# WECK HEM-O-LOK LIGATION SYSTEM

## Safety without compromise

## THE CLIP BANK

### EASY LOADING WITH CONVENIENT ADHESIVE STRIP

- Our Hem-o-lok ligation system combines speed and safety in one single procedure.
- Choose from a variety of ligating clip sizes for the ligation of vessels and/or tissues between 2 and 16 mm.
- The Hem-o-lok clip bank allows for effortless and precise loading, thus making surgical interventions more efficient.
- Closure of the clip is confirmed by tactile and audible feedback.
- The colour code of the clip bank corresponds to that of the applier.
- Each cartridge contains 6 clips.
- A special adhesive strip at the bottom of each cartridge enables you to choose the best possible site for clip delivery.
- Unlike absorbable clips, Hem-o-lok ligating clips can be removed with our specially developed removers if necessary.
- The clips are inert, non-toxic and radiolucent.
- The cartridges adhere to any sterile surface.

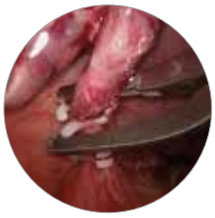
## THE APPLIERS

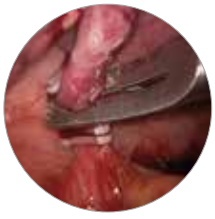
### PERFORMANCE FEATURES AND CLEANING OPTIONS

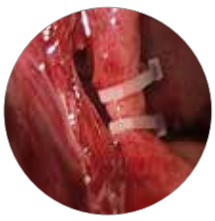
- Thanks to the special clip design, closure of the clip can be clearly felt by the surgeon during application.
- Both curved and angled appliers are available for open surgery.
- Endoscopic Hem-o-lok appliers are available in sizes ML, L, and XL. They can be taken apart for easy cleaning, thus eliminating potential contamination.
- A 360° rotation knob facilitates access and improves visibility.
- The appliers are colour-coded to match the colours of the corresponding cartridges.

# THE HEM-O-LOK LIGATION SYSTEM – PRECISION IN EVERY DETAIL

Teleflex is a leading manufacturer of metal and polymer clips. Our Weck Hem-o-lok ligation system forms a line of instruments perfectly adapted to each other, meeting all the special needs of surgeons, nurses and operating theatre personnel alike.







## THE CLIP

### TOP-CLASS FUNCTIONALITY

| CLIP SIZE | LIGATION OF VESSELS AND TISSUES |
|---|---|
| medium | 2 – 7 mm |
| medium-large | 3 – 10 mm |
| large | 5 – 13 mm |
| extra-large | 7 – 16 mm |

- Precision bosses engineered for maximum security.
- Penetrating lock: 1 x 2 teeth to provide effective closure.
- Bowed design enables added tissue to be encompassed.
- Tactile and audible response confirms that the Hem-o-lok ligating clip has locked onto vessel.
- Integrated teeth help prevent slippage in any direction.
- The surface properties of the non-absorbable polymer prevent infection.
- Living hinge provides flexibility when opening and closing.

## LIGATING CLIPS

### HEM-O-LOK LIGATING CLIPS

WECK

| REF. | CLIP SIZE | LIGATION OF VESSELS AND TISSUE | CLIPS/CARTRIDGE | CARTRIDGES/BOX | CLIPS/BOX |
|---|---|---|---|---|---|
| WK544220 | ● M | 2 – 7 mm | 6 | 14 | 84 |
| WK544230 | ● ML | 3 – 10 mm | 6 | 14 | 84 |
| WK544240 | ● L | 5 – 13 mm | 6 | 14 | 84 |
| WK544250 | ● XL | 7 – 16 mm | 6 | 14 | 84 |

## OPEN SURGERY

### APPLIERS

WECK

| REF. | CLIP SIZE | WORKING LENGTH | QTY |
|---|---|---|---|
| curved | | | |
| WK544113 | ● M | 20 cm | 1 |
| WK544170 | ● ML | 20 cm | 1 |
| WK544180 | ● L | 20 cm | 1 |

