



Special Medical Technology, Ltd.

**CRYOSPRAY**

**CS 1**



**CE** 1014

**Operating Instructions**

**Special Medical Technology**





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Device classification class: ..... **II a**

Device service life:..... **7 years**

**1. CAUTION**

Study cryosurgical principles before operation!

Never unscrew the Cryospray's black plastic head when any volume of coolant is in - DANGEROUS!

Incline the FULL cryospray during operation or manipulation up to angle 45° maximally! (a safety valve would open)

Use only LIQUID NITROGEN as a coolant!

## 2. INTRODUCTION

A cryogenic injury to tissue is the most natural local destructive modality.

The efficacy of liquid nitrogen for treatment and cure of basal cell carcinoma and other skin tumours is very high.

Cryosurgical devices for liquid nitrogen allowed the most rapid heat extraction from the tissue - no other coolant is so effective!

The CRYOSPRAY method - „CRYOSPRAYING“ - is the simplest and cheapest cryosurgical method.

The CRYOSPRAY method is suitable mainly for the treatment of smaller benign skin tumours.

The basic areas for utilisation of the CRYOSPRAY method are:

DERMATOLOGY  
SURGERY, PROCTOLOGY  
OPHTHALMOLOGY  
OTORHINOLARYNGOLOGY  
UROLOGY

**Caution:** For larger benign and for malignant tumours is necessary to use computerized contact up-to-date cryosurgical system KCH 450 with the rewarming up equipment - take advice of the producer!

## 3. HOW TO OPERATE WITH THE CRYOSPRAY CS 1

1. Unscrew the black plastic head /1/ of the device (see page 8)
2. Fill the device with the coolant - liquid nitrogen - up to 7 cm from the upper end of the thermos vessel /2/ approximately
3. Screw the black plastic head /1/ and tighten carefully
4. Prepare suitable size of operating jet /6/ (and/or a contact tip-see specification) and screw it into the nozzle of the cryospray /4/ - in the meantime the device is prepared for operation
5. Take the Cryospray by right or left hand and push the trigger /3/ while the operating jet /6/ (or contact tip) is in the right position - some milimeters from (in contact) the affection (pathological tissue)

6. Usually spray freezing by the Jets J4, J6 or J8 is from the distance of several millimeters for 5-30 seconds. When the frozen area is visible (white) the „spraying“ operation is over!

The best direction of the spraying is „tangent“ one to the finger /body/ of the patient. Use this direction always when possible.

The smallest spray tip - Jet J4 is designed for a very small and soft interventions (warts with children for inst.) - the " Interrupted Spray Effect" is used.

7. After operation treat the affection by usual sterile cover and invite the patient for the control in several next days.

#### **4. THE SIMPLIFIED CRYOSURGICAL TECHNIQUE**

„CRYOSPRAYING“ BY THE CRYOSPRAY CS 1 HAS THESE MAIN FEATURES:

- one hand operation - leave one hand free to manipulate lesion or adjacent skin
- instant pressure - no wait to pressure built-up
- easily portable - light-weight
- wide fill opening - easy filling with the coolant (liquid nitrogen) thanks to the broad filling neck
- all stainless steel thermos - safe, no rust, no risk of glass implosion
- special safe and regulation valve system - other control unnecessary
- vacuum insulation - very effective
- time saving, quick, economical, safe, simple
- for whole-day work - filling with the coolant (liquid nitrogen) is usually necessary once a day only
- possibility to locate a stream of nitrogen into very small area of the tissue - by 3 dimensions of precise jets (only necessary destructed tissue)

- new repumping apparatus PIPE 1 - for the quick and comfortable filling of the Cryospray (special accessories)
- new contact oper. tip - developed for the treatment of glaucoma with animals (special accessories) - useful for human ophthalmology - for eyelids

## 5. TECHNICAL PARAMETERS

Coolant: .....	liquid nitrogen ( - 196°C)
Capacity: .....	0,5 l
Pressure: .....	max. 95 kPa
Static holding time: .....	24 hours
Diameter: .....	70 mm
Height: .....	320 mm
Insulation: .....	vacuum
Weight without LN2: .....	470 g
Weight with LN2: .....	820 g

## 6. THE FULFILMENT OF LEGISLATIVE REQUIREMENTS

The conformity was reviewed with the product.

The manufacturer declares at its own responsibility exclusively that the product fulfils basic requirements stated in Annex 1 of Regulations of the Czech Government No. 336/2004 Coll. (93/42/EEC) in the relevant valid readings.

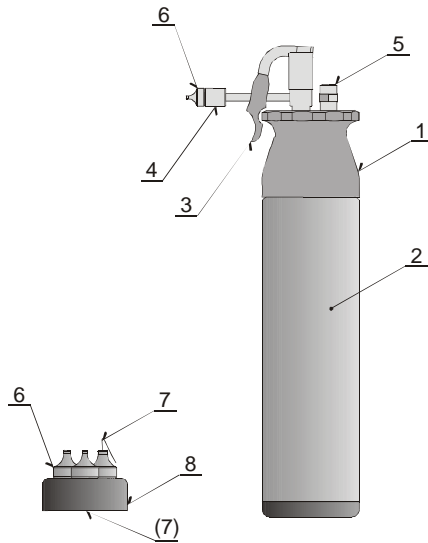
For the review were used these harmonised standards in a valid reading:

EN ISO 13485

The examination of the conformity was carried out in participation of the Authoritative person – Notified Body No. 1014.

The Manufacturer issued a Declaration of Conformity on this matter.

## 7. DESCRIPTION OF THE CRYOSPRAY CS 1



- 1 - Black plastic head
- 2 - Thermos
- 3 - Trigger
- 4 - Nozzle
- 5 - Safety valve
- 6 - Jet (three pcs in basic equipment - J 4, J 6, J 8)
- 7 - Wire for cleaning
- 8 - Small stand for 3 basic jets



## **INDEMNITY AGREEMENT**

Type: Cryospray CS 1

Serial number:

Date of sale:

Stamp and signature of supervisor:

Warranty conditions:

1. 24 months guarantee is given on the device when operated according to the Operating Manual, i. e. where there are possible defects in material or manufacture a replacement is made or the unit is repaired free of charge.
2. Manufacturer ensures that the device will have 24 months minimally the features given by its documentation - technical conditions and norms.
3. All repairs have to be realised by authorised service and/or by the manufacturer.
4. This certificate of Warranty is also the Certificate of Quality.



## RECORDS OF REPAIRS

Date of reception:

Description of malfunction:

Completion date:

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Signature and stamp of the service

Date of reception:

Description of malfunction:

Completion date:

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Signature and stamp of the service

Date of reception:

Description of malfunction:

Completion date:

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## END USER REGISTRATION CARD

PRODUCT: CRYOSPRAY CS1

Serial number:

Sales clerk:

User:

Name:

Organization:

Address:

Telephone:

Fax:

Herewith I confirm that I have got acquainted with the Operating Instructions and with the Guarantee Conditions and I will observe them.

Date:

Signature:

Dear customers,

will you tear this registration card out and forward it to the address: SMT Ltd., Papírenská 114/5, 160 00 Prague 6, Czech Republic, EU.

The objective of this registration is, partly, to improve the quality of services our firm offers to its customers, and, partly, to observe strict requirements of standards ISO 13485:2003 that our firm conforms and that the user of medical technology must be acquainted with.

In the next 3-9 months we will contact you again and will ask you for the filling of another our form (blank) - the "Feed Back"- which will be, thanks to your special opinions, a very good base for further development of our products. Thank you in advance for your kind cooperation.

Yours,

Special Medical Technology, Co.







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