Baxter

What would your Active Haemostasis strategy be for Matthew?

As the population ages, surgical complexity increases due to accumulation of comorbidities[1]

At least **62%** of adults **aged 65-74** have multiple comorbidities[1]

Prevalence of multiple comorbidities increases to **>80%** in adults aged **≥85**[1]

The population aged 65 and over will more than double by 2060[2]

Many patients have comorbidities or use medications that can compromise their coagulation status

1 in 7
adults have renal failure[3]

30%
of the US population use low-dose aspirin for CVD prevention[4]

1 in 50
adults have liver disease[5]

1 in 3
adults will be diagnosed with cancer in their lifetime[6]

Active adjunctive haemostats are more effective than passive haemostats[7-9]

	Active	Passive
Function independently of the patient's ability to generate clotting factors to achieve haemostasis	✓	✗
Effective regardless of coagulation status	✓	✗
Effective across a wide range of bleeding	✓	✗

A compromised coagulation status increases the risk of intraoperative bleeding complications[10]

Active haemostatic products are available as flowables, fibrin sealants or advanced patches

Active haemostatic products

Flowables
(thrombin + gelatin)

Fibrin sealant

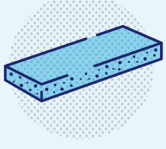
Advanced patches
with PEG or fibrin sealants

Passive haemostatic products

Oxidised cellulose

Collagens

Powders



Gelatin sponges

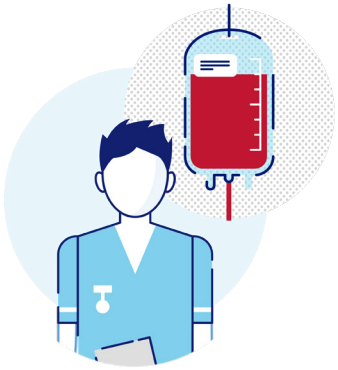
Polysaccharide spheres

Use of an active haemostat could significantly improve clinical outcomes and help hospitals save money[8,13]

Compared with a passive haemostat, use of an active haemostat can result in:

3x
faster haemostasis
in mild-to-moderate bleeding, regardless of coagulation status and initial bleeding rate[12]

24 mins
shorter operative time in CV procedures[11]



67%
lower revision rate in CV procedures[8]

53%
lower transfusion rate in CV procedures[8]

38%
reduction in minor complications in CV procedures[8]

£4.57m GBP*
annual net savings
with exclusive use of active haemostats in CV procedures[11]
(*$5.38m converted to GBP. 1 USD = 0.85 GBP)

References
1. Salive ME. Multimorbidity in older adults: prevalence and implications, Epidemiol Rev., 2013, vol. 35 (pg. 75-83); **2**. Mather M, Jacobsen LA, Pollard KM. Aging in the United States. Population Bulletin 70, 2015. Available at: https://www.prb.org/wp-content/uploads/2016/01/aging-us-population-bulletin-1.pdf (accessed January 2020); **3**. Centers for Disease Control and Prevention. Chronic Kidney Disease Surveillance System. Available at: https://nccd.cdc.gov/ckd/default.aspx (Accessed January 2020); **4**. Stuntz M, Bernstein, B., Recent trends in the prevalence of low-dose aspirin use for primary and secondary prevention of cardiovascular disease in the United States, 2012–2015, Preventive Medicine Reports. 2017; vol. 5 (pg.183–186); **5**. Centers for Disease Control and Prevention. Chronic Liver Disease and Cirrhosis. Available at: https://www.cdc.gov/nchs/fastats/liver-disease.htm (Accessed January 2020); **6**. American Cancer Society. Facts & Figures 2019: US Cancer Death Rate has dropped 27% in 25 Years, Jan 2019. Available at: https://www.cancer.org/latest-news/facts-and-figures-2019.html (Accessed January 2020); **7**. Slezak P, et al. A Comparative Efficacy Evaluation of Recombinant Topical Thrombin (RECOTHROM®) With A Gelatin Sponge Carrier Versus Topical Oxidized Regenerated Cellulose (TABOTAMP® /SURGICEL®) In A Porcine Liver Bleeding Model. Journal of Investigative Surgery. 2020; DOI: 10.1080/08941939.2019.1705444; **8**. Nasso G, et al. Prospective, Randomized Clinical Trial of the FloSeal Matrix Sealant in Cardiac Surgery, The Annals of Thoracic Surgery. 2009; vol. 88, issue 5, (pg.1520–6); **9**. Bracey A, et al. The Use of Topical Hemostatic Agents in Cardiothoracic Surgery, The Annals of Thoracic Surgery. 2017; vol. 104, issue 1, (pg.353–60); 10. Corral et al. Health and economic outcomes associated with uncontrolled surgical bleeding: a retrospective analysis of the Premier Perspectives Database. ClinicoEconomics and Outcomes Research. 22 July 2015, vol. 7, (pg.409-421); **11**. Tackett SM, Sugarman R, Kreuwel HTC, Alvarez P, Nasso G., Hospital economic impact from hemostatic matrix usage in cardiac surgery, J Med Econ. 2014; vol. 17, (pg. 670–6); **12**. Chapman WC, Wren SM, Lebovic GS, Malawer M. Effective management of bleeding during tumor resection with a collagen-based hemostatic agent. The American Surgeon. 2002 Sep 1; vol. 68, issue 9, (pg.802-807). **13**. Price JS, Tackett S, Patel V. Observational evaluation of outcomes and resource utilization from hemostatic matrices in spine surgery. J Med Econ. 2015;18(10):777-86. doi: 10.3111/13696998.2015.1046879. Epub 2015 Jun 1. Erratum in: J Med Econ. 2016;19(3):315-7. PubMed PMID: 25934148.

