INSTRUCTIONS FOR USE

SINGLE USE CIRCULAR STAPLER FOR RECTAL PROLAPSE AND HAEMORRHOIDS (CPH) AND ACCESSORIES

ENGLISH

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY

IMPORTANT!
This booklet is designed to assist in using this product. It is not a reference to surgical techniques.

INDICATIONS
CPH is a Circular Stapler product for Rectal Prolapse and Haemorrhoids and is a system with accessories that has application for general surgical treatment of haemorrhoids and anorectal wall defects by means of transanal stapling and resection of rectal mucosal and musculo-mucosal tissue resulting in occlusion of haemorrhoidal inflow, restoring the haemorrhoidal tissue and rectal anatomy to its normal physiological position.

PRINCIPLES OF OPERATION
This instrument is designed on the principles of surgical staplers. By placement of two circular peripheral lines of alternating and overlapping staples, the rectal mucosa above the anal canal can be sealed. The central circular cutting blade cuts the surplus tissue after the sealing to reconstruct the rectal mucosa.

CONTRAINDICATIONS
Do not use where the combined tissue thickness is less than 0.75 mm or greater than 1.5 mm, or where the internal diameter of the anal canal or the rectum will not accommodate the instrument and accessories. If the instrument is used on tissue less than 0.75 mm or greater than 1.5mm in thickness, an inadequate mucosal repair and inadequate haemostasis could result.

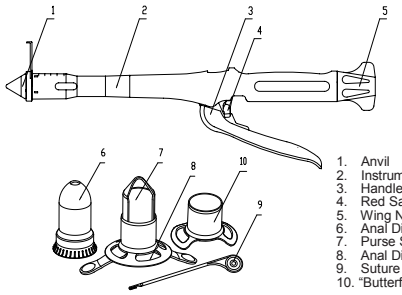
NOTE
This instrument shall be used according to the general instructions of staplers. The surgeons should have a deep understanding of the procedures for prolapse and /or haemorrhoids (Consult other materials for detailed information).

Carefully check the contents of the package.

1.	Circular Stapler	1 piece
2.	Anal Dilator	2 pieces
3.	Anal Dilator inner lining	1 piece
4.	Purse String suture anoscope	1 piece
5.	Suture threader	1 piece

DO NOT USE THE INSTRUMENT IF ANY DAMAGE OR SUSPECTED DAMAGE IS SEEN IN THE INSTRUMENT, ACCESSORIES, OR PACKAGING.

SCHEMATIC VIEW



1. Anvil
2. Instrument body
3. Handle Lever
4. Red Safety Catch
5. Wing Nut
6. Anal Dilator Inner Lining
7. Purse String Suture Anoscope
8. Anal Dilator
9. Suture Threader
10. "Butterfly" Anal Dilator

STAPLER INFORMATION

Product Code	Cartridge Colour	Staple Rows	Outside Diameter	Cutting Diameter	Staple Leg Length	Staple Crown Length	Staple Count	Closed Staple Height
CPH 32	White	2	32.5 mm	24 mm	4.2 mm	3.8 mm	32	0.75mm-1.5mm
CPH 34	Green	2	34.5 mm	26 mm	4.2 mm	3.8 mm	32	0.75mm-1.5mm
CPH 32HV	White	2	32.5 mm	24 mm	4.2 mm	3.8 mm	32	0.75mm-1.5mm
CPH 34HV	Green	2	34.5 mm	26 mm	4.2 mm	3.8 mm	32	0.75mm-1.5mm

Set contains: Circular Stapler for Prolapse and Haemorrhoids(CPH), Suture Threader, Anal Dilators (Standard and "Butterfly"), Anal Dilator Inner Lining and Purse String Suture Anoscope

The staples of this instrument are made of titanium and comply with ISO5832-2.

INSTRUMENT OPERATION

I . The appropriate Anal Dilator is selected according the patient anatomical needs between Standard and "Butterfly"). After complete lubrication of the anal margin the Anal Dilator with the Inner Lining in place, is introduced into the anus with the aid of short rotary movements (clockwise and anti-clockwise).
Note: The introduction of the Anal Dilator causes the reduction of the prolapse, the anoderm and parts of the rectal mucosa. Sometimes introducing a surgical sponge into the anus before the Anal Dilator can improve the reduction of the excess anoderm. After removing the Inner Lining, the prolapsed mucosa falls into the lumen of the Anal Dilator. As it is transparent, the Anal Dilator allows visualization of the dentate line, allowing the surgeon to check the correct positioning.

