

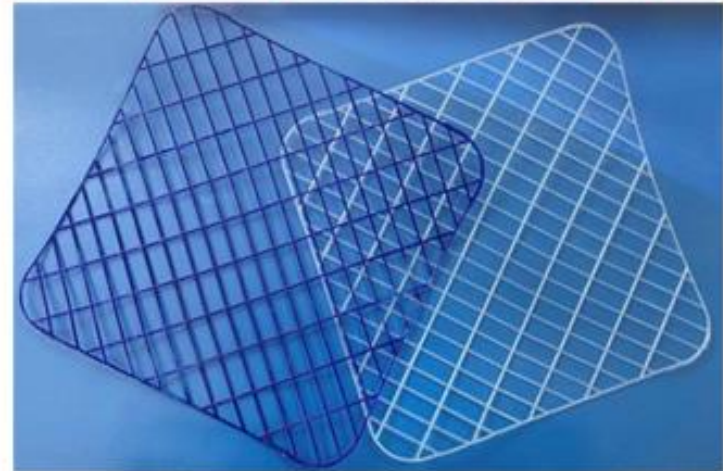
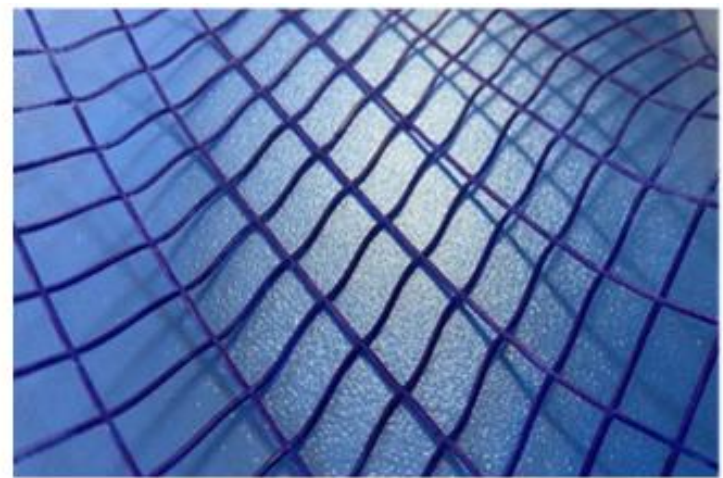
XyberCyl

**The XyberCyl Solution
Invisible Repair Device**



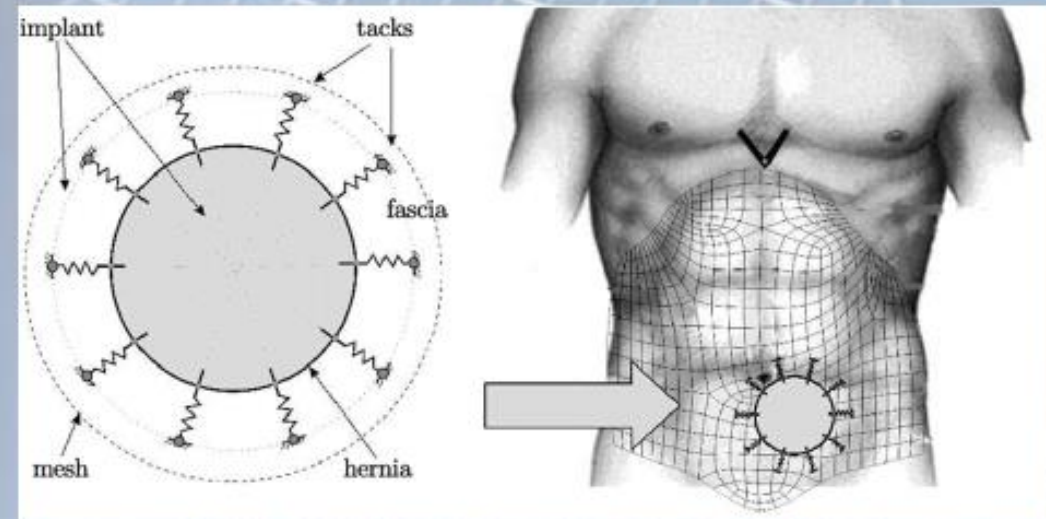
XyberCyl is a surgical mesh device that can be potentially utilized for different medical applications, such as ventral hernia repair, inguinal hernia repair, breast reconstruction, and more.

