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Planning

Surgical Mesh Fixation Devices

NHS Supply Chain

F01: Prior information notice

Prior information only

Notice identifier: 2023/S 000-037845

Procurement identifier (OCID): ocids-h6vhtk-042991

Published 22 December 2023, 1:10pm

Section I: Contracting authority

I.1) Name and addresses

NHS Supply Chain

Wellington House, 133-155 Waterloo Road

London

SE1 8UG

Email

Mohammad.Khan6@supplychain.nhs.uk

Country

United Kingdom

Region code

UK - United Kingdom

Internet address(es)

Main address

<https://www.supplychain.nhs.uk/>

I.3) Communication

Additional information can be obtained from the above-mentioned address

I.4) Type of the contracting authority

Body governed by public law

I.5) Main activity

Health

Section II: Object

II.1) Scope of the procurement

II.1.1) Title

Surgical Mesh Fixation Devices

II.1.2) Main CPV code

- 33140000 - Medical consumables

II.1.3) Type of contract

Supplies

II.1.4) Short description

This framework is for the supply of Surgical Mesh Fixation Devices. Surgical mesh is a woven sheet which is used as either a permanent or temporary support for organs and other tissues during surgery. The meshes are used in a variety of surgeries and reconstructive work including hernia and abdominal repairs, and reconstructive work such as breast reconstruction or pelvic organ prolapse. The framework includes most types of surgical mesh including synthetic, biological and hybrid mesh, and products which are used in conjunction with mesh fixation such as staples, glues and self-fixation mesh systems.

The framework is made up of four Lots:

Lot One: Synthetic Mesh

Lot Two: Biologic Mesh

Lot Three: Specialist Mesh

Lot Four: Fixation Devices

II.1.5) Estimated total value

Value excluding VAT: £72,000,000

II.1.6) Information about lots

This contract is divided into lots: Yes

Maximum number of lots that may be awarded to one tenderer: 4

II.2) Description

II.2.1) Title

Synthetic Mesh

Lot No

1

II.2.2) Additional CPV code(s)

- 33140000 - Medical consumables

II.2.3) Place of performance

NUTS codes

- UK - United Kingdom

II.2.4) Description of the procurement

Woven/knitted Mesh sheets intended for surgical implantation into a patient in order to strengthen internal tissues and provide support for internal organs. Synthetic Mesh product lines must be available in absorbable, semi absorbable and/or permanent versions; plug and patch product lines are also required.

II.2) Description

II.2.1) Title

Biologic Mesh

Lot No

2

II.2.2) Additional CPV code(s)

- 33140000 - Medical consumables

II.2.3) Place of performance

NUTS codes

- UK - United Kingdom

II.2.4) Description of the procurement

Biologic Mesh product lines must be available in a specific dimensions, shapes and supplied in both sheets for cutting by the surgeon if required during the procedure and pre-cut/ready for use with a range of sizes.

Biologic Mesh is non-woven and must be derived from animal collagen. Biologic Mesh absorbable/non-absorbable devices and biological/synthetic source may be made from an organic biomaterial such as, porcine dermis, porcine small intestine submucosa, bovine dermis or pericardium.

II.2) Description

II.2.1) Title

Specialist Mesh

Lot No

3

II.2.2) Additional CPV code(s)

- 33140000 - Medical consumables

II.2.3) Place of performance

NUTS codes

- UK - United Kingdom

II.2.4) Description of the procurement

Woven / knitted Mesh sheets (excluding full Biologics) and their associated products intended for use in complex medical procedures including but not limited to:

- Specialist hernia repair Mesh
- Abdominal Mesh
- Pelvic floor Mesh
- Composite Mesh
- 3D/4D Shaped Mesh
- Coated Mesh for Intra-Abdominal Repair
- Self-gripping mesh

Specialist Mesh product lines must be safe for patient implantation and each Specialist Mesh product line must be supplied in one or more of the following materials:

- Absorbable Synthetic Biological with Reinforcement
- Biological/Hybrid
- Contour Mesh (preformed Mesh)
- Synthetic/Hybrid
- Shaped
- Preformed Cut/Outs
- Self-Fixated

