol. Individual results may vary.*



### SUBCUTANEOUS FAT<sup>7,8</sup>

Large pinpoint bleeding circles, visible fat and blood vessels remain.

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## IMPORTANT SAFETY INFORMATION

### USE IN SPECIAL POPULATIONS

#### Geriatric Use

Clinical studies of NEXOBRID did not include sufficient numbers of subjects 65 years of age and older to determine whether they respond differently from younger adult subjects.

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## IMPORTANT SAFETY INFORMATION

### CONTRAINDICATIONS

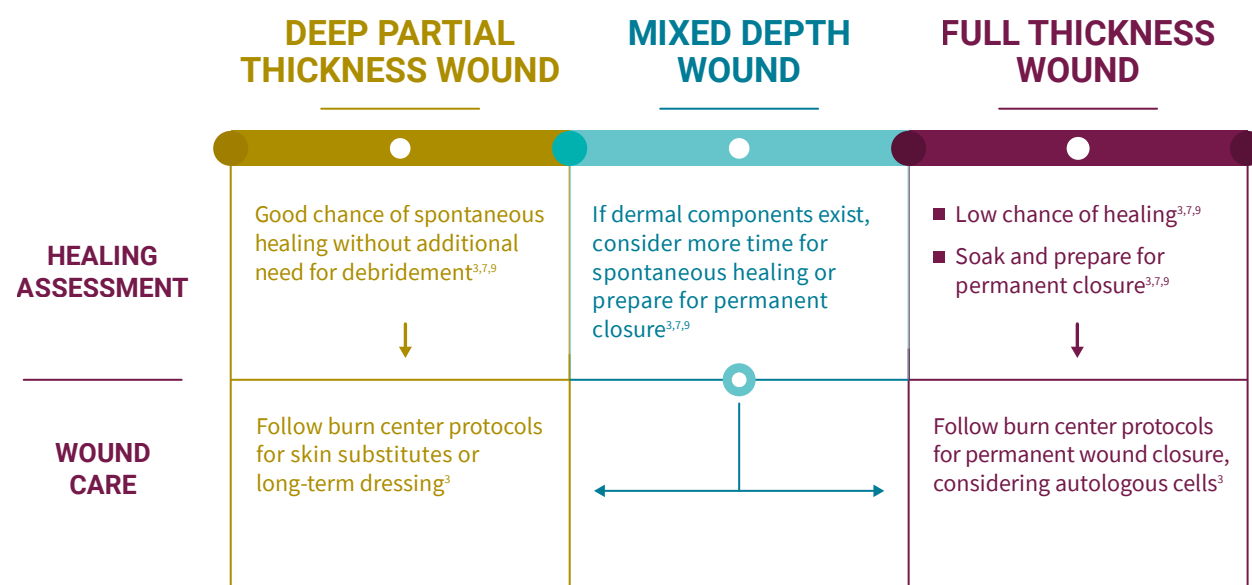
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## WOUND CARE AFTER NEXOBRID<sup>®</sup>

### WOUND CARE CONSIDERATIONS



### WOUND CARE AFTER ESCHAR REMOVAL<sup>1</sup>

Wound care following eschar removal should be based on the healthcare provider's clinical judgement (e.g., observe for spontaneous re-epithelialization or proceed with autograft)<sup>1</sup>

- Dress wound(s) sterilely according to burn center protocols



Image is a medical illustration. Individual results may vary.

### IMPORTANT SAFETY INFORMATION

#### WARNINGS AND PRECAUTIONS

##### Hypersensitivity Reactions

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NEXOBRID is not recommended for:

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Clinical studies of NEXOBRID did not include sufficient numbers of subjects 65 years of age and older to determine whether they respond differently from younger adult subjects.

To report negative side effects contact Vericel Corporation at 888-454-BURN (888-454-2876) or FDA at 1-800-FDA-1088 (1-800-332-1088) or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

**Please see [Full Prescribing Information](#).**

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# PRECISION IN ESCHAR REMOVAL<sup>2,8</sup>



Product  
illustration

NexoBrid® is an effective and selective enzymatic agent that removes eschar in adults and pediatric patients while preserving viable tissue.<sup>1,2,8</sup>

## IMPORTANT SAFETY INFORMATION

### ADVERSE REACTIONS

The most common adverse reactions (>5%) in adults were pruritus, pyrexia, wound complication, anemia, vomiting and insomnia. The most common adverse reactions (>5%) in pediatric patients were pruritus, pyrexia and vomiting.

**Please see additional IMPORTANT SAFETY INFORMATION throughout and Full Prescribing Information.**

 VERICEL® Burn Care

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