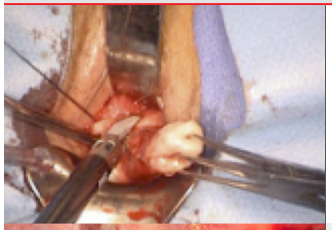
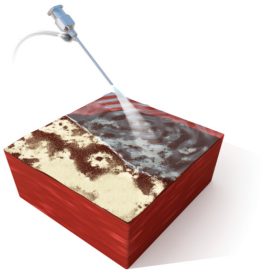
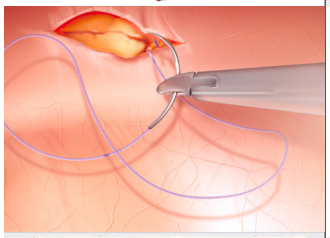
Ethicon Gynecologic Portfolio

Ethicon provides confidence inspiring tools designed to help reduce complications and give each patient the care that she deserves.

	Surgical goal	Complication	Ethicon portfolio capabilities	
	Gain access to target area through optimal visualization, dissection around and mobilization of structures.	Bleeding	Open	ENSEAL® X1 Large Jaw Tissue Sealer | MEGADYNE™ Electrosurgical Pencils
			Laparoscopic	ENSEAL® G2 Articulating Tissue Sealer | HARMONIC® HD 1000i Shears
			Vaginal	ENSEAL® X1 Large Jaw Tissue Sealer | MEGADYNE™ Electrosurgical Pencils HARMONIC® HD 1000i Shears
	Achieve optimal dissection of diseased tissue including lymph nodes and sealing that achieves hemostasis. Minimize damage to surrounding tissues.	Bleeding	Open	ENSEAL® X1 Large Jaw Tissue Sealer | MEGADYNE™ Electrosurgical Pencils
			Laparoscopic	ENSEAL® G2 Articulating Tissue Sealer | HARMONIC® HD 1000i Shears
			Vaginal	ENSEAL® X1 Large Jaw Tissue Sealer | MEGADYNE™ Electrosurgical Pencils HARMONIC® HD 1000i Shears
	Safely reduce the incidence of adhesions.	Adhesions	Open	GYNECARE INTERCEED® Absorbable Adhesion Barrier
	Achieve hemostasis with adjunctive hemostasis methods during procedure and prior to the vaginal cuff closure when control of bleeding by standard surgical techniques is ineffective or impractical to end.	Bleeding	Open/ Laparoscopic/ Robotic/Vaginal	SURGICEL® Powder Absorbable Hemostat VISTASEAL™ Fibrin Sealant (Human) SURGIFLO® Hemostatic Matrix Kit SURGICEL® SNoW Absorbable Hemostat
	Secure wound closure and address the risk factors associated with Surgical Site Infection.	Surgical Site Infections	Open/ Laparoscopic / Robotic	PDS® Plus Antibacterial Suture | MONOCRYL® Plus Antibacterial Suture STRATAFIX™ Knotless Tissue Control Devices | DERMABOND® PRINEO® Skin Closure System | Coated VICRYL® Plus Antibacterial (polyglactin 910) Suture
			Vaginal	PDS® Plus Antibacterial Suture | MONOCRYL® Plus Antibacterial Suture STRATAFIX™ Knotless Tissue Control Devices | Coated VICRYL® Plus Antibacterial (polyglactin 910) Suture
	Operating Room Safety	Bleeding/ Surgical Smoke	Open/ Laparoscopic/ Robotic/Vaginal	MEGADYNE™ Smoke Evacuation Pencils | MEGADYNE™ MEGA SOFT™ Universal Plus Reusable Patient Return Electrode | ETHIGUARD Blunt Point Needles

EVITHROM® Thrombin, Topical (Human) for Topical Use Only

Lyophilized Powder for Solution

EVITHROM® is a topical thrombin indicated as an aid to hemostasis whenever oozing blood and minor bleeding from capillaries and small venules is accessible and control of bleeding by standard surgical techniques (such as suture, ligature or cautery) is ineffective or impractical.

EVITHROM® may be used in conjunction with an Absorbable Gelatin Sponge, USP.

