Prostheses and Products for Hernioplasty

7

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Introduction

The use of prosthetic biomaterials in the repair of hernias of the abdominal wall is now very commonplace throughout the world. In the USA and Europe over 90% of all inguinal and ventral hernias are repaired with a prosthetic material or device. In other parts of the world, this is not the case. Limitations on the use of these products include a natural reluctance to place a foreign material into a primary hernia or the cost of these products. This is changing rapidly, however, as illustrated by the experience in the approach to inguinal hernia repair in the Department of Surgery in the Hospital Bludenz in Bludenz, Austria, where the Bassini and Shouldice repairs were used in 39% of the cases in 1993. By 1996, these two repairs were done in only 18% of patients because there was a marked increase in the use of prosthetic products to repair inguinal hernias [1]. This expansion is commonplace all over the world.

Incisional hernias will develop in approximately 13% of laparotomy incisions. The risk of herniation is increased by fivefold if a postoperative wound infection occurs. Other factors that predispose to the development of a fascial defect include smoking, obesity, poor nutritional status, steroid usage, etc. While some of these may be avoided, those patients that are found to have such a hernia can present difficult management problems due to the high potential for recurrence. Without the use of a prosthetic material, the recurrence rate is as high as 51% [2]. The use of a synthetic material will reduce this rate to 10–24% [3].

The laparoscopic repair of incisional and ventral hernias was first performed in 1991 and introduced in 1993 using the Soft Tissue Patch made by W.L. Gore and Associates (Elkhart, DE, USA) [4]. The recurrence rate that has been reported in recent literature varies from 0 to 11% but averages approximately 5.5%. The "ideal" prosthetic product has yet to be found. Many of the current materials have been developed to meet the requirements of this procedure but many of these, of course, have found a place in the open repair as well. In fact, modifications of these prostheses have occurred to the extent that many of the "laparoscopic" products can now be used interchangeably as "open" products and vice versa. This chapter will identify these goals and the properties of the various biomaterials that are on the market today. The rational for the choice of a material in the open and laparoscopic repairs of hernias of the abdominal wall will be developed.

There are several hundred different products that can be used in the repair of inguinal, ventral, incisional, and other hernias of the abdominal wall. In many of the products listed below, there is a paucity of published literature that verifies the claims that are made by the manufacturers. While this is the situation at the time of the production of this textbook, the reader is advised to reference the available journals to identify the uses and results of these materials. Much of the information discussed was obtained from the manufacturer directly.

Indications for Use of Prosthetic Materials

Surgeons recognize that the main purpose in the use of these materials will be the repair of a fascial defect in the abdominal wall. The main indications of use of the materials are listed in Table 7.1.

Musculofascial tissue strength can be lost in a variety of ways. The most common, of course, would be due to the external etiology of the weakness that develops after a laparotomy or other abdominal incision that is larger than that of the 5 mm laparoscopic trocar (although even this small incision can rarely develop a hernia). Another example would be the loss of tissue with trauma such as gunshot wounds. The increase of intra-abdominal pressure that results from significant weight gain will result in an internal source of weakening of the abdominal wall musculature. Poor nutritional

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Table 7.1 Indications for prostheses

Replacement of lost musculofascial tissue caused by:
Trauma
External
Internal
Infection
Reinforcement of native tissue weakness
Aging (laxity of tissues)
Neurological deficit (denervation)

Table 7.2 Natural prosthetic products

Autogenous dermal grafts	Whole skin grafts
Dermal collagen homografts	Porcine dermal collagen
Autogenous fascial heterografts	Lyophilized aortic homografts
Preserved dural homografts	Bovine pericardium

Table 7.3 Nonmetallic synthetic products "ideal surgical" material are listed in Table 7.4

Fortisan fabric (cellulose)	Polytetrafluoroethylene
Polyvinyl sponge	Polypropylene mesh/gelatin film
Polyvinyl cloth	Polyester-reinforced silicon sheeting
Nylon mesh	Silastic
Carbon fiber	Polyester (as a solid sheet)
Silicon-velvet composite	Carbon fiber

Table 7.4 Ideal surgical clinical characteristics of synthetic products

Permanent Repair of the Abdominal Wall (i.e., no recurrences)
Ingrowth characteristics that result in a normal pattern of tissue repair and healing
Does not alter the compliance of the abdominal wall musculature
Lack of adhesion predisposition
Cuts easily and without fraying
Inexpensive
Lack of long-term complications such as pain or fistualization

From Cumberland [10] and Scales [11]

or protein malnutrition is also a source of such problems. Other predisposing factors such as emphysema or the chronic bronchitis of individuals that smoke tobacco products results in a constant increase in intra-abdominal pressure because of a frequent cough. Life-threatening infections such as fasciitis and gangrene will produce large areas of necrosis and resultant tissue loss. More frequently, the development of a postoperative wound infection will increase the risk of herniation by as much a five times. In fact, almost 30% of patients that develop a postoperative incisional wound infection will eventually develop an incisional hernia [5].

The effects of aging and the declining ability of the elderly patients to repair the native tissues will lead to the loss of fascial integrity. This is commonly seen with the direct inguinal hernia. It also occurs with the enlargement of the linea alba that is referred to as diastasis recti. These latter defects can enlarge and occasionally become symptomatic, requiring repair. The disruption of collagen that is seen by the effects of smoking will have a similar effect (i.e., metastatic emphysema).

The most common defect that results from a denervation phenomenon follows the flank incision that is utilized in a nephrectomy, lumbar sympathectomy, or an anterior approach to the lumbar interbody fusion for degenerative disc disease. In these entities, there is usually not the defined fascial edge that is seen with the more common anterior abdominal wall defects. This is due to the broad surface of the denervated musculature that has intact fascia but lacks the reinforcement of healthy muscle tissue.

Prosthetic Materials: History

The use of materials for the repairs of hernias can be found in antiquity. It is believed that Heliodorus used the cellulose from a cotton or flax plant to effect scarification in the inguinal area to treat herniation in A.D. 25. The use of silver as a synthetic prosthesis was reported in 1900 [6]. Metallic biomaterials have also included the use of tantalum gauze mesh and stainless steel mesh. None of these materials gained wide acceptance because of the complications that were associated with their usage. These included lack of pliability, seroma development, wound infection, fatigue fractures, herniation through the fracture sites, abnormal scarification, adhesions, loss of structural integrity, and allergic reactions. Reoperation in these patients was particularly challenging.

Natural prostheses were considered as myofascial replacement shortly after the use of silver filigree [7]. Other materials that have been used are listed in Table 7.2.

These materials were used with good results in some cases but scarcity and cost limited their widespread adoption. Additionally, there were concerns of viral transmission as one case of Creutzfeld-Jacobs disease developed in a patient that had the use of a dural homograft. The development of other synthetic biomaterials that were closer to the ideal prosthesis hastened the demise of the use of these products in the past. As we now have seen over the last several years, some of these products have seen resurgence. Updated methods of processing these products have allowed for improved safety and efficacy resulting in an expansion of their use.

A series of nonmetallic synthetic prosthetic biomaterials were used as well (Table 7.3). As with the metal materials, there were significant disadvantages with these products also. These included infections, sinus tract formation, alteration of the product in vivo, and lack of incorporation

into the native tissues. The use of the carbon fiber in humans has never been attempted because of concerns of potential carcinogenicity (although it functioned fairly well in the experimental model). With some of these materials, newer hernia repair products have used these materials again because of more modern manufacturing capabilities.

The synthetic prosthetic materials can be divided into the absorbable and nonabsorbable products. There has been a recent introduction of non-synthetic biomaterials designed for usage in the repair of hernias, commonly referred to as the "biologics". These are based upon the use of porcine, bovine or cadaveric tissues to produce a collagen matrix. All of these products are not truly absorbable as they are intended to provide a scaffold for the native fibroblasts to incorporate natural collagen to repair a fascial defect. It is the goal of these devices to repair the hernia defect with the tissues of the patient as these will be degraded and replaced over time.

The synthetic nonabsorbable materials are of many types, sizes, and shapes. The use of these products is commonplace in the repair of inguinal hernias. The current use of the prosthesis in the tension-free concept of a repair of the incisional hernias has gained widespread acceptance within the last several years. With the exception of the very smallest of hernias, every laparoscopic approach employs a prosthesis. There is a growing trend to use a synthetic or, more commonly, biologic material to repair even the diaphragmatic hernias associated with gastroesophageal reflux disease.

The materials that are presented below are given in an arbitrary arrangement and with an accurate information that could be obtained. An effort was made, however, to stratify these products in a classification that grouped similar products together. I have attempted to identify all of the currently available products that are used in most parts of the world at the time of publication. Some of these materials have either no published clinical data or very scanty information as to the clinical performance characteristics. Therefore, it is certain, that some products and/or details have been overlooked despite my efforts to present all that I could identify. Due to the very large variation in the sizes of the products, little comment regarding the sizes of these products will be given. The reader is referred to the respective manufacturer for these details. Additionally, if a product or photo of a product is not shown, it is likely due to lack of assistance from a manufacturer in the provision of that information. It should also be noted that not all of these products are available in all countries. Manufacturers have limited the release of many of them to only selected areas of the world or have not obtained the necessary governmental approvals for clinical distribution at the time of this writing. Finally, it is certain that all of the available products are not included in this compilation. Many companies are quite small or have limited production. Therefore, if any of these that are not included it was not because of an intended omission but rather a lack of available information.

Absorbable Prosthetic Biomaterials

The general purpose of these is the temporary replacement of absent tissue (Table 7.5). The strength of these materials and the lack of permanency make some of them unsuitable for the permanent repair of any hernia.

Bio-A, TephaFLEX, and TIGR meshes represent a different type of mesh product. These products represent a new generation of materials that might fill a gap in the products that are available today. The clinical performance characteristics of these are somewhere between the biologic and synthetic materials. The exact fit for the repair of tissue defects has yet to be defined at this time. The *Bio-A* (Fig. 7.1) product is supplied in flat sheet. It is made of trimethylene carbonate and polyglycolic acid. It will maintain approximately 70% of its tensile strength for 21 days. Its use is multifaceted but it is touted for use instead of a biologic product. It serves as a scaffold to allow for fibroblastic infiltration and replacement by the patient's native collagen.

Safil Mesh (Fig. 7.2) is a polyglycolic acid material that will retain 50% of its strength for 20 days. It is not to be

Table 7.5 Absorbable products

Dexon, US Surgical Corp./Davis & Geck, Norwalk, CT, USA
Safil Mesh, B. Braun Surgical, Germany
TIGR mesh, Novus Scientific Pte Ltd., Singapore
TephaFLEX Mesh, Tepha, Inc, Lexington, MA, USA
Vicryl (knitted) mesh, Ethicon, Inc., Somerville, NJ, USA
Vicryl (woven) mesh, Ethicon, Inc., Somerville, NJ, USA

Fig. 7.1 Bio-A (flat sheets and hiatal hernia patch)

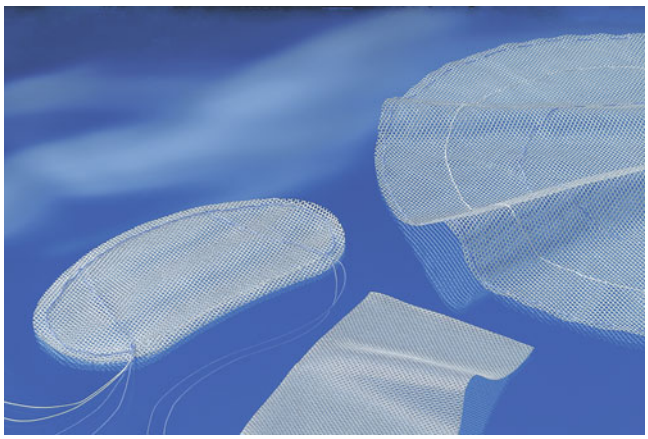


Fig. 7.2 Safil Mesh

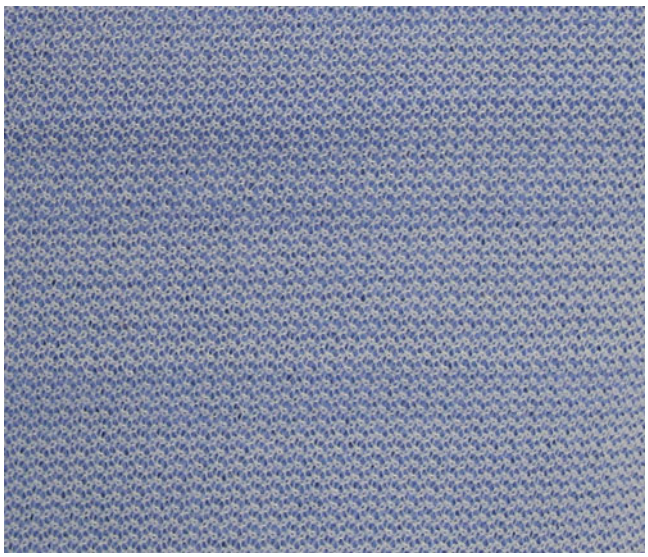


Fig. 7.3 TephaFLEX

considered a permanent repair for tissue. It is said to be used to strengthen the closure of the abdominal and chest walls. The above photo also shows the bags into which this material is also shaped for use in splenic preservation.

TephaFLEX (Fig. 7.3) is composed of poly-4-hydroxybutyrate (P4HB). It is degraded by hydrolysis and hydrolytic enzymatic processes. The absorption of the material is minimal until about 26 weeks postimplantation and is essentially complete in about 52 weeks.

TIGR Matrix Surgical Mesh (Fig. 7.4) is knitted from two different synthetic resorbable fibers, polyglycolic acid and polylactic acid (PLA). The Matrix is warp-knitted in a proprietary way, allowing it to gradually increase its relative degradation over time. The strength of the Matrix is comparable to conventional mesh implants for the initial 6–9 months following implantation. The first fiber (polyglycolic acid) appears to lose its functional capabilities in 2 weeks

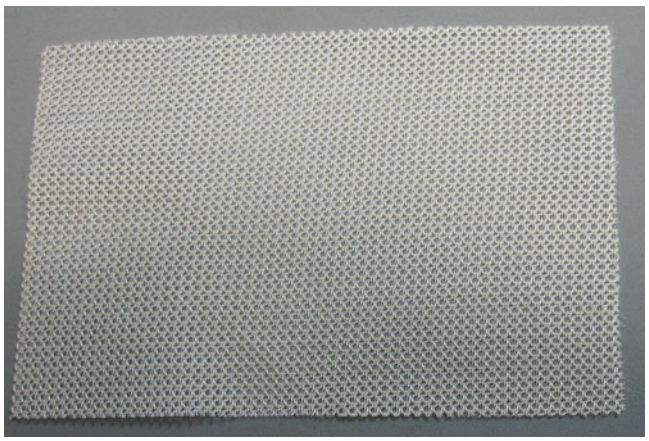


Fig. 7.4 TIGR Matrix Surgical Mesh

while the second fiber (PLA) maintains its strength for approximately 9 months.

The *Vicryl* and *Dexon* meshes are primarily PLA (Fig. 7.5). They can be affixed onto the fascia directly with sutures but are not of sufficient strength to formally repair a defect. Most frequently these are used to provide a buttress of support for the temporary closure of an infected incisional wound of the abdomen or in the patient with intra-abdominal sepsis or abdominal compartment syndrome. They have also been used in the treatment of complex or very large hernias that will be repaired in a staged fashion. In that instance, this product will be placed as a bridge and the patient will be returned to the operating room within a few days to perform the definitive procedure.

Biologic Products

As noted earlier, these products do not represent a new concept in hernia repair. They are marked improvement of the materials developed earlier in the last century. They are based upon a harvested collagen matrix that is manufactured into sheets of tissue-engineered materials that can be used to repair defects in the abdominal wall. The concept of these materials is that the biologic material will allow the migration of the patient's own fibroblasts onto them so that collagen will be deposited to form a "neo-fascia." Studies have shown that the extracellular matrix scaffolds from these materials show rapid degradation that is associated with remodeling to a tissue with strength that exceeds that of the native tissues [8]. For the most part, these are used in open techniques but there is some usage in laparoscopic methods especially in the repair of hiatal hernias.

There are similarities of all of the biologic products. They are all harvested from an organism that was alive. The type of source will dictate the size of the material and in most cases, the thickness of the product. The thickness will be variable in

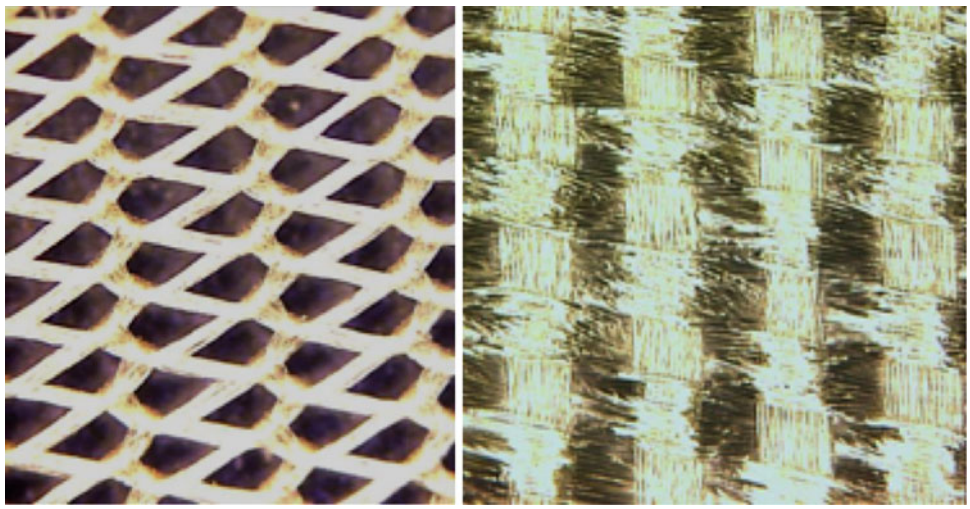


Fig. 7.5 Vicryl mesh, knitted (*left*) and woven (*right*)

nearly all of them. Some manufacturers have found creative techniques to increase the size of the materials available. All of the products are processed to eliminate all cellular and nuclear material as well as any prions. Following this, a few undergo another process to cross-link the collagen at the molecular level (these are noted when discussed below). The final stage is the sterilization of the prosthesis. It is beyond the scope of this chapter to cover all of these in detail. However, it should be considered, when using any of these materials, that the processing plays a large part into the characteristics and the clinical behavior of them postimplantation.

In general, the biologic products were introduced for use in contaminated fields such as a synthetic mesh infection. While they can be used in this manner, it is recommended that the wound should not possess gross pus as the collagenases of some bacteria and inflammatory cells can degrade these products. These products are finding a place in the repair of very complex noninfected hernias as well. One concern will be that if the patient possesses a collagen deficiency disorder, the remodeling of these products will not occur properly, leading to a predictable failure of the repair. It has also been learned over the last few years that these products perform best if they have direct contact with some type of vascularized tissue. Intuitively, if the expectation of these biologic scaffolds becomes infiltrated by fibroblasts and subsequent collagen deposition, blood supply will deliver these cells more rapidly. Consequently, a higher failure rate will be noted if a biologic prosthesis is used as a "bridge" between fascial edges.

Cadaveric Products

The human cadaveric products have a long history (Table 7.6). These products are similar in that they are not available in exceedingly large sizes. There is significant variability in the amount of stretch that each of these will undergo either at the time of implantation and subsequent to the procedure. This stretch varies from product to product and should be accounted for at the time of implantation. These products are not cross-linked and require rehydration. These are also commonly used in the repair of hiatal hernias.

Table 7.6 Cadaveric biologic prostheses

Alloderm, LifeCell Inc., Branchburg, NJ, USA (Fig. 7.6)
AlloMax, Davol, Inc., Warwick, RI, USA (Fig. 7.7)
DermaMatrix, Synthes CMF, West Chester, PA, USA
Flex HD, Ethicon, Inc., Somerville, NJ, USA (Fig. 7.8)

Fig. 7.6 AlloDerm

Bovine Products

The bovine products are from dermis, pericardium, or tendon (Table 7.7). Only the *SurgiMend* (Fig. 7.9) is fetal (dermal) tissue. There is a very unique product, *Easy Prosthesis (PPM/collagen)*, which is a combination of collagen from bovine

Fig. 7.7 AlloMax

Fig. 7.8 FlexHD

Table 7.7 Bovine biologic prostheses

Easy Prosthesis (PPM/Collagen), TransEasy Medical Tech.Co. Ltd., Beijing, China
SurgiMend, TEI Biosciences, Boston, MA, USA
Tutopatch, RTI Biologics, Alachua, FL, USA
Tutomesh, RTI Biologics, Alachua, FL, USA
Veritas, Synovis Surgical Innovations, St. Paul, MN, USA

tendon with polypropylene (PP) (see Fig. 7.116). It is discussed in the section titled "Prostheses for Incisional and Ventral Hernioplasty with an Absorbable Component." Because of the source of all of these products, there will be limitations on the size ranges available.

These are flat sheets. *Tutopatch* (Fig. 7.10) and *Tutomesh* (Fig. 7.11) are of the same source (pericardium) and processing. However, Tutomesh is perforated (unlike the other three products). The use of all of these bovine products has generally been limited to the incisional hernia repair. However there has been increasing application in the repair of hiatal hernias and occasionally in inguinal hernias. *Veritas* is pericardium also.

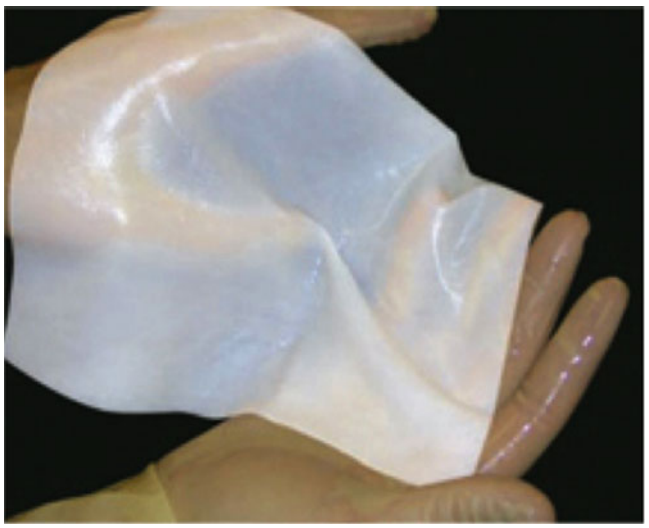


Fig. 7.9 SurgiMend

Fig. 7.10 Tutopatch

Fig. 7.11 Tutomesh

Table 7.8 Porcine biologic prostheses

CollaMend FM, Davol, Inc., Warwick, RI, USA
Fortagen, Organogenesis, Inc., Canton, MA
Permacol, Covidien, Inc., Mansfield, MA, USA
Strattice, LifeCell Inc., Branchburg, NJ, USA
Surgisis, Cook Surgical, Inc., Bloomington, IN
XenMatrix, Davol, Inc., Warwick, RI, USA
XCM Biologic Tissue Matrix, Synthes CMF, West Chester, PA, USA

Fig. 7.12 CollaMend FM

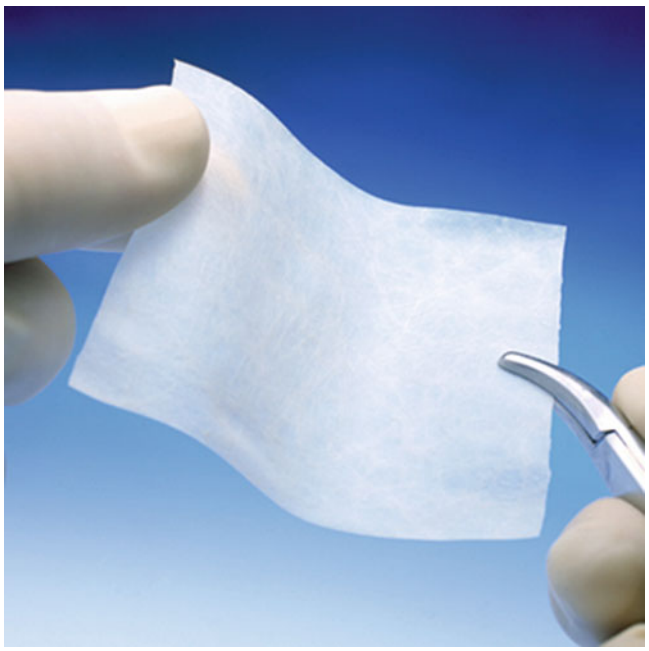


Fig. 7.13 FortaGen

Fig. 7.14 Permacol

Porcine Products

A number of these materials are available (Table 7.8). Depending on the manufacturer, they are in different sizes and shapes and construction. Some are laminated, some are cross-linked, some are perforated, some require rehydration, and others do not. These are specific to the product and it is recommended that the user follow the instructions for use that is provided with each product.

CollaMend FM (Fig. 7.12) is a cross-linked product derived from porcine dermis. All cross-linked products are bonded at the molecular level with one of the several different chemicals. The level of cross-linking will vary with the product and will impact the longevity of the matrix within the body. Generally, the cross-linked products will remain longer in the intact state and, as such, tend to behave more like a synthetic material than an absorbable one. However, all are eventually resorbed. This product requires rehydration and is fenestrated.

FortaGen (Fig. 7.13) is based upon porcine small intestinal submucosa as is the Surgisis below. The FortaGen material is a three or five-layer construct with a low level of cross-linkage that allows cellular infiltration and remodeling. *Permacol* (Fig. 7.14) is a dermal collagen-based product that is cross-linked and does not require rehydration. It, too, will be present for a prolonged period of time due to the cross-linkage of the collagen fibers. *BioDesign Surgisis Hernia Grafts* (Figs. 7.15, 7.16, and 7.17) are three products that are designed for the repair of specific hernias, ventral, inguinal, and hiatal. They all are developed from porcine small intestinal submucosa. These are laminated, sewn together, and fenestrated. It is one of the older products in the biologic market.

