

Single-Incision Surgery Today



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News and expert opinion
on the single-incision laparoscopic technique

Issue 1, 2010

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[Guest editorial]



Professor Helmut Weiss

Head of Surgical Department, St John of God (SJOG) Hospital, Salzburg, Austria

Professor Weiss has over 15 years' experience in the laparoscopic field. He has used the single-incision laparoscopic technique routinely in a variety of surgical areas (including colorectal, hepato-bilio-pancreatic, bariatric, general and gynaecological) since his appointment as Head of Surgical Department at SJOG Hospital in Summer 2008 – a department which has performed in excess of 500 single-incision laparoscopic procedures.

Building on the principles of conventional laparoscopic surgery, the single-incision laparoscopic technique is an evolution in minimally invasive surgery. Performed via a multi-channel access port inserted into a single incision, generally in the umbilicus, this technique could potentially offer patients:

- the potential for no visible scarring (when the incision is made in the umbilicus)
- the elimination of pain from multiple sites of entry
- quicker recovery compared with open surgery, meaning patients could spend less time in hospital.

Single-incision laparoscopic procedures have already been employed successfully in many surgical areas; in this edition, experienced surgeons discuss particular benefits seen in multiple surgical fields (pages 3–5). With its reduction in the number of incisions compared with conventional laparoscopy and the availability of specially designed instruments, single-incision laparoscopic procedures represent a valuable step forward towards the minimally invasive surgical ideals of the future. Furthermore, as a result of the potential benefits of the technique, the demand for single-incision laparoscopic procedures is gathering momentum among patients, as evidenced by recent media coverage and positive testimonials – two such patient case studies are featured later in this newsletter (page 7).

Planned and ongoing clinical trials are expected to demonstrate the benefits associated with the single-incision laparoscopic technique over the coming years. In particular, it is hoped that research will demonstrate that, compared with conventional laparoscopic procedures, single-incision laparoscopic

procedures can provide the potential for an optimal cosmetic result for the patient, with no increased risk. Further studies with large patient sample-sizes will be required to confirm advantages in terms of the reduction of pain, reduction in length of hospital stay and time to recovery. See pages 8–9 to read more about the clinical evidence surrounding the single-incision laparoscopic technique.

The single-incision laparoscopic technique holds promise, but some hurdles remain to its widespread uptake. As with any new procedure, there is a period of adjustment required for surgeons to adapt to the single-incision laparoscopic technique (as there was with the introduction of conventional laparoscopy), which may be associated with increased operating times initially. However, attendance at training courses and liaison with surgeons who are experienced in the technique will shorten this learning curve substantially. Secondly, the full cost-benefit ratio of single-incision laparoscopic procedures versus conventional laparoscopic procedures is not yet fully elucidated.

It is a worthwhile investment to work to overcome these hurdles and secure wider uptake of the single-incision laparoscopic technique, not only in terms of providing patients with the potential associated benefits, but also in terms of driving further progress in surgical advancement. I am convinced that the single-incision laparoscopic technique will meet expectations, playing an important role in further developing advanced procedural techniques.

Driving advancements with single-incision laparoscopic procedures

The single-incision laparoscopic technique has been employed across multiple fields of surgery, including bariatric, colorectal, general, gynaecological and urological, with reported benefits over more invasive surgical approaches. While many benefits are common to all fields, the technique appears to offer distinct advantages in some surgical disciplines. Here, prominent surgeons discuss the contribution that the single-incision laparoscopic technique has to offer in key surgical areas and the measures needed to establish this vital stepping stone to even more minimally invasive surgery.



Dr Roberto M Tacchino, MD
Assistant Professor of Surgery, Department of Surgery, Catholic University of the Sacred Heart, Rome, Italy

Dr Tacchino was one of the pioneers of the single-incision laparoscopic technique and has performed approximately 150 such operations, including cholecystectomies, gastric bandings, gastric bypasses and Scopinaro biliary pancreatic diversions.

The single-incision laparoscopic technique is a promising new option that offers patients the opportunity for more discreet surgery and will also drive surgery towards something that is simpler for the patient, compared with other surgical alternatives.