### APPLIERS, LONG

WECK

| REF. | CLIP SIZE | WORKING LENGTH | QTY |
|---|---|---|---|
| curved | | | |
| WK544115 | ● M | 27 cm | 1 |
| WK544171 | ● ML | 27 cm | 1 |
| WK544181 | ● L | 27 cm | 1 |
| WK544191 | ● XL | 27 cm | 1 |

### APPLIERS, LONG, 70° ANGLED

WECK

| REF. | CLIP SIZE | WORKING LENGTH | QTY |
|---|---|---|---|
| WK544114 | ● M | 27 cm | 1 |
| WK544172 | ● ML | 27 cm | 1 |
| WK544179 | ● L | 27 cm | 1 |
| WK544192 | ● XL | 27 cm | 1 |

### CLIP REMOVERS

WECK

| REF. | CLIP SIZE | WORKING LENGTH | QTY |
|---|---|---|---|
| WK544123 | ● M<br>● ML<br>● L | 27 cm | 1 |
| WK544124 | ● L<br>● XL | 27 cm | 1 |

*All Hem-o-lok ligating clips are sterile packaged. Ligating clip systems differ in their clip-closure characteristics.*
*It is the responsibility of the user to confirm security of clips on vessels or other tissue.*
*Not intended for contraceptive tubal occlusion.*

● M medium ● ML medium-large ● L large ● XL extra-large

## HEM-O-LOK TAKE-APART APPLIERS

WECK

| REF. | CLIP SIZE | Ø APPLIER | Ø TROCAR | WORKING LENGTH | QTY |
|---|---|---|---|---|---|
| straight | | | | | |
| WK544965T | ML | 5 mm | 5 mm | 33 cm | 1 |
| curved | | | | | |
| WK544995T | L | 10 mm | 10 mm | 33 cm | 1 |
| WK544990T | XL | 10 mm | 10 or 12 mm | 33 cm | 1 |

## HEM-O-LOK TAKE-APART APPLIERS, 20° ANGLED

WECK

| REF. | CLIP SIZE | Ø APPLIER | Ø TROCAR | Ø SILS | WORKING LENGTH | QTY |
|---|---|---|---|---|---|---|
| WK544965T20 | ML | 5 mm | 10 mm | 5 mm | 33 cm | 1 |
| WK544995T20 | L | 10 mm | 12 mm | 10 mm | 33 cm | 1 |
| WK544990T20 | XL | 10 mm | 15 mm | 12 mm | 33 cm | 1 |

## HEM-O-LOK NON-TAKE-APART APPLIER, LONG

WECK

| REF. | CLIP SIZE | Ø APPLIER | Ø TROCAR | WORKING LENGTH | QTY |
|---|---|---|---|---|---|
| straight | | | | | |
| WK544965L | ML | 5 mm | 5 mm | 45 cm | 1 |
| curved | | | | | |
| WK544995L | L | 10 mm | 10 mm | 45 cm | 1 |
| WK544990L | XL | 10 mm | 10 or 12 mm | 45 cm | 1 |

## HEM-O-LOK AUTO ENDO 5 APPLIERS

WECK

| REF. | CLIP SIZE | Ø APPLIER | Ø TROCAR | WORKING LENGTH | QTY |
|---|---|---|---|---|---|
| straight | | | | | |
| WK543965 | ML | 5 mm | 5 mm | 33 cm | 3 |

## CLIP REMOVERS

WECK

| REF. | CLIP SIZE | Ø REMOVER | Ø TROCAR | Ø SILS | WORKING LENGTH | QTY |
|---|---|---|---|---|---|---|
| straight | | | | | | |
| WK544121T | ML | 5 mm | 5 mm | – | 33 cm | 1 |
| WK544121L | ML | 5 mm | 5 mm | – | 45 cm | 1 |
| curved | | | | | | |
| WK544130T | L/XL | 10 mm | 10 or 12 mm | – | 33 cm | 1 |
| WK544130L | L/XL | 10 mm | 10 or 12 mm | – | 45 cm | 1 |
| 20° angled | | | | | | |
| WK544130T20 | L/XL | 10 mm | 12 or 15 mm | 12 mm | 33 cm | 1 |

## ENDOSCOPIC TAKE-APART APPLIER

Our take-apart endoscopic appliers can be detached for easy cleaning. The 360° knob facilitates access and improves visibility.

