

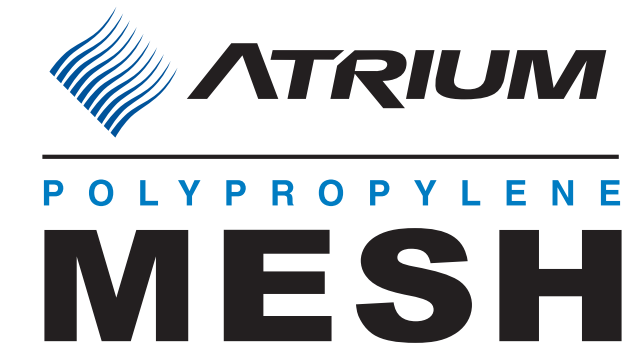
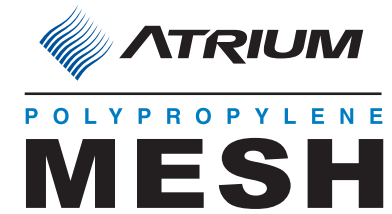
Comments from surgeons who have used Atrium's new Self-Forming Plug can be summarized as follows:

- ▶ "The Atrium Self-Forming plug fits the defect."
- ▶ "I like the center tab for ease of placement"
- ▶ "This is the first self-expanding mesh plug we've used that actually fits the hole, instead of the hole having to fit a preselected size."
- ▶ "Works well, even on "massive" hernias"
- ▶ "Generally, we've found one size plug can be used on a wide variety of both large and petite patients."
- ▶ "This plug requires no extra dissection."
- ▶ "You can be sure the plug is in place, no deployment is necessary."
- ▶ "The Atrium Plug and onlay is much softer - I like it"
- ▶ "Atrium's new Hernia Mesh is cost effective and quite easy to standardize on a few select universal sizes."

References

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3. Lichtenstein, IL, Shore, JM: Simplified Repair of Femoral and Recurrent Inguinal Hernias by a "Plug" Technique. Amer. J of Surg. 129: 439-444, 1974.
4. Rutkow IM, Robbins AW: Groin Hernia. Current Surgery Therapy/Cameron. 481-486, 1995.
5. Gilbert AI: Inguinal Hernia Repair: Biomaterials and Sutureless Repairs. Persp. Gen Surg. 2:113-129, 1991.
6. Gilbert AI: Sutureless Repair of Inguinal hernia. The Amer. J of Surg. 163: 331-335, 1992.
7. Rutkow IM, Robbins AW: The Hernia Plug Hernioplasty. Hernia Surgery, Surgical Clinics of North America. Vol. 73, No. 3, June 1993.

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 Hernia-Mate is a registered trademark of United States Surgical Corporation, Tyco Healthcare Group.
 Surgipro is a registered trademark of United States Surgical Corporation, Tyco Healthcare Group.



Self-Forming Plug

ORDERING INFORMATION

Code No.	Description/Size	Diagram 1	Diagram 2	Diagram 3
1010101-01	Small Plug Depth - 1.0" (2.5 cm) Onlay - 2" x 4" (5 x 10 cm)			
1010202-01	Medium Depth - 1.25" (3.2 cm) Onlay - 2" x 4" (5 x 10 cm)			
1010303-01	Large Depth - 1.5" (3.8 cm) Onlay - 2" x 4" (5 x 10 cm)			
1010404-01	Extra Large Depth - 1.75" (4.4 cm) Onlay - 2" x 4" (5 x 10 cm)			
1010202-05	Medium Depth - 1.25" (3.2 cm) Onlay - 2" x 4" (5 x 10 cm)			
1010303-05	Large Depth - 1.5" (3.8 cm) Onlay - 2.5" x 5" (6 x 12.5 cm)			



