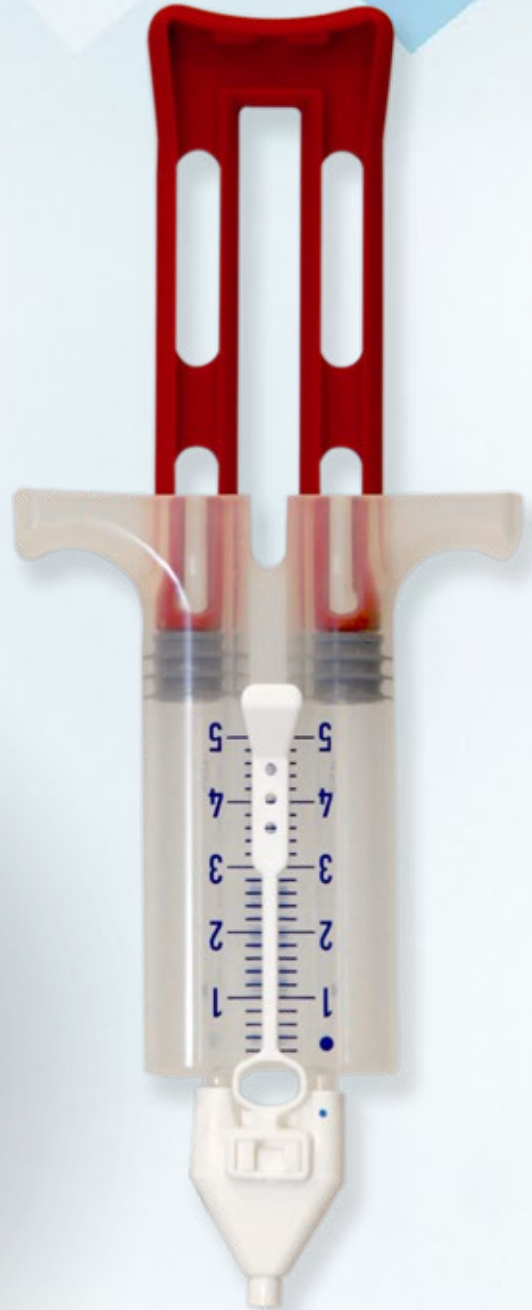




**TISSEEL**  
*[Fibrin Sealant]*

# THE ADVANTAGE HAEMOSTASIS & SEALING

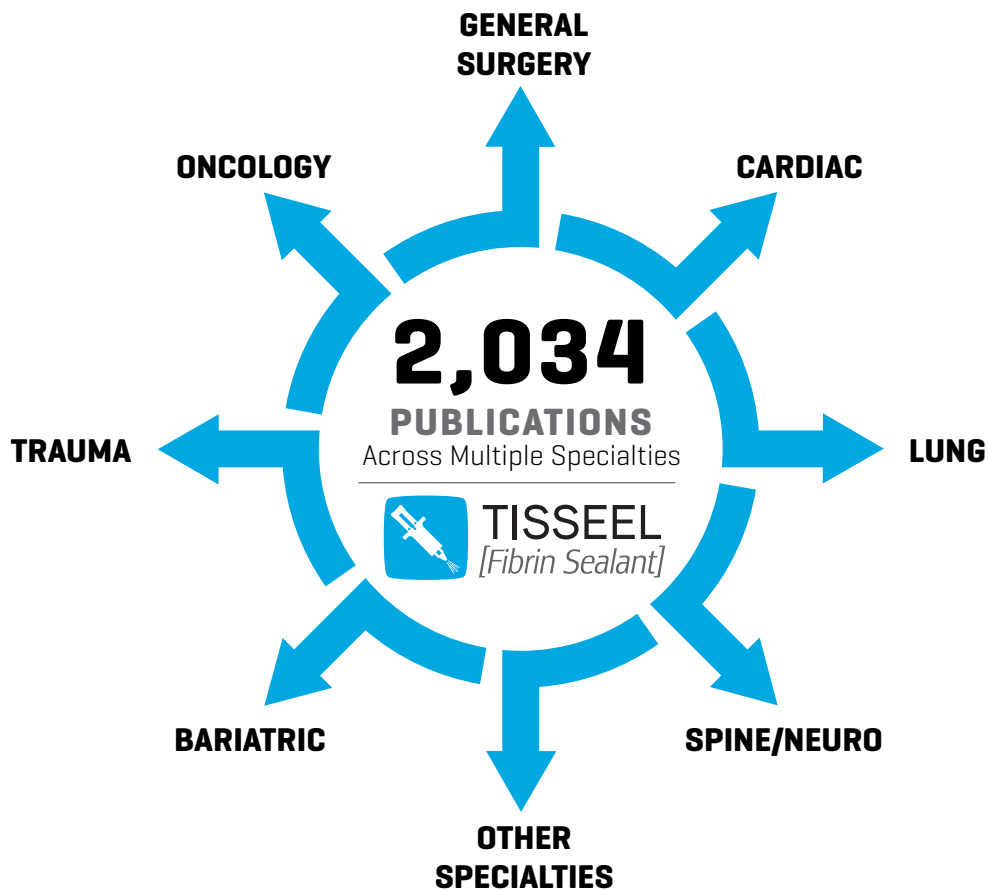


***Baxter***

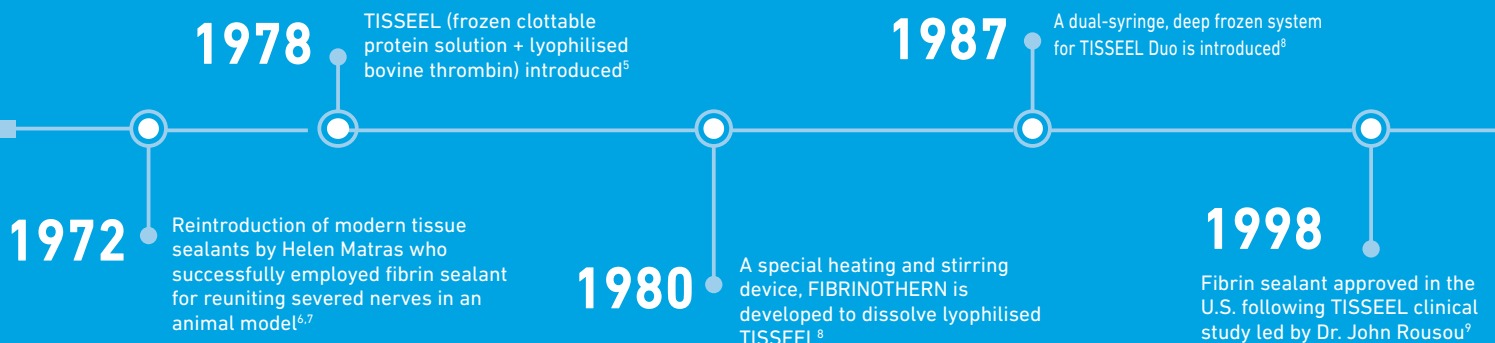
# THE TISSEEL ADVANTAGE

TISSEEL VH S/D is a two component Fibrin Sealant containing human derived Fibrinogen and Thrombin. The components mix to form a fibrin clot that mimics the **final stage of the coagulation cascade**.<sup>1,2,3</sup>