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Adverse Events should also be reported to Baxter Healthcare Ltd, by email (vigilanceuk@baxter.com) or by phone (+44 (0)1635 206360).

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PRESCRIBING INFORMATION - TISSEEL Ready to use Solutions for Sealant

(Please consult the Summary of Product Characteristics before prescribing)

Composition: prefilled double chamber syringe containing deep frozen Sealer Protein Solution (with aprotinin) and Thrombin Solution (with Calcium Chloride Dihydrate). Sealer Protein Solution contains 91mg/ml human fibrinogen (clottable protein) and 3000 KIU/ml aprotinin. Thrombin Solution contains 500 IU/ml human thrombin and 40 µmol/ml per ml calcium chloride. Presentations of 1, 2 or 5ml in each chamber resulting in total volume of 2ml, 4ml or 10ml of sealant. **Indications**: Supportive treatment where standard surgical techniques are insufficient, for improvement of haemostasis, as a tissue glue to promote adhesion, sealing or as suture support, in gastrointestinal anastomoses, in neurosurgery where contact with cerebrospinal fluid or dura mater may occur and for mesh fixation in hernia repair, as an alternative or adjunct to sutures or staples. **Dosage and Route**: For epilesional (topical) use only. Use of TISSEEL is restricted to experienced surgeons who have been trained in the use of TISSEEL. A thin layer is applied under direct vision to the tissue surface where required. Dose depends on the indication, application method and number of applications. For tissue adherence, it is recommended that the initial application cover the entire intended application area. As a guideline for the gluing of surfaces, 1 pack of TISSEEL 2 ml will be sufficient for an area of at least 10cm^2. Tissue surface should be as dry as possible before application. Do not use pressurized air or gas for drying the site. Application can be repeated if necessary but avoid reapplication of TISSEEL to pre-existing polymerized TISSEEL. Apply by drops or spray as needed depending on indication. **Side effects**: See Summary of Product Characteristics for detail. Postoperative wound infections. Fibrin degradation products increased. Hypersensitivity/anaphylactic reactions, anaphylactic shock, paresthesia, bronchospasm, wheezing, pruritus, erythema. Sensory disturbance. Bradycardia, tachycardia. Axillary vein thrombosis, hypotension, haematoma, embolism arterial, air embolism, cerebral artery embolism, cerebral infarction. Dyspnoea. Nausea, Intestinal obstruction. Rash, urticaria, impaired healing. Pain in an extremity. Procedural pain, pain, increased body temperature, flushing, oedema. Seroma, angioedema. **Class reaction**: Air or gas embolism, see Precautions. **Precautions**: Life threatening thromboembolic complications may occur if unintentionally applied intravascularly. Apply with care in coronary artery bypass surgery due to increased risk of inadvertent intravascular application. Must not be injected into highly vascularized tissue, such as nasal mucosa. When spraying TISSEEL, changes in blood pressure, pulse, oxygen saturation and end tidal CO_2 should be monitored because of the possibility of occurrence of air or gas embolism. Air or gas embolism, tissue rupture, or gas entrapment with compression, which may be life-threatening, have occurred with the use of spray devices employing a pressure regulator to administer fibrin sealant at higher than recommended pressures and in close proximity to the tissue surface. When applying by spray, follow the instructions provided with the spray device, with particular reference to gas pressure and distance from the tissue surface. Do not administer with spray devices in enclosed body areas. Take risk of compressive complications into account when applying in confined spaces. Use with caution in patients with prior exposure to aprotinin. Caution in patients with bovine protein allergies. Infectious diseases due to the transmission of infective agents cannot be totally excluded. Use of TISSEEL and batch number should be recorded in patient's notes. Excessive clot thickness may negatively interfere with product efficacy and the healing process. Oxidised cellulose-containing preparations should not be used with TISSEEL. **Contraindications**: Do not apply intravascularly. Hypersensitivity to active substances or other components. Not for the treatment of active or spurting arterial or venous bleeding. Not for replacement of skin sutures intended to close surgical wounds. **Interactions**: Avoid solutions containing alcohol, iodine and heavy metals. **Overdose**: Not reported. Legal category: POM Basic NHS price: 2ml - £97.50; 4ml - £195.00; 10ml - £443.75. **Marketing Authorisation Number and Holder**: PL 00116/0627 Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk IP24 3SE, UK. **Date of preparation:** January 2019