The single-incision technique offers many advantages over more invasive procedures; the benefit of minimal scarring is particularly invaluable to patients undergoing bariatric surgery, given the stigma that still exists around weight loss brought about by medical intervention, as it may not be obvious that patients have undergone a weight-loss procedure. In terms of medical benefit, we have also noted the rapid recovery rate reported in other fields of surgery, particularly following complex operations, such as gastric bypass. Another important attribute of this type of minimally invasive technique is its tendency to simplify surgery. With less invasive access, unnecessarily complex operations will be replaced with simpler ones that are equally as effective as conventional laparoscopic procedures. A cost-benefit analysis recently performed at the Catholic University of the Sacred Heart has revealed that the instrumentation costs of single-incision laparoscopic procedures for bariatric surgery – where disposable instruments are the norm – are generally equivalent to those for four-port surgery in Italy.

‘The benefit of minimal scarring is particularly invaluable to patients undergoing bariatric surgery, given the stigma that still exists around weight loss brought about by medical intervention.’

We are just at the beginning of this exciting new development, where surgeons are undergoing the inevitable learning curve associated with new techniques, and instrumentation developments and training of surgeons are still needed. But here we have an option that is applicable to many operations that are usually performed with four-port procedures and that has clear benefits for patients undergoing bariatric surgery.



Single-incision laparoscopic procedures in colorectal surgery



Dr Boris Vestweber
Staff Surgeon, Klinikum Leverkusen, Germany

Dr Boris Vestweber has performed approximately 90 procedures using the single-incision laparoscopic technique since March 2009, including cholecystectomies, sigmoid resections in diverticular disease and total / subtotal colectomies.

Our institution has performed a great number of single-incision laparoscopic colorectal procedures, including over 50 sigmoid resections. Aside from other benefits, the psychological impact of waking up to just a small plaster on the umbilicus appears to aid recovery, with patients mobilised more quickly than those who have undergone conventional laparoscopic surgery. Overall, patients appear much fitter.

'I am absolutely convinced that this technique is a positive development for colorectal surgery; I think it will play an important role in the journey towards natural-orifice transluminal endoscopic surgery (NOTES).'

As a result of our experience, all surgical procedures for benign colon disease undertaken at our institution are now performed using a single-incision laparoscopic technique. I am absolutely convinced that this technique is a positive development for colorectal surgery; I think it will play an important role in the journey towards natural-orifice transluminal endoscopic surgery (NOTES).

Single-incision laparoscopic procedures in general surgery



Dr Oscar Vidal Perez
Specialist in General & Digestive Surgery,
Department of Surgery, ICMDM, Hospital Clinic i
Provincial de Barcelona, Spain

Dr Oscar Vidal Perez has performed approximately 120 general procedures using the single-incision laparoscopic technique since December 2008, the majority of which have been appendectomies and cholecystectomies.

Although still relatively young, the single-incision laparoscopic technique is a positive step towards a future of less aggressive, minimally invasive general surgery. This is thanks to a shift in mindset among surgeons and to the development of specialised instruments and devices, which are easy to place on the patient and offer good visualisation.

'Although still relatively young, the single-incision laparoscopic technique is a positive step towards a future of less aggressive, minimally invasive general surgery.'

There are still some areas for development with the single-incision laparoscopic technique, both for manufacturers (e.g. the development of devices from which to hang organs to allow for sufficient manoeuvrability) and for the surgical community (e.g. greater attendance at training programmes). In our institution, we are working to refine our technique by maintaining a patient database and by videotaping all procedures to analyse and correct our movements.

I have no doubt that single-incision laparoscopic procedures will play an important role in the future of general surgery. I look forward to the results of clinical trials, which will hopefully confirm the benefits of this technique over conventional laparoscopic surgery and pave the way for further surgical advancements.

Single-incision laparoscopic procedures in gynaecological surgery



Dr Robin Crawford
Consultant Gynaecological Oncologist,
Addenbrookes Hospital, Cambridge University
Hospitals NHS Foundation Trust, UK

Dr Robin Crawford has performed 23 gynaecological procedures using the single-incision laparoscopic technique since June 2009, including oophorectomies, bilateral oophorectomies and hysterectomies.

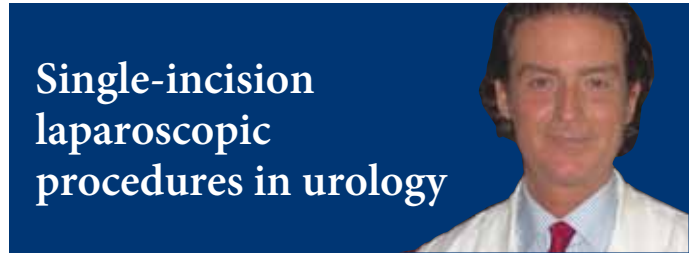
The single-incision laparoscopic technique has great potential in gynaecology. It requires appropriate training and additional instrumentation (some of which is available now and some still under development) for the modern surgeon to meet the great demand that exists for the single-incision laparoscopic technique among the public.

