SCHEDULE 2 – THE SERVICES

Service Specification No:	1758
Service	Specialised services for women with complications of mesh inserted for urinary incontinence and vaginal prolapse (16 years and above)
Commissioner Lead	
Provider Lead	

1. Scope

1.1 Prescribed Specialised Service

This service specification covers the multi-disciplinary team management of women with mesh complications consequent to mesh insertion vaginally or abdominally for urinary incontinence and prolapse. The multi-disciplinary team and surgery are provided by a designated Specialised Mesh Complications Service (Mesh Service).

1.2 **Description**

Mid urethral tape mesh is used to treat stress urinary incontinence in women, abdominal mesh is used to treat prolapse whilst vaginal mesh has also been used to treat prolapse. A small percentage of women can develop complications from mesh surgery. These complications may include:

- Vaginal exposure
- Extrusion into the urinary tract
- Extrusion into the bowel
- Infection
- Pain
- Fistulae
- Sexual dysfunction

All women with mesh complications must be discussed at the Mesh Service's Multi-Disciplinary Team (Mesh MDT).

For mesh extrusion into adjacent organs, this usually requires removal of the mesh and, a referral must be made to the Mesh MDT, members of whom will carry out the surgery.

For non-complex mesh complications, (lump, sinus or discharge or exposure of a small amount of mesh <1cm in the vagina) mesh removal may not always be required. However, if following discussion and agreement with the Mesh MDT, simple localised excision of minor mesh exposure into the vagina is recommended, this surgery can be performed by the Specialised Complex Surgery for Urinary Incontinence and Vaginal and Uterine Prolapse Regional MDT (Regional MDT) following discussion and agreement with the Mesh MDT. This is in line with the separate service specification in place for specialised complex surgery for urinary incontinence and vaginal and uterine prolapse.

For mesh complications with pain but with no exposure, extrusion, infection or fistulae, input from a specialist in pain management with an expertise in pelvic pain will be necessary through the Mesh MDT.

1.3 **How the Service is Differentiated from Services Falling within the Responsibilities of Other Commissioners**

Clinical Commissioning Groups commission non-specialised gynaecology and female urology services and Local Multi-Disciplinary Teams (Local MDT) to provide non-surgical and surgical options for women with primary stress urinary incontinence and primary organ prolapse. General Practitioners (GPs) and Local MDTs will refer women to their Regional MDTs, who provide NHS England commissioned treatment for complex and/or recurrent cases of urinary incontinence, combined urinary/and faecal incontinence and/or vaginal and uterine

prolapse where repeat surgery is required.

Local MDTS, Regional MDTs and Mesh MDTs will work within a clinical network arrangement.

Specialised complex surgery for urinary incontinence and vaginal and uterine prolapse services will work within a clinical network arrangement. Services providing Regional MDTs are responsible for ensuring that they deliver specialised treatment as part of an established network.

The regional specialised service must ensure that the Local MDTs within its network are working to: -

- Jointly agreed guidelines and pathways
- Referral guidelines and protocols

Specialised complex surgery services for urinary incontinence and vaginal and uterine prolapse that host specialised services for women with complications of mesh inserted for urinary incontinence and vaginal prolapse, must ensure that Local MDTs and Regional MDTs not hosting a Mesh Service within its network are working to: -

- Jointly agreed guidelines and pathways
- Referral guidelines and protocols
- Guidelines and protocols for patient follow up

2. Care Pathway and Clinical Dependencies

2.1 Care Pathway

This service specification covers the Mesh MDT management of women with complications of mesh inserted for urinary incontinence and vaginal prolapse including the provision of mesh removal surgery.

The service will ensure the provision of specialist assessment, care and treatment for women and adolescent girls aged 16. Patients under the age of 16 years are unlikely to require this intervention, but if there is concern that a patient under this age has complications of mesh, they should be referred to paediatric services and paediatric surgery/urology and a request for advice sent to one of the national centres for this service.

All women with complications of mesh are to be managed in these specialised centres. Management will vary depending on the type of mesh complication. Appropriate management will be determined by the Mesh MDT in collaboration with the Regional MDT.

