3. Product information

3.1. Product Description:

- **Design Principle**

  The working principle of the disposable circular stapler is similar to that of the stapler. It forms two rows of ring-shaped, interlaced staples in the tissue. Meanwhile, the redundant tissue inside is resected by the annular knife. The adjusting nut is rotated clockwise. The anvil which is driven by the screw moves towards the stapling & cutting assembly. When the clearance of the two is adjusted to a suitable position, the pointer will enter to the green region on the indication window. At this time, the tissue is pressed to the washer of the anvil. After the safety block is opened and the handle is held, the staple is fired. Meanwhile, the protrusive annular knife together with the washer can cut the inside tissue. The suturing and the cutting of the tissues are completed at the same time. The staple incurves and forms an interlaced "B" shape. Since small vessels can pass the gap of the "B"-shaped staple, it does not influence the blood supply for the suture site and the distal end, benefiting the healing of the stapled tissue. Compared with the traditional manual suture, it has the advantages of consistent tightness of suture, tidy incision, speediness and convenience, etc.

  Product is delivered sterile. Sterilization process undergoes routine control.

  The devices are single use, surgically invasive devices.

- **Intended therapeutic and/or diagnostic indications and claims**

  Disposable Circular Stapler is mainly suitable for end-end, end-side and side-side anastomosis throughout alimentary tract from esophagus to rectum. Particularly it is suitable for low rectal or high esophageal position where manual anastomosis is difficult.

  Scope of application: suitable for general surgery, thoracic surgery, slimming special treatment and colon and rectal surgery.

3.2. Composition

- This product mainly consists of an anvil, a protective cover, a stapling & cutting assembly, an elbow, an indication window, a safety stop, a free handle, a fixed handle, an adjusting nut, a washer, staples and an annular knife.

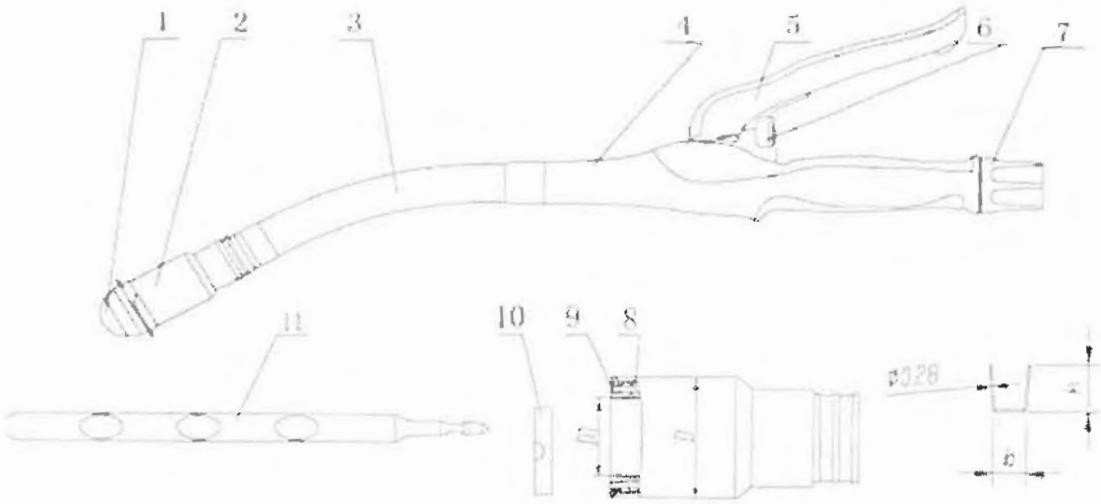
3.3. Basic Dimension and Specification

Specifications	Overall length (L)	OD of stapling & cutting assembly, (D: mm)	Diameter of circular blade, (D1:mm)	Staple(H:mm)
DH14	445±5mm	14	8.5	3.8±0.1
DH17		17	10	
DH19		19	12	4.5±0.1
DH21		21	14	
DH24		24	15	
DH26		26	17	
DH29		29	20	4.8±0.1
DH32		32	22	5.0±0.1
DH34		34	24	
DHT21		21	14	4.5±0.1
DHT24		24	15	

