Summary of Safety and Clinical Performance

Product
SOLID CLIP™ Single Use Clip Applier
Version
C
File Number
SSCP-CA-01

Prepared by		Reviewed by		Approved by	
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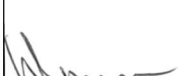
Position	RA specialist	Position	RA director	Position	R&D director
Date	2025-02-14	Date	2025-02-14	Date	2025-02-14
Signature		Signature		Signature	

List of Revision

Item	Version	Description of change	Date	Revision validated by the Notified Body
1	A	New establishment to be conformed with MDR.	2022-11-07	□Yes. Validation language: English □No
2	B	Modify the contents to conform to MDR Assessment Round 1	2024-05-21	□Yes. Validation language: English □No
3	*C*	*Modify the contents to conform to MDR Assessment Round 2*	*2024-10-22*	☒Yes. Validation language: English □No

Summary

Surgical clip appliers having a plurality of clips for applying the clips to body tissues and vessels during surgical procedures and their methods of use. Medscope clip applier is intended for the occlusion of vessels and other tubular structures in various types of laparoscopic procedures and radiographic marking.

1. Device identification and general information

1.1 Device trade name(s)

SOLID CLIP™ Single Use Clip Applier

1.2 Manufacturer's name and address

2F, No. 8, Keyi Street. Guang Yuan Technology Park, Zhunan Town, 35059 Miaoli County, TAIWAN

1.3 Manufacturer's single registration number (SRN)

TW-MF-000013932

1.4 Basic UDI-DI

47198769901Y4

1.5 Medical device nomenclature description / text

H020303, SUTURE DEVICES/ CLIP APPLIERS

1.6 Class of device

Class IIb, Rule 8

1.7 Year when the first (CE) was issued covering the device

2017

1.8 Authorized representative is applicable; name and the SRN

MedNet EC-REP IIb GmbH

1.9 NB's name and the NB's single identification number

TUV SUD Product service GmbH, 0123

2. Intended use of the device

2.1 Intended purpose

The SOLID CLIP Single Use Clip Applier is intended for permanent closure and ligation of appropriately sized vessels and other tubular tissues.

2.2 Indication(s) and target population(s)

Items	Contents
Indication for use	*Closure and ligation of appropriately sized vessels and other tubular tissues are required to achieve*

	the tissue dissection of the following laparoscopic surgery.
Intended patient population	Patient requiring ligation of vessels or other *tubular tissues*, but not suitable for newborn infants or premature neonates. No limit for gender, weight range and nationality.
Environments for use	The device will be opened in operating room of the hospital and operating in surgical.
Intended user	Trained medical professionals, Surgeon.
Contacted part (Organs / parts of the body / tissues or body fluids)	Jaw/ Shaft: Tissue Clip: Vessel
Duration of use or contact with the body	Titanium clip is implant.
Contact type (mucosal membranes, invasiveness or implantation)	Jaw/ Shaft: Tissue Titanium Clip: Implantation
Contraindications	1. Do not apply in contraceptive tubal occlusion, but might be used to achieve hemostasis of blood vessels following transection of the fallopian tube. 2. Do not use the device on renal artery, iliac artery, vessels of the central circulatory, other tissue structures or vessels upon which metal ligating clips would not normally be used.
Precautions required by the manufacturer	Warnings: 1. Remove the release plug before using this product. 2. Prior insertion or removal of the SOLID CLIP Single Use Clip Applier from a trocar sleeve (or with the aid of a converter), please ensure that the clip is not preloaded into the jaw, in order to prevent a clip from dropping into the body of the patient. If a clip appears on the jaw tip when removing the jaw from the targeted structure, please fully squeeze to close the jaw