Strattice is available in two thicknesses, firm and pliable. It is made from dermis. One of the more recent additions to the biologic market is *XenMatrix* (Fig. 7.18). However, it has really been available for several years but has only recently been brought to an expanded market. It is dermal based and is not cross-linked. It does not require rehydration or

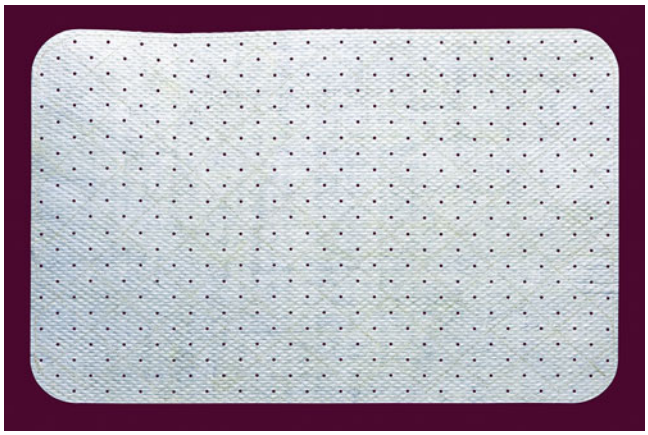


Fig. 7.15 Biodesign Surgisis Hernia Graft

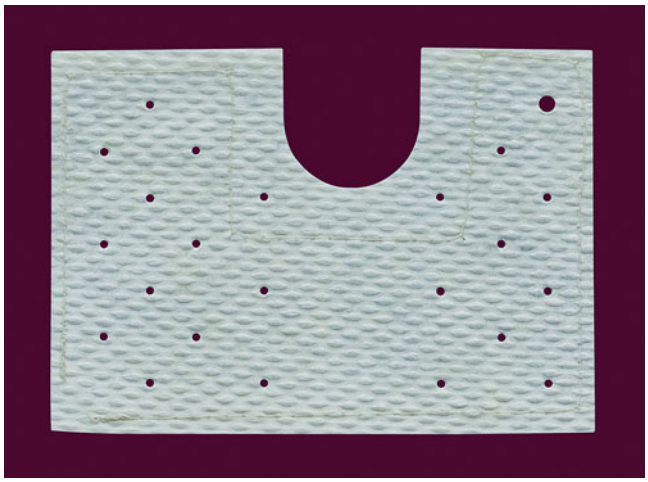


Fig. 7.16 Biodesign Surgisis Hiatal Hernia Graft

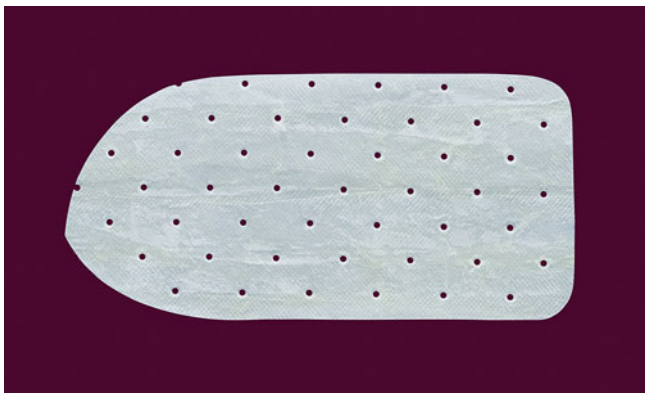


Fig. 7.17 Biodesign Surgisis Inguinal Hernia Graft

refrigeration. As with many of the biological materials, it can vary in thickness. *XCM Biologic Tissue Matrix* (Fig. 7.19) is also a non-cross-linked porcine dermal product and does not require rehydration.

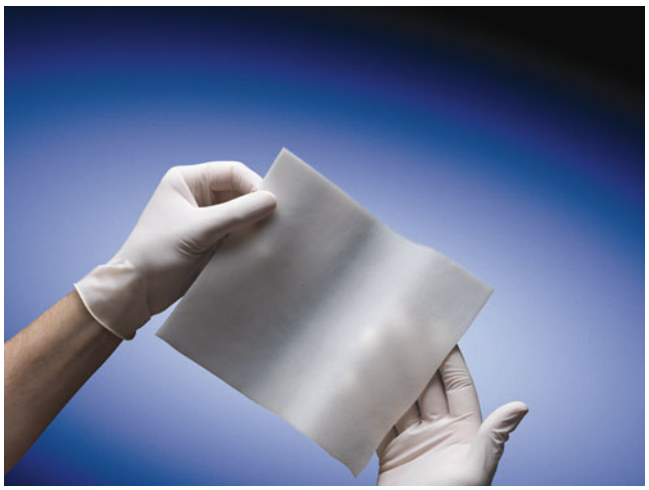


Fig. 7.18 XenMatrix

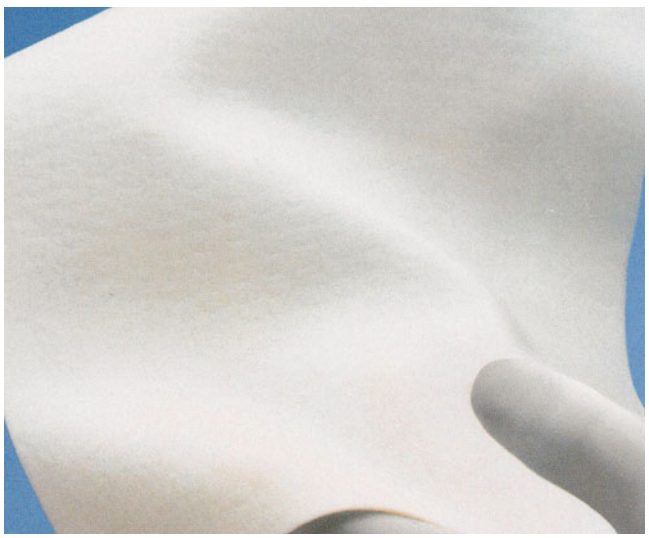


Fig. 7.19 XCM Biologic Tissue Matrix

Flat Prosthetic Biomaterials

The currently available products in use today are polypropylene (PP), polyester (POL), polytetrafluoroethylene (PTFE), expanded PTFE (ePTFE), or condensed PTFE (cPTFE). All are available in a variety of sizes and can be cut to conform to the dimensions that are necessary. There are currently so many products on the market today that it is quite difficult to become well versed in all of these materials. In fact, the similarities of these biomaterials may result in many of them to be considered a "commodity" type of a product, whereupon only the pricing of the material will influence the use of it. The most prominent and commonly used are PP materials (Table 7.9). These, typically, can be used either in the open or laparoscopic applications. Because of the complexities of

Table 7.9 Flat polypropylene products

Basic mesh, Di.pro Medical Devices, Torino, Italy
Basic Evolution mesh, *Di.pro Medical Devices, Torino, Italy*
Bard mesh, Davol, Inc., Warwick, RI, USA
Bard Soft mesh, Davol, Inc., Warwick, RI, USA
Biomesh P1, Cousin Biotech, Wervicq-Sud, France
Biomesh P8, Cousin Biotech, Wervicq-Sud, France
Biomesh P9, Cousin Biotech, Wervicq-Sud, France
Combi Mesh Pro, Angiologica, S. Martino Sicc., Italy
DynaMesh PP-Standard t, FEG Textiltechnik mbH, Aachen, Germany
DynaMesh PP- Light, FEG Textiltechnik mbH, Aachen, Germany
Easy Prosthesis, TransEasy Medical Tech.Co. Ltd., Beijing, China
Easy Prosthesis Lightweight, TransEasy Medical Tech.Co. Ltd., Beijing, China
Hertra 0, HerniaMesh, S.R.L., Torino, Italy
Hermesh 3,4,5,6,7,8, HerniaMesh, S.R.L., Torino, Italy
HydroCoat Mesh, Promethean Surgical Devices, East Hartford, CT, USA
Lapartex, Di.pro Medical Devices, Torino, Italy
Optilene, B. Braun Melsungen AG, Melsungen, Germany
Optilene LP, B. Braun Melsungen AG, Melsungen, Germany
Optilene Mesh Elastic, B. Braun Melsungen AG, Melsungen, Germany
Parietene, Covidien plc, Dublin, Ireland
Parietene LIGHT, Covidien plc, Dublin, Ireland
Premilene, B. Braun Melsungen AG, Melsungen, Germany
Prolene, Ethicon Inc., Somerville, NJ, USA
Prolene Soft Mesh, Ethicon Inc., Somerville, NJ, USA
Prolite, Atrium Medical Corporation, Hudson, NH, USA
Repol Angimesh 0,1,8,9, Angiologica, S. Martino Sicc., Italy
Restorelle, Mpathy Medical Devices, Raynham, MA
Surgimesh 1,2, XLight, Aspide Medical, St. Etienne, France
SurgimeshWN, Aspide Medical, St. Etienne, France
Surgipro Monofilamented, Covidien plc, Dublin, Ireland
Surgipro Multifilamented, Covidien plc, Dublin, Ireland
Surgipro Open Weave, Covidien plc, Dublin, Ireland
TiMESH, GfE Medizintechnik, Nuremburg, Germany
Trelex, Meadox Medical Corporation, Oakland, NJ, USA
VitaMESH—Proxy Biomedical Limited, Galway, Ireland

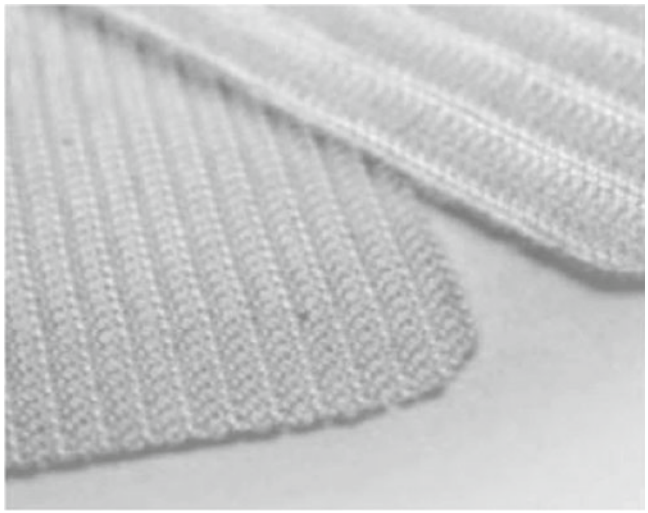


Fig. 7.20 Basic mesh

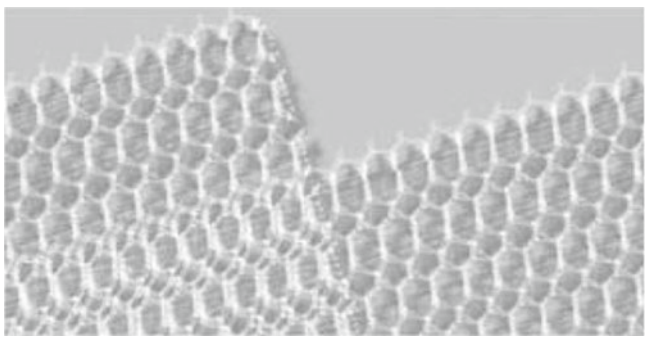


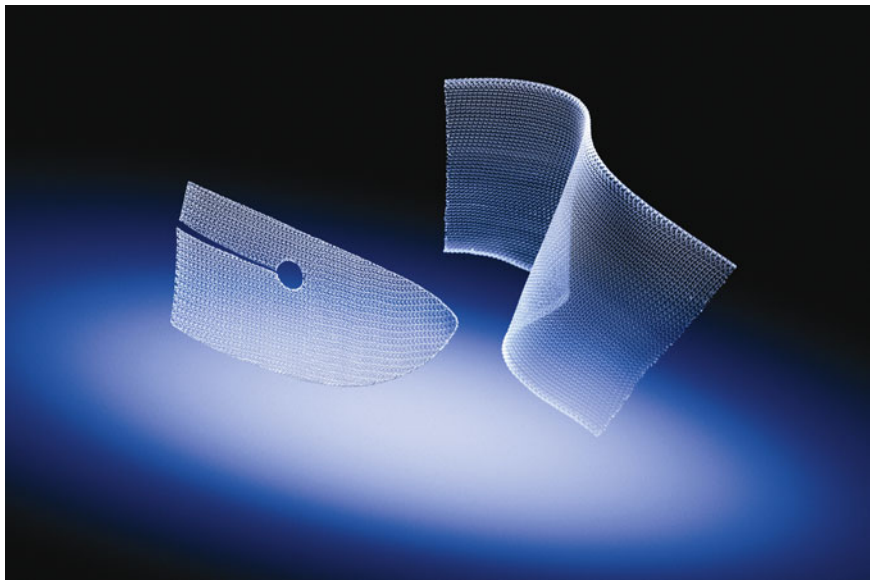
Fig. 7.21 Basic Evolution mesh

pore sizes and the multitude of differing weights and shapes of the PPM within each of these materials, this chapter could not expound upon all of them. The reader is referred to the manufacturer for further information in the exact densities, weights, and pore sizes of these products.

Basic mesh (Fig. 7.20) is a lightweight mesh. Di.pro has developed an ultra-lightweight version that is called Basic Evolution mesh (Fig. 7.21). Although most market penetration is in Europe, there are sites across the globe that have availability of this material. *Bard Mesh* (Fig. 7.22) is probably the oldest flat sheet of heavy weight polypropylene in existence, having been brought to market in the early 1960s. It is still in use today and like many of these prostheses, a lightweight version have been developed, the *Bard Soft Mesh* (Fig. 7.23). *Biomesh P1, P3, and P9* (Figs. 7.24, 7.25, and 7.26) products are differentiated from each other on the basis of the weight of the material. *Combi Mesh Pro* (Fig. 7.27) is a combination product that is also designed for incisional and ventral hernia repair. It is made of a thin layer of PPM bonded on one side with a thin polyurethane sheet. A colored thread that can be seen in the photo is added to facilitate the identification of the polyurethane layer. It can be easily pulled out after insertion of the product. While this product is designed for the laparoscopic repair, the manufacturer describes its use in the open technique.

DynaMesh (Fig. 7.28) comes in two weights; the standard is twice the weight of the lightweight product. *Easy Prosthesis* (Fig. 7.29) is available as *PPM* (medium weight) and *PMM*, which is lighter in weight and thinner than PPM. The *Easy Prosthesis Lightweight* (Fig. 7.30) is the lightest product of these. The *Hertra 0* mesh is designed for open repair of inguinal hernias, not laparoscopic, especially for the Trabucco repair. The *Hermesh 3–8* can be used either open or laparoscopic (Fig. 7.31). The graduated weights of these vary from the heaviest (3) to the lightest (8). *HydroCoat Mesh* is a new product that only recently received governmental approval

Fig. 7.22 Bard Mesh



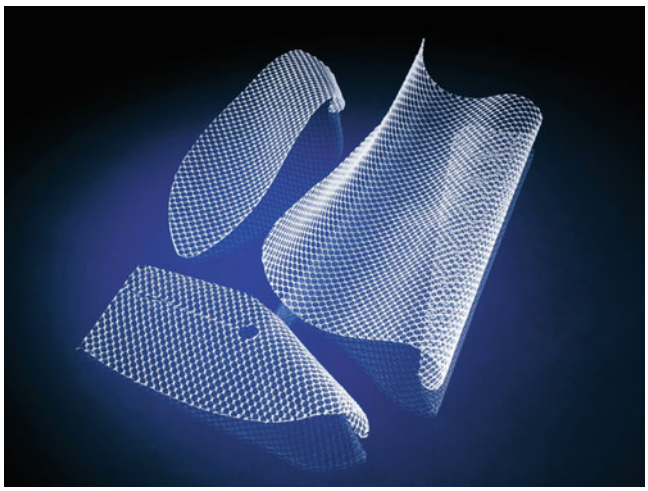


Fig. 7.23 Bard Soft Mesh

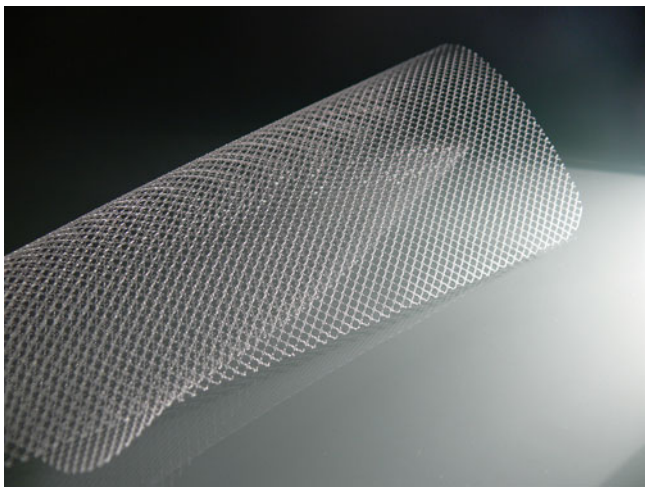


Fig. 7.25 Biomesh P3

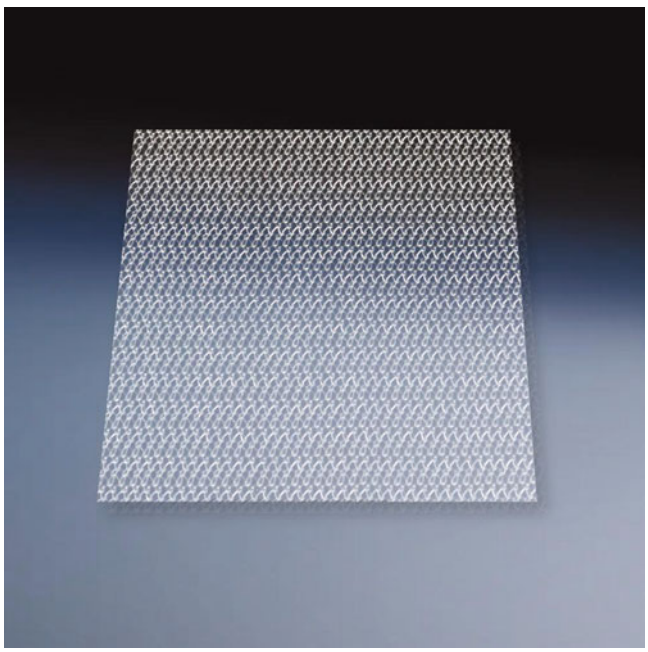


Fig. 7.24 Biomesh P1

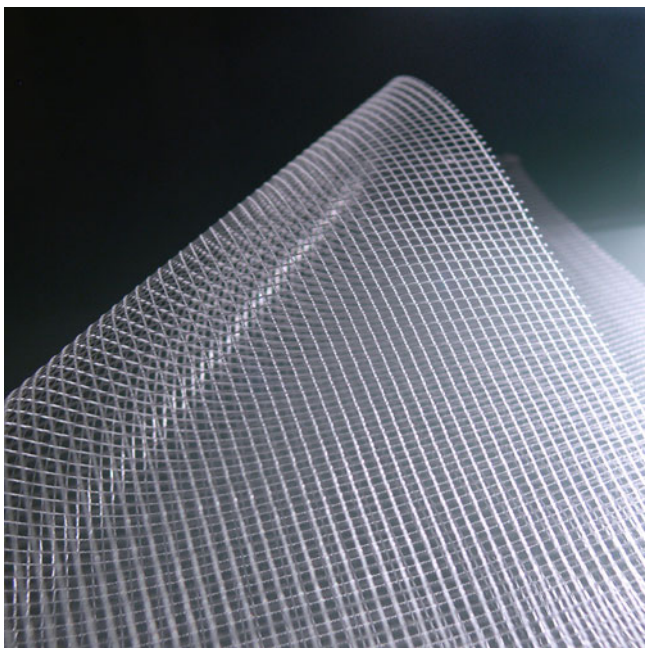


Fig. 7.26 Biomesh P9

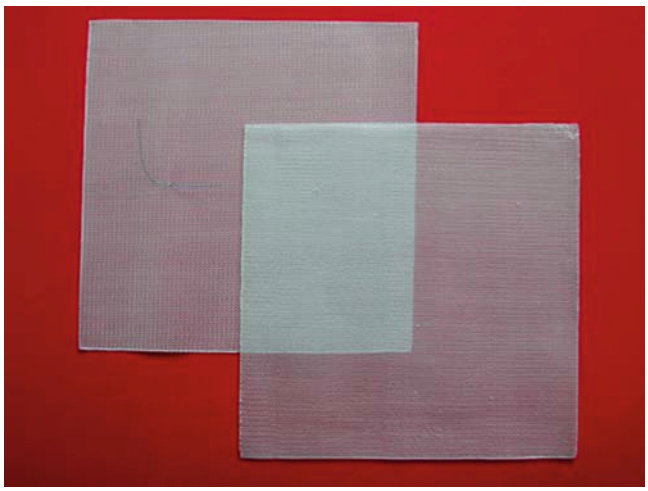


Fig. 7.27 Combi Mesh Pro

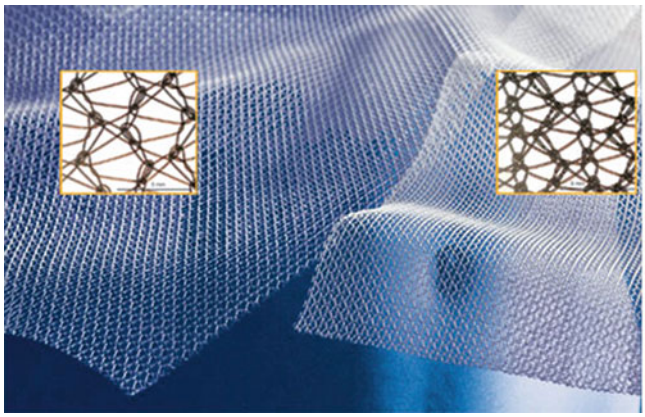


Fig. 7.28 DynaMesh: Light and Standard

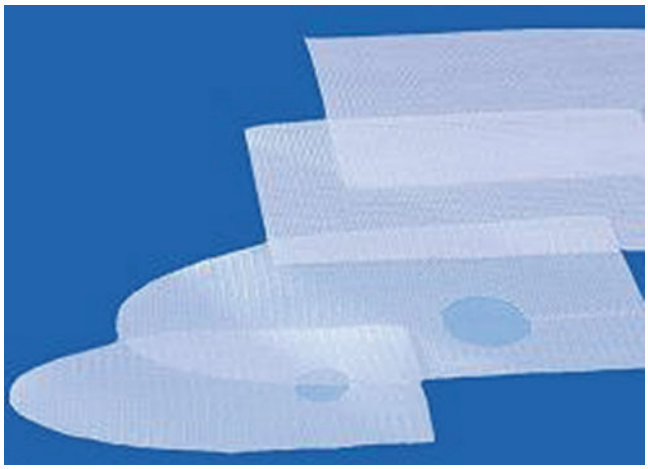


Fig. 7.29 Easy Prosthesis

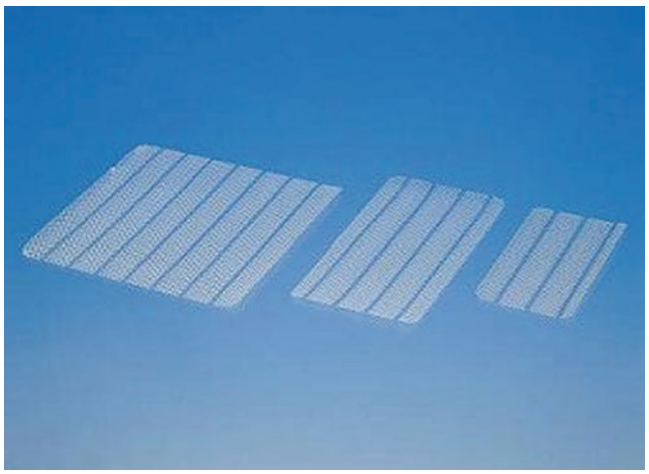


Fig. 7.30 Easy Prosthesis: Lightweight

Fig. 7.31 Hermesh variety

for clinical use. It is manufactured with PP that is coated with polyurethane. It is available with different configurations in differing thicknesses and differing microporous structures. It is unknown at this time if this can be placed in the intraperitoneal space. *Lapartex* (Fig. 7.32) is a heavier product than some of the other materials.

The *Optilene* products vary from the heaviest by that name to the lighter *LP* and the *Elastic*, the latter is very light and has larger pores than the other materials (Figs. 7.33, 7.34, and 7.35). Unlike some of the other prostheses, the blue lines in the Optilene do not signify an absorbable component. *Parietene and Parietene LIGHT* products are flat sheet products. *Premilene* (Fig. 7.36) is the heaviest weight product in the Braun flat mesh product line. *Prolene* (Fig. 7.37) is also a heavier weight mesh material and it is one of the older products available. Its lighter weight companion product, *Prolene Soft Mesh* (Fig. 7.38) has larger pores than the original mesh and blue lines to help differentiate it. *Prolite* (Fig. 7.39) was

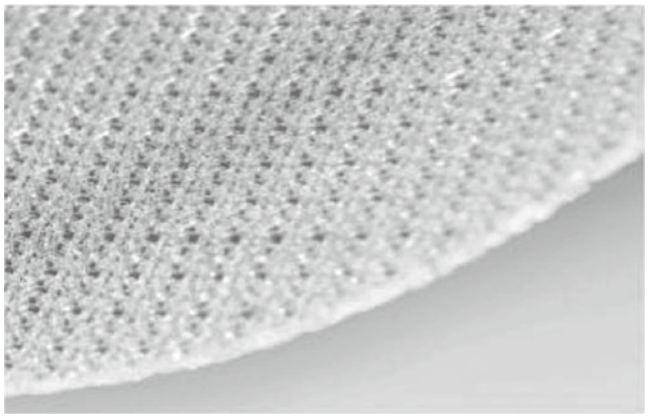


Fig. 7.32 Lapartex

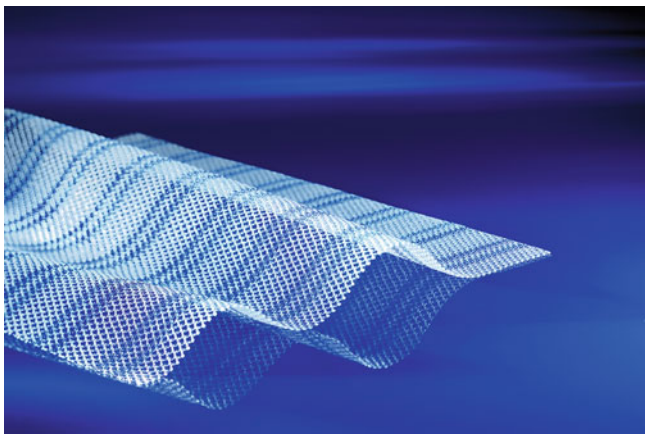


Fig. 7.33 Optilene

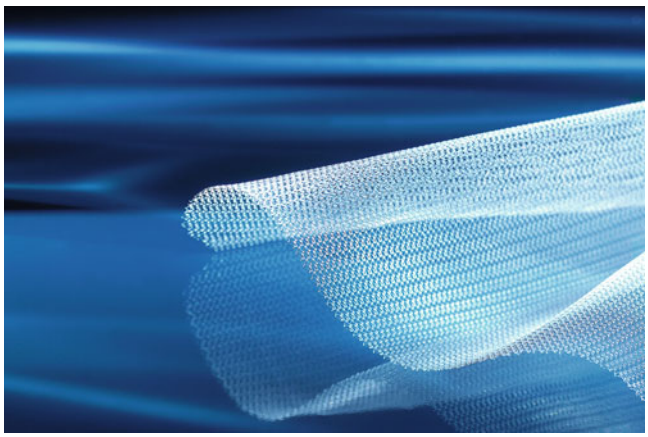


Fig. 7.34 Optilene LP

one of the earliest meshes that were introduced as a lighter weight material. The more recent *Prolite Ultra* (Fig. 7.40) possesses even less weight of mesh than the older one.

Restorelle is available but has little history in the hernia repair market as it has only recently received governmental

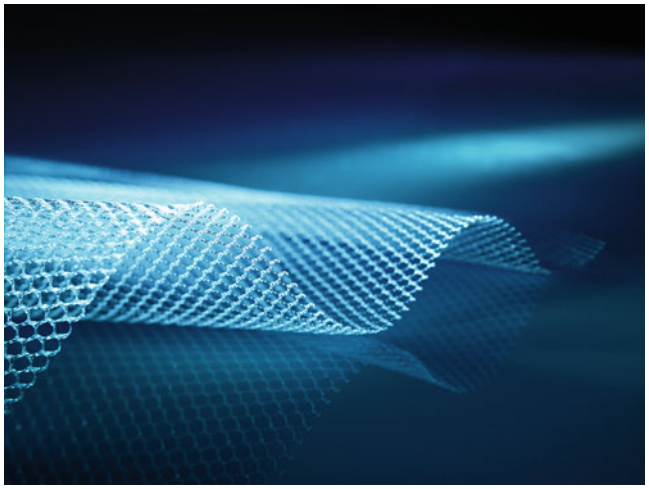


Fig. 7.35 Optilene Elastic

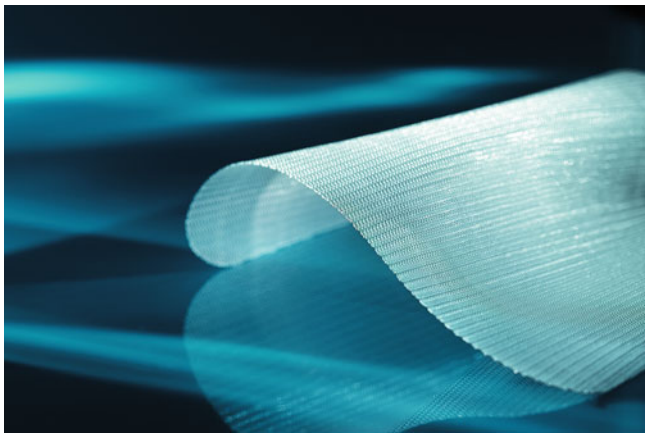


Fig. 7.36 Premilene

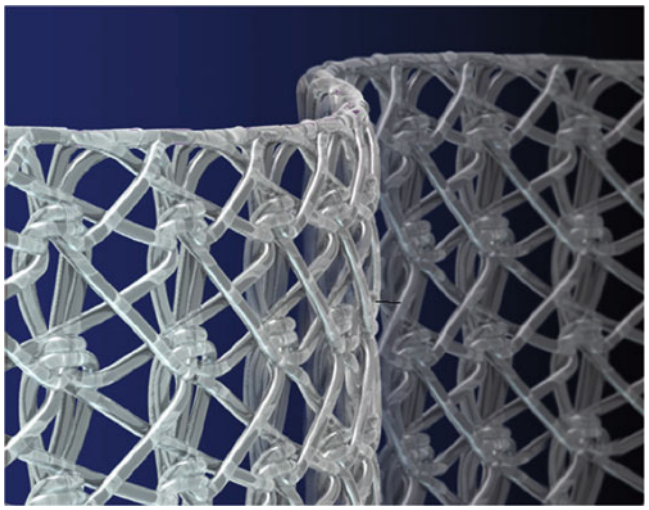


Fig. 7.37 Prolene

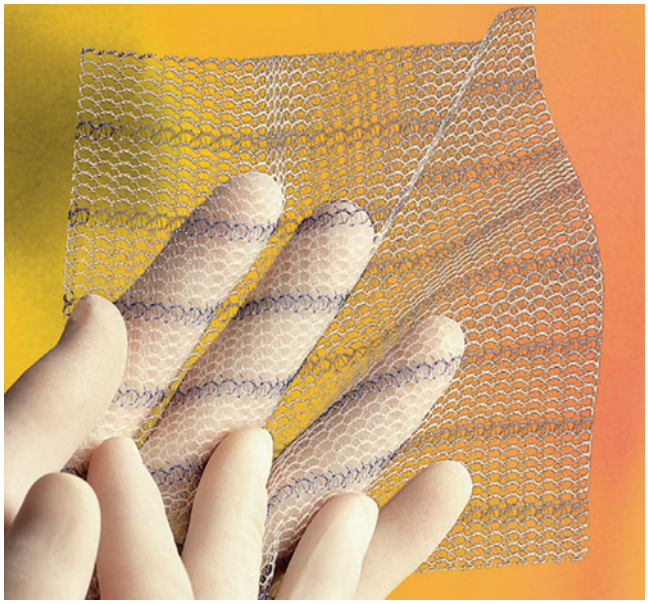


Fig. 7.38 Prolene Soft Mesh

Fig. 7.39 Prolite

approval. *Repol Angimesh 0, 1, 8,* and *9* (Fig. 7.41) are all similar and differentiated in the weights and weaves from each other. The 0 is the lightest and 9 is the heaviest. *SurgiMesh 1, 2,* and *XLight* are PP products similar to the other PP products. *SurgiMesh WN* (Figs. 7.42 and 7.43), however, is a nonwoven microfiber PP product that is extremely lightweight and has a differing microstructure

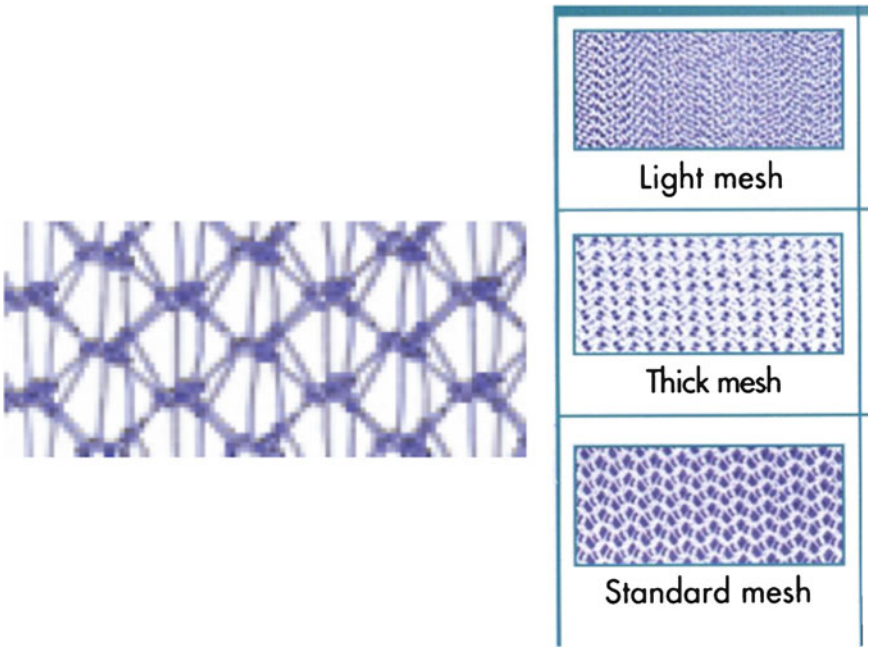
Fig. 7.40 Prolite Ultra

than the other materials listed in this section. *Surgipro* was originally introduced as a multifilamented mesh (Fig. 7.44). Because of the demand for a monofilamented product (Fig. 7.45), the second-generation product was released. The multifilament material is noticeably softer than the monofilamented one. There is now an open weave product called the *Surgipro Open Weave* (Fig. 7.46).

TiMESH (Fig. 7.47) is similar to the lightweight materials but differs from all of them in that there is a bonded layer of titanium on the fibers of the PP using nanotechnology (Fig. 7.48). This is supposed to allow ingrowth in a flexible manner while inhibiting the development of a scar plate. *Trelex* mesh is an older product that is heavier weight material. *VitaMESH* is of a single lightweight material promoted for laparoscopic inguinal repair.

The differences in the appearance of the prosthetics are easily seen in these photos. The size of the pores of these materials as well as the thickness of the product will have a significant impact on the stiffness. These factors affect the degree of scarring within the tissues. Additionally, the pore sizes vary greatly from each of these products. Since the last edition of this textbook, the lighter weight products have significantly impacted the prosthetic repair of hernias. The current thought is that, for the most part, there is less pain and a scar plate with these lightweight, larger pore meshes. In some cases, these may have become "too thin" and there are a few anecdotal reports of mesh fracture and hernia recurrence. Generally, these meshes are well accepted in the inguinal arena but one should be sure of the strength of these products in the ventral and incisional hernia repair.

Fig. 7.41 Repol 0, 1, 8, 9



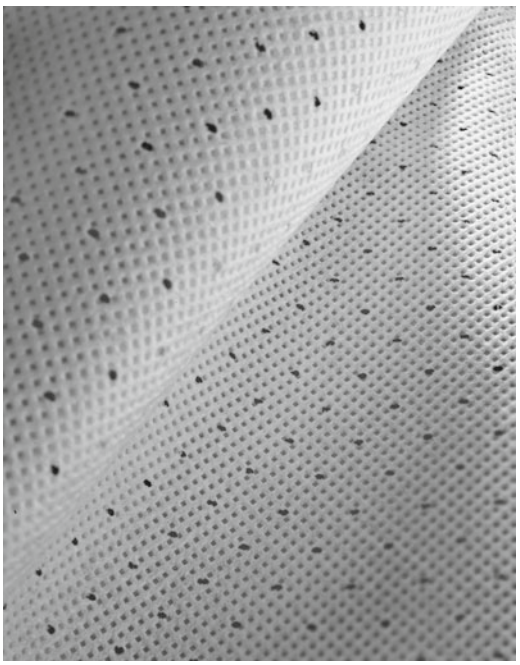


Fig. 7.42 SurgiMesh WN

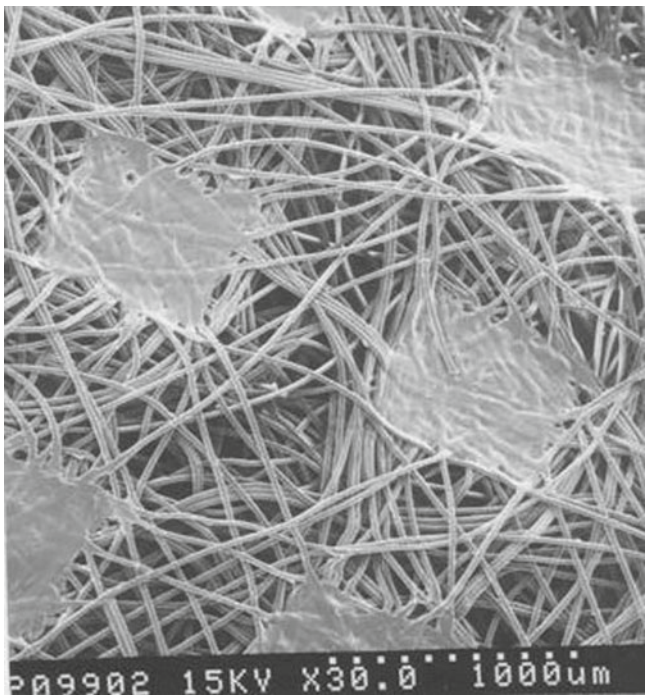


Fig. 7.43 SurgiMesh WN (scanning electron microscopic view)

The polyester biomaterials have seen more acceptance in Europe than in the USA in the past (Table 7.10). Currently, because of the development of newer products, these are used more frequently across the world than in prior times. Like the PP materials, these flat sheets listed can be used in inguinal and ventral hernia repair and can be placed either via an open approach or a laparoscopic technique. The majority of the polyester products that are currently available are produced in various configurations and most have some type of coating. Consequently, these are listed elsewhere in this chapter.

These flat sheets are the *Mersilene* (Fig. 7.49) mesh that has been available for many years and Angimesh R2 (Fig. 7.50). The *Parietex Flat Sheet Mesh* is available in two- or three-dimensional weaves, while the *Parietex Lightweight* (Fig. 7.51) product is a monofilament product.

Fig. 7.44 Surgipro, multifilamented

Fig. 7.45 Surgipro, monofilamented

Fig. 7.46 Surgipro Open Weave

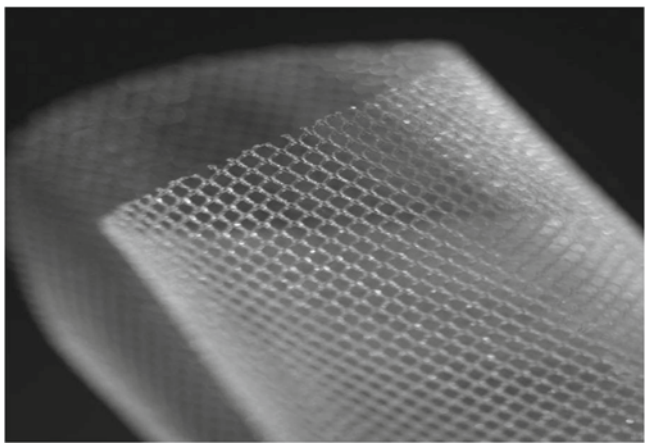


Fig. 7.47 TiMESH

Expanded PTFE prostheses (Table 7.11) have also been available in a flat sheet configuration for many years. In fact, the earliest products used in the intraperitoneal space for incisional hernia repair were of ePTFE. Because of their structure, they are solid and white unless an antimicrobial agent has been added.

The current DualMesh products are very similar in construction (Fig. 7.52). These represent the second generation

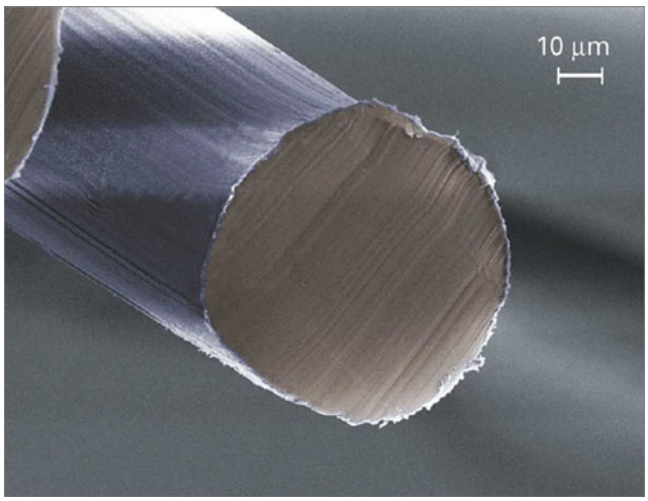


Fig. 7.48 TiMESH (scanning electron microscopic view)

Table 7.10 Flat polyester products

Angimesh R2, Angiologica, S. Martino Sicc., Italy
Mersilene, Ethicon Inc., Somerville, NJ, USA
Parietex Flat Sheet Mesh, Covidien plc, Dublin, Ireland
Parietex Lightweight Mesh, Covidien plc, Dublin, Ireland

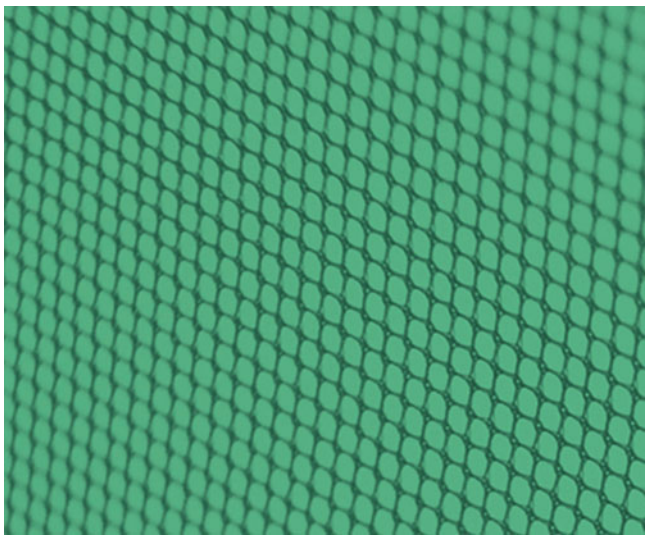


Fig. 7.49 Mersilene

of this prosthetic material. These all have two distinctly different surfaces. One side is very smooth and has interstices of 3 µm while the other has the appearance of corduroy with an approximate "ridge to ridge" distance of 1500 µm. This prosthesis is designed for use in the intraperitoneal space. The smooth side must therefore be placed facing the viscera as this minimizes the potential for adhesion formation. The rough surface is applied to the abdominal wall so that maximum parietal tissue penetration will occur. *DualMesh* is

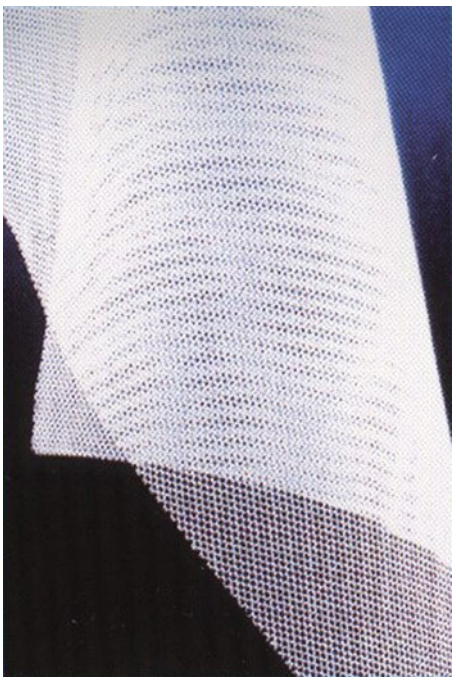


Fig. 7.50 Angimesh R2

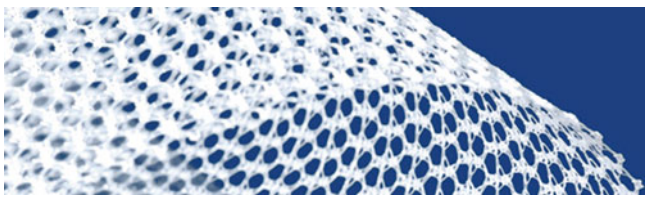


Fig. 7.51 Parietex Lightweight

Table 7.11 ePTFE products

DualMesh, W. L. Gore and Associates, Elkhart, DE, USA
DualMesh Plus, W. L. Gore and Associates, Elkhart, DE, USA
DualMesh Plus with Holes, W. L. Gore and Associates, Elkhart, DE, USA
Dulex, Davol, Inc.,Warwick, RI, USA
MycroMesh, W. L. Gore and Associates, Elkhart, DE, USA
MycroMesh Plus, W. L. Gore and Associates, Elkhart, DE, USA
Soft Tissue Patch, W. L. Gore and Associates, Elkhart, DE, USA

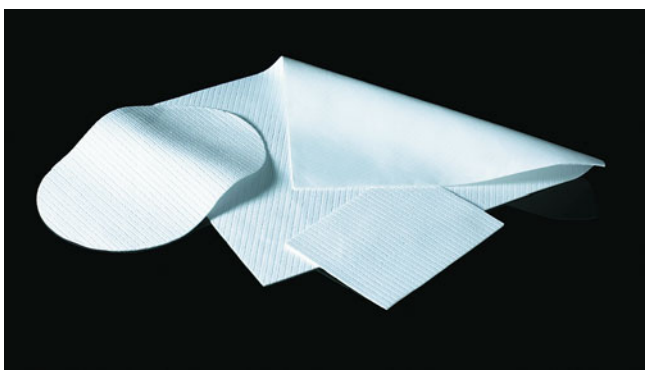


Fig. 7.52 DualMesh

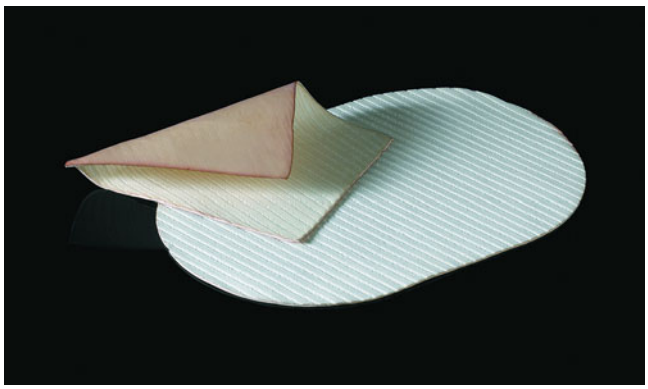


Fig. 7.53 DualMesh PLUS

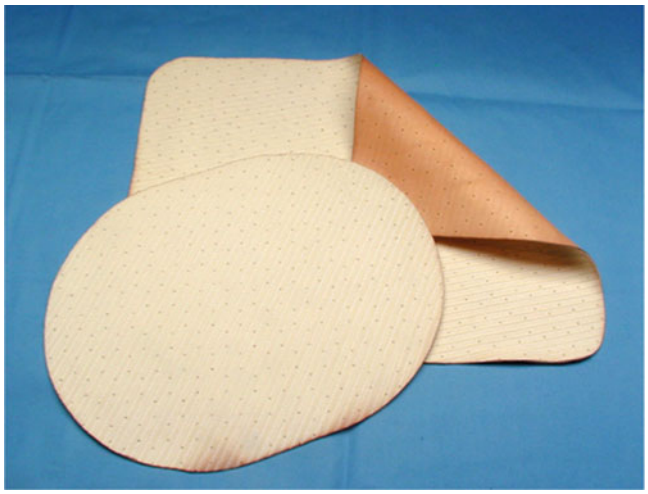


Fig. 7.54 DualMesh PLUS with Holes

available in one thickness, 1 mm. It is available with or without the impregnation of silver and chlorhexidine as *DualMesh PLUS* (Fig. 7.53). The 2-mm product is only available as DualMesh Plus with the antimicrobial agents within it. These two chemicals are antimicrobial agents that are added to decrease the risk of infection and, because of the silver, impart a brown color to the "PLUS" products. At this time, these products are the only materials impregnated with any type of any antimicrobial or bactericidal agents. *DualMesh PLUS with Holes* (Fig. 7.54) is of the same construction as that of the DualMesh. The penetration of the holes requires that this product is of 1.5 mm in thickness. The concept of the addition of these perforations is that there may be greater penetration of the fibroblasts and other cells across the material. Additionally, seroma formation might be diminished.

Dulex (Fig. 7.55) is manufactured of laminated ePTFE. One surface of the material is studded with numerous outcroppings as seen on the scanning electron microscopic view that are approximately 400 μm apart. This gives the product the gross appearance of sandpaper. The intent of this surface

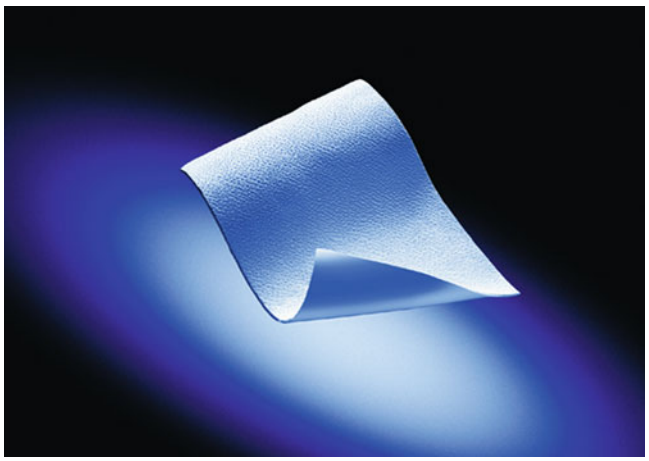


Fig. 7.55 Dulex

is to provide for greater fibroblastic attachment and subsequent greater collagen deposition on this parietal surface. When used in the intraperitoneal fashion, the smooth surface should contact the intestine.

MycroMesh (Fig. 7.56) is also a dual-sided perforated prosthetic with one surface of 3 μm and the other of 17–22 μm. The latter surface is textured. This material is perforated for reasons that are similar to that of the DualMesh Plus with holes. It is only 1 mm thick, however. *Mycromesh PLUS* (Fig. 7.57) is impregnated with the antimicrobials silver and chlorhexidine. It is not designed for intraperitoneal usage.

The earliest implant of these ePTFE products was the *Soft Tissue Patch* (Fig. 7.58). The variety of available configurations of this product has increased over the last several years. Its use, however, has waned because of the development of the other products that are listed in Table 7.12. Like the MycroMesh, it should not contact any viscera when applied.

Miscellaneous Flat Products

There are newer products that are PTFE-based (Table 7.12). The newest available one is that of INFINIT mesh (Fig. 7.59). This is pure PTFE that has been manufactured into a large pore mesh prosthetic material, which is very supple. This is not recommended for intraperitoneal use. The two other prostheses are made of condensed PTFE (cPTFE) and are designed for use in contact with the intestine. The MotifMesh (Fig. 7.60) and Omyra (Fig. 7.61) are similar in appearance. MotifMESH Tissue Engineering Biomaterial (Fig. 7.62) is based upon cPTFE technology but little is known of its properties or indications. It is sold as a product "that can be used to create a controlled extracellular matrix (ECM) through guided tissue regeneration".

