1. Introduction

Rational: To ensure the appropriate use of Flexi-Seal® FMS and to provide guidance documentation to support staff during the decision making process and during its application to their patient/s.

A Flexi-Seal, faecal management system is a temporary containment device consisting of a soft flexible, silicone catheter with a low pressure balloon, which is filled with water or saline to aid retention, and which is easily inserted into the patient’s rectum.

The catheter is attached to a closed end collection bag. The device is suitable for the collection of liquid or semi-liquid stools and has a port to allow for flushing of the system if required (Johnston, 2005).

Bowel/faecal management systems have been designed to provide a closed system for the management of liquid or semi-liquid faecal incontinence. They contain faeces and prevent faecal contamination of the environment.

THE SYSTEM CAN BE USED FOR A MAXIMUM OF 29 DAYS
NB BEYOND 29 days is at the Consultants discretion and must be documented in the notes.

2. Disease/condition/target population

Bedridden Adult with little or no bowel control and liquid/semi-liquid stool (>3 Episodes in 12 hours) scoring type 6-7 Bristol Stool Scale and one of the following:

- Extensive redness with no skin breakdown due to diarrhoea and faecal incontinence.
- Excoration of skin due to diarrhoea and faecal incontinence.
- Wounds or injuries to lower back and/or abdomen, pelvis, perineum and upper legs.
- Respiratory/cardiovascular or intracranial instability on movement to meet hygiene needs.
- Log rolling procedure to meet hygiene needs.
- Suspected or confirmed clostridium difficile
- Patient weight restricts effective skin care following faecal incontinence and diarrhoea
3. **Interventions**

1. Healthcare practitioner has achieved clinical competence in the use of the faecal management drainage system (FMS).
2. Information provided to patient, informed consent obtained to proceed (as per Trust Guidelines). Is unable to provide consent immediate next of kin provided with information regarding control and management of diarrhoea if appropriate.
3. A rectal examination is required to exclude faecal impaction with overflow.

4. **Contraindicated in the following patients**
   - Sensitive to any of the products within the kit (Silicone based products, Latex Free)
   - Large lower bowel or rectal surgery previous 12 months
   - Rectal or anal injury
   - Severe rectal or anal stricture or stenosis
   - Suspected or confirmed rectal mucosa impairment E.G Sever or ischaemic proctitis and mucosal ulcerations
   - Confirmed rectal or anal Tumour
   - Severe Haemorrhoids
   - Faecal impaction/Solid or soft formed stool
   - Inflammatory bowel conditions-At physicians discretion.

5. Following insertion the patient must be observed for persistent rectal pain, rectal bleeding or abdominal distension-Notify physician immediately.
6. The FMS can be used for up to 29 days and reinserted up to this point if dislodged or expelled by patient.
7. Clear documentation is required in the nursing notes to prompt timely removal of the device.
8. All bowel motions must be recorded on the fluid balance with Bristol stool scale noted to prompt timely removal should stool consistency change.
9. Infection prevention and control, use of protective clothing, hand washing and clinical waste disposal policies must be followed.
10. Directions for use

**Preparation of FMS**

- Collect appropriate equipment including protective clothing, lubricant and water or 0.9% Saline at room temperature.
- Ensure retention balloon is deflated; remove any air using aspiration port and syringe.
- Assemble FMS; lay out avoiding kinks/twists to system.
- Draw up 45 mls water/0.9% saline. Attach to inflation port.

**Preparation of patient.**

- Explain procedure to patient; maintain privacy and dignity at all times.
- Position patient in left lateral if able/or position to gain best access to patients bottom.

**Insertion of device**

- Lubricate balloon and finger to be used for insertion.
- Slide lubricated finger into insertion pocket located at the patient end of the irrigation line.
- Grasp catheter and insert balloon through anal sphincter until balloon is in the rectal vault.
- Inflate balloon through inflation port with syringe and 45mls of water or 0.9% Saline.
- Remove insertion finger from balloon pocket.
- Oval inflation indication chamber will expand as fluid is injected. Expansion should subside once 45 Mls inserted through inflation port.
- Gently pull catheter until resistance felt and balloon is sitting on rectal floor. Note position of circular indicator line at patient’s anus.
β Position drainage bag using strap on bedside to facilitate drainage of waste.
β Position patient comfortably
β Document date of insertion and faecal consistency

**Maintenance of device**

β Rectal pain, bleeding or abdominal distension, report to physician immediately.
β To avoid injury nothing should be inserted into anal canal while FMS is in situ. If required it can be removed and reinserted following absorption of medication or procedure.

