easyband

telemetrically adjustable gastric band

Instructions for Use

CE 0123

MR

Contents

endoart medical technologies

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1 General Information

Aim of the Device

The Easyband® is a medical implant for gastric banding in patients suffering from morbid obesity.

Gastric banding involves surgically placing a band around the stomach in a manner to create a small pouch in its superior section. The presence of this small pouch induces a satiety feeling so that the patient eats only a limited quantity of food in a single meal.

The Easyband® consists of a band connected by a cable to a small flat antenna which is placed underneath the skin. The Easyband® can be implanted by a laparoscopic procedure.

The band diameter may be adjusted in post-operative follow-ups. In contrast to existing gastric bands, adjustment of the Easyband® is not executed hydraulically, but telemetrically from outside of the body, in a non-invasive manner. Adjustment requires the use of an external control unit supplied separately (Figure 1).

Figure 1: *Easyband® control unit and external antenna*

Storage

Store in a dry place at room temperature.

2 Technical Description

2.1 Implant

General Description

The Easyband® implant is depicted in Figure 2. The components (1-3) which encircle the stomach form the gastric band, the antenna (5), which provides communication between the implant and the external control unit is placed below the skin, and finally the cable (4) connects the band to the antenna. A manipulation handle (6) facilitates the surgical procedure but does not remain implanted.

Figure 2 depicts the band in the locked position, i.e., the sleeve (3) has been inserted into the clip (2).

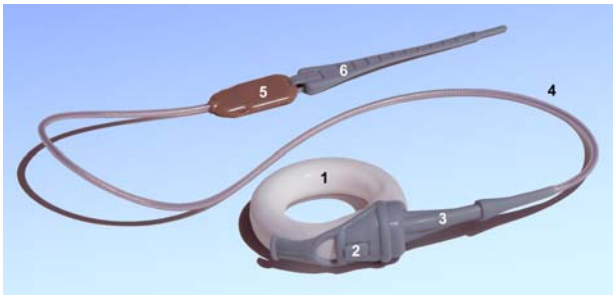

Figure 2: *General overview of the Easyband®: 1: band body, 2: clip, 3: sleeve 4: cable, 5: antenna, 6: manipulation handle.*

External Dimensions

The band (1) has a toric form with a fixed outer diameter of 50 mm and a variable inner diameter ranging from a maximum of 29 mm to 20 mm (see Figure 3). The thickness of the band is 13 mm. When the band is in the locked position, the sleeve (3) has a length of 50 mm.

All external components of the band are made of silicone. The clip and the sleeve are relatively rigid while the rest of the band is covered in a thin flexible membrane.

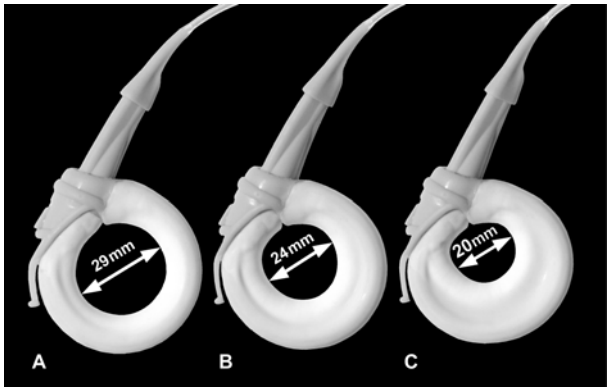

Figure 3: *The Easyband® implant in three different positions: diameters of 29 mm (A), 24 mm (B) and 20 mm (C).*

Adjustment Principle

Technically, adjustments are made by a flexible lead screw that runs throughout the interior of the band. This screw is pulled or pushed by an electrical motor.

To perform an adjustment, the external antenna, connected to the control unit, is placed directly over the implanted Easyband® antenna so that the two antennas can communicate.

