Obesity Catalogue 2012

BIORING®

adjustable gastric band

COUSIN BIOTECH

INNOVATIVE TECHNOLOGY FOR LESS PAIN

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Obesity has become an epidemic…

- Obesity is defined by the World Health Organization as "excess body weight in the form of fat. When accumulated, this fat can lead to severe health impairments".

From a clinical standpoint, body mass is determined by calculating a person's Body Mass Index (BMI).
BMI is equal to a person's weight in kg divided by his height in metres squared:
BMI (kg/m^2) = weight (kg)/height^2 (m^2)

The higher the BMI, the higher the risk of suffering from health problems is.

BMI thresholds: [1]

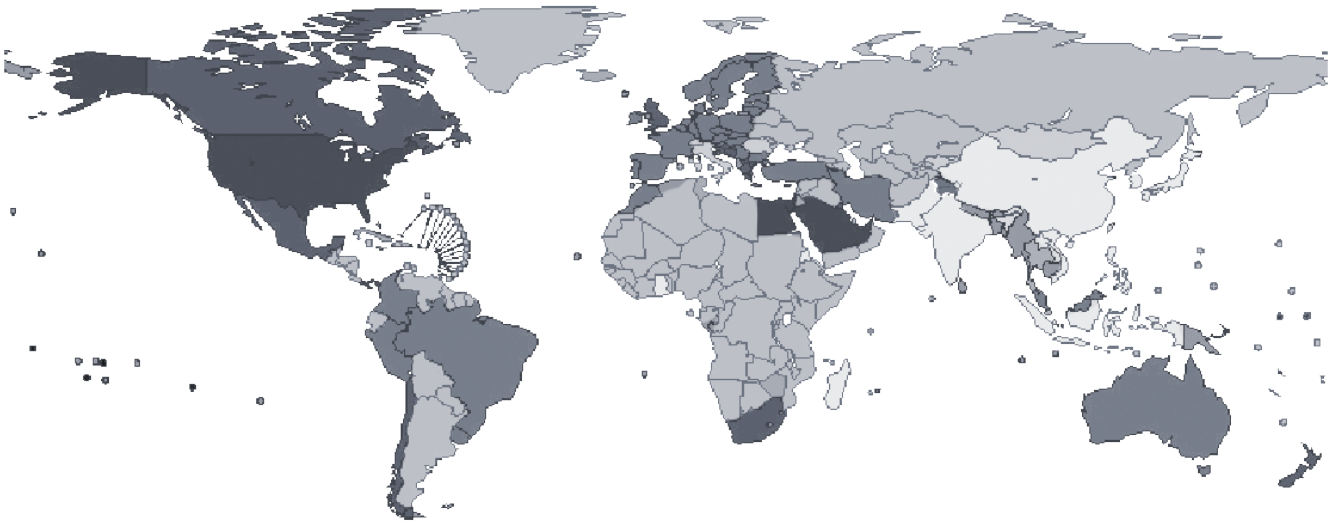
Underweight	Normal BMI	Overweight	Class I «moderate» obesity	Class II «severe» obesity	Class III «morbid» obesity

18,5 25 30 35 40

- Diseases associated with obesity are: [1]
  - cardiovascular diseases, including high blood pressure, stroke and coronary diseases,
  - type 2 diabetes,
  - certain types of cancer, mainly hormone-dependant and colorectal cancers,
  - respiratory diseases, chronic muscular-skeletal diseases, skin and fertility problems.

- The world has over 500 million obese adults. The prevalence of obesity is increasing and is expected to reach 700 million in 2015

- World map of obesity prevalence: [2]



% of obese adults (≥ 30.0 kg/m^2), most recent numbers:

50.0	10.0 - 20.0
40.0 - 50.0	5.0 - 10.0
30.0 - 40.0	0.0 - 5.0
20.0 - 30.0	no data

[1] World Health Organization (W.H.O.). Prevention and management of the global epidemic of obesity. Report of a WHO consultation on obesity, 3-5 june 1997. Geneva: WHO; 1997.
[2] According to WHO

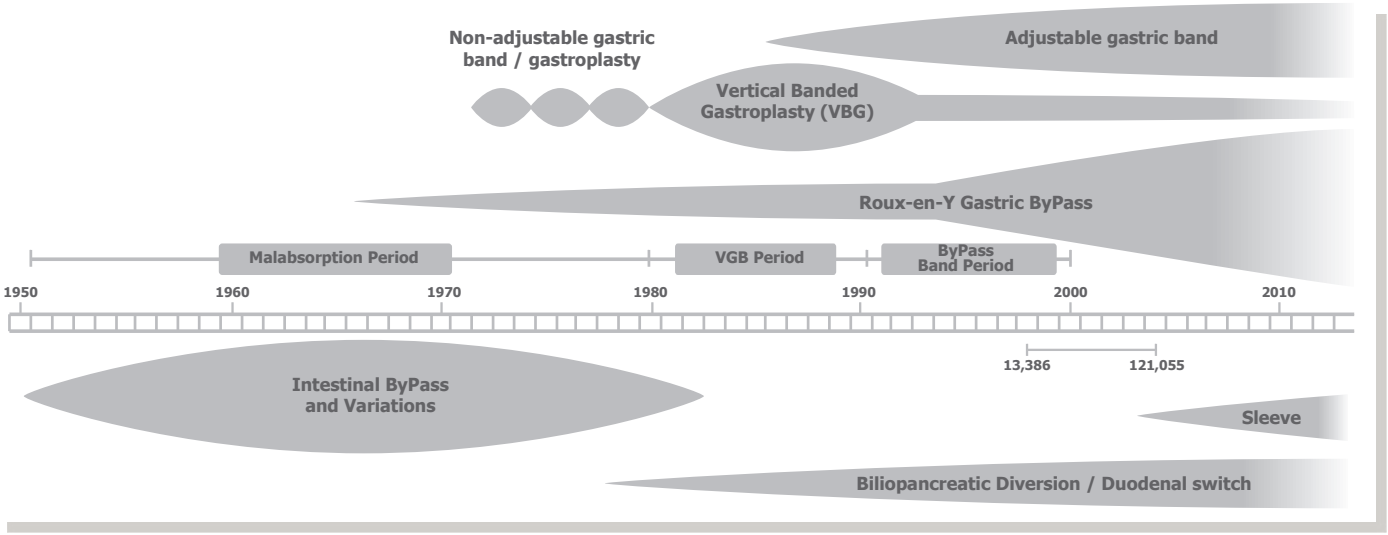
Obesity: how is it treated ?

