Why is Bulkamid different to other bulking agents?

**Non-particulate homogenous gel**

**Bulkamid**

- non-particulate permanent homogenous hydrogel consisting of 97.5% water and 2.5% polyacrylamide

- Predictable, controllable and precise urethral bulking due to volume of hydrogel

**Particulate combination gel**

**Other bulking agents**

- mini-particles in a transient carrier gel, which is absorbed shortly after implantation

- Inherent variability in urethral bulking due to absorption of transient gel and subsequent inflammatory response

### Clinical benefits

<table>
<thead>
<tr>
<th></th>
<th>Bulkamid</th>
<th>Macroplastique®</th>
<th>DuraspHERE®</th>
<th>Deflux®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety &amp; efficacy at 12 months $^2-^5$</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Long-term efficacy to 7 years $^6$</td>
<td>✔</td>
<td>×</td>
<td>×</td>
<td>×</td>
</tr>
<tr>
<td>Low acute complication rates (0 - 6%) $^2-^5$</td>
<td>✔</td>
<td>×</td>
<td>×</td>
<td>×</td>
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<tr>
<td>No long-term complications $^7-^10$</td>
<td>✔</td>
<td>×</td>
<td>×</td>
<td>×</td>
</tr>
<tr>
<td>No long-term tissue changes $^7-^10$</td>
<td>✔</td>
<td>×</td>
<td>×</td>
<td>×</td>
</tr>
</tbody>
</table>

$^*$ urinary retention / urinary tract infection
$^{**}$ e.g. migration, calcification, cyst formation, urinary retention
Safety and efficacy at 12 months

Number of patients: 345  (229 Bulkamid: 116 Contigen)
Study design: Randomised controlled trial, single blind
Previous incontinence surgery: 25% of patients

Number of patients
Study design
Previous incontinence surgery
Follow up period

% of patients cured or improved at 5 years (subjective)

Number of patients: 256
Study design: Observational
Previous incontinence surgery: None
Follow up period: 5 years

% of patients cured or improved at 7 years (subjective)

Number of patients: 352
Study design: Longitudinal observational
Previous incontinence surgery: None
Follow up period: 7 years

Durability at 5 and 7 years

% of patients cured or improved at 5 years

- Bulkamid®: 83% at 3 months
- Contigen®: 83% at 12 months

% of patients cured or improved at 7 years

- Bulkamid®: 77% at 5 years
- Contigen®: 70% at 7 years

Follow up period

- 5 years: 256
- 7 years: 352

Patients reported as cured or improved

- 6 months: Andrews (N=18) (First line treatment)
- 5 years: Pai (N=256) (Heterogeneous population)
- 7 years: Lobodasch (N=132)
- 12 months: Sokol (N=60)
- 12 months: Zivanovic (N=49)
- 12 months: Farrell (N=24)

Safety and efficacy at 12 months

- No SUI episodes at 12 months
- 77% for Bulkamid®
- 70% for Contigen®

Reduction in repeat injections

% of repeat injections required for a new vs. experienced implanter

- New user (N=12): 25%
- Experienced user (N=11): 9%

Learning curve

- Experienced user and first line treatment
- % of patients requiring 1 or 2 treatments

- 1st treatment (N=238): 93%
- 2nd treatment (N=18): 7%
Emerging risks of mid-urethral slings

Reported complications in review
(337 publications)

<table>
<thead>
<tr>
<th>Complication</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urethral obstruction*</td>
<td>2.3%</td>
</tr>
<tr>
<td>Vaginal, bladder and / urethral erosion*</td>
<td>1.8%</td>
</tr>
<tr>
<td>Refractory chronic pain</td>
<td>4.1%</td>
</tr>
<tr>
<td>Vesicovaginal fistulas</td>
<td>&lt;1%</td>
</tr>
</tbody>
</table>

“Considering the additional risks of refractory overactive bladder and bowel perforations, amongst others, the overall risk of a negative outcome after SMUS** implantation surgery is ≥15%”

Blaivas et al

Most women would prefer a bulking agent to a mid-urethral sling

Acceptability of treatments

<table>
<thead>
<tr>
<th>Treatment Type</th>
<th>Number of Patients</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major operation</td>
<td>(85% cure; 2% risk of self-catheterisation)</td>
<td>60</td>
<td>40</td>
</tr>
<tr>
<td>Minor operation</td>
<td>(85% cure; 2% risk of self-catheterisation)</td>
<td>40</td>
<td>60</td>
</tr>
<tr>
<td>Clinical procedure</td>
<td>(60% improvement; no long term risk)</td>
<td>20</td>
<td>80</td>
</tr>
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</table>

Is it now time to think about Bulkamid as a first line treatment?

References: