



Head Office

Dongkuk Techco Rubber Industries, Sdn. Bhd.
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Home Page

www.dongkuktechco.com.my

Contact Persons

Mr. D.K. Kim, Managing Director

Ms. EY Chong, Marketing and Sales

Business Hours

Monday - Friday : 9 a.m to 5 p.m

Saturday : 9 a.m to 1 p.m

Manufacturing Facility

Our factory is located in Sungai Petani, Kedah. It is approximately 32 km northeast from Penang and just 45 minutes drive.

Dongkuk Techco Rubber Industries, Sdn. Bhd.

Plot 31, Jalan 8, Bakar Arang Industrial Estate

Sungai Petani 08000, Kedah

Malaysia

Tel: +6 (04) 421-3527, 421-3567

Fax: +6 (04) 421-9900

Malaysia is +8 hours ahead of GMT



Dongkuk Techco, a quality assured company, is a premier manufacturer of natural rubber latex- based products since 1979.

Our expertise in production of high-quality and reliable products is recognized worldwide. With an access to vast natural resources, advanced technologies, skilled labor forces, and dedicated team of management, we focus on a specific objective.

“To meet our customer’ needs by providing quality products and personalized services.”

And as part of our continuous efforts to improve product quality and customer satisfaction, we have implemented the ISO Quality System throughout our production process and conduct extensive internal Research and Development.

Furthermore, we source compatible raw materials from reputed local and international suppliers and make sure that each delivery meets our internal quality standard. This practice not only ensures safety of our end users but our obligation to offer competitive prices to our customers.

At Dongkuk Techco, we are committed to our objective because we know that our valued customers search for a reliable and dedicated partner.

To learn more about our company and products, please contact us.

CONDOM

We offer a variety of condoms to meet each customer's preference and marketing demand without compromising overall product quality.

Our products are specially formulated and designed in order to provide an ultimate comfort, natural feeling and maximum protection to users.

We ensure consumer confidence by thoroughly testing each batch of condoms for physical properties such as bursting volume and pressure, water leakage, tensile strength, dimension, and seal integrity in accordance with international standards.

We are also aware that these physical tests are inadequate to ensure the maximum safety for the end-users. Therefore we perform external biocompatibility tests such as Protein Assay, Cytotoxicity, Penile and Vaginal Irritations, Acute Systemic Toxicity, Sensitization and Primary Skin Irritation.



CONDOM

In addition to having our own line of brands(SHADOW), we also specialize in OEM (private labels) for our customers.

With our expertise and experience in condom production, we can provide our customers on both brand development and marketing solutions.

In order to provide quality service, we work closely with a group of printers, designers, and suppliers, who are also specialists in their own industry.

For more information on our OEM service, please send us your inquiry.



Product Information

- Natural Rubber Latex Condom
- Electronically Tested
- With Reservoir-end
- Lubricated with Silicone Oil

Product Types

- 53mm Ordinary (smooth surface)
- 53mm Contoured (smooth surface)
- 53mm Ribbed (textured surface)
- 53mm Dotted (textured surface)
- 53mm Contoured/Ribbed/Dotted
- 53mm Ordinary without reservoir-end
- 49mm Ordinary (smooth surface)
- 54mm Ordinary (smooth surface)

Brands

- Shadow
- OEM available

Product Specification

- Length: Min. 170mm (for all sizes)
- Width: 49, 53, 54mm
- Thickness: Min. 0.04 to 0.08
- Bursting Volume: Min. 18 liters
- Bursting Pressure: Min. 1 KPa
- Freedom from Holes: AQL 0.25%
- Average Shelf Life: Max. 5 years
- Natural Rubber Latex:
Complies to US FDA 21
Code of Federal Regulation

Standard Compliance

- ASTM D 3492
- ISO 4074
- MS-113

Regulation Compliance

- SIRIM of Malaysia
- CE Directive 93/42 EEC /
MDR(EU) 2017/745
- ISO 13485

Test Requirements

- Electronic Pin-hole Test
- Bursting Volume & Pressure
(Unaged and Aged)
- Pin-hole (Water Leakage)
- Seal Integrity
- Dimension
- Biocompatibility Tests
(ISO 10993)
- Bioburden Test