DHT26		26	17	
DHT29		29	20	4.8±0.1
DHT32		32	22	5.0±0.1
DHT34		34	24	

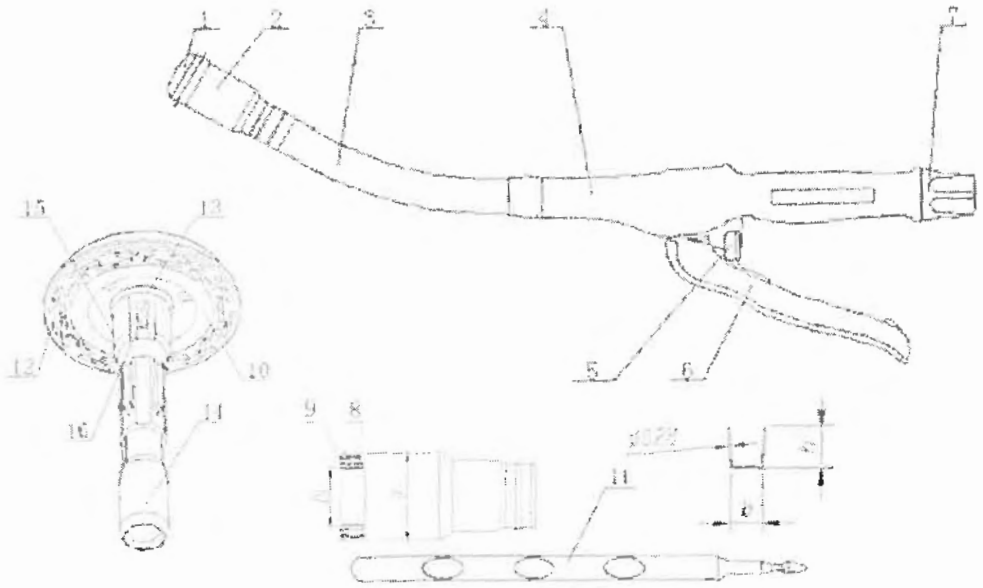
3.4. Product drawing

- **Model of DH**



1. Anvil kit; 2. Cutting kit 3. Shaft; 4. Fix handle; 5. Activate handle; 6. Safety; 7. Adjusting knob; 8. Circular blade; 9. Staple; 10. Base; 11. Lever;

- **Model of DHT**



1. Anvil kit; 2. Cutting kit 3. Shaft; 4. Fix handle; 5. Activate handle; 6. Safety; 7. Adjusting knob; 8. Circular blade; 9. Staple; 10. Base; 11. Lever; 12. Anvil; 13. Connection lever; 14. Spring cannula; 15. Connection shield; 16. Spring;

3.5. CONTRAINDICATIONS

- The device is not intended for use when severity of mucosal edema.
- The device is not intended for use with liver or spleen tissue.
- Do not use the devices on tissue(s) which cannot be inspected visually for hemostasis.
- Height of 2.0mm staple cannot be used on any tissue that is compressed to less than 0.65 mm in thickness, or that cannot be comfortably compressed to 1.0 mm or on aorta.
- Height of 2.5mm staple cannot be used on any tissue that is compressed to less than 1mm in thickness, or that cannot be comfortably compressed to 1.5 mm or on aorta.

3.6. Product performance requirements

3.6.1. Appearance

Under normal or corrected visual, there are freedom of feather edge, burr and broken defects.

The part surface shall be smooth, freedom of feather edge, burr and broken defects.

3.6.2. Material

The device shall be made according to clause 3.10.

3.6.3. Dimension

The device dimension shall meet with clause 3.3 requirements.

3.6.4. Cutting and stapling performance

The devices should be good cutting and stapling function, the blade should be freedom of feather edge, burr and broken defects.

Circular blade hardness is not less than $377HV_{0.2}$, and anvil hardness is not less than $30HV_{0.2}$.

3.6.5. Operation

There is no clip falling out when taken out from the primary package.

The safety can be removed smoothly.