Teleflex is a leading global provider of specialty medical devices used for diagnostic and therapeutic procedures in critical care, urology and surgery. Our mission is to provide solutions that enable healthcare providers to improve outcomes and enhance patient and provider safety.
We specialise in devices for general and regional anaesthesia, cardiac care, respiratory care, urology, vascular access and surgery and we serve healthcare providers in more than 140 countries. Teleflex also provides specialty products for medical device manufacturers.



Teleflex global operations: Australia, Austria, Belgium, Canada, China, Czech Republic, France, Germany, Greece, India, Ireland, Italy, Japan, Malaysia, Mexico, Netherlands, New Zealand, Portugal, Singapore, Slovak Republic, South Africa, Spain, Switzerland, United Kingdom, Uruguay and USA.

**YOUR INTERNATIONAL CONTACTS:**

**TELEFLEX HEADQUARTER INTERNATIONAL, IRELAND**
Teleflex Medical Europe Ltd., IDA Business and Technology Park,
Dublin Road, Athlone, Co Westmeath
Phone +353 (0)9 06 46 08 00 · Fax +353 (0)14 37 07 73
orders.intl@teleflex.com

**AUSTRALIA/NEW ZEALAND** +61 (0)3 84 12 03 21
**AUSTRIA** +43 (0)1 402 47 72
**BELGIUM** +32 (0)2 333 24 60
**CHINA (SHANGHAI)** +86 (0)21 6381 6399
**CHINA (BEIJING)** +86 (0)10 6418 5699
**CZECH REPUBLIC** +420 (0)495 759 111
**FRANCE** +33 (0)5 62 18 79 40
**GERMANY** +49 (0)7151 406 0
**GREECE** +30 210 67 77 717
**INDIA** +91 (0)44-2836 5040
**ITALY** +39 0362 58 911
**JAPAN** +81 (0)3 3379 1511
**NETHERLANDS** +31 (0)88 00 215 00
**PORTUGAL** +351 22 541 90 85
**SINGAPORE** +65 6447 5022
**SLOVAK REPUBLIC** +421 (0)3377 254 28
**SOUTH AFRICA** +27 (0)11 807 4887
**SPAIN** +34 918 300 451
**SWITZERLAND** +41 (0)31 818 40 90
**UNITED KINGDOM** +44 (0)1494 53 27 61

For detailed information see www.teleflex.com

The products in this catalogue may not be available in all countries.
Please contact your local representative. All data current at time of printing (05/2013).
Subject to technical changes without further notice.

**94 05 70 - 00 00 01 · REV A · MC / WM · 05 13 02**

Teleflex

EC Certificate Full Quality Assurance System: Certificate US19/819943647.00

The management system of

# Teleflex Medical

3015 Carrington Mill Blvd.,
Morrisville, NC, 27560, United States

has been assessed and certified as meeting the requirements of

# Directive 93/42/EEC

**on medical devices, Annex II (excluding Section 4)**

For the following products

**The scope of registration appears on page 2 of this certificate.**

This certificate is valid from 24 February 2020 until 14 July 2023
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 26 September 2000
and first certified by SGS Belgium NV since 01 February 2020.

Multiple certificates have been issued for this scope.
The main certificate is numbered US19/819943647.00

This is a multi-site certification.
Additional site details are listed on subsequent pages

Certification is based on reports numbered WW/MC 06866

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

# Teleflex Medical

## Directive 93/42/EEC

**on medical devices, Annex II (excluding Section 4).**

Issue 2

Detailed scope

**Sterile Hem-o-lok and Vesolock Ligation Clips,
Sterile and non-sterile Hemoclip Traditional, Hemoclip Plus, Horizon and Vesocclude
Metal Ligation Clips Sterile Deknatel® PTFE pledgets.
Sterile Polyester Nonabsorbable Surgical Sutures (POLYLENE/ "cottony"™ II,
"silky" II POLYDEK®, TEVDEK® II, NextStitch®, Capio™, NiceLoop™, TEVDEK®).
Sterile DEKLENE® II, DEKLENE® MAXXTM, CAPIOTM
and polypropylene non-absorbable surgical sutures.
Sterile BONDEK® and BONDEK® Plus Polyglycolic Acid Synthetic Absorbable Surgical
Sutures. Sterile Polyglytone 6211™ Monofilament Absorbable Surgical Sutures.
Sterile MONODEK® Polydioxanone Absorbable Surgical Sutures.
Sterile Hem-o-lok Automatic Clip Appliers.
Metal Ligation System.**

