# FDA approves Raplixa to help control bleeding during surgery

Bleeding is the name commonly used to describe blood loss. It can refer to blood loss inside the body (internal bleeding) or blood loss outside of the body (external bleeding).

Blood loss can occur in almost any area of the body. Typically, internal bleeding occurs when blood leaks out through damage to a blood vessel or organ. External bleeding occurs either when blood exits through a break in the skin, or when blood exits through a natural opening in the body, such as the mouth, vagina, or rectum. (1)

**In April 30, 2015 The U.S Food and Drug Administration approved Raplixa (fibrin sealant [human]), the first spray-dried fibrin sealant approved by the agency. It is used to help control bleeding during surgery.**

Raplixa ,is a biological product approved for use in adults to help control bleeding from small blood vessels when standard surgical techniques, such as suture, ligature or cautery, are ineffective or impractical. When applied to a bleeding site, Raplixa is dissolved in the blood and a reaction starts between the fibrinogen and thrombin proteins. This results in the formation of blood clots to help stop the bleeding. (2)

Raplixa is manufactured by ProFibrix BV, a wholly owned subsidiary of The Medicines Company, based in Parsippany, New Jersey.(2)

FINISH-3 is a Phase 3, international, randomized, single-blind, controlled trial ,compared the efficacy and safety of Fibrocaps, a ready-to-use, dry-powder fibrin sealant containing human plasma–derived thrombin and fibrinogen, vs gelatin sponge alone for use as a hemostat for surgical bleeding in 4 indications (ie, spinal, hepatic, vascular, soft tissue dissection). (3)

Adults with mild to moderate surgical bleeding (randomized 2:1; Fibrocaps vs gelatin sponge) were treated at a single bleeding site (day 1). Time to hemostasis (TTH) during 5 minutes was compared (log-rank statistic) within each indication. Safety follow-up continued to day 29. patients were treated (Fibrocaps, n = 480; gelatin sponge, n = 239) when undergoing spinal (n = 183), vascular (n = 175), hepatic (n = 180), or soft-tissue (n = 181) procedures. Fibrocaps was applied by spray device in 53% of all procedures (94% of hepatic and soft-tissue procedures). Fibrocaps significantly reduced TTH compared with gelatin sponge; estimated hazard ratios were 3.3, 2.1, 2.3, and 3.4 for the 4 surgical indications, respectively (each $p < 0.001$; primary end point). Fibrocaps significantly reduced median TTH for each indication ($p < 0.001$) and was superior for secondary efficacy end points of restricted mean TTH ($p < 0.001$) and probability of hemostasis at 3 ($p <$

0.001) and 5 ($p \leq 0.002$) minutes. Adverse event incidences were generally similar between treatment arms. (3)

IN Two randomized, controlled phase II trials Safety and efficacy of Fibrocaps applied directly or by spray device, in combination with gelatin sponge, was compared with that of gelatin sponge-alone in two randomized, single-blind controlled trials: FC-002 US (United States) and FC-002 NL (the Netherlands). A total of 126 adult patients were randomized (Fibrocaps: *n* = 47 [FC-002 US], *n* = 39 [FC-002 NL]; gelatin sponge alone: *n* = 23 [FC-002 US], *n* = 17 [FC-002 NL). One bleeding site was treated during a surgical procedure (*n* = 125). Time to hemostasis (primary end point) was measured, with a 28-d safety follow-up. Four surgical indications included hepatic resection (*n* = 58), spinal procedures (*n* = 37), peripheral vascular procedures (*n* = 30), and soft tissue dissection (*n* = 1). (4)

Mean (standard deviation) time to hemostasis was significantly shorter after Fibrocaps treatment than after gelatin sponge alone (FC-002 US: 1.9 [1.3] *versus* 4.8 min [3.1], *P* < 0.001; FC-002 NL: 2.2 [1.3] *versus* 4.4 min [3.1], *P* = 0.004). The incidence of hemostasis was greater after Fibrocaps compared with that of gelatin sponge alone within 3 min (FC-002 US: 83% *versus* 35%, *P* < 0.001; FC-002 NL: 77% *versus* 53%,*P* = 0.11), 5 min (94% *versus* 61%, *P* = 0.001; 95% *versus* 71%, *P* = 0.022), and 10 min (100% *versus* 78%,*P* = 0.003; 100% *versus* 82%, *P* = 0.025). (4)

The most commonly reported adverse reactions were surgical pain, nausea, constipation, fever and decreased blood pressure. (5)

In my opinion Raplixa will offers a very important option for surgical bleeding control and hemostasis, nevertheless its safety need conformation by post marketing studies.

***References:-***


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