Phasix™ Mesh for Incisional Hernia Prevention Regional Value Brief (Europe)



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Abbreviations

CDC Centers for Disease Control and Prevention	**CI** Confidence Interval	**COPD** Chronic Obstructive Pulmonary Disease
EVEREG el Registro Nacional de Hernia Incisional	**HCRU** Healthcare Resource Use	**HR** Hazard Ratio
IH Incisional Hernia	**IQR** Interquartile Range	**LOS** Length of Stay
OR Odds Ratio	**QoL** Quality of Life	**QLQ-C30** Quality of Life Questionnaire C30 v3.0
SD Standard Deviation	**SSI** Surgical Site Infection	**VHWG** Ventral Hernia Working Group

About This Value Brief



Introduction to the Phasix™ Mesh Value Brief

This Regional Value Brief

Is designed to demonstrate the clinical and economic burden of incisional hernia treatment and highlight the clinical and economic benefits of a prevention-based strategy using Phasix™ Mesh in Europe.

Guide to Content

- The regional value brief is based on data identified up until April 2025.
- It focuses on the burden and unmet needs associated with a treatment-based strategy for incisional hernia management and highlights the potential clinical and economic value of adopting a prevention-based strategy using Phasix™ Mesh.

1. Executive Summary

Millions of surgical procedures carrying the risk of incisional hernia development are performed each year (1-4). Incisional hernias occur close to or at the site of a prior surgical incision and are a common complication of open abdominal surgery, occurring in 5–53% of cases (5-13).

Colorectal surgery is one of the most widely documented risk factors for incisional hernia repair, with incidences reaching 49–53% in high-risk patient groups, such as those with malignant diseases (11-13).

In other high-risk patient groups (e.g. patients with morbid obesity or abdominal aortic aneurysm) the risk is up to 40% (14, 15).

- Incisional hernias reduce patients' physical and mental quality of life (QoL) (16-18), and cause discomfort and or pain in the majority of patients (19).
- They develop as a consequence of inadequate wound closure and secondary complications, such as wound infection (20, 21).
- The risk for incisional hernia is determined by a range of factors, including both patient-related (e.g. age and comorbidities) and operative risk factors (e.g. surgical speciality and post-operative complications) (22-24).
- As well as the impact on patients, incisional hernia is a considerable economic burden for national healthcare systems (10, 13).

For Example:

Incisional hernia costs over five years for all patients undergoing abdominal surgery in any given year in France were €67.7 million (2013/14) (13). Excess costs for patients with incisional hernia (vs those without) in England were £163.9 million over three years (2014–2017) (10).

The standard of care for treating abdominal/ventral hernia is surgical repair using mesh (25, 26), given the lower rates of recurrence compared with primary suture closure (26-28).

The choice of mesh is dependent on the patient, the defect, and the surgeon involved (25, 29).

Meshes are categorised as permanent synthetic, biologic, and bioabsorbable (25, 29-33). While permanent synthetic meshes offer high tensile strength, they can be associated with serious post-operative complications (27, 30, 32). Biologic meshes use biocompatible materials, but are more costly and have lower mechanical strength (vs permanent synthetic) (29, 30, 34). Their degradation rate can be difficult to predict, since it is dependent on colonising cells to deposit new extracellular matrix (34). Finally, bioabsorbable meshes provide comparable or improved clinical outcomes and a lower risk of post-operative complications vs synthetic meshes (29).

Prophylactic mesh augmentation has been shown to significantly reduce the incidence of incisional hernia following abdominal surgery (vs primary suture closure) (35), and, consequently, interest in prophylactic mesh for the prevention of incisional hernia is increasing (14, 15, 22, 35-40), particularly in settings of high-risk surgeries (14, 15, 37, 38) and for high-risk patients (22, 35, 39, 40).

This is reflected in guidelines for incisional hernia treatment, which include recommendations on prophylactic mesh use (25, 41-43). Nevertheless, mesh prophylaxis remains underused.

1. Executive Summary (cont.)

Phasix™ Mesh is a fully resorbable monofilament surgical mesh scaffold, indicated to reinforce soft tissue where weakness exists in patients undergoing abdominal, plastic, and reconstructive surgery in ventral hernia repair and other abdominal fascial defect procedures, including prophylactic use to reinforce surgical incisions (44).

Composed of the naturally occurring polymer, poly-4hydroxybutyrate (P4HB), Phasix™ Mesh offers comparable strength and flexibility to permanent synthetic polymers (44, 45).



The macroporous knitted monofilament structure of Phasix™ Mesh has a smaller surface area than other bioabsorbable or permanent synthetic meshes, which is associated with a consistently milder inflammatory response (46, 47), and facilitates quicker integration of the mesh with host tissue and more extensive tissue remodelling (45, 46).

The increased early tissue remodelling activity and predictable long-term resorption profile (12–18 months) of Phasix™ Mesh provide greater overall mechanical strength of the repaired abdominal wall, while allowing for a more gradual transfer of load bearing from the mesh to repaired tissue compared with biologic and more rapidly resorbable (2–6 months) synthetic meshes (31, 43, 45).

Clinical trials for Phasix™ Mesh in prophylaxis are ongoing (48-51). 3 retrospective reviews reported no instances of incisional hernia at ≤1-year post-index surgery with the prophylactic use of Phasix™ Mesh in high-risk surgical settings and patient groups (52-54), and the favourable long-term outcomes reported across systematic reviews (45, 55, 56), and a clinical trial with a follow-up period of 5 years (57), provide additional support for the prophylactic use of Phasix™ Mesh.

From an economic perspective, there is evidence that prophylactic use of mesh could lead to long term cost savings for national healthcare systems (58-60).



2. Value Story

Clinical Burden

- Patients with incisional hernias have high subsequent clinical burdens, including recurrences and complications (5-9, 19-22, 61, 62)
- Certain factors put patients at high risk for developing incisional hernias (10, 12, 13, 22-24, 43, 63-65)
- High-risk patients undergoing open laparotomies are associated with a high rate of incisional hernias which may require reoperation (13)
- The incidence of incisional hernia can be as high as 53% (5-13)

Economic Burden

- Incisional hernia is associated with a considerable economic burden for national healthcare systems (10, 13)
- Patients at high risk of incisional hernias have significantly higher costs than patients without incisional hernia (10)

Humanistic Burden

- Incisional hernias can reduce patient QoL (16-18)

Current Management

- The standard of care for hernia is surgical repair, using mesh (25, 26)
- Mesh utilisation has been proven to reduce the rate of incisional hernia (26-28)
- Interest in prophylactic mesh for the prevention of incisional hernia is increasing (14, 15, 22, 35-40), particularly for high-risk surgeries (14, 15, 37, 38) and high-risk patients (22, 35, 39, 40)
- Prophylactic mesh in the onlay position has lower rates of incisional hernia compared with primary sutures (35)
- Guidelines for incisional hernia treatment include recommendations on prophylactic mesh use, particularly for high-risk patient groups (25, 41-43)

Unmet Need

Why Invest in the Prevention of (Incisional) Hernias?

- There is no consistent standardised technique to close open abdominal incisions, preventing incisional hernia
- There is an unmet need to reduce the incidence of incisional hernia, while also reducing the risk of post-operative complications
- Hernia prevention would be of particular benefit in the group of high-risk patients (10, 17, 37) and for high-risk procedures, which are associated with the highest burden (10, 12, 17, 20, 41, 61-64, 74)

Why Phasix™ Mesh?

- Phasix™ Mesh is a well-established product (44-47, 55-57)
- Phasix™ Mesh is successful for complex abdominal wall reconstruction and fascial closure for hernia prevention (29, 45)
- Phasix™ Mesh minimises post-operative mesh-related complications and mesh removal (40)
- Phasix™ Mesh naturally and predictably degrades leaving no permanent foreign body (44)
- Phasix™ Mesh improves patient QoL (66)
- Phasix™ Mesh reduces the risk of post-operative incisional hernia (40)
- Several clinical trials evaluating the long-term efficacy of prophylaxis with Phasix™ Mesh to reduce the incidence of incisional hernia in high-risk patient groups and high-risk surgical settings are ongoing (48-51)
- The cost of using prophylactic mesh may be offset by reducing subsequent hernia repairs and complications and the associated healthcare utilisation

3. Background and Burden of Incisional Hernia

Key Messages

- Incisional hernias occur close to or at the site of a prior surgical incision and are a common complication of open abdominal surgery, affecting 5–53% of cases, with incidence rates depending on operative and patient-related risk-factors (5-9, 11-13)
- Patients with incisional hernia experience reduced physical and mental QoL (16), and 83% present with some discomfort and or pain (19)
- Secondary complications, such as wound infection, can interfere with the local inflammatory response and the normal wound healing process, ultimately leading to the development of incisional hernia (20, 21)
- Annually, there are 16,531,491 inpatient general surgical procedures in Germany (2023), 4,507,258 in the United Kingdom (UK) (2010), 5,413,996 in Italy (2022), 4,041,391 in Spain (2019), 782,842 in Greece (2007), and 710,074 abdominal surgical procedures in France (2013/14) (1-4, 13)
- The incidence of incisional hernia depends on a range of factors, including both patient-related factors (e.g. age and comorbidities) and operative risk factors (e.g. surgical speciality and post-operative complications) (22-24)
- High-risk patients undergoing open laparotomies are associated with a high rate of incisional hernias which may require reoperation (13)
- Incisional hernia is a considerable economic burden for national healthcare systems (10, 13), with associated costs of €67.7 million over five years for all patients undergoing abdominal surgery in any given year in France (2013/14) (13). Excess costs for patients with incisional hernia (vs those without) in England were £163.9 million over three years (10)

3.1. Background

A hernia is defined as a protrusion, bulge, or projection of an organ or part of an organ through a body wall that normally contains it (5). Incisional hernias occur near or along the site of previously made incisions and are the most frequent complication following open abdominal surgery, occurring in 5– 53% of cases, with incidence rates depending on operative and patient-related risk-factors (5-9, 11- 13).

