Summary Of Safety and Clinical Performance

1 Device identification and general information

1.1 Device trade name(s)

Durex natural rubber latex (NRL) condoms with silicone lubricant and benzocaine are marketed under multiple local trade names which include but are not limited to: Performa, Performax Intense, Mutual Pleasure, Extended Pleasure, Mutual Climax, Performance Booster, Settebello Lunga Durata, You&Me, Sync, Orgasmic, Placer Prolongado, Extreme.

NRL condoms with silicone lubricant and benzocaine are also available in some markets as part of mixed variety condom multi-packs under the trade names: Fun Explosion, Feel Fun, Surprise Me, Surprise Me Deluxe, Love Collection, Fun Mix, Surprise Mix and Magibox.

1.2 Manufacturer's name and address

Reckitt Benckiser Healthcare UK Ltd.
Dansom Lane
Hull
HU8 7DS
United Kingdom

1.3 Manufacturer's single registration number (SRN)

Placeholder for SRN until EUDAMED has been put into service.

1.4 Basic UDI-DI

BUDI - 5000158MDR005AV

1.5 Medical device nomenclature description / text

N.B. Placeholder for Device Nomenclature until EUDAMED has been put into service.

Device group: Male condoms
EMDN: U110101 - Devices for Urogenital system, Condoms

A medicated, natural rubber latex sheath intended to completely cover the penis during sex, to prevent sperm from gaining access to the female reproductive tract and/or prevent the transmission of sexually transmitted infections (STI). It contains a pharmaceutical substance typically intended to enhance the prophylactic/contraceptive properties of the condom or improve sexual experience. The device may also be textured. This is a single-use device.

1.6. Class of device

The device is currently certified as a Class III medical device in accordance with the European Medical Device Regulation, according to Annex VIII, Chapter III, Rules 14 (medicinal product) and 15 (contraception and prevention of sexually transmitted diseases).

Medical devices are classified into 4 basic classes according to the level of risk associated with the use of the device; Class I, Class IIa, Class IIb and Class III.

A number of factors are considered when classifying a device including:

- What is used for
- How long it will be used for
- Whether it is used inside or outside the body
- Whether it is powered
- If it contains any medicinal ingredients

Class III devices have the highest level of potential risk to patients or users and therefore are required to undergo in-depth assessments by approved bodies to ensure that they meet the relevant safety and performance requirements.

1.7. Year when the first certificate (CE) was issued covering the device

Durex condoms with silicone lubricant and benzocaine were CE marked under the current legal manufacturer (Reckitt) in 2010.

CE marking is a requirement for products that are subject to specific directives and are traded on the single market in the European Economic Area (EEA). It indicates that products comply with EU legislation and meets essential EU health, safety and environmental requirements allowing them to be sold throughout the EEA and moved freely within the European market.

1.8. Authorised representative if applicable; name and Single Registration Number

RB NL Brands B.V. Schiphol Blvd 207, 1118 BH Schiphol, NL.

SRN: NL-AR-000006055

1.9. Notified Body's name and single identification number

CE Certiso Ltd

H2092-Budakeszi, Erdö utca 101

Country: Hungary

Notified Body Number: 2409

2 Intended use of the device

2.1 Intended purpose

The principal intended purpose of NRL condoms with silicone lubricant and benzocaine is to provide a method of contraception and to prevent the transmission of STIs, through the physical barrier properties of the NRL condom.

NRL condoms with silicone lubricant and benzocaine are single-use, invasive (meaning it is inserted into a body cavity) devices that are worn prior to and during sexual intercourse, and then removed and disposed of following ejaculation or end of intercourse.

The addition of the benzocaine paste in the condom teat is intended to help prolong the time to ejaculation through topical de-sensitisation of the penile skin, as an additional action.

2.2 Indication(s) and target population(s)

Device indications are contraception and prevention of STI transmission.

An additional function is the topical de-sensitisation of the penile skin to temporarily prolong the time to ejaculation. The condoms are not intended to treat a medical condition.

The product is indicated for use by sexually active individuals who wish to prolong the duration of intercourse.

2.3 Contraindications and/or limitations

2.3.1 Contraindications

The device is contraindicated in users with a known allergy to latex and to benzocaine.

The condom should not be used if users have inflamed or broken skin.

2.3.2 Limitations

Users are advised to seek advice from a healthcare professional before use if their partner is pregnant or breastfeeding, as a precaution.

Users are advised to use only those lubricants that are recommended for use with condoms; some oil-based lubricants and some topical medications applied to the penis, anus or vagina may damage the condom.

See section 4 for further information on safety.

The condoms are intended for single use only.

Natural rubber latex and benzocaine are both potential sensitisers and may cause an allergic reaction in some users.

3 Device description

3.1 A description of the device

NRL condoms with silicone lubricant and benzocaine are a barrier contraceptive designed to deliver dual protection against pregnancy and the transmission of STIs, including human immunodeficiency virus (HIV). All device variants conform to ISO 4074:2015 Natural rubber latex male condoms - Requirements and test methods.

