WECK®

Weck®

Ligation Solutions

Metal and polymer ligation systems to help you ligate with security and confidence

Teleflex®

Weck® Ligation Solutions

Metal and polymer ligation systems to help you ligate with security and confidence

Beginning in Edward Weck's Manhattan storefront in 1884, Weck brand products have been there for surgeons — step-by-step — since the earliest days of modern surgery.

In 1963, the Weck brand redefined the closure market with the introduction of the Hemoclip® Traditional Metal Ligating Clip. Over the last fifty years, the Weck brand has continued to refine the science of closure to produce a line of metal and polymer ligation solutions demanded by surgeons around the world.

Whether you prefer the classic feel of metal clips or the modern flexibility of polymer, Teleflex offers ligation products designed to suit your distinct preferences and procedural needs:

- **Weck Hem-o-lok® Polymer Locking Ligation Systems** provide unparalleled security, based on an ex-vivo study, against leading competitors in three common clip failure modes*, the ability to ligate larger vessels through a smaller port, and cool ligation. Hem-o-lok Clips are ideal for both open and laparoscopic cases.
- **Horizon™ and Hemoclip Metal Ligation Systems** satisfy your need for traditional metal ligating clips for use in cardiovascular and general surgical applications. Available in a range of sizes, surgeons have relied on Weck Metal Clips for generations.

*Data on file (2013 internal study), Teleflex Incorporated, Report #D001591. Testing conducted on porcine carotids, sample size = 33, p≤ 0.05.Clinical performance cannot be extrapolated from the data. Testing pressures range beyond physiological pressures. The Weck® Hem-o-lok® medium/large clip was compared to Ethicon® LIGAMAX™ 5, Ethicon LIGACLIP® ERCA 10mm, and Covidien Endo Clip™ III. The Weck Hem-o-lok large clip was compared to Ethicon LIGACLIP ERCA Large Clips and Covidien Endo Clip™ L

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Weck® Hem-o-lok® Polymer Locking Ligation System

Secure-locking polymer technology

Confidence you can feel
Confidence. That's what the Weck® Hem-o-lok® Polymer Locking Ligation System from Teleflex provides. Confidence created by a ligation system designed for clip security — firmly seated in the applier, securely closed around the patient vessel.

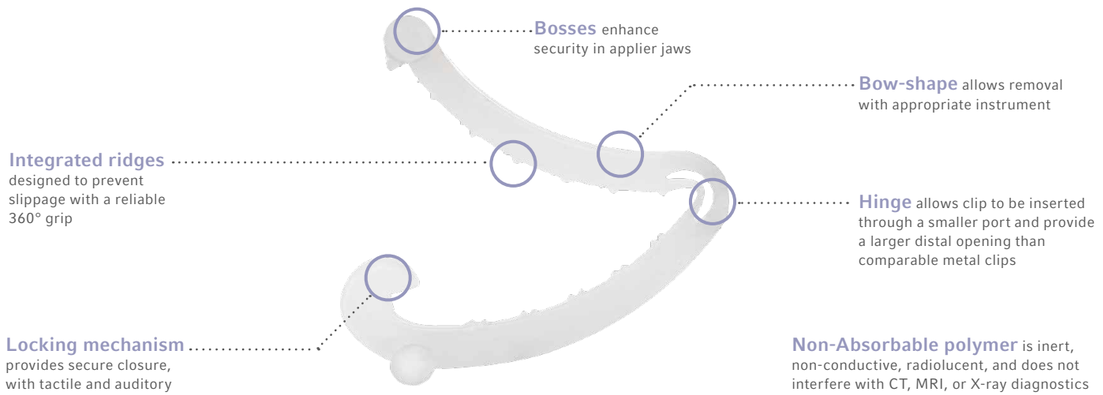
Security by design
Based on an ex-vivo study, the Hem-o-lok System delivers unparalleled ligation security compared to leading competitors in three common clip failure modes,* with the Weck Hem-o-lok Clip's integrated ridges and proprietary distal locking mechanism.

Polymer flexibility
The Hem-o-lok Clip's non-absorbable polymer composition and flexible hinge allow it to pass through a smaller port and provide a larger distal opening than comparable metal clips. As a result, Hem-o-lok Clips can ligate up to a 10 mm structure through a 5 mm port, and up to a 16 mm structure through a 10 mm port.

Cool ligation
Since the Hem-o-lok System is a cool ligation system, there's no chance of thermal spread to vital structures, a common concern of many surgeons when using energy-based ligation solutions.

Size ranges to meet your needs
The Hem-o-lok System is available in a range of clip sizes: Medium, Medium-Large, Large and Extra-Large. Our broad range of applier lengths (including 45 cm endoscopic appliers for extended reach) allows surgeons to deliver clips with control and confidence.

WECK® HEM-O-LOK® POLYMER LIGATION CLIP FEATURES



MANUAL LOAD APPLIERS

HEM-O-LOK OPEN APPLIERS
- Open appliers available in Medium, Medium-Large, Large, Extra-Large
- Available in 8" and 11" lengths and curved or right-angle jaws
- Opens at box lock for easy, thorough cleaning


544180


544179


544240

HEM-O-LOK ENDOSCOPIC APPLIERS
- Endoscopic appliers available in Medium-Large, Large, Extra-Large
- Available with 32 cm or extended-length 45 cm shafts
- Available in both one-piece and take-apart designs


544965


544995T

AUTOMATIC APPLIER

WECK AUTO ENDO5® CLIP APPLIER
- 5 mm automatic clip applier with 15 Medium-Large polymer clips
- Medium-Large clips designed for 3-10 mm size vessels
- Clip designed for security – offers greater confidence in secure occlusion


AE05ML

WECK AUTO ENDO10™ CLIP APPLIER
- 10 mm automatic clip applier with 12 Large polymer clips
- Large clips designed for 5-13 mm size vessels
- Long 35 mm shaft for enhanced reach


AE10LG

*Data on file (2013 internal study), Teleflex Incorporated, Report #D001591. Testing conducted on porcine carotids, sample size = 33, p≤ 0.05.Clinical performance cannot be extrapolated from the data. Testing pressures range beyond physiological pressures. The Weck® Hem-o-lok® medium/large clip was compared to Ethicon® LIGAMAX™ 5, Ethicon LIGACLIP® ERCA 10mm, and Covidien Endo Clip™ III. The Weck Hem-o-lok large clip was compared to Ethicon LIGACLIP ERCA Large Clips and Covidien Endo Clip™ L

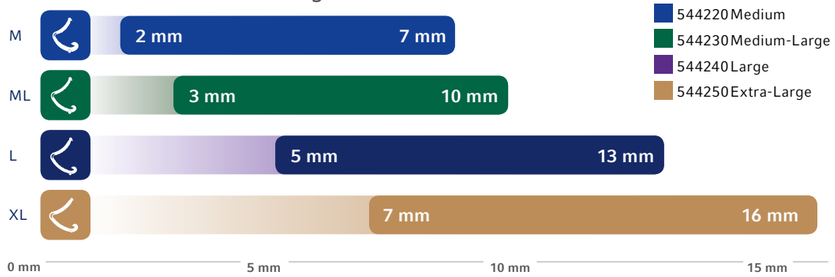
Hem-o-lok Ligating Clips are not intended for use as a fallopian contraceptive tubal occlusion device.

Hem-o-lok Ligating Clips are contraindicated for use in ligating the renal artery during laparoscopic donor nephrectomies.