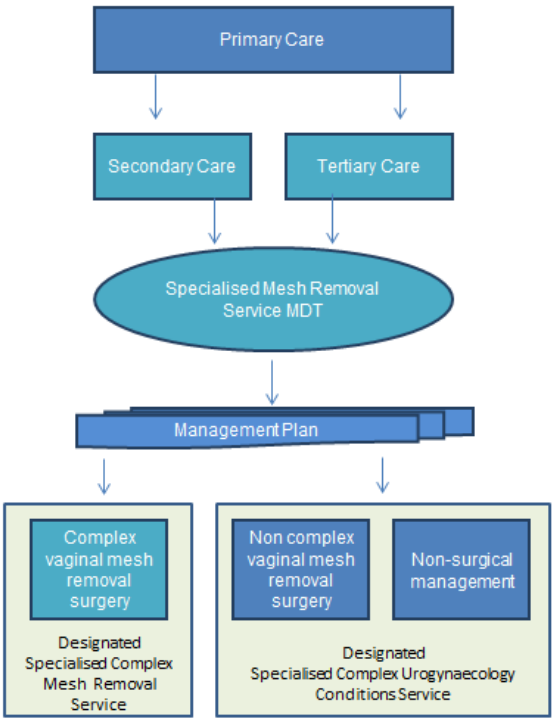
There must be good joint working between the Mesh MDT and the Regional MDT in order to most effectively manage and treat women with mesh complications.

All women with complications relating to mesh must be discussed by the Mesh MDT. The Mesh MDT, the Regional MDT and the patient will agree a treatment plan.

Regional MDTs can perform simple localised excision of minor mesh exposure if they have the appropriate surgical expertise and this has been agreed by the Mesh MDT.

For vaginal mesh complications women will:

- Be referred by the GP, Local MDT and/or the Regional MDT to the Mesh MDT for discussion.
- Be assessed in the outpatient setting by a consultant sub specialist in urogynaecology and/or a consultant urologist with expertise in female urological conditions.
- Have appropriate investigations of lower urinary tract and gastrointestinal tract function. If these investigations have already been done by the referring centre they must be made available for review.
- Have an anaesthetic review and appropriate investigations at their referring centre to ensure that they are fit for operative intervention.
- Be advised of the treatment plan to be offered. If complex mesh removal surgery is recommended by the Mesh MDT they will attend the Mesh Centre's Outpatients Department for discussion of this and any alternative treatment options and have a written copy of the MDT outcome and the outcomes of their outpatient meeting sent to them.
- Be returned to the care of the referring Regional MDT with a treatment plan for ongoing management if complex mesh removal surgery is not indicated or declined by the patient.



Management by category
Mesh complications are classified by the anatomical location which helps to determine how these are managed.

All mesh complication must be classified using the joint International Urogynaecological Association (IUGA)/International Continence Society (ICS) classification system. https://www.ics.org/complication

The Mesh MDT must include:

Core members:

- Named consultant sub-specialist in urogynaecology
- Named consultant Urologist with expertise in female urological conditions
- Consultant Radiologist with expertise in pelvic floor imaging
- A specialist in pain management with an expertise in pelvic pain
- A specialist nurse (urogynaecology, urology or incontinence)

Other membership may include:

- Named colorectal Surgeon with expertise in pelvic floor problems
- A pelvic floor specialist physiotherapist
- A plastic surgeon
- A neurologist
- A psychologist
- A psychosexual counsellor
- An occupational therapist
- Access to a member of the care of the elderly team
- A gastroenterologist
- Other specialist imaging
- A neurosurgeon

Administrative support for the MDT structure is required to co-ordinate the MDT and to provide data entry. The outcome of the MDT must be documented, and a clear pathway established to communicate information to the patient and the Regional MDT.

Referral processes and sources
Referrals will be accepted from GPs/primary care, Local MDTs and Regional MDTs. Good communication between the Mesh MDT and the Regional MDT is essential. The mechanism of communication will vary but can be via teleconferencing, video conferencing and face to face MDT meetings.

Outpatient Appointments

Following the Mesh MDT discussion, any additional investigations will be requested at the Specialised Mesh Complications Service Centre. A summary of the Mesh MDT discussion will be sent to the patient and they will be offered an outpatient appointment to discuss their diagnosis and management options with the Mesh MDT. The patient will be counselled and consented if they wish to proceed with surgery. Prior to surgery patients must have an anaesthetic review which should be at the time of consenting for and dating for surgery.

