MESH 2017

XIIIe symposium sur les prothèses pariétales

From tissue separating meshes to biosynthetics to a new hybrid mesh.

R.D. Berta
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Department of Gastroenterology
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Pisa, Italy

Disclaimer: some of the products mentioned in this presentation are "not available for sales in EU markets" and their status is : CE Mark pending

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Disclosure

Gore

From tissue separating meshes to biosynthetics to a new hybrid mesh.

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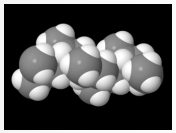
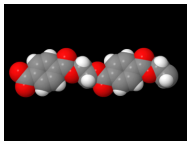
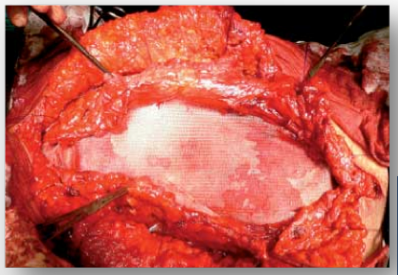
Rives - Stoppa Technique

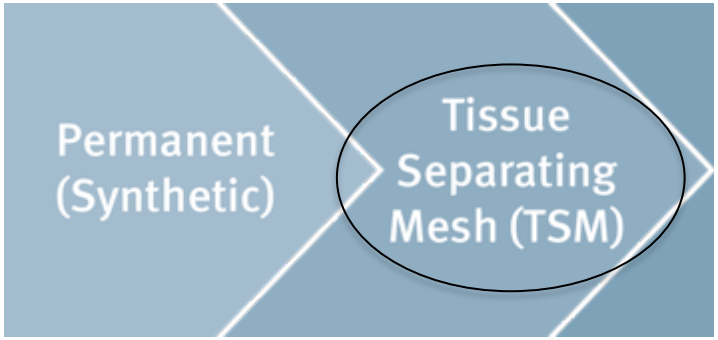


Polypropylene



Polyester





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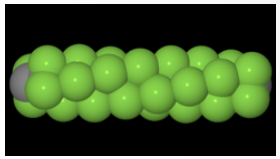
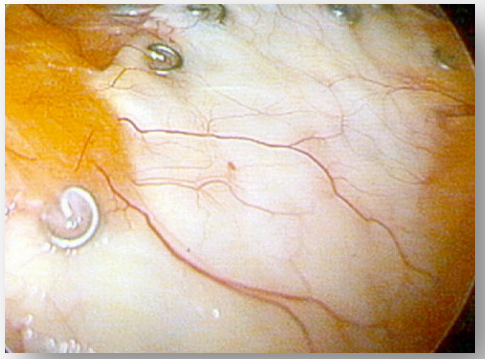


e- PTFE



A sufficiently sized and tension-free placed mesh is a key element of modern hernia surgery and abdominal wall repair.
For many indications, the standard of care is already excellent.

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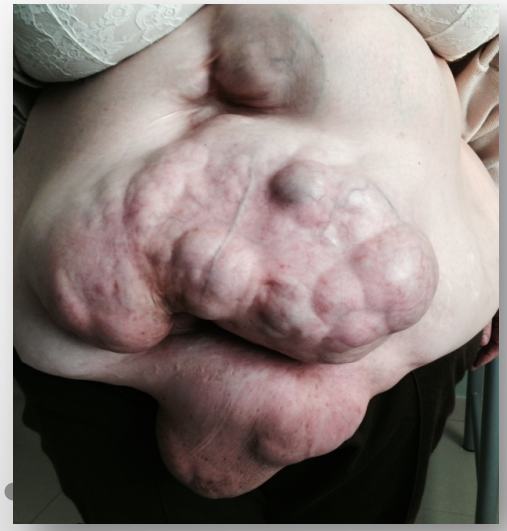
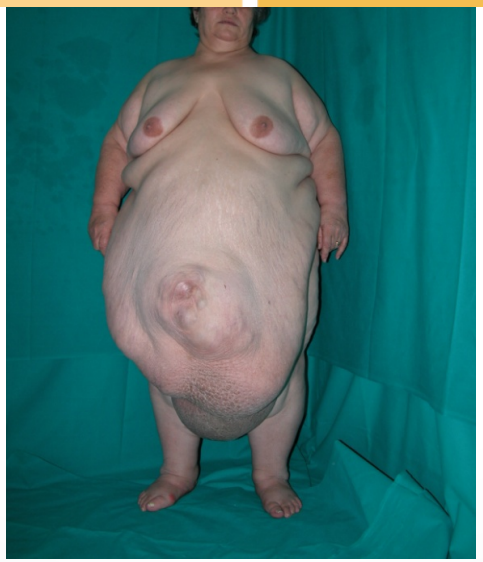
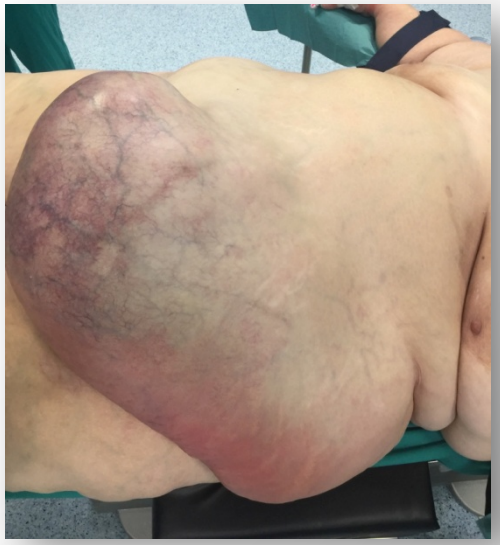
MULTIMORBID PATIENTS ARE PRONE TO INFECTIONS AND WOUND COMPLICATIONS

THE DEMANDS ON NEW SURGICAL TECHNIQUES , NEW MESH AND SCAFFOLD MATERIALS HAVE BECOME INCREASINGLY COMPLEX

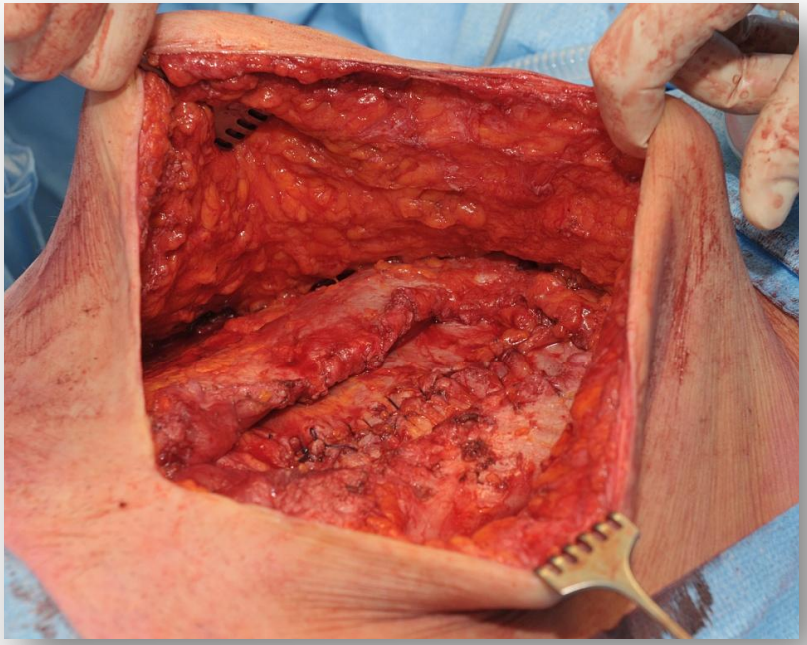
Grade 1	Grade 2	Grade 3	Grade 4
Low Risk	*Co-Morbid*	*Potentially Contaminated*	*Infected*
• Low risk of complications • No history of wound infection	• Smoker • Obese • Diabetic • Immunosuppressed • COPD	• Previous wound infection • Stoma present • Violation of the gastrointestinal tract	• Infected mesh • Septic dehiscence