Important Safety Information

- For topical use only.
- Do not inject.
- Apply EVITHROM® on the surface of bleeding tissue only.
- The amount of EVITHROM® required depends upon the area of tissue to be treated and the method of application. In clinical studies, volumes up to 10 ml were used in conjunction with Absorbable Gelatin Sponge.
- Do not use for the treatment of severe or brisk arterial bleeding.
- Do not use in individuals known to have anaphylactic or severe systemic reaction to human blood products. Hypersensitivity reactions, including anaphylaxis, may occur.
- There is a potential risk of thrombosis if absorbed systemically.
- May carry a risk of transmitting infectious agents such as viruses and theoretically, the Creutzfeldt-Jakob disease (CJD) agent, despite manufacturing steps designed to reduce the risk of viral transmission.
- The most common adverse reactions during clinical trial (reported in at least 2% of subjects treated with EVITHROM®) were prolonged activated partial thromboplastin time, increased INR, decreased lymphocyte count, prolonged prothrombin time and increased neutrophil count.
- None of the patients treated with EVITHROM developed antibodies to human thrombin or to human Factor V/Va. The clinical significance of these findings is unknown.

For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

021328-180430

SURGIFLO® Hemostatic Matrix Essential Product Information (Made from Absorbable Gelatin Sponge, USP)

DESCRIPTION

SURGIFLO® Hemostatic Matrix Kit is intended for hemostatic use by applying to a bleeding surface.

ACTIONS

When used in appropriate amounts SURGIFLO® Hemostatic Matrix is absorbed completely within 4 to 6 weeks.

INTENDED USE/INDICATIONS

SURGIFLO® Hemostatic Matrix , mixed with with sterile saline or thrombin solution, is indicated in surgical procedures (other than ophthalmic) as an adjunct to hemostasis when control of bleeding by ligature or other conventional methods is ineffective or impractical.

CONTRAINDICATIONS

- Do not use SURGIFLO® Hemostatic Matrix in intravascular compartments because of the risk of embolization.
- Do not use SURGIFLO® Hemostatic Matrix in patients with known allergies to porcine gelatin.
- Do not use SURGIFLO® Hemostatic Matrix in closure of skin incisions because it may interfere with the healing of skin edges. This interference is due to mechanical interposition of gelatin and is not secondary to intrinsic interference with wound healing.

WARNINGS

- SURGIFLO® Hemostatic Matrix should not be used in the presence of infection and should be used with caution in contaminated areas of the body
- SURGIFLO® Hemostatic Matrix should not be used in instances of pumping arterial hemorrhage. SURGIFLO® Hemostatic Matrix will not act as a tampon or plug in a bleeding site.
- SURGIFLO® Hemostatic Matrix should be removed from the site of application when used in, around, or in proximity to foramina in bone, areas of bony confine, the spinal cord, and/or the optic nerve and chiasm because it may swell resulting in nerve damage.
- Excess SURGIFLO® Hemostatic Matrix should be removed once hemostasis has been achieved.
- The safety and effectiveness of SURGIFLO® Hemostatic Matrix for use in ophthalmic procedures has not been established.
- SURGIFLO® Hemostatic Matrix should not be used for controlling post-partum intrauterine bleeding or menorrhagia.
- The safety and effectiveness of SURGIFLO® Hemostatic Matrix has not been established in children and pregnant women.
- The blue flexible applicator tip should not be trimmed to avoid exposing internal guidewire.
- The white straight applicator tip should be trimmed away from the surgical area. Cut a square angle to avoid creating a sharp tip.

PRECAUTIONS

- Safe and effective use of SURGIFOAM® Sponge has been reported in a published neurologic retrospective study involving 1700 cases in Europe. Safe and effective use in neurosurgery has not been proven through randomized, controlled clinical studies in the United States.
- SURGIFLO® Hemostatic Matrix is supplied as a sterile product and cannot be resterilized.
- SURGIFLO® Hemostatic Matrix should not be used for packing unless excess product that is not needed to maintain hemostasis is removed. SURGIFLO® Hemostatic Matrix may swell up to 20% upon contact with additional fluid.
- SURGIFLO® Hemostatic Matrix should not be used in conjunction with autologous blood salvage circuits.
- SURGIFLO® Hemostatic Matrix should not be used in conjunction with methylmethacrylate adhesives.
- In urological procedures, SURGIFLO® Hemostatic Matrix should not be left in the renal pelvis or ureters to eliminate the potential foci for calculus formation.