Packaging Description

- Both rectangular and square foil
types are available
- Foil Types: Aluminum, Plastic and
Paper
- Consumer Pack: 3- , 6- , 10- , and
12- piece
- Gross Box: 3 x 24 (half gross),
3 x 48, 6 x 24, 10 x 10 and 12 x 12
- Bulk packing: 100- ,144- and
300- piece
- Carton Box: Double-wall export
carton
- Lables: Standard shipping marks
with CE/US FAD/OEM labeling
requirements

INSTRUCTION OF USE A CONDOM

MD MEDICAL DEVICE



“FOR SINGLE USE ONLY”



“ DO NOT USE IF
PACKAGE IS DAMAGE ”

CE 1639



Manufactured By :

Dongkuk Techco Rubber Industries Sdn Bhd
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www.dongkuktechco.com.my

EC **REP**

MT Promedt Consulting GmbH
Ernst-Heckel-Strasse 7
66386 St. Ingbert, Germany

REF DTRI-001

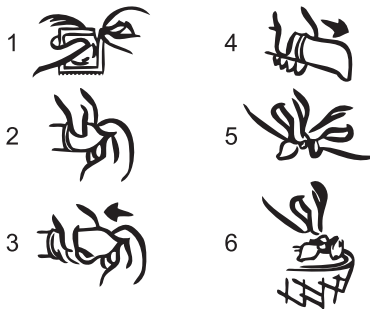
SN IFU-001

Date Issue : 01-05-2024

Revision No. : 4

According to ISO 4074 Standard.

Instruction of use



How to use

- Tear off the corner of the sachet pack. Do not use sharp objects to open the packing and be careful of your - or your partner's sharp fingernails.
- Pull back the foreskin of the erect penis. Hold the reservoir which will hold the semen between thumb and forefinger. Unroll the condom evenly with the other hand over the erect penis.
- After ejaculation withdraw the penis along with the condom from the vagina before the penis becomes flaccid. Remember to hold on the condom. Use each condom once only.
- Dispose of a used condom by wrapping it in tissue and throwing it into rubbish bin; Do not throw into toilet bowl.

Notice

A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

1. Handle the condom carefully, including removal from the package so as to avoid damage to the condom by fingernails, jewellery, etc.

2. When to put on the condom; the condom should be placed on the erect penis before any contact occurs between the penis and the partner's body, to assist in the prevention of sexually transmitted infections and pregnancy.

3. To stop and check if the user feels the condom slipping, as it may fall off the penis.

4. To stop and check if the user feels the condom tightening excessively on the penis, as this may lead to breakage.

5. Need to withdraw the penis soon after ejaculation, while holding the condom firmly in place at the base of the penis and holds onto the penis, ejaculated sperm remains inside the condom.

6. If an additional lubricant is desired, use the correct type of lubricant, which is recommended for use with condoms, and the need to avoid the use of oil-based lubricants, such as petroleum jelly, baby oil, body lotions, massage oils, butter, margarine, etc., as these are deleterious to the integrity of the condom.

7. Consult a doctor or pharmacist about the compatibility of topical medicines that might come in contact with the condom.

8. Seek medical assistance as soon as possible, at least within 72 h should a condom leak or burst during use.

9. If the individual container is obviously damaged, discard that condom and use a new one from an undamaged package.

10. Dispose of a used condom by wrapping it up in tissue and throwing it into rubbish bin; Never flush into toilet.

11. The condom is for single use. Do not reuse the condom. If reused there might be increased risk of failure or infection.

12. The condom is made of natural rubber latex, which might cause allergic reactions including anaphylactic shock. If a symbol for latex is used on the packaging, for those allergic to latex, please consult a doctor before using a condom.

13. If the rubber material is sticky/brittle/torn or obviously damage, do not use it. If the date has passed or if the packaging is damaged, do not use condoms. No condom can guarantee 100% contraception and protection against sexually transmitted infections (STI)

14. Keep away from children.



This condom is made of natural rubber latex which may cause allergic reactions.



Storage condition: Store in a cool, dry place away from direct sunlight.



Instruction for Use (IFU)

Trade Name : Shadow

Description of Condom : The device made of Natural Rubber Latex which is obtained from the tree Hevea Brasiliensis, which completely covers the erected penis during sexual intercourse.