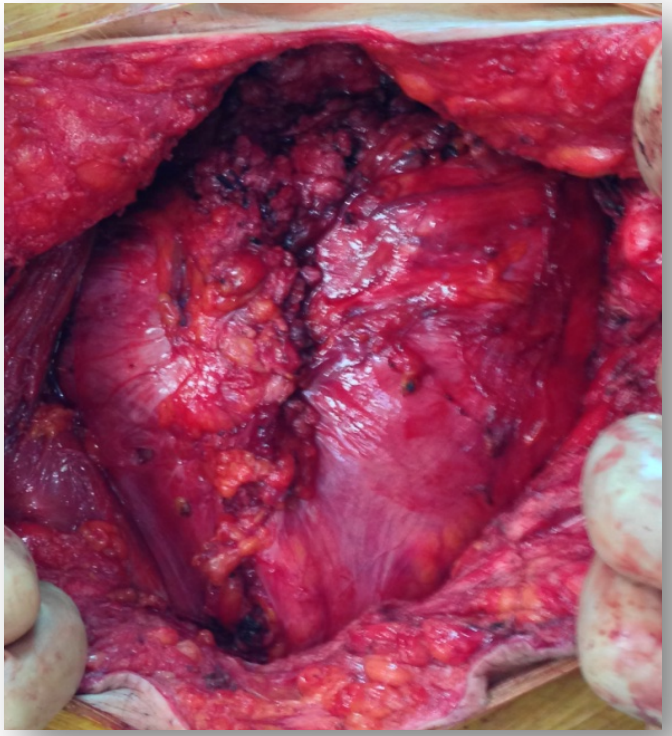




Complex Reconstructive Measures of the Abdominal Wall



ANTERIOR COMPONENT SEPARATION



POSTERIOR COMPONENT SEPARATION

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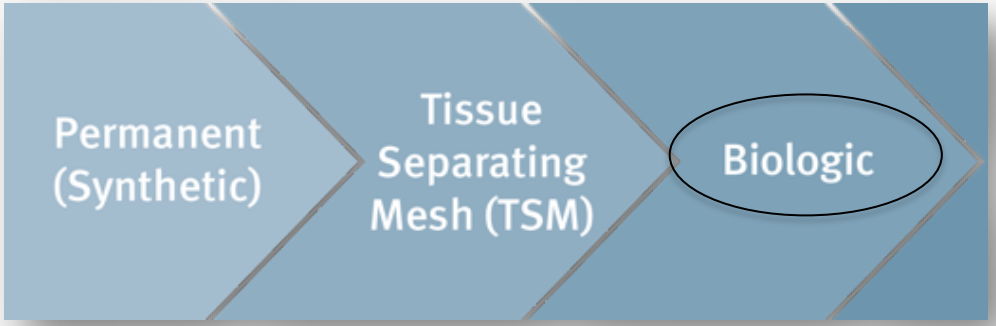
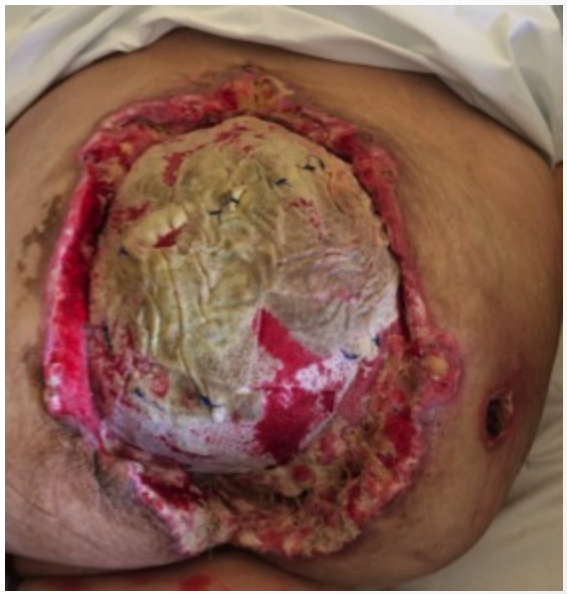
Hernia Device Evolution



Review

Biological Mesh Implants for Abdominal Hernia Repair
US Food and Drug Administration Approval Process and Systematic Review of Its Efficacy

Sergio Huerta, MD; Anubodh Varshney, MD; Prachi M. Patel, BS; Helen G. Mayo, MLS; Edward H. Livingston, MD



JAMA Surg. 2016

CONCLUSIONS AND RELEVANCE There is insufficient evidence to determine the extra costs associated with or the clinical efficacy of biological mesh materials for the repair of abdominal wall hernia.

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Hernia Device Evolution

RICH Study

Surgery
September 2012

50% clean contaminated 50% contaminated operation
66% SSO rate (30% SSI)
28% recurrence after 2 years follow up

Outcomes of Synthetic Mesh in Contaminated Ventral Hernia Repairs

Alfredo M Carbonell, DO, FACS, Cory N Criss, MD, William S Cobb, MD, FACS, Yuri W Novitsky, MD, Michael J Rosen, MD, FACS

Table 4. Surgical Site Occurrence, Surgical Site Infection, and Hernia Recurrence Rates of Patients Undergoing Clean-Contaminated and Contaminated Hernia Repairs

	SSO			30-Day SSI			Recurrence		
CDC wound classification	**n**	**%**	**Frequency, %**	**n**	**%**	**Frequency, %**	**n**	**%**	**Frequency, %**
Clean contaminated (n = 42)	11	26.2	11.0	3	7.1	3.0	3	7.1	3.0
Contaminated (n = 58)	20	34	20.0	11	19.0	7.0	4	6.8	4.0

SSI, surgical site infection; SSO, surgical site occurrence.

2013 J American College of Surgeons

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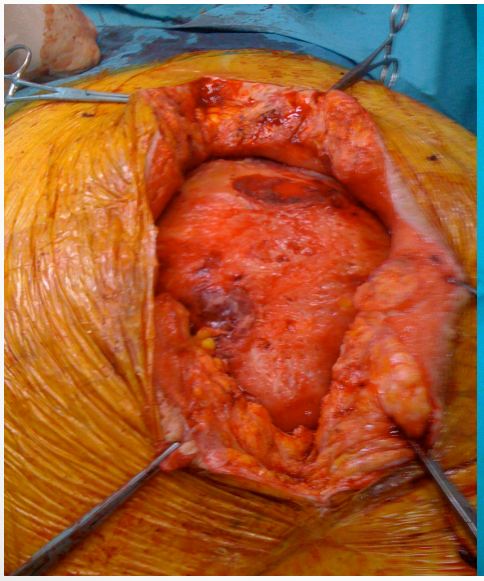
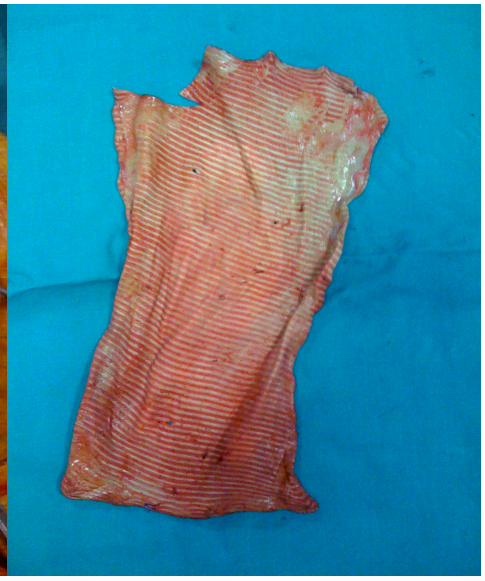
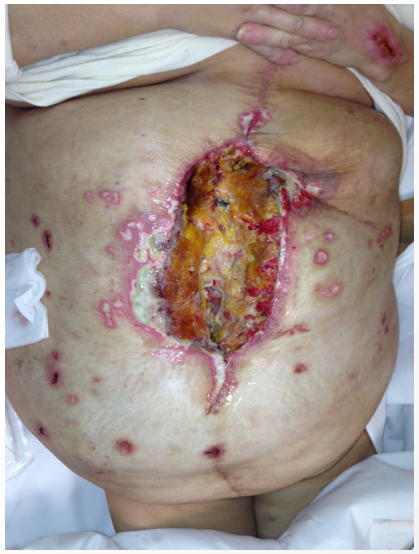
2003 – 2009 (Pisa – IT) RYGBP : 584 (540 laparosc / 44 Open)

RYGBP + synchronous open VHR with synthetic nonabsorbable / biologic meshes

SSO : 57 % (26 % INFECTION)







