OSSERVATORIO SIFO DISPOSITIVI MEDICI a cura del Laboratorio SIFO di Farmacoeconomia coordinatori del progetto ***Sabrina Trippoli – Valeria Fadda – Dario Maratea – Andrea Messori***	**Assegnato a**
J Urol. 2011 Jul;186(1):198-203. **Management of stress urinary incontinence following prostate surgery with minimally invasive adjustable continence balloon implants: functional results from a single center prospective study**. Rouprêt M, Misraï V, Gosseine PN, Bart S, Cour F, Chartier-Kastler E. PURPOSE: We determined the functional results and morbidity of balloon (ProACT™) implants for the treatment of male stress urinary incontinence after prostate surgery. MATERIALS AND METHODS: Between 2002 and 2008 a prospective, noncontrolled study was conducted. The ProACT implant consists of 2 adjustable balloons placed on either side of the native striated sphincter. The implants are adjusted by inflation during followup visits. The primary efficacy end point was postoperative continence as defined by the use of 0 to 1 pad daily. RESULTS: A total of 128 consecutive patients underwent implantation. Mean ± SD patient age was 71 ± 42.3 years (range 52 to 87). The severity of incontinence before ProACT was moderate (71), mild (40) and severe (17). Overall 25% of patients previously underwent pelvic radiotherapy. The mean number of daily pads per patient was 1.46 (vs 4.2 at baseline). Mean followup was 56.3 months (range 24 to 95). The functional result was success in 68% of patients with moderate/mild incontinence and the explantation rate was 18%. Among the 30 patients treated with radiotherapy before ProACT the success rate was only 46% and the incidence of urethral erosion was significantly higher (p = 0.005). CONCLUSIONS: The ProACT implant appears to be an option for the treatment of moderate male stress urinary incontinence, especially given the minimally invasive modalities of insertion, the capacity to adjust the inflation of the balloons to achieve postoperative continence and the relative reversibility.	**Lab SIFO Farmacoeconomia**
Heart. 2011 Jul;97(13):1041-7. Epub 2011 Feb 21.	**Lab SIFO Farmacoeconomia**

Cardiac resynchronisation therapy in patients with heart failure and a normal QRS duration: the RESPOND study. Foley PW, Patel K, Irwin N, Sanderson JE, Frenneaux MP, Smith RE, Stegemann B, Leyva F. OBJECTIVES: To evaluate the clinical response to cardiac resynchronisation therapy (CRT) in patients with heart failure and a normal QRS duration (<120 ms). SETTING: Single centre. PATIENTS: 60 patients with heart failure and a normal QRS duration receiving optimal pharmacological treatment (OPT). INTERVENTIONS: Patients were randomly assigned to CRT (n=29) or to a control group (OPT, n=31). Cardiovascular magnetic resonance was used in order to avoid scar at the site of left ventricular (LV) lead deployment. MAIN OUTCOME MEASURES: The primary end point was a change in 6 min walking distance (6-MWD). Other measures included a change in quality of life scores (Minnesota Living with Heart Failure questionnaire) and New York Heart Association class. RESULTS: In 93% of implantations, the LV lead was deployed over non-scarred myocardium. At 6 months, the 6-MWD increased with CRT compared with OPT ($p<0.0001$), with more patients reaching a ≥25% increase (51.7% vs 12.9%, $p=0.0019$). Compared with OPT, CRT led to an improvement in quality-of-life scores ($p=0.0265$) and a reduction in NYHA class ($p<0.0001$). The composite clinical score (survival for 6 months free of heart failure hospitalisations plus improvement by one or more NYHA class or by ≥25% in 6-MWD) was better in CRT than in OPT (83% vs 23%, respectively; $p<0.0001$). Although no differences in total or cardiovascular mortality emerged between OPT and CRT, patients receiving OPT had a higher risk of death from pump failure than patients assigned to CRT (HR=8.41, $p=0.0447$) after a median follow-up of 677.5 days. CONCLUSIONS: CRT leads to an improvement in symptoms, exercise capacity and quality of life in patients with heart failure and a normal QRS duration.	
Dig Dis Sci. 2011 Jul;56(7):2030-6. Epub 2011 Jan 25. **A double-layered (comvi) self-expandable metal stent for malignant gastroduodenal obstruction: a prospective multicenter study.** Kim YW, Choi CW, Kang DH, Kim HW, Chung CU, Kim DU, Park SB, Park KT, Kim S, Jeung EJ, Bae YM. BACKGROUND: A self-expandable metal stent (SEMS) has emerged as an effective palliative treatment for malignant gastroduodenal obstruction resulting from gastric or periampullary malignancy. Despite the stent's effectiveness, tumor ingrowth and stent migration remain complications requiring reintervention. The purpose of	**Lab SIFO Farmacoeconomia**

this study was to evaluate the efficacy and safety of a double-layered SEMS (Comvi). METHODS: We performed a prospective multicenter study in two university hospitals and two referral hospitals. In fifty consecutive patients with malignant gastroduodenal obstructions, placement of double-layered SEMS, comprising an outer uncovered stent and an inner covered stent that overlap each other, was performed. Palliation, efficacy, and incidence of complications were evaluated. RESULTS:Technical and clinical success was achieved in 100 and 88% of patients, respectively. There were no procedure-related complications. Five patients experienced stent migration (10%). For four of five patients' stent migration occurred within two weeks of stent placement. Stent collapse occurred in five patients after one month. Reintervention for stent migration, collapse, or tumor overgrowth was required for 14 (28%) patients. CONCLUSIONS:Endoscopic placement of a double-layered stent is a safe and effective modality for the palliation of malignant gastroduodenal obstruction. However, considering reintervention, this stent does not seem to add any clear advantage compared with preexisting uncovered stents. Migration, especially within the first two weeks, and stent collapse are still unresolved problems. The device should be fixed or the design modified to reduce these problem	