The condoms consist of natural rubber latex, a pharmaceutical grade silicone lubricant and a medicinal substance in the form of Performa lubricant with 5% benzocaine dosed within the condom teat. The benzocaine is intended to remain on the inside of the condom and therefore should not come into contact with the non-condom wearing partner, therefore, only the condom wearer is exposed to the local anaesthetic action of benzocaine. In the event that the non-condom wearing partner were to come into contact with this medicinal substance; the associated risks would be no higher during oral sex, than during anal or vaginal sex

The condoms are intended for single use only.

The condoms are presented in individual multilayer foil sachets within card cartons. The instructions for use are printed on the inside of the carton.

3.2 A reference to previous generations or variants if such exist, and a description of the differences

NRL condoms with silicone lubricant and benzocaine were brought to market under the previous legal manufacturer; SSL International, prior to acquisition by Reckitt in 2010.

The overall formulation and design have remained unchanged in this time, apart from the introduction of a broader range of shapes and dimensions, which do not impact the devices' intended purpose or compliance with ISO 4074:2015, but rather are intended to improve user experience. Any minor modifications to the device over the device's history have been rigorously assessed through technical testing and safety assessments to ensure there are no impacts on quality, safety, or efficacy.

3.3 Description of any accessories intended to be used in combination with the device

No accessories are intended to be used with the device.

3.4 Description of any other devices and products which are intended to be used in combination with the device

The device is not intended to be used with another device in order to achieve the primary intended purpose.

The device can be used with vaginal lubricants, specific restrictions to certain types of products are considered in section 4 and detailed in the product's labelling; on pack warnings and precautions can be found in section 4.4.

4 Risks and warnings

4.1 Residual risks and undesirable effects

This section of the SSCP (Summary of Safety and Clinical Performance) includes residual risks, other than those contraindications, limitations, warnings and precautions that are included in sections 2.3 and 4.4.

4.2 Description of residual risks and undesirable effects

While NRL condoms with silicone lubricant and benzocaine are safe for use when used as intended, a small number of residual risks remain. These risks include:

- Latex allergy
- Benzocaine allergy
- Device failure
- Choking on condom
- Methemoglobinemia

These risks will be discussed across sections 4.2.3-4.2.6.

4.2.1 Undesirable side-effects

Both latex and benzocaine are known to cause irritation or discomfort in certain individuals due increased natural sensitivity. While this is relatively rare, it is worth discussing with a healthcare professional before you use this product if you are unsure or suspect you may have a sensitivity to latex or benzocaine.

The known and foreseeable side effects related to use of the NRL condoms with silicone lubricant and benzocaine include:

- Genital irritation or discomfort due to latex – generally of mild severity and brief duration.
- Prolonged Hypoesthesia (decreased sensation) of the penis due to benzocaine.
- Skin, genital or eye irritation due to benzocaine. In the event of irritation cease use of the product and wash the affected area

If you experience any of these undesirable side effects, discontinue use of the product and contact a healthcare professional if necessary.

For more information on heightened sensitivity and symptoms due to allergies; see sections 4.2.3 and 4.2.4.

4.2.2 Device failure

Condoms are known not to be 100% effective against pregnancy or transmission of STIs. It is generally acknowledged that male condoms are effective in the prevention of pregnancy and STIs, with a 98% effectiveness rate when used consistently and correctly (Festin, 2020). Incidences of clinical failure of the device, including condom breakage or slippage during sexual intercourse, are low, and are often related to user error or misuse. Further to the low

failure rate, condoms are known to present few side effects, other than the potential allergic response to latex in sensitive users. Severe allergic reaction is very rare, and the majority of side effects are brief episodes of minor irritation or discomfort.

Typical contraceptive failure rate is 2%, meaning approximately 2 users out of every 100 will become pregnant in a year (Festin, 2020).

For a tabulated comparison of clinical failure rates in NRL condoms, please see Table 1.

Condoms cannot protect against STIs that are not primarily transmitted through exposure of the genital, oral or anal mucosae (mucous membrane) to infected bodily fluids i.e., STIs transmitted through close contact or direct contact with infected skin or sores, where these are not covered by the condom, such as genital herpes, warts, syphilis, pubic or body lice and scabies.

For an in-depth statistical analysis of condom failure rates see section 6.

4.2.3 Latex allergy

Latex is a known potential sensitiser and allergen. Type I (anaphylactic) and IV (cell-mediated) allergic reactions are known and foreseeable risks in relation to exposure to latex in sensitive individuals.

Risk factors include having:

- An atopic constitution (being pre-disposed to atopic eczema, allergic rhinoconjunctivitis, and/or allergic asthma)
- A history of allergy to latex or cross-sensitive allergens.

The symptoms of a localized allergic reaction to latex can include:

- Itching
- Redness
- Bumps
- Swelling
- Hives

It should be noted that severe allergic reactions are very rare.

4.2.4 Benzocaine allergy

Benzocaine is a known potential sensitiser and allergen. Type I and IV allergic reactions are known and foreseeable risks in relation to topically applied benzocaine. Severe allergic reactions are very rare.

The symptoms of a localized allergic reaction to benzocaine can include:

- Itching
- Redness
- Rash
- Swelling
- Blistering

4.2.5 Methemoglobinemia

Methemoglobinemia (MetHb) is a rare blood disorder. It is typically congenital (present from birth) and hereditary (genetically inherited from parents) but can be brought about through the use of anaesthetic agents.