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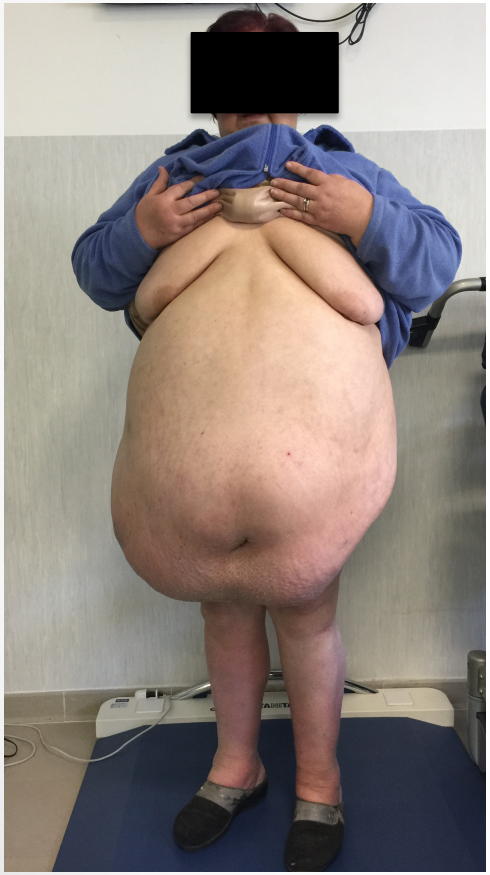
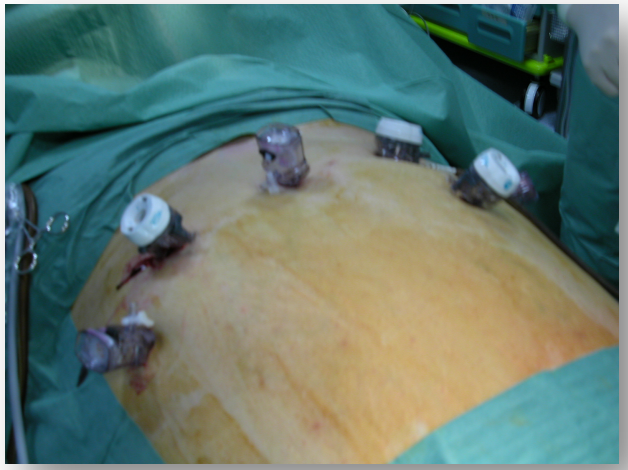
SSO higher in morbid obese patients VHR

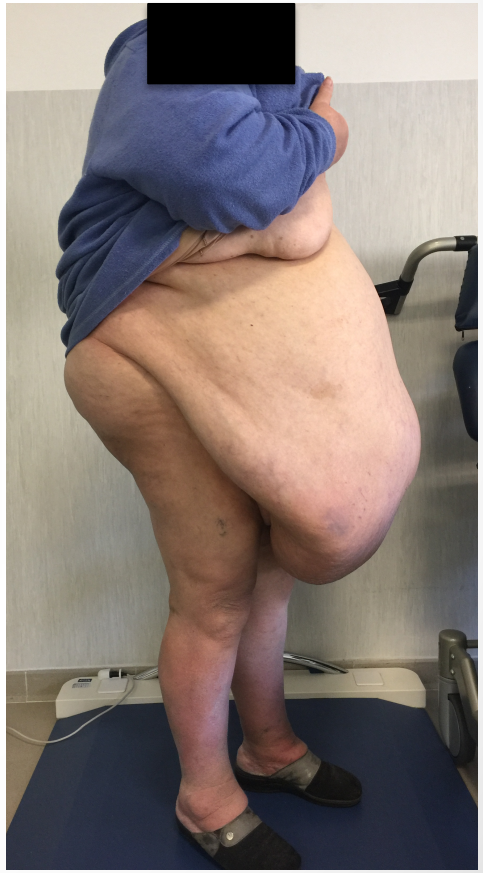
Maintain, whenever possible, the laparoscopic approach





Tailoring surgical approach for elective ventral hernia repair based on obesity and National Surgical Quality Improvement Program outcomes

Justin L. Regner, M.D., F.A.C.S.*, Mary M. Mrdutt, M.D., Yolanda Munoz-Maldonado, Ph.D.



Am J Surg (2015) 210 : 1024-1030

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< 65/70 y.o. **+ VH**

BMI > 40 / 35 + comorbidity

BARIATRIC SURGERY

LAPAROSCOPY

Sleeve Gastrectomy

LAPAROTOMY

RYGBP/LSG

WEIGHT LOSS

BRIDGE VH REPAIR
INTRAPERITONEAL
GORE BIO-A

Component Separation Ventral Hernia Repair (ACS/TAR)

Laparoscopic Ventral Hernia Repair (LVHR)

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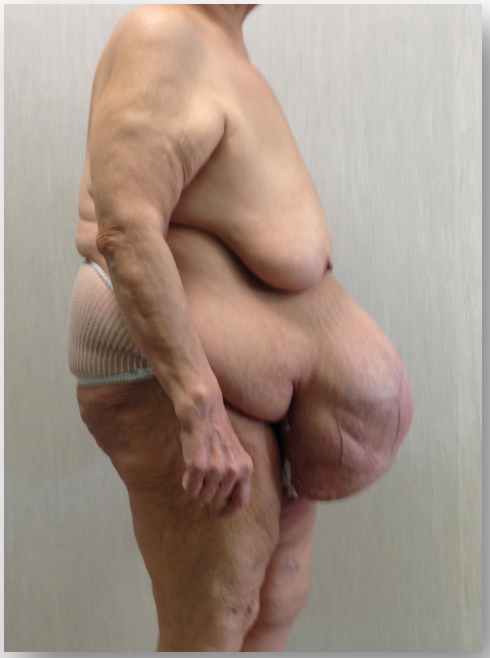
> 65 y.o + VH

BMI < 40 / 35 no comorbidity



WEIGHT LOSS DIETARY PROGRAM

LVHR – ACS/TAR

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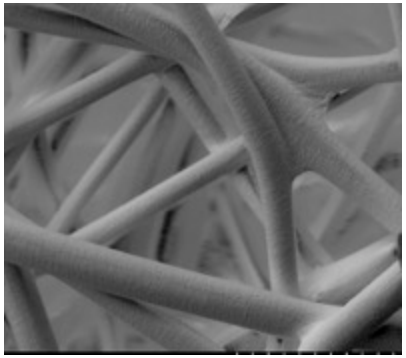
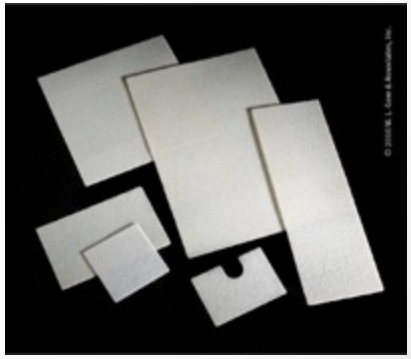
2011 introduction GORE BIO-A TISSUE REINFORCEMENT

- 67% PGA:33% TMC
  - Same bioabsorbable polymer as Maxon Suture
- Degradation primarily by hydrolysis in six to seven months
- Unique 3D web scaffold of highly interconnected pores

