Gmail **Equipe Delta SUPEL/ RO <delta.supel@gmail.com>**

Pregão Eletrônico Rondônia Supel 10/2019

2 mensagens

Licitação Hybrida <licitacao@hybridahospitalar.com.br> 25 de junho de 2019 08:44
Para: delta.supel@gmail.com

Bom Dia CPL

Segue em anexo solicitação de impugnação referente ao pregão eletrônico nº 10/2019

No aguardo de confirmação de recebimento.

Att,

Pauline Tavares **-** Assistente de licitação
Departamento de Licitação
Hybrida Hospitalar
licitação@hybridahospitalar.com.br
+55 91-3257-5160 / 3257-5056
91 - 99246-2801
Trav. Barão do Triunfo, 3540.
Ed. Infinity Corporate, 4º andar, 402
Belém-PA/Brasil (66095-055).

10 anexos

- **item 2 e 3.pdf** 773K
- **item 2 e 3 tamanhos.pdf** 1007K
- **item 4 e 5.pdf** 802K
- **item 4 e 5 tamanhos.pdf** 992K
- **Perfix Light Plug.pdf** 260K
- **milikan modified plug technique_PERFIX.pdf** 176K
- **Characterization of Adhesion, Contr_ventralexst.pdf** 511K
- **(ROBBINS) Mesh Plug Repair And Groin Hernia Surgery .pdf** 818K
- **Cata_logo Completo DAVOL_portugues.pdf** 630K
- **Oficio PE Telas.pdf** 305K

Equipe Delta SUPEL/ RO <delta.supel@gmail.com> 25 de junho de 2019 09:12
Para: Licitação Hybrida <licitacao@hybridahospitalar.com.br>

Sr. licitante bom dia!

Ao passo que acuso recebimento do vosso e-mail com pedido de esclarecimento, informo que estaremos encaminhando a **SESAU/CAF II ,** para que seja respondido o questionamento da mesma.

Atenciosamente,
Delta/SUPEL/RO.
[Texto das mensagens anteriores oculto]
--
Governo do Estado de Rondônia
Superitendência Estadual de Compras e Licitações - SUPEL/RO
Equipe DELTA
(69) 3216-5318

EXMO. SR. PREGOEIRO DA SUPERINTENDÊNCIA ESTADUAL DE COMPRAS E LICITAÇÕES DO ESTADO DE RORAIMA

REF. EDITAL DE LICITAÇÃO NA MODALIDADE PREGÃO ELETRÔNICO N° 10/2019-SUPEL-RO

HYBRIDA PRODUTOS HOSPITALARES LTDA, pessoa jurídica de direito privado, legalmente constituída e em regular funcionamento, inscrita no CNPJ/MF n° 12.544.921/0001-02, com sede na Travessa Barão do Triunfo, n º 3540, Salas 401,402 e 409, Bairro do Marco, CEP 66095-055, neste ato representada por sua sócia **ALEXSANDRA DE SOUZA ARAÚJO RIBEIRO**, que pode ser encontrada na sede da empresa, vem, mui respeitosamente a presença de Vossa Excelência apresentar, com fulcro no art. 41, §2º da Lei 8.666/93, e ainda, item 3 do Edital do certame c/c art. 18 §§ 1º e 2º do Decreto Estadual n.º 12.205/06 apresentar **IMPUGNAÇÃO** aos termos do Edital em epígrafe, pelas razões de fato e de direito que passa a expor:

O subscrevente tendo interesse em participar da licitação supramencionada, ao verificar as condições para participação do certame em comento deparou-se com algumas divergências como abaixo descrita:

I – VIOLAÇÃO AO PRINCÍPIO DA AMPLA CONCORRÊNCIA:

Ao proceder a análise do Edital do certame, bem como, dos descritivos dos itens objeto da licitação, salta aos olhos o equívoco na descrição dos itens 2, 3, 4 e 5, que seguem abaixo transcritos:

2	DISPOSITIVO PARA REPARO DE HÉRNIA INGUINAL, 100% POLIPROPILENO, COMPOSTO POR: TELA ANTERIOR (LARGURA: 4,5 CM; COMPRIMENTO: 10 CM); CONECTOR (DIÂMETRO: 1,9 CM; ALTURA: 1,3 CM) E TELA POSTERIOR (DIÂMETRO: 10 CM).	UNID	300	R$ 4.670,74	R$ 1.444.074,00
3	DISPOSITIVO PARA REPARO DE HÉRNIA INGUINAL,100% POLIPROPILENO, COMPOSTO POR: TELA ANTERIOR (LARGURA: 4,5 CM; COMPRIMENTO: 10 CM); CONECTOR (DIÂMETRO: 1,9 CM; ALTURA: 1,3 CM) E TELA POSTERIOR (DIÂMETRO: 7,5 CM)	UNID	300	R$ 4.955,61	R$ 1.525.761,00
4	DISPOSITIVO PARA REPARO DE HÉRNIA UMBILICAL, PARCIALMENTE ABSORVÍVEL, COM 4,3 CM DE DIÂMETRO, COMPOSTO POR: TELA DE POLIPROPILENO COM CAMADAS DE TELAS POLIDIOXANONA E CELULOSE OXIDADA REGENERADA	UNID	300	R$ 2.340,76	R$ 763.275,00
5	DISPOSITIVO PARA REPARO DE HÉRNIA UMBILICAL, PARCIALMENTE ABSORVÍVEL, COM 6,4 CM DE DIÂMETRO, COMPOSTO POR: TELA DE POLIPROPILENO COM CAMADAS DE TELAS POLIDIOXANONA E CELULOSE OXIDADA REGENERADA	UNID	300	R$ 3.242,88	R$ 1.040.187,00

A análise detida do Edital, indica de forma bastante clara que o descritivo dos produtos aponta para aqueles fabricados pela empresa Johnson & Johnson, a saber Prolene PHS (itens 2 e 3) e Ventral Patch (itens 4 e 5), senão observe o descritivo de referidos produtos no catálogo da marca, cuja íntegra segue em anexo.

Tal conduta é vedada pela Lei 8666/93, conforme se faz prova mediante a documentação que ora se junta. As especificações milimétricas de tamanho são absolutamente irrelevantes para o alcance do objetivo final, tendo em vista que inúmeras outras multinacionais trabalham com produto extremamente semelhante com variações ínfimas das dimensões solicitadas no certame e que alcançariam sem qualquer dificuldade a finalidade a que se destina o objeto licitado.

A manutenção dos referidos itens na forma descrita inicialmente apenas demonstrará o desvirtuamento da presente licitação e o direcionamento para os produtos acima identificados.

O artigo 7º, inciso I, parágrafo 5º, da Lei 8.666/93 estabelece que “é vedada a realização de licitação cujo objeto inclua bens e serviços sem similaridade ou de marcas, características e especificações exclusivas, salvo nos casos em que for tecnicamente justificável, ou ainda quando o fornecimento de tais materiais e serviços for feito sob o regime de administração contratada, previsto e discriminado no ato convocatório”.

Já o seu artigo 15, parágrafo 7º, inciso I, estabelece que deve haver a especificação completa do bem a ser adquirido “sem indicação de marca”, o que não se vislumbra no caso do presente edital convocatório, não podendo ser admitido esse tipo de excesso, violando assim as regras legais, não havendo nos presentes autos qualquer

justificativa ou apresentação de explicações estritamente técnicas que justifiquem o porque de determinada característica.

Assim, os itens 2, 3, 4 e 5 do edital encontram-se completamente direcionados a uma marca específica, o que por si só fere o princípio da isonomia consagrado no inciso I do art. 5º da CF, tendo em vista que o ato de convocação consigna cláusula manifestamente comprometedora e restritiva do caráter competitivo que deve presidir toda e qualquer licitação.

A manutenção dos requisitos supramencionados apenas demonstrará o desvirtuamento da presente licitação e o direcionamento para o os produtos comercializados pela J&J.

Das considerações acima escandidas deflui-se com clareza que as características exigidas no Edital do certame são específicas e indissociáveis a produtos comercializados exclusivamente pela J&J, não havendo qualquer razão técnica para fazê-lo e, ainda que por hipótese tais especificações fossem condição *sine qua non* a execução do objeto licitado mais uma vez não haveria razão a modalidade licitatória eleita, pois, a forma correta de licitação seria a inexigibilidade.

Ora, a administração pública poderá obter a mesma qualidade ou até superior no objeto da licitação com outros produtos, mas, certamente, por um preço muito menor do que o ofertado pela empresa representante dos produtos J&J.

As especificações editalícias dos produtos devem, portanto, ser suprimidas integralmente do Edital pois eivadas de vícios insanáveis, mantendo características de exigências despropositadas e desnecessárias à execução do objeto licitado, apresentando-se restritivas a necessária concorrência. A bem da verdade, tratam-se de exigências ilegais que frustram a regra imposta a administração da busca pela proposta mais vantajosa ao erário público.

Conforme exposto ao norte, existem atualmente no mercado equipamentos que, embora não tenham todas as características previstas no Edital, comprovadamente são tão ou mais eficientes que os produtos J&J, pelo que a restrição impugnada evidencia-se restritiva a concorrência, trazendo indubitável malefício a administração pública.

Saliente-se por oportuno, que nenhuma vantagem adicional será auferida pela Administração em exigir os produtos com todas as características constantes do Edital. Por isso afirma-se que as exigências do edital são ilegais e desarrazoadas.

A própria Lei de Licitação cuidou de alijar condutas como a adotada no Edital impugnado, *verbis:*

> Art. 3º. A licitação destina-se a garantir a observância do princípio constitucional da isonomia, a seleção da proposta mais vantajosa para a administração e a promoção do desenvolvimento nacional sustentável e será processada e julgada em estrita conformidade com os princípios básicos da legalidade, da impessoalidade, da moralidade, da igualdade, da publicidade, da probidade administrativa, da vinculação ao instrumento convocatório, do julgamento objetivo e dos que lhes são correlatos;
> § 1º É vedado aos agentes públicos:
> I - admitir, prever, incluir ou tolerar, nos atos de convocação, cláusulas ou condições que comprometam, restrinjam ou frustrem o seu caráter competitivo, inclusive nos casos de sociedades cooperativas, e estabeleçam preferências ou distinções em razão da naturalidade, da sede ou domicílio dos licitantes ou de qualquer outra circunstância impertinente ou irrelevante para o específico objeto do contrato, ressalvado o disposto nos §§ 5º a 12 deste artigo e no art. 3º da Lei nº 8.248, de 23 de outubro de 1991;

Na mesma senda, o Tribunal de Contas da União já se posicionou em situação semelhante a que ocorre no presente certame:

> REPRESENTAÇÃO. PREGÃO PRESENCIAL DO TIPO MENOR PREÇO (MENOR TAXA DE ADMINISTRAÇÃO). CONTRATAÇÃO DE EMPRESA ESPECIALIZADA NA PRESTAÇÃO DE SERVIÇOS DE ALIMENTAÇÃO COLETIVA (REFEIÇÃO-CONVÊNIO). CLÁUSULA EDITALÍCIA EXCESSIVAMENTE RESTRITIVA. CONCESSÃO DE MEDIDA CAUTELAR. AGRAVO. CONHECIMENTO. NEGADO PROVIMENTO.
> (...) deve ser preservado o caráter competitivo do certame, conforme apregoam o art. 3º, §1º, inciso I, da Lei 8.666/93 e o art. 3º, inciso II, da Lei 10.520/2002, sendo permitidas, nos termos do art. 37, inciso XXI, da CF/88, apenas exigências de qualificação técnica e

econômica ***indispensáveis*** à garantia do cumprimento das obrigações (TCU – 032.818/2012-6. Sessão 09/02/2011. Rel. Min. Augusto Sherman Cavalcanti).

Nota-se, portanto, que, mantidos os padrões definidos para os produtos contidos no instrumento convocatório haverá grave e irreparável violação aos Princípios da Legalidade e Moralidade que devem reger todo e qualquer ato do gestor público.

Diante do exposto, ficam desde já impugnadas as exigências contidas no Edital no que se refere a especificação dos produtos que em nada interfiram com o alcance do resultado final.

II – DO PEDIDO:

Assim, é o presente para apresentar as IMPUGNAÇÕES acima descritas, que seja julgada procedente, com a nulidade dos itens atacados e/ou retificações dos itens viciados, determinando a republicação do Edital, escoimado dos vícios apontados, com o objetivo de dar seguimento ao certamente de maneira legítima e segura.

São os termos.

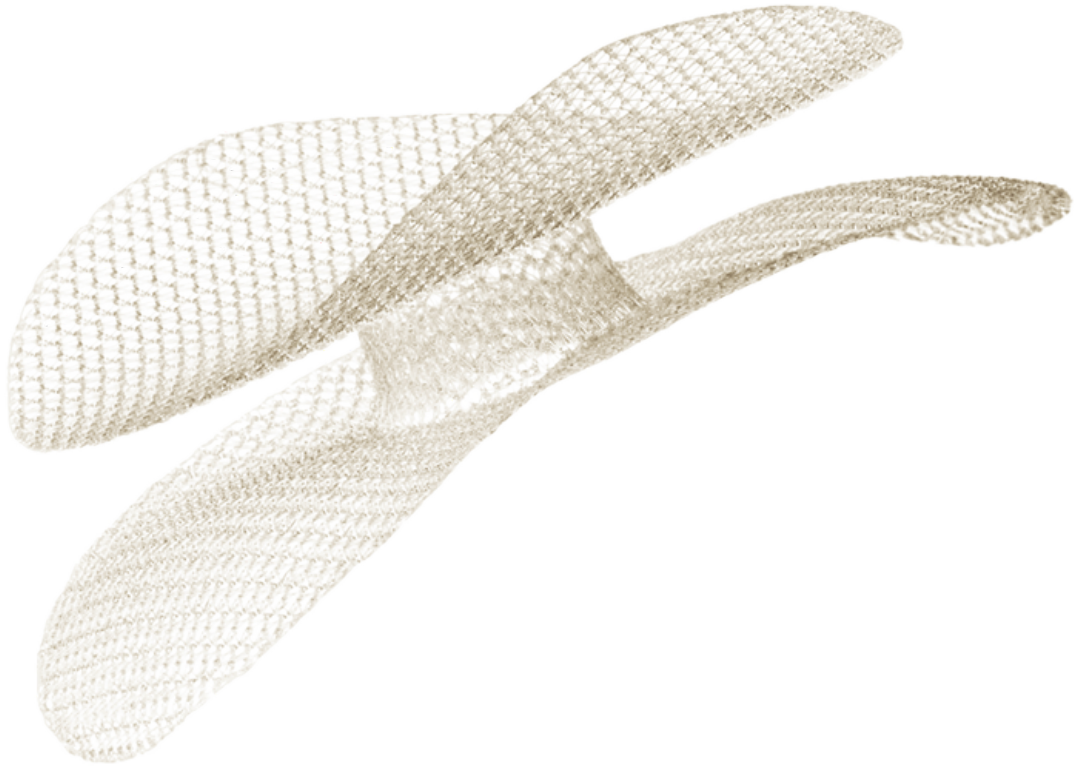
Pede deferimento.

Belém, 24 de junho de 2019.

ALEXSANDRA DE SOUZA ARAUJO RIBEIRO:63031230230

Assinado de forma digital por ALEXSANDRA DE SOUZA ARAUJO RIBEIRO:63031230230
Dados: 2019.06.25 08:31:55 -03'00'

HYBRIDA PRODUTOS HOSPITALARES LTDA



PROLENE® PHS

Oferece reparo posterior seguro a partir de uma abordagem anterior simples e possui três pontos de proteção. Ele demonstra resultados reprodutíveis com diferentes cirurgiões[1]. O design em bicamada comprovadamente combina reparo anterior e posterior primeiro dispositivo em tela de bicamada com baixa taxa de recidiva relatada[2]. Tempo operatório e de recuperação reduzido em comparação com a técnica de reparo de Lichtenstein[3].

Solicite uma Demonstração (tel:0800 707 5420)

Instruções de Uso	**Ver Especificação** (https://www.ethicon.com/latam/pt/epc/search/platform/telas%20%26%20fixadores%20para%20l filters%5Bfield_brand%5D%5B0%5D=PROLENE%C2%AE&lang=pt-default&last=field_br

Referências

1. Gilbert A, et al. Closer to an ideal solution for inguinal hernia repair: comparison between general surgeons and hernia specialists. Hernia. 2005;10:162-168.

2. Gilbert AI, Young J, Graham MF, Divilio LT, Patel B. Combined anterior and posterior inguinal hernia repair: intermediate recurrence rates with three groups of surgeons. Hernia. 2004;8(3):203-207.

3. Kingsnorth AN, et al. Prolene hernia system compared with Lichtenstein patch: a randomized double blind study of short-term and medium-term outcomes in primary inguinal hernia repair. Hernia. 2002;6:113-119.

Registro ANVISA nº80145900901.

Última Atualização: 1º de maio de 2018

Este site é de propriedade da Johnson & Johnson do Brasil Indústria e Comércio de Produtos para Saúde Ltda, única responsável por seu conteúdo, e destina-se a profissionais da saúde no Brasil.
Através de e-mail:
Email: ethicon_latam@its.jnj.com
Por telefone: 0800 707 5420
Por carta: Johnson & Johnson do Brasil Indústria e Comércio de Produtos para Saúde Ltda.
ATT. Departamento Regional de Marketing Digital
Endereço: Av. Presidente Juscelino Kubitschek, 2041, Torre B, Complexo JK.
Vila Olímpia, São Paulo – SP 04543-011

Telas & Fixadores Para Hérnia

← View all platforms

Marca

- ☐ ETHICON PHYSIOMESH™
- ☐ ETHICON SECURESTRAP®
- ☐ PROCEED®
- ☐ PROLENE® (9)
- ☐ ULTRAPRO ADVANCED™
- ☐ ULTRAPRO®
- ☐ VICRYL®

Grupo de produtos

- ☐ Flat Mesh (6)
- ☐ Hernia Mesh Devices (3)
- ☐ Hernia Mesh Fixation
- ☐ Tissue Separating Mesh

QTY / BX

- ☐ 1
- ☐ 2
- ☐ 3 (6)
- ☐ 6 (3)

X PROLENE®

PROLENE® Polypropylene Mesh

Código	Marca	Tamanho	QTY / BX	Descrição
PMH	PROLENE®	15cm x 15cm	6	Square
PML	PROLENE®	30cm x 30cm	3	Square

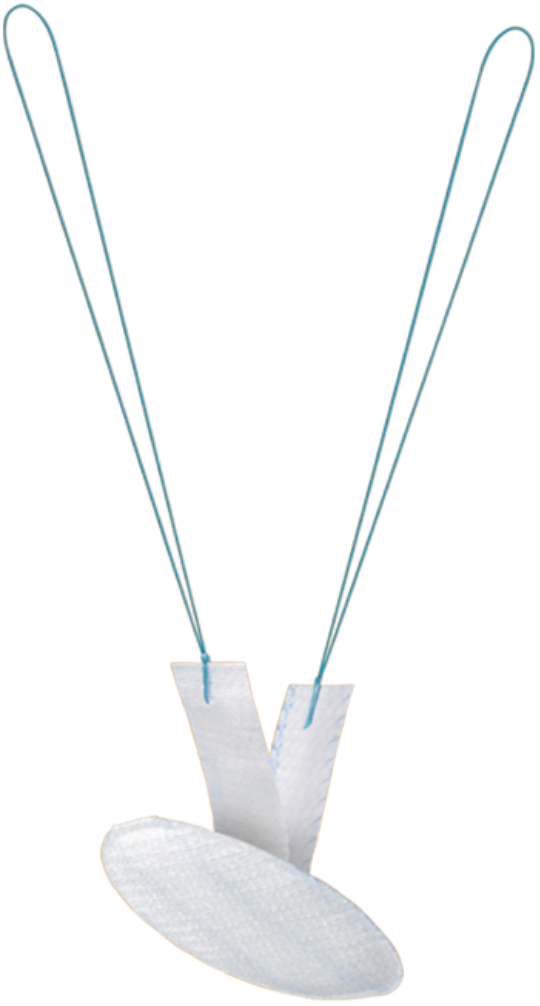
PROLENE® Soft Polypropylene Mesh

Código	Marca	Tamanho	QTY / BX	Descrição
SPMXXL	PROLENE®	35.6cm x 30cm	3	Rectangle
SPMLI	PROLENE®	25cm x 25cm	3	Square
SPMH	PROLENE®	15cm x 15cm	6	Square
SPMII	PROLENE®	7.6cm x 15cm	6	Rectangle

PROLENE® Polypropylene Hernia System

Código	Marca	Tamanho	QTY / BX	Descrição
PHSE	PROLENE®	5.5cm x 12.8cm	3	Extended
PHSM	PROLENE®	4.5cm x 10cm	3	Medium
PHSL	PROLENE®	4.5cm x 10cm	3	Large

Email: ethicon_latam@its.jnj.com
Por telefone: 0800 707 5420
Por carta: Johnson & Johnson do Brasil
Indústria e Comércio de Produtos para Saúde
Ltda.
ATT. Departamento Regional de Marketing
Digital
Endereço: Av. Presidente Juscelino
Kubitschek, 2041, Torre B, Complexo JK.
Vila Olímpia, São Paulo – SP 04543-011



PROCEED® Ventral Patch

Dispositivo de tela laminada flexível, estéril e parcialmente absorvível, projetado para o reparo de hérnias e outras deficiências da fáscia como aquelas causadas pelo uso de trocarte. Reparo resistente com potencial para baixa recorrência[1]. Reparos com tela demonstraram ser superiores em relação ao reparo com sutura em múltiplos estudos de reparo aberto de hérnia2*. O reparo com tela demonstrou uma taxa de recorrência de apenas 0% a 10% em múltiplos estudos2. O reparo com sutura convencional tem uma taxa de recorrência de até 63%[2].