The following technical characteristics of the adjustment should be noted:

- The screw, that enables the adjustment, is surrounded by a compressible material such that the forces applied on the stomach are well spread and not extreme
- The power necessary to drive the motor is transmitted inductively by the control unit. The implant does not contain any batteries
- During adjustment the Easyband® control unit displays the band diameter in real time

NOTE: The band is delivered adjusted to the maximum internal diameter of 29 mm.

Locking Principle

Figure 4 depicts the Easyband® in the unlocked position, and in the locked position (as delivered). Locking is performed by simple clipping. Note that in the unlocked position, the band retains a circular shape which facilitates placement of the device around the stomach.

Figure 4: *The band with clip unlocked and clip locked.*

Cable
The cable has a length of 40cm and a diameter of 2.6 mm. It consists of a silicone cladding covering a coaxial, electrically conductive cable connecting the antenna to the motor.

Antenna
The antenna consists of a case containing an electronic circuit capable of communicating with the external control unit. The case is made of a solid plastic (PEEK) with external dimensions 33x16x3.5 mm. The case has three suture loops to maintain the antenna's position once implanted.

Manipulation Handle
The manipulation handle has a length of about 9 cm and is made of silicone. This handle is useful for antenna manipulation during the implantation procedure. It must be cut and removed at the end of the procedure.

Biocompatibility
All surfaces of the Easyband® in contact with body tissues are composed of materials compatible with long term implantation.

Packaging and Sterilization
The Easyband® is steam sterilized (121 °C, 20 minutes). It is delivered sterile, double-wrapped in peel-away pouches and placed in a metal container filled with carbon dioxide and ready for implantation.

2.2 Microchip Card
The microchip card contains the implant's serial number and the band's diameter in mm.

The microchip card must be inserted into the Easyband® Control Unit when adjusting the device.

Figure 5: *The Easyband® microchip card.*

2.3 Patient Card
The patient card contains implant and manufacturer information and an MRI warning. (section 4.4.1).

The patient card should be filled in and given to the patient.

Figure 6: *The Easyband® patient card.*

2.4 Disposal
The Easyband®, its accessories and its packaging do not contain any dangerous material.

The Easyband®'s accessories and packaging can be eliminated through normal urban refuse (paper or plastic).

An explanted Easyband® will present biocontaminated material and should be treated in accordance with hospital policy for management and handling of such materials.

3 Indications
3.1 Indications
The Easyband® is indicated for patients with a Body Mass Index (BMI):

1. greater than 40 kg/m^2 or,
2. greater than 35 kg/m^2 with co-morbidities,

who have demonstrably failed to lose weight with non-invasive therapies such as dietary, physical, behavioral or drug therapies.

3.2 Contraindications
1. Patients with a Body Mass Index greater than 60 kg/m^2
2. Patients with severe inflammation of the gastrointestinal tract, including severe oesophagitis, gastric ulceration, duodenal ulceration, or other inflammatory disease such as Crohn's disease
3. Patients with potential upper gastrointestinal bleeding conditions such as oesophageal or gastric varices, or with congenital or acquired intestinal telangiectases
4. Patients with congenital or acquired anomalies of the gastrointestinal tract (atresias, stenoses)
5. Patients with severe cardio-pulmonary or organic disease
6. Patients with anatomical problems of the oeso-gastric junction
7. Patients with known or suspected allergies to implant materials in contact with body tissues: silicone and PEEK polymers
8. Patients with any contraindications to the surgical procedure for implanting the Easyband®
9. Patients whose abdominal structures (stomach, liver, etc.) have been damaged during preceding surgical procedures such that Easyband® placement is not possible or adapted
10. Patients with infection anywhere in the body or where an infection is possible before or during surgery
11. Patients under 18 years of age
12. Pregnant women
13. Patients treated with steroids
14. Patients addicted to alcohol or drugs
15. Patients mentally unstable or with a psychological profile which makes them unlikely to comply with the follow-up requirements and the dietary

restrictions (see section 4.2)