II . The Anal Dilator is then stitched to the perineum with 4 stitches at the cardinal points.
Note: The mucous membrane of the posterior vaginal wall in the female patient should not be sutured.
The four anchoring stitches to secure the Anal Dilator can be carried out before its insertion. By applying traction on the suture threads the insertion can be further facilitated.
Insert a well-lubricated Anal Dilator without sphincter stretch. Apply counter-traction on suture threads to facilitate insertion. It is possible to insert the Inner Lining first, then extract it and insert Anal Dilator with the Inner Lining in place. This facilitates complete dilatation of the anus.

ABORT PROCEDURE IF STENOSIS PRECLUDES PASSAGE.

III . The Purse String Suture Anoscope is introduced through the Anal Dilator.
This instrument will move the mucous prolapse along the rectal walls along a 270° circumference, while the mucosa that protrudes through the Purse String Suture Anoscope window can be easily contained in a suture that includes only mucosa and submucosa.
This suture placement must be carried out at least 2-3 cm above the apex of the haemorrhoids, the distance to be increased in proportion to the extension of the rectal prolapse. By rotating the Purse String Suture Anoscope, it will be possible to complete a purse-string suture around the entire anal circumference.
At each stitch, extract the Purse String Suture Anoscope then rotate it and insert it again. Rotating the Purse String Suture Anoscope while fully inserted in the Anal Dilator can twist the mucosa and cause improper asymmetric purse-string suture placement.
Do not tightly close the purse-string suture at this time. Confirm adequacy of purse-string, ensuring no gaps.

IV . The Circular Stapler for Prolapse and Haemorrhoids (CPH) is opened to its maximum position. Its anvil is introduced beyond the purse-string. The CPH is slightly withdrawn, enough to ensure the purse-string can be visualised. The purse-string is then tied with a single closing knot. With the help of the Suture Threader, the ends of the suture are pulled through and out of the lateral holes of the CPH.
Note:
Always open the CPH to the maximum position.
Should the insertion of the anvil beyond the purse-string be difficult, do not force: loosen the purse-string first, and then insert the anvil again.
Secure purse-string under direct visualization.
To pull-out each suture thread, just place it opposite to the exit side (i.e. Suture Threader in the left hole, suture thread extended to the right side).

V . The ends of the suture are knotted externally or held by a clamp. The casing of the CPH is introduced into the anal canal. During the introduction, it is advisable to partially tighten the CPH.
Note:
During this step the CPH should be gently pushed in, whilst the threads are pulled by the surgeon so that the prolapsed mucosa begins to be accommodated in the casing.
Align stapler along axis of the anal canal, and close the stapler while maintaining moderate tension on the purse-string.
Via a moderate traction on the purse-string, the prolapsed mucosa is accommodated by the casing of the CPH. The instrument is then tightened to the end by fully rotating the Wing Nut of the CPH clockwise. At this time the red indicator on the top of the CPH handle must be within the firing range (green area).

VI . Release the Red Safety Catch, and the CPH is then fired.
Note:
Do not attempt to release the Red Safety Catch until the instrument is ready to be fired. **(RED SAFETY CATCH SHOULD NOT BE RELEASED UNTIL THE RED INDICATOR IS WITHIN THE GREEN RANGE).**
Keeping the CPH in the closed position for 20 seconds after firing may act as a tamponade and promote haemostasis.
The CPH is slightly opened (half to three quarters revolutions) and extracted. Finally, the staple line is examined using the Purse String Suture Anoscope.
At the end of the closure the 4-5 cm mark should be at the level of the anal verge.
If the patient is a woman, check the posterior vaginal wall to be certain that it has not been incorporated in the staple line.
One turn of the Wing Nut should be sufficient to open the stapler. Additional turns could cause the interposition of mucosa between the anvil and the upper edge of the Anal Dilator, thus requiring for extraction of the Anal Dilator and CPH simultaneously.

VII. Inspect the staple line for bleeding and if necessary reinforce it with haemostatic stitches using 3-0 (2Metric) absorbable suture on a small needle.
Note:
Inspect the specimen to confirm that the technique has been properly performed. Additional/ancillary procedures (e.g. tag or papilla excision) can be performed either before or after stapling.
After firing, keeping the Anal Dilator in place significantly facilitates the inspection of the staple line.
Electro coagulation must be avoided for haemostasis because of the staples.