Anaesthesia-induced MetHb is very rare and is most commonly seen in cases of systemic exposure of high doses of anaesthetics such as benzocaine. Durex NRL condoms with benzocaine are intended to be used for topical application only. If used correctly and in accordance with the instructions for use, the benzocaine should only come into short-term contact with the condom wearer, thereby reducing the risk of MetHb. However, owing to potential device failure and product misuse the risk should still be considered.

For an in-depth statistical analysis of condom failure rates, see section 6.

Symptoms of acquired MetHb include:

- Bluish colouring of the skin (most commonly seen in the fingers and lips)
- Altered mental state
- Shortness of breath
- Rapid breathing and heartrate
- Headache
- Fatigue
- Nausea and vomiting

If MetHb is suspected contact a health care professional.

4.2.6 Choking on condom

While rare, reports of choking have been reported alongside condom use.

Always be careful when using condoms for oral sex, keep out of the reach of children and vulnerable populations.

4.3 Quantitative data

Quantitative safety information on the device includes pre-clinical and clinical trial data held by the manufacturer, data from the published scientific literature and data on the device gathered through post-market surveillance , including spontaneously reported incidents and user complaints.

Based on the data gathered from January 2017 to December 2022 through post-market surveillance of the device in market, estimations of occurrence have been made per million items sold:

- 0.036 serious incidents per million.
- 1.686 non-serious incidents per million.

It shall be noted the above calculations have been based upon the sale data from hundreds of millions of units shipped.

Serious incidents are typically those which require medical intervention (e.g. condom breakage resulting in unexpected pregnancy) while non-serious incidents typically result in discomfort or inconvenience (e.g. skin irritation while wearing condom).

While it is acknowledged that adverse incident reporting can be an unreliable measure of device safety, due to the limitations of under-reporting and possibility of obtaining detailed follow-up information directly from users, the data provides a useful indication of the acceptability of the safety profile of the device in market. In context of the number of condoms brought to market (manufactured device units) as an estimation of condom-use-incidents, the volume of reported adverse incidents represents a very low adverse incident ratio of less than one serious reported incident per million units released for sale.

The data gathered through post-market surveillance is consistent with the literature gathered through review of the generally acknowledged state of the art. All the reported events relate to known foreseeable risks or side effects in relation to condom use. No new risks or emerging trends have been identified from the data. No Field Safety Notices were issued in relation to any of the reported incidents. Serious cases were investigated and reported to authorities in accordance with regulatory requirements.

4.4 Warnings and precautions

Contraindications and limitations, and residual risks and undesirable effects are presented above in sections 2.3 and 4.2, respectively. Additional warnings and precautions for use of the device are as follows:

Before use:

Before you use this condom, check the expiry date on the condom wrapper. If the individual container is obviously damaged, throw that one away and use a new one from an undamaged package.

- Before you use this condom, check the expiry date on the condom wrapper. If the individual container is obviously damaged, throw that one away and use a new one from an undamaged package.

- This condom is made of natural rubber latex. If you have a known allergy to latex, do not use this condom as this may cause allergic reactions including anaphylactic shock.
- Condoms may present choking hazard. Keep out of reach of children.
- Only use lubricants recommended for use with condoms. Oil-based ones (petroleum jelly, baby oil and some pessaries) and some topical medicines that go on the penis or vagina can damage condoms.
- If pregnant or breast feeding – ask a health professional before use.
- Do not use these condoms if you or your partner has inflamed or broken skin.

During use:

- To help you get it on right first time, the Durex logo on the foil shows you the bottom of the condom.
- Avoid contact with eyes, broken skin or wounds.
- Put a condom on before the penis touches the other person. This helps to prevent pregnancy and the possibility of catching sexually transmitted infections during vaginal, anal or oral sex.
- Tear the wrapper open from the serrated edge. Be careful with the condom, it could get damaged by fingernails or sharp objects.
- If the condom doesn't unroll, it may be on backwards, discard and use a new one.
- Stop and check if you feel the condom slipping off or it's too tight on the penis because this might lead to breakage.
- If you use the condom for oral sex first, you should use a new condom for any other type of sex that follows.
- For anal sex, use additional lubrication on the outside of the condom.
- If you feel discomfort or irritation, stop use.
- STOP USE IMMEDIATELY AND CALL A DOCTOR: If you or your partner experiences breathing difficulties or get blue lips when using these condoms.
- If a condom leaks or bursts during sex consult a pharmacist or doctor as soon as possible and within 72 hours.

After use:

- You should take the condom off soon after ejaculation. Hold the condom firmly at the base of the penis before pulling out.
- If discomfort or irritation continue after use, seek medical advice.
- Premature ejaculation is a common problem, which can have many causes and may require medical consultation/supervision. If these condoms don't help, it's worth checking with your doctor. Serious incidents must be reported to Reckitt and the local competent authority who will provide further advice.
- Wash lubricant off penis after use.

- Only use a condom once. Reuse increases risk of failure or infection. Throw the foil and used condom into a bin. Don't flush down the toilet.
- If you or your partner develop a rash or irritation, such as burning or itching, discontinue use. If symptoms persist consult a doctor.

The device has not been subject to any Field Safety Notices or Corrective Actions.

4.5 Other relevant aspects of safety, including a summary of any field safety corrective action (including Field Safety Notice) if applicable

No other relevant aspects of safety are applicable.