	tip before removing the trocar sleeve and release the trigger to discard the formed clip outside the patient's body. 3. Prior squeezing the trigger to place a clip, please visually confirm that the clip is positioned free from other clips and obstructions. Firing a clip over an obstruction may result in malformed clips, which may cause a lack of hemostasis or damage to the jaw. 4. Ensure that the vessels or other tubular structures completely fit within the confines of the clip, otherwise may cause bleeding or damage. 5. When firing the device, squeeze the trigger firmly as far as it can go. Failure to squeeze the trigger can cause clip malformation, which may result in bleeding, leakage and/or tissue damage. 6. Confirm the closed clips are not applied across with others or obstructions when proceeding with the procedure of hemostasis. If minor bleeding and or leakage is observed after successive application, electrocautery or surgical suture, etc. 7. Do not excessively twist the jaw or overload the tissue when firing the SOLID CLIP™ Single Use Clip Applier. 8. Do not apply too much lateral load to the jaw; otherwise, jaw deformation tends to occur and will result in the undesirable firing of the clip. 9. When the jaw is nearby the tissue, do not close the unloaded jaw. 10. When transecting the occluded structure,

	leave a sufficient margin of tissue to reduce the potential for the shift of the clip, which can result in bleeding and/or leakage. 11. Endoscopic procedures should be performed only by physicians that had adequate training and familiarity with endoscopic techniques. Before performing any endoscopic procedures, please consult the medical literature relative to techniques, complications, and hazards. 12. A thorough understanding of the principles and techniques involved in endoscopic laser and electrosurgical procedures is necessary to avoid shock and burn hazards to both patient and user(s) or damage to the instrument. Verify compatibility of instrumentation and ensure that electrical isolation or grounding is not compromised. 13. Caution should be exercised when utilizing electrosurgical techniques in the vicinity of any metallic clip. Inadvertent contact with a metallic dip by energized electrosurgical devices may cause unintentional cauterization or electrocoagulation at or around the clip position site which may cause necrosis of the affected tissue. Dislodgement of the clip could occur, resulting in bleeding and or leakage. 14. SOLID CLIP ™ Single Use Clip Applier is not suitable for newborn infants or premature neonates. 15. Do not use the SOLID CLIP™ Single Use Clip Applier if the package is opened or damaged. In case of product failure, please contact the distributor or the manufacturer.

	16. The clip inside the device allows MRI and/or NMR performed at 3.0 Tesla or less strength after implantation. 17. The device is a sterile medical device manufactured by EO sterilization and is intended for single use only. Discard after using it; do not re-sterilize and use it again. 18. The device should be stored at room temperature away from sunlight and humidity. 19. If any serious incident has occurred in relation to the device, it should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. This device should be disposed of in accordance with all applicable regulations including, without limitation, those pertaining to human health and safety and the environment.
Single use / reusable	Single use clip applier is single use.
Repeat applications, including any restrictions as to the number or duration of re- applications	Do not reuse.

2.3 Contraindications and/or limitations

1. Do not apply in contraceptive tubal occlusion, but might be used to achieve hemostasis of blood vessels following transection of the fallopian tube.
2. Do not use the device on renal artery, iliac artery, vessels of the central circulatory, other tissue structures or vessels upon which metal ligating clips would not normally be used.

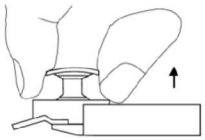
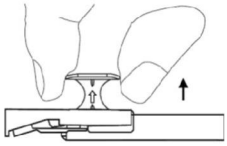
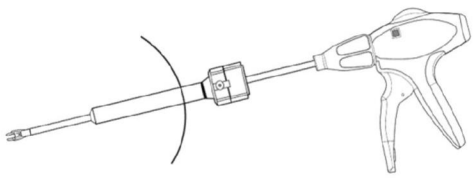
3. Device description