- **Scaffold for tissue generation**
- **Alternative to biologics**





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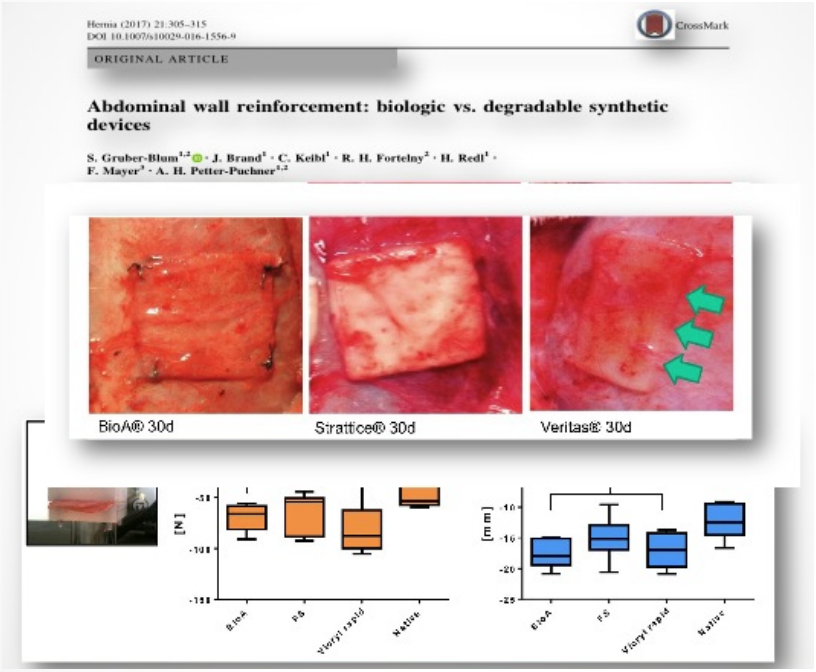
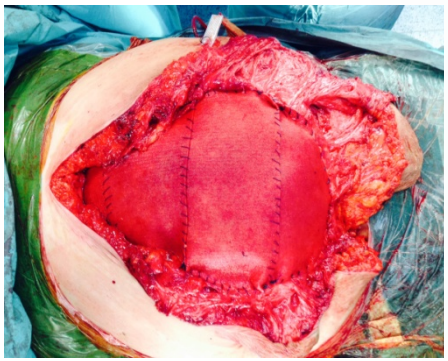
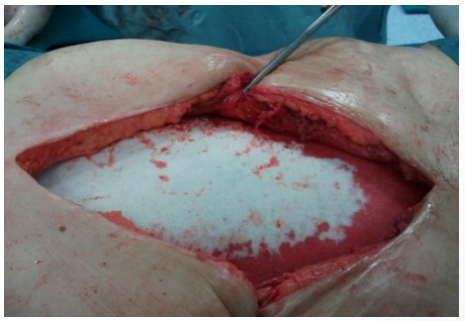
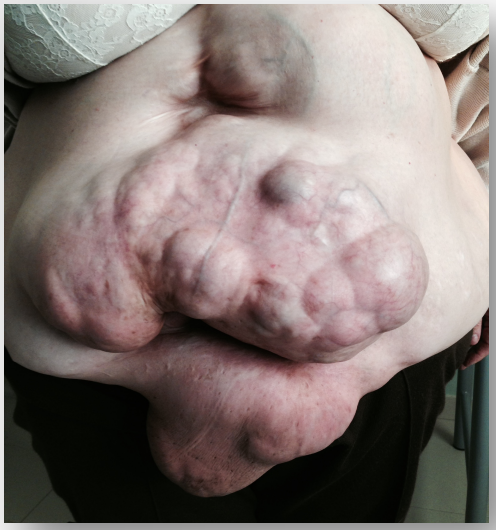




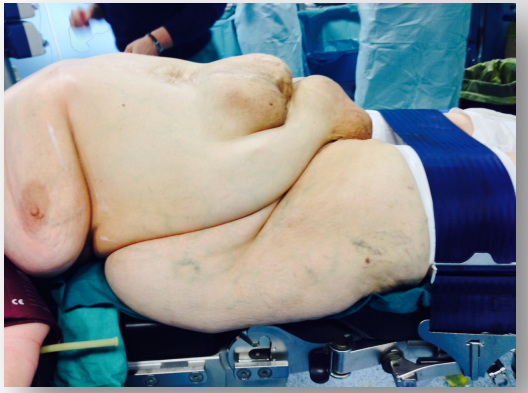


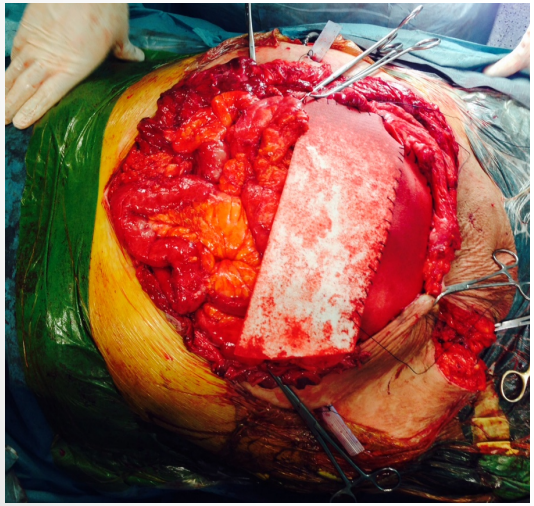
BioA® induces a mechanically more endurable scar formation as reinforcement

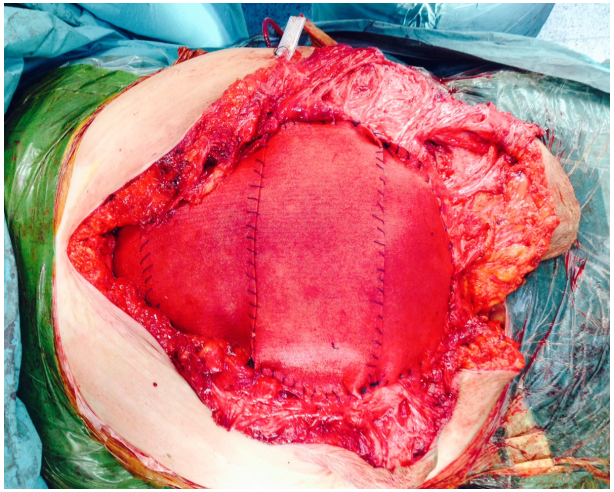
LAPAROTOMIC BARIATRIC SURGERY

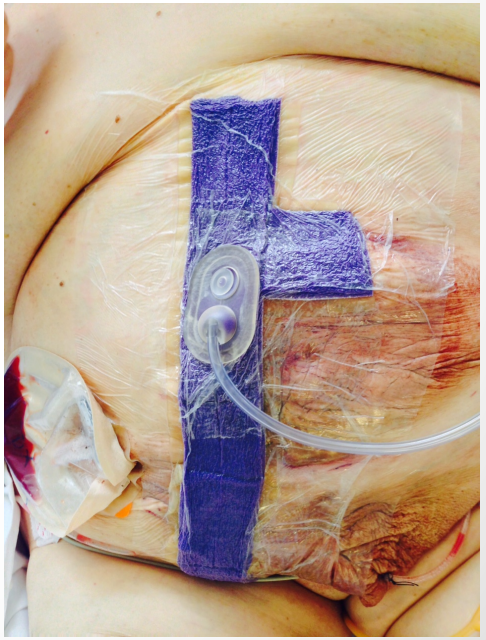


RYGBP /SG +
REINFORCEMENT/BRIDGE
VH REPAIR
INTRAPERITONEAL
GORE BIO-A



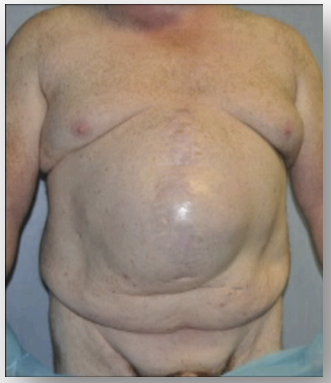
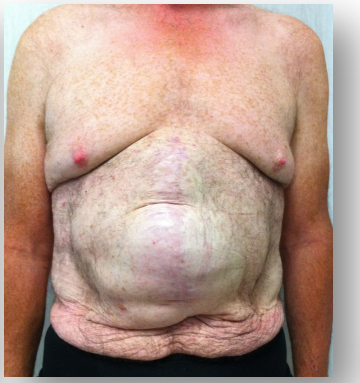
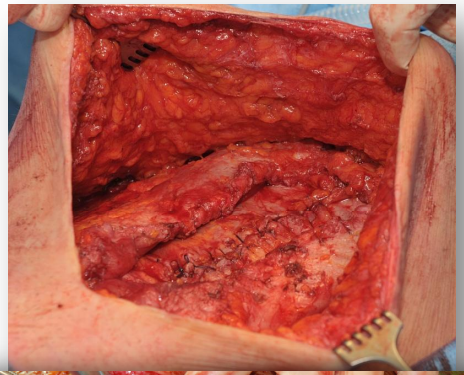
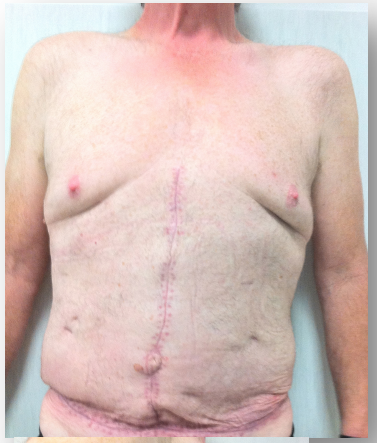
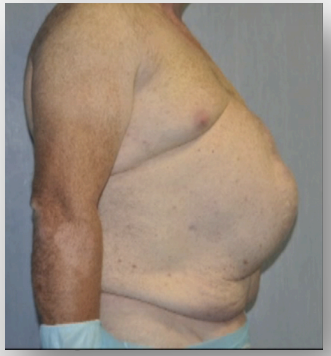
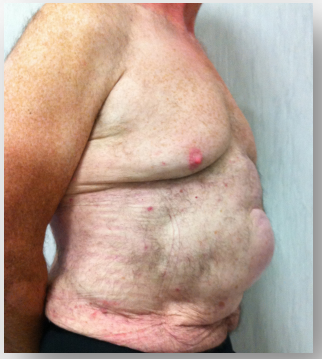
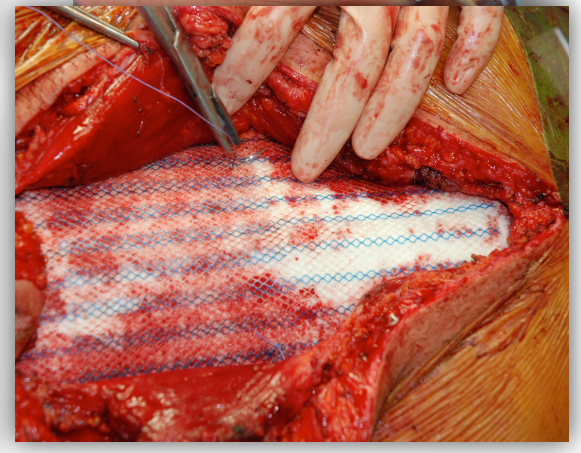
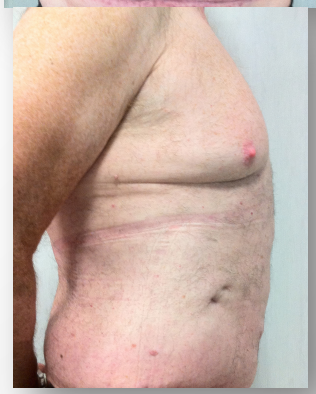






