AUSTRALIAN WOUND & SKIN ALLIANCE

Silicones in Wound Dressings

Dr Timothy Hughes, CSIRO Manufacturing

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Australia's National Science Agency



CSIRO Biomedical Manufacturing

To assist Australian Biotech and Medtech companies and academia in their growth strategies.

New products and processes for the biomedical sector – medical devices, diagnostics, drugs, vaccines, and efficient processes to produce them.



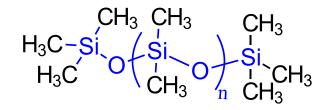


- I am not a clinician or a wounds expert
- Images of commercial products have been used as examples only
- No positive or negative recommendations for any specific products are made
- I am providing general information only

Properties of Silicones

• Silicone (aka siloxanes) are polymers of repeating silicon and oxygen atoms

Polydimethylsiloxane (PDMS)



Advantages

- Liquid, crosslinked to make a solid
- Chemically resistant (stable)
- High thermal stability
- Electric insulator
- High contact angle/low surface energy
- High gas/vapour permeability
- Inherently hydrophobic

Disadvantages

- Poor tear strength
- Harder to bond to other materials
- Relatively expensive

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soft, flexible, elastic, compliant chemical inertness biostable

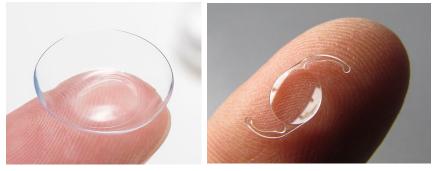
non adherent (wet tissue) high vapour/O₂ transfer non-wetting, water beads

Disadvantages

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Contact Lenses/IOLs



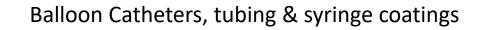
Implants

Electronic Encapsulants



Prostheses

Breathing Masks



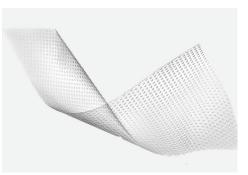


Due to their unique and desirable properties, silicones have found broad applications in medical devices

Silicones in Wound Dressings



Silicone adhesives Pressure sensitive Adhesives (PSA) (e.g. NuSil, Wacker etc)



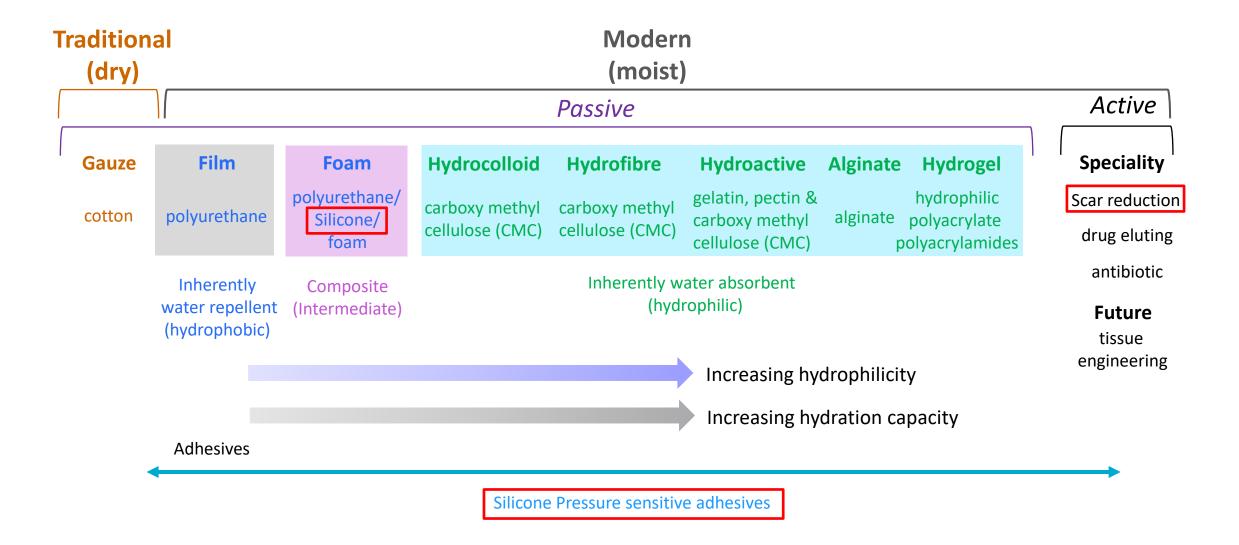
Non-adherent layers (e.g. Coloplast Biatain Contact)



