vantris®

VUR treatment

A DEFINITIVE SOLUTION FOR VUR

RELIABLE RESULTS,
EVEN IN HIGH-GRADE REFLUX.

Promedon

People + Innovation

Endoscopic treatment of vesicoureteral reflux

Preferred for the management of Vesicoureteral Reflux (VUR) in children, endoscopic treatment has numerous advantages over long-term antibiotic prophylaxis and surgical procedures.

Through a subureteral injection of tissue bulking substance, endoscopic treatment of VUR offers an effective and minimally invasive alternative to surgery when antibiotic prophylaxis fails to produce the desired results.

The benefits of endoscopic treatment

- Minimally invasive procedure.
- Treatment performed on an outpatient basis.
- Immediate results.
- Higher efficacy rate than antibiotic prophylaxis.
- No surgery-related risks.
- Unlike the surgical alternative, hospital visits and costs are significantly reduced.

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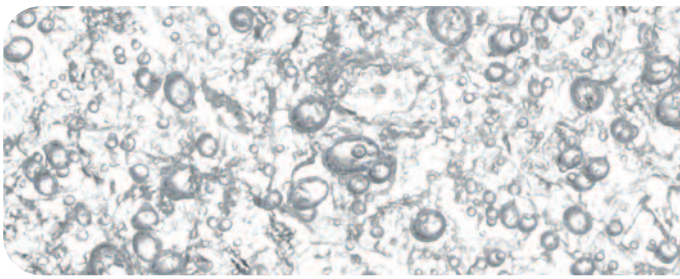
Safe and Effective Treatment

Vantris is a biocompatible, non-absorbable, synthetic tissue-bulking agent designed for the treatment of Vesicoureteral Reflux (VUR) in children.
As a hydrogel comprised of stable, highly malleable macroparticles, Vantris is resistant to particle migration.



Why Choose Vantris?

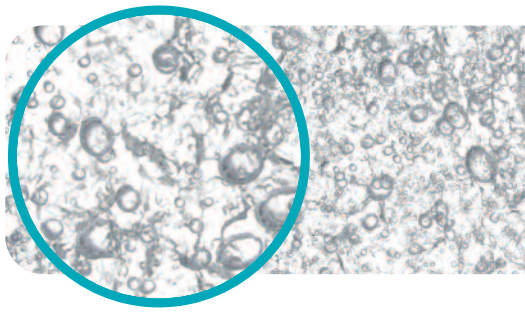
- 95,4 % Success rate [1] showed by clinical data at one-year follow up.
- Long-term bulking effect.
- Vantris has demonstrated to be effective even in high-grade reflux: 86,66% of cure in Grade IV and 100% in Grade V reflux, with a single injection procedure[2].
- According to the reports of the studies performed, absence of migration is observed mainly due to the size of its macroparticles, an average of 300 microns.
- Vantris is compound of biocompatible material that is non-immunogenic and non-antigenic. Additionally, its non-animal origin greatly reduces the risk of an allergic reaction[3].
- Precise injection due to the high-fluidity hydrogel that consists of amorphous and flexible macroparticles that can be extruded with 23-gauge needles.

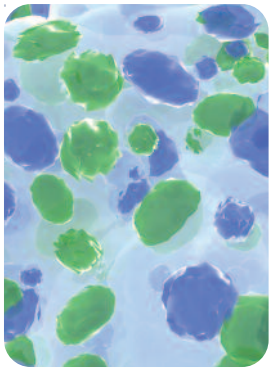
According to the description of an ideal tissue bulking agent [4], Vantris embodies the necessary characteristics to achieve a safe, effective and long-lasting result.

Vantris: substance properties

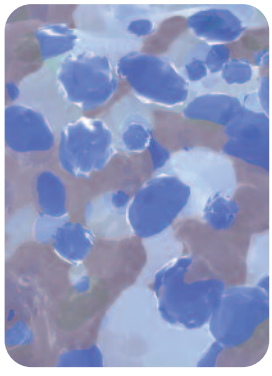
Vantris is a substance consisting of polyacrylate/polyalcohol copolymer (PPC) particles immersed in a carrier that contains 40% glycerol.

Once implanted, the carrier is eliminated unmetabolized by the reticuloendothelial system and excreted through the kidneys. However, the Vantris particles remain to ensure long-lasting bulking.

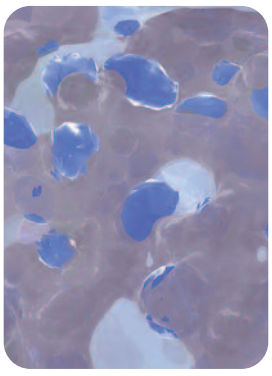




Injection day.



