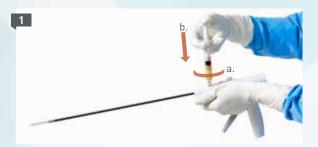
EASYGRIP Flo-41

PRECISION MIS DELIVERY SYSTEM

QUICK REFERENCE GUIDE

Initial & Repeat Product Set-up and Application Inside the sterile field



 a) Attach the FLOSEAL Matrix syringe to the EASYGRIP FLO-41 fill port. b) Fill the reservoir completely with FLOSEAL Matrix. Syringe may be removed if desired.



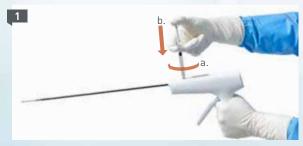
 Prime cannula by repeatedly pulling the trigger (approximately 2-3 pulls) until FLOSEAL Matrix is visible in the clear malleable tip. The EASYGRIP FLO-41 Applicator is now ready to use.



 Pull the trigger of the EASYGRIP FLO-41 to apply the FLOSEAL Matrix, per its instructions. Multiple pulls may be required to apply desired amount of FLOSEAL Matrix.

If additional FLOSEAL Matrix is required during the same surgical procedure, repeat steps 1&3. Priming is not required for repeated loading.

Residual Product Application Inside the sterile field



 If application of residual FLOSEAL Matrix is needed, <u>fill the provided 1.5 mL syringe</u> with non-heparinised <u>saline</u>. a) Attach saline syringe to EASYGRIP FLO-41 and <u>b) fill the reservoir with only 1.5 mL of non-heparinised saline</u>.



 Pull the trigger of the EASYGRIP FLO-41 Applicator System to apply residual FLOSEAL Matrix at the site of the bleed.



 If, after expelling all residual product from cannula, additional FLOSEAL Matrix application is required, the cannula must be purged of saline. Remove saline from the cannula and prime the device for additional use by repeating steps 1 & 2 above.

EasyGrip FLO-41 Indication

The EASYGRIP FLO-41 System is indicated for delivering FLOSEAL Haemostatic Matrix to bleeding sites through a 5mm or larger trocar.

Important Risk Information for EasyGrip FLO-41

Single use only. Do not reuse. Do not resterilise. Reuse or reprocessing of a single use device may lead to contamination and compromised device function or structural integrity. Do not use the EASYGRIP FLO-41 System if the packaging is damaged or open, or if the applicator is damaged, as this could lead to compromised device function.

Do not use air as a propellant to extrude haemostatic agent from the EASYGRIP FLO-41 System.

Do not use the EASYGRIP FLO-41 System to manipulate or retract organs or tissue.

Do not bend the malleable tip against organs or tissue.

Rx Only. For safe and proper use of this device, refer to the full Instructions for Use.

Any medical device product quality complaints (including medical device adverse incidents) relating to Baxter products can be reported directly to the Baxter Country Quality

Assurance Team: In the UK on +44 (0)1604 704603, or by email to UK_SHS_QA_Complaints@baxter.com. In Ireland on +353 (0)1 2065500 or by email to

shs_complaints_dublin@baxter.com

Alternatively please report directly to your Baxter Representative, who will take the details and forward to the Baxter Country Quality Assurance Team.

Medical device adverse incidents should also be reported: In the UK to the MHRA.

Reporting forms and information can be found at: www.mhra.gov.uk/safetyinformation/reportingsafetyproblems/index.htm . In Ireland to the HPRA. Reporting forms and information can be found at: http://www.hpra.ie/homepage/about-us/report-an-issue

ORDERING INFORMATION

EASYGRIP FLO-41	case of 6	ADS201865
FLOSEAL Haemostatic Matrix Needle Free, 5mL		1503353
FLOSEAL Haemostatic Matrix Needle Free, 10mL		1503354

For questions or ordering information, please contact your Baxter representative.

Advancing the art of healing

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