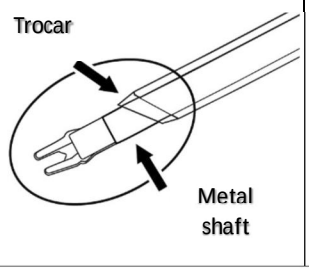
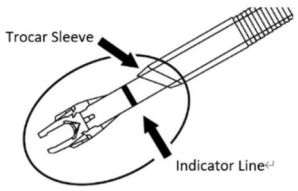
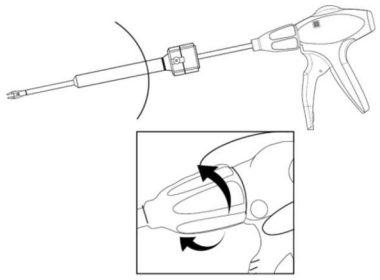
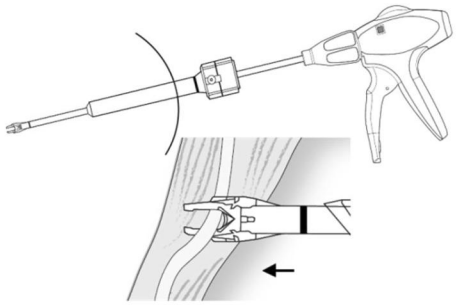
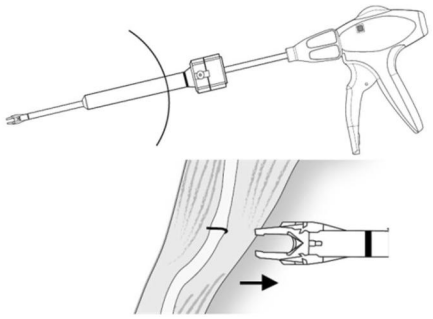
3.1 Description of the device

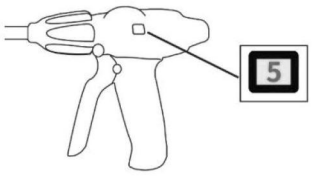
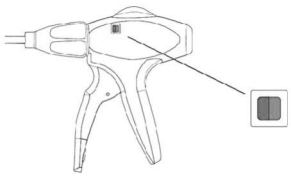
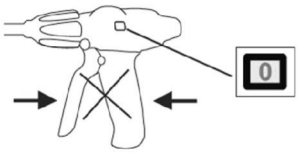
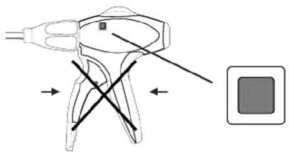
The SOLID CLIP™ Single Use Clip Applier is a EO sterile, single patient use device designed for an appropriately sized trocar sleeve or larger sized trocar sleeve with the use of a converter. It consists of a shaft with an outer diameter of 10 or 5 mm and length of 33 cm, a jaw for forming ligating

clips, a pistol handle, an actuation trigger, a 360 degrees rotational knob, and a clip counter.
The shaft with outer diameter 10 mm was preloaded 10, 15, 20 ML (Medium-Large) or 10, 15 L (Large) titanium clips, outer diameter 5 mm shaft only preloaded 10, 15 ML (Medium-Large) titanium clips. The titanium clip, which made of pure titanium, will be implanted; the outer tube and the jaw, which made of SUS304 and SUS630, will in contact with the patient's tissue below 24 hours. Squeezing the trigger places a titanium clip in the jaws and closes the jaws to form the clip on the occlusion of the vessel or tubular structure. Wide range specifications in clip specifications allow the user requires to use the device appropriately, and can also provide the user to select the corresponding and the optimum medical needs. The new or different technological characteristics are considered to be customer preference driven and didn't raise new questions of safety or effectiveness after non-clinical performance testing. The design of SOLID CLIP™ Single Use Clip Applier provides secured placement of the clip to the targeted vessel and enables the surgeon to apply the clips during a laparoscopic procedure without the need for withdrawing and reinserting the device each time a clip is put in place and closed. Safety interlock prevents the trigger to be squeezed when the clip is empty in the device. This feature will prevent closing the jaw without a clip condition, in order to minimize the risk of unintended duct or vessel damage. The Safety interlock still easy removal the device throughout the trocar.

By the clamping force in the blood vessels or tubular tissue to block the blood or body fluids. The mode of action can be referred to the IFU (SINGLE USE CLIP APPLIER), "DIRECTIONS FOR USE" to see the details.

<table>
<tr><td rowspan="2">1. Remove the release plug from the jaw and confirm the clip numbers will be consistent with the specification of the SOLID CLIP™ Single Use Clip Applier.</td><td>CA16 series</td><td>CA56 series</td></tr>
<tr><td>  </td><td>  </td></tr>
<tr><td>2. Insert the SOLID CLIP™ Single Use Clip Applier through an appropriately sized trocar sleeve.
Note: Ensure that a clip is not preloaded into the jaw, in order to prevent an open clip from dropping into the body of the patient.</td><td colspan="2">  </td></tr>
<tr><td>3. Upon the insertion of the SOLID CLIP™</td><td>CA16 series</td><td>CA56 series</td></tr>
</table>