Weck® Hem-o-lok® Polymer Locking Ligation System

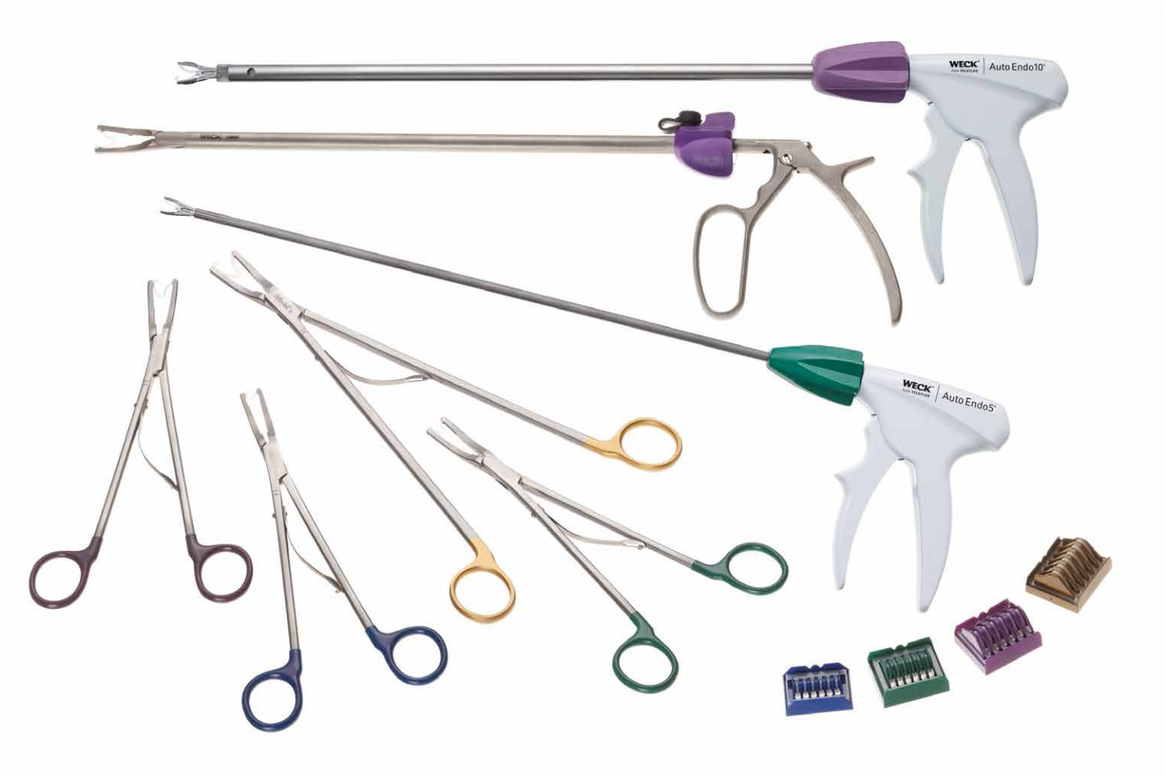
Secure-locking polymer technology

Vessel/Tissue Bundle Size Range



HEM-O-LOK POLYMER LIGATING CLIPS

- 544220 Medium
- 544230 Medium-Large
- 544240 Large
- 544250 Extra-Large



ORDERING INFORMATION

Weck Hem-o-lok Polymer Locking Ligation System

CLIPS	OPEN MANUAL LOAD APPLIERS/REMOVERS	ENDOSCOPIC MANUAL LOAD APPLIERS/REMOVERS	AUTOMATIC APPLIERS
M **544220** Hem-o-lok Medium Polymer Clips 6 clips/cartridge 14 cartridges per box, sterile	**544113** 8" Curved **544114** 11" Right-Angle (70°) **544115** 11" Curved **544123** 11" Remover (for M, ML, L)		
ML **544230** Hem-o-lok Medium-Large Polymer Clips 6 clips/cartridge 14 cartridges per box, sterile	**544170** 8" Curved **544171** 11" Curved **544172** 11" Right-Angle (70°) **544123** 11" Remover (for M, ML, L)	**Endo5® ML, 5 mm diameter** **544965** 32.5 cm applier **544965L** 45 cm applier **544965T** 34 cm applier, take-apart **544121** 32 cm remover (for ML and L) **544121L** 45 cm remover (for ML and L) **544121T** 32 cm remover, take-apart (for ML and L)	**AE05ML 35 cm Applier** 15 ML clips per applier, 3 appliers per box, sterile, disposable
L **544240** Hem-o-lok Large Polymer Clips 6 clips/cartridge 14 cartridges per box, sterile	**544179** 11" Right-Angle (70°) **544180** 8" Curved **544181** 11" Curved **544182** 10" Right-Angle (70°), narrow shaft **544123** 11" Remover (for M, ML, L) **544124** 11" Remover (for L, XL)	**Endo10™ L, 10 mm diameter** **544995** 32 cm applier, 10 mm **544995L** 45 cm applier, 10 mm **544995T** 34 cm applier, 10 mm, take-apart **544121** 32 cm remover, 5 mm (for ML and L) **544121L** 45 cm remover, 5 mm (for ML and L) **544121T** 32 cm remover, 5 mm, take-apart (for ML and L) **544130** 32 cm remover, 10 mm (for L and XL) **544130L** 45 cm remover, 10 mm (for L and XL) **544130T** 33 cm remover, 10 mm take-apart (for L and XL)	**AE10LG 35 cm Applier** 12 L clips per applier, 3 appliers per box, sterile, disposable
XL **544250** Hem-o-lok Extra-Large Polymer Clips 6 clips/cartridge 14 cartridges per box, sterile	**544191** 11" Curved **544192** 11" Right-Angle (70°) **544124** 11" Remover (for L, XL)	**Endo10™ XL, 10 mm diameter** **544990** 32 cm applier **544990L** 45 cm applier **544990T** 34 cm applier, take-apart **544130** 32 cm remover (for L and XL) **544130L** 45 cm remover (for L and XL) **544130T** 33 cm remover, take-apart (for L and XL)	
STORAGE TRAY		**544500** capacity: 3 endoscopic 32 cm appliers **P37319** capacity: 2-3 endoscopic 45 cm appliers	

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Weck® Horizon™ Metal Ligation System

Precise easy-loading titanium clips

The Horizon System is the premium Weck titanium clip ligation platform, providing surgeons a strong, secure clip coupled with an efficient, convenient easy-load cartridge system.

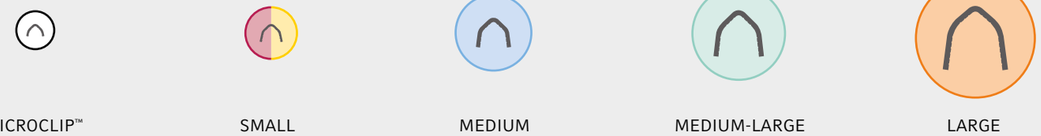
The Horizon Clip

The pre-formed chevron shape of the Horizon Clip engulfs tissue with precise tip-to-tip closure. The heart-shaped wire is designed to give each clip a firm grip on vessels, while the triangulated cross-section of the clip leg maximizes surface-to-surface contact between clip and jaw, practically eliminating clip fallout.