Colorectal surgery is one of the most widely documented risk factors for incisional hernia repair, with incidences reaching 49–53% in high-risk patient groups, such as those with malignant diseases (11-13).

In other high-risk patient groups (e.g. patients with morbid obesity or abdominal aortic aneurysm) the risk is up to 40% (14, 15).

The majority of incisional hernias are ventral incisional hernias, as abdominal incisions are more frequently made in the anterior abdominal wall (5).



While incisional hernias can occur following any surgical procedure requiring the incision of the abdominal wall, there are several surgical specialities, such as colorectal procedures, ostomy creation and takedown, liver transplant, gynaecology procedures, and urology procedures, that are associated with a high incidence of incisional hernia development, particularly in high-risk patient groups (Section 3.2.3.1) (10, 12, 15, 39, 67, 68).

Incisional hernias are associated with impaired patient QoL, both in physical and mental domains (16). Furthermore, the economic burden of incisional hernia to healthcare systems is considerable (69).

Patients who require incisional hernia repair following abdominal surgery in the UK reportedly have a mean total HCRU cost between index surgery and incisional hernia repair of £23,148 per patient, compared with £12,321 per patient for those who do not require incisional hernia repair, indicating that these high-risk patient groups require almost twice as many healthcare resources without even considering the costs of hernia repair (10). In France, the hospital-related costs of incisional hernia repair are estimated to be €67.7 million over five years nationally for all patients requiring incisional hernia repair in a single year following abdominal surgery (13). Estimated annual costs of treatment in the US are $7.3 billion (2011 USD) (69).

3.2. Aetiology, Epidemiology, and Risk Factors

3.2.1. Aetiology

Incisional hernias occurring shortly after abdominal surgery and during the wound healing period are often due to inadequate closure (22, 70).

The molecular pathogenesis of late-onset incisional hernias suggests that the disorganisation of the extracellular matrix and the disruption of collagen metabolism play pivotal roles in their development (20, 21).

Wound infection and other secondary complications can interfere with the local inflammatory response and interrupt collagen synthesis, ultimately disrupting the normal wound healing process.

3.2.2. Epidemiology

3.2.2.1. Numbers of Surgical Procedures

As described in Section 3.1, any open abdominal surgery carries a risk of incisional hernia (5-9). The data presented in this section illustrate the large number of open abdominal surgeries taking place. Each year, there are 16,531,491 inpatient general surgical procedures carried out in Germany (2023), 4,507,258 in the UK (2010), 5,413,996 in Italy (2022), 4,041,391 in Spain (2019), 782,842 in Greece (2007), and 710,074 abdominal surgical procedures in France (2013/14) (1-4, 13).

Inpatient admissions in England during the year 2022–23 for abdominal surgical specialties associated with high incidences of incisional hernia repair (10, 12, 15, 39, 67, 68) range from 612,462 admissions for urological surgery to 10,392 admissions for transplant surgery (Table 1) (71).

Table 1: Inpatient Admissions by Abdominal Surgical Speciality in England During 2022–23

Surgical Speciality	Total Patient with Index Surgery, N
Colorectal surgery	310,309
Urological surgery	612,462
Gynaecological surgery	474,070
Gynaecological oncology surgery	20,392
Hepatobiliary and pancreatic surgery	22,849
Transplant surgery	10,392

Source: NHS England, 2023 (71)

In Germany, there were 16,531,491 inpatient general surgical procedures performed in 2023 (1). Among the 20 most frequently performed inpatient surgeries, the number of surgical procedures of a type that is associated with a high incidence of incisional hernia repair (10, 12, 15, 39, 67, 68) ranged from 201,602 cholecystectomy procedures to 386,048 other intestinal surgeries (Table 2) (1).



Table 2: Inpatient Procedures by Surgical Speciality in Germany During 2023

Surgical Speciality	Total Patient with Index Surgery, N
Cholecystectomy	201,602
Local excision and destruction of diseased tissue of large intestine	212,465
Other surgery on intestine	386,048
Other Caesarean section	252,209

Source: Federal Statistical Office of Germany, 2024 (1)



During 2022, in Italy, there were 5,413,996 inpatient discharges following general surgical procedures (2). The number of specialist surgical discharges (completed procedures) that are correlated with high rates of incisional hernia (10, 12, 15, 39, 67, 68) ranged from 114,237 for myeloproliferative diseases and disorders and poorly differentiated neoplasms to 750,784 for diseases and disorders of the cardiovascular system (Table 3) (2).

Table 3: Inpatient Discharges by Surgical Speciality in Italy During 2022

Surgical Speciality	Total Patient with Index Surgery, N
Diseases and disorders of the respiratory system	555,191
Diseases and disorders of the cardiovascular system	750,784
Diseases and disorders of the digestive system	459,392
Hepatobiliary and pancreatic diseases and disorders	248,273
Kidney and urinary tract diseases and disorders	349,994
Myeloproliferative diseases and disorders and poorly differentiated neoplasms	114,237

Source: Italian Ministry of Health, 2024 (2).

In Spain, there were 4,041,391 million patients hospitalised in National Health Service hospitals in 2019 (3). The total number of patients hospitalised with high-risk comorbidities for the development of incisional hernia ranged from 206,000 patients with chronic obstructive pulmonary disorder (COPD) to 742,000 patients with malignant tumours (Table 4) (3).

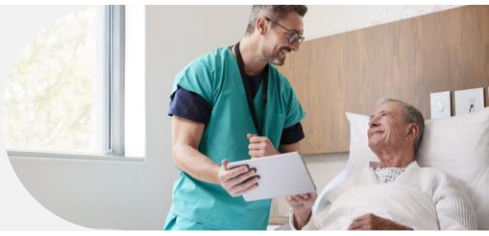

Table 4: Adult (Aged ≥40 Years) Inpatient Hospitalisations by Surgical Speciality in Spain During 2019

Surgical Speciality	Total Patient with Index Surgery, N
COPD	20.6
Ischaemic heart disease	24.5
Malignant tumours	72.4

Abbreviation: COPD, chronic obstructive pulmonary disease.
Source: Spanish Ministry of Health, 2022 (3).

In France, during 2013–14 there were 710,074 patients admitted for all types of abdominal surgery (13).

3.2.2.2. Incidence of Incisional Hernia

The reported incidence of incisional hernia in the current literature ranges from 5–53% (5-13) and depends on several factors, including patient-related risk factors (Section 3.2.3.1), such as age, and the presence of comorbidities, and operative risk factors (Section 3.2.3.2), including the surgical speciality, type of incision used, and post-operative complications (22-24).

Colorectal surgery is one of the most widely documented risk factors for incisional hernia repair, with incidences reaching 49–53% in high-risk patient groups, such as those with malignant diseases (11-13). In other high-risk patient groups (e.g. patients with morbid obesity or abdominal aortic aneurysm) the risk is up to 40% (14, 15).

- Of 297,134 patients who underwent abdominal surgery between 1st April 2014 and 31st March 2017 in England, 15,138 (5.1%) required incisional hernia repair within 6.5 years (10)
- There were 4,501 hernias (1,636 hernias/year) registered in the Spanish Registry of Incisional Hernias (EVEREG) between July 2012 and March 2015 (95 participating hospitals) (65)
- A total of 154,546 incisional hernia repairs were performed in Italy between 2015 and 2018 and most (86.55%) were performed as open procedures (72). In 2019, 87,182 hospitalisations with a main diagnosis of ventral hernia were reported (combined cases of acute, long-term, and rehabilitation admissions) (73)
- It is estimated that 104,000 incisional hernias are newly diagnosed in Germany annually and 50,521 incisional hernia repair procedures were coded for in 2015 (61)
- In France 710,074 patients underwent abdominal surgery in 2013–2014, with 32,633 patients (4.6%) and 5,117 patients (0.7%) requiring ≥1 and ≥2 incisional hernia repairs, respectively, in the subsequent five years (13)

3.2.3. Risk Factors

There is a wide range of risk factors for the development of incisional hernia that can be broadly categorised as either patient-related (Section 3.2.3.1) or operative (Section 3.2.3.2) (22, 39).

3.2.3.1. Patient-related Risk Factors

Patient-related risk factors for the development of incisional hernia include gender, age, smoking, immunosuppression with steroids or resulting from chemotherapy, radiotherapy exposure, and comorbidities, such as diabetes mellitus, COPD, hypoalbuminemia, malignant disorders, connective tissue disorders, and obesity (10, 22, 39).

