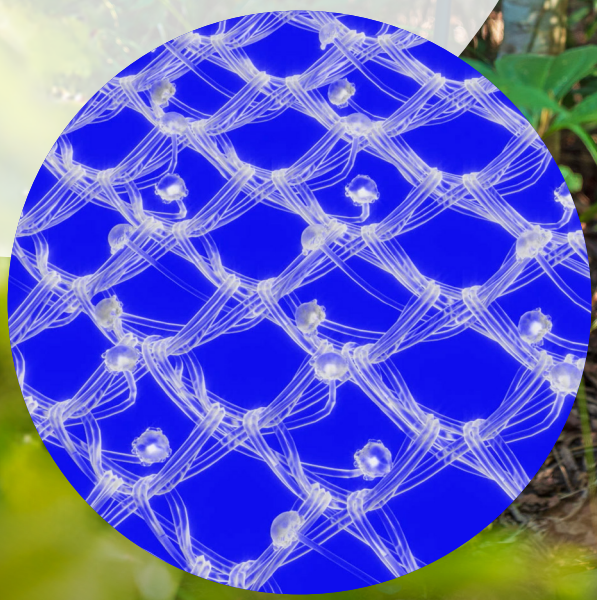
Medtronic

Let's get your patients moving again.

ProGrip™ self-gripping polypropylene mesh



The world of ProGrip™ self-gripping polypropylene mesh has expanded to provide more sizes for your inguinal and ventral hernia repair procedures.

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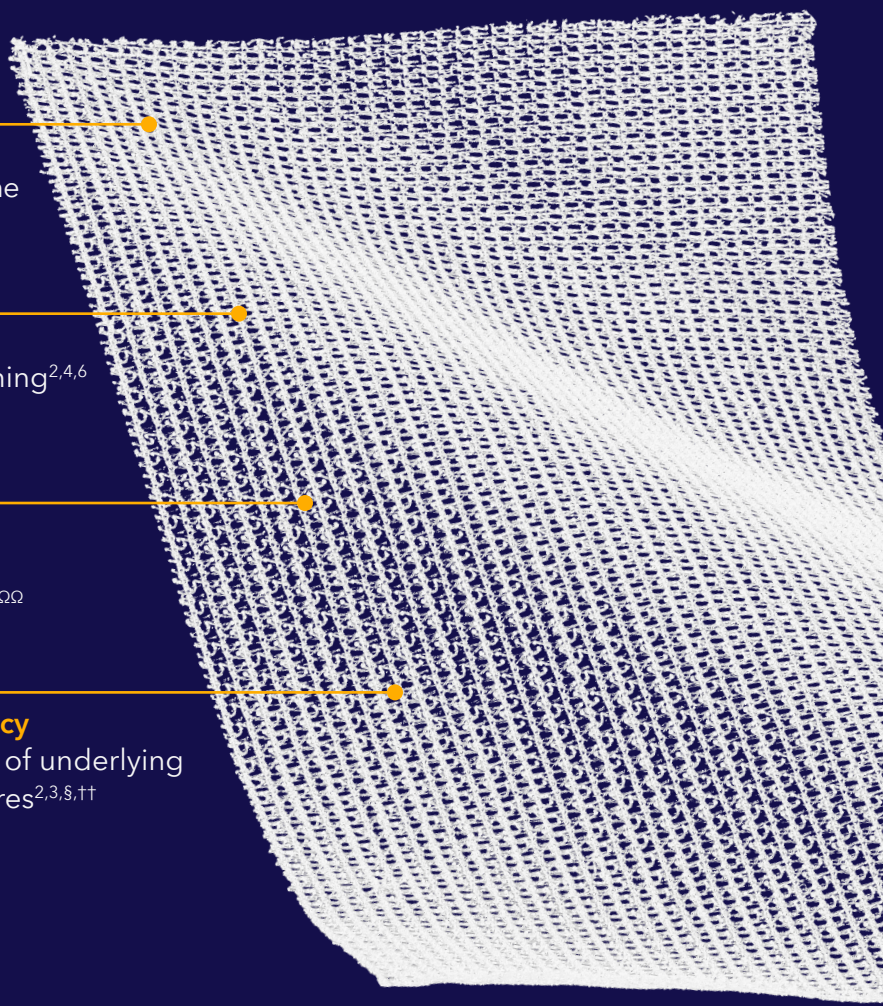
Uniform fixation[1,†,‡] – faster placement.[2,§,Ω]

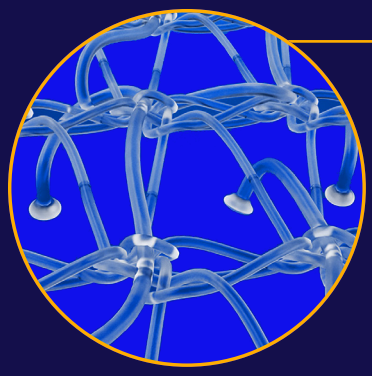
Now available in a comprehensive range of sizes to fit all inguinal and ventral hernia defects,[2-4,§,††,‡‡] the self-anchoring grips used in the ProGrip™ mesh family provide a vast constellation of uniform fixation points across the entire mesh surface.[1,†,‡]



Polylactic acid (PLA) resorbable microgrips
support good tissue integration[5,§§] and prevent the mesh from shifting during placement[2,§,††]

Immediate gripping
across the mesh surface facilitates easy positioning[2,4,6] and faster placement[2,§,Ω] of the mesh

Trimmable to different sizes
to meet your varying procedural needs[3,7,8,†,ΩΩ] – without impacting mechanical characteristics[3,§,ΩΩ]



Mesh transparency
aids visualization of underlying anatomic structures[2,3,§,††]

†Based on benchtop data, not necessarily indicative of human clinical outcomes. ‡The technique used to fixate the mesh (suture and/or tacks) is left up to the surgeon. The textile self-gripping feature makes it possible to position the mesh without fixation, depending on the size of the defect, the hernia position, and the quality of the anatomical structures. §Based on preclinical data, not necessarily indicative of human clinical outcomes. ΩCompared to flat sheet meshes. Based on feedback from 6 answers, 5 surgeons (83%), conducted in lab setting with cadaver. Surgeons compensated. ††Based on feedback from 6 surgeons, conducted in lab setting with cadaver. Surgeons compensated. ‡‡Applicable to PP1515G, PP2015G, PP3020G, PP3030G, PP4030G. §§Based on animal study, not necessarily indicative of human clinical outcomes. ΩΩIf a pre-cut mesh is trimmed, special care should be taken to preserve the sewing to limit the risk of recurrence. If a pre-cut mesh is trimmed, the green marking should not be cut as it could detach from the base textile. If the mesh is trimmed, the green marking may no longer be present, compromising its function.