ADVERSE EVENTS

A total of 142 patients received SURGIFOAM® Sponge during a clinical trial comparing SURGIFOAM® Sponge to another absorbable gelatin sponge. In general, the following adverse events have been reported with the use of absorbable porcine gelatin-based hemostatic agents:

- Gelatin-based hemostatic agents may serve as a nidus for infection and abscess formation and have been reported to potentiate bacterial growth.
- Giant cell granulomas have been observed at implant sites when used in the brain.
- Compression of the brain and spinal cord resulting from the accumulation of sterile fluid have been observed.
- Multiple neurologic events were reported when absorbable gelatin-based hemostatic agents were used in laminectomy operations, including cauda equina syndrome, spinal stenosis, meningitis, arachnoiditis, headaches, paresthesias, pain, bladder and bowel dysfunction, and impotence.
- The use of absorbable gelatin-based hemostatic agents during the repair of dural defects associated with laminectomy and craniotomy operations, has been associated with fever, infection, leg paresthesias, neck and back pain, bladder and bowel incontinence, cauda equina syndrome, neurogenic bladder, impotence, and paresis.
- The use of absorbable gelatin-based hemostatic agents has been associated with paralysis, due to device migration into foramina in the bone around the spinal cord, and blindness, due to device migration in the orbit of the eye, during lobectomy, laminectomy, and repair of a frontal skull fracture and lacerated lobe.
- Foreign body reactions, “encapsulation” of fluid, and hematoma have been observed at implant sites.
- Excessive fibrosis and prolonged fixation of a tendon have been reported when absorbable gelatin-based sponges were used in severed tendon repair.
- Toxic shock syndrome was reported in association with the use of absorbable gelatin-based hemostats in nasal surgery.
- Fever, failure of absorption, and hearing loss have been observed when absorbable hemostatic agents were used during tympanoplasty.

064302-161208

SURGICEL Essential Product Information

INDICATIONS

SURGICEL® Absorbable Hemostat (oxidized regenerated cellulose) is used adjunctively in surgical procedures to assist in the control of capillary, venous, and small arterial hemorrhage when ligation or other conventional methods of control are impractical or ineffective. SURGICEL® ORIGINAL, SURGICEL® FIBRILLAR™, SURGICEL® NU-KNIT®, and SURGICEL® SNoW™ Absorbable Hemostats can be cut to size for use in endoscopic procedures.

PRECAUTIONS

Use only as much SURGICEL® Absorbable Hemostat as is necessary for hemostasis, holding it firmly in place until bleeding stops. Remove any excess before surgical closure in order to facilitate absorption and minimize the possibility of foreign body reaction.

In urological procedures, minimal amounts of SURGICEL® Absorbable Hemostat should be used and care must be exercised to prevent plugging of the urethra, ureter, or a catheter by dislodged portions of the product.

Since absorption of SURGICEL® Absorbable Hemostat could be prevented in chemically cauterized areas, its use should not be preceded by application of silver nitrate or any other escharotic chemicals.

If SURGICEL® Absorbable Hemostat is used temporarily to line the cavity of large open wounds, it should be placed so as not to overlap the skin edges. It should also be removed from open wounds by forceps or by irrigation with sterile water or saline solution after bleeding has stopped.

Precautions should be taken in otorhinolaryngologic surgery to assure that none of the material is aspirated by the patient. (Examples: controlling hemorrhage after tonsillectomy and controlling epistaxis.)

Care should be taken not to apply SURGICEL® Absorbable Hemostat too tightly when it is used as a wrap during vascular surgery (see Adverse Reactions section of the complete product package insert).

ADVERSE EVENTS

"Encapsulation" of fluid and foreign body reactions have been reported.

There have been reports of stenotic effect when SURGICEL® Absorbable Hemostat has been applied as a wrap during vascular surgery.

Paralysis and nerve damage have been reported when SURGICEL® Absorbable Hemostat was used around, in, or in proximity to foramina in bone, areas of bony confine, the spinal cord, and/or the optic nerve and chiasm.

Blindness has been reported in connection with surgical repair of a lacerated left frontal lobe when SURGICEL® Absorbable Hemostat was placed in the anterior cranial fossa.

Possible prolongation of drainage in cholecystectomies and difficulty passing urine per urethra after prostatectomy have been reported.

For more information, please consult your doctor or for product quality and technical questions, call 1-800-795-0012. For complete product information including indications, contraindications, warnings, precautions, and adverse reactions, please reference the individual product package inserts.