**Each shift and then at least 4 hourly and on patient position change**

β Check for anal ulceration/trauma
β Check system for kinks, twists and obstruction, which would inhibit drainage.
β Irrigate if required to maintain drainage if stool particles obstructing flow. Using irrigation port and water at room temp. Note volume used to adjust fluid balance.
β Stool consistency using Bristol stool scale, remove if consistency < 6-7.

Change collection bag as required. Snap cap onto used bag after removal and double bag in clinical waste.
If patient expels FMS clean, deflate balloon and reinsert if still required, inflate balloon as directed on insertion

Anal area should be kept clean and dry, using barrier cream/spray if required. Excessive leakage around the device may require deflation of balloon, removal and reinsertion.

**Removal of device**

β Deflate retention balloon using luer lock syringe attached to inflation port. Slowly aspirate all fluid within balloon. Disconnect syringe and discard.
β Grasp catheter close to patient’s anus and gently slide it out of the anus.
β Note drainage for fluid balance.
β Double bag and dispose in clinical waste.

**Appendix** – Step by Step Illustration: Insertion, Maintenance, Removal of Flexi-Seal System
APPENDIX

STEP BY STEP ILLUSTRATION:

INSERTION
MAINTENANCE
REMOVAL
OF FLEXI-SEAL
In addition to the device kit, gloves and lubricant will be required.

Fill a 50mls syringe with 45mls of tap water or saline. Fluids must be warmed to room temperature. Attach the filled syringe to the inflation port of the Flexi Seal®.

*Ensure that the balloon is not inflated prior to insertion.*

Securely snap the collection bag to the connector at the end of the catheter.
Position the patient in the left lateral lying position to facilitate observation and access to the rectum. If unable to tolerate, reposition the patient so access to rectum is possible.

Use incontinence sheets / pads to prevent fouling of sheets / bed wear and promote patient comfort.

Unfold the length of the catheter to lay flat on already positioned clean incontinent sheets on the bed, extend the collection bag towards the foot of the bed.

Insert a lubricated gloved index finger into the retention balloon cuff finger pocket for digital guidance during device insertion.

Coat the balloon end of the catheter with lubricating jelly.
Grasp the catheter and gently insert the balloon end through the anal sphincter until the balloon is inside the rectal vault.

Inflate the balloon (syringe will already be attached to inflation port as described earlier), with 45mls of room temperature water or saline by **SLOWLY** depressing the syringe plunger.

The oval inflation indication chamber on the inflation port will expand as fluid is injected. The normal expansion should subside once the plunger stops. **If the inflation indicator chamber remains excessively expanded after the syringe is empty, the balloon is not properly inflating.**
This is likely the result of improper balloon positioning.
To correct this: use the syringe to withdraw the fluid from the balloon, reposition the balloon in the rectal vault and re inflate the balloon, rechecking the inflation indicator as described above.
Remove the syringe from the inflation port, and gently pull, in a downward direction, on the soft silicon catheter. This will ensure that the balloon is firmly secured in the rectum and is positioned against the rectal floor.

Position the length of the flexible silicone catheter along the patient’s leg to avoid kinks and/or obstruction.

Take note of the position indicator (black line encircling silicon tube – refer to diagram on page 3) relative to the patient’s anus. Observe for changes in location of position indicator line as a means to determine movement of the retention balloon in the patient’s anus. This may indicate the need for the balloon or device to be repositioned.

Now hang the collection bag by the strap at a convenient location on the bedside ensuring that it is below the level of the patient.
Maintenance and Removal of the Device

Maintenance

If the silicone catheter becomes blocked with solid particles, it can be rinsed by filling a 50ml syringe with tap water, at room temperature, attaching the syringe to the irrigation port and gently pressing the syringe plunger.

Repeat the procedure as often as necessary to maintain proper functioning of the device. Flushing the device as described above is an optional procedure for use only when needed to maintain the unobstructed flow of stool into the collection bag.

*If repeated flushing with water does not return the flow of stool through the catheter, the device should be inspected to ascertain that there is no external obstruction. If no source of obstruction of the device is detected, use of the device should be discontinued.*

Change the collection bag as needed. Snap the cap onto each used bag and discard as per Trust Waste policy.
To remove the catheter from the rectum, THE RETENTION BALLOON MUST BE DEFLATED.

Attach a syringe to the inflation port; slowly withdraw all the water from the retention balloon (45mls)
Disconnect the syringe and discard.