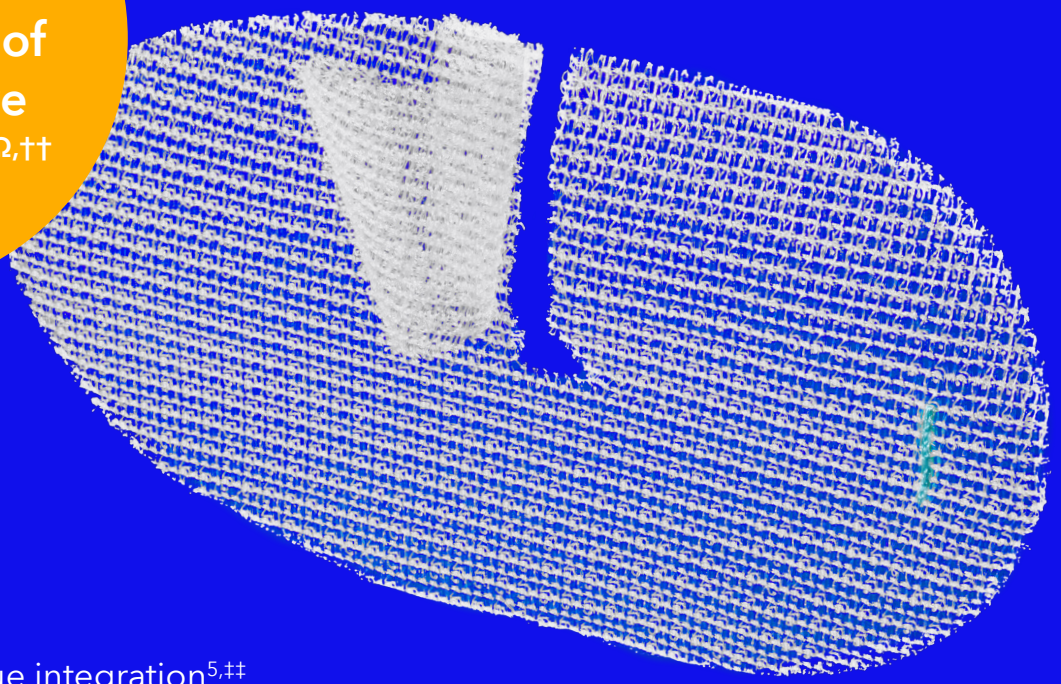
Risk statement: Mesh complications may include but are not limited to acute and chronic pain, extrusion/erosion, hematoma, infection, inflammation, recurrence, and/or seroma. See full risk statements on last page.

Features and benefits

Big advantages for your inguinal hernia repairs.

The uniform fixation[1,†,‡] of ProGrip™ self-gripping polypropylene mesh gives you the confidence of positive clinical outcomes expressed in terms of low hernia recurrence rates and improved patient quality of life.[9–12,§]

Lower pain scores and lower dosing of postoperative analgesics[13,§,Ω,††]



- Good tissue integration[5,‡‡]
- Reduced need for additional fixation[3,10–12,††]
- Prevents shifting of the mesh during placement[2,§§,ΩΩ]
- Significantly shorter procedure times than sutured mesh[10,13,14,§]

†Based on benchtop data, not necessarily indicative of human clinical outcomes. **‡**The technique used to fixate the mesh (suture and/or tacks) is left up to the surgeon. The textile self-gripping feature makes it possible to position the mesh without fixation, depending on the size of the defect, the hernia position, and the quality of the anatomical structures. **§**Applicable to PP1208DL, PP1208DR, PP1509G. **Ω**A study conducted by M. Kapischke showed a beneficial impact of the self-gripping mesh on pain score and a lower dosing of postoperative analgesics during hospital stay compared to a sheet of polypropylene mesh. **††**The textile self-gripping feature makes it possible to position the mesh without fixation, depending on the size of the defect, the hernia position, and the quality of the anatomical structures. **‡‡**Based on animal study, not necessarily indicative of human clinical outcomes. **§§**Based on preclinical data, not necessarily indicative of human clinical outcomes. **ΩΩ**Based on feedback from 6 surgeons, conducted in lab setting with cadaver. Surgeons compensated.

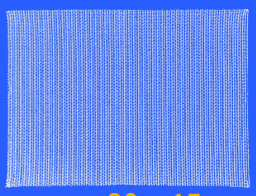
Risk statement: Mesh complications may include but are not limited to acute and chronic pain, extrusion/erosion, hematoma, infection, inflammation, recurrence, and/or seroma. See full risk statements on last page.

