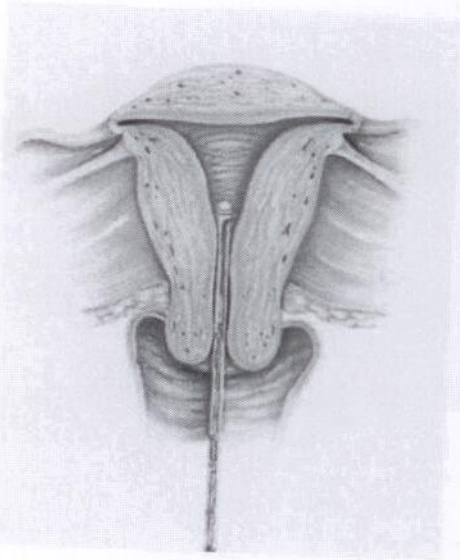
Pipelle®

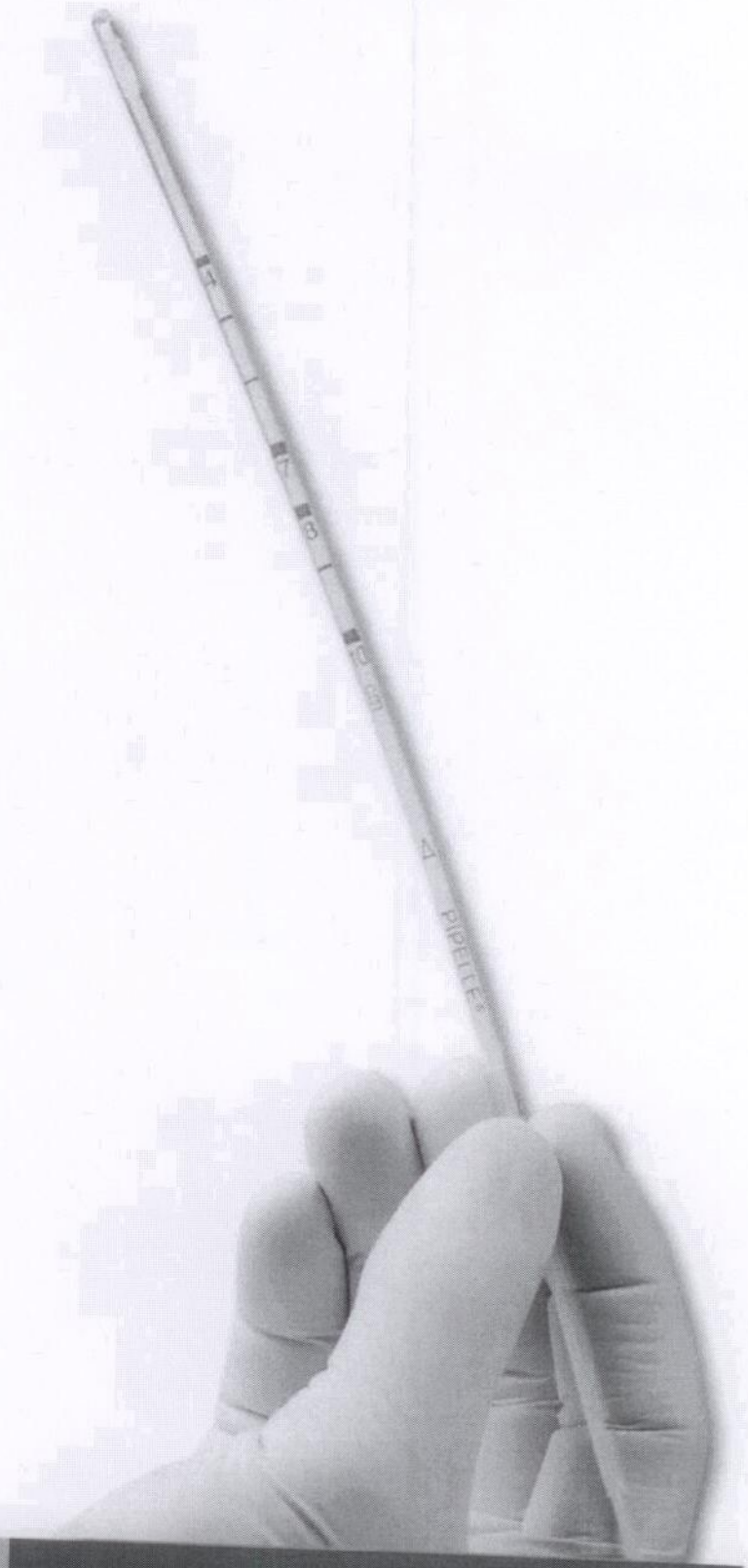
141 PIRKIMO DALIS

The most widely recognized name in endometrial sampling

Features and Benefits

- Consistently reliable
- Excellent patient acceptance
- Extraordinarily safe
- Rapid, simple technique
- Clinically-documented effectiveness
- Maximum sample yield
- Made in the U.S.A.