**Sterile and Non-sterile External stapling system (including stainless steel staples,
staplers and removers), Sterile, EFx endo fascial closure system (abdominal access),
Sterile, EFx shield fascial closure system (abdominal access),
Sterile, EFx classic fascial closuresystem (abdominal access)
Sterile stainless steel surgical Sutures
Sterile FORCE FIBER® surgical sutures.
Sterile Chest drainage and autotransfusion systems, Sterile Thoracic Catheters,
Sterile and Non-sterile Aortic Punch,
Non-sterile Self Retaining Tissue retractor/blades**

# Teleflex Medical

## Directive 93/42/EEC

**on medical devices, Annex II (excluding Section 4).**

Issue 2

Detailed scope

**Non-sterile Anaesthesia and respiratory Circuits including breathing bags and water traps, Non-sterile Heated Humidifiers, Non-sterile Non-Prefilled Humidifiers and Nebulizers, Non-sterile Small Volume Nebulizers, Sterile Prefilled Humidifiers and Nebulizers (saline or water) with adaptors, Sterile Prefilled unit dose vial /solution for nebulisation, Non-sterile Respiratory therapy Adaptors and connectors, Sterile Column and Reservoirs including adaptors, Non-sterile Nasal cannula (including gas sampling), Non-sterile Cannula and Supply Tubing, Nonsterile CPAP Cannula System, Non-sterile Manual resuscitators and PEEP valves, Non- sterile Respiratory and anaesthesia masks, Non- sterile Gas scavenging mask, Sterile Endotracheal tubes, Sterile Endobronchial tubes, Non-sterile Suction and Aspirating Tubes, Sterile Vented Thoracic Chest Seal, Sterile Operative Cholangiogram Catheters, Sterile Abdominal Access and Insufflation devices, Sterile Capillary drains, Sterile Percutaneous Surgical System (MiniLap and Grip graspers), Sterile Percutaneous Surgical System (Mini Polar electrosurgical probe and MiniGrip Bipolar Graspers), Non-sterile Heat and Moisture Exchangers**

**Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.**

Additional facilities

**375 Forbes Blvd, Mansfield, MA, 02048-1805, United States**

**ARTICLE 120 SELF-DECLARATION**

EU MDD DECLARATION OF CONFORMITY GLOBAL ADDENDUM

FOR EXTENDED TRANSITION TO MDR

| | |
|---|---|
| **Legal Manufacturer (LM)** | Name:<br>Teleflex Medical Inc.<br><br>Address:<br>3015 Carrington Mill Blvd.<br>Morrisville, NC 27560 USA |
| **Authorized Representative** | Name:<br>Teleflex Medical<br><br>Address:<br>IDA Business and Technology Park<br>Dublin Road<br>Athlone<br>Co. Westmeath<br>Ireland |
| **Incoming Notified Body (MDR NB)** | Name:<br>BSI Netherlands<br><br>Identification Number:<br>CE 2797 |
| **Notified Body That Issued the Certificate Under MDD (MDD NB)** | Name:<br>SGS Belgium NV<br><br>Identification Number:<br>CE 1639 |

Teleflex Medical Inc. declares that the product(s) listed in Appendix A meet the provisions of Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 (MDR) as regards the transitional provisions for certain medical devices.