5 Summary of clinical evaluation and post-market clinical follow-up

5.1 Summary of clinical data related to equivalent device, if applicable

Not applicable - conformity of the device has not been assessed on the basis of equivalence.

5.2 Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable

Study reference: #06E2614 PH, April 10, 2007 (unpublished data).

Sponsor: SSL HEALTHCARE, France.

Conducted by DERMSCAN Group clinical testing centre, France.

Investigational devices: PERFORMA F0628AA (NRL condom with benzocaine) versus NATURAL I0626AA (standard NRL condom).

Study dates: February 9, 2007 to March 30, 2007.

Objectives:

Primary: Clinical evaluation, under medical control, of the tolerance of a condom with benzocaine versus standard condom after 2 weeks of use of each device.

Secondary: Subjective evaluation of the acceptability of a condom with benzocaine versus standard condom, completed by subjects following each 2 week use period.

Endpoints:

Tolerance: Clinical examination and collection of signs reported by the subjects.

Cosmetic acceptability: Subjective evaluation questionnaire.

Inclusion criteria:

- Healthy, male[1] subjects between 18 and 65 years old.
- Subject having given his/her informed, written consent.
- Subject willing to cooperate and adhere with study protocol.
- Subject usual user of condom and would commit to have at least one sexual relation per week with use of condom.
- 50% of subjects with premature ejaculation (self-described).
- 50% without premature ejaculation (self-described).

Exclusion criteria:

- Cutaneous pathology (skin condition) on the studied zone (eczema, etc.).
- Use of topical or systemic treatment during the previous weeks liable to interfere with the assessment of the cutaneous tolerance of the investigational product.
- Subject enrolled in another clinical trial during the study period.

Enrolled subjects:

43 male subjects (44 enrolled) age 32 ± 2 years (19 to 61 years old). One subject lost to follow-up.

Methodology:

Open and intra-individual study. Condoms were used at least twice per week for 2 weeks per condom type. Subjects completed a daily log of condom use and tolerance. Subjects returned to site following each 2-week period for clinical examination and to complete a subjective evaluation questionnaire.

Results:

Under clinical examination, 2 subjects (4.6%) reported side effects: one experienced slight burning sensation of the penis for 2 minutes following first use. The second experienced slight stinging for 40 minutes following first use. Both were considered possibly related by the study investigator but not clinically relevant.

No clinical, functional, or physical signs were observed during clinical examination of the subjects. The investigator deemed the device tolerability to be very good.

Subjective tolerability responses included 2 subjects who reported irritation during the study and one subject reporting discomfort with use of the PERFORMA condom. One subject reported discomfort with use of the NATURAL condom.

Overall subjective acceptability responses included subjective agreement of condom reliability (88%), ease of use (89%), suitable lubrication (86%) and prolonging the duration of sexual relations (61%) with use of the PERFORMA condom.

[1] Male in this context, is in reference to sex, not gender.

5.3 Summary of clinical data from other sources, if applicable

No clinical investigations have been identified on the device in the published clinical literature or registries.

Individual medical case reports have been identified in the literature, relating to exceptional cases of serious incidents in association with NRL condoms with silicone lubricant and benzocaine, or similar devices. All reported cases relate to the known risk of allergic contact dermatitis hypersensitivity reaction to benzocaine (Refer to case report references for further detail; Ljubojevc et al 2018; Sharma et al. 2018; Foti et al. 2004; Muratore et al. 2008; Placucci et al. 2006).

5.4 An overall summary of the clinical performance and safety

NRL condoms with silicone lubricant and benzocaine are based on well-established technology and materials. Manufactured under legal manufacturer Reckitt, they have been designed with the primary intended purpose as a contraceptive and for the prevention of the transmission of STIs. As an additional function they have also been designed to prolong the duration of intercourse by delaying the time to ejaculation.

5.4.1 Clinical performance

The primary intended purpose of NRL condoms with silicone lubricant and benzocaine has been demonstrated through conformity of the device to ISO 4074:2015: Natural rubber latex male condoms - Requirements and test methods. This standard specifies the minimum requirements for the manufacture and quality control of NRL male condoms, through stability and finished product testing to confirm conformance with minimum acceptable quality limits. NRL condoms with silicone lubricant and benzocaine have been shown to exceed these requirements.

The additional function, to prolong the duration of intercourse by delaying ejaculation in users, is delivered via the inclusion of 140mg of a semi-solid paste containing 5%, benzocaine dosed inside the condom teat.

State of the Art review of the published literature has established that delaying ejaculation may be desirable in a significant number of men, who report bother, annoyance or frustration with perceived rapid ejaculation and associated sexual dissatisfaction, independent of any formal diagnosis of premature ejaculation (Butcher et al., 2020, Martin-Tuite & Shindel, 2020). Topical anaesthetics such as benzocaine have a long history of use and are an established therapeutic option for the purpose of penile desensitisation, and benzocaine 3.0% to 7.5% is specifically monographed for this indication by the US FDA under Code 21 of the Federal Regulations (CFR) number 348.10 on “Analgesic, aesthetic, and antipruritic active ingredients”.

The acceptability of the NRL condoms with silicone lubricant and benzocaine has been assessed via user perception and handling studies conducted by the current and previous legal manufacturers, demonstrating that users find the use of the condoms acceptable and perceive the benefit of the condoms for delaying ejaculation.