Fig. 7.56 MycroMesh

Fig. 7.57 MycroMesh PLUS

Table 7.12 Plug type prosthetic devices and manufacturer

INFINIT mesh,W. L. Gore & Associates, Elkhart, DE, USA
MotifMESH, Proxy Biomedical Ltd, Galway, Ireland
MotifMESH Tissue Engineering Biomaterial, Proxy Biomedical Ltd, Galway, Ireland
Omyra, B. Braun Melsungen AG, Melsungen, Germany
REVIVE, Biomerix Corporation of Fremont, CA, USA

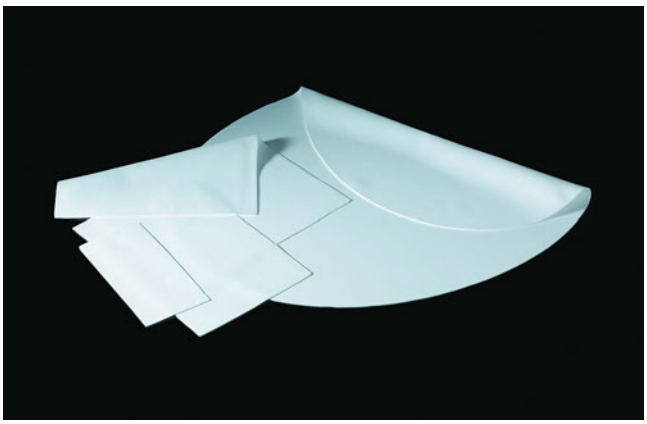


Fig. 7.58 Soft Tissue Patch

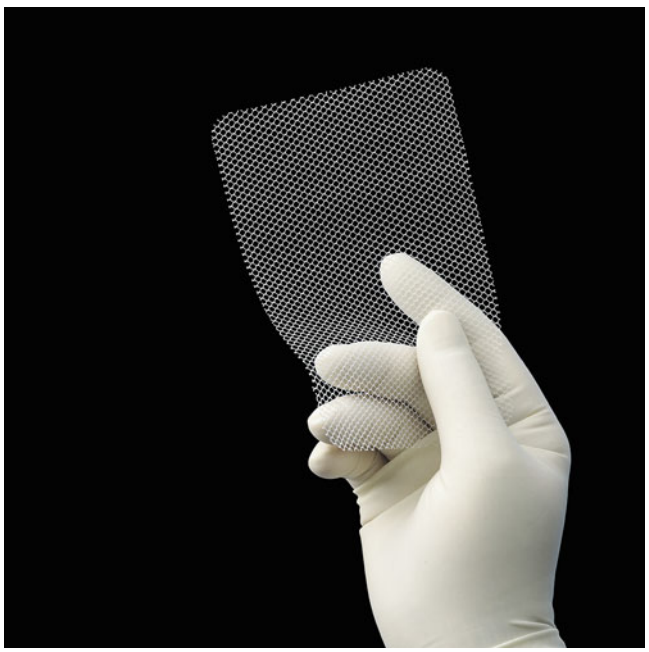


Fig. 7.59 INFINIT

Fig. 7.60 MotifMESH

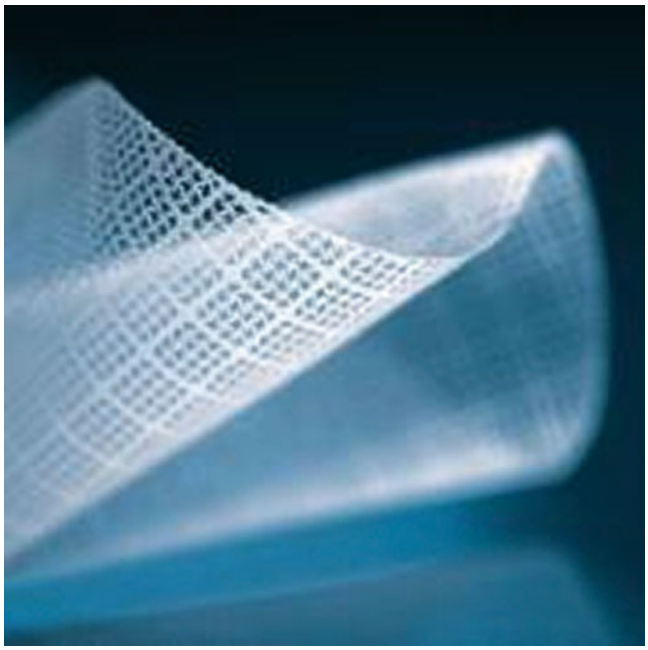


Fig. 7.61 Omyra

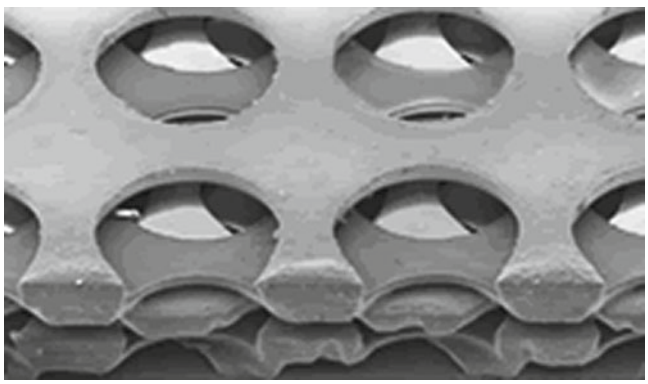


Fig. 7.62 MotifMESH Tissue Engineering Biomaterial

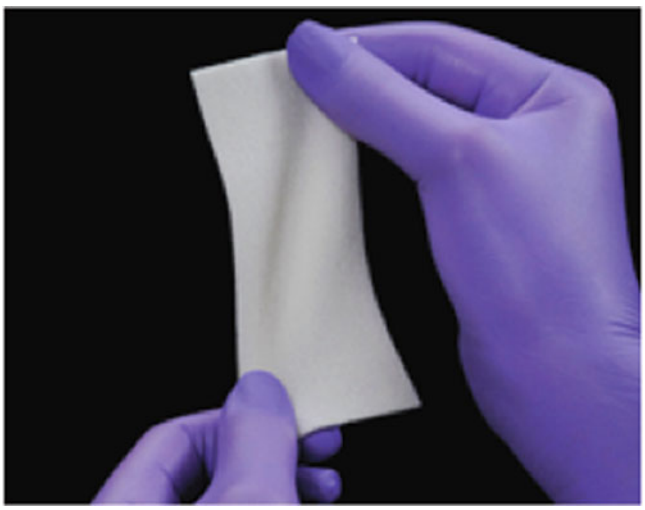


Fig. 7.63 REVIVE

Table 7.13 Flat mesh devices

Angimesh Pre 5,8,9, Angiologica, S. Martino Sicc., Italy
Angimesh Pre 5D, 8D, 9D, Angiologica, S. Martino Sicc., Italy
Bard Mesh, Davol, Inc., Warwick, RI, USA
Bard Soft Mesh, Davol, Inc., Warwick, RI, USA
Biomesh A2, Cousin Biotech, Wervicq-Sud, France
EaseGrip, Covidien plc, Dublin, Ireland
Easy Prosthesis, TransEasy Medical Tech.Co. Ltd., Beijing, China
Folded mesh A5 A5-XCO, A9-XCO, Angiologica S. Martino Sicc., Italy
HydroCoat Mesh, Promethean Surgical Devices, East Hartford, CT, USA
MycroMesh, W. L. Gore & Associates, Elkhart, DE, USA
Optilene mesh, B. Braun, Melsungen AG, Melsungen, Germany
P3, Di.pro Medical Devices, Torino, Italy
P3 Evolution, Di.pro Medical Devices, Torino, Italy
SurgimeshPET, Aspide Medical, St. Etienne, France
SurgiMesh WN, Aspide Medical, St. Etienne, France
T4 Pre-shaped Mesh with Hertra onlay mesh, HerniaMesh, S.R.L., Torino, Italy
T5 Pre-shaped Mesh with Hertra onlay mesh, HerniaMesh, S.R.L., Torino, Italy
TiPATCH, GfE Medizintechnik GmbH, Nuremburg, Germany

An interesting product that is different from all of the other products listed above is the *REVIVE* mesh (Fig. 7.63). It is made of their proprietary Biomerix Biomaterial that is a cross-linked and reticulated polycarbonate polyurethane-urea. It is a three-dimensional, open-cell, macroporous structure. There is no clinical data at the time of this writing as it has just received governmental approval for clinical use.

Flat Mesh Devices for Inguinal Hernioplasty

There are several modifications of the shape of the synthetic meshes described above. For the most part, the ones listed in Table 7.13 are merely the same permanent material that is

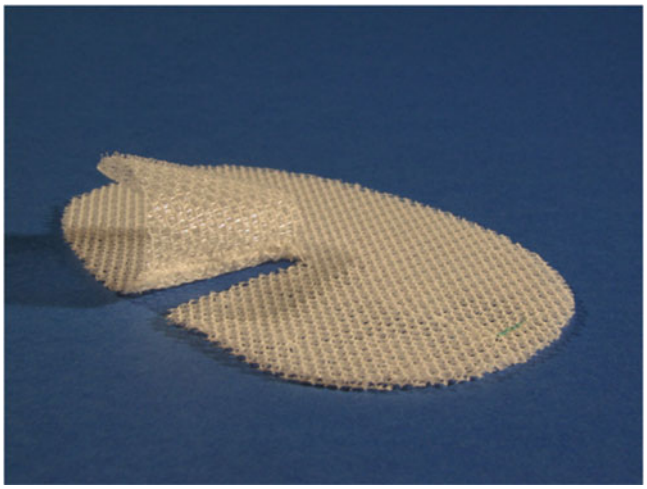


Fig. 7.64 EaseGrip

Fig. 7.65 P3

either pre-shaped with rounded edges and/or have a slit and/or keyhole to be used for open inguinal hernia repair. Some of these keyholes will be located on the long axis of the mesh to be placed while others will be placed on the short axis of the mesh. If there is a significant modification, it is noted below.

EaseGrip (Fig. 7.64) is composed of the three-dimensional POL of Parietex (see above) and is manufactured with a left and a right mesh. It is elliptical in shape with a colored marker on the median edge of the prosthesis to indicate the location of the suture that is placed at the pubic tubercle for fixation. There is a self-gripping flap that is designed to overlap the slit that is precut into the biomaterial, which allows for the exit of the cord structures through the mesh. This flap is placed in the inferior position of the inguinal floor. The manufacturer recommends that the external oblique fascia be closed below the cord structures so that there is no direct contact with the polyester fabric.

The *P3* (Fig. 7.65) is manufactured in light, medium, and heavy weight PPM with products for the male and

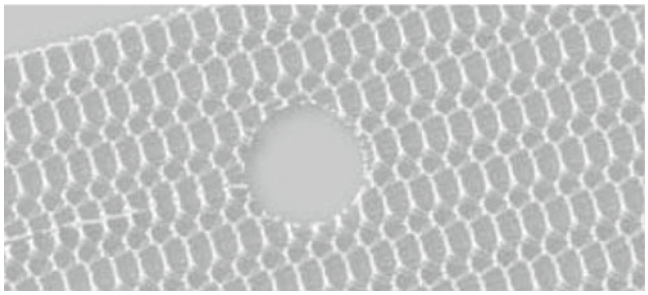


Fig. 7.66 P3 Evolution

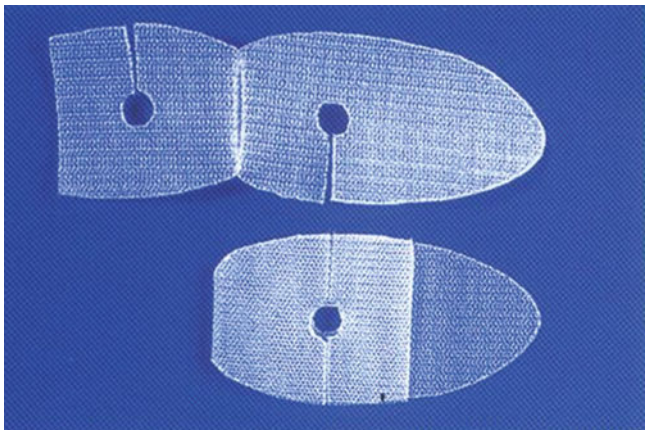


Fig. 7.67 Folded Mesh

Fig. 7.68 SurgiMesh PET (open)

female patient. The "male" product is supplied with a slit and keyhole for the cord structures to pass while the "female" product has no slit or hole. Only the "male" mesh is provided in the heavy weight mesh. The *P3 Evolution* (Fig. 7.66) version is similar but ultra-lightweight. The *Folded Mesh* (Fig. 7.67) has two connected pieces of PPM. The larger piece is placed onto the floor of the inguinal canal and the smaller piece overlaps the larger to cover the internal inguinal ring. *SurgiMesh PET* (Fig. 7.68) is a

Fig. 7.69 TiPATCH

three-dimensional POL product that has a hole to allow the passage of the cord during open repair and a flap designed to cover the slit in the product. *SurgiMesh WN* (Figs. 7.42 and 7.43) is available in two different thicknesses. The *TiPATCH* (Fig. 7.69) is made of the same material as TiMESH (Figs. 7.47 and 7.48) but this has two overlapping pieces of the mesh to cover behind the cord structures of the inguinal hernia repair.

Combination Flat Synthetic Prosthetics for Hernioplasty

This grouping of these products is made because there is a permanent portion of these materials and an absorbable component to the product. These prostheses are not meant to contact any viscera. (Table 7.14)

Adhesix (Fig. 7.70), *Parietene ProGrip*, and *Parietex ProGrip* (Fig. 7.71) all have self-attaching portions of the prosthesis so that once placed onto the tissue surface, they will fixate themselves. These "gripping portions" are absorbable. The permanent portions of Adhesix and Parietene ProGrip are made of PP while the Parietex ProGrip is POL. Adhesix has a coating on one side that is made of polyvinylpyrrolidone and polyethylene glycol. This coating turns into an adhesive gel when it comes into contact with both heat and humidity. Both of the ProGrip products contain grippers, which are prominent in Fig. 7.71, made of PLA. These all can be used either open or laparoscopically. Because

Table 7.14 Combination products

Adhesix, Cousin Biotech, Wervicq-Sud, France
Easy Prosthesis II, TransEasy Medical Tech.Co. Ltd., Beijing, China
Parietene ProGrip, Covidien plc, Dublin, Ireland
Parietex ProGrip, Covidien plc, Dublin, Ireland
Vypro, Ethicon, Inc., Somerville, NJ, USA
Vypro II, Ethicon, Inc., Somerville, NJ, USA
Ultrapro, Ethicon, Inc., Somerville, NJ, USA

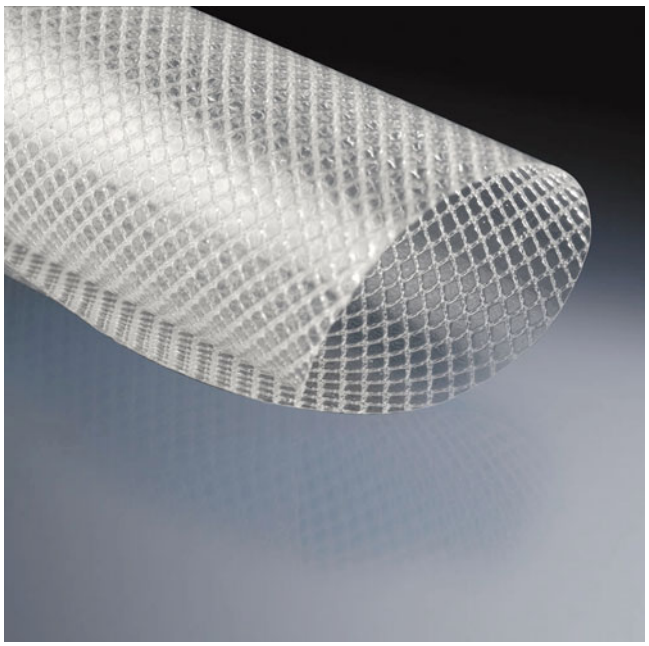


Fig. 7.70 Adhesix

of the gel coating rather than grippers on the Adhesix, it is easier to reposition, if necessary.

Easy Prosthesis II (Fig. 7.72) is a partially absorbable product. It is a combination of PP and poly(glycolide-cocaprolactone) [PGCL] monofilaments. The PGCL portion will be completely absorbed within 90–120 days. The materials, *Vypro* and *Vypro II* (Fig. 7.73) are actually a combination of PP and the absorbable polymer polydioxanone (PDO). The combination of these materials results in a very pliable and malleable material. Once the PDO has been absorbed, the PP that remains has very large interstices into which the fibroblasts and collagen are deposited. The aim of these products is the improvement in the abdominal wall compliance that is more normal in function because of the very lightweight PP that remains. *Ultrapro* (Fig. 7.74) mesh is a similar concept and is manufactured from approximately equal parts of the absorbable poliglecaprone-25 monofilament fiber and the nonabsorbable lightweight PP. A portion of the PP is dyed. The absorbable portion is essentially absorbed by 84 days.

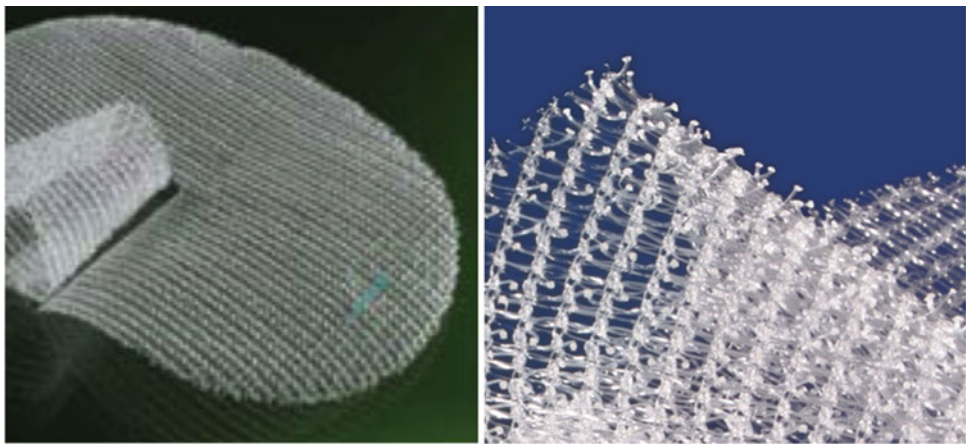


Fig. 7.71 Parietex ProGrip (Close-up of the grippers on the right)

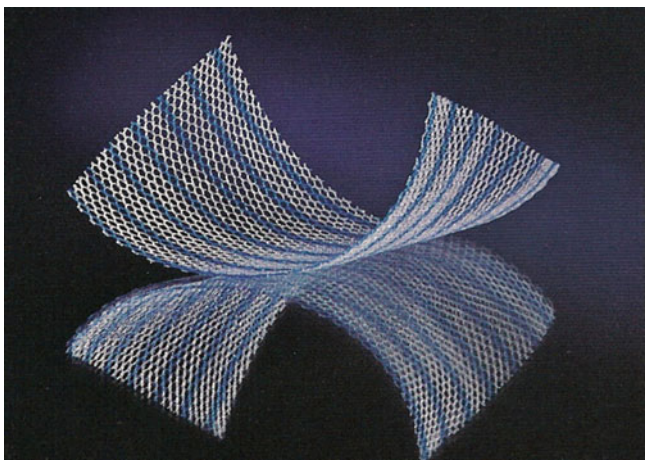


Fig. 7.72 Easy Prosthesis II

Preformed Prosthetic Devices for Open Hernioplasty

There has been a significant amount of interest in the repair of inguinal and femoral hernias utilizing one of the many preformed prosthetic devices in the last several years. The manufacturers of these prostheses have developed several ingenious products for this use. All are of a polypropylene biomaterial with the exception of the Parietex Plug (Table 7.15). There is currently an increasing interest by a few surgeons in the application of some of these for the repair of other hernias of the abdominal wall such as umbilical and ventral hernias.

The first commercially successful device was that of the PerFix Plug and patch. The repair of inguinal hernias with this product simply involves the insertion of the plug through the fascial defect into the extraperitoneal plane, which is then secured to the edges of the fascia. Additionally, they also employ the use of an overlay of an additional piece of mesh to complete the repair. There are structural differences with these products that alter the concept of each one. Some surgeons also modify these plugs prior to insertion to more completely protect the preperitoneal space.

There are several "self-forming" plugs. These are flat, round, and without a hole rather than being pre-shaped, as one would expect a true plug-like product. The *Basic plug* is one of these (Fig. 7.75). The makers of such devices believe that this is a "one-size fits all" concept in that they can be utilized in any size of a fascial defect. Other products that correspond to this design are the *Self-Forming Plug* (Fig. 7.76) and the *SurgiMesh EasyPlug Standard* (Fig. 7.77) and the *Parietex Plug*. The Self-Forming Plug differs from the other two single layer products in that it is made of three circular flat meshes constructed of Atrium mesh. These are bonded together with a tab on one surface to allow for the grasping of the product by forceps during insertion. This is still soft and pliable so that it assumes the shape of the defect rather than forcing itself into the defect. It is available in different sizes.

The *Easy Prosthesis Plug* (Fig. 7.78) is a traditionally designed plug with petals within it. These can be modified, if needed, depending upon the choice of the surgeon. The *4D Dome* (Fig. 7.79) is different from all of the other plug type devices. It is a single layer of PP but it is shaped into a rounded, rather than a pointed, shape. The insertion and fixation is the same as the more traditional plugs.

The *PerFix Plug* (Fig. 7.80) is available in four different sizes. This is the most mature of these commercial products. Because of the trend to lighter weight PP in the repair of hernias, it is also available in the *PerFix Light Plug* (Fig. 7.81). These allow for modification of the plug in that the surgeon can remove the inner petals at the time of implantation. Some

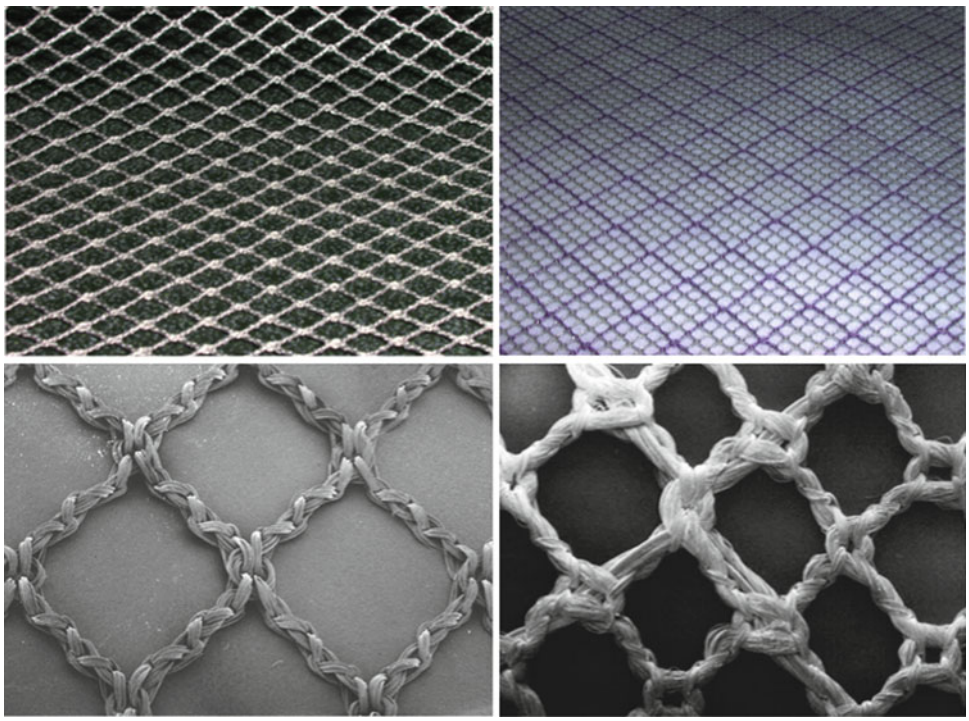


Fig. 7.73 Vypro (left) and Vypro II (*right*)

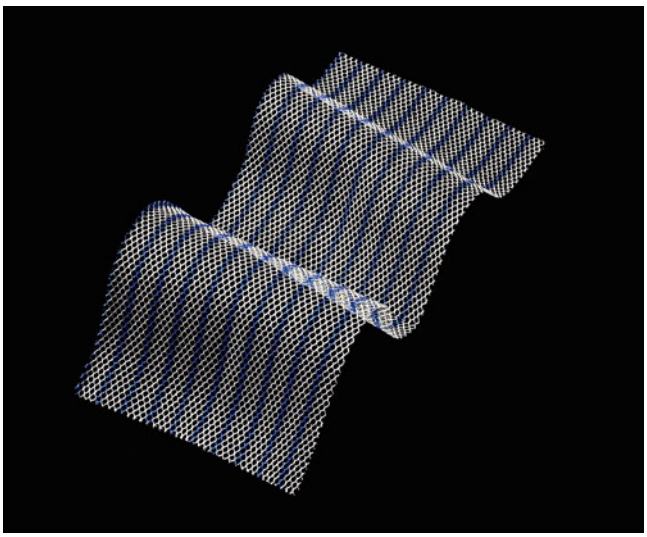


Fig. 7.74 Ultrapro

surgeons have reported good results with completely opening the petals in the preperitoneal space [9]. Other products that are also fluted but do not allow any modification are the *Premilene Mesh Plug* (Fig. 7.82) and the *Repol Flower* (Fig. 7.83). The *Proloop Plug* (Fig. 7.84) is a pointed type of plug but it lacks any internal structure so it, too, cannot be modified. As shown in the photo, this product is quite different in appearance in the other plug devices. Although preformed into a cylindrical shape, it is very supple and conforms to the defect into which it is inserted.

Table 7.15 Plug type products

Basic plug, Angiologica, S. Martino Sicc, Italy
Easy Prosthesis Plug, TransEasy Medical Tech.Co. Ltd., Beijing, China
4D Dome, Cousin Biotech, Wervicq-Sud, France
Parietex Plug, Covidien plc, Dublin, Ireland
PerFix Plug, Davol Inc., Warwick, RI, USA
Perfix Light Plug, Davol Inc., Warwick, RI, USA
Premilene Mesh Plug, B. Braun Melsungen AG, Melsungen, Germany
Proloop Plug, Atrium Medical Corporation, Hudson, NH, USA
Repol Plug Cap, Angiologica, S. Martino Sicc., Italy
Repol Plug Flower, Angiologica, S. Martino Sicc., Italy
Self-Forming Plug, Atrium Medical Inc., Hudson, NH,
SurgiMesh EasyPlug Standard, Aspide Medical, St. Etienne, France
SurgiMesh WN EasyPlug, Aspide Medical, St. Etienne, France
SurgiMesh WN EasyPlug "No Touch", Aspide Medical, St. Etienne, France
T2 Plug, HerniaMesh, S.R.L., Torino, Italy
T3 Plug, HerniaMesh, S.R.L., Torino, Italy
TEC Evolution plug—Di.pro Medical Devices, Torino, Italy
TiLENE plug, GfE Medizintechnik, Nuremburg, Germany WEB
TP plug, Di.pro Medical Devices, Torino, Italy
TiPLUG—GfE Medizintechnik, Nuremburg, Germany WEB
Ultrapro Plug, Ethicon Inc., Somerville, NJ, USA

The *Repol Plug Cap* represents a concept that combines a small piece of a flat PPM and a cone-shaped plug (Fig. 7.85).