Grasp the catheter as close to the patient as possible and gently slide it out of the anus.

Dispose of the device in accordance with Trust Waste Disposal Policy.
You need to be able to answer True to ALL the questions below in order to use Flexi-Seal® Faecal Management System.

<table>
<thead>
<tr>
<th>True/False</th>
<th>Reason for Incontinence</th>
</tr>
</thead>
<tbody>
<tr>
<td>True</td>
<td>The patient is incontinent with liquid or semi-liquid stool</td>
</tr>
<tr>
<td>False</td>
<td>The patient is over 18</td>
</tr>
<tr>
<td>False</td>
<td>The patient is not sensitive or known to have had allergic reactions to any component within the kit</td>
</tr>
<tr>
<td>False</td>
<td>The patient has not had lower large bowel or rectal surgery within the last year</td>
</tr>
<tr>
<td>False</td>
<td>The patient does not have suspected or confirmed rectal mucosal impairment</td>
</tr>
<tr>
<td>False</td>
<td>The patient does not have any rectal or anal injury</td>
</tr>
<tr>
<td>False</td>
<td>The patient does not have a confirmed rectal/anal tumour, stricture or fistula</td>
</tr>
<tr>
<td>False</td>
<td>The patient does not have hemorrhoids of significant size and/or symptoms</td>
</tr>
<tr>
<td>False</td>
<td>The patient does not have a faecal impaction</td>
</tr>
<tr>
<td>False</td>
<td>The patient does not have any in-dwelling or anal device (e.g. transrectal or deflative mechanism (e.g. suppositories or enemas in place))</td>
</tr>
</tbody>
</table>

Assessment Consistency of stool (please tick):

- Solid
- Semi-Solid
- Semi-Liquid
- Liquid

Date Inserted:

You need to be able to answer True to ALL the questions below in order to use Flexi-Seal® Faecal Management System.

Adapted with kind permission from Great Western Hospital - Swindon

Pre-Insertion Check List

Name:

Unit Number:

Date Inserted:

Day No.:

Date:

NHS Foundation Trust

Torbay and South Devon
## Flexi-Seal System in the Management of Faecal Incontinence

### Use of Collated by Clinical Effectiveness

---

**Maintenance Check List**

**Date:** / /  
**Day No.:**

<table>
<thead>
<tr>
<th>Patient Name:</th>
<th>Inserted by:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Unit Number:</th>
<th>Date of Insertion:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Recommended to check device every two hours**

<table>
<thead>
<tr>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Start Time:</th>
</tr>
</thead>
<tbody>
<tr>
<td>12am</td>
</tr>
<tr>
<td>2am</td>
</tr>
<tr>
<td>3am</td>
</tr>
<tr>
<td>4am</td>
</tr>
<tr>
<td>5am</td>
</tr>
<tr>
<td>6am</td>
</tr>
<tr>
<td>7am</td>
</tr>
<tr>
<td>8am</td>
</tr>
<tr>
<td>9am</td>
</tr>
<tr>
<td>10am</td>
</tr>
<tr>
<td>11am</td>
</tr>
<tr>
<td>12pm</td>
</tr>
<tr>
<td>1pm</td>
</tr>
<tr>
<td>2pm</td>
</tr>
<tr>
<td>3pm</td>
</tr>
<tr>
<td>4pm</td>
</tr>
<tr>
<td>5pm</td>
</tr>
<tr>
<td>6pm</td>
</tr>
<tr>
<td>7pm</td>
</tr>
<tr>
<td>8pm</td>
</tr>
<tr>
<td>9pm</td>
</tr>
<tr>
<td>10pm</td>
</tr>
<tr>
<td>11pm</td>
</tr>
<tr>
<td>12am</td>
</tr>
</tbody>
</table>

© 2019 F.S. Smedley & Sons, LLC. © Flexi-Seal is a registered trademark of F.S. Smedley & Sons, LLC.
ErieProduct is an authorized user. ErieProduct, Inc., Wernersville, PA, distributed by G&G Medical, Inc.
(866) 38-4777

Flexi-Seal System in the Management of Faecal Incontinence, use of  
Page 12 of 12  
Collated by Clinical Effectiveness
**Protocols & Guidelines – Document Control**

This is a controlled document. It should not be altered in any way without the express permission of the author or their representative. On receipt of a new version, please destroy all previous versions.

