I want a product that works with my technique

My patients don’t want to feel the mesh

Minimize the amount of foreign material implanted

Color sticky notes represent customer insights

Third party trademarks used herein are trademarks of their respective owners.
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Plug with a Proven Mesh

The first and only macroporous, partially absorbable mesh plug made from ULTRAPRO® Partially Absorbable Lightweight Mesh

- ULTRAPRO Mesh provides long-term improvement in quality of life, with significant relief from movement limitations at 1-year postsurgery versus presurgery (P < 0.001)①
- The ULTRAPRO® Portfolio offers low rates of recurrence (<2%) for a lasting repair, based on data from the IHMR and a multicentric German quality control study①③⑩

ULTRAPRO® Partially Absorbable Lightweight Mesh

ULTRAPRO® Hernia System

ULTRAPRO® Plug

N=151
99.3%
recurrence-free
at 1 year①

N=2792
99.6%
recurrence-free
at 1 year②

N=71
98.6%
recurrence-free
at 1 year③

0.7% recurrence rate

0.4% recurrence rate

1.4% recurrence rate

* Data from a prospective, longitudinal study of 71 patients receiving open hernia repair with ULTRAPRO® Plug from the IHMR. Two additional patient-reported recurrences could not be medically confirmed by a clinician
† Data from a prospective, longitudinal study of 151 patients receiving open hernia repair with ULTRAPRO® Partially Absorbable Lightweight Mesh from the IHMR
‡ Data from a prospective, longitudinal study of 2792 patients receiving hernia repair with ULTRAPRO® Hernia System from the IHMR

References
No Change in Technique

Improved patient comfort without changing your technique

Relies on familiar, easily reproducible “plug & patch” technique\(^1\)\(^2\)

- No need to create a preperitoneal space
- Orientation markings aid placement, alignment, and fixation

Large-pore, partially absorbable mesh promotes good tissue in-growth\(^*\)

- Leaves behind 65% less foreign material compared with heavier-weight mesh after partial absorption\(^4\)

\(^1\) ULTRAPRO COMFORT PLUG™ Partially Absorbable Hernia Repair Device Instructions for Use. Ethicon Inc.

\(^*\) Evidence shown in an animal model.
Device Details

ULTRAPRO COMFORT PLUG Device is a sterile plug device made from ULTRAPRO® Partially Absorbable Lightweight Mesh for open repair of groin hernias

The device consists of a three-dimensional plug and a flat, preshaped onlay patch manufactured from nonabsorbable polypropylene monofilament and absorbable poliglecaprone 25 monofilament fibers. The structure of the plug contains ribs made from dyed (D&C Violet No. 2) polydioxanone polymer fibers.

The plug is composed of undyed ULTRAPRO Mesh. Dyed ribs are laminated to the plug mesh. Ribs are made from dyed (D&C Violet No. 2) polydioxanone polymer film.

The onlay patch is a pre-shaped, dyed ULTRAPRO Mesh.

After absorption of the poliglecaprone 25 components, only the polypropylene mesh remains in the body, which is 65% less foreign material compared to heavyweight mesh after partial absorption.4 The structure and size of this remaining mesh is designed to withstand the physiological forces of the abdominal wall.

References
How supplied
ULTRAPRO COMFORT PLUG Device is available in two sizes of plug (40 mm and 55 mm) with one size of onlay mesh (7 cm x 14 cm). ULTRAPRO COMFORT PLUG Device is supplied in boxes of one, three, or six devices. Each unit is sterile and individually wrapped in sterile packaging

Indications for use
The ULTRAPRO COMFORT PLUG Device is indicated for reinforcement of soft tissue, where weakness exists, in procedures involving soft tissue repair, such as groin hernia defects

For full Prescribing Information, see page 16

References
1. ULTRAPRO COMFORT PLUG™ Partially Absorbable Hernia Repair Device Instructions for Use. Ethicon Inc.
### Ordering Information

**Product can be ordered direct through Johnson & Johnson Health Care Systems, Inc. (JJHCS) and through distributor channels**

#### Electronic ordering options

**Note:** Placing orders electronically avoids minimum order fees for hospitals

- **Order 360™:** order360.jnjgateway.com
  For questions about your order, visit the website or call 1-866-565-4283

- **Global Healthcare Exchange:** ghx.com
  For questions about your order, visit the website or call 1-800-YOUR-GHX

**Electronic Data Interchange**
Call JJHCS EDI Help Line: 1-800-262-2888

#### Nonelectronic/Manual ordering options

Call JJHCS at 1-800-255-2500 (option 1) between 8:30 a.m. and 8:00 p.m. eastern time, or fax your order to 1-832-562-2212 or 1-800-997-1122. For more information or product support, call 1-877-ETHICON (384-4266)