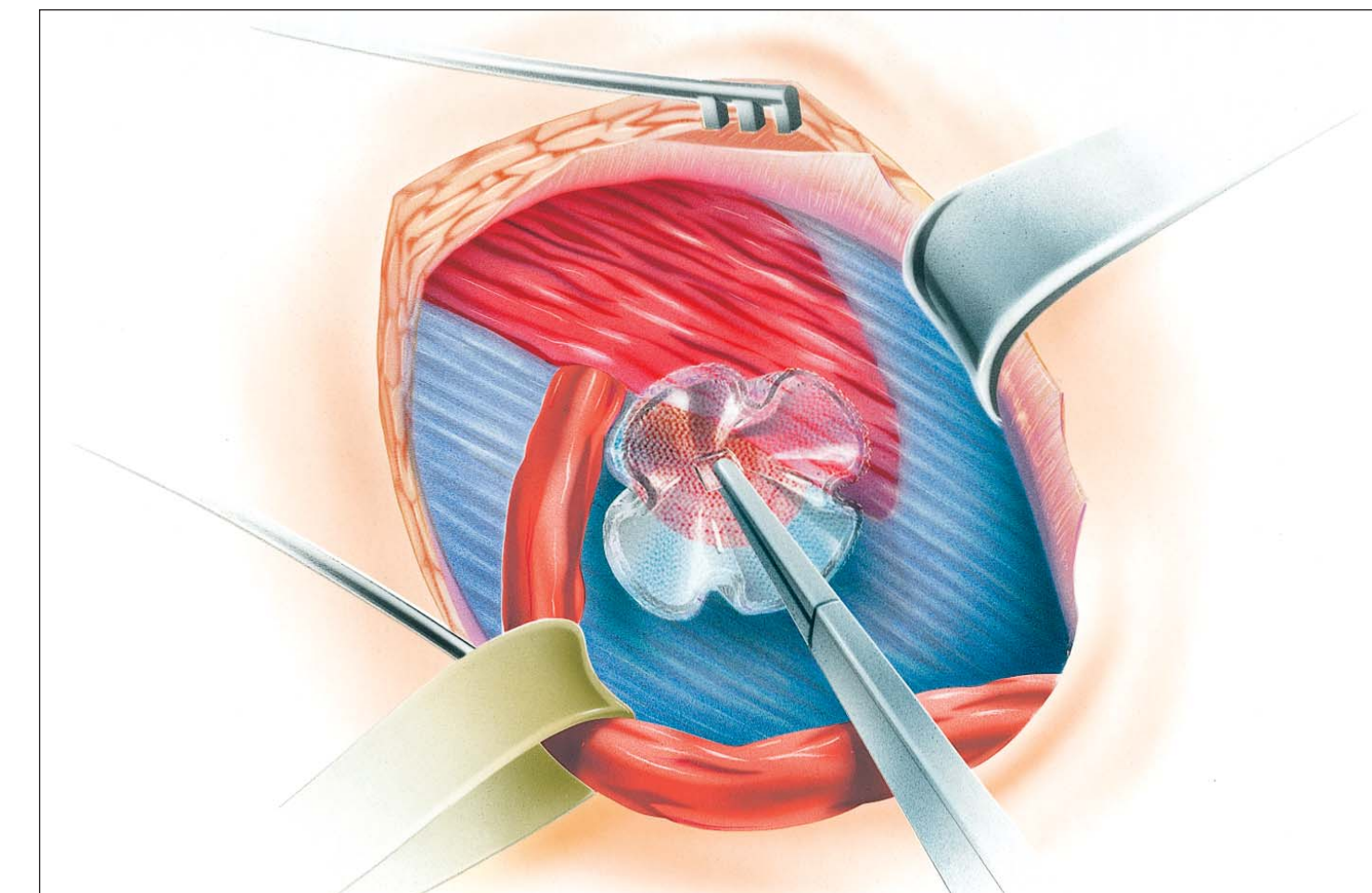
ATRIUM MEDICAL CORPORATION
 5 Wentworth Drive, Hudson, New Hampshire U.S.A. 03051
 ☎ 603-880-1433 📠 603-880-6718

ATRIUM MEDICAL CORPORATION
 Rendementsweg 24, LIII
 3641 SL Mijdrecht, The Netherlands
 ☎ +31-297-230-420 📠 +31-297-230-422

ATRIUM AUSTRALIA-PACIFIC RIM PTY. LTD.
 L1 Bridgepoint
 3 Brady Street
 Mosman NSW 2088 Australia
 ☎ +61-2-9960-0169 📠 +61-2-8969-2735

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An Atlas of Inguinal Hernia Repair with a Self-Forming Mesh Plug



Harold S. Goldstein, M.D., F.A.C.S.