Features and benefits

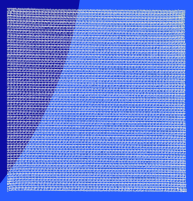
Expanding to meet all of your ventral hernia repair needs

Gain the flexibility you've been waiting for. Introducing five large polypropylene mesh sizes to fit all sizes of ventral hernia defects[2-4,†,‡,§]:

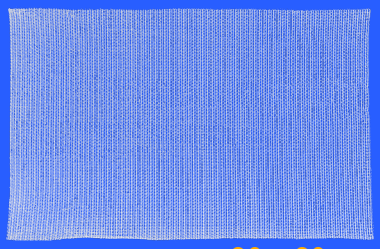
- 15 × 15 cm
- 20 × 15 cm
- 30 × 20 cm
- 30 × 30 cm
- 40 × 30 cm



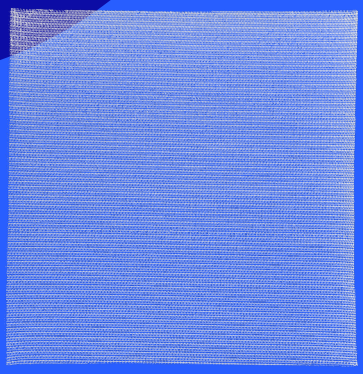
20 × 15 cm



15 × 15 cm



30 × 20 cm



30 × 30 cm

40 × 30 cm

- Uniform fixation across the mesh surface[1,Ω,††,‡‡]
- Reduced need for additional fixation,[15,Ω,‡‡] eliminating associated pain[6,8,10-12,14-16,‡‡]
- Faster mesh placement (including fixation) compared to flat sheet meshes[2,†,‡‡]

†Based on preclinical data, not necessarily indicative of human clinical outcomes. ‡Based on feedback from 6 surgeons, conducted in lab setting with cadaver. Surgeons compensated. §Applicable to PP1515G, PP2015G, PP3020G, PP3030G, PP4030G. ΩBased on benchtop data, not necessarily indicative of human clinical outcomes. ††The technique used to fixate the mesh (suture and/or tacks) is left up to the surgeon. ‡‡The textile self-gripping feature makes it possible to position the mesh without fixation, depending on the size of the defect, the hernia position, and the quality of the anatomical structures. §§Based on feedback from 6 answers, 5 surgeons (83%), conducted in lab setting with cadaver. Surgeons compensated.

Risk statement: Mesh complications may include but are not limited to acute and chronic pain, extrusion/erosion, hematoma, infection, inflammation, recurrence, and/or seroma. See full risk statements on last page.

Clinical confidence. Economic efficiency.

ProGrip™ polypropylene self-gripping mesh accommodates physicians in their surgical techniques and clinical cases through its enablement of extraperitoneal mesh placement, its quality of perioperative handling, and its compatibility with open surgical approaches.[4,6,8,14]

60% stronger
peeling strength
than fibrin sealant fixation at 8 weeks[17,18,†,‡,§]

Position and place
in less than
60 seconds[19,†]

Significantly shorter
procedure times than sutured mesh [10,13,14,†]

Product specifications	
Mesh[20]	2-D textile structure with grips
Raw material[20]	Polypropylene (PP)
Mono / multifilament[20]	Monofilament Ø0,10 mm
Grips[20]	Polylactic acid (PLA)
Mono / multifilament[20]	Monofilament Ø0,15 mm
Contribution to mesh fixation[21]	> 8 weeks
Pore size[22,Ω]	1.6 mm × 0.6 mm
Thickness[22,Ω]	1.3 mm
Surface density (before grips absorption)[22,Ω]	76 g/m^2
Surface density (after grips absorption)[23,Ω]	43 g/m^2

†Applicable to PP1208DL, PP1208DR, PP1509G. ‡Based on preclinical animal and benchtop studies, not necessarily indicative of human clinical outcomes. §ProGrip™ self-gripping polypropylene mesh and ProGrip™ self-gripping polyester mesh have equivalent gripping properties. ProGrip™ self-gripping polyester mesh has stronger peel strength than Bard™* soft mesh fixed to soft tissue using absorbable Baxter Tisseel™* glue at eight weeks. Accordingly, ProGrip™ self-gripping polypropylene mesh has stronger peel strength than Bard™* soft mesh fixed to soft tissue using absorbable Baxter Tisseel™* glue at eight weeks. ΩMean value measured on one batch. Values may differ slightly within and between batches, or by using an alternate testing method.

Risk statement: Mesh complications may include but are not limited to acute and chronic pain, extrusion/erosion, hematoma, infection, inflammation, recurrence, and/or seroma. See full risk statements on last page.

FDA 510(k) clearance letter – inguinal

U.S. FOOD & DRUG ADMINISTRATION

9/22/2022

Covidien
Jonas Gulmez
Senior Regulatory Affairs Specialist
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K220540
Trade/Device Name: ProGrip Self-Gripping Polypropylene Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: August 9, 2022
Received: August 11, 2022

Dear Jonas Gulmez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

FDA 510(k) clearance letter – inguinal

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Deborah A. Fellhauer -S

Deborah Fellhauer RN, BSN
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

FDA 510(k) clearance letter – ventral

January 18, 2024

Sofradim Production
% Nancy Sauer
Regulatory Affairs Senior Director
Covidien llc
200 Medtronic Drive
Lafayette, Colorado 80026

Re: K232373
Trade/Device Name: Progrip™ Self-Gripping Polypropylene Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: December 18, 2023
Received: December 18, 2023

Dear Nancy Sauer:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

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The 510(k) letter only confirms the device's legal market status in the U.S. and should not be interpreted as an FDA approval or endorsement of the product.

FDA 510(k) clearance letter – ventral

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tek N. Lamichhane -S

Digitally signed by Tek N. Lamichhane -S
Date: 2024.01.18 15:36:39 -05'00'

Tek Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Instructions for use (IFU) – inguinal
(PP1208DL, PP1208DR, PP1509G)

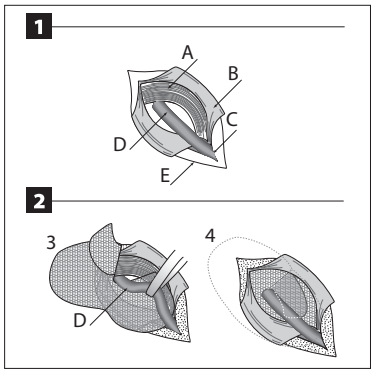
COVIDIEN™

ProGrip™

Self-Gripping Polypropylene Mesh

PT00170788

(99)7500317



en

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT!

