3M | Prevena™
Single Use Negative Pressure Wound Therapy

PRM | Proactive Risk Management (PRM) with 3M™ Prevena™ Therapy

Plastic Surgery

Advancing the standard of care

Helping to protect plastic surgery incisions beyond the OR

Plastic surgery patient care doesn’t end in the OR

In an increasingly overwhelmed healthcare system, healthcare providers are asked to do more with fewer resources. Combined with the increasing prevalence of comorbidities and other risk factors adds to the potential for postoperative complications beyond the operating room despite best-in-class care provided.

Postoperative complications can create a ripple effect of consequences, like disrupted healing, extended hospital stays, and poor patient outcomes. Today’s complex care environment makes protecting against the ripple effect of these complications a high priority.

Surgical success is largely in the eyes of the patient

In addition to stopping the ripple effect and protecting patients, surgeons and hospitals from potential consequences, surgeons are increasingly judged according to aesthetic outcomes that can be marred by seromas, hematomas and/or infections possibly resulting in additional procedures.

Anxious patients will add a layer of scrutiny to the surgical process and surgeons must carefully navigate the stress and expectations involved, knowing that ultimately success is largely in the eyes of the patient.

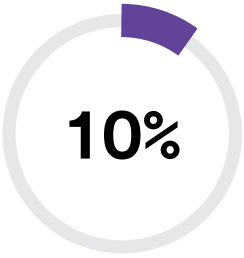
Recognizing the risks of reconstructive surgery

Your confidence in the OR can help give patients peace of mind. However, that confidence can be lost when your patient is discharged. At that point there can be multiple concerns, including swelling, infections and improper tissue integration. 3M can help deliver positive outcomes for you and your patient.

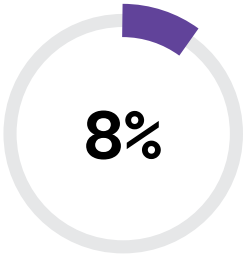
After mastectomy or breast reconstruction:

Postmastectomy breast reconstruction is on the rise, and more patients are requesting and qualifying for immediate reconstruction, which has a higher complication rate.

Infection rate[1] (implants or autologous)



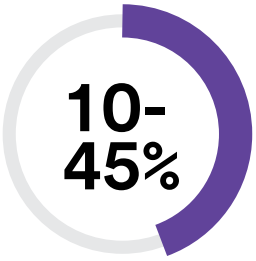
Wound infection[2]



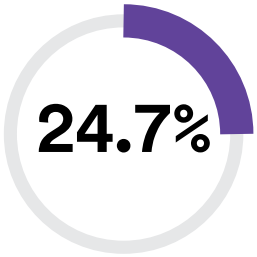
Skin necrosis rate[3]

After abdominal surgery:

Perfusion-related complications like infection, seroma, hematoma and necrosis are common with abdominal surgeries, and many may become complex and costly complications.



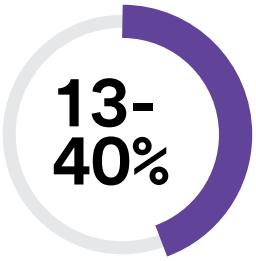
Complication rate in abdominoplasty procedures[4]



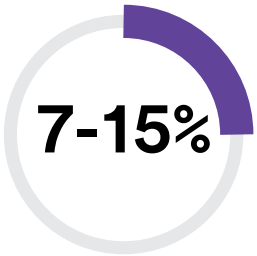
Complication rate with deep inferior epigastric perforators flap surgery[5]

After amputations:

Wound healing after amputations can be difficult due to low tissue perfusion. Various factors can further compromise blood flow and the wound healing environment, increasing the risk of complications in the residual limb and impacting outcomes.