Intended Purpose : Natural Rubber Latex Condom used for contraception and for prophylactic purposes to prevent pregnancy and sexually transmitted infection (STI)

Intended Users or Patient Population : The condom is intended for public use focusing on male population



HOW TO USE / WARNING / CAUTIONS

How to use and Indication : The condom should be placed on the erect penis before any contact occurs between the penis and the partner's body to assist in the prevention the risk of sexually transmitted infections (STI) and prevent unwanted pregnancy.

Contra-indications: The condom is made of natural rubber latex, which might cause allergic reactions including anaphylactic shock

Performance characteristics of the device firmly holds onto the penis, ejaculated sperm remains inside the condom

Any residual risks, and any undesirable side-effects: As per risk management, the residual risks identified was latex allergy specified above and film breakage, this contributed by use of

- damage package - if the individual container is obviously damaged to discard that condom and use a new one from an undamaged package., the need to handle the condom carefully, including removal from the package so as to avoid damage to the condom by fingernails, jewellery, etc.,
- not following storage condition , condom should store in cool dry place away from direct sunlight
- used more than once: A statement that the condom is for single use and that if reused there might be an increased risk of failure or infection.1
- not referring to IFU before use: the need to stop and check if the user feels the condom slipping off or tightening excessively onto the penis because this might

lead to breakage, the need to withdraw the penis soon after ejaculation, while holding the condom firmly in place at the base of the penis

● use of incompatible lubricants or medicine: the need, if an additional lubricant is desired, to use the correct type of lubricant which is recommended for use with condoms and the need to avoid the use of oil-based lubricants, such as petroleum jelly, baby oil, body lotions, massage oils, butter, margarine, etc., as these are deleterious to the integrity of the condom, the need to consult a doctor or pharmacist about the compatibility of topical medicines that might come in contact with the condom.

● for device intended for use together with other devices: details on use of incompatible lubricants or medicine provided above.

Warnings, precautions and / or measures to be taken in the event of malfunctioning of the condom or changes in its performance that may affect safety: (i) If the rubber material is sticky / brittle / torn or obviously damaged, do not use it. (ii) If the date has passed or if the packaging is damaged, do not use condoms.

No condoms can guarantee 100% contraception and protection against sexually transmitted infections (STI).

Warning or precautions to be taken in order to facilitate safe disposal of the condom: Dispose of condom hygienically: wrap it up in tissue and throw away in bin. Never flush into toilets.

For devices intended for use by lay persons, the circumstances in which the user should consult a healthcare professional, advice to seek medical assistance as soon as possible, at least within 72 h should a condom leak or burst during use, the need to consult a doctor or pharmacist about the compatibility of topical medicines that might come in contact with the condom

Limitations for condoms are like

- Potential for latex allergies and skin irritation
- Potential for condom breakage or slippage if not used properly
- Limited protection against some sexually transmitted infections like herpes and HPV

ⓧ FOR SINGLE USE ONLY : A condom is used only once. Need to use a new condom every time the user has sex. Reuse increases the risk of contamination by sexually transmitted diseases (STD) and integrity of the condom increasing the risk of pregnancy.