5.4.2 Clinical safety

Clinical evaluation of in-use tolerance demonstrated the device was very well tolerated. The study has been described in section 5.2 above.

In-use data on the device has been gathered through ongoing post-market surveillance and post-market clinical follow-up activities, including monitoring of the reported clinical literature, collation and analysis of reported adverse incidents, consumer complaints and other market incidents, on a continual basis over the market history.

The post-market surveillance data supports that the clinical risk in relation to condom and benzocaine use is low, with adverse incidents generally mild, non-serious and of short duration; more serious incidents being very rare. Analyses of this data provides reasonable assurance of the clinical safety of the device.

No adverse trends or unacceptable risks have been identified during ongoing post-market surveillance/post-market clinical follow-up activities.

5.4.3 Overall benefit-risk

The clinical benefits of NRL condoms with silicone lubricant and benzocaine for their primary intended purpose are clear and widely acknowledged. Male condoms are a well-established technology with a long history of use, generally acknowledged as an important therapeutic option for contraception and STI prevention. They are widely available with few risks or contraindications, particularly in consideration to other therapeutic options, and, along with female condoms, are the only therapeutic option that offers dual prevention of both unplanned pregnancy and STIs.

It is generally acknowledged that male condoms, when used correctly and consistently are a 98% effective contraceptive over the course of a year, with a low rate of clinical failure (Festin, 2020). This being the case without the simultaneous use of other forms of contraception.

It is widely recognised that adequate access to effective contraception and STI prevention methods, sexual and reproductive health education and services are essential to reduce the economic and health burdens, and associated morbidity and mortality, of unplanned pregnancy and transmission of STIs worldwide. Given their dual benefits, male condoms play a major role in the prevention strategy and as such they are widely recommended in national and international clinical practice guidelines and by healthcare bodies and sexual health organisations. Condom manufacturers, including Reckitt, healthcare providers and health organisations work to improve sexual health education and access to services to drive appropriate and consistent use of condoms.

On the basis of conformance with ISO 4074:2015, supported by the generally acknowledged State of the Art and in-use post-marketing surveillance data, it can be concluded that NRL condoms with silicone lubricant and benzocaine can deliver their primary intended clinical benefits in terms of prevention of STIs and pregnancy when used consistently and correctly, with the additional benefit of prolonging the duration of intercourse, due to the addition of benzocaine.

The risks of NRL condoms with silicone lubricant and benzocaine have been well-characterised through:

- Generally acknowledged state of the art regarding known and foreseeable risks and side effects
- Biological safety risk assessment considering suitability and biocompatibility of the device raw materials and components
- Clinical evaluation and user testing considering user acceptability and tolerability
- Data gathered through post-market surveillance and post-market clinical follow-up on the device in market.

The risks have been systematically assessed via a risk management process in accordance with BS EN ISO 14971:2019+A11:2021. All risks have been evaluated for potential occurrence and severity, and risk control measures introduced where necessary to reduce risks as far as possible.

Residual risks have been considered in the risk management file for the device, in accordance with ISO 14971:2019+A11:2021, and deemed to be acceptable. Instructions, warnings and residual risk information are clearly presented on pack to allow appropriate user selection, advise on the appropriate use of the device, highlight precautions needed, and alert the user to warning signs and symptoms of an adverse reaction.

Given the low likelihood of occurrence of serious harms, the risks are deemed acceptable when weighed against the benefits of the device and are compatible with a high level of protection of health and safety of the user.

Taking into account the clinical evidence available, together with evaluation of the technical documentation pertinent to the device, it can be concluded that the benefits associated with the use of NRL condoms with silicone lubricant and benzocaine outweigh any risks to the user.

5.5 Ongoing or planned post-market clinical follow-up

Ongoing post-market surveillance and post-market clinical follow-up activities are conducted by the Legal Manufacturer in accordance with the appropriate quality management system procedures compliant to BS EN ISO 13485:2016+A11:2021 and EU Medical Device Regulation 2017/745, in order to continue to monitor the device in market for any adverse trends. The data is used to continually update the technical documentation including the device risk management, in accordance with ISO 14971:2019+A11:2021, and the Clinical Evaluation Report in accordance with EU Medical Device Regulation Article 61 and Annex XIV.

As an outcome of the review of technical and clinical data undertaken through clinical evaluation of the device, no new risks or emerging trends have been identified with regards to the clinical safety of the device and no inconsistencies, gaps or unanswered questions have been determined with regards to clinical performance, safety or benefit-risk that need to be addressed through post-market surveillance and post-market clinical follow-up activities. With regards to the additional function of NRL condoms with silicone lubricant and benzocaine, this is consistent with the generally acknowledged State of the Art and the

available data is considered to demonstrate sufficient evidence of the additional function of the benzocaine in the device.

However, to consider the additional benefits of the device further; a clinical study being conducted on behalf of Reckitt is currently planned and will generate further clinical data of the device's clinical performance and safety in-use, as well as providing further data on the delay of ejaculation.

6 Statistical analysis of condom failure rates

6.1 Device failure

Condoms are known to not be 100% effective against pregnancy or transmission of STIs: It is generally acknowledged that male condoms are effective in the prevention of pregnancy and STIs when used consistently and correctly, with a 98% effectiveness rate when used as intended (Festin, 2020).