TISSEEL USE HAS BEEN DEMONSTRATED IN OVER **2,000** PUBLICATIONS ACROSS MULTI-SPECIALTIES<sup>4</sup>



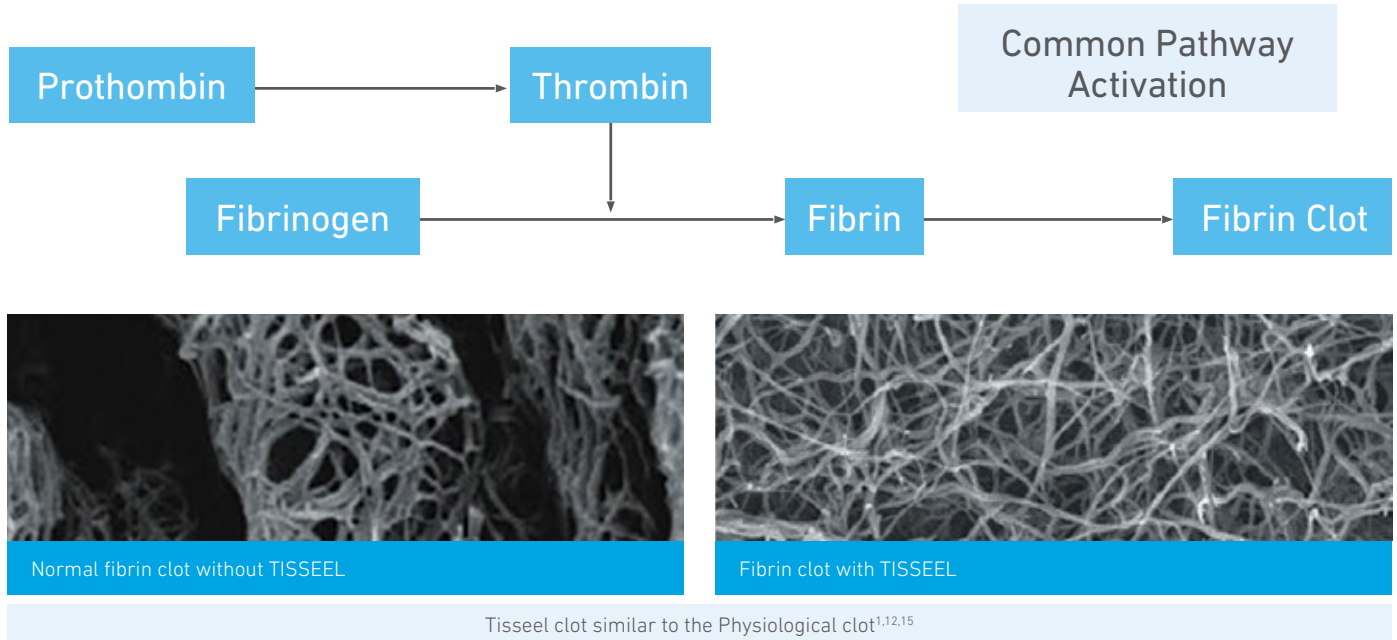
## 40 YEARS OF CONTINUOUS INNOVATION



# MECHANISM OF ACTION

TISSEEL Clot is Similar to Physiological Clot<sup>1,12,15</sup>

Upon mixing Sealer Protein (human) and Thrombin (human), soluble fibrinogen is transformed into fibrin, that polymerises into a net-like matrix and firmly adheres to exposed collagen<sup>12</sup>. This **achieves haemostasis** and **gluing of tissue**.



# UNIQUE COMBINATION OF COMPONENTS

TISSEEL contains Aprotinin, a synthetic **clot stabiliser** and a **high concentration** of Fibrinogen

	TISSEEL <sup>10</sup>
FIBRINOGEN	72 -110mg/mL
THROMBIN	400-625 IU/mL
APROTININ	2250-3750 KIU/mL

2005-2006

The EASYSpray application system introduced in 2005 and DUPLOSPRAY system introduced in 2006<sup>4</sup>

2007

TISSEEL VH S/D (frozen) with synthetic aprotinin was approved in the US<sup>4</sup>