This declaration is made on the basis that the product(s) listed in Appendix A are currently compliant to:

☒ Council Directive 93/42/EEC dated 14 June 1993, as amended by 2007/47/EC (MDD), the provisions of Article 120(3c), and are intended to or have been confirmed to meet the provisions of Regulation (EU) 2017/745 (MDR)

☐ Council Directive 93/42/EEC dated 14 June 1993, as amended by 2007/47/EC (MDD), the provisions of Article 120(3c), Article 120(2) points (a) or (b) of MDR and are intended to meet the provisions of Regulation (EU) 2017/745 (MDR).

☐ Council Directive 93/42/EEC dated 14 June 1993, as amended by 2007/47/EC (MDD), and Article 120(3c) of MDR

Furthermore, Teleflex Medical Inc. declares:

☒ A formal application has been lodged in accordance with Section 4.3, first subparagraph, of Annex VII MDR before MDD certificate expiration or before 26 May 2024. The LM and MDR NB have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII MDR before 26 September 2024.

☒ A Quality Management System (QMS) will be implemented in compliance with Article 10(9) of Regulation (EU) 2017/745 (MDR) prior to 26 May 2024. Documentation regarding this QMS has been included as part of the application for conformity assessment made to the MDR NB. The MDR NB will complete an assessment of the QMS as part of its conformity assessment activities.

☒ Post-market surveillance, market surveillance, vigilance, and economic operator requirements will be conducted pursuant to Article 120(3e) of the Regulation (EU) 2017/745 (MDR).

☒ The extended transitional period for the product(s) listed in Appendix A shall end on the dates stated in Appendix A, as set forth in Article 120 (3) of the MDR.

**Approvals**

| | |
|---|---|
| **Name and Title of Approver:** | Kim Campbell, Sr. Regulatory Affairs Manager |
| **Signature of Approver:** |  |
| **Date Approved:** | 11-Jul-2023 |
| **Place of Issue:** | Teleflex Medical Inc.<br>3015 Carrington Mill Blvd.<br>Morrisville, NC 27560 USA |

**Change History for Declaration of Conformity Addendum:**

| Revision | Date | Change Order Number or N/A | Reason for Revision |
|---|---|---|---|
| 00 | See Agile | DCO-068469 | Initial Release through DCO-068469 |

**APPENDIX A**

| Product Name | Product Code(s) | MDD EC Certificate(s) No | MDD EC Certificate(s) Expiry Date | End date for Transition Period | MDR Product Class | MDR Class Rule | MDR Conformity Assessment Route(s) | Scheduled MDR Submission Date |
|---|---|---|---|---|---|---|---|---|
| **Polymer Manual Ligation System (**Polymer Ligating Clips) | 544220<br>544230<br>544233<br>544240<br>544243<br>544250<br>544253 | 93/42/EEC – US19/819943647<br><br>EC Design Examination Certificate –US19 US19/819943636 | 14-JUL-2023 | 31-DEC-2028 | Class III | Rule 8 | Annex IX | 15-Dec-2022 |

# EC DECLARATION OF CONFORMITY

| | |
|---|---|
| Legal Manufacturer Name and Address: | **Teleflex Medical**<br>3015 Carrington Mill Blvd<br>Morrisville NC, 27560<br>USA |
| Authorized Representative Name and Address: | **Teleflex Medical**<br>IDA Business and Technology Park<br>Dublin Road<br>Athlone, Co. Westmeath, Ireland |
| Notified Body Name and Address: | ☐ *Class I: Not Applicable*<br>☒ *Class Is, Im, IIa, IIb, III*<br><br>**SGS Belgium NV,**<br>SGS House, Noorderlaan 87-<br>2030 Antwerp, Belgium<br>CE 1639 |

☐ **Class I**

Teleflex Medical declares that the products herewith comply with the requirements of the Council Directive 93/42/EEC dated 14, June 1993 as amended by 2007/47/EC and is in accordance with Annex *Insert Annex Number* and *Insert Version (ISO, BSI BS EN ISO, etc.)* ISO 13485:*Insert Publication Date*, as implemented by the European Union's Medical Devices Regulations.