16. Patients who are not willing to comply with the follow-up requirements and dietary restrictions (see section 4.2)
17. Patients already implanted with a device sensitive to radio-frequency emissions such as an implantable pacemaker, implantable defibrillators, cochlear implants, implantable pumps, implantable neurostimulators, etc. (see section 4.4.2)

3.3 Complications

Possible complications with the Easyband® are the same as those found with existing hydraulic gastric bands:

- Perforation of the stomach or damage to abdominal structures during the surgical procedure
- Damage to the band during the surgical procedure
- Stomach obstruction
- Dilation of the gastric pouch
- Slippage of the band down the stomach
- Erosion of the stomach wall by the band, or migration of the band through the stomach wall
- Infection

The total absence of the hydraulic access-port eliminates all port related complications encountered with existing gastric bands, i.e., leakage, disconnection, injection–related discomfort and pain, etc. Nonetheless, there is a risk that the band diameter may not be adjustable if the antenna was incorrectly implanted, moves, or turns with time so that the coupling criteria shown in Figure 7 are not met (see section 4.5).

3.4 Side Effects

Possible side effects with the Easyband® are the same as with all gastric bands:

- Nausea and vomiting
- Gastrooesophageal reflux
- Oesophagitis, dysphagia
- Dyspepsia, constipation, aerophagia, diarrhea
- Pains (abdominal, antenna location, surgical wounds)
- Asthenia, alopecia

There are no side effects shown to be associated with the telemetric system. The levels of electromagnetic emission conform to current standards (i.e., cellular phones).

4 Precautions and Warnings

4.1 Patient Selection

Successful treatment of obesity with gastric banding depends heavily on the patient's involvement. In fact, the patient must be capable and motivated enough to attend regular follow-up visits and to follow the strict nutritional guidelines imposed by such a therapy (see section 4.2). **Patient selection should include a thorough evaluation and work-up.**

The patient must understand the expected benefits, possible complications, and side effects that the implantation of an Easyband® presents.

It is also important that the patient is aware of other available therapeutic alternatives. For the choice of the adequate therapy, guidelines [1] should be followed. In all cases, the patient should have sufficient time to contemplate the procedure before agreeing to Easyband® implantation.

4.2 Post-operation Follow-up Visits

Successful treatment of obesity with gastric banding depends heavily on the quality of the patient's follow-up visits. **It is recommended that the patient be followed by a multidisciplinary group capable of providing all of the necessary competencies such as surgery, psychotherapy, nutritional advice, exercise and internal medicine.**

During the first 4 weeks following device implantation, the patient must follow a strict liquid diet. The next 4 weeks the patient must consume pureed food before returning to a normal diet. However, in all cases, the patient's must chew their food properly, must avoid very large meals, and must follow a well balanced diet.

If a patient treated with the Easyband® becomes pregnant, the band may be opened to allow more food intake.

Follow-up visits must also serve to rapidly identify possible complications and, if necessary, their correction in due time.

4.3 User Training

Every surgeon performing a Easyband® implantation procedure must be **trained in the treatment of obesity by gastric banding**. See guidelines [1] for recommendations.

These instructions for use only contain basic information and warnings for the correct implantation of the Easyband®. Additionally, **EndoArt offers technical information trainings for Easyband® users**. It is compulsory that all Easyband®users participate in one of these trainings in order to ensure correct use.

4.4 Interaction with other Medical Devices

4.4.1 Magnetic Resonance Imaging (MRI)

The Easyband® contains magnetic materials, and intense magnetic fields may produce a risk to the patient or alter the function of the Easyband®. This is particularly true with Magnetic Resonance Imaging (MRI). A high intensity magnetic field may induce relatively large forces on the implant and subsequently on the stomach. A large magnetic field may also damage the Easyband®'s internal adjustment mechanism to a degree that future adjustment may become impossible.

Furthermore, during an MRI scan, the presence of the Easyband® will induce an artifact on the image and the RF fields may induce heating of the implanted Easyband.

[1] Obesity surgery: evidence-based guidelines of the European Association for Endoscopic Surgery (EAES). Surg Endosc. 2005 Feb;19(2):200-21.