#### Customer support

For product use assistance, clinical guidelines, service and repair, emergency assistance, copy of 510(k) clearance letter or complaints, please contact our Customer Support Center at customersupport@eesus.jnj.com or by calling 1-877-ETHICON (384-4266). Our support center is staffed 24 hours a day, 7 days a week by qualified nurses to answer your product-related questions

For complete product details, see Instructions for Use. For more information, contact your local Ethicon representative or call 1-877-ETHICON (384-4266)
## Competitive Code Conversions

### ULTRAPRO COMFORT PLUG Device – 40 mm codes

<table>
<thead>
<tr>
<th>Mnfr</th>
<th>Code #</th>
<th>Description</th>
<th>Plug diameter</th>
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<tr>
<td>Ethicon</td>
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# Competitive Codes - Comparable to 40mm ULTRAPRO COMFORT PLUG Device

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<th>Mnfr</th>
<th>Code #</th>
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<tr>
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<td>BARD</td>
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<td>Poly-4-Hydroxybutyrate (P4HB)</td>
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Code Cross-Reference
Plug with Proven Mesh
No Change in Technique
Instructions for Use

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Additional Resources
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## Competitive Codes - Comparable to 40mm ULTRAPRO COMFORT PLUG Device

<table>
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<th>Mnfr</th>
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<td>30801</td>
<td>ProLite Ultra™ Mesh - Self Forming Plug with Onlay</td>
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<tr>
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## Competitive Codes - Comparable to 40mm ULTRAPRO COMFORT PLUG Device

<table>
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<td>ATRIUM</td>
<td>30901</td>
<td>ProLoop™ Mesh - ProLoop with Onlay</td>
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<td>ATRIUM</td>
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<th>Mnfr</th>
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<td>GORE® BIO-A® Hernia Plug</td>
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### ULTRAPRO COMFORT PLUG Device - 55 mm codes

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<td>Ethicon</td>
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<td>UPLUG556</td>
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### Competitive Codes - Comparable to 55mm ULTRAPRO COMFORT PLUG Device

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<td>112970</td>
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<td>117180</td>
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## Competitive Codes - Comparable to 55mm ULTRAPRO COMFORT PLUG Device

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<th>Mnfr</th>
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<td>Self Forming Plug with Keyhole Slit Onlay</td>
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## Competitive Codes - Comparable to 55mm ULTRAPRO COMFORT PLUG Device

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<td>COVIDEN</td>
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<td>Parietex™ Plug and Patch System 65cm round plug</td>
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<td>Non-Absorbable</td>
<td>Polyester</td>
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<td>COVIDEN</td>
<td>PNP8X3</td>
<td>Parietex™ Plug and Patch System 8cm round plug</td>
<td>80mm (flat)</td>
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<td>Non-Absorbable</td>
<td>Polyester</td>
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</tbody>
</table>
Instructions for Use

ETHICON
ULTRAPRO COMFORT PLUG™
Partially Absorbable Hernia Repair Device

Made by Johnson & Johnson Medical GmbH
Instructions for Use
Instructions for Use

ULTRAPRO COMFORT PLUG™
Partially Absorbable Hernia Repair Device

DESCRIPTION
The ULTRAPRO COMFORT PLUG™ Partially Absorbable Hernia Repair Device is composed of a fully absorbable partial lumen 
PRO™ Partially Absorbable Lightweight Mesh. Dyed ribs are laminated to the Plug mesh. Fibers are made from dyed (D&C Vio 
PRO™ Mesh is manufactured from approximately equal parts of absorbable copolymer and non-absorbable sheath. Color Index 
Polyglactin 910 (3050) is identical to the material used for MONOCRYL™ Polyglactin 910. After absorption of the polyglactin 25 
Polypropylene mesh remains. The structure and size of this remaining mesh is designed to withstand the physiological forces 

APPLICATIONS
An appropriate Plug should be chosen according to the size of the defect. The fiber and/or water 

ADVERSE REACTIONS
Potential adverse reactions with device implantation are those typically associated with surgically 

STERILITY
The device is sterilized by Ethylene Oxide. Do not resterilize. Do not use if package is opened or 

STORAGE
Store at or below 30°C. Do not use after expiry date.

TRANSPARENCY
A transversal cut that identifies the type, city, registration date and lot number of the device is 

CAUTION
Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed healthcare 

SYMBOLS USED ON LABELING
- Do not reuse
- Do not resterilize
- Catalogue number
- Use By – Year and Month
- Sterile. Method of sterilization: Ethylene Oxide
- Recommended storage conditions: below 30°C (86°F).
- Do not use if the product
- C A U T I O N: F e d e r a l (U.S.A.) l a w r e s t r i c t s t h i s d e v i c e t o s a l e b y 
- Do not use if package is opened or damaged.
- Batch number

BATCH NUMBER
To clearly identify the device that was implanted.