- Surgery is the answer to failed diets and drugs.

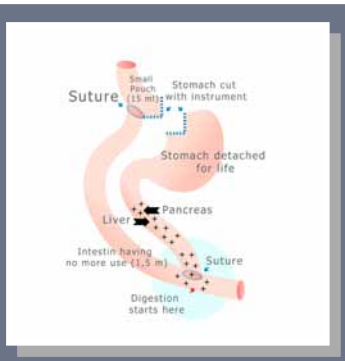
The idea of treating obesity with surgery appeared in 1952. [1]

- Two principles: :
  - restriction: limit the quantity of food ingested by reducing stomach volume,
  - malabsorption: decrease the assimilation of food with digestive tract bypass surgery.

- History of the development of bariatric surgery: [2]

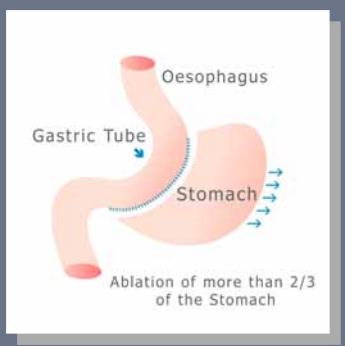


BYPASS



BAND

SLEEVE



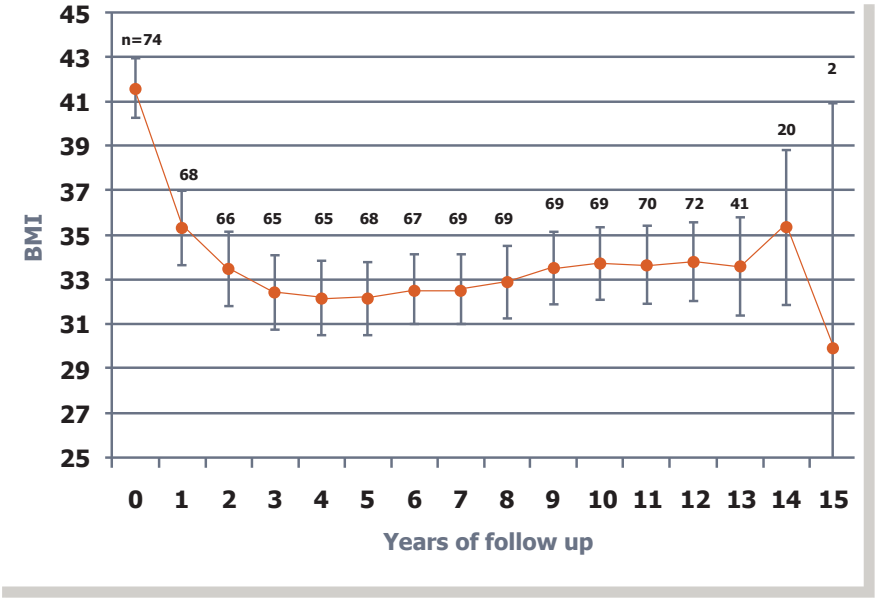
- Obesity surgery modifies the anatomy of the digestive system. It is recommended for a BMI of ≥40 kg/m² or BMI ≥35 kg/m² with associated co-morbidity factors. [3-4-5]
  The indications for the BIORING® gastric band comply with international recommendations.

- The three main techniques are:
  - Bypass: malabsorption and restriction,
  - adjustable gastric band: restriction,
  - the Sleeve: restriction.

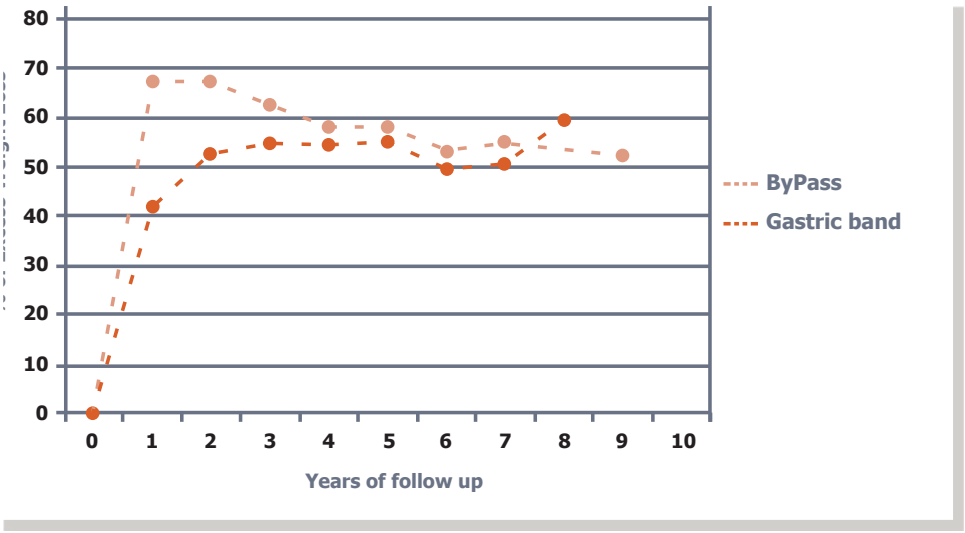
[1] Henrikson V. «Kan tunntarmsresektion forsvaras som terapi mot fettsot». (Can small bowel resection be defended for therapy for obesity?) Nordisk Medicin 47:744, 1952.
[2] Miller MR, et al. Surgical management of obesity: current state of procedure evolution and strategies to optimize outcomes. Nutr Clin Pract. 2011 Oct; 26(5):526-33.
[3] Scottish Intercollegiate Guidelines Network. Obesity in Scotland Integrating prevention with weight management. Edinburgh: SIGN; 1996.
[4] National Institutes of Health, National Heart Lung and Blood Institute. Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults: Executive summary. Am J Clin Nutr 1998;68:899-917.
[5] Association Française d'Études et de Recherches sur l'Obésité, Association de Langue Française pour l'Étude du Diabète et des Maladies Métaboliques, Société de Nutrition et de Diététique de Langue Française. Recommandations pour le diagnostic, la prévention et le traitement des obésités en France. Cah Nutr Diet 1998;33:10-42.

