

Technical Sheet

Straumann® Regenomer®
NIBEC Co., Ltd.



PRODUCT INDICATION

| | |
|---------------------|---|
| Product type | Dental wound dressing and extraction socket filler: Self expanding biodegradable Collagen Matrix |
| Indication | <ul style="list-style-type: none">• Bone filling augmentation for use in filling of extraction sockets (FDA, CE)• Augmentation or reconstructive treatment of the alveolar ridge (FDA)• Elevation of maxillary sinus floor (FDA)• To stop bleeding after an odontectomy (CE)• To cover the surface of a wound created by an odontectomy to prevent contamination and infection of the wound (CE)• To relieve pain at the wound site due to wound coverage (CE) |

PRODUCT PROPERTIES

| | |
|-------------------------------------|--|
| Origin | Type I collagen purified from porcine skin source in Korea |
| Storage temperature | Room temperature (15~25°C) |
| Product Specifications | <ul style="list-style-type: none">• Absorbable and sponge-like structure• Excellent extraction socket preservation• Outstanding biocompatibility• Easy handling and versatile options |
| Component Parts | Type I collagen |
| Sterilization / Disinfection | Sterilized by gamma irradiation |
| Shelf life | 3 years |
| Regulatory status | FDA and KFDA, CE mark in progress |
| Entry on the market | 2014 in South Korea EU: October 2018 FDA: Jan 2019 |

MANUFACTURING

Product

Y10 console:28×38×26 cm L×H×W

Step 1: Purification of collagen from Porcin dermis

Step 2: Filling in each shape mold

Step 3: Freeze drying

Step 4: Physical crosslinking

Step 5: Packaging

Step 6: End Gamma radiation sterilization

Packaging

- Plug: 5 EA/BOX (40mg, 100mg/unit)
- Block: 5 EA/BOX (10mg, 20mg/unit)

AVAILABLE PRODUCT LINE

| Product | Type | Size | Amount (mg) | Unit # per Box | Art.-No. |
|------------|-------|-------|-------------|----------------|----------|
| Regenomer® | Plug | 8×18 | 40 | 5 | RSP1-S |
| | Plug | 12×25 | 100 | 5 | RSP2-L |
| | Block | 6×5×7 | 10 | 5 | RSB1-S |
| | Block | 8×7×9 | 20 | 5 | RSB2-L |

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