CooperSurgical

Pipelle®

Rapid, simple technique with proven clinical performance

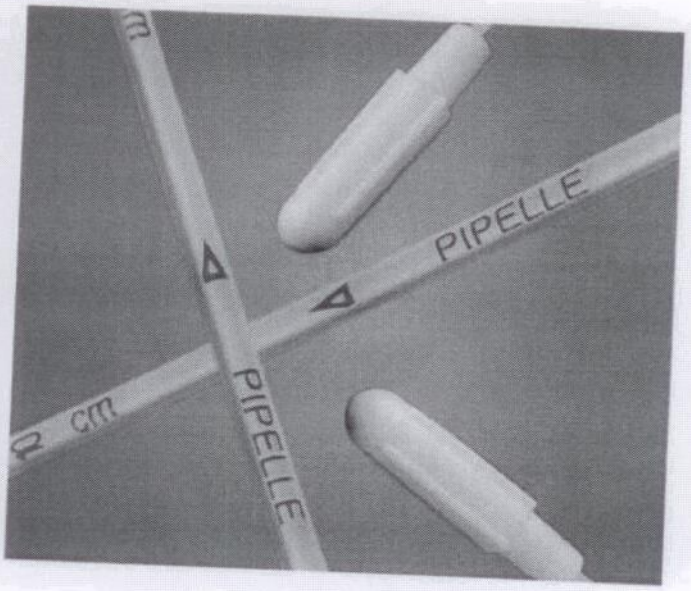
- 3.1mm O.D. and flexibility allows for ease of insertion into most uteri
- Internal piston creates a vacuum for sample collection without any sharp or painful edges
- Procedure comfortably performed in as little as 30 seconds following basic patient preparation
- Completely self-contained with no noisy pump or clumsy syringes

Safe, Simple Sample Collection

Once within the uterine cavity, a vacuum is established within the Pipelle by manually retracting its internal piston. Sample collection is easily achieved by simply rotating the device constantly between your fingers as you slowly pass the Pipelle several times between the fundus and the internal os. The Pipelle provides unparalleled patient acceptance while achieving optimum uterine wall contact and maximum tissue yield.

Pipelle® is the "Gold Standard" in Endometrial Sampling. Utilizing a Simple Technique with Proven Clinical Performance and Reliability.

Created by a gynecologist for the gynecologist. Pipelle's insightful design and exacting manufacture provide you with safe, simple, effective and cost-efficient performance that can be relied upon time, after time, after time.



Pipelle Ordering Information

Product Number: 8200

Packaging: Sterile, individually-packaged units of 25

CooperSurgical

CooperSurgical is the leading company dedicated to providing medical devices and procedure solutions that improve health care delivery to women regardless of clinical setting. Our company is fostering that position through expansion of its core businesses and introduction of advanced technology-based products which aid clinicians in the management and treatment of commonly seen conditions.

203.601.5200 | 800.243.2974 | coopersurgical.com | 95 Corporate Dr. | Trumbull, CT 06611
also at www.YouTube.com/CooperSurgical

Form #80993 Rev 01/12

8200 • Pipelle® Endometrial Suction Curette

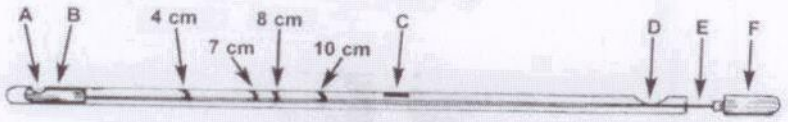
Directions for Use (English)

CE 0086

DESCRIPTION

The Pipelle® is a single-use, sterile, disposable, suction curette for obtaining a histologic biopsy of the uterine mucosal lining or sample extraction of uterine menstrual content for microscopic examination or culturing.

The device consists of a clear, flexible, polypropylene sheath that is 26.5 cm (overall) 23.5 cm (effective) length with a 3.1 mm OD (Outside Diameter) and a 2.6 mm ID (Internal Diameter). The sheath is marked with colored, graduated markings from 4 cm to 10 cm, distance from the distal tip of the sheath to indicate the depth of insertion of the sheath into the uterus during use (see diagram below).



The 4, 7, 8, and 10 cm point depth markings on the sheath are accentuated and numbered. At 4 mm from the distal tip of the sheath is the center of the curette opening (A) which is 1.93 mm in diameter. This opening has sharp edges and leads to the lumen of the sheath. An EVA piston (B) affixed to the distal end of a soft acetal resin rod (E) can be moved forward and backward within almost the full length of the lumen of sheath. This is accomplished by manipulation of the knob (F) affixed to the proximal end of the piston rod which extends beyond the proximal end of the sheath. The piston is prevented from being totally pulled from within the sheath by means of an indentation (D) in the sheath located 1 cm from its proximal end. An orientation mark (C) indicates the position of the curette opening.

Rapid movement of the piston within the sheath from its fully inserted position to its maximum retracted position creates a negative pressure (suction) within the lumen of the sheath. This negative pressure draws the mucosal tissue through the curette opening and into the lumen of the sheath as the curette scrapes against the endometrial wall while it is maneuvered within the uterine cavity.

WARNINGS

In patients with amenorrhea, obtaining an endometrial biopsy with the Pipelle should be performed only after confirmation of the absence of detectable circulating HCG levels.

CAUTION

U.S. Federal law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE

Histologic biopsy of the epithelium and glandular mucosal layer (endometrium) of the uterine wall or sample extraction of uterine menstrual content for:

- Detection of endometrial carcinoma and precancerous conditions

Certificate

Production Quality Assurance

No. CE 69386

Issued to:

CooperSurgical Inc.,
also trading as Ackrad Laboratories
Prism Healthcare, Milex, Medscand,
Wallach Surgical Devices,
SAGE In-Vitro Fertilization and
Lone Star Medical Products
95 Corporate Drive, Trumbull, Connecticut
06611
USA

In respect of:

The manufacture of devices as detailed in the Supplementary Information

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex V, Section 3.2.
For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First Issued: **30 Aug 2002**
Expiration Date: **28 Aug 2017**

Date: **9 Aug 2012**

Conditions of Approval
Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate unless specifically agreed with BSI.

raising standards worldwide™

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: +44 (0)845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A member of the BSI Group of Companies.