Solicite uma Demonstração (tel:0800 707 5420)

Instruções de Uso	Ver Especificação	(https://www.ethicon.com/latam/pt/epc/search/platform/telas%20%26%20fixadores%20para%20l filters%5Bfield_brand%5D%5B0%5D=PROCEED%C2%AE&filters%5Bfield_qty_bx%5D%5B1%5D default&last=field_qty_bx)

Especificações de Produto

Código do Produto	
PVPM (https://www.ethicon.com/latam/pt/epc/code/PVPM?lang=pt-default)	Circle
PVPS (https://www.ethicon.com/latam/pt/epc/code/PVPS?lang=pt-default)	Circle

Referências

1. Bringman S, Tollens T, Murdoch J, Jones P, Mitchell J, McRoy L. Laparoscopic hernia repair surgery using a tissue-separating flat mesh (TSM)—12 month patient reported outcomes from the international hernia mesh registry (IHMR).

2. Cassar K, Munro A. Surgical treatment of incisional hernia. Br J Surg. 2002; 89(5):534-545.

3. *Com base em uma pesquisa de literatura MEDLINE.

Registro ANVISA nº80145901218.

Última Atualização: 1º de maio de 2018

Este site é de propriedade da Johnson & Johnson do Brasil Indústria e Comércio de Produtos para Saúde Ltda, única responsável por seu conteúdo, e destina-se a profissionais da saúde no Brasil.
Através de e-mail:
Email: ethicon_latam@its.jnj.com
Por telefone: 0800 707 5420
Por carta: Johnson & Johnson do Brasil Indústria e Comércio de Produtos para Saúde Ltda.
ATT. Departamento Regional de Marketing Digital
Endereço: Av. Presidente Juscelino Kubitschek, 2041, Torre B, Complexo JK.
Vila Olímpia, São Paulo – SP 04543-011

ETHICON | Shaping the future of surgery

Telas & Fixadores Para Hérnia

← View all platforms

Marca

- ☐ ETHICON PHYSIOMESH™
- ☐ ETHICON SECURESTRAP®
- ☑ PROCEED® (2)
- ☐ PROLENE®
- ☐ ULTRAPRO ADVANCED™
- ☐ ULTRAPRO®
- ☐ VICRYL®

Grupo de produtos

- ☐ Flat Mesh
- ☐ Hernia Mesh Devices
- ☐ Hernia Mesh Fixation
- ☐ Tissue Separating Mesh (2)

QTY / BX

- ☐ 1
- ☑ 2 (2)
- ☐ 3
- ☐ 6

X PROCEED® X 2

PROCEED® Ventral Patch

Código	Marca	Tamanho	QTY / BX	Descrição
PVPS	PROCEED®	4.3cm x 4.3cm	2	Circle
PVPM	PROCEED®	6.4cm x 6.4cm	2	Circle

Email: ethicon_latam@its.jnj.com
Por telefone: 0800 707 5420
Por carta: Johnson & Johnson do Brasil Indústria e Comércio de Produtos para Saúde Ltda.
ATT. Departamento Regional de Marketing Digital
Endereço: Av. Presidente Juscelino Kubitschek, 2041, Torre B, Complexo JK.
Vila Olímpia, São Paulo – SP 04543-011

PAPER

The Millikan Modified Mesh-Plug Hernioplasty

Keith W. Millikan, MD; Brice Cummings, PA; Alexander Doolas, MD

Hypothesis: A modified technique for mesh-plug hernioplasty is a safe and efficacious option for primary unilateral inguinal herniorrhaphy.

Design: Prospective analysis of 1056 patients who underwent primary unilateral inguinal hernioplasty.

Setting: A private university medical center.

Patients: One thousand twenty-five men and 31 women (mean age, 49 years) with primary unilateral inguinal hernias that were surgically repaired between May 1, 1997, and November 1, 2001.

Intervention: We performed a modified technique using a mesh plug and local anesthesia with intravenous sedation. The modified technique consisted of placing the mesh plug into the preperitoneal space and suture fixation of the plug using the inner petals.

Main Outcome Measures: Surgical morbidity, hernia recurrence, postoperative pain medication used, and return to normal activities.

Results: We included 642 indirect and 414 direct hernias. Mean operative time was 25 minutes; mean recovery room time, 45 minutes. All procedures were performed as outpatient surgery. One thousand thirteen patients (95.9%) returned to normal activities within 3 days. All manual laborers returned to work on postoperative day 14. Only 169 patients (16.0%) required prescription pain medication. At 1-year follow-up, 1045 patients (99.0%) have been examined, and 1 recurrence (0.1%) has been detected. No mesh infection has occurred, and 19 hematomas spontaneously resolved. Five patients (0.5%) required treatment for persistent postoperative pain.

Conclusions: The modified mesh-plug hernioplasty uses a minimum of medical resources and is associated with a small amount of postoperative pain and an early return to normal activities and manual labor with a minimal documented early recurrence rate. The Millikan modified mesh-plug hernioplasty should be adopted as the gold standard for unilateral primary inguinal hernioplasty.

Arch Surg. 2003;138:525-530

From the Department of General Surgery, Rush-Presbyterian-St Luke's Medical Center, Chicago, Ill. Dr Millikan is a member of the Speaker's Bureau for Davol, Inc, Cranston, RI.

Since Bassini[1] described his primary inguinal hernia repair in 1890, many advancements and modifications of groin herniorrhaphy and hernioplasty have been described.[2-7] Mesh repairs for inguinal hernias have become generally accepted as the solution to reduce tension on a repair during the past 2 decades.[8] Mesh plugs were first introduced by Lichtenstein and Shore[9] for femoral and recurrent hernias in the 1970s. Gilbert[10] described a sutureless mesh-plug and patch repair for indirect hernias in the 1980s. Rutkow and Robbins[6,11,12] followed this with a description of a mesh-plug and patch repair for all varieties of inguinal hernias in the early 1990s. Since then, Rutkow and Robbins[13] have reported their repair results with a premade manufactured plug and patch.

Criticism of the mesh-plug hernioplasty by others who use alternative mesh repairs has surfaced during the past decade.[14-20] Critics of the mesh-plug hernioplasty describe mesh shrinkage, erosion, and migration and chronic pain as reasons not to use mesh plugs in primary hernia repair. We modified the mesh-plug hernioplasty in 1997 to possibly eliminate previous criticism of the mesh plug and reported our early results in 2001.[21] We have continued to use and prospectively follow this modification of the Rutkow and Robbins mesh-plug hernioplasty in an effort to determine its safety and efficacy in a large number of patients.

METHODS

We conducted a prospective analysis of 1056 patients with unilateral primary inguinal her-

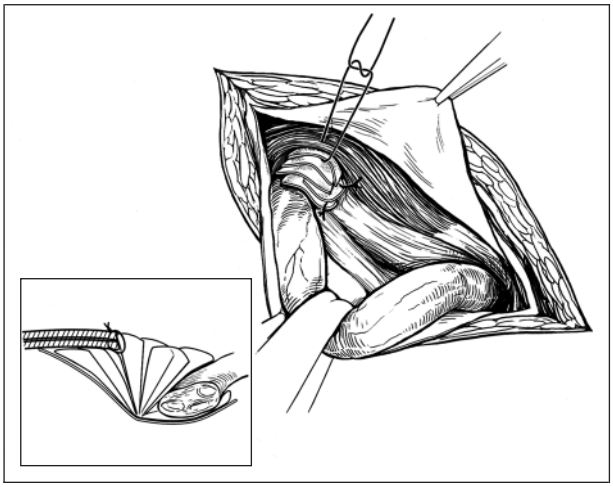


Figure 1. Anterior and transverse (inset) illustration of the mesh-plug placement and fixation for an indirect inguinal hernia.

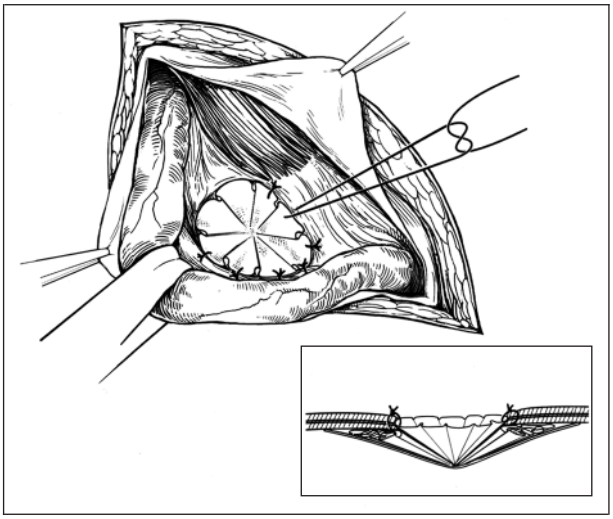


Figure 2. Anterior and transverse (inset) illustration of the mesh-plug placement and fixation for a direct inguinal hernia.

nias undergoing a modified mesh-plug hernioplasty from May 1, 1997, through November 1, 2002, at Rush-Presbyterian-St Luke's Medical Center, Chicago, Ill. The study population consisted of 1025 men and 31 women with a mean age of 49 years (range, 15-96 years). Four hundred sixty-five patients were manual laborers. Patients covered by worker's compensation were excluded from this study. Hernia type was determined at the time of operation. The following tabulation lists the types of hernias encountered according to the classification by Gilbert[22]:

Hernia Classification	No. of Patients
Indirect	642
Type I	78
Type II	506
Type III	58
Direct	414
Type IV	376
Type V	38

Pantaloon hernias were categorized by the dominant type of the 2 hernias present. Operating and recovery room times, return to normal activities, postoperative pain medication used, and return to manual labor were recorded into a data registry.

All procedures were performed by 2 of us (K.W.M. and A.D.). The operative technique was modified from the previous mesh-plug hernioplasty described by Rutkow and Robbins.[6] For type I and II indirect hernias, the inside petals of a large plug were sutured to the internal oblique portion of the internal ring, allowing for the outer surface of the plug to form an underlay preperitoneal patch of the indirect defect (**Figure 1**). If the internal ring of a type II hernia is patulous, an additional suture is placed through an inside petal, securing it to the lateral shelving edge of the inguinal ligament. Absorbable suture material is used for plug fixation of types I and II hernias. For type III indirect and type IV or V direct hernias, the center inside fluted cone (petal) of an extra large plug was sutured to the Cooper ligament, the conjoined tendon, and the shelving edge of the inguinal ligament, allowing for the outer surface of the plug to form an underlay preperitoneal patch of the hernia defect (**Figure 2**). Monofilament permanent suture material was used for plug fixation of types III, IV, and V hernias. For types IV and V hernias, the transversalis fascia at the base of the hernia was circumferentially incised to allow the plug to be placed into the preperitoneal space. For types I, II, and III hernias, the indirect sac is highly dissected and placed into the preperitoneal space, allowing for the plug to subsequently be placed into the preperitoneal space. We used the Perfix Plug (Davol, Inc, Cranston, RI; a division of C. R. Bard, Inc, Murray Hill, NJ) exclusively for all hernia repairs. We performed all repairs with 1% lidocaine hydrochloride (Xylocaine; Astra Pharmaceutical Products, Inc, Westborough, Mass) and intravenous sedation as determined by the anesthesiologist. Sixty milligrams of intramuscular ketorolac tromethamine was given in the recovery room before discharge for postoperative pain. All patients were required to return 7 to 10 days after repair for wound evaluation and manual labor clearance. Postoperative complications were recorded during this visit. Patients were also required to return at 1 year for evaluation and physical examination. If a patient moved from the local area, a practicing surgeon in the patient's nearby area was contacted to perform the 1-year follow-up evaluation. Patients were then contacted by telephone interview every 6 months to continue follow-up of recurrence rate and occurrence of chronic pain. Eleven patients have been lost to follow-up after their initial postoperative evaluation.

RESULTS

There were 642 indirect and 414 direct hernias. Mean operative time was 25 minutes (range, 20-29 minutes). Mean recovery room time was 45 minutes (range, 25-59 minutes). All patients were discharged as outpatients. Of the 1056 patients, 887 (84.0%) required only over-the-counter pain medication postoperatively; 169 (16.0%) required prescription pain medication ranging from 2 to 10 days in duration; and 1013 (95.9%) were able to perform normal activities without prescription pain medication within 3 days. The remaining 4.1% of patients returned to normal activities within 10 days. All 465 manual laborers returned to work without restriction on postoperative day 14.

We recorded a total of 26 postoperative complications (2.5%). Nineteen postoperative hematomas were nonexpanding and were treated by observation. Seven patients returned with urinary retention and required catheterization. Two of these patients subsequently required transurethral resection of the prostate for significant benign hypertrophy of the prostate. No wound or mesh infections, orchitis, sinus tracts, or plug migration occurred.

At 1 year, 1045 patients have been examined, and 1 recurrence has been detected, for an overall recurrence rate of 0.1%. The patient with the recurrence had a type III scrotal hernia and returned at 4 months postoperatively complaining of a groin bulge. At reexploration, the mesh plug had pulled away from the Cooper ligament, resulting in a direct hernia recurrence. The patient required an onlay mesh repair. The remaining 1044 patients have been followed up for a mean of 22 months (range, 12-48 months) without a documented recurrence.

Five patients (0.5%) returned from 9 to 31 months postoperatively with significant groin and/or leg pain. Three of these patients responded to a series of local steroid injections. Two patients required anesthesia pain center nerve ablation, and both still have some residual pain that is related to position. However, both are able to maintain full-time employment. At present, no patient has required reexploration for mesh removal or nerve transection.

COMMENT

Mesh repairs for primary inguinal hernias have reduced the recurrence rate from greater than 10% in tissue-to-tissue herniorrhaphy to approximately 1%.[23] The question in today's surgical environment is not how to attain a tension-free repair with a 1% recurrence rate, but which mesh hernioplasty (Lichtenstein, Stoppa, laparoscopic, Kugel, or mesh-plug) is the simplest technique to master, has the lowest complication rate, has the shortest recovery or rehabilitation time, and is overall most cost-effective. Starting with reports in the early 1990s, Rutkow and Robbins[13] have shown that the mesh-plug hernioplasty has less than a 1% recurrence rate, is technically simple, and can be performed in less than 30 minutes under epidural anesthesia as an ambulatory procedure, with more than 95% of patients fully recovered in 3 days. In an attempt to confirm and possibly improve on these excellent results, we switched from laparoscopic and Lichtenstein repairs to a modified mesh-plug hernioplasty in 1997. Our results in this series confirm that a modified mesh-plug hernioplasty can achieve less than a 0.1% recurrence rate with a 3-day recovery and minimal complications and can be performed with the patient under local anesthesia and intravenous sedation in less than 30 minutes on an ambulatory basis.

The history and principles behind mesh-plug hernioplasty span 3 decades, starting with Lichtenstein and Shore[9] in 1974. They reported results of a cylindrical roll of polypropylene mesh placed in recurrent or femoral hernia defects. This technique was replaced by the onlay mesh repair popularized in the 1980s by Lichtenstein et al.[5] Shocket[24] in 1985 reported placing polypropylene preperitoneally to buttress primary inguinal hernia repairs. Gilbert[10] used this principle to place a cone of mesh preperitoneally and allowed it to flatten out in this space for indirect hernias. Gilbert proposed that this repair was sutureless and did not require tissue-to-tissue approximation. The shortcoming of this repair was that it could only be used in indirect hernias, but on the other hand, Gilbert's procedure confirmed that a mesh could be placed preperitoneally from a standard anterior inguinal approach. Rutkow and Robbins[6,12,13] subsequently started using a cone similar to Gilbert's repair for all varieties of inguinal hernias. They modified the technique by fashioning the size of the cone to the size of the defect and suturing the edge of the cone to the edges of the defect with absorbable suture material. An onlay mesh was also placed on the inguinal floor to reinforce adjacent areas of the inguinal floor not presently affected by the hernia. Since the plug repairs the hernia, no sutures are required in the onlay mesh to secure it to the inguinal floor other than the suture that approximates the tails of the onlay around the cord structures at the internal ring. The problem with the roll-your-own variety of plug used by Rutkow and Robbins was that it had a sharp point at the apex that potentially could erode into adjacent structures. Also, with the contraction of wound healing, the plug could shrink and possibly migrate into the inguinal canal. Realizing these shortcomings, Rutkow and Robbins modified the plug to smooth out the apex and imbricate the outer umbrella to have a plug much larger than the hernia defect and that could radially conform to the defect.[13] They also added inner petals to the plug to act as filler bodies, which in theory should limit the amount that the plug could shrink and should decrease the possibility of plug migration.

We modified the Rutkow and Robbins technique by using the inner petals to fixate the plug with sutures to the anatomical structures used in most hernia repairs. For indirect hernias, the inner petals are sutured to the shutter mechanism (internal oblique muscle) medially of the internal ring, and in large patulous rings also to the inguinal ligament. This allows for the outer umbrella to open and flatten out in the preperitoneal space. This simulates the sutureless repair of indirect hernias by Gilbert.[10] For direct hernias, the inner cone (petal) is sutured to the conjoined tendon medially and to the Cooper ligament and inguinal ligament laterally, allowing for the outer umbrella and the other petals to open and flatten out in the preperitoneal space similar to mesh placed in a Stoppa, laparoscopic, or Kugel repair. These modifications eliminate the possibility of plug migration or of the inner petals protruding into the inguinal canal. The sutured plug is completely preperitoneal in an almost flat configuration, with its structure allowing it to spring open and close like a fireplace bellows so that no tension is placed across the inguinal floor. In effect, this repair is the only true tension-free mesh hernioplasty, whereas the others, specifically the Lichtenstein repair, are not tension free, because a completely flat mesh fixed across the inguinal floor will become taut when a patient stands, coughs, or strains. This same effect occurs in a laparoscopically fixated preperitoneal flat mesh. We believe this tension-free modification reduces medial induced rectus muscle spasm, which accounts for most pain after inguinal mesh hernioplasty or tissue-to-tissue herniorrhaphy. Our 3-day return to normal activities and only a 16.0% use of postoperative prescription pain medication gives us proof of this hypothesis.

The procedure is performed with the patient under local anesthesia with intravenous sedation, which avoids the general anesthesia required in laparoscopic repairs. The fact that all patients are able to leave the ambulatory facility within 1 hour confirms the minimal effect

of the anesthesia and surgical procedure on the patients. Patients are not restricted from any activities except heavy lifting of greater than 50 pounds for 2 weeks. Manual laborers are allowed to return to work without restriction in 2 weeks. We maintain that some collagen should be deposited to reinforce mesh position before heavy lifting is allowed. All manual laborers, with the exception of those covered by worker's compensation, have returned to work without restriction after the 2-week waiting period.

Since an anterior approach is used for this technique, most surgeons should be comfortable with it. Deploying the plug directly into the hernia defect simplifies preperitoneal placement, which makes laparoscopic, Stoppa, and Kugel mesh placement more difficult to master.[4,7,25] Fixing the plug to the same anatomical structures used in tissue-to-tissue repairs keeps an anatomical basis for this repair and also teaches our residents in training the appropriate anatomical landmarks of the inguinal region. Performing the procedure in less than 30 minutes keeps the operating room cost to a minimum. Using a 4- to 5-cm incision on patients of all sizes keeps the repair in the realm of minimally invasive surgery. Nearly a thousand surgeons have visited our facility for a 4-hour training course in the modified technique and have been able to adopt it without further training. We believe only a simple technique could have such a short learning curve.

Our complication rate is minimal. Hematomas are expected in small numbers after hernia repairs, and in this series they resolved without intervention. No infections occurred in this series, which may be a result of our use of intravenous antibiotics before the start of the procedure. A less than 1% urinary retention rate is also evidence of the minimal trauma to the groin that results after this repair. A less than 0.5% long-term pain rate is an indication that nerve entrapment is unlikely when the plug position is entirely preperitoneal. No plug to date has been removed for infection, pain, or migration. Our single recurrence was a type III scrotal hernia, which indicates that the plug in this case was not large enough to flatten out in the preperitoneal space with sufficient underlay to prevent recurrence. This type of hernia should be repaired with a large onlay mesh.

Cost can sometimes be very difficult to measure. If one accepts that hernia repairs should include mesh placement, then, other than the cost of the mesh, our procedure takes less than 30 minutes to perform under local anesthesia, with less than 1 hour of recovery room time as an outpatient procedure. These results are as cost-effective as a surgeon can achieve with regard to hernia repairs. Also, a procedure in which almost 96% of patients have fully recovered in 3 days and that allows manual labor in 2 weeks puts very little strain on our patients and their economic work status.

The modified mesh-plug hernioplasty technique solved or reduced many of the problems associated with other mesh-plug hernioplasties. The technique is simple and can be mastered by all general surgeons. Operating room and recovery room times are kept to a minimum. Pain and its required medication are reduced to a few days. Recovery and return to physical labor are at most extended for only 2 weeks. Cost is kept to a minimum. Early recurrence, as measured by results of the physical examination, is less than 0.1%.

CONCLUSIONS

The modified mesh-plug hernioplasty uses a minimum of medical resources, is associated with an early return to normal activities and manual labor, and has minimal complications with a low recurrence rate. We believe that this procedure should be adopted as the gold standard repair for unilateral primary inguinal hernias.

Accepted for publication January 23, 2003.

This study was presented at the 110th Scientific Session of the Western Surgical Association, Vancouver, British Columbia, November 20, 2002, and is published after peer review and revision. The discussions that follow this article are based on the originally submitted manuscript and not the revised manuscript.

Corresponding author and reprints: Keith W. Millikan, MD, University Surgeons, 1725 W Harrison St, Suite 810, Chicago, IL 60612 (e-mail: Keith_Millikan@rush.edu).