- Long-term gastric band results show that it is an effective solution to lose weight.

Change in BMI after gastric band surgery. [1]



- Over the long term, the Bypass and gastric band techniques provide an equivalent level of weight loss [2]



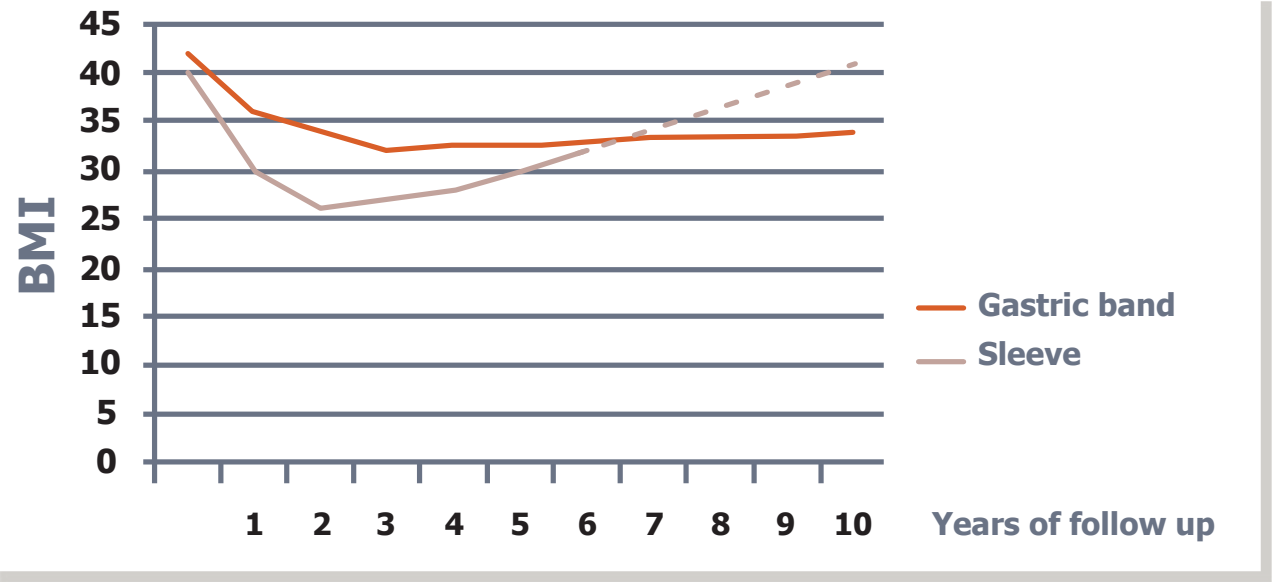
- Since the beginning of the decade, complications associated with the band have decreased tenfold following improvements to surgical techniques and the device. [3-4]

- Complications are less severe with a band than they are with a Sleeve or Bypass. [5]

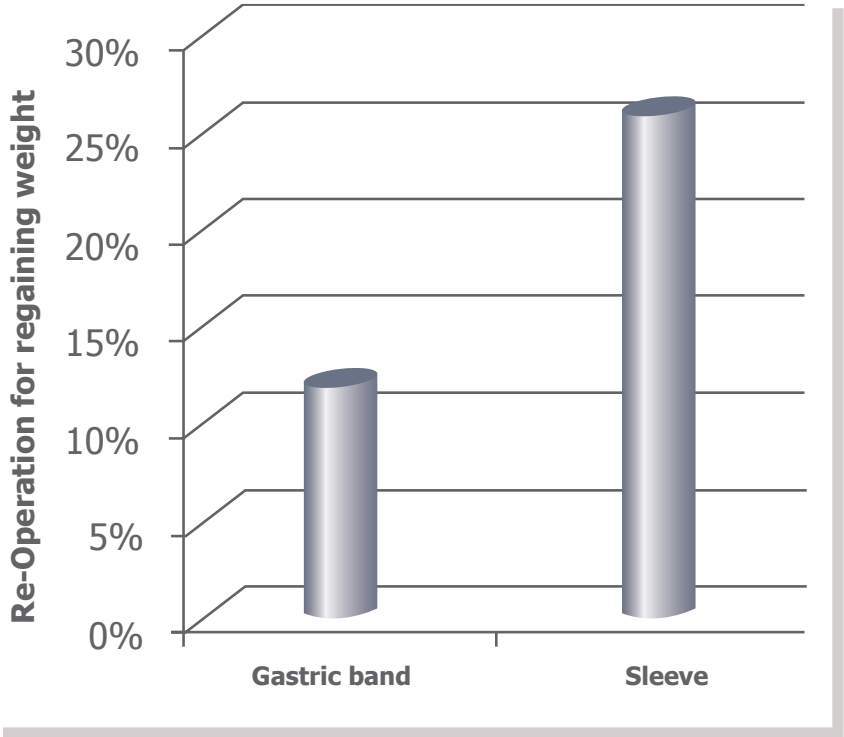
[1] Himpens J. Band, bypass and sleeve. XVI World Congress of the International Federation for the Surgery of Obesity and Metabolic Disorders, 2011.
[2] O'Brien P. et al. Bariatric surgery: mechanisms, indications and outcomes. Journal of gastroenterology and hepatology, 2010 - Wiley Online Library.
[3] O'Brien P. et al. Gastric banding : long terme outcome data . XVI World Congress of the International Federation for the Surgery of Obesity and Metabolic Disorders, 2011.
[4] Favretti et al. The Gastric Band: First-Choice Procedure for Obesity Surgery-World Journal of Surgery, 2009 - Volume 33, Number 10, 2039-2048.
[5] Himpens J. et al. A prospective randomized study between laparoscopic gastric banding and laparoscopic isolated sleeve gastrectomy: results after 1 and 3 years. Obes Surg. 2006 Nov;16(11):1450-6.

Bariatric surgery and regaining weight.