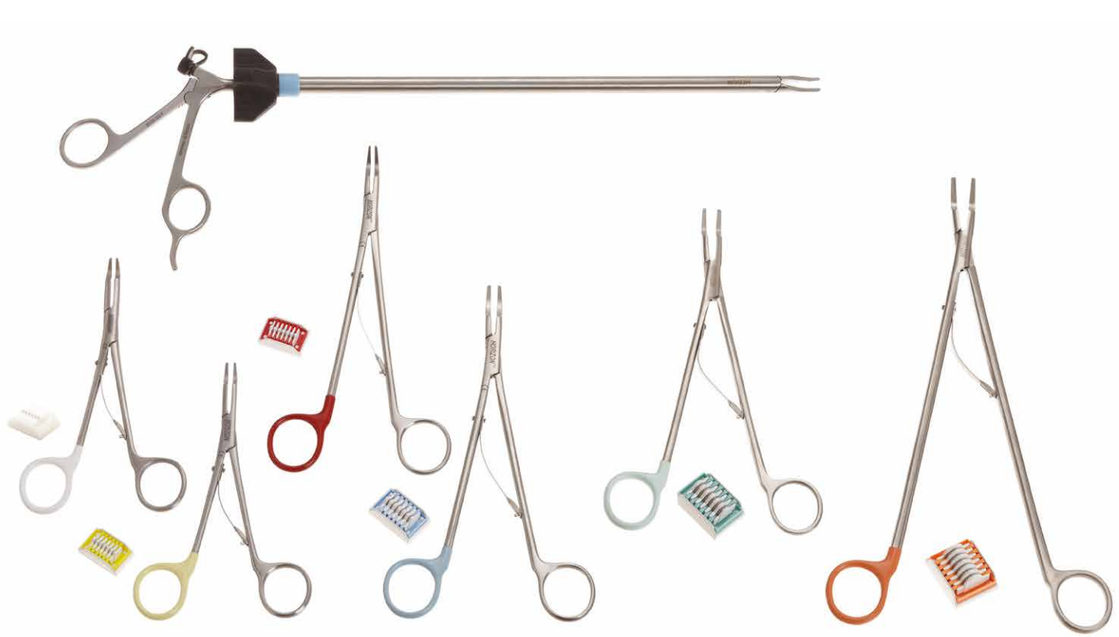
The Horizon Cartridge

The design of the Horizon Cartridge creates a nearly frictionless one-hand load. Horizon Cartridges are color-coded to match appliers and adhesive backing allows convenient placement of the cartridge to any sterile area.

Clip images represent approximate, not exact, sizes.



MICROCLIP™ SMALL MEDIUM MEDIUM-LARGE LARGE



OPEN APPLIERS

- Available with curved (20°), angled (55°) or right-angled (70°) jaws
- Opens at box-lock for easy, thorough cleaning
- Available in a wide range of applier lengths including 14"

ENDOSCOPIC APPLIERS

- Medium, Medium-Large, and Large
- Extended length available (45 cm shaft)
- Large, lightweight rotation knob allows one-finger, 360° rotation of applier shaft
- Flush ports for thorough cleaning

338110

CLIP OPTIONS

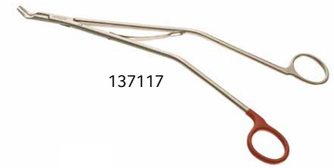
- The Horizon Clip Cartridge provides easy and precise loading that can enhance surgical procedure efficiency
- Both 6- and 24-clip cartridges are available

002200

002205

SPECIALTY APPLIER

- The Horizon 11" Multi-Angle Access Open Surgical Applier for small (wide slot) clip cartridges incorporates a 45° angled jaw (or curved jaw) for an optimal angle of access to the surgical target
- The Horizon Endosaphenous Vein Applier incorporates a 5 mm shaft diameter with a 7 mm angled jaw for ligation of vein branches



137117

238200

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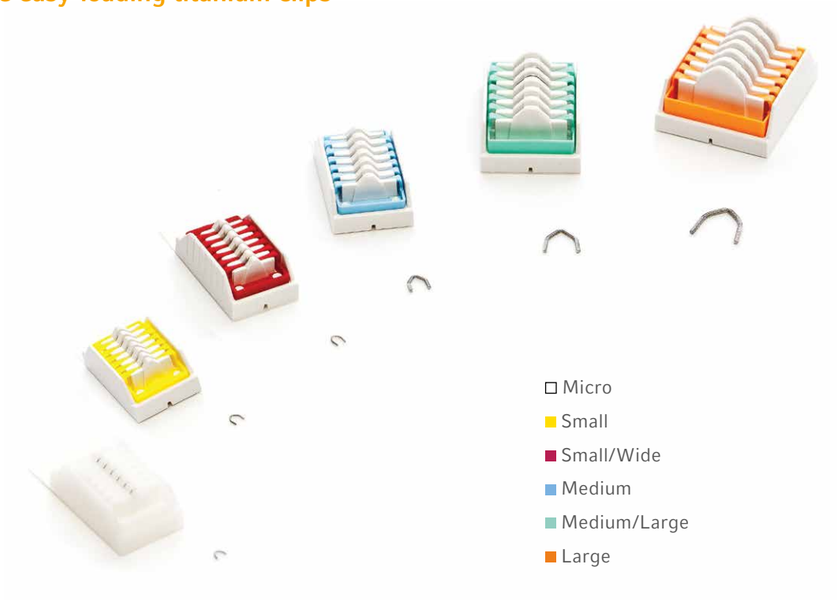
Weck® Horizon™ Metal Ligation System

Precise easy-loading titanium clips



ORDERING INFORMATION

Weck Horizon Metal Ligation System

TITANIUM LIGATING CLIPS

ITEM CODE	CLIP SIZE	CLIPS/CARTRIDGE	CARTRIDGES/BOX	CLIPS/BOX
005200	MicroClip™	6	30	180
001200	Small	6	30	180
001204	Small	24	25	600
001201	Small-Wide	6	30	180
001205	Small-Wide	24	25	600
002200	Medium	6	30	180
002204	Medium	24	25	600
003200	Medium-Large	6	20	120
003204	Medium-Large	24	15	360
004200	Large	6	20	120
004204	Large	24	15	360

ORDERING INFORMATION

Weck Horizon Metal Ligation System

OPEN SURGICAL APPLIERS

ITEM CODE	APPLIER LENGTH	CLIP SIZE	JAW TYPE*
537061	6" (15 cm)	MicroClip	Curved
537081	8" (20 cm)	MicroClip	Curved
137061	6" (15 cm)	Small	Curved
137081	8" (20 cm)	Small	Curved
137085	8" (20 cm)	Small	Angled
137111	11" (28 cm)	Small	Curved
137062	6" (15 cm)	Small-Wide	Curved
137082	8" (20 cm)	Small-Wide	Curved
137086	8" (20 cm)	Small-Wide	Angled
137112	11" (28 cm)	Small-Wide	Curved
237061	6" (15 cm)	Medium	Curved
237081	8" (20 cm)	Medium	Curved
237085	8" (20 cm)	Medium	Angled
237111	11" (28 cm)	Medium	Curved
237115	11" (28 cm)	Medium	Angled
237117	11" (28 cm)	Medium	Right-Angled
237141	14" (35.5 cm)	Medium	Curved
237145	14" (35.5 cm)	Medium	Angled
337081	8" (20 cm)	Medium-Large	Curved
337085	8" (20 cm)	Medium-Large	Angled
337111	11" (28 cm)	Medium-Large	Curved
337115	11" (28 cm)	Medium-Large	Angled
337117	11" (28 cm)	Medium-Large	Right-Angled
337141	14" (35.5 cm)	Medium-Large	Curved
337145	14" (35.5 cm)	Medium-Large	Angled
437081	8" (20 cm)	Large	Curved
437085	8" (20 cm)	Large	Angled
437111	11" (28 cm)	Large	Curved
437115	11" (28 cm)	Large	Angled
437117	11" (28 cm)	Large	Right-Angled
437141	14" (35.5 cm)	Large	Curved
437145	14" (35.5 cm)	Large	Angled

ENDOSCOPIC LIGATING APPLIERS

ITEM CODE	APPLIER LENGTH	DIAMETER	CLIP SIZE	JAW TYPE
238110	12" (31 cm)	10 mm	Medium	Endoscopic
238170	18" (45 cm)	10 mm	Medium	Endoscopic
238200	13" (32 cm)	5 mm Shaft, 7 mm Jaw	Medium	Endosaphenous
338110	13" (32 cm)	10 mm	Medium-Large	Endoscopic
338170	18" (45 cm)	10 mm	Medium-Large	Endoscopic
438110	14" (36 cm)	12 mm	Large	Endoscopic
438170	18" (45 cm)	12 mm	Large	Endoscopic

ENDOSCOPIC LIGATING APPLIERS – TAKE-APART

ITEM CODE	APPLIER LENGTH	DIAMETER	CLIP SIZE	JAW TYPE
238110T	11" (28 cm)	10 mm	Medium	Endoscopic
338110T	11" (28 cm)	10 mm	Medium-Large	Endoscopic

SPECIALTY OPEN SURGICAL LIGATING APPLIERS

ITEM CODE	APPLIER LENGTH	CLIP SIZE	JAW TYPE
137117	11" (28 cm)	Small-Wide	45° Angled
137118	11" (28 cm)	Small-Wide	Curved

METAL CLIP REMOVERS (REMOVES ALL WECK METAL CLIPS)

ITEM CODE	APPLIER LENGTH	STYLE
523120	6.5" (16.5 cm)	Straight
523121	10.5" (26.7 cm)	Bent Shaft, 30° Angle

Weck Ligating Clips are not intended for use as a contraceptive tubal occlusion device.

