

EC DECLARATION OF CONFORMITY

Legal Manufacturer Name and Address:	Teleflex Medical 3015 Carrington Mill Blvd. Morrisville NC, 27560 USA
Authorized Representative Name and Address:	Teleflex Medical IDA Business and Technology Park Dublin Road Athlone, Co. Westmeath, Ireland
Notified Body Name and Address:	<input checked="" type="checkbox"/> <i>Class I: Not Applicable</i> <input type="checkbox"/> <i>Class Is, Im, Ila, Ilb, III</i>
<input checked="" type="checkbox"/> Class I <p>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 VII and BSI BS EN ISO 13485:2016, as implemented by the European Union's Medical Devices Regulations.</p>	
<input type="checkbox"/> Class Is, Im, Ila, Ilb, III <p>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 <i>Insert Annex Number</i> and <i>Insert Version (ISO, BSI BS EN ISO, etc.)</i> ISO 13485:<i>Insert Publication Date</i>, as implemented by the European Union's Medical Devices Regulations as verified by the Notified Body listed above:</p> <p>Teleflex Medical confirms that no other application has been lodged with another Notified Body for the same devices related Quality Management System.</p> <p>Teleflex Medical agrees to develop, implement, and maintain a formally-recognized Quality Management System to ensure continued adequacy and efficacy.</p> <p>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.</p> <p>Teleflex Medical confirms that no medicinal products/drugs are incorporated in any devices covered by the Device Schedule.</p> <p>Teleflex Medical agrees to inform the appointed Notified Body of any planned or unplanned substantial change to the Quality Management System.</p> <p>Teleflex Medical agrees to inform the appointed Notified Body of any planned or unplanned significant change to the Device Schedule, if applicable.</p>	
Product Name:	Metal Ligating Clip Appliers and Removers
Classification:	Class I, Rule 6
EC Certificates No.:	Canadian – ISO 13485:2016 – US18/81827522 (MDSAP) European – ISO 13485:2016 / BS EN ISO 13485:2016 – US97/10878
Conformity Assessment Routes:	Annex VII of the MDD (93/42/EEC), EC Declaration of Conformity