<table>
<thead>
<tr>
<th>Ref: 1309</th>
<th>Title: Flexi-Seal System in the Management of Faecal Incontinence, Use of</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Issue:</td>
<td>6 July 2018</td>
</tr>
<tr>
<td>Version:</td>
<td>3</td>
</tr>
<tr>
<td>Author:</td>
<td>Senior Sister Matron</td>
</tr>
<tr>
<td>Index:</td>
<td>Gastroenterology (Medical Unit)</td>
</tr>
<tr>
<td>Classification:</td>
<td>Protocol</td>
</tr>
<tr>
<td>Applicability:</td>
<td>Allerton ward and Trustwide</td>
</tr>
</tbody>
</table>

**Equality Impact:**
The guidance contained in this document is intended to be inclusive for all patients within the clinical group specified, regardless of age, disability, gender, gender identity, sexual orientation, race and ethnicity & religion or belief

**Evidence based:** Information not supplied

**References:**
Produced following audit: No
Audited: No

**Approval Route:**
See ratification  Date Approved: 2 July 2018

Approved By: Clinical Governance Lead for General Surgery
Clinical Director of Pharmacy

**Links or overlaps with other policies:**
0356 Consent for Examination and Treatment
All TSDFT Trust strategies, policies and procedure documents.

**PUBLICATION HISTORY:**

<table>
<thead>
<tr>
<th>Issue</th>
<th>Date</th>
<th>Status</th>
<th>Authorised</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>30 December 2010</td>
<td>New</td>
<td>Medical Director</td>
</tr>
<tr>
<td>1</td>
<td>19 September 2013</td>
<td>Date Change</td>
<td>Nurse Consultant Gastrointestinal Disease</td>
</tr>
<tr>
<td>2</td>
<td>1 November 2013</td>
<td>Amendment</td>
<td>Clinical Director of Nursing and Professional Practice in the Community Medical Director Clinical Director of Pharmacy</td>
</tr>
<tr>
<td>3</td>
<td>6 July 2018</td>
<td>Amended</td>
<td>Clinical Governance Lead for General Surgery Clinical Director of Pharmacy</td>
</tr>
</tbody>
</table>
The Mental Capacity Act 2005

The Mental Capacity Act provides a statutory framework for people who lack capacity to make decisions for themselves, or who have capacity and want to make preparations for a time when they lack capacity in the future. It sets out who can take decisions, in which situations, and how they should go about this. It covers a wide range of decision making from health and welfare decisions to finance and property decisions.

Enshrined in the Mental Capacity Act is the principle that people must be assumed to have capacity unless it is established that they do not. This is an important aspect of law that all health and social care practitioners must implement when proposing to undertake any act in connection with care and treatment that requires consent. In circumstances where there is an element of doubt about a person’s ability to make a decision due to ‘an impairment of or disturbance in the functioning of the mind or brain’ the practitioner must implement the Mental Capacity Act.

The legal framework provided by the Mental Capacity Act 2005 is supported by a Code of Practice, which provides guidance and information about how the Act works in practice. The Code of Practice has statutory force which means that health and social care practitioners have a legal duty to have regard to it when working with or caring for adults who may lack capacity to make decisions for themselves.

“The Act is intended to assist and support people who may lack capacity and to discourage anyone who is involved in caring for someone who lacks capacity from being overly restrictive or controlling. It aims to balance an individual’s right to make decisions for themselves with their right to be protected from harm if they lack the capacity to make decisions to protect themselves”. (3)

All Trust workers can access the Code of Practice, Mental Capacity Act 2005 Policy, Mental Capacity Act 2005 Practice Guidance, information booklets and all assessment, checklists and Independent Mental Capacity Advocate referral forms on iCare

http://icare/Operations/mental_capacity_act/Pages/default.aspx

Infection Control

All staff will have access to Infection Control Policies and comply with the standards within them in the workplace. All staff will attend Infection Control Training annually as part of their mandatory training programme.
Rapid (E)quality Impact Assessment (EqIA) (for use when writing policies)

<table>
<thead>
<tr>
<th>Policy Title (and number)</th>
<th>Version and Date</th>
</tr>
</thead>
</table>

**Policy Author**
An (e)quality impact assessment is a process designed to ensure that policies do not discriminate or disadvantage people whilst advancing equality. Consider the nature and extent of the impact, not the number of people affected.