This booklet is designed to assist in using this product. It is not a reference to surgical techniques.

This device was designed, tested, and manufactured for single patient use only. Reuse and/or reprocessing and/or re-sterilization of this device may lead to its failure and subsequent patient injury, and may create the risk of contamination and patient infection. Do not reuse, reprocess, or re-sterilize this device.

DESCRIPTION

ProGrip™ self-gripping polypropylene mesh is designed for extraperitoneal mesh placement by open anterior approach.

ProGrip™ self-gripping polypropylene mesh is available in 2 forms:

- Pre-cut elliptic slit mesh with self-gripping, overlapping flap: Right (PP1208DR code) or Left (PP1208DL code) anatomical side.

  The pre-cut elliptic slit meshes with overlapping flap are made of non-absorbable knitted monofilament polypropylene and resorbable polylactic acid monofilament grips on one of their sides. A colored yarn (green) marker is present on the medial edge.
- Rectangular mesh (PP1509G code).

The mesh is made of a non-absorbable knitted monofilament polypropylene and resorbable polylactic acid monofilament grips on one of its sides.

The non-absorbable textile is designed to ensure long term reinforcement of soft tissues. The macroporous textile provides strength required to withstand biomechanical stresses throughout the healing period, while allowing for tissue ingrowth. As the textile integrates, host tissue ingrowth is intended to provide strength to the repair.

The monofilament polylactic acid grips facilitate placing and positioning the mesh, and they contribute to fixation of the overlapping flap and the mesh to the surrounding tissue for at least eight (8) weeks. The polylactic acid grips are bioresorbable. Over the time, they resorb in vivo by hydrolysis and are metabolized by the body into CO_2 and H_2O. Preclinical studies showed that the polylactic acid material is essentially resorbed in 36 to 50 months post-implantation. However, the resorption period depends on numerous factors including patient-related factors.

The colored yarn (green) marker on the medial edge of the pre-cut mesh helps orientation.

The detailed composition listed below refers to the estimated maximum amount of each material and substance to which a patient can be exposed when 1 unit of the largest size of ProGrip™ self-gripping polypropylene mesh is implanted (ie PP1509G). These amounts could be less for smaller sizes or shapes or if the mesh is trimmed by the practitioner prior to implantation.

Mesh composition: monofilament polypropylene yarn (up to 0.567 g) | polylactic acid monofilament resorbable grips (up to 0.446 g) | only for PP1208DR and PP1208DL codes: Colored polyester yarn (green) marker (0.005 g).

ProGrip™ self-gripping polypropylene mesh is at least as effective, in terms of recurrence rate, as its therapeutic alternatives (mesh repair and suture-only repair) when used as indicated. However, the success of any hernia repair, regardless of whether mesh is used, depends on a number of factors, including surgical technique and patient comorbidities.

INDICATIONS

ProGrip™ self-gripping polypropylene mesh is intended for use in reinforcement of abdominal wall soft tissue where weakness exists, in procedures involving inguinal hernia repair via anterior tension-free approach.

CONTRAINDICATIONS

- As ProGrip™ self-gripping polypropylene mesh will not stretch to accommodate growth, its use is not appropriate in patients in a period of growth or pregnancy.
- Any foreign material may potentiate or prolong infection in the presence of bacterial contamination, and as such, the use of ProGrip™ self-gripping polypropylene mesh is not appropriate in an infected or contaminated site. Furthermore, this product should be used with the understanding that infection may require removal of the mesh.
- ProGrip™ self-gripping polypropylene mesh is not intended to be used for laparoscopic hernia repair.

POSSIBLE COMPLICATIONS

The possible complications associated with the use of ProGrip™ self-gripping polypropylene mesh are those typically associated with surgically implantable meshes: acute and chronic pain, allergic reaction to the components of the product, extrusion/erosion, hematoma, infection, inflammation, recurrence and/or seroma. Other possible complication inherent to the surgical procedure may occur.

The incidence and severity of complications may depend on numerous factors, including but not limited to the type and size of the defect, the mesh fixation, the surgical technique and patient-related factors (e.g., comorbidities). A thorough assessment of each patient's medical history and condition should be made to determine the suitability for implantation of this device. The treatment of complications may require one or more revision surgeries, that may not necessarily resolve the complications and may pose risks of subsequent complications. Being a permanent implant designed to integrate into tissues, significant dissection may be required if the mesh needs to be removed, in part or in whole. It is important that patients are given complete information regarding possible complications.

Any adverse event or serious incident that occurs in relation to the device should be reported to the manufacturer and/or the competent authority of the country in which the patient is established, as applicable per the federal, national or local regulations.

WARNINGS

1. Do not use the device past the labeled expiration date.
2. The device is provided in a double sterile packaging. Upon receipt of shipment, ensure that the packaging is not open or damaged and retains its sealed integrity. Do not use the device if the package is open or damaged or if the integrity of the packaging appears compromised.
3. Open the last packaging only for the placement of the mesh and handle the latter using clean sterile gloves and instruments.
4. The mesh is not designed for repair of parastomal hernias.
5. The mesh is not intended for repair of pelvic organ prolapse and treatment of stress urinary incontinence.
6. Do not place the mesh in direct contact with the viscera. Direct contact with the viscera may lead to risks of adhesions, fistula formation, and bowel obstruction. Do not implant the mesh in an intra-peritoneal position. When implanting in a pre-peritoneal site, the mesh shall be placed with the grips towards the muscle fascia with the mesh completely covered with peritoneum.
7. For women planning future pregnancies, the surgeon should be aware that this product will not stretch enough as the patient grows.
8. Ensure that the mesh is adequately fixated. To avoid injury, exercise caution if fixating the device in the presence of nerves or vessels.
9. The mesh should not be overly stretched when it is being put in place in order to maintain the elasticity and the porosity of the reinforcement. A moderate and equal tension should be applied in all directions for fixation in order to account for wound shrinkage during the healing process.
10. The mesh should assure necessary overlap beyond the margins of the defect according to the surgeon's practice.
11. If a pre-cut mesh is trimmed, special care should be taken to preserve the sewing to limit the risk of recurrence.
12. If a pre-cut mesh is trimmed, the green marking should not be cut as it could detach from the base textile. If the mesh is trimmed, the green marking may no longer be present, compromising its function.
13. ☣ Unused product, explant, and packaging may be a potential biohazard. Handle and dispose them with the necessary precautionary measures in accordance with accepted medical practices and with applicable local, state, and federal laws and regulations on disposal of packaging and medical waste.