- Between 10 to 25% of patients operated regain weight 5 years post-operation. [1-2]
- Curves for the evolution in BMI over time show a quick regaining of weight after a Sleeve alone. [3]



- The rate of re-intervention after a Sleeve is twice as high as with a gastric band.
- Diagram of re-intervention for regaining weight after a Sleeve and gastric band: [3]



[1] Stacy et al. Beyond the systemic review-Bariatriac Times. 2011 ; 8(5 suppl) :9-10.
[2] Sjöström L. et al. Lifestyle, diabetes, and cardiovascular risk factors 10 years after bariatric surgery. N Engl J Med. 2004 Dec 23;351(26):2683-93.
[3] Himpens J. Band, bypass and sleeve. XVI World Congress of the International Federation for the Surgery of Obesity and Metabolic Disorders, 2011.

- In conclusion, the band shows:

  - long-term loss of excess weight, equivalent to the ByPass technique.
  - less severe complications
  - re-intervention rate for regaining weight twice as low as after a Sleeve
  - slower regaining of weight than after a Sleeve alone

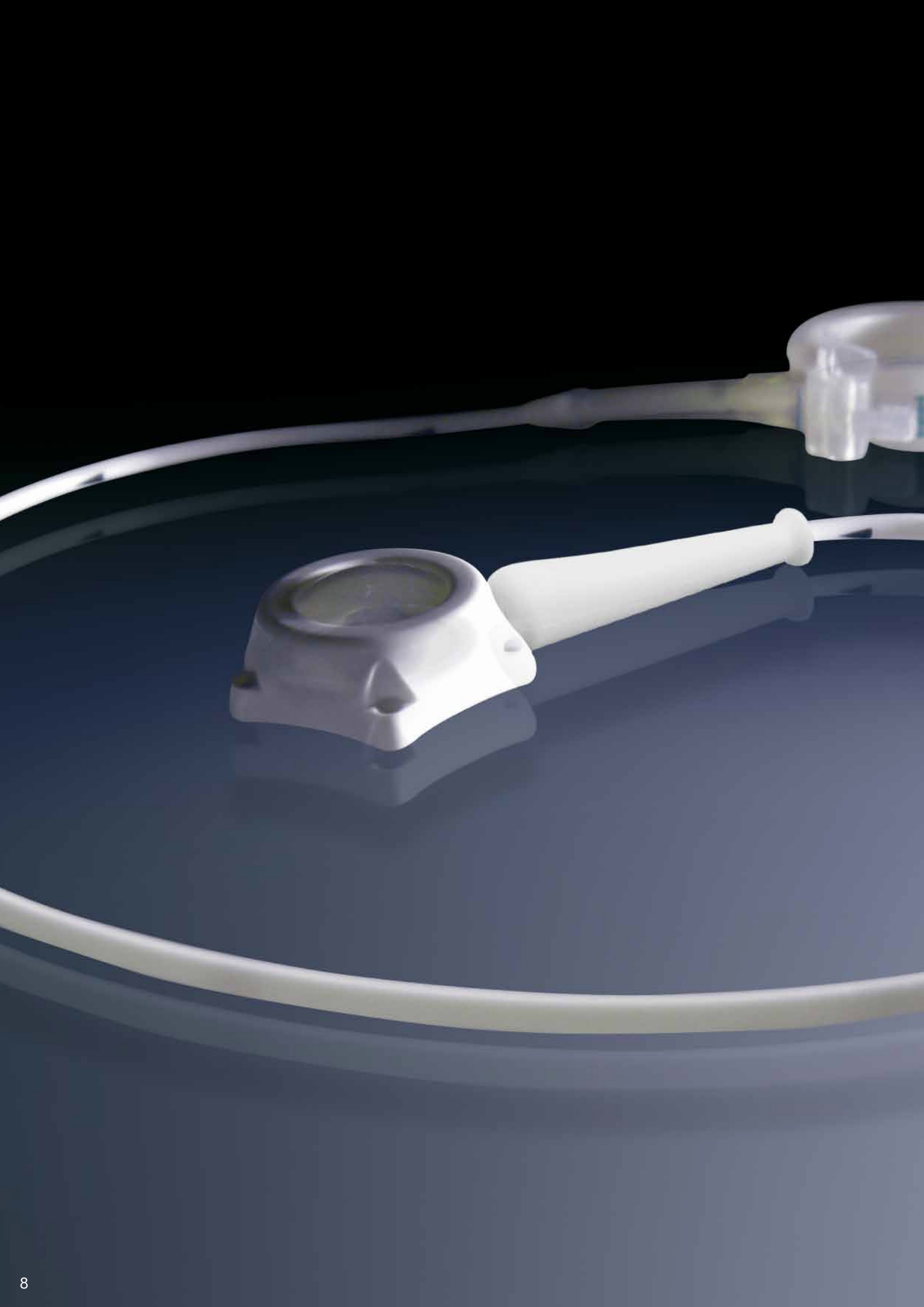
- Placing a gastric band is ideal in a patient's bariatric surgery course.
  As a first intervention, because this surgery is:
  - less invasive than all the other techniques,
  - reversible, it can be followed by other interventions. [1-2]