2006

TISSEEL VH SD (frozen) approved by US FDA<sup>4</sup>

2017

Introduction of Snap Lock attachment for MIS applicators<sup>4</sup>

# TISSEEL HAS MORE FIBRINOGEN

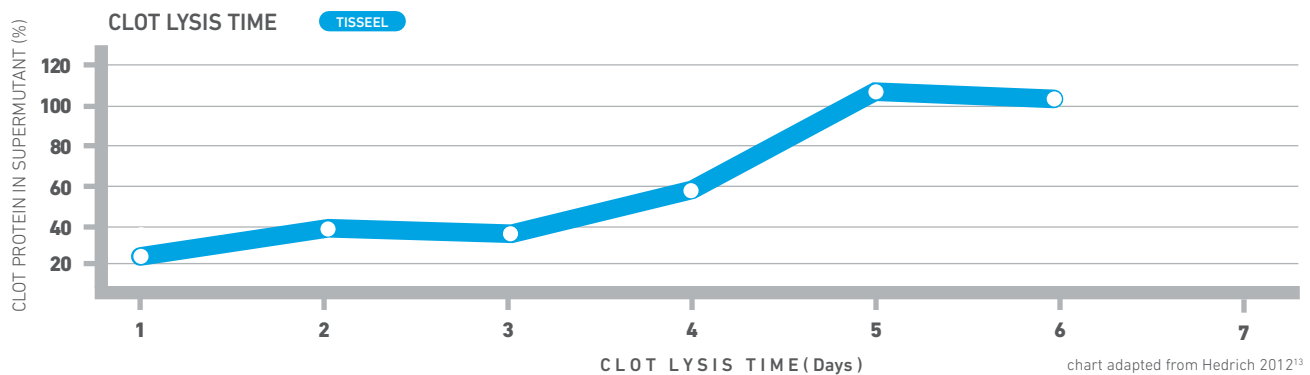
## Natural Fibrin Power

TISSEEL contains up to **30x the fibrinogen concentration** of fibrinogen in human plasma – 72 mg/mL vs. 2 to 5 mg/mL.<sup>2,10</sup> Fibrinogen is responsible for the fibrin clot strength which enables sealing and adherence of tissue.<sup>7</sup>

# 5X THE STRENGTH OF A NORMAL CLOT

## Provides Greater Tensile Strength<sup>11</sup>

TISSEEL's **clot strength, stability** and increased time to clot degradation are key factors that support **wound healing**.<sup>12</sup> TISSEEL contains aprotinin, the most effective exogenous clot stabiliser known.



# LONGER TIME TO RESORPTION<sup>12\*\*</sup>

TISSEEL forms a clot that remains in the body for 9-10 days

Clot stability is important because early detachment of clot from tissue can lead to haemorrhage, loss of adhesion and sealing.

TISSEEL IS EXPECTED TO BE FULLY RESORBED IN 9-10 DAYS

1  
DAY

2  
DAYS

3  
DAYS

4  
DAYS

5  
DAYS

6  
DAYS

7  
DAYS

8  
DAYS

9  
DAYS

10  
DAYS

# PATIENT PROFILES

TISSEEL is especially helpful in complex patients

- Effective in **poor tissue characteristics** (such as friable tissue)<sup>14</sup>
- Effective in **heparinised patients**<sup>1</sup>

# BROAD COVERAGE FOR OPEN & MIS

## DUPLOSPRAY MIS REGULATOR / EASYSpray REGULATOR

The DUPLOSPRAY MIS & EASYSpray REGULATOR SYSTEM deliver TISSEEL **easily, safely\*** and with a **uniform spray**, enabling maximum product utilisation and **broad area coverage**.



### DUPLOSPRAY MIS SYSTEM – LAPAROSCOPIC & ROBOTIC SURGERY

- 4 rigid applicators available for precise delivery of TISSEEL in MIS
- System supports “Stop & Start” use during surgery
- For use with CO<sub>2</sub> gas only



### EASYSpray REGULATOR SYSTEM – OPEN SURGERY

- EASYSpray system provides 12.5x more surface coverage than dripped TISSEEL<sup>10</sup>
- System supports “Stop & Start” use during surgery
- Compatible with medical air

## SPRAY COVERAGE<sup>10</sup>

### Maximum Coverage Using Spray

Spraying TISSEEL enables a thin, uniform spray for consistent product utilization and broad area coverage.