Investigations

Many of the investigations will have already been performed by the referring Regional MDT, local MDT or GP and must be made available to the Mesh MDT prior to the initial outpatient appointment. These investigations will allow for an extended or advanced assessment of both mesh and non-mesh related anatomical and functional problems and an assessment of urinary, bowel and sexual function. However, further or repeat investigations may be required and these can include*:

- Urodynamics
- Videourodynamics
- Ambulatory urodynamics
- Ultrasound – pelvic floor and endoanal
- Cystoscopy
- Anorectal studies
- Magnetic Resonance Imaging (MRI)
- Computed Tomography (CT)
- MAG3 Renogram scan
- Barium or MR defecating proctogram
- Bowel motility studies

**Note that the above is not an exhaustive list of investigations*

Treatment Strategy

The Mesh MDT review will determine the treatment and management strategy for all women with mesh complications.

If conservative measures are recommended, the patient can be treated by the referring Regional MDT with the agreement of the Mesh MDT. The referring Regional MDT can also carry out simple localised excision of minor mesh exposure into the vagina if that is also agreed by the Mesh MDT.

If at any time patients fail their conservative management or develop additional or new problems, they will be referred back to the Mesh MDT for further discussion.

Second outpatient appointment (telephone call)

A second outpatient appointment (telephone call) will be made (at a minimum of 4 weeks after the initial outpatient appointment) to discuss any new concerns and to confirm their consent for surgical intervention.

Follow up

All patients following Mesh removal surgery will:

- Have a post discharge telephone follow up by a nurse specialist (2-4 weeks post-surgery)
- Have a face to face outpatient review (at 4 months and 12 months post-surgery)
- Be referred back to the referring Regional MDT for annual telephone follow up reviews for up to 5 years post-surgery.

The referring Regional MDT will formally update the Mesh MDT regarding patient outcomes after their annual telephone reviews to allow for accurate data registry entry. On discharge from the Specialised Complex Surgery for Urinary Incontinence and Vaginal and Uterine Prolapse Service at 5 years, there will be clear instructions for the GP to refer back if there are any new issues.

Data Management, Audit and Governance

- The management of mesh complications consequent to mesh insertion vaginally or abdominally for urinary incontinence and prolapse will take place in specialist Mesh Services that provide treatment by consultants working within a Mesh MDT structure operating within a clinical network arrangement.
- Mesh Services are responsible for ensuring that they deliver specialised treatment as part of a network.
- Specialised Complex Surgery Services for Urinary Incontinence and Vaginal and Uterine Prolapse Services that host Mesh Services must ensure that Local MDTs and Regional MDTs within its network are working to jointly agreed guidelines and protocols, referral guidelines, guidelines and protocols for

patient follow up.

- The Mesh MDT must convene at least once each month. The Mesh MDT is quorate if there are at least 3 members in attendance. There must be at least a sub specialist in urogynaecology and a consultant urologist with expertise in female urological conditions and the specialist nurse or the physiotherapist from the extended MDT. If the case is relevant, the consultant colorectal surgeon must also be included in the MDT to ensure quoracy.
- Individual Trusts providing complex Mesh Services must use trust appraisal system to ensure surgeons: are appropriately trained and current in their practice; adhere to clinical guidance; comply with national data requirements; and report complications.
- All procedures must be recorded on the British Society of Urogynaecology (BSUG) databases and the subsequent Pelvic Floor national database that will form part of the development of a national registry.
- All adverse incidents (Als) must be reported to the Medicines and Healthcare Products Regulatory Agency (MHRA) including reporting retrospectively, regardless of whether the Mesh Service carried out the original procedure.
- All additional reporting requirements for individual patients also apply, for e.g. reporting to local incident systems, the National Reporting and Learning System (NRLS) and serious incidents to Strategic Executive Information System (StEIS).
- All surgeons undertaking Mesh surgery must submit their data to the BAUS Audit and/or BSUG database and the national database/registry. This data must be submitted as an index procedure for their yearly appraisal. All trust Responsible Officers (RO) must ensure compliance with this.
- It is incumbent upon trust ROs and individual clinicians to ensure that these practices become embedded and are sustained long term.
- Specialist Mesh Services will provide surgery in compliance with current NICE guidelines.
- NHS England does not recognise the achievement of BSUG accreditation as an endorsement to deliver this service specification. It acknowledges that the accreditation process is an indication of good working practices. All Specialised surgeons providing complex surgery for urinary incontinence and vaginal and uterine prolapse services hosting the Mesh Service and Mesh MDT, must be members of the appropriate subspecialist society. All urogynaecologists must have BSUG membership. All female urologists forming part of the specialist MDT must have membership of the FNUU section of BAUS with confirmed 100% entry onto the BSUG database.
- There needs to be clear documented evidence that can demonstrate competency to perform complex vaginal mesh removal surgery for all surgical members of the MDT. Advanced laparoscopic surgery and advance open surgery is not within the repertoire of most gynaecologists or urologists who perform primary surgery. Appropriately trained surgeons with expertise in complex pelvic surgery (specialist urogynaecologist / specialist urologist +/- specialist colorectal surgeon) can only perform these techniques.
- All issues related to medical devices must be reported to the MRHA yellow card scheme.
- Providers will enter all procedures involving implants on the national registry along with organised follow up and an audit of outcomes.
- All specialised services for women with complications of mesh inserted for urinary incontinence and vaginal prolapse must meet annually in a clinical summit to present data and discuss outcomes.

