

VoiceInject®

Autologous fat as a filler for glottal insufficiency



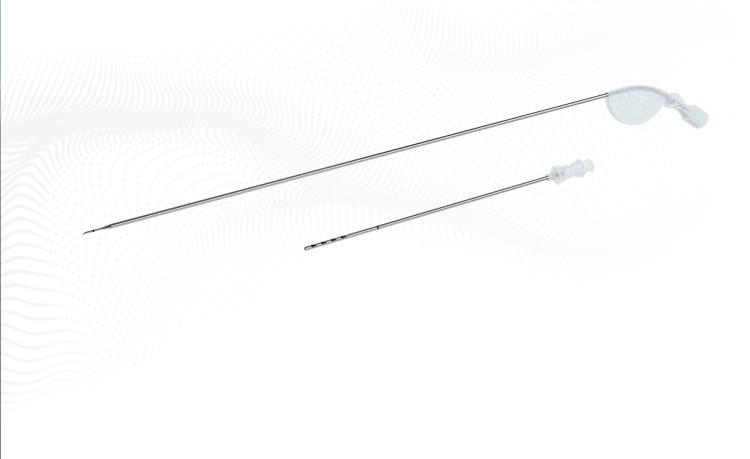


VoiceInject®

Vocal fold augmentation has been an established and effective method of treating glottal insufficiency for years.

It is a minimally invasive procedure that quickly restores the patients natural voice. Patients themselves favour this procedure because of the body's high acceptance rate and the benefits of using the patients' own fat.

SPIGGLE & THEIS developed **VoiceInject**® for the successful and patient-friendly treatment of glottal insufficiency.



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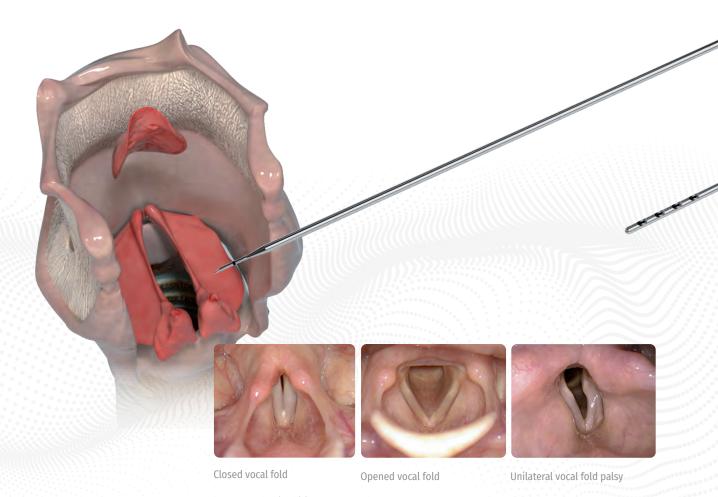
Prof. Dr. Markus M. Hess Deutsche Stimmklinik, Hamburg, Germany

» Autologous fat tissue is unique because it is a combination of a reabsorbable and a permanent component. «

Vocal fold augmentation is a safe and effective treatment method to improve vocal quality when the glottis does not close completely. Patients appreciate the use of endogenous material, such as autologous fat. Autologous fat demonstrates good elastic properties and is fully biocompatible. Augmentation can be performed bilaterally on vocal folds.

Medical indications:

- · Presbyphonia
- Scarring
- Chordectomy
- Vocal fold atrophy
- Recurrent nerve paresis

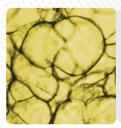


Source: Deutsche Stimmklinik Management GmbH

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- No injection of synthetic material
- Minimally invasive treatment with maximum patient comfort
- Injection and harvesting cannula designed for optimal application and protection of the harvested fat cells
- Sterile system



Human fat cells

Ideal filler for use in the human body

- $\bullet \ {\tt Biocompatible} \ {\tt autologous} \ {\tt tissue}$
- Easily harvested
- Long term benefit

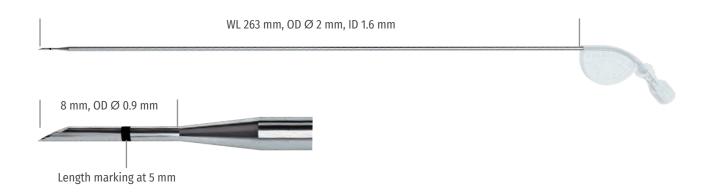
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Injection Needle

Special attention has been given to the careful transport and injection of fat cells into the vocal folds. Thanks to the high-volume design and extra thin cannula wall, VoiceInject® makes it easy to inject fat cells without damaging them.

Properties

- · High-volume lumen to protect the harvested fat cells
- Facet cut for simple and safe injection into the vocal fold
- Optimal length for transoral injection, working length 263 mm, overall length 332 mm
- Needle tip: 8 mm with marking of the injection depth at 5 millimeters
- Removable handle
- · Luer Lock connector



VoiceInject®-Injection needle, 1 piece

3080-1000-01

VoiceInject®-Injection needle, 5 pieces

3080-1005

Lipo Harvesting Cannula

Careful harvesting is crucial to ensure successful and longer lasting autologous fat augmentation in the vocal folds. In addition to a low level of negative pressure when harvesting, the special shape, arrangement and cut of the suction holes ensure safe harvesting of the fat cells. Once harvested, the cannula tube provides the fat cells with enough space, so that they can be drawn up into the syringe, without added pressure.

Properties

- · Atraumatic beveled suction holes on the cannula tip
- · Low suction pressure, thanks to manually build-up pressure
- · Special arrangement of the suction holes
- Harvesting cannula with large-volume inner shaft
- Length marking at 37.5 mm





Atraumatic beveled suction holes

The Lipo Harvesting Cannula is only available as a component of the Lipo Harvesting-Set.

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Lipo Harvesting-Set

- 1x lipo harvesting cannula
- 1x 14G cannula
- 4x 10 ml syringes
- 4x 1 ml syringes
- 1x Discofix® C (connector for fat transfer)
- 4x Luer Lock plugs
- 4x push-in stoppers

3080-0100



Benchtop Centrifuge

- 6-fold swing-out motor
- 6 tubes
- Small and light weight
- 200-240V/50-60Hz

2300EBA270



Application and Handling of the VoiceInject®-System

Step 1: Fat extraction Sampling of homogeneous fat tissue with patented extraction system. Step 2: Preparation of the extracted fat tissue Use centrifuge to separate harvested tissue (max 3000 rpm for 3 minutes). Drain blood cells, serum, free acids and cell debris and keep the fat tissue.

Step 3: Transfer fat tissue

• Transfer fat tissue into 1 ml syringes using the connector.



Step 4: Micro re-injection

• Inject fat tissue into the vocal folds as needed.



9

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