Developing the technique may be a route by which more laparoscopic procedures in gynaecology are offered, reducing the role of open surgery. Moving forward, the consideration of single-incision laparoscopic procedures will allow gynaecological surgeons to review their approach and ensure that they are providing the most effective care for their patients.

'It could well be that single-incision laparoscopic procedures have the potential to become the gold standard in the future.'

It will be important to see more laparoscopic surgery being offered by appropriately trained people in gynaecology in the next few years; this would deliver fewer complications and reduce the duration of hospital stays. It could well be that single-incision laparoscopic procedures have the potential to become the gold standard in the future – we must wait and see.

Single-incision laparoscopic procedures in urology



Dr Vincenzo Ferrara
Head Consultant of Urology Section,
Jesi Hospital, Italy

Dr Vincenzo Ferrara has performed approximately 35 urological procedures using the single-incision laparoscopic technique since March 2009, including partial and radical nephrectomies, ureterolithotomies, pyeloplasties and extra-peritoneal radical prostatectomies and associated lymphadenectomies.

Once the single-incision laparoscopic technique has been mastered, it is safe and effective and applicable to many urological laparoscopic procedures. Not only are single-incision laparoscopic procedures associated with the potential for no visible scarring and elimination of pain associated with numerous incisions, but the technique could also reduce surgical complications compared with open surgery, such as abdominal wall complications (vascular, neural and muscular injuries) and internal organ injuries. Furthermore, this can be achieved without compromising results or lengthening operating times.

'The single-incision laparoscopic technique already represents important progress in patient treatment and is likely to replace 'classic' laparoscopy in the near future.'

Given the benefits associated with the technique, the learning curve associated with its use (approximately 10 procedures) does not detract from this as a very effective technique for urological surgery. While the future development of new instrumentation allowing for easier removal of large surgical specimens or for greater comfort or safety would improve its use, the single-incision laparoscopic technique already represents important progress in patient treatment and is likely to replace 'classic' laparoscopy in the near future.



[Single-incision laparoscopic procedures in the USA]



Dr Homero Rivas

Assistant Professor of Surgery, Director of Surgical Innovation, Division of General Surgery, Department of Surgery, Stanford University School of Medicine, CA, USA

Dr Homero Rivas began to perform single-incision laparoscopic procedures clinically in 2007 – one of the first to adopt the technique – and has since performed approximately 250 such cases, including adrenalectomies, appendectomies, cholecystectomies, colectomies, hysterectomies and oophorectomies.

Over the last 5 years in the USA, widespread efforts to perform natural-orifice surgery to minimise post-surgical scarring have proved challenging and have been associated with safety and effectiveness issues. However, in that time, the single-incision laparoscopic technique has been established as an alternative way to reach the same cosmetic goal, with the concomitant medical benefits that this approach theoretically brings.

Uptake of the single-incision laparoscopic technique in the USA – with operations now numbering in the thousands – reflects its excellent value proposition for both patients and surgeons. For patients, it offers a potential route to minimal scarring and the possibility of many other benefits, such as the elimination of pain resulting from multiple entry points and faster recovery compared with open surgery. For surgeons, it presents an opportunity to differentiate individual practices, with dramatic effects on referral patterns. Our practice, for example, has seen an influx of patients coming from other practices and regions – the return on investment has been very high.

In contrast to natural-orifice surgery, this new technique can be easily learnt and quickly adopted. Beginning with basic operating procedures, such as appendectomies and cholecystectomies, some surgeons in the USA are now turning to the single-incision laparoscopic technique for more complex operations, such as colon, endocrine, hepatic and rectal surgery, and the number of experts and complex operations performed using this technique will only increase. This is also true globally, with single-incision laparoscopic procedures seemingly well received in places throughout Asia, Europe, the Middle East and South America.

Over the last 20 to 25 years we have been able to reproduce most operating procedures laparoscopically, but very few further advancements have been made. The single-incision laparoscopic technique has broken this impasse, providing an evolutionary shift; as such, it has captured the minds of patients and surgeons alike.