Similar products are the T2 and T3 *Plugs*. These devices are also significantly different from all of the other plugs. The *T2 Plug* (Fig. 7.86) has a circular piece of flat mesh that has a rounded plug portion affixed to it whereas the *T3 Plug* (Fig. 7.87) has a rectangular piece of mesh affixed to it. There are differing sizes that are chosen based upon the size of the defect. With any of these three devices, one can insert the plug component into the preperitoneal space and use the flat portion to sew to the fascial edges as a small onlay or underlay.

The *SurgiMesh WN EasyPlug* (Fig. 7.88) differs in several ways. It is of the non-knitted PP and also has two strips to allow for easier fixation. The *SurgiMesh WN EasyPlug* "No Touch" (Fig. 7.89) device is a preformed plug with variable geometry and is adjustable to the size of the defect. An applicator is supplied to make this a "no touch" implantation. As purse-string suture is part of the device to help in sizing of the plug.

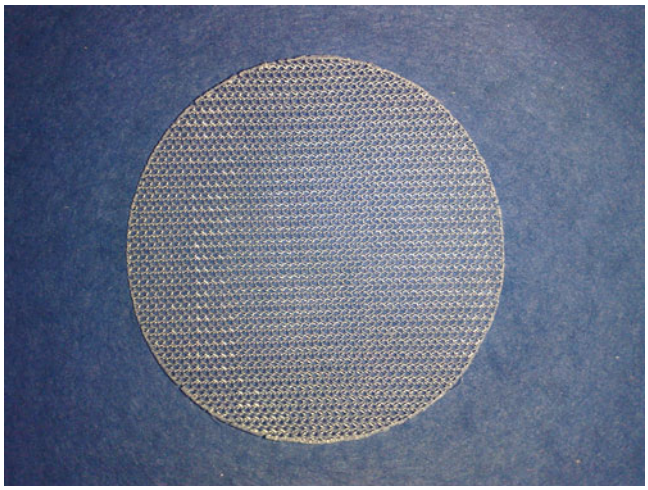


Fig. 7.75 Basic Plug

The *TEC Evolution* plug (Fig. 7.90) is made in the conical shape and is fluted, as are most plugs, but of an ultra-lightweight PP material. There is a second design of the TEC Evolution plug (Fig. 7.91) that has lightweight petals and a medium weight base. The *TiLene Plug* (Fig. 7.92) is of the TiMesh product that has been previously described. It is a flat product that will conform to the hernia defect as it is inserted. The outer layers of the petals are medium weight PP and the inner petals are a lighter weight PP. The *TP* plug is a rounded mesh with or without an eccentric hole and with or without a slit to that hole. The TiPLUG (Fig. 7.93) is also made of TiMESH. It has a flap through which the cord structures are to be placed. As such, it differs from all of the other plugs listed. The *Ultrapro Plug* (Fig. 7.94) is made from the previously described Ultrapro mesh. The absorbable and nonabsorbable portions are connected by the absorbable poliglecaprone-25 fibers.

Extraperitoneal Prosthetic Devices for Open Inguinal Hernioplasty

The posterior repair of open inguinal hernias is based upon the approach into the preperitoneal space. The use of a preformed prosthetic device in this space represents an emulation of the Stoppa repair and the giant prosthetic repair of the visceral sac of Wantz. The products that have been manufactured

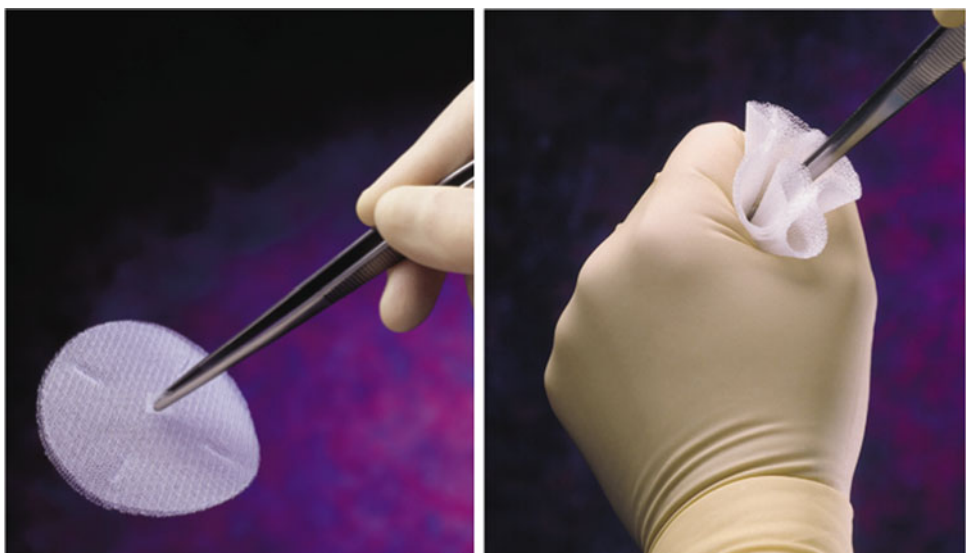


Fig. 7.76 Self-forming Plug

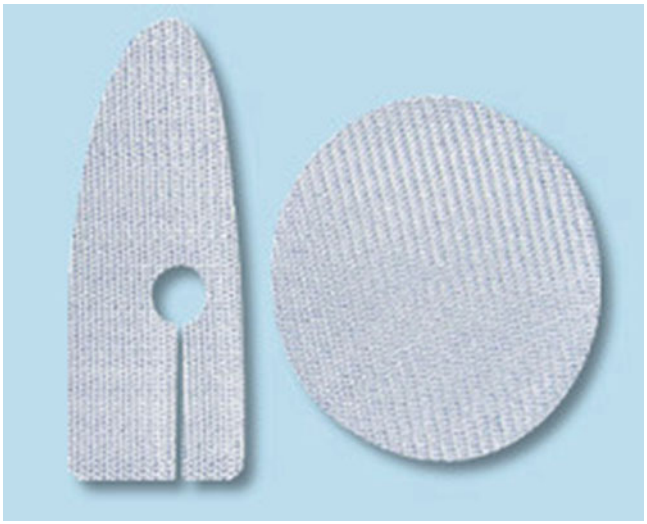


Fig. 7.77 SurgiMesh EasyPlug Standard

Fig. 7.78 Easy Prosthesis Plug

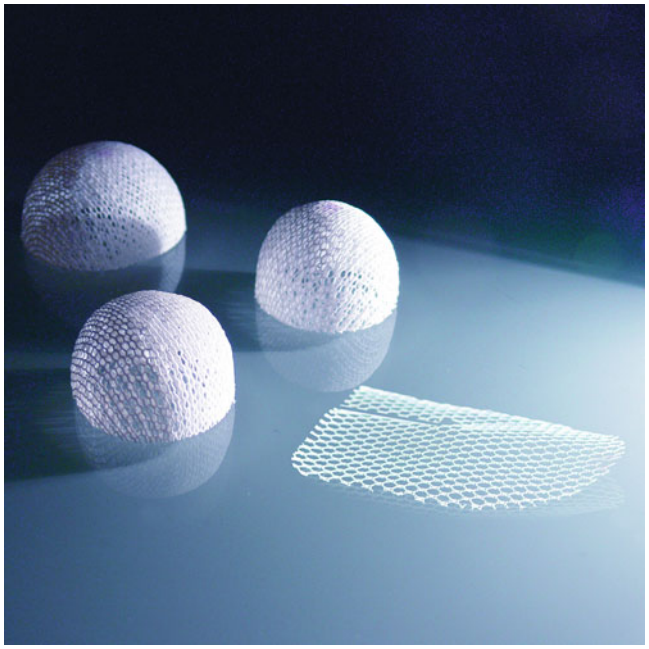


Fig. 7.79 4D Dome

for this concept are not "giant" prostheses, however (Table 7.16).

Easy Prosthesis (self-forming) hernia repair patch (Fig. 7.95) has two bonded PP layers. One will lie in the preperitoneal space and the other as an onlay in the inguinal hernia repair. The *Easy Prosthesis (preperitoneal)* hernia repair patch (Fig. 7.96) also has an underlay portion but instead of the flat sheet of PP, there are petals that can be stitched to the fascial edges of the hernia itself. This is similar to the plug and patch repair as the product is supplied with an onlay patch to place underneath the external oblique.

The *Kugel Patch* (Fig. 7.97) consists of two oblong circular flat meshes of Bard mesh. One of these has a slit to allow the insertion of a finger to aid in the positioning of the product. Near the edge of the device is a polyester ring that maintains the shape of the device after insertion into the preperitoneal space. There are several sizes of this product as well as those that are in a circular configuration. The *Modified Kugel Patch* (Fig. 7.98) adds a strap of PP to assist in the positioning of the product. In addition, this strap can be sewn to the edges of the fascial defect in the inguinal floor. This device also comes with an onlay piece of PP to be placed onto the internal oblique aponeurosis. The *Polysoft Patch* (Fig. 7.99) is similar to the Kugel patch in that it is designed for placement exclusively in the preperitoneal space. Its shape is very similar to the laparoscopic 3D Max (see Fig. 7.109). It currently is available only in Europe.

The *Prolene Hernia System* (Fig. 7.100) is similar to the Easy Prosthesis (Fig. 7.95) in that it is designed to place mesh in the extraperitoneal plane and onto the inguinal floor as a traditional tension-free repair. The difference between the two products is that the older PHS has a connector piece that attaches the rounded underlay portion and the elliptical portion. There are three size of the PHS, medium, large, and extended. The choice of the size will depend upon the size and type of defect as well as the size of the patient and location of the hernia. These have also been used for umbilical and ventral hernias. The *Ultrapro Hernia System* (Fig. 7.101) is a combination product that is made from Ultrapro flat mesh that has the identical shape as the PHS that has incorporated poliglecaprone-25. The latter product is wound with the PP fibers and is placed as a film to ease the use of the device. This absorbable component of the Ultrapro will leave behind a very lightweight PPM to repair the hernia.

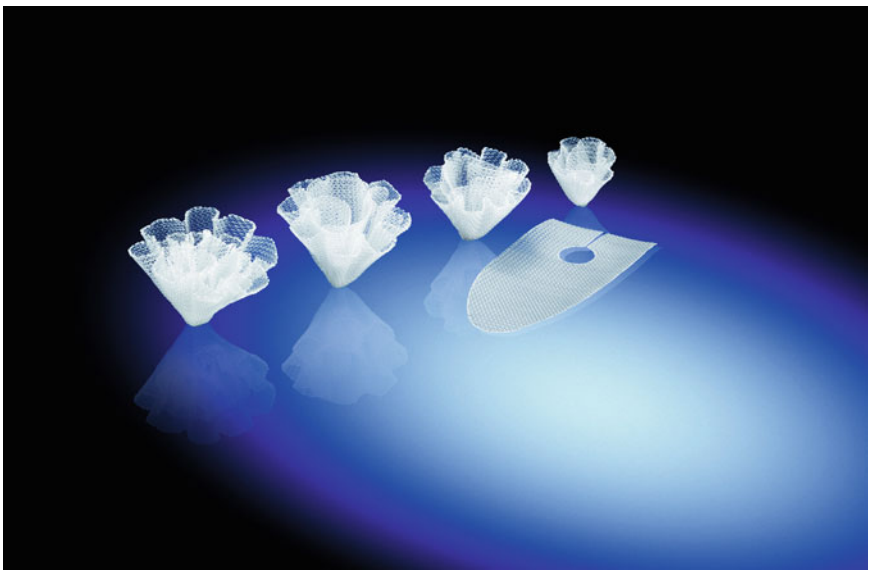


Fig. 7.80 PerFix Plug

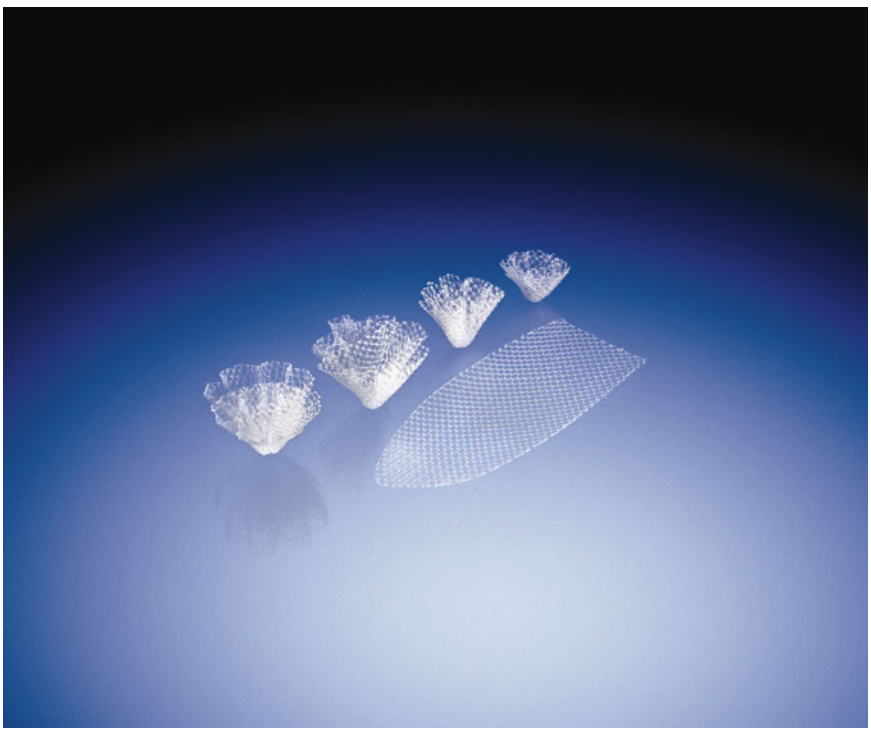


Fig. 7.81 PerFix Light Plug

The *Prolene 3D Patch* (Fig. 7.102) is a three-dimensional device, which possesses two different portions of this product. The diamond-shaped portion is inserted into the preperitoneal space. A single pull of the suture causes the diamond to flatten out underneath the tranversalis fascia. The overlay portion is then secured as in the tension-free repairs. It is available in two sizes of the diamond portion and with or without a pre-shaped overlay.

Pre-shaped Products for Laparoscopic Inguinal Hernioplasty

The history of laparoscopic repair of inguinal hernias involved flat meshes of one type or another. This continues to be the most frequently used prosthetic product for this operation (Tables 7.10, 7.11, and 7.12). There are, however, a number of devices that have been constructed for this

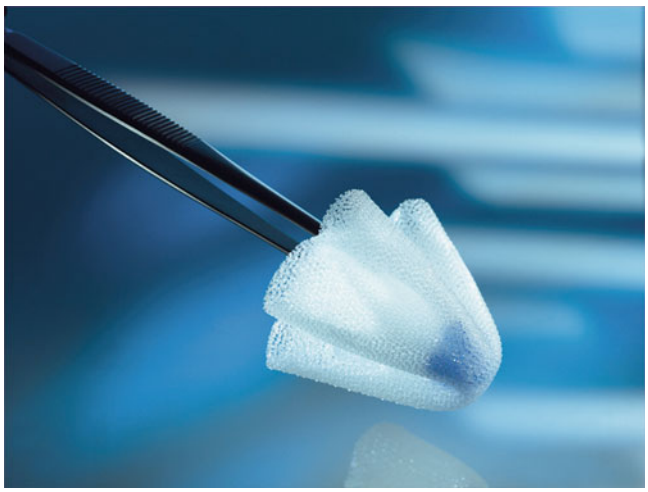


Fig. 7.82 Premilene Mesh Plug

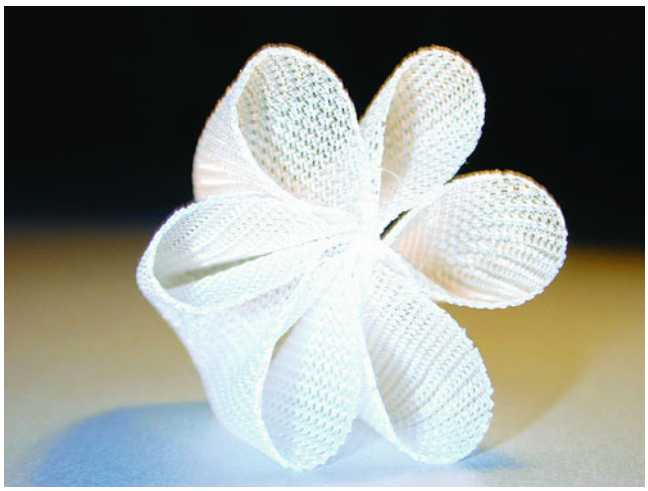


Fig. 7.83 Repol Flower

Fig. 7.84 Proloop Plug

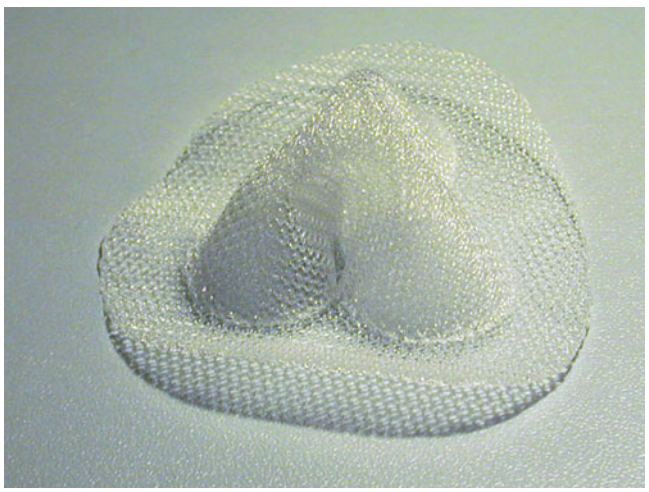


Fig. 7.85 Repol Plug Cap

procedure (Table 7.17). These all attempt to ease the placement of the prosthetic over the myopectineal orifice or serve to conform to the anatomic surfaces at that site of the repair. These can be placed with either the transabdominal preperitoneal (TAPP) or totally extraperitoneal (TEP) approaches. A few are manufactured to make fixation with any type of fastener unnecessary.

The *C-LAP* (Fig. 7.103) lightweight PP prosthesis is designed for laparoscopic inguinal hernia repair. It is a PP product with slits, curves, and shapes to conform to the inguinal floor. These are labeled as male with direct and indirect designs or female in a single design. *Parietex Anatomical Mesh* (Fig. 7.104) is of the same three-dimensional weave of POL as the other Parietex products on the lower portion of the product which is softer and designed to lie on the vessels. The portion that is placed on the posterior aspect of the inguinal floor is a more rigid two-dimensional weave to aid in handling. It is generally used with the application of some type of fixation but some surgeons do not see the need to add these fasteners. It has a left and right design. The *Folding Mesh with Suture* (Fig. 7.105) is shaped as a flat polyester mesh with rounded edges. To aid in the insertion and deployment of this mesh in the preperitoneal space during the laparoscopic repair, there is a suture that is woven through the material. This suture is placed such that when it is pulled tight the mesh will be drawn into a small somewhat cylindrical shape. It is then placed into the preperitoneal space

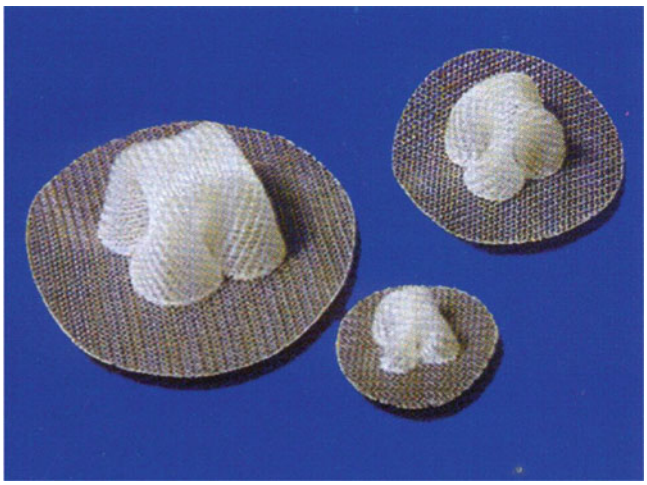


Fig. 7.86 T2 Plug

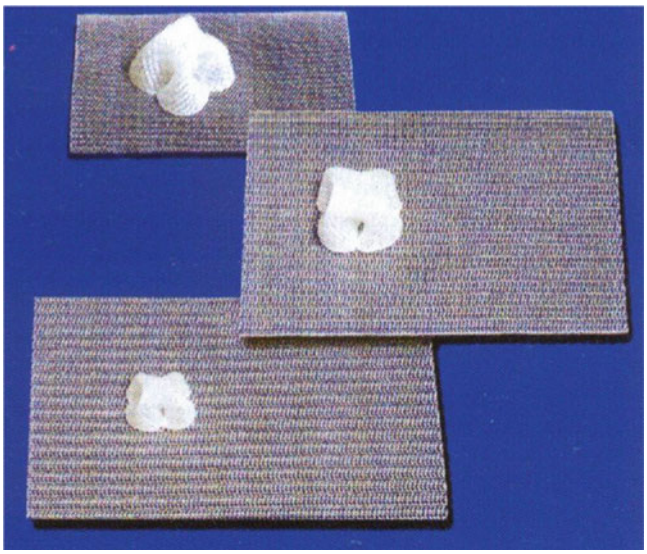


Fig. 7.87 T3 Plug

whereupon the suture is cut, allowing the mesh to resume its original shape. It can then be positioned appropriately. This device is also available with a slit if one desires to place the cord structures within the slit.

Rebound HRD (Fig. 7.106) is a rather unique concept in hernia repair. This device is designed to maintain the shape of the product after introduction into the preperitoneal space by the incorporation of a self-expanding nitinol alloy frame at the perimeter of the mesh. There is an introducing tube that is also shown in the figure. The mesh itself is also unusual in that it is a macroporous cPTFE, which is tied to the frame with a polyethylene-braided suture. This prosthesis can also be used with an open approach. Because of the presence of this nitinol, this is the only prosthesis that can be visualized on radiologic studies postoperatively.

Fig. 7.88 SurgiMesh WN EasyPlug

Fig. 7.89 SurgiMesh WN EasyPlug "No Touch"

Fig. 7.90 TEC Evolution

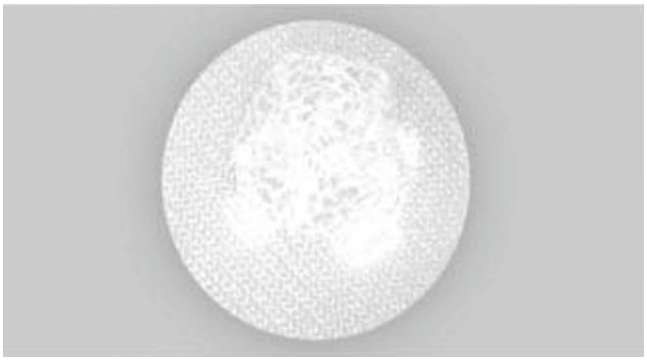


Fig. 7.91 TEC Evolution (second design)

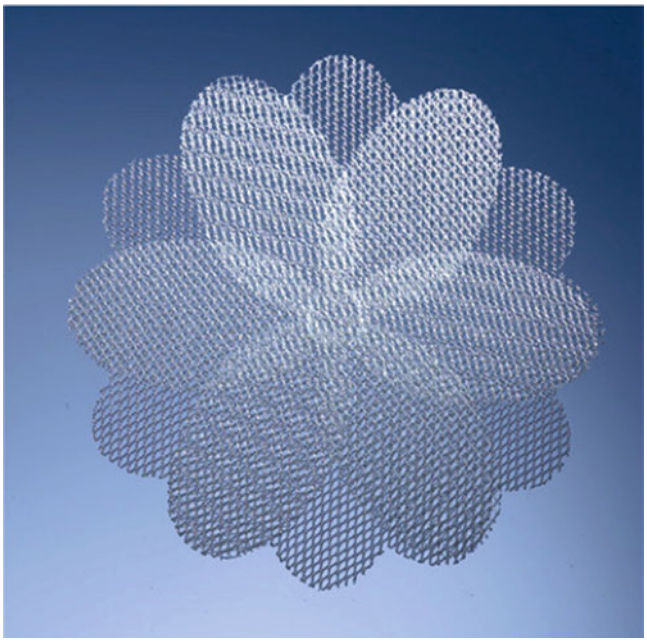


Fig. 7.92 TiLENE Plug

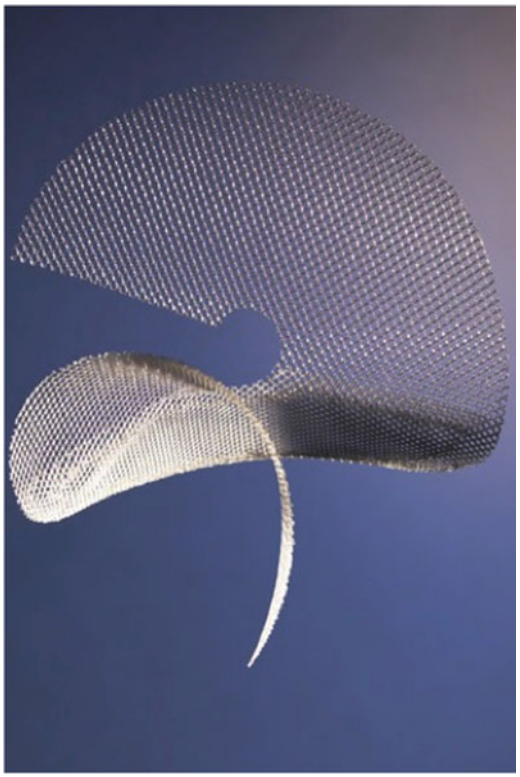


Fig. 7.93 TiPLUG

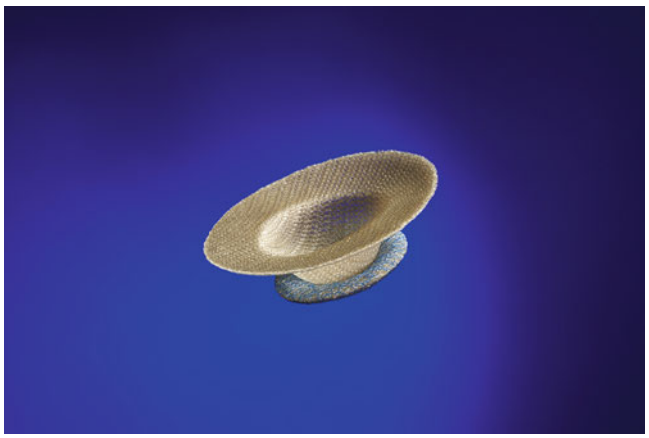


Fig. 7.94 Ultrapro Plug

SurgiMesh WN (Figs. 7.42 and 7.43) has the same structure as that of most of the SurgiMesh products listed in the prior tables. There are two laparoscopic products. One is a single flat square sheet with a rounded portion cutout on one corner. This is to be placed at Cooper's ligament. The other product has a keyhole and a flap to allow the product to be placed onto the posterior wall of the inguinal canal with the cord structures placed in the keyhole. The flap then covers the slit and keyhole to seal this defect in the mesh. *SurgiMesh PET* (Fig. 7.107) is a POL product that is available in an anatomical shape requiring limited fixation. The two-dimensional structure (not the three-dimensional) is designed for laparoscopic use. *SurgiMesh XD* (Fig. 7.108) is of two different types of PP. It is of a shape to allow placement in the inguinal floor laparoscopically. As shown in the photo, the majority of the product is perforated and composed of non-woven, non-knitted PP. The smooth portions of the prosthesis are of knitted PP. The vertical portion is to align with the spermatic cord and the horizontal portion is to align with Cooper's ligament.