12 Weeks.



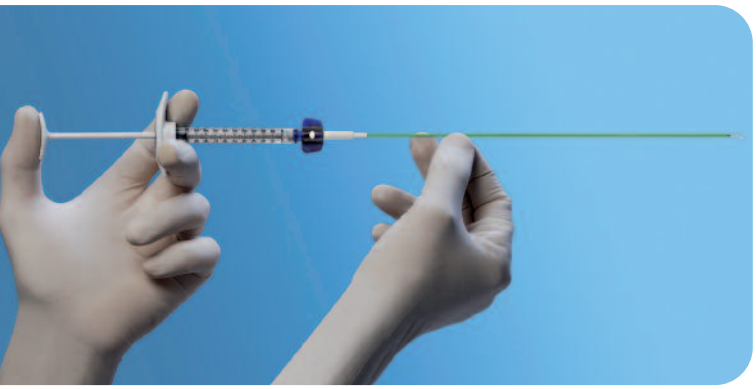
2 Years.

- Structural water
- Glycerol
- Tissue
- PPC

The **safe** and **innovative technology** of Vantris

• Vantris has been developed as a non-absorbable, synthetic, injectable material, with high stability and durability, aiming at long-term effectiveness.

• Vantris hydrogel particles are comprised of a polyacrylate/polyalcohol copolymer.



• In recent years, the components of Vantris have been successfully and widely utilized throughout the medical and biotechnology industries for the following:

- Intraocular lenses
- Artificial organs
- Injectable material for plastic and reconstructive surgery
- Drug delivery systems
- Bulking for embolization of hypervascularized tumors

• Biocompatibility: The material has been successfully tested in cytotoxicity, sensitization, irritation or intracutaneous reactivity, acute systemic toxicity, subchronic and subacute toxicity, genotoxicity, implantation, chronic toxicity, carcinogenicity and migration tests.

• Vantris physicochemical properties make it a highly stable material that withstands thermal or pH changes that can arise in treated tissues.

• Vantris particles comply with the requirements of an **ideal biomaterial**[4]:

- Non-toxic, non-pyrogenic, non-hemolytic, non-inflammatory.
- Non-allergenic, non-carcinogenic, non-teratogenic, non-cytotoxic and painless for patients.
- Effective: functional, absence of migration, reliable, durable, and easy to implant material.
- Biocompatible.

• Biological tests have shown absence of migration to other organs, due to the size of its particles[5]; it produces no allergic reactions or chronic inflammatory processes (granuloma formation).

• Vantris has demonstrated, in a comparative evaluation of histopathological changes through time with two commonly used substances, to be the bulking agent that generates the least tisular reaction and inflammatory infiltration, minimum fibrotic tissue and also proved that it does not generate any calcifications [6].

Macroparticles

• When compressed, the malleable macroparticles of Vantris change in shape to enable extrusion with **23-gauge** needles.

• When these particles are implanted in the ureterovesical junction, the material acts as an enlarger, increasing the volume of the area and correcting the anatomy of the meatus and the distal ureter, preventing urine from returning to the ureter after being stored in the bladder.

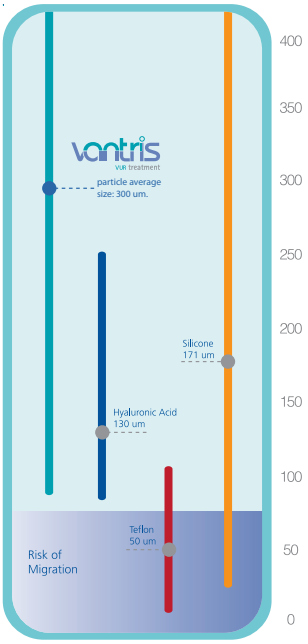
• The particles increase the tissue volume, generating a minimum fibrotic growth around them, 70 microns thick.

Superior Performance

Vantris macroparticles have an average size of 300 um, which is a key factor in the absence of migration reported by studies. Therefore, there is no risk of migration to the area around the injection or to other parts of the body.

The testing of Vantris in animals has proven the absence of particle migration.(5)

Fig. 1: Comparison of injectable material particles size.



The risk of migration is directly correlated with the size of the particles. (Fig. 1).