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Product Codes:	Product Description	CE Distribution Date:	GMDN Code
Weck Horizon / Hemoclip Metal Clips			
114527	Hemoclip Plus EndoTouch Applier, Medium-Large, 25° Angled, 13"	2010-03	35798
137061	Horizon Applier, Small, Curved, 6"	2010-03	35798
137062	Horizon Applier, Small-Wide, Curved, 6"	2010-03	35798
137081	Horizon Applier, Small, Curved, 8"	2010-03	35798
137082	Horizon Applier Small-Wide, Curved, 8"	2010-03	35798
137085	Horizon Applier, Small, Angled, 8"	2010-03	35798
137086	Horizon Applier, Small-Wide, Angled, 8"	2010-03	35798
137111	Horizon Applier, Small, Curved, 11"	2010-03	35798
137112	Horizon Applier, Small-Wide, Curved, 11"	2010-03	35798
137117	Horizon Multi-Angle Applier, Small-Wide, 45° Angle, 11"	2010-03	35798
137118	Horizon Multi-Angle Applier, Small-Wide, Curved, 11"	2010-03	35798
237061	Horizon Applier, Medium, Curved, 6"	2010-03	35798
237081	Horizon Applier, Medium, Curved, 8"	2010-03	35798
237085	Horizon Applier, Medium, Angled, 8"	2010-03	35798
237111	Horizon Applier, Medium, Curved, 11"	2010-03	35798
237115	Horizon Applier, Medium, Angled, 11"	2010-03	35798
237117	Horizon Applier, Medium, Right Angle, 11"	2010-03	35798
237141	Horizon Applier, Medium, 20° Curved, 14"	2010-03	35798
237145	Horizon Applier, Medium, 55° Angled, 14"	2010-03	35798
238110	Horizon Endoscopic Applier, Medium, 10mm, 11"	2010-03	35798
238170	Horizon Endoscopic Applier, Medium, 10mm, 18"	2010-03	35798
337081	Horizon Applier, Medium-Large, Curved, 8"	2010-03	35798
337085	Horizon Applier, Medium-Large, Angled, 8"	2010-03	35798
337111	Horizon Applier, Medium-Large, Curved, 11"	2010-03	35798
337115	Horizon Applier, Medium-Large, Angled, 11"	2010-03	35798
337117	Horizon Applier, Medium-Large, Right Angle, 11"	2010-03	35798
337141	Horizon Applier, Medium-Large, 20° Curved, 14"	2010-03	35798
337145	Horizon Applier, Medium-Large, 55° Angled, 14"	2010-03	35798
338110	Horizon Endoscopic Applier, Medium-Large, 10mm, 11"	2010-03	35798
338170	Horizon Endoscopic Applier, Medium-Large, 10mm, 18"	2010-03	35798
437081	Horizon Applier, Large, Curved, 8"	2010-03	35798
437085	Horizon Applier, Large, Angled, 8"	2010-03	35798
437111	Horizon Applier, Large, Curved, 11"	2010-03	35798
437115	Horizon Applier, Large, Angled, 11"	2010-03	35798
437117	Horizon Applier, Large, Right Angle, 11"	2010-03	35798
437141	Horizon Applier, Large, 20° Curved, 14"	2010-03	35798
437145	Horizon Applier, Large, 55° Angle, 14"	2010-03	35798
438110	Horizon Endoscopic Clip Applier, Large, 12mm, 11"	2010-03	35798
438170	Horizon Endoscopic Clip Applier, Large, 12mm, 18"	2010-03	35798
523105	Hemoclip Traditional Applier, Medium, Right Angle, 8"	2010-03	35798
523106	Hemoclip Traditional Applier, Medium, Right Angle, 11"	2010-03	35798
523109	Hemoclip Traditional Applier, Medium, Curved, 6"	2010-03	35798
523110	Hemoclip Traditional Applier, Medium, Curved, 8"	2010-03	35798
523111	Hemoclip Traditional Applier, Medium, Curved, 11"	2010-03	35798
523120	Weck Metal Clip Removing Forceps, Straight, 6"	2010-03	10895
523121	Weck Metal Clip Removing Forceps, Angled Shanks, 10"	2010-03	10895
523130	Weck Metal Ligating Clip Cartridge Base, 7"	2010-03	58050
523140	Hemoclip Traditional Applier, Small, Curved, 6"	2010-03	35798
523150	Hemoclip Traditional Applier, Small, Curved, 8"	2010-03	35798
523151	Hemoclip Traditional Applier, Small, Curved, 11"	2010-03	35798