For the reasons exposed above, an MRI exam may be performed only under the following conditions:

- **Only a static magnetic field of 1.5 Tesla can be used**
- **The patient has been implanted for more than 8 weeks**
- **No body coil shall be used neither for transmission nor for reception. Only imaging of the upper or lower limbs and head scanning with surface transmit and receiving coils should be considered.**

4.4.2 Active Medical Devices

The Easyband® by itself, does not emit any electromagnetic signals. However, **the Easyband® Control Unit may effect the proper function of other implants which use electrical power implanted in the patient.** Consequently, the implantation of the Easyband® is not recommended in patients who already carry such devices. Likewise, it is not recommended to implant a device which uses electrical power in a patient that already carries the Easyband® unless one makes sure that no further adjustments of the band's diameter are made.

4.4.3 X-Ray and Ultrasound Tests

The Easyband® is fully compatible with diagnostic tests using ion radiation (X-Rays, scanners, Positron Tomography, etc.). However, **the proper function of the implant may be altered by therapeutic levels of ion radiation or ultrasonic energy.**

4.5 Safe Use Precautions

In order to ensure that the Easyband's internal diameter can be adjusted by the Easyband® Control Unit, the coupling criteria defined in Figure 7 must be met. During implantation, the Easyband® antenna must be positioned in a way to ensure these criteria are met and that the antenna is fixed in position using its three suture loops.

The silicone membrane covering the entire band, and, to a lesser extent, the cable's silicone cladding, are fragile. These components must be manipulated with caution and according to the rules laid out in chapter 5.1, "Handling the Easyband®".

Contrary to practice with existing hydraulic bands, the surgeon must not separate the implantable components. **If the Easyband® cable is cut, it is no longer possible to reconnect it.**

During every implantation procedure, it is recommended that a second implant (reserve implant) is available. This is necessary in the event that an implant is damaged during the implantation procedure.

4.6 Pressure Variations

The interior of the Easyband® is not solid and does contain some airspace and, may inflate or deflate if there are large external pressure variations (depressurization or over-pressurization respectively).

Laboratory studies have shown:

1. Airplane travel and mountain climbing present no risk to the patient due to the decreasing atmospheric pressure with altitude
2. The over-pressurization found during swimming or snorkeling (less than 5 m depth) presents no risk for the patient. However, **SCUBA diving by patients carrying a Easyband® is not recommended.**

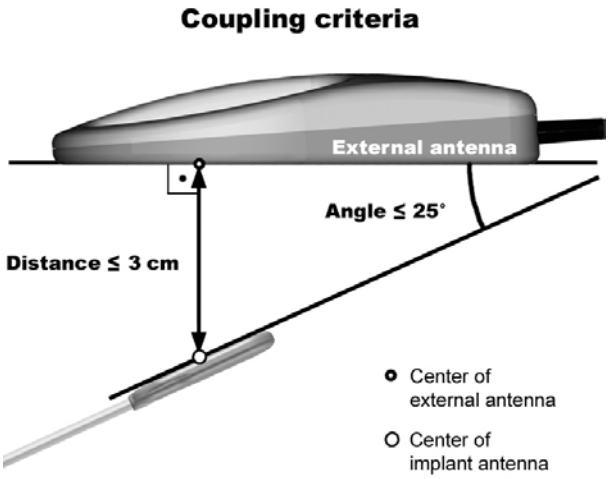

Figure 7: Definition of coupling criteria. *The criteria are defined in terms of:*

1) the distance between the center of external antenna and the center of the Easyband® antenna. The maximal allowable distance is 3 cm

2) the angle between the plane of the external antenna and the plane of the Easyband® antenna. The maximal allowable angle is 25°

4.7 Precautions concerning Packaging

- Do not reuse and re-sterilize the Easyband®
- Do not implant the Easyband® after the "use by date"
- Do not implant the Easyband® if the packaging is damaged