PRESCRIBING INFORMATION – ARTISS

Please consult the Summary of Product Characteristics before prescribing

Name and composition: ARTISS Solutions for Sealant – one prefilled double chamber syringe containing Sealer Protein Solution (with aprotinin) deep frozen in one chamber and Thrombin Solution (with calcium chloride) deep frozen in the other chamber. Sealer Protein Solution contains 91mg/ml human fibrinogen (clottable protein) and 3000 KIU/ml aprotinin. Thrombin Solution contains 4 IU/ml human thrombin and 40µmol/ml calcium chloride. Presentations of 1, 2 or 5ml in each chamber resulting in total volume of 2ml, 4ml or 10ml of total volume of product ready for use. Contains human factor XIII co-purified with human fibrinogen in a range of 0.6 – 5 IU/ml. **Indication**: Hospital use only. A tissue glue to adhere / seal subcutaneous tissue in plastic, reconstructive and burn surgery, replacement or adjunct to sutures or staples. Adjunct to haemostasis on subcutaneous tissue surfaces. **Dosage and Route**: The use of ARTISS is restricted to experienced surgeons who have been trained in the use of ARTISS. For epilesional use. Dose individualised and governed by indication, application methods and number of applications. Guide – 1 pack ARTISS 2ml sufficient for an area at least 10 cm^2. Avoid excess granulation by applying only a thin layer. Surface of the wound should be as dry as possible. **Side effects**: See summary of product characteristics for detail. Risk of anaphylactic reaction. Intravascular injection may lead to life-threatening thromboembolic events. Hypersensitivity or allergic reactions. In isolated cases these reactions have progressed to severe anaphylaxis. Pruritus and skin graft failure. **Precautions**: Caution applying ARTISS using pressurised air or gas, not to be used with Easy Spray / Spray Set system in enclosed body areas. Any application of pressurised air or gas is associated with a potential risk of air or gas embolism, tissue rupture or gas entrapment with compression, which may be life threatening or fatal. Use spray device pressure within manufacturers recommended range, not exceeding 2.0 bars. Do not spray closer than 10-15 cm from tissue surface. Monitor blood pressure, pulse, oxygen saturation, end tidal CO_2 for possibility of occurrence of air or gas embolism. Not indicated for use where a fast clotting sealant is required, especially in cardiovascular surgery. Not for use in neurosurgery or gastrointestinal or vascular anastomoses. Excessive clot thickness may interfere with efficacy and wound healing. Care to prevent adhesion at undesired sites. Signs of hypersensitivity include hives, urticaria, tightness of chest, wheezing, hypotension, anaphylaxis. Risk of anaphylaxis increased if previous exposure to aprotinin. In event of hypersensitivity or anaphylaxis discontinue use and remove polymerised product from surgical site. Oxycellulose containing preparations may reduce ARTISS efficacy. Infectious diseases due to transmission of infective agents cannot be totally excluded. Use of ARTISS and batch number should be recorded in patient's notes. Carefully evaluate in patients with allergies to bovine proteins. **Contra-indications**: Not indicated to replace sutures intended to close surgical wound. Not for treatment of massive and brisk arterial or venous bleeding. Not for intravascular use. Hypersensitivity to active substances or excipients. **Interactions**: Avoid solutions containing alcohol, iodine and heavy metals. The effects of ARTISS on fertility have not been established. **Overdose**: No cases of overdose have been reported. **Legal Category**: POM Basic NHS price: 2ml kit - £97.50; 4ml kit £195; 10ml kit £443.75. Marketing Authorisation Number and Holder: ARTISS – PL 00116/0634, Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk. IP24 3SE. **Date of Preparation**: April 2018

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