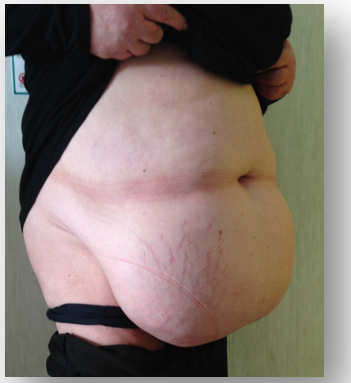
AFTER WEIGHT LOSS

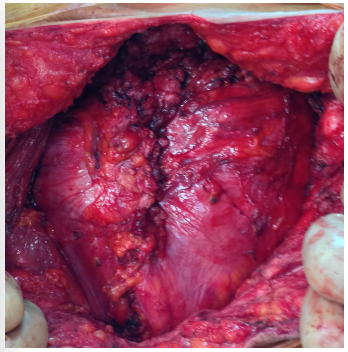
2011 -2013
Anterior Component Separation (ACS) Repair
GORE BIO-A + lightweight Polypropylene

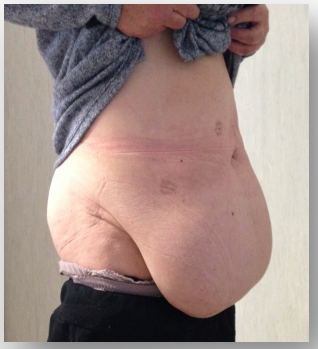









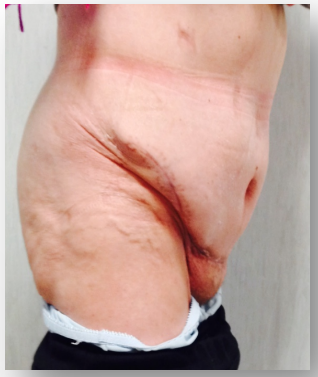
AFTER WEIGHT LOSS

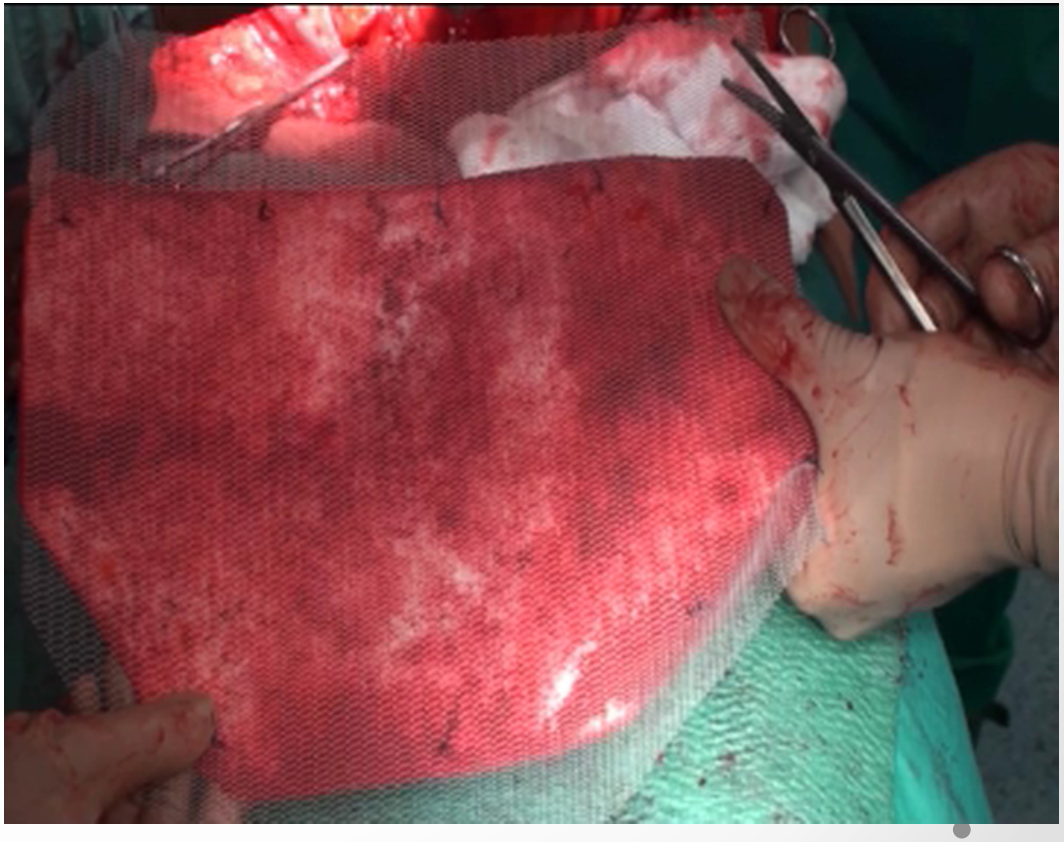
2013
Transversus Abdominal Release (TAR)
GORE BIO-A + medium-weight Polypropylene











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ORIGINAL ARTICLE

OPEN

Multicenter, Prospective, Longitudinal Study of the Recurrence, Surgical Site Infection, and Quality of Life After Contaminated Ventral Hernia Repair Using Biosynthetic Absorbable Mesh

The COBRA Study

Michael J. Rosen, MD, Joel J. Bauer, MD,† Marco Harmaty, MD,† Alfredo M. Carbonell, DO,‡ William S. Cobb, MD,‡ Brent Matthews, MD,§ Matthew I. Goldblatt, MD,¶ Don J. Selzer, MD, MS,|| Benjamin K. Poulose, MD, MPH,** Bibi M. E. Hansson, MD, PhD,†† Camiel Rosman, MD,†† James J. Chao, MD,‡‡ and Garth R. Jacobsen, MD§§*