5 Medical Procedures

5.1 Implantation

The laparoscopic implantation procedure for the Easyband® can be divided into the following major steps:

1. Anesthesia and patient positioning
2. Creation of the pneumoperitoneum with carbon dioxide, insertion of trocars and laparoscopic instruments
3. Dissection of the tissues surrounding the stomach
4. Introduction of the Easyband® into the abdomen
5. Placement of the Easyband® around the stomach
6. Placement of the Easyband® antenna
7. Removal of instruments and trocars, incision closure
8. Final inspection

The following details of each step differ from surgeon to surgeon: patient positioning, number and diameter of each trocar, dissection technique (perigastric, pars flaccida or combined), etc. Steps 1,2,3 and 7 are not

specific to the Easyband®. Therefore, it is assumed that the surgeon understands these steps as part of a common gastric band procedure. Steps 4,5,6 and 8 pertain to specific handling of the Easyband® and are thus described in the rest of this chapter.

NOTE: The Easyband® can also be implanted by laparotomy where a laparoscopic procedure is impossible or inappropriate.

Handling the Easyband®

The white or transparent parts of the Easyband® are fragile and thus extreme care should be taken during handling (see specific instructions below).

The grey parts may be handled using atraumatic laparoscopic instruments. The following handling precautions should be followed.

1. The membrane covering the band is very fragile

The body of the silicone band cannot be handled with instruments because of the fragile silicone membrane (see Figure 8). If necessary, the silicone membrane may

Figure 8: *The silicone band cannot be handled with instruments*

be pushed with a blunt (non-sharp) part of an instrument (see Figure 9).

2.The cable is relatively fragile

The cable may be handled with the cautious use of an atraumatic clamp (see Figure 10), keeping in mind that the transparent silicone cladding is quite thin and that excessive pulling or severe flexion may damage the cable or its connections to the sleeve or to the antenna.

3. The other band components may by handled with atraumatic clamps

The remaining Easyband® components were specifically designed to be handled using **atraumatic** clamps. These components are the grey coloured-silicone parts (clip, sleeve and manipulation handle, see Figure 11) and the antenna.

The grey colored silicone components are notched or grooved in order to avoid slipping on the surface with clamps: there is a notch at the end of the clip handle, a notch in the middle of the sleeve, and pads on the manipulation handle.

4. Be careful when removing the camera

Pay particular attention to not leave any unsupervised sharp instruments near the band if removing the camera temporarily (for example, to clean its objective).

5. In case of doubt, do not implant the device

If, after difficult handling, or for any other reason, there

Figure 9: *The silicone membrane may be moved by pushing it with a blunt instrument.*

Figure 10: *The cable may be handled with the cautious use of an atraumatic clamp.*

is a doubt about the band's integrity, the Easyband® must not be implanted. If appropriate or necessary, the reserved implant may be used.

Easyband® Insertion

The Easyband® may be inserted into the abdomen either through an 18 mm trocar or direclty through the skin. The Easyband® should be inserted into the abdomen after performing the dissection to create the retro-gastric tunnel in order to avoid any inadvertent damage to the implant by the surgical instruments.

Just prior to insertion, open the Easyband® metal packaging container and remove the double-wrapped Easyband® sterile packaging. The Easyband® must be inserted in the abdomen no more than 5 minutes after opening the metal packaging container.

Figure 11: *The grey silicone parts of the implant may be handled with atraumatic clamps. From left to right: clip, sleeve and manipulation handle.*

Insertion through a trocar

For the insertion of the Easyband through the 18 mm trocar, it is necessary to use the Easyband® Introduction Tool (accessory supplied separately).

The band is delivered in a locked position (Figure 4, bottom). Completely unlock the band as shown in Figure 4, top.

Immerse the Easyband® in physiological liquid in order to facilitate passage through the trocar.

Place the Easyband® clipping ring into the distal portion of the Easyband® introduction tool as shown in Figure 12A. Gently straighten the band, placing the notch on the gray colored sleeve of the band into the groove provided on either side of the introduction tool, as illustrated in Figure 12B. The Easyband® is now ready for insertion into the 18 mm trocar, as shown in Figure 12C.