Silicone gel sheets Reduce scar formation (burns) (e.g. Smith+Nephew Cica-care)

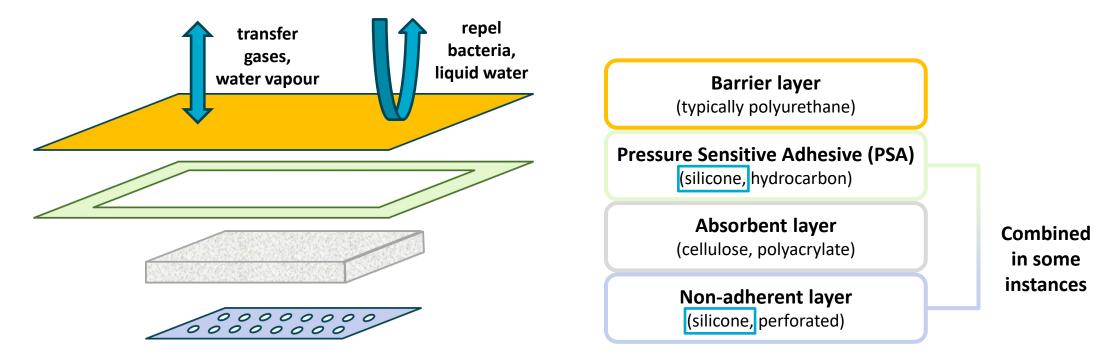
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Classification of Wound Dressings based upon Composition



Foam Dressings are Composites

- Commercially available wound dressing are made of multiple materials/layers
- Laminar composites, may be described by one component, but they are often multiple materials



What are manufactures and authors referring to as <u>Silicone Foam Dressings</u>?

• Non-adherent layer, adhesives or both?



Zetuvit Plus Silicone Border (an example)

Instructions for use

Product description

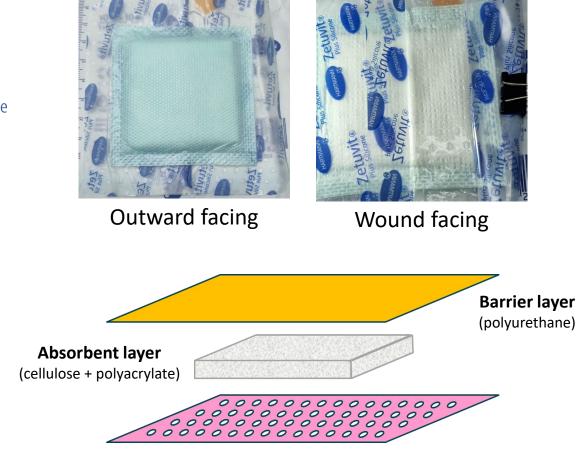
Zetuvit Plus Silicone Border is a sterile self-adhesive superabsorbent dressing with a silicone interface for the treatment of moderately to heavily exuding, chronic and acute wounds. The silicone layer in contact with the wound allows easy application and almost painless, atraumatic removal. The absorbent pad absorbs and retains the exudate.

Composition

Zetuvit Plus Silicone Border comprises a semi-permeable polyurethane backing film, a perforated silicone film towards the side facing the wound and an absorbent pad in between those two layers. Acrylic adhesive is used to bind these layers together. The backing film is permeable to air but waterproof, which allows the patient to shower. The perforated silicone film facing the wound side facilitates the application of the dressing and promotes non-adherence to the wound. The absorbent pad comprises cellulose and superabsorbent polyacrylate for the absorption and retention of exudate and is wrapped in a <u>hydrophilic cellulose tissue</u>. It is covered with a <u>hydrophobic green nonwoven</u> (100% Polypropylene) to indicate the side facing away from the wound. On the other side, the product features a very soft, white, hydrophilic nonwoven (viscose and polyamide).