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Document #: FRM-000751	Revision#: 00	Issue Date: See Agile	Parent Document: WI-003907
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523165	Hemoclip Traditional Applier, Medium-Large, Curved, 8"	2010-03	35798
523166	Hemoclip Traditional Applier, Medium-Large, Curved, 11"	2010-03	35798
523167	Hemoclip Traditional Applier, Medium-Large, Right Angle, 8"	2010-03	35798
523168	Hemoclip Traditional Applier, Medium-Large, Right Angle, 11"	2010-03	35798
523175	Hemoclip Traditional Applier, Large, Curved, 8"	2010-03	35798
523177	Hemoclip Traditional Applier, Large, Right Angle, 8"	2010-03	35798
523178	Hemoclip Traditional Applier, Large, Right Angle, 11"	2010-03	35798
523180	Hemoclip Traditional Applier, Large, Curved, 11"	2010-03	35798
523540	Hemoclip Traditional Precision Applier, Small, Curved, 6"	2010-03	35798
523550	Hemoclip Traditional Precision Applier, Small, Curved, 8"	2010-03	35798
523551	Hemoclip Traditional Precision Applier, Small, Curved, 11"	2010-03	35798
533105	Hemoclip Plus Applier, Medium, Right Angle, 8"	2010-03	35798
533106	Hemoclip Plus Applier, Medium, Right Angle, 11"	2010-03	35798
533108	Hemoclip Plus Applier, Medium, 45° Angle, 11"	2010-03	35798
533109	Hemoclip Plus Applier, Medium, Curved, 6"	2010-03	35798
533110	Hemoclip Plus Applier, Medium, Curved, 8"	2010-03	35798
533111	Hemoclip Plus Applier, Medium, Curved, 11"	2010-03	35798
533140	Hemoclip Plus Applier, Small, Curved, 6"	2010-03	35798
533150	Hemoclip Plus Applier, Small, Curved, 8"	2010-03	35798
533151	Hemoclip Plus Applier, Small, Curved, 11"	2010-03	35798
533152	Hemoclip Plus Applier, Small, Right Angle, 8"	2010-03	35798
533164	Hemoclip Plus Applier, Medium-Large, 45° Angle, 11"	2010-03	35798
533165	Hemoclip Plus Applier, Medium-Large, Curved, 8"	2010-03	35798
533166	Hemoclip Plus Applier, Medium-Large, Curved, 11"	2010-03	35798
533167	Hemoclip Plus Applier, Medium-Large, Right Angle, 8"	2010-03	35798
533168	Hemoclip Plus Applier, Medium-Large, Right Angle, 11"	2010-03	35798
533175	Hemoclip Plus Applier, Large, Curved, 8"	2010-03	35798
533177	Hemoclip Plus Applier, Large, Right Angle, 8"	2010-03	35798
533178	Hemoclip Plus Applier, Large, Right Angle, 11"	2010-03	35798
533180	Hemoclip Plus Applier, Large, Curved, 11"	2010-03	35798
533181	Hemoclip Plus Applier, Large, 45° Angle, 11"	2010-03	35798
534140	Hemoclip Plus Applier Small Strongpoint, Curved, 6"	2010-03	35798
534150	Hemoclip Plus Applier Small Strongpoint, Curved, 8"	2010-03	35798
534151	Hemoclip Plus Applier Small Strongpoint, Curved, 11"	2010-03	35798
537061	Horizon Applier, Micro, Curved, 6"	2010-03	35798
537081	Horizon Applier, Micro, Curved, 8"	2010-03	35798
237115DR	Horizon Applier, Medium, Angled, Double-Ring Coat, 11"	2010-03	35798
238110T	Horizon Take-Apart Endoscopic Clip Applier, Medium	2010-03	35798
337115DR	Horizon Applier, Medium-Large, Angled, Double-Ring Coat, 11"	2010-03	35798
337117DR	Horizon Applier, Medium-Large, Right Angle, Double-Ring Coat, 11"	2010-03	35798
338110T	Horizon Take-Apart Endoscopic Applier, Medium-Large	2010-03	35798
437111DR	Horizon Applier, Large, Curved, Double-Ring Coat, 11"	2010-03	35798
437115DR	Horizon Applier, Large, Angled, Double-Ring Coat, 11"	2010-03	35798
437117DR	Horizon Applier, Large, Right Angle, Double-Ring Coat, 11"	2010-03	35798
238200	Horizon Endo Saphenous Vein (ESV) Applier, Medium, 13"	2011-02	35798
137062DR	Horizon Applier, Small-Wide, Curved, Double-Ring Coat, 6"	2010-03	35798
137082DR	Horizon Applier Small-Wide, Curved, Double-Ring Coat, 8"	2010-03	35798
237081DR	Horizon Applier, Medium, Curved, Double-Ring Coat, 8"	2010-03	35798
237111DR	Horizon Applier, Medium, Curved, Double-Ring Coat, 11"	2010-03	35798
237117DR	Horizon Applier, Medium, Right Angle, Double Ring Coat, 11"	2010-03	35798
337081DR	Horizon Applier, Medium-Large, Curved, Double-Ring Coat, 8"	2010-03	35798
337111DR	Horizon Applier, Medium-Large, Curved, Double-Ring Coat, 11"	2010-03	35798
137061R	Horizon Applier, Small, Curved, 6", Refurbished	2012-06	35798
137062R	Horizon Applier, Small-Wide, Curved, 6", Refurbished	2012-06	35798
137081R	Horizon Applier, Small, Curved, 8", Refurbished	2012-06	35798
137082R	Horizon Applier Small-Wide, Curved, 68", Refurbished	2012-06	35798