The annual clinical summit will include clinical performance and outcomes including surgical and non-surgical outcomes and patient feedback.

Mesh Services must provide patients with information on all mesh and non-mesh treatment options, types of treatment and risks and allow them time to consider their options. They must always legally obtain patient informed consent and ensure to record the discussion between the clinician and patient about the treatment procedure; the alternatives; recommendations; and questions/understanding.

Reasonable time should be allowed once the patient has been given the information and the opportunity to ask questions before signing and/or confirming a consent form. The General Medical Council (GMC) guidance should be followed when obtaining consent.

2.2 Interdependence with other Services

Specialist urogynaecology, specialist urology and colorectal surgery must be co-located within the same Trust. These must be a consultant sub specialist in urogynaecology, a consultant urologist with expertise in female urological conditions and a colorectal surgeon specialist in pelvic floor disorders. Specialist nursing in urogynaecology, urology or continence and pelvic floor physiotherapy must also be co-located.

There must also be a co-located Consultant Radiologist with expertise in pelvic floor imaging and access to adult critical care services.

The following services must also be co-located or be available to the Mesh MDT: -

- Plastic surgery
- Neurology
- Psychology
- Psychosexual counselling
- Occupational therapy
- The Elderly Care Team
- Gastroenterology
- Other specialised imaging
- Neurosurgery

3. Population Covered and Population Needs

3.1 Population Covered By This Specification

This service specification covers the multi-disciplinary team management of women with mesh complications consequent to mesh insertion vaginally or abdominally for urinary incontinence and prolapse. The multi-disciplinary team and surgery are provided by a designated Mesh Service.

The service outlined in this specification is for patients ordinarily resident in England* or otherwise the commissioning responsibility of the NHS in England (as defined in Who Pays?: Establishing the responsible commissioner and other Department of Health guidance relating to patients entitled to NHS care or exempt from charges).

* Note: for the purposes of commissioning health services, this EXCLUDES patients who, whilst resident in England, are registered with a GP Practice in Wales, but INCLUDES patients resident in Wales who are registered with a GP Practice in England.

3.2 Population Needs

Stress urinary incontinence affects approximately 1 in 3 women older than 18 years at some point in their lives. It is estimated that a woman who is currently 18 years old has a 14% chance of having surgery for stress urinary incontinence during her lifetime.

Prolapse of the vaginal wall and uterus are common conditions affecting up to 50% of women who have given birth.

11% of women undergo a surgical prolapse repair by the age of 80 years and the socio-economic and psychological and physical impacts of stress urinary incontinence and prolapse are considerable.

Approximately 15% of women who have had a stress incontinence operation will have a persistent/recurrent urinary incontinence and require further surgery. Approximately 10% of women who have had surgery for prolapse, will develop symptoms and signs of recurrent prolapse in the same compartment. This is defined in the International Urogynaecological Association (IUGA)/ International Continence Society (ICS) joint report, as prolapse arising from the same site that will require specialist treatment services.