Properties and mode of action

Zetuvit Plus Silicone Border absorbs exudate and retains it in the absorbent pad. It features a micro-adherent, a silicone interface and borders, so no additional materials are required to secure the dressing. The backing film is bacteria and showerproof. The dressing changes can be carried out atraumatically and almost painlessly.



Non-adherent layer / Pressure Sensitive Adhesive (PSA) (silicone, perforated)

Further Example Foam Dressings

All are described as foam dressings with silicone adhesive/interfaces but there are structural differences:

Some have an adhesive centre and border



Zetuvit Plus Silicone Border (Hartman)



Hydrocellular Foam Dressing (Baremedical)



Biatain Silicone Lite (Coloplast)

As clinical performance is likely to be influence by structure and composition, is it correct to refer to them as a single grouping?

Some have adhesive over foam but no border



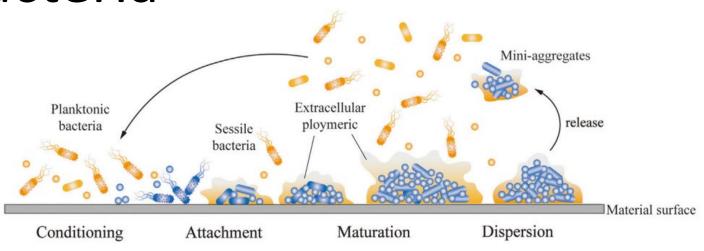
Silicone Foam Dressing Non-Border (KIS)

Some have no adhesive over the centre, but have adhesive over outer edge of foam



Aquacel Ag (Convatec)



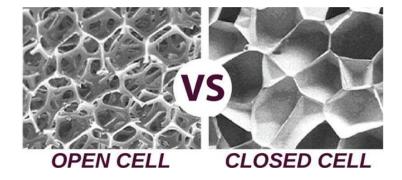


- Bacteria can grow on silicone
 - Bacteria can also grow on many polymers
- Bacteria can form biofilms on polymers, which can lead to infections
 - Antibacterial agents incorporated in wound dressing to reduce infections
- Are silicones more or less prone to bacterial growth than other polymers?
 - Difficult to say, limited unbiased clinical studies between silicone and non-silicone wound dressings to draw conclusions from
 - Confounded by many types of wounds, bacteria, and dressings

Exudate Absorption in the Absorbent Layer

• Open Pore vs Closed Pore Foams

Open pore/cell enables transfer of fluid



• Inherently hydrophilic vs Inherently hydrophobic

| Mator in poros | Water in | innerently hydrophilic |
|----------------|------------|----------------------------|
| Water in pores | vvalet III | materials have much higher |
| & material | pores only | • |
| | • • | water absorption capacity |

Inhorontly by drophilio

- Once the absorption capacity is reached, no more exudate can be absorbed
- Potential higher risk of maceration for foam type dressings
 - As exudate is sealed in barrier layer

Silicones as Non-Adherent Layers

- Purpose
 - Stop cellular ingrowth/wound adhesion into absorbent layer
 - Reduce pain upon dressing removal
- Taking advantage of silicone's properties
 - Soft, compliant material
 - Relatively low cell attachment to wet silicone
 - Thin perforated film to allow fluid transfer
 - Silicones are hydrophobic, water beads on silicones
 - Silicones have high oxygen permeability
 - But the hydrated absorbent foam is likely to counter this advantage



Higher magnified image of perforated silicone interface layer on top of absorbent layer

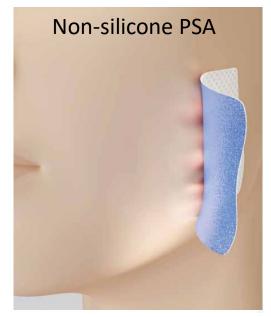


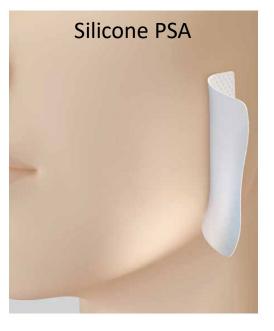
Pressure Sensitive Adhesives (PSA)

- Forms reversible adhesion to dry skin with pressure
- Viscoelastic materials (materials that exhibit both liquid and solid properties)
- Under pressure they can flow but stop moving once pressure is removed
- Can be made from natural and synthetic rubbers, acrylics and silicones