**Who may be affected by this document?**

| Patients/Service Users | Staff | Other, please state... |

**Could the policy treat people from protected groups less favourably than the general population?**

**PLEASE NOTE: Any ‘Yes’ answers may trigger a full EIA and must be referred to the equality leads below**

<table>
<thead>
<tr>
<th>Age</th>
<th>Gender Reassignment</th>
<th>Sexual Orientation</th>
<th>Race</th>
<th>Disability</th>
<th>Religion/Belief (non)</th>
<th>Gender</th>
<th>Pregnancy/Maternity</th>
<th>Marriage/ Civil Partnership</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes ☐ No ☐</td>
<td>Yes ☐ No ☐</td>
<td>Yes ☐ No ☐</td>
<td>Yes ☐ No ☐</td>
<td>Yes ☐ No ☐</td>
<td>Yes ☐ No ☐</td>
<td>Yes ☐ No ☐</td>
<td>Yes ☐ No ☐</td>
<td>Yes ☐ No ☐</td>
</tr>
</tbody>
</table>

**Is it likely that the policy could affect particular ‘Inclusion Health’ groups less favourably than the general population?**

(substance misuse; teenage mums; carers; travellers; homeless; convictions; social isolation; refugees)

| Yes ☐ No ☐ |

Please provide details for each protected group where you have indicated ‘Yes’.

**VISION AND VALUES:** Policies must aim to remove unintentional barriers and promote inclusion

Is inclusive language used throughout? Yes ☐ No ☐ NA ☐

Are the services outlined in the policy fully accessible? Yes ☐ No ☐ NA ☐

Does the policy encourage individualised and person-centred care? Yes ☐ No ☐ NA ☐

Could there be an adverse impact on an individual’s independence or autonomy? Yes ☐ No ☐ NA ☐

**EXTERNAL FACTORS**

Is the policy a result of national legislation which cannot be modified in any way? Yes ☐ No ☐

What is the reason for writing this policy? (Is it a result in a change of legislation/ national research?)

Who was consulted when drafting this policy?

<table>
<thead>
<tr>
<th>Patients/Service Users</th>
<th>Trade Unions</th>
<th>Protected Groups (including Trust Equality Groups)</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Staff</th>
<th>General Public</th>
<th>Other, please state...</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

What were the recommendations/suggestions?

Does this document require a service redesign or substantial amendments to an existing process? **PLEASE NOTE: ‘Yes’ may trigger a full EIA, please refer to the equality leads below**

| Yes ☐ No ☐ |

**ACTION PLAN:** Please list all actions identified to address any impacts

<table>
<thead>
<tr>
<th>Action</th>
<th>Person responsible</th>
<th>Completion date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**AUTHORISATION:**
By signing below, I confirm that the named person responsible above is aware of the actions assigned to them

Name of person completing the form

Validated by (line manager)
Please contact the Equalities team for guidance:
For South Devon & Torbay CCG, please call 01803 652476 or email marisa.cockfield@nhs.net
For Torbay and South Devon NHS Trusts, please call 01803 656676 or email pfd.sdhct@nhs.net

This form should be published with the policy and a signed copy sent to your relevant organisation.

1. Consider any additional needs of carers/parents/advocates etc., in addition to the service user
2. Travelers may not be registered with a GP - consider how they may access/be aware of services available to them
3. Consider any provisions for those with no fixed abode, particularly relating to impact on discharge
4. Consider how someone will be aware of (or access) a service if socially or geographically isolated
5. Language must be relevant and appropriate, for example referring to partners, not husbands or wives
6. Consider both physical access to services and how information/communication is available in an accessible format
7. Example: a telephone-based service may discriminate against people who are d/Deaf. Whilst someone may be able to act on their behalf, this does not promote independence or autonomy
Clinical and Non-Clinical Policies – New Data Protection Regulation (NDPR)

Torbay and South Devon NHS Foundation Trust (TSDFT) has a commitment to ensure that all policies and procedures developed act in accordance with all relevant data protection regulations and guidance. This policy has been designed with the EU New Data Protection Regulation (NDPR) in mind and therefore provides the reader with assurance of effective information governance practice.

NDPR intends to strengthen and unify data protection for all persons; consequently, the rights of individuals have changed. It is assured that these rights have been considered throughout the development of this policy.

Furthermore, NDPR requires that the Trust is open and transparent with its personal identifiable processing activities and this has a considerable effect on the way TSDFT holds, uses, and shares personal identifiable data. The most effective way of being open is through data mapping. Data mapping for NDPR was initially undertaken in November 2017 and must be completed on a triannual (every 3 years) basis to maintain compliance. This policy supports the data mapping requirement of the NDPR.

For more information:
- Contact the Data Access and Disclosure Office on dataprotection.tsdft@nhs.net,
- See TSDFT’s Data Protection & Access Policy,
- Visit our GDPR page on ICON.