Wound complications after lower extremity amputations[6,7]



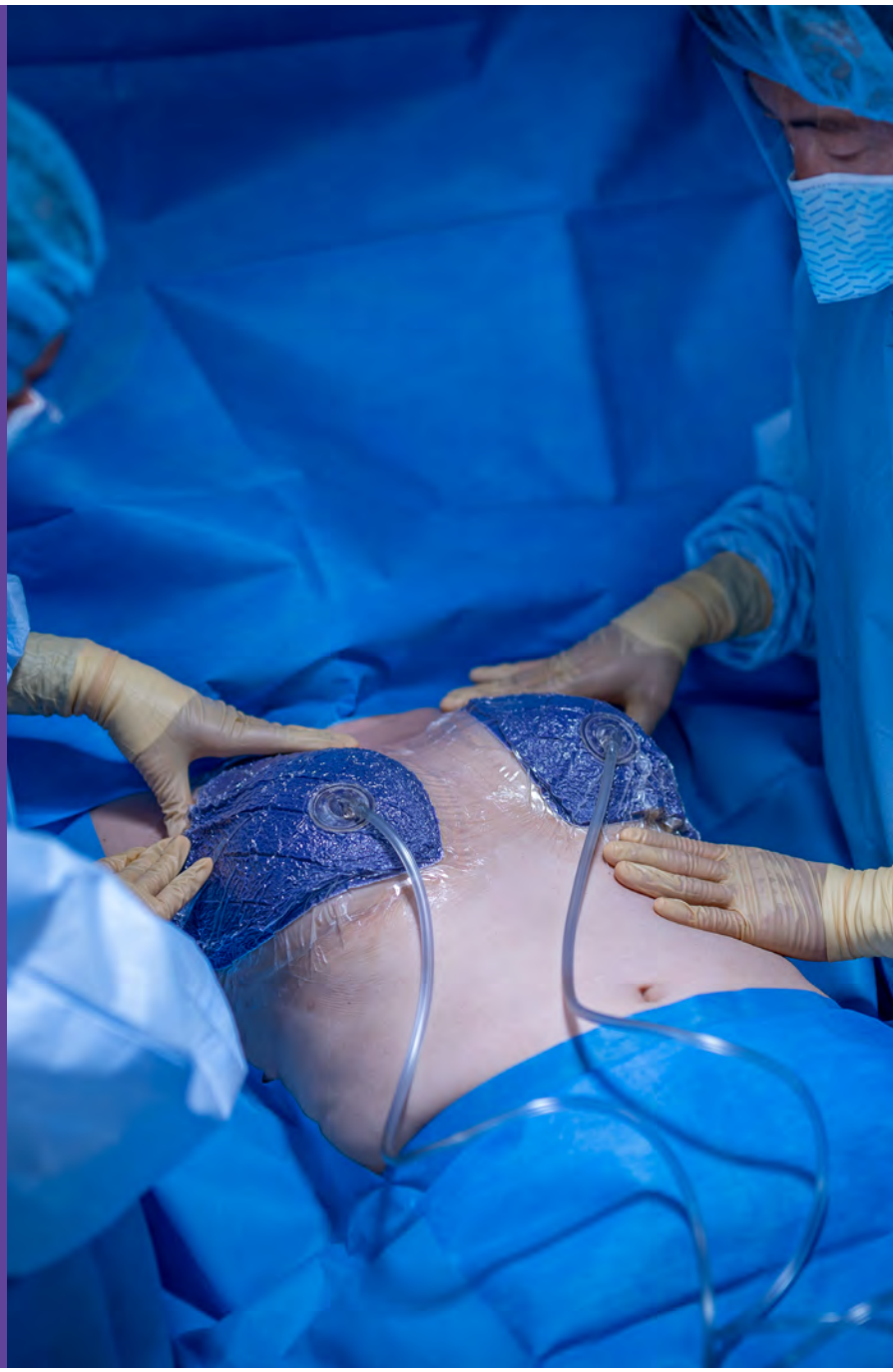
Mortality rate after lower extremity amputaitons[7,8]

Extend your control over postoperative healing.

3M™ Prevena™ Therapy is the first closed-incision negative pressure therapy (ciNPT) solution of its kind to help reduce the risk or incidence of seromas and superficial surgical site infections (SSIs) in Class I and II wounds.* It helps protect the incision site after surgery up to 7 days — extending your control over postoperative healing and helping patients at risk of developing complications.

Prevena Therapy offers surgeons the confidence to help protect patients beyond the OR.