Department of Surgery, University of Miami Medical School and
 Veterans Administration Medical Center, Miami, Florida



An Atlas of Inguinal Hernia Repair with A New Self-Forming Mesh Plug

Harold S. Goldstein, M.D., FACS

Department of Surgery, University of Miami Medical School
And Veterans Administration Medical Center
Miami, Florida

Introduction

Inguinal herniorrhaphy is the most common surgical intervention performed by general surgeons today. Over 700,000 inguinal herniorrhaphy procedures are performed annually in the U.S alone.^{1,2}

During the past 30 years various forms of polypropylene mesh plugs have become an accepted method to repair primary and recurrent hernias. The simplified insertion technique combined with reported low complication, infection and recurrence rates have made 3-dimensional hernia plug repair a very appealing procedure for most primary hernia repairs.

In 1974 Lichtenstein and Shore first described using a “cylindrical shaped plug” made of polypropylene surgical mesh material to treat recurrent femoral and recurrent inguinal hernias.³ They described the cylindrical mesh plug technique as a method which decreases the amount of overall dissection and results in diminished patient discomfort.⁴ This concept of a 3-dimensional plug repair was described as being a simpler and more reliable method of hernia repair than conventional suturing techniques. It was believed by “filling” the defect with prosthetic material, such a technique may result in lower recurrence rates. However, most “table made” cylindrical plugs lacked the necessary radial support to help maintain stability and fixation within the defect.

In 1987 Gilbert fashioned a pointed cone-shaped plug from a flat piece of monofilament polypropylene mesh.^{5,6} This cone shaped plug was designed to provide more radial support than the Lichtenstein and Shore cylindrical plug. However, it lacked the interior bulk to completely fill the defect. This conical plug design also had a rather

pointed apex that could potentially cause tissue irritation and/or patient discomfort during insertion.

In 1995 Rutkow and Robbins treated primary and recurrent hernias with a preformed shaped plug that included multiple layers of pleated polypropylene Marlex® mesh, to provide ease of insertion and provide for more material within the defect. The pleated cone shape included layers or petals of polypropylene mesh to provide additional internal bulk for filling the defect.^{4,7} Because this plug is preformed in size, with a preset shape, the surgeon must carefully select the proper size to fill and contain the defect. Essentially the “hole must fit the pre-formed plug.”

Since most “preshaped” cone plugs can easily be compressed, the amount of external radial force to hold the plug in position and prevent protrusion through the defect, is subject to proper size selection to prevent plug migration or movement during healing. Since most hernia defects tend to be conical or funnel shaped, with the widest part closest to the peritoneum, placing a conical shape “preformed” plug in reverse to the anatomy of the defect may pose some concerns when the apex of a preshaped plug is narrow and pointed.

The mechanics of repairing a hernia defect with a mesh plug is elegantly simple. The plug repair has been compared to placing a cork into a bottle. Placement of the plug is easy and direct. The plug fills the structural defect created during the dissection of the hernia. Use of a mesh plug is also another form of “tension-free” hernia repair. No additional dissection or creation of a pocket is required. The quick infiltration of fibroconnective tissue into the porous polypropylene material, along with a reduction in dissection when compared to other traditional types of hernia repair, allows for a more rapid recovery, less patient discomfort, and quicker return to full activity. In primary hernia repair, the addition of an onlay over the plug helps prevent future herniation if surrounding tissue becomes deficient.