CAUTION
Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed healthcare 

S Y M B O L S U S E D O N L A B E L I N G
- Do not reuse
- Do not resterilize
- Catalogue number
- Use By – Year and Month
- Sterile. Method of sterilization: Ethylene Oxide
- Recommended storage conditions: below 30°C (86°F).
- Do not use if the product
- C A U T I O N: F e d e r a l (U.S.A.) l a w r e s t r i c t s t h i s d e v i c e t o s a l e b y 
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- C A U T I O N: F e d e r a l (U.S.A.) l a w r e s t r i c t s t h i s d e v i c e t o s a l e b y 
- Do not use if package is opened or damaged.
- Batch number
May 30, 2014

Ethicon, Inc.
Reynaldo Librojo
Director, Regulatory Affairs
Route 22 West, P.O. Box 151
Somerville, NJ 08876

Re: K133198
Trade/Device Name: ULTRAPRO COMFORT PLUG Partially Absorbable Hernia Repair Device
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: May 22, 2014
Received: May 28, 2014

Dear Mr. Reynaldo Librojo,

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. 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 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
510(k) Clearance Letter

Ethicon Inc.
October 2019

Traditional 510(k) – ULTRAPRO COMFORT PLUG

4 INDICATIONS FOR USE STATEMENT

510(k) No (if known):

Device Name: ULTRAPRO COMFORT PLUG™ Partially Absorbable Hernia Repair Device

Indications for Use: The ULTRAPRO COMFORT PLUG™ Partially Absorbable Hernia Repair Device is indicated for reinforcement of soft tissue, where weakness exists, in procedures involving soft tissue repair, such as groin hernia defects.

Prescription Use ___Y___ AND/OR Over-The-Counter Use ______
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE–CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter L. Hudson -S

Page 12 of 49
Clinical Literature

**Gilbert Repair – a New Gold Standard?**

First Results of 2792 Patients of a Multicentric German Quality Control Study

Ralph Lorenz MD, Andreas Koch MD, Martin Wiese, Henry Born MD for the working group

In collaboration with AN - Institute for quality management in the operative medicine Otto-von-Guericke-Universität Magdeburg

26 ambulatory Hernia centers in Germany

- Online - project since 2000
- Pilot phase for 2 years 16 hernia centres in Germany now joining 26 hernia centers in Germany
- criteria: pain and recurrence
- only Hernia surgery with 3-D-meshes
- Follow up after 4, 12 and 52 weeks (examination)
- Independent patient questionnaire with Carolina Comfort Scale after 4, 12 and 52 weeks

**Results**

- The rate of intraoperative and postoperative complications is very low
- The recurrence rate after 1 year is very low
- Follow up after 4, 12 and 52 weeks (Recurrence rate)

**Conclusion:**

- Gilbert repair using the partly absorbable Ultrapro Hernia System® combines a simple and safe open access with a secure posterior mesh placement
- The Gilbert Repair is usable in most of all groin hernias as well in recurrent cases, in our study it was mostly used in large size direct or combined hernias
- With 3 available sizes of the UHS® there is a possibility for a tailored concept adapted on the size of the hernia
- A high rate of day cases is possible
- The rate of intra- and postoperative complications is very low
- The recurrence rate after 1 year is very low
- The patient satisfaction is very high
- Our results are comparable with other current comparative studies (1),(2),(3)

**ASA Classification**

- Ultra pro Hernia System = UHS®

**Follow up after 4, 12, and 52 weeks (Patients satisfaction with Carolina Comfort Scale)**

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<th>UHS® (n=2792)</th>
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<tr>
<td>Classification</td>
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<tr>
<td>Recurrence after 4 weeks</td>
<td>7 (0.25%)</td>
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<tr>
<td>Recurrence after 12 weeks</td>
<td>10 (0.35%)</td>
</tr>
<tr>
<td>Recurrence after 52 weeks</td>
<td>10 (0.35%)</td>
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<table>
<thead>
<tr>
<th>Follow up after 4, 12, and 52 weeks (Recurrence rate)</th>
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<tbody>
<tr>
<td>4 weeks</td>
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<tr>
<td>12 weeks</td>
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<tr>
<td>52 weeks</td>
</tr>
</tbody>
</table>

**Literature**


**Authors**

- Ralph Lorenz MD, SCHWARZEN Klinikverwaltung 24/95, D - 11396 Berlin, lofers@schwarzen.de
- Andreas Koch MD, FACS, Chirurgische Klinik Cottbus, Thomä Strasse 322, D - 03057 Cottbus
- Martin B. Weise, Gesundheitszentrum Kelkheim Frankenallee 1, D - 63776 Kelkheim
Clinical Literature

INTRODUCTION

Macroporous, partially absorbable mesh has been adopted in both open and laparoscopic hernia repair. We report prospectively collected 12-month post-operative outcomes in patients undergoing open hernia repair, implanted with a flat macroporous partially absorbable mesh (MPPWR).