<table>
<tr><td>Single Use Clip Applier through the trocar sleeve and prior to loading a clip into the jaw. Ensure the metal shaft (CA16 series) or the indication line (CA56 series) on the shaft is fully visible. This can prevent interference between the jaw and the trocar.</td><td> 
</td><td> 
</td></tr>
<tr><td>4. Turn the Rotation Knob 360 ◦ in either direction to adjust the visibility of the jaw.</td><td colspan="2">  </td></tr>
<tr><td>5. Place the jaw around the vessels or other tubular structures, making sure it is positioned completely within the jaw. Squeeze the trigger to push the clip into position in the jaw. Ensure the clip is loaded and properly positioned within the jaw before continuing to firmly squeeze the trigger to close the clip. (An audible click will be heard/felt.)</td><td colspan="2">  </td></tr>
<tr><td>6. Release the trigger and remove the jaw from the vessels and other tubular structures to complete the closure of the clip. Repeat Step 4 for subsequent applications.</td><td colspan="2">  </td></tr>
<tr><td colspan="3">Description of the Counter Window</td></tr>
<tr><td>1. The counter window shows a yellow block</td><td>CA16 series</td><td>CA56 series</td></tr>
</table>

<table>
<tr><td>to warn the user when there are only 5 clips left in the SOLID CLIP™ Single Use Clip Applier (CA16 series).
2. When 3rd clip is left, a green/red bar will begin to appear in the counter window on top of the SOLID CLIP™ Single Use Clip Applier (CA56 series) handle.</td><td>  </td><td>  </td></tr>
<tr><td rowspan="2">3. When there are no clips left in the SOLID CLIP™ Single Use Clip Applier (CA16 series), the counter window will show “0”, indicating the clip quantity is zero. A Safety Interlock feature will prevent the handle and trigger from being squeezed.
4. When the clip is empty, the red bar completely fills the counter window of SOLID CLIP™ Single Use Clip Applier (CA56 series).</td><td>CA16 series</td><td>CA56 series</td></tr>
<tr><td>  </td><td>  </td></tr>
<tr><td colspan="3">Note: If the counter window shows there are clips left while removing the device, ensure that there is no clip in the Jaw to prevent the clip from dropping into the body of the patient. The safety interlock feature will prevent the trigger be squeezed when the clip is closing the jaw without a clip condition, in order to minimize the risk of unintended duct or vessel damage.</td></tr>
</table>

3.2 A reference to previous generation(s) or variants if such exist, and a description of the differences

There are no previous generations of the device produced. The devices currently produced are the same design as produced previously.

3.3 Description of any accessories which are intended to be used in combination with the device

Prior to insert the clip applier, the device must be combined the trocar. The trocars have been tested and can be used in combination with Single use clip applier as shown in the following list:

No.	Brand and model	Specification requirements	Testing result
1	Brand: Ethicon Model type: MA02905	Inner Diameter of trocar is 5.9 mm. Passing CA56 series through the trocar is unobstructed	The Single use clip applier can pass smoothly through and operate normally.
2	Brand: ConMed Corporation Model type: BV-5X70	Inner Diameter of trocar is 5.8 mm. Passing CA56 series through the trocar is	The Single use clip applier can pass smoothly through and operate normally.

		unobstructed	
3	Brand: ConMed Model type: CORE DYNAMICS REF16162	Inner Diameter of trocar is 11.4 mm. Passing CA16 series through the trocar is unobstructed	The Single use clip applier can pass smoothly through and operate normally.
4	Brand: Covidien Model type: MA93160 (5-12mm)	Inner Diameter of trocar is 12.8 mm. Passing CA16 and CA56 series through the trocar is unobstructed	The Single use clip applier can pass smoothly through and operate normally.