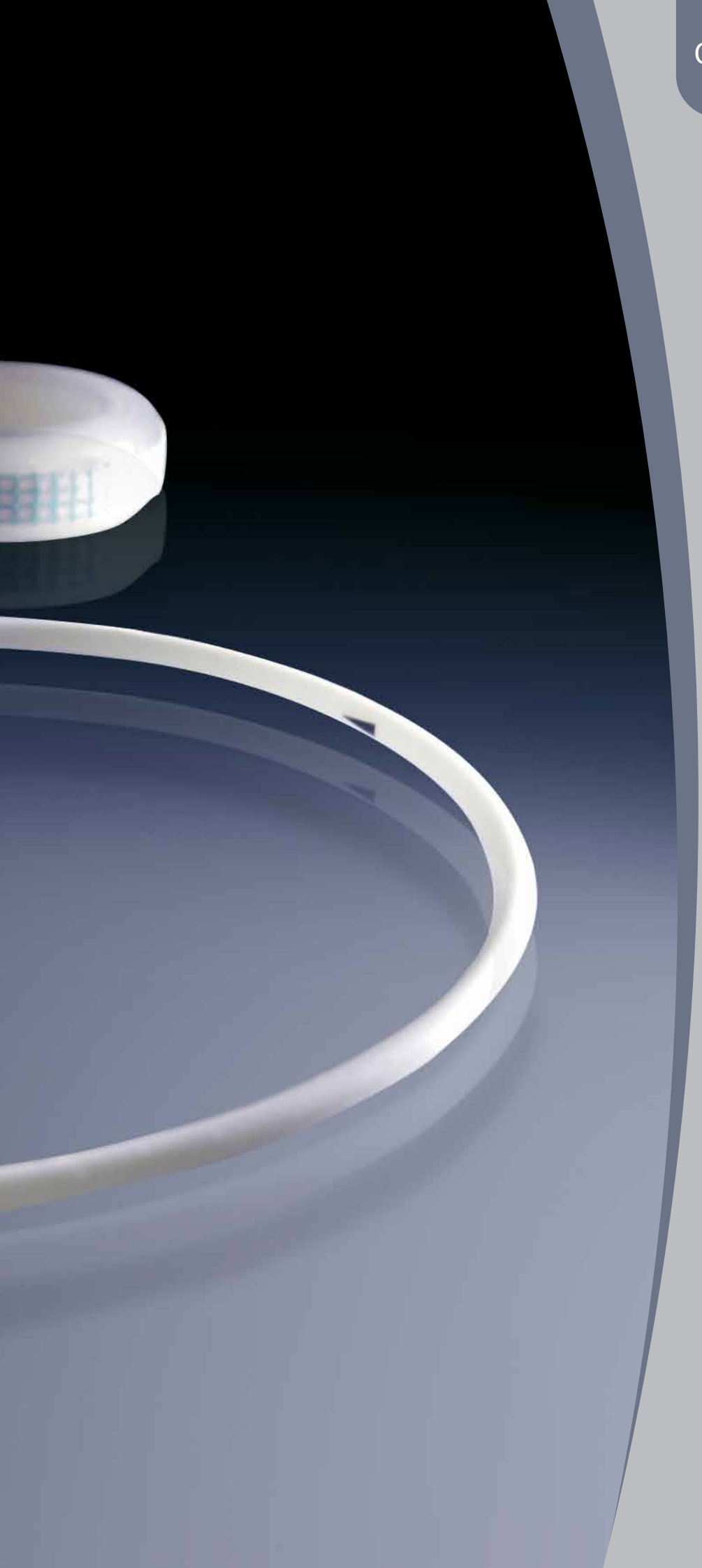
  Placement of a band can be performed as secondary surgical revision after gastric pouch dilation after Bypass or Sleeve surgery. [3]

Comparative table of results of various interventions: [4]

	Band	Sleeve	ByPass
Safety	+++	++	++
Efficacy	++	++	++
Durability	+++	?	+++
Side effects	+	+	++
Mini invasive	+++	++	++
Controllable/adjustable	Yes	No	No
Reversibility	Yes	No	No
Follow-up required	+++	+	++
Complications	- problems linked to the port: infections, rotation, catheter rupture, leakage, - slippage and pouch dilation, - stomach lesions: erosion, migration.	- early post-operative haemorrhage, - ulcers, stenosis, leakage - nutritional deficiencies - inflammation of the oesophagus - GERD, - stomach dilation, - fistula.	- nutritional deficiencies - surgical complications: ulcers, leakage, shrinking between the stomach and intestines, haemorrhage, intestinal occlusion, - functional complications: hypoglycaemia, dumping syndrome, constipation.

[1] Steffen R, et al. Successful multi-intervention treatment of severe obesity: a 7-year prospective study with 96% follow-up. Obes Surg. 2009 Jan; 19(1):3-12.
[2] Nienhuijs S.W. et al. Revision after sleeve gastrectomy. Abstract-CD XVI World Congress of the International Federation for the Surgery of Obesity and Metabolic Disorders, 2011.
[3] González J et al . Laparoscopic adjustable gastric band as a salvage procedure after failed roux-en-y gastric bypass- Abstract-CD XVI World Congress of the International Federation for the Surgery of Obesity and Metabolic Disorders, 2011.
[4] O'Brien P. et al. Bariatric surgery: mechanisms, indications and outcomes. Journal of gastroenterology and hepatology, 2010 - Wiley Online Library.





Advantages for the surgeon

BIORING® easily inserted through a 12 mm trocar.

Transparency prevents the unpleasant «flash» effect.

Catheter labelled with arrows for better orientation.

Slips easily into the retro-gastric tunnel.

Easily placed, with its pre-formed circle shape, ready to be locked.

Easy closing system.

Visual guide helps ensure locking.

Clip system that can be reopened for repositioning.

Catheter and band are radiopaque.

The BIORING® band was specifically designed to avoid the usual complications described in the literature: erosion, slippage, pouch dilation.

It was specifically designed for the Pars Flaccida technique.
Since 2003, our patented band has shown its efficacy.

Frontal plane of the BIORING®

and another band

BIORING® :
Smooth angles

Other band:
Triangle folds

Low pressure

High pressure

.... Prevent erosion

One of the causes of erosion is gastric wall trauma when implanting the band. [1]

- The BIORING®: trauma free band.
  Flexible and extensible silicone, with no rigid components.
  The streamlined and thin body offer a trauma free passage in the narrow retro-gastric tunnel.
  Its circular memory form allows encircling without pressure on the stomach.

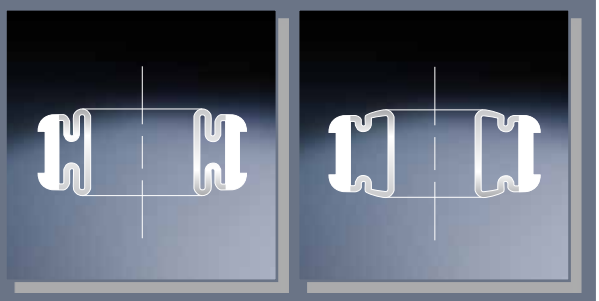
- The BIORING®: multidirectional distribution of forces.
  The forces resulting from inflation are exerted in several directions, thus decreasing pressure on the stomach.

