

# Fixation sleeves

## Product Information



## Material Compliance

### REACH ARTICLE 33 (1)

This product information refers to the BIOTRONIK Fixation sleeves (EFH-6F-W, EFH-6F-W (1), EFH-7F-W, EFH-7F-W (1), EFH-8F-W, EFH-8F-W (1), EFH-16, EFH-16 (1), EFH-20, EFH-20 (1), EFH-22, EFH-22 (1), EFH-25, EFH-25 (1), EFH-27, EFH-27 (1), EFH-28, EFH-28 (1), EFH-30, EFH-30 (1)), including packaging material.

It is used to pass on supplier information in accordance with Article 33 (1) of the REACH Regulation, reflects our current knowledge and is subject to regular review.

The product information contains no statement on product properties and no statement about potential risks for patients. One or more articles<sup>1</sup> in the product contain listed SVHC candidates at a concentration  $\geq 0.1\%$  (w/w) in accordance with Article 59 (1) of Regulation (EC) 1907/2006 (REACH).

Inventory Number	Name
CAS: 556-67-2 EC: 209-136-7	Octamethylcyclotetrasiloxane (D4)
CAS: 541-02-6 EC: 208-764-9	Decamethylcyclopentasiloxane (D5)
CAS: 540-97-6 EC: 208-762-8	Dodecamethylcyclohexasiloxane (D6)

<sup>1</sup> In Article 3 (3) of the REACH Regulation, article is defined as "object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition". Therefore, products may fall under the scope of Article 33 REACH because of the articles or materials they contain, although the concentration of an SVHC candidate is below the 0.1% (w/w) limit of the entire product.