

**SD-SPEEDX  
USER INSTRUCTIONS**

Selecting SD-SPEEDX, you have chosen a self-developing dental film that combines outstanding diagnostic quality with simple, immediate use. We are sure you will find this professional device extremely useful in your dental practice. The high quality images obtained, the unique, instantaneous self-development function, the reduced dimensions and guaranteed hygiene make this product one of today's most advanced, revolutionary devices in conventional dental radiography. We trust you will be fully satisfied with SD-SPEEDX. Please read this booklet for further information regarding optimal, safe use of your dental film.

**IDENTIFICATION OF THE PRODUCT**

This technical sheet refers to the class IIA Medical Device called SD-SPEEDX. SD-SPEEDX is a self-developing dental radiographic film for endoral diagnosis.

**MANUFACTURER**

GSM Medikal Ltd - P.O Box 42 - Tire Izmir Region - Turkey

**COMPOSITION**

Each box of SD-SPEEDX contains 50 individually-packed, ISO Format 2 - 3X4 cm, group D sensitivity, self-developing dental radiographic films. Each self-developing film consists of an hermetically-sealed, two-color (white/blue) main plastic pouch containing, in the upper part, the radiographic film and, in the slightly swollen lower part, a device containing an exclusive development and fixing solution – see illustration No. 1.

**INDICATIONS**

SD-SPEEDX is a diagnostic instrument that makes it possible to obtain radiographic images with excellent definition and high level contrast. SD-SPEEDX self-developing dental radiographic films have been researched, designed and produced for easy, instantaneous development in full light without any need for developing tanks, dark rooms, etc. Its perfectly ergonomic shape permits precise, safe positioning, making it possible to reach all areas of the mouth without irritating the tissues and without any feeling of discomfort for the patient. SD-SPEEDX are soft to use, without sharp corners or edges as they are made of carefully formulated plastic materials in order to minimize risks of injury and allergies. The flexibility of the plastic pouch reduces the risk of distortion of the image caused by bending of the film

**HYGIENE**

SD-SPEEDX radiographic films are hygienically protected and treated at the end of the production cycle by spraying a specific disinfectant solution for safety and hygiene. To prevent contamination during use, each envelope should be opened from the side indicated only at the time of taking the x-ray. Always disinfect before use on the patient.

**HOW TO USE SD-SPEEDX**

To display the following directions for use, interact with the illustrations printed on the packaging:

**1. HOW TO OPEN THE PACK:** open the protective envelope, from the side indicated by the OPEN arrow, pulling the tabs slightly apart. Extract SD-SPEEDX carefully.

**2. POSITIONING:** position only the part containing the radiographic film in the patient's mouth, making sure that the lower part of the device is always on the outside.

**3. IDENTIFICATION OF THE IRRADIATED SIDE:** when positioning the film, for subsequent identification of the image, take as reference the light blue side that indicates the side opposite the radiation source. Each film is marked on the edge with an orientation dot - endodontic dimple - whose raised part, corresponding to the white side of the external pouch, indicates the irradiated side.

**4. EXPOSURE:** irradiate the film according to the exposure times recommended in the graph provided below.

**5. DEVELOPMENT:** proceed with instantaneous self-development of the film in full light, carrying out the following operations very quickly in sequence:

- With both thumbs of your hands overlapped, exert a slight pressure on the lower part of SD-SPEEDX. The development and fixing liquid will flow rapidly into the zone containing the exposed film. Make sure that all the liquid reaches the film to be developed; otherwise, squeeze it with your fingers.

- Hold SD-SPEEDX upright, with the film facing down and, rotating your thumb up and down, massage delicately and evenly for about 30-45 seconds so that the development and fixing liquid acts uniformly on the film. During this operation, do not allow the solution to flow back through the central corridor of the pouch; exert pressure with your other thumb to obstruct the corridor.

- Turn SD-SPEEDX upside down, with the film facing up and grasping the pouch by the opening tabs, use your fingers to return all the liquid to the lower part.

- Cut the edge with the scissors to open the plastic pouch sufficiently to permit only extraction of the developed film; development solution residues will remain inside the pouch.

- Grasp the film with the specific pincers and rinse immediately on both sides in running water; after washing, let the film dry at ambient temperature – see film archiving paragraph.