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Document #: FRM-000751	Revision#: 00	Issue Date: See Agile	Parent Document: WI-003907
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137085R	Horizon Applier, Small, Angled, 8", Refurbished	2012-06	35798
137086R	Horizon Applier, Small-Wide, Angled, 8", Refurbished	2012-06	35798
137111R	Horizon Applier, Small, Curved, 11", Refurbished	2012-06	35798
137112R	Horizon Applier, Small-Wide, Curved, 11"	2012-06	35798
237061R	Horizon Applier, Medium, Curved, 6", Refurbished	2012-06	35798
237081R	Horizon Applier, Medium, Curved, 8", Refurbished	2012-06	35798
237085R	Horizon Applier, Medium, Angled, 8", Refurbished	2012-06	35798
237111R	Horizon Applier, Medium, Curved, 11", Refurbished	2012-06	35798
237115R	Horizon Applier, Medium, Angled, 11", Refurbished	2012-06	35798
337081R	Horizon Applier, Medium-Large, Curved, 8", Refurbished	2012-06	35798
337085R	Horizon Applier, Medium-Large, Angled, 8", Refurbished	2012-06	35798
337111R	Horizon Applier, Medium-Large, Curved, 11", Refurbished	2012-06	35798
337115R	Horizon Applier, Medium-Large, Angled, 11", Refurbished	2012-06	35798
337117R	Horizon Applier, Medium-Large, Right Angle, 11"	2012-06	35798
437081R	Horizon Applier, Large, Curved, 8", Refurbished	2012-06	35798
437085R	Horizon Applier, Large, Angled, 8", Refurbished	2012-06	35798
437111R	Horizon Applier, Large, Curved, 11", Refurbished	2012-06	35798
437115R	Horizon Applier, Large, Angled, 11", Refurbished	2012-06	35798
437117R	Horizon Applier, Large, Right Angle, 11", Refurbished	2012-06	35798
137117R	Horizon Multi-Angle Applier, Small-Wide, 45° Angle, 11", Refurbished	2012-06	35798
137118R	Horizon Multi-Angle Applier, Small-Wide, Curved, 11", Refurbished	2012-06	35798
237117R	Horizon Applier, Medium, Right Angle, 11", Refurbished	2012-06	35798
237141R	Horizon Applier, Medium, 20° Curved, 14", Refurbished	2012-06	35798
237145R	Horizon Applier, Medium, 55° Angled, 14", Refurbished	2012-06	35798
337141R	Horizon Applier, Medium-Large, 20° Curved, 14", Refurbished	2012-06	35798
337145R	Horizon Applier, Medium-Large, 55° Angled, 14", Refurbished	2012-06	35798
437141R	Horizon Applier, Large, 20° Curved, 14", Refurbished	2012-06	35798
437145R	Horizon Applier, Large, 55° Angle, 14", Refurbished	2012-06	35798
537061R	Horizon Applier, Micro, Curved, 6", Refurbished	2012-06	35798
537081R	Horizon Applier, Micro, Curved, 8", Refurbished	2012-06	35798
523105R	Hemoclip Traditional Applier, Medium, Right Angle, 8", Refurbished	2012-06	35798
523106R	Hemoclip Traditional Applier, Medium, Right Angle, 11", Refurbished	2012-06	35798
523109R	Hemoclip Traditional Applier, Medium, Curved, 6", Refurbished	2012-06	35798
523110R	Hemoclip Traditional Applier, Medium, Curved, 8"	2012-06	35798
523111R	Hemoclip Traditional Applier, Medium, Curved, 11", Refurbished	2012-06	35798
523140R	Hemoclip Traditional Applier, Small, Curved, 6", Refurbished	2012-06	35798
523150R	Hemoclip Traditional Applier, Small, Curved, 8", Refurbished	2012-06	35798
523151R	Hemoclip Traditional Applier, Small, Curved, 11", Refurbished	2012-06	35798
523165R	Hemoclip Traditional Applier, Medium-Large, Curved, 8", Refurbished	2012-06	35798
523166R	Hemoclip Traditional Applier, Medium-Large, Curved, 11", Refurbished	2012-06	35798
523167R	Hemoclip Traditional Applier, Medium-Large, Right Angle, 8", Refurbished	2012-06	35798
523168R	Hemoclip Traditional Applier, Medium-Large, Right Angle, 11", Refurbished	2012-06	35798
523175R	Hemoclip Traditional Applier, Large, Curved, 8", Refurbished	2012-06	35798
523177R	Hemoclip Traditional Applier, Large, Right Angle, 8", Refurbished	2012-06	35798
523178R	Hemoclip Traditional Applier, Large, Right Angle, 11", Refurbished	2012-06	35798
523180R	Hemoclip Traditional Applier, Large, Curved, 11", Refurbished	2012-06	35798
523540R	Hemoclip Traditional Precision Applier, Small, Curved, 6", Refurbished	2012-06	35798
523550R	Hemoclip Traditional Precision Applier, Small, Curved, 8", Refurbished	2012-06	35798
523551R	Hemoclip Traditional Precision Applier, Small, Curved, 11", Refurbished	2012-06	35798
523120R	Weck Metal Clip Removing Forceps, Straight, 6", Refurbished	2012-06	10895
523121R	Weck Metal Clip Removing Forceps, Angled Shanks, 10", Refurbished	2012-06	10895
523130R	Weck Metal Ligating Clip Cartridge Base, 7", Refurbished	2012-06	58050
533105R	Hemoclip Plus Applier, Medium, Right Angle, 8", Refurbished	2012-06	35798
533106R	Hemoclip Plus Applier, Medium, Right Angle, 11", Refurbished	2012-06	35798
533108R	Hemoclip Plus Applier, Medium, 45° Angle, 11", Refurbished	2012-06	35798
533109R	Hemoclip Plus Applier, Medium, Curved, 6", Refurbished	2012-06	35798