PRECAUTIONS

1. Users should be familiar with surgical procedures and techniques involving the use of surgical mesh before employing this device.
2. This device should only be used by experienced practitioners who do so under their own responsibility.

1 SCHEMATIC VIEW

A) INTERNAL OBLIQUE MUSCLES

B) EXTERNAL OBLIQUE MUSCLE

C) CUTANEOUS INCISION

D) CORD

E) LARGE CURVE

2 OPERATING STEPS

Pre-cut mesh:

For the mesh with a self-gripping flap, the right and left mesh are identified on the labels as such: "RIGHT" means the right side of patient and "LEFT" means left side of patient.

1. This mesh can be used whole or cut to the required dimensions. The surgeon should assure necessary overlap of the mesh beyond the margins of the defect according to practice.

CAUTION: The mesh should assure necessary overlap beyond the margins of the defect, according to the surgeon's practice.

CAUTION: If a pre-cut mesh is trimmed, special care should be taken to preserve the sewing to limit the risk of recurrence.

CAUTION: If a pre-cut mesh is trimmed the green marking should not be cut as it could detach from the base textile. If the mesh is trimmed, the green marking may no longer be present, compromising its function.

2. The mesh should be presented, slit upward, flap open, colored yarn (green) marker toward the pubis, grip side facing the deep muscular plane.
3. Fit the slit around the cord (D). (See illustration section 2, step 3).
4. Fold the flap back onto the mesh (See illustration section 2, step 4). Gripping is reversible to allow slit closure to be adjusted several times. Spread out the large curve of the mesh so that it perfectly fits the inguinal ligament, then completely spread the mesh, centering by positioning the cord in the central orifice to completely cover all weak areas.
5. The technique used to anchor the mesh (suture) is left up to the surgeon. The textile's self-gripping feature makes it possible to position the mesh without fixation, depending on the size of the defect, the hernia position, and the quality of the anatomical structures. Compatibility with other fixation devices may not have been established. Using means of fixation other than those for which compatibility is established may lead to mesh damage. It is suggested to fixate the mesh at a distance of approximately 1 cm from the edge of the mesh.

CAUTION: The mesh should not be overly stretched when it is being put in place in order to maintain the elasticity and the porosity of the reinforcement. A moderate and equal tension should be applied in all directions for fixation in order to account for wound shrinkage during the healing process.

CAUTION: Ensure that the mesh is adequately fixated. To avoid injury, exercise caution if fixating the device in the presence of nerves or vessels.

6. The slit can also be sutured around the cord with one stitch, depending on the case.

Rectangular mesh:

1. This mesh can be used whole or cut to the required dimensions. The surgeon should assure necessary overlap of the mesh beyond the margins of the defect according to practice.

CAUTION: The mesh should assure necessary overlap beyond the margins of the defect, according to the surgeon's practice.

2. The mesh can be fixed to the Cooper's ligament and/or to the anterior muscular plane. Fixation can also be used between the posterior muscular plane and the anterior aponeurotic one (external oblique muscle).
3. The technique used to anchor the mesh (suture) is left up to the surgeon. The textile's self-gripping feature makes it possible to position the mesh without fixation, depending on the size of the defect, the hernia position and the quality of the anatomical structures. Compatibility with other fixation devices may not have been established. Using means of fixation other than those for which compatibility is established may lead to mesh damage. It is suggested to fixate the mesh at a distance of approximately 1 cm from the edge of the mesh.

CAUTION: The mesh should not be overly stretched when it is being put in place in order to maintain the elasticity and the porosity of the reinforcement. A moderate and equal tension should be applied in all directions for fixation in order to account for wound shrinkage during the healing process.

CAUTION: Ensure that the mesh is adequately fixated. To avoid injury, exercise caution if fixating the device in the presence of nerves or vessels.

STERILIZATION METHOD

ProGrip™ self-gripping polypropylene mesh is a sterile single-use device. It is sterilized by ethylene oxide. Do not re-sterilize.

FOLLOW-UP

ProGrip™ self-gripping polypropylene mesh is intended for permanent implantation. It is not intended to be removed, repaired, or replaced in normal conditions of use. It does not require particular follow-up. Necessity and modalities of patient follow-up shall be determined by exerting medical judgment and per accepted medical practice inherent to hernia surgery.

STORAGE

ProGrip™ self-gripping polypropylene mesh does not require any special storage conditions.

MAGNETIC RESONANCE IMAGING (MRI) COMPATIBILITY

ProGrip™ self-gripping polypropylene mesh poses no known hazards resulting from exposure to any Magnetic Resonance (MR) environment. It is classified as MR safe.

TRACEABILITY

A traceability label is attached to every device package which identifies the type and lot number of the device. This label should be affixed to the patient's permanent medical record to clearly identify the device that was implanted.

A patient implant card is also supplied with every device package. It shall be provided at discharge to the patient who has been implanted with the device if required by applicable federal, national or local regulations. This patient implant card includes information allowing the identification of the device and a website address from which the patient can access additional information.

For European residents: After the EUDAMED website is launched, the Summary of Safety and Clinical Performance (SSCP) can be found at https://ec.europa.eu/tools/eudamed.

IFU current as of 01/2024 when this brochure was approved by Medtronic. For the most current IFU, please contact your sales rep.