The band is released from the introduction tool by sliding the gray colored band sleeve out of the groove on the introduction tool once it is fully inserted into the 18 mm trocar as in Figure 12D. With the sleeve released from the introduction tool, the introduction tool may be removed from the trocar. The band, connecting cable, and antenna may now be pulled completely into the abdomen and removed from the trocar. This should be performed in one step in order to avoid prolonged contact between the silicone membrane and the inside of the trocar which is relatively sharp. The band is designed so that it can be straightened temporarily, as illustrated, without being damaged.

WARNING: Never push the band down the trocar.

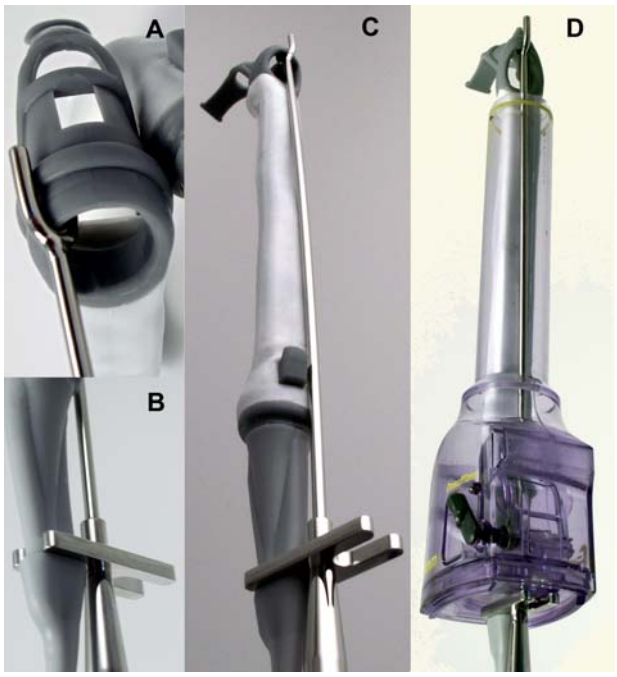

Figure 12: *A: Placing the introduction tool on the clip. B: Correct placement of the sleeve into the notch of the introduction tool: C: View of properly loaded introduction tool. D: Easyband and introduction tool placed through 18 mm trocar.*

Insertion through the skin

Completely undo the band (unclip and remove the antenna).

Temporarily remove one of the trocars. If necessary, enlarge the incision for the Easyband® insertion.

Positioning of the Easyband®

An intra-gastric calibration balloon may be used to define the band's optimum vertical position around the stomach.

The insertion of the band into the retro-gastric tunnel is done by first passing the manipulation handle. It may be grasped directly with an instrument adapted to pass through the retro-gastic tunnel or it can have a loop of suture thread installed at its end. The manipulation handle is then pulled such that the antenna and cable pass through. Subsequently, grasp the sleeve and pull the band through.

Once the band is in position, it may by locked into place by pulling on its two extremities as shown in Figure 13. To do this, insert the antenna though the clip's opening (Figures 13A and 13B). Pass the entire cable and the beginning of the sleeve through the opening.

With one clamp grasp the extremity of the clip and with the other, the sleeve. Proceed with locking the band by pulling on both clamps and inserting the clip into its receptacle.

At this point, please check visually that the band is intact, i.e., that it has not been damaged by surgical instruments.