GORE® BIO-A® Tissue Reinforcement

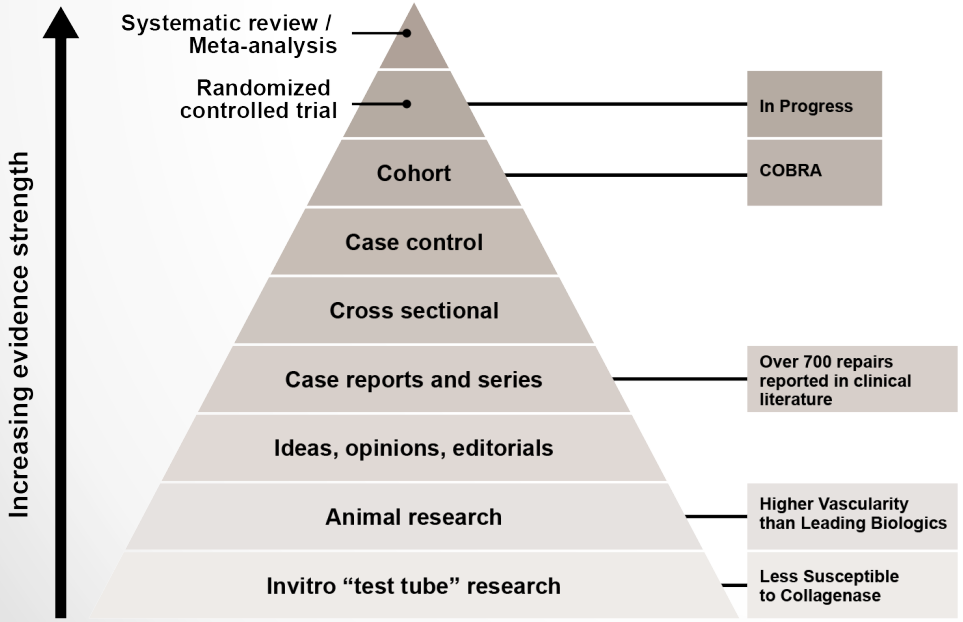
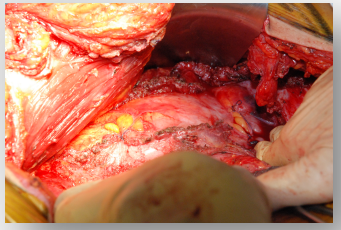


TABLE 4. Postoperative Wound Events and Surgical Site Infections*

Variables	n = 104
Wound events*, n (%)	33 (28)
Surgical site infection†	21 (18)
Seroma	6 (6)
Fistula	2 (2)

TABLE 3. Recurrence and Risk Baseline Factors for Postoperative Hernia Recurrence

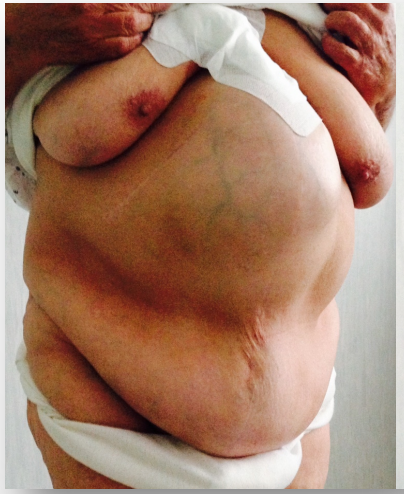
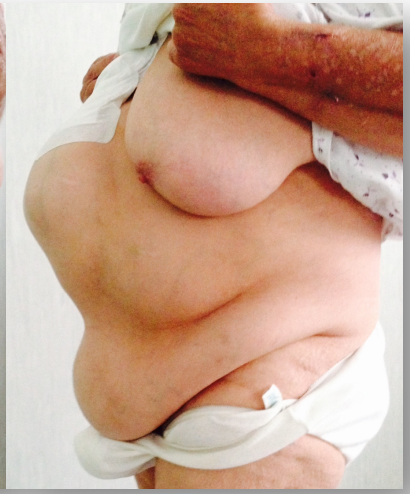
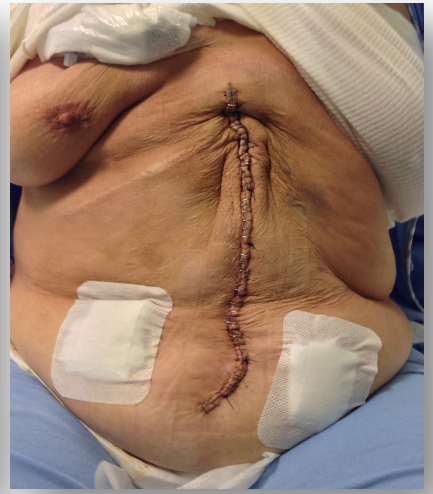
	Intent-to-treat Population (n = 104)		
	16 (15.4)		
Variables Hernia Recurrence, n (%) Risk Baseline Factors	Patients With Hernia Recurrence (n = 16)	Patients Without Hernia Recurrence (n = 88)	*P*
BMI (kg/m^2), mean (range)	30 (22–39)	27 (17–40)	0.046
Defect length (cm), mean (range)	11 (5–20)	15 (3–27)	0.044
Postoperative superficial incisional wound infection, n (%)	5 (31%)	4 (5%)	0.004



RESULTS
Jan 2011- Dec 2016

Operation	*PTS*	*M-F*	*Age yo*	*BMI*	*Hernia cm2*	*Follow-up mo*
53	51	13-39	56,6 (39-77)	32,3	150,2 (50-392)	34,3

2003-09 **SSO 57%** (26% infection)
2011-16 **SSO 27%** (3,7 % infection) Recurr. 5,6%

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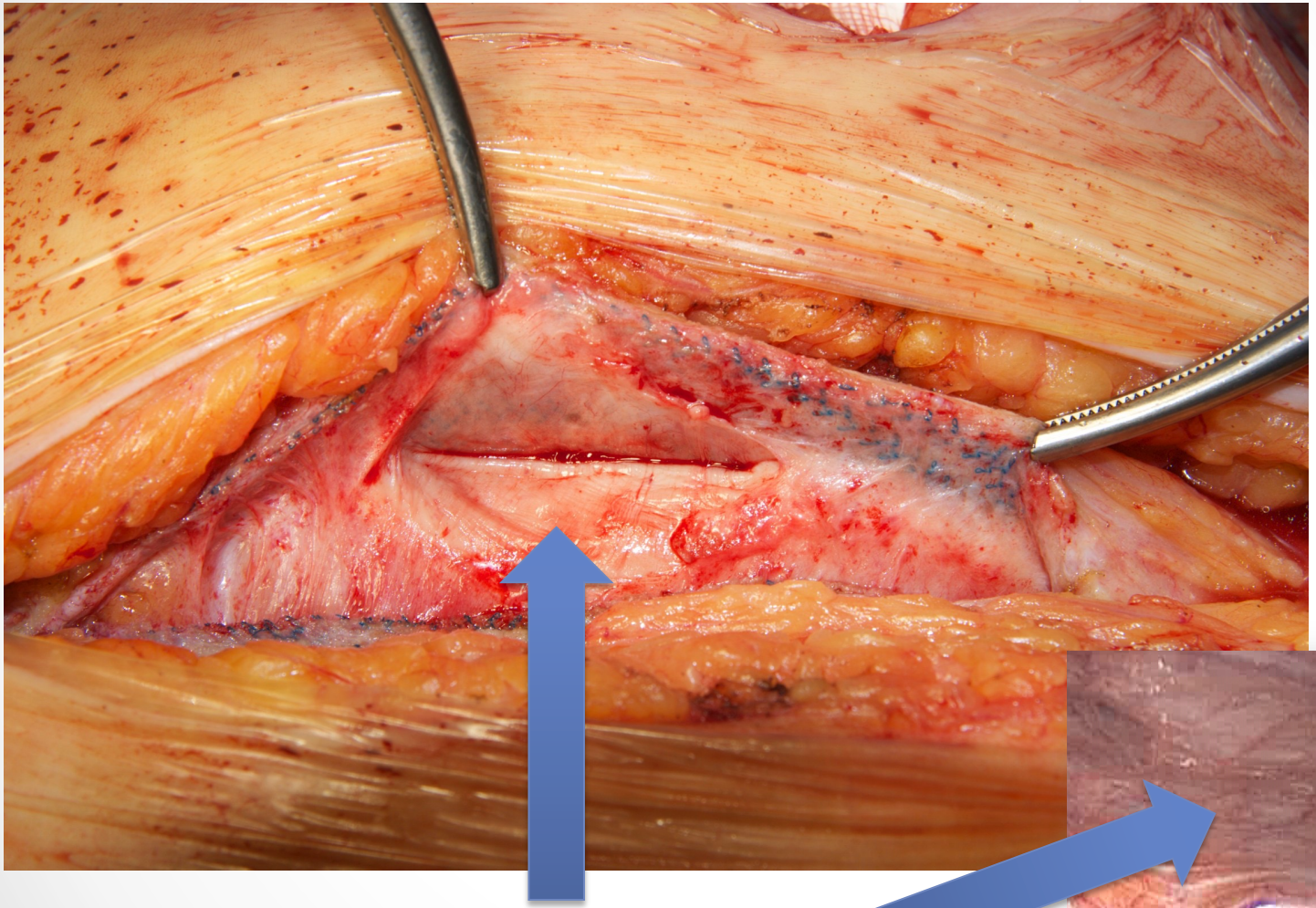