REFERENCES

1. Bassini E. Uber die Behanlung des Leitenbruchs. *Langenbecks Arch Surg.* 1890; 40:429-476.
2. McVay CB. Inguinal and femoral hernioplasty: anatomic repair. *Arch Surg.* 1948; 57:524-530.
3. Shearburn EW, Myers RN. Shouldice repair for inguinal hernia. *Surgery.* 1969; 66:450-459.
4. Stoppa R, Watlaumont CH, Verhaeghe P, Henry X. Tulle de Dacron et cure chirurgicale des hernies de l'aine. *Chirurgie.* 1983;109:847-854.
5. Lichtenstein IL, Shulman AG, Amid PK, Montllor MM. The tension-free hernioplasty. *Am J Surg.* 1989;157:188-193.
6. Rutkow IM, Robbins AW. "Tension-free" inguinal herniorrhaphy: a preliminary report on the "mesh plug" technique. *Surgery.* 1993;114:3-8.
7. McKernan JB, Laws HL. Laparoscopic repair of inguinal hernia using a totally extraperitoneal prosthetic approach. *Surg Endosc.* 1993;7:26-28.
8. Schulman AG, Amid PK, Lichtenstein IL. The safety of mesh repair for primary inguinal hernias: results of 3,019 operations from five diverse surgical sources. *Am Surg.* 1992;58:255-257.
9. Lichtenstein IL, Shore JM. Simplified repair of femoral and recurrent inguinal hernias by a "plug" technique. *Am J Surg.* 1974;128:439-440.
10. Gilbert AI. Sutureless repair of inguinal hernia. *Am J Surg.* 1992;163:331-335.
11. Robbins AW, Rutkow IM. The mesh-plug hernioplasty. *Surg Clin North Am.* 1993; 73:501-512.
12. Rutkow IM, Robbins AW. 1669 Mesh plug hernioplasties. *Contemp Surg.* 1993; 43:141-147.
13. Robbins AW, Rutkow IM. Mesh plug repair and groin hernia surgery. *Surg Clin North Am.* 1998;78:1007-1023, vi-vii.
14. Chuback JA, Singh RS, Sills C, Dick LS. Small bowel obstruction resulting from mesh plug migration after open inguinal hernia repair. *Surgery.* 2000;127:475-476.
15. Dieter RA Jr. Mesh plug migration into scrotum: a new complication of hernia repair. *Int Surg.* 1999;84:57-59.
16. Pelissier EP, Blum D, Damas JM, Marre P. The plug method in inguinal hernia: a prospective evaluation. *Hernia.* 1999;4:201-204.
17. Palot JP, Avisse C, Calliez-Tomasi JP, Greffier D, Falment JB. The mesh plug repair of groin hernias: a three year experience. *Hernia.* 1998;2:31-34.
18. Amid PK, Lichtenstein IL. Long-term result and current status of the Lichtenstein open tension-free hernioplasty. *Hernia.* 1998;2:89-94.
19. Amid PK. Classification of biomaterials and their related complications in abdominal wall hernia surgery. *Hernia.* 1997;1:15-21.
20. Le Blanc KA. Complications associated with the plug-and-patch method of inguinal herniorrhaphy. *Hernia.* 2001;5:135-138.
21. Millikan KW, Cummings B, Doolas A. A prospective study of the mesh-plug hernioplasty. *Am Surg.* 2001;67:285-289.

22. Gilbert AI. An anatomic and functional classification for the diagnosis and treatment of inguinal hernia. *Am J Surg.* 1989;157:331-333.
23. Millikan KW, Deziel DJ. The management of hernia: considerations in cost effectiveness. *Surg Clin North Am.* 1996;76:105-116.
24. Shocket E. Routine rapid preperitoneal Marlex mesh buttressing in the repair of all inguinal hernias. *Contemp Surg.* 1985;26:22-27.
25. Kugel RD. Minimally invasive, nonlaparoscopic, preperitoneal, and sutureless, inguinal herniorrhaphy. *Am J Surg.* 1999;178:298-302.

DISCUSSION

Jeffrey Landercasper, MD, LaCrosse, Wis: I congratulate Dr Millikan and colleagues on completing a prospective evaluation of a modification of the mesh-plug technique for inguinal hernia repair. Their results are outstanding, and a few numbers deserve to be repeated. There were 1025 men and 31 women who underwent a primary unilateral inguinal hernia repair with suture fixation of the inner petals of a mesh plug into the preperitoneal space. The data collection was prospective. The mean operative time was only 25 minutes. Follow-up occurred in 99% of patients, and only 1 recurrence was detected at the 1-year follow-up visit. The authors conclude, "The Millikan modified mesh-plug repair should be adopted as the gold standard for unilateral primary inguinal hernia repair." The authors' conclusion is provocative, and I suspect it will generate some further discussion in the audience. I have some questions.

1. Please define further your criteria for patient inclusion and exclusion. You had 1 recurrent hernia in a patient with a scrotal hernia. Were there other patients with large hernias, scrotal hernias, and sliding hernias who were included and repaired successfully, or were the larger-hernia patients excluded from this trial? Were there any acute or incarcerated hernias?

2. Where are the women? You had more than 1000 men but only 31 women in the trial. The gender difference of 33:1 is not representative of the general population of patients with hernias. Did you exclude some women from this trial? If so, why? Did you exclude teenagers with small indirect inguinal hernias?

3. Did you include any patients with femoral hernias, perhaps discovered incidentally at the time of inguinal groin surgery? You described suture fixation of the inner petals of the mesh plug to Cooper's ligament. Do you then have a transition stitch laterally, such as Chester McVay described with a McVay repair? If so, this aspect of your repair has some similarity to the McVay repair, albeit without any tension, and the McVay repair was occasionally used for femoral hernias, too.

4. If you do suture mesh to Cooper's ligament, have you had patients with deep venous thrombosis from the inflammatory reaction of the mesh next to the external iliac vein?

5. Do you utilize different size plugs for different size patients and different size defects, and, if you do, how do you choose the appropriate size?

6. Last question. Is your technique easy to learn and reproducible? What is the success and failure rate of others with this technique? How quick is the learning curve?

In summary, the authors, in a prospective evaluation of a new technique of hernia repair, have shown excellent results. I conclude that surgeons such as these authors who are dedicated to the study and improvement of existing techniques can achieve outcomes equal to or better than those reported historically in the literature. This technique may not yet be the gold standard, but rather, based on this report, is worthy of the gold standard of testing, ie, testing in a randomized prospective trial.

James R. Debord, MD, Peoria, Ill: I have 3 questions. (1) Many people who advocate the plug remove some petals. Am I assuming that you do not remove any petals in your technique? (2) There are probably as many plugs now on the market as surgeons doing the plug repair. Do you think it makes any difference which brand or type of plug is used? (3) Finally, if you look at your excellent results, as good as they are, they are not all that much different from Lichtenstein's original results with just an onlay patch. So what is the plug actually doing?

Jack Pickleman, MD, Chicago, Ill: I would like to quote from the Martha Stewart *Book of Etiquette*. Don't you think it's just a bit tacky, Keith, to name a new operation after yourself and immediately declare it the gold standard?

David R. Farley, MD, Rochester, Minn: The results are the best I have seen in the literature. I do this type of repair myself, but my patients have more problems with urinary retention than you report. I would really like some technical expertise on the local anesthetic that you use for these hernia repairs.

Dr Millikan: First, patient inclusion. All patients for this study with unilateral hernias were included except patients who came into the emergency room with an incarcerated or strangulated hernia, because we do these patients under a spinal or general anesthestic, and they were excluded. Also, it is my personal bias that if you have a strangulated or incarcerated hernia, you have to look for viability of the bowel. If there is any question of it, mesh should not be placed in those patients, and surgical residents and our surgeons should know how to do tissue-to-tissue repairs. So those patients were excluded.

Were there other scrotal hernias, sliding hernias? In my slide I categorized the different types of hernias. There were 58 type III by the Gilbert classification of hernias, which by description are sliding or scrotal hernias basically. We had 1 recurrence in that group. That's about 2%. We thought that was unacceptable. Now, for that type of hernia, we recommend a large onlay repair, and that is one of the times that I would go back to the Lichtenstein repair. There were no acute or incarcerated hernias in this series.

Where are the women? I'm not sure, Dr Landercasper. Thirty-three to 1; I have always been told in the surgical literature it is a 20:1 ratio. Ours was higher, but this is what we saw. In our original study that had 283 patients, we had 10 women and 273 men, so it was 27:1 in that study. We are seeing even more men now.

Women with small hernias were not excluded. We do not place the onlay patch in a woman with an indirect hernia. I personally have never seen a woman with a direct hernia. I have seen femoral hernias and indirect hernias that have large rings, but I personally have never seen a direct hernia, so we do not place the onlay patch in women.

Do we exclude teenagers? There are different varieties and sizes of teenagers. My personal bias is if someone hasn't gone through their growth spurt or reached puberty, mesh should not be placed. So we do not place mesh in young, small teenagers, but if we saw a football player, a junior in high school that was 210 pounds, and he had an inguinal hernia, we would place the plug and mesh in him.

What is the age range? It was 15 to 96 years. We did not find any incidental femoral hernias in this group. Now, it is a very small incision, and I can say we don't look for incidental hernias like the laparoscopic surgeons do when they do their laparoscopic repairs. We have not found this to be a problem. We have not seen femoral hernias come back later on. We do not have a transition stitch. We place the first stitch in Cooper's ligament so that the outer umbrella can actually cover the femoral space for direct hernias, but we do not place a transition stitch.

I have not had a deep vein thrombosis. I have had a few surgeons call me up who are using a plug technique who have described this. I believe that this comes from if you have a type I indirect hernia. We remove at least 4 of the 8 petals to reduce the bulk of the plug, because for a normal-size ring in a type I hernia, you do not need that bulky of a plug. There are smaller

plugs. I am cost conscious. We only keep large and extra-large on the shelf. So that's why I would rather remove petals than have all of these different types of plugs on our shelf.

Is your technique easy to learn? Are your outcomes reproducible? One thing I didn't mention is, on Monday hernia day, at least 5 to 10 surgeons come and visit for training. We have had 1000 surgeons in approximately 4 years come through our institution for training, and of that thousand, these were surgeons who did not know about the modified technique or were not using plugs at all. In a survey 6 months afterwards, 85% of them have adopted the technique as their standard procedure of choice now. I don't have any outcome results on their reproducibility of this technique, but I can say if 85% changed their way of doing things in a 4-hour teaching session, it is very simple and easy to learn.

Dr DeBord, when do I remove petals? When I think the plug is too bulky for the internal ring. But that's about the only time in small indirect hernias. We do not remove petals for any direct hernia, basically. The brand of the plug? This is the original plug that was on the market. I don't like to be an advertiser for anything. People have mimicked the plug, and there are other types of plugs out there. This is the only one in my estimation that allows me to suture the inside petals and have an underlay preperitoneal that is not inverted. There is another type of plug that is inverted that to me would push right out of the preperitoneal space. Because of the plug being inverted like this, the pelvic pressures help the umbrella open up into a flat space.

Is this different from the original Lichtenstein repair? It definitely is. The pain reported with this is less. Also, in Dr Lichtenstein's original article, he had 3125 patients; only 2500 of them were followed up, and there was a 0.2% recurrence rate. The question is, when you have 625 patients that weren't followed, were the recurrent hernias in that group, because in most series the recurrences go to somebody else to be fixed, and you lose those patients to follow-up. Even if all 11 patients of ours had a recurrent hernia that we missed, we would only have a 1% recurrence rate in this series, basically.

Dr Pickleman, there are certain reasons for emphasis, and I have taken this after you, basically. If I didn't put my name on it, no one would have really read the article seriously. This raises people's eyes. I also wanted to separate it from Drs Rutkow and Robbins' repair. I don't want this to be considered their repair, because theirs is not truly a preperitoneal repair. To say it is the gold standard, I think at some point in time in hernia repair, in this year 52% of all hernia repairs in the United States will be done by the plug method. There are different types of plugs, but the plug method is becoming more than 50% of the market share in hernia repair. So at some point in time, we have to define a gold standard, and I decided to define that as now. That may not be correct.

Dr Farley, as far as local anesthesia goes, we use 1% Xylocaine [lidocaine hydrochloride] with bicarbonate, and I have excellent nurse anesthetists and anesthesiologists who use propofol. We call it IV sedation. It is really a light general. We also participated in a phase 3 trial recently of giving patients the night before Vioxx [rofecoxib] and then using a COX-2 inhibitor IV during the procedure and sending them home on a COX-2 inhibitor. That totally eliminates all narcotic medication. Now that phase 3 trial has just come to completion—and hopefully the COX-2 inhibitor IV will be on the market soon—and we will switch completely from giving patients prescriptions of Darvocet [acetominophen and propoxyphene napsylate] or Vicodin [acetominophen and hydrocodone bitartrate] and totally just use COX-2 inhibitors in the future.

Alexandre Dumas Street - 2100 –
10nd floor
São Paulo, SP
ZIP 04717-004

bd.com

Perfix Light Plug

O reparo cirúrgico das hérnias inguinais é um dos procedimentos mais realizados no mundo ocidental, com alto impacto econômico em saúde pública. Estima-se que 5% da população irá desenvolver uma hérnia da parede abdominal ao longo da vida. Da sua totalidade, 75% ocorrem na região inguinal; dois terços são hérnias indiretas. Os homens são 25 vezes mais acometidos do que as mulheres. Estrangulamento, complicação grave mais comum de uma hérnia, ocorre em apenas 1% a 3% dessas hérnias. Ocorre mais comumente nos extremos da vida e nas hérnias inguinais indiretas, quando comparadas com hérnias inguinais diretas.

O objetivo deste relatório é demonstrar os benefícios da tela PerFixTM Light Plug e os seus benefícios em relação à diminuição de tempo cirúrgico, diminuição de dor aguda pós-operatória e qualidade de vida quando utilizada na cirurgia de hérnia inguinal, comparado aos efeitos do dispositivo convencional.

Este dispositivo combina os benefícios da colocação de uma tela no espaço interfascial e na região pré-peritoneal livres de tensão. Essas telas apresentam um formato ideal, uma configuração pré-moldada, são fisiologicamente inertes e – o mais importante – a técnica de colocação é de fácil ensinamento, com uma eficácia reprodutível entre cirurgiões em instituições do mundo inteiro. A BARD PerFixTM Light Plug (DAVOL Inc; Canston, USA) é uma tela de polipropileno monofilamentar de baixa gramatura composta por duas partes independentes: um plug (sublay mesh) e um patch (onlay mesh). É aproximadamente 50% mais leve, em comparação com as telas de alta gramatura. Outro benefício evidente associado a este dispositivo é o design dinâmico, que confere uma perfeita adaptação e incorporação tecidual, além de uma quantidade de material implantado reduzida.

A PerFixTM Light Plug tem se tornado muito popular em função da simplicidade e facilidade de sua utilização para correção de hérnias inguinais. Uma análise prospectiva recente de 1.056 pacientes demonstrou que o uso da PerFixTM Light Plug para correção de hérnias inguinais emprega mínimos recursos médicos e é associada com uma pequena taxa de dor pós-operatória, um retorno precoce às atividades diárias e trabalhos manuais, com uma taxa mínima de recidiva precoce. Por fim, a hernioplastia utilizando a técnica de plug and patch com o uso da PerFixTM Light Plug deve ser adotada como “padrão ouro” nas hernioplastias inguinais primárias e unilaterais. A literatura cirúrgica acumulou dados rapidamente desde a introdução destes dispositivos. Os resultados são, de modo geral, melhores ou comparáveis àqueles alcançados com o reparo de Lichtenstein. Poucas complicações foram descritas, exceto a problemática dor crônica não incapacitante na região inguinal. A técnica de plug and patch é minimamente invasiva, livre de tensão, com pequena incisão e dissecção limitada. Estudos não randomizados demonstraram baixa taxa

Alexandre Dumas Street - 2100 –
10nd floor
São Paulo, SP
ZIP 04717-004

bd.com

de recidiva e rápida recuperação pós-operatória. Além disso, há a possibilidade de realizar o procedimento no formato ambulatorial, reduzindo os custos diretos.

O tempo de recuperação é menor, particularmente àqueles pacientes com uma demanda de atividades físicas menor, diminuindo, assim, os custos indiretos. Somado a isso, esta técnica é de fácil aprendizado e reprodutibilidade. A qualidade dos procedimentos modernos para correção de hérnia inguinal é medida por diferentes critérios, tais como: eficácia, efetividade, custo-benefício e conforto do paciente. O uso da técnica plug and patch preenche estas demandas de forma exata. Diminuição do tempo de internação e menor uso de analgésicos (4+-3 dias) levam a um retorno precoce nas atividades diárias (6+-3 dias), incluindo também exercícios físicos.

Por fim, o uso do dispositivo PerFixTM Light Plug pela técnica de plug and patch para correção de hérnias inguinais demonstrou uma facilidade do ponto de vista técnico, tendo em vista que, quando utilizado, diminuiu significativamente o tempo cirúrgico, quando comparado ao método convencional. Isso implica, sem dúvida alguma, em diminuição dos custos cirúrgicos globais, pois a redução no tempo operatório acaba diminuindo, também, o uso de anestésicos e o tempo total de sala cirúrgica.

Catherine Simões de Abreu
Gerente de Produto - Surgery

Alexandre Dumas Street - 2100 –
10nd floor
São Paulo, SP
ZIP 04717-004

bd.com

Referências Bibliográficas

- Millikan KW, Deziel DJ. The management of hernia. Considera- tions in cost effectiveness. Surg Clin North Am 1996 Feb; 76(1):105- 16.
- Adamonis W, Witkowski P, Smietański M, Bigda J, Sledziński Z. Is there a need for a mesh plug in inguinal hernia repair? Randomized, prospective study of the use of Hertra 1 mesh compared to PerFix Plug. Hernia 2006 Jun; 10(3):223-8.
- Poobalan AS, Bruce J, King PM, Chambers WA, Krukowski ZH, Smith WC. Chronic pain and quality of life following open inguinal hernia repair. Br J Surg 2001 Aug; 88(8):1122-6.
- Paajanen H, Scheinin T, and Vironen J. Commentary: Nationwide analysis of complications related to inguinal hernia surgery in Finland: a 5-year register study of 55,000 operations. Am J Surg 2010 Jun; 199(6):746-51.
- Paajanen H, Varjo R. Ten-year audit of Lichtenstein hernioplasty under local anaesthesia performed by surgical residents. BMC Surg 2010 Aug; 10:24.
- Hindmarsh AC, Cheong E, Lewis MP, Rhodes M. Attendance at a pain clinic with severe chronic pain after open and laparoscopic inguinal hernia repairs. Br J Surg 2003 Sep; 90(9):1152-4.
- Huang CS1, Huang CC, Lien HH. Prolene hernia system compared with mesh plug technique: a prospective study of short- to mid-term outcomes in primary groin hernia repair. Hernia 2005 May; 9(2):167-71.
- Rutkow IM, the PerFix plug repair groin hernia. Surg Clin North Am 2003 Oct; 83(5):1079-98, VI.
- Zieren J, Neuss H, Philipp AW, Müller JM. Postoperative comfort after plug-and-patch repair of recurrent inguinal hernia. Eur J Surg 2002; 168(1):18-21.
- Brooks DC. A prospective comparison of laparoscopic and tension-free open herniorrhaphy. Arch Surg 1994 Apr; 129(4):361-6.
- Rutkow IM, Robbins AW. The mesh plug technique for recurrent groin herniorrhaphy: a nine-year experience of 407 repairs. Surgery 1998 Nov; 124(5):844-7.
- Zieren J, Zieren HU, Jacobi CA, Wenger FA, Müller JM. Prospective randomized study comparing laparoscopic and open tension-free inguinal hernia repair with Shouldice's operation. Am J Surg 1998 Apr;175(4):330-3.

0039-6109/98 $8.00 + .00

MESH PLUG REPAIR AND GROIN HERNIA SURGERY

Alan W. Robbins, MD, and Ira M. Rutkow, MD, MPH, DrPH

Since the mid-1980s, dramatic progress has been made in the evolution of hernia surgery, highlighted by the increasing use of prosthetic mesh.[27, 30] This is heightened by the fact that repair of groin hernia is now the most common major operation performed by the general surgeon, with an expected 750,000 such repairs to be completed in the United States in 1998.[28] Of these surgical operations, it is estimated that almost 80% will involve placement of a mesh prosthesis. Among the new mesh-based "tension-free" hernioplasties (i.e., laparoscopy, Lichtenstein, and plug), the use of mesh plugs has garnered many spirited enthusiasts, and plug herniorrhaphy has become the fastest growing hernia repair used by American surgeons. What is it about this utilitarian and simple surgical procedure, often described as little more than placement of an internal truss, that has allowed it to rapidly become one of the mainstays of the modern surgeon's hernia armamentarium?

HISTORY OF HERNIA PLUGS

The technique of plugging the inguinal canal to prevent the emergence of herniated tissue seems to have been first conceived in the early part of the 19th century. In the mid-1830s, Pierre Nicholas Gerdy (1797–1856), a Parisian surgeon, conceptualized plugging the inguinal canal with an inverted fold of skin, scrotal or otherwise, maintained in position by both sutures and creation of a caustic-induced inflammatory response.[6] It was during the same era that C. W. Wutzer (1789–1858), professor of surgery in Bonn, proposed temporary placement of a foreign

From The Hernia Center, Freehold, New Jersey

body (i.e., a wooden hernia plug pushing the scrotal skin and testicle in front of it) to help invaginate and hold tissue until the inguinal canal was closed by inflammatory adhesions.[51] Writing in the *Organ für die gesammte Heilkunde* (1841), Wutzer's primitive device would eventually go through countless modifications, with some of the best known European and American surgeons using the apparatus.