4. Risks and warnings

4.1 Residual risks and undesirable effects

Complications of this product are identical to those possibly triggered by laparoscopic procedures and include, without limitation, *Infection, Leakage/Bleeding, Hematoma and Intra abdominal abscess, the quantitative data on side-effects were describe in Section 5.3.*

4.2 Warnings and precautions

1. Remove the release plug first before using this product
2. Remove the release plug first before using this product. Prior to insertion or removal of this product from a trocar sleeve (or with the use of a converter), please ensure that the clip is not preloaded into the jaw, to prevent a clip from dropping into the patient's body. If a clip appears on the jaw tip when removing the jaw from the targeted structure, please fully squeeze to close the jaw tip before removing the trocar sleeve and release the trigger to discard the formed clip outside the patient's body
3. Prior to squeezing the trigger to place a clip, visually confirm that the clip is positioned free of other clips and obstructions. Firing a clip over another clip may result in malformation of the clip, which may cause a lack of hemostasis or damage to the jaw
4. Ensure that the target completely fits within the confines of the clip, or bleeding/ damage may occur.
5. When firing the clip, squeeze the trigger firmly as far as it will go. Failure to squeeze the trigger can cause a malformed clip, resulting in bleeding or damage to the tissue.
6. Confirm the closed clip that is not applied across with others or obstructions and carry out the hemostasis procedure. If minor bleeding, it is advised to adequately apply electrocautery or surgical suture, etc.
7. Do not excessively twist the jaw or overload the tissue when firing this product.
8. Do not apply too much lateral load to the jaw; otherwise, jaw deformation tends to occur and will result in the undesirable firing of the clip.
9. When the jaw is nearby the tissue, do not close the unloaded jaw.

10. When transecting the occluded structure, leave a sufficient margin at the end of tissue to avoid the shift of the clip, which can cause bleeding and/ or leakage.
11. Endoscopic procedures should be performed only by physicians having adequate training and familiarity with endoscopic techniques. Prior to performing any endoscopic procedures, consult the medical literature relative to techniques, complications, and hazards.
12. A thorough understanding of the principles and techniques involved in endoscopic laser and electrosurgical procedures is necessary to avoid shock and burn hazards to both patient and user(s) or damage to the instrument. Verify compatibility of instrumentation and ensure that electrical isolation or grounding is not compromised.
13. Caution should be exercised when utilizing electrosurgical techniques in the vicinity of any metallic clip. Inadvertent contact with a metallic clip by energized electrosurgical devices may cause unintentional cauterization or electrocoagulation at or around the clip site, affecting the tissue. Dislodgement of the clip could occur, resulting in bleeding and/or leakage.
14. This product is not intended for use in newborn infants or premature neonates.
15. DO NOT use this product if the package is opened or damaged. In case of product failure, please contact the distributor or the manufacturer.
16. The clip inside this device allows MRI and/or NMR performed at 3.0 Tesla or less strength after it is implanted.
17. This product is a sterile medical device manufactured by EO sterilization and is intended for single use only. Discard after using it; do not re-sterilize and use it again.
18. This product should be stored at room temperature away from sunlight and humidity.

4.3 Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable

There has not been any Field Safety Corrective Action (FSCA) or Field Safety Notice (FSN) for any Medscope's product.

5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

5.1 Summary of clinical data related to similar device, if applicable

5.1.1 The basic information of similar device

Name	*Endo Clip™ II Clip Applier and* *Endo Clip™ III Clip Applier*
Manufacturer	*Covidien LLC.*
Has valid MDD CE certificate	*0123*
Type	*Endo Clip™ II Clip Applier, 176657* *Endo Clip™ III Clip Applier, 176630*

5.1.2 Due to the clinical data is not available to public in literature from Covidien LLC. Endo Clip™ II Clip Applier, neither independently published nor as company presentation, current clinical data is based on published literatures, which were summarized in Section 5.3, from the literatures, we list side-effects that may occur after clip applier surgery.

5.2 Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable

There were no specific clinical investigations performed on the device before CE-marking.