In order to guarantee the band's position and to avoid the risk of slippage, perform an appropriate number of

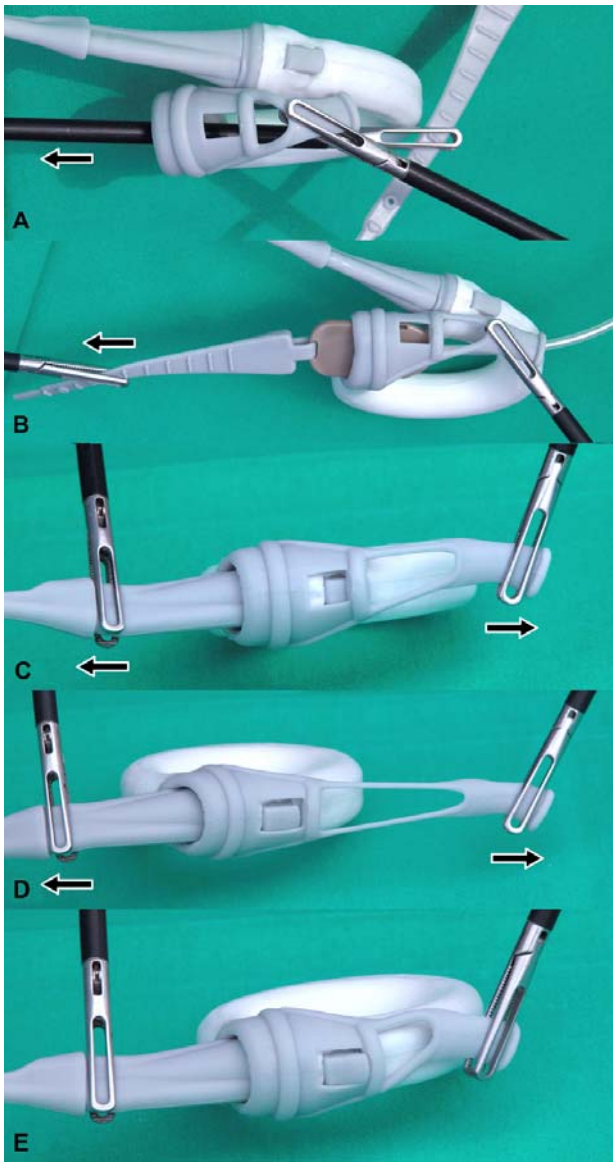

Figure 13: *Passing the antenna through the clipping ring and closing the band.*

gastro-gastric sutures using non-absorbable suture thread. **Pay special attention not to puncture the band with the needle during this manipulation.**

Since the sleeve is relatively rigid, orient the band such that there is no risk of damaging abdominal structures.

It is possible to unlock the clip if necessary.

Antenna Positioning

The antenna should be placed subcutaneously above the sternum. Exit the antenna from the abdomen. Then, prepare a subcutaneous channel from the sternum to the exit point of the cable. **The channel should be wide enough** to allow an easy pull-through of the antenna to its final position above the sternum.

From the sternum, pass a grasping tool through the channel and pull the antenna through by grasping its manipulation handle. **Pay attention to the force and handling of the cable as it is relatively fragile.**

Once the antenna is in place at the base of the sternum, cut the manipulation handle as shown on Figure 14 and position the antenna at the base of the sternum.

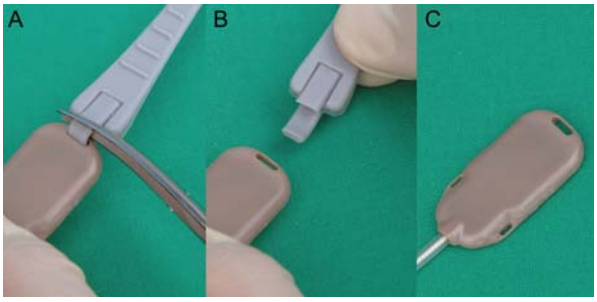

Figure 14: *Cutting of the manipulation handle.*

The antenna should be placed such that the coupling criteria defined in Figure 7 (section 4.5) are met. It should not be implanted too deeply (less than 3 cm from the skin) with its flat surface parrallel to the patient's skin.

Verify that the cable is implanted without being strained, and that it does not make any large angles. Also verify that there is no risk of pressing on nearby structures and that the cable does not go just under the clip handle.

Suture the antenna into place using the three suture loops provided. It is recommended that non-absorbable 2-0 suture be used.