This presentation will focus primarily on one area: ventral hernia repair.



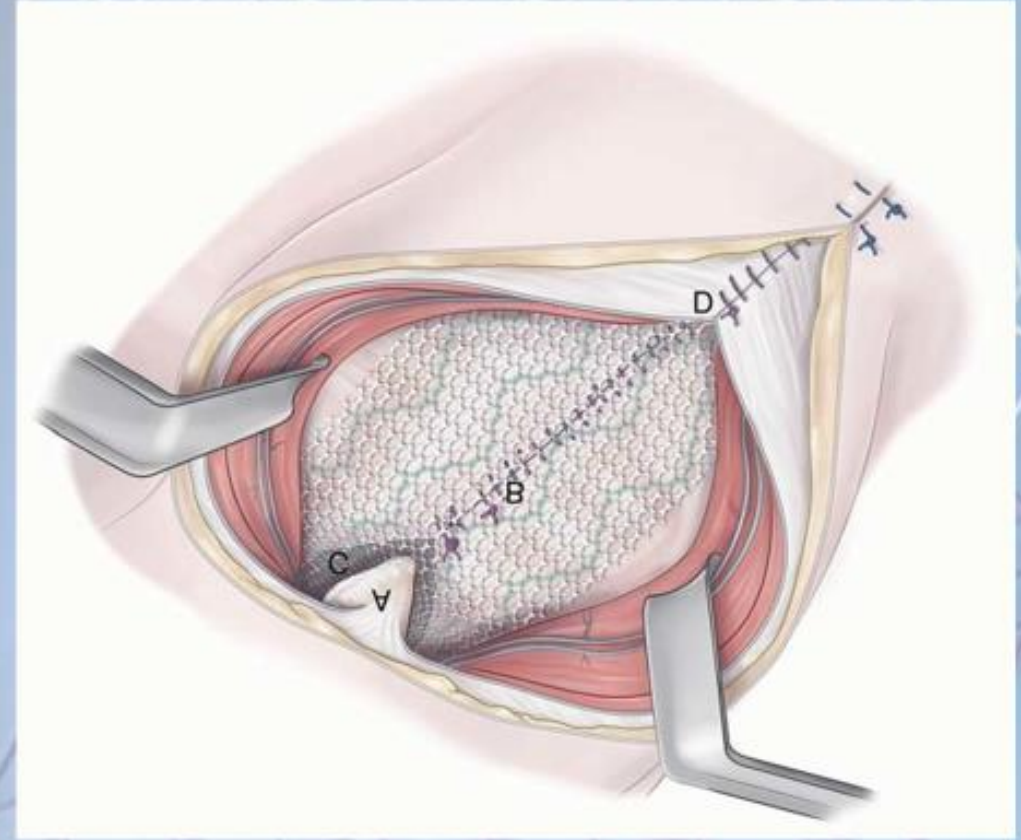
Ventral hernia repair or abdominal wall defect repair has one primary objective: repair of the hernia/defect in a manner that promotes and acts as a catalyst for (and certainly does not inhibit) natural healing.

This natural healing process – which can take time to reach completion – must take into consideration the complex mechanical characteristics of the abdomen (just hold your hand to your abdomen when coughing, sneezing, or even arising from a sitting position).



The extreme load acting in the human abdomen that can damage the implant connections and result in recurrence of the condition is an internal pressure that can reach the value of 270 mm Hg. This load can commonly appear during post-operative coughing or jumping.