5.3 Summary of clinical data from other sources, if applicable

5.3.1 Summary of Literature review

A literature review has been conducted to support the clinical safety and performance of the subject device, quantitative data on side-effects or residual risks relate to clinical data. The results are summarized in the following table:

Literature	*Clinical Claim*	*Justification*
M. Yamazaki,H. Yasuda,K. Koda (2015) Single-incision laparoscopic cholecystectomy: a systematic review of methodology and outcomes. Surg Today.45(5):537-48.	*Different operative methods of Single-incision laparoscopic cholecystectomy to treat acute cholecystitis.*	*The postoperative side-effects and occurrence rate of cholecystectomy using different methods including clip applier were collected in the article.*
G. S Mannu, M. K Sudul, J. H .-Silva, E. Cumber,F. Li, A. B Clark, Y. K Loke (2017) *Closure methods of the appendix stump for complications during laparoscopic appendectomy (Review). Cochrane Database Syst Rev.11(11):CD006437.*	*Closure of the appendix stump during laparoscopic appendectomy.*	*A variety of methods to close the appendix stump are used and compared, including titanium clips, ligature, stapler device.*
X.-M. Ai,L.-C. Ho,N.-Y. Yang,L.-L. Han,J.-J. Lu,X. Yue (2018) A comparative study of ultrasonic scalpel (US) versus conventional metal clips for closure of the	*closure of the cystic duct in laparoscopic cholecystectomy.*	*Eight studies met eligibility criteria in this meta-analysis eventually, ultrasonic scalpel (US) group compare with metal clips*

cystic duct in laparoscopic cholecystectomy (LC): A meta-analysis. Medicine (Baltimore).97(51): e13735.		*group in laparoscopic cholecystectomy.*
S. R. Knight,A. Ibrahim,N. Makaram,P. Patil,M. S. James Wilson (2019) The use of polymeric clips in securing the appendiceal stump during laparoscopic appendicectomy: a systematic review. Eur J Trauma Emerg Surg.45(4):665-670.	*securing the appendiceal stump during laparoscopic appendicectomy*	*Ten studies were included, appendiceal stump closure during laparoscopic appendicectomy using polymeric clips compared to other methods of stump closure were included.*
Aafke H van Dijk, et al. (2018) Systematic review of cystic duct closure techniques in relation to prevention of bile duct leakage after laparoscopic cholecystectomy	*closure of the cystic duct in laparoscopic cholecystectomy.*	*Not possible to either recommend or discourage any of the techniques for cystic duct closure during LC with respect to cystic duct leakage.*

Base on the state of the art literature, there still have some adverse events that may happen when using clip applier, we compare the adverse events from SOTA literature and from the Medscope PMCF results of *Single Use Clip as following*

Item	*Outcome*	*Occurrence rate*
Safety parameter	*Leakage/Bleeding*	*1.0%*
	Infection	*0.62%*
	Organ lesion/Injury	*0.06%*
	Hematoma	*0.13%*
	Intra-abdominal abscess	*0.84%*
Performance parameter	*Technique Failure*	*2.8%*

**Abscesses can occur anywhere in the abdomen and retroperitoneum. They mainly occur after surgery, trauma, or conditions involving abdominal infection and inflammation, particularly when peritonitis or perforation occurs.*

5.3.2 Long-term safety and performance from SOTA literature

One of the long-term concerns with clips applier is the risk of migration. Migration can lead to serious complications, including damage to nearby structures, such as blood vessels or organs.

5.4 An overall summary of the clinical performance and safety

The complaint rate for the clip applier is low which is indicative of the performance and safety of the device. There is nothing new from the clinical literature that would indicate that clip applier is not performing adequately or is unsafe. The biocompatibility risk of the materials (polymer plastic and titanium metal) used in clip applier was determined to be low due to published literature and recognized international standards, as well as more than a decade of use. In risk, there are still some are existed including (1) jammed, (2) tissue damage, and (3) biliary fistula from market products. However, benefits in clinical in clinical evaluation from literatures are (1) reliable cystic duct ligation function and (2) shorten the operation time in surgery.

5.5 Ongoing or planned post-market clinical follow-up

5.5.1 Summary of the latest approved PMCF plan for the device

(1) Scientific literature review

We collect the scientific literature as part of the annual update.

(2) Survey data

In 2022 and 2023, a total of 3 and 5 PMCF questionnaires (Table 1) were collected through distributor, respectively. From the 2022 PMCF, Total Sold Number of Clip Applier is 1611 PCS; From the 2023 PMCF, Total Sold Number of Clip Applier is 14368 PCS. A provider questionnaire was developed to record the indication for the procedure, operation success or failure, reason for failure, and patient healthy condition after surgery. Surgery failure was defined as the hemorrhage, bleeding, leakage, abscess, infection or tissue Injury.