063768-180827

VISTASEAL™ Fibrin Sealant (Human) IMPORTANT SAFETY INFORMATION

INDICATION

VISTASEAL™ is indicated as an adjunct to hemostasis for mild to moderate bleeding in adults undergoing surgery when control of bleeding by standard surgical techniques (such as suture, ligature, and cautery) is ineffective or impractical. VISTASEAL is effective in heparinized patients.

CONTRAINDICATIONS

Do not inject directly into the circulatory system.

Do not use for the treatment of severe or brisk arterial bleeding.

Do not use in patients with history of anaphylaxis or severe systemic reactions to human blood products.

Do not use VISTASEAL for spraying unless the minimum recommended distance from the applicator tip to the bleeding site can be achieved.

WARNINGS AND PRECAUTIONS

Thromboembolic events may occur if VISTASEAL is administered intravascularly.

Only spray VISTASEAL if it is possible to accurately judge the distance from the spray tip to the tissue surface.

Hypersensitivity reactions can occur.

May carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

ADVERSE REACTIONS

The most common adverse reactions (reported in >1% of clinical trial subjects) were nausea and procedural pain.

For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

115517-190529

SURGIFLO® Hemostatic Matrix Kit Essential Product Information (Made from Absorbable Gelatin Sponge, USP) with Thrombin

DESCRIPTION

SURGIFLO® with Thrombin (SURGIFLO® Hemostatic Matrix Kit) is intended for hemostatic use by applying to a bleeding surface.

ACTIONS

When used in appropriate amounts SURGIFLO® is absorbed completely within 4 to 6 weeks.

INTENDED USE/INDICATIONS

SURGIFLO®, mixed with thrombin solution, is indicated in surgical procedures (other than ophthalmic) as an adjunct to hemostasis when control of bleeding by ligature or other conventional methods is ineffective or impractical.

CONTRAINDICATIONS

- Do not use SURGIFLO® in intravascular compartments because of the risk of embolization.
- Do not use SURGIFLO® in patients with known allergies to porcine gelatin.
- Do not use SURGIFLO® in closure of skin incisions because it may interfere with the healing of skin edges. This interference is due to mechanical interposition of gelatin and is not secondary to intrinsic interference with wound healing.

WARNINGS

- SURGIFLO® should not be used in the presence of infection and should be used with caution in contaminated areas of the body
- SURGIFLO® should not be used in instances of pumping arterial hemorrhage. SURGIFLO® will not act as a tampon or plug in a bleeding site.
- SURGIFLO® should be removed from the site of application when used in, around, or in proximity to foramina in bone, areas of bony confine, the spinal cord, and/or the optic nerve and chiasm because it may swell resulting in nerve damage.
- Excess SURGIFLO® should be removed once hemostasis has been achieved.
- The safety and effectiveness of SURGIFLO® for use in ophthalmic procedures has not been established.
- SURGIFLO® should not be used for controlling post-partum intrauterine bleeding or menorrhagia.
- The safety and effectiveness of SURGIFLO® has not been established in children and pregnant women.
- The blue flexible applicator tip should not be trimmed to avoid exposing internal guidewire.
- The white straight applicator tip should be trimmed away from the surgical area. Cut a square angle to avoid creating a sharp tip.

PRECAUTIONS

- Safe and effective use of SURGIFOAM® Sponge has been reported in a published neurologic retrospective study involving 1700 cases in Europe. Safe and effective use in neurosurgery has not been proven through randomized, controlled clinical studies in the United States.
- SURGIFLO® is supplied as a sterile product and cannot be resterilized.
- SURGIFLO® should not be used for packing unless excess product that is not needed to maintain hemostasis is removed. SURGIFLO® may swell up to 20% upon contact with additional fluid.
- SURGIFLO® should not be used in conjunction with autologous blood salvage circuits.
- SURGIFLO® should not be used in conjunction with methylmethacrylate adhesives.
- In urological procedures, SURGIFLO® should not be left in the renal pelvis or ureters to eliminate the potential foci for calculus formation.