The "external" invagination method held sway against virtually all other surgical cures until open incision methods came into prominence during the 1870s.[46] The one open plug paper that attracted a large share of attention was authored by William Macewen (1848–1924) of Glasgow in 1886.[19] He attempted to plug the inguinal canal with a bundled-up or multiply pleated portion of the hernial sac, which was "secured to the abdominal circumference of the [internal] ring." With the advent of the Bassini/Halsted era (circa 1890s) and formal reconstruction of the inguinal floor and internal ring with full restoration of obliquity, the concept of plugging fell into disfavor and eventual disuse.[2, 17] In the same age, Theodore Billroth (1829–1894) is given credit by Vincenz Czerny (1842–1916) with first prophesizing that the problem of groin herniation would not be effectively resolved until artificial replacement of attenuated or damaged tissues became possible. As Czerny quotes Billroth, "If we could artificially produce tissues of the density and toughness of fascia and tendon, the secret of the radical cure of hernia would be discovered."[3]

Since the advent of the "modern" era of hernia surgery 1 century ago and, despite their longstanding popularity, all tissue-based groin herniorrhaphies have had the common disadvantage of creating tension on the suture line. Which layers of tissue are approximated and whose name is applied to various eponymous repairs matter little. Over the years, traditional "tensioned" hernia repairs became more complex, using tissue flaps or grafts, transposition of various tissue layers, and differing "relaxing" incisions; however, the final common denominators were always the same: technically difficult repairs resulting in tissue under tension, greater numbers of complications, patient discomfort and disability coupled with prolonged rehabilitation, and recurrence rates considered too high. A most important advance in the avoidance of tissue tension came in the late 1950s, when Francis Usher (1908–1980) of Texas first reported on the use of a prosthetic polypropylene mesh (Marlex) in the repair of inguinal and incisional hernias.[47, 48]

With the availability of a safe and easy-to-use prosthetic material, the concept of plugging was re-examined by Irving Lichtenstein (b. 1920). In 1968, he began using a rolled cylindrical or "cigarette" mesh plug as treatment of femoral and recurrent inguinal hernias and reported on its efficacy in 1974.[14] After dissecting and inverting the hernia sac, a cylindrical plug was created by rolling a 2 × 20 cm or longer piece of Marlex mesh into a solid cigarette configuration. The plug is inserted into the femoral or recurrent inguinal defect, and several anchoring sutures are placed. Almost 3 decades of follow-up have since demonstrated the efficacy of this type of cigarette plug repair.[1, 16–18, 43–45] Lichtenstein and colleagues[16] recently wrote:

> A plug is preferable to a patch for several reasons. First, it forms a complete occlusion of the defect without tension. Second, its slight extension into the properitoneal cavity prevents the protrusion of omentum or bowel into a cul-de-sac that an onlay patch might create. Finally, a plug is obviously a much stronger barrier and can be fixed to a small rim of scar tissue. Laying down a secure flat patch with adequate overlap requires a wider dissection of tissue.

The next logical step in the evolution of mesh plugs was reported by Arthur Gilbert (b. 1932) in the late 1980s. After experimenting with Lichtenstein-type rolled cylindrical plugs in the treatment of primary indirect hernias, Gilbert improved on the device's design by taking a flat piece of mesh and fashioning it into a cone or umbrella shape.[8–10] He believed that the umbrella plug represented an improvement over the cigarette plug because "the opened umbrella configuration attaches itself to the deep side of the abdominal wall in a greater circumference than did the previous rolled plug."[7]

To fully understand the continued development of mesh plugs and the concept of a "tension-free" herniorrhaphy, it is helpful to review the classification system of groin hernias advanced by Gilbert and expanded on by Rutkow (b. 1948) and Robbins (b. 1938).[9, 42] This system is based on the status of the inguinal floor, the competency of the internal ring, and the integrity of the transversalis fascia-transversus abdominis aponeurosis layer. Types 1, 2, and 3 are indirect hernias. Types 4 and 5 are direct hernias. Type 1 has a tight internal ring, which, when the hernia sac is reduced, holds it in position. Type 2 has a moderately enlarged internal ring, which measures less than 4 cm. Type 3 has a patulous internal ring of more than 4 cm, which occupies most of the inguinal floor. Type 4 is a direct hernia with a fusiform defect occupying the entire floor of the inguinal canal. Type 5 is a diverticular defect of the inguinal floor. Type 6 encompasses those inguinal hernias consisting of both indirect and direct components (i.e., pantaloon hernias). Type 7 covers all femoral hernias. As with any classification system, there can be numerous variations and combinations that must be accounted for. Therefore, these variables, including primary versus recurrence, reducible versus incarcerated versus strangulated, sliding component, and lipoma, must be individually noted in describing a specific hernia.

Learning of Gilbert's success with umbrella- or cone-shaped mesh plugs and how such a prosthetic device fulfilled the criteria of a tension-free hernioplasty, as originally described by Lichtenstein and Alex Shulman (1915–1996),[15] Rutkow and Robbins began using hand-fashioned "umbrella" plugs in 1989. Initially repairing only type 1 and 2 indirect defects, Rutkow and Robbins were soon buoyed by their success and began to expand the repertoire of plug repairs to encompass type 3 indirect defects. The major difference between types 1, 2, and 3 repairs was that it was found necessary to more adequately anchor the mesh plug to the crural margins of the attenuated internal ring with multiple interrupted sutures to properly fix the prosthesis in position. This technical detail was necessary because in a type 3 defect, the normal shutter

mechanism of the internal ring is rendered incompetent, thus making the ring no longer capable of retaining the plug in place or maintaining the hernia sac in a reduced position.

As Rutkow and Robbins' confidence in the umbrella plug evolved, they extended the clinical parameters to include treatment of all groin hernias, both primary and recurrent. For example, knowing the normal shutter mechanism of the internal ring is destroyed in type 3 indirect hernias, including displacement of the inferior epigastric vessels medially with impingement on the direct space, it was reasoned that the same repair principles would apply to type 4 fusiform direct hernias. This is possible because both types 3 and 4 produce essentially the same tissue defect (i.e., destruction of the posterior inguinal floor), the only difference being the position of the inferior epigastric vessels, which have no structural significance. In essence, if a small defect could be plugged with a mesh plug, so could a larger defect, the only caveat being that in the absence of a competent sling and shutter mechanism, the device would absolutely require adequate suturing to the fascial margins to maintain position. Similar principles would be applicable to recurrent inguinal hernias because the muscular margins of the hernia defect are replaced by rigid scar tissue. Type 5 diverticular direct and type 7 femoral hernias were also found easily repaired with an umbrella plug. By the end of 1991, Rutkow and Robbins were using mesh plugs to treat all types of groin hernias and, in mid-1993, reported their results on almost 1700 hand-rolled "umbrella" plug hernioplasties.[22, 29, 42]

In spring 1993, Rutkow and Robbins helped develop, and the C.R. Bard Company began to market, a preformed umbrella hernia plug (PerFix) made out of Marlex mesh. This was the first ready-to-use device and consisted of a fluted outside layer combined with an inside arrangement of eight mesh "petals." Rutkow and Robbins found the premade plug simpler to use than attempting to improvise a hand-rolled hernia plug at the operating table, noted by the fact that their operative times using a premade versus a hand-rolled device decreased an average of 4 minutes per case. In spring 1995, Rutkow and Robbins authored the first scientific article in a peer-reviewed journal on premade plugs.[37]

By 1998, various other preformed hernia-plug–like devices had also become commercially available. When combined with the extensive experience of surgeons using hand-rolled umbrella devices, it is evident that the mesh plug hernioplasty is now widely accepted, having undergone a full decade of evaluation. More to the point, by 1998, the phrases tension-free and mesh plug hernia repair were wholly integrated into the working vocabulary of most American surgeons.

MESH PLUG OPERATIVE TECHNIQUE

Preoperative Routine

Because we prefer a premade PerFix plug versus a hand-rolled device, our use of a premade PerFix plug is described. For patients

fewer than 40 years of age with no signs or symptoms of medical problems, no preoperative investigation is required. Individuals 40 years of age or more undergo an electrocardiogram and a complete blood count. When appropriate (e.g., cardiac or pulmonary difficulties), patients are advised to consult an internal medicine or family practice specialist to receive medical clearance specifically for ambulatory surgery.

Epidural anesthesia is used routinely, except in instances in which back and spinal surgery contraindicates its application. Such regional anesthesia allows patients to cough or strain on command and assist in testing the integrity of the plug repair. The epidural agent (a 20-mL ampule of 3% chloroprocaine [Nesacaine] to which is added a 2-mL ampule of Sublimaze [fentanyl]), in addition to intravenous midazolam (Versed), preserves most motor function, which permits patients to move their lower extremities while under a profound sensory block with little peritoneal sensation. Because chloroprocaine has rapid onset and short duration, patients are able to walk within 60 minutes of the end of the procedure. Mesh plug repairs, being tension-free, can also be adequately performed using local anesthesia with accompanying intravenous sedation.

The operative site (only the skin where the incision is to be made) is shaved just before the procedure. The skin is prepared with povidone-iodine and alcohol, and a self-adhesive clear plastic drape is placed on the operative site, followed by customary draping. Antibiotics are not given, nor is the mesh plug soaked in an antibiotic solution.

Repair Technique

An oblique, 4-cm to 6-cm incision of the epidermis, overlying the internal ring, is made. All subsequent tissue dissection, including that of the hernial sac off the spermatic cord structures, is done with electrocautery. This instrument provides excellent hemostasis and helps reduce postoperative hematoma and seroma formation. The usual blood loss during a routine mesh plug hernia repair is less than 5 mL.

The external oblique aponeurosis is opened and a self-retaining blunt-tipped Adson-Beckmann retractor, together with a handheld double-sided retractor, provides excellent exposure. If the ilioinguinal and genitofemoral nerves are found, they are preserved; otherwise, they receive no special attention. The spermatic cord is mobilized at the level of the pubic tubercle, and a rubber drain is placed around the cord structures.

For indirect hernias, including large scrotal ones, the sac is approached initially by separating the cremasteric fibers longitudinally along the spermatic cord so as not to destroy the cremasteric reflex. In completing an indirect herniorrhaphy, the most important element is a high dissection of the sac, not a high ligation. A high dissection is considered to be complete once the preperitoneal fat pad at the base of

the indirect sac is visualized. The freely dissected, unopened sac and any adjacent lipomata are then simply placed back through the internal ring into the abdominal cavity. A mesh plug is inserted, tapered end first, through the internal ring and placed into position just beneath the crura (Fig. 1), in essence acting as a togglelike device. With small, indirect hernias, the plug is kept in place by putting one or two interrupted sutures (3-0 polyglactin 910 [Vicryl]) through the outside fluted portion of the prosthesis and the crura. These are not meant to be strength stitches, and any crural tissue, regardless of how flimsy it may appear, usually suffices. In larger indirect and scrotal hernias, the plug should always be secured to the margins of the patulous internal ring with multiple interrupted sutures. In a PerFix plug repair, if the plug's bulk is considered excessive and if concern exists that the patient may feel it postoperatively, especially for individuals with asthenic physiques or the very narrow defect, then some of the inside mesh petals should be removed.

In both fusiform and saccular direct hernias, the attenuated transversalis tissue is raised with a clamp and the sac is circumscribed at its midportion so as to expose preperitoneal fat (Fig. 2). This creates an opening into the preperitoneal plane, where the plug must ultimately lie. The freed sac and overlying attenuated transversalis fascia-transversus

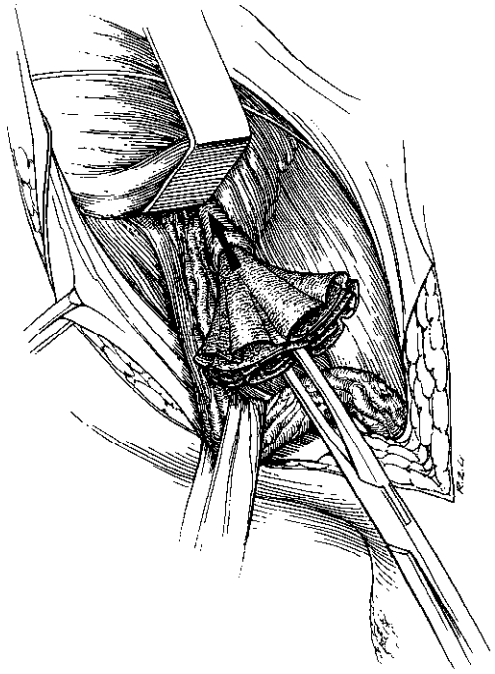


Figure 1. Placement of a mesh plug into the internal ring.

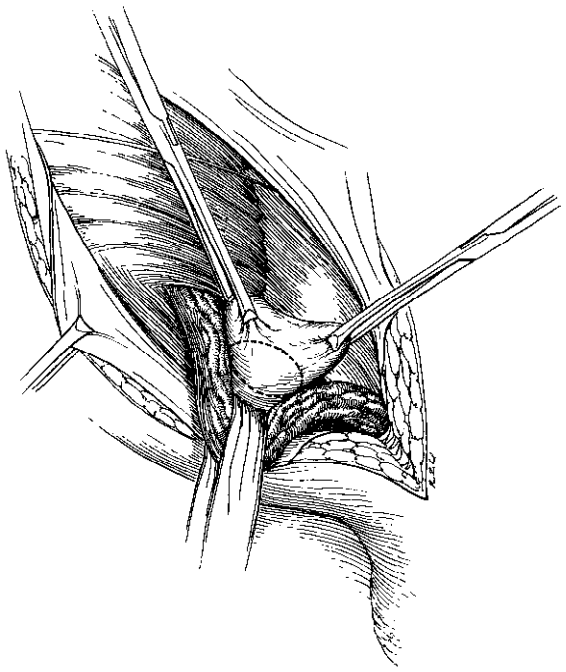


Figure 2. A direct defect is elevated to demonstrate the area of its midportion to be circumscribed.

abdominis aponeurosis layer are invaginated. As in an indirect repair, a plug is inserted narrow end first through the newly created defect in the floor (serving as a togglelike device) and secured with multiple interrupted sutures to surrounding intact tissue (Fig. 3). Because Marlex mesh has a well-documented Velcro-like reaction to tissue, any surface usually suffices to help hold the plug in position. In some pantaloon hernias, with two separate and distinct defects, placement of two or even more plugs has been appropriate.

All indirect and direct primary hernioplasties are reinforced with a second piece of flat Marlex mesh (Fig. 4). This onlay patch is placed using sutureless technique on the anterior surface of the posterior wall of the inguinal canal from the pubic tubercle to above the internal ring. The lateral portion of the preshaped onlay patch includes an aperture for the spermatic cord. This split section is sutured back to itself to provide an opening for the cord while functioning as a pseudo–internal ring. The onlay patch is intended solely to strengthen the direct space in an indirect repair and the area of the internal ring in a direct repair. The onlay piece of mesh is not an integral part of the current repair but is meant to serve as a form of prophylaxis against future herniation by creating further tissue ingrowth in the remainder of the inguinal canal.

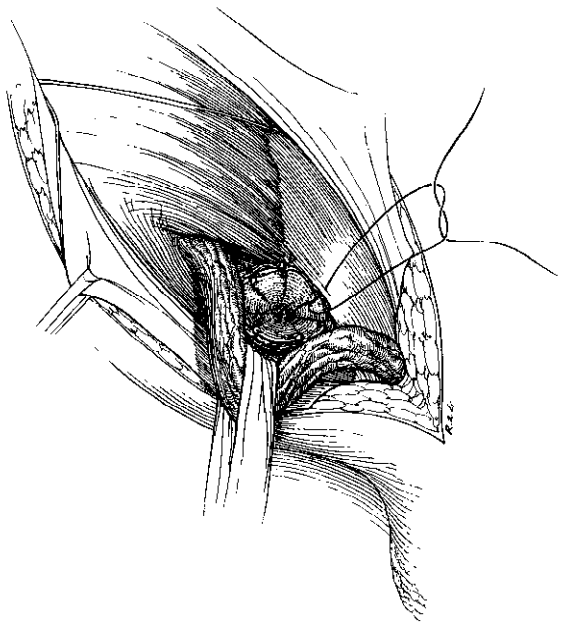


Figure 3. Placement of a mesh plug into a direct defect.

Most importantly, despite the presence of a sutureless onlay patch, the mesh plug procedure, as described here, should not be confused with another well-known, tension-free, mesh-based technique, the Lichtenstein repair, which consists solely of a circumferentially sutured onlay patch. There is little doubt that the Lichtenstein repair is an effective surgical operation, but, in our experience, the mesh plug hernioplasty yields equally low recurrence rates and is far simpler to perform, requiring a smaller incision and diminished tissue dissection. Such surgical simplicity leads to less postoperative discomfort.

Cord structures are placed on the anterior surface of the onlay patch. The external oblique aponeurosis is reapproximated over the cord structures with a continuous absorbable suture. Scarpa's fascia and subcutaneous tissues are brought together and the skin edges are coapted with a running subcuticular stitch of the same material. A transparent, self-adhesive dressing is placed over the incision.

The plug repair is applicable to femoral hernioplasty. Using an infrainguinal approach, the mushroomlike appearance of a femoral hernia can be seen extending from the femoral canal. Adhesions between the hernial sac and surrounding tissues are freed. If the femoral opening is too small and the sac too bulky to be reduced adequately, the sac is divided and ligated. It should then be possible to reduce the remaining proximal portion of the sac. The sac is reduced from outside in through

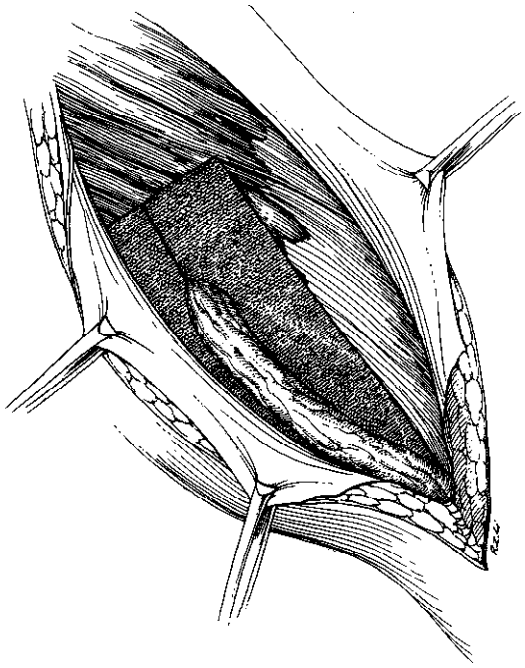


Figure 4. Onlay patch in position against the inguinal floor.

the femoral canal. Using a PerFix plug, all inside petals are removed, and only the outside fluted layer of mesh is placed through the opening of the femoral canal. After proper positioning, the plug is secured with interrupted sutures to the surrounding fascia or other tissues that compromise the opening of the femoral canal. An onlay patch is not required.

The plug technique is suitable for virtually all recurrent groin hernias. In operating on such defects, the rule is to dissect as little as possible. Therefore, no routine attempts to identify fused anatomic layers are made. Unlike primary repairs, with a recurrent hernia, the spermatic cord is not mobilized routinely because attempts at such mobilization can cause damage to an already compromised cord. The recurrent direct sac, be it fusiform or saccular, is simply dissected down to its base on the inguinal floor. Although disparate elements of the spermatic cord may be intimately attached to the sac, all that is necessary is a gentle dissection to peel such structures off the wall of the sac. The base is circumscribed to help release the sac completely from adjacent scarred areas. The recurrent indirect sac is similarly freed, albeit to the level of the internal ring. The sac is reduced without ligation or excision. The plug is inserted into the defect and always secured with several anchoring sutures between it and the scarred margins of the rigid defect in the

inguinal floor or the scarred internal ring. An onlay patch may be used if sufficient room is available (i.e., if in the course of the dissection the spermatic cord was mobilized off the inguinal wall) to place it in position.

For recurrent hernias involving a transplanted cord (i.e., Halsted 1 repair), the generic principle of minimal dissection is adhered to. The herniated tissue is freed and reduced through the pseudo–internal ring in the external oblique aponeurosis, which overlies the true internal ring. No attempt is made to dissect the fused external oblique aponeurosis–inguinal floor layer. A mesh plug is inserted in the previously described manner through both the pseudo- and true internal rings and secured in position.

Postoperative Routine

Patients are discharged within 2 hours of the end of the operation. The only analgesic used postoperatively is a single 60-mg intramuscular injection of ketorolac tromethamine (Toradol) given in the recovery room. On discharge, patients are provided a prescription for propoxyphene napsylate and acetaminophen tablets (Darvocet-N 100). All patients are encouraged to remain active but are requested not to shower or drive a car for 24 hours. They are instructed to begin lifting weights of up to 10 kg whenever they like. All patients, assuming that they feel comfortable, are told to resume normal daily activities (e.g., dinner engagements, gardening, light exercise, and walking), including return to work, at their own discretion. Manual labor may be resumed in 2 weeks, and other intensive activities (e.g., bicycling, jogging, and tennis) in a proportionately shorter time. All reasonable activities may be resumed by the end of the second or third postoperative week. Patients have their postoperative checkup during the first or second week, when the self-adhesive dressing is removed.

RESULTS

From January 1989 to December 1997, a total of 3268 patients underwent mesh plug hernioplasties, with 88% (2861) of the hernias primary and 12% (407) recurrent (Table 1). This consisted of 1708 hand-rolled Marlex mesh plugs and 1560 premade Marlex mesh PerFix plugs. The duration of an average PerFix plug procedure, from skin incision to skin closure, was approximately 17 minutes for a primary hernioplasty. For a recurrent repair, the average operative time was less than 20 minutes.