Between 2008/09 to 2016/17 194,107 patients had urogynaecological procedures of which 96,286 were for urogynaecological prolapse and 101,538 were for stress urinary incontinence.

Overall patients with reported urogynaecological procedures to treat urogynaecological prolapse or stress urinary incontinence has reduced year on year from 25,416 patients in 2008/09 to 17,349 patients in 2016/17, a reduction of 32%.

Tape insertion procedures for stress urinary incontinence

- Between 2008/09 to 2016/17, 100,516 patients had a reported tape insertion procedure for stress urinary incontinence.
- In 2016/17 there were 7,245 patients who had an insertion for this procedure group type, a reduction of 48% from 2008/09 when 13,990 patients were recorded.

Non-tape procedures for stress urinary incontinence

- Between 2008/09 to 2016/17, 1,195 patients had a reported non-tape procedure for stress urinary incontinence.
- In 2016/17 there were 133 patients who had this procedure group type, a reduction of 6% from 2008/09

when 141 patients were recorded.

Mesh insertion procedures for urogynaecological prolapse

- Between 2008/09 to 2016/17, 27,016 patients had a reported mesh insertion procedure for urogynaecological prolapse.
- In 2016/17 there were 2,680 patients who had an insertion for this procedure group type, a reduction of 13% from 2008/09 when 3,073 patients were recorded.

Non-mesh procedures for urogynaecological prolapse

- Between 2008/09 to 2016/17, 71,350 patients had a reported a non-mesh procedure for urogynaecological prolapse.
- In 2016/17 there were 7,334 patients who had this procedure group type, a reduction of 12% from 2008/09 when 8,338 patients were recorded.

Patients who have had removal procedures

The number of patients that have had urogynaecological procedures that relate to the removal of material associated with tape and mesh has varied. Increasing from 580 patients in 2008/09 to 679 patients in 2012/13 before decreasing to 502 patients in 2016/17 an overall reduction of 13% between 2008/09 to 2016/17.

3.3 Expected Significant Future Demographic Changes

There are no expected significant demographic changes but the use of mesh sling as a treatment for female SUI is decreasing, with a reduction by about 50% between 2008 and 2017. This highlights a change in patient choice and surgical practice, which is likely to reflect concerns about longer term complications, outcomes and risk of surgery after mesh insertion.

3.4 Evidence Base

- NICE (2019) Urinary incontinence and pelvic organ prolapse in women: management CG123
- NHS England 'Mesh Oversight Group Report' July 2017
- NICE (2015) Urinary incontinence in women: management. CG171'
- NICE (2012) Urinary incontinence in neurological disease: assessment and management. CG 148
- NICE (2017) Extra urethral (non-circumferential) retro-pubic adjustable compression devices for stress urinary incontinence in women IPG576
- NICE (2016) Single-incision short sling insertion for stress urinary incontinence in women, IPG566
- NICE (2008) 'Surgical repair of vaginal wall prolapse using mesh, NICE Interventional Procedures Guidelines IPG267'
- NICE (2009) 'Infracoccygeal sacrolpopexy using mesh for uterine prolapse repair, NICE Interventional Procedures Guidelines IPG280'
- NICE (2009) 'Infracoccygeal sacrolpopexy using mesh for vaginal vault prolapse repair, NICE Interventional Procedures Guidelines IPG281
- NICE (2009) 'Insertion of mesh uterine suspension sling (including sacrohysteropexy) for uterine prolapse repair, NICE Interventional Procedures Guidelines IPG282' NICE (2009) 'Sacrocolpopexy using mesh for vaginal vault prolapse repair, NICE Interventional Procedures Guidelines IPG283'
- NICE (2017) 'Sacrocolpopexy with hysterectomy using mesh for uterine prolapse repair, IPG577

4. Outcomes and Applicable Quality Standards

4.1 Quality Statement – Aim of Service

The service has the following aim:

To provide a designated specialised service for women with complications of mesh inserted for urinary incontinence and vaginal and uterine prolapse through a multi-disciplinary team management approach.

