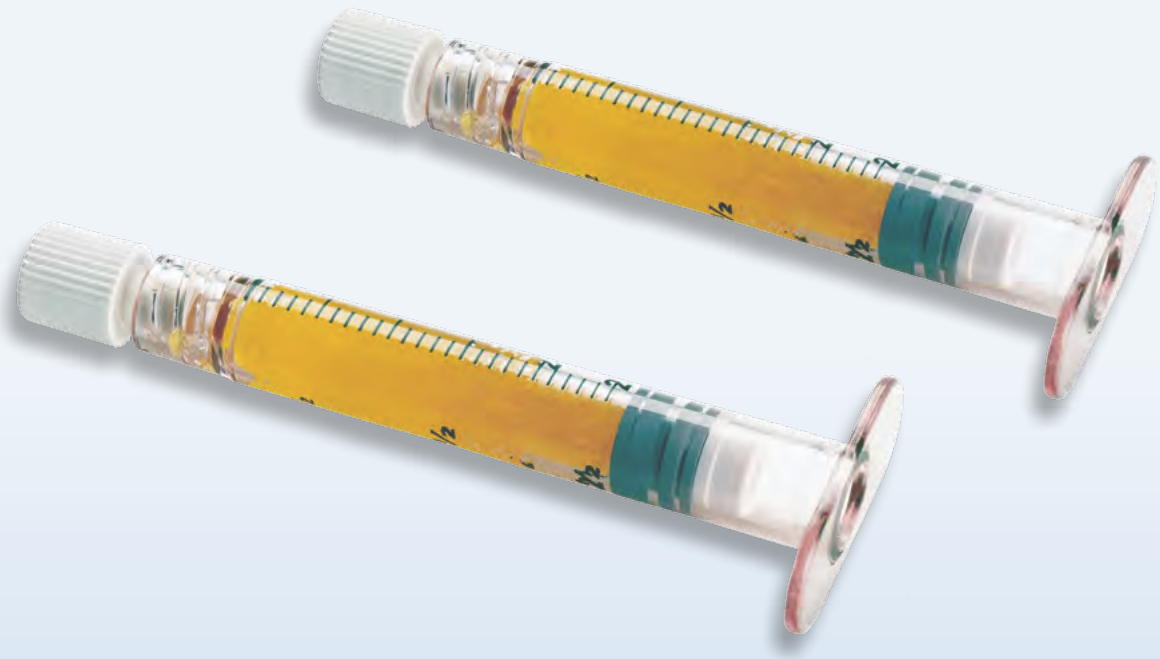
Ptq®
IMPLANTS



Safe. Simple. Restorative.

» Minimally invasive treatment for faecal incontinence
» Proven performance since 2002
» Effective in the short-term and beyond

Cogentix
Medical

Ptq®
IMPLANTS

Safe. Simple. Restorative.

PTQ® Implants are indicated for trans-sphincteric implantation in the Internal Anal Sphincter (IAS) for the treatment of passive faecal incontinence due to a weak or disrupted internal anal sphincter.

PTQ fills “the gap” between conservative and invasive treatments and provides results in the short term and beyond.

> “Considering the complexity of anal incontinence and the need to provide adequate care ... injection of a bulking agent is an attractive minimally invasive option.”[1]

Safe

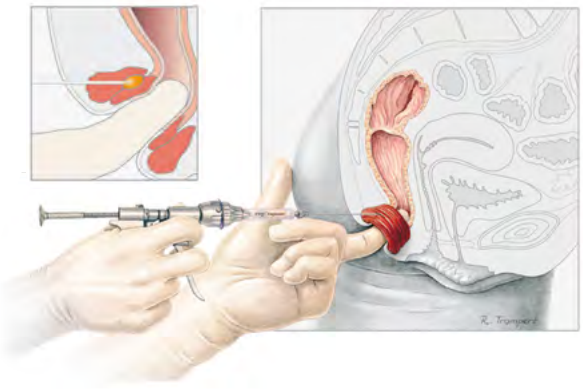
- Used to treat faecal incontinence since 2002
- Technology based on 20 years of experience with Macroplastique®, the leading urinary bulking agent in Europe
- Treatment is generally well-tolerated by patients
- Complications typically minor and transient

Simple

- Minimally invasive
- Immediate results
- Simple technique
- Local anaesthesia
- Outpatient / day case procedure

Restorative

- Up to 95% of patients show a significant improvement in incontinence scores[1,2]
- Provides sustainable improvement for 12-24 months[1-10]
- Improves patient quality of life[1-3, 6, 11]
- Reinjection is safe and effective[4]
- Helps improve anal asymmetry index which may be linked to increased maximum resting anal canal pressures[1]



"Injection of [PTQ Implants] provided a marked improvement in fecal continence and quality of life in patients with internal sphincter dysfunction, despite the presence of pudendal neuropathy"[4]

Clinical Highlights

Effective in the Short Term and Beyond

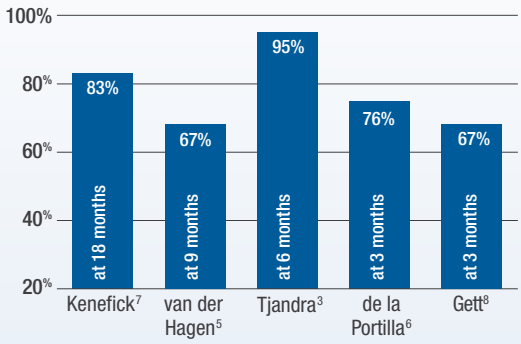
- Majority of patients cured/improved following PTQ treatment[1-11]
- Studies indicate that the maximum improvement typically occurs between 3 and 12 months[1, 4, 5, 8-11]
- Significant improvements over baseline are maintained at 18 or 24 months[2, 6-8, 10]
- At 28 month median follow-up:
  - 70% of patients were continent and extremely satisfied[2]
  - 95% of patients maintained continence from 6 weeks[2]

