

Technical Sheet

Straumann® Emdogain® FL
Institut Straumann AG



PRODUCT INDICATION

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|--------------|--|
| Product type | Adjunct to scaling and root planing and dental hygiene procedures |
| Indication | <p>Emdogain® FL is intended for subgingival and topical application in conjunction with scaling and root planing procedures to provide periodontal pocket regeneration in a minimally invasive way: without surgical flap.</p> <ul style="list-style-type: none">Emdogain® FL has been shown to be effective in residual pockets with probing depths from 5 mm to 9 mm with no furcation involvement in patients with adequate plaque control.Emdogain® has also been shown to enhance the early healing of periodontal soft tissue wounds resulting from the instrumentation of periodontal pockets. |

PRODUCT PROPERTIES

| | |
|------------------------------|---|
| Origin | Sweden |
| Storage temperature | 2°C–8°C |
| Product specifications | <ul style="list-style-type: none">Straumann® Emdogain® consists of one unit of Straumann® Emdogain® (0.15ml or 0.3ml) and one unit of Straumann® PrefGel® (0.6 ml) and 2 application syringesStraumann® Emdogain® contains 30 mg/ml Enamel Matrix DerivativeStraumann® PrefGel® contains Ethylenediaminetetraacetate (EDTA) 24% |
| Accessories | N/A |
| Sterilization / Disinfection | Sterile & Single use |
| Shelf life | 2 years from the date of production |
| Regulatory status | CE-marked |
| Entry on the market | March 2019 |

MANUFACTURING

| | |
|--------------------|--|
| Production process | Manufactured from porcine unerupted tooth buds according to the highest pharmaceutical standards under current good manufacturing practice (cGMP). Complies with all relevant ISO and FDA standard and guidelines. |
| Packaging | Cardboard packaging |

AVAILABLE PRODUCT LINE

| Product | Type/Size/Amount | Art.-No. |
|---------------------------------|--|----------|
| Straumann® Emdogain® FL 0.15 ml | Contains 0.15 ml Emdogain®, 0.6 ml PrefGel® and 2 application cannulas | 075.130 |
| Straumann® Emdogain® FL 0.3 ml | 0.3 ml Emdogain®, 0.6 ml PrefGel® and 2 application cannulas | 075.131 |

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