



THD GATEKEEPER



Use

THD Gatekeeper is a system for the treatment of faecal incontinence and soiling.

THD Gatekeeper allows the implantation of 6 prostheses in the intersphincteric space of the anal canal through a special Delivery System. These prostheses exerting pressure on the sphincter (internal and external) improve the sphincter tone resulting in increased continence.

General Description

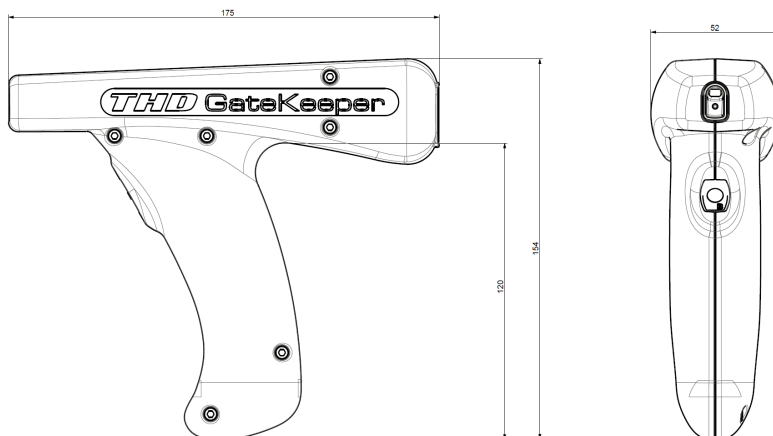
The THD Gatekeeper system includes an applicator powered by batteries (Delivery System) and a dispenser kit (Self Expandable Implant). Both devices are sterile and disposable.

The implantable prosthesis is made with HYEXPAN, a unique synthetic material able to expand through the absorption of body fluids. The prostheses are implanted in the intersphincteric space of the anal canal by the Delivery System: here the prostheses absorb the body fluids and then expand to reach their final hydrated size.

The Gatekeeper prostheses are inert and biocompatible, have long-term stability and can be easily localized with an endoanal ultrasound: once the body fluids are absorbed, the prostheses become softer and their consistence can be compared to the surrounding sphincter muscle tissue. Once the prostheses become thicker, they remain within the intersphincteric space of the anal canal and the risk of spontaneous dislocation is very low. In the end, thanks to their characteristic shape-memory, they can adapt to the complex physiological aspect of the defecation process by either allowing or blocking the passage of the stool when necessary. The Gatekeeper Delivery System, made of a medical material, allows for a guided, easy and precise positioning of the prosthesis.

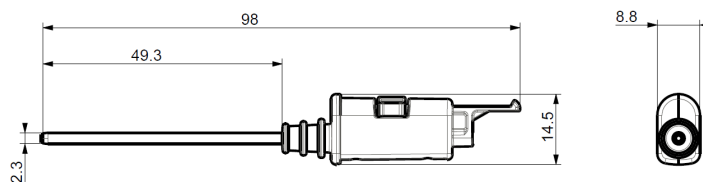


Delivery System Features



Length	175 mm
Height	155 mm
Width	52 mm
Handle Height	120 mm
Handle Width	37 mm
Battery	4.5 V Alkaline
Weight	300 g

Self Expandable Implant Dimensional Features



Length	98 mm
Height	14.5 mm
Width	8.8 mm
Tube Diameter	2.3 mm
Tube Length	49.3 mm
Weight	4 g

Code	Contents		Packaging
820005	THD GATEKEEPER – 6X Self Expandable Implant		Sterile/Disposable
Code	Q.ty	Description	
820003	1	THD Gatekeeper Delivery System	
820004	6	THD Gatekeeper Self-Expandable Implant	