Weck Ligating Clips are contraindicated for use in ligating the renal artery during laparoscopic donor nephrectomies.

*Curved 20°, Angled 55°, Right-Angle 70°

Weck® Hemoclip® Metal Ligation Systems

Classic metal clip ligation relied on by surgeons for years

HEMOCLIP TRADITIONAL METAL LIGATING CLIPS

- Friction fit loading system
- Available in titanium and tantalum
- Cartridge base to assist loading

HEMOCLIP PLUS SYSTEM

The Hemoclip Plus System is an evolution of the classic metal Hemoclip. Hemoclip Plus Metal Ligating Clips feature:

- An easy-load cartridge system
- Available in titanium
- Clip loads from the cartridge with minimal pressure
- Adhesive or non-adhesive clip cartridges

CLIP OPTIONS

- Chevron-shaped clip for precise tip to tip closure
- Heart-shaped wire for tenacious grip on vessels
- Lateral transverse grooves for increased vessel contact

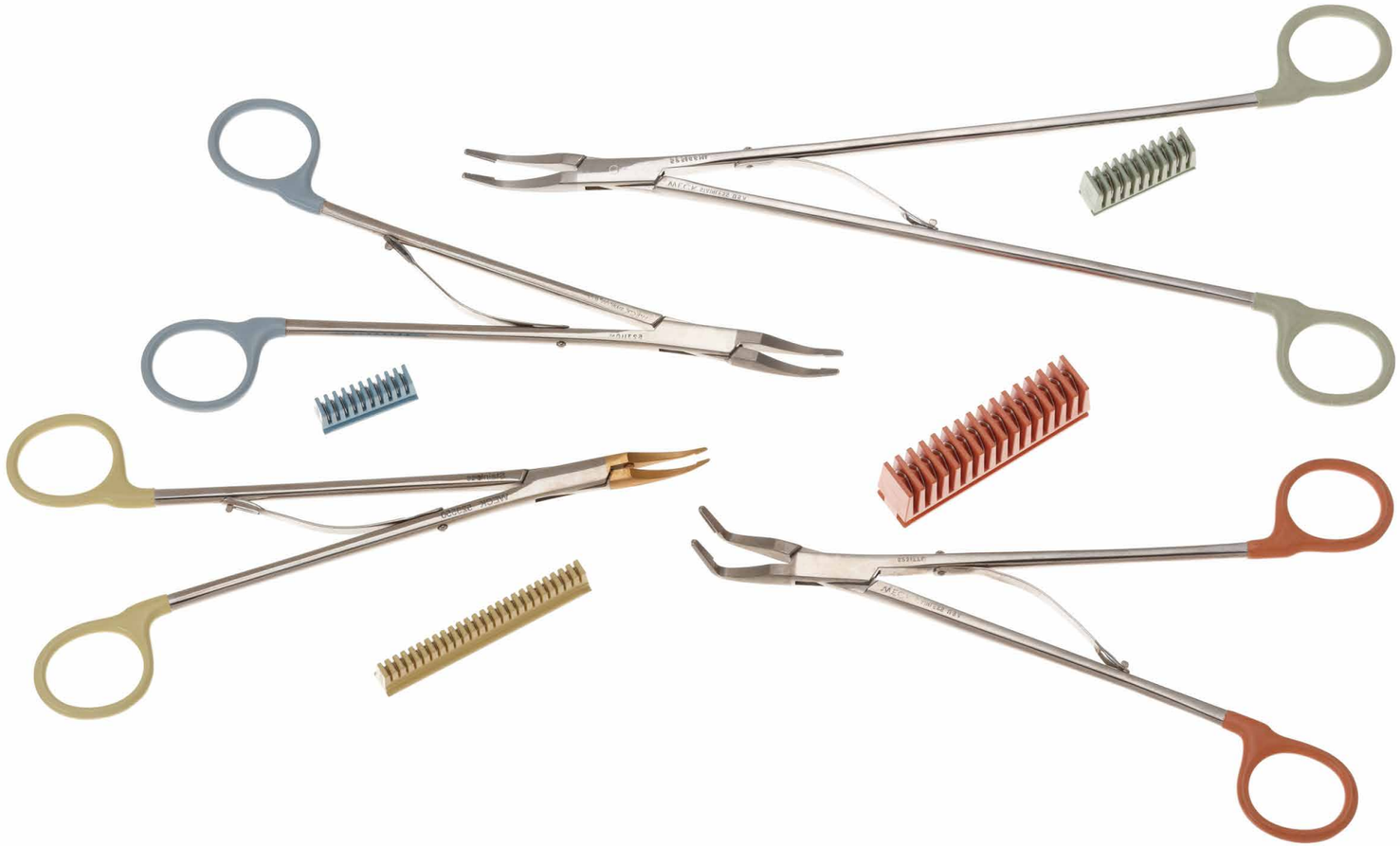
523130

OPEN APPLIERS

- Available in a variety of lengths and tip angles
- Opens at box-lock for easy cleaning

Curved tip

Right angle tip



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Weck® Hemoclip® Metal Ligation Systems

Classic metal clip ligation relied on by surgeons for years

ORDERING INFORMATION

Weck Hemoclip Traditional Clips and Appliers

Small Medium Medium/Large Large

HEMOCLIP TRADITIONAL-TITANIUM LIGATING CLIPS

ITEM CODE	CLIP SIZE	CLIPS/ CARTRIDGE	CARTRIDGES/ BOX	CLIPS/BOX
523735	Small	25	12	300
523835	Small	10	24	240
523700	Medium	25	10	250
523800	Medium	10	20	200
523760	Medium/Large	10	20	200
523860	Medium/Large	10	16	160
523770	Large	15	10	150
523870	Large	10	12	120

HEMOCLIP TRADITIONAL-TANTALUM LIGATING CLIPS

ITEM CODE	CLIP SIZE	CLIPS/ CARTRIDGE	CARTRIDGES/ BOX	CLIPS/BOX
523135	Small	25	12	300
523335	Small	10	24	240
523100	Medium	25	10	250
523300	Medium	10	20	200
523160	Medium/Large	10	20	200
523360	Medium/Large	10	16	160
523170	Large	15	10	150
523370	Large	10	12	120

HEMOCLIP TRADITIONAL LIGATING CLIP APPLIERS

ITEM CODE	CLIP SIZE	APPLIER LENGTH	JAW TYPE
523140	Small	6" (15 cm)	Curved
523150	Small	8" (20 cm)	Curved
523151	Small	11" (28 cm)	Curved
523105	Medium	8" (20 cm)	Right Angled
523106	Medium	11" (28 cm)	Right Angled
523109	Medium	6" (15 cm)	Curved
523110	Medium	8" (20 cm)	Curved
523111	Medium	11" (28 cm)	Curved
523165	Medium/Large	8" (20 cm)	Curved
523166	Medium/Large	11" (28 cm)	Curved
523167	Medium/Large	8" (20 cm)	Right Angled
523168	Medium/Large	11" (28 cm)	Right Angled
523175	Large	8" (20 cm)	Curved
523177	Large	8" (20 cm)	Right Angled
523178	Large	11" (28 cm)	Right Angled
523180	Large	11" (28 cm)	Curved