Certificate

Supplementary Information to CE 69386

Issued to:
CooperSurgical Inc., also trading as Ackrad Laboratories
Prism Healthcare, Milex, Medscand, Wallach Surgical Devices,
SAGE In-Vitro Fertilization and Lone Star Medical Products
Trumbull, Connecticut
USA

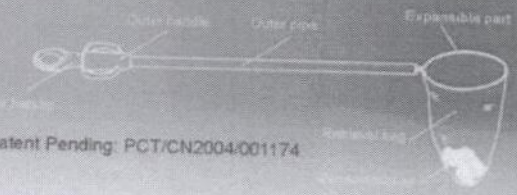
Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of
Curettes
Cytology Sampling Devices
Embryo Transfer Catheters
Endometrial suction curettes
Fiberoptic Catheters
INCA Nasal Cannulae Set with sterile nasal prongs
Intrauterine Insemination Catheters
Laparoscopic Smoke Evacuation Systems
Retractors

First Issued: 30 Aug 2002
Expiration Date: 28 Aug 2017

Date: 9 Aug 2012

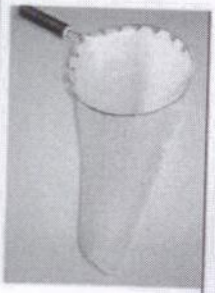
PIRKIMO DALIS 175

G T.K Medical

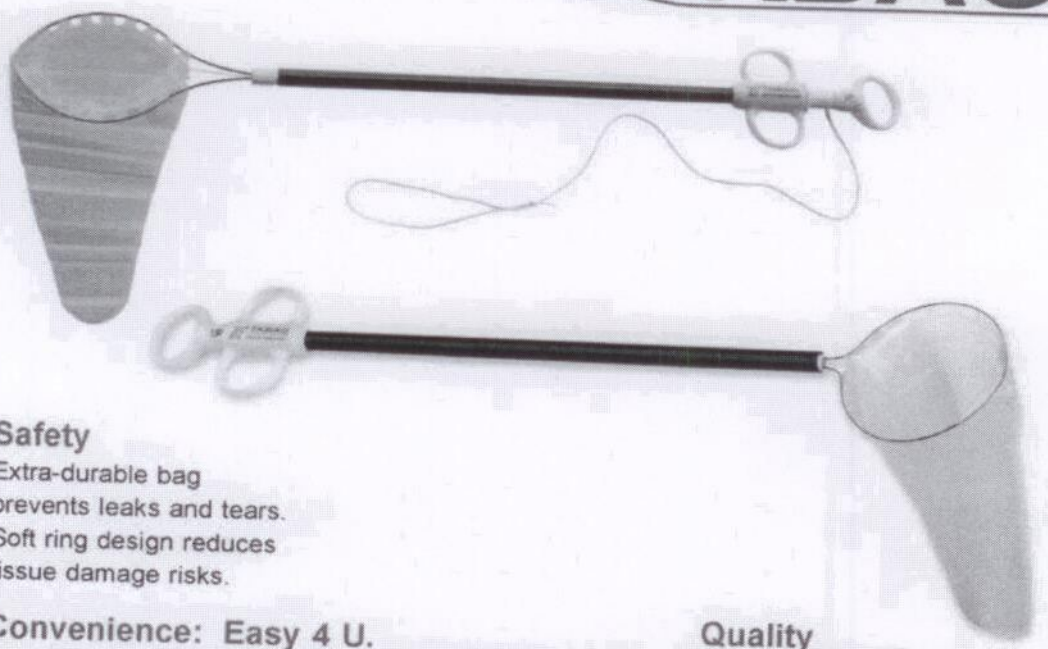


Patent Pending: PCT/CN2004/001174

TKBAG®



SPECIMEN RETRIEVAL BAG



Safety

Extra-durable bag
prevents leaks and tears.
Soft ring design reduces
tissue damage risks.

Convenience: Easy 4 U.

Easy in, easy out, easy open, easy close; Saves time!
Multiple sizes including extra-large

Pouch with string is optional

Quality

Strict, extensive raw material selection and 31 quality inspection steps on every TKBAG.

The TKBAG/ Retriever Bag is used in all types of laparoscopic surgery for removing excised tissues/specimen through a small surgical incision. It can be introduced through 10mm or lager size trocar canula.
It comes in a variety of sizes,(as shown in the table below) and is suitable for a wide range of procedures including, Gallbladders, Appendices, Ectopic pregnancies, Lymph nodes, Ovaries, Lung wedges, Sections of bowel, Splenectomies, Nephrectomies and more.