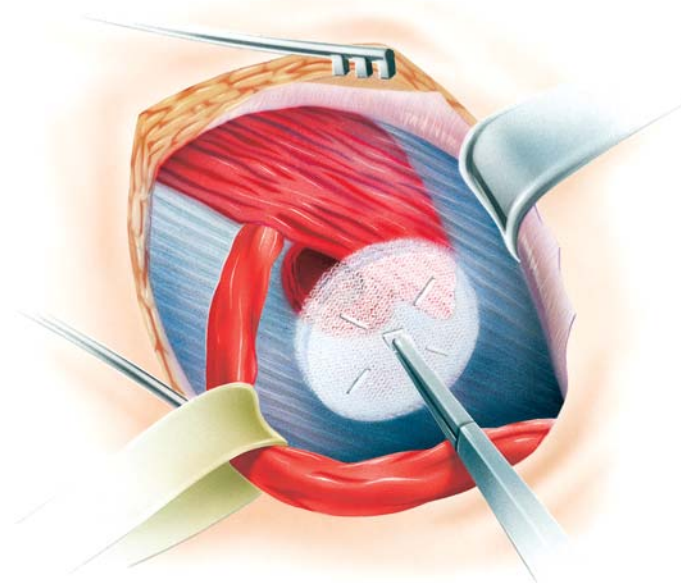
Preformed Plug Designs

The shape and design of the ideal mesh plug has been as varied as imagination has allowed. As previously described mesh plugs have been formed by rolling flat mesh into a cylindrical shape or shaping it into pointed cones.

Today there are a number of “pre-formed” polypropylene mesh plugs available such as the Marlex® mesh PerFix® hernia plug (C.R. Bard), Surgipro® Hernia-Mate® (United States Surgical) and Prolene® Hernia System (Ethicon Inc. - Johnson & Johnson).

Both the Marlex PerFix preformed mesh plug and the Surgipro Hernia-Mate conical plug are similar in conical shape and design, and offer sizes with internal layers to help increase bulk (or can be trimmed to

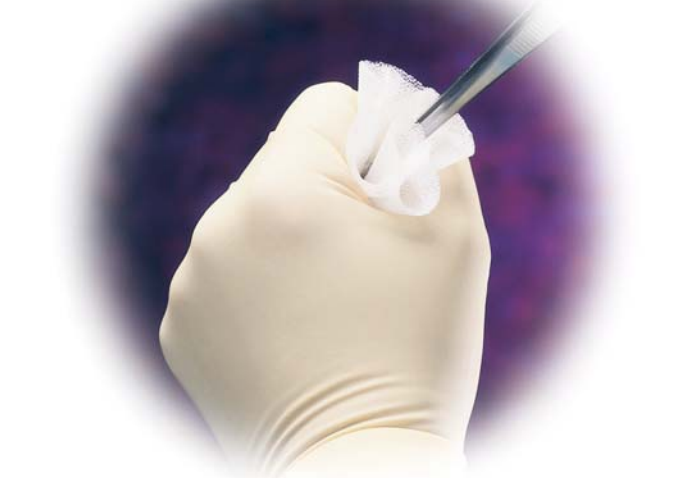
FIGURE 2
Grasp the center tab of the Self-Forming Plug with forceps or a hemostat.



help reduce bulk). The pointed preshape cone design of these preformed plugs can limit their ability to completely fill certain defects, especially if one were to use the same shape and size as the defect. Hence, traditional conical shaped plugs such as PerFix and Hernia-Mate preshapes may not completely fill the widest part of the defect (extra space shouldn't be there).