- The BIORING®: no stomach pinching.
  The bellows system avoids the formation of triangle shaped folds that are aggressive on the stomach and silicone.
  Creases are rounded to avoid friction.

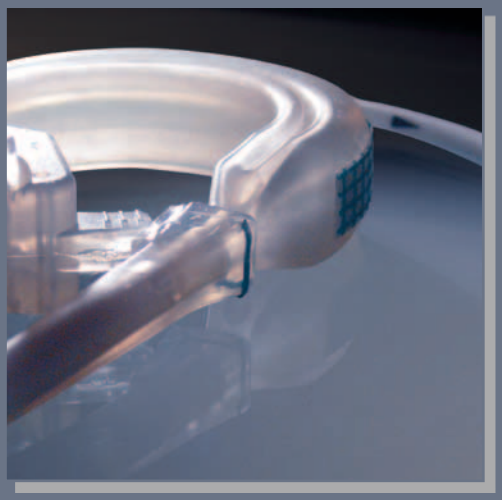
.... Prevent slippage

- The BIORING®: low-pressure band.
  Injecting liquid into the band can cause pressure on the stomach wall.
  The larger the contact surface between the band and the stomach, the better pressure is distributed.
  The band thus exerts less pressure on the stomach.
  It is a low-pressure band.

[1] Iyad Eidet al. Complications associated with adjustable gastric banding for morbid obesity: a surgeon's guide. Can J Surg. 2011 February; 54(1): 61–66.



Frontal plane of the bellows before and after inflation



Frontal plane of the bellows during inflation

- The BIORING®: the bellows system.
  Like an accordion, the bellows are always the same height, even when inflated.
  It constantly preserves a large contact surface with the stomach.
  Silicone is not stretched or thinned, and retains its natural adhesive properties.

- The BIORING®: a shock absorbing effect.
  The bellows follow the natural peristaltic movement of the stomach.
  Physiological movement is preserved.
  Gastro-gastric sutures, if used, are fixed points.
  They can give rise to a lever effect, which can cause the stomach to slip.

  This lever effect is compensated by the bellows that absorb the various forces.

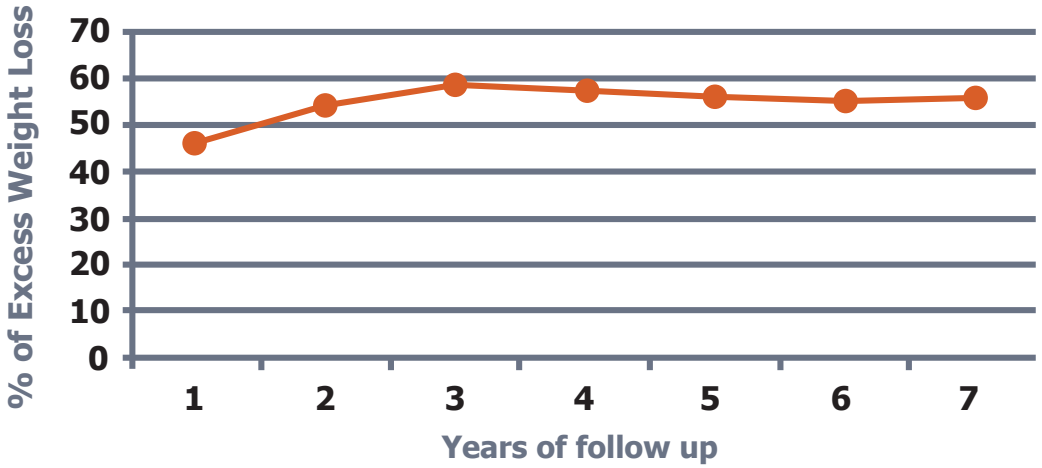
Prevent pouch dilation

- The BIORING®: optimal adjustment.
  Adequate adjustment is essential.
  The volume of liquid injected causes progressive and controlled tightening.
  The inflated surface spreads evenly around the stomach.

Prevent leakage

- Monoblock injection guarantees longevity.

- A prospective study has shown the efficacy of BIORING® on weight loss at 7 years. [1]



The implantation of the BIORING® band is a safe and simple operation. Average weight loss is considered successful (% excess weight loss >50).
It lasts after 5-7 years post-operation.

- A randomised, double-blind international study compared the results of the BIORING® band to a com petitor's band for 36 months: [2-3]

EWL (excess weight loss),	BIORING®	Competitor's band
12 months	40	36
36 months	57	38

At 36 months, complications are: [3]

	BIORING®	Competitor's band
Oesophageal dilation	4.5%	12.0%
Gastric pouch dilation	0%	4.0%
Band slippage	0%	0%
Band erosion	0%	0%
Catheter leaking	4.5%	8.0%
Port rotation	0%	4.0%

- A clinical study evaluated the placing of a band in the case of regaining weight after bariatric surgery failure. [4]
  The BIORING® is recommended in this case.
  Its streamlined form and shape memory allow for passage without trauma to the dissected narrow zone.

[1] Erik Niville et al. A Mid-term Experience with the Cousin Bioring—Adjustable Gastric Band. Obesity Surgery 2011.
[2] F. Pattou. Randomized Controled Study Comparing LAGB with Bioring (Cousin) and Lapband (Allergan): One Year Outcome. OBES SURG 2009 19:953–1076.
[3] Outcome after laparoscopic adjustable gastric banding using BIORING® versus VANGUARD®- A prospective randomised study Etude terminée le 10/03/2011. Rapport clinique final établi par la société Mediscan (Paris) et validé le 08/07/2011. Résultats non publiés.
[4] P.Grumillier. Pose d'un nouvel anneau gastrique après échec de chirurgie bariatrique restrictive. Le journal de coelio-chirurgie, 2005.

