GUIDELINES FOR THE USE OF FIBRIN SEALANTS
1.0 Policy Statements

1.1 Regional Health Authorities shall develop policies, processes and procedures for ordering, distribution and storage of Fibrin Sealants.

1.2 Regional Health Authorities shall develop a record keeping system which makes it possible to trace the blood product. The system shall document:
   1.2.1 Name of product.
   1.2.2 Lot number.
   1.2.3 Expiry date.
   1.2.4 Blood product identification number.
   1.2.5 Volume.
   1.2.6 Dosage and/or volume and number of vials, pre-filled syringes, or kits used.
   1.2.7 Date administered.

1.3 Regional Health Authorities shall develop a policy to ensure that informed consent of the recipient is obtained prior to transfusion or administration of blood components or blood products.

1.4 Fibrin Sealants shall be:
   1.4.1 Used only by a physician.
   1.4.2 Stored, transported and prepared according to the conditions specified in the manufacturer’s instructions. (See product monograph.)

1.5 Fibrin Sealants shall not be:
   1.5.1 Used to treat severe or brisk arterial bleeding.
   1.5.2 Used in the presence of infection.
   1.5.3 Mixed with other medicinal products.
   1.5.4 Used after expiry date.
   1.5.5 Used in individuals known to have anaphylactoid/anaphylactic or severe systemic reaction to human blood products, aprotinin or materials of bovine or porcine origin. (See General Information section for signs and symptoms of anaphylactoid, anaphylactic or severe systemic reaction.)

1.6 Fibrin Sealant vials, prefilled-syringes, and/or kits are single patient use only. Unused product shall be discarded.
1.7 Spray application devices shall be used within the pressure range and at a
distance recommended by the spray device manufacturer.

1.8 The completed blood product administration card shall be returned to the
Transfusion Medicine Laboratory following administration of Fibrin
Sealants as per facility policy.

1.9 All Regional Health Authorities shall develop a procedure to ensure that
recipients of blood components and/or blood products are notified in
writing. A process shall be in place to notify recipients that they received a
human plasma derived product.

*See product-specific monograph for full prescribing information.

2.0 Definitions

2.1 Blood Product: Therapeutic product derived from human plasma and
produced by a manufacturing process.

2.2 Fibrin Sealant: Human plasma derived products that may be used for one
or more of the following indications (see product monograph for product-
specific indication(s):
   1. As an adjunct to standard methods of surgical repair such as sutures,
      staples, electrocautery and/or patches.
   2. As an adjunct to hemostasis for use in patients undergoing surgery.
   3. As an adjunct to standard surgical techniques to prevent leakage from
      anastomoses.
   4. To seal or glue tissue.
   5. To support wound healing.
   6. To adhere autologous skin grafts to surgically prepared wound beds
      resulting from burns.

2.3 Informed Consent: Voluntary agreement given by a person or a patients’
responsible proxy (e.g. a parent) for participation in a study, immunization
program, treatment regimen, invasive procedure, etc., after being informed
of the purpose, methods, procedures, benefits, and risks.

2.4 Transfusion Medicine Laboratory: Hospital Blood Bank
3.0 General Information

3.1 Fibrin Sealants are prepared from human plasma.

3.2 Fibrin Sealants are treated by manufacturing processes such as vapor heat, solvent detergent, or pasteurization to reduce the risk of transmitting infectious disease. (Refer to product monograph for product-specific information.)

3.3 Fibrin Sealants should not be applied to application sites cleansed with alcohol, iodine or heavy metal ions. Contact with such substances can denature fibrin sealants. (Refer to product monograph for product-specific information.)

3.4 The safety and effectiveness of Fibrin Sealants has not been established for all patients. (See product monograph.)

3.5 Fibrin Sealants should not be injected intravascularly. (See product monograph for product-specific information.)

3.6 Physicians should consider maximum swell volume and the potential effects on surrounding anatomic areas when using Fibrin Sealants.

3.7 As with any plasma derivatives, anaphylactic or severe systemic reactions may occur. Signs and symptoms include: bradycardia, tachycardia, hypotension, flushing, bronchospasm, wheezing, dyspnea, nausea, urticaria, angioedema, pruritus, erythema and paresthesia.

3.8 Application of Fibrin Sealants using a spray device at pressures exceeding manufacturer recommendations may result in air/gas embolism.

3.9 Patients must be monitored for adverse transfusion events following administration of Fibrin Sealants.
4.0 Process or Procedure

4.1 Each facility shall develop a process for Fibrin Sealant labelling to ensure all blood products administered are traceable.

4.2 Each facility shall develop and maintain written policies and standard operating procedures to ensure that blood products are administered safely, for clinically appropriate conditions and are used according to manufacturer instructions.

4.3 Manufacturer’s instructions for reconstitution, preparation and administration shall be followed.

5.0 Records Management

5.1 The Transfusion Medicine Laboratory shall retain the recipient administration data file indefinitely.

5.2 All administration records in the recipient’s medical chart shall be retained in accordance with the health care facility policy.

5.3 Temperature monitoring records for blood products shall be retained a minimum of five years.

5.4 For each product issued, a record system shall be in place which documents:
   1. Recipient’s family and given names.
   2. Recipient’s identification number.
   3. Name of blood product.
   4. Lot number.
   5. Expiry date.
   6. Volume and/or potency.
   7. Manufacturer.
   8. Dosage/vials used.
   10. Date and time of issue.
   11. Identity of the person issuing the blood product.
   12. Identity of the person transporting the blood product to the recipient’s location.
5.5 Each facility shall have a record system that ensures a copy of all information relating to the patient and the administered blood product forms a permanent record for the patient. The record system shall be organized and maintained in such a way that it is possible to trace blood products from their distributor to final disposition (i.e. administration or destruction). The records system shall also provide a means to locate and access all records in the facility related to a given product.

6.0 References and Supporting Documents