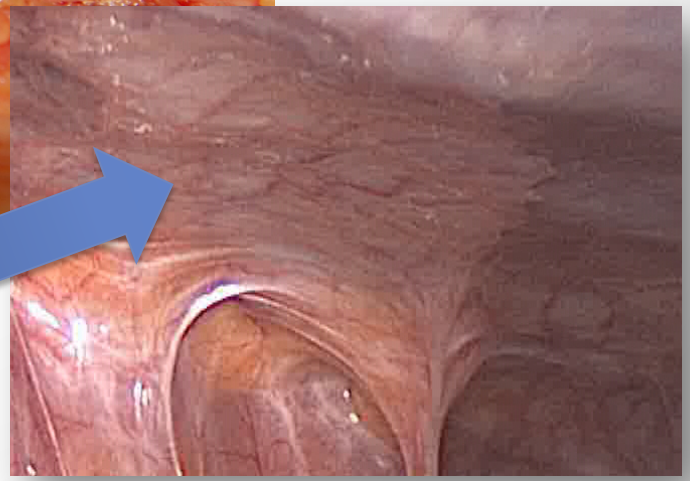

BIO-A + PP after 1-2 ys

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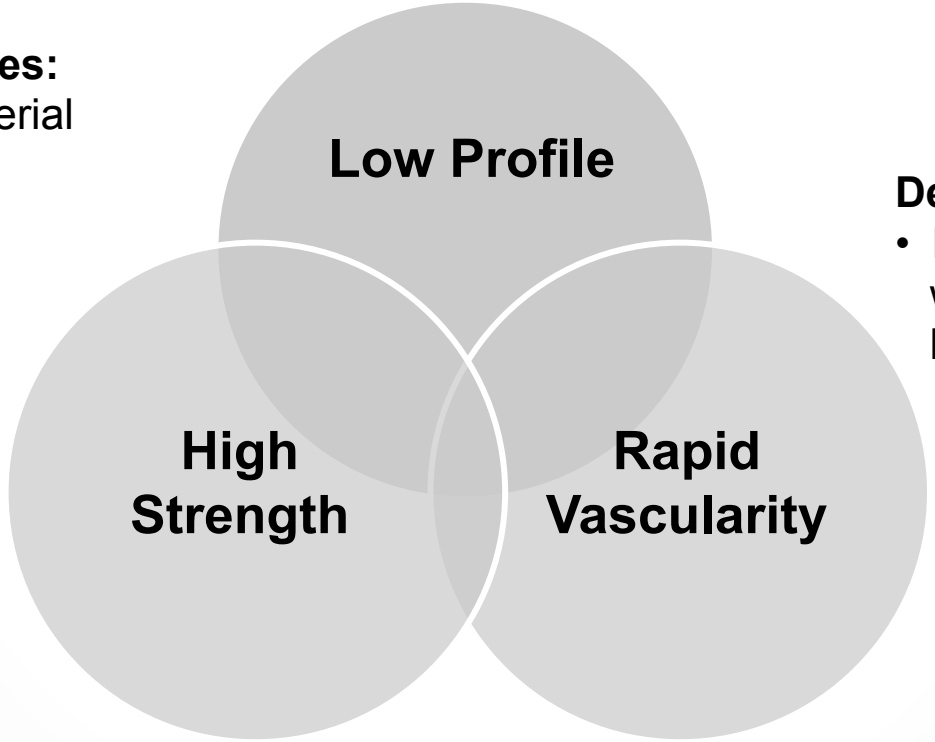
Desirable Attributes:
- Less foreign material
- Potentially lower inflammation



Desirable Attributes:
- Favorable for high risk wounds and challenging hernia repairs

Desirable Attributes:
- Appropriate for bridging
- Long-term durability

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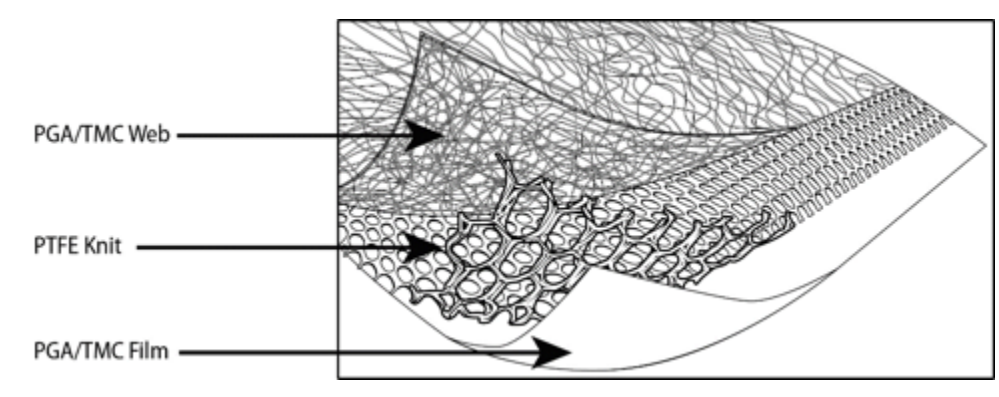
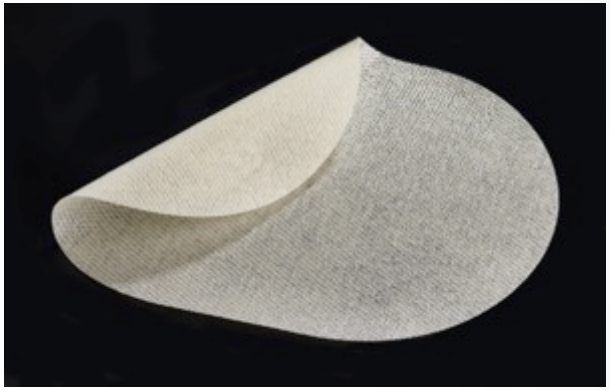
GORE® SYNECOR Biomaterial





Parietal Surface – GORE® BIO-A® Web

Macroporous PTFE Knit – dense, monofilament fiber

Visceral Surface – PGA / TMC film (nonporous)

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FDA Clearance

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 11, 2015

W.L. Gore & Associates Incorporated
Ms. Barbara Smith
Official Correspondent
301 Airport Road
Elkton, Maryland 21921

Re: K152609
Trade/Device Name: GORE SYNECOR Biomaterial
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: September 11, 2015
Received: September 14, 2015

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to ma… the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152609

Device Name

GORE SYNECOR Biomaterial

Indications for Use *(Describe)*

The GORE SYNECOR Biomaterial device is intended for use in the repair of hernias and abdominal wall or thoracic wall soft tissue deficiencies that may require the addition of a non-absorbable reinforcing or bridging material.

http://www.accessdata.fda.gov/cdrh_docs/pdf15/K152609.pdf

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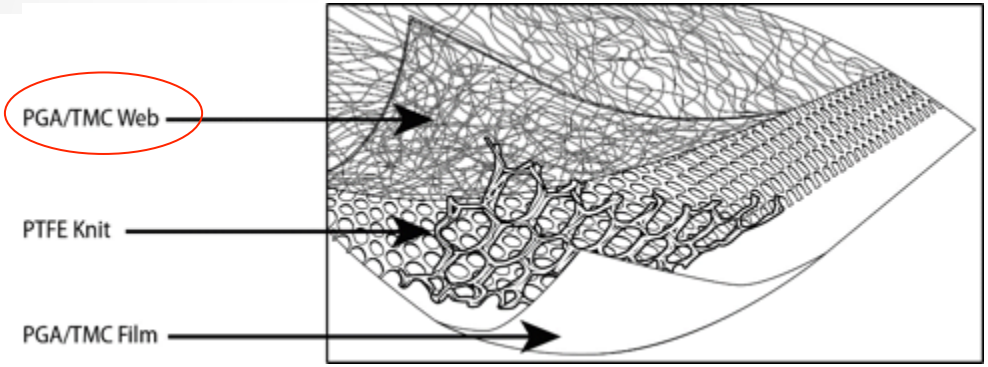
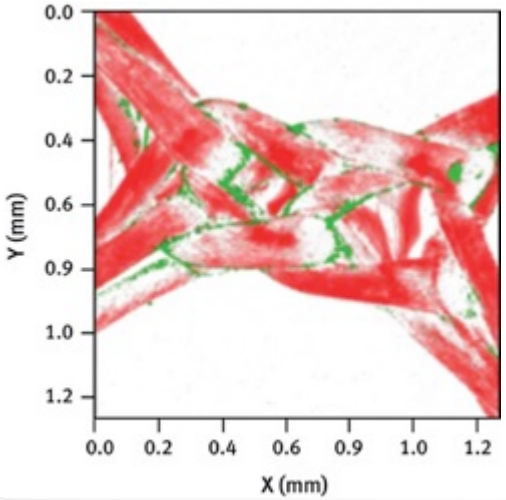
PTFE Knit, strength (ball burst)

