

Technical Sheet

ImplantSafe®
dentognostics GmbH



PRODUCT INDICATION

Product type	Lateral flow rapid test
Indication	<ul style="list-style-type: none">• The product detects elevated levels of the collagenase, aMMP-8 (active matrix metalloproteinase-8), an enzyme that destroys tissue, in gingival crevicular fluid (GCF) or peri-implant sulcus fluid (PISF)• If detected in time, the development of peri-implantitis can usually be halted and existing peri-implantitis can be successfully treated by a dentist or periodontist in cooperation with a dental hygienist or dental assistant

PRODUCT PROPERTIES

Origin	dentognostics GmbH, Tatzendpromenade 2, 07745 Jena, Germany
Storage temperature	2°C–25°C
Product specifications	<ul style="list-style-type: none">• Each ImplantSafe® test is meant to be used on 1 site (implant or tooth). Only 1 collection strip should be used to collect and elute the sample even though 2 strips are provided (1 is provided as a reserve in case of dropping/ bending the first one)• The ImplantSafe® tests should be administered by the dentist or hygienist as the first thing immediately when the patient sits in the dental chair. There should be no treatment or activity in the mouth before the test.• Patients should avoid eating, drinking anything but water, smoking, using mouthwash, or brushing their teeth for at least 20 minutes before the test• It is ok to use the ImplantSafe® test even in a purulent or bleeding pocket/sulcus• Only a brief puff of air should be used to dry the pocket/sulcus• The ImplantSafe® test is meant to be used to screen generally healthy implants or to monitor the implants/ pockets of patients in a recall phase after peri-implant/periodontal therapy• Retesting should occur no sooner than 2 weeks after basic preventive treatments and no sooner than 6 weeks after periodontal/peri-implant therapy
Component Parts	<ol style="list-style-type: none">1. GCF/PISF collection strips: 1 sterile pack of collection strips to collect the sample at the implant/tooth (contains 2 strips, 1 as a reserve) [REF33506ETDE GCF/PISF collection strips CE 0481] (GCF: gingival crevicular fluid, sulcus fluid; PISF: peri-implant sulcus fluid)2. Vial with 600 µl of elution buffer: Vial with liquid to elute the aMMP-8 from the collection strips [REF33505ETDE buffer vial]3. DIPSTICK test: 1 pouch containing 1 aMMP-8 DIPSTICK Test to analyze the collected eluate [REF33501ETDE aMMP-8 rapid test]4. Short instructions: Instructions with pictograms to describe the procedure5. Instructions for use: instructions with detailed information for carrying out the test
Sterilization / Disinfection	<ul style="list-style-type: none">• The product is aseptically manufactured and sterile• The product is for single use only
Shelf life	18 months
Regulatory status	In vitro diagnostic device (IVD) with CE mark
Entry on the market	2011

AVAILABLE PRODUCT LINE

Product	Type/Size/Amount	Art.-No.
PerioSafe®/ImplantSafe® DR	25 Tests	970-00225
PerioSafe®/ImplantSafe® DR	50 Tests	970-00250
PerioSafe®/ImplantSafe® Pool DR	25 tests	970-00325
PerioSafe®/ImplantSafe® Pool DR	50 tests	970-00350
ORALyzer®	complete, incl. Drawer 4&5, Printer	970-00001
Drawer for PerioSafe® PRO DRS	1 drawer	970-00005
Drawer for PerioSafe®/ImplantSafe® DR	1 drawer	970-00007

HOTLINE

UK: (+44) 01 296 651230
Italy: (+39) 800 810 500
Germany: (+49) 761 450 13 50

International Headquarters

Institut Straumann AG
Peter Merian-Weg 12
CH-4002 Basel, Switzerland
Phone +41 (0)61 965 11 11
Fax +41 (0)61 965 11 01
www.straumann.com