# COMpression anastomosis ring (CAR* 27/ColonRing*) Post maRketing Evaluation Study

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A new surgical device for the creation of compression anastomoses, the ColonRing*, which is nickel- titanium based, has been introduced. Safety and efficacy of the device have been established in previous clinical studies and the device has been...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Anal and rectal conditions NEC |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON34905

**Source**
ToetsingOnline

**Brief title**
COMPRES

### Condition

- Anal and rectal conditions NEC

**Synonym**
anastomosis, reconnection between intestine

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** NiTi Surgical Solutions, Ltd.
**Source(s) of monetary or material Support:** financiering op basis van contract met industrie

## Intervention

**Keyword:** ColonRing, colorectal resection, compression anastomosis, stapler

## Outcome measures

### Primary outcome

The primary study outcome is the rate of leaks.

Anastomotic leakage will be defined as clinical symptoms such as fever or sepsis in combination with pelvic abscess, rectovaginal fistula or peritonitis within 30 days postoperatively leading to a clinical and * or radiological interventional procedure of the subject, or operation that confirms the leakage which has been determined to be related to the device.

### Secondary outcome

Rate of other device related complications and other parameters during hospitalization and post procedure.

The post operative parameters that will be measured during hospitalization period:

1. Hospitalization time (two dates will be recorded: ready for discharge and discharge). The later noting where the subject was discharged to - e.g. nursing home or home

2. First day to first postoperative flatus

3. First day to first postoperative bowel movements

4. First day of first postoperative toleration of liquids and solids (time to *keeping them down*)

Other device related complications during and post procedure - the following complications will be examined for relation to the device.

5. Intraoperative device failure (including cases of conversion to stapled or sutured anastomosis that are device related)

6. Bleeding

7. Stricture (either clinical evidence of a stricture or the inability to pass a 12 mm sigmoidoscope through the anastomosis in a procedure that does not include a diversion). Note - strictures are unlikely to occur within the study period

8. Septic complication (including wound infection, pelvic infection, peritonitis, abscess)

9. Readmission, re-operation, death within 30 days of the procedure. Note - a death will be considered related by physician discretion if it occurs as a result of peritonitis, colon obstruction or leak at the anastomosis site.

10. Extra colonic complications (including urinary infection, urinary retention, DVT, pneumonitis, pulmonary embolism, cardiac, injury to other organs - e.g. spleen, ureter)

Length of time and ease of surgical procedure:

The length of time and ease of the surgical procedure will be assessed by the performing surgeon. The length of time of the procedure will be defined as the time taken for creation of an anastomosis from the time of completion of two bowel ends to the beginning of the leak test.

The ease of the surgical procedure as well as the extraction of the device will

be rated on a scale of 1 to 5 with 1 being very difficult, 2 difficult, 3

fairly easy, 4 easy and 5 being very easy.

Ring expulsion time and awareness. The time of expulsion of the ColonRing* and

the ability of the subject to notice this event will be recorded for every

subject.

## Study description

**Background summary**

The most common complications of colorectal anastomoses are strictures and leaks. The leak rate has remained significant over the past years. In lower rectal procedures, the incidence of leak is substantially higher than after procedures in the colon. Some leaks will require surgical intervention and can lead to significant short term and long term morbidity with impaired quality of life and bowel function. Leakage will also increase the postoperative mortality. It was shown that when a leak is present, the associated risk of postoperative mortality is increased to a range of 6% to 39%. As a result of the complications following colorectal procedures with the current technology of stapling or suture techniques, the idea of tissue compression has been revisited.

Currently, colorectal anastomoses are created either with staplers or by a hand-sewn technique. Both staplers and sutures evoke an inflammatory response due to a foreign body reaction at the site of the anastomosis, which may provide a track for bacteria to infect the site. Both have other limitations: staplers have been reported to have a propensity to stricture formation and it has been noted that tumor cells are adherent to suture material. However, the speed of the stapler's procedure and the ability to anastomose at a lower level than that with sutures, make staplers the most commonly used practice for colorectal procedures today.

The current mechanical (i.e., stapling pins) or traditional suturing techniques do not provide a completely *sealed* reconnection due to the gaps between sutures or staples, until the body*s healing process *plugs* the microperforation defects. Although considerable progress has been made in the

field of surgical equipment and peri-operative management; complications related to creation of an anastomosis in colorectal procedures using these techniques remain major problems. These complications may be associated with the operator, the surgical technique, the subjects overall condition and comorbidities, but often occur with no obvious or known risk factor. Typical complications include leakage, stricture, bleeding, septic complications, extra colonic complications and others. While some complications are clinically silent, others require surgical or medical interventions and can lead to significant morbidity, prolonged hospitalization and increased cost, and even mortality.