Product Code	Bag Diam (mm)	Bag length (mm)	Volume (ml)	Qty/Box
HSD-60	60	120	75	10
HSD-80	80	175	200	10
HSD-80/C	80	175	200	10
HSD-100	100	170	350	10
HSD-130	130	175	700	10

TÜVRheinland

CE 0197
ISO9001
ISO13485

PIRKIMO DALIS 175

Add: A601 Guangzhou International Business Incubator, Guangzhou Science Park, Guangzhou, P.R. of China. Mobile: +86 139 0225 9487
Tel: +86 20 3761 9648/32290169 Fax: +86 20 3761 6020/32290395 Http: //www.tk-medical.com E-mail: sales@tk-medical.com

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

TÜVRheinland®

Registration No.: HD 60077298 0001

Report No.: 17025753 001

Manufacturer:
Guangzhou T.K Medical
Instrument Co., Ltd.
A601, Guangzhou International
Business Incubator
Guangzhou Science Park
510663 Guangzhou, Guangdong
China

Products:
- Retriever Bags
- Trocar Kits
- Trocars
- Veress Needles
- Wound Protectors/Retractors

Replaces Approval, Registration No.: DD 60032403 0001

Expiry Date: 2017-08-09

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2012-08-10

Date: 2012-08-10

Notified Body

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Obstetrical Products

180 PIRKIMO DALIS

Mityvac® and Mystic® II

Softer, safer vacuum assisted delivery systems

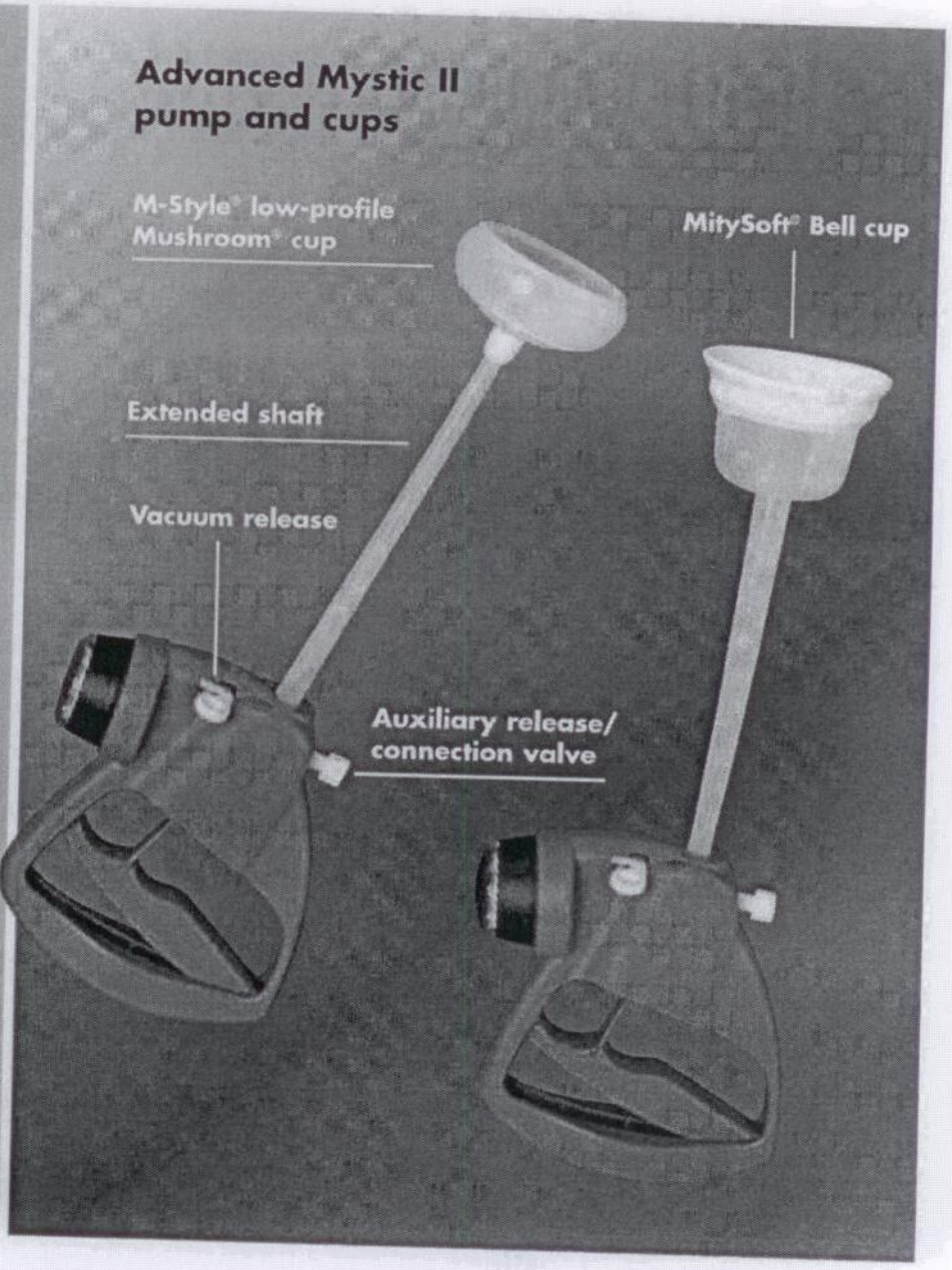
Enhancing a winner—the Mityvac line of vacuum assisted delivery systems