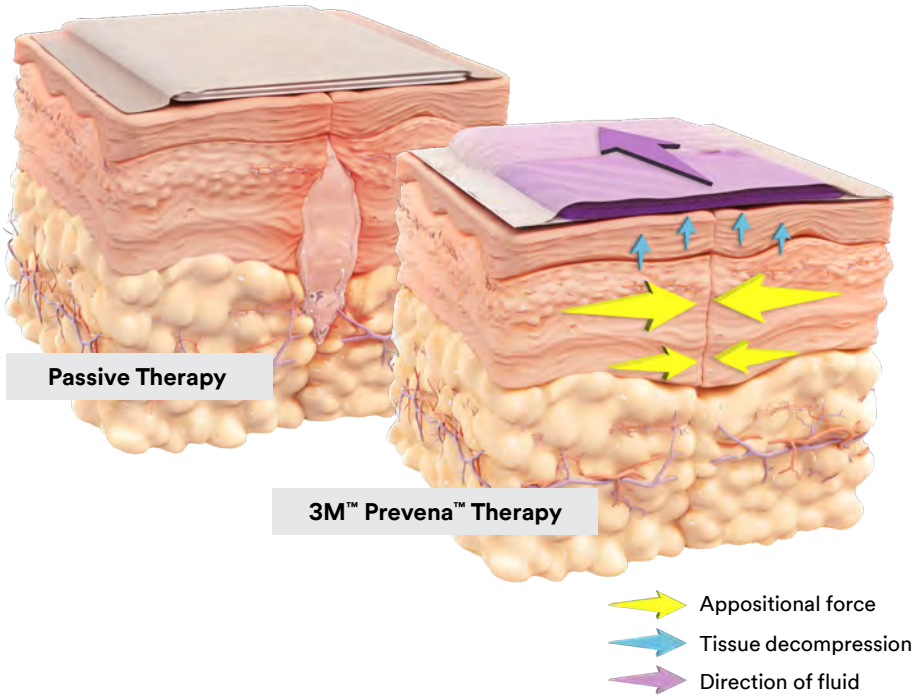
- **Acting as a barrier to external contamination**
- **Delivering continuous -125 mmHg up to 7 days**
- **Helping to hold incision edges together**
- **Decreasing lateral tension of sutured/stapled incisions[8]**
- **Removing fluids and infectious materials****
- **Reducing edema**



*The effectiveness of Prevena Therapy in reducing the incidence of SSIs and seroma in all surgical procedures and populations has not been demonstrated. See full indications for use and limitations at HCBGRegulatory.3M.com.
**In a canister.

The advanced science of 3M™ Prevena™ Therapy

Prevena Therapy utilizes continuous -125 mmHg negative pressure therapy, reticulated open cell foam (ROCF) dressing technology, and optimized exudate management (replaceable canister) over closed incisions to help enhance healing.



Designed to help optimize postoperative care:

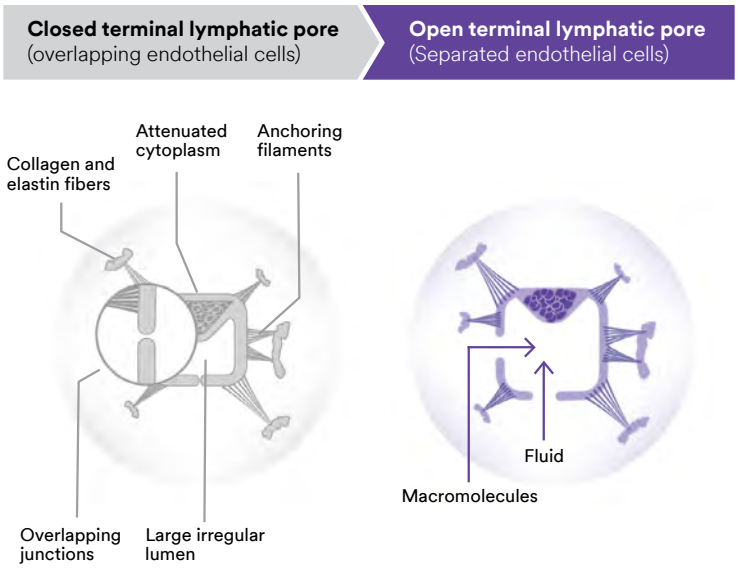
- Contours allow for even distribution of negative pressure
- Bolster and stabilize the incision and surrounding soft tissue
- Enhanced fluid management*
- Conforms to allow movement

How Prevena Therapy may help reduce postoperative edema**

The effects of negative pressure therapy applied to intact skin were evaluated using finite element analysis (FEA).[12]

Based on the analysis, it is hypothesized that negative pressure therapy on intact skin provides volumetric expansion that may help:

- Expand the tissue beneath the dressing, pulling the tissue open
- Lower local interstitial fluid pressure
- Open lymphatics to allow fluid clearance



*In a canister.
**Information contained within conducted bench and animal studies have not been evaluated by the U.S. Food & Drug Administration. Results have not been confirmed in human studies.

