

## COVER PROBE TECHNICAL INFORMATION

### Definition

- Attachment of the probe transducer, that is generally used for clinical exploration in echography.

### General features

- The cover probe is flexible, made in latex of natural rubber (used as attachment of the probe transducer). Available in two versions: lumbar/abdominal and vaginal/rectal.



### Applications

- The cover probe lumbar/abdominal is indicated for favour the hygienic condition of the probe and maintain the clearness of the image. The cover probe vaginal/rectal is indicated for contain the gel used for the echography, in order to obtain a better image.



### Medical Device according to the directive 93/42 CEE modified

#### By the directive 2007/47/CE

#### Implementation with D.Lgs. n°37 del 25-01-2010

#### **Class IIa** (code 00 090144 200 000 – vaginal/rectal)

- Use: invasive medical device. CE 0120

#### **Class I** (code 00 092144 200 000 - lumbar/abdominal)

- Use: Non invasive medical device in contact with skin.

### Conformity

- DIRECTIVE CEE 93/42,
- Quality Assurance System: certified according to UNI EN ISO 9001:2008.

### Technical specification

RAW MATERIAL	Natural latex	
	Lumbar/ abdominal	Vaginal/rectal
LENGTH – mm	192 ± 7	192 ± 7
WIDTH – mm	52 ± 2	37 ± 2
WEIGHT – gr	1,95 ± 0,3	1,46 ± 0,3
TICKNESS – mm	0,080 ± 0,005	0,09 ± 0,005
VOLUME OF EXLOSION - L	≥ 18	≥ 10
BREAKING STRENGTH - N	≥ 50	≥ 50
BREAKING TENSION %	≥ 650	≥ 650
PRESSURE OF EXPLOSION - L	≥ 1,00	≥ 1,80



## COVER PROBE TECHNICAL INFORMATION

<b>Sterile</b>	<b>No</b>
<b>Latex in the product</b>	<b>Yes</b>
<b>Latex in the package</b>	<b>No</b>
<b>Validity</b>	<b>5 years if stored properly</b>
<b>Storage instructions</b>	<b>Store in a cool, dry place, away from heat and direct sunlight</b>

### Product sterilization

- Non sterile product.

### Biocompatibility

- TEST of BIOCOMPATIBILITY: cytotoxicity, allergic sensitization, cutaneous irritation.

### Disposal

- In compliance with applicable laws. The product can be assimilable with the hospital waste or special waste.

### Indications for use for cover probe vaginal/rectal

- Avoid the contact with people allergic to the latex.
- Adapt for probe transducer for vaginal and rectal echography.
- Do no use with abdominal and lumbar probe transducer.
- Avoid the contact with oily gel.

### Indications for use for cover probe lumbar/abdominal

- Avoid the contact with people allergic to the latex
- Compatible with probe transducer for lumbar and abdominal echography.
- Avoid the contact with oily gel that can damage it.

### Quality control

- Products are controlled in according to the coded procedures.
- The product is controlled according to the sampling in AQL and aesthetic – visual– functional tests.

### Packaging

**Labels and/or packages have the following:**

Product name
Manufacturer
Dimension
Date and batch of production
Validity
Storage instruction
Item bar code

### Packaging material

- Single in aluminium wrapper, in unit of carton dispenser of 144 pz.



## COVER PROBE TECHNICAL INFORMATION

### Manufacturer

- KAREX (MALAYSIA)

### Supplier

- Artsana S.p.A. Via Saldarini Catelli 1, 22070 Grandate (Como) Italy.

### Assortment

Code	Type	Package	Unit
00 090144 200 000	Vaginal/ rectal	1 pz	144 pz
00 092144 200 000	Lumbar/ abdominal	1 pz	144 pz

### The Technical Director

ARTSANA S.p.A.  
Dr. MAURO CASSANI  
Medical Devices Department  
Technical Director

Artsana S.p.A. considers the information in this document confidential and non-disclosable. Artsana reserves all rights to change this document based on technical developments and amendments to relative product standards.