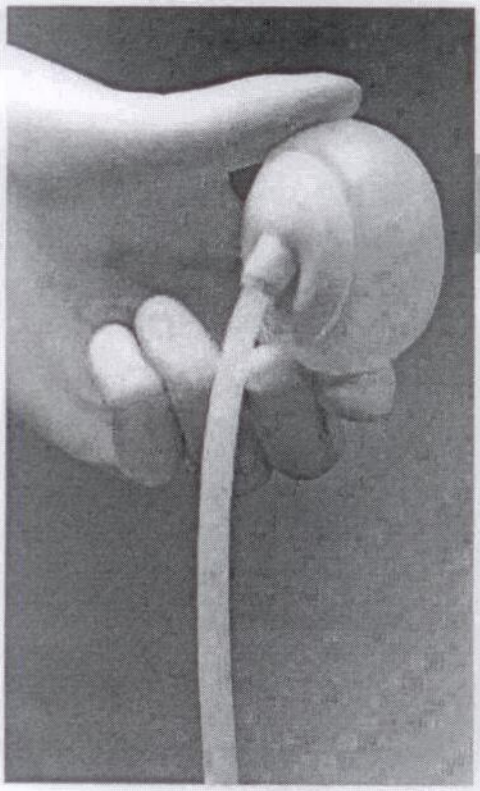
Features

- **Gentle**
  MitySoft Bell cup protects vaginal wall and cradles baby's head
- **Low Profile**
  Flexible Mystic M-Style Mushroom® cup flexes up to 90° in any direction to facilitate use in non occiput anterior positions
- **Ease of Use**
  Prominent trigger release disengages vacuum
- **Safety**
  Handle rotates without transferring to the cup
- **Self Limiting**
  Mystic II's is specially designed vacuum will not exceed 5 cmHg (580 mm Hg)

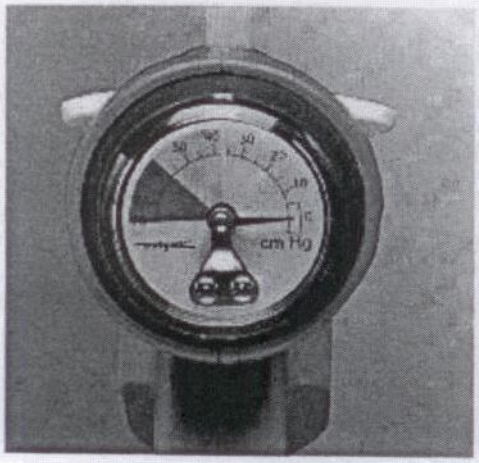
CooperSurgical

Keeping You at the Forefront of Women's Health Care™





New low-profile M-Style cup



Easy-to-read color-coded gauge

Quality features that set Mystic II apart

Gentle and effective

- Semi-rigid mushroom-style cup with new low-profile stem provides smoother insertion for non-OA presentations.
- Safe, atraumatic design of the Mystic MitySoft® Bell cup design ensures mom's comfort and baby's safety.
- Natural grip provides reliable and comfortable performance for the clinician.

Easy to use

- Unparalleled pump action creates vacuum with minimal effort.
- Easy-to-read color-coded vacuum gauge.
- Mini-grip handle contoured for smaller hands and grip spans for better control with traction.

Superior control

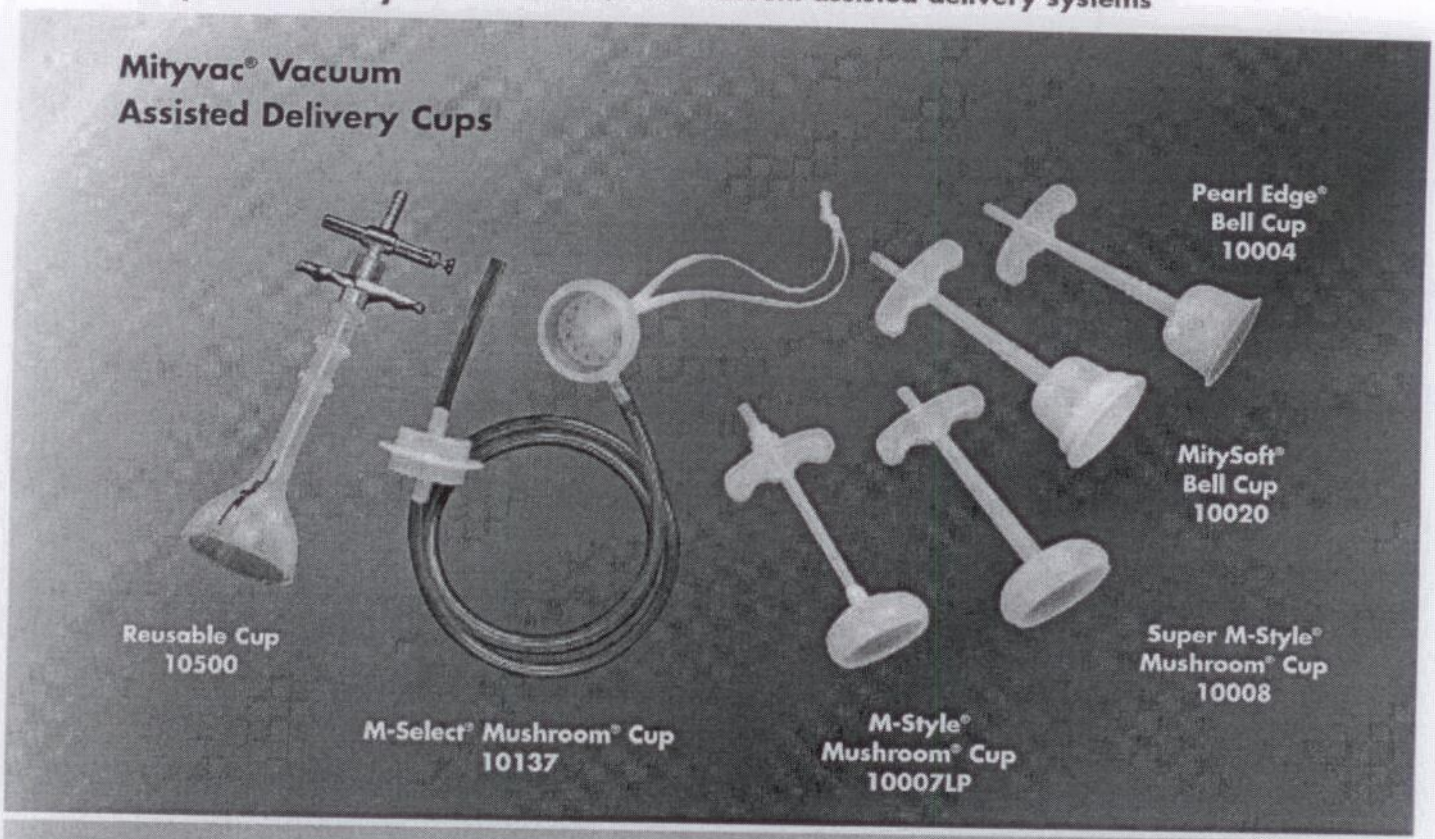
- Easy-to-reach vacuum release valve improves clinician control.
- Ergonomic design allows intuitive handling.
- Freely rotating cup minimizes torsion-related injuries.