ADVERSE EVENTS

A total of 142 patients received SURGIFOAM® Sponge during a clinical trial comparing SURGIFOAM® Sponge to another absorbable gelatin sponge. In general, the following adverse events have been reported with the use of absorbable porcine gelatin-based hemostatic agents:

- Gelatin-based hemostatic agents may serve as a nidus for infection and abscess formation and have been reported to potentiate bacterial growth.
- Giant cell granulomas have been observed at implant sites when used in the brain.
- Compression of the brain and spinal cord resulting from the accumulation of sterile fluid have been observed.
- Multiple neurologic events were reported when absorbable gelatin-based hemostatic agents were used in laminectomy operations, including cauda equina syndrome, spinal stenosis, meningitis, arachnoiditis, headaches, paresthesias, pain, bladder and bowel dysfunction, and impotence.
- The use of absorbable gelatin-based hemostatic agents during the repair of dural defects associated with laminectomy and craniotomy operations, has been associated with fever, infection, leg paresthesias, neck and back pain, bladder and bowel incontinence, cauda equina syndrome, neurogenic bladder, impotence, and paresis.
- The use of absorbable gelatin-based hemostatic agents has been associated with paralysis, due to device migration into foramina in the bone around the spinal cord, and blindness, due to device migration in the orbit of the eye, during lobectomy, laminectomy, and repair of a frontal skull fracture and lacerated lobe.
- Foreign body reactions, “encapsulation” of fluid, and hematoma have been observed at implant sites.
- Excessive fibrosis and prolonged fixation of a tendon have been reported when absorbable gelatin-based sponges were used in severed tendon repair.
- Toxic shock syndrome was reported in association with the use of absorbable gelatin-based hemostats in nasal surgery.
- Fever, failure of absorption, and hearing loss have been observed when absorbable hemostatic agents were used during tympanoplasty.

063756-161128

SURGICEL® Powder Absorbable Hemostat Essential Product Information

INDICATIONS

SURGICEL® Powder (oxidized regenerated cellulose) is used adjunctively in surgical procedures to assist in the control of capillary, venous, and small arterial hemorrhage when ligation or other conventional methods of control are impractical or ineffective.

CONTRAINDICATIONS

- Do not inject or place SURGICEL® Powder into an open blood vessel. Do not use to treat bleeding from large defects in arteries or veins.
- SURGICEL® Powder should not be used to control hemorrhage from large arteries or veins.
- When SURGICEL® Powder is used to help achieve hemostasis in, around, or in proximity to foramina in bone, areas of bony confine, the spinal cord, or the optic nerve and chiasm, it must always be removed after hemostasis is achieved since it will swell and could exert unwanted pressure.
- SURGICEL® Powder should not be used for implantation in bone defects, such as fractures, since there is a possibility of interference with callus formation and a theoretical chance of cyst formation.

WARNINGS

- Closing with SURGICEL® Powder in a contaminated wound without drainage may lead to complications and should be avoided.
- SURGICEL® Powder should not be impregnated with anti-infective agents or with other materials such as buffering or hemostatic substances.
- SURGICEL® Powder is dry and there may be difficulties in precise delivery under certain circumstances. Unintentional device placement may result in powder scattering and device migration that may increase the risk of adhesion formation.
- Although SURGICEL® Powder is bactericidal against a wide range of pathogenic microorganisms, it is not intended as a substitute for systemically administered therapeutic or prophylactic antimicrobial agents to control or to prevent postoperative infections.
- Do not attempt to trim the applicator tip.

PRECAUTIONS

- SURGICEL® Powder should not be used in conjunction with autologous blood salvage circuits, because its fragments may pass through the transfusion filters of blood-scavenging systems.
- Use only as much SURGICEL® Powder (oxidized regenerated cellulose) as is necessary and apply only where needed for hemostasis. Remove any excess before surgical closure in order to facilitate absorption and to minimize the possibility of foreign body reaction.
- In urological procedures, minimal amounts of SURGICEL® Powder should be used and care must be exercised to prevent plugging of the urethra, ureter, or a catheter by dislodged portions of the product.
- Since absorption of SURGICEL® Powder could be prevented in chemically cauterized areas, its use should not be preceded by application of silver nitrate or any other escharotic chemicals.
- If SURGICEL® Powder is used temporarily to line the cavity of open wounds, it should be removed by irrigation with sterile water or saline solution after bleeding has stopped.
- Precautions should be taken in otorhinolaryngologic surgery to ensure that none of the material is aspirated by the patient (e.g., controlling hemorrhage after tonsillectomy and controlling epistaxis).
- This applicator tip is not intended for laparoscopic or other endoscopic use.

