Intended Use

Single use blood collection needle with an integrated holder and sterile fluid path, intended to be used by healthcare professionals for the collection of human venous blood for the purpose of in vitro diagnostic testing. The device includes an integrated safety shield designed to be activated with one hand, to reduce the risk of an accidental needlestick injury and a flash chamber to inform the user of successful venous access.

Manufacturing Information

(Legal) Manufacturer: Becton, Dickinson and Company
Belliver Industrial Estate
Belliver Way
Roborough, Plymouth, PL6 7BP, UK

Standards & Certificate Numbers: EN ISO 13485

Country of origin: UK

Certification body: BSI (0086)

Sterilisation

Method: Gamma Radiation
SAL: 10^4
Standards applied: EN ISO 11137

Compliance

Classification: Class IIa

Product Specification

Cannula Dimensions:
- External Dimensions (gauge x inch): 21 G x 1
- External Dimensions (mm): 0.8 x 25.4
- Internal Diameter (mm): 0.635

Global medical device nomenclature (GMDN): 35209

Material Safety Data Sheet (MSDS): Not applicable

Shelf-Life: 3 years

IV / Shield Colour: Green

Does product contain?
- Latex (NRL): No
- Dry Natural Rubber (DNR): No
- Phthalates: No
- Material of animal origin: No

Product Storage: Do not expose to direct sunlight

Contains paper, polyethylene (PE), high density polyethylene (HDPE) and adhesive

1. Holder
   Polypropylene (PP)
2. NP Sleeve
   Synthetic Isoprene
3. NP Cannula
   Stainless Steel (304 Grade)
4. Hub
   Polystyrene (PS)
5. Blood Droplet Reduction System
   Polyethylene (PE) and Stainless Steel (304 Grade)
6. Flash Chamber
   Polystyrene (PS)
7. Safety Shield
   Polypropylene (PP)
8. IV Cannula
   Stainless Steel (304 Grade)
9. IV Shield
   Polypropylene (PP)
10. Peel Tab
All labelling complies with the requirements of the European Medical Devices Directive 93/42/EEC and includes CE marking.

### Packaging Specifications

<table>
<thead>
<tr>
<th>Unit Pack</th>
<th>Shelf Pack</th>
<th>Case Pack</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 unit pack weight (kg):</td>
<td>0.37</td>
<td>0.37</td>
</tr>
<tr>
<td>50 unit pack volume (m³):</td>
<td>0.0026623</td>
<td>0.0026623</td>
</tr>
<tr>
<td>50 unit pack dimensions LxHxW (mm):</td>
<td>160 x 129 x 129</td>
<td>160 x 129 x 129</td>
</tr>
<tr>
<td>400 unit pack weight (kg):</td>
<td>3.33</td>
<td>3.33</td>
</tr>
<tr>
<td>400 unit pack volume (m³):</td>
<td>0.0257507</td>
<td>0.0257507</td>
</tr>
<tr>
<td>400 unit pack dimensions LxHxW (mm):</td>
<td>539 x 273 x 175</td>
<td>539 x 273 x 175</td>
</tr>
</tbody>
</table>

### Further Reading

2. BD White Paper VS9222, User Assessment of the BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle for Safety Shield Activation and Flash Visibility
12. Posters from 14th Journée GERES Marseille - 23 Mai 2003
   - N. Jobit, La Réduction des ABE : Objectif atteint