3 band sizes:

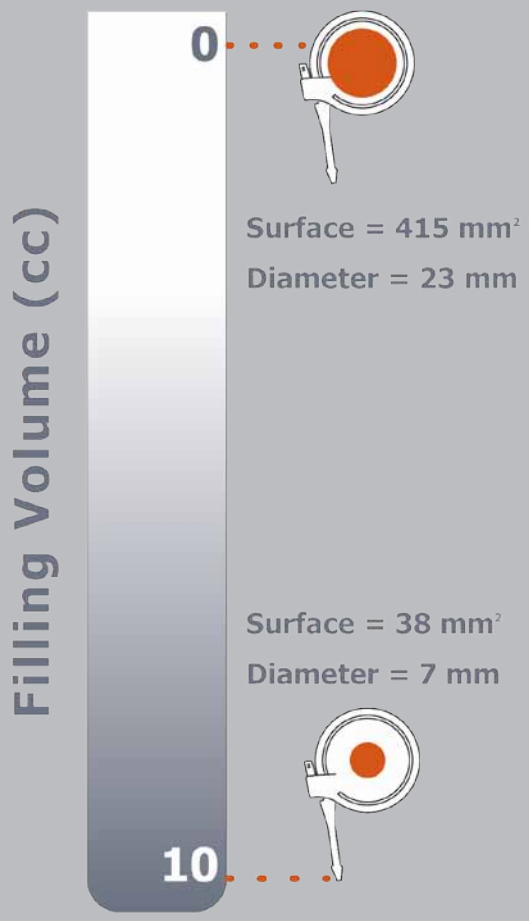
The 3 sizes perfectly adapt to the patient's anatomy and the surgeon's technique.

A wide range of adjustment is possible to optimise control of satiety.

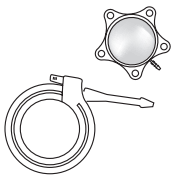
- **BIORING® SMALL** [1]

It can be appropriate for revision after a gastric pouch dilation that can occur after a Sleeve or Bypass.

- Filling diagram, internal surface and diameter of the band:



	Small
Maximum filling volume	10 cc
Band length	7.3 cm
Trocar	12 mm

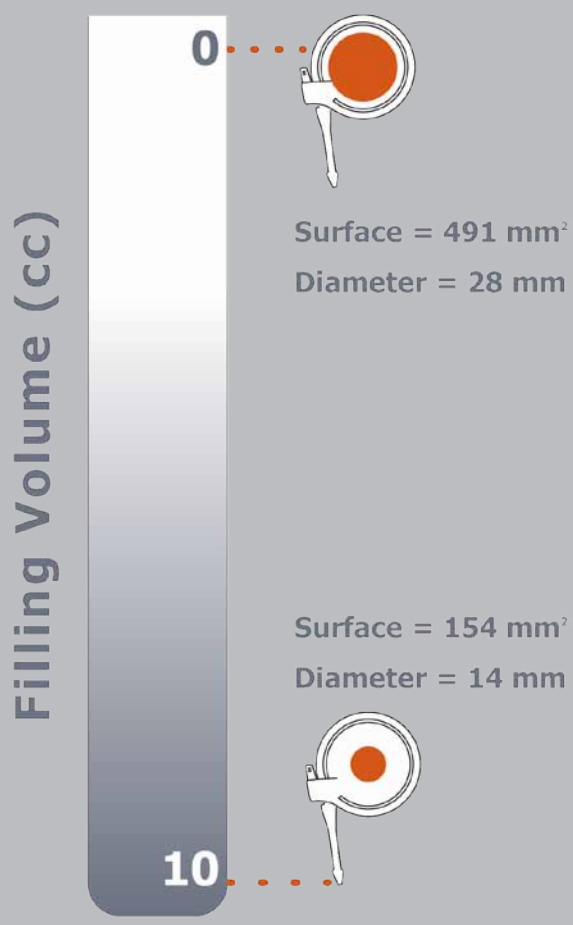
Shape	Product codes	Description	Type of port
	RINGS 20 000	Band + Syringe + Catheter rinser + Gripping tab + Connector + Huber needle	Port to suture
	BCBRI20 AD U	Band + Syringe + Catheter rinser + Gripping tab + Connector + Huber needle	Self-adhesive port

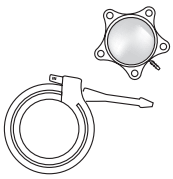
[1] Respecting the following indications: BMI≥40 kg/m² or BMI≥35 kg/m² with associated comorbidity factors.

- **BIORING® MEDIUM** [1]

It adapts to most patients

- Filling diagram, internal surface and diameter of the band:



Shape	Product codes	Description	Type of port
	BCB RI23 PO U	Band + Syringe + Catheter rinser + Gripping tab + Connector + Huber needle	Port to suture
	BCB RI23 AD U	Band + Syringe + Catheter rinser + Gripping tab + Connector + Huber needle	Self-adhesive port

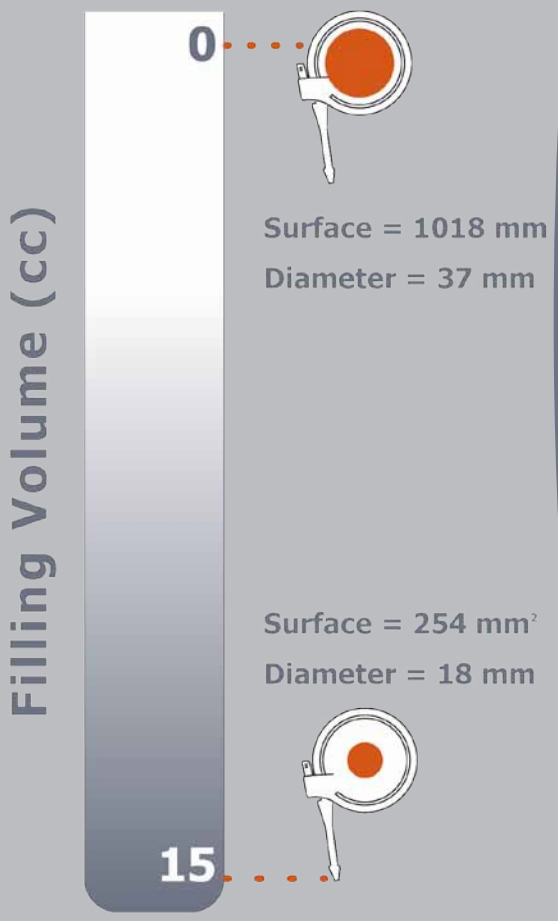
	Medium
Maximum filling volume	10 cc
Band length	7.9 cm
Trocar	12 mm

[1] Respecting the following indications: BMI≥40 kg/m² or BMI≥35 kg/m² with associated comorbidity factors.