Recurrences were determined solely via physical examination, with supplemental telephone interviews in fewer than 10% of cases, especially commencing in the fourth postoperative year. Follow-up information was 99% at 1 week, 95% at 1 year, 88% at 2 years, 80% at 3 years, 67% at 4 years, and 52% at 5 years. Beyond 5 years, the authors have found

Table 1. ANATOMIC LOCATION AND PHYSICAL CLASSIFICATION OF 3268 MESH PLUG REPAIRS (JANUARY 1989–DECEMBER 1997)

	Primary (n = 2861)		Recurrent (n = 407)	
	No.	Percentage	No.	Percentage
Location				
Right indirect	1037	36	81	20
Right direct	436	15	139	34
Right femoral	22	<1	5	1
Right pantaloon	92	3	15	4
Left indirect	809	28	57	14
Left direct	373	13	99	24
Left femoral	10	<1	2	<1
Left pantaloon	82	3	9	2
Classification				
Type 1	259	9	12	3
Type 2	1239	43	111	27
Type 3	348	12	17	4
Type 4	605	21	72	18
Type 5	204	7	164	40
Type 6	174	6	24	6
Type 7	32	1	7	2

increasing difficulty in obtaining adequate follow-up studies. This is not unreasonable given the older age status of the patients and the relatively mobile nature of the northeastern American population. As contrasted with tissue-based tension repairs, wherein 50% of recurrences do not appear until more than 5 years later, recurrences following prosthetic-based hernioplasties usually occur within the first 3 years.

Of the 2861 patients with a primary hernia repair, 19 (< 1%) total recurrences have been reported. Fifteen (79%) of these followed the repair of 983 primary direct or pantaloon hernias or a location-specific recurrence rate of 1.5%. Four (21%) of these total known recurrences followed the repair of 1846 primary indirect hernias or a location-specific recurrence rate of 0.2%. No recurrences have been reported in the 32 primary femoral repairs. Of the 19 total recurrences from primary plug repairs, 13 (68%) were detected during the first postoperative year, four (21%) were found in the second postoperative year, and two (11%) were noted in the third postoperative year or later.

Of the 407 patients with a recurrent hernia repair, 14 (3%) re-recurrences have been reported. Six (2%) of these occurred in the 320 patients with a first-time recurrence. Eight (9%) occurred in the 87 patients who had previously suffered from two or more recurrences. Of the 14 total re-recurrences, nine (64%) were detected during the first postoperative year, four (29%) were found in the second postoperative year, and one (7%) was noted in the third postoperative year or later.

A severe infection requiring antibiotic treatment and local wound care was noted in 19 patients (< 1%); however, to date, a Marlex mesh

plug has not been involved in an infectious process requiring its removal. No instances of draining sinus tracts, ischemic orchitis, long-term pain, vascular and embolic phenomena, or plug migration have been reported. No difficulties with the plug impinging on or eroding into adjacent anatomic structures have been reported. No cases of urinary retention requiring a prostatectomy have been reported since 1992.

Questioning of patients at their first postoperative visit revealed that 1709 (52%) took no pain medication. A total of 1278 (39%) used nothing more than nonprescription pain medicine (e.g., acetaminophen, aspirin, or ibuprofen). The remaining 281 individuals (9%) filled their "one-time" prescription for 15 Darvocet N-100 tablets.

A total of 3104 patients (95%) returned to normal daily activities within 3 days of their mesh plug hernioplasty. Ninety-eight percent resumed normal activities by the end of 1 week, and virtually all patients were able to complete normal daily activities by the end of the second postoperative week.

DISCUSSION

A 9-year personal experience in almost 3300 patients and a growing number of articles in the surgical literature and various book chapters attest to the efficacy and utilitarian nature of the mesh plug hernioplasty.[4, 11, 20–24, 31, 33–36, 38–41, 49, 50, 52–54] It is a technically simple surgical operation, which, in a standardized form, can be used to repair virtually any groin hernia. This runs counter to the time-honored philosophy of differing repairs for various types of primary and recurrent hernias. Much like in the Shouldice Hospital, where surgeons use the same anatomic repair for all varieties of groin hernias, we believe that good results come from standardization of herniorrhaphy technique. In this way, surgeons become proficient at performing one type of hernia repair, thus achieving a more concentrated technical experience versus completing a hodgepodge of repairs and never mastering one.

In contrast with a mesh patch, a plug is technically easier to work with and far simpler to secure to surrounding tissues. The umbrella-shaped configuration handles easily and forms a total occlusion of the defect. The interstices of the mesh plug become completely infiltrated with fibroblasts, and the plug remains permanently strong. The mesh is not subject to deterioration, rejection, or shrinkage and, in the authors' experience, when properly placed, is virtually never felt by patients postoperatively.

As with any implanted foreign body, concerns regarding the long-term fate and side effects of a mesh must be acknowledged; however, Marlex, unlike most other prosthetic meshes, has been in clinical use for 4 decades. Consequently, much information is available about its biologic compatibility, highlighted by a noticeable lack of adverse events. There is little doubt that over time mesh plugs become encased and infiltrated by fibroblastic ingrowth secondary to the process of cicatrization. This

is evidenced in a recent study using postoperative herniography performed 2 weeks after placement of an umbrella mesh plug.[13] The herniograms were reported as essentially normal, with no contour defects within the abdomen from residual hernia sacs or protruding plugs. More to the point, a paucity of reports is available in regard to umbrella plugs eroding into nearby structures or unsuspected migration. Similarly, no scientific documentation of umbrella plug shrinkage leading to excessive numbers of recurrences is available.

Most impressively, the umbrella plug hernioplasty helps reduce operative morbidity and short-term and long-term postoperative discomfort. From a physiologic standpoint, the mesh plug repair is a preperitoneal procedure via an anterior surgical incision. Clearly, the indwelling plug bridges a tissue gap while partially buttressing the posterior inguinal wall, similar to a toggle device. Because the sine qua non of the plug method is decreased dissection, surgeons no longer have to labor under the misconception, engendered by tension repairs, that every anatomic structure in the inguinal canal must be identified and dissected free. This unnecessary traumatization leads to increased "pain and suffering," the phrase that has made hernia surgery such an ugly epithet for the lay public.

Our experience in treating more than 6000 patients with hernias and a decade of experience with mesh plugs have led us to re-examine several key surgical principles. One of the great myths of hernia surgery concerns the correlation of prostatic hyperplasia and postoperative urinary retention. Use of minimal dissection, placement of a simple hernia plug, and ultra-short-acting epidural anesthesia has essentially eliminated urinary retention. No correlation exists between prostatic size, preoperative urinary difficulties, and the necessity for postoperative catheterization. Accordingly, we do not subscribe to the concept of prophylactic prostatectomy before groin herniorrhaphy.

Although much has been written concerning ilioinguinal and genitofemoral neuralgia secondary to inguinal herniorrhaphy, we have never been able to correlate pain and numbness with preservation or sacrifice of the nerves, nor have we operated on any individual for supposed ilioinguinal or genitofemoral neuralgia. Conservative management is the key, and patients who experienced numbness or sharp pain uniformly report complete diminution of the symptoms following several months of nonoperative management.

We firmly believe that chronic postherniorrhaphy neuralgias are mostly a product of tension-producing sutured repairs. The repair, not the rare entrapment of a nerve, is the cause of the pain. In addition, a large segment of patients experience sharp pain, supposedly from their hernia, before surgery. When they are operated on, the pain initially subsides but returns in a few months. From then on, the disability is classified as postoperative neuralgia. We contend that this subset of patients has no evidence of true postoperative related neuralgia. Instead, their hernial bulge has been repaired and the chronic pain cycle temporarily masked by acute incisional pain. Unfortunately, in some cases, it

is only a matter of time before chronic groin sprain discomfort returns under the guise of ilioinguinal-genitofemoral syndrome.

Among the most vexing of postoperative complications is testicular swelling followed by ischemic orchitis, with an atrophied testicle as the end result. The incidence of this problem is increased when attempts are made to repair a large scrotal hernia or a recurrent hernia in which the hernia sac is strongly adherent to the spermatic cord structures and surrounded by inflammatory or scar tissue. This difficult situation was obviated after we began to use the plug technique, especially for recurrent hernias. Because no attempt is made to identify unrecognizable anatomic planes, the cord structures do not need to be mobilized, and dissection is kept to a minimum. With difficult-to-dissect scrotal hernias, the sac is divided in its midportion, the proximal segment is ligated, and a high dissection is completed. The distal sac is left in place after being splayed open with electrocautery. Hydrocele formation has not been a major problem.

Regarding the fate of hernia sacs, because the peritoneum is a highly sensitive structure, the long-held belief that ligating a sac is an important adjunct to a groin hernia operation does nothing more than lead to a "miniature peritonitis." This iatrogenic peritonitis is one of the factors contributing to the postoperative discomfort and malaise that accompany sutured hernia repairs. The inverted hernia sac simply involutes without problems in a few days. Hernia sacs should not be routinely opened for manual or visual inspection. Assuming that no evidence of strangulation, acute incarceration, or some other pathologic condition is present, it is best that the unopened sac be simply placed back into the abdominal cavity.

Here is one note of caution about those patients with multirecurrent hernias who present for placement of an umbrella plug. With a 9% recurrence rate in such individuals, our series suggests that alternative approaches should be considered for the pursuant repair, including an anterior preperitoneal approach and prosthetic buttress repair (i.e., Nyhus), an anterior preperitoneal giant prosthetic reinforcement of the visceral sac (i.e., Stoppa and Wantz), or a posterior preperitoneal laparoscopic repair.

A growing national and international experience in the repair of virtually all groin hernias with a mesh hernia plug has resulted in a low recurrence rate combined with a marked diminution of postoperative complications. The plug repair never requires expensive, technologically advanced equipment, and, as noted, growing numbers of studies have begun to demonstrate the superiority of open mesh plug repairs to other mesh-based hernioplasties. We hope that the present-day financial foolishness of requiring expensive technology to perform this most common of general surgical operations will become a thing of the past.[25] With development of a more sophisticated understanding of outcome measures for groin hernia repair (e.g., comorbidities, complication rates, demographics, expectations, health status, recurrences, rehabilitation, socioeconomics, technical difficulty, and utilization), the appeal of one

repair over another must now extend beyond the simple calculation of a recurrence rate.[5, 26]

On a pragmatic note, the mesh plug technique is among the easiest of hernia repairs for the average surgeon to understand and requires a minimal learning curve. This is inherent in our growing advocacy of surgical minimalism. If the same or better results can be obtained via a technically simple and efficient operation (i.e., mesh plugs), then it becomes difficult to fathom the rationale for a more complex approach (i.e., laparoscopy or Lichtenstein). The ease of a surgical procedure is as important as the mechanical advantages offered by a method and, similarly, the more foolproof a technique, the better. As a matter of everyday practicality, the simplicity and safety of the mesh plug hernioplasty have enabled us to make the transition from a hospital-based operating room environment to a more patient-friendly and less costly ambulatory surgical facility.[32]

References

1. Amid PK, Shulman AG, Lichtenstein IL: Femoral hernia resulting from inguinal herniorrhaphy: The "plug" repair. Contemp Surg 39:19, 1991
2. Bassini E: Ueber die Behandlung des Leistenbruches. Arch Klin Chir 40:429, 1890
3. Billroth T (ed): Czerny V: Beiträge zur Operativen Chirurgie. Stuttgart, F Enke, 1878
4. Brooks DC: A prospective comparison of laparoscopic and tension-free open herniorrhaphy. Arch Surg 129:361, 1994
5. Burney RE, Jones KR, Coon JW, et al: Core outcomes measures for inguinal hernia repair. J Am Coll Surg 185:509, 1997
6. Gerdy PN: Nouvelles opérations pour guérir radicalement les hernies du ventre. Gaz Hôp 1:10, 1836
7. Gilbert AI: An anatomic and functional classification for the diagnosis and treatment of inguinal hernia. Am J Surg 157:331, 1989
8. Gilbert AI: Inguinal hernia repair: Biomaterials and sutureless repair. Perspect Gen Surg 2:113, 1991
9. Gilbert AI: Prosthetic adjuncts to groin hernia repair: A classification of inguinal hernias. Contemp Surg 32:28, 1988
10. Gilbert AI: Sutureless repair of inguinal hernia. Am J Surg 163:331, 1992
11. Goussous HG: Effectiveness of the mesh plug technique. Surgery 117:600, 1995
12. Halsted WS: The radical cure of inguinal hernia in the male. Ann Surg 17:542, 1893
13. Kahn AM, Hamlin A: Herniography following indirect hernioplasty using the Marlex "mesh plug" technique. Am Surg 61:947, 1995
14. Lichtenstein IL, Shore JM: Simplified repair of femoral and recurrent inguinal hernias by a "plug" technique. Am J Surg 128:439, 1974
15. Lichtenstein IL, Shulman AG: Ambulatory outpatient hernia surgery, including a new concept, introducing tension-free repair. Int Surg 71:1, 1986
16. Lichtenstein IL, Shulman AG, Amid PK: The cause, prevention, and treatment of recurrent groin hernia. Surg Clin North Am 73:529, 1993
17. Lichtenstein IL, Shulman AG, Amid PK: The tension-free repair of groin hernias. *In* Nyhus LM, Condon RE (eds): Hernia, ed 4. Philadelphia, JB Lippincott, 1995, p 237
18. Lichtenstein IL, Shulman AG, Amid PK: Twenty questions about hernioplasty. Am Surg 57:730, 1991
19. Macewen W: On the radical cure of oblique inguinal hernia by internal abdominal peritoneal pad, and the restoration of the valved form of the inguinal canal. Ann Surg 4:89, 1886

20. Palot JP, Flament JB: The plugs. *In* Chevrel JP (ed): Hernias and Surgery of the Abdominal Wall, ed 2. Berlin, Springer-Verlag, 1998, p 214
21. Péllisier EP, Blum D: Le plug dans la hernie inguinale, etude prospective de faisabilité. Ann Chir 30(suppl):63, 1996
22. Robbins AW, Rutkow IM: The mesh-plug hernioplasty. Surg Clin North Am 73:501, 1993
23. Robbins AW, Rutkow IM: Mesh plug hernioplasty. *In* Maddern GJ, Hiatt JR, Phillips EH (eds): Hernia Repair: Open Versus Laparoscopic Approaches. New York, Churchill Livingstone, 1997, p 125
24. Robbins AW, Rutkow IM: Open mesh plug hernioplasty: The less invasive procedure. *In* Szabó Z, Lewis JE, Fantini GA, et al (eds): Surgical Technology, International, ed 5. San Francisco, Universal Medical Press, 1996, p 87
25. Rutkow IM: Laparoscopic hernia repair, the socioeconomic tyranny of surgical technology. Arch Surg 127:1271, 1992
26. Rutkow IM: The recurrence rate in hernia surgery: How important is it? Arch Surg 130:575, 1995
27. Rutkow IM: A selective history of groin herniorrhaphy in the 20th century. Surg Clin North Am 73:395, 1993
28. Rutkow IM: Surgical operations in the United States: then (1983) and now (1994). Arch Surg 132:983, 1997
29. Rutkow IM, Robbins AW: 1669 mesh-plug hernioplasties. Contemp Surg 43:141, 1993
30. Rutkow IM, Robbins AW: Demographic, classificatory and socioeconomic aspects of hernia repair in the United States. Surg Clin North Am 73:413, 1993
31. Rutkow IM, Robbins AW: Groin hernia. *In* Cameron J (ed): Current Surgical Therapy, ed 5. St Louis, CV Mosby, 1995, p 481
32. Rutkow IM, Robbins AW: Groin hernia surgery in an office-based surgical suite. *In* Nyhus L, Condon R (eds): Hernia, ed 4. Philadelphia, JB Lippincott, 1995, p 250
33. Rutkow IM, Robbins AW: Hernia repair: The mesh plug hernia repair. *In* Carter DC, Russell RCG, Pitt HA (eds): Atlas of General Surgery, ed 3. London, Chapman & Hall, 1996, p 59
34. Rutkow IM, Robbins AW: Hernioplastik mit der Netzplombe. Chirurg 68:970, 1997
35. Rutkow IM, Robbins AW: The Marlex mesh PerFix groin hernioplasty. Eur J Surg 164:549, 1998
36. Rutkow IM, Robbins AW: The mesh-plug groin hernia repair. *In* Bendavid R (ed): Prostheses and Abdominal Wall Hernias. Austin, RG Landes, 1994, p 106
37. Rutkow IM, Robbins AW: Mesh plug hernia repair: A follow-up report. Surgery 117:597, 1995
38. Rutkow IM, Robbins AW: The mesh plug technique for recurrent groin herniorrhaphy: A 9 year experience of 407 repairs. Surgery, in press
39. Rutkow IM, Robbins AW: Open mesh plug hernioplasty. Prob Gen Surg 12:121, 1995
40. Rutkow IM, Robbins AW: Open tensionless mesh-plug groin herniorrhaphy. *In* Skandalakis L, Gadacz T, Mansberger A, et al (eds): Modern Hernia Repair, ed 2. New York, Parthenon, 1996, p 204
41. Rutkow IM, Robbins AW: Recurrent inguinal hernias. *In* Cameron J (ed): Current Surgical Therapy, ed 6. St Louis, Mosby–Year Book, 1998
42. Rutkow IM, Robbins AW: "Tension-free" inguinal herniorrhaphy: A preliminary report on the "mesh plug" technique. Surgery 114:3, 1993
43. Shulman AG, Amid PK, Lichtenstein IL: The "plug" repair of 1402 recurrent inguinal hernias. Arch Surg 125:265, 1990
44. Shulman AG, Amid PK, Lichtenstein IL: Plug repair of recurrent inguinal hernias. Contemp Surg 40:30, 1992
45. Shulman AG, Amid PK, Lichtenstein IL: Prosthetic mesh plug repair of femoral and recurrent inguinal hernias: The American experience. Ann R Coll Surg Engl 74:97, 1992
46. Stoppa R, Wantz GE, Munegato G, et al (eds): Hernia Healers, An Illustrated History. Velizy Villacoublay, France, Arnette, 1998, p 60
47. Usher FC, Hill J, Ochsner J: Hernia repair with Marlex mesh. Surgery 46:718, 1959
48. Usher FC, Ochsner J, Tuttle LD: Use of Marlex mesh in the repair of incisional hernias. Am Surg 24:969, 1958

49. Wantz GE: Experience with the tension-free hernioplasty for primary inguinal hernias in men. J Am Coll Surg 183:351, 1996
50. Wantz GE: Inguinal hernia repair: *In* reply. J Am Coll Surg 186:104, 1998
51. Wutzer CW: Ueber radicale Heilung beweglicher Leisten-Brüche. *In* Naumann MEA, Wutzer CW, Kilian HF (eds): Organ für die gesammte Heilkunde. Bonn, Henry & Cohen, 1841, p 1
52. Zieren J, Zieren HU, Jacobi CA, et al: The plug and patch technique for inguinal hernia repair in adults. Zentrabl Chir 122:545, 1997
53. Zieren J, Zieren HU, Jacobi CA, et al: Prospective randomized study comparing laparoscopic and open tension-free inguinal hernia repair with Shouldice's operation. Am J Surg 175:330, 1998
54. Zieren J, Zieren HU, Wenger FA, et al: Laparoskopische oder konventionelle Reparation der Leistenhernie mit Kunststoffnetzen? Langenbecks Arch Chir 381:289, 1996

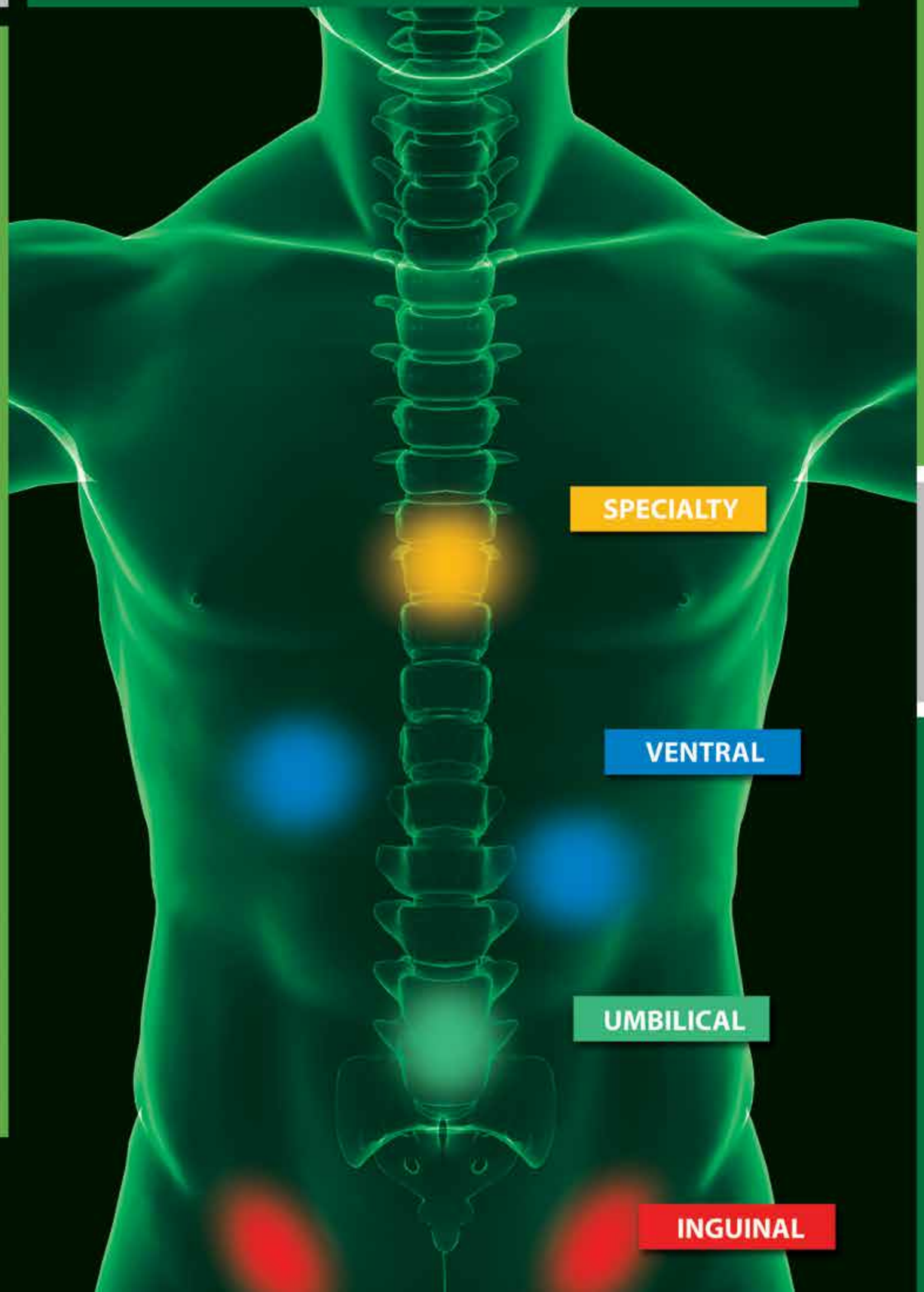
Address reprint requests to
Ira M. Rutkow, MD, MPH, DrPH
7 Pamela Street
Marlboro, NJ 07746-1621

BARD
DAVOL INC.