II.2) Description

II.2.1) Title

Fixation Devices

Lot No

4

II.2.2) Additional CPV code(s)

- 33140000 - Medical consumables

II.2.3) Place of performance

NUTS codes

- UK - United Kingdom

II.2.4) Description of the procurement

Fixation device product lines must be designed to hold surgical Mesh in place following its insertion into the patient and be available in absorbable and permanent versions

II.3) Estimated date of publication of contract notice

24 January 2024

Section IV. Procedure

IV.1) Description

IV.1.8) Information about the Government Procurement Agreement (GPA)

The procurement is covered by the Government Procurement Agreement: Yes

Section VI. Complementary information

VI.3) Additional information

This PIN is intended to invite supplier engagement to further assist of the procurement and overall solution. It is anticipated that there will be supplier engagement which will cover the intended sourcing approach, regulatory compliance expectations within the ITT procedure.

To register an expression of interest for this tender opportunity please register on the Jaggaer eProcurement Portal - <https://nhssupplychain.app.jaggaer.com/> and express your interest in "SQ_458 - Expression Of Interest".

Expressions of interest for the supplier engagement must be received by 10:00BST on 22 Jan 2024. Further details regarding engagement will be shared in the new year.

It is anticipated that the tender documents and Contract Notice will be published at the end of January 2024. It is intended that the Framework Agreement will be let for an initial term of 2 years, with optional extensions to not exceed a maximum 4 years overall.

The following certification will be a requirement of the upcoming tender exercise and Applicants may be required to include evidence of this within their tender submission.

- ISO 9001:2015 or equivalent externally accredited and up-to-date quality standard certificate(s) to cover all segments of the Applicant's (and the product's) supply chain. This should include but not be limited to manufacturing, storage, distribution and customer service. Further information in respect of certification requirements will be set out in the notice for the forthcoming procurement. If such certificates are not in the name of the Applicant then the Applicant must supply a copy of agreements setting out the authority and responsibilities of all parties in the supply chain and provide evidence of ISO9001:2015 or equivalent for all relevant parties in the supply chain.

- Public Liability Insurance cover of £5m per claim in the name of the Applicant

- Product Liability Insurance cover in the name of the Applicant of £5m per claim or £5m per claim and in the annual aggregate

- Declaration of Conformity and UKCA Certification to demonstrate compliance to UK Medical Device

Regulations 2002 or Declaration of Conformity and CE Certification to d-Declaration of Conformity and UKCA Certification to demonstrate compliance to UK Medical Device Regulations 2002 or Declaration of Conformity and CE Certification to demonstrate

compliance to Medical Devices Directive 93/42/EEC or Medical Device Regulation 2017/745 (where applicable).

If an Applicant commits to obtain ISO9001:2015 or equivalent quality standard certificate, Public Liability Insurance or Product Liability Insurance certification at the time of their tender submission then the requirement is that such certification is in place prior to the commencement date of the framework agreement (in order for NHS Supply Chain to place orders with the successful Applicant).

The NHS has adopted PPN 06/20 (taking account of Social Value), and therefore this future Framework Agreement will include some qualitative evaluation questions on Social Value with a min. weighting of 10% towards the award. For more information please see: <https://www.gov.uk/government/publications/procurement-policy-note-0620-taking-account-of-social-value-in-the-award-of-central-government-contracts>. In addition, from April 2023: the NHS adopted the Government's 'Taking Account of Carbon Reduction Plans' (PPN 06/21) requiring all suppliers with new contracts for goods, services, and/or works with an anticipated contract value above £5 million per annum, to publish a carbon reduction plan for their direct emissions. From April 2024, the NHS will expand this requirement for all new contracts, irrespective of value. Suppliers bidding on NHS Supply Chain tenders will also be required to submit an Evergreen Assessment, please see <https://www.england.nhs.uk/nhs-commercial/central-commercial-function-ccf/evergreen/>. PPN02/23 "Tackling Modern Slavery in Government Supply Chains" will also apply.