**Study objective**

A new surgical device for the creation of compression anastomoses, the ColonRing*, which is nickel- titanium based, has been introduced. Safety and efficacy of the device have been established in previous clinical studies and the device has been cleared by the US Food & Drug Administration (FDA) and has obtained CE mark. The ColonRing* has been marketed since 2008 and over 3000 procedures have been performed to date worldwide.
Preliminary reports from early studies show that this device may address the limitations that led to the failure of the earlier products for compression anastomosis. Pre clinical studies using the ColonRing* suggest superiority of the device over staplers. The clinical results from various studies with the device suggest that the device is comparable to the current anastomosis stapling technique. It may have the potential to reduce leak rate and other complications during and post procedure, specifically parameters related to the hospitalization period.

The proposed study is a post marketing study intended to gather and record additional data to further evaluate the performance of the ColonRing* device in regards to the creation of a colorectal anastomosis.

**Study design**

prospective, multicenter, open label, non-randomized post marketing study

**Intervention**

In subjects who meet the inclusion/exclusion criteria the anastomosis will be created using the ColonRing.

**Study burden and risks**

Participation in this study will involve mostly standard of care procedures (considered by most doctors as the currently-accepted method of treatment for a

disease or condition). However, risks associated with the surgical procedure involving the ColonRing* are described as follows:

• Likely Risks: Risks are similar to those related to all surgery and anesthesia. Risks relating to surgery and anesthesia will be the same whether using the standard method or the ColonRing*.

• Less Likely Risks: Bleeding, narrowing, or blockage at the reconnection site could occur. The ring forms a water tight seal; however, if a leak were to occur, it would likely occur in the area around the ring. A leak in this area could cause an infection, an abscess (abdominal infection), or a fistula (abnormal tube or opening between different parts of intestine or between the intestine and other tissue). These could require antibiotic therapy, another operation for repair, the construction of an ostomy (opening of the intestine through the skin into a bag to divert the stool while the bowel heals), or for the placement of a drain into the infected area. The occurrence of such a leak increases other complications and has been shown to increase the risk of death after surgery. Similar leaks may also occur when using the standard stapler or suture for reconnection.

• Rare Risks: An unknown allergy to nickel could occur (part of the device*s ring is nickel).
In the unexpected event that the device does not pass out the body, it may be necessary to attempt removal using a finger, a proctoscope or another operation.

• Unforeseen Risks: The treatment with the ColonRing* may involve some additional risks, the nature of which are unknown. Although the ColonRing* device is FDA approved, CE certified for this use, and was used in over 3000 clinical procedures, there may be side effects that have not yet been reported.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

1. Subject is >= 18 years old.
2. BMI < 34.
3. Subject is planned to undergo a non-emergency (i.e., elective) operation with the creation of an anastomosis using the ColonRing*.
4. Subject signs and dates a written informed consent form (ICF) and indicates an understanding of the study procedures.

## Exclusion criteria

1. Subject has a known allergy to nickel.
2. Subject is planned to undergo an emergency procedure or has a diagnosis of bowel strangulation, peritonitis, bowel perforation, local or systemic infection, ischemic bowel, carcinomatosis.
3. Subject has participated in another clinical study which may affect this study*s outcomes within the last 30 days.
4. Subject's ASA (American Society of Anesthesiology) score 4 or 5.
5. Subject has a concurrent or previous invasive pelvic malignancy.
6. Subject has a systemic or incapacitating disease.
7. Subject has extensive local disease in the pelvis.
8. Subject requires more than one anastomosis during the surgery.
9. Women who are known to be pregnant.

# Study design

## Design

**Study type:** Interventional

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

## Recruitment

NL

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| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 18-06-2010 |
| Enrollment: | 40 |
| Type: | Actual |

## Medical products/devices used

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|---|---|
| Generic name: | Compression Anastomosis Ring (CAR□27/ ColonRing□) |
| Registration: | Yes - CE intended use |

# Ethics review

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| Approved WMO Date: | 27-04-2010 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

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| Approved WMO Date: | 11-02-2011 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
| --- | --- |
| CCMO | NL31790.060.10 |