Incidences of clinical failure of the device, including condom breakage or slippage during sexual intercourse, are low, and are often related to user error or misuse. For a breakdown of typical condom failure rates and STI transmission rates with condom use refer to Table 1 and table 3, for a breakdown of these failure rates for Durex NRL condoms with silicone lubricant and benzocaine see table 2, while a breakdown of general failure rates can be found in section 4.3. Further to the low failure rate, condoms are generally acknowledged to present few contraindications or side effects, except allergic response to latex in sensitive users, but severe allergic reaction is very rare, and the majority of side effects are transient cases of minor irritation or discomfort. Condoms containing benzocaine are also considered safe when used as intended with low incidence of benzocaine related adverse reactions.

Male condoms are a widely used, invasive prophylactic for STIs and by this same physical barrier form an effective contraceptive method against pregnancy, they are highly effective at preventing the transfer of STIs through bodily fluids typically found on the head of the penis. They are less effective at preventing the transmission of STIs which can be transmitted through contact with infected skin around or outside of the genital area not covered by the condom sheath, such as genital herpes, warts, syphilis, pubic or body lice and scabies. For a comparison of NRL condom efficacy in preventing transmission of STIs, see table 3.

Parasitic infections, such as scabies and pubic lice, can be transmitted through close physical contact and sharing bedding, towels or clothing, but have also been associated with sexual activity (CDC, 2015; Tai, 2020). Hence the use of condoms has no effect on the transmission rate of these types of infections.

Both accidental pregnancy and STI transmission can also occur as a result of condom failure (e.g., through breakage or slippage). Table 1 below demonstrates this by comparing breakage and slippage rates seen in literature focusing on NRL condoms of various designs form multiple different manufacturers. This data covers numerous studies conducted from 1997-2020 and demonstrates the acceptable failure rate of NRL condoms, using a variety of NRL condom designs and manufacturers, and in doing so demonstrating ~2% to be the typical failure rate of NRL condoms.

This level of performance and reliability is adhered to by the device in question, as demonstrated the table below:

Table 1: Clinical failure rates for NRL condoms

Study reference	Condom type tested	Clinical breakage		Clinical slippage	
		(%)	95% CI	(%)	95% CI
Rosenberg and Waugh, 1997	Straight shaft condom	0.28	0.15 - 0.48	0.63	0.42 – 0.90
Macaluso et al., 2000	Baggy condom	1.6	Not specified	2.23	Not specified
	Straight shaft condom	1.2	Not specified	3.53	Not specified
Wong et al., 2000	Various latex condoms	1.2	0.7 – 1.8	2.1	1.2 – 3.0
Golombok et al., 2001	Straight shaft and thick	3.3 (anal)	Not specified	3.0 – 3.5 (anal)	0.42 – 0.90
		2.1 – 2.2	Not specified	2.4 – 2.5	Not specified
Bounds et al., 2002	Easy-on condom	3.5	Not specified	1.2	Not specified
Steiner et al., 2003	Thin, easy-on	1.2	Not specified	2.0	Not specified
Siegler 2019	Unspecified latex condom	Anal sex 0.4	Only specified for clinical failure	0.3	Only specified for clinical failure
		Vaginal sex 1.1	Not specified	0.8	Not specified
Ting et al., 2019	Easy on condom	0.52	Not specified	1.04	Not specified
Nel et al., 2020	Easy-on condom	0.4	0.3 to 1.1	3.6	-4.7 to 1.0
Average		Clinical breakage (%)		Clinical slippage (%)	
		1.41		1.95	

In order to assess the performance of Durex NRL condoms, a clinical investigation was carried out by Reckitt to evaluate the performance rate of natural rubber latex condoms of varying thickness in healthy monogamous couples. Condoms of varying thicknesses had their tolerance tested in over 225 couples.

The investigation gauged the performance of a range of Durex condoms. It was found that over the course of the investigation the new variant was found to have clinical failure rate (breakage or slippage) of around 2%, which is in line with other condoms currently on the market.

There were no serious adverse incidents reported throughout. In conclusion, the Durex NRL lubricated condom were shown to be safe and well tolerated, and as effective as the two NRL reference condoms.

This investigation demonstrated that Durex NRL condoms hold a similar level of reliability to condoms from other manufacturers present on the market, as demonstrated by Table 1 showing typical clinical failure rate values.

6.2 Pregnancy prevention and condom use

While pregnancy rates for those using condoms differs between studies, condoms have an inherent, albeit small, chance to break or slip, hence there is a low chance of clinical condom failure. Condoms, when used correctly, are found to have a 2% failure rate. This means that if 100 women were to use condoms (with no other form of contraception) for one year; 2 out of 100 women may become pregnant (WHO, 2018).

Over the last several years hundreds of millions of units of Durex NRL condoms with silicone lubricant and benzocaine have been shipped. During this time a number of incidents have been reported relating to condom breakage/slippage, pregnancy and STI contraction, a breakdown of which can be seen in table 2:

Table 2: Incidents reported per Durex condom sale

Incident reported	Number of reports	Ratio (per million)*
Condom breakage/slippage	118	0.150
Pregnancy	31	0.039
STI transmission	27	0.034

3*Ratios are calculated based upon sales figures and total number of reports received between Jan2017-Dec2022

6.3 STI transmission and condom use

The following table demonstrates the efficacy of male condoms in preventing STI transmission.