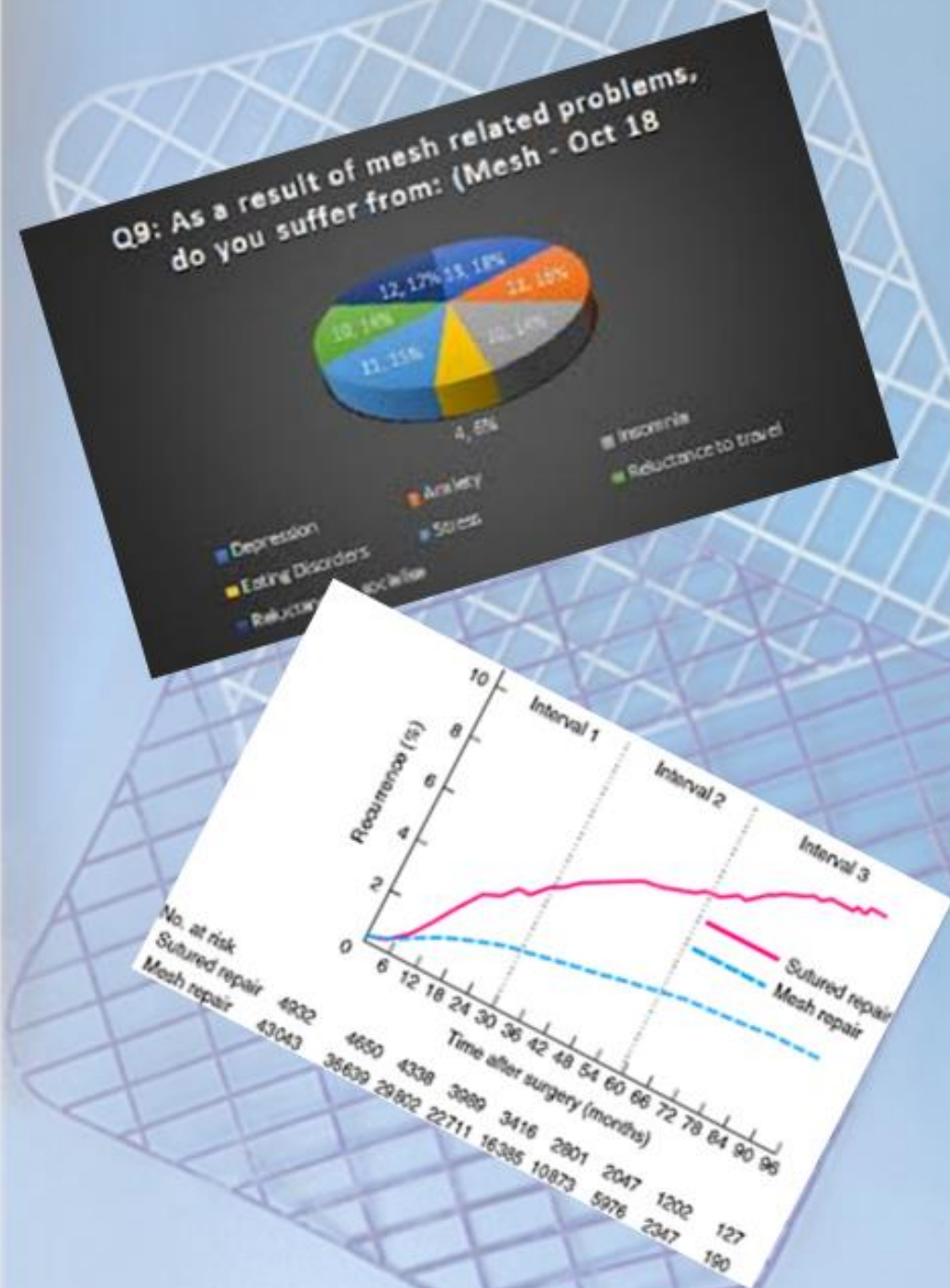
Thus, due to these inherent mechanics of the abdomen, the repair of an abdominal defect requires a method whereby the repaired area can be “held together” long enough to complete the repair process.



Since the 1980's, surgical mesh in its various iterations has been the abdominal repair support method of choice. Unfortunately, and without exception, surgical meshes are recognized as foreign bodies – resulting in a series of undesirable consequences. These can include scarification, mesh shrinkage or even failure, chronic pain, chronic infection, adhesions – and, most importantly, inhibit natural healing (and, as we have stated earlier, natural healing is the primary objective of the hernia repair process).



