smith&nephew
ENTACT◇
Septal Stapler

Technical specifications

Indications for use

The ENTACT septal stapler delivers implantable septal staples that are intended to connect internal tissues to aid healing and for approximation of soft tissue during nasal septal surgery.

Device classification

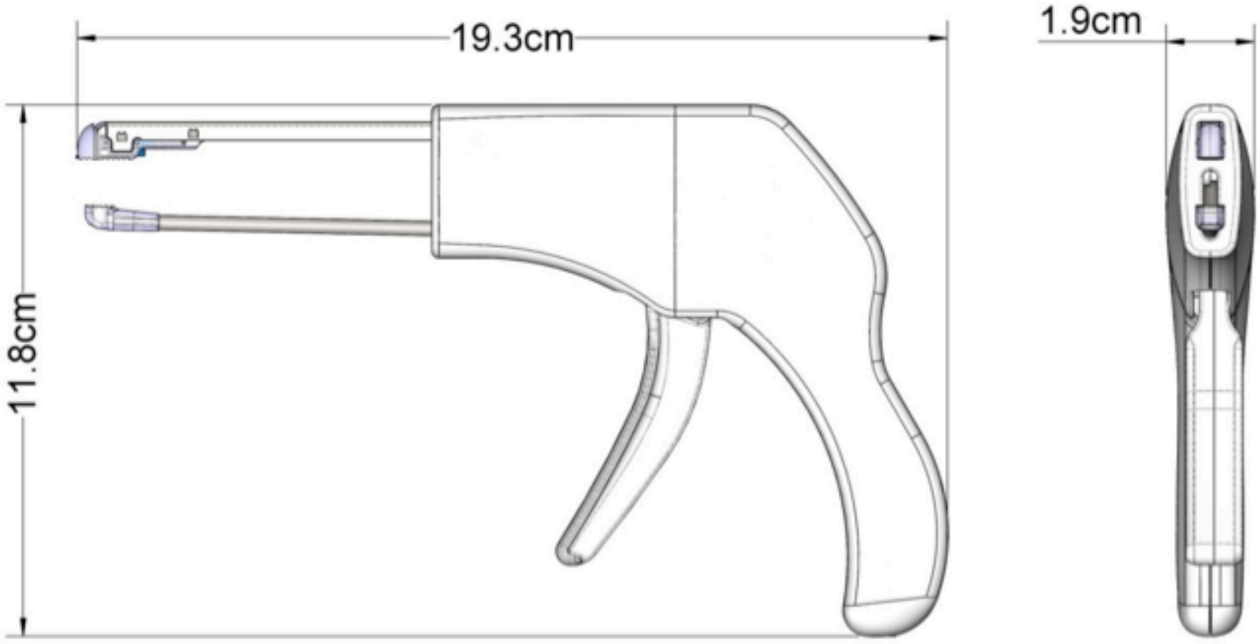
This device is considered Class III, per Rule 8 of Section 2.4 Annex IX of the Medical Device Directive MDD 93/42/EEC.

Main standards applied

- ISO 10993-1 – Biological evaluation of medical devices
- ISO 11137-1; 11137-2 – Sterilization of health care products – radiation
- ISO 11737-1; 11737-2 – Sterilization of medical devices – microbiological methods
- ISO 11607-1; 11607-2 – Packaging of terminally sterilized medical devices
- ISO 13485 – Medical devices – quality management systems – requirements for regulatory purposes
- ISO 14155-1 – Clinical Investigation of medical devices for human subjects
- ISO 14630 – Non-active surgical implants – general requirements
- ISO 14971 – Medical devices – application of risk management to medical devices

Product description

1. Configurations
   a. 601-00100: ENTACT septal stapler, 3-pack (3 devices per pack)
   b. 601-00100S: ENTACT septal stapler, 1-pack (1 device per pack)
2. General/specific dimensions
   a. Device:



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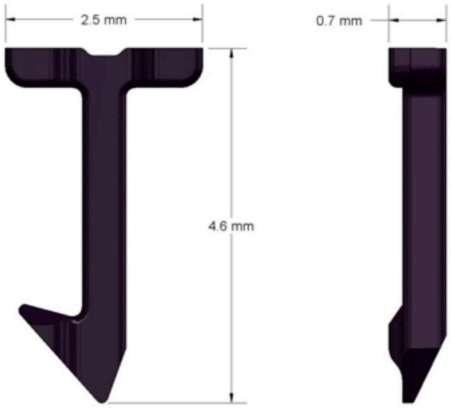
b. Staple: 2.5mm X 4.6mm X 0.7mm



3. Materials used
   a. Device: Medical grade polycarbonate, stainless steel, and nitinol
   b. Staple: 5/95 polylactide-co-glycolide polymer

Packaging

1. The ENTACT® septal stapler delivers up to eight (8) implants via a manual device that is sealed in a foil pouch. Foil pouches are placed in an SBS carton.
2. Overall package dimensions
   a. 601-00100: 29.1cm X 17.8cm X 4.4cm
   b. 601-00100S: 29.1cm X 17.8cm X 1.6cm
3. Sterilization: Gamma irradiation

Storage and transportation conditions

1. Devices can be shipped using normal transit methods. Do NOT expose to temperatures above 50°C.
2. Devices are temperature sensitive and should be stored in an environment typically used for storing medical devices. Do NOT store above 50°C.

Shelf life

The shelf life of the ENTACT septal stapler implants is 36 months from the date of manufacture. The expiration date is clearly displayed on the carton label.

Dispose condition

Sharp edges are exposed when handle is depressed. Dispose of stapler per procedures for sharp objects. Packaging is not considered hazardous material and can be discarded according to the hospital's usual procedures for disposal of medical materials.

Cleaning and sterilization instructions

The contents of this package are designed for single use only. Do NOT resterilize. Do NOT use after expiration date. Do NOT use if package is damaged.

Special handling instructions

Store between -20 to 25°C. Do NOT expose to temperatures above 50°C.

Latex free denotation

The ENTACT septal stapler is composed of stainless steel, nitinol and polycarbonate. It is not made with natural rubber latex parts. It is required that all manufacturing/assembly be conducted using nitrile or similar latex-free gloves in order to prevent the accidental introduction of latex particles.

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