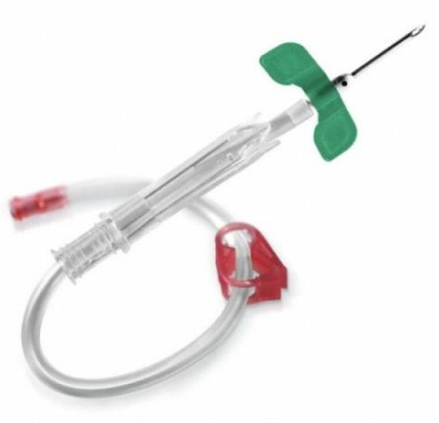
B BRAUN
SHARING EXPERTISE

DIACAN SAFETY

ARTERIAL AND VENOUS SAFETY FISTULA NEEDLES FOR DIALYSIS TREATMENTS

The Diacan Safety is purposely designed and engineered to disarm the needle's sharp tip after use and can help to reduce accidental transmission of infections by preventing needlestick injuries. As your partner in safety, we are convinced maintaining nursing-staff safety is one of the most important goals aside from patient safety in dialysis.



1. TECHNICAL-FUNCTIONAL CHARACTERISTICS

- "Push-over the needle" irreversible safety activation using one hand
- Two-phase Facet profile
- Extra-thin walls
- Silicon-coated lumen
- Red or black dot showing current bevel position
- Back eye for optimized flow on arterial needle
- Color-coded Luer Lock connection
- Color-coded clamps & wings
- Single-use
- DEHP-free & Latex-free
- Gamma Sterile STERILE R

2. DIACAN SAFETY PORTFOLIO

Article code	A / V	Needle Length	Needle Diameter	Tubing Length	Wing Color	Packaging
7023454NP	Arterial	20mm	15G	300mm	Blue Gray	500 pcs / outer box 10,000 pcs / pallet
7023554NP	Venous	20mm	15G	300mm	Blue Gray	
7023456NP	Arterial	25mm	15G	300mm	Blue Gray	
7023556NP	Venous	25mm	15G	300mm	Blue Gray	
7023464NP	Arterial	20mm	16G	300mm	Light Green	
7023564NP	Venous	20mm	16G	300mm	Light Green	
7023466NP	Arterial	25mm	16G	300mm	Light Green	
7023566NP	Venous	25mm	16G	300mm	Light Green	
7023474NP	Arterial	20mm	17G	300mm	Red Violet	
7023574NP	Venous	20mm	17G	300mm	Red Violet	

All products have a shelf life of 5 years

3. COMPONENT MATERIAL

Part Name	Material
AVF Safety Protector	Polypropylene
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
Packaging: Outer box	Double corrugated board
Packaging: Inner box	Duplex board
Packaging: Unit packing	Sterile paper and nylon film

4. PRODUCT CLASSIFICATION

Classification according to the Council Directive 93/42/EEC concerning medical devices Annex IX: **IIa (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

CE 0123

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)*