☒ **Class Is, Im, IIa, IIb, III**

Teleflex Medical declares that the products herewith comply with the requirements of the Council Directive 93/42/EEC dated 14, June 1993 as amended by 2007/47/EC and is in accordance with Annex *II (Including Section 4)* and *BSI BS EN* ISO 13485:*2016*, as implemented by the European Union's Medical Devices Regulations as verified by the Notified Body listed above:

Teleflex Medical confirms that no other application has been lodged with another Notified Body for the same devices related Quality Management System.

Teleflex Medical agrees to develop, implement, and maintain a formally-recognized Quality Management System to ensure continued adequacy and efficacy.

Teleflex Medical agrees to develop, implement and maintain a documented post-production experience monitoring process, including the notification of reportable events under the European Medical Device Vigilance System Guidelines.

Teleflex Medical confirms that no medicinal products/drugs are incorporated in any devices covered by the Device Schedule.

Teleflex Medical agrees to inform the appointed Notified Body of any planned or unplanned substantial change to the Quality Management System.

Teleflex Medical agrees to inform the appointed Notified Body of any planned or unplanned significant change to the Device Schedule, if applicable.

| | |
|---|---|
| **Product Name:** | Polymer Ligation Clips |
| **Classification:** | Class III, Rule 8 |
| **EC Certificates No.:** | **Canadian –** ISO 13485:2016 – US18/8187522 (MDSAP)<br>**European –** BSI BS EN ISO 13485:2016 – US97/10878.00<br>**European Directive 93/42/EEC –**US19/819943647<br>**EC Design Examination Certificate –**US19 US19/819943636 |
| **Conformity Assessment Routes:** | Annex II (including Section 4) of the MDD (93/42/EEC), Full Quality Assurance System |

| Product Codes | Product Description | CE Distribution Date | GMDN Code |
|---|---|---|---|
| | **Hem-o-lok® Ligating Clips** | | |
| 544220 | Hem-o-lok M (formerly SMX) Polymer Clips 6 clips/Cart; 14 Cart/Box | 08/2000 | **56711** |
| 544230 | Hem-o-lok ML Polymer Clips 6 clips/Cart; 14 cart/Box | 02/2002 | **56711** |
| 544233 | Hem-o-lok ML Polymer Clips 3 clips/Cart; 14 cart/Box | 06/2015 | **56711** |
| 544240 | Hem-o-lok L (formerly MLX) Polymer Clips 6 clips/Cart; 14 cart/Box | 03/1999 | **56711** |
| 544243 | Hem-o-lok L (formerly MLX) Polymer Clips 3 clips/Cart; 14 cart/Box | 06/2015 | **56711** |
| 544250 | Hem-o-lok XL Polymer Clips 6 clips/Cart; 14 cart/Box | 09/2003 | **56711** |
| 544253 | Hem-o-lok XL Polymer Clips 3 clips/Cart; 14 cart/Box | 06/2015 | **56711** |
| | **Vesolock™ Ligating Clips** | | |
| 41114V | Vesolock MED Clip 6/cart 14/BOX | **2020-01** | 56711 |
| 51114V | Vesolock MED Clip 6/cart 14/BOX | **2020-01** | 56711 |
| 61114V | Vesolock LG Clip 6/cart 14/BOX | **2020-01** | 56711 |
| 71114V | Vesolock XLG Clip 6/cart 14/BOX | **2020-01** | 56711 |

**** Indicates the item is within the scope of and in compliance with European Directive 2011/65/EU, The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment***

| | |
|---|---|
| **Name and Title of Approver:** | **Hope West**<br>Senior Regulatory Affairs Specialist, Surgical |
| **Signature of Approver:** | |
| **Date Approved:** | |
| **Site Where Approved:** | **Teleflex Medical**<br>3015 Carrington Mill Blvd<br>Morrisville NC, 27560<br>USA |
| | |

