PPE Specification

**PPE Specification**

**ORIGINA**

**ORIGINAL, SURGICEL NU-KNI **and** SURGICEL FIBRILLAR US FIP**

(For dental application of this product, reference should be made to the dental usage section of this insert.**)

**DESCRIPTION**

Surgicel® Absorbable Hemostat is a sterile absorbable fabric moistened with a suspension of oxidized regenerated cellulose (oxidized regenerated collagen) and tannic acid. When used properly in minimal amounts, Surgicel® Absorbable Hemostat, upon exposure to blood, absorbs as much as 20 times its dry weight in a relatively short period of time. Use Surgicel® Absorbable Hemostat as a hemostatic agent in a wide variety of surgical applications, including

**APPLICATIONS**

- Various types of surgical procedures
- Gynecologic procedures, including hysterectomy and rectopexy
- Otorhinolaryngologic procedures
- Vascular surgery
- Dermatologic procedures
- Gastroenterologic procedures
- Ophthalmologic procedures
- Other surgical procedures

**POSSIBLE CONTRAINDICATIONS**

- Allergic reaction to oxidized regenerated cellulose
- Excessive or uncontrollable bleeding
- Uncooperative patient

**ADVERSE REACTIONS**

No untoward adverse reactions have been reported with the use of Surgicel® Absorbable Hemostat. Because of the absorbable nature of surgicel, it appears to be a physical effect rather than any alteration of the normal physiologic clotting mechanisms. After Surgicel® Absorbable Hemostat has been saturated with blood, it swells to ten to twenty times its original volume. The swelling does not affect performance. The Surgicel® Fibrillar™ form of the product allows the surgeon to grasp with forceps any amount desired for application to the bleeding site and easily control its pressure. The fibrillar form is made of a loose network of threads which permits easy removal if it should extend beyond the site of application. This material fills a gap between the more fibrous forms of the product and the more granular forms such as Surgicel® Absorbable Hemostat. The material is free flowing when dry and needs no lubrication for easy insertion. It is biocompatible and biodegradable, and its use is not associated with any untoward reactions. It is absorbable and leaves a residue of pure cellulose. When properly used, it leaves no appreciable residue. Its useful action is limited to the time that it is required. It must always be removed after hemostasis is achieved since it will swell and could exert unwanted pressure.

**WARNINGS**

Surgicel® Absorbable Hemostat should not be used for any purpose other than the purpose for which it is intended. It is not intended as a substitute for systematically administered antibiotics and prophylactic antibiotic agents to control or prevent postoperative infections. **PRECAUTIONS**

Use only as much Surgicel® Absorbable Hemostat as is necessary for hemostasis, holding firmly in place until bleeding stops. Remove any excess before surgical closure in order to facilitate approximation of tissues. With the possibility of internal fibrinolysis, in certain cases, the fibrinolytic agents may be used to prevent plugging of the lumen, ureter, or catheter by absorbed portions of the product.

**SUGGESTIONS**

Surgicel® Absorbable Hemostat in a dermabrasion and dermatologic surgery. Surgicel® Absorbable Hemostat has been reported useful as a hemostatic agent in such gynecologic procedures as hysterectomy and rectopexy. When used as a hemostatic adjunct in such gynecologic procedures as hysterectomy and rectopexy, it tends to form a barrier to the development of an abscess. The fibrillar form may be more effective in such procedures because of its tendency to disperse. The fibrillar form may be more easily removed after hemostasis is achieved. Surgicel® Absorbable Hemostat may be applied as a powder during surgical procedures. It is not compatible with autoclaving or ethylene oxide sterilization. Surgicel® Absorbable Hemostat in dermabrasions and dermatologic surgery.

**REFERENCES**

**IFU PRINTING SPECIFICATION SHEET**

**PAGE LAYOUT**

**FOLD PATTERN**

**DRAWING IS NOT TO SCALE:** DRAWINGS REFLECT INFORMATION FOR PRODUCTION OF PRINTED PIECES AND DO NOT CONTAIN ACTUAL ARTWORK.

This document or data herein or herewith is not to be reproduced, used or disclosed in whole or part without the permission of Ethicon, Inc.

**STOCK**

n/a