This high degree of “failure” and its associated risk (>17% average failure rate for inguinal hernias; >35% for ventral hernias) has obviated the prophylactic use of surgical meshes against the source of the most common abdominal defects – a laparotomy incision causing incisional hernia. Prophylactic use of a “safe” surgical mesh at the site of an incision would prevent a significant number of ventral hernias (more than 1/2 million ventral hernias are repaired annually in North America).



The use of surgical threads can be traced back as far as 3000 BC. Surgical threads were created from many different sources (plant, animal, synthetic). The use of nylon surgical thread was first reported in 1941. For the past 80+ years, nylon and other composite materials have been used as surgical threads – all with one common underlying characteristic – they are invisible to the human body (i.e. there is no foreign body reaction).

In other words, there is no question of inhibition of natural healing when utilizing surgical thread.



XyberCyl is based upon a surgical technique developed by Dr. Joel Gorman as an improvement to the Abrahamson Shoelace Repair. This technique was successfully utilized by Dr. Gorman in more than 1,200 surgeries over the past 25 years, primarily for abdominal defect and other types of surgical repairs.



Based upon mean follow-up times of 11 years for hundreds of patients, the technique, which has been now incorporated in the XyberCyl device:

- Promoted natural muscle and tissue regeneration (“natural healing”)
- Was non-infectable and biologically invisible
- Resulted in virtually zero cases of chronic infection, foreign body reaction, adhesions, mechanical failure, tissue erosion, scarification, mesh shrinkage, and other common issues found with synthetic and biological mesh devices

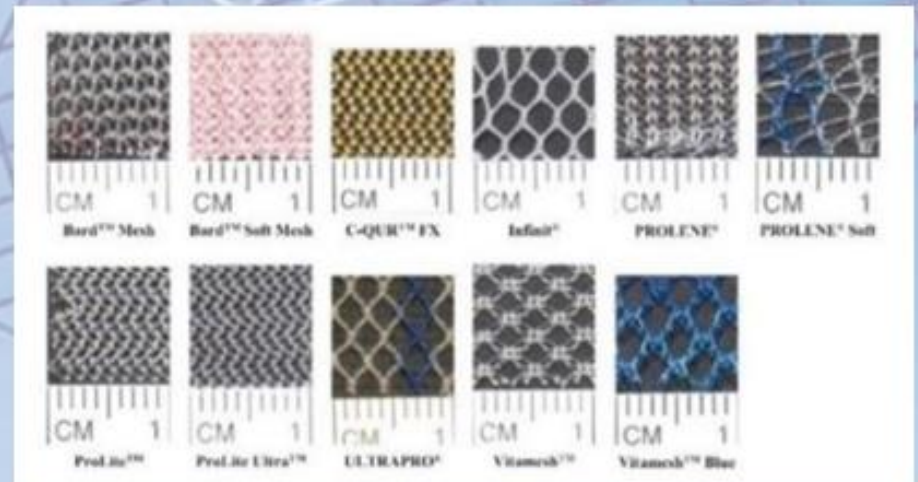
In short, XyberCyl is a biologically invisible implant that mechanically stabilizes defective tissues in a way that overcomes or prevents physical impediments to spontaneous natural healing.

In an article published in the Journal of the Mechanical Behavior of Biomedical Materials entitled “The failure of polypropylene surgical mesh in vivo”, the following was written:

“Whilst some of these mesh products are made from natural biological materials and some from resorbable polymers, the majority are made from fibres of polypropylene, formed into sheets by weaving or knitting. ... There are over 100 different types on the market which vary considerably in their method of construction, fibre diameter and spacing, and material properties.” and,