Sharing of expertise and training – whether through academia or sponsorship by companies such as Covidien – will be crucial to better establishing the single-incision laparoscopic technique and bringing its benefits to patients. However, key to this technology entering the mainstream is increased recognition of the ease of the single-incision laparoscopic procedure. This is not a difficult technique to master and is truly something that can be learnt quickly to the benefit of patients and surgeons worldwide.

Patient case studies: Growing demand for single-incision laparoscopic procedures

There is an increasing demand among patients for single-incision laparoscopic procedures, in line with the wealth of media coverage and growing awareness around the potential cosmetic and medical benefits associated with the technique. Here, we take a close look at two case studies to provide first-hand insight into the patient experience of the single-incision laparoscopic technique.



Name: Susie
Age: 30 years of age
Occupation: Nurse
Procedure: Nephrectomy

The situation: Deterioration of a long-standing kidney dysfunction led Susie's surgeon to recommend a complete nephrectomy for Susie. Susie already had a three-inch abdominal scar (which occasionally felt lumpy and sore) from previous emergency renal surgery when she was 2 years of age. The traditional laparoscopic procedure using three incisions may have left her with more scarring.

The procedure: Susie's surgeon offered her Europe's first single-incision nephrectomy in 2008.

The patient benefit: The potential for no visible scarring was a primary factor in Susie's decision to undergo the procedure; other reasons included the potential elimination of pain from multiple incisions and for a quicker recovery compared with open surgery.

'I was delighted that the single-incision laparoscopic procedure was an option for me. The fact that it could leave me without any noticeable scars was a huge deciding factor.' – Susie



Name: Clancy
Age: 30 years of age
Occupation: Computer engineer
Procedure: Cholecystectomy

The situation: Dissatisfied with an original diagnosis of irritable bowel syndrome, Clancy sought a second opinion about his debilitating stomach pains. An ultrasound scan showed that the actual cause was gallstones, at which point his specialist recommended a cholecystectomy. Having never undergone surgery, Clancy was concerned about the amount of time he would need away from work.

The procedure: Following discussion with his specialist and after carrying out independent internet research, Clancy opted for a single-incision laparoscopic procedure because of the potential for rapid recovery it could offer over open surgery.

The patient benefit: Clancy had his single-incision laparoscopic procedure on a Thursday and was able to work a little from home the next day. By the following Monday, he had returned to the office.

'I didn't want to spend too much time away from work – it was [about] getting better as quickly as I could. The pain went away after 2 or 3 days. The scar is barely noticeable and I can't speak highly enough about the single-incision laparoscopic procedure.' – Clancy



Clinical evidence for the single-incision laparoscopic technique

The evidence in support of the single-incision laparoscopic technique is increasing, with the emergence of new publications and the continuation of ongoing clinical trials to evaluate the safety and efficacy of single-incision laparoscopic procedures. Here, we provide you with summaries of some of the key references in the field, as well as an essential reading list of interesting and informative publications about the technique and an overview of key trials.

Elective transumbilical compared with standard laparoscopic cholecystectomy **Bresadola F, et al. *Eur J Surg* 1999;165:29–34**

This randomised, open study compared transumbilical laparoscopic cholecystectomy (using two ports) with conventional laparoscopic cholecystectomy (using four ports) in 90 patients in terms of pain and analgesia use, cost, side effects and cosmesis. Among the 57 evaluable patients (n=25 transumbilical, n=32 standard), there were no complications, side effects or conversions to open cholecystectomy. Patients in the transumbilical surgery group had significantly ($p<0.05$) lower pain scores and needed significantly ($p<0.05$) less analgesia during the first 24 hours after surgery than those in the conventional laparoscopy group. This led the authors to conclude that, following the completion of an initial learning curve, it is possible to perform transumbilical cholecystectomy without some of the difficulties associated with standard laparoscopic procedures.

New: Single-incision transumbilical laparoscopic surgery **Brunner W, et al. *Eur Surg* 2009;41:98–103**

The authors demonstrate that single-incision laparoscopic procedures allow for non-visible post-operative scarring and further reduction of surgical trauma in a study of 136 patients who underwent single-incision laparoscopic procedures for surgery of the appendix, gall bladder, colon, oesophagus, liver, adrenal gland or inguinal hernia or for symptomatic adhesions. There were no intraoperative adverse events or significant perioperative complications noted. After 1–4 weeks' follow-up, patients presented with optimal cosmetic results without apparent scarring.

