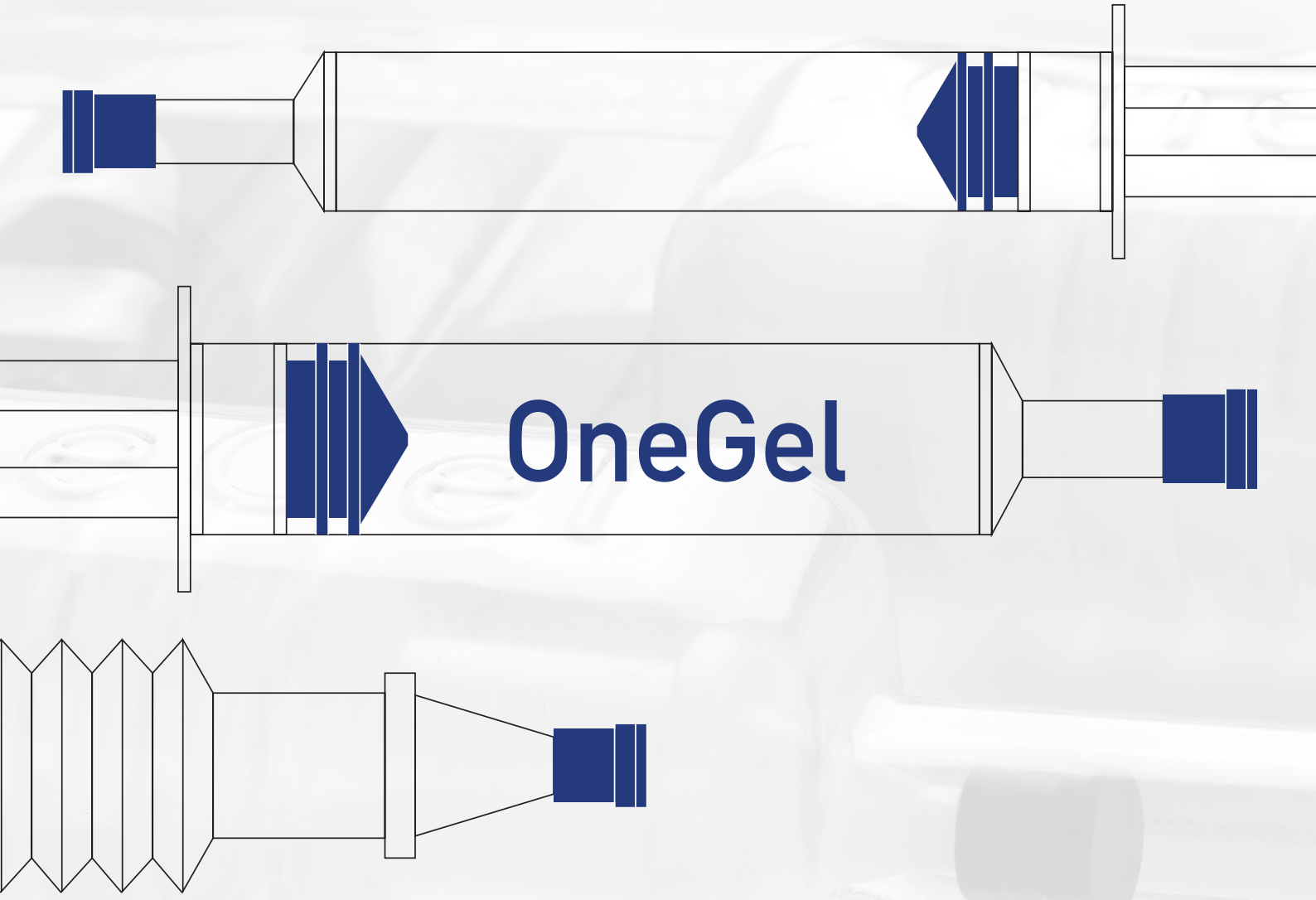
Digitally signed by Bunic Gheorghe
Date: 2022.04.13 21:53:15 EEST
Reason: MoldSign Signature
Location: Moldova



LUBRICANT GEL WITH LIDOCAINE

USAGE

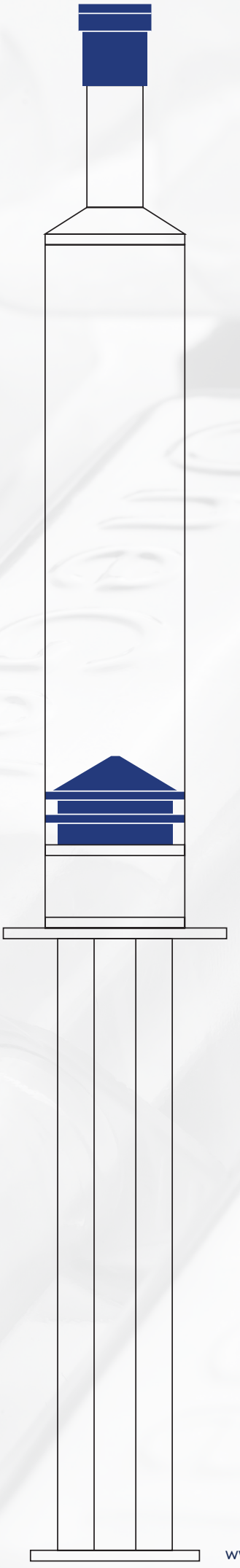
·Remove the syringe/accordion tube (6ml/11ml/12.5g) by tearing off the sterile packaging.
·Remove the stopper at the end of the syringe/accordion tube.
·Pour a drop of gel to facilitate application.
·After placing the syringe tip on the area to be lubricated, gently squeeze some ONEGEL Lidocaine Lubricating Gel by pressing the plunger of the syringe/accordion tube.