Gender
Male gender has been shown to be a statistically significant risk factor for the development of incisional hernia within 5 years of the patient's index abdominal surgery (HR 1.44; [95% CI: 1.39, 1.48]; p<0.0001) (Table 5) (10)

Age
The risk of incisional hernia progressively increases with patient age, with patients aged 51–70 years old (HR 1.82; [95% CI: 1.75, 1.89]; p<0.001) and patients aged ≥71 years old (HR 1.83, [95% CI: 1.75, 1.92]; p<0.001) reportedly having almost twice the risk of incisional hernia compared with patients aged 18–50 years old (Table 5) (10)

Immunosuppression
Patients who are immunosuppressed, e.g. transplant patients (64), or cancer patients receiving chemotherapy or radiotherapy (68, 74), have an impaired wound healing process, leading to an increased risk of incisional hernia (HR 1.26; [95% CI: 1.14, 1.40]; p<0.001) (Table 5) (10)

Comorbidities
Patients undergoing incisional hernia repair are reported to have higher rates (vs no incisional hernia repair) of diabetes (15.2% vs 12.5%), smoking (23.5% vs 18.1%), COPD (8.6% vs 5.1%) and obesity (18.7% vs 14.7%) at the time of their index surgery (10). Additionally, the risk of incisional hernia development is statistically significantly higher in patients who have ≥2 comorbidities vs patients who have no comorbidities (HR 1.74; [95% CI: 1.69, 1.80]; p<0.001) (Table 5) (10)

Table 5: Patient-related Risk Factors for Incisional Hernia Repair

Risk Factor	Hazard Ratio	95% CI	P-value
Gender			
Female	Reference	Reference	Reference
Male	1.44	1.39, 1.48	<0.001
Age			
18 – 50 years old	Reference	Reference	Reference
51 – 70 years old	1.82	1.75, 1.89	<0.001
≥ 71 years old	1.83	1.75, 1.92	<0.001
Charlson Comorbidity Index			
0	Reference	Reference	Reference
1	0.65	0.41, 1.02	0.061
≥ 2	1.74	1.69, 1.80	<0.001
Comorbidities			
Diabetes†	1.31	1.25, 1.37	<0.001
Smoking†	1.38	1.33, 1.44	<0.001
COPD†	1.91	1.80, 2.02	<0.001
Obesity†	1.29	1.24, 1.35	<0.001
Immunosuppression†	1.26	1.14, 1.40	<0.001

Abbreviations: CI, confidence interval; COPD, chronic obstructive pulmonary disease
Source: Smith, 2024 (10)
† Reference level = absence of comorbidity

3.2.3.2. Operative Risk Factors

Operative risk factors for incisional hernias include the surgical speciality, incision site, surgical technique, and post-operative complications, such as abdominal sepsis and recurrence (22, 65). Other operative and patient-related factors can compound the hernia risk (10, 22).

Surgical Speciality

The rates of incisional hernia repair at 6.5 years after index surgery are highest for colorectal surgery (10.0%) and hepatobiliary surgery (8.2%) (Table 6) (10)

Table 6: Post-operative Incidence of Incisional Hernia Repair at 6.5 Years by Surgical Speciality (England, 2014-2017)

Surgical Speciality	Total Patient with Index Surgery, N	Incisional Hernia Repair, N (%)
Overall abdominal surgery	297,134	15,138 (5.1%)
Bariatric and Gastrectomy surgery	18,344	635 (3.5%)
Colorectal surgery	68,127	6, 778 (10.0%)
Gynaecological surgery	83,268	2,142 (2.6%)
Hepatobiliary surgery	9,693	797 (8.2%)
Transplant surgery	11,548	781 (6.8%)
Urologic surgery	75,663	3,030 (4.0%)
Vascular surgery	30,491	975 (3.2%)

Source: Smith, 2024 (10)

- Colorectal surgery is one of the most widely documented risk factors for incisional hernia repair, with incidences reaching 49–53% in high-risk patient groups, such as those with malignant diseases (11-13)
- The creation of an ostomy, an artificial opening in the abdominal wall, is associated with high incidences of incisional hernia (48.3%) and parastomal hernia (52.9%), with both occurring in the same patient in 35.6% of cases ($p<0.001$) (6). Additionally, the reversal of an ostomy, also referred to as stoma takedown, has a reported incidence of incisional hernia at the previous stoma site of 34.6% (63)
- Kaplan-Meier estimates of the rate of incisional hernia development following liver transplantation at one, five, and 10 years post-transplantation are reported to be 4.5%, 13.6%, and 19.0%, respectively (64)
- Incisional hernia is among the most common complications associated with open abdominal aortic aneurysm repair, with a reported incidence of 36.6% in patients with comorbidities such as diabetes mellitus (17)

Emergency Procedures

Operative status (emergency vs elective) of the index abdominal procedure has been shown to be a significant risk factor for the development of incisional hernia (HR 2.31; [95% CI: 1.54, 3.48]; $p<0.001$) (12). Similarly, significantly more patients who undergo emergency hernia repair surgery (vs elective) require reoperation within 30 days (8.2% vs 3.5%, $p=0.0014$) (65)

Recurrence and Reoperations

Recurrences constitute a considerable proportion of incisional hernia repairs (22.2%) and significantly more patients undergoing repairs of recurrent incisional hernias require reoperation within 30 days compared with patients undergoing primary incisional hernia repairs (5.7% vs 3.2%, $p=0.0016$) (65)

Type of Incision

There is limited evidence in the published literature on the incidence of incisional hernia by incision type. Available data show that midline incisions, including those at sample extraction sites, have the highest rate of incisional hernia post-surgery (43). Furthermore, there is evidence that both transverse (HR 0.45; [95% CI: 0.21, 0.97]; $p=0.041$) and inverted L type (HR 0.60 [95% CI: 0.37, 0.98]; $p=0.042$) incisions are associated with a significant reductions in the risk of developing incisional hernia compared with standard midline incisions (12)

Surgical Technique

The risk of incisional hernia repair is almost doubled for patients undergoing laparotomy compared with patients undergoing laparoscopy (HR 1.9; [95% CI: 1.7, 2.1]; $p<0.0001$) (13)

Contamination and Wound Infection

Surgical site infection (SSI) is a post-operative complication that is significantly associated with incisional hernia development (vs no SSI) (HR 1.95; [95% CI: 1.45, 2.64]; $p<0.001$) (12)

3.3. Clinical and Humanistic Burden of Incisional Hernia

Incisional hernia can vary in presentation and progression, ranging from asymptomatic to incarceration, which is one of the most severe complications of incisional hernia and occurs in 6–15% of cases (22).

An incarcerated hernia is defined as a hernia that cannot be reduced from the site of the protrusion.

When the blood flow to the herniated content is occluded, it is referred to as strangulated (62).

Incarceration of hernias can result in pain or obstruction of an involved organ (62). Strangulated hernias are often painful and may cause nausea, vomiting, peritonitis, sepsis, and cardiovascular collapse (62). Incarcerated or strangulated hernias commonly require emergency surgical repair and can lead to intestinal tissue necrosis requiring bowel resection, which is associated with substantial further morbidity for patients (75, 76). For example, post-operative complications are more commonly reported in patients who have undergone hernia repair and bowel resection compared with hernia repair only (67% vs 36%, p=0.035) (75).

While 17% of patients with incisional hernia present asymptomatically or without acute abdominal pain (19, 62), 83% of patients report discomfort, intermittent pain and gastrointestinal symptoms, e.g. postprandial fullness (19, 22, 61, 62).

Incisional hernias following colonic cancer resection have also been associated with a reduced QoL as measured by the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire C30 v3.0 (QLQ-C30) in terms of global health (p<0.01), physical functioning (p<0.01), role functioning (p<0.01), emotional functioning (p<0.01), and social functioning (p<0.05) vs no hernia (17, 18).



Secondary surgical complications are significantly more frequent in patients with incisional hernia (vs without) (31% vs 22%, p<0.001); complications include small bowel obstruction, superficial wound cellulitis, post-operative bleeding, and sepsis (77).

The risk of incisional hernia was also found to correlate with all-cause reoperation rates, with 79% of high-risk patients undergoing reoperation following hernia repair compared with 26% of low-risk patients (77). Emergency incisional hernia repairs have worse outcomes than elective procedures and can lead to substantial further morbidity (12). In the UK, the 90-day mortality rates following incisional hernia repair are 2.3% and 3.4% in patients aged <70 and ≥70 years old, respectively (78). Emergency hernia surgical repair procedures in the United States reportedly have an average mortality rate of 3.3% (79).

3.4. Economic and Societal Burden of Incisional Hernia

Incisional hernia is associated with a substantial economic and societal burden (10, 13).

In France, mean hospital costs of incisional hernia repair (2013/2014) were approximately €4,153 per repair. The cost of incisional hernia repair for all patients undergoing abdominal surgery in a given year equates to €67.7 million over five years (13). In addition to the length of stay (LOS) for the incisional hernia repair procedure (mean 6.3 days), patients who developed incisional hernia within 5 years of abdominal surgery were reported to have an increased mean LOS during the index surgery (12 days) compared with all patients who underwent abdominal surgery (8.0 days) (13).

The mean total cost of an incisional hernia repair (direct and indirect) for employed patients in 2011 was €10,107.

For these employed patients, the indirect costs associated with incisional hernia repair in France reportedly exceed the direct costs (€5,376 vs €4,731 per repair, respectively). The average total cost for incisional hernia repair, regardless of employment, was estimated to be €6,451. These findings suggest that a reduction of 5% in the rate of incisional hernia repair following abdominal surgery could result in national cost savings of around €4 million in France (80).

In the UK, patients undergoing incisional hernia repair are reported to have more healthcare contacts, longer LOS at index surgery, and more Accident and Emergency visits compared with those with no incisional hernia repair post index surgery.

Incisional hernia repair is associated with an average HCRU cost of £23,148 compared with £12,321 in patients with no incisional hernia repair, indicating that these high-risk patient groups require almost twice as many healthcare resources, without even considering the costs of hernia repair (Table 7) (10). Data from the British Hernia Society illustrate the risk of repeated hernias following an initial incisional hernia repair: 10.6% of patients undergoing elective hernia repair in 2016–2017 had a hernia repair procedure in the preceding three years (81).