CATÁLOGO DE PRODUTOS

Inguinal, Ventral, Umbilical, Fixadores,
Implantes Biológicos, Hemostáticos

REPARO DE TECIDOS MOLES.
PROCEDIMENTO CORRETO.
PRODUTO CORRETO.
RESULTADO CORRETO.



BARD

100 ANOS DE QUALIDADE,
INTEGRIDADE, SERVIÇO E INOVAÇÃO

Inguinal, Ventral, Umbilical, Fixadores, Implantes Biológicos, Hemostáticos

REPARO DE TECIDOS MOLES.
PROCEDIMENTO CORRETO.
PRODUTO CORRETO.
RESULTADO CORRETO.

Bard™ Mesh

TELA PLANA - 100% POLIPROPILENO

Tela plana de polipropileno monofilamentar, de alta gramatura, sintética, indicada para reparos de hérnias inguinais, femorais e ventrais, além de correção de defeitos da parede abdominal.
Marca Bard - Davol Inc, procedência EUA.
Densidade 105g/m^2, Tamanho do poro 0,55mm^2.

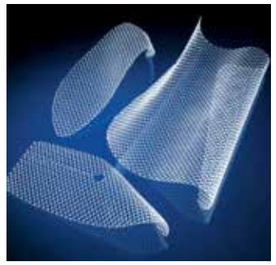
REF	TAMANHO
0112640	1" x 4" (2.5cm x 10cm)
0112650	2" x 4" (5cm x 10cm)
0112660	10" x 14" (25cm x 35.5cm)
0112670	2" x 12" (5cm x 30.5cm)
0112680	3" x 6" (7.5cm x 15cm)
0112720	6" x 6" (15cm x 15cm)
0112700	Pre-shaped, 1.8" x 4" (4.5cm x 10cm)
0112710	Pre-shaped with spermatic cord opening, 1.8" x 4" (4.5cm x 10cm)
0113700	Large Pre-shaped, 2.4" x 5.4" (6cm x 13.7cm)
0113710	Large Pre-Shaped with spermatic cord opening, 2.4" x 5.4" (6cm x 13.7cm)

RMS 80689090038

Soft Mesh Bard™

TELA PLANA - 100% POLIPROPILENO

Tela plana de polipropileno monofilamentar, de baixa gramatura, sintética, indicada para reparos de hérnias inguinais, femorais e ventrais, além de correção de defeitos da parede abdominal.
Marca Bard - Davol Inc, procedência EUA.
Densidade 44g/m^2, Tamanho do poro 6,29mm^2.



REF	TAMANHO
0117008	2" x 4" (5cm x 10cm)
0117009	3" x 6" (7.5cm x 15cm)
0117010	4" x 6" (10cm x 15cm)
0117011	6" x 6" (15cm x 15cm)
0117012	Pre-shaped, 1.8" x 4.0" (4.5cm x 10cm)
0117013	Pre-shaped with keyhole, 1.8" x 4.0" (4.5cm x 10cm)
0117014	Large Pre-shaped, 2.4" x 5.4" (6cm x 13.7cm)
0117015	Large Pre-shaped with keyhole, 2.4" x 5.4" (6cm x 13.7cm)
0117016	12" x 12" (30,5cm x 30,5cm)

RMS 80689090039

PerFix™ Light Plug

TELA ESPECIAL SISTEMA DUPLO

Tela tridimensional de polipropileno, monofilamentar, de baixa gramatura, sintética, com sistema duplo constituído de uma camada externa canelada e pétalas internas unidas em forma de cone, mais uma tela pré-moldada independente deste dispositivo a fim de evitar hérnias adjacentes. Permite reparo anterior e posterior de hérnias inguinais e femorais. Marca Bard - Davol Inc, procedência EUA. Densidade: 59g/m^2. Tamanho do poro: 6,29mm^2.

REF	TAMANHO
0117050	Small PerFix Light Plug, 1.0" x 1.4" (2.5cm x 3.4cm)
0117060	Medium PerFix Light Plug, 1.3" x 1.6" (3.3cm x 3.9 cm)
0117070	Large PerFix Light Plug, 1.6" x 1.9" (4.1 cm x 4.8 cm)
0117080	Extra Large PerFix Light Plug, 1.5" x 2.0" (3.8 cm x 5.0 cm)
0117150	Small PerFix Light Plug, 1.0" x 1.4" (2.5 cm x 3.4cm)
0117160	Medium PerFix Light Plug, 1.3" x 1.6" (3.3 cm x 3.9cm)
0117170	Large PerFix Light Plug, 1.6" x 1.9" (4.1cm x 4.8 cm)
0117180	Extra Large PerFix Light Plug, 1.5" x 2.0" (3.8 cm x 5.0 cm)

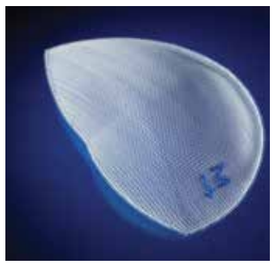
RMS 80689090037

Código SUS	Descrição SUS	Tela Bard Correspondente
07.02.05.054-7	Tela inorgânica de polipropileno com sistema duplo	Perfix Light Plug – todos os códigos
07.02.05.055-5	Tela inorgânica de polipropileno grande (acima de 401cm^2)	Bard mesh – código 0112660 Soft mesh - código 0117016
07.02.05.056-3	Tela inorgânica de polipropileno média (101 a 400cm^2)	Bard mesh – códigos 0112670, 0112680, 0112720 Soft mesh – códigos 0117009, 0117010, 0117011
07.02.05.057-1	Tela inorgânica de polipropileno pequena (até 100 cm^2)	Bard mesh – códigos 0112640, 0112650 Soft mesh – códigos 0117008, 0117012, 0117013, 0117014, 0117015.

3DMax™ Mesh

TELA ESPECIAL INGUINAL

Tela tridimensional de polipropileno, monofilamentar, de alta gramatura, sintética, pré-moldada com formato anatômico da região inguinal. Extremidades seladas e marcador medial(M) que auxilia o posicionamento correto da tela durante o procedimento de reparo de hérnias por via laparoscópica. O formato tridimensional e o posicionamento correto pode reduzir a necessidade de fixação com grampos ou colas. Marca Bard - Davol Inc, procedência EUA. Densidade: 148g/m^2. Tamanho do poro: 0,55mm^2.



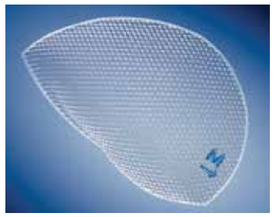
REF	TAMANHO
0115310	Medium, Left 3DMax Mesh, 3" x 5" (8.5cm x 13.7cm)
0115311	Large, Left 3DMax Mesh, 4" x 6" (10.8cm x 16.0cm)
0115312	Extra-Large, Left 3DMax Mesh w/Orientation Markers, 5" x 7' (12.4cm x 17.3cm)
0115320	Medium, Right 3DMax Mesh, 3" x 5" (8.5cm x 13.7cm)
0115321	Large, Right 3DMax Mesh, 4" x 6" (10.8cm x 16.0cm)
0115322	Extra-Large, Right 3DMax Mesh w/Orientation Markers, 5" x 7' (12.4cm x 17.3cm)

RMS 80689090059

3DMax™ Light Mesh

TELA ESPECIAL INGUINAL

Tela tridimensional de polipropileno, monofilamentar, de baixa gramatura, sintética, pré-moldada com formato anatômico da região inguinal. Extremidades seladas e marcador medial(M) que auxilia o posicionamento correto da tela durante o procedimento de reparo de hérnias por via laparoscópica. O formato tridimensional e o posicionamento correto pode reduzir a necessidade de fixação com grampos ou colas. Marca Bard - Davol Inc, procedência EUA. Densidade: 42g/m^2. Tamanho do poro: 6,29mm^2.



REF	TAMANHO
0117310	Left, Medium, 3.1" x 5.3" (7.9cm x 13.4cm)
0117311	Left, Large, 4.1" x 6.2" (10.3cm x 15.7cm)
0117312	Left, Extra-Large, 4.8" x 6.7" (12.2cm x 17.0 cm)
0117320	Right, Medium, 3.1" x 5.3" (7.9cm x 13.4cm)
0117321	Right, Large, 4.1" x 6.2" (10.3cm x 15.7cm)
0117322	Right, Extra-Large, 4.8" x 6.7" (12.2cm x 17.0 cm)

RMS 80689090052

Sepramesh™ IP Composite

TELA ESPECIAL VENTRAL - BARREIRA ABSORVÍVEL

Tela separadora de tecidos semi-absorvível, composta por uma face parietal de polipropileno monofilamentar e uma face visceral revestida de Hidrogel (hialuronato de sódio, carboximetilcelulose e fibras de polietilenoglicol interligando as duas faces) absorvido em 30 dias. Desenvolvida com tecnologia Sepra para cirurgias intra-abdominais via laparoscópica ou aberta. Marca Bard - Davol Inc, procedência EUA. Densidade do polipropileno: 101g/m^2. Densidade total da tela revestida: 234g/m^2. Tamanho do poro: 0,35mm^2.

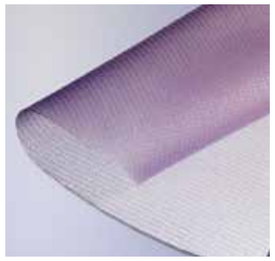
REF	TAMANHO
5959360	3" x 6" (7.6 cm x 15.2 cm) Rectangle
5959480	4" x 8" (10.2 cm x 20.3 cm) Rectangle
5959680	6" x 8" (15.2 cm x 20.3 cm) Rectangle
5959812	8" x 12" (20.3 cm x 30.5 cm) Rectangle
5959124	12" x 14" (30.5 cm x 35.6 cm) Rectangle

RMS 80689090036

Ventralight™ ST Mesh

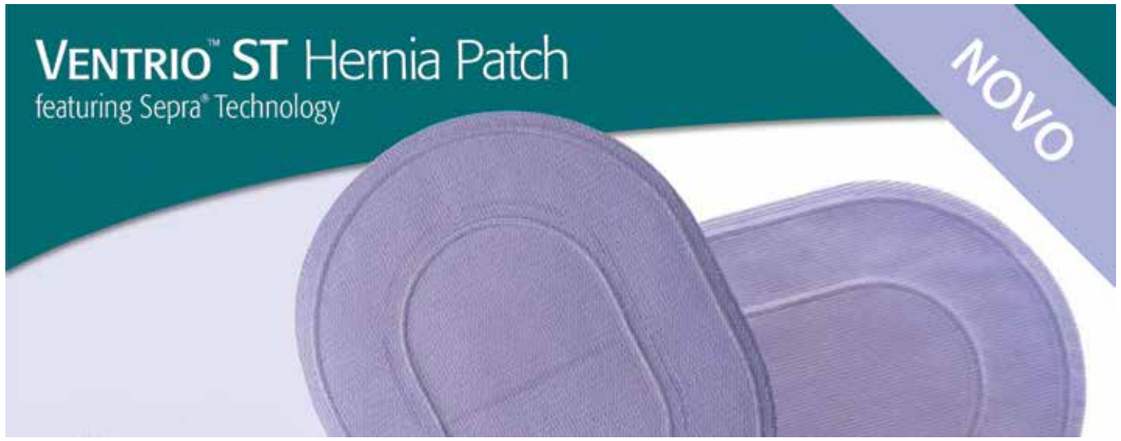
TELA ESPECIAL VENTRAL - BARREIRA ABSORVÍVEL

Tela separadora de tecidos semi-absorvível, composta por uma face parietal de polipropileno monofilamentar e uma face visceral revestida de Hidrogel (hialuronato de sódio, carboximetilcelulose e fibras de polietilenoglicol interligando as duas faces) absorvido em 30 dias. Desenvolvida com tecnologia Sepra para cirurgias intra-abdominais via laparoscópica ou aberta. Marca Bard - Davol Inc, procedência EUA. Densidade do polipropileno: 51 g/m^2. Densidade total da tela revestida: 213 g/m^2. Tamanho do poro: 0,40 mm^2.



REF	TAMANHO
5954450	(11,4 cm) Círculo
5954460	(10,2 cm x 15,2 cm) Elipse
5954680	(15,2 cm x 20,3 cm) Elipse
5954610	(15,2 cm x 25,4 cm) Oval
5954790	(17,8 cm x 22,9 cm) Elipse
5954810	(20,3 cm x 25,4 cm) Elipse
5954113	(25,4 cm x 33,0 cm) Elipse
5954124	(30,5 cm x 35,6 cm) Retângulo

RMS 80689090020



Ventrio™ ST

TELA ESPECIAL VENTRAL - BARREIRA ABSORVÍVEL

Tela separadora de tecidos semi-absorvível, composta por uma face parietal de polipropileno monofilamentar de baixa gramatura com bolsos e anéis para facilitar o posicionamento, e uma face visceral revestida de Hidrogel (hialuronato de sódio, carboximetilcelulose e fibras de polietilenoglicol interligando as duas faces) absorvido em 30 dias. Desenvolvida com tecnologia Sepra para cirurgias intra-abdominais via aberta. Marca Bard - Davol Inc, procedência EUA.
Densidade do polipropileno 37g/m2. Densidade total da tela revestida 101g/m2. Tamanho do poro 4,5mm2

REF	TAMANHO
5950030	3.1" x 4.7" (8.0 cm x 12.0 cm) Small Oval
5950040	4.3" x 5.5" (11.0 cm x 14.0 cm) Medium Oval
5950050	5.4" x 7.0" (13.8 cm x 17.8 cm) Large Oval
5950010	3.0" (7.6 cm diameter) Small Circle
5950020	4.5" (11.4 cm diameter) Large Circle
5950070	7.7" x 9.7" (19.6 cm x 24.6 cm) Extra Large Oval
5950080	8.7" x 10.7" (22.1 cm x 27.1 cm) Extra Large Oval
5950090	10.8" x 13.7"" (27.4 cm x 34.9 cm) Extra Large Oval
5950060	6.1" x 10.1" (15.5 cm x 25.7cm) Midline

RMS 80689090029

Ventralight™ ST Echo PS™

TELA ESPECIAL VENTRAL - BARREIRA ABSORVÍVEL

Tela separadora de tecidos semi-absorvível, composta por uma face parietal de polipropileno monofilamentar e uma face visceral revestida de Hidrogel (hialuronato de sódio, carboximetilcelulose e fibras de polietilenoglicol interligando as duas faces) absorvido em 30 dias, tecnologia Sepra. Sistema Echo de posicionamento acoplado a tela, constituído de um balão inflável que facilita o implante da prótese, incluindo o desenrolar da tela, posicionamento e a colocação propriamente dita durante o processo laparoscópico. Após a fixação da prótese, o balão é desinsuflado e removido rapidamente do abdomen. Marca Bard - Davol Inc, procedência EUA.
Densidade do polipropileno: 51 g/m2. Densidade total da tela revestida: 213 g/m2. Tamanho do poro: 0,40 mm2.

REF	TAMANHO
5955600	(15,2 cm) Círculo
5955680	(15,2 cm x 20,3 cm) Elipse
5955610	(15,2 cm x 25,4 cm) Oval
5955790	(17,8 cm x 22,9 cm) Elipse
5955800	(20,3 cm) Circular
5955810	(20,3 cm x 25,4 cm) Elipse

RMS 80689090057

Composix™ E/X Mesh

TELA ESPECIAL VENTRAL - BARREIRA PERMANENTE

Tela separadora de tecidos, composta por uma face parietal de polipropileno monofilamentar de alta gramatura, uma face visceral de e-ptfe submicrônico (politetrafluoretileno expandido) e acabamento com overlap de 5mm do e-ptfe sobre a face parietal. Fácil manipulação durante os reparos de hérnias ventrais por via aberta ou laparoscópica. Marca Bard - Davol Inc, procedência EUA. Densidade total da tela (polipropileno e e-ptfe): 262g/m^2. Tamanho do poro polipropileno: 0,55mm^2, tamanho do poro e-ptfe: 0,00033mm^2.

REF	TAMANHO
0123460	4" x 6" (10cm x 15cm) Elliptical
0123680	6" x 8" (15cm x 20cm) Elliptical
0123790	7" x 9" (18cm x 23cm) Elliptical
0123810	8" x 10" (20cm x 25cm) Elliptical
0123113	10" X 13" (25cm x 33cm) Elliptical
0123114	10" x 14" (25cm x 36cm) Rectangular

RMS 10178010117

Composix™ L/P Mesh

TELA ESPECIAL VENTRAL - BARREIRA PERMANENTE

Tela separadora de tecidos, composta por uma face parietal de polipropileno monofilamenar de baixa gramatura, uma face visceral de e-ptfe submicrônico (politetrafluoretileno expandido) e acabamento com overlap de 5mm do e-ptfe sobre a face parietal. Fácil manipulação durante os reparos de hérnias ventrais por via aberta ou laparoscópica. Os 5 maiores tamanhos possuem um dispositivo para auxiliar a introdução da tela na cavidade. Marca Bard - Davol Inc, procedência EUA. Densidade total da tela (polipropileno e e-ptfe): 218g/m^2. Tamanho do poro polipropileno: 6,29mm^2, tamanho do poro e-ptfe: 0,00033mm^2.

REF	TAMANHO
0134450	4.5" (11.4 cm) Circle
0134460	4.2" x 6.2" (10.8cm x 15.9cm) Elliptical
0134680	6.2" x 8.2" (15.9cm x 21.0cm) Elliptical
0134610	6.2" x 10.2" (15.9cm x 26.1cm) Oval
0134790	7.2" x 9.2" (18.4cm x 23.5cm) Elliptical
0134810	8.2" x 10.2" (21.0cm x 26.1cm) Elliptical
0134113	10.2" x 13.2" (26.1cm x 33.7cm) Elliptical
0134114	10.2" x 14.2" (26.1cm x 36.2cm) Rectangle

RMS 80689090040 / RMS 80689090041 (com introdutor)

XenMatrix™

IMPLANTES BIOLÓGICOS

Implante Biológico com estrutura de colágeno porcino non cross linked, permitindo a infiltração celular precoce e revascularização sem perda significativa de resistência durante o período de cicatrização. Marca Bard – Davol Inc, procedência EUA.

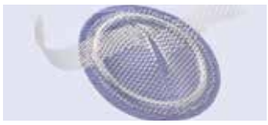
REF	TAMANHO
1161015	Retângulo 10 x 15cm
1161020	Retângulo 10 x 20cm
1161028	Retângulo 10 x 28cm
1161520	Retângulo 15 x 20cm
1161525	Retângulo 15 x 25cm
1162020	Quadrado 20 x 20cm
1162025	Retângulo 20 x 25cm
1161928	Retângulo 19 x 28cm
1161935	Retângulo 19 x 35cm

RMS 80689090051

Ventralex™ ST Hernia Patch

TELA ESPECIAL UMBILICAL - BARREIRA ABSORVÍVEL

Tela separadora de tecidos semi-absorvível, composta por uma face parietal de polipropileno monofilamentar de baixa gramatura e uma face visceral revestida de Hidrogel (hialuronato de sódio, carboximetilcelulose e fibras de polietilenoglicol interligando as duas faces) absorvido em 30 dias, tecnologia Sepra. Possui anel de memória, o que facilita o implante intra-abdominal durante os reparos por via aberta de hérnias umbilicais, pequenas hérnias ventrais e fechamento de incisões de trocartes. Marca Bard – Davol Inc, procedência EUA. Densidade do polipropileno 37g/m2. Densidade total da tela revestida 101g/m2. Tamanho do poro 4,5mm2



REF	TAMANHO
5950007	Ventralex ST Circular 4.3 cm
5950008	Ventralex ST Circle 6.4 cm
5950009	Ventralex ST Circle 8.0 cm

RMS 80689090054

Ventralex™ Hernia Patch

TELA ESPECIAL UMBILICAL - BARREIRA PERMANENTE

Tela separadora de tecidos, composta por uma face parietal de polipropileno monofilamentar com bolsos para facilitar o posicionamento, uma face visceral de e-ptfe submicrônico (politetrafluoretileno expandido) e acabamento com overlap de 5mm do e-ptfe sobre a face parietal. Possui anel de memória, o que facilita o implante intra-abdominal durante os reparos por via aberta de hérnias umbilicais, pequenas hérnias ventrais e fechamento de incisões de trocartes. Marca Bard - Davol Inc, procedência EUA. Densidade total da tela (polipropileno e e-ptfe): 299g/m^2. Tamanho do poro polipropileno: 0,42mm^2, tamanho do poro e-ptfe: 0,00033mm^2.

REF	TAMANHO
0010301	Small Circle w/strap, 1.7" (4.3cm) diameter
0010302	Medium circle w/strap, 2.5" (6.4cm) diameter
0010303	Large Circle with Strap, 3.2" (8.0cm) diameter

RMS 10178010251

PermaFix™

FIXADOR - SISTEMA DE FIXAÇÃO PERMANENTE

Dispositivo para fixação, estéril e de utilização única indicado para fixação de telas e aproximação de tecidos moles. Possui opções com 15 e 30 fixadores permanentes de polímero. Os fixadores têm 6,7mm e penetram 5mm no tecido. O dispositivo de fixação possui uma cânula com 36cm de comprimento e 5mm de diâmetro externo e pode ser utilizado em cirurgias abertas e laparoscópicas. Ambas as opções possuem contadores de disparos na parte posterior do dispositivo de fixação.