Final Inspection

Before the patient leaves the operating room, perform the test described in the Annex in order to verify that the implant is functioning properly.

Write the patient's information on the microchip card and keep it either in the patient's file or in the Easyband® Control Unit carrying case.

Fill in the patient card and give it to the patient.

5.2 Post-operation Interventions

Diameter Adjustment

Band diameter adjustment is performed using the Easyband® Control Unit external control unit. Refer to the control unit instruction manual before making band adjustments.

It is recommended that the first band diameter adjustment be made 4 to 6 weeks after implantation. Future adjustments are made considering the patient's weight loss and any side effects that have developed.

X-Ray Exam

An X-Ray exam of the band can be routinely performed or if complications are suspected.

Band components can be visualized with a simple X-Ray. In particular, the plane defined by the screw determines the band's orientation.

5.3 Laparoscopic Reintervention

The removal or re-positionning of the Easyband® can by performed by laparoscopy. During reintervention, the Easyband® may temporarily inflate due to the presence of carbon dioxide. It is thus recommended that the device be removed from the abdomen directly through the skin, and not through a trocar.

6 Definition of Symbols

Sterilized using steam

Caution, consult accompanying documents

Do not reuse

Do not use if packaging is damaged

Reference number

Serial number

Date of manufacture

Use by date

CE conformity marking

Patient Identification

MR (Magnetic Resonance) Conditional

CE marking granted 2005.

Annex: Easyband® Test

This test verifies correct function of the Easyband®. If the control unit displays information other than that described below, please refer to the instructions for use supplied in the control unit's carrying case.

1. Connect the external antenna to the control unit. Turn the control unit on by pressing the ON/OFF key for more than one second. Wait until the control unit asks for the microchip card:

PLEASE INSERT CARD

2. Insert the microchip card delivered with the implant being tested in the control unit's slot. Wait until the control unit displays the band's diameter. For a new implant, this diameter is 29 mm:

STOPPED @ 29.0mm DIAM

3. Place the external antenna over the implanted Easyband® antenna.

4. Press the COUPLING key. Verify that the control unit briefly displays the following message:

CARD & IMPLANT MATCHED

5. Verify the coupling quality between the external antenna and the Easyband®'s antenna; at least one green coupling indicator light should be on and the display should show:

COUPLING CORRECT

6. Briefly press the CLOSE key. The band diameter will then start to decrease. The control unit continuously displays the band diameter.

7. Once the diameter has decreased by 0.2 mm, briefly press the CLOSE key. The control unit displays the message:

STOPPED @ 28.8mm DIAM

8. Briefly press the OPEN key. The diameter of the band will start to increase. The control unit continues to display the band diameter.

9. The Easyband® is functioning properly if the display successively shows the following diameters; 28.8, 28.9, 29.0 and then finally the message:

DEVICE FULLY OPEN

10. If the message "DEVICE FULLY OPEN" does not appear, press the OPEN button a second time. If the message finally appears, then the Easyband® is functioning properly.

11. If neither of the two sequences described in points 9 or 10 appear, refer to the instructions provided with the control unit's carrying case.

easyband®

DECLARATION OF CONFORMITY

We

EndoArt SA
PSE-B
CH-1015 Lausanne

Declare under our sole responsibility that the product

Easyband®

1. Conforms to the essential requirements of the European Council Directive 90/385/EEC on Active Implantable Medical Devices,

   Conformity assessment procedure: annex 2.3 (quality system) and annex 2.4 (examination of the design of the product),

   Notified body: TüV Product Service GmbH, Germany, number 0123,

   Applied standard: EN 45502-1.

2. Conforms to the essential requirements of the European Council Directive 99/5/EEC on Radio & Telecommunication Terminal Equipment,

   Conformity assessment procedure: annex II, internal production control,

   Applied standard: EN 300 330-2.

Lausanne, June 23, 2006.

P. Dro, CEO

N. Stergiopulos, CSO