ADVERSE EVENTS

- Paralysis and nerve damage have been reported when other SURGICEL® products were used around, in, or in proximity to foramina in bone, areas of bony confine, the spinal cord, and/or the optic nerve and chiasm.
- Blindness has been reported in connection with surgical repair of a lacerated left frontal lobe when other SURGICEL® products were placed in the anterior cranial fossa (see WARNINGS and PRECAUTIONS).
- Foreign body reactions have been reported with other products from the SURGICEL® Family of Absorbable Hemostats.
- Burning has been reported when other SURGICEL® products were applied after nasal polyp removal. Headache, burning, stinging, and sneezing in epistaxis and other rhinological procedures, and stinging when SURGICEL® product was applied on surface wounds (varicose ulcerations, dermabrasions, and donor sites) have also been reported.
- For more information and technical questions, call 1-800-795-0012. For complete information including indications, contraindications, warnings, precautions, adverse reactions, and directions for use, consult the product package insert.

071582-180827

GYNECARE INTERCEED® ABSORBABLE ADHESION BARRIER

Essential Product Information

INDICATIONS

GYNECARE INTERCEED Adhesion Barrier is indicated as an adjuvant in open (laparotomy) gynecologic pelvic surgery for reducing the incidence of postoperative pelvic adhesions after meticulous hemostasis is achieved consistent with microsurgical principles.

CONTRAINDICATIONS

The use of GYNECARE INTERCEED Adhesion Barrier is contraindicated in the presence of frank infection. GYNECARE INTERCEED Adhesion Barrier is not indicated as a hemostatic agent. Appropriate means of achieving hemostasis must be employed.

WARNINGS

The safety and effectiveness of GYNECARE INTERCEED Adhesion Barrier in laparoscopic surgery or any procedures other than open (laparotomy) gynecologic microsurgical procedures have not been established.

Postoperative adhesions may be induced by GYNECARE INTERCEED Adhesion Barrier application if adjacent tissues (eg, ovary and tube) and structures are coapted or conjoined by the device, or if GYNECARE INTERCEED Adhesion Barrier is folded, wadded or layered. Care must be taken to apply GYNECARE INTERCEED Adhesion Barrier in single layers, interposed between adjacent anatomic structures at risk for adhesion formation.

Postoperative adhesions may occur in the presence of GYNECARE INTERCEED Adhesion Barrier if meticulous hemostasis is not achieved prior to application. As with all foreign substances, GYNECARE INTERCEED Adhesion Barrier should not be placed in a contaminated surgical site. Potentially contaminated surgical sites include hysterotomy following labor and/or prolonged rupture of membranes. The performance of GYNECARE INTERCEED Adhesion Barrier at potentially contaminated surgical sites has not been determined.

PRECAUTIONS

Use only a single layer of GYNECARE INTERCEED Adhesion Barrier, since multiple layers of packing or folding will not enhance the adhesion barrier characteristics and may interfere with the absorption rate of GYNECARE INTERCEED Adhesion Barrier. Care should be exercised in applying GYNECARE INTERCEED Adhesion Barrier to a pelvic organ not to constrict or restrict it. If the product comes in contact with blood prior to completing the procedure, it should be discarded, as fibrin deposition cannot be removed by irrigation and may promote adhesions formation.

Ectopic pregnancies have been associated with fertility surgery of the female reproductive tract. No data exist to establish the effect, if any, of GYNECARE INTERCEED Adhesion Barrier on the occurrence of ectopic pregnancies. No adequate studies have been conducted in women who have become pregnant within the first month after exposure to GYNECARE INTERCEED Adhesion Barrier. No teratogenic studies have been performed. Therefore, avoidance of conception should be considered during the first complete menstrual cycle after use of GYNECARE INTERCEED Adhesion Barrier. The safety and effectiveness of using GYNECARE INTERCEED Adhesion Barrier in combination with other adhesion prevention treatments have not been clinically established.

GYNECARE INTERCEED Adhesion Barrier is supplied sterile. As the material is not compatible with autoclaving or ethylene oxide sterilization, GYNECARE INTERCEED Adhesion Barrier must not be resterilized.

Foreign body reactions may occur in some patients.

Interactions may occur between GYNECARE INTERCEED Adhesion Barrier and some drugs used at the surgical site.

Pathologists examining sites of GYNECARE INTERCEED Adhesion Barrier placement should be made aware of its usage and of the normal cellular response to GYNECARE INTERCEED Adhesion Barrier 'to facilitate proper evaluation of specimens'.

ADVERSE REACTIONS

The type and frequency of adverse events reported are consistent with events typically seen following surgery. Postsurgical adhesions may occur in the presence of GYNECARE INTERCEED Adhesion Barrier.

For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

087421-180205