Patients and procedures that may benefit from 3M™ Prevena™ Therapy

A multidisciplinary group of surgical and infectious disease experts developed an algorithm to guide when to consider using closed-incision negative pressure therapy (ciNPT).[13] They recommend that surgeons consider using ciNPT for patients at high risk for developing surgical site occurrences (SSOs) or who are undergoing a high-risk procedure or a procedure that would have highly morbid consequences if a surgical site infection (SSI) occurred.

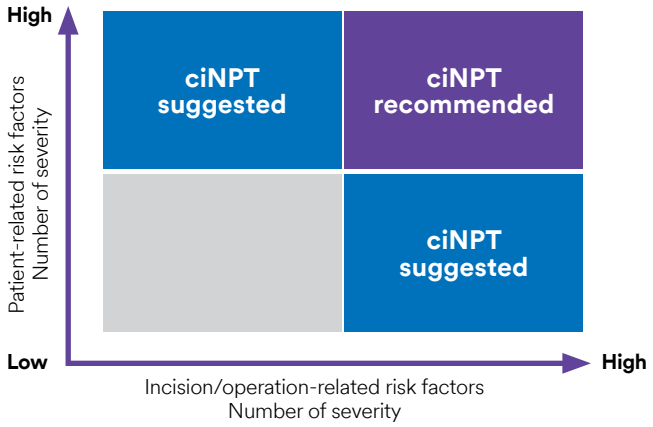
Consensus recommendations based on:

- Literature review
- ciNPT experiences
- Known risk factors for SSOs

Findings:

- Numerous publications reported SSI risk factors, with the most common including obesity (body mass index ≥30 kg/m^2); diabetes mellitus; tobacco use; or prolonged surgical time
- It is recommended that the surgeon assess the individual patient's risk factors and surgical risks

Risk factor assessment for ciNPT



Additional factors to consider:

Patient-related risk factors		Patient-related risk factors	
• Diabetes mellitus	• Active alcoholism	• High tension incision	• Prolonged operation time
• Acetylsalicylic acid Score ≥3	• Male sex	• Repeated incisions	• Post-surgical radiation
• Advanced age	• Hematoma	• Extensive undermining	• Mechanically unfavorable site
• Obesity	• Chronic renal insufficiency	• Traumatized soft tissue	
• Active tobacco use	• Chronic obstructive pulmonary disease	• Edema	
• Hypoalbuminemia		• Contamination	
• Corticosteroid usage		• Emergency procedure	

Procedure/operation-related risk factors:

General	Plastic	Orthopedic	Vascular	Cardiovascular
• Open general	• Post-bariatric abdominoplasty	• Open reduction and internal fixation of fractures	• Above/below knee amputation	• Sternotomy
• Open colorectal	• Breast reconstruction	• Fasciotomy	• Synthetic graft implantations	
• Open urology	• Big soft tissue defects	• Above/below knee amputation		
• Open obstetrics/ gynecology	• Soilage risk			
• Incisional hernia repair				

FDA indications for use

3M™ Prevena™ 125 Therapy Unit and 3M™ Prevena™ Plus 125 Therapy Unit manage the environment of closed surgical incisions and remove fluid away from the surgical incision via the application of -125 mmHg continuous negative pressure. When used with legally marketed compatible dressings, Prevena 125 Therapy Unit and Prevena Plus 125 Therapy Unit are intended to aid in reducing the incidence of seroma and, in patients at high risk for post-operative infections, aid in reducing the incidence of superficial surgical site infection in Class I and Class II wounds.

Note: The effectiveness of Prevena Therapy in reducing the incidence of SSIs and seroma in all surgical procedures and populations has not been demonstrated.
See full indications for use and limitations at HCBGRegulatory.3M.com.