HEMOCLIP TRADITIONAL LIGATING CLIP PRECISION APPLIERS

ITEM CODE	CLIP SIZE	APPLIER LENGTH	JAW TYPE
523540	Small	6" (15 cm)	Curved
523550	Small	8" (20 cm)	Curved
523551	Small	11" (28 cm)	Curved

HEMOCLIP LIGATING CLIP ACCESSORIES

ITEM CODE	CLIP SIZE	APPLIER LENGTH	JAW TYPE
523120	Removing Forceps	6" (15 cm)	Straight
523121	Removing Forceps	10" (25.4 cm)	Angled Shanks
523130	Cartridge Base	7" (17.78 cm)	

ORDERING INFORMATION

WECK HEMOCLIP PLUS CLIPS AND APPLIERS

Small Small/Wide Medium Medium/Large Large

HEMOCLIP TRADITIONAL-TITANIUM LIGATING CLIPS

ITEM CODE	CLIP SIZE	CLIPS/ CARTRIDGE	CARTRIDGES/ BOX	CLIPS/BOX
533735	Small w/tape	25	12	300
533737	Small	25	12	300
533835	Small w/tape	10	18	180
533837	Small	10	18	180
534735	Small Strongpoint w/tape	25	12	300
534737	Small Strongpoint	25	12	300
534835	Small Strongpoint w/tape	10	18	180
534837	Small Strongpoint	10	18	180
533700	Medium w/tape	25	10	250
533702	Medium	25	10	250
533800	Medium w/tape	10	18	180
533802	Medium	10	18	180
533860	Medium-Large w/tape	10	12	120
533862	Medium-Large	10	12	120
533870	Large w/tape	10	12	120
533872	Large	10	12	120

HEMOCLIP PLUS LIGATING CLIP APPLIERS

ITEM CODE	CLIP SIZE	APPLIER LENGTH	JAW TYPE
533140	Small	6" (15 cm)	Curved
533150	Small	8" (20 cm)	Curved
533151	Small	11" (28 cm)	Curved
533152	Small	8" (20 cm)	Right Angled
534140	Small Strongpoint	6" (15 cm)	Curved
534150	Small Strongpoint	8" (20 cm)	Curved
533105	Medium	8" (20 cm)	Right Angled
533106	Medium	11" (28 cm)	Right Angled
533108	Medium	11" (28 cm)	Angled
533109	Medium	6" (15 cm)	Curved
533110	Medium	8" (20 cm)	Curved
533111	Medium	11" (28 cm)	Curved
533164	Medium-Large	11" (28 cm)	Angled
533165	Medium-Large	8" (20 cm)	Curved
533166	Medium-Large	11" (28 cm)	Curved
533167	Medium-Large	8"(20 cm)	Right Angled
533168	Medium-Large	11" (28 cm)	Right Angled
114527	Medium-Large	13" (32 cm)	Endoscopic
533175	Large	8" (20 cm)	Curved
533177	Large	8" (20 cm)	Right Angled
533178	Large	11" (28 cm)	Right Angled
533180	Large	11" (28 cm)	Curved
533181	Large	11" (28 cm)	Angled

HEMOCLIP LIGATING CLIP ACCESSORIES

ITEM CODE	CLIP SIZE	APPLIER LENGTH	JAW TYPE
523120	Removing Forceps	6" (15 cm)	Straight
523121	Removing Forceps	10" (25.4 cm)	Angled Shanks
523130	Cartridge Base	7" (17.78 cm)	

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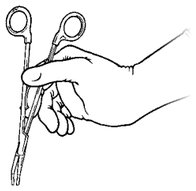
Weck® Clip Loading Methods

Manual applier technique

RING-HANDLED APPLIER GUIDELINES

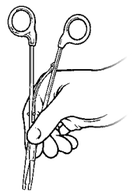
To prevent jaw applier damage or dropped clips, the user should avoid any grasp that can compress the two shanks of the applier during loading. Applier is held at an angle appropriate to sliding the jaws into the cartridge.

Preferred Loading Methods



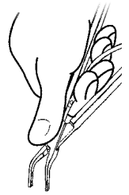
Method #1 Shank and Spring

One shank and the spring are held between the thumb and index finger, which is placed between shafts to spread jaws and stabilize loading.



Method #2 Pencil Grip

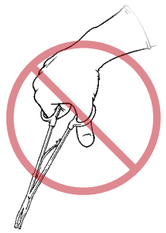
Box-lock is held between the thumb and side of index finger, with tips of index finger and other fingers supporting box-lock area for stability. The index finger is behind the box-lock, not beside it.



Method #3 Angled Appliers

Thumb should be placed on top of the box-lock while other fingers support one side of the shaft.

What to Avoid

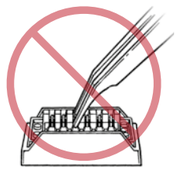


Grasping the applier at both rings tends to force applier tips together and "fights" the loading action. This may cause the applier to twist or rock, allowing jaw damage or misloaded clips.

Holding both shanks of applier, even near the box-lock, may also tend to force jaws together during loading. Keep the index finger behind the box-lock or shank.

RING HANDLE AND ENDOSCOPIC APPLIER CLIP LOADING

Proper Jaw Angle



Applier jaws need to be positioned perpendicular to the cartridge body for slide-in of the jaw into the cartridge seat. It is necessary to set the shanks of the applier (the main body of the applier) at an acute angle to the cartridge.

Warranty/Repair

Send all appliers in need of repair or refurbishment to:

Teleflex® Applier Repairs
4620-A Industry Lane
Durham, NC 27713

For applier repairs outside the U.S., contact your local distributor.

Open Surgical Appliers

All Weck Ring Handled Reusable Open Surgical Appliers are covered by a warranty. Teleflex will repair, or replace, free of charge, these appliers as long as the appliers are used as intended for application of Weck Clips and have not been repaired by unauthorized personnel.

Endoscopic Surgical Appliers

Weck Manual Load Endoscopic Appliers are covered by a three year warranty on defects in materials and workmanship and a three year repair service on tip alignment and refurbishment as long as the appliers are used as intended for application of Weck Clips and have not been repaired by unauthorized personnel.

Teleflex | Toll Free: 866.246.6990 | www.teleflex.com

Care and Maintenance

Weck® Open and Endoscopic Clip Appliers

CLEANING

Follow hospital, Association of the Advancement of Medical Instrumentation (AAMI), Association of Perioperative Registered Nurses (AORN), or regional standards for cleaning your appliers.

Open Appliers

Opening the box lock:

- Lightly squeeze shanks together with one hand
- Lift the spring off the flag
- Open the applier

Endoscopic Appliers — One Piece

Endoscopic appliers are provided with a cleaning port, which permits access to the interior channels and cavities. Uncap the cleaning port and flush the applier with warm distilled or filtered water for approximately two minutes or until the visible gross debris is removed from the device.

Lubrication

Lubrication is essential every time instruments are processed. Do not use mineral oil, petroleum, or silicone-based products. Use a non-silicone water-soluble lubricant prior to sterilization.

Sterilization

STERILIZATION METHOD	INSTRUMENT CONFIGURATION	TEMPERATURE	EXPOSURE TIME (MINIMUM)	DRYING TIME (MINIMUM)
US PARAMETERS				
Pre-vacuum	Wrapped	270°F (132° C)	4 minutes	10 minutes
Pre-vacuum	Wrapped	275°F (135° C)	3 minutes	10 minutes
Gravity Displacement	Wrapped	275°F (135° C)	10 minutes	10 minutes
NON-US PARAMETERS				
Pre-vacuum	Wrapped	273°F (134° C)	3 minutes	10 minutes
Pre-vacuum	Wrapped	279°F (137° C)	3 minutes	10 minutes
Gravity Displacement	Wrapped	270°F (132° C)	10 minutes	10 minutes

INSPECTION

Please examine endoscopic and open appliers for potential damage before use in surgery. Pay particular attention to the jaws. Damaged or misaligned jaws may not allow clips to close acceptably for occlusion of intended structure.

