

# DIACAN PRO

## ARTERIAL AND VENOUS FISTULA NEEDLES FOR DIALYSIS TREATMENTS

The extra-thin-walled, siliconized needle secures a laminar flow and ensures a high blood flow. The siliconization of Diacan Pro reduces blood coagulation; the highly flexible tube material is DEHP and latex free.



### 1. TECHNICAL-FUNCTIONAL CHARACTERISTICS

- Extra-thin walls
- Silicon-coated Lumen
- Red or Black dot showing bevel position
- Back eye for optimized flow on arterial needle
- Color-coded Luer Lock connection
- Color-coded clamps
- Color-coded wings
- Single-use
- DEHP-free & Latex-free
- Gamma Sterile STERILE <sup>R</sup>

### 2. DIACAN PRO PORTFOLIO

Article code	A / V	Needle Length	Needle Diameter	Tubing Length	Wing Color	Packaging
7023256NP	Arterial	25mm	15G	300mm	Blue Gray	500 pcs / box 10,000 pcs / pallet
7023356NP	Venous	25mm	15G	300mm	Blue Gray	
7023255NP	Arterial	25mm	15G	150mm	Blue Gray	1000 pcs / box 20,000 pcs / pallet
7023355NP	Venous	25mm	15G	150mm	Blue Gray	
7023253NP	Arterial	20mm	15G	150mm	Blue Gray	
7023353NP	Venous	20mm	15G	150mm	Blue Gray	
7023266NP	Arterial	25mm	16G	300mm	Light Green	500 pcs / box 10,000 pcs / pallet
7023366NP	Venous	25mm	16G	300mm	Light Green	
7023265NP	Arterial	25mm	16G	150mm	Light Green	1000 pcs / box 20,000 pcs / pallet
7023365NP	Venous	25mm	16G	150mm	Light Green	
7023263NP	Arterial	20mm	16G	150mm	Light Green	
7023363NP	Venous	20mm	16G	150mm	Light Green	
7023274NP	Arterial	20mm	17G	300mm	Red Violet	500 pcs / box 10,000 pcs / pallet
7023374NP	Venous	20mm	17G	300mm	Red Violet	
7023273NP	Arterial	20mm	17G	150mm	Red Violet	1000 pcs / box 20,000 pcs / pallet
7023373NP	Venous	20mm	17G	150mm	Red Violet	

All products have a shelf life of 5 years

### 3. DIACAN PRO MATERIAL INFORMATION

Part Name	Material
AVF cannula	Stainless Steel SUS 304
Needle cap	Polycarbonate
AVF turnable wing	Polyethylene
AVF hub	Polyvinylchloride
Mini clamp	Polypropylene
AVF tubing	Polyvinylchloride
AVF Luer connector	Polyvinylchloride
EL Luer cap	Polyethylene
Eye mark	Red and Black Carbon
Lubricant	Silicone
<b>Packaging:</b> Outer box	Double corrugated board
<b>Packaging:</b> Inner box	Duplex board
<b>Packaging:</b> Unit packing	Sterile paper and nylon film

### 4. PRODUCT CLASSIFICATION

Classification according to the Council Directive 93/42/EEC concerning medical devices Annex IX: **Ila (Rule 7)**

- GMDN code: 12741
- CND code: A010401

### 5. PRINTING REQUIREMENTS

Terminology, graphical symbols and information applied to medical equipment are designed according to:

- **EN 980:2008** (*Symbols for use in the labelling of medical devices*)
- **EN 1041:2008** (*Information supplied by the manufacturer of medical devices*)

### 6. PACKAGING DESIGN

Labels contain **27 languages** and have been designed according to the recommendations of:

- *European Medical Device directive*

#### **Languages are:**

German, English, Bulgarian, Czech, Danish, Estonian, Spanish, Finnish, French, Greek, Hungarian, Croatian, Italian, Kazakh, Lithuanian, Latvian, Dutch, Norwegian, Polish, Portuguese, Romanian, Serbian, Russian, Swedish, Slovenian, Slovakian, Turkish

## 7. PACKAGING REQUIREMENTS

All products are packed according to:

- **EN1041** (*Information supplied by the manufacturer of medical devices*)
- **EN 980** (*Symbols for use in the labelling of medical devices*)
- **ISO 11607** (*Packaging for Terminally Sterilized Medical Devices*)
- **EN 868-5:1999** (*Packaging for sealable pouches and reels of porous and plastic film construction*)

Each packaging unit contains the lot number information, shelf life information and sterilization information. The outer box and inner box contain a bar coding EAN 13 and EAN 128

## 8. LIST OF APPLICABLE STANDARDS



The following harmonized standards apply:

- **ISO 14971:2007** (*Risk Management for Medical Devices*)
- **ISO 13485:2003** (*Stability and expiry date, storage, transport*)
- **ISO 10993** (*Biocompatibility*)
- **ISO 9626:1995/A1:2001** (*Stainless steel needle tubing of Medical Devices*)
- **ISO 11607-1:2006** (*Requirements for materials, sterile barrier systems and packing systems*)
- **EN 20594-1:1993/A1:1997** (*Conical fitting*)
- **EN 1632** (*Clean-room technology*)

Sterilization:

- **ISO 11737-1:2006** (*Sterilization of Medical Devices*)

Medical Device Directive 93/42/EWG:

- **ISO 9001** (*Quality Management systems – Requirements*)
- **ISO 13485** (*Medical devices – Quality Management systems – Requirements for regulatory purposes*)