

COMMON COMPLAINTS WITH SKIN CLOSURE SYSTEMS

1. Blistering of the Skin

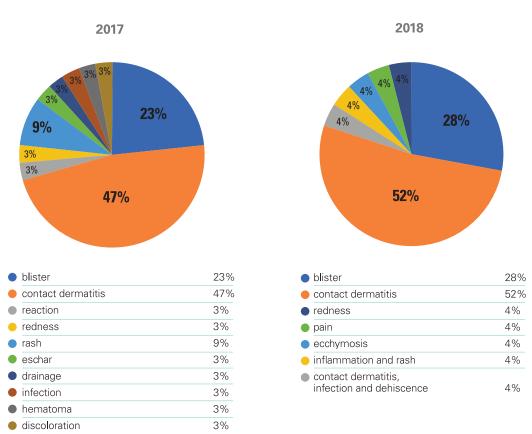
- 2. Allergic Reactions and Redness of Skin
- 3. Mesh Releasing from Skin Prematurely

FDA Maude Database Reporting

After separating out the MAUDE database reports, blistering is a significantly larger issue with mesh + adhesive type devices than with the topical skin adhesive devices. Blisters are reported as co-symptoms for both skin closure systems and topical skin adhesives, mainly alongside contact dermatitis for both device types.

Standalone blistering is reported more consistently as an adverse event with skin closure systems (>20% of reports in 2017 and 2018). The major differences between the two devices are the addition of a polyester mesh AND where the accelerant is located within the device.

Medical Conditions Where Blisters Were Reported



IT STARTS WITH THE MESH

Initiator free mesh for less patient exposure.

exofin fusion® system removes all initiators from the mesh itself to reduce patient exposure. Instead, the initiator is delivered with the polymerized adhesive.

Extracted samples showed a **61% REDUCTION** in the amount of initiator that the patient could be exposed to.



KEEPING MESH ON THE SKIN

The **exofin fusion**® mesh pattern has larger openings which allow more adhesive to flow through the mesh and on to the patient's skin. The more open design allows the adhesive to create a stronger bond on the skin and keep the mesh secure and in place for the desired amount of time.

Unlike the competition, the **exofin fusion**® adhesive will polymerize (dry) on the patient's skin even if it is not directly on the mesh. This eliminates the need to clean up the wet adhesive that tends to get on surrounding areas during application.

Lastly, measured amounts of adhesive have been added to the kit providing just the right amount of adhesive for each size of mesh.



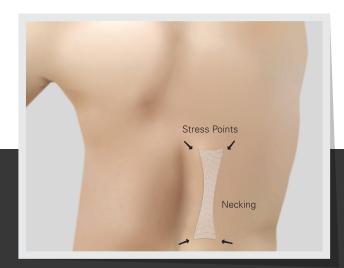
REDUCING SKIN STRESS & STRAIN

The traditional design of skin closure systems lend themselves to stress between the highly elastic skin and the rigid polyester mesh. Straight lines can cause friction to occur where stress points are located, and are typically in the four corners.

The shape of the Exofin Fusion mesh features curved ends. This reduces the area that is under stress and dissipates the friction and force across the entirety of the material.

Mesh Under Stress - Traditional Design

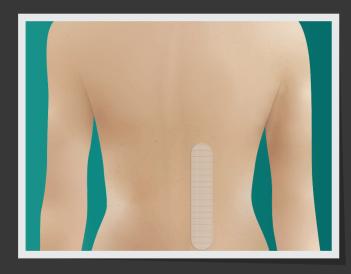


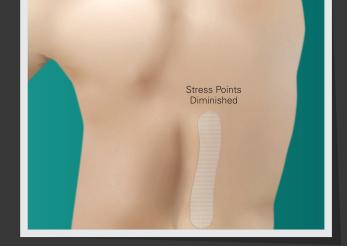


When Applied

Stretched

Mesh Under Stress - Curved Mesh Design





When Applied

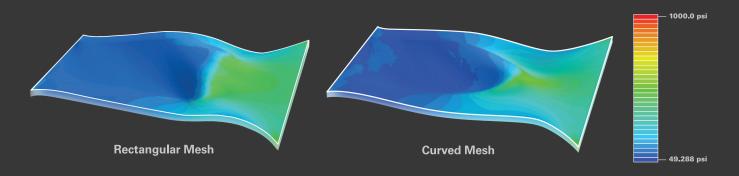
Stretched

THE SHAPE OF THINGS TO COME



Substantial Reduction in Skin Stress*

Strain = 33.3% (Model Length 152.44mm)



	RECTANGULAR MESH	CURVED MESH	REDUCTION (%)
High Stress Area (mm²)	1258	417	66.8%
Max Stress (psi)	933	730	21.8%
Total Force (lbf)	1913	1095	42.8%

NEW PRODUCT

exofin fusion® 30cm

Longer mesh which is ideal for the orthopedic area of the hospital. Great for use on **Total Knee Replacement** procedures.

Blisters can occur when mesh is too short for the patient, especially obese patients.

Longer mesh gives enough slack at both the proximal and distal ends to reduce force on skin when at 90-degree angle during rehab.

Longer mesh eliminates the need to use multiple 22cm devices.

No cutting and overlapping required when adding additional mesh strip.

Cost savings versus 60cm.

Contact your local representative for evaluation samples.



ORDER INFORMATION

PRODUCT CODE #	PRODUCT DESCRIPTION	CONTENTS	DIMENSIONS	CUBE	WEIGHT
		(Quantity)	(LxWxH)	(FT³)	(LBS/OZ)
	Skin Closure System				
M1222	exofin fusion® Skin Closure System 22cm	2 Systems	13.125 x 4.125 x 4.5	0.141	0.4 lb
M1230	exofin fusion® Skin Closure System 30cm	2 Systems	13.125 x 4.125 x 4.5	0.141	0.4 lb
M1244	exofin fusion® Skin Closure System 60cm	2 Systems	13.125 x 4.125 x 4.5	0.141	0.4 lb



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