INSTRUCTIONS FOR STARR
Ensure compatibility of all instruments and accessories prior to using the instrument (refer to Warnings and Precautions). Semicircular stapling may require additional equipment. The following instructions relate to the placement of two (anterior and posterior) adjoining semicircular staple lines, using a second circular stapler and a metal spatula in addition.

1. Remove the red spacer tab by turning the Wing Nut counterclockwise two revolutions.
2. When the patient is under adequate anesthesia, and following anal sphincter massage and dilation, carefully insert the selected Anal Dilator and Inner Lining. After assuring proper positioning with the dentate line protected behind the barrel of the Anal Dilator, affix the Anal Dilator to the perineum by multiple sutures.
   WARNING: Avoid excessive dilation of the anal sphincters to avoid the potential for damage.
3. After assessing the extent and margins of the anorectal defect, carefully place a metal spatula through one of the apertures of the Anal Dilator in such a way that it lies along the posterior anal canal wall to protect against inadvertent inclusion of the posterior mucosa in the anterior staple line.
4. The Purse String Suture Anoscope is then inserted into the Anal Dilator with the open window positioned for good visualization of the anal canal for placement of the purse-string suture. Place multiple semicircular purse-strings into the rectal wall to include at least 180 degrees of the rectal circumference. Keep in mind that the staple line must be at least 2 cm above the dentate line. Ensure that the posterior vaginal wall mucosa is NOT captured within the sutures. Place the subsequent purse-string sutures at 1-2 cm intervals above the first until the entire disuse defect has been included. Use a strong, monofilament suture for the purse-strings. Remove the Purse String Suture Anoscope after the application of the purse-string sutures.
5. Tie the purse-string suture tails together at each end of the parallel suture lines. Insert the fully opened Circular Stapler into the anal canal, passing the anvil beyond the purse-string sutures.
6. Insert the Suture Threader through the suture threader conduits (note there are 4 suture conduits in the CPH) and pull the ends of the suture through the staple housing. The ends of the suture may be knotted externally of fixed using a clamp.
   Note: Using adequate traction on the suture during instrument closure will promote proper tissue resection.
   Closing and firing the instrument (as described in steps 7 and 8) excises the excess tissue and performs a stapled anterior rectal repair. The staple line must reside at least 2 cm above the dentate line.
7. Close firmly by turning the Wing Nut clockwise; firmly compress tissue while observing the indicator in the gap setting scale for adequate closure.
   Note: When tightening the Wing Nut, ensure a tight closure on affected tissue.
   To promote hemostasis it is recommended to wait approximately 30 seconds after completely closing the instrument before firing the stapler.
   While closing the instrument, keep it in the proper orientation with respect to the anal canal. Inspect to ensure that extraneous tissue is excluded.
   As the final adjusting revolution is approached, the red indicator in the gap setting scale moves into the green range of the gap setting scale.
   Caution:. After instrument closure and before firing, check the posterior vaginal wall once more to avoid incorporation of the vaginal mucosa in the resection or staple line.
   Caution:. DO NOT fire the instrument if the red indicator is not advanced as far as possible within the green range of the gap setting scale.
8. To fire the instrument, draw the Red Safety Catch back toward the Wing Nut until it sits into the body of the instrument.
   If the safety cannot be released the instrument is not in the safe firing range.
   Caution: To ensure that the instrument remains in the safe firing range, DO NOT turn the Wing Nut once the safety has been released.
9. When the safety has been released, squeeze the firing handle with firm, steady pressure until the firing handle is fully parallel to the instrument handle. The surgeon will feel reduced trigger pressure as the instrument completes the firing cycle. The firing cycle is complete when the firing handle reaches its stopping point, and the firing handle is parallel to the instrument handle.
   WARNING: Do not fire the instrument more than one time. Additional firings could result in tissue damage
10. After firing, release the firing handle. Allowing it to return to its original position, and re-engage the Red Safety Catch. If necessary, pull the firing handle back to its original position to reset the safety.
11. To promote hemostasis, it is recommended to wait approximately 20 seconds after firing and re-engage the safety before opening the instrument. Open the instrument by turning the adjusting knob counterclockwise as indicated on the handle.
12. To remove the instrument, open the instrument one-half to three quarter revolutions of the Wing Nut.
13. To ensure the anvil is free from tissue, rotate the instrument 90 degrees in both directions. To withdraw the open instrument, gently apply rearward traction whilst simultaneously rotating.
    Occasionally, the maneuver can be hampered by the interposition of the mucous membrane between the head and upper edge of the Anal Dilator and the Circular Stapler. Under these conditions it may be easier to extract the Anal Dilator and the Circular Stapler simultaneously.
14. The staple line may be examined using the Purse String Anoscope or other suitable instruments. If bleeding from the staple line occurs, additional absorbable sutures may be applied.
15. Remove the tissue specimen by cutting it from with the circular knife.
    Caution: Squeezing the firing handle exposes the knife. Confirm that the Red Safety Catch is engaged prior to removing the excised tissue from within the circular knife.
16. If minimal mucosal bridge is formed where a staple connects the two edges of the tissue approximation, the mucosal bridge should be cut with scissors
17. To create the posterior, transverse semicircular staple line, reposition the metal spatula to protect the anterior staple line while the posterior redundant rectal tissue is excised and stapled.
18. Reinsert the Purse String Anoscope and place 2-3 semicircular purse-strings, one above the other at approximately 1-2 cm intervals, in the rectal wall. Laterally, at least one suture should extend to meet the lateral edge of the anterior staple line so that the anterior corners will be captured with the posterior staple line. In this way a continuous ring of staples consisting of two laterally overlapping semicircles will be achieved.
19. Repeat Steps 6-15 above to complete the procedure using the second circular stapler to create the posterior staple line.