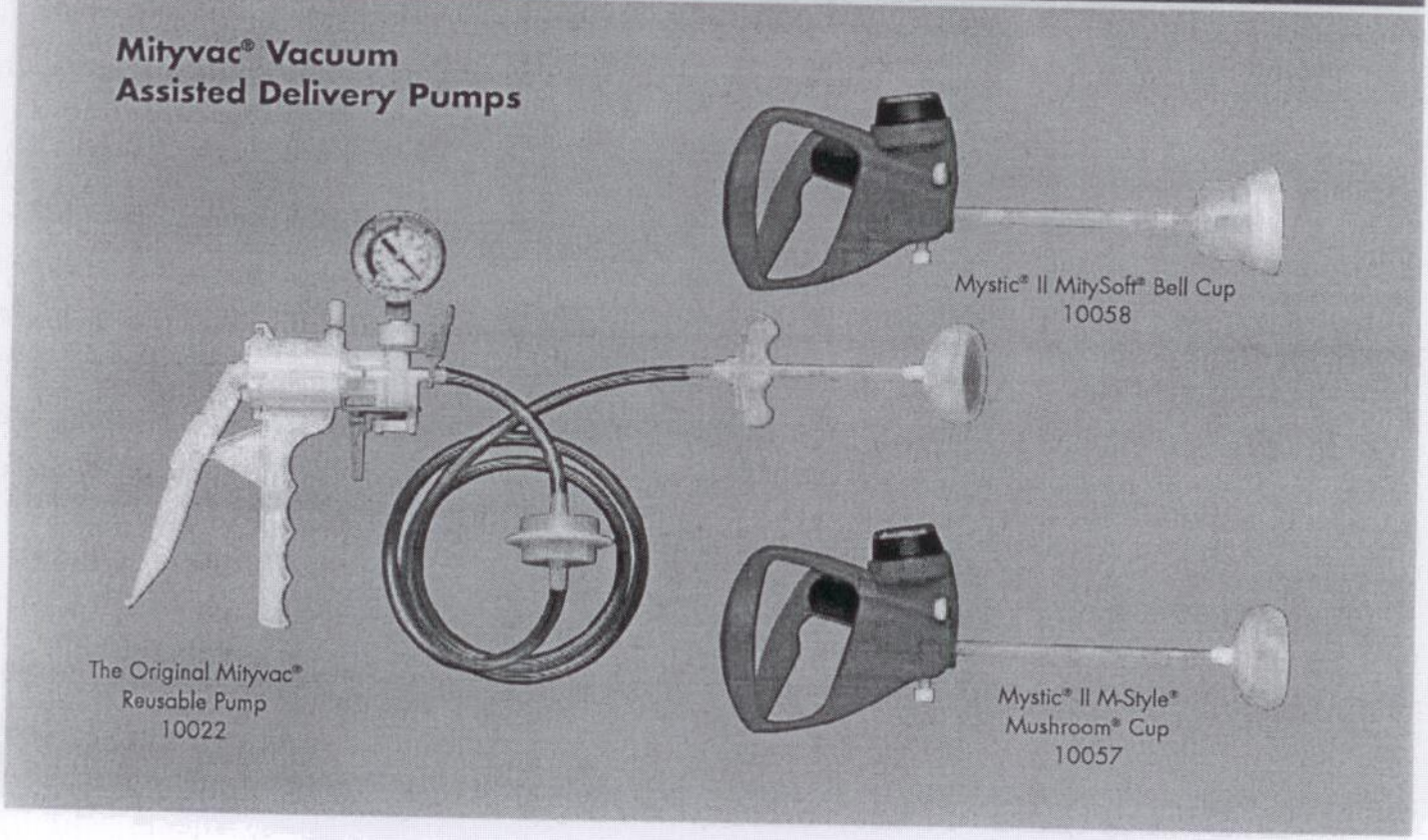
Versatile

- Extended stem and low-profile cup make Mystic II appropriate for both cesarean and vaginal deliveries.
- Available in the most popular cup styles (MitySoft Bell or M-Style Mushroom).
- Offered as a self-contained unit with hand pump, or with separate accessory compressor pump.