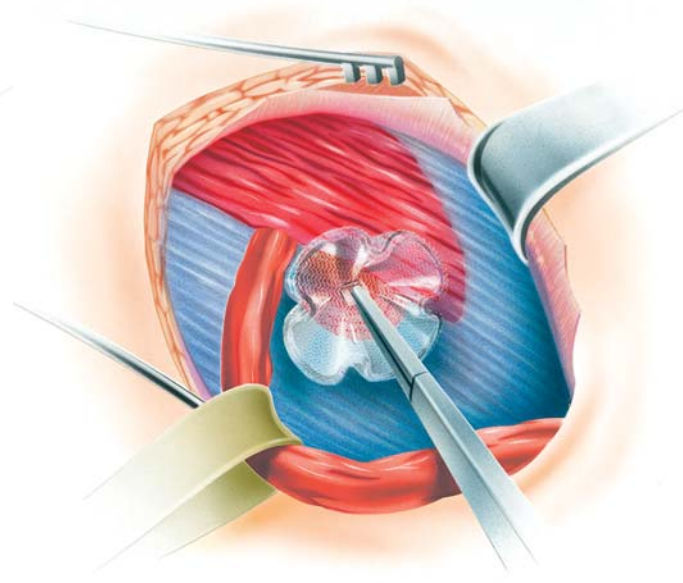
The new Eithcon Prolene Hernia System features a unique “three-in-one” design, combining a preattached onlay patch and bottom underlay patch with a “hollow” connector section of mesh in between. This

FIGURE 1



Self-Forming Plug design expands to conform to the anatomical shape and size of the defect and completely fill the defect.

FIGURE 3
Center the Self-Forming Plug over the defect and gently push it into the defect. This space does not require additional dissection to accept the prosthesis. No deployment of the plug is required.



system tends to require more extensive dissection and significantly more surgical manipulation to deploy, than the other commercially available 3-dimensional mesh plugs.

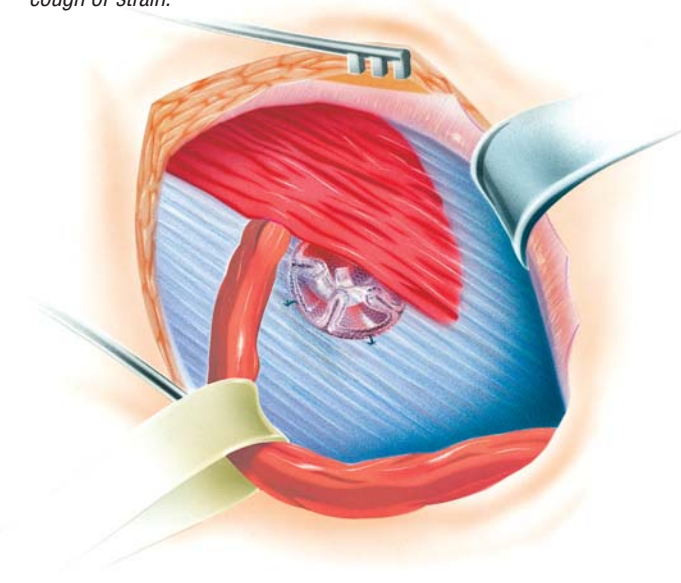
Novel Self-Forming Plug Design

Mesh plugs perform best when tissue is in direct contact with a smooth wall of mesh material. It is perhaps equally important for the mesh plug to conform to the anatomical shape and form of the defect. The ideal mesh plug should also fill the entire space and remain fixed within the defect with as smooth and blunt as abdominal contact surface as possible.

A new Self-Forming Plug design developed by Atrium Medical Corporation is the next logical design, as it is truly the first self-forming shape that expands into and conforms to the entire shape and space of the defect (Figure 1). When this unique self-forming plug is inserted, it fills the defect more completely, with a flatter, broader tip for better defect containment and patient comfort. Its thin profile mesh construction allows the surrounding tissue to encompass the mesh without the stiffness of a preformed plug. Its multi-layered circular design is easy to insert and completely fills the space that is formed by dissection of the hernia sac. No further dissection is needed to accommodate the prosthesis and no special deployment techniques are required.