These economic burden data further confirm that incisional hernia repair is more common in high-risk patient groups with multiple comorbidities (10, 22, 77) (see also Section 3.2.3.1). Prevention strategies targeting these patient groups could potentially be cost-effective.

Table 7: Healthcare Resource Use and Costs in the UK, for 15,138 Patients Undergoing Incisional Hernia Repair (Index Procedure Between 2014 And 2017)

Healthcare Resource Use	Incisional Hernia Repair	No Incisional Hernia Repair	Difference (Repair vs No Repair)
Index surgery LOS, days, median (IQR)	7 (4, 13)	3 (2, 7)	4
Number of patients with ≥1 nonelective admission, n (%)	12,296 (81.2%)	160,481 (56.9%)	24.3%
Number of patients with ≥2 nonelective admissions, n (%)	9,454 (62.5%)	104,227 (37.0%)	25.5%
Number of non-elective inpatient admissions per patient, median (IQR)	2 (1, 5)	1 (0, 3)	1
Number of elective inpatient admissions per patient, median (IQR)	1 (0, 1)	0 (0, 0)	1
Total cumulative LOS for non-elective inpatient admissions per patient, days, median (IQR)	8 (1, 28)	1 (0, 10)	7
Total Costs, Mean per Patient (SD)			
Admission for index surgery	£5,774.78 (4,114.23)	£4,567.13 (3,718.68)	£1,207.65
Non-elective inpatient admissions following index surgery	£10,718.94 (16,613.09)	£5,086.53 (10,680.38)	£5,632.41
Outpatient visits	£4,095.12 (3,867.99)	£2,666.84 (3,345.16)	£1,428.28
All-cause cumulative HCRU costs	£23,147.70 (19,071.64)	£12,320.55 (13,054.75)	£10,827.15
Total cost of care for matched cohort size[†] (All-cause HCRU costs x number of IH repairs)	£350,409,883	£186,508,486	£163,901,397.00

Abbreviations: HCRU, healthcare resource use; IH, incisional hernia; IQR, inter quartile range; LOS, length of stay; SD, standard deviation.
[†] N=297,134.
Source: Smith, 2024 (10)

4. Current Management of Incisional Hernia

Key Messages

- The standard of care for incisional hernia is surgical repair, using mesh (25, 26)
  - The choice of treatment and mesh depends on several factors relating to the patient, the defect, and the surgeon (25, 29)
- Incorporating surgical mesh during incisional hernia repair is associated with lower rates of recurrence compared with primary suture closure (26-28)
- Meshes are categorised as permanent synthetic, biologic, and bioabsorbable (25, 29-33)
  - Permanent synthetic meshes offer high tensile strength, but can be associated with serious post-operative complications (27, 30, 32)
  - Biologic meshes use biocompatible materials, but are more costly and have lower mechanical strength (vs permanent synthetic) (29, 30, 34)
  - Bioabsorbable meshes provide comparable or improved clinical outcomes and a lower risk of post-operative complications vs synthetic meshes (29, 82)
- Interest in prophylactic mesh for the prevention of incisional hernia is increasing (14, 15, 22, 35-40), particularly for high-risk surgeries (14, 15, 37, 38) and high-risk patients (22, 35, 39, 40)
  - Prophylactic mesh augmentation significantly reduces the incidence of incisional hernia following abdominal surgery (vs primary suture closure) (p=0.0004) (35)
  - Prophylaxis with bioabsorbable mesh is increasingly viewed as a cost-effective or potentially cost-saving alternative to using biologic meshes (83, 84)
- Guidelines for incisional hernia treatment include recommendations on prophylactic mesh use (25, 41-43)
- There is an unmet need for a preventative approach for reducing the incidence of incisional hernia. In particular, there is an unmet need for prophylaxis with a slowly bioabsorbable mesh that effectively reduces the incidence of incisional hernia, while also reducing the risk of post-operative complications

Surgical repair of incisional hernias is often required to relieve common symptoms, e.g. pain and discomfort, and to prevent or resolve severe complications, including incarceration and strangulation (85).

Meshes used as the standard of care for hernia repair are also used at the time of primary laparotomy in order to reduce the risk of developing incisional hernia in high-risk patients (Section 3.2.3.1) (25).

4.1. Repair

Modern abdominal wall closure techniques incorporate a surgical mesh as the standard of care during laparoscopic ventral and incisional hernia repair (25, 26). The choice of treatment option and mesh depends on several factors, such as patient risk factors (Section 3.2.3.1), defect size and location, and surgeon experience and preference (25, 29).



4.1.1. Suture Closure

The combination of small continuous sutures (5 mm spacing) with a slowly absorbable material for the closure of elective midline incisions is recommended (43). Clinical data have shown that, for midline incisions with a mean length of 22 cm, short-stitch suturing (5 mm spacing) reduces the rate of incisional hernia at one year post-surgery compared with traditional long (1 cm spacing) sutures (21% vs 13%; p=0.0220) (86). A longer term follow-up (10–13 years) is ongoing (87). In contrast, for the closure of a midline laparotomy with an incision length ≥15 cm, short sutures (vs traditional long sutures) appear to provide little benefit (incidence of hernia at three years post-surgery: 7.58% vs 10.45%; p=0.316) (88).

4.1.2. Mesh Reinforcement

The use of surgical mesh in incisional hernia repair is associated with lower rates of hernia recurrence compared with suture repair (26-28). A variety of mesh options are available, including synthetic (Section 4.1.2.1), biologic (Section 4.1.2.2), and bioabsorbable (Section 4.1.2.3) meshes (25, 29-33).

4.1.2.1. Synthetic Mesh

The first meshes developed for hernia repair were made of synthetic materials (e.g. polyester, polypropene, and expanded polytetrafluoroethylene) (30). While synthetic materials offer good tensile strength, most are permanent and do not degrade over time (27, 29, 31).

Common Complications Reported with Synthetic Meshes Include:

- inflammation and elasticity loss
- an increased risk of infection (post-operative infections reported in 4% of patients who received mesh repair vs 2% of patients who received suture repair), restricting their use in contaminated fields (27, 31)

Permanent synthetic meshes are generally susceptible to erosion, particularly those constructed from polypropylene and polyester, which provoke an aggressive and chronic inflammatory response, and can potentially be eroded into the bowel or form inappropriate adhesions (30, 31). Other serious complications associated with most permanent mesh materials and structures include chronic pain, fistula, seroma, encapsulation and rejection (27, 30, 32).

4.1.2.2. Biologic Mesh

Biologic meshes refer to those derived from human, bovine, porcine, or fish decellularised tissue and aim to address the issues associated with synthetic meshes, while maintaining sufficient mechanical support, stimulating tissue remodelling and creating a durable repair (31, 34, 89). The extracellular matrix-based scaffolds of biologic meshes are intended to be repopulated by native cells, and are usually absorbed by the body (30, 89). Offering better biocompatibility than synthetic meshes, biologic meshes promote tissue remodelling, lead to milder inflammatory responses, and reduce the occurrence of fibrosis and fistulae (33).



However, biologic meshes have lower mechanical strength and a higher risk of hernia recurrence (vs permanent synthetic) (30, 33);

in addition, their degradation rate can be difficult to predict, since it is dependent on colonising cells to deposit new extracellular matrix (34). Complex manufacturing processes also make biologic meshes more expensive, which has been cited as a barrier to their wider adoption for incisional hernia repair (29,30, 34).

4.1.2.3. Bioabsorbable Mesh

Bioabsorbable meshes are made of synthetic materials that are absorbed by the body.

Time to full resorption varies from 2–36 months depending on their composition (82). Bioabsorbable meshes are designed to provide comparable clinical outcomes with permanent synthetic mesh while reducing the risk of long-term mesh-related complications (82).

In a meta-analysis (10 studies on bioabsorbable, 12 studies on synthetic, and 14 studies on biologic mesh) recurrence was reported in 9% (95% CI: 2, 19) of hernia repairs using bioabsorbable mesh, compared with 13% (95% CI: 8, 19) and 20% (95% CI: 14, 25) with synthetic and biologic meshes, respectively (29). Furthermore, in a separate meta-analysis reported in the same publication (four studies on bioabsorbable and five studies on both biologic and synthetic meshes) the incidence of infected mesh, a complication which frequently requires reoperation, was reported to be 0% (95% CI: 0, 2) with slowly absorbable biosynthetic mesh, compared with 2% (95% CI: 0, 7) and 9% (95% CI: 0, 25) for biologic and synthetic meshes, respectively (29). Meshes that are resorbed before tissue remodelling is complete (2–6 months) have a hernia recurrence rate of 75–100%, limiting their usefulness (31, 43, 82).



4.2. Prophylaxis

Given the substantial clinical and economic impact of incisional hernia (Sections 3.3 and 3.4), and the complications of hernia repair (Section 4.1), potentially leading to a vicious cycle of hernia repairs with each repair leading to a higher chance of hernia recurrence (90), there is an increasing focus on prevention (36), especially for high-risk patients (Section 3.2.3.1) (10, 39).

While there is conflicting data about the long-term efficacy of short-stitch suturing techniques for incisional hernia prevention (86, 88), a growing body of evidence supports the benefit of prophylactic mesh augmentation in reducing the occurrence of hernia in high-risk surgical specialities (14, 15, 37, 38) and high-risk patients (22, 35, 39, 40).

A meta-analysis of two studies (involving 175 patients who received prophylactic mesh placement and 168 patients who underwent primary suture closure)

showed that prophylactic mesh augmentation significantly reduces the incidence of incisional hernia at five years following abdominal surgery (vs primary suture closure) (OR 0.15; [95% CI: 0.03, 0.85]; p=0.03) (35).