The *3D Max* and *3D Max Light* (Fig. 7.109) products are similar in shape and sizes (medium, large, and extra large). They differ in the weight of the PP within each product. The former is of the heavy weight Bard mesh and the latter is of the lighter Bard Soft Mesh. Both have an "M" and an arrow on the medial aspect of the product to indicate the positioning

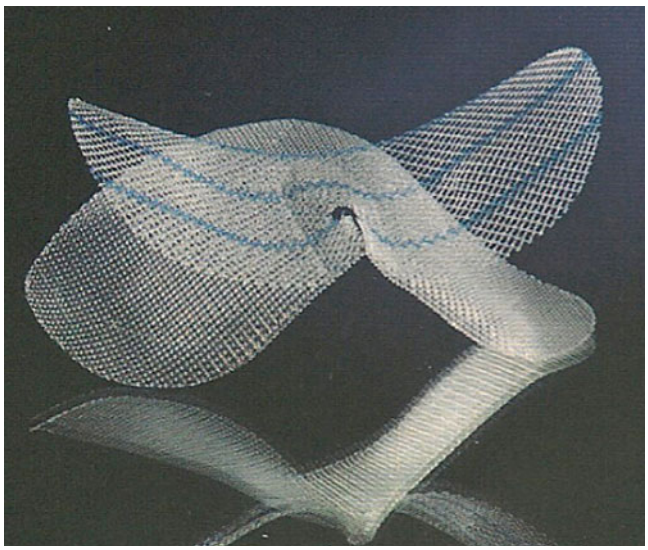


Fig. 7.95 Easy Prosthesis Self-forming Hernia Repair Patch

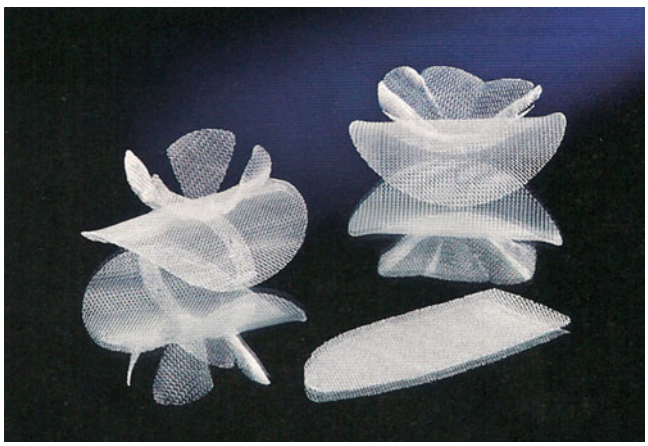


Fig. 7.96 Easy Prosthesis Preperitoneal Hernia Repair Patch

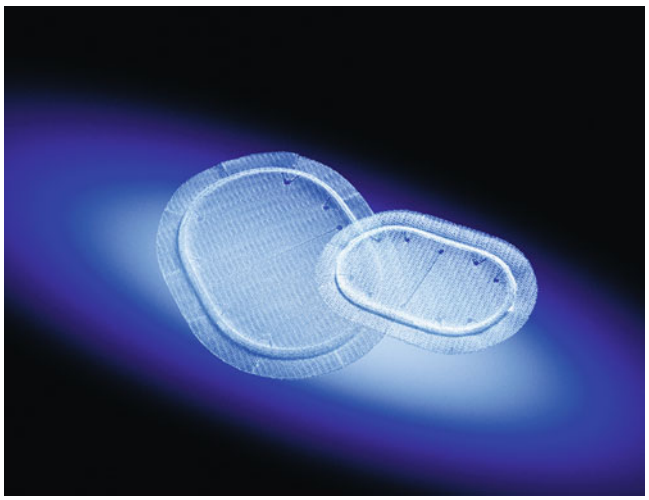


Fig. 7.97 Kugel Patch

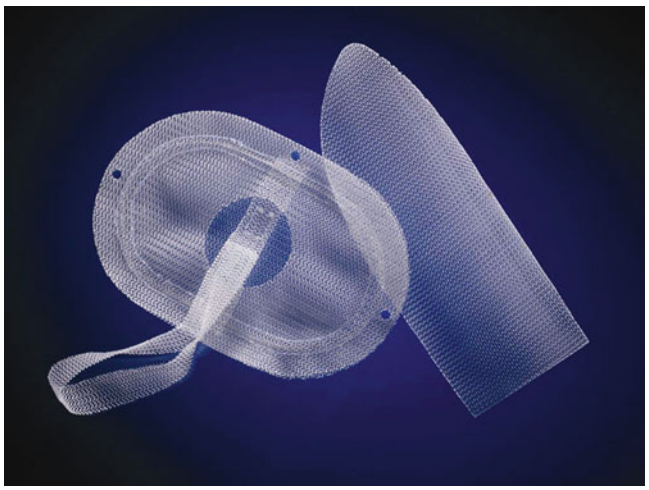


Fig. 7.98 Modified Kugel Patch

Table 7.16 Flat devices and their manufacturer

Easy Prosthesis (Self-forming), TransEasy Medical Tech.Co. Ltd., Beijing, China
Easy Prosthesis (Preperitoneal), TransEasy Medical Tech.Co. Ltd., Beijing, China
Kugel Patch, Davol Inc., Warwick, RI, USA
Modified Kugel Patch, Davol Inc., Warwick, RI, USA
Polysoft Patch, Davol Inc., Warwick, RI, USA
Prolene Hernia System, Ethicon Inc., Somerville, NJ, USA
Prolene 3D Patch, Ethicon Inc., Somerville, NJ, USA
Ultrapro Hernia System, Ethicon Inc., Somerville, NJ, USA

of the prosthesis. These are curved to conform to the shape of the pelvis. Because of this curved shape, there is a right and left product. There is also an indentation on the inferior aspect of the product to indicate the location of the iliac vessels. *Visilex* (Fig. 7.110) is flat Bard mesh that has a stiffer border designed to ease the manipulation of the product in the preperitoneal space.

Prostheses for Incisional and Ventral Hernioplasty with an Absorbable Component

The original impetus behind the development of these products was the popularity of the laparoscopic methodology. In general, however, all of these prosthetic devices can or have been used in both open and laparoscopic incisional hernioplasties. All of these have the common purpose to repair the hernia and prevent the development of adhesions with the attendant complications associated with this result of the healing processes. These are generally referred to as "tissue-separating" meshes as they create an

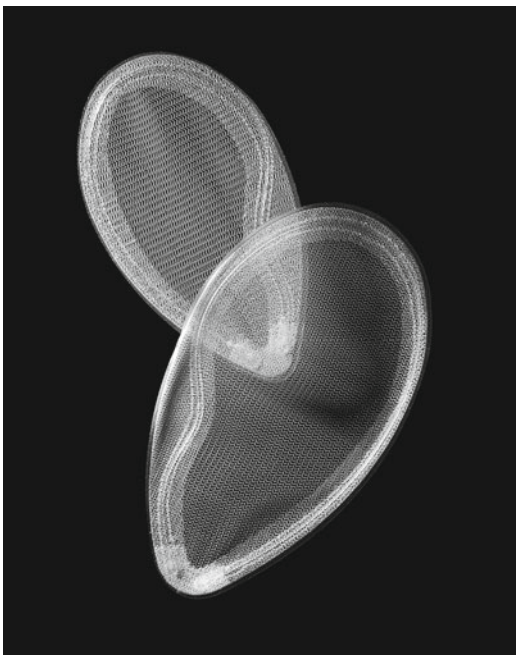


Fig. 7.99 PolySoft Patch

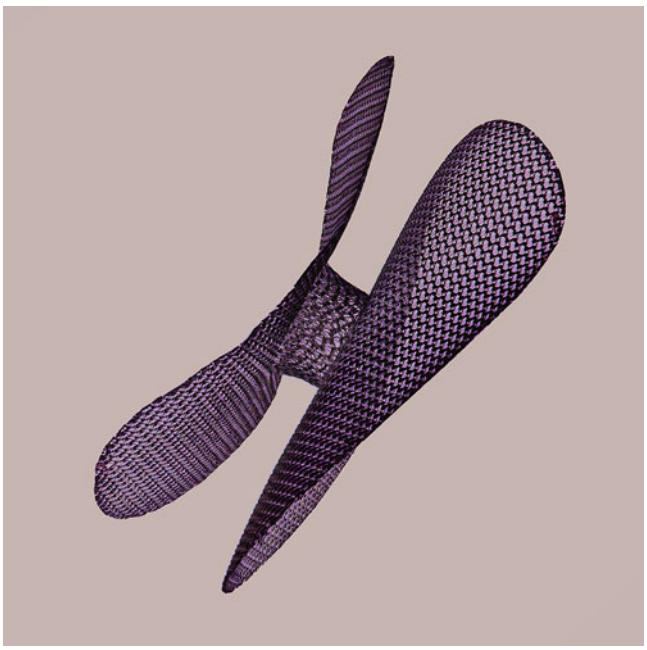


Fig. 7.100 Prolene Hernia System (PHS)

absorbable barrier between the permanent product and the viscera (Table 7.18).

The resorption of that nonpermanent substance leaves a permanent layer of mesh that will incorporate into the tissues of the patient. The controversial part of this idea is the fact that the problems that are related to the development of adhesions following the implantation of a synthetic biomaterial

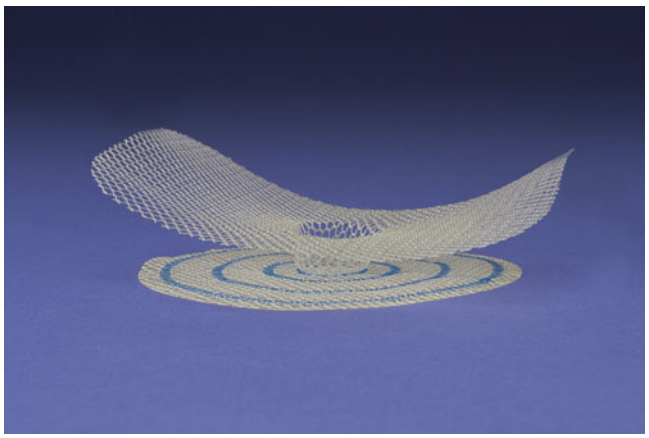


Fig. 7.101 Ultrapro Hernia System (UHS)

do not become manifest for many years postimplantation. Therefore, the late effects of these products will necessitate many years of follow-up to validate these claims. At the present time, however, these meshes do seem to live up to their expectations.

Adhesix is the same product that was listed in Table 7.14. It is touted that this can be used in the preperitoneal position, the retrorectus space, or as an onlay but it is not designed for use in contact with the viscera. Consequently if differs for all of the other products listed in Table 7.18 below. *Biomerix Composite Surgical Mesh* is composite of three products, the Biomerix Biomaterial, REVIVE, described in the "Miscellaneous Flat Mesh section," PP, and a resorbable lactide-caprolactone film (Fig. 7.63).

CA.B.S.' Air SR (Fig. 7.111) has a permanent component of 25% lightweight PP and 75% resorbable poly-L-lactic acid (PLLA). It differs from all of the other products in that it has two permanent sutures with needles that are attached and it is also accompanied by a balloon dissection device as it the CA.B.S.' Air described below (see Fig. 7.123). This device is designed for use in umbilical hernia repair. The entire product is inserted; the balloon is used to dissect the tissues and is then removed, leaving behind the prosthesis with the attached sutures to fixate it.

C-QUR (Fig. 7.112) is made of a lightweight PP onto which Omega-3 Fatty Acid (O3FA) has been into and onto the product. These fatty acids are in a cross-linked gel that covers both sides of the material and impart a characteristic dark yellow color. O3FA will absorb over a period of 3–6 months. *C-QUR EDGE* (Fig. 7.113) adds a reinforced edge to the product to enhance fixation stability and ease of use. *C-QUR Lite* (Fig. 7.114) is like the C-QUR but contains a thinner layer of the O3FA such that the coating will last only about 30 days. *C-QUR OVT* is a single-layer product like the C-QUR but adds as second layer of the product that is cut into flaps to ease its fixation in open hernia repair. The *C-QUR V-Patch* (Fig. 7.115) is designed for umbilical hernia

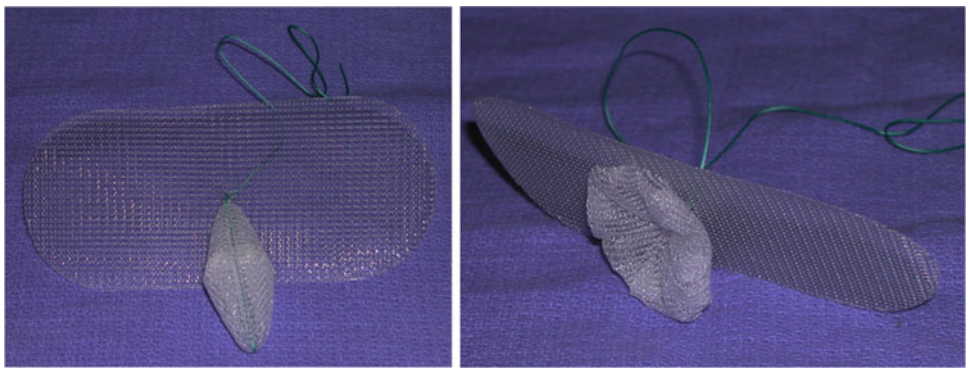


Fig. 7.102 Prolene 3D Patch, pre-deployment (*left*), and post-deployment (*right*)

Table 7.17 Pre-shaped products for laparoscopic inguinal hernia repair

CLAP, Di.pro Medical Devices, Torino, Italy
Parietex Anatomical Mesh, Covidien plc, Dublin, Ireland
Parietex Folding Mesh with Suture, Covidien plc, Dublin, Ireland
Rebound HRD, Minnesota Medical Development, Plymouth, MN, USA
SurgiMesh WN, Aspide Medical, St. Etienne, France
SurgiMeshPET, Aspide Medical, St. Etienne, France
SurgiMesh XD, Aspide Medical, St. Etienne, France
3D Max, Davol, Inc., Warwick, RI, USA
3D Max Light, Davol, Inc., Warwick, RI, USA
Visilex, Davol, Inc., Warwick, RI, USA

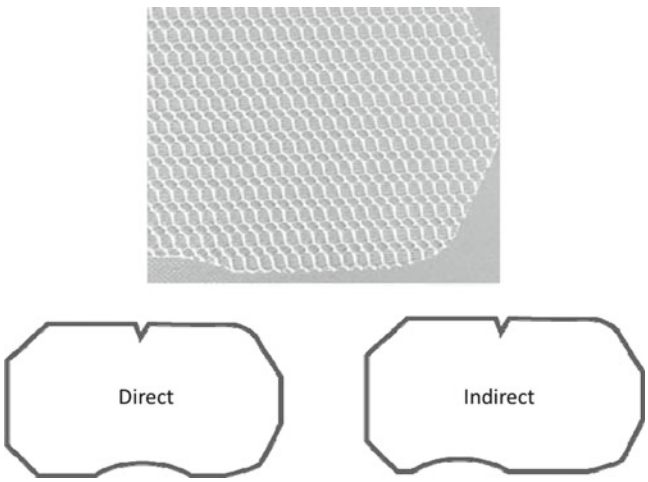


Fig. 7.103 C-LAP

repair but one could see its use for smaller incisional hernias as well. There is an O3FA reinforcement washer that stiffens the product to ease insertion. The fixation straps are secured to the edge of the defect and the excess is removed.

Easy Prosthesis (PPM/Collagen) (Fig. 7.116) is a very unique concept at this time. Bovine tendon is configured and bonded to PP. At the time of this writing there are no other combination biologic/synthetic meshes available, although several are in research stages. This collagen layer becomes a continuous gel within 1 h of implantation. It is said to minimize visceral attachment and, as such, can be used intraperitoneally. Little is known of the clinical results of this product. It is available in several sizes and shapes and can be used for parastomal and hiatal hernia repairs as well, as shown in the photo.

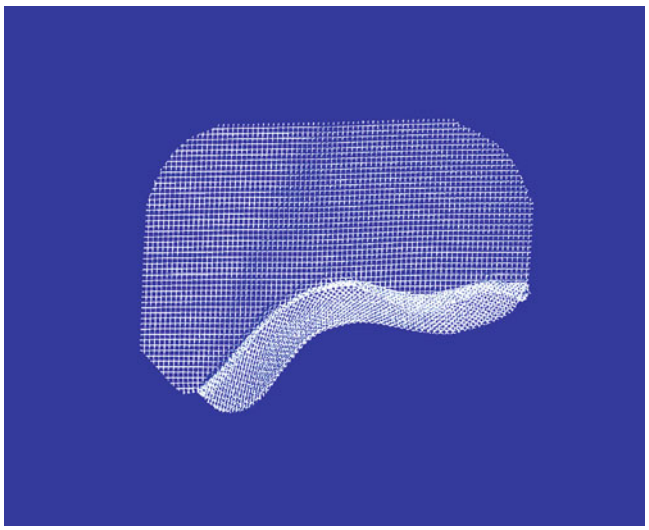


Fig. 7.104 Parietex Anatomical Mesh

Parietene Composite is a little known PP described earlier that is coated with the hydrophilic collagen and other substances that are used in the better-known Parietex Composite discussed below. *Parietex Composite* (Fig. 7.117) is the same POL biomaterial that is described earlier in this chapter. It has an incorporated hydrophilic layer of a mixture of oxidized Type I atelocollagen, polyethylene glycol, and glycerol, which is absorbable. It is also available as the *Parietex Composite Skirted Mesh* (Fig. 7.118). The skirt is a second layer placed over the larger mesh itself to allow for easier

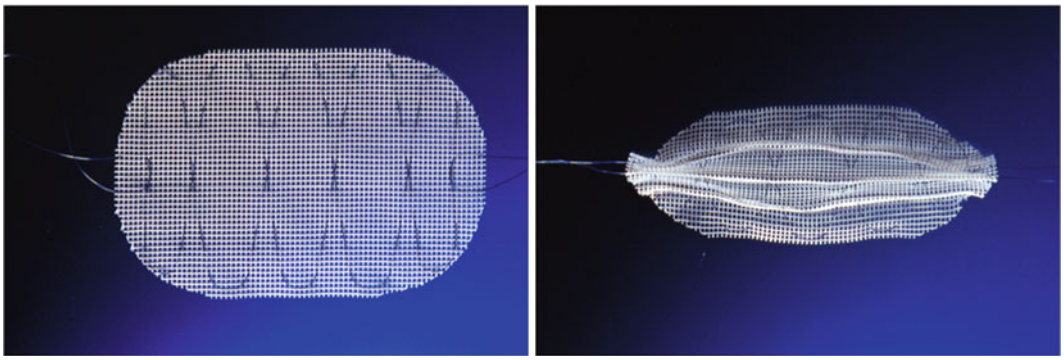


Fig. 7.105 Folding Mesh with Suture, unfolded (*left*) and folded (*right*)

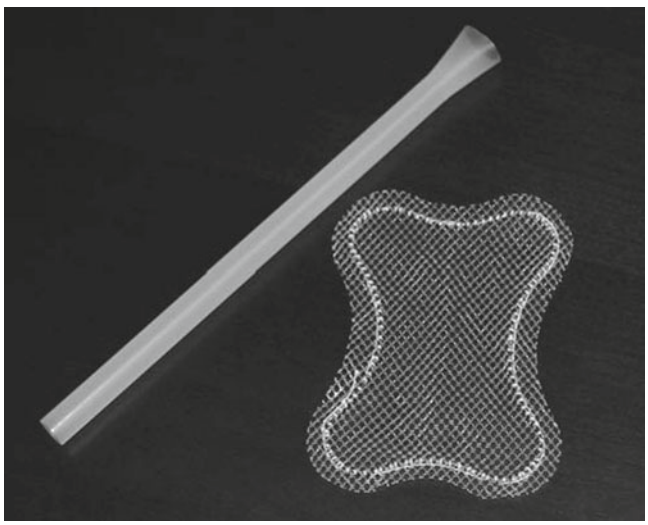


Fig. 7.106 Rebound HRD

Fig. 7.107 SurgiMesh PET (laparoscopic)

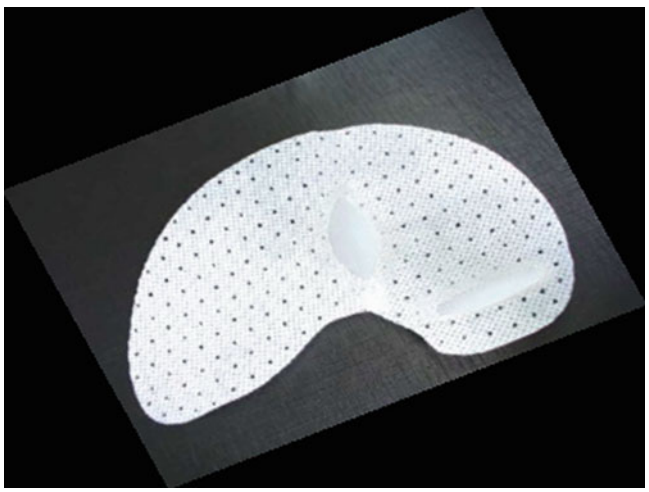


Fig. 7.108 SurgiMesh XD

Fig. 7.109 3D Max, light (*left*), and regular (*right*)

placement of the fixation devices that can be used to fix the product to the anterior abdominal wall in the open technique. *Parietene ProGrip* and *Parietex ProGrip* (Fig. 7.71) also differ in that: the former is of PP and the latter is of POL. Both have the PLA grippers (described earlier in this chapter) so that they do not need fixation.

PHYSIOMESH Flexible Composite Mesh (Fig. 7.119) is made of macroporous PP laminated between two undyed polyglecaprone-25 films, which are absorbable. Another PDO film bonds these three layers together. For orientation

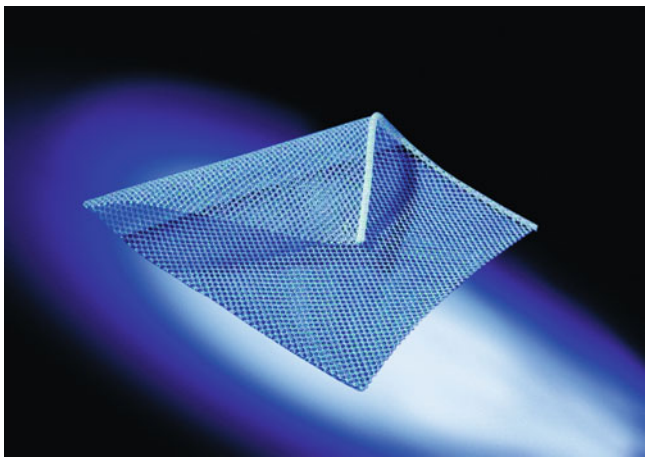


Fig. 7.110 Visilex

Table 7.18 Prostheses with an absorbable component

Adhesix, Cousin Biotech, Wervicq-Sud, France
Biomerix Composite Surgical Mesh, Biomerix Corporation, Fremont, CA
CA.B.S. 'Air SR, Cousin Biotech, Wervicq-Sud, France
C-QUR, Atrium Medical Corp., Hudson, NH, USA
C-QUR EDGE, Atrium Medical Corp., Hudson, NH, USA
C-QUR Lite, Atrium Medical Corp., Hudson, NH, USA
C-QUR OVT Mesh, Atrium Medical Corp., Hudson, NH, USA
C-QUR V-Patch, Atrium Medical Corp., Hudson, NH, USA
Easy Prosthesis (PPM/Collagen), TransEasy Medical Tech.Co. Ltd., Beijing, China
Parietene Composite (PPC), Covidien plc, Dublin, Ireland
Parietex Composite (PCO), Covidien plc, Dublin, Ireland
Parietex Composite (PCO) Skirted Mesh, Covidien plc, Dublin, Ireland
Parietene ProGrip, Covidien plc, Dublin, Ireland
Parietex ProGrip, Covidien plc, Dublin, Ireland
PHYSIOMESH, Ethicon, Inc., Somerville, NJ, USA
Proceed, Ethicon, Inc., Somerville, NJ, USA
PVP, Ethicon, Inc., Somerville, NJ, USA
SepraMesh IP, Davol, Inc., Warwick, RI, USA
Ventralex ST, Davol, Inc., Warwick, RI, USA
Ventrio ST, Davol, Inc., Warwick, RI, USA

purposes a dyed PDO film marker of the is added. *Proceed* (Fig. 7.120) is composed of an oxidized regenerated cellulose (ORC) fabric and Prolene Soft Mesh which is encapsulated by a PDO polymer that holds this together. The fabric acts as a barrier to separate the PP from the tissue. The ORC is absorbed within 4 weeks. An issue with this product is the fact that the instructions for use state "Proceed Mesh has an ORC component that should not be used in the presence of uncontrolled and/or active bleeding as fibrinous exudates may increase the chance of adhesion formation." The *PVP* or *Proceed Ventral Patch* (Fig. 7.121) has an ORC layer that is placed toward the intestine to protect it from the PPM product above it. In this product, there is an additional layer of

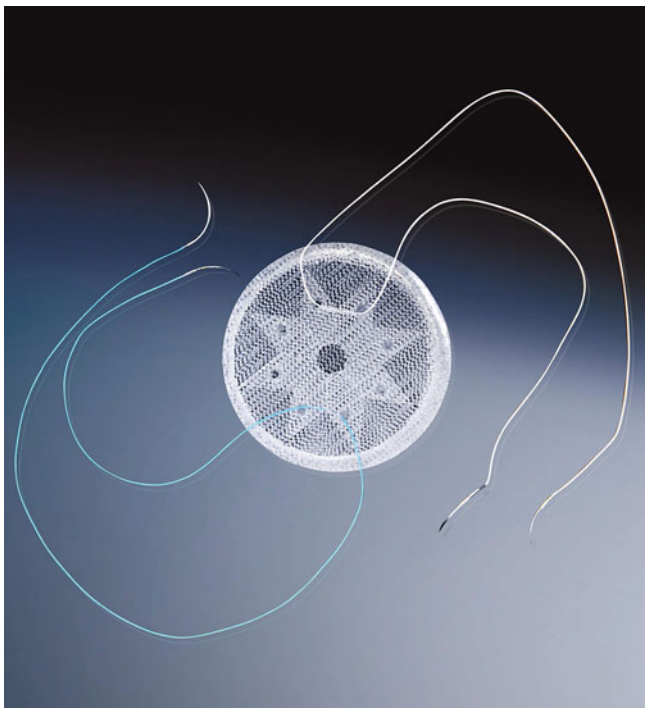


Fig. 7.111 CA.B.S'Air SR

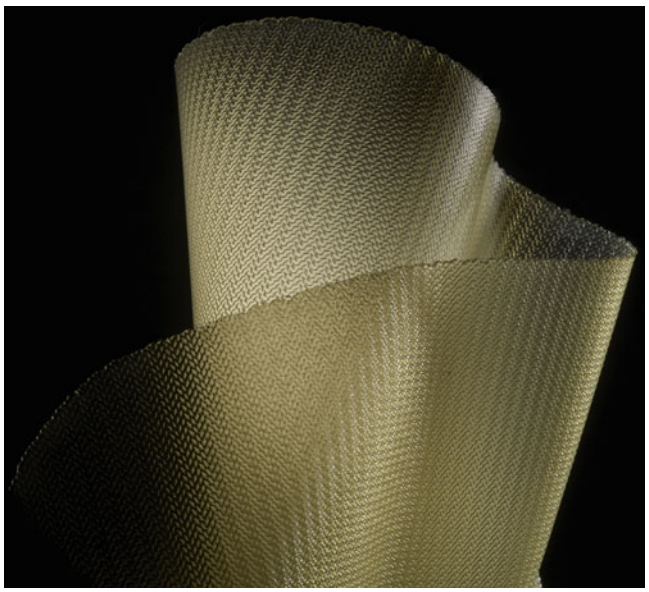


Fig. 7.112 C-QUR

PDO polymer and a positioning ring to provide memory. Vicryl mesh (polyglactin 910) is placed on top of the PDO and is encapsulated with a PDO film. The sutures that are seen in the photo are of polyester.