Improvements in Quality of Life

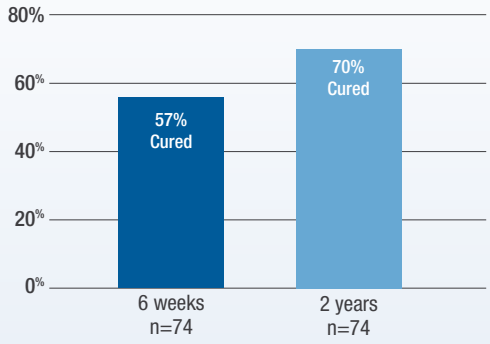
- Significant improvements in all QoL domains in clinical studies (follow-up range of 6 weeks - 42 months)[1-4, 6, 10, 11]
- Significant improvements in SF-12 physical health scale at 12 months[3, 4]
- Significant improvements in SF-36 physical health and social function scores at 18 months[7]
- Significant improvements in resting and squeeze pressures[2]

"Beneficial effects of [PTQ] Implants can continue for up to 4 years."[2]

Patients Cured/Improved After PTQ® Treatment



PTQ® Patients Cured Through 2 Years[2]



"There was a significant improvement in all domains of the faecal incontinence quality of life scale in the PTQ group at 6 weeks and 6 months ... By contrast there was no improvement in any domain ... in the Durasphere group ..."[3]

Ptq®
IMPLANTS

Product Information

Catalog Number	Product Description	Procedure Requirements
PTQ-2.5	**PTQ Implants** 2.5 ml unit	3 units
AD	**Reusable Administration Device** Includes syringe adapter	1 device
PRN-090	**Uroplasty Rigid Needle** 18 gauge x 90 mm long	1 needle

1. Oliveira, L.C.C., Jorge, J.M.N., Yussuf, S. Habr-Gama, A., Kiss, D., & Cecconello, I. (2009). Anal incontinence improvement after silicone injection may be related to restoration of sphincter asymmetry. *Surgical Innovation, 16*(2), 155-161.
2. Bartlett,L. & Ho, Y.H.(2009). PTQ™ anal implants for the treatment of faecal incontinence. *British Journal of Surgery, 96*, 1468-1475.
3. Tjandra, J.J., Chan, M.K.Y., & Yeh, H.C.H. (2009). Injectable silicone biomaterial (PTQ™) is more effective than carbon-coated beads (Durasphere®) in treating passive faecal incontinence - A randomised trial. *Colorectal Dis., 11*, 382-389.
4. Tjandra, J.J., Lim, J.F., Hiscock, R., & Rajendra, P. (2004). Injectable silicone biomaterial for fecal incontinence caused by internal anal sphincter dysfunction is effective. *Dis Colon Rectum, 47*, 2138-2146.
5. van der Hagen, S.J., van Gemert, W.G., & Baeten, C.G. (2007). PTQ™ Implants in the treatment of faecal soiling. *Br J. Surgery, 94*, 222-223.
6. de la Portilla, F., Fernández, A., León, E., Rada, R., Cisneros, N., Maldonado, V.H., Vega, J., & Espinoda, E. (2008). Evaluation of the use of PTQ™ implants for the treatment of incontinent patients due to internal anal sphincter dysfunction. *Colorectal Dis, 10*, 89-94.
7. Kenefick, N.J., Vaizey, C.J., Malouf, A.J., Norton, C.S., Marshall, M., & Kamm, M.A. (2002). Injectable silicone biomaterial for faecal incontinence due to internal anal sphincter dysfunction. *Gut, 51*, 225-228.
8. Gett, R., Gyorki, D., Keck, J., Chen, F., & Johnston, M. (2007). Managing faecal incontinence: The role of PTQ injections. Royal Australian and New Zealand College of Surgeons Annual Scientific Congress. *The Australian and New Zealand Journal of Surgery, 77*(Suppl 1), A16.
9. Gaj, F., Trecca, A., & Crispino, P. (2007). "[Efficacy of PTQ agent in the treatment of faecal incontinence]." Chir Ital, 59(3), 355-359.
10. Tjandra, J.J., Tan, J., Lim, F., & Murray-Green, C. (2006). Long-term results of injectable silicone biomaterial for passive fecal incontinence - A randomized trial. *Dis Colon Rectum, 49*(5), 730-731.
11. Bach, S., Lindsey, I., George, B., Cunningham, C., & McC. Mortensen, N.J. (2004). Implantable silicone for passive fecal incontinence secondary to internal anal sphincter deficiency. Poster ASCRP, Dallas, USA.

For complete instructions for use, storage, warnings, indications, contraindications, precautions, adverse reactions and disclaimer of warranties, please refer to the insert accompanying each PTQ product or online at www.cogentixmedical.com. PTQ is a registered trademark. PTQ is manufactured by Uroplasty, LLC. Models are for illustrative purpose only. 65002C 9/15

Cogentix Medical

cogentixmedical.com

Hofkamp 2,
6161 DC Geleen
The Netherlands

TEL +31 (0)46.423.79.20
FAX +31 (0)46.423.79.22
info.holland@cogentixmedical.com

Manchester Business Park
3000 Aviator Way
Manchester M22 5TG

TEL 0800.032.5964
FAX 0800.032.5965
info.uk@cogentixmedical.com

CE 0473