PTFE Knit: Bacterial Adherence Study





Green: Bacteria
Red: Polymer

Via confocal fluorescence imaging, the interaction of *S. aureus* to various knitted polymer materials was compared and it was concluded that:

- Bacteria localize in the knot or overlapping fiber areas of all the knits
- No bacteria was located within the materials
- PTFE had the least bacteria on the surface

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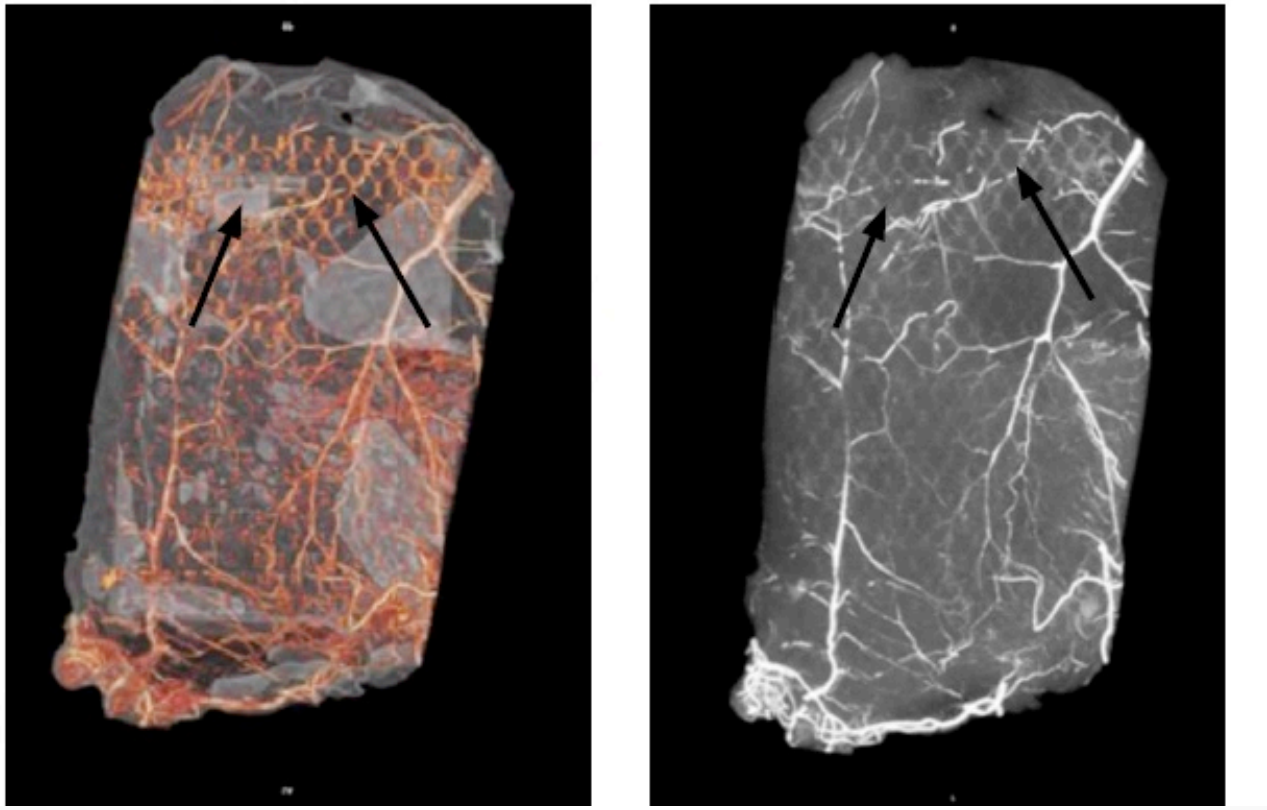
GORE® SYNECOR Biomaterial Vascularity at Seven Days



Arrows indicate area where blood vessels are penetrating through the PTFE knit at seven days post implantation

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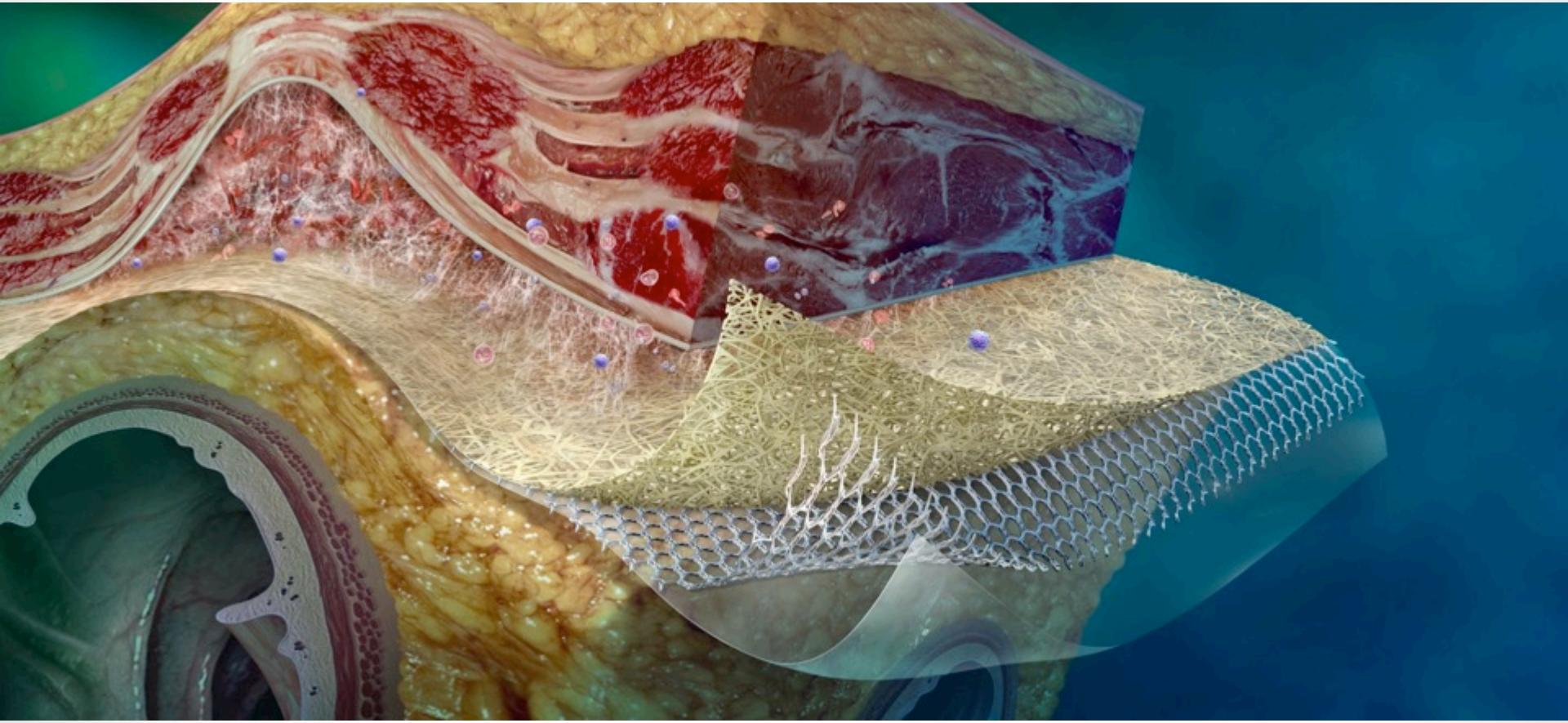
GORE® SYNECOR Biomaterial



Disclaimer: some of the products mentioned in this presentation are "not available for sales in EU markets" and their status is : CE Mark pending