Silicone PSA

- Gentle, flexible, and breathable
- Biocompatible, hypoallergenic and low irritation to skin
 - Typically, better than non-silicone PSAs which have more additives
- Removable (cleanly), typically less force than non-silicone PSAs







- Silicones have unique properties which make them applicable to many medical device applications
 - Safe and effective in numerous medical devices
- Silicone foam dressings are varied in composition and structure
 - Perhaps shouldn't be treated as a single grouping
- Silicones play a key role in wound dressings
 - As non-adherent layers to reduce wound adhesion resulting in reduced pain upon dressing exchange
 - As pressure sensitive adhesives enabling reversible adhesion of wound dressings to skin
- Foam dressings may need to be exchanged before the absorbent layer reaches saturation
 - To reduce the risk of excess fluid in the wound and potential maceration

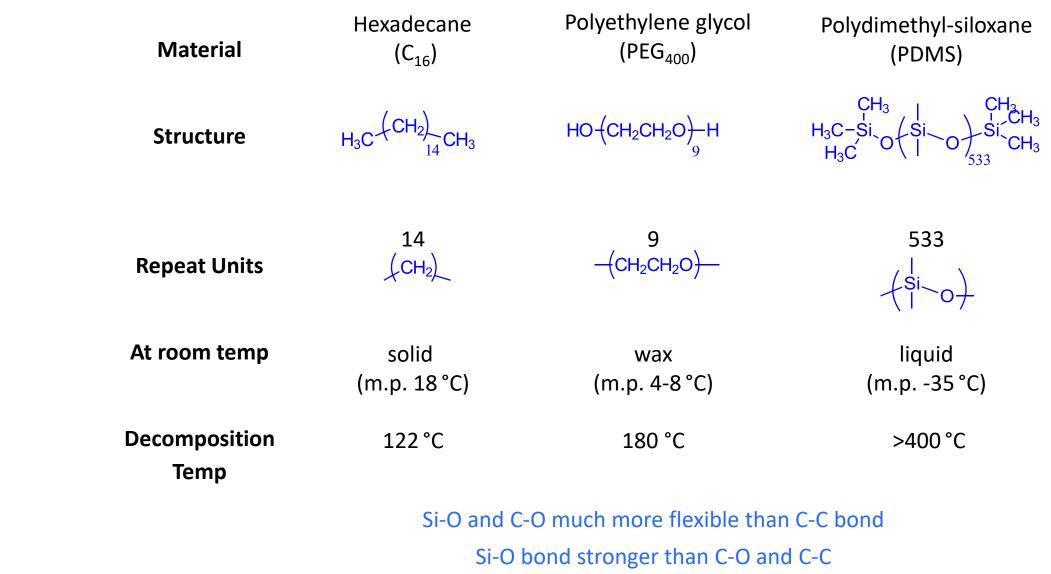


Thank you

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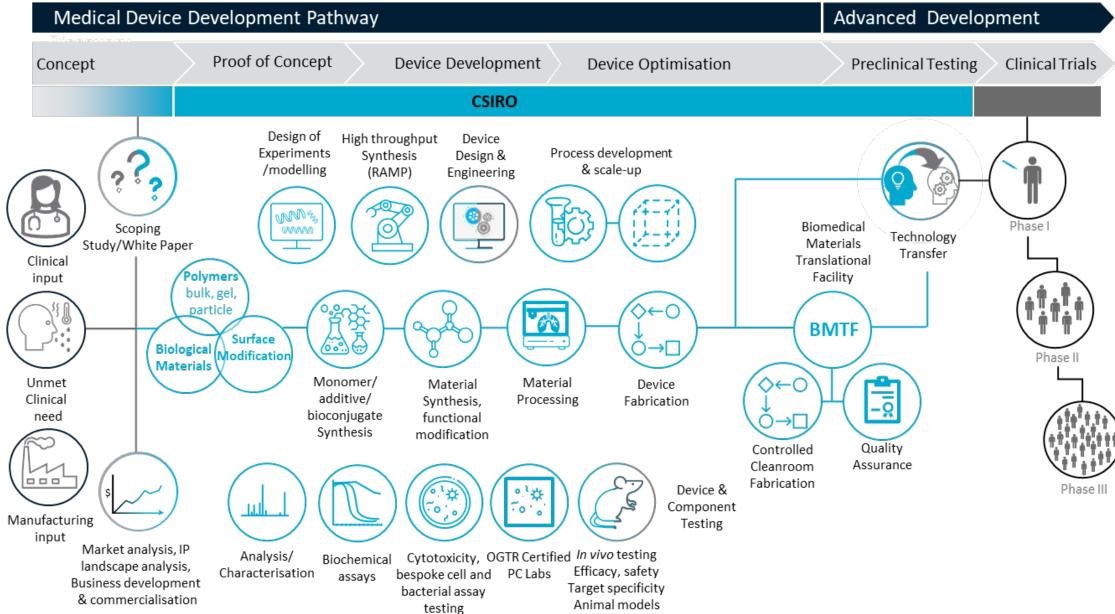
Comparison: Silicones to Hydrocarbons