PRECAUTIONS
This instrument shall be used only by surgeons having adequate training of the stapling techniques and procedure for prolapse and hemorrhoids and/or instructed by experienced persons.

1. 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.
2. The instrument shall not be used if it is damaged or dropped.

WARNINGS

1. The instrument is sterile and if the sterile isolation layer is broken, it cannot be used. Do not use the instrument if the package is broken. If anything contained is broken, contact the salespersons of our company.
2. This device is for single use only. Do not reuse it.
3. Check the product codes, specification, expiration date and the integrity of the packaging before using the products.
4. Remove the instrument carefully after firing. Never withdraw the instrument by force.
5. 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 procedure.
6. Do not immerse the instrument and accessories in alcohol or any quaternary ammonium solutions.
7. Always inspect the staple line for haemostasis. Metal clips, staples, or sutures contained in the area to be stapled may affect the integrity of the stapled mucosal repair. Corrective action, if required, may include the use of sutures or electrocautery.
8. Ensure that the tissue thickness is within the indicated range, and that it is evenly distributed in the instrument. Uneven distribution of excessively thick tissue may result in unacceptable staple formation and can result in staple line leakage.
9. Ensure that the firing handle is fully squeezed to ensure proper staple formation and cutting of tissue.
10. Squeezing the firing handle will expose the knife. Engage the Red Safety Catch prior to removing the excised tissue from within the circular knife.
11. Keep the staple line at least 1.5 to 2 cm above the dentate line.
12. Avoid excessive dilation.
13. Avoid incorporation of the underlying muscularis in the resection or staple line when treating prolapse and haemorrhoids.
14. Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.
15. Dispose of all opened instruments whether used or unused. Ensure that the Red Safety Catch is engaged prior to disposal of the CPH.Do Not Re-sterilize the CPH Haemorrhoidal Circular Stapler or accessories.
    Re-sterilization may compromise the functionality of the instrument or accessories causing malfunction of the device which may result in wound leakage or disruption.

PACKAGE AND STORAGE

1. This instrument is sterilized by irradiation with Co60.
2. Use the instrument before the expiration date labeled on the package. The expiry date will be five years after sterilization if the packaging is not broken.

RECOMMENDED STORAGE CONDITIONS
Store at room temperature away from moisture sunlight and direct heat.

FDA CE 0123 STERILE R

Frankenman International Limited
Suite B, 13F, Wing Tat Commercial Building
121-125 Wing Lok Street, Sheung Wan, HongKong
t: +852 3106 3035
f: +852 3585 0519
www.frankenman.hk

EC REP
Shanghai International Trading Corp. GmbH(Hamburg)
Eiffestrasse 80, 20537 Hamburg, Germany
t: 0049-40-2513175
f: 0049-40-255726

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