Clinical evidence supporting the use of 3M™ Prevena™ Therapy is growing

Peer-reviewed meta-analysis of 16 studies across various plastic surgery procedures demonstrated **Prevena Therapy helped significantly reduce the risk of various surgical site complications (SSCs) compared to the standard of care while helping to improve health economic outcomes.**[13]

Reduced clinical complication risk:

47% — **Surgical site complications**
11 studies; $p<0.001$**

24% — **Surgical site infections**
8 studies; p=0.113

31% — **Seromas**
8 studies; $p=0.358$

53% — **Dehiscence***
9 studies; $p=0.001$**

54% — **Skin necrosis***
5 studies; $p=0.002$**

157.5ml — **Drainage***
4 studies; $p<0.069$**

35% — **Reoperation**
8 studies; $p=0.074$

0.9 days — **Hospital length of stay**
5 studies; $p<0.001$**

For more clinical evidence, scan the code below to visit our clinical evidence compendium.

*The use of Prevena Therapy for the reduction in the incidence of dehiscence, necrosis, and drainage has not been reviewed by the U.S. FDA.
**Statistically significant ($p < 0.05$).
Calculation(s) are derived based on the relative patient group incidence rate reported in this study.

Rethink incision management

3M™ Prevena™ and Prevena Restor™ Dressings help protect the incision while providing even distribution of negative pressure therapy to help reduce the risk of complications, optimize the healing environment, and enhance the recovery experience.

Prevena Dressings and Prevena Restor Dressings can be applied to various procedures and anatomical locations.

3M™ Prevena™ Dressings

Linear Coverage

Prevena Dressings help protect and manage the environment of closed surgical incisions and remove fluid away from the surgical incision via the application of continuous negative pressure.

Linear coverage

Designed to manage linear, intersecting, and multiple incisions

Pre-shaped designs for peel and place application

3M™ Prevena™ Peel and Place Dressing – 13 cm

3M™ Prevena™ Peel and Place Dressing – 20 cm

3M™ Prevena™ Plus Peel and Place Dressing – 35 cm

Designed for flexibility and user customization

3M™ Prevena™ Customizable Dressing

Designed to perform for you and your patients

Acts as a barrier
Designed to minimize external contamination to help reduce surgical site complications

Precision designed
Dressings seamlessly conform to the patient for even distribution of negative pressure and allows for patient movement

Easy to use
A variety of peel and place dressings are available, plus customizable options

Shower-friendly
See Prevena Therapy Patient and Clinician Guides for additional details

3M™ Prevena Restor™ Dressings

Area Coverage

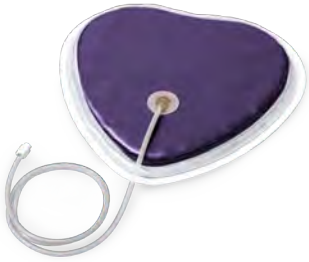
Prevena Restor Dressings offer comprehensive protection for a variety of anatomical locations. When combined with negative pressure, the dressings help provide stabilization of the incision and protect the surgical site and surrounding soft tissue.

Expanded coverage area
Designed to extend coverage and manage the surgical site and surrounding soft tissue envelope

Pre-shaped designs for peel and place application

3M™ Prevena Restor™ Arthro•Form™ Dressing

3M™ Prevena Restor™ Axio•Form™ Dressing



3M™ Prevena Restor™ Bella•Form™ Dressing

Designed for flexibility and user customization

3M™ Prevena Restor™ Adapti•Form™ Dressing

The power behind 3M™ Prevena™ Therapy

3M™ Prevena™ Plus 125 Therapy Unit

One single-use negative pressure therapy unit compatible with all 3M™ Prevena™ Dressings.

Negative pressure features:

- Pre-set, continuous negative pressure therapy at -125 mmHg for up to 7 or 14 days (with dressing changes every 7 days)
- Disposable, single patient use
- Rechargeable battery

Specifications:

- Dimensions: Approx 8.9 × 16.3 × 5.49cm
- Weight with empty canister: 0.64lbs (0.29kg)

Prevena Dressings are also compatible with 3M traditional negative pressure therapy devices: 3M™ V.A.C.® Ulta Therapy Unit, 3M™ ActiV.A.C.® Therapy Unit

Proactive Risk Management with 3M™ Prevena™ Incision Therapy

Proactive Risk Management (PRM) with Prevena Therapy provides healthcare professionals with an evidence-based, standardized approach that helps to advance the standard of care for closed incision negative pressure therapy.