Table 3: STI transmission rates with condom use

STI	Study findings on condom efficacy	Supporting study	Participants/ sample group
Highly preventable through condom use			
HIV	Reduced transmission by 78%	Hughes et al., 2012	3,297 HIV discordant couples
	Reduced transmission by 80.2% with typical use and 94.2% with perfect use	Weller and Davis-Beaty, 2002	From 14 different studies
	Reduced transmission by 80-90%	Liu et al., 2014	45,615 HIV discordant couples
Chlamydia	Significantly reduced transmission (OR = 0.71; 5% CI = 0.53 – 0.94)	Ahmed et al., 2001	17,264 sexually active individuals
	Inconsistent condom use associated with increases transmission risk		
	Condoms used correctly and consistently reduce risk by 59%	Crosby et al., 2012	929 clinic attendees, tested negative at baseline
	Chlamydia infection significantly associated with not using a condom during the last sexual intercourse (p=0.048) and irregular use of condoms in the 6 months prior to the survey (p=0.002).	Matteelli et al., 2016	2,718 students
Syphilis	Significantly reduced transmission (OR = 0.71; o5% CI = 0.53 – 0.94)	Ahmed et al., 2001	17,264 sexually active individuals
	Rates of syphilis increased over the study-period, with a significant linkage between increasing incidence and imperfect condom use.	Braun et al., 2014	293 HIV infected individuals
	Patients who always use a condom reduced the risk of failure or reinfection by 72% compared with patients who	Luo et al., 2017	1,113 patients being treated for syphilis

STI	Study findings on condom efficacy	Supporting study	Participants/ sample group
	never use a condom (AOR, 0.28; 95% CI 0.08-0.75; p = 0.02).		
Gonorrhoea	Significantly reduced transmission (OR = 0.71; o5% CI = 0.53 – 0.94)	Ahmed et al., 2001	17,264 sexually active individuals
	In men reporting one or more event of breakage/slippage, 25.4% tested positive for gonorrhoea. In men not reporting breakage/slippage, 17.2% tested positive.	Crosby et al., 2014	412 young males*
	Infection rates for consistent condom users lower for men and women for: gonorrhoea (AOR, 0.87 and 0.71 respectively).	Shlay et al., 2004	126,220 patient visits
Trichomoniasis	Condoms used correctly and consistently reduce risk by 59%	Crosby et al., 2012	929 clinic attendees, tested negative at baseline
	Reduction in STI rates associated with condom use: lab-confirmed STI was 6.21 times more likely if vaginal sex took place without a condom.	Masese et al., 2017	451 females*
	Significantly decreased risk of trichomoniasis infection.	Sanchez et al., 2003	917 female* sex workers at STI clinic
	Trichomonas infection declined from 3.5% to 0.5% with sex education and consistent condom use.		
T-cell lymphocytic virus type 1 (HTLV-1)	The adjusted OR for association of consistent condom use with HTLV-I antibody was 0.3 (95% CI, 0.1–0.8, p=0.02).	Sanchez et al., 1998	400 female* sex workers attending an STI clinic
Less preventable through condom use			
Herpes simplex virus (HSV) types 1 and 2	Condoms reduced transmission rates of HSV-2: male* to female* by 96% and female* to male* by 65%	Magaret et al., 2016	911 HSV-2 and HIV-1 discordant couples

STI	Study findings on condom efficacy	Supporting study	Participants/ sample group
	30% lower risk of HSV-2 transmission with consistent condom use.	Martin et al., 2009	5384 HSV-2 negative people
	Rate of HSV-2 transmission decreased with condom use.	Tobian et al., 2009	6,396 men
Human papillomavirus (HPV)	Pairs who always used condoms with previous partners were 27% less likely to have HPV (95% CI, 9% - 42%).	Burchell et al., 2014	482 Pairs
	Pairs who had used condoms consistently with previous partners had a lower prevalence of HPV in current partnerships		
	Four studies showed significantly protective effect of consistent condom use on HPV infection and on regression of cervical neoplasia	Lam et al., 2014	Participants of 8 separate studies
	Four studies: Protective effect observed but not significant		
	In men who reported >1 partner, always using condoms was strongly and significantly associated with reduced HPV detection (adjusted OR, 0.22; 95% CI, 0.08–0.59).	Nielson et al., 2010	463 men
Bacterial vaginosis (BV)	Consistent condom use associated with decrease in risk (AOR = 0.55: 95% CI = 0.35 – 0.88) for bacterial vaginosis and associated vaginal microflora.	Hutchinson et al., 2007	871 women at high risk of STI
	Patients that had previously used no protection had a BV cure rate of 98.2% after consistent condom use with significant post-treatment difference (P<0.001)	Thulkar et al., 2010	400 women with recurrent vaginitis
	Adjusted 6-month prevalence ratio comparing consistent to inconsistent condom use: 0.99 (95% CI: 0.85–1.13) for women with BV at baseline 0.62 (95% CI: 0.30–0.94) for women with BV at baseline. Male condoms appeared to protect against BV occurrence, but not BV recurrence.	Yotebieng et al., 2009	563 women with BV at baseline

* Male/female in this context, is in reference to sex, not gender.