Open and Endoscopic Appliers

Alignment:
Always check the alignment of the applier jaws before use.
When closed, jaw tips should be directly aligned and not offset

Open Appliers

Check the following components of your open clip appliers:

Spring:
Examine to ensure spring is not loose, bent, or rusted

Flag Condition:
Examine to ensure flag is not missing or damaged

Applier Management

Two convenient options to manage your open appliers

An essential part of accurate ligation is a finely crafted applier, designed specifically for Weck® Clips and maintained to the highest standards. We are proud to provide, service, maintain and replace these appliers for you — ensuring that each clip is applied by a device designed specifically for that clip.

TWO WAYS TO OBTAIN HORIZON™, HEM-O-LOK®, HEMOCLIP® PLUS AND TRADITIONAL APPLIERS:

Option 1 — Applier Purchase

All Weck Appliers are available for purchase. Purchased open appliers will be maintained, repaired or replaced for as long as you own them, at no charge, through Teleflex® as long as the appliers are used as intended for application of Weck Clips and have not been repaired by unauthorized personnel. Contact your local Surgical Sales Representative for more details.

Option 2 — Applier Loaner Program

Hospitals purchasing Weck Clips can take advantage of the Teleflex Applier Loaner Program. Weck Open Metal Clip Appliers are loaned to the hospital for use with Weck Clips. Teleflex will maintain, repair or replace all appliers needed to be sufficient for the volume of Weck Clips being used. These appliers will be provided to the hospital at no charge for exclusive use with Weck Clips. If the hospital discontinues its use of Weck Clips, then the appliers are to be returned to Teleflex (Signed Loaner Agreement required).

Product Use Information

Weck Metal and Polymer 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.

Weck Ligating Clips are contraindicated for use in ligating the renal artery during laparoscopic donor nephrectomy. In procedures other than laparoscopic donor nephrectomy, Teleflex recommends ligation of the renal artery with more than one clip on the patient side with a minimum distal renal artery cuff of 2–3 mm beyond the distal clip. Application of a second clip on all other vessels other than the renal artery should be dictated by the surgeon's judgment. Security of the closure should be confirmed after ligation.

Always check the alignment of the applier jaws before use. When closed, jaw tips should be directly aligned and not offset. Alignment of the jaw is critical for safe application of the clip. If this is not done, patient injury may occur. Follow the Instructions for Use for proper maintenance, care and cleaning necessary to ensure proper functionality.

Do not attempt to close the jaws on a vessel or anatomic structure without a clip properly loaded into the jaws. Closure of empty jaws on a vessel or anatomic structure may result in patient injury. Before applying a clip, verify the structural size and condition of the vessel or structure and use the proper size clip. Ligating clip systems differ in closure characteristics according to clip design and other variables. It is the responsibility of the user to select structures for the application of clips and confirm secure grip of the clips after placement, and after the use of other surgical devices in the immediate area of the application.

Your Weck Applier has been designed and calibrated for use with specific Hem-o-lok, Horizon, Hemoclip Plus or Hemoclip Traditional Ligating Clips as indicated. If applicable, applier color coding matches the color of the ligating clip cartridge for which it is to be used. Weck does not assume responsibility for unsatisfactory results caused by the use of any equipment or clips not specifically identified by Weck as an integral part of that specific system.

For clip and associated applier information, please refer to the Instructions for Use included with the applier.

For more information visit **teleflex.com/ligation**

Teleflex is a global provider of medical technologies designed to improve the health and quality of people's lives. We apply purpose driven innovation – a relentless pursuit of identifying unmet clinical needs – to benefit patients and healthcare providers. Our portfolio is diverse, with solutions in the fields of vascular and interventional access, surgical, anesthesia, cardiac care, urology, emergency medicine and respiratory care. Teleflex employees worldwide are united in the understanding that what we do every day makes a difference. For more information, please visit teleflex.com.

Teleflex is the home of Arrow®, Deknatel®, Hudson RCI®, LMA®, Pilling®, Rüsch® and Weck® – trusted brands united by a common sense of purpose.

Corporate Office

Phone +1 610 225 6800, 550 E. Swedesford Road, Suite 400, Wayne, PA 19087, USA

Regional Offices

United States: Phone +1 919 544 8000, Toll Free +1 866 246 6990, cs@teleflex.com, 3015 Carrington Mill Boulevard, Morrisville, NC 27560, USA

Latin America: Phone +1 919 433 4999, la.cs@teleflex.com, 3015 Carrington Mill Boulevard, Morrisville, NC 27560, USA

International: Phone +353 (0)9 06 46 08 00, orders.intl@teleflex.com, Teleflex Medical Europe Ltd., IDA Business and Technology Park, Dublin Road, Athlone, Co Westmeath, Ireland

Australia/New Zealand 1300 360 226
Austria +43 (0)1 402 47 72
Belgium +32 (0)2 333 24 60
Canada +1 (0) 905 943 9000
China (Shanghai) +86 (0)21 6163 0965
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 6632 3600
Korea +82 2 536 7550
Mexico +52 55 5002 3500
Netherlands +31 (0)88 00 215 00
Portugal +351 22 541 90 85
Singapore +65 6439 3000
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 more information, please visit teleflex.com.

Rx Only. Caution: U.S. federal law restricts this device to sale by or on the order of a physician. Hem-o-lok Ligating Clips are contraindicated for use as a fallopian contraceptive tubal occlusion device and contraindicated for use in ligating the renal artery during laparoscopic donor nephrectomies.

Teleflex®

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Teleflex Medical
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Holds Certificate Number: FM 544574

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design and manufacture of non-active digestive tract devices; non-active gynaecological devices, non-active regional anaesthesia devices, non-active respiratory devices, non-active surgical devices, non-active urology devices and active surgical devices.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2009-03-09
Effective Date: 2023-02-12
Latest Revision Date: 2023-01-26
Expiry Date: 2026-02-11

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 540595**

Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

In respect of:

The design and manufacture of non active digestive tract devices; non active gynecological devices; non active regional anaesthesia devices; non active respiratory devices; non active surgical devices; non active urology devices.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2009-01-13** Date: **2020-06-09** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 540595

Issued To:

Teleflex Medical
IDA Business and Technology Park
Dublin Road
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Number	Device Name	Intended purpose per IFU
Class III		
---	EpiStar CSE - Spinal-Epidural Anaesthesia Kits	See CE 544836
---	Spinostar Spinal Needles	See CE 560441
Class IIb		
10735	Sterile Percutaneous Nephrostomy Catheter	Puncture and dilation of percutaneous approaches into the upper urinary tract.
35404	Sterile Tracheostomy Tube	Cannulation of tracheostomised patients through an existing tracheostoma.
14099	Sterile Tracheostomy Tube	Cannulation of tracheostomised patients, in whom the stoma was created by percutaneous dilative tracheostomy.
58005	Sterile Ureter Stent	Routine drainage of the renal pelvis via the ureter or a ureter-skin stoma to an external collection site.
34924	Sterile Suprapubic Cystotomy Set	Routine suprapubic drainage of the bladder
31074	Sterile Ureterocutaneostomy Catheter	Routine drainage of urine through a ureterocutaneous stoma site.