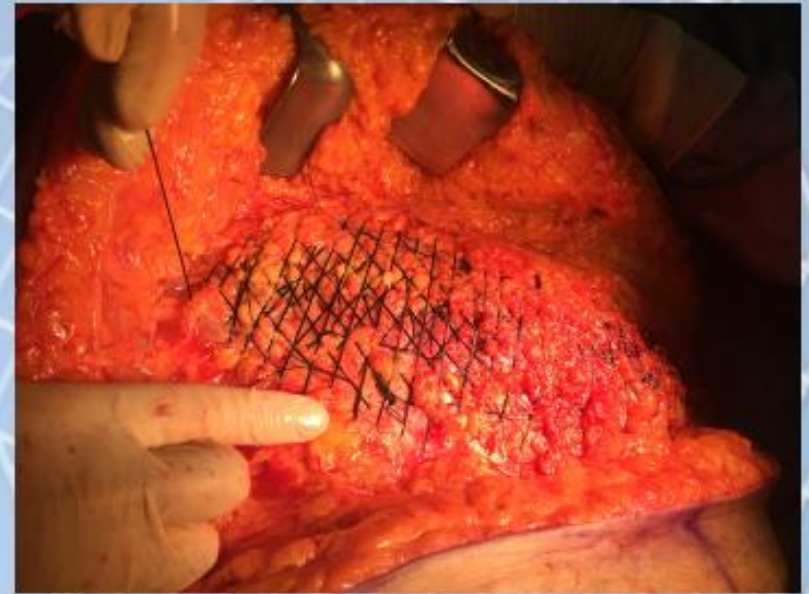
“PP mesh has been used for over fifty years in operations to repair abdominal hernias, in which a patch of material is sutured to the abdominal wall to prevent the hernia from reforming.” and,

[For certain types of surgeries:]
“During the last few years, evidence has emerged of failures in [some of] these products which have resulted in them being discontinued in many parts of the world.”

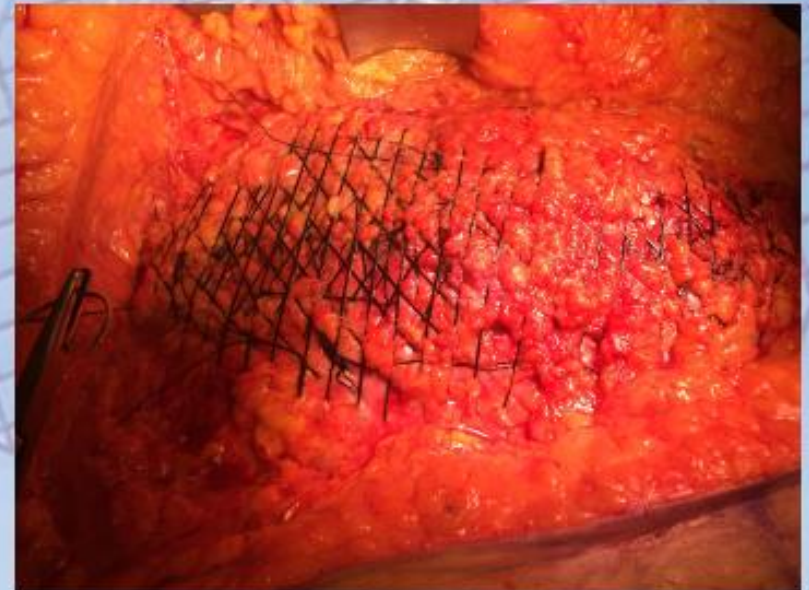


As mentioned earlier, the basis for the XyberCyl device is the surgical technique developed by Dr. Gorman. This technique has many benefits and eliminates the flaws and failures of standard surgical meshes, most significantly:

- The surgery is performed on an outpatient basis with local anesthetic (surgery in the morning, home by late afternoon)
- Zero complications and post-operation issues
- Stimulates and promotes measurable natural healing
- No hernia recurrence



Note mesh-like appearance of the sutures



Intellectual Property

US Patent US 10,792,142 BE

European Patent EP 2 819 616 BE1

Two patents pending: US and European

Future plans include additional patent applications that will facilitate expansion and extension of the existing patents (granted and pending).

United States Patent
Gorman

10,792,142
October 6, 2020

Implantable areal device for supporting tissue

Abstract

An implantable areal device for supporting defective musculo-fascial tissue mechanically and by regeneration of areolar and fascial tissue. The device is formed by a plurality of thread sections that define a plurality of void spaces. At least one of the void spaces is more than one-hundred square millimeters in area. A method for supporting defective musculo-fascial tissue mechanically and by in-situ tissue engineering that includes the fixation of the device by open surgical techniques to defective musculo-fascial tissue. As a result, this fixation immediately provides mechanical support of the tissue, and subsequently provides physiological repair by allowing regenerative precursor cells to infiltrate freely into the void spaces and to proliferate therein, leading to regeneration of volumetric anatomy of functionalized musculo-fascial tissue.

