

STERILITY INFORMATION

Devices are delivered sterile or non-sterile.

A. NON STERILE DEVICES

➤ STERILIZATION METHOD

Non sterile plates and screws are provided for sterilization by health care professionals prior to use. They are packaged non-sterile in plastic bags. The device cannot be sterilized in this bag.

Guidelines for cleaning and sterilization are detailed in IFU.

All non-sterile devices must be cleaned and sterilized prior to use by qualified professionals.

Recommended method: steam sterilization in autoclave:

	US Sterilization (only for United States)	EU sterilization (only for Europe)
Sterilizer	Dynamic-air-removal steam sterilizer	
Temperature	270 °F / 132.2 °C	134 °C / 273.2 °F
Exposure time	4 min	18 min
Drying time	20 min	20 min

The EU sterilization protocol (134 °C - 18 min) is not validated for prion inactivation cycle in the US sterilizers.

➤ PRODUCT SHELF LIFE

The implants are made from titanium. The properties of this material do not degrade at room temperature and normal humidity for extended periods of time. Therefore, shelf life is not applicable because of low likelihood of time-dependent product degradation.

Sterility Report Potters Report

Karin Nielsen-Saines



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