NHS Outcomes Framework Domains

Domain 1	**Preventing people from dying prematurely**	**X**
Domain 2	**Enhancing quality of life for people with long-term conditions**	**X**

Domain 3	**Helping people to recover from episodes of ill-health or following injury**	**X**
Domain 4	**Ensuring people have a positive experience of care**	**X**
Domain 5	**Treating and caring for people in safe environment and protecting them from avoidable harm**	**X**

4.2 Indicators Include:

Number	Indicator	Data Source	Outcome Framework Domain	CQC Key question
Clinical Outcomes				
101	Numbers of patients referred for complications of mesh insertion for urinary incontinence and prolapse	Provider	2,3,5	effective
102	Proportion of patients treated by the specialist team	Provider	2,3,5	effective
103	Proportion of patients treated by the regional MDT with agreement by the Mesh MDT	Provider	2,3,5	effective
104	Proportion of patients having abdominal surgery	Provider	2,3,5	effective
105	Proportion of patients having laparoscopic surgery	Provider	2,3,5	effective
106	Mean length of stay in hospital	Provider	2,3,5	effective
107	Proportion of patients with symptom relief post operatively at 4 weeks	Provider	2,3,5	effective
108	Proportion of patients with urinary continence post operatively	Provider	2,3,5	effective
109	Proportion of patients who have received counselling/psychological support	Provider	2,3,5	effective
Patient Experience				
201	Patients and carers are provided with information	Self-declaration	4	caring, responsive
202	Feedback from patients is reviewed and informs service development and improvements	Self-declaration	4	caring, responsive

203	Patients discuss treatment options with multi-disciplinary team	Self-declaration	4	caring, responsive
204	The service is collecting Patient reported outcomes	Self-declaration	4	caring, responsive
Structure and Process				
001	There is a specialist team	Self-declaration	2,3,5	effective, safe
002	All patients are discussed at the specialist MDT meeting	Self-declaration	2,3,5	effective, safe
003	There are clinical guidelines in place	Self-declaration	2,3,5	effective, safe
004	There are patient pathways in place	Self-declaration	2,3,5	effective, safe
005	The service is submitting data to a national database/registry	Self-declaration	2,3,5	effective, safe

4.3 Commissioned providers are required to participate in annual quality assurance and collect and submit data to support the assessment of compliance with the service specification as set out in Schedule 4A-C

4.4 Applicable CQUIN goals are set out in Schedule 4D

5. Applicable Service Standards

5.1 Applicable Obligatory National Standards

5.2 Other Applicable National Standards to be met by Commissioned Providers

- NICE (2015) Urinary incontinence in women: management. CG171'
- NICE (2012) Urinary incontinence in neurological disease: assessment and management. CG 148
- NICE (2017) Extra urethral (non-circumferential) retro-pubic adjustable compression devices for stress urinary incontinence in women IPG576
- NICE (2016) Single-incision short sling insertion for stress urinary incontinence in women, IPG566
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- NICE (2009) 'Infracoccygeal sacrolpopexy using mesh for vaginal vault prolapse repair, NICE Interventional Procedures Guidelines IPG281
- NICE (2009) 'Insertion of mesh uterine suspension sling (including sacrohysteropexy) for uterine prolapse repair, NICE Interventional Procedures Guidelines IPG282' NICE (2009) 'Sacrocolpopexy using mesh for vaginal vault prolapse repair, NICE Interventional Procedures Guidelines IPG283'
- NICE (2017) 'Sacrocolpopexy with hysterectomy using mesh for uterine prolapse repair, IPG577
- NICE (2019) Urinary incontinence and pelvic organ prolapse in women: management CG123

5.3 Other Applicable Local Standards

Not applicable

6. Designated Providers (if applicable)

7. Abbreviation and Acronyms Explained

The following abbreviations and acronyms have been used in this document:

MDT	Multi-disciplinary Team
GP	General Practitioners
IUAG	International Urogynaecological Association
ICS	International Continence Society
MRI	Magnetic Resonance Imaging
CT	Computed Tomography
TVT	Tension free vaginal tape
BAUS	British Association of Urological Surgeons
BSUG	British Society of Urogynaecology
AIs	Adverse incidents
MHRA	Medicine and Healthcare Products Regulatory Agency
NRLS	National Reporting and Learning System
StEIS	Serious incidents to Strategic Executive Information System
SUI	Serious Untoward Incident
RO	Responsible Officers
GMC	The General Medical Council
FNUU	Female, Neuro-urological and Urodynamic Urologists (FNUU)
NICE	National Institute for Health and Care Excellence

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