- Dispose of the plastic bag and its residual contents – see environment protection paragraph.

**SUGGESTIONS FOR USE**

Some practice may be required to get used to using a SD-SPEEDX film but its outstanding performance and ease of use will confirm the exceptional validity of this product. For the very best results, follow the directions for use carefully and store the product in a suitable environment, protected against excessive heat and humidity. If stored in a refrigerator, let the film warm at ambient temperature before use. Increasing the recommended development times does not have any significant effects on the image but negative effects are obtained reducing the times. The ideal development conditions are an ambient temperature of 20° C (68° F) or slightly higher while temperatures of more than 27° C (80° F), especially if combined with a very strong massage, may damage the film. The best development results are obtained complying with the times indicated and with a meticulous massage so that the action of the liquid is evenly distributed on the entire surface of the film.

**PRECAUTIONS DURING USE**

SD-SPEEDX is a medical device for professional use only. Before using SD-SPEEDX, check that the packaging is intact. Do not store the films at temperatures above 24°C (75°F) and do not expose them to direct sunlight or other sources of heat. Remember to close the box after use.

**PRESERVATION AND STORAGE**

Unsuitable preservation and storage conditions may have far-reaching repercussions on the quality of radiographic films, causing fast aging and therefore poor quality images. SD-SPEEDX radiographic films have a life of 18 months if preserved in a cool dry place, at a temperature of between 10° and 24°C (50-75°F) with a relative humidity of between 30-50%, protected against sources of heat, chemical products and any type of radiation. Cold storage at 5 - 8°C (41-46°F) extends product life. Remember however to return the film to ambient temperature before use. The product must not be frozen.

**PROTECTION OF THE ENVIRONMENT**

Do not dispose of the product in the environment after use. Residuals must be disposed of or treated according to the legislation in force in each country.

**EXPIRY DATE AND STAMPING**

To obtain the best results, use the film before the expiry date. The lot number and expiry date are indicated on each envelope and on the box. The expiry date refers to the product correctly preserved with its packaging intact.

**FILM ARCHIVING**

In accordance with ISO 5466:1992 specifications, preservation of the image in a SD-SPEEDX film without alteration is guaranteed for a minimum period of 10 years. To achieve this standard of archiving, the film must be washed in running water for at least 2 minutes. Washing makes it possible to eliminate residual substances and prevents discoloration of the film during storage.

**WARRANTY**

Limitation of responsibility. This product will be replaced in the case of ascertained manufacturing or packaging defects. Except for these cases, the product is sold without any other warranty against defects, damage or losses caused by negligence or other causes.

**FOR PROFESSIONAL USE ONLY**

SD-SPEEDX is designed and sold for professional use only in dental practice and must be used according to the specific directions, methods and precautions for use. The information provided is based on currently available data and on our knowledge and does not, however, constitute any guarantee of the characteristics of the product and shall not be construed as establishing any legal contractual relationship. As the conditions and method of use are beyond our direct control, we assume no responsibility for results not complying with the user's expectations. GSM Medikal shall not be held responsible for any damage or injury caused by improper usage or incorrect manipulation.

**PRODUCT CONFORMITY**

SD-SPEEDX is a CE marked product complying with European Community Directive 93/42/EEC - Medical Device Directive. SD-SPEEDX has been produced according to ISO 3665:1996 standards. Continuous, repeated quality inspections are carried out on all our products during production and packaging. For any complaints and suggestions, take note of the lot number indicated on the packaging and write to our customer service.


**WARNINGS**

Caution! read the instructions carefully before use. For professional use in dental practice only. The expiry date refers to the product correctly preserved in its intact packaging. Before opening the box, check that the safety seals are intact. GSM Medikal shall not be held responsible for improper usage of this medical device or usage not complying with the directions and instructions for use. Keep the product in a safe place out of the reach of children. Do not dispose of the product in the environment after use. Do not swallow. Avoid contact of the development liquid with the skin and eyes. Preserve the instructions and the box until all the films have been used.