Prevena Central

Prevena Central is your one-stop platform for all things Prevena Therapy. Designed with busy healthcare professionals in mind, Prevena Central provides incision management resources that help advance the standard of care. **Visit 3M.com/PrevenaCentral** for more information.

For more information about implementing PRM in your practice, contact your 3M representative.

Additional customer resources:

- Live clinical training and product support thousands of healthcare professionals trained annually
- Product evaluation program
- Clinical and reimbursement support hotlines
- Centralized, on demand clinical and technical support

Ordering Information

SKU	Description	UOM
Therapy Devices		
PRE4000US	3M™ Prevena™ Plus 125 Therapy Unit – 7 day	Each
PRE4010	3M™ Prevena™ Plus 125 Therapy Unit – 14 day	Each
Dressings		
PRE1155US	3M™ Prevena™ Peel and Place Dressing – 13 cm	Case of 5
PRE1055US	3M™ Prevena™ Peel and Place Dressing – 20 cm	Case of 5
PRE3255US	3M™ Prevena™ Plus Peel and Place Dressing – 35 cm	Case of 5
PRE4055US	3M™ Prevena™ Plus Customizable Dressing	Case of 5
PRE5055	3M™ Prevena Restor™ Arthro•Form™ Dressing – 33 cm x 30 cm	Case of 5
PRE5155	3M™ Prevena Restor™ Arthro•Form™ Dressing – 46 cm x 30 cm	Case of 5
PRE5255	3M™ Prevena Restor™ Bella•Form™ Dressing – 21 cm x 19 cm	Case of 5
PRE5355	3M™ Prevena Restor™ Bella•Form™ Dressing – 24 cm x 24 cm	Case of 5
PRE5455	3M™ Prevena Restor™ Bella•Form™ Dressing – 29 cm x 27 cm	Case of 5
PRE5555	3M™ Prevena Restor™ Axio•Form™ Dressing – 29 cm x 28 cm	Case of 5
PRE6055	3M™ Prevena Restor™ Adapti•Form™ Dressing – 49 cm x 28 cm	Case of 5
Accessories		
PRE1095	3M™ Prevena™ 45 ml Canister	Case of 5
PRE4095	3M™ Prevena™ Plus 150 ml Canister	Case of 5
44001674	3M™ Prevena™ Plus 125 Therapy Unit Power Supply (available if needed)*	Each
413628	3M™ V.A.C.® Therapy System Power Cord (available if needed)*	Each
Kits		
PRE1001US	3M™ Prevena™ Incision Management System – 20 cm	Each
PRE1101US	3M™ Prevena™ Incision Management System – 13 cm	Each
PRE3201US	3M™ Prevena™ Plus Incision Management System – 35 cm	Each
PRE4001US	3M™ Prevena™ Plus Customizable Incision Management System	Each
PRE1121US	3M™ Prevena™ Duo Incision Management System – 13 cm/13 cm	Each
PRE3321US	3M™ Prevena™ Plus Duo Incision Management System – 13 cm/20 cm	Each
PRE5001	3M™ Prevena Restor™ Arthro•Form™ Incision Management System – 33 cm x 30 cm	Each
PRE5101	3M™ Prevena Restor™ Arthro•Form™ Incision Management System – 46 cm x 30 cm	Each
PRE5221	3M™ Prevena Restor™ Bella•Form™ Incision Management System – 21 cm x 19 cm	Each
PRE5321	3M™ Prevena Restor™ Bella•Form™ Incision Management System – 24 cm x 24 cm	Each
PRE5421	3M™ Prevena Restor™ Bella•Form™ Incision Management System – 29 cm x 27 cm	Each
PRE5501	3M™ Prevena Restor™ Axio•Form™ Incision Management System – 29 cm x 28 cm	Each
PRE6001	3M™ Prevena Restor™ Adapti•Form™ Incision Management System – 49 cm x 28 cm	Each

*Both 44001874 and 413628 are required to recharge the Prevena Plus Therapy Unit.

See why 3M™ Prevena™ Therapy is trusted by surgeons to help protect patients beyond the OR.

For more information or to request an evaluation, contact your 3M representative or visit 3M.com/PrevenaCentral.

Note: Specific indications, limitations, contraindications, warnings, precautions and safety information exist for these products and therapies. Please consult a clinician and product instructions for use prior to application. Rx only.

References:

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