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Applicant: Name City State Country Type
Gorman; Joel Kiryat Yearin N/A IL
Family ID: 62556472
Appl. No.: 15899,083
Filed: February 19, 2018



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Questions about this communication ?
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Date
12.09.19

Reference I33177WOEP	Application No./Patent No. 13755292.3 - 1113 / 2819616
Applicant/Proprietor Incorpracyl Technologies Ltd.	

Decision to grant a European patent pursuant to Article 97(1) EPC

Following examination of European patent application No. 13755292.3 a European patent with the title and the supporting documents indicated in the communication pursuant to Rule 71(3) EPC (EPO Form 2004C) or in the information (EPO Form 2004W, of. Notice from the EPO dated 8 June 2015, OJ EPO 2015, A52) dated 09.05.19 is hereby granted in respect of the designated Contracting States.

Patent No. : 2819616
Date of filing : 28.02.13
Priority claimed : 28.02.12/USP201261603958
27.02.13/USP201361769767

Designated Contracting States and Proprietor(s)
: AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI
LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR
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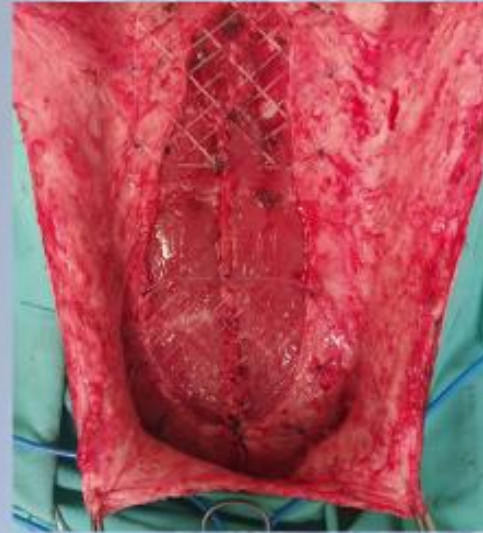
Proof of Concept

Two porcine POC studies were undertaken: Open and Laparoscopic, comparing XyberCyl to two of the leading meshes in the market today.

In the Open study, XyberCyl and Prolene meshes were implanted in an onlay position; a control area in each animal was designated between the implantation of each type of mesh.

In the Laparoscopic study, XyberCyl and Ventralight ST meshes were implanted laparoscopically.

Open Study



XyberCyl



Prolene

Laparoscopic Study



XyberCyl



Ventralight ST

Study Results

The POC studies in large animals have now shown conclusively that XyberCyl is suitable for open and laparoscopic placement, and that it gives results uniquely reflecting its true biocompatibility, as expected from the handwoven predicate technique. And, as likewise expected, in distinction to that shrinkage and suppression of healthy non-scarified healing shown by conventional meshes (Prolene and Ventralight ST).

Open Study		
Parameter	XyberCyl	Product "P"
Natural Healing	Robust	Inhibited
Inflammatory Response	No	Yes
Thickness of Healing Response	2.1 cm	0.8 cm
Healing Compared to Control	Equivalent	Significantly Less
Palapable Stiffening	No	Yes
Laparoscopic Study		
Parameter	XyberCyl	Product "V"
Natural Healing	Yes	Suppressed
Integration - Surrounding Tissue	Yes	No
Shrinkage	0%	17%
Wrinkling/Folding	None	Prominent
Adhesions	None	None

Summary

XyberCyl meets or exceeds the following characteristics and requirements of the ideal mesh:

- Noncarcinogenic
- Chemically inert
- Resists mechanical strain
- Capable of being sterilized
- No foreign body reaction
- Amenable to fabrication in the necessary form

- No allergic or hypersensitivity reaction
- Resistant to infection
- Resistant to adhesions on visceral side
- Response similar to autologous tissue
- No chronic pain or stiff abdomen
- No chronic infection
- Low shrinkage and recurrence rate
- Permanent



Thank You !!

For more information, please contact:

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