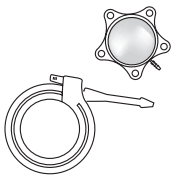
- **BIORING® XL [1]**

It adapts
- to the most obese patients BMI ≥ 60 kg/m2,
- to band revisions,
- to men with significant Belsey fat.

- Filling diagram, internal surface and diameter of the band:



	X Large
Maximum filling volume	15 cc
Band length	11 cm
Trocar	12 mm

Shape	Product codes	Description	Type of port
	BCB RIXL PO U	Band + Syringe + Catheter rinser + Gripping tab + Connector + Huber needle	Port to suture
	BCB RIXL AD U	Band + Syringe + Catheter rinser + Gripping tab + Connector + Huber needle	Self-adhesive port

[1] Respecting the following indications: BMI≥40 kg/m² or BMI≥35 kg/m² with associated comorbidity factors.

Implantable port

BIORING® ports were specifically designed to avoid the usual complications described in the literature:
- rotation
- leakage
- disconnections
- infections

Prevent rotation

- Ø 34mm base:
  large contact surface, better stability,
- 5 possible fixation points
- Stable pentagonal shape.

Prevent leaks

- Connection bolt to avoid leaks due to injections.
- Large septum: easy to puncture.

Prevent catheter ruptures

- Flexible, smooth connector: no rubbing angle with the catheter and prevents the shearing effect,
- Catheter and connector in flexible silicone: prevents abrasive rubbing.

Frontal plane of the connector

Prevent disconnections

- Triple safety locking system,
- Thick lip: audible and safe clipping,
- Triple flange: high catheter resistance,
- Reinforced at the cannula/body junction: no risk of breaking.

Port to suture

Self-adhesive port

Implantable Port

Two models available:

- port to suture
- self-adhesive port

Technical characteristics:

- « Low profile » : 10.2 mm high,
- Septum Ø 16mm
- Radio opaque.

Flat port, wide septum:

- easier band adjustment
- patient comfort.

SELF-ADHESIVE PORT

Unique

Adapted design
- « Low profile »
- Large septum
- Safe connection

Rapidity
- No suture
- Saves time

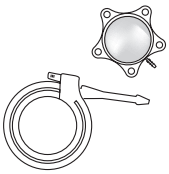
A-traumatique
- No sutures
- No hooks
- No staples

Efficacy
- Self-adhesive [1]
- Directly on the fascia

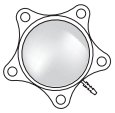
[1] Champault G et al. A «self adhering» prothesis for hernia repair: experimental study. Hernia 2009, 13:49-52

ADHESIX® BIORING®

- Gastric band with self-adhesive port

Shape	Product codes	Sizes (cm)	Description
	BCBRI20 AD U	Ø 2,3	Band + Syringe + Catheter rinser + Gripping tab + Self-adhesive Port + Connector + Huber needle
	BCBRI23 AD U	Ø 2,8	
	BCBRIXL AD U	Ø 3,7	

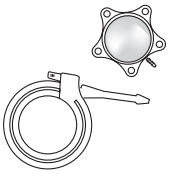
- Replacement kit with self-adhesive port

Shape	Product codes	Description
	BCB RIRE AD U	Self-adhesive port + Connector + Huber needle + Catheter + Connector + Obturator + Catheter rinser

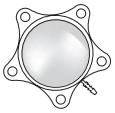
One sterile implant per box

BIORING®

- Gastric band with port to suture

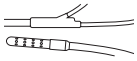
Shape	Product codes	Sizes (cm)	Description
	RINGS 20 000	Ø 2,3	Band + Syringe + Catheter rinser + Gripping tab + Port + Connector + Huber needle
	BCB RI23 PO U	Ø 2,8	
	BCBRIXL PO U	Ø 3,7	

- Replacement kit with port to suture

Forme	Référence	Description
	BCB RIRE PO U	Port to suture + Connector + Huber needle + Catheter + Connector + Obturator + Catheter rinser

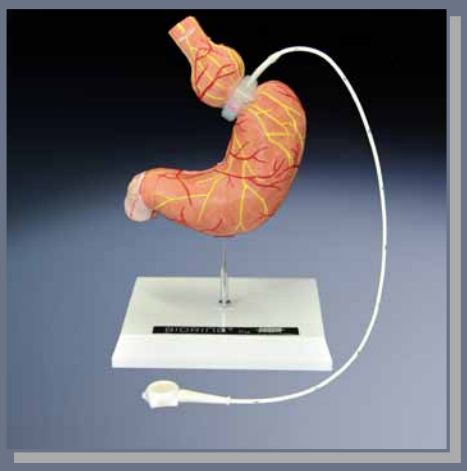
One sterile implant per box

Accessories

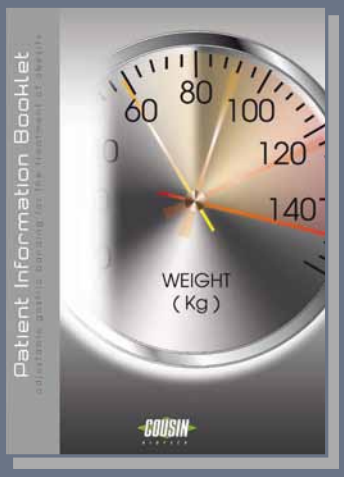
Shape	Product codes	Sizes	Description
	RING CATH 00	30 French, length: 1490 mm	Gastric calibration tube
	BCB RIHU BE U	diameter: 0,9 mm / 20G length: 80 mm / 3 ¼ inch	Box of 50 straight Huber needles

Sterile Accessories

- Demo case for **BIORING®** product range



- Stomach model presenting the **BIORING®** band



- Patient information booklet

- Post-operative advice for patients

Notes

Photos and texts non contractual. Specifications can be modified without notice. CABOBEGB01
Cousin Biotech SAS with a capital of 334 384 € 398 460 261 RCS Lille – VAT No. FR34 398 460 261 – 28/10/2011

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