Mityvac® and Mystic® II

Softer, safer vacuum assisted delivery systems





ORDERING INFORMATION

Product #	Description of Cups and Accessories	Diameter	Order Quantity
10004	Pearl Edge® Bell Cup with 4" tubing and filter	60 mm	12 per box
10007LP	M-Style® Mushroom® Cup with 4" tubing and filter	50 mm	12 per box
10008	Super M-Style® Mushroom® Cup with 4" tubing and filter	56 mm	12 per box
10020	MitySoft® Bell Cup with 4" tubing and filter	64 mm	12 per box
10137	M-Select® Mushroom® Cup with 4" tubing and filter	50 mm	12 per box
10500	Reusable Vacuum Delivery Cup	70 mm	1 per box
Pumps			
10022	Mityvac® Reusable Pump	N/A	1 per box
10057	Mystic® II Pump with M-Style® Mushroom® Cup	50 mm	12 per box
10058	Mystic® II Pump with MitySoft® Bell Cup	64 mm	12 per box
Accessories			
16177	Mityvac® Reusable Pump Replacement Gauge	N/A	1 per box
16710	Mityvac® Reusable Pump Maintenance Kit	N/A	1 per box

CooperSurgical

www.coopersurgical.com

Mityvac® and Mystic® II

95 Corporate Drive, Trumbull, CT 06611
800.243.2974 • 203.601.5200

To find out more about the Mityvac® and Mystic® II, or to place an order call 800.243.2974.

Form # 81158 02/08

Certificate

Production Quality Assurance

No. CE 69386

Issued to:

CooperSurgical Inc.,
also trading as Ackrad Laboratories
Prism Healthcare, Milex, Medscand,
Wallach Surgical Devices,
SAGE In-Vitro Fertilization and
Lone Star Medical Products
95 Corporate Drive, Trumbull, Connecticut
06611
USA

In respect of:

The manufacture of devices as detailed in the Supplementary Information

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex V, Section 3.2.
For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First Issued: 30 Aug 2002 Date: 9 Aug 2012
Expiration Date: 28 Aug 2017

Conditions of Approval
Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate unless specifically agreed with BSI.

raising standards worldwide™

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: +44 (0)845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL UK. A member of the BSI Group of Companies.

Certificate

Supplementary Information to CE 69386

Issued to:
CooperSurgical Inc., also trading as Ackrad Laboratories
Prism Healthcare, Milex, Medscand, Wallach Surgical Devices,
SAGE In-Vitro Fertilization and Lone Star Medical Products
Trumbull, Connecticut
USA

The manufacturer of
CT CloseSure Systems and CT CloseSure XL
Fetal and Vascular Dopplers
Gelpacks for heat therapy
Ophthalmic, Gynaecology and Dermatology Cryosurgery Systems
Sterile Bronchitrac Suction Catheters
Sterile Colpotomizer Systems
Sterile Disposable Uterine Manipulator-Injectors
Sterile Esophageal Balloon Catheters
Sterile Elliptosphere Catheters
Sterile *H/S* Catheters sets with Kraton Balloons
Sterile Retractors
Sterile Surgery Kits, Retractor Kits, Stays and Dilamezinsert
Sterile Tampa Catheters
Sterile Trocars, Cannulas and Trocar/Cannula Kits
Sterile Vacuum Assisted Delivery Extractor Cups, Delivery Pumps and Delivery Kits
Vaginal Pessaries