Instructions for use (IFU) – ventral
(PP1515G, PP2015G, PP3020G, PP3030G, PP4030G)

COVIDIEN™

ProGrip™
Self-Gripping Polypropylene Mesh

PT00190884

(99)7500345

en

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT!

This booklet is designed to assist in using this product. It is not a reference to surgical techniques.

This device was designed, tested, and manufactured for single patient use only. Reuse and/or reprocessing and/or re-sterilization of this device may lead to its failure and subsequent patient injury and may create the risk of contamination and patient infection. Do not reuse, reprocess, or re-sterilize this device.

DESCRIPTION

ProGrip™ self-gripping polypropylene mesh is designed to allow extraperitoneal mesh placement for the repair of inguinal and ventral hernias by open approach.

ProGrip™ self-gripping polypropylene mesh is a sterile non-pyrogenic device made of a non-absorbable knitted monofilament polypropylene and resorbable polylactic acid monofilament grips on one of its sides.

ProGrip™ self-gripping polypropylene mesh is available in different sizes and forms (rectangular or square).

The non-absorbable textile is designed to ensure long term reinforcement of soft tissues. The macroporous textile provides strength required to withstand biomechanical stresses throughout the healing period, while allowing for tissue ingrowth. As the textile integrates, host tissue ingrowth is intended to provide strength to the repair.

The monofilament polylactic acid grips facilitate placing and positioning the mesh, and they contribute to fixation of the mesh to the surrounding tissue for at least eight (8) weeks. The polylactic acid grips are bioresorbable. Over the time, they resorb in vivo by hydrolysis and are metabolized by the body into CO_2 and H_2O. Predinical studies showed that the polylactic acid material is essentially resorbed in 36 to 50 months post-implantation. However, the resorption period depends on numerous factors including patient-related factors.

The detailed composition listed below refers to the estimated maximum amount of each material and substance to which a patient can be exposed when 1 unit of the largest size of ProGrip™ self-gripping polypropylene mesh is implanted (i.e., PP4030G). These amounts could be less for smaller sizes or if the mesh is trimmed by the practitioner prior to implantation.

Mesh composition: monofilament polypropylene yarn (up to 5.04 g) | polylactic acid monofilament resorbable grips (up to 3,96 g)

ProGrip™ self-gripping polypropylene mesh is at least as effective, in terms of recurrence rate, as its therapeutic alternatives (mesh repair and suture-only repair) when used as indicated. However, the success of any hernia repair, regardless of whether mesh is used, depends on a number of factors, including surgical technique and patient comorbidities.

INDICATIONS

ProGrip™ self-gripping polypropylene mesh is intended for use in reinforcement of abdominal wall soft tissue where weakness exists, in procedures involving inguinal and ventral hernia repair by open approach.

CONTRAINDICATIONS

- As ProGrip™ self-gripping polypropylene mesh will not stretch to accommodate growth, its use is not appropriate in patients in a period of growth or pregnancy.
- Any foreign material may potentiate or prolong infection in the presence of bacterial contamination, and as such, the use of ProGrip™ self-gripping polypropylene mesh is not appropriate in an infected or contaminated site. Furthermore, this product should be used with the understanding that infection may require removal of the mesh.

POSSIBLE COMPLICATIONS

The possible complications associated with the use of ProGrip™ self-gripping polypropylene mesh are those typically associated with surgically implantable meshes: acute and chronic pain, allergic reaction to the components of the product, extrusion/erosion, hematoma, infection, inflammation, recurrence and/or seroma. Other possible complication inherent to the surgical procedure may occur.

The incidence and severity of complications may depend on numerous factors, including but not limited to the type and size of the defect, the mesh fixation, the surgical technique and patient-related factors (e.g., comorbidities). A thorough assessment of each patient's medical history and condition should be made to determine the suitability for implantation of this device. The treatment of complications may require one or more revision surgeries, that may not necessarily resolve the complications and may pose risks of subsequent complications. Being a permanent implant designed to integrate into tissues, significant dissection may be required if the mesh needs to be removed, in part or in whole. It is important that patients are given complete information regarding possible complications.

Any adverse event or serious incident that occurs in relation to the device should be reported to the manufacturer and/or the competent authority of the country in which the patient is established, as applicable per the federal, national or local regulations.

WARNINGS

1. Do not use the device past the labeled expiration date.
2. The device is provided in a double sterile packaging. Upon receipt of shipment, ensure that the packaging is not open or damaged and retains its sealed integrity. Do not use the device if the package is open or damaged or if the integrity of the packaging appears compromised.
3. Open the last packaging only for the placement of the mesh and handle the latter using clean sterile gloves and instruments.
4. The compatibility of ProGrip™ self-gripping polypropylene mesh with trocars and laparoscopic instruments has not been established.
5. The mesh is not designed for "bridging" repair technique with the mesh placed in an "inlay" position. The "inlay" repair technique is defined as cutting mesh to the size of the defect, positioning the mesh in the abdominal wall defect and then suturing the edges of the mesh to the edges of the defect. In any case, every effort should be made to close the defect.
6. The mesh is not designed for repair of parastomal hernias.
7. The mesh is not intended for repair of pelvic organ prolapse and treatment of stress urinary incontinence.
8. The mesh is not intended for repair of chest wall defects.
9. Do not place the mesh in direct contact with the viscera. Direct contact with the viscera may lead to risks of adhesions, fistula formation, and bowel obstruction. Do not implant the mesh in an intra-peritoneal position.
10. When implanting in a pre-peritoneal site, the mesh shall be placed with the grips towards the muscle fascia with the mesh completely covered with peritoneum. The self-gripping side of the mesh can be differentiated from the smooth non-gripping side visually or through tactile feel.
11. For women planning future pregnancies, the surgeon should be aware that this product will not stretch enough as the patient grows.
12. Ensure that the mesh is adequately fixated. To avoid injury, exercise caution if fixating the device in the presence of nerves or vessels.
13. The mesh should not be overly stretched when it is being put in place in order to maintain the elasticity and the porosity of the reinforcement. A moderate and equal tension should be applied in all directions for fixation in order to account for wound shrinkage during the healing process.
14. The placement of the mesh should assure necessary overlap beyond the margins of the defect according to the surgeon's practice. When possible, a minimum of 5 cm overlap over the edges of the defect is recommended for ventral hernia repair.
15. Unused product, explant, and packaging may be a potential biohazard. Handle and dispose them with the necessary precautionary measures in accordance with accepted medical practices and with applicable local, state, and federal laws and regulations on disposal of packaging and medical waste.