REF	QUANTIDADE
0113119	15 Grampos permanentes
0113120	30 Grampos permanentes

RMS 80689090058

SorbaFix™

FIXADOR - SISTEMA DE FIXAÇÃO ABSORVÍVEL

Dispositivo para fixação, estéril e de utilização única indicado para fixação de telas e aproximação de tecidos moles. Possui opções com 15 e 30 fixadores absorvíveis de PDLA (derivado do ácido láctico). Os fixadores têm 6,7mm, penetram 5 mm no tecido e são reabsorvidos em aproximadamente 12 meses. O dispositivo de fixação possui uma cânula com 36cm de comprimento e 5mm de diâmetro externo e pode ser utilizado em cirurgias abertas ou laparoscópicas. Ambas as opções possuem contadores de disparos na parte posterior do dispositivo de fixação.

REF	QUANTIDADE DE FIXADORES
0113115	15 fixadores absorvíveis
0113116	30 fixadores absorvíveis

RMS 10178010269

Arista™ AH

HEMOSTÁTICOS

Hemostático em pó, absorvível, derivado de vegetal, acelera o processo de coagulação em sangramentos capilares, venosos e arteriais, para atingir a hemostasia em minutos independente do status de coagulação do paciente. Utilizado em cirurgias abertas e laparoscópicas. Não é necessário refrigeração, sem mistura, pronto para uso.

REF	TAMANHO
SM0005-USA	1g (partículas hemostático absorvível) – 5 un
SM0002-USA	3g (partículas hemostático absorvível) – 5 un
AM0005	10/cs. - Aplicador com 38 cm

RMS 80114540007

Avitene™

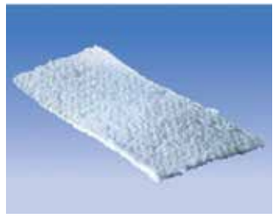
HEMOSTÁTICOS

Hemostático absorvível, derivado de colágeno bovino ativo microfibrilar, acelera o processo de coagulação através da agregação plaquetária e liberação de proteínas para a formação de fibrina, resultando em hemostasia rapidamente. Utilizado em cirurgias abertas e laparoscópicas, possui 5 apresentações: Pó, Folhas (Sheets), EndoAvitene, Seringa pré carregada e Esponja (Ultrafoam).

Avitene™ Flour

REF	TAMANHO
1010010	0,5g – 6 un
1010020	1g – 6 un
1010590	5g – 6 un

Avitene™ Sheets
(Non-woven web)



REF	TAMANHO
1010080	3,5 cm x 3,5 cm – 6 un
1010090	7,0 cm x 3,5 cm – 6 un
1010110	7,0 cm x 7,0 cm – 6 un

EndoAvitene™ Collagen Hemostat

REF	TAMANHO
1010150	10 mm EndoAvitene™ Collagen - 6 un 50 mm x 15 mm x 1 mm preloaded sheet - 6 un 1 mm diameter, 42 cm usable length - 6 un
1010260	5 mm EndoAvitene™ Collagen - 6 un 50 mm x 5 mm x 1 mm preloaded sheet - 6 un 5 mm diameter, 42 cm usable length - 6 un

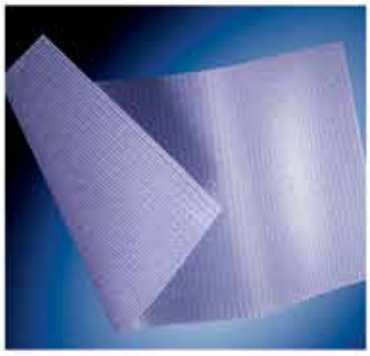
SyringeAvitene™ Collagen Hemostat

REF	TAMANHO
1010340	1 gram SyringeAvitene™ Collagen - 6 un 1 gram preloaded flour - 6 un 2 cm (0,8") diameter - 6 un 16,5 cm (6,5") usable length - 6 un

Avitene™ UltraFoam™ Collagen Sponge

REF	TAMANHO
1050020	2,0 cm x 6,25 cm x 7 mm (12,5 sq cm ¾" x 2½" x ¼") - 12 un
1050030	8.0 cm x 6,25 cm x 1 cm (50 sq cm 31⁄8" x 2½" x 3⁄8") - 6 un
1050040	8,0 cm x 12,5 cm x 1 cm (100 sq cm 31⁄8" x 5" x 3⁄8") - 6 un
1050050	8,0 cm x 12,5 cm x 3 mm (100 sq cm/Thin 31⁄8" x 5" x 1⁄8") - 6 un

RMS 10210550044, RMS 10355870078



Distribuidor autorizado:

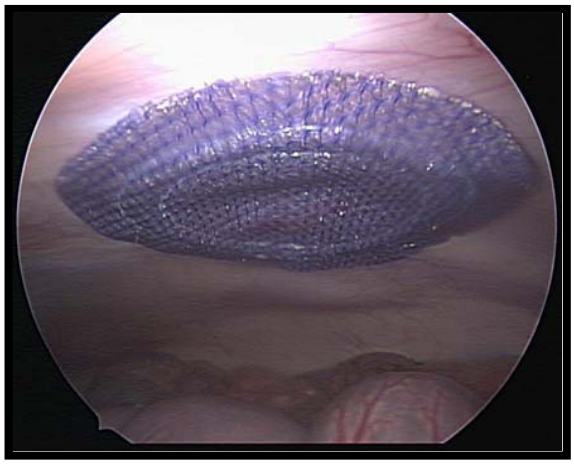
Davol Inc. Subsidiária de
C.R. Bard, Inc.
100 Crossing Boulevard
Warwick, RI 02886
1.800.556.6275

Bard Brasil
Rua Alexandre Dumas, 2.100 • 10º andar
Ed. Corporate Center • Chác. Sto. Antonio
04717-004 • São Paulo • SP • Brasil
Tel/Fax: + 55 11 5180-0200
www.davol.com

BARD
DAVOL INC.

Ventralex™ ST Hernia Patch:

Characterization of Adhesion, Contracture and Histological properties following *in vivo* implantation, as compared to an Oxidized Regenerated Cellulose Barrier Device in a porcine model



Jeffrey R. Scott, Ph.D., Jesse O. Hansen, B.S., M.B.A., Robert E. Richard, Ph.D.

C.R. Bard, Inc. – Davol, Warwick, RI

ABSTRACT

Ventralex™ ST Hernia Patch (VxST) [C.R. Bard, Inc. - Davol, Warwick, RI] is an implantable device designed to repair small hernias (such as umbilical and trocar site hernias). The product is designed with a polypropylene anterior mesh layer to allow rapid tissue ingrowth and a posterior layer composed of Sepramesh™ IP Composite [C.R. Bard, Inc. - Davol, Warwick, RI]. The Sepramesh™ IP Composite layer possesses a bioresorbable coating which minimizes peritoneal tissue attachments (adhesions) to the prosthesis. The anterior mesh layer is composed of a light-weight large-pore knitted structure which features a pocket and straps to facilitate positioning, ease of use and fixation. In addition, the product also relies on a bioresorbable recoil ring which allows the device to be folded for insertion while retaining its planar shape for flat positioning against the abdominal wall. The primary objective of this preclinical study was to evaluate the performance of the Ventralex™ ST Hernia Patch and Proceed™ Ventral Patch (PVP) [Ethicon, Inc., Somerville, NJ] over a short-term two week follow-up period, prior to complete absorbable barrier resorption. Peritoneal tissue attachment (adhesion), mesh contracture and histological properties were evaluated following bilateral implantation/fixation in a clinically-relevant porcine model of simulated open ventral hernia repair. The study population consisted of 8 female Yorkshire pigs [(two groups; n=4 animals/group; 2 devices/animal)], which were euthanized at 2 weeks post-implantation. Ventralex™ ST Hernia Patch demonstrated significantly less peritoneal tissue attachment (adhesion) severity and percent area coverage, as compared to PVP. Ventralex™ ST Hernia Patch also demonstrated significantly less percent area mesh contracture, as compared to PVP. Furthermore, histological analysis demonstrated a robust host inflammatory/fibrotic response for PVP associated with marked macrophage, lymphocyte, giant cell, neutrophil, and eosinophil infiltration, and fibrosis which was greater than that observed for Ventralex™ ST Hernia Patch. In summary, Ventralex™ ST Hernia Patch demonstrated significantly less peritoneal tissue attachments (adhesions), mesh contracture, and a reduced host inflammatory/fibrotic response, as compared to PVP when evaluated in a porcine model of simulated open ventral hernia repair over a short-term two week follow-up period.

INTRODUCTION

Recent advances in synthetic materials and techniques for surgical hernia repair/soft tissue reconstruction have resulted in reduced patient recovery time, stronger repairs, and fewer complications.[1, 2] The Ventralex™ Hernia Patch [C.R. Bard, Inc. - Davol, Warwick, RI], a self-expanding polypropylene and expanded polytetrafluoroethylene (ePTFE) based device, represents one such innovation for the repair of small hernias (such as umbilical) and trocar site deficiencies. Ventralex™ Hernia Patch incorporates an internal recoil ring and anterior positioning strap to facilitate proper device insertion, placement and fixation. Ventralex™ Hernia Patch was introduced in 2002, and has been successfully implanted in patients worldwide with acceptable clinical outcomes.[3-6] Products like this have demonstrated acceptable

outcomes, and these repairs primarily require the permanent implantation of foreign synthetic materials, such as polypropylene, polyester, and/or ePTFE.[7] There is a growing trend towards the use of absorbable (non-permanent) materials for soft tissue repair. The intent is to reduce the volume of foreign material permanently implanted into the patient, while not compromising clinical outcomes. Proceed™ Surgical Mesh [Ethicon, Inc., Somerville, NJ], and Sepramesh™ IP Composite represent two such product innovations recently developed for laparoscopic ventral hernia repair. These products incorporate absorbable barriers primarily comprised of Oxidized Regenerated Cellulose (ORC) (Proceed™), and chemically modified sodium hyaluronate (HA), carboxy-methylcellulose (CMC) and polyethylene glycol (PEG) hydrogel (Sepramesh™ IP) respectively. Recently the ORC barrier utilized in Proceed™ Surgical Mesh, has been incorporated into an umbilical hernia patch (PVP).[8]

The design of Ventralex™ ST Hernia Patch incorporates the Sepramesh™ IP Composite technology, which minimizes peritoneal tissue attachments (adhesions) to the prosthesis while retaining the design of the Ventralex™ Hernia Patch.[3-6] Additional improvements to that design include a bioabsorbable recoil ring (poly-dioxanone) and a lighter weight anterior mesh, both of which serve to reduce the volume of permanently implanted material for the patient.

Therefore, the primary objective of this preclinical study was to evaluate the performance of the Ventralex™ ST Hernia Patch and PVP over a short-term two week follow-up period, prior to complete absorbable barrier resorption. Peritoneal tissue attachment (adhesion), mesh contracture and histological properties were evaluated following bilateral implantation/fixation in a clinically-relevant porcine model of simulated open ventral hernia repair.

METHODS

Study Population:

The study population consisted of 8 female Yorkshire (Sus Scrofa) pigs (implant weight: 51.0 ± 2.5 kg; explant weight: 55.4 ± 4.1. kg),

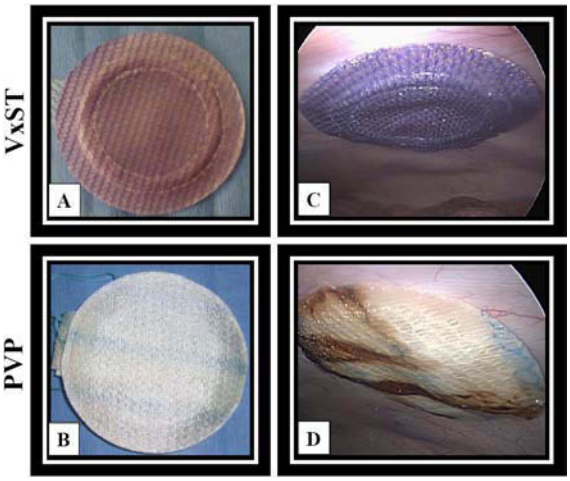


Figure 1. Implantation

Representative photographs of Ventralex™ ST Hernia Patch (VxST) (top) and PVP (bottom) pre-implantation (A, B) and immediately post-implantation (C, D).

which were randomly divided into two groups of 4 pigs, and each bilaterally implanted intra-peritoneally with either Ventralex™ ST Hernia Patch or PVP within a given pig respectively (2 devices / animal) (Mean ± SD).

Implantation:

Following preparation of the ventral abdomen for aseptic surgery, one midline camera trocar hole (12 mm), and two lateral trocar holes (12 mm) were made following abdominal insufflation, one on each side of the abdomen. Following bilateral trocar removal, a 1.9 cm skin incision was made at each trocar hole site, to accommodate the insertion and placement of two 6.4 cm diameter Ventralex™ ST Hernia Patch or PVP devices into the abdominal (intra-peritoneal) cavity (one device/trocar-incision site). Each device was measured, folded in the direction of the anterior strap(s), inserted through the trocar incision, one on the left and one on the right side of abdomen, and expanded within the peritoneal cavity. The anterior straps were used to further position and center each device in place. The device straps were then fixated to the abdominal wall in the subcutaneous plane with interrupted trans-fascial 3-0 Prolene™ sutures. The straps were then cut to closely approximate the plane of the abdominal wall. Although Ventralex™ ST Hernia Patch can be additionally fixated utilizing the anterior polypropylene pocket, for

the purpose of direct comparability to PVP each device was only fixated via the anterior straps. Laparoscopy was performed immediately following implantation to ensure that each device was lying flat in the intra-peritoneal space. Each device was laparoscopically photographed and the abdomen was slowly desufflated to ensure proper fixation and product orientation. Midline and lateral trocar incisions were repaired with standard closure techniques. Pigs were then recovered from anesthesia and allowed free access to food and water *ad libitum*.

Explantation:

Prior to explantation, laparoscopy was performed and recorded to assess the test articles via offline video playback analysis. The overlying skin and adipose tissue were then removed from the entire abdomen, and the abdomen was dissected bilaterally in a caudal direction. The abdominal cavity was slowly opened to expose each device, which were photographed for the case record. The entire abdominal wall was then resected, photographed, and visually inspected to assess the integrity of the each device, associated peritoneal tissue attachments (adhesions) and mesh contracture. Each device was then carefully dissected to prepare two (2) representative mesh specimens that were immersion-fixed in 10% neutral buffered formalin for further histological processing.

Peritoneal Tissue Attachment:

Peritoneal tissue attachments (adhesions) were evaluated by two methods.

1) Scoring: Grading of peritoneal tissue attachment (adhesion) severity utilizing the following scoring scale.

0. No Adhesions Observed

1. Loose adhesion requiring blunt dissection only

2. Firm adhesion requiring sharp dissection, (without extensive vascularity)

3. Firm adhesion requiring sharp dissection, (with extensive vascularity)

4. Firm adhesion requiring sharp dissection, with extensive fibrotic ingrowth, (with extensive vascularity)

5. Grade 4, with firm attachment to visceral organs (bowel, liver, spleen)

2) Percent peritoneal tissue attachment (adhesion) coverage: offline morphometric photographic assessment utilizing ImageJ version 1.44 image analysis software, provided by the National Institutes of Health [Bethesda, MD]. ImageJ image analysis software was utilized to quantify the percent peritoneal tissue attachment (adhesion) coverage for each device. Individual photographs were taken of each device following explantation utilizing a Fujifilm FinePix V10 5.1 megapixel digital camera [Fujifilm, Greenwood, SC], with a ruler fixated in the frame. Each digital photograph was individually imported into ImageJ software, and calibrated utilizing the fixed scale in each image. The percent peritoneal tissue attachment (adhesion) coverage was calculated by subtracting the total open test article area from the total test article area. This resulted in the determination of the total peritoneal tissue attachment (adhesion) area. The total peritoneal tissue attachment (adhesion) area was then divided by the total test article area and multiplied by 100 to yield an overall percentage of peritoneal tissue attachment (adhesion) coverage (see formulas below).

1. [(Total Test Article Area) – (Total Open Area)] = Total Adhesion Area

2. [(Total Adhesion Area) / (Total Test Article Area)] x 100 = % Coverage

Mesh Contracture:

The area of each test article was determined using the offline image analysis technique documented above using the formula below:

1. [(Implant Area – Explant Area) / (Implant Area)] x 100 = % Area Contracture

Histological Analysis:

All histological analysis was conducted by an independent board certified veterinary pathologist at Charles River Laboratories - Pathology Associates [Frederick, MD]. The explanted immersion-fixed (10% neutral

buffered formalin) devices (with tissue) were cross-sectioned and a sample taken for paraffin processing, embedding, and sectioning. Paraffin embedded sections (~4-5 microns) were mounted onto glass slides and stained with H&E and/or Masson's Trichrome. Ventralex™ ST Hernia Patch specimens were evaluated to determine the host inflammatory/fibrotic response, as compared to PVP following *in vivo* implantation over a short-term two week follow-up period. The host response associated with each device was evaluated based on the standardized scoring system defined by Charles River Laboratories - Pathology Associates [Frederick, MD] outlined below. Briefly, specimens were scored for inflammatory cell infiltrates (neutrophils, eosinophils, macrophages, lymphoyctes, giant cells), fibroplasias/fibrosis (granulation tissue), angiogenesis, hemorrhage and necrosis using the following scoring system:

0. no response
1. minimal/barely detectable
2 . mild/slightly detectable
3. moderate/easily detectable
4. marked/very evident

Statistical Analysis:

To compare the peritoneal tissue attachment (adhesion) and contracture properties of both devices, the data was collected, analyzed, interpreted, and graphically displayed with GraphPad Prism version 5.03 statistical software [GraphPad Software, La Jolla, CA]. Peritoneal Tissue Attachment (Adhesion) Severity Scoring data was analyzed with Wilcoxon Rank Sum Test (Mann-Whitney U Test). Percent Peritoneal Tissue Attachment (Adhesion) Coverage and Percent Mesh Contracture data was evaluated by Student's t-test. Statistical significance was set at $P < 0.05$. It should be noted that lower peritoneal tissue attachment (adhesion) score/coverage and percent mesh contracture values are indicative of more biocompatible device performance. The histological data was summarized and presented in tabular format (statistical mode).

RESULTS

Gross Necropsy:

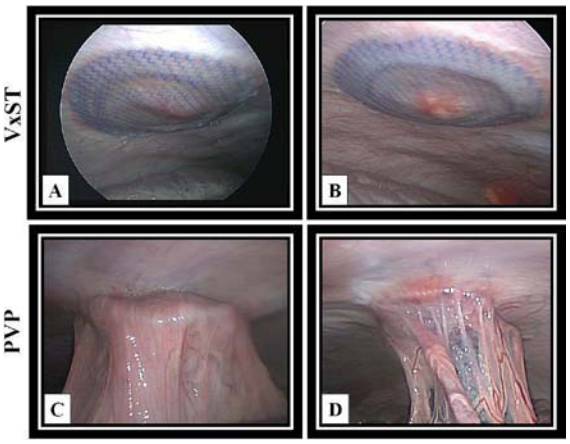


Figure 2.
Gross Necropsy / Explantation

Representative laparoscopic photographs of Ventralex™ ST Hernia Patch (VxST) (A, B) and PVP (C, D) at two weeks post-implantation. Ventralex™ ST Hernia Patch demonstrated significantly less peritoneal tissue attachment (scoring/percent area coverage) and percent mesh contracture, as compared to PVP.

Peritoneal Tissue Attachments (Adhesions):

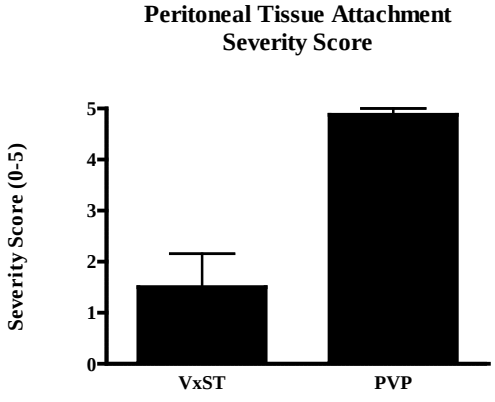
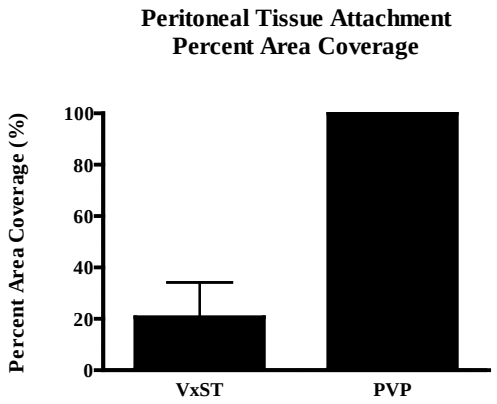


Figure 3.
Peritoneal Tissue Attachment (Scoring)

Ventralex™ ST Hernia Patch (left) demonstrated a significantly lower severity score (1.50 ± 0.65 / 5.00), as compared to PVP (right) (4.88 ± 0.13 / 5.00) at two weeks post-implantation

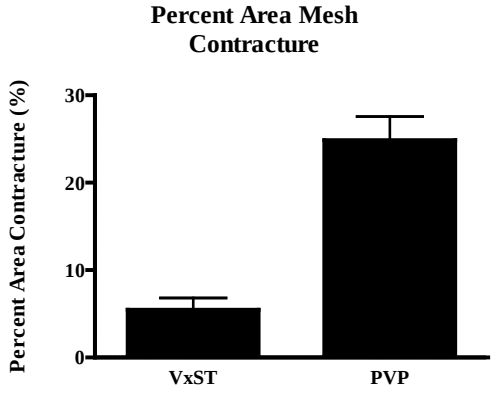


Mean ± SEM; P < 0.05

Figure 4.
Peritoneal Tissue Attachment (Adhesion) Percent Area Coverage

Ventralex™ ST Hernia Patch (left) demonstrated significantly lower percent area coverage (20.67 ± 13.57%), as compared to PVP (right) (100.00 ± 0.00%) at two weeks post-implantation.