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533110R	Hemoclip Plus Applier, Medium, Curved, 8", Refurbished	2012-06	35798
533111R	Hemoclip Plus Applier, Medium, Curved, 11", Refurbished	2012-06	35798
533140R	Hemoclip Plus Applier, Small, Curved, 6", Refurbished	2012-06	35798
533150R	Hemoclip Plus Applier, Small, Curved, 8", Refurbished	2012-06	35798
533151R	Hemoclip Plus Applier, Small, Curved, 11", Refurbished	2012-06	35798
533152R	Hemoclip Plus Applier, Small, Right Angle, 8", Refurbished	2012-06	35798
533164R	Hemoclip Plus Applier, Medium-Large, 45° Angle, 11", Refurbished	2012-06	35798
533165R	Hemoclip Plus Applier, Medium-Large, Curved, 8", Refurbished	2012-06	35798
533166R	Hemoclip Plus Applier, Medium-Large, Curved, 11", Refurbished	2012-06	35798
533167R	Hemoclip Plus Applier, Medium-Large, Right Angle, 8", Refurbished	2012-06	35798
533168R	Hemoclip Plus Applier, Medium-Large, Right Angle, 11", Refurbished	2012-06	35798
533175R	Hemoclip Plus Applier, Large, Curved, 8", Refurbished	2012-06	35798
533177R	Hemoclip Plus Applier, Large, Right Angle, 8", Refurbished	2012-06	35798
533178R	Hemoclip Plus Applier, Large, Right Angle, 11", Refurbished	2012-06	35798
533180R	Hemoclip Plus Applier, Large, Curved, 11", Refurbished	2012-06	35798
533181R	Hemoclip Plus Applier, Large, 45° Angle, 11", Refurbished	2012-06	35798
534140R	Hemoclip Plus Applier Small Strongpoint, Curved, 6", Refurbished	2012-06	35798
534150R	Hemoclip Plus Applier Small Strongpoint, Curved, 8", Refurbished	2012-06	35798
Vesocclude Metal Ligation Applier / Remover			
70010	Vesocclude Remover CVD 11"	2020-01	35649
70060	Vesocclude Remover STRAIGHT 6"	2020-01	35649
70212	Vesocclude Applier SMALL CVD 11"	2020-01	35649
70212L	Vesocclude Applier SMALL CVD 11"	2020-01	35649
70262	Vesocclude Applier SMALL CVD 6" 152MM	2020-01	35649
70282	Vesocclude Applier SMALL CVD 8" 203MM	2020-01	35649
70282L	Vesocclude Applier SMALL CVD 8"	2020-01	35649
70285	Vesocclude Applier SMALL 55° ANG 8"	2020-01	35649
70285L	Vesocclude Applier SMALL 55° ANG 8"	2020-01	35649
70312	Vesocclude Applier SW CVD 11" 280MM	2020-01	35649
70362	Vesocclude Applier SW CVD 6" 152MM	2020-01	35649
70382	Vesocclude Applier SW CVD 8"	2020-01	35649
70385	Vesocclude Applier SW 55° ANG 8"	2020-01	35649
70412	Vesocclude Applier MED CVD 11" 280MM	2020-01	35649
70415	Vesocclude Applier MED 55° ANG 280MM	2020-01	35649
70417	Vesocclude Applier MED 70° ANG 280MM	2020-01	35649
70462	Vesocclude Applier MED CVD 6" 152MM	2020-01	35649
70482	Vesocclude Applier MED CVD 8" 203MM	2020-01	35649
70485	Vesocclude Applier MED 55° ANG 8" 203MM	2020-01	35649
70512	Vesocclude Applier ML CVD 11" 280MM	2020-01	35649
70515	Vesocclude Applier ML 55° ANG 11" 280MM	2020-01	35649
70582	Vesocclude Applier ML CVD 8" 203MM	2020-01	35649
70585	Vesocclude Applier ML 55° ANG ML 8" 203MM	2020-01	35649
70612	Vesocclude Applier L CVD 11" 280MM	2020-01	35649
70615	Vesocclude Applier L 55° ANG 11" 280MM	2020-01	35649
70617	Vesocclude Applier L 70° ANG 11"	2020-01	35649
70682	Vesocclude Applier L CVD 8" 203MM	2020-01	35649
70685	Vesocclude Applier L 55° ANG 8"	2020-01	35649
80402X	Vesocclude Applier MED Endo CVD 13" 33CM	2020-01	35649
80502X	Vesocclude Applier ML Endo CVD 13" 280MM	2020-01	35649
80602	Vesocclude Applier L Endo CVD 11"	2020-01	35649
90502	Vesocclude APLR ML Endo D 10/11MM L 18" 457MM	2020-01	35649
90602	Vesocclude APLR ML Endo D 12MM L 18" 457MM	2020-01	35649

