

|                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |         |         |         |
|-----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|---------|---------|
| <b>Product Name</b>         | i-gel® paediatric, supraglottic airway                                                                                                                                                                                                                                                                                                                                                                                                                                                               |         |         |         |
| <b>Reference number</b>     | 8201000                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 8215000 | 8202000 | 8225000 |
| <b>Product Type</b>         | i-gel® Supraglottic Airway                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |         |         |         |
| <b>Manufacturer</b>         | Intersurgical                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |         |         |         |
| <b>Materials</b>            | <div>            PP - Protective cradle<br/>           TPE - Body<br/>           ABS - Connector         </div>                                                                                                                                                                                                                                                                                                     |         |         |         |
| <b>Packaging</b>            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |         |         |         |
| <b>Unit Packaging</b>       | Individually packaged                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |         |         |         |
| <b>Box quantity</b>         | 10                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |         |         |         |
| <b>Pallet quantity</b>      | 1020 (for 8201000, 8215000, 8202000); 800 (for 8225000)                                                                                                                                                                                                                                                                                                                                                                                                                                              |         |         |         |
| <b>Instructions for Use</b> | <div>           Instructions for use with product<br/>           Instructions for use with each box         </div> <div>           No<br/>           Yes         </div>                                                                                                                                                                                                                                                                                                                              |         |         |         |
| <b>Applicable Standards</b> | BS EN ISO 13485: Medical devices - Quality management systems - Requirements for regulatory purposes<br>BS EN ISO 9001: Quality Management Systems - Requirements<br>BS EN ISO 15223-1: Medical Devices - Symbols to be Used with Medical Device Labels, Labelling, & Information to be Supplied<br>BS EN ISO 11712: Anaesthetic and Respiratory equipment - Supralaryngeal airways and connectors<br>BS EN ISO 5356-1: Anaesthetic and respiratory equipment. Conical connectors. Cones and sockets |         |         |         |
| <b>Sterile</b>              | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |         |         |         |
| <b>Shelf life</b>           | 2 years                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |         |         |         |
| <b>Disposal Methods</b>     | Following use, the product must be disposed of in line with local healthcare hygiene and waste disposal protocols and regulations                                                                                                                                                                                                                                                                                                                                                                    |         |         |         |
| <b>Re-use</b>               | <div>            Single use only         </div>                                                                                                                                                                                                                                                                                                                                                                   |         |         |         |

## Product characteristics

| Technical information                  | 8201000 | 8215000 | 8202000          | 8225000          |
|----------------------------------------|---------|---------|------------------|------------------|
| Patient size                           | Neonate | Infant  | Small Paediatric | Large Paediatric |
| Size                                   | 1.0     | 1.5     | 2.0              | 2.5              |
| Patient weight (kg)                    | 2–5     | 5–12    | 10–25            | 25–35            |
| Weight including packaging (g)         | 36      | 50      | 62               | 95               |
| Internal volume of airway channel (ml) | 5.5     | 8.0     | 13.9             | 20.7             |



**Material  
Abbreviations**

|      |                                      |
|------|--------------------------------------|
| ABS  | Acrylonitrile Butadiene Styrene      |
| AL   | Aluminium                            |
| Cu   | Copper                               |
| EPDM | Ethylene Propylene Terpolymer Rubber |
| EVA  | Ethylene-vinyl acetate               |
| HDPE | High Density Polyethylene            |
| HIPS | High Impact Polystyrene              |
| LDPE | Low Density Polyethylene             |
| LSR  | Liquid Silicone Rubber               |
| MBS  | Methacrylate Butadiene Styrene       |
| NRL  | Natural Rubber Latex                 |
| PA   | Polyamide (Nylon)                    |
| PC   | Polycarbonate                        |
| PE   | Polyethylene                         |
| PIR  | Polyisoprene rubber                  |
| POM  | Polyoxymethylene                     |
| POP  | Ethylene based plastomer             |
| PP   | Polypropylene                        |
| PPTA | Poly (p-phenylene terephthalamide)   |
| PS   | Polystyrene                          |
| PSU  | Polysulfone                          |
| PU   | Polyurethane                         |
| PVC  | Poly Vinyl Chloride                  |
| SB   | Styrene Butadiene                    |
| Si   | Silicone                             |
| SS   | Stainless Steel                      |
| TPE  | Thermoplastic Elastomer              |
| SBC  | Styrene Butadiene Copolymer          |
| SEBS | Styrene-Ethylene-Butadiene-Styrene   |

