Palodex Group

PROTECTIVE BAGS
BIOCOMPATIBILITY ANALYSIS SUMMARY

Document ID:	D529914	Rev. 1
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Revision history

Revision	Date (dd.mm.yyyy)	Author	Description of changes
1	16.01.2020	Fan Xi	Initial revision.

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1. PURPOSE

The purpose of this document is to summarize the biocompatibility analysis for the Protective Bags. Protective bags include bags for imaging plates to be used with intra-oral imaging plate systems (Hygiene Bag) and protective covers for patient positioning parts of extraoral x-ray systems: bite block protective cover, lip support protective cover, chin support protective cover, ear plug protective cover, temple support protective cover and nasion support protective cover (Hygiene Cover). All hygiene bags listed in the report in patient contact for intra-oral x-ray are used to protect the reusable imaging plate from the moisture and other impurities present in the patient's mouth during examination. All hygiene covers listed in the report in patient contact for extra-oral x-ray are used in patient positioning to prevent cross-contamination between patients during examination. All Protective Bags are single-use products.

This Biocompatibility Analysis Summary Report covers Protective Bags used with intra-oral imaging plate scanners and extraoral x-ray devices.

Biocompatibility analyses are written per material and this, as well as the OP 3D Biocompatibility analysis summary document, references individual material specific analyses and concludes the overall biocompatibility status for Protective Bags.

2. SCOPE

All parts in patient contact in normal use of the Protective Bags are listed in the table below. No foreseeable misuse cases are identified.

Table 1 Protective Bags and their categorization per ISO 10993 standard, material details and biocompatibility analysis references.

Part type:	**Type of contact:**	**Contact duration:**	**Code name**	**Material type**	**Material detail**	**PDX material code**	**Biocomp analysis**	**Conclusion**
Hygiene Bag Optibag Size 0, 1, 2, 3	Mucosal membrane (Normal use)	<5min	211424 Hygiene bags optibags size 0 211425 Hygiene bags optibags size 1 211426 Hygiene bags optibags size 2 211427 Hygiene bags optibags size 3	LDPE	411146/411148	213145	D515422	PASS
Hygiene Bag Classic Size 0, 1, 2, 3	Mucosal membrane (Normal use)	<5min	7300150-SDX Hygiene bags classic S0 7300151-SDX hygiene bags classic S1 7300152-SDX Hygiene bag classic s2 7300133-SDX Hygiene bag classic s3	PE	416953	213144	D515837	PASS
Occlusal 4C Hygiene Bag	Mucosal membrane (Normal use)	<5min	205328 OCCLUSAL 4C HYGIENE BAG	PE	416953	213144	D515837	PASS
Hygiene Bag Digora Bag Size 0, 1, 2, 3	Mucosal membrane (Normal use)	<5min	221306 hygiene bag digora bag size 0 221307 hygiene bag digora bag size 1 221308 hygiene bag digora bag size 2 221309 hygiene bag digora bag size 3	PE	416953	213144	D515837	PASS
Hygiene Bag Disposal plastic bag big FMX	Mucosal membrane (Normal use)	<5min	7300115-SDX disposable plastic bag big FMX	PE	416953	213144	D515837	PASS

Hygiene Bag Disposal plastic bag small FMX	Mucosal membrane (Normal use)	<5min	7300116-SDX disposal plastic bag small FMX	PE	416953	213144	D515837	PASS
Hygiene Bag Disposal plastic bag size 1 FMX	Mucosal membrane (Normal use)	<5min	7300117-SDX disposal plastic bag size 1 FMX	PE	416953	213144	D515837	PASS
Hygiene Bag Disposal plastic bag size 4	Mucosal membrane (Normal use)	<5min	7300134-SDX disposal plastic bag size 4	PE	416953	213144	D515837	PASS
EAR HOLDER COVER	Skin (Normal use)	<5min	213068 EAR HOLDER COVER	PLA	2003 D	212976	D515855	PASS
TEMPLE SUPPORT DISP, COVER	Skin (Normal use)	<5min	212017 TEMPLE SUPPORT DISP, COVER	PE	FA5224	212880	D515424	PASS

Note: Hygiene covers: 213517 CHIN CUP DISPOSABLE COVER ROLL 200, 213113 LIP SUPPORT COVER, 213509 BITE BLOCK DISP.COVER ROLL, 212018 NASION SUPPORT DISPOSABLE, 207254 EAR HOLDER COVER are handled in D518946 OP 3D biocompatibility analysis summary.

Legend to acronyms for the mentioned plastics:
LDPE: low density polyethylene, PE: Polyethylene. PLA: Polylactic Acid.

3. REFERENCE DOCUMENTS

Note: Reference documents common for all materials.

[1] *EN ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk* management process

[2] *FDA Guidance for Industry and Food and Drug Administration Staff, June 16, 2016. Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*

4. BIOCOMPATIBILITY ANALYSIS

The referenced biocompatibility analyses in Table 1 and in D518946 OP 3D Biocompatibility analysis summary have been made per ISO 10993-1:2009. ISO 10993-1:2018 does not impact the completed analysis or categorization of the parts. Original analyses are valid and comply also with ISO 10993-1:2018.

The skin or mucosal membrane contact of the Protective Bags is very short in duration, less than 5 minutes. The contact is with healthy skin or mucosal membranes. Per ISO 10993-1:2018 table A.1 [1] the duration category is “Limited, less than 24 hours”. Table A.1 Biocompatibility Evaluation Endpoints in

FDA guidance for biocompatibility [2] aligns with ISO 10993-1:2018 table for parts coming into skin or mucosal membrane contact for limited time.

The potential risks can be that the patient gets cross contamination or allergic reaction of the patient contacting parts. Due to the very short contact time the probability for the risk to occur is remote or seldom. The use of all materials is supported by literature or safe history of use or biocompatibility testing evidence.

All patient contacting materials have a long history of safe use in Palodex dental devices, in similar nature of contact and duration. Biocompatibility analysis reports of all individual materials listed in the table 1 and in D518946 OP 3D Biocompatibility analysis summary include details of item categorization according to EN ISO 10993-1:2018, material analysis and history of use with references to literature, logistics and manufacturing process aspects related to biocompatibility and references to biocompatibility testing if applicable.

5. CONCLUSION

All used patient contact materials are evaluated according to ISO 10993-1:2018, for the nature and duration of contact. It is concluded that the material testing and/or evaluation appropriately address the biocompatibility risks related to Protective Bags. In all cases, the materials are found suitable and biocompatible safe for use in the patient contact parts.