Single-port urological surgery: single-center experience with the first 100 cases **White WM, et al. *Urology* 2009;74:801–4**

This prospective study evaluated perioperative outcomes in 100 patients who underwent single-incision laparoscopic urological procedures (n=74 renal, n=26 pelvic). No intraoperative complication occurred; however, six patients required conversion to conventional laparoscopy. At 11 months' follow-up, nine Clavien Grade II and two Clavien Grade IIIb surgical complications occurred. The authors concluded that single-incision laparoscopic urological procedures are feasible, offer improved cosmesis and may offer reduced pain.

Trial title	Clinical trials.gov identifier	Sponsor	Procedure	Primary endpoint	Sample size	Study period
Randomized, controlled study of different pain scores in single transumbilical incision laparoscopic cholecystectomy versus classic laparoscopic cholecystectomy	NCT00872287	G. Hatzikosta General Hospital, Ionnina, Greece	Single-incision laparoscopic cholecystectomy versus conventional laparoscopic cholecystectomy	Significantly lower abdominal and shoulder-pain scores following single-incision laparoscopic cholecystectomy (except invisible scar) [Designated as safety issue: Yes]	40	Sep 2008 – Dec 2008
Single incision laparoscopic cholecystectomy	NCT00678873	University of Texas Southwestern Medical Center, Dallas, TX, USA	Single-incision laparoscopic cholecystectomy	Safety and feasibility (time frame: 12 months) [Designated as safety issue: Yes]	20	Mar 2008 – Mar 2009
A randomized trial of single-port laparoscopic cholecystectomy versus four-port laparoscopic cholecystectomy	NCT00892879	Providence Health Care, Portland, OR, USA	Laparoscopic cholecystectomy surgery	Post-operative pain scores (visual analogue pain scale from 0–10) assessed on Day 1 post-op and at the post-operative follow-up visit in clinic	50	Feb 2009 – Feb 2011
Single-port access cholecystectomy versus standard laparoscopic cholecystectomy – randomized study	NCT00904865	University Hospital, Geneva, Switzerland	Single-incision laparoscopic cholecystectomy versus conventional laparoscopic cholecystectomy	Cosmesis, body image and quality-of-life scale (time frame: at 1 month) [Designated as safety issue: No]	200	Feb 2009 – Feb 2011
Prospective, randomized, controlled trial of traditional laparoscopic cholecystectomy versus SILS™ Port laparoscopic cholecystectomy	NCT00832767	Covidien	Single-incision laparoscopic cholecystectomy (using a Covidien SILS™ Port) versus conventional laparoscopic cholecystectomy	Feasibility and safety of single-incision laparoscopic cholecystectomy (using a Covidien SILS™ Port) versus four-port laparoscopic cholecystectomy as indicated by intra-operative and post-operative adverse events (time frame: 10 time points to 1 year) [Designated as safety issue: Yes]	200	Apr 2009 – Sep 2011
A randomized, controlled trial of single-incision laparoscopic (SILS) versus conventional laparoscopic appendectomy for the treatment of acute appendicitis	NCT00997516	University of California, San Francisco, CA, USA, and Covidien	Single-incision laparoscopic appendectomy (using a Covidien SILS™ Port) versus conventional laparoscopic appendectomy	Pain in the first 12 hours after surgery (time frame: 12 hours) [Designated as safety issue: No]	150	Jan 2010 – Aug 2012

Note: List of key trials as at January 2010. Only one of the clinical trials listed here use the Covidien SILS™ Port

The single-incision laparoscopic technique: Essential reading

- Bresadola F, Pasqualucci A, Donini A, *et al.* Elective transumbilical compared with standard laparoscopic cholecystectomy. *Eur J Surg* 1999;165:29–34
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- Chambers W, Bucsak M, Lamparelli M and Dixon A. Single-incision laparoscopic surgery (SILS) in complex colorectal surgery: a technique offering potential and not just cosmesis. *Colorectal Dis* [Epub ahead of print]
- Fader AN, Escobar PF. Laparoendoscopic single-site surgery (LESS) in gynecologic oncology: technique and initial report. *Gynecol Oncol* 2009;114:157–61
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- Hirano D, Minei S, Yamaguchi K, *et al.* Retroperitoneoscopic adrenalectomy for adrenal tumors via a single large port. *J Endourol* 2005;19:788–92
- Jutley RS, Khalil MW, Rocco G. Uniportal vs standard three-port VATS technique for spontaneous pneumothorax: comparison of post-operative pain and residual paraesthesia. *Eur J Cardiothoracic Surg* 2005;28:43–6
- White WM, Haber GP, Goel RK, *et al.* Single-port urological surgery: single-center experience with the first 100 cases. *Urology* 2009;74:801–4
- Vidal O, Valentini M, Espert JJ, *et al.* Laparoendoscopic single-site cholecystectomy: a safe and reproducible alternative. *J Laparoendosc Adv Surg Tech A* 2009;19:599–602
- Vidal O, Valentini M, Ginestà C, *et al.* Laparoendoscopic single-site surgery appendectomy. *Surg Endosc* 2010;24:686–91



