

PROFEEL DHD PLATINUM

User Information:

a. Use:

It is intended for surgical work and for single use only. The re-use of sterile medical gloves could lead to the following issues:

- Loss of product traceability
- Improper cleaning processes leading to a risk of cross-contamination
- Cleaning of glove between uses leading to glove damage, with loss of glove integrity, leading to increased risk of holes and tears during re-use.

b. Precaution for Use:

Inspect the glove prior use. Ensure the glove does not have any flaws and was not damaged when donning. It is important to select appropriate size of glove to prevent discomfort.

c. Ingredients

This product contains natural rubber latex which may cause allergic reactions including anaphylactic responses. Some gloves may contain further ingredients that are known to be a possible cause of allergies to sensitive individuals, including irritation and/or allergic reactions. If this occurs, seek appropriate medical advice immediately.

d. Storage

- The product is kept away from direct sun and fluorescent lighting and stored in an environment with temperature not exceeding 40° C.
- The storage place shall not contain any equipment that generates ozone.
- The product shall not be in direct contact with metals.
- Avoid contact with oil-based antiseptic phenols or their derivatives, greases, petroleum jelly, petroleum spirit, paraffin, or other related compounds.
- Sterility is assured provided that the pouch-seal is intact and not broken.
- The expiry date is 3 years from the date of manufacture indicated on the package and is valid for the properly stored product.

e. Wearing Instruction

Donning

1. Peel opens the outer pack starting from the top corners. Then grip the inner pack – which is sterile – through your gown and open it to display the gloves.
2. With your gown covering your fingers, use your right hand to pick up the left glove. Hold your left hand palm up, fingers straight. Lay the glove on your left wrist, and grip the cuff with your left thumb. Place your right thumb inside the top cuff edge. Make a fist with your right hand and stretch the glove over your left fingertips.
3. Keeping your left fingers straight, pull down the glove.
4. Repeat the above procedure to don the other glove.

Doffing

As you remove the gloves, avoid allowing the outside surface of the gloves to come in contact with your skin, because the outer surface will have been contaminated with blood and other body fluids. Avoid letting the gloves snap, as this may cause contaminants to splash into your eyes or mouth or onto your skin or other people in the area.

Remove used gloves before touching anything: Countertops, faucets, pens and pencils are frequently contaminated because healthcare workers touch them while wearing used gloves.

1. Rinse gloves hands in a basin of decontamination solution to remove blood or other body fluids.
2. Grasp one of the gloves near the cuff and pull it partway off. The glove will turn inside out. It is important to keep the first glove partially on your hand before removing the second glove to protect you from touching the outside surface of either glove with your bare hands.
3. Leaving the first glove over your fingers, grasp the second glove near the cuff and pull it part of the way off. The glove will turn inside out. It is important to keep the second glove partially on your hand to protect you from touching the outside surface of the first glove with your bare hands.
4. Pull off the two gloves at the same time, being careful to touch only the inside surfaces of the gloves with your bare hands.
5. As the surgical gloves are recommended for single use only, dispose of them properly. Wash hands immediately after gloves are removed since gloves may contain tiny holes or tears that leave you at risk of exposure to contaminated blood and other fluids.

f. Disposal

Dispose of the device in accordance with the local laws and regulations applicable of the country.

g. Composition

Gloves are manufactured from natural rubber latex. The surface material may assist the user putting the gloves on.


h. Limitation/Caution/Warning

- The information provided is for products in a new condition and does neither reflect the actual duration of protection in the workplace nor does it reflect the potential differentiation between 'mixtures' and 'pure chemicals'.
- Before use, it is recommended to check if the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperature, abrasion and degradation. Before usage, inspect the gloves for any defect or imperfections.
- The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only.
- When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves.
- The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen. If more information is required, please contact your local distributor in the first instance. More information can be obtained from the following link www.wrpworld.com or by contacting the WRP technical team quoting the product article number.


- Before using the product, try it in the real condition of use.
- The glove is a device subject to wear, so frequent replacement is recommended and in all cases where imperfections are observed.
- Wear gloves with dry, clean hands.
- In rare cases, transient skin reactions and hypersensitivity reactions may occur. In case of reaction, discontinue use.

i) Conformity and Performance

Personal Protective Equipment of Complex Design Category III, in compliance with European Regulation (EU) 2016/425, type tested to EN 420:2003+A1: 2009, EN ISO 374-1:2016 Type B, EN 374-2:2014, EN 16523-1:2015, EN 374-4:2013 & EN ISO 374-5:2016, CE2797; CE Class IIa Sterile Medical Device, in compliance with 93/42/EEC, type tested to EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009 and ASTM D3577.

Tested in accordance with EN ISO 374-5:2016 	Tested Against Viruses The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.
	Protection against bacteria and fungi - Pass
	Protection against viruses - Pass

Declaration of conformity is available at our website www.wrpworld.com

EN ISO 374-1:2016/ TYPE B  KPT	Tested in accordance with EN ISO 374-1:2016	EN 16523-1:2015 Permeation Level	EN 374-4:2013 Degradation
	40% Sodium Hydroxide (K)	6	-36.7%
	30% Hydrogen Peroxide (P)	6	5.6%
	37% Formaldehyde (T)	6	-11.3%
EN 374-4:2013 Degradation results indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.			

EN ISO 374-1:2016 Permeation levels based on breakthrough times as follows:						
Performance Level						
0	1	2	3	4	5	6
Minimum breakthrough Time (min)						
>0	>10	>30	>60	>120	>240	>480

Tested in accordance with EN 374-2:2014	
7.2 Air Leak	N/A
7.3 Water Leak	PASS

Notified Body responsible for ongoing conformity and certification
BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
(Notified Body CE 2797)

j) Manufactured By



WRP Asia Pacific Sdn Bhd 1 4 7 8 1 7 V

Lot 1, Jalan 3, Kawasan Perusahaan Bandar Baru Salak Tinggi,
43900 Sepang, Selangor Darul Ehsan, MALAYSIA
Office +60-3-8706 1486 Facsimile +60-3-8706 1557
Email customer_wrp@wrpworld.com

k) EU Representative

EC REP & Importer into the Eu

REMESCO Handelsges.m.b.H.

Muthgasse 36/19, A-1190 Vienna, AUSTRIA
Office +43-1-328-50-88 Fax +43-1-328-29-49
Email office@remesco.com

l) Symbols