Despite supporting guideline recommendations (Section 4.3), prophylactic mesh augmentation for incisional hernia prevention is underused. This is due to a perceived lack of evidence, concerns around short-term costs, infection risk, complications, longer time in surgery, and a lack of knowledge and training among surgeons who are not hernia specialists (38, 91).

The risk of incisional hernia development is also significantly influenced by the location of prophylactic mesh placement (35).

In the same meta-analysis, compared with primary suture closure, mesh placed in the onlay position was associated with a greater reduction in the risk of incisional hernia (OR 0.17; [95% CI: 0.08, 0.35]; p<0.00001) at three years post-surgery vs the intraperitoneal position (OR 0.59; [95% CI: 0.29, 1.19]; p=0.14) (p-interaction=0.02) (35).

To date, synthetic mesh has been more frequently evaluated for prophylactic mesh augmentation than biologic or bioabsorbable mesh (35).

However, the prophylactic use of bioabsorbable mesh is increasingly viewed as a cost-effective or even cost-saving alternative to biologic meshes (83, 84), and could improve clinical outcomes for patients deemed at a higher risk of incisional hernia development by the operating surgeon.

4.3. Prophylactic Mesh Use in Guidelines

Several guidelines published by professional societies for the management and repair of incisional hernia have recently been updated to include recommendations on prophylactic mesh augmentation (25, 41-43). Some guidelines only offer weak recommendations, citing limited or weak evidence in the available literature as the reason for the lack of robust recommendations (41, 43, 92). Other guidelines do not provide specific recommendations for the prophylactic use of mesh (93). An overview of key guidelines and recommendations for prophylactic mesh reinforcement is provided in Table 8.

The European and American Hernia Societies

published updates to their guidelines for the closure of abdominal wall incisions in 2022 to include recommendations on prophylactic mesh augmentation (43). It is suggested that prophylactic mesh augmentation can be considered in addition to suture closure during an elective midline laparotomy to reduce the risk of incisional hernia without increasing the risk of SSI. Permanent synthetic mesh is suggested for prophylactic use with placement in either the onlay or retromuscular plane (43).

The International EndoHernia Society

first published a three-part series of guidelines on the laparoscopic repair of both primary ventral and incisional abdominal wall hernias in 2014 (25, 26, 94), with the final publication covering mesh technology and including a dedicated subsection for hernia prophylaxis (25).

Updates were subsequently published in 2019 to cover recent developments in surgical techniques and relevant technological advances (42, 95). The updated guidelines state that prophylactic mesh reinforcement in the onlay plane can reduce the incidence of incisional hernia following elective midline laparotomy compared with sublay mesh placement and primary suture closure (42). Additionally, prophylactic mesh augmentation is recommended in high-risk patients in both the original and updated guidelines, e.g. those with morbid obesity, aortic aneurysm, or patients undergoing colorectal surgery (25, 42), and it is suggested in the updated guidelines that prophylactic onlay mesh may become the standard in midline laparotomies involving high-risk patients (42). Furthermore, the guidelines state that the application of prophylactic mesh during primary colostomy formation shows promise for preventing parastomal hernias and recommend a prophylactic mesh is placed at the site of primary stoma formations (42).



The Interventional Procedures Guidance

published by the National Institute for Health and Care Excellence in 2019 presents a set of recommendations for the reinforcement of permanent stomas to prevent parastomal hernias (92). The guidance outlines that, due to limited evidence of efficacy and potential complications, the reinforcement of permanent stomas with synthetic or biologic mesh should not be performed without obtaining patient consent, informing local clinical governance and defining audit or research procedures (92).

The Association of Coloproctology of Great Britain and Ireland

guidelines for the prevention and treatment of parastomal hernia recommend prophylactic use of permanent synthetic mesh in cancer patients undergoing elective permanent end colostomy creation, as it may reduce the risk of parastomal hernia (41).

The Hernia Interest Group of South Africa Guidelines for the Management of Ventral Hernias

state that measures shown to reduce SSI could reduce the incidence of incisional hernia (96). The measures outlined in the guidelines include prophylactic antibiotics, anti-bacterial sutures, wound protectors, care bundles, and the use of mesh (96). The guidelines also specifically recommend offering prophylactic mesh placement for patients having a permanent stoma fitted, and should be considered for the closure of midline laparotomies in high risk patients (recommendation grade: strong) (96).

Table 8: Overview of Published Guidelines Recommending Prophylactic Mesh Augmentation

Guideline (Author, Year) (Reference)	Responsible Organisation	Recommendations and Statements on Prophylaxis	Quality of Evidence and Strength of Recommendation
Updated guidelines for closure of abdominal wall incisions (Deerenberg, 2022) (43)	European and American Hernia Societies	**Statement:** Prophylactic mesh augmentation following elective midline laparotomy can be considered in addition to suture closure to reduce the risk of incisional hernia	Quality of evidence[†]: Low Strength of recommendation[†]: Weak
		Recommendation: Permanent synthetic mesh is suggested over biologic or synthetic absorbable meshes for prophylactic use in either the onlay or retromuscular plane	Quality of evidence[†]: Very low Strength of recommendation[†]: Weak
Guidelines for laparoscopic treatment of ventral and incisional abdominal wall hernias: Parts I–III (Bittner, 2014) (25, 26, 94)	The International EndoHernia Society	**Statement:** Prophylactic mesh placement reduces the incidence of incisional hernia in high-risk groups (e.g. those with morbid obesity or aortic aneurysm	Quality of evidence[‡]: Level 2
		Statement: Prophylactic mesh placement in primary stoma formation reduces the rate of parastomal hernia without increasing associated morbidity	Quality of evidence[‡]: Level 1
		Recommendation: Prophylactic mesh augmentation is recommended following open abdominal surgery in high-risk patients (e.g. those with morbid obesity or aortic aneurysm	Strength of recommendation[‡]: Grade B
		Recommendation: Prophylactic mesh should be placed at the primary stoma formation	Strength of recommendation[‡]: Grade A
Update of Guidelines for laparoscopic treatment of ventral and incisional abdominal wall hernias: Parts A & B (Bittner, 2019) (42, 95)	The International EndoHernia Society	**Statement:** Prophylactic mesh reinforcement in the onlay plane can reduce the incidence of incisional hernia following elective midline laparotomy (vs in the sublay plane or primary suture closure)	Quality of evidence[‡]: Level 1
		Statement: Prophylactic mesh placement during primary colostomy formation shows promise for preventing parastomal hernias	Quality of evidence[‡]: Level 1
		Statement: Prophylactic mesh placement reduces the risk of incisional hernia in high-risk patient groups (e.g. those with morbid obesity, or patients undergoing colorectal surgery)	Quality of evidence[‡]: Level 1
		Recommendation: Prophylactic onlay mesh may become the standard in midline laparotomies involving high-risk patients	Strength of recommendation[‡]: Grade B
		Recommendation: Prophylactic mesh should be placed at the primary stoma formation	Strength of recommendation[‡]: Grade A
The Interventional Procedures Guidance: Reinforcement of a permanent stoma with a synthetic or biological mesh to prevent parastomal hernia (Powell, 2019) (92)	National Institute for Health and Care Excellence	**Recommendation:** Reinforcement of permanent stomas with synthetic or biologic mesh should not be performed without obtaining patient consent, informing local clinical governance and defining audit or research procedures	No specific classification/ grading provided
Prevention and treatment of parastomal hernia: a position statement on behalf of the Association of Coloproctology of Great Britain and Ireland (ACPGBI Parastomal Hernia Group, 2018) (41)	The Association of Coloproctology of Great Britain and Ireland	**Statement:** Permanent synthetic mesh may reduce the incidence of parastomal hernia in cancer patients undergoing elective surgery for permanent end colostomy formation only	Quality of evidence[§]: Moderate
		Recommendation: Prophylactic permanent synthetic mesh is recommended in cancer patients undergoing elective permanent end colostomy creation and may reduce the risk of parastomal hernia	Strength of recommendation[§]: Weak
Guidelines for the Management of Ventral Hernias (Bougard, 2016) (96)	The Hernia Interest Group of South Africa	**Statement:** Patients having a permanent stoma fashioned should be offered prophylactic mesh placement	No specific classification/ grading provided
		Recommendation: Prophylactic mesh reinforcement should be considered in patients at risk of developing trocar site hernias	Grade of recommendation[¶]: Strong

Abbreviations: ACPGBI, Association of Coloproctology of Great Britain and Ireland; GRADE, Grading of Recommendations, Assessment, Developments and Evaluation; . [†] The Grading of Recommendations, Assessment, Developments and Evaluation (GRADE) approach was used to evaluate evidence, classifications range from very low (X000) to high (XXXX) (43); [‡] evidence graded as level 1A, 1B, 2A, 2B, 2C, 3, 4; or 5, recommendations graded as level A, B, C, or D (25, 26, 42, 94, 95); [§] evidence graded as high quality, moderate quality, low quality, or very low quality, recommendations graded as strong in favour of intervention, weak in favour of intervention, weak against intervention, or strong against intervention (41); [¶] grading system adopted from the Agency for Healthcare Research and Quality, including category A (strong), category B (moderate), category C (weak), and category X (avoid) (96).