Covidien training pathway: Learning and refining the single-incision laparoscopic technique

As a global leader in surgical devices and education, Covidien offers comprehensive partnership support for surgeons and hospitals looking to establish or develop the single-incision laparoscopic technique. As part of this support, Covidien offers a complete training pathway for surgeons at all stages of adoption of the single-incision laparoscopic technique, from learning the basics through to refining skills at expert level. Covidien training programmes provide valuable, comprehensive support, resources and hands-on experience for surgeons, helping to shorten the learning curve, establish the technique in hospitals and support quicker uptake of single-incision laparoscopic procedures. For more information, please contact your local Covidien representative.



Preliminary support

- Questionnaires
- Pre-course materials
 - Clinical publications
 - Podcasts
- Step-by-step guides
- Procedural DVDs
- Simulators



Masterclass programme

- Hands-on workshops (using simulators)
- Business case for single-incision laparoscopic procedures
- Ethical guidelines
- Web resources
- Expert support networks for trainees



Clinical immersion

- Trainee visits expert surgeon at experienced centre
- Exposure to numerous single-incision laparoscopic procedures
- Participation/observation in procedures
- In-depth practical guidance and support



Mentorship

- Experienced surgeon visits trainee at own centre
- In-depth practical guidance and support
- Access to patient education courses
 - Patient literature
 - Patient charts

Covidien's SILS™ product portfolio

To complement its approach of comprehensive partnership with surgeons and hospitals, Covidien offers a wide range of devices and instrumentation to support the single-incision laparoscopic technique. In 2009 the US Patent Board ranked Covidien as the number-one innovator within the medical devices and services industry, above 121 other companies. Rank is awarded not just for the number of patents granted, but also for the strength of the science and healthcare industry impact.

SILS™ Port

The first port indicated for single-incision laparoscopic surgery, this flexible soft-foam port conforms to the body and can accommodate up to three instruments through a single incision, offering surgeons an immediate advancement in patient care. Launched in early 2009, the Covidien SILS™ Port has already been nominated by the UK National Health Service as one of the 'Top 10 innovations of 2009'^a, confirming Covidien's role as a leader in surgical innovation.

^aNHS Supply Chain. NHS Supply Chain leads the way for innovation [press release]. 9 November 2009. http://www.supplychain.nhs.uk/portal/pls/portal/!PORTAL.wwwpob_page.show?_docname=5350629.PDF. Accessed 8 March 2010



SILS™ Stitch

The only automated articulating suturing device with up to 75° articulation and 360° tip rotation. Covidien's SILS™ Stitch makes suturing easier at challenging angles, giving surgeons maximal control, greater precision and unparalleled access in single-incision surgery.



SILS™ hand instruments

An exciting advancement in endoscopic tissue manipulation, Covidien's new SILS™ Clinch, Dissect, Hook and Shears instruments are designed to enhance flexibility and visualisation in single-incision surgery, offering improved precision and manoeuvrability in a tight operating space.

(Available in May 2010)



Roticulator™ articulating instruments

Roticulator™ Endo Dissect™, Endo Grasp™ and Endo Mini-Shears™ 5 mm instruments offer unmatched versatility and flexibility for use in both single-incision procedures and conventional laparoscopic procedures, enabling freedom of movement and ease of use.

This document contains information about the single-incision laparoscopic technique and its potential benefits. Neither the information presented nor the benefits described can be related to the Covidien SILS™ Port. Clinical studies are underway to establish if the benefits of the single-incision laparoscopic technique can be expected from the SILS™ Port. This document was produced by Alphamaxim Healthcare Communications. The content does not necessarily represent the views of Alphamaxim Healthcare Communications.

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