

# 5 YEAR FOLLOW-UP OF AQUAMID® INJECTIONS FOR FACIAL SOFT-TISSUE AUGMENTATION

SAFETY AND EFFICACY DATA IN 116 PATIENTS

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## BACKGROUND

Polyacrylamide hydrogel (Aquamid®) is an injectable soft volume filler. It is a non-absorbable, homogeneous, particle-free hydrogel composed of approx. 97.5% water and 2.5% cross-linked polyacrylamide. Its filling effect is solely due to the injected volume only. Aquamid® efficacy and safety have been documented in several clinical trials involving more than 1,000 patients.

Approved in Europe since 2001, it is available in 40 countries worldwide with more than 300,000 injections performed to date.

A multicentre study was initiated to evaluate the safety and efficacy of Aquamid®. Initially the study was designed as a 1-year follow-up with 251 patients.

In the interest of evaluating the long-term safety and efficacy the study was extended to also include 24, 36/48 and 60-month follow-up.

## STUDY DESIGN

A 5 year prospective, European multicentre study of 116 of the initial 251 patients. Both efficacy and safety of Aquamid injections for facial soft-tissue augmentation were evaluated.

Standardized photographs were taken before treatment and at each follow-up visit. Blood and urine samples were collected and analyzed. Safety evaluation also included adverse event reporting at each follow-up visit. Aesthetic outcome was rated by patients and physicians at each follow-up visit.

## CLINICAL RESULTS

More than 90% of patients were satisfied or very satisfied with the aesthetic results after Aquamid® treatment at 60 months. Investigators assessment evaluated the aesthetic results as good or very good in more than 90% of the patients.

Most adverse events related to the treatment were mild

or moderate. In the 5 year period only 2 serious adverse events were reported and these were infections related to injection procedure. These infections were resolved with antibiotic treatment. There were no unexpected adverse events. Blood and urine values showed no clinically significant findings.

The 5-year results are consistent with the data from the 1-year, 2-year and 3- to 4-year follow-ups.

## CONCLUSION

Injections of Aquamid® for facial soft-tissue augmentation are safe and effective with very high patient and investigator satisfaction after 5 years.

## SUMMARY

- 60-month, European multi-center, prospective study evaluating the safety and aesthetic outcome of Aquamid® for facial soft tissue augmentation.
- 251 patients enrolled in the initial study, 116/251 patients completed the 60-month follow-up protocol extension.
- More than 90% of aesthetic results were assessed as good/very good by investigators and more than 90% of aesthetic results were judged as satisfying/very satisfying by patients.
- Infections related to the injection procedure were the only serious adverse events, and were successfully treated with antibiotics.
- The 60-month safety evaluation showed few and no unexpected adverse events.
- Five year data suggest no long-term complications.
- Aquamid® injections for facial soft tissue augmentation provide safe, natural and long lasting results up to 5 years with high patient satisfaction.



## CONTURA

Contura is a medical technology company based in Denmark that develops and commercializes soft tissue fillers.

Contura's products – Aquamid® for facial contouring and Bulkamid® for the treatment of female urinary incontinence – are manufactured using the company's patented polyacrylamide hydrogel technology.

Aquamid is sold through a network of local distributors in 40 countries. Ethicon Inc., a Johnson & Johnson company, holds the exclusive worldwide distribution rights for Bulkamid and has started to sell the product in Europe.

Clinical trials evaluating Aquamid and Bulkamid are ongoing in the United States. Data from these trials will be used to support FDA applications for these products. Aquamid and Bulkamid are not approved for sale in the US.

Contura's products are developed, manufactured and tested in Denmark in compliance with the European regulatory requirements for medical devices.

## AQUAMID

Aquamid® is a soft volume filler, which integrates with the body's own tissue and gives a natural look and feel. Produced using Contura's patented hydrogel technology, Aquamid is composed of app. 97.5% non-pyrogenic water and 2.5% cross-linked polyacrylamide and enjoys an unmatched track record of continuous high levels of patient satisfaction.

Aquamid was approved in Europe in 2001 and is available in 40 countries worldwide. Over 300,000 Aquamid injections have been performed to date.

Science has always been the driving force behind Aquamid products. The efficacy and safety of Aquamid have been documented in several clinical trials involving more than 1,000 patients. These studies have been published in peer-reviewed journals.

It is currently under clinical investigation in the U.S. for the aesthetic treatment of facial wrinkles/folds. For more information please visit [www.aquamid.com](http://www.aquamid.com).