SepraMesh (Fig. 7.122) is a single layer of polypropylene is covered by barrier that is a combination of carboxymethylcellulose and hyaluronic acid. It is bound together with

Fig. 7.113 C-QUR EDGE

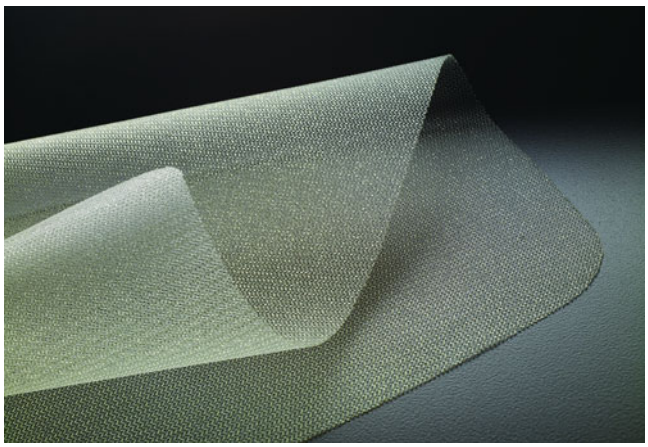


Fig. 7.114 C-QUR Lite

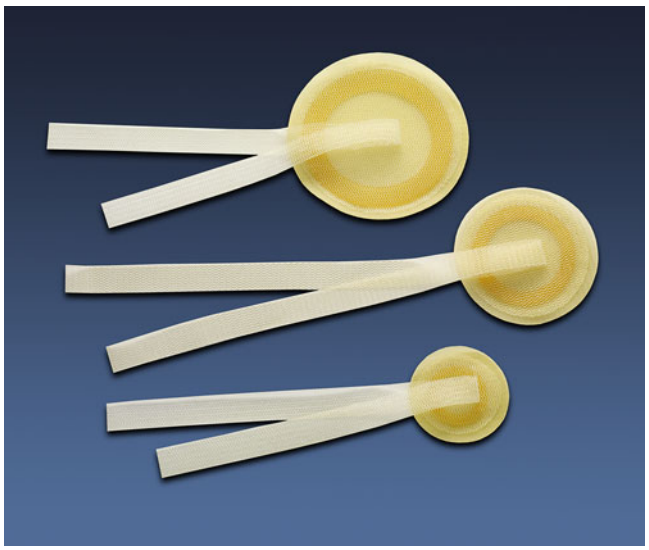


Fig. 7.115 C-QUR V-Patch

Fig. 7.116 Easy Prosthesis (polypropylene/collagen composite surgical mesh)

polyglycolic acid fibers and a hydrogel. This is the only product in this section that requires brief immersion into saline solution prior to its use to activate the gel. This hydrogel swells following implantation to cover the fixation devices that are used. This portion of the product is stated to last approximately 4 weeks, at which point, it has been resorbed. The "Sepra" technology has been extended to the Ventralex (see Fig. 7.135) and Ventrio (see Fig. 7.136) products. The ePTFE surface has been replaced with the tissue-separating hydrogel that is used on the SepraMesh prosthesis. These products are called *Ventralex ST* and *Ventrio ST*.

Combination Permanent Materials for Incisional and Ventral Hernioplasty

There has been an incredible increase in the number of permanent products available for the open and/or laparoscopic repair of incisional and ventral hernias since the last edition of this textbook (Table 7.19). All of those listed below are a combination of a single product that is manufactured in two different forms or, more commonly, a combination of two different products. The method of fixation of these products differs from each manufacturer. There are some that have been described earlier in this chapter that are single products and are not described again here (Table 7.11). What is consistent in all of the prostheses is the creation of some type of a barrier to adhesion formation while allowing for

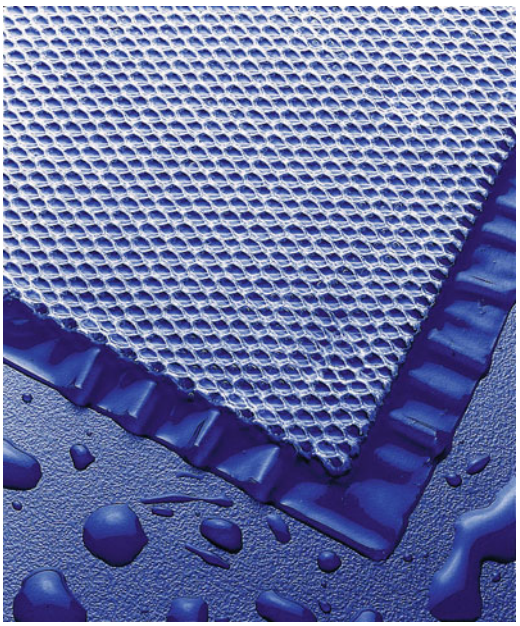


Fig. 7.117 Parietex Composite

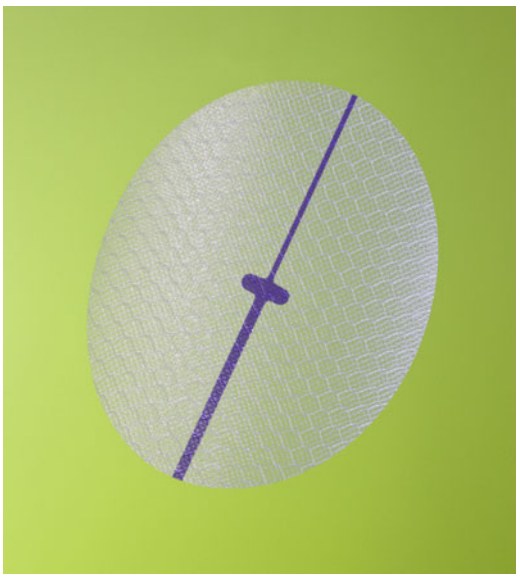


Fig. 7.119 PHYSIOMESH

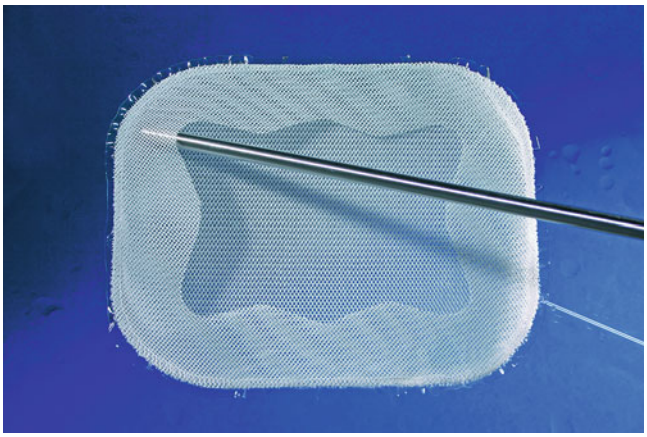


Fig. 7.118 Parietex Composite Skirted Mesh

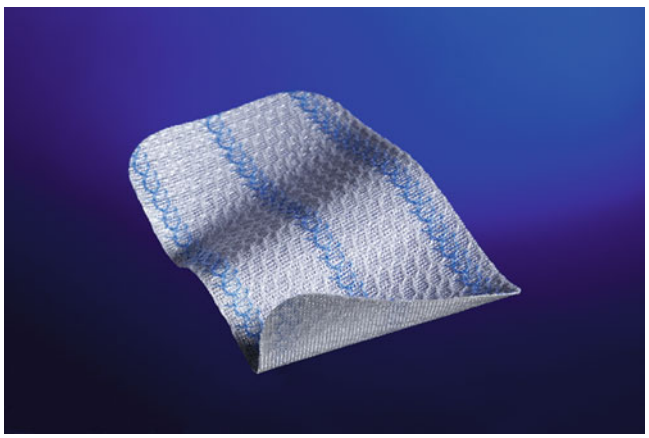


Fig. 7.120 Proceed

ingrowth on the parietal side of these meshes to repair a hernia effectively.

The *CA.B.S.* '*Air* (Fig. 7.123) is similar to the *CA.B.S.*' *Air SR* (Fig. 7.111) device described above. They both are constructed of two materials and inserted with the aid of a balloon dissection device that is removed (Fig. 7.124). The SR device is semi-resorbable while the CA.B.S.' Air is totally made of permanent material. These materials are PP on the parietal surface and ePTFE on the visceral surface. It is available in three sizes and with two or four sutures. They are both marketed for umbilical hernia repair but undoubtedly other hernias will lend themselves to these devices.

ClearMesh Composite (CMC) is a pure PP mesh (Fig. 7.125). There is a textured side that is composed of a

Fig. 7.121 Proceed Ventral Patch (PVP)

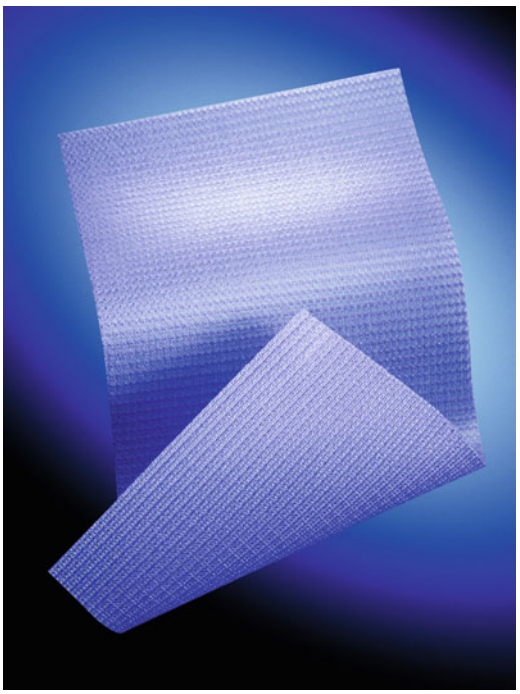


Fig. 7.122 Sepramesh

Fig. 7.123 CA.B.S. 'Air

Fig. 7.124 CA.B.S. 'Air and the balloon dissection device

Table 7.19 Ventral hernia products entirely of permanent material

CA.B.S 'Air, Cousin Biotech, Wervicq-Sud, France
ClearMesh Composite (CMC), Di.pro Medical Devices, Torino, Italy
Combi Mesh, Angiologica, S. Martino Sicc., Italy
Composix E/X Mesh, Davol, Inc., Warwick, RI, USA
Composix Kugel (CK) Patch, Davol, Inc., Warwick, RI, USA
Composix L/P Mesh, Davol, Inc., Warwick, RI, USA
DynaMesh IPOM, FEG Textiltechnik mbH, Aachen, Germany
IntraMesh T1, Cousin Biotech, Wervicq-Sud, France
IntraMesh W3, Cousin Biotech, Wervicq-Sud, France
Intramesh PROT1, Cousin Biotech, Wervicq
Omyra Mesh, B. Braun Melsungen AG, Melsungen, Germany
MotifMESH, Proxy Biomedical Ltd., Galway, Ireland
Rebound HRD V, Minnesota Medical Development, Plymouth, MN, USA
Relimesh, HerniaMesh, Torino, Italy
SurgiMesh XB, Aspide Medical, St. Etienne, France
SurgiMesh TintraP, Aspide Medical, St. Etienne, France
TiMesh, GfE Medizintechnik, Nuremburg, Germany
Ventralex (ST), Davol, Inc., Warwick, RI, USA
Ventrio (ST) Hernia Patch, Davol, Inc., Warwick, RI, USA

single filament macroporous weave and a nonadhesive side that is composed of a nonporous smooth PP film. It is for use in the intraperitoneal space. The 2P is elliptical in shape and the 2P-C is round. *Combi Mesh* is virtually identical to the Combi Mesh Pro described in the inguinal hernia section (Fig. 7.27). The only difference is that these are larger sizes. This product is designed for placement into the intraperitoneal position with the polyurethane layer facing the viscera.

Composix E/X Mesh (Fig. 7.126) is flat Bard mesh on one side and ePTFE on the other side. The edge of the perimeter of the elliptically shaped product is sealed to prevent contact of viscera to the PP. It is a low profile mesh that is best suited for laparoscopic repairs. *Composix Kugel (CK) Patch* (Fig. 7.127) is a self-expanding product that has Bard mesh on one side and ePTFE on the other as does the E/X and L/P

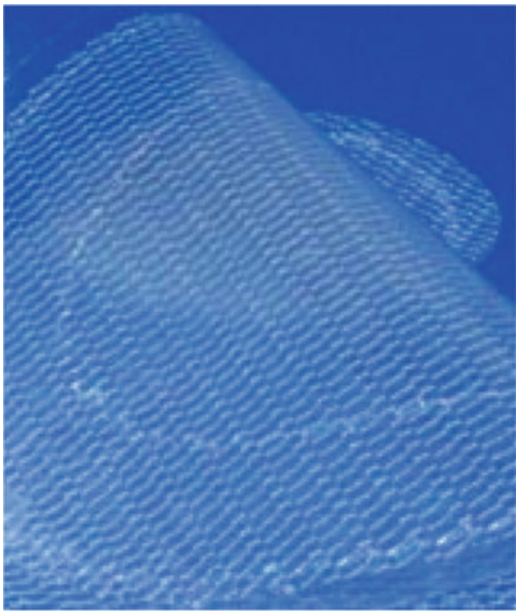


Fig. 7.125 ClearMesh Composite (CMC)

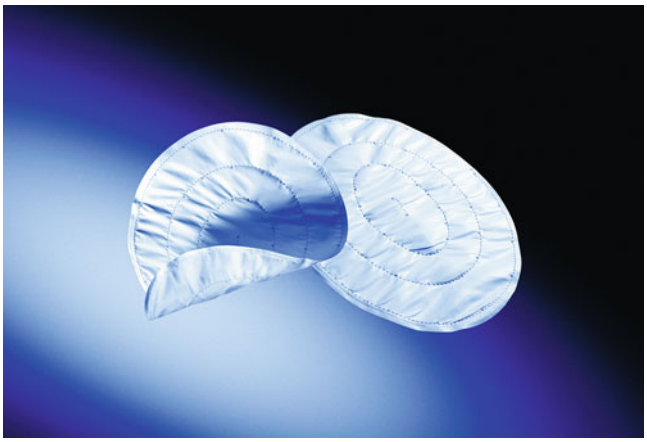


Fig. 7.126 Composix E/X

Fig. 7.127 Composix Kugel (CK) Patch

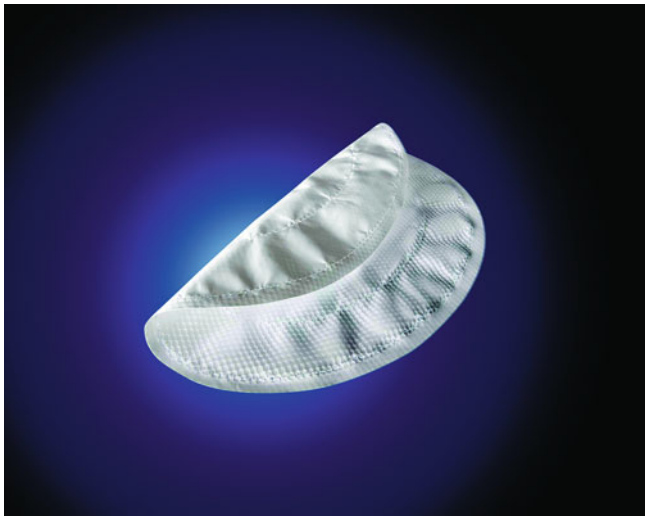


Fig. 7.128 Composix L/P

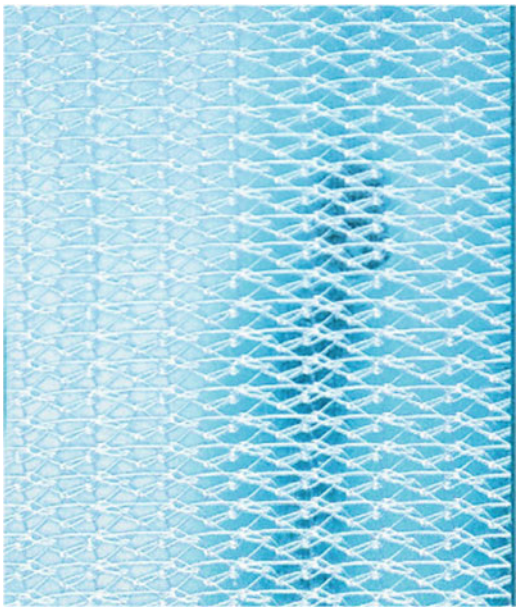


Fig. 7.129 DynaMesh IPOM

products. There is an additional POL ring that causes it to assume its shape after introduction into the abdominal cavity to facilitate fixation. This ring is of a smaller diameter with an improved weld than the earlier version of the product. *Composix L/P* (Fig. 7.128) is very similar to the Composix E/X except that the former uses the lighter Bard Soft Mesh rather than the Bard mesh. It is specifically designed for laparoscopic usage and can be used with an optional introduction tool. The two mesh layers are sutured together with ePTFE suture for all three of these prosthetic devices.

DynaMesh IPOM (Fig. 7.129) is a similar PP weave as the DynaMesh described above but it is slightly lighter than the latter product. This version is intertwined with polyvi-

Fig. 7.130 IntraMesh T1

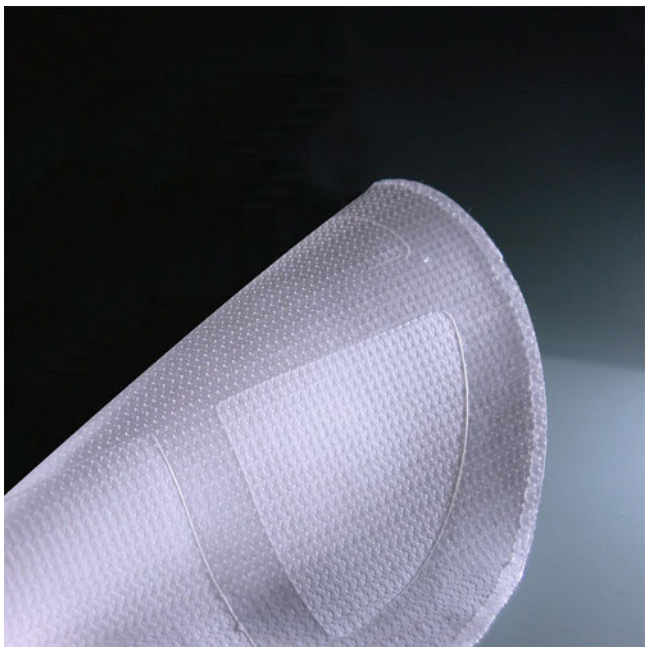


Fig. 7.132 IntraMesh PROT1

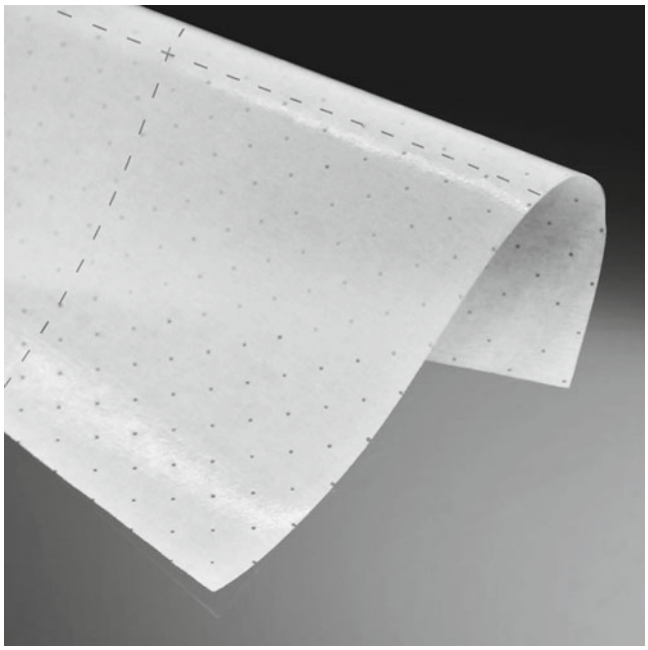


Fig. 7.131 IntraMesh W3

nylidene fluoride (PVDF), which is also a monofilament. Because of this PVDF tissue-separating component it can be placed onto the viscera. *IntraMesh T1* (Fig. 7.130) is similar to the Composix product line in that it is composed of one layer of PP and a second layer of ePTFE. There are lines on the product to delineate the midportions of each side to ease positioning for the laparoscopic approach. *IntraMesh W3* (Fig. 7.131), like the other IntraMesh products, is designed for intraperitoneal usage. This mesh is also marked but is POL based. There is one layer of nonwoven polyethylene terephthalate with microperforations for parietal attachment and a visceral surface with dimethyl siloxane. *IntraMesh PROT1* (Fig. 7.132) is a combination of the other two IntraMesh prostheses. It is round with two layers of PP and ePTFE. In addition, as can be seen in the photo, there is another layer of dimethyl siloxane designed to strengthen the fixation points. Cousin Biotech also sells a "mesh roller" which is a device to aid in the rolling of these materials to ease insertion via a trocar.

MotifMESH (Fig. 7.60) *and Omyra Mesh* (Fig. 7.61) were discussed the "Miscellaneous Flat Mesh Section" (Table 7.13). Omyra Mesh is said to be a bacterial resistant anti-adhesive mesh. Unlike the W. L. Gore & Associates products, there is no antimicrobial or antibacterial substance added to the product. It is made of lightweight cPTFE.

Rebound HRD V is of the same concept as the Rebound HRD described above. It has a nitinol ring around the perimeter of the oval shape. The mesh product in this version is cPTFE. It is designed for use in the intraperitoneal space. *Relimesh* (Fig. 7.133) is another product that incorporates the PP on one surface and ePTFE on the other to allow placement against the viscera. It is a lighter weight product compared to other HerniaMesh products. Because of this, it can be rolled for insertion via a trocar.

SurgiMesh XB (Fig. 7.134) has a nonwoven, non-knitted structure as does the SurgiMesh WN described earlier. It has an additional layer of silicone to allow contact with the viscera and is microperforated. *SurgiMesh TintraP* is a

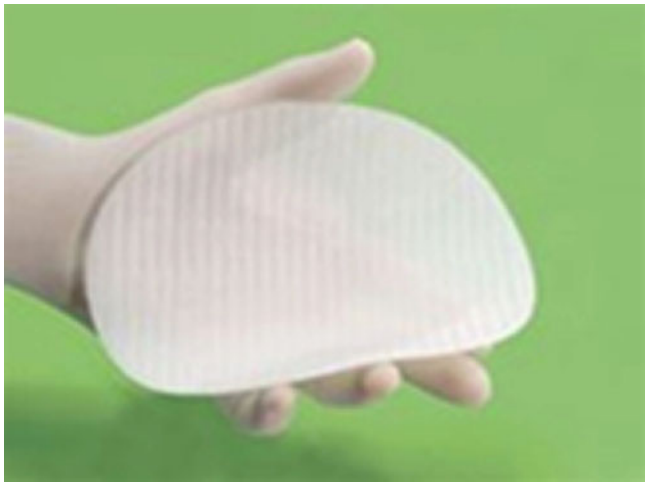


Fig. 7.133 Relimesh

Fig. 7.135 Ventralex

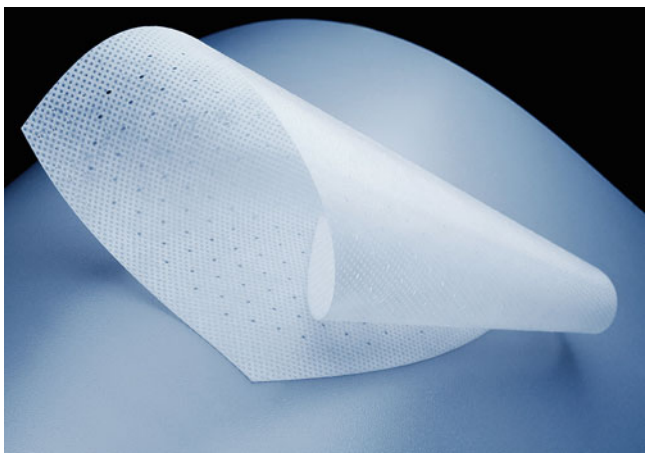


Fig. 7.134 SurgiMesh XB

Fig. 7.136 Ventrio Hernia Patch

similar product but is round and to be used with smaller hernias such as trocar and umbilical hernias. TintraP is made to include strips to fix the product to the edge of the fascia. Additionally, the prosthesis is supplied "pre-loaded" over an introducer that aids in deployment of the device in the preperitoneal space. *TiMesh* (Figs. 7.47 and 7.48) is the same material that has been described in several locations within this chapter. The titanized PPM can be used in the intraperitoneal location (per the manufacturer).