First Issued: **2009-01-13** Date: **2020-06-09** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 540595

Issued To:

Teleflex Medical
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0106	Sterile Transurethral Catheter	---
MD 0101	Sterile Tracheostomy Retainer Set	---
MD 0106	Sterile Rectal Tube	---
MD 0101 MD 1102	Sterile Breathing Circuit	---
MD 0101 MD 1102	Non-sterile Breathing Circuit	
MD 0101	Sterile Cricothyrotomy Set	---
MD 0102	Sterile Epidural Set	---
MD 0101	Sterile EZ Blocker Kit	---
MD 0106	Sterile Guidewire	---
MD 0106	Sterile Kidney Stone Extractor	---
MD 0101	Sterile Tracheal Tube	---
MD 0101	Non-sterile Tracheal Tube	---
MD 0101	Sterile Laryngeal Mask	---
MD 0101	Non-sterile Laryngeal Mask	---

First Issued: **2009-01-13** Date: **2020-06-09** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 540595

Issued To:

Teleflex Medical
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0106	Sterile Laparoscopy Bag	---
MD 0101	Sterile Bronchial Tube	---
MD 0101	Sterile Suprapubic Cystotomy Set	---
MD 0303	Sterile Drainage Tube	---
MD 0101	Sterile Tracheostomy Tube, Inner cannula	---
MD 0106	Sterile Ureter Catheter	---
MD 0102	Sterile Needle Introducer	---
MD 0101	Sterile Percutaneous Nephrostomy Catheter	---
MD 0106	Non-sterile Temperature Sensor	---
MD 0101	Sterile Breathing Bag	---
MD 0101 MD 0106	Sterile Irrigation System for Ureterocutaneostomy	---

First Issued: **2009-01-13** Date: **2020-06-09** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 540595**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
Arrow International CR, a.s. Jamska 2359/47 Zdar Nad Sazavou 59101 Czech Republic	**Design** **Manufacture**
Arrow International CR, a.s. Prazska 209 Hradec Kralove 50004 Czech Republic	**Design**
Arrow Medical Ltd Hatton Garden Industrial Estate Kington Hereford HR5 3RB United Kingdom	**Manufacture**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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Subcontractor:	**Service(s) supplied**
BBF Sterilisationsservice GmbH Willy-Rüsch-Straße 10/1 71394 Kernen Germany	**Radiation (Gamma Sterilization)**
Chelle Medical Limited Le Rocher P.O Box 221 Victoria Mahe Seychelles	**Manufacture**
Chemiczna Spółdzielnia Pracy Technochemia ul. Fabryczna 3 05-600 Grójec Poland	**ETO Sterilization**
Contract Medical International, spol. sr.o. Vážní 848 500 03 Hradec Králové Czech Republic	**Manufacture**

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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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Subcontractor:	**Service(s) supplied**
Daqing Medical Device (Tianjin) Co., Ltd 10A & 11A Tianzhi Industrial Center No.12 Hong Yuan Road Xiqing Economic Development Area 300385 Tianjin People's Republic of China	**Manufacture**
Degania Silicone Limited Kibbutz 1513000 Degania Bet Israel	**Manufacture**
Forefront (Xiamen) Medical Devices Co., Ltd No. 28 Haijing East Road & No. 61 Haijing South Road Xiamen Area of China (Fujian) Pilot Free Trade Zone 361026 Xiamen, Fujian People's Republic of China	**Manufacture**

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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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Subcontractor:	**Service(s) supplied**
Forefront Medical Technology (Pte) Ltd 35 Joo Koon Circle Singapore 629110 Singapore	**Manufacture**
M.E.M., Inc. 8 Bishop Lane Madison Connecticut 06443 USA	**Manufacture**
Medicoplast International GmbH Heusweilerstrasse 100 DE-66557 Illingen Germany	**ETO Sterilization**
Parker Hannifin CSS Merrillville 1201 East 86th Place Merrillville IN, 46410 United States	**Manufacture**

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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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Subcontractor:	**Service(s) supplied**
Plaxtron Industrial (M) Sdn. Bhd. Plot 28, Kawasan Perusahaan Jelapang II Zon Perdagangan Bebas, Ipoh Perak 30020 Malaysia	**Manufacture**
Professional Contract Sterilization Inc. 40 Myles Standish Blvd Taunton Massachusetts 02780-1026 USA	**ETO Sterilization**
safemed medical devices s.r.o Trabantská 292 19015 Praha 9 Czech Republic	**Manufacture**

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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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Subcontractor:	**Service(s) supplied**
sfm medical devices GmbH Brückenstraße 5 63607 Wächtersbach Germany	**ETO Sterilization** **Manufacture**
SINA-SterilGamma Sdn. Bhd. LOT 88077, Jalan Perigi Nenas 7/1 Taman Perindustrian Pulau Indah 42907 Pelabuhan Klang. Selangor Malaysia	**ETO Sterilization**
SP Medical A/S Møllevej 1 4653 Karise Denmark	**Design** **Manufacture**
SP Medical Sp. z o.o. UI. Ceramiczna 2K 98-220 Zduńska Wola Poland	**Manufacture**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
STERIS AST CZ s.r.o. Prumyslová Zona Kosikov 80 Velka Bites 59501 Czech Republic	**ETO Sterilization**
Synergy Sterilisation (M) Sdn Bhd. Plot 203 Kuala Ketil Industrial Estate Kuala Ketil Kedah 09300 Malaysia	**ETO Sterilization**
Synergy Sterilisation Kulim (M) Sdn. Bhd Lot 71, Kulim Industrial Estate Kulim Kedah 09000 Malaysia	**ETO Sterilization**

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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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Subcontractor:	**Service(s) supplied**
Teleflex Medical Asia Pte. Ltd. 21 Merchant Road #04-01 Royal Merukh S.E.A 058267 Singapore	**Design** **Manufacture**
Teleflex Medical Sdn. Bhd. Lot PT 2577, Jalan Perusahaan 4 34600 Kamunting Perak Malaysia	**Design** **ETO Sterilization** **Manufacture**
The Laryngeal Mask Company (Malaysia) Sdn. Bhd. Lot 19 & 1920 Industrial Zone Phase 1 Kulim Hi-Tech Park Kulim 09000 Malaysia	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 540595**

Date: **2020-06-09**

Issued To: **Teleflex Medical**
IDA Business and Technology Park
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Ireland

Date	Reference Number	Action
13 January 2009	7245725	First issue.
17 March 2009	7325719	Company address amended. Extension to scope. Addition of Willy Rüsch, Germany as subcontractor for design and manufacture.
25 August 2009	7399879	Addition of 'epidural catheter Epistar and Epistar CSE' to scope. Addition of SFM as significant subcontractor for manufacture. Addition of 'design' to services supplied by Teleflex Medical Malaysia, Arrow International CR, a.s. and Arrow International Inc., Czech Republic.
11 November 2009	7455515	Addition of CeMed GmbH for manufacturing to the list of significant subcontractors.
20 April 2010	7497906	Laryngeal Mask added to scope. Addition of Tianjin Medis Medical Device Co. Ltd as significant subcontractor for manufacture.
08 September 2010	7558508	Scope reworded in accordance with generic device groups. Certificate renewal.
23 May 2012	7778467	Correction of significant subcontractor address and addition of new scope activities for subcontractors.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 540595**
Date: **2020-06-09**
Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
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Co. Westmeath
Ireland

Date	Reference Number	Action
04 February 2013	7932588	The addition of a significant subcontractor SP Medical A/S.
14 May 2014	8134266	Addition of peripheral angioplasty balloon catheters to product family, covered by scope expression 'non-active surgical devices'. Addition of significant subcontractors Hotspur Technologies, Inc and Teleflex Medical Asia Pte Ltd.
09 March 2015	8293488	Addition of 8 crucial suppliers.
28 August 2015	8406490	Certificate renewal. Removal of Hotspur Technologies, Inc. from list of significant subcontractors.
05 August 2016	8571081	Addition of Contract Medical International, spol. sr.o. to the list of significant subcontractors. Addition of EZ Blocker non-active respiratory device.
09 January 2017	8665617	Change to the address of subcontractor (Forefront).
16 July 2018	8939923	Addition of Daqing Medical Device (Tianjin) Co., Ltd to the list of significant subcontractors.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 540595**

