

물 품 규 격 서

- 입찰공고번호 : (학)일송학원 관리국 제2025-183호
- 입찰건명 : 영상의학과(초음파실) Cryoablation Console, Portable 구매
- 수요기관 : 한림대학교성심병원
- 납품장소 : 수요기관 희망장소 입고도
- 물품내역 등

연번	품명(영문, 국문)	규격 및 사양	총 구매 예정수량 (Q'TY)	1회 최대 발주수량	Warranty 기간	단위 (Unit)
1	Cryoablation Console, Portable (이동형 냉동수술기)	하단 참조	1	1	검수(합격)일로부터 3년 종료월 말일까지	SET

□ 공통사항

- 장비의 설치와 작동 및 교육은 무상으로 제공한다.
- 수요기관 담당자 입회하에 계약상대자는 제품의 설치 테스트 및 시험작동을 실시하여야 한다.
- 무상 하자담보 책임기간은 물품 검수(합격)일로부터 3년 종료월 말일 까지를 기본 원칙으로 하며 계약상대자의 추가 제안에 따라 3년을 초과하여 설정할 수 있다.
- 무상 하자담보 책임기간 중 수요기관의 사정으로 인하여 부서 및 장비의 위치가 불가피하게 이동을 필요로 할 경우 설명 및 설치가 무상으로 이루어진다.
- 무상 하자담보 책임기간 중 중 공급된 장비의 부속품이 단종된 경우 수요기관이 인정하는 동등 이상의 장비로 무상 교체가 이루어져야 한다.
- 계약상대자는 어떠한 상황에서도 애프터서비스를 위하여 전문서비스 인력을 제공하여야 하며 애프터서비스를 위하여 교체 부품을 보관하여야 한다.
- 계약상대자는 장비 납품 시 납품일을 기준하여 제품 제조년월이 6개월 이내인 장비를 납품하고 납품장비에 해당 제조년월이 명시되어야 한다.
- 기존 노후 의료장비 철거 및 회수(또는 보상판매) 조건으로 제안할 수 있다.

〈규격 · 사양〉

A. Features

The Cryoablation System is a portable system intended for cryoablative tissue destruction using a minimally invasive procedure. The system is computer-controlled with a touch screen user interface that allows the user to control and monitor the procedure.

The Cryoablation System uses high-pressure argon gas that circulates through closed-tip cryoablation needles to induce tissue freezing. Freezing is due to the Joule-Thomson effect augmented by a recuperative heat exchanger within the cryoablation needle. Active tissue thawing is achieved by controlling the heating element inside CX-type needles to provide active helium-free thawing (i-Thaw™ or FastThaw™) and track ablation (Cautery).

Cryoablation treatments are delivered by small diameter cryoablation needles that are inserted into the target lesion, usually under CT image guidance. When multiple cryoablation needles are placed into or near the target tissue and freezing is initiated, an ice ball grows around the distal end of the needle shafts.

In time, the ice balls coalesce and completely engulf and destroy the target tissue.

The cryoablation needle design and the temperature of the argon gas, as well as the freeze duration, determine the size and shape of the ice ball. Tissue ablation is achieved by repeated freeze and thaw cycles with both freezing and thawing contributing to cell death. Each freeze-thaw cycle consists of a freeze cycle followed by a thaw cycle. Generally, multiple freeze-thaw cycles are used to achieve complete destruction of the target tissue.

An important benefit of cryoablation is that imaging procedures, such as ultrasound and CT, can display the location and size of the ice ball. This benefit of cryoablation is used for proper control of the therapy.

During use, the procedure must be monitored using image guidance to ensure adequate tissue coverage and to avoid damage to adjacent structures.

In addition to image guidance, Galil Medical provides temperature sensors to aid in monitoring tissue temperature near the target site and adjacent critical structures. These temperature sensors can provide quantitative data to supplement the qualitative information provided by the imaging modality.

B. Specifications

1. Product Specifications

(1) Console

- (a) Weight : 20Kg
- (b) Height : 28 cm (Monitor Down), 48 cm (Monitor Up)
- (c) Foot Print : 36 cm * 53 cm

(2) Cart

- (a) Weight : 23Kg
- (b) Height : 91 cm
- (c) Foot Print : 35 cm * 53 cm

(3) Electrical Specification

- (a) Input Voltage : 100 to 240 VAC, Single Phase
- (b) Input Frequency : 50 ~ 60 Hz
- (c) VA Rating : 250 VA
- (d) IP Rating : IP10
- (e) Fuse Rating : T 2A
- (f) Electrical Protection : Class I , Type BF Protection against shock
- (g) Signal Input / Output : One Ethernet Port / One USB 2.0 Full-speed Port

2. Operation Conditions

- (1) Storage temperature : -15°C to 50°C
- (2) Storage relative humidity : 10% to 90%
- (3) Operating temperature : 10°C to 40°C
- (4) Operating relative humidity : 30% to 75%
- (5) Argon Gas Supply
 - (a) Purity Level : 99.998% or Higher
 - (b) Solid Particle Size : 5µm
- (6) Gas Cylinder Specifications
 - (a) Nominal Pressure : 3,500 psi, 241 bar, 24.1 Mpa
 - (b) Maximum Pressure : 4,500 psi, 310 bar, 31 Mpa
 - (c) Recommended Volume of Gas Cylinder : 42 ~ 50l
- (7) Required Gas Pressure : 3,500 psi (Nominal Working Pressure) / 3,200~3,800 psi (Working Pressure Limits)

C. Consist of(per 1 Set)

- 1. Console (1ea)
- 2. Cryoablation Console Cart (Optional, 1ea)
- 3. Cryoablation System User Manual (1ea)
- 4. Cryoablation Quick Reference Guide (1ea)
- 5. USB Flash Drive (4GB) (1ea)
- 6. High pressure Argon gas supply line (1ea)
- 7. Ethernet cable (3M) (1ea)
- 8. Wrench (1ea)
- 9. Accessory Bag (1ea)
- 10. EZ-Connect to Dual Cylinder Adaptor (Optional, 1ea)

D. Remarks

- . Warranty : 검수(합격)일로부터 3년 종료될 말일