PRECAUTIONS

1. Users should be familiar with surgical procedures and techniques involving the use of surgical mesh before employing this device.
2. This device should only be used by experienced practitioners who do so under their own responsibility.

OPERATING STEPS

1. The choice of the mesh size is determined by the surgeon. This mesh can be used whole or cut to the required dimensions. The surgeon should assure necessary overlap of the mesh beyond the margins of the defect according to practice.

CAUTION: The placement of the mesh should assure necessary overlap beyond the margins of the defect, according to the surgeon's practice. When possible, a minimum of 5 cm overlap over the edges of the defect is recommended for ventral hernia repairs.

2. The product shall be placed grips either up or down in retromuscular space, grips down when placed in an onlay position, grips up in pre-peritoneal space to avoid their direct contact with peritoneum.

CAUTION: When implanting in a pre-peritoneal site, the mesh shall be placed with the grips towards the muscle fascia with the mesh completely covered with peritoneum. The self-gripping side of the mesh can be differentiated from the smooth non-gripping side visually or through tactile feel.

CAUTION: Do not place the mesh in direct contact with the viscera. Direct contact with the viscera may lead to risks of adhesions, fistula formation and bowel obstruction. Do not implant the mesh in intraperitoneal position.

3. The technique used to fixate the mesh (suture and/or tacks) is left up to the surgeon. Compatibility with other fixation devices may not have been established. Using means of fixation other than those for which compatibility is established may lead to mesh damage. If tacks are used to fixate the mesh, the use of Covidien™ fixation devices is recommended. It is suggested to fixate the mesh at a distance of approximately 1 cm from the edge of the mesh. The textile self-gripping feature makes it possible to position the mesh without fixation, depending on the size of the defect, the hernia position and the quality of the anatomical structures.

CAUTION: The mesh should not be overly stretched when it is being put in place in order to maintain the elasticity and the porosity of the reinforcement. A moderate and equal tension should be applied in all directions for fixation in order to account for wound shrinkage during the healing process.

CAUTION: Ensure that the mesh is adequately fixated. To avoid injury, exercise caution if fixating the device in the presence of nerves or vessels.

4. In case of inguinal hernia repair, the mesh can be fixed to the Cooper's ligament and/or to the anterior muscular plane. Fixation can also be used between the posterior muscular plane and the anterior aponeurotic one (external oblique muscle).

STERILIZATION METHOD

ProGrip™ self-gripping polypropylene mesh is a sterile single-use device. It is sterilized by ethylene oxide. Do not re-sterilize.

FOLLOW-UP

ProGrip™ self-gripping polypropylene mesh is intended for permanent implantation. It is not intended to be removed, repaired, or replaced in normal conditions of use. It does not require particular follow-up. Necessity and modalities of patient follow-up shall be determined by exerting medical judgment and per accepted medical practice inherent to hernia surgery.

STORAGE

ProGrip™ self-gripping polypropylene mesh does not require any special storage conditions.

MAGNETIC RESONANCE IMAGING (MRI) COMPATIBILITY

ProGrip™ self-gripping polypropylene mesh poses no known hazards resulting from exposure to any Magnetic Resonance (MR) environment. It is classified as MR safe.

TRACEABILITY

A traceability label is attached to every device package which identifies the type and lot number of the device. This label should be affixed to the patient's permanent medical record to clearly identify the device that was implanted.

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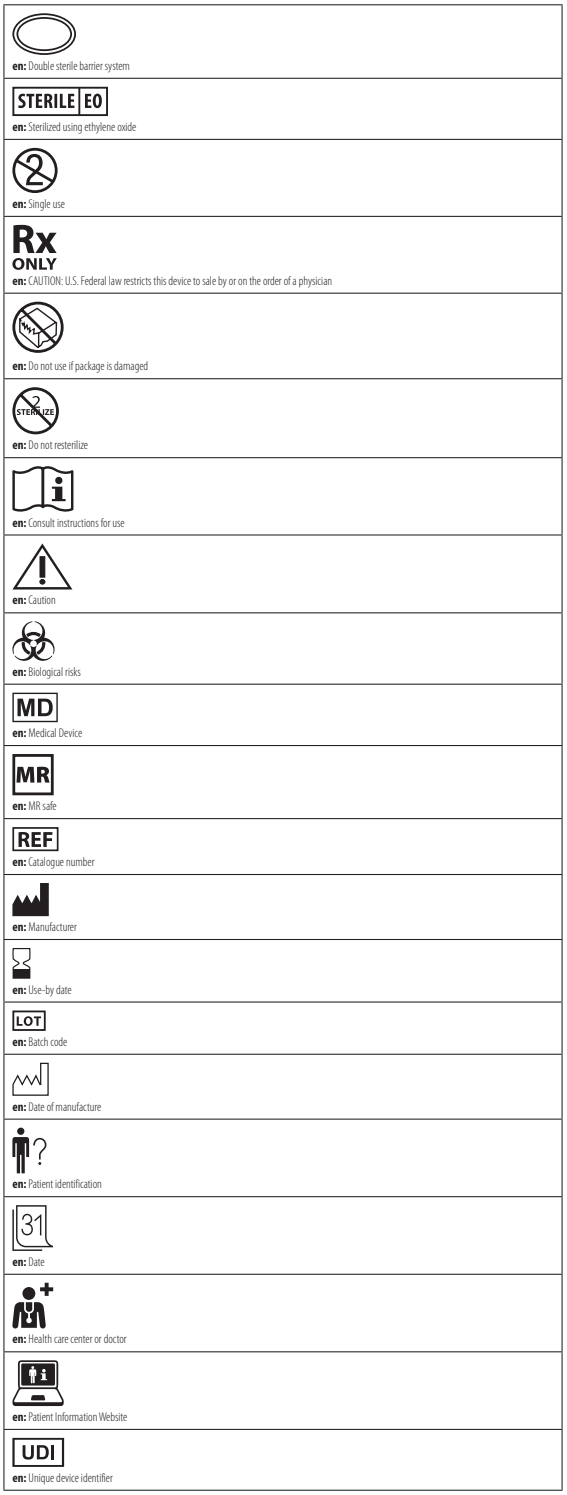
IFU current as of 01/2024 when this brochure was approved by Medtronic. For the most current IFU, please contact your sales rep.