The contour of the new Atrium Self-Forming Plug allows for maximum contact of the thin polypropylene mesh with the lateral walls of the defect, with less channels than some preformed plugs. More mesh surface area comes in contact with the tissue, so ingrowth of fibroconnective tissue can be facilitated quickly and more completely. After insertion, the Self-Forming plug presents a more natural shape that is

FIGURE 4
The outer layer of the Self-Forming Plug is fastened to the musculature of the internal ring with several monofilament or absorbable sutures. The round shape completely fills the defect. The patient is asked to cough or strain.



more anatomical, to help maximize patient comfort with less risk of migration. Unlike some commercially available preformed products, the Atrium Self-Forming Plug “fits the hole” for a more uniform and complete fit.

The Atrium Self-Forming Plug is constructed of 3 layers of polypropylene mesh welded together at the 12-3-6 and 9 o'clock positions. A convenient center tab is present to grasp the plug with forceps or a hemostat for fast, easy placement. The Self-Forming Plug is available in 4 sizes - small, medium, large and extra large to fit various sizes of defects. If necessary, it is easy to reduce the depth of the plug simply by cutting the outer rim of the mesh in a circular fashion, down to the weld seams. By removing material from the circumference, the overall depth is reduced. Removing pie shaped wedges between the welds can reduce the volume or bulk of the plug for smaller, tighter defects. It is important that the weld seams remain intact to maintain the integrity of the Self-Forming Plug.

Surgical Technique

Indirect hernia repair:

The indirect sac is completely dissected free from the cord structures. Once the hernia has been reduced the Atrium Self-Forming Plug is sized, positioned and inserted in three easy steps and a mesh onlay is attached:

FIGURE 5
An onlay piece of mesh is placed and either stapled, tacked or fastened with interrupted sutures.

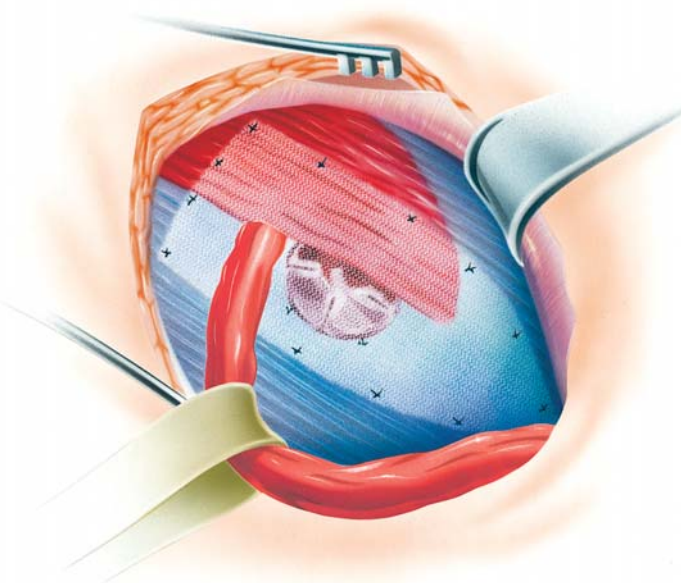


Figure 2: Grasp the center tab of the Self-Forming Plug with forceps or a hemostat.

Figure 3: Center the Self-Forming Plug over the defect and gently push it into the defect. This space does not require additional dissection to accept the prosthesis. No deployment of the plug is required.

Figure 4: The outer layer of the Self-Forming Plug is fastened to the musculature of the internal ring with several monofilament or absorbable sutures. The round anatomical shape expands completely to fill the defect after insertion. The patient is asked to cough or strain.

Figure 5: An onlay piece of mesh is placed and either stapled, tacked or fastened with interrupted sutures.

Direct Hernia Repair

The direct sac is circumscribed close to its base, usually with electrocautery. The hernia is thus reduced through this newly formed ring of transversalis fascia. Using the same three easy steps as in indirect hernia repair the Self-Forming Plug is positioned and inserted into the preperitoneal space and its outer layer is sutured to the fascial ring with several monofilament sutures. An onlay piece of mesh is placed and either stapled, tacked or fastened with interrupted sutures. Plugs can be placed at the internal inguinal ring and in the floor of the canal when a combined hernia is treated. Peritoneal openings are closed to prevent bowel contact with polypropylene mesh. Any onlay mesh patch completes the repair.