The clips can be fired continuously without block.

3.6.6. Closure

The closure pressure is not less than 3.6kPa, and no leakage or tear.

3.6.7. Surface roughness

The metal part surface roughness is not exceed 0.8um.

3.6.8. Clip hardness

The clip hardness is 40~50HRC.

3.6.9. Corrosion resistance

There is no corrosion at the surface when tested according to YY/T 0149-2006, clause 5.4b.

3.6.10. Handle safety

The handle safety is liable and shall be not fall out.

3.6.11. Package integrity

The primary package is integrity without broken, and peeling strength is 0.1~0.5N/mm.

3.6.12. Sterile

The device is provided as sterile with EO sterilization method and EO residual is not less than 4mg each day.

3.7. Critical Performance

- The visible appearance should be flat and smooth, without any sharp edges, burrs and cracks. The adjusted and located mark with orange and green color should be identified clearly
- Anvil and stapler should be assembly smoothly ， and without any clamping stagnation and loosening. Insurance institutions should be open and closed flexible. Safe and reliable.
- The staples should not be dropped or missing and the head should be sharp enough.
- The knife should be sharp enough and without any turing edge and collapse.
- The pressure of anastomosis should be able to withstand not less than 3.6Kpa， and no leakage and tearing occurred.
- The device is sealed packaging with blister box and dialysis paper， the contact surface should be smooth and continuous ， and no delamination or tearing between blister box and paper.
- WARNINGS AND PRECAUTIONS
- A thorough understanding of the principles and techniques involved in laser， electrosurgical， and ultrasonic procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments .Ensure that electrical insulation or grounding is not compromised. Do not immerse electrosurgical instruments in liquid unless the instruments are designed and labeled to be immersed.
- Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques， complications and hazards prior to performance of any minimally invasive procedure.
- Minimally invasive instruments may vary in diameter from manufacturer to manufacturer. When minimally invasive instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure.
- Pre-operative radiotherapy may result in changes to tissue. These changes may, for example， cause the tissue thickness to exceed the indicated range for the selected staple, Careful consideration should be given to any pre-surgical treatment the patient may have undergone， which may require alterations to surgical technique or alternative surgical procedures.
- Do not attempt to release safety until the instrument is ready to be fired.（SAFETY SHOULD NOT BE RELEASED UNTIL THE ORANGE INDICATOR IS WITHIN THE GREEN RANGE）

- Always check the security of the anvil prior to firing.
- Do not immerse the instrument in alcohol or any quaternary ammonium solutions.
- Always inspect the anastomotic staple line for hemostasis and check the completed anastomosis for integrity and leakage. Metal clips, staples, or sutures contained in the area to be stapled may affect the integrity of the anastomosis. Corrective action, if required, may include the use of sutures or electrocautery.
- Ensure that the purse-string sutures are tied snugly against the anvil shaft and trocar shaft and that no redundant tissue is present.
- Ensure that the tissue thickness is within the indicated range， and that it is evenly distributed in the instrument. Excess tissue on one side may result in unacceptable staple formation and can result in staple line leakage.
- Before firing, ensure that the orange indicator is fully within the green range of the tissue compression scale.
- Attempting to force the trigger to complete the closing stroke with too much tissue or thickened tissue may result in poor staple line integrity with possible leakage or disruption. In addition, instrument damage or failure may result.
- Ensure that the firing trigger is fully squeezed to ensure proper staple formation and cutting of tissue.
- The firing stroke must be completed. Do not partially fire the instrument .Incomplete firing can result in malformed staples, incomplete cut line, bleeding, and leakage from the staple line and/or difficulty removing the device.
- Squeezing the firing trigger exposes the knife， Engage the red safety prior to removing the washer and tissue donuts from within the circular knife .Do not re-squeeze the firing trigger as this may damage the anastomosis.
- Keep the trocar visible at all times to prevent personal injury or inadvertent trauma to adjacent structures. Do not use the anvil shaft to assist in piercing the tissue by placing it over the unexposed trocar. To avoid inclusion of tissue within the anvil shaft. Do not use it for piercing.
- During device insertion， ensure the safety remains in the locked position to prevent inadvertent activation of the firing trigger which could lead to unintended knife exposure and premature partial or full staple deployment.
- Do not clamp across or grip on the locking springs when attempting to reattach the anvil.
- Do not fire the instrument if the orange indicator is not fully within the green range of the Tissue Compression Scale
- Squeezing the firing trigger will expose the knife. Engage the red safety prior to removing washer and donuts from within the circular knife.
- Instruments or devices which come into contact with bodily fluids may require special disposal handing to prevent biological contamination.
- Dispose of all opened instruments /devices whether used or unused. Ensure safety is engaged prior to disposing instrument/devices.

