

Specialist Medical Supplies

A.B.N. 20 059 553 070

Unit 2/1 Talavera Rd

North Ryde NSW 2113

Phone: 61 2 9889 2533

Fax: 61 2 9889 1780

Email: specmedical@bigpond.com

www.smsmedical.com.au

Safety alert – Bulkamid® Hydrogel

TGA reference: RC-2022-RN-01138-1

TGA reference: RC-2022-RN-01111-1

ARTG entry 150554 and 292380

10 August 2022

Dear

Update of Bulkamid® Instructions for use and Patient information leaflet

We would like to inform you on the following updates to the of the Bulkamid® Hydrogel Instructions for use (IFU) and Patient information leaflet (PIL). The quality, safety and performance of the device is not affected. The updates are merely clarifications and specifications of the use and administration of the device, and the fact that the efficacy of the device may diminish over time.

Updates of the “Warnings/Precautions” section in the IFU:

- The original wording *“During the bulking procedure, the blood vessels must always remain visible at the site of injection to avoid the risk of necrosis”* has been revised with addition of *“and potential leakage of hydrogel”*.
- The sentence *“The efficacy of the device may diminish over time”* has been added.
- The sentence *“A change to the device insertion technique can lead to implant complications”* has been added.
- The sentence *“Bulkamid® Hydrogel is intended for female patients, above the age of 18 years that have failed conservative treatments”* has been added.

Updates of the PIL:

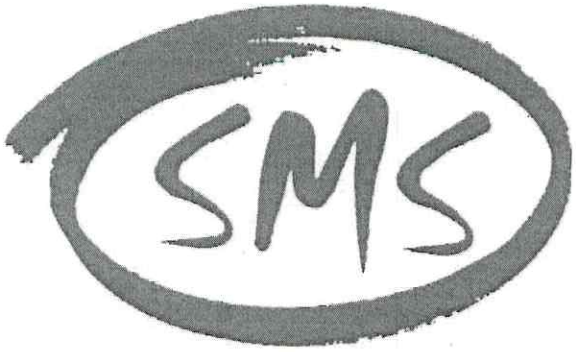
- The wording about side effects has been updated to include migration: *“Migration of injected material is a theoretical risk which has not been observed for Bulkamid”*.

The revised versions of the IFU and PIL with markups of changes are attached to this letter (Attachment 1 and 2).

Reason for the updates

The updates have been made as a follow-up to a post market review/investigation that TGA and Advisory Committee on Medical Devices (ACMD) have conducted to determine if bulking agents used to treat stress urinary incontinence remain compliant with the TGA Essential Principles. The updates have been done in cooperation with TGA.

Addition of “potential leakage of hydrogel®” clarifies that the risk of necrosis, due to superficial or



Specialist Medical Supplies

A.B.N. 20 059 553 070

Unit 2/1 Talavera Rd

North Ryde NSW 2113

Phone: 61 2 9889 2533

Fax: 61 2 9889 1780

Email: specmedical@bigpond.com

www.smsmedical.com.au

excessive injection of Bulkamid® Hydrogel, may potentially result in the leakage of the hydrogel. The wording "The efficacy of the device may diminish over time" is a new wording added for clarification. After treatment, patients continue to undergo normal anatomical and physiological changes over time which may lead to reduced bulking efficiency or recurrence of urinary incontinence. This may not have been clear to all users in the previous text.

The wording "A change to the device insertion technique can lead to implant complications" has been added in the IFU to reinforce the importance of using the correct injection technique, as described in the "Method of administration" section.

The wording "Bulkamid® Hydrogel is intended for female patients, above the age of 18 years that have failed conservative treatments" has been added to specify that, in line with national and international treatment guidelines, patients must have failed conservative treatment prior to considering Bulkamid.

Migration of the device is a potential risk, which has been observed for other urethral bulking agents, but not observed for Bulkamid® Hydrogel. This potential risk is already mentioned in the IFU and has now been added to the PIL, to allow the patient to consider this potential risk prior to treatment.

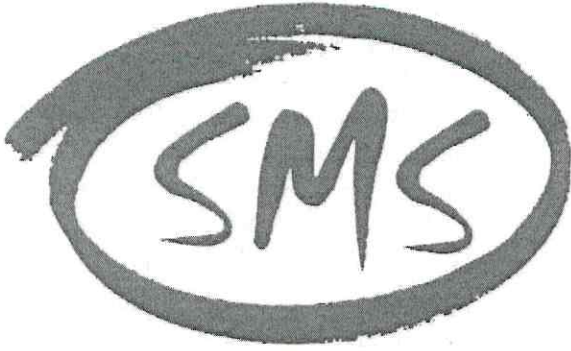
Recommendations

This is a non-recall action with a safety alert describing updates to the IFU and PIL clarifying warnings and precautions related to the use of Bulkamid® Hydrogel. The updates have no implications for previously treated patients since no safety concerns have been identified in relation to the updates.

Please remember that training and educational material regarding injection techniques of Bulkamid® Hydrogel is available.

Please contact sponsor/distributor SMS Medical or sponsor Emergo Australia, if you have any question regarding this letter.

ARTG	Device Name	Sponsor
150554	Bulkamid® Urethral Bulking System	Specialist Medical Supplies Pty Ltd
292380	Bulkamid® Hydrogel	Emergo Australia



Specialist Medical Supplies

A.B.N. 20 059 553 070

Unit 2/1 Talavera Rd

North Ryde NSW 2113

Phone: 61 2 9889 2533

Fax: 61 2 9889 1780

Email: specmedical@bigpond.com

www.smsmedical.com.au

Emergo Australia contact details:

201 Sussex Street, Darling Park, Tower II, Level 20

Sydney, NSW 2000 Australia

T: +61 (0)2.9006 1662

E: AUNZVigilance@ul.com

Kind regards

A rectangular area containing a handwritten signature in dark ink, which appears to be 'Peter Hudson'.

Peter Hudson

Director

Specialist Medical Supplies Pty Ltd, and on behalf of Contura International A/S

Enclosures:

Attachment 1. Bulkamid Hydrogel Instructions for use, 10116-001 April 2022 with markups

Attachment 2. Bulkamid Patient Information Leaflet, 101113-002 – 05/2022 with markups