4.4. Unmet Need

Incisional hernia repair is associated with a considerable clinical burden for patients (Section 3.3) (12, 19, 22, 61, 62, 77, 79) and economic burden for healthcare systems (Section 3.4) (10, 13). As such, there is an unmet need for the adoption of a preventative strategy to reduce the incidence of incisional hernia. Hernia prevention would be of particular benefit in the group of high-risk patients (Section 3.2.3.1) (10, 22, 39) or for high-risk procedures (Section 3.2.3.2), which are associated with the highest burden (10-13, 17, 22, 43, 63-65).

There is a range of meshes available for incisional hernia prophylaxis, which have demonstrated improved outcomes (vs primary suture closure) (Section 4.2).

However, there are common post-operative complications reported for existing synthetic, biologic, and bioabsorbable meshes. Permanent synthetic mesh can increase the risk of long-term mesh-related complications, which can be mitigated by using the more biocompatible biologic meshes. However, the complex manufacturing procedures involved with processing biologic materials leads to substantially higher costs (29, 30, 34).

Additionally, a recent meta-analysis of hernia recurrences following elective open ventral hernia repairs demonstrated that biologic meshes are associated with a higher incidence of hernia recurrence compared with permanent synthetic meshes (OR 2.75; [95% CI: 1.76, 4.31]; p<0.00001) (97). Bioabsorbable meshes are a promising alternative for balancing comparable or improved patient outcomes with long-term cost implications, although, some bioabsorbable meshes for hernia repair are resorbed before tissue remodelling is complete and the integrity of the abdominal wall is sufficiently restored to prevent recurrence (82). As bioabsorbable mesh is resorbed, unlike a permanent synthetic mesh, if reoperation is required due to postoperative complications, surgeons are unlikely to have to cut through the existing mesh to access the original incisional hernia repair site (83, 98).

These key complications of existing meshes highlight the opportunity for a slowly bioabsorbable mesh that effectively reduces the risk of incisional hernia, is well tolerated, and reduces the risk of post-operative complications (Section 4.1.2). While this will be beneficial to all patients, the unmet need is greatest among high-risk patients (Section 3.2.3.1) and for high-risk procedures (Section 3.2.3.2).



5. Product Information

Key Messages

- Phasix™ Mesh is a fully resorbable monofilament surgical mesh scaffold for the treatment and prevention of incisional hernia (44)
- Phasix™ Mesh is indicated to reinforce soft tissue where weakness exists in patients undergoing abdominal, plastic, and reconstructive surgery in ventral hernia repair and other abdominal fascial defect procedures, including prophylactic use to reinforce surgical incisions (44)
- Composed of the naturally occurring polymer, poly-4hydroxybutyrate (P4HB), Phasix™ Mesh offers comparable strength and flexibility to permanent synthetic polymers (44, 45)
- The macroporous knitted monofilament structure of Phasix™ Mesh has a smaller surface area than other bioabsorbable or permanent synthetic meshes, which is associated with a consistently milder inflammatory response (46, 47)
- The macroporous design of Phasix™ Mesh promotes rapid neovascularisation during the early wound healing phase, facilitating quicker integration of the mesh with host tissue and more extensive tissue remodelling (45, 46)
- The increased early tissue remodelling activity and predictable long-term resorption profile (12–18 months) of Phasix™ Mesh provide greater overall mechanical strength of the repaired abdominal wall, while allowing for a more gradual transfer of load bearing from the mesh to repaired tissue compared with biologic and more rapidly resorbable (2–6 months) synthetic meshes (31, 43, 45)



Figure 1: Phasix™ Mesh
Source: BD (99)

5.1. Product Overview

Phasix™ Mesh (Figure 1) is a knitted monofilament mesh scaffold, composed of poly-4 hydroxybutyrate (P4HB), a fully resorbable naturally occurring polymer with a comparable strength and flexibility to permanent synthetic polymers (44, 45).

5.2. Product Use

Phasix™ Mesh is currently indicated to reinforce soft tissue where weakness exists in patients undergoing abdominal, plastic, and reconstructive surgery in ventral hernia repair and other abdominal fascial defect procedures, including prophylactic use to reinforce surgical incisions (44). Contraindications and product warnings can be found in Appendix A: Contraindications and Product Warnings for Phasix™ Mesh.

5.3. Regulatory Status

Approved.
Phasix™ Mesh is indicated to reinforce soft tissue where weakness exists in patients undergoing abdominal, plastic, and reconstructive surgery in ventral hernia repair and other abdominal fascial defect procedures, including prophylactic use to reinforce surgical incisions (44).

5.4. Product Features

Phasix™ Mesh is a slowly resorbable biosynthetic hernia mesh implant that combines the mechanical strength of permanent synthetic meshes (low recurrence rates) with the tissue remodelling properties of biologic meshes (45).

Key features of Phasix™ Mesh may overcome the long-term mesh-related complications associated with permanent synthetic meshes (Section 4.1.2.1) and the high hernia recurrence rates observed with biologic meshes (Section 4.1.2.2) (45).

Compared with other commercially available types of bioabsorbable and permanent synthetic meshes, the macroporous knitted monofilament structure of Phasix™ Mesh (Figure 2) has a smaller surface area, which is associated with a consistently milder inflammatory response (46, 47).

Phasix™ Mesh results in lower levels of bacterial colonisation and abscess formation compared with microporous multifilament mesh structures when challenged with bacterial inoculation in animal models (45, 47, 100).

Poly-4-hydroxybutyrate is a biologically derived polymer of a naturally occurring human metabolite, 4 hydroxybutyrate (4HB), which induces the upregulation of antimicrobial peptides (AMPs) and stimulates macrophages to assist with bacterial clearance (45, 100, 101). Phasix™ Mesh may actively (AMP upregulation) and passively (small surface area) reduce the rate of long-term mesh-related complications compared with permanent synthetic meshes (29, 45).

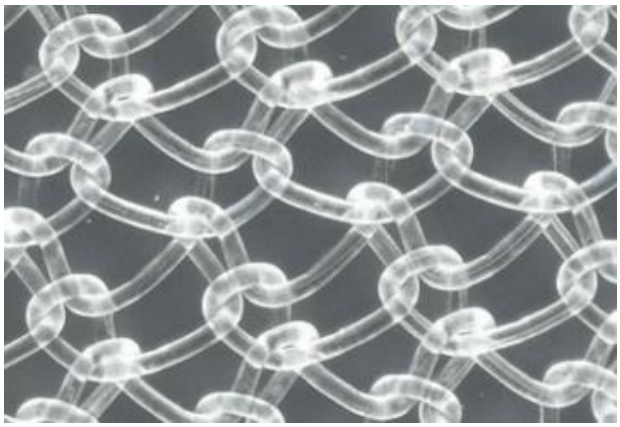

Figure 2: Phasix™ Mesh SEM (20X) photo of knitted monofilament structure
Abbreviations: P4HB, poly-4-hydroxybutyrate; SEM, scanning electron microscopy
Source: Scott et al. 2016 (46)



The macroporous mesh structure also promotes rapid neovascularisation during the early wound healing phase, facilitating quicker integration of the mesh implant with host tissue and more extensive tissue remodelling (45, 46). Increased tissue remodelling activity during the early wound healing phase and the predictable long-term resorption profile (12–18 months) of Phasix™ Mesh leads to a greater overall mechanical strength of the repaired abdominal wall and a more gradual transfer of load bearing from the mesh to repaired tissue compared with biologic and more rapidly resorbable (2-6 months) synthetic meshes (31, 43, 45).

6. Clinical Value of Phasix™ Mesh

Key Messages

Several clinical trials evaluating the long-term efficacy of prophylaxis with Phasix™ Mesh to reduce the incidence of incisional hernia in high-risk patient groups and surgical settings are ongoing (48-51)

- Clinical trials with longer-term follow-up periods (36–60 months) evaluating the efficacy of Phasix™ Mesh for the prevention of incisional hernia in high-risk patient groups after open midline laparotomy (48), liver transplantation via midline laparotomy (49), gastrointestinal surgery via midline abdominal incisions (50), and the closure of a temporary ileostomy (51), are currently ongoing

3 retrospective reviews reported no instances of incisional hernia at ≤1-year post-index surgery with the prophylactic use of Phasix™ Mesh in high-risk surgical settings and patient groups (52-54)

The favourable long-term outcomes reported across systematic reviews (45, 55, 56), and a clinical trial with a follow-up period of 5 years (57), provide additional support for the prophylactic use of Phasix™ Mesh

Phasix™ Mesh improves patient QoL (66)

6.1. Overview of the Clinical Evidence for the Prophylactic Use of Phasix™ Mesh

The prophylactic use of Phasix™ Mesh for the prevention of incisional hernia is supported by several retrospective reviews with follow-up periods ranging from a mean of 6 months to 4 years. Most of which reported no instances of incisional hernia (0%); 2 publications reported 8% parastomal hernia occurrence. In addition, these publications reported acceptably low incidences (0–35%) of common post-operative complications (e.g. SSI) in high-risk patient groups (40, 52-54,*). Multiple long-term clinical trials evaluating the efficacy of Phasix™ Mesh in high-risk patient groups for the prevention of incisional hernia are ongoing (48-51). The favourable outcomes achieved with Phasix™ Mesh in hernia repair (Section 6.4) may also be considered an indicator that Phasix™ Mesh is likely to be efficacious and well tolerated in a prophylactic setting.

6.2. Evidence for Prophylactic Use of Phasix™ Mesh

6.2.1. Retrospective Reviews of Prophylactic Mesh Augmentation

A retrospective review of the efficacy and safety of prophylactic mesh augmentation using Phasix™ Mesh was conducted in 50 high-risk patients who underwent stoma creation/takedown or open aortic surgery in the US between July 2014 and March 2020 (40). The primary indications for surgery included: ileal conduit stoma creation for bladder cancer (64%); abdominal aortic aneurysm (12%); colon, rectal, or prostate cancer requiring end colostomy (10%); and various other complex vascular or abdominal pelvic illnesses (14%) (40). The primary outcome reported was the rate of incisional hernia, while secondary outcomes included the incidence of mesh-related and other complications (40).

Overall, 10 patients (20%) developed a hernia at a median follow-up of 2.2 years. Six of the 10 hernias (60%) occurred at locations other than where the prophylactic mesh had been placed, and the remaining four were parastomal hernias (40).

No post-surgical complications were reported by 64% of patients (40). Seroma (4%) and SSI (4%) were the most commonly observed complications (40). There were no cases of mesh infections or deep-space infections, and no deaths related to mesh placement (40).

These findings demonstrate that prophylactic mesh augmentation using Phasix™ Mesh is a well-tolerated and effective technique for the prevention of incisional hernias in high-risk patients. In comparison, without prophylactic mesh, incisional hernia is reported to occur considerably more frequently in high-risk patients; for example in 49–53% of patients with malignant diseases undergoing colorectal surgery (11-13) (Section 3.2.3.2), or up to 40% in other high-risk patient groups (e.g. patients with morbid obesity or abdominal aortic aneurysm) (14, 15).



A retrospective cohort study of patients (n=38) who underwent robot-assisted cystectomy with ileal conduit formation at a single centre in the US between June 2010 and August 2017 evaluated the efficacy of prophylactic mesh placement for the prevention of incisional hernia (52). Prophylactic mesh was placed in the retrorectus position in 18 patients, with bioabsorbable mesh placed in 15 patients (Phasix™ in 14 patients; Gore Bio-A in one patient), biologic mesh in three patients (all Strattice™), and no prophylactic mesh was placed in the remaining 20 patients (52). At a mean follow-up of 11 months, there were no hernia occurrences or mesh-related complications observed in the prophylactic mesh group (52). In comparison, hernia occurrence was reported at a mean follow-up of 21 months in one patient (5%) without prophylactic mesh placement (52).

In a retrospective single surgeon case series review involving all patients who underwent prophylactic mesh augmentation between January 2016 and October 2017 at the University of Pennsylvania, early post-operative outcomes were evaluated for 18 patients with prophylactic mesh augmentation and a matched cohort of patients without prophylactic mesh augmentation (53). After a mean follow-up of 6 months, no patients with prophylactic mesh augmentation developed incisional hernia compared with 5.3% of patients without prophylactic mesh augmentation (p=ns) (53). Additionally, no difference in the incidence of surgical site occurrences (SSO) were documented between the two patient groups (mesh vs no mesh) (53).

A retrospective cohort study of patients diagnosed with upper GI cancer (n=44) who underwent radical resection at a tertiary academic surgical unit in a 2-year time interval evaluated the efficacy of prophylactic Phasix™ mesh for the prevention of incisional hernia (54). Included patients had all undergone elective gastrectomy (n=17) or esophagectomy (n=27) through a midline incision, with Phasix™ mesh placed in an onlay fashion. After a mean follow-up of 12 months, no patients with prophylactic mesh augmentation developed incisional hernia (n=32 [72%] with available data) (54).

A retrospective analysis compared data on 50 patients undergoing ileostomy closure with prophylactic Phasix™ mesh reinforcement for colorectal cancer vs. data from a matched cohort of 50 patients undergoing ileostomy reversal without mesh augmentation. Data on prophylactic Phasix™ mesh reinforcement was collected prospectively between February 2016 and February 2020 in the Club Hernie registry. A significantly lower rate of stoma site incisional hernia, diagnosed by CT scan was observed after a mean follow-up of 4 years in the mesh group (8% vs. 24% in the control group, p = 0.029). Mesh augmentation did not increase the incidence of SSI (4% in the mesh group vs. 6% in the control group, p = 1) or length of hospital stay (mesh group 5 days vs. control group 6 days, p = 0.28). Mean operating time in the mesh group was 49.8 minutes (versus 60.5 minutes in the control group), whereby the mean additional time for mesh positioning was only 6.7 + 3.9 minutes.*

6.3. Ongoing Clinical Trials for Prophylactic Use of Phasix™ Mesh

In addition to the published real-world evidence documenting the efficacy and safety of using Phasix™ Mesh in a prophylactic setting (40, 52-54), there are a number of ongoing clinical trials aiming to demonstrate the long-term efficacy for prophylactically using Phasix™ Mesh to reduce the incidence of incisional hernia in high-risk patient groups or surgical settings.

The Prophylactic Reinforcement of Ventral Abdominal Incisions Trial (PREVENT; NCT03911700) aims to evaluate the efficacy of Phasix™ Mesh implantation at the time of midline fascial closure compared with primary suture closure for the prevention of incisional hernia in high-risk patients after open midline laparotomy (48). In this ongoing, prospective, international (Austria, Belgium, France, Germany, US), open label, randomised, controlled trial, patients are randomised (1:1) to one of the two treatment groups in the operating room after fascial closure (48). It is estimated that 477 adult patients (aged ≥18 years) will be enrolled who are undergoing elective open midline laparotomy (incision length ≥5 cm), with a hernia risk of moderate or greater, and who have not previously undergone hernia repair (48).

The primary outcome of PREVENT is the occurrence of incisional hernia in each treatment group (Phasix™ Mesh or control group) at 36 months (48). Secondary outcomes include:

- Incidence of incisional hernia at each follow-up time point (through 60 months)
- Incidence of device-related adverse events (through 60 months)
- Length of surgical procedure in minutes (Study Day 0)
- Length of time for wound closure in minutes (Study Day 0)
- Length of hospital stay in days (through hospital stay, typically 3 days)
- HRQoL, measured by SF-12v2 (PCS and MCS) and EQ-5D-3L scores (through 60 months

Primary completion of PREVENT trial is expected in December 2029, and the final study completion is forecast for December 2031 (48).

The PRevention of INCisional hernia after liver transplantation (PRINC) trial (NCT03222102) aims to evaluate whether the prophylactic use of Phasix™ Mesh in abdominal wall closure can reduce the risk of incisional hernia following liver transplantation compared with a standard surgical technique (49). The PRINC trial is a prospective, open label, randomised, controlled trial of Phasix™ Mesh in adult patients (aged ≥18 years) undergoing their first liver transplantation via midline laparotomy (49). With an estimated drop-out rate of 10%, 178 patients will need to be enrolled and subsequently randomised to one of the two treatment groups (49).

The primary outcome is the time to incisional hernia over a 12-month period, with and without prophylactic Phasix™ Mesh reinforcement (49). Patients will undergo ultrasound examinations of the wound area at 1, 3, 6, 12, and 24 months post-transplantation for the detection of incisional hernia (49). Secondary outcomes include:

- Time to incisional hernia over a 24-month period
- Incidence of complications related to mesh placement, such as haematoma, seroma, chronic pain, wound dehiscence, and mesh infections or removals

Study recruitment completion of the PRINC trial was estimated for December 2021. However, the results of the trial are yet to be published (49).

The Prevention of Incisional Hernia With Biosynthetic Mesh at the Site of Temporary Ileostomy Closure (PRINCESS) trial (NCT05400083) is a prospective multi-center, observational study aiming to evaluate the efficacy of prophylactic Phasix™ Mesh for the prevention of incisional hernia following the closure of a temporary ileostomy in adults (aged ≥18 years) (51). The primary outcome is the incidence of incisional hernia at 24 months, detected by CT scan or ultrasonography (51).

Study completion of the PRINCESS trial was estimated for May 2024, although the results of this trial remain to be published (51).

Secondary outcomes measured after surgery through 24 months post-index also include (51):

- Incidence of early and late complications, using the Clavien-Dindo classification
- Post-operative pain, measured by VAS
- QoL, measured by Carolinas Comfort Scale (CCS) and EQ-5D-5L
- Budget impact analysis, measured by direct healthcare costs (fixed and variable)

In addition to the studies outlined above, there are several other ongoing clinical trials currently evaluating the prophylactic use of Phasix™ Mesh with long-term follow-up periods,

including the Prevention of post-operative ventral hernias (POVH) by using a prophylactic onlay Phasix™ Mesh trial, the Prophylactic mesh after orthotopic liver transplantation (OLTx) for hernia reduction study (PROMETHEUS), and the Prophylactic Onlay Mesh for Incisional Hernia Prevention in Midline Surgery in Patients at Risk (PROMIS) trial. The primary objective of these studies is to establish whether Phasix™ Mesh can reduce the incidence of incisional hernia beyond the predicted timescale for the full resorption of Phasix™ Mesh (12–36 months) in high-risk patient groups (BD data on file). The PROMIS trial also includes the incidence of SSI ≤3 months (±14 days) post-implantation as a primary endpoint. Interim results from the PROMIS trial presented when 30 patients had been enrolled reported that no perioperative complications had been observed, 3 patients experienced SSI, and 2 patients developed seroma (50). Additionally, in the 12-month follow-up data available for 15 patients, no further complications or incisional hernia were documented (50).

6.4. Evidence of efficacy and safety of Phasix™ Mesh in ventral and incisional hernia repair

There is a large and growing body of evidence that demonstrates the long-term efficacy and safety of Phasix™ Mesh for incisional hernia repairs (45, 55-57).