Mesh Contracture:



Mean ± SEM; P < 0.05

Figure 5.
Percent Area Mesh Contracture

Ventralex™ ST Hernia Patch (left) demonstrated significantly less percent area mesh contracture (5.46 ± 1.35%), as compared to PVP (right) (24.87 ± 2.70%) at two weeks post-implantation.

Histological Analysis:

	Inflammatory Cell Infiltration					Other Parameters			
	Mac	Lym	GC	Neu	Eos	Fib	Ang	Hem	Nec
VxST	3	1	3	1	0	3	2	0	0
PVP	4	3	4	4	2-3	4	3	3	3-4

Table 1. Histological Scoring

Ventralex™ ST Hernia Patch (VxST) (top) and PVP (bottom) specimens harvested at explant were independently evaluated for inflammatory cellular infiltration, fibrosis, angiogenesis, hemorrhage and necrosis utilizing the following standardized scoring system defined by Charles River Laboratories - Pathology Associates [Frederick, MD]. Ventralex™ ST Hernia Patch demonstrated less inflammatory cellular infiltration [macrophages (3/4 vs. 4/4), lymphocytes (1/4 vs. 3/4), giant cells (3/4 vs. 4/4), neutrophils (1/4 vs. 4/4), eosinophils (0/4 vs. 2-3/4)], and less fibrosis (3/4 vs. 4/4), angiogenesis (2/4 vs. 3/4), hemorrhage (0/4 vs. 3/4) and necrosis (0/4 vs. 3-4/4), as compared to PVP at two weeks post-implantation.

Cell Infiltration

Mac: Macrophages
Lym: Lymphocytes
GC: Giant Cells
Neu: Neutrophils
Eos: Eosinophils

Parameters

Fib: Fibrosis
Ang: Angiogenesis
Hem: Hemorrhage
Nec: Necrosis

Scoring Scale

0: No response

1: Minimal / Barely Detectable

2: Mild / Slightly Detectable

3: Moderate / Easily Detectable

4: Marked / Very Evident

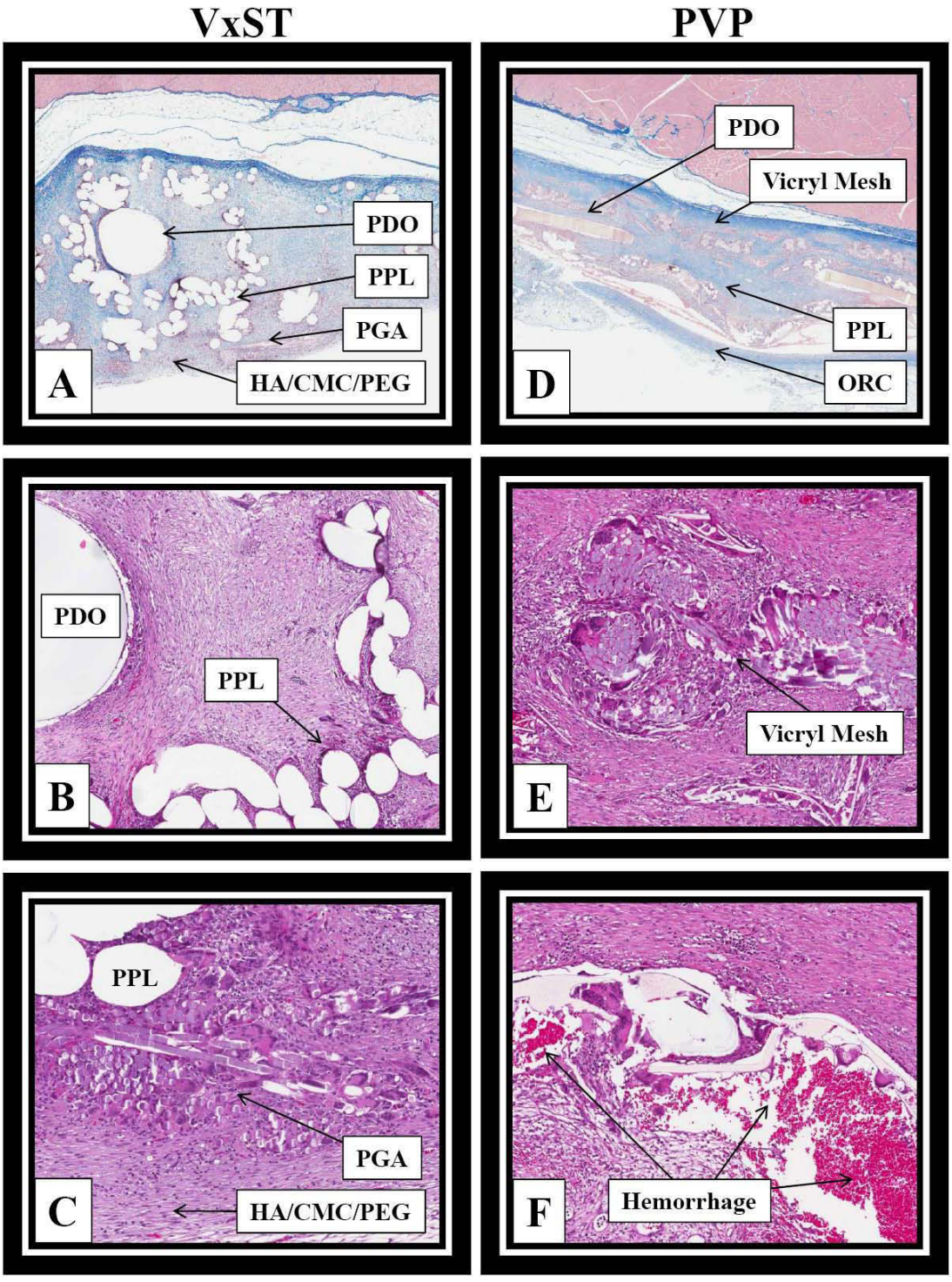


Figure 5. Histological Photomicrographs

Masson's Trichrome (A, D) and H&E (B, C, E, F) stained slides demonstrate both permanent and absorbable components of Ventralex™ ST Hernia Patch (VxST) (A-C) (left) and PVP (D-F) (right) respectively.

Abbreviations

PDO:	Polydioxanone
PGA:	Polyglycolic Acid
PPL:	Polypropylene
ORC:	Oxidized Regenerated Cellulose
HA	Hyaluronate
CMC:	Carboxymethylcellulose
PEG:	Polyethyleneglycol

DISCUSSION

This preclinical assessment of Ventralex™ ST Hernia Patch and PVP demonstrated marked differences in peritoneal tissue attachment (adhesion) formation, mesh contracture and histological parameters. Ventralex™ ST Hernia Patch demonstrated significantly less peritoneal tissue attachment (adhesion) severity / percent area coverage, percent mesh contracture, and host inflammatory/fibrotic response properties, as compared to PVP.

Visceral protection is a key function expected of the absorbable barrier coatings used in both Ventralex™ ST Hernia Patch and PVP. These coatings have been designed to minimize peritoneal tissue attachments (adhesions) which can lead to potential secondary complications. Interestingly, the results obtained in this study are similar to those which have been previously reported. Pierce *et al.* demonstrated acceptable performance for Sepramesh™ IP Composite, as evidenced by lower adhesion severity scores (1.0 ± 0.0 / 4.0 vs. 2.8 ± 1.0 / 4.0) and percent area coverage (0.0 ± 0.0% vs. 28.8 ± 16.1%), as compared to Proceed™ Surgical Mesh[9]. It should be noted that the ORC barrier used in Proceed™ Surgical Mesh and HA/CMC/PEG barrier used in Sepramesh™ IP Composite, are identical to the primary barriers utilized in PVP and Ventralex™ ST Hernia Patch respectively.

At implantation, devices are typically selected to facilitate mesh coverage of a given surgical defect, in an effort to ensure adequate soft tissue reinforcement and minimize the chance of hernia recurrence. Pierce *et al.* demonstrated a greater than four-fold higher percentage of mesh contracture for Proceed™ Surgical Mesh (29.7 ± 12.5%), as compared to Sepramesh™ IP Composite (6.4 ± 8.4%)[9]. Similarly, our data suggests a greater than four-fold higher percentage of mesh contracture for PVP (24.87 ± 2.70%), as compared to Ventralex™ ST Hernia Patch (5.46 ± 1.35%). Taken together, these results suggest that components of the ORC barrier present in both Proceed™ Surgical Mesh and PVP may elicit greater mesh contracture, as compared to the HA/CMC/PEG barrier used in Sepramesh™ IP Composite and Ventralex™ ST Hernia Patch.

Both post-operative peritoneal tissue attachments (adhesions) and mesh contracture are a potential source for negative sequelae associated with prosthetics that elicit an inappropriate host inflammatory/ fibrotic response. Independent histological analysis of specimens from this short-term two week preclinical study demonstrated a heightened host inflammatory / fibrotic response for PVP, as indicated by higher scores for macrophage, lymphocyte, giant cell, neutrophil and eosinophil infiltration, as compared to Ventralex™ ST Hernia Patch. Furthermore, PVP demonstrated greater fibrosis, angiogenesis, hemorrhage, and necrosis, as compared to Ventralex™ ST Hernia Patch.

CONCLUSIONS

Overall, Ventralex™ ST Hernia Patch demonstrated significantly less peritoneal tissue attachments (adhesions), mesh contracture, and a reduced host inflammatory/fibrotic response, as compared to PVP when evaluated in this porcine model of simulated open ventral hernia repair. The data suggests that the biological response to Ventralex™ ST Hernia Patch may minimize the development of post-operative complications, such as peritoneal tissue attachment (adhesions) and mesh contracture, which were observed and associated with a heightened response for PVP in this preclinical model.

ACKNOWLEDGEMENTS

This study was conducted at DaVinci Biomedical Research Products, Inc., S. Lancaster, MA, an AAALAC accredited pre-clinical testing facility. This study was approved by the Institutional Animal Care and Use Committee (IACUC) of DaVinci Biomedical Research Products, Inc., and was conducted in compliance with all regulations regarding the humane treatment of laboratory animals. All histological analysis was conducted by an independent board-certified veterinary pathologist (Lucas H. Brennecke, D.V.M., Ph.D.) at Charles River Laboratories - Pathology Associates (Frederick, MD). Funding for this study was provided by C.R. Bard, Inc. - Davol.

REFERENCES

1. Sauerland, S., Schmedt, C.G., Lein, S., Leibl, B.J., and Bittner, R. Primary incisional hernia repair with or without polypropylene mesh: a report on 384 patients with 5-year follow-up. *Langenbecks Arch Chir* 390 (5):408-12. 2005.
2. Aslani, N. and Brown, C.J. Does mesh offer an advantage over tissue in the open repair of umbilical hernias? A systematic review and meta-analysis. *Hernia* 14(5):455-62. 2010.
3. Martin, *D.F., Williams, R.F.*, Mulrooney, T., and Voeller, G.R. Ventralex mesh in umbilical/epigastric hernia repairs: clinical outcomes and complications. *Hernia* 12(4):379-83. 2008.
4. Hadi, H.I., Maw, A., Sarmah, S., and Kumar, P. Intraperitoneal tension-free repair of small midline ventral abdominal wall hernias with a Ventralex hernia patch: initial experience in 51 patients. *Hernia* 10(5):409-13. 2006.
5. Vychnevskaia, K., Mucci-Hennekinne, S., Casa, C., Brachet, D., Meunier, K., Briennon, X., Hamy, A., and Arnaud, J.P. Intraperitoneal mesh repair of small ventral abdominal wall hernias with a ventralex hernia patch. *Dig Surg* 27(5):433-5. 2010.
6. Iversen, E., Lykke, A., Hensler, M., and Jorgensen, L.N. Abdominal wall hernia repair with a composite ePTFE/polypropylene mesh: clinical outcome and quality of life in 152 patients. *Hernia* 14(6):555-60. 2010.
7. Amid, P.K., Shulman, A.G., Lichtenstein, I.L., and Hakakha, M. Biomaterials for abdominal wall hernia surgery and principles of their applications. *Langenbecks Arch Chir* 379(3):168-71. 1994.
8. Tollens, T., Struyve, D., Aelvoet, C., and Vanrijkel, J.P. Introducing the proceed ventral patch as a new device in surgical management of umbilical and small ventral hernias: preliminary results. *Surg Technol Int* 19:99-103. 2010.
9. Pierce, R.A., Perrone, J.M., Nimeri, A., Sexton, J.A., Walcutt, J., Frisella, M.M., and Matthews, B.D. 120-day comparative analysis of adhesion grade and quantity, mesh contracture, and tissue response to a novel omega-3 fatty acid bioabsorbable barrier macroporous mesh after intraperitoneal placement. *Surg Innov* 16(1):46-54. 2009.

COVER PHOTO

Laparoscopic photograph of Ventralex™ ST Hernia Patch immediately following deployment and fixation in a simulated porcine model of open ventral hernia repair.

DISCLAIMER

This study represents a preclinical evaluation of Ventralex™ ST Hernia Patch following *in vivo* implantation in a porcine model. Results may not correlate to performance in humans.

ILUSTRÍSSIMO (A) SENHOR (A) PREGOEIRO (A) OFICIAL DA SUPERINTENDÊNCIA ESTADUAL DE LICITAÇÕES DO ESTADO DE RONDÔNIA – SUPEL/RO

Via: delta.supel@gmail.com

Ref.: Edital de Pregão Eletrônico nº. 010/2019

A Empresa QUALITY COMERCIAL DE PRODUTOS MEDICOS E HOSPITALARES LTDA, pessoa jurídica de direito privado, regularmente inscrita no CNPJ sob n° 14.070.112/0001-23, situada na Rua João Goulart, nº. 2425, bairro São Cristóvão, Porto Velho/RO, CEP: 76804-050, sabendo-se que a empresa referida participa de licitações na esfera Municipal, Estadual e/ou Federal, vêm por meio desta, com supedâneo na lei nº 8666/93 e demais dispositivos aplicáveis a espécie, apresentar **IMPUGNAÇÃO,** bem como solicitar esclarecimentos com intuito de eliminar qualquer dúvida sobre a elaboração e realização do processo licitatório.

Conforme se extrai do anexo I – Termo de Referência, o objeto da presente licitação é o registro de preços para futura e eventual aquisição de material de consumo (MATERIAIS DE ALTA COMPLEXIDADE - DRENOS, SONDAS E OUTROS), para atender demanda necessária de todas as unidades da Secretaria Estadual de Saúde. Conforme descrição completa no Termo de Referência. A pedido da Secretaria de Estado da Saúde/SESAU-RO, por um período de 12 meses.

A ora Impugnante, frente a intenção de participar do presente processo licitatório, realizou a minuciosa análise do Edital, observando que o item 01 merece revisão e consequentemente deve ter corrigida a especificação, objetivando prestigiar os princípios que norteiam a Administração Pública – legalidade, impessoalidade, moralidade, publicidade e eficiência[1].

Ademais, face à importância evidente do procedimento em voga para a Administração, por sua amplitude, a Impugnante SOLICITA URGÊNCIA na análise do mérito da presente Impugnação, a fim de evitar prejuízos sérios para as empresas interessadas em participar do certame, bem como ao próprio erário, uma vez que se permanecerem as atuais descrições editalícias, reduzir-se-á relevantemente a competitividade, o que fere um princípio basilar do processo licitatório – a ampla concorrência.

I – DO MÉRITO:

[1] Art. 3º A licitação destina-se a garantir a observância do princípio constitucional da isonomia, a seleção da proposta mais vantajosa para a administração e a promoção do desenvolvimento nacional sustentável e será processada e julgada em estrita conformidade com os princípios básicos da legalidade, da impessoalidade, da moralidade, da igualdade, da publicidade, da probidade administrativa, da vinculação ao instrumento convocatório, do julgamento objetivo e dos que lhes são correlatos.

Constata-se a presença de possível direcionamento à marca específica na descrição dos itens 04 e 05 do Anexo II, vez que faz-se a menção de característica de produto ímpar, o que, evidentemente, direciona para a marca que realiza fabricação do equipamento daquela característica, restringindo a participação de demais fabricantes e fornecedores que detenham produtos que atendam tecnicamente o objetivo escorreito do Edital.

Adiante, pontua-se o fato de que a descrição do item deve ser quanto a sua especificação técnica, funcionalidade e fatores correlatos, de modo que pontos específicos não possuem interferência em sua essência funcional e nem sequer relação a aplicabilidade técnica. Assim, resumidamente, as singularidades de características impedem a ampla participação de empresas que detenham produtos com a correta especificação técnica.

Pois bem, o Lote 01 itens 04 e 05, constam com a seguinte redação:

Item 5: DISPOSITIVO PARA REPARO DE HÉRNIA UMBILICAL, PARCIALMENTE ABSORVÍVEL, COM 4,3 CM DE DIÂMETRO, COMPOSTO POR: TELA DE POLIPROPILENO COM CAMADAS DE TELAS POLIDIOXANONA E CELULOSE OXIDADA REGENERADA.

Item 6: DISPOSITIVO PARA REPARO DE HÉRNIA UMBILICAL, PARCIALMENTE ABSORVÍVEL, COM 6,4 CM DE DIÂMETRO, COMPOSTO POR: TELA DE POLIPROPILENO COM CAMADAS DE TELAS POLIDIOXANONA E CELULOSE OXIDADA REGENERADA.

Nessa esteira de raciocínio, ressaltamos a necessidade de correção da descrição, em obediência ao artigo 3º, parágrafo 1º, inciso I, Lei 8666/93, vejamos:

> § 1º É vedado aos agentes públicos:
> I - admitir, prever, incluir ou tolerar, nos atos de convocação, cláusulas ou condições que comprometam, restrinjam ou frustrem o seu caráter competitivo, inclusive nos casos de sociedades cooperativas, e estabeleçam preferências ou distinções em razão da naturalidade, da sede ou domicílio dos licitantes ou de qualquer outra circunstância impertinente ou irrelevante para o específico objeto do contrato, ressalvado o disposto nos §§ 5º a 12 deste artigo e no art. 3º da Lei nº 8.248, de 23 de outubro de 1991;

Diante do exposto, impugna-se o Edital nº. 010/2019, haja vista que a descrição merece correção e/ou substituição do texto. Assim, sugere-se a seguinte redação, capaz de abranger todas as fabricantes e fornecedores:

Item 5: DISPOSITIVO PARA REPARO DE HÉRNIA UMBILICAL, PARCIALMENTE ABSORVÍVEL, **ENTRE 4,3 A 4,6 CM DE DIÂMETRO**, COMPOSTO POR: TELA DE POLIPROPILENO COM CAMADAS DE TELAS POLIDIOXANONA E CELULOSE OXIDADA REGENERADA **OU** COMPOSTA DE TECIDO POLIÉSTER MONOFILAMENTAR TRIDIMENSIONAL NÃO ABSORVÍVEL **OU** COM COMPOSIÇÃO QUE ATENDA A TÉCNICA APLICADA, POSSUINDO A MESMA FINALIDADE E ATINGINDO O FIM A QUE SE DESTINA.

Item 6: DISPOSITIVO PARA REPARO DE HÉRNIA UMBILICAL, PARCIALMENTE ABSORVÍVEL, **ENTRE 6,4 A 6,6 CM DE DIÂMETRO**, COMPOSTO POR: TELA DE POLIPROPILENO COM CAMADAS DE TELAS POLIDIOXANONA E CELULOSE OXIDADA REGENERADA **OU** COMPOSTA DE TECIDO POLIÉSTER MONOFILAMENTAR

TRIDIMENSIONAL NÃO ABSORVÍVEL **OU** COM COMPOSIÇÃO QUE ATENDA A TÉCNICA APLICADA, POSSUINDO A MESMA FINALIDADE E ATINGINDO O FIM A QUE SE DESTINA.

A necessária correção é fator determinante, em atenção a competitividade no certame e prevenção de prejuízos ao erário, uma vez que a competição diz respeito, também, ao melhor preço e a logística de entrega.

Não atende ao interesse público uma contratação desnecessariamente onerosa, em que a Administração Pública poderia obter um material de mesma ou superior eficiência por um preço menor, desde que inexista descrição que indique direcionamento.

Não obstante ser mais que defeso que a Administração Pública tem o direito de decidir qual o tipo de contratação melhor lhe convém, entretanto, estas devem, inquestionavelmente, respeitar os ditames legais previstos na Lei n. 8.666/93, nos princípios que norteiam a Administração Pública e demais dispositivos aplicáveis a espécie.

Assim sendo, tem-se claro que a alteração ora pleiteada não materializará prejuízos ao processo licitatório, servirá apenas como maneira de regularizar o certame a fim de que seja respeitada a livre e ampla concorrência (princípio da competitividade), bem como a economicidade, eis que com o maior número de participante, maior será a desejada economia à Administração Pública.

II - DO PEDIDO:

Ante ao fartamente exposto, requer-se a reformulação do Edital de Pregão nº. 10/2019-RO, em especial, com a correção da descrição dos itens 04 e 05 do Anexo II, providenciando, em caráter imediato.

Nestes termos,
Pede e espera Deferimento.

Porto Velho/RO, 25 de junho de 2019 (terça-feira).

SYLVIO FEITOSA DE FREITAS
ANALISTA DE LICITAÇÕES – OAB/MT 16.461/O
QUALITY MEDICAL