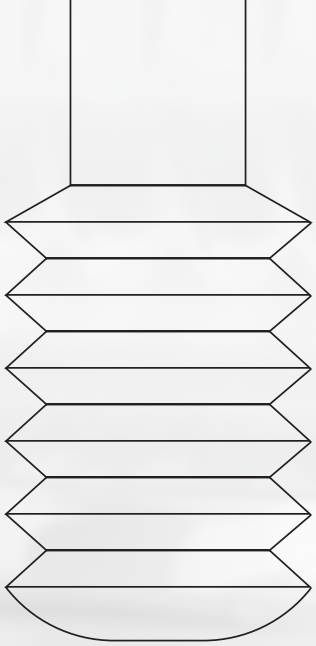
COMPOSITION

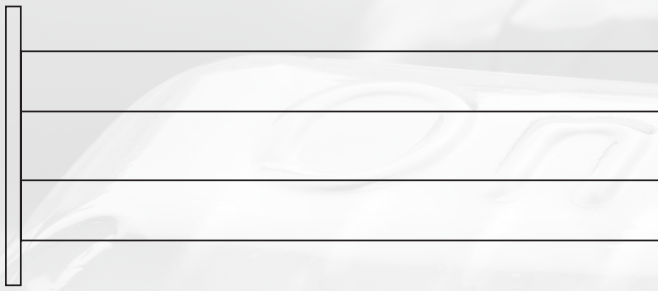
- Pure Water
- Propylene Glycol, Hydroxyethylcellulose (Lubricant)
- Lidocaine Hydrochloride (Local Anesthetic)
- Chlorhexidine Gluconate - 20% Concentration (Antiseptic)
- Methyl Hydroxybenzoate (Preservative)
- Propyl Hydroxybenzoate (Preservative

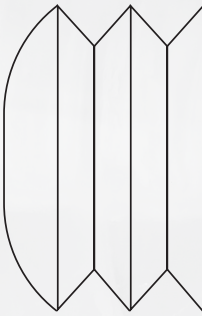
It is a Class III Medical Device within the scope of 93 / 42 / EEC Medical Device Regulation CE 1783

STERILE









KAF GRUP
SAĞLIK HİZMETLERİ

KAF GRUP SAĞLIK HİZMETLERİ İNŞ. SAN. VE TİC. LTD. ŞTİ.
www.**kafgrup**.com | www.**wancare**.com.tr | info@kafgrup.com | wan.care & kafgrup

ONEGEL

IMAGE	BARCODE	BRAND	PRODUCT CODE	DESCRIPTION	PCS/PACK.	
		ONEGEL	KAF G27-6	**LUBRICANT GEL WITH LIDOCAINE (STERILE)**	6ML	
		ONEGEL	KAF G27-11	**LUBRICANT GEL WITH LIDOCAINE (STERILE)**	12ML	
		ONEGEL	KAF G27-12,5	**LUBRICANT GEL WITH LIDOCAINE (STERILE)**	12,5 GR	

TÜRK STANDARDLARI ENSTİTÜSÜ

TURKISH STANDARDS INSTITUTION

Full Quality Assurance Certificate

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

Notified Body	:	Türk Standardları Enstitüsü (TSE) - Necatibey Cad. No:112 Bakanlıklar Ankara Turkey (NB 1783)
Company Name	:	KAF GRUP SAĞLIK HİZMETLERİ İNŞ. SAN. VE TİC. LTD. ŞTİ.
Company Address	:	ATAKENT MAH. 221. SOK. NO:3A ROTA OFFICE A BLOK KAT 14 D:83 34200 KÜÇÜKÇEKMECE/ İSTANBUL/ TURKEY
Manufacturing Site	:	BARDAKÇI MAH. TEKNOKENT SK. NO:3 TUŞBA/ VAN/ TURKEY
Scope	:	ONEGEL LUBRICANT GEL WITH LIDOCAINE (STERILE)
GMDN Code	:	37717
Classification Rule	:	Rule 5 and Rule 13, Class III
Inspection Report Number	:	2203-MDD-173/2020-02
First Issue Date	:	24.05.2021
Validity Date	:	26.05.2024

The manufacturer's quality system is inspected in accordance with Annex II of the Medical Device Directive and the quality system meets the requirements of Medical Device Directive Annex II. The Notified Body has the right to carry out the necessary inspections in accordance with Medical Device Directive Annex II Section 5. For Class III products covered by this certificate, a EC Design Examination Certificate issued in accordance with Medical Device Directive Annex II Section 4 is also required.

Certificate No: 1783-MDD-238

TÜRK STANDARTLARI ENSTİTÜSÜ * DİREKTİFLER MÜDÜRLÜĞÜ * DIRECTORATE OF DIRECTIVE * TURKISH STANDARDS INSTITUTION * 1783 TSE

Fırat HACIOĞLU
Deputy Director of Directives
ANKARA Rev00, 24/05/2021

Please check the validity of certificate from TSE's web page "https://basvuruportal.tse.org.tr/Genel/FirmaArama.aspx?ref=en#open"