*** 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**

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Name and Title of Approver:	Kim Campbell RA Team Lead, Surgical
Signature of Approver:	
Date Approved:	05May2020
Site Where Approved:	Teleflex Medical 3015 Carrington Mill Blvd. Morrisville NC, 27560 USA

Canadian Classification

The following devices meet Canadian requirements as listed:

Device	Canadian License #	Issue Date	Class of Product
533105	87334	2011-10-05	2
533106	87334	2011-10-05	2
533108	87334	2011-10-05	2
533109	87334	2011-10-05	2
533110	87334	2011-10-05	2
533111	87334	2011-10-05	2
533140	87334	2011-10-05	2
533150	87334	2011-10-05	2
533151	87334	2011-10-05	2
533152	87334	2011-10-05	2
533164	87334	2011-10-05	2
533165	87334	2011-10-05	2
533166	87334	2011-10-05	2
533167	87334	2011-10-05	2
533168	87334	2011-10-05	2
533175	87334	2011-10-05	2
533177	87334	2011-10-05	2
533178	87334	2011-10-05	2
533180	87334	2011-10-05	2
533181	87334	2011-10-05	2
534140	87334	2011-10-05	2
534150	87334	2011-10-05	2
534151	87334	2011-10-05	2
533105R	87334	2012-07-06	2
533106R	87334	2012-07-06	2
533108R	87334	2012-07-06	2
533109R	87334	2012-07-06	2
533110R	87334	2012-07-06	2
533111R	87334	2012-07-06	2
533140R	87334	2012-07-06	2
533150R	87334	2012-07-06	2
533151R	87334	2012-07-06	2
533152R	87334	2012-07-06	2
533164R	87334	2012-07-06	2
533165R	87334	2012-07-06	2
533166R	87334	2012-07-06	2
533167R	87334	2012-07-06	2