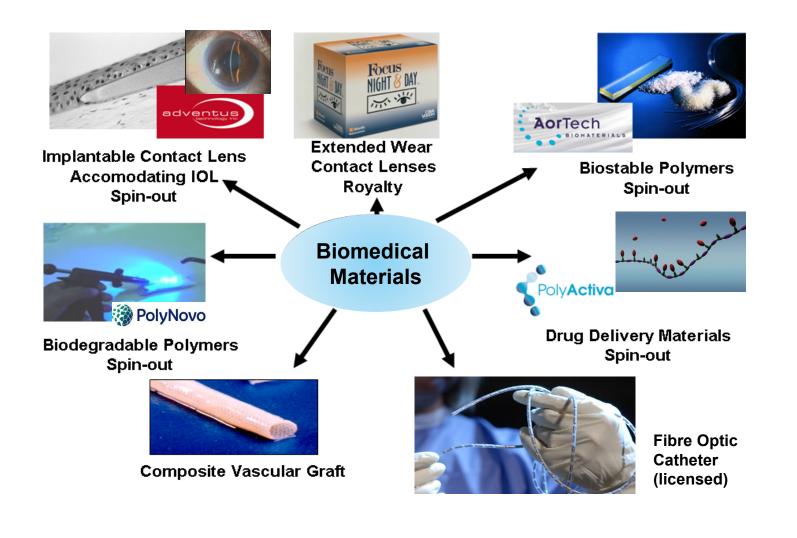
Working with us: Biomedical Manufacturing

Our comprehensive medical device capabilities



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Our Track Record in Biomaterials & Medical Devices





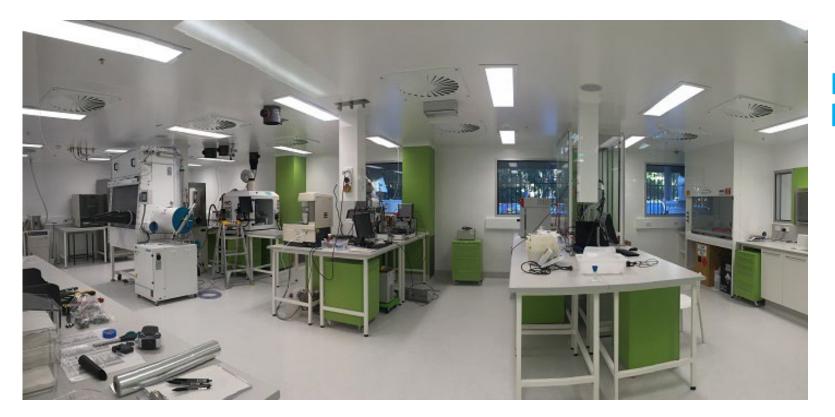
3D printed titanium sternum and ribs. © http://www.anatomics.com/





Titanium ankle bone implant made using CSIRO's state-ofthe-art Arcam 3D printer. Image courtesy Anatomics

Biomedical Materials Translational Facility



Facilities include cleanroom labs for:

- Wet Chemistry
- Polymer Synthesis & Processing
- Surface Modification
- Device Fabrication
- Ceramic Biomaterials
- Cell Biology