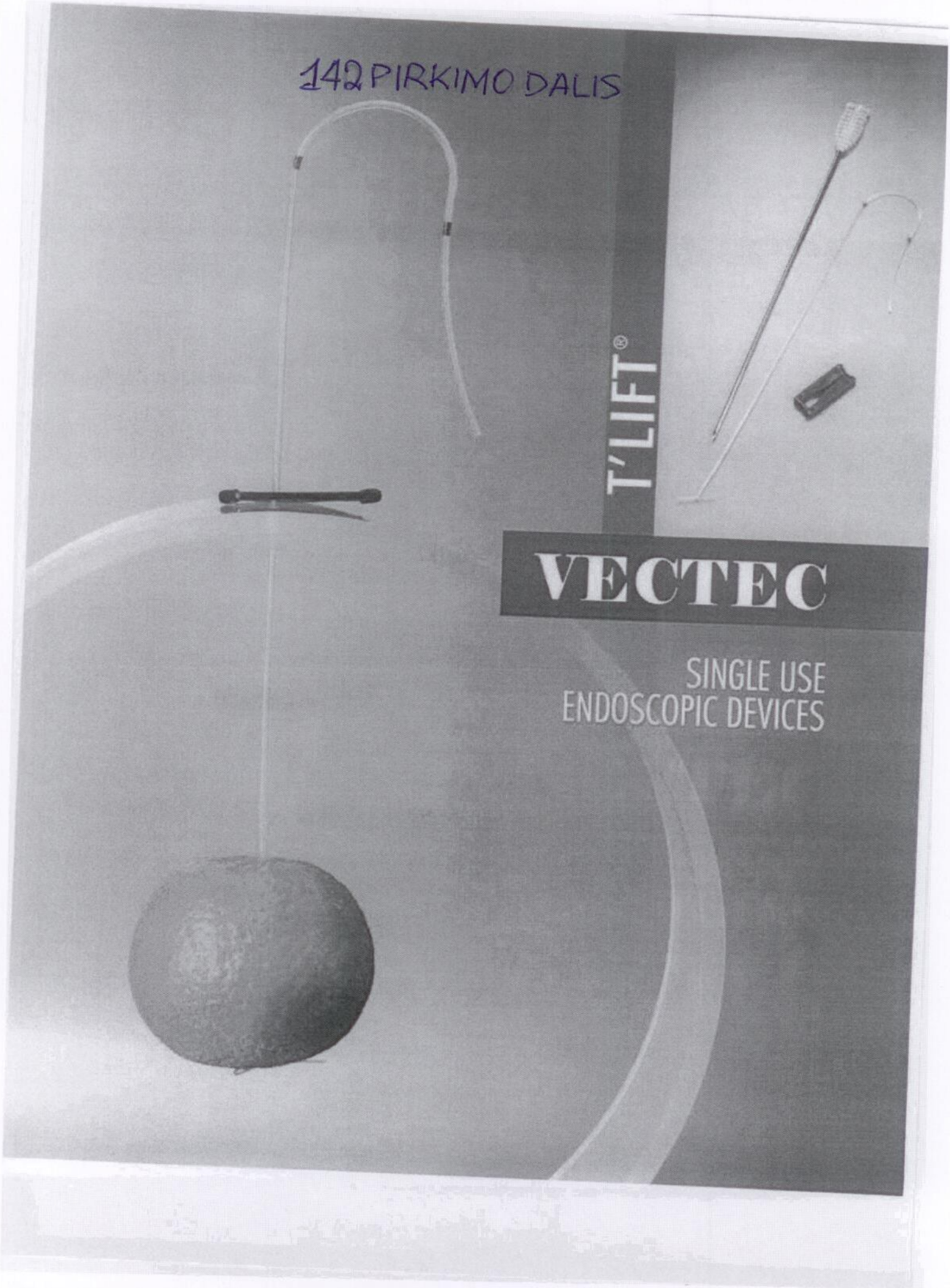
First Issued: **30 Aug 2002**
Expiration Date: **28 Aug 2017**

Date: **9 Aug 2012**

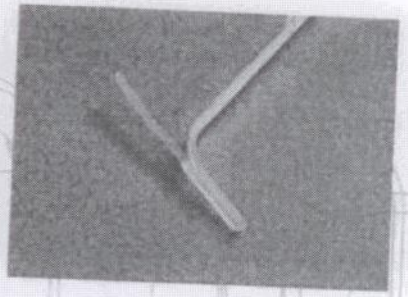
raising standards worldwide™

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: +44 (0)845 080 9000

142 PIRKIMO DALIS



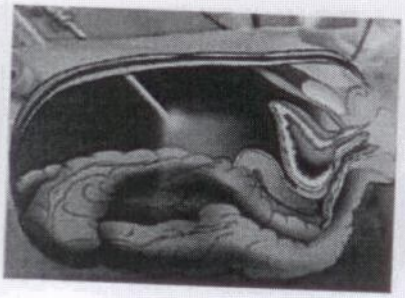
VECTEC

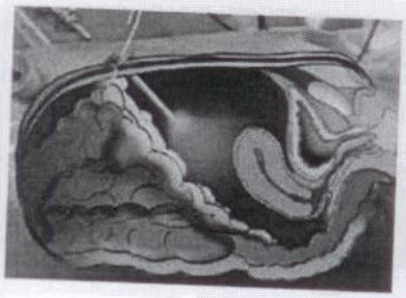


T'LIFT®

TISSUE RETRACTION SYSTEM :

- Provide operating space
- Hold and expose the organs





Reference	Commercial name	Packaging includes	Nb of units per box
AW16 280	T'LIFT®	- 2 T'LIFT® - 1 introducer - 2 locking clips	25 & 12

Patent application : PCT/IB2010/002759

ADVANTAGES

- Stable and effective retraction
- Easy to use
- Percutaneous introduction: no incision, no trocar needed
- Reduced degree of Trendelenburg
- Quick and simple variation of retraction height during surgery

MD Class IIa

Made in France

UNION EUROPÉENNE en AUVERGNE

VECTEC
Bioparc - Vichy - Hauterive
03270 Hauterive
FRANCE
Phone : +33 (0)4 70 58 41 70
Fax : +33 (0)4 70 58 41 79
Email : vectec@vectec.fr
www.vectec.fr

APPROVAL

EC Directive 93/42/EEC Annex II, Article 3
Full Quality Assurance System
Medical Devices

TÜVRheinland®

Registration No.: HD 60041616 0001

Report No.: 28411625 001

Manufacturer:
Vectec S.A.
Bioparc
03270 Hauterive
France

Scope:
Design/development and manufacturing of disposable surgical endoscopic instruments

(see attachments for products included)

Date of Expiry: 18.11.2016

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date 11.01.2012

Dipl.-Ing. D. Meier

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. 0197 to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

Attachment to
Registration No.: HD 60041616 0001
Report No.: 28411625 001

Manufacturer:
Vectec S.A.
Bioparc
03270 Hauterive
France

Scope:

Products included:

scissors, forceps, hooks, pneumoperitoneum needles, trocars, retractors for surgical and electrosurgical applications for digestive, gynaecological and urological surgeries.

For following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- oocyte puncture cannula guide
- electrical connection cable

Certification Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Dipl.-Ing. D. Meier

Date 11.01.2012

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