INVITATION TO TENDER

FOR ENDOSCOPY, ENDOUROLOGY & ONCOLOGY ABLATION CONSUMABLES & ASSOCIATED PRODUCTS

ITT REFERENCE PROJECT_1333

ATTACHMENT 4b LOT 3 SPECIFICATION

LOT 3 SPECIFICATION:
ONCOLOGY ABLATION CONSUMABLES & ASSOCIATED PRODUCTS

Introduction

Interventional Oncology is now the fourth pillar of cancer care, alongside medical, radiation and surgical oncology. If offers minimally invasive, organ sparing and quicker convalescent period. Image guided ablation is the method used for ablating tumours in soft tissue organs of the body, including but not limited to; Liver, Kidney, Prostate and Lung. This can also be used in other areas of the body such as Bone, Adrenal and Thyroid. During tumour ablation, the thermal technology e.g. heat-based energy with radiofrequency ablation or microwave ablation and cold based energy such as cryoablation are used to heat or freeze tissue to cytotoxic levels, ensuring that the temperature of the device causes cell death. In addition, non-thermal technologies are available to destroy tumours, these are involving the pulsed electrical current to punch holes in the cancer cells either irreversibly as in Irreversible Electroporation or reversibly as in Electrochemotherapy.

Interventional Oncology Ablation is a minimally invasive surgical method to treat malignant tumour in soft tissue organs and bones. Probes are used to destroy malignant tumour without the need for incision in surgery. Computed Tomography (CT) Ultrasound (US) or Magnetic Resonance Imaging (MRI) is used to guide and position the needle probe/antenna into the organ to ablate the tumour. This can be done through various methods, including but not limited to; Cryoablation, Radiofrequency Ablation, Microwave Ablation, Irreversible Electroporation and Electrochemotherapy.

Lot 3 Structure:

Lot Number	Lot Title
3.1	Microwave Ablation Therapy
3.2	Cryoablation Therapy
3.3	Irreversible Electroporation Ablation
3.4	Radiofrequency Ablation Therapy
3.5	Electrochemotherapy
3.6	Oesophageal Ablation
3.7	Histotripsy Ablation

Standards and Legislation

STANDARD / CERTIFICATION
Where products are classed as Medical Devices as per the definition under Medical Devices Regulation 2017/745 the following will apply: **Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)** All products must have their CE or UKCA marking evident on the product and/or packaging. **Or** **Medical Devices Regulation 2017/745** All products must have their CE marking evident on the product and/or packaging. **Active Implantable Medical Device Directive (AIMDD) 90/385/EEC (as amended) or Medical Devices Regulation 2017/745** All products must have their CE marking clearly evident on the product and/or packaging. **BS EN 45502-1:2015 or equivalent** Active implantable medical devices. General requirements for safety, marking and information to be provided by the manufacturer **ISO9001**

3.1 Microwave Ablation Therapy:

Microwave ablation is a form of thermal ablation used to treat malignant tumour under imaging guidance. MWA uses electromagnetic waves in the microwave energy spectrum to heat the water molecules within the cancer cells in order to produce tissue-heating effects.

Including but not limited to:

Microwave Ablation Probe

Generators

Associated Products

3.2 Cryoablation Therapy:

Cryoablation is a process that uses extreme cold to destroy tissue. Cryoablation is performed using hollow needles through which cooled, thermally conductive, fluids are circulated. Cryoprobes are positioned adjacent to the target in such a way that the freezing process will destroy the diseased tissue.

Including but not limited to:

- Cryotherapy Ablation Cryoprobe
- Generators
- Associated Products

After the procedure, the patient usually stays in hospital overnight, although some may go home the same day. Cryoablation therapy is less invasive than surgery, so there is usually less blood loss, a shorter hospital stay, shorter recovery period and less pain.

3.3 Irreversible Electroporation Ablation:

Irreversible electroporation is a soft tissue ablation technique using ultra short but strong electrical fields to create permanent and hence lethal nanopores in the cell membrane, to disrupt cellular homeostasis. Often used in organs with a more critical structure, including but not limited to the Pancreas, Liver, Kidney and Prostate.

Including but not limited to:

- Irreversible Electroporation Electrode
- Generators
- Associated Products

3.4 Radiofrequency Ablation Therapy:

Radiofrequency ablation for malignant tumour is a minimally invasive procedure that uses alternating current that produce frictional heat that leads to destruction of malignant cells. The radiologist uses imaging tests to guide a thin needle through the skin or through an incision and into the tumour tissue within soft tissue organs.

Including but not limited to:

- Radiofrequency Electrode
- Radiofrequency Patient Return Electrode Grounding Pad
- Generators
- Associated Products

3.5 Electrochemotherapy:

Electrochemotherapy is a non-thermal tumour ablation modality based on electrical pulses directly applied to the tumour volume and combined with a single intravenous, intravesical or intertumoral drug administration. The electrical current increases the cell membranes permeability and allows the drug to access the cytosol and exert its toxicity, thus resulting in a locally enhanced chemotherapy.

Often used in organs with a more critical structure, including but not limited to the Pancreas, Liver, Bladder, Kidney, Pancreas and Sarcoma.

Including but not limited to:

- Electrochemotherapy Electrode
- Generators
- Associated Products

3.6 Oesophageal Ablation:

This technology system is a type of Cryotherapy that is indicated for the treatment of, but not limited to, oesophageal and airway diseases, such as oesophageal cancer, by delivering liquid nitrogen (LN2) at -196°C. LN2 is the coldest cryogen available and the only cryogen capable of ablating benign and malignant cells. Liquid nitrogen spray cryotherapy traps and flash-freezes water in cells causing cell death while preserving the extracellular matrix, promoting a rejuvenate healing response.

Including but not limited to:

- Esophageal Liquid Nitrogen Spray Cryotherapy Passive Catheter
- Esophageal Liquid Nitrogen Spray Cryotherapy Active Catheter
- Console
- Connector and Suction Tubing
- Associated Products
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3.7 Histotripsy Ablation:

Histotripsy is a non-invasive medical technique that uses high-intensity focused ultrasound (HIFU) on targeted tissue.

This technology is a non-thermal and non-ionizing, non-invasive form of focused ultrasound that uses high amplitude very short pulses designed to mechanically destroy and liquify targeted tissue, such as liver tumours, at sub-cellular levels.

This sublot covers all single use accessories required to complete a histotripsy procedure including but not limited to:

- Histotripsy procedure kit
- Coupling kit
- Patient membrane
- Bubble removal tool

- Coupling band
- Inspection mirror
- Membrane cradle
- Fluidics disposable kit

Products may be offered as a kit or as individual components as per the suppliers' standard SKU. Where a kit is offered a full specification of the kit contents must be provided.