**SAFETY**

CE marking confirms that SD-SPEEDX complies with the necessary safety requirements. The development and fixing liquid contained in SD-SPEEDX consists of a aqueous solution with the following active principles:  
- Potassium hydroxide Cas 1310-58-3  
- Potassium sulfite Cas 10117-38-1

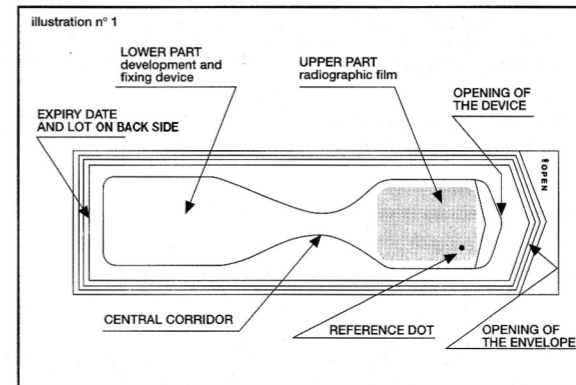
As regards classification and indications of harmfulness, the development and fixing liquid is as follows:













 R 20/22 harmful if swallowed  
R 36/38 irritating for the eyes and skin  
Xn Harmful

In the case of contact, adopt the usual safety measures when handling chemical substances. The product safety sheet complying with European Community Directive 91/155 EEC, filed with the Supervisory Authorities, is available at the request of the user.

**EMERGENCIES**

Swallowing: induce vomiting and consult a doctor. Contact with the skin: wash with running water and soap. Contact with the eyes: wash with running water for a few minutes keeping the eyelids open and consult a doctor. Contact with the mucous of the mouth: rinse with water.



	DO NOT RE-USE		PRESERVATION WARNINGS
	USE BEFORE		PRESERVATION WARNINGS
	LOT NUMBER		PRESERVATION WARNINGS
	CAUTION! SEE THE DIRECTIONS FOR USE		PRESERVATION WARNINGS
	CE MARKING		GREEN POINT
	Xn HARMFUL		GREEN POINT

EXPOSURE CHART		60 kV 7 mA	70 kV 7 mA	65 kV 10 mA	70 kV 10 mA
MAXILLARY	MOLARS	0,50	0,25	0,32	0,25
	BICUSPIDS	0,40	0,20	0,25	0,20
	CUSPIDS	0,32	0,18	0,20	0,18
MANDIBULAR	MOLARS	0,40	0,20	0,25	0,20
	BICUSPIDS	0,32	0,18	0,20	0,18
	CUSPIDS	0,25	0,16	0,18	0,16
	INCISORS	0,25	0,16	0,18	0,16

Adjust condition and time according to patient and apparatus

**ERROR DISPLAY**

PREVENTION	CAUSE	ERROR
1) CHECK SETTING OF EXPOSURE TIME 2) INCREASE EXPOSURE TIME ACCORDING TO THE OBJECT AND SPEED OF THE FILM.	UNDEREXPOSED IMAGE	FAINT IMAGES 1) THE STRUCTURE IS NOT SHOWN 2) LOW CONTRAST
CHECK THE POSITION OF THE PATIENT	OVEREXPOSED IMAGE - EXPOSURE TIME TOO LONG	DARK IMAGES - LOW CONTRAST
CHECK THE POSITION OF THE PATIENT	THE PATIENT MOVED DURING EXPOSURE	IMAGES NOT VERY CLEAR - BLURRED
COMPLY WITH THE TIMES INDICATED AND CHECK THAT THE LIQUID HAS FLOWED DOWN COMPLETELY - MASSAGE THOROUGHLY AND EVENLY	INCORRECT SELF-DEVELOPMENT - LIQUID NOT MIXED THROUGH MASSAGE OR NOT ACCORDING TO DIRECTIONS FOR USE	SPOTTING
OPEN THE DEVICE ONLY AFTER COMPLETE SELF-DEVELOPMENT COMPLY WITH THE DEVELOPMENT TIMES INDICATED	EXPOSURE TO THE LIGHT	IMAGES WITH DARK AREAS FROM THE EDGE TOWARDS THE INSIDE
STORE THE FILM ACCORDING TO THE PARAMETERS INDICATED - CHECK EXPIRY DATE	FILM STORED FOR TOO LONG OR IN UNSUITABLE CONDITIONS	IMAGES VEILED AND WITH LOW CONTRAST
WASH THOROUGHLY BEFORE DRYING	UNSUITABLE OR INSUFFICIENT WASHING	YELLOW-BROWN IMAGES WITH GRADUAL LOSS OF DENSITY DURING STORAGE