

# Topical Surgical Sealants FACTSHEET

## 1. What is it?

Topical surgical adhesives are available to assist haemostasis in the surgical setting. These vary from sealants and glues to medicated sponges. Most fibrin sealants and medicated sponges are derived from human blood products. Fibrin sealant can also be made from the patients' own blood. Fibrin glues are usually not derived from human blood products but are synthetic based. The list of products below is by no means exclusive however it does illustrate the variety of products currently available for use

## 2. Current Products Available in UK

Composition	Product	Company	Type
Human fibrinogen and thrombin, Tranexamic acid	Quixil	Johnson & Johnson <a href="http://www.jnj.com">http://www.jnj.com</a>	Fibrin Sealant
Human fibrinogen and thrombin	Evicel	Johnson & Johnson <a href="http://www.jnj.com">http://www.jnj.com</a>	Fibrin Sealant
Human fibrinogen and thrombin, bovine aprotinin	Tisseel	Baxter international <a href="http://www.baxter.com">http://www.baxter.com</a>	Fibrin Sealant
Human fibrinogen and thrombin, equine collagen, human albumin	Tachosil	Nycomed <a href="http://www.nycomed.com/en/menu/">http://www.nycomed.com/en/menu/</a>	Medicated Sponge
Purified bovine serum albumin and gluteraldehyde	BioGlue	Cryolife <a href="http://www.cryolife.com/home">http://www.cryolife.com/home</a>	Surgical adhesive
Patients own blood	Vivostat	Vivolution <a href="http://www.mediconvalley.com/">http://www.mediconvalley.com/</a>	Autologous Fibrin Sealant

*NB. Products containing components derived from human blood products. Manufacturers take steps to reduce virus contamination through donor selection, virus testing of each donation and heat treatment of the human fibrinogen, but the possibility of these products passing on infection cannot be totally excluded.*

## 3. Licensed use/contraindications of these products

Product	Licensed Use	Contraindication
<b>Quixil</b>	To improve haemostasis and reduce operative and post operative bleeding and oozing in liver and orthopaedic surgery. Support of haemostasis in which standard surgical techniques are inadequate	Should not be used in procedures in which contact with the CSF or dura matter could occur
<b>Evicel</b>	As above and additional licence for suture support in vascular surgery	Evicel is not contraindicated in Neuro or spinal procedures
<b>Tisseel</b>	<p><b>Haemostasis</b> - for use as an adjunct to haemostasis in surgery involving cardiopulmonary bypass and treatment of splenic injuries. Satisfactory for use in fully heparinised patients undergoing cardiopulmonary bypass</p> <p><b>Sealing</b> - for use as an adjunct in the closure of colostomies</p>	<p>Contraindicated in patients that have known hypersensitivity to bovine aprotinin</p> <p>Must not be injected directly into the circulatory system</p> <p>Tisseel is not contraindicated in Neuro or spinal procedures</p>

Product	Licensed use	Contraindications
<b>TachoSil</b>	Is indicated for supportive treatment in surgery for improvement of haemostasis where standard techniques are insufficient	Allergic type hypersensitivity reaction possible Thromboembolic complications may occur if applied intravascularly
<b>Vivostat</b>	Any surgical setting including neurosurgery	Patient need to be at least 18kg to safely remove the 120mls of blood to make the product. It can also be used in paediatric patients where plasma is removed instead of blood
<b>Bio Glue</b>	All parenchyma tissue	Contraindicated in patients that have known hypersensitivity to bovine albumin. Must not be injected directly into the circulatory system

#### 4. Research Based Evidence of Uses in Specific Surgical Specialties

- Autologous platelet gel and fibrin sealants may be effective in reducing peri-operative blood loss in orthopaedic surgery<sup>1</sup>
- Routine usage of surgical adhesives and glues in patients having lung resections cannot yet be recommended however they may be useful in selected situations<sup>2</sup>
- Fibrin sealants are safe and effective for use as an adjunct to haemostasis in patients undergoing cardiac surgery<sup>3</sup>
- Fibrin sealants are mostly used in vascular surgery to control anastomotic bleeding<sup>4</sup>
- In tonsillectomies fibrin sealants/glues have been shown to be effective both as a haemostatic agent but also in reducing pain following a tonsillectomy<sup>5</sup>

A paper from 2006 evaluating the differences between fibrin sealants is referenced<sup>6</sup>

#### 5. References

1. Lessen MR, Solar S, Kjersgaard AG, Olsen C, Lind B, Mittet K, Ganesh HC. A pilot study of the effects of Vivostat patient-derived fibrin sealant in reducing blood loss in primary hip arthroplasty *Clinical & Applied thrombosis/Haemostasis* 12 (3);352-7, 2006
2. J Tambiah, R Rawlins, D Robb, T Treasure. Can tissue adhesives and glues significantly reduce the incidence and length of postoperative air leaks in patients having lung resections? *Best Evidence Topics*, October 2007
3. Lowe J, Lubner J, Levitsky S, Hantak E, Montgomery J, Schiestl N, Schofield N, Marra S, TISSEEL Clinical Study Group. Evaluation of the topical haemostatic efficacy and safety of TISSEEL VH S/D fibrin sealant compared with currently licensed TISSEEL VH in patients undergoing cardiac surgery: a phase 3, randomized, double-blinded clinical study. *Journal of Cardiovascular surgery*. 48(3):323-31, 2007 Jun
4. Stephens J, Robless P, Jenkins M, Cheshire N. Re: Does fibrin glue reduce complications after femoral artery surgery? A randomized trial. (comment) Comment on: *Eur J Vasc Endovasc Surg*. 2002 Sep; 24 (3): 196-201; PMID 12217279
5. Vaiman M, Eviatar E, Shlamkovich N, Segal S. Effect of modern fibrin glue on bleeding after tonsillectomy and adenoidectomy *Annals of Otolaryngology, Rhinology & Laryngology* 112(5) 410-4.
6. Tredree R, Beierlein W, Debrix I, Eisert A, Goffredo F, Gomez de Salazar E, Rambourg P, Saint-Remy JM, Sturm C, Watson N. Evaluating the differences between fibrin sealants: Recommendations from an international advisory panel of hospital pharmacists. *The European Journal of Hospital Pharmacy Science* Volume 12, 2006 issue 1 3-9

The information contained in this factsheet is accurate and up to date at the time of publication. We do not accept any responsibility for any errors and omissions.

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