Instructions for use (IFU) – ventral
(PP1515G, PP2015G, PP3020G, PP3030G, PP4030G)



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Ordering information

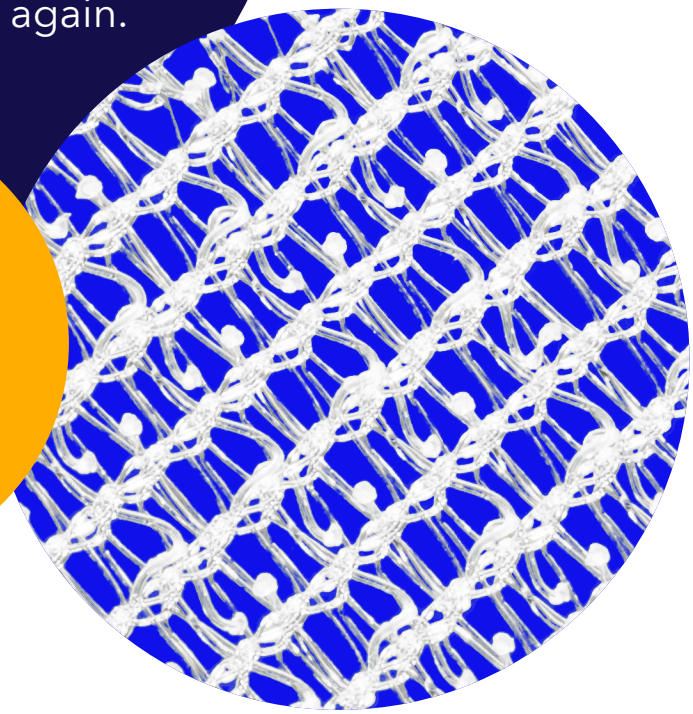
Sizes you need. Grips you love.

By putting more choice in surgeons' hands, the ProGrip™ self-gripping polypropylene mesh portfolio has you and your patients covered for hernia repairs large and small.

Item number	Description	Dimensions	Shape	Side	Qty.
PP1208DL	ProGrip™ self-gripping polypropylene mesh	12 cm × 8 cm (4.7 in × 3.0 in)	Elliptical pre-cut with flap, marking	Left	1
PP1208DR	ProGrip™ self-gripping polypropylene mesh	12 cm × 8 cm (4.7 in × 3.0 in)	Elliptical pre-cut with flap, marking	Right	1
PP1509G	ProGrip™ self-gripping polypropylene mesh	15 cm × 9 cm (6.0 in × 3.5 in)	Rectangular	N/A	1
PP1515G	ProGrip™ self-gripping polypropylene mesh	15 cm × 15 cm (5.9 in × 5.9 in)	Square	N/A	1
PP2015G	ProGrip™ self-gripping polypropylene mesh	20 cm × 15 cm (7.9 in × 5.9 in)	Rectangular	N/A	1
PP3020G	ProGrip™ self-gripping polypropylene mesh	30 cm × 20 cm (11.8 in × 7.9 in)	Rectangular	N/A	1
PP3030G	ProGrip™ self-gripping polypropylene mesh	30 cm × 30 cm (11.8 in × 11.8 in)	Square	N/A	1
PP4030G	ProGrip™ self-gripping polypropylene mesh	40 cm × 30 cm (15.7 in × 11.8 in)	Rectangular	N/A	1

Gain the confidence of a technology used, tested, and trusted globally.[24–28]

With more than 5 million implants used in 27 countries, ProGrip™ technology is trusted by surgeons worldwide to provide a secure hernia repair[24–28] – delivering the improved comfort and recovery[24–28] necessary to help your patients get moving again.



Inguinal risk statement (PP1208DL, PP1208DR, PP1509G): Mesh complications may include but are not limited to acute and chronic pain, extrusion/erosion, hematoma, infection, inflammation, recurrence, and/or seroma. ProGrip™ self-gripping polypropylene mesh is not intended to be used for laparoscopic hernia repair. Do not place the mesh in direct contact with the viscera. Direct contact with the viscera may lead to risks of adhesions, fistula formation, and bowel obstruction. Do not implant the mesh in an intra-peritoneal position. When implanting in a pre-peritoneal site, the mesh shall be placed with the grips towards the muscle fascia with the mesh completely covered with peritoneum.

Ventral risk statement (PP1515G, PP2015G, PP3020G, PP3030G, PP4030G): Mesh complications may include but are not limited to acute and chronic pain, extrusion/erosion, hematoma, infection, inflammation, recurrence, and/or seroma. The compatibility of ProGrip™ self-gripping polypropylene mesh with trocars and laparoscopic instruments has not been established. Do not place the mesh in direct contact with the viscera. Direct contact with the viscera may lead to risks of adhesions, fistula formation, and bowel obstruction. Do not implant the mesh in an intra-peritoneal position. When implanting in a pre-peritoneal site, the mesh shall be placed with the grips towards the muscle fascia with the mesh completely covered with peritoneum.

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