HAZARD	RISK	MANAGEMENT
Latex allergy	<p>Latex condoms contain protein that can cause allergic reactions – itchiness, redness of skin, swelling, runny nose, sneezing, dizziness, wheezing, lightheaded feeling and anaphylactic shock. Out of these, anaphylactic shock is life-threatening and may result in death.</p> <p>Hypersensitivity (allergy) to natural latex products is either immediate (Type I) or delayed (Type IV). Immediate reaction, which is a type I reaction (anaphylaxis), and delayed hypersensitivity reaction, which is a type IV reaction. Symptoms include urticaria or skin rash/hives, itching, cough, watery eyes, sneezing, running nose, chest tightness, shortness of breath, wheezing, confusion, low blood pressure, and dizziness. It has been reported in spouses as well.</p> <p>Although the protein content is reduced to absolute minimum during the manufacturing process, its complete eradication is near impossible.</p>	<p>Alternatives to latex condoms include synthetic condoms, made of polyurethane, or natural membrane condoms (made from lamb intestine). However, polyurethane condoms are less effective than latex condoms, mainly due to slippage. The safety and performance of these alternative materials still need to be demonstrated.</p> <p>Currently there are no materials that can be recommended as a complete alternative, including safety with respect to the transmission of infectious microbes compared to NRL condoms.</p> <p>Graphene and Nano lubricated condoms are new in the market and others in futuristic approach may include wearable technology/Technology driven condom and invisible Condoms. Nevertheless, both Correct and Consistent use of condoms needs to be promoted for HIV/STI prevention.</p>
Interaction with other devices	<p>Oil based lubricants including massage oils, petroleum jelly, baby oil, baby lotions, butter to name a few, may decrease the strength of the condom and therefore may potentially jeopardize its efficacy. There is also incompatibility of condoms with the some OTC medicines that are used on the penis or vagina.</p>	<p>Currently lubricated condoms are the choice and they contain silicone oil as the lubricant. However, some users tend to use additional lubricants for better performance and pleasure. In such cases, water based lubricants are recommended. The compatibility of condoms with topical OTC medicines must be verified with the pharmacist / physician.</p>
Shelf life	<p>Using a condom beyond its expiry does not guarantee any protection due to aging. The risk of using an expired condom is more than unwanted pregnancies and STDs.</p> <p>Unwanted pregnancy is the first risk of using a condom beyond its expiry. The pre-ejaculate from the male partners are sufficient to cause pregnancy. The tensility of the condom may have reduced and the condom can actually tear or break, again breaching the protection from pregnancy.</p> <p>The risk of STDs and other infections is potentially higher with expired condoms. The expired condom may break inside the vagina during an intercourse.</p>	<p>Never use an expired condom.</p> <p>The manufacturer tests the shelf life of the device and declares the same on the product label. The risk of contracting STDs or ending up with an unwanted pregnancy using an expired condom is only to the user and the manufacturer has no liability.</p> <p>The device users are therefore advised to take a serious look at the device's expiry date and follow all instructions as indicated for proper protection.</p>
Susceptibility to environmental influences	<p>Inappropriate storage of the condoms can diminish their quality and performance. Heat, exposure to excessive sunlight, moisture and UV can cause the condoms to break.</p>	<p>A cool, dry environment is the ideal storage condition for a condom. For better shelf-life, store the condoms at a temperature between 28 to 35 °C in a cool, dry place, away from direct sunlight. Do not store condoms at high temperatures and humidity. Device users are advised to thoroughly read and understand the product IFU.</p>



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SHADOW®

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SHADOW[®]

Sexy yet strong, **SHADOW[®]** condoms give you silky smooth pleasure for everyday use. Made from the highest quality natural latex, **SHADOW[®]** condoms provide a snug fit for maximum sensitivity, offering you the ultimate in intimate pleasures with complete peace of mind. The varied range of **SHADOW[®]** products ensure that there is always a selection to suit your particular tastes and desires of the moment . . .



SHADOW[®] CLASSIC FIT

Regular

Enjoy the reliability and comfort of this timeless classic that offers maximum protection for your ultimate enjoyment.



SHADOW[®] 3 IN 1

3 in 1

A sexy color of ultimate sophistication provides visual stimulation and enhanced excitement for those special occasions.



SHADOW[®] DELIGHT

Studded / Dotted

Sensuously studded all around, DELIGHT provides that extra enhancement for more intense pleasure.



SHADOW[®] CONTEMPORARY FIT

Ribbed

The ribbing is guaranteed to excite and raise temperatures in the bedroom to increase your sexual pleasure.



SHADOW[®] SMOOTH FIT

Contoured

Specially designed contours provide a cozier fit that heightens sensitivity and intimacy between you and your partner.

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Ms. EY Chong, Marketing and Sales

SHADOW[®]

Classic Fit

- 3 - piece pack
- 12 - piece pack
- 144 - piece pack
- Regular
- Made of premium natural latex
- Premium quality
- Silky smooth

3 in 1

- 3 - piece pack
- 12 - piece pack
- 144 - piece pack
- Dotted - Ribbed - Contoured
- Made of premium natural latex
- Premium quality
- Ultimate in sexiness

Delight

- 3 - piece pack
- 12 - piece pack
- 144 - piece pack
- Studded / Dotted
- Made of premium natural latex
- Premium quality
- Extra titillation

Contemporary Fit

- 3 - piece pack
- 12 - piece pack
- 144 - piece pack
- Ribbed
- Made of premium natural latex
- Premium quality
- Sensuous

Smooth Fit

- 3 - piece pack
- 12 - piece pack
- 144 - piece pack
- Contoured
- Made of premium natural latex
- Premium quality
- Tight fit



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