

# TECHNICAL DATASHEET

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## Vitrectomy Packs OS4 Single Use MD 0105.17

### General Information

|                      |                                                                                                                                                 |
|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|
| Intended use:        | The procedure packs are intended to be used during surgical procedures in ophthalmic surgery for:<br><br>- use with Oertli Instruments products |
| For use with device: | Oertli OS 4 surgery unit.                                                                                                                       |
| Notified Body:       | DQS Medizinprodukte GmbH, 60433 Frankfurt am Main, Germany                                                                                      |
| Certification:       | CE0297                                                                                                                                          |
| Classification:      | Class IIa according to rule 7.1                                                                                                                 |
| GMDN-Code:           | 45150                                                                                                                                           |
| Manufacturer:        | Oertli Instrumente AG, 9442 Berneck, Switzerland                                                                                                |

### Technical Data

|                        |                                                                                                     |
|------------------------|-----------------------------------------------------------------------------------------------------|
| Type of use:           | Single use                                                                                          |
| Sterilization methode: | Ethylenoxid (ETO) sterilization                                                                     |
| Shelf life:            | 3 years                                                                                             |
| Instructions for use:  | See datasheet of component                                                                          |
| Packaging:             | Sterile barrier system: PETG blister with Tyvec seal<br><br>Protective packaging: cardboard box     |
| Packaging size:        | 1 cardboard box contains 6 blisters.                                                                |
| Package contents:      | See at the section "List of content" for the specific content of each article of this product group |
| PVC:                   | Yes                                                                                                 |
| Phthalates:            | No                                                                                                  |
| Animal origin:         | No                                                                                                  |

## DESCRIPTION OF MODEL

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### List of content



| Article Number | Description                                                                                                                                                                                                                             | OS4 Cassette | Infusion set | Caliburn trocar system | SPS Cutter | Continuous Flow Cutter (CFC) | Endo illuminator with ViPer scleral indenter | Endo illuminator panorama/widefield with ViPer scleral indenter | Air delivery line with 3-way stopcock | Display cover |
|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|--------------|------------------------|------------|------------------------------|----------------------------------------------|-----------------------------------------------------------------|---------------------------------------|---------------|
| VV660113BP     | Vitrectomy pack OS 4 23G: cassette, SPS cutter, endo illuminator panorama with ViPer scleral indenter, Caliburn trocar system, air delivery line with 3-way stopcock, infusion set, display cover, sterile/single use, box of 6         | ✓            | ✓            | 23G                    | 23G        |                              |                                              | 23G shielded                                                    | ✓                                     | ✓             |
| VV660212DP     | Vitrectomy pack OS 4 20G: cassette, CF cutter, endo illuminator 90° with ViPer scleral indenter, air delivery line with 3-way stopcock, infusion set, display cover, sterile/single use, box of 6                                       | ✓            | ✓            |                        |            | 20G                          | 90° 20G                                      |                                                                 | ✓                                     | ✓             |
| VV660212DPA    | Vitrectomy pack OS 4 20G: cassette, CF cutter, endo illuminator panorama (23G) with ViPer scleral indenter, air delivery line with 3-way stopcock, infusion set, display cover, sterile/single use, box of 6                            | ✓            | ✓            |                        |            | 20G                          |                                              | 23G shielded                                                    | ✓                                     | ✓             |
| VV660213BA     | Vitrectomy pack OS 4 23G (without endo illuminator): cassette, CF cutter, Caliburn trocar system, air delivery line with 3-way stopcock, infusion set, display cover, sterile/single use, box of 6                                      | ✓            | ✓            | 23G                    |            | 23G                          |                                              |                                                                 | ✓                                     | ✓             |
| VV660213BC     | Vitrectomy pack OS 4 23G (without Caliburn trocar system): cassette, CF cutter, endo illuminator panorama with ViPer scleral indenter, air delivery line with 3-way stopcock, infusion set, display cover, sterile/single use, box of 6 | ✓            | ✓            |                        |            | 23G                          |                                              | 23G shielded                                                    | ✓                                     | ✓             |

## DESCRIPTION OF MODEL

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| Article Number | Description                                                                                                                                                                                                                    | OS4 Cassette | Infusion set | Caliburn trocar system | SPS Cutter | Continuous Flow Cutter (CFC) | Endo illuminator with ViPer scleral indenter | Endo illuminator panorama/widefield with ViPer scleral indenter | Air delivery line with 3-way stopcock | Display cover |
|----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|--------------|------------------------|------------|------------------------------|----------------------------------------------|-----------------------------------------------------------------|---------------------------------------|---------------|
| VV660213BP     | Vitrectomy pack OS 4 23G: cassette, CF cutter, endo illuminator panorama with ViPer scleral indenter, Caliburn trocar system, air delivery line with 3-way stopcock, infusion set, display cover, sterile/single use, box of 6 | ✓            | ✓            | 23G                    |            | 23G                          |                                              | 23G shielded                                                    | ✓                                     | ✓             |
| VV660215B      | Vitrectomy pack OS 4 25G: cassette, CF cutter, endo illuminator 90° with ViPer scleral indenter, Caliburn trocar system, air delivery line with 3-way stopcock, infusion set, display cover, sterile/single use, box of 6      | ✓            | ✓            | 25G                    |            | 25G                          |                                              | 90° 25G                                                         | ✓                                     | ✓             |
| VV660215BA     | Vitrectomy pack OS 4 25G (without endo illuminator): cassette, CF cutter, Caliburn trocar system, air delivery line with 3-way stopcock, infusion set, display cover, sterile/single use, box of 6                             | ✓            | ✓            | 25G                    |            | 25G                          |                                              |                                                                 | ✓                                     | ✓             |
| VV660215BB     | Vitrectomy pack OS 4 25G (without cassette): CF cutter, endo illuminator panorama with ViPer scleral indenter, Caliburn trocar system, air delivery line with 3-way stopcock, display cover, sterile/single use, box of 10     |              | ✓            | 25G                    |            | 25G                          |                                              | 25G shielded                                                    | ✓                                     | ✓             |
| VV660215BP     | Vitrectomy pack OS 4 25G: cassette, CF cutter, endo illuminator panorama with ViPer scleral indenter, Caliburn trocar system, air delivery line with 3-way stopcock, infusion set, display cover, sterile/single use, box of 6 | ✓            | ✓            | 25G                    |            | 25G                          |                                              | 25G shielded                                                    | ✓                                     | ✓             |

## DESCRIPTION OF MODEL

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| Article Number | Description                                                                                                                                                                                                                      | OS4 Cassette | Infusion set | Caliburn trocar system | SPS Cutter | Continuous Flow Cutter (CFC) | Endo illuminator with ViPer scleral indenter | Endo illuminator panorama/widefield with ViPer scleral indenter | Air delivery line with 3-way stopcock | Display cover |
|----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|--------------|------------------------|------------|------------------------------|----------------------------------------------|-----------------------------------------------------------------|---------------------------------------|---------------|
| VV660217BP     | Vitrektomie pack OS 4 27G: cassette, CF cutter, endo illuminator widefield with ViPer scleral indenter, Caliburn trocar system, air delivery line with 3-way stopcock, infusion set, display cover, sterile/single use, box of 6 | ✓            | ✓            | 27G                    |            | 27G                          |                                              | 27G widefield                                                   | ✓                                     | ✓             |

Table 1: model description