**Canadian Classification**

The following devices meet Canadian requirements as listed:

| Product Code | Product Description | Canadian License # | Issue Date | Class & Rule of Product |
|---|---|---|---|---|
| | **Hem-o-lok® Ligating Clips** | | | |
| 544220 | Hem-o-lok M (formerly SMX) Polymer Clips 6 clips/Cart; 14 Cart/Box | 2813 | 1999/05/17 | III Rule 1 |
| 544230 | Hem-o-lok ML Polymer Clips 6 clips/Cart; 14 cart/Box | 2813 | 1999/05/17 | III Rule 1 |
| 544240 | Hem-o-lok L (formerly MLX) Polymer Clips 6 clips/Cart; 14 cart/Box | 2813 | 1999/05/17 | III Rule 1 |
| 544250 | Hem-o-lok XL Polymer Clips 6 clips/Cart; 14 cart/Box | 2813 | 1999/05/17 | III Rule 1 |
| | **Vesolock™ Ligating Clips** | | | |
| 41114V | Vesolock MED Clip 6/cart 14/BOX | 101403 | 2018/07/13 | III Rule 1 |
| 51114V | Vesolock MED Clip 6/cart 14/BOX | 101403 | 2018/07/13 | III Rule 1 |
| 61114V | Vesolock LG Clip 6/cart 14/BOX | 101403 | 2018/07/13 | III Rule 1 |
| 71114V | Vesolock XLG Clip 6/cart 14/BOX | 101403 | 2018/07/13 | III Rule 1 |

| | |
|---|---|
| **Product Description** | Hem-o-lok and Vesolock Ligating Clips are non-absorbable, non-active polymer implantable devices designed for use in general surgical procedures that require vessel or anatomical structure ligation. |
| | |

| | |
|---|---|
| **Indications for Use** | Hem-o-lok ligating clips are intended for use in procedures involving ligation of vessels or tissue structures. Surgeons should apply the appropriate size clip for the size of the vessel or tissue structure to be ligated such that the clip completely encompasses the vessel or tissue structure.<br><br>Vesolock ligating clips are intended for use in procedures involving ligation of vessels or tissue structures. Surgeons should apply the appropriate size clip for the size of the vessel or tissue structure to be ligated such that the clip completely encompasses the vessel or tissue structure. |
| | |
| **Intended Use** | Hem-o-lok ligating clips are intended for use in procedures involving ligation of vessels or tissue structures. Surgeons should apply the appropriate size clip for the size of the vessel or tissue structure to be ligated such that the clip completely encompasses the vessel or tissue structure.<br><br>Hem-o-lok and Vesolock ligating clips are intended for use in procedures involving ligation of vessels or tissue structures. Surgeons should apply the appropriate size clip for the size of the vessel or tissue structure to be ligated such that the clip completely encompasses the vessel or tissue structure. |
| | |
| **Contraindications** | Hem-o-lok and Vesolock ligating clips are not intended for use as a fallopian contraceptive tubal occlusion device.<br><br>Hem-o-lok and Vesolock ligating clips are contraindicated for use in ligating the renal artery during laparoscopic donor nephrectomies. |
| **Manufacturing Site(s)** | **Product Line** / **Manufacturing Site Name** / **Manufacturing Site Address**<br>**Hem-o-lok Ligating Clips** — Hudson Respiratory Care Tecate S. de R.L. — Prolongacion Eusebio Quino<br>1316 Rancho El Descanso<br>Tecate B.C. 21478<br>Mexico<br>**Vesolock Ligating Clips** — Robling Medical, Inc. — 90 Weathers Street<br>Youngsville, NC 27596<br>USA |
| **Sterilizer** | ☐ N/A: The product is sold non-sterile.<br>☒ The product is sold sterile.<br><br>**Product Line** / **Sterilization Site Name** / **Sterilization Site Address**<br>**Hem-o-lok Ligating Clips** — Sterigenics — Cycle 34<br>2971 Olympic Industrial Drive SE<br>Suite 116<br>Atlanta, GA 30339<br>USA<br><br>Cycle 183<br>1302 Avenue T |

| | | | |
|---|---|---|---|
| | | | Grand Prairie, TX 75050 USA |
| | **Vesolock Ligating Clips** | Steris Applied Sterilization Technologies Isomedix Operations Inc. | 2072 Southport Road, South Carolina, 29306 USA |

**Standards**

The Legal Manufacturer claims compliance with the following standards:

| Standard Number | Standard Issue Date | Standard Name |
|---|---|---|
| Refer to Essential Requirements Checklist for list of standards. | N/A | N/A |