Ventralex (Fig. 7.135) is a self-expanding PP device (because of the outer ring of POL) that is fixed with ePTFE on one side to allow placement adjacent to viscera. It is round but smaller than the larger products such as the Composix products described above. It is intended for use in the smaller defects of the abdominal wall such as trocar or umbilical hernias. There is a pocket to allow for a digit to be inserted for placement. Two long straps are attached and are to be used for fixation to the fascia. They are very long as this product can be inserted through a laparoscopic trocar to aid in the prevention of trocar hernias. The *Ventrio Hernia Patch* (Fig. 7.136) comprises two layers of mesh product. PP that is stitched to an ePTFE layer as the tissue-separating component. Within the PP surface there are "tubes" (similar to the Composix Kugel mesh) that house the absorbable PDO monofilament rings to give the mesh rigidity to aid in positioning and fixation. The purple PDO ring is absorbed within 6–8 months. A second-generation product is due to be released in which the anterior PP will be constructed of a lighter weight PP. There are other minor differences that will not be noted by the surgeon.

Stomal Hernia Prevention and Repair Products

The development of a hernia, wherever a stoma is created, has been the challenge in the life of all patients with some type of an ostomy. Traditionally, relocation or primary closure was used to repair these hernias. It is now recognized that this is fraught with failure in most cases. Consequently,

Table 7.20 Stomal prostheses

Colostomy Mesh, HerniaMesh, Torino, Italy
CK Parastomal Patch, Davol, Inc., Warwick, RI, USA
DynaMesh-IPST, FEG Textiltechnik mbH, Aachen, Germany
Easy Prosthesis (PPM/Collagen), TransEasy Medical Tech.Co. Ltd., Beijing, China
Parietex Composite (PCO) Parastomal Mesh, Covidien plc, Dublin, Ireland
Stomaltex, Di.pro Medical Devices, Torino, Italy
2P-ST, Di.pro Medical Devices, Torino, Italy
TiLENE Guard, GfE Medizintechnik, Nuremburg, Germany

Fig. 7.137 Colostomy Mesh

Fig. 7.138 CK Parastomal Patch

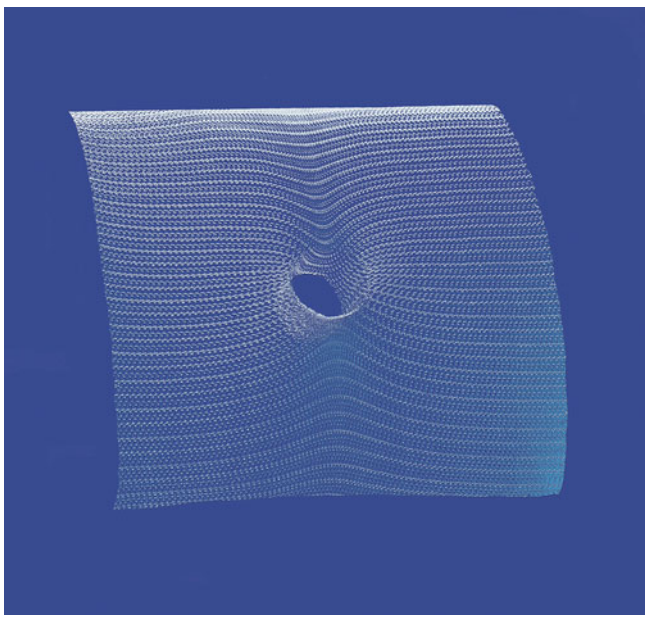


Fig. 7.139 DynaMesh-IPST

the use of a prosthetic material has become nearly standard to repair these hernias. In fact, recent trends indicate that the use of a mesh of some type when the stoma is created may be the preferred option. Prevention has become the new effort in mesh construction (Table 7.20). As with many of the other products in this chapter, these can generally be used with the open or laparoscopic technique.

Colostomy Mesh (Fig. 7.137) is a single layer PP product. It has a 5-cm hole in the center of the material through which the intestine can be placed during stomal creation. Of course, the mesh can be cut if this product is used to repair a parastomal hernia. It is available in a "rigid" and a "semi-rigid" construction. The *CK Parastomal Patch* (Fig. 7.138) is to be used to repair an existing parastomal hernia. Like the other CK products, it has a POL memory recoil ring and is made of PP and ePTFE. It has a precut slit and a circular opening to allow passage of the intestine. The ePTFE around the collar is reinforced to inhibit stretching of the opening. Additionally, there are flaps of ePTFE that will lie on the intestine at the completion of the implantation.

DynaMesh-IPST (Fig. 7.139), like its parent material, is made of both PVDF and PP. It is pre-shaped and three-dimensional. *Easy Prosthesis (PPM/Collagen)* (Fig. 7.116) was previously discussed in the section titled "Prostheses for Incisional and Ventral Hernioplasty with an Absorbable

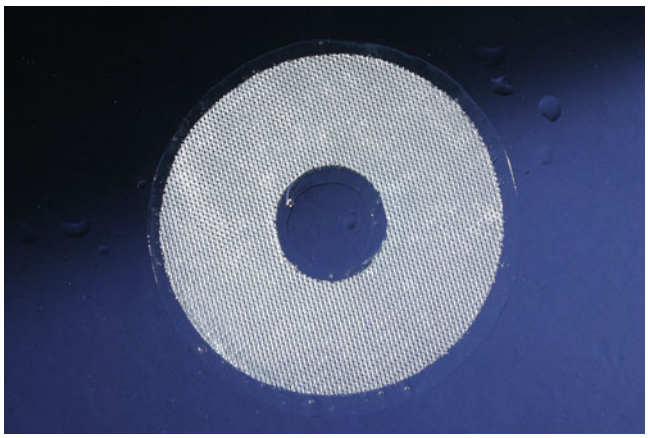


Fig. 7.140 Parietex Composite Parastomal Mesh with hole

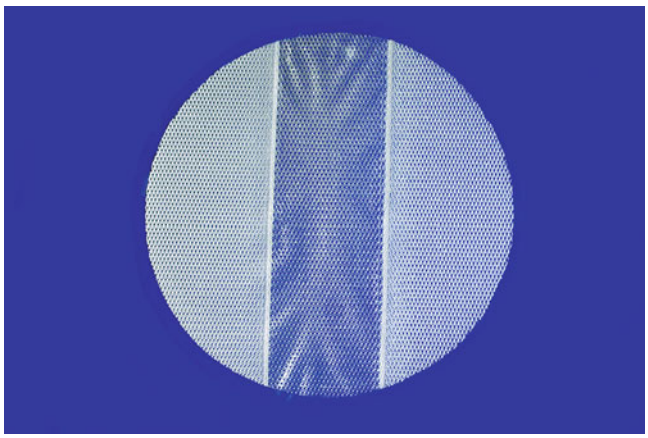


Fig. 7.141 Parietex Composite Parastomal Mesh without hole

Component." As seen in the figure, there is a shape that is similar to many of these products designed for stomal hernia prevention and repair. *Parietex Composite Parastomal Mesh* is of the same material as that described previously. This is supplied in two sizes and is available with a hole (Fig. 7.140) or without a hole and only a central band (Fig. 7.141). The opening of the hole can either be 3.5 or 5.0 cm.

Stomaltex (Fig. 7.142) is a macroporous heavyweight PP product similar to their Basic flat mesh (Fig. 7.20) described in the earlier section on flat PPM meshes. It does not include any tissue-separating material. The *2P-ST* prosthesis is of the "protected" CMC material as their flat sheets for intraperitoneal usage. It is supplied with a central hole that is either 3 or 5 cm in diameter. *TiLENE Guard* (Fig. 7.143) is of titanized PP (Fig. 7.48). It is supplied with a flap, which is closed after the intestine is placed through the central hole. It is supplied in the light and dual-weight (light and medium) meshes. There is a set, which contains TiLENE mesh that is to be applied as a "sandwich" technique to repair or prevent herniation through the stoma location.

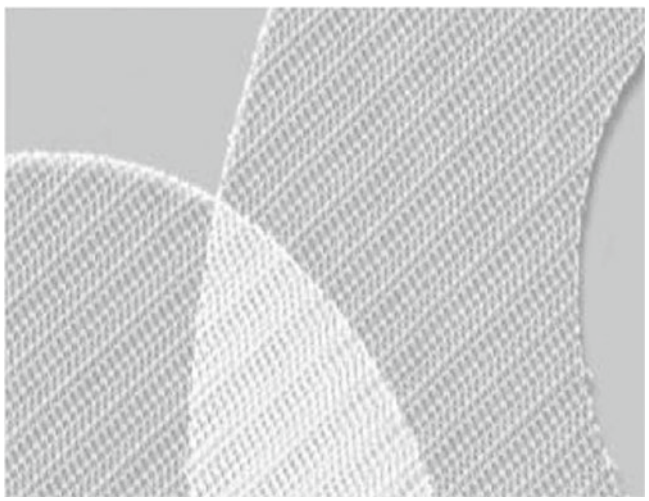


Fig. 7.142 Stomaltex

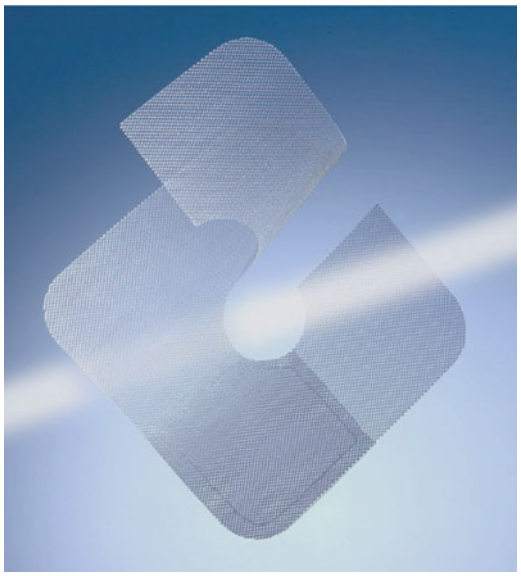


Fig. 7.143 TiLENE Guard

Hiatal Hernia Repair Products

The use of permanent meshes to repair hiatal hernias has been commonplace for many years. The introduction of the biologic products has resulted in a decline in the application of the permanent products at this position. The real concern is of erosion of the product into the esophagus or infection with a permanent prosthesis. While the application of flat meshes such as unprotected PP or POL has been used, these products were designed to mitigate against these concerns (Table 7.21).

CruraSoft Patch (Fig. 7.144) is made of two products. One surface is of PTFE mesh designed to encourage tissue penetration and ingrowth. The other is ePTFE, which will

Table 7.21 Permanent hiatal hernia repair products

CruraSoft, Davol, Inc., Warwick, RI, USA
Easy Prosthesis (PPM/Collagen), TransEasy Medical Tech.Co. Ltd., Beijing, China
Parietex Composite (PCO) Hiatal Mesh, Covidien plc, Dublin, Ireland
TiSURE, GfE Medizintechnik, Nuremburg, Germany

Fig. 7.144 CruraSoft

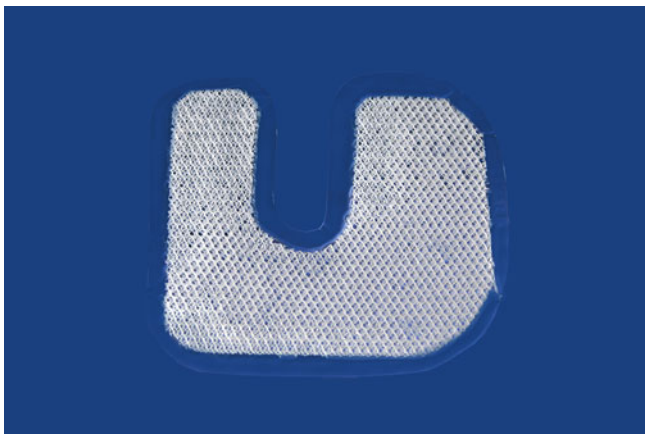


Fig. 7.145 Parietex Composite Hiatal Mesh

have visceral contact to diminish adhesions. There is an additional flap of ePTFE to cradle the esophagus and decrease the risk of adhesion and erosion into it. This prosthesis can be placed either over an open hiatus or re-approximated crura. The latter approach will represent a tension-free repair. It is available in two sizes and can be either sutured or stapled in place. *Easy Prosthesis (PPM/Collagen)* (Fig. 7.116) was previously discussed in the section titled "Prostheses for Incisional and Ventral Hernioplasty with an Absorbable Component." As seen in the figure, there is a shape that is similar to the CruraSoft above, which is designed for use in repair of the hiatal crura.

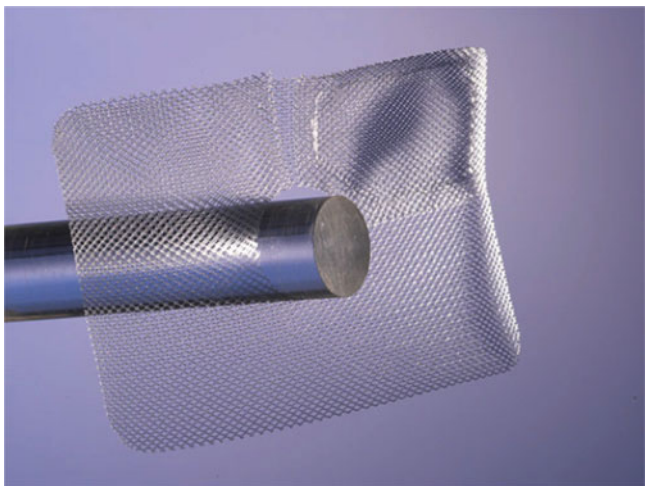


Fig. 7.146 TiSURE

Parietex Composite Hiatal Mesh (Fig. 7.145) is made of the same material as the parent PCO product. It possesses a U-shaped defect that is slightly off-center that is to be positioned below the esophagus. The legs of the product will lie on the crura. It is available in two sizes also.

TiSURE (Fig. 7.146) is a rectangular mesh that has a central hole and a flap made from TiMESH (Fig. 7.47). It differs from the other products listed in that it possesses that flap which mandates complete encirclement of the esophagus. It can be fixed with either fibrin glue or sutures. It is not recommended to use metal fixation devices on this product because of the risk of complications from these devices.

Fixation Devices

Fixation devices became prevalent early in the development of the laparoscopic repair of hernias. The earlier versions were 10 or 12 mm devices, some of which are still available today. More commonly the 5 mm versions have become the most popular. Most recently, recognition of the requirement of these devices on a temporary basis has led to the introduction of absorbable platforms. Currently, there is a variety of these devices that one may choose to fixate the meshes placed in hernia repair, whether inguinal or ventral and via an open or laparoscopic technique (Table 7.22). Surgeon preference and the mesh chosen will dictate the decision. One should consider the total length of these fasteners, as the depth of penetration will be dependent upon the thickness of the mesh used to repair the hernia. For example, a 5 mm fastener will provide no more of tissue penetration than 4 mm when used with 1 mm prosthesis.

The *AbsorbaTack* (Fig. 7.147) is a 5 mm fixation device which provides an absorbable synthetic polyester copolymer screw-like fastener derived from lactic and glycolic acid.

It measures 5.1 mm in length. It is offered in both a 10 or 20 tack configuration. The tacks are significantly absorbed within 3–5 months with complete absorption within 1 year. The *Amid Hernia Stapler* (Fig. 7.148) is designed to fixate the onlay mesh in a Lichtenstein hernia repair of the groin but will likely find applications for other type of hernias. It contains 17 titanium "box" type staples. Its contents can also be used to close the skin at the completion of the procedure.

The *Endo Universal Stapler* (Fig. 7.149) is to be used via a 10 or 12 mm trocar. It delivers a "box-type" staple of titanium and can be rotated 360° and has 65% of articulation. It can be used in four different positions. The *MultiFire Hernia Stapler* (Fig. 7.150) is introduced through a 12 mm trocar. It has "box-shaped" staples that will fixate the prosthesis into which it is fired. The *MultiFire VersaTack Stapler* (Fig. 7.151) is designed for open usage. It, too, can be rotated 360°. These three staplers can be used with interchangeable disposable loading units that contain either the 4.0 or 4.8 mm staples and delivering ten staples. These staples are usually acceptable for use with MRI and NMR up to three Tesla.

The *PermaSorb* (Fig. 7.152) device delivers a poly (D,L)—lactide (PDLLA) fastener that has two barbs on the end of it. They are delivered over an introducer needle. This product is available in either a 5 or 12 shot shaft; the latter being longer is best suited for laparoscopic procedures while the former is for open methods. These fasteners are fully absorbed at 16 months. *PermaFix* and *SorbaFix* (Fig. 7.153) deliver the same size (6.7 mm) screw-type fasteners by an identical delivery mechanism with a pilot tip and mandrel. Both of these fasteners are available in either 15 or 30 devices delivered via a 5 mm product. Sorbafix is made of the same material as the PermaSorb ad is purple, while the Permafix is made of grey molded permanent polymer, making it nonabsorbable.

The *ProTack* (Fig. 7.154) was one of the earlier products that delivered a fastener by a 5 mm device. It delivers a permanent titanium helical fastener. It is available with 30 tacks. These are the easiest fixation products to visualize on a plain radiologic study. They are 3.9 mm in total length.

The *SECURESTRAP* (Fig. 7.155) is a new 5 mm laparoscopic device for hernia repair. It is a multi-fire, single-use device pre-loaded with *25* absorbable straps. The straps are composed of a blend of PDO and L(-)-lactide and glycolide dyed with D&C Violet No. 2. This product does not screw into the tissues and has two legs similar to the staplers. The ends of these straps are barbed to aid in fixation. The width between the points is 3.5 mm. The length of the entire device is 6.7 mm but the distance from the inner portion of the strap to the point of fixation of the strap is 4.9 mm (i.e., the "grip").

The *Stat Tack* (Fig. 7.156) and Tacker (Fig. 7.157) devices deliver helical titanium tacks virtually identical to the ProTack (Fig. 7.154). The former device is shorter and designed for open hernia repair, delivering only 15 tacks. The Tacker is longer as it is designed for laparoscopic techniques and delivers 30 tacks in the single-use device. There is an available multiuse handle of the Tacker that can be attached to an available tube of 20 tacks. This is a unique concept for fixation products. The multiuse product has a shorter tube than the single-use product.

Table 7.22 Fixation devices for hernia repair

AbsorbaTack, Covidien plc, Dublin, Ireland
Amid Stapler, SafeStitch Medical Inc., Miami, FL, USA
Endo Universal Stapler, Covidien plc, Dublin, Ireland
Multifire Endo Hernia Stapler, Covidien plc, Dublin, Ireland
Multifire VersaTack Stapler, Covidien plc, Dublin, Ireland
PermaFix, Davol, Inc., Warwick, RI, USA
PermaSorb, Davol, Inc., Warwick, RI, USA
ProTack, Covidien plc, Dublin, Ireland
SecureStrap, Ethicon Inc., Somerville, NJ, USA
SorbaFix, Davol, Inc., Warwick, RI, USA
Stat Tack, Covidien plc, Dublin, Ireland
Tacker, Covidien plc, Dublin, Ireland

Mesh Delivery Devices

At the time of this writing, there are a few devices that have been developed to ease the insertion of the meshes used in laparoscopic repair of hernias, mainly the incisional and

Fig. 7.147 AbsorbaTack

ventral locations. These include the *Mesh GPS* device by Surgical Structure Ltd. (Moshav Herev Le'Et, Israel), the *PrecisionPass Laparoscopic Delivery Device* (Davol, Inc., Warwick, RI, USA), and the *PatchAssist* (Polytouch Medical Ltd., Tel Aviv, Israel). Davol, Inc. recently purchased the Mesh GPS product and may change the name to Echo. This is not certain at this time, however.

The *Mesh GPS* device comprises three components, an inflatable spreading balloon, an adaptor, and an inflation unit/pump. These combine to assist spreading and deploying the mesh used to repair the hernias. The *PrecisionPass* device assists in the rolling of a mesh into a tubular shape for introduction via a laparoscopic trocar (Fig. 7.158). The *PatchAssist* (Fig. 7.159) fixes the mesh to itself allowing it to be rolled into a tube and introduced. Upon introduction, the device is opened, deploying the mesh and holding the mesh onto the abdominal wall to ease positioning and fixation.

Fig. 7.148 Amid Hernia Stapler

Conclusion

The use of a prosthetic material for all hernia repairs is the norm rather than an isolated event. The purpose of this chapter is to identify and differentiate the products that can be used in hernioplasties. It is as complete as we could make this at this time. Undoubtedly by the time of the printing of this textbook, others will have become available. The surgeon should choose carefully.

I believe that the ideal material has not yet been developed. There are, however, many that have been described above that do function quite well for the surgeon and the patient. Perhaps in the future, the use of genetic engineering will produce a product that is based from the protein of the patient and will allow the patient to incorporate a "natural" and "native" product into the tissues without fear of infection or adhesions. A permanent solution to the quest of the perfect biomaterial may be the result.

Acknowledgment I want to thank the following for the valuable inclusive photos that were supplied for inclusion in this chapter: Atrium Medical Inc., Davol, Inc., Ethicon Inc., W.L. Gore & Associates.

Fig. 7.149 Endo Universal Stapler

Fig. 7.150 Multifire Hernia Stapler

Fig. 7.151 MultiFire VersaTack Stapler

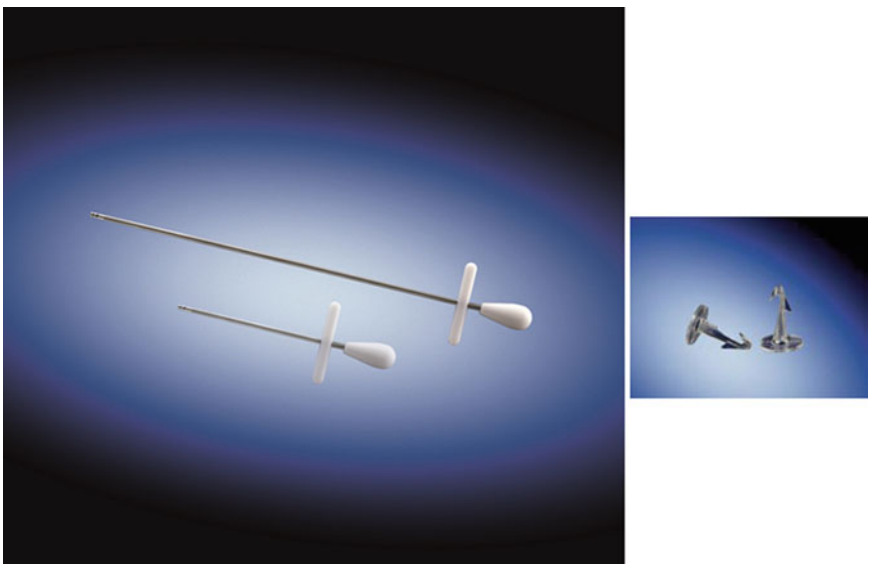


Fig. 7.152 PermaSorb

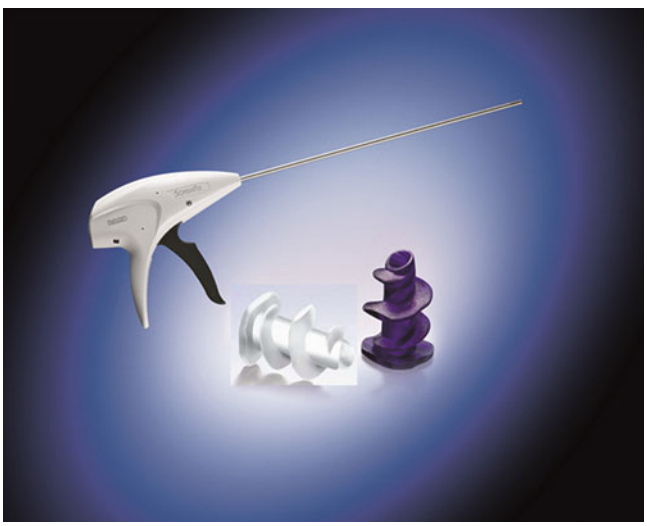


Fig. 7.153 SorbaFix device with SorbaFix (*purple*) and PermaFix (*grey*) fasteners

Fig. 7.154 ProTack

Fig. 7.155 SECURE*STRAP* and the Strap fastener

Fig. 7.156 Stat Tack

Fig. 7.157 Tacker

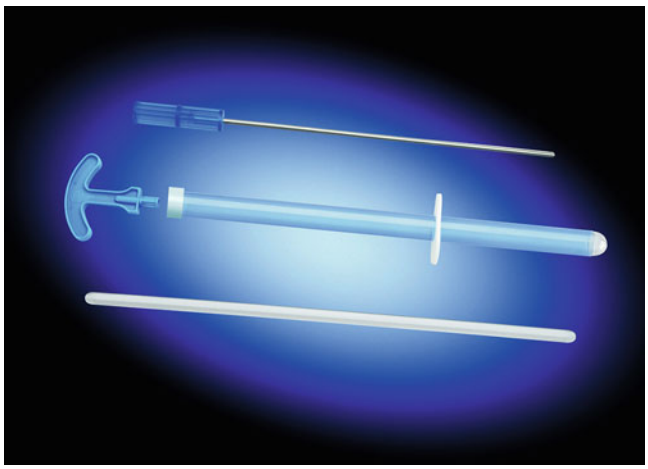


Fig. 7.158 PrecisionPass Laparoscopic Delivery Device

Fig. 7.159 PatchAssist

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