Date: **2020-06-09**

Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Date	Reference Number	Action
4 March 2019	7779566	Traceable to NB 0086.
Current	3124666	Certificate renewal. Addition of supplementary product information table. Removal of Control of Sterilization from Service(s) supplied for Arrow International CR, a.s. (Zdar), Arrow International CR, a.s. (Hradec Kralove), Contract Medical International spol. sr.o., SP Medical A/S, sfm medical devices GmbH, Teleflex Medical Asia Pte. Ltd. and Teleflex Medical Sdn. Bhd. Removal of Crucial Supplier from Service(s) supplied for Arrow Medical Ltd, Chelle Medical Limited, Forefront (Xiamen) Medical Devices Co., Ltd, Forefront Medical Technology (Pte) Ltd, Parker Hannifin CSS Merrillville, Plaxtron Industrial (M) Sdn. Bhd. and The Laryngeal Mask Company (Malaysia) Sdn. Bhd. Addition of Manufacture to Service(s) supplied for Arrow Medical Ltd, Chelle Medical Limited, Forefront (Xiamen) Medical Devices Co., Ltd, Forefront Medical Technology (Pte) Ltd, M.E.M., Inc., Parker Hannifin CSS Merrillville, Plaxtron Industrial (M) Sdn. Bhd., and The Laryngeal Mask Company (Malaysia) Sdn. Bhd. Removal of Manufacture from Service(s) supplied for Arrow International CR, a.s. (Hradec Kralove) Addition of Degania Silicone Limited, safemed medical devices s.r.o and SP Medical Sp. z.o.o. as subcontractors for Manufacture.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 540595**

Date: **2020-06-09**

Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Date	Reference Number	Action
		Addition of STERIS AST CZ s.r.o., Synergy Sterilisation (M) Sdn Bhd., Synergy Sterilisation Kulim (M) Sdn Bhd., Chemiczna Spółdzieknia, Medicoplast International GmbH, Professional Contract Sterilization Inc., SINA-SterilGamma Sdn Bhd and Teleflex Medical Sdn. Bhd. as subcontractors for ETO Sterilization. Addition of BBF Sterilisationsservice GmbH as subcontractor for Gamma Sterilization. Removal of CeMed GmbH, Tianjin Medis Medical and Willy Rüsch GmbH Administrative correction of details for Arrow Medical Ltd, Chelle Medical Limited, Contract Medical International spol. sr.o., Daqing Medical Device (Tianjin) Co., Ltd, Forefront (Xiamen) Medical Devices Co., Ltd and SP Medical A/S. Change of address for Teleflex Medical Asia Pte. Ltd. Name change from Süddeutsche Feinmechanik GmbH (SFM) to sfm medical devices GmbH Name change from Parker Medical Systems Division - Merrillville to Parker Hannifin CSS Merrillville

ARTICLE 120 SELF-DECLARATION

EU MDD DECLARATION OF CONFORMITY GLOBAL ADDENDUM

FOR EXTENDED TRANSITION TO MDR

Legal Manufacturer (LM)	Name: Teleflex Medical Inc. Address: 3015 Carrington Mill Blvd. Morrisville, NC 27560 USA
Authorized Representative	Name: Teleflex Medical Address: IDA Business and Technology Park Dublin Road Athlone Co. Westmeath Ireland
Incoming Notified Body (MDR NB)	Name: BSI Netherlands Identification Number: CE 2797
Notified Body That Issued the Certificate Under MDD (MDD NB)	Name: SGS Belgium NV Identification Number: 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. 3015 Carrington Mill Blvd. 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
Metal Manual Ligation System (Metal Ligating Clips)	001200 001204 001201 001205 002200 002204 003200 003204 004200 004204 005200 523100 523135 523160 523170 523300 523335 523360 523370 523700 523735 523760 523770 523800 523835 523860 523870 533700 533702 533735 533737 533800 533802 533835 533837 533860 533862 533870	BS EN ISO 13485:2016 – US97/10878 European Directive (Design Examination) 93/42/EEC – US19/819943634	14-JUL-2023	31-DEC-2028	Class III	Rule 8	Annex IX	30-Aug-2021

	533872 534735 534737 534835 534837							

EC Design Examination Certificate: Certificate US19/819943634

Teleflex Medical

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

Device Identification:

Sterile and non-sterile Hemoclip Traditional, Hemoclip Plus, Horizon and Vesocclude Metal Ligation Clips

Intended Purpose of Device:

Sterile and non-sterile ligating clips intended for use in procedures that require the ligation of vessels or anatomic structures, including cardiac and neurological procedures

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on Medical Devices, Annex II, Section 4

It is certified that the manufacturer's design dossier (and product, where applicable) for the above device has been examined and, based on the evidence submitted, it is considered that the device conforms to the relevant Essential Requirements of EC Directive 93/42/EEC.

This certificate is issued in conjunction with a certificate covering the full quality assurance system to Annex II, which must be subject to satisfactory surveillance audits.

This certificate is valid from 01 February 2020 until 25 October 2023
Issue 1. Certified since 25 October 2018
and first certified by SGS Belgium NV since 01 February 2020

Certification is based on report number WW/PCI 606960 dated 20 August 2018

Addenda to that report have been issued on the following dates:

Addendum Date	Reason for Addendum
06 January 2020	Addition of Vesocclude Metal Ligation Clips

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

Certificate US97/10878.02

The management system of

Teleflex Medical

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

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

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

This certificate is valid from 13 July 2021 until 14 July 2024
and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date.
Issue 2. Certified since 26 September 2000

Multiple certificates have been issued for this scope
The main certificate is numbered US97/10878.00

The validity of this certificate depends on the validity of the main certificate.

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

UKAS MANAGEMENT SYSTEMS
0005

21HC 13485 2016 0421 M2

Teleflex Medical

ISO 13485:2016
EN ISO 13485:2016

Issue 2

Detailed scope

Design, development, manufacture and distribution of reusable medical and surgical instruments for general and specialty use; sterile and non-sterile disposable surgical, urology, anaesthesia and respiratory medical devices, sterile disposable electrosurgical medical devices. Design of Non-Sterile Nasal and Oral Mucosal Devices. Design and development of sterile single use absorbable and non-absorbable sutures, pledgets and suture guides and manufacturing of non-sterile absorbable and non-absorbable suture material.. Manufacturing of sterile single use absorbable and non-absorbable sutures.

Distribution of sterile single use absorbable and non-absorbable sutures and non-sterile suture material. Distribution of medical devices for endoscopy; fiber optic illuminators; sterile single use instruments for cardiovascular and general surgical procedures.

UKAS MANAGEMENT SYSTEMS
0005

Certificate US97/10878.00

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

ISO 13485:2016
EN ISO 13485:2016

For the following activities

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

This certificate is valid from 15 July 2021 until 14 July 2024
and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date.
Issue 22. Certified since 26 September 2000

Multiple certificates have been issued for this scope
The main certificate is numbered US97/10878.00
This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

UKAS MANAGEMENT SYSTEMS
0005

21HC 13485 2016 0421 M2

Teleflex Medical

ISO 13485:2016
EN ISO 13485:2016

Issue 22

Detailed scope

Design, development, manufacture and distribution of reusable medical and surgical instruments for general and specialty use; sterile and non-sterile disposable surgical, urology, anaesthesia and respiratory medical devices, sterile disposable electrosurgical medical devices. Design of Non-Sterile Nasal and Oral Mucosal Devices. Design and development of sterile single use absorbable and non-absorbable sutures, pledgets and suture guides and manufacturing of non-sterile absorbable and non-absorbable suture material.. Manufacturing of sterile single use absorbable and non-absorbable sutures.

Distribution of sterile single use absorbable and non-absorbable sutures and non-sterile suture material. Distribution of medical devices for endoscopy; fiber optic illuminators; sterile single use instruments for cardiovascular and general surgical procedures.

Additional facilities

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

UKAS MANAGEMENT SYSTEMS
0005