7 Possible diagnostic or therapeutic alternatives

Condoms, both male and female, are the only dual method effective for both prevention of pregnancy and protection from the majority of STIs. Both are well-established and require no prescription, although female condoms are less widely available, more expensive than male condoms, and clinical data on their performance is more limited.

The extensive research into male condoms has established their performance and benefits for contraception and prevention of STIs and HIV when used consistently and correctly and their use is widely advocated by health and governmental organizations (WHO 2019, 2020a, 2020b).

For the prevention of pregnancy, a variety of contraceptive methods are available, including the oral contraceptive pill, long-acting reversible contraceptives such as Intrauterine Devices, injectables, and sterilization, most of which have a good clinical evidence-base and have been in widespread use for years.

All contraceptives are associated with some degree of side effects. Generally, the most common side effects are considered to be manageable, though there may rarely be more serious health risks for some methods that should be taken into consideration for certain users.

Contraceptive choice should be considered with regards to the user's lifestyle preferences and risk factors.

Numbing agents like benzocaine have a long history of use and are recommended by medical associations as a treatment option for helping to delay ejaculation, by reducing sensitivity of the penis (Hatzimouratidis et al., 2018). Various alternative topical anesthetic preparations are available. These condoms are not intended to treat diagnosed premature ejaculation.

8 Suggested profile and training for users

The device is intended for use by sexually active individuals. Advice and instructions for use are presented on the product labelling to aid the user in appropriate selection, donning and use of the condom. No specialist training is required.

9 Reference to any harmonised standards and guidance applied

Table 4: List of applicable references

Reference	Title
Applicable legislative acts	
Medical Device Regulation EU 2017/745	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices
Applicable standards	
BS EN ISO 13485:2016+A11:2021	Medical devices – Quality management systems Requirements for regulatory purposes.
BS EN ISO 14971:2019+A11:2021	Medical devices – Application of risk management to medical devices.
BS EN ISO 15223-1:2021	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.
BS EN ISO 4074:2015	Natural latex rubber male condoms – Requirements and Test Methods
BS EN ISO 20417:2021	Medical Devices – Information to be supplied by the manufacturer.
BS EN ISO 10993-1: 2020	Biological evaluation of medical devices. Evaluation and testing within a risk management process
BS EN ISO 10993-5: 2009	Biological evaluation of medical devices. Tests for in vitro cytotoxicity
ISO 10993-10: 2021*	Biological evaluation of medical devices. Tests for skin sensitization
BS EN ISO 10993-11: 2018	Biological evaluation of medical devices. Part 11: Tests for systemic toxicity
BS EN ISO 10993-17: 2009	Biological evaluation of medical devices. Part 17: Tests for allowable limits for leachable substances
BS EN ISO 10993-18: 2020	Biological evaluation of medical devices. Part 18: Chemical characterization of medical device materials within a risk management process.
BS EN ISO 10993-23:2021*	Biological evaluation of medical devices - Part 23: Tests for irritation
BS EN 62366-1:2015 +A1:2020	Medical Devices. Application of usability engineering to medical devices
ISO 14155:2020	Clinical investigation of medical devices for human subjects – Good Clinical Practice
Guidance	
ICH Q1A (R2)	Stability testing of new drug substances and drug products
PD ISO/TR 24971:2020	Medical devices. Guidance on the application of BS EN ISO 14971.
MEDDEV 2.7/1 rev.4	Clinical Evaluation Reports for Medical Devices
MEDDEV 2.12/1 rev.8	Vigilance system (2019) – Additional guidance
MDCG 2020-5 April 2022	Guidance on borderline between medical devices and medicinal products under regulation (EU) 2017/745 on medical devices
MDCG 2020-6 April 2020	Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC. A guide for manufacturers and notified bodies
MDCG 2020-7 April 2020.	Post-market clinical follow-up Plan Template. A guide for manufacturers and notified bodies

MDCG 2020-8 April 2020	Post-market clinical follow-up Evaluation Report Template. A guide for manufacturers and notified bodies
MDCG 2019-9 August 2019	Summary of safety and clinical performance. A guide for manufacturers and notified bodies
MDCG 2021-24 October 2021	Guidance on classification of medical devices
MDCG 2021-25 October 2021	Regulation (EU) 2012/745 – application of Medical Device Regulation requirements to "legacy devices" and to devices on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC

* *Biocompatibility studies for irritation and sensitisation were conducted according to BS EN ISO 10993-10:2013, the ISO Standard applicable at the conducting laboratory at the time the studies were conducted. A gap analysis has been performed and the biocompatibility studies are also compliant with the current ISO standards: ISO 10993-10:2021 Biological evaluation of medical devices — Part 10: Tests for skin sensitization AND ISO 10993-23:2021 Biological evaluation of medical devices — Part 23: Tests for irritation.*

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11 Revision history

SSCP revision number	Date Issued	Change description	Revision validated by the Notified Body
V1	May 2023	SSCP has been prepared as new requirement for class III devices under Medical Device Regulation. This SSCP refers to NRL condoms with silicone lubricant and benzocaine manufactured by Reckitt.	[No] Validation language: English