(3) PMCF plan

We have implemented an approach to collecting feedback from clinical users via our distributors. Each year, distributors gather input from hospitals and healthcare professionals who are actively using the device in various surgical procedures. The feedback is focus on device performance, clinical safety and user experience. These data are collected and reported back to the manufacturer to ensure that any emerging risks are identified early and addressed appropriately.

5.5.2 If any emerging risks, complications or unexpected device failures have been detected, and how these will be followed up

If there are any emerging risks, complications, or unexpected device failures these will feed into the risk analysis and be investigated.

6. Possible diagnostic or therapeutic alternatives

The summary of the specific conditions under which method can be considered is as following:

(1) Endoloops offers a reliable way to control the larger vessels when exceed the diameter that other methods can reliably secure.

(2) Intracorporeal knotting tying suture need more time to complete, it can be used when reducing the risk of operative site infection is a priority, sutures can reduce post-operative infection compared to other method.

(3) Stapler offers quick closure during surgery, it can be used for the surgery which need to take more time, but it has the risk of vascular bleeding, to avoid the major vessels should be considered.

(4) Clip can be used in emergency or time-sensitive procedures, a clip applier is advantageous as it allows for rapid ligation compared to suturing.

(5) Harmonic scalpel can be used for delicate or small diameter structures and vessels due to it can reduce local thermal damage and cause less collateral damage, but only suit for smaller vessel ligation.

(6) Monopolar electrocautery can be used for rapid and effective cutting or coagulation of tissues, due to it may cause the local tissue heating and damage, it should be used for the areas without critical adjacent nerves or major vessels.

(7) Bipolar electrocautery is preferred to use near delicate structures such as nerves or vital organs due to it can minimizing the risk of damage to adjacent tissues. But it only be used for vessel ≤ 6 mm.

There is no particular method that is recommended, the final decision on the method to be used will rely on the surgeon's training and experience.

7. Suggested profile and training for users

Endoscopic procedures should be performed only by physicians that had adequate training and familiarity with endoscopic techniques. Before performing any endoscopic procedures, please consult the medical literature relative to techniques, complications, and hazards.

8. Reference to any harmonized standards and CS applied

Standard Number	Standard Title
Reg. EU 2017/745	Regulation (EU) 2017/745 of the European Parliament and of the

	council on medical devices
Reg. No 1907/2006	Registration, Evaluation, Authorisation and Restriction of Chemicals
Reg. No 528/2012	Biocidal Products Regulation
Reg. No 1272/2008	Classification, labelling and packaging of chemical substances and mixture
MEDDEV 2.7/1 Revision 4	Clinical Evaluation – A Guidance for Manufacturers and Notified Bodies under Directives 93/42/EEC and 90/385/EEC
MEDDEV 2.12-1 Rev.8	Guidelines on a Medical Devices Vigilance System.
MEDDEV 2.12-2 Rev.2	Post market clinical follow-up studies a guide for manufacturers and notified Bodies.
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes.
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices.
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
EN ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
EN ISO 10993-6:2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation.
EN ISO 10993-7:2008	Biological evaluation of medical devices — Part 7：Ethylene oxide sterilization residuals.
EN ISO 10993-10:2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.
EN ISO 10993-12:2021	Biological evaluation of medical devices — Part 12: Sample preparation and reference materials.
EN ISO 10993-17:2023	Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents.
EN ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical

	characterization of medical device materials within a risk management process.
EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation.
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices — Part 1： Requirements for materials, sterile barrier systems and packaging systems.
EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices — Part 2： Validation requirements for forming, sealing and assembly processes.
EN ISO 11737-1:2018	Sterilization of medical devices - Microbiological methods — Part 1：Determination of a population of microorganisms on products.
EN ISO 11737-2:2020	Sterilization of medical devices - Microbiological methods — Part 2：Tests of sterility performed in the definition, validation and maintenance of a sterilization process.
EN ISO 15223-1:2021	Symbols to be used with medical device labels, labelling and information to be supplied.
EN ISO 11135:2014	Sterilization of health care products - Ethylene oxide -Requirements for the development, validation and routine control of a sterilization process for medical devices.
ISO 20417:2021	Medical devices-information to be supplied by the manufacturer.