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533168R	87334	2012-07-06	2
533175R	87334	2012-07-06	2
533177R	87334	2012-07-06	2
533178R	87334	2012-07-06	2
137061R	87334	2012-07-06	2
137062R	87334	2012-07-06	2
137081R	87334	2012-07-06	2
137082R	87334	2012-07-06	2
137085R	87334	2012-07-06	2
137086R	87334	2012-07-06	2
137111R	87334	2012-07-06	2
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80402X	94160	6/18/2018	2
80502X	94160	6/18/2018	2
80602	94160	6/18/2018	2
90502	94160	6/18/2018	2
90602	94160	6/18/2018	2

Product Description	Weck and Vesocclude Ligating Appliers and Removers are designed for use in general open and endoscopic surgical procedures where the appropriate corresponding Weck and Vessocclude Ligating Clips are normally applied. The appliers and removers are manufactured from stainless steels, which allow for durability, reprocessing, and reuse. Clip appliers are manually operated and deliver one clip at a time.										
Indications for Use	<p>Weck and Vesocclude Ligating Clip Appliers are indicated for use as delivery devices for Weck metal ligating clips. Other ligating clips cannot be used with these appliers.</p> <p>Weck and Vesocclude Metal Ligating Clip Removing Forceps are designed to allow the removal of all Weck metal ligating clips during open procedures.</p>										
Intended Use	<p>Weck and Vesocclude Ligating Clip Appliers are indicated for use as delivery devices for Weck metal ligating clips. Other ligating clips cannot be used with these appliers.</p> <p>Weck and Vesocclude Metal Ligating Clip Removing Forceps are designed to allow the removal of all Weck metal ligating clips during open procedures.</p>										
Contraindications	<p>Weck and Vesocclude ligating clips are not intended for use as a contraceptive tubal occlusion device.</p> <p>Weck and Vesocclude ligating clips are contraindicated for use in ligating the renal artery during laparoscopic donor nephrectomies.</p>										
Manufacturing Site(s)	<table border="1"> <thead> <tr> <th>Manufacturing Site Name</th> <th>Manufacturing Site Address</th> </tr> </thead> <tbody> <tr> <td>Weck Ligating Appliers/Removers Tecomet Inc.</td> <td>5307 95th Ave. Kenosha, WI 53144 United States</td> </tr> <tr> <td>Weck Ligating Appliers/Removers Koscher & Wuertz</td> <td>Einsteinstrasse 7 Spaichingen, DE-BW Germany 78549</td> </tr> <tr> <td>Vesocclude Ligating Appliers Trimed LLC</td> <td>9310 Focal Point Raleigh, NC 27617</td> </tr> </tbody> </table>			Manufacturing Site Name	Manufacturing Site Address	Weck Ligating Appliers/Removers Tecomet Inc.	5307 95 th Ave. Kenosha, WI 53144 United States	Weck Ligating Appliers/Removers Koscher & Wuertz	Einsteinstrasse 7 Spaichingen, DE-BW Germany 78549	Vesocclude Ligating Appliers Trimed LLC	9310 Focal Point Raleigh, NC 27617
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Sterilizer	<input checked="" type="checkbox"/> N/A: The product is sold non-sterile. <input type="checkbox"/> The product is sold sterile. <table border="1" style="margin-top: 10px;"> <thead> <tr> <th>Sterilization Site Name</th> <th>Sterilization Site Address</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> </tr> </tbody> </table>			Sterilization Site Name	Sterilization Site Address						
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