METHODS

The International Hernia Mesh Registry (IHMR) is a prospective multi-center registry to collect longitudinal data on hernia mesh products, up to 3 years post-surgery with 12 month follow-up from 13 centers across 8 countries, following open hernia repair using ULTRAPRO™ Flat Mesh. Clinical, quality of life, and adverse event data were collected and quality of life questionnaires vary between centers. Surgical data was collected for all operations. Respondents were asked to rate their satisfaction with surgery. One hundred ninety-one (191) patients across 13 centers (Figure 1) underwent an open hernia repair with ULTRAPRO™ Flat Mesh (Figure 2), and their demographics are noted in Table 1. These patients are those that were reached or would have reached their 12 month follow-up. Types of hernia procedures, deep inferior epigastric pedicle techniques and mesh fixation methods are shown in Table 2. The results were compared to previous data on hernia repair (Figure 5). The most common adverse events were followed through 12 months (Figure 6). The CCS mean pain and mean movement limitation changes from baseline: through 12 months are noted in Figures 7 and 8.

CONCLUSIONS

MPPWR open hernia repair twelve month outcomes exhibit improvement in pain and movement limitations compared to baseline, and was associated with a rate of recurrence.

REFERENCES

PMID:19790215. Clinical Literature

Acknowledgments

IHMR is funded by IDEXX Surgical Care and acknowledges the contribution of the following institutions: The Regina Learning Facility, After Flos, Steller (France); Generali Global, Brussels, Belgium; Smurfit Kappa, Belgium; Studebaker, Italy; and the University of California, San Francisco, USA, for their support.

*Correspondence: RT, IDEXX Surgical Care, 451 Main Street, Andover, MA 01810, USA. Tel: 978-770-2457; E-mail: rob@idexx.com
12 Month Outcomes Following Open Hernia Repair with a Partially Absorbable Plug and Patch Device

Carl Doerhoff¹, Peter Lydon², Jeffrey Hammond³, Christine Romanowski ³ Pete Jones³
¹Surgicare of Missouri, 1705 Christy Drive, Suite 215, Jefferson City, Missouri 65101
² Eastern Massachusetts Surgery Center, 100 Morse Street, Norwood, MA 02062
³ Clinical Development & Medical Affairs, ETHICON Surgical Care, Johnson & Johnson Global Surgery Group

Background:
The popularity of the plug and patch technique for hernia repair stems from the ease of performing this surgical procedure. A two-component, partially absorbable device was developed primarily for groin hernias to fill or reinforce hernia defects and to provide support during wound healing.

Methods:
The International Hernia Mesh Registry, a prospective multi-center registry collects data on hernia mesh products. Patients complete Carolinas Comfort Scale™ (CCS), validated QOL questionnaire specific to herniorrhaphy at baseline and 1, 6, 12 and 24 months postoperatively. Symptomatic patient is defined as one providing a response of >1 to any CCS™ question. Patients who underwent open herniorrhaphy with a partially absorbable plug and patch device (ULTRPRO™ Plug, Ethicon, Somerville, NJ) and completed up to 12 months postoperative follow-up were included. McNemar tests were used to compare symptomatic events.

Results:
92 patients enrolled across 7 centers with 12 month data available for 71 patients. Mean age 57.6 years (15.2 SD) and mean BMI 26.4 kg/m² (3.9 SD). Hernia types: 90.2% inguinal; 8.7% umbilical; 1.1% femoral, 94.6% were primary repairs. Fixation methods: 97.8% sutures; 1.1 % sutures and glue; 1.1% none. Anesthesia utilized; 57.6% general, 42.4% local. Most procedures (78.3%) were < 1 hour long and median duration in hospital; 0.0 (0.0, 3.0) nights. Preoperatively, incidence of patient reported symptomatic pain (56.5%) decreased (7.5% ) p<0.001; symptomatic movement limitations (35.9%) decreased (4.5%) p < 0.001 at 12 months postoperatively, respectively. Most common adverse event was seroma, 7.6 % patients. There were 4 patient reported recurrences; 1 medically confirmed, 1 confirmed as not a recurrence and 2 yet to be confirmed, due to patients not returning for assessment.

Conclusion:
These results indicate that inguinal hernia repair with this plug and patch is associated with significant improvement compared to baseline in pain and movement limitations at 12 months postoperatively.
Product Information Brochures

ULTRAPRO COMFORT PLUG Device Brochure

ULTRAPRO® Portfolio Brochure
For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.