

MATERIAL DATA SHEET

Product: Geistlich Bio-Gide® and Geistlich Bio-Gide® Perio

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Geistlich Bio-Gide® and Geistlich Bio-Gide® Perio are medical devices regulated according EC-Guidelines. It is not possible to apply the Material Safety Data Sheet (MSDS) questions for medical devices. The Material Data Sheet informs shortly about material properties. For detailed information please read the package insert of Geistlich Bio-Gide® and Geistlich Bio-Gide® Perio or contact us.

1. IDENTIFICATION OF PRODUCT & MANUFACTURER

Product		Geistlich Bio-Gide® Geistlich Bio-Gide® Perio
Manufacturer	Name:	Geistlich Pharma AG
	Address:	Bahnhofstrasse 40 CH-6110 Wolhusen/Switzerland
	Phone:	+41-(0)41-492 56 30
	Fax:	+41-(0)41-492 56 39
	Email:	biomaterials@geistlich.ch
	Web:	http://www.geistlich.com

2. COMPOSITION & PHYSICOCHEMICAL PROPERTIES

Geistlich Bio-Gide® and Geistlich Bio-Gide® Perio are made of porcine collagen. Collagen is one of the most thoroughly researched natural biomaterials. It is a fiber protein that contains hydroxyproline and has a triple helix structure, resulting in great tensile strength. The structure is very similar to human collagen. The membranes are resorbed enzymatically by collagenases and do not have to be removed.

3. POSSIBLE HAZARDS

Health hazards

Geistlich Bio-Gide® and Geistlich Bio-Gide® Perio are used in dental practices. The product should be handled as described in the package insert.

No risks of Geistlich Bio-Gide® and Geistlich Bio-Gide® Perio and for the dentist and assistants are known.

Geistlich Bio-Gide® and Geistlich Bio-Gide® Perio should not be used in patients with a known allergy against collagen and in presence of infected wounds.

Environmental hazards

none (natural material, sterilized)

Other hazards

none

4. MEASURES IN CASE OF UNINTENDED DISPOSAL

none (natural material, degradable)

5. HEALTH EFFECTS & BIOCOMPATIBILITY

Health effects

Geistlich Bio-Gide® and Geistlich Bio-Gide® Perio are used in combination with bone or bone substitute materials in Guided Bone Regeneration and Guided Tissue Regeneration procedures. Geistlich Bio-Gide® and Geistlich Bio-Gide® Perio are stabilizing the blood clot and separating soft tissue from the bone, preventing the ingrowth of soft tissue into the bone or bone substitute.

Biocompatibility

Biocompatibility for Geistlich Bio-Gide® and Geistlich Bio-Gide® Perio was assessed according to the international standard ISO 10993-1. Long-term experience with Geistlich Bio-Gide® and Geistlich Bio-Gide® Perio show an excellent biocompatibility of the collagen material.

However, due to the presence of collagen and due to the prolonged resorption time an inflammatory response might occur in rare cases.

6. STORAGE & HANDLING

Handling	Geistlich Bio-Gide® and Geistlich Bio-Gide® Perio should be handled as described in the package insert. The principles of sterile handling must be observed.
Storage	Expiry date: indicated on each package Do not use after expiry date
Storage conditions	Storage at room temperature (15-25° C) under dry conditions.
Additional information	The contents of the double blister are designed for single use only. Discard any unused material. Resterilization is not possible.
Packaging	Geistlich Bio-Gide® and Geistlich Bio-Gide® Perio are delivered in a double sterile packaging. The product is sterile unless packaging has been opened or damaged. If the sterile packaging has been damaged, the product must not be used.
Transport	Recommended storage conditions should also be followed during transport.

7. DISPOSAL

Geistlich Bio-Gide® and Geistlich Bio-Gide® Perio are degradable materials. The manufacturing process and sterilization minimize risks of contamination with pathogens. Geistlich Bio-Gide® and Geistlich Bio-Gide® Perio can be disposed as ordinary waste.

8. INFORMATIONS ACCORDING TO REGULATIONS

EEC Regulations	93/42/EEC
EEC labeling	CE-Mark
FDA	510(k) Notification

The manufacturing of Geistlich Bio-Gide® and Geistlich Bio-Gide® Perio is subjected to a quality control system based on international standards (ISO 9001:2008 / ISO 13485:2003/AC:2007), and is checked regularly by independent experts and authorities.

9. FURTHER INFORMATIONS

Please read the package insert for further information or contact us directly.

17. NOV. 2011 *O. Zumbühl*

Dr. Othmar Zumbühl
Geistlich Pharma AG
Head of Quality Assurance

S. Wäsche 28.10.11

Dr. Susana de Azevedo Wäsche
Geistlich Pharma AG
Head of Global Regulatory Affairs