TOTAL VOLUME	TISSEEL
2 mL	100 cm <sup>2</sup>
4 mL	200 cm <sup>2</sup>
10 mL	500 cm <sup>2</sup>

\*CAUTION: Any application of pressurised gas may be associated with a potential risk of air or gas embolism, tissue rupture or gas entrapment with compression, which may be life-threatening. Be sure to take appropriate measures to address these risks by observing the recommended minimum spraying distance and the maximum pressure provided in the appropriate spray set instructions for use.

## TISSEEL [Fibrin Sealant]

TISSEEL [Fibrin Sealant] TISSEEL [Fibrin Sealant] Two-Component Fibrin Sealant, Deep-Frozen, Vapour Heated (VH) and Solvent Detergent (S/D) treated, TISSEEL VH S/D.

**INDICATIONS Australia:** TISSEEL is indicated as adjunct to haemostasis during surgical procedures, when control of bleeding by conventional surgical techniques is ineffective or impractical; as a sealant as an adjunct for closure of colostomies; as a sealant and/or adhesive for use in autologous chondrocyte implantation (ACI) or matrix-induced autologous chondrocyte implantation (MACI) procedures; mesh fixation in non-iatrogenic abdominal wall hernia repair, as an alternative to sutures, staples or tacks.

**INDICATIONS New Zealand:** TISSEEL is indicated as adjunct to haemostasis during surgical procedures, when control of bleeding by conventional surgical techniques is ineffective or impractical; and as a sealant as an adjunct for closure of colostomies; as a sealant and/or adhesive for use in autologous chondrocyte implantation (ACI) or matrix-induced autologous chondrocyte implantation (MACI) procedures; for mesh fixation in inguinal, femoral and incisional hernia repair, as an alternative or adjunct to sutures, staples or tacks.

**CONTRAINDICATIONS:** Known hypersensitivity to aprotinin or any other component of TISSEEL. Injection of TISSEEL into tissues is contraindicated. Such use has been associated with inadvertent intravascular injection which may result in life-threatening thromboembolic complications, can lead to intravascular coagulation which may increase likelihood and severity of acute hypersensitivity reactions in susceptible patients. TISSEEL should be applied with caution to minimise any risk of intravascular application, for example in coronary bypass surgery. TISSEEL should only be applied topically. Soft tissue injection of TISSEEL carries the risk of an anaphylactic reaction and/or local tissue damage.

**PRECAUTIONS:** Viral and prion risk due to human plasma derived sealer protein concentrate and thrombin. Products made from human plasma may contain infectious agents which can cause disease. Standard measures are taken to prevent infection but when medicinal products are prepared from human blood or plasma, the possibility of transmitting infective agents cannot be totally excluded and this also applies to unknown or emerging viruses and other pathogens. Administration of TISSEEL may result in allergic reactions. For patients with a known allergic diathesis, history of hypersensitivity to medical products or has previously received aprotinin-containing products (including previous use of TISSEEL) a careful risk-benefit assessment should be carried out prior to administration. Risk of immunisation against proteins such as aprotinin is increased if repeated exposure occurs within six months. TISSEEL contains synthetic aprotinin which is structurally identical to bovine aprotinin so use in patients with allergies to bovine proteins should be carefully evaluated. Life threatening air or gas embolism, tissue rupture, or gas entrapment with compression have occurred with the use of spray devices employing a pressure regulator to administer TISSEEL, relating to the use of spray devices at higher than recommended pressures and/or in close proximity to the tissue surface. The risk appears to be higher when Tisseel is sprayed with air, compared to CO<sub>2</sub> and therefore cannot be excluded with Tisseel when sprayed in open wound surgery. TISSEEL alone is not indicated for severe or brisk arterial or venous bleeding. Should not be used for sealing neuroanastomoses. Do not inject into nasal mucosa. TISSEEL alone is not indicated for the treatment of massive and brisk arterial or venous bleeding. If fibrin sealants are applied in confined bodily spaces, the risk of compressive complications should be taken into account.

## References

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