- This device is packaged and sterilized for single use only. Multiple patient use may compromise the device integrity or create a risk of contamination that, In turn, may result in patient injury or illness.
- Do not use if the inner packing is damaged;

3.8. Product Classification

Article 9 of the MDD requires that devices should be classed into Class I, IIa, IIb or III in accordance with Annex IX.

Similar products may be grouped into families for the purpose of classification and Technical File development when appropriate.

The family product shall be defined and identified in the Technical File product description.

According to Annex IX, Part III, **Rule 8 (2.4.1)** of the Council Directive MDD 93/42/EEC of June 1993, the cutter and stapler are transient use invasive device and but the staples were implanted into the body, then the devices are in **Class IIb**.

The **Generic device group** is clamed as *Intraluminal Circular Stapler, single-use (59975)* and **Device subcategory** is belong to *MD 0302: Suture material and clamps.*

3.9. Reference to similar and previous generations of the device.

Similar devices of the same product groups from the manufacturer were described, and similar device (e.g. *Ethicon Intraluminal Circular Stapler (ILS); Medtronic DST Series™ EEA™ Staplers*) from other manufacturer was also referenced into the clinical evaluation report.

3.10. Bill of material (BOM):

The device was made of medical grade materials that have been used into medical devices many years, detailed information as following:

Component	Material	Applied standard
Staples	TA1, TA2	ISO 5832-2
Circular blade	06Cr19Ni10	ISO 7153-1
Reload, Handle	ABS	GB12672
Connection lever	PE	/
Primary package	Tyvek 1059B+PET film	/

The Organization shall purchase incoming materials only from approved suppliers that have satisfied the selection and evaluation criteria as described in the DP. These suppliers shall be listed in the Approved

Supplier List.

The material purchasing activities have been identified and documented in the DP. A detailed specification for the material used to manufacture is described in the Raw Material List. This information shall be used during material purchasing.

The incoming product quality of each batch of purchased material shall be inspected according to specification.

Inspection methods and purchased product verification activities shall be as described in the DP. The status of acceptance shall be as described in the DP- Identification and Traceability. Trained and competent personnel at site shall perform incoming material verification activities.

3.11. Safety:

The device must comply with ISO Biocompatibility Guideline ISO 10993 series and ISO 14630 standards for safety.

3.12. Sterilization and Packaging:

The devices were sterilized by EO sterilization method which was conducted in house. EO sterilization validation should be conducted according to the SOP, and detailed information was described in the ***Annex CE0201-02:* EO sterilization validation report.**

The shelf time of product is **5 years** after EO sterilization.

The primary material is coated paper and blister pack, re-qualification about packaging process should be conducted according to DP, and detailed information was described in the ***Annex CE0201-03:* Packaging validation report,** which including packaging sealing validation, aging trial and package transportation evaluation.

3.13. Labelling:

Package labeling shall include product specification, production lot number, quantity, product description, consult instruction for use, use by date, manufacturing date, do not re-use, do not use if package is damaged, caution, sterilization using Radiation, storage ambient, manufacturer and EU representative information, etc.

Information for labelling was drafted as per **Product labelling: *Annex CE0201-04*** in this Technical File.

The Organization shall ensure that only approved packaging labels shall be used and distributed together with the products.

Each product unit is properly packaging to ensure its packing integrity without any damages or deterioration in nature. The production lot number and manufacturing date are identified.