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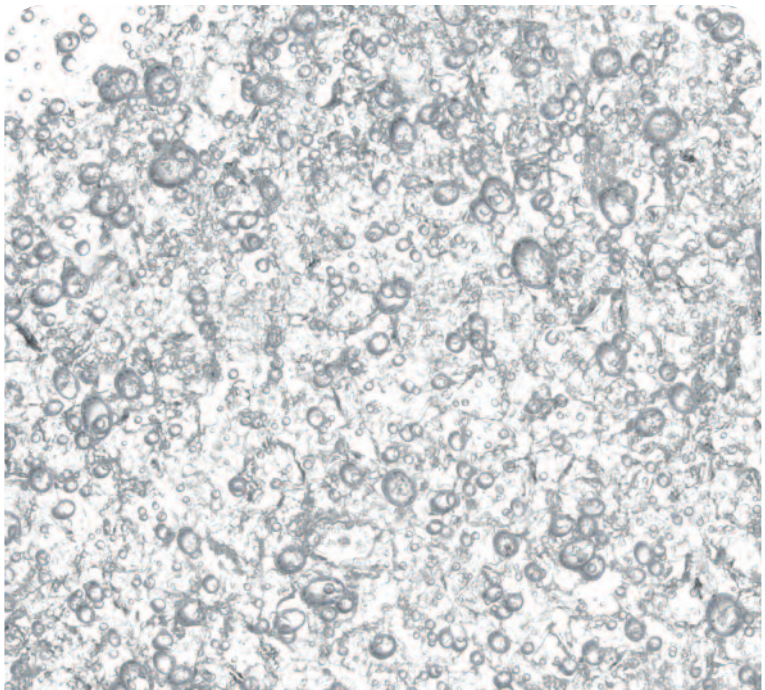
An **effective**, **simple**, and **safe** procedure

As a minimally invasive procedure, an endoscopic injection of Vantris requires no hospitalization and is usually free of any short-term and long-term complications.

In most cases, this outpatient procedure results in a quick recovery from the anesthesia as well as an immediate correction of the VUR. This in turn allows patients to return to their normal daily activities after a short period of time.

Vantris provides a high level of reflux resolution after single endoscopic injection[7]. Due to the substance features, Vantris has demonstrated high performance with very low VUR recurrence, unlike other biodegradable bulking agents which show up to 26% reflux recurrence after one year[8].



Step-by-step STING procedure:

In most cases, Vantris is injected under general anaesthesia.

In order to perform the procedure, the following components are necessary:

- 1 syringe. The quantity to be used will depend on each particular case.
- 1 flexible injection needle or alternatively 1 metal semi-rigid injection needle. It is recommended to use the injection needles developed by Promedon, with the following features:
- 23 G flexible injection needle

Or alternatively:

- 22 G metal semi-rigid injection needle.
- 1 cystoscope with a straight working channel of 4 Fr or more, according to the chosen needle.

1. The free flow through the injection needle is verified using saline solution.

2. The syringe is connected to the injection needle passing material through it until the substance appears at the needle tip. Insert the injection needle into the cystoscope.

3. Prior to the injection, the meatus should be observed with different volumes of bladder filling in order to choose the ideal situation (Figure A).

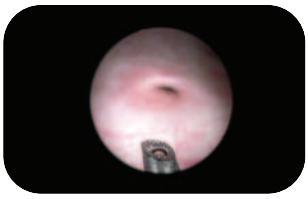
Ensure that the tip of the needle is facing the ureteral side at a 6 o'clock position.

4. The submucosa of the bladder is punctured at the six o'clock position, 3 mm under the ureteral meatus, 4 to 5 mm depth (Figure B). The anatomy of the ureteral meatus defines the selection of the puncture site and number of punctures needed.

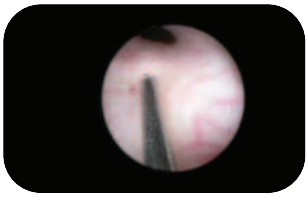
5. The material is then slowly injected until the ureteral wall is adequately modified (bulkiness). More punctures may be performed until the desired effect is reached (Figure C and D).

6. Once the injection is completed, the needle is kept in its position for 30 seconds. Then, the needle is removed.

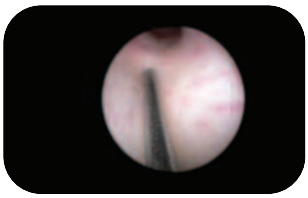
7. Once the procedure has been completed, the bladder is emptied, the cystoscope removed, and an optional voiding cystoureterogram (VCUG) may be performed to verify reflux repair.



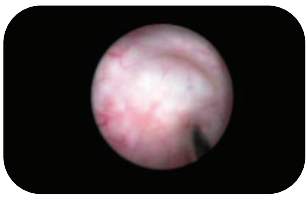
[Figure A] Ureteral meatus prior to injection.



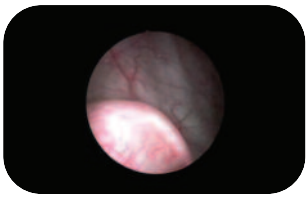
[Figure B] Insertion site for needle.



[Figure C] Location of needle during injection.



[Figure D] Tissue growth in the meatus after a successful injection.



[Figure E] Final view of bulking in the ureteral meatus.

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VUR treatment

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Ordering information

Product Code: BAR 1J
1 ml Vantris syringe – Ref: BARI-1J

CE 0197

B-80-03 (03) / 04-Mar-11

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