A recent meta-analysis investigated the efficacy and safety of Phasix™ Mesh in ventral hernia repair across 21 studies, including 1,858 patients with median follow-up periods ranging from 1.6–62.3 months. Rates of hernia recurrence (9%; [95% CI: 6, 15]), SSI (10%; [95% CI: 6, 16]), and total complications (35%; [95% CI: 9, 42]) were low (56). Studies with >18 months of follow-up data showed similarly low rates of hernia recurrences (9%; [95% CI: 4, 17]), SSI (9%; [95% CI: 4, 16]), and total complications (31%; [95% CI: 23, 41]) (56).

Ahmed et al, 2024 (55), performed a meta-analysis of data from six studies using Phasix™ Mesh in clean (n=391) or contaminated (n=81) ventral and incisional hernia repairs evaluated the pooled proportion of SSI, SSO, and total surgical complications associated with clean and contaminated cases (55). The pooled proportions of complications in clean and contaminated wounds were 2% vs 9% (p=0.03) for SSI, 14% vs 35% (p=0.006) for SSO, 17% vs 50% (p=0.009) for total surgical complications, and 8% vs 4% (p=0.769) for hernia recurrences. The pooled reoperation rate in 298 clean cases from four studies was 5% (95% CI: 0, 15) (55).

A scoping review of P4HB meshes used for soft-tissue repair and reconstructive surgery included >30 published studies evaluating the use of Phasix™ Mesh (45). Overall, the findings of the included studies show that Phasix™ Mesh resulted in comparable or lower rates of hernia recurrence and fewer complications (e.g. SSI and seroma formation) compared with permanent synthetic and biologic meshes (45). Phasix™ Mesh consistently performed well in clean or contaminated wounds (Centers for Disease Control and Prevention [CDC] and Ventral Hernia Working Group [VHWG] classifications), and provided long-term mechanical strength at hernia repair sites beyond its predictable resorption period of 12–18 months (45).

Results from the five-year follow-up of the Slowly Resorbable Biosynthetic P4HB Mesh (Phasix™) in VHWG Grade 3 Incisional Hernia Repair trial (NCT02720042) demonstrate the long-term efficacy and safety of Phasix™ Mesh for the prevention of incisional hernia recurrence in high-risk patient groups (57). This prospective international single-arm study enrolled adult patients (aged ≥18 years) who underwent an elective VHWG Grade 3 midline incisional hernia repair with Phasix™ Mesh between 2016 and 2017. The primary outcome was the incidence of incisional hernia within five years following the repair (n=61), and secondary outcomes included long-term mesh complications, abdominal wall pain (as measured by visual analogue score [VAS]), and mesh-related reinterventions (57). A recurrence rate of 15.9% (95% CI: 6.9, 24.8) was reported at five years post-index (57). No patients experienced long-term mesh-related complications, incarcerations, or required reintervention due to mesh-related complications (57). The median (range) abdominal wall pain VAS score of the scar area after 5 years was 0 (0–2) and there were no mesh explanations for chronic pain (57).

In a study among 51 patients who had undergone ventral hernia repair augmented with Phasix™ Mesh (66), QoL related to abdominal wall function and health was assessed, using the Hernia-Related Quality of Life Survey (HerQLes)[1]. Mean HerQLes scores improved significantly vs before surgery at all time points (0–2 yrs, 3–4 yrs, and 5 yrs, $p<0.05$); 3–4 yr and 5-year scores were also significantly improved over 0–2 yr scores (p=0.001 and p=0.043, respectively). These data suggest that the prophylactic use of Phasix™ Mesh could be a successful strategy for the prevention of incisional hernia in the high-risk patient groups.

[1] Higher scores indicate better QoL.

7. Economic Value of Phasix™ Mesh

Key Messages

Economic models evaluating prophylactic mesh use or different mesh types in repair settings indicate that prophylactic use of Phasix™ Mesh could lead to long-term cost savings for national healthcare systems (58-60).

- In the Italian healthcare system setting, increasing the use of bioabsorbable synthetic meshes relative to other types of mesh in hernia repair could lead to cost savings of €770 per patient, totalling €153 million over five years (59)
- A US cost-utility analysis of prophylactic mesh augmentation vs primary suture closure showed mesh to be the dominant strategy (58)
- A 1% annual reduction of hernia repairs in the US could lead to cost-savings of $139.9 million for the US national healthcare system (60)

The reduction in the incidence of incisional hernia recurrence with Phasix™ Mesh in a treatment setting (45, 55-57 ,59)

and the post-operative complications commonly associated with permanent synthetic (Section 4.1.2.1), biologic (Section 4.1.2.2), and rapidly resorbed biosynthetic meshes (Section 4.1.2.3), indicate the considerable opportunities for long-term cost savings for national healthcare systems (58, 59).

7.1. Economic Evidence Supporting the Prophylactic Use of Mesh in General

- Incisional hernia treatment is a major economic burden for national healthcare systems (Section 3.4). However, most of the associated direct costs are related to high-risk patient groups with multiple comorbidities, further increasing their risk of developing secondary complications, including infections and hernia recurrences requiring reoperation (90). Based on the estimated direct and indirect costs of a hernia repair in France, a 5% reduction in the incidence of incisional hernia repairs in France could translate to annual cost savings of around €4 million for the French national healthcare system (80).

- In a cost-utility analysis conducted from the US societal perspective, prophylactic mesh augmentation with a synthetic mesh was shown to be more effective and less costly (mean cost per patient $15,450; average QALY of 21.21) than primary suture closure without mesh (mean cost $17,182; average QALY of 21.17) (58). Sensitivity analysis confirmed the dominance of prophylactic mesh augmentation compared with primary suture closure at a willingness-to-pay threshold of $50,000/QALY (58).

- Additionally, it is estimated that a 1% reduction in ventral hernia repairs, achieved with mesh prophylaxis or decreasing the incidence of hernia recurrences, could equate to annual cost-savings of $139.9 million for the US national healthcare system (60).

7.2. Economic Evidence Supporting Prophylactic Use of Phasix™ Mesh

While bioabsorbable synthetic meshes (€2,523 per unit) are more costly than permanent synthetic meshes (€1,007 per unit), they are less expensive than biologic meshes (€5,542 per unit) (costs from Italy, 2017) (59). A 2017 budget impact model in the Italian setting indicates that increasing the use of bioabsorbable synthetic meshes may lead to healthcare system savings of €770 per patient, totalling €153 million over five years (59).



While these data are based on use in treatment of incisional hernia, rather than prophylaxis, it is highly likely that the results will be transferrable to the prophylactic setting.

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9. Appendix A: Contraindications, Warnings, Precautions and Adverse Reactions for Phasix™ Mesh

Contraindications

Because Phasix™ Mesh is fully resorbable, it should not be used in repairs where permanent wound or organ support from the mesh is required.

Warnings

1. Phasix™ Mesh must not be put in direct contact with the bowel or viscera.
2. The use of any mesh or patch in a contaminated or infected wound can lead to fistula formation and/or extrusion of the mesh.
3. Mesh manufacture involves exposure to tetracycline hydrochloride and kanamycin sulfate. The safety and product use for patients with hypersensitivities to these antibiotics is unknown. The use of this mesh in susceptible patients with known allergies to tetracycline hydrochloride or kanamycin sulfate should be avoided.
4. The safety and effectiveness of Phasix™ Mesh in the following applications has not been evaluated or established:
    a. Pregnant or breastfeeding women b. Pediatric use c. Neural and cardiovascular tissue.
5. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require the removal of the mesh.
6. To prevent recurrences when repairing hernias or to prevent occurrences when reinforcing surgical incisions prophylactically, the mesh should be sized with appropriate overlap for the size and location of the defect or surgical incision, taking into consideration any additional clinical factors applicable to the patient. Careful attention to mesh fixation placement and spacing will help prevent excessive tension or gap formation between the mesh and fascial tissue.
7. The mesh is supplied sterile. Prior to use, carefully examine package and product to verify neither is damaged and that all seals are intact. Do not use if the foil pouch or package is damaged or open, or if the center of the temperature indicator on the foil pouch is black.
8. This mesh has been designed for single use only. Reuse, reprocessing, resterilization, or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the mesh and may lead to mesh failure which may result in injury to the patient. Reuse, reprocessing, resterilization, or repackaging may also create a risk of contamination of the mesh and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the mesh may lead to injury, illness, or death of the patient or end user.
9. If unused Phasix™ Mesh has been in contact with instruments or supplies used on a patient or contaminated with body fluids, handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations to prevent risk of transmission of viral infections.
10. This mesh is not for the use of repair of pelvic organ prolapse via transvaginal approach.
11. This mesh is not for the use of treatment of stress urinary incontinence.
12. Phasix™ Mesh has not been studied for use in breast reconstructive surgeries

Precautions

1. Please read all instructions prior to use.
2. Only physicians qualified in the appropriate surgical techniques should use this mesh. Users should be familiar with mesh strength and size requirements. Improper selection, placement, positioning, and fixation of the mesh can cause subsequent undesirable results.
3. Clinical data in accordance with EU MDR has not been established for laparoscopic/robotic procedures.
4. The safety and effectiveness of Phasix™ Mesh in the proximity of existing or excised cancer has not been established.

Adverse Reactions

In preclinical testing, Phasix™ Mesh elicited a minimal tissue reaction characteristic of foreign body response to a substance. The tissue reaction resolved as the mesh was resorbed. Possible complications may include, but are not limited to infection, seroma, pain, mesh migration, wound dehiscence, hemorrhage, adhesions, hematoma, inflammation, allergic reaction, extrusion, erosion, fistula formation and recurrence of the hernia or soft tissue defect.

Please, consult product labels and instructions for use for indications, contraindications, hazards, warnings, and precautions.
Not all products, services, claims or features of products may be available or valid in our local area. Please check with your local BD representative.



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